



## Coordination Centre for Clinical trials Heidelberg (KKS HD)

The Coordination Centre for Clinical trials Heidelberg (KKS HD), located at Medical Faculty Heidelberg, Germany, is initially being funded by the German Ministry of Education and Research (BMBF) and the Medical Faculty. More than 80 staff members support the whole spectrum of clinical research with a focus on conception, planning, conducting, and analysing innovative clinical studies according to current laws and international guidelines, e. g. Good Clinical Practice (ICH-GCP). The KKS HD has been working effectively since July 2000 and has been evaluated by different audits and expert assessments with successful outcome concerning quality and efficiency. KKS HD is involved in innovative phase I to IV studies according to German Drug Law and projects following Medical Device Regulations (MDR) inclusive in vitro diagnostics and innovative therapeutic agents (e. g. parvovirus in oncology). All functions will be performed according to Standard Operating Procedures (SOPs) of KKS HD which are based on ICH-GCP guidelines, the implementation of GCP and current national and international laws, incl. implementation of EU/CTR 536/2014. In order to ensure the quality, the patient protection, compliance with ethical and legal stipulations as well as the application of adequate methods KKS HD provides e. g. the following services to clinical trials:

- **Project Management and Regulatory Affairs:** co-authorship for study protocols and essentials documents, application and authorisation processes to ethics committees and competent authorities inclusive ongoing reporting procedures, logistic and documentation for study drugs and devices, supportive writing integrated study reports
- **Quality Assurance:** Review of study protocols and study-related documents for consistency and to ensure that all clinical research activities are planned and performed according to ethical and legal principles as well as to ICH-GCP guidelines with control of data protection; support in inspections and audits
- **Clinical Monitoring:** Investigators' training, individual site initiation visits, following risk-based approaches off-site or on-site visits for source data verification, to ensure that rights and well-being of study participants are protected and investigators comply with the approved protocols and amendments
- **Pharmacovigilance:** Providing professional staff (safety officer and safety data manager) and validated infrastructure to collect initial SAE reports, to keep an eye on data consistency and follow up reports, and to ensure in time reporting to ethic committees, investigators and competent authorities, as requested. Annual safety reports will be issued in close cooperation with the coordinating investigator.
- **Data Management and Biometrics:** Definition of study design and clinical endpoints, sample size calculation, biometrical study report according to statistical analysis plan, data management procedures to ensure data collection according to study schedule; providing internet based Case Report Forms (CRF) using validated Remote Data Entry (RDE) Tool; validation of data, query processing and cleaning of data base before evaluation according to statistical analysis plan; statistical study report

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