

The Centre for Clinical Trials of the Witten/Herdecke University (ZKS-UW/H)

The Centre for Clinical Trials at the Witten/Herdecke University (ZKS-UW/H) acts as a central trial office for various decentralised study institutions at the university and its clinical sites (Köln-Merheim, Witten, Wuppertal, Datteln). The ZKS-UW/H became a member of the KKS Network on 28 April 2010.

The ZKS-UW/H pools the competence and infrastructures available at different study sites, for example, by the Centre for Clinical Trials and Innovation at the Institute for Research in Operative Medicine (German abb.: IFOM) (Director: Professor Neugebauer, PhD) in Köln-Merheim, by the research structure of the Institute of Clinical Pharmacology (German abb.: IKPH) (Director: Professor Thürmann, MD) in Wuppertal as well as by the Institute of Medical Biometry and Epidemiology (German abb.: IMBE) (Director: Professor Kruppenauer, PhD) in Witten. Several additional site management organisations (SMOs) are also available at the clinical sites of the Witten/Herdecke University.

Major steps in the development of the ZKS-UW/H to today's standing were the establishment of a Regional Surgical Centre of the Witten/Herdecke University and the University of Cologne at the university campus in Köln-Merheim and the certification of the Centre for Clinical Trials and Innovation (German abb.: ZKSI) at the Institute for Research in Operative Medicine according to ISO 9001:2008 in June 2010. In July 2010, the Medical Faculty of Health at the Witten/Herdecke University established a chair for 'Clinical Trial and Regulatory Aspects', and the head of this department is also responsible for the scientific and administrative management of the ZKS-UW/H.

Interdisciplinary research

Since November 2010, Professor Neugebauer has been the chairman of the board of directors of the ZKS-UW/H, which is one of four interdisciplinary centres of the Witten/Herdecke University. All four centres support the main focus of research of the Faculty of Health, i.e. integrative and personalised public health care.

The ZKS-UW/H assists in the preparation, implementation and evaluation of clinical research projects, both industry-initiated and particularly investigator-initiated randomised multicentre trials.

The main focus of the ZKS-UW/H lies on the compliance with international quality standards, regulatory requirements and international guidelines as well as on a central quality management system.

Close cooperation between clinicians and researchers is guaranteed by rotating positions within the Witten/Herdecke University and the German Surgical Trial Network 'CHIR-Net'.

Service portfolio

The service portfolio of the ZKS-UW/H includes all aspects involved in the implementation of all phases of clinical trials:

- Checking the practicability of clinical trial plans,
- Preparation of study protocols (according to GCP requirements),
- Biometrical planning and preparation of the statistical analysis plan,
- Implementation and reporting of biometrical analyses,
- Support with regard to regulatory requirements (ethics committee, federal authorities, clinical trial registration),
- On-site assistance in patient recruitment and data processing,
- Assistance in the design of case report forms (CRFs),
- Planning financial and human resources as well as infrastructure, particularly in industry-initiated trials,
- National and international trial organisation,
- Training programmes for clinical research personnel.

Contact ZKS-UW/H

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