



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

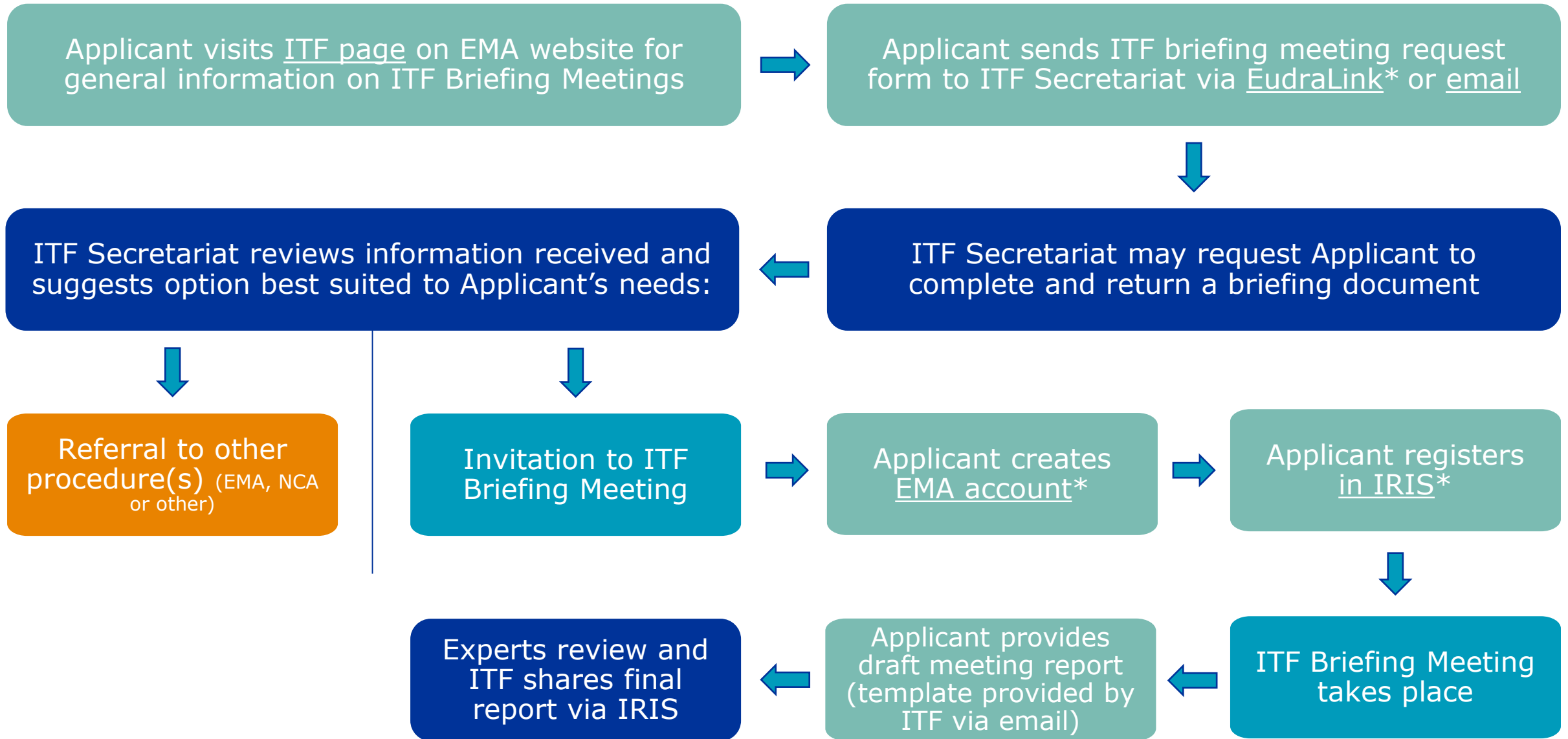
Applying for an Innovation Task Force Briefing Meeting (ITF BM)

Step-by-step guide and frequently asked questions

ITFsecretariat@ema.europa.eu

An agency of the European Union





*See next slide for more information on EMA's secure platforms for exchange of confidential information

To initiate ITF Briefing Meeting:

- Send the ITF Briefing Meeting Request Form via [EudraLink](#) or email to ITF Secretariat ITFSecretariat@ema.europa.eu (human) or ITFvet@ema.europa.eu (vet)
- Upon request from ITF Secretariat, provide the ITF Briefing Document (BD)(max 30 pages)

Once ITF Briefing Meeting is confirmed:

- Register in IRIS
- Submit the following documents via IRIS:
 - Short presentation (3 slides in total) for presentation by the ITF Coordinator to the relevant EMA Scientific Committee, containing:
 - *Description of product (e.g., structure/technology/method);*
 - *Mechanism of action / Use in drug development;*
 - *Key topics for discussion*
 - Full presentation and list of participants (for the ITF BM)

During the meeting:

- Take notes to create a draft meeting report describing the **topics discussed** at the meeting, the **outcome of the discussion** and a **list of participants** (a template will be provided before the meeting)

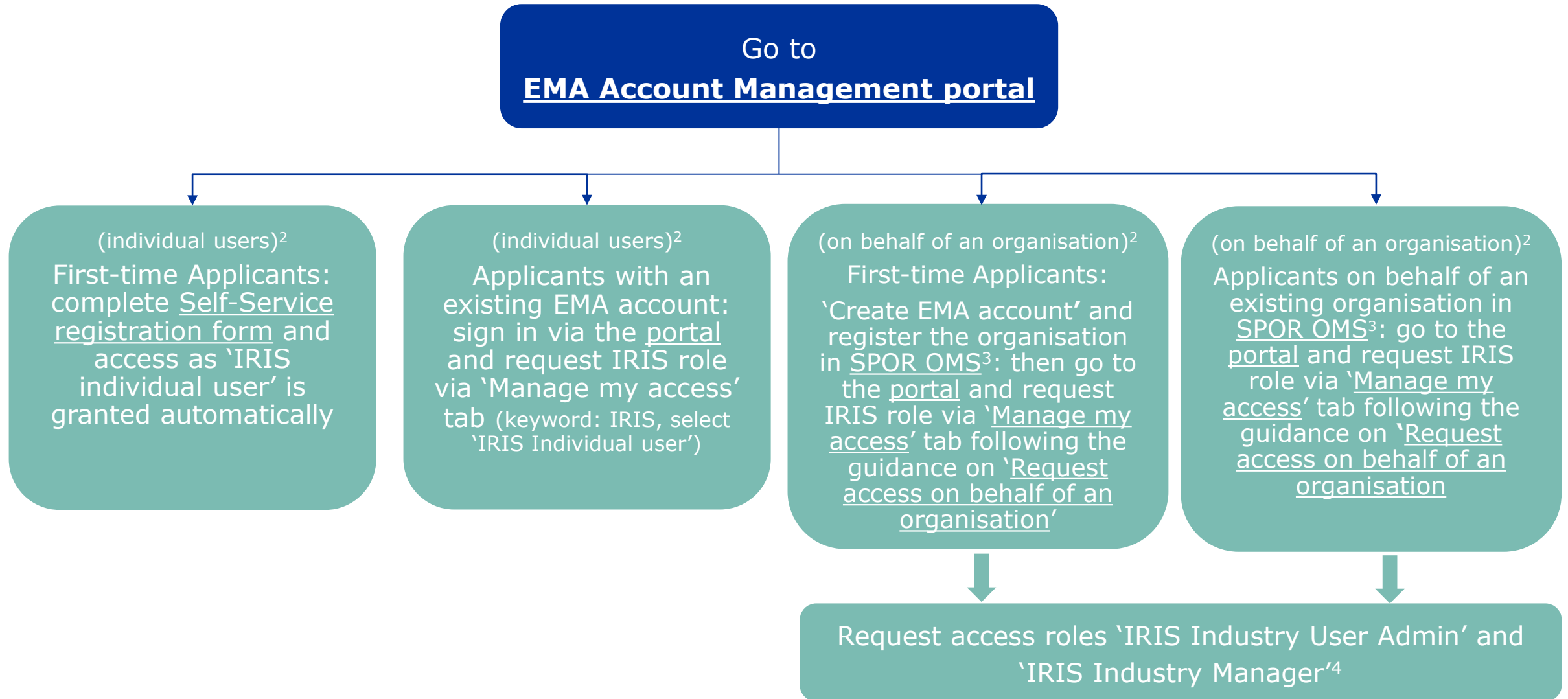
After the meeting:

- Upload the draft meeting report to IRIS within **10 working days** of the meeting
- A final version of the meeting report, reviewed by the subject-matter experts, will be available in IRIS within **2-4 weeks** of receipt of the draft version



- 1) The [EMA Account Management Portal](#) is EMA's secure online platform where you can request and manage access to EMA applications. [Create an EMA account \(Self-Register\)](#).
- 2) [EudraLink](#) is EMA's secure file transfer system, through which you send your confidential documents. You can request a EudraLink account via the [EMA Service Desk](#) after you have created an EMA account.
- 3) [IRIS](#) is the platform for applicants and EMA to communicate, share information and deliver documents concerning *specific procedures*. You should request access to IRIS via the [EMA Account Management Portal](#) only **after** you have been invited to an ITF Briefing Meeting.

Only if invited to an ITF Briefing Meeting: Steps for IRIS access¹

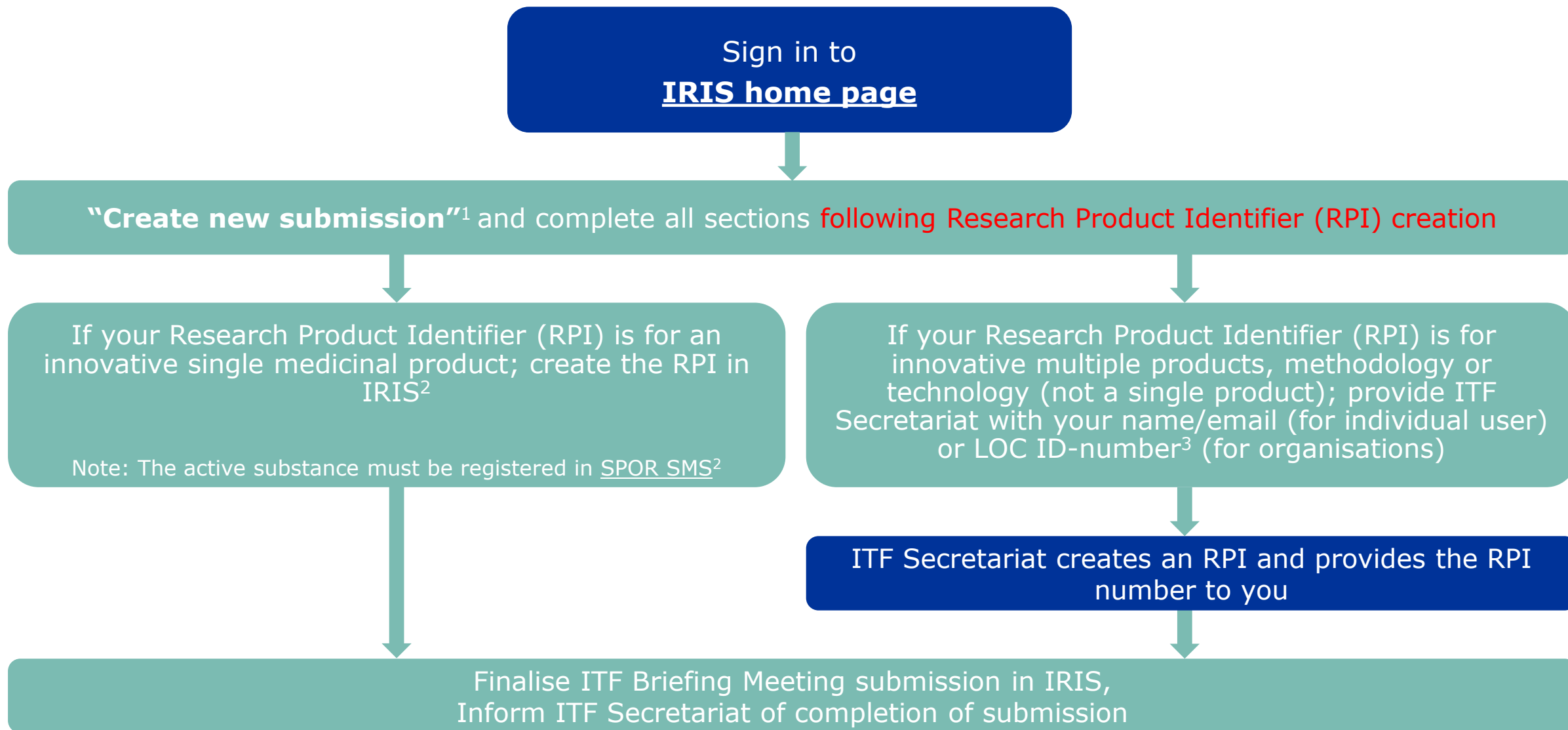


¹ For detailed information on the complete IRIS registration process, refer to the [IRIS guide to registration](#)

² If unsure, refer to the checklist in section 2 of the [IRIS guide to registration](#)

³ For detailed information on organisation registration in SPOR, refer to the [IRIS guide to registration](#), section 4

⁴ For IRIS access roles and permission descriptions, refer to [IRIS guide to registration](#), section 5



¹ For detailed information, refer to section 2.3 in the [IRIS guide for applicants](#)

² Refer to section 7 & 8 of [IRIS guide to registration](#)

³ LOC ID – Location ID linked to the organisation



What is an Innovation Task Force Briefing Meeting (ITF BM)?

- ITF Briefing meetings are **informal** meetings on innovative methods, technologies and substances related to drug development
- Requests for the meetings can be submitted at **any time**
- Participants are **subject-matter experts** from the EU regulatory network
- Briefing meetings typically last **90 minutes** (30-40 minutes presentation by the Applicant, 50-60 minutes joint discussion on the identified topics)
- They are chaired by the ITF Coordinator using **WebEx** and slides are shared and presented by the Applicant
- There is **no limit** to the number of participants (Webex meetings only)



How soon after requesting will I know if I'm eligible for an ITF Briefing Meeting?

- The **innovative aspect** of the product/method/technology and the **type of issues/topics** for discussion listed on the request form are reviewed
- You can expect initial feedback **1-3 weeks after submission** of your request form
- The ITF Secretariat will contact you and either
 - request additional information via a Briefing Document, or
 - refer you to another service more suitable to your needs (EMA, NCA or other)
- Once an ITF Briefing meeting has been granted, the **ITF Secretariat** offers **available dates** for the meeting (usually within 4-6 weeks) along with **instructions and timelines** of required outstanding documents/info for the meeting
- The Innovation Task Force supports innovation during **any stage of development**; however, most meetings are organised during **early stages** (proof of concept)



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 (NAM) to replace the use of animals in the testing of medicines
- Treatments intended to tackle antimicrobial resistance (AMR)
- Innovative methods for medicines in pregnancy & breastfeeding
- Combination products and trials
- Platform technologies for new medicines

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?**



How are the meeting minutes captured?

Pre-meeting the Applicant is provided with a **meeting report template** including the list of EMA participants

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

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