NTA ethics
Industry view

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From the archive

- October 1996
  - Regional Ethics committees (REK) 10 years
  - The REK system seen from the outside
  - Randi Riise, Norwegian Medicines Control Authority

From the archive – NoMA vs REK

- Principles:
  - Access to source data (patient notes)
  - Withdrawal of data from patients withdrawing their consent?
  - Placebo arms?

- Individual cases:
  - Morphine to healthy volunteers?
  - Ending treatment in patients in need of treatment?
  - Cigarettes to ex-smokers?

From the archive

- REK vs REK vs REK vs REK vs REK
  - Access to source data
  - Placebo treatment in patients with
    - Mild/moderate hypertension
    - Migraine

From the archive -

- Main topics
  - Where is the border between science and ethics?
  - Are the REKs approving or giving advice?
  - How do the REKs need to comply with
    - Documentation
    - Evaluation
    - Timelines
    - NoMA evaluations and decisions

    - Concequences of CT directive??

From the more recent archive

- January 2017
  - REK 30 years
  - The REK system seen from the outside and a little bit from the inside
  - Randi Riise, CRO/Pharma industry

- REK vs REK vs REK vs REK vs REK vs REK vs REK
  - Biobanks
  - Genetic sampling (ICF)
  - Broad consents
  - Quality of consents
  - Each committee their own pet subject?
    - --and you no longer know which committee----

Obstacles in Norway

- REK is normally not the problem for industry
  - Competent
  - Open for discussion
  - (Industry applications are normally complete and sufficiently detailed)

- Consistency would be welcome

- Hospitals – lack of systems
- Physicians – negative to industry
- Contracts – takes too long
- Data protection officials

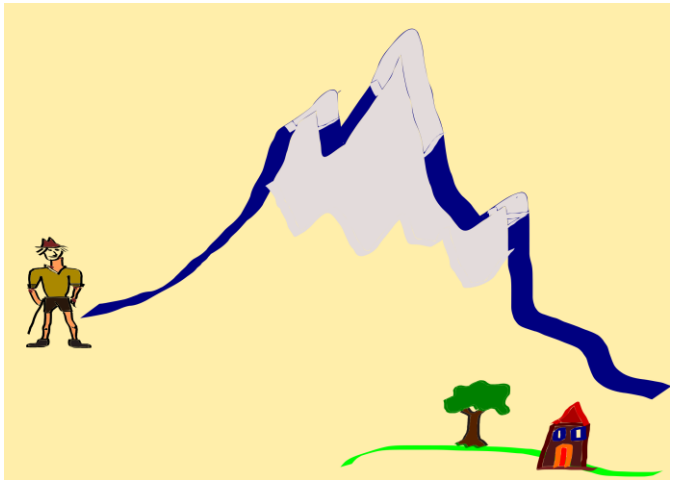
Regulation

- Making the EU more attractive for clinical trials
- Reversing the decrease in number of trials in the EU
- Maintaining high standards of patient safety

- Transparency
- Consistency
- Effectiveness
- Reliability
  - Timelines
  - Evaluation
    - Science
    - Ethics

Challenges

- National systems in each MS being
  - Effective
  - Predictable
  - Competent
  - -focused on ethics
- Cross-national collaboration with
  - Close interaction
  - Harmonized evaluation processes
  - Willingness to learn from best practice
  - Willingness to learn from each other



- How difficult could that be??

Different ethics?

- Different within EU?
- Different between Nordic countries?
- Different within each country?

- Different between
  - Industry
  - REK/NEM system
  - Academia

  ?

Different ethics?

- Drug trials
  - Intervention
    - Do we physically harm the subject?
  - ICH-GCP 2.3
    - The rights, safety and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society

- Other trials (registry, chart, observational, retrospective---)
  - Interest of society
  - Consent requirements
  - Waiver of professional secrecy
    - Do we offend the subject (with or without him/her knowing?)?

Separate committees for medicinal products

- Advantages
  - Consistency between projects
  - Consistency between industry projects/other projects
  - Efficiency
  - Professionality
  - Competence
  - Continuous development and qualification
  - Timelines
  - Procedures
- Disadvantages
  - «Ethics for drug studies»
  - Lack of learning across project categories
    - ICF principles
    - Data protection
    - Exception from IC
    - Waiver of professional secrecy

Harmonized Nordic system

- One Nordic committee for drug studies
  - Efficient
  - Consistent
  - One set of procedures
  - Close communication
  - Strong, coordinated Nordic voice in the EU system
- Harmonized committees in each country
  - Efficient on national level
  - May be efficient on Nordic level, if
    - Harmonized procedures
    - Harmonized practice
    - Close, scheduled communication
- Harmonized national committees, harmonized within the Nordics

Industry wish-list

- Within Europe
  - Nordic reputation of
    - High quality performance
    - Consistent and reliable output
    - Ethics evaluation to be trusted
- Within the Nordics
  - Harmonized procedures
  - Common ways of working
  - Close communication
- Within each country
  - Effectiveness between (and within) committees
  - Consistency between committees
  - «Each cleaning their own house»

Industry vision

Look to the Nordics