

# System Demo 26Q2

## Public System Demo

25 June 2026





# Welcome & Introduction

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

# Housekeeping



Please note that this session is being live streamed.  
It is being recorded and will be available on the EMA Corporate Website

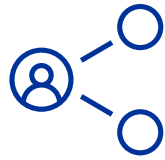


Participants may be able to ask questions or share feedback via Slido, with the option of remaining anonymous, If you choose to use Slido, you consent to the processing of your personal data as explained in the EMA Data Protection Notice for Webex (europa.eu).



To view the video in the highest quality, click on the settings symbol and select 720p or a higher resolution  
To watch the video in full screen mode, click on watch on Youtube to watch it on YouTube.com

# 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.

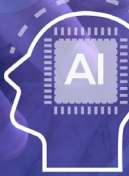
Creates a safe space for early identifications of defects or design flaws and for the generation of new ideas to improve over time.



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



01 01 001  
01 01 01

**17 September  
2026**

Is the next public system demo

# Agenda

**09:00**

**Welcome / Introductions**

**09:05 – 11:15**

**Product Lifecycle Management Value Stream (PLM VS)**

Union Product Database (UPD)

Regulatory Procedure management (RPM) for Product Lifecycle Management on IRIS

Electronic product information (ePI)

Electronic Common Technical Document version 4.0 (eCTD v4.0)

Electronic application forms (eAF)

**10:30 – 10:40**

**Break**

Product Management Service (PMS)

Product user interface (PUI)

**11:15 – 11:40**

**Monitoring Value Stream (MON VS)**

EudraGMDP

**11:40 – 12:20**

**Research & Development Value Stream (R&D VS)**

Clinical Trials Information System (CTIS) modernisation

**12:20 – 12:35**

**Technology Lifecycle Management Value Stream (TLM VS)**

EMA Account Management – improved user interface (UI) to request access on behalf of an organisation

**12:25**

**Closing**

# Give feedback & ask questions through Slido



## Option 1 - 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



## Option 2 - Poll

Feedback shared only with product team  
Stays open for comments till 2 July  
Please identify yourself  
Give the product team feedback and  
suggestions about your priorities

Join at  
**slido.com**  
**#9116 064**

Step 1 - Go to slido.com

Select room

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- MTA - JIRA replacement
- R&D - TRIP Digital Workspace for Horizon scanning
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Step 2 – Choose/switch to the room for  
the right product

Step 3 - Choose Q&A or Polls as  
appropriate

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# 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*

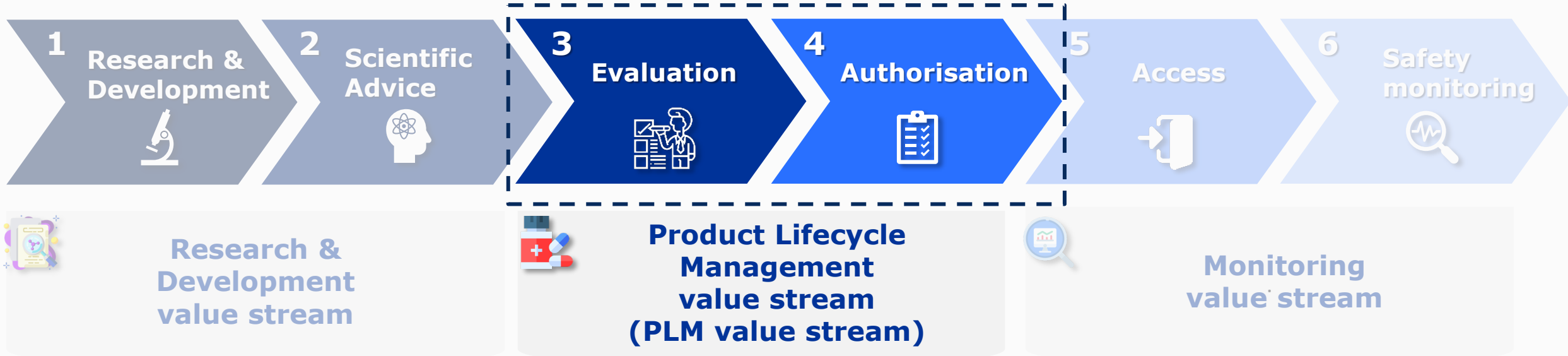
## Monitoring

*Capabilities to monitor availability and safety of products*

## Technology Lifecycle Management and Information Security

*Capabilities to manage information technology and security*

## Lifecycle of a centrally authorised medicinal product





# PLM VS | Union Product Database(UPD)

Saskia Schiemann, UPD Network Product Owner

Beyhan Mustafov, UPD Product Owner

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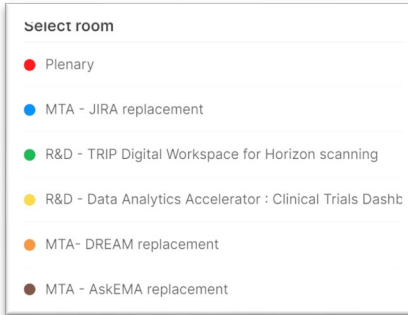
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# UPD – Union Product Database (1/3)



## Committed objectives 26Q2

## Demo

**Granting the UK(NI) competent authority** (Veterinary Medicines Directorate) **partial read and write access to UPD** via UI and API

- *UK(NI) users have access to search and view CAPs and UK(NI) authorised products.*
- *UK(NI) users can create and update NAP/Homeopathic/PET/parallel trade products.*
- *UK(NI) cannot be the RMS of DCP/SRP/MRP/MRPh products. UK(NI) users cannot create products for these procedure types, but they can update National data of CMS products where authorisation country is UK(NI) for these procedure types.*
- *UK(NI) users can view and approve (or reject) the VNRA submissions for UK(NI) products.*
- *UK(NI) cannot be selected as 'Foreseen decision maker.*
- *UK(NI) users can view the VNRA submissions for CAP products.*
- *UK(NI) users can perform transfer of ownership for products under their responsibility.*
- *UK(NI) users do not have access to Volume of sales data in UPD. Access to sales data for veterinary medicinal products authorised and marketed in the territory of UK(NI) is provided via the Antimicrobial Sales and Use (ASU) platform.*

NO

*Released on  
12 May 2026*

# UPD – Union Product Database (2/3)



## Committed objectives 26Q2

## Demo

### Improving Product Summary Card and Availability Status in UPD UI

- *A click on Product name in the Search result table opens a new tab in the browser to display the View product page.*
- *Revamped product summary card displays: Full product name, Authorisation status, Procedure type, Availability status at product level, Product identifier, Permanent identifier and Documents.*
- *Documents in the summary card are displayed in a three-column table: language abbreviation, document abbreviation type i.e. SPC, PL, AR, etc. and document name.*
- *The availability status is now displayed at product level, e.g. if there is at least one package with the Availability status "Marketed", the availability status at product level will be "Marketed".*

NO

*To be released on  
26 June 2026*

- *The availability status for newly created products and packages will be set automatically to 'Not marketed', in accordance with Vet EU IG Chapter 2. The current approach, 'No data provided', will be deprecated.*

NO

*Postponed to Q3  
2026 due to  
potential change  
in the RMS term  
definition for 'Not  
marketed'*

# UPD – Union Product Database (3/3)



Committed objectives 26Q2	Demo
<b>Enabling UI users to export all product search results.</b> The current restriction of 10,000 products per .csv file extract will be removed.	NO <i>To be released on 26 June 2026</i>
<b>Preventing NCAs from assigning/selecting, the EMA or EC as Responsible authority and/or Product owner when creating or updating DCP/SRP/MRP products.</b>	NO <i>Postponed to late 2026, as more analysis and development are needed</i>
<b>Enabling NCA and MAH users to receive notification (in UI and via email) when a product update has failed</b>	NO <i>Postponed to late 2026, due to other priorities and lack of capacity</i>

# UPD – Q2 additional changes and achievements



## Additional enhancements

- ✓ **Changes to the error report CSV file generated when the submission of volume of sales data fails:** all previously entered data in columns '*Volume of sales*', '*Species Identifier*', '*Species %*', '*Dose Factor*' and '*Comment*' are removed from the file.
- ✓ **The date format in UPD UI is aligned to European date format i.e. DD/MM/YYYY.** Any edit or view date field in UPD UI now follows the DD/MM/YYYY date format.
- ✓ **Active substance table within Manufacturing Business Operation section in 'View product page' now display multiple rows for active substances,** if they have more than one manufacturer.
- ✓ **'Bulk upload'** functionality does not support upload of documents for veterinary Homeopathic medicinal products and VMPs that are intended for animals exclusively kept as pets.
- ✓ **When creating a DCP product** using 'import existing information' functionality, **NCA UI user can only use the products for which their competent authority is the RMS.**



## New/revised guidance and training materials

- ✓ Updated [UPD access policy](#).
- ✓ Updated [UPD Registration Guide](#).
- ✓ Updated [Revised EU IG Chapter 7](#).

# 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](#)

## Annual Change Adoption Survey



The annual survey is now open. All users are encouraged to provide feedback to support continuous improvement. The survey is quick to complete and responses will remain anonymous.



# PLM VS | Regulatory Procedure Management (RPM) for Product Lifecycle Management on IRIS

Madalina Duta-Mare, RPM for PLM Product Owner

# Give feedback & ask questions



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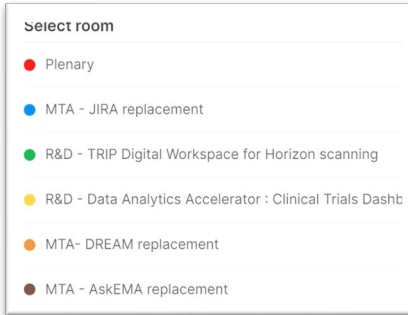
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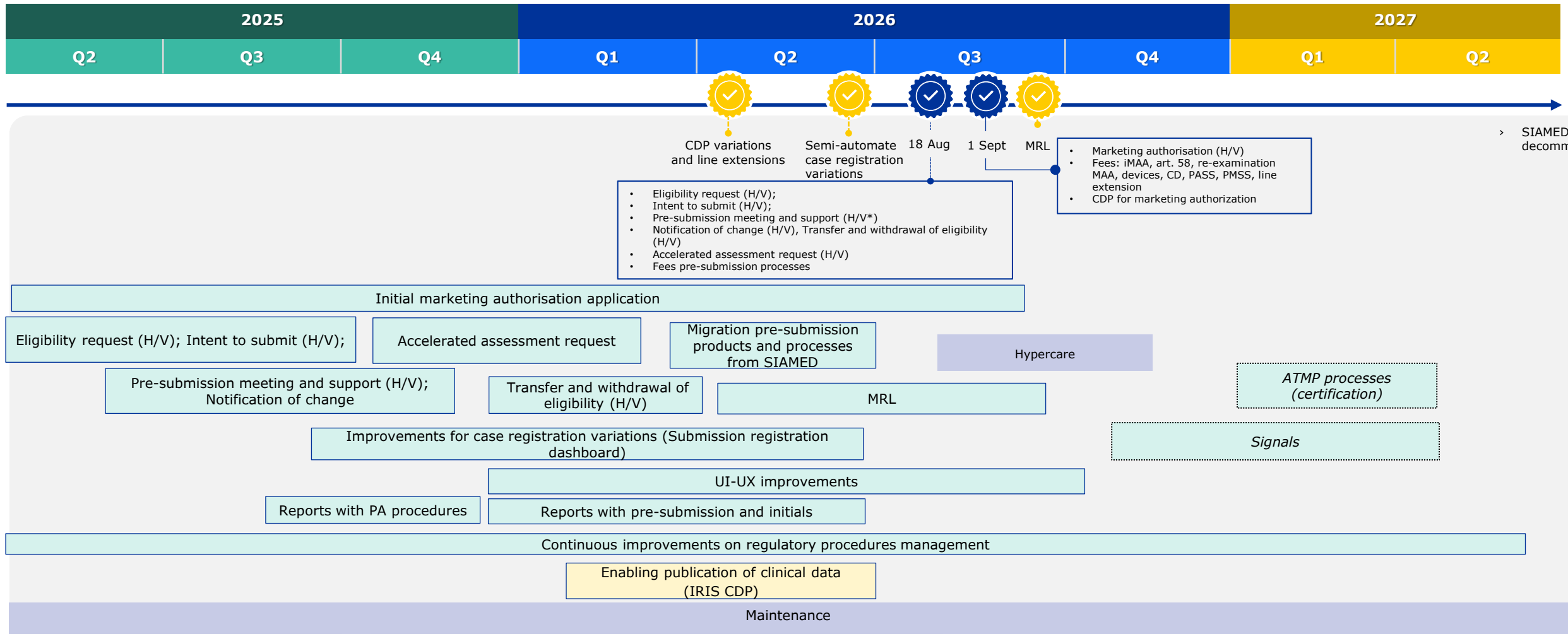


Q&A | Polls

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# Regulatory procedure management in IRIS roadmap (Epic 3)



**Acronyms**

- CDP:** Clinical data publication
- PA:** Post Authorisation
- ATMP:** Advanced Therapy Medicinal Products
- CD:** Companion Diagnostic
- MRL:** Maximum Residue Limits

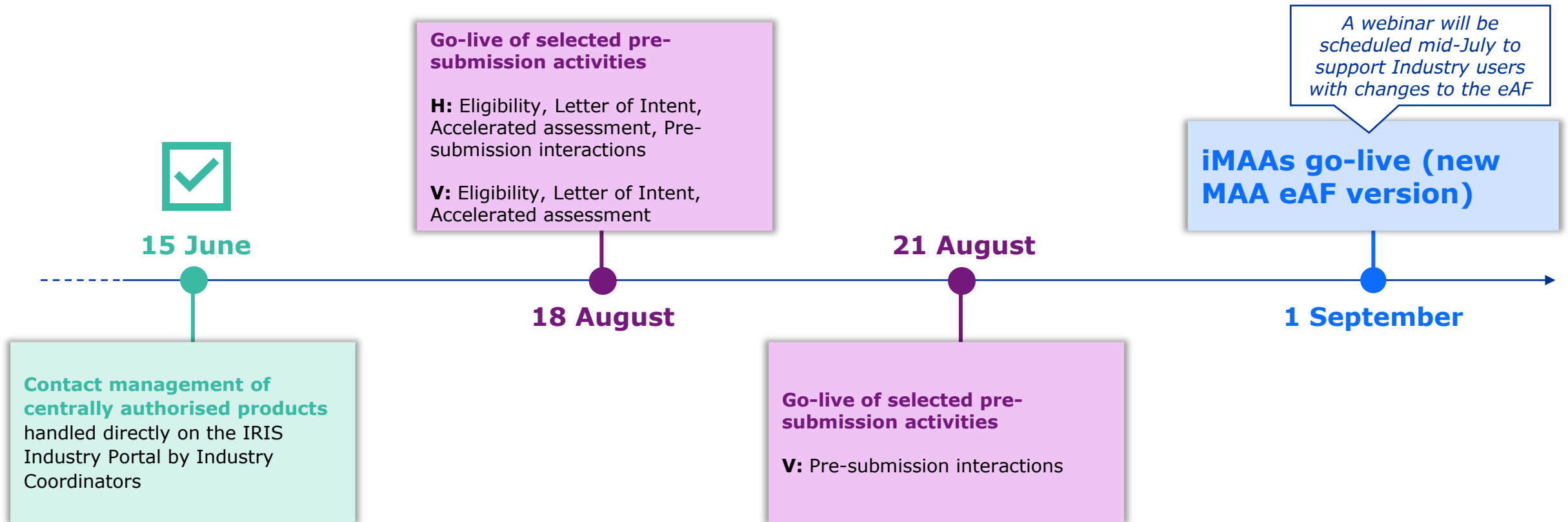
**Legend**

- Go-live:** Blue gear icon with checkmark
- Milestone:** Yellow gear icon with checkmark
- Dev. activities:** Light blue box
- Maintenance/Hypercare:** Purple box
- Enabler:** Yellow box
- Proposed activities for after Epic 3:** Dashed box

\* The roll-out of Pre-submission meeting V will occur on 21 August

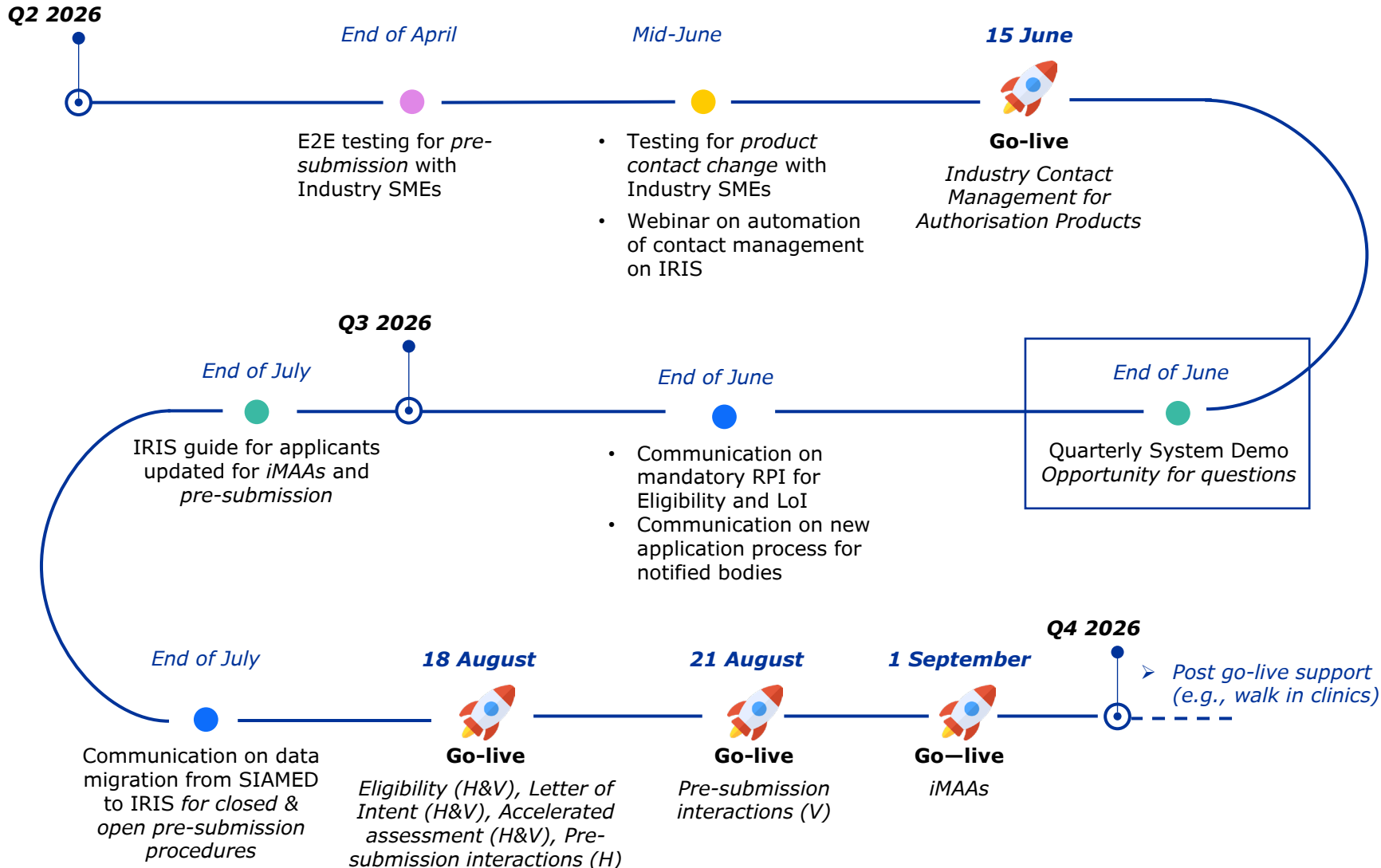


# Key milestones for industry users



As these milestones approach, a range of **support activities** will be provided to Industry users to facilitate the transition to IRIS.

# Change management activities



## Support ecosystem

- Biweekly engagement with Industry SMEs for Epic 3 procedures
- Ad hoc updates to the Industry FAQ
- Walk-in clinics (*from September, 2 times per week*)
- Additional support as needed

## Legend

- Engagement
- Testing activities
- Training/ Guidance materials
- Communication

# Need a refresher? Start here!

Before the go-live, explore **previous IRIS demonstrations** and **webinars** to familiarise yourself with key processes, functionalities, and upcoming changes. Access the presentation materials and webinar recordings below.

## Public System Demo – Q325

17 September 2025

### Topics covered

- Eligibility
- Letter of Intent



[Slides](#)

Slides 75-82



[Recording](#)

Timing: 2:46:00 – 3:10:00

## Public System Demo – Q425

16 December 2025

### Topics covered

*Pre-submission interactions*



[Slides](#)

Slides 40-44



[Recording](#)

Timing: 2:07:46 – 2:26:07

## Contact management for authorisation products

11 June 2026

### Topics covered

*Management of authorisation product contacts*



*Slides and recording will be available soon on the EMA website*



# Where to find IRIS guidance and support



## [IRIS Guide for applicants](#)

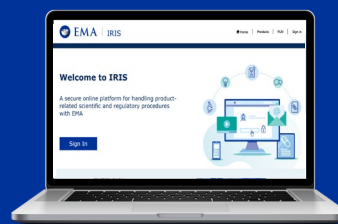
Comprehensive **step-by-step guidance** to create, submit and manage IRIS applications

Portal to **raise a ticket** for **technical assistance**, including issues related to access, accounts, submissions or system functionality



## [EMA service desk \(ServiceNow\)](#)

*Do you need support?*



**IRIS**

## [IRIS guide to registration and RPIs](#)



**Detailed preliminary requirements** for all IRIS submissions, including substance and Research Product Identifier registration

Brief document that lists and describes the **new features and fixed issues** included in the release of the IRIS Portal

## [Public release notes](#)



# Pre-submission product identifier transformed to EMEA format

**H0000xxx**  
**V0000xxx**



**EMEA/H/C/00xxx**  
**EMEA/V/C/00xxx**

## Decommissioning of pre-submission identifier

- **The current pre-submission identifiers** product identifiers will be **decommissioned**.
- At submission of **Eligibility and Letter of Intent**, or upon **positive PRIME eligibility**, products will be assigned directly an EMEA identifier, which will be used throughout the entire product lifecycle

## Data migration to IRIS

- Products migrated from **SIAMED** to **IRIS** will be converted from the short pre-submission format to the **EMEA** format automatically

### What this means for applicants:

- A single, harmonised business identifier used from pre-submission through the entire product lifecycle
- Applicants should use the EMEA identifier in all regulatory communications



## **Live demonstration** on *Withdrawal of authorisation products and regulatory entitlements*

**Scope:** To withdraw Authorisation Product with pre-submission status and related Regulatory Entitlements. For pre-authorisation only



# PLM VS | Electronic product information (ePI)

Elizabeth Scanlan, ePI Product Owner

Evinn Drusys, ePI Network Product Owner

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# Achievements



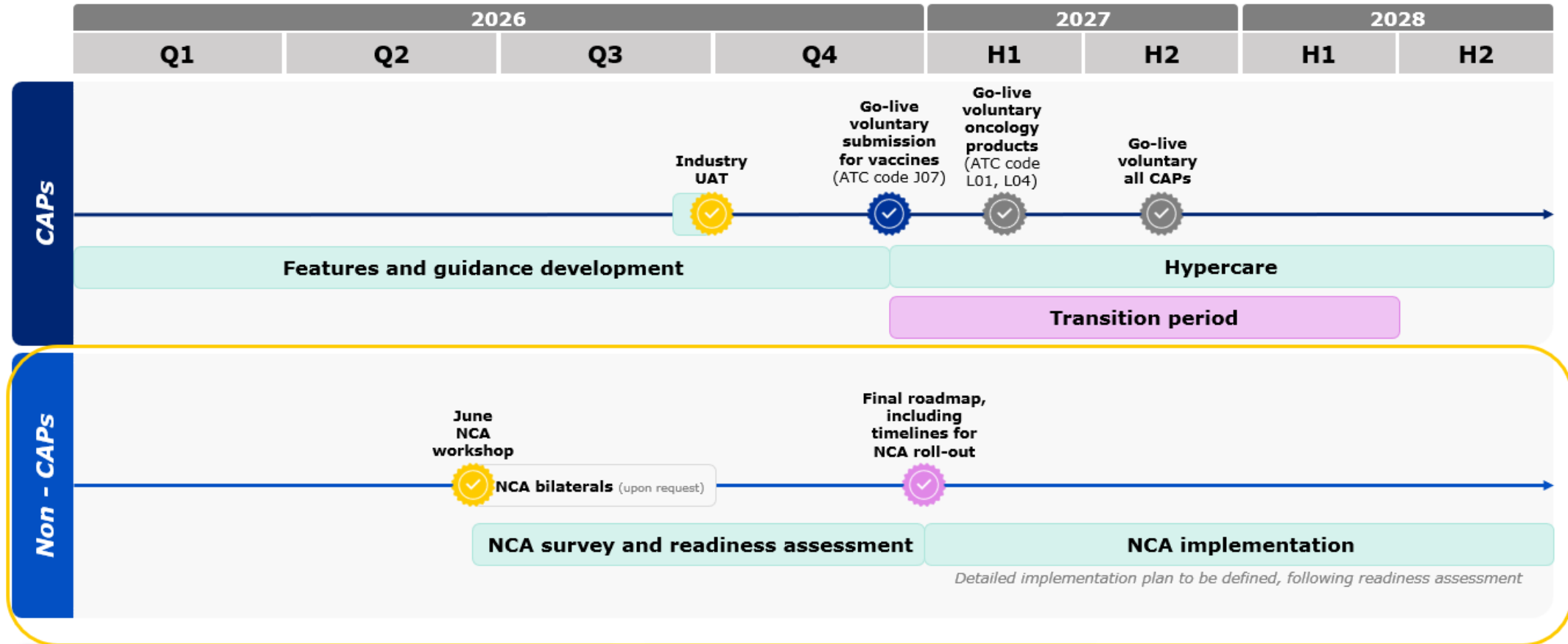
**NCA ePI open day:** NCA readiness assessment ongoing

**Performance:** 'create new ePI' significantly more performant

**Link to authorisation medicinal product:** linking CAP ePI to authorised medicinal product will be mandatory to enable workflow

**Bug fixing**

# NCA readiness: towards an implementation roadmap



**NCA ePI Open Day with participation of every Member State** took place 10 June



Currently scheduling **NCA bilaterals**; NCAs requested to complete **survey**



## Live Demonstration



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

Kristiina Puusaari, eCDT v4.0 Product Owner

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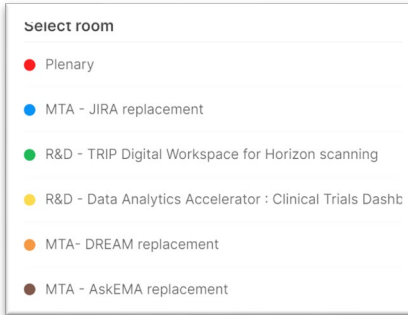
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# eCTD v4.0 – Q2 achievements

## Testing phase for CAPs new MAAs in eCTD v4.0

- **Optional use for CAPs new MAAs** in eCTD v4.0 format live from 22 December 2025.
- **New testing phased** started. Applicants are invited to **perform eCTDv4.0 test submissions**.
- **Parallel submissions to production** (in eCTD v3.2.2 format) **and test** (in eCTD v4.0 format) are also **welcome** to help applicants familiarise themselves with the new standard.

## Technical pilot activities

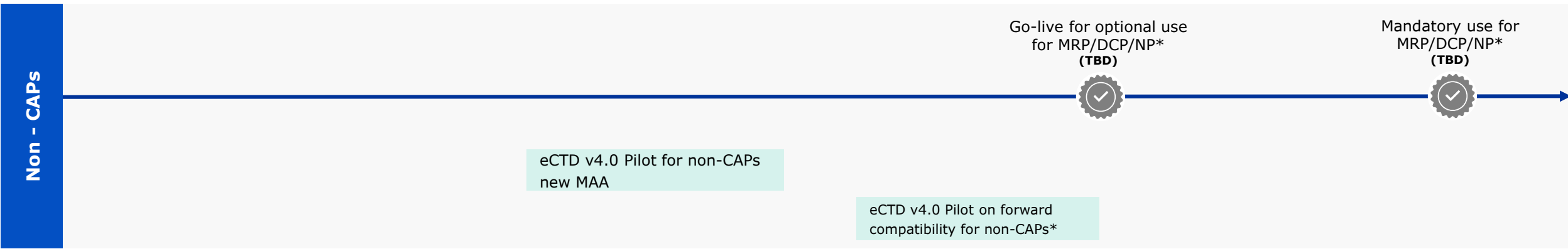
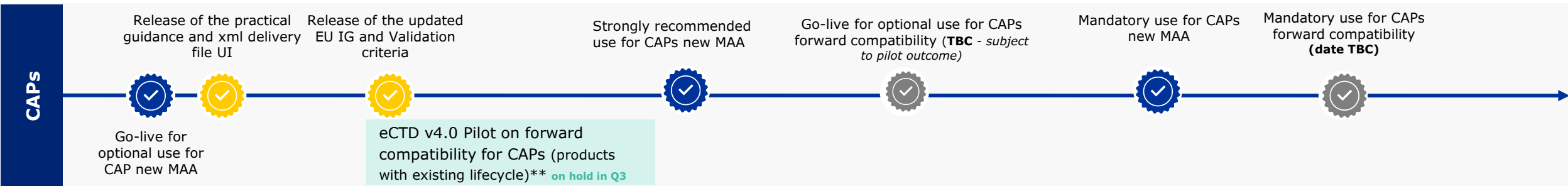
- **Technical pilot on Forward Compatibility for CAPs** (i.e. products with existing eCTD v3.2.2 lifecycle) **kicked-off** in **April 2026**.
- The pilot has identified **technical challenges** which are **currently being addressed**.
- 2<sup>nd</sup> pilot phase for Forward Compatibility for CAPs is planned to start in Q4 2026.
- **Preparation for non-CAPs new MAA** technical pilot **ongoing**. Pilot launch is expected in Q3/Q4 2026.

## Steps toward Central Repository feasibility study

- A **feasibility study** on the Central Repository is being initiated, 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

2025	2026				2027				2028			
Dec	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4



**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
- TBC Go-live
- Dev. activities

\*Dependency on Central Repository go/no-go decision

\*\*Subject to technical feasibility



# PLM VS | Electronic application forms (eAF)

Kristiina Puusaari, eAF Epic Owner and eSubmissions Product Owner

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# Human and Veterinary eAF v1.28.0.0 – Key changes

**Version 1.28.0.0 of the interactive PDF electronic application form (eAF) for human and veterinary marketing authorisation application (MAA) is now available on the eAF website, together with the associated release notes.**

## Purpose



**Address structural limitations** in the current form and support **alignment with the ISO Identification of Medicinal Products (IDMP)** data model.

## Outcome



**More structured and interoperable representation** of medicinal product information **across the EU regulatory network.**

## No regulatory changes



The proposed **changes do not modify the regulatory intent** or the type of information collected in the form.

## Benefits



**More accurate representation** of complex medicinal products and ensuring that **key product attributes** (such as product composition, packaging, manufacturing responsibilities and administration characteristics) can be described in a **consistent and machine-readable way.**

# Human and Veterinary MAA eAF v1.28.0.0 – Testing and Rollout

**Version 1.28.0.0 of the interactive PDF electronic application form (eAF) for human and veterinary marketing authorisation application (MAA) is now available on the eAF website, together with the associated release notes.**

## Initial testing



Completion of **user acceptance testing (UAT)** led by **EMA** involving **selected NCA and MAH representatives**.

May 2026

## Extended MAH testing



**MAHs (H) completed the PDF form testing**, reporting their feedback during the first week of June 2026.

June 2026

## CAP MAA use



Industry **must** use the version **1.28.0.0 eAFs**, for **all new CAP Human or Veterinary marketing authorisation applications** sent to EMA from **28 July 2026** onwards.

July 2026

## Rollout for other product types H&V



For non-CAP procedures, use of the updated eAFs is **optional** from **1<sup>st</sup> September 2026** and **mandatory** from **1<sup>st</sup> January 2027**. Further details will be shared through the [eSubmission website](#).

September 2026 -  
January 2027

# Variations eAF – Updates



## Annual Update for Human Variations

The human variation eAFs, PLM portal and interactive PDFs, were updated to support the **annual update notification**. Both updated forms will be made available in early July, on the PLM portal and eSubmission eAF website, with the relevant transition details.

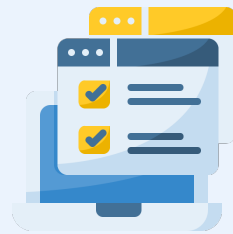
## Veterinary variation form

**An updated version of the veterinary variation form** is being finalised and will be published on the **eSubmission website, together with the transition timeline**.

## Performance improvements

**The performance improvements for PLM web-based eAF are being implemented**, with particular focus on better supporting large applications.

# Human variations eAF - statistics



**17 293 non-CAP applications** created in the PLM Portal (since March 2025)



**9 547 Centralised Procedure application forms created** since the go-live

# Human variations – PLM web-based eAF

## **Mandatory use for CAPs**

### **1<sup>st</sup> Sept 2026**

The PLM Portal web-based variation form will be in **Mandatory use for all CAPs variations from September 2026.**

From 1 September date onwards, any human CAP variation submissions sent to EMA using the **interactive PDF eAF will be rejected** unless it is accompanied by a valid and **justified technical reason preventing the use** of the PLM web-based eAF.

The possible technical issues preventing the use of PLM eAF are detailed here: [Upcoming mandatory use of PLM web-based eAF for CAPs · PLM](#)

Further details on how to **justify the exceptional use of the PDF eAF** will be communicated prior to the beginning of the Mandatory use for CAPs.



# Known eAF Issues and Bugs



List of **known issues and bugs** is **continuously reviewed**, and fixes are planned for each sprint.



## Reminder

Please review the eAF **Release Notes, Navigation Guide and the Q&A document** if you have issues. If you experience a known issue, please consider if you need to raise a service desk ticket and carefully select the correct category in ServiceNow.

## Known PLM eAF issues



### 1. Performance issue for large applications

A known performance limitation in the PLM portal eAF prevents the creation of large applications (for scenarios covering around 200 products and more).

There are several activities planned for 2026 to improve the behaviour.

### 2. Medical Devices section

A known issue in the Medical Devices section requiring use of the interactive pdf eAF.

# Known Issues and Bugs – outside eAF

## Known issues



### 1. PMS issues (*affecting CAPS and non-CAPs*)

The complete list of known PMS issues can be found in the following document: [product-management-service-pms-frequently-asked-questions-faqs\\_en.pdf](#) (page 16), with the expected resolution date. The issues range from “Duplicated products and packages ” and “Duplicated entries” to “Truncated full product name”. Please consult the list and potential action for the MAHs before raising a ticket.

### 2. Organisational data issues (*affecting CAPS and non-CAPs*)

A known issue in the intermediate dataverse layer from where the Organisation data is fetched to the eAF is continuing to impact number of products/users/applications. A platform level review is ongoing to ensure that the issue can be solved without negatively affecting various systems that feed from this data.

Several workarounds were applied in eAF to address OMS synchronisation issues. Similar approach will be further analysed and implemented (contact person and proof of payment).



# PLM VS | Product Management Service (PMS)

Marcos Fernandez Gomez, PMS Co-Product Owner

# Give feedback & ask questions



## Option 1 - Q&A

Questions and answers are public  
You may upvote the questions  
Top questions are answered verbally  
Questions & available answers published  
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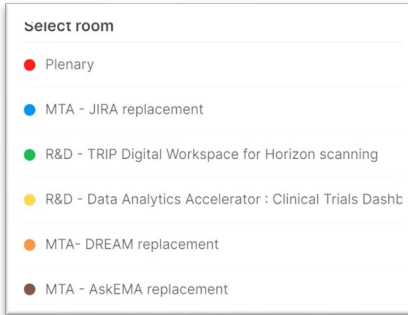
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Stays open for comments till 2 July  
Please identify yourself  
Give the product team feedback and  
suggestions about your priorities

Join at  
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Step 1 - Go to slido.com



Select room

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



Q&A | Polls

Step 3 - Choose Q&A or Polls as  
appropriate

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# PMS – Product Management Service



Achievements 26Q2	Demo
<ul style="list-style-type: none"><li>• Release of Beta version of <b>Public PMS API</b></li></ul>	YES
<ul style="list-style-type: none"><li>• Analysis performed to improve deltas between XEVMPD and PMS</li></ul>	NO
<ul style="list-style-type: none"><li>• Improvement of <b>deltas between SIAMED and PMS</b></li></ul>	NO
<ul style="list-style-type: none"><li>• <b>DQ activities:</b><ul style="list-style-type: none"><li>• ATC codes missing in PMS are now captured</li><li>• Removal of duplicated packages (still ongoing)</li></ul></li></ul>	NO

# Access to Public PMS API



Request access through [EMA Account Management](#) → no need to belong to any organisation. Free access.



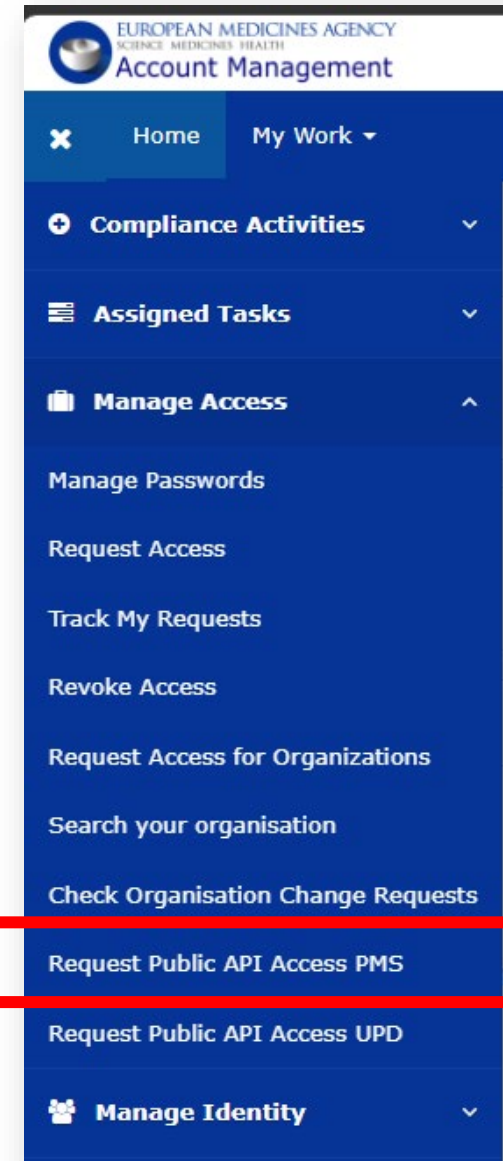
After accepting Terms and Conditions of Use a set of credentials are provided via email.



Users can start using the Public PMS API



Information can be found in [EU IG Chapter 1](#)



# PMS – Product Management Service



## PMS Q&A Clinics every month

**1-hour sessions** where the PMS team is available to **answer your questions** regarding the Product Management Service (PMS) User Interface (PUI) and the Application Programming Interface (API).



## PMS FAQ document

- Review the [FAQ document](#) in the PLM portal as this document contains a direct **record of frequently asked questions**, as well as an overview of **known issues**, including current status and progress update
- The majority of questions raised during the Q&A clinics are covered in the FAQ document



## Live Demonstration



# PLM VS | Product user interface (PUI)

Marcos Fernandez Gomez, PMS UI Co-Product Owner

# Give feedback & ask questions



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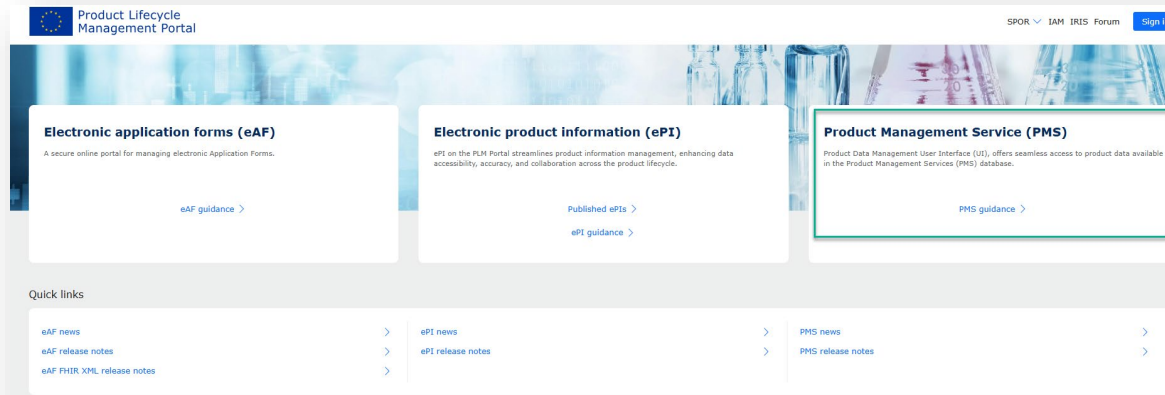
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# Product UI



Achievements 26Q2	Demo
<ul style="list-style-type: none"><li>▪ Start the implementation of the user journey for the product creation in the Product UI</li></ul>	NO
<ul style="list-style-type: none"><li>▪ Continue delivering UX/UI enhancements and critical bug fixes<ul style="list-style-type: none"><li>▪ Guidance and help page</li><li>▪ Manufacturer reference number, effective date and regulatory agency of MBO is now optional</li></ul></li></ul>	YES



# Upcoming events



## Q&A clinics on PMS PUI and API

- **9 July 2026** (9:30 – 10:30 CEST): [Event page](#)
- **23 July 2026** (9:30 – 10:30 CEST): [Event page](#)
- **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

- **8 July 2026** (15:30 – 16:00 CEST): [Event page](#)
- **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

- **9 July 2026** (15:00 – 16:00 CEST): [Event page](#)
- **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*

**8 July 2026** (10:00 – 12:30 CEST):  
[registration available on event page on EMA website](#)



## Live 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*

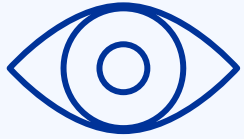
## Monitoring

*Capabilities to monitor availability and safety of products*

## Technology Lifecycle Management and Information Security

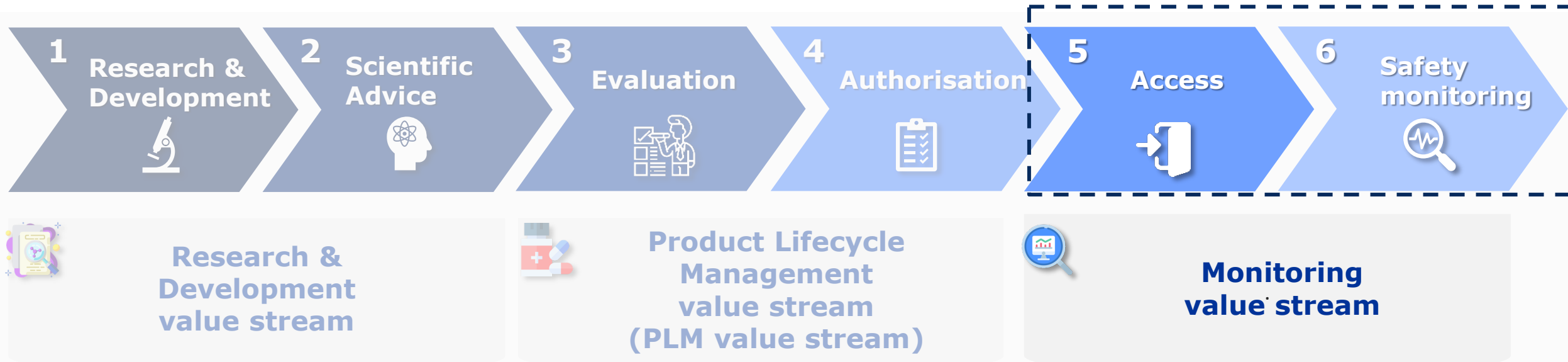
*Capabilities to manage information technology and security*

# 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





# 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



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# 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



## Date 26Q1

- Onboarding NPO, SMEs and dev team
- UX interviews
- MIA creation
- Public/Private searches



## Date 26Q2

- GMP, GMP SNC
- APIreg



## Date 26Q3

- UAT1 test strategy
- UAT1 start MIA & GMP
- APIreg
- WDA



## Date 27Q1

- **MVP Go-live APIreg, WDA, GDP**
- 2nd epic: Addition of NPL functionalities
- Planning Module review
- Reporting/analytics needs



## Date 26Q4

- GDP, GDP SNC
- UAT2 start all other modules
- **MVP Go-Live MIA & GMP**



## Date 27Q3/Q4

Decommission of legacy EudraGMDP



## Date 2028

Operate and maintain new EudraGMDP

## + Next steps (2026)

- **June:** Communication & UAT invitations
- **September:** UAT
- **Post-UAT:** Training & support materials

# User Acceptance Testing (UAT)

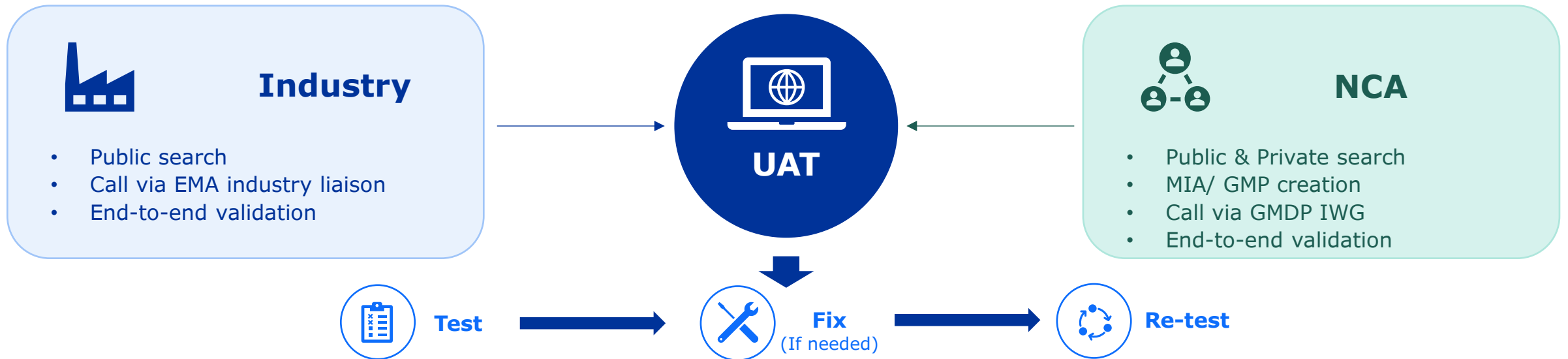


September 2026 | One UAT phase (~1 week, with possible extension)



## Preparation

Invitations | Communications | Onboarding



## Support & Feedback during UAT

Guided test scripts | Support sessions | Feedback collection

## EudraGMDP Demo Functionalities:

- Public search & document consultation
- Private (restricted) search
- Creation of
  - Good Manufacturing Practice (GMP) certificates/ Good manufacturing practice statement of non-compliance (GMP SNC)



## Live Demonstration

# EMA Value Streams

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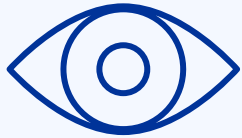
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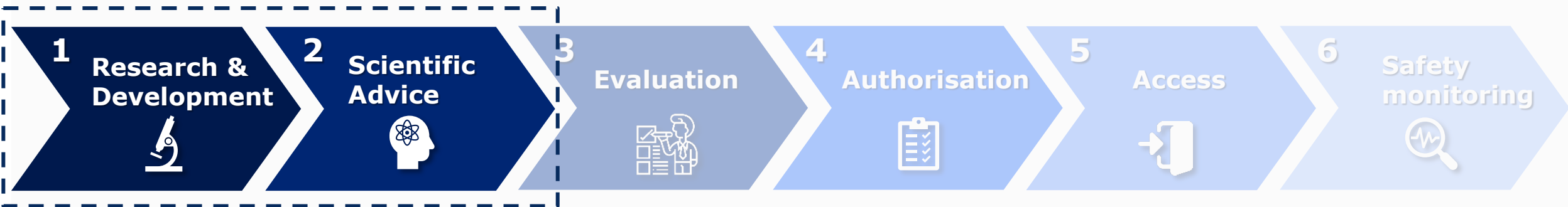
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# Managing the medicinal product lifecycle



*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



**Research & Development value stream**

**Product Lifecycle Management value stream (PLM value stream)**

**Monitoring value stream**



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

Annual safety report (ASR) submission

Ana Rodriguez, CTIS Product Owner

# Give feedback & ask questions



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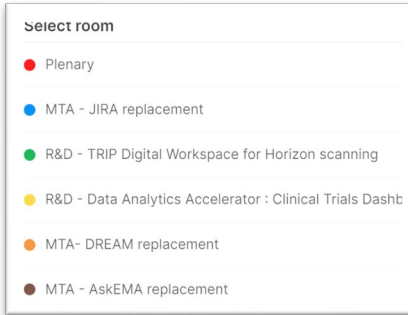
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Q&A | Polls

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# CTIS Modernisation- New Safety Module



Committed objective 26Q2	Demo
<b>Safety Module MVP</b> – Fix critical and high bugs identified in <b>SaMS</b> UAT	<b>NO</b>
<b>Safety Module MVP</b> – Complete <b>ASR submission</b> implementation	<b>NO</b>
<b>Safety Module MVP</b> – Complete <b>ASR assessment</b> implementation	<b>YES</b>
<b>Safety Module MVP</b> - Complete <b>Safety Role Management</b> implementation	<b>NO</b>



## Demonstration

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*Capabilities to monitor availability and safety of products*

## Technology Lifecycle Management and Information Security

*Capabilities to manage information technology and security*



# TLM VS | EMA Account Management – improved user interface (UI) to request access on behalf of an organisation

Carlo De Vittoria, Identity and Access  
Management (IAM) Product Owner

Jhonny Oliveira, Identity and Access  
Management (IAM) Platform Manager

# Give feedback & ask questions



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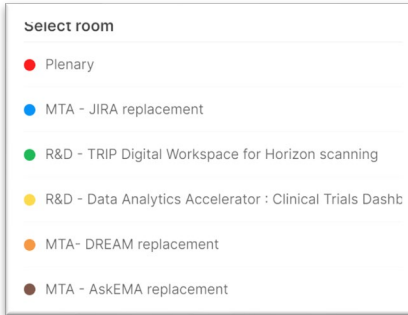
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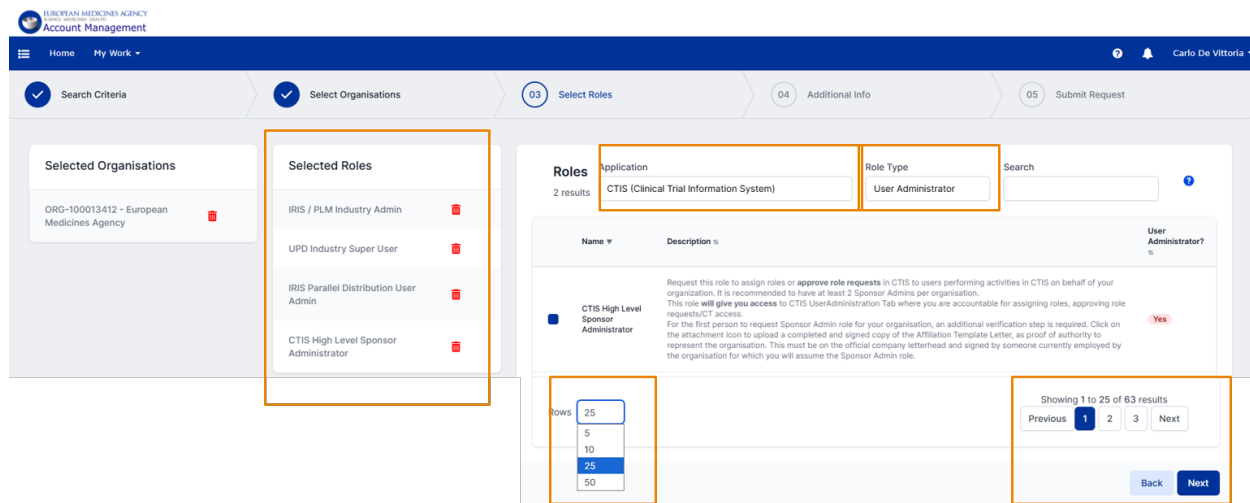
Q&A | Polls

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# Improved user interface (UI) to request access on behalf of an organisation

As the number of application and roles is growing the user interface for selecting roles have been improved allowing to better filter the available roles.



Filter by applications

display only the relevant roles for the user

Filter by Type

select between User Administrator roles<sup>1</sup> and normal roles

Role Shopping kart

Remove unnecessary roles before submission

Paging

improve performance and clarity

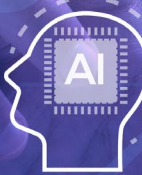
<sup>1</sup> allowing to manage other users in EMA Account Management



## Demonstration

**LLM**

LARGE LANGUAGE MODELS



01 01 001  
01 01 01

**17 September**

**2026**

Is the next public system demo