EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

13 February 2024, 10:00 – 11:30 Central European Time (CET)
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**.*

*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.*

Agenda

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1	**Welcome** **10:00 – 10:05**	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*
2	**Progress of Regulatory Procedure Management (RPM) for PLM transition to IRIS** **10:05 – 10:15**	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*
3	**RPM roadmap** **10:15 – 10:20**	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*
4	**1st roll-out impacts on pharmaceutical companies** **10:20 – 10:30**	**Simona Griniene** *Regulatory Procedure Management for PLM Subject Matter Expert*
5	**IRIS Industry Portal Demo** **10:30 – 10:45**	**Sonja Nolte** *Regulatory Procedure Management for PLM Subject Matter Expert*
6	**Next Steps** **10:45 – 10:50**	**Simona Griniene** *Regulatory Procedure Management for PLM Subject Matter Expert*
7	**Q&A Session** **10:50 – 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 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 Initial MA procedure to IRIS
- Integrate necessary changes: build improvements, create new opportunities for efficiency
- Integrate regulation & improve

A controlled transition

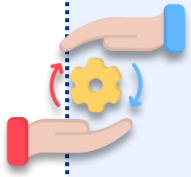
Procedures will be developed and transitioned in phases in a lean and simple way and in the shortest possible time. This will:

- 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

For questions: www.slido.com Code: #RPMUPDATE

Focus on 1st roll-out & next steps



- **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* ***44 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.

Next Steps:

- **Additional functionalities** will be incrementally released.
- By Q4 2024, **all post-authorisation processes will be managed on IRIS** impacting **all MAHs with Centrally Authorised Products (CAPs)**

RPM Roadmap

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

Regulatory Procedure Management for PLM Timeline (January 2024)

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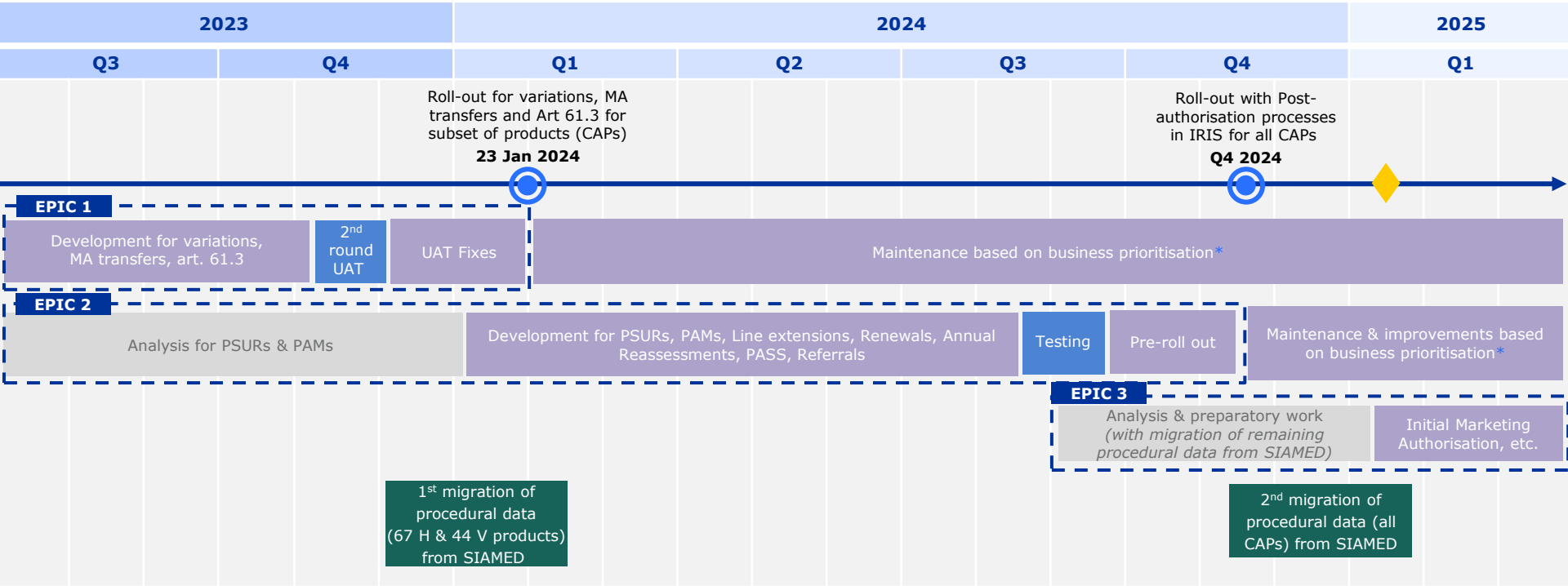

Please note the ongoing development of RPM will happen epic by epic, with incremental improvements across the entire regulatory procedure management landscape.

Acronyms

CAPs: Centrally Authorised Products
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

1st roll-out impact on pharmaceutical companies

Simona Griniene, *Regulatory Procedure Management for PLM SME*

What is changing for impacted MAH users after 1st roll-out (1/3)

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MAH Contact person

- The MAH contact person - 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** to:
  - receive all EMA notifications/emails on the submission;
  - access the submission in the IRIS Industry Portal and follow the case until closure;
  - change the submission contacts and add users as managers/ contributors to access/ modify submission
- **Only individual email address** of the MAH contact person is accepted in IRIS. Generic emails (e.g. regulatory@namecompany.com) are not accepted.

  ! *Auto-forward rules can be set up within every organisation*
- Several **other IRIS roles can be assigned** within the organisation with different access roles (IRIS eAF Industry User Admin, manager, contributor, coordinator)

What is changing for impacted MAH users after 1st roll-out (2/3)

EMA Communication and document exchange format

Emails sent from EMA to the Industry portal contact will 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.
! When answering, it is important not change the heading of the email.

During the procedure, the document exchange (outside eCTD/ VNeeS) will take place via IRIS Industry portal, where the Industry user:

- directly uploads documents in the "**Input from industry**" subfolder available within every submission
  ! EMA receives automatic notification once the document is uploaded by the Industry user
- accesses documents uploaded by EMA in the "**Output from EMA**" subfolder available within every submission
  ! Industry portal contact receives automatic notification once the document is uploaded by EMA

*Information on **submission outcome*** will be **visible in the IRIS Industry Portal** under "Outcome" along with the documents in the "Output from EMA" subfolder.

For questions: www.slido.com Code: #RPMUPDATE

What is changing for impacted MAH users after 1st roll-out (3/3)

Lead product indication 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 as explained in Slide 10
- set up a lead MAH for payment related activities

Procedure withdrawal

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

What stays the same for impacted MAHs after 1st roll-out

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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** (via email)
- Receipt of **European Commission Decision** (via Eudralink)
- **Content** of the documentation
- **Guarantee of confidentiality**

IRIS Industry Portal Demo

Sonja Nolte, *Regulatory Procedure Management for PLM SME*

IRIS Industry Portal post- 1st roll-out: Demonstration

Live Demonstration

Next steps

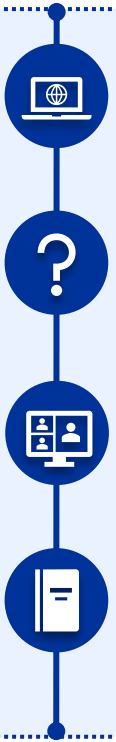
Simona Griniene, *Regulatory Procedure Management for PLM SME*

Next actions for MAHs

For all MAHs with CAPs:

- Please request access as an IRIS Industry user via the EMA Account Management System
- For instructions, refer to sections 5 & 6 of the IRIS guide to registration, substances and Research Product Identifiers

Next Steps



Public System Demo - *26 March 2024*

Q&A Clinics - *Q2 2024*

Training for MAHs with CAPs - *Q2 to Q4 2024*

User guide update - *Q2 to Q4 2024*

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*

Closing

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

Further information

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