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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.



Presentations will be* available at:

- SPOR Portal Documents section
- EMA Events Web Page



Recordings will be available at:

- EMA YouTube Channel
- EMA Events Web Page



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR API

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

Presented by Andrei Idu and Angel Sempere Sanchez

SPOR Webinar Series – 4-14 October 2024





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

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



Introduction to and update on the SPOR API v1 and v3



Provide concrete examples of how to use the APIs



Guide API users to relevant documentation and support



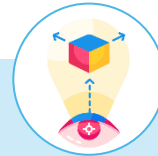
Share latest SPOR API news and planned features and improvements





Why use an API?

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"

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, ...

API – Why should you use it?

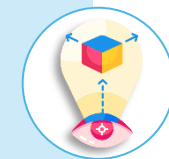
APIs are ideal for **machine-to-machine integration**:

- 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)



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*](#))



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.

The SPOR API comes in two parts: V1 and V3

SPOR V1:



Provides access to RMS and OMS resources, not FHIR

- Access granted to any user upon request – **see previous webinar recordings on EMA's youtube channel**

SPOR V3:



V2 has been released internally to EMA and a limited amount of users, V3 is released fully for both external and internal use and applies a different authentication/authorisation mechanism

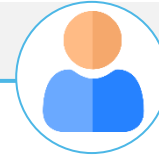
Provides access to PMS and SMS resources

- Both SMS and PMS are still under development of significant features which may impact their API
- Both APIs implement the **FHIR Standard v4.4.0 (R5 Preview #2)**
- OAuth2 Client Credentials flow for authorisation
- SMS – released in April 2024, for NCAs and Industry (including any registered user)
- PMS – currently access granted to Industry since July 2024, NCA access to follow beginning of Q1 2025



250,000 API calls in 24h on average

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

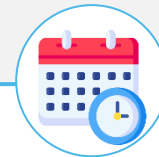


170 Registered accounts serving over 70k users



Busiest periods for RMS

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



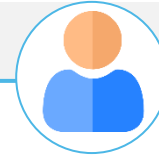
Busiest periods for OMS

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



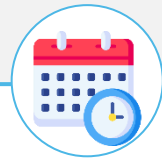
**100,000 API calls in
24h on average**

- Over 95% PMS



108

Registered accounts



**Busiest periods
for PMS**

- 1PM-3PM
- 8AM-10AM

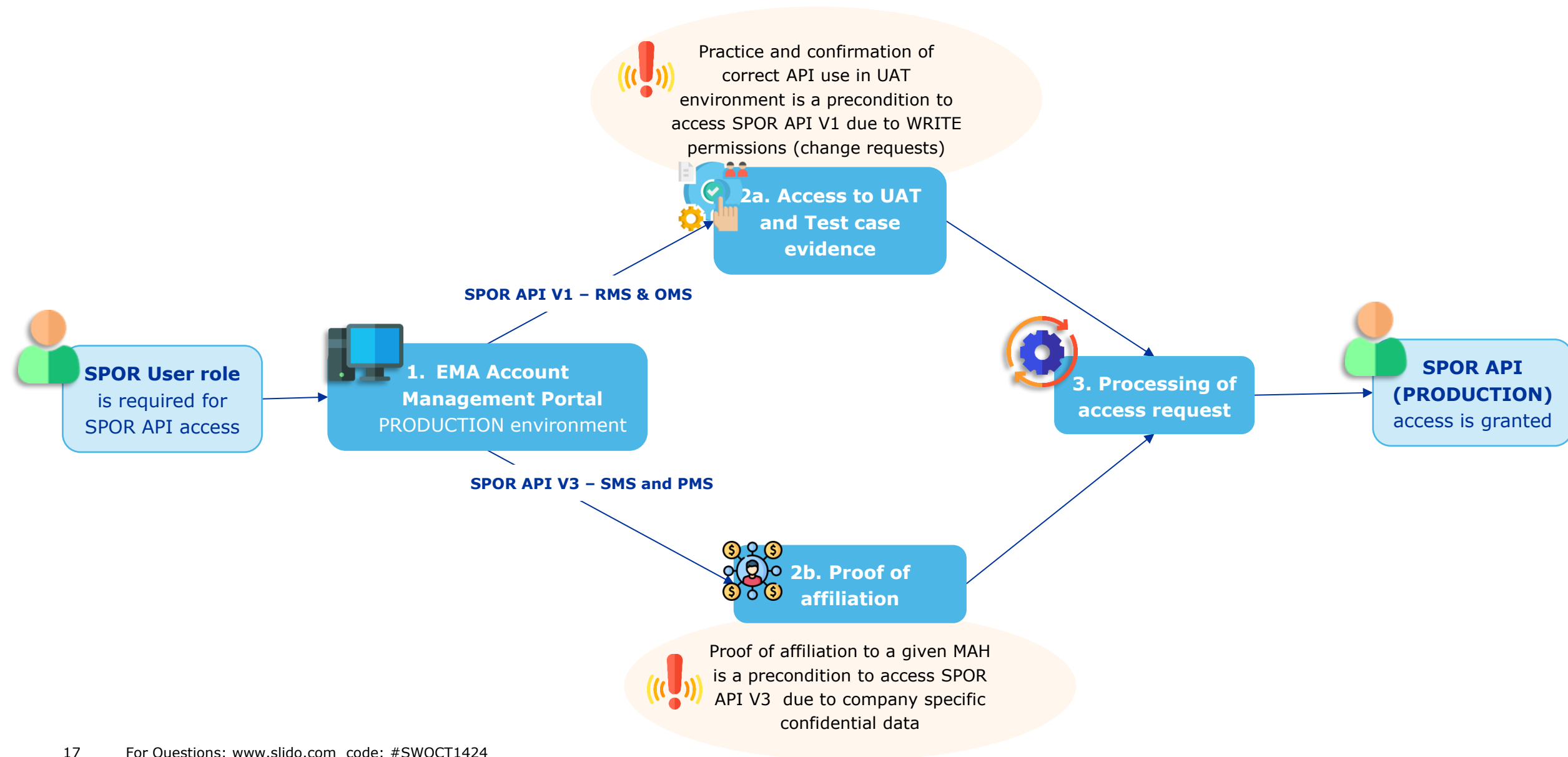


**Busiest periods
for SMS**

- 1PM-3PM
- 8AM-10AM



Request access to SPOR API





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

➔ Username - use "Organisation name" + "API" as first and second names

➔ Email - use unique e-mail address (not somebody else's personal email address)

➔ (If needed, Submit CR to OMS) Affiliate to the right Organisation

➔ (If needed, first create Org super user role) then **select role**

➔ If SPOR V1 - Industry User role (or NCA Translator / NCA User role)

➔ If SPOR V3 – PLM Industry/NCA Admin or SMS Industry/NCA Super User



For SPOR API V1 – RMS & OMS 2a. Access to UAT and Test case evidence

! IMPORTANT: Practice and confirmation of correct API use in UAT environment is a precondition to access SPOR API V1 due to WRITE permissions (change requests)

Self-Register using the **EMA Account Management portal - UAT environment**: - same as step 1

Complete **SPOR API Access Request Form**

Raise **EMA Service Desk request** for SPOR API access.

Attach SPOR API Access Request Form → EMA processes SPOR API UAT Access Request

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

NOTE: Please read the documentation available in the SPOR Portal (Documents->View), particularly Z3 to Z7



SPOR API V3 – SMS and PMS 2b. Proof of affiliation

! IMPORTANT: Proof of affiliation to a given MAH is a precondition to access SPOR API V3 due to company specific confidential data

Self-Register using the **EMA Account Management portal – request the and provide proof of affiliation – requires approval from EMA**

Use EMA Account Management to self-service client credentials via Request API Access menu item

NOTE: Section 4.3.1 of SMS guidance for external users (europa.eu) and Section 3 of ISO IDMP IG for PMS Chapter 1 details how to register for API access



3. EMA processes access request

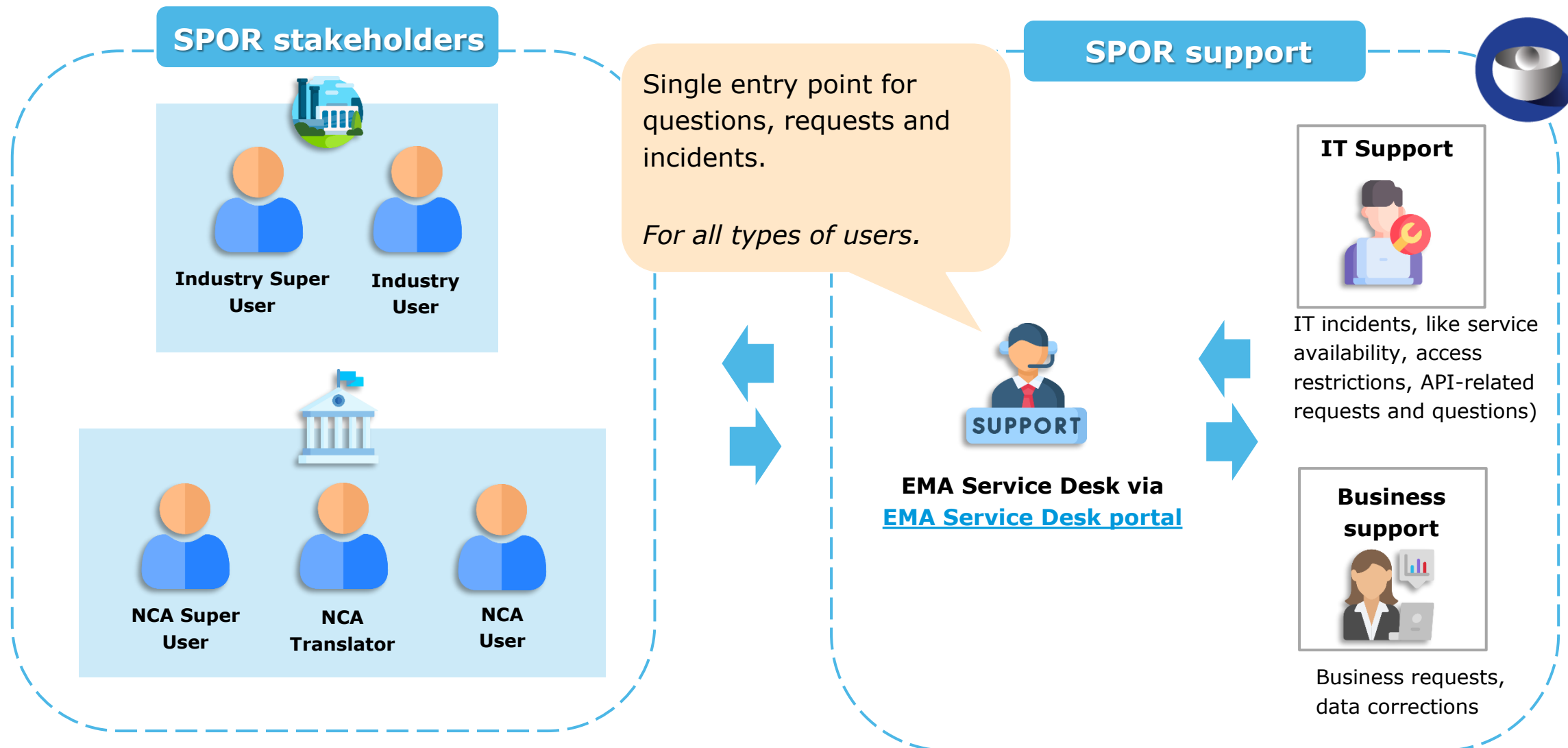


Email is sent with Oauth2 client credentials

Role is granted



SPOR Help, Support & Communications



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 year, the system has been more and more stable and on the occasions we had an incident, we have been able to recover within an hour.

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

For Questions: www.slido.com code: #SWOCT1424

General Technical	
<div> <div> Document Name </div> <div> Document Description </div> </div>	
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

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	2021-10-24
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	2021-06-06
D - OMS Controlled Vocabularies	Guidance - Controlled vocabularies used in OMS	2017-06-12
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 - SPOR 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 eAF Integration - Webinar 18 March 2022	Webinar - API registration process and OMS/EMA API integration and tips	2022-04-04

API access



PMS Implementation Guide

[Substance and product data management services | European Medicines Agency \(EMA\) \(europa.eu\)](#)

- Chapter 1 – Registration requirements
- Chapter 2 - Data elements for the electronic submission of information on medicinal products for human use
- Chapter 6 - Technical specifications on structure and format: Technical specifications for the API, contains description of principles, security, resources, calls, end-points



SMS

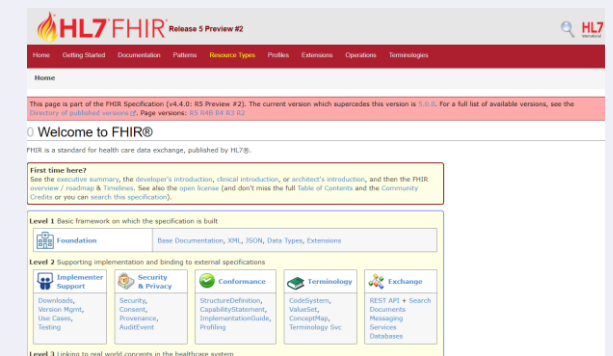
[SMS guidance for external users \(europa.eu\)](#)



1 December 2023

SMS guidance for external users

Both PMS and SMS make use of the FHIR standard functionality
[Index - FHIR v4.4.0 \(hl7.org\)](#)





For Questions: www.slido.com code: #SWOCT1424



API resources and concepts









Key documents:

 Item	 Purpose
SPOR API V1 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 V1 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 V1 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)





General API Concepts:

 Item	 Definition
 Authentication/Authorisation	<ul style="list-style-type: none"> V1: Basic authentication over HTTPS is the only supported mode currently. V3: Oauth 2.0 Client Credentials flow RBAC authorization with provisioning via the EMA Account management portal
 Versioning	<ul style="list-style-type: none"> All service calls include the version in the URI (/v1/xyz for RMS & OMS and soon v3/xyz for SMS & PMS). V1 and V3 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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/>

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	V1: 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 for V1 is 1000 - attribute pagesize – in case of RMS and 200 for OMS, and 100 for SMS and PMS
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



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



Resources accessible via the SPOR V1 API:

RMS

- ☐ List
- ☐ Term
- ☐ Translation
- ☐ Change Request
- ☐ Document
- ☐ Search Query
- ☐ Subscription
- ☐ Tag
- ☐ Preferred Name

OMS

- ☐ Organisation
- ☐ Location
- ☐ Change Request
- ☐ Document

Resources accessible via the SPOR V3 API:

PMS

- ☐ MedicinalProductDefinition
- ☐ PackagedProductDefinition
- ☐ AdministrableProductDefinition
- ☐ DeviceDefinition
- ☐ ManufacturedItemDefinition
- ☐ RegulatedAuthorization
- ☐ ClinicalUseIssue
- ☐ Ingredient
- ☐ DocumentReference

SMS

- ☐ SubstanceDefinition



API demo and tips



This section covers:

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



DEMO



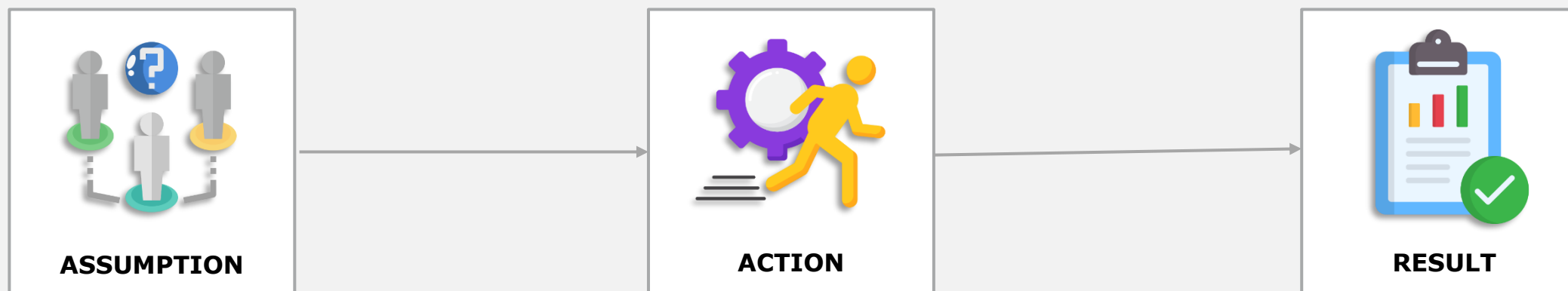
DEMO

- **Organisation and Location merges** and **version reason**
- Other capabilities: 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** can 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



- 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**
- 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**
- 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



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

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.

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  <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>
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      <code>ORQ-110000643</code>
    </identifier>
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      <code>ORG-100119491</code>
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      <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" c
  <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/>
```



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



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



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



New Version related fields

Each new version of an **Organisation or Location** will have **3 new fields**

1. The RMS Term ID to state the reason a new version was created for – the RMS List is to be confirmed
2. The RMS Term Name for display purposes
3. The Comment added by the Data Steward that approved the change which led to the new version

```
<city>Lezama</city>
<country>Spain</country>
</address-detail>
</address-details>
</address>
<version-type-code>20000104400604</version-type-code>
<version-type-name>Location standardisation update</version-type-name>
<version-comment>INC0048138 back to previous data</version-comment>
<version-timestamp>2024-06-25T12:31:30.37+02:00</version-timestamp>
</location>
```



DEMO



DEMO

- **Licensed list RMS Term ID search**
- Other capabilities: 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



PMS News page

Check:

- News
- Events announcements
- Downtime comms

Check regularly



PLM Newsletter

- See planned PMS engagement activities for upcoming quarter
- **Subscribe** [here](#)

Receive via email quarterly after subscription



PMS webinars

Latest training sessions:

- [Access & use PMS PUI](#) (3 Jun 2024)
- [Access & use PMS API](#) (8 Jul 2024)
- [Pack sizes submissions webinar](#) (11 Jul 2024)

Announced via EMA's Website Events Pages - usually with registration



PMS FAQ Document + PLM Portal Forum

- Check FAQs on PMS (Document)
- Ask questions (Forum)

Check regularly



Quarterly System Demos

- See the latest developments
- Give your feedback on features and priorities
- **Next system demo:** 12 Dec 2024

Announced via EMA's Website Events Pages - broadcast live



PMS Web Page

Find:

- > PMS overview
- > EU Implementation Guide

Check for general info on PMS

DEMO



DEMO

- **Searching** for Substances
- Getting a specific Substance **by ID**
- Identifying **key data elements** – Name, Type, Status, Replacement ID, Codes: *SVG*, *xEVMPD*, Custom attributes

TIPS



- The Search endpoint returns the same data for a specific Substance as the Get By ID endpoint
- Maximum number of substances that can be returned is **200 on a single page** (default is 10), but this **can** be changed by using parameter **_count**
- Currently the history of Substances is not supported
- Integration approach: local caching with periodic refresh using the last updated parameter **_lastUpdated=gt2024-09-04T00:00:00**

SVG Flag

```
99 </code>
100 <code id="13485310">
101   <code>
102     <coding>
103       <system value="https://spor.ema.europa.eu/v1/lists/1000000000009/terms/200000025197" />
104       <code value="1" />
105     </coding>
106   </code>
107 </code>
```

Term Id	Term Name
200000025197	Substance Validation Group

Relationship/hierarchy to other Substances

```
295 </name>
296 <relationship id="2521908">
297   <extension url="https://ema.europa.eu/fhir/conversionFactor">
298     <valueDecimal value="0.75" />
299   </extension>
300   <substanceDefinitionReference>
301     <reference value="SubstanceDefinition/100000079790" />
302   </substanceDefinitionReference>
303   <type>
304     <coding>
305       <system value="https://spor.ema.europa.eu/v1/lists/200000004946" />
306       <code value="200000004954" />
307       <display value="Salt to Parent" />
308     </coding>
309   </type>
310 </relationship>
311 </SubstanceDefinition>
```

- 1 Hostname for pagination: replace with spor.azure-api.net
- 2 Response for Get By Id may be corrupted – work around is ***SubstanceDefinition?_id=SUBSTANCE_ID*** instead of *SubstanceDefinition/SUBSTANCE_ID*



SPOR API News



2024: PMS and SMS Read API Access

Access to read structured data for use in various regulatory processes, for example eAF or ESMP

PMS Read API:

Industry access granted starting July 2024

NCA access to be granted end of Q4 2024

[Chapter 1 - Registration requirements \(europa.eu\)](#)

SMS Read API:

Access granted to any type of user in April 2024

[SMS guidance for external users \(europa.eu\)](#)



2024: OMS and RMS Stability and new features

OMS API:

Version reason – target release for Q1 2025

Read API refactoring for increased performance – improved 10x

RMS API:

Term version history – target release for Q1 2025



Planned Features and Improvements

Q4 2024 – Q1 2025
PMS API for NCAs

Q1 2025
OMS Version Reason

Q1 2025
RMS Term Version History

2025
PMS FHIR R5

To be planned and communicated via PLM value stream
SMS adoption of FHIR R5 will be planned separately

No plans for OMS and RMS move to FHIR



Key takeaways and 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 V3 and how to Request access to SPOR API



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

- First phase of rearchitecting SPOR for future proofing concluded
- Shared other planned improvements for OMS and RMS
- Shared the plan of implementation to adopt FHIR R5 to start in 2025 with PMS



Provide concrete examples of how to use the API

- Provided a SPOR API demo and tips
- Showcased OMS merge/unmerge process, OMS version reason
- Showcased getting RMS Ids for licensed lists
- Demo of the SMS API





Any questions on the webinar?



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

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



Further information

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Glossary



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	<p>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.</p> <p>Business epics are large initiatives that deliver Solutions needed by the business/customers</p> <p>Enabler epics are pieces of work that extend the architectural infrastructure of the solution under development or improve the performance of the value stream</p>

For Questions: www.sido.com code: #SWOCT1424



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



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

For Questions: www.smdo.com code: #SWOCT1424



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