



Center for Clinical Studies (CCS) Erlangen

The CCS Erlangen is a joint service facility of the Medical Faculty of the Friedrich-Alexander University Erlangen-Nuremberg (FAU) and the University Hospital Erlangen (UKER), which was founded in 2008.

From Study Idea to Study Conclusion

With its range of services, the CCS primarily addresses physicians and scientists from FAU and UKER, but also external institutions and companies. The CCS is the central point of contact for the planning and implementation of clinical study projects such as:

- Clinical trials according to the German Drug Law (AMG) – Phase I to IV (also ATMP)
- Clinical trials with medical devices (MDR/MPDG)
- Other clinical studies

Main Fields of Activity

The main focus of the CCS-Erlangen is to provide consultation and support to investigators in planning, organizing and conducting self-initiated clinical trials (IITs).

The CCS-Erlangen provides the following services:

- Consultation and planning of clinical studies
- Study coordination and project management
- Support with third-party funding applications
- Regulatory study support
- Preparation of clinical trial protocols and all necessary essential documents
- Clinical monitoring, lead monitoring
- TMF management
- SAE management for clinical trials (eDrug-Safety Database VigilanceONE)
- Biometrics/Biostatistics
- Management of insurance for subject trial participation
- Counter-calculation of contract research proposals
- Basic and advanced GCP courses and GCP refresher courses (according to recommendations of BÄK/AKEK) in cooperation with the Chair of Clinical Pharmacology and Clinical Toxicology of FAU
- Implementation of IATA hazardous materials courses

Our quality management system is certified according to DIN ISO 9001:2015.

Cooperation with other Institutions in Erlangen

The long-standing and congenial cooperation between the CCS and other internal institutions of the University Hospital Erlangen and the FAU enables extending the range of services available for clinical studies in Erlangen:

- eCRF programming and data management is carried out through cooperation with the Medical Center for Information and Communication Technology (MIK) of the UKER
- Production of test medication/preparation of IMPD. The pharmacy of the UKER is in possession of manufacturing authorization for clinical investigational medicinal products according to § 13 AMG for selected sterile and non-sterile dosage forms. Since 2007, the pharmacy has been manufacturing investigational medicinal products



for clinical trials in accordance with EU GMP guidelines, working closely with hospitals, study centers, investigators and the pharmaceutical industry.

- MS-based metabolomics analyses as well as the targeted mass spectrometric detection of biomarkers or drugs can be integrated into drug related clinical studies in cooperation with the Mass Spectrometry Unit of the Chair of Clinical Pharmacology and Clinical Toxicology at FAU (Prof. Dr. med. M. Fromm). There is also close cooperation with the chair in the areas of pharmacokinetic analyses, drug interactions, pharmacogenetics, cardiovascular risk markers and risk factors, as well as in continuing education and training.

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