

Short Profile of Interdisciplinary Centre for Clinical Trials at the University Medical Centre Mainz

Institution

IZKS is a professional academic research organisation at the University Medical Centre (UMC) Mainz. IZKS connects clinical study activities in clinical trial units with non-clinical and methodological study activities. Implementation and development of IZKS is funded by German Federal Ministry of Education and Research for continuous optimisation of multicentre clinical trials, for building regional trial networks and for improving qualification of study personnel.

70 trained and experienced medical, scientific and technical employees contribute to planning, conduct, evaluation and publication of clinical trials.

Extensive training programmes have been established for internal and external study staff.

Core Competences

Full scope of clinical research with focus on conception, planning, conduct and analysis of innovative clinical studies according to ICH-GCP

- Efficient and quality-oriented conduct of clinical trials in 11 professional clinical trial units: Cardiology, Dermatology, Gynaecology, Gastroenterology, Hepatology/ Infectiology, Immunology/Haematology, Neurology, Oncology, Paediatrics, Psychological Disorders, Pulmonology
- Broad spectrum of methods and patients in 24 disease areas
- Sponsor responsibility in clinical trials: full service or individual services
- Project management
- Writing of study protocol and study report
- Quality management
- Regulatory Affairs
- Monitoring
- Biometrics and Data Management
- Information technology including Electronic Data Capture System (EDC) and web-based randomisation
- Pharmacovigilance including SUSAR reporting and Annual Safety Report
- Education and training for investigators, scientists, study nurses, monitors and medical students

Cooperations

IZKS Mainz is member of the German KKS network (www.kks-netzwerk.de) and the TMF („Telematik Plattform für Medizinische Forschungsnetze“, TMF: www.tmf-ev.de).

IZKS has established cooperations with academic and non-academic hospitals, private physicians, study groups, paediatric network (PAED-Net: www.paed-net.org), surgical network (CHIR-Net: www.chir-net.de), competence networks in medicine and with pharmaceutical and medical device industry.

IZKS offers cooperations to industry concerning

- Industry Initiated and Investigator Initiated Trials: from hypothesis to publication
- Selection of clinical relevant biomarkers and surrogates
- Communication with authorities and ethics committees

CONTACT:

Head of IZKS: Dr. M. Seibert-Grafe, Phone: +49 (0)6131/3934630, seibert-grafe@izks-mainz.de

Deputy Head of IZKS: Dr. T. Gorbauch, Phone: +49 (0)6131/3934666, gorbauch@izks-mainz.de