



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instructions on how to apply for an ITF Briefing Meeting

ITFsecretariat@ema.europa.eu

itfvvet@ema.europa.eu





How to apply?

Request for early interaction on innovative developments Innovation Task Force Briefing Meeting (ITF BM) request form

To apply for an ITF briefing meeting, please complete this form and send it (as a Word document) to the email addresses indicated below.

- ITFsecretariat@ema.europa.eu (human medicines)
- ITFvet@ema.europa.eu (veterinary medicines)

You may use Eudralink to send the form. Eudralink provides an encrypted transmission to protect your confidential information. (First, create an [EMA account \(Self-Register\)](#). Then, request a [Eudralink account](#) via the [EMA ServiceNow](#)).

Please email us if you have further questions.



Applicant sends the ITF briefing meeting request form via [Eudralink*](#) or email to (ITFSecretariat@ema.europa.eu (human) or ITFvet@ema.europa.eu (veterinary))

ITF Briefing Meeting Briefing Document

This briefing document needs to be completed for your:

- Product / Substance (section 1)

AND/OR

- Method / Methodology / Technology (section 2)



EMA may request applicant to complete and send a briefing document (max. 30 pages)



EMA reviews information received within 1-3 weeks and suggests option best suited to applicant's needs (i.e. referral to other procedure(s) or briefing meeting)

*Eudralink is EMA's secure platforms for exchange of confidential information. For more information about EMA account management and Eudralink account, please click [here](#).



If invited to an ITF briefing meeting



Applicant registers in [IRIS](#)*.
To register in IRIS and create a Research Product Identifier (RPI), refer to the [IRIS guide to registration and RPIs](#).
N.B. The Secretariat creates the RPI for multiple products/methodology/technology/method and other topic.

To submit the ITF briefing meeting request and supporting documents in IRIS, refer to the [IRIS guide for applicants](#).



During an ITF briefing meeting



Take notes to create a draft meeting report describing the **topics discussed** at the meeting and the **outcome of the discussion** (a template is provided).



After an ITF briefing meeting



Upload the draft meeting report to IRIS within **10 working days**



A final version of the meeting report, reviewed by the subject-matter experts, will be uploaded to IRIS within **2-4 weeks** of receipt of the draft version



Frequently asked questions

What is an ITF briefing meeting?

How soon after requesting will I know if I am eligible for an ITF briefing meeting?

What are examples of topics discussed at ITF briefing meetings?

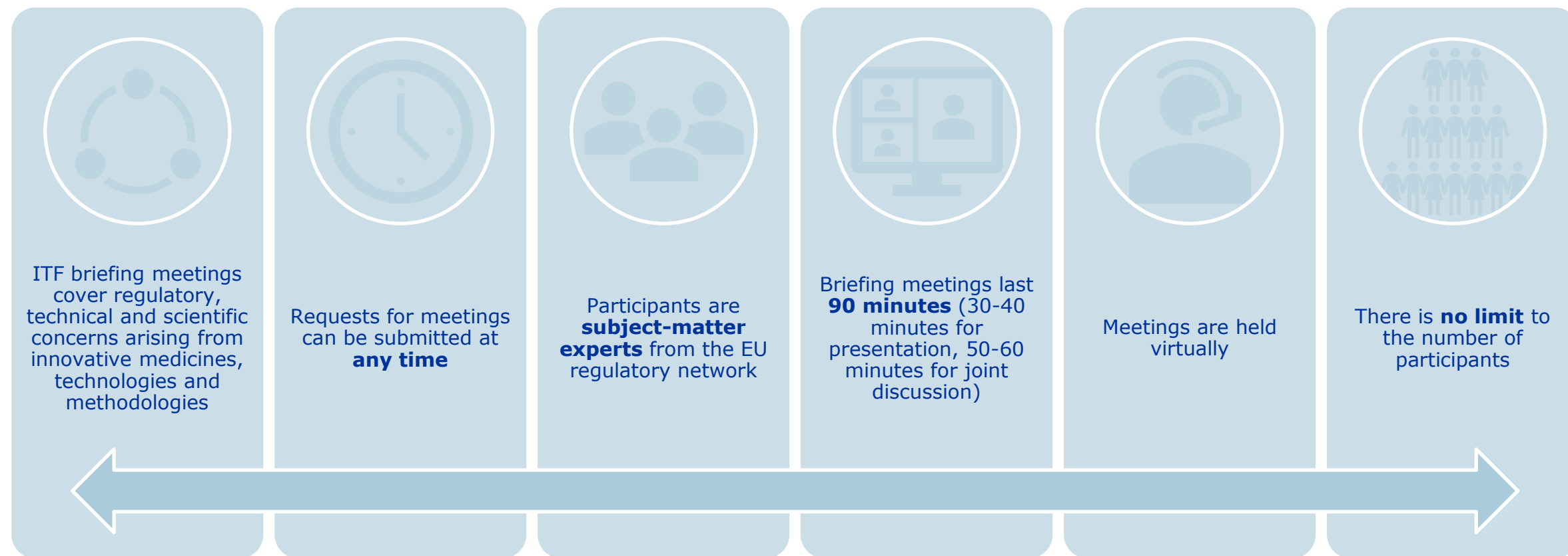
How should we phrase our discussion topics?

How is the meeting captured?



Frequently asked questions

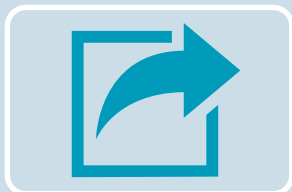
What is an ITF briefing meeting?





Frequently asked questions

How soon after requesting will I know if I am eligible for an ITF briefing meeting?



You can expect feedback within **1-3 weeks after submission** of the request form.

The Secretariat can:

- request additional information via a Briefing Document, or
- refer you to another service more suitable to your needs (EMA, National Competent Authorities or other)



Once an ITF briefing meeting has been granted:

The Secretariat offers available dates for the meeting (**within 4-6 weeks**) along with instructions and timelines for registration and submission of required documents in IRIS.



Frequently asked questions

What are examples of topics discussed at ITF briefing meetings?

Complex clinical trial methodologies

Digital technologies (including artificial intelligence and machine learning)

Innovative manufacturing methods

Nanotechnologies

Pharmacogenomics

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

How should we phrase our discussion topics?

We remind you that the views expressed in ITF Briefing meetings are the opinions of the participants and may not reflect the opinion of the EMA 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 ITF have **comments / suggestions** with regard to...
We would **like to discuss** suggestions with regard to...
Would the ITF have **proposals** with regard to...
Should any other guidelines and/or guidance be **considered?**



Frequently asked questions

How is the meeting captured?



The Applicant is provided with a **meeting report template** including the list of participants



The Applicant is asked to prepare a **draft meeting report** within 10 working days with the **topics discussed** and the **outcome of the discussion**



The draft meeting report is circulated for comments to participants, reviewed by the Coordinator and a **final version** of the meeting report is uploaded to IRIS within 2-4 weeks