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Biomarkers in drug development

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Abstract

Biomarkers can be used in multiple ways to aid drug development. Some of these include: understanding the mechanism of action of therapeutics, aiding in designing clinical trials (for example, stratification or patient selection), use as a surrogate of a clinical endpoint or to identify the appropriate patient subpopulation before prescribing a specific therapeutic.

There are currently three paths to facilitate integration of biomarkers in drug development at CDER, FDA. 1) Biomarkers are evaluated in the context of a specific drug/biologic through submissions such as Investigational new drug (IND), new drug application (NDA) and Biologics License Application (BLA). 2) the Voluntary eXploratory Data Submission (VXDS) pathway is a non-regulatory process established to promote scientific exchange relevant to exploratory biomarker data. 3) the .Biomarker Qualification process is intended to provide a framework for scientific development and regulatory acceptance of biomarkers for broad use in drug development. Qualified biomarkers can be utilized in the agreed upon context of use in multiple drug development programs without a need to submit additional data.

Biography

Shashi Amur is currently the Biomarker Qualification Science Coordinator in the Office of Translational Sciences, CDER, FDA. Dr. Amur received her Ph.D. in biochemistry from Indian Institute of Science, India and completed post-doctoral fellowships at Temple University and at UCLA. She then gained experience in diagnostic and biotech sectors (Specialty Laboratories in Santa Monica, CA and Applied Biosystems in Foster City, CA, Immune tolerance network and Neotropix, Inc.) before joining FDA as a senior genomics reviewer in the Office of Clinical Pharmacology (OCP) and reviewed genomics- and biomarker-relevant sections of regulatory submissions.

Dr. Amur has been an invited speaker at national and international conferences, and the author of 37 scientific publications. Her current research interests include pharmacogenomics, HLA-associated adverse events and biomarkers in Autoimmune Diseases and in Alzheimer's disease.

Dr. Amur has served as Chair of the Pharmacogenomics Science Interest Group and Chair of OCP Science Day Committee at OCP, CDER, FDA and has organized seminars and workshops in CDER, FDA. She is currently the Chair of the Pharmacogenomics Focus Group at AAPS.