MEDIZINISCHE FAKULTÄTUNIVERSITÄTSKLINIKUM MAGDEBURG A. ö. R.

COORDINATION CENTER FOR CLINICAL STUDIES

Range of Services

The KKS Magdeburg works according to the Good Clinical Practice Guidelines (GCP) and the applicable regulations (e.g. AMG, MP, GCP-V). It has the task of effectively supporting all clinical trial processes, implementing standards and ensuring the quality of patient-oriented clinical research.

If the physicians and scientists of the University Hospital A.ö.R. as well as the Medical Faculty are interested in conducting a clinical trial, in particular non-commercial trials (IITs), for which the Otto-von-Guericke University, Medical Faculty, is responsible as sponsor, the KKS Magdeburg will issue a Initial Consultation to the planned clinical trial according to AMG or MP, in order to ensure GCP-compliant reporting and implementation of these projects.

The initial consultation ensures that a correct decision is made regarding the conduct of the study in accordance with the applicable regulations: AMG study, MP study or non-AMG study / non-MP study. Therefore, the KKS Magdeburg also offers its support in the preliminary stages of other research projects. This includes, among other things, advice on possible research funding in close cooperation with the Research Unit.

Once a decision has been made, further study support is generally limited to IIT studies only. If desired, the KKS Magdeburg will take over the Project Management, Monitoring and SAE-Management (written agreement).

Due to the regulations, the KKS Magdeburg, as the quality assurance unit of the sponsor, is always obliged to monitor the performance of a clinical trial.

To this end, the KKS Magdeburg works closely with the following institutions, among others:

Internal Cooperations

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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