



CALYX™

# Best Practice: Managing Picklists in Data Administration

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 Date	Summary of Change(s) (Refer to Release Notes for Full Description)
v7.0	30-Apr-2021	Update Best Practice for v7.0 – Impact
N/A	01-Apr-2021	Update Best Practice for Calyx Rebranding – No Impact
v6.2 CHF6	21-Oct-2020	Update Best Practice for v6.2 CHF6 – No Impact
v6.2 CHF5	03-Aug-2020	Update Best Practice for v6.2 CHF5 – Impact
N/A	08-Apr-2020	Corrected Reason for Premature Ending value
v6.2 CHF4	28-Feb-2020	Update Best Practice for v6.2 CHF4 – 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

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### 3 Document Purpose and Scope

The purpose of this document is to provide a Best Practice for Calyx RIM Data Administrators. It provides recommended processes for managing updates to the Out of The Box (OTB) picklist values that are available in Data Administration.

For each picklist the following is defined:

- Picklist Name
- Description
- Entity Location
- Data Source
- Recommended Practice for Managing Updates
- System Rules, Data Dependencies and Relationships

The *System Rules, Data Dependences and Relationships* column may refer Business Administrators to Best Practice documentation which resides on <http://help.liquent.com>:

[https://help.liquent.com/InSight\\_6-2-0/GUID-B1B7B7FD-DC0B-48EB-80A1-12EB13231225.html](https://help.liquent.com/InSight_6-2-0/GUID-B1B7B7FD-DC0B-48EB-80A1-12EB13231225.html)

Please reference these Best Practice documents to further support Business Administrator responsibilities.

Please note there are several picklists available in Data Admin where the associated attribute has been hidden in the OTB configuration. These picklists are maintained in Data Admin for clients who have retained the legacy field. There are also some sections in Data Admin that have been created for functionality that is not currently available. In both cases these picklists are formatted with a light grey font within the document.

### 3.1 Application Maintenance

Application Maintenance
<ul style="list-style-type: none"> <li>Age Span Population Values</li> <li>Application Category Values</li> <li>Application Status Values</li> <li>Application Type Values</li> <li>Country Values</li> <li>CTA Product Role Values</li> <li>Legal Status Values</li> <li>MedDRA Term Values</li> <li>Medical Condition Investigated Values</li> <li>Procedure Type Values</li> <li>Reason for Premature Ending Values</li> <li>Region Values</li> <li>Region Type Values</li> <li>Trial Design Values</li> <li>Trial Phase Values</li> <li>Trial Scope Values</li> <li>Trial Subject Groups Values</li> </ul>

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Age Span Population Values</b>	The ages of those being tested in a trial, such as in utero, infant, adolescent, etc.	CT Shared Data	Clinical Trial Application Form	Align with changes made to the CTA Form	
<b>Application Category Values</b>	The Application Category is used in Global Project Planning. Every Application Type in Calyx RIM is mapped to an Application Category. This allows	GPP Create New Application – Package Set Registration	Calyx Defined: Best Practices	Consult <a href="http://help.liquent.com">help.liquent.com</a> for best practice.  Follow internal Change Management Processes.	Check with a Calyx Regulatory Consultant before making any changes to the OTB values.

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
	Applications of the appropriate Type to be created via the GPP wizards.				
<b>Application Status Values</b>	Current status of the Application in that market, e.g. Planned, Approved, Withdrawn.	Application	Calyx Defined: Best Practices	Consult help.liquent.com for best practice.  Follow internal Change Management Processes.	Must first create Associated Countries values and Application Category  Refer to Calyx RIM for Registrations Best Practice: INTERNAL and External Status Values
<b>Application Type Values</b>	Identifies the Type of application (e.g., Clinical Trial, Marketing Authorisation)	Application	Regulatory Agency Guidance (US: application-type.xml v1.11) Calyx Defined	Consult help.liquent.com for best practice.  Follow internal Change Management Processes.	Check with a Calyx Regulatory Consultant before making any changes to the OTB values.
<b>Country Values</b>	Identifies the country name, ISO Country Code, eCTD Country code, regulatory authority, regulatory abbreviation, agency eCTD code, and region.  The Country Codes defined are used to	Application	The Country Code is derived from the ICH Website: 2-digit ISO Codes (3166.2)  eCTD Country Codes are derived from the <a href="#">EMA Website</a>	Align with changes to ISO Codes.  Align with changes to eCTD Codes	Check with a Calyx Regulatory Consultant before making any changes to the OTB values.

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
	support Publishing and XEVMPD processes				
<b>CTA Product Role Values</b>	The roles a product plays in a trial, such as IMP, comparator, and placebo.	Comparator	Calyx Defined: Best Practices	Consult help.liquent.com for best practice.  Follow internal Change Management Processes.	
<b>Legal Status Values</b>	Identifies how the product is sold to consumers (e.g., Over the Counter).	Application Package Set Registration Country	FDA Website; EMA Defined	Align with changes made by Regulatory Agency.	
<b>MedDRA Term Values</b>	MedDRA term for a clinical trial.	CT Shared Data	Client Defined	Follow internal Change Management Processes.	
<b>Medical Condition Investigated Values</b>	Condition being investigated by the trial.	CT Shared Data	Client Defined	Follow internal Change Management Processes	
<b>Procedure Type Values</b>	Identifies the strategy used in the regulatory approval process (e.g., National, Centralized Procedure, Mutual Recognition Procedure, Decentralized Procedure).	Application	XEVMPD Controlled Vocabularies - Authorisation Procedures Calyx Defined: Best Practices	Align with updates to XEVMPD Controlled Vocabularies For Procedure types not impacted by XEVMPD Consult help.liquent.com for best practice.  Follow internal Change Management Processes.	Do not modify the OTB values unless for the express purpose to support XEVMPD updates.
<b>Reason for Premature Ending Values</b>	For example, safety, lack of efficacy, trial never commenced, etc.	CTA Application	Clinical Trial Application Form	Align with changes made to the CTA Form.	Field applies to CTA, but not IND, Applications.

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Region Values</b>	Identifies the regions abbreviation and name. For example, Canada is CAN.	Application	Client Defined	Follow internal Change Management Processes.	Check with a Calyx Regulatory Consultant before making any changes to the OTB values.
<b>Region Type Values</b>	Region type(s) to support business processes	Application	Calyx Defined: Best Practices Client Defined	Follow internal Change Management Processes.	The Regulatory Region and External System Procedure Type Code types exist in the system by default. The name of a region type must be unique within the system.
<b>Trial Design Values</b>	For example, randomized, open, single blind, double blind, parallel group, cross over.	CT Shared Data	Clinical Trial Application Form	Align with changes made to the CTA Form.	
<b>Trial Phase Values</b>	For example, phase I, phase II, phase III, etc.	CT Shared Data	Clinical Trial Application Form	Align with changes made to the CTA Form.	
<b>Trial Scope Values</b>	For example, diagnosis, prophylaxis, therapy, safety, efficacy, pharmacokinetic, pharmacodynamic.	CT Shared Data	Clinical Trial Application Form	Align with changes made to the CTA Form.	
<b>Trial Subject Groups Values</b>	For example, healthy, patients, women-child bearing potential, woman-child bearing potential on	CT Shared Data	Clinical Trial Application Form	Align with changes made to the CTA Form.	

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
	contraceptives, pregnant, nursing, emergency situation, incapable of giving consent, etc.				

### 3.2 Assembly (Publishing)

**Assembly**

- Assembly Category Values
- Assembly DTD/Schema Types
- Assembly Status Values
- Assembly Subcategory Values

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Assembly Category Values</b>	The Assembly high-level category.	Assembly	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	Create Assembly Category values before creating Assembly Subcategory values
<b>Assembly DTD / Schema Types</b>	XML based Document Type Definitions	eCTD Assembly	Calyx Defined: Based on current agency guidance	Consult help.liquent.com for best practice.	Do not modify the OTB values
<b>Assembly Status Values</b>	The current Status of the Assembly updated using the "Update Assembly Status". Default = In Draft	Assembly	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Assembly Subcategory Values</b>	The Assembly low level category. The available options depend on the Category selected.	Assembly	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes	Must first create Associated Assembly Category values

### 3.3 Assembly Variables (Publishing)

Assembly Variables
<ul style="list-style-type: none"> <li>Assembly Repository Variables</li> <li>Assembly System Defined Variables</li> <li>Assembly User Defined Variables</li> <li>LIQUENT InSight Assembly Variables</li> </ul>

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Assembly Repository Variables</b>	Used to pull document attributes from the DMS-repository for use in a submission.	Technical Administration Repositories	Client Defined	Follow internal Change Management Processes.	Check with a Calyx Regulatory Consultant before making any changes to the latest values.
<b>Assembly System Defined Variables</b>	Preconfigured in Calyx RIM. System-defined variables. Resolve to values calculated during publishing or prepare for publishing.	Values that populate publishing attributes	Calyx Defined: Best Practices	Consult help.liquent.com for best practice.	Whilst the name of a system-defined variable can be changed, the value to which the variable resolves cannot be changed.
<b>Assembly User Defined Variables</b>	User-defined variables used in the assembly for	Values that populate publishing attributes	Client Defined	Follow internal Change Management Processes.	

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
	<p>both electronic and paper publications.</p> <p>These variables are resolved during publishing and used within the eCTD XML metadata, tabs, TOCs, and volume names.</p>				
<b>LIQUENT Assembly Variables</b>	<p>Calyx RIM assembly variables resolve to attribute values stored in Calyx RIM, such as application name and assembly status. They are calculated during publishing or prepare for publishing.</p>	<p>Values that populate publishing attributes</p>	<p>Calyx Defined: Best Practices</p>	<p>Consult help.liquent.com for best practice.</p>	<p>No modification possible</p>

### 3.4 Change Maintenance

<b>Change Maintenance</b>
<p>Change Type Values</p> <p>Event-Change Detail Status Values</p>

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Change Type</b>	Category of Change being progressed e.g. CMC, Artwork, Clinical	Change	Client Defined	Follow internal Change Management Processes.	
<b>Event-Change Detail Status</b>	Status of the Change Detail associated at the Event	Event Change Detail	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	Refer to Calyx RIM for Registrations Best Practice: INTERNAL and External Status Values

### 3.5 Custom Lists Maintenance

<b>Custom Lists Maintenance</b>
<a href="#">Custom List Names</a> <a href="#">Custom List Values</a>

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Custom List Names</b>	Values represent client-added fields which have their own picklist values	Custom List field names display on the client-specified screen which as a best practice appear as a prefix on the Custom List Name.	Client Defined	Follow internal Change Management Processes.	Best practice naming convention: Entity Name Custom Field Name Example: Sequence Filing Owner The Custom Lists are created via configuration

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Custom List Values</b>	Picklist values for Custom Lists	Values that display in drop-down/selection boxes of the associated Custom List Name field.	Client Defined	Follow internal Change Management Processes.	Must first create Custom List Names. List values can be created or deactivated at any time.

### 3.6 DMS Integration (Publishing)

**DMS Integration**

- Bind to Label Values
- Bind to Status Values
- Rendition Identifier Values

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System rules, Data Dependencies and Relationships
<b>Bind to Label Values</b>	Values that populate the Default Binding Rule field on Document Attributes screen	Assembly Document	Client Defined	Follow internal Change Management Processes.	<p>For documents assigned to SharePoint in Calyx RIM, the Label or Status attributes cannot be changed and can only bind to the file version. SharePoint supports minor and major file versions but does not support labels and statuses.</p> <p>For Veeva documents, binding to a label is supported only when the label is set to</p>

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System rules, Data Dependencies and Relationships
					CURRENT. Veeva does not use labels. When the label is set to CURRENT, the latest version of the document is used.
<b>Bind to Status Values</b>	Values that populate the Default Binding Rule field on Document Attributes screen	Assembly Document	Client Defined	Follow internal Change Management Processes.	Same as above
<b>Rendition Identifier Values</b>	Values to allow non-default renditions to be used for publishing jobs.	Assembly Document Registration Attachment	Client Defined	Follow internal Change Management Processes.	<p>For a Veeva or Documentum repository, the name Standard Rendition cannot be changed.</p> <p>For each rendition name, for each server type only one rendition identifier value can be active at a time.</p> <p>For a Veeva or Documentum repository, the rendition identifier values for the rendition named Standard Rendition cannot be deactivated.</p> <p>Additional PDF rendition formats can be defined in</p>

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System rules, Data Dependencies and Relationships
					Calyx RIM configuration to trust them as PDFs. The additional renditions must comply to the PDF standard.

### 3.7 Event Maintenance

Event Maintenance
<ul style="list-style-type: none"> <li>Action Type Values</li> <li>EU Grouping or Worksharing Values</li> <li>Event Status Values</li> <li>Event Type Values</li> <li>PSUR Report Code Values</li> <li>Secondary Event Type Values</li> <li>Timeline/Event Plan Type Values</li> <li>Timeline/Event Plan Values</li> </ul>

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System rules, Data Dependencies and Relationships
<b>Action Type Values</b>	Type of approval required to consider the Event active  For example, Implementation without Notification	Event	Client Defined	Follow internal Change Management Processes.	
<b>EU Grouping or Worksharing Values</b>	Identifies whether an Event is part of a sharing or workgroup activity	Event	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	Check with a Calyx Regulatory Consultant before making any

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System rules, Data Dependencies and Relationships
					changes to the OTB values.
<b>Event Status Values</b>	For example, planned, in effect, in discussion, approved, refused, etc.	Event	Calyx Defined: Best Practices	Consult help.liquent.com for Calyx RIM for Registrations Best Practice: INTERNAL and External Status Values. Follow internal Change Management Processes.	
<b>Event Type Values</b>	Identifies a regulatory activity taking place  For example, Annual Report, New Drug Original Filing, Supplement etc.	Event	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	Maps to Secondary Event Type Values
<b>PSUR Report Code Values</b>	Abbreviation associated with the PSUR being reported on.  For example, A = Authorized, AQ = Authorized with Qualifications, LA = Lack of Approval, V = Voluntary Marketing Application Withdrawn by Company, AR = Authorization Renewal	Event	EMA Defined	Align with changes made by Regulatory Agency.	

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System rules, Data Dependencies and Relationships
<b>Secondary Event Type Values</b>	Further classifies the Event Type For example, Abridged Filing, Active Substance, Variation Type IB	Event	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	Must first create associated Event Type value
<b>Timeline/Event Plan Type</b>	The Timeline/Event Plan Type can be Procedure Type, Event Type, or None.	Event	Calyx Defined: Best Practices	N/A	No modification possible
<b>Timeline/Event Plan</b>	An ordered set of milestones that represent the progression of event statuses that are expected to occur for an event	Event	Client Defined	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	Country values must be created first Event Status values must be created first

### 3.8 Notifications

<b>Notifications</b>
Notification Specifications Notifications

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System rules, Data Dependencies and Relationships
<b>Notification Specifications</b>	A set of predefined criteria used to create notifications automatically when the criteria in the	N/A	Client Defined	Follow internal Change Management Processes.	Notification Specifications cannot be created in Data Admin

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System rules, Data Dependencies and Relationships
	<p>specification is met. Notification specifications apply to all instances of the associated entity that satisfy the criteria mentioned in the specification.</p> <p>All Global specifications created using the Notifications wizard appear on the Notifications Specifications tab in Data Administration.</p> <p>New Record notifications are displayed on the Notification Specifications Data Administration tab.</p>				
<b>Notifications</b>	<p>All Notifications created for a specific instance of an entity (whether created using the wizard or created automatically based on a specification) appear on the Notifications tab for the entity and on the</p>	Entity Notifications Tab	Client Defined	Follow internal Change Management Processes.	Notifications cannot be created in Data Admin

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System rules, Data Dependencies and Relationships
	Notifications tab in Data Administration.				

### 3.9 Other

Other
<ul style="list-style-type: none"> <li>Concentration Measure Type Values</li> <li>Denominator Unit Values</li> <li>Entity XML/UI Mappings</li> <li>Home Page Display Properties</li> <li>Indications/Intended Use Values</li> <li>Language Values</li> <li>Legal Basis Values</li> <li>Length Unit of Measure Values</li> <li>MAH/Development Sponsor/Organisation Values</li> <li>Master File Location (MFL) Values</li> <li>Message Sender Values</li> <li>Numerator Unit Values</li> <li>Previous EV Code Values</li> <li>Quantity Unit of Measure Values</li> <li>Reason for E-Signature Values</li> <li>Reason for Termination/Withdrawal Values</li> <li>SME Status Values</li> <li>Sub-Indication Values</li> <li>System Alert Type Values</li> <li>Unit of Measure Prefix Values</li> <li>Unit of Presentation Values</li> <li>Weight Unit of Measure Values</li> </ul>

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Concentration Measure Type Values</b>	Refers to concentrations for the unit being defined. OTB values include Equal, Range, etc	Component Active Ingredient PDS Flu Strain detail Substance Detail	XEVMPD Controlled Vocabularies - Concentration Types	Align with updates to XEVMPD Controlled Vocabularies.	

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
		Dosage Schedule Detail (Vet)			
<b>Denominator Unit Values</b>	Low limit values for Concentration measures	Component Active Ingredient Reference Active Ingredient PDS Flu Strain detail Substance Detail Dosage Schedule Detail (Vet) (Low Amount Denominator Unit, High Amount Denominator Unit)	XEVMPD Controlled Vocabularies – Units of Measurement and Units of Presentation	Align with updates to XEVMPD Controlled Vocabularies.	
<b>Entity XML UI Mappings</b>	Defines XML mappings that override default Calyx RIM entity screens, e.g., CT Application screen is mapped to CT Application XML file, prompting Calyx RIM to display different fields on Clinical Trial Application screens.	Product Family Application Component Registration	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	Check with a Calyx Regulatory Consultant before making any changes to the OTB values.
<b>Home Page Display Properties</b>	Offers selection of Home Page drop-down and allows overwrite of OTB	Home screen	Client Defined	Follow internal Change Management Processes.	

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
	display values, e.g., Copy Event can be renamed Make Another Event.				
<b>Indications/Intended Use Values</b>	List of all possible indications/intended use for all Product Families.	Product Family PDS – Indication / Intended Use detail	Client Defined	Maintain as required.  The ability to update a MedDRA version in bulk using Mass Update is available. There are two options:  Update and Overwrite to update the new version for all selected Indications  or  Update and Preserve to update the new version for only those selected Indications which have no values	For XEVMPD the MedDRA Low Level Terms are required  Sub-Indication values must first be established and available for assignment to Indications (Veterinary only)
<b>Language Values</b>	Available languages, e.g., French, English, Dutch.  Used to support XEVMPD processes	Full Product Presentation Registration Attachment	The two-letter language code ISO 639-1:2002 Alpha-2 code is assigned to the language.	Align with changes to ISO Codes	The default value is set to Active. The standard set of extra fields can be configured for this value.  For upgrades client may need to populate these values in data admin (ISO 639-1:2002 Alpha-2 code)

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Legal Basis</b>	Assigned name and code for the legal basis of the product	Application Registration	XEVMPD Controlled Vocabularies - Legal Basis	Align with updates to XEVMPD Controlled Vocabularies.	Do not modify the OTB values, unless for the expressed purpose to support XEVMPD updates.
<b>Length Unit of Measure Values</b>	Unit of measure for length, e.g., meter, inch.	PDS Component Characteristics	Client Defined	Follow internal Change Management Processes.	
<b>MAH/Development Sponsor/Organisation Values</b>	Name and address information for marketing holder authorization/ development sponsors and legal representatives; also applies to EVMPD; can have twenty extra text fields, five extra date fields, and five extra number fields configured.	Product Family Registration	XEVMPD Controlled Vocabularies - Organisations	Align with updates to XEVMPD Controlled Vocabularies.	For full data development, Country value must be in the system.
<b>Master File Location (MFL) Values</b>	Name of the company that holds the Pharmacovigilance System Master File (PSMF).	Registration Package Set Type	Client Defined	Align with XEVMPD Processes.	For full data development, Country value must be in the system
<b>Message Sender Values</b>	Initiator of XEVPRM message	XEVPRM message wizard	Client Defined	Align with XEVMPD Processes.	
<b>Numerator Unit Values</b>	Numerical value for the strength of a substance.	Component Active Ingredient	XEVMPD Controlled Vocabularies – Units of Measurement	Align with updates to XEVMPD Controlled Vocabularies.	

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
		Reference Active Ingredient Flu Reference Strain PDS Flu Strain PDS Substance (Low Amount Numerator Unit, High Amount Numerator Unit)			
<b>Previous EV Codes</b>	Previous, valid EV Codes for XEVMPD	Data Admin Substance Data Admin Pharmaceutical dosage form Data admin Route of Administration	Client Defined	Align with XEVMPD Processes.	
<b>Quantity Unit of Measure Values</b>	The quantity or count number of the item being measured, e.g., ml, mg.	Pharmaceutical Product (Product Quantity Unit) PDS Package Detail (Component Quantity Unit) PDS Dose Schedule	Client Defined	Follow internal Change Management Processes.	
<b>Reason for E-Signature Values</b>	This field is populated when a modification is made to the record. The information in this field only displays in the Audit Reports. Upon entering	When e-Signature is enabled, the Reasons dropdown menu displays whenever e-Signature appears.	Client Defined	Follow internal Change Management Processes.	

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
	the Modify screen, the entry field is blank. It is also only available when eSignature functionality is enabled.				
<b>Reason for Termination/Withdrawal</b>	This client-defined field documents the reason an entity was terminated or withdrawn.	Product Application Registration Event Sequence	Client Defined	Follow internal Change Management Processes.	
<b>SME Status Values</b>	Small and Medium Enterprise Classifications	Data Admin MAH	XEVMPD Controlled Vocabularies - SME Status	Align with updates to XEVMPD Controlled Vocabularies.	
<b>Sub Indication Values</b>	Used in Animal Health Product Detail sets to provide additional break down of indications.	PDS Species Indications Data Admin Indication / Intended Use	Client Defined	Follow internal Change Management Processes.	Indication values must first be established and available for Sub-Indications to be assigned
<b>System Alert Types Values</b>	Describes the type of system alert.	Create System Alert screen	Client Defined	Follow internal Change Management Processes.	
<b>Unit of Measure Prefix Values</b>	Prefix used with Numerator and Denominator values	Component Active Ingredient Reference Active Ingredient Flu Reference Strain PDS Flu Strain	XEVMPD Controlled Vocabularies – Units of Measurement	Align with updates to XEVMPD Controlled Vocabularies	

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
		PDS Substance (Low Amount Denominator Prefix, High Amount Denominator Prefix)			
<b>Unit of Presentation Values</b>	A qualitative term describing the discrete unit in which a component is presented to describe strength or quantity in cases where a quantitative unit of measurement is not appropriate, e.g., patch, tablet	Pharmaceutical Product PDS Package Detail	Client Defined	Follow internal Change Management Processes.	
<b>Weight Unit of Measure Values</b>	The weight unit of the component being described.	PDS Component Characteristics	Client Defined	Follow internal Change Management Processes.	

### 3.10 Product Detail Set Maintenance

Product Detail Set Maintenance
Color Values
Compendial Designation/Source Values
Dose Frequency Values
Human Consumption Product Values
Label Type Values
Manufacturer Values
Manufacturing Functions Values
Material Type Values
Material Values
Medical Device Part Code Values
Packaging Category Values
Packaging Type Values
Product Detail Set Status Values
Product Material Values
Production Type Values
QC Status Values
Shape Values
Shelf Life Category Values
Shelf Life Type Values
Species Values
Storage Condition Values
Substance Role Values
Substance Type Values
Time Unit Values
Volume Unit of Measure Values

Picklist Name	Description	PDS Node Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Color Values</b>	The color of the Component	Component Characteristic	Client Defined	Follow internal Change Management Processes.	

Picklist Name	Description	PDS Node Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Compendial Designation/Source Values</b>	Identifies the Pharmacopeia Designation of the Substance, e.g., USP,	Active Ingredient Substance	XEVMPD Controlled Vocabularies - Reference Sources	Align with updates to XEVMPD Controlled Vocabularies.	
<b>Dose Frequency Values</b>	Used in Animal Health Details to define the administration frequency in for a product	Species>Indication> Dose Schedule	Client Defined	Follow internal Change Management Processes.	
<b>Human Consumption Production Values</b>	Used in animal heath product details to indicate whether the indicated species is used for human consumption	Species>Routes of Administration> Withdrawal Times	Client Defined	Follow internal Change Management Processes.	
<b>Label Type Values</b>	The type of label being associated with the PDS	Labels	Client Defined	Follow internal Change Management Processes.	
<b>Manufacturer Values</b>	Companies that provide manufacturing or manufacturing support services	Manufacturer  Multiple locations on the PDS  Function  Active Ingredient  Substance  Manufacturing Process	Client Defined	Follow internal Change Management Processes.	The following attribute values are associated with Manufacturers and must be created first:  Active Ingredients  Materials  Excipients  Manufacturing Functions  Packaging
<b>Manufacturing Function Values</b>	The manufacturing activity the manufacturer	Manufacturer	Client Defined	Follow internal Change Management Processes.	

Picklist Name	Description	PDS Node Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
	performs, e.g. Dosage Form Production, Packaging Form Retesting, Product	Multiple locations on the PDS Function Active Ingredient Substance Manufacturing Process			
<b>Material Type Values</b>	The type of material, e.g., a by-product or ingredient	Manufacturing Process Step Material	Client Defined	Follow internal Change Management Processes.	
<b>Material</b>	The name of the actual material	Manufacturing Process Step Material	Client Defined	Follow internal Change Management Processes.	
<b>Medical Device Part Code Values</b>	The part code number associated with the medical device	Medical Device	Client Defined	Follow internal Change Management Processes.	
<b>Packaging Category Values</b>	Lists Primary, Secondary, and Tertiary packaging categories.	Packaging	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	
<b>Packaging Type Values</b>	Types of packaging e.g., blister, box, bottle	Packaging	Client Defined	Follow internal Change Management Processes.	Package Category values must be created first
<b>Product Detail Set Status Values</b>	Possible realized status values for the Product Detail Set	Product Detail Set Attributes	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	Refer to Calyx RIM for Registrations Best Practice: INTERNAL

Picklist Name	Description	PDS Node Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
					and External Status Values
<b>Product Material Values</b>	Identifies the material of the package or component.	Component Medical Device Detail (Device Material & Device Alternate Material)  Packaging Detail (Container Material & Container Alternate Material)	Client Defined	Follow internal Change Management Processes.	
<b>Production Type Values</b>	Used in Animal Health Product Details to identify species sub-categories (beef cattle, dairy cattle)	Species	Client Defined	Follow internal Change Management Processes.	
<b>QC Status Values</b>	Used to QC the status of a Product Detail	All PDS Product Details when enabled	Client Defined	Follow internal Change Management Processes.	Consider the Potential impact on QC functionality
<b>Shape Values</b>	The physical shape of the component	Component Characteristic	Client Defined	Follow internal Change Management Processes.	
<b>Shelf Life Category Values</b>	Describes the Type of Shelf Life, e.g., Labeled or Registered	Shelf-Life	Client Defined	Follow internal Change Management Processes.	
<b>Shelf Life Type Values</b>	Describes the Type of Shelf Life, e.g., Original, After Opening	Shelf-Life	Client Defined	Follow internal Change Management Processes.	

Picklist Name	Description	PDS Node Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Species Values</b>	Used in Animal Health Product Details to identify the target species for the product	Species	Client Defined	Follow internal Change Management Processes.	Must first populate Production Type Values
<b>Storage Condition Values</b>	The appropriate conditions for storing the active ingredient	Shelf Life	Client Defined	Follow internal Change Management Processes.	
<b>Substance Role Values</b>	Identifies the role of the Substance e.g., Catalyst	Substance	Client Defined	Follow internal Change Management Processes.	
<b>Substance Type Values</b>	Defines Substance value as Excipient or Adjuvant	Substance	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	OTB values must be retained because these are required for XEVMPD. Do not re-purpose the excipient or adjuvant values
<b>Time Unit Values</b>	Shelf life time values, e.g., days, months, years	Shelf Life	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	
<b>Volume Unit of Measure Values</b>	Volume measure for a characteristic	Component Characteristics	Client Defined	Follow internal Change Management Processes.	

### 3.11 Product Family Maintenance

Product Family Maintenance
ATC Values Division Values Product Family Status Values Product Family Values Substance Class Values Substance Values Therapeutic Area Values Therapeutic Class Values Trade Name Values

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>ATC Values</b>	Anatomical Therapeutic Chemical Class codes identify drug product, active substance, route of administration and dose.	Product Family	Anatomical Therapeutic Chemical (ATC) Code	Align with updates to Anatomical Therapeutic Chemical (ATC) Code	
<b>Division Values</b>	References divisions that handle medical devices, i.e., Office of Device Evaluation.	Product Family	FDA	Align with changes made by Regulatory Agency.	
<b>Product Family Status Values</b>	Active, Planned or Withdrawn are the default values with Calyx RIM.	Product Family	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	Refer to Calyx RIM for Registrations Best Practice: INTERNAL and External Status Values
<b>Product Family Values</b>	Describes the family category associated with the product family, e.g.,	Product Family	Client Defined	Follow internal Change Management Processes.	Mapping to correct XML override files is maintained in Other

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
	Medical Devices, Pharma, veterinary, etc.				Maintenance / Entity XML/UI Mappings
<b>Substance Class Values</b>	Class to which Substances belong.	N/A	XEVMPD Controlled Vocabularies – Substance Classes	Align with updates to XEVMPD Controlled Vocabularies.	
<b>Substance Values</b>	Identifies active, non-active and adjuvant values that are associated with the Product Family and PDS detail values under Application/Events within the Product Family.	Product Family Product Detail Set Active Ingredient Product Detail Set Substances	XEVMPD Controlled Vocabularies – Substances	Align with updates to XEVMPD Controlled Vocabularies.	Must first create the following values: -Development Sponsor -EVMPD Compendial Designation
<b>Therapeutic Area Values</b>	Identifies values for therapeutic area names, such as oncology and pulmonary, that populate a drop-down list available when a product family is modified.	Product Family	CDER Website	Align with changes made by Regulatory Agency.	
<b>Therapeutic Class Values</b>	Identifies values for a therapeutic class, such as ace inhibitors and antacids; groups similar drugs used to treat a condition.	Product Family	FDA Website	Align with changes made by Regulatory Agency.	
<b>Trade Name Values</b>	Trade Name field values display in the Available Trade Name selection	Product Family	Client Defined	Follow internal Change Management Processes.	

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
	box of the Product Family window	Countries Detail on the PDS PDS Attributes			

### 3.12 Product Maintenance

Product Maintenance
<ul style="list-style-type: none"> <li>Applicable Standards Values</li> <li>Conformity Assessment Body Values</li> <li>Conformity Assessment Path Values</li> <li>Country Specific Detail Type Values</li> <li>Country Specific Detail Values</li> <li>Device Allergenicity Values</li> <li>Device Nomenclature Values</li> <li>Device Sterility Indicator Values</li> <li>Device Type Values</li> <li>Device Usage Values</li> <li>Dosage/Pharmaceutical Form Values</li> <li>EC Cert Values</li> <li>Global Harmonization Task Force (GHTF) Class Values</li> <li>Global Medical Device Nomenclature (GMDN) Code Values</li> <li>Manufacturing Location Values</li> <li>Medical Device Values</li> <li>Product Characteristics Values</li> <li>Product Status Values</li> <li>Product Strength Unit Values</li> <li>Route of Administration Values</li> <li>Special Measure Values</li> <li>Sterilization Requirement Values</li> <li>Sterilization Values</li> <li>Summary of Technical Documentation (STED) Values</li> <li>UMDNS Code Values</li> </ul>

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Applicable Standards Values</b>	Standards to which the medical device must comply	Product: Medical Device & Pharma Medical Device	Client Defined	Follow internal Change Management Processes.	
<b>Conformity Assessment Body Values</b>	A body, which may include a third party or a supplier's testing laboratory, or a certification body, that performs conformity assessment, or testing, to an importing Party's Technical Regulations.	Product: Medical Device & Pharma Medical Device	Client Defined	Follow internal Change Management Processes.	
<b>Conformity Assessment Path Values</b>	Path taken to access medical device conformity to include Annex II-VII (and combinations)	Product: Medical Device & Pharma Medical Device	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	
<b>Country Specific Detail Type Values</b>	Provides the ability to track Country specific Medical Device information	Product: Medical Device & Pharma Medical Device	Calyx Defined: Best Practices Client Defined	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	
<b>Country Specific Detail Values</b>	Provides the ability to track Country specific Medical Device information	Product: Medical Device & Pharma Medical Device	Calyx Defined: Best Practices Client Defined	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	
<b>Device Allergenicity Values</b>	Identifies whether the device contains allergens or materials of concern	Product: Medical Device & Pharma Medical Device	Client Defined	Follow internal Change Management Processes.	

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Device Nomenclature Values</b>	Classification system to classify medical devices in the European market.	Product: Medical Device & Pharma Medical Device Component Medical Device	Client Defined	Follow internal Change Management Processes.	
<b>Device Sterility Indicator Values</b>	Identifies if the device is supplied as sterile.	Product: Medical Device & Pharma Medical Device Component Medical Device	Client Defined	Follow internal Change Management Processes.	
<b>Device Type Values</b>	Identifies the type of device using a controlled vocabulary.	Product: Medical Device & Pharma Medical Device Component Medical Device	Client Defined	Follow internal Change Management Processes.	
<b>Device Usage Values</b>	How the device is being used	Product: Medical Device & Pharma Medical Device Component Medical Device	Client Defined	Follow internal Change Management Processes.	
<b>Dosage/Pharmaceutical Form Values</b>	Identifies the way a drug is used, e.g., capsule, tablet, or liquid.	Product: Pharma, Pharma Medical Device, Flu Vaccine Component: Pharma, Pharma Medical Device, Flu Vaccine	XEVMPD Controlled Vocabularies – Pharmaceutical Dose Forms	Align with updates to XEVMPD Controlled Vocabularies.	Maps to Route of Administration

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>EC Cert Values</b>	Design certifications for Class III medical device products	Product: Medical Device & Pharma Medical Device	Client Defined	Follow internal Change Management Processes.	
<b>Global Harmonization Task Force (GHTF) Class Values</b>	The GHTF-defined class to which the medical device belongs	Product: Medical Device & Pharma Medical Device	GHTF	Align with GHTF Values.	
<b>Global Medical Device Nomenclature (GMDN) Code Values</b>		Product: Medical Device & Pharma Medical Device  Component Medical Device	GMDN Agency	Align with updates by GMDN Agency	
<b>Manufacturing Location Values</b>	Location where the medical device is manufactured	Product: Medical Device & Pharma Medical Device  Component Medical Device	Client Defined	Follow internal Change Management Processes.	
<b>Medical Device Values</b>	The Medical Device that is the product	Pharmaceutical Product	XEVMPD Controlled Vocabularies – Medical Devices	Align with updates to XEVMPD Controlled Vocabularies.	
<b>Product Characteristics Values</b>	Controlled term that describes the actual product characteristic	Pharmaceutical Product	Client Defined	Follow internal Change Management Processes.	
<b>Product Status Values</b>	Realized Status of the product	Product	Calyx Defined: Best Practices	Consult <a href="http://help.liquent.com">help.liquent.com</a> for best practice. Follow internal Change Management Processes.	Refer to Calyx RIM for Registrations Best Practice: INTERNAL and External Status Values

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Product Strength Unit Values</b>	Strength values associated with active ingredients in the product, such as milligrams, grams, etc.	Product	Client Defined	Follow internal Change Management Processes.	
<b>Route of Administration Values</b>	Lists the method in which the dosage form is taken, e.g., oral	Product Component	XEVMPD Controlled Vocabularies - Routes of Administration	Align with updates to XEVMPD Controlled Vocabularies.	Maps to Dosage/Pharmaceutical Form Values
<b>Special Measure Values</b>	Identifies whether the medicinal product is subject to special measures via controlled vocabulary.	Full Product Presentation	Client Defined	Follow internal Change Management Processes.	
<b>Sterilization Values</b>	Type of sterilization used for the medical device, e.g., steaming, radiation, etc.	Product: Medical Device & Pharma Medical Device  Component Medical Device & Pharma Medical Device	Client Defined	Follow internal Change Management Processes.	
<b>Sterilization Requirement Values</b>	Requirements for sterilizing the Product	Product: Medical Device & Pharma Medical Device  Component: Medical Device & Pharma Medical Device	Client Defined	Follow internal Change Management Processes	

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Summary of Technical Documentation (STED) Values</b>	Client-specific summary of technical documentation IDs	Product: Medical Device & Pharma Medical Device	Client Defined	Follow internal Change Management Processes.	
<b>UMDNS Code</b>					

### 3.13 Project Maintenance

Project Maintenance
Project Status Values Project Type Values

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Project Status Values</b>	The Status of the Project	Project	Client Defined	Follow internal Change Management Processes.	Refer to Calyx RIM for Registrations Best Practice: INTERNAL and External Status Values
<b>Project Type Values</b>	The Type of Project, such as New Application or Withdraw Product	Project	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	System Specified, can be renamed but new values cannot be created

### 3.14 Publishing Requirements Maintenance

<b>Publishing Requirements Maintenance</b>
Electronic Format Requirement Values

Picklist Name	Description	Entity Location	Data Source	Recommended Process for Updates	System Rules, Data Dependencies and Relationships
<b>Electronic Format Requirement Values</b>	Not currently used	Not currently used	Not currently used	Not currently used	Not currently used

### 3.15 Reference Maintenance

<b>Reference Maintenance</b>
Reference Content Values Reference Participant Values Reference Status Values Reference Type Values

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Reference Content Values</b>	The content of the Reference, such as Approval	Reference	Client Defined	Follow internal Change Management Processes.	Reference Type must be created first
<b>Reference Participant Values</b>	Organizations involved in the content, such as FDA or EMA	Reference	Client Defined	Follow internal Change Management Processes.	Reference Type must be created first
<b>Reference Status Values</b>	The Status of the Reference	Reference	Client Defined	Follow internal Change Management Processes.	Reference Type must be created first Refer to Calyx RIM for Registrations Best

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
					Practice: INTERNAL and External Status Values
<b>Reference Type Values</b>	Type of reference, such as Letter, Agenda, Telephone Call	Reference	Client Defined	Follow internal Change Management Processes.	

### 3.16 Registration Maintenance

#### Registration Maintenance

EMA Authorisation Status Values  
 Medicinal Product Type Values  
 Qualified Person Responsible for Pharmacovigilance (QPPV) Values  
 Registration Status Values

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>EMA Authorisation Status Values</b>	The status of the authorisation of the medicinal product, as defined by the FPP, using only those values prescribed by the XEVMPD Controlled Vocabulary (CV) list.	Full Product Presentation	XEVMPD Controlled Vocabularies – Authorisation Status	Align with updates to XEVMPD Controlled Vocabularies.	
<b>Medicinal Product Type Values</b>	Describes the type of Medicinal Product.	Registration Package Set Type	XEVMPD Controlled Vocabularies – Medicinal Product Types	Align with updates to XEVMPD Controlled Vocabularies.	

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>QQPV (Qualified Person Responsible for Pharmacovigilance) Values</b>	The person responsible for Pharmacovigilance.	Registration Package Set Type	EMA Agency	Update as required align with XEVMPD Processes.	
<b>Registration Status Values</b>	Status of the Registration	Registration	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	Refer to Calyx RIM for Registrations Best Practice: INTERNAL and External Status Values

### 3.17 Sequence Maintenance

Sequence Maintenance
<a href="#">Filing Type Values</a> <a href="#">Sequence Status Values</a>

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Filing Type Values</b>	Identifies the type of filing, such as Supplement, Withdrawal. Used to support Publishing.	Sequence	Regulatory Agency Guidance Calyx Defined: based on Regulatory Guidance	Consult help.liquent.com for best practice.	Consider publishing impacts before making changes
<b>Sequence Status Values</b>	Status of the Sequence	Sequence	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	Refer to Calyx RIM for Registrations Best Practice: INTERNAL and External Status Values

### 3.18 SPOR Maintenance

SPOR Maintenance
ATC RMS Values
Compendial Designation/Source RMS Values
Concentration Measure Type RMS Values
Country RMS Values
Denominator/Numerator Unit RMS Values
Dosage/Pharmaceutical Form RMS Values
EMA Authorisation Status RMS Values
Language RMS Values
Legal Basis RMS Values
Medical Device RMS Values
Medicinal Product Type RMS Values
Procedure Type RMS Values
Route of Administration RMS Values
Unit of Measure Prefix RMS Values

This section is designed to maintain the European Medicines Agency (EMA) Substance, Product, Organisation and Referential (SPOR) service. According to the roadmap designed by EMA the SPOR support starts with an introduction of OMS (Organisation management service) and RMS (Referentials management service) components.

To support the integration with RMS API, and to enable adding the controlled vocabulary for referentials data from the external system, Calyx RIM provides the ability to enable and configure the SPOR services.

- Application Maintenance > Country Values
- Application Maintenance > Procedure Type Values
- Other > Concentration Measure Type Values
- Other > Denominator Unit Values
- Other > Language Values
- Other > Legal Basis Values
- Other > Numerator Unit Values
- Other > Unit of Measure Prefix Values
- Product Detail Set Maintenance > Compendial Designation/Source Values
- Product Family Maintenance > ATC Values
- Product Maintenance > Dosage/Pharmaceutical Form Values
- Product Maintenance > Medical Device Values
- Product Maintenance > Route of Administration Values
- Registration Maintenance > EMA Authorisation Status Values

- Registration Maintenance > Medicinal Product Type Values

Sample Views from Data Administration

Example 1

Country RMS Values - Country	
Term Name:	* Republic of Finland
Short Name:	Finland
Term Identifier:	100000000394
Status Type:	Current

Country	
◀ Back	
Country Code:	FI
Country Name:	Finland
eCTD Code:	fi
RMS Term Name:	Republic of Finland 100000000394
Active Flag:	Active

Example 2

Denominator/Numerator RMS Values - Units of Measurement	
Term Name:	* gram(s)
Short Name:	
Term Identifier:	100000110654
Status Type:	Current

Numerator Unit Values	
Numerator Unit Name:	* Gram(s)
Numerator Code:	* G
RMS Term Name:	gram(s) 100000110654

Example 3

EMA Authorisation Status RMS Values - Authorisation Status	
Term Name:	* Valid
Short Name:	
Term Identifier:	100000072099
Status Type:	Current

EMA Authorisation Status Values	
Authorisation Status:	* Valid
Status Code:	* 1
RMS Term Name:	Valid 100000072099

Picklist Name	Description	Entity Location*	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>ATC RMS Values</b>	ATC RMS Values - Anatomical Therapeutic Chemical Classification System	N/A	EMA Agency - SPOR System Referentials List: Anatomical Therapeutic Chemical Classification System	Align with EMA SPOR System Referentials.	<p>If the SPOR service has been enabled and configured through the appropriate options in the insightConfig.bat or insight.var files, the values from the EMA SPOR REST Server are loaded to the corresponding RMS Table. All values are loaded with Inactive status.</p> <p>When values are modified after the first loading, during the next loading the entered values are overwritten with the values from EMA SPOR REST Server.</p>
<b>Compendial Designation/Source RMS Values</b>	Compendial Designation/Source RMS Values - Source of Information	N/A	EMA Agency - SPOR System Referentials List: Source of Information	See above	<p>If the SPOR service has been enabled and configured through the appropriate options in the insightConfig.bat or insight.var files, the values from the EMA SPOR REST Server are loaded to the corresponding RMS</p>

Picklist Name	Description	Entity Location*	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
					Table. All values are loaded with Inactive status.  When values are modified after the first loading, during the next loading the entered values are overwritten with the values from EMA SPOR REST Server.
<b>Concentration Measure Type RMS Values</b>	Concentration Measure Type RMS Values - Units of Measurement Type	N/A	EMA Agency - SPOR System Referentials List: Units of Measurement Type	Align with EMA SPOR System Referentials.	See above
<b>Country RMS Values</b>	Country RMS Values - Country	N/A	EMA Agency - SPOR System Referentials List: Country	See above	See above
<b>Denominator/Numerator Unit RMS Values</b>	Denominator/Numerator Unit RMS Values - Units of Measurement	N/A	EMA Agency - SPOR System Referentials List: Units of Measurement	See above	See above
<b>Dosage/Pharmaceutical Form RMS Values</b>	Dosage/Pharmaceutical Form RMS Values - Combined Pharmaceutical Dose Form	N/A	EMA Agency - SPOR System Referentials List: Combined Pharmaceutical Dose Form	See above	See above
<b>EMA Authorisation Status RMS Values</b>	EMA Authorisation Status RMS Values - Authorisation Status	N/A	EMA Agency - SPOR System Referentials List: Authorisation Status	See above	See above

Picklist Name	Description	Entity Location*	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Language RMS Values</b>	Language RMS Values - Language	N/A	EMA Agency - SPOR System Referentials List: Language	See above	See above
<b>Legal Basis RMS Values</b>	Legal Basis RMS Values - Application Legal Basis	N/A	EMA Agency - SPOR System Referentials List: Application Legal Basis	See above	See above
<b>Medical Device RMS Values</b>	Medical Device RMS Values - XEVMPD Medical Device	N/A	EMA Agency - SPOR System Referentials List: XEVMPD Medical Device	Align with EMA SPOR System Referentials.	<p>If the SPOR service has been enabled and configured through the appropriate options in the insightConfig.bat or insight.var files, the values from the EMA SPOR REST Server are loaded to the corresponding RMS Table. All values are loaded with Inactive status.</p> <p>When values are modified after the first loading, during the next loading the entered values are overwritten with the values from EMA SPOR REST Server.</p>
<b>Medicinal Product Type RMS Values</b>	Medicinal Product Type Values - XEVMPD Medicinal Product Type	N/A	EMA Agency - SPOR System Referentials List:	See above	See above

Picklist Name	Description	Entity Location*	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
			XEVMPD Medicinal Product Type		
<b>Procedure Type RMS Values</b>	Procedure Type RMS Values - EU Regulatory Authorisation Procedure	N/A	EMA Agency - SPOR System Referentials List: EU Regulatory Authorisation Procedure	See above	See above
<b>Route of Administration RMS Values</b>	Route of Administration RMS Values - Routes and Methods of Authorisation	N/A	EMA Agency - SPOR System Referentials List: Routes and Methods of Authorisation	See above	See above
<b>Unit of Measure Prefix RMS Values</b>	Unit of Measure Prefix RMS Values - Units of Measurement Prefix	N/A	EMA Agency - SPOR System Referentials List: Units of Measurement Prefix	See above	See above

### 3.19 Submission Maintenance (Publishing)

Submission Maintenance
Applicant Contact Type Values
Applicant Contact Values
Applicant ID Values
Application Form Type Values
Font Definition Values
Leaf Status Values
PDF Properties Values
Promotional Material Audience Type Values
Promotional Material Doc Type Values
Promotional Material Type Values
Regulatory Activity Lead Values
Submission Product Type Values
Sequence Description Values
Sub Filing Type Values
Supplement Effective Date Type Values
Telephone Number Type Values
Drug Registration File Documents Section Values
Drug Registration File Documents Values

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Applicant Contact Type Values</b>	The Applicant Contact Types that match the codes that the regulatory agency provides	Folder (m1-us v. 3.3)	Regulatory Agency Defined (US: Applicant-contact-type.xml V1.2)	Align with changes made by Regulatory Agency.	Check with a Calyx Regulatory Consultant before making any changes to the OTB values.
<b>Applicant Contact Values</b>	All active Applicant Contact values.	Folder (m1-us v. 3.3)	Client Defined	Follow internal Change Management Processes.	Needs to be defined prior to a US v. 3.3 submission
<b>Applicant ID Values</b>	The Applicant ID.	Application	Client Defined	Follow internal Change Management Processes.	Needs to be defined prior to any submission which uses the type of Applicant ID
<b>Application Form Type Values</b>	The Application Form Types that match the	Folder (m1-us v. 3.3)	Regulatory Agency Defined (US: form-type.xml V1.1)	Align with changes made by Regulatory Agency.	Check with a Calyx Regulatory Consultant before making any

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
	codes that the regulatory agency provides.				changes to the OTB values.
<b>Font Definition Values</b>	The fonts that can be used in tab sheets created in Calyx RIM Publisher	Tab Sheet	Calyx Defined: based on Calyx RIM Rendering default configuration		
<b>Leaf Status Values</b>	The status that can be assigned to a Leaf. When assigned, helps to identify the Leafs in an assembly that need to be published or have already been published. Three "out-of-the-box" statuses are provided:  Planned  Ready for Publish  Published  Default value is Planned	Assembly Leaf	Calyx Defined: Best Practices	Consult help.liquent.com for best practice.  Follow internal Change Management Processes.	When published the leaf status gets automatically updated from 'Planned' to 'Published'
<b>PDF Property Values</b>	The PDF properties that can be used in Leaf Elements and Publishing Settings Library	PDF Properties	Client Defined	Follow internal Change Management Processes.	
<b>Promotional Material Audience Type Values</b>	The promotional material audience types that match the code that the regulatory agency provides.	Folder (m1-us v. 3.3)	Regulatory Agency Defined	Align with changes made by Regulatory Agency.	Check with a Calyx Regulatory Consultant before making any changes to the OTB values.

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Promotional Material Doc Type Values</b>	The promotional material doc types that match the codes that the regulatory agency provides	Folder (m1-us v. 3.3)	Regulatory Agency Defined	Align with changes made by Regulatory Agency.	Check with a Calyx Regulatory Consultant before making any changes to the OTB values.
<b>Promotional Material Type Values</b>	The promotional material types that match the codes that the regulatory agency provides.	Folder (m1-us v. 3.3)	Regulatory Agency Defined	Align with changes made by Regulatory Agency.	Check with a Calyx Regulatory Consultant before making any changes to the OTB values.
<b>Regulatory Activity Lead Values</b>	Health Canada groups that can take the lead in reviewing the regulatory activity that a regulatory transaction support.	Folder (m1-ca v. 2.2)	Regulatory Agency Defined	Align with changes made by Regulatory Agency.	Check with a Calyx Regulatory Consultant before making any changes to the OTB values.
<b><u>Submission Product Type Values</u></b>	To maintain the submission product types of the China region. The values for Region, eCTD Code, Product Type and Applicable DTD/Schema can be entered or selected in their respective fields.	CN 1.0 Folder	Regulatory Agency Defined	Align with changes made by Regulatory Agency.	Needs to be defined prior to a China 1.0 Folder eCTD submission  Check with a Calyx Regulatory Consultant before making any changes to the OTB values.
<b>Sequence Description Values</b>	The values that Health Canada defines to describe a sequence (regulatory transaction).	Folder (m1-ca v. 2.2)	Regulatory Agency Defined	Align with changes made by Regulatory Agency.	Check with a Calyx Regulatory Consultant before making any

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
					changes to the OTB values.
<b>Sub Filing Type Values</b>	The sub filing types that match the codes that the regulatory agency provides.	Folder (m1-us v. 3.3)	Regulatory Agency Defined	Align with changes made by Regulatory Agency.	Check with a Calyx Regulatory Consultant before making any changes to the OTB values.
<b>Supplement Effective Date Type Values</b>	The supplement effective date types that match the codes that the regulatory agency provides.	Folder (m1-us v. 3.3)	Regulatory Agency Defined	Align with changes made by Regulatory Agency.	Check with a Calyx Regulatory Consultant before making any changes to the OTB values.
<b>Telephone Number Type Values</b>	The telephone number types that match the codes that the regulatory agency provides.	Folder (m1-us v. 3.3)	Regulatory Agency Defined	Align with changes made by Regulatory Agency.	Check with a Calyx Regulatory Consultant before making any changes to the OTB values.
<b>Drug Registration File Documents Section Values</b>	To maintain the drug registration file documents section of the EAEU region, The values for Section Code and Section Name can be entered in their respective fields.	EAEU Leaf	Regulatory Agency defined	Align with changes made by Regulatory Agency.	Needs to be defined prior to a EAEU eCTD submission  Check with a Calyx Regulatory Consultant before making any changes to the OTB values.
<b>Drug Registration File Documents Values</b>	To maintain the drug registration file documents of the EAEU	EAEU Leaf	Regulatory Agency defined	Align with changes made by Regulatory Agency.	Needs to be defined prior to a EAEU eCTD submission

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
	region,. The values for Section, Document Code and Name can be entered in their respective fields.				Check with a Calyx Regulatory Consultant before making any changes to the OTB values.

### 3.20 Submission Plan Maintenance (Publishing)

<b>Submission Plan Maintenance</b>
Submission Plan Status Values

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Submission Plan Status Values</b>	The Status of the Submission Plan.	Submission Plan	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	Applicable to US Grouped Submissions, only.

### 3.21 Task Maintenance

<b>Task Maintenance</b>
Secondary Task/Sub-Task Type Values Task/Sub-Task Priority Values Task/Sub-Task Status Progression Values Task/Sub-Task Status Values Task/Sub-Task Type Values

Picklist Name	Description	Entity Location	Data Source	Recommended Practice for Managing Updates	System Rules, Data Dependencies and Relationships
<b>Secondary Task/Sub-Task Type Values</b>	Additional information to further identify the type of task, for example, assemble documentation, marketing approval, etc.	Task	Client Defined	Follow internal Change Management Processes.	Task Type must be created first
<b>Task/Sub-Task Priority Values</b>	Denotes the priority given to the Task or Sub-Task.	Task	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	
<b>Task/Sub-Task Status Progression Values</b>	Contains To/From Status mappings for repeatedly used Tasks. Functionality controls available Status drop-down values if selected Task Type (or Task Type/Secondary Task Type combination) are mapped to a Task Status Progression in Data Administration.	Task	Client Defined	Follow internal Change Management Processes.	
<b>Task/Sub-Task Status Values</b>	Status values for the Task	Task	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	Refer to Calyx RIM for Registrations Best Practice: INTERNAL and External Status Values
<b>Task/Sub-Task Type Values</b>	Type of Task activity, such as Annual Report or Renewal	Task	Calyx Defined: Best Practices	Consult help.liquent.com for best practice. Follow internal Change Management Processes.	