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Study design: How not to ruin a perfectly good product with a perfectly flawed study design

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No two studies are alike, however there are many principles that carry across all studies for both drugs and devices. These principles are discussed in the domestic and international regulations: ICH E6, ICH E8, FDA CFR Title 12: 312, FDA CFR Title 12: 812, ISO 14155:2011. This presentation will discuss certain key principles and how to apply them to your study design.

Why don't studies always show statistical significance for their primary endpoint(s)? There are many reasons for this, the first of which is an ineffective product. Sometimes products just don't work as they are projected too. However, properly designed studies may be able to catch an ineffective product earlier in the development phase cycle – and the sooner it is determined that a product is ineffective, the more money saved for the developer. A second reason that many studies fail to show statistical significance is because they were poorly designed or implemented. Examples of this include: underpowering, inappropriate patient population, poor comparison group/controls, or the wrong dosing.

This presentation will discuss the different types of study designs, and how small changes can make a big difference in the outcome of your study.

Biography

Dr. Wilkerson and Dr. Baker have complementary and integrated expertise, forming an extremely powerful and knowledgeable research leadership team. Both have extensive experience in US and global product development for drugs, biologics and devices. Additionally, both have led clinical project/programs and/or departments and served as project advisors on numerous project teams, and have been responsible for the strategic planning of development programs for drugs, biologics, and devices in a variety of therapeutic areas. They have published more than 20 articles in reputed journals. Dr. Wilkerson holds her PhD in Biochemistry from the Stanford University School of Medicine, where she was a National Science Foundation Pre-Doctoral Fellow. Dr. Baker holds her PhD in Biometry and Epidemiology from the Medical University of South Carolina.