EMA
EUROPEAN MEDICINES AGENCY

Instructions on how to apply for a Portfolio & Technology Meeting (PTM)

Businesspipeline@ema.europa.eu

Why and how to apply

Why

- 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.

How

- Applicants can express their interest in a PTM by completing the online application form, which is published twice a year in Q1 and Q4.
- The timelines for the subsequent steps is outlined in the published call for expression of interest.

Pharmaceutical companies with large medicinal product portfolios can apply to attend free-of-charge virtual informal meetings with EMA.

If invited

Brief TC

with the PTM coordinator to discuss the details of the PTM organisation

Provision of briefing document (BD):

- BD includes background information, topics for discussion, including questions.
- Available online
- Expected 4-6 weeks before the PTM

Presentation

Expected 1 week before the PTM

During the PTM

- Applicants take notes to create a draft meeting report outlining the topics discussed during the meeting and the outcome of the discussions.
- The template is available online.

After the PTM

PTM Secretariat

shares the meeting report template with the final list of participants for completion

Applicants send the draft meeting report

to: businesspipeline@ema.europa.eu via EudraLink* within approximatively **10 working days**

Final version of the meeting report reviewed by subject-matter experts

sent to the Applicants via EudraLink within **10 working days** of receipt of the draft version

***** EudraLink is EMA's secure platforms for exchange of confidential information. You need to have an EMA account to request an EudraLink account. For more information about EMA account management and EudraLink account, please click here.

Frequently asked questions

What is a Portfolio and Technology Meeting (PTM)?

What are examples of topics discussed at PTM?

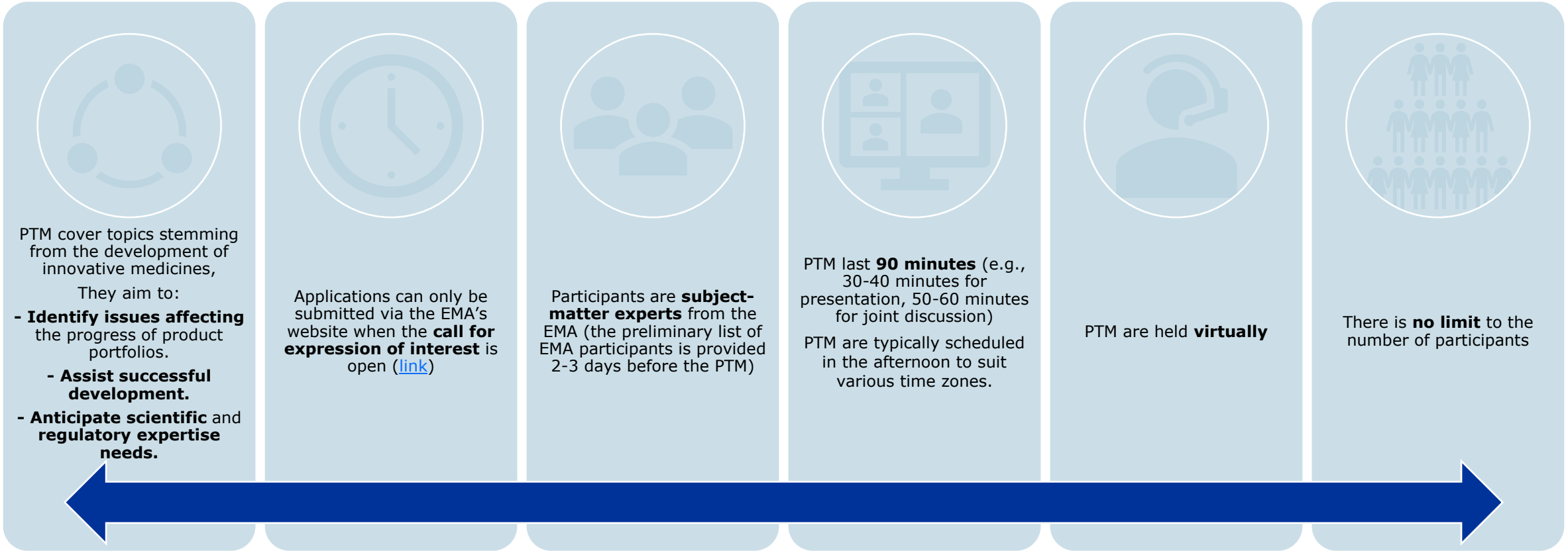
Why should I complete Section 7 of the form - Areas of particular interest to the regulators?

How should we phrase our discussion topics?

How is the meeting captured?

Frequently asked questions

What is a Portfolio and Technology Meeting (PTM)?



Frequently asked questions

What are examples of topics discussed at PTMs?

- Complex clinical trial methodologies
- Digital technologies (including artificial intelligence and machine learning)
- Innovative manufacturing methods
- Nanotechnologies
- Policy-related
- Smart materials and synthetic biology
- New approach methodologies (NAMs)
- Treatments intended to tackle antimicrobial resistance (AMR)
- Innovative methods for medicines in pregnancy & breastfeeding
- Combination products and trials
- Platform technologies for new medicines

Frequently asked questions

Why should I complete Section 7 of the form - Areas of particular interest to the regulators?

In this section of the application form, the EMA would like to gather applicants' perspectives on topics of particular interest to the regulators, regardless the proposed topics for discussion during the PTM.

Information provided will be considered in a holistic manner and used to support horizon scanning, resource planning, and to future-proof the regulatory network.

If, for any reasons, applicants choose not to reply, we kindly ask to provide a brief explanation.

Frequently asked questions

How should we phrase our discussion topics?

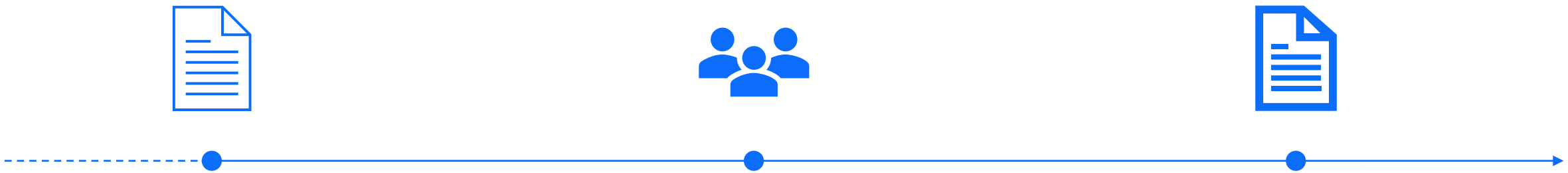
We remind you that the views expressed in PTM are the opinions of the participants and may not reflect the opinion of EMA's scientific committees.

Therefore, the answers provided should not be interpreted as regulatory guidance or review recommendations for an application, but as a preliminary set of scientific and regulatory considerations of the information presented. We advise you to phrase your topics accordingly:

What is the **experts' opinion** on…
Does the participants have **comments / suggestions** with regard to…
We would **like to discuss** suggestions with regard to…
Would the participants have **proposals** with regard to…
Should any other guidelines and/or guidance be **considered?**

Frequently asked questions

How is the meeting captured?



Applicants are provided with a meeting report template including the list of participants

Applicants are requested to draft a meeting report within 10 working days, detailing the topics discussed and the outcome of the discussions

The draft meeting report is circulated for comments to participants, reviewed by the Coordinator and a final version of the meeting report is sent via EudraLink back to applicants within 10 working days

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Thank you

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