



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Agile transformation update

---

**Industry Standing Group (ISG) meeting, 21 March 2023**





- ❖ As of 16 January 2023, **Zaide Frias**, Head of Digital Business Transformation Task Force (TDT Task Force), **is the new Chair of the Portfolio Board.**
- ❖ The Portfolio Management Office and the new Lean-Agile Centre of Excellence responsible for the **Agile transformation** report to Zaide Frias.
- ❖ Zaide Frias will now also be the co-chair for Agile Ceremonies (Quarterly Portfolio Sync and Strategic Portfolio Review) with Karl Broich, HMA NPAG representative.
- ❖ Tony Humphreys, Head of Regulatory Science and Innovation Task Force, will continue as vice-Chair
- ❖ Hilmar Hamann continues to support 'Agile way of working' for I-Div.

EMA's portfolio has been organised into five different Value Streams that have been endorsed by EXB on 1<sup>st</sup> of December  
Value Stream Leadership – VSOwners/VSMangers - has been appointed by the Executive Director in January 2022

## **Managing the Agency**

*Capabilities to manage the Agency and coordinate and support the network*

Owner: Mireia Castillon  
Manager: Rob Hopping

## **Research and Development**

*Capabilities to support the development of new medicines and generation of scientific evidence*

Owner: Steven Le Meur  
Manager: Nektaria Varela

## **Product Lifecycle Management**

*Capabilities to manage the authorisation and lifecycle of medicinal products and certain medical devices*

Owner: Karl Hamilton  
Manager: Melanie Loveday/Hannes Kulovits

## **Monitoring**

*Capabilities to monitor availability and safety of products*

Owner: Pedro Pina Ferreira  
Manager: Pedro Oliveira

## **Technology Lifecycle Management and Information Security**

*Capabilities to manage information technology and security*

Owner: Leonidas Tertipis  
Manager: Pedro Rodriguez

- Network Portfolio delivery transition completed, governance transformation ongoing
  - From 2 product teams in Dec 2021 to ~25 product teams now
  - Started building a longer term view of the portfolio
- Guidance on interpretation of Confidentiality Undertaking issued
  - SME nomination and evaluation process under review
  - Additional guidance on selection process to be developed
- Many nominations received for Subject Matter Experts (SMEs)
  - In total now 21 Industry SMEs in 6 product teams
  - Plans to publish SME names on EMA website
- High level of interest in December System Demo
  - Recording and Q&A document available on event page
  - Q1 2023 SD tomorrow (22 March), Q2 2023 SD on 22 June

19 December 2022  
EMA/28183/2023

Guidance on the interpretation of document:  
Confidentiality Undertaking for network Product Owner  
and Subject Matter Experts (SMEs) in European Medicines  
Agency's agile way-of-working (EMA/250671/2022)

## Quarterly system demo - Q1 2023 [Share](#)

### Table of contents

- Event summary
- Documents
- Video recording - 09:00 - 13:00 Amsterdam time (CET)

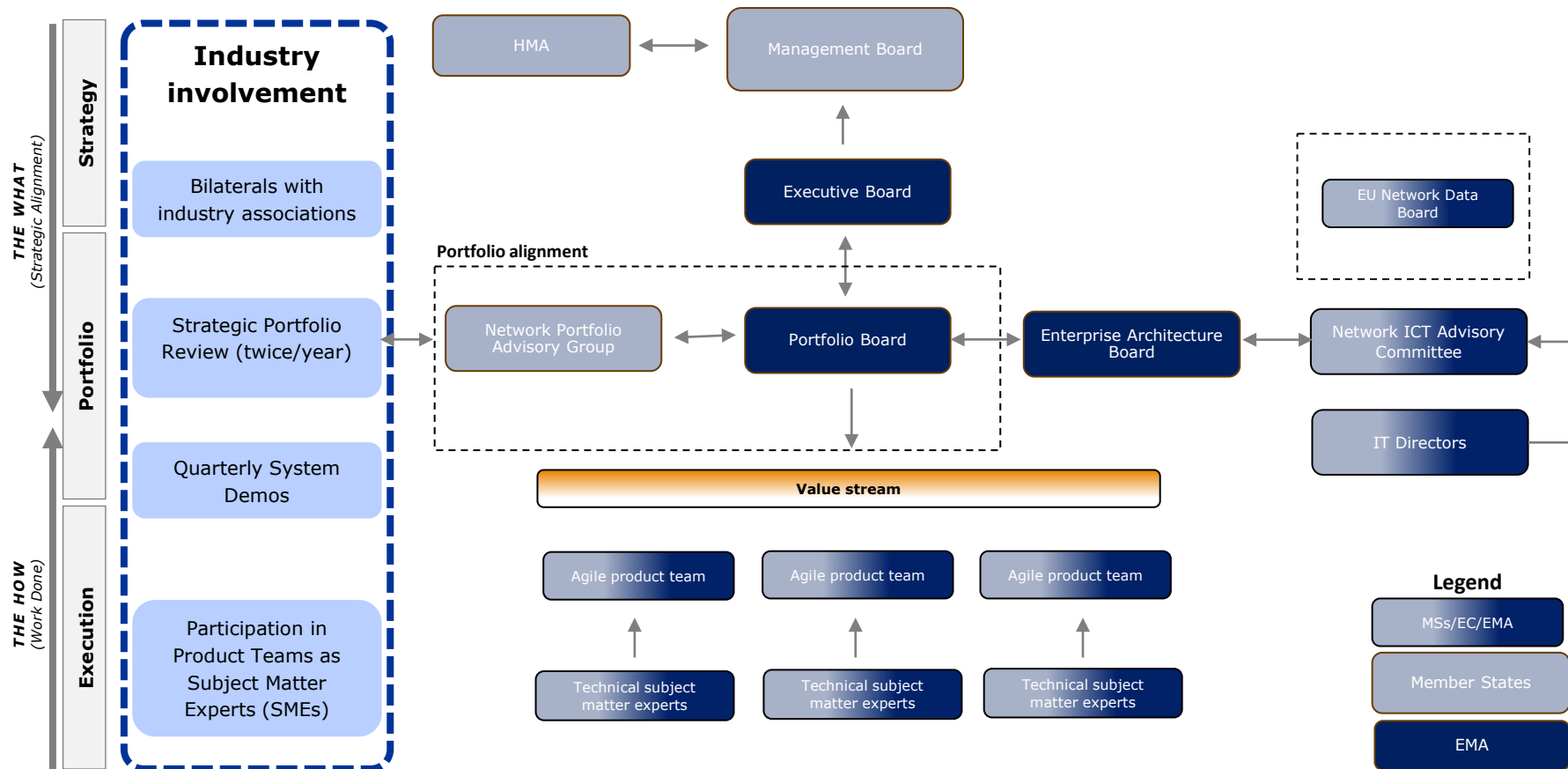
📅 **Date:** 22/03/2023

📍 **Location:** Online, 09:00 - 13:00 Amsterdam time (CET)

### Event summary

This is the first system demo of 2023, the sixth ever held by EMA as part of its [Agile transformation](#).  
A system demo is a ceremony held at the end of a programme increment (a three-month period of work) to demonstrate the developments achieved in that period and collect stakeholder feedback.  
Participants have the opportunity to review what has been delivered, comment and ask questions on future product increments (planned chunks of work on the final system).

# Industry engagement in Agile governance



Strategic  
feedback

- **Strategic Portfolio Review** with industry
  - Input on high-level plans for the coming 2 to 5 years
  - Dedicated portfolio review with industry planned for end of April (date tbc)

Tactical  
feedback

- **Quarterly System Demos**
  - Event page on EMA corporate website, livestream via YouTube
  - Feedback via Slido.com on demo'ed or new functionalities and features

Operational  
input

- Industry **Subject Matter Experts** (SMEs)
  - Participation in product teams, reviewing and giving detailed input on the epics they are involved in
  - SMEs represent their wider industry community, not just their company and/or the trade association that nominated them
  - SME participation mostly via virtual meetings and written input (rarely F2F meetings)

Operational  
feedback

- Value Stream & Product Team level **change management** as appropriate
  - Change management resources increased at value stream level



Value Stream	Product	Industry Association
Product Lifecycle Management	ePI	Medicines for Europe
		EUCOPE
	Product Management Service (PMS)	EUCOPE
		EFPIA
		Vaccines Europe
		Medicines for Europe
		AESGP
	Regulatory Procedure Management (RPM) for PLM	Europa Bio
		Medicines for Europe
		Medicines for Europe
		AnimalhealthEurope
		AnimalhealthEurope
		AnimalhealthEurope
	Union Product Database (UPD)	AnimalhealthEurope
AnimalhealthEurope		
Monitoring	European Shortages Monitoring Platform (ESMP)	Medicines for Europe
		EFPIA
		Vaccines Europe
	Union Pharmacovigilance Database (UPhV)	AnimalhealthEurope
		AnimalhealthEurope
		Access Vetmed

## Ongoing calls for industry SME nominations

Value Stream	Product	Role	Closing date
Product Lifecycle Management	eCTD v4.0	SMEs - Industry	3 Feb 2023 Assessment ongoing

## Upcoming calls for industry SME nominations

Value Stream	Product	Role	Expected date
Product Lifecycle Management	PLM Portal: Electronic Application Forms (eAF)	SMEs - Industry	Q2 2023
Monitoring	Signal and Safety Analytics (SSA)	SMEs - Industry	Q4 2023