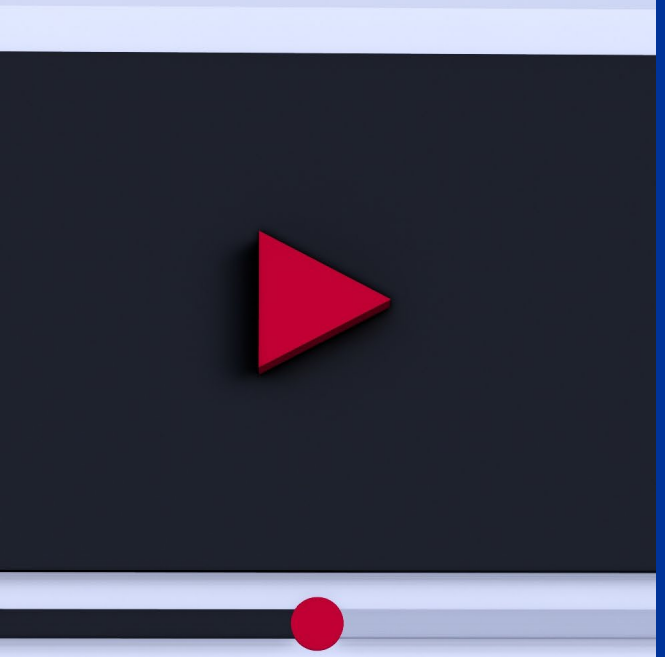
EMA
EUROPEAN MEDICINES AGENCY

System Demo 25Q4

Public System Demo

16 December 2025



Welcome & Introduction

Joris Wiemer, Change Management Lead, EMA

Housekeeping

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

Participants may be able to ask questions or share feedback via Slido, with the option of remaining anonymous*.

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

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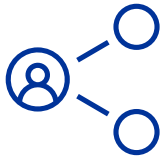
slido # 9116064

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.**

Is recorded and published on the EMA **Corporate web site**

26 March

Is the next public system demo

Agenda

09:30	**Welcome / Introductions**
09:35 – 12:00	Product Lifecycle Management Value Stream (PLM VS)
	Electronic application form (eAF)
	Electronic Common technical Document version 4 (eCDT v4.0)
	Union Product Database (UPD)
	Product Management Service (PMS)
10:35 -10:50	**Break**
	Product user interface (PUI)
	Electronic product information (ePI)
	Regulatory Procedure Management (RPM) for Product Lifecycle Management on IRIS
12:00 -12:15	Research & Development Value Stream (R&D VS)
	Clinical Trials Information System (CTIS) modernisation – new CTIS safety module
12:15-12:30	Monitoring Value Stream (MON VS)
	Antimicrobial Sales & Use (ASU) platform
12:30-12:35	Product Lifecycle Management Value Stream (PLM VS) Data Analytics Platform (DAP) – BI reports for NCAs
12:35	**Closing**

Give feedback & ask questions

Option 1 - Q&A

Questions and answers are public
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Questions & available answers published on event page on EMA website

Option 2 - Poll

Feedback shared only with product team
Stays open for comments till 24 December
Please identify yourself
Give the product team feedback and suggestions about your priorities

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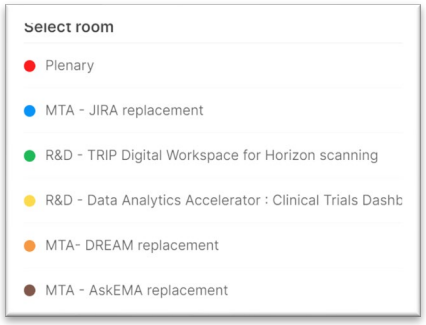

Step 2 – Choose/switch to the room for the right product

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

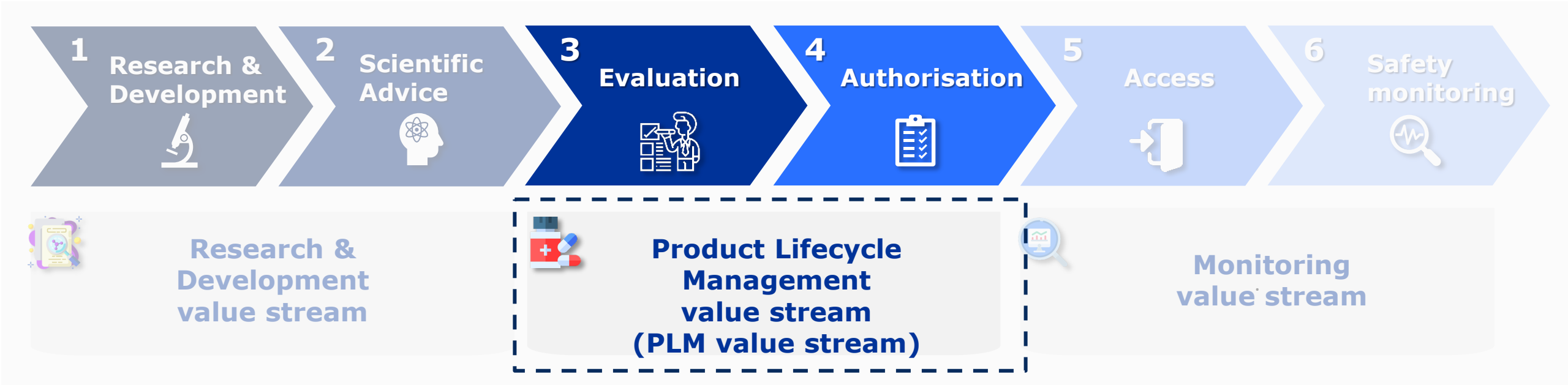
Capabilities to monitor availability and safety of products

Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

EMA

Lifecycle of a centrally authorised medicinal product



PLM VS | Electronic Application Form (eAF)

Kristiina Puusaari, eAF Epic Owner

eAF – Human Variations electronic Application Form

Committed objectives 25Q4	Demo
Enabled the final production version of the **new variation classification** (mandatory from 15 January 2026)	**NO**
Enable deletion of organisation in Present and Proposed with OMS organisation selection e.g. **deletion of a manufacturer** so that the applicant can use OMS instead of free text fields	**NO**
Enable use of the latest OMS information when selecting the **reference MAH** when creating the application form (to avoid having to use the interactive pdf eAF in case where the latest OMS information is not available in dataverse (workaround to a known issue)	**NO**
Improved **UX/UI** for Product selection, Add scope, Present/Proposed Organisation to improve user experience	**NO**
Other deliverables and achievements 25Q4	**Demo**
Q&A document updated and accessible on the PLM Portal	**NO**
5000 new non-CAP eAFs created by users in Q4 so far	**NO**

Human variations eAF – **Updated Variation Classification Guideline (15 January 2026)**

- The updated Variation Regulation Classification Guideline has been made available in the interactive pdf eAF v1.28.0.0 and in the PLM Portal web-based variation form January 2026 version.

- Applicants are reminded that applications using the v1.28.0.0 or the January 2026 version of the form **must not be submitted** to the EMA **prior to 15th January 2025** CET 00:00. Applications received before the 15th January 2025 will be rejected and the application must be resubmitted on or after the 15th January 2026.

- Applicants are also reminded that new variation applications using the September 2021 version must not be submitted after 14th January 2026 CET 23:59. Variation applications for new variation procedures using the old classification guideline received by the EMA after this date will be rejected with the exception of Type IA variations where the implementation date is prior to 15th January 2026.

Known 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 issues

1. Corrupted Products (*affecting CAPS and non-CAPs)*

A small number of corrupted products are still visible in the eAF causing errors when selected, and while a list of these products is unavailable, the PMS team is working on a fix and users should raise a service desk ticket if affected.

3. 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 different systems that feed from this data

5. National rules for Super-grouping, WS and Grouping

The PLM Form has pre-defined calculations based on the variation regulation that currently cannot be overwritten. We are working on user story to allow more flexibility for national variations

2. Duplicate Products (*affecting CAPS and non-CAPs)*

Some packaged medicinal products appear under two different medicinal products due to data errors from xEVMPD/PMS, causing eAF errors that block progress, users should report the issue via a service desk ticket. In most of these cases you may be asked to use the interactive PDF version instead. The relevant teams have prioritised the fix for this issue in Q1 2026.

4. Inability to de-select packages for products authorised in pack size level (*affecting only non-CAPs)*

For non-CAP products all pack sizes are currently selected, and it is not possible to de-select packages in the web based eAF. There are ongoing discussions with relevant groups to address this limitation.

Human variations eAF - statistics

8101 non-CAP applications
created in the PLM Portal since February 2025

7351 Centralised Procedure application forms received by EMA
since the go-live

Upcoming eAF events

Q&A Clinic on new variations creation

08 January 2026

Training on interactive PDF form change - MAA Human

February 2026 – Date to be defined

Training on changes and improvements in eAF Webform - Human variations

February 2026 – Date to be defined

Training on interactive PDF form change - MAA Veterinary

March 2026 – Date to be defined

Guidance Material to be consulted

- **Training Videos available on PLM Portal at this Link**
- **User Guide available on PLM Portal at this Link**
- **Q&A document available on PLM Portal at this Link**

PLM VS |Electronic Common Technical Document version 4 (eCDT4)

Kristiina Puusaari, eCDT v4.0 Product Owner

eCTD v4.0 – Q4 achievements

Updated documentation published

- Updated validation criteria and vocabularies **published**
- Practical guidance for vendors and applicants published (before end of 2025)
- Updated draft validation criteria **published** for comments (in December 2025)
- EU IG being reviewed and updated – will be published in Q1 2026

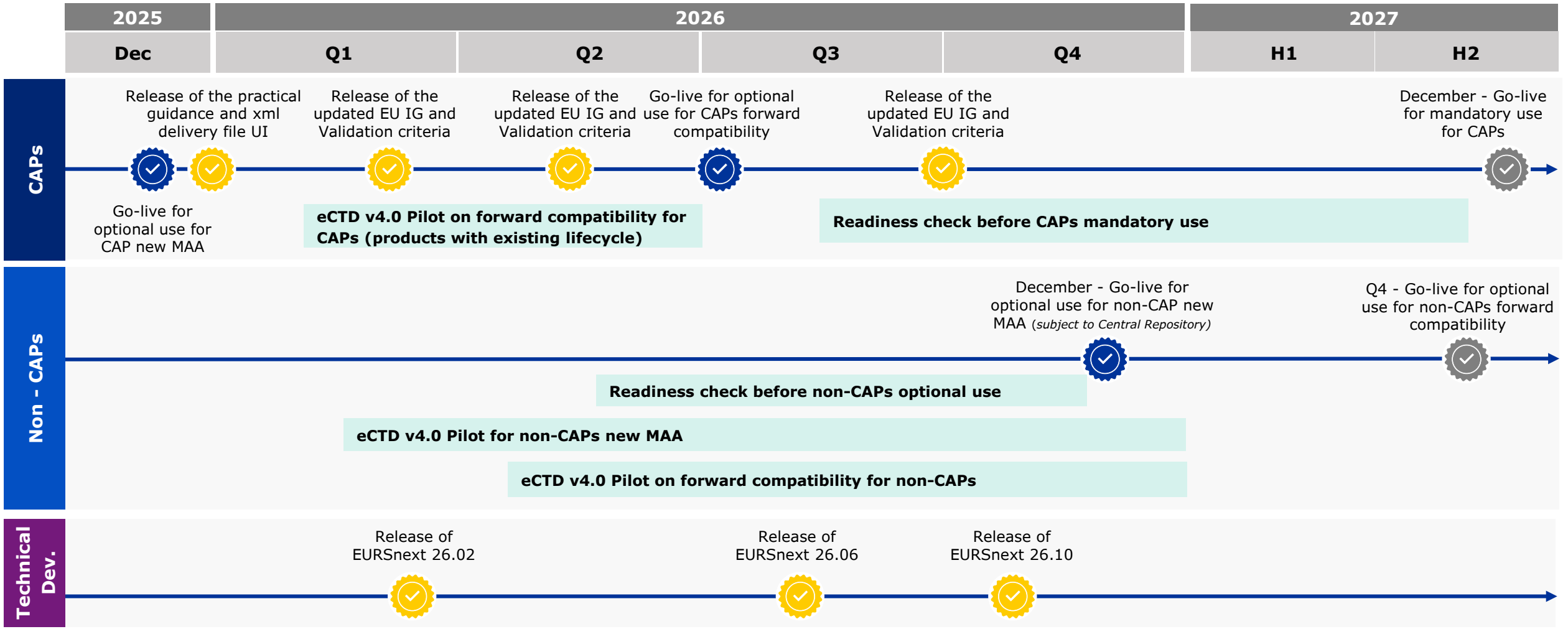
Technical pilot for CAPs new MAAs held

- **Successful** technical pilot ran for CAPs new MAAs with large number of varied submissions received
- Pilot planned for **Forward Compatibility** i.e. products with existing eCTD v3.2.2 lifecycle – pre-announcement made to ensure vendors and MAHs are getting ready
- Pre-planning for non-CAPs new MAA technical pilot

Optional use for CAPs new MAAs

- Go-live of optional use for CAPs new MAAs in eCTD v4.0 format from 22nd December 2025
- Applicants are requested to contact EMA prior to any eCTD v4.0 format submission to ensure that the assessment teams are ready

EURSnext and eCTD v4.0 implementation roadmap - NCAs



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

PLM VS | Union Product Database(UPD)

Saskia Schiemann, UPD Network Product Owner

Beyhan Mustafov, UPD Product Owner

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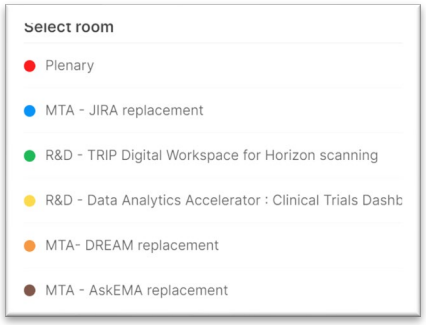

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UPD – Union Product Database

Committed objectives 25Q4	Demo
Enable MAH users to submit changes to QPPV and PSMF data in bulk via Variations Not Requiring Assessment **for non-CAPs**	***YES*** *Released on 5-12-25*
Improve 'sorting' in UI search results	NO *Released on 5-12-25*
Remove certain system validation rules for marketing authorisation transfers to allow smooth update of the product data when products are missing mandatory data or having data quality issues	NO *Released on 7-11-25*
Enable users to browse and filter the Variation Requiring Assessment procedure number in the View VNRA Submission page	NO *Released on 7-11-25*

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UPD – Q4 achievements

Highlights

- ✓ MAH can now submit changes to QPPV and PSMF data via Variations Not Requiring Assessment for non-CAPs.
- ✓ Several system validation checks for Transfer of ownership have been removed.
- ✓ Improved ‘Sorting’ of search results across pages for Product search, OPAD functionality and View VNRA submission.

Additional enhancements

- ✓ A CMS NCA is enabled to approve/reject submitted VNRA code A2 ‘Change in the (invented) name’ for products under DC/MR/SR procedure.
- ✓ Parallel trade products can be updated after the Source and/or destination reference products are surrendered.

New/revised guidance and training materials

- ✓ A new Questions & Answers document for Network users was published.
- ✓ UPD webinar for NCAs on available UPD APIs held on 6 November 2025 (recording available at *EUNTC*).
- ✓ Revised UPD registration guide for UI and API users
- ✓ Revamped the UPD page on the EMA website.

Live Demo: *How MAH users can submit changes to QPPV and PSMF information for non-centrally authorised products via C.1, C5 or C6 VNRAs*

Live Demonstration

Important notices

Upcoming deadlines and actions

Volume of Sales submission deadline

Marketing authorisation holders are required to **submit their 2025 volume of sales data** for veterinary medicinal products in the Union Product Database (UPD) **by 28 February 2026.**

API credentials renewal

Competent authorities and marketing authorisation holders' **super users must renew their UPD API credentials** before expiration.

Refer to the **email received on 25 November** for instructions.

Useful materials

Guides

- UPD registration guide *for UI and API users*
- UPD Implementation Guide
- Guidance for NCAs *on email addresses configuration, updating packages and VNRA highlighting.*
- 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 (***NEW*** video for MAH users on *how to submit changes to QPPV and PSMF for non-CAPs)*
- ***NEW* API webinar recording** and presentation available on EU NTC for Network users

Q&A Documents

- UPD Q&As for Network users (***NEW***)
- UPD Q&As for Industry users
- UPD Q&As about VoS

PLM VS | Product Management Service (PMS)

Marcos Fernandez Gomez, PMS Co-Product Owner

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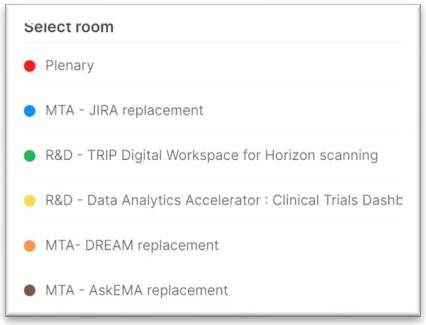

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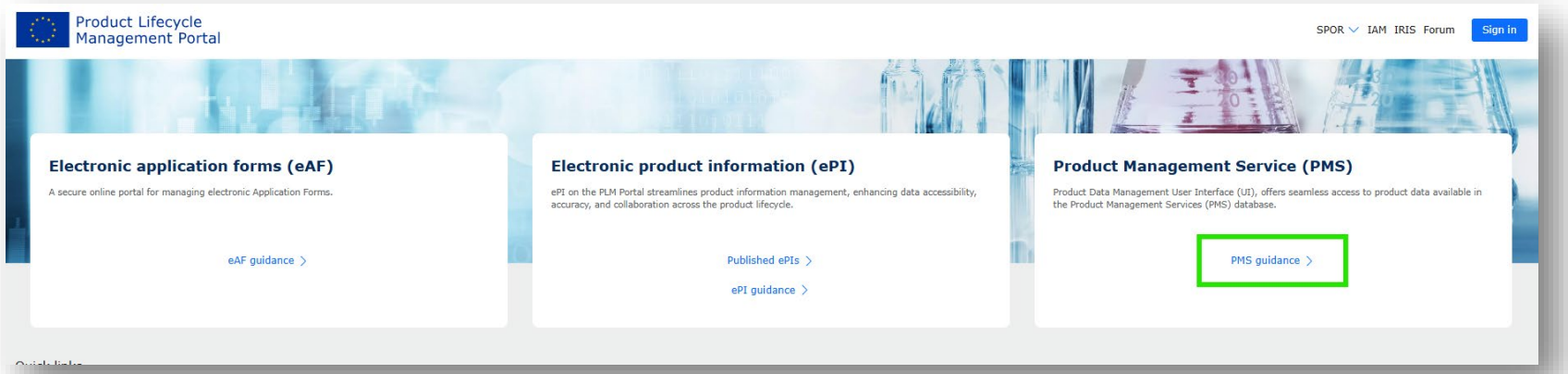
PMS – Product Management Service

Committed objectives 25Q4	Demo
Build the public PMS API infrastructure and start the internal testing phase in the UAT environment	***YES***
Remove MA number at product level when different pack sizes have different MA numbers.	NO
Unit of presentation field in the pharmaceutical product is missing	NO
Packaged medicinal products **transferred** in XEVMPD are not reflected in PMS (ongoing)	NO



Please, review the FAQ document in the PLM Portal

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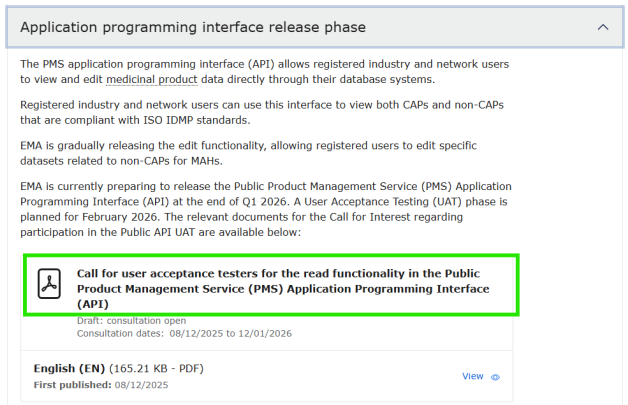
Public PMS API

External UAT taking place in Q1 2026

- **Call for interest** is opened is opened **until 12/01/2026**
- **UAT** taking place in **Feb 2026**


Application programming interface release phase

The PMS application programming interface (API) allows registered industry and network users to view and edit medicinal product data directly through their database systems.

Registered industry and network users can use this interface to view both CAPs and non-CAPs that are compliant with ISO IDMP standards.

EMA is gradually releasing the edit functionality, allowing registered users to edit specific datasets related to non-CAPs for MAHs.

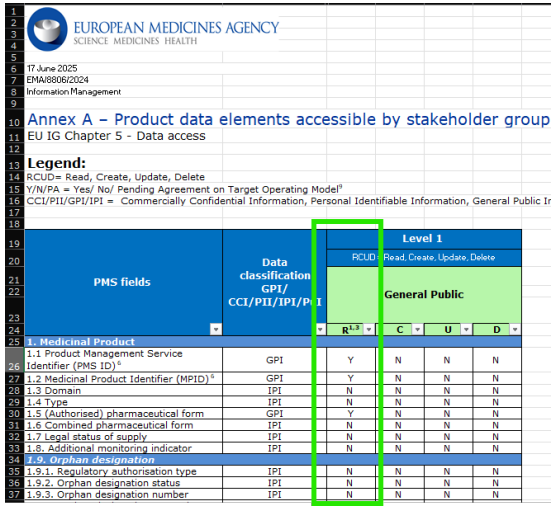
EMA is currently preparing to release the Public Product Management Service (PMS) Application Programming Interface (API) at the end of Q1 2026. A User Acceptance Testing (UAT) phase is planned for February 2026. The relevant documents for the Call for Interest regarding participation in the Public API UAT are available below:

Call for user acceptance testers for the read functionality in the Public Product Management Service (PMS) Application Programming Interface (API)
Draft: consultation open
Consultation dates: 08/12/2025 to 12/01/2026

English (EN) (165.21 KB - PDF)
First published: 08/12/2025
View

Annex A of Chapter 5

- **Annex A of Chapter 5** provides the information on which data will be publicly available.


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 June 2025
EMA/88062/2024
Information Management

Annex A – Product data elements accessible by stakeholder group
EU IG Chapter 5 - Data access

Legend:
RCUD= Read, Create, Update, Delete
Y/N/PA = Yes/ No/ Pending Agreement on Target Operating Model[3]
CCI/PII/GPI/IPI = Commercially Confidential Information, Personal Identifiable Information, General Public Ir

PMS fields	Data classification GPI/ CCI/PII/IPI/P...I	Level 1 RCUD - Read, Create, Update, Delete: General Public R[1,3]	C	U	D
1. Medicinal Product					
1.1 Product Management Service Identifier (PMS ID)[5]	GPI	Y	N	N	N
1.2 Medicinal Product Identifier (MPID)[6]	GPI	Y	N	N	N
1.3 Domain	IPI	N	N	N	N
1.4 Type	IPI	N	N	N	N
1.5 (Authorised) pharmaceutical form	GPI	Y	N	N	N
1.6 Combined pharmaceutical form	IPI	N	N	N	N
1.7 Legal status of supply	IPI	N	N	N	N
1.8. Additional monitoring indicator	IPI	N	N	N	N
1.9. Orphan designation					
1.9.1. Regulatory authorisation type	IPI	N	N	N	N
1.9.2. Orphan designation status	IPI	N	N	N	N
1.9.3. Orphan designation number	IPI	N	N	N	N

Different search parameters

- EMA will be implementing different search parameters in the API
- For example, search by:
  - PMS ID
  - MA number
  - Product name
  - Active substance
  - Strength
  - AS + Strength + authorised dose form

PLM VS | Product User Interface (PUI)

Veronica Lipucci Di Paola, PMS UI Co-Product Owner

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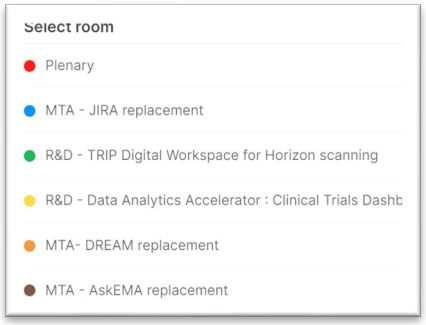

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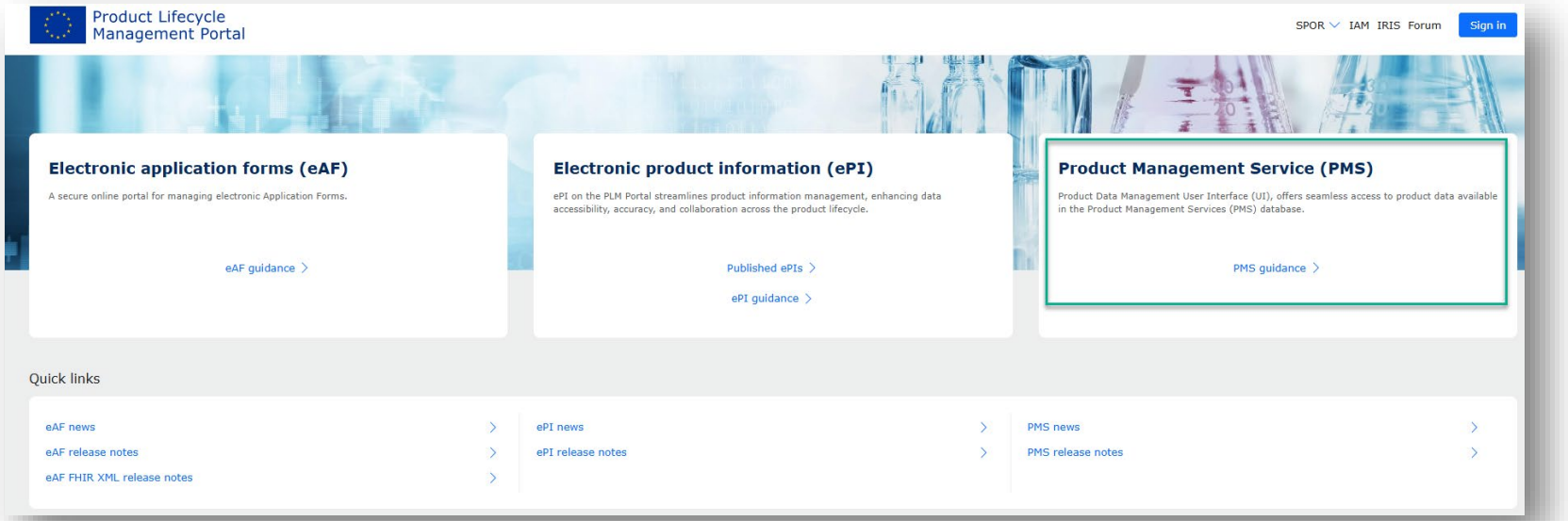
Product UI

Committed objectives (PMS UI) 25Q2	Demo
▪ Improve Product UI by enhancing BI reports, refining UX/UI on key pages, and optimising bulk update capabilities. These updates aim to address user feedback and support efficient product management.	**YES**



Upcoming events




Q&A clinics on PMS PUI and API

- **13 January 2026** (15:00 – 16:00 CET): Event page
- **10 February 2026** (15:00 – 16:00 CET): Event page
- **10 March 2026** (15:00 – 16:00 CET): Event page
- **14 April 2026** (15:00 – 16:00 CEST): Event page
- **12 May 2026** (15:00 – 16:00 CEST): Event page

Q&A Clinics on SOR

- **13 January 2026** (11:00 – 12:00 CET): Event page
- **10 February 2026** (11:00 – 12:00 CET): Event page
- **10 March 2026** (11:00 – 12:00 CET): Event page
- **14 April 2026** (11:00 – 12:00 CEST): Event page
- **12 May 2026** (11:00 – 12:00 CEST): Event page

Q&A Clinics on XEVMPD

- **15 January 2026** (15:00 – 16:00 CET): Event page
- **12 February 2026** (15:00 – 16:00 CET): Event page
- **12 March 2026** (15:00 – 16:00 CET): Event page
- **16 April 2026** (15:00 – 16:00 CEST): Event page
- **13 May 2026** (15:00 – 16:00 CEST): Event page

SPOR & XEVMPD status update webinar

Registration open

28 January 2026 (10:00 – 12:30 CET): *registration available on event page on EMA website*

Live Demonstration

PLM VS | electronic product information (ePI)

Evinn Drusys, ePI Network Product Owner,

Elizabeth Scanlan, ePI Product Owner

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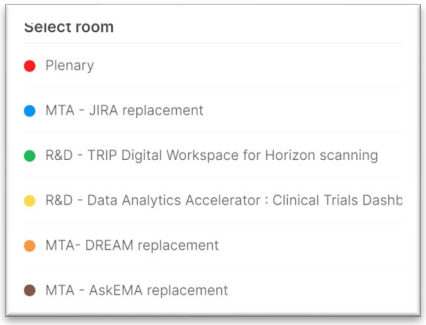

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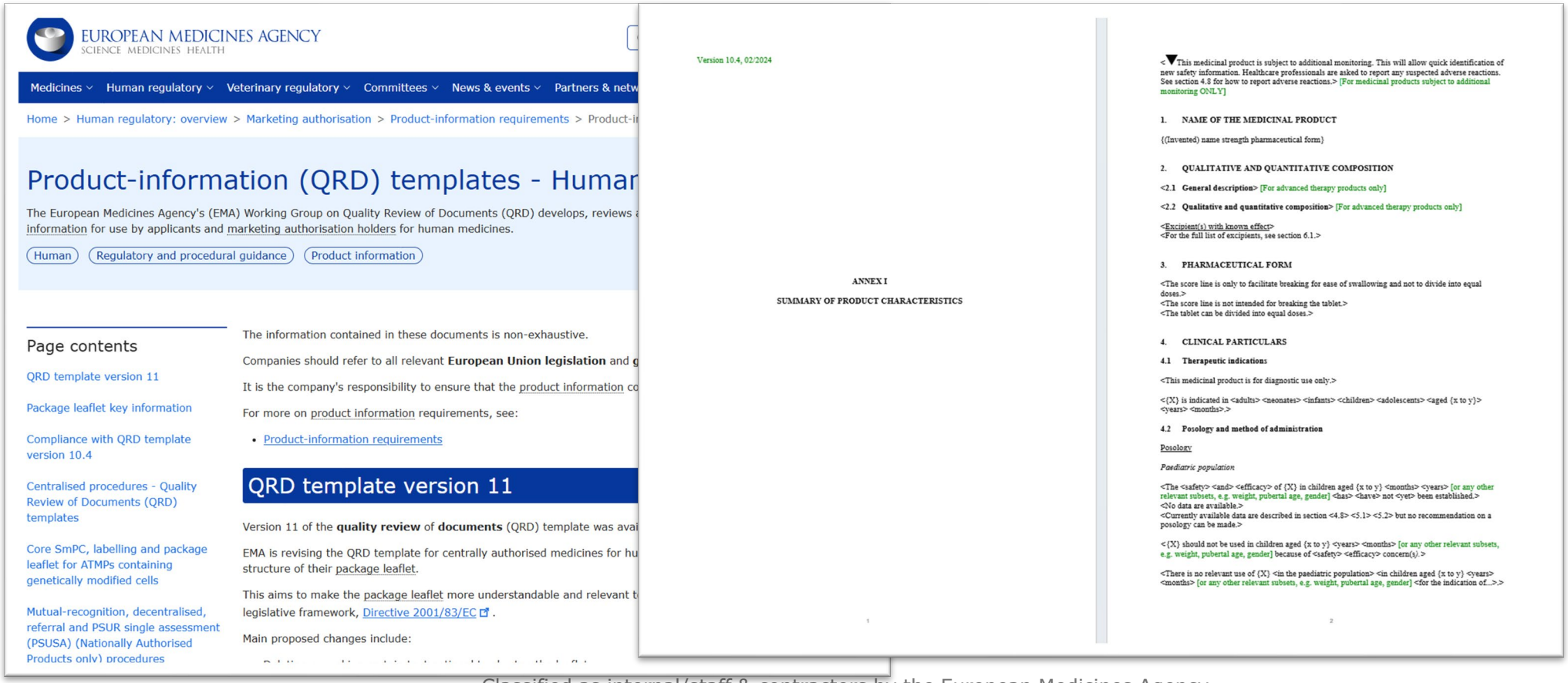
Achievements	
Implement **Add co-author** from another organisation	✓
Display QRD template version lists publicly	✓
Enable **QRD template versioning**	✓



Live Demonstration

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

Madalina Duta-Mare, RPM Product Owner

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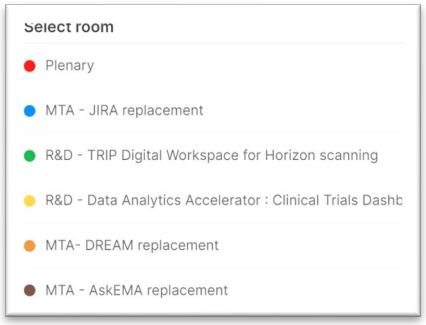

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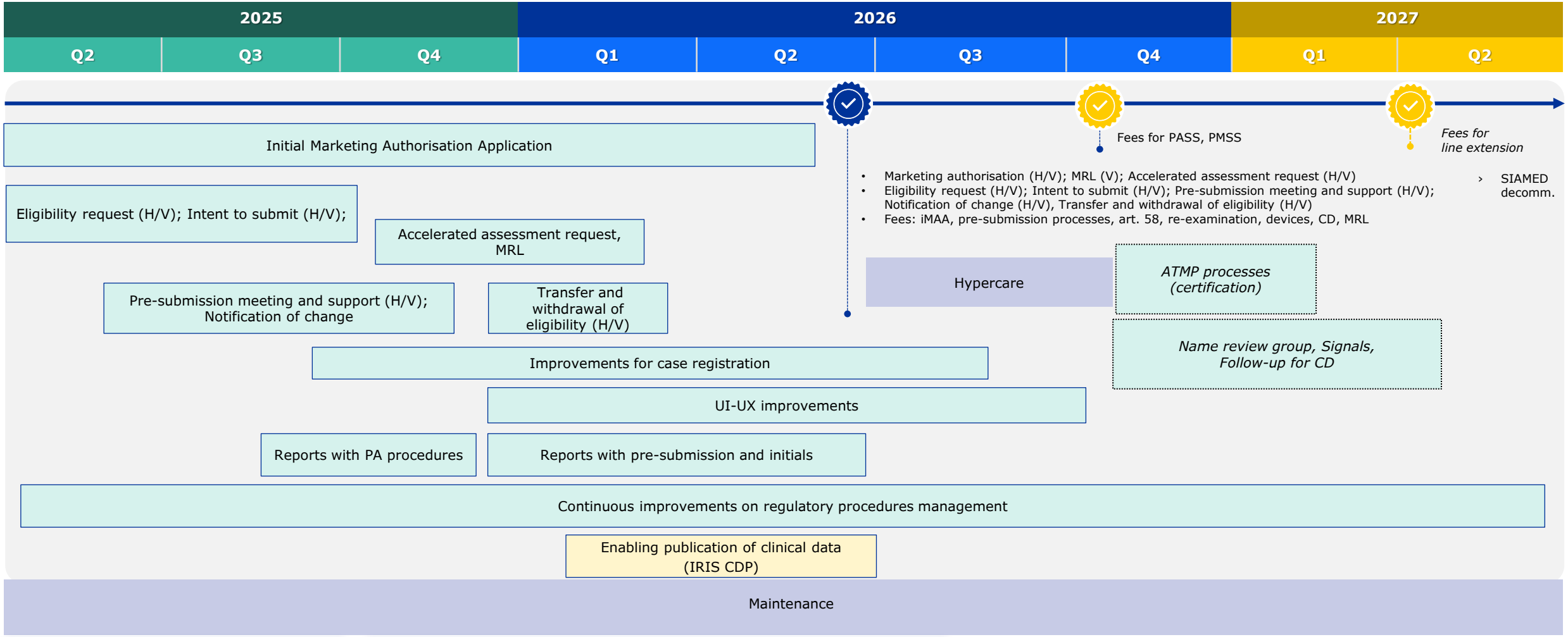
Regulatory Procedure Management in IRIS roadmap (Epic 3) – 24/11/2025



Acronyms

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

Legend

Go-live
Milestone
Dev. activities
Maintenance/ Hypercare
Enabler
Proposed activities for after Epic 3

EMA

Regulatory Procedures Management

EUROPEAN MEDICINES AGENCY

Achievements	Demo
Enhance the three key regulatory and applicant support processes initiated in Q3 (**eligibility/intent, presubmission interactions, notification of changes**) strengthening compliance, operational efficiency and applicant experience.	YES
Analyse and develop a process to allow and facilitate **accelerated assessment of medicines** in the centralised procedure	NO
Develop **fee process for letter of intent and notification of change**	NO
Implement system and functionality **improvements** to enable a smoother system interaction, **reduce the manual checks** and corrections to improve efficiency and user **trust** in the system	NO
Implement **changes to MAA process** based on user acceptance testing feedback to enhance automation and improve overall efficiency in case management	NO
Design and initiate development for automations for **case and product record creation** to reduce manual data entry and change impact for MAA validation and case registration teams to support a more **efficient registration** process and **minimise** manual input **errors**.	NO

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

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

Give feedback & ask questions

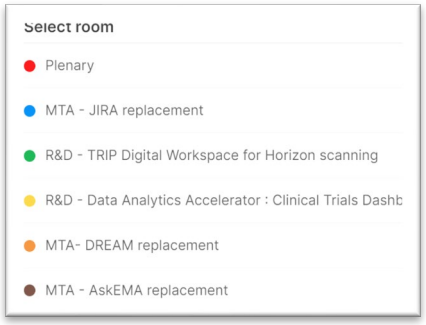
Option 1 - Q&A

Questions and answers are public
You may upvote the questions
Top questions are answered verbally
Questions & available answers published on event page on EMA website

Option 2 - Poll

Feedback shared only with product team
Stays open for comments till 24 December
Please identify yourself
Give the product team feedback and suggestions about your priorities

Step 1 - Go to slido.com



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

Step 3 - Choose Q&A or Polls as appropriate

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CTIS Modernisation- New Safety Module

Committed objective 25Q4	Demo
Safety Module MVP – Complete and validate **SaMS selection**	**YES**
Safety Module MVP – Finalise the analysis and design of **ASR submission**	**NO**
Safety Module MVP - Analysis and design of **ASR assessment**	**NO**

Demonstration

Monitoring VS |Antimicrobials Sales & Use (ASU) platform

Anastasia Pickford, ASU Product Owner

Give feedback & ask questions

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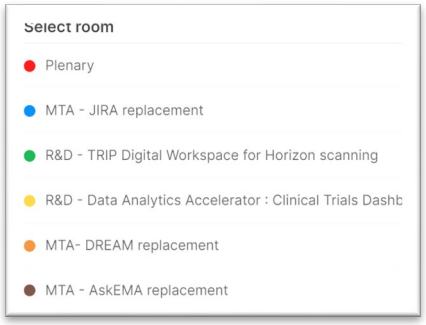

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Antimicrobial Sales and Use (ASU) Platform

Vision

A **reference European surveillance system** for EU/EEA member states to **submit data on sales and use of antimicrobials in animals**, enabling data intelligence to detect patterns and help develop **measures against antimicrobial resistance**, thus contributing towards the One Health goal of safeguarding animal and public health.

1 UPD / PMS

- Access to ASU
- VMP information
- HMP information

2 National collection systems

Data on sales and use of antimicrobials in animals

ASU Platform

3 PowerBI analytics tool

1. Data validation
2. Data analysis
3. Report preparation
4. **Public access to data**

ASU Public Power BI dashboards

Dynamic extension of annual surveillance reports, further understand consumption patterns and guide targeted interventions

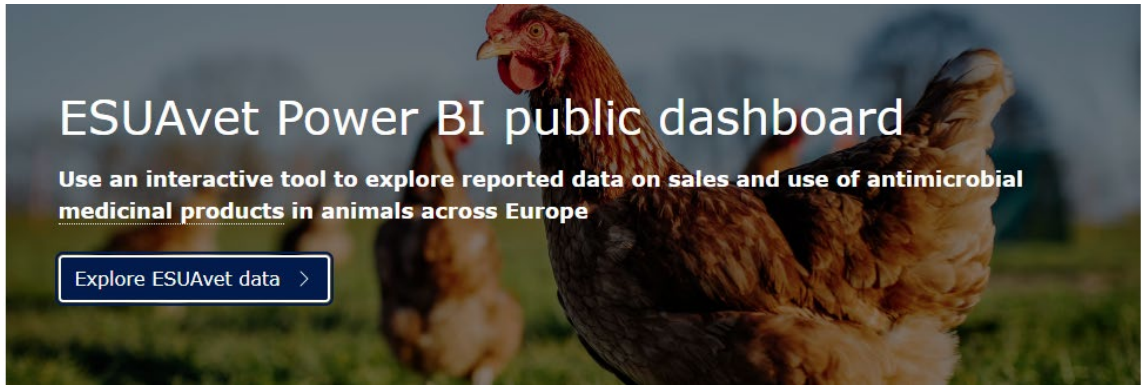
Public access to ASU data, driving transparency and stakeholder engagement, while protecting sales data confidentiality

Maximising the use of Power BI to provide enhanced visualisations, interactivity and data analytics.

ASU Public Power BI dashboards

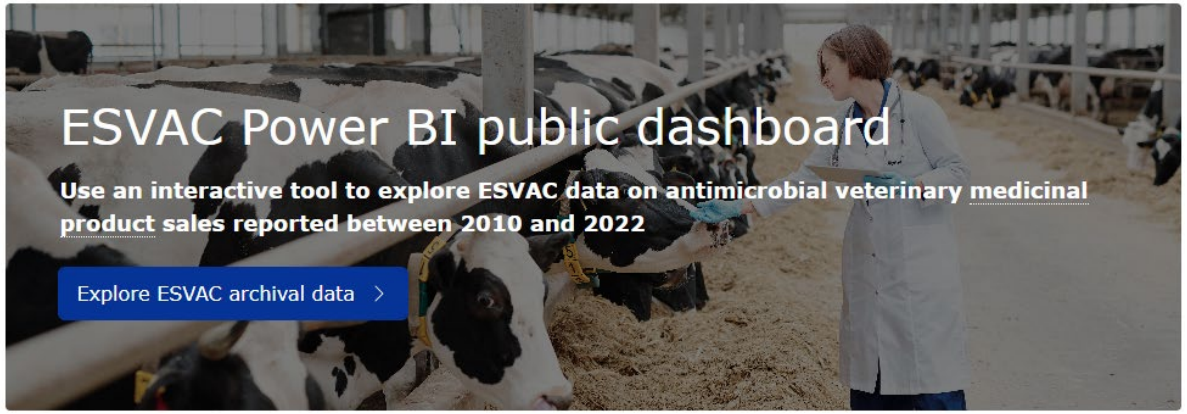
ESUAvet Public Power BI dashboard

- Contains published **ASU 2023 and 2024 sales data**, dynamically updated.
- Link available on the EMA ESUAvet reports webpage
- Direct link: here
- Indicator: mg sold per kg of animal biomass
- Future updates: improvements + use data



ESVAC archive Power BI dashboard

- Archive of **historic sales data collected between 2010 and 2022** under the ESVAC project
- Link available on the EMA ESVAC project webpage
- Direct link: here
- Indicator: mg sold per PCU



Live Demonstration

PLM VS | Data Analytics Platform (DAP) – Business Intelligence reports for NCAs

Michael Vogl, DAP-BI Product Owner

Data Analytics Platform (DAP) – Reporting capabilities

- ✓ First **IRIS model** delivered in the **DAP Gold layer**, **optimized for reporting and scalable analytics**, ready to be leveraged throughout 2026.
- ✓ **Revamped IRIS Power BI dashboards for NCAs** to be deployed in PROD at the beginning of 2026.
- ✓ First version of **Data Quality rules for human products based on ISO-IDMP** delivered in the DAP, with visualisation in Power BI.
- ✓ Based on the new IRIS gold-layer data model, first **dashboard for post-authorisation procedures** to be deployed in PROD at the beginning of 2026.
- ✓ Monthly **XEVMPD Excel report replaced by a Power BI dashboard**.

Live Demonstration

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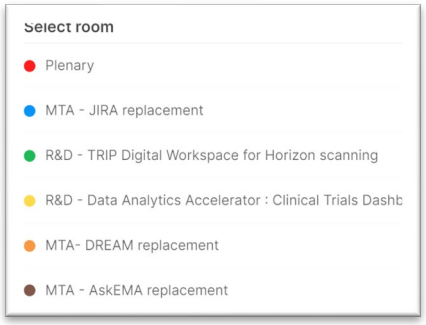

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26 March

Is the next public system demo

Season's greetings

from the European Medicines Agency's staff and the Executive Director

Весели празници • Felices fiestas • Šťastné a veselé svátky • Med de bedste ønsker • Mit den besten Wünschen • Häid pühi • Χρόνια Πολλά • Meilleurs Vœux • Beannachtaí na féile • Sretne i ugodne blagdane • Buone feste! • Priecīgus svētkus • Linksmų švenčių • Kellemes ünnepeket! • Il-Festi t-tajba • Met onze beste wensen • Wesołych Świąt • Boas Festas • Sărbători fericite • Šťastné a veselé sviatky • Vesele praznike • Hyvää joulua • God Helg