



Introduction to Statistics in Pharmaceutical Clinical Trials

Todd Durham, J Rick Turner

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This book is a self-contained introduction to Statistics, presented in the context of clinical trials and pharmaceutical drug development. It focuses on the statistical analyses most commonly used in drug development and is therefore an ideal introduction to pharmaceutical statistics. Instead of introducing a series of statistical techniques, the book's organizational structure follows the order in which numerical information and statistical analyses are used in trials and new drug development. All students taking classes in pharmaceutical sciences and clinical research need a solid knowledge and understanding of the nature, methods, application and importance of Statistics. They need to understand: why, and how data are collected in clinical trials; how these data are summarized and analyzed; what the results mean in the context of the clinical research question; and, how the results are communicated to regulatory agencies and to scientific and medical communities. This title therefore adopts a unique approach and concept in organization of the content. It begins with an introduction to statistical theory, analysis and interpretation. This is followed by a discussion of t-tests and confidence intervals. Readers are then taken through the whole process of new drug development (using one specific example throughout) that is meaningful in the context of their broader studies. Throughout this process, statistical techniques and analyses are introduced in the order in which they are employed during the process. The book's realistic scientific and progressive organization from pre-clinical trials to clinical pharmacology through clinical trials is novel, meaningful and educationally powerful. The book emphasises the importance of descriptive statistics as well as inferential statistics, something that is rarely done. Supplementary material is included for this text on the PharmPress website in the form of PowerPoint lecture notes on Statistics (based on content of this book) that can be downloaded by lecturers.

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