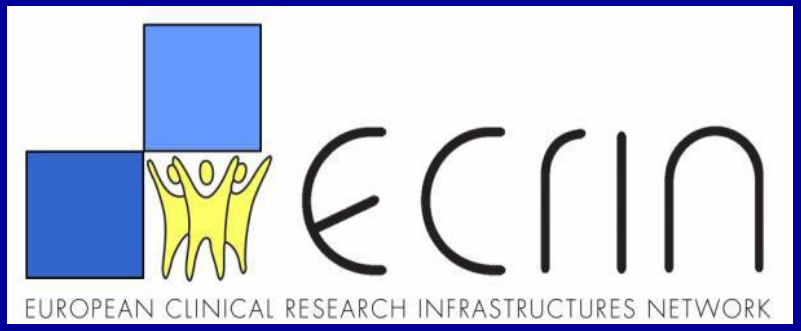

ECRIN proposals for amendments to the Declaration of Helsinki: placebo, informed consent, transparency

Christian Gluud, Jacques Demotes-Mainard, Vittorio Bertelé, Rita Banzi, Xavier Carné, Silvio Garattini and ECRIN

Copenhagen Trial Unit, Denmark

European Clinical Research Infrastructure (ECRIN)

ECRIN, an infrastructure supporting international cooperation in clinical trials

- **Connecting 23 national clinical reseach infrastructures in Europe**
- **EU funded**
- **About 25 clinical trials**

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK

Declaration of Helsinki soon to – and what 50 years!!!!

Proposals for amendments to DoH

- Placebo
- Informed consent
- Transparency
- Thorough knowledge and clinical relevance
- Risk of interventions
- Medical research limits the risks
- Independence and quality of research ethics committees

Placebo (§32)

Problem: Clarification is needed to prevent misuse of placebo

- **Placebo, or no treatment, is acceptable only in studies where no current proven treatment exists**
- **The patients who receive placebo or no treatment must not be subject to any risk of harm ("serious or irreversible" must be deleted!!)**

Informed consent (§32)

Problem: Participants take risks without expected benefits in non-inferiority and equivalence trials

- **The benefits, risks, burdens and effectiveness of an intervention must preferably be tested in a superiority design rather than a non-inferiority or equivalence design**
- **Patient information should explicitly and unequivocally mention the use of a non-inferiority or equivalence design, and its absence of anticipated individual benefit**

Transparency (§19) (§30)

Problem: Transparency is still lacking

- **Clinical trial database must be compliant with the World Health Organization International Clinical Trial Register Platform**
- **Registration must include the full protocol and amendments**
- **Deposition of raw anonymised data for the scientific community**

Thorough knowledge and clinical relevance (§12 and §31)

Problem: Most trial protocols lack thorough knowledge and focus on clinical relevance

- **Thorough knowledge should be obtained by systematic reviews when relevant (§12)**
- **Clinical relevance should prevail over methodological or statistical considerations (§31)**

Risk of interventions (§8)

Problem: No mention of the risks of interventions in randomized clinical trials and clinical practice

- **The risks of interventions within and outside randomized clinical trials do not seem to differ**

Medical research limits the risks (§8)

Problem: No explicit mention in DoH of the positive consequences of medical research

- **Medical research limits the risk of an intervention to a relatively small population for a relatively short time**
- **This is advantageous compared to the introduction of an intervention into clinical practice without sufficient medical research backing the intervention**

Independence and quality of research ethics committees (§15)

Problems: Many committees lack full independence and sufficient training

- **Research ethics committees must be fully independent of the researcher, the sponsor, their host institution, and any other undue influence**
- **Its members must undergo appropriate training**

Thank you very much for your attention and consideration!