

Developing New Drugs

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I first became interested in statistics for drug development when I was a student intern at Eli Lilly. It was then that I realized how prominent a role statistics plays in the pharmaceutical industry.

Before the Food and Drug Administration (FDA) will approve marketing of a new drug, the drug is tested through three stages of clinical trials. Phase I trials enroll healthy volunteers to characterize the safety and tolerability of the drug and to study its absorption and elimination by the body. Phase II trials are small-scale studies of the safety and effectiveness of the drug in patients for whom it is designed. Phase III trials are typically conducted on a large number of patients to evaluate the effectiveness and safety of the drug in detail. Statistical analysis of the results of these clinical trials provides the evidence on which the FDA bases its final decision on whether or not to approve the new drug application.

As a clinical statistician, I am responsible for collaborating with research scientists and physicians. My responsibilities include designing clinical trials and determining how many subjects will be required for the study. I also plan the statistical analysis and interpret the results. In addition, I carry out methodological research to find new ways to handle the many challenging statistical issues that arise in clinical trials.

Because of the diverse and complex nature of clinical trials, each individual trial raises many unique and specific issues that require creative solutions. For example, how should we deal with missing data due to disease progression in cancer patients?When should we stop a trial if safety concerns appear to outweigh the benefits, or if the drug works so well that we should give it to all patients? These are the kinds of challenges that deeply attract me to this profession. I experience great satisfaction from knowing that my work benefits patients by contributing to high scientific standards in clinical trials.