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SCIENCE MEDICINES HEALTH

Regulatory Procedure Management for Product Lifecycle Management on IRIS – Overview for Industry

July 2024

An agency of the European Union

Roadmap for 2024-2025

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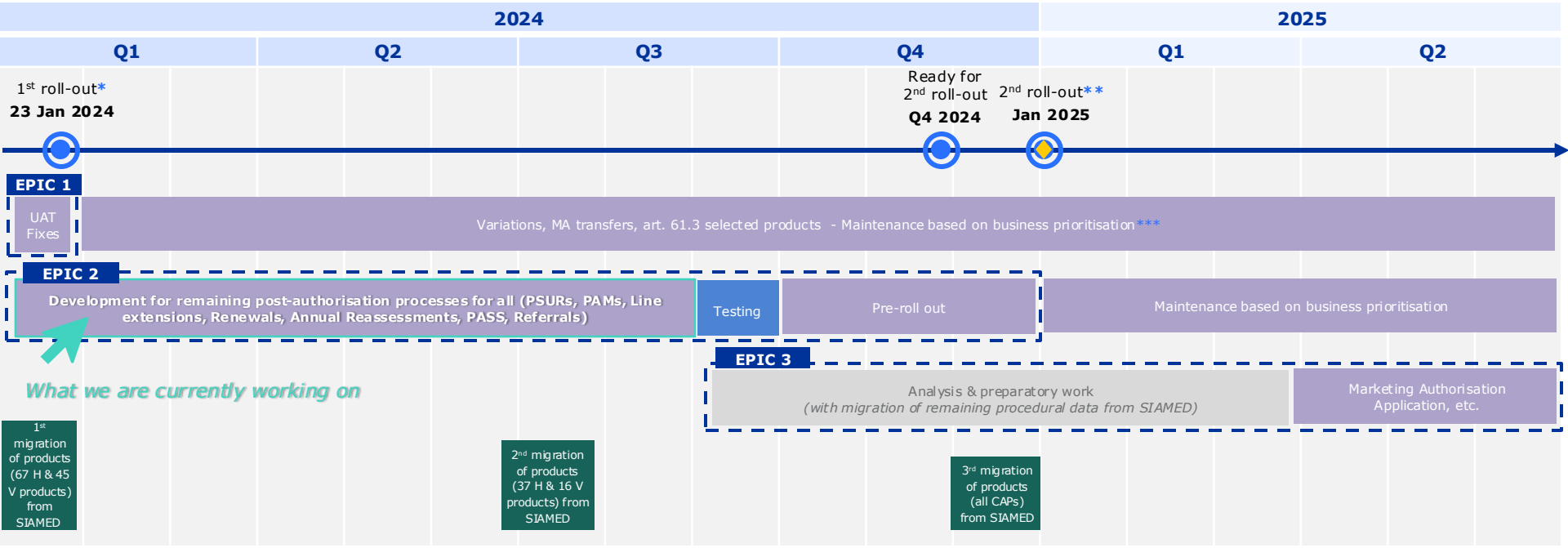

*for variations, MA transfers and Art 61.3 for subset of products (CAPs)

with Post-authorisation processes in IRIS for all CAPs (and involved NAPs) → **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
MA: Marketing Authorisation
NAPs: Nationally Authorised Products
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 next development steps

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)*

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**

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

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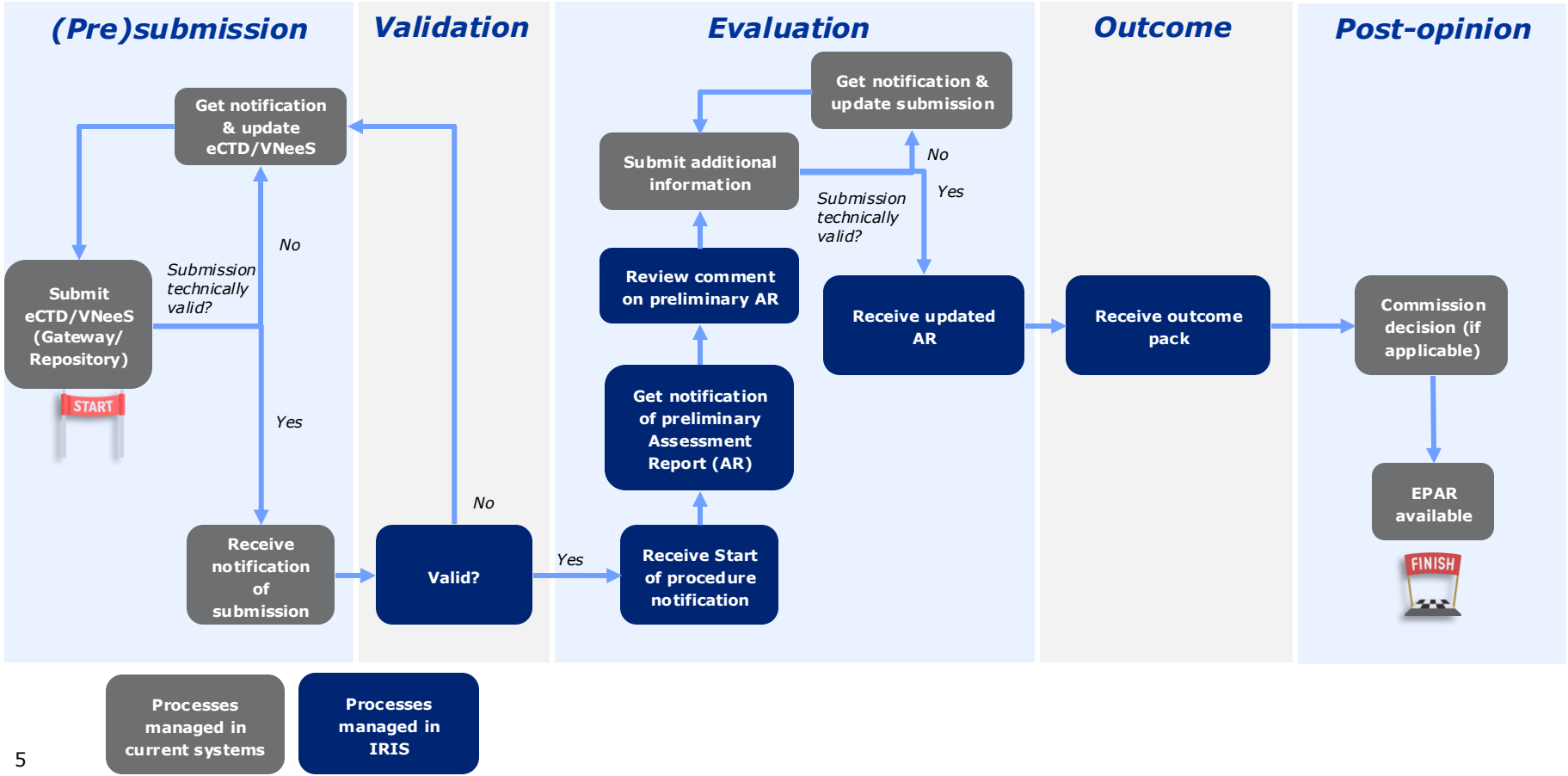
What stays the same

- **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**

General RPM process flow for MAHs



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** **(Human) and** **here** **(Veterinary)**

How EMA is supporting the change

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