The role of Ethics Committees in clinical trials

Perspectives from the Danish Medical Research Ethics Committees (MRECs)

Helle Christiansen, PhD, Head of European Affairs

National Center for Ethics, Science and Ethics, Research Ethical Assessment, Denmark

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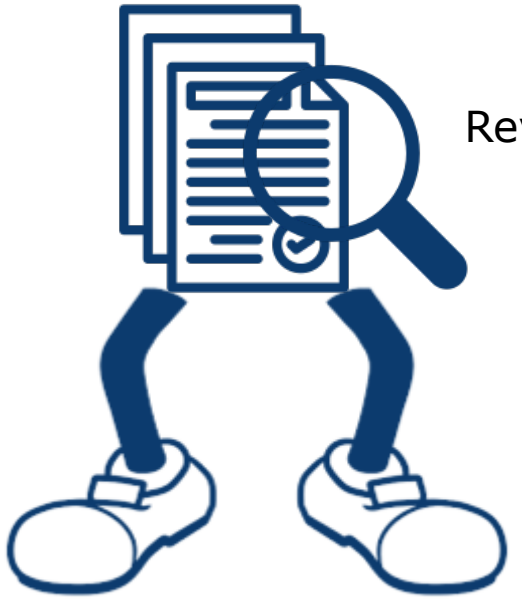
Review of clinical trial applications stands on two legs



Review of clinical trial application

National Competent Authorities (NCAs)

Medical Research Ethics Committees (MRECs)

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The review of the MRECs is mainly a national matter

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**

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MREC participation and collaboration with NCA are national decisions

One clinical trial application dossier

Amongst others:
- Protocol
- Investigator's Brochure
- Scientific advice/PIP

Review by MRECs

Amongst others:
- Recruitment arrangements
- Subject info/informed consent
- Financial /other arrangements

Review by NCA

Part I
Central RMS conclusion

Part II
Conclusion by MS

One decision per Member State (MS)

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RMS: Reporting Member State

The frame of the review by MRECs are decided by EU CTR

Content of dossier

Submission through EU portal

Timelines

Fixed format of assessment report

Best practice

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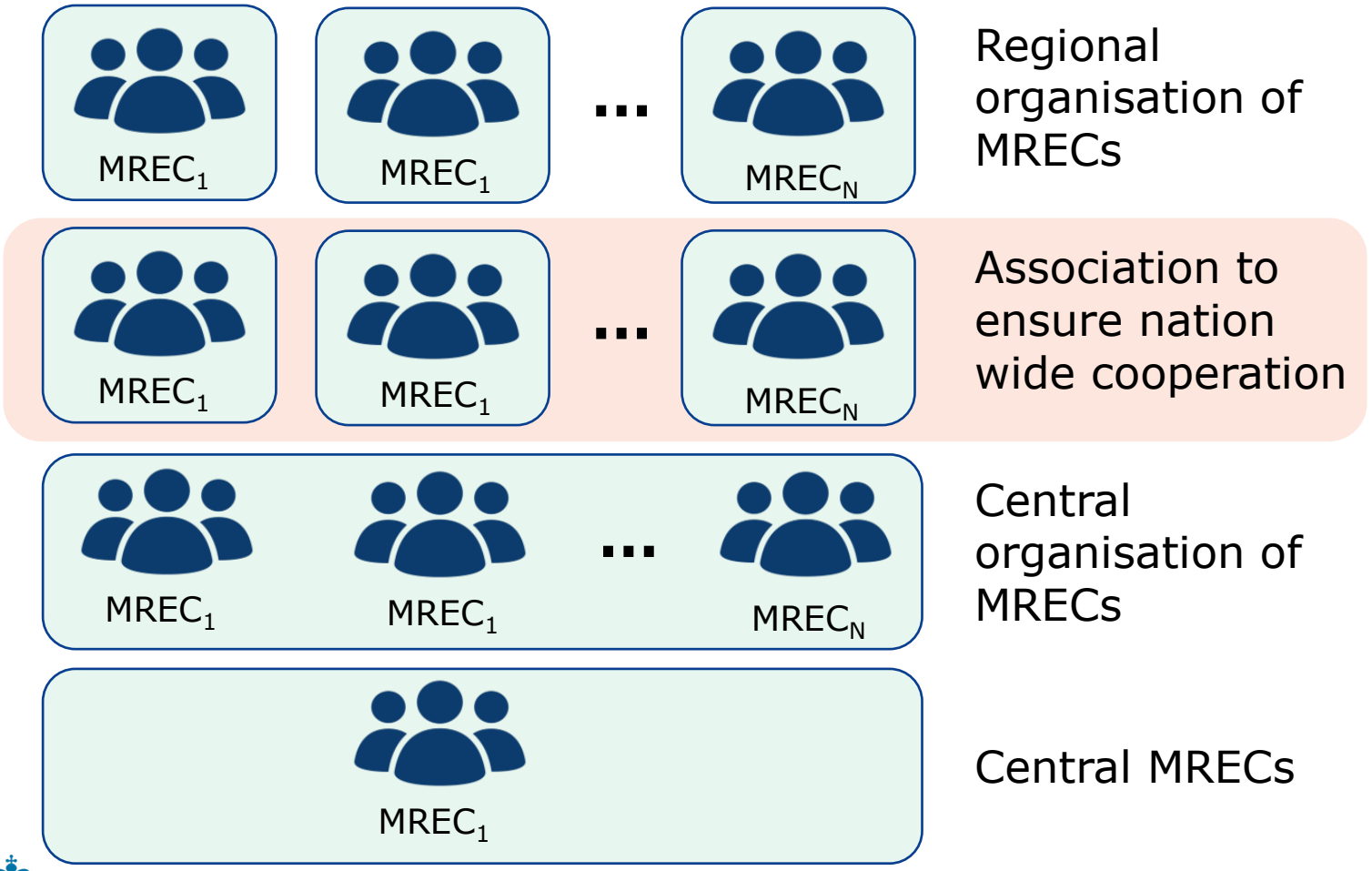
Collaboration is needed between the diverse organisations of the MRECs in EU MSs



EU ethics platform

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Secretariat supporting MRECs

Summary

Implementation of the CTR have introduced a **new way of working** for the Danish MRECs

- Increased collaboration with the National Competent Authorities
- Framework of the review by MRECs is strictly controlled by CTR

    -> there is a need for discussion and alignment between the MRECs from other MSs

    -> it is a essential to establish a dedicated platform to increase the level of alignment between the MRECs of the different MSs in the EU

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