Clinical Trials Facilitation and Coordination Group

Cooperation between Member States and the European Commission

CTFG Co-Chairs

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Presented at the EC-DG SANTE/HMA-CTFG/EMA joint training on the Regulation (EU) No 536/2014

Clinical Trials Facilitation and Coordination Group

Established in 2004

Working group under Heads of Medicines Agency (HMA)

Members: clinical trial experts from EU/EEA Member States

Two members elected co-chairs, ~6 plenary meetings per year

Scope: Facilitate, harmonise and coordinate regulatory and scientific issues relating to clinical trials

Some CTFG procedures...

Developed Voluntary Harmonisation Procedure (VHP) in 2009
Joint assessment and conclusion on trial application core documents
~1800 multinational clinical trials
VHP+ in certain MS also includes Ethics Committees

Safety assessment worksharing

developed concept of saMS - ***s****afety* ***a****ssessment* ***M****ember* ***S****tate*

worksharing on Annual Safety Reports (DSURs) and SUSARs

Consolidated opinion

developed concept providing harmonised consolidated opinions on topics of general interest (now in first pilot stage)

Some CTFG activities…

CTIS - participation in development and governance, tracking MS preparedness, best practise, guidance, training

CTFG sub-groups

- ’New Trends’
- Decentralised trials
- Complex trial design
- Interplay between regulations on *in vitro* diagnostic medical devices and clinical trials
- Safety
- Registries

Cooperation with the EU regulatory network and exchange with stakeholders

- **Cooperation** with the **European Commission DG SANTE** and **DG RTD** (e.g. CTEG and future CTAG, CTFG-IVD steering committee - in vitro diagnostic medical devices in clinical trials)
- **Participation** in **EMA pandemic Task Force** (COVID-ETF)
- **Participation** in **Innovation Group (INNO)** including HMA (CTFG), EMA (SAWP, ITF), HMA-EMA (EU-IN) and EUnetHTA
- **Participation** in HMA-EMA-EU Network Training Centre (NTC)
- **Interchange** with **EMA committees** and **working groups**, e.g. PDCO, GCP-IWG
- **Meetings** with **External stakeholders** - industry, academia and patient organisations