

Partners

- ➔ Clinical Departments, Trials Conduct Units, Pre-Clinical departments and institutes of the University of Cologne

- ➔ Institute of Medical Statistics, Informatics and Epidemiology (IMSIE)

- ➔ CECAD Cologne – Cluster of Excellence

- ➔ Center for Integrated Oncology (CIO)

- ➔ National research groups, e.g.
 - > German CLL-Study Group (GCLLSG)
 - > German Hodgkin Study Group (GHSG)
 - > German Neuroblastoma Study Group

- ➔ Cochrane Haematological Malignancies Group (CHMG)

- ➔ Institute for Health Economics and Clinical Epidemiology (IGKE)

- ➔ Center for Health Services Research Cologne (ZVFK)

- ➔ Networks in the field of clinical research, e.g.
 - > retina.net
 - > FungiResearch
 - > KKS-Netzwerk e.V.
 - > Surgical Network (CHIR-Net)
 - > TMF – Technology, Methods, and Infrastructure for Networked Medical Research
 - > Competence Networks in Medicine
 - > European Clinical Research Infrastructures Network (ECRIN)

- ➔ University hospitals, hospitals and surgery networks

- ➔ Contract Research Organisations (CRO)

- ➔ Pharmaceutical Companies

- ➔ Medical devices manufacturers



Please do not hesitate to contact us for further information or if any open questions remain!

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Zertifiziertes
Managementsystem



UNIVERSITY OF COLOGNE

Clinical Trials
Centre Cologne

Clinical Trials Centre (CTC) Cologne

Clinical trials are an indispensable component of medical progress and innovation. Only clinical trials allow the systematic analysis of the efficiency, tolerability and safety of new and already approved drugs, medical devices as well as new forms of treatments or medical interventions. Hence the need for clinical trials as a prerequisite for the continuous optimization of diagnostics and therapy.

The principal task of the CTC Cologne as institution of the Faculty of Medicine is the support of clinical trials in compliance with GCP, international directives, guidelines and standards. This applies to trials with industrial partners and academic partners (Investigator Initiated Trials, IITs) as well as all trials initiated by faculty members.

Consequently, the CTC Cologne provides a broad range of infrastructure and services. Hereby, it offers its support for the informed, effective and quality-assured implementation of clinical research and development projects – from concept to publication.

Services

COUNSELLING

- ➔ Trial design and concepts
- ➔ Regulatory classification
- ➔ Sources of funding
- ➔ GCP-compliant quality management
- ➔ Translation of basic research results
- ➔ Sponsor's trial related duties in accordance with AMG / MPG / GCP
- ➔ Trials with specific patient populations

TRIAL PREPARATION AND CONDUCT

- ➔ Trial protocol development, sample size calculation
- ➔ Preparation and provision of CRF (electronic, paper CRF)
- ➔ Applications to the authorities and to the ethics committee including patient insurance
- ➔ Project management and budget planning
- ➔ Contract preparation and tracking
- ➔ Flying Study Nurses
- ➔ SAE management (incl. MedDRA-coding)
- ➔ Monitoring (incl. risk-adapted planning)
- ➔ Trial-specific personnel training

DATA MANAGEMENT

- ➔ Development and validation of the database
- ➔ Central randomization
- ➔ Database maintenance and support in database analysis

SITE MANAGEMENT SYSTEM

- ➔ Recording and management of trials in compliance with WHO criteria
- ➔ Web-based portals for the institution's active clinical trials
- ➔ Document management, CV database and researcher portfolio

COLLABORATION WITH STUDY SITES

- ➔ Feasibilities
- ➔ Contact to hospitals, institutes and surgery networks
- ➔ Trial-specific counselling

MEDICAL WRITING

- ➔ Study protocols
- ➔ IB, IMPD, manuals, dossier sections
- ➔ Study Reports, publications

QUALITY MANAGEMENT

- ➔ Development, establishment and safeguard of determined (international) quality standards
- ➔ Internal quality assurance
- ➔ Certified in accordance with ISO 9001

TRIAL ANALYSIS AND TERMINATION

- ➔ Statistical analyses
- ➔ Clinical study reports
- ➔ Archiving

BASIC AND ADVANCED TRAINING

- ➔ Certified courses e.g. for investigators IMP / IMD, principal investigators and training for monitors, study nurses
- ➔ Further activities and events related to methodological and practical aspects of clinical trials
- ➔ Inhouse-trainings



Photo: University Hospital of Cologne



Please find additional contact information on the back.