



Major Clinical Trials

SiLVER Study: “A prospective, open-labeled, randomized clinical trial comparing Sirolimus-containing versus mTOR-inhibitor-free immunosuppression in patients undergoing liver transplantation for hepatocellular carcinoma”

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: “A Unified Approach to Evaluating Cellular Immunotherapy in Solid Organ Transplantation”

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

EXPAND Study: “EXtended PANcreas Donor Program”

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

MISOT-I Study: “Safety and feasibility of multipotent adult progenitor cells for immunomodulation therapy after liver transplantation: A phase I study of the MiSOT study consortium”

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 aimed 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 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 (Hematology & Oncology, University Hospital Regensburg)
- Prostate Cancer (Hematology & Oncology, University Hospital Regensburg)
- Peripheral artery disease (Vascular Surgery, University Hospital Regensburg)

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