
Predictive Biomarkers in Oncology

Sunil Badve • George Louis Kumar
Editors

Predictive Biomarkers in Oncology

Applications in Precision Medicine

 Springer

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I would like to thank all the people who have guided, encouraged, and supported me throughout my career. Additionally, acknowledge the contributions of those who did not, but for them, I would not have learnt the value of success and the importance of character. A very humble thank you.

Sunil Badve, MD, FRCPath

“We are like dwarfs on the shoulders of giants, so that we can see more than they, and things at a greater distance, not by virtue of any sharpness on sight on our part, or any physical distinction, but because we are carried high and raised up by their giant size.”

- Bernard of Chartres

To my dear father, Joseph, and my late mother, Miriam, for their unconditional love.

To my extraordinarily talented wife, Sujatha, for her continued support of my endeavors.

To my wonderful children, Vikram and Raj, for bringing so much joy to my life.

George Louis Kumar, PhD, MBA

Preface

“Precision/personalized or stratified medicine” refers to the tailoring of medical treatment or drug administration to the individual characteristics of each patient treatment. It does not literally mean that a pharmaceutical company makes a drug for an individual patient for consumption and treatment but rather means the ability to stratify (or classify) individuals into subpopulations that differ in their responsiveness to a specific drug. A marker that provides information on the likely response to therapy, i.e., either in terms of tumor shrinkage or survival of the patient, is termed “predictive biomarker.” Examples include HER2 test to predict response to trastuzumab (Herceptin®) in breast cancer, the KRAS test to predict response to EGFR inhibitors like cetuximab (Erbix®) and panitumumab (Vectibix®) in lung cancer, or the BCR-ABL oncogene detection to predict response to the tyrosine kinase inhibitor imatinib (Gleevec®) in chronic myelogenous leukemia.

Despite their promise in precision medicine and the explosion of knowledge in this area, there is not a single source on this subject that puts all this evidence together in a concise or richly illustrated and easy to understand manner. This book will provide a collection of ingeniously organized, well-illustrated, and up-to-date authoritative chapters divided into five parts that are clear and easy to understand.

Part I will provide an overview of biomarkers and introduce the basic terminologies, definitions, technologies, tools, and concepts associated with this subject in the form of illustrations/graphics, photographs, and concise texts.

Part II describes the signaling pathways controlling cell growth and differentiation altered in cancer. This part will analyze how predictive biomarkers are altered (expressed or amplified) across cancer types.

Part III will explore how predictive biomarkers play a role in patient stratification and tailored treatment in relationship to specific cancers (e.g., breast, gastric, lung, and other tumors).

Part IV will discuss how regulatory processes, quality and policy issues, companion diagnostics, and central laboratories help validate predictive biomarker assays.

Part V will wrap up with a description of precision medicine clinical trials around the world, and its successes and disappointments, challenges, and opportunities. This part will also summarize all FDA-approved drugs in oncology.

We hope that the proposed textbook will serve as a definitive guide for practicing pathologists, pathology residents, and personal in the pharmaceutical

or diagnostic industry interested in learning on how “predictive biomarkers” are used in precision cancer therapy.

We wish to thank Sujatha Kumar, Yesim Gökmen-Polar, Bharat Jasani, Katherina Alexander, and Victoria Alexander for proofreading. Special thanks to Michael D. Sova, Developmental Editor at Deved, Inc., for superb editorial assistance during the production of this book.

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