MedEthicsEU

Priorities and deliverables 2025-2026

Monique Al & Helle Christiansen, co-chairs MedEthicsEU

MSP-AG, dd 20 March 2026

MedEthicsEU

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, 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

- CTCG/MedEthicsEU best practices
  - Best practices on drafting considerations endorsed
  - Next best practice together with CTCG: work in progress

- Harmonised templates
  - Harmonised template on recruitment and informed consent procedures: endorsed by MedEthicsEU and CTAG; implementation plan for 2026– in development

- Translations
  - Translations of patient facing documents (if required by MS) to be moved to part II dossier: endorsed by MedEthicsEU and CTAG; implementation date aligned with implementation article 11 workaround – work in progress

Deliverables and priorities 2025-2026

- Update MedEthicsEU workplan for 2026+ is work in progress
  - Biotech Act
  - FAST-EU pilot
  - EU4Health Joint Action FACT-EU
- New working group on MDR/IVDR studies and MREC review: started in 2026
- Continue participation in several ACT-EU priority actions and CTR collaborate

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- MedEthicsEU inputs and discussions have had an impact on the proposed revisions of CTR
- Now the continued negotiations will be the responsibility of the Member States
- MedEthicsEU will support discussions and initiatives for implementation of the revised CTR.