MEDIZINISCHE FAKULTÄTUNIVERSITÄTSKLINIKUM MAGDEBURG A. ö. R.

COORDINATION CENTER FOR CLINICAL STUDIES

SAE-Management

In clinical trials of drugs or medical devices, adverse or unexpected effects may occur in addition to the desired or expected effect.

These adverse effects or (serious) adverse events (SAEs) must be continuously documented and, if necessary, reported to the authorities and ethics committees within specified deadlines.

For monocentric and smaller multicenter clinical trials, we assume documentation and reporting obligations for the performance of clinical trials in accordance with AMG und MP:

- Consulting and training on documentation and notification requirements within the scope of clinical trials in accordance with regulatory requirements for medicinal products and medical devices
- Coordination of documentation and reporting according to regulatory requirements
- Processing and follow-up of Serious Adverse Events (SAEs)
- Reporting of SAEs in medical devices (sponsor obligation) or suspected cases of Serious Unexpected Adverse Reactions (SUSARs) in drugs to authorities and ethics committees
- Preparation of SAE manuals
- Assistance in the preparation of the Development Safety Update Report (DSUR) for authorities and, if necessary, sending it to them for drug studies
- Preparation of line listings

For larger multicenter clinical trials, external providers are used.

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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