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Nota di bibliografia	Includes bibliographical references at the end of each chapters and index.
Nota di contenuto	Overview of Oncology Drug Development -- A Global Perspective on First-In-Man Dose Selection: Oncology and Beyond -- Controversies in Oncology: Size-Based vs. Fixed Dosing -- Clinical QTc Assessment in Oncology -- Expediting Drug Development: Breakthrough Therapy Designation -- Pharmacokinetics and Pharmacodynamics of Tyrosine Kinase Inhibitors -- Combination Development -- Role of Pharmacokinetics-Pharmacodynamics in Biosimilar Assessments -- Pharmacokinetics and Pharmacogenetics of Metronomics -- Modeling Tumor Growth in Animals and Humans: an Evolutionary Approach -- Practical Considerations for Clinical Pharmacology in Oncology Drug Development: A Survey of Approvals from 2009-2015 -- New Advancements in Exposure-Response Analysis to Inform Regulatory Decision-Making .
Sommario/riassunto	Back cover copy In this volume, the specific challenges and problems facing the evaluation of new oncology agents are explored with regards to pharmacokinetic, pharmacodynamic modeling and clinical pharmacology development strategies. This book delivers, with an emphasis on the oncology therapeutic area, the goals set in the first

three volumes: namely – to provide clinical pharmacologists practical insights for the application of pharmacology, pharmacokinetics and pharmacodynamics for new drug development strategies. Pharmacokinetic-pharmacodynamicconcepts for tyrosine kinases,the evaluation of cardiac repolarization prolongation through QTc interval effects, efficacy- and safety-response analyses to support new drug approvals, clinical and preclinical tumor growth modeling, and flat- vs weight-based dose selection are showcased from an oncology clinical pharmacologist’s point-of-view. Oncology development strategies are surveyed for new FDA-approvals to identify patterns in expectations at time of first approval. The special considerations necessary to address combination drug development, metronomics, biosimilars and breakthrough therapies are also presented. .