



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Agile transformation update

Industry Standing Group (ISG) meeting, 22 November 2022

Presented by Hilmar Hamann, Head of IM Division, EMA

An agency of the European Union



EMA is continuing its Agile transformation journey, moving from a traditional Waterfall IT Governance Framework towards a SAFe / Agile approach:

Replacing numerous boards and project level governance bodies

Shift from a focus on output and delivery via contract negotiation

Move from milestone plans and big bang releases

Moving from following a long-term plan of locked down requirements

Replacing the repetitive effort of project-based funding and control

Shift from little transparency of choices by overlapping Boards

with ceremonies and Agile portfolio management

to a focus on outcomes via customer collaboration

to having continuous planning and incremental delivery

to responding to change by working in small increments

with fixed budgets to focus on continuous delivery

towards open ceremonies and transparent decision making

EMA Agile transformation aims at obtain the following benefits:



Higher levels of **transparency** on how decisions are made and the outcomes



Clear **ownership** of decision-making



Improved business and IT **alignment**



Highly focused **portfolio-management** practices



Better communications within the Network and Industry

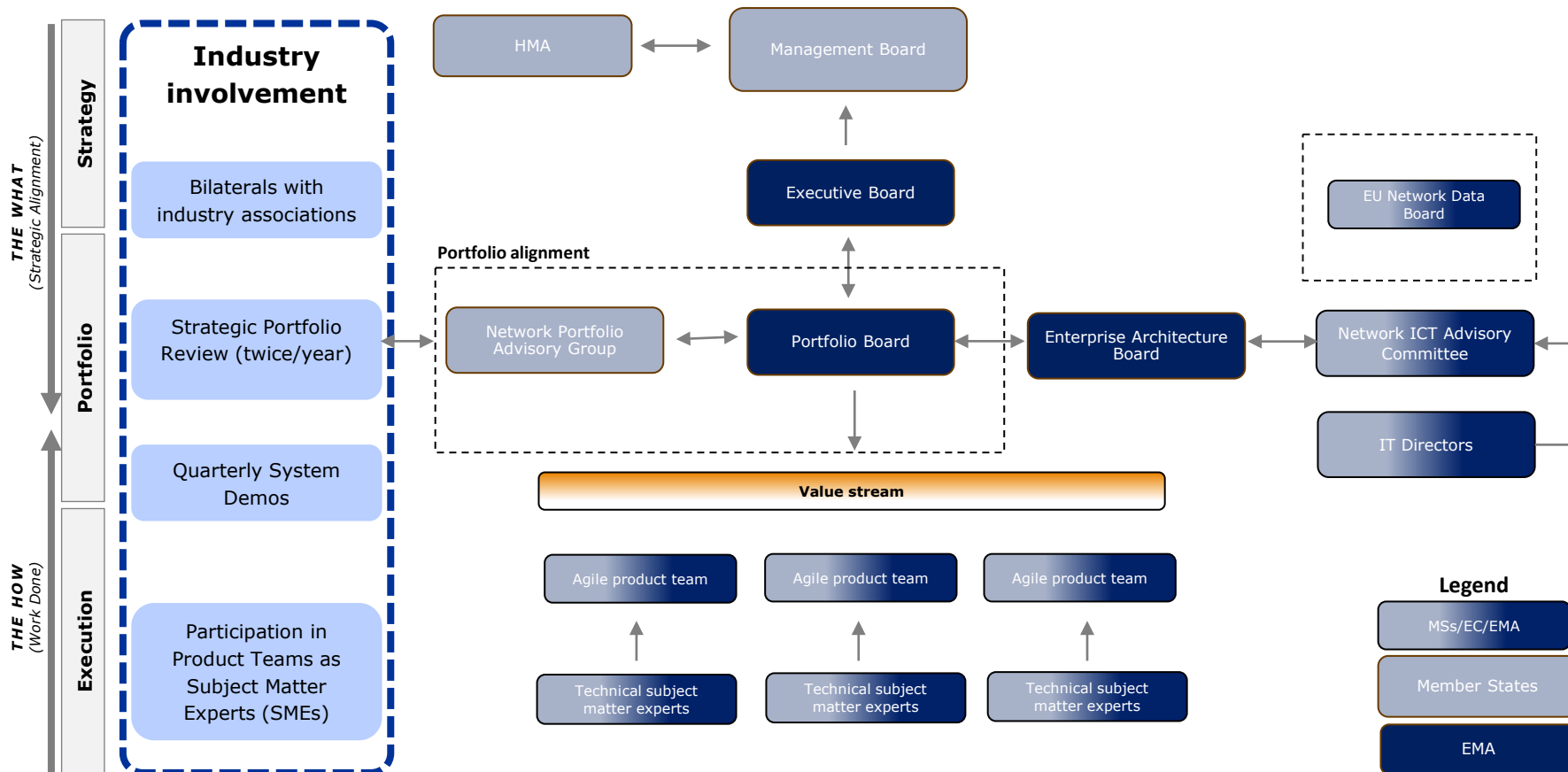


Greater focus on value

Industry engagement in Agile governance



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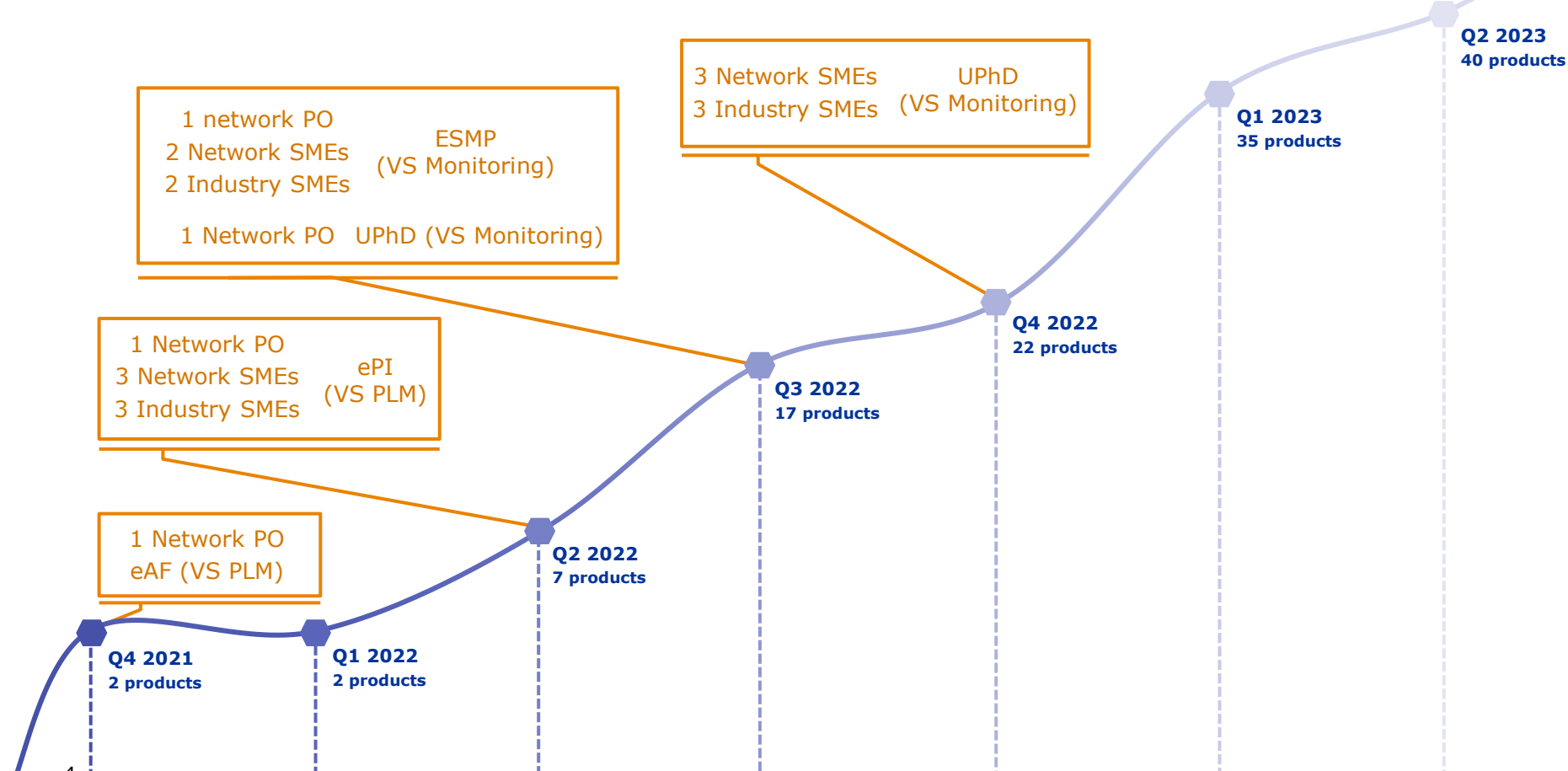




Active external Product Owners and SMEs



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Ongoing/upcoming calls for nominations from Industry

Value Stream	Product	Role	Expected date
PLM	PMS – Product Management Services	SMEs (2)	Q4 2022
PLM	RPM – Regulatory Procedure Management (aka IRIS)	SMEs (4)	Q4 2022
PLM	UPD	SMEs (3)	Q4 2022
PLM	eCTD	SMEs (TBC)	Q1 2023
Monitoring	Signal and Safety Analytics	SMEs (TBC)	Q4 2023 (TBC)

- Twice annual participation at **Strategic Portfolio Review** with industry
 - June and November 2022
 - March and September 2023
- Attendance at **System Demos** of Industry (quarterly)
- Participation in Product Teams as **Subject Matter Experts (SMEs)**
 - Coaching; Agile events; participation in PI Plannings as appropriate
- Product Team level **change management** as appropriate
- **EMA corporate website**, including summaries of ceremonies
- **Industry stakeholder liaison**
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