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Some possibilities in trial design to reduce sample size

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Abstract

In many cases, the sample size necessary to achieve a biosimilarity in Phase III trials can be very large. Hence, we may look to find ways to reduce the sample size while still maintaining acceptable Type I and Type II error rates. The reason for the large sample size is that the standard error of the treatment effect is often fairly large, yielding a small equivalence margin. In this talk, the speaker will present methodologies for calculating the equivalence margin through a disease-progression model. Given an equivalence margin, trial design has a large impact on sample size. Strategies to control sample size and reduce risk include building in an alpha-preserving interim analysis for futility, optimizing the choice of endpoint and indication, and using a functional data analysis approach to improve statistical analysis performance.

Biography

Russell Reeve, Ph.D., has worked in the pharmaceutical industry for more than 20 years. He is the author of more than 20 peer-reviewed journal articles in the field of statistics, has given numerous statistics talks, has been a leader in model-based drug development since developing the methodology in the 1990s, and has expertise in adaptive trial design. He is currently Senior Director in the Innovation group at Quintiles, where he is group leader of the Biosimilars Biostatistics Working Group, and has lead trial design for numerous biosimilars programs.