



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Innovation Task Force Services (ITF)

EIC – EMA Info Day: Regulatory support for the development of innovative medicines and technologies



Regulatory Science and Innovation Task Force



Catalysing the integration of science and technology in medicines development



Enabling and leveraging research and innovation in regulatory science



Driving collaborative evidence generation – improving the scientific quality of evaluations



Advancing patient-centred access to medicines in partnership with healthcare systems

Addressing emerging health threats and availability/therapeutic challenges



Multidisciplinary platform
for preparatory dialogue and orientation on
**innovative methods, technologies and
medicines**

Support **innovative** drug development

Early informal dialogue with opinion leaders
(can be requested at any stage of develop.)

1,5-hour discussion – Free of charge

Brainstorming “style” on innovation in areas
without existing guidance

First step to engage is submit completed [3-
page template](#)





What topics can be discussed during ITF meetings?

Scientific topics:

e.g., pre-clinical development, manufacturing, quality aspects...

Regulatory topics:

e.g., "There is no guidance on this type of novel product. How can we proceed?"

Legal topics:

e.g., "Is my product a medicinal product?" → relevance for evidence generation requirements

*We do **not** discuss business models/case, however discussions will facilitate decision making*



Which types of developments are discussed during ITF meetings?

Emerging therapies

- Gene therapies
- Cell therapies
- Targeted therapies
- Engineered tissues
- Nanotechnology used in medicines



Emerging methods

- 3Rs (Replacement, Reduction and Refinement)
- New delivery routes
- New delivery systems

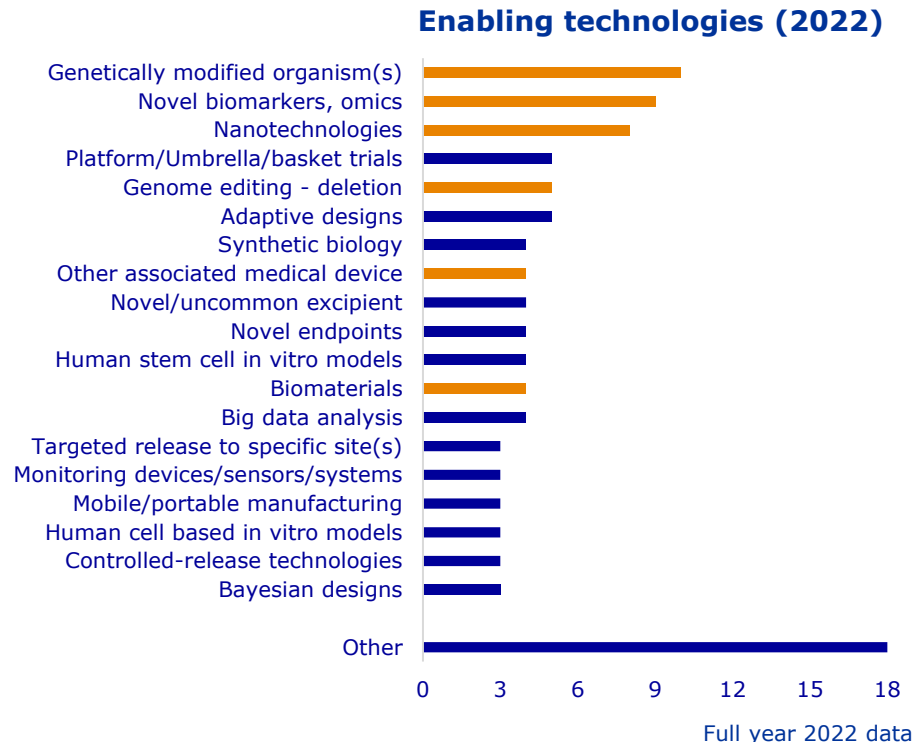
Emerging Technologies

- Digital technologies
- Clinical Trial methodology
- *Omics* data
- Novel manufacturing
- Platform technologies
- Associated medical devices

Novel and promising technologies that have the potential to enable innovation

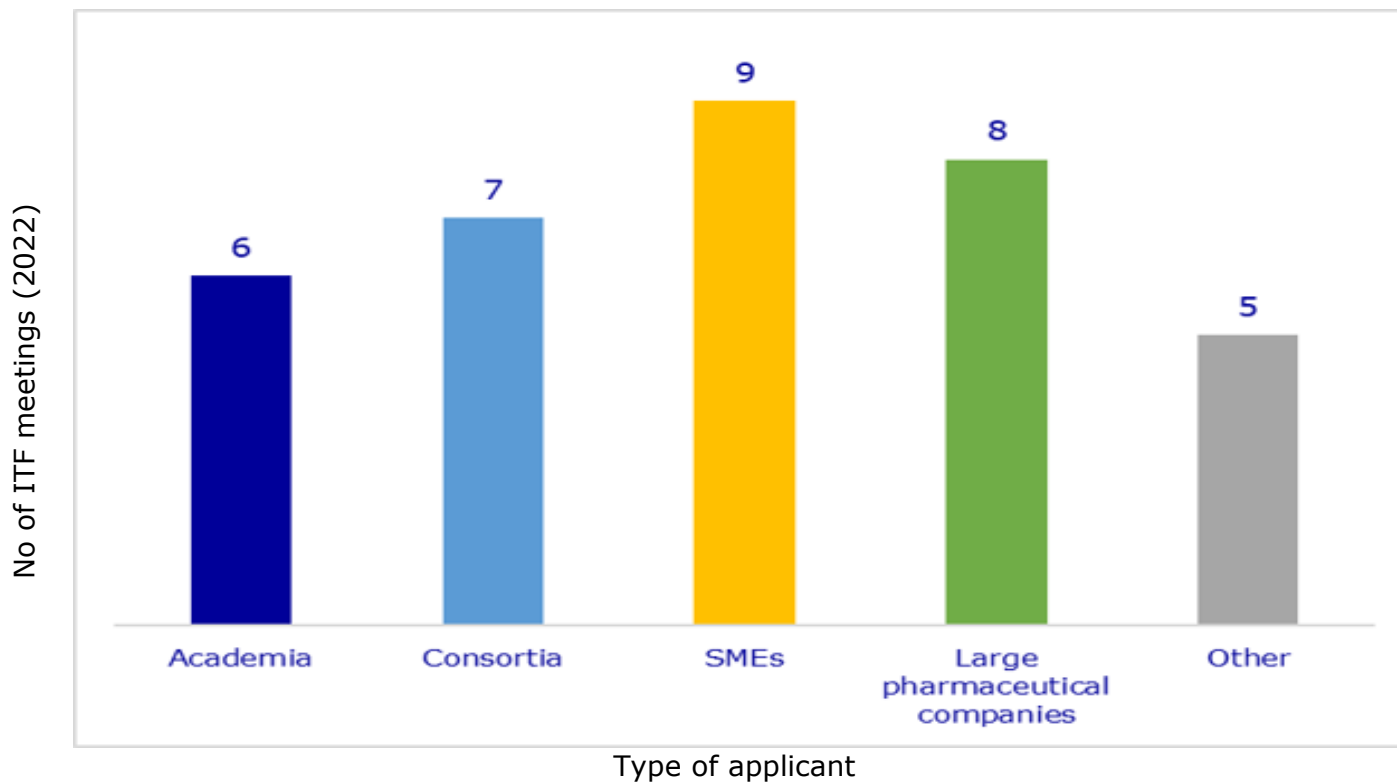
- Highest amount of enabling technologies related to new **genetically modified organisms, novel biomarkers & omics data**, and **nanotechnologies**.
- **Orange**: enabling technologies overlapping with EIC pathfinder Health Legacy – technology focus

→ *identification of trends*

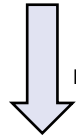




Type of ITF applicants



Applicant sends a [Request Form](#)



ITF / EMA
multidisciplinary team

Evaluation

Applicant ↔ ITF team



Submission of a Briefing Document

- Background on topic/technology
- Rationale for seeking guidance
- Proposed topics for discussion
- Applicant's position on topics

How to contact us:

ITFsecretariat@ema.europa.eu



Not
suitable



Suitable

Applicant ↔ ITF team

Referral (EMA, NCA, other)

Planning of ITF Briefing Meeting

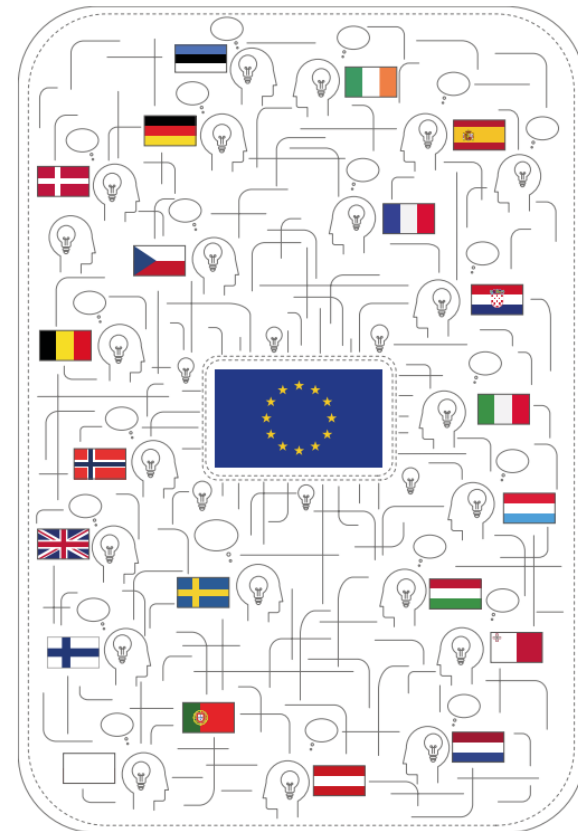


Who are the experts joining the ITF meetings?

EU-Innovation Network:

- ITF team (EMA staff with respective competences/expertise)
- Members of EMA Committees / Working parties
- Experts of National Competent Authorities (50+ CA, 27 member states)
- Any further expertise required to address the topics, CoI permitting, eg device, software (AI), manufacturing Ethic Committees, Inspectors etc
- Other International Regulator as discussed with applicant (FDA, Swissmedic, HAS (Singapore))

[European Experts Database](#)





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Examples of ITF meetings & feedbacks





ITF Meeting - Example 1

Applicant & status of project:

Academia; *proof-of-concept*

Type of development:

Gene therapy for neurological disorder

Link to EIC Pathfinder Health

- Cell & tissue engineering & Reprogramming Tech
- Nanotechnology



Reasons for contacting EMA-ITF:

Next steps bringing the *innovation forward towards patients?*

Evidence requirements for innovative medicinal products.

Topics & Feedbacks:

- What is the most appropriate delivery method? (*adenoviral, extracellular vesicles, liposomes*)
- Pre-clinical strategy:
use of *iPSC* for *proof-of-concept* [*gene downregulation*]; *animal disease models* & toxicology data



ITF Meeting - Example 2

Applicant & status of project:

SME; Pre-clinical

Type of development:

In vivo bioprinting of autologous cells

Link to EIC Pathfinder Health

- Materials for health
- Cell & tissue engineering
- Lab & Organ-on-chip



Reasons for contacting EMA-ITF:

- Product classification
- What are likely evidence requirements for market entry for this technology?

Topics & Feedbacks

- Cells expanded *ex vivo* are an Advanced Therapy Medicinal Product ([ATMPs](#))
- The [bioprinter](#) is an independent delivery device

Next steps:

Medical device experts should be consulted for the certification of the bioprinter



ITF Meeting - Example 3

Applicant & status of project:

Academia, proof-of-concept

Type of development:

- Novel treatment strategies for ocular opacities

Link to EIC Pathfinder Health

- Nanotechnology
- Imaging



Reason for contacting EMA-ITF

- What is the principle Mode of Action?
- What are the evidence requirements for market entry?
- Who shall we contact next / Next steps?

Topics & Feedbacks

- Type of innovative product:
nanoparticles, dyes, encapsulated dyes
- Mode-of-action of the product defines its nature
(*pharmacological vs mechanic*)

Next steps:

Based on the mechanical mode-of-action, the product is a medical device. The applicant shall contact the national competent authority for certification.



Thank you!

Any questions?

Acknowledgements: Valentina Cordo, Constantinos Ziogas, Ralf Herold

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