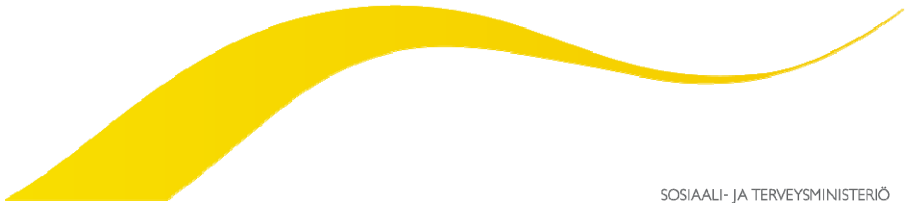
CLINICAL TRIALS REGULATION

Status of implementation in Finland

Juliana Tenovuo 23.10.2017



SOSIAALI- JA TERVEYSMINISTERIÖ

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 spring 2018, preceded by a public consultation
- First consultation has already been made, some areas need to be consulted separately in the near future

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 assessments of clinical trials on medicinal products for human use to be assessed by one national ethical committee which replaces TUKIJA
- Both Fimea and the national ethics committee will assess part I (the ethics committee only some parts), ethics committee will assess 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

The organization of the new ethics committee

- The new ethics committee will be established under the Ministry of Social Affairs and Health as an independent organ
- The ethics committee must have members of expertise in clinical trials, medicine, statistics, ethics and law. There also has to be a layman who represents patients.
- The ethics committee also has other tasks in addition to the assessment of clinical trials. It is suggested that the committee for example works as the expert organization in questions regarding research ethics and takes part in international cooperation between the relevant authorities.

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 in 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 the 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
- English for the most part will be accepted as the language of the application documents. The documents for the research subjects need to be in Finnish or Swedish.
- Appeal procedure: first step is to seek rectification 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 or a contact person of the sponsor
- Cost of the investigational medicinal products possibly to be covered by the subjects in some cases
- Level of fees
- Possible adoption of the cluster trials procedures
- Other legislation related to clinical trials, such as biobank act, tissue law and medicines act

Informed consent and the GDPR

- It is still unclear how the Clinical Trials regulation should be interpreted with the General Data Protection regulation
- The biggest open question is how the data from clinical trials can be used after withdrawal of the consent
- The WP29 is expected to give an interpretation regarding the inconsistencies between the CTR and the GDPR, which hopefully clarifies the issue

Thank you!

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