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**.*

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Housekeeping notes – Q&A

Join at
slido.com
#8749 717

- 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.***

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SCIENCE MEDICINES HEALTH

SPOR API

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

Presented by Adrian Costeanu and Angel Sempere Sanchez

SPOR Webinar Series – 2-12 October 2023

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: #8749717

Goals of the session

Introduction to and update on the SPOR API v1

Provide concrete examples of how to use the API

Guide API users to relevant documentation and support

Share latest SPOR API news and planned features and improvements

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Agenda

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1. Welcome
2. Why use an API? (SPOR API V1 vs V2)
3. Request access to SPOR API
4. SPOR Help, Support & Communications
5. API resources and concepts
6. API demo and tips 
7. SPOR API News 

8. Planned Features and Improvements 

9. Key takeaways and Conclusions 
10. Q&A Session
11.




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Why use an API?

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API – A definition (1/2)

- Some aspects of an API (from Wikipedia)
  - *"It is a set of **routines**, **protocols**, and tools for building software applications."*
  - *"It expresses a **software component** in terms of its **operations**, **inputs**, **outputs**, and **underlying types**."*

- An API is *not:*
  - A software component that you install on a computer.
  - A process that automates human activities.
  - An end-to-end system where your NCA is 1 end and EMA the other end.
  - "Active Product Ingredient"

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API – A definition (2/2)

*"It expresses a **software component** in terms of its **operations**, **inputs**, **outputs**, and **underlying types**."*

Element	Description
Software component	System hosted at EMA
Operations	Search, read and write
Inputs	Search terms, documents, metadata attributes
Outputs	Documents, metadata attributes
Underlying types	PSUR (eCTD & NeeS), Assessment Reports, AR Comments, Recommendation, substances, products, …

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API – Why should you use it?

APIs are ideal for **machine-to-machine integration**:

- It offers a set of services to exchange data based on parameters that identify the business objects
- Returns responses structured conveniently to be parsed using popular programming languages
- It does not focus on human interaction and presentation, but rather in machine-processable presentation

APIs let clients **consume the data according to their business needs**:

- In big chunks and short number of interactions
- In small chunks, as soon as they are available
- Of only certain entities that they are interested in
- Although APIs are machine oriented, often they are human-readable to simplify their adoption and allow other use cases (low code integrations, BPM engines, exports for human users…)

APIs allow users to automatically search, browse, export, determine changes to data and **keep data constantly synchronised** with their local system (unlike a UI that you cannot automate or easily figure out what changed)

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API – How to start

1. Read a **brief overview on** API types and use cases
   - *What is an Application Programming Interface (API)? | IBM*
   - *What is an API? | (API) Application Program Interface Definition (axway.com)*
2. Choose a **tool to start requesting** to public APIs
   - *Postman is a complete and free application (Sending your first request | Postman Learning Center)*
3. Explore **free APIs**
   - *Dog API by kinduff*
   - *Free Dictionary API*
   - *API - RijksData (rijksmuseum.nl)*
   - *… or many more (GitHub - public-apis/public-apis: A collective list of free APIs)*

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Overview of the API

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API – Users and technicalities

Users:

Registered users and with appropriate capabilities

- User must be registered in the EMA Account Management Portal
- The API access is authorised if:

1. The user belongs to an organisation
2. The user can demonstrate the understanding of the API specification

Technicalities:

1. **Protocol:** HTTP (secured) with basic authentication
2. **Message representations:** XML (default), JSON, Zipped CSV (in some endpoints)
3. **Architectural style:** RESTful Web Services.

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SPOR V1 vs V2

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ted

The SPOR API comes in two parts: V1 and V2

SPOR V1:

Provides access to RMS and OMS resources, not FHIR

- Access granted to any user upon request – see next section

SPOR V2:

Provides access to PMS and SMS resources

- Both SMS and PMS are currently under development of significant features including their API
- Both APIs implement the **FHIR Standard v4.4.0 (R5 Preview #2)**
- OAuth2 authorisation approach for when fully public
- SMS – access granted to NCAs and EMA – Request to the EMA Service Desk
  - *NCA and Industry access management on roadmap for Q4 2023*
- PMS – currently access granted to EMA only
  - *NCA access management on roadmap for Q4 2023, Industry in 2024*

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SPOR API V1 Statistics

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400,000 API calls in 24h on average

- 100k OMS API calls
- 160k RMS API calls
- 120k coming via WebUI

15% increase compared to 6 month ago

165
Registered accounts
serving over 69k users

20% increase compared to 6 month ago

Busiest periods for RMS

- 2AM-4AM
- 6AM-8AM
- 8AM-10AM

Busiest periods for OMS

- 8AM-10AM
- 10AM-12AM
- 6AM-8AM

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Request access to SPOR API

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Request access to SPOR API

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SPOR Portal

- RMS & OMS dictionary are available on the (Production) SPOR Web portal
  - http://spor.ema.europa.eu/sporwi/
- SMS Substances export is also available here on its own page https://spor.ema.europa.eu/smswi

- Please read the documentation available in the SPOR Portal (Documents->View), particularly:
  - Z3 - SPOR API Access - Q&A
  - Z4 - SPOR API Access - Webinar 27 November 2017
  - Z5 - EMA - API General Terms of Service - Terms of Use
  - Z6 - SPOR API Access Request Form
  - Z7 – SPOR API Access and Usage – Webinar 18 March 2022

EMA Account Management Portal

- EMA Account management system that provides functionality for users to manage their accounts, passwords and access to various EMA applications (including SPOR);

- There are two different environments which API access requestors will need to use to complete their registration process:
  - UAT environment: https://register-test.ema.europa.eu/
  - PRODUCTION environment: https://register.ema.europa.eu/

EMA Service Desk Portal

- EMA Service Desk for information technology (IT) systems.
- https://support.ema.europa.eu/

- API access requestors will need to use this system to request API access

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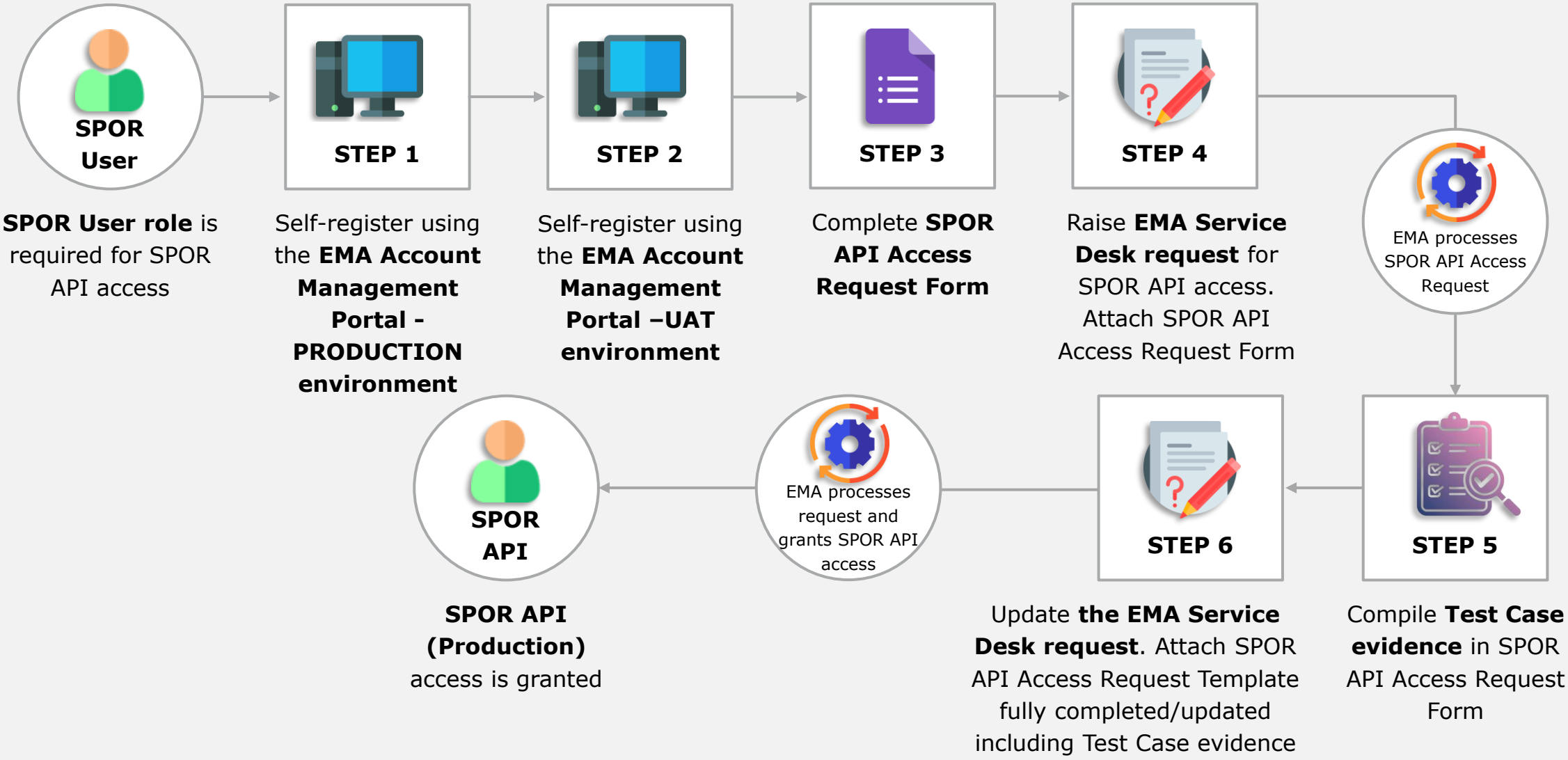
Request access to SPOR API



SPOR User role is required for SPOR API access

Self-register using the **EMA Account Management Portal - PRODUCTION environment**

Self-register using the **EMA Account Management Portal –UAT environment**

Complete **SPOR API Access Request Form**

Raise **EMA Service Desk request** for SPOR API access. Attach SPOR API Access Request Form

Compile **Test Case evidence** in SPOR API Access Request Form

Update **the EMA Service Desk request**. Attach SPOR API Access Request Template fully completed/updated including Test Case evidence

SPOR API (Production) access is granted

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Request access to SPOR API

SPOR User role is required for SPOR API access

Self-register using the **EMA Account Management Portal - PRODUCTION environment**

1. Self-Register using the **EMA Account Management portal - PRODUCTION environment**:

- Include your organisation and API e.g."PharmaCo Ltd. API" as first and second names so that the username is constructed from those values to simplify identification.
- A unique e-mail address should be used for the API. Do not use somebody else's personal email address as they may use it to self-register in future at the EMA Registration Portal.
- Affiliate yourself to the right Organisation. If the Organisation does not exist please submit a Change Request to OMS.
- Once self-registered, request an Industry User role (or NCA Translator / NCA User role). Note that the organisation must have first registered a Super User.

Even if you are already a registered user (i.e have valid user credentials) a new dedicated user should be created for SPOR API (PRODUCTION) access.
This user needs to be affiliated to the relevant Organisation to be able to see the corresponding Change Requests (CRs).
A SPOR User role (Industry Super User/User; NCA Super User/User/Translator) is also required to enable adequate access/permissions.

Self-register using the **EMA AM Portal –UAT environment**

Self-Register using the **EMA Account Management portal - UAT environment:**

The registration process needs to be replicated as in the production EMA account management portal.
However:

- if the Organisation does not exist please choose any available Organisation
- The Organisation will still need to have a super user assigned to it before you can submit an Industry User / NCA translator or NCA user role.

To receive SPOR API access you will need to perform certain Test Cases in a dedicated TEST/UAT environment.
This step may not be required if these Test Cases have already been executed e.g. by your Software provider.

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Request access to SPOR API

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Complete **SPOR API Access Request Form**

- The tab "SPOR API Access Request" must be completed before submitting the request for access to SPOR API - See below instructions for "SPOR API Access Request"
- The tabs "RMS Test Cases" and "OMS Test Cases" can be completed before/during the request for SPOR API access and must be completed for access to be granted - See below instructions for "Test Cases".

- Raise **EMA Service Desk request** for SPOR API access.
- Attach SPOR API Access Request Form

Compile **Test Case evidence** in SPOR API Access Request Form

Compile **Test Case evidence**
• Verify the integration with UAT API and perform relevant Test Cases
• Compile test evidence or relevant references
• Complete SPOR API Access Request Form - RMS Test Cases and/or OMS Test Cases or SPOR API Access request

If you do not need to carry out the Test Cases (e.g. they were previously carried out by your Software provider), you should still submit evidence of the Test execution (reference to the original request) and of your relationship with such 3rd party provider.
You can do this together with step 3.

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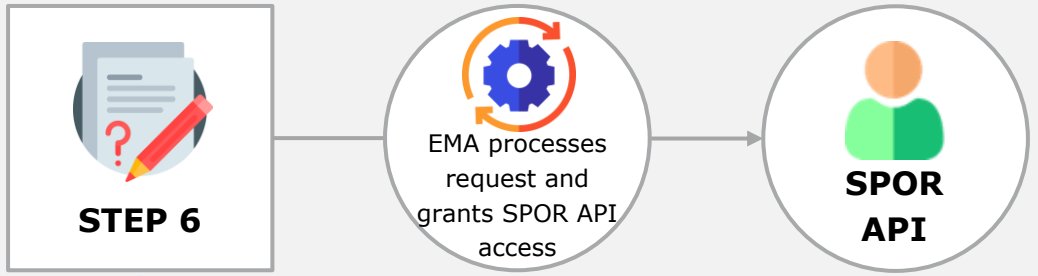
Request access to SPOR API



SPOR API (Production)
access is granted

Update **the EMA Service Desk request**.
Attach SPOR API Access Request Template fully completed/updated including Test Case evidence

Update the EMA Service Desk request (or raise a new one) for SPOR API access:

- Attach the SPOR API Access Request Form fully completed/updated including Test Case evidence.

Outputs from the UAT test cases must be submitted with a final request to confirm access to the Production API.
EMA will validate test outputs and process the API access request.

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SPOR Help, Support & Communications

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SPOR Help & Support

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SPOR stakeholders

Industry Super User

Industry User

NCA Super User

NCA Translator

NCA User

Single entry point for questions, requests and incidents.

For all types of users.

SPOR support

EMA Service Desk via
EMA Service Desk portal

IT Support

IT incidents, like service availability, access restrictions, API-related requests and questions)

Business support

Business requests, data corrections

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Monitoring of the system

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Overview of the process

- The health of the system is being continuously and automatically monitored
- If issues are identified, our team is notified and will analyze and initiate corrective action
  - Within EMA business hours: Immediately
  - Outside of EMA business hours: As soon as possible
- If the issue cannot be resolved within a limited period of time (typically 4 hours), a notification is posted in the ServiceNow portal, informing about the issue and, if appropriate, any workarounds.
- Over the last few months, the system has extremely stable and on the two occasions we had an incident, we have been able to recover within max an hour.

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OMS/RMS portal - documents

OMS Web UI (europa.eu)

OMS portal Documents:

- Link access to export the document
- Short description of document content
- Last update date

See the section "Where to find information" for the list of all related documents

General | Technical

Page 1 of 1

Document Name ▲	Document Description
OMS Conceptual Data Model	The Conceptual Data Model of OMS
OMS Logical Data Model	The Logical Data Model (LDM) implemented in OMS
OMS Logical Data Model for MDM - documentation	Description of the elements in the OMS Logical Data Model
RMS and OMS 2.02.02 release notes	Improvements introduced with the version 2.02.02 release for RMS and OMS
SPOR API sample payloads	Example of the use of API calls available in the OMS/RMS solution
SPOR Integration Patterns	Contains description based on the API Specification on how to combine multiple calls to achieve specific business scenarios
SPOR-API-Specification	Technical specification of the Application Programming Interface (API) which provides access to SPOR services
XSD schema	XSD schema example for the SPOR API

Domain specific Data models and documents

SPOR API key technical documents – see also next section

General | Technical

Document Name ▲	Document Description	Published Date
A - About OMS	General - Legal disclaimer, copyright and other policies of using Organisation and Location data.	2017-06-26
A1 - OMS Introduction - Webinar 21 October 2021	Webinar - OMS Key principles, services and activities - 21 October 2021	2021-02-04
A2 - Quick initiation process flow	Guidance - Quick reference guidance for first time users: introduction, access and add/update records	2022-02-03
A3 - OMS FAQs	Guidance - OMS Frequently Asked Questions	2023-02-13
A4 - OMS Introduction - Webinar 10 March 2022	Webinar - OMS services, activities and statistics - 10 March 2022	2022-03-14
A5 - OMS News Items	NEWS - Recent changes implemented, open discussions, future discussions and upcoming functionalities	2023-02-23
A6 - OMS Introduction - Webinar 15 September 2022	Webinar - OMS services, activities and statistics - 15 September 2022	2022-09-20
B - OMS 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 - OMS Data Quality standards	Guidance - Data quality standards applied in OMS	2023-03-09
C1 - OMS DQ - Webinar 25 September 2018	Webinar - Key principles and rules covered in OMS Data Quality standards - 25 September 2018	2018-11-19
C2 - OMS DQ - Webinar 26 February 2019	Webinar - OMS Data Quality Issues - 26 February 2019	2019-08-16
C3 - OMS Guidance on Assessing Organisation Names and Location Data	Guidance - When minor differences between organisation names and location data are acceptable	2021-02-16
C4 - OMS Mapping Guidance	Guidance – Process for mapping and when to create an OMS change request	2021-06-02
D - OMS Controlled Vocabularies	Guidance - Controlled vocabularies used in OMS	2017-06-16
E - OMS Change Requests	Guidance - Rules and Supporting documentation required by change request type	2023-01-23
F - OMS Web User Manual	Manual - How to search, view, export data and request a new/updated data in OMS web Portal.	2018-04-17
G - Using OMS data in eAF - Webinar 27 June 2018	Webinar - OMS landscape and its use in eAF and in CESP in the future - 27 June 2018	2018-06-27
G1 - Q&A on eAF Mandatory use of OMS	Process - OMS mandatory for CAPs from November 1st onwards - Questions and Answers	2021-10-06
H - Manufacturer organisations in the OMS dictionary	Process - Manufacturer organisation data lifecycle in the context of regulatory activities and who is responsible for registration/updating organisation data about manufacturers in the OMS.	2018-12-18
I - Impacts of OMS merge on EMA systems	Guidance – Validation of OMS consuming system data after the merge takes place in OMS	2021-04-28
J - CT registration Headed letter template	Template - For requesting the creation of sponsors and/or clinical trial sites	2023-01-23
U - About SPOR	General - Legal disclaimer, copyright and other policies of using SPOR data.	2017-06-26
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
Z - SPOR User Registration Manual	Manual - How to register for EMA systems and request SPOR user roles.	2023-02-14
Z1 - SPOR User Registration - Webinar 5 October 2017	Webinar - How to register for EMA systems and request SPOR user roles - 5 October 2017	2020-07-15
Z2 - SPOR Super User Affiliation Template Letter	Template - For requesting the organisation's first SPOR Super User role.	2020-09-20
Z3 - SPOR API Access - Q&A	Process - How to request access to SPOR API - Questions and Answers	2017-12-06
Z4 - SPOR API Access - Webinar 10 November 2021	SPOR API Access - Webinar 10 November 2021	2021-11-11
Z5 - EMA - API General Terms of Service - Terms of Use	EMA - API General Terms of Service - Terms of Use	2021-06-29
Z6 - SPOR API Access Request Form	SPOR API Access Request Form	2021-11-08
Z7 - SPOR API Access and Usage - Webinar 18 March 2022	Webinar – API Registration Process and OMS/RMS API usage demo and tips	2022-04-04

API access

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API resources and concepts

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API resources and concepts (1/6)

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Key documents:

Item	Purpose
SPOR API specification	This formal specification describes all of the general principals and a comprehensive list of all available endpoints for RMS and OMS (e.g. SPOR API v1). It is the recommended entry point for any developer (https://spor.ema.europa.eu/v1/documents/c75e7047-8f02-4ce6-b81e-c5380e825a27?app-domain=OMS&doc-type=TECHNICAL)
SPOR API XSD Schema	This document formally describes the data format that all different payloads must conform to, both as input and as output of the endpoint calls. This is also part of the recommended entry point for any developer (https://spor.ema.europa.eu/v1/documents/c75e7047-8f02-4ce6-b81e-c5380e825a27?app-domain=OMS&doc-type=TECHNICAL)
SPOR Integration patterns	This contains a description based on the API specification on how to combine multiple calls to achieve specific business scenarios (https://spor.ema.europa.eu/v1/documents/b344ba89-6d6b-415a-aa71-c437760be808?app-domain=OMS&doc-type=TECHNICAL)
SPOR API sample payloads	This is a particular instantiation from the above, that is, it contains specific examples for most of the API endpoints. It is however not meant to be a full catalogue or a formal representation of the data (https://spor.ema.europa.eu/v1/documents/c75e7047-8f02-4ce6-b81e-c5380e825a27?app-domain=OMS&doc-type=TECHNICAL)

All resources located in https://spor.ema.europa.eu/

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API resources and concepts (2/6)

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General API Concepts:

Item	Definition
Authentication/ Authorisation	• Basic authentication over HTTPS is the only supported mode currently. Other options such as Oauth may be inspected in the future • RBAC authorization with provisioning via the EMA Account management portal
Versioning	• All service calls include the version in the URI (/v1/xyz for RMS & OMS and soon v2/xyz for SMS & PMS). V1 and v2 are **not** compatible and we plan to maintain v1 for the foreseeable future • The XSD schema is versioned independently from the service with the format **majorV.minorV**
Resources, verbs, representation	• A resource is anything that can be identified and manipulated with a set of verbs (lists, terms, organisations, documents, etc.). Described in the API specification and, more formally, in the XSD schema. Always UTF-8 encoded. • The resources can be represented in XML or JSON. Additionally, ZIP may be used for file downloads. • Verbs represent the actions can be applied on the SPOR resources; implemented as HTTP methods (see below)
HTTP	• POST, PUT, GET, DELETE methods are used to create, update, retrieve and delete resources • HTTP status codes are used to signal success (2xx) or failure (4xx, 5xx). The range of 4xx codes is used to represent multiple possible outcomes of the service call

All resources located in https://spor.ema.europa.eu/

API resources and concepts (3/6)

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SPOR API Concepts:

Concept/Query/issue	Definition/Answer/resolution
SSL certificates (in testing environments)	Certificates exposed in test environments are typically signed by the internal EMA CA. This may change in the future, but at the moment it is necessary to either ignore the client-side security warning or to import the root and intermediate certificates in the local trust-store
Unaffiliated users	A user is unaffiliated if it is not yet linked to an organisation. **Unaffiliated users cannot use the SPOR API**
Pagination	In order to iterate through the pages of a resultset, it is mandatory to use page, pagesize and searchtoken. Please inspect the next-page, previous-page elements of the responses to better understand its usage Note: The maximum results on a page is 1000 - attribute pagesize – in case of RMS
Bad Requests	The POST payload for some of the actions is not always easy to compose. Referring the payload examples document or to the network capture of the Web UI may help to get the payload right
Query parameter Validation	At the moment, incorrect query parameters are simply ignored by the system. Although this is a valid implementation, we have detected that it may be challenging for implementers in terms of finding typos in their calls. In future releases, this shall be addressed and a comprehensive query parameter validation shall be offered

All resources located in https://spor.ema.europa.eu/

API resources and concepts (4/6)

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Tools for exploring and understanding the API:

Item	Purpose	Location
Postman	A GUI to easily debug HTTP calls, header and payload composition/inspection. It is recommended to use the stand-alone version rather than browser-attached app	https://www.getpostman.com/
SoapUI	Comprehensive web service testing framework. Typically used similarly to Postman but, in addition, usually the base for automated testing	https://www.soapui.org/
SPOR Web UI	The SPOR Web UI is fully based on the SPOR API v1 to provide its functionality. That makes it a good tool to analyse endpoint usage and payload composition and interpretation. However in no way it is a replacement for the API formal specification	https://spor.ema.europa.eu/sporwi/
Code Beautify	JSON and XML (among others) formatter, very useful to capture network traces and analyse them	https://codebeautify.org/
Richardson Maturity Model	A model (developed by Leonard Richardson) that breaks down the principal elements of a REST approach into three steps. These introduce resources, http verbs, and hypermedia controls	Various Internet resources

All resources located in https://spor.ema.europa.eu/

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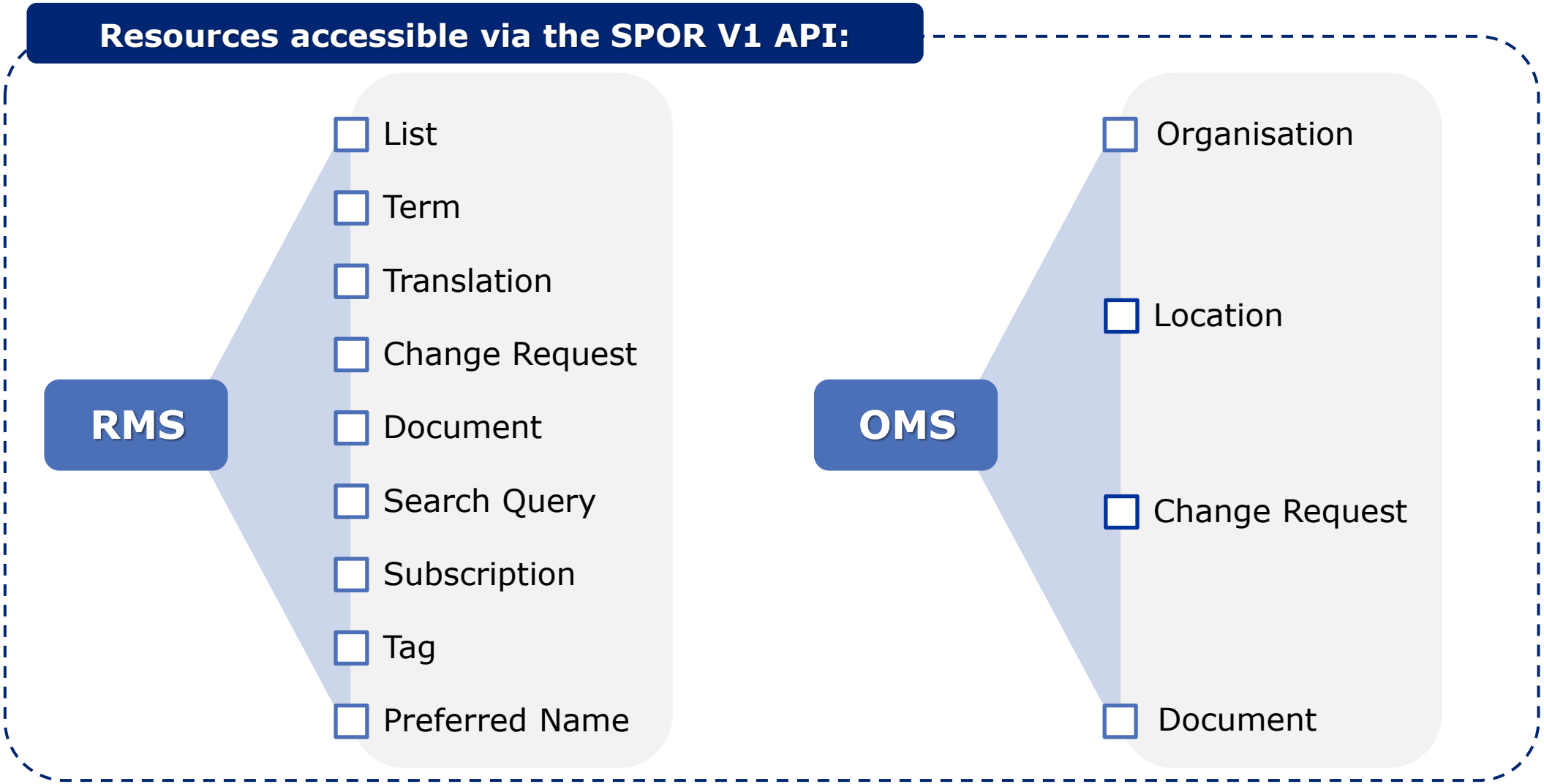
API resources and concepts (5/6)



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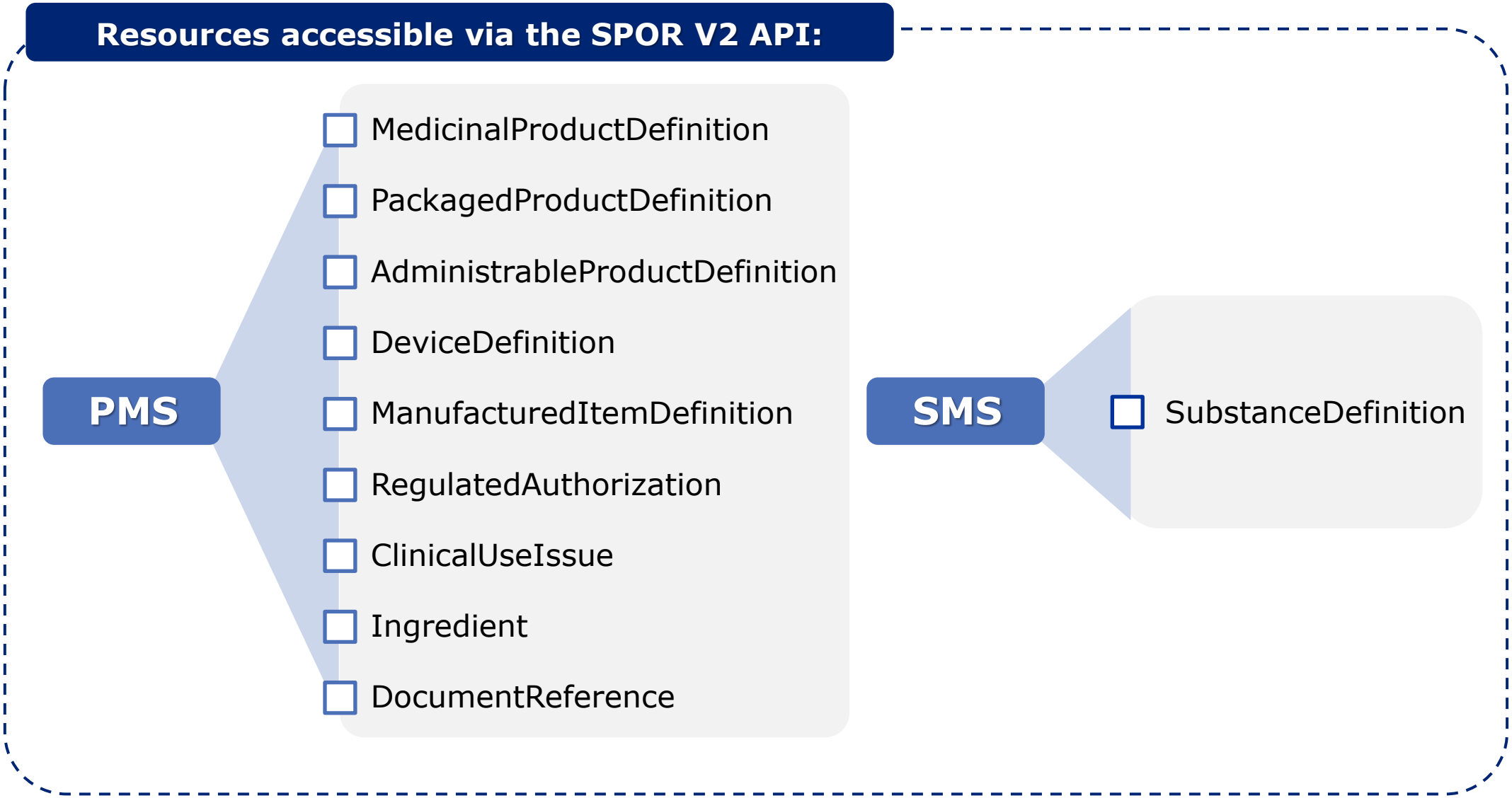
API resources and concepts (6/6)



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API demo and tips

 For Questions: www.slido.com code: #8749717

API Demo and Tips Introduction

This section covers:

- ✓ Demos on usage of the SPOR API to **access OMS resources**
- ✓ Explanation of the **merge process**
- ✓ Demos on usage of the SPOR API to **access RMS resources**

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API Demo and Tips - OMS

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DEMO

- Full list of organisations and locations
- Searching for organisations and locations
- Obtaining organisation and location details

TIPS

- Even if a user has correct SPOR roles, HTTP-401 will be returned as far as the API role is not granted
- Maximum number of organisations or locations that can be returned is **200 on a single page** (default is 20) – controlled by **pagesize** (e.g. /v1/organisations?ORG-10000391*&pagesize=5)
- API call can be build to **specifically** return the info you need, not **all**/too much (e.g. https://spor-uat.ema.europa.eu/v1/locations?org-id=ORG-1000068*&locstatus=ACTIVE~INACTIVE&pagesize=100&sortby=org-name&versions=true)
- If **all** organisations are to retrieved then parameter **pagesize=0 c**an be used (e.g. spor.ema.europa.eu/v1/organisations?pagesize=0), but pagesize=0 cannot be provided in conjunction with any other query parameters except versions=true or versions=false.
- Some attributes (e.g. address) can be found in multiple languages
- If a LocID starts with ORQ- instead of LOC-, do not consider -> it means the location is still Provisional

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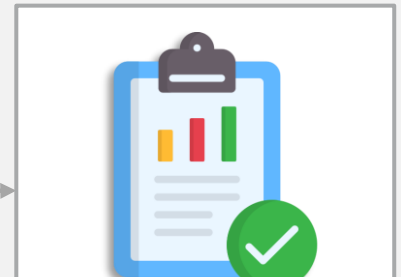
API and Merge Process (1/4)

ASSUMPTION

- An Organisation ID or Location ID published by the OMS will be **retained for the lifetime of the system** and will **always** point to a **single data record**

ACTION

- Organisation A and organisation B are merged in OMS
- This could be due to a business merge/acquisition of companies or to clean duplicated records
- Only **one** of the organisation identifier survives as **golden record** – the one with the lowest OrgID; others will still be **linked to the golden record**, they ***will not be Inactivated nor deleted***



RESULT

- If we consider Org A with the lowest OrgID and **golden record**, it means when searching for Org B, this OrgID still works and points to Org A
- To ensure stability of possible references from external systems, every action referring a non-surviving merged record will keep on working and returning data that belongs to the golden record
- NOTE: the above applies to Locations too

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API and Merge Process (2/4)

EUROPEAN MEDICINES AGENCY

spor-uat.ema.europa.eu/v1/organisations/ORG-100119491

Apps | Space: Informatica... | JSIS online | Login - Oracle Ente... | SOLR | IDD SPOR | IDQ SPOR | Website | Citr

This XML file does not appear to have any style information associated with it. The document tree is shown below.


```
<organisation xmlns="http://ema.europa.eu/schema/spor" schema-version="2.0" query-timestamp="2021-11-10T09:34:03.734"
  <operational-attributes created-on="2021-11-09T16:14:58.195Z" modified-on="2021-11-09T16:45:19.474Z"/>
  <organisation-id id="ORG-100119491">
    <link rel="self" href="https://spor-uat.ema.europa.eu/v1/organisations/ORG-100119491"/>
  </organisation-id>
  <active-request>false</active-request>
  <identifiers>
    <identifier code-system="100000167474" code-system-name="OMS Request Identifier">
      <code>ORQ-110000643</code>
    </identifier>
    <identifier code-system="100000167446" code-system-name="OMS Organisation Identifier">
      <code>ORG-100119491</code>
    </identifier>
    <identifier code-system="100000167446" code-system-name="OMS Organisation Identifier">
      <code>ORG-100119492</code>
    </identifier>
    <identifier code-system="100000167474" code-system-name="OMS Request Identifier">
      <code>ORQ-110000644</code>
    </identifier>
  </identifiers>
  <mappings/>
```


spor-uat.ema.europa.eu/v1/organisations/ORG-100119492

Apps | Space: Informatica... | JSIS online | Login - Oracle Ente... | SOLR | IDD SPOR | IDQ SPOR | Website | Citrix

This XML file does not appear to have any style information associated with it. The document tree is shown below.


```
<organisation xmlns="http://ema.europa.eu/schema/spor" schema-version="2.0" query-timestamp="2021-11-10T09:39:06.976"
  <operational-attributes created-on="2021-11-09T16:14:58.195Z" modified-on="2021-11-09T16:45:19.474Z"/>
  <organisation-id id="ORG-100119491">
    <link rel="self" href="https://spor-uat.ema.europa.eu/v1/organisations/ORG-100119491"/>
  </organisation-id>
  <active-request>false</active-request>
  <identifiers>
    <identifier code-system="100000167474" code-system-name="OMS Request Identifier">
      <code>ORQ-110000643</code>
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    </identifier>
    <identifier code-system="100000167474" code-system-name="OMS Request Identifier">
      <code>ORQ-110000644</code>
    </identifier>
  </identifiers>
  <mappings/>
```


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API and Merge Process (3/4)

EUROPEAN MEDICINES AGENCY

Handling merged organisations – to be implemented locally

After a GET v1/organisations?org-modified-after={modifiedDate:dateTime} – to synchronize with OMS, for each organisation id (identifier.code) in an organisation's identifiers perform an API request GET v1/organisations/{orgId:string}.

- If the organisation id is equal to the main organisation id in the response, then this is the surviving organisation of a merge
- Otherwise the organisation id is that of a non-survivor which was merged into the organisation id in the response

Pseudo code:

- GET v1/organisations?org-modified-after={modifiedDate:dateTime}
- FOR EACH identifier.code IN organisation.identifiers GET v1/organisations/{orgId:string}
- IF orgId == organisation.organisation-id#id THEN ORGANISATION IS SURVIVER
- ELSE ORGANISATION IS MERGED INTO organisation.organisation-id#id
- END FOR EACH

For Questions: www.slido.com code: #8749717

API and Merge Process (4/4)

Handling merged locations – to be implemented locally

After a GET v1/locations?loc-modified-after={modifiedDate:dateTime} – to synchronize with OMS, for each location id (identifier.code) in a location identifiers perform an API request GET v1/locations/{locId:string}.

- If the location id is equal to the main location id in the response, then this is the surviving location of a merge
- Otherwise, the location id is that of a non-survivor which was merged into the location id in the response

Pseudo code:

- GET v1/locations?loc-modified-after={modifiedDate:dateTime}
- FOR EACH identifier.code IN location.identifiers GET v1/locations/{locId:string}
- IF locId == location.location-id#id THEN LOCATION IS SURVIVER
- ELSE LOCATION IS MERGED INTO location.location-id#id
- END FOR EACH

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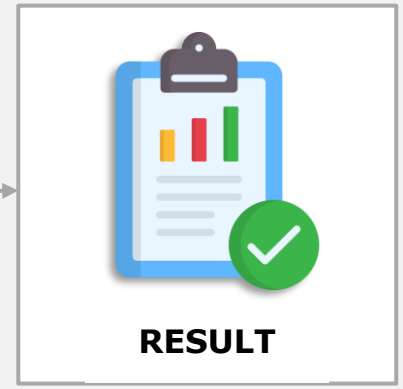
API and Unmerge Process

ASSUMPTION

- Organisations/Locations have been onboarded from different source systems into OMS and may have been merged in the process
- When Organisations/Locations have been merged this means that in **one record** there could be **different mapped IDs** e.g. if Organisation A and Organisation B have been merged, and Org A identifier was kept as golden record, it means when searching for Org B, this OrgID still works and points to Org A

ACTION

- Organisation A and organisation B are unmerged in OMS
- This is only used to resolve a previously incorrect merge – we do not use this when companies sell business units
- **Two** separate organisations exist as **golden record,** Organisation A and Organisation B – the original IDs will be split across records, original IDs will be returned to original organisations



RESULT

- When searching for Org B, this OrgID only points to Org B (and no longer points to also Org A) - **Org B <u>appears</u> similar to a new Organisation**
- NOTE: the above applies to Locations too

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API demo and tips - RMS

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DEMO

- Exporting and browsing lists
- Obtaining list and term details
- Searching for terms

TIPS

- Even if a user has correct SPOR roles, HTTP-401 will be returned as far as the API role is not granted
- Maximum number of terms that can be returned is **1000 on a single page** (default is 20), but this **can** be changed by using parameter **pagesize**
- The **RMS ID** of a term from an **externally-maintained lists** (e.g. MedDRA or ATC) can be retrieved by using the following API: https://spor.ema.europa.eu/v1/lists/100000000004/mappings?source-term-id=10007512
- Update of terms is **not** supported; in order to request update to a term submit an update term **Change Request**
- Currently the history of some terms does not work properly (e.g. versions=true does return **only** latest version, not **all**) -> this is being addressed and we should have it fixed as soon as possible
- Possible tactic for maintaining terms: local caching with periodic refresh

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SPOR API News

 For Questions: www.slido.com code: #8749717

SPOR API News

2023: Focus on reliability and throughput

Context:

The initial Scalability and Performance requirements of the SPOR API for OMS and RMS are surpassed by the actual usage today

- Current business as usual day has approximately 400K API requests
- The user base is increasing with a factor that is above initial expectations

Latest SPOR API news:

- **Last improvements** carried out at SPOR
- **Rearchitecting SPOR** for future proofing
- **First roll out**: API rate limiting
  - What changed
  - Experience
  - Insights

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SPOR API News: rolled out July 12th

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SPOR API V1 Rate Limiting – What changed

The current architecture can manage usual usage, however it is vulnerable to **peaks** in usage.

To protect the SPOR API from peaks in usage we introduced an API request **Rate Limiting** mechanism that spreads use/API requests/queries over longer periods

Description:

- Implemented in OMS gets of ORGs and LOCs (all and by id) and in all RMS gets
- **General** limit to maximum **1000 requests per minute**
- **Per user** limit to maximum **60 requests per minute**
- The timeframe is rolling, the limit applies to the last window of 60 seconds
- At the moment OMS Change requests and RMS put and post methods are **unaffected.** This feature will be extended to these APIs in the future and further information will be shared ahead of time. Please stay tuned!

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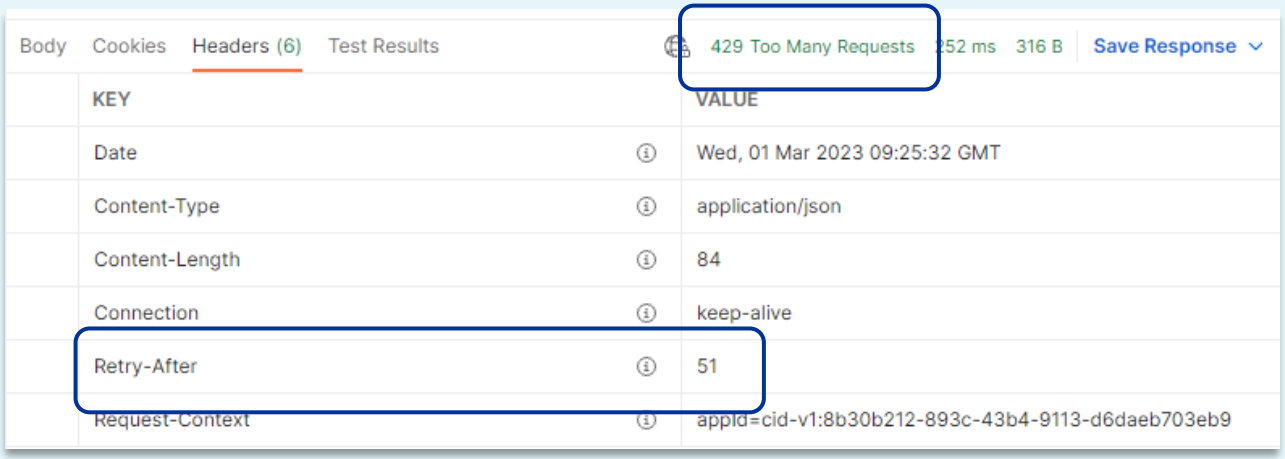
SPOR API V1 Rate Limiting – Experience

1. **You are informed** –> **HTTP Status 429 Too Many Requests**
   - API users and integration code should expect and manage the HTTP Status 429 Too Many requests returned when the quota of requests per minute has been reached
2. **You should retry** -> **Retry-After (seconds)**
   - The HTTP Header Retry-After informs how many seconds the API user needs to wait before their following request will be allowed
3. **The response body can be ignored**



How does it impact your processing:

1. Your requests are <u>always responded</u>
2. You will notice it only if you go over the maximum rate

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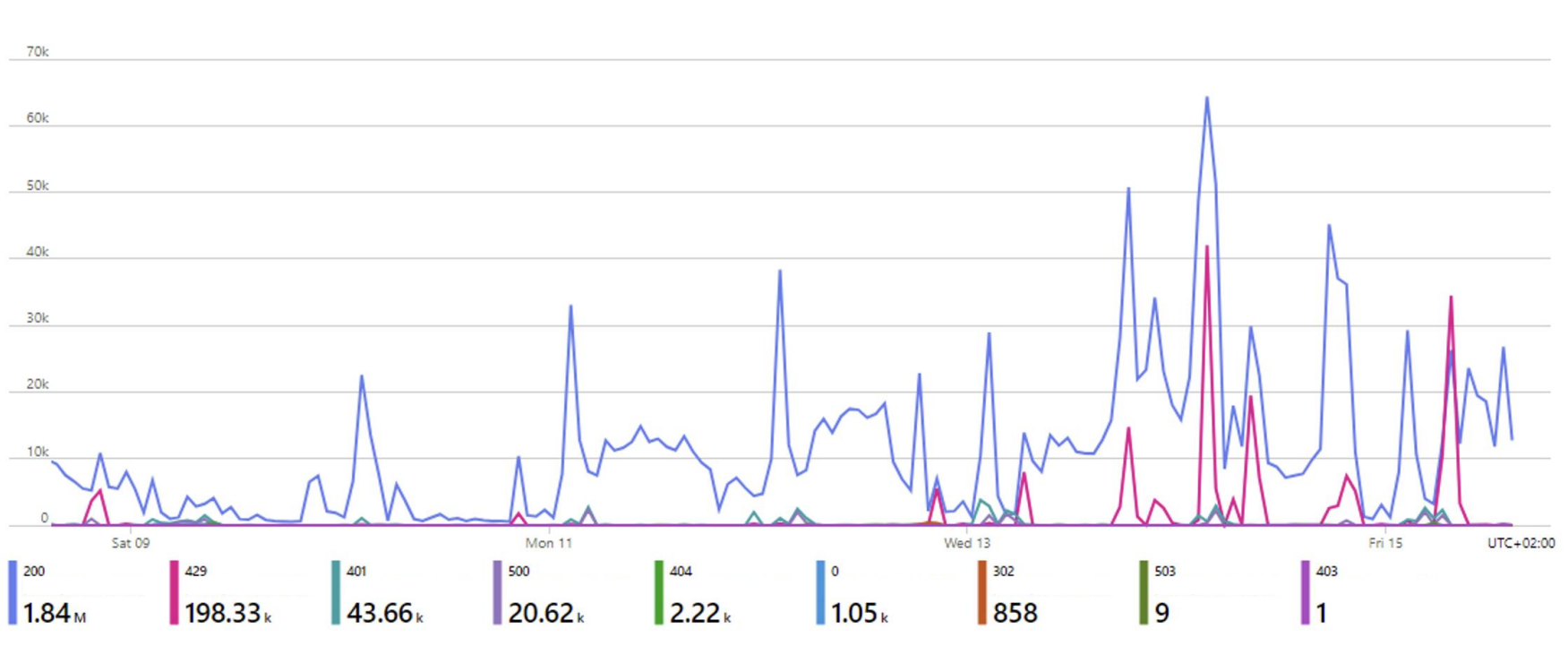
SPOR API V1 Rate Limiting – Insights (1/2)



Initial takeaway:

1. **It affects single individuals at a time.**
   Normally, only single individual consumers are affected by the limiting. The global fence (affecting all users) is not reached
2. **It has improved the stability of the system,** by removing the downtimes caused by the overload of single consumers
3. **It's in the pipeline to gradually allow more requests per minute**, as we analyse that the system can hold with the revised settings

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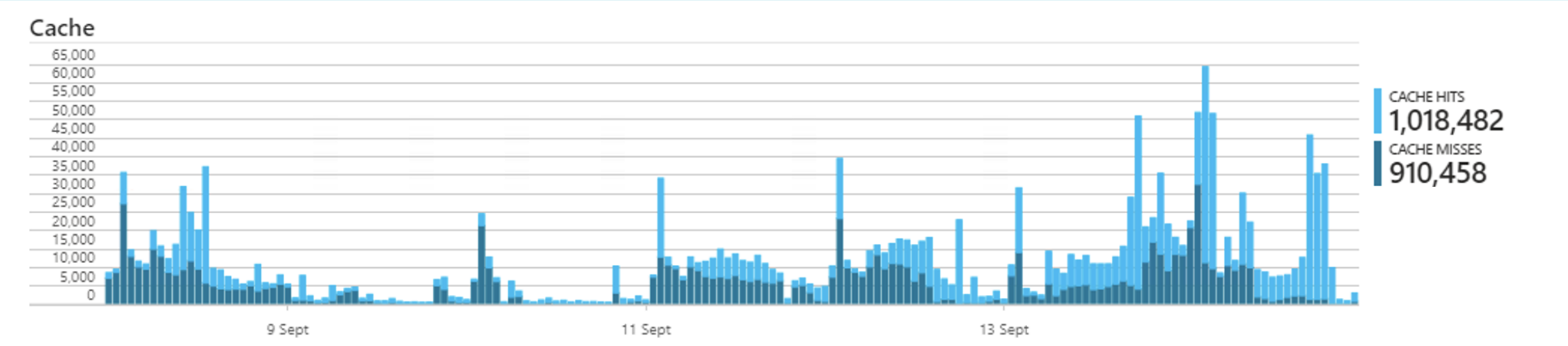
SPOR API V1 Rate Limiting – Insights (2/2)

- **Introducing cache at API management level**
  - The new developments have brought a set of tools that not only protect the system, but also enable for best response times under busiest moments of the day
- **You benefit from the high usage of the system**
  - At busy times, requests from other consumers are warming up your next requests and placing the response directly at the API entrypoint level. As a result, responses are around 10 times faster



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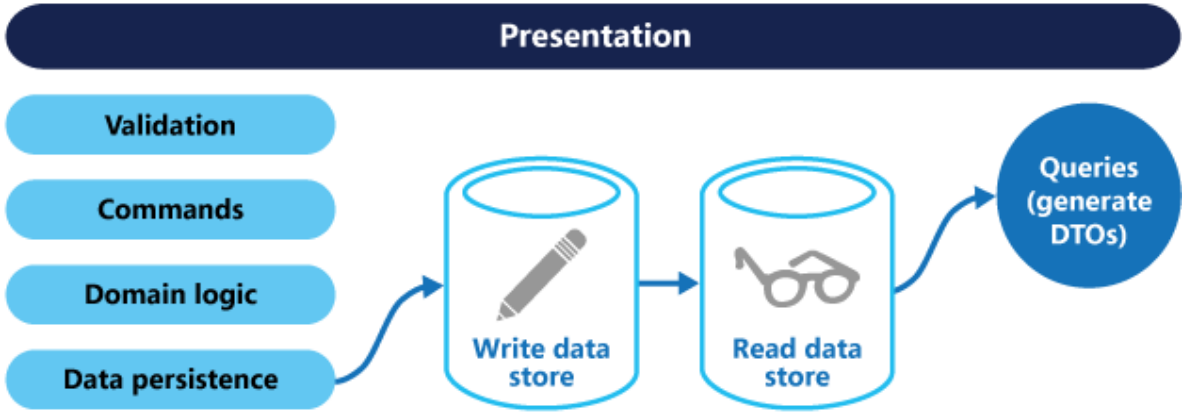
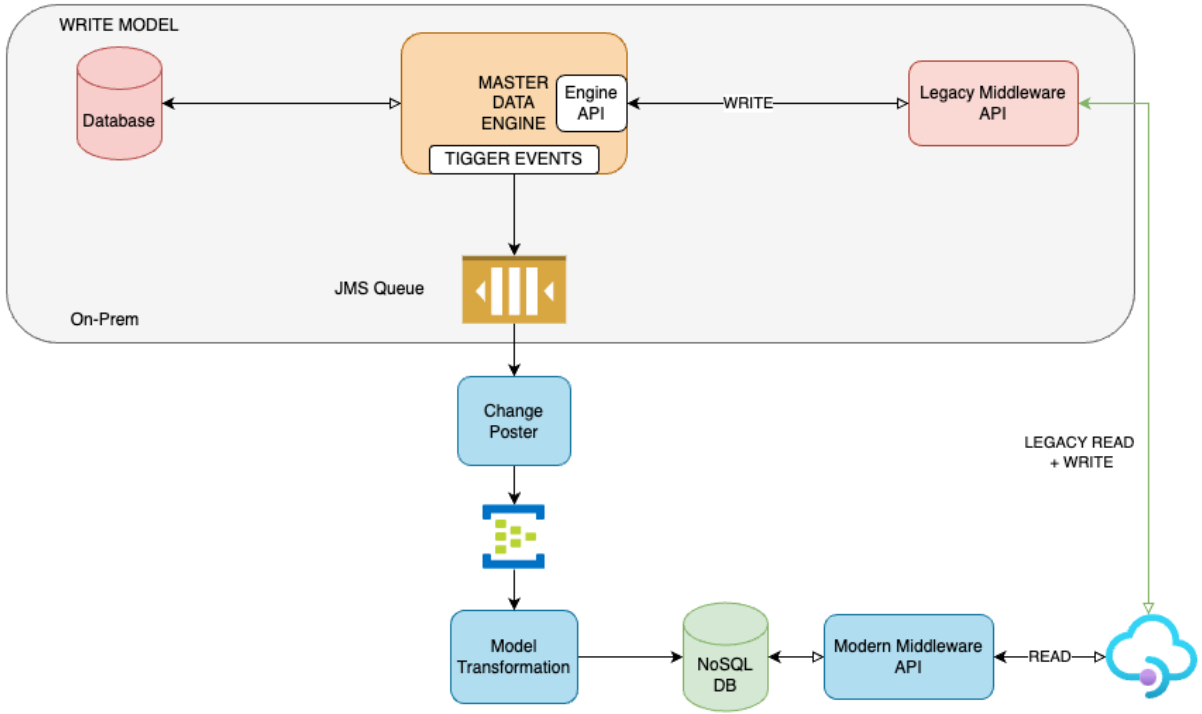
During **2023 we are evolving the SPOR API architecture** to be able to handle current and future Scalability and Performance requirements

The target architecture splits the Master Data process and the API offering

- The API will be served from highly available and scalable resources, implemented with the focus on data availability
- The Master Data process increases the throughput and reliability after decoupling from the variable loads of the consumers





Figures from 'Azure Cloud Design Patterns, CQRS'

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During **2023 we are evolving the SPOR API architecture** to be able to handle current and future Scalability and Performance requirements

Key aspects

1. The API contract remains the same

The new API request and response format is the same than the current one. No modifications to the integrations are neede.

2. The Roll-Out will be phased

1st phase Q4 2023:

- GET Organisations endpoints (with history)
- Search Organisations by criteria (with history)

2nd phase Q1 2024:

- GET Locations endpoints (with history)
- Search Locations by criteria (with history)

3. The response is preloaded

The response times will greatly improve, avoiding computation and I/O dependencies compared to the current implementation

4. API reads will be isolated from MDM core maintenance and downtime

Going towards 99.99% availability

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Figures from 'Azure Cloud Design Patterns, CQRS'

Planned Features and Improvements

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Planned Features and Improvements

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Q2 2023

Performance and stability improvements on OMS

- Rate limiting and other optimisations

Q4 2023

Rollout of SPOR v2

- SMS API: EMA, NCA and industry access
- PMS API: Initial access of PMS API to EMA and NCAs only
- Updates to SPOR API V2 Specification to be ready for the UATs

Q4 2024

Redefining the internal MDM landscape

- We are seeking to simplify the internal landscape and processes to optimise our Master Data operations, together with the Cloud Migration Strategy of EMA
- The API decoupling of v1.1, v1.2 and v2 will minimise greatly the impact to the consumers

Q4 2023

SPOR v1.1: extending OMS v1

- New architecture, core-compatible with v1
- Base for 1.x extensions
- Currently under acceptance testing
- Available for all the current user base

Q2 2024

SPOR v1.2: extending RMS v1

- Following the OMS rearchitecting
- Currently under analysis
- Targeting all the current RMS user base
- Adding Oauth2 to OMS and RMS for enhanced security and access

TBC

FHIR R5

- Dependency: Azure API for FHIR R5 PaaS
- Impact: UPD, PMS, SMS and eAF roadmaps are affected
- Effort: Requires data replication/transformation effort and support for both versions simultaneously

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Key takeaways and conclusions

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Takeaways & Conclusions

Introduction to and update on the SPOR API v1

- Clarified what is and what is not an API; User and technicalities
- Clarified SPOR API V1 vs V2 and how to Request access to SPOR API V1

Provide concrete examples of how to use the API

- Recap SPOR API resources and concepts
- Provided a SPOR API demo and tips, particularly addressing OMS merge/unmerge process

Guide API users to relevant documentation and support

- SPOR help & support available through EMA Service Desk
- System Monitoring in place
- SPOR Portal contains key documents about API resources and concepts

SPOR API news & Planned Features and Improvements

- Clarified focus for 2023 on rearchitecting SPOR for future proofing
- Shared last improvements carried out and planned roll out of API rate limiting
- Shared other planned improvements: Version 2 of OMS and OMS API; SMS and PMS APIs and the Upgrade MDM

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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 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
Product Management Service (PMS)	9 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

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Further information

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

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
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Glossary

Glossary (1/4)

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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)

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)

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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