

■ COMPANY PROFILE



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History and Mission

As a wholly owned subsidiary of the Stiftung Institut für Herzinfarktforschung, a non-profit foundation, we have been managing registry studies, non-interventional studies and randomized clinical trials of phases II, III and IV for more than twenty years. We support research on cardiovascular diseases, risk factors and concomitant diseases. Healthcare research and post-market studies are our key areas, as well as randomized therapy strategy comparisons and disease registries.

Highlights

Experience

- More than 20 years of research experience in Cardiology and other indications
- Healthcare Research
- Post-market studies
- Therapy strategy comparison trials
- Disease registries
- §137e SGB V studies („Erprobungsrichtlinie“)
- Sponsorship of IITs

One-stop-shop for most projects

- Mid-sized CRO
- All relevant services in-house

In-house developed eCRF system “EBogen”

- High usability
- Flexible adaptation to study requirements



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BVMA Member since 2021
Audit passed in 2021



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Services

Regulatory Affairs Consulting

- Study design and planning
- Competent Authority and Ethics Committee submissions

Medical Writing

- Study protocol development
- Interim and final study reports
- Abstracts, publications and congress support

Project Management

- Clinical project management
- Communication between all project parties
- DSMB management

Site Management / Monitoring

- Site selection
- Contract negotiations
- Clinical monitoring
- Site support

Patient services

- Telephone patient follow-up
- Collection and adjudication of relevant medical documents for patient reported events

Data Management

- CRF design
- Data management plans
- Data validation plans
- Clinical trial database
- Integrated online plausibility and consistency checks
- Manual data review
- Query management
- Live status reports

Event adjudication

- Collection of medical reports and imaging data
- Organization of clinical event committees for event adjudication

Statistics

- Statistical study planning and consultation services
- Sample size calculations
- Statistical analysis plans
- Creation of statistical analyses and reports



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