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Scaled Average Bioequivalence Statistics for the Non-Statistician

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Far too often statistics is viewed as a black box into which data enters one side and results exit from the other, with the calculations performed in between considered far too complex or abstract for all but a statistician to understand. Most pharmaceutical scientists have finally become comfortable with the 90% confidence interval approach for average bioequivalence (ABE), at least in non-replicated studies. With the advent of the scaled average bioequivalence (SABE) method, we now have a powerful, but far more confusing statistical approach which requires reference replication. The black box associated with this method appears even larger than the one that exists for ABE. To add to the confusion surrounding FDA's recently disclosed calculations for SABE, the myth continues to spread that all we need to do is calculate the standard 90% confidence intervals and apply some "scaled" regulatory limit to the results. A simplified explanation of the SABE calculations, how they relateand do not relate to ABEwill be presented.In addition, minimal statistical concepts familiar to most scientists will be used to explain the inner workings of the SABE black box.

Biography

Charles Bon, M.S., is president and founder of Biostudy Solutions LLC, a pharmaceutical consulting company specializing in bioequivalence evaluations, located in Wilmington, NC. He has 38 years experience in all facets of bioequivalence testing, with 31 years employed with Phase I CROs. He served as member of FDA's outside panel that assisted with the development of the current guidance for bioequivalence testing of topical corticosteroids, as well as on FDA's blue ribbon panel for population and individual bioequivalence. He has published papers in the area of bioequivalence testing and is co-author,with Sanford Bolton, on the 4th and 5th editions of the textbook"Pharmaceutical Statistics."