Centrale Commissie Mensgebonden Onderzoek

MedEthicsEU

Group of national representatives of medical research ethics committees

Monique Al, CCMO, The Netherlands

with thanks to Helle Christiansen, DKETIK, Denmark
MSP Meeting, EMA Amsterdam, 22 October 2024

MedEthicsEU

- Representatives of national medical research ethics committees (MREC) in EU/EEA

- MRECs involved in the assessment of clinical trials falling under the scope of the clinical trial regulation (CTR, EU no 536/2014), clinical investigations falling under the scope of the medical device regulation (MDR, EU no 2017/745) and/or performance studies falling under the scope of the in-vitro diagnostics regulation (IVDR, EU no 2017/746)

- Participants (mix of staff and committee members) from 24 member states
- Pending/not participating: CZ, HR, IS, LI (follows Suis legislation), LU, MT

Special group of the European Commission DG-Sante

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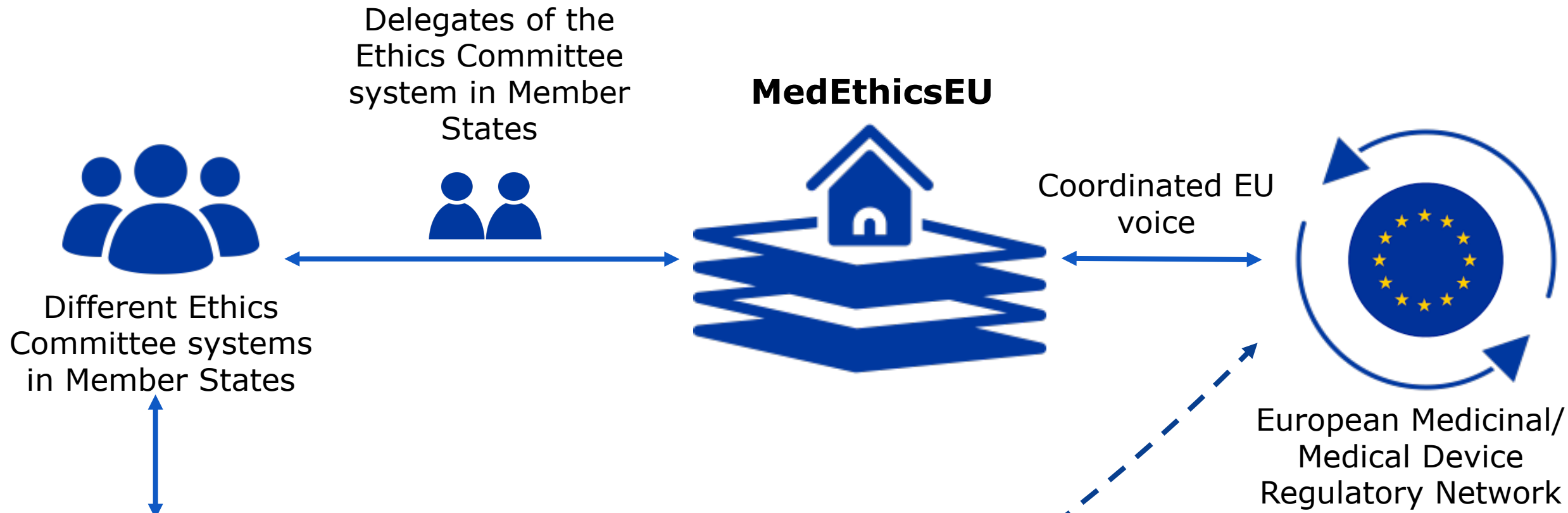
Official Launch MedEthicsEU – 15 February 2024

The group aims at **strengthening collaboration between the medical research ethics committees** reviewing clinical trials applications falling under the **CTR, MDR and/or IVDR.**

- 24 participating MS from EU/EEA – members nominated by national contact points
- anchored under the umbrella of EU COM – DG SANTE
- chaired by Monique Al (NL) and Helle Christiansen (DK)
- forum for discussion and mutual learning
- align and promote harmonisation on operational procedures while keeping ethical standards
- provide transparency on structural differences, work procedures and positions of the ethics committees between MS
- integrate the ethics voice in the European Regulatory Network
- establish cooperation with European entities in field of clinical research, like CTAG, CTCG, EUREC, EMA, CIE WG, IVD WG, ...

A network to strengthen the cooperation, exchange experiences, setting up best practices and integrate ethics in the European Regulatory Framework



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Align and promote harmonisation on operational procedures while keeping ethical standards

Review by MREC

A clinical trial may be conducted only if **the rights, safety, dignity and well-being of subjects** are **protected** and **prevail** over all other interests

A clinical trial is designed to **generate reliable and robust data**

✓ Regular board meetings MedEthicsEU and EUREC – exchange and collaboration

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MedEthicsEU – state of play

- Finalising the rules of procedures and pending nominations
- Participate in CTR collaborate project (CTCG initiative anchored in ACT EU)
- Participate in COMBINE project – second phase (single procedure combined studies)
- Participate in ACT EU PA on pandemic preparedness
- Align position with respect to article 11 procedures (mixed part I and part II multinational application)
- Aligned agreement on transition trials and EU Q&A on unexpected change of principal investigator → published on Eudralex volume 10
- Subgroup on best practices (led by IE) – collaboration with CTCG best practice subgroup
- Part II templates: first revision started on template informed consent and patient recruitment (subgroup led by FI)
- Overview part II requirements per MS (led by NL) – published on MedEthicsEU webpage

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Clinical trials - MedEthicsEU - Group of national representatives of Medical Research Ethics Committees

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General introduction

In accordance with the Clinical Trials Regulation (EU) 536/2014 (CTR) Article 4, 'A clinical trial shall be subject to scientific and ethical review and shall be authorised in accordance with this Regulation' and that 'The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned.'

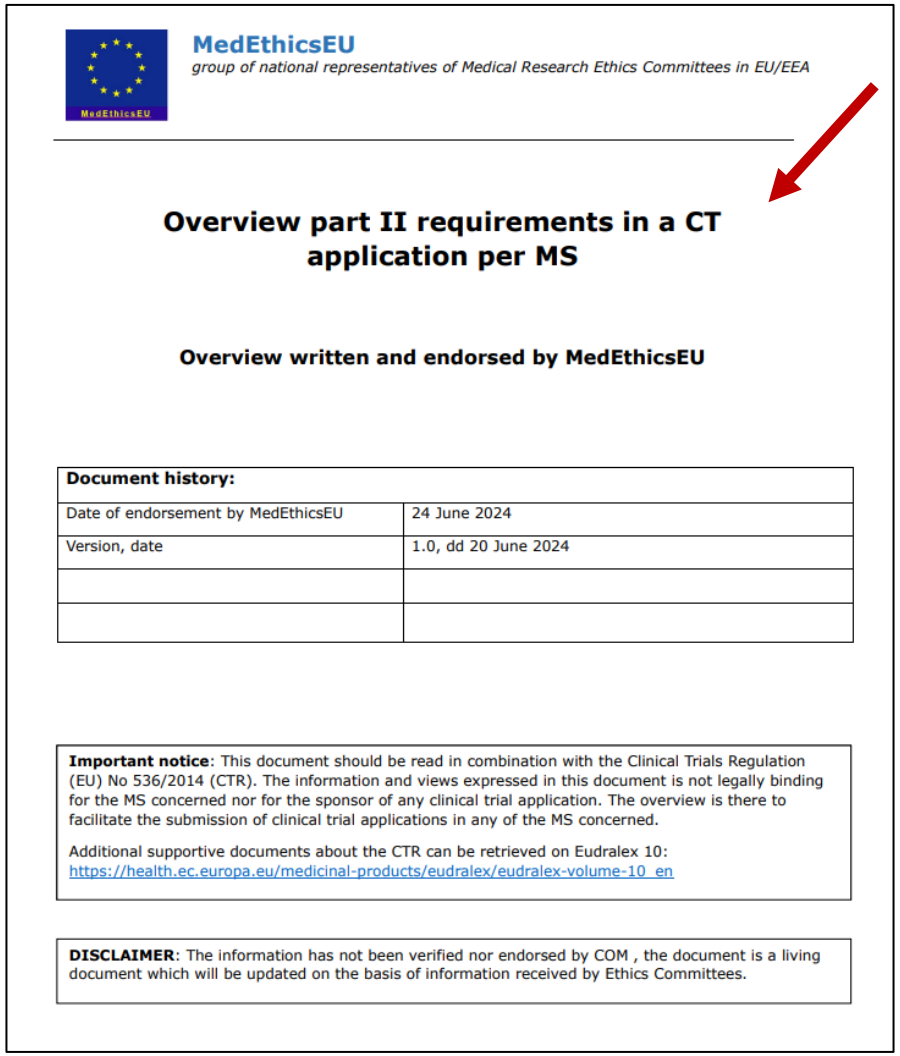
The Ethics Committee is empowered to review and give opinions on clinical trials application prior to their authorisation in line with the Clinical Trials Regulation and the national law of the respective Member State where appropriate.

MedEthicsEU is a group of national representatives of medical research ethics committees (MRECs) that was created in February 2024 to provide a forum for discussion and mutual learning between EU/EEA Member States Ethics Committees. This allows enhanced cooperation between Member States' Ethics Committees and further supports harmonisation in the ethics review of clinical trials in Europe.

The Ethics Committees of each EU/EEA Member State are independent bodies. One to two regulatory experts are nominated as national representatives of their MRECs in MedEthicsEU.

Deliverables

MedEthicsEU completed a first report on their survey on national Part II Clinical Trial Application (CTA) requirements, to which 17 Member States have contributed.



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group of national representatives of Medical Research Ethics Committees in EU/EEA

Overview part II requirements in a CT application per MS

Overview written and endorsed by MedEthicsEU

Document history:	
Date of endorsement by MedEthicsEU	24 June 2024
Version, date	1.0, dd 20 June 2024

Important notice: This document should be read in combination with the Clinical Trials Regulation (EU) No 536/2014 (CTR). The information and views expressed in this document is not legally binding for the MS concerned nor for the sponsor of any clinical trial application. The overview is there to facilitate the submission of clinical trial applications in any of the MS concerned.

Additional supportive documents about the CTR can be retrieved on Eudralex 10: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en

DISCLAIMER: The information has not been verified nor endorsed by COM , the document is a living document which will be updated on the basis of information received by Ethics Committees.

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Conclusion – lessons learned so far

To improve coordination and streamline regulatory and ethics review in clinical trials assessment processes:

- Get to know each other (background, procedures, framework, focus areas)
- Respect and open mindset
- Interact with stakeholders (e.g. sponsors, investigators, patient organisations)
- Collaborate on (internal and external) best practices, guidances, Q&As on topics of common interest
- Don’t forget a coordination mechanism and an implementation plan (including training)
- Use project management tools

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Thank you for your attention!