EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Technical Webinar: Regulatory Procedure Management for PLM in IRIS for Network Users

Agile Value Stream:
Research & development
Product lifecycle management
Monitoring
Managing the Agency
Technology Lifecycle Management & Information Security

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** 14:00 – 14:05	**Ramona Zemache** *Customer Portfolio Analyst*
2	**Regulatory Procedures Management Product** 14:05 – 14:10	**Madalina Duta-Mare** *Regulatory Procedure Management for PLM Product Owner*
3	**Context Diagrams** 14:10 – 14:15	**Ashish Sonwalkar** *PLM Domain architect*
4	**Data flows** 14:15 – 14:30	**Ashish Sonwalkar** *PLM Domain architect*
5	**Q&A Session** 14:30 – 14:50	**Moderator: Ramona Zemache** *Customer Portfolio Analyst*
6	**IRIS Platform** 14:50 – 15:00	**Carlos Felipe Hernandez Arques** *IRIS Platform Architect*
7	**IRIS Platform dimensions** 15:00 – 15:45	**Rob Van Buren** *Managing consultant* **Carlos Felipe Hernandez Arques** *IRIS Platform Architect*
8	**Q&A Session** 15:45 – 15:55	**Moderator: Ramona Zemache** *Customer Portfolio Analyst*
9	**Closing** 15:55 – 16:00	**Simona Griniene** *Regulatory Procedure Management for PLM Subject Matter Expert*

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

Background

Regulatory Procedure Management for PLM Timeline (January 2024)

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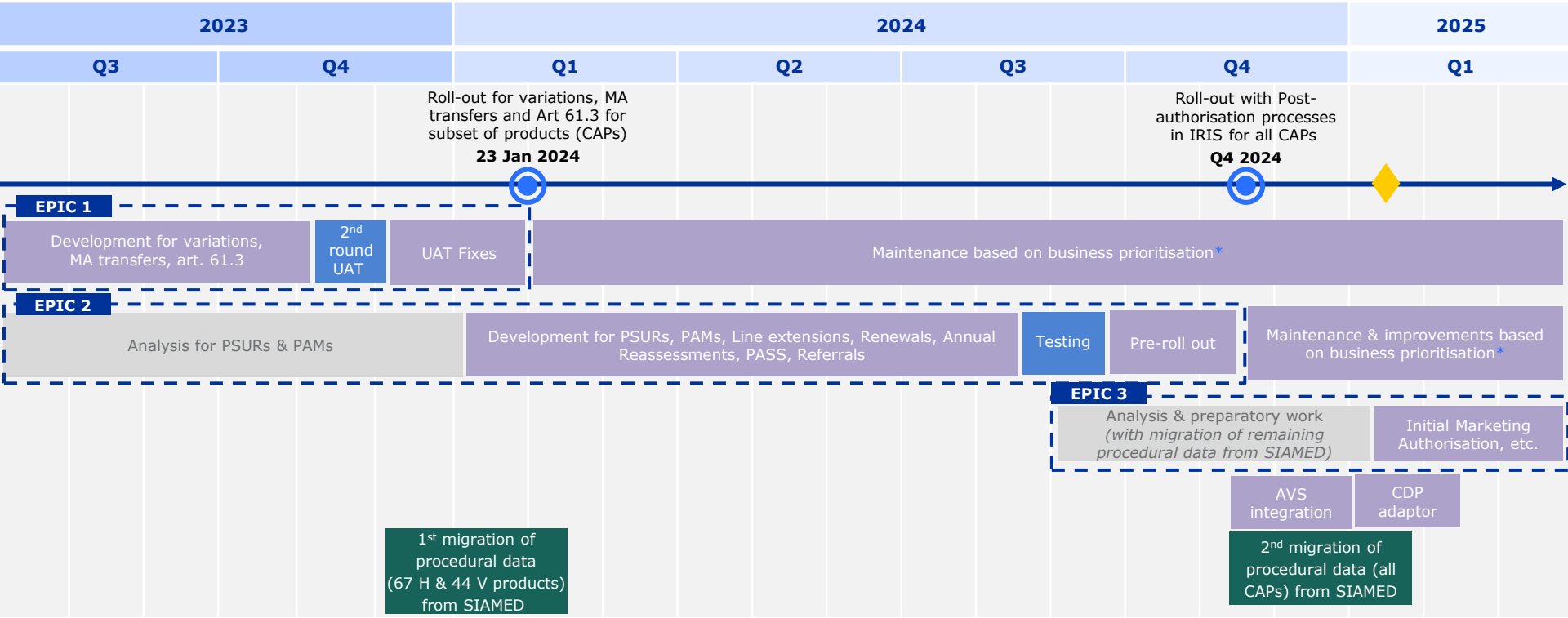


Please note the ongoing development of RPM will happen epic by epic, with incremental improvements across the entire regulatory procedure management landscape.

Acronyms

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

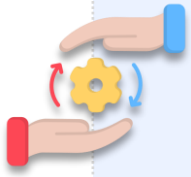
Migration activities

UAT activities

Analysis & preparatory activities

New Fee Regulation

Focus on 1st roll-out & next steps



1st roll-out:

- **Type of procedures**: Variations, Art. 61.3 notifications, Marketing Authorisation Transfers for H&V domains;
- **Products:** 67 human generic products out of 150 (unlimited MA generics) and 44 veterinary products (subset of medicinal products)
- **Network users** can access all information related to the procedures through the **IRIS Network Portal**
- Only the selected products will be managed on IRIS **till the end of the year**

Next Steps:

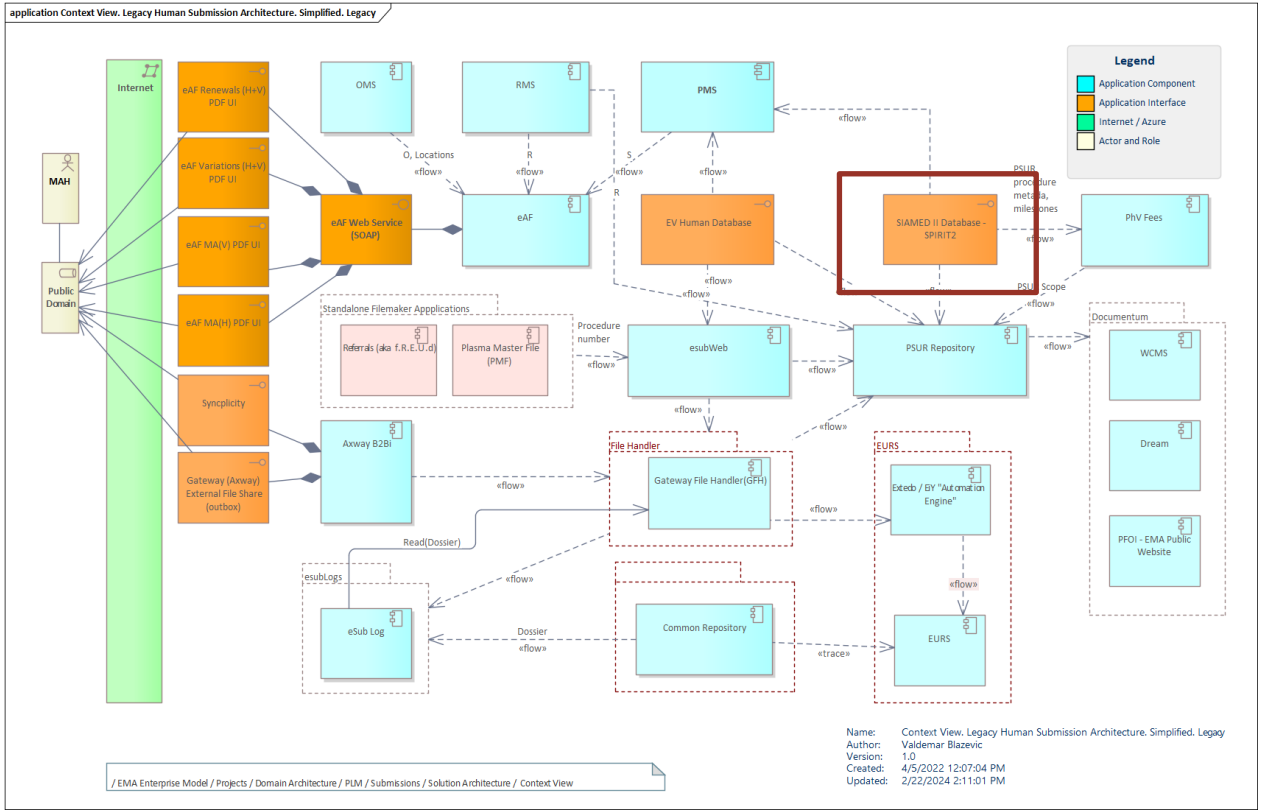
- By Q4 2024, **all post-authorisation processes** (PSURs, PAMs, Line extensions, Renewals, Annual Reassessments, PASS, Referrals) **for all products will be managed on IRIS**.

PLM RPM Domain architecture

RPM epic 1 that onboarded variations, 61.3 notifications and Transfer of marketing authorization processes into IRIS focuses on CAPs

Submission Architecture Context diagram

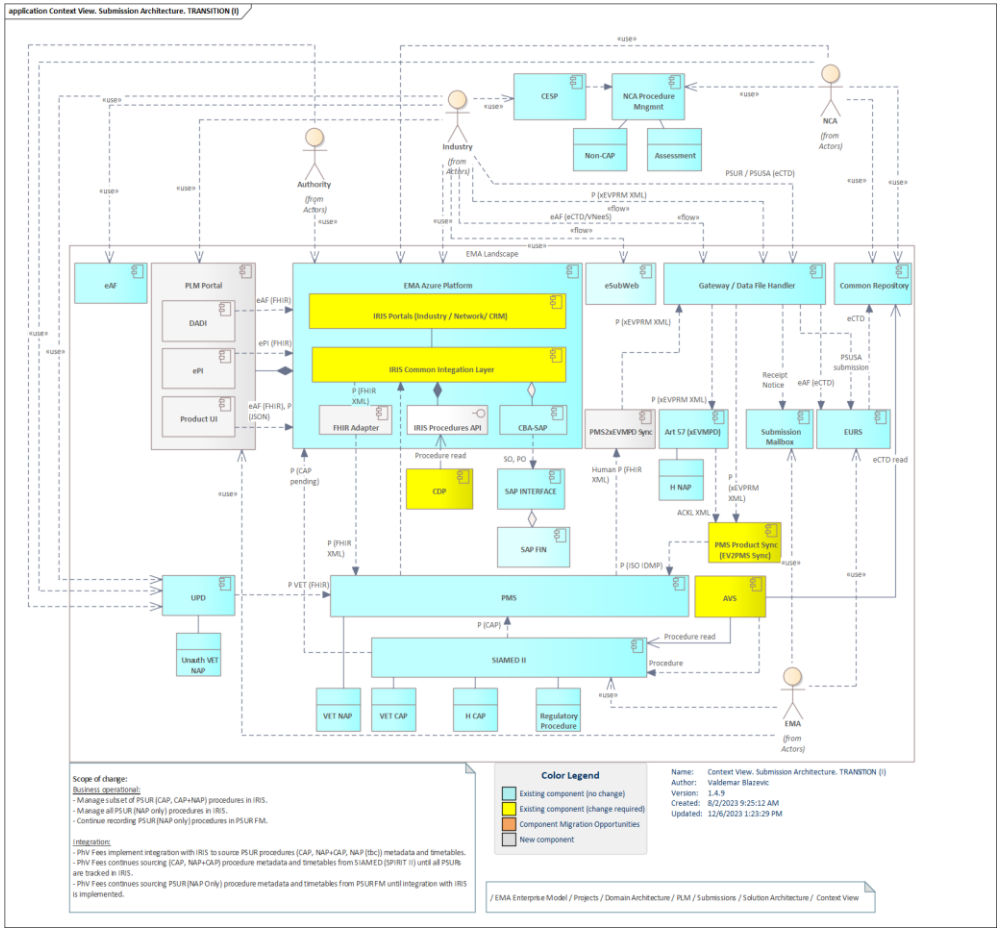
Submission architecture with SIAMED



- Variations, Article 61.3, MA transfer regulatory procedures are handled in **SIAMED**
- The **submission** is made via the **Gateway**
- The **dossiers** are retained in the **Common repository**

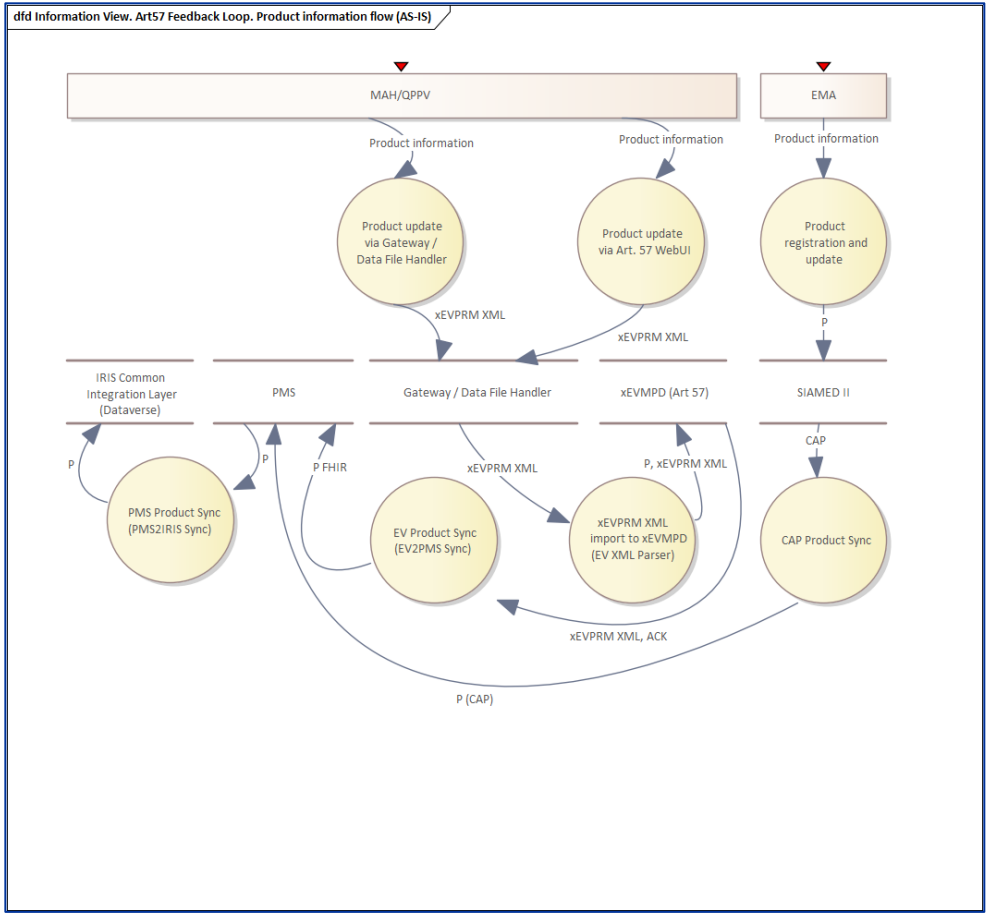
Submission architecture transition

- Variations, Article 61.3, MA transfers procedures are handled **partly in IRIS** (i.e. only for transitioned medicinal products) and the rest in SIAMED
- The submission of the eCTD and VNeeS packages remains supported by the **Gateway and the Common Repository**.

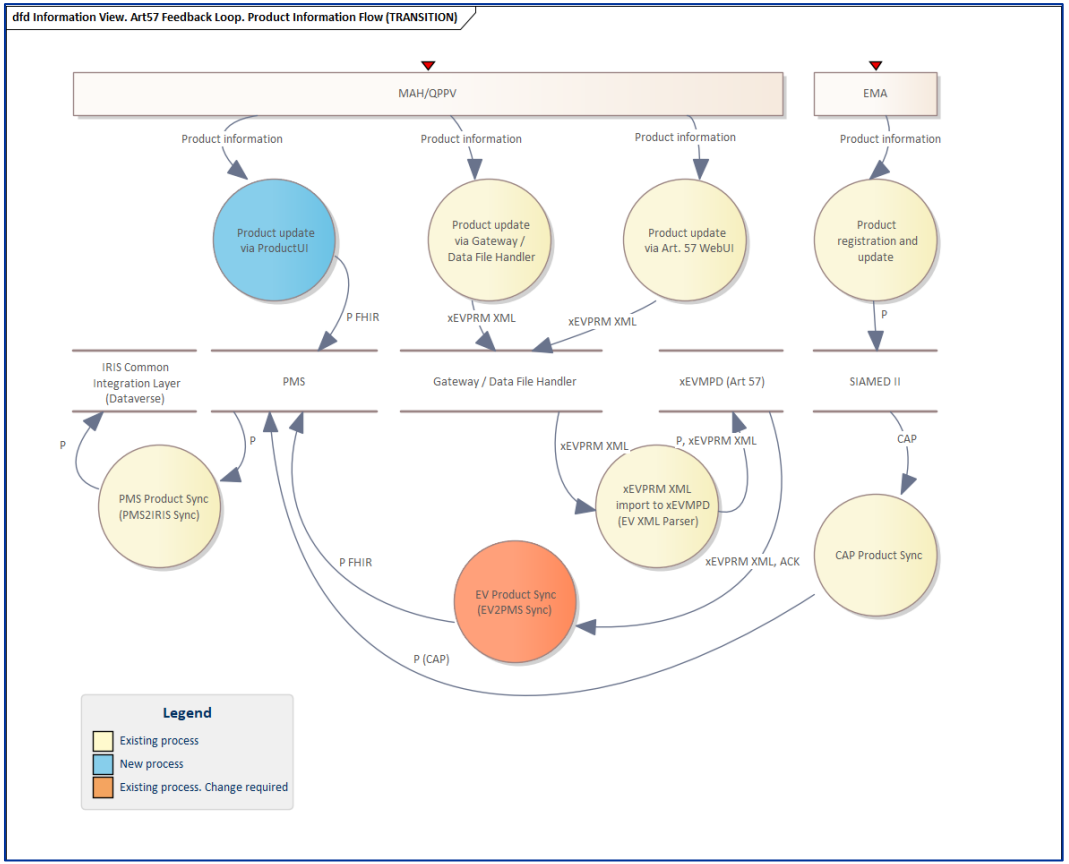


Product data flow

Product information flow (AS-IS)



Product information flow (Transition)



Key takeaways for product data

PMS (Product Management System)

- EMA's central product database
- Maintains a "golden record" implementing the ISO IDMP standard

IRIS and PMS Integration

- IRIS maintains an up-to-date copy of PMS's latest product data, excluding history
- Product data in IRIS Dataverse is stored in a custom, IRIS-optimized data model (non-ISO IDMP)

Q&A session

IRIS

IRIS Platform / Capability Map – v5

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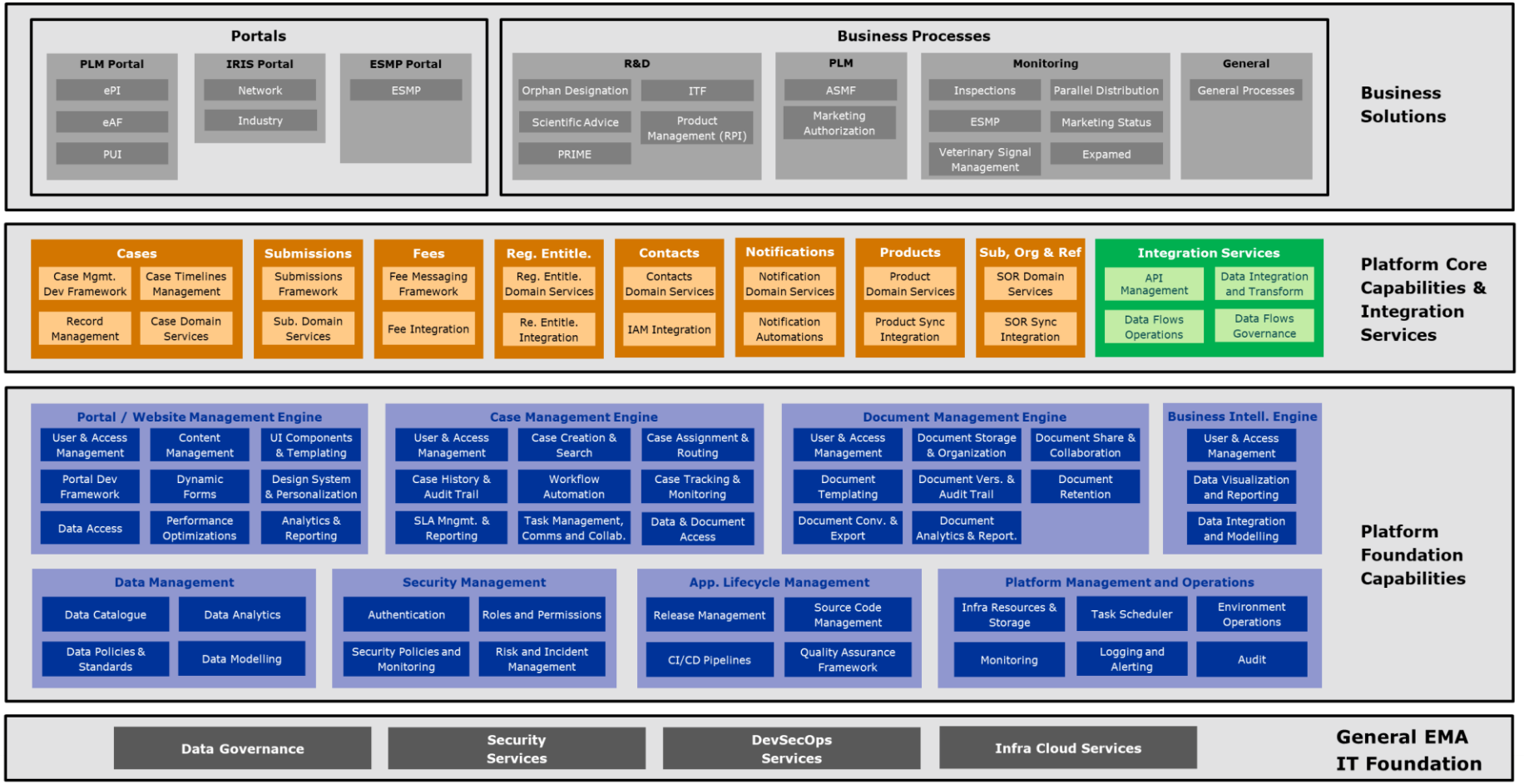

IRIS Platform / Capability Map – v5 – Technology View

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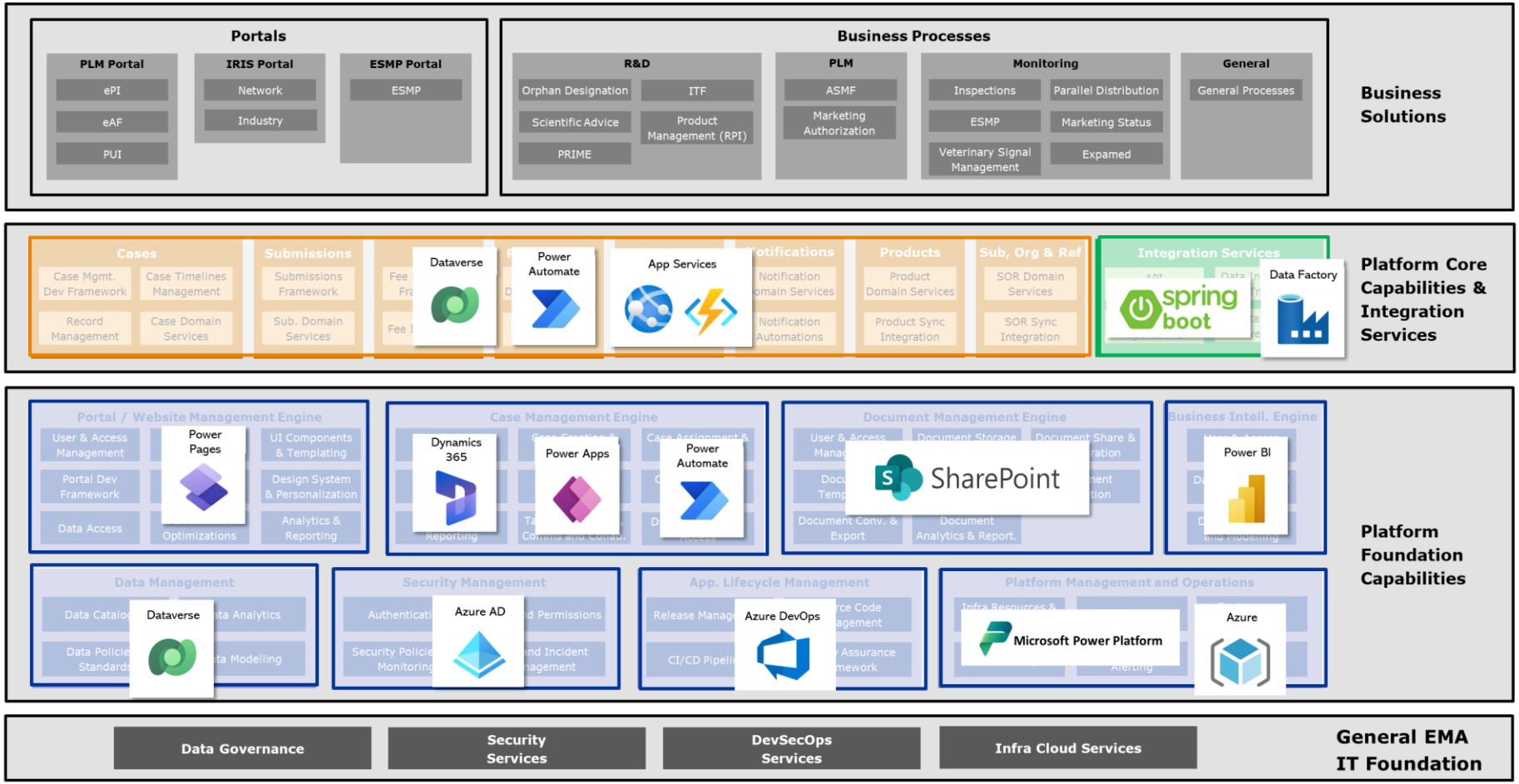
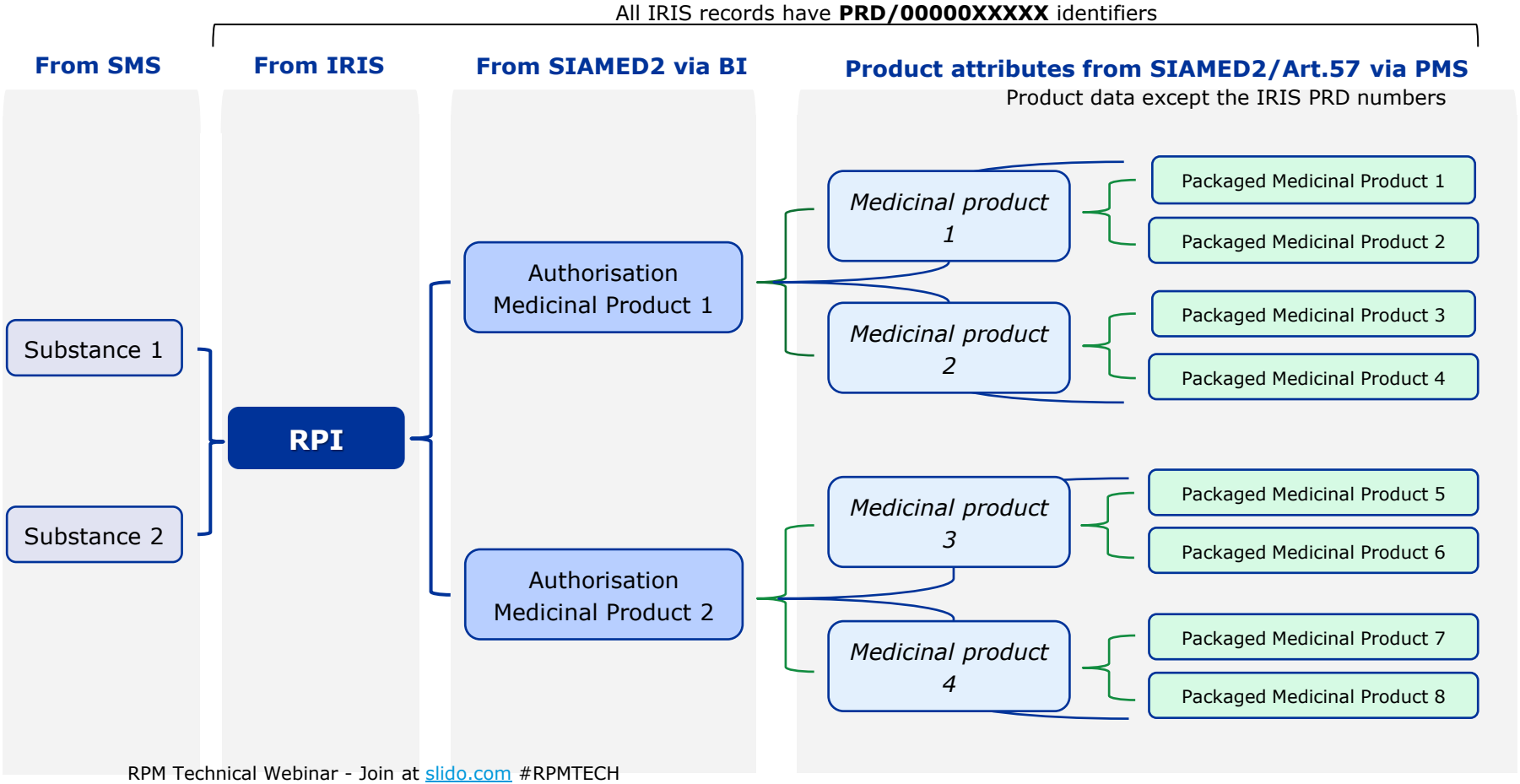


IRIS Platform dimensions

Impacted business area

Product and Case (aka procedure) number change

IRIS Product concept - Substance and product model in IRIS



Details on product and case numbers

Product & procedure numbers in IRIS do not follow the same format as in SIAMED.

IRIS Product (PRD) number characteristics

- assigned when creating a new product in IRIS and remain permanent throughout the product lifecycle.
- The PRD number is a different number from the article 57 database number
- no 1:1 relationship with SIAMED numbers (SIAMED Product number is on Authorisation level, but IRIS PRD number is given at all product levels which includes RPI, **Authorisation,** Medicinal, Package)
- **no *business meaning*** (IRIS assigns automatically the numbers when the records are created)
- presented on the IRIS Network Portal

IRIS Procedure/ Case number characteristics

- IRIS case numbers **do not relate to IRIS PRD numbers**, differently from SIAMED
- limited *business meaning* in the case number → only including the process type information (e.g., Type II starts with "EMA/VR/"). ***There is no logic between the product and the case.***

Examples of new procedure numbers:

- **Variation:** EMA/**VR**/0000076556
- **MA transfer:** EMA/**T**/0000076539

Details on Authorisation product and case numbers

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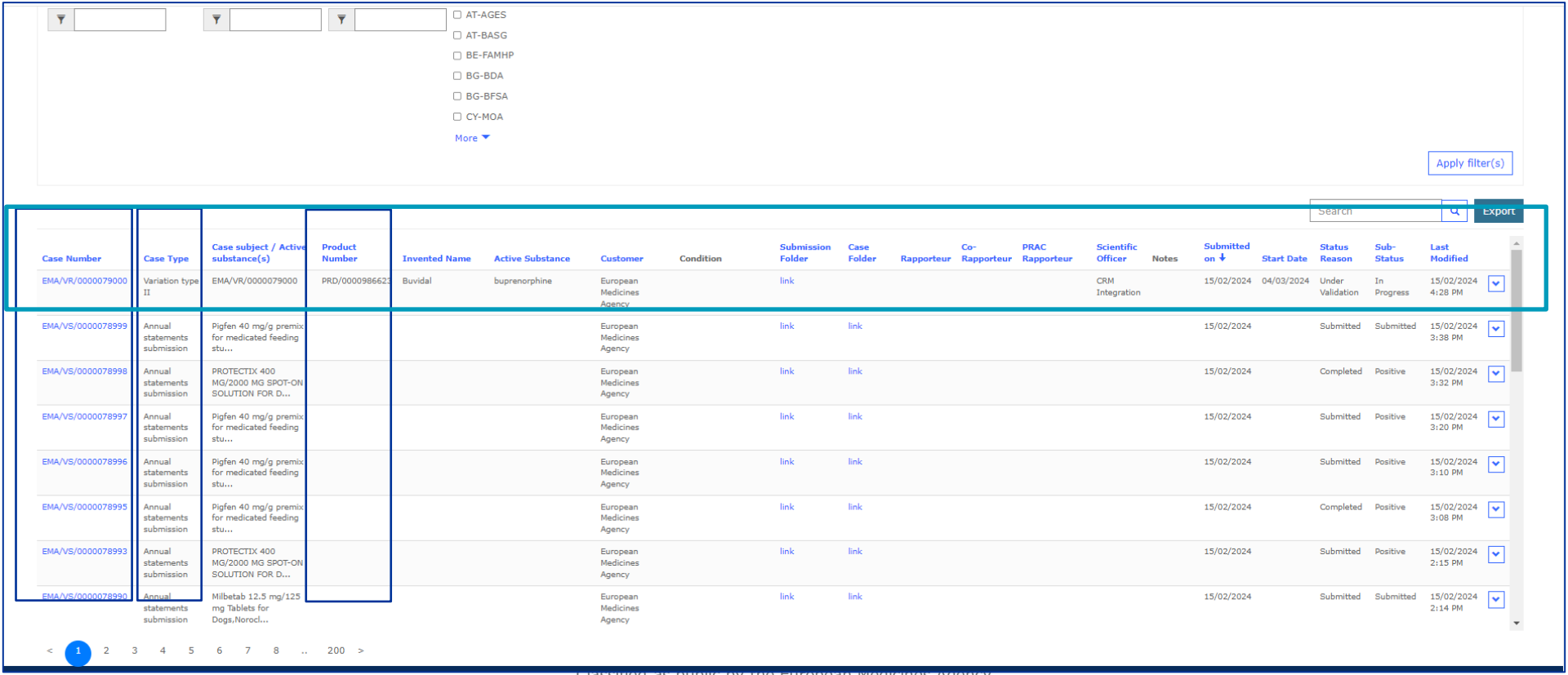
A **view on the IRIS Network Portal** provides information about *cases, procedure type, and connected products*.
For post-authorisation processes, the PRD number that is shown is relevant for the authorisation product level



Access Management and security

Access Management and Security

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Authentication

Based on standard Oauth protocol through Azure AD that is the target Identity Provider for EMA staff and collaborators.

Authorisation (general)

EMA IAM to configure roles and grant access to IRIS Network Portal for IRIS EMA Regulatory roles. These are mapped to technical roles in IRIS ecosystem.

Data access

The IRIS data repositories allow the implementation of data access authorisation at table/column level via roles.

Audit and logging

IRIS logs user actions, changes, and system events. The auditory system allows the implementation of detailed auditory at table/ column level.

Data encryption

IRIS implements data in transit and data at rest encryption leveraging on the standard capabilities of MS Power Platform

Source code security

The source code of IRIS is monitored on a regular basis with the purpose of identifying security vulnerabilities.

Penetration tests

As part of the agency security program, IRIS follow a regular agenda of penetration tests cycles to identify security vulnerabilities.

SharePoint

SharePoint for document sharing

SharePoint Limits

- Recommended maximum of **10 concurrent editors** for a single document in Microsoft 365.
- Absolute limit for **concurrent co-authors is 99**; beyond this, users may encounter a "File in use" error and can only open a read-only copy.
- User experience may vary based on document complexity, network conditions & other factors.

User Configuration

- **Favorites and other personal configurations** (E.g.: alerts on modification of documents) are bound to the user account within the EMA Microsoft 365 instance.
- These configurations are restricted to the context of the user's account.

Technical Stability

- **No major incidents** reported regarding technical stability.

Email notifications

Email notifications

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From → **To**

- Email notifications to personal **AND** manually maintained generic NCA email addresses
- Documentation sharing via Eudralink

- email notifications sent **ONLY** to the main case resources' personal mailboxes (rapporteurs, per-reviewers, etc.) and Eudranet mailboxes (e.g. All Human CHMP <LIST-H-CHMP@EUDRA.ORG>) as per current timelines.
- no possibility to send emails to generic NCA email addresses
- recommended for NCAs to implement their own auto-forwarding rules if neccessary.

Emails format and good practices

- EMA IRIS emails come from **EMA-IRIS@id.ema.europa.eu** and contain a **routing ID** (e.g., IRIS:NNNNNNNNNNN) --> token format
- When answering, do **not change the subject of the email**
- Forwarding from the IRIS Portal is not possible → each NCA needs to create forwarding rules in their Exchange environment

Statistical analysis & reports

Statistical analysis & reports

NCAs will be able to get **information on the on-going procedures** to manage their workload (and other reporting needs)

HOW?

In transition architecture:

- **views on IRIS Network Portal** as per current capability (with procedures in progress, their timelines, and resources)

In target architecture:

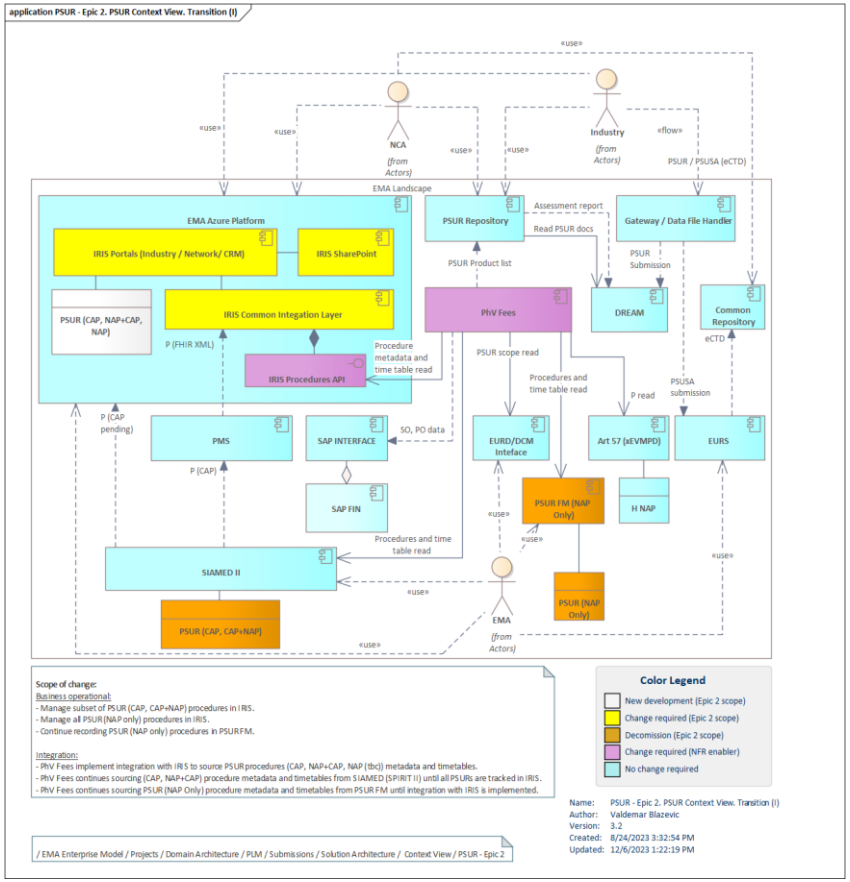
- **Power BI reports** (if licences are not an issue → under verification)

  OR

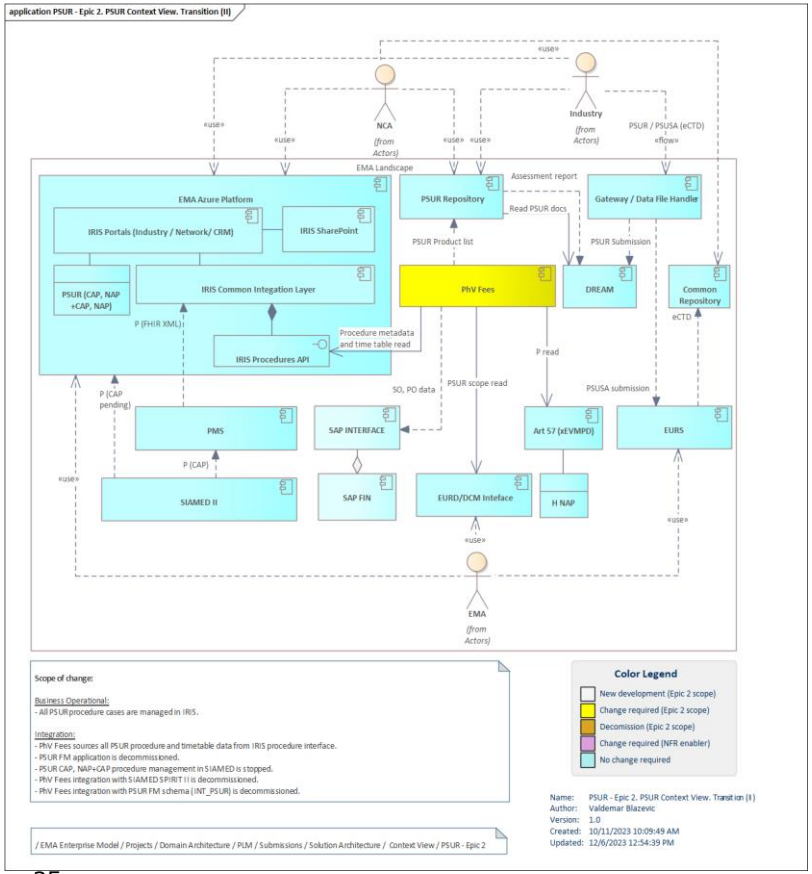
- **Data analytics platform** (timeline TBC depending on the roadmap)

Q&A session

Annex



- subject to presentation in a future workshop



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IRIS data model (entities)

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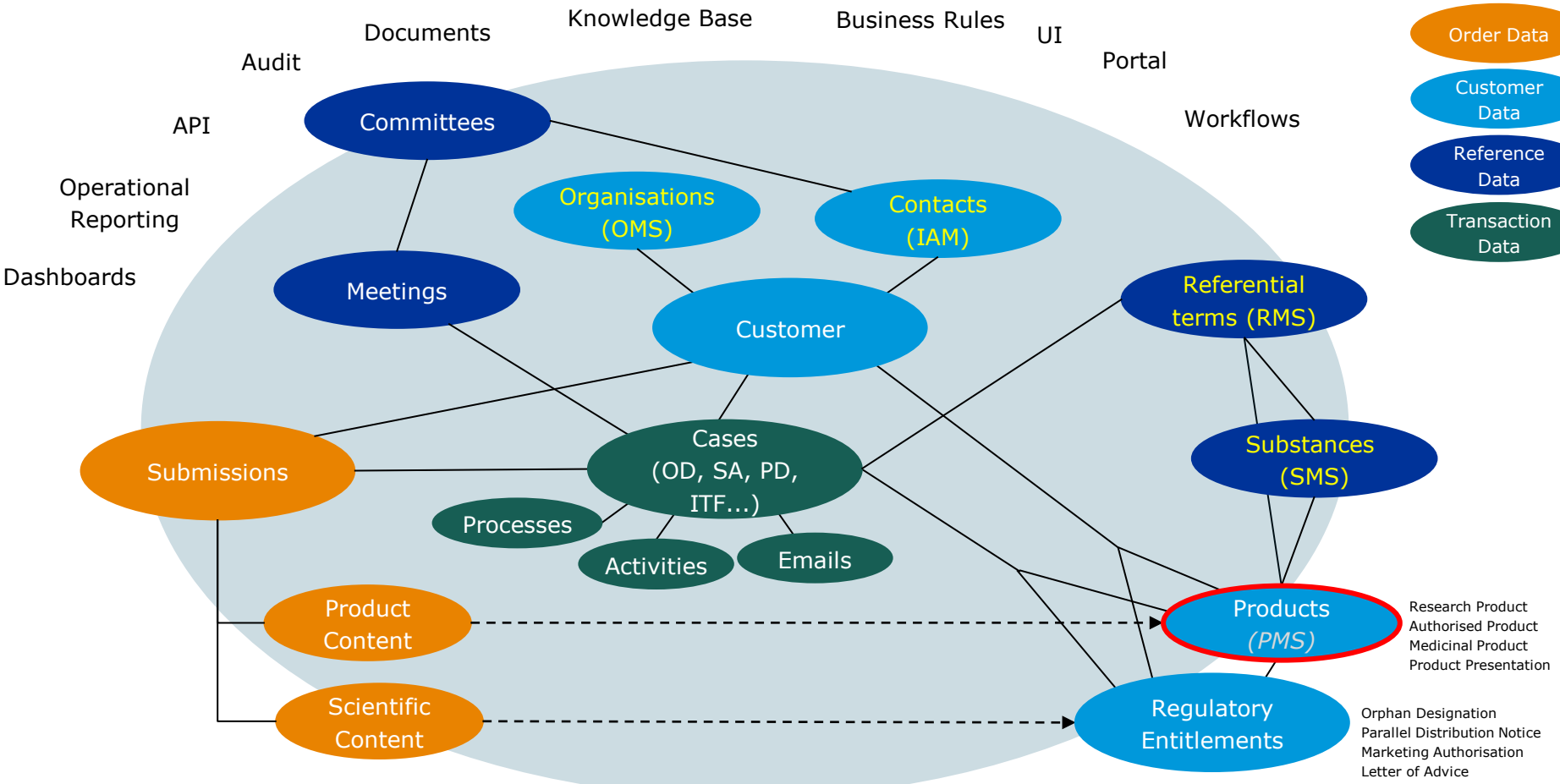

IRIS Product concept - Substance and product model in IRIS (alternate representation)

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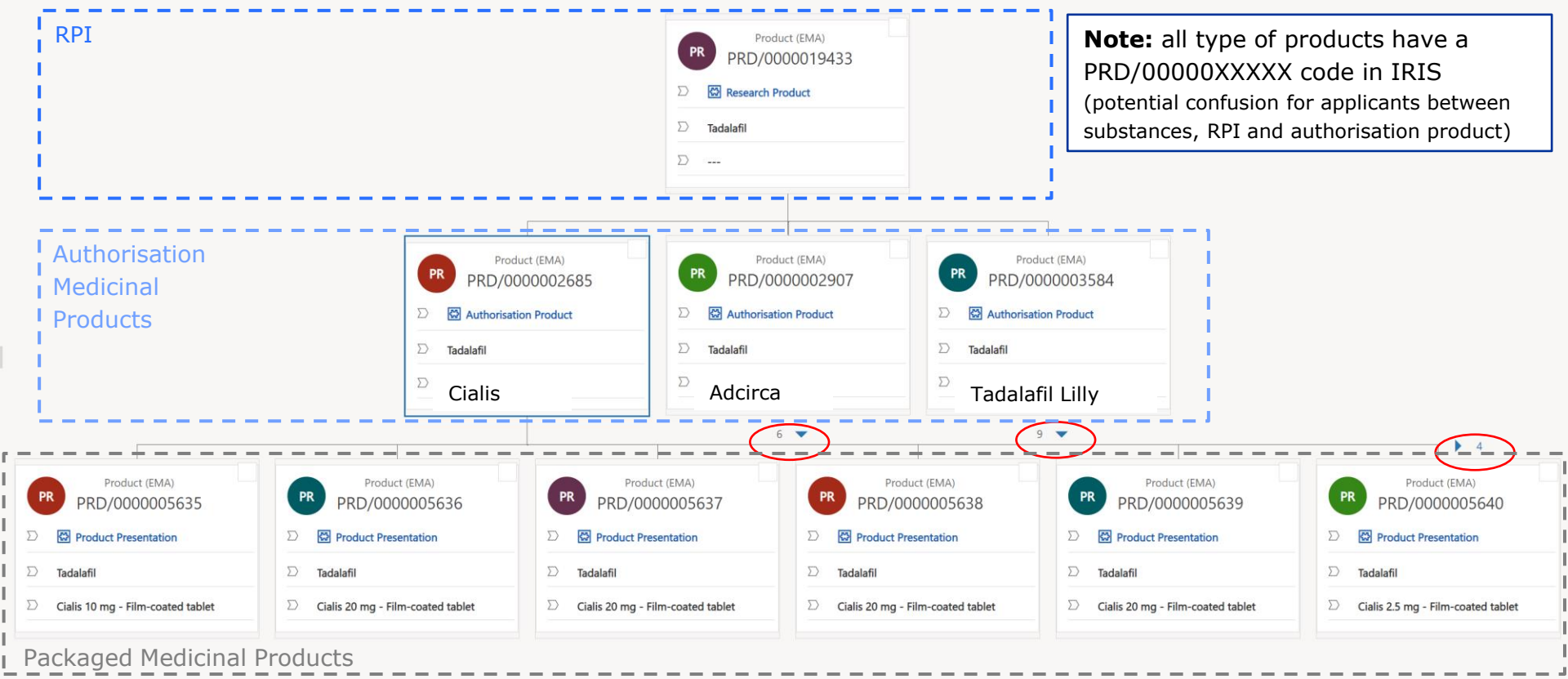

10 presentation products for Cialis, 6 for Adcirca (4 surrendered), 9 for tadalafil Lilly