DESCRIPTION

Discover how biomarkers can boost the success rate of drug development efforts

As pharmaceutical companies struggle to improve the success rate and cost-effectiveness of the drug development process, biomarkers have emerged as a valuable tool. This book synthesizes and reviews the latest efforts to identify, develop, and integrate biomarkers as a key strategy in translational medicine and the drug development process. Filled with case studies, the book demonstrates how biomarkers can improve drug development timelines, lower costs, facilitate better compound selection, reduce late-stage attrition, and open the door to personalized medicine.

*Biomarkers in Drug Development* is divided into eight parts:

- Part One offers an overview of biomarkers and their role in drug development.

- Part Two highlights important technologies to help researchers identify new biomarkers.

- Part Three examines the characterization and validation process for both drugs and diagnostics, and provides practical advice on appropriate statistical methods to ensure that biomarkers fulfill their intended purpose.
Parts Four through Six examine the application of biomarkers in discovery, preclinical safety assessment, clinical trials, and translational medicine.

Part Seven focuses on lessons learned and the practical aspects of implementing biomarkers in drug development programs.

Part Eight explores future trends and issues, including data integration, personalized medicine, and ethical concerns.

Each of the thirty-eight chapters was contributed by one or more leading experts, including scientists from biotechnology and pharmaceutical firms, academia, and the U.S. Food and Drug Administration. Their contributions offer pharmaceutical and clinical researchers the most up-to-date understanding of the strategies used for and applications of biomarkers in drug development.

ABOUT THE AUTHOR

MICHAEL R. BLEAVINS, PhD, is cofounder of Michigan Technology and Research Institute. He retired from Pfizer/Warner-Lambert/Parke-Davis in 2006 and has twenty-three years of experience in pharmaceutical research, development, and biomarkers with more than sixty-five peer-reviewed publications.

CLAUDIO CARINI, MD, PhD, FRCPath, is Chief Medical Officer and Vice President for Clinical Research at Fresenius. Previously, Claudio served as Global Head of Translational Medicine at MDS and Global Head of Biomarkers at Hoffmann-La Roche. Claudio has more than twenty years of experience in the field of immunology and biomarkers and has authored more than 200 publications in international and domestic peer-reviewed journals.

MALLÉ JURIMA-ROMET, PhD, is Senior Director for Development and Regulatory Services at MDS Pharma Services, where she provides strategic and scientific consulting to pharmaceutical and biotech sponsors, and leads drug development program teams. Mallé has authored over forty peer-reviewed publications and is an adjunct professor at the University of Montreal.

RAMIN RAHBARI, MS, is cofounder and Senior Consultant at Innovative Scientific Management. Previously, Ramin has held positions at Pfizer, Synaptic, and Parke-Davis pharmaceutical companies, leading cross-functional biomarker teams.
For additional product details, please visit https://www.wiley.com/en-us