



REK

DE REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Current status Norway

Seminar NTA

January 30, 2017

Current status

- Undecided
- Processes in the Ministries regarding regulation/new legislation has been started
- Tentative initiatives for Nordic cooperation (from Ministry of Health)
- Informal inquiry and processes on the part of REC
- Planning with The Medicinal Authority of Norway

A view from REC – qualified guess

- Value of Nordic committee – yes, but unfeasible and unrealistic, at least in the short run
- Probable that there will be established 2 new REC committees that will fulfill the requirements of the EU regulation for CT- and only deal with CT
- Served by one of the present secretariates
- Cost estimates submitted to Ministry

Qualified guess

- The Norwegian Medicines Agency as national coordinator
- The Norwegian Medicines Agency administers IT system (separate from REC's IT-system SPREK)

Inquiry and suggestions by REC to Ministry

- After field trips to Sweden and Denmark
- Conclusion: precluded Nordic model; national solutions in different directions
- Internal processes within REC for preparation
- Inquiry (30 pages)

Inquiry

- Organizational changes from present status under the medical faculties, either as a «section» under a Ministry or as a «section» under the central administration of the universities

Inquiry

- How to implement CT:
- either by including CT in present system, while changing from fixed deadlines to «running» deadlines for all projects;
- Or establishing (at least) two new REC committees with separate «handling» with the Medicinal Authority.

Planning with The Norwegian Medicines Agency (NoMA)

- Premises: NoMA as national contact point and coordinator, REC will engage in all phases (part I and II), NoMA as administrator for case management, workflow with REC
- Local database and simple IT system for com. with REC (not considered feasible to do all case management in EU portal)
- NoMA communicates with EU portal