Housekeeping notes – Personal data protection notice

*Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website and YouTube channel.***

*Throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.*

*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.*

For Questions: www.slido.com code: #SWOCT724

Housekeeping notes – Q&A

EUROPEAN MEDICINES AGENCY

Join at
slido.com
#SWOCT724

- Join via **QR code** or **slido.com -** *please provide your questions and comments in Slido only*
- **Send or upvote the questions** you want to hear answered – *before raising a question check whether its has been raised already and vote for it*

Q&A Management

- Questions will be shown on the screen and managed live in the Q&A session
- EMA colleagues will attempt to **address questions in writing throughout the session**
- EMA colleagues will **verbally address (unanswered) top voted questions** at the end in the live Q&A session.

Unanswered questions

- This can be due to high volume of questions or assistance of a specific colleague not available today is required.
- Unanswered questions will be reviewed, and the **most relevant ones may be addressed** in other webinars or in a FAQ document.
- We may request that you ask **Questions on specific issues/cases** in Service Desk to be tracked, investigated and adequately assigned.

Webinar materials sharing

Presentations will be* available at:

- SPOR Portal Documents section
- EMA Events Web Page

*1st version of presentation already published, to be updated with final version (if necessary)

Recordings will be available at:

- EMA YouTube Channel
- EMA Events Web Page

For Questions: www.slido.com code: #SWOCT724

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Referentials Management Services (RMS)

7 October 2024, 10:00 – 12:00 Central European Summer Time (CEST)

Presented by Veronica Lipucci Di Paola

SPOR Webinar Series – 7-11 October 2024

SPOR Webinars

During **SPOR webinars,** EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

Webinar title	Date	Time
SPOR Data Governance	4 October 2024	10:00-12:00 CEST
Referentials Management Service (RMS)	7 October 2024	10:00-12:00 CEST
Substance Management Service (SMS)	8 October 2024	10:00-12:00 CEST
Organisation Management Service (OMS)	9 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for MAH	10 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for Sponsors	11 October 2024	10:00-12:00 CEST
Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API	14 October 2024	10:00-12:00 CEST

For Questions: www.slido.com code: #SWOCT724

Goals of the session

Increase **Awareness of RMS activities**

Share **status update of RMS service**

Provide insights on xEVMPD-**RMS data mapping**

For Questions: www.slido.com code: #SWOCT724

Agenda

1. **Welcome**
   10:00 – 10:05
2. **Introduction to RMS**
3. **RMS processes**
4. **RMS Change request process**
5. **RMS Data mappings** NEW
6. **Break**
   11:00 – 11:10
6. **RMS Statistics**
7. **RMS Documentation & Help**
8. **RMS status update**
9. **Key takeaways & Conclusions**
10. **Q&A Session**
    11:45 – 12:00

For Questions: www.slido.com code: #SWOCT724

Introduction to RMS

 For Questions: www.slido.com code: #SWOCT724

What is RMS

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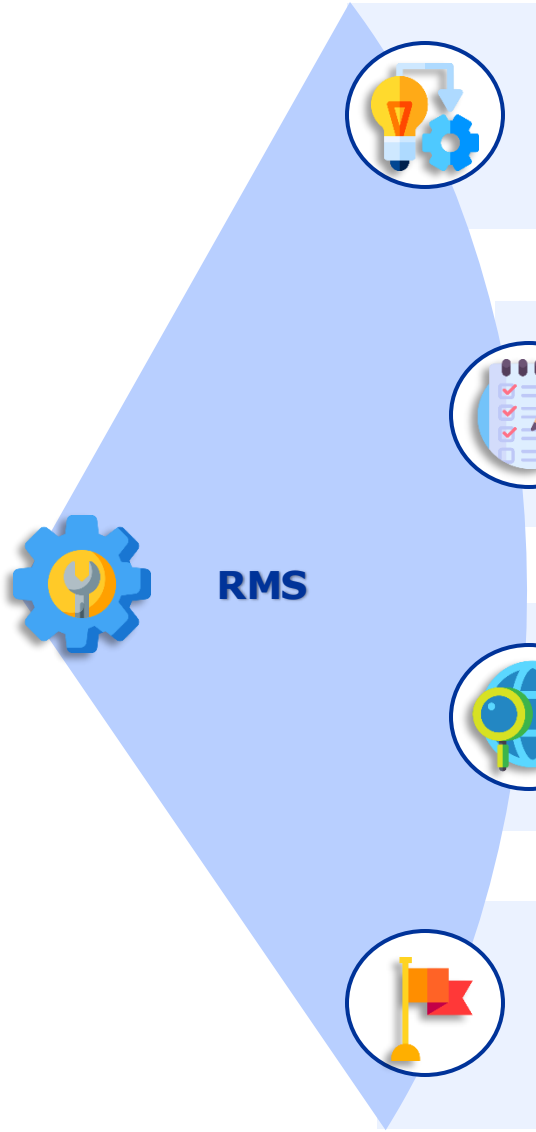

Implements

RMS implements **ISO IDMP 11239 and 11240 standards** and provides **Lists and Terms** of Referentials – Dictionary of controlled vocabularies or lists

Contains

RMS contains approximately **215 lists** (and growing) from **different maintenance organisations** such as EDQM standard terms (dosage forms, routes of administration); WHO (ATC Human, ATC Vet); MSSO (MedDRA) as well as some internally managed lists (e.g. Age Range, Variation classification list, EU Territorial Authority, etc.)

Provides

RMS **replaces EUTCT** and provides a centralised and **single source of referential data** to be used across the EU Regulatory Network and Pharmaceutical industry to support regulatory processes

Available

RMS **went live in June 2017** and provides a **backward compatible API that mimics EUTCT**

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Lists and owners

As of **October 2024**, RMS contains **215 lists** (and growing) from **different maintenance organisations:**

EDQM (16)

- Pharmaceutical dose form
- Combined Term
- Routes and Methods of Admin.
- Patient friendly
- Administration method
- Etc.

EMA (193)

- Lists migrated from EUTCT (e.g. Age Range, Application Legal basis, Target Species, Breeds, VedDRA etc.)
- Lists required for OMS, PMS, EV Vet, Clinical Trials, Scientific Advice
- Etc.

Others (6)

- ISO (Language)
- MSSO (MedDRA)
- WHO (INN)
- WHO CC (ATC H & ATC V)

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RMS Functionalities

Search

- Simple Search
- Advanced Search
- Saved Searches

Browse/View

- List of lists
- Terms within lists
- Term details
- List Information Document

Export

- Full lists/ selected terms/ translations.
- CSV or XML

Change Requests

- Search CR / View CR / Edit CR / Delete CR
- Submit CR: New/ update/ delete Term or New/ Update list

Tags

- Groupings of terms within a list or across lists for quick reference

Subscription

- E-mail notifications of (major/ minor) changes within lists selected by the user

Translation

- Search/View
- Online
- Offline (bulk upload)

Documents

- General
- Technical
- NCA

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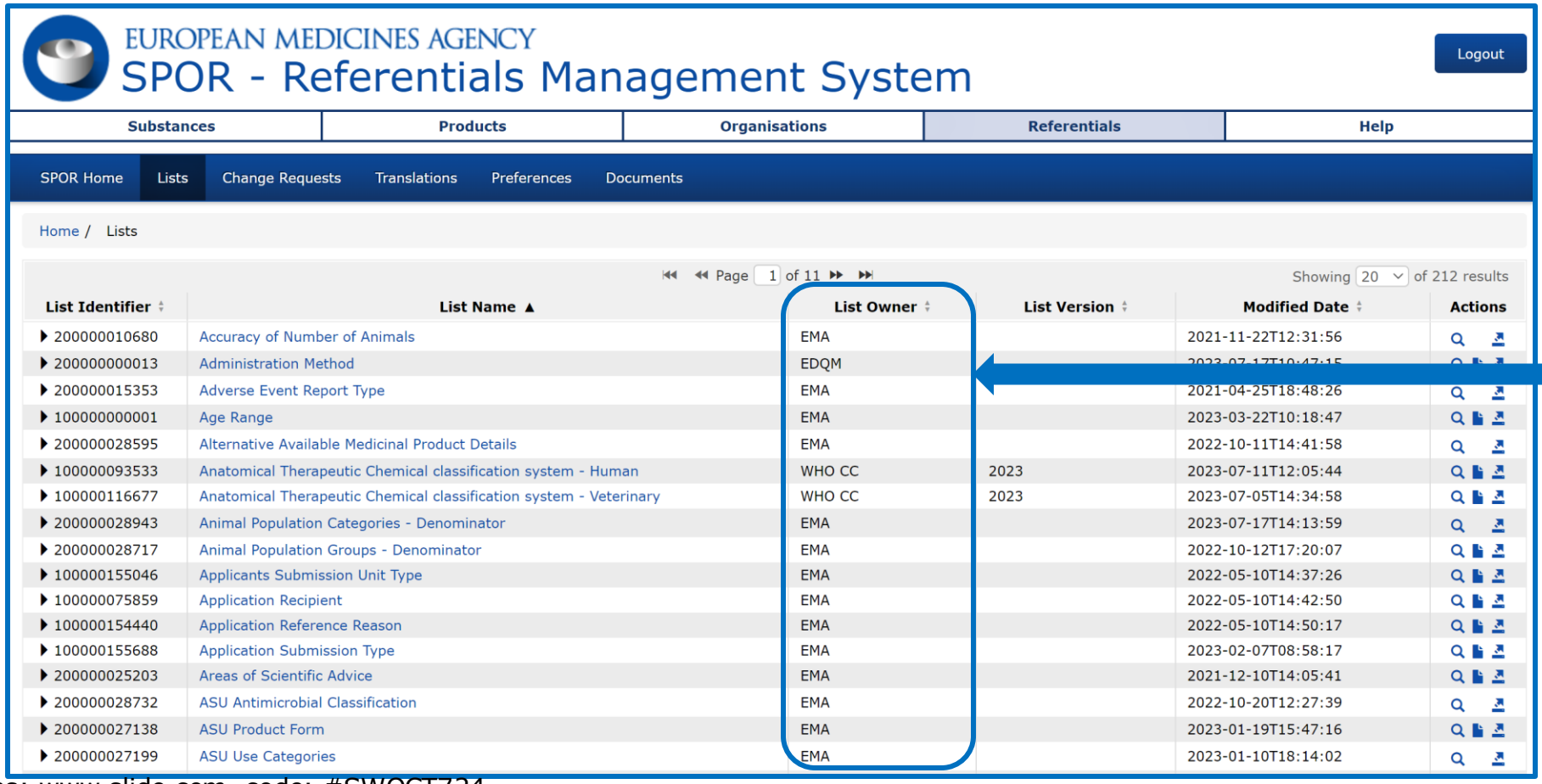
RMS Business Particulars

What EMA can do:

- EMA can process/**validate** all Change Requests (CRs), i.e. create **provisional terms**
- EMA can finalise/approve CRs for EMA-owned lists and will **liaise with relevant List Owner** to finalise CRs for externally managed lists

List Information Document:

- Contains details on **List Owner**, this can also be seen in the List of Lists view (see below)
- Where **EMA is identified as List Owner** the list information will specify the **Subject Matter experts that will be consulted**



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List Information Document

List Information Document:

- One List Information document per list
- Located in the RMS portal
- Contains **important practical information** on the specific RMS list:

Description	**Uses**	**Domain**	**Other names**
List Owner	**List Object ID (OID)**	**Copyright & other disclaimers**	**List Hierarchy**
List-specific extended attributes	**Type of Change requests**	**Justification & Supporting documentation**	**Validation Process**
Approval Process			

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List Information Document

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SPOR - Referentials Management System

Logout

Substances | Products | Organisations | Referentials | Help

SPOR Home | Lists | Change Requests | Translations | Preferences | Documents

Home / Lists

Page 5 of 11

Showing 20 of 212 results

List Identifier	List Name ▲	List Owner	List Version	Modified Date	Actions
200000000001	IT Application	EMA		2023-03-15T12:20:05	
100000072057	Language	ISO		2023-05-30T14:24:11	
100000072051	Legal Status for the Supply	EMA		2023-06-08T10:06:53	
200000030156	Lifestyle Factors	EMA		26T11:31:17	
100000160406	Manufacturing Activity	EMA		2023-01-31	
100000116045	Marketing Authorisation Application Legal Basis	EMA		2022-11-29T12:20:30	
100000072052	Marketing Status	EMA	1	2023-03-15T16:41:56	
200000026028	Master File Identifier Type	EMA		2022-05-04T10:26:59	
220000000070	Master File Type	EMA	1	2022-12-12T15:13:34	
200000003199	Material	EMA		2023-07-11T10:47:31	
100000075868	Maximum Dose Type	EMA		2009-10-15T12:26:00	
100000000007	Maximum Residue Limit Classification	EMA		2016-02-26T15:29:00	
100000073341	Maximum Residue Limit Provision	EMA		2021-12-10T16:39:58	
100000107013	Maximum Residue Limit Species	EMA		2023-04-20T17:30:18	
100000126393	Maximum Residue Limit Therapeutic Classification	EMA		2019-06-08T22:15:49	

List Information Document

For Questions: www.slido.com code: #SWOCT724

List Information Document

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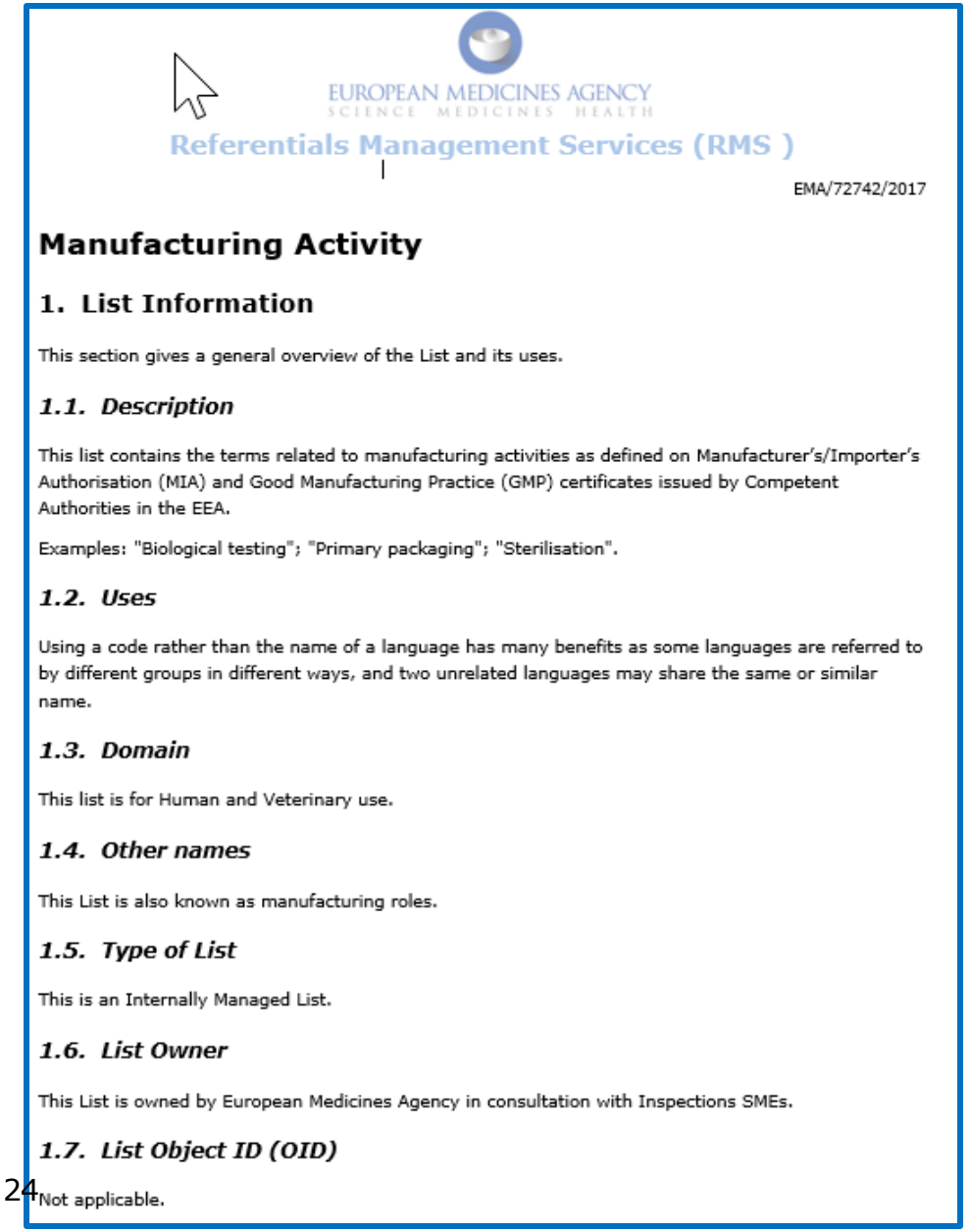

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SCIENCE MEDICINES HEALTH

Referentials Management Services (RMS)

EMA/72742/2017

Manufacturing Activity

1. List Information

This section gives a general overview of the List and its uses.

1.1. Description

This list contains the terms related to manufacturing activities as defined on Manufacturer's/Importer's Authorisation (MIA) and Good Manufacturing Practice (GMP) certificates issued by Competent Authorities in the EEA.

Examples: "Biological testing"; "Primary packaging"; "Sterilisation".

1.2. Uses

Using a code rather than the name of a language has many benefits as some languages are referred to by different groups in different ways, and two unrelated languages may share the same or similar name.

1.3. Domain

This list is for Human and Veterinary use.

1.4. Other names

This List is also known as manufacturing roles.

1.5. Type of List

This is an Internally Managed List.

1.6. List Owner

This List is owned by European Medicines Agency in consultation with Inspections SMEs.

1.7. List Object ID (OID)

Not applicable.

For Questions: www.slido.com code: #SWOCT724

List Information Document

EUROPEAN MEDICINES AGENCY

1.8. Copyright and other disclaimers

The content of this list and associated intellectual property rights were developed under projects funded by the EMA therefore becoming the property of the EMA.

Reproduction is authorised provided the source is acknowledged.

2. List Data Structure

The RMS documentation under the "Documents" tab describes the data structure and common attributes of the List and the Terms within the list. The section describes any attributes that are specific to the list.

2.1. List Hierarchy

This List is Hierarchical.

2.2. List-Specific Extended Attributes

The Terms in this List have the following Extended Attributes:

1) Form section: This attribute allows filtering out in which section of the eAF the terms should be used.

3. Change Requests

This section describes the type of Change Requests for this List and how to apply them. System specific instructions are available within the Help.

3.1. Type of Change Requests

You can make the following types of Change Requests on this List:

- New,
- Update (not recommended for National Specific Terms),
- Remove (make "Non-Current").

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List Information Document

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3.2. Justification & Supporting Documentation

Please supply a justification for the request:

- (Add Term) List a few similar existing Terms and explain why none of them accurately apply

- (Add Term) Describe the required Term, its proposed name and definition (highlighting the difference to existing terms)

- (Add Term) Describe whether the new term is to be used prospectively or to cover legacy data

- (Add Term) Describe whether the new term is to be used across EU or to cover a national/regional need

- (Update Term) The term details are incomplete (e.g. short names, other names, description, domain, etc.)

- (Update Term) The term details require minor correction (e.g. typo, inconsistent info)

- (Update Term) You don't agree with the Term details. Describe the required change (highlighting the difference to existing Term details)

- (Delete Term) Why the Term should no longer be used

- (Delete term) Which Term(s) should be used instead

Please attach any Supporting information to support the request/term/definition such as:

- legal reference if applicable

- Business requirement

- Scientific requirement.

3.3. Validation Process

The standard RMS validation process applies to check if the Change request:

- includes the relevant justification and supporting documentation

- is complete and clearly instructed

- is adequate to this List

Validation occurs within two working days of receipt of the change request. For Add term change requests a provisional term will be issued upon validation of the change request..

3.4. Approval Process

The standard RMS approval process applies for this List.

The final approval of the change request is expected to occur within one month.

4. Document History

Version	Who	When	What
1.0	EMA	31/01/2017	

In **section 4, Document History** is reported:

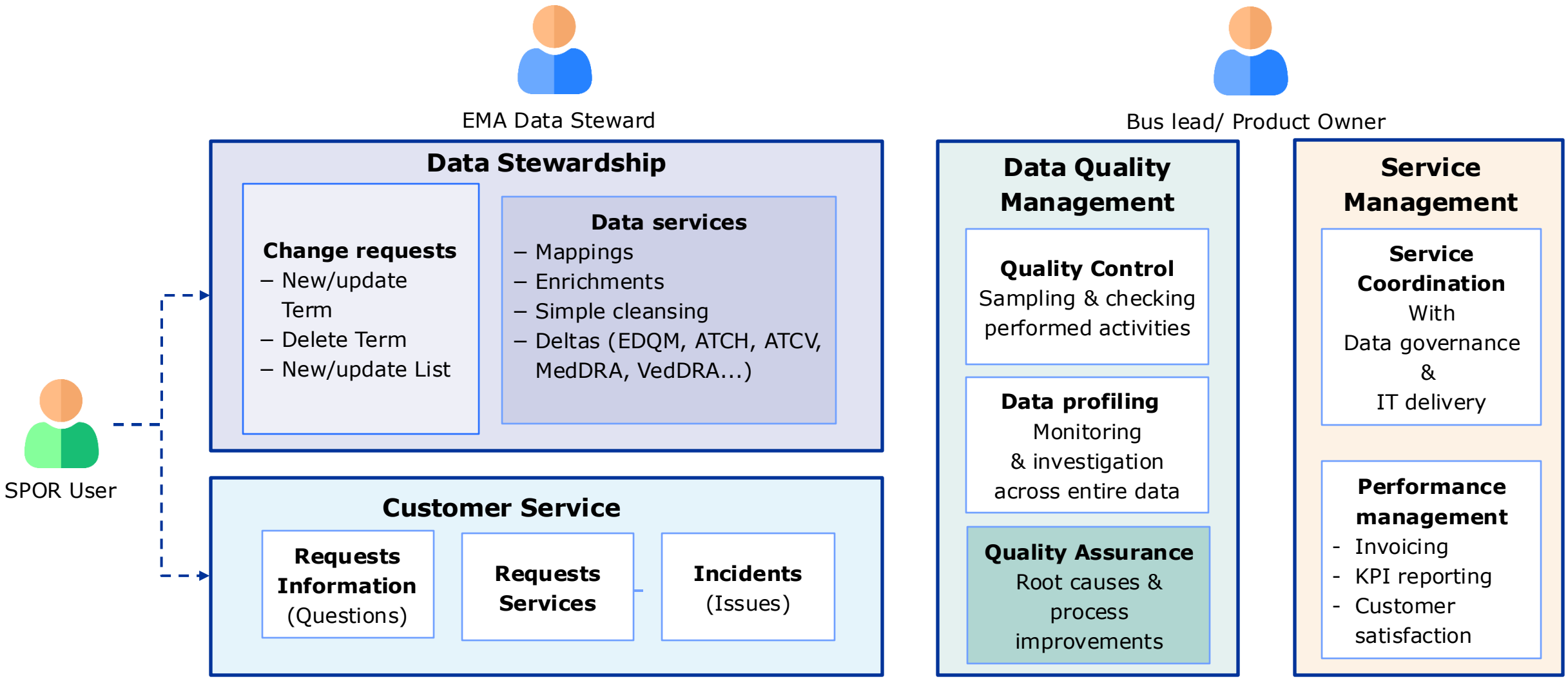
- Any initial version always start with version number 1.0 followed by date of approval/approver
- Any subsequent update of the List Information Document followed by the relevant updated version number and the date of approval/approver

 For Questions: www.slido.com code: #SWOCT724

RMS processes

 For Questions: www.slido.com code: #SWOCT724

RMS Data Management Processes



Data management processes are defined, operational and are monitored/reported on

Details for each SPOR domain are elaborated in individual webinars this week.

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RMS Change Request process

 For Questions: www.slido.com code: #SWOCT724

SPOR Change Request process at a glance

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Submission

Requestor

Submit RMS CR:
- Add Term*
- Update Term!
- Delete Term!
- Add List
- Update List!

Also** include **supporting documentation.

Validation

EMA Data Stewards

Guidance/ references & tools

Data Stewards validate all RMS CRs using guidance/ references & tools

2 – 5 Working days SLA (terms)
5 – 20 Working days SLA (lists)

- **RMS returned =** questions asked to requestor
- **RMS CR valid** = provisional Term published/ created(*) For list CRs, list preparation will start.
- **RMS CR invalid**= reasons in notification
  If disagreement, raise ticket in ServiceNow.

Approval/ Rejection

EMA Data Stewards in consultation with List Owner

1 - 2 months SLA (terms)
2 - 6 months SLA (lists)

- **RMS CR approved** = term updated(*!) in the RMS dictionary
  List created/updated(!) in the RMS dictionary
- **RMS CR rejected** = reasons in notification
  If disagreement, raise ticket in ServiceNow.

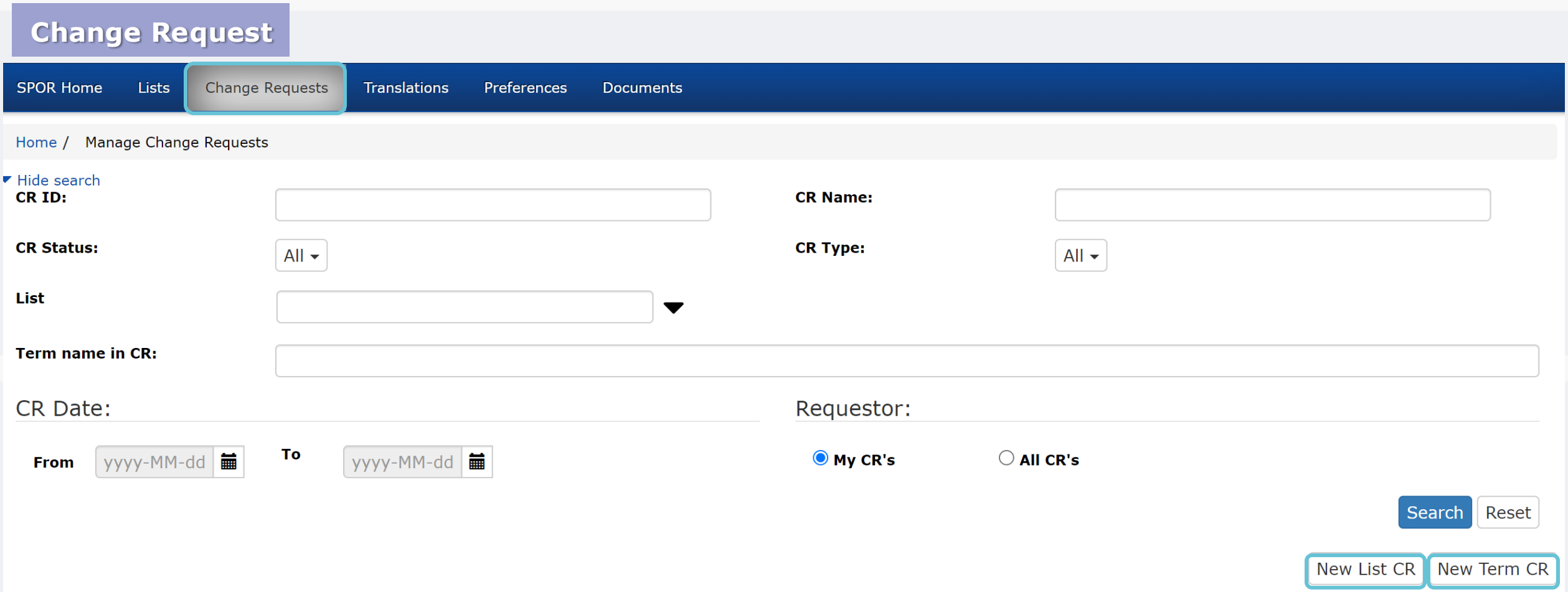
Referential data owners

(List Owners as per List Information)
EDQM, ISO, MSSO, WHO, EMA, etc

For Questions: www.slido.com code: #SWOCT724

Creating a Change Request

EUROPEAN MEDICINES AGENCY



For Questions: www.slido.com code: #SWOCT724

Creating a Change Request

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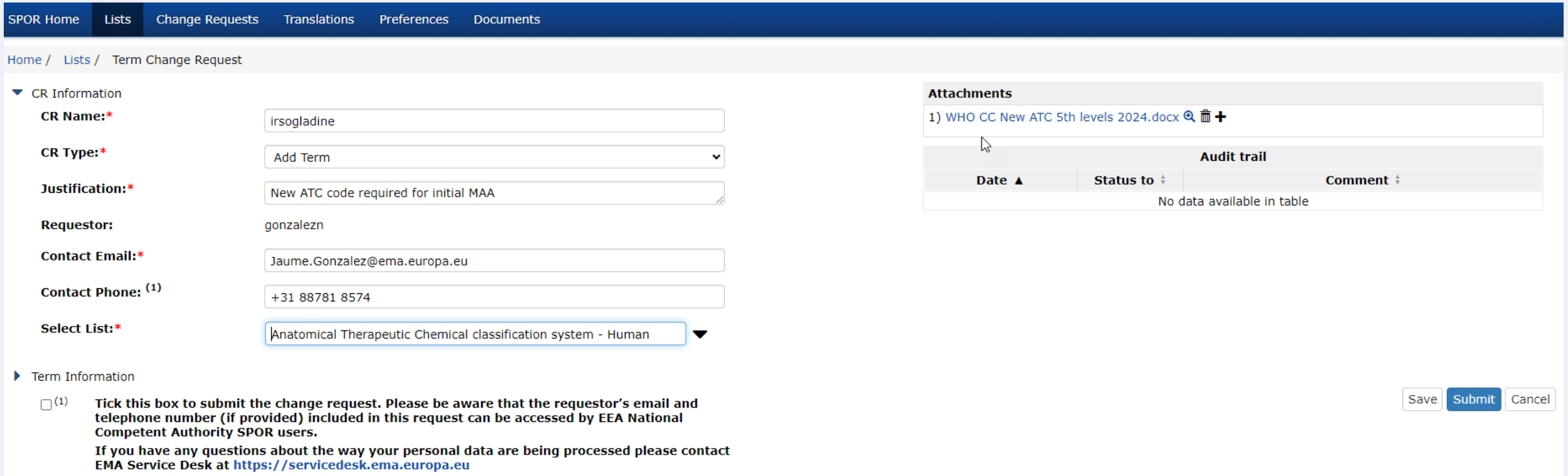
Change Request Information



For Questions: www.slido.com code: #SWOCT724

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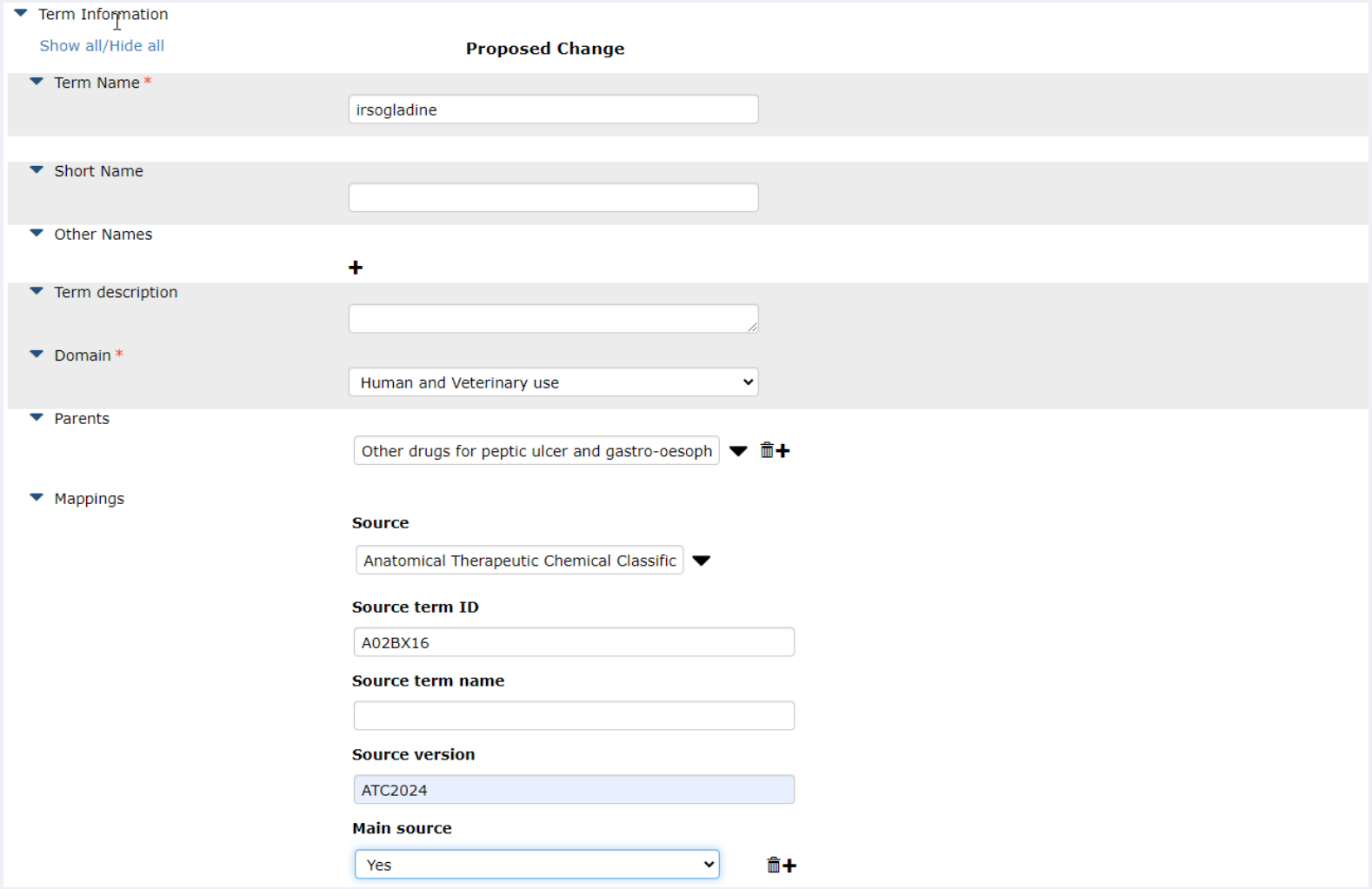
Term Information



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Creating a Change Request

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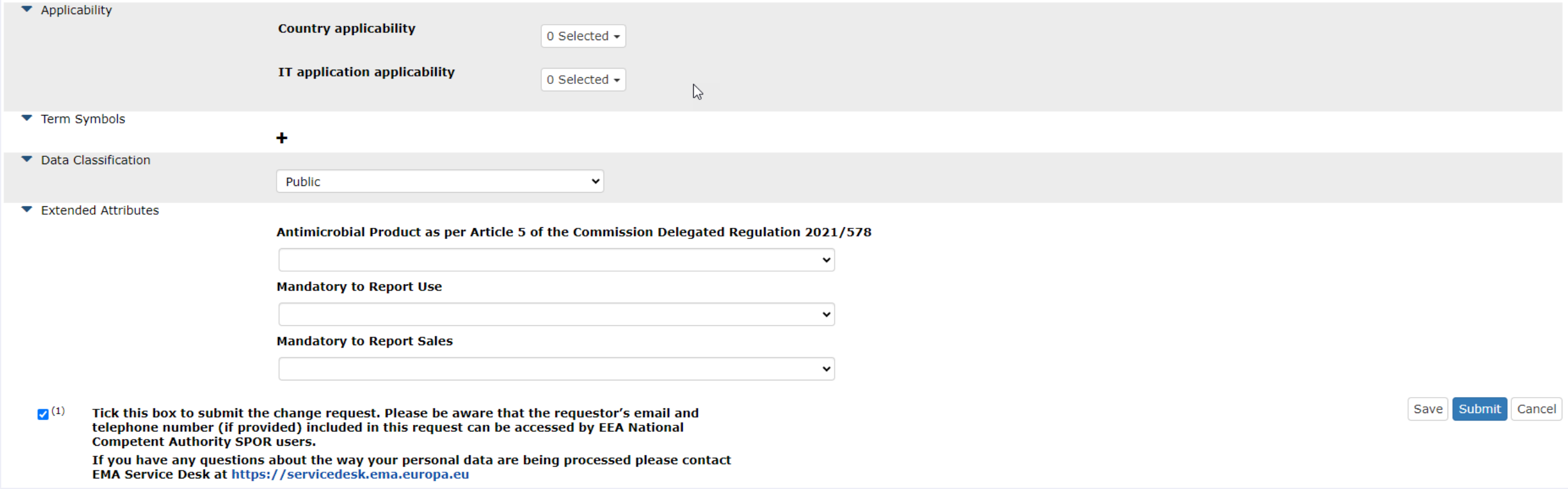
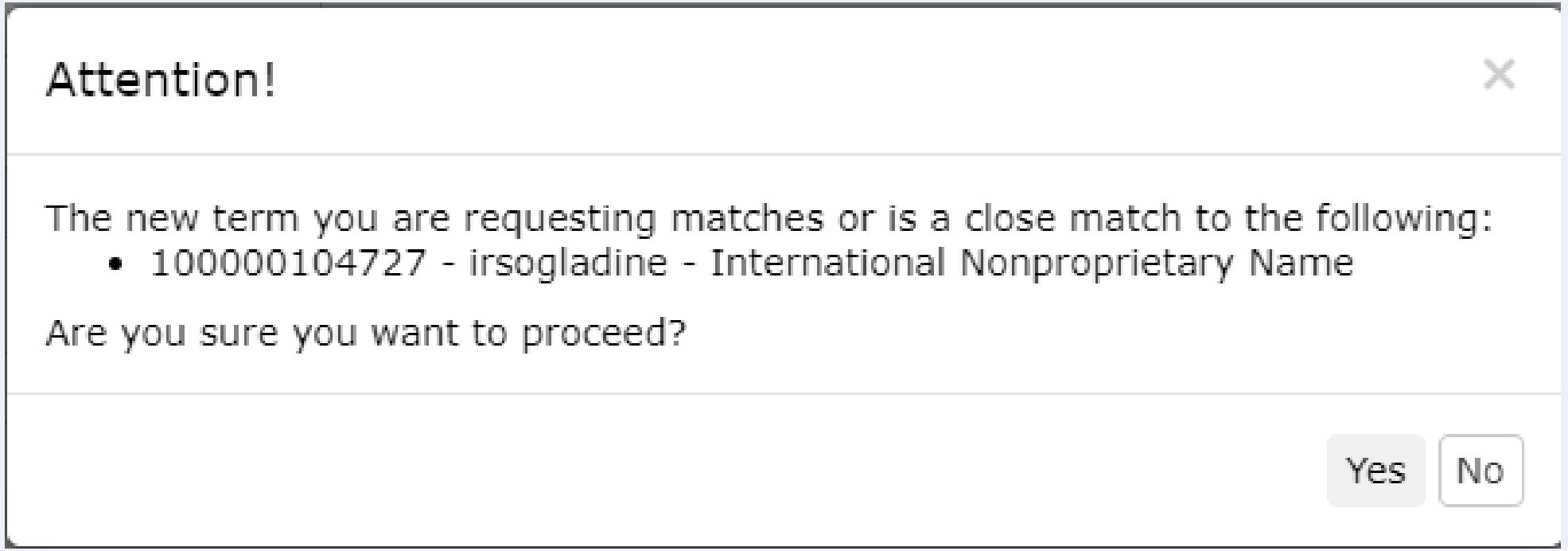
Term Information



For Questions: www.slido.com code: #SWOCT724

Creating a Change Request

Duplicate Warning!



For Questions: www.slido.com code: #SWOCT724

Creating a Change Request

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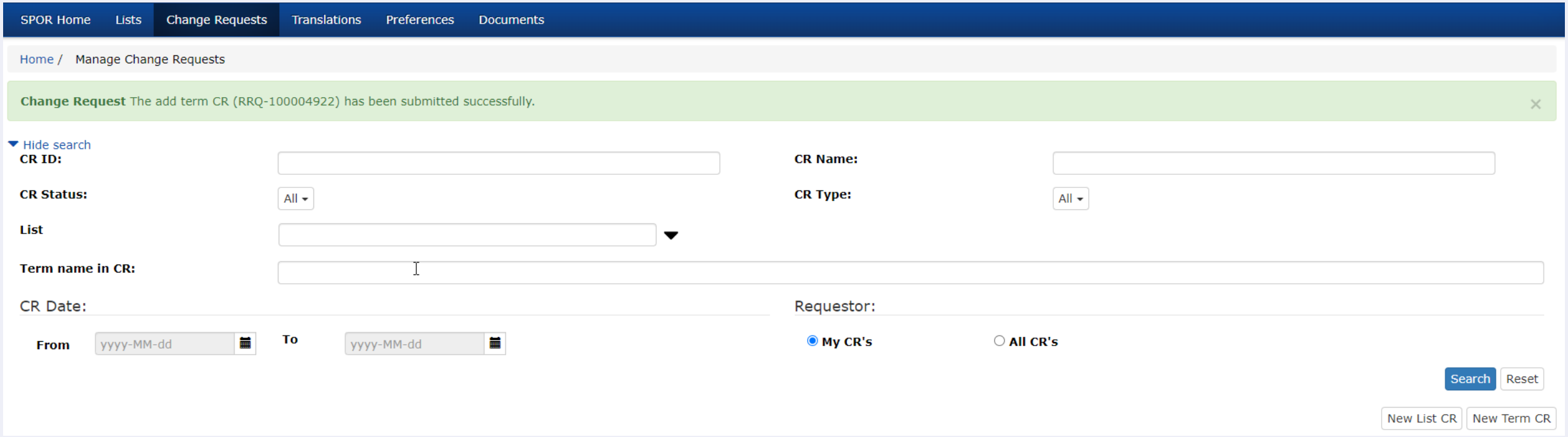
CR confirmation



For Questions: www.slido.com code: #SWOCT724

Creating a Change Request

EUROPEAN MEDICINES AGENCY

Step 1. Acknowledgement of receipt

RMS CR-RRQ-100004922 Step 1 Change Request - Submitted

MN

MDM-noreply@emea.europa.eu
To Gonzalez Jaume

Reply | Reply All | Forward

Thu 20/07/2023 14:37

Dear Sir/Madam,

RMS System has received a new Change Request "irsogladine" with the identifier RRQ-100004922.
Type of Change Request: ADD_TERM
Reason for request: New ATC code required for initial MAA
You can click here to see this Change Request in RMS.

Regards,
SPOR Data Management
(This is an automated e-mail, please do not reply as e-mails to this address will not be monitored)

For Questions: www.slido.com code: #SWOCT724

Creating a Change Request

EUROPEAN MEDICINES AGENCY

Step 2. Validation message

RMS CR-RRQ-100004922 Step 2 Change Request - Valid

MN

MDM-noreply@emea.europa.eu
To Gonzalez Jaume

Reply | Reply All | Forward

Thu 20/07/2023 14:42

Dear Sir/Madam,

The Change Request "irsogladine" with the identifier RRQ-100004922has been validated and found to be **Valid**.
Type of Change Request: [ADD_TERM]
Reason for request: [New ATC code required for initial MAA]

The Controlled Term that was the subject of this Change Request is now available in RMS with the status of "Provisional" and an identifier of 200000032419.

The following comments apply:Dear Requestor, As per WHO CC recommendation, we are hereby publishing the term requested as final. Best regards.

You can click here to see this Change Request in RMS.

You will receive a further notification when this Change Request has been reviewed.

Regards,
SPOR Data Management
(This is an automated e-mail, please do not reply as e-mails to this address will not be monitored)

For Questions: www.slido.com code: #SWOCT724

Creating a Change Request

EUROPEAN MEDICINES AGENCY

Step 3. Approval message

RMS CR-RRQ-100004922 Step 3 Change Request - Approved

MN

MDM-noreply@emea.europa.eu
To Gonzalez Jaume

Reply | Reply All | Forward

Thu 20/07/2023 14:45

Dear Sir/Madam,

The Change Request "irsogladine" with the identifier RRQ-100004922has been **Approved.**These changes are now published on 200000032419
Type of Change Request: ADD_TERM
Reason for request: New ATC code required for initial MAA

The following comments apply:Dear Requestor, As per WHO CC recommendation, we are hereby publishing the term requested as final. Best regards.

You can click here to see this Change Request in RMS.

Regards,
SPOR Data Management
(This is an automated e-mail, please do not reply as e-mails to this address will not be monitored)

For Questions: www.slido.com code: #SWOCT724

Creating a Change Request

EUROPEAN MEDICINES AGENCY

Term published in RMS

Page 1 of 1

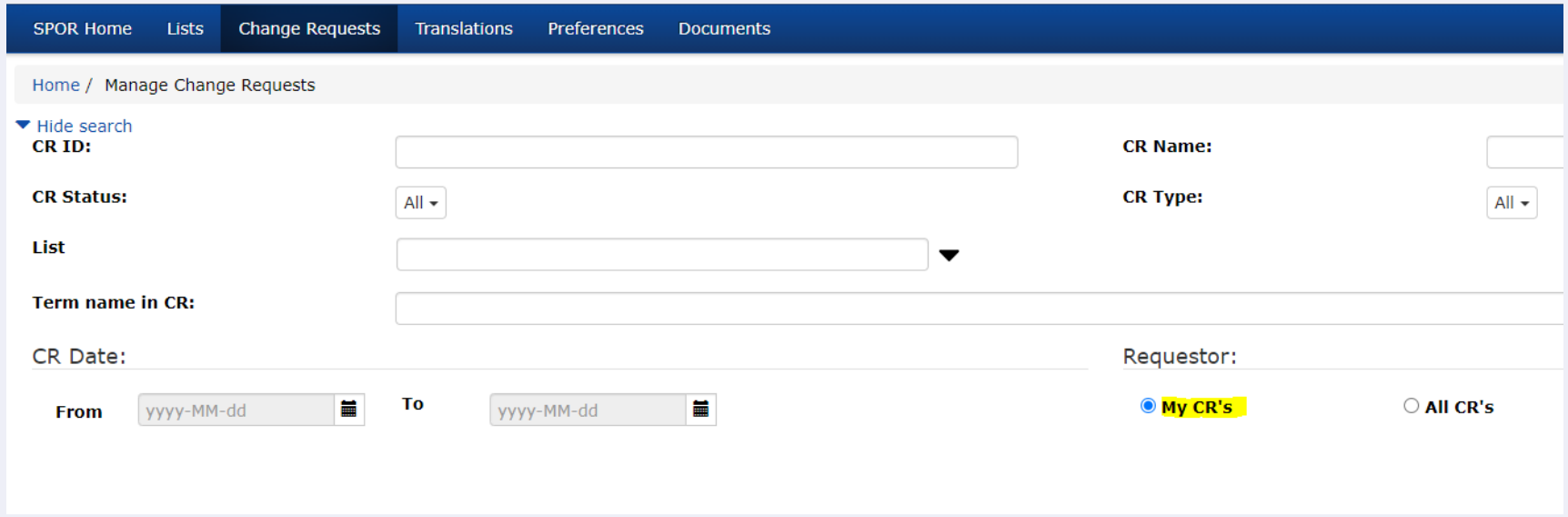
Identifier ▲	Term Name	Short Name	Source Id	Status
100000093554	ALIMENTARY TRACT AND METABOLISM		A	CURRENT
100000093541	DRUGS FOR ACID RELATED DISORDERS		A02	CURRENT
100000093542	ANTACIDS		A02A	CURRENT
100000093615	DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)		A02B	CURRENT
100000093616	H2-receptor antagonists		A02BA	CURRENT
100000093627	Prostaglandins		A02BB	CURRENT
100000093630	Proton pump inhibitors		A02BC	CURRENT
100000093636	Combinations for eradication of Helicobacter pylori		A02BD	CURRENT
100000093643	Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)		A02BX	CURRENT
100000093644	carbenoxolone		A02BX01	CURRENT
100000093645	sucralfate		A02BX02	CURRENT
100000093646	pirenzepine		A02BX03	CURRENT
100000093647	methiosulfonium chloride		A02BX04	CURRENT
100000093648	bismuth subcitrate		A02BX05	CURRENT
100000093649	proglumide		A02BX06	CURRENT
100000093650	gefarnate		A02BX07	CURRENT
100000093651	sulglicotide		A02BX08	CURRENT
100000093652	acetoxolone		A02BX09	CURRENT
100000093653	zolimidine		A02BX10	CURRENT
100000093654	troxipide		A02BX11	CURRENT
100000093655	bismuth subnitrate		A02BX12	CURRENT
100000093656	alginic acid		A02BX13	CURRENT
100000093657	carbenoxolone, combinations excl. psycholeptics		A02BX51	CURRENT
100000093658	carbenoxolone, combinations with psycholeptics		A02BX71	CURRENT
100000093659	gefarnate, combinations with psycholeptics		A02BX77	CURRENT
200000003448	rebamipide		A02BX14	CURRENT
200000030528	teprenone		A02BX15	CURRENT
200000032419	irsogladine		A02BX16	CURRENT

For Questions: www.slido.com code: #SWOCT724

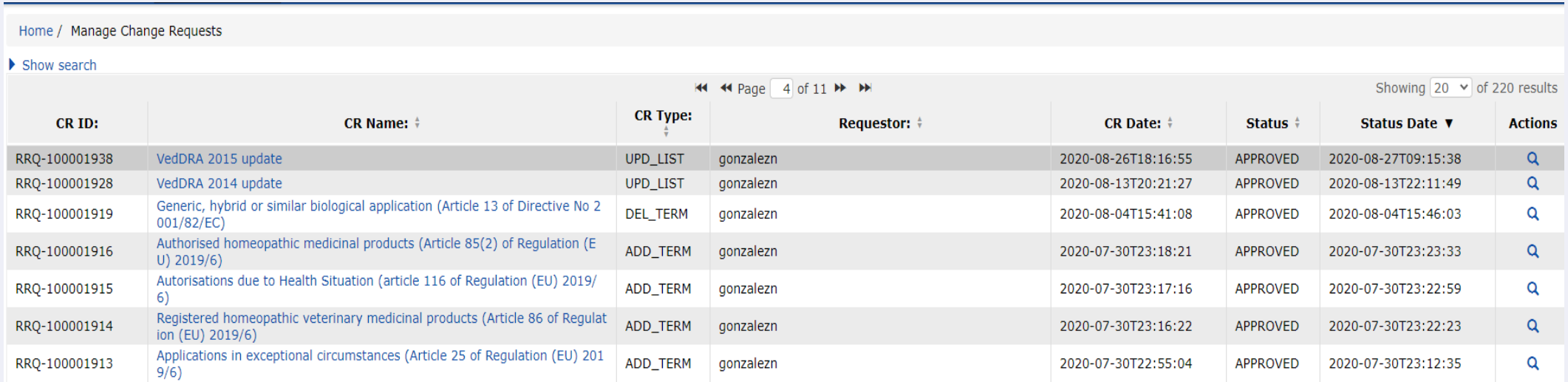
Browsing your Change Requests

EUROPEAN MEDICINES AGENCY

Search Change Request



View Change Requests



CR ID:	CR Name:	CR Type:	Requestor:	CR Date:	Status	Status Date ▼	Actions
RRQ-100001938	VedDRA 2015 update	UPD_LIST	gonzalezn	2020-08-26T18:16:55	APPROVED	2020-08-27T09:15:38	
RRQ-100001928	VedDRA 2014 update	UPD_LIST	gonzalezn	2020-08-13T20:21:27	APPROVED	2020-08-13T22:11:49	
RRQ-100001919	Generic, hybrid or similar biological application (Article 13 of Directive No 2001/82/EC)	DEL_TERM	gonzalezn	2020-08-04T15:41:08	APPROVED	2020-08-04T15:46:03	
RRQ-100001916	Authorised homeopathic medicinal products (Article 85(2) of Regulation (EU) 2019/6)	ADD_TERM	gonzalezn	2020-07-30T23:18:21	APPROVED	2020-07-30T23:23:33	
RRQ-100001915	Autorisations due to Health Situation (article 116 of Regulation (EU) 2019/6)	ADD_TERM	gonzalezn	2020-07-30T23:17:16	APPROVED	2020-07-30T23:22:59	
RRQ-100001914	Registered homeopathic veterinary medicinal products (Article 86 of Regulation (EU) 2019/6)	ADD_TERM	gonzalezn	2020-07-30T23:16:22	APPROVED	2020-07-30T23:22:23	
RRQ-100001913	Applications in exceptional circumstances (Article 25 of Regulation (EU) 2019/6)	ADD_TERM	gonzalezn	2020-07-30T22:55:04	APPROVED	2020-07-30T23:12:35	

For Questions: www.slido.com code: #SWOCT724

Creating a Change Request

EUROPEAN MEDICINES AGENCY

Term published in RMS

SPOR Home | Lists | Change Requests | Translations | Preferences | Documents

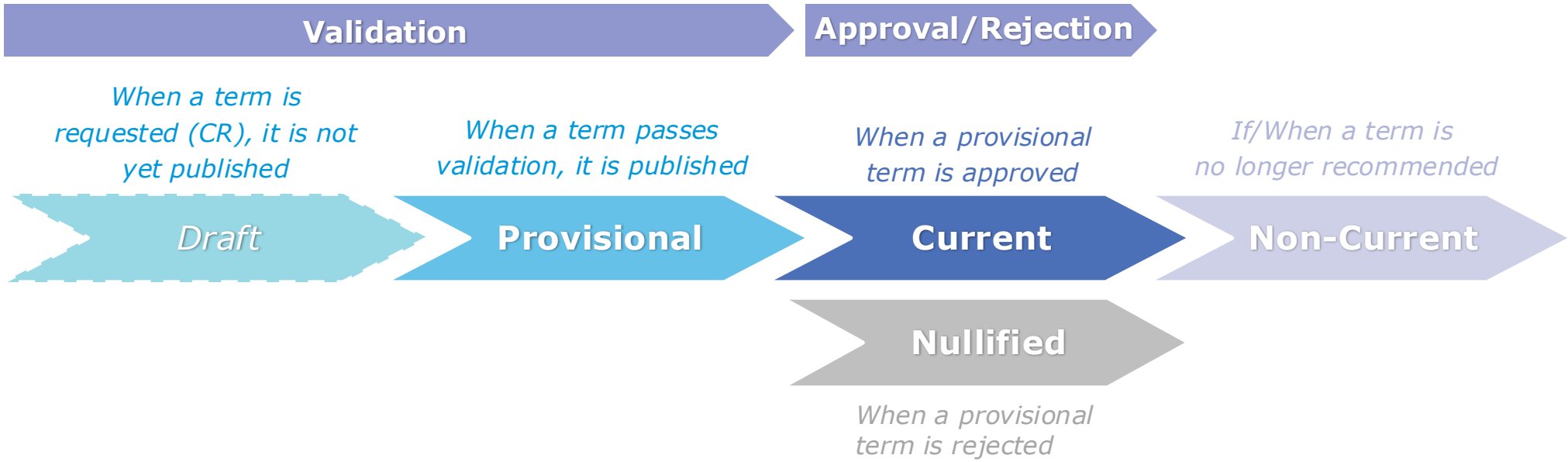
Home / Lists / Anatomical Therapeutic Chemical classification system - Human / irsogladine

Show all/Hide all

Identifier		200000032419
Operational Attributes		
Term Name	en	irsogladine
Status		CURRENT **Modified on:** 2023-07-20T14:44:33 **by** ema
Domain		Human and Veterinary use - H&V
Parents		
Hierarchy		irsogladine (level=5) / Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD) (level=4) / DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD) (level=3) / DRUGS FOR ACID RELATED DISORDERS (level=2) / ALIMENTARY TRACT AND METABOLISM (level=1)
Mappings		**Source Of Information:** Anatomical Therapeutic Chemical Classification System - Human **Source Term ID:** A02BX16 **Source Version:** ATC2024 **Main Source?:** yes
Data Classification		PUBLIC
User preferences		

For Questions: www.slido.com code: #SWOCT724

Change Request Phases & Term Statuses



Recommended use of **RMS terms statuses in regulatory procedures**:

- Industry **should** submit applications using **PROVISIONAL** or **CURRENT** terms
- In certain regulatory procedures Industry **can** submit applications using **NON-CURRENT** terms e.g. in variations
- Before finalising the assessment NCAs **should** check the Term status and should only approve applications using Terms which are **CURRENT**

RMS CR tips – xEVMPD lists!

*Submit **Change Request** in [RMS Portal]*

XEVMPD lists

As of January 2024, users can no longer create terms in XEVMPD.

Upon request EMA creates new terms, in **both RMS and XEVMPD** to ensure data mapping across controlled vocabularies is in place.

Impacted XEVMPD / RMS lists:

XEVMPD list	RMS list
Administrable Pharmaceutical Forms	Pharmaceutical Dose form
ATC Codes	ATC Human; National Classification List
Authorised Pharmaceutical Forms	Combined Pharmaceutical Dose form; Pharmaceutical Dose form; Combination Package; Combined Term;
Route of Administration	Routes and Methods of Administration

Please specify in the RMS CR that the term is also required for XEVMPD!

For Questions: www.slido.com code: #SWOCT724

RMS CR tips – EV & PMS lists

*Submit **Change Request** in [RMS Portal]*

EDQM lists

- When a **new EDQM term is required** for the electronic submission of medicinal products
- When the approved SmPC contains **legacy terms not yet available/mapped** in RMS/XEVMPD
- Note: Supporting documentation shall be provided when requesting new terms

ATC Code (Human) list

- **Only ATC codes officially assigned by WHO** are created in Anatomical Therapeutic Chemical classification system – Human. The requested term must either exist on ATC website or users should submit the letter from WHO confirming the term request as supporting documentation.

- Other National **"ATC like codes" (non-WHO ATC)** are created in National Classification list.
- Should an ATC like code be requested in WHO list it will be rejected!
- An SMPC of the relevant product should be attached as supporting documentation.
- *Note: If the product is not authorised with an ATC code then for XEVMPD "Not applicable" or "Not assigned" from National Classification list should be used*

For Questions: www.slido.com code: #SWOCT724

RMS CR tips – other PMS related & most requested lists

*Submit **Change Request** in RMS Portal*

Manufacturing Activity list

- List reviewed in Q1 2024 by multidisciplinary group of experts (QWP/BWP/IWG/CMDv/CMDv) – minutes are available in SPOR Portal
- Next review is in Q1 2025
- Industry should **map/use available RMS terms** to enrich required PMS Manufacturer's elements
- User should **check the minutes to avoid submission of duplicate CRs** already evaluated.

Shelf-Life Type & Special Precautions for Storage list

Not required for PMS

- **Revision** by multidisciplinary group of experts is **planned in Q1 2025**
- Data elements are **NOT required as PMS data enrichment** in 2024
- **CRs submitted in the context of PMS will be put on hold/rejected**
- **CRs should be submitted if related to eAF**

Material list

Not required for PMS

- Data elements are **NOT required as PMS data enrichment** in 2024
- Add/Update term CR for single material are acceptable and reviewed by SMS Team
- Add/Update term CR for combination of materials CR should not be submitted as they will be rejected.

Break (10 minutes)

Let's have a short break!

RMS Data mapping

RMS-EV data mapping

EUROPEAN MEDICINES AGENCY

XVEMPD-RMS data mapping

- To support XEVMPD to PMS migration EMA has mapped all not nullified EV Codes against the RMS ID/terms of the relevant RMS lists

- For transparency, EMA has published the following **XEVMPD-RMS data mapping files** in the RMS portal (Documents section):
  - XEVMPD-RMS/EDQM Route of Administration terms mapping_V2
  - XEVMPD-RMS/EDQM Pharmaceutical Dose Form terms mapping_V2
  - XEVMPD-RMS/WHO-National ATC codes mapping_V2

- These files should support XEVMPD users in **identifying the actions to take with regards to terms/reference data** as well as **any correction needed to the product data submitted in XEVMPD**
- Users are recommended to check if the **EV Code** reported in their XEVMPD products **have any identified action/correction**

For Questions: www.slido.com code: #SWOCT724

RMS-EV data mapping service: EDQM CR process pt2

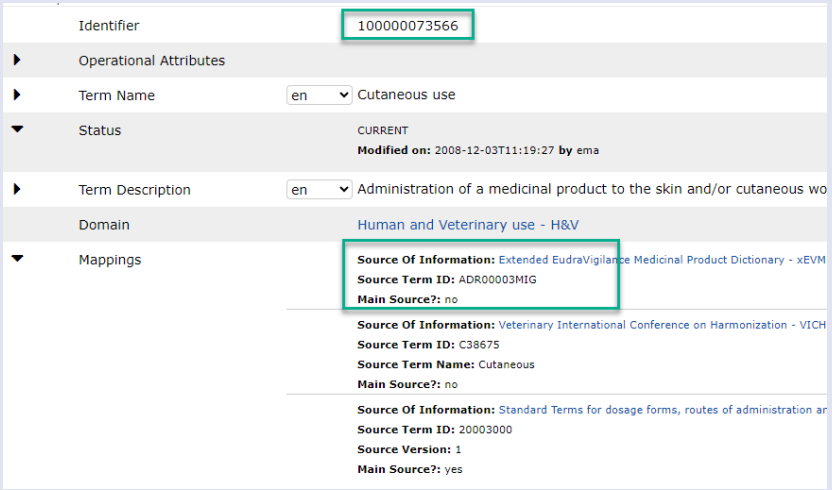
EUROPEAN MEDICINES AGENCY

How to read the XVEMPD-RMS data mapping files?

Case scenario 1: Exact match – No action is required

XEVMPD EV Code	XEVMPD Administration Route Name	XEVMPD Type	XEVMPD Status	RMS Term ID	RMS Term Name	RMS Status	XEVMPD Proposed Replacement EV Code	XEVMPD Proposed Replacement Administration Route Name	Case	XEVMPD Action for Users
ADR00001MIG	AURICULAR USE	Standard	Not nullified	100000073564	Auricular use	CURRENT	Not applicable	Not applicable	Exact match	No action required
ADR00002MIG	BUCCAL USE	Standard	Not nullified	100000075275	Buccal use	CURRENT	Not applicable	Not applicable	Exact match	No action required
ADR00003MIG	CUTANEOUS USE	Standard	Not nullified	100000073566	Cutaneous use	CURRENT	Not applicable	Not applicable	Exact match	No action required
ADR00004MIG	DENTAL USE	Standard	Not nullified	100000073567	Dental use	CURRENT	Not applicable	Not applicable	Exact match	No action required
ADR00005MIG	ENDOCERVICAL USE	Standard	Not nullified	100000073569	Endocervical use	CURRENT	Not applicable	Not applicable	Exact match	No action required

There is no need to update the product in XEVMPD since the EV code matches a CURRENT RMS term.



For Questions: www.slido.com code: #SWOCT724

RMS-EV data mapping service: EDQM CR process pt2

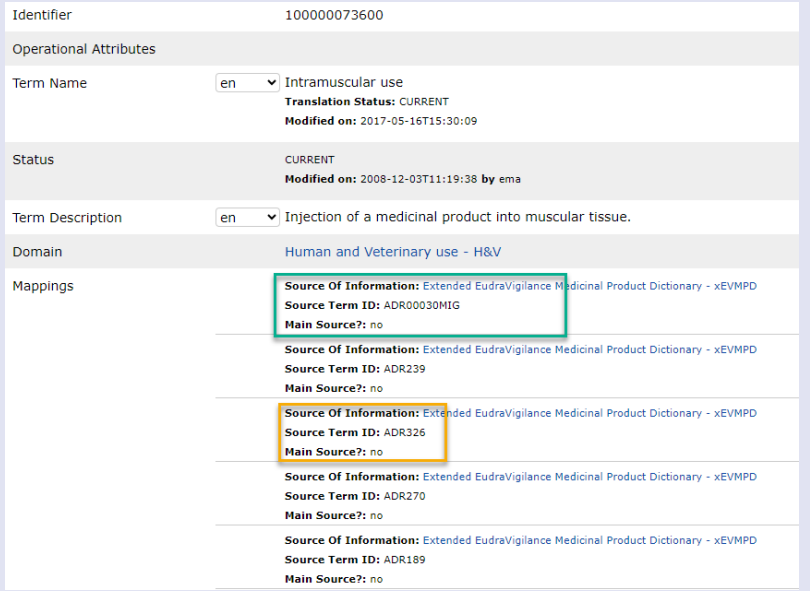
EUROPEAN MEDICINES AGENCY

How to read the XVEMPD-RMS data mapping files?

Case scenario 2: Match but review

XEVMPD EV Code	XEVMPD Administration Route Name	XEVMPD Type	XEVMPD Status	RMS Term ID	RMS Term Name	RMS Status	XEVMPD Proposed Replacement EV Code	XEVMPD Proposed Replacement Administration Route Name	Case	XEVMPD Action for Users
ADR775	INTRATYMPANIC	Proposed	Not nullified	100000073564	Auricular use	CURRENT	ADR00001MIG	Auricular use	Matched but review	Review mapping. Term not to be used /
ADR776	INTUBATION SURFACTANT EXTU	Proposed	Not nullified	100000073571	Endotracheopulmonary u	CURRENT	ADR00007MIG	Endotracheopulmonary use	Matched but review	Review mapping. Term not to be used /
ADR777	LESS INVASIVE SURFACTANT A	Proposed	Not nullified	100000073571	Endotracheopulmonary u	CURRENT	ADR00007MIG	Endotracheopulmonary use	Matched but review	Review mapping. Term not to be used /
ADR771	ENTERAL FEEDING TUBE	Proposed	Not nullified	100000073576	Gastroenteral use	CURRENT	ADR00070MIG	Gastroenteral use	Matched but review	Review mapping. Term not to be used /
ADR785	INHALATION GAS	Proposed	Not nullified	100000073584	Inhalation use	CURRENT	ADR00078MIG	Inhalation use	Matched but review	Review mapping. Term not to be used /
ADR663	INTRADERMAL	Proposed	Not nullified	100000073595	Intradermal use	CURRENT	ADR00023MIG	Intradermal use	Matched but review	Review mapping. Term not to be used /
ADR326	INTRAMUSCULAR	Standard	Not nullified	100000073600	Intramuscular use	CURRENT	ADR00030MIG	Intramuscular use	Matched but review	Review mapping. Term not to be used /

- The **XEVMPD EV code** (e.g. ADR326 - INTRAMUSCULAR) matches with a **CURRENT RMS ID** (e.g. 100000073600 - Intramuscular use), however the *product record(s) referencing the concerned EV code need to be reviewed* to ensure that the **identified XEVMPD proposed replacement EV code** (e.g. ADR00030MIG - INTRAMUSCULAR USE) and **identified RMS term** (e.g. 100000073600 - Intramuscular use) correctly apply to the concerned products.
- MAH should **replace** the currently referenced **XEVMPD EV code** (e.g. ADR326) with the **XEVMPD proposed replacement EV code** (e.g. ADR00030MIG) in their concerned product record(s).
- MAH **should not use** in any current product records, nor in upcoming future submissions the referenced **XEVMPD EV code** (e.g. ADR326) so it can be nullified by the EMA.
- EMA to further replace with the standard term (e.g. ADR00030MIG) in any outstanding product records, validate product records and nullify the duplicate XEVMPD EV code (e.g. ADR326) in XEVMPD.



For Questions: www.slido.com code: #SWOCT724

RMS-EV data mapping service: EDQM CR process pt2

EUROPEAN MEDICINES AGENCY

How to read the XEVMPD-RMS data mapping files?

Case scenario 3: Legacy data / Review is required

XEVMPD EV Code	XEVMPD Administration Route Name	XEVMPD Type	XEVMPD Status	RMS Term ID	RMS Term Name	RMS Status	XEVMPD Proposed Replacement EV Code	XEVMPD Proposed Replacement Administration Route Name	Case	XEVMPD Action for Users	XEVMPD Action for EMA
ADR129	CONJUNCTIVAL USE	Standard	Not nullified	100000075251	Conjunctival use	NON_CURRENT	Mapping is not po	Mapping is not possible without us	Legacy term	Select the correct route of administration	Pending users action
ADR135	INTRA-ABDOMINAL USE	Standard	Not nullified	100000075246	Intraabdominal use	NON_CURRENT	Mapping is not po	Mapping is not possible without us	Legacy term	Select the correct route of administration	Pending users action
ADR93	INTRADUODENAL USE	Standard	Not nullified	100000075241	Intraduodenal use	NON_CURRENT	Mapping is not po	Mapping is not possible without us	Legacy term	Select the correct route of administration	Pending users action
ADR00025MIG	INTRAHEPATIC USE	Standard	Not nullified	100000075273	Intrahepatic use	NON_CURRENT	Mapping is not po	Mapping is not possible without us	Legacy term	Select the correct route of administration	Pending users action
ADR288	INTRANASAL USE	Standard	Not nullified	100000075242	Intranasal use	NON_CURRENT	Mapping is not po	Mapping is not possible without us	Legacy term	Select the correct route of administration	Pending users action
ADR00039MIG	INTRATRACHEAL USE	Standard	Not nullified	100000075272	Intratracheal use	NON_CURRENT	Mapping is not po	Mapping is not possible without us	Legacy term	Select the correct route of administration	Pending users action
ADR107	INTRAVASCULAR USE	Standard	Not nullified	100000075257	Intravascular use	NON_CURRENT	Mapping is not po	Mapping is not possible without us	Legacy term	Select the correct route of administration	Pending users action
ADR00040MIG	INTRAVENOUS BOLUS USE	Standard	Not nullified	100000075271	Intravenous bolus use	NON_CURRENT	Mapping is not po	Mapping is not possible without us	Legacy term	Select the correct route of administration	Pending users action
ADR635	INTRAVENOUS DRIP	Proposed	Not nullified	100000075270	Intravenous drip use	NON_CURRENT	Mapping is not po	Mapping is not possible without us	Legacy term	Select the correct route of administration	Pending users action
ADR00041MIG	INTRAVENOUS DRIP USE	Standard	Not nullified	100000075270	Intravenous drip use	NON_CURRENT	Mapping is not po	Mapping is not possible without us	Legacy term	Select the correct route of administration	Pending users action

- If the case is "**Legacy term**", the terms are mapped to **NON-CURRENT** RMS IDs due to **legacy data**; if/when possible MAHs should update their product data by using the most appropriate CURRENT term, as applicable.

For Questions: www.slido.com code: #SWOCT724

RMS-EV data mapping service: EDQM CR process pt2

EUROPEAN MEDICINES AGENCY

How to read the XEVMPD-RMS data mapping files?

Case scenario 4: Incorrect RoA term used

XEVMPD EV Code	XEVMPD Administration Route Name	XEVMPD Type	XEVMPD Status	RMS Term ID	RMS Term Name	RMS Status	XEVMPD Proposed Replacement EV Code	XEVMPD Proposed Replacement Administration Route Name	Case	XEVMPD Action for Users
ADR188	SOLUTION FOR INJECTION OR INFUSION	Proposed	Nullified	200000017724; 20	Solution for injection;	NON_CURRENT	Not a RoA	Not a RoA	Incorrect RoA term used	Select the correct route of administration. Term not to be used / not to be requeste
ADR660	CONCENTRATE FOR SOLUTION FOR INFUSION	Proposed	Not nullified	200000017723	Concentrate for solutio	NON_CURRENT	Not a RoA	Not a RoA	Incorrect RoA term used	Select the correct route of administration. Term not to be used / not to be requeste
ADR309	INFUSION	Standard	Not nullified	200000016449	Infusion	NON_CURRENT	Not a RoA	Not a RoA	Incorrect RoA term used	Select the correct route of administration. Term not to be used / not to be requeste
ADR231	INJECTION	Proposed	Not nullified	200000016447	Injection	NON_CURRENT	Not a RoA	Not a RoA	Incorrect RoA term used	Select the correct route of administration. Term not to be used / not to be requeste
ADR335	INJECTION	Standard	Not nullified	200000016447	Injection	NON_CURRENT	Not a RoA	Not a RoA	Incorrect RoA term used	Select the correct route of administration. Term not to be used / not to be requeste
ADR328	LOCAL INJECTION	Proposed	Nullified	100000075243	Local use	NON_CURRENT	Not a RoA	Not a RoA	Incorrect RoA term used	Select the correct route of administration. Term not to be used / not to be requeste

- If the case is "**Incorrect RoA terms used**", the mapping:

  Although, to facilitate PMS migration, the terms used in EV were mapped to RMS RoAdm non-current/legacy terms, these are **non-RoA terms**! **Users shall correct their products** to the most appropriate and relevant **CURRENT RoA** instead of these referenced EV codes.
- As of October, the 3rd version of the excel file RoA RMS-XEVMPD mapping is available!

For Questions: www.slido.com code: #SWOCT724

RMS-EV data mapping

EUROPEAN MEDICINES AGENCY

What is the impact to Industry?

Scenario of mapped XEVMPD-RMS terms	Impact to MAHs - RMS	Impact to MAHs - XEVMPD
1. Exact match to current/standard term or new "valid" standard term **XEVMPD** / **RMS** Tablet (PDF) / Tablet Prolonged-release pessary (PDF) / Prolonged-release pessary (new ST)	Mapping to the standard term was done in RMS **No action is required**	**No action is required**
2. Match but review **XEVMPD** / **RMS** Scored Film-coated Tablet (PDF) / Film-coated tablet Tablet**s** (PDF) / Tablet	**Please review XEVMPD to RMS mapping** - If mapping correct/applies to all products: no action - If mapping is missing or incorrect, update RMS CR to update the EV-RMS mapping	Product **could** be updated in XEVMPD by selecting correct term
3. Legacy term **XEVMPD** / **RMS** Intranasal use (RoA) / Intranalas use (**non-current**) Oromucosal spray (PDF) / Oromucosal spray (**non-current**)	Mapping and creation of legacy term was done in RMS, current term is indicated where possible **No action is required**	**If/when possible**, product **should** be updated in XEVMPD to use current standard term (variation)
4. Incorrect RoA term used **XEVMPD** / **RMS** Solution for injection (not RoA) / Solution for injection (non-current/ not RoA)	Mapping to non-current terms was done in RMS, however these are not an RoA terms! No action in required.	Product **shall** be updated in XEVMPD to use the most appropriate and correct current standard term to ensure data quality and load in PMS.

Any question in relation to the mappings performed can be raised in **Service Now – RMS**. If additional/new terms are needed – raise a change request in RMS

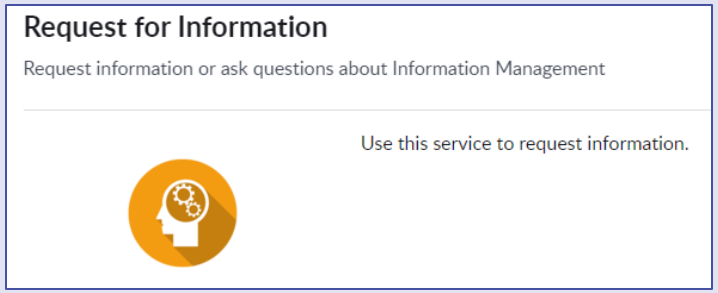
RMS-EV data mapping

How can MAHs liaise with EMA?

Requestor

Ask a Question in RMS Service Desk →

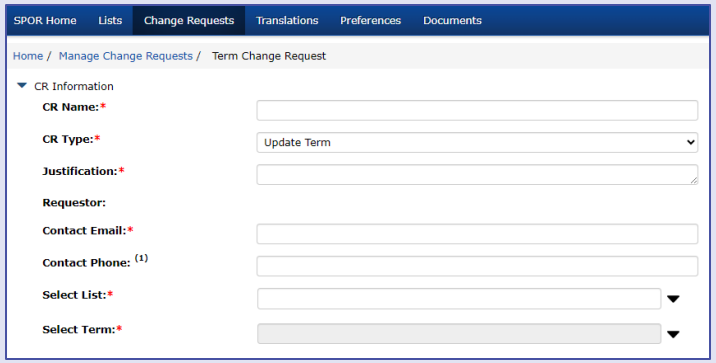
Customer Services



- If XEVMPD-RMS data mapping is NOT clear to user, please submit a '*Request for Information*' (Service: SPOR + Service Offering: RMS)
- RMS team will provide the relevant clarification.

Submit **Change Request** in RMS Portal →

EMA Data Stewards



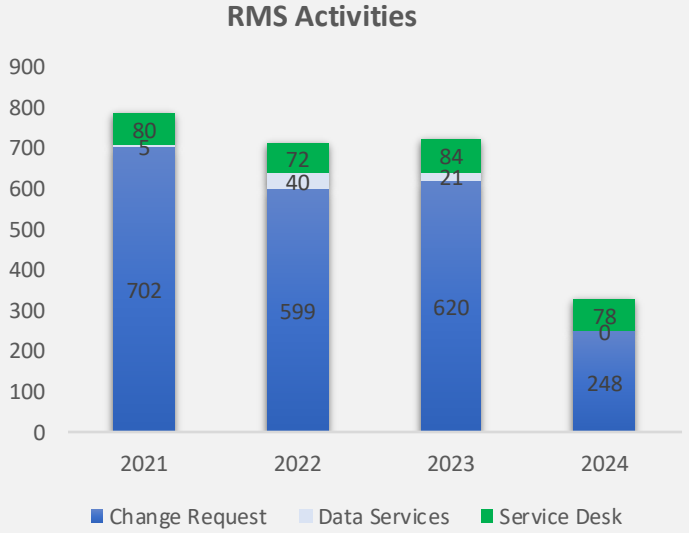
- If XEVMPD-RMS data mapping is clear to user, it is deemed incorrect and has been incorrectly applied across all products, please submit an **CR to Update RMS Term**.
- RMS team will assess the CRs using guidance/references & tools in consultation with List owner(s)

RMS Statistics

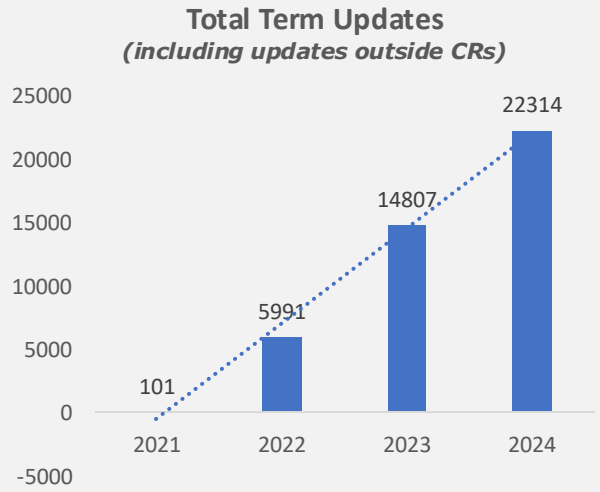
RMS Statistics – RMS Activities

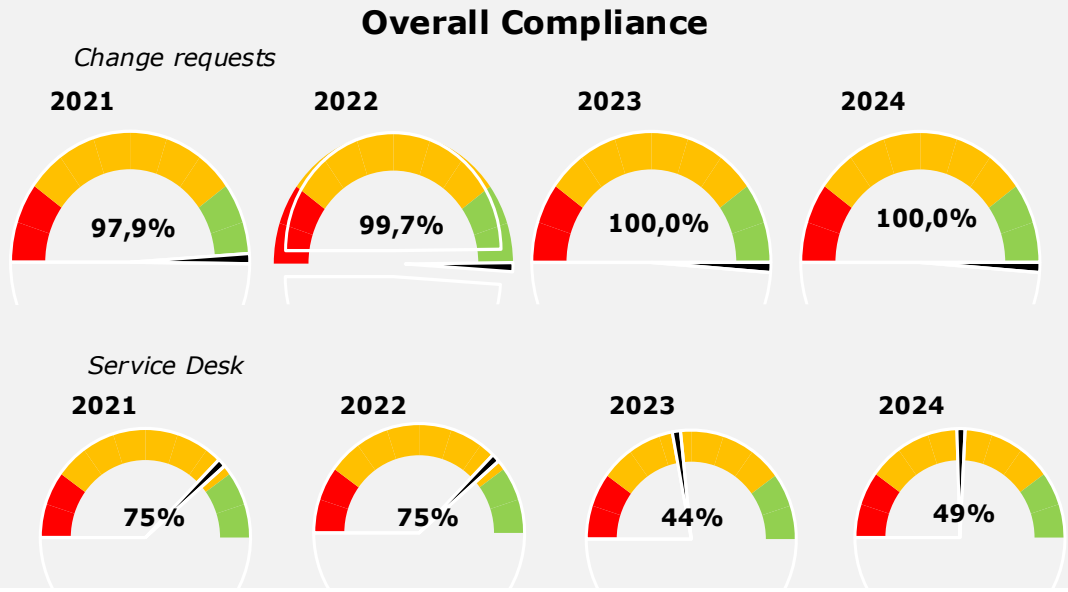
- The number of **change requests** (248) for the first half of 2023 **follows the 2023 trend**.
- *No new lists were requested in 2024*
- The number of **Service Desk tickets** in H1 2024 (78) already reached the overall numbers for previous years. This is due to blocking MAHs to create terms in XEVMPD in Jan as well as the preparatory activities of data mapping to support PMS
- **100%** of CRs were resolved **within SLA** in 2024.

- Compliance with Service Desk tickets in H1 2024 was **lower than average** and this is mainly due to some (2/43) **IT incidents which required in-depth investigation** and took longer than expected.
- Note that these incidents only involved 2/43 tickets. Therefore, the impact of this broken SLAs was deemed minimal.
- In Q2 2024, a total of 8303 terms have been mapped with the EV terms to support the quality of PMS data loaded from XEVMPD



up to Q2 2024 cumulative
Data services represent CRs for new lists in RMS





For Questions: www.slido.com code: #SWOCT724

RMS Documentation & Help

SPOR Documents & Help (I)

EUROPEAN MEDICINES AGENCY

Reference documents accessible from the SPOR portal

Main documentation required to successfully use RMS services:

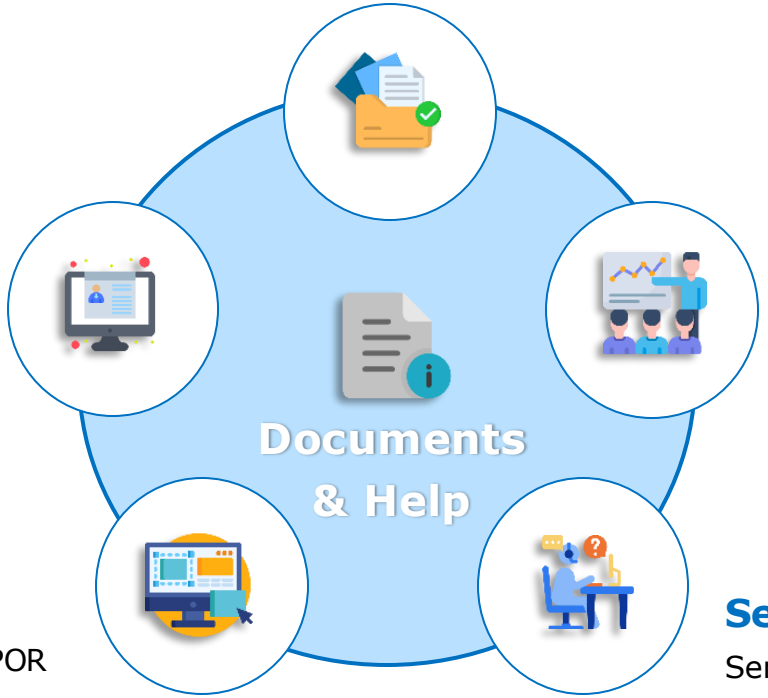
- RMS web user manual – guidance on SPOR services, e.g. searching, exporting data, requesting CRs, translations, etc.
- SPOR user registration manual (how to register for SPOR)
- SPOR affiliation template (to register the first industry super user)
- RMS New List Template & Quick Reference Card for RMS Term Change Requests
- SPOR SLAs (SLA are indicative and may be reviewed in future)
- PPTs from RMS webinars

EMA Account Management Portal

- To create a new EMA account in order to obtain access to EMA systems (including SPOR).
- To request SPOR user role.

Account Management Portal.

**Dedicated webinar scheduled for 18 April, recording will be made available in due course.*



Training videos

- RMS & OMS training videos available to view on the @emainfo channel.
- Videos of RMS webinars with tips/tricks and questions raised from users (RMS Training modules)

EMA corporate website

- SPOR vision and general introduction to SPOR projects
- SPOR related information and documents

ServiceNow Portal

Service requests, issues, requests for technical support shall be submitted through the ServiceNow Portal.

For any help needed and not found in docs.

For Questions: www.slido.com code: #SWOCT724

SPOR Documents & Help (II) - SPOR Portal

EUROPEAN MEDICINES AGENCY

SPOR - Documents

PPTs of RMS Webinars

Recordings are on YouTube

Process Guidance

Operating Model; Quick reference cards for CRs, SLAs; list template

SPOR Info + Q&A

Performance

Statistics & customer satisfaction surveys

EUROPEAN MEDICINES AGENCY
SPOR - Referentials Management System

Substances | Products | Organisations | Referentials | Help

SPOR Home | Lists | Change Requests | Translations | Preferences | Documents

View
Manage

Home / View Documents

General | Technical | NCA

Document Name ▲	Document Description	Published Date
A - About RMS	General - Legal disclaimer, copyright and other policies of using referential data.	2016-06-19
A1 - RMS Introduction - Webinar 21 October 2021	Webinar - RMS Key principles, services and activities - 21 October 2021	2021-11-11
A2 - RMS Introduction - Webinar 10 March 2022	Webinar - RMS services, activities and statistics - 10 March 2022	2022-03-15
A3 - RMS Introduction - Webinar 21 September 2022	Webinar - RMS services, activities and statistics - 21 September 2022	2022-09-22
A5 - SPOR API Access and Usage - Webinar 18 March 2022	API Registration process and OMS/RMS API usage demo and tips	2022-04-04
B - RMS Operating Model	Policy - Range of services available for stakeholders to use and/or request new/updated data, including stakeholder interactions and roles.	2018-05-25
C - RMS New List Template	Template for requesting one or several new lists.	2022-06-08
F - RMS Web User Manual	Manual - How to search, view, export data and request a new/updated data in RMS web portal.	2020-09-17
G - Quick Reference Card for RMS Term Change Requests	Manual - Quick instructions for RMS users on how to submit term change requests	2021-08-05
U - About SPOR	General - Legal disclaimer, copyright and other policies of using SPOR data.	2016-04-06
V - SPOR Questions & Answers	General - Compiled questions on a variety of topics, including user registration, Industry on-boarding, and eAF integration.	2018-02-12
V1 - RDM Customer Satisfaction Survey 2021	SPOR Customer Satisfaction Survey November 2021	2022-01-31
V2 - RDM Customer Satisfaction Survey 2022	SPOR Customer Satisfaction Survey October 2022	2023-02-13
X - SPOR SLAs	General - Service Level Agreement (SLAs) for the SPOR data services.	2021-02-17

For Questions: www.slido.com code: #SWOCT724

SPOR Documents & Help (II) - SPOR Portal

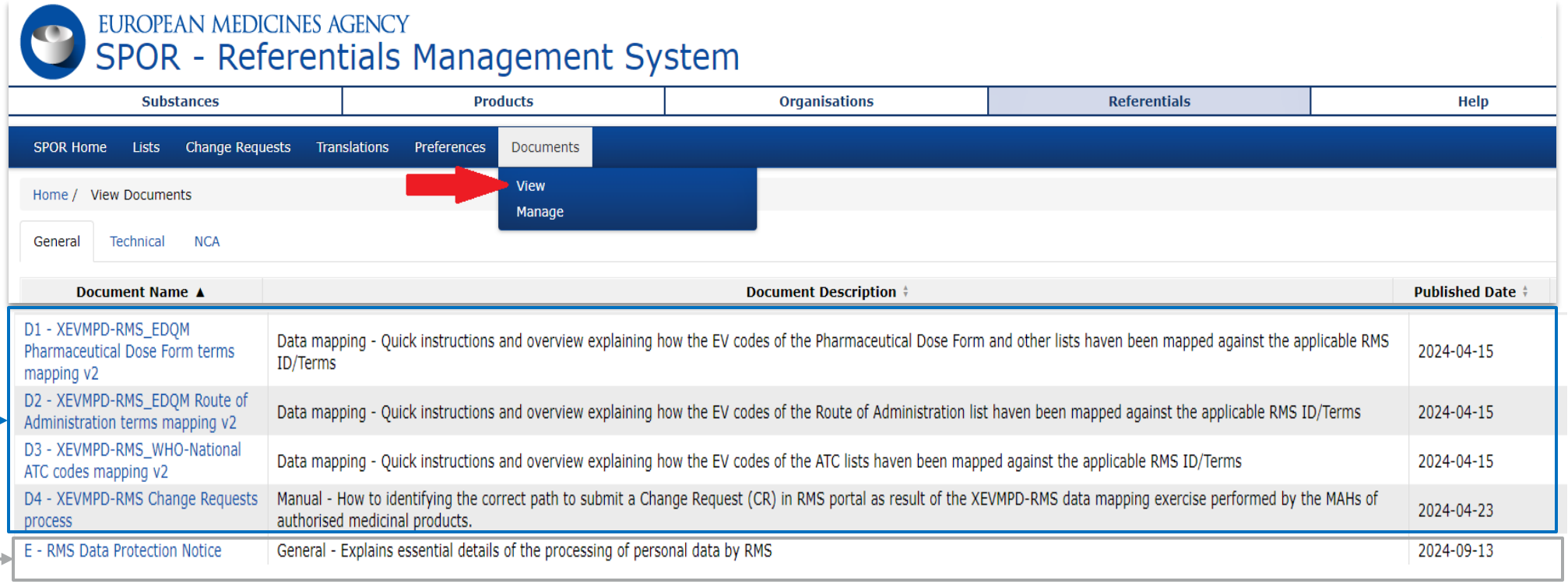
SPOR - Documents

XEVMPD-RMS Data Mapping

How EV codes are mapped in RMS and applicability

RMS Data Protection Notice (DNP)

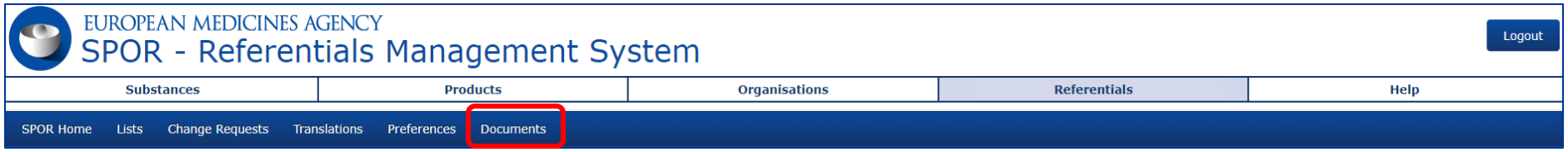
How personal data are processed in RMS



 For Questions: www.slido.com code: #SWOCT724

SPOR Documents & Help (III) - SPOR Portal

RMS Web UI (europa.eu)



Before start

- F – RMS Web User Manual
- V – SPOR Questions & Answers
- A3 – RMS Introduction – Webinar 21 September 2022

Access

- Z – SPOR User Registration Manual
- F – RMS Web User Manual
- Z2 – SPOR User Affiliation Template Letter

API

- A5 – SPOR API Access and Usage
- Z3 – SPOR API Access – Q&A
- Z4 – SPOR API Access – Webinar 10 November 2021

Change request process

- F – RMS Web User Manual
- C –RMS New List Template
- G –Quick Reference Card for RMS Term CRs
- A3 – RMS Introduction – Webinar 21 September 2022

For Questions: www.slido.com code: #SWOCT724

RMS status update

Planned RMS Activities

EUROPEAN MEDICINES AGENCY

	Q3 2023	Q4 2024	Q1 2025	Q2 2025
Deliver efficient and effective regulatory data services	**Customer Services**			
	Increased QC/QA			
	Data Management (Change requests & Data services)			
	1 Review xEVMPD – RMS mappings		EMDN bulk update process	
	Guidance on xEVMPD – RMS mappings		EMDN list	
	Data Quality			
	Review and update: PDF			6
	Review & Update: UoM list	5		
	2 VedDRA v20	4 MedDRA v27.1	Consult with SMEs for review of Manufacturing activity list 7	Consult with SMEs for review of Shelf life & Special prec.
	New/updated DQ profiles + Update on DQ reports (e.g. completion/improvement of term descriptions + assignment of current terms to non-current terms)			
Improve customer satisfaction and success	**Documentation**			
	Review and adding of the missing list info docs for key lists			
	3 RMS Data Protection Notice			
	XEVMPD-RMS CR process Mapping files: D1,**D2**,D3			
	Awareness & visibility			
	SPOR update webinars	SPOR week		
Modernise Data & Information Management	Information Management Modernisation initiatives			
	Previous versions of an RMS term via API			
	RMS Portal upgrade & improvements			
			RMS - MedDRA API integration	
	Prioritised Epics (tbc)			

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Work completed – Highlights of what has been done in the last quarter

EUROPEAN MEDICINES AGENCY

	WHY	HOW & WHEN	IMPACT/ BENEFITS to users
1 **Updated guidance on XEVMPD – RMS mappings**	Users unaware how their terms have been mapped across EV-RMS and what action (if any) is needed on their products to ensure smooth migration to PMS.	• RMS **terms & mappings** of the impacted list have been reviewed • XEVMPD-RMS Guidance documents inclusive of **instructions** have been released in Q3 supporting XEVMPD/RMS users. Required actions/steps have been communicated at the PMS Info Day. • **New versions are now available** on the RMS portal containing additional information.	• enhance users ´awareness, • reduce the number of questions received on this topic • improve XEVMPD/PMS data quality • Users should avoid to use non-current/nullified RMS terms and repoint the products where possible to use only current terms
2 **VedDRA V20 updates**	New version 20 released by CVMP.	Version 20 has been adopted by CMDV in July and published in RMS in August.	Users can use the most updated version and terms from the VedDRA list in their Regulatory Activities.
3 **RMS Data Protection Notice**	To comply with the GDPR requirements on processing Personal Identifiable Information (PII).	RMS Data Protection Notice (DPN) has been endorsed and published in September 2024. Further measures will be taken in relation to the EMA data steward role to protect PII.	RMS DPN provides clear information to RMS users on how their personal data will be processed and which data will be accessible, by whom and how
4 **MedDRA V27.1 updates**	New version 27.1 has been released by MSSO	Version 27.1 has been published in RMS at the end of September 2024.	Users can use the most updated version and terms from the MedDRA list owned by MSSO in their Regulatory Activities.

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What's next? – Highlights of what will be done in the next quarter

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	WHY	HOW & WHEN	IMPACT/ BENEFITS to users
Review & Update UoM	5 Units of Measurements (UoM) list lacks specific terms details to support generation of PHPID based on UCUM codes.	• **UoM list review is ongoing** - term name and code will be **aligned to UCUM standards**, symbol will be reviewed, dimension/unit type will be reviewed/completed • Final UoM list version expected in RMS in Q3.	Users can rely on highest quality of UoM master data to map & structure their products
Review EDQM PDF list	6 Pharmaceutical Dose Form (PDF) list owned by EDQM requires review to support PMS and also PHPID generation.	Review is **ongoing** to i**dentify the current/replacement terms to be used instead of non-current terms** as well as **complete the DF characteristics of all legacy** PDF terms	Users can access the recommended current PDF terms reported under terms with status "non-current" where applicable.
Review of Manufacturing Activity list	7 The interest in submitting CR for this type of list is high due to the release of PMS edit functionalities.	Consultation to start at the end of Q4 2024 with SMEs multidisciplinary group of experts (QWP/ BWP/ IWG/ CMDv) to review on the 2 CRs received since Jan 2024 and missing term descriptions.	• MAH can further map to those terms and those alone for PMS implementation. • The outcome will be reported in the minutes (RMS portal / Document section)

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Highlights to you

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What's changed?

- Q3 24 - Update VedDRA
- Q4 2023 - SPOR Unaffiliated users can submit CRs
- Q4 2023 - Improved MedDRA list hierarchies and primary SOCs
- Q4 2023 - Improved list info documents for key lists (Units of Measurement, Application submission type, EU Procedural Authority Role, VedDRA)
- Q4 2023 - Consultation with SMEs for review Manufacturing activities
- Q1 2024 - Guidance on xEVMPD – RMS mappings
- Q2 2024 - MedDRA V27.0 Updates
- Q3 2024 - RMS Data Protection Notice

Ongoing work

- Review and update UoM
- Review and update EDQM PDF list
- Consultation with SMEs to review Manufacturing Activity list (2 CR and missing term descriptions)

Future changes *(What's next?)*

- RMS Portal upgrade & Improvements
- Consultation with SMEs for review of key lists (Special precautions for storage & Shelf life)

Future changes *(What's later?)*

- RMS – MedDRA API integration
- Previous versions of an RMS term via API
- Publication of EMDN list

Acronyms

CRs: Change Requests
MedDRA: Medical Dictionary for Drug Regulatory Activities
SOC: System Organ Class
VedDRA: Veterinary Dictionary For Drug Regulatory Activities
SMEs: Subject matter experts
EMDN: European Medical Device Nomenclature
xEVMPD: Extended EudraVigilance medicinal product dictionary
API: Application Programming Interface

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Key Takeaways and Conclusions

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Takeaways & Conclusions

Increase Awareness of RMS activities

- ***For information/background:*** *intro, RMS processes (CR, Serv Desk)*
- ***Data stewardship*** *(CRs) and* ***customer services*** *in place with excellent performance*
- ***Updates:*** *revised statistics, integration in business processes*

Share Current and planned activities

- ***XVEMPD-RMS data mapping exercise*** *performed to support PMS migration and data quality*
- ***New VedDRA and MedDRA lists*** *available*
- ***Ongoing review*** *of* ***Pharmaceutical Dose Form and Units of Measurement*** *terms*
- ***Planned Consultation with multidisciplinary SMEs on Manufacturing activities*** *(terms and descriptions)*

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Quiz Time

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Any questions on the webinar?

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SPOR Webinars

During **SPOR webinars,** EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

Webinar title	Date	Time
SPOR Data Governance	4 October 2024	10:00-12:00 CEST
Referentials Management Service (RMS)	7 October 2024	10:00-12:00 CEST
Substance Management Service (SMS)	8 October 2024	10:00-12:00 CEST
Organisation Management Service (OMS)	9 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for MAH	10 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for Sponsors	11 October 2024	10:00-12:00 CEST
Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API	14 October 2024	10:00-12:00 CEST

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Further information

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Glossary

Glossary (1/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
API	Application Programming Interface
Art. 57	Article 57 of Regulation (EU) 726/2004, which requires marketing authorisation holders to electronically submit to the Agency information on all medicinal products for human use authorised in the EU
CAP	Centrally Authorised Product
CR	Change request
CTIS	Clinical Trials Information System
DADI	Digital Application Dataset Integration
DMP	Development Medicinal Product
DCP	De-centralised Procedure
DQ	Data Quality
eAF	Electronic Application Form
ePI	Electronic Product Information
eCTD	Common Technical Document in electronic format
EMA DB	European Medicines Agency Data Board
EMRN	European Medicines Regulatory Network
Epic	An epic is a container with one common objective, for a development initiative large enough to require analysis, definition of a minimal viable product (MVP) and financial approval before implementation. An epic usually takes more than one Programme Increment to complete and is broken into multiple Features. Business epics are large initiatives that deliver Solutions needed by the business/customers Enabler epics are pieces of work that extend the architectural infrastructure of the solution under development or improve the performance of the value stream

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Glossary (2/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
ESMP	European Medicines Shortages Monitoring Platform
ESMDP	European Medicinal Devices Shortages Monitoring Platform
EURS	European Review System for eCTDs
EU-SRS	European Substance Reference System
EUTCT	European Union Telematics Controlled Terms
FHIR	Fast Healthcare Interoperability Resources
HMA	Heads of Medicines Agencies
IAM	Identity and Access Management
ICSR	Individual Case Safety Report
IDMP	The ISO IDMP standards specify the use of standardised definitions for the identification and description of medicinal products for human use
INN	International Nonproprietary Names
IRIS	A secure online platform for handling product-related scientific and regulatory procedures with EMA (iris.ema.europa.eu)
KUG	Key User Group
KPI	Key Performance Indicator
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
Mon	Monitoring Value Stream

Glossary (3/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
MRP	Mutual Recognition Procedure
NAP	Nationally Authorised Product
NCA	National Competent Authority
NDB	Network Data Board
NICTAC	Network ICT Advisory Committee represents the network IT community
NPAG	Network Portfolio Advisory Group represents the Management Board and HMAs
OD	Orphan Designation
OMS	Organisation Management Service
PB	Portfolio Board
PI	Programme Increment, a three month period of work
PI Planning ceremony	A quarterly event to plan work for the entire Value Stream in the next quarter, ensuring that teams and stakeholders have a shared mission and vision
PIP	Paediatric Investigation Plan
PLM	Product Lifecycle Management Value Stream
PMS	Product (Data) Management Service
PO	Product Owner (PO) is the Agile team member primarily responsible for maximizing the value delivered by the team by ensuring that the team backlog is aligned with customer and stakeholder needs.
RMS	Referential Management Service
R&D	Research and Development Value Stream

Glossary (4/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
SAFe	Scaled Agile Framework
SIAMED	An Information System for the management of regulatory procedure for centrally authorised products
SLA	Service Level Agreement
SPOR	Substance, Product, Organisation and Referential
SmPC	Summary of product characteristics
SMS	Substance Management Service
SQI	Service Quality Indicator (metric)
SVG	Substance Validation Group
UNII	Unique Ingredient Identifier
USAN	United States Adopted Names
Value Stream	Value Streams represent the series of steps that an organization uses to implement Solutions that provide a continuous flow of value to the Business/Customer
VSM	EMA Value Stream Manager (VSM) is a "Servant Leader and Coach" for the Value Stream teams
VSO	EMA Value Stream Owner (VSO) has the primary responsibility for the business outcomes, including the delivery of business outcomes, in their Value Stream
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary

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