



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Product Management Service (PMS) Application Programming Interface (API) Training

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8 July 2024, 14:00 - 15:00 CEST

Presented by Marcos Fernández Gómez and Veronica Lipucci Di Paola  
*PMS Co-product Owners*

An agency of the European Union





1

## Welcome

5 min

**Veronica Lipucci Di Paola,**  
PMS Product Co-Owner, EMA

2

## Overview & access to PMS API

10 min

**Veronica Lipucci Di Paola,**  
PMS Product Co-Owner, EMA

3

## Read data through PMS API (with demo)

15 min

**Marcos Fernández Gómez,**  
PMS Product Co-Owner, EMA  
**Andrei Idu,**  
SPOR Architect, EMA

4

## Next steps

5 min

**Marcos Fernández Gómez,**  
PMS Product Co-Owner, EMA

5

## Q&A

20 min

**Moderator: Caterina Scarpati,**  
PMS Change Management Team

6

## Closing

5 min

**Veronica Lipucci Di Paola,**  
PMS Product Co-Owner, EMA  
**Marcos Fernández Gómez,**  
PMS Product Co-Owner, EMA



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



At certain points 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**  
**#PMSAPI**



- 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.



**Today's webinar** aims at sharing:

- Overview of PMS API
- The process to request access to PMS API
- How to read data through the PMS API
- Next steps



# Overview & access to PMS API

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## *As of 3 July 2024, PMS API is live for Industry users!*



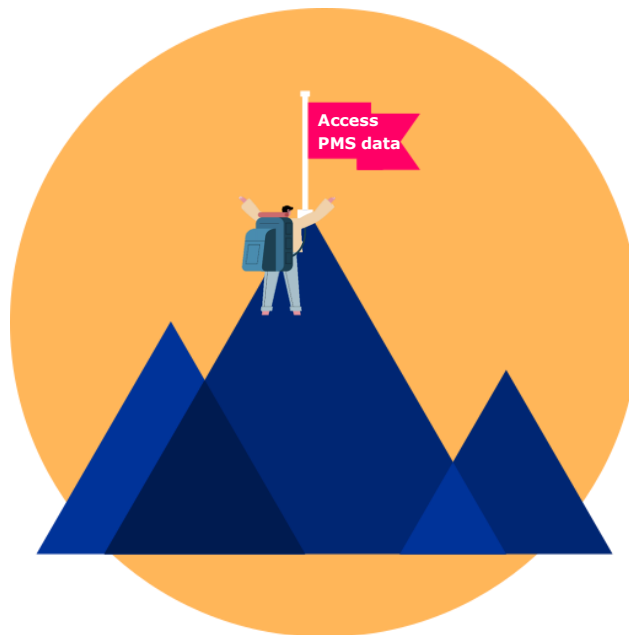
+4500 CAPs  
+400K NAPs



Authorised  
product data



Read-only  
mode



PMS data are accessible to:

- EU Regulators (PUI)
- MAHs (API & PUI)
- General Public (PUI)



### **Released system:**

- Product User Interface (PUI)
- Application Programming Interface (API) for MAHs



### **Next release:**

- API for NCAs

# Recap: Access to PMS product data through PUI

As of 31 May 2024, relevant users can access and read their **CAPs data\*** through:

## PLM Product User Interface



**Synalar forte 2 mg/g crema**

PMS ID: 600001127663 | Authorisation Country: ES | MAH: ORG-100000224 | Authorisation Status: Valid - Transferred marketing authorisation  
Version Number: — | Last updated date: —

**Medicinal Product**

Medicinal Product

PMS ID: 600001127663

Domain: Human use

EV Code: —

**Medicinal product name**

| Full name                  | Country          |
|----------------------------|------------------|
| Synalar forte 2 mg/g crema | Kingdom of Spain |

**Legal status of supply**: —

**(Authorised) Pharmaceutical form**: Cream

**Combined pharmaceutical dose form**: —

**Paediatric use indicator**: Yes

**Language**: —

**Full indication text**: —

**Product Classification**



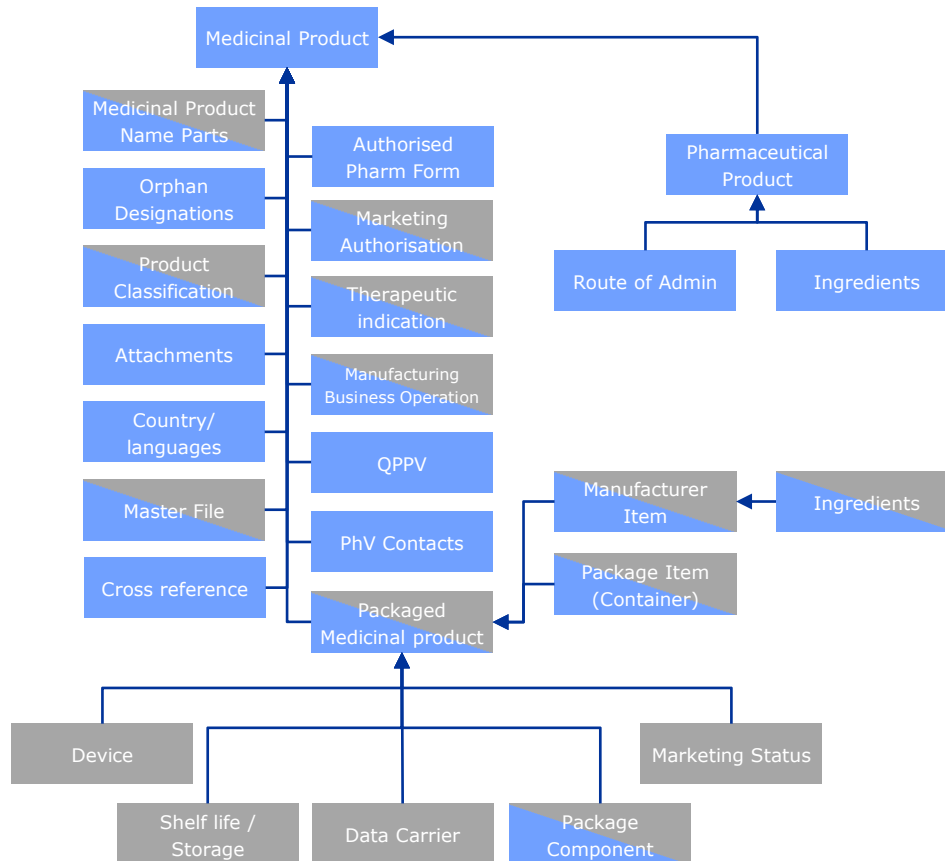
As of 3 July 2024, Industry users can access and read their **CAPs and NAPs data** through:

## PMS API

```
1 <?xml version="1.0" encoding="utf-8"?>
2 <Bundle xmlns="http://hl7.org/fhir">
3   <id value="600009529467" />
4   <meta>
5     <versionId value="2" />
6     <lastUpdated value="2024-01-17T23:58:05.603+00:00" />
7   </meta>
8   <type value="searchset" />
9   <entry>
10     <fullUrl value="MedicinalProductDefinition/600009529467" />
11     <resource>
12       <MedicinalProductDefinition>
13         <id value="600009529467" />
14         <contained>
15           <Provenance>
16             <target>
17               <reference value="#" />
18             </target>
19             <occurredDateTime value="2024-01-17T18:15:03+01:00" />
20             <recorded value="2024-01-18T00:58:00.548+01:00" />
21             <reason>
22               <text value="Data modification(s)" />
23             </reason>
24             <agent>
25               <role>
26                 <coding>
27                   <system value="http://terminology.hl7.org/CodeSy
28                   <code value="author" />
29                 </coding>
30               </role>
```

 **NCAs will have access to API later this year, when a new released API version will enable their access**

- The **PMS** data model is completed with a combination of the available data from both **SIAMED II** and **XEVMPD**.
- Authorised product data are loaded into PMS as per migration rules stated in the published [EU IG Chapter 7](#).
- Given the high volume of new data elements in PMS vs the existing number of XEVMPD/SIAMED attributes, ~ **80 fields are empty** & will have to be **enriched by MAH**, as applicable.
- PMS API Manufacturer resource is not in line with latest draft version of EU IG Chapter 2.



Data migrated to PMS & therefore accessible for PMS API/PUI users.

Data not available during the initial load & therefore not accessible for PMS API/PUI users. These data will have to be enriched by MAHs in the future

## PMS User roles

### Admin roles

| User             | Admin role names        |
|------------------|-------------------------|
| Industry user(s) | IRIS/PLM Industry Admin |
| NCA user(s)      | IRIS/PLM NCA Admin      |
| EMA user(s)      | IRIS/PLM EMA Admin      |

### Industry roles

| User                    | Role names               | PMS Access Level<br>(EU IG Ch.5) |
|-------------------------|--------------------------|----------------------------------|
| <b>Industry user(s)</b> | PMS Industry<br>API User | Level 2 (active)                 |

### Regulator roles

| User               | Role names                      | PMS Access Level<br>(EU IG Ch.5) |
|--------------------|---------------------------------|----------------------------------|
| <b>NCA user(s)</b> | API Competent<br>Authority User | Level 3<br>(not active)          |

#### User guide releases in Mid-May 2024:

- [EU IG Chapter 1](#) version 3
- [EU IG Chapter 5](#) version 2
- [Annex A](#) to EU IG Chapter 5
- [On-boarding of users to SPOR data services](#)



## IRIS/PLM Industry Admin & PMS Industry API

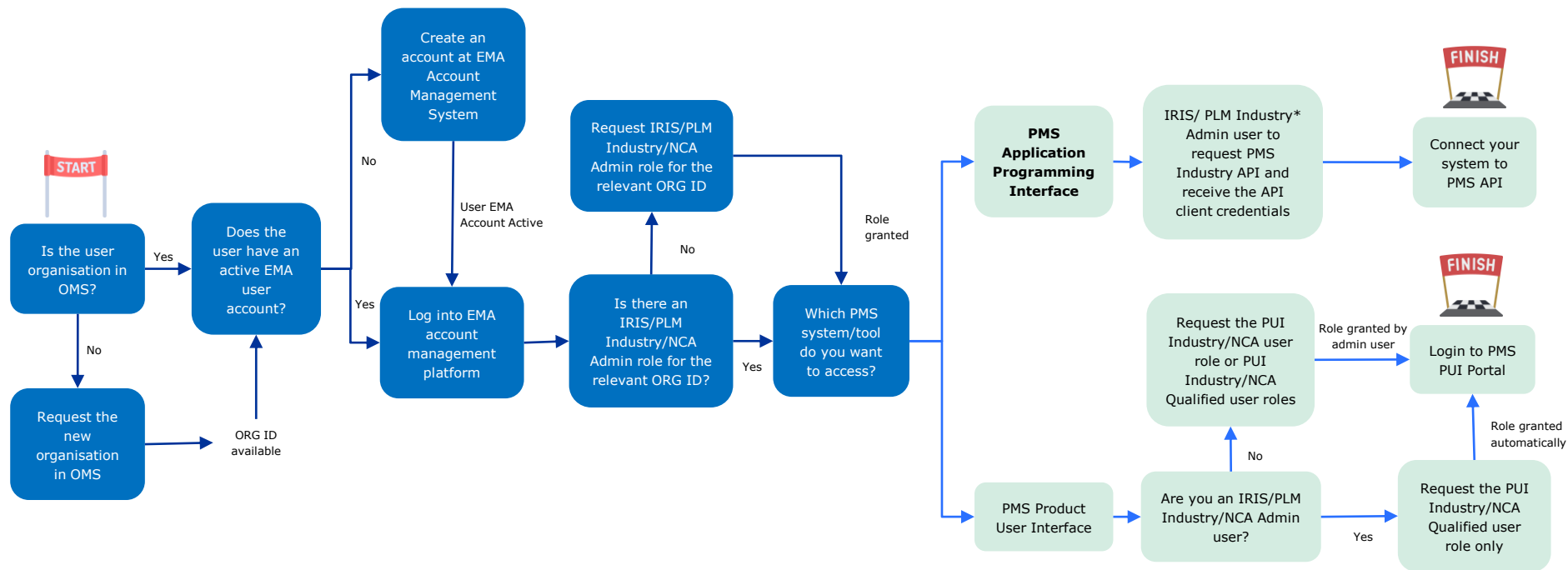
- > **Existing role in IAM!** *previously named IRIS / eAF Industry Admin and IRIS / eAF Competent Authority Admin respectively*
- > Users having this **role granted prior the date of PMS go-live (31 May 2024)** can see their **role name updated** in their IAM account management platform and do not need to request it again.



### *Key role characteristics and recommendations*

| PMS Industry Admin                                                                                                                                                                                                                                                                                                                      | PMS Industry API                                                                                                                                                                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• <b>No direct READ access to PMS API</b></li><li>• <b>1<sup>st</sup> Admin</b> of Organisation is <b>approved by IRIS / PLM EMA Admin</b>; from 2<sup>nd</sup> Admin onwards, Org Admin can approve it</li><li>• Each organisation recommended to have <b>at least two Admin users</b></li></ul> | <ul style="list-style-type: none"><li>• Approved IRIS/PLM Industry Admin user can request <b>PMS Industry API</b> user role throughout IAM account</li><li>• <b>PMS API Client Credentials are</b> generated only upon request by the Admin users to <b>READ PMS API</b></li></ul> |

# PMS User Registration Process



*\*NCAs will have access to API later this year, when a new released API version will enable their access*

## **PMS EU IDMP Implementation guide:**

- [EU IG Chapter Introduction – EU Implementation guide](#)
- [EU IG Chapter 1](#) version 3
- [EU IG Chapter 5](#) version 2
- [Annex A](#) to EU IG Chapter 5

## **SPOR Guide:**

- [On-boarding of users to SPOR data services](#)





## Read data through PMS API

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## Live Demonstration





## To do

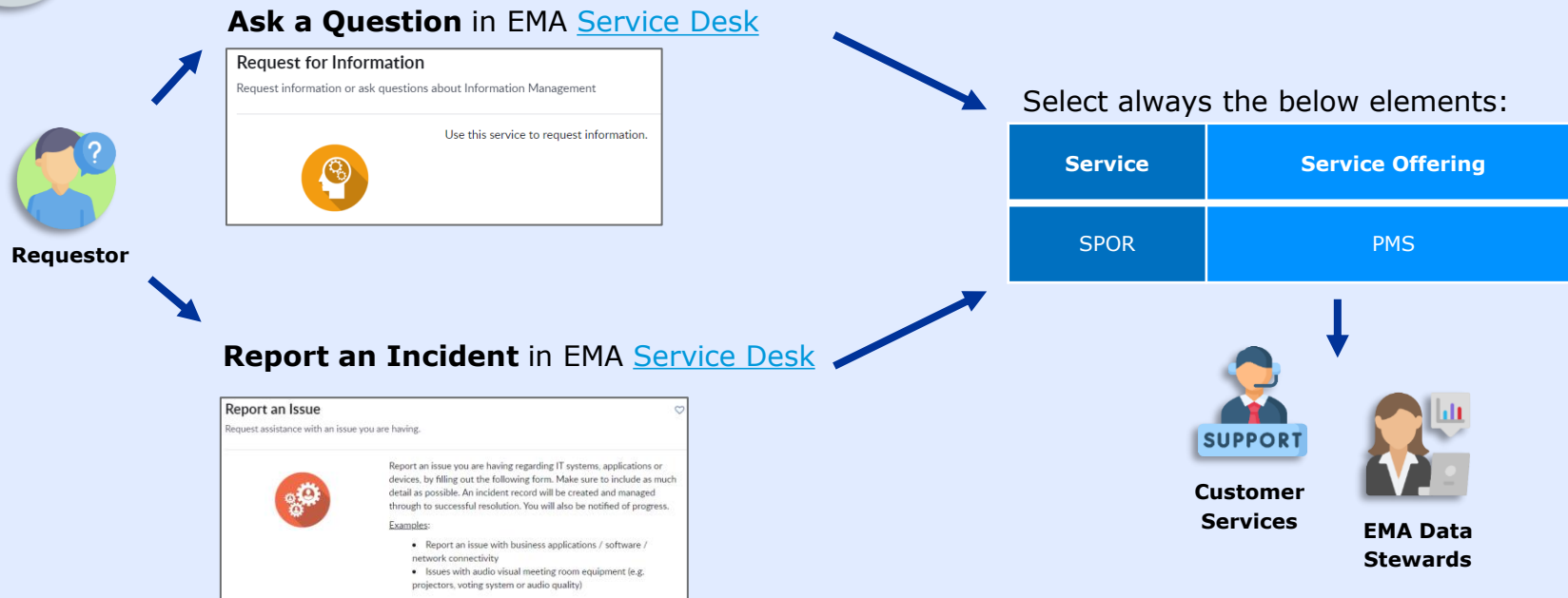
1. Request Admin role for your organisation
2. Request API client credentials



## Tips

- **Reminder:** only Industry users can access the PMS API for now
- If you **do not see your products:**
  - ✓ Make sure your credentials are for the same ORG ID as the MAH these products belong to
  - ✓ Check that the mapping between XEVMPD and OMS is correct
  - ✓ Make sure the conditions explained in Chapter 7 are met for the initial migration
- While checking your products, **consider:**
  - Discrepancies can be flagged via Service Now (please, provide as much information as possible)\*

## Which Service Now ticket type can PMS users select in case of issues?





## Next steps

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## Quarterly System Demos

- See and discuss the latest developments of the system
- Give your feedback on features and priorities

Announced via EMA's  
Website Events Pages



## PMS Web Page

Find:

- > PMS overview
- > EU Implementation Guide

Check regularly



## PLM Portal

### Forum + PMS News page

- Check:
  - > News
  - > Release notes
  - > Downtime comms
- Ask questions (Forum)

Check regularly



## Industry & Network SMEs

The Industry & Network SMEs are your connection to product development.

Engagement to be  
determined by NPO & SMEs

# Upcoming communication & engagement activities for PMS

| Q3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                             | Q4                                                                                                                                                        |                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Jul                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Aug                                                                                                                                                                                                                                                                                                                                                                                                                                         | Sep                                                                                                                                                                                                                                                                                                                                                         | Oct                                                                                                                                                       | Nov                                                                                                                                                                                                                                                           | Dec                                                                                                                                                                                                                                        |
| <br><b>EU IG Ch 7 update</b><br><br><br><b>EU IG Ch 1 update</b><br><br><br><b>API Go-live for Industry</b><br><i>(All products view-only)</i><br><br> <br><b>API training session</b> <b>Pack sizes training session</b> <b>Q&amp;A clinics</b> | <br><b>EU IG Ch 5 &amp; PUI user guide update</b><br><br><br><b>PUI go-live for NAPs</b><br><i>(view-only)</i><br><br><br><b>API Go-live for NCAs</b><br><i>(All products view-only)</i> | <br><b>Public system demo</b><br><br><br><b>EU IG Ch 2 update</b><br><br><br><b>API training session</b> | <br><b>Training session on NAPs H var submissions in web-based eAF</b> | <br><b>PLM Newsletter publication</b><br><br><br><b>Training on write access to PMS</b> | <br><b>EU IG Ch 3, 4 update</b><br><br><br><b>Public system demo</b> |
| Continuous enhancement to PUI layout & release of functionalities                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                           |                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                            |
| Discussion on Enrichment process and process to submit ESMP data via PMS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                           |                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                            |
| Discussion on PMS Access Level 1 to expand the publicly available dataset via PUI                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                           |                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                            |
| PLM portal – continuous performance improvements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                           |                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                            |



Throughout the month of July 2024, the PMS team will be available to **answer your questions** on API & PUI use during two 30 mins sessions:

- **16 July 2024** (10:00 – 10:30 CEST):  
[register here](#)
- **23 July 2024** (10:00 – 10:30 CEST):  
[register here](#)



Further details on **planned PMS engagement activities** provided on the **quarterly PLM Newsletter**.



***Next edition to be published in mid-July 2024***



**Subscribe** by scanning the **QR code** or through this [link](#).



# Thank you for your interest!

## Further information

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