EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on Human Variations web-based electronic Application Form implementation on Product Lifecycle Management Portal

6 November 2023, 13:30 – 15:00 Central European Time (CET)
Webinar: WebEx

Agenda

EUROPEAN MEDICINES AGENCY

1	**Welcome / Introduction** 13:30 – 13:35	**Kristiina Puusaari**, *eAF Product Owner, EMA*
2	**Update on NAPs release and next steps** 13:35 – 14:00	**Kristiina Puusaari**, *eAF Product Owner, EMA* **Marcos Fernandez Gomez**, *PMS Product Owner, EMA*
3	**Update on Product Data Management UI and PMS API implementation** 14:00 – 14:15	**Veronica Lipucci Di Paola**, *PMS Product Owner, EMA*
4	**Demo on new features released/under development** 14:15 – 14:30	**Noel Diamant,** *eAF Network Product Owner, UNICOM**
5	**General Q&A session** 14:30 – 14:55	**Moderator:** **Cristina Pepato,** *eAF & PMS Change Manager*
6	**Closing** 14:55 – 15:00	**Kristiina Puusaari**, *eAF Product Owner, EMA* **Veronica Lipucci Di Paola**, *PMS Product Owner, EMA* **Marcos Fernandez Gomez**, *PMS Product Owner, EMA*

*The UNICOM Innovation Action has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 875299.

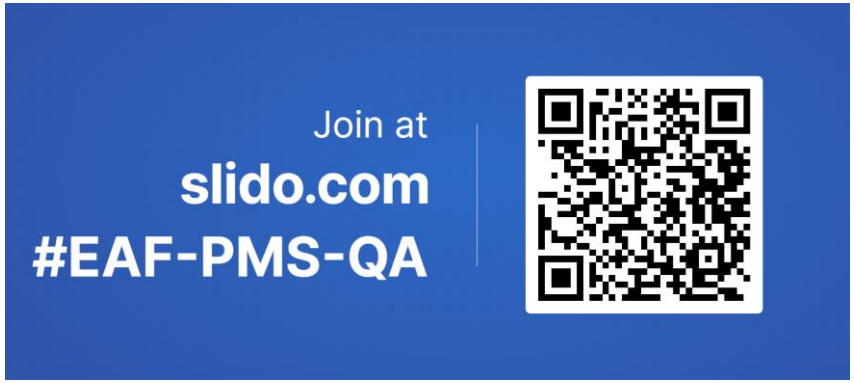
*Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website and YouTube channel.***

*At certain points throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.*

*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.*

Send your questions via Slido

EUROPEAN MEDICINES AGENCY



1. Join via the QR code or link

2. Send or upvote the questions you want to hear answered

3. Questions will be shown on the screen and managed live in the Q&A session

Introduction

Kristiina Puusaari, *eAF Product Owner, EMA*

Update on NAPs release and next steps

Kristiina Puusaari, *eAF Product Owner, EMA*

Marcos Fernandez Gomez, *PMS Product Owner, EMA*

eAF Vision

Implement **web replacements of interactive PDF electronic Application Forms (eAFs)** for Human & Veterinary medicinal products to:

1. Enable user-friendly capture and handling of marketing authorisation, variation and renewals application data for applicants and regulators

2. Ensure consistency across IT systems and the availability of high-quality ISO IDMP compliant information.

PMS Vision

Product Management Services (PMS) will make available, for human and machine interaction, **structured, standardised and consistent authorised product data** from across the European Medicines Regulatory Network.

PMS data will be used by regulators and industry in regulatory and non-regulatory procedures as well for the general benefit of European citizens.

Human Variations eAF – next key steps and milestones

EUROPEAN MEDICINES AGENCY

Known & target timeframe

November 2022

Go-live of human variation eAF supporting CAPs only

December 2023

Update on Q1 2024 releases

Q1 2024

All split CAPs* available in eAF

All NAPs in eAF

Load and test PMS data across EMA systems for quality issues

Incremental release of functionalities required for mandatory use

*CAPs migrated from SIAMED not following ISO IDMP structure. For this reason, they have undergone a further step in the data migration to PMS in addition to the match and merge protocol.

Note: CAPs and NAPs data in PMS is sourced from EMA's internal database (SIAMED) and XEVMPD

Acronyms

CAPs: Centrally Authorised Products

NAPs: Nationally Authorised Products

XEVMPD: eXtended EudraVigilance Medicinal Product Dictionary

Legend

Key step/ Milestone

Dev activities for Human variations eAF

Recurring activity

Timeframes

Key enablers for split CAPs/NAPs release on eAF & ongoing work

EUROPEAN MEDICINES AGENCY

Key enablers for split CAPs and NAPs release

1. **Bug fixing** across PMS & IRIS products
2. **Release of all products from PMS** to the IRIS UAT environment
3. **Successful execution** of internal **UATs** to confirm bug fixing across PMS & IRIS products

Ongoing work on eAF features

- **Name translations** to be implemented *ahead of NAPs release*
- Kindly be aware that **additional features** pertaining to the use of the forms for NAPs will be **introduced at a later stage** (*after NAPs release*).

  Initially, there will be some limitations due to unavailable features (e.g., the form will not be available for homeopathic products), but it will *still be valuable for individuals to use the eAF for NAPs to familiarise with the form*.

Update on XEVMPD initial load to PMS

EUROPEAN MEDICINES AGENCY

PMS team is working on the **initial load of data from XEVMPD to PMS**

Some **bugs were found** on initial load and XEVMPD to PMS deltas:

- Management of pharmaceutical products
- Transfer of CAPs in XEVMPD
- Match and merge of CAPs with data quality issues

PMS team is working to solve these issues and test them before been able to deploy it in production

PMS is also **collaborating with**:

- **OMS** to have available the XEVMPD to OMS deltas to be able to map organisations when they are created in XEVMPD
- **RMS** to map or create the corresponding term available or to be created in XEVMPD so 1:1 match is established when loading data from XEVMPD to PMS.

Note: *Starting from Jan 2024, users can no longer request terms in XEVMPD. Instead, they should request terms directly in SPOR.*

Focus on split CAPs (IDMP compliant)

EUROPEAN MEDICINES AGENCY

*Split CAPs are also **part of the migration of data** from XEVMPD to PMS*

Initially migrated CAP product

PMS ID	Product name	Presentations
600000001234	Aranesp - 20 mg - solution for injection	EU/1/01/185/059 EU/1/01/185/047 EU/1/01/185/005 EU/1/01/185/006 EU/1/01/185/035 EU/1/01/185/078 EU/1/01/185/079

Split CAP

PMS ID	Product name	PMS ID
600000004567	Aranesp 20 micrograms solution for injection in pre-filled pen	EU/1/01/185/059 EU/1/01/185/047
600000008900	Aranesp 20 micrograms solution for injection in pre-filled syringe	EU/1/01/185/005 EU/1/01/185/006 EU/1/01/185/035 EU/1/01/185/078 EU/1/01/185/079

Additional information can be found in **Ch 7 of the EU IG** (*updated version to be released in Dec 2023*)

NAPs Data Release – key questions

When will NAPs be available on the PLM Portal eAF?

The **NAPs will gradually become available from PMS in the web-based eAF for human medicinal products variations**. When the product upload starts (target Q1 2024), it will take a few weeks to conclude. An official announcement will confirm the completion of the NAPs upload.

What do I do if I cannot find a NAP in the eAF?

NAPs initial load will take a couple of weeks to be completed since the start of the migration.

Once the initial load has been completed and the official announcement been sent, if you are not able to find your product in the PLM portal, **check that in XEVMPD your product is not nullified and has**:

- Authorised Pharmaceutical Form
- Legal basis
- Medicinal product type
- Authorisation status different from *Not Valid - Superseded by Marketing Authorisation Transfer* or *Not Valid - Superseded by Marketing Authorisation Renewal/Variation*
- You have logged in with the same MAH as the one in XEVMPD

If you still cannot find it, please raise a ticket in Service desk (select *PLM portal* service in Report an Issue)

Join at slido.com #EAF-PMS-QA

Next steps

EUROPEAN MEDICINES AGENCY

Before NAPs release

- **Update** on development progress (Dec 2023)
- Public **System Demo** (Dec 2023)

After NAPs release

- **Release** of features and functionalities **required for mandatory use**
- **eAF User Acceptance Testing announcement** (2 months in advance)
- **eAF UAT** (2-week duration) of the version of the form ready for transition
- **Confirmation** of transition start (2 months in advance)
- **Transition period** (6 months)
- Start of **mandatory use**

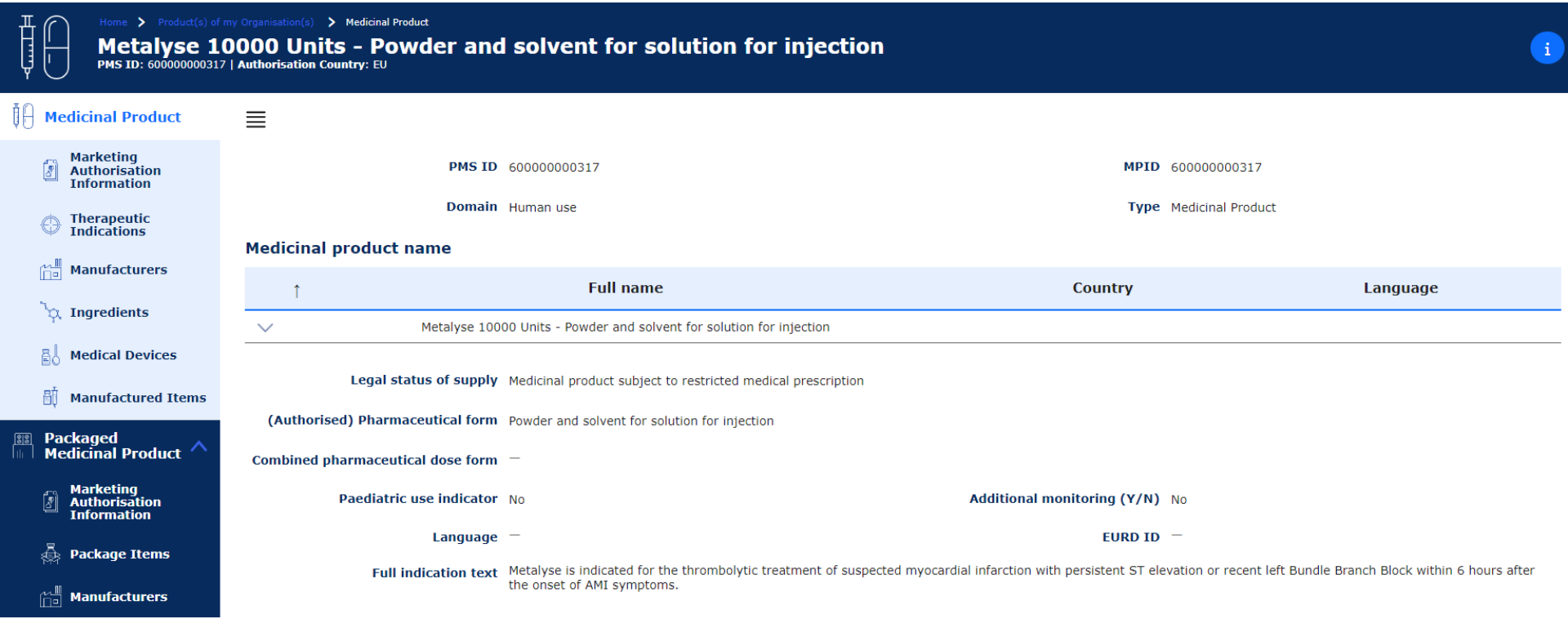
Update on Product Data Management UI and PMS API implementation

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

Product UI – completed work

EUROPEAN MEDICINES AGENCY

View pages** of the Product UI are ready as well as **security and access management

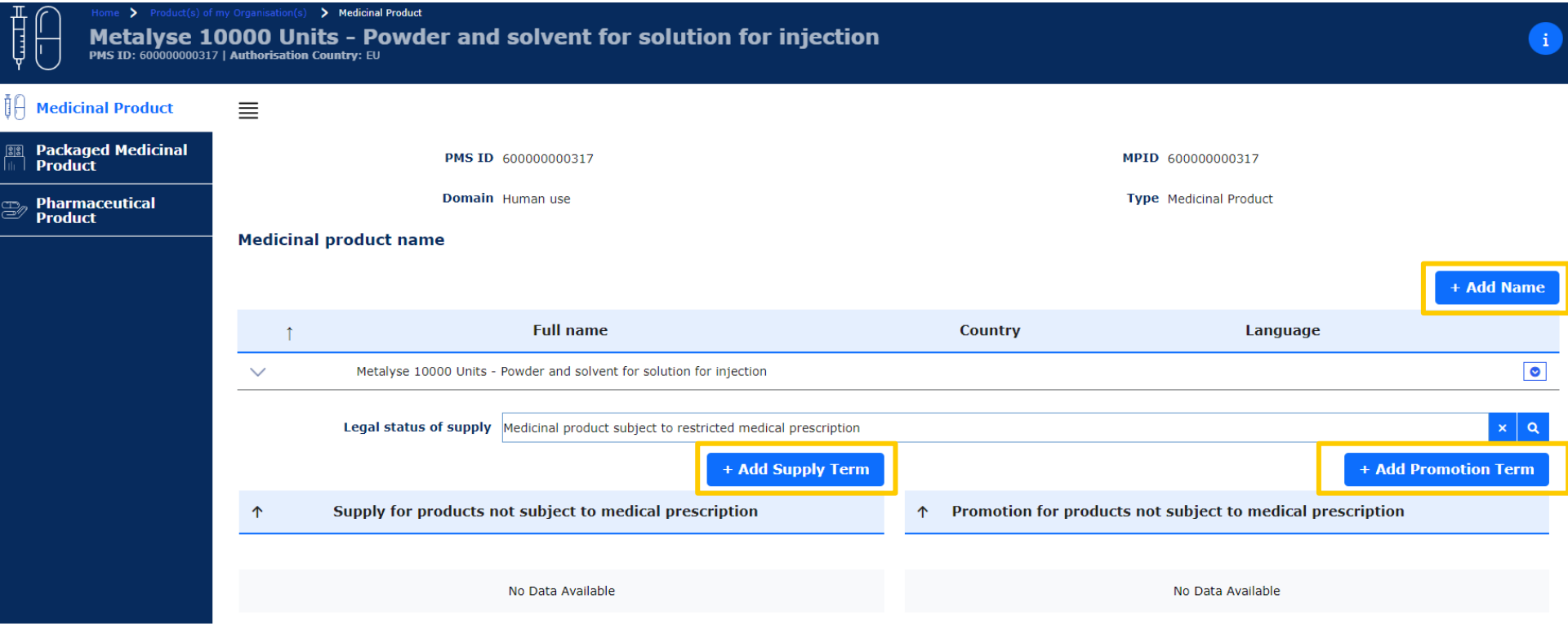


 Join at slido.com #EAF-PMS-QA

Product UI – ongoing work

EUROPEAN MEDICINES AGENCY

***Edit pages** of the Product UI are under development*



 Join at slido.com #EAF-PMS-QA

Product Data Management User Interface UAT

EUROPEAN MEDICINES AGENCY

Scope

- Ensure that all the read pages of the user interface can be accessed by external users
- Confirm the correct implementation of Security, Access Management and user roles
- Receive feedback on the layout and structure of the different sections, subsections and data fields.

Participants

- PMS Industry & Network SMEs
- PMS Network Product Owner

Timeline

- 1st round (13 – 24 Nov 2023)
- 2nd round (4 – 15 Dec 2023)
- 3rd round (15 – 26 Jan 2024)

Product UI next deliveries

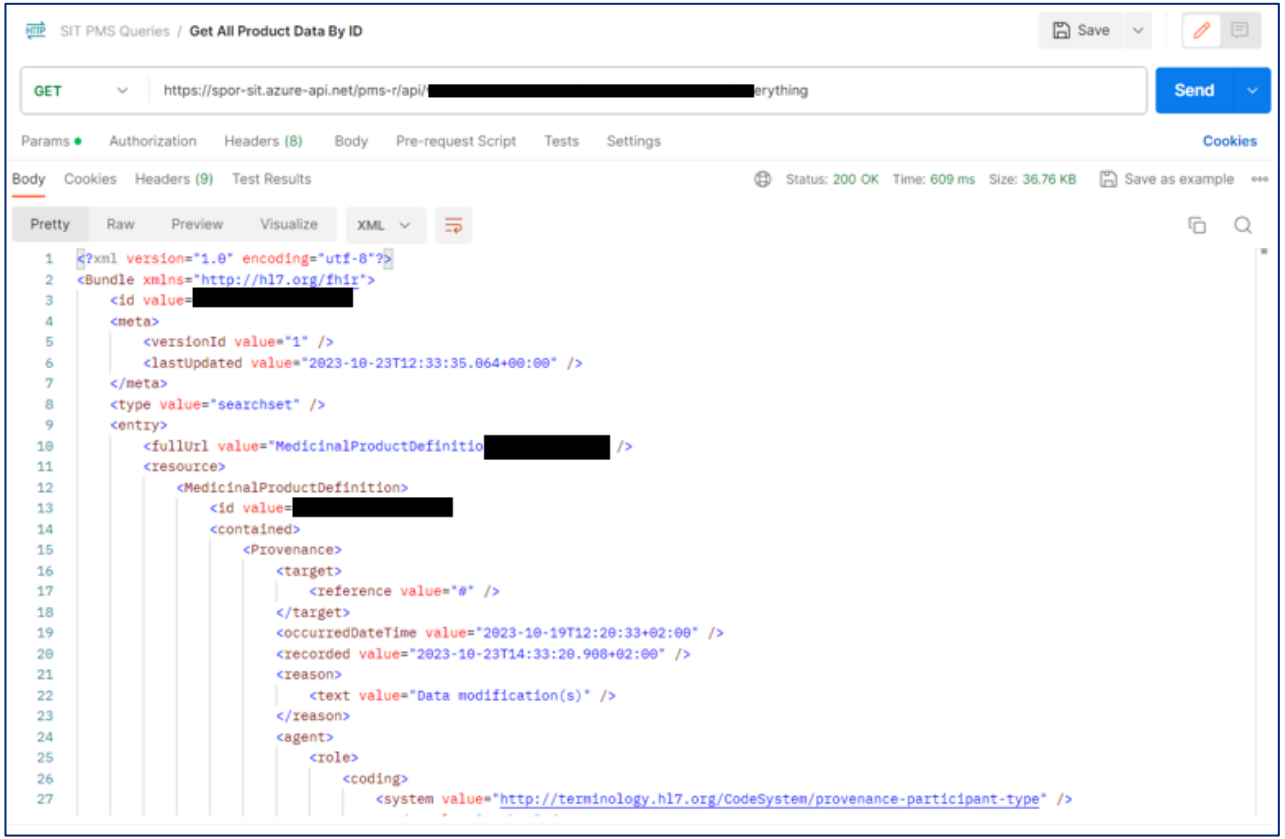
What we aim to deliver by Q1 2024

- User manual
- PMS Access Policy
- Completion of edit page (internal deliverable)
- Completion of Alpha UAT
- Launch of Beta UAT

For additional information on the Product UI, please check the system demo

PMS API – completed work

Security and access management *is implemented in read PMS API*



 Join at slido.com #EAF-PMS-QA

PMS Application Programming Interface UAT

EUROPEAN MEDICINES AGENCY

Scope

- Confirm the correct implementation of Security and Access Management of read PMS API

Participants

- PMS Industry & Network SMEs
- PMS Network Product Owner

Timeline

- 1st round (13 – 24 Nov 2023)
- 2nd round (Date TBD based on outcome)

Additional deliveries on PMS

EUROPEAN MEDICINES AGENCY

What we have done so far

- Alignment of PMS data model
- Different initial loads of XEVMPD data to lower environments
- Bugs identification and prioritisation (from internal UAT)

What we aim to deliver by Dec 2023

- Updated versions of:
  - EU IG Chapter 2
  - EU IG Chapter 7
- New release of:
  - EU IG Chapter 9
  - PMS Access Policy
- Completion of Alpha API UAT

 Join at slido.com #EAF-PMS-QA

Demo on new features released/under development

Noel Diamant, *eAF Network Product Owner, UNICOM**

*The UNICOM Innovation Action has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 875299.

Demo on features released/ under development

Live Demonstration

Q&A session

Moderator: Cristina Pepato, *eAF & PMS Change Manager*

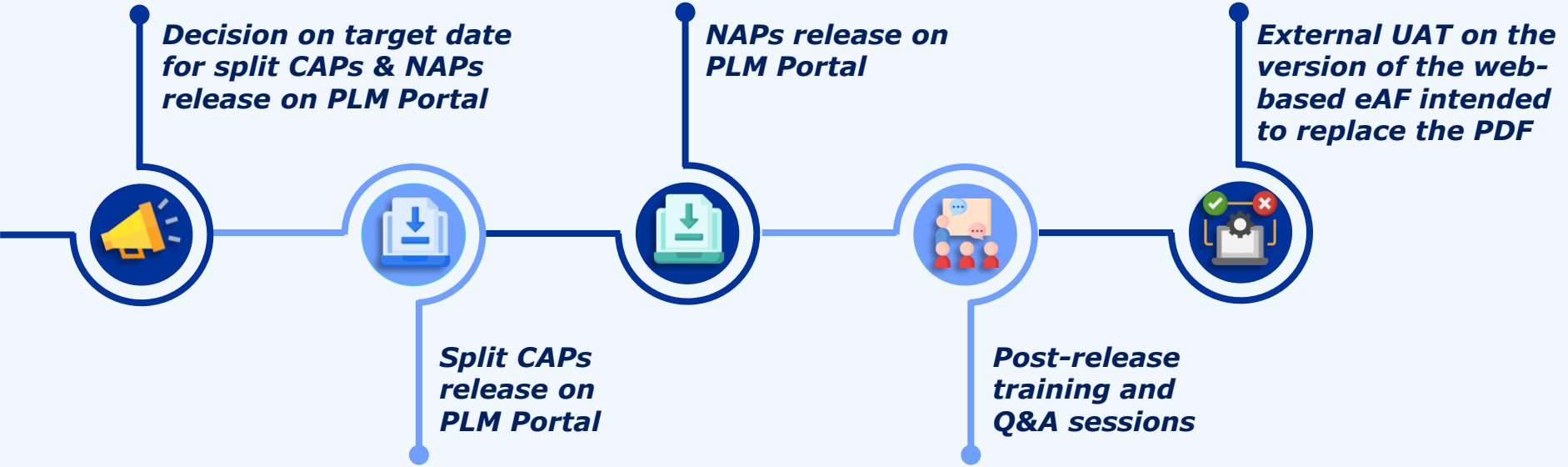
Closing

Kristiina Puusaari, *eAF Product Owner, EMA*

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

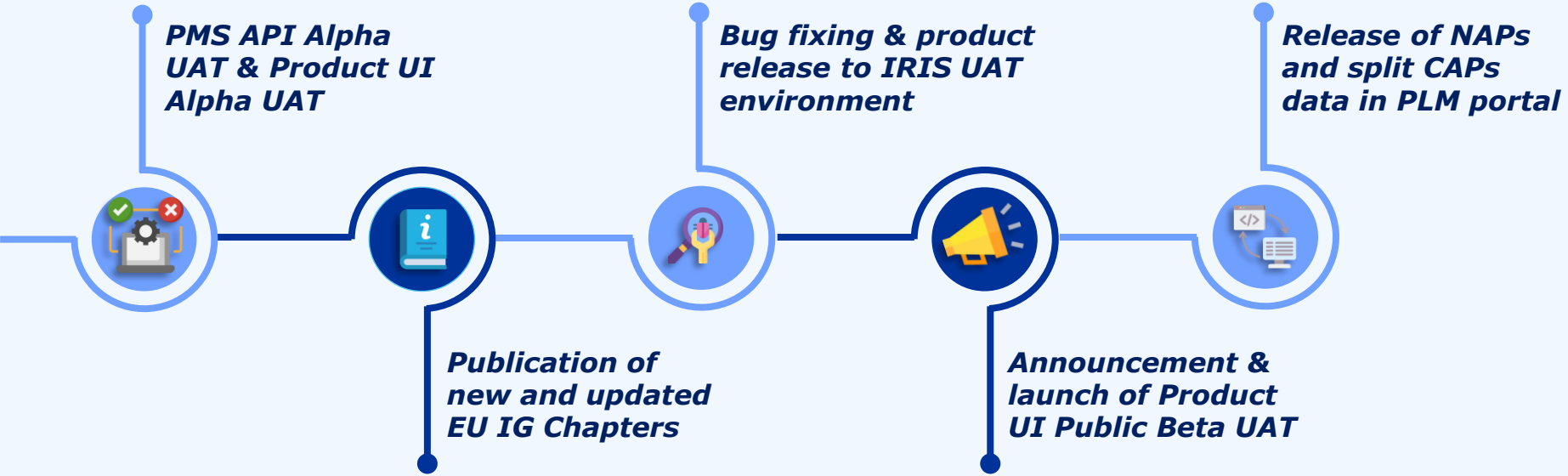
Marcos Fernandez Gomez, *PMS Product Owner, EMA*

Recap - Next planned activities for eAF



Recap - Next planned activities for PMS

EUROPEAN MEDICINES AGENCY



 Join at slido.com #EAF-PMS-QA

Next event: PLM Value Stream Deep-Dive Webinar

EMA aims to provide a **comprehensive overview of its value streams** and their respective products & solutions through dedicated webinars.

Next Webinar: 30 November 2023, 14:00 – 16:00 CET

The **Product Lifecycle Management (PLM) value stream Deep-Dive Webinar** is the first of this series and aims at **illustrating the interconnections** between the various digital products being delivered by this value stream (including eAF and PMS).
Registration link

Useful Materials

Guides

- PLM Portal Guide to registration
- PLM Portal Guide to navigation

Q&A Docs

- eAF-PMS Joint Q&A Doc
- H Var eAF-PMS Frequently Asked Questions (FAQs) document

Webinar recordings

- eAF-PMS Q&A Clinic – session 2 (22/06/23)
- eAF-PMS Q&A Clinic – session 1 (15/06/23)
- eAF Training Webinar (02/02/2023)

Training videos

- How to monitor Application Forms Status on the PLM Portal (link)
- How to select the scope of the variation application on the PLM Portal (link)
- How to fill in the "Procedural Information" section of the eAF on the PLM Portal (link)
- How to fill in the "Additional Information" section of the eAF on the PLM Portal (link)
- How to fill in the "Finalisation" section of the eAF on the PLM Portal (link)

Further information

https://plm-portal.ema.europa.eu/
http://esubmission.ema.europa.eu/cessp/cessp.htm

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to eSubProgofficer@ema.europa.eu

Follow us on **@EMA_News**

Annex

eAF Key Changes

FROM	TO
Current PDF forms use outdated technology and take long time to open	A modern web-based input form for applicants with a familiar, human readable PDF output and a new machine-readable XML for digital processing (FHIR data exchange)
Limited use of structured data	ISO IDMP/FHIR compliant structured data can be (re)used to populate web forms. They also guarantee two-way exchange of data between application web forms and PMS
Manual, labour intensive procedure management	Streamlined and simplified processes, with automated data imports and lean process and technology (i.e. IRIS) to facilitate procedure handling by regulators

Human Variations eAF – what we have done so far

EUROPEAN MEDICINES AGENCY

Before Go-live

- Set up an **infrastructure** to support all forms (e.g. landing page, form structure, data model, solution design)
- Develop an **initial, MVP version of the form for variations for human medicinal products**
- **Development** of a human readable PDF output containing FHIR XML
- **Fine-tuning and testing of the form** for variations for human medicinal products (only for CAPs)
- Put **maintenance support** in place
- Perform **access management, security checks** and preparing for **deployment into production**
- Work in collaboration with PMS to establish the approach for **enriching and cleansing product data**

After Go-live

- **Launch of the H var web-based form (only for CAPs)**
- Preparing work for **the H var web-based form (CAPs & NAPs)**