MedEthicsEU – overview activities

Monique Al and Helle Christiansen, co-chairs MedEthicsEU

MSP Advisory Group Meeting 18 June 2026

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MedEthicsEU

Special group of the European Commission DG-Sante

Representatives of **national medical research ethics committees** (MRECs).

Representatives from **26 Member States** in EU/EEA and consists of both **secretariat staff** and **committee members**.

MRECs involved in **review of clinical research** under the clinical trial regulation (**CTR**), medical device regulation (**MDR**), and in-vitro diagnostics regulation (**IVDR**).

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Workplan MedEthicsEU 2025-2026

- Describes the planned actions/initiatives of MedEthicsEU for the period 2025-2026
- Topics prioritized by the members of MedEthicsEU for 2025-2026 and ongoing activities of MedEthicsEU
- Five main categories:
  - Harmonisation on requirements part II dossier
  - Harmonisation on operational procedures
  - Coordinated procedures across regulations (CTR, MDR, IVDR)
  - Review of ethical aspects
  - Collaboration within the EU regulatory network

- Annually review to allow for flexibility and to adapt to the current situation of the MSs

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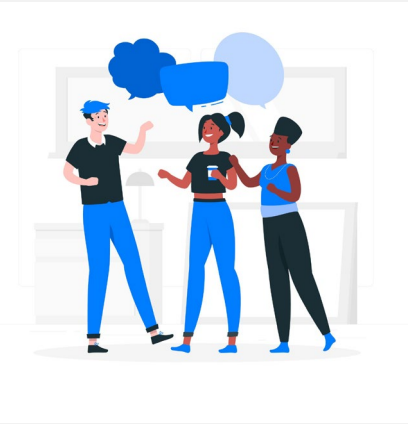
Deliverables and priorities 2025-2026

- Biotech Act
  - MedEthicsEU board 12 points discussion paper with proposals to change the CTR (e.g. on regulatory flexibility and simplification, alignment DoH, alignment CTR/MDR/IVDR, harmonised procedures/templates, legal provisions PHE trials, key importance ethical review, role MedEthicsEU) – shared with Commission
  - Reflections on the Biotech Act published 16 dec 2025 continue in 2026

- Harmonised templates
  - Overview part II requirements per MS – regular updates, published on MedEthicsEU webpage
  - Harmonised template on recruitment and informed consent procedures: endorsed by MedEthicsEU and CTAG; published on Eudralex volume 10, transition period June-Aug 2026
  - New template tbc (eg ICF, compensation, other?)



- CTCG/MedEthicsEU best practices
  - Best practices on drafting considerations endorsed
  - Next best practice together with CTCG: conditional approvals

- Translations
  - Translations of patient facing documents (if required by MS) to be moved to part II dossier: endorsed by MedEthicsEU and CTAG; implementation date 27 April 2026 (together with implementation article 11 workaround)

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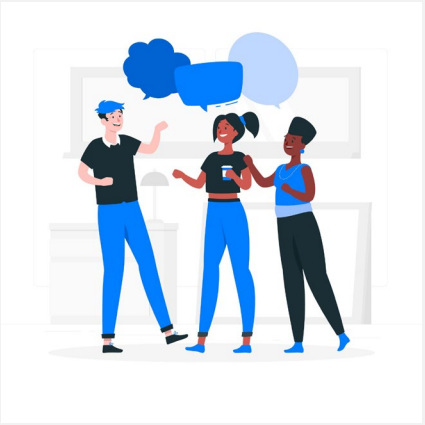
Deliverables and priorities 2025-2026

- New working group on MDR/IVDR studies and MREC review: started in 2026

- Monthly meetings:
  - **Insights into the national Ethics system (fixed format, 1-2 MS presenting)**
  - knowledge sharing and discussions on ad hoc topics (identified during review CTAs); identifying topics for best practices, guidances, training
  - "List of agreements": eg on format audio/video material part II, transparency list of members Ethics Committee



- Joint MedEthicsEU-CTCG meetings
  - First meeting 19 May 2026;
  - Next meeting 18 November 2026 and more to come

- Strenghten collaboration within the network
  - Continue participation in several ACT-EU priority actions, COMBINE program and CTR collaborate
  - Contribute to guidances (Risk based approaches in CTs, Internal guidance for assessor paediatric trials)
  - Other initiatives tbc

- Joint Action (FAST-EU) to to support to the implementation of the Clinical Trials Regulation and improvement of the clinical trials landscape in the EU and EEA (coordinator AT- AGES)
  - In-kind support MedEthicsEU

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Deliverables and priorities

Regulatory Convergence of Medical Research Ethics'

Proposal for Joint Action for MS to support to the implementation of the Clinical Trials Regulation and improvement of the clinical trials landscape in the EU and EEA (coordinator AT- AGES) – FACT-EU

- WP7 " Medical Research Ethics Committee Integration & Collaboration"
  - 7.1 Identification of challenges and convergence opportunities by mapping Ethics Committee processes and NCA–MREC interfaces
  - 7.2 Development of guidance for assessment of Part II across MSs
  - 7.3 Development of guidance for MREC–NCA collaboration on Part I assessment
  - 7.4 MREC knowledge-sharing activities across Member States and with NCAs

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Next step

- Publish list of agreements
- Scoring of topics for workplan 2026-2027
- Inventory on resources
- Strenghten collaboration within network
- Update workplan 2026-2027

Version 1.0, 26 May 2025

MedEthicsEU work plan 2025-2026

A. Introduction

MedEthicsEU is a group of national representatives from the medical research ethics committee (MREC)[1] organisations in their respective member states. Established in 2024 as a special group under the European Commission, MedEthicsEU serves as a forum to strengthen collaboration between MRECs reviewing applications for clinical trials involving medicinal products (regulated by CTR 536/2014), medical devices (regulated by MDR 2017/745), and in vitro diagnostics (regulated by IVDR 2017/746).

Primary objectives for MedEthicsEU

- To provide a forum for discussion and mutual learning between MRECs on the differences related to structures, operational procedures and the review on clinical trial applications by medical research ethics committees between Member States
- To align and promote harmonisation on operational procedures and the review by medical research ethics committees among Member States in compliance with ethical standards
- To establish cooperation with relevant European level entities in the field of clinical research[2]

This work plan describes the priority actions of MedEthicsEU for the period 2025-2026.
The work plan will be revisited annually to allow for flexibility and to adapt to the current situation of the member states.
The workplan consist of topic prioritized by the members of MedEthicsEU for 2025-2026 and ongoing activities of MedEthicsEU.
It will be implemented through active knowledge sharing, general case discussions, collaborative problem-solving, and ultimately capturing member state positions for key deliverables. These will be published on the MedEthicsEU webpage. In instances where achieving harmonisation is not possible, the group will seek to identify and understand the underlying constraints.

[1] Defined as an ethics committee reviewing clinical trials applications falling under the Clinical Trials Regulation (EU) 536/2014, performance study applications falling under the In Vitro Diagnostics Regulation (EU) 2017/746 and clinical investigation applications falling under Medical Device Regulation (EU) 2017/745 in the EU/EEA Member States (MS).
[2] In particular, CTAG (Clinical Trials Coordination and Advisory Group as per the CTR), the European Medicines Agency (EMA), the Clinical Investigation subgroup (CIE), the In Vitro Diagnostics subgroup (IVD) of the Medical Device Coordination Group (MDCG) and CTCG (Clinical Trials Coordination Group of Heads of Medicines Agencies) regarding research ethics matters

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Thank you for the attention!

medethicseu@ec.europa.eu

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