

MEDPACE GERMANY

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Resources and Experience

- Office established in 2003
- General Manager – over 10 years experience in the clinical research industry, with a background in medical writing
- Clinical Trial Managers – over 5 years experience in clinical research working with various pharma companies and CROs
- Project Coordinators – many years experience on multiple indications
- Safety Director – qualified in pharmacovigilance

Therapeutic Expertise

Medpace Germany employees have collective experience in the following therapeutic areas and types of trials:

- Phase I-IV
- Cardiology – hypocholesterolemia, myocardial infarction
- Metabolism – diabetes mellitus
- Oncology – adrenal carcinoma
- HIV
- Herpes

Services

Site Monitoring

- Perform site evaluation, initiation, routine monitoring, and closeout visits
- Ensure drug accountability
- Collect and maintain essential documents
- Perform data and safety monitoring, including EDC and CRFs

Regulatory

- Submit regulatory submissions and ongoing reports to authorities
- Correspond with ethics committee and central and local IRBs, as appropriate
- List and maintain trial details on National Research Register
- Export permit application and renewals for international material transfer
- Prepare, distribute, and track essential trial documents and master file

Project Management

- Ensure feasibility and protocol compliance
- Perform site identification and evaluation
- Coordinate local investigator meeting, if applicable
- Negotiate and manage investigator agreements and payments

- Oversee clinical trial supply importation and distribution
- Manage audits
- Manage archival of trial materials

Why Germany?

- Trial sites in Germany are starting to develop SOPs for the conduct of clinical trials
- Investigative sites have networks in place with private practices for patient referrals
- Investigators will support and highly market medications which they find effective to their patients
- English language skills are high in all levels of trial sites (PI, Sub-I, study nurses, lab technicians, etc.) and therefore not a barrier
- ICH GCP compliant Health Authority and Ethics Committee approval processes
- Experienced trial staff; many investigators are members of advisory boards and are key opinion leaders within their field
- High standard of data quality from trial sites
- Research can be done in both private and public sectors
- Excellent support infrastructure – air/railroad network, telecommunications, IT, etc.