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: #2968723

Housekeeping notes – Q&A

Join at
slido.com
#2968 723

- 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

*If you would like to **receive recordings and presentations via email**, please register your e-mail address in Slido (www.slido.com) using the **event code #5864645.***

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Referentials Management Services (RMS)

3 October 2023, 10:00 – 12:00 Central European Summer Time (CEST)

Presented by Veronica Lipucci Di Paola

SPOR Webinar Series – 2-12 October 2023

H2 2023 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 and XEVMPD Data Governance	2 October 2023	10:00-12:00 CEST
Referentials Management Service (RMS)	3 October 2023	10:00-12:00 CEST
Organisation Management Service (OMS)	4 October 2023	10:00-12:00 CEST
Substance Management Service (SMS)	5 October 2023	10:00-12:00 CEST
Product Management Service (XEVMPD)	6 October 2023	10:00-12:00 CEST
Service Desk for SPOR and XEVMPD	10 October 2023	10:00-12:00 CEST
EMA Account Management	11 October 2023	10:00-12:00 CEST
SPOR application programming interface (API) - SPOR API	12 October 2023	10:00-12:00 CEST

For Questions: www.slido.com code: #2968723

Goals of the session

Increase **Awareness of RMS activities**

Share **current and planned activities**

Show how RMS is addressing **customer feedback**

For Questions: www.slido.com code: #2968723

Agenda

1. **Welcome**
   10:00 – 10:05
2. **Introduction to RMS**
3. **RMS processes**
4. **RMS Change request process**
5. **RMS Data Quality Management** NEW
6. **RMS Statistics**
7. **RMS Documentation & Help**
8. **RMS in Projects/Systems**
9. **Planned RMS Activities** NEW
10. **Key takeaways & Conclusions**
11. **Q&A Session**
    11:45 – 12:00

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Introduction to RMS

For Questions: www.slido.com code: #2968723

What is RMS

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RMS

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 **213 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**

For Questions: www.slido.com code: #2968723

Lists and owners

As of October 2023, RMS contains **213 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 (192)

- 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 (5)

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

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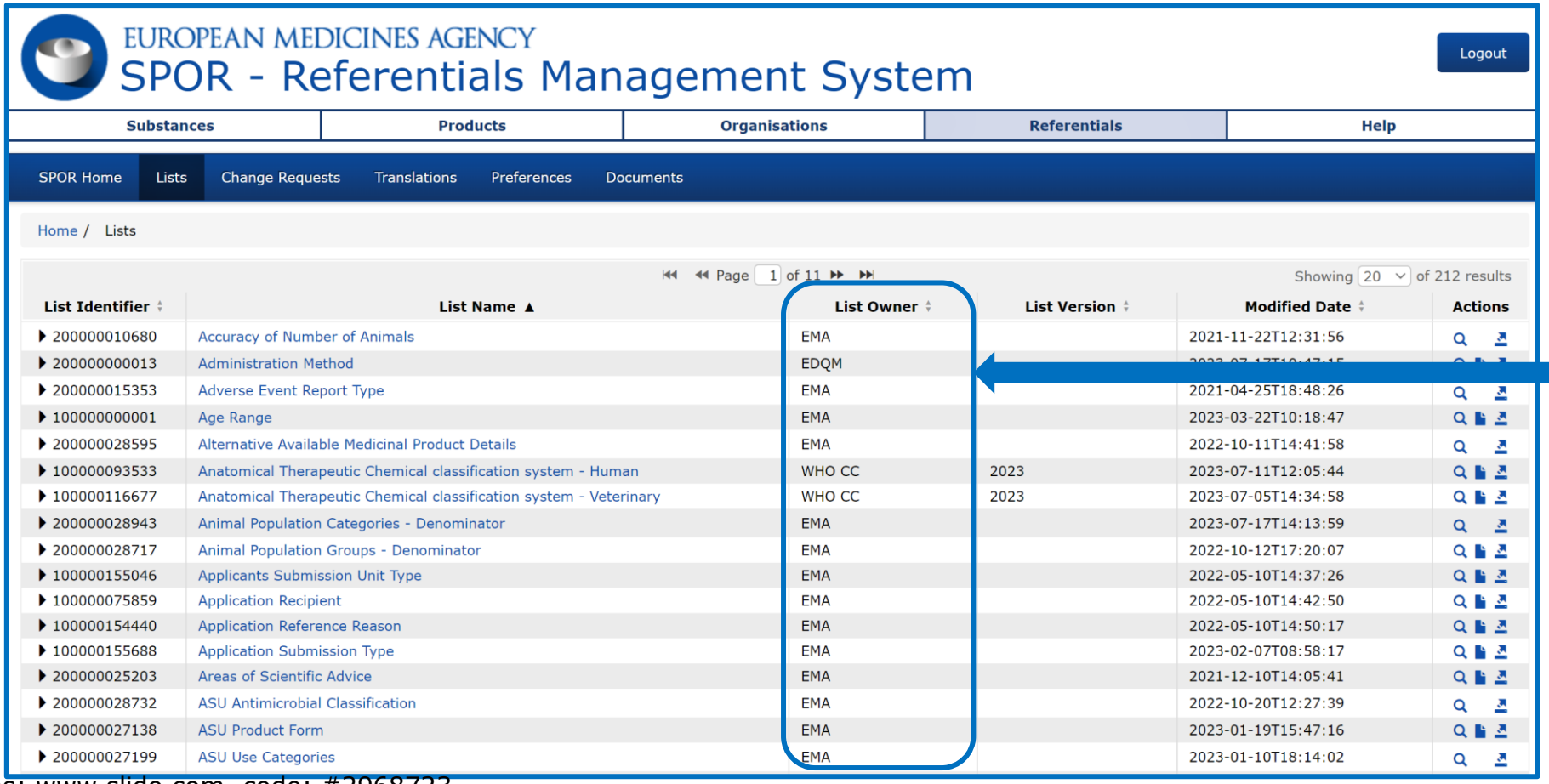
RMS Business Particulars

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**



For Questions: www.slido.com code: #2968723

List Information Document

List Information Document:

- One 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			

For Questions: www.slido.com code: #2968723

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		[illegible]T11:31:17	
100000160406	Manufacturing Activity	EMA		2023-01-31[illegible]	
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: #2968723

List Information Document

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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: #2968723

List Information Document

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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").

For Questions: www.slido.com code: #2968723

List Information Document

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4. Document History

Version	Who	When	What
1.0	EMA	31/01/2017	

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.

For Questions: www.slido.com code: #2968723

RMS processes

 For Questions: www.slido.com code: #2968723

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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

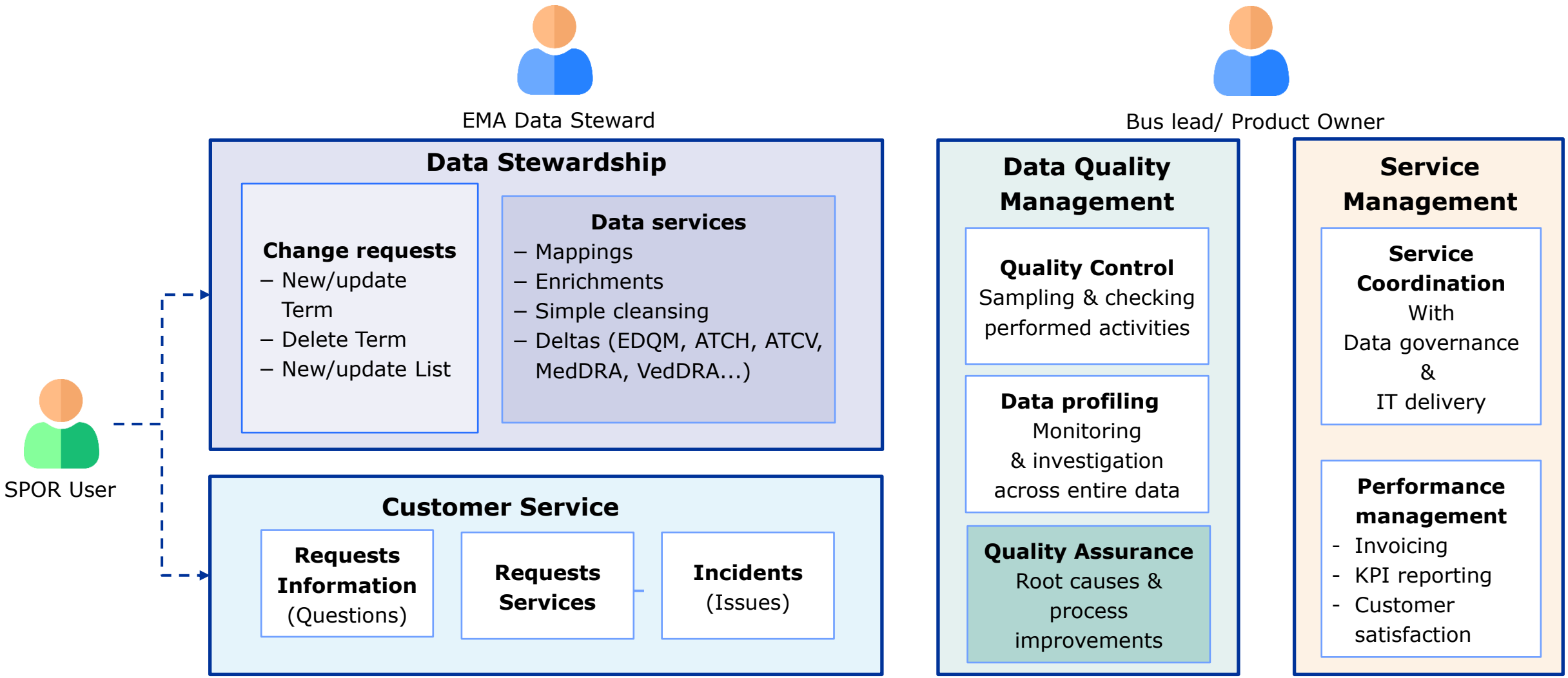
- Search/View
- Online
- Offline (bulk upload)

Documents

- General
- Technical
- NCA

For Questions: www.slido.com code: #2968723

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.

For Questions: www.slido.com code: #2968723

RMS Change Request process

 For Questions: www.slido.com code: #2968723

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 doc umentation.

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: #2968723

Creating a Change Request

EUROPEAN MEDICINES AGENCY

Change Request

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

Home / Manage Change Requests

Hide search

CR ID:

CR Name:

CR Status: All

CR Type: All

List

Term name in CR:

CR Date:

From yyyy-MM-dd **To** yyyy-MM-dd

Requestor:

My CR's **All CR's**

Search Reset

New List CR New Term CR

For Questions: www.slido.com code: #2968723

Creating a Change Request

EUROPEAN MEDICINES AGENCY

Change Request Information

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

Home / Lists / Term Change Request

CR Information

CR Name:* irsogladine

CR Type:* Add Term

Justification:* New ATC code required for initial MAA

Requestor: gonzalezn

Contact Email:* Jaume.Gonzalez@ema.europa.eu

Contact Phone: (1) +31 88781 8574

Select List:* Anatomical Therapeutic Chemical classification system - Human

Attachments

1) WHO CC New ATC 5th levels 2024.docx

Audit trail

Date ▲	Status to	Comment
No data available in table		

Term Information

(1) **Tick this box to submit the change request. Please be aware that the requestor's email and telephone number (if provided) included in this request can be accessed by EEA National Competent Authority SPOR users.**

If you have any questions about the way your personal data are being processed please contact EMA Service Desk at https://servicedesk.ema.europa.eu

Save | Submit | Cancel

For Questions: www.slido.com code: #2968723

Creating a Change Request

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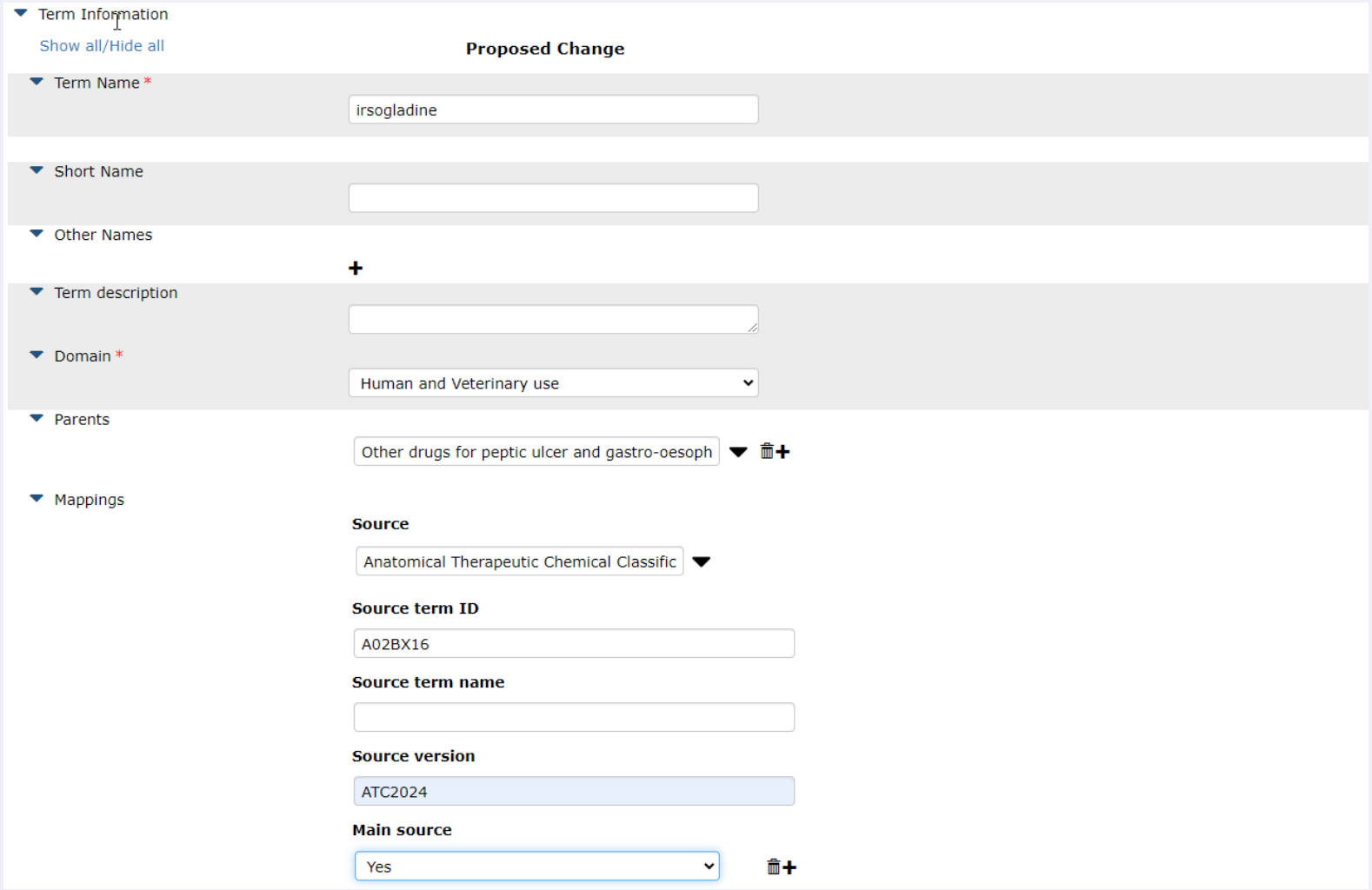
Term Information



For Questions: www.slido.com code: #2968723

Creating a Change Request

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Term Information

Applicability

Country applicability 0 Selected

IT application applicability 0 Selected

Term Symbols

+

Data Classification

Public

Extended Attributes

Antimicrobial Product as per Article 5 of the Commission Delegated Regulation 2021/578

Mandatory to Report Use

Mandatory to Report Sales

(1) **Tick this box to submit the change request. Please be aware that the requestor's email and telephone number (if provided) included in this request can be accessed by EEA National Competent Authority SPOR users.**

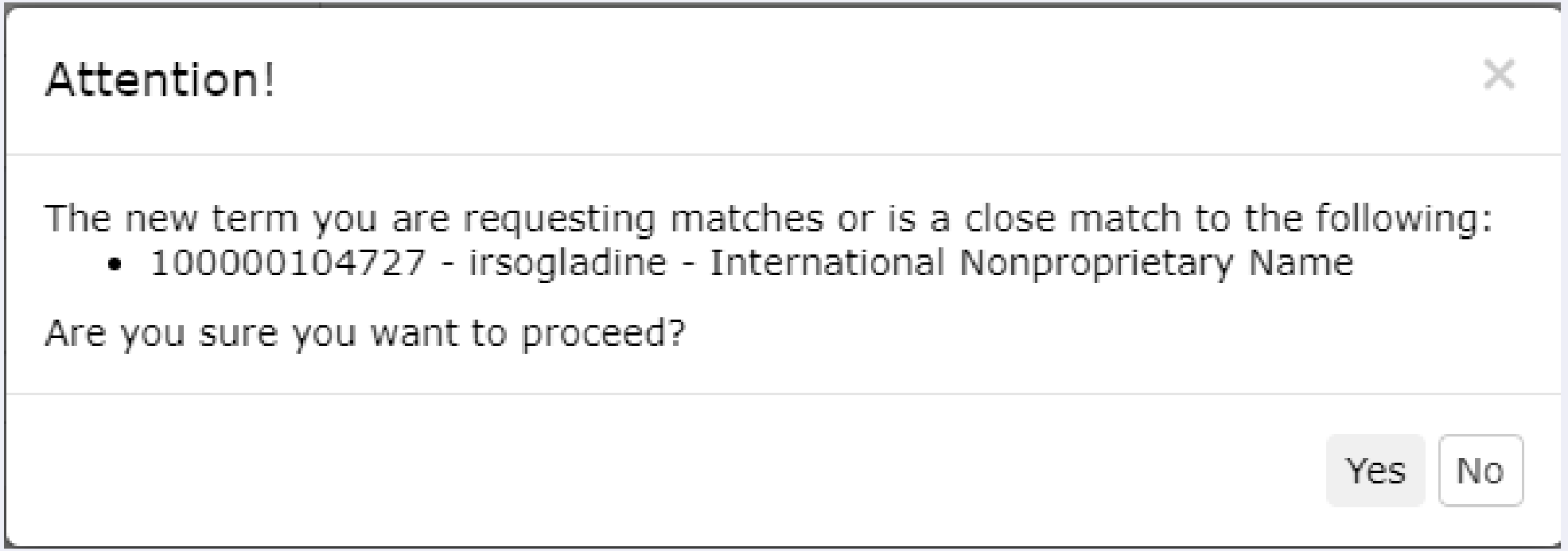
If you have any questions about the way your personal data are being processed please contact EMA Service Desk at https://servicedesk.ema.europa.eu

Save Submit Cancel

For Questions: www.slido.com code: #2968723

Creating a Change Request

Duplicate Warning!



For Questions: www.slido.com code: #2968723

Creating a Change Request

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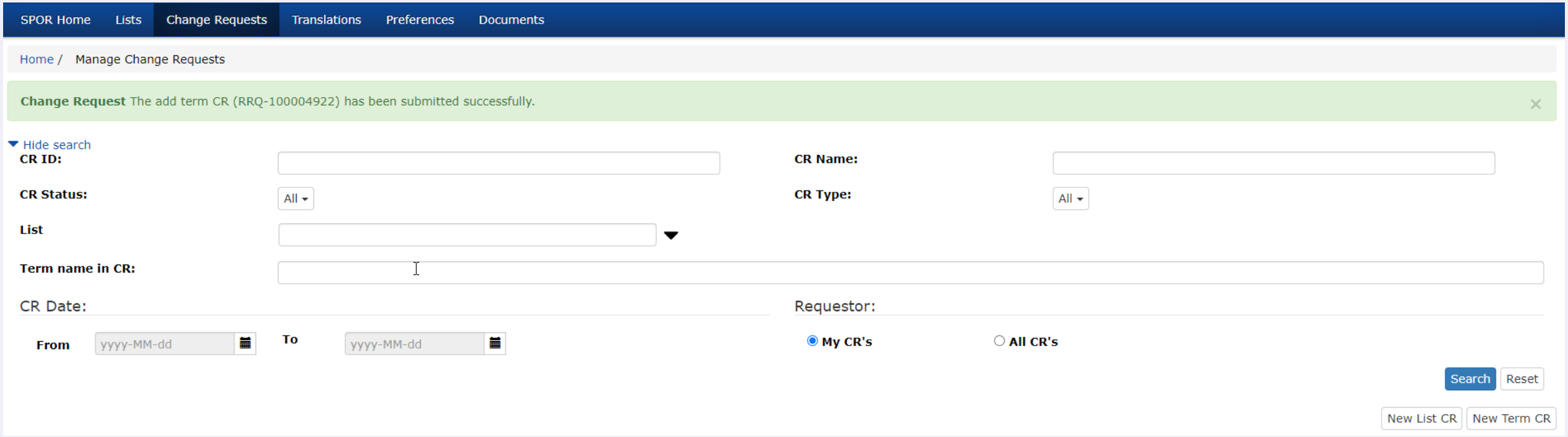
CR confirmation



For Questions: www.slido.com code: #2968723

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: #2968723

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: #2968723

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: #2968723

Creating a Change Request

EUROPEAN MEDICINES AGENCY

Term published in RMS

Page 1 of 1

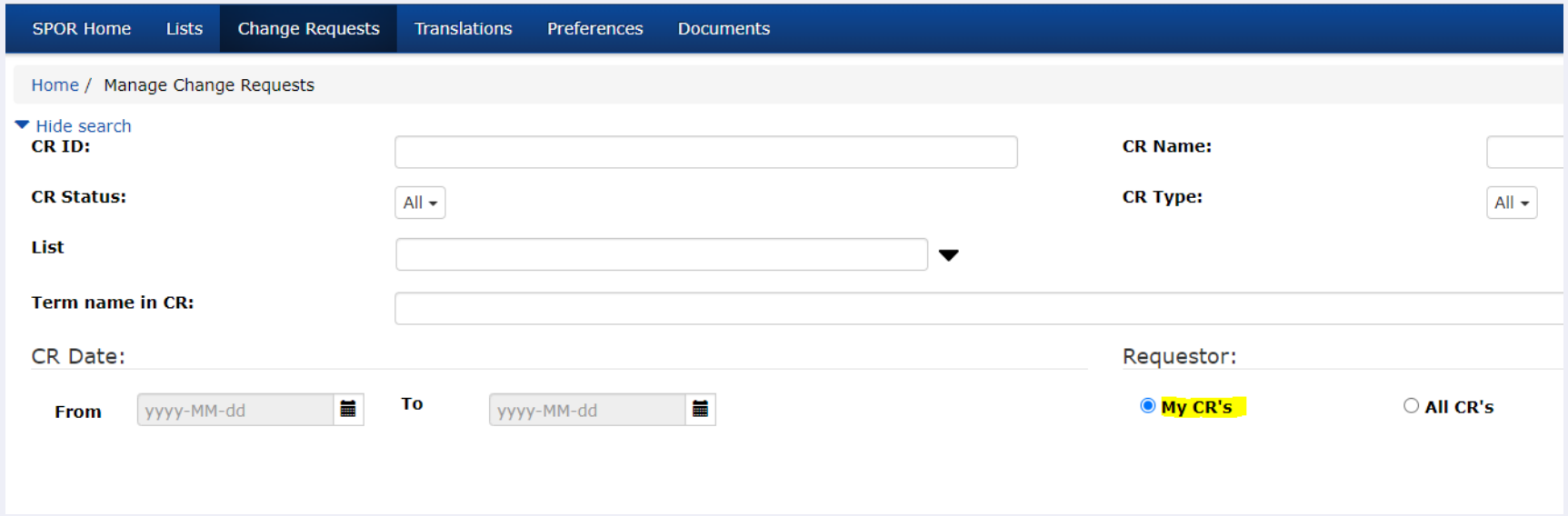
Identifier ▲	Term Name	Short Name	Source Id	Status
100000093554	ALIMENTARY TRACT AND METABOLISM		A	CURRENT
100000093541	DRUGS FOR ACID RELATED DISORDERS		A02	CURRENT
100000093542	ANTACIDS		A02A	CURRENT
100000093615	DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)		A02B	CURRENT
100000093616	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: #2968723

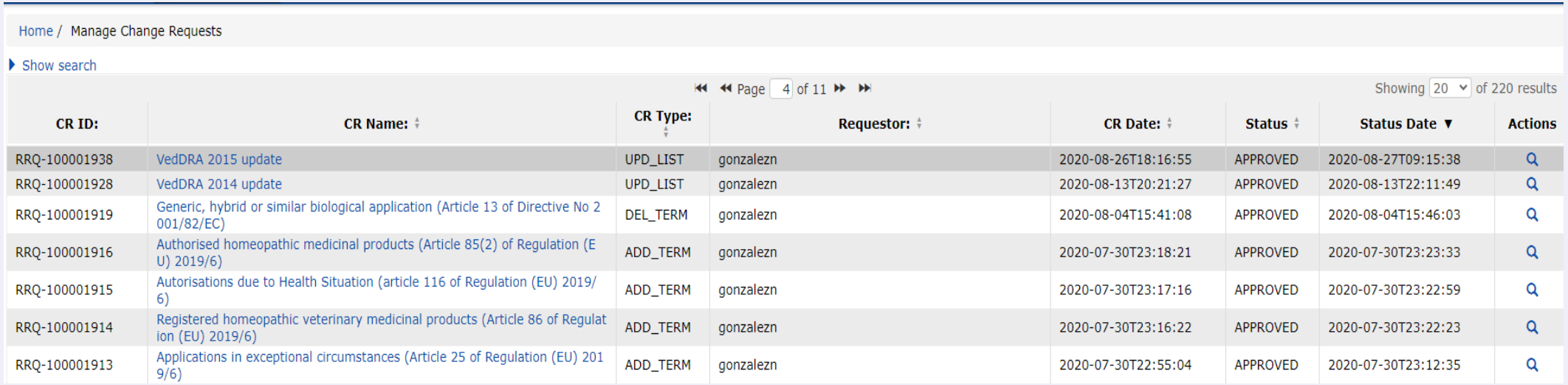
Browsing your Change Requests

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: #2968723

Creating a Change Request

EUROPEAN MEDICINES AGENCY

Term published in RMS

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

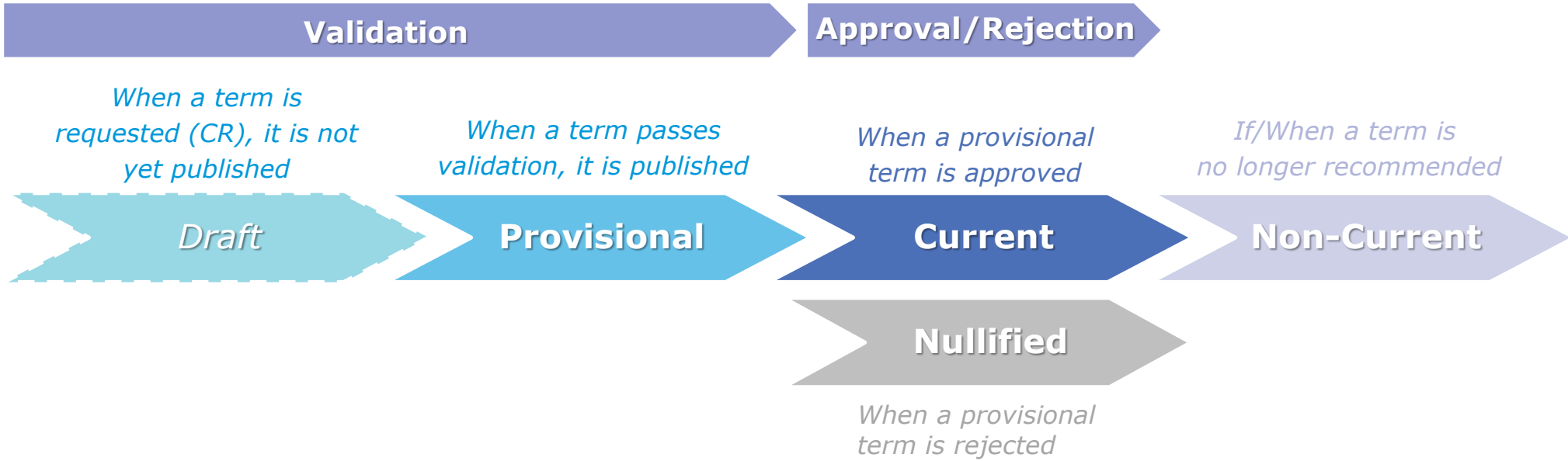
Home / Lists / Anatomical Therapeutic Chemical classification system - Human / irsogladine

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: #2968723

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**

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RMS Data Quality Management

 For Questions: www.slido.com code: #2968723

SPOR Data Quality Management at a glance

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Data services
Identified defects/errors are corrected in OMS

Proactive

Reactive

Quality Assurance
- Root causes are analysed and where possible preventive actions are identified/ implemented
- Process improvements

Activity Monitoring

Data mgmt Task

Quality Control
- Tasks are routinely sampled (~20%) and inspected to detect errors
- Sampled tasks are re-inspected by EMA to calibrate QC results

Data Monitoring

Data

Data Profiling
- Profiles are built to identify data not meeting the DQ rules
- KPIs are developed

SUPPORT

Customer Services

DQ Defects
- Defects/errors are classified into **Major/Minor**

Issues
- Issues reported to Service Desk on DQ of Orgs/Locs

Data Quality is ACCEPTABLE if:

<5% major errors (duplicates, incorrect approval/rejection incorrect merges)

AND

<10% minor errors (inconsistent details)

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RMS Data Quality Management

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	Data Quality Errors		Processing Errors	
	Minor	**Major**	**Minor**	**Major**
Data services	• Incorrect standardisation (e.g. Naming conventions with target species: "Cattle (cow)" vs "Cow –Cattle–" • Typos (e.g. spelling mistakes) • Capitalisation issues (e.g. small capitals vs sentence capitals • Issues with extended attributes (e.g. wrong country grouping for a term in the Country list)	• Duplicates • Terms created in the wrong list (e.g. term from combined pharmaceutical dose form created in pharmaceutical dose form list) • Essential information missing (e.g. ATC name with ATC code missing)	• *Same as minor data quality errors for data services*	• *Same as major data quality errors for data services*
Change request	• Incorrect standardisation • Typos • Capitalisation issues • Issues with extended attributes	• Duplicates • Terms created in the wrong list • Essential information missing (e. g. ATC name with ATC code missing)	• *Same as minor data quality errors for change requests*	• *Same as major data quality errors for change requests* • Incorrect rejection/approval of a CR

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RMS Statistics

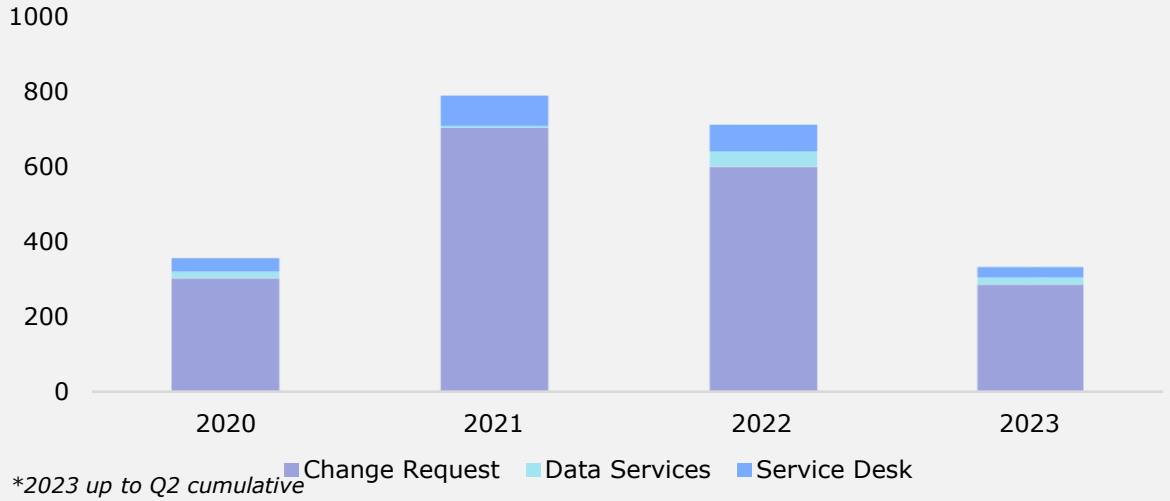
 For Questions: www.slido.com code: #2968723

RMS Statistics – RMS Activities

- The number of change requests (287) for the first half of 2023 **follows the 2022 trend**.
- The **50% reduction in data services** in H1 2023 is due to the *exceptional peak of new lists in 2022 for the Real World Data Catalogues* project.
- The number of Service Desk tickets in H1 2023 (27) is within the rough order of magnitude of 2021 and 2022 (~ 75 tickets per year).

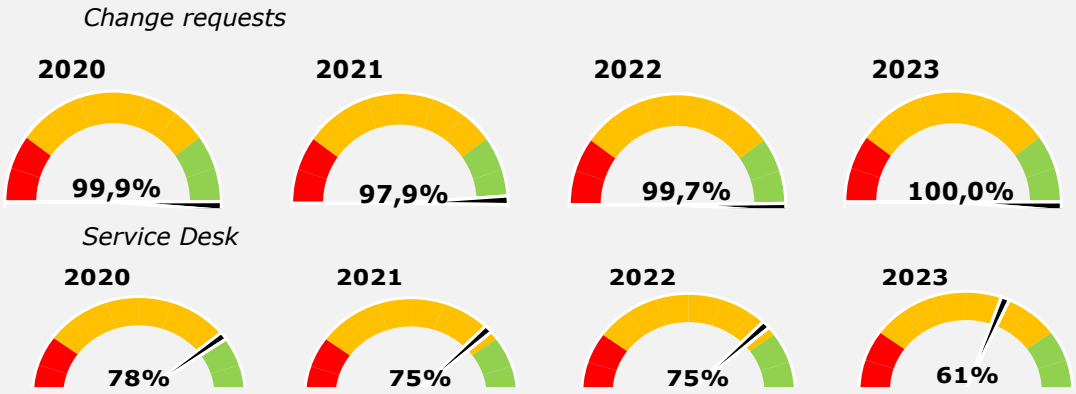
- **100%** of CRs were resolved **within SLA** in 2022.
- Compliance with Service Desk tickets in H1 2023 was **lower than average** and this is mainly due to some **IT incidents which required in-depth investigation** and took longer than expected.
- Note that these incidents only involved 2/27 tickets. Therefore, the impact of this SLAs was deemed minimal.

RMS Activities



**2023 up to Q2 cumulative*

Overall Compliance



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RMS Documentation & Help

 For Questions: www.slido.com code: #2968723

SPOR Documents & Help (I)

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Reference documents accessible from the SPOR portal

Main documentation required to successfully use RMS services:

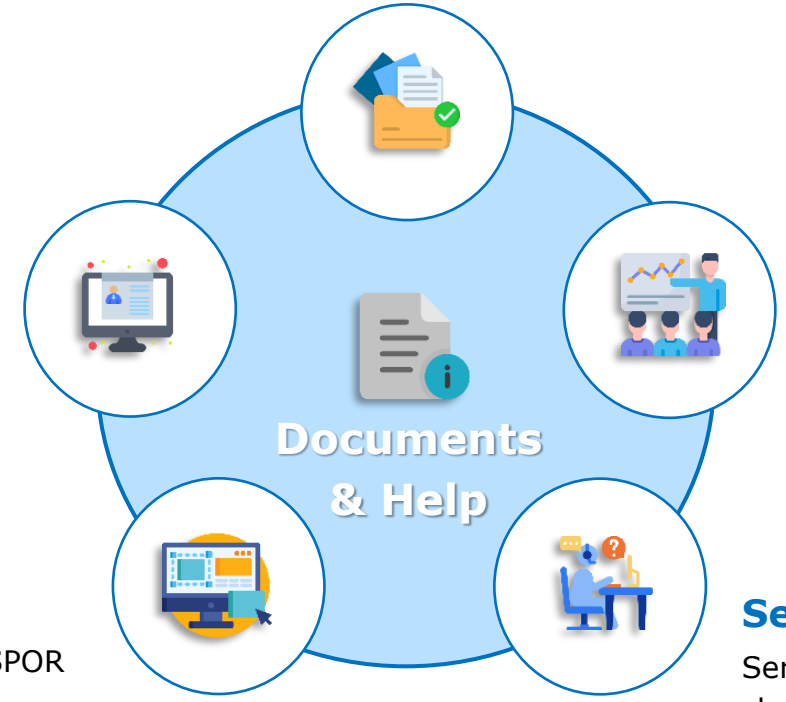
- RMS web user manual – guidance on SPOR services, e.g. searching, exporting data, requesting CRs, translations, etc.
- SPOR user registration manual (how to register for SPOR)
- SPOR affiliation template (to register the first industry super user)
- RMS New List Template & Quick Reference Card for RMS 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.

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SPOR Documents & Help (II) - SPOR Portal

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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

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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

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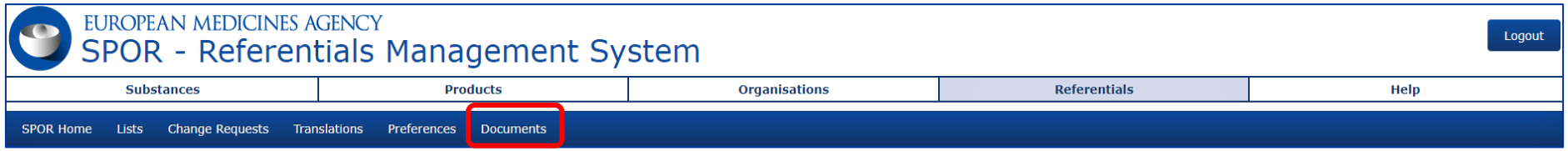
SPOR Documents & Help (III) - SPOR Portal

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

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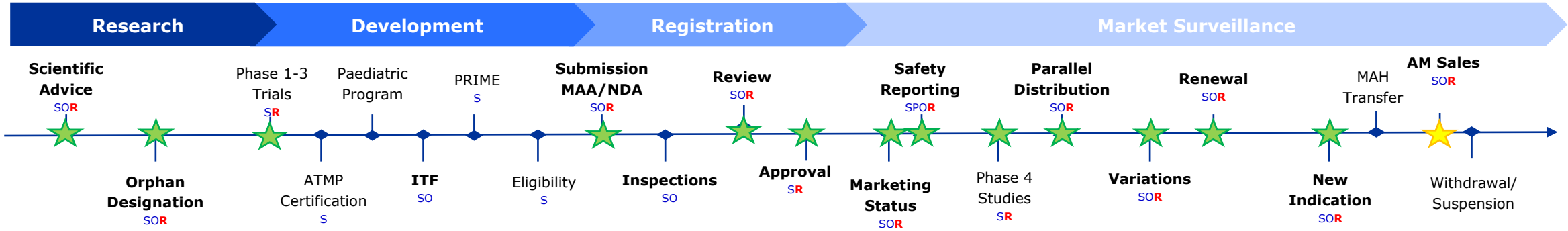
RMS in Projects/Systems

 For Questions: www.slido.com code: #2968723

RMS Integration in regulatory processes



Legend

- Implemented
- Planned
- Not planned yet

System	Domain	Process
EudraCT & CTIS	**H**	Phase 1-4 Trials
IRIS	**H&V**	Scientific Advice + Orphan Designation + Inspections + Parallel Distribution
eAF & PMS* & eAF & ePI*	**H&V**	Submission MAA, Variations, Renewal
SIAMED II	**H&V**	Review, Approval
UPD	**V**	Approval
CorpGXP	**H&V**	Inspections + Manufacturing Import Authorisation + Wholesale Distribution Authorisation
EVVET3 & ESVAC	**V**	Safety reporting
PSUR repository & EU PAS & XEVMPD*	**H**	Safety reporting
ASU	**V**	Antimicrobial sales and use
Real World Data (Healthcare Data)	**H**	Pharmacovigilance

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EMA systems consuming RMS lists

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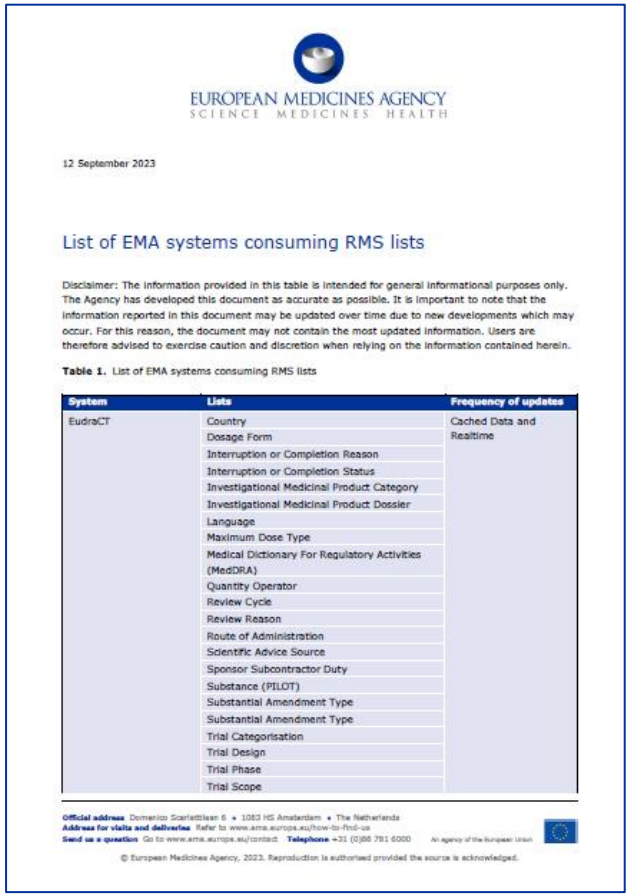
A9 - **List of EMA systems consuming RMS lists** is available on [RMS portal - Document folder]



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SCIENCE MEDICINES HEALTH

12 September 2023

List of EMA systems consuming RMS lists

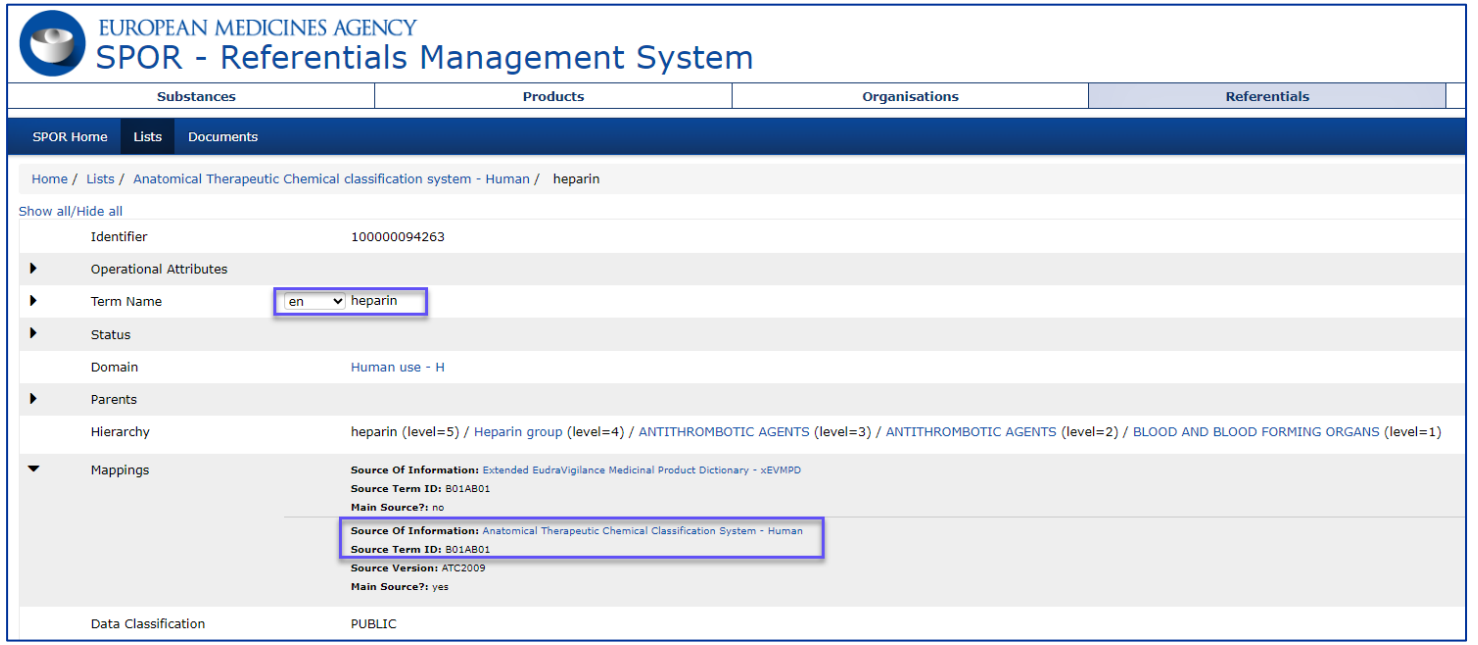
Disclaimer: The information provided in this table is intended for general informational purposes only. The Agency has developed this document as accurate as possible. It is important to note that the information reported in this document may be updated over time due to new developments which may occur. For this reason, the document may not contain the most updated information. Users are therefore advised to exercise caution and discretion when relying on the information contained herein.

Table 1. List of EMA systems consuming RMS lists

System	Lists	Frequency of updates
EudraCT	Country	Cached Data and Realtime
	Dosage Form	
	Interruption or Completion Reason	
	Interruption or Completion Status	
	Investigational Medicinal Product Category	
	Investigational Medicinal Product Dossier	
	Language	
	Maximum Dose Type	
	Medical Dictionary For Regulatory Activities (MedDRA)	
	Quantity Operator	
	Review Cycle	
	Review Reason	
	Route of Administration	
	Scientific Advice Source	
	Sponsor Subcontractor Duty	
	Substance (PILOT)	
	Substantial Amendment Type	
	Substantial Amendment Type	
	Trial Categorisation	
	Trial Design	
	Trial Phase	
	Trial Scope	

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact Telephone +31 (0)88 781 6000 An agency of the European Union

Example of RMS Integration in regulatory processes – ATC list in eAF



EUROPEAN MEDICINES AGENCY
SPOR - Referentials Management System

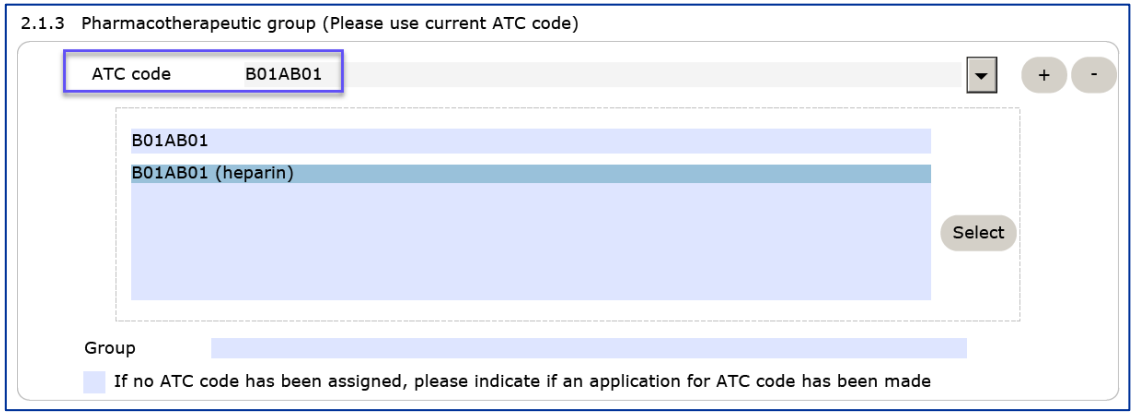
Substances | Products | Organisations | Referentials

SPOR Home | Lists | Documents

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

Show all/Hide all

Identifier	100000094263
Operational Attributes	
Term Name	en heparin
Status	
Domain	Human use - H
Parents	
Hierarchy	heparin (level=5) / Heparin group (level=4) / ANTITHROMBOTIC AGENTS (level=3) / ANTITHROMBOTIC AGENTS (level=2) / BLOOD AND BLOOD FORMING ORGANS (level=1)
Mappings	**Source Of Information:** Extended EudraVigilance Medicinal Product Dictionary - xEVMPD **Source Term ID:** B01AB01 **Main Source?:** no **Source Of Information:** Anatomical Therapeutic Chemical Classification System - Human **Source Term ID:** B01AB01 **Source Version:** ATC2009 **Main Source?:** yes
Data Classification	PUBLIC



2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code B01AB01 + -

B01AB01

B01AB01 (heparin)

Select

Group

If no ATC code has been assigned, please indicate if an application for ATC code has been made

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RMS recent & planned activities

 For Questions: www.slido.com code: #2968723

Recent/Planned RMS activities

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Activities for 2024 to be adjusted based on Customer Satisfaction Survey's results

	Q3 2023	Q4 2023	Q1 2024	Q2 2024
Deliver efficient and effective regulatory data services	**RMS – Customer Services**			
	Process improvement – Simplify Incident mgt			
	RMS - Data Management (Change requests & Data services)			
	RMS - Outsourcing CR/Deltas/SD/List Information documents – Knowledge Transfer			
	1 RMS – XEVMPD daily synchronisation (submission of proposed terms)			
	2 New service – Provision of translations by NCAs via List Update CR			
	RMS – Data Quality Deltas - Enrichments – New lists			
	New lists for IRIS	MedDRA 26.1 + VedDRA 2023	EMDN (tbc)	3 ATC H&V 2024
	MedDRA 27.0	New Lists for CTIS (tbc)		
	4 Process improvement – data profiling & monitoring, starting with missing descriptions and non-current terms missing replacements.			
	DQ improvement – consultation with SMEs for Special Prec. For Storage, Shelf Life and Manuf. Activities 6			
	DQ improvements – 1) inclusion of missing term descriptions, 2) enrichment of non-current terms with replacement (current) terms, 3) enrichment of UoM list, e.g. relevant attributes populated for all terms (e.g. dimension, unit type), presence of UCUM codes, etc.			
Improve customer satisfaction and success	**RMS – Documentation**			
	5 RMS Master List Info review and publication in RMS portal	RMS pipeline (tbc)		
	RMS – Publication of missing List Info Documents and holistic review of all List Info Documents			
	RMS – Awareness & visibility			
	SPOR week	SPOR Customer Satisfaction survey	STWP plenary (tbc)	SPOR webinars / Translations Webinar (tbc)
Modernise Data & Information Management	Information Management Modernisation initiatives			
	Infrastructure/technical improvements	RMS – Bug fixes (failed generation of RMS exports, fixing of MedDRA SOC information, API improvements, formatting issues with csv exports)		
	Prioritised Epics (MedDRA API, provision of historical RMS versions via API, harmonisation of SPOR access rights)			

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Recent/Planned Service Process Improvements 2023 (I)

EUROPEAN MEDICINES AGENCY

	WHY	HOW & WHEN	IMPACT to users:	
RMS – XEVMPD daily synchronisation	To support successful PMS & eAF implementation and synchronisation of information in xEVMPD and RMS.	Proposed and/or standard terms are requested via RMS: •Term not available in RMS and XEVMPD → to be requested via a **'New term'** change request •Term available in RMS but not in XEVMPD → to be requested via **'Update term'** change request (*From July 2023)* •Creation of proposed terms **in XEVMPD** by sponsors and MAHs to be **blocked** (*From Q1/2024)*	***Impact**:* Change in process, users become familiar with requesting data via RMS ***Benefit:*** Improved data quality; less issues with PMS migration and data being used by eAF	1
Provision of translations by NCAs via List Update change request	Facilitate & support NCAs with translations upon request as an alternative to bulk upload or provision of individual translations by NCAs.	**As of April 2023** • NCA submits change request – list update + attach Excel template with translations • EMA team to upload translations on behalf of NCA	Faster availability of translations in the RMS portal	2

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Recent/Planned Service Process Improvements 2023 (II)

EUROPEAN MEDICINES AGENCY

	 WHY	 HOW & WHEN	 IMPACT to users:	
Data Quality - Deltas	Faster publication of updates to external lists (ATCH, ATC V, MedDRA and VEDDRA) is required	**Next update in Q1 2024 -** SLAs for list updates have been revised and will be done within 1-2 months of publication by list owner	Faster updates to external lists (ATCH, ATC V, MedDRA and VEDDRA) should minimise CRs & improve lists usage experience	3
RMS Data profiling & monitoring	Improve RMS Data Quality	• **Ongoing in September 2023 -** Creation of a dashboard to analyse terms missing descriptions and non-current terms missing replacement terms in the "Current term" field. **–** • **Starting in Q4 2023 -** Create process to monitor, inspect and correct weekly	Users should see improved data quality in RMS: • Additional term definitions should improve understanding of terms and lists. • The inclusion of replacement terms for non-current terms should provide users with alternatives to terminology issues and improve regulatory submissions	4
Documentation	Reacting to feedback from customer satisfaction survey where customers demanded more/better documentation	✓ Nine (9) list info docs have been created/updated since the last RMS webinar (April 2023), including: "Target Species", "Variation Classification – Veterinary", "Master File Type", "Regulatory Entitlement Type" and "Record Status". ✓ **September 2023 -** A10 - Master List Information Document Spreadsheet – doc consolidating in one place the details/information for all lists in RMS (& subsequent updates) • **Planned throughout 2024 -** What's new/News - information of topics/items under discussion or for implementation	Enhanced supporting documentation allowing improved awareness.	5

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Recent/Planned Service Process Improvements 2023 (III)

EUROPEAN MEDICINES AGENCY

Review of 3 RMS lists:

- **Manuf. Activities**
- **Shelf life**
- **Special Prec. for Storage**

WHY

These are highly technical lists which require deep expertise. Any requests involving these lists should be assessed by the relevant subject matter experts (SMEs).

HOW & WHEN

- **Ongoing since June 2023 -** Requests for these lists will be invalidated
- **Starting in Q4 2023 -** All invalid requests will be collected and relevant SMEs (e.g. IWG/QWP/BWP) will be consulted every 3-6 months)
- Following conclusions from SMEs, RMS database will be updated and SPOR users who submitted the requests will be informed.

IMPACT to users:

Time to complete the assessment of the terms requested may be longer than usual but given the nature of the lists this is required.

In exchange, requests will be reviewed by the best experts in the area resulting in improved data quality and awareness of these 3 lists.

6

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Planned Information Management Modernisation initiatives 2023

EUROPEAN MEDICINES AGENCY

WHY

HOW & WHEN

RMS API versioning

Enhancement of RMS API capabilities required to improve user experience and data availability

Enable to retrieve historical/older term versions via API:

- **Q3 2023** assessment/ feasibility
- **Q4 2023 – Q1 2024 -** implementation

MedDRA API

Improve data quality (currency of data)

Consume the MedDRA updates live from MedDRA API instead of MedDRA 6-monthly updates:

- **Q3 2023 -** assessment/feasibility
- **Q4 2023 – Q1 2024 -** implementation

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Quiz Time

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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

- ***RMS-EV*** *daily sync*
- ***New Translation*** *upload service via CR*
- ***Revised and shortened SLAs***
- ***Planned user experience improvements*** *(UI and API) and data quality*

Show how RMS is addressing customer feedback

- *New* ***DQ management process*** *(data profiling & monitoring) in place*
- *Plan for* ***updated/improved*** *documentation*

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Any questions on the webinar?

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H2 2023 SPOR Webinars

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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 and XEVMPD Data Governance	2 October 2023	10:00-12:00 CEST
Referentials Management Service (RMS)	3 October 2023	10:00-12:00 CEST
Organisation Management Service (OMS)	4 October 2023	10:00-12:00 CEST
Substance Management Service (SMS)	5 October 2023	10:00-12:00 CEST
Product Management Service (XEVMPD)	6 October 2023	10:00-12:00 CEST
Service Desk for SPOR and XEVMPD	10 October 2023	10:00-12:00 CEST
EMA Account Management	11 October 2023	10:00-12:00 CEST
SPOR application programming interface (API) - SPOR API	12 October 2023	10:00-12:00 CEST

For Questions: www.slido.com code: #2968723

Further information

Contact us through ServiceNow @ https://support.ema.europa.eu/

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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

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