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Norwegian Medical
Products Agency

ACT EU Paediatrics Trials in EU/EEA

Workshop on the Assessment of Clinical Trials Applications involving Paediatric Patients

14 and 15 July

Hybrid meeting/ EMA, Amsterdam, Meeting Room 1D

Program committee:

Marianne Lunzer, CTCG chair

Monique Al, CTCG and MedEthcisEU chair

Christian B. (Kit) Roes, MWP chair

Dominik Karres, EMA PME office

Anette Solli Karlsen, PDCO/NOMA

Report to annual EnprEMA meeting 20th november 2025

Anette Solli Karlsen

Norwegian Medicines Product Agency

Team leader, clinical trial assessor

PDCO alternate

About the event

- Hands-on workshop on the evolving landscape of paediatric clinical trials, fostering cross-team collaboration to shape their future in the EU/EEA.
- This two-half-days hybrid event will offer participants the opportunity to:
 - 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;
 - Become part of a growing community of experts for paediatric clinical trials for cross border discussions on feasibility of clinical trials in this vulnerable population.

Agenda – day 1

- Session 1: Setting the scene (moderators: Marianne Lunzer and Monique Al)
 - The first descriptive analysis of paediatric clinical trial assessments under the new EU Clinical Trial Regulation. *Laura Fankhauser (Hopp Children's Cancer Center Heidelberg (KiTZ), Department of Pediatric Oncology, Hematology, Immunology, and Pulmonology, Heidelberg University Hospital, Heidelberg, Germany)*
 - Paediatric specific clinical development challenges – methodological considerations and its use in practise. *Dominik Karres (Pediatrics Medicines Office EMA) and Sabine Scherer (PDCO member, BFARM Germany)*
 - Equitable access to health care through research: Paediatric CT in the context of the revised Declaration of Helsinki and CTR article 32. *Martine de Vries (Head of the Department of Medical Ethics and Health Law Paediatrician Leiden University Medical Center)*
- Session 2: Panel discussion (moderator: Anette Solli Karlsen)
 - Industry perspective by Scott Diede. *Merck Research Laboratories, United Kingdom*
 - Academic perspective by Michel Zwaan. *Prinses Maxima Centre Utrecht, Netherlands*
 - Patient perspective by Tomasz Grybek. *Eurordis Rare Disease Europe*
- Session 3 BOS: Use cases for discussion (facilitators to moderate)

Use cases for discussion

Group	Topics
1	- Dosing - CT without prospect of direct benefit
2	- How much adult data is needed/ Proof of concept
3	- Methodology/ extrapolation - Inclusion of adolescents in adult trials - Dosing
4	- Prospect of direct benefit/benefit to the group - (min) burden and risk - Patient perspective
5	- Inclusion of adolescents - Global perspective

Agenda – day 2

- Session 4: Breakout sessions continued
 - Preparation for plenary feedback
 - Explore in your group if there is a need to develop principles/ guiding frameworks
 - Conclusions should lead to actionable recommendations
- Session 5: Feedback break-out sessions
- Session 6: Conclusions and next steps (Maranne Lunzer/Monique AI)
- Closing remarks (CTCG, PDCO, MWP, program committee)

Key messages

- Timely workshop to address relevant issues related to assessment of paediatric clinical trials in EU/EEA
- Clear message to continue this dialogue between regulatory decision makers, Ethics, investigators, sponsors and patient representatives
- Concrete follow up actions, including formal implementation of a collaboration between PDCO and CTG
- Acknowledgement about the importance to extend methodology implementation activities, such as related to ICH E11A Guideline to include also, e.g. clinical trial assessors and ethics committees

Next steps - CTCG

◆ CTCG actions:

- Analyse the **Ethical considerations document** to see if an update is needed in the light of the discussions of today
- Invite Ethics committees for ad hoc meeting on **interpretation of CTR art 32 e, f, g**
- Be open for discussion on the trial design
- Survey on national laws
- Establish collaboration CTCG PDCO
- Give input to guidance updated and/or created by PDCO and MWP
- Co-author **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)
- Update **BP on considerations for paediatric trials?**

Questions/comments?



Article 32 - Clinical trials on minors (backup slide)

- 1. A clinical trial on minors may be conducted only where, in addition to the conditions set out in Article 28, all of the following conditions are met:
 - (a) the informed consent of their legally designated representative has been obtained;
 - (b) the minors have received the information referred to in Article 29(2) in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;
 - (c) the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in Article 29 (2) to refuse participation in, or to withdraw from, the clinical trial at any time, is respected by the investigator;
 - (d) no incentives or financial inducements are given to the subject or his or her legally designated representative except for compensation for expenses and loss of earnings directly related to the participation in the clinical trial;
 - (e) the clinical trial is intended to investigate treatments for a medical condition that only occurs in minors or the clinical trial is essential with respect to minors to validate data obtained in clinical trials on persons able to give informed consent or by other research methods;
 - (f) the clinical trial either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;
 - (g) there are scientific grounds for expecting that participation in the clinical trial will produce:
 - (i) a direct benefit for the minor concerned outweighing the risks and burdens involved; or
 - (ii) some benefit for the population represented by the minor concerned and such a clinical trial will pose only minimal risk to, and will impose minimal burden on, the minor concerned in comparison with the standard treatment of the minor's condition.
- 2. The minor shall take part in the informed consent procedure in a way adapted to his or her age and mental maturity.
- 3. If during a clinical trial the minor reaches the age of legal competence to give informed consent as defined in the law of the Member State concerned, his or her express informed consent shall be obtained before that subject can continue to participate in the clinical trial.

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