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Autore	Senn Stephen
Titolo	Statistical issues in drug development // Stephen Senn
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Edizione	[2nd edition.]
Descrizione fisica	1 online resource (522 p.)
Collana	Statistics in practice
Disciplina	615/.190727
Soggetti	Drug development - Statistical methods
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	A brief and superficial history of statistics for drug developers -- Design and interpretation of clinical trials as seen by a statistician -- Probability, Bayes, P-values, tests of hypotheses, and confidence intervals -- The work of the pharmaceutical statistician -- Allocating treatments to patients in clinical trials -- Baselines and covariate information -- The measurement of treatment effects -- Demographic subgroups : representation and analysis -- Multiplicity -- Intention to treat, missing data and related matters -- One-sided and two-sided tests and other issues to do with significance and P-values -- Determining the sample size -- Multicentre trials -- Active control equivalence studies -- Meta-analysis -- Cross-over trials -- n-of-1 trials -- Sequential trials -- Dose-finding -- Concerning pharmacokinetics and pharmacodynamics -- Bioequivalence studies -- Safety data, harms, drug monitoring, and pharmaco-epidemiology -- Pharmaco-economics and portfolio management -- Concerning pharmacogenetics, pharmacogenomics, and related matters.
Sommario/riassunto	Drug development is the process of finding and producing therapeutically useful pharmaceuticals, turning them into safe and effective medicine, and producing reliable information regarding the appropriate dosage and dosing intervals. With regulatory authorities

demanding increasingly higher standards in such developments, statistics has become an intrinsic and critical element in the design and conduct of drug development programmes. Statistical Issues in Drug Development presents an essential and thought provoking guide to the statistical issues and controversies involved in drug

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