MEDIZINISCHE FAKULTÄTUNIVERSITÄTSKLINIKUM MAGDEBURG A. ö. R.

COORDINATION CENTER FOR CLINICAL STUDIES

Project Management

The project management is responsible for the execution of a clinical trial according to valid regulations. (AMG, MP) of great importance, as this can ensure that a clinical trial is conducted in compliance with GCP.

After the InitialConsultation the project planning phase begins. We support you, among other things, in defining the objectives, structuring the project, time management, cost calculation, test plan preparation and risk management. Furthermore, the project management includes the project organization, the study correspondence, the contract design, the insurance, the feasibility check of the study sites, the authority notifications (if necessary also the notification of amendments) at the BfArM (for clinical examination according to MP via DIMDI) or at the PEI, the responsible ethics committee and, in the case of a clinical trial according to the AMG, at theState Administration Office, the registration of the clinical trial with and the documentation of the study documents (TMF).

A feasibility check is carried out in advance to determine the suitability of a trial site. This also includes checking the qualifications of all those involved in the clinical trial (relevant regulations, GCP). If required, training courses are offered.

Before submitting the documents to the Ethic Commission and authority, an agreement is signed between the sponsor and the investigator outlining all study-specific responsibilities.

The course of the clinical trial is accompanied by regularly requested update reports until its completion. During the course, annual reports for the ethics committee, the annual safety reports (DSUR) for the authorities, and an overview of the finances and the insurance have to be prepared. In additionn internal Audits performed by the sponsor at the trial centers as a quality assurance measure.

At the end of the project, we also support you in the preparation of the final report and take over tasks such as the notification of the end of the study or also the study extension with the authorities and the archiving of the study documents (TMF) in accordance with the legal requirements.

In the case of multicenter clinical trials, investigator meetings may be organized to discuss any problems or questions that arise within the team and to exchange information about the course of the study.

In addition, project management works closely with the Monitor and the SAE-Management together.

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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