Record Nr. UNINA9910678021603321 Pharmacometrics: the science of quantitative pharmacology / / edited **Titolo** by Ene I. Ette, Anoixis Corporation, Paul J. Williams, University of the Pacific and Anoixis Corporation Hoboken, New Jersey: ,: Wiley-Interscience, , [2007] Pubbl/distr/stampa ©2007 **ISBN** 1-118-67951-2 1-280-82698-3 9786610826988 0-470-08797-8 0-470-08796-X Descrizione fisica 1 online resource (1227 p.) Classificazione 44.38 Disciplina 615.1 615/.1 Soggetti Pharmacology **Pharmacokinetics** Lingua di pubblicazione Inglese **Formato** Materiale a stampa Livello bibliografico Monografia Description based upon print version of record. Note generali Nota di bibliografia Includes bibliographical references and index. Nota di contenuto PHARMACOMETRICS: CONTENTS: CONTRIBUTORS: PREFACE: ACKNOWLEDGMENTS: 1. Pharmacometrics: Impacting Drug Development and Pharmacotherapy; PART I GENERAL PRINCIPLES; 2. General Principles of Programming: Computer and Statistical; 3. Validation of Software for Pharmacometric Analysis: 4. Linear. Generalized Linear, and Nonlinear Mixed Effects Models; 5. Bayesian Hierarchical Modeling with Markov Chain Monte Carlo Methods; 6. Estimating the Dynamics of Drug Regimen Compliance; 7. Graphical Displays for Modeling Population Data; 8. The Epistemology of Pharmacometrics; 9. Data Imputation PART II POPULATION PHARMACOKINETIC BASIS OF PHARMACOMETRICS10. Population Pharmacokinetic Estimation Methods; 11. Timing and Efficiency in Population Pharmacokinetic/Pharmacodynamic Data Analysis Projects; 12. Designing Population Pharmacokinetic Studies for Efficient Parameter

Estimation; 13. Population Models for Drug Absorption and Enterohepatic Recycling: 14. Pharmacometric Knowledge Discovery from Clinical Trial Data Sets: 15. Resampling Techniques and Their Application to Pharmacometrics; 16. Population Modeling Approach in Bioequivalence Assessment

PART III PHARMACOKINETICS / PHARMACODYNAMICS RELATIONSHIP: BIOMARKERS AND PHARMACOGENOMICS, PK/PD MODELS FOR CONTINUOUS DATA, AND PK/PD MODELS FOR OUTCOMES DATA17.

Biomarkers in Drug Development and Pharmacometric Modeling; 18.

Analysis of Gene Expression Data; 19. Pharmacogenomics and Pharmacokinetic/Pharmacodynamic Modeling; 20. Empirical

Pharmacokinetic/Pharmacodynamic Models: 21. Developing Models of Disease Progression: 22. Mechanistic

Pharmacokinetic/Pharmacodynamic Models I; 23. Mechanistic Pharmacokinetic/Pharmacodynamic Models II; 24. PK/PD Analysis of Binary (Logistic) Outcome Data

25. Population Pharmacokinetic/Pharmacodynamic Modeling of Ordered Categorical Longitudinal Data26. Transition Models in Pharmacodynamics: 27. Mixed Effects Modeling Analysis of Count Data: 28. Mixture Modeling with NONMEM V; PART IV CLINICAL TRIAL DESIGNS; 29. Designs for First-Time-in-Human Studies in Nononcology Indications; 30. Design of Phase 1 Studies in Oncology; 31. Design and Analysis of Clinical Exposure: Response Trials: PART V PHARMACOMETRIC KNOWLEDGE CREATION: 32.

Pharmacometric/Pharmacodynamic Knowledge Creation: Toward Characterizing an Unexplored Region of the Response Surface 33. Clinical Trial Simulation: Theory34. Modeling and Simulation: Planning and Execution: 35. Clinical Trial Simulation: Efficacy Trials: PART VI PHARMACOMETRIC SERVICE AND COMMUNICATION; 36. Engineering a Pharmacometrics Enterprise; 37. Communicating Pharmacometric Analysis Outcome; PART VII SPECIFIC APPLICATION EXAMPLES; 38. Pharmacometrics Applications in Population Exposure-Response Data for New Drug Development and Evaluation; 39. Pharmacometrics in Pharmacotherapy and Drug Development: Pediatric Application

40. Pharmacometric Methods for Assessing Drug-Induced QT and QTc Prolongations for Non-antiarrhythmic Drugs

## Sommario/riassunto

Pharmacometrics is the science of interpreting and describing pharmacology in a quantitative fashion. The pharmaceutical industry is integrating pharmacometrics into its drug development program, but there is a lack of and need for experienced pharmacometricians since fewer and fewer academic programs exist to train them. Pharmacometrics: The Science of Quantitative Pharmacology lays out the science of pharmacometrics and its application to drug development, evaluation, and patient pharmacotherapy, providing a comprehensive set of tools for the training and development of pharmac