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SCIENCE MEDICINES HEALTH

Update webinar on Regulatory Procedure Management for Product Lifecycle Management on IRIS

13 June 2024, 10:00 – 11:30 Central European Summer Time (CEST)
Webex Webinar

Housekeeping

*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**.*

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Agenda

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1	**Welcome** 10:00 – 10:05	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*
2	**Progress & roadmap of RPM for PLM transition to IRIS** 10:05 – 10:15	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*
3	**Key impacts and actions on pharmaceutical industries** 10:15 – 10:25	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*
4	**Periodic Safety Update Reports (PSURs)** 10:25 – 10:35	**Sara Santos** *Regulatory Procedure Management for PLM Subject Matter Expert*
5	**IRIS Industry Portal Demo** 10:35 – 10:50	**Sara Santos** *Regulatory Procedure Management for PLM Subject Matter Expert*
6	**Next Steps** 10:50 – 10:55	**Sara Santos** *Regulatory Procedure Management for PLM Subject Matter Expert*
7	**Q&A Session** 10:55 – 11:25	**Moderator:** **Caterina Scarpati** *Regulatory Procedure Management for PLM Change Management Team*
8	**Closing** 11:25 – 11:30	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*

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

Progress and roadmap of Regulatory Procedure Management (RPM) for Product Lifecycle Management (PLM) transition to IRIS

Madalina Duta-Mare, *Regulatory Procedure Management for PLM Product Owner*

EMA's approach to transferring procedures to IRIS

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Stage 1 *(2018-2021)*

- Learning to use IRIS (Microsoft dynamics)
- Transfer relatively standalone procedures

Stage 2 *(2022-2025)*

- Move **post-authorisation** procedures to IRIS in a controlled manner to have a system ready for new fee regulation in 2025

*Variations, Art 61.3, Transfers, PSURs, PAMs, Line extensions, Renewals, Annual Reassessments, PASS, Referrals**

Stage 3 *(2025 onwards)*

- Move **marketing autorisation application** procedure to IRIS
- Integrate necessary changes: improvements, create new opportunities for efficiency
- Integrate regulation & improve

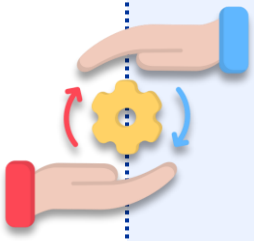
A controlled transition

Procedures will be developed and transitioned in phases in a lean and simple way and in the shortest possible time. This will:

- Enable a gradual **learning curve** & **evolve with users' feedback**
- Enable **incremental migration of procedural data** starting from products with lower regulatory complexity
- Allow to **meet new fee regulation implementation** deadline (Jan 2025)

*note: Development started with the lifecycle procedures to enable processing of high number submissions such as variations

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

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

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Roadmap for 2024-2025

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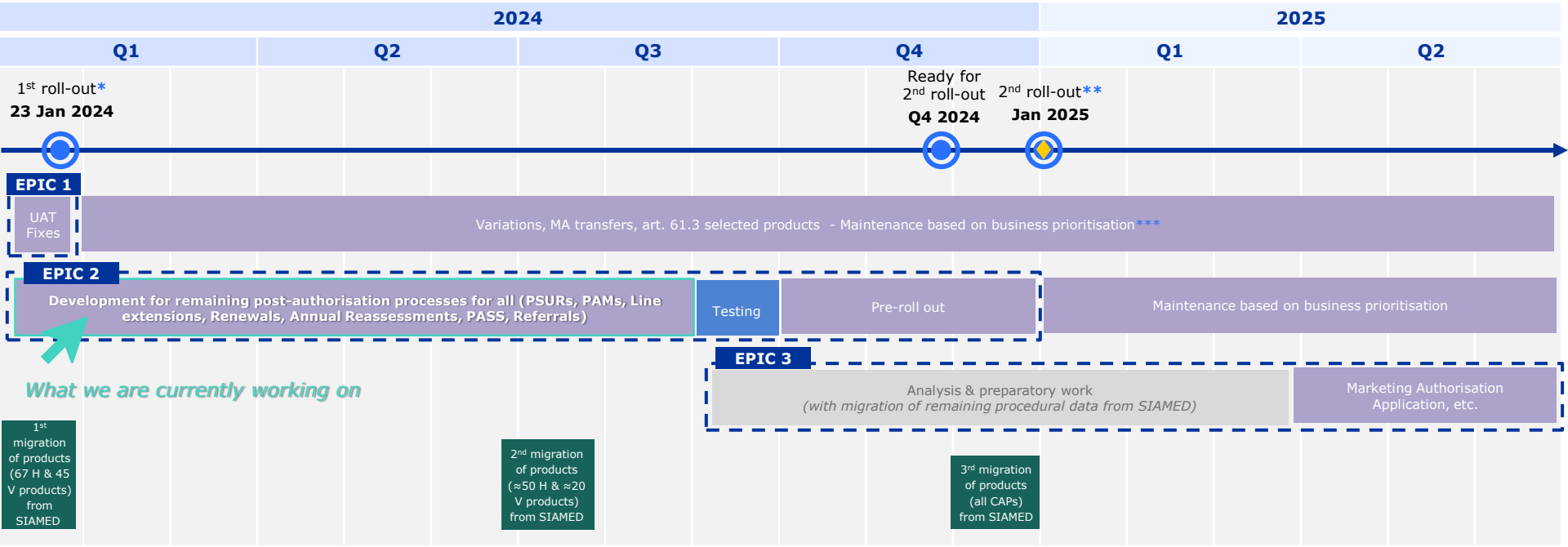

*for variations, MA transfers and Art 61.3 for subset of products (CAPs)

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 and actions on MAHs

Madalina Duta-Mare, *Regulatory Procedure Management for PLM Product Owner*

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**

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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**/0000076559

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**

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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 in 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**

Procedure management platforms to use & when

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Product type	Procedure Management Platform	
	SIAMED	**IRIS**
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)*

Periodic Safety Update Reports (PSURs)

Sara Santos, *Regulatory Procedure Management for PLM SME*

Key changes for PSURs

#	Process step	Scope	Change
1	(pre)Submission	NAP	• Submission of PSUR via the Submission Gateway/PSUR repository remains unchanged. • IRIS will be the case management system. Both CAP and NAP submissions are recorded in IRIS for PSUR procedures handled by the EMA. • There is a need that all NAP products are registered in PMS as IRIS sources NAP product data from PMS.
2	(pre)Submission	CAP, NAP	A EURD entity is linked to the case which includes relevant details of the EURD list
3	(pre)Submission	CAP, NAP	Pharmacovigilance fee system will source procedure start date from IRIS instead of SIAMED and PSUR Filemaker.
4	Evaluation/ Outcome	CAP, NAP	Any document related to the PSUR (e.g. preliminary AR, outcome documents) is shared with MAH via IRIS Industry Portal (rather than Eudralink)
5	Outcome	CAP, NAP	The final version of the AR is uploaded in the PSUR repository for record keeping.

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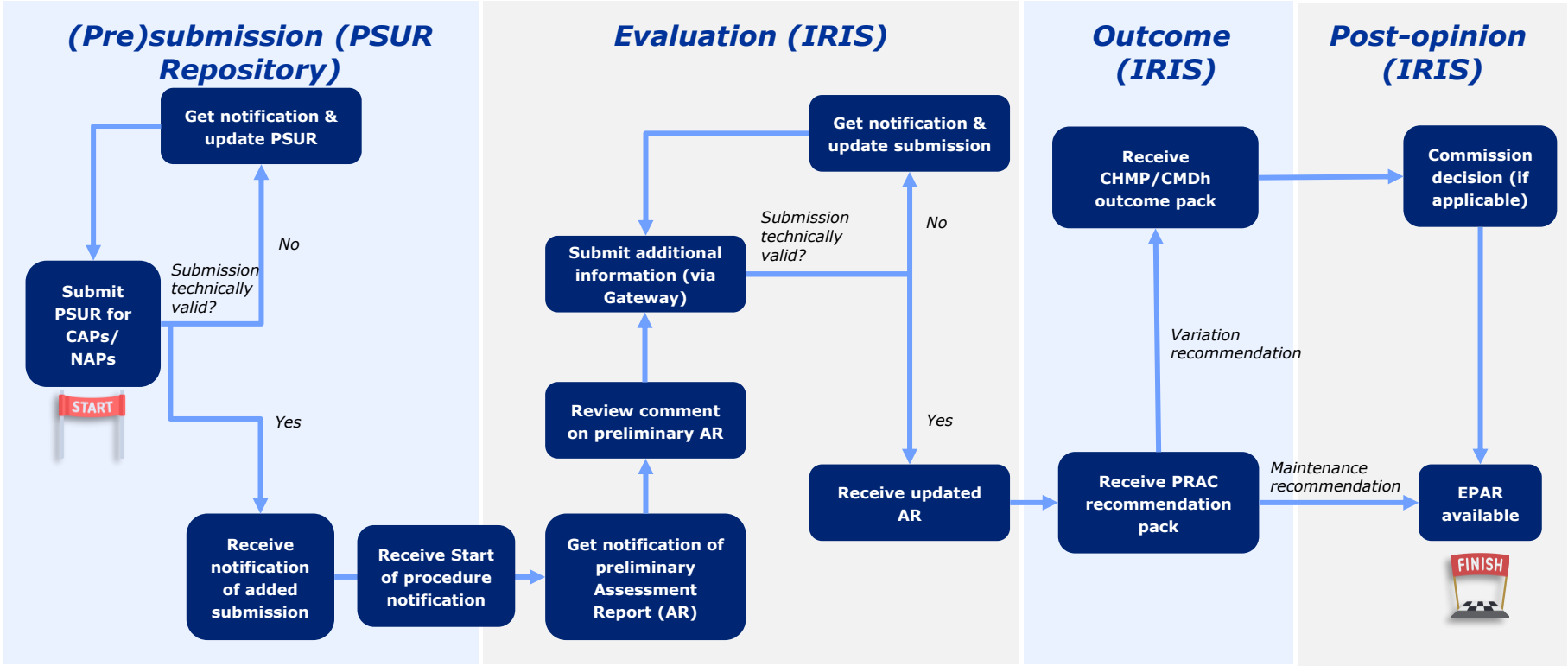
PSUR Process flow for MAHs



IRIS Industry Portal Demo

Sara Santos, *Regulatory Procedure Management for PLM SME*

IRIS Industry Portal: Demonstration

Live Demonstration

Next steps

Sara Santos, *Regulatory Procedure Management for PLM SME*

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*

How EMA is supporting the change

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2024							2025		
June	July	August	September	October	November	December	January	February	March
Update session for Industry *13 Jun*				***Training session for MAHs***		***RPM 2nd roll-out***			***Industry users survey***
Industry users survey			***User Acceptance Testing (with SMEs)***				***Q&A Clinics for MAHs***		
System demo			***System demo***			***System demo***			***System demo***
	Update FAQ			***User guide update***	***Update FAQ***			***Improve User guide***	***Update FAQ***

Please note dates will be confirmed in due time

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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

Q&A Session

Moderator: Caterina Scarpati, *RPM for PLM Change Management Team*

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Audience Q&A Session

ⓘ Start presenting to display the audience questions on this slide.

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Please fill in the survey

ⓘ Start presenting to display the poll results on this slide.

Closing

Madalina Duta-Mare, *Regulatory Procedure Management for PLM Product Owner*

Further information

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