

The Coordinating Centre for Clinical Trials Halle

The KKS Halle has been a service provider of the Medical Faculty of the Martin Luther University of Halle-Wittenberg since 2002. The expiration of start-up funds granted by the federal government has been compensated by raising external funds and by the financial commitment by the Medical Faculty.

Since its establishment, the KKS Halle has been responsible for approximately 100 research projects, of which 37 are supported at present.

The KKS Halle currently employs 20 members of staff, such as physicians, nurses, scientists, health care scientists, medical documentation specialists as well as engineers, each of them having attended further education to work in clinical research. The KKS Halle permanently cooperates with the Institute of Medical Epidemiology, Biometry and Informatics (IMEBI).

Service portfolio: From supporting university sponsorship to safety reporting to mobile GCP courses

The University of Halle was one of the first KKS sites to create a regulatory framework for becoming authorised to assume responsibility as a sponsor according to the German Medicinal Products Act. The necessary processes were developed by the KKS Halle in cooperation with the KKS Leipzig. Since that time, the KKS Halle supports the Dean of the Medical Faculty as the representative of the sponsor in the application of clinical trials and quality management.

The KKS Halle supports all stages of clinical research projects, i.e. design, implementation and evaluation. Comprehensive study support includes project management, medical writing, biometry, data management and, if required, monitoring. Study assistance at study sites as well as safety reporting have also become of increasing importance. The KKS Halle has expanded its safety reporting since 2008 using a specially developed, custom-designed database according to ICH and GCP requirements. Furthermore, the KKS Halle has attained the EMA EudraVigilance User Certificate for the electronic reporting of SUSARs.

A further focus of the KKS Halle is placed on the qualification of clinical research personnel. The KKS employs rotating physicians and offers regular courses for principal investigators; since 2008, the mobile GCP courses offered by the KKS Halle have become very popular.

Focused on oncology: The KKS Halle as the German trial coordination office of an international EORTC trial

In accordance with the statutes of the KKS Halle, the majority (about 75%) of contracting partners are the departments and institutes of the clinics and the Medical Faculty, respectively, of the University of Halle-Wittenberg. The remaining 25% are external partners, mostly public service institutions. More than 70% of the projects supported by the KKS Halle are investigator-initiated trials (IIT).

The main focus of activities of the KKS Halle is on clinical trials in neurology and oncology, particularly with regard to gastrointestinal tumours. The largest project at present is the PETACC-6 trial on Pre-operative Radiochemotherapy in Rectal Cancer under the

sponsorship of the European Organisation for Research and Treatment of Cancer (EORTC). In this international randomised comparative trial, the KKS Halle is responsible for the coordination, project management and monitoring of 150 German study sites. Recruitment ended in September 2011 earlier than expected. A further project associated with the PETACC-6 trial initiated by the KKS Halle and sponsored by the German Cancer Aid focuses on improving the participation of elderly patients in oncological studies (Abb.: AMOTE).

Perspective: Transregional visibility

In early 2009, the KKS Halle moved to new premises with view of the University Hospital and the City of Halle, which is seen as a promising position for strengthening the role of the KKS Halle as a regional competence centre in clinical trials and as simultaneously providing transregional visibility. The KKS Halle aims at intensifying its cooperation with clinics strongly involved in clinical trials, such as the departments of haematology and oncology, gastroenterology and paediatric oncology.

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