Your benefit

Take advantage of our staff's extensive professional experience and expertise!
The KKS Heidelberg provides you with competent support services so you can be sure your clinical research project is carried out to a high standard and in a timely manner throughout all stages of the clinical trial process (design, conduct and analyses):

- analysis of weak points of the study concept
- central planning, coordination, monitoring and analysis of your clinical trial
- comprehensive project management, continuous tracing of the course of the study
- ensuring compliance with international guidelines and quality standards (e.g. ICH-GCP) as well as local laws (German Drug Law, German Medical Device Law etc.)
- relief from bureaucratic procedures e.g. by assigning application procedures and reporting obligations to the KKS
- faster approval of your trials
- increased productivity of your staff and higher availability for jobs matching their qualification and skills
- improved data quality, for example for authorisation applications or sale of substances
- high international acceptance of the results of your study

Contact

Our interdisciplinary team will be happy to advise you at any time and without obligation. Please ask for an individual appointment:

Coordination Centre for Clinical Trials
KKS Heidelberg
Head: Steffen P. Luntz, MD
University Hospital Heidelberg
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For detailed and up-to-date information on our offers and services please visit our website:

www.kks-hd.de

KKS Heidelberg
Koordinierungszentrum für Klinische Studien

UniversitätsKlinikum Heidelberg

Coordination Centre for Clinical Trials (KKS) Heidelberg

Comprehensive Support of Your Clinical Research

Our profile

The KKS Heidelberg is a clinical trials competence centre directly located at one of the foremost and world-renowned University Hospitals in Germany.

The KKS Heidelberg offers professional support of clinical trials primarily to the academic clinicians of the University Hospital, but also to other interested investigators and the industry.

The KKS Heidelberg is experienced in the development of study designs, the conduct and analysis of clinical trials from phase I to IV in accordance with national and international regulations. We are familiar not only with studies according to German Drug Law but also with trials under the German Medical Device Law and free studies, i.e. studies not subject to a specific law.

High professional expertise, continuing training of our more than 30 members of staff and regular internal and external quality controls ensure compliance with the highest international standards.

The KKS Heidelberg is one of the founding members of the consortium of Coordinating Centres for Clinical Trials, the KKS Network and the BioRegion Rhein-Neckar-Dreieck.

KKS Network
Coordinating Centres for Clinical Trials

BioRegion
Rhein-Neckar-Dreieck

Our services (extract)

- consultation throughout all stages of the trial process
- design, conduct and management of clinical trials from phase I to IV in accordance with the German Drug Law or German Medical Device Law and of projects not regulated by a specific law
- biometry: study design and sample size estimation, statistical analysis and (integrated) clinical study report
- administration and financial management, contractual matters
- extensive support of your application for public or industrial grants
- assumption of sponsor responsibilities according to German Drug Law and German Medical Device Law, incl. SAE management
- submission of applications to ethics committees and competent authorities
- study coordination and quality assurance
- site recruitment and feasibility checks
- laboratory sample and drug logistics
- preparing and managing documents (TMF, ISF)
- central randomization
- monitoring conform to ICH-GCP, incl. risk-adapted procedures as well as continuous support and encouragement of sites
- data management using validated systems, incl. remote data entry (RDE)
- site management organization, study documentation
- support in case of external audits and inspections
- integrated support of the final report and publication activities
- training and further education for clinical trial staff
- pediatric studies in cooperation with PAED-NET (pediatric module at the KKS)

Our cooperation partners (extract)

QUINTILES

Roche

B|BRAUN
SHARING EXPERTISE

DGC

dkfz. GERMAN CANCER RESEARCH CENTER IN THE HELMHOLTZ ASSOCIATION

NCT NATIONALES CENTRUM FÜR TUMORERKRANKUNGEN HEIDELBERG

FIM First in Man Heidelberg

We are committed to raise the international acceptance of clinical research in Germany.