



## **The Coordinating Centre for Clinical Trials Heidelberg (KKS HD)**

The Coordinating Centre for Clinical Trials Heidelberg (KKS HD) is a facility of the Medical Faculty of the Ruprecht Karls University Heidelberg. The core business of the KKS HD is the full support of investigator-initiated clinical trials. In addition, the KKS HD is also responsible for supervising the sponsor function of the University Hospital Heidelberg through conduct of compulsory counselling and internal audits in Heidelberg. Since 2009, this service is also available to the University Hospital Mannheim. In this way, methodological consultancies on clinical trials, assistance in funding applications, provision of templates for the preparation of study documents and other services can be provided free of charge to members of the Medical Faculty and external researchers.

### **Full or modular services**

If requested, the KKS HD can provide the full range of scientific services, such as project management, monitoring, biometry, data management, pharmacovigilance, regulatory affairs and reporting. Via a cooperative venture with the Department of Clinical Pharmacology in Heidelberg, the KKS HD is also able to offer the use of a phase I unit. Such long-term and labour-intensive services are individually calculated for each clinical trial and agreed upon by contract. Substantial fee deductions apply to members of the Medical Faculty and academic institutions.

In 2008, the KKS HD established a system for supervising the duties of a sponsor in investigator-initiated clinical trials according to the German Drug Law (German abbr.: AMG). Recently, these processes have also been adapted and implemented for clinical trials according to the German Medical Devices Act (German abbr.: MPG). Via the compulsory consultancy for investigators with regard to organisational structures, complete allocation of tasks, financing, and compliance with applicable laws as well as subsequent internal audits, projects that do not directly fall into the KKS HD's responsibility benefit from its expertise, too. The early timing of the consultancy allows for any necessary modifications of important aspects prior to the submission of a study protocol to the ethics committee.

### **Success in the 'Call for tender: Clinical Trials'**

The KKS HD has assisted in the implementation of many and often extensive investigator-initiated trials by means of practical study designs and budget plans as well as by its active support in the raising of third-party funding. Last year alone, ten major project applications supported by the KKS HD were assessed positively, yielding nearly € 16 million for the Medical Faculty of the University of Heidelberg. In the first five rounds of the funding programme for clinical trials offered by the German Research Foundation (German abbr.: DFG) and the German Federal Ministry of Education and Research (German abbr.: BMBF), the KKS HD achieved a funding quota of 24% for its supported applications; the average quota in Germany is 7.5%.



### **Cooperation structure 'First-in-Man'**

Highly innovative approaches in the development of drugs to be applied for the first time in man present a special challenge. In 2009, the KKS HD was co-founder of the cooperation structure 'First-in-Man' (FIM Heidelberg), which was established by an experienced multidisciplinary research association of specialised partners, such as the Medical Faculty of University Heidelberg, the University Hospital Heidelberg and the German Cancer Research Centre Heidelberg (German abbr.: DKFZ). The objective of this association is to offer a one-stop service for design, conduct and evaluation of innovative early-phase trials with medicinal products. Such trials may focus on haematologic, oncologic, rheumatologic or immunologic topics

### **Interface between the development of medical devices and clinical application**

The KKS HD supports approximately 80 clinical trials per year, either providing the full range of services or partial services. Scientists conducting clinical trials with medical devices especially benefit from the expertise of the KKS HD and its approximately 40 members of staff, particularly because the stricter legal requirements introduced in March 2010 have increased the demand for professional study support.

The KKS HD is an attractive partner for small and medium-sized enterprises (German abbr.: KMU), too: Its staff members are experienced in clinical trials with medical devices for different indications prior to CE certification. In conjunction with the direct proximity to clinicians, this allows the expedient and target-oriented design and implementation of clinical research projects in a 'one-stop-shopping' strategy.

### **Contact KKS Heidelberg**

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