

Statistical Considerations for Design and Analysis of Bridging Studies



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Introduction In biological product development, a wide range of analytical methods are used to ensure product quality throughout the lifecycle of a product. These methods include tests for product identity, purity, concentration, and potency. As the product progresses through early-stage to late-stage development, and ultimately manufacturing, a parallel effort is made to improve the analytical methods, taking advantage of emerging state-of-art analytical technologies and increased understanding of drug mechanism of action. Bridging studies should be conducted to demonstrate that when compared...

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