Details

Coordination Centre for Clinical Trials (KKS) Heidelberg (KKS-HD)

The KKS Heidelberg at the Medical Faculty Heidelberg, was initially funded by the German Ministry of Education and Research (BMBF) and the Medical Faculty. More than 50 staff members support the entire spectrum of clinical research within the scope of planning, conduct, analysing, and interpretation of innovative clinical trials according to the applicable regulations and international guidelines, e.g. Good Clinical Practice (ICH-GCP). The KKS Heidelberg has been working effectively since July 2000 and has been evaluated in several audits and expert assessments with favourable outcomes regarding the quality and efficiency of its work-flows and procedures. KKS Heidelberg is involved in some innovative phase I to IV trials carried out according to German Drug Law as well as in projects pursuant to Medical Device Law, including in-vitro diagnostics and innovative therapeutic agents (e.g. ParvOryx in oncology or Myrcludex in infectious disease). All activities are being executed according to the Standard Operating Procedures (SOPs) of the KKS Heidelberg being based on ICH-GCP guidelines and applicable regulations. In order to comprehensively ensure a high quality, an adequate patients' protection, a compliance with ethical and legal requirements as well as the employment of adequate research methods the KKS Heidelberg provides the following services to clinical trials: Project Management and Regulatory Affairs, Quality Assurance, Clinical Monitoring, Pharmacovigilance, Data Management and Biometrics.

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Host Institution

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http://www.medizinische-fakultaet-hd.uni-heidelberg.de

Scientific Domain

Primary Subjects:
- Medicine

Secondary Subjects:
- Biology

Category

Clinical Research Centers

Scientific Services

KKS Heidelberg provides the following services: - Project Management and Regulatory Affairs: comprehensive support in preparation of the study protocol and essential documents, submission process (IEC's and competent authorities), inclusive ongoing reporting procedures, logistics and documentation of study drug- or device-related procedures. - Quality Assurance: review of the study protocol and study-related documents for their consistency and in order to ensure the regulatory and ICH-GCP compliance of all clinical research activities . - Clinical Monitoring: investigators' training, individual site initiation visits, continuous on-site visits for source data verification, in order to ensure the protection of rights and well-being of study participants and to ensure the compliance of investigators with the current versions of the trial protocol and its amendments. - Pharmacovigilance: providing professional staff (safety officer and safety data manager) and infrastructure to adequately process the SAE reports and to ensure the compliance with regulatory reporting requirements, preparation of periodic safety reports (DSURs). - Data Management and Biometrics: statistical contribution to the study design, including estimation of sample size and definition of appropriate end-points, preparation of a biometrical study report according to statistical analysis plan; providing paper-based (CRF) or internet based, validated Remote Data Entry (RDE) tool; query management.

Scientific Equipment

- MACRO (RDE-System)
- Clincase (RDE System)
- Vigilance One (Pharmaco Vigilance System)

Keywords

- clinical phase I to IV studies
- clinical trials
- clinical research
- ICH-GCP
- German Drug Law
- Medical Device Law
- Project Management
- Regulatory Affairs
- Quality Assurance
- Clinical Monitoring
- Pharmacovigilance
- Data Management
- Biometrics
- Investigator initiated trials (IIT's)

Networks

KKS-Network (KKS-N); Network of German Coordination Centres for Clinical Trials
http://www.kks-netzwerk.de/

TMF – Technology, Methods, and Infrastructure for Networked Medical Research
http://www.tmf-ev.de/

FIM Heidelberg (First-in-Men)
http://www.klinikum.uni-heidelberg.de/FIM-Heidelberg.110975.0.html

Users per annum

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External Users in total: etwas 700 Wissenschaftler für Beratungen, Fortbildungen und Begleitung eigener Studien
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External Users outside of EU: 10