References

Major Clinical Trials

The **SiLVER Study** is a large international multicenter IIT sponsored by the University Hospital Regensburg, with Prof. Edward K. Geissler, PhD as Sponsor Representative, carried out in 13 countries (Europe, Canada and Australia), involving 45 participating study centers and 525 patients. Our clinical trials team coordinated this Phase III, prospective, open-labeled, randomized clinical trial comparing Sirolimus-containing versus mTOR-inhibitor-free immunosuppression in patients undergoing liver transplantation for hepatocellular carcinoma. (2006 – 2015) www.silver-study.org

The ONE Study is an EU FP7 Collaborative and Large-Scale Integrating Project on translational research in cell-based immunotherapy, coordinated by Prof. Edward K. Geissler, PhD, as Chief Investigator and EU Project Leader, and our clinical trials team. This international consortium consists of 16 partners, ten of which are academic institutions and six are companies that support research. In the context of this EU project, one phase-IV and six phase-I/II clinical trials are being conducted at eight trial centers located in five countries (France, Germany, Italy, UK and USA). (2010 - 2017) www.onestudy.org

The EXPAND Study (**EX**tended **PAN**creas **D**onor Program) is a German non-AMG study, designed as a prospective controlled multicenter feasibility study to investigate a new pancreas allocation system for transplantation in Germany. (2011 - 2016) www.expand-study.org

Monitoring of **The MISOT-I Study:** an IIT conducted on behalf of the University Hospital Regensburg by Apl.-Prof. Dr. med. Marc H. Dahlke as Sponsor Representative. This pioneering Phase I study aims to assess the safety and feasibility of MAPC (MultiStem®, Athersys Inc.) therapy in patients after liver transplantation. (2013 - 2017) www.misot.eu

In addition, we provide our services to other/external sponsors in the following indications:

- Alzheimer's disease (Washington University, St. Louis, Missouri, USA)
- Medulloblastoma (Neuro-oncology, medbo, University Regensburg)
- Glioma (Istituto Neurologico, Milano / Neurosurgery, UHR)
- Actinic Keratosis (Dermatology, UHR)
- Septic multi-organ dysfunction (Surgery, UHR)
- Acute Myeloid Leukemia (Hematology & Oncology, UHR)
- Prostate cancer (Hematology & Oncology, UHR)
- Peripheral artery disease (Vascular Surgery, UHR)

Studies may be performed in cooperation with the
Center for Clinical Studies (ZKS)
at the University Hospital Regensburg.

General Information

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Welcome to coTrial Associates

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ZKS Partnership

Our group cooperates together with the Center for Clinical Studies (ZKS) at the University Hospital Regensburg as a Central Study Unit to support all of your clinical trial needs.

Areas of Expertise

Start-up Activities/Consulting

- Consultation on IITs and other clinical trials (Phase I-IV)
- Study design and planning according to ICH-GCP guidelines as well as local law (AMG) and international standards
- Feasibility
- Budget planning and tracking
- Site contract negotiation and implementation
- Collection of essential documents
- Obtaining patient insurance

Project Management and Quality Assurance

- Oversight and management of the complete clinical trial
- Interface to all involved stakeholders
- Proactive and efficient working procedures
- Budget monitoring and supervision (on time-on budget)
- SOP development and maintenance
- Quality Assurance

Monitoring and Site Management

- Study site initiation visits, regular site monitoring visits and close-out visits in German and English speaking countries (including USA)
- Timely follow-up (visit reports, issue escalation, etc.)
- Training of site staff
- Comprehensive consultation and contact with the sites
- Ensure data quality and adherence to protocol

Areas of Expertise

Pharmacovigilance

- Safety data management
- xEVMPD submission and amendments
- SAE management and SUSAR reporting (incl. eSUSAR reporting)
- Medical assessment
- DSUR - Annual Safety Report preparation and submission
- Data Safety Monitoring Board (DSMB) coordination

Regulatory Affairs

- Clinical Trial Applications to ethics committees (ECs) and competent authorities (including internationally)
- Submission of substantial amendments
- Notification to local authorities

Medical Writing

- Study protocols and amendments
- Patient Information and Informed Consent
- Final Clinical Study Report

Project Administration and Coordination

- Investigational Medicinal Product (IMP) supervision, monitoring and accountability for all sites
- Essential document preparation and tracking
- Development and maintenance of Trial Master File
- Administrative and logistical support, e.g. site payments for patient participation
- Organization of Investigator meetings
- Medical editing by native English speakers
- Preparation for archiving