Center for Clinical Studies (CCS Erlangen)

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Aims and structure

In 2008, the Center for Clinical Studies (CCS) was founded as a service unit shared by the Faculty of Medicine and the UK Erlangen. From an organizational point of view, it is affiliated with the UK Erlangen as one of its central facilities. Its tasks comprise:

1. Provision of counseling and support to members of the Faculty of Medicine and staff of UK Erlangen for the conception, planning, conduct, and analysis of clinical studies, taking into account the relevant legal and regulatory requirements
2. Support to UK Erlangen for fulfilling the tasks and duties of the sponsor in clinical studies
3. Administration of the insurance for participants in clinical studies
4. Organization of educational events on all aspects of clinical studies

Since its inception, CCS participated in about 550 clinical research projects of members of the Faculty of Medicine and of UK Erlangen. These projects comprise several multinational clinical studies in Europe as well as several projects involving the first administration to humans of novel medicinal products (first-in-man trials).
CCS is structured into the areas of study management and clinical monitoring, quality management, and pharmacovigilance.
CCS is an associated member of both, the KKS-Netzwerk e.V., the association of the German university clinical study centers, and the Technologie- und Methodenplattform für die vernetzte medizinische Forschung e.V. (TMF), the umbrella organization for networked medical research in Germany.

Counseling and support for clinical studies

Counseling

Each year, CCS provides a broad range of counseling services, especially in the preparatory phase of clinical studies. The main focus is on so-called investigator-initiated trials (IIT), planned and conducted by members of the Faculty of Medicine and of UK Erlangen. CCS evaluates the feasibility of the research project from an economic and organizational perspective as well as its compliance with the relevant legal and regulatory requirements. All counseling services are provided free of charge.

Study management and clinical monitoring

Prior to clinical study start, CCS offers various services, ranging from the generation of the study protocol to obtaining approval from competent authorities and endorsement of the study protocol by ethics committees. This includes multicenter and multinational clinical research projects.
During the conduct of the clinical study, CCS provides clinical monitoring, if requested by the sponsor or project leader.

Quality management

Institutions which assume sponsor responsibilities in clinical studies are required to follow standard operating procedures (SOP). The section quality management within CCS helps identify and develop the relevant SOP.
If requested by the sponsor or project leader, CCS performs audits of study sites or other institutions involved in a clinical study to assess their compliance with regulatory requirements. On request, CCS provides advice and guidance for inspections by the regulatory authorities.

Pharmacovigilance

For clinical studies subject to AMG (Medicinal Products Act) or MPG (Medical Devices Act) and sponsored by UK Erlangen, CCS ensures the documentation and timely notification of serious adverse events according to legal and regulatory requirements. For this task, CCS uses a dedicated and certified database.

Administration of the insurance for participants in clinical studies

CCS administers the insurance for participants in clinical studies initiated by members of the Faculty of Medicine and of UK Erlangen. This comprises obtaining insurance offers and accompanying the project until its conclusion.

Education

At the request of the Faculty of Medicine, CCS in collaboration with the Chair of Clinical Pharmacology and Clinical Toxicology has currently conducted more than 50 educational events for investigators, coordinating investigators, and staff involved in clinical studies. Along with conveying the relevant legal and regulatory requirements, the sessions focus on practical aspects and recommendations which often have a major impact on the feasibility and timely recruitment of clinical studies. Currently more than 1,000 physicians from UK Erlangen and the associated academic teaching hospitals have attended the courses.