EMA
EUROPEAN MEDICINES AGENCY

System Demo 26Q3

Public System Demo

17 September 2026

Recording and replay access

RECORDING

This session is being recorded

A replay will be available on this event's page on the EMA website.

FROM

1 SEPT. 2026

IMPORTANT CHANGE

Recordings have moved to EMA event pages

Most public webinar and event recordings will no longer be published on EMA's YouTube channel. A replay will be available on this event's page on the EMA website.

PREVIOUSLY

EMA YouTube channel

FROM 1 SEPTEMBER 2026

EMA website event pages

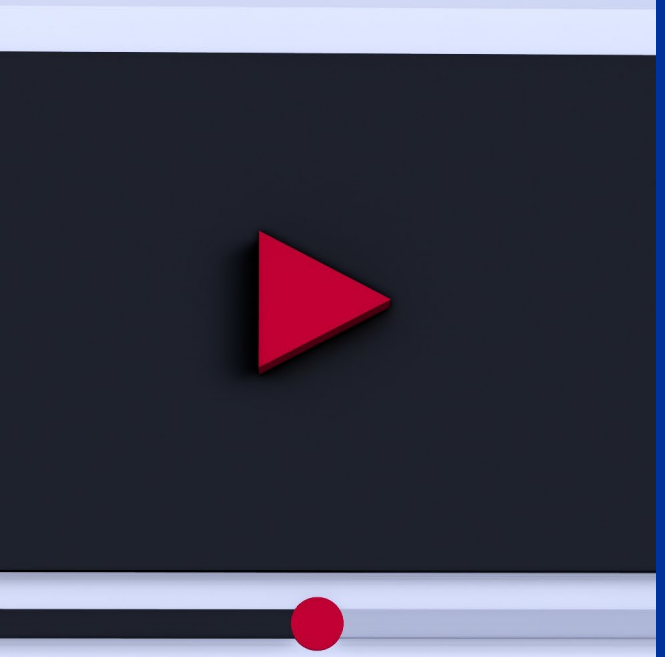
Housekeeping

Please note that this session is being live streamed.
The recording will be available on the EMA Corporate Website, on the event page.

Participants are able to ask questions and share feedback via Slido, with the option of remaining anonymous *.

To view the video in the highest quality, click Settings in the bottom right-hand corner of the video and select High.
To watch the video in full screen mode, click the arrow icon to watch it on Panopto.

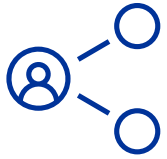
*If you choose to use Slido, you consent to the processing of your personal data as explained in the EMA Data Protection Notice for Webex (europa.eu).



Welcome & Introduction

Jean-Michel Becar, Head of Portfolio Management Office, EMA

System demo at EMA



Agile teams showcase the features they have been working on in the last 3 months

Creates an opportunity to gain a **shared understanding** of the current **state of the products and solutions** on a regular cadence.

It provides an objective measure of **progress** towards the goal of the PI.

Creates a safe space for early identifications of defects or design flaws and for the generation of new ideas to improve over time.

Enables the attendees to provide **instant feedback** allowing the Agile teams to make **necessary adjustments** to the solutions they are building and focus on **what is important.**


LLM
LARGE LANGUAGE MODELS
AI
01 01 001
01 01 01
10 December
2026
Is the next public system demo

Agenda

09:00	**Welcome / Introductions**
09:05 – 09:45	**Research & Development Value Stream (R&D VS)**
	Clinical Trials Information System (CTIS) modernisation
09:45 – 11:10	**Product Lifecycle Management Value Stream (PLM VS)**
	Product Management Service (PMS) and product user interface (PUI)
10:30 – 10:40	Break
	Electronic Common Technical Document version 4.0 (eCTD v4.0)
	Electronic product information (ePI)
	Union Product Database (UPD)
11:10 – 11:30	**Monitoring Value Stream (MON VS)**
	EudraGMDP
11:30	**Closing**

Give feedback & ask questions through Slido

Audience Q&A

Questions and answers are public

You may upvote the questions

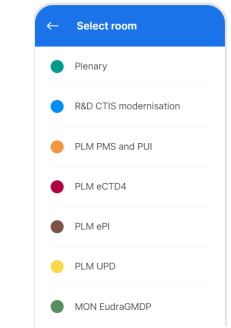
Top questions are answered verbally

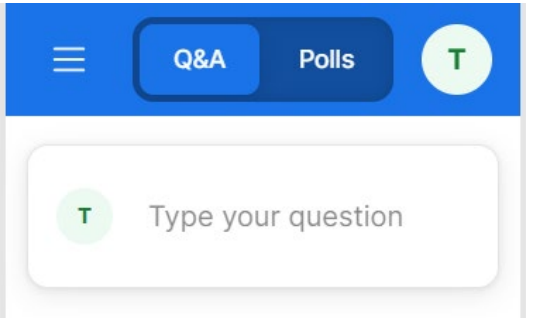
Questions & available answers published on event page on EMA website

Join at

slido.com

#9116 064





Step 1 - Go to slido.com and join the event for this demo

Step 2 – Choose/switch to the room for the right product

Step 3 – Write a questions/feedback, or upvote an existing question

* If you choose to use Slido, you consent to the processing of your personal data as explained in the EMA Data Protection Notice for Webex (europa.eu).

EMA Value Streams

Managing the Agency

Capabilities to empower EMA staff and support the Network through modernisation and digitalisation of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration

Research and Development

Capabilities to support the development of new medicines and generation of scientific evidence

Product Lifecycle Management

Capabilities to manage the authorisation and lifecycle of medicinal products and certain medical devices

Monitoring

Capabilities to monitor availability and safety of products

Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

EMA

Managing the medicinal product lifecycle

Integrating data and technology, the R&D value stream enables the development of medicines through efficient processes and generation of scientific evidence for the benefit of public and animal health in the EU.

Lifecycle of a medicinal product

1 Research & Development

2 Scientific Advice

3 Evaluation

4 Authorisation

5 Access

6 Safety monitoring

Research & Development value stream

Product Lifecycle Management value stream (PLM value stream)

Monitoring value stream

R&D VS | Clinical Trials Information System (CTIS) Modernisation

Ana Rodriguez, CTIS Product Owner

CTIS Modernisation- New Safety Module

Committed objective 26Q3	Demo
Role Management - Complete **Role Management** for Safety Module	**YES (Main Focus)**
Safety Module MVP – Complete **ASR submission** implementation	**YES**
Safety Module MVP – Complete **ASR assessment** implementation	**YES**
Safety Module MVP – Fix critical and high bugs identified in **SaMS** UAT	**NO**

Role Management: main changes

- Improved the User Interface
- Implementation of a two tabs solution i.e. a clinical trial tab and a safety tab under “My roles” and the “User Management” functionalities
- Implementation of new Safety Roles
- The possibility to export the list of roles in the User Management functionality

slido # 9116064

Roles Overview – Safety tab

Sponsor

Role name
- Sponsor Safety Admin- New
- ASR Submitter

Authority

Role name
- Authority Safety Admin- New
- ASR Decision Maker Submitter (EAM managed- New)
- ASR Assessor
- MS Inspector- New
- MS Viewer Full Rights- New

Roles in the CT Tab and Safety Tab are separate e.g the ASR Submitter role must be assigned to a user in both the Clinical Trial and Safety tab to enable that user to perform all activities in both the old and new Safety Modules.

slido # 9116064

Roles Overview – Safety tab - Assignment

SPONSOR

Sponsor Admin

Scope: All or specific trial →
- ASR Submitter
- Sponsor Safety Admin

Sponsor Safety Admin

Scope: All or specific trial →
- ASR Submitter
- Sponsor Safety Admin

AUTHORITY

EMA Admin

Scope: All (excl. ASR Assessor) or specific trial →
- Authority Safety Admin
- ASR Assessor (Specific Trial only)
- MS Inspector
- MS Viewer Full Rights
- ASR Submitter
- Sponsor Safety Admin

MS Admin

Scope: All (excl. ASR Assessor) or specific trial →
- Authority Safety Admin
- ASR Assessor (Specific Trial only)
- MS Inspector
- MS Viewer Full Rights

Authority Safety Admin

Scope: All (excl. ASR Assessor) or specific trial →
- ASR Assessor (Specific Trial only)
- MS Inspector
- MS Viewer Full Rights
- Authority Safety Admin

Note: *ASR Decision Maker Submitter has to be self requested through EAM (EMA Account Management) like the MS Admin.*

slido # 9116064

Safety Roles - Sponsor

Role	Scope	System	High Level Permissions
Added in Safety Tab			
Sponsor Safety Admin	All / Specific trial	CTIS	• Only role management permissions.
ASR Submitter	All / Specific trial	CTIS	• New ASR permissions to be added.
To be removed from CT Tab (upon end of transition period)			
ASR Submitter	All / Specific trial	CTIS	• Replaced by ASR Submitter.

- sponsor-guidance-new-safety-module-annual-safety-report_en.pdf

slido # 9116064

Safety Roles – Authority

Role	Scope	System	High Level Permissions
Added in Safety Tb			
Authority Safety Admin	All / Specific trial	CTIS	• Only role management permissions.
ASR Decision Maker Submitter	All	EAM	• New saMS and ASR permissions to be added. • Includes SharePoint access.
ASR Assessor	Specific trial	CTIS	• New saMS and ASR permissions to be added. • **No SharePoint access**.
MS Viewer full rights	All / Specific trial	CTIS	• New saMS and ASR permissions to be added – Only viewer permissions.
MS Inspector	All / Specific trial	CTIS	• New saMS and ASR permissions to be added – Only viewer permissions.
Modified in EAM			
EC Admin	All	EAM	• New saMS and ASR permissions to be added – Only viewer permissions. • Old permissions to be removed upon end of transition period.
To be removed from CT Tab (upon end of transition period)			
ASR Decision Maker Submitter	All / Specific trial	CTIS	• Replaced by ASR Decision Maker Submitter (added in new Safety Tab).
ASR Assessor	All / Specific trial	CTIS	• Replaced by ASR Assessor (added in new Safety Tab).

Remarks:

- ASR Decision Maker Submitter has to be self requested through EAM (EMA Account Management).

member-states-guidance-new-ctis-safety-module-annual-safety-report_en.pdf

slido # 9116064

Migration – Role Management

Current role in CT Tab	Migrated role at go-live to the Safety Tab
ASR Submitter – All trials	ASR Submitter – All trials
ASR Submitter – Specific trial	ASR Submitter – Specific trial
ASR Decision Maker Submitter – All trials	NA – To be self requested in EAM
ASR Decision Maker Submitter – Specific trial	NA – Does not exist anymore
ASR Assessor – All trials	NA – Does not exist anymore
ASR Assessor – Specific trial	ASR Assessor – Specific trial
CT Admin – All trials	Sponsor Safety Admin – All trials
CT Admin – Specific trial	Sponsor Safety Admin – Specific trial
National Organisation Admin – All trials	Authority Safety Admin – All trials
National Organisation Admin – Specific trial	Authority Safety Admin – Specific trial

Roles requiring manual assignment after go-live (no migration)

- ASR Decision Maker Submitter
- MS Viewer Full Rights and MS Inspector — New roles without equivalent prior role

Remarks

- Existing CTIS Enterprise Safety roles are retained until end of ASR transition period
- During the transition period, roles will not be synchronized between the old and new Safety Module safety roles. For example, the ASR Submitter role must be assigned in both the Clinical Trial and Safety tab to enable users to perform all activities in both the old and new Safety Modules. This responsibility lies with the end users.
- For trials created via CT centric approach, the Sponsor Safety Admin will be automatically assigned by the system to all CT Admin holders upon IN CTA authorization.

slido # 9116064

Demonstration

EMA Value Streams

Managing the Agency

Capabilities to empower EMA staff and support the Network through modernisation and digitalisation of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration

Research and Development

Capabilities to support the development of new medicines and generation of scientific evidence

Product Lifecycle Management

Capabilities to manage the authorisation and lifecycle of medicinal products and certain medical devices

Monitoring

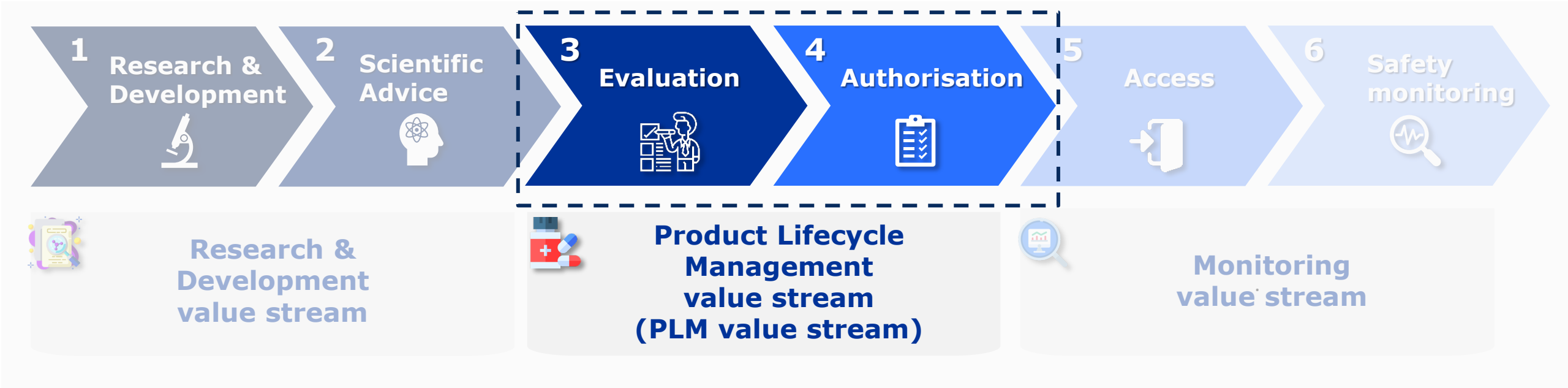
Capabilities to monitor availability and safety of products

Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

EMA

Lifecycle of a centrally authorised medicinal product



PLM VS | Product Management Service (PMS) and product user interface (PUI)

Veronica Lipucci Di Paola, PMS Co-Product Owner

Give feedback & ask questions through Slido

Audience Q&A

Questions and answers are public

You may upvote the questions

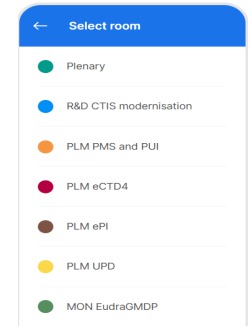
Top questions are answered verbally

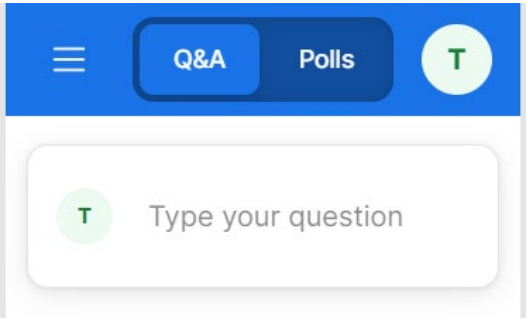
Questions & available answers published on event page on EMA website

Join at

slido.com

#9116 064





Step 1 - Go to slido.com and join the event for this demo

Step 2 – Choose/switch to the room for the right product

Step 3 – Write a questions/feedback, or upvote an existing question

* If you choose to use Slido, you consent to the processing of your personal data as explained in the EMA Data Protection Notice for Webex (europa.eu).

PMS – Product Management Service

Achievements 26Q3	Demo
Eliminated stalled processing of API updates: Enrichment failures could leave Medicinal Products stuck, preventing processing altogether. The PMS API now supports non-blocking enrichments and enhanced error handling.	NO
Continue upgrading PMS API to FHIR R5 to improve interoperability, enable data access in the latest FHIR version, and reduce future reliance on the FHIR adapter.	NO
DQ activities: • Finalised cleansing duplicated packages and product definitions of NAPs; • Analysis and rollout of the strategy for using Marketing Authorisation Numbers as new grouping business rules for XEVMPD deltas in the following countries: AT, IE, DE, DK, EE, ES, LU, NO, NL, and SE. • Release of a refactored sync between SIAMED and PMS, having a new backend in charge of creating FHIR payloads and merging with existing data from other sources • Fixed a step between XEVMPD and PMS leading to the loss of large XEVMPD messages	NO

Product UI

Achievements 26Q3	Demo
Enable the PMS target operating model by completing the user journey (pages) for MAHs to create pending products in the Product UI.	YES
Enable SIAMED decommissioning by completing the user journey (pages) for EMA staff (in transition phase) and MAHs (in target phase) to update authorised products in the Product UI.	NO
Improve Product UI usability and reliability through UX enhancements and bug fixes.	NO

Upcoming events

Q&A clinics on PMS PUI and API

- **10 September 2026** (9:30 – 10:30 CEST): Event page
- **24 September 2026** (9:30 – 10:30 CEST): Event page
- **8 October 2026** (9:30 – 10:30 CEST): Event page

Q&A Clinics on SOR

- **9 September 2026** (15:30 – 16:00 CEST): Event page
- **7 October 2026** (15:30 – 16:00 CEST): Event page
- **11 November 2026** (15:30 – 16:00 CET): Event page
- **9 December 2026** (15:30 – 16:00 CET): Event page

Q&A Clinics on XEVMPD

- **10 September 2026** (15:00 – 16:00 CEST): Event page
- **8 October 2026** (15:00 – 16:00 CEST): Event page
- **12 November 2026** (15:00 – 16:00 CET): Event page
- **10 December 2026** (15:00 – 16:00 CET): Event page

SPOR & XEVMPD status update webinar

Registration open

7 October 2026 (10:00 – 12:30 CEST): *registration available on event page on EMA website*

Live Demonstration

Coffee break

We're back at 10:25

Join at

slido.com

#9116 064

PLM VS |Electronic Common Technical Document version 4 (eCTD v4.0)

Kristiina Puusaari, eCDT v4.0 Product Owner

Give feedback & ask questions through Slido

Audience Q&A

Questions and answers are public

You may upvote the questions

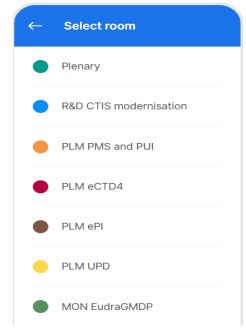
Top questions are answered verbally

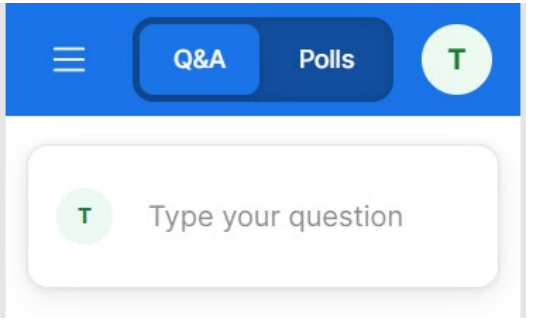
Questions & available answers published on event page on EMA website

Join at

slido.com

#9116 064





Step 1 - Go to slido.com and join the event for this demo

Step 2 – Choose/switch to the room for the right product

Step 3 – Write a questions/feedback, or upvote an existing question

* If you choose to use Slido, you consent to the processing of your personal data as explained in the EMA Data Protection Notice for Webex (europa.eu).

eCTD v4.0 – Q3 achievements

Optional use for CAPs new MAAs in eCTD v4.0

- **Optional use** for **CAPs new MAAs** in eCTD v4.0 format is **encouraged**
- Applicants are invited to **submit eCTDv4.0 test submissions** to gain experience and confidence and **feedback** from EMA
- **First eCTD v4.0 submission received and evaluation is going smoothly**

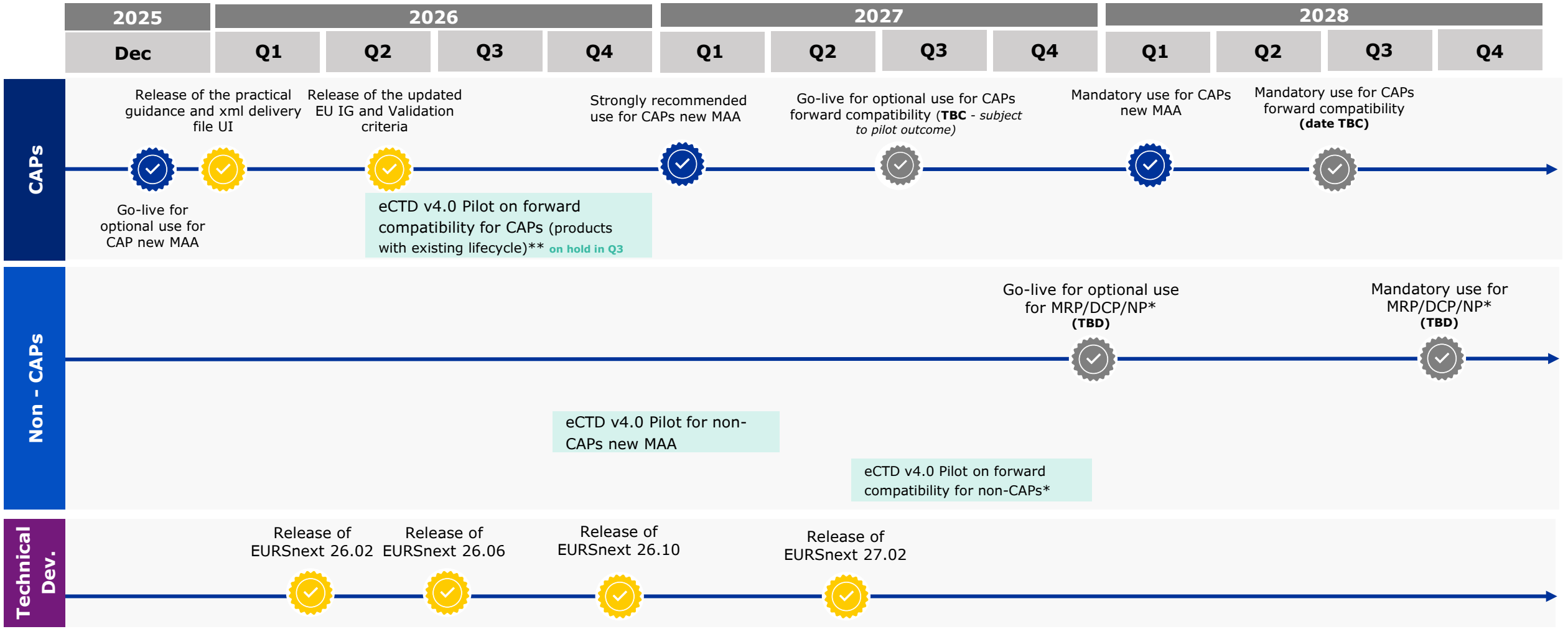
Technical pilot activities

- **Technical pilot on Forward Compatibility** (products with existing eCTD v3.2.2 lifecycle) **for CAPs** paused following technical issues/limitations found in the pilot.
- Pilot will be re-launched in Q4 2026.
- **Preparation** for **non-CAPs new MAA** technical pilot **ongoing**. Pilot launch is expected in Q4 2026.

Central Repository feasibility study

- A **feasibility study** on the Central Repository is ongoing with outcomes expected in Q1 2027.
- The study will support the **go/no-go decision for a Central Repository** and will inform the **next implementation steps** of eCTD v4.0 for non-centrally authorised products

eCTD v4.0 & EURSnext implementation roadmap



Acronyms

CAP: Centrally Authorised Product

Non-CAP: Non- Centrally Authorised Product

IG: Implementation Guide

TBC: To be confirmed

MAA: Marketing Authorisation Application

UI: User Interface

Legend

Go-live

Milestone

Dev. activities

TBC Go-live

*Dependency on Central Repository go/no-go decision

**Subject to technical feasibility

PLM VS | Electronic product information (ePI)

Elizabeth Scanlan, ePI Product Owner

Evinn Drusys, ePI Network Product Owner

Give feedback & ask questions through Slido

Audience Q&A

Questions and answers are public

You may upvote the questions

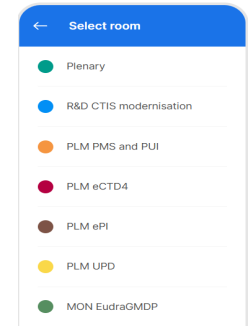
Top questions are answered verbally

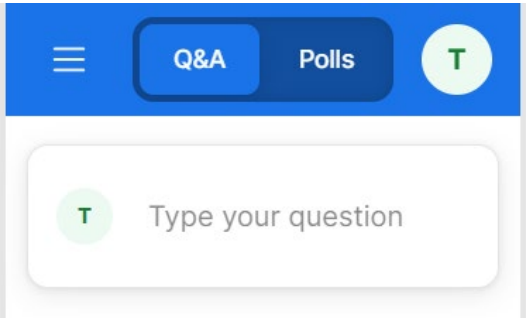
Questions & available answers published on event page on EMA website

Join at

slido.com

#9116 064





Step 1 - Go to slido.com and join the event for this demo

Step 2 – Choose/switch to the room for the right product

Step 3 – Write a questions/feedback, or upvote an existing question

* If you choose to use Slido, you consent to the processing of your personal data as explained in the EMA Data Protection Notice for Webex (europa.eu).

Achievements

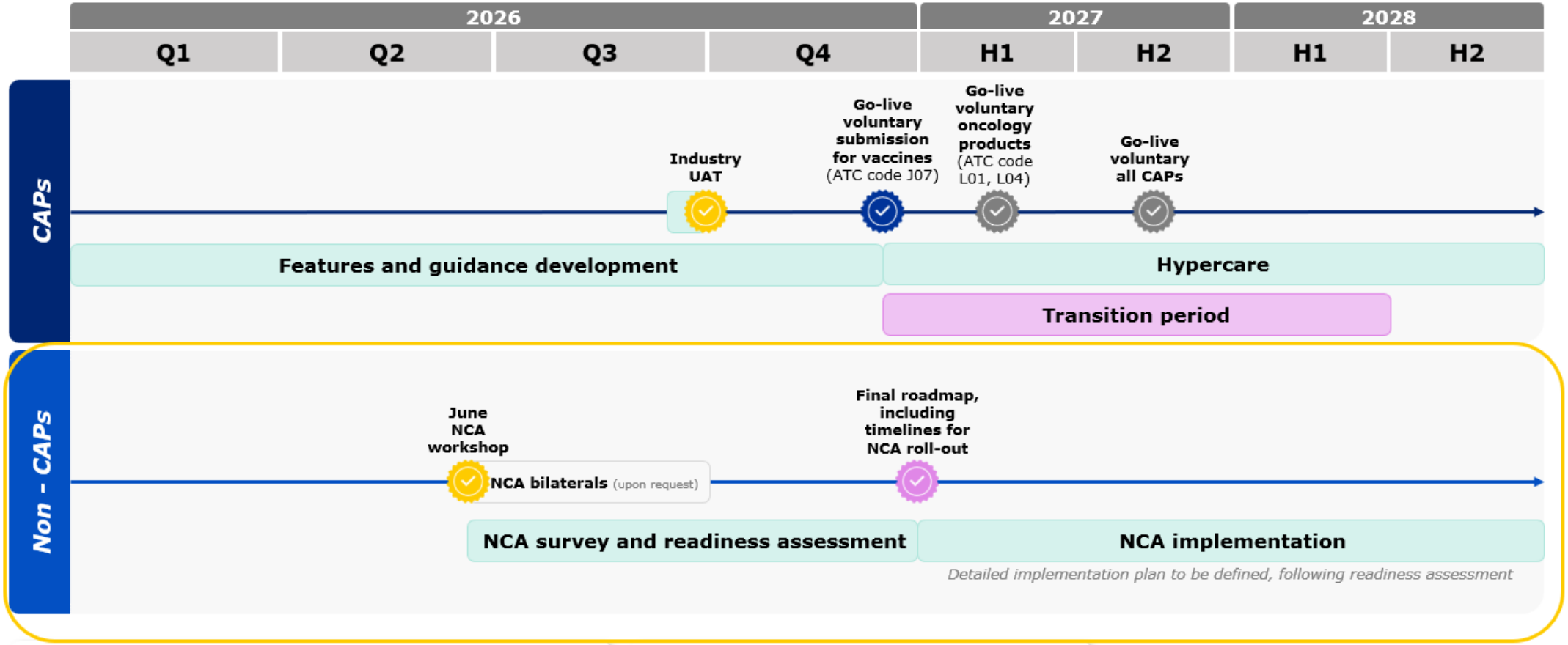
Industry testing: prepared UAT environment for external testing

Guidance: Guide for translators and Guide for CAP business processes published

ePI at eSubmissions: for CAP submissions applicants will inform EMA on ePI in the eSubmission delivery file

Performance improvements & Bug fixing

NCA readiness: towards an implementation roadmap



NCA survey data collection complete: results now under analysis to inform NCA roadmap

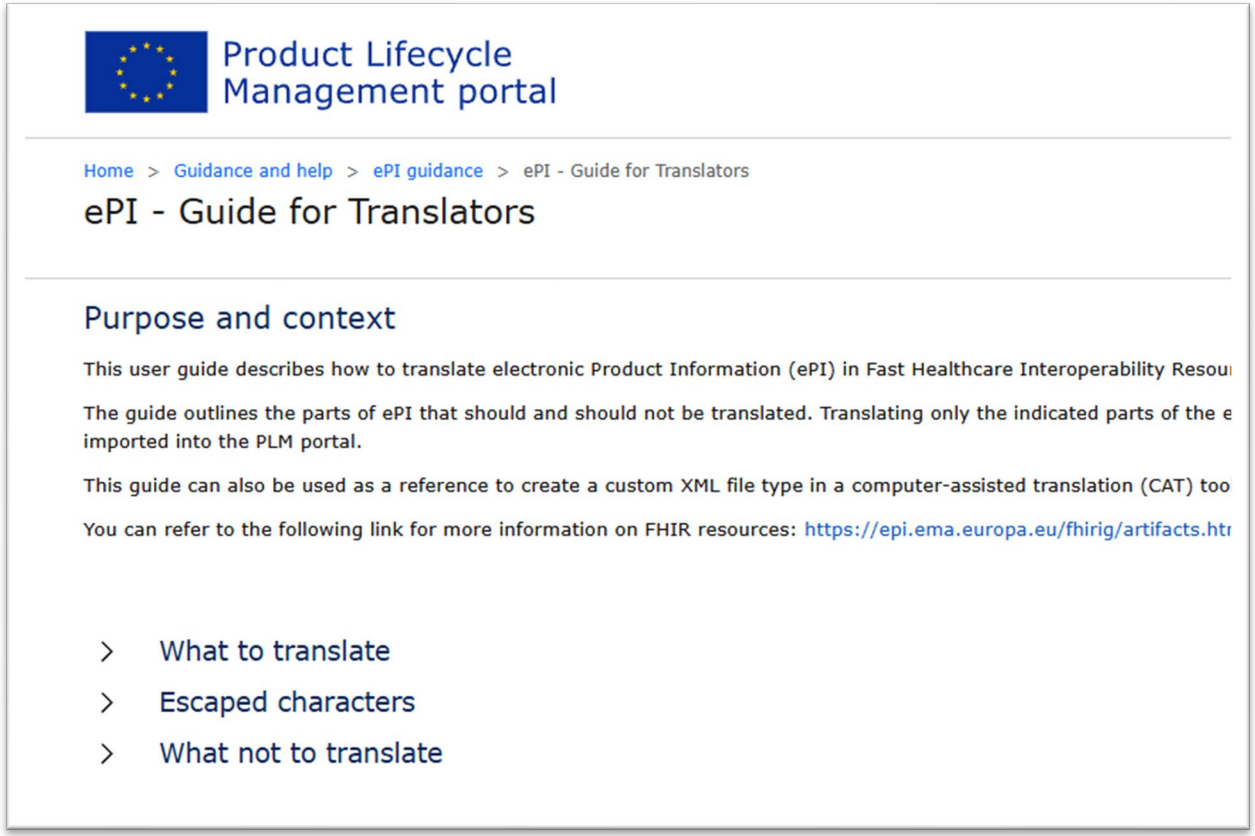
NCA bilaterals ongoing

External UAT for industry

- Create and update an ePI
- Add co-authors
- Use the editor
- Import FHIR
- Preview
- Submit, deactivate or delete
- Export

Testing dates: 28 SEPT – 09 OCT 2026

New guidance published



Product Lifecycle Management portal

Home > Guidance and help > ePI guidance > ePI - Guide for Translators

ePI - Guide for Translators

Purpose and context

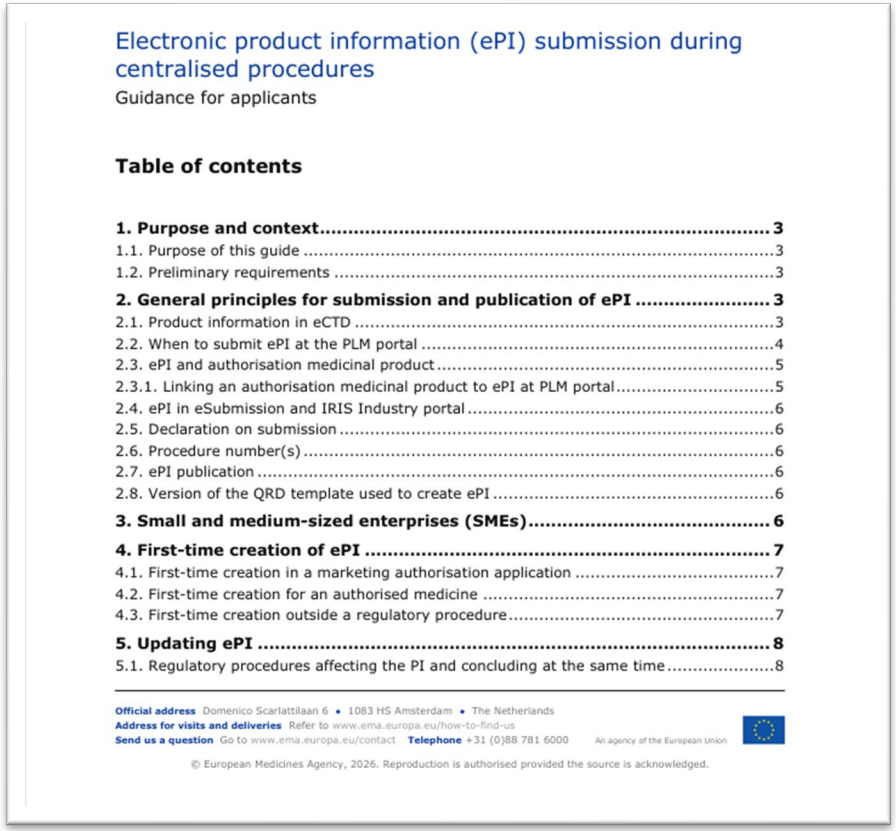
This user guide describes how to translate electronic Product Information (ePI) in Fast Healthcare Interoperability Resou

The guide outlines the parts of ePI that should and should not be translated. Translating only the indicated parts of the e imported into the PLM portal.

This guide can also be used as a reference to create a custom XML file type in a computer-assisted translation (CAT) too

You can refer to the following link for more information on FHIR resources: https://epi.ema.europa.eu/fhirig/artifacts.ht

- What to translate
- Escaped characters
- What not to translate



Electronic product information (ePI) submission during centralised procedures

Guidance for applicants

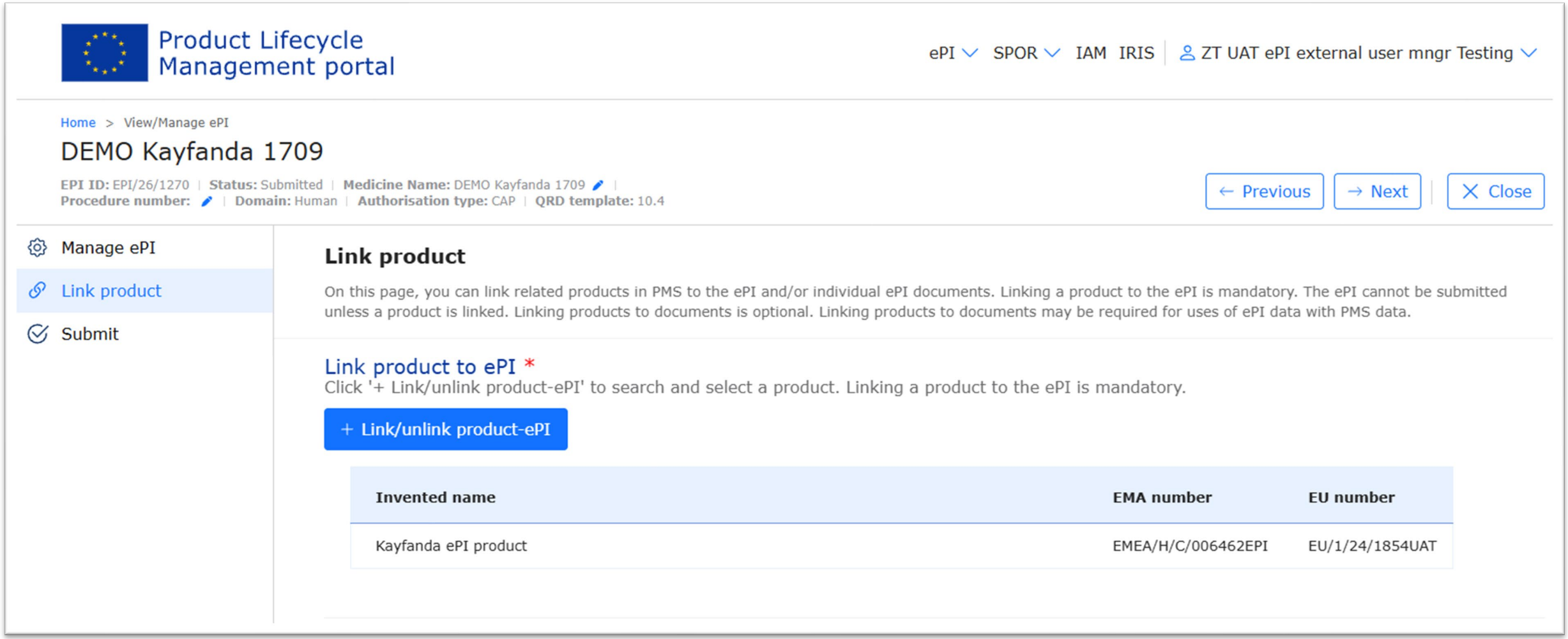
Table of contents

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

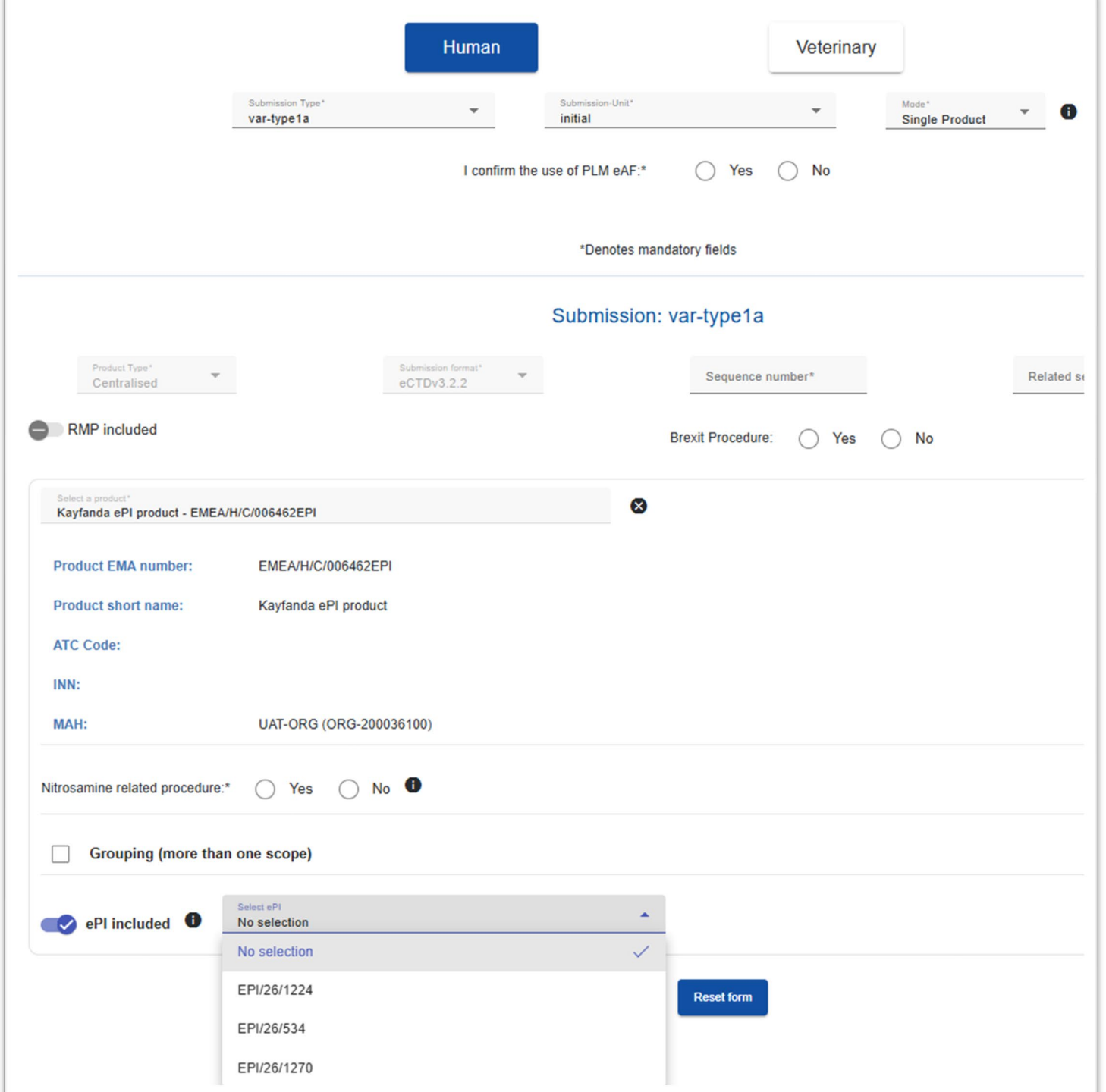
EMA

Live Demonstration: ePI at eSubmission

CAP ePI linked to product (mandatory)



ePI details at eSubmissions



PLM VS | Union Product Database(UPD)

Saskia Schiemann, UPD Network Product Owner

Beyhan Mustafov, UPD Product Owner

Give feedback & ask questions through Slido

Audience Q&A

Questions and answers are public

You may upvote the questions

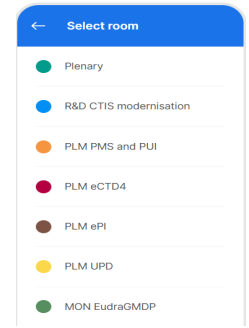
Top questions are answered verbally

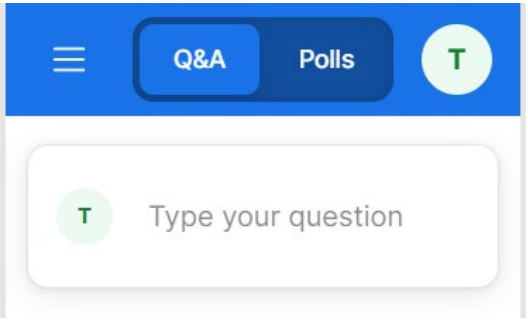
Questions & available answers published on event page on EMA website

Join at

slido.com

#9116 064





Step 1 - Go to slido.com and join the event for this demo

Step 2 – Choose/switch to the room for the right product

Step 3 – Write a questions/feedback, or upvote an existing question

* If you choose to use Slido, you consent to the processing of your personal data as explained in the EMA Data Protection Notice for Webex (europa.eu).

UPD – Union Product Database (1/4)

Committed objectives 26Q3	Demo
MAH users can retrieve their **volume of sales** data submissions without any time restrictions. *The previous 2-year limit has been removed.*	NO *Released on 4/09/2026*
After a transfer of ownership, the new MAH can now automatically retrieve **volume of sales** data submitted by the previous MAH. *Past submissions (2022-2026) will be corrected by a datafix.*	NO *Released on 4/09/2026*
Retrieve **volume of sales** is enhanced with two additional search filters: • ATC Vet code • Product owner (MAH Org ID)	NO *Released on 4/09/2026*
Retrieve **volume of sales** .csv file is also enriched with three additional columns*: • ATC Vet code • Product owner (MAH Org ID) • Species name - *for the species identifier associated with the package for which the volume of sales is provided* * ***These additional columns are not available in the .csv files for download package data and volume of sales submission data for MAH users***.	NO *Released on 4/09/2026*

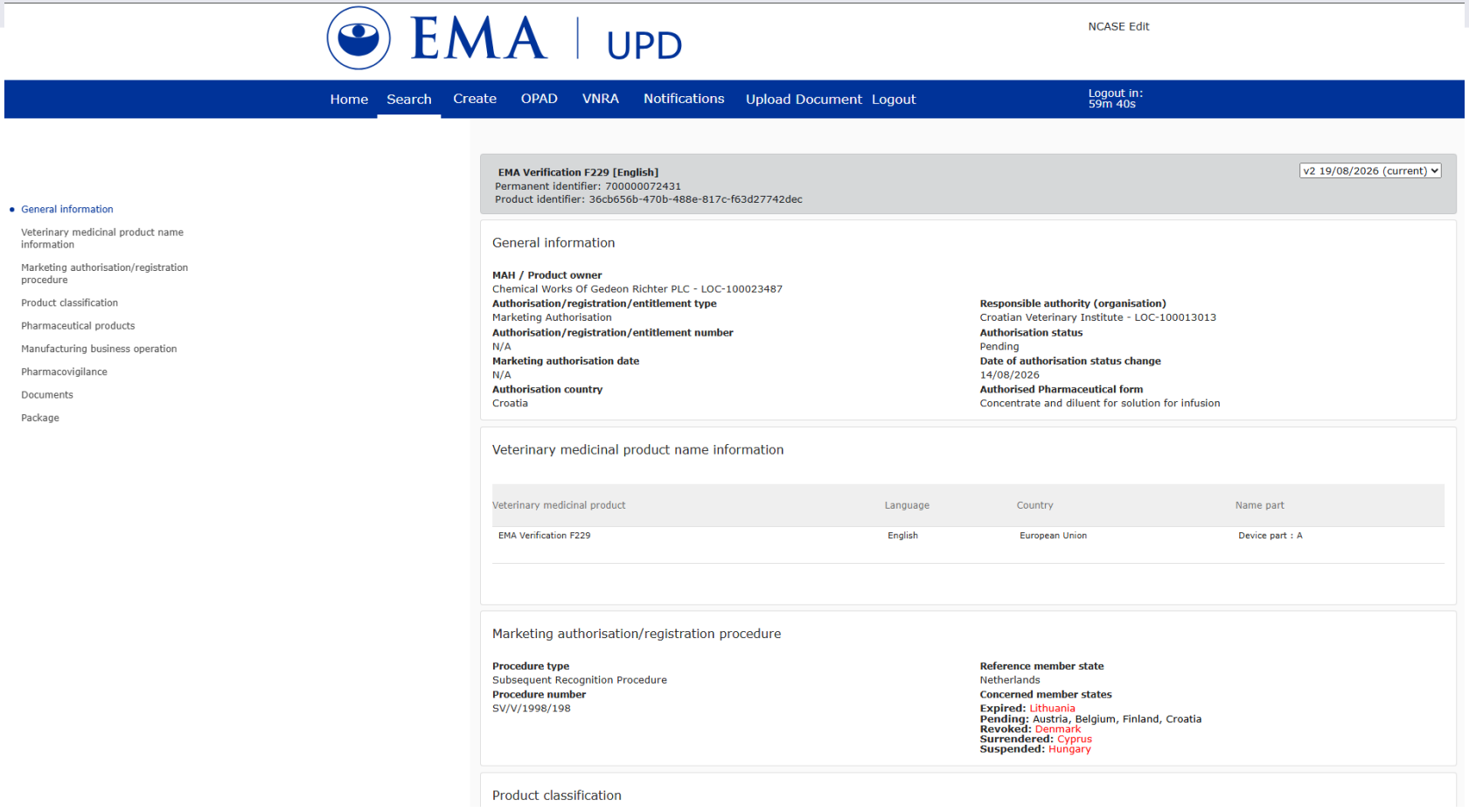
UPD – Union Product Database (2/4)

Committed objectives 26Q3	Demo
Availability status for newly created packages in a non-CAP product is set by default to 'Not marketed'* ** The default value of availability status **for non-CAP products** is changed from 'No data provided' to 'Not marketed'. Registered homeopathic products, parallel traded and products intended only for pets under Article 5(6) are excluded, as it is not mandatory to submit information on availability status for these products.*	NO *Released on 4/09/2026*
A new search parameter '_lastUpdated' is added and available for use in the UPD Public API* ** This parameter is commonly used to retrieve the last version of a product, making it useful for incremental synchronisation scenarios.*	NO *Released on 31/07/2026*

UPD – Union Product Database (3/4)

Committed objectives 26Q3	Demo
For DCP/MRP/SRP/MRP after harmonisation procedures the CMS products are displayed with their respective marketing authorisation status. Expired, Revoked, Surrendered and Suspended CMS products are always highlighted in RED.	NO *Released on 4/09/2026*

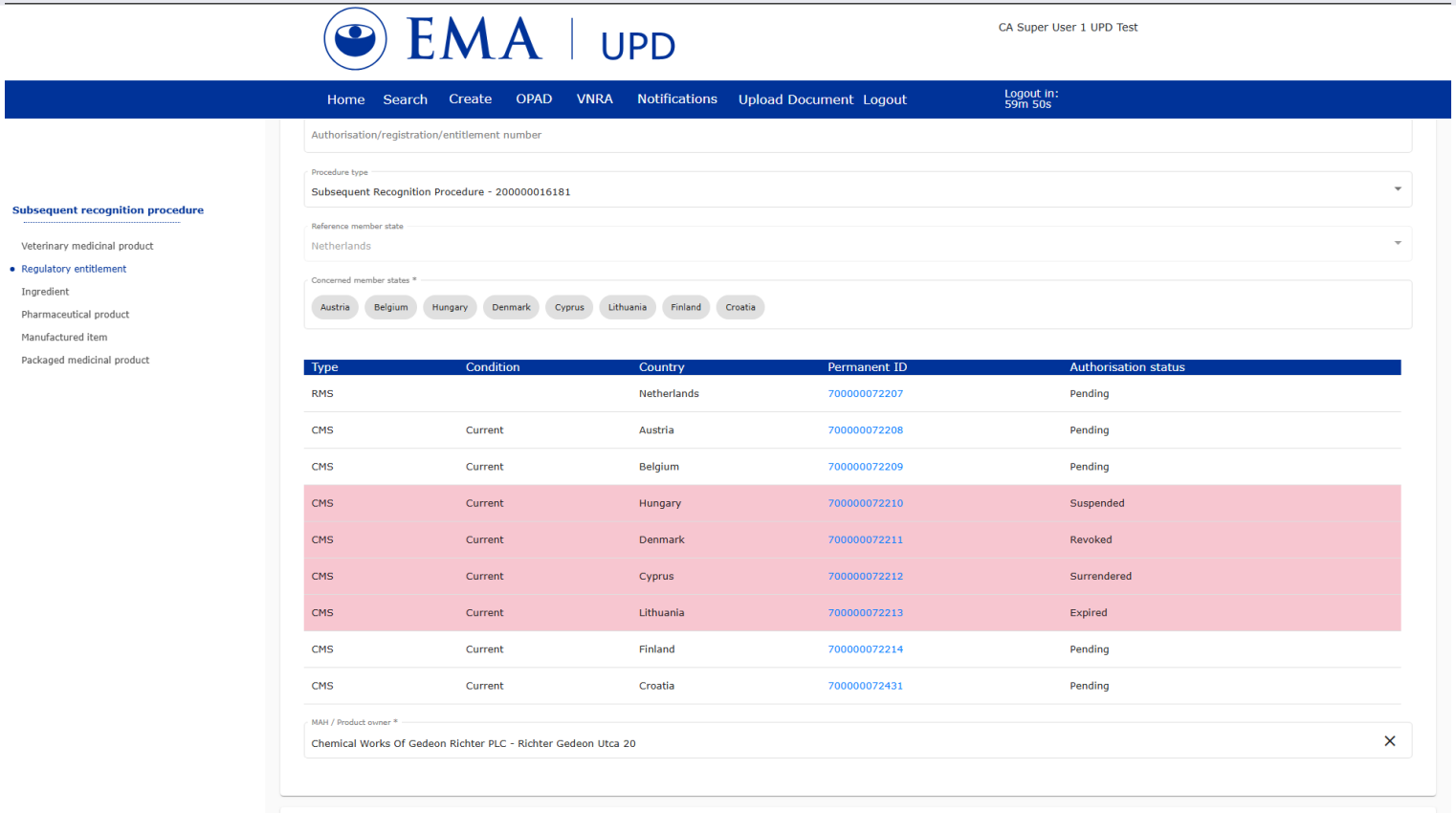
For NCA and MAH UI users in 'View' page



UPD – Union Product Database (4/4)

Committed objectives 26Q3	Demo
For DCP/MRP/SRP/MRP after harmonisation procedures the CMS products with their marketing authorisation status are now displayed. Here also Expired, Revoked, Surrendered and Suspended CMS products are always highlighted in RED.	NO *Released on 4/09/2026*

For NCA UI users in 'Edit' page



UPD – Q3 additional changes and achievements

Additional enhancements

- ✓ **For DCP/MRP/SRP/MRP after harmonisation procedures in the NCA ‘Edit’ page the table with CMS countries has new column** with permanent ID and a hyperlink to view product page.
- ✓ **Back to search results button is removed** from the View product page when opened in a new tab.
- ✓ **MAH UI user can select only products with 'valid', 'pending' and 'suspended’ MA status** for submission of variation not requiring assessment.
- ✓ **Enhanced login retention and traceability**.

New/revised guidance and training materials

- ✓ Updated UPD Public API with the a new search parameter ‘_lastUpdated’.
- ✓ Updated video tutorial for NCA users about ‘How to view and download volume of sales data’ will be published soon.
- ✓ Updated video tutorial for MAH users about ‘How to view and download volume of sales data’ will be published soon.

Useful materials

Guides

- UPD registration guide *for UI and API users*
- UPD EU Implementation Guides
- Guidance for MAHs *on the calculation of dose factor, how to configure email addresses for UPD notifications*

Release notes

- Periodically published on EMA's UPD webpage

Webinars and Trainings

- EMA's UPD webpage
- Video tutorials

Q&A Documents

- UPD Q&As for Network users
- UPD Q&As for Industry users
- UPD Q&As about VoS

Reminder to MAHs

As per Article 58(6) of Regulation (EU) 2019/6, **each MAH is obligated to submit information on the availability for each veterinary medicinal product in each relevant Member State**.

All MAHs are reminded to submit availability information in UPD and keep it always up-to-date.

EMA Value Streams

Managing the Agency

Capabilities to empower EMA staff and support the Network through modernisation and digitalisation of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration

Research and Development

Capabilities to support the development of new medicines and generation of scientific evidence

Product Lifecycle Management

Capabilities to manage the authorisation and lifecycle of medicinal products and certain medical devices

Monitoring

Capabilities to monitor availability and safety of products

Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

EMA

Monitoring value stream (MON VS)

Empowering stakeholders with optimal data and tools to assess and monitor availability, safety and quality of medicines ***to achieve higher standards of public and animal health protection in the EU.***

Lifecycle of a centrally authorised medicinal product

1 Research & Development

2 Scientific Advice

3 Evaluation

4 Authorisation

5 Access

6 Safety monitoring

Research & Development value stream

Product Lifecycle Management value stream (PLM value stream)

Monitoring value stream

Monitoring VS |EudraGMDP

Public/private search and creation of Good Manufacturing Practice (GMP) certificate and Statement of Non-compliance (GMP SNC)

Ivana Radic, EudraGMDP Product Owner

Give feedback & ask questions through Slido

Audience Q&A

Questions and answers are public

You may upvote the questions

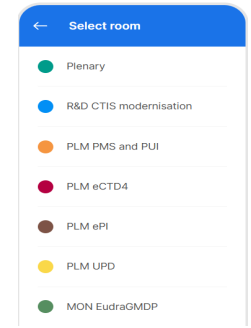
Top questions are answered verbally

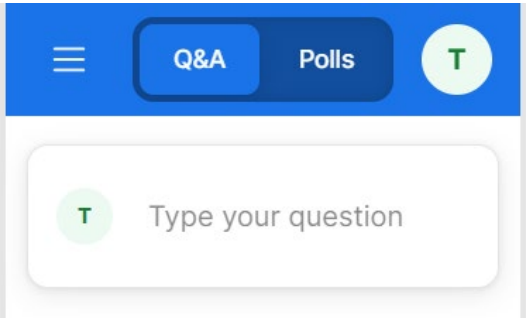
Questions & available answers published on event page on EMA website

Join at

slido.com

#9116 064





Step 1 - Go to slido.com and join the event for this demo

Step 2 – Choose/switch to the room for the right product

Step 3 – Write a questions/feedback, or upvote an existing question

* If you choose to use Slido, you consent to the processing of your personal data as explained in the EMA Data Protection Notice for Webex (europa.eu).

Overview of EudraGMDP

EudraGMDP is the **EU/EEA's official database** for GMP and GDP certificates and authorisation information.
It supports regulators in submitting the legally required documents and enables stakeholders to search and access this data. The database was launched to the public in 2011 and includes:

- Manufacturing/ Importation Authorisations (**MIA**);
- Wholesale Distribution Authorisations (**WDA**);
- Good Manufacturing Practice (**GMP**) and Good Distribution Practice (**GDP**) certificates, or Non-Compliance Statements (**SNC**);
- Registrations of Active Pharmaceutical Ingredient manufacturers, importer and distributors (**APIreg**).

The **new platform** replaces outdated components, enhances public/private search, and refactors the core modules listed above (MIA, WDA, GMP/SNC, GDP/SNC, APIreg) to support consistent, reliable and efficient regulatory workflows.

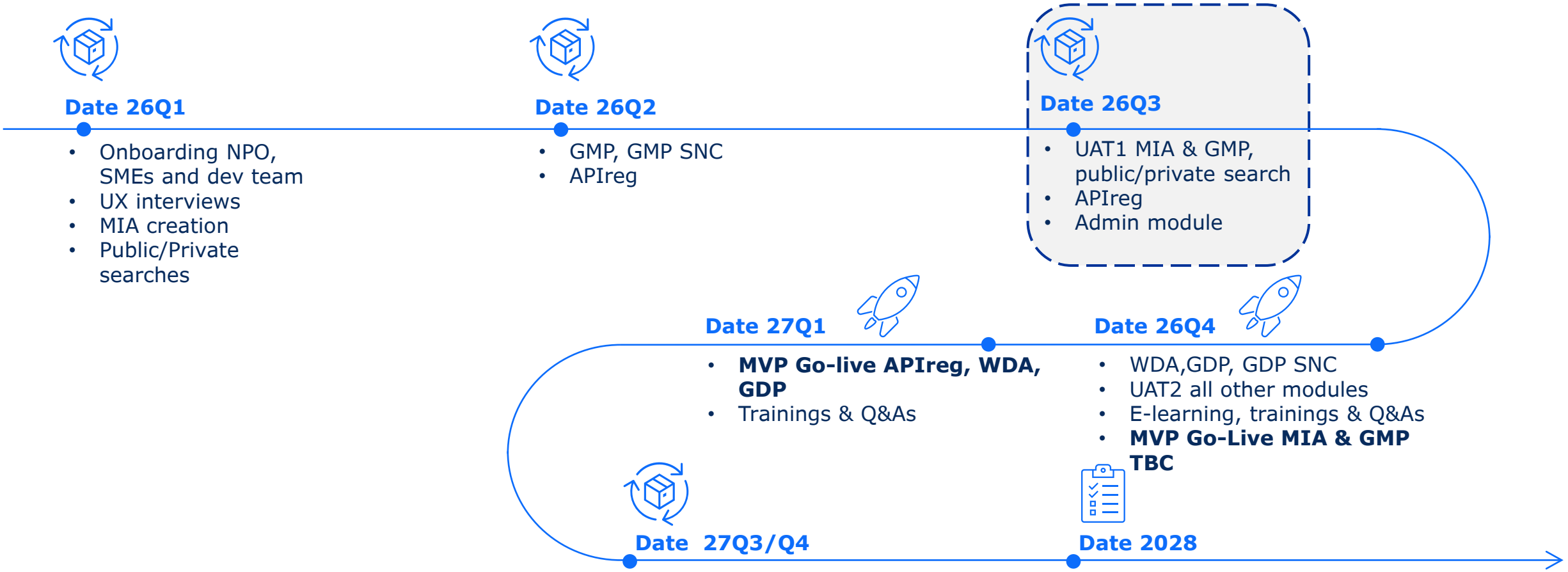
Benefits of modernisation

Strengthened Strategic & Regulatory Readiness

Increased System Stability & Efficiency

Enhanced User Experience

EudraGMDP modernisation roadmap



EudraGMDP Demo Functionalities:

- Public/private search
- Admin module
- Creation of
  - Registration of an active substance manufacturer, importer or distributor (APIreg)

Live Demonstration

https://eudragmdp-uat.ema.europa.eu

Chat

Google | Eudra Common Di... | Webtop | SAP new | Employee Center... | Cases Inspections -... | EudraGMDP | EudraGMDP datab... | GMP | Other favorites

EMA | EudraGMDP

EudraGMDP guidance and help

Find authorisations, registrations, certifications and compliance statements

Type of document | Organisation name | Organisation ID | Country *

Search

Advanced filters

EudraGMDP is the European database on manufacturing, import and wholesale-distribution authorisations, and good manufacturing-practice (GMP) and good-distribution-practice (GDP) certificates.

Learn more about EudraGMDP

Documents available on this website:


LLM
LARGE LANGUAGE MODELS
AI
01 01 001
01 01 01
10 December
2026
Is the next public system demo