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**TRIGA-S
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BVMA member since 2018
Audit passed in 2018



HISTORY AND MISSION

TRIGA-S is a privately-owned clinical research organization and a well-established partner for the in vitro diagnostic (IVD) and medical device industry since almost 20 years. We offer tailor-made solutions for clinical studies and laboratory service including analytical and clinical performance studies in our own S2 laboratory as well as sample testing/management, storage and study logistics. Our GCP/GCLP trained teams work according to IVDR, MDR and national regulations.



HIGHLIGHTS

20 years of experience in IVD and medical device studies.

20 years of experience in sample management, processing and testing.

290 m² S2 safety laboratory for performing in vitro diagnostic studies and providing laboratory support.

Study logistics including assembling/shipping sample collection kits and temperature-controlled shipments of clinical samples

330 m² temperature-controlled human sample and reagent storage at RT, 4°C, -20°C, -80°C. Real time web-based temperature monitoring of sample/reagent temperature.

SERVICES

Clinical Trial Management and Monitoring Services

- Project management for national and international clinical and technical trials
- Planning study design and conduction, medical writing
- Development of study protocol, CRFs and training materials
- Submission to IRB/EC and regulatory authorities
- Site assessment, selection and monitoring
- Preparation and maintenance of the trial master file (TMF)
- Supply of study material
- Training of the study staff
- (S) AE / (S) ADE Documentation and notification to the sponsor
- Preparation of audits and inspections
- Participation in publication writing

Laboratory Services

- Planning of sample collections
- Providing sample collection kits
- Sample preparation and processing
- Application testing and analytical test validation
- Tailor-made laboratory information system
- Investigational site for exploratory/pilot/performance evaluation and post-launch studies (e.g. clinical chemistry, immunochemistry, serology)

Clinical Trial Logistic Services for IVD, MD and Pharma studies

- Organisation of the entire study logistics and sample collection worldwide, conform with the standards for traceability
- Barcode and label management
- Temperature-controlled storage of clinical specimen and study materials
- Transfer of shipping documentation and customs clearance
- Flexible solutions for short-term study changes

