



Arbeitskreis Medizinischer Ethik-Kommissionen

in der Bundesrepublik Deutschland e.V.

Der Vorstand

AKEK | Charlottenstraße 42 | 10117 Berlin

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Massive Functional Problems of the EU Clinical Trials Portal CTIS Threaten Drug Research in Europe

Regulation (EU) No. 536/2014 on clinical trials on medicinal products is applicable since end of January 2022. In accordance with this regulation all research projects involving medicinal products for human use must be applied for and approved throughout Europe via the electronic portal CTIS starting January 31, 2023. Without sufficient functionality of this portal, the entire system of the EU regulation is in danger of failing.

The Working Group of Medical Ethics Committees in the Federal Republic of Germany (Arbeitskreis Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland, AKEK) and associations of applicants for drug trials from academic research¹ and the pharmaceutical industry², the German Association of Medical Faculties (Medizinischer Fakultätentag), Association of University Hospitals (Verband der Universitätsklinika) and the German Medical Association (Bundesärztekammer, BÄK) agree that the CTIS portal suffers from serious deficiencies even after 10 months of practice and is largely unmanageable for all parties involved. These deficiencies have not been eliminated in the past months, but have increased. As a result, the submission of applications for clinical trials as well as their processing by the ethics committees is massively impaired and unmanageable. This will foreseeably lead to a considerable weakening of the competitiveness of Europe as a research region and to disadvantages and risks for patients. There is a real danger that the dysfunctionality of the CTIS portal will lead to a permanent migration of drug trials to other regions of the world. This would also have negative consequences for early access to new therapies for patients in Germany and the EU. In addition, the careful review of research applications by ethics committees is severely hampered by the dysfunctionality of the portal.

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¹ German University Medicine (Deutsche Hochschulmedizin (DHM)); Network of Coordinating Centers for Clinical Trials (Netzwerk der Koordinierungszentren für Klinische Studien (KKS-Netzwerk)).

² German Medicines Manufacturers' Association (Bundesverband der Arzneimittel-Hersteller (BAH)); German Pharmaceutical Industry Association (Bundesverband der Pharmazeutischen Industrie (BPI)); Association of Research-Based Pharmaceutical Companies (Verband der forschenden Pharma-Unternehmen (vfa)); Federal Association of Contract Research Organisations (Bundesverband Medizinischer Auftragsinstitute (BVMA)).

The Working Group of Medical Ethics Committees and the above-mentioned associations therefore consider it as being urgently necessary that the transitional period pursuant to Art. 98 (2) of Regulation 536/2014, which expires on January 31, 2023, be suspended until the functionality of the EU portal CTIS has actually been established and demonstrated. The German Government is urged to align with other EU Member States to bring about such a moratorium in a timely manner.



Prof. Dr. Georg Schmidt
(für den Vorstand des Arbeitskreises Medizinischer Ethik-Kommissionen)