



# ACT EU Priority Action: Action plan to support non-commercial Multinational CTs

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October 10<sup>th</sup>, 2023

Annual workshop of the European network of paediatric research at the EMA

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An agency of the European Union



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# Accelerating Clinical Trials in the EU

**ACT EU** is business change initiative to **transform the EU clinical research environment** in support of medical innovation and better patient outcomes.

- **Builds on the momentum** of the Clinical Trials Regulation and CTIS
- **Driven by** the Network Strategy to 2025 (EMA/HMA) and the EU Pharmaceutical Strategy (EC)
- Launched 13 January 2022 by European Commission, EMA and HMA
- **Priority areas**
- Webpage: [https://accelerating-clinical-trials.europa.eu/index\\_en](https://accelerating-clinical-trials.europa.eu/index_en)



Mapping & governance



Implementation of the Clinical Trials Regulation



Multinational clinical trials by non-commercial sponsors



Multi-stakeholder platform



Good clinical practice modernisation



Clinical trials analytics



Scientific advice



Clinical trial methodologies



Clinical trials safety

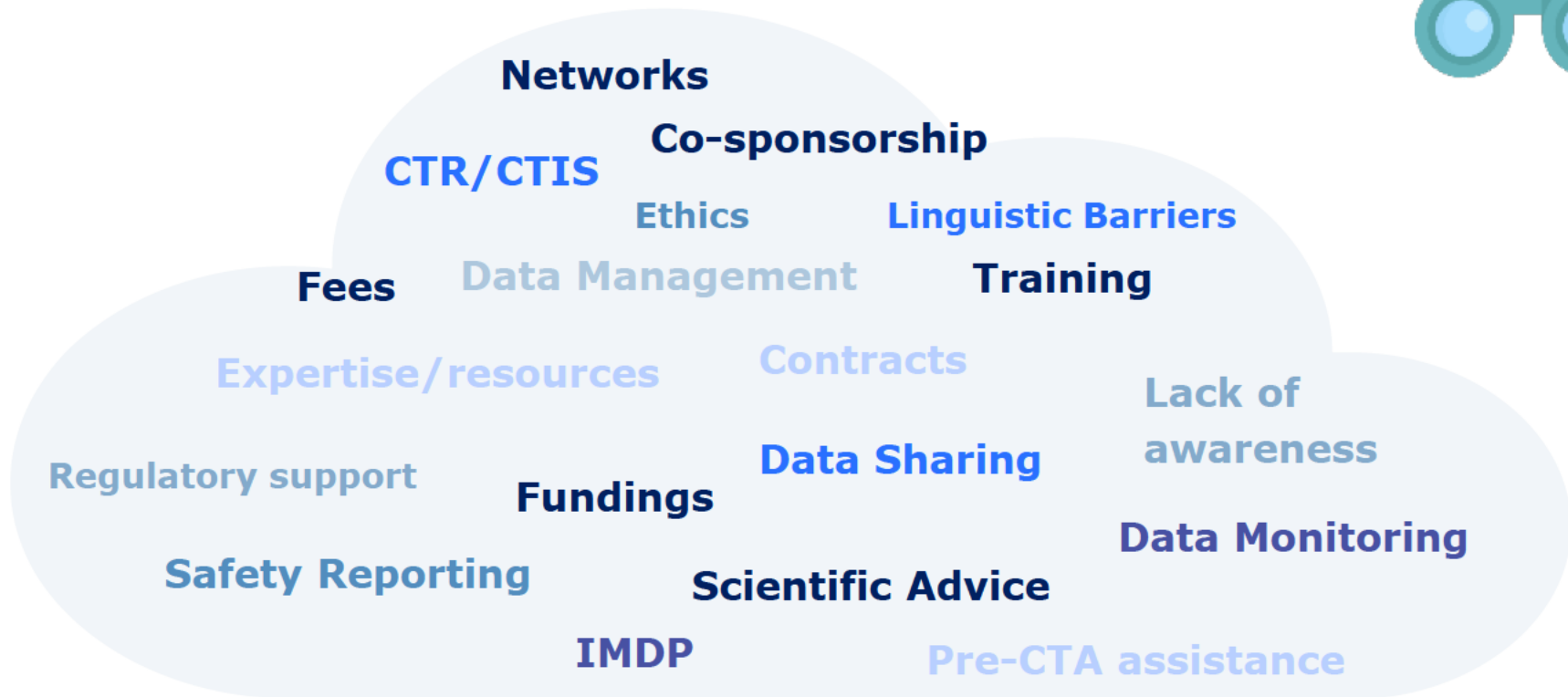


Clinical trials training curriculum



Clinical trials in public health emergencies

# Non-commercial multinational CTs: topics and hurdles



## Non-commercial CTs: more topics from EnprEMA

1. Training on **CTIS functionalities & Transition** trials
2. Clinical Trials on drug **repurposing**
3. Navigating the **regulatory landscape**
4. Assistance on **protocol writing**
5. Clinical Trials in **public health emergencies**



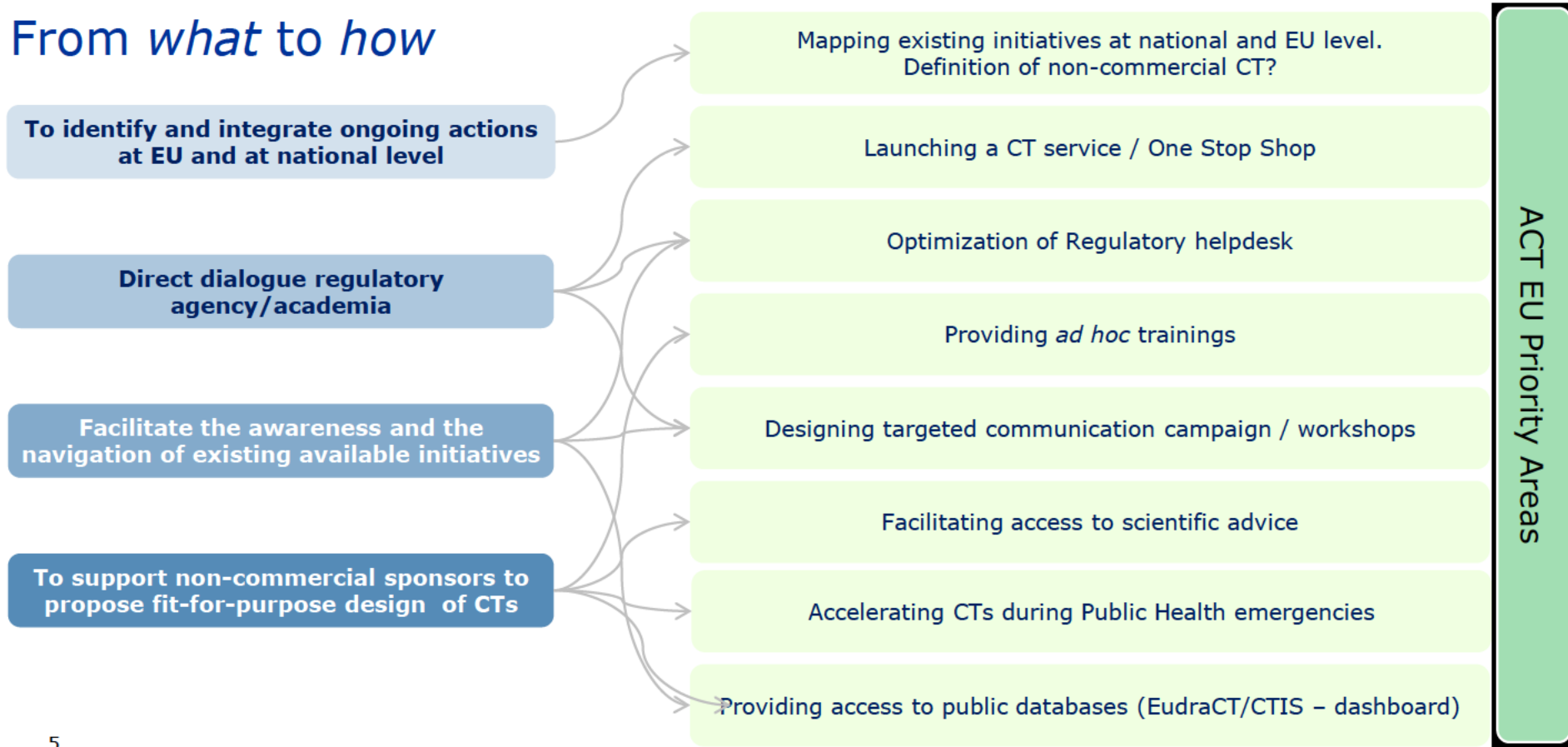
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**- Which of these areas need to be addressed most urgently to support academic sponsors conduct multi-national CTs? - Are there other areas that you can identify?**



# From *what* to *how*



# Key activities: Mapping initiatives



## Mapping existing initiatives at

- ❖ national level
- ❖ EU level

## Definition of non-commercial CT

- ❖ Investigator initiated CTs; non-profit CTs, Academic CTs, independent CTs.
- ❖ Implication for funders



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# Key activities: CT service / One stop shop



## Webpage under ACT EU:

- Dedicated to non-commercial CTs
- Link to **Academia webpage** on EMA website
- Link to **volume 10** – sponsor quick guide. Commission Q&A

## Regulatory helpdesk

- Assessing feasibility of a direct channel for contact with regulatory authorities
- Simplifying access and reinforcing existing support.



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## Key activities: Scientific Advice



Facilitating access to **scientific advice** through:

- ❖ **Waivers**
- ❖ **Fee reductions**



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# Outcome of the MSP kick-off meeting

Agreement on a model for the MSP

## Multi-stakeholder platform

Multistakeholder  
workshops

Engagement  
tools  
(consultations,  
surveys...)



### MSP Advisory Group

Call for nominees in October 2023

Stakeholder representatives  
providing:

- strategic advice
- Steer on engagement of stakeholders



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# MSP Advisory Group composition

- 1 **Regulatory Co-chair** appointed by ACT EU SG
- 1 **Stakeholder Co-chair** selected amongst non-commercial representatives and agreed by ACT EU SG.

**Initially 20 stakeholder permanent representatives** appointed via public call for expression of interest:

**4 per stakeholder** group from:

- industry EU trade organisations,
- patients/consumers organisations (inc. PCWP\*),
- healthcare professionals organisations (inc. HCPWP\*\*),
- academia and funders.

\* Patients/Consumers Working Party

\*\* Healthcare Professionals Working Party



- MSP AG stakeholder's representatives: nominations based on guiding **criteria** with additional ad hoc stakeholders based on agenda topic.

Plus:

- 2 representatives of **ethics bodies** (noting complementary initiatives with ethics bodies)
- *Ad hoc* participation including international authorities, HTA and payers based on agenda topics.
- Meetings supported *ad hoc* by representatives of ACT EU Priority Actions

# Any questions?

## Further information

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