1.	Record Nr.	UNINA9910830834503321
	Autore	Senn Stephen
	Titolo	Statistical issues in drug development / / Stephen Senn
	Pubbl/distr/stampa	Hoboken, New Jersey ; ; West, Sussex, England : , : Wiley Blackwell, , [2021] ©2021
	ISBN	1-119-23859-5 1-119-23860-9 1-119-23861-7
	Edizione	[Third edition.]
	Descrizione fisica	1 online resource (643 pages)
	Collana	Statistics in practice
	Disciplina	615.19
	Soggetti	Drug development - Statistical methods
	Lingua di pubblicazione	Inglese
	Formato	Materiale a stampa
	Livello bibliografico	Monografia
	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 Trial -- 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	"This will be the third edition of Statistical Issues in Drug Development, and will be fully revised and updated to include information on the latest industry standards and guidelines. Both the first (1997) and second (2007) editions were very well received and the book has

become a standard. This book is unique in providing a thorough and critical discussion of the most important and controversial issues encountered by statisticians and their life scientist colleagues on both sides of the regulatory divide in drug development. The primary purpose of the book is to encourage and facilitate discussion between statisticians and their colleagues of the many complex statistical issues that arise in drug development. The book will be suitable as a course of self-instruction for statisticians who are new to the pharmaceutical industry, either because of recent graduation or change of career. It will also act as an authoritative reference for those working in drug development, and provide possible topics for discussion in journal forums"--