



**Arbeitskreis Medizinischer
Ethik-Kommissionen**
in der Bundesrepublik Deutschland e.V.



Dysfunction of the EU Clinical Trials Information System may harm clinical research in Europe

The EU Clinical Trials Regulation (CTR) 536/2014 on clinical trials of medicinal products for human use is mandatory from 31 January, 2023. Clinical Trial Applications (CTA) must be submitted via a common portal, the Clinical Trials Information System (CTIS). The Association of Medical Ethics Committees in Germany (AKEK) held an extraordinary general assembly on 6 March, 2023 with the participation of the Federal Physicians Chamber of Germany (BÄK). At this meeting, all participating Ethics Committees of the AKEK agreed that the CTIS still has significant shortcomings and requested an independent EU audit of the system by the end of this year in order to avoid further jeopardizing patients and the EU as an attractive location for clinical research.

The EU Clinicals Trials Regulation (CTR) 536/2014 on clinical trials of medicinal products for human use is binding since 31 January, 2023. All Clinical Trial Applications (CTA) must be submitted via a central portal, the Clinical Trials Information System (CTIS). According to Article 80 of the CTR this portal „shall be technically advanced and user-friendly so as to avoid unnecessary work.”

After one year of experience working with CTIS the AKEK members resume, that the requirements of Article 80 are far from being met. At their extraordinary assembly on 6 March, 2023 in the presence and with the support of the Federal Physicians Chamber of Germany (Bundesärztekammer, BÄK) the members stated that there are major functional deficiencies in CTIS and demand immediate action. All members criticized the CTIS portal as dysfunctional, poorly structured, user-unfriendly, and error-prone. An enormous additional workload focused on unnecessary formalities is hampering the case-by-case assessment of Clinical Trial Applications.

AKEK and BÄK see the danger of serious delays in the testing and introduction of novel therapies and the risk that clinical trials could be activated without sufficient diligence. Reactions from various other European countries also point in this direction. Clinical scientists from academic institutions and the Association of Research-Based Pharmaceutical Companies also report similar problems with CTIS. This could be dangerous for patient safety. An international drift of clinical research to non-European countries is an additional danger, as it damages research activities on our continent.

AKEK and BÄK therefore call for two measures:

- A systematic and independent EU-wide audit of CTIS involving all users should be conducted within this year to evaluate whether Article 80 of the CTR is being violated and whether CTIS needs a general modification and improvement.
- Clinical trials conducted under the former Clinical Trials Directive (CTD) 2001 in accordance with the CTR will have to be transitioned to CTIS over a period of three years. This might affect several thousand trials across Europe. To reduce the severe functional problems and increased workload with CTIS, this transition rule should be completely abandoned so that all such trials can be completed under the CTD.