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Title

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Abstract

The legitimacy of clinical trials on incapacitated subjects which have no direct benefit for the individual subject has always been a strongly contested ethical and legal issue. This article discusses whether and under which circumstances these studies might be admissible before examining how the legislator and international regulations have dealt with this subject. The article will show that the fundamental rights of both the German Basic Law (Grundgesetz) as well as those of the Charter of Fundamental Rights of the European Union would allow research with benefit only for the group of the incapacitated subject to a greater extent than national legislation (especially the German Drugs Act [Arzneimittelgesetz]) is allowing at the moment. Under the regime of the new EU Regulation No. 536/2014 on clinical trials on medicinal products which will come into effect in Mai 2016 (at the earliest), the European legislator has now set a new course. For the first time on European level, the regulation will allow clinical trials on incapacitated adults which have no direct benefit for the individual subject but only for the group they are part of. It is now for the German legislator to decide

whether he will seize the opportunity to establish stricter national rules – and thus sustaining the existing rules for incapacitated adults – or not. His decision might also have influence on other fields of clinical research which do not fall under the new regulation such as non-interventional clinical trials on medicinal products, epidemiological research or trials on medical devices. This article will provide general guidelines for the treatment of these studies and for possible reforms of the existing legislation on medicinal products. (HRK / Abstract übernommen)