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Current regulatory trends and applicability of biomarkers in drugs, biologics and devices: A US FDA Outlook

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The U.S. Food and Drug Administration (FDA) defines a biomarker as "a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions." The increasing worldwide trend in the utilization of biomarkers has shown to be a significant element in the field of healthcare. Biomarkers have been integrated as measuring outcomes in the regulation of drugs, devices and biologics. Biomarkers in drug and medical device development provide information concerning detection of disease states in early stages as well as efficacious treatment options. For example, non-specific biomarkers such as WBC, D-dimers, C-reactive protein and criteria to diagnose sepsis have also played a part in therapy. In a recent study, biomarkers were utilized for a mice model of retinopathy of prematurity to ultimately benefit premature neonates in the early detection of this disorder. Based on the current trend, biomarkers offer an optimistic, yet challenging perspective on the future of its incorporation into personalized medicine. Clinicians can potentially measure and identify positive and negative responses to therapies benefitting both providers and patients. However, there have been several challenges in application of biomarkers due to lack of regulations in developing these biomarkers. In order to address these challenges, the FDA developed the Biomarker Qualification Program to establish the regulatory framework in biomarker evaluation and acceptance. As part of this program the FDA is working together with external stakeholders to develop a list of qualified biomarkers that can be applied in development of any drug, biologic or medical device. With more regulations put in place to assess and verify a biomarker's value, the integration of biomarkers will continue to expand our understanding of human health.

Biography

Dr. Nina Mezu-Nwaba is a Captain with the United States Public Health Service and a Senior Compliance Officer in the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration. She has over 20 years of clinical, retail, and regulatory experience, with expert knowledge in OB/GYN, Gastroenterology, Surgical and Urology products. Dr. Mezu-Nwaba has been with the FDA for over 17 years and has held positions at the Office of Generic Drugs, the Center for Drug Evaluation and Research, CDRH Office of Device Evaluation, and CDRH Office of Surveillance and Biometrics. She obtained her Doctor of Pharmacy from the University of Maryland at Baltimore, a Masters in Biomedical Science from Georgetown University, and a Masters in Public Health from the Johns Hopkins Bloomberg School of Public Health. Dr. Mezu-Nwaba has represented the FDA in Berlin, Puerto Rico, and the U.S. as the Liaison for International Standards committees. She actively participates in community health outreach, mentoring, as well as international humanitarian missions. Dr. Mezu-Nwaba seeks to bridge gaps in health-disparities through voluntary service with the Commissioned Corps, Health and Human Services, MI Foundation in Nigeria, Rotary Club, and serving the USPHS in Indian Health Reservations and other U.S. locations.

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