

1. Record Nr.	UNINA9910707210703321
Autore	O'Hara J. M.
Titolo	Advanced information systems design : technical basis and human factors review guidance / / prepared by J. M. O'Hara, J. C. Higgins/BNL, J. Kramer/NRC
Pubbl/distr/stampa	Washington, DC : , : Division of Systems Analysis and Regulatory Effectiveness, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, , March 2000
Descrizione fisica	1 online resource (various pagings) : illustrations
Soggetti	Nuclear power plants - Control rooms - Human factors
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Title from title screen (viewed on July 1, 2016). "NUREG/CR-6633." "BNL-NUREG-52563." "Manuscript completed: January 2000; date published: March 2000." "J. Kramer, NRC project manager." "Performing organization: Department of Advanced Technology, Brookhaven National Laboratory"--Bibliographic data sheet.
Nota di bibliografia	Includes bibliographical references.

2. Record Nr.	UNINA9910254282103321
Autore	Chuang-Stein Christy
Titolo	Quantitative Decisions in Drug Development / / by Christy Chuang-Stein, Simon Kirby
Pubbl/distr/stampa	Cham : , : Springer International Publishing : , : Imprint : Springer, , 2017
ISBN	3-319-46076-5
Edizione	[1st ed. 2017.]
Descrizione fisica	1 online resource (XV, 248 p. 27 illus., 11 illus. in color.)
Collana	Springer Series in Pharmaceutical Statistics, , 2366-8695
Disciplina	519.5
Soggetti	Statistics Biometry Pharmacy Pharmaceutical technology Quality control Reliability Industrial safety Statistics for Life Sciences, Medicine, Health Sciences Biostatistics Drug Safety and Pharmacovigilance Pharmaceutical Sciences/Technology Quality Control, Reliability, Safety and Risk
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di bibliografia	Includes bibliographical references at the end of each chapters and index.
Nota di contenuto	Clinical Testing of a New Drug -- A Frequentist Decision-making Framework -- Characteristics of a Diagnostic Test -- The Parallel Between Clinical Trials and Diagnostic Tests -- Incorporating Information from Completed Trials in Future Trial Planning -- Choosing Metrics Appropriate for Different Stages of Drug Development -- Designing Proof-of-Concept Trials with Desired Characteristics -- Designing Dose-response Studies with Desired Characteristics -- Designing Confirmatory Trials with Desired Characteristics -- Designing Phase 4 Trials -- Other Metrics That Have Been Proposed to Optimize Drug Development Decisions -- Discounting Prior Results to

Sommario/riassunto

This book offers a high-level treatise of evidence-based decisions in drug development. Because of the inseparable relationship between designs and decisions, a good portion of this book is devoted to the design of clinical trials. The book begins with an overview of product development and regulatory approval pathways. It then discusses how to incorporate prior knowledge into study design and decision making at different stages of drug development. The latter include selecting appropriate metrics to formulate decisions criteria, determining go/no-go decisions for progressing a drug candidate to the next stage and predicting the effectiveness of a product. Lastly, it points out common mistakes made by drug developers under the current drug-development paradigm. The book offers useful insights to statisticians, clinicians, regulatory affairs managers and decision-makers in the pharmaceutical industry who have a basic understanding of the drug-development process and the clinical trials conducted to support drug-marketing authorization. The authors provide software codes for select analytical approaches discussed in the book. The book includes enough technical details to allow statisticians to replicate the quantitative illustrations so that they can generate information to facilitate decision-making themselves.