



## **The Clinical Trials Unit Freiburg**

**Over the past 14 years, the Clinical Trials Unit Freiburg – previously termed ‘ZKS Freiburg’ – has become an independent central service department with currently 55 members of staff, representing a strong partner of hospitals, science and industry.**

The Clinical Trials Unit Freiburg was founded as one of the first Coordinating Centres for Clinical Trials by the Medical Faculty and the University Hospital Freiburg in 1997.

The initial set-up of the centre included Professor Herbert Maier-Lenz as the director and only three members of staff; the centre was funded by the German Federal Ministry of Education and Research as part of the funding programme for Coordinating Centres for Clinical Trials for six years. Today, the Clinical Trials Unit Freiburg and its 55 members of staff provide their expertise on the entire spectrum of clinical trials from design to evaluation throughout Europe. The services of the Clinical Trials Unit Freiburg are directed at researchers in the medical-scientific field as well as in the industrial sector.

### **Transregional networks and centres of excellence**

The Clinical Trials Unit Freiburg is a cooperation partner of the joint epidemiologic project ‘National Cohort, Cluster Baden-Wuerttemberg-Saarland’ funded by the German Federal Ministry of Education and Research. In the main phase of the project, 10 000 volunteers are planned to be included in Freiburg alone.

At European level, the Clinical Trials Unit Freiburg acts as a European trial coordination office for the network of excellence ‘Translational Research in Europe for the Assessment and Treatment of Neuromuscular Diseases’ (TREAT NMD). This network — funded by the European Union — connects 21 partner organisations from 11 European countries in order to develop new therapies and uniform standards for the treatment of patients with neuromuscular diseases. The Clinical Trials Unit Freiburg develops and maintains valuable software applications, such as a database for regulatory affairs and a trial site database, for supporting the implementation and conduct of international clinical trials.

### **Facilitating funding by initiatives and competency**

The Clinical Trials Unit Freiburg is a founding member of the integrated research and treatment centre ‘Chronic Immunodeficiency’ (CCI), which has been funded by the German Federal Ministry of Education and Research since its establishment in 2008. Besides its services in study design and implementation, the Clinical Trials Unit Freiburg also provides expertise on biomaterial databases and offers training programmes for rotating physicians.

The CCI, the ‘Freiburg Centre for Rare Diseases’ (German abb.: FZSE), the Institute of Medical Biometry and Medical Informatics (IMBI) and the Clinical Trials Unit Freiburg are joint founders of the ‘German Methodological Coordinating Centre for Rare Diseases’ funded by the German Federal Ministry of Education and Research.



The Clinical Trials Unit Freiburg has special expertise in the promotion of translational cancer research. The Clinical Trials Unit Freiburg is a co-founder of the tumour centre 'Ludwig Heilmeyer — Comprehensive Cancer Centre Freiburg' (CCCF) and is also the trial centre in charge; in this capacity, the Clinical Trials Unit Freiburg is integrated into the 'German Consortium for Translational Cancer Research' (German abb.: DKTK) funded by the German Federal Ministry of Education and Research.

### **Evidence-based medicine**

The Clinical Trials Unit Freiburg is particularly committed to evidence-based medicine as well as to transparency in clinical research. Since 2008, the Clinical Trials Unit Freiburg and the German Cochrane Centre have been jointly responsible for the 'German Clinical Trials Register' (German abb.: DRKS [www.drks.de](http://www.drks.de)) available at the IMBI. This register has been recognised by the World Health Organisation, thus fulfilling the requirements of the International Committee of Medical Journal Editors (ICMJE).

The Clinical Trials Unit Freiburg also cooperates with the coordinating office for health services research of the work group 'Clinical epidemiology' at the IMBI.

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