



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## PMS SG Webinar

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9 September 2022





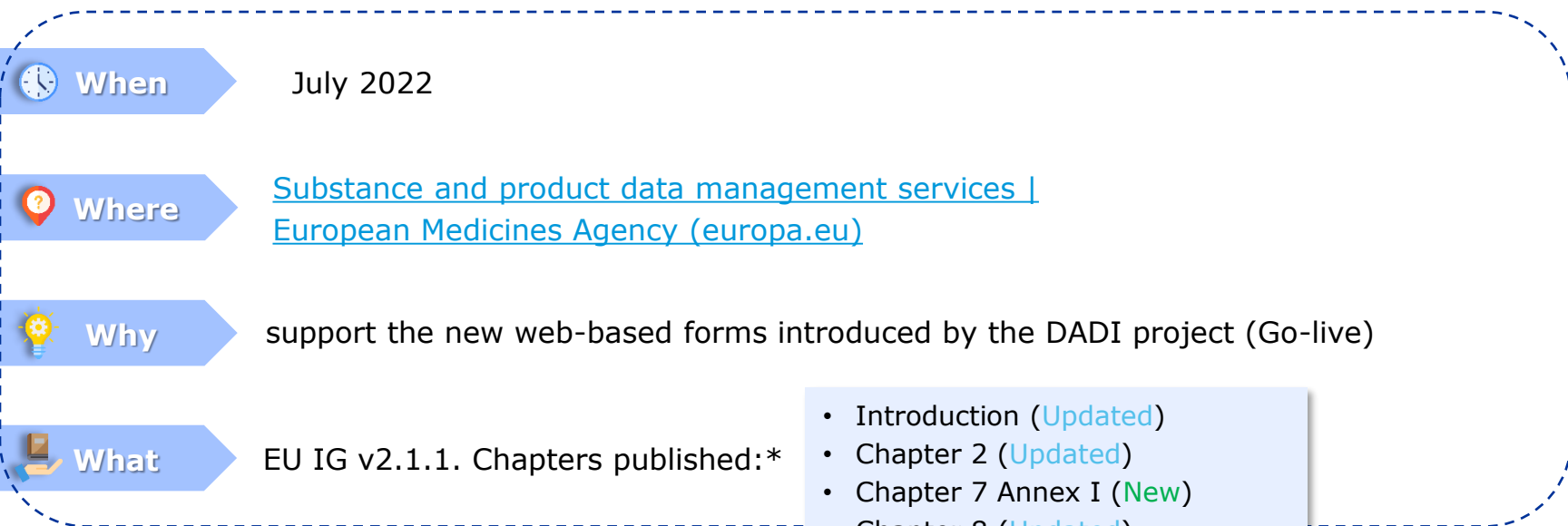


## EU IG v2.1.1 release

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*The PMS EU Implementation Guide for the submission of data on medicinal products defines the **implementation requirements of the ISO IDMP standards** and will be the basis for submission and exchange of medicinal product data in the EU.*

- The **current version** of [PMS EU Implementation Guide](#) is version 2.1.1, released in July 2022
- The PMS EU Implementation Guide is **updated on an as needed basis** when enough material changes merit updating the document
- **Future releases** of the EU Implementation Guide will be announced in advance and follow appropriate stakeholder consultation procedures



- Introduction ([Updated](#))
- Chapter 2 ([Updated](#))
- Chapter 7 Annex I ([New](#))
- Chapter 8 ([Updated](#))
- Annex I to Chapter 8 ([Updated](#))

## **What's next?**

- Update of Chapter 7 supporting DADI release 2
- Alignment of Chapter 6 & API specs to latest PMS Data Model



## Added Lists

- Medicinal Product Type (200000025915)
- Medical Device Classification (200000025960)
- Medical Device Legislative Category (200000025965)
- Master File Identifier type (200000026028)



## Updated Lists

- Units of Measurement (100000110633)
- Medicine Profile (200000003186)
- IT Application (2000000000001)
- Source of Information (1000000000009)
- Legal Status for the Supply (100000072051)
- Marketing Status (100000072052)
- Master File Type (2200000000070)
- Medicine Profile (200000003186)



## To Finalise

- Reason (Provenance)
- Medical Device Type
- Origin of the substance (*DADI*)

## 1.18. Attached document

- 1.18.6. URL value
- 1.18.7. (Attached document)  
Status

## 4. Packaged Medicinal Product

- 4.3. Manufacturer

## 4.8. Package item (container)

- 4.8.5.1. Quantity operator
- 4.8.6.1. Identifier value
- 4.8.6.2. Identifier system

## 4.10. Medical Device

- 4.10.5.1. Quantity operator
- 4.10.6. Medical device description
  - 4.10.6.1. Language
- 4.10.7. Medical device description of intended purpose
  - 4.10.7.1. Language
- 4.10.8. Medical device classification
- 4.10.9. Medical device manufacturer

## 4.11. Manufactured Item

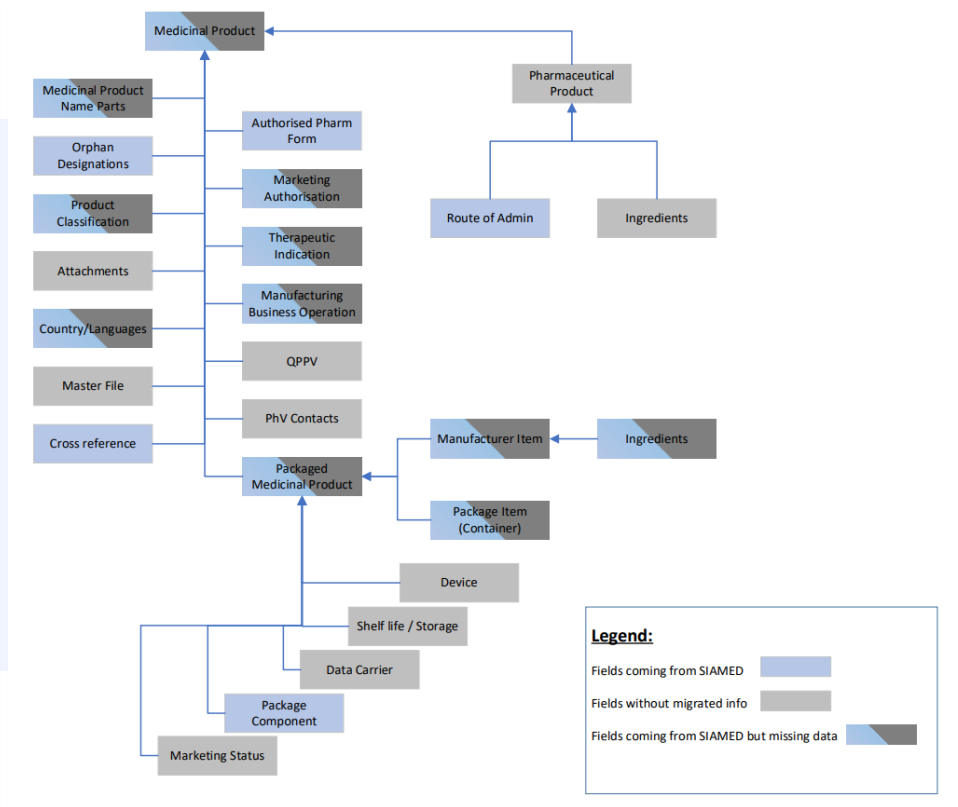
- 4.11.2.1. Quantity operator

- › Chapter 8, Ch.8 Annex I, and Ch.2 Annex II aligned to Chapter 2
- › Technical details, FHIR/ISO info, data type, values, complementary data
- › Revised conformances & field repeatability
- › **Editorial updates** across EU IG
- › Additional **examples** in Chapter 8
- › **New section** on *Submission of information on medicinal products with valid marketing authorisation in the territory of Northern Ireland to be sold in Northern Ireland* (same registration procedure as per xEVMPD applies to PMS)

- › Clarified MPIDs assignment rules based also on the initial migration
- › Clarified **business rules** on:
  - Legal status of supply ≠ at package level (sections 1.7 vs 4.5)
  - 3.3. Intended effect
  - 1.20.8. (Manufacturing business operation) Medicines Regulatory Agency Organisation & 2.9 (Marketing authorisation) Regulator
  - 4.10 Medical device

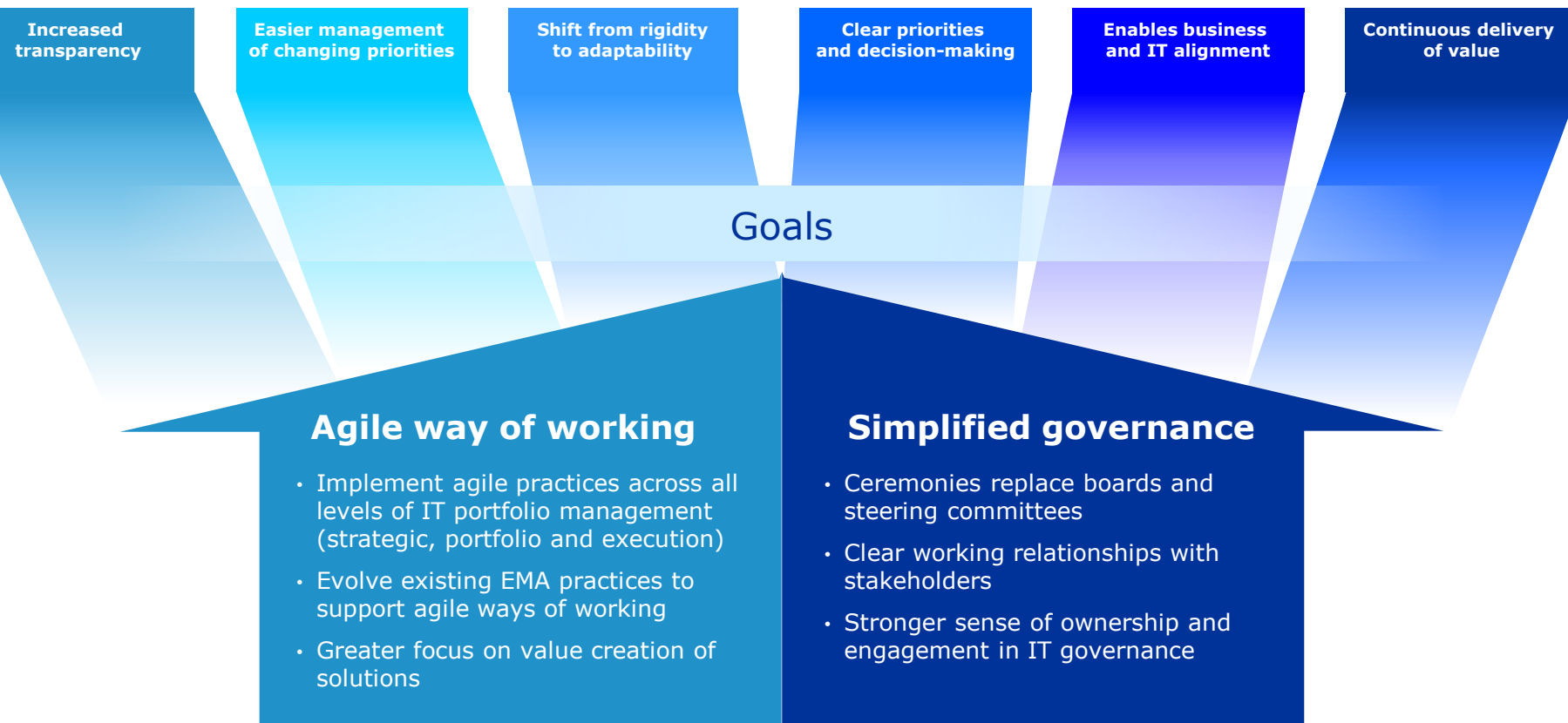


- New **Annex I to Chapter 7** was released as part of EU IG v2.1.1 to support DADI go-live
- In this Annex, only **migration rules** for data coming from SIAMED and that will be shown in the DADI variation form at go-live are provided
- **New version of Chapter 7** will be provided before xEVMPD and SIAMED data is in PMS production

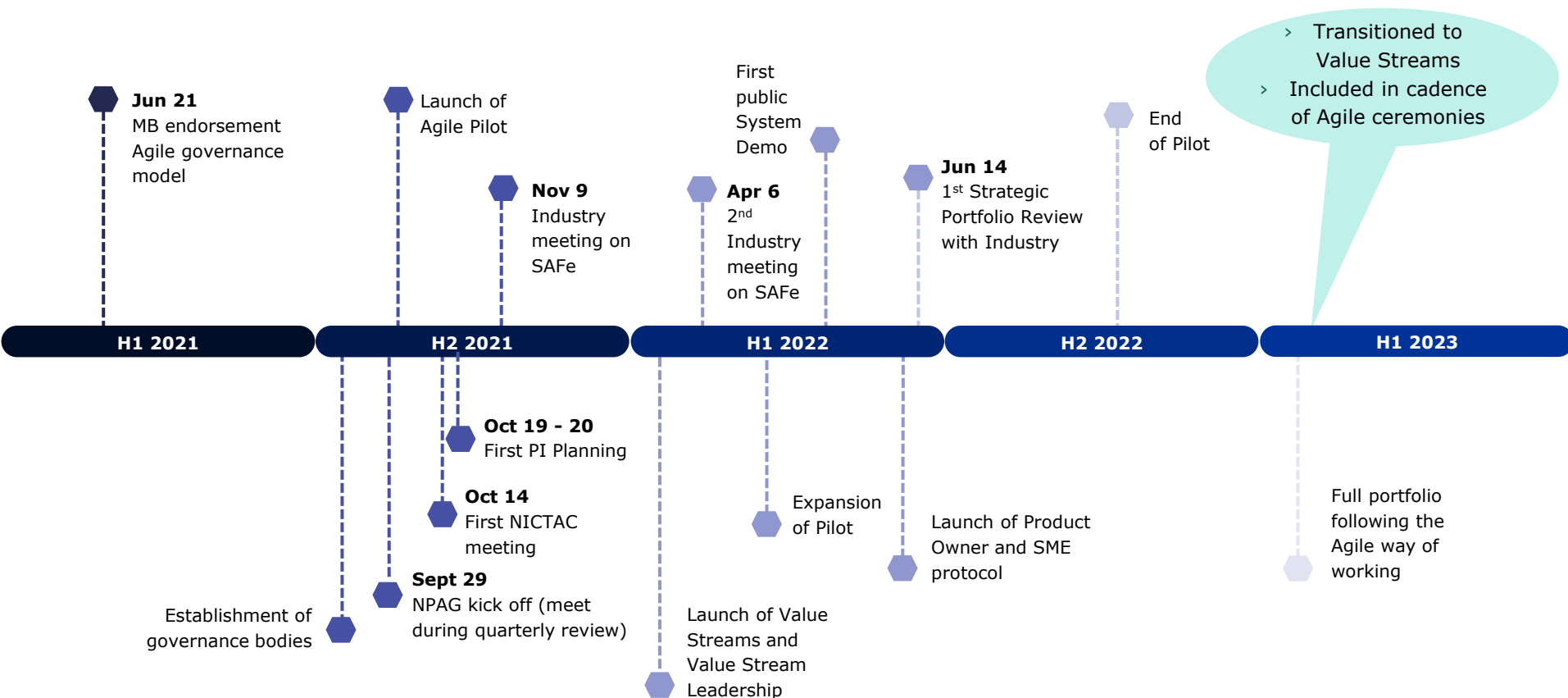




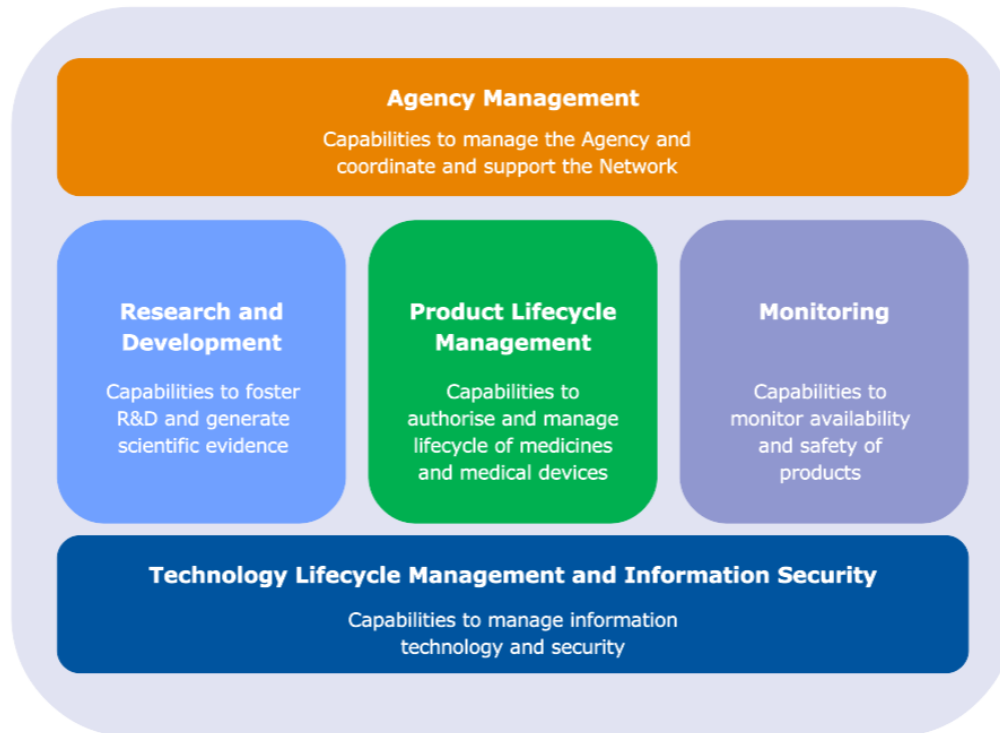
## Transitioning SPOR Governance to SAFe Governance



# Milestones on the Agile transition

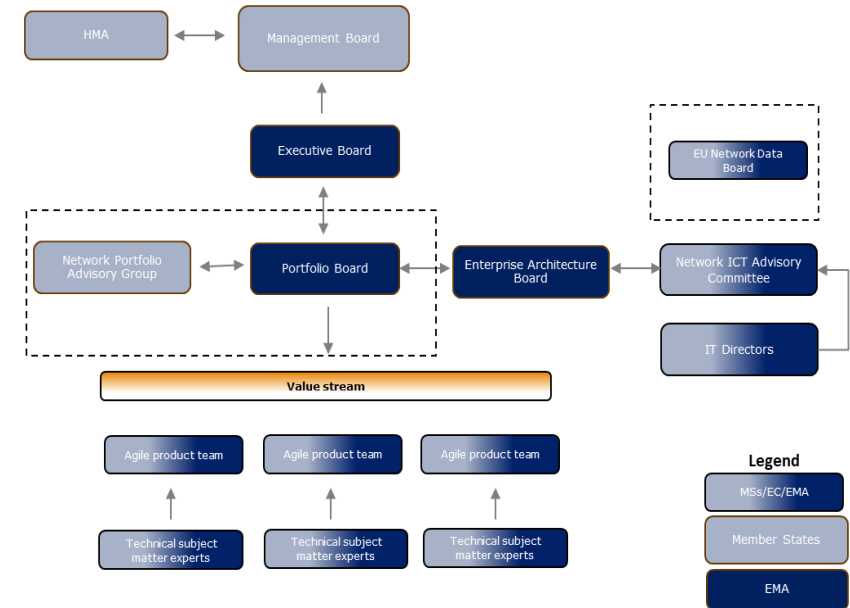


EMA has adopted 5 Agile Value Streams, designed to reflect the fundamental purpose of the organisation and align to the overall value it provides

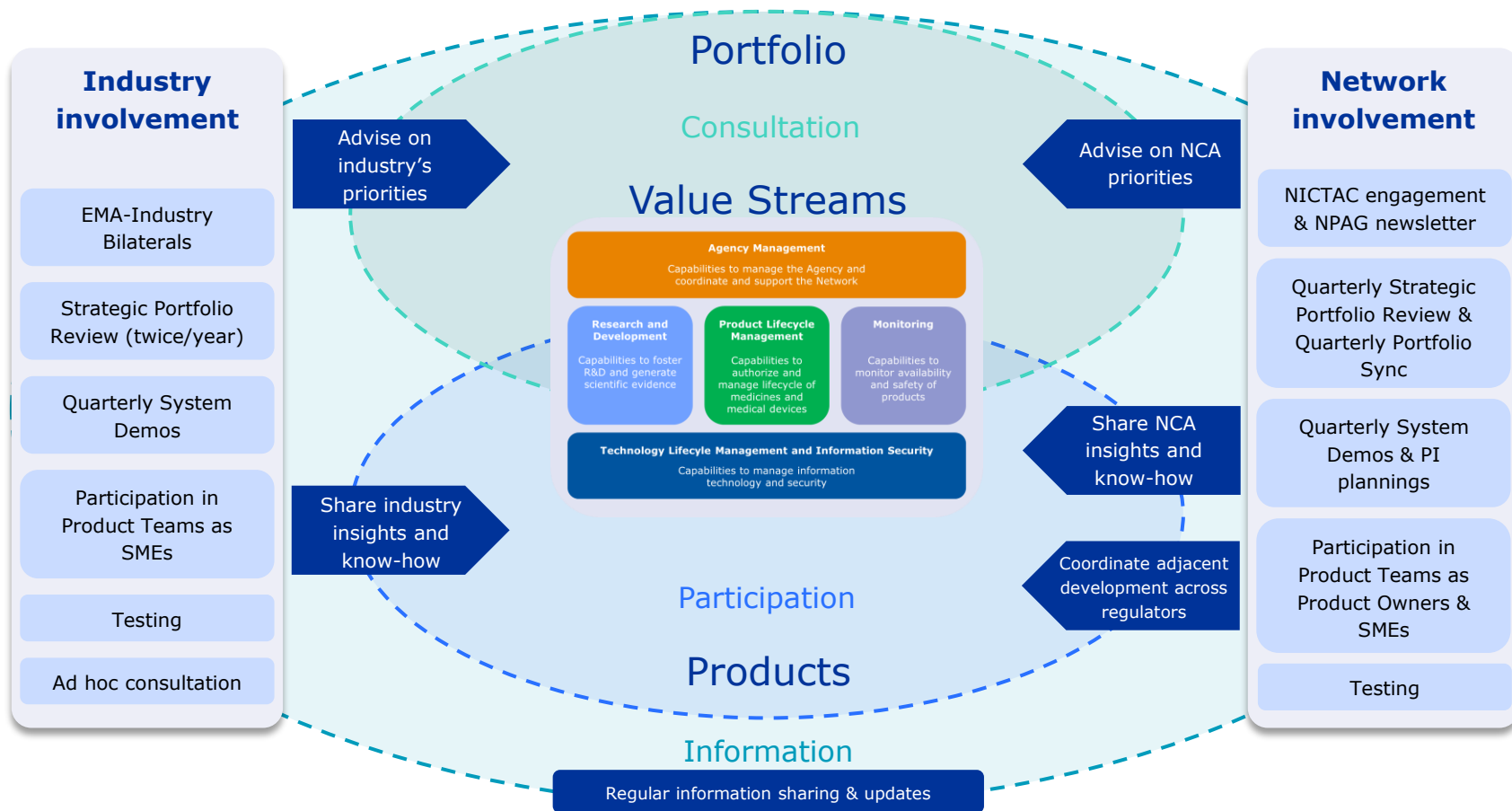


Pre-Agile, approx. 50 governance bodies existed across IT portfolio with no single governance approach

eu telematics  
epi spor task force  
common repository working  
eu tmb data steering group  
repository working group ace  
raw data nvr coordination group  
key user group ctis forum  
big data steering spor key user  
iris steering committee teab  
advisory group  
dec



The new Agile way of working and governance requires the pre-Agile governance bodies to transition to the new approach of ceremonies, governance bodies and external representatives joining Product Teams in Agile roles



# It is time to transition SPOR to this way of working

All **IT governance** will transition to SAFe

At minimum that means establishing a **cadence of ceremonies** in line with SAFe governance

Transitions to SAFe governance are managed by value stream on a product-by-product basis

**UPD** and other products are being transitioned to SAFe in parallel

All current SPOR governance bodies will be transitioned to Agile **by end of 2022**



| Actor                   | Role today                                                                                                                                                              | Transition to:                                                                                                                                                                                                                     |                                                                                   |                                                                                                                                                                                                                                                                                    |                                                                                                                                    |                                                                                     | Interested partners & stakeholders                                                                                     | Timeframe                                        |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
|                         |                                                                                                                                                                         | NPAG                                                                                                                                                                                                                               | (strategic) Portfolio Review                                                      | Network Product Owner(s)                                                                                                                                                                                                                                                           | Network SME                                                                                                                        | Industry SME                                                                        |                                                                                                                        |                                                  |
| SPOR Taskforce          | Advising on <ul style="list-style-type: none"><li>planning</li><li>development</li><li>Implementation</li><li>maintenance of the SPOR data services in the EU</li></ul> |                                                                                                                                                   |  |                                                                                                                                                                                                  |                                                 |  | <ul style="list-style-type: none"><li>Ad hoc engagement</li><li>Regular information flow</li><li>System Demo</li></ul> | One more meeting in Q4 22                        |
| SPOR co-chairs meetings | Advice on priority setting                                                                                                                                              |                                                                                                                                                   |  |                                                                                                                                                                                                  | Fulfilled by the same PMS & SME roles below<br> |                                                                                     | -                                                                                                                      | Q4 2022                                          |
| PMS SG                  | Prepare proposals regarding aspects related to SPOR projects                                                                                                            | -                                                                                                                                                                                                                                  | -                                                                                 |   <br>Calls currently open |                                                                                                                                    |                                                                                     | -                                                                                                                      | PO & SME Call for interest open – Q4 2022        |
| PMS Process & Data FGs  | Inform operational development of EU IG content                                                                                                                         | -                                                                                                                                                                                                                                  | -                                                                                 |                                                                                                                                                                                                                                                                                    |                                                                                                                                    |                                                                                     | -                                                                                                                      |                                                  |
| SMS SG                  | Prepare proposals regarding aspects related to SPOR projects                                                                                                            | -                                                                                                                                                                                                                                  | -                                                                                 |                                                                                                                                                                                                  |                                                 |  | -                                                                                                                      | Expected call for expression of interest in 2023 |
| SPOR Key user group     | Prepare proposals SPOR Data Service Management - operations                                                                                                             | OMS & RMS are <b>not strictly under the Agile governance as there is no major IT work going on.</b> There is the need for a group of SMEs to discuss data governance issues – to be revisited upon the review of the EUNDB mandate |                                                                                   |                                                                                                                                                                                                                                                                                    |                                                                                                                                    |                                                                                     |                                                                                                                        | Until further notice                             |
| SPOR Change Network     | Cascade communications about SPOR implementation to their stakeholder groups<br><br>Not active group                                                                    | -                                                                                                                                                                                                                                  | -                                                                                 | -                                                                                                                                                                                                                                                                                  | -                                                                                                                                  | -                                                                                   | <ul style="list-style-type: none"><li>Ad hoc engagement</li><li>Regular information flow</li><li>System Demo</li></ul> |                                                  |

**Key**  
**PMS roles**  
**SMS roles**  
**None-SPOR specific roles (currently fulfilled)**



All current SPOR governance bodies will be transitioned to Agile by end of 2022



Network POs, SMEs, NPAG, quarterly strategic portfolio reviews are exclusively the new governance mechanisms



Engagement and consultation with stakeholder groups will happen widely, but on an ad hoc basis and through public ceremonies, supported by regular communications



## Calls for expression of interest (Network PO, SMEs)



## Role Presentation

The Network Product Owner is *the* representative of the network for a product. As the voice of the network the Network PO brings both context expertise and insights on relative priorities to help steer product development. The Network PO supports and collaborates closely with an EMA PO.



## Role responsibilities

- Maximize (business) value of the product to ensure outcomes meet user's needs & expectations
- Manages together with the EMA Product Owner for managing the team backlog, ensuring that the user stories are well defined, estimated, prioritised, and refined for the Product Team to implement
- Actively attend and contribute to Ceremonies for the benefit of the network for the product
- Supports identification and recruitment of Network SMEs
- Define and accept Stories
- Represents network stakeholders and is the voice of the customer.
- Listens to and engages with network stakeholders
- Ensure quality of the work
- Negotiates the scope and work to be performed with the Developers during the Sprint



## Enablers

- Access to SAFe Agile Certification & Coaching
- Flexible division of work with EMA PO based on relative strengths
- Reimbursement for PI Planning attendance
- Training and coaching

**~ 50% FTE**



## Role Presentation

Industry or Network experts provide advice and recommendations as well as occasional hands-on work for the benefit of consistent process enhancement across value streams for a specific business process. Input is at the invitation of Product Owner.



## Role responsibilities

- Provides expert input on the subject matter of the product to help develop Epics or features for prioritization
- Support the product owners with insights on behalf of industry or network stakeholder groups to inform prioritization of features
- Participates in the development of specific user stories where advice/guidance is needed
- Participates in PI Planning or other ceremonies as needed, upon the invitation of the product owner or value stream owner



## Enablers

- Access to SAFe Agile training & Coaching
- Reimbursement for attendance of ceremonies (Network only; not Industry)

**~ 20% FTE**

## Network Product Owner

- Call open on **15 September 2022** and will close on **6 October 2022**
- Deadline for selection is **6 October 2022 E.O.B.**
- Start date for this role is **20 October 2022**
- Expected end date **31 December 2023**

## SMEs (Network & Industry)

- Call open on **15 September 2022** and will close on **4 November 2022**
- Deadline for selection is **25 November 2022 E.O.B.**
- Expected start **5 December 2022**
- Expected end date **31 December 2023**



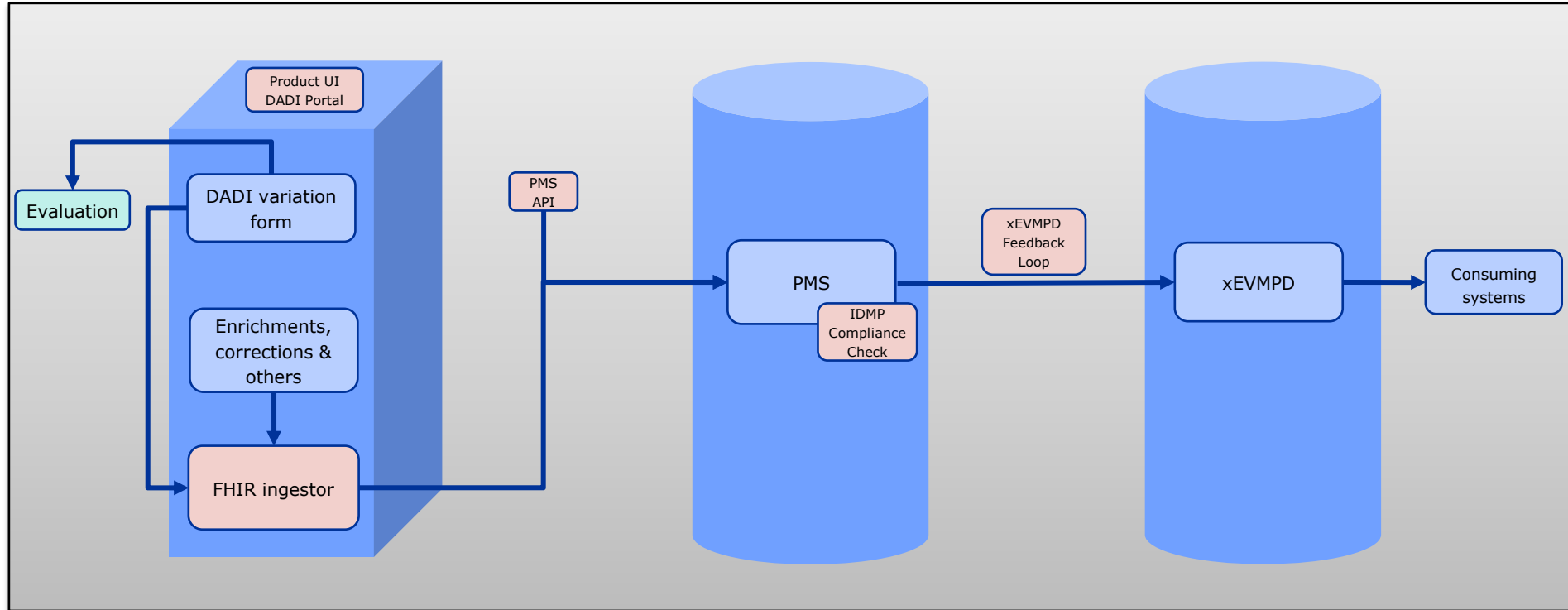
### Note:

- Q4 Programme Increment Planning will proceed without a Network PO
- The aim is to involve the Network PO in the evaluation of SME candidatures
- Non-SME Stakeholder consultation will be supported by System Demo's and ad hoc sessions, as & when needed as well as supported by regular communications
- With the launch of the calls, all current SPOR governance bodies will be transitioned to Agile by end of 2022
- The calls for were disseminated through EMA's standard e-mail distribution channels to HMA members, NCA IT Directors and to the relevant Industry stakeholder organisations (human domain) to further cascade the message accordingly.



## Next Steps

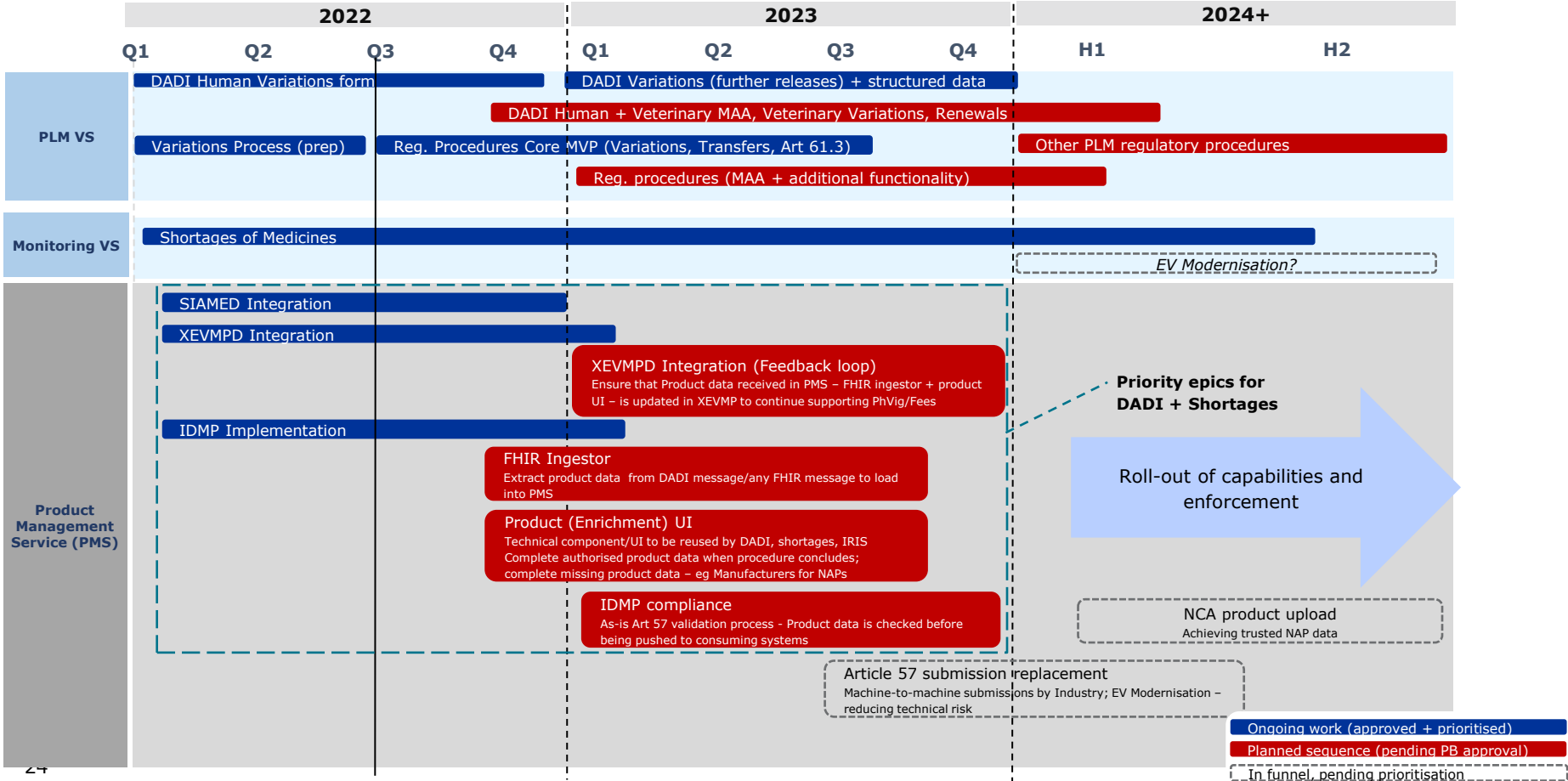
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Under discussion



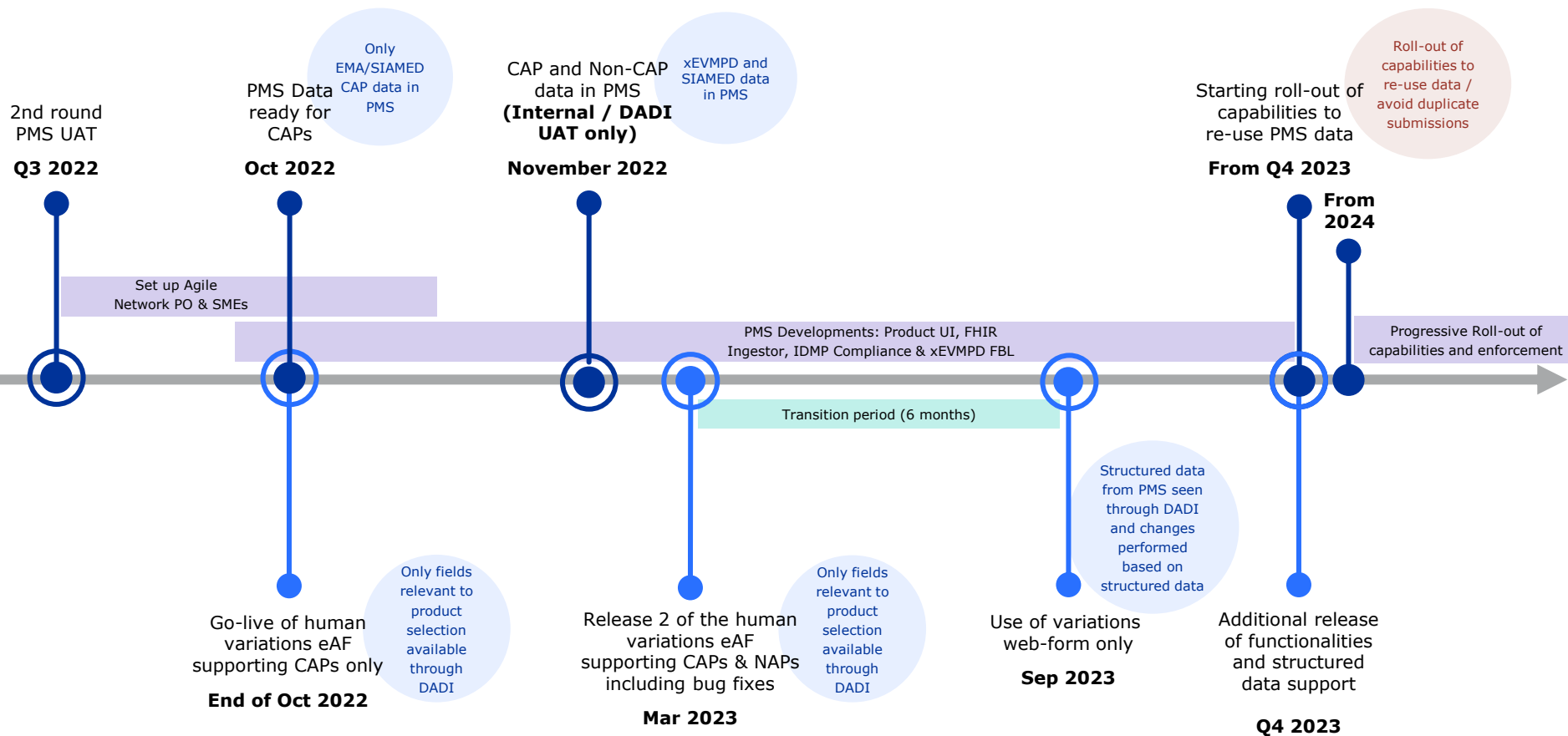
# PMS vs Portfolio Roadmap



# Roadmap of Future Releases



EUROPEAN MEDICINES AGENCY





## During Q3 2022

- › **2<sup>nd</sup> round of initial load** from xEVMPD and SIAMED was performed

## October 2022

- › SIAMED data will be available in PMS to support DADI go-live (**CAPs only**) - Only fields relevant to product selection are available through DADI
- › Deltas from SIAMED will be implemented to maintain data in PMS

## November 2022

- › xEVMPD and SIAMED data will be made available in PMS to support next DADI release (internal use only for DADI UAT)

## March 2023

- › **xEVMPD and SIAMED data will be available in PMS** to support 2<sup>nd</sup> DADI release => matched and merged CAP products between xEVMPD and SIAMED
- › Only fields relevant to product selection are available through DADI

## From March 2023

- › Use of DADI variation form or eAF (until Sept 2023)
- › No enrichment to PMS data is foreseen before Q4 2023
- › xEVMPD submissions are still applicable at least until Q4 2023

## Q4 2023 – DADI release 3

- › additional functionality and structured data support, means:
- › **current section** of form contains data as-is from PMS - with or without data, with corrected or uncorrected data – does not need to be corrected/completed (some corrections could be done in xEVMPD and the change would be propagated to PMS.)
- › **proposed section** with only structured data as suggested by applicant;
- › For DADI release 3, **PMS data does not need to be corrected/enriched in advance.**

## Q4 2023 – PMS:

- › ***Progressive Roll-out of Capabilities (FHIR Ingestor, Enrichment, PMS UI...) on a Voluntary Basis***
  - FHIR ingestor and XEVMPD FBL to receive/import the structured data changes as they come in to ensure the data in PMS is updated with the procedures.
  - Product UI that will support enrichments & corrections
  - There are benefits in submitting corrections/enrichments so the data can be reused in subsequent applications: less need for Industry to re-enter the same data across multiple applications, less need for regulators to check the same data, less likelihood for questions/validation issues, overall process efficiencies for Industry and regulators

## TBD! Plan for Enforcement

- › The data for the full PMS iteration 1 scope will be needed when there is art 57 submission replacement which is planned for 2024.
- › *It is likely that the new extended mandate will increase the urgency of receiving structured data on manufacturers but impacts (critical medicines vs all)/timelines are still under discussion.*

## Useful links

- Find an overview of PMS on the [EMA Website PMS Page](#)
- Find general information on PMS in the [new Joint DADI-PMS Q&A Document](#)
- If you need any assistance, raise a [Service Desk](#) ticket

## Useful links

You can directly contact the PMS team for questions about the presented topics:

- [Veronica.lipuccidipaola@ema.europa.eu](mailto:Veronica.lipuccidipaola@ema.europa.eu)
- [Marcos.fernandezgomez@ema.europa.eu](mailto:Marcos.fernandezgomez@ema.europa.eu)