EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Product Lifecycle Management Value Stream Deep-Dive Webinar

30 November 2023, 14:00 – 16:00 (CET)

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Agenda

1	**Introduction to Product Lifecycle Management (PLM) Value Stream** 15 min	**Karl Hamilton** *Value Stream Owner* **Hannes Kulovits, Melanie Loveday** *Value Stream Managers*
2	**Q&A Session** 10 min	**Moderator:** **Joris Wiemer,** *EMA Change Management Lead*
3	**PLM VS Products overview** 60 min	**PLM Value Stream Product Owners**
4	**Q&A Session** 25 min	**Moderator:** **Joris Wiemer,** *EMA Change Management Lead*
5	**Conclusions and final questions** 10 min	**Ivo Claassen, Alexis Nolte, Zaide Frias** *EMA Business Owners* **Moderator: Joris Wiemer,** *EMA Change Management Lead*

Aim of this webinar

Our Focus: **P**roduct **Li**fecycle **M**anagement value stream

Today's webinar aims at sharing:

- the goals of the Network Portfolio's PLM value stream
- how PLM delivers on the Network Strategy's goals
- what work is being done
- how the IT products in the value stream connect

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Send your questions via Slido

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 to the Product Lifecycle Management (PLM) Value Stream

Karl Hamilton, *PLM Value Stream Owner, EMA*

Background to the creation of Value Streams

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2021: start of EMA's **Agile Transformation process**

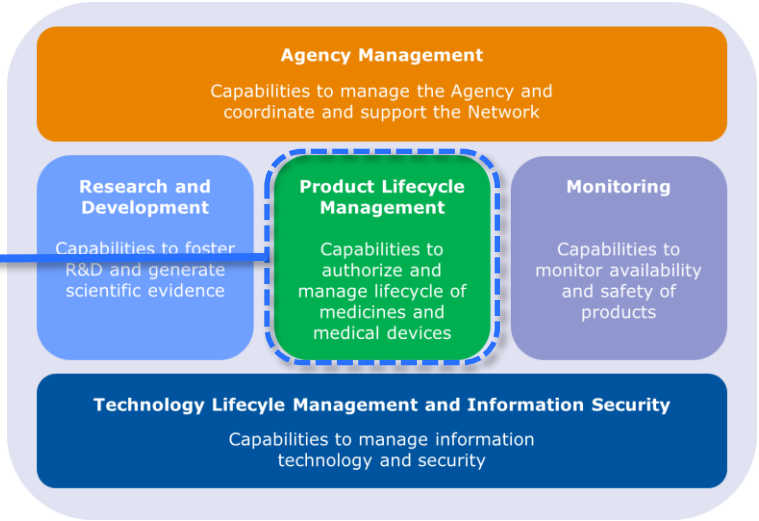
Main goal

Strengthen alignment between business and IT and continuously deliver value by making our delivery more flexible, transparent and adaptive to change.

Creation of 5 Agile Value Streams

Our focus today:

Product Lifecycle Management Value Stream and its digital products



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Product Lifecycle Phases of CAPs & related Value Streams

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Product Lifecycle of a centrally authorised medicinal product

1 Research & Development

2 Scientific Advice

3 Evaluation

4 Authorisation

5 Access

6 Safety monitoring

Research & Development value stream

Product Lifecycle Management value stream

Monitoring value stream

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Our vision for Product Lifecycle Management

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Ultimate goal

benefitting public and animal health in the European Union

Need

valuable regulatory services and reliable information

Key stakeholders

- Citizens
- Healthcare providers
- Regulators
- Industry

How does the PLM VS meet stakeholders' need?

Delivering end-to-end PLM procedures & data exchange, which are:

data-driven

efficient

digitally connected

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Our vision for Product Lifecycle Management

EUROPEAN MEDICINES AGENCY

*To enable **data-driven**, **efficient** and **digitally connected end-to-end product lifecycle management procedures** and **data exchange** which offer valuable regulatory services and reliable information to citizens, healthcare providers, regulators and industry – benefitting public and animal health in the European Union*

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Product Lifecycle Management – Connecting the Value Stream

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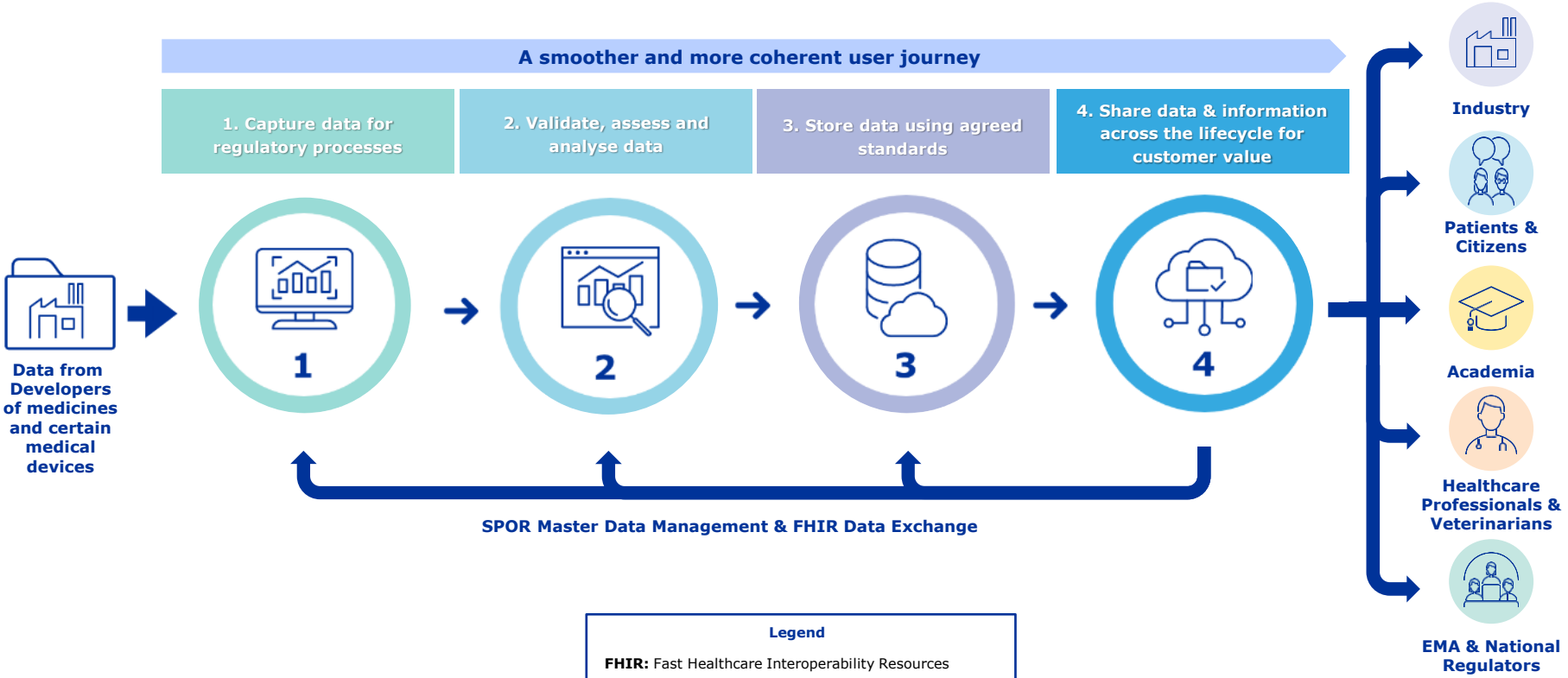

Legend

FHIR: Fast Healthcare Interoperability Resources

SPOR: Substance, Product, Organisation and Referentials

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From EMA's strategic Focus Areas to PLM VS objectives

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Key strategic focus areas from EMA Network Strategy for 2025

1. *Data analytics digital tools and digital transformation*
2. *Innovation*
3. *Sustainability of the Network with operational excellence*

PLM value stream objectives

- *Make **applications** for regulatory procedures **easier to create and submit***
- *Provide useful **tools for review and real-time-collaboration** in the assessment process*
- *Ensure **data is captured in a structured way** and can be more easily reused and shared*
- *Create systems that **share validated and accurate product data** and information with stakeholders*

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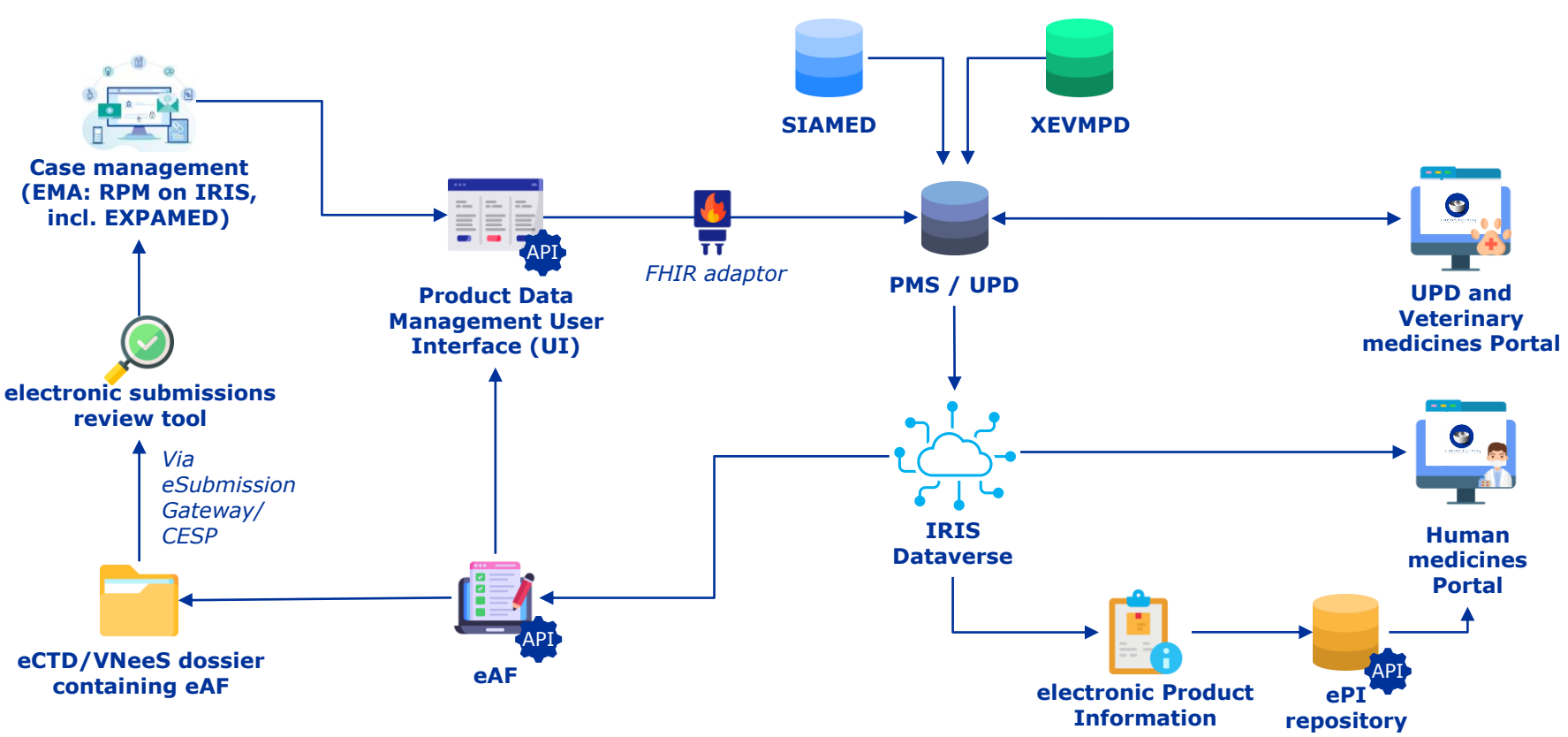
Overview of Product Lifecycle Management activities



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PLM Value Stream Portals & Services

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PLM Portal

Web-based eAF

Product Data Management UI/API

ePI

eSubmission

electronic submissions review tool

Gateway

UPD

UPD data (V Medicines)

SPOR

PMS data (H Medicines)

IRIS

Regulatory Procedure Management

EXPAMED

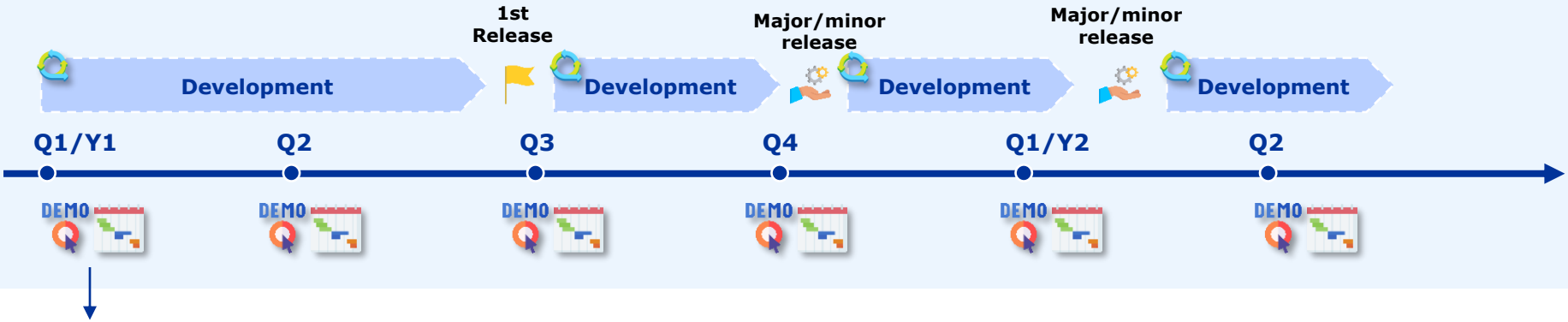
V Medicines Web Portal

H Medicines Web Portal

(available in the future)

Product & Portfolio Roadmap development

The work on each value stream product outlines as follows:



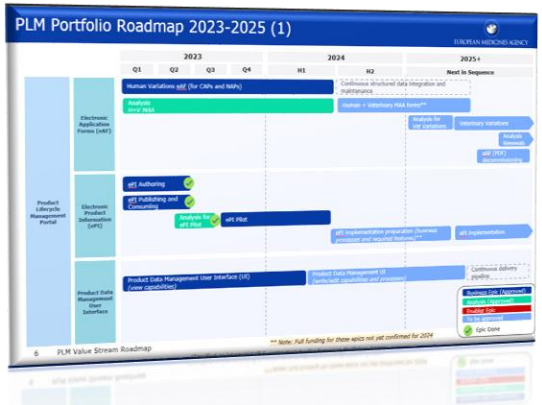
Agile ceremonies (quarterly):

- **Public system demo** to present the developments from the previous quarter
- **Prioritisation of features for development** to define the roadmap for the next quarter

Legend

- *1st release*
- *Public System Demo*
- *Prioritisation of features for development*
- *New functionalities, bug fixes, improvements*

PLM Portfolio roadmap (available on EMA Website)



Working together for PLM VS success

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Valdemar Blazevic
Domain Architect

Karl Hamilton
PLM VS Owner

Hannes Kulovits
PLM VS Manager

Melanie Loveday
PLM VS Manager

Alexis Nolte
Head of H Division (BO)

Ivo Classen
Head of V Division (BO)

Zaide Frias
Head of Digital Business Transformation TF (BO)

Kristiina Puusaari
eAF & eCTD v4.0 PO

Noel Diamant
eAF Network PO (UNICOM)

Marcos Fernandez Gomez
PMS & Product UI PO

Veronica Lipucci Di Paola
PMS & Product UI PO

Dino Soumpasis
PMS Network PO

Melanie Carr
Head of S Division (BO)

Hilmar Hamann
Head of I Division (BO)

Elizabeth Scanlan
ePI PO

Evinn Drusys
ePI Network PO

Madalina Duta-Mare
RPM for PLM PO

Beyhan Mustafov
UPD PO

Michael Vogl
EXPAMED PO

Joris Wiemer
PLM VS Change Manager

PLM VS CM Team

Network SMEs

Industry SMEs

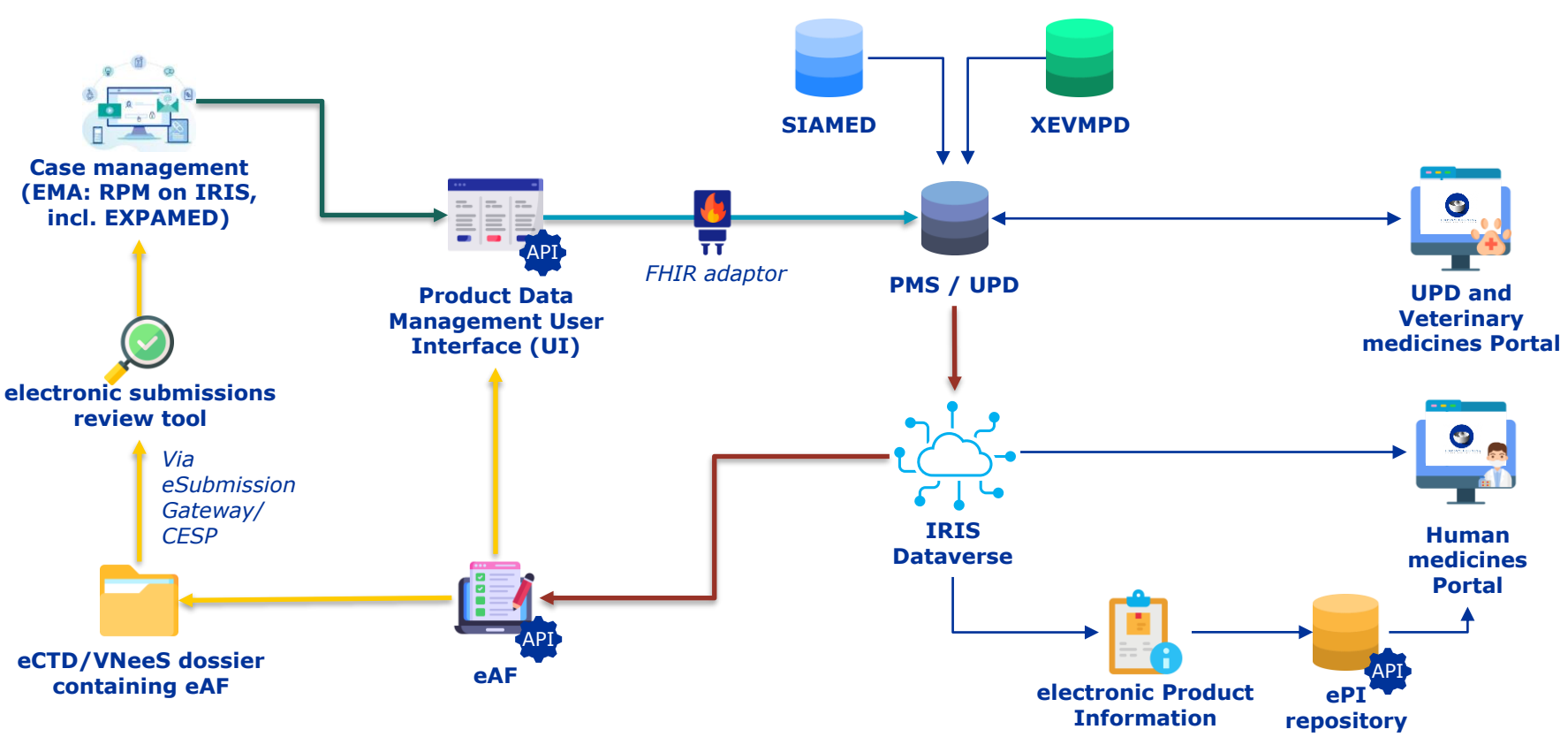
Development teams

Focus on electronic Application Form

Kristiina Puusaari, *eAF EMA Product Owner*
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.

Overview of Product Lifecycle Management activities



omissions
tool

/ia
eSubmission
Gateway/
CESP

S dossier
g eAF

eAF

eAF vision & key changes

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Vision

*Streamline **user-friendly data input** for marketing authorisations, variations, and renewals, maintain **consistency in IT systems** and provide **high-quality ISO IDMP compliant information**, through the **creation of web-based forms for Human & Veterinary medicinal product applications***

Key changes

New web-based eAFs

Use of ISO IDMP/ FHIR compliant structured data

Streamlined & simplified processes

Sequencing of epics

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Work completed	Ongoing work	Future work *(What's next?)*	Future work *(What's later?)*
Human Variations eAF (CAPs)	Human Variations eAF (CAPs + NAPs)	Human MAA eAFs	Renewals eAF
		Vet MAA eAFs	Vet Variations eAF
		eAF API	

Acronyms

API: Application Programming Interface

CAPs: Centrally Authorised Products

NAPs: Nationally Authorised Products

MAA: Marketing Authorisation Applications

IMPORTANT: this slide **DOES NOT represent timelines or sequencing of release** but pieces of work or events to be delivered and the impact on users.

eAF Business Value

- **Provision of digital, user friendly, adaptable application forms**
- Consistent **high-quality ISO IDMP** compliant data
- **Standardised data entry**, thus making forms easier to access, process, validate, transmit and re-use
- **Reuse of data** in end-to-end processes
- **Integration with product lifecycle management processes** to optimise regulatory procedure management
- **Easier and more automated** applications' validation and processing by National Competent Authorities (NCAs), reducing errors and discrepancies

Top 3 FAQs on eAF

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1. NAPs & SPLIT CAPs RELEASE ON PLM PORTAL eAF

Key enablers for NAPs & split CAPs release on PLM Portal:

1. **Bug fixing Release of all products to PLM Portal** UAT environment
2. **Successful execution** of internal **User Acceptance Testing (UAT)** to confirm bug fixing for eAF use

2. NEXT UAT

- The UAT will take place when **all the necessary functionalities and features supported by the current PDF forms** (required for mandatory use) will be included in the web-based form
- It will be announced **at least 2 months in advance**

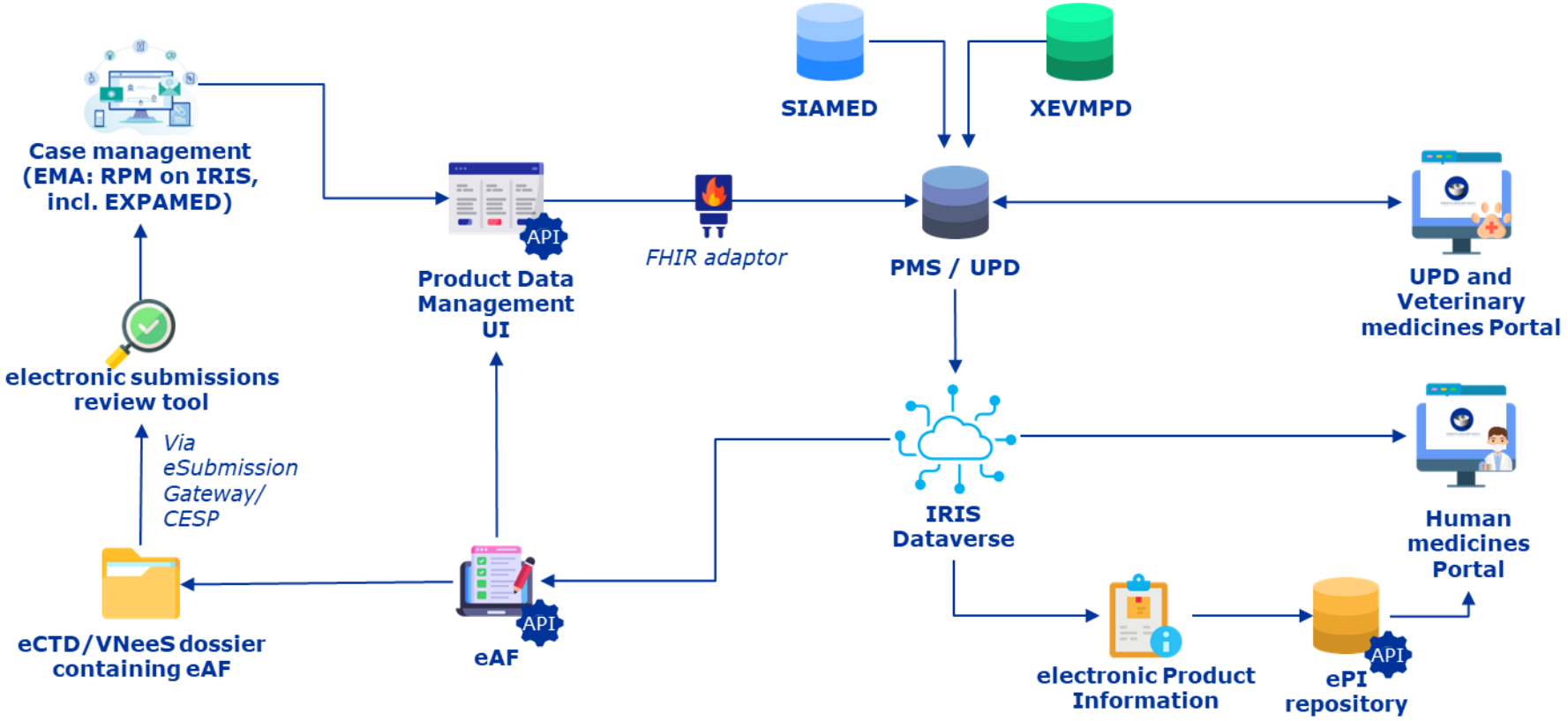
3. START OF TRANSITION PERIOD

- The **transition period** will start after a successful UAT, when the eAF has all the features necessary to start mandatory use and any issue identified during UAT has been solved
- The transition will be announced **at least 2 months in advance**

Focus on Product Management Service (PMS) & Product Data Management UI (User Interface)

Marcos Fernandez Gomez, *PMS & Product UI Product Owner, EMA*

Overview of Product Lifecycle Management activities



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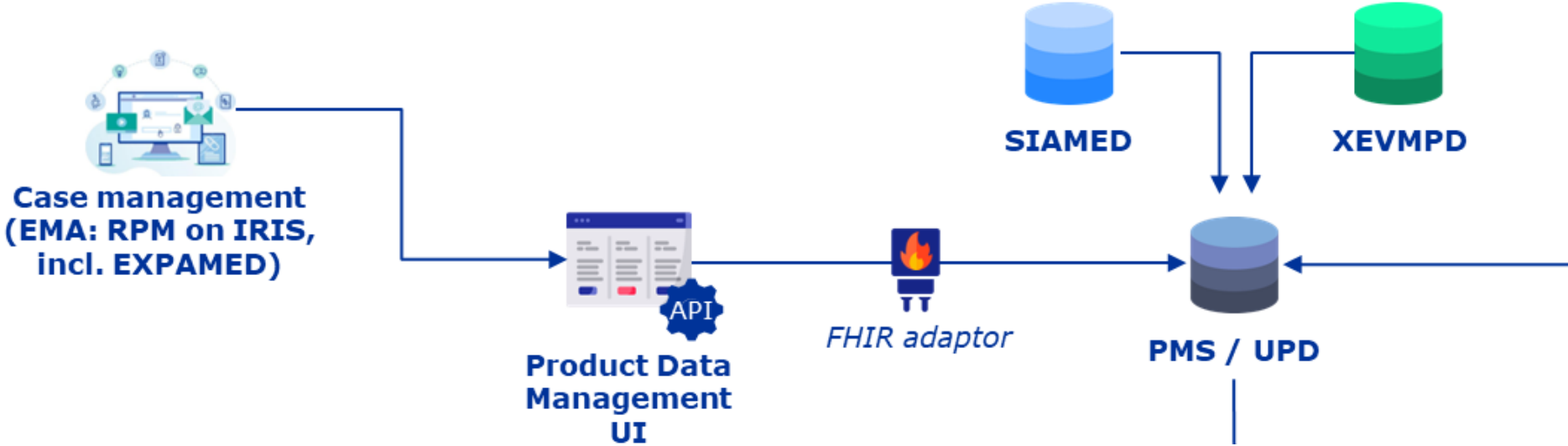
SIAMED
XEVMPD
Case management (EMA: RPM on IRIS, incl. EXPAMED)
API
Product Data Management UI
FHIR adaptor
PMS / UPD

PMS vision & key changes

EUROPEAN MEDICINES AGENCY

Vision

Product Management Service (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.*

Key changes

Product data storage in PMS database

Delivery of ISO IDMP-compliant structured data

User interface/ API to access data in PMS

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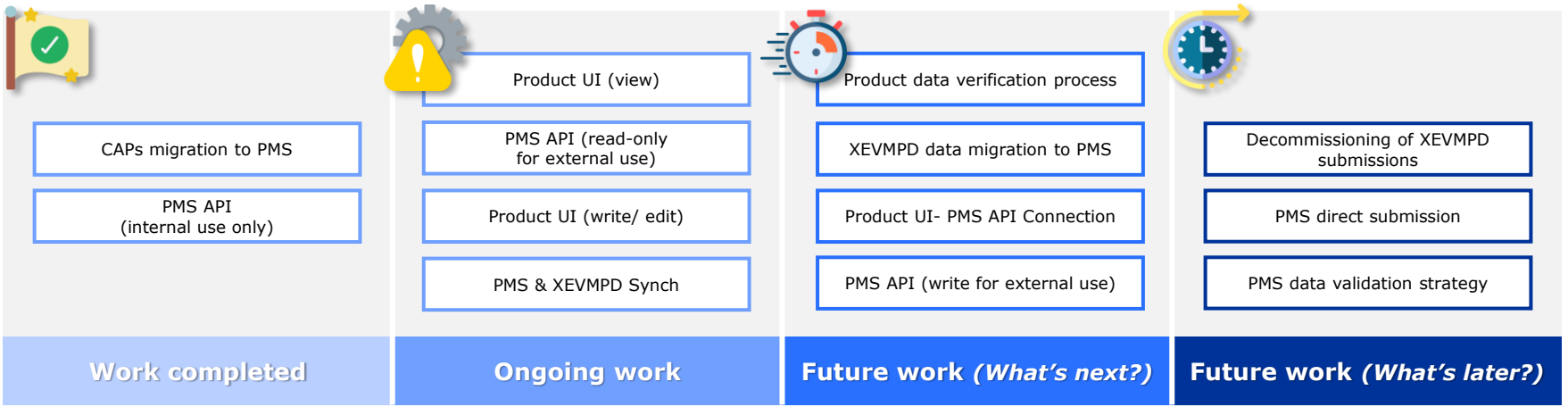
Sequencing of epics



Acronyms

API: Application Programming Interface

CAPs: Centrally Authorised Products

NAPs: Nationally Authorised Products

XEVMPD: Extended EudraVigilance medicinal product dictionary

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PMS Business Value

- **Harmonisation of messaging standards** in the EU (FHIR)
- **Data standardisation & consistency**
- **Reusability of data** by different stakeholders
- **Avoidance of data duplication**
- **Streamlined regulatory processes**
- **Trustworthy and good quality data** source
- **Effective implementation** of the **target operating model (TOM)** for managing human medicinal product data

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Top 3 FAQs on PMS

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1. DATA IN PMS

- For the first release, the **data in PMS comes from SIAMED II** - the internal EMA database where CAP product data is stored and maintained.
- For the next release, **XEVMPD data will also be migrated to PMS**. XEVMPD data is provided and maintained by MAHs for both CAPs and Non-CAPs.

2. XEVMPD

- EMA is working to **decommission XEVMPD submissions** and guarantee that submissions can be done directly to PMS.
- Until further notice, the **current process for submission of product data to XEVMPD** shall be followed. MAHs are encouraged to continue **paying attention to the data quality** as it might impact PMS.

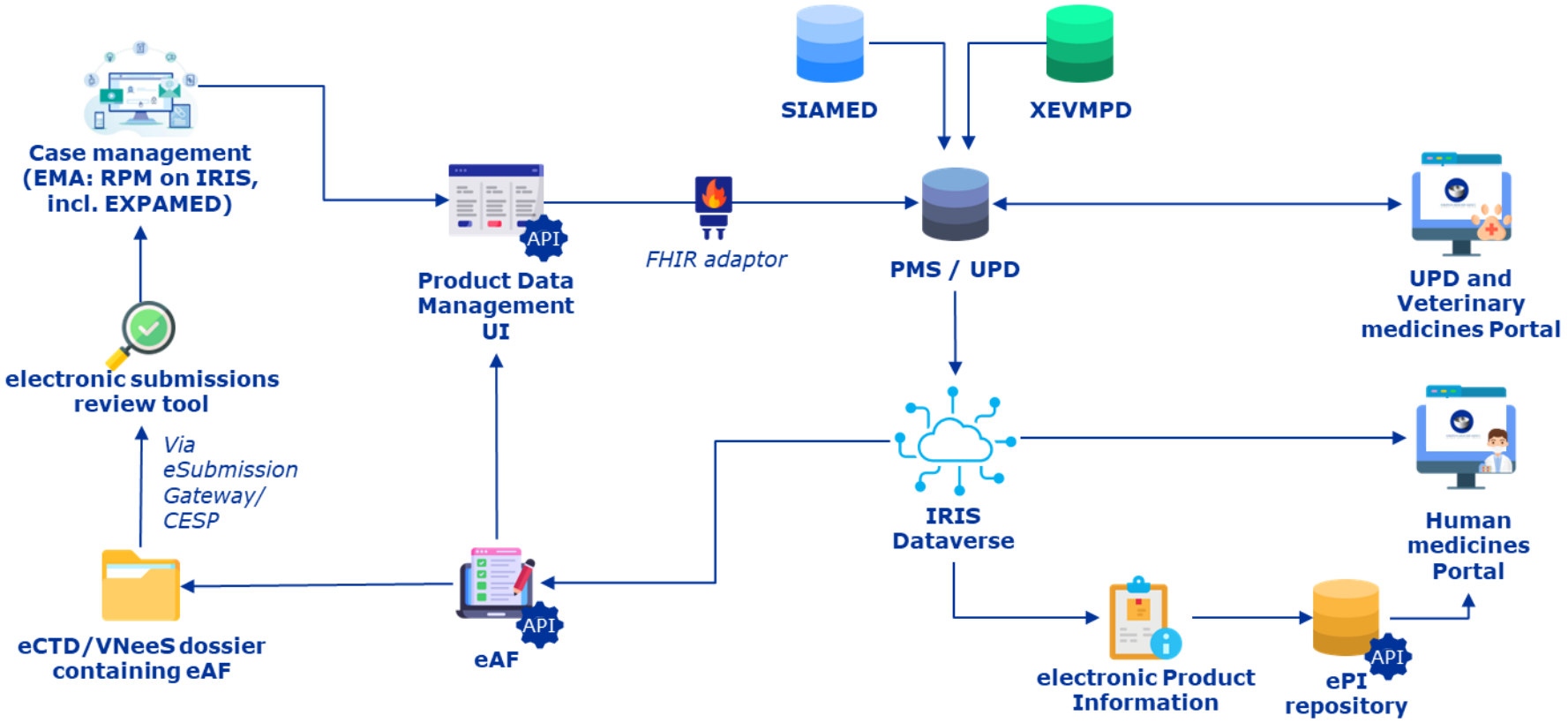
3. NEXT USER ACCEPTANCE TESTING

- **Product Data Management UI UAT: Alpha & Beta UATs** will take place in Q1 2024
- **PMS API UAT:**
  - **Alpha UAT** will take place in Q1 2024
  - **Beta UAT** is planned to take place in H1 2024

Focus on electronic Common Technical Document (eCTD) v4.0

Kristiina Puusaari, *eCTD v4.0 Product Owner, EMA*

Overview of Product Lifecycle Management activities



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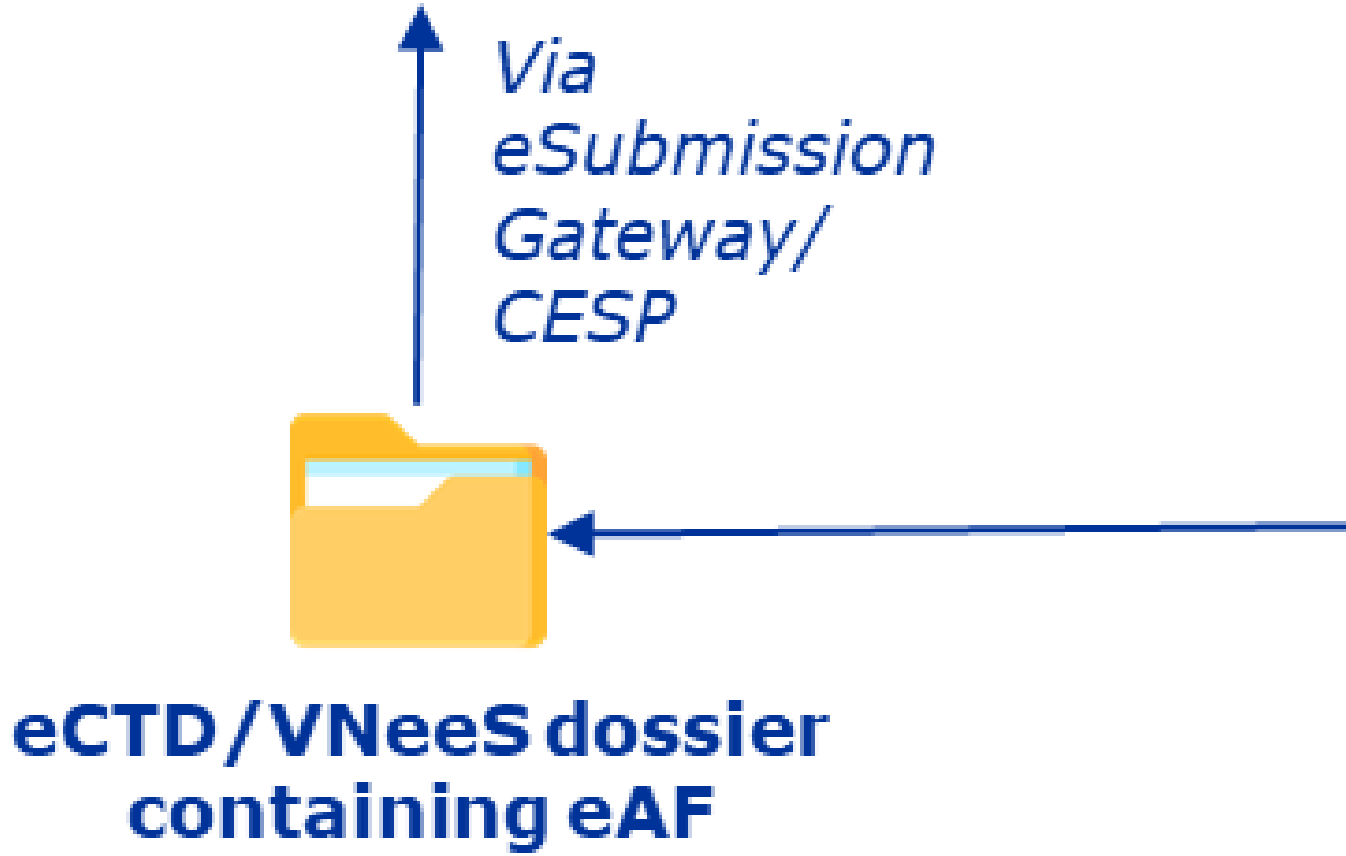
Via
eSubmission
Gateway/
CESP
eCTD/VNeeS dossier
containing eAF

eCTD v4.0 vision & key changes

EUROPEAN MEDICINES AGENCY

Vision

Implementation of internationally harmonised common rules (electronic Common Technical Document (eCTD) v4.0) *to enable a modern and streamlined electronic submission process for human medicinal products in the EU*

Key changes

Simplification of specifications' maintenance

Streamlined & simplified process to correct and modify information

Re-use of submitted documents across applications

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Sequencing of epics

eCTD v4.0 SMEs working group established

Work completed

eCTD v4.0 Specification Review

EU IG and related documents update

Ongoing work

Pilot for CAPs

Optional use for CAPs

Pilot for non-CAPs

Future work *(What's next?)*

Mandatory use for CAPs

Optional use for non-CAPs

Mandatory use for non-CAPs

Future work *(What's later?)*

Acronyms

CAPs: Centrally Authorised Products

eCTD: electronic Common Technical Document

EU IG: European Union Implementation Guide

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eCTD v4.0 Business Value

- **Simplification of all lifecycle activities** including flexible implementation of new submission requirements or modifications of the granularity of presented contents
- Provision of **internationally harmonised common rules** to create and handle an electronic submission
- **Single electronic exchange message** for regulatory information complying to regulatory standards
- **Re-use/sharing of documents** across products and submissions
- Improved **quality** and **accessibility of data**
- Significant **reduction of maintenance effort** for submission management and reviewing tools

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Top 3 FAQs on eCTD v4.0

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1. eCTD v4.0 MANDATORY

- Timeline is made public regularly
- The **first step** will be the **pilot for CAPs**, which is planned for Q4 2024

2. WEBINARS/WORKSHOPS PLANNED FOR eCTD v4.0

- Product team is currently preparing a **Vendor workshop** that will take place in **Q1 2024**
- **Further webinars** will be planned before the **mandatory use for CAPs**

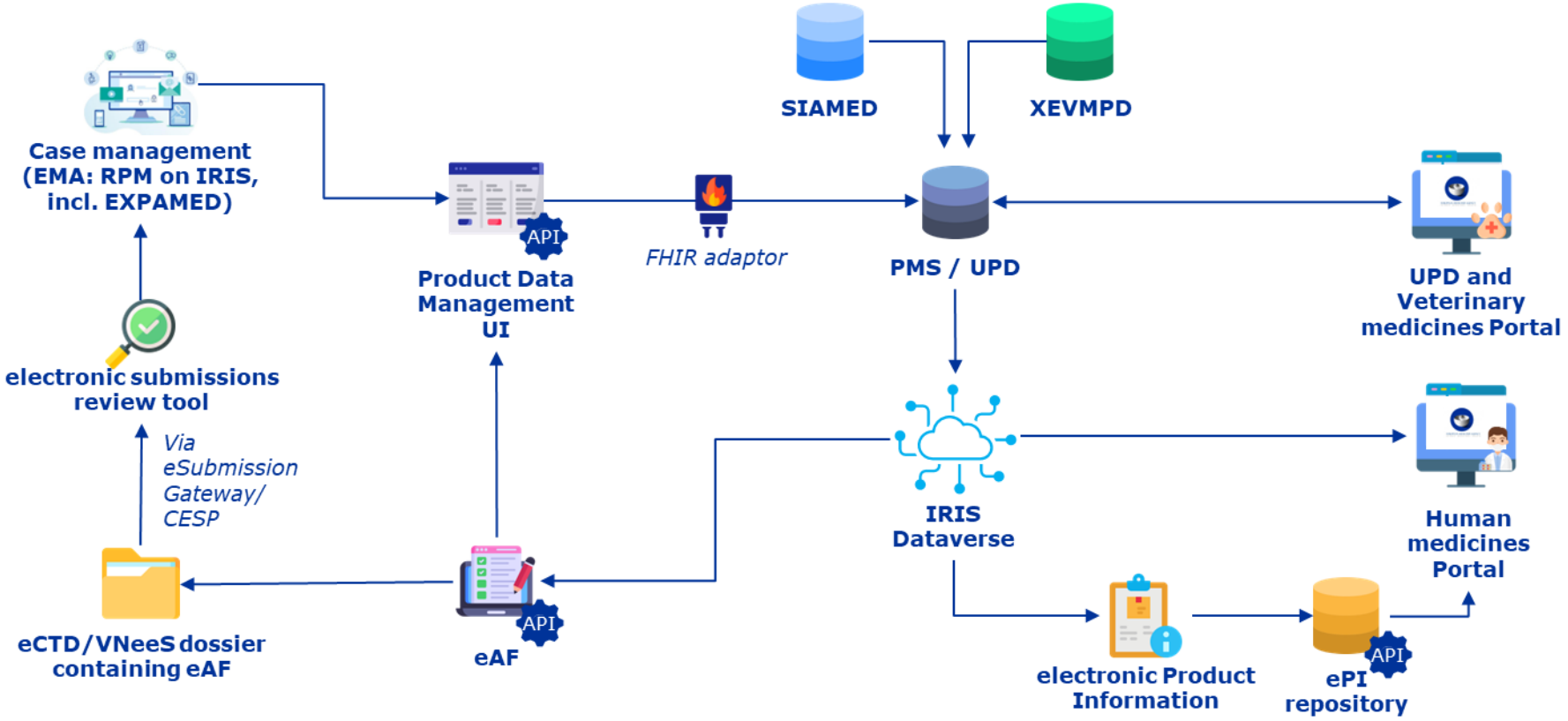
3. RE-USE OF DOCUMENTS

- **For CAPs, the re-use of docs will be accepted**
- For Non-CAPs special conditions might be applicable, options still under discussion

Focus on electronic Product Information (ePI)

Evinn Drusys, *ePI Network Product Owner*

Overview of Product Lifecycle Management activities



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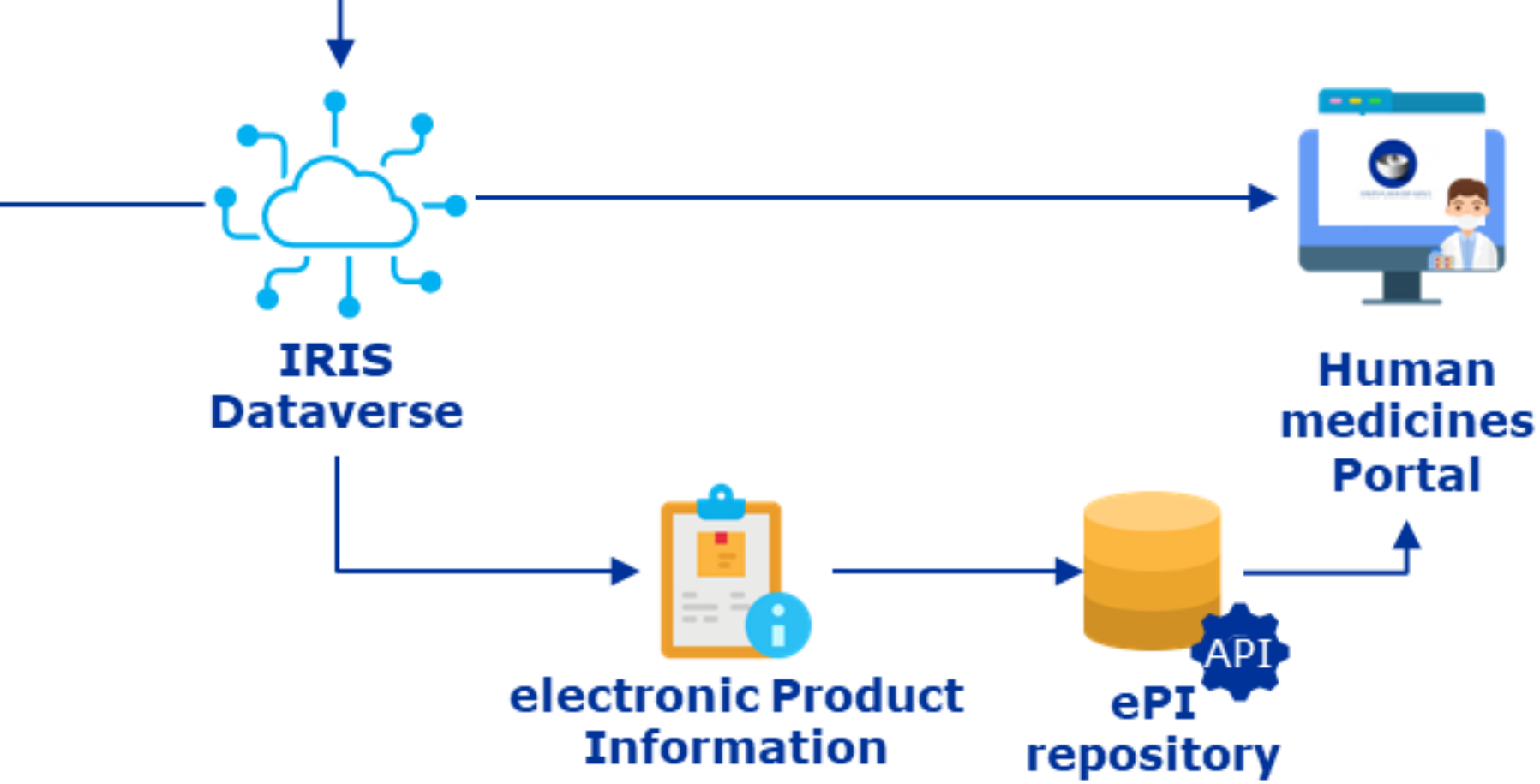
IRIS
Dataverse
Human
medicines
Portal
electronic Product
Information
API
ePI
repository

ePI vision & key changes

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Vision

*Make available **up-to-date and easily accessible, regulator-authorised electronic product information** on safe and effective use of human medicines in all available EU languages for all EU citizens*

Key changes

Harmonised ePI on medicines within EU

Product Information stored in FHIR and instantly available via API

Easier process to find ePI in different languages

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Sequencing of epics

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ePI Authoring Tool MVP

ePI publishing and consuming MVP

Work completed

Pilot for CAPs, NAPs, MRP and DCP

Ongoing work

ePI pre-implementation

Future work *(What's next?)*

ePI implementation

Future work *(What's later?)*

Acronyms

CAPs: Centrally Authorised Products

DCP: Decentralised Procedures

MRP: Mutual Recognition Procedures

MVP: Minimum Viable Product

NAPs: Nationally Authorised Products

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ePI Business Value

- **Up-to-date** Product Information **easily accessible** to partners & stakeholders
- **Easy ePI availability** of different medicinal products through the PLM portal and API
- Facilitate **distribution of information** according to consumers' needs
- **Information accessible** to consumers with diverse abilities
- **Quick and immediately visible online update** of Product Information

Top 3 FAQs on ePI

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1. ePI PILOT

- The ePI **pilot runs throughout July 2023 – July 2024** and will provide guidance for future development before implementation.
- Using a **Minimum Viable Product (MVP)**, it envisages the initial introduction of ePI at the beginning (creation of ePI prior to submission) and end (publication via API). **At a later stage, ePI can be integrated end-to-end into the procedure management.**
- The ePI team has created a **User Guide available on the PLM Portal**

2. ePI FUNCTIONALITIES

- The **MVP** consists of an **ePI authoring tool, repository and application programming interface**, and associated **guidance and business processes**. Functionalities include Rich text editing, Adding a co-author, Preview, Duplication of ePI documents, Export to Word, Export to FHIR, Publish via an application programming interface (API).

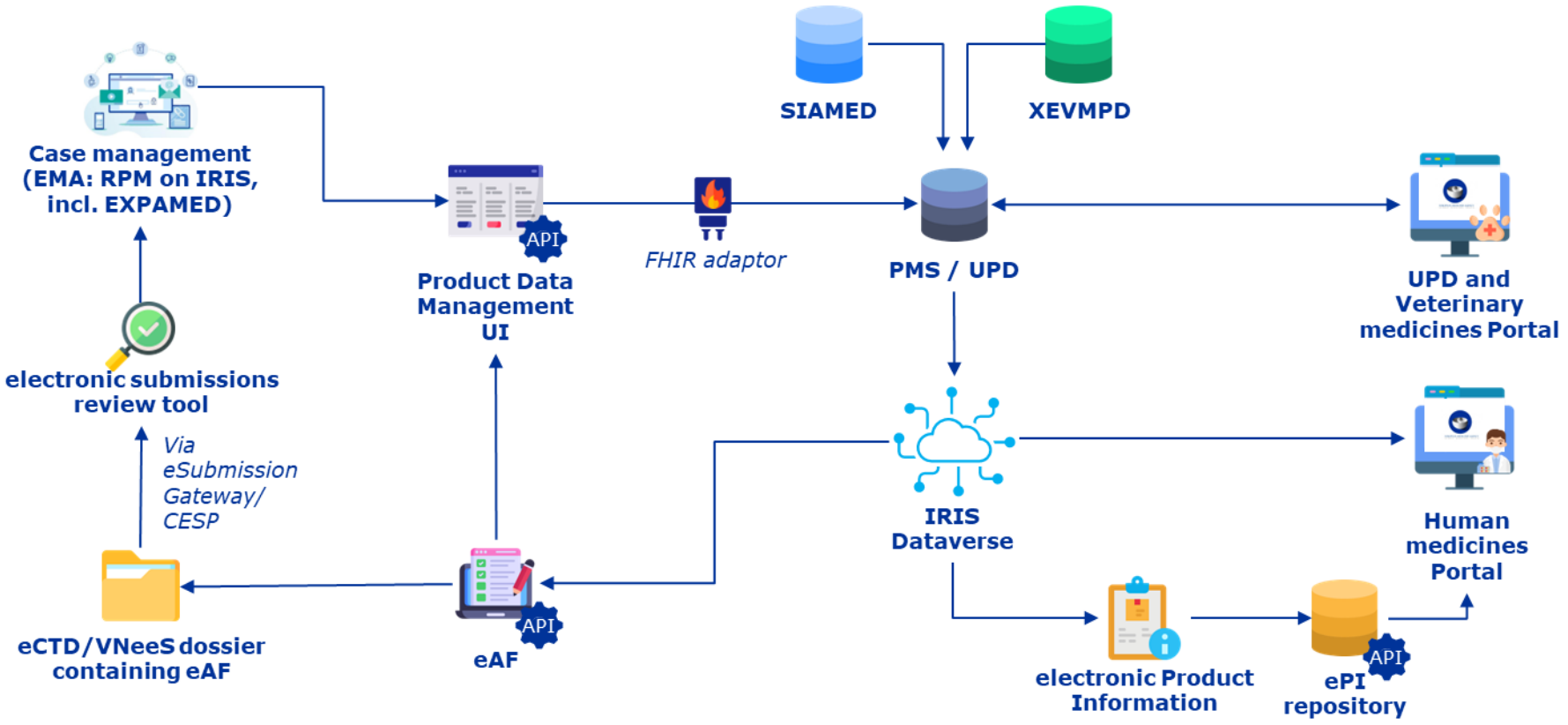
3. ePI LINK WITH SPOR & eAF

- In the MVP, **SPOR** is used for aspects such as product information section headings (RMS), marketing authorisation holder and competent authority (OMS). The objective is to fully maximise the use of SPOR data; in the MVP this will however not yet be the case. A stepwise approach is taken as per the Agile methodology.
- The objective is to **maximise the synergies with ePI and eAF**, which are part of the same Product Lifecycle Management value stream.

Focus on Regulatory Procedure Management (RPM) for PLM

Madalina Duta-Mare, *RPM for PLM EMA Product Owner*

Overview of Product Lifecycle Management activities



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Case management (EMA: RPM on IRIS, incl. EXPAMED)

Produc Manag

RPM for PLM vision & key changes

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Vision

*Enhance **end-to-end medicinal product lifecycle management in IRIS platform** for Centrally Authorised Products by improving efficiency, data quality and collaboration, thus facilitating easier and secure access to information.*

*It enables **consistency of data** in an end-to end information flow by **exchanging and reusing ISO IDMP data** across IT systems*

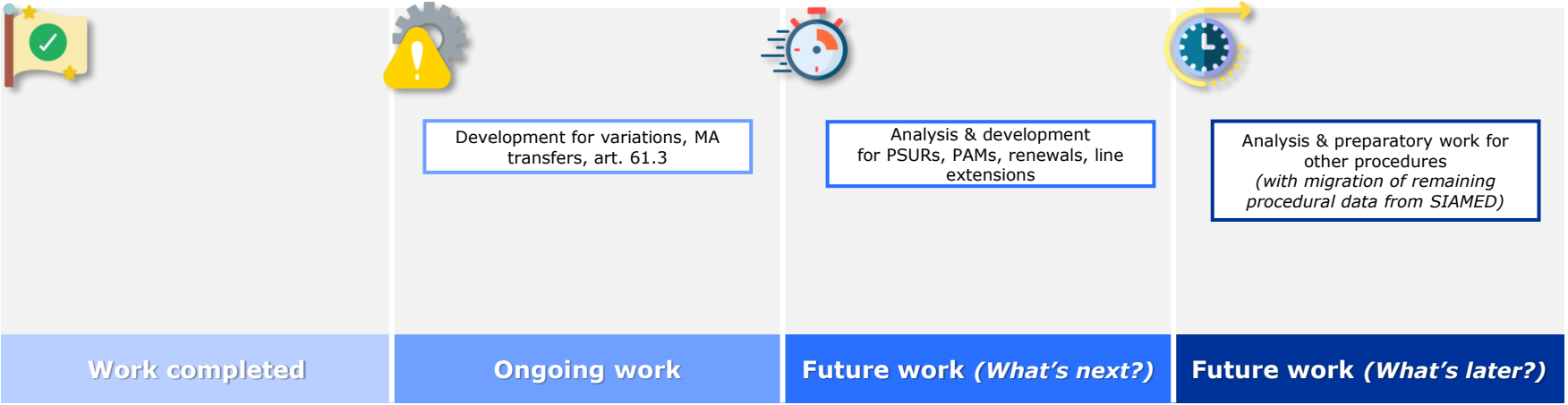
Key changes

New cloud-based technology

Standardised functionalities for Human and Vet & automated checks

Re-use of SPOR master data

Sequencing of epics



Acronyms

MA: Marketing Authorisation

PAMs: Post-Authorisation Measures

PSURs: Periodic Safety Update Reports

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RPM for PLM Business Value

- **Single process and system** with **standardised functionalities** for human and vet
- **Increased efficiency, optimised decision-making process and reduced number of errors** enabled by automation
- **Improved overall quality of data** ensured by the re-use of master data
- **Better collaboration** with NCAs enabled by more secure and improved collaboration tools to search, retrieve and share documents
- **Increased transparency and security** (consequently, reduced burden on e-mails to address queries)

Top 3 FAQs on RPM

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1. IRIS RELATIONSHIP WITH OTHER PORTALS

- IRIS will be used for the **entire product lifecycles enabled by the transitioned regulatory procedures**.
- Other functions, like eCTD/NeeS submission, will continue to be performed on separate portals.

2. PRODUCTS AFFECTED BY IRIS TRANSITION

- The transition to IRIS will **almost exclusively impact CAPs,** as IRIS is designed for managing regulatory procedures with EMA.
- However, a **small subset of NAPs' MRPs and DCPs** that are included in procedures overseen by EMA (e.g. worksharing, PSUSA). For these specific cases, NAPs will also be affected by IRIS.

3. NOTIFICATIONS MANAGEMENT

- Whenever the EMA provides MAHs with a document (e.g. assessment reports, opinions), the designated **contact person will receive an email notification**.
- This notification will serve as a general alert indicating the presence of new documents or information that require their attention. In general, this a pull system where information is available in the portal for the user to access at any time without necessarily waiting for a notification.

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Focus on Union Product Database (UPD)

Beyhan Mustafov, *UPD EMA Product Owner*

Overview of Product Lifecycle Management activities

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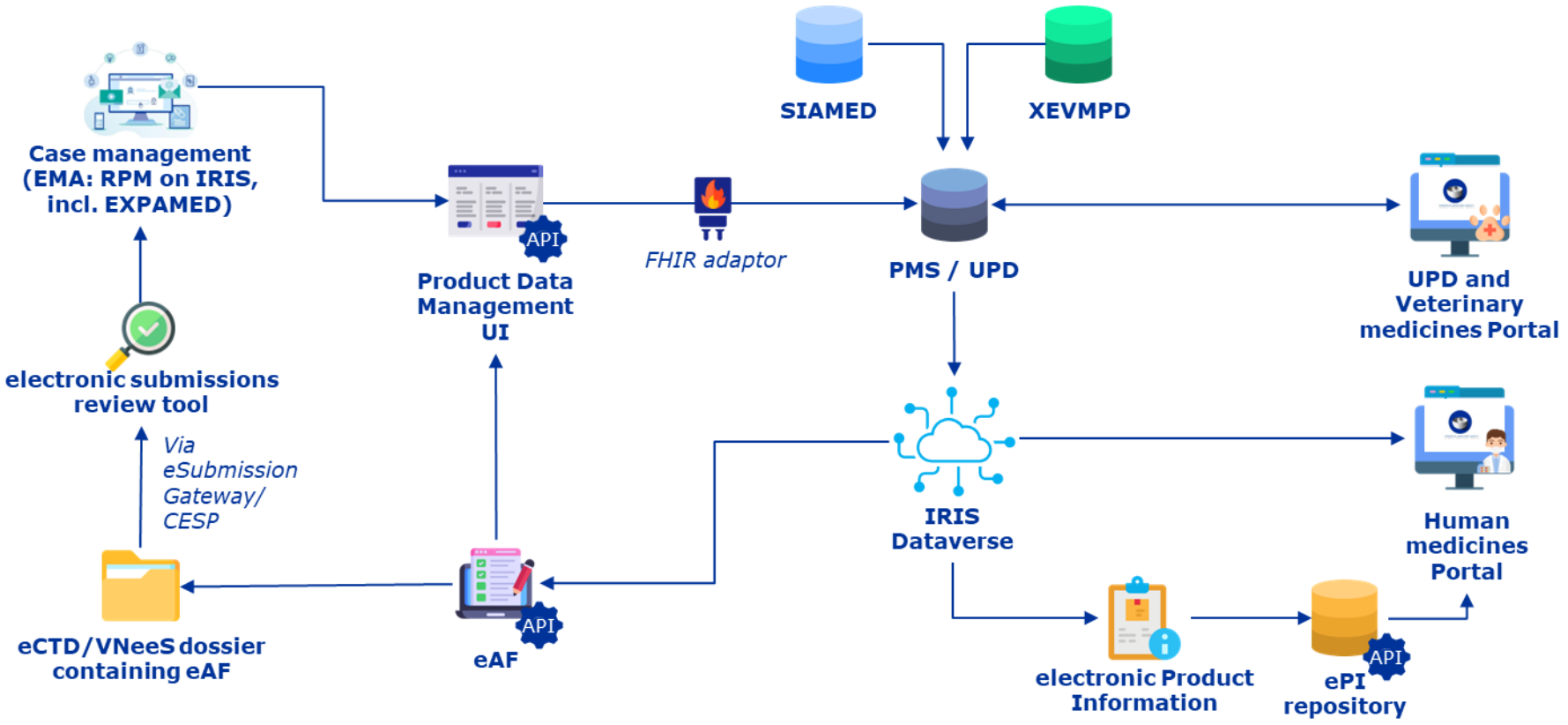

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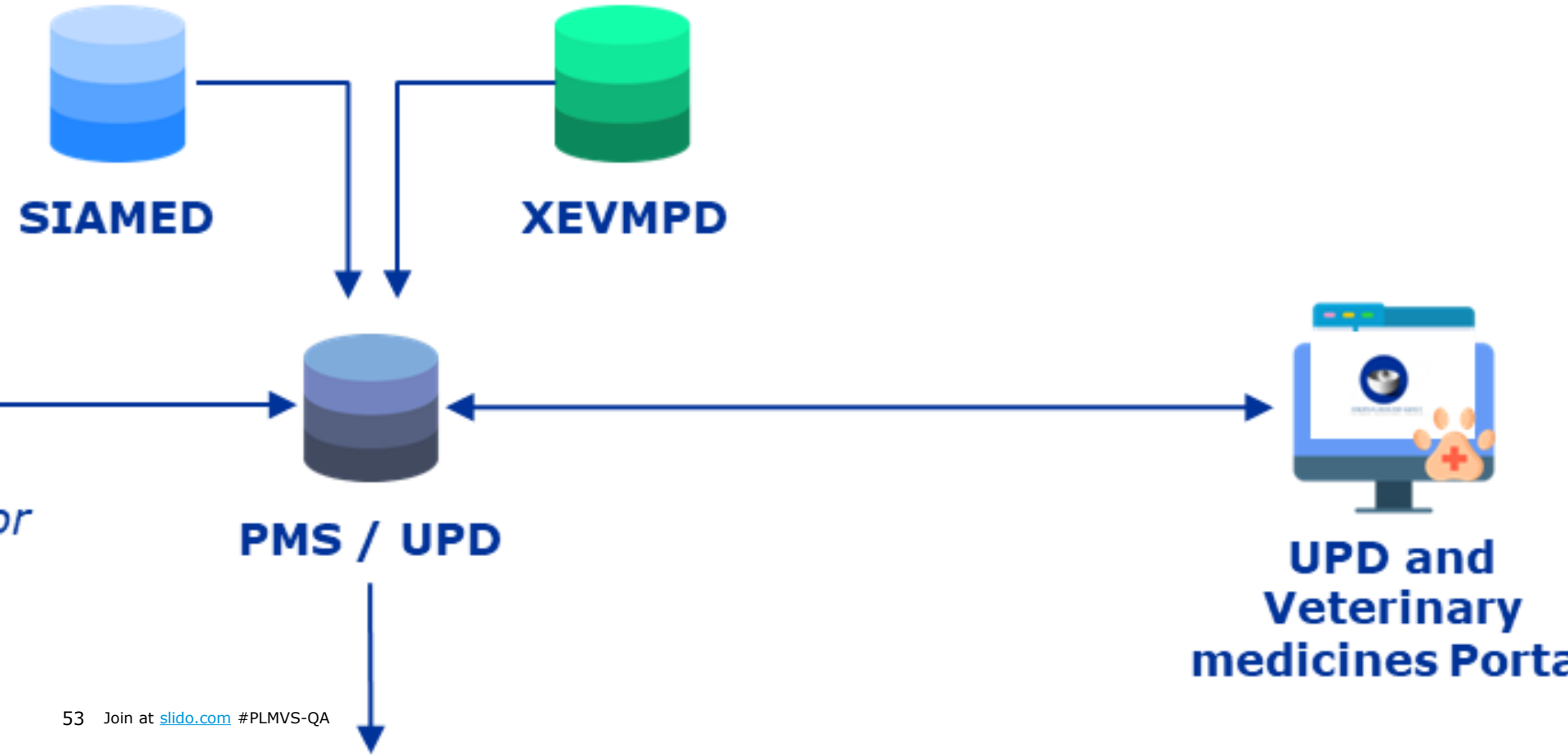
SIAMED
XEVMPD
PMS / UPD
UPD and
Veterinary
medicines Porta

UPD vision & key changes

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Vision

*The **Union Product Database (UPD)** provides a **single source of information for all veterinary medicinal products (VMPs) approved and available in the EU/EEA**, including management of specific regulatory activities e.g. variations not requiring assessment.*

*It is a **trusted, transparent and high-quality source for product data** used by all veterinary stakeholders.*

Key changes

Single source of product information on all VMPs

MAH submissions and NCA management of VNRAs

MAH reporting of Availability Status and Volume of Sales

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Sequencing of epics

Work completed	Ongoing work	Future work *(What's next?)*	Future work *(What's later?)*
UPD went live in 2022 and since then delivered over 90 post-go live business requirements and change requests	Ability to upload one document to several products Addition of Procedure number in all search forms Filters applied to Substances QPPV and PSMF information becoming part of national product data New fields in the VoS download file	Management of certain VNRAs affected by national data when impacting MRP/DCP/SRP **VNRA supergrouping**: • MAHs ability to define the foreseen decision maker during the submission process • Inclusion of Decision maker field in the results Notifications table and in the VNRA Submissions table • Make additional information available at submission level Enrich search criteria capabilities for search functionality in the UPD Portal	Save and resume draft VNRA submissions by a MAH Automatic sending of notifications (email notifications) API for MAHs and other EU organisations Provision of detailed information in the notification triggered by an update

Acronyms

DCP: Decentralised Procedure
EU: European Union
MAH: Marketing Authorisation Holder
MRP: Mutual Recognition Procedure
PSMF: Pharmacovigilance System Master File
QPPV: Qualified Person for Pharmacovigilance
SRP: Subsequent Recognition Procedure
VNRA: Variation not Requiring Assessment
VoS: Volume of Sales

IMPORTANT: this slide **DOES NOT represent timelines or sequencing of release** but pieces of work or events to be delivered and the impact on users.

UPD Business Value

- **Improved data quality** and consistency by using controlled vocabulary
- **Increased transparency** on VMPs available in EU/EEA
- **Use of UPD for variations** which do not require scientific assessment (VNRA)
- Database for **effective network collaboration**
- **Reduced administrative burden** on MAHs and NCAs
- Provision of **Volume of Sales data**, paramount for Antimicrobial Sales and Use reporting
- Provision of **Availability Status**
- **Interconnection with the Union Pharmacovigilance Database and Antimicrobials Sales and Use platform** (including the volumes of sales data)

Top 3 FAQs on UPD

EUROPEAN MEDICINES AGENCY

1. HOW TO REGISTER FOR UPD

Users with an **existing account for other EMA-hosted systems** (e.g. Eudralink, IRIS, SPOR) can use the same credentials, but will need to apply for the relevant UPD role(s) for their account on the EMA Account Management Portal. Users can check whether they already have an EMA account and get more info about **EMA SSO** (Single Sign-on) by visiting https://register.ema.europa.eu.

2. WHAT DATA SHOULD MAHs SUBMIT TO THE UPD

Marketing authorisation holders must **submit the following** to the Union Product Database:

- Volume of sales (VoS);
- Availability status of the product;
- Any changes to the authorisation status in case of suspension or revocation;
- Variations not requiring assessment;
- Third country product names;
- MAH product grouping (optional but recommended).

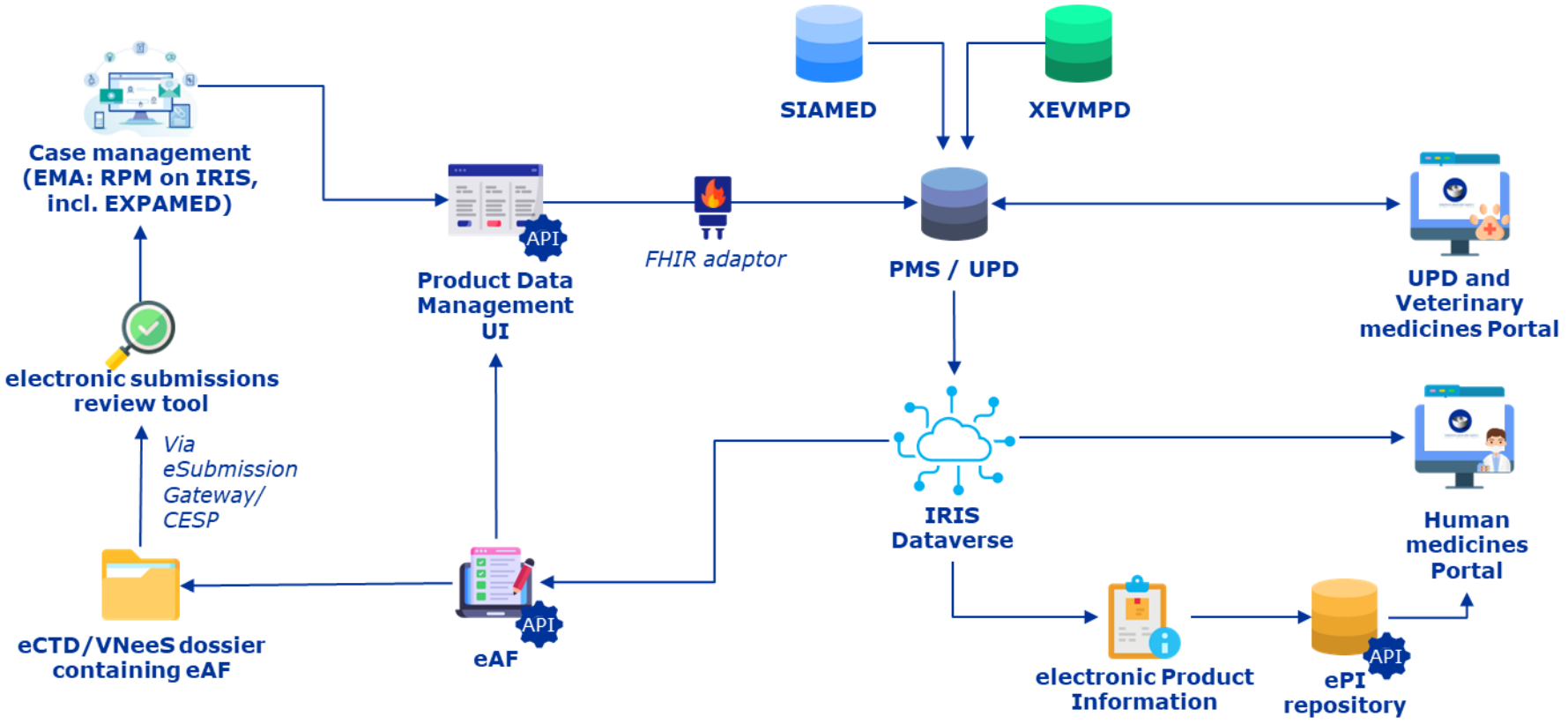
3. WHAT DATA SHOULD CAs SUBMIT TO THE UPD

Competent Authorities must **upload and maintain product information** into the UPD, using either an API or a web user interface.
It is paramount to ensure that the **data quality at product and package level in UPD is to highest possible standard.** This applies to all veterinary medicinal products authorised in the EU via mutual recognition, decentralised procedure, national procedure or centralised procedure.

Focus on EXPAMED

Michael Vogl, *EXPAMED EMA Product Owner*

Overview of Product Lifecycle Management activities



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Case management (EMA: RPM on IRIS, incl. EXPAMED)

Prod

EXPAMED vision & key changes

EUROPEAN MEDICINES AGENCY

Vision

*Enable the **assessment of the data** provided within the context of **Clinical Evaluation Consultation Procedure (CECP)** and **Performance Evaluation Consultation Procedure (PECP)** by both internal (EMA EXPAMED Secretariat) and external stakeholders (evaluators and notified bodies) through a **single Experts Management Tool**, in order to ensure an **end-to-end robust clinical evaluation** across the EU.*

Key changes

New system with updated technology and integrated tools

Single platform for communication and data repository

Improved accessibility with a single log-in

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EXPAMED Business Value

- **Increase of efficiency** thanks to manual tasks' reduction and less duplication of work
- **Improvement of User Experience** with user-friendly system functionalities
- **Improvement of the medical device experts' selection process** and their contracts and payments activities
- **Improvement of accessibility and data protection**
- **Increased transparency** of information

EXPAMED is live

The Expert panels on medical devices and in vitro diagnostic medical devices (EXPAMED) lifecycle management tool went live in IRIS, on 29 March 2023.

The new tool enables the collaborative assessment of the data provided within the context of the clinical evaluation consultation procedure (CECP) and performance evaluation consultation procedure (PECP) by both internal (EMA EXPAMED Secretariat) and external stakeholders (experts).

Top 3 FAQs on EXPAMED

EUROPEAN MEDICINES AGENCY

1. PRODUCTS HANDLED IN EXPAMED

The EXPAMED system is only handling **Medical Devices Class III implantable** or **Class IIb active devices** intended to administer or remove medicinal products

2. ENGAGEMENT OF EXPERTS

The **full internal procedure lifecycle for the CECP and PECP processes** mandated to be carried out by the expert panels is **handled in the system** – this includes the collaboration between the experts and the agency while drafting the output documents.

3. SUBMISSION OF INFORMATION

In the absence of EUDAMED, the information is submitted through the **European Commissions Secure system CIRCABC** to the Agency and transferred to the internal systems.

Conclusions and general questions

Ivo Claassen, *EMA Business Owner and Head of Veterinary Medicines*

Alexis Nolte, *EMA Business Owner and Head of Human Medicines*

Zaide Frias, *EMA Business Owner and Head of Digital Business Transformation*

Moderator: Joris Wiemer, *EMA Change Management Lead*

Agenda for this section

- Q&A (Slido)
- Words from our business owners
- A quick poll for your feedback (Slido)
- How to stay informed on PLM work

How to stay informed on PLM VS Work

EUROPEAN MEDICINES AGENCY

System Demos

- See and discuss the latest developments of the system
- Give your feedback on features and priorities

Announced via EMA's Website Events Pages

Network Portfolio web page

- Consult updated Network Portfolio roadmap
- Stay informed on Agile ceremonies

To be published on EMA Website & available for subscription

PLM Portal & IRIS Forums

- Check:
  - News
  - Release notes
  - Downtime comms
- Ask questions

Check regularly

Industry & Network SMEs

The Industry & Network SMEs are your connection to product development.

Engagement to be determined by NPO & SMEs

Closing

Karl Hamilton, *PLM Value Stream Owner, EMA*