Workshop for assessors from NCAs and MRECs on paediatric clinical trials

ACT EU Paediatrics Trials in EU/EEA

CTCG-PDCO-MWP initiative

Two-day hybrid workshop - 14/15 July 2025

Objectives

- Discuss the interpretation of CTR 536/2014 article 32;
- Understand the implications of article 19 and 20 of the latest version of the Declaration of Helsinki (Helsinki, October 2024);
- Give input on challenges regarding the review process of paediatric clinical trials in EU/EEA;
- Discuss real cases which show different assessment approaches across EU/EEA

Agenda

- Setting the scene
  - Descriptive analysis of paediatric clinical trial assessments under new CTR
  - Paediatric specific clinical development challenges – methodological considerations and its use in practice
  - Equitable access to health care through research – Paediatric clinical trials in context of the revised Declaration of Helsinki and CRT article 32
  - Industry perspective
  - Academic perspective
  - Patient perspective
- Panel discussion
- Breakout sessions with feedback reported back to plenary
- Conclusions and next steps
- Closing remarks from CTCG, MWP and PDCO

Topics covered by cases in breakout session groups:

Dosing

CT without prospect of direct benefit

Proof of concept

How much adult data is needed

Methodology/ extrapolation

Inclusion of adolescents in adult trials

Prospect of direct benefit/benefit to the group; (min) burden and risk

Patient perspective

Global perspective

Next steps

Publication of workshop report

Analyses to better understand hurdles in MSs:

- Survey on national laws

Current 'guidance landscape' fit for purpose?

- Analyse the document Ethical considerations for clinical trials with minors to see if an update is needed in the light of the workshop discussions and conclusions
- Update assessors best practice document on considerations specific for paediatric trials
- Guidance for sponsors directing towards good justification and provision of full PIP as part of the submission dossier, early engagement of investigators and patients, explain paradigm shift (DoH, CTR)

Enable information sharing, discussions and learnings across decision makers (from PIP to CTA):

- Organise meeting on interpretation of CTR art 32 e, f, g (PDCO, NCA, MRECs)
- Share information via collaboration between CTCG and PDCO
- Involvement in guidance/Q&A updates and/or created by PDCO, CTCG and MWP as co-author or in commenting phase (including Ethics)

Thank you