MEDIZINISCHE FAKULTÄTUNIVERSITÄTSKLINIKUM MAGDEBURG A. ö. R.

COORDINATION CENTER FOR CLINICAL STUDIES

Monitoring

According to ICH-GCP E6 and DIN EN ISO 14155:2020, continuous monitoring is an indispensable instrument of quality control in clinical trials.

The regular visits to the study center, as well as the telephone and written contacts with the study center staff, primarily serve to ensure the safety and rights of the study participants. Monitoring includes ensuring protocol and GCP-compliant operations, adequate documentation of study data (paper or eCRF) that can be verified against source data, and compliance with applicable regulatory requirements. Center-specific problems can be identified and resolved at an early stage and the timely progress of the clinical trial can be ensured.

The sponsor is required to clearly regulate the scope, type and procedure of monitoring, as well as the tasks of the monitor in a study-specific monitoring plan.

Further, the Monitoring Plan serves to clearly describe reporting lines, follow-up, and remediation of deficiencies.

Before the first patient can be enrolled in a Clinical Trial, an initiation visit is conducted at the trial site, the prepared investigator's folder is handed over, and the Clinical Trial is thus officially started.

In the subsequent stages, regular visits take place, the timing and frequency of which are study- and trial center-specific (e.g., dependent on the recruitment rate/data quality/form of the CRF) or dependent on contractual agreements, the trial plan, and any stipulations in the monitoring plan. It is advisable to conduct the first visit of the monitor after trial site initiation at the earliest possible time, usually after the inclusion and documentation of the first patients. This allows the early identification of center-specific problems and difficulties in the conduct of the study and the avoidance of errors.

During the final visit, which serves to ensure the proper completion of the clinical trial at the trial site, any unanswered questions regarding data and handling of remaining investigational medicinal products, trial products or study material are clarified and the obligations after completion of the clinical trial are discussed. No study participant may be enrolled in the Clinical Trial after the final visit. All study-specific procedures must be completed. Archiving of study documents is the responsibility of the study site.

The monitor works closely with the responsible Projekt- and the SAE-Management together.

KKS Netzwerk
Koordinierungszentren für Klinische Studien

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Anfahrt und Lageplan

Beratungsübersicht EK

KKS Beratungsanfrage

Hinweisblatt Studienplanung

Schulungsangebote intern NEU

Schulungsangebote extern

Regularien

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

Mitteldeutsches
Kompetenznetz
Seltene Erkrankungen