



ASSOCIATING SPOR VALUES IN DATA ADMIN

1 Revision History

When Ennov releases a new version of Ennov InSight, they issue Release Notes which explain the new features and updates. The Ennov 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, Ennov 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)
v7.3.4	20-May-2025	Update Best Practice for Ennov rebranding & for v7.3.4 – No Impact
v7.1	13-Jun-2022	Initial Release

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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.

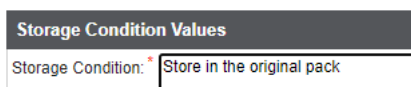
The terms do not need to be identical, but they do need to have the same meaning and granularity alignment e.g. under the Legal Status of the Supply the RMS value of 'Medicinal product subject to medical prescription' could be mapped to a Data Admin value of 'Prescription Only' but not to a value of '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.

5.1 Steps to associate an RMS or OMS ID

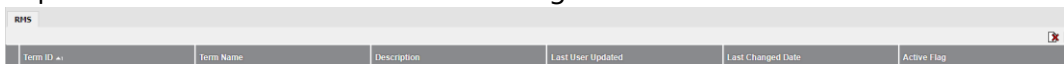
5.1.1 Scenario 1: Associating Identical values

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 the new value & Save.



A screenshot of a software interface showing a picklist titled "Storage Condition Values". Below the title, there is a text input field with the value "Store in the original pack" and a small green plus icon to its right.

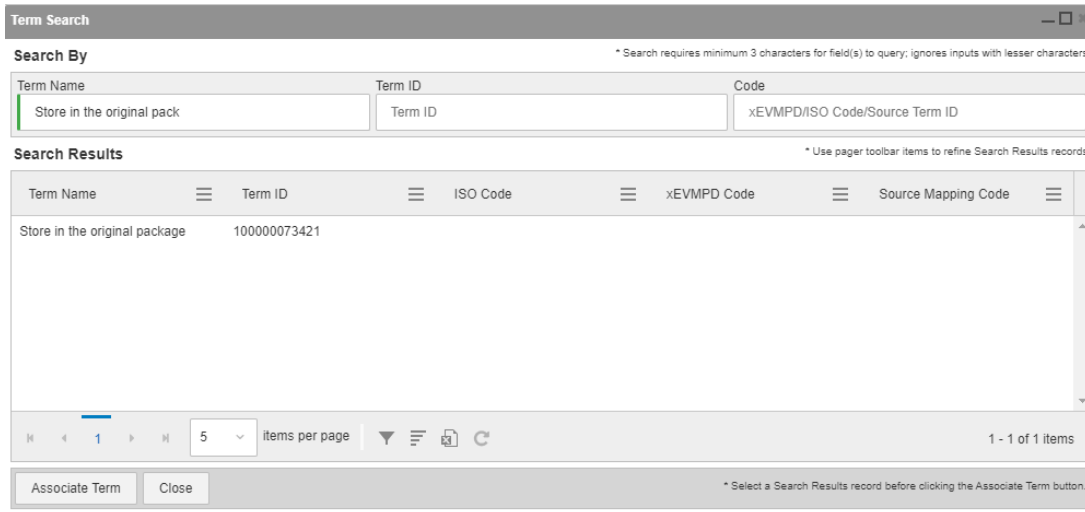
4. Open the value to be associated and navigate to the RMS tab at the bottom of the screen.



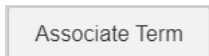
A screenshot of a software interface showing a table with the following columns: Term ID, Term Name, Description, Last User Updated, Last Changed Date, and Active Flag. The table is currently empty.

5. Select the  button to associate the term ID.

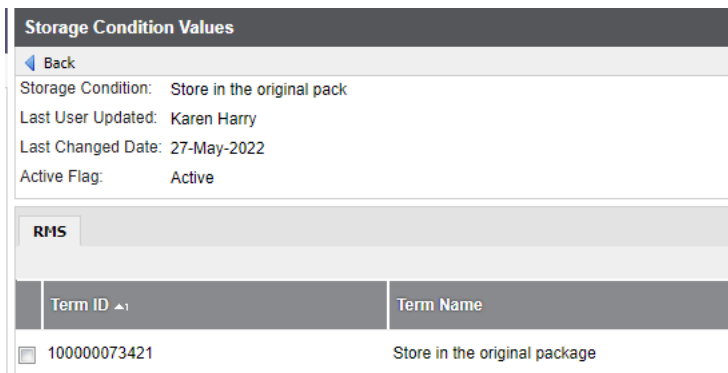
The tool auto-populates the data admin value in the Search By 'Term Name' and searches for a matching value in the associated RMS Master List and automatically presents the RMS term to be associated where an identical value exists in the Search Results.



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



7. The screen refreshes and the value is associated.



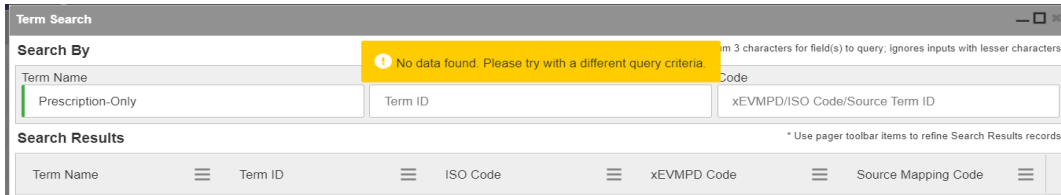
5.1.2 Scenario 2a: Associating non-identical values by Term Name

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



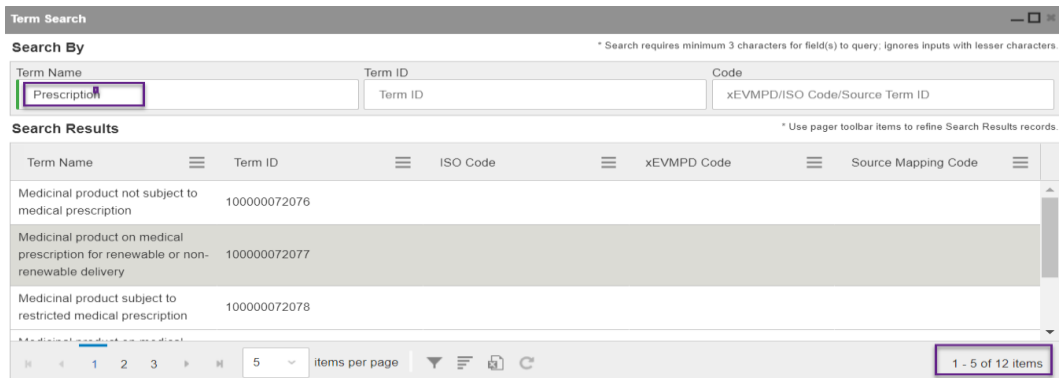
5. Select the button to associate the term ID.

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.

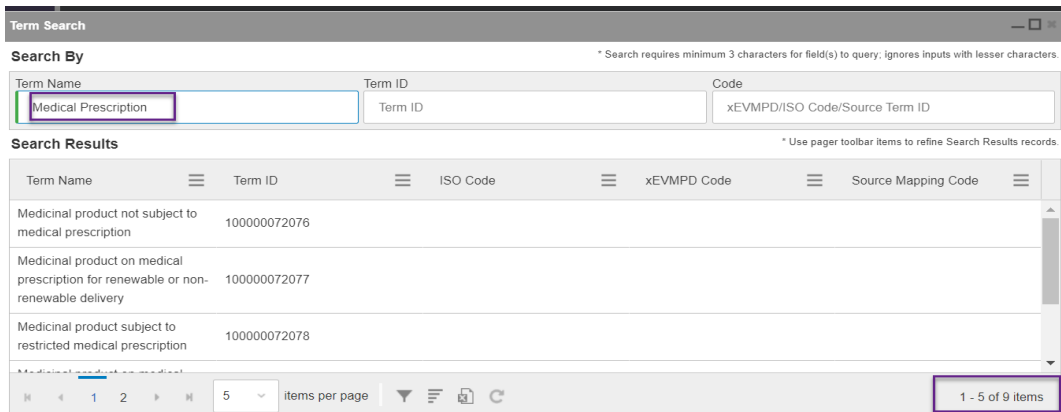


In this example updating the value in the term name from 'Prescription-Only' to 'Prescription' will be sufficient to locate possible values.

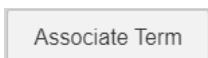
Twelve results are returned in Term ID order and the first 5 are displayed by default.



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.

Term Search

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

Term Name: EU Decentralised Procedure
Term ID: 7
Code: 7

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

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.

Term Search

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

Term Name: Decentralised Procedure
Term ID: 100000155060
Code: 7

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

Term Name	Term ID	ISO Code	xEVMPD Code	Source Mapping Code
Decentralised Procedure	100000155060		7	DCP

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:

MAH/Development Sponsor/Organisation Values

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MAH/Development Sponsor/Organisation Name: A-MED GMBH

Address: GENERAL-ARNOLDSTRASSE6, SALZBURG, 5020, AT

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

Term Search

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

Organisation Name: A-MED GMBH
Address/City/Country: GENERAL-ARNOLDSTRASSE6
Code: 7

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

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

Term Search

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

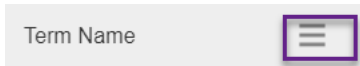
Organisation Name: A-MED GMBH
Address/City/Country: ARNOLD
Code: 7

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

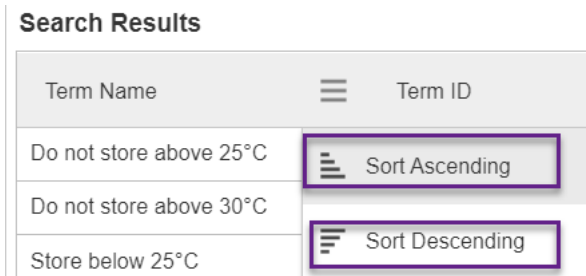
Organisation...	Organisatio...	Address	City	Country	Location ID	xEVMPD	Organisatio...
ORG-100001358	A-Med GmbH	General-Arnold-Strasse 6	Salzburg	Austria	LOC-100009138	ORG18003	Pharmaceutical company

5.2 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.



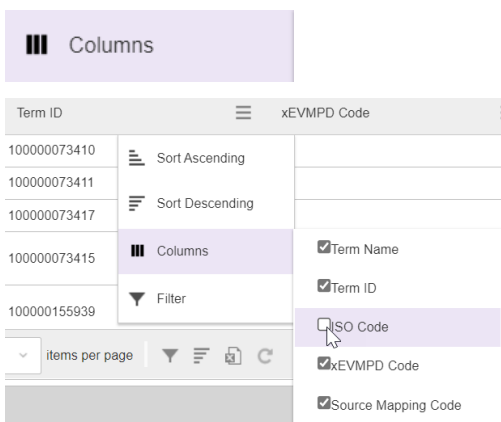
Select to Sort Ascending or Sort Descending.



5.3 Remove Columns from Search Results

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

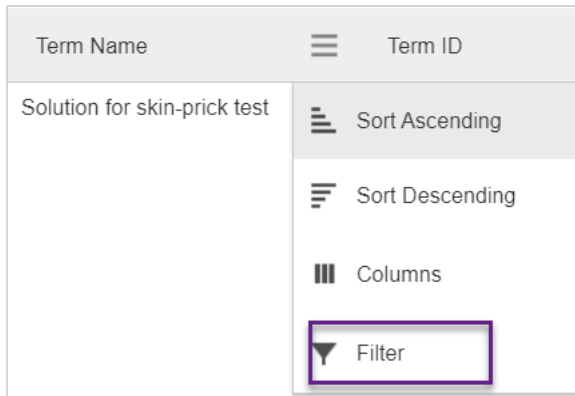
Select the Columns option to deselect or select the columns to display.



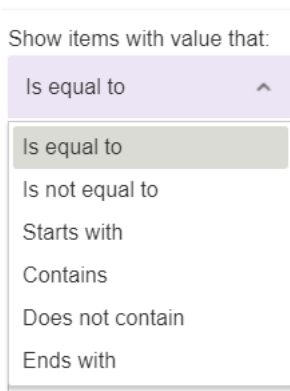
5.4 Using the Filter functionality

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.

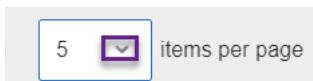
Filter Option	Description	Example
Is equal to	Returns only the value corresponding precisely to the given string.	Entering "Medicinal product not subject to medical prescription" will return that value only.
Is not equal to	Returns all values, except the value corresponding precisely to the given string.	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.

Filter Option	Description	Example
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.

5.5 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.

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 5

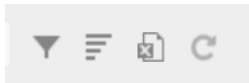
Buttons: Associate Term, Close

Dropdown menu: 5, 10, 20, 50, 100

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5.6 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

5.7 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

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Regulatory Entitlement Type: Orphan Designation

Last User Updated: SYSMANT

Last Changed Date: 22-Nov-2021

Active Flag: Active

Default Flag: Yes

RMS 

Term ID ^{A1}	Term Name	Description	Last User Updated	Last Changed Date	Active Flag
<input checked="" type="checkbox"/> 220000000062	Orphan Designation		Karen Harry	31-May-2022	Active