

## The Centre for Clinical Trials Essen (ZKSE)

# The Centre for Clinical Trials Essen is a facility of the Medical Faculty at the University of Duisburg-Essen that was initiated by the departments and institutes of the Medical Faculty. The ZKS Essen has been a member of the KKS Network since 2006.

The Centre for Clinical Trials Essen supports clinical studies in a practical and qualityoriented manner. A special feature of the ZKSE is that since its foundation in 2006 it has been in operation without any governmental funding. The proficiency of the ZKSE rests upon the commitment and the long-term experience of its staff members as well as upon the cooperation with the Institute for Medical Informatics, Biometry and Epidemiology (IMIBE), which initiated the foundation of the ZKSE in 2006. Already in 1998, the IMIBE prepared and implemented 23 SOPs for clinical research and, in 2002, the institute developed the first cost-saving monitoring concept.

### Service portfolio and objectives

At present, the ZKSE acts as a scientific provider for more than 20 clinical trials (and) still more in planning. The services provided by the ZKSE include pre- and post-authorisation trials with medicinal products, trials on non-drug treatments, trials with medicinal products, non-interventional trials as well as epidemiologic and genetic-epidemiologic trials. Main objectives are the improvement of prophylactic, therapeutic and diagnostic procedures as well as gaining new knowledge about the aetiology and pathogenesis of diseases.

The ZKSE supports research groups, competence networks and associations in biometrical and methodological matters as well as with regard to raising external funds for all areas of patient-oriented clinical research. For example, the ZKSE played a major role in the successful accreditation of the West German Cancer Centre as a Top Oncological Centre.

### Guarantee of quality: The quality label ZKSE

Apart from individual consultancies, the ZKSE offers a weekly consultation hour, thus supporting researchers from hospitals and businesses in the implementation of clinical research projects. In addition, training programmes contribute to successful study support on-site. Our regular training program consists of GCP-courses, medical device courses, and a training for study assistants. We also offer "special events/training for study groups" or on demand. Attendance fees are met by the Medical Faculty, so that participation in these courses is free of charge for employees of the University Hospital of Duisburg-Essen.



### 'medico//s': Recruitment and documentation

In cooperation with the IT centre of the University Hospital of Duisburg-Essen, the hospital information system 'medico//s' was implemented as a standard system at the ZSKE and tailored to the specific requirements for conducting clinical research projects. For patient recruitment, any characteristics already stored in the system, such as diagnosis, age, sex or laboratory results, can be used for a comparison with inclusion and exclusion criteria. With this system, the ZSKE responded to a central problem in the implementation of clinical trials because more than 50% of all research projects take longer than anticipated due to recruitment problems. Such problems are as well caused by These problems are mainly caused by the high workload of physicians in patient care and complicated inclusion and exclusion criteria.

### **Contact ZKS Essen**

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