EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Innovation in Medicines

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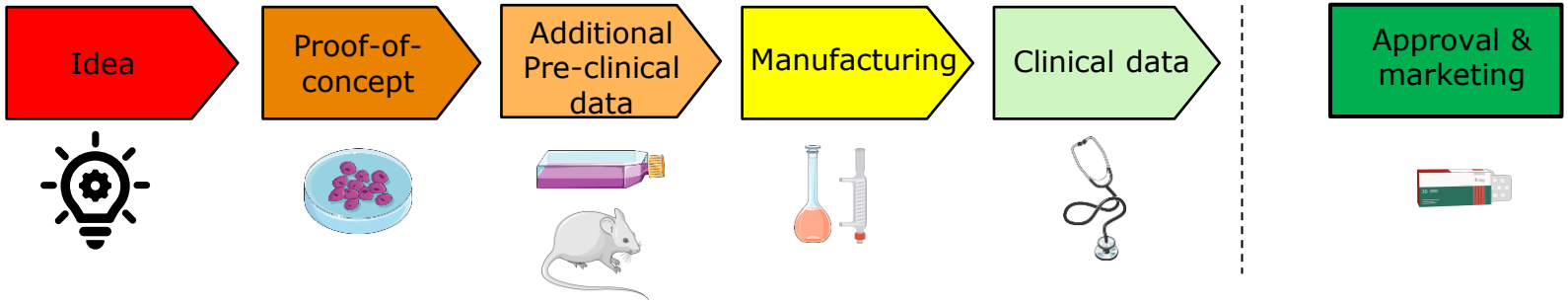
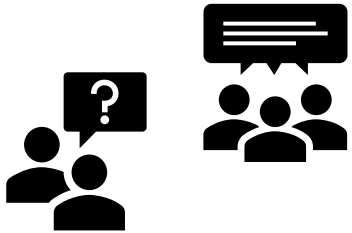
An agency of the European Union

The journey of innovation





Early dialogue between innovators and regulators is fundamental

EMA interactions across the medicine life cycle

Dedicated entry point for small, medium-sized enterprises (SMEs) **SME office**

Innovation Task Force (ITF) & **European Innovation Network** (EU-IN)

Dedicated **academia entry point**

Orphan Drug Designation

Qualification of novel methodologies

PRIority MEdicines (**PRIME** designation)

Scientific Advice (SA) / **Protocol Assistance** (PA)

ATMP classification & certification

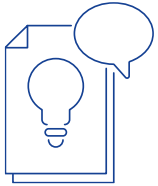
EU Health Technology Assessment (HTA)

Paediatric Investigation Plan (PIP)

Submission of **Marketing Authorization Application**

Post-authorization activities

What is the role of the Innovation Task Force?



Medicine & technology development

- Support drug development via early informal dialogue on scientific, legal and regulatory issues
- Preparing for formal procedures (e.g., scientific advice, qualification)

Agency & network development

- Address impact of emerging therapies and technologies on the regulatory system
- Identifying emerging trends that may require regulatory support
- Collaboration with the national innovation offices (*EU Innovation Network*) to address gaps in regulatory support to innovation

Innovation Task Force (ITF) briefing meetings

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Multidisciplinary platform

for preparatory dialogue and orientation on

innovative methods, technologies and medicines

- Support **innovative** drug development
- **Early informal** dialogue with opinion leaders
- 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

The process

Applicant sends a Request Form

ITF / EMA multidisciplinary team

Evaluation

Applicant ⇄ **ITF team**

Referral (EMA, NCA, other)

Not suitable

Submission of a Briefing Document

Suitable

Planning of ITF Briefing Meeting

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

Applicant ⇄ **ITF team**

How to contact us:
ITFsecretariat@ema.europa.eu

Which types of developments are discussed during ITF meetings?

Emerging therapies

- Cell & gene therapies
- Targeted therapies
- Nano-medicines

Emerging methods

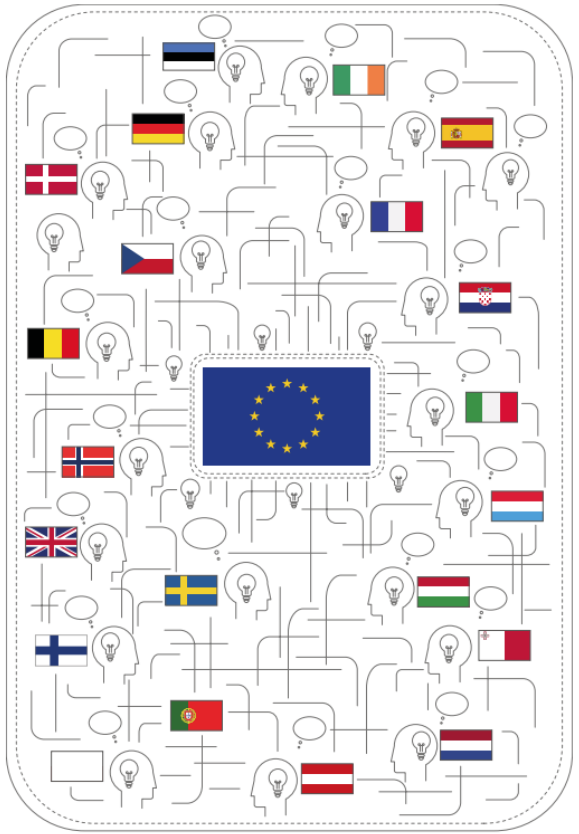
- Organ-on-chip & 3Rs
- Clinical trial methodology
- New drug delivery systems

Emerging Technologies

- Digital technologies
- Novel manufacturing
- Platforms

Who are the experts joining the ITF meetings?

- ITF team
- Members of EMA Committees / Working Parties
- Representatives of National Competent Authorities (27 members states)
- Any further expertise required to address the topics (diagnostics, software, AI, manufacturing & quality, inspectors…)
- Other international regulators as agreed with the applicant (FDA, Swissmedic, HAS-Singapore, Health Canada)



European Experts Database

Key topics discussed in 2022

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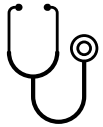
Methodology of clinical trials

- Novel endpoint
- Adaptive design
- Platform/umbrella/basket trials



Big data

- Novel biomarkers & omics
- Real-world evidence

Stakeholder interactions

Digital healthcare

- Monitoring devices/sensors
- Data collection
- Patient-reported outcomes

Associated medical devices

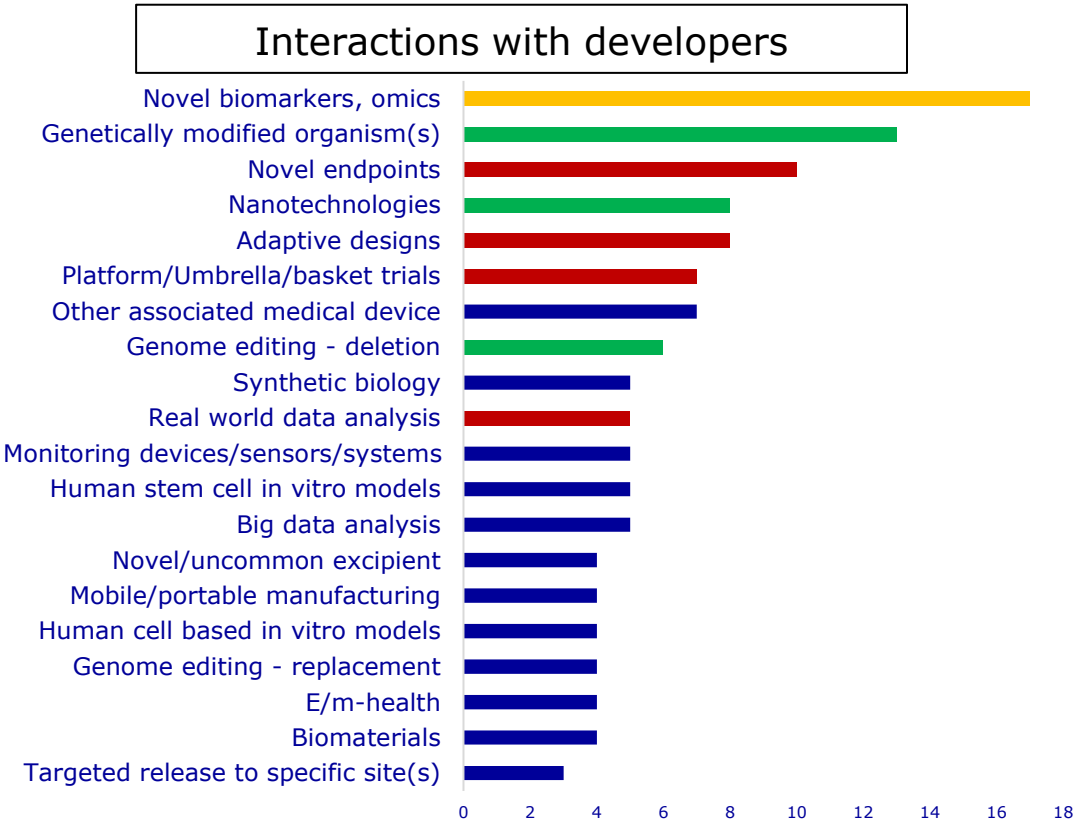
- *In vitro* diagnostics
- Companion diagnostics

Genome editing

- Gene editing
- Gene therapies

Enabling technologies

Novel and promising technologies that have the potential to enable innovation



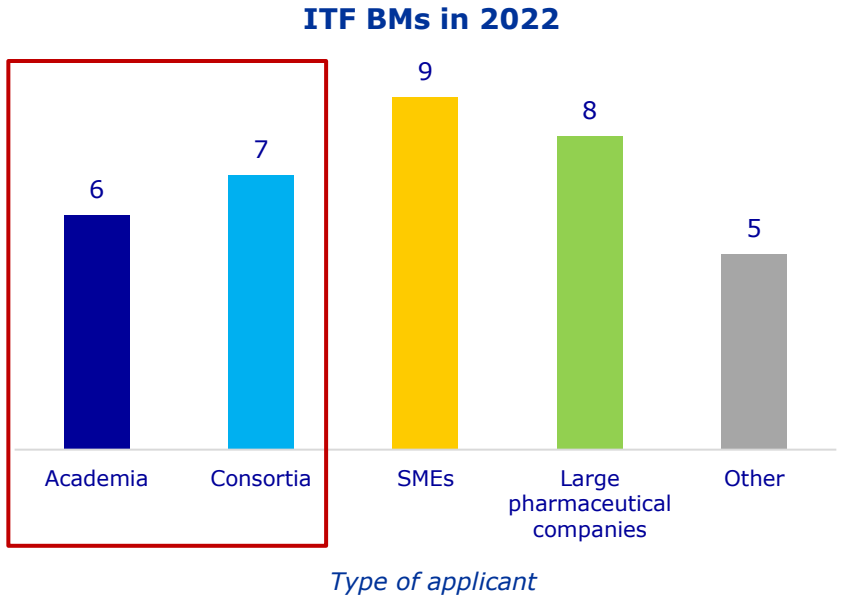
Non-clinical development

Clinical developments

Methodology

Full year 2022 data

40% of ITF briefing meetings involved an academic applicant



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Examples of ITF meetings & feedbacks

ITF Meeting - Example 1

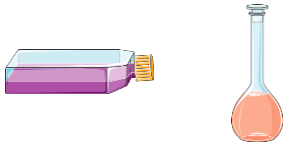
Applicant & status of project:
Academia, *proof-of-concept*

Type of development:
Gene therapy for neurological disorder

Reasons for contacting EMA:
The applicant lacks expertise on the development of medicinal products.

How can we bring the *innovation forward towards patients*?

Enabling technologies
- Genome editing
- Nanotechnologies



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

ITF Meeting - Example 2

Applicant & status of project:
Small-medium enterprise (SME);
Pre-clinical stage

Type of development:
Bioprinting of autologous cells

Enabling technologies
- Biomaterials
- Cell & tissue engineering

Reasons for contacting EMA:
- How is the product classified?
- What is the regulatory status 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 vision impairment

Enabling technologies
- Nanotechnologies

Reason for contacting EMA
Is our novel strategy a novel medicinal product or a medical device?

Topics & Feedbacks
- Type of innovative product: *nanoparticles*
- Mode-of-action of the product defines its nature (pharmacological vs mechanic)

Next steps:
Based on the mechanical mode-of-action, the product is likely to be classified as medical device. The applicant will contact the national competent authority for certification.

Conclusions:

- **ITF briefing meetings** are a brainstorming-type of interaction that provides initial guidance to medicine & methodologies developers

- **Early dialogue** between developers (*innovators*) and regulators is fundamental to bring innovative medicines towards patients

Thank you for your attention!

For additional information: Innovation in medicines

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