WORK EXPERIENCE

Since 2011: Freelance Statistician

8 YEARS Associate Director Data Management and Biostatistics
MediGene AG, Planegg/ Martinsried, Germany

6 YEARS Project Manager
BZT GmbH, Munich, Germany

5 YEARS Scientific Assistant
Bavarian Research Unit Public Health, Munich, Germany
estimate GmbH, Augsburg, Germany

EXPERIENCE IN CLINICAL TRIALS

Oncology
Infectious diseases
Pain, inflammatory diseases/autoimmune diseases
Nutrition
Cosmetics

EDUCATION

Dr.rer.biol.hum. (Ph.D. in Human Biology)
Studies in Biology at the Ludwig-Maximilians University, Munich, Germany

Univ. Degree in Statistics (Dipl.-Stat.)
Studies in Statistics at the Ludwig-Maximilians University, Munich, Germany

MEMBERSHIPS

International Association for Biometrics, German Region

SERVICES

Dr. Anette Knoll offers the complete range of biostatistical services.

More than 14 years of statistical experience in various therapeutic areas and profound knowledge of ICH-GCP, national and international regulatory requirements ensure maximum quality throughout all stages of your product development.

STATISTICAL CONSULTING

- Study design consulting for phase I to IV clinical trials, non-interventional studies (post-marketing surveillance) and epidemiologic trials, including adaptive and flexible study designs
- Statistical input for protocol development
- Contribution to advisory board meetings
- Specialised preparation of scientific advice meetings with regulatory agencies
- Statistical support for Data Safety Monitoring Boards (DSMBs) and Independent Data Monitoring Committees (IDMCs)
- Statistical support for submissions to registration authorities

BIOSTATISTICS

- Biostatistical planning and consulting
- Sample size calculation
- Statistical parts of clinical trial protocol (development and review)
- Statistical analysis plans (SAPs) including mock tables and listings
- Data review meetings
- Statistical reports
- Statistical contribution to fully integrated study reports
- Key result memos
- Integrated summary of safety and efficacy
- Statistical input to annual safety reports
- Statistical input to publications and presentations

PROGRAMMING

- Biostatistical evaluations with SAS® and other state-of-the-art software
- Interim and final analyses
- Special programming for publications

PERSONAL AND INDIVIDUAL ACCOMPANYING OF YOUR CLINICAL TRIAL

STATISTICAL SERVICE ON YOUR KEY QUESTIONS

- Statistical consultancy in every aspect of your clinical trial
- Individual modelling of trial designs and analysis strategies, sample size calculations consistent with ICH-GCP and other regulatory guidelines
- Statistical analysis plans in accordance with the client's needs
- Statistical programming – tables, figures and listing preparation according to your SOPs and specifications
- Statistical writing
- Application of state-of-the-art software such as SAS®, nQuery Advisor®, etc.

PLEASE FEEL FREE TO CONTACT ME!

- The work can be tailored according to your SOPs and templates.
- All services can be contracted separately.

DR. ANETTE KNOLL

FREELANCE STATISTICIAN

STATISTICS AND MORE

DR. ANETTE KNOLL

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