



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](#).

1

Join via **QR code** or **slido.com**



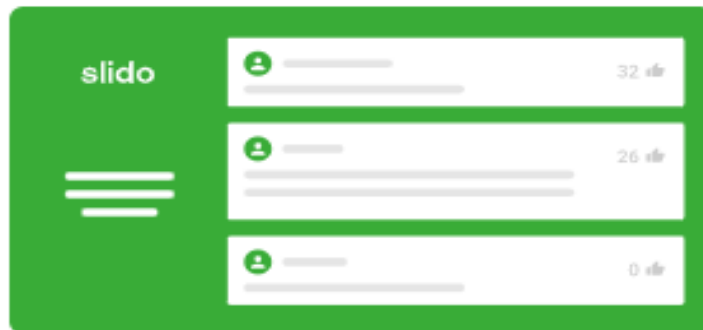
2

Send or upvote the questions
you want to hear answered



3

Questions will be shown on the screen
and **managed live in the Q&A session**



4

**Questions not addressed during
this session** may be addressed in
subsequent webinars and/or in
FAQ document in SPOR Portal







EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Referentials Management Services (RMS)

18 April 2023

SPOR Week – 17-20 April 2023

SPOR week is a **full week of webinars** during which EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

 Webinar title	 Date	 Time
<u>SPOR and XEVMPD Data Governance</u>	17 April 2023	10:00-12:00 CET
<u>Service Desk for SPOR and XEVMPD</u>	17 April 2023	14:00-16:00 CET
 <u>Referentials Management Service (RMS)</u>	18 April 2023	10:00-12:00 CET
<u>Organisation Management Service (OMS)</u>	18 April 2023	14:00-16:00 CET
<u>Substance Management Service (SMS)</u>	19 April 2023	10:00-12:00 CET
<u>Product Management Service (XEVMPD)</u>	19 April 2023	14:00-16:00 CET
<u>Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API</u>	20 April 2023	10:00-12:00 CET
<u>EMA Account Management</u>	20 April 2023	14:00-16:00 CET



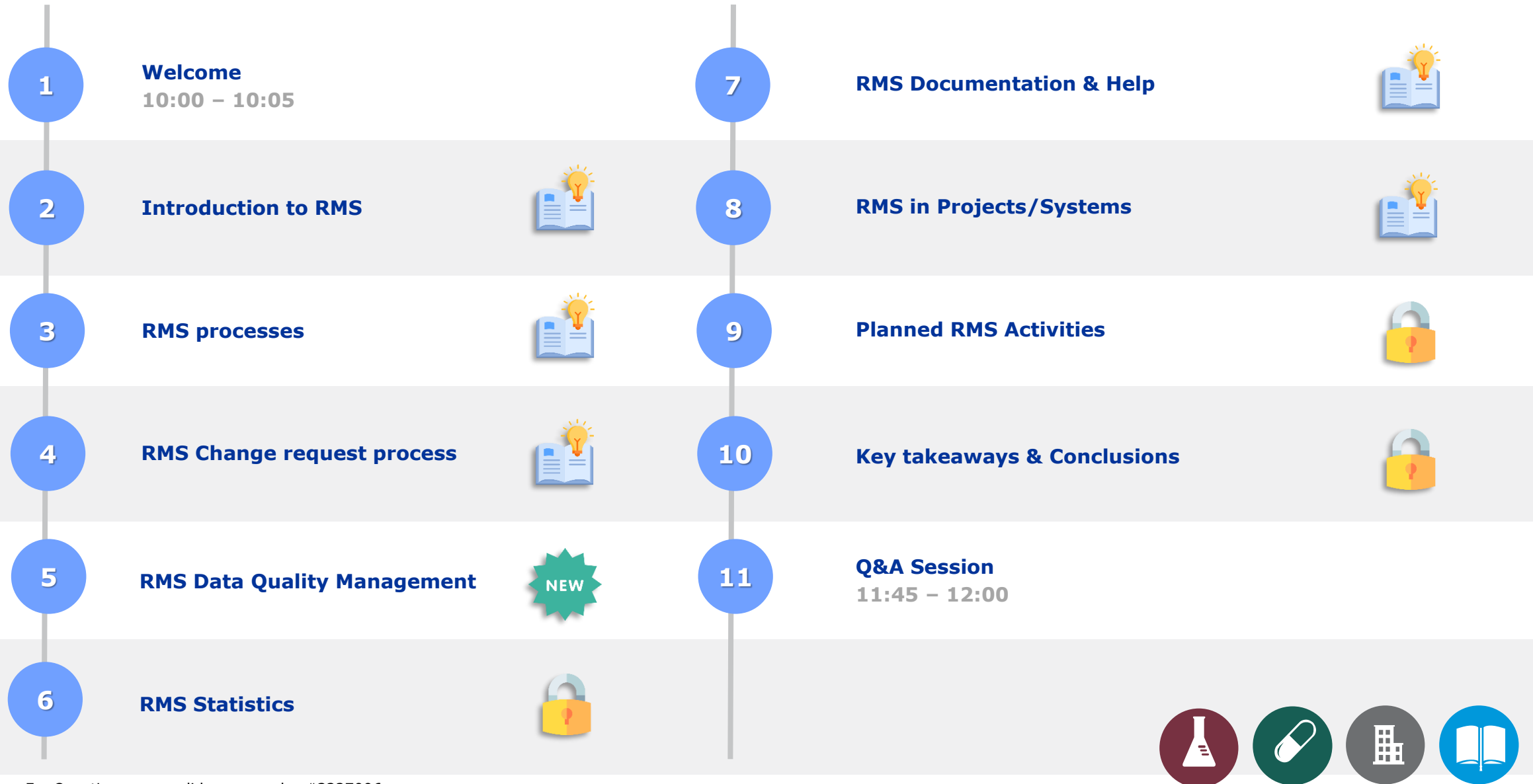
Increase **Awareness of RMS activities**



Share **current and planned activities**

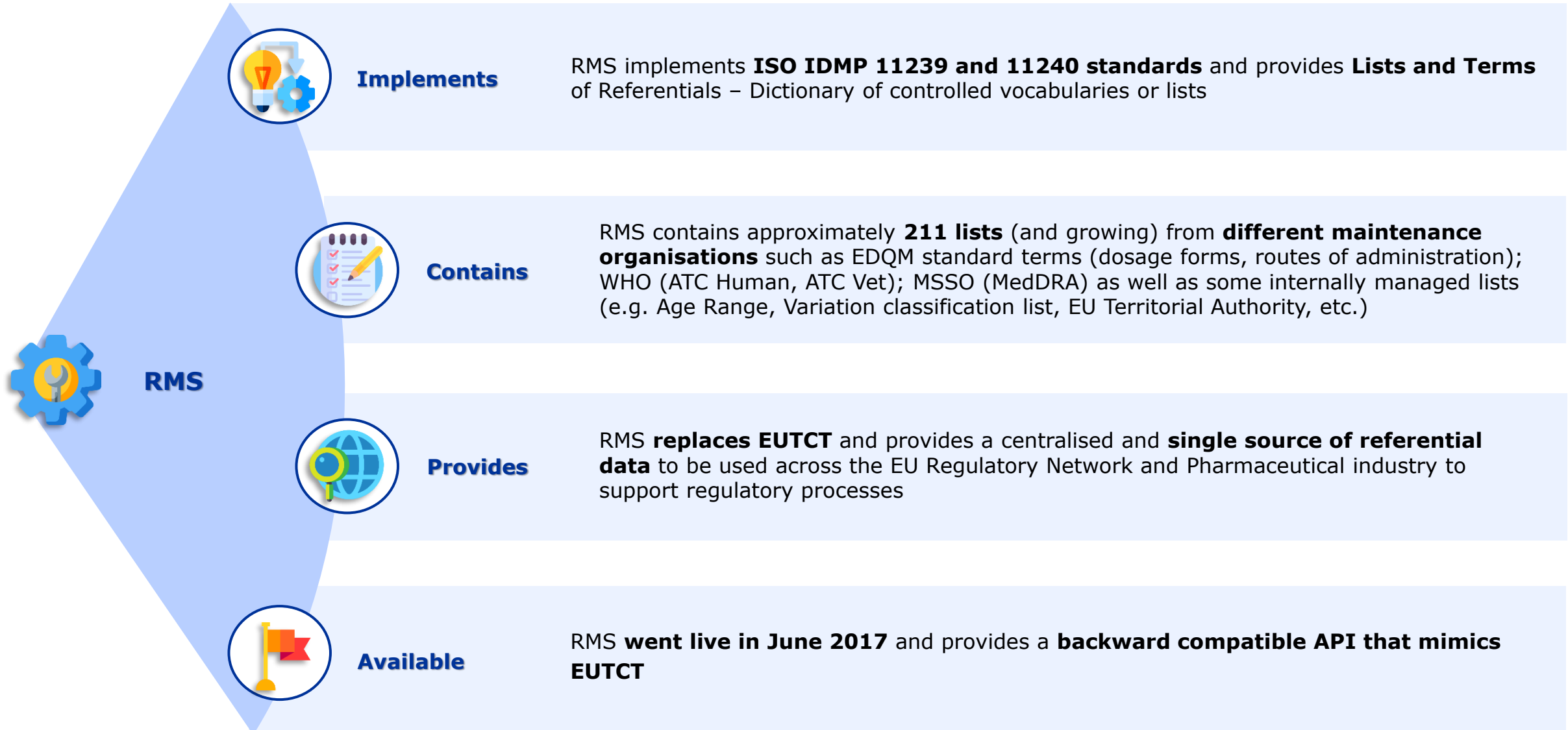


Show how RMS is addressing **customer feedback**





Introduction to RMS



As of April 2023, RMS contains **211 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 (191)

- 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 (4)

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



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

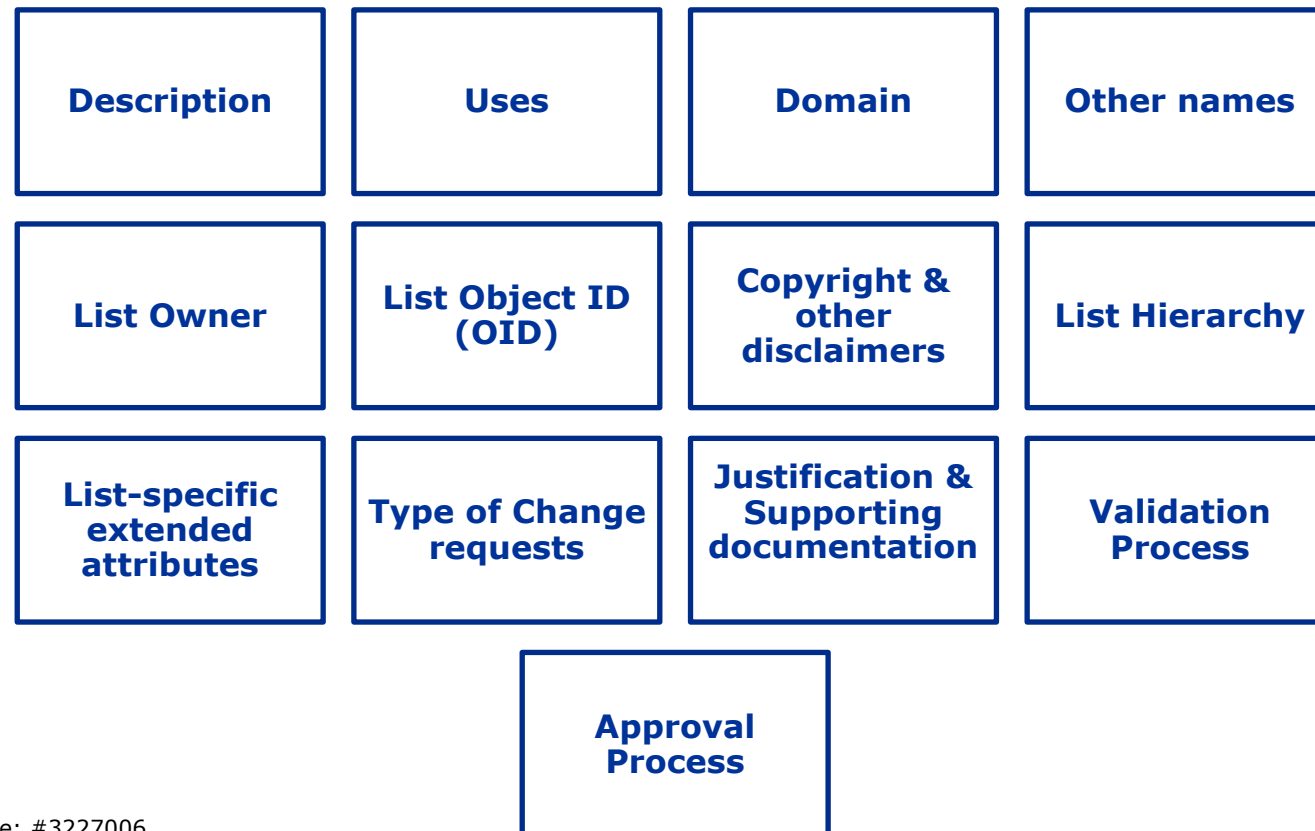
Document:

- 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**

 EUROPEAN MEDICINES AGENCY SPOR - Referentials Management System					
<div>Substances</div> <div>Products</div> <div>Organisations</div> <div>Referentials</div> <div>Help</div>					
<div>SPOR Home</div> <div>Lists</div> <div>Documents</div>					
Home / Lists					
<div> <div> <div>⏪</div> <div>⏴</div> <div>Page 1 of 2</div> <div>⏵</div> <div>⏩</div> </div> <div>Showing 100 of 146 results</div> </div>					
List Identifier ↕	List Name ↕	List Owner ▼	List Version ↕	Modified Date ↕	Actions
▶ 100000093533	Anatomical Therapeutic Chemical classification system - Human	WHO CC	2020	2020-09-29T12:00:40	Q D
▶ 100000116677	Anatomical Therapeutic Chemical classification system - Veterinary	WHO CC	2020	2020-05-14T15:19:42	Q D
▶ 100000000006	Medical Dictionary For Regulatory Activities	MSSO	23.1	2020-09-23T17:32:41	Q D
▶ 100000072057	Language	ISO		2019-12-09T10:27:14	Q D
▶ 100000000001	Age Range	EMA		2017-10-24T13:48:08	Q D
▶ 100000072049	Regulatory Entitlement Status	EMA		2020-09-07T17:19:36	Q D
▶ 200000000026	OMS Request Reason	EMA		2017-06-15T11:14:09	Q D


List Information **Document:**

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





List Identifier ↕	List Name ▲	List Owner ↕	List Version ↕	Modified Date ↕	Actions
▶ 2000000000013	Administration Method	EDQM		2022-02-14T16:38:30	Q D U
▶ 1000000000001	Age Range	EMA		2021-11-23T09:25:02	Q D U
▶ 100000093533	Anatomical Therapeutic Chemical classification system - Human	WHO CC	2022	2022-02-09T15:01:19	Q D U
▶ 100000116677	Anatomical Therapeutic Chemical classification system - Veterinary	WHO CC	2022	2022-03-01T14:45:28	Q D U
▶ 100000155046	Applicants Submission Unit Type	EMA		2021-03-22T10:19:58	Q D U
▶ 100000075859	Application Recipient	EMA		2021-11-08T10:38:11	Q D U



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SCIENCE MEDICINES HEALTH

Referentials Management Services (RMS)

EMA/72782/2017

Target Species

1. List Information

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

1.1. Description

This list describes the species for which the veterinary medicinal products are intended for.

Examples: "Adult female cat"; "Panda"; "Turkey".

The species described in this list are not a category of taxonomic classification, ranking below a genus or subgenus and consisting of related organisms capable of interbreeding. The terms in this list reflect merely a practical collection of terms used in the Product literature.

1.2. Uses

This list is used in tracking systems or in SPCs and other product literature to describe the species for which the veterinary medicinal products are intended for.

1.3. Domain

This list is for Veterinary use only.

List Information Document



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)

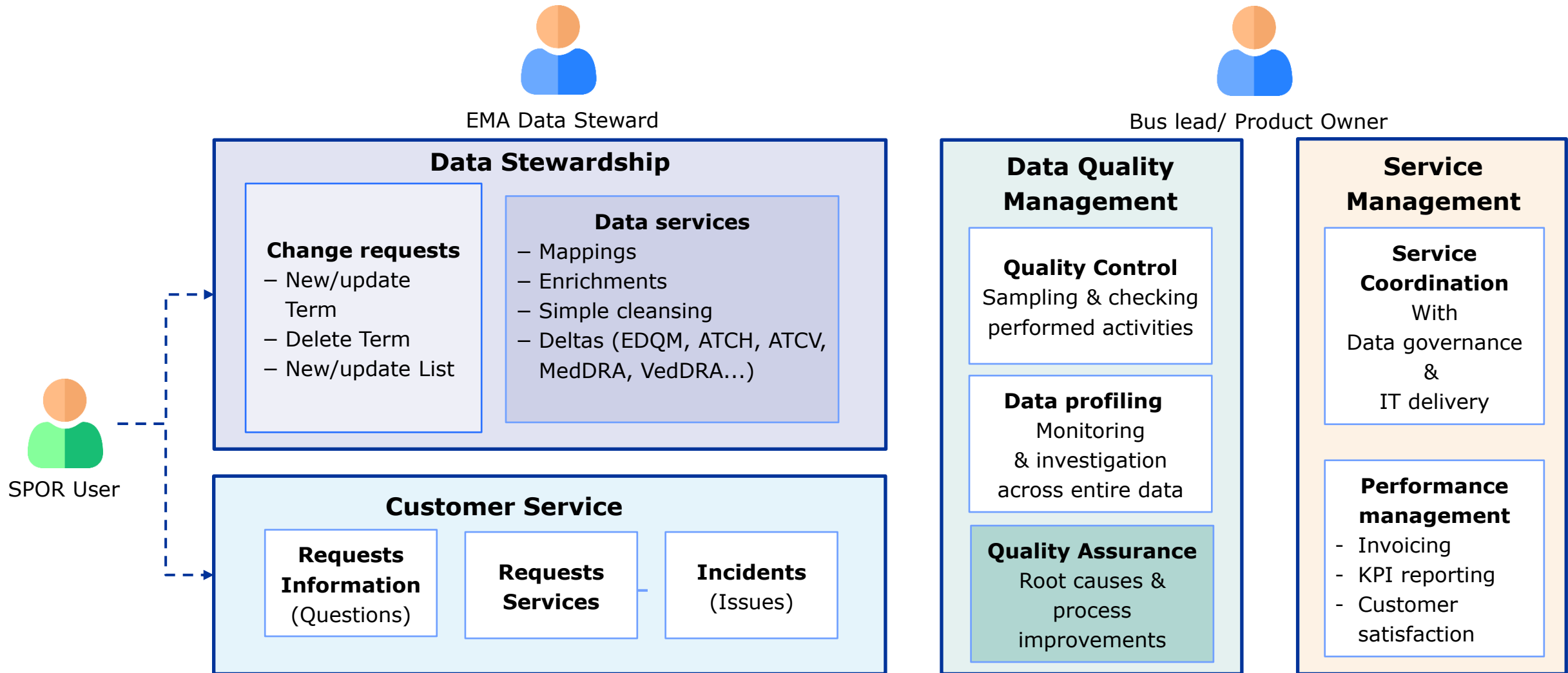


Documents

- General
- Technical
- NCA



RMS processes



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

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

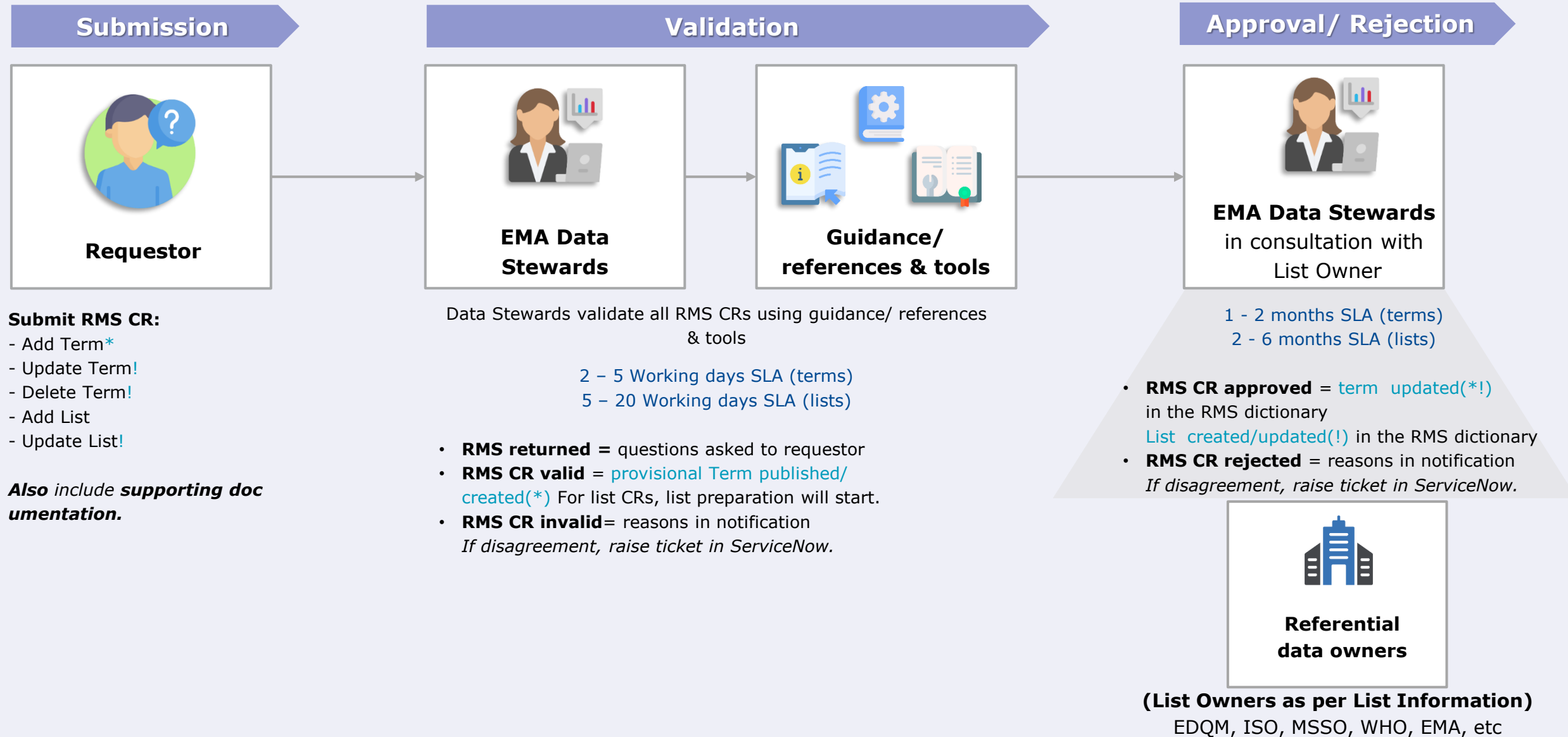


RMS Change Request process

SPOR Change Request process at a glance



EUROPEAN MEDICINES AGENCY





Change Request

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

Home / Manage Change Requests

▼ Hide search

CR ID:

CR Status:

List

Term name in CR:

CR Date: To

CR Name:

CR Type:

Requestor:

☒ My CR's ☐ All CR's

Change Request Information

Home / Manage Change Requests / Term Change Request

▼ CR Information

CR Name:*

CR Type:*

Justification:*

Requestor: gonzalezn

Contact Email:*

Contact Phone: ⁽¹⁾

Select List:*

Attachments

No documents found, click to add +

Audit trail

Date ▲	Status to ▼	Comment ▼
No data available in table		



Term Information

▼ Term Information

Show all/Hide all

Proposed Change

▼ Term Name *

▼ Current term name

+

▼ Short Name

▼ Other Names

+

▼ Term description

▼ Domain *

Human and Veterinary use ▼

▼ Parents

+

▼ Mappings

+

▼ Applicability

Country applicability

0 Selected ▼

IT application applicability

0 Selected ▼

▼ Term Symbols

+

▼ Data Classification

Public ▼

▼ Extended Attributes

Browsing your Change Requests



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Search Change Request

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

Home / Manage Change Requests

▼ Hide search

CR ID:

CR Status:

List

Term name in CR:

CR Date: To

CR Name:

CR Type:

Requestor: ☒ My CR's ☐ All CR's

View Change Requests

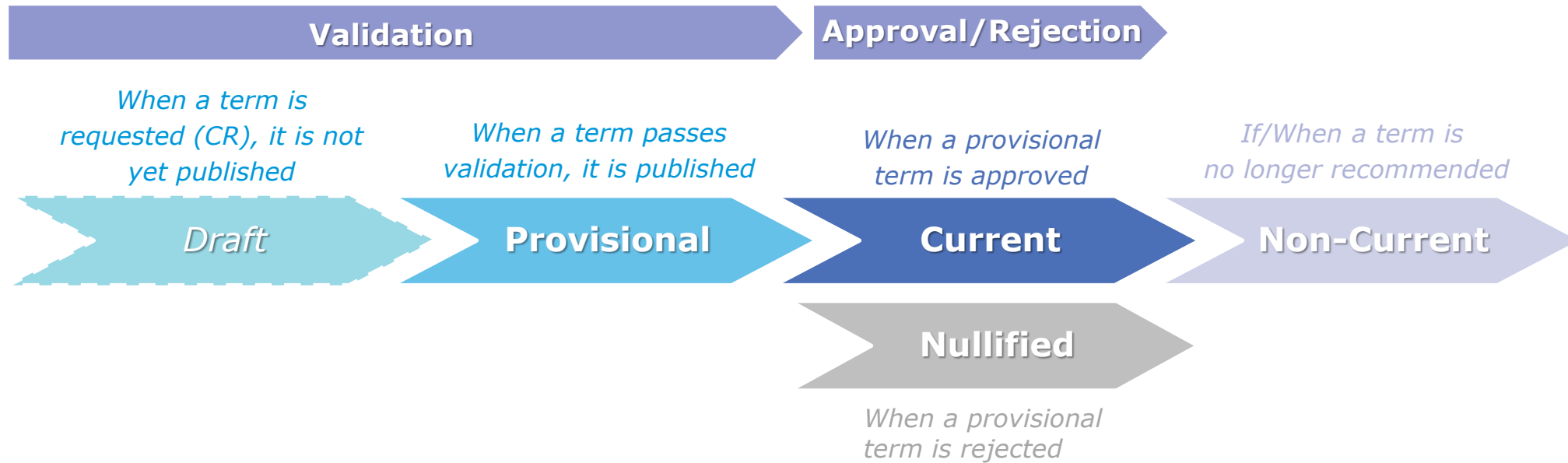
Home / Manage Change Requests

► Show search

Page 4 of 11

Showing 20 of 220 results

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	Q
RRQ-100001928	VedDRA 2014 update	UPD_LIST	gonzalezn	2020-08-13T20:21:27	APPROVED	2020-08-13T22:11:49	Q
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	Q
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	Q
RRQ-100001915	Authorisations 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	Q
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	Q
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	Q

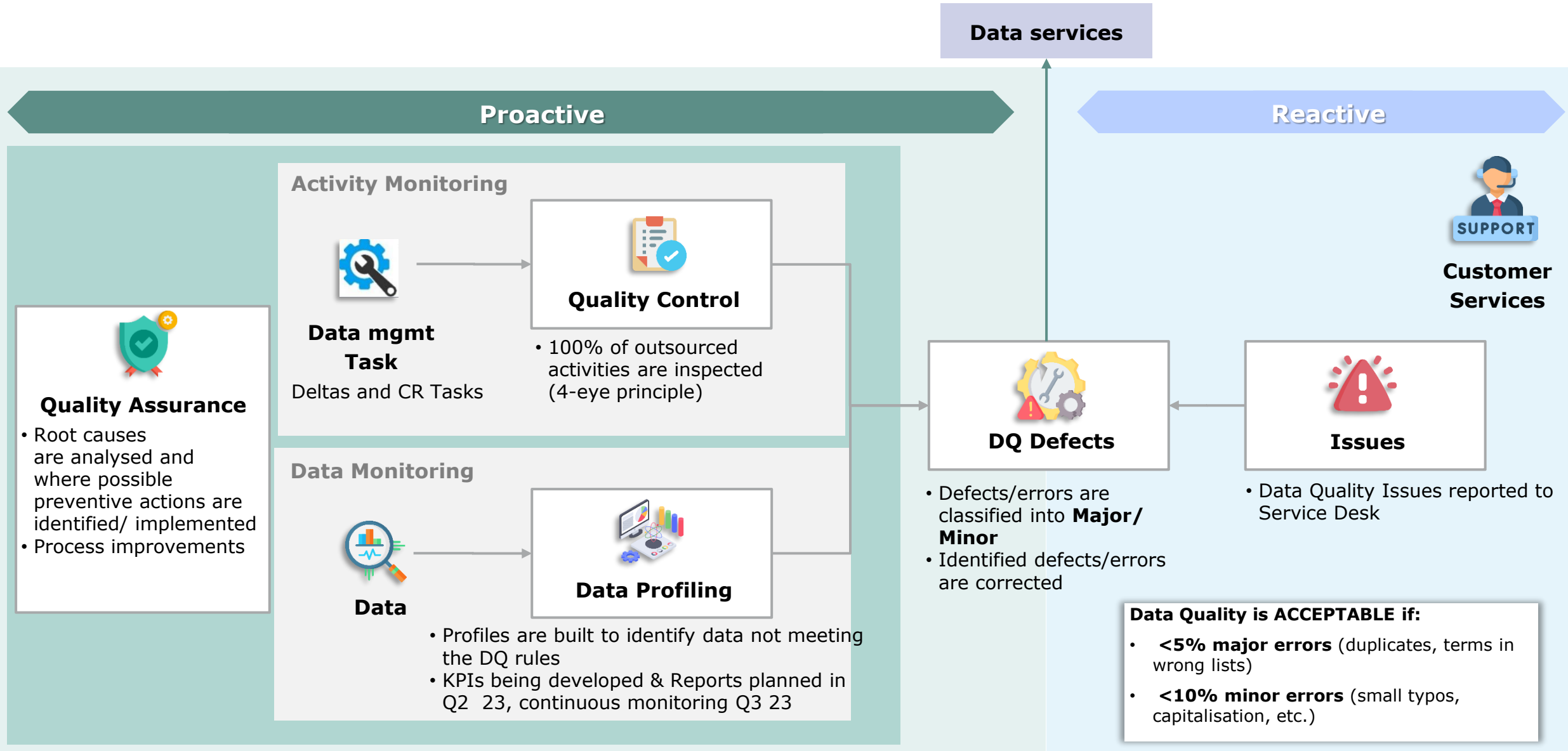


Recommended use of **RMS terms statuses** in regulatory procedures:

- 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 Data Quality Management





Data Quality Errors

Minor

- Incorrect standardisation
- Typos
- Capitalisation issues
- Issues with extended attributes

Major

- Duplicates
- Terms created in the wrong list
- Essential information missing (e.g. ATC name with ATC code missing)



Processing Errors

Minor

- *Same as minor data quality errors for data services*

Major

- *Same as major data quality errors for data services*

Minor

- Incorrect standardisation
- Typos
- Capitalisation issues
- Issues with extended attributes

Major

- Duplicates
- Terms created in the wrong list
- Essential information missing (e.g. ATC name with ATC code missing)

Minor

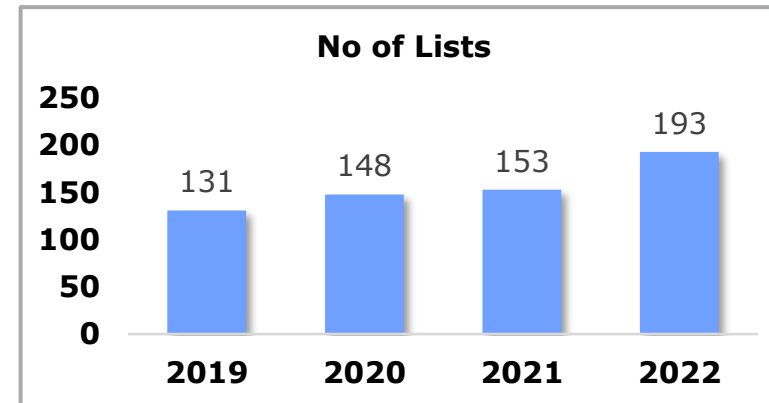
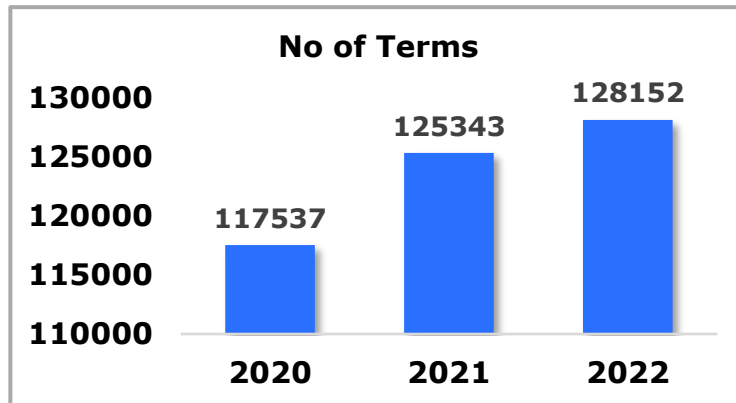
- *Same as minor data quality errors for change requests*


Major

- *Same as major data quality errors for change requests*
- Incorrect rejection/approval of a CR



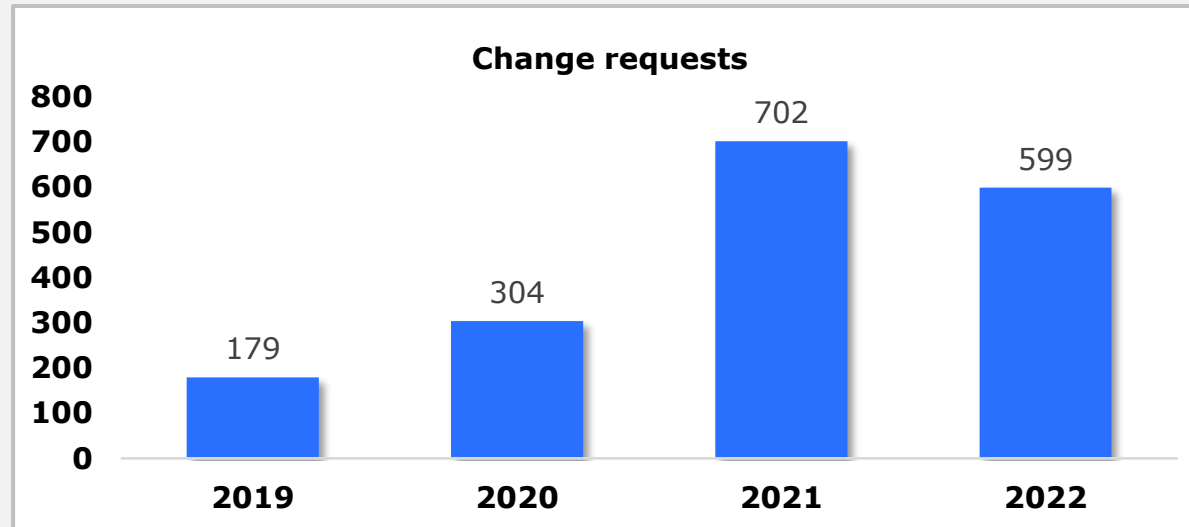
RMS Statistics



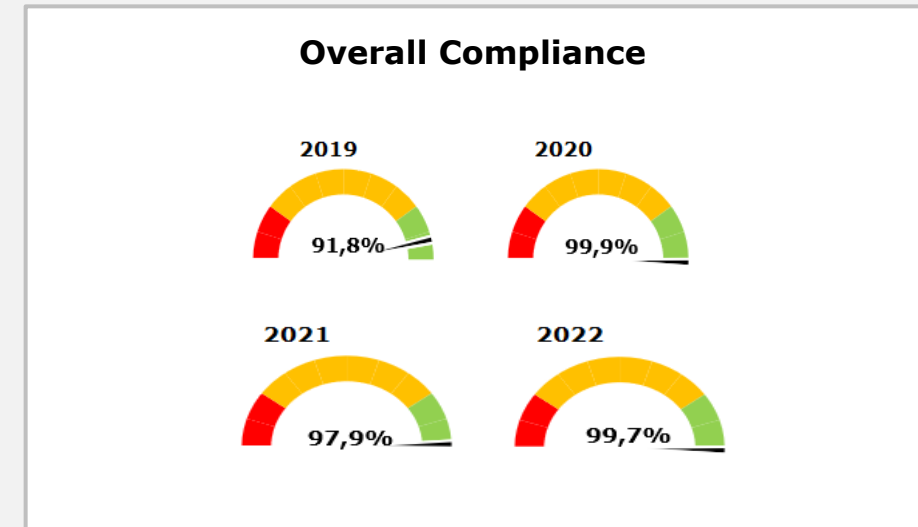
- 
- The **increase in terms** (~+2800) in 2022 was mainly linked to the creation of new lists for EMA projects and other maintenance activities (e.g. mapping activities for PMS implementation).
 - The big **increase in lists** (+40) in 2022 concerned mainly new lists required for several projects including PMS, IRIS, eAF and ASU, Real World Data, ePI and the ESMP (shortages) projects.



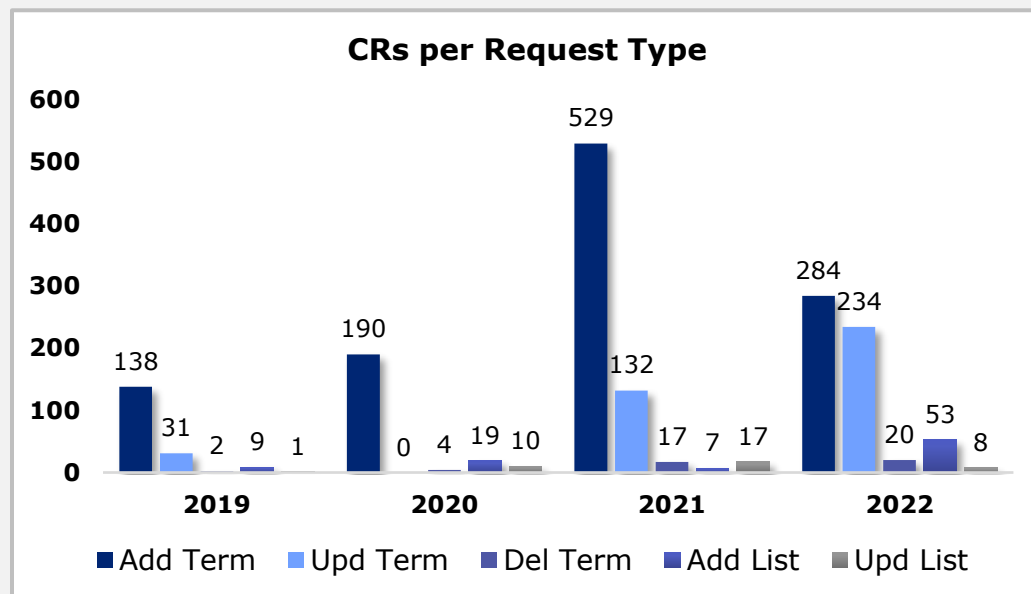
Milestone: 200th RMS list reached in January 2023!



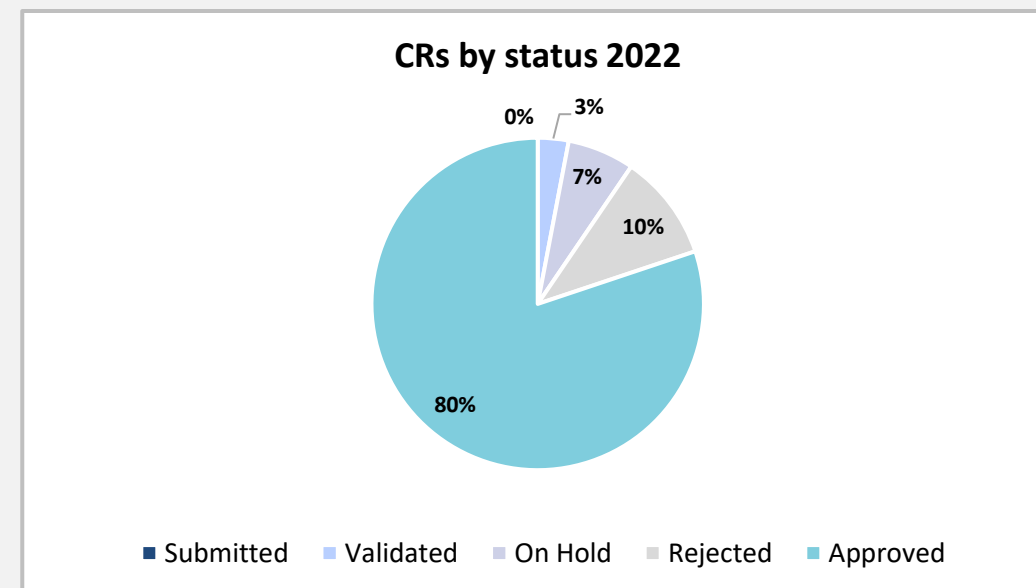
Change requests **decreased 14%** in 2022 compared to 2021, mainly because of the *exceptional peak of CRs in 2021* due to Art. 57 – RMS mapping activities, EVVET3 implementation and UPD implementation which were completed by 2022.



100% of CRs were resolved **within SLA** in 2022.

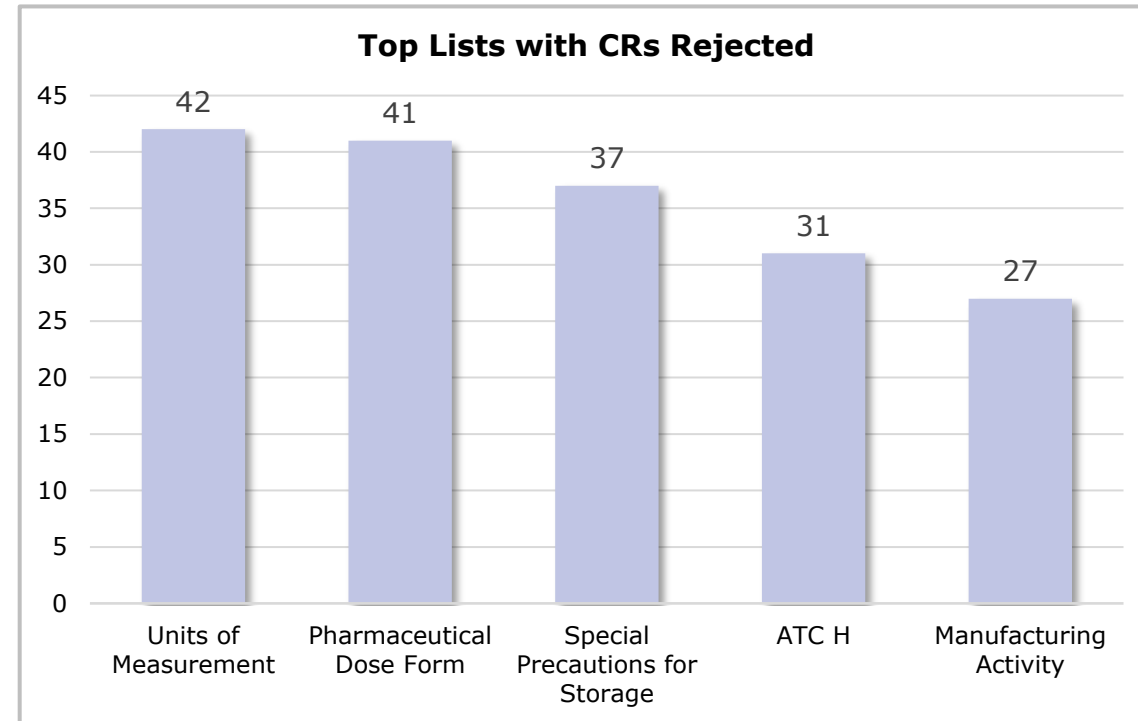
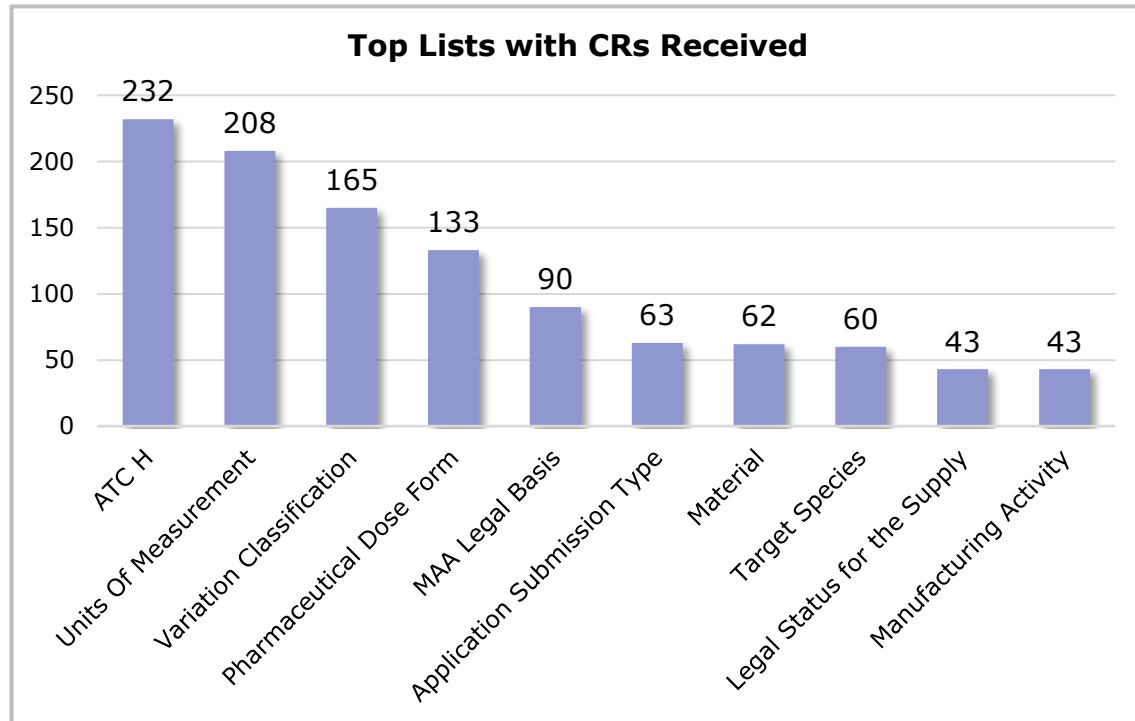


General decrease in most types of CRs in 2022 is linked to the completion of Art. 57 – RMS mapping activities, as well as UPD & EVVET3 implementation which peaked in 2021.



In 2022 the “approved” CRs continued to be the main status, and **only 13 %** of CRs were “**rejected**” which is a **17% decrease in comparison to 2021**.

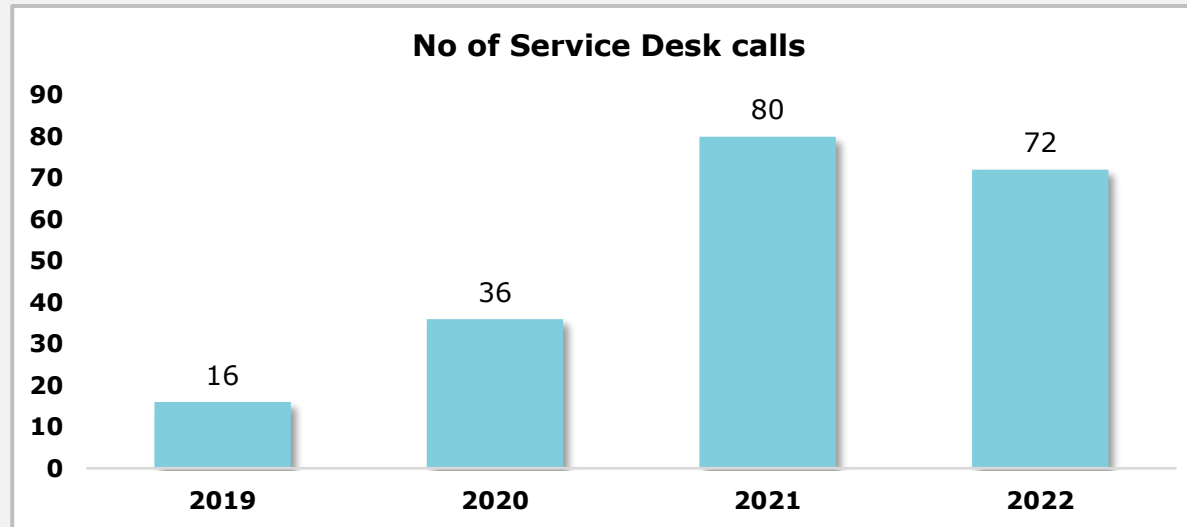




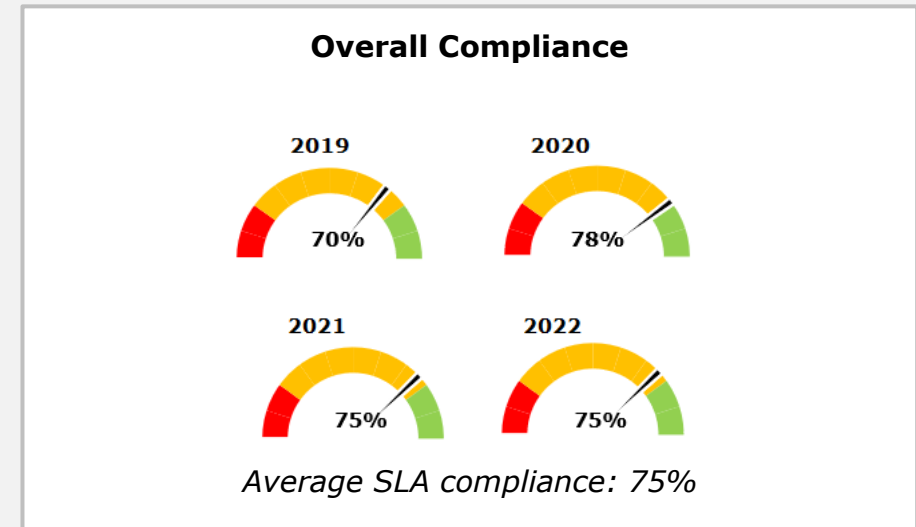
- **Rejection rate** has significantly **improved** with time (**12%** in 2022 vs **22%** overall since go live), combined with an increasingly **higher number of CRs received** (480 CRs in 2022 vs 400 CRs in 2021 and 206 CRs in 2020).
- We continue to notice that some lists are **popular and also cause many rejections**:
 - **Units of Measurement** list is the 2nd highest list in terms of CRs and the one with **most rejected CRs**;
 - **Manufacturing Activity** list ranks as the 10th highest list in numbers of CRs received and has a **rejection rate of more than 60%** (27 CRs requested out of 43).

*We remind users to **familiarise themselves with List information** for these particular lists.*





The **number of Serv desk tickets** in 2022 were in the **same order of magnitude of 2021**, with most tickets concerning questions on mapping of referentials, term details, SPOR access, list updates, translations, export of lists, versioning in RMS, etc.



75% service desk tickets were resolved **within the agreed SLAs.**

***RMS has only 72 tickets**, 13 of which could not be quickly resolved due to IT limitations which has impacted overall SLA calculations – not many customers are impacted



User Perspective

Customer Satisfaction Survey

0,00% Incidents/volume (terms)

0,006% Incidents/users

1 DQ Incident

14809 Users

128345 Terms

Customer Satisfaction



Data Services and Data Quality in RMS were **positively rated** overall:

- **78%** of the users graded **Data Services** as "Good" or "Excellent"
- **86%** of the users rated **Data Quality** in RMS Services as either "Good" or "Excellent".



RMS Documentation & Help

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

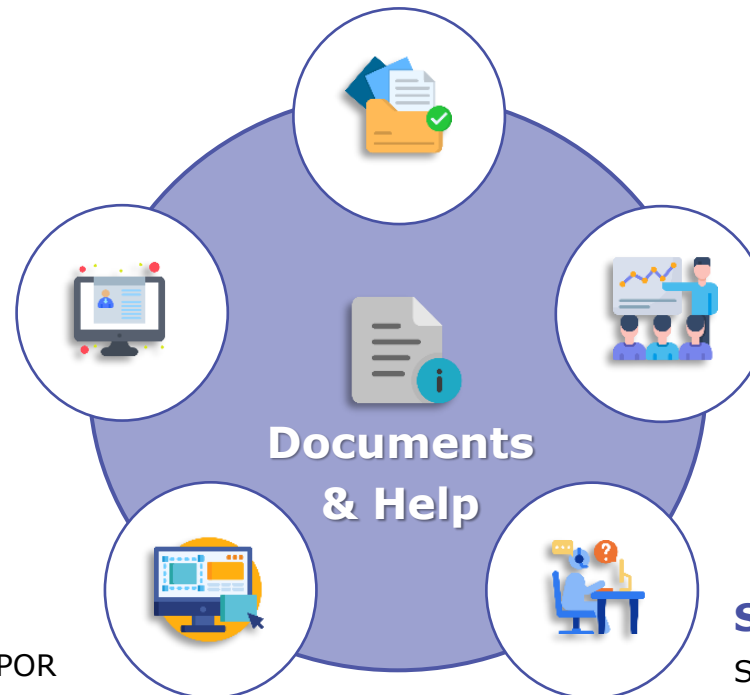
- To create a new EMA account in order to obtain access to EMA systems (including SPOR).
- To request SPOR user role.

[Account Management Portal](#).

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

EMA corporate [website](#)

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



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](#))

ServiceNow Portal

Service requests, issues, requests for technical support shall be submitted through the [ServiceNow Portal](#).

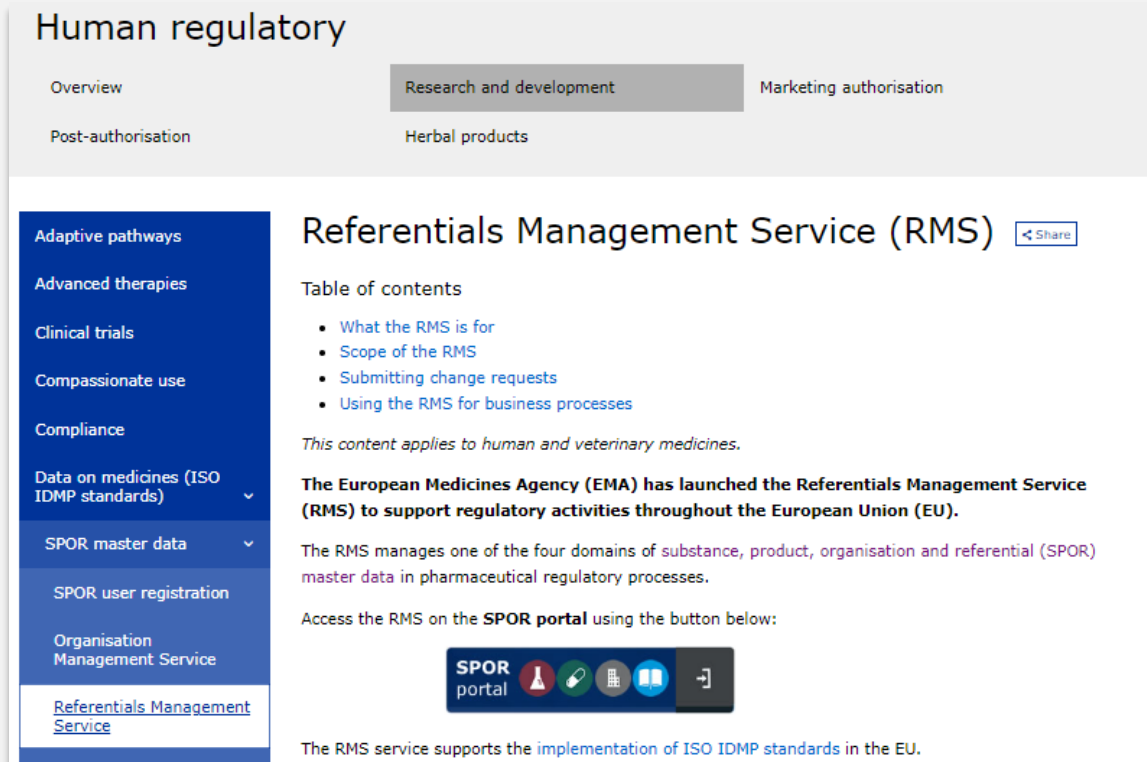
For any help needed and not found in docs.

EMA Corporate website – RMS info



What:

- Background information
- Info on SPOR projects
- RMS vision & RMS project



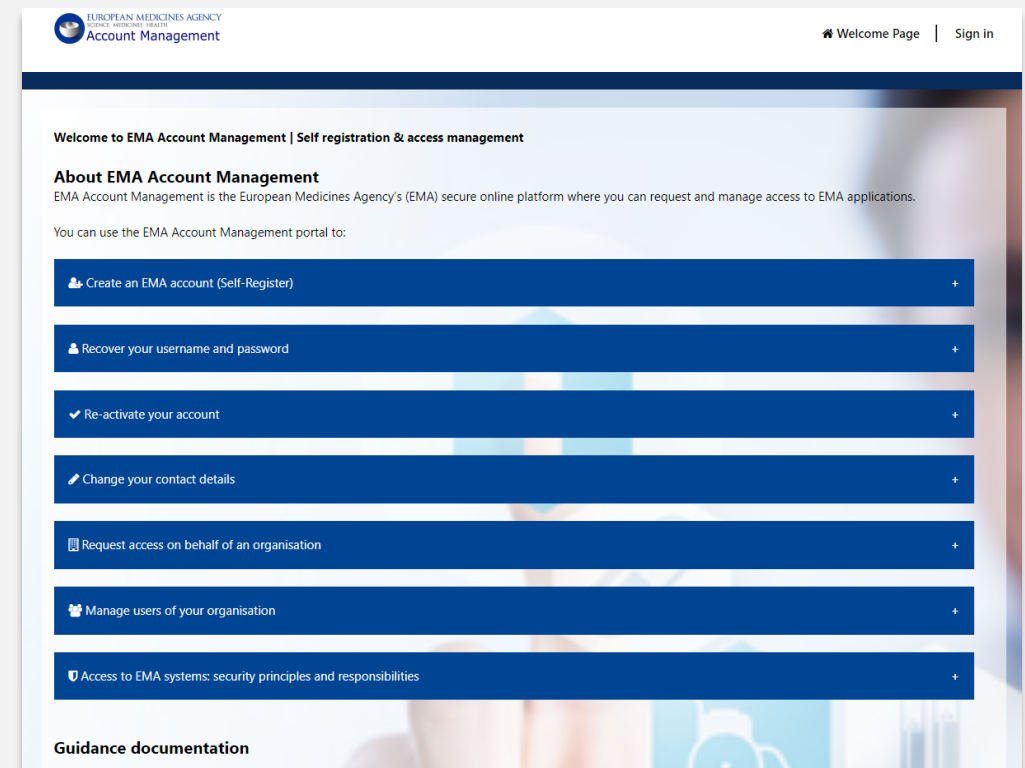
The screenshot shows the EMA Corporate website's 'Human regulatory' section. The 'Referentials Management Service (RMS)' page is highlighted. The page includes a table of contents with links to 'What the RMS is for', 'Scope of the RMS', 'Submitting change requests', and 'Using the RMS for business processes'. It also features a 'Share' button and a 'SPOR portal' button. The page text states: 'The European Medicines Agency (EMA) has launched the Referentials Management Service (RMS) to support regulatory activities throughout the European Union (EU). The RMS manages one of the four domains of substance, product, organisation and referential (SPOR) master data in pharmaceutical regulatory processes. Access the RMS on the SPOR portal using the button below:'. A sidebar on the left lists various regulatory topics, with 'Referentials Management Service' selected.

EMA Account Management



What:

- General guidance on how to register users and use IAM tool
- Detailed instructions for RMS are in a ppt in SPOR portal and in videos on youtube



The screenshot shows the EMA Account Management portal. The header includes the EMA logo and 'Account Management' text. The main content area is titled 'Welcome to EMA Account Management | Self registration & access management'. It provides an overview of the platform and lists several actions users can take: 'Create an EMA account (Self-Register)', 'Recover your username and password', 'Re-activate your account', 'Change your contact details', 'Request access on behalf of an organisation', 'Manage users of your organisation', and 'Access to EMA systems: security principles and responsibilities'. A 'Guidance documentation' section is also visible at the bottom.



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

Home / View Documents

View

Manage

General

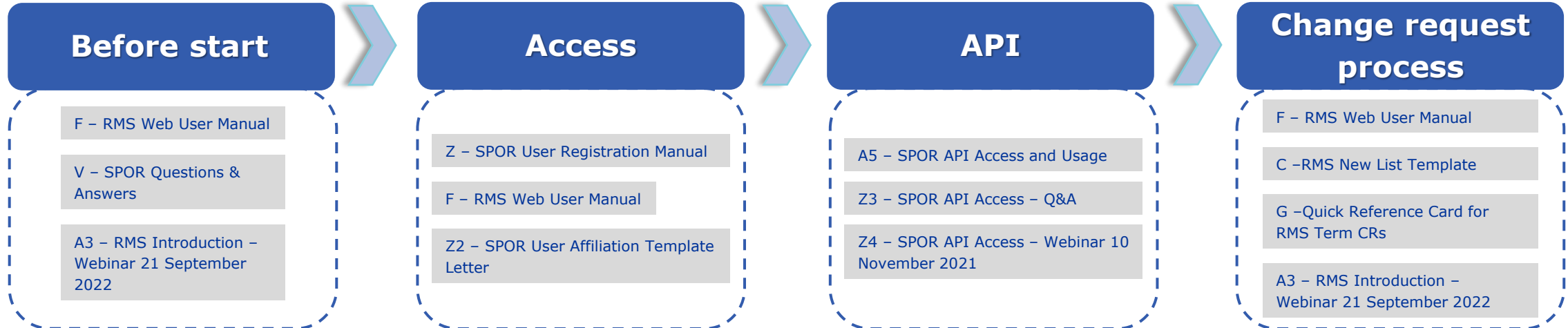
Technical

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



[RMS Web UI \(europa.eu\)](https://europa.eu)





EMA YouTube Channel



What:

- Videos of webinars, related PPTs can be found in SPOR portal

The screenshot shows the EMA YouTube channel page. The channel name is "European Medicines Agency" with the handle "@emainfo" and 17.6K subscribers. The navigation bar includes HOME, VIDEOS, LIVE, PLAYLISTS, COMMUNITY, CHANNELS, and ABOUT. A search bar contains the text "rms". The video list includes:

- SPOR Learning Module: RMS01 - Overview of RMS** (11:40, 1.8K views, 5 years ago)
- Introduction to Referential Management Service (RMS): Industry Webinar** (1:29:35, 175 views, 3 months ago)
- EMA SPOR RMS training** (11:40, 24:39, 3.3K views, 1 year ago)
- Industry Webinar - Introduction to RMS services and activities** (36:54, 3.3K views, 1 year ago)

ServiceNow - SPOR Dashboard



What:

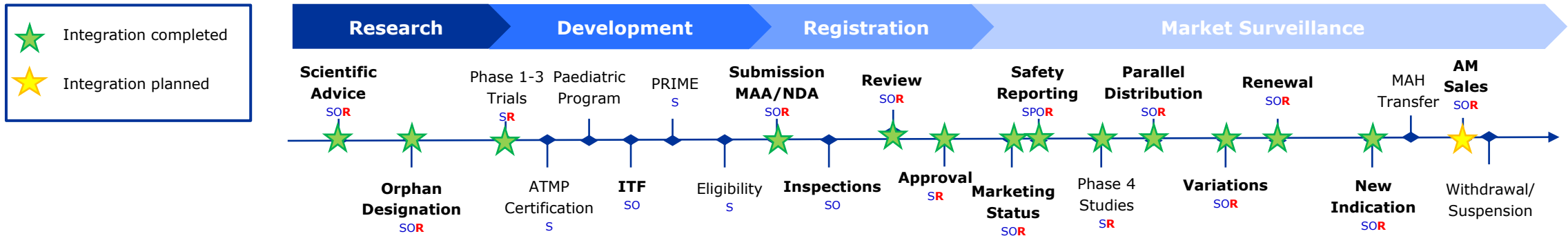
- For any help needed and not found in docs.
- Request support with an RMS CR that cannot be submitted via the RMS Portal.
- Report a technical issue with the use of the RMS Portal or Application Programming Interface (API) or to address concerns with the data in RMS.

The screenshot shows the ServiceNow SPOR Dashboard. The header includes the EMA logo, "ServiceNow", a search bar, and a "Go to BackEnd" link. The navigation bar includes IT, Facilities Support, Employee Center, and Home. The main content area is titled "SPOR" and includes a "Browse SPOR" section with filters and sort options. The dashboard displays a grid of request and report options:

- Request SMS services**: Request assistance with the management of substance...
- Request XEVMPD/Art.57...**: Request assistance with the management of product...
- Request OMS services**: Request assistance with the management of...
- Request RMS Service**: Request assistance with the management of referential...
- Report an Issue with SMS**: Report an issue with the Substance Management...
- Report an Issue with XEVMPD/Art.57**: Report an issue with the eXtended EudraVigilance...
- Report an issue with OMS**: Report an issue with the Organisation Management...
- Report an issue with RMS**: Report an issue with the Referentials Management...
- Request SPOR API Services**: Questions and access request to the SPOR API...
- Report an Issue with SPOR API**: Report an issue with the SPOR API access or conte...
- Report an Issue with PMS**: Report an issue with the Product Management...



RMS in Projects/Systems



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



Planned RMS activities



Q1 2023

Q2 2023

Q3 2023

Q4 2023



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

Revised SLAs for list updates (including translations)

1

RMS – XEVMPD daily synchronisation

2

New service – Provision of translations by NCAs via List Update CR

RMS – Data Quality

Deltas - Enrichments – New lists

3 ATC H&V 2023

New lists for IRIS

MedDRA 26.0

EMDN (tbc)

MedDRA 26.1 + VedDRA 2023

New Lists for CTIS (tbc)

New Lists for Real World Data

4

Process improvement – data profiling & monitoring

DQ improvements – inc term description, & replacement terms for non-current terms

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

STWP plenary

SPOR week

List Publication webinar

Translations webinar

RMS webinar

SPOR Customer Satisfaction survey

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, harmonisation of SPOR access rights)



Improve customer satisfaction and success



Modernise Data & Information Management



WHY



HOW & WHEN



IMPACT to users:

RMS – XEVMPD daily synchronisation

Required for successful PMS & eAF implementation - failure to follow this process may result in synchronisation issues with products and issues with the use of eAF.

- All terms from the relevant XEVMPD lists are created in RMS and EudraVigilance – Planned start Q2 2023
- Creation of proposed terms in XEVMPD to be blocked – date tbc (deltas will have to be considered until this is the case).

Get used to requesting terms to RMS first as this will be discontinued in XEVMPD

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 Q2 2023

- NCA submits change request – list update + attach Excel template with translations
- EMA team to upload translations on behalf of NCA

Enhanced support to ensure speedy availability of translations in the RMS portal

2



WHY

Faster publication of updates to external lists (ATCH, ATC V, MedDRA and VEDDRA) is required



HOW & WHEN

Lists will be updated within 1-2 months of publication by list owner – Q2 2023



IMPACT to users:

Faster updates to external lists (ATCH, ATC V, MedDRA and VEDDRA) should minimise CRs & improve lists usage experience

Data Quality - Deltas

3

RMS Data profiling & monitoring

Improve RMS Data Quality

Increased RMS resources resulting in increased checks of data quality.

- Build reports of data quality aspects to look at (e.g. non-current terms without replacement; terms without descriptions, terms without translations, etc.) – Q2 2023
- Create process to monitor, inspect and correct weekly - Q3 2023

Data quality improvement – users should see improved data quality in RMS

4

Documentation

Reacting to feedback from customer satisfaction survey where customers demanded more/better documentation

- Master list information – document consolidating in one place the details/information for all lists in RMS (& subsequent updates) – Q2 2023
- What's new/News - information of topics/items under discussion or for implementation – Q3 2023
 - Review/ of list information docs – 2023

Enhanced supporting documentation allowing improved awareness

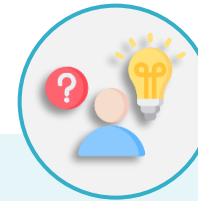
5



WHY

RMS API versioning

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



HOW & WHEN

Enable to retrieve historical/older term versions via API – tbc Q4 2023

MedDRA API

Improve data quality (currency of data)

Consume the MedDRA updates live from MedDRA API instead of MedDRA 6-monthly updates – assessment/feasibility Q2 2023; implementation tbc Q4 2023

Background

- RMS SLA for **list updates** is **2-6 month** after publication by list owner
- MedDRA is updated 2x/year
- ATC H, ATC V, VEDDRA, is updated 1x/year

RMS Services over time



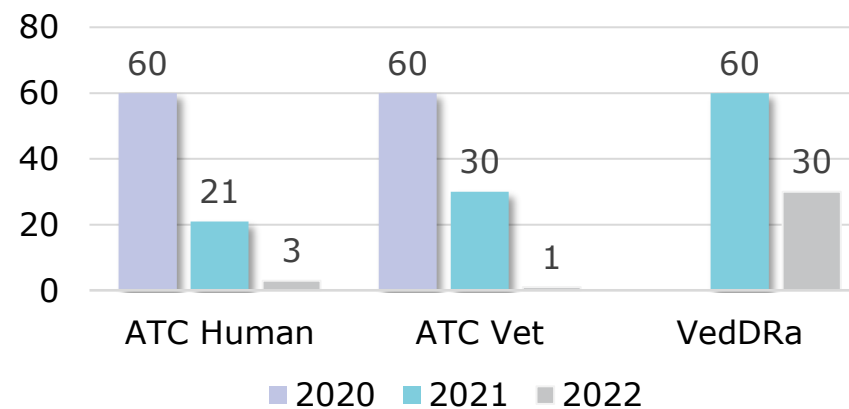
Conclusions

- The RMS team is **updating** external lists **within the agreed SLAs**.
- **Publication times have been improving over the years.**

Next steps

- RMS team is committed to do these **updates in a shorter period!**
- See revised List update SLA in the next slide

Days waiting for list publications



CURRENT LIST UPDATE SLAs

Type of request	75% of requests	90% of requests	Expected outcome
Update List	<ul style="list-style-type: none"> Validated within 15 working days. Resolved within 2 months when owned by RMS. 	<ul style="list-style-type: none"> Validated within 20 working days. Resolved within 6 months when owned by RMS. 	The list is updated if the request is validated and approved.



PROPOSED LIST UPDATE SLAs

Type of request	75% of requests	90% of requests	Expected outcome
Update List - by List Owner (e.g. ATC H/ATC V/MedDRA/VedDRA)	Validated within 5 WD Resolved within 1 month	Validated within 10 WD Resolved within 2 months	The list is updated if the request is validated and approved.
Update List - translations (as provided by NCA translator)	Validated within 5 WD Resolved within 1 month	Validated within 10 WD Resolved within 2 months	The list is updated if the request is validated and approved.
Update List - not requiring List Owner/SME consultation (e.g. changes already endorsed by CVMP/CHMP/QRD)	Validated within 5 WD Resolved within 2 months	Validated within 10 WD Resolved within 2 months	The list is updated if the request is validated and approved.
Update List - requiring List Owner/SME consultation (e.g. major updates or structural changes to lists)	Validated within 5 WD Resolved within 2 months	Validated within 10 WD Resolved within 6 months	The list is updated if the request is validated and approved.



Summary of improvements

- **Faster validation** throughout from 15-20 WD to 5-10WD – informing foreseen SLA & giving predictability to users
- **New service** for uploading Translations – 1-2 months
- **Faster and more targeted resolution:**
 - Update List – by List Owner
i.e Externally managed lists from 2-6 months to 1-2 months
 - Update list – not requiring List Owner/SME consultation - from 2-6 months to 1-2 months
 - Update list requiring List Owner/ SME consultation – **unchanged** - still 2-6 months – as this requires frequent/lengthy consultations



Key Takeaways and 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*

SPOR week is a **full week of webinars** during which EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

 Webinar title	 Date	 Time
<u>SPOR and XEVMPD Data Governance</u>	17 April 2023	10:00-12:00 CET
<u>Service Desk for SPOR and XEVMPD</u>	17 April 2023	14:00-16:00 CET
 <u>Referentials Management Service (RMS)</u>	18 April 2023	10:00-12:00 CET
<u>Organisation Management Service (OMS)</u>	18 April 2023	14:00-16:00 CET
<u>Substance Management Service (SMS)</u>	19 April 2023	10:00-12:00 CET
<u>Product Management Service (XEVMPD)</u>	19 April 2023	14:00-16:00 CET
<u>Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API</u>	20 April 2023	10:00-12:00 CET
<u>EMA Account Management</u>	20 April 2023	14:00-16:00 CET



Any questions on the webinar?





Further information

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Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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