



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



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

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

Join at  
**slido.com**  
**#3951 938**



- 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.



**Presentations** will be\* available at:

- SPOR Portal Documents section
- EMA Events Web Page

\*1<sup>st</sup> 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](http://www.slido.com)) using the **code #3951938**.*



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Service Desk for SPOR and XEVMPD

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

*Presented by Veronika Baker, Marcelo Nahmijas and Taavi Pehme*

SPOR Webinar Series – 2-12 October 2023



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
<b>Service Desk for SPOR and XEVMPD</b>	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



Explain **how the EMA Service Desk works**



**Clarify the use of ServiceNow** to raise requests/questions and to report issues



Provide information on **planned improvements for external customers**

1

**Welcome**  
14:00 – 14:05

2

**Interaction with EMA Service Desk**

3

**Access to EMA Service Desk**

4

**Issue with an IT application**

5

**Request for service(s)**

6

**Request for information**

7

**SPOR services**

8

**Resolving/closing of tickets and follow-up**

9

**Points to consider: The DOs and DON'Ts**

10

**ServiceNow: roadmap and planned improvements**



11

**Key takeaways and Conclusions**



12

**Q&A Session**  
15:45 – 16:00





## Interaction with EMA Service Desk

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Presented by Taavi Pehme





- Service Desk (SD) is the first point of contact and the owner for all incidents
- SD resolves, manages, monitors, reports and follows up the incidents through the entire life cycle including internal and external contributors



SD monitors and reports on the cross-agency daily status of the Application as well as the historical performance of the operations



SD participates in cross-agency planning activities, service improvement workshops, and provides constructive proposals and feedback



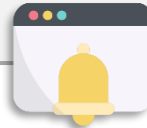
SD is responsible for maintaining the IT knowledge Base on the ServiceNow portal allowing you to find information quickly



Service Desk (SD) owns the end-user communication of service disruptions and outages via ServiceNow portal, e-mail and other possible channels

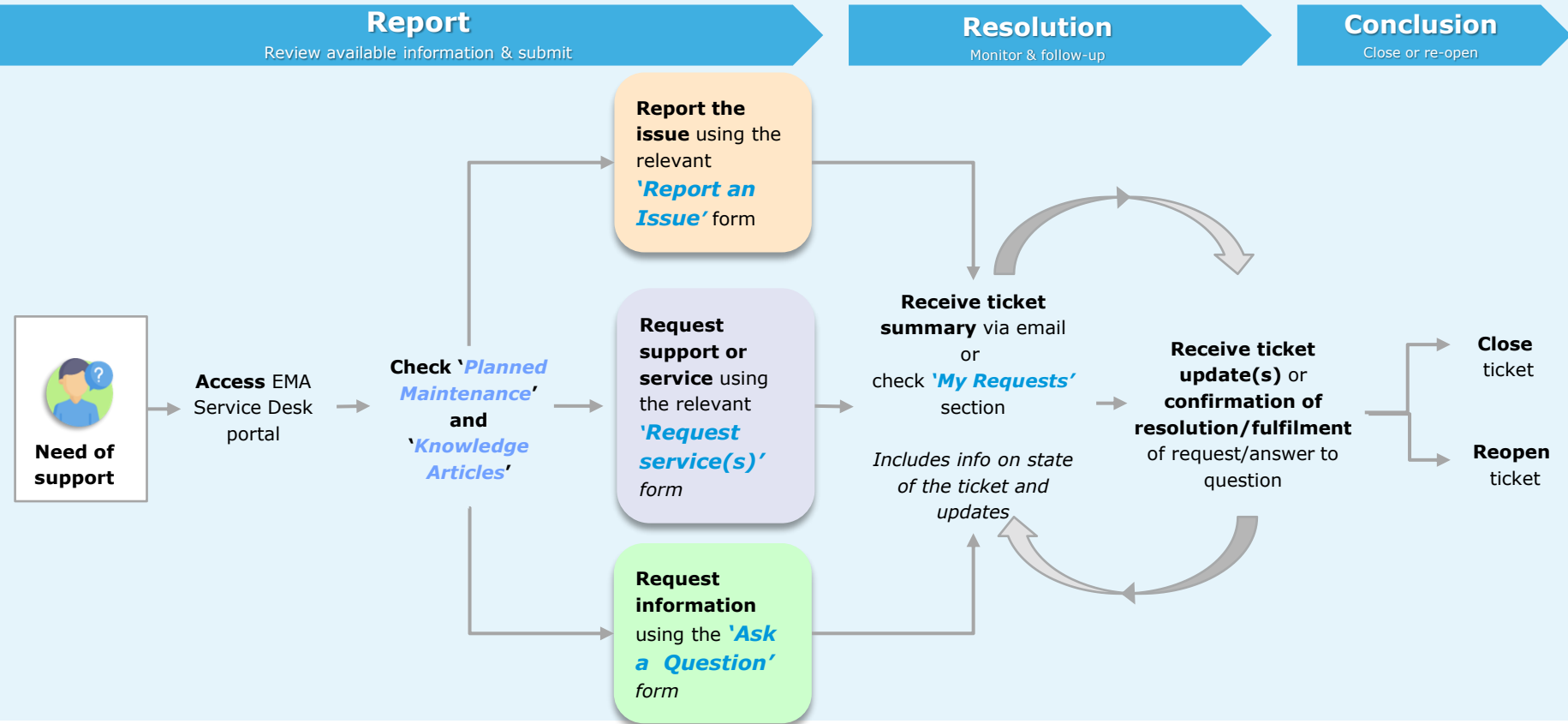


SD works closely together with Business to identify the priorities and main customer concerns/interests



SD obtains the estimates of issue resolution from the application development teams and keeps users informed via regular ticket updates

# Service Desk process flow: From customers' perspective



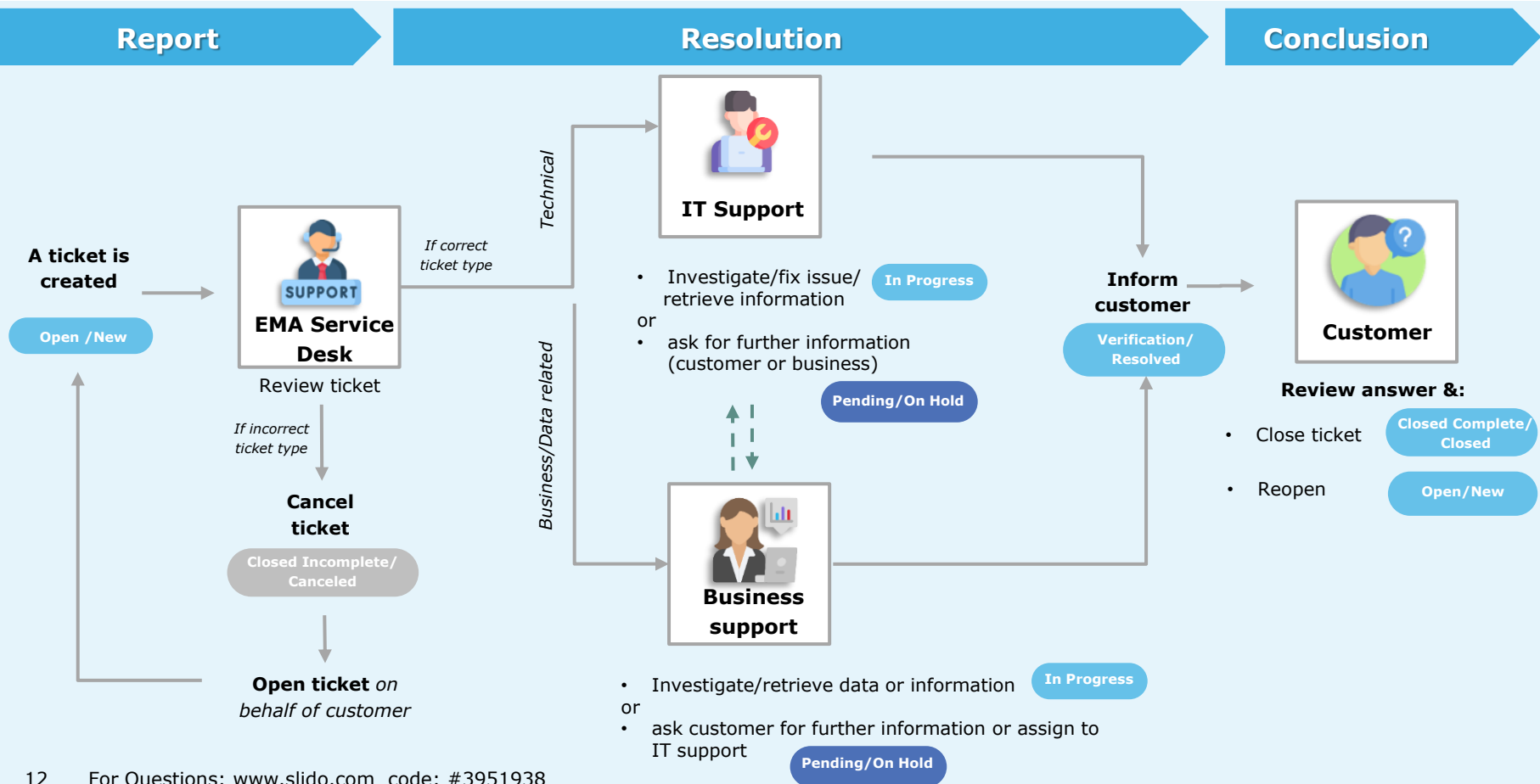


# Access to EMA Service Desk

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Presented by Marcelo Nahmijas as a system demonstration

# Service Desk process flow: From EMA perspective



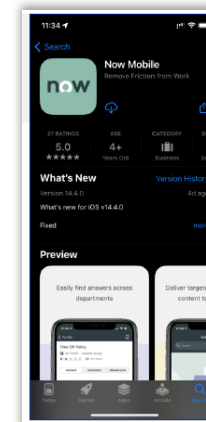
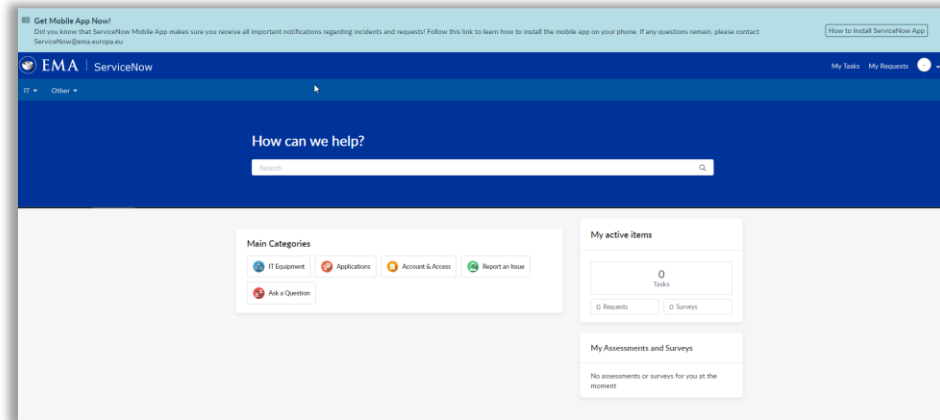
**ServiceNow** was introduced as the tool to access EMA Service Desk portal **on 12 September 2022**, and it is available as a **web and mobile application**



Web View



Mobile App





## Log in to the ServiceDesk portal

Log in to the ServiceDesk portal using your **Active Directory External account credentials**

- To set up your Active Directory External account credentials go to EMA Account Management portal and sign in using your EMA account credentials

*If unsure what your password is, use 'Forgot Password' to re-set it*

- If you do not have an EMA account, create an EMA account



## Two-factor authenticator

Add a **two-factor authenticator** in case you have none registered in our systems

*If experiencing issues with two factor authentication, please contact this number:*

*+31 (0)88 781 8520 or email address: [servicenow@ema.Europa.eu](mailto:servicenow@ema.Europa.eu)*



## User management

Dedicated webinar on user management (EMA Account Management webinar) is available on 11 October



[knowledge base article](#)



## Search panel

- for **knowledge articles** that might help answer your question/resolve an issue
- for the **required form** to submit your enquiry



## Main Categories

- **Browse** available **forms and knowledge articles** for each section

## Planned Maintenance announcements

## Quick links

 to other services

## My active items

- Overview of open **tickets submitted or watched by you**

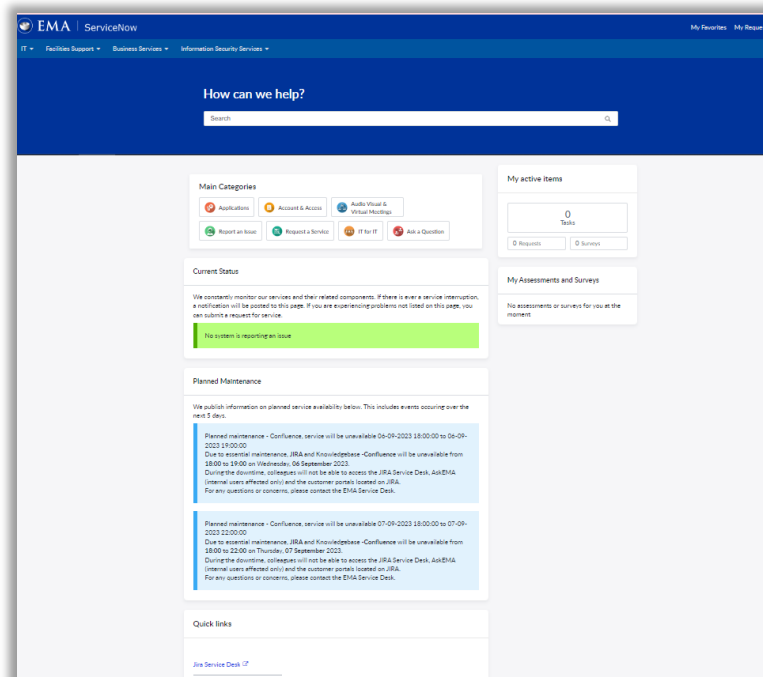
## My Assessments and Surveys

## My Favorites

- Overview of **articles and request forms** marked as **'favourite'**

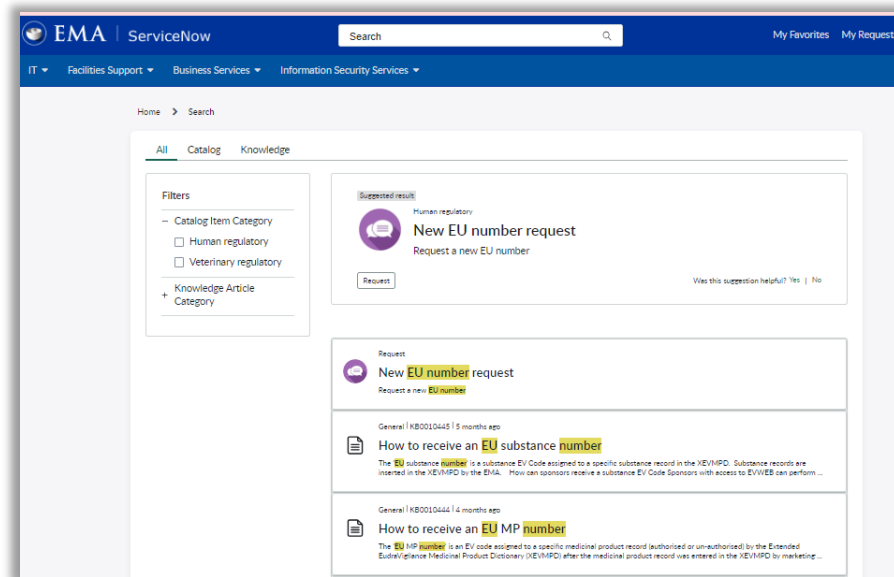
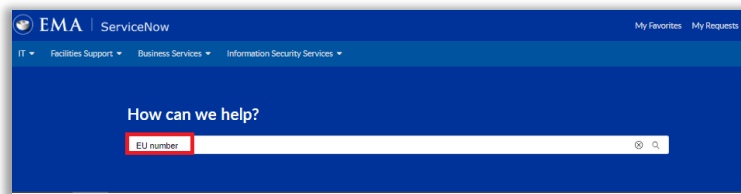
## My Requests

- Overview of **tickets opened/watched by you**





Search for available **knowledge articles** to help you find the required answer





Search for available **forms** to submit your enquiry

EMA | ServiceNow

IT Facilities Support Business Services Information Security Services

How can we help?

technical issue



EMA | ServiceNow

IT Facilities Support Business Services Information Security Services

Home > Search

All Catalog Knowledge

Filters

- Catalog Item Category
  - ☐ SPOR
  - ☐ EudraCT
  - ☐ PLM Portal - eAF
  - ☐ Account
  - ☐ eSubmission/Gateway
  - ☐ Applications
  - ☐ Building Maintenance
  - ☐ Business Services
  - ☐ EudraGMDP
  - ☐ IRIS
- + Knowledge Article Category

Suppressed result

SPOR

Report an Issue with PMS

Report an issue with the Product Management Services (PMS)

Request

Was this suppression helpful? Yes | No

Request

Report an issue with PMS

Report an issue with the Product Management Services (PMS)

Request

Report an issue with SMS

Report an issue with the Substance Management Services (SMS)

Request

Report an issue with OMS

Report an issue with the Organisation Management Services (OMS)

Request

Report an issue with RMS

Report an issue with the Reference Management Services (RMS)

Request

Report an issue

Request assistance with an issue you are having.

Request

Report an issue with XEVMPD/Art.57

Report an issue with the extended European Medicines Product Dictionary (XEVMPD)

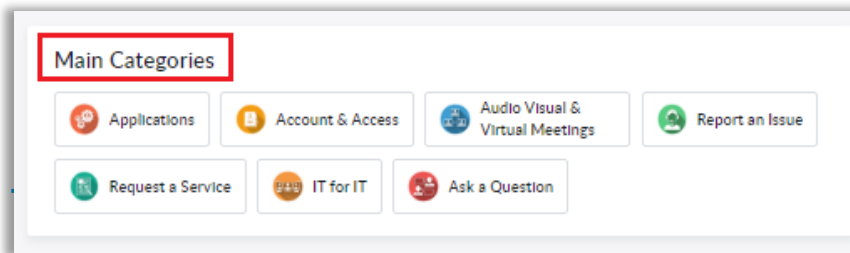
Request

Report an issue with EudraCT

Report a technical issue in a discussion on EudraCT EU Clinical Trials Register



- **Applications:** Browse forms and articles related to EMA applications
- **Accounts & Access:** Browse Account & Access related forms and articles (e.g.: EudraVigilance registration related access, Eudralink account etc.)
- **Audio Visual & Virtual meetings:** available by default, no forms available
- **Report an Issue form:** Quick access to the forms to report a **technical issue** with an IT application
- **Request a Service:** Quick access to the forms to **request a service** related to IT applications
- **IT for IT:** Browse available articles related to Infrastructure Transformation
- **Ask a Question form:** Quick access to the form to request information





Information about an upcoming maintenance of various IT applications

## Planned Maintenance

We publish information on planned service availability below. This includes events occurring over the next 5 days.

=====

Due to essential maintenance, the EudraCT website is going to have a downtime today between 18 and 18.30 (CET). We apologise for any inconvenience caused.


=====

Due to maintenance the Splatbox will be unavailable for a short while. Our maintenance will start at the 9th of March at 23:00 CET.



Quick links to other webpages/services

## Quick links

[Jira Service Desk](#) 



Overview of open tickets submitted/watched by you and any open surveys

## My active items

0  
Tasks

1 Requests

1 Surveys

## My Assessments and Surveys

 EMA - IT Satisfaction survey

RITM0036888 • Due in 4d

NEW

Overview of articles and request forms marked as 'Favourites'

Overview of tickets submitted by you (open/closed/any status)

EMA | ServiceNow

Search

My Favorites My Requests

IT Facilities Support Business Services Information Security Services

Home > My favorites

### My favorites

Browse favorites

All (5)

Articles (2)

Requests (3)

Sort by Date added (newest)

Request	Request	Request
<b>Request for Information</b> Request information or ask questions about Information Management	<b>Report an Issue with XEVMPD/Art.57</b> Report an issue with the extended Eudra/Glance Medicinal Product Dictionary (XEVMPD)	<b>Request XEVMPD/Art.57 Services</b> Request assistance with the management of product data in XEVMPD/Art.57
<b>Article</b> <b>How to set up Multi-Factor authentication (MFA) to access...</b> How to set up Multi-Factor authentication (MFA) to access EMA Cloud application. The article explains the process of setting up Multifactor Authentication (MFA) in order...	<b>Article</b> <b>How to receive an EU substance number</b> The 'EU substance number' is a substance EV Code assigned to a specific substance record in the XEVMPD. Substance records are inserted in the XEVMPD by the EMA...	

EMA | ServiceNow

Search

My Favorites My Requests

IT Facilities Support Business Services Information Security Services

Home > Requests

### My Requests

View Any status Search all requests

Request	State	Updated
<a href="#">Change request for organisation X</a> RITM0042064	Closed Complete	2mo ago
<a href="#">Request for EV Code of an authorised medicinal products</a> RITM0046097	Closed Complete	5mo ago
<a href="#">Question: Visibility of attachments in the Article 57 database</a> RITM0036888	Closed Complete	6mo ago

### My Watched Requests

View Open Search open requests

You do not have any requests



# Issue with an IT application

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Presented by Marcelo Nahmijas as a system demonstration





## Report an issue ('Incident')

### To report a technical issue with an IT application

**Examples:** *Unable to perform the required action in an application, error messages when working with an application, system not performing as expected etc.*

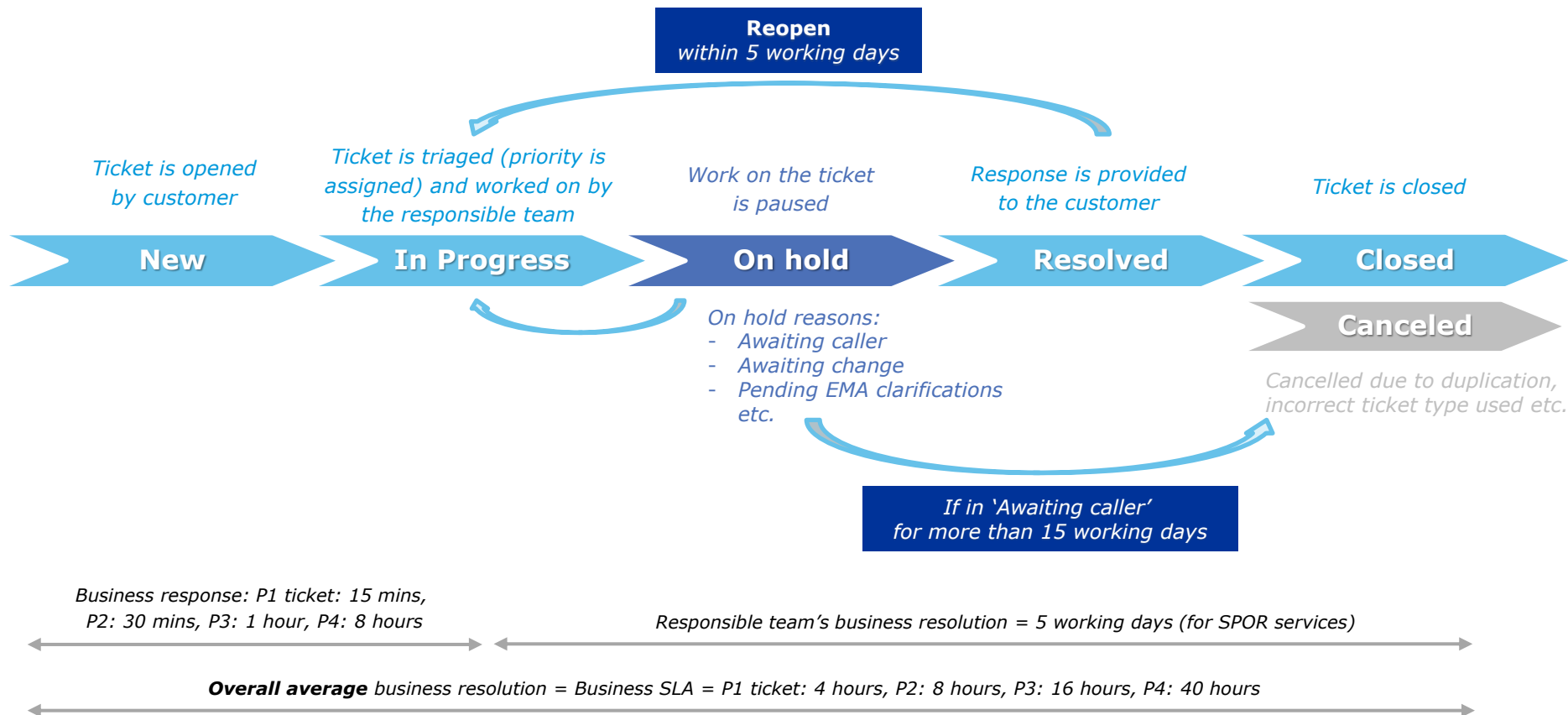
1 In the 'Main Categories' select '**Report an Issue**' option

2 Enter details of your request in the form

3 Specify the correct '**Service**' and '**Service Offering**' to identify the application to which your issue relates to  
→ *the ticket is assigned to the correct team*

4 Add attachments (if required) and submit the form

The screenshot shows the 'Main Categories' section with a red box highlighting the 'Report an Issue' button. Below this is the 'Report an Issue with XEVMPD/Art.57' form. The form includes a title bar, a description of the service, a 'Raise this request on behalf of' dropdown, a 'Subject' field, a 'Description' field, and an 'Attachments' section. The 'Subject' field contains 'EVWEB for XEVMPD not working'. The 'Description' field contains a message about experiencing issues with the XEVMPD user interface (EVWEB) and mentions an attachment. The 'Attachments' section shows a file named 'Step by step description and screenshots.docx' (19.2 KB) uploaded 'just now'. A 'Submit' button is visible on the right side of the form.





Incident priority is determined based on:

- **Impact** – measure of the **effect** of an incident, problem or change **on business processes**
- **Urgency** – measure of **how long the resolution can be delayed** until an incident, problem, or change has a **significant business impact**

## Impact

### High:

- Affects an **important/business critical system**
- Affects possibly **large number of users**
- Has **severe impact on** the Agency's **normal business operation**

### Medium:

- Affects only **non-critical business systems**,
- Affects a **group of users**
- The Agency **can still perform its most critical work**

### Low:

- Affects **non-critical system**
- Affects a **single user or a small number of users**
- The Agency **can still carry out most operational business activities**

## Urgency

*High:* Must be resolved asap

*Medium:* Must be resolved soon, typically because there is a business-critical deadline at hand

*Low:* Can be managed safely over a longer timeframe, the situation is already under control



## Timeframes for response

- Individual teams have their own operational level agreements (OLA)
- One ticket can be assigned to multiple different teams (business, IT); each team works within their assigned OLAs

Service Type	Priority	Response	SLA	Resolution	SLA
Incident	P1 – Critical	1/4 Hour	100%	4 Hours	80%
	P2 – Urgent	1/2 Hour		8 Hours	
	P3 – Medium	1 Hour		16 Hours	
	P4 – Low	8 Hours		40 Hours	



# Request for service(s)

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Presented by Marcelo Nahmijas as a system demonstration

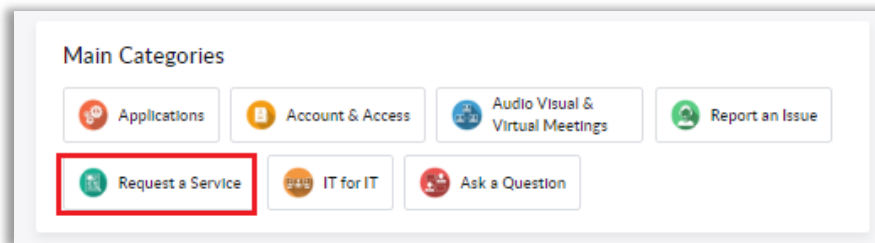


## Request for service(s)

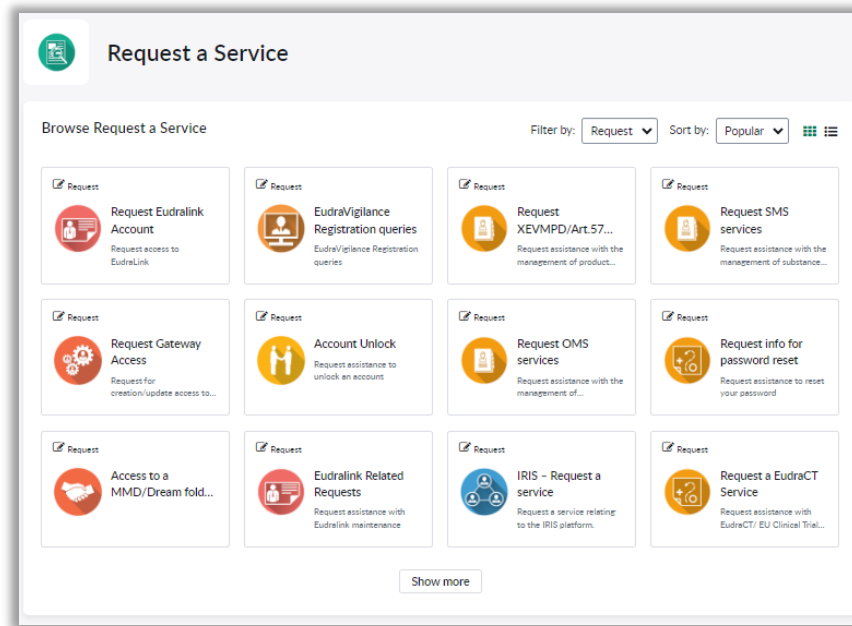
To **request service related to data in an application** (e.g., SMS, XEVMPD/Art57, Eudralink, EudraCT etc.)

**Examples:** Request for data, insert/update of data, change of data, registration for training, support with management of data etc.

1 In the 'Main Categories' select 'Request a Service'



2 Find the required application topic





3

Select the required application form

4

Enter details of your request in the form, add attachments (if required) and submit the form

**Request a Service**

Browse Request a Service

Filter by: Request Sort by: Popular

- Request Eudralink Account
- Request EudraVigilance Registration queries
- Request XEVMPD/Art.57...**
- Request SMS services
- Request Gateway Access
- Account Unlock
- Request OMS services
- Request info for password reset
- Access to a MMD/Dream fold...
- Eudralink Related Requests
- IRIS - Request a service
- Request a EudraCT Service

Show more

**Request XEVMPD/Art.57 Services**

Request assistance with the management of product data in XEVMPD/Art 57

Submit

- Use this service to request support with management of product data in the extended EudraVigilance Medicinal Product Dictionary (XEVMPD)/Article 57 database, to request XEVMPD e-learning training registration or knowledge evaluation or to raise concerns following the validation of your organisation's product data performed in the XEVMPD.

\* Raise this request on behalf of

\* Subject

Request for XEMPD e-learning knowledge evaluation

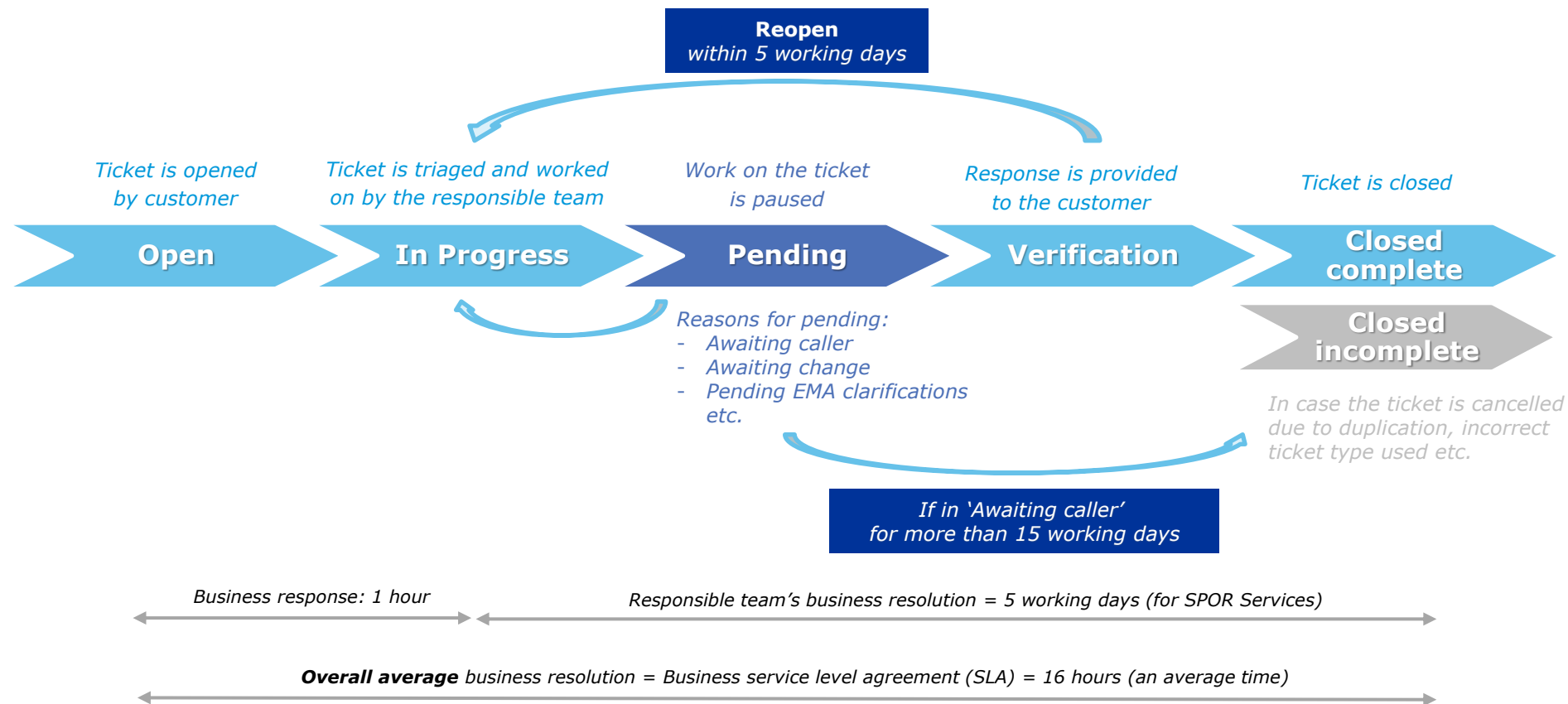
\* Description

Dear EMA,

I have studied the available training materials and I would like to register for the knowledge evaluation for the XEVMPD e-learning training.

Please find my details below:

Add attachments







# Request for information

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Presented by Marcelo Nahmijas as a system demonstration

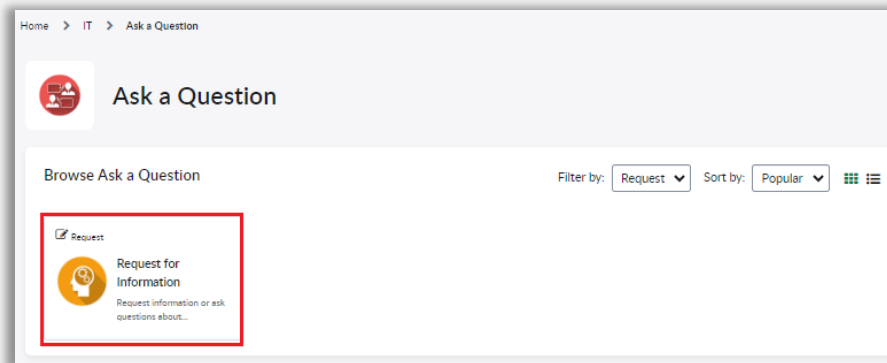
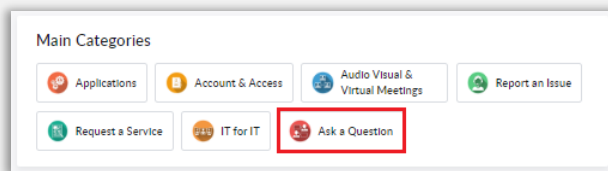


## Request for information (‘Ask a Question’)

To request information or ask questions about data/processes related to an application

**Examples:** Questions on how to manage data within an application, how to use the application, business processes, where to find information and documentation etc.

1 In the ‘Main Categories’ select ‘Ask a Question’





## Request for information (‘Ask a Question’)

To request information or ask questions about data/processes related to an application

**Examples:** *Questions on how to manage data within an application, how to use the application, business processes, where to find information and documentation etc.*

2 Enter details of your enquiry in the form


3 Specify the correct ‘**Service**’ and ‘**Service Offering**’ to which your enquiry relates to  
→ *ticket is assigned to the correct team*

4 Add attachments (if required) and submit the form

### Request for Information

Request information or ask questions about Information Management

Use this service to request information.



\* Raise this request on behalf of

\* Subject

\* Service

\* Service Offering


\* Description  

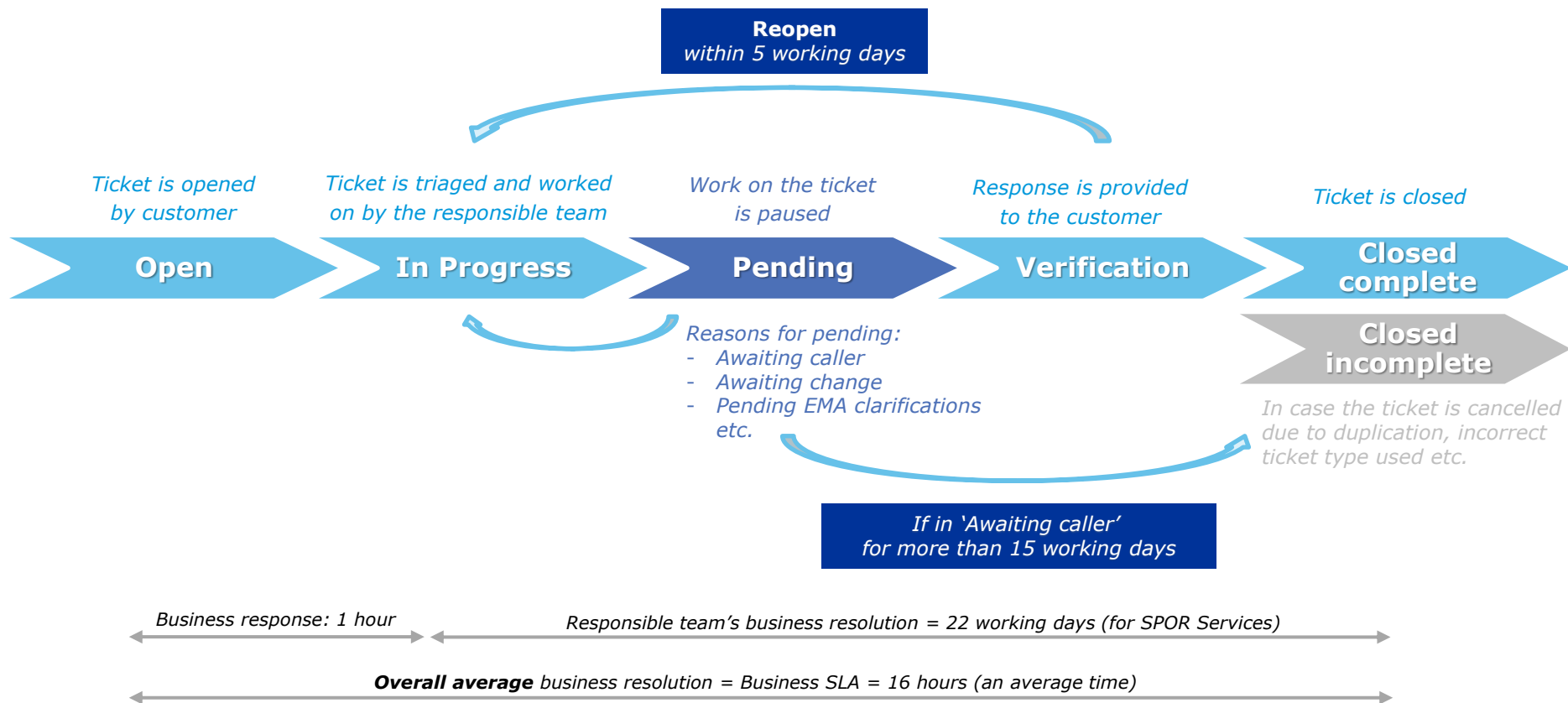
Dear Sirs,

can you please confirm if we are required to submit in the Article 57 database information on medicinal products with valid marketing authorisation in Northern Ireland?

Thank you in advance.

Kind regards,|

 Add attachments



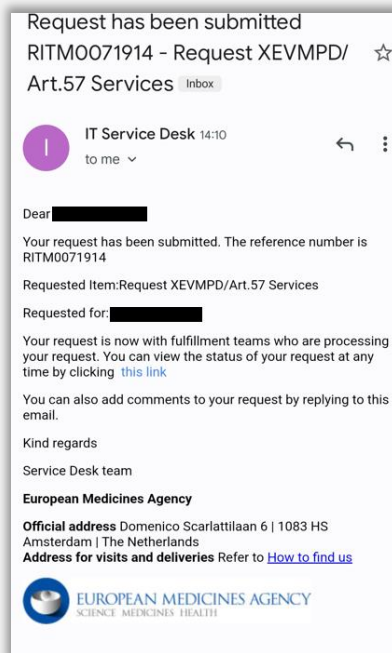
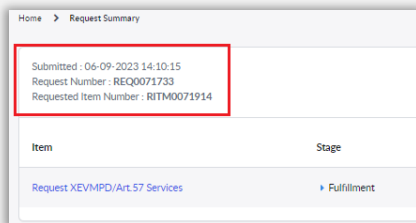


# Resolving/closing of tickets and follow-up

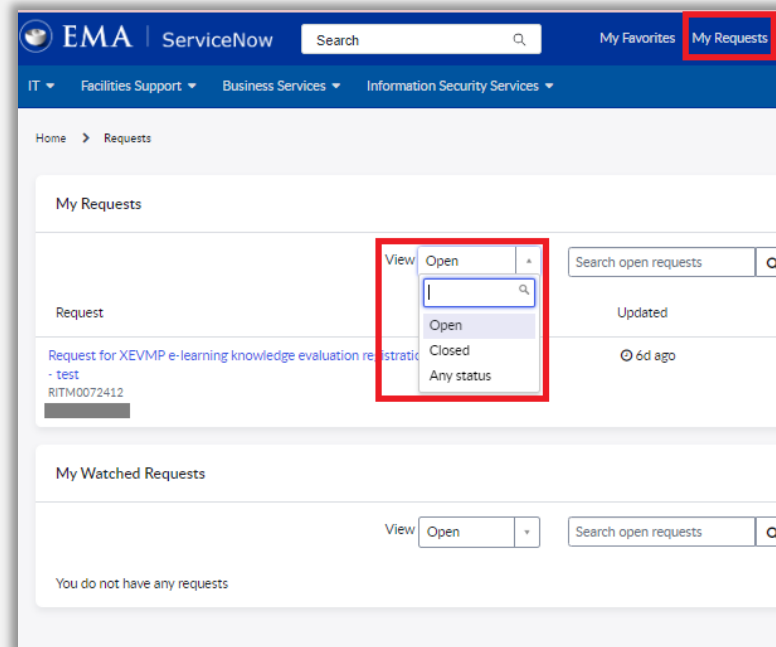
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Presented by Marcelo Nahmijas as a system demonstration

- 1 Once a ticket is submitted, the **ticket summary** will be provided **on screen** and **via a confirmation email**



- 2 An **overview** of all logged tickets is available in **'My Requests'**
- **Open** tickets are displayed by default
  - To view **closed or all tickets**, change the value in the 'View' section





**'Activity':** Ticket updates, follow-up(s) and answer(s)

Home > My Request - RITM0071906

Number: RITM0071906      Created: 8d ago      Updated: a day ago      Status: Closed Complete

Question: Question: IDs in the XEVMPD

Opened: 8d ago

Steps: completed

To add a paragraph in your message, press Shift + Enter.

Activity   Attachments   Additional Details

AS: Dear [redacted]

Thank you for contacting the EMA ServiceNow.

Please note that no PMS IDs are available in XEVMPD. The identifiers in XEVMPD are called EV codes. PMS IDs will be assigned by PMS only.

Hope this clarifies your query.

Kind regards  
Art 57 QC team

VB: [redacted]      RITM0071906 Created      8d ago

Start

**'Attachments':** Submitted or received attachments

Home > My Request - RITM0071906

Number: RITM0071906      Created: 8d ago      Updated: a day ago      Status: Closed Complete

Question: Question: IDs in the XEVMPD

Opened: 8d ago

Steps: completed

To add a paragraph in your message, press Shift + Enter.

Activity   **Attachments**   Additional Details

Drop files here

**'Additional details':** Original ticket description

Home > My Request - RITM0071906

Number: RITM0071906      Created: 8d ago      Updated: a day ago      Status: Closed Complete

Question: Question: IDs in the XEVMPD

Opened: 8d ago

Steps: completed

To add a paragraph in your message, press Shift + Enter.

Activity   Attachments   **Additional Details**

Raise this request on behalf of [redacted]

Subject: Question: IDs in the XEVMPD

Service: SPOR

Service Offering: XEVMPD/Art.57

Description: Dear Sir, Madam,

Can you please confirm if/where in the XEVMPD we can find PMS IDs for our medicinal products?


Thanks in advance for your clarification.

Kind regards,

3

- When a **ticket is updated** (i.e.: an answer is provided/more information is requested) customers receives a **notification via email**
- **Ticket progress** can also be checked in 'My Requests' section -> see **change in the 'State'**

Request RITM0071914 has been commented - PRD1234567 to be nullified in XEVMPD XCOMP Inbox ☆

 IT Service Desk 14:55  
to me ▾

Dear,

The following Request has been updated with new information:

**Requested item number:** RITM0071914

**Summary:** PRD1234567 to be nullified in XEVMPD XCOMP

**Description:** Dear Sir, Madam,

We just submitted in the XEVMPD XCOMP environment an AMP information which should not have been submitted. The EV Code PRD1234567 was assigned to this product entry submitted by mistake. Can you please nullify it on our behalf?

Thanks in advance.

With regards,

You can review the comment and the status of the request through [this link](#).

Kind regards

Service Desk team

**European Medicines Agency**

**Official address** Domenico Scarlattilaan 6 | 1083 HS Amsterdam | The Netherlands

Home > Requests

My Requests

View Any status ▾ Search all requests

Request	State	Updated
<a href="#">Question: Question: IDs in the XEVMPD</a> RITM0071906	Closed Complete	⌚ a day ago
<a href="#">PRD1234567 to be nullified in XEVMPD XCOMP</a> RITM0071914	Closed Complete	⌚ a day ago
<a href="#">Request for XEVMP e-learning knowledge evaluation registration - test</a> RITM0072412	Pending	⌚ 6d ago





1

Review the received answer via email or in 'My Requests'

2

If satisfied with the answer provided, close the ticket using the '**Confirm Close**' function

3

If more information is required regarding the answer provided, reopen the ticket using the '**Reopen**' function

Home > My Request: RITH0071914

Number: RITH0071914

Status: Closed about an hour ago Updated: 14m ago Verification

PRD1234567 to be nullified in XEVPMD XCOMP

Reopen Confirm Close

Message: Dear [redacted],

Thank you for contacting the EMA Service Desk.

Since the product was submitted in the XCOMP environment and have not been validated by the EMA (i.e. the "Product Validity" field displays "Not Assessed"), you can therefore nullify the product EV Code PRD1234567 by your own by submitting an XEVPRM with operation type "Nullification" (4) assigned to the EV Codes.

Please refer to section 2.4.7 Nullification of AMP entities and/or step 5 of Process map 13 - Nullification of an AMP entity of Chapter 3.8. Extended EudraGloss product report message (XEVPRM) user guidance ([http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2012/03/WC500123681.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500123681.pdf)) for related information.

Please also note that Gateway registered organisations create a nullification XEVPRM using EVWEB and submit this XEVPRM as a ZIP file using EV Post functionality available in the secure area of the EudraGloss website (the "Send" button will not be available for the organisation in EVWEB).

Please refer to the XEVPMD Data-Entry Tool (EVWEB) User Manual ([https://www.ema.europa.eu/en/documents/other/extended-eudraGloss-medical-product-dictionary-xevmpmd-data-entry-tool-user-manual\\_en.pdf](https://www.ema.europa.eu/en/documents/other/extended-eudraGloss-medical-product-dictionary-xevmpmd-data-entry-tool-user-manual_en.pdf)) section 4.9. How to Use EV Post.

Kind regards,  
Art 37 OC team

RITH0071914 Created

Home > My Request: RITH0071914

Number: RITH0071914

Status: Closed about an hour ago Updated: 14m ago Verification

PRD1234567 to be nullified in XEVPMD XCOMP

Reopen Confirm Close

Message: Dear [redacted],

Thank you for contacting the EMA Service Desk.

Since the product was submitted in the XCOMP environment and have not been validated by the EMA (i.e. the "Product Validity" field displays "Not Assessed"), you can therefore nullify the product EV Code PRD1234567 by your own by submitting an XEVPRM with operation type "Nullification" (4) assigned to the EV Codes.

Please refer to section 2.4.7 Nullification of AMP entities and/or step 5 of Process map 13 - Nullification of an AMP entity of Chapter 3.8. Extended EudraGloss product report message (XEVPRM) user guidance ([http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2012/03/WC500123681.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500123681.pdf)) for related information.

Please also note that Gateway registered organisations create a nullification XEVPRM using EVWEB and submit this XEVPRM as a ZIP file using EV Post functionality available in the secure area of the EudraGloss website (the "Send" button will not be available for the organisation in EVWEB).

Please refer to the XEVPMD Data-Entry Tool (EVWEB) User Manual ([https://www.ema.europa.eu/en/documents/other/extended-eudraGloss-medical-product-dictionary-xevmpmd-data-entry-tool-user-manual\\_en.pdf](https://www.ema.europa.eu/en/documents/other/extended-eudraGloss-medical-product-dictionary-xevmpmd-data-entry-tool-user-manual_en.pdf)) section 4.9. How to Use EV Post.

Kind regards,  
Art 37 OC team

RITH0071914 Created

# Service Desk: roadmap and planned improvements

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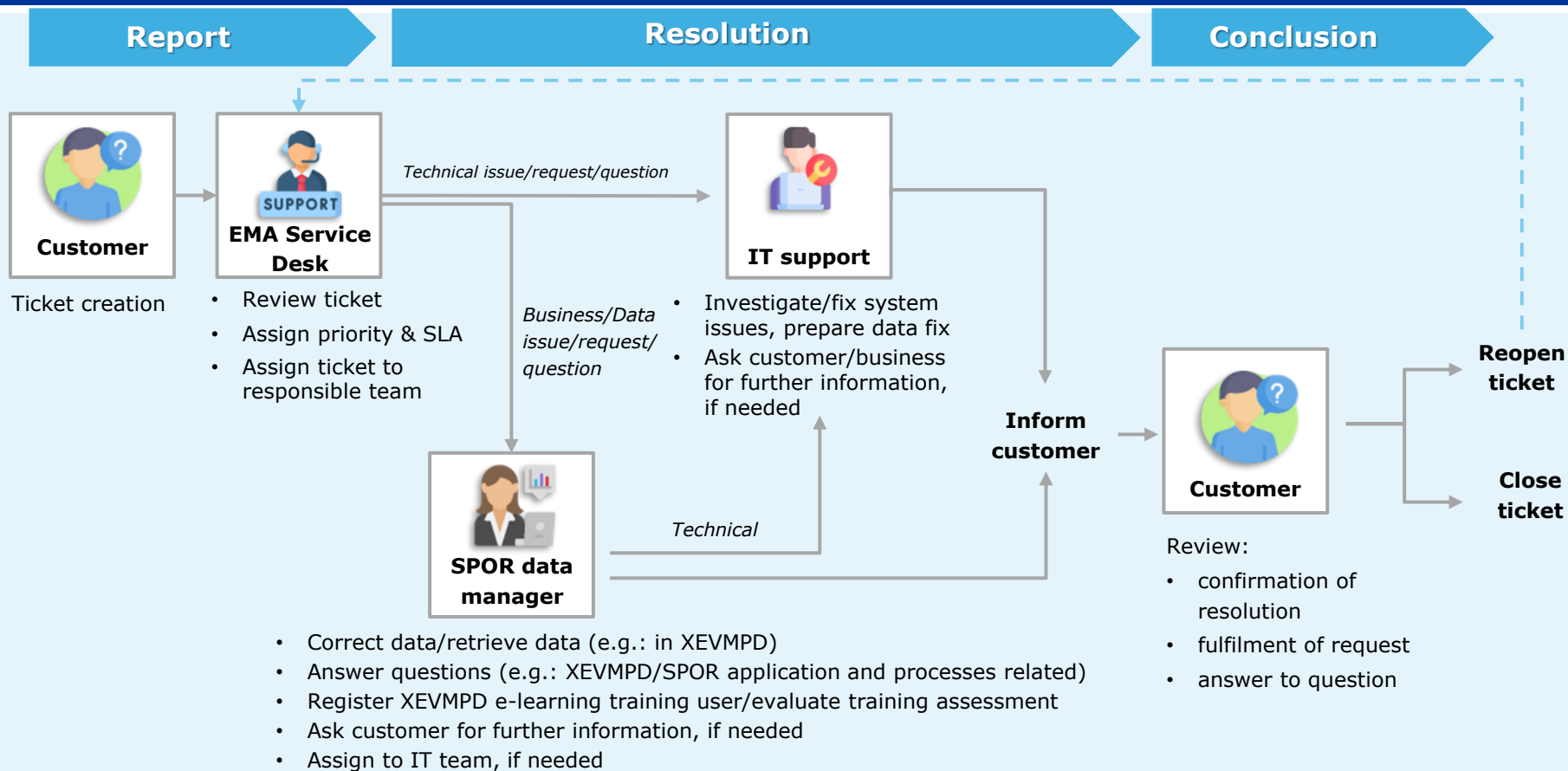
Presented by Marcelo Nahmijas during the system demonstration



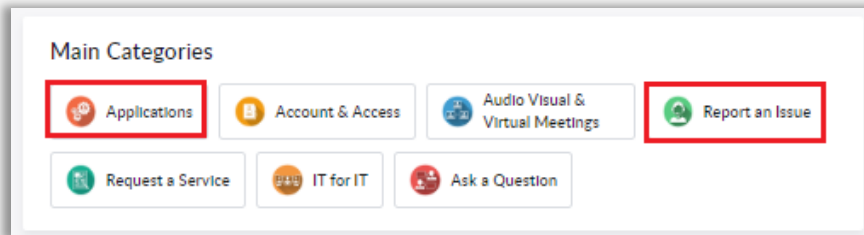
# SPOR services

---

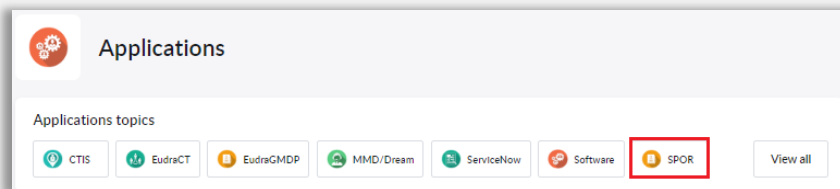
Presented by Veronika Baker



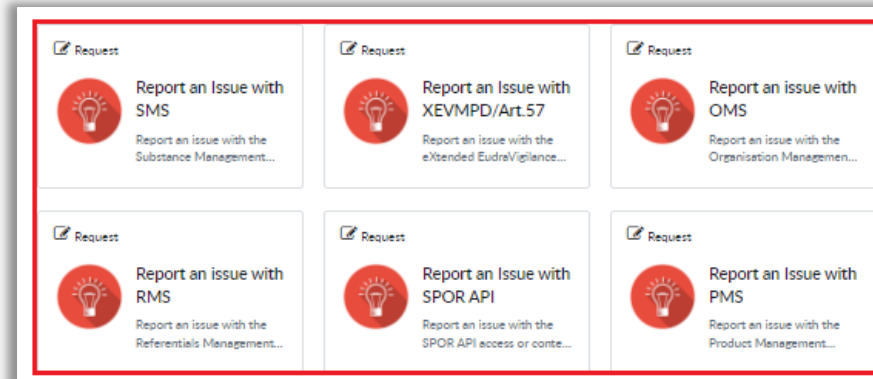
1 Go to 'Applications' or directly to 'Report an Issue':



1.1 If via 'Applications', select 'SPOR' icon in the 'Application topics'



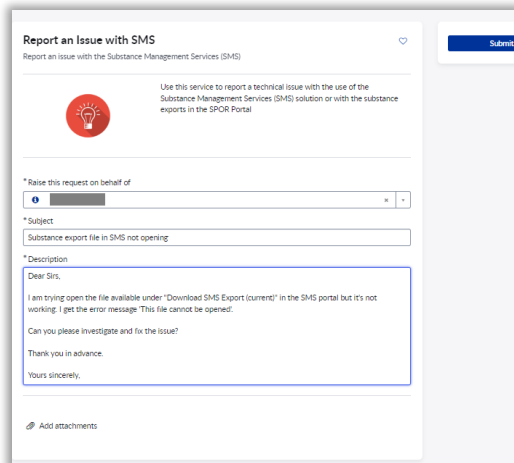
2 Select the relevant SPOR related form



3 Enter details of your issue and submit the form

## Report an issue with SMS application

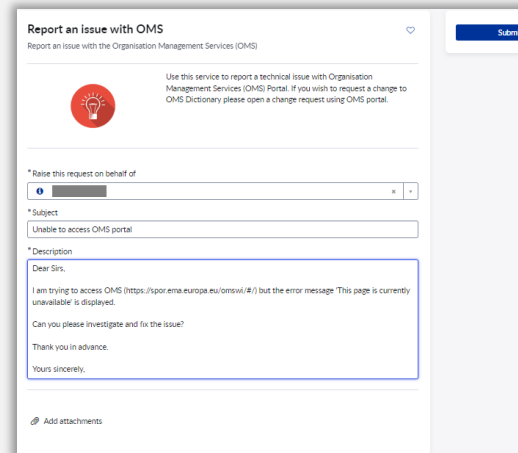
Use this service ([link](#)) to **report a technical issue with the Substance Management Services (SMS) portal or with the substance exports in the SPOR Portal (UI)**



The screenshot shows the 'Report an issue with SMS' form. It includes a title bar with a heart icon and a 'Submit' button. The main content area has a light blue header with a lightbulb icon and instructions: 'Use this service to report a technical issue with the use of the Substance Management Services (SMS) solution or with the substance exports in the SPOR Portal'. Below this is a form with fields for 'Raise this request on behalf of' (with a dropdown menu), 'Subject' (with a text input), and 'Description' (with a text area). The description field contains a sample message: 'Dear Sirs, I am trying open the file available under "Download SMS Export (current)" in the SMS portal but it's not working. I get the error message "This file cannot be opened." Can you please investigate and fix the issue? Thank you in advance. Yours sincerely,'. At the bottom, there is an 'Add attachments' link.

## Report an issue with OMS application

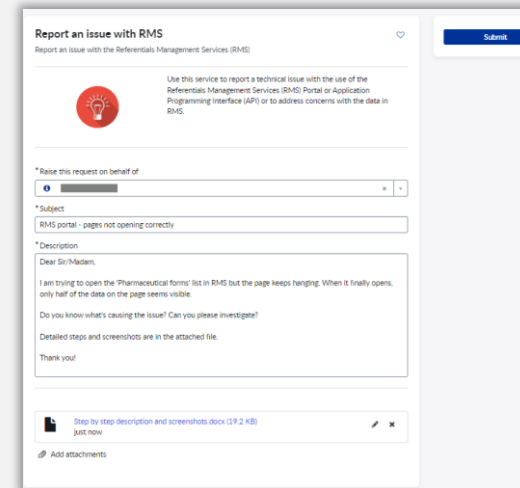
Use this service ([link](#)) to **report a technical issue with the Organisation Management Services (OMS) Portal**



The screenshot shows the 'Report an issue with OMS' form. It includes a title bar with a heart icon and a 'Submit' button. The main content area has a light blue header with a lightbulb icon and instructions: 'Use this service to report a technical issue with Organisation Management Services (OMS) Portal. If you wish to request a change to OMS Dictionary please open a change request using OMS portal'. Below this is a form with fields for 'Raise this request on behalf of' (with a dropdown menu), 'Subject' (with a text input), and 'Description' (with a text area). The description field contains a sample message: 'Dear Sirs, I am trying to access OMS (https://spor.ema.europa.eu/omsui/#/) but the error message "This page is currently unavailable" is displayed. Can you please investigate and fix the issue? Thank you in advance. Yours sincerely,'. At the bottom, there is an 'Add attachments' link.

## Report an issue with RMS application

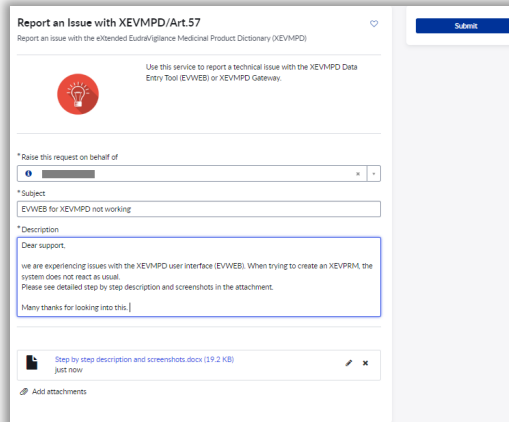
Use this service ([link](#)) to **report a technical issue with the use of the Referentials Management Services (RMS) Portal**



The screenshot shows the 'Report an issue with RMS' form. It includes a title bar with a heart icon and a 'Submit' button. The main content area has a light blue header with a lightbulb icon and instructions: 'Use this service to report a technical issue with the use of the Referentials Management Services (RMS) Portal or Application Programming Interface (API) or to address concerns with the data in RMS'. Below this is a form with fields for 'Raise this request on behalf of' (with a dropdown menu), 'Subject' (with a text input), and 'Description' (with a text area). The description field contains a sample message: 'Dear Sir/Madam, I am trying to open the "Pharmaceutical forms" list in RMS but the page keeps hanging. When it finally opens, only half of the data on the page seems visible. Do you know what's causing the issue? Can you please investigate? Detailed steps and screenshots are in the attached file. Thank you!'. Below the description field, there is a file attachment preview showing 'Step by step description and screenshots.docx (19.2 KB) just now'. At the bottom, there is an 'Add attachments' link.

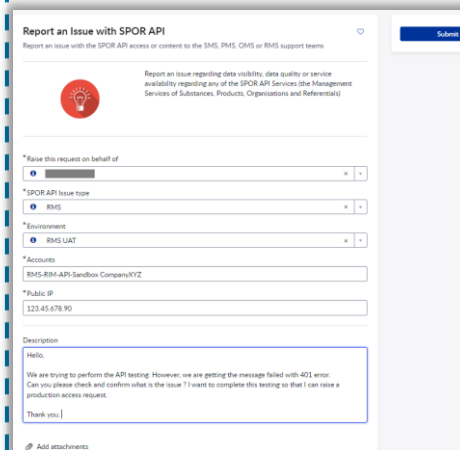
## Report an issue with XEVMPD

Use this service ([link](#)) to report **a technical issue with the XEVMPD Data Entry Tool (EVWEB) or XEVMPD Gateway**



## Report an issue with SPOR API

Use this service ([link](#)) to **report an issue with data visibility or service availability regarding any of the SPOR API Services (OMS/RMS)**

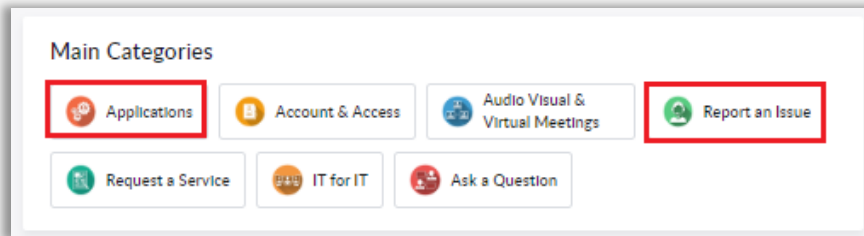


### PMS & SMS are still in development:

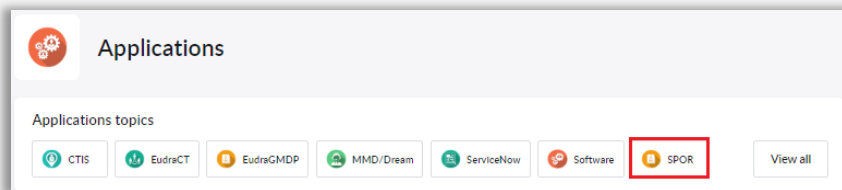
- No access to PMS is yet available
- SMS API is currently available for NCA only

# Request a service related to the XEVMPD or SPOR application

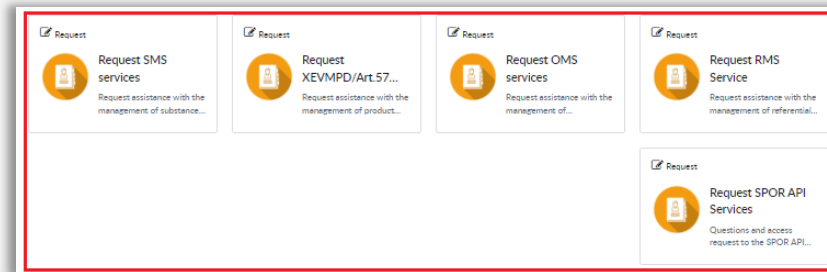
## 1 Go to 'Applications'



### 1.1 If via 'Applications', select 'SPOR' icon in the 'Application topics'



## 2 Select the relevant SPOR related form



## 3 Enter details of your request and submit the form




Use this service ([link](#)) to request support with **management of product data in the XEVMPD/Article 57 database** or to **request XEVMPD e-learning training registration or knowledge evaluation** or to **raise objections with validation related change**

## To request:

- **Amendment of data** such as
  - nullification of validated entities (AMP, MAH or sponsor organisation)
  - amendment of information in invalidated AMPs
  - changing the marketing authorisation status of AMPs invalidated by mistake back to valid
- **Clarification/change following the validation of AMP data** in the XEVMPD
- **Validation/re-validation of AMPs**
- **'Previous EV Code'**
- **A copy of the XEVPRM ACK if not received by the MAH/sponsor**
- **Addition of terms to XEVMPD controlled vocabularies**
- **Registration for XEVMPD e-learning training** (initial registration, assessment evaluation)



### Request XEVMPD/Art.57 Services

Request assistance with the management of product data in XEVMPD/Art 57



- Use this service to request support with management of product data in the extended EudraVigilance Medicinal Product Dictionary (XEVMPD)/Article 57 database, to request XEVMPD e-learning training registration or knowledge evaluation or to raise concerns following the validation of your organisation's product data performed in the XEVMPD.

\* Raise this request on behalf of


\* Subject

\* Description

Dear Sirs,

can you please nullify the PRD123456 as this is validated AMP entry and are unable to do so at our end? The correct product entry that we maintain is PRD78910.

Thank you in advance. |

 Add attachments

Submit

Use this service ([link](#)) to request the **registration of a new substance term** or the **update of an existing substance term**

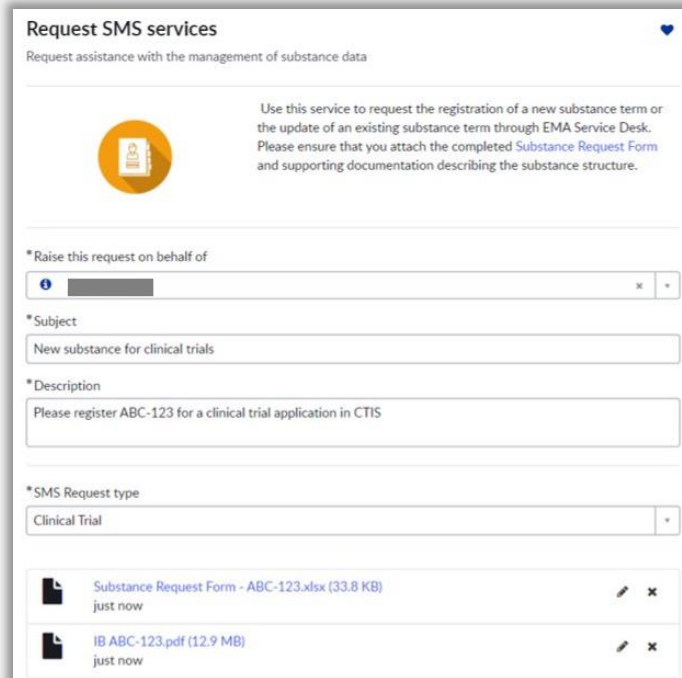
1 To request **addition of a new substance**, include:

- **Brief description** of the substance
- **Substance request form** AND
- **Supporting documentation** describing the substance nomenclature/structure (e.g., SmPC, Investigator's Brochure, company specifications, section A.3 Medical Plausibility of Orphan Designation, draft package for Scientific Advice, etc.)

2 To request **update of an existing substance**, include:

- The **SMS ID or EV Code** of the substance to be updated in the Description
- The **new name** to be added in the Description
- **Supporting documentation** describing the substance nomenclature/structure (e.g., SmPC, Investigator's Brochure, company specifications, section A.3 Medical Plausibility of Orphan Designation, draft package for Scientific Advice, etc.)

*In the 'SMS Request type' -> select the applicable value*



The screenshot shows the 'Request SMS services' form. At the top, it says 'Request assistance with the management of substance data'. Below this is an orange circular icon with a document and a magnifying glass. To the right of the icon, it says: 'Use this service to request the registration of a new substance term or the update of an existing substance term through EMA Service Desk. Please ensure that you attach the completed [Substance Request Form](#) and supporting documentation describing the substance structure.'

The form has several fields:

- \* Raise this request on behalf of: [Dropdown menu with a blue 'i' icon and a grey bar]
- \* Subject: [Text box containing 'New substance for clinical trials']
- \* Description: [Text box containing 'Please register ABC-123 for a clinical trial application in CTIS']
- \* SMS Request type: [Dropdown menu with 'Clinical Trial' selected]

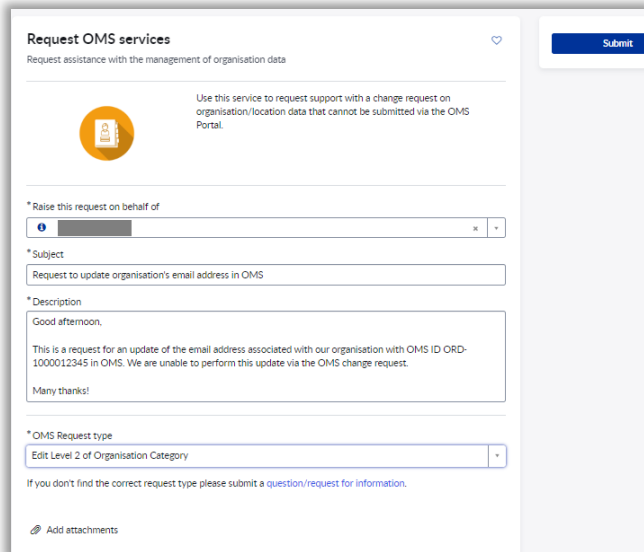
At the bottom, there is a list of attachments:

- Substance Request Form - ABC-123.xlsx (33.8 KB) just now [Edit icon] [Close icon]
- IB ABC-123.pdf (12.9 MB) just now [Edit icon] [Close icon]

## Request OMS services

Use this service ([link](#)) to request **support with a change request on organisation/location data** that cannot be submitted via the OMS Portal

*Example: a request to update contact details (phone/email) currently published*

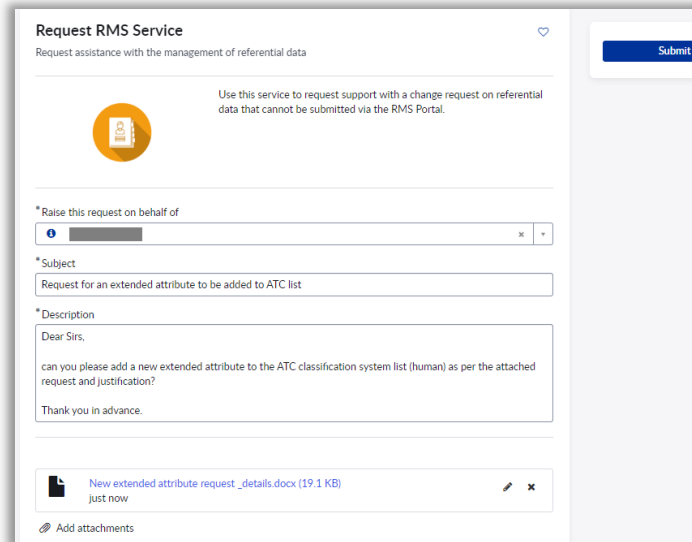


The screenshot shows the 'Request OMS services' form. At the top, it says 'Request assistance with the management of organisation data'. Below this is an orange circular icon with a document symbol. The text explains: 'Use this service to request support with a change request on organisation/location data that cannot be submitted via the OMS Portal.' The form has several fields: '\* Raise this request on behalf of' with a dropdown menu, '\* Subject' with a text box containing 'Request to update organisation's email address in OMS', '\* Description' with a text box containing 'Good afternoon, This is a request for an update of the email address associated with our organisation with OMS ID ORD-1000012345 in OMS. We are unable to perform this update via the OMS change request. Many thanks!', and '\* OMS Request type' with a dropdown menu showing 'Edit Level 2 of Organisation Category'. At the bottom, there is a link 'If you don't find the correct request type please submit a question/request for information.' and an 'Add attachments' button.

## Request RMS services

Use this service ([link](#)) to request **support with a change request on referential data** that cannot be submitted via the RMS Portal

*Example: a request to populate data such as extended attributes that cannot be requested through a change request*



The screenshot shows the 'Request RMS Service' form. At the top, it says 'Request assistance with the management of referential data'. Below this is an orange circular icon with a document symbol. The text explains: 'Use this service to request support with a change request on referential data that cannot be submitted via the RMS Portal.' The form has several fields: '\* Raise this request on behalf of' with a dropdown menu, '\* Subject' with a text box containing 'Request for an extended attribute to be added to ATC list', '\* Description' with a text box containing 'Dear Sirs, can you please add a new extended attribute to the ATC classification system list (human) as per the attached request and justification? Thank you in advance.', and a file upload section showing 'New extended attribute request\_details.docx (19.1 KB) just now'. At the bottom, there is an 'Add attachments' button.

Use this service ([link](#)) to **request API access** to the different SPOR Services (SMS, PMS, OMS and RMS)

- In the 'SPOR API Request type' -> select the required value
- In the 'Environment' -> select the relevant value

Requesting an access for API will grant access for **OMS & RMS only**.




**PMS & SMS are still in development:**

- No access to PMS is yet available
- SMS API is currently available for NCA only

### Request SPOR API Services

Questions and access request to the SPOR API (SMS, PMS, OMS or RMS)



Technical questions or requests for API access to the different SPOR Services (the Management Services of Substances, Products, Organisations and Referentials of the EMA).

*Please note that requesting an access for API automatically will grant access for OMS & RMS. PMS & SMS are still in development and a different request should be submitted*

\*Raise this request on behalf of

x

\*Subject

Request for access to RMS API

\*SPOR API Request type

RMS

x

\*Environment

RMS PROD

x

\*Accounts

userXYZ\_p1

Public IP

123.45.678.90

Description

Dear Sir/Madam,

hereby I request access to RMS API, please let me know if any further information is needed aside from the information in the attachment.

Thank you and good day to you.

\*Attachment

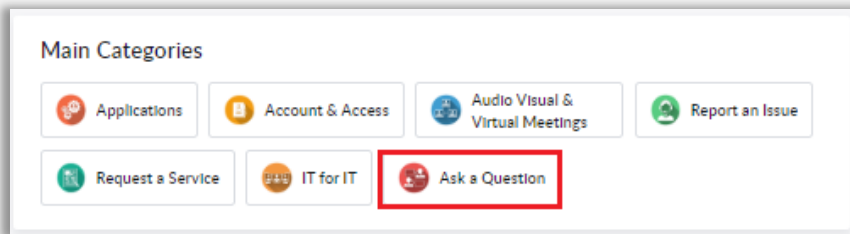
RMS API access.docx

Upload

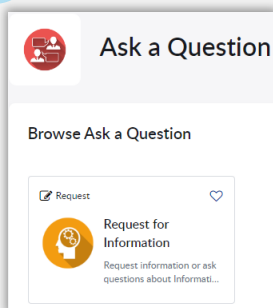
Delete

Submit

1 Go to 'Ask a Question'



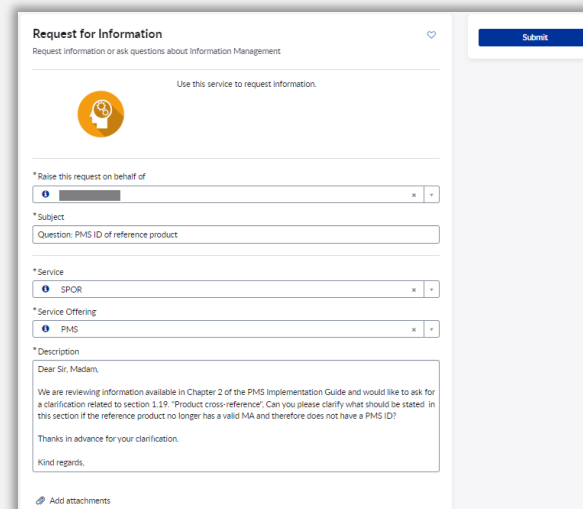
2 Click on 'Request for Information'



3

Enter details of your request for information and:

- In the 'Service' -> select '**SPOR**'
- In the 'Service Offering' -> select the required value (e.g., **SPOR registration, SMS, PMS, OMS, RMS, XEVMPD** etc.)



Request for Information

Request information or ask questions about Information Management

Use this service to request information.

\* Raise this request on behalf of

\* Subject

Question: PMS ID of reference product

\* Service

\* Service Offering

\* Description

Dear Sir, Madam,

We are reviewing information available in Chapter 2 of the PMS Implementation Guide and would like to ask for a clarification related to section 1.19 "Product cross-reference". Can you please clarify what should be stated in this section if the reference product no longer has a valid MA and therefore does not have a PMS ID?

Thanks in advance for your clarification.

Kind regards,

Add attachments

4

Submit the form



# Points to consider: The DOs and DON'Ts

---

Presented by Veronika Baker



## DOs

- **Submit tickets using the correct forms**

If incorrect → the triage team cancels/closes the existing ticket and new ticket is opened on behalf of the customer

- *Leads to unnecessary delays in responding to your enquiry; ticket needs to be triaged again*

- **Reference the correct 'Service' and 'Service Offering'**

If incorrect → ticket assigned to the incorrect support team

- *Leads to unnecessary delays in responding to your enquiry;*
- *An answer provided by the incorrect support team might be generic and not tailored to your needs*

- **Provide as much information as possible**

E.g.: if reporting a technical issue, include step by step description, screenshots, organisation ID, any XML files submitted etc.

If not provided → customer is asked for that information

- *Leads to unnecessary delays in investigating the issue*



## DON'Ts

- Log a ticket using **incorrect form hoping for a faster response**

-> the existing ticket is cancelled/closed by the triage team & new ticket is opened on behalf of the customer:

- *Leads to unnecessary delays in responding to your enquiry; ticket needs to be triaged again*

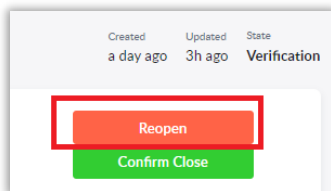
- **Submit the same issue/request/question via multiple tickets or channels**

- *Leads to unnecessary delays in responding to your enquiry;*
- *An answer provided by the incorrect support team might be generic and not tailored to your needs*
- *Duplication of efforts from EMA Service Desk -> time spent on dealing with duplicate queries is not spent addressing other user needs*



## DOs

- **To follow-up on the received answer, reopen the ticket** (within the 5 WD period)



- **Open a new ticket to ask a question not related to the original ticket or to the provided answer**
  - The new question will need to be triaged again to determine type/urgency and whether it needs to be addressed by a new team
  - To prioritise resources, we monitor new tickets faster/more frequently than those considered resolved/closed



## DON'Ts

- **Reopen closed tickets to ask questions not related to the answer provided or the original ticket description**
  - The ticket will be closed again
  - You will be advised to open a new ticket





## Key takeaways and conclusions

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This presentation explained **how SPOR helpdesk is currently managed**



A **demonstration** of ServiceNow was provided



An overview of the SLAs applicable for each ticket type to be raised via the ServiceDesk was included



After this presentation, customers should feel more **confident in using the tool** correctly, know where to **find information proactively** and **how to raise their issues/submit requests/ask questions using the correct forms**





# Any questions on the webinar?

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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
<b>Service Desk for SPOR and XEVMPD</b>	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



## Further information

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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](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

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## Glossary

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Acronym	Name
<b>API</b>	Application Programming Interface
<b>Art. 57</b>	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
<b>CAP</b>	Centrally Authorised Product
<b>CR</b>	Change request
<b>CTIS</b>	Clinical Trials Information System
<b>DADI</b>	Digital Application Dataset Integration
<b>DMP</b>	Development Medicinal Product
<b>DCP</b>	De-centralised Procedure
<b>DQ</b>	Data Quality
<b>eAF</b>	Electronic Application Form
<b>ePI</b>	Electronic Product Information
<b>eCTD</b>	Common Technical Document in electronic format
<b>EMA DB</b>	European Medicines Agency Data Board
<b>EMRN</b>	European Medicines Regulatory Network
<b>Epic</b>	<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>





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



Acronym	Name
<b>MRP</b>	Mutual Recognition Procedure
<b>NAP</b>	Nationally Authorised Product
<b>NCA</b>	National Competent Authority
<b>NDB</b>	Network Data Board
<b>NICTAC</b>	Network ICT Advisory Committee represents the network IT community
<b>NPAG</b>	Network Portfolio Advisory Group represents the Management Board and HMAs
<b>OD</b>	Orphan Designation
<b>OMS</b>	Organisation Management Service
<b>PB</b>	Portfolio Board
<b>PI</b>	Programme Increment, a three month period of work
<b>PI Planning ceremony</b>	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
<b>PIP</b>	Paediatric Investigation Plan
<b>PLM</b>	Product Lifecycle Management Value Stream
<b>PMS</b>	Product (Data) Management Service
<b>PO</b>	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.
<b>RMS</b>	Referential Management Service
<b>R&amp;D</b>	Research and Development Value Stream



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