ClinStat® GmbH

Institute for clinical research and statistics

Your success is our commitment

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About us

ClinStat is an independent contract research organization. We offer services especially for pharmaceutical companies, medical device manufacturers, clinics and health companies.

We support you in planning, conducting, reporting and publication of your results of clinical trials, non-interventional trials or desk research.

Key aspects of our working practice:

- Clinical trials phase I to IV
- Post-marketing studies
- Health Services Research / Public Health
- Health economics / modeling
- Meta-analyses / Indirect comparisons

Our core skills are:

- Statistical Consulting and Evaluation
- Market Access
- Quality Management
- Data Management
- Medical Writing

As a solid partner we are ready to work in extensive indications. In the following therapeutic areas we have long time experience:

- ✓ Anti-infectives and HIV
- ✓ Circulatory disorders
- ✓ Metabolic disorders
- ✓ Psychiatry / Psychotherapy
- ✓ Cardiovascular Disease
- ✓ Anesthesiology / Pain Management
- ✓ Gynecology
- ✓ Urology
- ✓ Ophthalmology
- ✓ Oncology
- ✓ Neurology
- ✓ Medical Devices

We also support you with short-term internal bottlenecks and help to distribute your resources efficiently. Our highly qualified scientific experts are the cornerstone of our success.

Statistical Consulting and Evaluation

For high-quality studies and valid study results qualified biostatisticians are essential. They will be involved in every study phase beginning with the generation of the study plan.

ClinStat accompanies you with its experienced and competent experts from the protocol right up to the compiling of the study report.

We take on the following tasks for you:

Study Planning

- Concept of the statistical study design
- Consulting at the choice of target criteria
- Sample size calculation
- Selection of the evaluation methodology
- Generation of the biometric part of study protocol
- Randomization

Statistical Monitoring

- Interim analysis and reports
- Preparation of Statistical Analysis Plan (SAP) including mock tables

Statistical Analysis of Studies

- Study oriented interpretation of the results and preparation of biometric or integrated reports
- Review of clinical reports, meta-analyses
- Participate in meetings with supervisors

Health Economics and Health Services Research

Health economics investigates and evaluates the allocation of limited resources in medicine and in the health care industry. Limited economic resources mean for sponsors not only in borderline cases, in the sense that the best possible financing decisions between different but similar health benefits must be justified. The prerequisite is that the evidence of the benefits of health service is proved. Compared to potential competitors, it is for providers of advantage if savings or an incremental additional benefit of its own product can be proved.

ClinStat's Health Economics and Supply Research Service support you in the development and implementation of:

Medical expenses studies
- Cost-Effectiveness Analyses
- Health Economic Appendix for clinical trials (Piggy-Back)
- Dossier Preparation: HTA, AMNOG
- Epidemiological Studies
- Health Services Research
- Systematic Reviews
- Meta-Analysis / Indirect Comparisons
- Database-/Register- Analyses
- Quality of Life- / PRO-Analyses

AMNOG Services

- Strategic Consulting related to Market Access and cost-benefit analysis
- Analysis of the therapeutic or diagnostic benefit and additional benefits
- Preparation and support of the Federal Joint Committee (FJC) Consulting
- Preparation of the Benefit Dossier (§ 35a SGB V)
- Methodical Consulting
- Systematic review, Meta-Analysis, Indirect Comparisons
- Budget Impact Analyses, Cost Analyses

Quality Management

Clinical trials must fulfill the requirements of ICH GCP criteria. Therefore the safety and welfare of patients or of volunteers has first priority.

The development of relevant and regulatory recognized report of study results is our primary goal adhering full compliance with their requirements.
We ensure the quality standards of your projects with means of:

- ✓ Standard operating procedures (SOPs)
- ✓ Validation of software
- ✓ Validation of evaluation programs
- ✓ Re-analysis, additional analyses

Data Management

An accurate data management is an important factor in clinical research. In the planning, generation, validation and documentation of the study database, we ensure that a complete, correct and reliable electronic data capture will be possible. To ensure the integrity and validity we implement quality assurance and quality monitoring measures.

Our services in detail:

- Creation of data management manual consisting of DM-Plan and DM-Report
- Customized database design according to CDISC
- CRF Design and Printing
- Data Collection
- Data validation including plausibility checks
- CRF and Query Management
- Coding of diseases, AEs, SAEs, and concomitant medications (ICD, MedDRA, ATC)
- SAE and External Data Alignment
- Compliance with the ICH-GCP guidelines and other national and international standards and regulations
- Work closely with all staff members involved in the study

Medical Writing

Medical writing and the generation of research-related documents should fully meet the regulatory and clinical demands. This is guaranteed by a careful approval process, ongoing monitoring and review.

All trial results must be presented precisely, accurately and clearly.

Our experienced team prepares all study-related documents and presentations for you.

We assist you in the preparation of:

- Medical scientific informations from literature
- Study Protocol
- Case Report Forms (CRFs)
- Clinical Study Reports
- Expert Reports
- Meta-analyses
- Safety Reports
- Interim Reports, Final Reports
- Submission of documents to authorities and ethics committees