



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR Task Force meeting

26 January 2023, 14:00 – 15:30 (CET)

Webinar: Webex





Welcome

Isabel Chicharo, *SPOR Co-Chair & PMS Epic Owner, EMA*



1

Welcome

14:00 – 14:10 (10 min)

Isabel Chicharo

SPOR Co-Chair & PMS Epic Owner, EMA

2

SPOR TF in review

14:10 – 14:30 (20 min)

Alexis Nolte

Head of Human Medicines Division, EMA

3

SPOR governance towards Agile transformation

14:30 – 15:00 (30 min)

Karl Hamilton

*Product Lifecycle Management (PLM)
Value Stream Owner*

4

Updates on SPOR

15:00 – 15:15 (15 min)

Isabel Chicharo

*SPOR Co-Chair & PMS
Epic Owner, EMA*

5

How to stay connected to work on SPOR

15:15 – 15:25 (10 min)

Joris Wiemer

PLM VS Change Manager

6

Closing

15:25 – 15:30 (5 min)

Isabel Chicharo

*SPOR Co-Chair & PMS Epic
Owner, EMA*

Veronica Lipucci Di Paola

Product Co-Owner for PMS, EMA

Marcos Fernandez Gomez

Product Co-Owner for PMS, EMA



Present the **key achievements of the SPOR Taskforce** over the years



Explain the transition of the SPOR governance to **Agile governance**



Present updates on **PMS SMEs nominations status**



Explain **how to stay updated** with SPOR developments

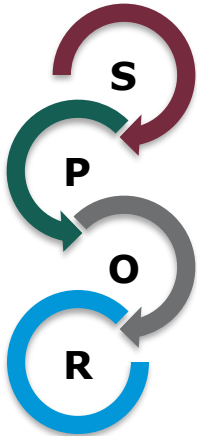






SPOR Task Force in review

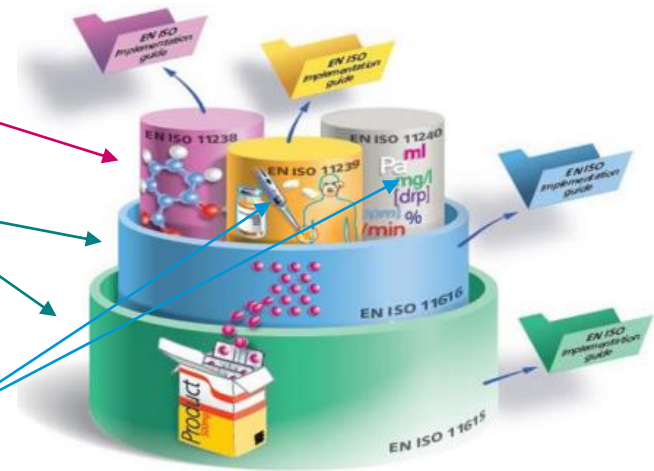
Alexis Nolte, *Head of Human Medicines Division, EMA*



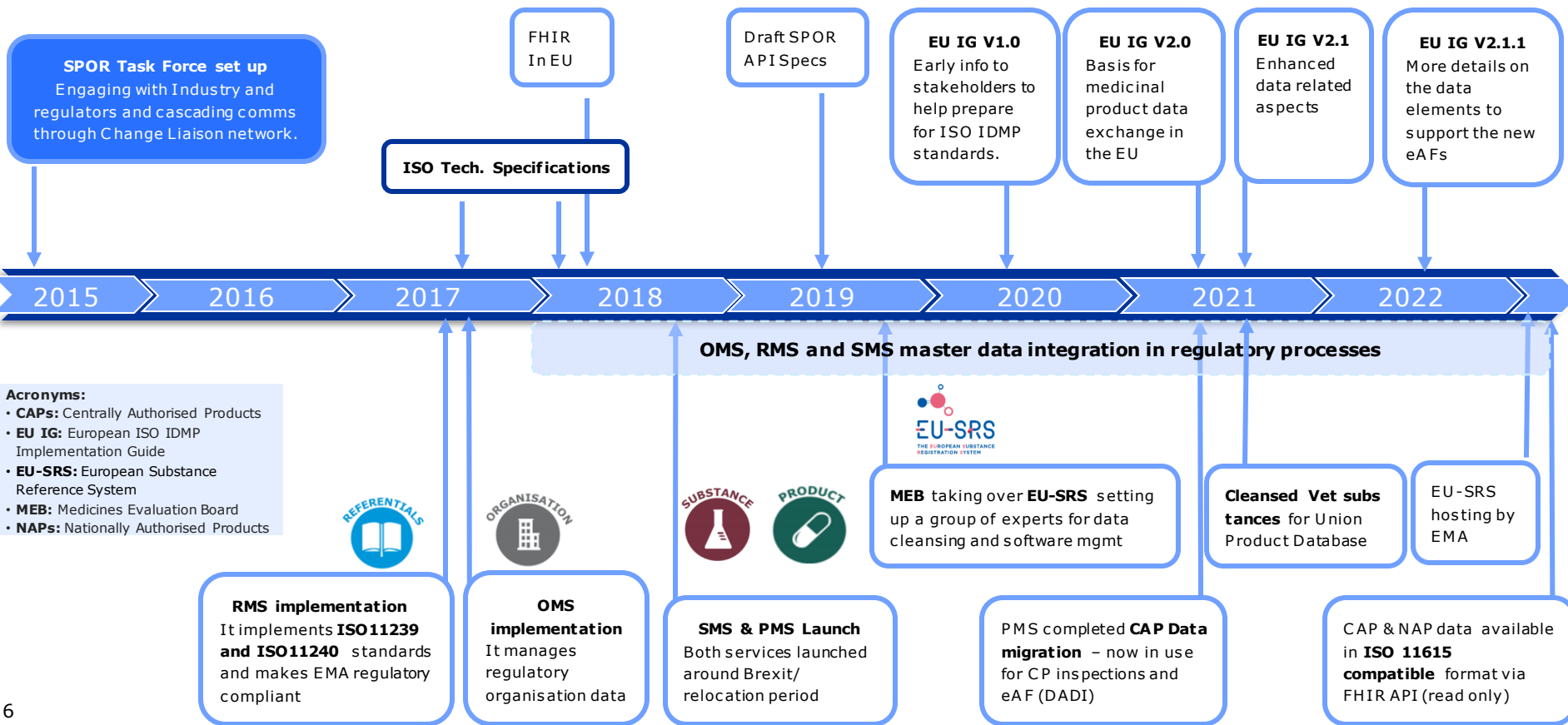
Deliver master data quality services on **Substances, Products, Organisations and Referentials** and **enhance the quality**, consistency and availability of **medicinal product data** used by EU regulatory Network



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

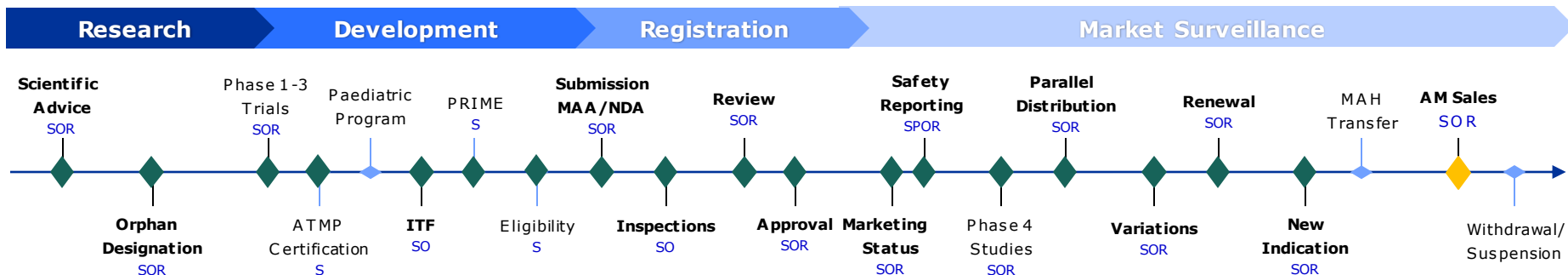


SPOR Task Force achievements and contribution to EU



SOR integration into EU Regulatory processes

In the **first 5 years** since SPOR data services go-live, **many of the regulatory processes throughout the product lifecycle** are using **data from SMS, OMS, RMS** and more will in the future – *use of PMS product data will follow*



Thank you to all the contributors and collaborators of the SPOR Taskforce!

We really appreciate your **effort, cooperation and valuable contribution** towards the SPOR achievements for the benefit of public and animal health in the EU



We look forward to continuing the good work in "Agile mode"



Moving towards an Agile Governance

EMA is phasing into an **Agile way of working and governance model** for IT systems and services, to be more effective.

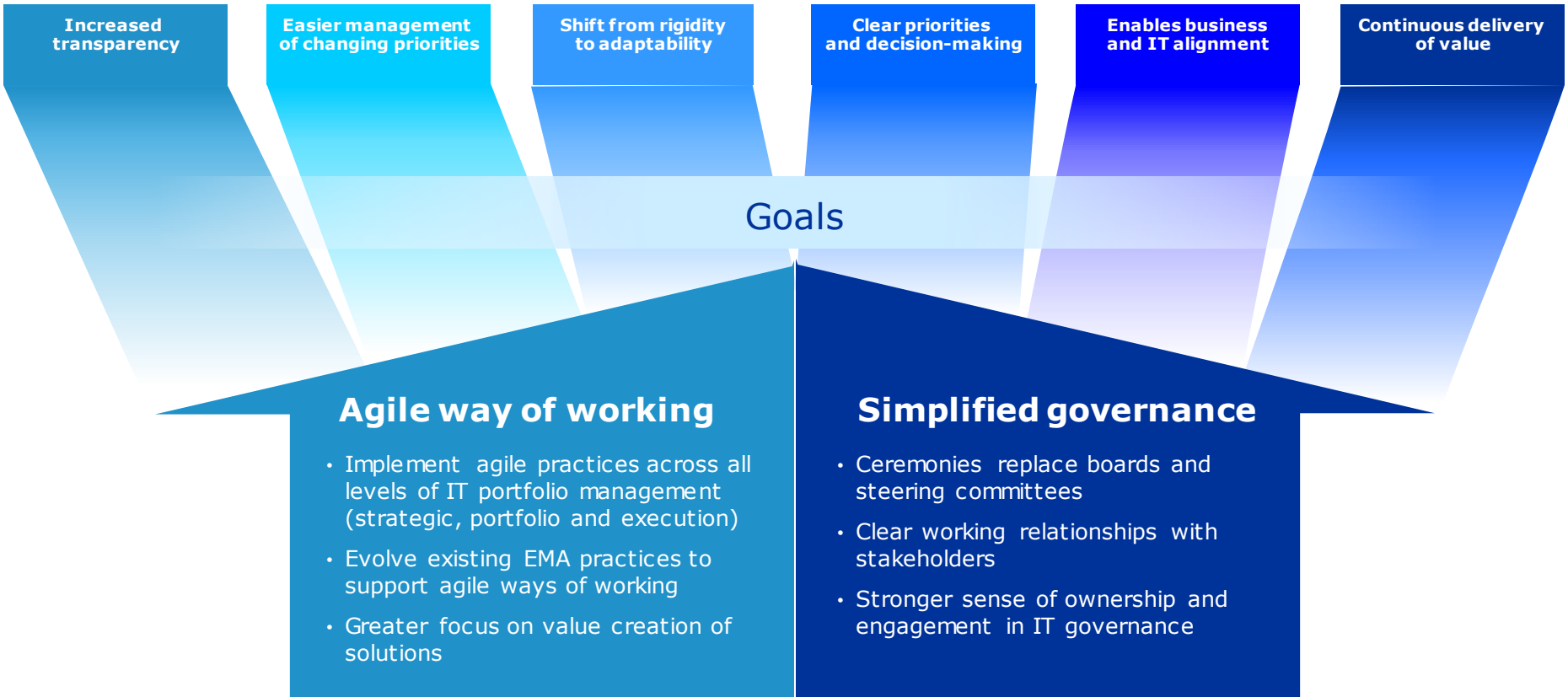
All current **SPOR governance will retire and transition to Agile** by end of 2022 where appropriate

This transition will help **long term support for SPOR & facilitate collaboration** with stakeholders and experts

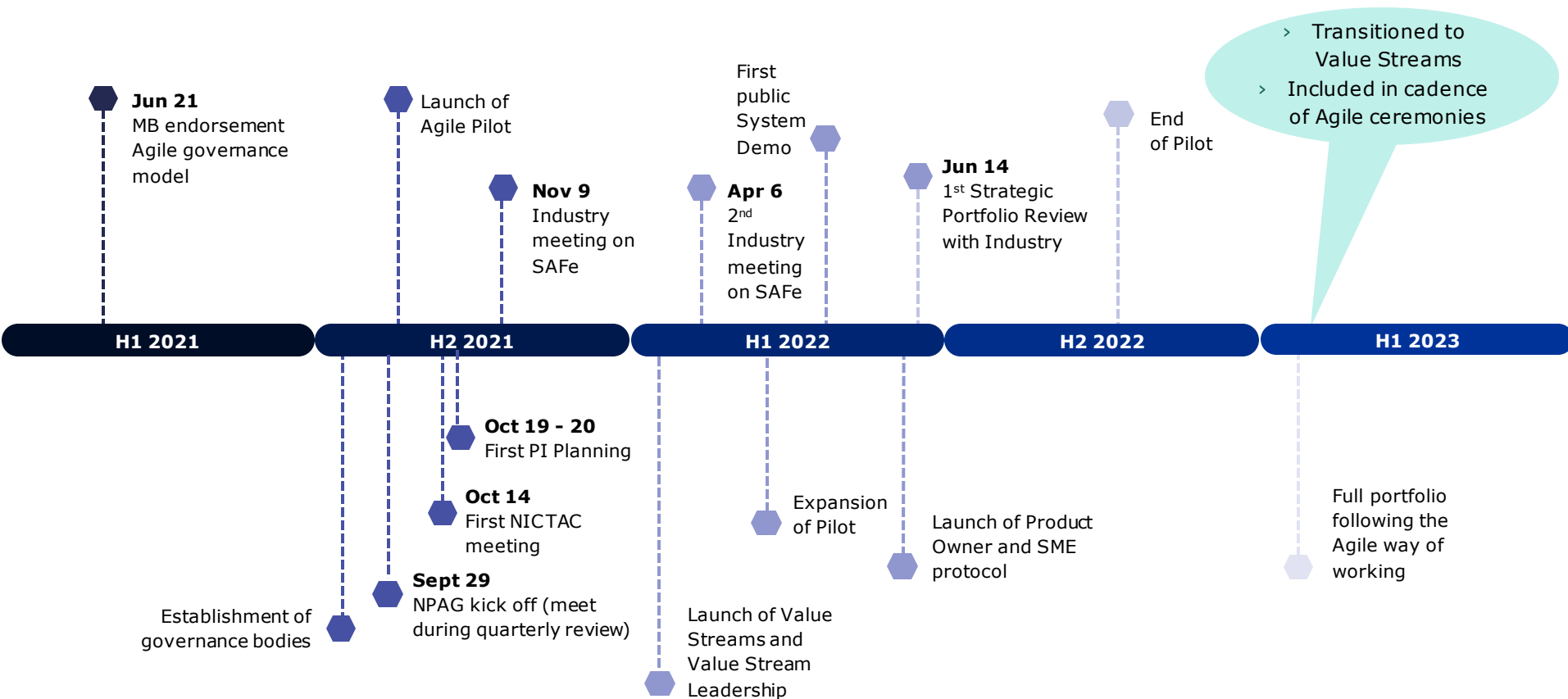


SPOR governance towards Agile transformation

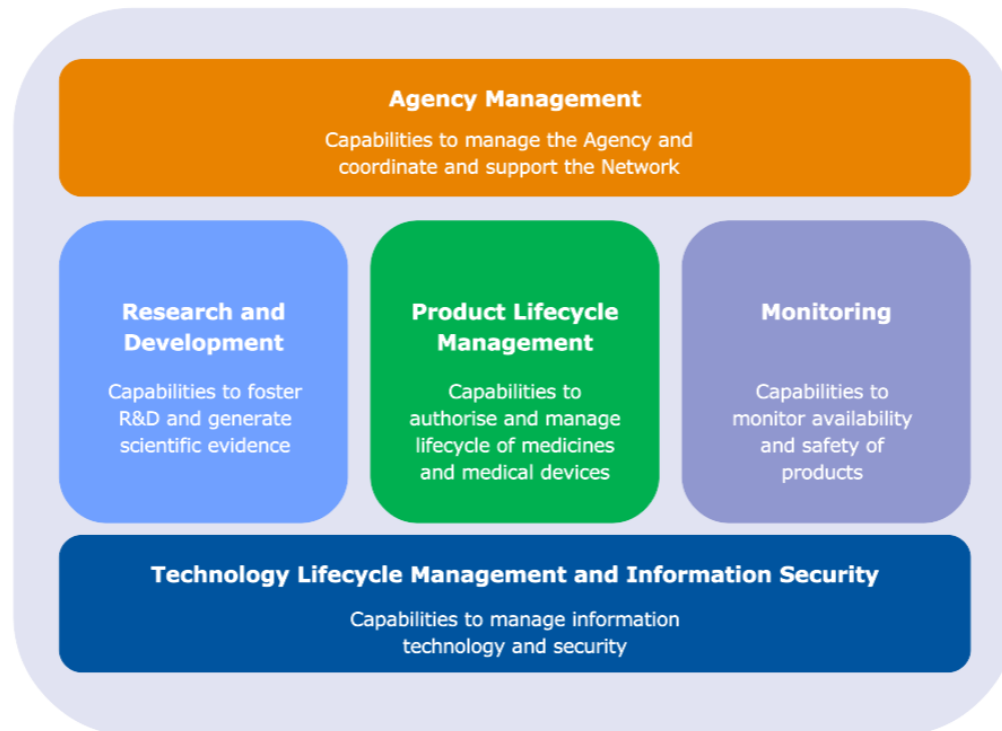
Karl Hamilton, *Product Lifecycle Management Value Stream Owner, EMA*



Milestones on the Agile transition



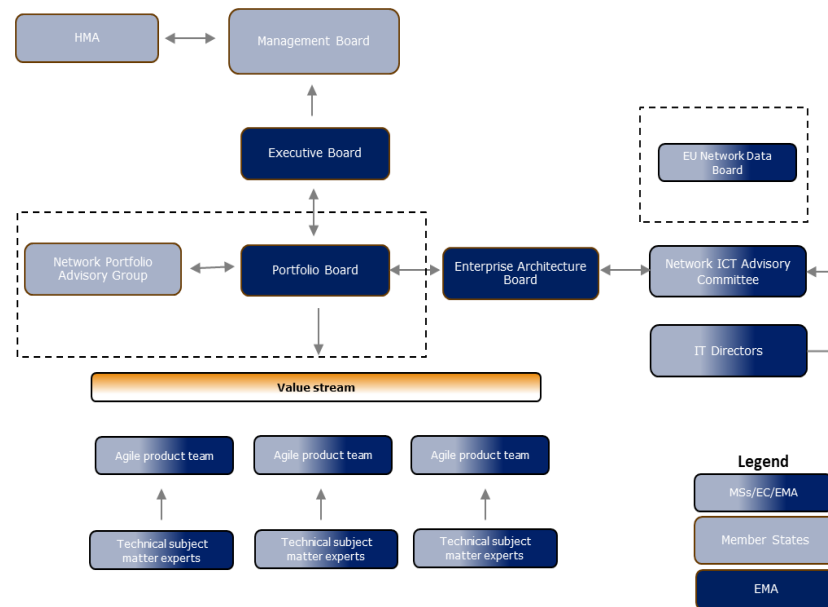
EMA has adopted **5 Agile Value Streams**, designed to reflect the fundamental purpose of the organisation and align to the overall value it provides



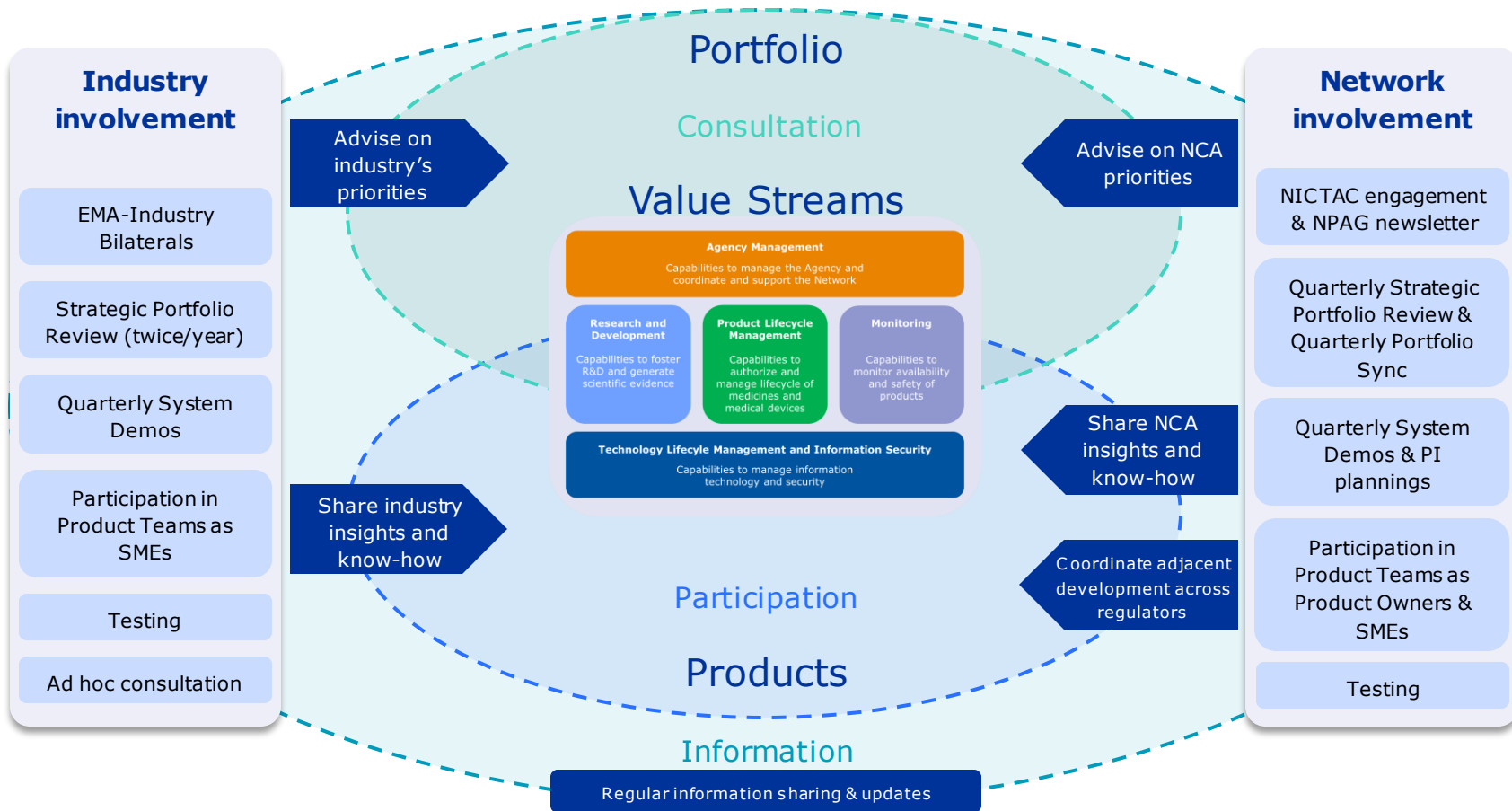
Pre-Agile governance

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



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"> planning development Implementation maintenance of the SPOR data services in the EU 						<ul style="list-style-type: none"> Ad hoc engagement Regular information flow System Demo 	One more meeting in Jan 23
SPOR co-chairs meetings	Advice on priority setting				-	-	-	Jan 2023
PMS SG	Prepare proposals regarding aspects related to SPOR projects	-	-				-	NPO Call for interest open – Jan 2023
PMS Process & Data FGs	Inform operational development of EU IG content	-	-	Calls currently open			-	
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 not strictly under the Agile governance as there is no major IT work going on. 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 Not active group	-	-	-	-	-	<ul style="list-style-type: none"> Ad hoc engagement Regular information flow System Demo 	

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



The SPOR Taskforce, stakeholder groups and focus groups will be disbanded in their current forms as **SPOR governance bodies transition to Agile governance** by January 2023 - *Engagement and consultation with stakeholder groups will happen widely, but on an ad hoc basis and through public ceremonies, supported by regular communications*



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



Each one of the **SPOR services will continue to exist.**



PMS and SMS will be immediately picked up by the R&D and Product lifecycle Management value streams as there is or will be in the near future active development work on the systems to support these services.



RMS and OMS do not have major IT work going on at this time.



Since its purpose is different, the **SPOR Key user group** - *which focuses on data management and data governance of SPOR services once in operations (not IT delivery)* - is temporarily kept, pending the review of the EU NDB's own mandate.

COMPLETED



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 prioritisation
- 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)



Timelines

- Call opened on **15 September 2022** and closed on **4 November 2022**
- Deadline for selection is **25 November 2022**
- Nominations sent on **7 December 2022**

~ 20% FTE

Step 1: Application

- ✓ **Network SME:**
 - 4 positions offered
 - 5 applications received
- ✓ **Industry SME:**
 - 4 positions offered
 - 10 applications received

Step 3: Approval

- ✓ Candidates with **highest scoring** have been **submitted for endorsement** at the Portfolio Board (PB)
- ✓ **PB approved proposed nominees** with no comments/objections on Friday 25th Nov
- ✓ **HMA representatives** (members of NPAG) have endorsed the nominations on Friday 2nd Dec

Step 5: SME onboarding process

- ✓ Selected SME **confirm the assignment** (i.e., sign confidentiality agreement, gain relevant system access)
- ✓ SMEs have mandatory attendance of:
 - **online training & SAFe eLearning**
 - at least **one Q&A monthly session** with Agile coaches (1st availability: 31 Jan 2023)
- ✓ Official **onboarding/welcome in PMS project:**
 - definition of tasks/scope/topics where to contribute
 - how to work with POs and other Product SMEs
 - participation to Agile Ceremonies and meeting

Step 2: Assessment

- ✓ All **application and CVs evaluated** by PMS POs against the criteria set out in the call

Step 4: Notification to applicants

- ✓ Selected and non-selected SMEs **notified by EMA**
- ✓ **Official onboarding notification** sent in **Dec**
 - Network SMEs announced to the HMA by the Portfolio Board
 - Industry SME announced to the Industry Secretariats through the EMA Industry liaison
- ✓ **Product Owner(s)** and/or **Value Stream Owner** notifies to all other relevant stakeholders and publicly announce the PMS SMEs



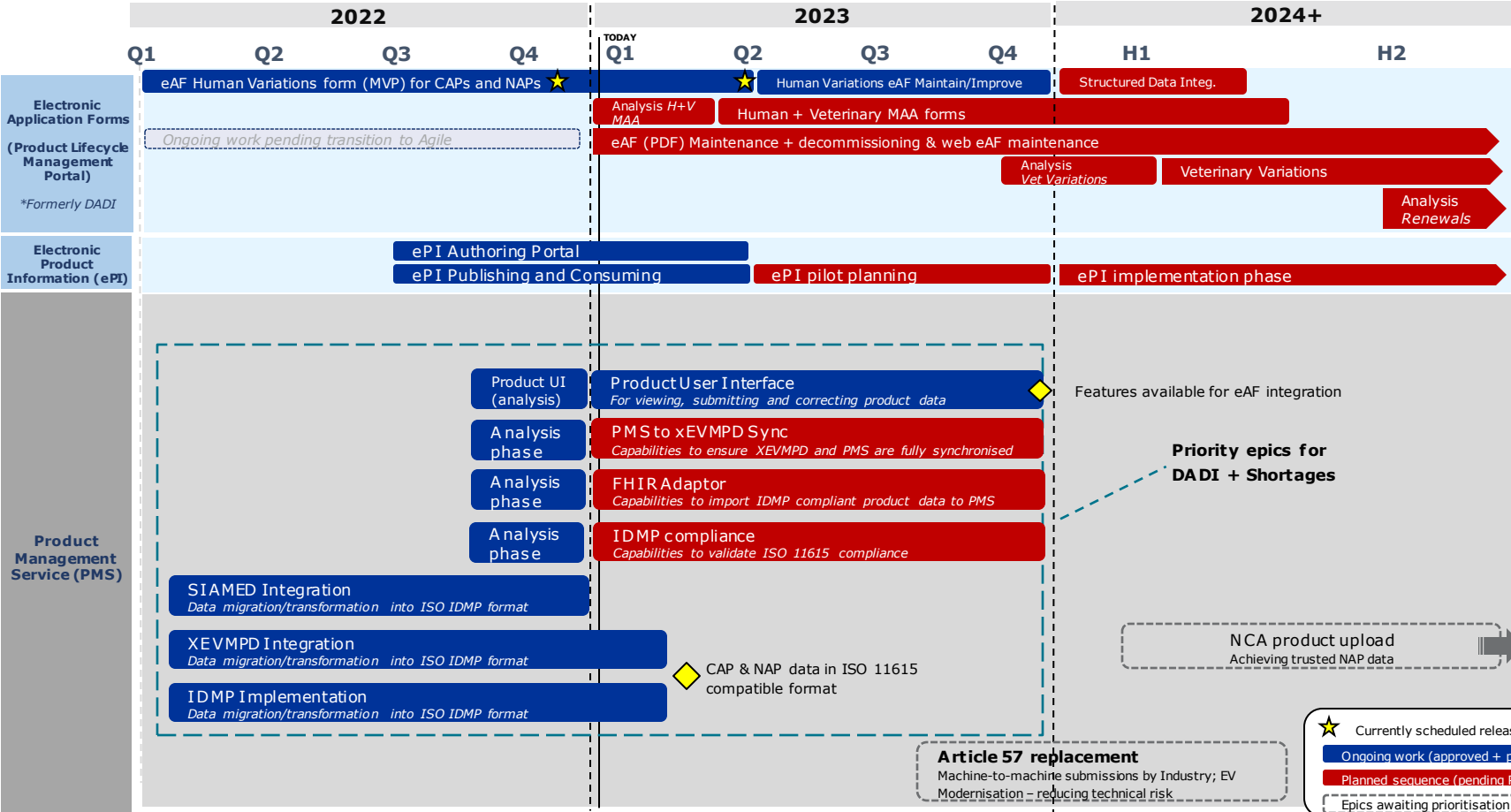
Updates on SPOR

Isabel Chicharo, *SPOR Co-Chair & PMS Epic Owner, EMA*



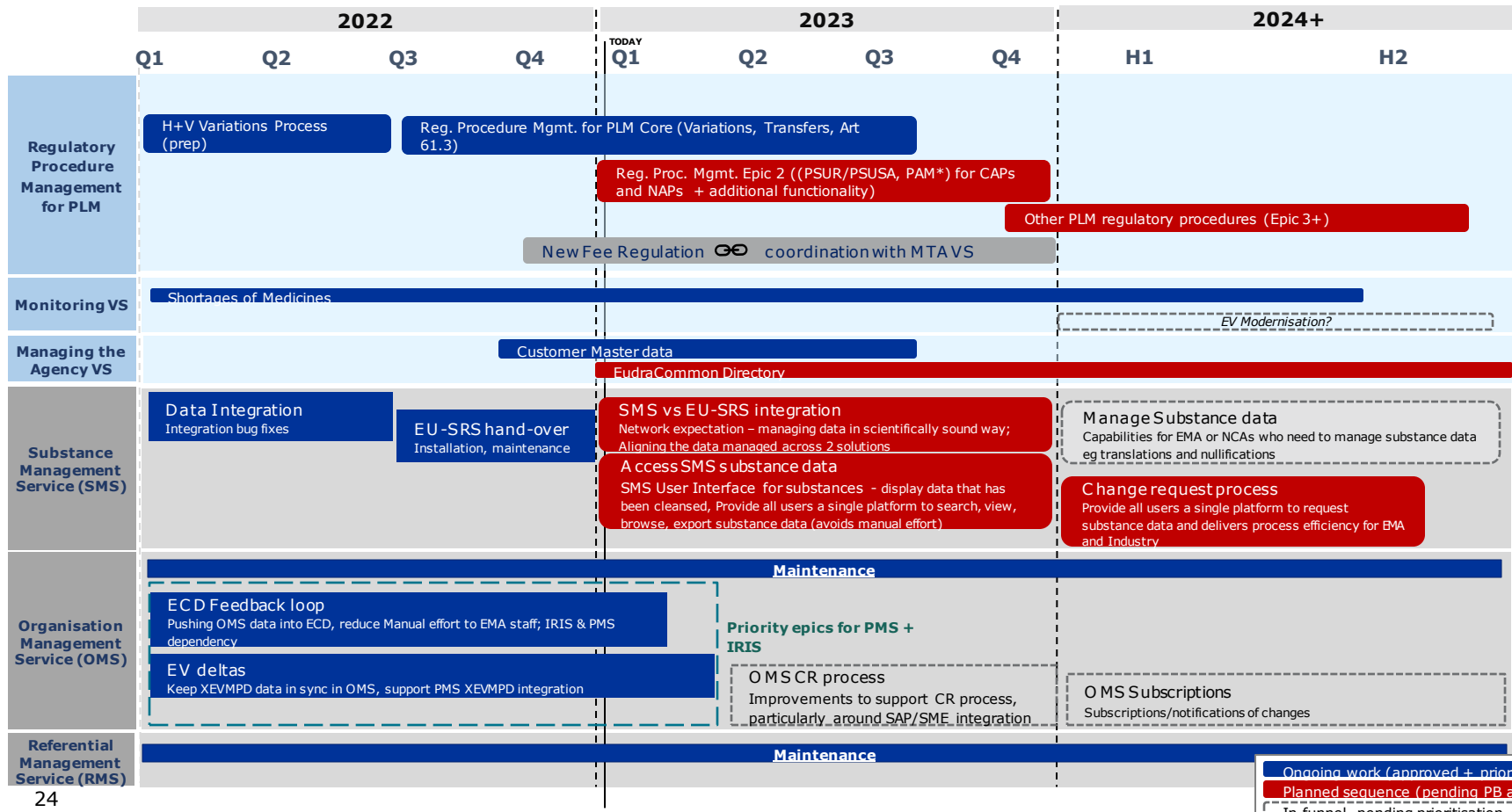
- The illustrated roadmap is a **subset of the Network Portfolio Roadmap**, shared and discussed with Stakeholders at the **Strategic Portfolio Reviews**, focusing only SPOR.
- The illustrated roadmap reflects **what the EMA will prioritize / work on**
- EMA acknowledges that this does **not yet address impact** on stakeholders
- As work is being developed, **impacts on stakeholders will be better understood** and communicated through dedicated webinars/ channels

How PMS Epics support Portfolio Roadmap





How SMS/OMS/RMS support Portfolio Roadmap



- Ongoing work (approved + prioritised)
- Planned sequence (pending PB approval)
- In funnel, pending prioritisation



SMS PO



Pedro Batista

PMS POs



**Marcos Fernandez
Gomez**



**Veronica
Lipucci Di Paola**

OMS PO



Debora Martins

RMS PO



Jaume Gonzales



How to stay connected to work on SPOR

Joris Wiemer, *PLM VS Change Manager, EMA*



System Demo

- See and discuss the latest developments of the system
- Give your feedback on features and priorities

Announced via EMA's Website
Events Pages



S, P, O & R Webinars

Discussion of new developments, updates in SPOR and new releases.

Announced via EMA's Website
Events Pages



SMEs & Network PO in products team

The Network Product Owner & Network SMEs, as well as Industry SMEs are your connection to product development.

Engagement to be determined by
NPO & SMEs



SPOR Webpage

- Download EU Implementation Guide Updates
- Access Q&A documents

Subscribe to the RSS feed



Strategic Quarterly Portfolio Review

Review with representatives of NCAs & Industry – to discuss strategic questions and priorities and advise the EMA Portfolio board.

Connect to your HMA's, IT Directors & Industry Association as appropriate



PLM Portal Forum

- News
- Release notes
- Down-time communications

Check regularly

We are exploring other means to share information with a community of interest.



Public System Demo (March 2023 – date to be announced soon)

Next webinars for S, O, R (April 2023)



Closing

Thank you for your contribution.

Isabel Chicharo, *SPOR Co-Chair & PMS Epic Owner, EMA*

Veronica Lipucci Di Paola, *Product Co-Owner for PMS, EMA*

Marcos Fernandez Gomez, *Product Co-Owner for PMS, EMA*



The SPOR Taskforce has made important **contributions in data standardisation around ISO IDMP** in the EU



All current **SPOR governance will retire and transition to Agile** by Jan 2023 where appropriate



SPOR Taskforce and focus groups members can **stay connected and work with SPOR** through a variety of means – SMEs will be key!