Clinical Trial Regulation 536/2014

Cooperation between MS and the European Commission

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EC-DG SANTE/HMA-CTFG/EMA

joint training - March 9-10, 2021

Clinical Trial Facilitation and Coordination Group (CTFG)

- **Type:** non-public meeting, informal group
- **Organizer and chair:** Heads of Medicines Agencies, chaired by 2 co-chairs elected from the members
- **Attendees:** Representatives from the national competent authorities for the authorisation of clinical trials on human subjects, the European Commission and the European Medicines Agency
- **Purpose CTFG**
  - forum for discussion to agree on common principles and processes to be applied throughout the European medicines regulatory network.
  - Promoting harmonisation of clinical trial assessment decisions and administrative processes across the national competent authorities (NCAs)

Clinical Trials Expert Group (CTEG)

- **Type:** non-public meeting, informal group
- **Organizer and chair:** DG SANTE, European Commission
- **Attendees:** 1 representative from **NCA and EC** per MS, EMA observer.
- **Meeting:** 4 times/year, with thematic *ad hoc* meetings as necessary
- **Purpose CT EG**:
  - To provide the COM with advice and expertise on clinical trials in relation to the preparation and implementation of legislation and policy initiatives.
  - Draw up and adopt guidelines and documents related to the transition from the CTD to the CTR and to the implementation of the Regulation

Clinical Trials Coordination and Advisory Group (CTAG)

- **Type:** non-public meeting, formal group established by the CTR art. 85
- **Organizer and chair:** DG SANTE, European Commission
- **Attendees:** 1 representative per MS (national contact point), EMA.
- **Meetings:** regular and *ad hoc* when necessary
- **Purpose CTAG**
  - support the exchange of information on the experience acquired with regard to the implementation of this Regulation
  - assist the Commission in providing the support on coordinated safety assessment
  - prepare recommendations on criteria regarding the selection of a RMS

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National contact points

- Designated by the Member States (one/MS)
- List is public: https://ec.europa.eu/health/sites/health/files/files/clinicaltrials/contact-points_clinical-trials_reg-536-2014.pdf
- Function:
  - Facilitate procedures in initial trial applications and applications for substantial modifications
  - Members of the CTAG

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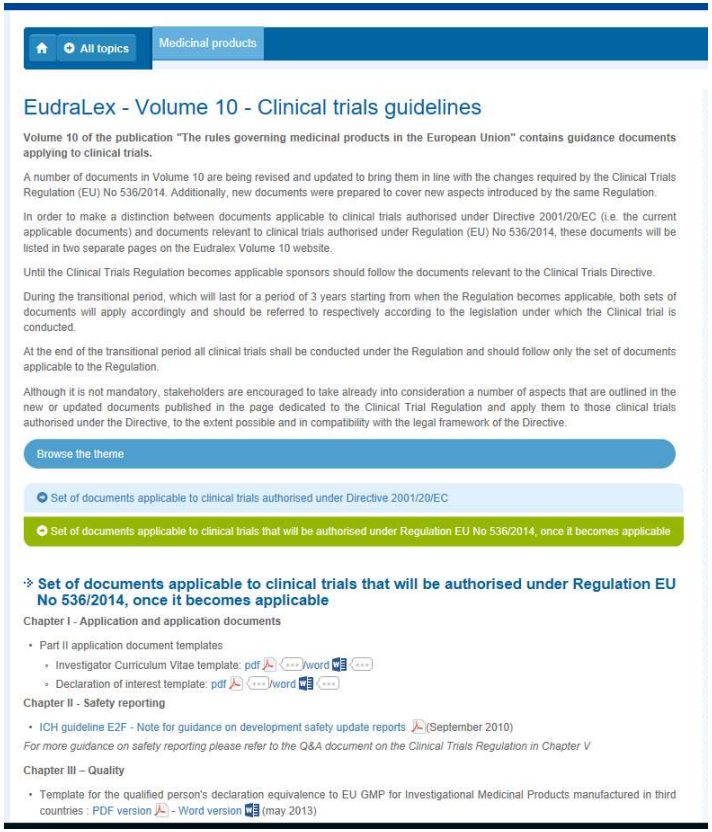
Guidance documents, training

- DG SANTE (CTEG) guidance documents: EudraLex-Volume 10
- Collaboration with EMA and CTFG
- Separately for the Directive 2001/20/EC and the Regulation (EU) No 536/2014
- Stakeholders are encouraged to follow the documents for CTR as much as possible and in compliance with the Directive.



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Additional collaborations

- Training: joint COM/EMA/CTFG-HMA training
- CTIS development: coordinated jointly by EMA, COM with MS involvement
- IA for coordinated safety assessment: EMA/CTFG/COM drafting team (joint CTEG/CTFG review)
- Joint guidelines e.g.:
  - Joint COVID-19/CT Guidance
  - General QnA for CTR (safety chapter by CTFG)
  - Guideline to interface IVDR/CTR (in progress, driven by CTFG)

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Thank you

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