Exploring the dynamics of partner collaboration with ACT EU

MSP Annual meeting 22 October 2024

Clinical trials: the EU landscape

EMRN groups involved in the clinical trials life cycle

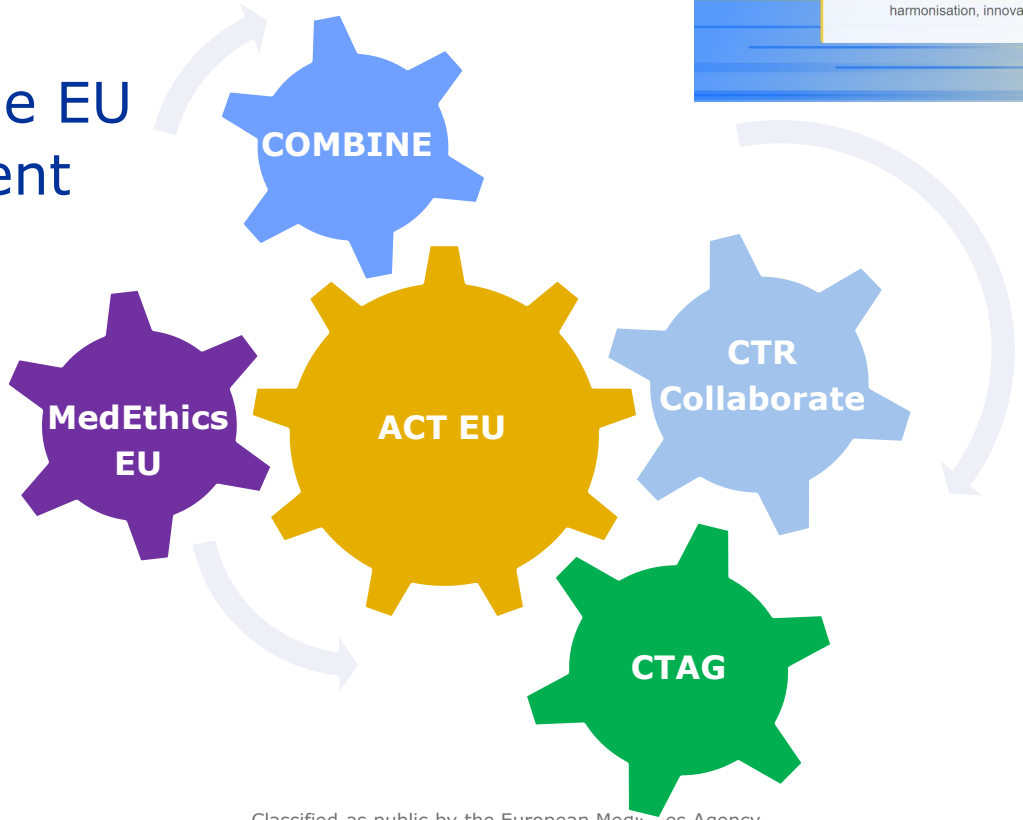
- Clinical Trials Coordination and Advisory Group (CTAG)
- Clinical Trials Coordination Group (CTCG)
- CTCG assessors round table (ART)
- MedEthicsEU
- INNO Steering Group
- GCP Inspectors' Working Group (GCP IWG)
- ACT EU Steering Group (ACT EU SG)
- EU Innovation Network (EU-IN)
- Scientific advice working party (SAWP)
- Methodology working party (MWP)
- Innovation Task Force (ITF)
- Emergency Task Force (ETF)

More information on the ACT EU website: [Mapping & governance]

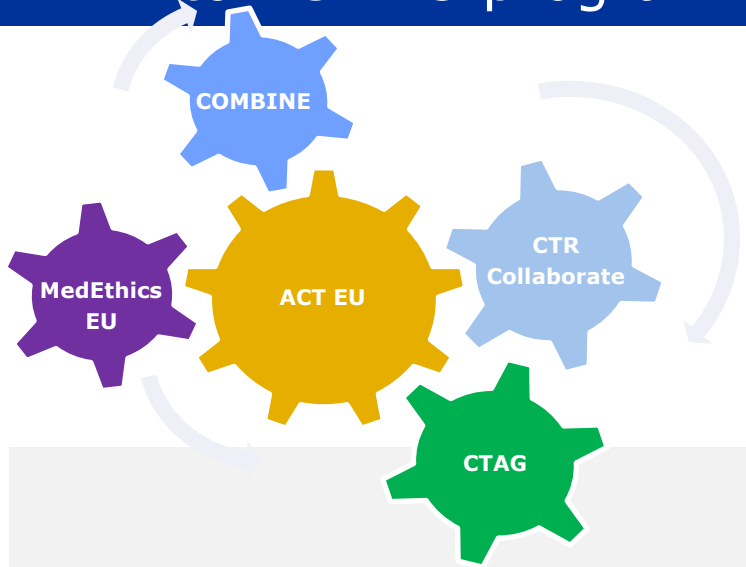
Key groups/initiatives partnering to improve the EU CT environment

Better, faster, optimised clinical trials

Improving the clinical trials environment in the European Union through harmonisation, innovation and collaboration with stakeholders.



Link to ACT EU programme



ACT EU Steering group

Trilateral programme board

Programme office

Members of CTR Collaborate, COMBINE, MedEthicsEU, CTAG are represented within the ACT EU governance and throughout the programme and enable links across partnering groups & initiatives

- PA1 Mapping & Governance
- PA2 Implementation of the Clinical Trials Regulation
  - *PA2.1 Multinational CTs by non-commercial sponsors*
- PA3 Multi-stakeholder platform
- PA4 Good clinical practice modernisation
- PA5 Clinical trials analytics
- PA6 Communications
- PA7 Consolidated advice on clinical trials
- PA8 Clinical trials methodologies
- PA09 Clinical Trials Safety
- PA10 Clinical trials training curriculum
- PA11 Clinical trials in Public Health Emergencies

CTR Collaborate initiative

- Scope:
  - Initiative led by Clinical Trials Coordination Group (CTCG) focusing on harmonised procedures, support to sponsors and trust building
  - Operational/procedural aspects and CTIS use
  - Contributes to the successful implementation of the CTR and provides data on issues which will contribute to a holistic overview of the landscape bottlenecks.
- Composition: MSs (NCA and Ethics)
- Heads of Medicines Agencies: Clinical Trials Coordination Group (hma.eu)

Clinical Trials Coordination and Advisory group (CTAG)

- Scope:
  - Established as per article 85(1) of Clinical Trials Regulation (536/2014)
  - Represent the view of their Member State in the context of the CTR
  - Support the exchange of information between the Member States and the Commission on the experience acquired with regard to the implementation of the Regulation.
  - Important role in the successful implementation of the CTR.
- Composition: Clinical Trial Regulation National Contact Points (one representative per Member State), CTCG observer, EMA observer, led by the European Commission.
- Register of Commission expert groups and other similar entities (europa.eu)

MedEthicsEU

- Scope: To strengthen collaboration between the medical research ethics committees reviewing clinical trials applications falling under the Clinical Trials Regulation (CTR), performance study applications falling under the In Vitro Diagnostics Regulation (IVDR) and clinical investigation applications falling under Medical Device Regulation (MDR) in the EU/EEA Member States.
- Composition: A group of national representatives of Medical Research Ethics Committees appointed by CTAG and established as a special group under the umbrella of the European Commission.
- MedEthicsEU - European Commission (europa.eu)

COMBINE programme

- Scope: to analyse the root causes of the challenges encountered by sponsors in conducting combined studies and identify possible solutions to these challenges.
- Composition: Representatives of competent authorities for clinical trials and medical devices, the European Commission, medical research ethics committees, the European Medicines Agency and relevant medicinal product and medical device sector stakeholders.
- Combined studies - European Commission (europa.eu)