EMA
EUROPEAN MEDICINES AGENCY

Product Management Service Info-Day

21 May 2025

Session 2: From strategy to reality – PMS in the Network Portfolio

Join at Slido.com with the code #PMS-INFO-25 for Q&A and feedback

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Chairs:

Zaide Frias
Co-chair of Regulatory Optimization Group (ROG), Chair of Portfolio Board (PB) and Head of Digital Business Transformation Task Force

Pelle Persson
Member of Network ICT Advisory Committee (NICTAC) and Network Data Steering Group (NDSG)

Speakers:

Steven Le Meur
R&D Value Stream Owner

Anne-Marie Van NederKassel
PLM Value Stream Owner

Pedro Pina Ferreira
MON Value Stream Owner

Isabel Chicharo
PMS Epic Owner and Head of Regulatory Data Management

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Speakers:

Steven Le Meur
R&D Value Stream Owner

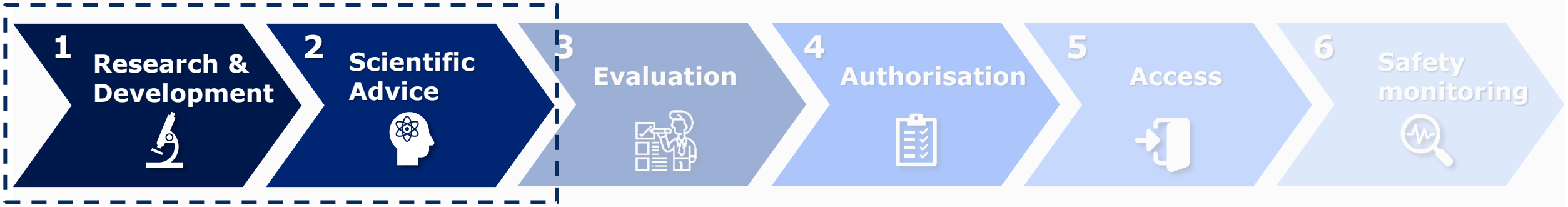
Topic:

PMS in the Research & Development value stream

Managing the medicinal product lifecycle

Integrating data and technology, the R&D value stream enables the development of medicines through efficient processes and generation of scientific evidence for the benefit of public and animal health in the EU.

Lifecycle of a medicinal product



Research & Development value stream

Product Lifecycle Management value stream (PLM value stream)

Monitoring value stream

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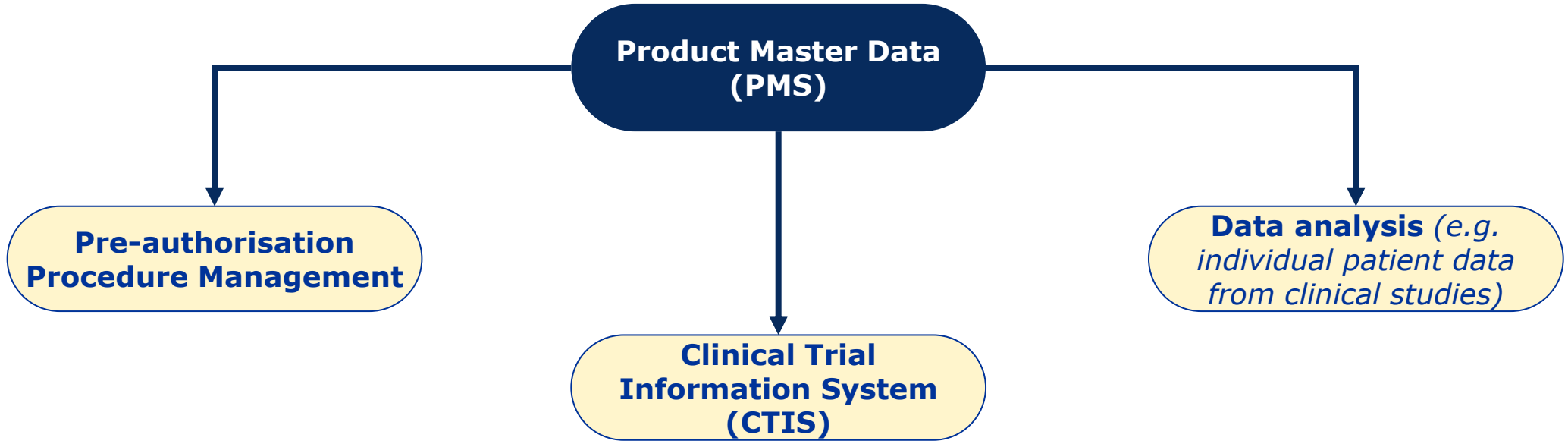
PMS in the R&D value stream

"Integrating data and technology, the R&D value stream enables the development of medicines through efficient processes and generation of scientific evidence for the benefit of public and animal health in the EU."



PMS-supported R&D value stream solution

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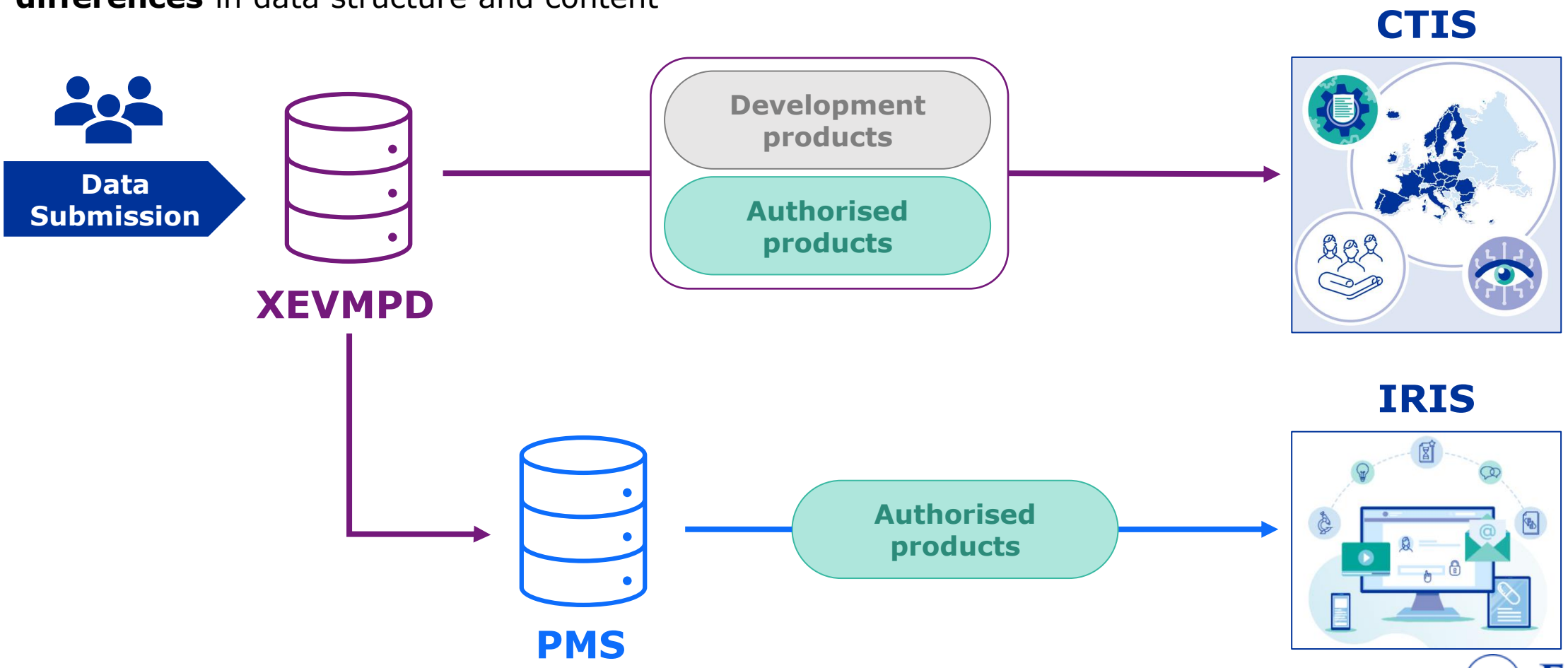
As-is situation and challenges

- **2 repositories** of medicinal product information
- **differences** in data structure and content



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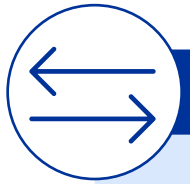
Key benefits of replacing XEVMPD with PMS

Improved Product Lifecycle Management

Management of the lifecycle of medicinal products, from development to commercialisation, in one system to facilitate regulatory, safety, and clinical trial management activities.



Enhanced interoperability

Benefits from the ISO IDMP (Identification of Medicinal Products) data standard, facilitating cross-border data exchange

Advanced reporting and analytics

Allows stakeholders (e.g. regulatory authorities, sponsors, MAHs, manufacturers) to track updates on a medicinal product more efficiently *(including regulatory status, safety monitoring and adverse event reporting, clinical trial results, …)*

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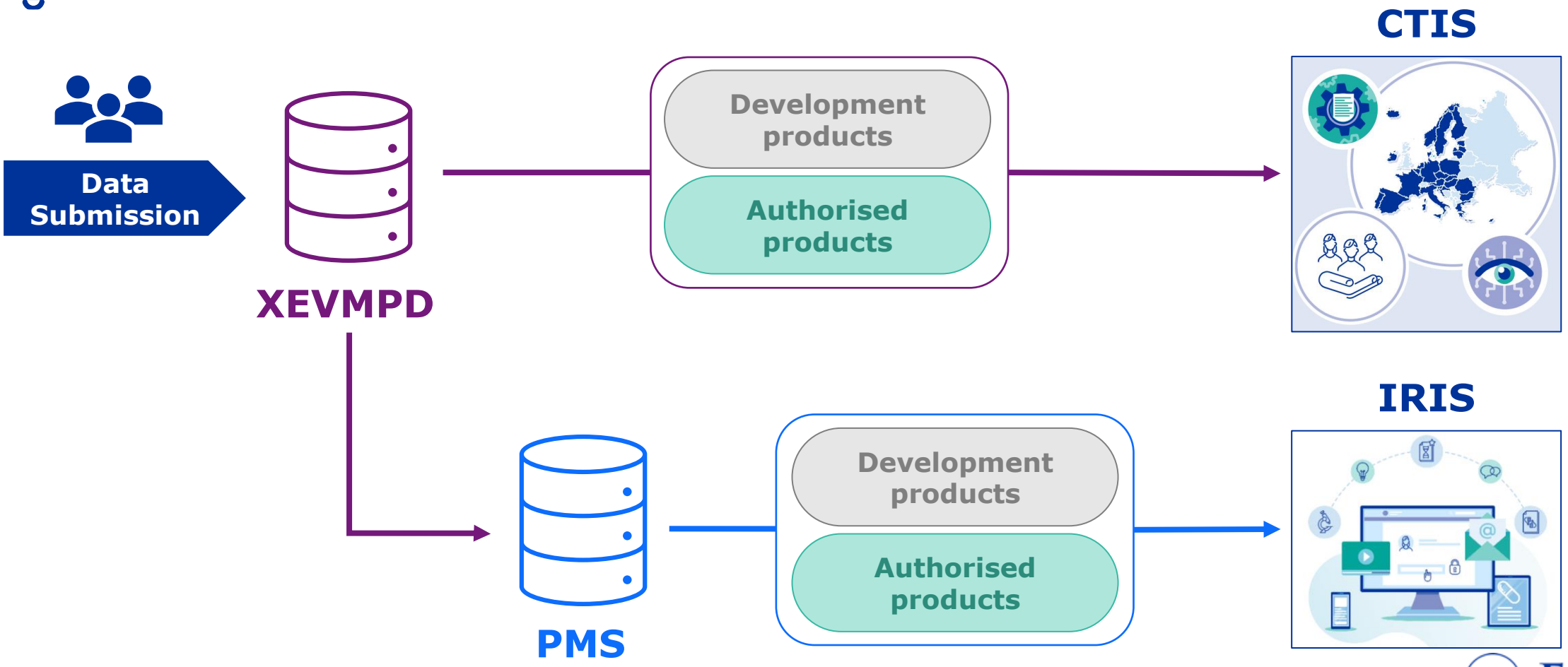
To-be situation and opportunities (1)

Key change → Migrate the **human development product information to PMS**, i.e. both development and authorised medicinal products now available in PMS



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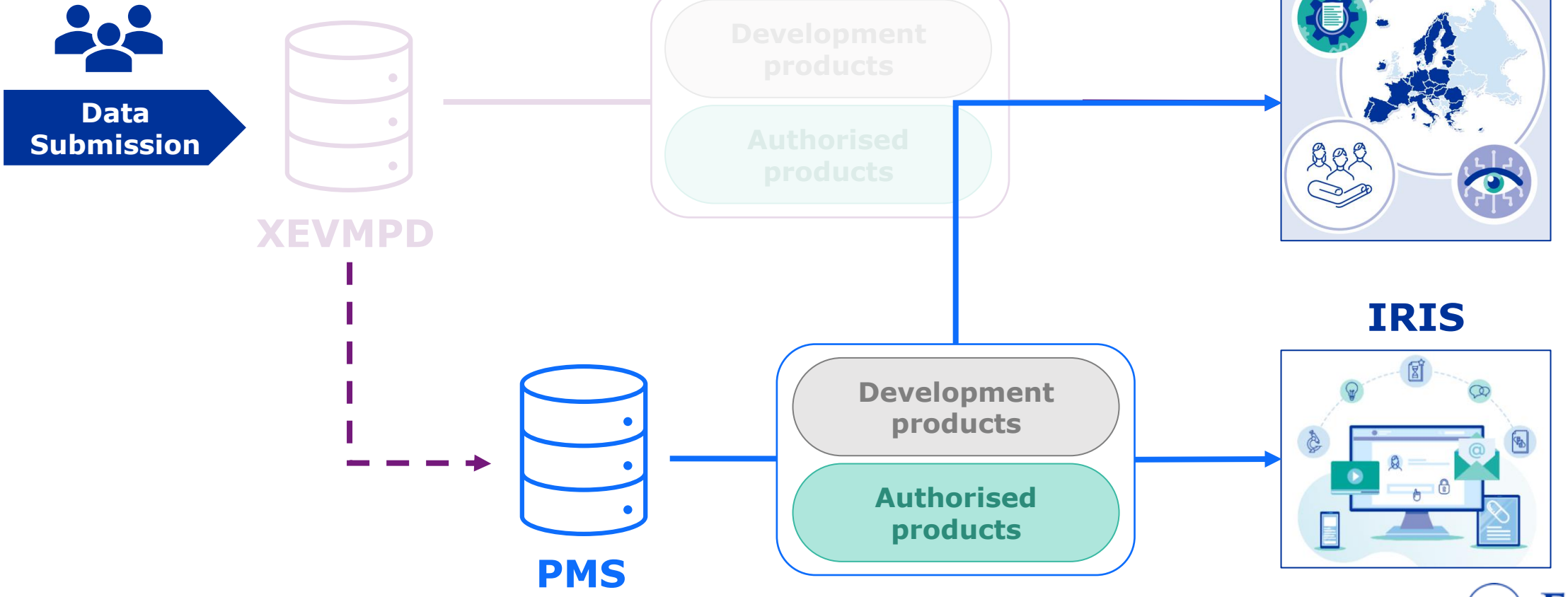
To-be situation and opportunities (2)

Key change →

- Remove dependency on XEVMPD
- Repoint consuming systems to PMS



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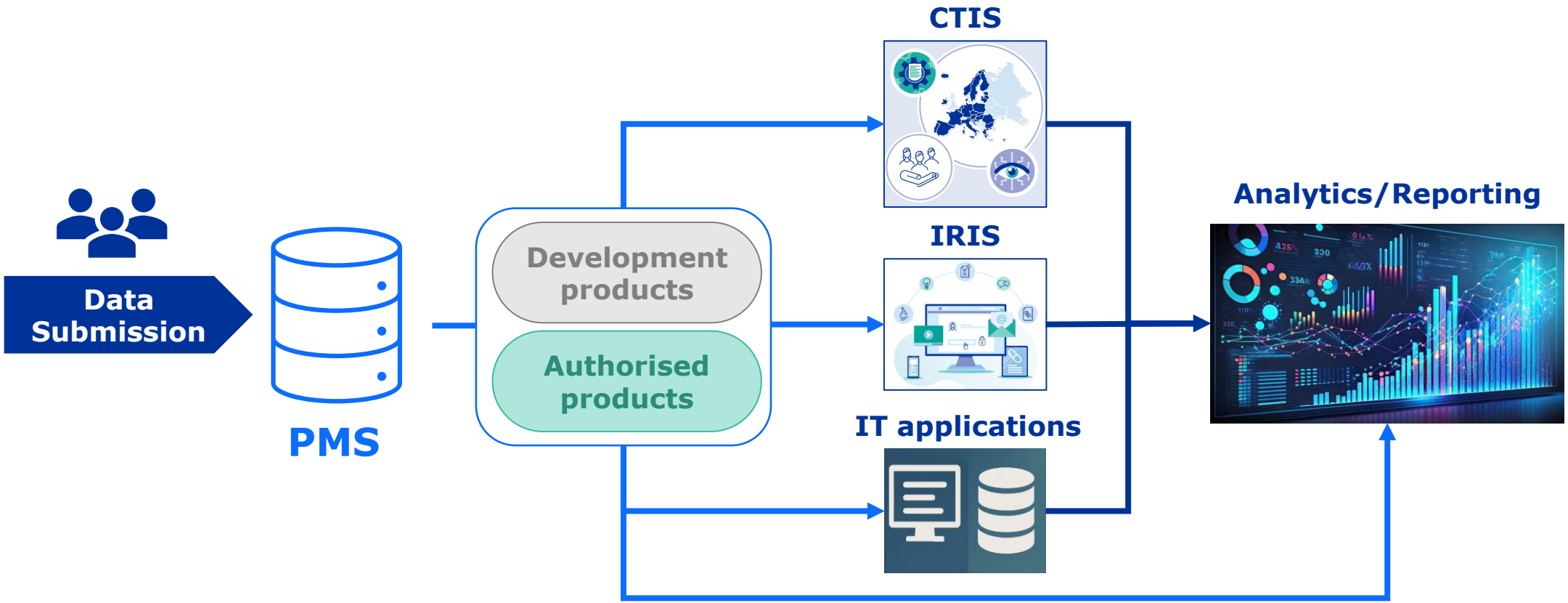
To-be situation → Benefits

- Submission of development and authorised medicinal product information in PMS only
- Consuming systems are all connected to PMS (master data)
- Develop and integrate analytics capabilities



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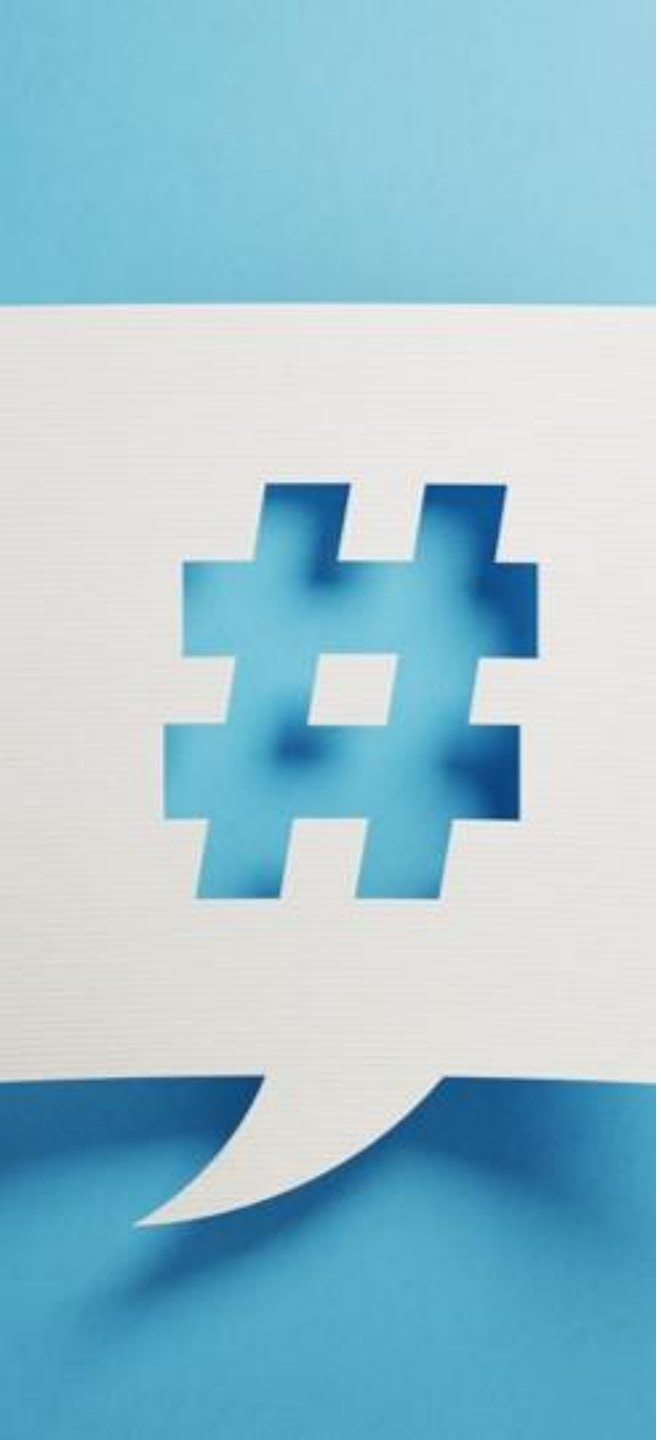

Key takeaways & conclusions

1. **Unique and shared repository** of trusted product master data for all human medicinal products in the EU throughout their life cycle (development and authorised)

2. Management of **human medicinal product information in only one system** – i.e. PMS - provides significant benefits: data submission, data quality and data management **based on the ISO IDMP standard**

3. Availability of both development and authorised medicinal product information in PMS will **streamline the regulatory and product lifecycle management**, benefiting all stakeholders

4. **Better data analytics / reporting capabilities** to generate insights across systems

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Speakers:

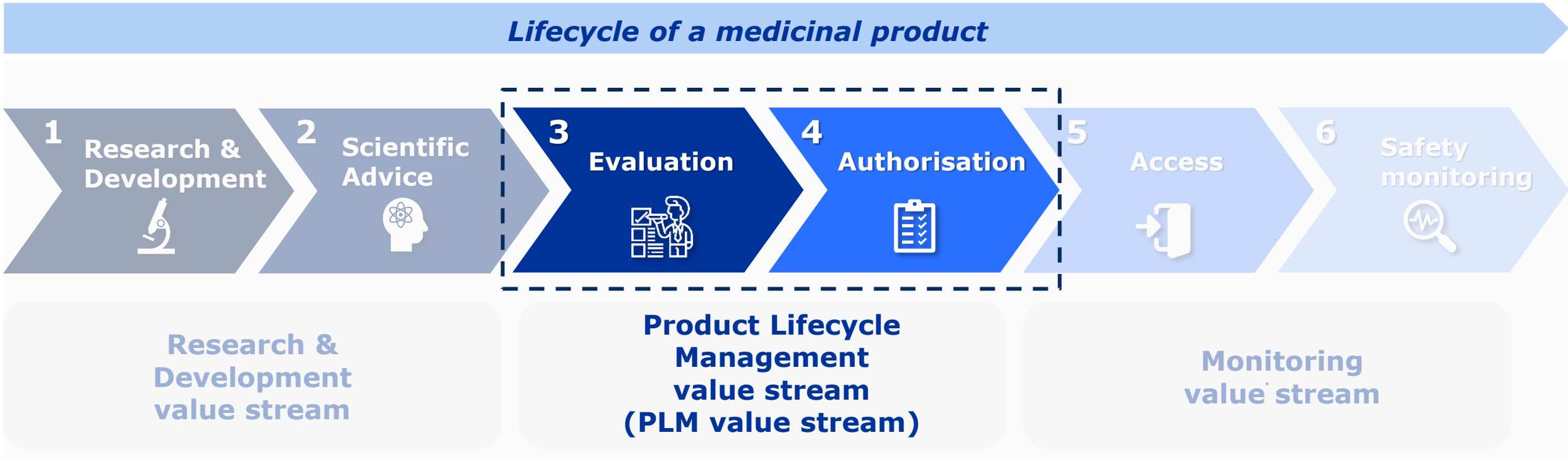
Anne-Marie van Nederkassel
PLM Value Stream Owner

Topic:

PMS in the Product Lifecycle Management value stream

Managing the medicinal product lifecycle

*Empower stakeholders with the **best possible digital tools and data** to enable efficient, data-driven management of the medicinal Product Lifecycle, and to exchange product data and product information for the benefit of public and animal health in the EU.*



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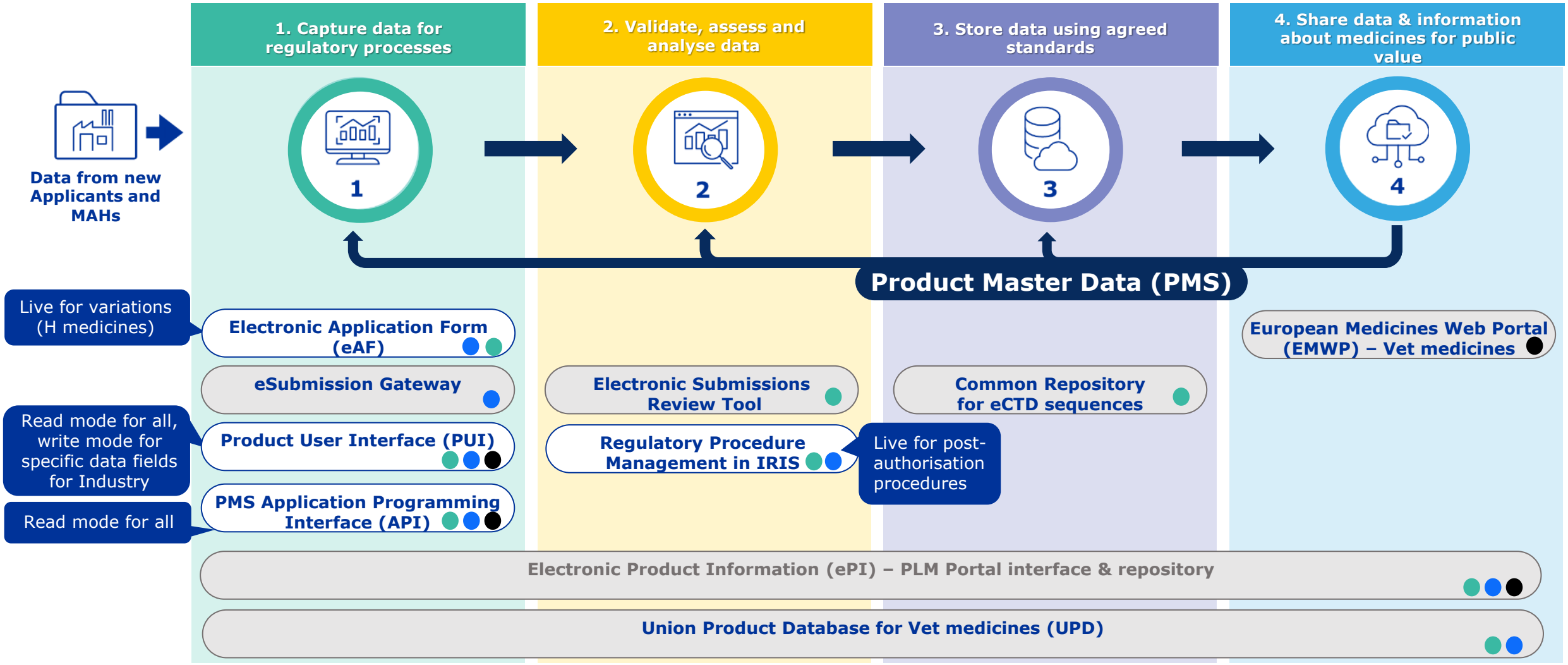
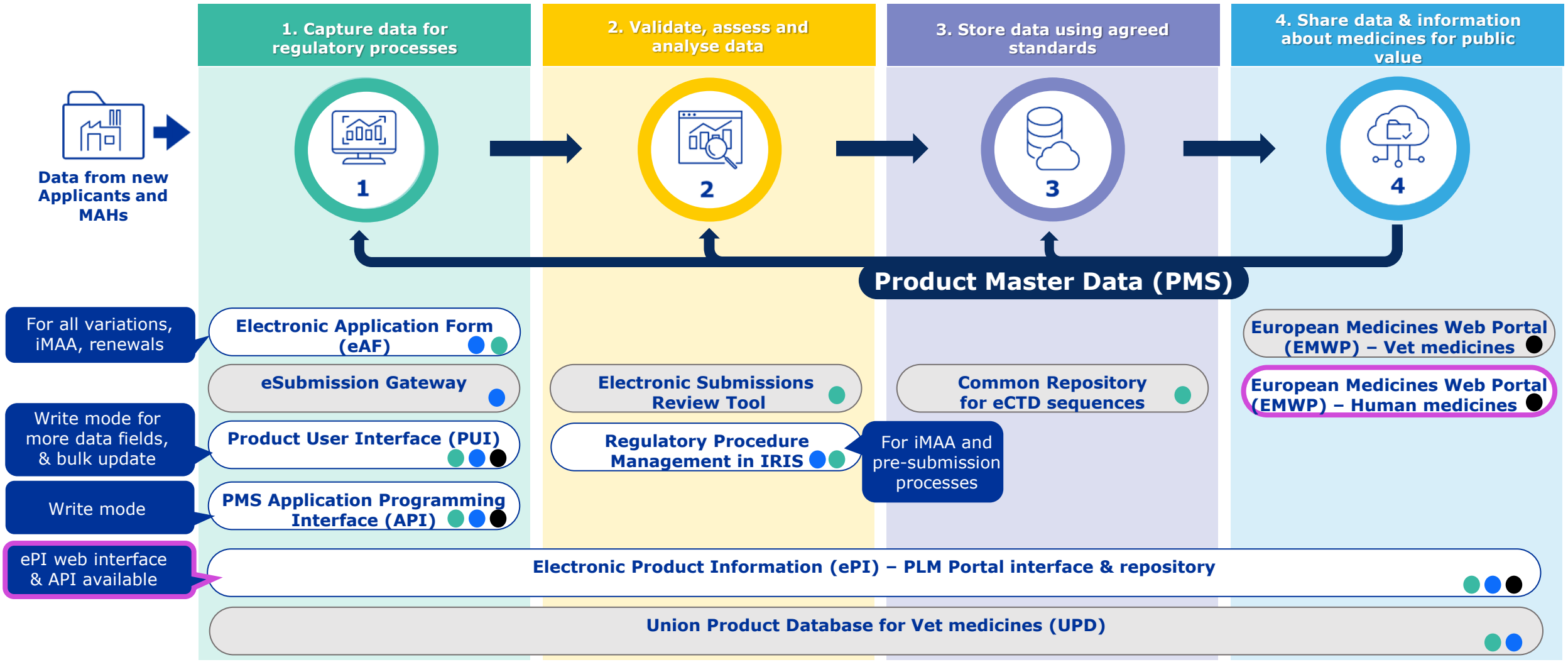
Delivering value through integrated data journey – 2025 status



Delivering value through integrated data journey – Future aspirations



Solution status

Live – Consuming PMS product master data

Live - Not consuming PMS product master data

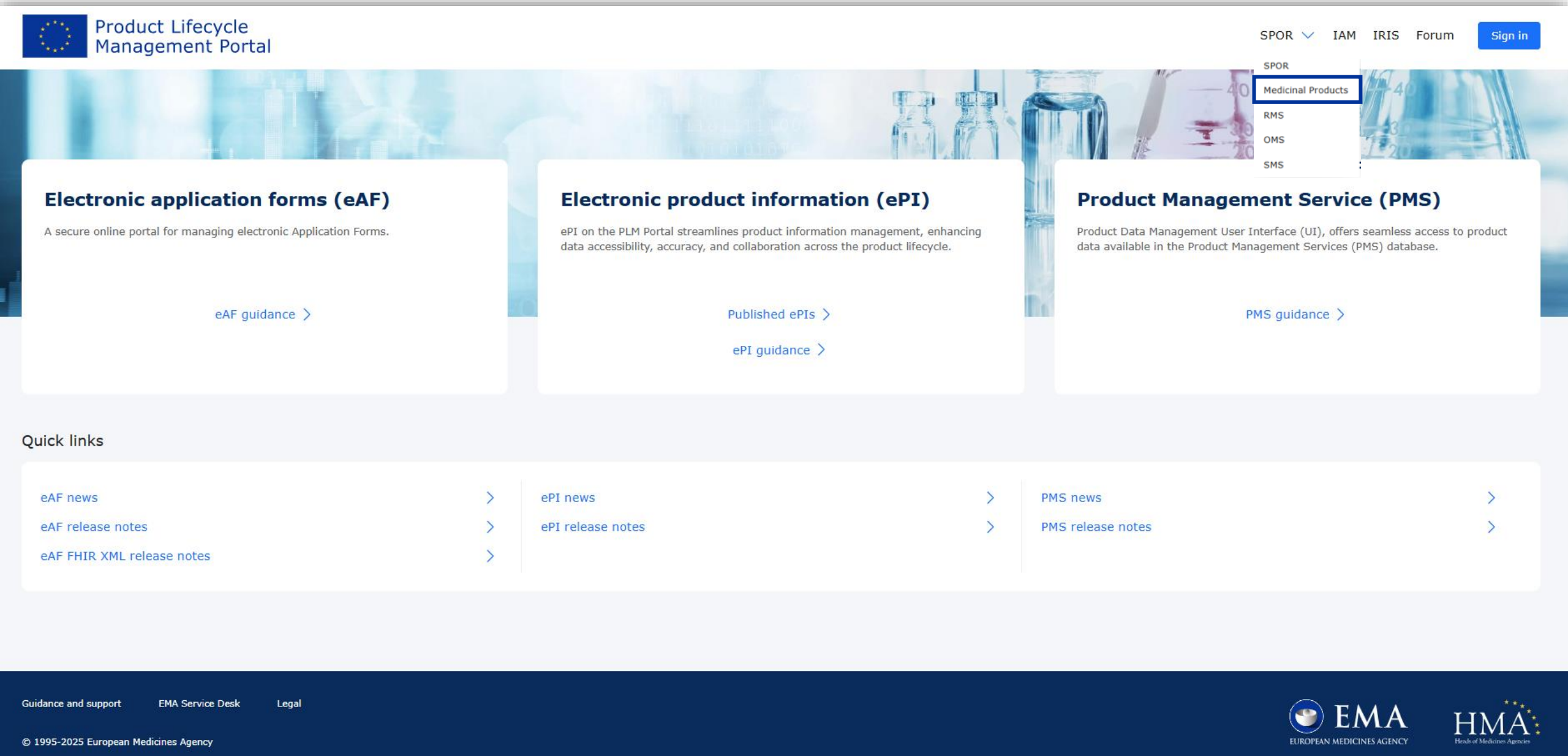
Target users

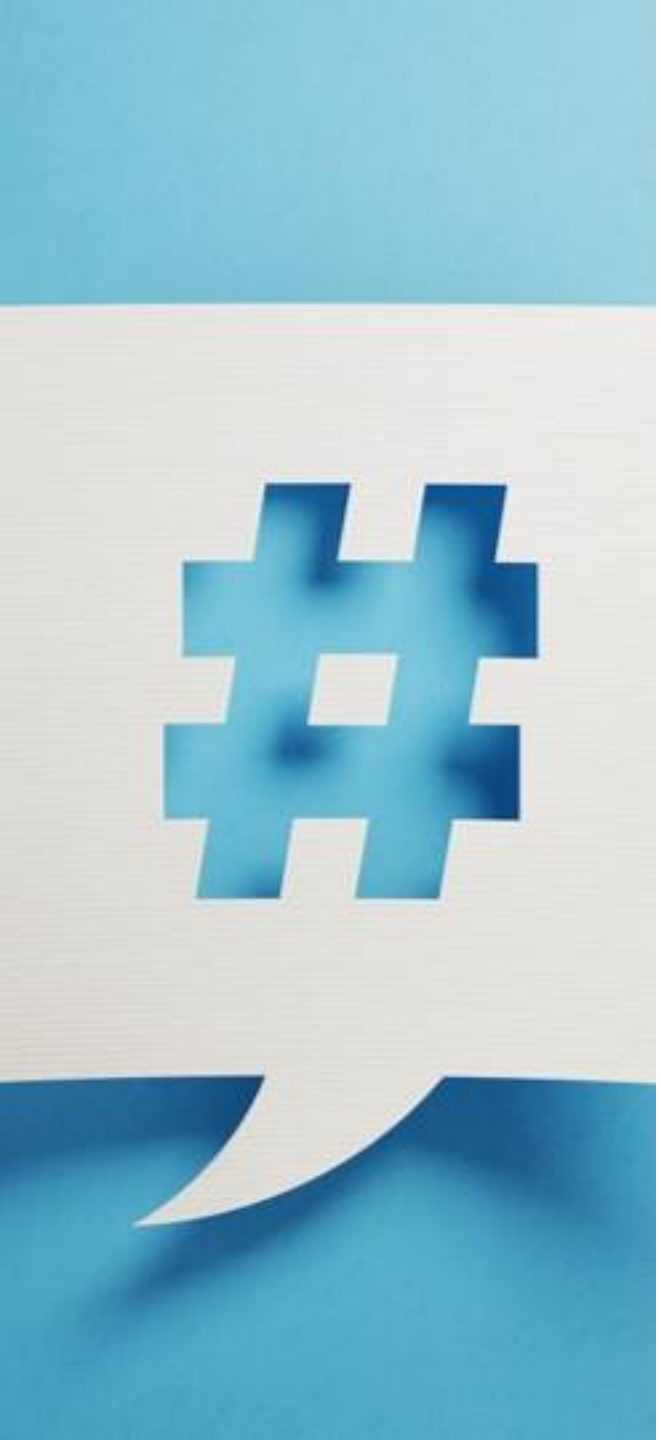
EMA and NCA

Industry

Public

PLM portal: web user interface to capture structured product data





Key takeaways & conclusions

1. PMS enables a **data-driven**, **efficient and digitally connected** way to manage the medicinal product lifecycle.

2. **Great achievements for PMS in 2024-2025**
   - PMS contains CAPs and non-CAPs structured product data for H medicines.
   - NCA and Industry have access to PMS through API and Product UI.

3. **Further PMS development** needed to realise more value:
   - Data quality
   - Enrichment of data fields
   - Processes to keep PMS up-to-date at all times with validated data.

4. **Millions of PMS beneficiaries**, directly or indirectly: regulators, industry and patients!

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Speakers:

Pedro Pina Ferreira
MON Value Stream Owner

Topic:

PMS in the Monitoring value stream

Managing the medicinal product lifecycle

Empowering stakeholders with optimal data and tools to assess and monitor availability, safety and quality of medicines **to achieve higher standards of public and animal health protection in the EU**

Lifecycle of a medicinal product

1 Research & Development

2 Scientific Advice

3 Evaluation

4 Authorisation

5 Access

6 Safety monitoring

Research & Development value stream

Product Lifecycle Management value stream (PLM value stream)

Monitoring value stream

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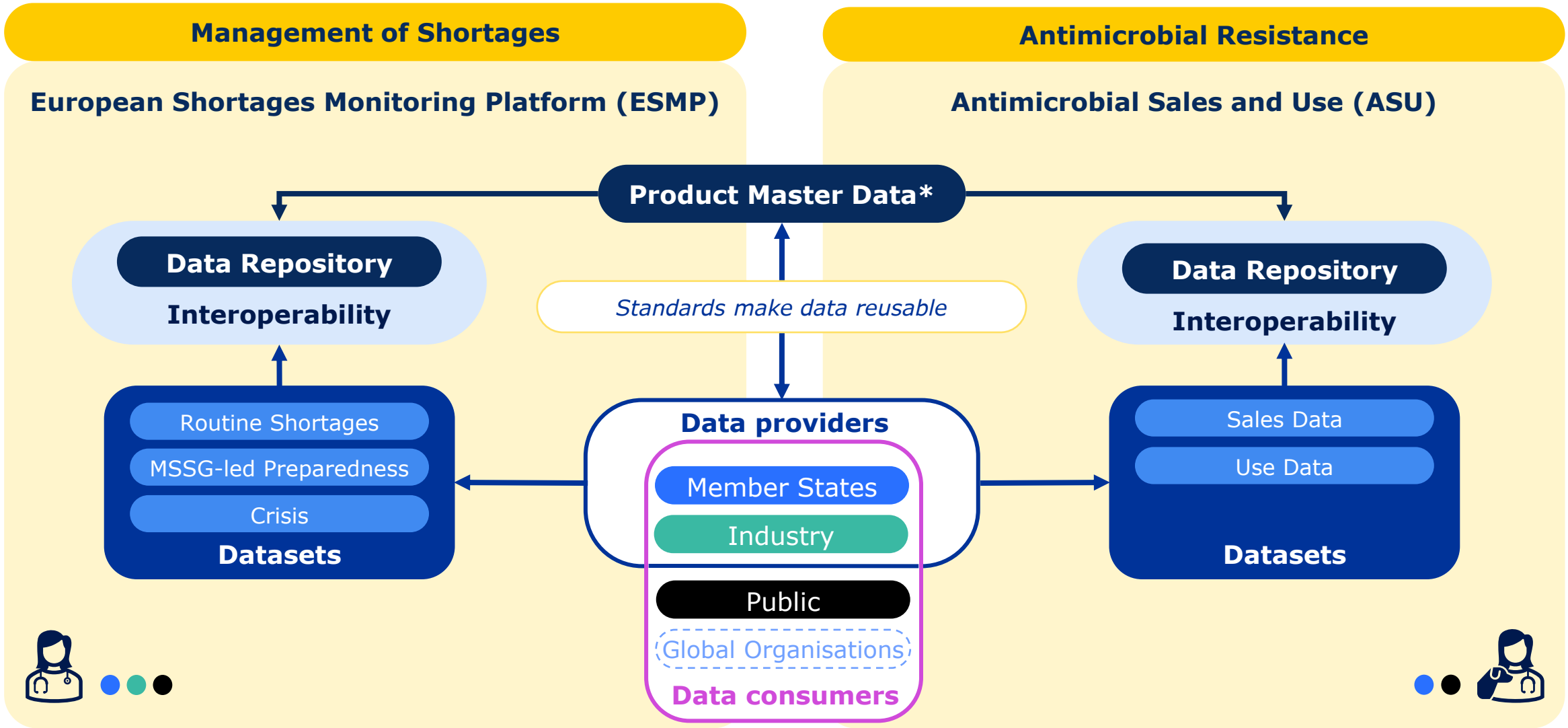
Master data is king on EU platforms



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**Product master Data is sourced from PMS and UPD*

Future

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Numbers enabled by interoperable data

Sustainable business practices and transparency

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(1) Data reflects the status at the end of April 2025
(2) 2023 data collected during last year's data call

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Data is a shared investment

Multiple stakeholders can provide value

The Power of Product Master Data Identifiers

Data Standardisation	Data Exchange	Data Globalisation
Product Dictionary	Information	Collaboration

ESMP

- EU coordination for faster actions
- Increase predictability during PHE/ME
- Mitigate the impact of shortages on patients
- Improve crisis preparedness

→ **Patients have their medicines** when they need them

ASU

- Promote appropriate antimicrobial use
- Implement targeted actions and measures
- Review AMR EU and national action plans

→ **Increased awareness** of animal antimicrobial consumption in the EU

Investment (*)

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(*) Data Enrichment, Data Mapping, Data Quality

Unlocking the value of data for patients

Aim for an impactful Return On Investment (ROI)

The Power of Product Master Data Identifiers

Data Standardisation	Data Exchange	Data Globalisation
Product Dictionary	Information	Collaboration

Benefits

- ESMP: **Patients have their medicines** when they need them
- ASU: **Increased awareness** of animal antimicrobial consumption in the EU

Investment =

ROI

Human and Animal Health

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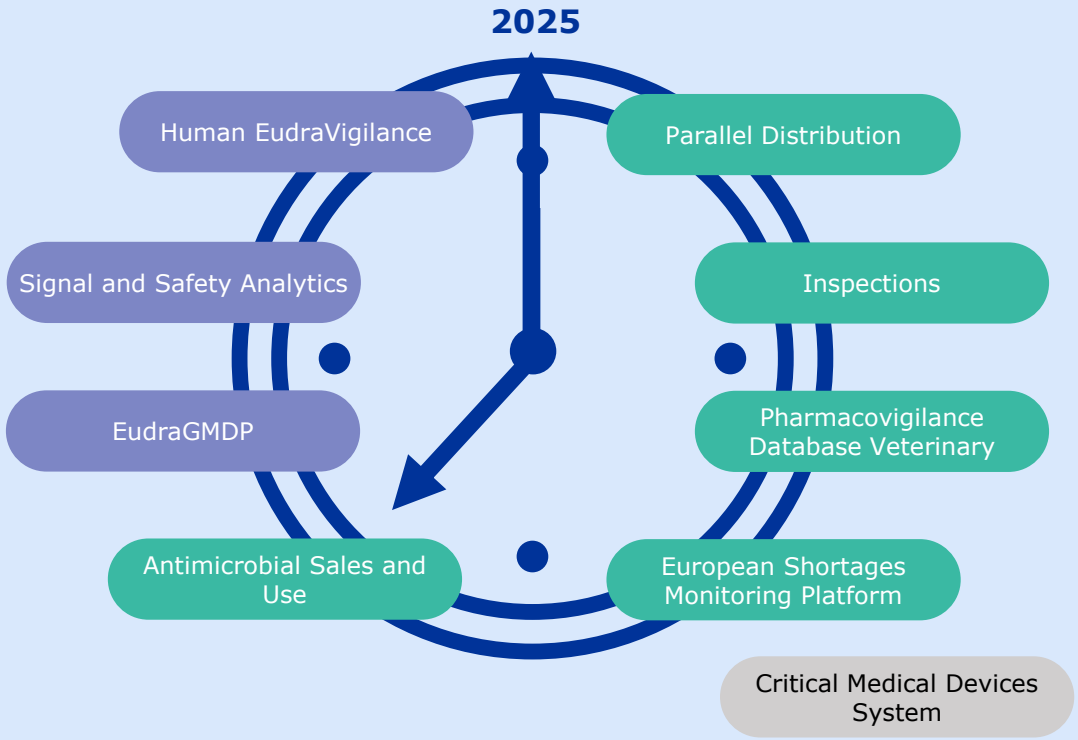
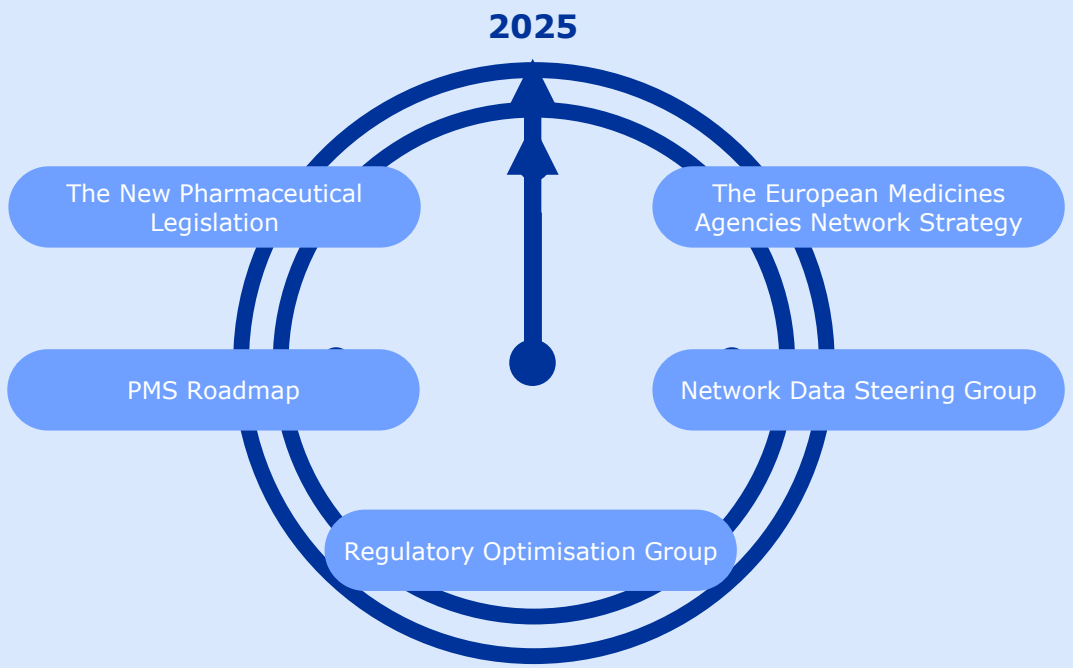
Coordinated alignment for shared success

The multi-clock dilemma

Monitoring value stream clock



Time-critical clocks



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Product Master Data compliance Done/Progress

Product Master Data compliance To Be Planned

No need for Product Master Data compliance

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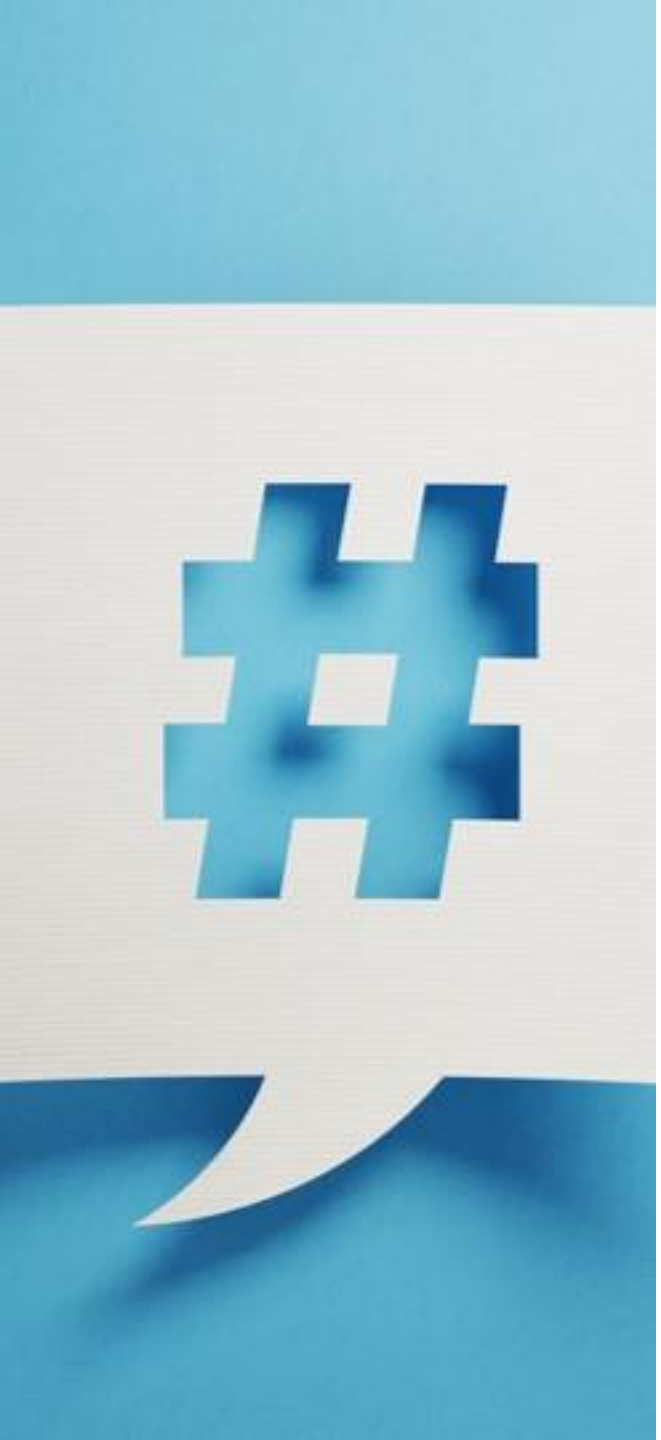

Key takeaways & conclusions

1

Product master data is king

Standardised data creates a sustainable, reusable, and transparent common language for EU-wide communication.

2

Data is a long-term asset

Shared investment in product master data today builds a more efficient, AI-ready future for the benefit of human and animal health.

3

Coordinated alignment for shared success

Collaborating and sharing the same targets requires trade-offs and prioritisation to maximise value delivery.

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Speakers:

Isabel Chicharo
PMS Epic Owner and Head of Regulatory Data Management

Topic:

PMS, where is it heading

Opportunities brought by standardised, shared product data

Automations and interoperability across the Network

Faster, more efficient regulatory actions

- managing procedures
- reporting shortages reporting
- monitoring antimicrobial sales & use

Public access to product information

European Health Data Space support

e.g. cross-border e-prescription and e-dispensation

Enabling future regulatory compliance

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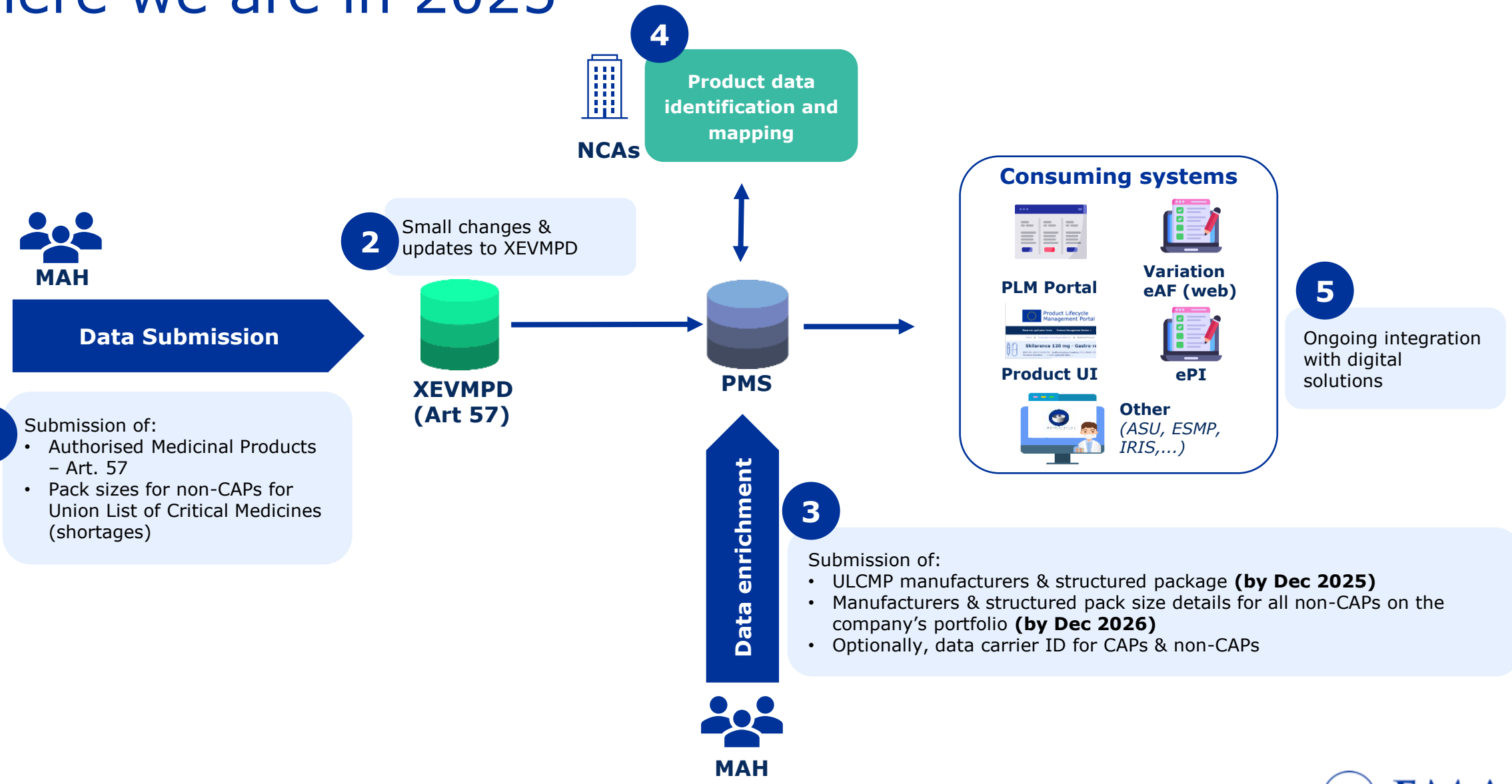
Where we are in 2025



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Where we are heading in 2026

Legend

+ New activities

MAH

Data Submission

1 Submission of:
- Authorised Medicinal Products – Art. 57
- Pack sizes for non-CAPs for Union List of Critical Medicines (shortages)

+ Pack sizes for all non-CAPs on the company's portfolio

2 Small changes & updates to XEVMPD

+ UI upgrade

XEVMPD (Art 57)

NCAs

4 **Product data identification and mapping**

+ Aligning data
+ Address missing products

PMS

Consuming systems

PLM Portal

Variation eAF (web)

Product UI

ePI

Other *(ASU, ESMP, IRIS,...)*

5 Ongoing integration with digital solutions

Data enrichment

MAH

3 Submission of:
- ULCMP manufacturers & structured package **(by Dec 2025)**
- Manufacturers & structured pack size details for all non-CAPs on the company's portfolio **(by Dec 2026)**
- Optionally, data carrier ID for CAPs & non-CAPs - recommended in there is an ePI

+ Additional data enrichment

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Moving forward with PMS

What it takes

- Enable data submission & management in PMS
- Address legacy data and systems
- Integrate with regulatory processes

Who needs to be involved

- Multiple teams across different value streams
- NCAs, MAHs and sponsors

When it will be done

- Many network and portfolio priorities
- NDSG & ROG recommendation
- No formal prioritisation has taken place yet

How it will be done

- With consideration of resource & system dependencies
- Close collaboration
- Open stakeholder communication

*PMS implementation (particularly XEVMPD replacement) is a **multi-year effort.***

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First step

Legend

✓ Benefits

NDSG & ROG recommendations

- *In a timely manner to support New Pharma Legislation*
- *Enabling submission of Investigational (IMP) and Authorised medicinal product (AMP) data via the PMS API or PUI*
- *Consuming existing/legacy systems repointed to PMS*
- *Discontinue XEVMPD at a given cut-off date*
- *Data quality is ensured via an agreed validation process - Various models of NCA and MAH involvement to be considered and to be informed by the EMA/HMA ROG feasibility study*
- *Regular updates to partners and stakeholders*

2 **Dedicated Data qualification of legacy data**
Various models to be proposed by ROG OG

NCAs

Product data qualification

MAHs & Sponsors

Data Submission

XEVMPD

PMS

1
MAHs & Sponsors submit all product data in the same way:
- investigational
- pending
- Authorised
- Any required enrichments

✓ Submission simplification

✓ Maintenance of a single repository
✓ Data flow simplification
✓ Data Quality improved

Consuming systems

PLM Portal

Variation eAF (web)

Product UI

ePI

Other *(ASU, ESMP, IRIS,...)*

Newly developed systems:
- Data Analytics Platform (DAP)
- …

Repointed existing /legacy systems:
- SAP
- CTIS
- EV
- PSUR
- EV DAS, SSA,
- …

3 Existing /legacy systems integrated, ongoing integration with new solutions

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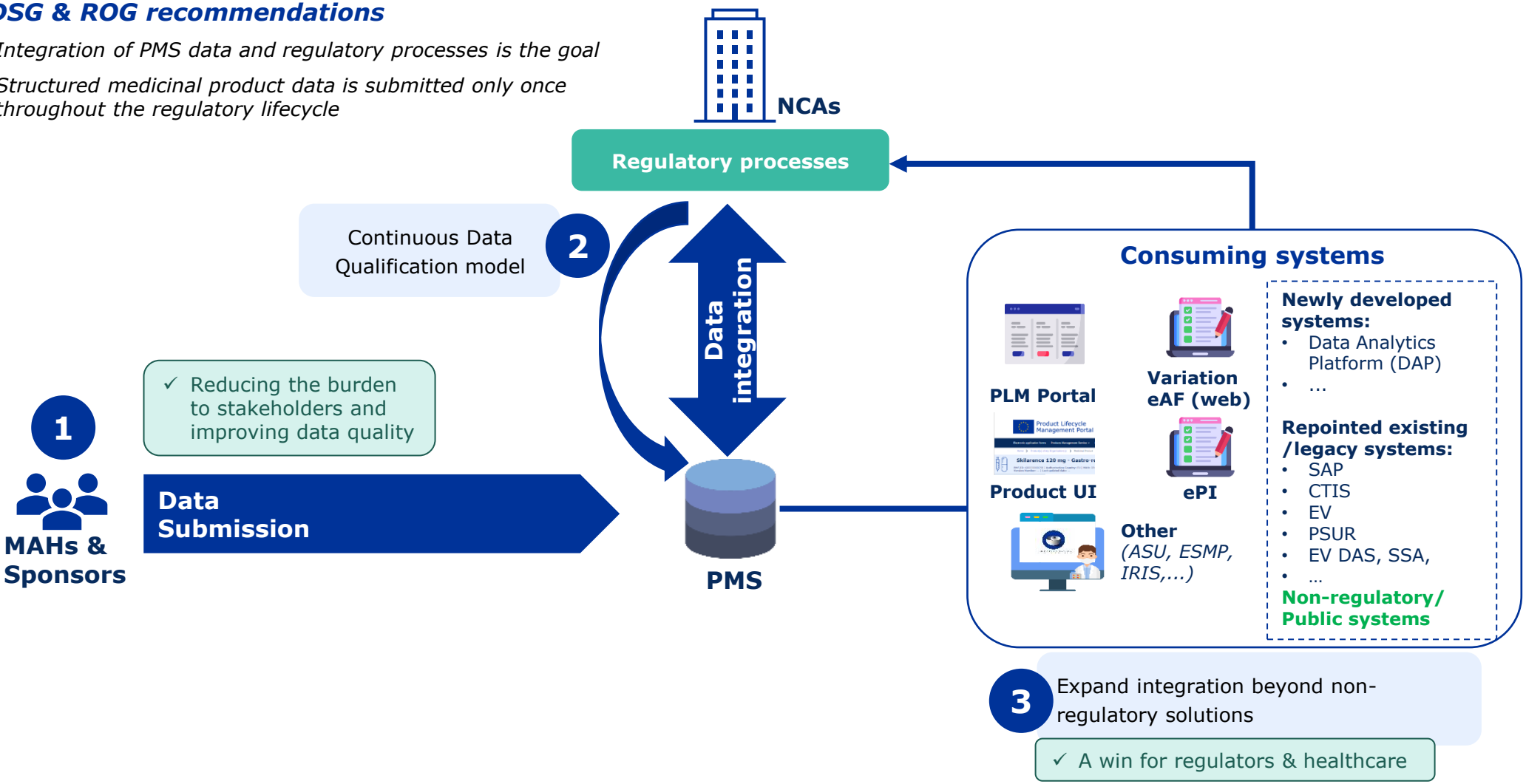
Goal for PMS

Legend

✓ Benefits

NDSG & ROG recommendations

- *Integration of PMS data and regulatory processes is the goal*
- *Structured medicinal product data is submitted only once throughout the regulatory lifecycle*



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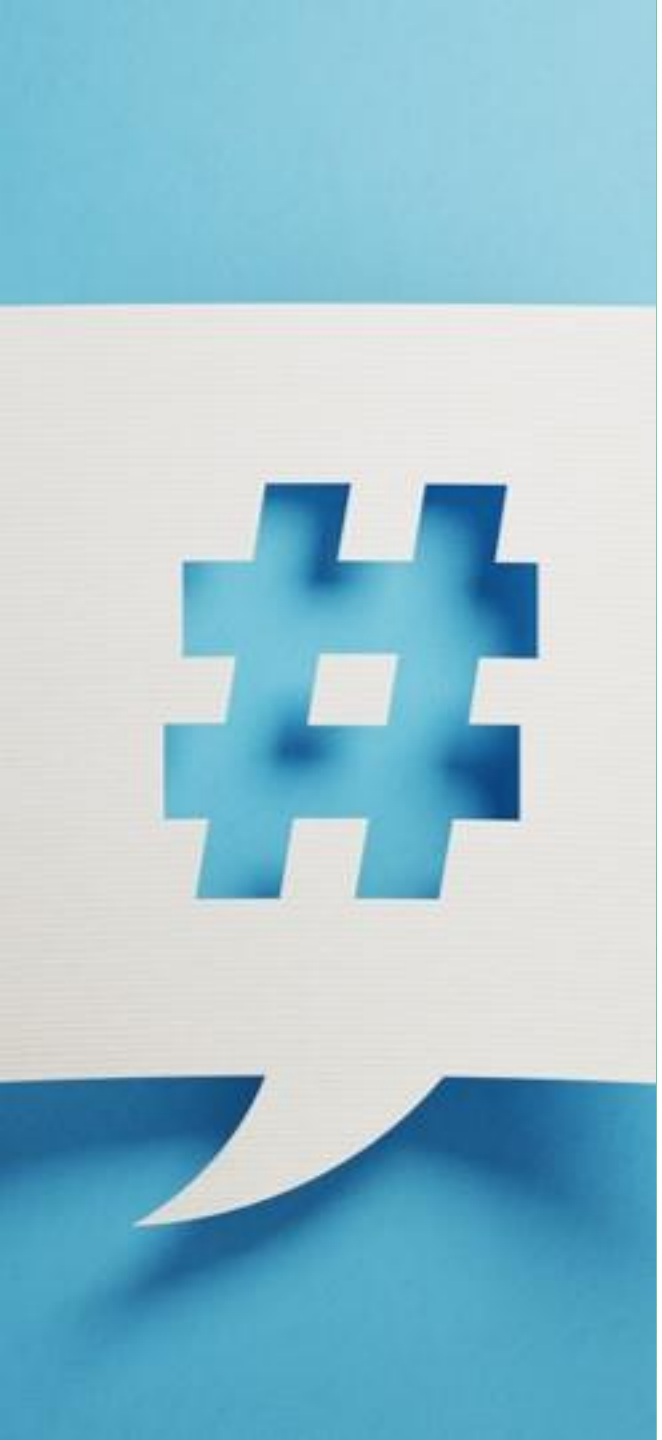

Key takeaways & conclusions

1

In the near future

- XEVMPD submissions support Art 57 obligations as well as needed enrichments
- Enrichments are expanded to all products in the portfolio
- NCAs mapping activities are progressing, initially aligning products and then ensuring that information in them is consistent across PMS and National systems

2

A first step is foreseen to simplify submissions and data flows

- In a timely manner to support New Pharma Legislation
- Enabling submission of both Investigational (IMP) and Authorised medicinal product (AMP) data via the PMS API or PUI
- Consuming existing/legacy systems repointed to PMS
- Discontinuation of XEVMPD at a given cut-off date

3

***To further reduce the burden to stakeholders and improve data quality*:**

- Integration of PMS data and regulatory processes is the goal
- Structured medicinal product data submitted throughout the regulatory lifecycle

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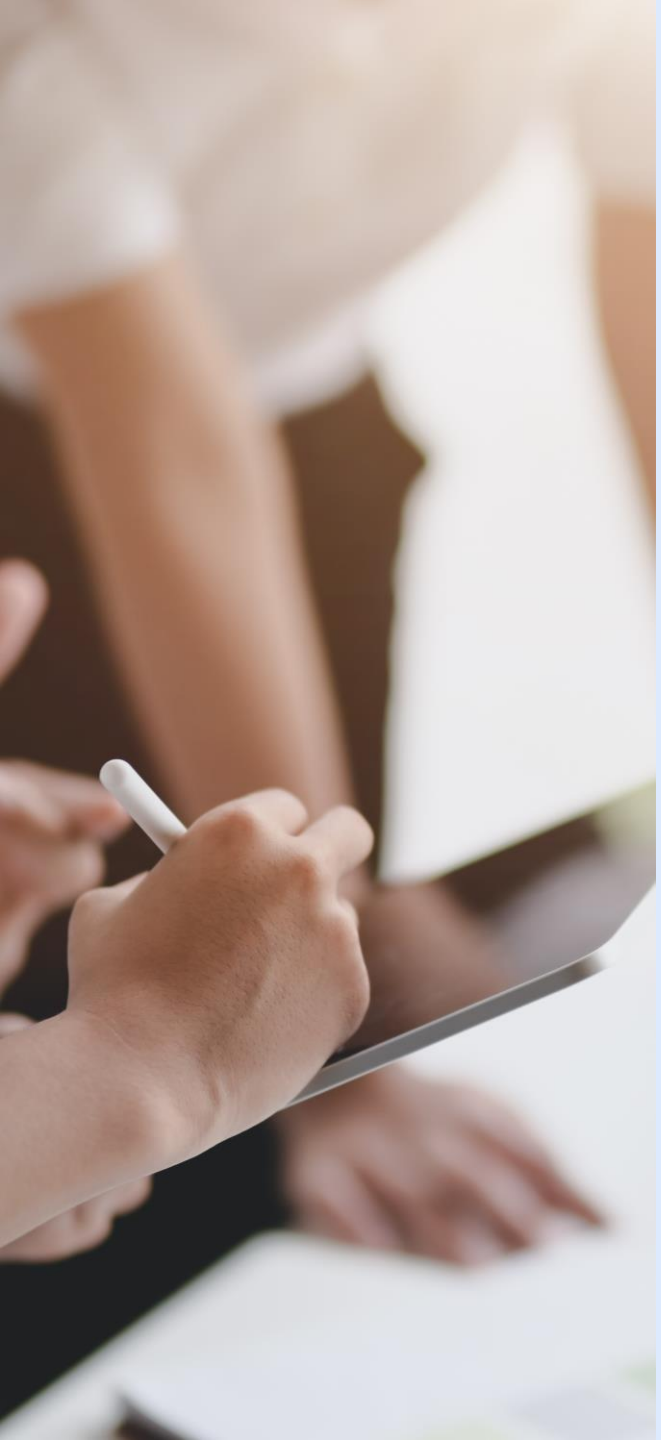

Your feedback matters

- Please spare a few minutes to **complete the quick survey we just launched** in Slido, sharing **your feedback on this specific session**
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Q&A session

Q&A housekeeping rules

- We will begin by answering a **few questions from participants in the room**, followed by **selected questions from Slido,** which will also be addressed verbally
- We will **not answer questions in writing** during the day
- The **unanswered questions** will be reviewed after the event, and the most **frequent/ relevant ones** will be added to the online **PMS FAQ document**.

How to ask a question?

On-site participants

- **Raise your hand** then ask your question orally (please unmute your microphone)

Online participants

- **Join Slido.com** using this code **#PMS-INFO-25** or scanning the QR code on top
- Ask your questions and vote the ones you would most like to be answered

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