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Trial Designs for Biosimilars Development

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Abstract

In February 2012, the FDA issued guidance documents for the development of biosimilars, including scientific considerations. However, the exact details of what clinical trial designs will meet Agency scrutiny regarding bioequivalence have not been publicly disclosed. The FDA appears to be taking a "wait and see" approach as to what acceptable study designs may look like for biosimilar products to garner approval. In this talk, we discuss several trial design options for both Phase I and Phase III. Many options are available to the trial designer, including choice of endpoints, time on study, fixed design or adaptive (e.g., group sequential), single dose or multiple dose. For each phase, we discuss several of the more common design choices, the effect of the design on statistical considerations and power, and different options that appear to have acceptance. Finally, we mention the effect of design on site and country selection.

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.