



CALYX™

CALYX™ Best
Practice:
Associating SPOR
Values in Data
Admin
Calyx RIM 7.2.2.

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. The Calyx Business Consulting Team 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) (Refer to Release Notes for Full Description)
7.1	13-Jun-2022	Initial Release
7.2.2.	17-Apr-2023	Updated to include SPOR updates for Calyx RIM 7.2.2

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3 Document Purpose

The purpose of this document is to provide a Best Practice for Data Administrators to manage the manual association of the EMA SPOR Master List values with the corresponding Data Administration values displayed in the User Interface

4 Scope

Associating Referential (RMS) and Organisational (OMS) Term Names & IDs in Data Admin in support of IDMP preparedness

5 Associating an RMS or OMS term in Data Admin

The SPOR Master Lists are mapped to the Data Admin picklists that are presented in the User Interface. For IDMP the impacted Data Admin picklist values need to be associated to the equivalent RMS or OMS Term ID.

The terms do not need to be identical, but they do need to have the same meaning and granularity alignment e.g. under the Legal Status of the Supply the RMS value of ‘Medicinal product subject to medical prescription’ could be mapped to a Data Admin value of ‘Prescription Only’ but not to a value of ‘Prescription or Restricted Prescription’. Conversely the RMS term of Medicinal product not subject to medical prescription could be mapped to a data admin value of ‘Over the Counter’ and ‘General Sales’

Where appropriate the same RMS ID can be associated with more than one Data Admin value e.g., the EU Procedure Types ‘EU CP Bio’ and ‘EU CP New Active’ can both be mapped to the RMS ID & Term Name; 100000155059; Centralised Procedure.

Listed below are the SPOR Master Lists and the corresponding Data Admin value picklist


SPOR Master List replicated in Data Admin	Mapped to Data Admin Section	Mapped to Data Admin Value List	Calyx RIM Version
Anatomical Therapeutic Chemical Classification System – Human	Product Family Maintenance	ATC Values	7.1
Application Legal Basis	Other	Legal Basis Values	7.1
Application Submission Type	Other	Application Submission Type Values	7.1
Combination Package	Product Maintenance	Dosage/Pharmaceutical Form Values	7.1
Combined Pharmaceutical Dose Form	Product Maintenance	Dosage/Pharmaceutical Form Values	7.1
Combined Term	Product Maintenance	Dosage/Pharmaceutical Form Values	7.1

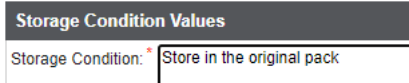
SPOR Master List replicated in Data Admin	Mapped to Data Admin Section	Mapped to Data Admin Value List	Calyx RIM Version
Contact Party Role	Registration Maintenance	Qualified Person Responsible for Pharmacovigilance (QPPV) Values	7.1
Country	Application Maintenance	Country Values	7.1
Data Classification	Product Detail Set Maintenance	Data Classification Type Values that will map to Confidentiality Indicator on the Manufacturer Values Global Detail Sets	7.1
Domain	N/A	Included in submission message rules - based on Product Family Type	7.1
EU Regulatory Authorisation Procedure	Application Maintenance	Procedure Type Values	7.1
Ingredient Role	Product Detail Set Maintenance	Substance Role Values	7.1
Language	Other	Language Values	7.1
Legal Status for Supply	Application Maintenance	Legal Status Values	7.1
Manufacturing Activity	Product Detail Set Maintenance	Manufacturing Functions Values	7.1
Marketing Status	Registration Maintenance	Marketing Status Values	7.1
Master File Type	Registration Maintenance	Master File Type Values	7.1
Material	Product Detail Set Maintenance	Product Material Values	7.1
Medical Dictionary For Regulatory Activities	Other	Indications/Intended Use Values	7.1
Medicinal Product Name Part Type	Registration Maintenance	Medicinal Product Name Part Type Values	7.1
Organisation	Other	MAH/Development Sponsor/Organisation Values Manufacturer Values	7.1
Packaging	Product Detail Set Maintenance	Packaging Type Values	7.1
Pharmaceutical Dose Form	Product Maintenance	Dosage/Pharmaceutical Form Values	7.1
Product Category	Product Maintenance	Product Category Type Values	7.1

SPOR Master List replicated in Data Admin	Mapped to Data Admin Section	Mapped to Data Admin Value List	Calyx RIM Version
Product Cross Reference Type	Product Maintenance	Product Cross Reference Type Values	7.1
Product Information Document Type	Application Maintenance	Product Information Document Type Values	7.1
Quantity Operator	Other	Concentration Measure Type Values	7.1
Reason for Marketing Unavailability	Registration Maintenance	Risk of Supply Shortage Reason Values	7.2
Regulatory Entitlement Status	Application Maintenance	Orphan Status Values	7.1
Regulatory Entitlement Type	Application Maintenance	Regulatory Entitlement Type Values	7.1
Routes and Methods of Administration	Product Maintenance	Routes of Administration Values	7.1
Shelf-Life Type	Product Detail Set Maintenance	Shelf-Life Type Values	7.1
Special Precaution for Storage	Product Detail Set Maintenance	Storage Condition Values	7.1
Substance	Product Family Maintenance	Substance Values	7.2
Units of Measurement	Other	Units of Measurement Values	7.1
Units of Presentation	Other	Unit of Presentation Values	7.1
XEVMPD Medical Devices	Product Maintenance	Medical Device Values	7.1
XEVMPD Medicinal Product Type	Registration Maintenance	Medicinal Product Type Values	7.1

5.1 Steps to associate an RMS or OMS ID


5.1.1 Scenario 1: Associating Identical values

1. Locate the Data Admin picklist e.g. Storage Condition Values under the Product Detail Set Maintenance section
2. Where necessary create a new value by selecting the  button
3. Add new value & Save



4. Open the value to be associated and navigate to the RMS tab at the bottom of the screen

Term ID	Term Name	Description	Last User Updated	Last Changed Date	Active Flag
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5. Select the  button to associate the term ID

The tool auto-populates the data admin value in the Search By 'Term Name' and searches for a matching value in the associated RMS Master List and automatically presents the RMS term to be associated where an identical value exists in the Search Results

Term Search

Search By * Search requires minimum 3 characters for field(s) to query; ignores inputs with lesser characters.

Term Name	Term ID	Code
Store in the original pack	Term ID	xEVMPD/ISO Code/Source Term ID

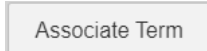
Search Results * Use pager toolbar items to refine Search Results records.

Term Name	Term ID	ISO Code	xEVMPD Code	Source Mapping Code
Store in the original package	100000073421			

5 items per page 1 - 1 of 1 items

Associate Term Close * Select a Search Results record before clicking the Associate Term button.

6. Click on the entry to be associated and Select 'Associate Term'



7. The screen refreshes and the value is associated

Storage Condition Values

Back

Storage Condition: Store in the original pack

Last User Updated: Karen Harry


Last Changed Date: 27-May-2022

Active Flag: Active

RMS


Term ID	Term Name
100000073421	Store in the original package

5.1.2 Scenario 2a: Associating non-identical values by Term Name

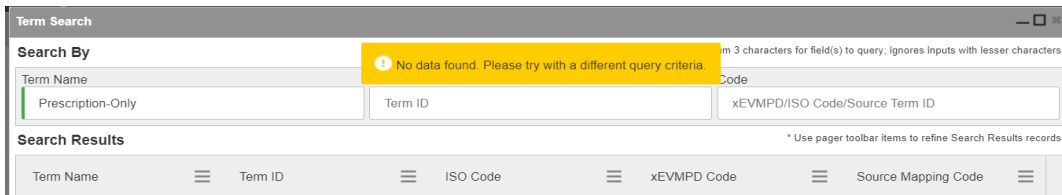
1. Locate the Data Admin picklist e.g. Storage Condition Values under the Product Detail Set Maintenance section
2. Where necessary create a new value by selecting the  button
3. Add new value & Save
4. Open the value to be associated and navigate to the RMS tab at the bottom of the screen



Term ID	Term Name	Description	Last User Updated	Last Changed Date	Active Flag
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5. Select the  button to associate the term ID

The tool searches for a matching value in the associated Master List, if one does not exist the filter functionality can be used. In this example a Legal Status of ‘Prescription Only’ in Data Admin needs to be associated with the RMS term of ‘Medicinal Product Subject to Medical Prescription’. Where there is no matching value a message is displayed ‘No data found. Please try with a different query criteria’. Note: a minimum of 3 characters needs to be entered to query.



Term Search

Search By

Term Name: Prescription-Only

Term ID: [Empty]

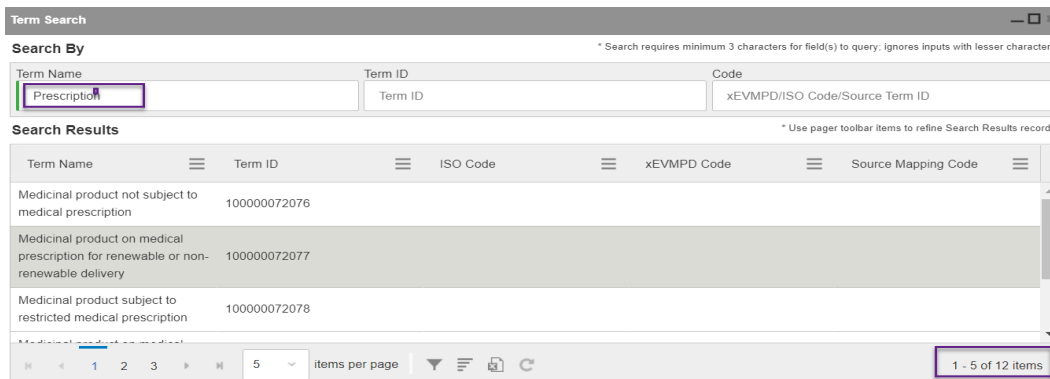
Code: xEVMPD/ISO Code/Source Term ID

Search Results

No data found. Please try with a different query criteria.

In this example updating the value in the term name from ‘Prescription-Only’ to ‘Prescription’ will be sufficient to locate possible values

Twelve results are returned in Term ID order and the first 5 are displayed by default



Term Search

Search By

Term Name: Prescription

Term ID: Term ID

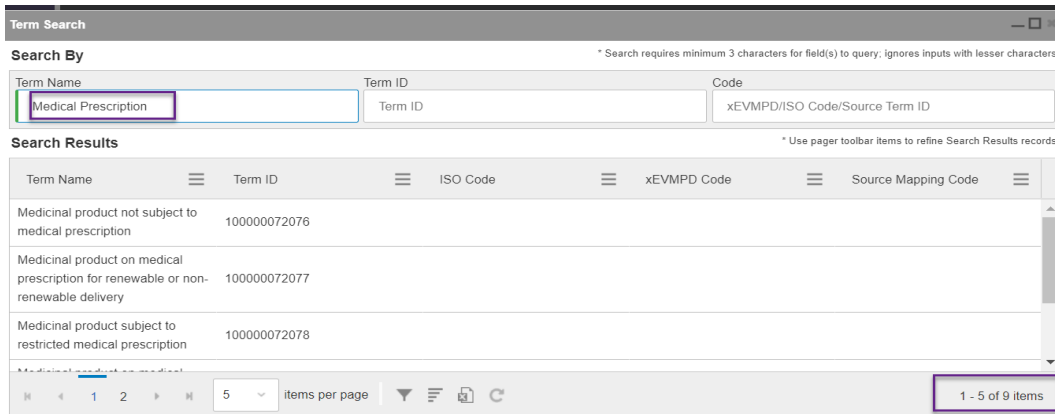
Code: xEVMPD/ISO Code/Source Term ID

Search Results

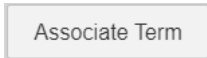
Term Name	Term ID	ISO Code	xEVMPD Code	Source Mapping Code
Medicinal product not subject to medical prescription	100000072076			
Medicinal product on medical prescription for renewable or non-renewable delivery	100000072077			
Medicinal product subject to restricted medical prescription	100000072078			

1 - 5 of 12 items

The results can be further refined by adding to the search string e.g., Medical Prescription restricts the number of results to nine

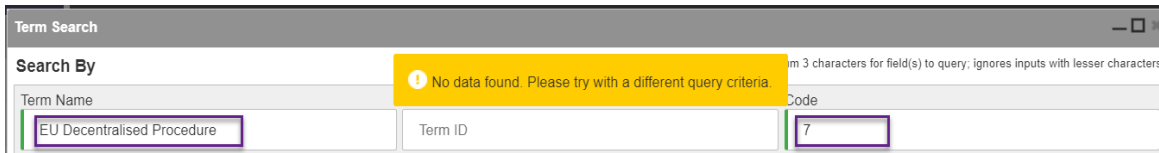


6. Locate the value to be associated and select 'Associate Term'

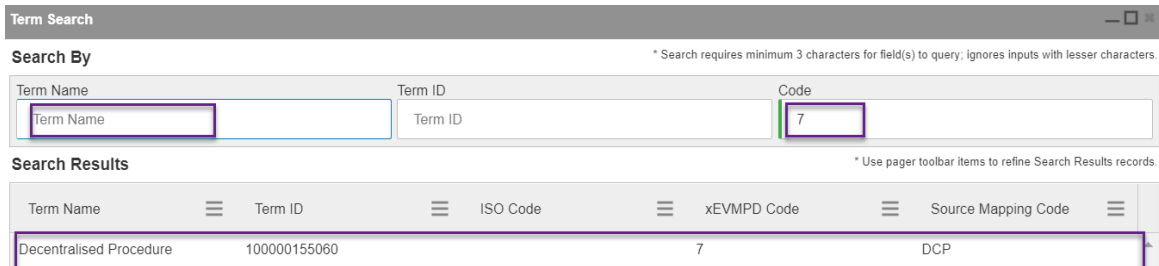


5.1.3 Scenario 2b: Associating non-identical values by Code ID

In this example the EU Procedure Type in Data Admin of 'EU Decentralised Procedure' returns no matching RMS Values. The Search screen is auto-populated with the Term Name and the Code from the Procedure Type Value attributes

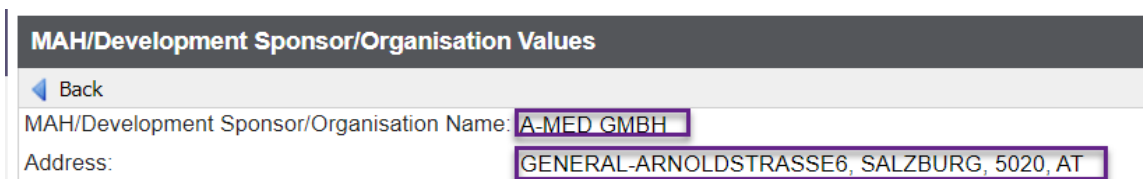


To locate the correct procedure value in RMS remove the text from the term name and retain the code information. The Decentralised Procedure value is available for selection.

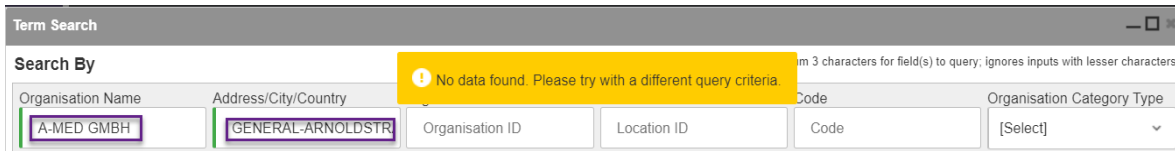


5.1.4 Scenario 2c: Associating non-identical values by Address Details

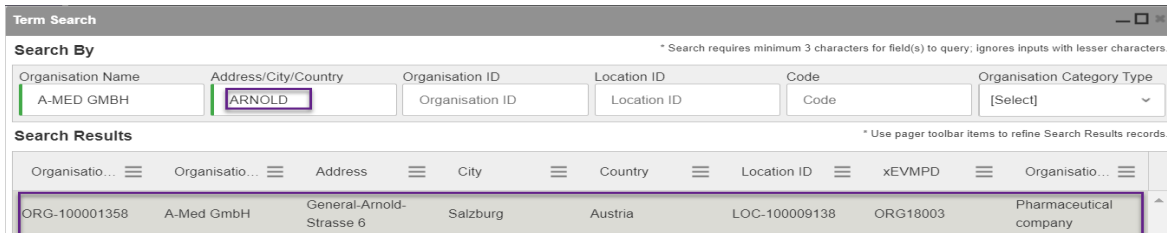
To assist in locating Organisations (MAHs) And Manufacturers in the SPOR OMS value list it is possible to use address information. In this example the MAH Name and Address in Data Admin are entered as seen below:



When these details are auto-populated in the Search screen no results are returned

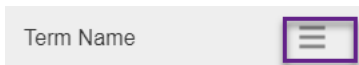


By modifying the details in the Address/City/Country field to include 'ARNOLD' only the details in OMS are located

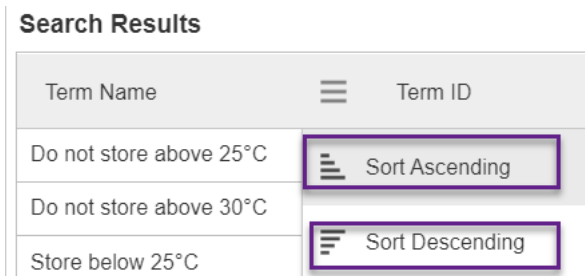


6 Using the Sort functionality

Where multiple results are returned it is possible to sort the results by selecting the menu option adjacent to the value that is the preferred sort option e.g. Term Name



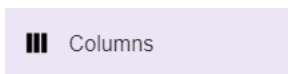
Select to Sort Ascending or Sort Descending

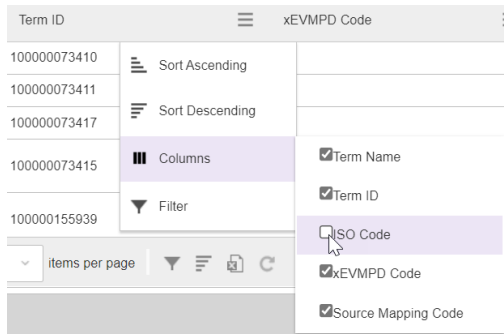


7 Remove Columns from Search Results

To remove columns from the Search Results, select the menu option adjacent to any of the Search Results Headings.

Select the Columns option to deselect or select the columns to display

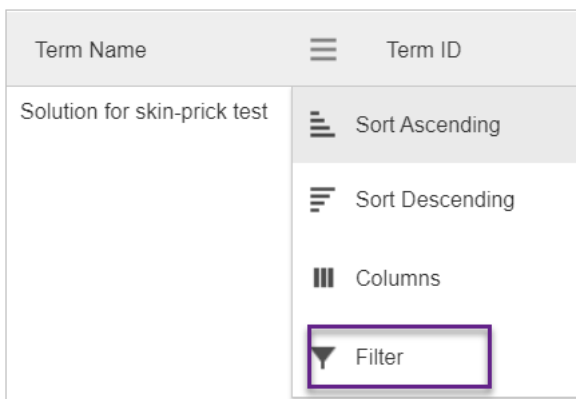




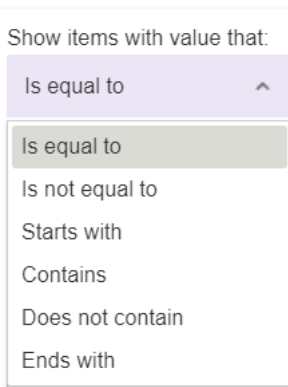
8 Using the Filter functionality

Optionally it is also possible to use the filter functionality by selecting the menu option adjacent to the criteria to filter on

Search Results



When the Filter option is selected it is possible to search for multiple conditions including 'Equal to', 'Contains', 'Ends with'



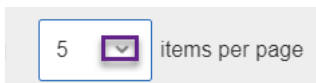
Filter options (or operators) compare the fields in the filter against values you provide. The table below provides some examples from the Legal Status values list.

Filter Option	Description	Example
Is equal to	Returns only the value corresponding precisely to the given string	Entering “Medicinal product not subject to medical prescription” will return that value only.
Is not equal to	Returns all values, except the value corresponding precisely to the given string	Entering “Medicinal product not subject to medical prescription” will return all values except this value.
Starts with	Returns all values that start with the letter, number, string of text.	Entering just the letter V, will return all values beginning with V, in this example all values that start “V”, e.g. Veterinary medicinal product not subject to veterinary prescription
Contains	Returns all the values containing at least the given string	Entering the word “restricted” returns all values that contain the word restricted, e.g. Medicinal product subject to restricted medical prescription
Does not contain	Returns all values that does not contain a specified string	Entering “vet” will return all the values except those that contain the word vet.
Ends with	Returns all values that ends with the specified string	Entering “sizes” will return all those values that end with the word sizes, e.g. Medicinal product subject to medical prescription exempt for some pack sizes
AND	Returns all values that satisfies the conditions for the first AND second filter option selected.	Entering filter option 1 Contains “Special” AND filter option 2, “Restricted”, returns all values that contain both of the entered strings, e.g. “Medicinal product subject to special and restricted medical prescription
OR	Returns all values that either satisfies the conditions for the first option OR and the second filter option selected.	Entering filter option 1, contains “Special” OR filter option 2, contains “Restricted”, returns all values that contain either of the entered strings, e.g., “Medicinal product subject to special medical prescription” as well as e.g. “Medicinal product subject to special and restricted medical prescription, that actually contains both values

9 Change the number of display value

The default number of results returned per page is set to 5. To increase the number of values displayed on a per search basis:

1. Click on the down arrow next to items per page



2. Select the number of search results to be displayed. Note this selection does not persist

Search Results

Term Name	Term ID
Do not store above 25°C	100000073410
Do not store above 30°C	100000073411
Store below 25°C	100000073412
Store below 30°C	100000073413
Store in a refrigerator (2°C – 8°C)	100000073414

Navigation: 1 2 3

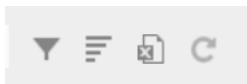
Items per page dropdown: 5, 10, 20, 50, 100

Buttons: Associate Term, Close

Page 1 of 1

10 Additional options

At the bottom of the screen additional menu items are available



To clear all Filters click



To clear the Sort click



To export results to excel click




To refresh results click



11 Disassociating an RMS or OMS Term

To disassociate an RMS or OMS term

1. Locate the value in the appropriate Data Admin Table
2. Click the value to open
3. Navigate to the RMS Tab
4. Select the value to disassociate
5. Select the disassociate button 

Regulatory Entitlement Type Values

[Back](#)

Regulatory Entitlement Type: Orphan Designation

Last User Updated: SYSMANT

Last Changed Date: 22-Nov-2021

Active Flag: Active

Default Flag: Yes

RMS

Term ID	Term Name	Description	Last User Updated	Last Changed Date	Active Flag
<input checked="" type="checkbox"/> 220000000062	Orphan Designation		Karen Harry	31-May-2022	Active