Second Edition

Statistical Thinking for Non-Statisticians in Drug Regulation

Statistical Thinking for Non-Statisticians in Drug Regulation, Second Edition, is a need-to-know guide to understanding statistical methodology, statistical data and results within drug development and clinical trials.

It provides non-statisticians working in the pharmaceutical and medical device industries with an accessible introduction to the knowledge they need when working with statistical information and communicating with statisticians. It covers the statistical aspects of design, conduct, analysis and presentation of data from clinical trials in drug regulation and improves the ability to read, understand and critically appraise statistical methodology in papers and reports. As such, it is directly concerned with the day-to-day practice and the regulatory requirements of drug development and clinical trials.

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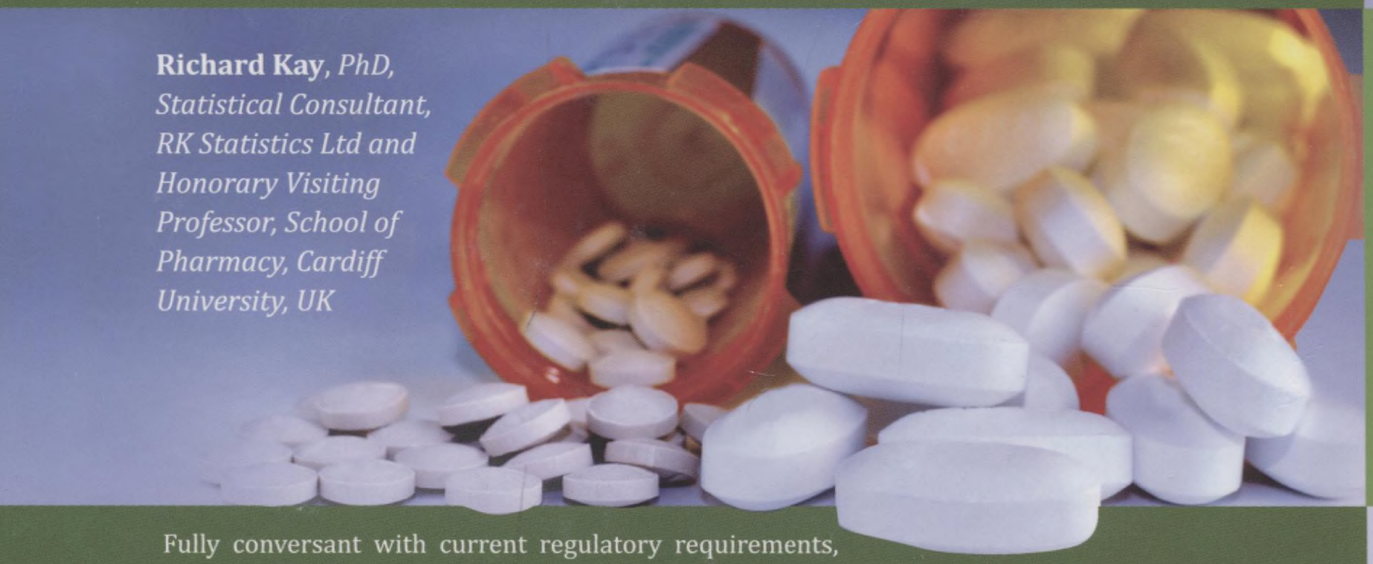

Fully conversant with current regulatory requirements, this second edition includes five new chapters covering Bayesian statistics, adaptive designs, observational studies, methods for safety analysis and monitoring and statistics for diagnosis.

Authored by a respected lecturer and consultant to the pharmaceutical industry, *Statistical Thinking for Non-Statisticians in Drug Regulation* is an ideal guide for physicians, clinical research scientists, managers and associates, data managers, medical writers, regulatory personnel and for all non-statisticians working and learning within the pharmaceutical industry.

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