Jens Winicker
Managing Director
Jens.Winicker@winicker-norimed.com

Dr. Elfriede Lindauer
Managing Director
Elfriede.Lindauer@winicker-norimed.com

Dr. Dr. Norbert Banik
Managing Director
Norbert.Banik@winicker-norimed.com

Winicker Norimed GmbH
Medizinische Forschung

Deutschherrnstrasse 15-19
90429 Nürnberg, Germany
Tel. +49 911 92680 0

Sendlinger-Tor-Platz 11
80336 München, Germany
Tel. +49 89 2306968 70

Helmholtzstrasse 2-9, Aufgang H
10587 Berlin, Germany
Tel. +49 911 92680 8675

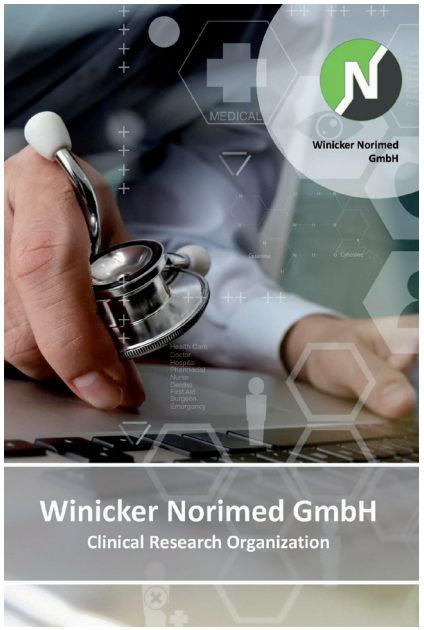
www.winicker-norimed.com

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

Winicker Norimed

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.

SERVICES

Set-up of Clinical Trials / Non-Interventional and Medical Device Studies
- ▷ Feasibility / investigator selection
- ▷ CTA / EC submissions
- ▷ e-CRF and paper CRF development

Project Management and Monitoring
- ▷ Full service project management
- ▷ On-site and in-house monitoring

Clinical Data Management
- ▷ Data base 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

Pharmacovigilance/Safety Writing
- ▷ AE / SAE management
- ▷ Case narratives, medical reviews, reporting, literature screening
- ▷ DSUR, PSUR/PBRER and RMP development and maintenance

Biometry
- ▷ Statistical evaluation 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 and ISO 14155, NIS-specific trainings