5. Agile Transformation Update

21st September 2023

6th Industry Standing Group (ISG) meeting

EUROPEAN MEDICINES AGENCY

- **Agile transformation roadmap**

- **Retrospective workshops with (industry) SMEs**

- **Update on Subject Matter Experts calls**

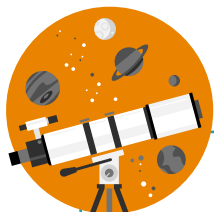EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The LACE (Lean Agile Centre of Excellence)

Marcella Castagna– Head of LACE and Value Stream Owner

ISG meeting 21 September 2023

An agency of the European Union

EUROPEAN MEDICINES AGENCY

VISION

To implement the Lean-Agile (SAFe) way of working in the Network Portfolio across its Value Streams within 3 years and explore it across EMA's operations within 5 years.

AGILE EMA

MISSION

To enable EMA to become a Lean-Agile organisation that adapts to and thrives in a constantly changing environment by:
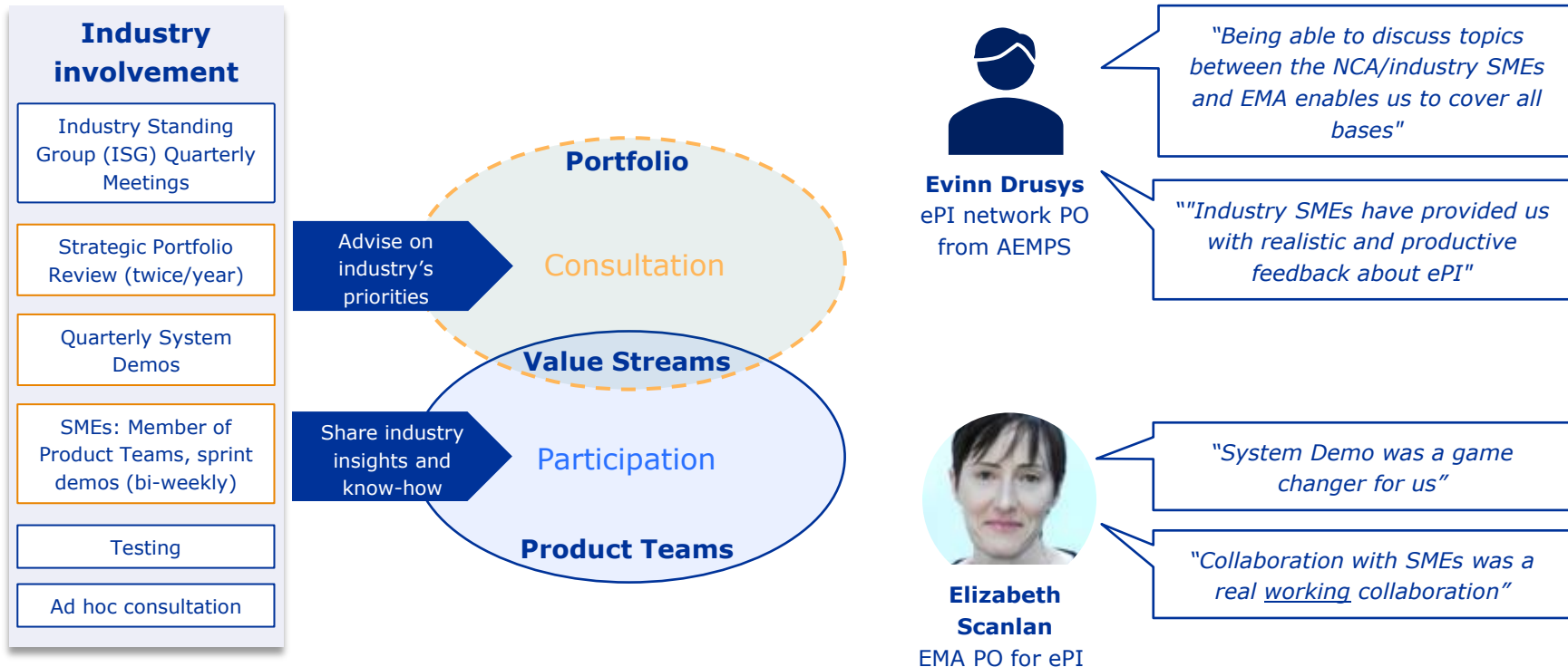
➢ Leading the Agile Transformation
➢ Designing, building & optimising the Network portfolio management practices
➢ Applying the SAFe methodology

Agile Coaches / SAFe Practice Consultant (SPC) / Change Managers*

How do we work together with you?

What people say about collaboration with Industry:

Industry involvement

- Industry Standing Group (ISG) Quarterly Meetings
- Strategic Portfolio Review (twice/year)
- Quarterly System Demos
- SMEs: Member of Product Teams, sprint demos (bi-weekly)
- Testing
- Ad hoc consultation

Portfolio

Advise on industry's priorities → Consultation

Value Streams

Share industry insights and know-how → Participation

Product Teams

Evinn Drusys
ePI network PO from AEMPS

"Being able to discuss topics between the NCA/industry SMEs and EMA enables us to cover all bases"

""Industry SMEs have provided us with realistic and productive feedback about ePI"

Elizabeth Scanlan
EMA PO for ePI

"System Demo was a game changer for us"

"Collaboration with SMEs was a real working collaboration"

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Maturing SAFe expertise

- Role Based Training:
  - 2022: 128 staff members, SAFe at EMA available also for SMEs (e-learning)
  - 2023: 88 staff member, leadership training

Maturing Lean Portfolio Management

- 9th Program Interval (PI) event this month
- New: Participatory Budgeting and Quarterly Budget Review. Prioritisation based on customer values and EMA Objectives

Epic delivered so far in 2022

- Experts Management Tool
- New EMA Intranet
- EXPAMED Expert Management and Collaboration
- ePI authoring
- ePI Publishing & Consuming

Futurespective with Industry and Network SMEs and POs

- How can we deliver more value to our partner and stakeholders with customer-centric solutions? (Define future desired state)
- 34 Industry SMEs involved in the Agile teams
- New calls for SMEs in the pipeline

Roadmap to SAFe @ EMA

European Medicines Agency

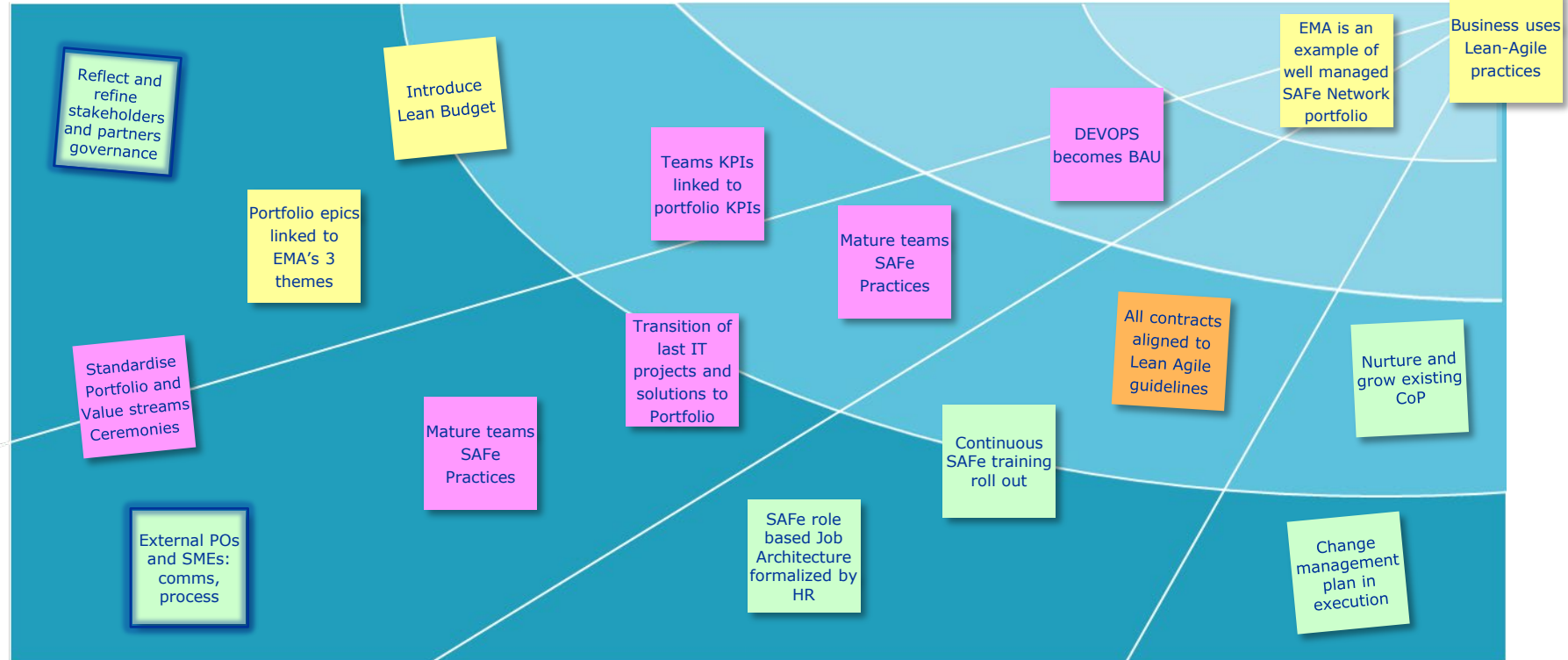**2023- walk** | Measure & Grow | **2024- run** | Measure & Grow | **2025- master** | Measure & Grow | **2026 and beyond**

Portfolio Management

- Reflect and refine stakeholders and partners governance
- Introduce Lean Budget
- Portfolio epics linked to EMA's 3 themes
- Standardise Portfolio and Value streams Ceremonies
- Mature teams SAFe Practices
- Teams KPIs linked to portfolio KPIs
- Transition of last IT projects and solutions to Portfolio
- Mature teams SAFe Practices
- DEVOPS becomes BAU
- EMA is an example of well managed SAFe Network portfolio
- Business uses Lean-Agile practices
- All contracts aligned to Lean Agile guidelines
- Nurture and grow existing CoP
- Continuous SAFe training roll out
- External POs and SMEs: comms, process
- SAFe role based Job Architecture formalized by HR
- Change management plan in execution

Teams' and tech. agility   **Organisational Agility**   **Mindset & training**

Retrospective workshops with SMEs: What's next

Joris Wiemer – Digital Transformation Workforce - Change Manager

6th Industry Standing Group (ISG) meeting

Retrospective Workshops with POs and SMEs

Goal:

Conduct a retrospective on the PO, NPO and SME interactions with each other and the Network and Industry communities as this is a core part of EMA's agile governance model.

POs, NPOs and SMEs were invited to provide feedback in a "futurespective" – reasoning from a desired future state back towards what is needed to get there.

Steps in the retrospective:

1. Collect feedback, identify best practices and challenges

2. Analyse & refine   **Current step**   Initial focus is on operational and tactical improvements.

3. Agree actions and implement

Feedback gathered from:
- Ceremonies
- Daily interactions
- 3 workshops
  - POs & NPOs (9/6)
  - Network SMEs (13/7)
  - Industry SMEs (20/7)

Summary of PO, NPO & SME feedback

What's working well

For **industry SMEs & their community**

- Regular meetings & email exchange with Trade Associations representatives

- Some products' SMEs set up industry support teams of non-SME peers

- At least one product's SMEs have created a charter to establish roles & responsibilities

- Actively working on reviewing and comparing all guidance documents, surveys, KPIs and documents

For **NCAs POs + SMEs & their community**

- Are able to structurally join meetings and contribute

- Are in the process of building networks inside their NCA and with peers

- Share experiences from national systems they are aware of

- Feel they are able to reflect network impacts they are aware of

In the **Product teams collaboration** (including SMEs)

- Onboarded their SMEs

- Weekly touch points with follow-up and outcomes shared by email

- SMEs for several products enabled to contribute to testing and piloting of products

Topics raised for improvement

- **Access to system and tools** to allow close collaboration on design and testing

- **Community connections** still developing for some products and lack a forum

- **Decision legitimacy** concerns regarding ability of SMEs to deliver consensus

- **Cross-product visibility** & strategic influence for industry

- **Time allocation** challenging for some SMEs or due to over asking by product team

- **Transparency on system issues** is a barrier to understanding the system and explaining t to peers

- **Selection and onboarding** is challenging and not standardised

- **Member state initiatives and legal** requirements challenging to consider in EMA system development

- **Timelines** are unclear which results in NCA and Industry's inability to plan and contribute

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Update on Subject Matter Experts calls

Tanja Äijö – Portfolio Management Office – Portfolio Stakeholder Engagement Officer

6th Industry Standing Group (ISG) meeting

Improvements to EMA corporate website

Update to Network Portfolio page

https://www.ema.europa.eu/en/about-us/how-we-work/information-management/network-portfolio

- Network Portfolio Roadmap

New page on Stakeholder Participation

https://www.ema.europa.eu/en/about-us/how-we-work/information-management/stakeholder-participation-information-management

- List of active industry SMEs
- List of planned calls for industry SMEs

6 Network Product Owners

- eAF, ePI, ESMP, UPhV, ASU, PMS

26 Network Subject Matter Experts

- ePI, ESMP, UPhV, PMS, ASU, RPM for PLM, UPD, eCTD v4

34 Industry Subject Matter Experts

- New SME calls expected to be launched in Q4/2023 or Q1/2024

Most mandate durations expected to be extended beyond current end date

Upcoming calls for external PO/SME nominations

Value Stream	Product	Role	Expected date
Monitoring	Signal and Safety Analytics (SSA)	Network PO SMEs – Network **SMEs - Industry**	Q4/2023 Q4/2023 Q1/2025
Product Lifecycle Management	European Medicines Web Portal	Network PO SMEs – Network **SMEs - Industry**	Q3 or Q4/2024 Q1/2024 Q1/2024
Research & Development	Clinical Trials Information System (CTIS)	**SMEs - Industry**	Q4/2023 or Q1/2024

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