EU Clinical Trials Regulation vs. eettisten toimikuntien tehtävät ja organisaatio Suomessa

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Report on the Ethical Review Process of Clinical Trials in the Nordic Countries

The Challenges and Opportunities of the New Clinical Trials Regulation

Nordic Trial Alliance Working Group 1 on Ethics

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Background

The need for a reform of the current legislation and practices is based on the new EU Regulation No 536/2014 on clinical trials on medicinal products for human use. The new Regulation necessitates all member and associated states to make significant changes in their legislation and practices with regard to their assessment processes concerning clinical trials.

The current estimate of the EMA is that the implementation will take place in 2017.

Regulation vs. Directive

The EU Regulation No 536/2014 repeals the Directive that has been criticized by stakeholders for having increased the regulatory burden and costs of conducting clinical trials in the EU.

This is one of the main motivations for the new Regulation – to re-establish the EU's competiveness in clinical trials and in pharmaceutical development.

Requirements for ethical review

"It should be left to the Member State concerned to determine the appropriate body or bodies to be involved in the assessment of the application to conduct a clinical trial and to organise the involvement of ethics committees within the timelines for the authorisation of that clinical trial as set out in this Regulation. Such decisions are a matter of internal organisation for each Member State. When determining the appropriate body or bodies, Member States should ensure the involvement of laypersons, in particular patients or patients' organisations. They should also ensure that the necessary expertise is available. In accordance with international guidelines, the assessment should be done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. The persons assessing the application should be independent of the sponsor, the clinical trial site, and the investigators involved, as well as free from any other undue influence."

Challenges

- New technology to be developed
- The timelines will be challenging to all involved parties
- Ethical review will remain national and not strictly regulated – quality, predictability, harmonization?
- Sponsors, CROs and sites/investigators need to learn to use the new system

Opportunities

- The Nordic countries are committed to developing efficient procedures
- Nordic harmonization may be achieved
- May become easier for sponsors to start a country – may help small countries with efficient procedures
- Small sites may benefit: shared phase 1 studies, demanding phase 2 studies, rare diseases

Ethical review in Finland?

- Planning has been started
- Nordic harmonization should be achieved
- One national, relatively small committee for clinical drug trials, with frequent meetings, efficient procedures, sufficient resources and a large pool of experts?
- Close collaboration with Fimea – Part 1 and Part 2 cannot be strictly separated and information exchange will be needed?
- Regional committees need to be maintained for ethical assessment of other types of clinical research