

# Product Management Service Info-Day

21 May 2025





# **Session 1: PMS a strategic Network data asset**

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



## Chairs:



**Peter Arlett**

*Co-chair of the  
Network Data  
Steering Group  
(NDSG) and Head of  
Data Analytics and  
Methods Task Force*



**Emmanuel Cormier**

*ESMP Business  
Sponsor and Head of  
Regulatory Science  
and Innovation Task  
Force*

## Speakers:



**Aimad Torqui**

*Member of Network Portfolio  
Advisory Group (NPAG),  
Network Data Steering  
Group (NDSG) and  
Regulatory Optimization  
Group (ROG)*



**Georg Neuwirther**

*Member of Network Data  
Steering Group (NDSG)  
and Regulatory  
Optimization Group (ROG)  
PMS Operational Group*



**Pelle Persson**

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



**Jerome De Barros**

*European Commission  
representative (DG SANTE)*

Speakers:



**Aimad Torqui**

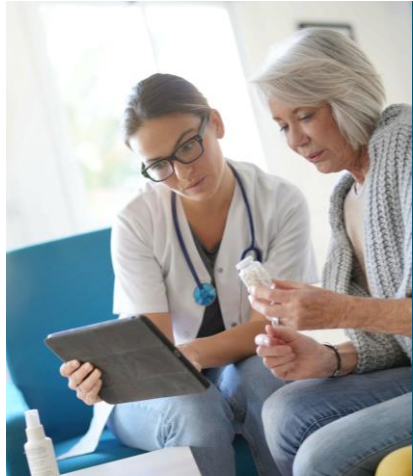
*Member of Network  
Portfolio Advisory Group  
(NPAG), Network Data  
Steering Group (NDSG)  
and Regulatory  
Optimization Group  
(ROG)*

Topic:

# The European medicines agencies network strategy 2028

# EMANS to 2028

## Strategic Focus Areas (themes)



**Theme 1:  
Accessibility**



**Theme 2:  
Leveraging  
data,  
digitalisation  
and artificial  
intelligence**



**Theme 3:  
Regulatory  
science,  
innovation and  
competitiveness**



**Theme 4:  
Antimicrobial  
resistance and  
other health  
threats**



**Theme 5:  
Availability  
and supply**



**Theme 6:  
Sustainability  
of the network**

[The European medicines agencies network strategy 2028](#)

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Classified as public by the European Medicines Agency

# EMANS 2028

## Driving digital transformation and sustainability



### Theme 2 Leveraging data, digitalisation and AI

Data driven network

Experimentation / innovation

Technology modernization and  
cybersecurity

### Theme 6 Sustainability of the network

Capabilities

Shared operating model

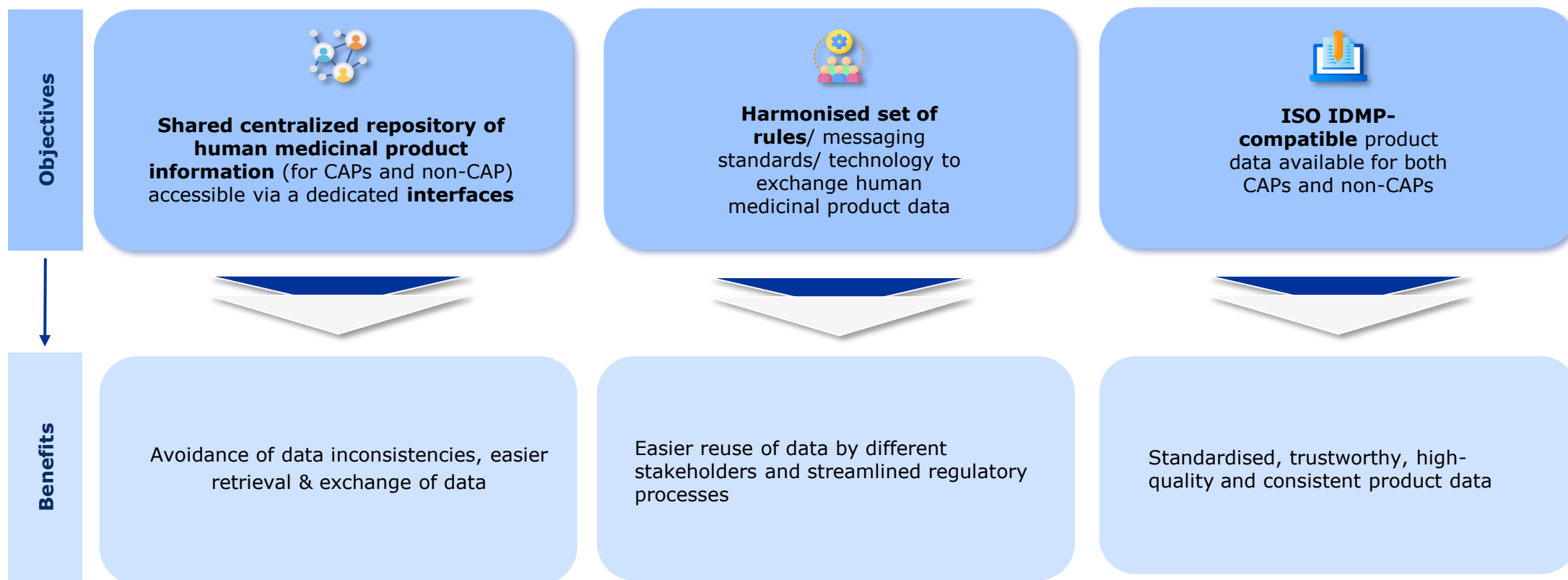
Technology modernization and  
pharma legislation

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# Product vision, main objectives and benefits



**Product Management Service (PMS)** will make available, for human and machine interaction, **structured, standardised and consistent human authorised medicinal product data** from across the European Medicines Regulatory Network. PMS data will be used by regulators and industry in **regulatory and non-regulatory procedures** as well for the general benefit of European citizens.



# Objectives of theme 2: Leveraging data, digitalisation and artificial intelligence



## Goal 2.1 (data for decision making)

2.1.1: **Embed the use of EU healthcare data** from diverse populations in the network's processes, including in support of the EHDS implementation, and pilot the use of novel types of data (e.g. synthetic data, patient experience data or data for personalised medicine, e.g. genomic data)

2.1.2: Ensure a **high level of interoperability** (including through the use of master data), **standardisation and quality of data**, addressing potential biases and ethical considerations, and ensure that the network data assets are appropriately managed

**"Shared Source of Truth" \***

**PMS API**

**eAF**

**Product UI**

\* – also Theme 6



## Goal 2.1 (digitalisation, experimentation and innovation)

2.2.1 **Reinforce the network's digital infrastructure in line with the Network Portfolio Vision to drive the digital transformation of the network's scientific and regulatory processes**

**Information Security**

**Legacy Modernisation\***

2.2.2: Foster a culture of **continuous experimentation and innovation** across the network

**Data Analytics & AI**

**ePI**



## Goal 2.3 (artificial intelligence)

2.3.1: **Leverage experimentation and technological advances in AI** to support the digital business transformation of the EU network

**Data Analytics & AI**

2.3.2: Harness the potential of **AI throughout the medicines' lifecycle**

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Speakers:



**Georg Neuwirth**  
*Member of Network  
Data Steering Group  
(NDSG) and Regulatory  
Optimization Group  
(ROG) PMS Operational  
Group*

Topic:

# EMRN Data Strategy and Network Data Steering Group (NDSG) Workplan

# From Vision to Implementation

## Business Strategy



[The European medicines agencies network strategy 2028](#)

### EMANS 2028

Provides long term direction for **business** areas.

## Data strategy



[Draft-EMRN Data Strategy public consultation November 2024](#)

### EMRN Data Strategy

Aligns uses of data with business priorities.

## Data Planning

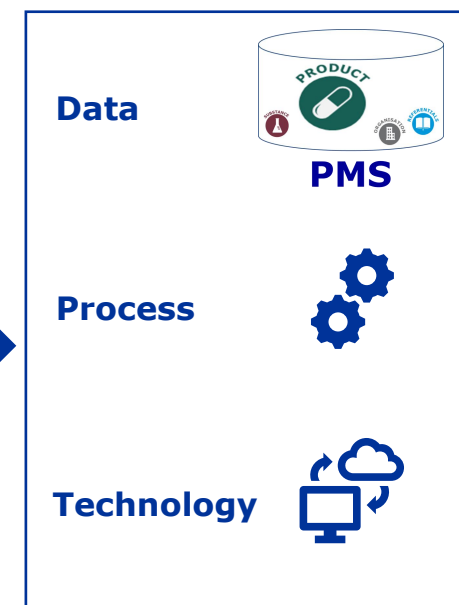


[Network Data Steering Group workplan 'Data and AI in medicines regulation to 2028'](#)

### NDSG Workplan

Ensures Data Management improvements align with expected business value.

## Implementation



### Building blocks and processes

Ensures Data is managed in line with expected business needs.

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# Problems addressed by the Data Strategy

- **Data not findable, accessible nor reusable**

*What data do we have? Where is it? What standards apply? Who owns the data? Who can access? Who can I ask for data? Is this data the same as that data?*

- **Data quality monitoring & fix not systematic/ standardised**

*How should data quality be monitored? Who should monitor? Who is responsible for fixing it? What is adequate data quality?*

- **Roles, responsibilities & definitions in data management vary and are not formalised**

*Who works on what data? Who is responsible for what? What does a data owner do? What does "data asset" mean?*

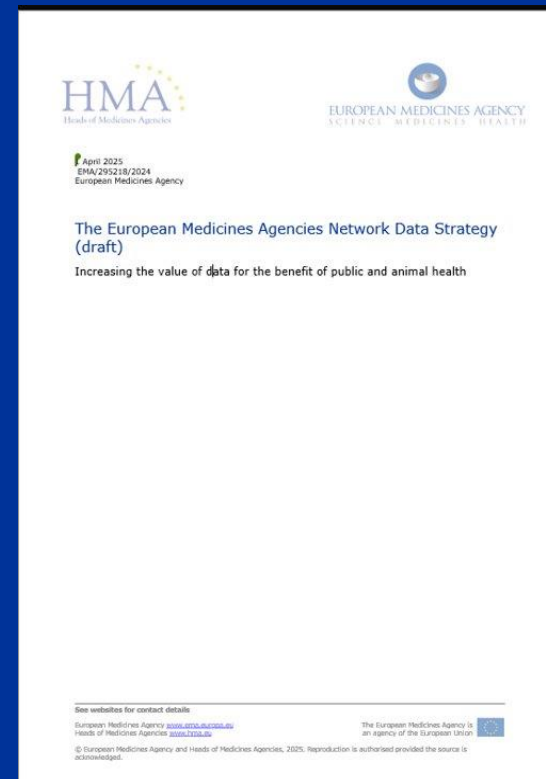
- **Difficulties to solve issues on data matters between systems**

*Who should be addressed? Who can decide - when, where and how? How can it be fixed?*

- **Different working standards & structures, unclear processes**

*What working agreements apply? How can we understand the process?*

- **Manual processing/ use of data is time-consuming, risk for errors, inconsistent outcomes**



[Draft-EMRN Data Strategy\\_public\\_consultation November 2024](#)

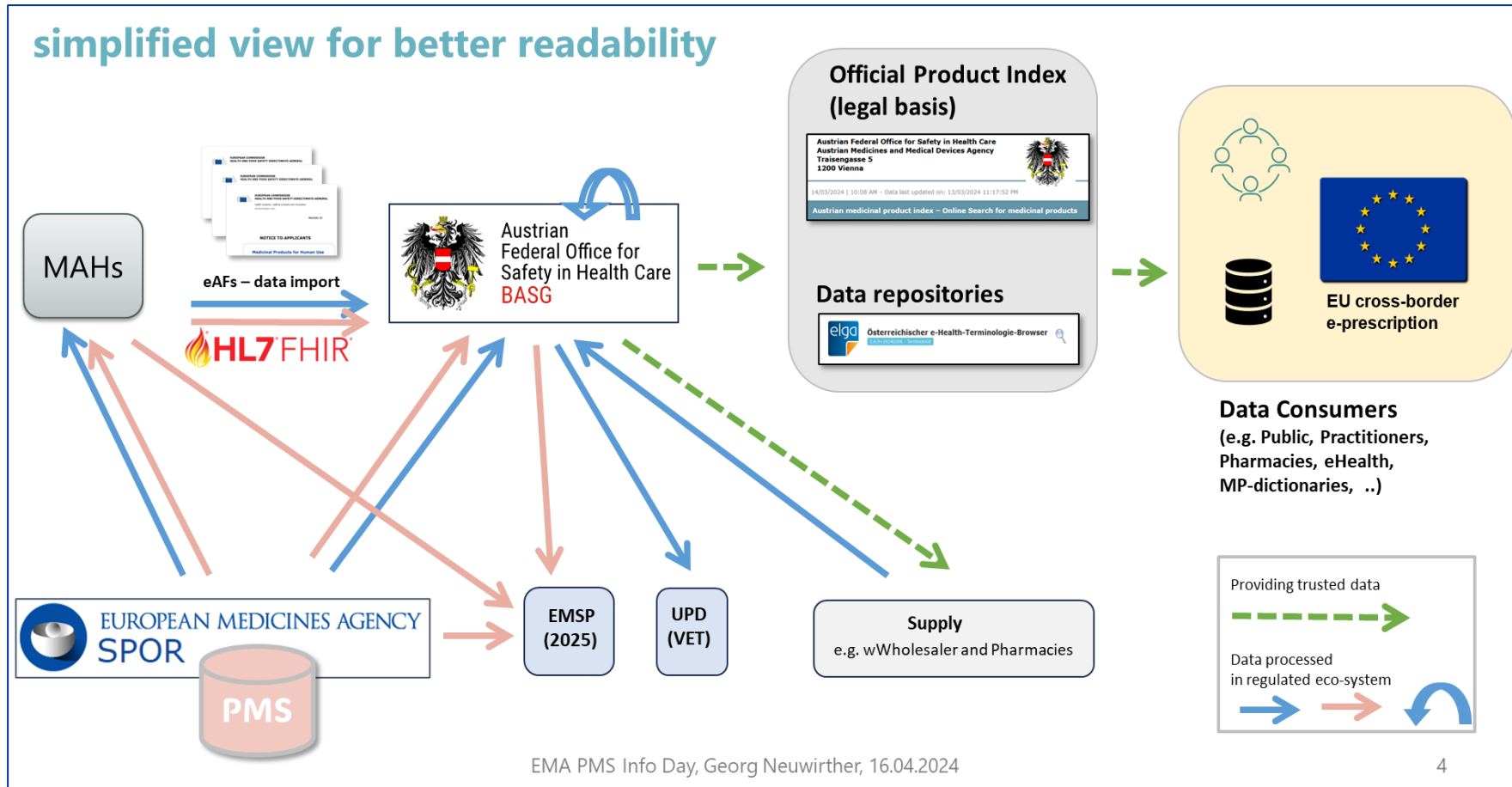
**We can do better** on Efficiency, transparency, collaboration, problem-solving, service and decision-making by **leveraging good local practices**

The EMRN is not fully realising public / animal health or business benefit from data – **better data governance is part of the solution**

**SPOR PMS plays an important role in achieving the goals!**

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# Need for alignment and interoperability



- The flow of data/information in the EU Network is **complex**
- Through SPOR/ PMS, we are **embedding common standards and master data into the daily work** of regulators across the network and facilitating efficient communication with industry.

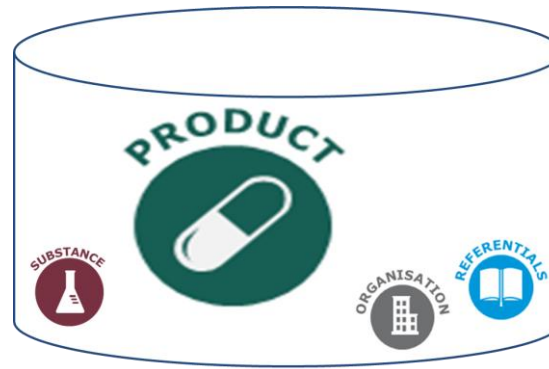
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# Product Master Data Management

## Opportunities

A shared data repository for all Medicinal products

as a trusted data source for regulatory activities and data-driven processes in the EMRN (like ESMP)



# PMS

## Challenges

- How to achieve and maintain the expected data quality level?

- e.g. At moment data feeding via XEVMPD, therefore not supporting data consistency across the EMRN

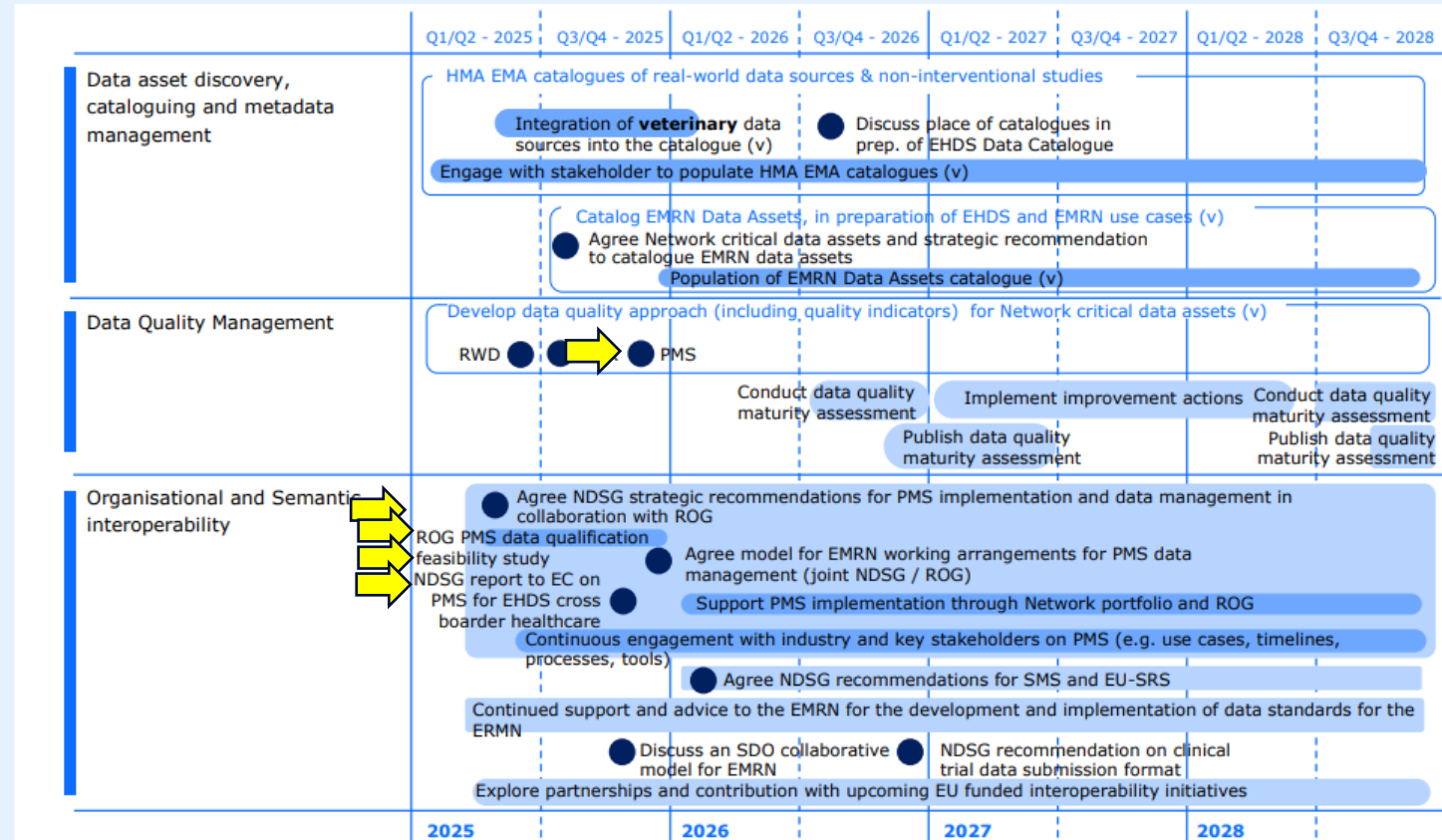
- e.g. "regulators systems, PMS and industry system's data might differ ..."

- How to implement efficient business and technical processes?

# How managing master data is reflected in the NDSG workplan?

## WORKSTREAM OVERVIEW

### Data interoperability



● Deliverable/activity    Timeframe (v): Scope applicable to veterinary aspects

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## Key activities and milestones

- NDSG strategic recommendations for PMS implementation and data management in collaboration with ROG – Adopted by NDSG in April, presented to HMA and MB in May
- ROG PMS data qualification feasibility study – From June to December
- Agree model for EMRN working arrangements for PMS data management (joint NDSG/ROG) - December 2025
- PMS Data quality approach – December 2025



Speakers:



**Pelle Persson**

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

Topic:

# PMS and interoperability, a joint effort on all levels

# PMS: A strategic European asset



## PMS: a shared trusted source of information

- Enables EMANS 2028 and Data Strategy objectives
- Foundation for interoperability, regulatory efficiency
- Trusted shared source for both regulators and external stakeholders



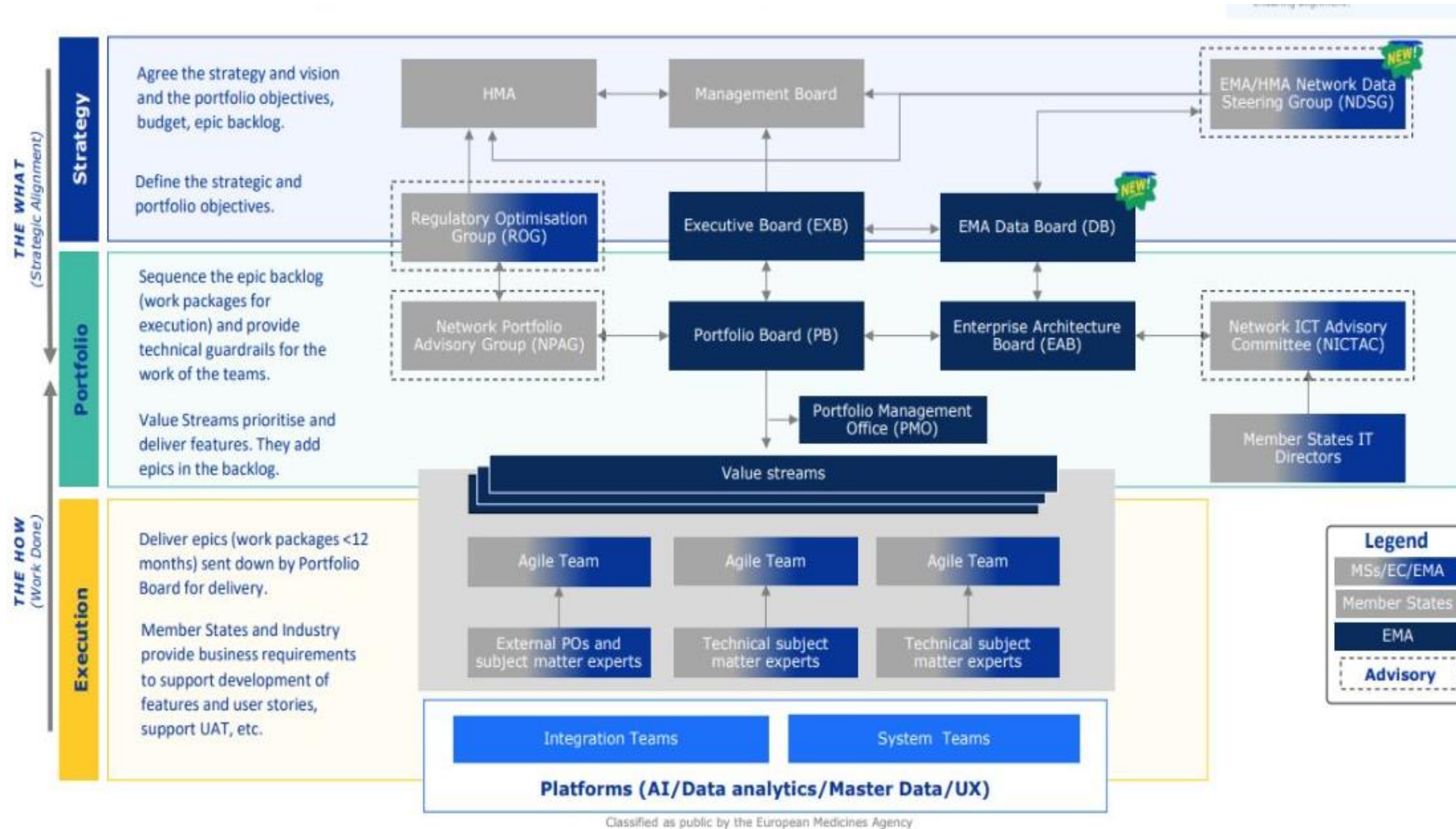
## Network opportunities

- Harmonising national exchange formats
- Cross border – from bi-national to European wide through EHDS
- PMS as source for richer, higher-quality patient information - ePI

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# Network Portfolio Governance



- **Network portfolio is supported by multiple groups who contribute at different levels and from different perspectives:**

- *NDSG > data flows, data management*
- *ROG > operating models, business process*
- *NICTAC > interoperability*
- *Agile delivery > prioritisation, implementation*

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# Make it happen

## – PMS and interoperability enablers

Interoperability levels and governance for cross-border developed products



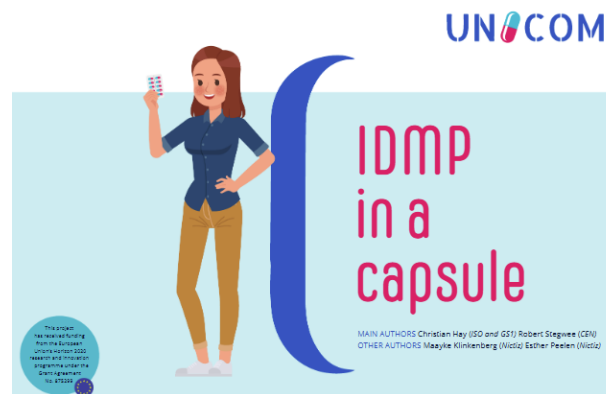
**PMS and interoperability it delivers is a joint effort on all levels**

- **PMS in the Network portfolio**
- **NDSG workplan**
- **NICTAC workplan**
- **HMA initiative – joint collaboration**
- **NCA activities**

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# HMA IDMP Community of Experts (CoE)

- HMA established of an **IDMP Community of Experts (CoE)**
  - Include experts from EMA and all willing NCAs: to strengthen the ongoing IDMP implementation at regulator level
  - Lead: SE (Pelle Persson, Christer Backman) and AT (Georg Neuwirther)
- **Keep up momentum and teamwork**, build on the positive collaboration in UNICOM
- in close collaboration with EMA initiatives by
  - Supporting knowledge sharing
  - Providing overview of IDMP status at NCA level
  - Enhancing Data harmonisation
- Regular liaison with NDSG, HMA, ROG



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**Supporting  
network activities**

Speakers:



**Jerome De Barros**  
*European Commission  
representative (DG  
SANTE)*

Topic:

# European Health Data Space (EHDS)

# European Health Data Space (EHDS) in a Nutshell – what is it about?

## 1 Primary use = use of data for the delivery of healthcare

- Improving patients' access to their health data;
- Ensuring seamless exchanges for continuity of healthcare.

## 2 Requirements for electronic health record (EHR) systems

- Creating a single market for electronic health records systems, supporting both primary and secondary use.

## 3 Secondary use = use of data for research and public interest purposes

- Making data available for research, policy-making etc. in a safe and secure way.

See

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32025R0327>.

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**What are we  
talking about?**

### Primary use

- Patient summary
- e-Prescription
- Dispensation
- Medical images
- Medical test results
- Discharge reports

### EHR systems

- compliance & interoperability

### Secondary use

- Exchange of data





# Value of a trusted EU wide product data source for EHDS

## A trusted EU-wide product data source:

### is essential for ePrescription and eDispensation because it:

- ✓ Ensures **accurate identification of medicines** across countries.
- ✓ Supports **cross-border interoperability**, enabling prescriptions from one country to be correctly interpreted and dispensed in another.
- ✓ Improves **patient safety** by reducing medication errors.
- ✓ Streamlines **workflows** for pharmacies and healthcare providers.

It enables safer, smoother, and more consistent digital prescribing and dispensing across the EU.

### adds key value to secondary use of health data in the EHDS by:

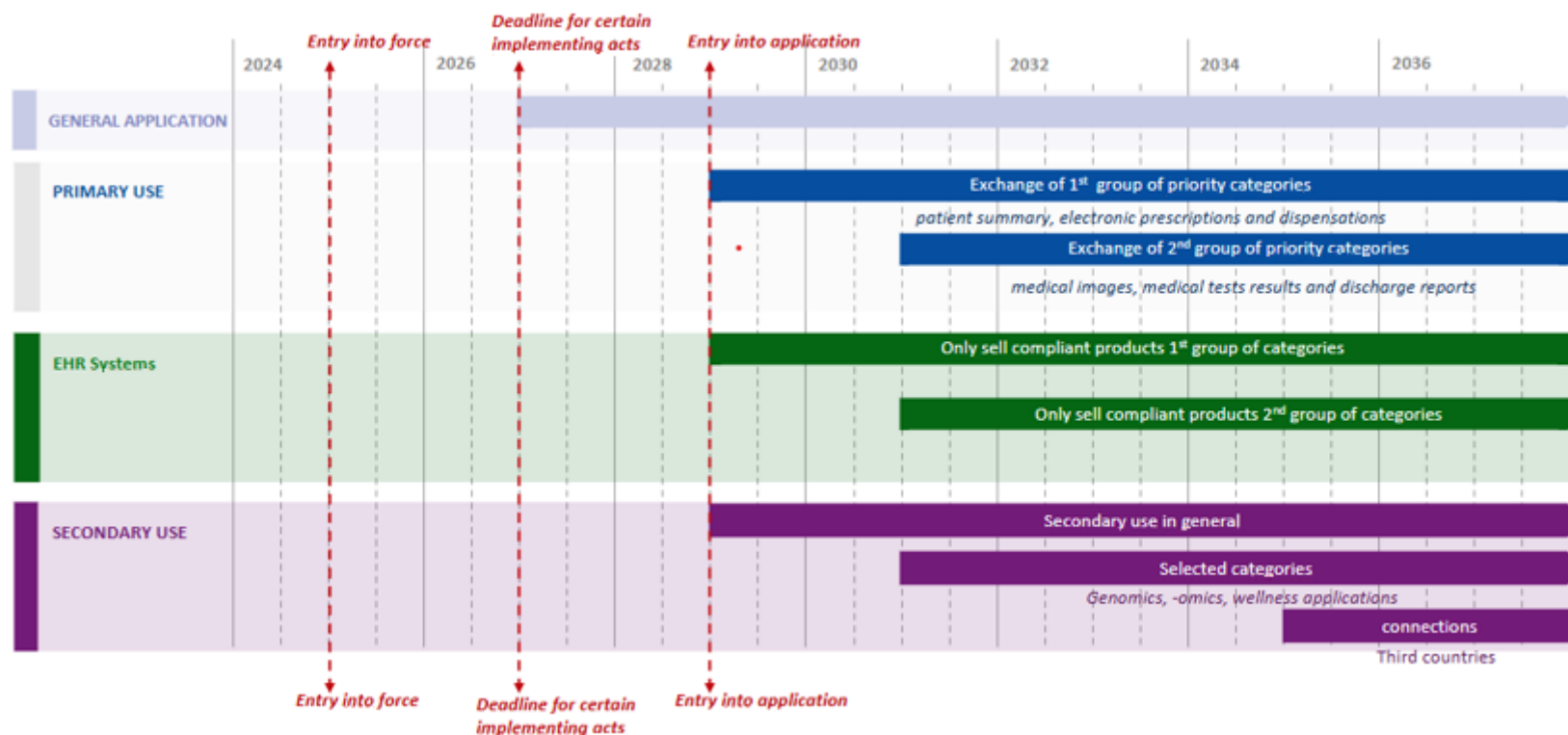
- ✓ Ensuring **data consistency and quality** across countries.
- ✓ Enabling **accurate links between treatments and outcomes**.
- ✓ Supporting **cross-border research and public health comparisons**.
- ✓ Enhancing **public health surveillance** and early safety signal detection.
- ✓ Informing **evidence-based policy and regulation** at EU level.

It ensures that research and public interest uses of health data are reliable, comparable, and impactful across the EU.

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# EHDS – Overall timeline for application



## Key milestones

- 2025: EHDS entry into force
- **2027: Implementing acts published** (expected to be based on existing eHealth ePrescription/eDispensation guideline)
- **2029: entry into application - all in place for Presc/eDisp** and most secondary use
- 2031: entry into application - advanced set of categories

# Panel Discussion



# 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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# 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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