The Interdisciplinary Centre of Clinical Trials (IZKS) Mainz

As a central research platform of the University Medical Centre Mainz we support the research of doctors, scientists, start-up companies as well as our academic partners in the science-life industry. Our services include the consultation on clinical research projects as well as their development and execution in accordance with the Medicinal Products Act (AMG) and the Medical Device Regulation, In-Vitro Diagnostics Regulation and Medical Device Law Implementation Act (MDR/ IVDR, and MPDG). The teamwork of experienced doctors, data analysts, computer scientists, and life scientists ensures that these research projects' are conducted on a high level of quality and effectiveness, especially during the development and execution stages. Furthermore, the IZKS Mainz is responsible for the (continuous) education of the trial staff on the AMG, the Regulation (EU) 536/2014 as well as the MDR/IVDR and MPDG in accordance with their up-to-date curriculum.

Our integrated Medical Device Innovation Centre (MIC) focuses on MDR-compliant and efficient development of medical devices and procedures based on closed cooperation between clinics and manufacturers. The MIC also supports the evaluation, the clinical use and safety of medical devices in the Post-Market Surveillance (PMS) phase to ensure continuous surveillance after CE-certification.

Optimizing Clinical Research

In 1999 the Coordination Centre for Clinical Trials Mainz (KKS) was founded to strengthen the structural integrity and competence of the patient oriented clinical research of the University Medical Centre Mainz. In 2007, the IZKS Mainz (funding code: 01KN1103) formed out of the KKS through constant advancement and the allocation of the clinical trial sites grant of the German Federal Ministry of Education and Research (BMBF). Until April 2015, the BMBF sponsored the IZKS Mainz to optimize clinical research and consolidate the successful German contributions to the field.

Providing Methodological and Scientific Competence during the Clinical Trial Proceedings

The IZKS Mainz accompanies their research partners throughout the clinical trial proceeding – from the initial idea to the final publication – with its methodical and scientific approach. We provide competent support to doctors, researchers as well as public institutions and companies that plan an investigator initiated trial (IIT) or a sponsor initiated trial (SIT). It is imperative to us that the application for public funds or gain of support from the pharmaceutical industry is on equal standing to the efficient and safe implementation of the trials. Furthermore, the IZKS Mainz assists in the conceptualization of studies, their efficient implementation including the management of related responsibilities, and statistical data analysis. We offer to either completely manage the clinical trial proceedings, including the sponsor related tasks that can be delegated, or just assume a partial role in selected areas if required.

Our Services (incomprehensive list)

Consultation and Development

- Generating ideas
- Trial design with calculation of sample size

Trial Coordination / Project Management

- Counselling from conceptualizing ideas to publication
- Coordinating all administrative, logistical, and regulatory aspects

Clinical Monitoring

- Continuous quality controls on behalf of the sponsor (ensuring that the trial proceedings are in accordance with ICH-GCP, reporting side effects, verifying the proper handling of the clinical trial products etc.) by the monitor (clinical research associate, CRA)
- Selection of test centres, initiation of the trials, regular monitoring, and writing the close-out-report

Safety Management

- Managing serious adverse events (SAEs)
- Handling of SAE reconciliations

Biometry/ Statistics

- Planning sample size calculation
- Preparing statistical analysis

Data Management

- Creating case report forms (CRFs) and patient diaries
- Providing data access, incl. user support

E-Trial systems and –processes

- Project websites with integrated trial tools
- Individual software development

Regulatory Affairs and Quality Management

- Submitting applications to the competent federal authorities and the ethics committee (permits, votes etc.)
- Reporting of study sites to the regional authorities

(Continuous) Education Certificates

- Courses for investigators in accordance with the AMG/ EU regulation 536 or MDR/IVDR and MPDG
- Internal trainings, study nurse courses, introductory courses on the topic of clinical research for students

Trial portfolio

- Studies in accordance with the AMG, phases I – IV
- Studies in accordance with the MPDG
- Interventional studies outside of AMG and MPDG
- Healthcare research
- Register studies, diagnostic studies
- Post authorization safety studies (PASS)

ECRIN Certificate

In 2016, the IZKS of the University Medical Centre Mainz was certified as one of six highly qualified data centres in Europe by ECRIN (European Clinical Research Infrastructure Network). Therefore, the IZKS Mainz executes clinical trials efficiently, safely, and in compliance with EU-regulations in the data management field as certified by ECRIN.

Translational Research and Healthcare Research

Besides supervising and performing clinical trials, we dedicated ourselves to the advancement of translational research as well as healthcare research. Therefore, the IZKS has established a register for severe asthma cases and heart failure with up-to-date informational exchange technology to account for the efficiency of the treatment options and ensure the supply with the appropriate medications.

Information regarding courses:

E-Mail: izks-kurs@izks-mainz.de

Phone: 06131/17-9943

Do you have an idea for a clinical study?

E-Mail: Beratung@izks-mainz.de

Phone: 06131/17-9913

About IZKS Mainz

- Head of the IZKS: Dr. med. Michael Hopp
- E-Mail: office@izks-mainz.de
- Website: https://www.izks-mainz.de/
- Established in: 1999 (forming out of the medical faculty)
- Network member since: 1999
- Staff: 65 (in 2023)