

# ZKS Tübingen

## Zentrum für Klinische Studien

### **Center for Clinical Trials**

The Center for Clinical Trials Tübingen (ZKS Tübingen) is a facility of the Faculty of Medicine together with the Tübingen University Hospital (UKT). Since its foundation in 2012, the ZKS Tübingen supports all aspects of clinical trials, guarantees and improves the quality of the patient-oriented clinical research. The ZKS is DIN EN ISO 9001:2015 certified.

### **Conception, conduct and coordination**

The ZKS Tübingen offers consultancy, coordination and support to the clinical trial centers and physicians at the UKT, as well as other institutions, industry, study groups and medical professional societies in the design and conduct of clinical trials. It gives advice to about 50 clinical trials a year in regard to the study design, the protocol, the management according to the “Good Clinical Practice” (GCP) guidelines and the study budget. The ZKS Tübingen serves as mediator and coordinator for medical research projects for the pharmaceutical industry and contract research organizations (CROs).

The ZKS Tübingen consists of following departments: project management, quality management, pharmacovigilance, monitoring and finance. It cooperates with the Center for Rare Diseases (ZSE), the Institute for Clinical Epidemiology and Applied Biometry (IKEAB) and the Center for Pediatric Clinical Studies (CPCS) at the UKT. The sharing of resources and expertise assures an excellent competence for Investigator Initiated Trials in all medical indications.

### **Range of activities of the ZKS Tübingen**

#### **Consultation on the Conception of a Clinical Trial**

- Study design
- Regulatory classification
- German regulations and laws
- Obligations of the sponsor
- Options for financial support
- Consultation on statistical aspects in collaboration with IKEAB
- Budget calculation
- Review of study documents
- Advice on research proposals

#### **Preparation and Conduct of Clinical Trials**

- Project management from planning to archiving
- Protocol development
- Application to ethic committees and national authorities
- Drafting of contracts
- Datamanagment (paper CRF and RDE)
- Monitoring, incl. risk-based monitoring
- Pharmacovigilance

**Trial Registry**

- Registration of all clinical trials at the UKT
- Web-Portal for clinical sites

**Quality Management**

- GCP-conform quality management (DIN EN ISO 9001:2015 certified)
- Set-up of a central unit to support the conduct of clinical studies
- Implementation of UKT-wide standards for study conduct
- Internal auditing of clinical sites
- Preparation and review of audits and inspections

**Education and Training**

- GCP-training for investigators
- Placement of internships
- Internal seminars on study conduct and on the implementation of our quality management system

**Good Clinical Practice**

The ZKS Tübingen is committed to guarantee the highest quality of standard in the conduct of clinical studies at the UKT, through the implementation of UKT-wide standard operating procedures (SOPs). Moreover the ZKS Tübingen verifies that the studies are conducted according to the “GCP” guidelines and to national and international regulations.

**Contact**

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