Conference Abstract

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Title: **Fair Access to Clinical Trials for Incompetent Subjects under the new EU Regulation No. 536/2014**

Abstract text: Clinical trials involving subjects unable to give consent raise numerous ethical concerns, particularly if there are no scientific grounds for expecting that participation in the trial will produce a direct benefit to the subjects. But it is widely recognized that there is both a practical need and an ethical demand for conducting such research. The exclusion of incompetent subjects from "non-beneficial" clinical trials would withhold development of various fields of medicine of special importance for the populations represented by the subjects, and – in result – would unjustly deprive those classes of future patients from access to new, safer and more efficient medical products.

The aim of this presentation is to critically analyze legal requirements for conducing "non-beneficial" clinical trials on subjects unable to give consent, especially minors and patients in emergency situations, prescribed by the new Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, in the light of relevant provisions of the WMA Declaration of Helsinki (2013), and the Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (2005).

I will argue that the new Regulation is both under protective and overprotective for these classes of subjects/future patients. It is under protective, because it adopts an ambiguous definition of minimal risk and minimal burden. The ambiguity stems for the added phrase "in comparison with the standard treatment of the subject's condition" which allows for a relative and prone to exploitation interpretation of the threshold. And it is overprotective as it does not allow for "non-beneficial" clinical trials in emergency situations, and introduces the minimal risk standard as a general requirement for conducting clinical trials in such situations. I will propose a more adequate (non-comparative and objective) interpretation of the minimal risk threshold adopted by the new EU Regulation.

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