



Dr. Manfred Koehler
Chief Executive Officer
manfred.koehler@koehler-eclinical.com

KOEHLER eClinical GmbH
Hornusstr. 16
79108, Freiburg, Germany

Tel. +49 761 50318 0
Fax +49 761 50318 30

www.koehler-eclinical.com

BVMA member since 2012
Audits passed in 2012 and 2015



HISTORY AND MISSION

KOEHLER eClinical is an independent owner-operated contract research organization with over 20 years experience in providing clinical research services to the biopharmaceutical industry and life science organizations.

If you are looking for excellence in data management, biostatistics and EDC solutions KOEHLER eClinical is your reliable partner in study planning, conduct, evaluation and publication.



HIGHLIGHTS

KOEHLER eClinical is the successor company which was formed by the merger of Dr. Manfred Koehler GmbH Pharma Biometrics Consulting and its affiliated company clinIT AG, specialized in EDC solutions.

Quality of service is our top priority and is guaranteed by the extensively trained and highly qualified team and confirmed by regular external and internal audits. Our company is ISO 9001:2008 certified. We are proud to be an employee-oriented, family-friendly company with a dedicated team and low staff turnover.



SERVICES

Data Management and Data Integration

- (e)CRF design
- Database setup and maintenance
- CRF tracking and status reporting
- Data entry
- External data integration (e.g. central lab data, ECG data)
- Data validation and query management
- Medical review
- Serious Adverse Events (SAE) reconciliation
- Coding (e.g. MedDRA, WHO-Drug Dictionary)
- Database transfer
- Clinical data standardization and integration
- Mapping of clinical database to CDISC SDTM
- SDTM annotated blank CRF
- Generation of ADaM data based on SDTM
- Consistency checks between SDTM and ADaM
- Compliance checks with open CDISC validator

Biostatistics Services

- Contribution to study design
- Power analysis and sample size calculation
- Randomization
- Statistical analysis plans
- Periodic data monitoring and safety reviews by data safety monitoring board
- Statistical modelling
- Statistical analysis and reports
- Statistical support for publications
- SAS programming

Medical writing

