



*QUALITY & STATISTICS!



* QuoData Service About Us

QuoData has been providing statistical consulting services, assisting with all aspects of experimental design, evaluation, and interpretation of clinical research and epidemiological studies. We can look back on over 20 years of experience in quality and statistics. As the heart of QuoData is advanced statistical methods, we go above and beyond the usual industry standards. This enables us to not only lay emphasis on validating the data and methods but also to provide accurate, data-driven conclusions with high reliability.

QuoData GmbH
Quality & Statistics
Prellerstraße 14
01309 Dresden-Germany

T +49 - (0)3 51 - 40 28 86 7 - 0
F +49 - (0)3 51 - 40 28 86 7 -19
info@quodata.de
www.quodata.de



Challenge
us! **NOW**

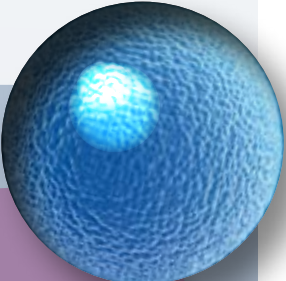


*QUALITY & STATISTICS!



* QuoData Service Human Clinical Trials

Enable evidence-based
value development



Get in
touch
with us!

Consistent, Collaborative, Creative:

Design and evaluation of human clinical trials



Human clinical trials

Adding value by formal assessment of causal evidence to support your development of diagnostics, new drugs, biological products, medical devices/therapies or treatments (e.g., surgical procedures among others). During a trial or an epidemiological study, more and more information is gained about the diagnostic / drug / medical device / treatment, its risks and how well it may or may not work. Pooling all this empirical evidence together, our team of experts help you to rigorously evaluate it.

We provide comprehensive services, right from statistical design of studies, accelerated literature reviews, to quantitative and qualitative evaluation.

Target audience

- Clinical research institutes
- Hospitals that are active in medical research
- Diagnostic companies
- Medical device manufacturers quality
- Pharmaceutical companies
- Clinical Research Organization (CRO)

We provide comprehensive services for design and statistical evaluation of the following types of non-commercial and commercial clinical studies

- 1** Non-commercial clinical studies: investigator-initiated trials (IIT)
 - according to GCP guidelines and the declaration of Helsinki
- 2** Diagnostic studies
 - according to EU regulation 2017/746
- 3** Clinical studies for medical devices
 - according to EU regulation 2017/745
- 4** Clinical studies for pharmaceuticals
 - according to GCP guidelines and ICH guidelines

Our services include:

- Consulting related to statistical aspects of study design and the study protocol
 - Study objective, study population, study design, and study procedure
 - Statistics: primary and secondary endpoints, statistical methods, estimation of sample size, level of significance and power
- Consulting related to Statistical Analysis Plan (SAP)
 - Sample size
 - Randomization
 - Statistical methods / approaches / procedures
- Statistical evaluation
 - Plausibility check of data
 - Statistical evaluation taking into account drop-outs
- Reporting of results

For more information visit us at
www.quodata.de/en