



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Portfolio & Technology Meetings

Summary of first experiences & next steps for refinement based on feedback received

Presented by Enrico Tognana on 02 December 2024
Business Analysis & Forecasting
Innovation and Development Accelerator - Regulatory Science and Innovation Task Force

An agency of the European Union





- ❑ First round of PTMs
- ❑ Initial feedback
- ❑ Future calls for expression of interest
- ❑ Take home message



Portfolio and Technology meetings

- ❑ One of the available services from the European Medicines Agency to support innovative medicines and associated technology developments in the European Union
- ❑ Pharmaceutical companies with large medicinal product portfolios can apply to attend these informal meetings
- ❑ Portfolio & Technology Meetings are free-of-charge and held virtually
- ❑ Discussion is focusing on a pipeline of products rather than on single product or technology



First round experience with PTMs

- ❑ Awareness of portfolio and **emerging technologies** for network preparedness
- ❑ **Knowledge sharing** and joint brainstorming on upcoming challenges
- ❑ Helicopter view of **major trends** by therapeutic area to inform resource allocation
- ❑ Insight on **scientific and regulatory hurdles** affecting pipeline development
- ❑ **Public call** for expression of interest
- ❑ **Updated** application **form** to capture innovation and frame discussion points
- ❑ **Briefing document** created *ex novo* to improve preparatory phase
- ❑ **Updated minutes** to capture key discussion points, next steps and follow-ups



Initial feedback

- ❑ Via early engagement meetings fostering innovation survey until end of 2024
 - Industry Stakeholders and EU Network survey on Early engagement meetings fostering innovation*

- ❑ Via Business Analysis & Forecasting at any time
 - businesspipeline@ema.europa.eu

* Presented @ 12th Industry stakeholder platform on research and development support on 4 July 2024

4 Experience with PTMs @ the 13th Industry stakeholder platform on research and development support

Classified as public by the European Medicines Agency



Initial feedback

- General satisfaction with the available published information
- Relevant to the regulatory strategy and submission timelines
- Open feedback appreciated
- Application form not always considered clear and flexible
- Challenging to provide relevant information one year in advance



Future calls for expression of interest 2025 PTMs

Pharmaceutical companies with **large medicinal product portfolios** can apply to attend informal meetings with EMA to:

- identify any issues impacting the progress of product portfolios and assist successful development;
- capture innovative and disruptive technologies;
- anticipate the scientific and regulatory expertise needed to assess future applications.

These meetings are **free-of-charge** and held **virtually**.

APPLICATIONS CLOSED

Applications are open for the meetings to be held in Q1 and Q2 2025.

Apply by 15 November 2024 via the **application form** available below:

[Portfolio and technology meetings application form](#)

EMA will advise applicants on the next steps by the end of December 2024.

EMA will publish a call for Q3 and Q4 2025 meetings in Q1 2025.

Contact:

businesspipeline@ema.europa.eu



Future calls for expression of interest

Lessons learnt – improvements:

- ❑ Split calls in two tranche
- ❑ Link to EMAN strategy
- ❑ Updated application form
 - Clearer instructions
 - To prompt joint brainstorming on upcoming challenges



Take home message

- ❑ PTMs is one of the many possible interactions at EMA
- ❑ Bear in mind the remit of this interaction
 - Knowledge sharing and joint brainstorming on upcoming challenges
 - Disruptive Technology & Innovation
- ❑ Improved knowledge management
- ❑ Open dialogue is key
- ❑ Feedback is paramount to keep the service fit for purpose



Thank you for your attention

Further information

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