MEDIZINISCHE FAKULTÄTUNIVERSITÄTSKLINIKUM MAGDEBURG A. ö. R.

COORDINATION CENTER FOR CLINICAL STUDIES

Profile

Otto von Guericke University Magdeburg as sponsor for clinical trials

For each clinical trial conducted after Arzneimittelgesetz (AMG) bzw. Medizinproduktedurchführungsgesetz (MPDG) a sponsor in the sense of Section 4 (24) AMG or No. 63 recitals MDR must be named. This sponsor bears the overall responsibility for the clinical trial.

The sponsor's overall responsibility includes, in particular, securing funding, initiating and organizing the clinical trial, and monitoring it.

Some funding organizations (BMBF / DLR, DFG) require the naming of a sponsor as well as the commitment to the guidelines for good clinical practice. (ICH-GCP-Guideline) principles also apply to studies that are not subject to the AMG or the MDR..

Sponsor-Model

In the case of clinical trials in humans that are initiated and managed by employees of Otto von Guericke University Magdeburg (OvGU) (Investigator Initiated Trials; IITs), OvGU Magdeburg assumes the role of sponsor.

The Rector of the OvGU Magdeburg has assigned the Dean of the Faculty of Medicine with the performance of these sponsoring duties by internal assignment of tasks. The executive body is the KKS Magdeburg. For the assumption and guarantee of sponsor duties, additional qualified third parties can be involved.

KKS Magdeburg has established a quality management system in accordance with the ICH-GCP E6 (R2) guideline and DIN EN ISO 14155:2020. This includes first and foremost the operational processes. This means that the KKS Magdeburg has a Erstberatung and, in the further course of planning and implementing an IIT, the Projektmanagement, the Monitoring and the SAE-Management takes over. Continuous monitoring of ongoing processes enables problems to be identified and rectified at an early stage and preventive measures to be initiated. In addition, the quality management system includes processes for Qualitätssicherung.

The assumption of sponsor tasks is regulated internally in a sponsor-examiner agreement. In this agreement, the responsible director of studies is authorized to represent OvGU Magdeburg as a sponsor in external relations. For contracts, the responsible director of studies receives the authority to negotiate but not to conclude. Contracts are concluded by the OvGU Magdeburg, Faculty of Medicine, represented by the Dean. Prior to this, a review takes place at the KKS Magdeburg.

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Anfahrt und Lageplan

KKS-Nutzungsordnung_ZMF

KKS Beratungsanfrage

Hinweisblatt Studienplanung

Kurzleitfaden Eine Studie-Ein Votum

Schulungsangebote intern NEU

Regularien

Links
KKS-Netzwerk
BfArM
BfS
Paul-Ehrlich-Institut **PEI**
Bundesministerium für Gesundheit
European Medicines Agency **EMA**
Registrierung **DRKS**
Ethikkommission **AKEK**
ICH