

Clinical Trial Centre Leipzig (ZKS Leipzig)

Clinical Trial Centre Leipzig coordinates clinical research projects for the University of Leipzig and combines all activities and competences with regard to the design and implementation of clinical trials.

The ZKS Leipzig, which was founded as a facility of the Medical Faculty at the University of Leipzig in 2007, consists of three organisational units: The Coordinating Centre for Clinical Trials (German abbreviation: KKS), the Site Management Organisation (SMO) and the ZKS Academy.

The Coordinating Centre for Clinical Trials and the Site Management Organisation act as scientific partners and service providers for physicians and scientists of the University Hospital Leipzig. The service portfolio of ZKS Leipzig includes all aspects of clinical trial research. The methodologically and scientifically oriented Coordinating Centre for Clinical Trials founded in 1999 mainly provides traditional study support for investigator-initiated trials. Such support includes the design and preparation of a trial, informatics and telematics, project management, data management, clinical monitoring, safety management, statistical analyses and reporting.

Since 2007, the Site Management Organisation mainly supports the organisation and implementation of clinical trials in cooperating departments and institutions of the University Hospital Leipzig as well as in academic teaching hospitals in the cities of Leipzig and Zwickau, in which local trial units have been established. Specially trained study assistants and study tutors are responsible for administrative tasks as well as for the medical attendance of study patients, which considerably reduces the workload of investigators.

Training programmes at the ZKS Academy

The broad spectrum of advanced training programmes in patient-oriented clinical research offered by the ZKS Leipzig is organised by the ZKS Academy. Courses for principal investigators, directors of clinical investigation (in Germany only) and study assistants are offered at regular intervals. Since 2010, an additional systematic education in clinical research is available for physicians and scientists: The part-time Master study programme 'Clinical Research and Translational Medicine'.

Expertise in genetic statistics

As a response to the increasing importance of genetic analyses, the ZKS Leipzig has developed a methodological module in genetic statistics (German abb.: GSM). The availability of large study populations and affordable high-throughput processes allow the systematic examination of genotype-phenotype correlations within given study populations as well as comparisons with control groups. In this context, the ZKS Leipzig closely cooperates with the Interdisciplinary Centre for Bioinformatics (German abb.: IZBI) and the Institute for Medical Informatics, Statistics and Epidemiology (IMISE).

Risk-adapted monitoring

The ZKS Leipzig has also responsible for the development of a risk analysis procedure for clinical trials as well as for the definition of risk-adapted strategies for on-site monitoring. The efficiency of these strategies is currently tested in a large cluster-randomised trial including twelve different clinical trials (project ADAMON funded by the German Federal Ministry of Education and Research, ref. no. 01EZ0876).

National and international cooperation

The ZKS Leipzig participates in several national and international joint research projects. The Coordinating Centre for Clinical Trials acts as a trial centre for the competence networks Sepsis (SepNet) and Heart Failure (CNHF) and is responsible for telematics and information services. This connection allows the implementation of large-scale clinical trials of international reputation. For the international EuroNet Paediatric Hodgkin's Lymphoma Group – a network of European study groups -, the ZKS Leipzig not only coordinates the implementation of Europe-wide clinical trials but also provides the joint data platform.

Furthermore, the Clinical Trial Centre Leipzig is responsible for one of the central projects at the Integrated Research and Treatment Centre (IFB) Adiposity Diseases: The IFB Data Centre supports cooperation partners in setting up clinical trials including biometry, data management, databases and quality management.

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