

Partners

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

- ➔ Institute of Medical Statistics and Computational Biology University of Cologne, Faculty of Medicine (IMSB)

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

- ➔ University hospitals, hospitals and surgery networks

- ➔ Contract Research Organisations (CRO)

- ➔ Pharmaceutical Companies

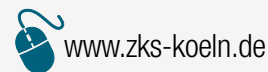
- ➔ Medical devices manufacturers



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

CONTACT

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UNIVERSITY OF COLOGNE

**Clinical Trials
Centre Cologne**



As of January 2020

Photo: University Hospital of Cologne

Clinical Trials Centre (CTC) Cologne

Clinical trials are an essential component of medical progress: As a competent research partner the Clinical Trials Centre (CTC) Cologne bundles the complete range of services for the successful planning, implementation and publication of clinical trials.

Located at the University of Cologne, the CTC Cologne as a specialized institution accompanies and accelerates latest research approaches with specific scientific services and infrastructure.

The CTC Cologne supports Europe-wide physicians and scientists at universities, clinics and research clusters (Investigator Initiated Trials, IITs) as well as pharmaceutical companies and medical device manufacturers in almost all indications. The CTC Cologne operates according to the standards of GCP as well as relevant national and international directives, guidelines and standards.

The CTC Cologne acts as a link between the University Hospital and the University of Cologne: due to the close cooperation with natural sciences and the coordination of scientific networking, promising findings from basic research can be quickly transferred to clinical practice. An ISO-certified, detail oriented quality management system supports the paramount duty of CTC Cologne: The well-being and safety of patients.

Additionally, the Academy of CTC Cologne qualifies study staff through specific clinical research related training courses.



Photo: University Hospital of Cologne

Services

CONSULTING

- ➔ Trial concept and design, trial feasibility
- ➔ Regulatory classification
- ➔ Cost calculation
- ➔ Financing sources and funding options
- ➔ Sponsor responsibilities according to AMG/MPG/GCP

TRIAL PREPARATION

- ➔ GCP-compliant quality management including RBQM
- ➔ Trial conception and sample size calculation
- ➔ Site feasibility
- ➔ Contact to clinics, institutes and practitioners networks
- ➔ Development of trial protocol, patient informed consent form, manuals, etc.
- ➔ eCRF development
- ➔ Setup and validation of the trial database
- ➔ Regulatory management (e.g. trial registration, trial application to authorities and ethics committees)
- ➔ Drafting and tracking of contracts (e.g. trial sites, service providers)

TRIAL CONDUCT

- ➔ Project management
- ➔ Maintenance of databases, ongoing data management
- ➔ Safety management (using a validated safety database)
- ➔ Medical monitoring
- ➔ On-site and remote monitoring



TRIAL ANALYSIS AND COMPLETION OF TRIALS

- ➔ Statistical analyses
- ➔ Preparation of clinical study reports, publications, etc.
- ➔ Registration of results (e.g. PharmNet.Bund, EU-CTR)
- ➔ Support with trial archiving

QUALITY MANAGEMENT

- ➔ Established (international) quality standards
- ➔ Internal quality assurance
- ➔ Certified according to ISO 9001

FLYING STUDY NURSE SERVICES

- ➔ Trial site assistance, Feasibility Management
- ➔ Preparation and support of monitoring visits, site audits and inspections
- ➔ Process improvement for trial sites

BASIC AND ADVANCED TRAINING

- ➔ Courses for investigators and subinvestigators (IMP), principle investigators and investigators (IMD), coordinating investigators, study nurses etc.
- ➔ Further activities and events related to methodological, regulatory and medical aspects of clinical trials. Inhouse-trainings



Please find additional contact information on the back.