

## COMPANY PROFILE



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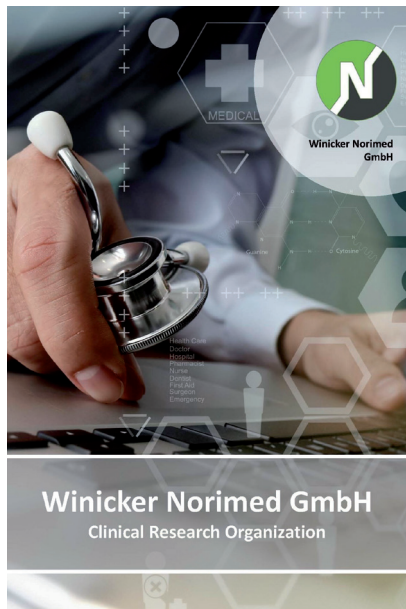
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## History and Mission

**Winicker Norimed GmbH**, established in 1993, is a full service Contract Research Organization. We offer a full range of services in clinical research from planning through reporting. We manage and conduct phase II-IV clinical trials, studies with medical devices and non-interventional studies, and offer various services related to benefit assessments, epidemiology and health services research. Advising you professionally and providing individual support are our top priorities.

## Highlights

Our highly skilled personnel have many years of professional experience in clinical research and consist of physicians, pharmacists, life scientists, statisticians, physicists, engineers, psychologists and other specialists with a medical background. Our reputation is based on professionalism, personal commitment and an efficient, client-oriented approach. We deliver quality services by strictly working according to applicable laws and regulations, international guidelines as well as ICH GCP / ISO14155 and by following our own or our clients' Standard Operating Procedures.



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BVMA member since 1993  
Audits passed in 2000, 2003,  
2006, 2009, 2012, 2015 and  
2018

[www.winicker-norimed.com](http://www.winicker-norimed.com)

## Services

### Set-up of Clinical Trials / Non-Interventional and Medical Device Studies

- Feasibility / investigator selection
- CTA / EC submissions
- eCRF and paper CRF development

### Project Management and Monitoring

- Full service project management
- On-site and in-house monitoring

### Clinical Data Management

- Database development according to sponsor's or CDISC standard
- Coding (incl. MedDRA and WHO-DD)
- Data validation and cleaning / quality control
- Online tutorials, study specific e-learning
- Supporting site interviewing / survey

### Safety (Pharmaco- and Medical Device Vigilance) / Safety Writing

- AE / SAE management
- Data management in Winicker Norimed's or clients' safety database
- Case narratives, medical reviews, reporting, literature / social media screening
- DSUR, PSUR / PBRER and RMP development and maintenance

### Biometry

- Statistical analysis based on standard analytical procedures with SAS
- Meta-analyses for scientific documentation

### Medical Writing

- Clinical study documentation according to relevant guidelines
- Clinical documentation for licensing procedures

### Benefit Assessment & Health Services Research

- Strategic consulting; development, writing and review of benefit assessment dossiers, supporting G-BA advice; methodological reports
- Studies for health service research and comparative effectiveness

### Trainings for Investigators and Study Personnel (online and face-to-face)

- GCP, GVP, MPG and ISO 14155, NIS-specific training