

Center for Clinical Studies Jena (ZKS)

The Center for Clinical Studies was founded in November 2008 as a scientific service unit of Jena University Hospital (JUH) and has built up an efficient infrastructure for clinical studies at JUH. On 12 November 2014, during the 19th general assembly of the Network of the Coordinating Centers for Clinical Trials (KKS-Network), Jena University Hospital's Center for Clinical Studies has been admitted as a new associated member.

By establishing this center, Jena University Hospital enhances long-term and high level patient oriented clinical research in an academic environment. ZKS Jena offers professional support in conception, study coordination/project management and regulatory issues as well as in data management, IT, biometrics and monitoring. In addition, training courses are offered on a regular basis.

Custom-made project support

Staff of ZKS Jena offer comprehensive advice on scientific, organizational, regulatory, methodological and financial aspects of clinical studies to any scientist from Jena University Hospital who wants to initiate a clinical study. In a step-by-step approach, feasibility of the study is assessed and necessary fields of cooperation are discussed. This advice is free of charge for scientists from Jena University Hospital. After scientific and clinical relevance as well as financial feasibility of the planned study have been confirmed, support for all aspects of the study or for specific subtasks is provided. By offering different extents of assistance, investigators get custom-made support for their projects.

Study labeling at Jena University Hospital

ZKS Jena was the leading contributor for implementing study labeling at Jena University Hospital. In order to record all study patients at JUH electronically, the study label has been added as a program component to SAP, tagging all patients who are included in clinical studies. In addition, information on the respective study (e.g. study design, study conduct and information on possible side effects) is recorded. This information is available for all JUH staff involved in the patient's treatment. Furthermore, a medical data warehouse consisting of study and treatment data is being built up (i2b2, Informatics for Integrating Biology & the Bedside). Its main purpose is to help assess feasibility of future studies. Apart from well-established data capture systems like OpenClinica® or Limesurvey®, ZKS Jena offers development of individual software solutions for studies if needed.

Medical Registries

In addition to clinical studies, ZKS Jena has considerable expertise in the area of medical registries which are an important source of knowledge for quality assurance and for assessing medical care in daily routine.

Management structure

Prof. Dr. Frank M. Brunkhorst, who has wide experience in research management and research promotion of clinical studies, has been acting as scientific director of ZKS Jena since June 2013. Ms. Isabella Schiller is managing director and Prof. Brunkhorst's deputy. This dual leadership of scientific-medical and regulatory expertise not only guarantees optimized procedures in giving advice and applying for clinical research projects but also facilitates participation of ZKS Jena in national and international joint research projects. Moreover, being one of four sites in the new laender, ZKS Jena provides a platform for further exploiting the not yet used potential for patient recruitment in middle and eastern Germany.

Cooperations

ZKS Jena cooperates with all departments and institutes of Jena University Hospital and also with external customers from national and international university hospitals, public research institutes and associations, and from industrial research. Since June 2013, ZKS Jena has supported all clinical studies of the Integrated Center for Research and Treatment (IFB) Center for Sepsis Control and Care (CSCC) with regard to scientific methodology. In the field of biometrics and biostatistics, a close cooperation with Jena University's Institute of Medical Statistics, Computer Sciences and Documentation exists. Since 2013, the Research Group for Clinical Epidemiology at CSCC Jena (head: Prof. A. Scherag) is another cooperation partner. The Integrated Biobank Jena (IBBJ), located at the Institute of Clinical Chemistry and Laboratory Diagnostics (temporary head: Dr. M. Kiehntopf) is ZKS Jena's cooperation partner in the area of biobanking. This cooperation guarantees adherence to quality standards and to current ethical, legal and data protection relevant framework conditions.

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