Why Biostatisticians are Essential for Successful Clinical Trial Management

BY UTE BORONOWSKY article published by Labiotech

The role of biostatisticians goes far beyond analyzing data at the end of a clinical study. Instead, they should be involved in clinical trial management right from the start to maximize the chances for a new drug's market approval.

Biostatisticians in clinical trial management have a long to-do list. They advise on study design, calculate the right sample size, and ensure that the enrolled patients are correctly randomized. They help define endpoints, provide definitions for data analysis and create tables and figures for the clinical study report.

Malin Schollin

"People often think that biostatistics comes in at the end of a clinical trial, but this can lead to a lot of issues, for example, when you find out too late about missing data or incorrect randomization."

"There is great value in having a statistician on board during the entire project because then we can take part in the decision making, and help assess how it will affect analyses, evaluation, or results," said Malin Schollin, Director of Biostatistics at LINK Medical, a Swedish contract research organization.

Meaningful data at manageable costs

The work of biostatisticians starts with the preparation of the clinical study protocol.

Christina Ehrenkrona

"The clinical study protocol is really the core of any clinical study. In addition, the clinical study protocol defines the objectives and endpoints to be assessed during the clinical trial. Biostatisticians need to understand the scientific question underlying the study to give input to suitable parameters that can be measured with statistical relevance.

“Sometimes, we do real detective work in order to find the necessary input for the sample size calculation,” said Ehrenkrona. “Together with the clinicians, we research the studies that have been done before for similar treatments and how the data in these previous studies have been collected and analyzed.”

Biostatisticians also suggest exploratory endpoints in early phases that might be useful in future studies.

“You often see that the primary endpoint changes between early and late clinical phases to apply the knowledge gained along the way. We provide guidance on what is measurable, analyzable, and clinically relevant,” added Gunnar Danielsson, Senior Regulatory Advisor at LINK Medical.

Gunnar Danielsson

Avoiding bias in clinical study data

Another essential task for biostatisticians is to support the randomization and stratification of study participants to avoid bias in the resulting data. Bias can occur when clinical trial results are affected by factors not related to the treatment being tested.

Stratification of patient subgroups – those receiving either the treatment or placebo – ensures that the subgroups are sufficiently homogeneous to be comparable.

Especially with sites in different countries or environments, it is essential to ensure that subgroups should contain a representative partition of the local population.

“A classic example is the initial association between alcohol consumption and lung cancer – not considering that many people who regularly consume alcohol also smoke a lot. We need the input from clinicians on what might be affecting the treatment to obtain meaningful data on the treatment effect,” Schollin explained.

Biostatistics for successful market authorization

Maybe the most important document that biostatisticians create is the statistical analysis plan. It outlines in detail how the collected data will be used, analyzed, and displayed in tables and figures.

To pave the way for successful market authorization, the information the biostatisticians prepare for the clinical study report must be both statistically valid and compliant with regulatory requirements.

“The statistical analysis plan is a document that contains all our recipes,” Ehrenkrona explained. “It is finalized and signed before the database is

locked and the data unblinded, meaning that we can assign the patients to the treatment groups. If we haven't prepared our plan carefully, there's no second chance."

Clinical trial management is a team effort

Conducting a clinical development program is a team effort that includes input from medical, clinical operations, pharmacovigilance, and regulatory professionals, as well as a continuous involvement of biostatistics and data management experts.

Maintaining the same team throughout different clinical trials increases shared knowledge and allows lessons learned to be taken to the next clinical phase – saving time and cost while increasing the overall quality of the trial, and, ultimately, the chances for successful market authorization.

"At LINK Medical, our biostatistics team includes professionals with expertise in biostatistics, programming, and senior advisors with knowledge of regulatory requirements, giving our clients the broadest possible knowledge base," Danielsson concluded.

Contact LINK Medical to learn more about how the biostatisticians at LINK Medical can support your clinical trial management!