

Major Clinical Trials

Team

The SILVER Study is an international multicenter IIT sponsored by the University Hospital Regensburg, with Prof. Edward K. Geissler, PhD as Sponsor Representative, 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, of which ten 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 (EXtended PANcreas Donor Program) is a German non-AMG study, designed as a prospective controlled multicenter feasibility study to investigate a new pancreas allocation system 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

Other Clinical Trials:

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 of Regensburg)
- Glioma (Istituto Neurologico, Milano / Neurosurgery, University Hospital Regensburg)
- Actinic Keratosis (Dermatology, University Hospital Regensburg)
- Septic multi-organ dysfunction (Surgery, University Hospital Regensburg)
- Acute Myeloid Leukemia (Oncology, University Hospital Regensburg)
- Prostate cancer (Oncology, University Hospital Regensburg)
- Peripheral artery disease (Vascular Surgery, University Hospital Regensburg)

Certain studies have been performed in cooperation with the Center for Clinical Studies (ZKS) at the University Hospital Regensburg.

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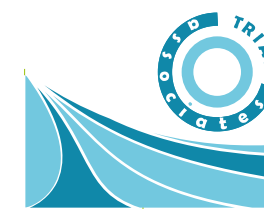
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Professional Clinical Trial Services

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Welcome to coTrial Associates

Our experienced team can offer you a wide range of clinical trial services to support your Investigator-Initiated Trials (IITs) and other clinical studies.

Our clinical trials support team consists of health care professionals and scientists with considerable international experience in initiating and conducting Phase I-IV clinical trials according to the ethical principles outlined in the Declaration of Helsinki, and consistent with national laws (e.g. AMG, GCP-V) and international standards (ICH-GCP).

coTrial Associates is an excellent alternative to an expensive CRO. Please contact us for a reasonable estimate in covering all your clinical trial needs.

**Let our experienced team help
you achieve your goals!**



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.

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 analyses
- 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

Regulatory Affairs

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

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

Pharmacovigilance

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

Data Entry and Data Management

- Data entry
- Central review of entered data
- Data validation
- Query management
- Ensure data integrity

Medical Writing

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

Study Site Tasks – Study Nurse Services

- Preparation and coordination of patient visits
- Documentation in (e)CRF
- Drug accountability
- Contact person for CRA

Project Administration and Coordination

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