



Multistakeholder Platform event, 22 October 2024

The Clinical Trials Coordination and Advisory Group – CTAG



Governance – where CTAG stands



Priority Action 1
on Governance

[Mapping & governance - European Union](#)
(europa.eu)

Legal basis of CTAG, Article 83 and 85

CHAPTER XV

COOPERATION BETWEEN MEMBER STATES

National contact points

- Each Member State shall designate one national contact point in order to facilitate the functioning of the procedures set out in Chapters II and III.
- Each Member State shall communicate the contact point referred to in paragraph 1 to the Commission. The Commission shall publish a list* of the national contact points.
- To support the exchange of information between the Member States and the Commission on the experience acquired with regard to the implementation of this Regulation;

[*List available on Eudralex volume 10](#)

CTAG mission & tasks

- To assist the Commission to support the effective and efficient implementation of the CTR (e.g. interpretation of legal provisions).
- To represent the view of their Member State in the context of the CTR; ensuring appropriate coordination between the organisations involved in the implementation of the CTR in their Member State, including but not limited to the national competent authorities and ethics committees;
- To exchange information on the experience acquired with regard to the implementation of this Regulation (e.g. transitional trials).
- Development of the Questions & Answers document on the CTR
- Endorsement of key documents such as templates for Part II

Examples of matters addressed in CTAG since the entry into application of the CTR

- Adoption and publication of the Implementing regulation for safety cooperation
- Adoption and publication of the Delegated regulation on labelling requirements for unauthorised investigational and unauthorised auxiliary medicinal products
- Appointment of the CTAG representative in the EMA Emergency Task Force
- Guidance for transition trials
- Interpretation of the CTR and consequent review of the Q&A document and templates part II
- Consultation on the CTR survey n.1 and n.2 + KPI definition
- COMBINE programme

Administrative information and processes

- Chaired by the Commission
- **Membership:** 1 representative for each Member State plus 1 CTCG observer and 1 EMA observer.
- **Meetings:** At least 4 meetings a year, and whenever the situation requires on a request from the Commission or a Member State
 - Already 5 meetings in 2024, other meetings are being planned ; 5 meetings in 2023 ; 4 meetings in 2022
 - Any CTAG member can suggest agenda items
 - Minutes and rules of procedure available on [Register of Commission Expert Groups and Other Similar Entities](#)