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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 m<sup>2</sup> 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 m<sup>2</sup> 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