Author

GODT, Christine

Title

Probandenschutz und moderne medizinische Forschung / Christine Godt und Karsten Engelke

Publication year

2010

Source/Footnote

In: Wissenschaftsrecht. - 43 (2010) 1, S. 2 - 27

Inventory number

28156

Keywords

Wissenschaft : Medizin ; Forschungsförderung ; Wissenschaft und Wirtschaft

Abstract

The article analyses the scope of protection for test persons in phase I clinical trials (transition from animal testing to clinical tests in humans). Since recently, research institutions and start-ups hit the news because of derailed testings. In earlier days, only clinical trials of phases III and IV caught the attention of the larger audience because of the high number of people involved. However, it is the dramatic course of phase I trials which highlight the risks involved in innovation. Whereas economic safety via obligatory insurance coverage is standard in Germany, European and more so non-European guidelines only require fault based liability. The article portrays the most recent cases, reviews the applicable rules in multicenter studies, and inquires the modern changings in the clinical testing landscape. Its most important finding is that the trials business has moved from industry into research institutions. Research institutions improve the marketability of their innovations by conducting phase I studies. The recent cases reflect not only specific modern risks of biomedical pharmaceutical innovative compounds. They also reflect a new set-up of clinical trials which are not conducted by university hospitals and sponsored by ?big pharma?, but conducted and sponsored by

research institutions in a networked international environment (multicenter studies). The article thoroughly describes the current legal situation in Germany and contrasts it with the European Good Clinical Practice Guidelines. It concludes that both, the German and more so the European legal situation does not cover properly the risks taken by test persons. In the end, it submits five proposals to mitigate the situation. (1) It proposes an additional test step for innovative compounds which are designated to have an effect on the human immune response. After being tested in laboratory model animals the substance should be tested in animals which share the human immuno response. (2) European guidelines should require a medical doctor to supervise (and be present) when the substance is administered to humans. (3) Liability rules should be harmonized for clinical trials across Europe. The authors do not advocate a non-fault based liability rule, but a reversal of the burden of proof. In addition, they call for the coverage of immaterial damages for pain and suffering. (4) They advocate a compulsory insurance for the benefit of test persons (safeguarding against risks of permanent disability). Research institutions should not be exempt from obligatory coverage. Economic safety should be adapted as a standard of good clinical practice in the Helsinki Declaration. (5) Coverage for clinical trials is yet a good business for insurance companies without significant risks to the industry. The article reflects about its role in the pursuit of clinical trials. It argues that it should adopt a role as an advisor for the ?best risk absorber? (here the research institutions) to better manage the growing risks involved in testing innovative substances. By this, insurances could grow into a role of institutional patient advocates in the long run. (HRK / Abstract übernommen)