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Update on IRIS Product Life Cycle Management roll-out - 12th Industry Stakeholder Platform

19 June 2024

Regulatory Procedure Management (RPM) for PLM – recap & plans for 2024-2025

Francisco Penaranda, H Lead Process Manager, EMA

Roadmap for 2024-2025

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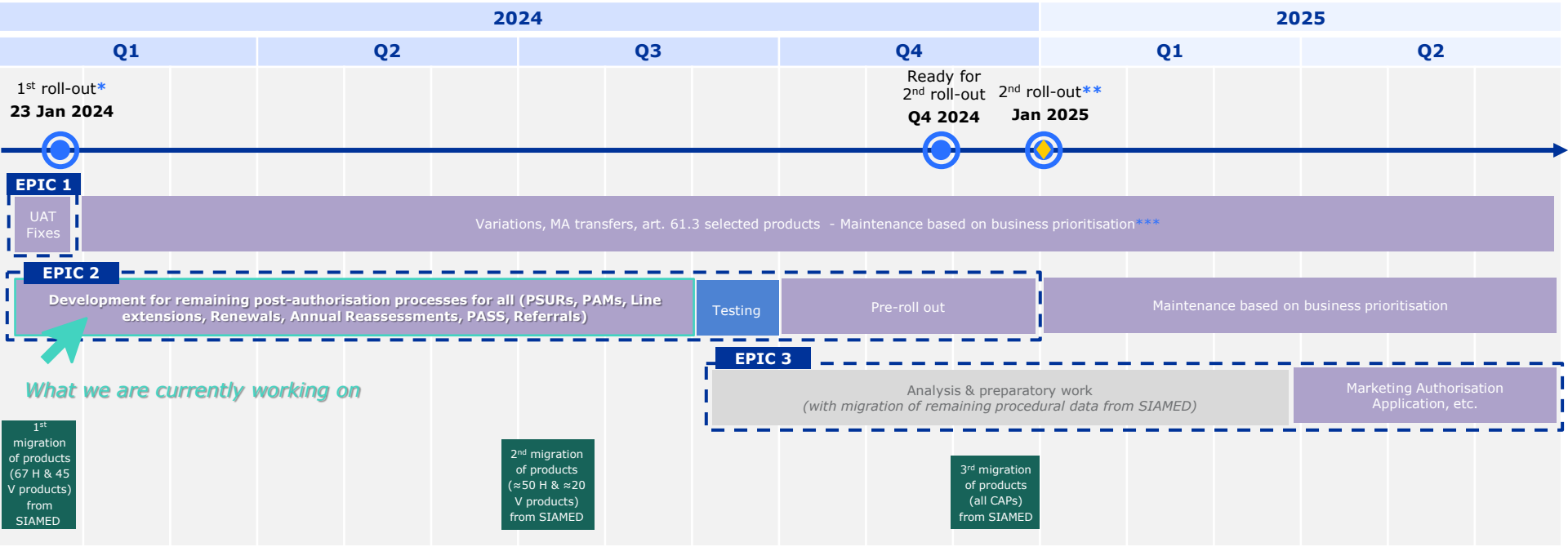

*for variations, MA transfers and Art 61.3 for subset of products (CAPs)

**with Post-authorisation processes in IRIS for all CAPs → all EMA-led post-authorisation processes will be managed in IRIS in 2025

***Please note the ongoing development of RPM will happen epic by epic, with incremental improvements across the entire regulatory procedure management landscape.

Acronyms

AVS: Assisted Validation System

CAPs: Centrally Authorised Products

CDP: Clinical Data Publication adaptor

MA: Marketing Authorisation

PAMs: Post-Authorisation Measures

PASS: Post-Authorisation Safety Study

PSURs: Periodic Safety Update Reports

UAT: User Acceptance Testing

Legend

Milestone

Development activities

Migration activities

UAT activities

Analysis & preparatory activities

New Fee Regulation

Key impacts for MAHs & actions

Madalina Duta-Mare, *Product Owner,* IRIS *Regulatory Procedure Management (PLM), EMA*

What stays the same for impacted MAHs working with RPM in IRIS

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What stays the same

- **MAH's submission and responses to RSI via eCTD/VNeeS submissions**
- **Timelines** and **active email notifications** on the main milestones of the submission (e.g. start of the procedure, requests for Supplementary information (RsI), Outcomes etc.
- Requests for **withdrawal of single scopes in grouped variations** (via email)
- Receipt of **European Commission Decision** (via Eudralink)
- **Content** of the documentation
- **Guarantee of confidentiality**

Key changes for Industry users

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Case number use

Format: {agency ID}/{process group type (case form)}/{unique case number (10digits)}

Examples: Human: EMA/**VR**/0000076556

Veterinary: EMA/**VRA**/0000076556

While the current format contains detailed information within the procedure numbers, IRIS offers this **visibility through dashboards and views** within the system

EMA communication format

- **Emails sent from EMA** to the Industry portal contact contain **basic administrative information** on the submissions and the link to the IRIS industry portal *(no Eudralinks or attachment in the emails).*
- Emails from EMA IRIS will always come from EMA-IRIS@id.ema.europa.eu and contain a routing ID.
- During the procedure, the **document exchange** (outside eCTD/ VNeeS) takes place via **IRIS Industry portal**, relevant for **CAP** and **NAP MAHs** (in case of EMA led procedures, e.g. **PSUSA NAP**)

MAH Contact person

- The **MAH contact person for CAPs** - user stated in MAA eAF section 2.4.3 - for the product, by default becomes **portal contact and submission manager** in IRIS for the procedure

Lead product for Worksharing procedures

- For WorkSharing procedures in the Cover letter, the MAHs are requested to **indicate the "Lead product"** within the procedure in order to:
  - ✓ assign the correct Industry portal contact
  - ✓ set up a lead MAH for payment-related activities

Procedure withdrawal

- Procedure withdrawal (whole procedure) to be requested via **Industry Portal**

Communication with CAP MAHs for procedures

EMA-led procedures managed in IRIS will include **CAPs**.

MAHs have the obligation to indicate a **product contact** for communication between EMA and the MAH (see Notifying EMA of changes to contact persons)

- The product contact person will be used for as default contact communication regarding the IRIS case.
- At their end, the contact person for the MAH will receive a notification and will be able to view the case data and collaborate with EMA for documents exchange.
- The contact can also add other users to view/collaborate and can change the contact person in the portal, for a specific case.

Communication with non-CAP MAHs for procedures containing NAPs

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EMA-led procedures managed in IRIS will include **Nationally Authorised Products (NAP/MRP/DCP) for PSUR, PASS and Referrals**.

MAHs will be requested to **indicate a contact person** for those procedures:

- The contact person will be used for communication regarding the IRIS case.
- At their end, the contact person for the MAH will receive a notification and will be able to view the case data and collaborate with EMA for documents exchange.
- The contact can also add other users to view/collaborate and can change the contact person in the portal, for a specific case.

Action required for Industry by the end of 2024

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1 *MAHs to be registered on OMS*

2 *MAHs products contact person for Post-authorisation procedures has EMA account* ***(CAP and NAP MAHs)***

How to request access? Via the EMA Account Management System for all affiliated roles.

Instructions are available in the IRIS guide to registration and RPIs. *It is crucial that all new submissions in IRIS created from CRM for PLM procedures reaches the correct portal contacts.*

3 *Update product contact information*

Generic mailboxes are not supported for contact points:

MAHs to submit an **updated form** to **change all product contacts to personal emails**.

→ Instructions to submit the form **here**

What is IRIS replacing

Tools that IRIS will replace

From

- *Eudralink*
- *Emails with attachments*

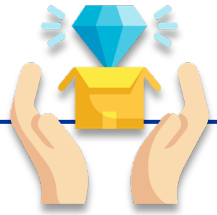
To

- *Industry Portal*
- *Emails without attachments*

Key benefits of the change

→ Improved communication & transparency

→ Real-time insights into case



PLM Value Stream Portals & Services

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PLM Portal

Web-based eAF

PMS UI/API

ePI

eSubmission

electronic submissions review tool

Gateway

SPOR

PMS data (H Medicines)

UPD

UPD data (V Medicines)

IRIS

Regulatory Procedure Management

EXPAMED

H Medicines Web Portal

(to be developed)

V Medicines Web Portal

Procedure management platforms to use & when

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		Procedure Management Platform	
		SIAMED	**IRIS**
Product type	***January migrated CAPs***	Procedures submitted until 22 January 2024	Procedures submitted from 23 January 2024
	July migrated CAPs	Procedures submitted until 30 June 2024	Procedures submitted from 1 July 2024
	All other CAPs	Procedures submitted until 31 December 2024	Procedures submitted from 1 January 2025

NOTE: *Submission of all regulatory procedures of the product lifecycle will still be performed via the current systems (i.e. Gateway and PSUR repository)*

Next steps

Coming up

Public System Demos – *26 Jun 2024, end of Sep 2024, Dec 2024*

Training session for MAHs - *November 2024*

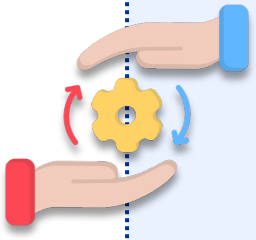
User guide & FAQ update - *November 2024*

Q&A Clinics - *Q1 2025*

Q&A

Annex

Where we are after the 1st roll-out



- **1st roll-out** of Variations, Art. 61.3 Notifications, Marketing Authorisation Transfers on IRIS took place on **23 January 2024**
- For the first transition to IRIS, EMA has selected a **subset of medicinal products: *67 human generic products*** *out of 150 (renewed MA generics) and* ***45 veterinary products***
- This impacts the Industry users from Marketing Authorisation Holders (MAHs) with selected products, as they **need to access IRIS** to:
  - view case status
  - withdraw a case
  - update case contacts/ contributors/ managers
  - retrieve documents sent by EMA and submit non-eCTD(NeeS) documents.

Key next development steps

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July 2024

Migration of additional human & veterinary products to IRIS with low regulatory complexity (for Variations, MA transfers, art. 61.3)

September 2024

External user Acceptance testing with Industry & Network Subject Matter Experts (for Epic 2 procedures)

Q4 2024

Migration of all remaining CAPs to IRIS

January 2025

2nd roll-out with all post-authorisation processes and related workload

How EMA is supporting the change

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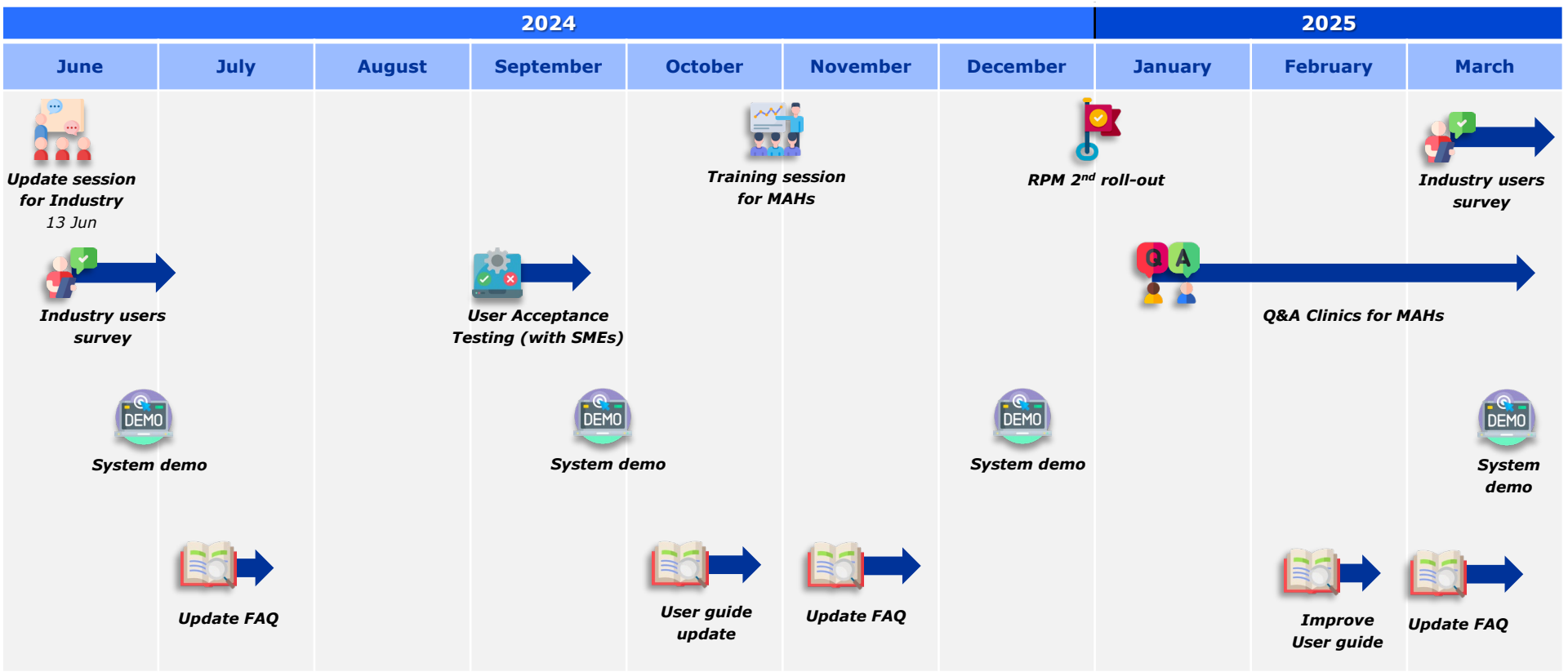

! Please note dates will be confirmed in due time

Useful resources for Industry IRIS users for RPM

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IRIS Forum: find latest news of RPM for PLM and post your questions

Industry FAQ Document: find general frequently asked questions on RPM transition to IRIS

User Guide for applicants: find specific instructions to use IRIS for transitioned procedures

IRIS email: ask specific questions on IRIS use