Clinical Trials Regulation

-status of implementation in Finland

Working group

- A working group was set up in September 2015 by the Ministry of Social Affairs and Health
- representatives from Ministry of Social Affairs and Health, Finnish Medicines Agency FIMEA, National Committee on Medical Research Ethics TUKIJA, regional ethics committees, The National Advisory Board on Social Welfare and Health Care Ethics ETENE, academia and pharmaceutical industry
- the working group was tasked with drafting a proposal for the necessary legislative changes in the form of a draft government proposal
- the legislative changes are planned to be introduced in the Parliament in fall 2017, preceded by a public consultation

Current planned solutions: ethical assesment

- current situation: TUKIJA assesses about 25 % of clinical trials and the regional committees the rest
- plan for future: all ethical assesments of clinical trials on medicinal products for human use to be assessed by one national ethical committee which replaces TUKIJA
- the new ethics committee will probably be organizationally separate from the competent authority Fimea
- both Fimea and the ethics committee will assess part I (the ethics committee only some parts), ethics committee part II
- Fimea will make the national decision
- co-operation to ensure smooth handling in a tight schedule
- Fimea to be the national contact point

Impact on other medical research legislation

- currently all medical research is regulated in Medical Research Act (488/1999), clinical trials in part also in Medicines Act (395/1987), + in decrees and administrative regulations
- the plan is to gather national legislation to one Clinical Trials Act (on human medicines)
- necessary technical amendments to be made in Medical Research Act
- in addition, the working group reviews whether some aspects could be harmonised so that same rules apply in other medical research as well (e.g. informed consent and vulnerable populations)
- regional ethics committees continue to assess other medical research

Some other planned national aspects

- current system (regulatory patient insurance and private insurance, including Pharmaceutical injuries insurance) assessed to meet the demands of the damage compensation provision
- possible adoption of the cluster trials procedures
- English for the most part accepted as a language in the application form
- appeal procedure: first step is to seek rectification (omprövning) from Fimea, then an appeal to an administrative court

Examples of some other still-to-be-decided issues

- organisational issues of the ethics committee assessing clinical trials
- other tasks TUKIJA currently has, e.g. offering a second opinion on a negative statement by a regional ethics committee
- requirement of a legally designated representative of the sponsor or a contact person
- cost of the investigational medicinal products possibly to be covered by the subjects in some cases
- level of fees

Thank you!

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