Reviewer's report

Title: Clinical research in Finland in 2002 and 2007: quantity and type

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Reviewer: Markus Hartmann

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The paper from Elina Hemminki and colleagues deals with a topic of raising significance, the need for quantitative data on numbers and type of clinical research. Although Finland has a rather small number of inhabitants and is therefore not ‘heavyweight’ in terms of numbers of trials conducted and publication activities, its current system for national registration of all kinds of interventional and non-interventional studies on medical (and I believe also behavioral) research including human subjects shows features unique in Europe.

With view to the changing regulatory environment (EU Pharmacovigilance legislation) and the increasing demand from HTA bodies to provide effectiveness data, the relevance of non-controlled study designs and observational studies intends to augment. Indeed very few data are available showing the proportion of clinical drug trials in terms of the overall number of studies reviewed by ethics committees.

The exposition, data descriptions and analysis are solid; however one critical issue (see comment No 3) requires clarification. My comments are hence mainly intended to assist readers in their assessment of the data and to provide references for additional cross-links.

1) Section ‘Background’: In relation to reference 12, please cite/name the ‘comparison countries’ in the text, as the cited reference is only available in Finnish.

2) Section ‘Methods’: It is not well explained, why years 2002 and 2007 have been chosen for this prior-posterior comparison. A comparison of years 2003 and 2007 would have had the advantage to have data available for direct comparison with the ICREL report (see reference 21) which compared data from year 2003 with those for year 2007.

3) Section ‘Methods’: It is however not clear whether the data collection was based on the (mandatory) national research registry (i.e. online data compilation) or on individual, written/sent responses from each of the 20 REC. In the latter case it is critical (Major compulsory revision) that the authors provide additional information about the return rate of data/answers to their investigation as the probability is low that each REC answered to 100% to the authors’ request to provide data.

4) Section ‘Results’: In Table 1, a distinction is made between ‘Other medical research’ and ‘Other research’. The respective footnote 2 in Table 1 refers readers to the methods section, but neither in that section nor in the Appendix a
definition of both categories is provided for readers not familiar with Finnish law. Please provide explanations and/or definitions.

5) Section ‘Results’: In Table 2 (and Table 3), the description ‘main content’ is used with five classifications therein. In European Pharmaceutical law (for medicinal products as well as for medical devices) three main intentions for healthcare products (and interventions) are distinguished: 1) prevention/prophylaxis of disease, 2) treatment of disease (and/or disabling or perturbing conditions), and 3) diagnosis of disease. In this context, it is unclear to readers what the classification ‘biomedical’ is meant/used for. Please provide explanation.

6) Section ‘Discussion’: Apart from Finland, valuable data on the distribution of clinical trials in comparison to other forms of medical research exists for the Netherlands, where a central ethics committee (CCMO) oversees a large proportion of medical research done in the Netherlands. The annual statistics (‘CCMO Jaarverslag’) are publicly available since year 2000 and might serve as a useful reference to discuss the Finnish findings.

7) Overall manuscript: The manuscript is quite long. It is recommended to shorten the manuscript significantly and omit some passages – especially those that refer to findings outlining some specificities of the Finnish health care system (e.g. chapter on ‘Geographical distribution’) and which are therefore of limited interests for readers abroad.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I have not received any reimbursement, fees, funding, salary from any organisation that may in any way gain or lose financially from the publication of this manuscript.

Not owning any stocks, shares, patents. No other competing financial interests.

I declare that I have no competing interests.