

COMPANY PROFILE



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History and Mission

For over 30 years, **METRONOMIA** has been the exceptional CRO partner for biostatistical services and consulting, clinical data management and medical writing. Our team of 85 highly skilled and committed employees serve the needs of global customers and their projects with the highest degree of flexibility, reliability and quality. Over 600 successfully conducted projects in all clinical development phases and major therapeutic areas are testament to our achievement of data science excellence.

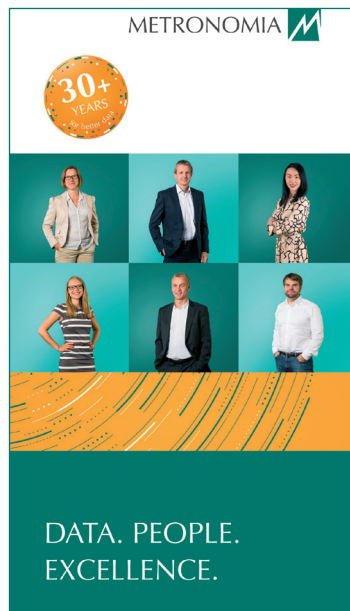
Highlights

Our Unique Selling Points:

- 100% local to Germany, 100% diverse and 100% global coverage
- Direct access to expert statisticians & data managers
- State-of-the-art knowledge, processes & technology
- Seamless integration with and extension of your team
- Enduring partnerships through outstanding customer satisfaction

Our Commitment:

- Exceptional quality & precision
- High acceptance by national & international authorities
- Minimization of risks & maximization of potential of your clinical data



METRONOMIA
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BVMA member since 2015
Audits passed in 2015, 2018 and 2021



www.metronomia.net

Services

Biostatistical Consulting

- Study design consulting
- Statistical planning, sample size and power calculation, simulation studies
- Regulatory agency meetings

Medical Writing

- Study protocols and CSRs
- DSURs
- Publications

Biostatistical Services

- Statistical Analysis Plan
- Full range of CDISC services
- Statistical programming
- Data Review Meeting
- Integration of studies and pooled analyses
- Independent DMC statistician & DSMB support
- Randomisation / IWRS

Non-Clinical Support

- Non-clinical statistics
- Biological data processing
- Non-clinical medical writing

Partnered Full-Service and Tailored Service Packages

- Feasibility studies and site recruitment
- Project management, clinical monitoring, RBM
- Safety management
- Regulatory services

Clinical Data Management

- eCRF & Database set-up
- Data validation
- Medical review and coding
- SAE management
- (e)PRO support
- EDC systems: Quadranteq Clincase and Medidata RAVE
- EDC services: User training, global 24/7 helpdesk

Trial Rescue Services

- Risk assessment and minimization
- Corrective and Preventative Action (CAPA) plans and implementation
- Project management and vendor oversight
- Uninterrupted data collection, processing, analysis and reporting