

We Understand the Dynamic Needs of Biotech

The key elements for a successful biotech company are not the same as for a typical pharma company. Because Quintiles started out as a small group of biostatisticians, we fully appreciate the challenges that a smaller organization can face in a large industry. We know that you need a customized, tailored approach when considering a partner for your statistical needs.

Quintiles Biostatistics has the tools to help you succeed. We offer strategic consulting in protocol design and planning to help you make optimal decisions on study design, sample size, study planning, analysis methods, and precise interpretation and presentation of results. Our internal Center for Statistics in Drug Development (CSDD) group consists of highly experienced statisticians who bring a wealth of knowledge and first-hand experience in the clinical trials arena. We can also tap into our expert external consultants from both the academic and drug development industries to bring an even bigger and broader level of knowledge to your specific statistical challenges.



CASE STUDIES

On one pivotal trial, our Center for Statistics in Drug Development (CSDD) was able to decrease an originally proposed sample size by almost 50%.

This was accomplished by:

- > Taking a different approach to the sample size calculation
- > Modifying the interim analyses set-up, and
- > Incorporating relevant covariates in the analysis

This proposed approach was fully accepted by the FDA reviewer.

In a recent very large Phase III trial, our CSDD group proposed an unblinded sample size re-assessment near the end of the study. The protocol was approved by the FDA and saved the sponsor two months in the expected duration of the study.

Broad Therapeutic Area Experience

Whether your indication is oncology, CNS, infectious disease, cardiovascular or one of the other critical areas of need, we will assign a specialized team that has the therapeutic experience you require and the professional expertise that you want.

Committed to Biotech

Quintiles has a dedicated group of project managers who work only with biotech companies. This group brings to your project invaluable knowledge and leadership that is critical to your success. Our proactive statisticians bring the flexibility, efficiency, teamwork and responsiveness you need.

Beyond Standard Analysis Services

Quintiles Biostatistics also offers:

- > Strategic consulting
- > Drug Development Plans
- > Adaptive Clinical Trials
- > Feasibility analyses
- > Due diligence
- > Event rate analysis to predict LPLV

- > Safety and Adjudication committee support
- > Periodic safety reporting
- > Data mining algorithms for protocol deviation and event detection
- > Site fraud detection analysis
- > Automated patient narratives
- > Pre-lock production strategies to decrease time from database lock to final CSR
- > Submission strategies and analysis
- > Statistical representation at regulatory agencies

CASE STUDIES (CONTINUED)

One of our CSDD statisticians worked closely alongside a sponsor to develop their Phase III strategy and program. By re-evaluating the sponsor's original study design strategy, the Phase III confirmatory studies were redesigned to meet – with fewer patients – a shorter timeline that still met efficacy requirements and size of safety database. Our statistician also supported the sponsor at the end of the Phase II meeting with the FDA when the redefined plan was accepted. This collaborative approach resulted in a cost savings of \$8 million.

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