

Predictive, Preventive and personalized Medicine & Molecular Diagnostics

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Role for prognostic and predictive biomarkers in personalized medicine

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Multiple biomarkers have been used in drug development and clinical practice for a number of years. However, there has been confusion about the definitions and inconsistent use of key terms—including biomarkers and surrogates. Recently, an FDA-NIH Biomarker Working Group developed a glossary of terms and definitions to ensure consistency and clarity, termed BEST (Biomarkers, Endpoints, and other Tools), to advance scientific progress. The BEST glossary describes seven categories of biomarkers: diagnostic, prognostic, susceptibility/risk, predictive, pharmacodynamic/response, monitoring and safety biomarkers. Prognostic biomarker is defined as a biomarker used to identify likelihood of a clinical event, disease recurrence or progression in patients who have the disease or medical condition of interest and these biomarkers are often used as eligibility criteria in clinical trials to identify patients who are more likely to have clinical events or disease progression. An example is *PIK3CA* mutation status in women with *HER2*-positive metastatic breast cancer undergoing first line therapy. It has been reported that women with tumors harboring a *PIK3CA* mutation had worse progression-free survival compared with women with *PIK3CA* wild-type tumors regardless of treatment group. Predictive biomarker is defined as a biomarker used to identify individuals who are more likely than similar individuals without the biomarker to experience a favorable or unfavorable effect from exposure to a medical product or an environmental agent. These biomarkers can be used to identify individuals more likely to respond favorably or unfavorably to treatment. Examples include selection of newly diagnosed AML (acute myeloid leukemia) patients with *FLT3* mutation positivity for treatment with midostaurin for increased likelihood of favorable response. The assays for predictive biomarkers are often co-developed with the therapeutics and become companion diagnostics where both the test and the drug would be used in the clinical management of the patient. The diagnostic tests being considered in this context may be used to identify patients most likely to respond to a drug, patients most likely to fail to respond to a drug, and/or patients most likely to exhibit adverse events that might contraindicate drug administration. Prognostic and predictive biomarkers can be integrated into drug development through the drug approval process as well as through qualification of the biomarkers through the Biomarker Qualification Program at CDER, FDA. These two categories of biomarkers can help identify the “right” sub-populations in clinical trials of therapeutics for a variety of diseases and be useful in clinical trial enrichment. The predictive biomarkers can additionally help tailor treatment appropriate for individual patients. Both approaches help advance the goal of personalized medicine.

Biography

Shashi Amur has expertise in the area of disease biomarkers, biomarkers in drug development and pharmacogenomics. She joined FDA as a Senior Genomics Reviewer in the Office of Clinical Pharmacology (OCP) in 2005, served as the Scientific Lead of the Biomarker Qualification Program from 2012-2017 at the Office of Translational Sciences (OTS) and is currently working as a Scientific Advisor in OTS, CDER, FDA. Prior to joining FDA, she was the Associate Director of Assay Development at Neotropix, Inc. and Immune Tolerance Network. She received her PhD in Biochemistry from Indian Institute of Science, India and completed Post-doctoral Fellowship at Temple University and at University of California at Los Angeles, in Neurobiology and Neuromolecular Biology. She then joined Specialty Laboratories in Santa Monica, CA as a Research Scientist in the Molecular Biology division. Following this, she was a Senior Scientist at Applied Biosystems and gained expertise in application of DNA sequencing and PCR technologies.

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