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Sample Size Considerations in Clinical Trials Pre-market Approval

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Abstract

An important exercise in the design of protocols for new drugs is determining the number of patients required to address study objectives. This is important on a per protocol basis, as well as for the entire clinical development plan. Adequate numbers of patients must be studied within and across the phases of clinical development to justify moving forward with each phase as well as to support regulatory dossier filing. The phases of clinical development and their objectives are reviewed and their connection to labeling discussed. Statistical requirements for sample size determination are presented and recommendations made relative to the size of trials in each phase of clinical development pre-market approval.

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