CHAPTER

10

Biostatistics—Part II

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I. INTRODUCTION

A question commonly asked of statisticians in clinical trials is, "How many subjects do I need for this study?" This question is not easily answered as it depends on a number of practical and statistical considerations. In general, the sample size should be large enough to provide a reasonable answer to the underlying research objective of the study, but must be reasonably set based on the total patient population under investigation, the available study budget, or the length of time available for study evaluation. Wittes (1) stated that, "[t]he sample size of a trial must be large enough to allow a reasonable chance of answering the question posed but not so large that continuing randomization past the point of near-certainty will lead to ethical discomfort."

II. DISCUSSIONS THAT IMPACT SAMPLE SIZE DETERMINATION

The assumptions necessary for defining the sample size should be listed in the Clinical Study Protocol. These assumptions are often comprised from answers to the following questions:

- What is the primary objective of the study?
- What measure will be used to determine this outcome for a given subject?
- What is the clinically meaningful difference?
- What treatment effect is expected?
- What data analysis technique is appropriate for determining a difference between treatments?
- What degree of certainty is expected or required for ascertaining treatment difference?

[1]Wittes J. Sample size calculations for randomized controlled trials. Epidemiol. Rev. 2002;24(1).

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