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Future of biomarkers in drugs, biologics, and device development: A US FDA initiative

Nina Mezu-Nwaba[1], **Danielle Mae Thanh**[2] and **Amy Amanda Nwaba**[3]
[1]United States Food and Drug Administration, USA
[2]Touro University California, USA
[3]Vanderbilt University, USA

Statement of the Problem: Biomarkers are a core part of medical treatment used in diagnosing, detecting, and treating diseases. However, some nonspecific biomarkers may pose challenges due to poor predictive value for forecasting subsequent clinical course in patients with suspected infections, adverse events, and disease state progression. The purpose of this study is to review the evidence for biomarkers and their role in diseases, describe the future direction of biomarkers, and support the Biomarker Qualification Program, which was established to support the United States Food and Drug Administration (FDA), Center for Drug Evaluation and Research's (CDER's) work with external stakeholders to develop biomarkers that aid in the drug development process.

Findings: Biomarkers are applicable in drug, biologic, and device development and are regulated by the FDA. Biomarkers such as troponin have their place in early detection of cardiac injury. Other well established applications of biomarkers include blood pressure, pulse oximetry, creatinine clearance, hemoglobin A1C, which are crucial for baseline therapy assessment. Non-specific biomarkers, such as WBC, D-dimers, C-reactive protein and criteria to diagnose sepsis have also played a part in improving therapy. The importance of including biomarkers in drug, device and biologic development derives from its potential innovative benefit in targeted patient care and personalized medicine.

Conclusion & Significance: Emerging studies have evaluated biomarkers for critical conditions, such as early detection of sepsis or assessment of oxygen levels for predicting retinopathy in premature neonates. Biomarkers can aid as useful means towards monitoring medical device treatment outcomes as well. Further research is needed for evaluation of current therapy and detection of early stages of cancer. Other findings can contribute to the encouragement of novel biomarkers development for future medicinal and research use.

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.

Nina.Nwaba@fda.hhs.gov

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