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Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Basic ideas in clinical trial design -- Sampling and inferential statistics -- Confidence intervals and p-values -- Tests for simple treatment comparisons -- Adjusting the analysis -- Regression and analysis of covariance -- Intention-to-treat and analysis sets -- Power and sample size -- Statistical significance and clinical importance -- Multiple testing -- Non-parametric and related methods -- Equivalence and non-inferiority -- The analysis of survival data -- Interim analysis and data monitoring committees -- Bayesian statistics -- Adaptive designs -- Observational studies -- Meta-analysis -- Methods for the safety analysis and safety monitoring -- Diagnosis -- The role of statistics and statisticians.
Sommario/riassunto	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