# MREC participation a

- Chair of the Dutch Association for MRECs
- NL decentralized integrated review system
  - Harmonization process
  - Redefining collaboration with the CA
- Regulatory assessment may be suboptimal – but regulatory is only one aspect of the assessment
- However, we are proud of our integrated medical-ethical review system
  - Medical: physician-scientists with experience in clinical reserach: medical need, feasibility, valid hypothesis, risk-benefit, scientific validity, clinical equiposie, etc
  - Other members: ethics, legal expert, lay person, clin pharmacologist and hopsital pharmacist, pediatrician, (bio)statistician, MDR expert
  - Ethics: placebo vs standard treatment, clinical equipoise, vulnerable populations, mitigation of risks and burden, validity of IC process, fair subject selection, post-trial access, etc
- In a broader sense:
  - Ethics forum needed with representatives from each MS
  - Scientific advice may need MREC participation/ ethical assessment
  - Training and harmonziation across Europe urgently needed as well as solving interpretation differences between MS
  - Make sure innovation is not lost in the process

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

**Part I**
**Central RMS conc**

Review by NCA

ent
nts

DANISH NATIONAL CENTER FOR ETHICS



RMS: Reporting Member State