



Clinical Trial Centre Leipzig (ZKS Leipzig)

The Centre for Clinical Trials Leipzig, ZKS, coordinates clinical trial research for the University of Leipzig and bundles all activities and competencies for conducting clinical trials. It was founded in 1999 as an institution of the Leipzig Medical Faculty and consists of three fields of activity: the methodological support of studies, the central service for trial sites (site management) for Leipzig University Medical Centre and the ZKS Academy.

The areas of methodological support and site management see themselves as scientific partners and service providers for physicians and scientists at Leipzig University Medical Centre and support them in all aspects of clinical study research.

The methodological-scientific division of the ZKS has been in operation since 1999 and focuses on scientifically initiated clinical studies with classical study support. This includes study planning and preparation, informatics and databases, project management, data management, clinical monitoring, safety management, statistical analysis and reporting.

Since 2007, the Site Management unit has offered central support for study-conducting clinics and departments at Leipzig University Medical Centre. This includes assistance in setting up and expanding clinical study units, in the administrative preparation of clinical trials, targeted training for non-medical study-related personnel, and the development and implementation of quality assurance measures. This significantly reduces the workload of the clinics' investigators.

Training programmes at the ZKS Academy

The ZKS Leipzig bundles its education, training and continuing education offerings in the field of patient-oriented clinical research under the umbrella of the ZKS-Academy. In addition to courses for investigators, study directors and study assistants, a part-time master's program "Clinical Research & Translational Medicine" has been offering systematic training for physicians and natural scientists in the field of clinical research since 2010.

Risk-adapted monitoring

Under the leadership of the ZKS Leipzig, a procedure for risk analysis of clinical trials was developed and risk-adapted strategies for on-site monitoring were defined. Their effectiveness was tested in a large, cluster-randomized study involving twelve different studies (ADAMON project, funded by the BMBF, funding code 01EZ0876).