



KKS Dresden

### **The Coordinating Centre for Clinical Trials Dresden**

**The KKS Dresden — a facility of the Medical Faculty of the Dresden University of Technology (TU Dresden) — represents a qualified partner in clinical research. The main focus of the KKS Dresden is placed on the professional implementation of clinical research projects, as well as the transfer of knowledge in certified training courses.**

The KKS Dresden was established at the Medical Faculty Carl Gustav Carus of the Dresden University of Technology and funded by the German Federal Ministry of Education and Research until 2008.

With the establishment of the KKS Dresden, a permanent infrastructure was created guaranteeing the design, implementation and evaluation of clinical trials according to international quality standards. The scientific services provided by the KKS Dresden, which include consultancy, support of funding applications, the design and implementation of clinical research projects and the qualification of clinical research personnel, represent a vital part of the Medical Faculty's efforts to promote clinical research. For this reason, the Medical Faculty continues to partly cover the cost of KKS personnel. The cooperation of the KKS Dresden with the cluster of excellence at the Dresden University of Technology, the Centre for Regenerative Therapies Dresden (CRTD) and the University Cancer Centre Dresden (UCC) in various projects actively supports translational research and strengthens the city of Dresden as a location for research.

The first clinical trial was implemented in August 2003; today, the KKS Dresden covers all processes connected with the professional conduct of clinical research projects. Up to now, the 15 staff members of the KKS Dresden have been involved in nearly 100 clinical trials, and about 40 projects ranging from monocentric trials to international multicentre trials are currently in progress.

### **Quality management on behalf of sponsors according to the German Medicinal Products Act**

Since 2005, the Dresden University of Technology has acted as a sponsor of numerous investigator-initiated trials. In this function, the Dresden University of Technology is supported by a quality assurance system that was specially designed for this purpose by the KKS.



### **Training programmes: Tailored to individual needs**



Location of the KKS Dresden

The qualification of investigators and other clinical research personnel has a significant impact on the professional implementation of clinical research projects. For this reason, the certified training courses offered by the KKS Dresden convey the complex processes of a clinical trial in a clear and practical manner. GCP courses for investigators, scientific clinical research personnel and study assistants are offered at regular intervals. The two-day courses for principal investigators, which are based on the KKS curriculum, are also in increasing demand from external investigators.

In addition, the KKS Dresden develops training programmes that are tailored to individual needs. Such programmes are often developed in cooperation with other partners: For example, since summer 2009, a course for principal investigators has been offered in cooperation with the German Society for Orthopaedics and Trauma Surgery (DGOU) and the German Arthrosis Aid (Deutsche Arthrose-Hilfe e.V.) that is specifically tailored to investigators working in this medical field.

### **Checked and approved: Data management according to CDISC standard**

The KKS Dresden has been audited several times, and one auditor commented 'Small but excellent!'. Auditors particularly commended the data management system that offers the possibility of web-based data entries, because database programming as well as other features are already in line with the internationally prevailing CDISC standard.

The study software MACRO used by the KKS Dresden has an audit trail: As a result, data modifications can always be traced back to the person responsible for the data entry. Additionally, data entries are immediately checked by means of programmed plausibility checks. The Director of the KKS Dresden, Dr. Xina Graehlert, views this software as very effective because it reduces the high costs for monitoring.



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### **Active support of evidence-based research projects**

An exemplary model of a clinical trial was designed and conducted by an investigator who had joined the KKS Dresden after working in a hospital. In order to compare the therapeutic regimen for patients with atopic dermatitis, study participants were randomised: The first group of patients was treated according to a pre-established, evidence-based algorithm, and the second group received individual therapies recommended by a dermatologist. The algorithm developed by the investigator proved to be effective and applicable in daily practice.

The KKS Dresden also actively supported the organisationally demanding randomised clinical trial ERGODEM on the efficacy of ergotherapy in domestic settings for patients with dementia. This trial was funded by the German Federal Ministry of Health in connection with the 'Lighthouse project on dementia' (Leuchtturmprojekt Demenz). The unique feature of the clinical trial was that not only patients but also their partners were investigated, which presented a huge challenge to patient recruitment. This project involved physicians in three different trial centres as well as 10 specially trained occupational therapists. The KKS Dresden was responsible for the extensive data management and monitoring of this clinical research project.

### **Contact KKS Dresden**

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