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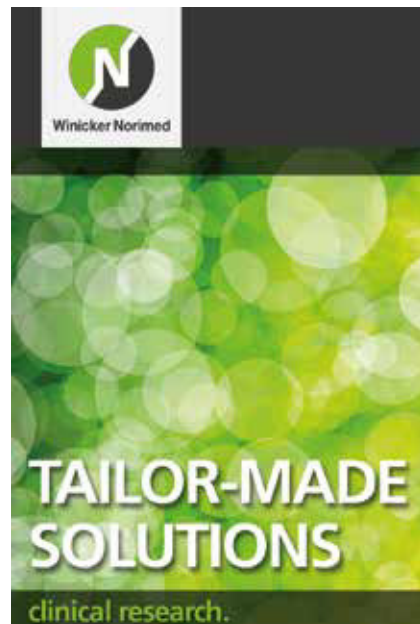
www.winicker-norimed.com

BVMA member since 1995
 Audits passed in 2000, 2003,
 2006, 2009, 2012 and 2015



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, medical device and non-interventional studies and offer various services related to benefit assessments, epidemiology and health services research. Advising you professionally and providing you with individual support are our top priorities.



HIGHLIGHTS

Our highly skilled personnel have many years of professional experience in clinical research and consist of physicians, life scientists, statisticians, 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 always working according to applicable laws and regulations, international guidelines as well as ICH GCP and by following our own or our clients' Standard Operating Procedures.

SERVICES

Set-up of Clinical Trials and Non-Interventional Studies

- ▷ Feasibility / investigator selection / meetings / trainings
- ▷ CTA / EC submissions
- ▷ e-CRF and paper CRF development

Project Management and Monitoring

- ▷ Full service project management, payment of investigator fees
- ▷ On-site and in-house monitoring, site management

Clinical Data Management

- ▷ Data base development according to sponsor's or CDISC standard
- ▷ Coding (using standard coding dictionaries, incl. MedDRA and WHO-DD)
- ▷ Data validation and cleaning / quality control

Pharmacovigilance

- ▷ AE / SAE management of medicinal products and medical devices
- ▷ Case narratives, medical reviews, reporting, literature screening
- ▷ PSUR / PBRER and RMP update and management

Biometry

- ▷ Statistical consulting / statistical analysis plan / randomisation plan
- ▷ Statistical evaluation based on standard analytical procedures with SAS
- ▷ Meta-analyses for scientific documentation

Medical Writing

- ▷ Clinical study reports (ICH-E3) / clinical trial protocols (ICH-E6)
- ▷ Clinical documentation according to ICH-M4 for licensing procedure
- ▷ Protocols, progress and final reports for PASS according to GVP Module VIII

Benefit Assessment & Health Services Research

- ▷ Strategic consulting; development, writing and review of benefit assessment dossiers, supporting G-BA advice; methodological reports
- ▷ Concepts and management of epidemiological studies, studies for health services research (incl. use of HER) and comparative effectiveness

Trainings for Investigators and Study Personnel

- ▷ GCP-trainings, GCP-refresher, NIS-specific trainings