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An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

National Regulatory Supports for Innovation

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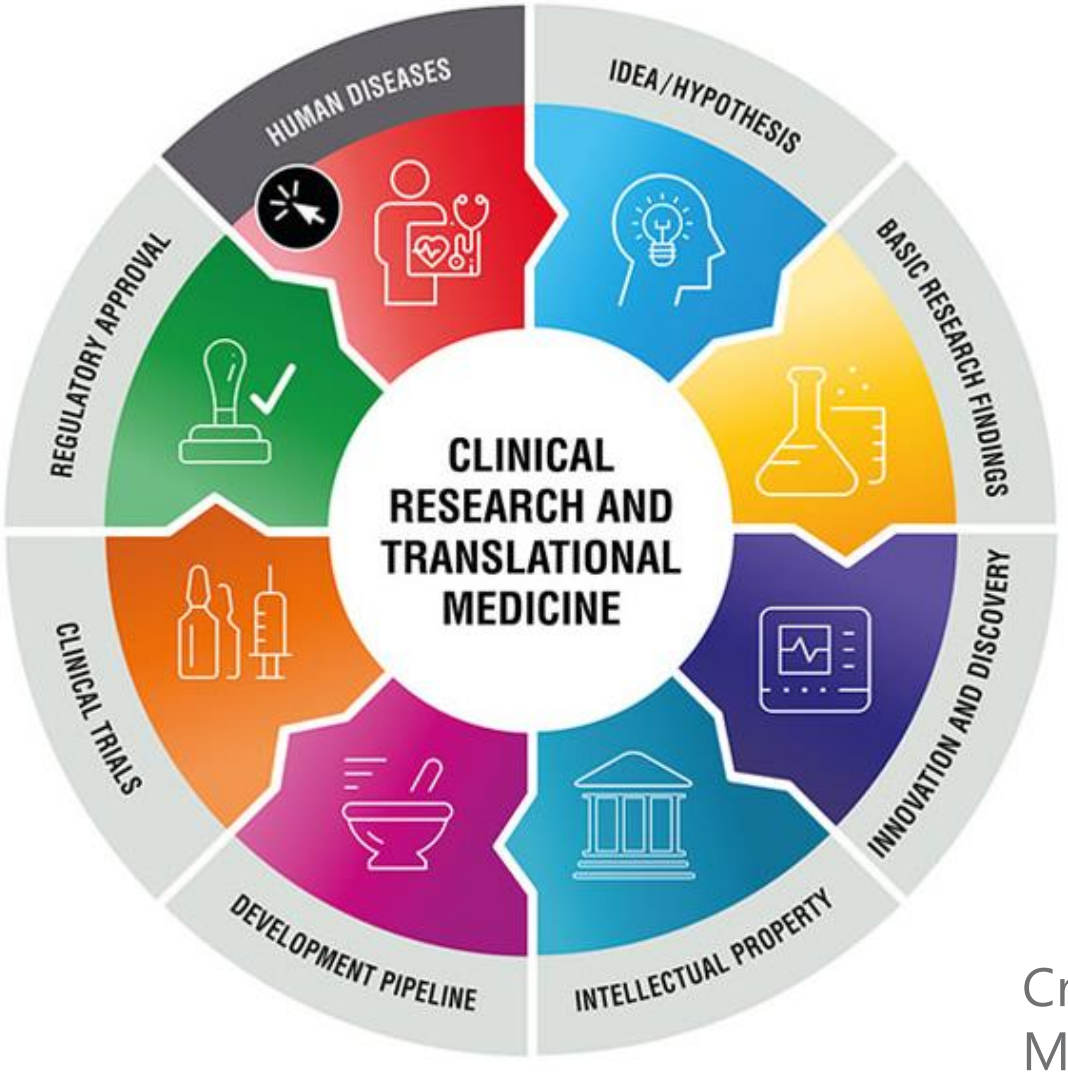
Strengthening life-sciences innovation across Europe

21st November 2023, Clayton Burlington Hotel

Presentation Overview

- Brief overview of the EU-Innovation Network (EU-IN)
- Examples of regulatory supports for Innovation at national level
- Highlight relevant initiatives

Health Product Innovation Ecosystem



Credit:
Monash University, Australia

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EU-Innovation Network (EU-IN)

EU-IN: Translation of EU strategies into tangible outcomes

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EU-Innovation Network

- NCA Innovation Offices
- EMA's Innovation Taskforce

Objectives of the EU-IN

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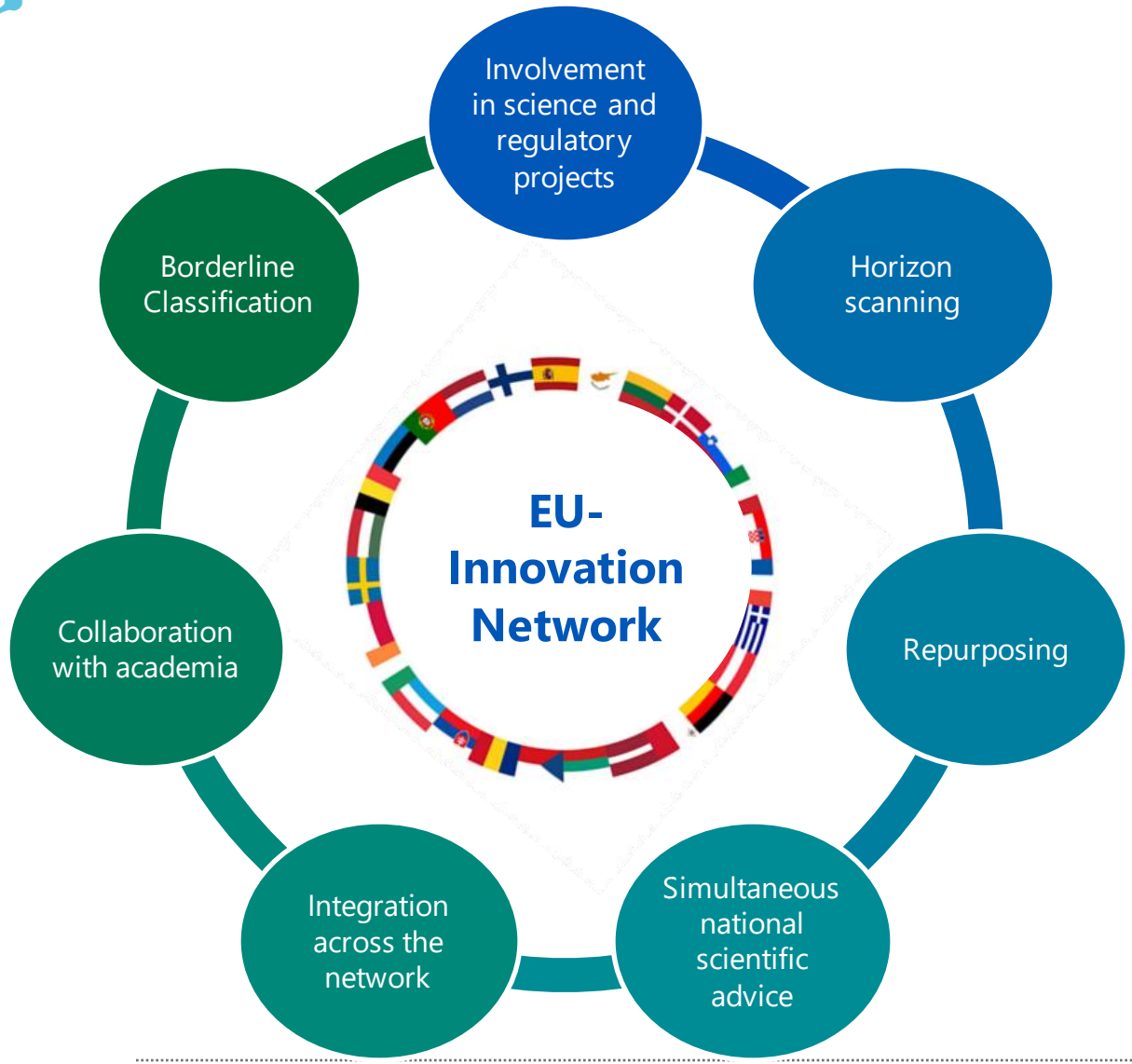
Innovators meet regulators

- Increase visibility and encourage use of the available regulatory supports at national and EU level
- Address gaps in early regulatory support to innovation
- Strengthen engagement between regulators and innovators

> Welcome to the EU Innovation Network // EU-IN

EU-IN activities



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HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 March 2020

EMA/172147/2020

Mandate of the European Innovation Network

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Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 February 2023
EMA/120370/2023

EU-Innovation Network Workplan 2023

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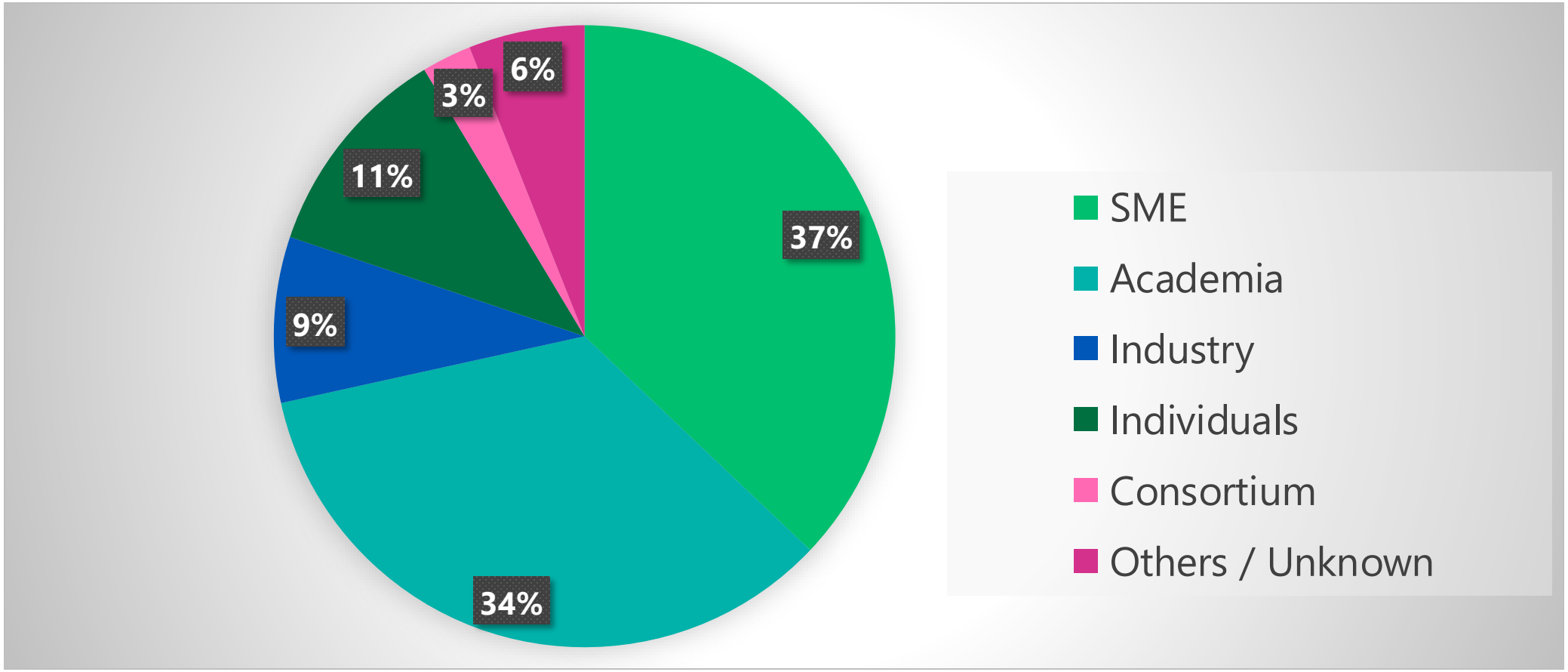
National regulatory supports for innovation

National Innovation Offices

- Initial point of contact for innovators to submit queries
- Queries can be submitted at any stage of development including initial research
- Help to identify relevant guidance or regulatory considerations
- Identification of other regulatory supports at both national and European level that can also be accessed as development proceeds

Origin of Queries to the HPRA's Innovation Office



National Scientific Advice

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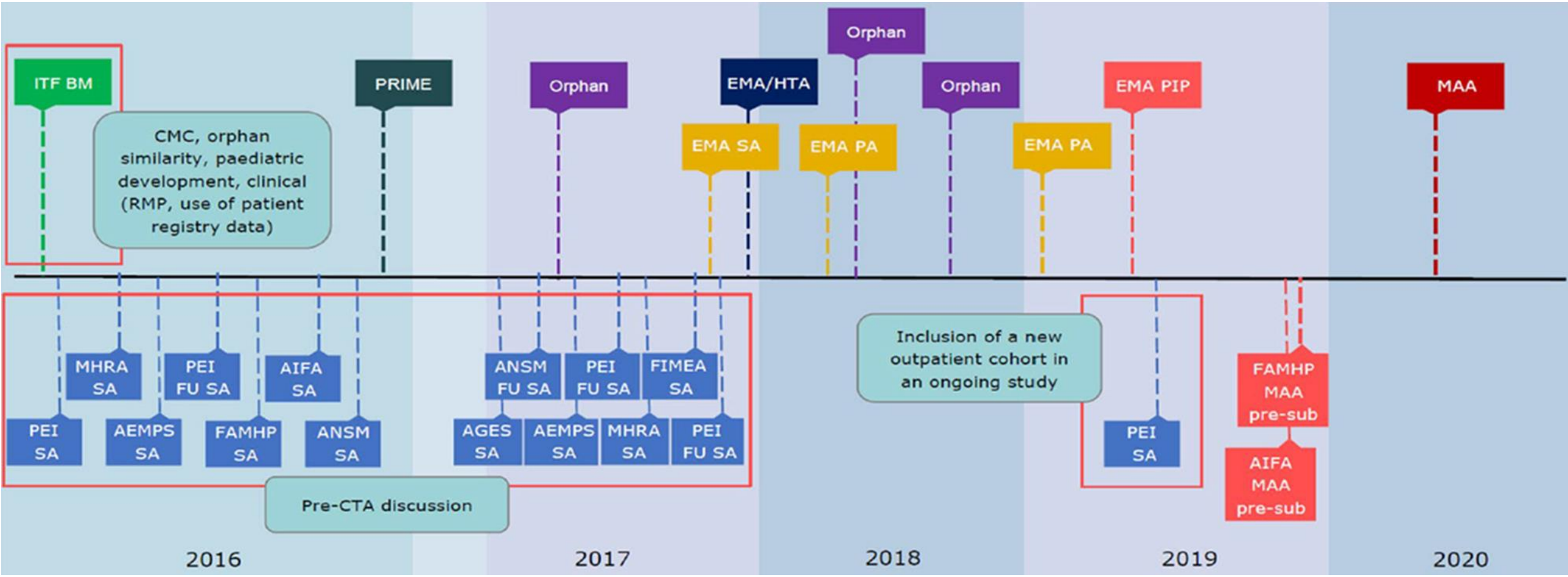
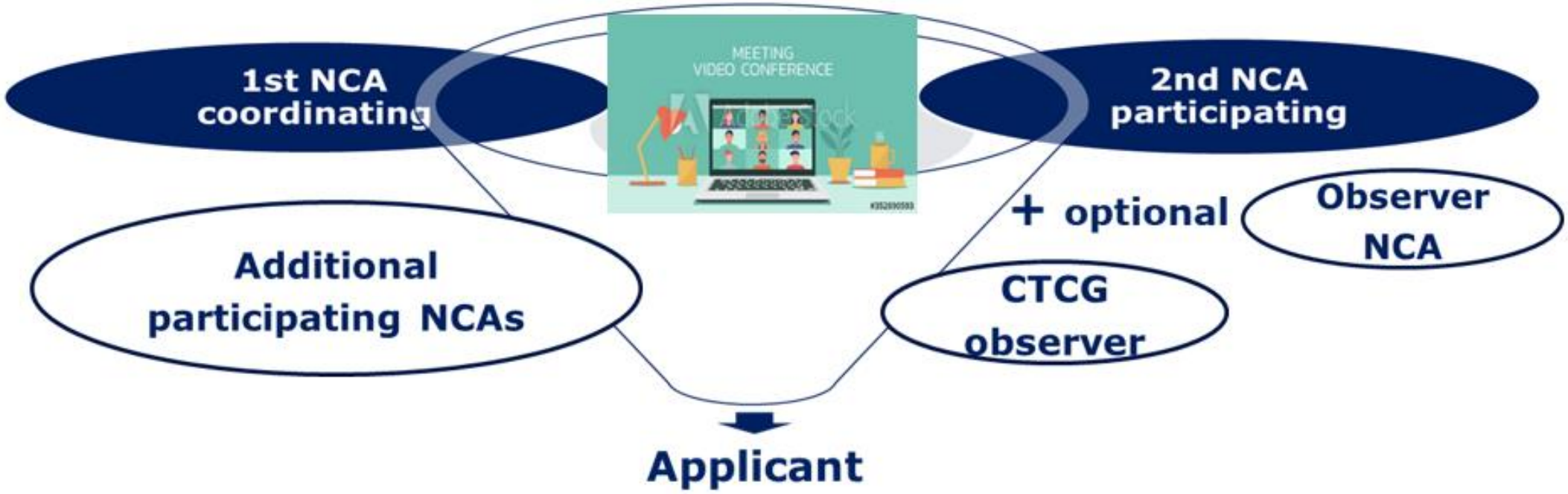
Guide for
National Scientific and Regulatory Advice

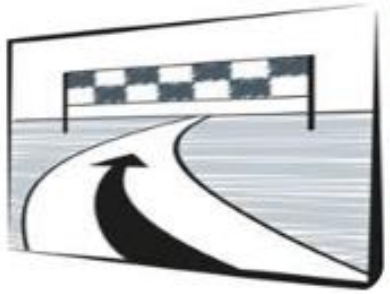
- Medicinal products for human use
- Any stage of development
- Quality, pre-clinical and or clinical aspects
- Meeting to discuss questions raised by applicant
- Written advice issued within 30 days of the meeting
- Swift Scientific Advice: quality and / or regulatory only, advice in writing within 30 days

Use of available regulatory supports



Simultaneous National Scientific Advice (SNSA)





- Single entry point (SNSA@pei.de), common application form & briefing book. Existing national fees apply.
- Agreed process and predictable timetable set at the start of the procedure with flexibility under special circumstances
- Clearly documented outcome of position of each NCA in meeting report

CSA-STARS: Strengthening Training of Academia in Regulatory Sciences

- Consortium of 21 partners from 18 European countries represented via their NCA & EMA (plus 4 associated partners) and DLR-PT
- Coordination team: BfArM, PEI, DLR-PT (Germany)
- Representatives from EU-Innovation Network
- www.csa-stars.eu

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 825881

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Clinical trial supports and initiatives

Clinical Trial Supports

- Pre-submission meetings
  - General advice to sponsors of clinical trials, clinical investigations or performance studies planning a submission to HPRA in the near future
- Implementation of clinical trials regulation
  - Dedicated HPRA webpage (www.hpra.ie/CTR) with guidance and training materials
  - Dedicated email address for queries: CTReg@hpra.ie

Accelerating Clinical Trials in the EU (ACT EU)

- Co-led by EC, HMA and EMA
- Aim is to transform the EU clinical research environment in support of medical innovation and better patient outcomes
- 11 priority actions with a focus on:
  - Enabling clinical trials (particularly multinational trials)
  - Innovative trial methods
  - GCP modernisation
  - Stakeholder engagement
- https://accelerating-clinical-trials.europa.eu/

ACT EU Priority Actions

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1. Mapping and Governance
2. Implementation of the Clinical Trials Regulation
3. Multi-stakeholder platform
4. Good Clinical Practice modernisation
5. Clinical trials analytics
6. Targeted communications
7. Scientific advice
8. Clinical trial methodologies
9. Clinical trials safety
10. Clinical trials training curriculum
11. Clinical trials in public health emergencies

See ACT EU Workplan 2023-2026 for further details

Benefits from Supporting Innovation

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- Support a dynamic innovative environment within Europe
- Strengthen links between regulatory authorities and innovators
- Clarify regulatory requirements at an early stage and help to avoid issues at later stages of development
- Inform the future development of regulatory tools and approaches
- Facilitate patient access to innovative health products

Thank you

Contact your national innovation office:
National Innovation Offices Contacts

Information on the EU-IN including SNSA:
EU Innovation Network (EU-IN)