



# Optimising the EU infrastructure for methodology guidance

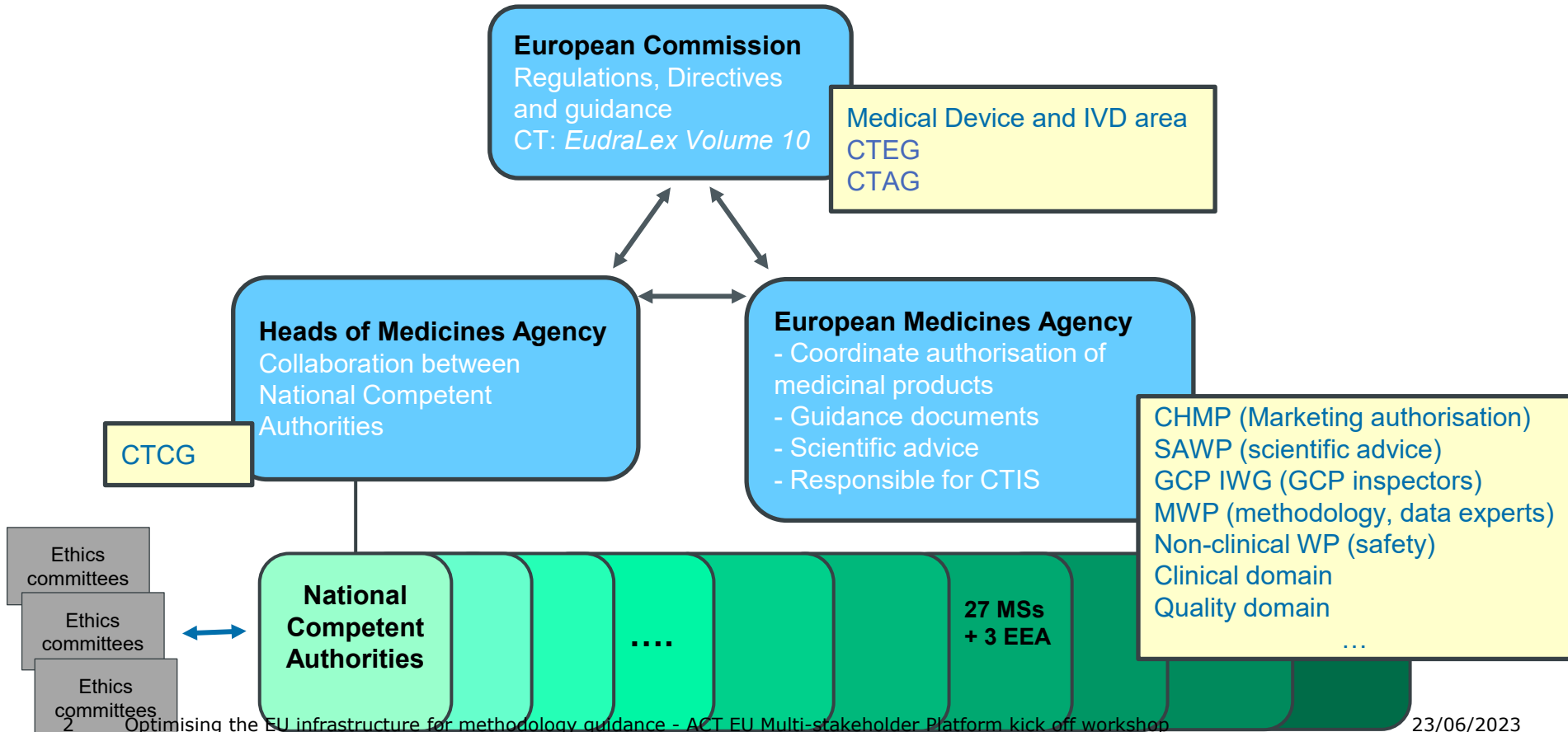
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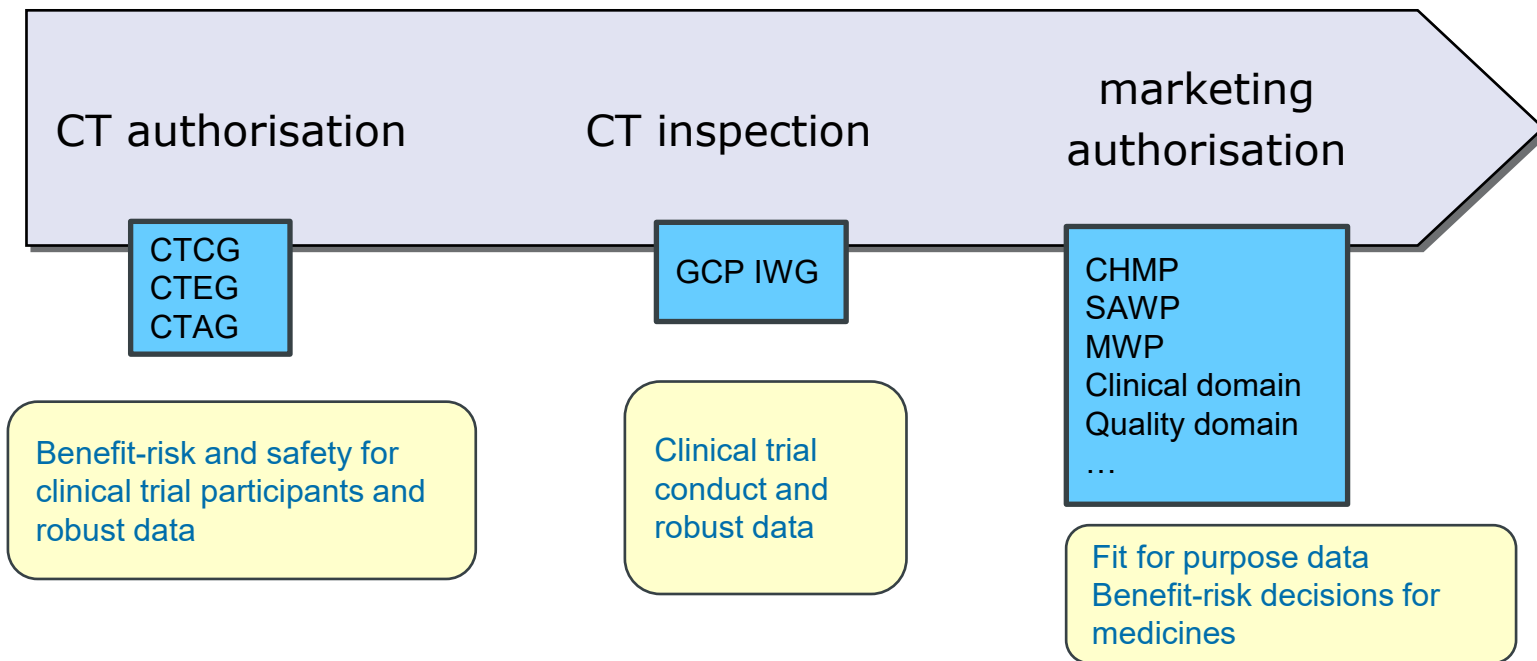
ACT EU MSP kickoff meeting – 23rd of June, 2023

# Agenda

- Guidance development - status quo
- Priority Action 8 on Methodology guidance
  - Vision and objectives
  - Deliverables
  - Methodology Workshop - possibilities for involvement



# Different perspectives on clinical trials through the life cycle



To facilitate aligned clinical trial guidance development across our European network resulting in high impact guidance documents implemented in practice



## Awareness

Ensure mutual awareness of our guidance landscape across EU expert groups



## Involvement

Ensure involvement of all relevant stakeholders at the right time to facilitate alignment, consolidation and implementation of methodology guidance



## Together

Bring together clinical trial authorisation by Member States and down-stream decision makers



## Navigate

Help our stakeholders navigate the EU clinical trial guidance landscape



## Learning

Ensure capture and sharing of lessons learned

# Deliverables



**Roadmap** to clarify guidance landscape with overview of key existing, ongoing and planned guidance activities.



**Methodology workshop** to facilitate alignment and consolidation of guidance development.



**Best Practice** on how to develop guidance documents with prefilled suggestive PM templates.



**Process for coordination** of guidance development to ensure sustainable coordination of methodology guidance development.

# 1) Roadmap



**Broad definition of 'methodology guidance'** – any document developed by the EMRN providing guidance on clinical trial design and conduct e.g. Q&As, reflection papers, guidelines..

Clarify guidance landscape with overview of key existing, ongoing and planned guidance activities.

Design, functionality and data of the roadmap to be discussed. Pilot on new ACT EU webpage.

## Complex clinical trials ▼

- ▶ CTCG recommendation paper
- ▶ Q&A on complex trials
- ▶ MWP guidance (in preparation)

## Other Topic Keyword ▼

- ▶ Guidance document I
- ▶ Guidance document II (etc...)

## 2) Methodology workshop



Multi-stakeholder event

On-site workshop at EMA Nov 2023

Inviting a broad range of experts from the network and external stakeholders

Break-out sessions organised on topic level to explore: existing guidance, gaps and need for additional guidance



Awareness of guidance activities and exchange of perspectives



Alignment and consolidation of guidance development



Sharing best practice PM on guidance projects



Identification of guidance need and scope specific methodology topics



### 3) Best Practice for guidance development



Best Practice on how to develop guidance documents with prefilled project management templates to ease planning.



Capture and share lessons learned on facilitation of guidance development.



Facilitate implementing guidance.

### 4) Process for coordination of guidance development



Process for coordination of guidance development across the network as well as continuous update of the Roadmap.



Support involvement of relevant expert groups and the right time.



Ensure a sustainable coordination of methodology guidance development

## Next steps



**Methodology Workshop** planned for Nov 2023 – official announcement coming soon.



We ask **your input** on the most relevant trends in clinical trial methodology for which regulatory guidance is needed.

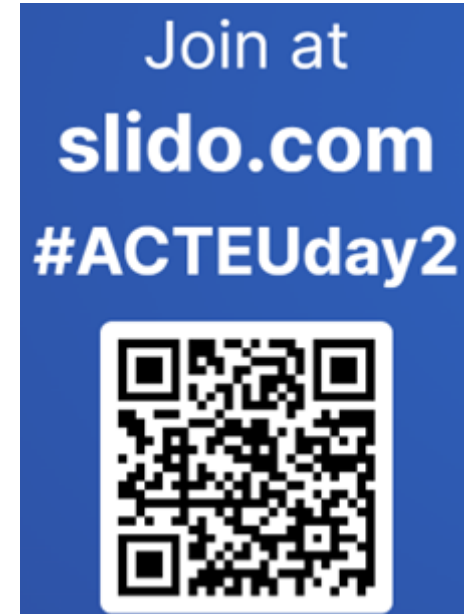


Topic proposals can be made with the registration and today!

## Methodology Workshop – topic proposals:

**What are the most relevant trends in clinical trial methodology for which regulatory guidance is needed?**

Go to [slido.com](https://www.slido.com)



Thanks a lot for your time and input!  
We look forward to collaborate.