MEDIZINISCHE FAKULTÄTUNIVERSITÄTSKLINIKUM MAGDEBURG A. ö. R.

COORDINATION CENTER FOR CLINICAL STUDIES

Good Clinical Practice - GCP

GCP's guiding principles are:

- the compatibility of the clinical trial with the law, ethical principles and their concretization in the Declaration of Helsinki
- the start of the clinical trial with a minimum of risk and with the least possible burden for the trial subjects and society
- the rights, safety, and well-being of the trial subjects take precedence over the interests of science and society
- the design of the clinical trial must be reasonable in light of the available preclinical and clinical data
- an appropriate, detailed protocol/CIP must be available
- the clinical trial is conducted in accordance with the protocol/CIP previously "approved" by the Ethics Committee
- adequate care of the trial subjects by a qualified physician is ensured
- all participating persons are qualified by education and training for the tasks they are to perform
- the written consent of the subject is obtained after proper informed consent has been obtained
- proper documentation of the clinical trial for the purpose of ensuring and verifying its usefulness is ensured
- confidentiality and data protection regulations for the protection of the trial subjects are observed
- the use of the trial medication is in accordance with the protocol
- the manufacturing, handling and storage of the investigational medicinal product is performed in accordance with the applicable Good Manufacturing Practice (GMP)
- the medical device is used in accordance with the CIP
- a quality management system is in place, which is applied according to the written specifications

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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