COMPANY PROFILE

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History and Mission

Studies. Services. Solutions. TRIGA-S GmbH is a specialised Contract Research Organisation (CRO) with over 25 years of experience in analytical and clinical performance studies for in vitro diagnostics (IVDs) and companion diagnostics (CDx). As an ISO 13485-certified CRO with our own in-house BSL-2 contract laboratory, we support IVD manufacturers with conformity assessment under the IVDR – and pharmaceutical companies from exploratory R&D analytics through to CDx validation. We deliver compliant and audit-ready results for your regulatory success – so you can face audits with confidence and achieve fast, secure market entry.

Highlights

- In-house BSL-2 contract laboratory – for safe and precise analytics
- 25+ years of IVD expertise
- ISO 13485-certified, GCP/GCLP-compliant
- European and international logistics with full chain-of-custody traceability
- Functional Service Provider (FSP)
- Flexible & adaptable – fast project setup, last-minute changes, no minimum quantities

BVMA

www.bvma.de

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BVMA member since 2018
Audits passed in 2018,
2021 and 2024

TRIGA-S
Studies. Services. Solutions.

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Services

Study Management & Monitoring

From study preparation, site management, monitoring, and data management – including eCRF design and maintenance – to the audit-ready final report, TRIGA-S manages your IVD study in accordance with the IVDR, ISO 20916, and, if applicable, CFR, to ensure full traceability and a submission-ready outcome.

Biostatistics & Evidence

Guideline-compliant analysis plans (SAP), conservative sample size planning, and validated analysis reports (SAR) that stand up to audits and regulatory authorities. Including Post-Market Performance Follow-up (PMPF).

Sample Management

A validated process for the entire sample lifecycle – from receipt, storage, aliquoting, and processing through to labelling and global shipping.

Contract Analytical Testing & Applications

From exploratory contract testing and feasibility studies to method comparisons and application works – precise, comparable, and submission-ready, even with the smallest sample volumes. In-house BSL-2 laboratory: clinical chemistry assays, immunoassays, ELISAs, and real-time PCR.

Clinical Study Supply Management

Worldwide coordination of study logistics: from the assembly of validated collection kits and temperature-controlled storage to global shipping – regulatory and customs-compliant, with full chain-of-custody traceability.

All services can be booked individually, in combination, or as a complete end-to-end solution.

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