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Titolo	Statistical methods for evaluating safety in medical product development // editor, A. Lawrence Gould
Pubbl/distr/stampa	Chichester, England : , : Wiley, , 2015 ©2015
ISBN	1-118-76310-6 1-118-76307-6 1-118-76309-2
Descrizione fisica	1 online resource (391 p.)
Collana	Statistics in Practice
Disciplina	615.5072/4
Soggetti	Clinical trials Drugs - Testing
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	Safety graphics / A. Lawrence Gould -- QSAR modeling : prediction of biological activity from chemical structure / Andy Liaw and Vladimir Svetnik -- Ethical and practical issues in phase I trials in healthy volunteers / Stephen Senn -- Phase I trials / A. Lawrence Gould -- Summarizing adverse event risk / A. Lawrence Gould -- Statistical analysis of recurrent adverse events / Liqun Diao, Richard J. Cook, and Ker-Ai Lee -- Cardiovascular toxicity, especially QT/QTc prolongation / Arne Ring and Robert Schall -- Hepatic toxicity / Donald C. Trost -- Neurotoxicity / A. Lawrence Gould -- Safety monitoring / Jay Herson -- Sequential testing for safety evaluation / Jie Chen -- Evaluation of post-marketing safety using spontaneous reporting databases / Ismail Ahmed, Bernard Begaud, and Pascale Tubert-Bitter / Pharmacovigilance using observational/longitudinal databases and web-based information / A. Lawrence Gould.
Sommario/riassunto	This book gives professionals in clinical research valuable information on the challenging issues of the design, execution, and management of clinical trials, and how to resolve these issues effectively. It also provides understanding and practical guidance on the application of contemporary statistical methods to contemporary issues in safety

evaluation during medical product development. Each chapter provides sufficient detail to the reader to undertake the design and analysis of experiments at various stages of product development, including comprehensive references to the relevant literature
