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 Q3.
- The timelines for the subsequent steps are 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

Applicants provide *briefing document (BD)*:

- ***BD*** includes: background information, topics for discussion, including questions
- ***BD template*** is available online
- Expected 4-6 weeks before the PTM

Applicants provide *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 *meeting report 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*

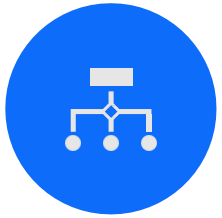
to: businesspipeline@ema.europa.eu via *EudraLink** within approximatively **10 working days**

Final* version of the *meeting report

reviewed by subject-matter experts sent back to the Applicants via *EudraLink* within **10 working days** of receipt of the draft version

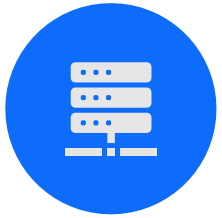
***** EudraLink is EMA's secure platforms for exchange of confidential information. You need to have an EMA account to request an EudraLink account. For more information about EMA account management and EudraLink account, please click here.

Frequently asked questions



What is a Portfolio and Technology Meeting (PTM)?

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



How is the meeting captured?

When and how the topics for discussion are provided?

Can additional topics be added after submitting the online application form for the PTM?

What are examples of topics discussed at PTM?

How should I phrase our discussion topics?

Classified as public by the European Medicines Agency

Frequently asked questions (F&Qs)

What is a Portfolio and Technology Meeting (PTM)?

PTM cover topics stemming from the development of innovative medicines,

They aim to:

- **Identify issues affecting** the progress of product portfolios.
- **Assist successful development.**
- **Anticipate scientific** and **regulatory expertise needs.**

Applications can only be submitted via the EMA's website when the **call for expression of interest** is open (link)

Participants are **subject-matter experts** from the EMA (the preliminary list of EMA participants is provided 2-3 days before the PTM)

PTM last **90 minutes** (e.g., 30-40 minutes for presentation, 50-60 minutes for joint discussion)

PTM are typically scheduled in the afternoon to suit various time zones.

PTM are held **virtually**

There is **no limit** to the number of participants

Frequently asked questions

When and how the topics for discussion are provided?

When the call for expression of interest is open on the EMA website, applicants provide the topics for discussion by completing the *online application form*.

Can additional topics be added after submitting the online application form for the PTM?

In principle no, however applicant can request the modification, and it will be dealt on case-by-case basis.

PTM is granded based on the topics provided in the online application form. The topics are used to select the EMA expert panel and plan the meeting the date. Any modification will have to be assessed individually.

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)
- 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 application 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 I phrase our discussion topics?

Be reminded 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…*
*Do the participants have **comments / suggestions** with regard to…*
*We would **like to discuss** suggestions with regard to…*
*Would the participants have **proposal** with regard to…*
*Should any other guidelines and/or guidance be **considered?***

Frequently asked questions

How is the meeting captured?

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

Applicants are requested to ***draft*** *the* ***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 EMA participants, reviewed by the Coordinator and the ***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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