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Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Biomarkers Are Not New / Ian Dews -- Biomarkers : Facing the Challenges at the Crossroads of Research and Health Care / Gregory J. Downing -- Enabling Go/No Go Decisions / J. Fred Pritchard and M. Lynn Pritchard -- Developing a Clinical Biomarker Method with External Resources : A Case Study / Ross A. Fredenburg -- Imaging as a Localized Biomarker : Opportunities and Challenges / Jonathan B. Moody, Philip S. Murphy, and Edward P. Ficaró -- Imaging for Early Clinical Drug Development : Integrating Imaging Science With Drug Research / Philip S. Murphy, Mats Bergstrom, Jonathan B. Moody, and Edward P. Ficaró -- Circulating microRNAs as Biomarkers in Cardiovascular and Pulmonary Vascular Disease : Promises and Challenges / Miranda K. Culley and Stephen Y. Chan -- Characterization and Validation Biomarkers in Drug Development : Regulatory Perspective / Federico Goodsaid -- Fit-for-Purpose Method Validation and Assays of Protein Biomarkers During Drug Development / Jean W. Lee, Yuling Wu, and Jin Wang -- Applying Statistics Appropriately for Your Biomarker Application / Mary Zacour --

Qualification of Safety Biomarkers for Application to Early Drug Development / William B. Mattes and Frank D. Sistare -- A Pathologist's View of Drug and Biomarker Development / Robert W. Dunstan -- Development of Serum Calcium and Phosphorus as Clinical Biomarkers for Drug-Induced Systemic Mineralization : Case Study with a MEK Inhibitor / Alan P. Brown -- New Markers of Kidney Injury / Sven A. Beushausen -- Biomarkers from Bench to Bedside and Back -- Back Translation of Clinical Studies to Pre-clinical Models / Damian O'Connell, Zaki Shaikhibrahim, Frank Kramer, and Matthias Ocker -- Translational Medicine -- A Paradigm Shift in Modern Drug Discovery and Development : The Role of Biomarkers / Giora Z. Feuerstein, Salvatore Alesci, Frank L. Walsh, J. Lynn Rutkowski, and Robert R. Ruffolo, Jr. --.

Clinical Validation and Biomarker Translation / Ji-Young V. Kim, Raymond T. Ng, Robert Balshaw, Paul Keown, Robert McMaster, Bruce McManus, Karen Lam, and Scott J. Tebbutt -- Predicting and Assessing an Inflammatory Disease and Its Complications : Example from Rheumatoid Arthritis / Christina Trollmo and Lars Klareskog -- Validating In Vitro Toxicity Biomarkers Against Clinical Endpoints / Calvert Loudon and Ruth A. Roberts -- Opportunities and Pitfalls Associated with Early Utilization of Biomarkers : Case Study in Anticoagulant Development / Kay A. Criswell -- Integrating Molecular Testing into Clinical Applications / Anthony A. Killeen -- IT Supporting Biomarker Enabled Drug Development / Michael Hehenberger -- Identifying Biomarker Profiles Through the Epidemiologic Analysis of Big Healthcare Data Implications for Clinical Management and Clinical Trial Design : A Case Study in Anemia of Chronic Kidney Disease / Gregory P. Fusco -- Computational Biology Approaches to Support Biomarker Discovery and Development / Bin Li, Hyunjin Shin, William L. Trepiccho, and Andrew Dörner -- Biomarkers in Pharmaceutical Development : The Essential Role of Project Management and Teamwork / Lena King, Malle Jurima-Romet, and Nita Ichhpurani -- Novel and Traditional Nonclinical Biomarker Utilization in the Estimation of Pharmaceutical Therapeutic Indices / Bruce D. Car, Brian Gemzik, and William R. Foster -- Ethics of Biomarkers : The Borders of Investigative Research, Informed Consent, and Patient Protection / Sara Assadian, Michael Burgess, Breanne Crouch, Karen Lam, and Bruce McManus -- Anti-Unicorn Principle : Appropriate Biomarkers Don't Need to Be Rare or Hard to Find / Michael R. Bleavins and Ramin Rahbari -- Translational Biomarker Imaging : Applications, Trends and Successes Today and Tomorrow / Patrick McConville and Deanne Lister --.

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## Sommario/riassunto

"This book continues the legacy of a well-established reference within the pharmaceutical industry -- providing perspective, covering recent developments in technologies that have enabled the expanded use of biomarkers, and discussing biomarker characterization and validation and applications throughout drug discovery and development. Several case studies of biomarkers that have helped and hindered decision making are presented, as well as an overview of the areas where proper use of biomarkers can substantively impact timelines and costs by streamlining development programs, enabling selection of better compounds and reducing late stage attrition, and facilitating personalized medicine. The new edition updates existing information with developments in pre-clinical and clinical testing and introduces substantial new materials on data mining, decision making, and personal genetic tools. With such significant expansion and revision, the 2nd edition ensures Biomarkers in Drug Development remains a key resource for biotechnology and major pharmaceutical companies, and

their efforts to improve and expedite drug development"-- Provided by  
publisher.

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