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EUROPEAN MEDICINES AGENCY

Product Management Service Info-Day

21 May 2025

Session 4:
PMS, our shared journey

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

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Chairs:

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PMS Business Sponsor and Head of Human Medicines Division

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Speakers:

Veronica Lipucci Di Paola
EMA PMS Product Owner

Dino Soumpasis
Network PMS Product Owner, BfArM

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Javier Monvoisin
PMS Subject Matter Expert (SME), Medicines for Europe

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Speakers:

Veronica Lipucci Di Paola
EMA PMS Product Owner

Dino Soumpasis
Network PMS Product Owner, BfArM

Topic:

PMS Status Update

Product Management Service achievements

Date	Product UI Milestone	PMS API Milestone
May 2024	**Read-only** for MAHs & NCAs (CAPs)	–
July 2024	–	**Read-only** for MAHs (CAPs & non-CAPs)
Sep 2024	**Read-only** for MAHs & H&V NCAs (CAPs & non-CAPs)	**Read-only** for H&V NCAs (CAPs & non-CAPs)
Dec 2024	-	**Read-only** for H-only NCAs (CAPs & non-CAPs)
Jan 2025	**Write access** for MAHs (non-CAPs)	-

In **2024:** all authorised CAPs and non-CAPs data have been migrated to PMS from XEVMPD/SIAMED, enabling read access for all stakeholders to PUI and API

In **2025:** Enrichment of data in PMS is launched

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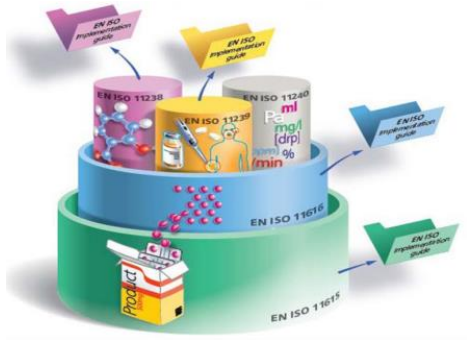
PMS Data Model

Colour legend

- Medicinal Product definition
- Regulated Authorisation (Marketing Authorisation)
- Manufacturer / Organization definition
- Therapeutic indication
- Packaged Medicinal Product Definition
- Pharmaceutical Product
- Ingredient

ISO IDMP	Description
ISO 11238	Data elements and structures for unique identification and exchange of regulated information on Substances
ISO 11239	Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
ISO 11240	Data elements and structures for unique identification and exchange of units of measurement
ISO 11616	Data elements and structures for unique identification and exchange of regulated pharmaceutical Product information
ISO 11615	Data elements and structures for unique identification and exchange of regulated medicinal Product information



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PMS

ePI

eAF

ASU

ESMP

IRIS Portal

PMS

ePI

eAF

ASU

ESMP

IRIS Portal

PMS data needed for ePI

"The linkage of an ePI and its product in PMS is done through the PMS ID and the Data Carrier Identifier (CDI) ensuring full traceability from regulatory, public and marketed information."

PMS Data Element	ePI Field	Purpose/Impact
Product Management Service Identifier (PMS ID)	PMS ID	• Auto-filled for consistency • Standard terminology used • Ensures controlled vocab • Enables structured tracking • Enables data exchange
Data Carrier Identifier	Data Carrier Identifier Value	

PMS → IRIS Dataverse → ePI → Regulatory/Public Use

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PMS

ePI

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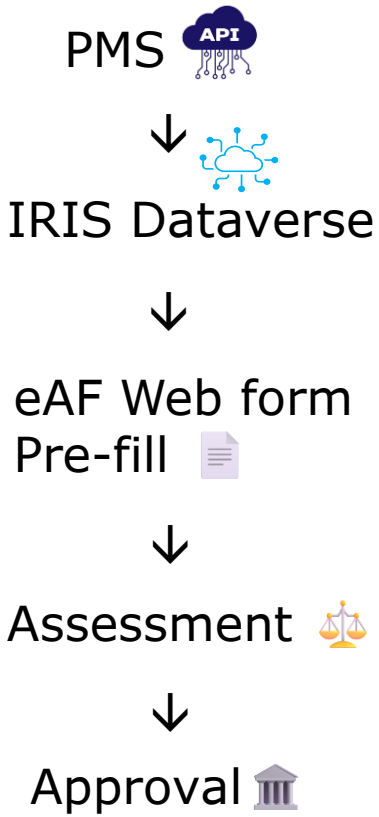
ESMP

IRIS Portal

PMS data needed for eAF

"PMS delivers structured product data that pre-populates and supports key fields in the electronic Application Form (eAF) for variations."

PMS Data Element	eAF Section	Purpose/Impact
Product Management Service Identifier (PMS ID)	Product Selection	• Auto-filled for consistency • Standard terminology used • Avoids free text errors • Ensures controlled vocab • Enables structured tracking • Enables data exchange
Medicinal Product Identifier (MPID)		
Domain		
Type		
(Authorised) pharmaceutical form		
Medicinal Product Full Name		
Marketing authorisation number (MP/PMP)		
Marketing authorisation Country		
Marketing authorisation holder (organisation)		
Marketing authorisation procedure (Id, type)		
Marketing authorisation status (MP/PMP)		
Packaged Medicinal Product Identifier (PCID)		
Package description; Pack size		
Ingredient (Active substance)		
ATC code(s) & ATC Flag; GMO; PSMF; Medical Device;	Proposed Changes/Structured Changes	



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PMS

ePI

eAF

ASU

ESMP

IRIS Portal

PMS data needed for ASU

"PMS enables the collection and analysis of ASU data by prepopulating the templates with standardised and complete product data."

PMS Data Element	ASU Field	Purpose/Impact
Product Management Service Identifier (PMS ID)	PMS ID	• **Product identification** • **Calculation of total amount of antimicrobial active substance per product presentation** • **Antimicrobial use data analysis**
Packaged Medicinal Product Identifier	Package ID	
Marketing authorisation number	Marketing authorisation number	
Procedure type – Medicines approval system	Procedure type	
Medicinal product name	Medicinal product name	
(Authorised) pharmaceutical form	ASU product form	
Pack size	ASU pack size	
Manufactured item quantity	ASU pack size	
ATC code(s)	ATC code	
Reference substance or Substance	ASU substance	
Reference strength or Strength (concentration and presentation)	ASU strength	

API PMS → 📄 ASU Template Pre-fill → 📈 Analysis

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EMA

PMS

ePI

eAF

ASU

ESMP

IRIS Portal

PMS data needed for ESMP

"PMS provides structured product data that supports the fulfillment of ESMP requirements for critical medicines."

PMS Data Element	ESMP Section	Purpose/Impact
Product Management Service Identifier (PMS ID)	Product Information	• Auto-filled for consistency • Standard terminology used • Avoids free text errors • Ensures controlled vocab • Enables structured tracking • Enables data exchange
Packaged Product Management Service Identifier (PMS ID)		
Full Product Name		
Short Product Name		
Active Substance		
Strength		
Pharmaceutical Dose Form		
Pack Size		
Packaging		
PCID		
Country of Authorisation		
Organisation ID/Name	Manufacturer's Organisation Information	
Organisation Location ID/City/Country		
Operation ID/Type		

API PMS → IRIS Dataverse → ESMP Template Pre-fill → Analysis/Crisis Preparedness

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EMA

PMS

ePI

eAF

ASU

ESMP

IRIS Portal

PMS data needed for IRIS Portal procedures

"Procedures taking place on the IRIS Portal leverage PMS data to support various regulatory activities, including:

- *Inspections, using medicinal products, manufacturer data and operations migrated from SIAMED to PMS*
- *Parallel Distribution, relying on PMS data for centrally authorised products (CAPs) to track distribution case forms*
- *CAPs marketing status*
- *PSURs, PASS, referrals: CAPs and non-CAPs*
- *Variations for CAPs and non-CAPs WS*
- *Other procedures of the product lifecycle for CAPs (e.g. renewals, post authorisation measures, etc)*

IRIS Portal uses PMS Data Derived From:	**Purpose/Impact**
• Product data uploads from **XEVMPD** and **SIAMED** • Enrichment data submissions by non-CAP MAHs (i.e. structured manufacturer operations and pack size data)	• Auto-filled for consistency • Standard terminology used • Avoids free text errors • Ensures controlled vocab • Enables structured tracking • Enables data exchange

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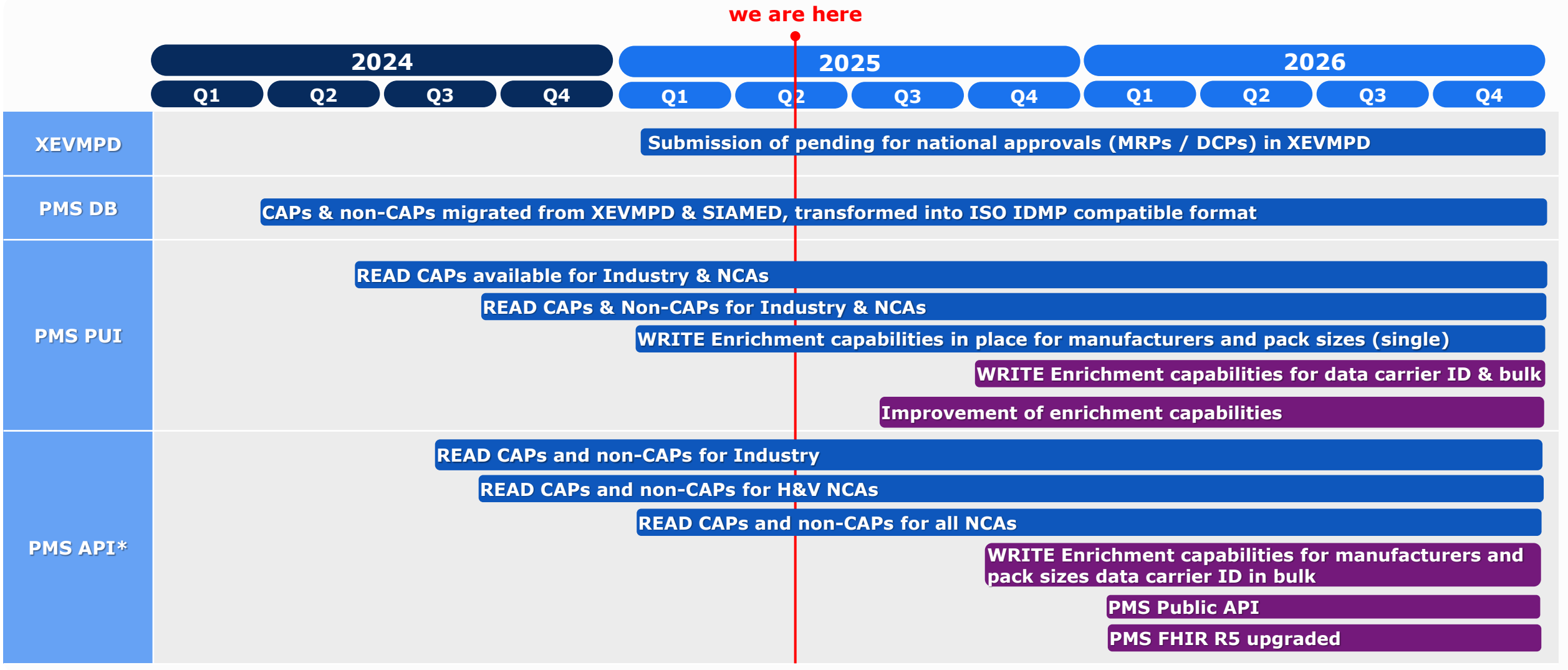
What capabilities are and will be available to users



Legend | **Delivered capability** | **Planned delivery**

*Write PMS API IG updated in May

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Key Activities for NCAs

- **Request PMS access** to the **Product User Interface** or **Application Programming Interface** and **optional review structured products data** including the manufacturers and pack sizes information submitted by MAHs for non-CAPs.
- **Continue adoption of ISO IDMP standards** and **align NCA databases with the PMS data model**, where applicable, to enable ISO IDMP compatibility, seamless machine-to-machine communication, and interoperability.
- **NCA vs PMS Data Mapping:** Ensure medicinal product data in the NCA database is accurately **mapped to PMS** master data. **Seek EMA support** to map legacy product data to PMS and establish a process to keep new PMS product data updated in your system.
- **Collaborate with software developer/vendors** to ensure seamless **machine-to-machine integration** between NCA databases and the PMS API for accurate data exchange from PMS to NCA systems.

What EMA is doing to support NCAs

1) Monthly PMS data mapping meetings *until December 2025 for NCA staff representatives to:*

- Report on **data mapping progress** (number of NCAs that submitted data, records mapped, and identified issues)
- Facilitate the **exchange of lessons learned** among NCAs
- Host **Q&A sessions** to address NCA data mapping queries

2) Public monthly PMS Q&A Clinics*:* 17 June, 22 July, 28 August, 18 September, 14 October, 18 November, 18 December

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Key Activities for MAHs pt.1

- **Request PMS access** to the PUI or/and API and ensure RIM systems are ready for MAHs to access product data through PMS API.
- **Align product data to ISO IDMP**. Ensure data is accurate, up-to-date, and ready for submission.
- **Submit & maintain products following data under Art.57 requirement:**
  - Packaged products in XEVMPD & initial dataset of structured data [i.e. ***manufacturer,*** *(including CRO data*),* and ***pack size*** data] in PMS according to the timelines:
    - Products **under ULCM** list: Deadline for data submission is **December 2025**.
    - All **other products**: Deadline for data submission is **December 2026**.
- **Work closely with software developers/vendors** to ensure a seamless machine-to-machine connection between the MAH's RIM system and the PMS API for accurate future data submission.

What EMA is doing to support MAHs

1) **Public training webinars** to demo new releases and explain key actions for MAHs
2) **Public PMS Q&A clinics**
3) **Publish PMS-related guidance documents** (i.e. PMS Q&A, EU IG, PUI Navigation guide etc.)

*: Contract Research Organisations (CRO) data apply to non-CAPs with BE studies and support ESMP and referral procedures.

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Key Activities for MAHs pt.2

XEVMPD/PMS Data submission timelines

Regulatory activity	XEVMPD	PMS *(Recommended)*
Initial MA	Within 15 calendar days from the date of MA notification	Within 15 calendar days from the date of MA notification
Post-approval ie. variation	Within 30 calendar days from the date of the authorised changes	Within 30 calendar days from the date of the authorized changes

For the moment, EMA accepts that PMS manufacturers and pack size data are submitted monthly.

Reference documents

1) Electronic submission of medicinal product information by marketing-authorisation holders
2) PMS EU IG Chapter 2 (updated in May)
3) PMS EU IG Chapter 3 (updated in May)

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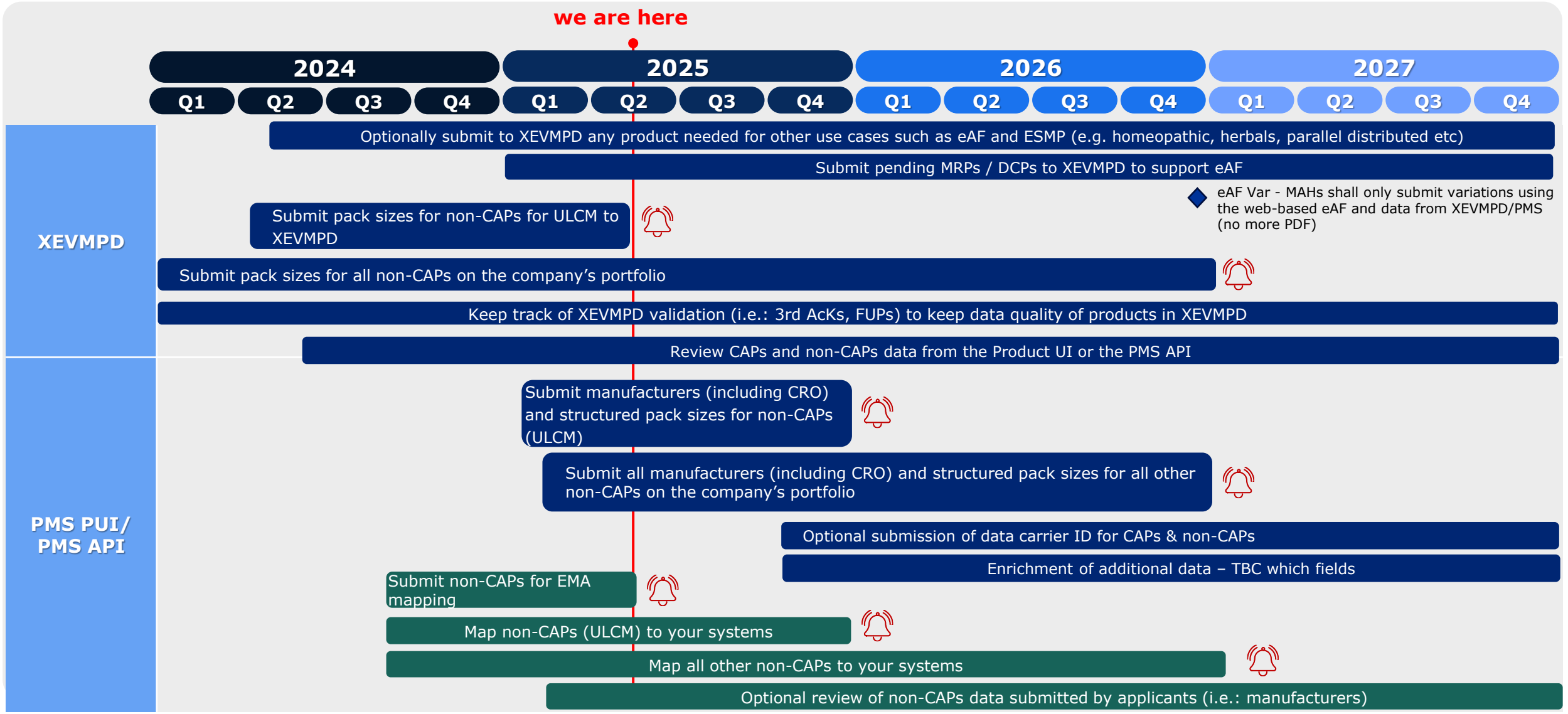
Key PMS activities for Industry and NCAs to support other use cases



Legend Industry action | NCA action | Deadline

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Upcoming events

Q&A clinics on Product UI and API

- **17 June 2025** (11:00 – 12:00 CEST): Event page
- **22 July 2025** (11:00 – 12:00 CEST): Event page
- **28 August 2025** (10:00 -11:00 CEST): Event page
- **18 September 2025** (10:00 – 11:00 CEST): Event page
- **14 October 2025** (11:00 – 12:00 CEST): Event page
- **18 November 2025** (11:00 – 12:00 CEST): Event page
- **18 December 2025** (11:00 – 12:00 CEST): Event page

Quarterly system demo

Live broadcast on event page

26 June 2025 (9:00 – 11:30 CEST)

Event page

SPOR & XEVMPD status update webinars

Live broadcast on event page

- **9 July 2025** (10:00 – 12:30 CEST): Event page
- **8 October 2025** (10:00 – 12:30 CEST): Event page

PMS Progresses: How to stay informed

PMS News page

Check:
- News
- Events announcements
- Downtime comms

Check regularly

PLM Newsletter

- See planned PMS engagement activities for upcoming quarter
- **Subscribe** here

Receive via email quarterly after subscription

PMS webinars

- **Q&A Clinics** to answer users' questions
- **Targeted training sessions** on PMS systems' use

Check EMA's Website Events Pages (when also targeting Industry), EU-NTC (for Network only)

PMS FAQ Document + PLM Portal Forum

- Check FAQs on PMS (Document)
- Ask questions (Forum)

Check regularly

Quarterly System Demos

- See the latest developments
- Give your feedback on features and priorities
- **Next system demo:** 26 Jun 2025

Announced via EMA's Website Events Pages - broadcast live

PMS Web Page

Find:
- PMS overview
- EU Implementation Guide

Check for general info on PMS

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Speakers:

Elisabeth Godet
PMS Subject Matter Expert (SME), Vaccines Europe

Topic:

Industry Overview: How is Industry prepared to implement PMS IDMP?

Substance, product, organisation and referential (SPOR) data are **a core asset** for evidence-based decisions
Sponsors and applicants play a crucial role in generating pivotal scientific data from substances and medicinal products

Preclinical Development | Clinical phases | Post-approval Lifecycle management

Data supporting public health

Regulatory Submissions Data

Real World Data
Clinical Trials

Real World Data
Pharmacovigilance

Data used to generate insights and evidence that support decisions on the safety, efficacy, and quality of medicines

Visit: Data in Regulation

European medicines agencies network strategy 2028

- **Path to accessibility**
- **Leveraging data, digitalisation and artificial intelligence**
- **Regulatory science, innovation and competitiveness** (Clinical Trials & Manufacturing)
- **Antimicrobial resistance and other health threats**
- **Availability and supply of medicines**
- **Sustainability of the network**

SPOR data are essential for the monitoring of medicines' safety and shortages

Visit: European Medicines Agencies Network Strategy to 2028

Sponsors, Applicants and MAHs are essential contributors, submitting structured product data throughout the lifecycle - crucial to leverage the power of data for public health

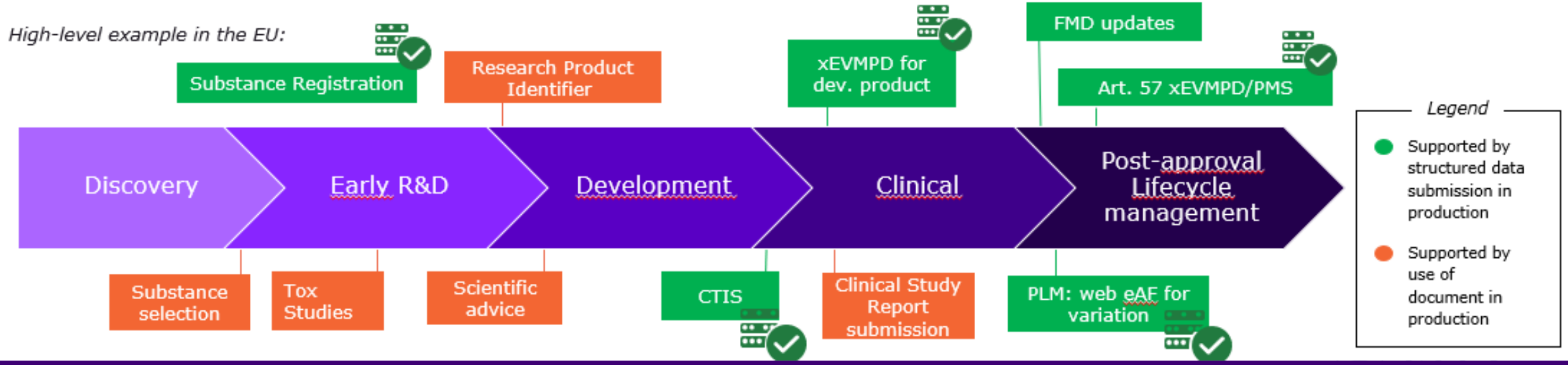
The implementation of IDMP standards marks a paradigm shift for the pharma industry

Towards Data-Driven - moving from documents to real-time data exchanges opens new possibilities for efficiency and innovation

Evidence-based decisions

- **Shift to data-driven processes**: Transition from **documents** to **data** as the primary source and for in-process exchanges.

- **Key implications**:
  - **Data** can be prioritized over documents in the **decision-making process**
  - **Data Lifecycle**: Managing both submitted and pending for approval/approved data for the same datapoint.
  - **Scientific vs. Regulatory truth**: Balancing scientifically approved information with regulatory data accuracy.
- **System requirements**: Need to manage data, not just documents.
- **Master data connectivity**: Complete knowledge integration through IDMP-compatible SPOR master data.



Substance and product structured data can strengthen evidence-based decisions, leveraging connected systems across the EU regulatory network

Industry drivers for implementing IDMP

Business drivers

- **Stronger Compliance & Access** – Meets PV regulations and improves patient access to approved, relevant information.
- **Accelerated Time to Market** – Enables faster submissions, reviews, and patient access to treatments.
- **Better Shortage Management** – Enhances reporting and reduces stockouts and overstocking.
- **Lower Admin Burden** – Minimizes post-approval work with easier data-driven updates.

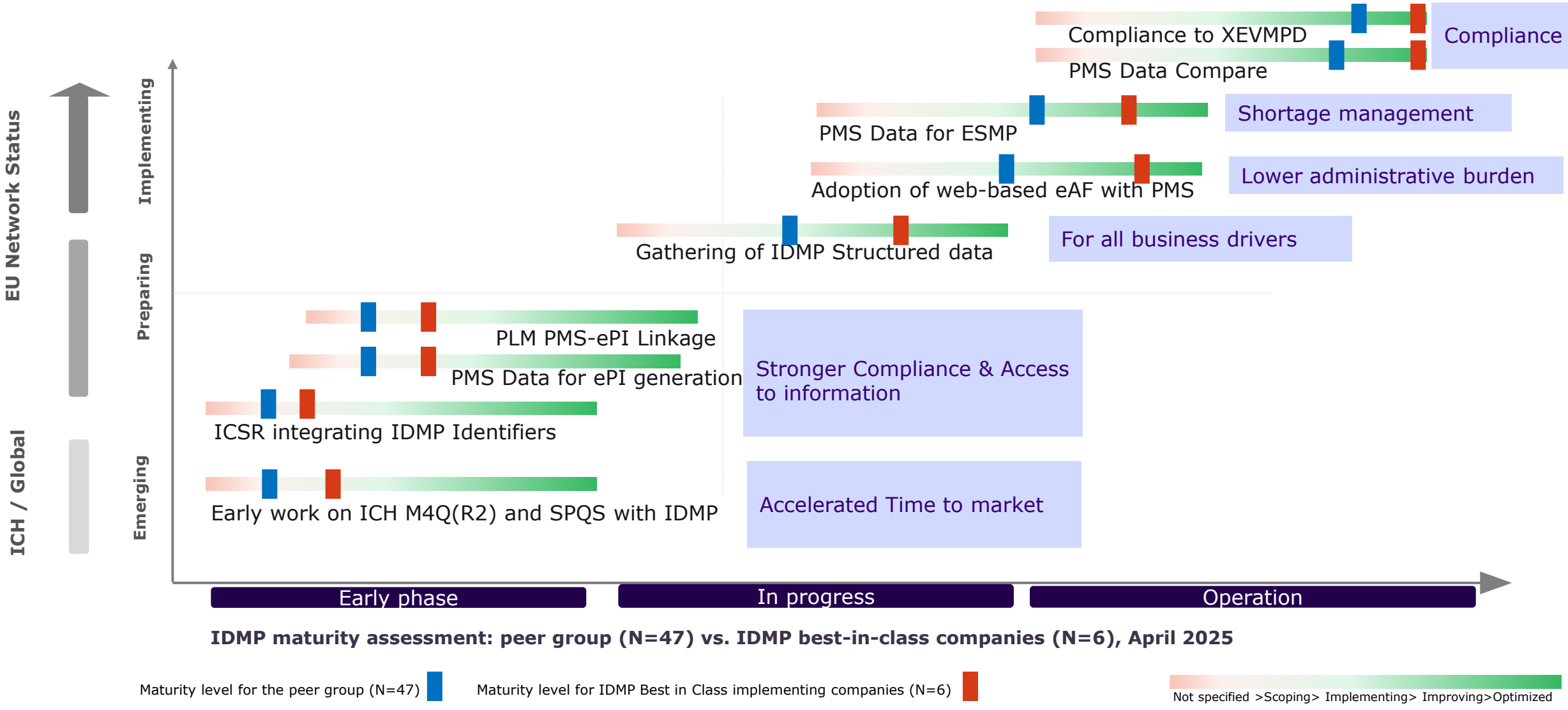
IDMP Program Objectives

- **Enhanced Data Quality** – Ensures accuracy, consistency, and reliable operations.
- **Improved Connectivity & Interoperability** – Value through data re-use. Enables seamless data flow and reduces manual work.
- **Boosted Efficiency**– Streamlines processes using AI and automation.
- **Simplified Reporting & Compliance** – Eases reporting and improves cross-functional data exchange.

The mutual benefits of SPOR leveraging consistent, high-quality data across the EU regulatory network can only be realized when the entire European Medicines Regulatory Network is fully committed to achieve interoperability through SPOR

Beyond PMS, ICH Structured Product Quality Submissions (SPQS) topic is IDMP North Star

Assessment of maturity level of product data activities, from a survey with 47 companies in April 2025: average and IDMP best-in-class companies - those reporting advanced capabilities and early, strong alignment with IDMP objectives.



IDMP maturity assessment: peer group (N=47) vs. IDMP best-in-class companies (N=6), April 2025

Maturity level for the peer group (N=47)

Maturity level for IDMP Best in Class implementing companies (N=6)

Not specified >Scoping> Implementing> Improving>Optimized

The execution of the EU network data strategy and the progress of ICH M4Q(R2), SPQS are key to achieving the full delivery of the industry IDMP implementation

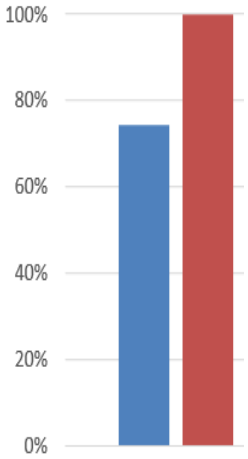
Survey indicates progress on Product Data Readiness for the PMS Compliance dates

Industry Key Steps to IDMP Readiness

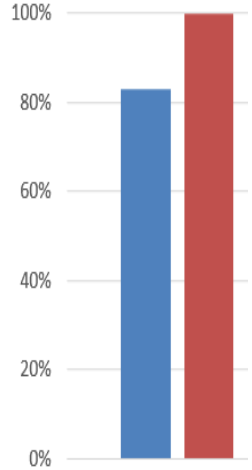
Strengthen expertise → Set up Governance → Build Process → Assess Data

On going PMS Data preparedness activities

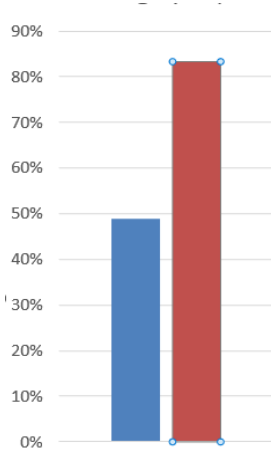
XEVMPD Data Quality → PMS map and compare → PMS Enrichment plan → PMS Enrichment execution



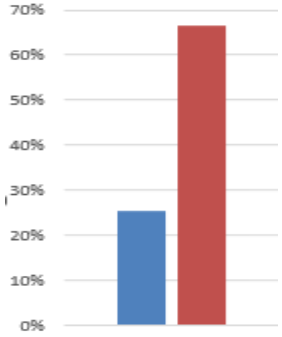
Process 3ACK and proceed with XEVMPD data correction or submit a ticket in EMA Service Now, as appropriate



Map and **compare** product data between **RIMs and PMS**



Have project structured to enrich PMS for ESMP by due dates



Have started using **PUI** to enrich PMS for ESMP use case

3ACK: xEVMPD message carrying the outcomes of the EMA data quality activities

Percentage of peers currently active (N=47)

Percentage of IDMP Best in Class implementing companies currently active (N=6)

Each step builds the foundation for sustainable IDMP compliance. Progress depends on PMS roadmap/features release, early alignment with SPOR expectations, portfolio (count of non-CAPs ULCM), processes, systems.

Industry recommendations to EU Network

1

Key Objectives guiding PMS delivery

- **Accelerate the release of the PUI Bulk edit** and **Write PMS APIs** to enable efficient data submission and maintenance
- **Progress on XEVMPD decommissioning of electronic submission of product data**
- **Consider minimising additional data enrichment** until a robust data validation and maintenance process is established

2

Data Validation & Conflict Resolution

- Consider implementation of **data validation process** applicable to the medium-long future for data submitted by MAHs in PMS
- Consider a **collaborative and structured process** for managing and reviewing enriched data and a way to **handle conflicts and data discrepancies**

3

Operational & Engagement

- Continue delivering **webinars** and **training materials** to provide regular updates as PMS rules evolve
- Maintain up-to-date **PMS Q&A** and **PMS Known Issues** reporting identified data quality issues and bug-fix timelines
- Enhance **EMA ServiceNow** process for **ticket resolution**
- **Timely address data sync issues** with quality controls
- Share insights with **PMS SME Group**

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Conclusions

Industry and the EU Network **share a vision** of unlocking the full value of regulatory and health data. **Progressing** on the implementation of IDMP is foundational to **enabling data-driven decisions** and the responsible AI adoption – ultimately improving public health outcomes.

PMS is a **strategic asset**, and the industry remains **committed to progressing IDMP** implementation as a long-term enabler of regulatory agility, **interoperability**, and innovation. **High-quality master data** is central to unlocking this value across the product lifecycle.

Now is the **time to act**. To fully harness the power of data and AI, organizations must accelerate their efforts: fully implement the product and substance data standards, invest in governance and assess data quality maturity—driving faster, safer access to better medicines across the EU.

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Speakers:

Javier Monvoisin
PMS Subject Matter Expert (SME), Medicines for Europe

Topic:

Preparing for PMS Implementation: An Industry Perspective

Use Cases for Industry Implementation

Data Integrity and Quality

Data Integrity and Quality

- Enhance the accuracy and consistency of product data
- Internal integration of product data

Use Cases and Values

- Simplify execution of complex reporting and compliance
- Simplified shortages management.
- Create significant internal value via implementation of improved levels of interoperability across a company's infrastructure reducing administrative burden

Patient Access and Compliance

Use Cases for Industry Implementation

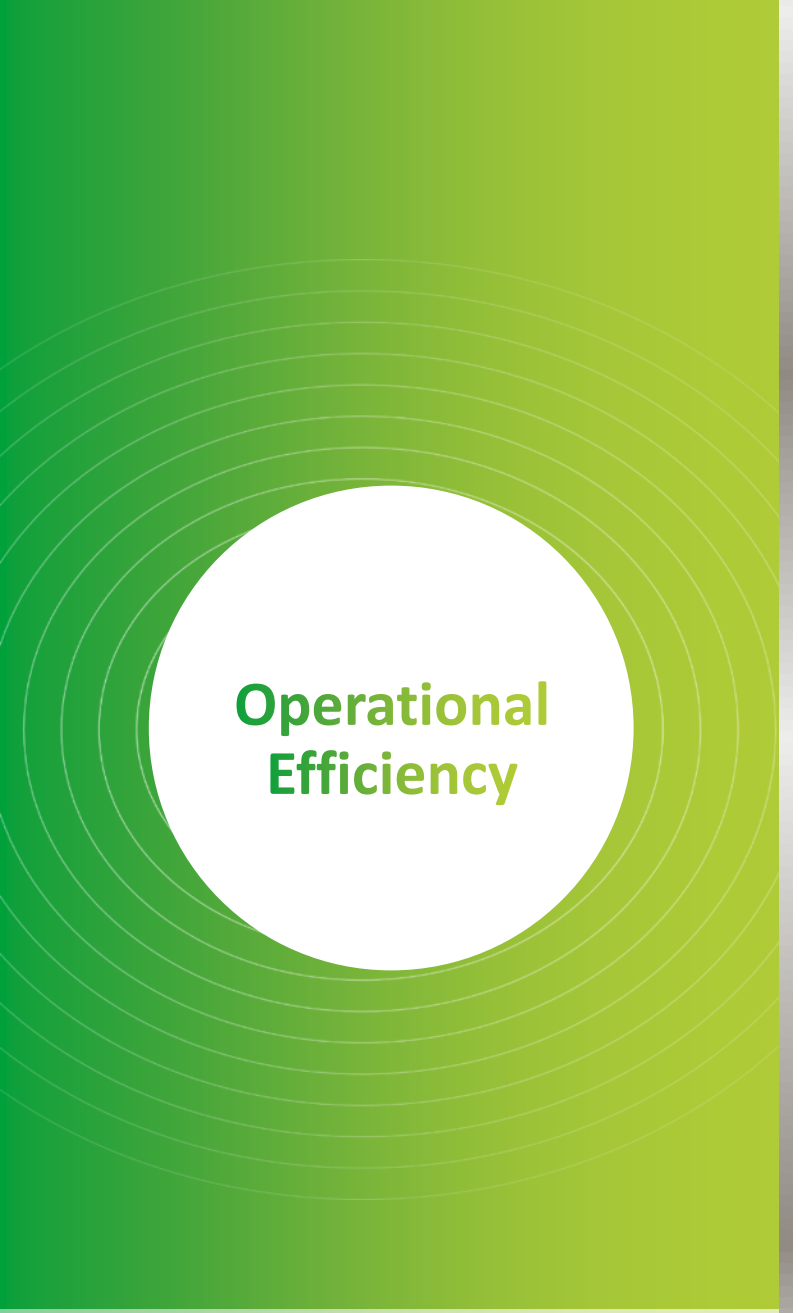
Patient Compliance and Access to Medicine Information

- Ensure adherence to legislative and operational requirements
- Improved access to medicines information for patients

Use Cases and Values

- Driver for ePI enabling better patient access to medicine information
- Industry value through realization in reduction in administration and a potential return on investment due to reduction in labour costs

Use Cases for Industry Implementation



Operational Efficiency

- Streamlining of processes
- Reduction in duplication
- Allow for easier utilization of AI and Automation

Use Cases and Values

- Increase opportunities to leverage AI and Automation
- Faster and more efficient submission and approval process resulting in benefits to Industry, Regulators, Patients and HCP’s
- Reduction in post approval workloads

Use Cases for Industry Implementation

Enhanced Safety

Improved Pharmacovigilance and Monitoring

- Proactive safety monitoring and improved risk management

Use Cases and Values

- Facilitate early detection and response to adverse events
- Enhance the ability to identify, assess and mitigate risks associated with medicinal products across the portfolio
- Increase transparency on where and how data is being leveraged.

Implementation Strategy

Companies with large portfolios

- Machine to machine exchange via API is a must
- Vendor lead times dictate implementation timelines
- Cost impact based on infrastructure needs
- Manual data transformation not practical

Companies with smaller portfolios

- Predominantly manually driven work
- More reliance on user interface
- More time spent on per record basis
- Cost impact based on FTE required to support process

This has a significant impact on the steps that Industry have already taken and are planning on taking in the future

Programme for PMS Implementation

- Establish a dedicated cross functional PMS implementation team
- Regular steering team meetings to oversee progress and discuss solutions to challenges
- Keep up to date with EMA developments surrounding PMS requirements and data standards (Regulatory Intelligence)

- Integration of PMS requirements into existing workflows across all relevant functions e.g PV, RA, Commercial
- Update internal SOPs to include PMS data validation steps

- Upgrade regulatory systems to include PMS data support
- Implementation of cross functional system data connectivity reducing duplication of data and divergence
- Upgrade and implement corporate master data management systems to incorporate PMS data fields as source data

- Article 57 data restructuring and submission to align with PMS (packset splits)
- Data cleansing and alignment with SPOR across multiple systems (not just regulatory owned systems)
- Implement corporate wide data standards for product data using PMS terminology. Requires extensive change management especially at internal manufacturing sites.

Legend

Low effort | Medium effort | High effort

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Conclusion

- PMS is a cornerstone in the regulatory framework, ensuring that the EMA, NCA's and industry can effectively manage and exchange medicinal product information, ultimately safeguarding public health and ensuring access to Medicines across the EU

- All Stakeholders across Industry and Regulators (NCA's and EMA) should collaborate closely, sharing expertise and resources, to ensure the successful implementation and maintenance of the PMS database to support internal and external use cases across the network

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Speakers:

Fakhredin Sayed Tabatabei
PMS Subject Matter Expert (SME), Medicines Evaluation Board

Topic:

Our Shared Journey
NCAs' Perspective

Data quality of legacy data in PMS

As Is

- Data is taken from XEVMPD (MAH), SIAMED (EMA) and enriched in PMS (MAH)
- Data format in PMS follows international standards (IDMP and FHIR)

To Be

- Enhanced standardization and interoperability for NCAs, EMA, MAHs and end users
- Trustworthy legacy data as a foundation for medicinal product lifecycle management
- Legacy data will fulfill data qualification agreements and will support use cases (e.g. Regulatory Activities via the eAF, ESMP, CTIS, IRIS)
- Legacy data will be consistent between PMS and EMA/NCA databases

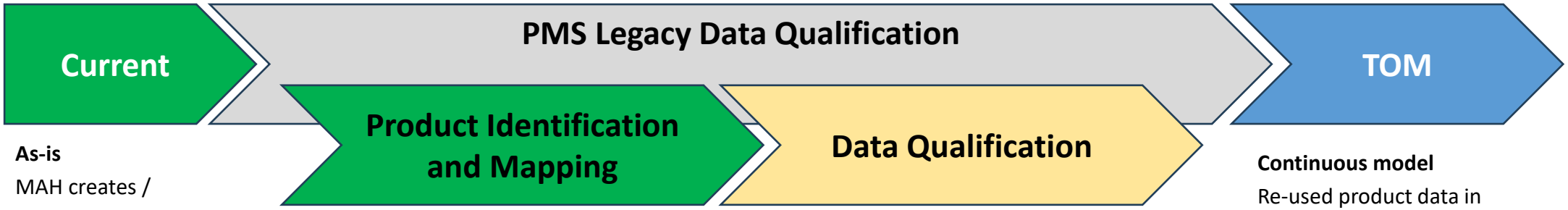
- ✓ **The goal is to reach quality of data desirable for identified use cases, while minimizing the workload of the Network by facilitating shared responsibilities**

Product Mapping and Data Qualification

Stepwise implementation towards a future Target Operation Model

Definition

- ✓ The process of ensuring that the data submitted by MAHs, stored and published in PMS, is the same as the data approved by the NCA, stored and published at national level
- ✓ When identifying missing product or data discrepancies, it may involve updating data



As-is
MAH creates / updates in PMS

Dedicated effort
Same product/ packages in PMS and EMA/ NCA databases

- EMA provides mapping support to NCAs

Dedicated effort
Identical data-elements in PMS and NCA databases

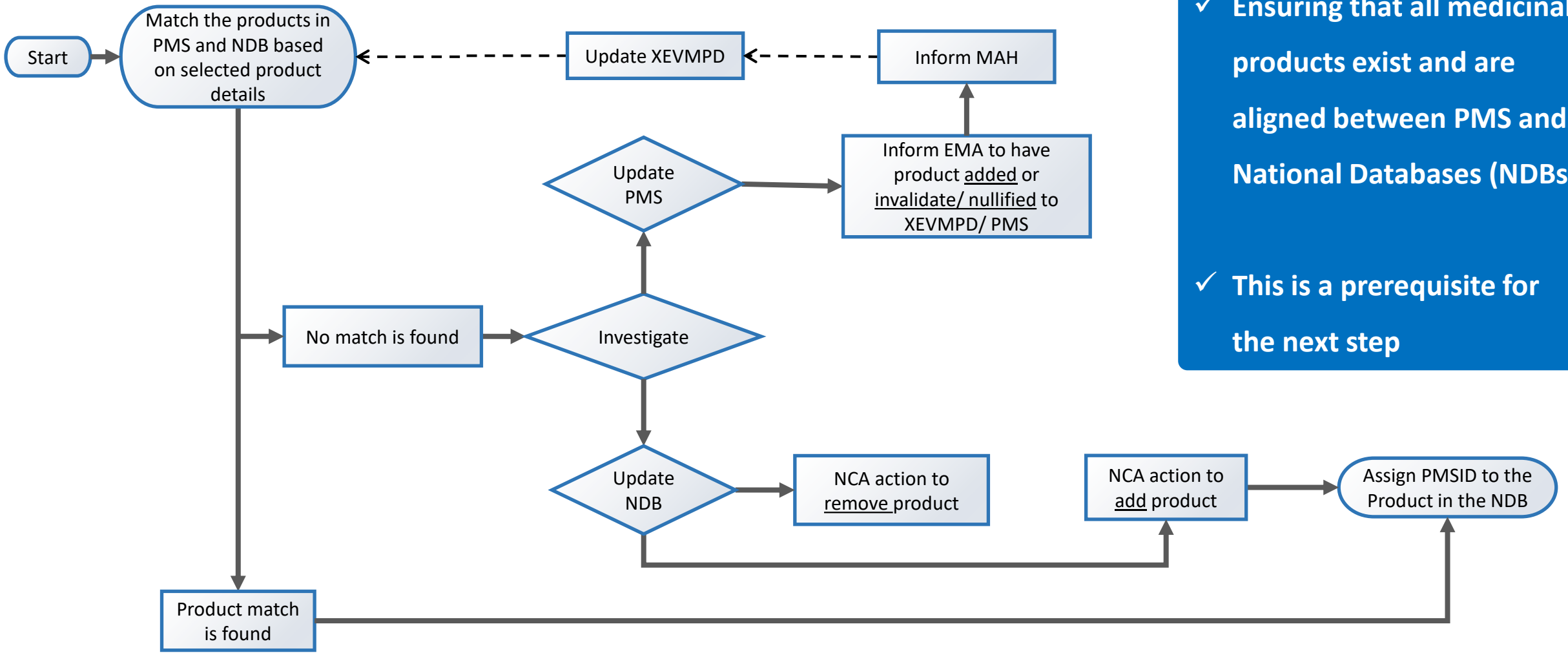
- Data-elements stored in PMS is aligned with the data approved by the NCA

Continuous model
Re-used product data in regulatory processes and applications using the eAF

Ongoing
Under planning
To be

Product Identification and Mapping

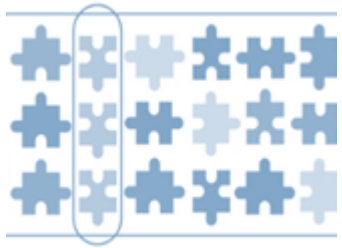
Simplified Flowchart



- ✓ Ensuring that all medicinal products exist and are aligned between PMS and National Databases (NDBs)
- ✓ This is a prerequisite for the next step

Data Qualification

Feasibility Study

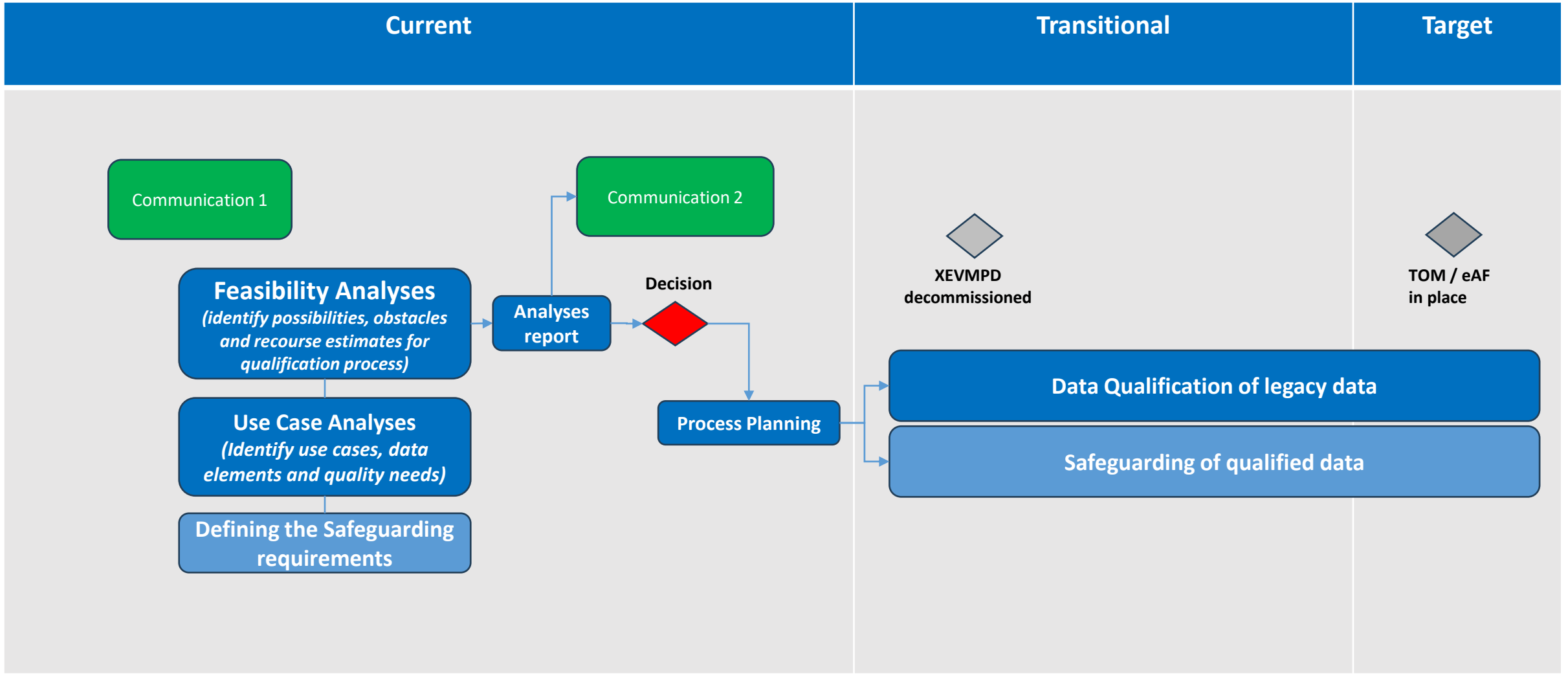


Evaluate the consistency of selected data elements between PMS and EMA/NCA databases

Draft a feasible process that is to ensure legacy data qualification and inform the network

- ✓ **Objectives are to identify possibilities, obstacles and resource estimates for qualification process, as well as use cases, data elements and quality needs**
- ✓ **Some systems initially benefiting from data qualification are ESMP, PLM portal, eAFs, ePI**

PMS Legacy Data Qualification Roadmap



Moving forward toward Product Master Data

Preparation

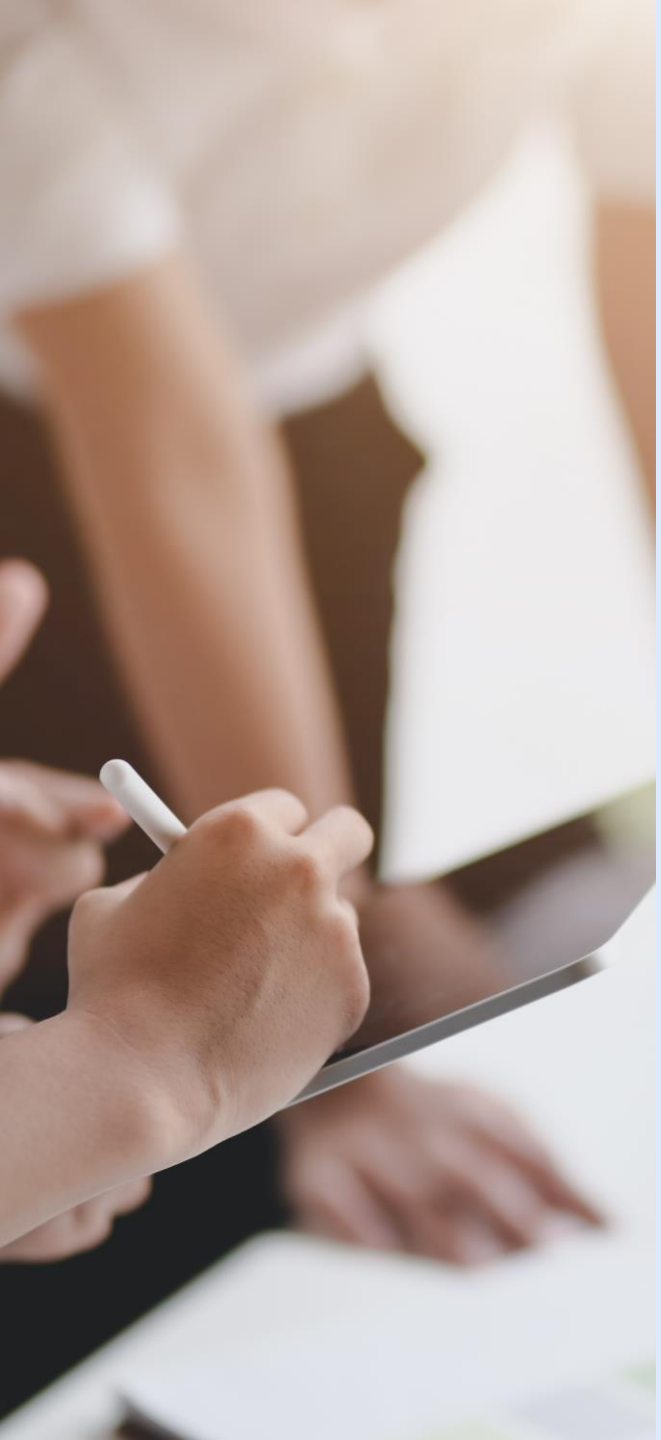
Collaboration

Outcome

CBG MEB

MEDICINES EVALUATION BOARD

GOOD MEDICINES USED BETTER



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- 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

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Online participants

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