EMA
EUROPEAN MEDICINES AGENCY

System Demo 25Q1

Public System Demo

26 March 2025

Welcome & Introduction

Jean-Michel Becar, Head of the Portfolio Management Office

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*.

* 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).

slido # 9116064

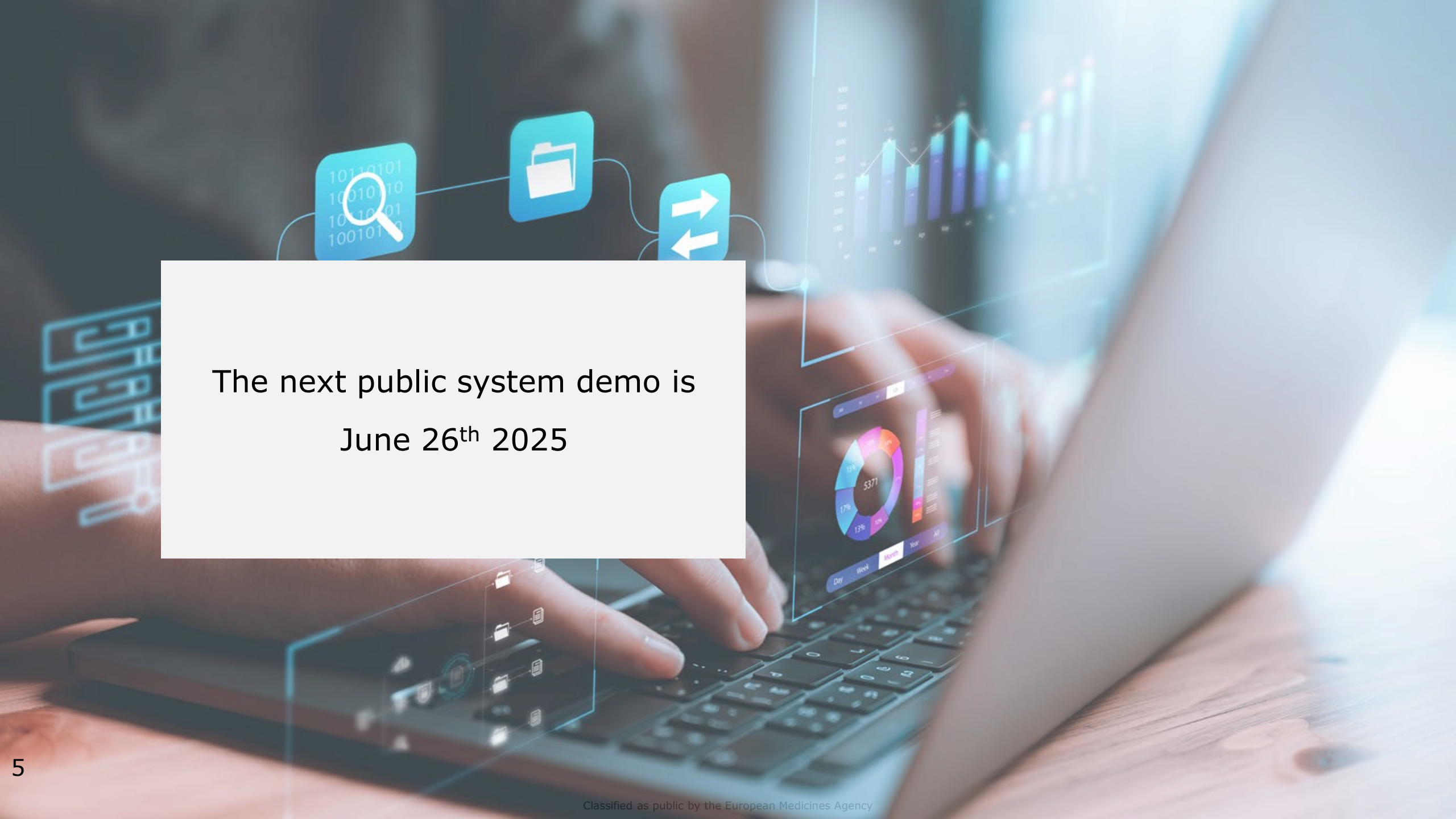
EMA public system demo

Is a major part of the **transparency goal** of the Agency's new governance: lean and agile.

Shows an integrated view on what has been built in the past 3 months (Planning Interval (PI)) .

Is an opportunity for the audience to **give instant feedback** to the Agency's development teams to build the right solution.

Is recorded and published on the EMA **Corporate website**.



The next public system demo is

June 26th 2025

Agenda

09:00	**Welcome / Introductions**
09:05-09:25	Research & Development Value Stream (R&D VS)
09:05	Data Analytics Platform (DAP) – Trial Map
09:25-11:25	Product Lifecycle Management Value Stream (PLM VS)
09:25	Product Management Service (PMS) and Product User Interface (PUI)
10:05	**Coffee break**
10:15	Electronic Product Information (ePI)
10:45	Electronic Application Form (eAF)
11:10	Union Product Database (UPD)
11:25	**Closing**

Give feedback & ask questions

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Questions and answers are public
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Option 2 - Poll

Feedback shared only with product team
Stays open for comments till 02nd April
Please identify yourself
Give the product team feedback and suggestions about your priorities

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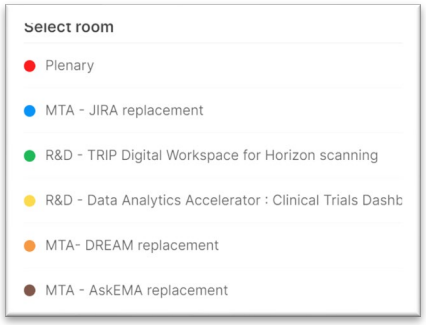

Step 2 – Choose/switch to the room for the right product

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

R&D VS | Trial Map
Data Analytics Platform (DAP)

Laura Pioppo, ACT EU Programme Manager

IJsbrand den Rooijen, Trial Map Product Owner

EMA

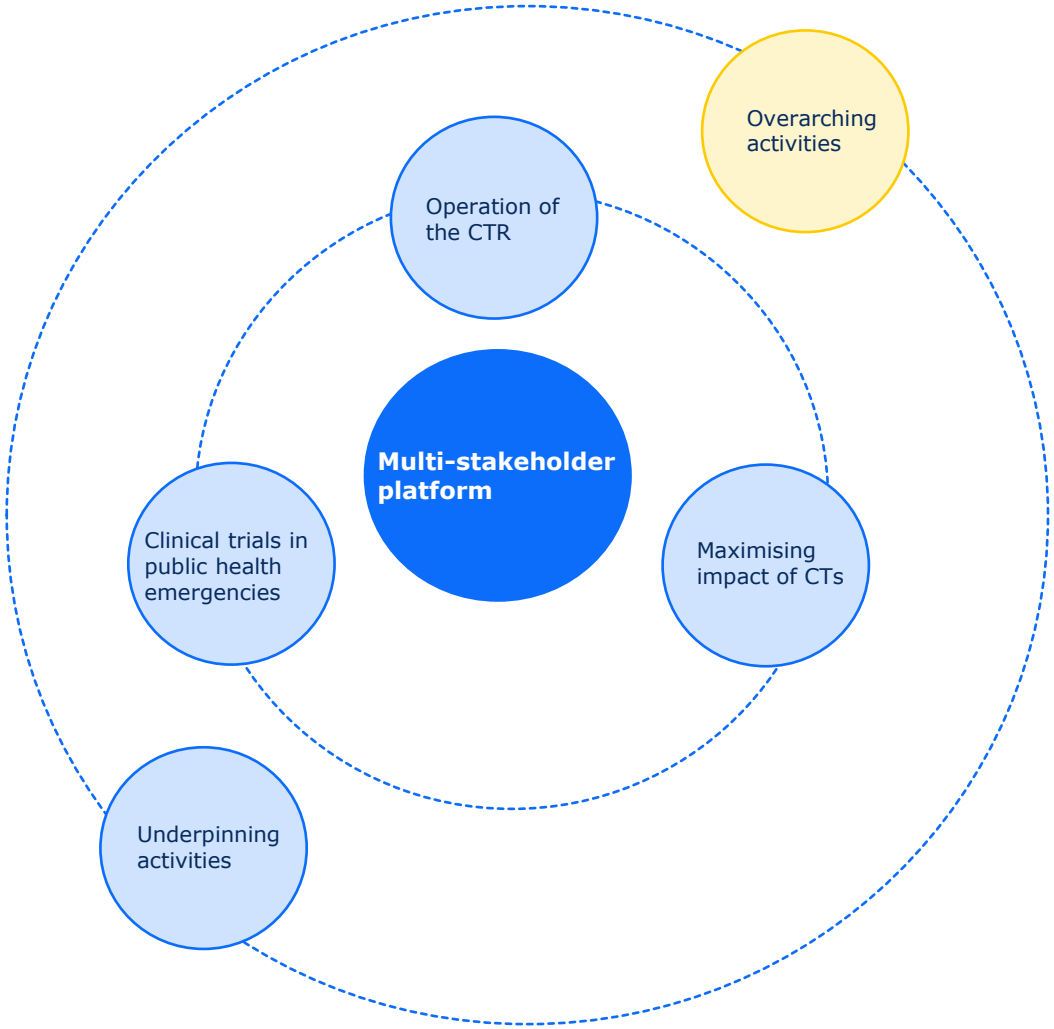
ACT EU partners

- A joint initiative by the European Commission, Heads of Medicines Agencies and EMA
- Established in 2022
- Building on the momentum of the implementation of the Clinical Trials Regulation (CTR)

Our vision is to have **better, faster and optimised** clinical trials in the EU, creating a favourable environment for clinical research.

ACT EU partners

ACT EU focus 2025-2026



Overarching activities:

- ACT EU governance
- Multi-stakeholder Platform

Operation of the Clinical Trials Regulation:

- Implementation of the Clinical Trials Regulation
- Support for non-commercial sponsors
- Clinical trials safety

Maximising impact of clinical trials – design and conduct of excellent clinical trials:

- Good clinical practice modernisation
- Consolidated advice on clinical trials
- Clinical trials methodologies

Underpinning activities:

- Communication
- Clinical trials analytics
- Clinical trials training

More information on the ACT EU website: Workplan 2025-2026

Background and context

- The ACT EU multi-stakeholder workshop on Clinical Trials Analytics in January 2024 brought together different stakeholders with a collective ambition: to identify research priorities that maximise the value of CT data to support evidence-based decision making and fuel innovation.
- A key takeaway was that access to data for patients & patient organisations is critical for informed decision-making and effective advocacy.

…a simple, patient oriented, dashboard available in CTIS, that patients, their carers or their healthcare professionals, can use to locate potentially suitable trials for the patient, should be set up by EMA.“

Patient representative at the ACT EU CT Analytics workshop, Jan 2024

The ACT EU Trial Map

- Integrated in the CTIS Public Portal
- Empowers patients and healthcare professionals:
  - Provides easy **access to information** about clinical trials operating in a geographic area
  - Improves **access to trials** by making it easy to find the contact information for each clinical trial site
  - Increases **findability of trials** by allowing for medical condition searches in lay language
- Currently the map supports searches in English - more EU languages to be available in the future

Trial Map Demo

IJsbrand den Rooijen, Trial Map Product Owner

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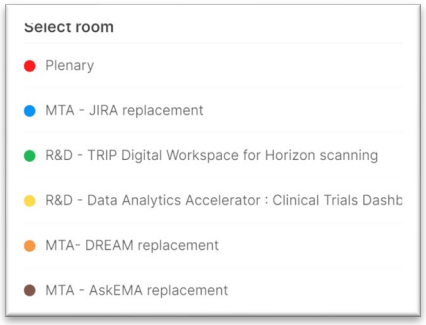

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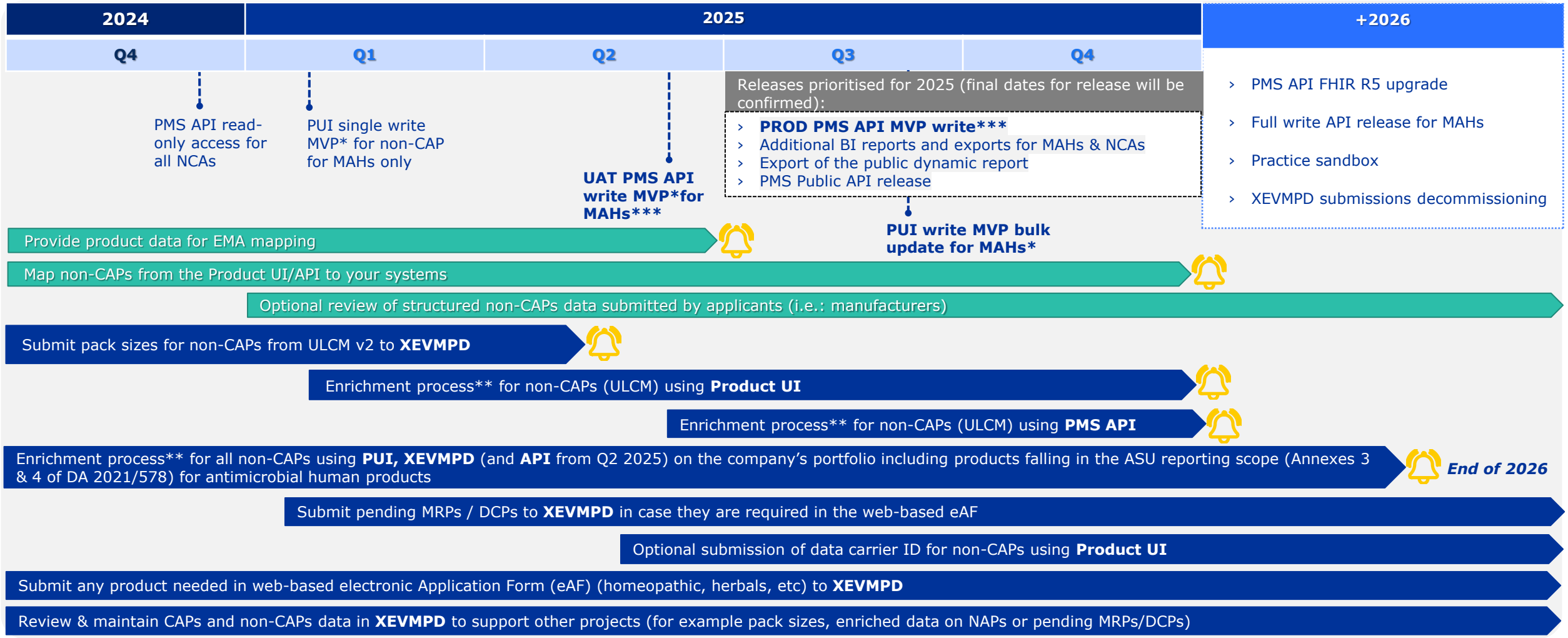
PLM VS | Product Management Service (PMS) and Product User Interface (PUI)

Marcos Fernandez Gomez, PMS Product Owner

Product Management Service roadmap



* MVP: limited to structured pack size data, manufacturers and MBOs
**only for structured pack size data, manufacturers and MBOs
*** Subject to Industry user's readiness

Legend

NCA action | MAH action | Milestone | Deadline

Acronyms

- **API:** Application Programming Interface
- **ASU:** Antimicrobial Sales and Use
- **CAPs:** Centrally Authorised Products
- **DCP:** Decentralised Procedures
- **eAF:** electronic Application Form
- **MAHs:** Marketing Authorisation Holders
- **MRP:** Mutual Recognition Procedure
- **MVP:** Minimum Viable Product
- **NCAs:** National Competent Authorities
- **PUI:** Product User Interface
- **UAT:** User Acceptance Testing
- **ULCM:** Union List of Critical Medicines

Product Management Service (PMS) – Q1 achievements

Key achievements:

Knowledge Transfer

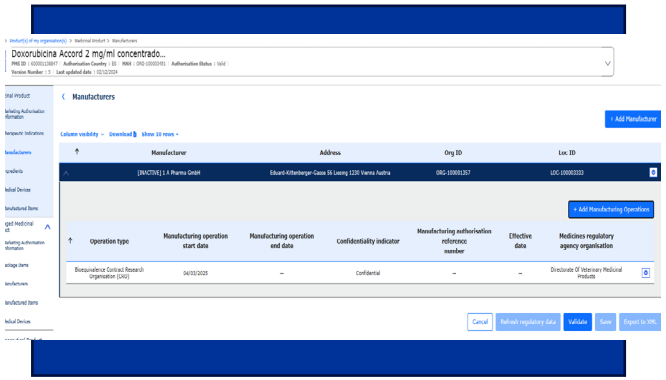
- Knowledge transfer to the new development team was successfully performed

Product User Interface (PUI) – Q1 achievements

Key achievements:

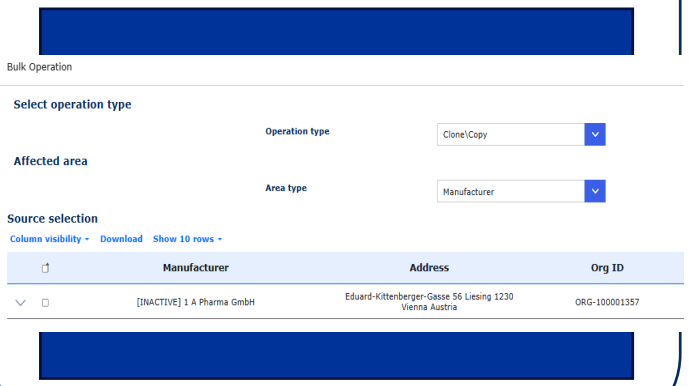
Enrichment MVP

- On January, the MVP for the enrichment process was delivered in production



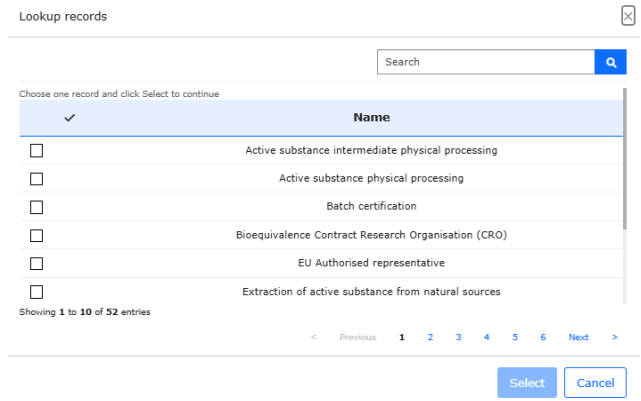
Initial implementation of bulk enrichment

- The implementation of the bulk update functionality has started in Q1.



Improvements of Enrichment MVP

- Several improvements were performed:
  - Short name on MBO list

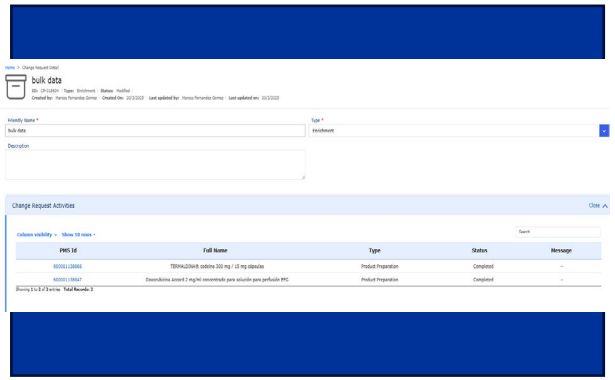


Product User Interface (PUI) – Demonstration

Topics:

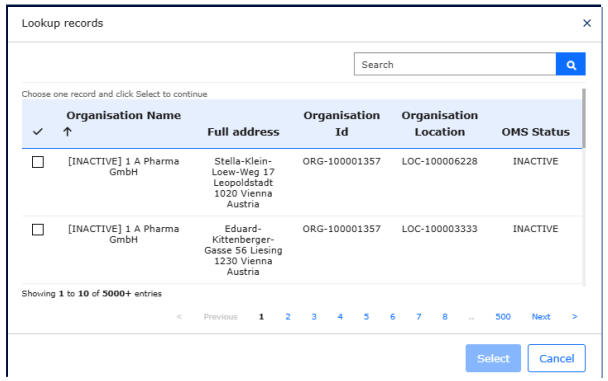
View and Track Change Request Activities

- Access further details on the changes submitted
- Improve the traceability of the changes applied to each of the selected product



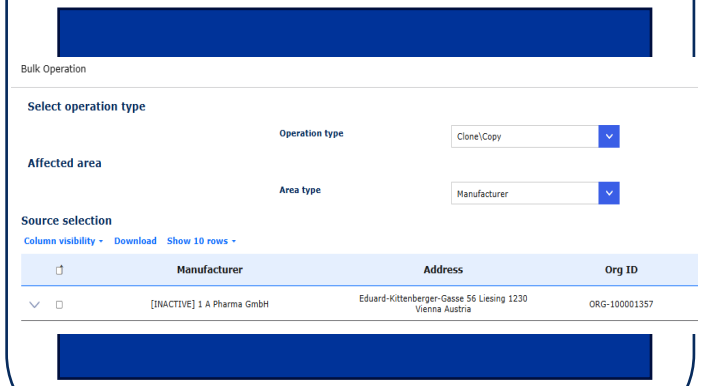
All Manufacturers (Active and Inactive)

- When searching for manufacturers, both active and inactive organisations can be found.



Bulk Update – initial implementation

- Several products can be selected when creating a change request and changes performed to one product can be applied to the others.



Upcoming events

Q&A clinics on PMS UI and API

From March to June 2025

- **25 March 2025** (11:00 – 12:00 CET): Event page
- **29 April 2025** (11:00 – 12:00 CEST): Event page
- **19 May 2025** (15:00 – 16:00 CEST): Event page
- **17 June 2025** (11:00 – 12:00 CEST): Event page

SPOR & XEVMPD status update webinars

WebEx link on event pages

- **9 April 2025** (10:00 – 12:30 CEST): Event page
- **9 July 2025** (10:00 – 12:30 CEST): Event page
- **8 October 2025** (10:00 – 12:30 CEST): Event page

PMS Info-Day

21 May 2025 (9:00 – 17:30 CEST)

Live broadcast on event page

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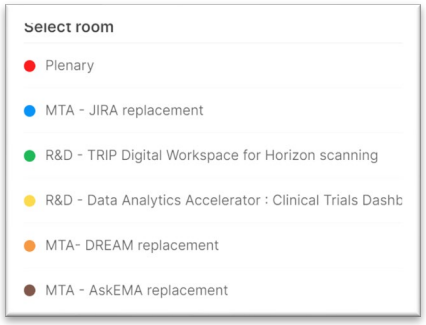

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PLM VS | electronic product information (ePI)

Elizabeth Scanlan, ePI Product Owner

Evinn Drusys, ePI Network Product Owner

Electronic product information (ePI) – Q1 achievements

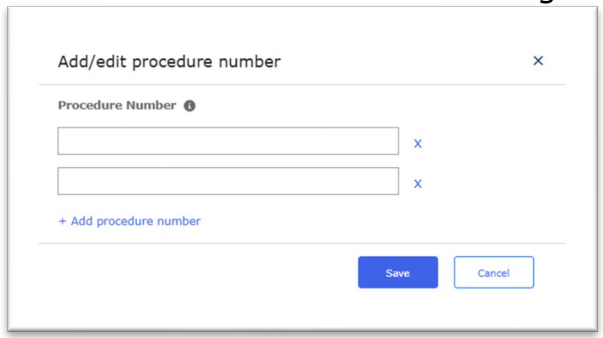
Key achievements:

FHIR import & IG updates

- Fixed **issues identified by early testers**
- **IG updates** (e.g., RMS codes for custom subsections added)
- **ePI examples** available with IG
- Stakeholders who want to validate their ePI against the EU ePI Common Standard can **validate locally**

ePI can have multiple procedure numbers

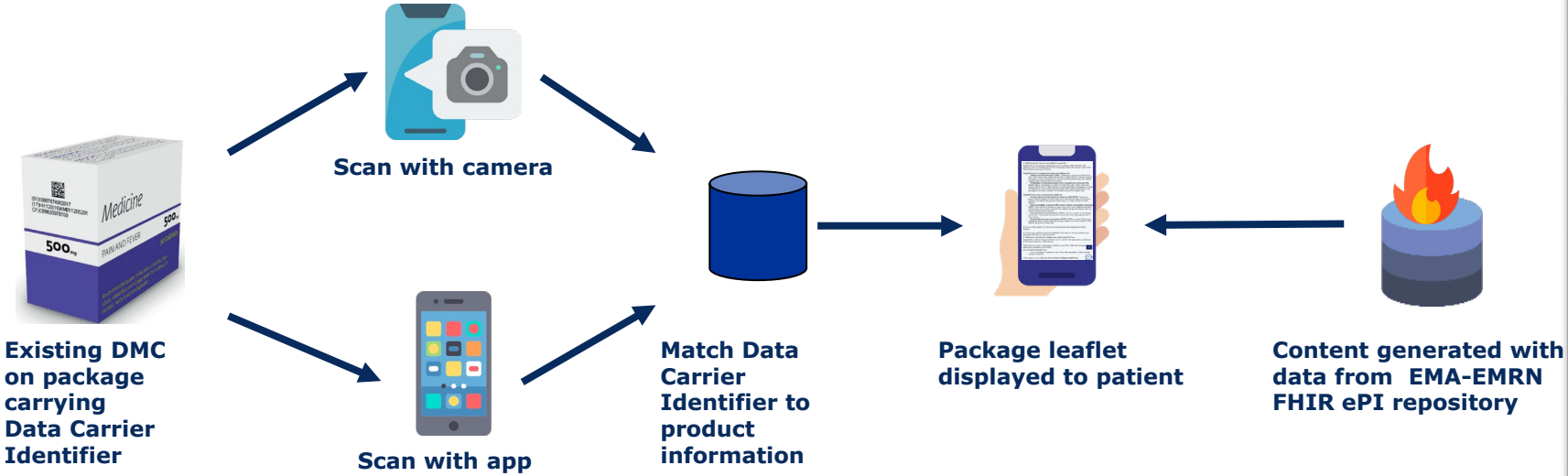
- **More than one procedure number can be added to the ePI** at the PLM portal for ePIs that include changes from multiple procedures
- Procedure numbers will be **reflected in the FHIR** message



Reflection paper for public consultation

- How can we realise the benefits of ePI and **deliver it into the hands of patients** across Europe?
- **Reflection paper open for public consultation** until end June

Digital format easily accessible to all patients



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 31 March 2025
2 EMA/95076/2025
3 European Medicines Agency

4 Reflection paper on linking to electronic product
5 information (ePI) from EU medicine packages
6 Draft

Start of public consultation	31 March 2025
End of consultation (deadline for comments)	30 June 2025

7 Comments should be provided using this EUSurvey form. For any technical issues with the form, please contact the EUSurvey Support.

8

Keywords	Electronic product information, ePI, summary of product characteristics, package leaflet, DataMatrix, data carrier identifier, patients, healthcare professionals

- ❑ Data matrix code (already on the box and used for anti-falsification) preferred to adding additional QR code
- ❑ Availability of EU wide solution is desirable in cross-industry collaboration

Live Demo:
Add multiple procedure numbers to an ePI

Review updates to the ePI IG and guide to validation

Live Demonstration

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Join at
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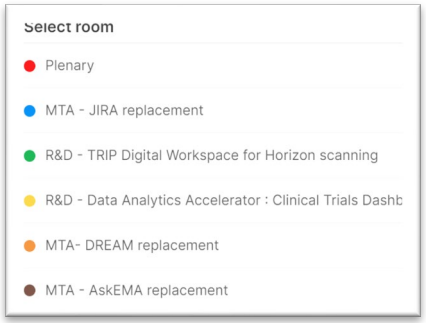

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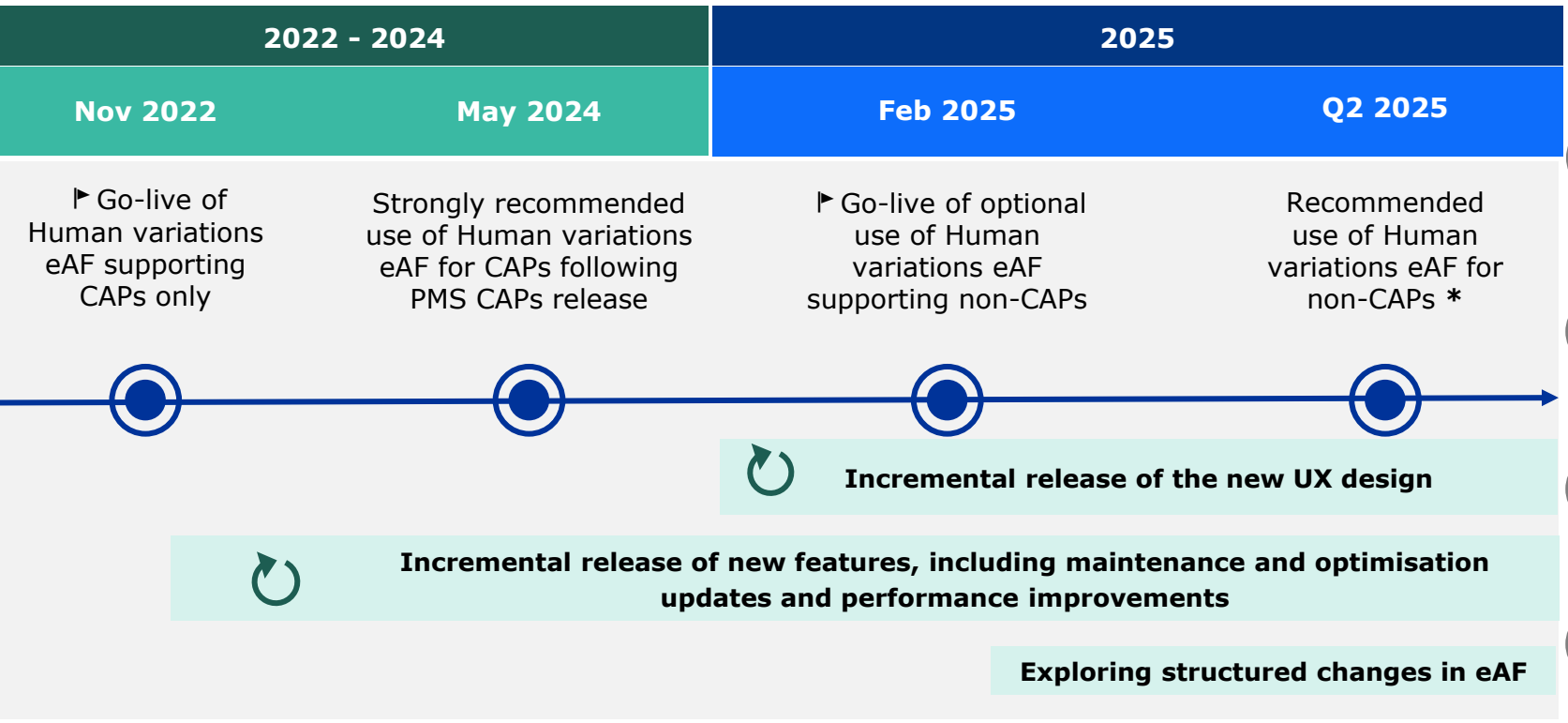
PLM VS | electronic Application Form (eAF)

Kristiina Puusaari, eAF Product Owner

Human variations eAF – Key steps and milestones (March 2025)



2026 and beyond (TBC)	
UAT minus 2 months	UAT announcement *("Transition ready" form available)*
2 months after UAT	Confirmation of transition period start date *
2 months after confirmation	Start of transition period
6 months after transition start	Use of the Human variations web-form only

TBC	
Analysis & development of web forms	Marketing Authorisation Applications, Veterinary variations, Renewals

TBC: To be confirmed, more precise information will be communicated in due time
Note: CAPs and NAPs data in PMS are sourced from EMA's internal database and XEVMPD

Acronyms

CAPs: Centrally Authorised Products

NAPs: Nationally Authorised Products

XEVMPD: eXtended EudraVigilance Medicinal Product Dictionary

Legend

- Key milestone
- Key milestone
- Dev activities for Human variations eAF
- Recurring activity

* on the condition that no major issues are identified

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Human variations eAF – Q1 achievements

Key achievements:

Optional use for non-CAPs

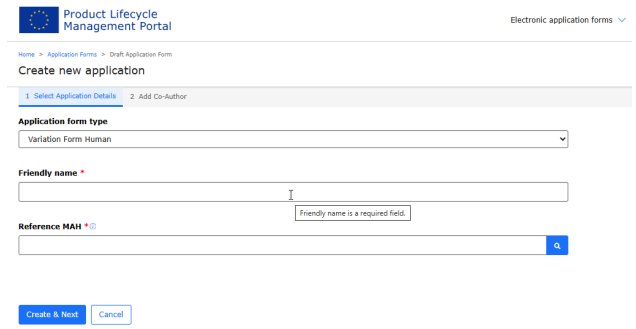
- Start of optional use for non-CAP (MRP/DCP/NP) procedures.
- Continue strongly recommended use for CAP procedures

Feb 2025

Go-live of optional use of Human variations eAF supporting non-CAPs

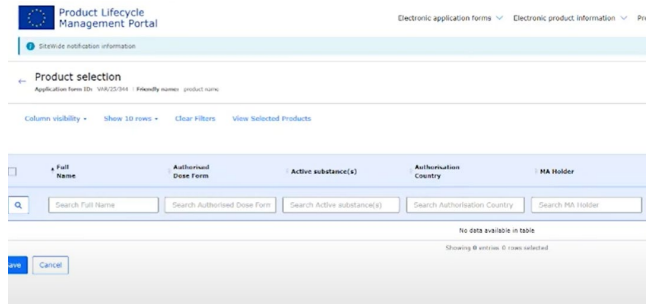
Create new application form

- New User Interface design implementation
- Note: functional improvements implementation in Q3 2025



Product Selection improvement

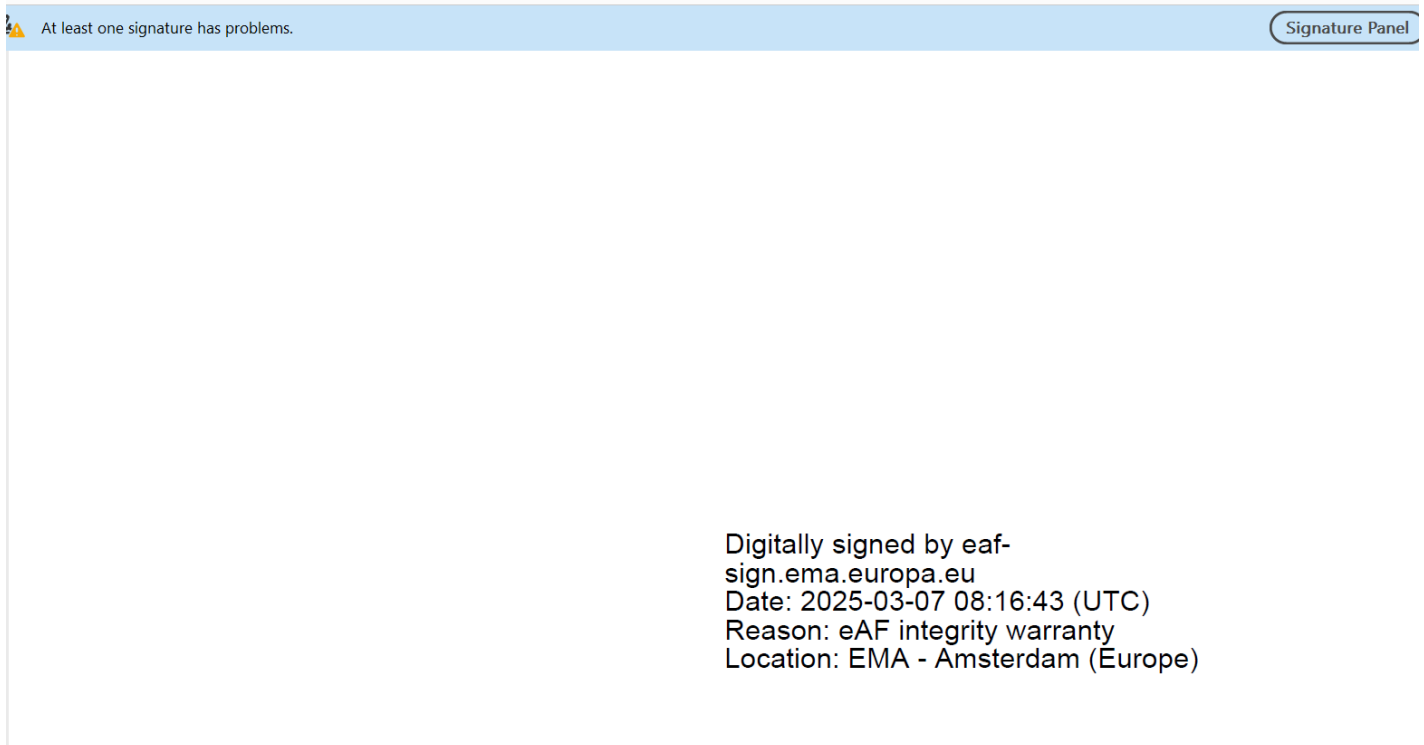
- New User Interface design implementation
- Note: functional improvements implementation in Q3 2025



Integrity Stamp Feature

Updates

- Upon ‘Finalisation’ the **PLM Portal web based human variation eAF** will be locked and moved to the ‘Completed’ tab (the form can be opened for further editing if necessary)
- The finalised form contains an **uncertified** digital ‘signature’ called eAF integrity warranty
- The system automatically includes the stamp on all forms that are **finalised**
- The applicants **can include additional digital signature(s)** into the finalised form (exported pdf)
- It is **not possible** to include an image of a signature or a simple non certified ‘adobe signature’ to the form after the stamp is included
- Forms that have not been finalised (i.e. do not contain the integrity stamp) will be rejected by the regulators – date to be confirmed!
- There is **no** integrity stamp in the ‘legacy’ interactive pdf eAFs. The feature is strictly for the PLM Portal eAFs



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Known Issues and Bugs

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

Reminder

Please **do not open a ticket in Service Desk** if you identify any known issues when filling in the eAF/reviewing the products/product data. **Stakeholders will be notified as we solve the issues**.

Duplicate user roles for same organisation

The PLM Portal users should ensure that they do not request duplicate roles for the same organisation entity, for example if the user has eAF applicant manager and eAF applicant coordinator role for the same company, there may be various different issues when using the PLM Portal web based eAF form (e.g. user cannot save changes, duplicated fields etc).

- Higher role always contains all rights of a lower role
- If you detect any unusual behaviour in the form, please check the roles and remove any duplicate roles for the same organisation

Live Demo:

Create a new form
Product selection
Present and proposed
Proof of payment

Live Demonstration

Q1 2025 eAF events

eAF training on web-based application form functionalities for non-CAPs variations - 11 February 2025 (10:30 – 12:30 CET) – Event web-page

eAF training on web-based application form functionalities for CAPs and non-CAPs variations - 27 February 2025 (10:30 – 12:30 CET) – Event web-page

Q&A Clinic #1 on web-based application form functionalities for CAPs and non-CAPs variations – **06 March 2025** (11:00 – 11:30 CET) – Event web-page

Q&A Clinic #2 on web-based application form functionalities for CAPs and non-CAPs variations - 13 March 2025 (11:30 – 12:00 CET) – Event web-page

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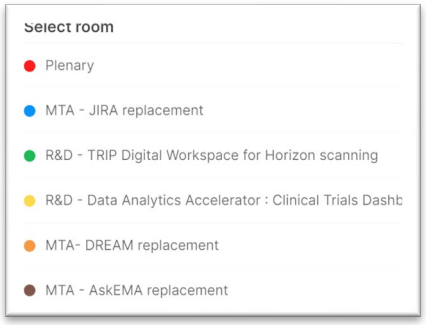

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PLM VS | Union Product Database (UPD)

Beyhan Mustafov, UPD Product Owner

New **Industry read-only API** and guidance documents

UPD data is accessible to MAHs via:

- UI - public portal
- UI – restricted area
- **Since 31 January, read-only API**

Where to find API guidance:

- UPD Registration guide for UI and API users
- Vet EU IG Chapter 5: Technical specifications
- API specifications
- EMA Account Management platform
- UPD Access Policy
- Vet EU IG Chapter 2: Format for the electronic submission of veterinary medicinal product information

Webinar for veterinary MAHs held on 27 February 2025 on an industry dedicated read API

- Event page

SPOR Guide:

- On-boarding of users to SPOR data services

Webinar: EMA Account Management, what's new?

- Event page

New **Public read-only API** and guidance documents

UPD data is accessible to the general public via:

- UI - public portal
- **Since 31 January, read-only API***

Where to find API guidance:

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***To note**

the current API configuration does not provide access to product information (SPC, PL, Labelling) documents and public assessment reports. To retrieve these documents please use the public portal.

NCA API for Products/Procedures - switch to version 3 by 1 July 2025

Since 31 January 2025, version 3 (v3) of the API for UPD Products/Procedures is available and the current **version 2 (v2) will be deprecated on 1 July 2025.**

To note

- Existing NCA users will have to **adopt version 3 (v3)** of the API for UPD Products/Procedures **no later than 30 June 2025**.
- The v3 API requires **OAuth 2.0 authentication** and authorisation. Moreover, each endpoint mandates the use of a **valid Bearer Token** for access.
- **Testing in UAT first is strongly recommended.**
- **During the transition it is possible to use v2 and v3 API for UPD Products/Procedures in parallel**.

Details of this process are outlined in the UPD registration guide for UI and API users section 5.1.1. Please note that only the 'Super user' of your organisation can request an API access, and this only takes a few minutes. Further technical guidance and specifications for API users can be found in Chapter 5 of the EU Implementation Guide on veterinary medicines data in the UPD. For technical queries/issues please open a ticket via Service Desk.

Changes to the list of variations not requiring assessment (VNRAs)

Commission Implementing Regulation (EU) 2025/163 established a **revised list of VNRAs** and starts to apply from 20 April 2025. An updated VNRA list with 54 changes **will be implemented in UPD by 25 April 2025**.

Key changes:

Nullified VNRA codes

- **Two codes B.11.b and B.45** will be **nullified** and not visible anymore after the implementation.
- Submissions made before the implementation that include these nullified codes will be processed.

New VNRA codes

- **Six new codes** will be introduced and available after 25 April 2025:
  - **B.11.e**
  - **B.12.i**
  - **B.12.j**
  - **B.44.a**
  - **B.44.b**
  - **C.10.f**

Updates to VNRA code descriptions

- **Descriptions** and associated **requirements** will be **updated for 46 VNRA codes**.

UPD email notifications functionality

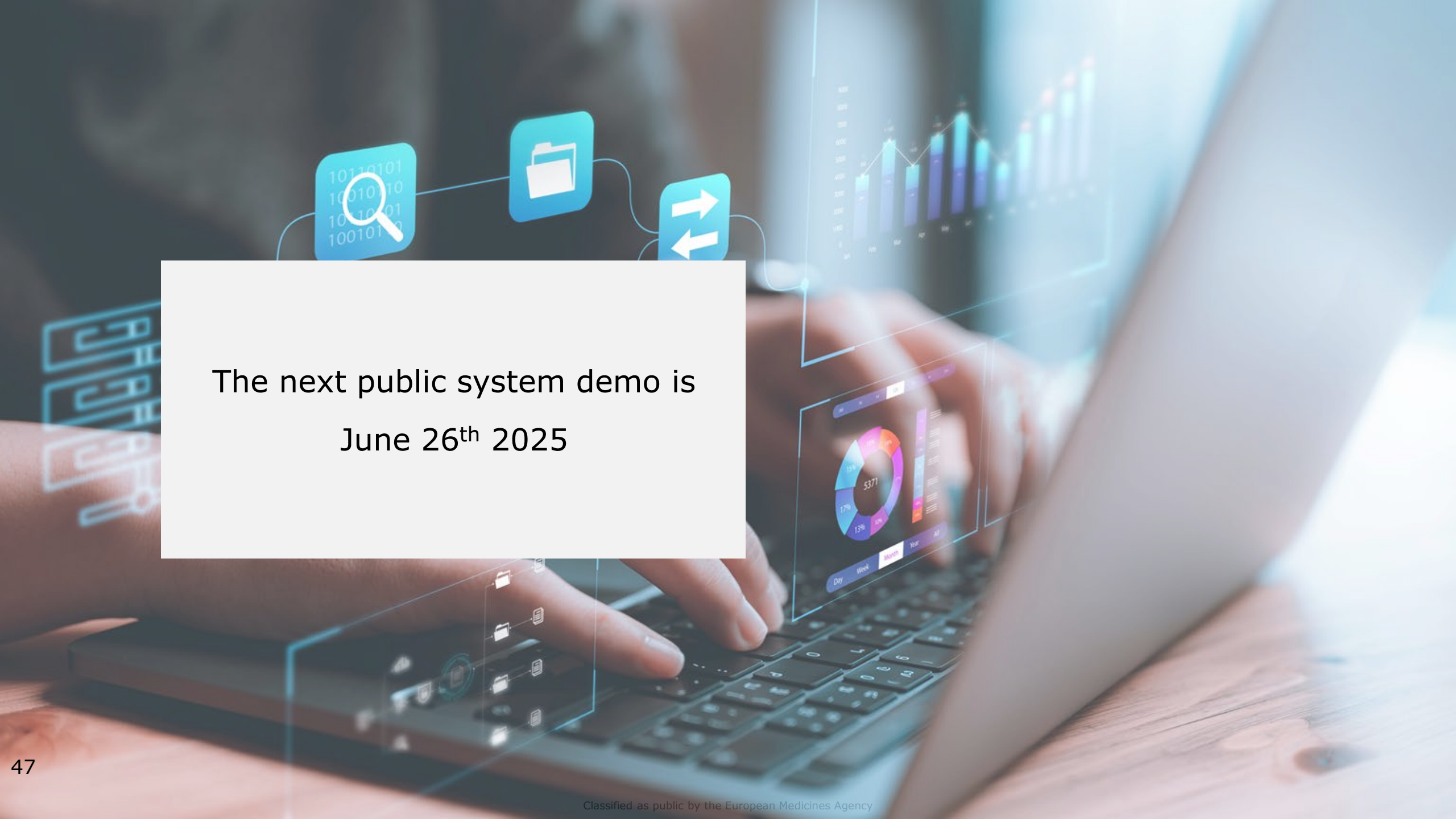
UPD super users from both marketing authorisation holders (MAH) and national competent authorities (NCAs) can **configure email addresses to receive notifications about product-related actions**.

Reminder

Since June 2024, **UPD NCA and MAH super users** are able to register email addresses to receive **notifications on updates related to products** within their portfolio and under their responsibility. This functionality can help ensure timely notifications and prompt actions.

For **guidance** on how to enable this feature, please consult the following resources:

- Guidance for NCAs
- Guidance for MAHs



The next public system demo is

June 26th 2025

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Thank you

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