



14 NOVEMBER 2025
Hybrid Event

CTR and how to move forward: MedEthicsEU perspective

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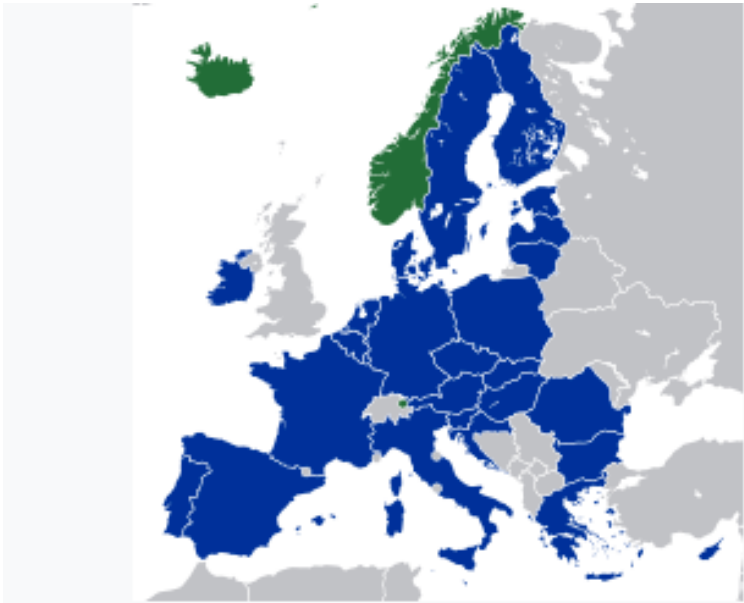


Attractiveness is built through
cooperation, not competition.

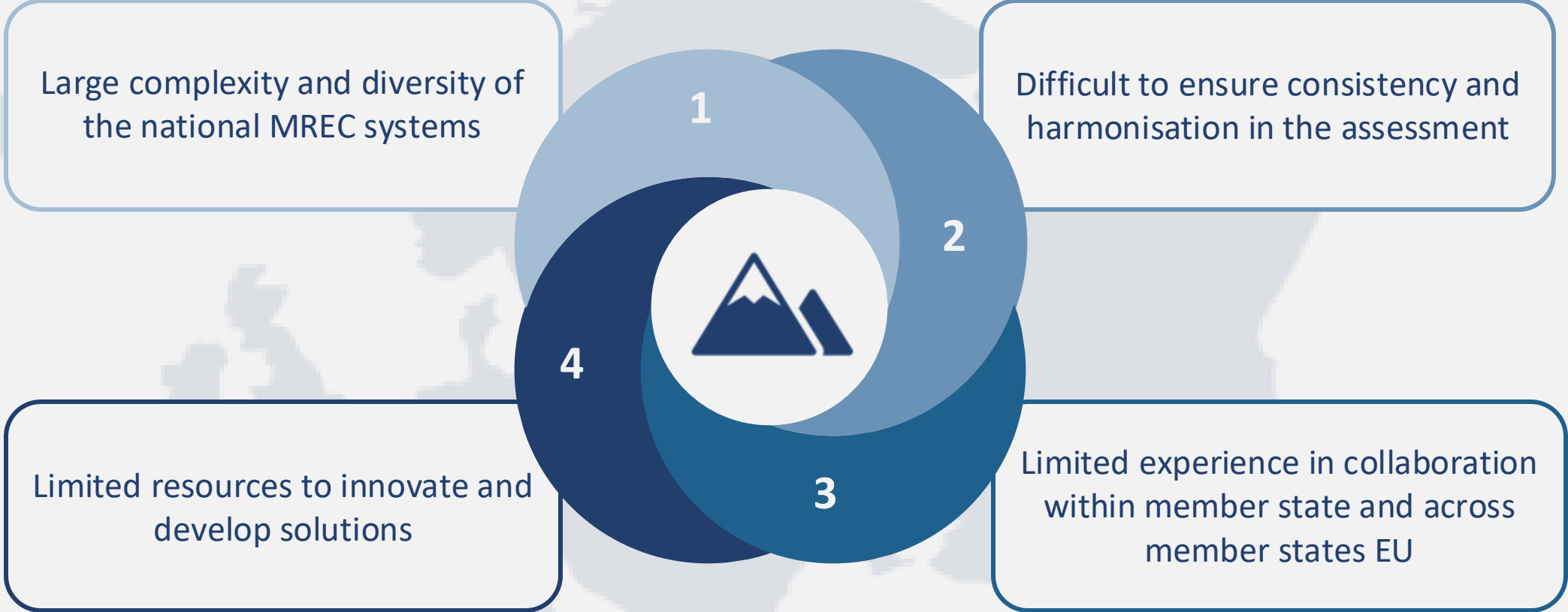
Europe remains relevant only
when it acts as one.



EU moto: United in diversity



CTR implementation: key barriers for the MRECs



The complexity of the MREC system in EU



Establishment of MedEthicsEU

1. Establishment

...Kick-off February 15, 2024.

2. Nomination

...Members of MedEthicsEU are nominated by the National Contact Point (CTAG).
...Official start 15 October 2024

3. Initial meetings

...get to know each other
...understand the diversity between Member States
...strengthen the collaboration between MS

5. Workplan and outputs

...MedEthicsEU workplan and “list of agreements”.
...Transparency on part II requirements.

4. Areas of interest

...Overview of opinions, procedures, Q&As
...Forum to discuss specific aspects in assessment of clinical trials.
...MedEthicsEU involvement in other EU-fora.

What is the composition of MedEthicsEU?



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

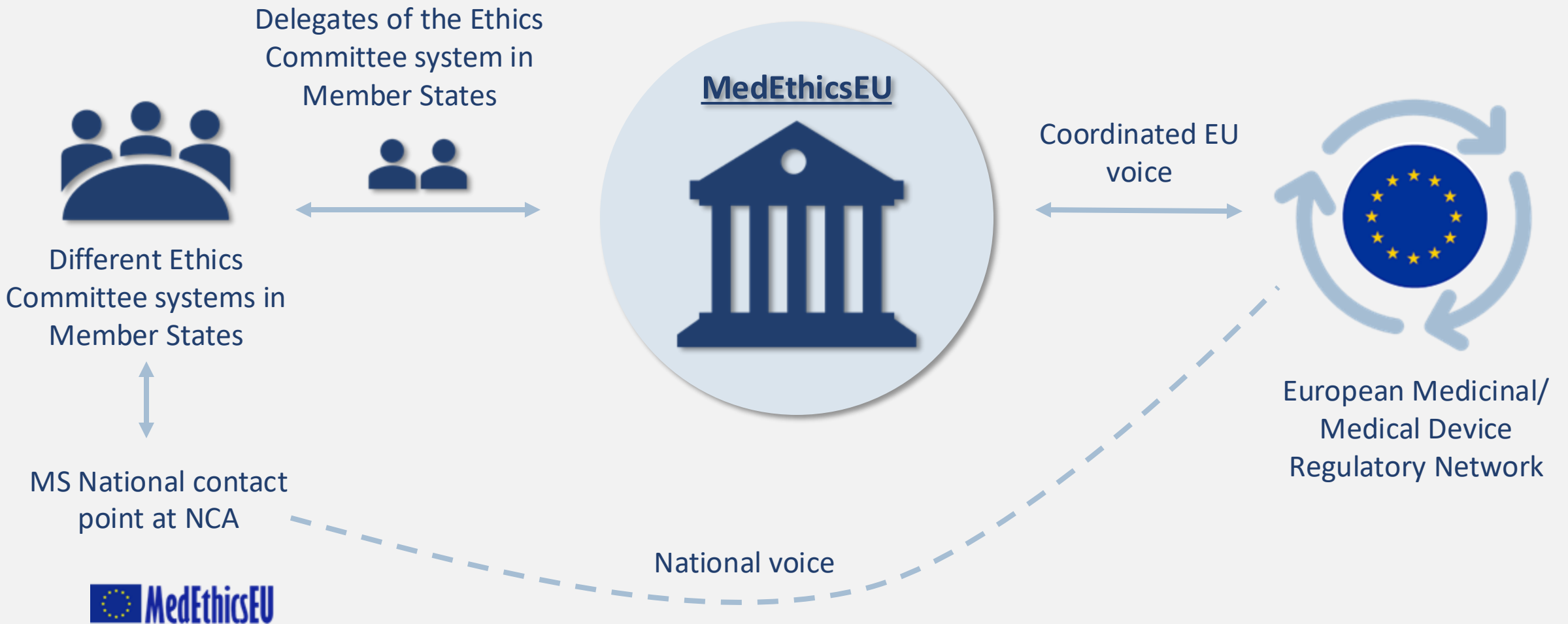


Representatives from **26 Member States** in EU/EEA and consists of both **secretariat staff** and **committee members**.



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

Strengthening the cooperation through the creation of MedEthicsEU





The goal of MedEthicsEU

- ✓ **Ensure** that EU is an attractive and competitive region for clinical research
- ✓ **Share** experiences in a forum where ethical aspects of clinical trials are the main focus
- ✓ **Harmonise** procedures and content of the scientific and ethical review with respect for national law and cultural differences
- ✓ **Create** overview and transparency for stakeholders and develop guidance.

Towards the goals



SHARE



HARMONISE



CREATE

SHARE



- Maintain an **open conversation** in the group
- **Harmonise** when possible and be transparent when we can't
- Ensure **appropriate processes** for Member State inputs
- Ensure that the **voice of the MedEthicsEU** is also present **in other regulatory EU fora**



HARMONISE



- Develop internal **Best Practices** to **harmonise the assessments procedures** (Considerations/RFI)
- Ensure **training of ethics committees** in Best Practices (e.g. IncreaseNET training)
- Develop and update **EU templates** to **align Part II requirements** (e.g. recruitment template)
- Secure **better resources** for the work in MedEthicsEU (Joint Action Proposal)



SHARE



CREATE

CREATE



- Create **MedEthicsEU workplan** with prioritised topics
- Collect information on use of national **templates**, national **laws** and national **guidelines** and publish overview on webpage ([MedEthicsEU - European Commission](#))
- Develop and publish **guidance for sponsors** (e.g. CTR [Q&A 3.13 on change of principal investigator](#))
- Publish “**list of agreements**” on MedEthicsEU webpage



Collaboration on EU initiatives and activities

Supporting clinical trials in the EU*

Supporting the implementation of the [Clinical Trials Regulation](#) and further harmonisation (**CTR Collaborate**)

Maintaining and improving the Clinical Trials Information System ([CTIS](#)), the IT tool of the CTR

Accelerating Clinical Trials in the EU (**ACT EU**) initiative: EMA, HMA and EC to deliver *better, faster and smarter clinical trials* and support innovation

Supporting efforts to streamline trials of medicines & medical devices (**COMBINE programme**)

*Slide EMA about ACT EU

CTR and Biotech Act: MedEthicsEU discussion paper on 12 items

1. Introduce risk-proportionate, flexible procedures and reduce administrative burden - simplified procedures for LICT
2. Role of MedEthicsEU and harmonised procedures
3. Reform the assignment process (with better balancing CoI) for MREC
4. No general centralization of MREC assessment into one MREC for all EU MS
- 5-7 Clarify core definitions, simplify/streamline regulatory framework, use plain precise language
8. Revise rigid provisions for trials on minors (Article 32)
9. Add legal provisions for public health emergencies (PHE)
10. Serious breach reporting
11. CTR/MDR/IVDR synchronisation
12. CTIS upgrade: Enable CTIS to operate efficiently, fostering trust in the system while minimizing administrative burden.

The essence of an MREC review



- Assessment of the ethical and scientific validity and value
- Alignment with international acknowledged guidelines
- Protection of the rights, well-being, and safety of participants
- Ensure local applicability by a broad perspective from experts and patient representatives
- Protects ethical principles such as autonomy, beneficence, non-maleficence, and justice.

Lessons learned for a new collaboration



Collaboration across Member States, **authorities** and **stakeholders** is **crucial** for success



Increased **awareness** and prioritisation on the **continuous development** of the **ethics committee system**



Create political awareness in Member States to **ensure resources**



Thank you for your attention!

Vă mulțumim pentru atenție!
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