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How does eAF, PMS, ePI, Shortage Monitoring fit together?

Georg Neuwirther, Head of IT AGES - Austrian Medicines and Medical Devices Agency

DGRA, 2024

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Agenda

45min

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- **Introduction**
- **PMS, eAF, ePI, ESMP**
- **UNICOM – a best practice of bringing topics together**
- **Take Home Message**

Georg Neuwirther
Email: Georg.Neuwirther@ages.at LinkedIn

Spoiler

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" ..... It's about data and new opportunities through (extended) digitalisation of our business processes ... "

Data in all minds

Many initiatives

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16 December 2021
EMA/447502/2021

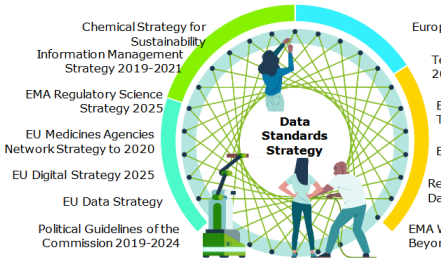
European Medicines Regulatory Network Data Standardisation Strategy

HMA — EUROPEAN MEDICINES AGENCY

Data Standardisation Strategy | Development

From December 2020 an in-depth analysis has been performed on the overall IT, policies and data standards landscape within the EMRN.

Background Documents* — **Interviews**



369 Use Cases

82 People have been interviewed as part of the landscape analysis.

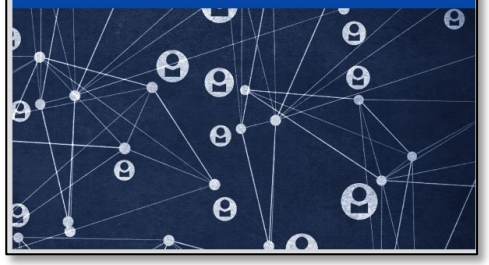
194 Use Cases

70 organisations/ associations responded to the survey

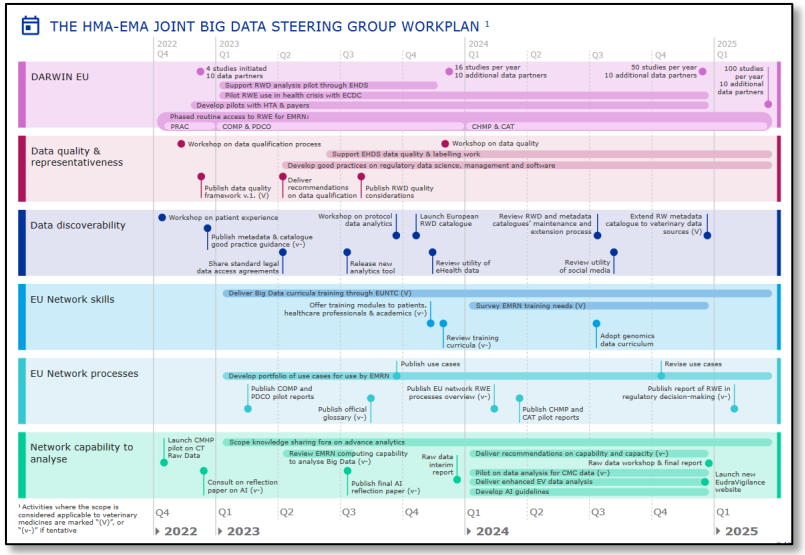
* *Please note that this is a non-exhaustive overview*

European medicines agencies network strategy to 2025

Protecting public health at a time of rapid change



THE HMA-EMA JOINT BIG DATA STEERING GROUP WORKPLAN [1]



- Substance Management Services (SMS)
- Product Management Services (PMS)
- Organisation Management Services (OMS)
- Referentials Management Services (RMS)

Expectations (internally and externally)

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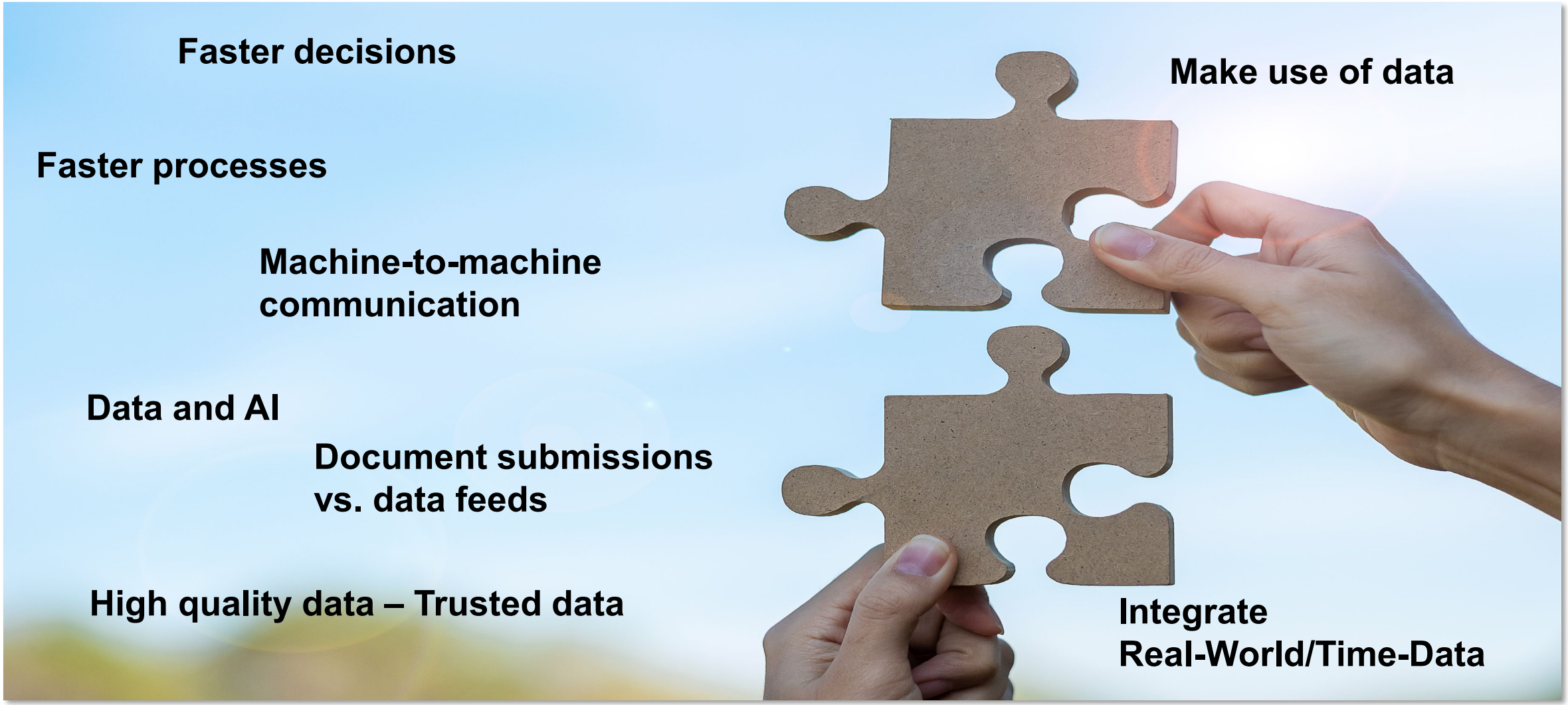

Motivation for today …

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…. let's go on an early summer journey through interesting subject areas and identify potential benefits - plus how to prepare for the journey …

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SPOR PMS

… a new player goes online …

PMS Vision

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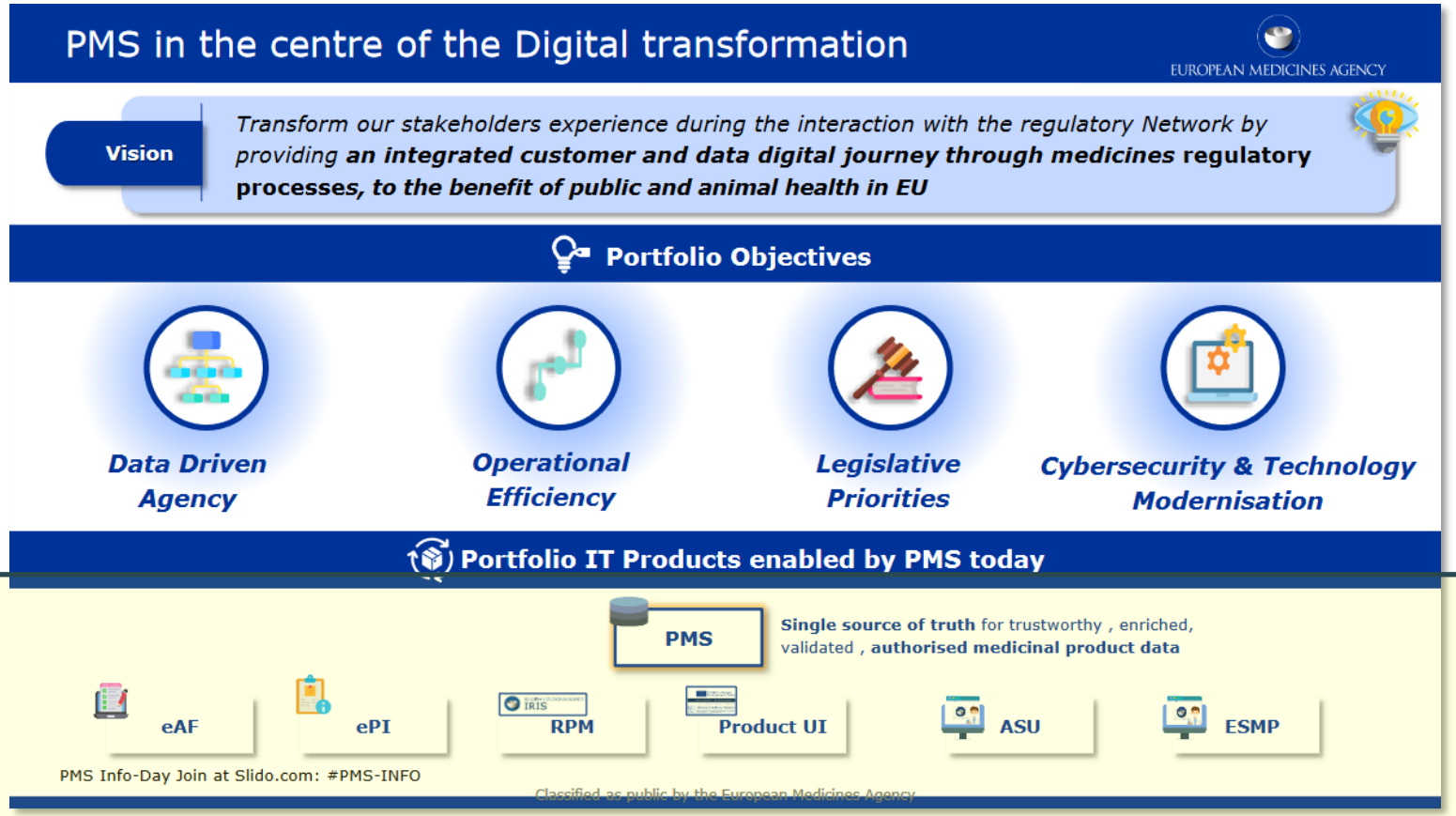

Source: EMA PMS Info-Day, April 2024

„... PMS' objective is to become a SHARED data source for several pan-European use cases .."

If so, then we need to ensure compatibility

"Virtual connections"

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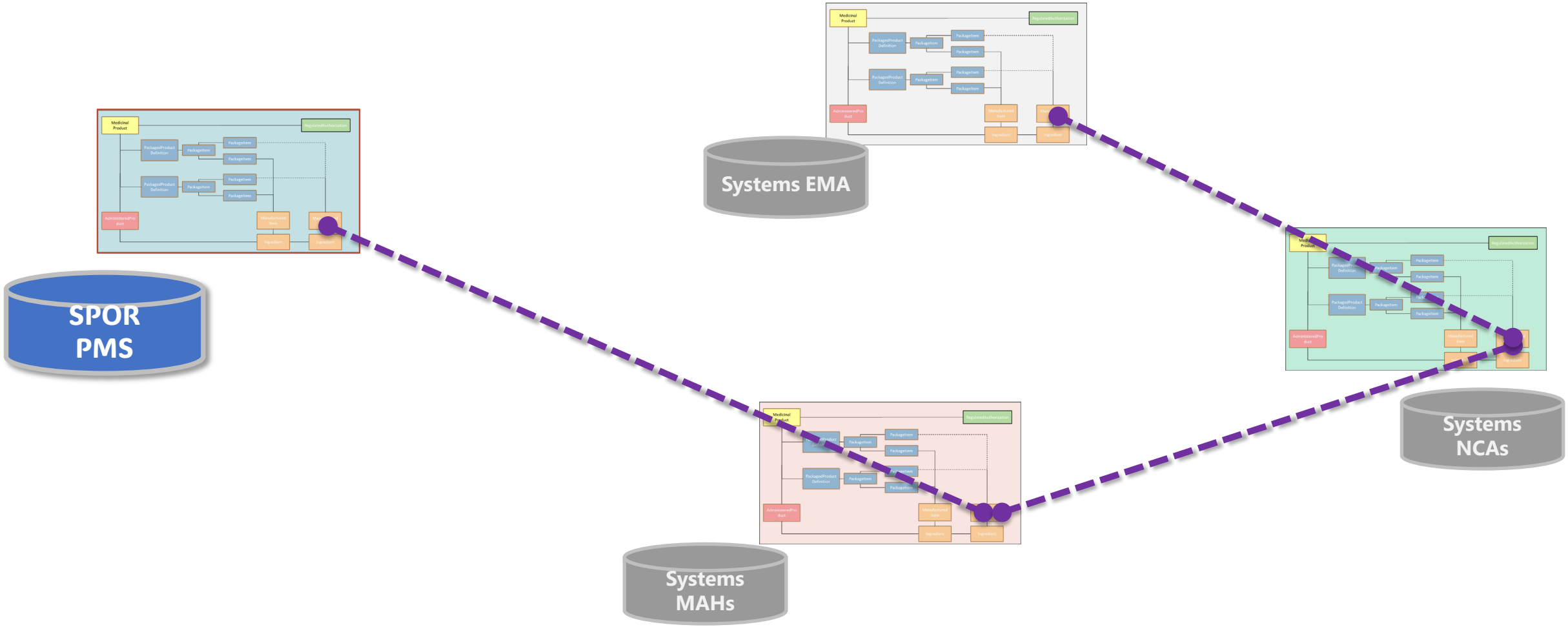

Medicinal Products – Data Flow

simplified view for better readability

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MAHs

eAFs – data import

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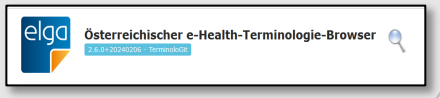
Official Product Index
(legal basis)

Data repositories



EU cross-border e-prescription

Data Consumers
(e.g. Public, Practitioners, Pharmacies, eHealth, MP-dictionaries, ..)

EUROPEAN MEDICINES AGENCY
SPOR

PMS

ePI

ESMP (2025)

Logistic data
e.g. Wholesaler and Pharmacies

Providing trusted data

Data processed
in regulated eco-system

UPD – Union Product Database

1st conclusion

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In our data value chain we* are simultaneously creators, contributors and consumers of high-quality trustworthy data.

Interoperability of data, processes and IT systems are key success factors.

*** Regulators, Applicants, Industry stakeholders, eHealth stakeholders, MP-Dictionaries, ..**

Interoperability considering SPOR PMS 1/2

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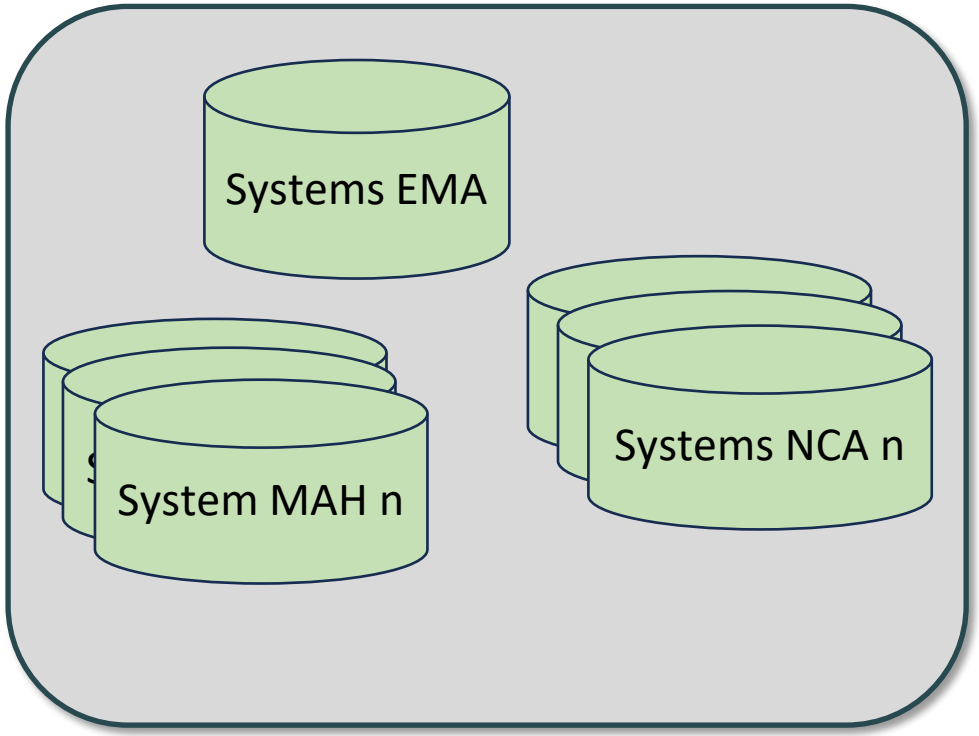
Shared data repository



IT-systems in the EMRN

Interoperability measures, e.g.

- ISO-IDMP standards and annexes
- **European IDMP Implementation guide**

ISO IDMP

- FHIR definitions
- FHIR implementation guides and profiles

HL7 FHIR

- Shared common dictionaries
- SPOR interface (API)

S(P)OR

Interoperability considering SPOR PMS /2

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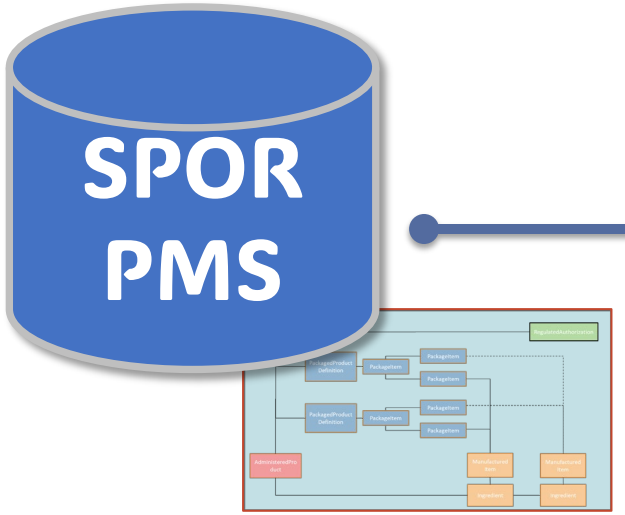

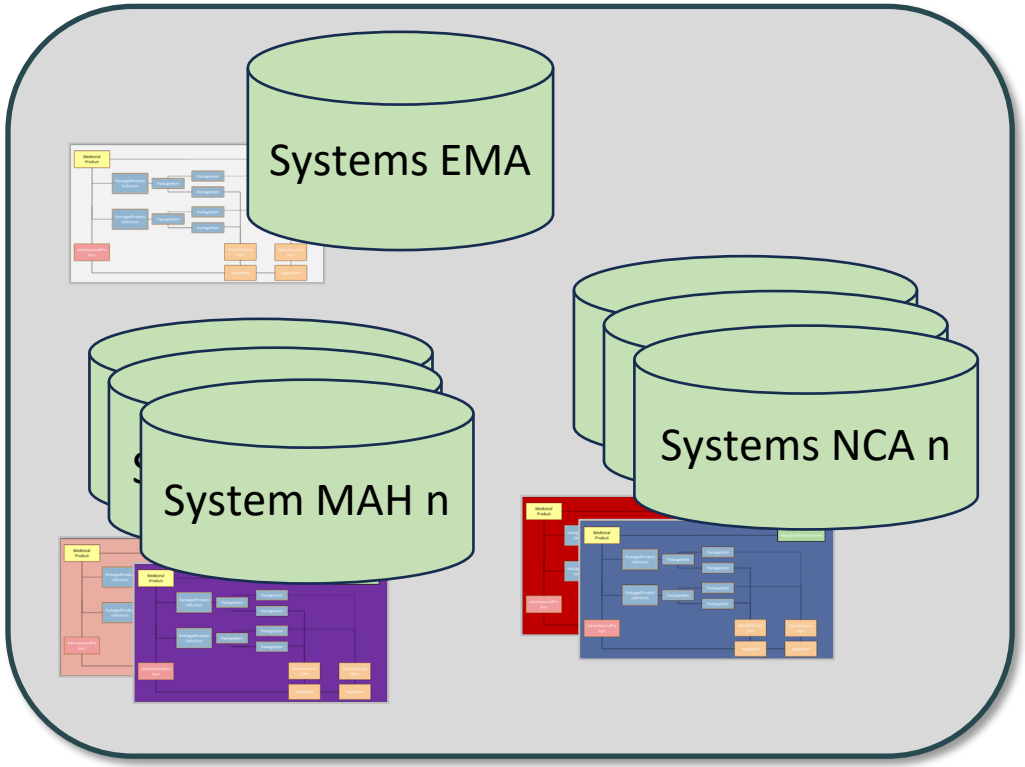

IT-systems in the EMRN

Interoperability measures will result in:

- Compatible data models
- IT-enabled business rule execution and validation
- Shared unique identifiers across systems
- Efficient exchange and synchronisation processes

→ Trust in data (flows)

Re-Cap – PMS implements ISO-IDMP

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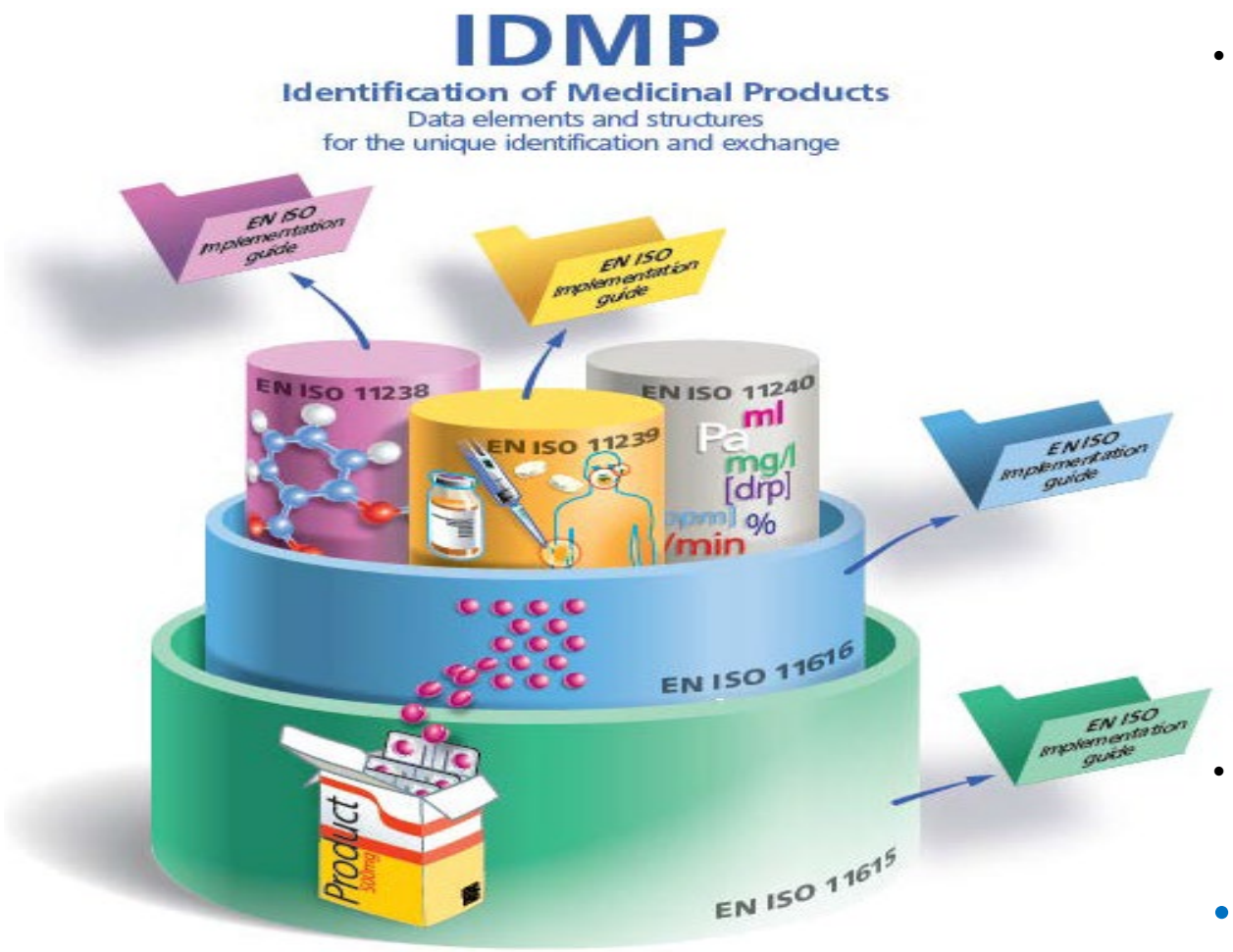
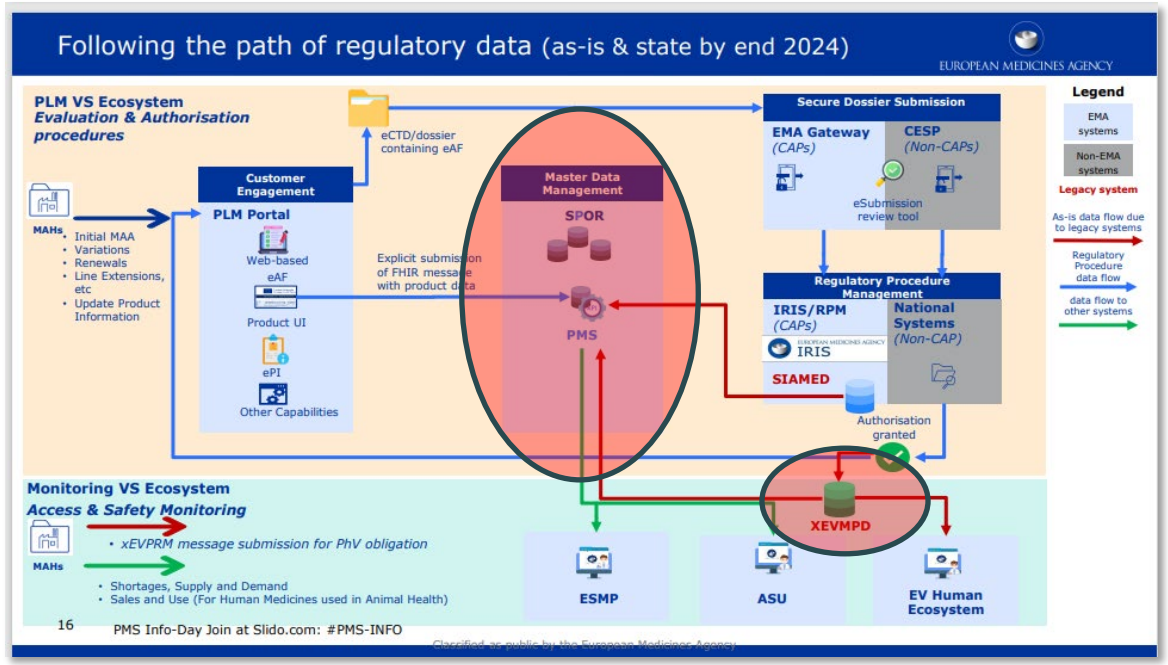
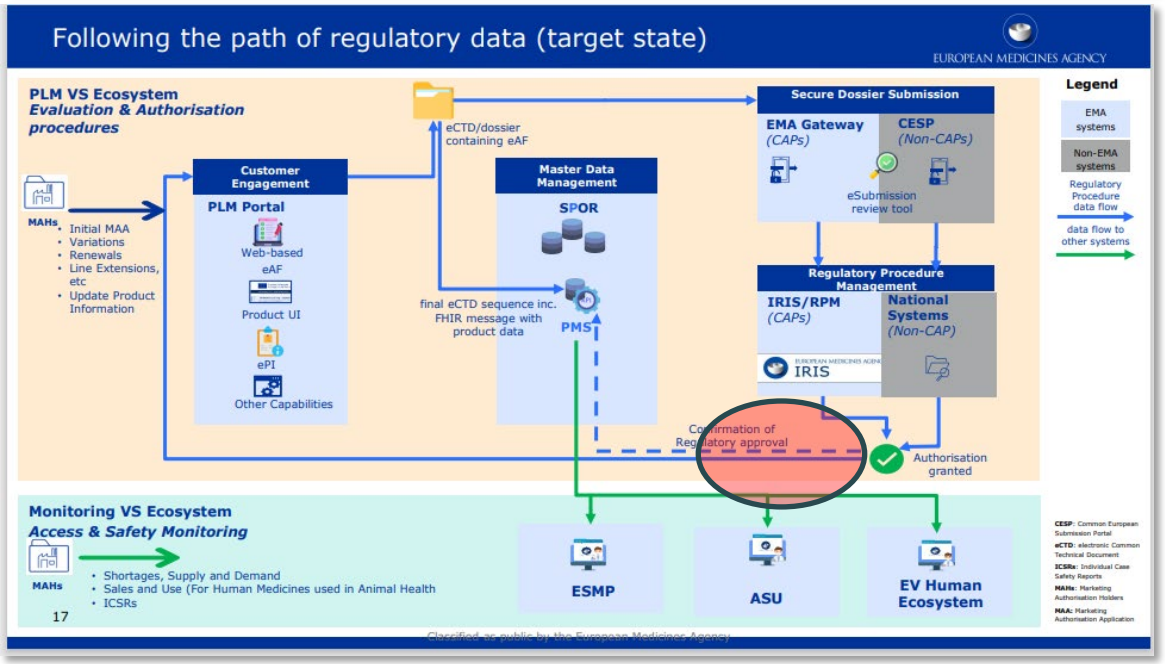


Source: EMA

- The **ISO IDMP standards** establish definitions and concepts and describe data elements and their structural relationships that are required for the unique identification of:
  - **Medicinal product information (MPID/PCID) - ISO 11615**
  - **Pharmaceutical product information (PHPID) - ISO 11616**
  - **Substances (Substance ID) - ISO 11238**
  - **Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239**
  - **Units of measurement (UCUM) - ISO 11240**
- ISO IDMP standards apply to both authorised and developmental medicinal products for Human and Veterinary use
- **PLUS EU implementation guidance!**





Source: EMA PMS Info-Day, April 2024

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Key Findings

- PMS will become **a shared** source for several **EMA organised pan-European use cases**
  - like ESMP, ASU, eAFs, ePI, ..
- **XEVMPD (ART57)** data - originally collected for **PHV purposes -** is now also used **for regulatory activities**
- PMS will also support **the EV Human Ecosystem**
  - **no separate messages for** XVEMPD and PMS are foreseen in future
- PMS data will be updated **via eAF FHIR datasets provided in dossier submissions**
  - !Currently several options of the data feeding process are under discussion - "TOMs"
- Regulator systems can connect to SPOR PMS for **approval purposes**
  - **No details available (see also "TOM" discussions)**

SPOR PMS – Guidance

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Source @ EMA: here

- Start reading with examples (**Chapter 8 – Practical examples)**

This gives a good overview.

- Make sure that XEVMP data is of good quality – due to usage in regulatory activities
- *Plan resources (personal, perhaps IT) for the following tasks …*

Status PMS

Timelines

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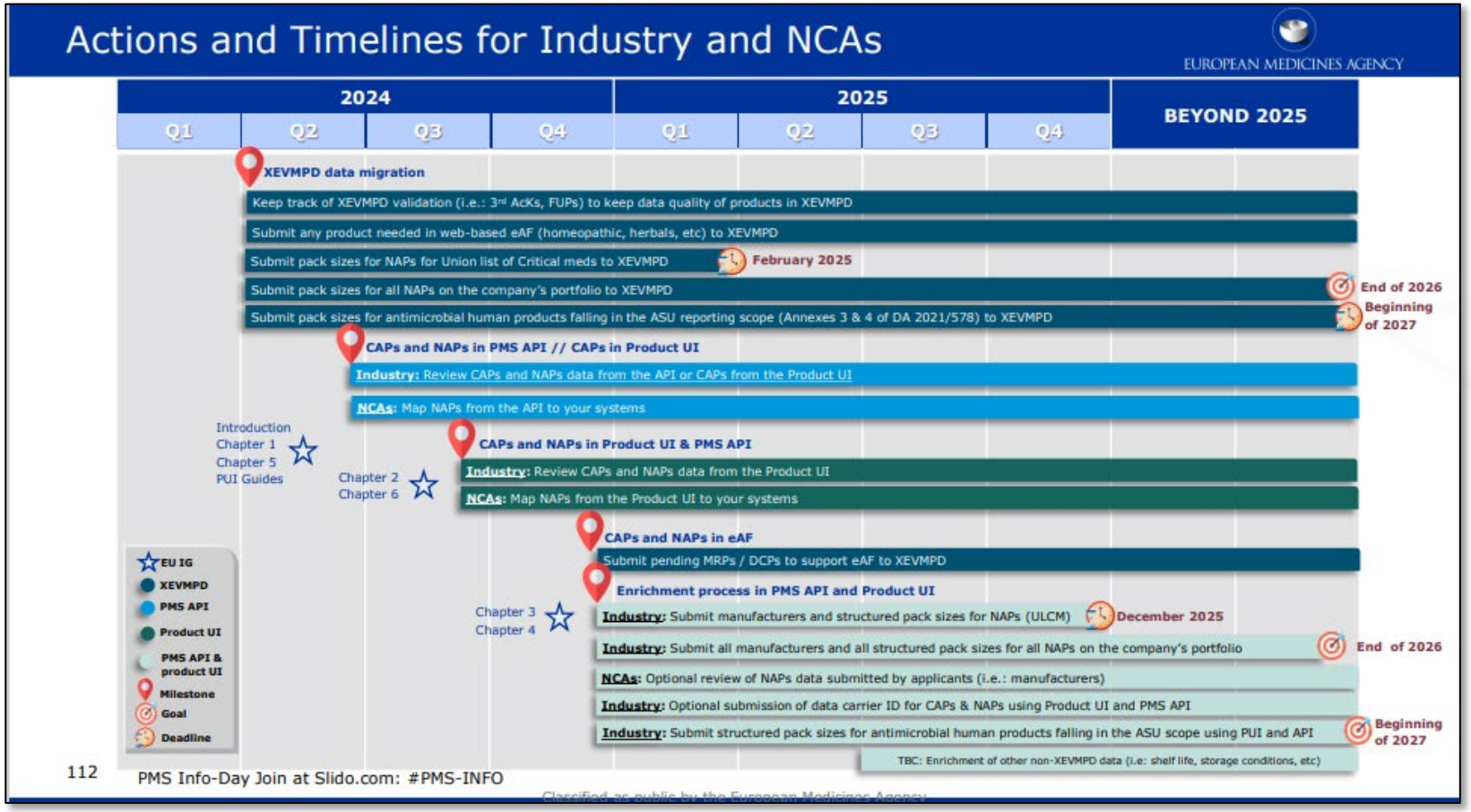

Source: EMA PMS Info-Day, April 2024

Todos:

- Do „Stichproben" of your products in XEVMPD and PMS
- Add missing products needed for eAFs (e.g. herbals)
- Activities for ESMP and ASU (see next pages)

PMS: Access to medicinal product data

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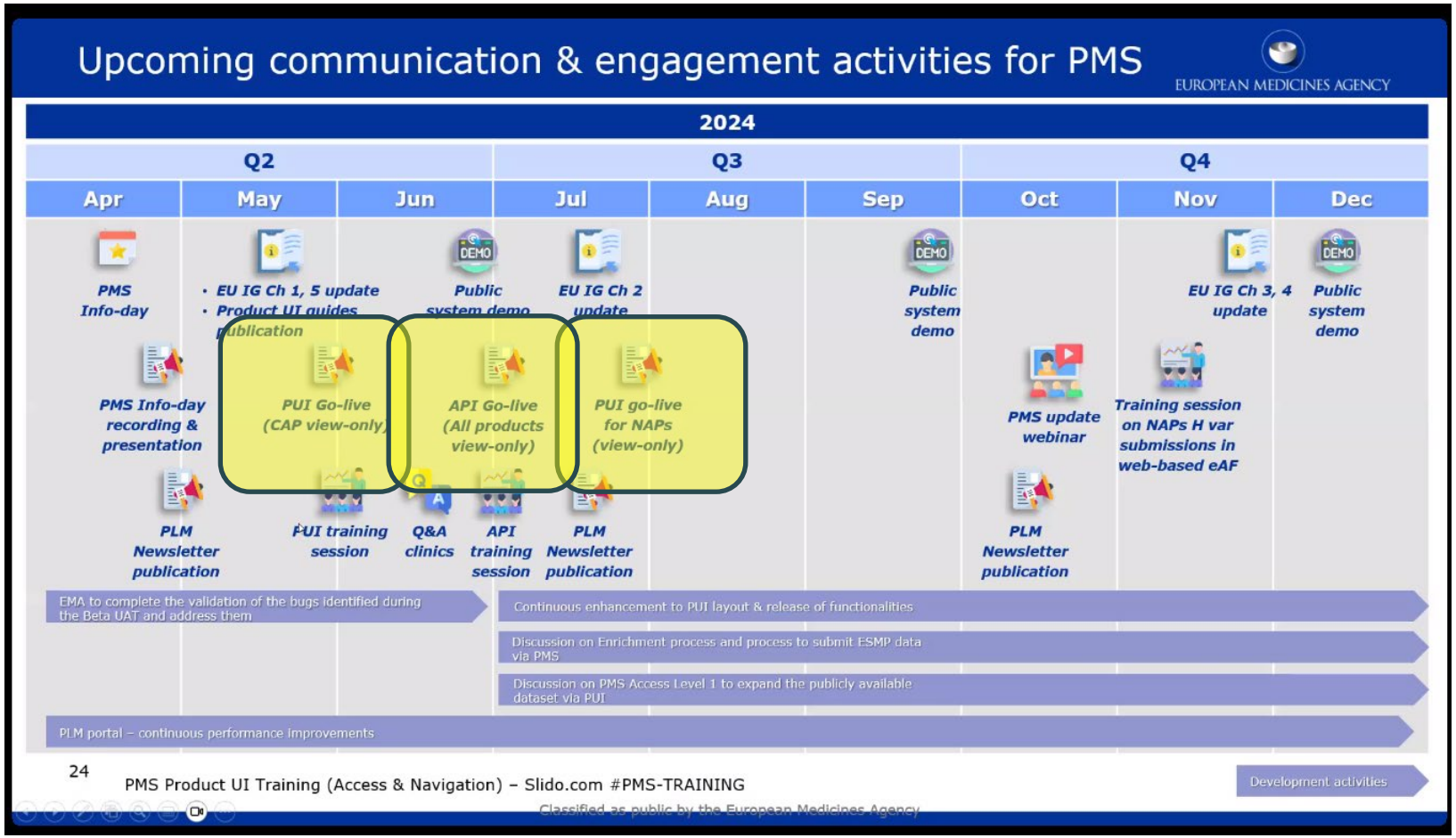

Source: EMA PMS Info-Day, April 2024

Read Access for PMS data

- PUI* CAPs: End of May 2024
- PUI* NAPs: End of July 2024
- API* all: End of June 2024

***PUI**: User-Interface for PMS

***API**: machine-to-machine interface for PMS data

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The new eAF creation tool

Georg Neuwirther

New technology for the Electronic Application Form eAF

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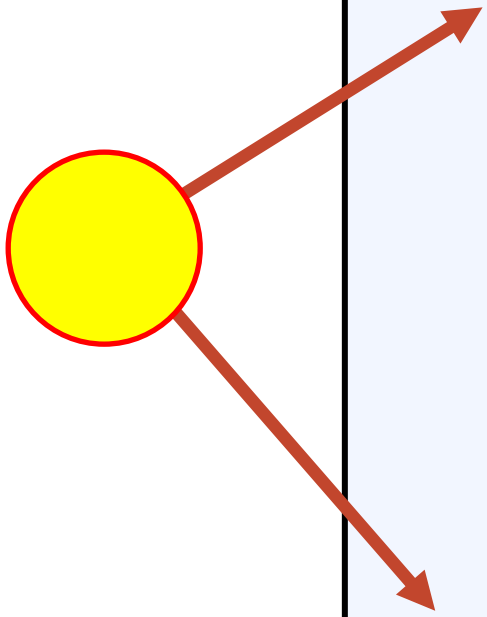
Business Value

Provision of digital, user friendly, adaptable application forms



- Consistent **high-quality ISO IDMP** compliant data – right from the start of regulatory activities
- **Standardised data entry**, thus making forms easier to access, process, validate, transmit and re-use
- **Reuse of data** in end-to-end processes
- **Integration with product lifecycle management processes** to optimise regulatory procedure management
- **Easier and more automated** applications' validation and processing by National Competent Authorities (NCAs), reducing errors and discrepancies
- **Standardised data-backbone** supporting machine-to-machine communication

eAF

Re-using of application forms data

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Product Lifecycle Management Portal

PLM Portal

Applicants

Initial Applications

Lifecycle Management

PDF-based forms including structured data elements

Since 2015: DES-format
Since 2022+stepwise roll-out of FHIR format

FHIR

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SPOR

SPOR PMS

Regulators

Regulatory IT-Systems

eAF - Roadmap

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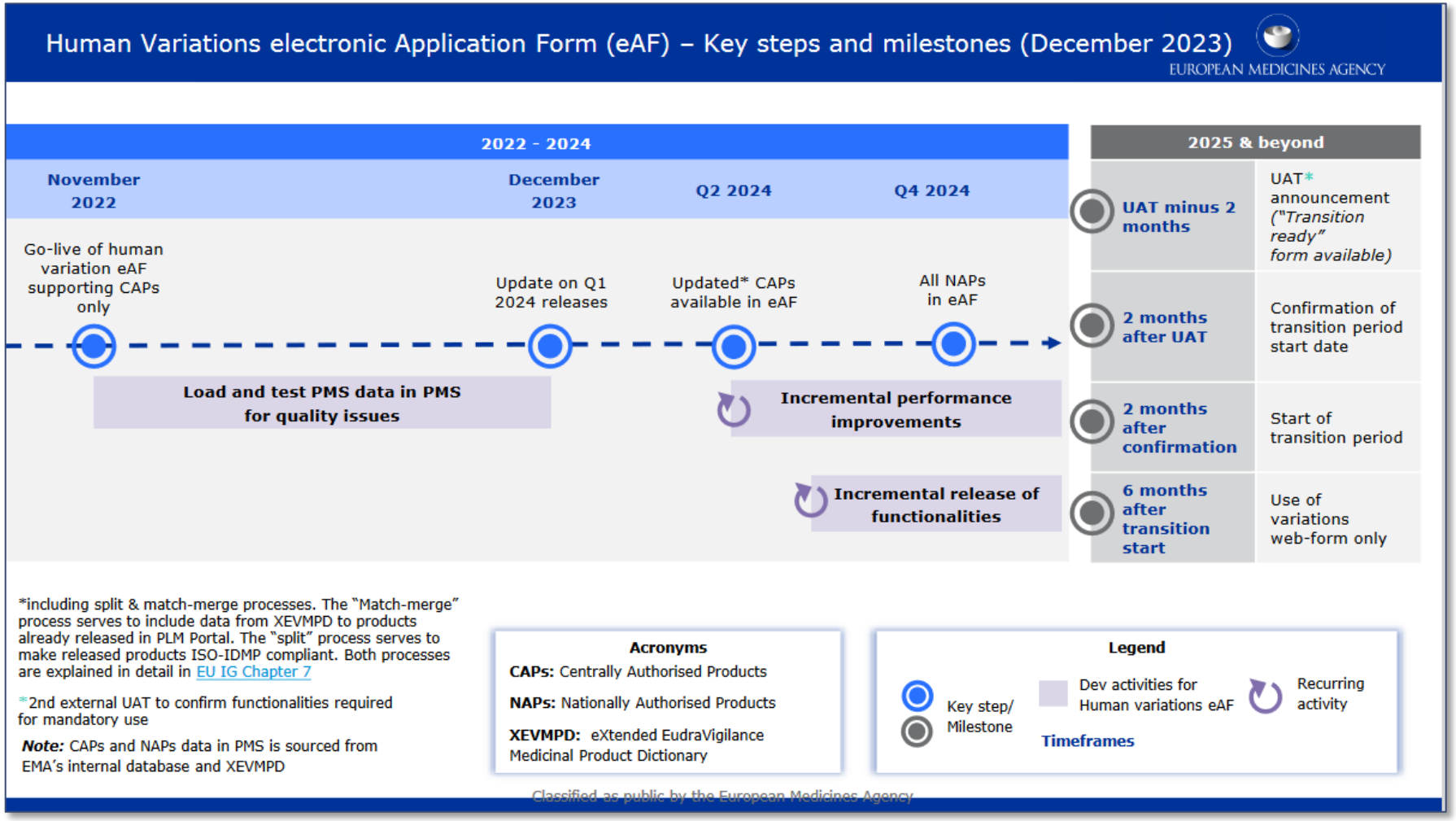

Source: https://esubmission.ema.europa.eu/cessp/202312_eAF%20implementation%20timeline.pdf

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ePI

EMA-HMA-EC ePI pilot & beyond

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Landscape – PLM Portal – SPOR PMS - ePI

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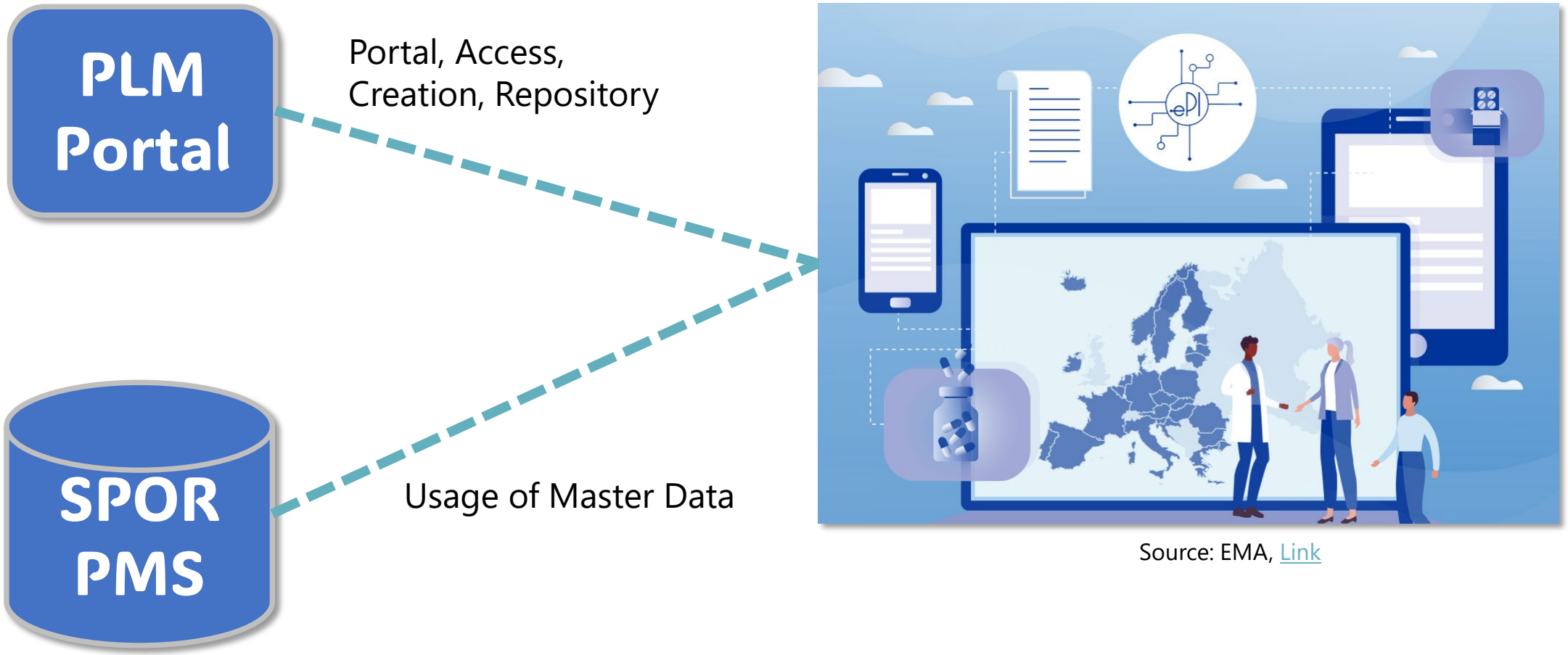

Source: EMA, Link

PMS Data used in ePI

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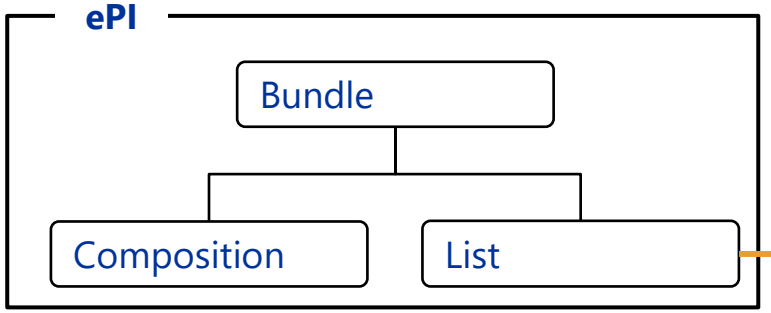
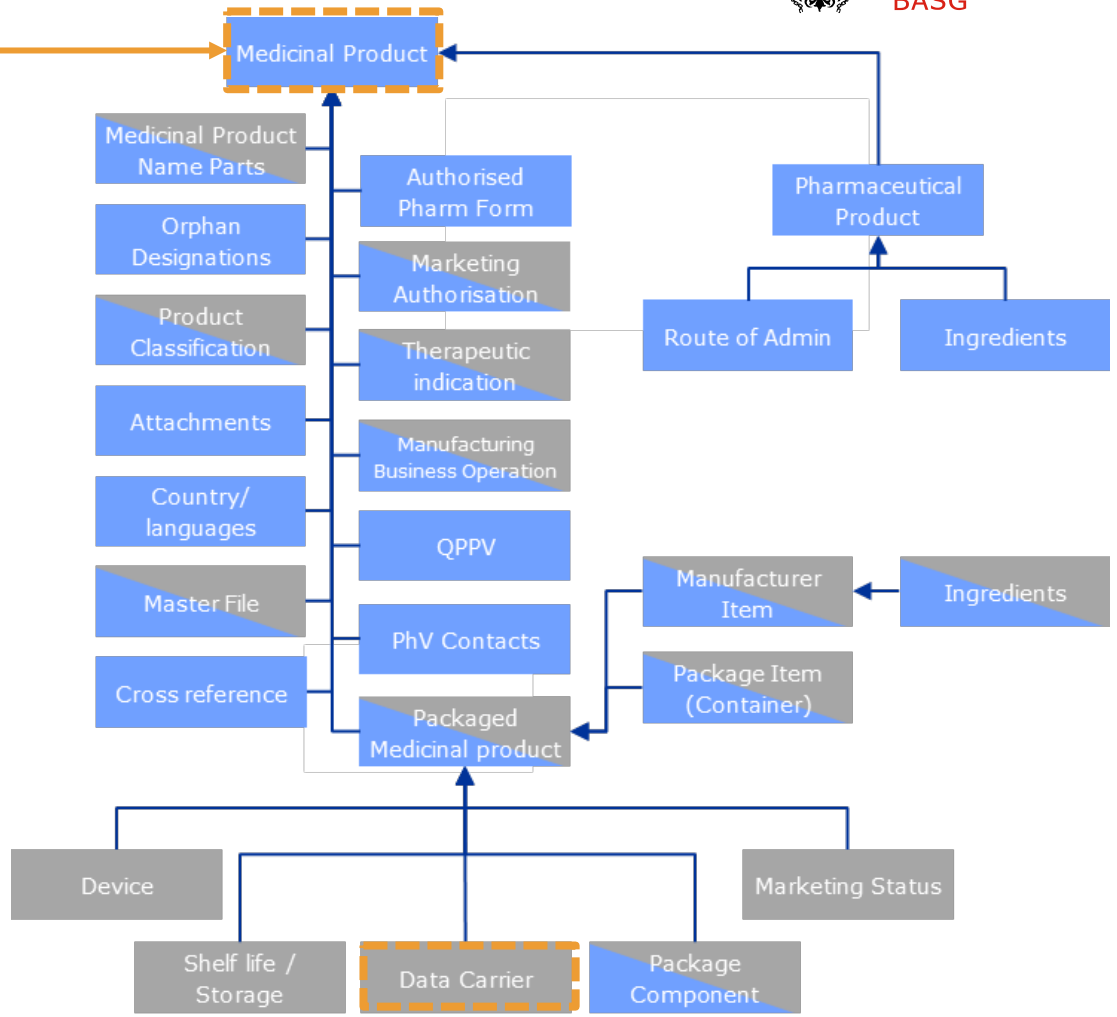
- ePI will be **linked to the relevant medicinal product(s)** enabling consuming systems to leverage both ePI data and product data from PMS

- ePI documents (e.g., PL, SmPC) will be associated with the relevant **GTINs** using the **Data Carrier field** enabling use of ePI data in applications linking to ePI by scanning the data matrix code on the medicine package





Source: EMA, 2024

PMS Data fields used by ePI

ePI – Data Enrichment

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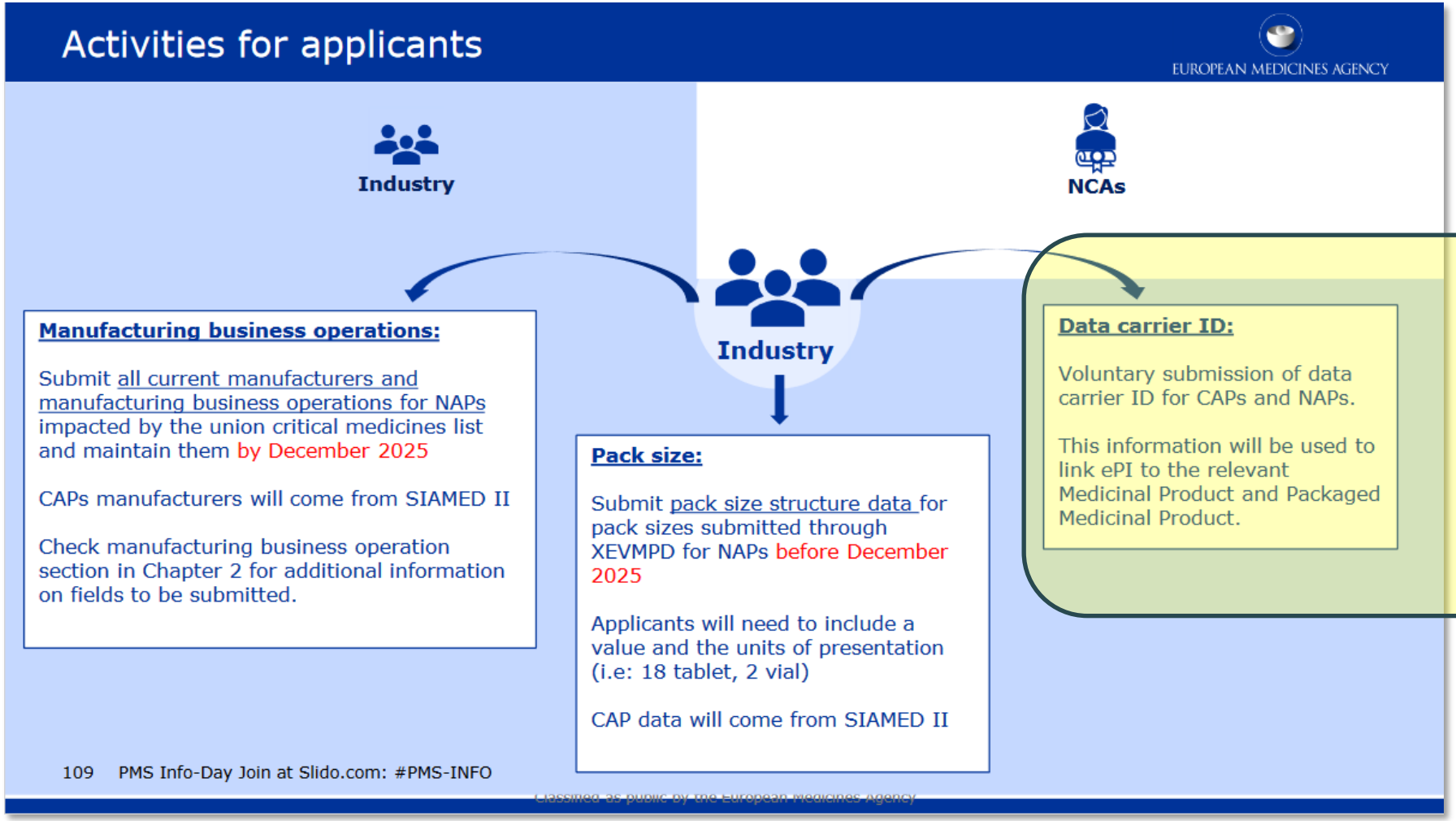

NTIN „PZN“ for AT

Source: EMA PMS Info-Day, April 2024

Notice

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- **„ for AT:** *… ePI does not mean that packs are now automatically distributed without printed information. These are separate topics with different timelines and legal bases …* **“**

Re-Cap

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- "**.. ePI** is authorised, statutory product information for human medicines (i.e. **summary of product characteristics, package leaflet and labelling**) in a semi-structured format created using the **EU ePI Common Standard**. ePI is adapted for electronic handling and allows dissemination via the web, e-platforms and print. .."

Key principles outline ePI benefits: published January **2020**

Link @ EMA

https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi

EU ePI common standard based on FHIR to support a harmonised ePI across the EU network

https://github.com/EuropeanMedicinesAgency/EU-ePI-common-standard

FHIR

ePI - Roadmap and outlook

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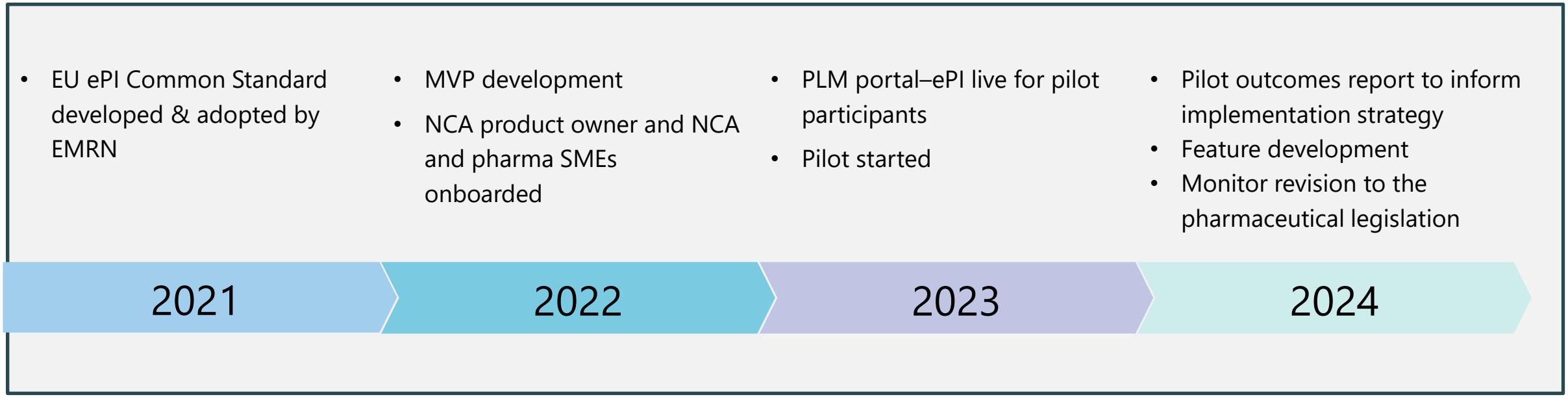

Next **system demo** live on YouTube and EMA website on 26th June

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European Shortages Monitoring Plattform ESMP

Overview

EU Regulation 123/2022

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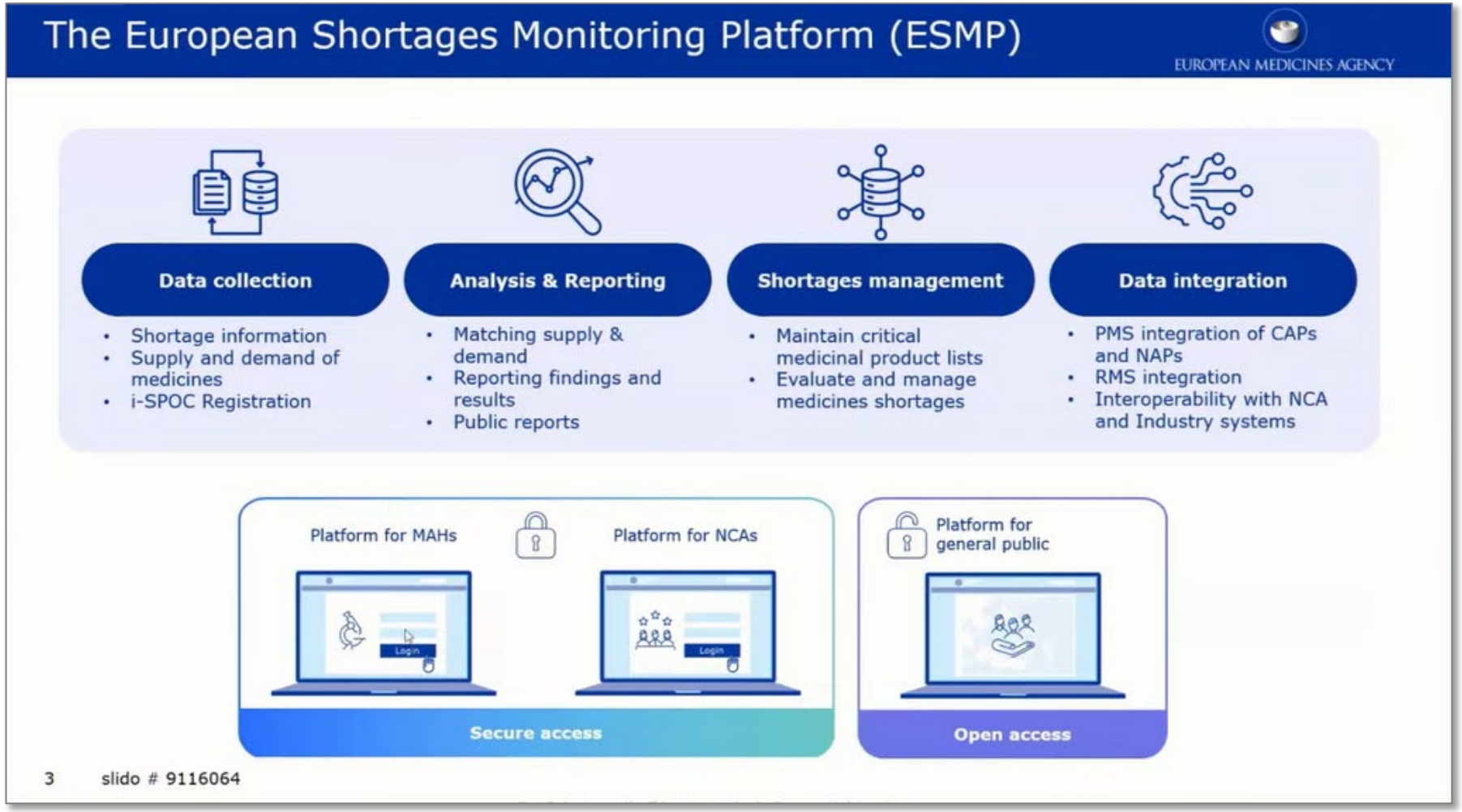

Source: EMA System Demo, 26.03.2024

Landscape – PLM Portal – SPOR PMS - ePI

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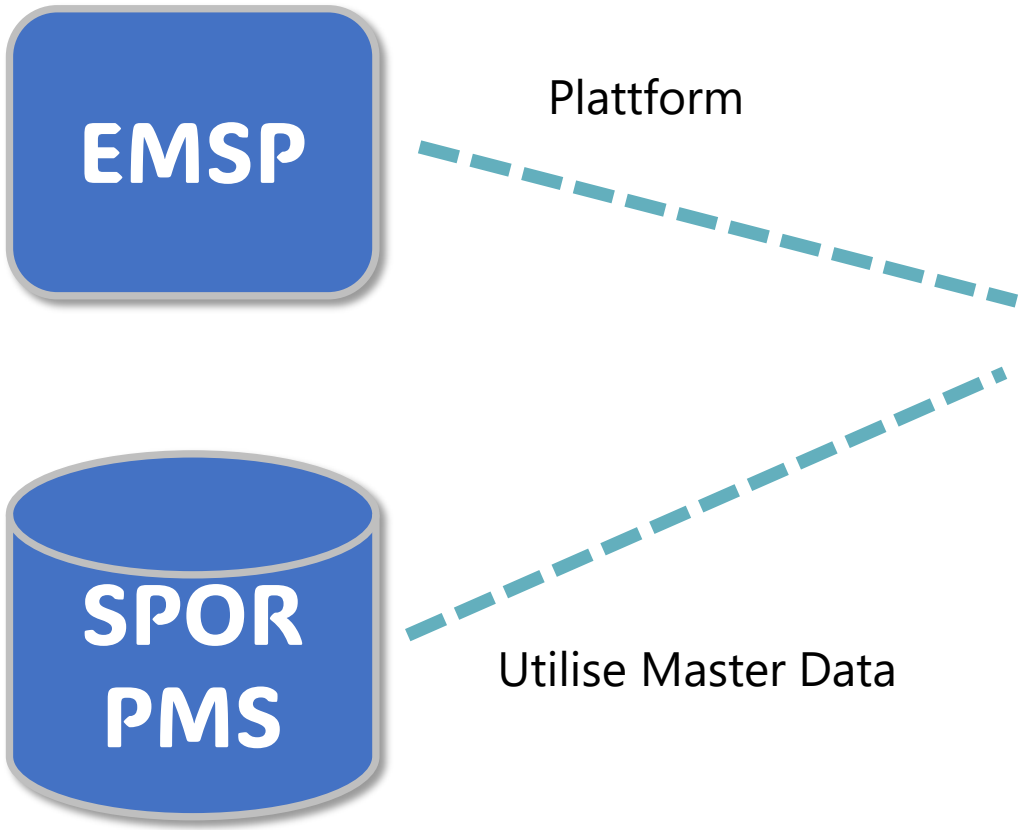
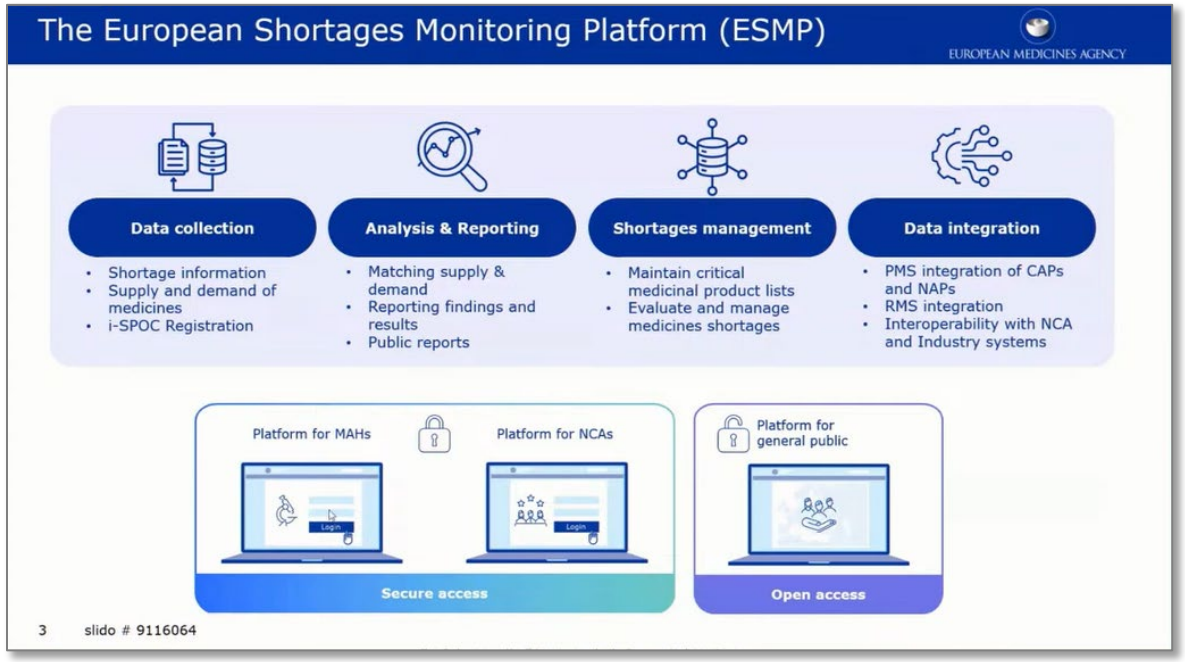




Source: EMA, Link

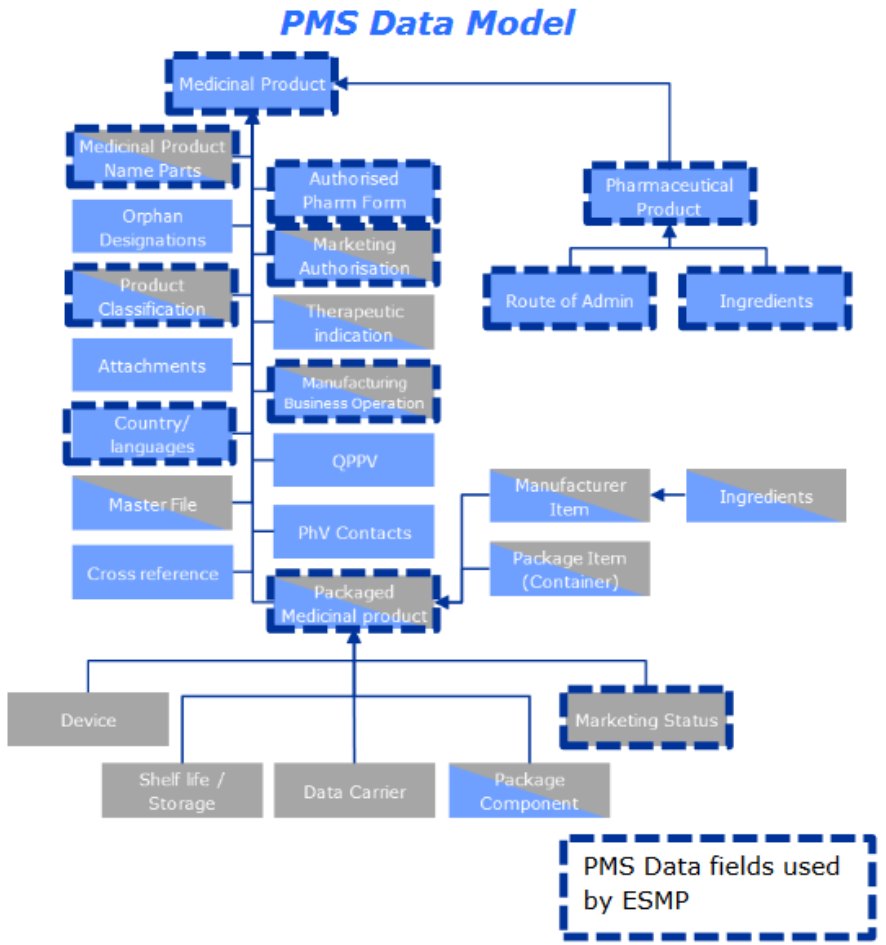
How ESMP uses PMS data (1/2)

EUROPEAN MEDICINES AGENCY

PMS will be used to retrieve data on **medicinal products** to pre-populate reporting templates in the ESMP, to **facilitate data collection, insertion, analysis,** and **management**

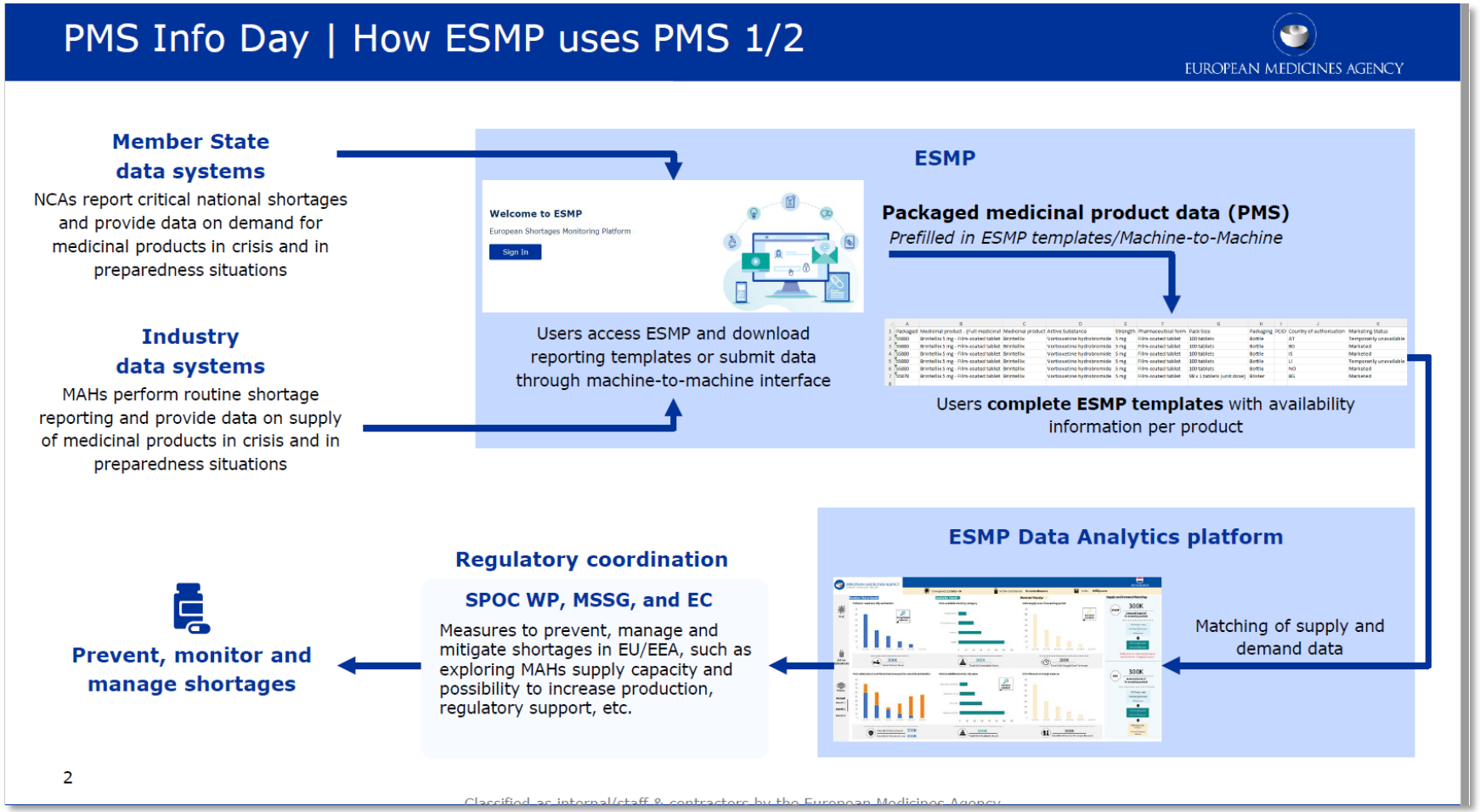
Examples of data uses:

- **pack sizes** for precise data submission, linkage to Industry and NCA databases and quantitative data analysis in matching of supply and demand
- **ATC codes** to identify and classify products
- **manufacturing site** information to assess supply chain vulnerabilities
- **marketing status** information for medicine availability



PMS Info-Day Join at Slido.com: #PMS-INFO

Source: EMA PMS Info-Day, April 2024

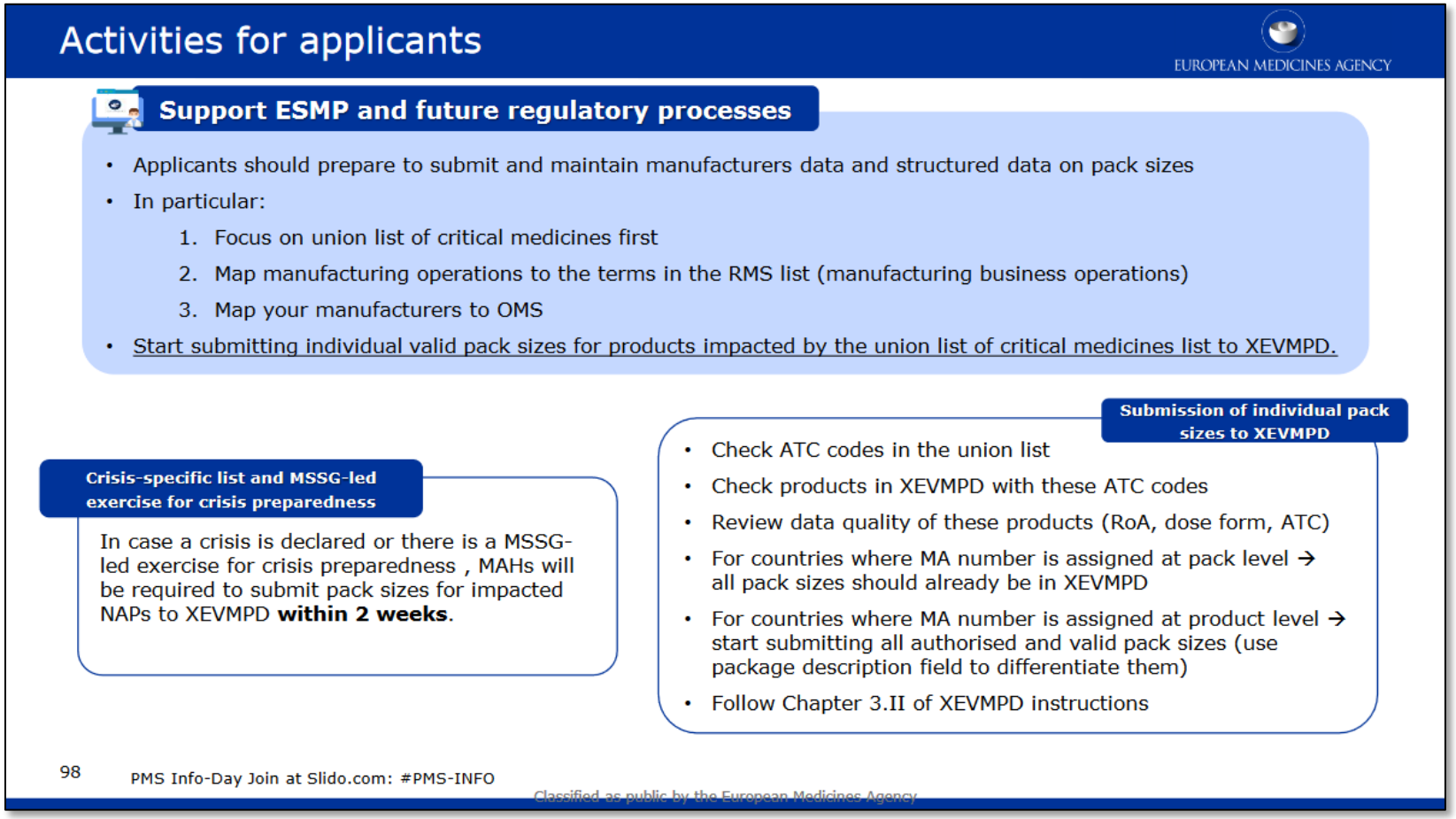


Source: EMA PMS Info-Day, April 2024

Reporting templates will be prefilled with PMS data

From 2025/26 further features for "machine-to-machine communication" are planned

-- Interoperability



Timelines see next slide

Source: EMA PMS Info-Day, April 2024

ESMP and ASU

European Shortages Monitoring Plattform / Antimicrobial Sales and Use

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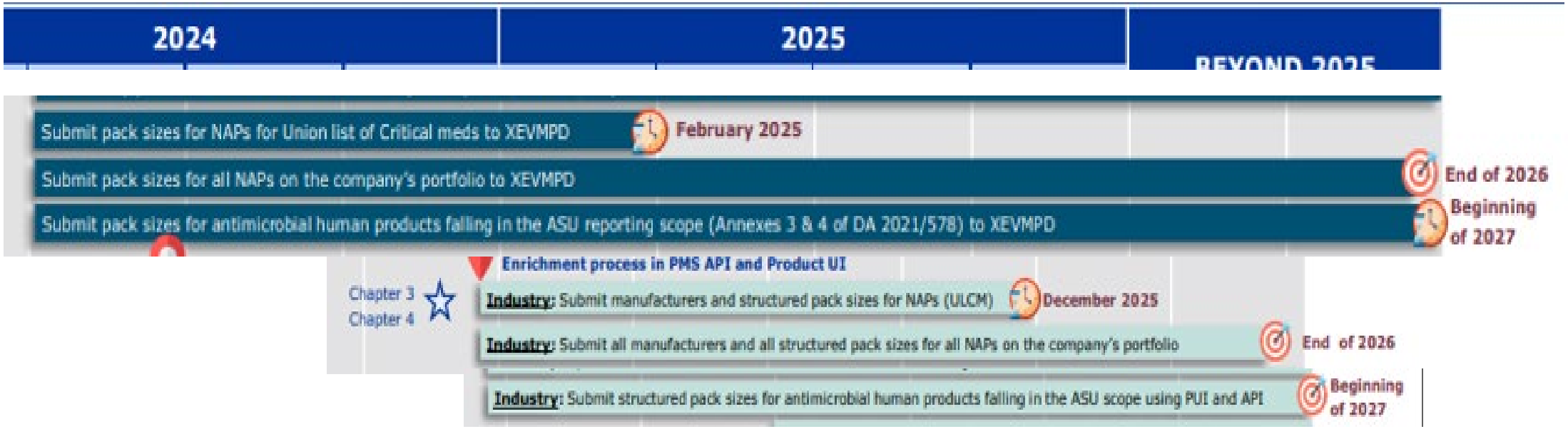
Source: EMA PMS Info-Day, April 2024



- *Link to Union list of Critical medicines: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-and-availability-issues/availability-critical-medicines*
- *For NCAs: Mapping NAPs and optional review*

Another use case - ASU

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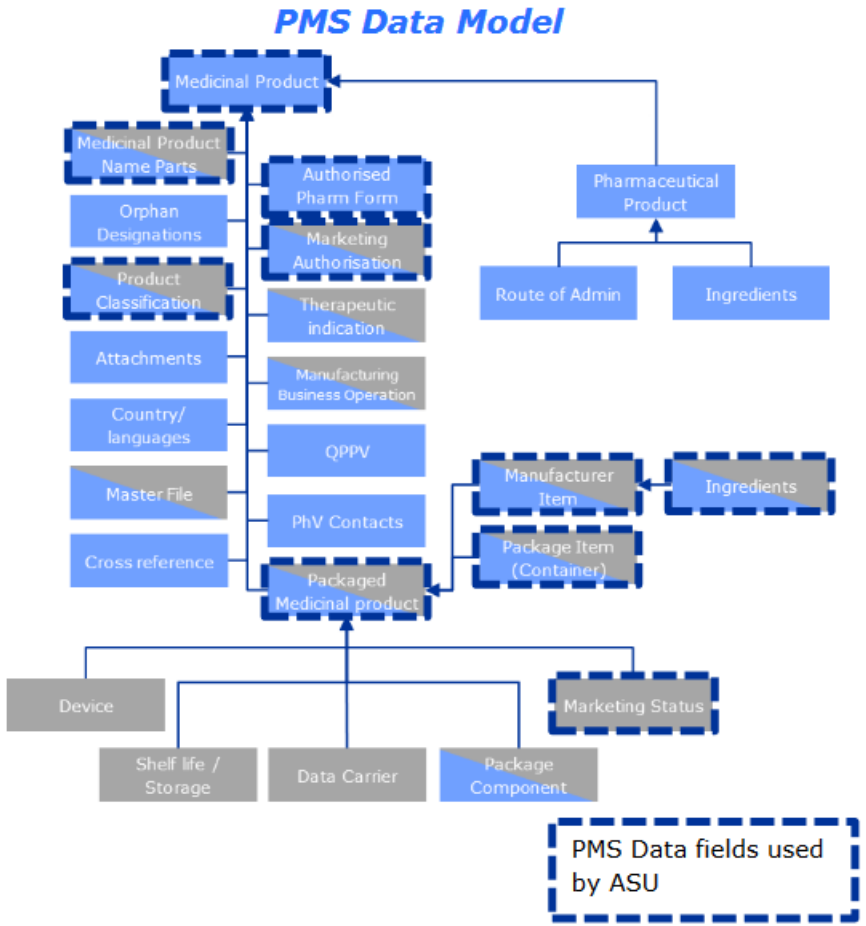
How ASU use PMS data

EUROPEAN MEDICINES AGENCY

- As per Art. 57 of Reg. (EU) 2019/6, Member States **shall report to the Agency data on the use of antimicrobial in animals** and this includes use of any human antimicrobial medicinal product that may have been prescribed to animals as per Articles 112, 113 and 114 of the same regulation.
- ASU will enable all users **to search across all human medicinal products that fall in the ASU reporting scope** to pick the ones they want to report on.



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PMS Info-Day Join at Slido.com: #PMS-INFO

Source: EMA PMS Info-Day, April 2024

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UNICOM

a best practice where “fitting together” happened

Who we are

UNICOM – facts

H2020 Funded Project

11.2020 – 05.2024 (54 months)

21M € Total Budget

90 Deliverables (135 incl. versions)

41 partners, 19 countries

- 9 Standard Development Organisations
- 11 National Competent Authorities for Medicinal Products
- 10 National eHealth Competence Centers / National eHealth Contact Points
- 4 Industry partners (Health IT)
- 2 Research Organisations
- 2 Medicinal Database Providers
- 3 Non-profit organisations

UNICOM (unicom-project.eu)

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Key achievements in 8 minutes

UNICOM

Impact on Processes

- Gap Analysis of Existing and Need for New Standards and Profiles
- EU-SRS Implementation and going live
- DADI – Electronic application forms
- IDMP implementation on National level
- Contributions in eHDSI Waves 6 and 7 (2022-2024)
- IDMP Coding Principles and Guidance for ICSRs
- Implementation guidelines for use of IDMP within MPD

Resources and Assets

- IDMP in a capsule
- Minimum Attribute List and Pilot Product List (PPL)
- UNICOM FHIR IDMP server, UNICOM FHIR IG, and IDMP product browser for test and reuse
- Smart Substitution Component and Patient Facing App

Knowledge exchange

- Community of Expertise
- Trans-Atlantic exchange and workshops
- NCA Best Practice exchanges
- Contribution to Research papers

https://youtu.be/sfdsWxuz9Uc?list=UUBsNj4B33Q7-50XTXdqAGIg

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Conclusions

PLM Portal – “a door to the world”

Austrian
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Safety in Health Care
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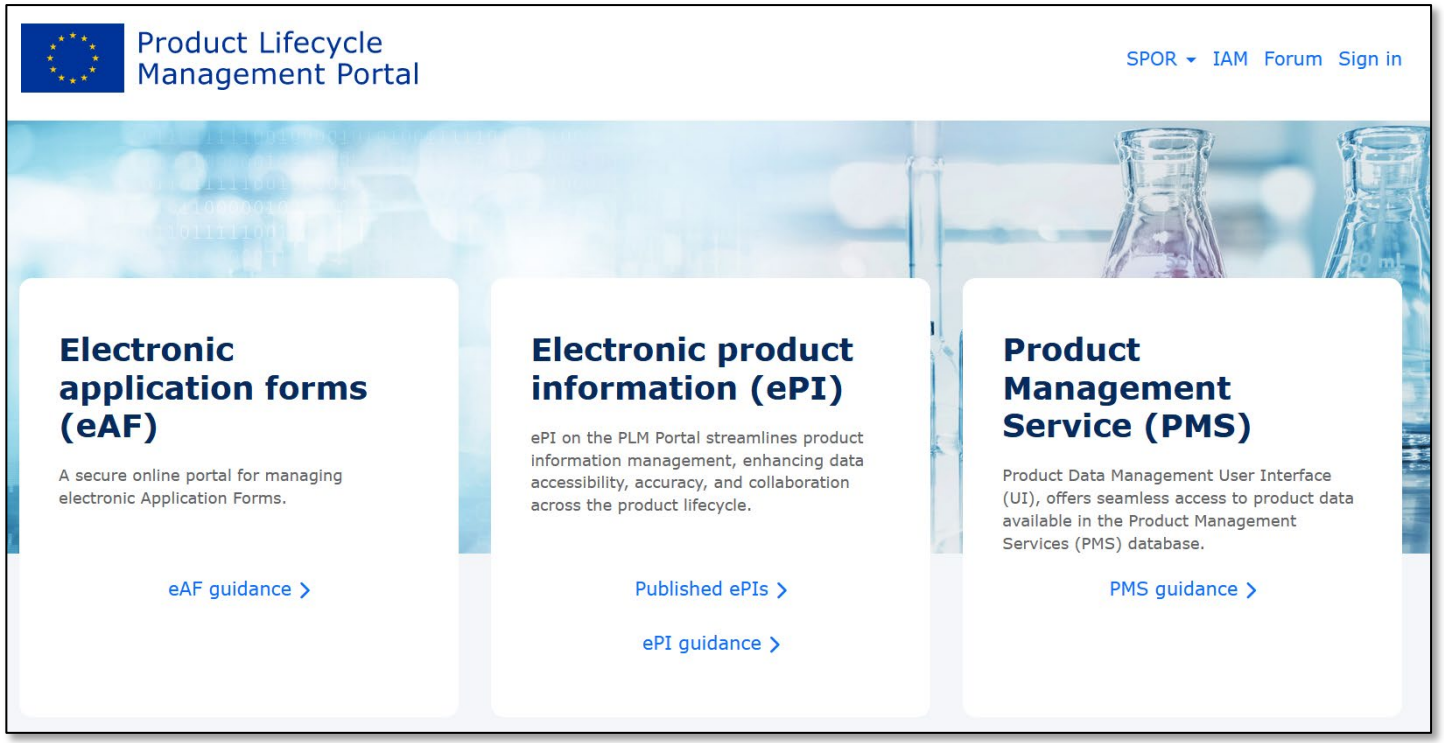


EMSP

Interoperability

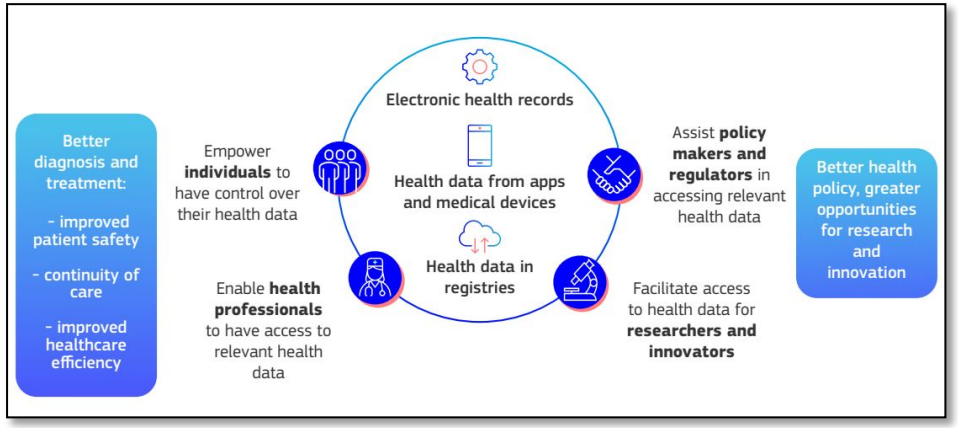
The success of the next digitalisation steps depends on the degree of
interoperability of data, processes and IT systems
and next data consumers/scenarios are already waiting for trustworthy data

Empowering patients

Source: EMA

e.g. "Master data of medicinal products are a central prerequisite for cross-border activities, EU-Patient-Summary

European Health Data Space



Source: EC, https://www.european-health-data-space.com/

The EMRN is one source for trusted master data
For primary and secondary use of data

Take Home Message

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- **XEVMP data is now becoming relevant for regulatory activities**
  - e.g. for medicinal product masterdata in eAFs; might delay applications!
  - Please check your data quality in XEVMP

- **Consider resources for data enrichments**
  - Packages, Pack sizes/units needs to be enriched in XEVMP and PMS
  - Manufacturer data needs to be enriched in PMS for ESMP

- **Consider interoperability measures at your level to ensure consistent data (flows)**
  - ISO-IDMP and EU implementation guides
  - FHIR for data exchange
  - Usage of SPOR OMS, RMS, SMS

Questions and Contact

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Your business processes are already looking forward to being adapted so that you can make the best use of new data driven opportunities - ☺

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