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SCIENCE MEDICINES HEALTH

Update on Network Portfolio activities

Industry Standing Group (ISG) meeting, 28 June 2024

Presented by Zaide Frias, Head of Digital Business Transformation Task Force

An agency of the European Union

Topics covered

- **Network Portfolio update**
- **Industry Participation in Regulatory Optimisation Group (ROG)**
- **Industry Subject Matter Experts**

Network Portfolio update

2024 and beyond: Network Portfolio roadmap

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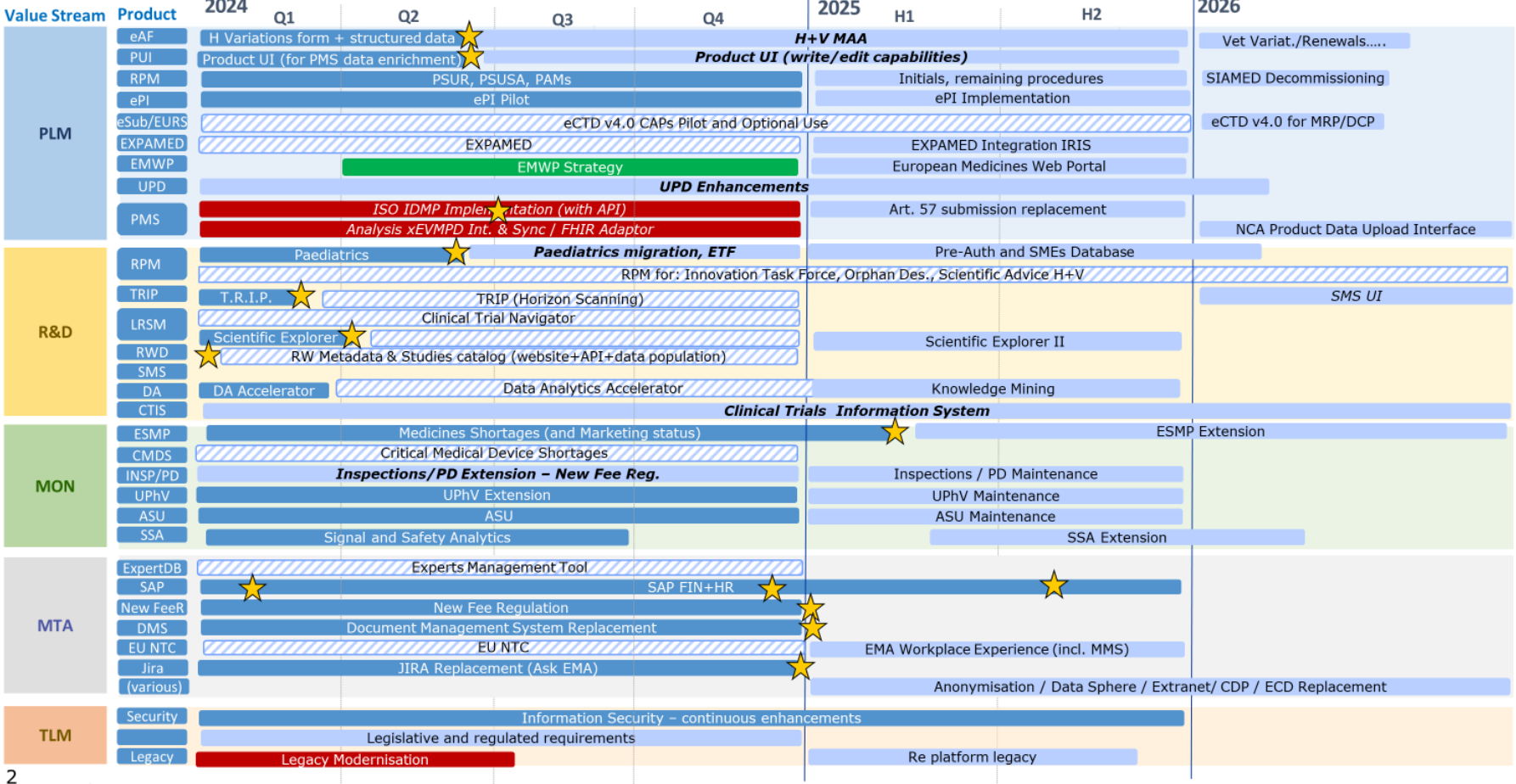

Ceremonies/updates since ISG in September 2023

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- Quarterly **System Demo Q1/2024** on 26 March (link to event page)
- Updated **Network Portfolio Roadmap 2024-2026** published (link to pdf document & link to Network Portfolio page)
- **Clinical Trials Information System** onboarded to agile way of working, incl. 6 industry Subject Matter Experts (link to current list of industry SMEs)
- **Product Lifecycle Management** value stream deep-dive webinar 30 Nov 2023 (link to event page)
- **Antimicrobial Sales and Use (ASU) Platform** launch in Jan 2024 (link to news item)
- **European Shortages Monitoring Platform (ESMP) webpage** went live in April (link to news item)
- Quarterly **PLM Insights newsletter** – first issue in April 2024. Subscribe at European Commission Newsroom
- **Product Management Service (PMS)** info day on 16 April (link to event page)
- **PMS Product User Interface** went live on 31 May in read-only mode (link to PLM Portal news item)
- Industry update webinar on **Regulatory Procedure Management** on 13 June (link to event page)
- Webinar on **New Fee Regulation** for veterinary MAHs on 20 June (link to event page)
- **ESMP** Essentials and Industry Reporting Requirements webinar on 24 June (link to event page)
- Quarterly **System Demo Q2/2024** on 26 June (link to event page)

Upcoming webinars/events/ceremonies

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- Quarterly **System Demos** on 18 September and 12 December
- **Public webinar on Substance, Product, Organisation, Referentials (SPOR)** Regulatory Data Management (RDM) services status update on 10 July (link to event page)
- **Clinical Trials Information System (CTIS) walk-in clinics** (links to 10 July and 19 Sept live broadcasts)
- **CTIS sponsor and end user training** programme 23-26 September (link to event page)
- **Regulatory Optimisation Group (ROG) virtual workshop with industry** representatives on 10 October
- **Strategic Portfolio Review on 19 November with industry** participation

- New Value Stream/Product specific events added to EMA corporate website regularly (Upcoming events page)

Regulatory Optimisation Group (ROG)

Co-Chairs: Zaide Frias (EMA) & Rúna Hauksdóttir Hvannberg (ICMA, Iceland)

Strategic advisor: Aimad Torqui (MEB, The Netherlands)

Regulatory Optimisation Group (ROG)

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HMA
Heads of Medicines Agencies

Network Strategy

Initial mandate: The Heads of Medicines Agencies (HMA)/ EMA Regulatory Optimisation Group is the primary platform to develop Network thinking on reduction of regulatory burden

ROG re-activation and revamped mandate endorsed at the HMA meeting under the Swedish Presidency in 2023 Uppsala

New mandate

Leverage digitalisation, experimentation and innovation as an opportunity to deliver optimised regulatory processes, data-driven ways of working and a connected user-journey for EMRN and its wider stakeholders'

Agile Governance bodies

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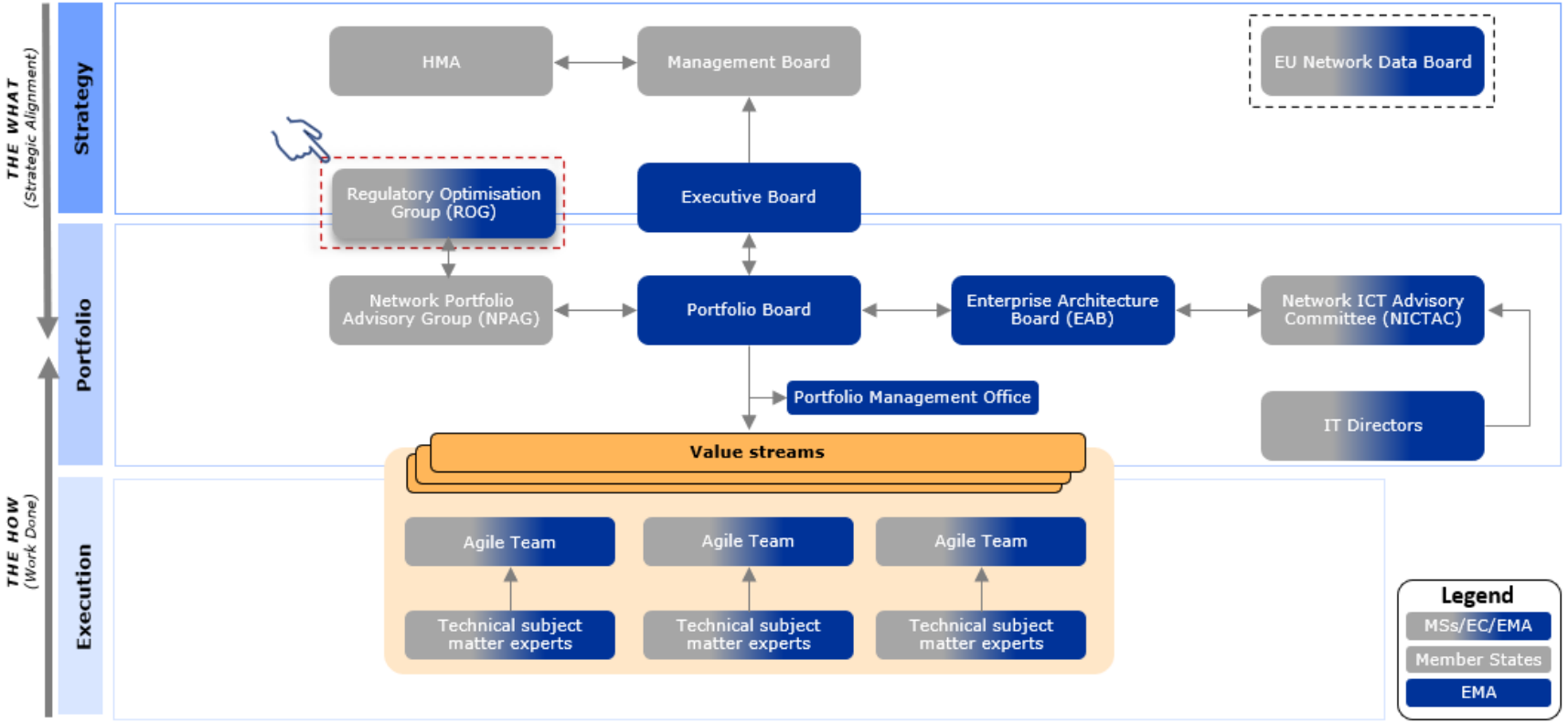

ROG new mandate and focus areas

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Guiding principles

To provide input on relevant topics and serve as a think tank for other groups

- to the **Network Portfolio Advisory Group (NPAG),** which in turn provides recommendations to the EMA Portfolio Board and Agile Value Streams
- to the **Veterinary Strategy Focus Group**

1. **Legislative**
   Contribute to revision and implementation
2. **Digital**
   Network data transformation / interoperability
3. **Human**
   Admin burden: to support Network operations
4. **Veterinary**
   Admin burden: to support Network IT and operations

Key challenges and focus on:

- **Complex and changing regulations and subsequent implementation (humans and veterinary)**
- **Data quality and integrity: The accuracy, completeness, and integrity of data are critical to fulfill regulatory responsibilities**
- **Legacy systems: Many national medicines agencies and EMA have legacy IT systems that are difficult to integrate with new systems**
- **Complexity of data models across systems. IT systems must be able provide accurate and timely data to support regulatory decision-making (adverse event reporting, clinical trial data, and manufacturing data)**

Current focus

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2. Digital
Network data transformation / interoperability

Dependencies / key stakeholders

EMA Scaled Agile Framework and governance model

Strategic guidance from Network Portfolio Advisory Group (NPAG) / IT directors

Problem Statement

Absence of a unified platform for Network POs and SMEs impacts decision legitimacy

Missed opportunities in matching expertise with value streams

Inconsistent understanding of country-specific needs

Alignment between Network Portfolio and NCA Roadmaps

Lack of a harmonised vision for NCAs data transformation in key product portfolios

Objectives

Support the alignment of EMA and NCAs on the strategic and tactical level

Improve the governance model though empowering Network POs/SMEs

Enable Agile delivery within the Network

Actions

‼ **Establish a wider Network business representatives' community** under ROG umbrella

Way forward

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- Operationalise ‘Network Business Representatives Community’
  - **Design collaboration framework**
    - To support NCAs’ operations: sharing of operational business practices and optimisation of processes and procedures
    - To support decision legitimacy: Product Owners (PO) and Subject Matter Experts (SME), country-specific data needs, with the purpose of assigning appropriate experts to their corresponding value streams
  - Strengthen the alignment of NCAs (IT) strategies with the Network Portfolio objectives
  - First pivotal use case is the set-up of **PMS operational group**

ROG & Industry collaboration

The group consists of members within the Network (NCAs, CMDh, CMDv, EMA) and **will meet with Industry representatives** at certain timepoints

Workshop between ROG members & Industry representatives* **10 October 2024**

Set up a collaboration model by designing it based on concrete challenges

*By invitation only. Ensure consistency by aligning the Strategic Portfolio Review and ROG plenary meetings with Industry representatives

External Product Owners and Subject Matter Experts

Current status of external POs and SMEs

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8 Network Product Owners

- ePI, ESMP, UPhV, ASU, PMS, CTIS, SSA, eAF (appointment of new Network PO ongoing)

37 Network Subject Matter Experts in 12 product teams

- ePI, ESMP, UPhV, PMS, ASU, RPM for PLM, UPD, eCTD v4.0, CTIS, CTIS Business Intelligence, Clinical Trials Navigator, SSA

39 Industry Subject Matter Experts in 8 product teams

- ePI, ESMP, UPhV, PMS, RPM for PLM, UPD, eCTD v4.0, CTIS
- SME names and email addresses published at https://www.ema.europa.eu/en/about-us/how-we-work/information-management/stakeholder-participation-information-management
- Mandates ending in 2023 were extended by 12 months
- Call for Signal and Safety Analytics SMEs expected to be launched in Q4/2025
- Calls for additional SMEs could be launched if departing SMEs need to be replaced

Any questions?

Further information

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