Extensive expertise from a single source

Winicker Norimed, established in 1993, is a full service Contract Research Organization, located in Southern Germany in the center of Nuremberg. Our highly skilled team of experts has many years of experience in clinical research and consists of physicians, life scientists, psychologists, statisticians and other specialists with medical background. Our reputation is based on professionalism, personal commitment and an efficient client-oriented cooperation. We deliver quality by exclusively working according to internationally accepted standards, Good Clinical Practice and by following our or our clients' Standard Operating Procedures.

Winicker Norimed offers a full range of services in clinical research, from individual consultation up to complete study planning and conduct. We are specialized in phase II-IV clinical trials, non-interventional studies, clinical investigations and post market clinical follow-up studies with medical devices, epidemiological studies and registers.

Depending on your individual needs, we provide you with full or partial service.

Winicker Norimed is a member of the Federal Association of Contract Research Organizations (BVMA).

Additional services may be provided upon request.

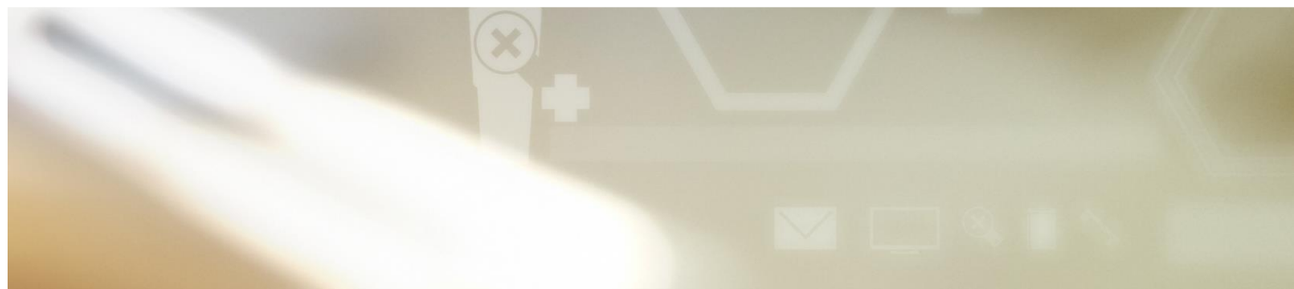
Please visit our internet homepage (www.winicker-norimed.com) for further information.

Winicker Norimed GmbH
Medizinische Forschung
Deutschherrnstraße 15-19
D-90429 Nürnberg

E-Mail: wn@winicker-norimed.com
www.winicker-norimed.com

Winicker Norimed GmbH

Clinical Research Organization



Expert know-how and experience

Set-up of Clinical Projects

- Consulting
- Clinical trials phase II-IV
- Non-interventional studies, epidemiological studies and registers
- Clinical investigations and post market clinical follow-up studies with medical devices
- CRF (paper and electronic) development
- Applications to competent authorities and ethics committees
- ICH-GCP and ISO 14155 training in accordance with the requirements of the German medical association (certified by several state chambers of physicians)

Project Management

- Handling of site contracts
- Continuously updated status reports
- Regular study team meetings and trouble shooting
- Study logistics
- Maintenance of the trial master file
- Management of investigator fees

Monitoring

- On-site and remote monitoring in accordance with ICH-GCP and/or ISO 14155
- Continuous interaction with data management
- Site management

Clinical Data Management

- Data base development in accordance with CDISC standard
- Coding (according to standard coding dictionaries, incl. MedDRA and WHO-DD)
- Data entry
- Intelligent character recognition (ICR)
- Data validation and cleaning (including audit trail)

We are at your service

Winicker Norimed GmbH

Vigilance

- Pharmacovigilance and Medical Device Vigilance
- Case processing, including support with incident processing for medical devices
- Conduct of follow-up procedures
- Processing of line listings
- Reporting to competent authorities
- Reconciliations

Biometry

- Statistical consulting
- Statistical analysis plan
- Randomisation plan
- Statistical evaluation based on standard analytical procedures with SAS
- Biometrical report
- Meta-analyses for scientific documentation

Medical Writing

- Clinical study protocols according to ICH-E6
- Clinical investigation plans according to ISO 14155 and MEDDEV
- Clinical study reports according to ICH-E3
- Clinical investigation reports according to ISO 14155
- Clinical documentation according to ICH-M4 for national or international licensing procedures
- Publication manuscripts

Benefit Assessment and Health Services Research

- Writing of dossiers for benefit assessments, including G-BA advice applications
- Strategic consulting for market access
- Design and conduct of studies for health services research (including studies on EHR)
- Development of adequate study designs and conducting of epidemiological studies