Organization to Promote Biomarker Development

The launch of a new independent, nonprofit organization, the National Biomarker Development Alliance (NBDA), created to engage leaders in industry, academia, patient groups, and government from across the country, was announced on January 13 at the National Press Club (Washington, DC) by the Research Collaboratory at Arizona State University (ASU). The mission of the NBDA is to address the "complex and urgent challenge of creating the standards needed to support end-to-end evidence-based biomarker development in order to significantly advance precision (personalized) health care." The NBDA was established in 2013 after 2 years of planning by the founders and informed by a large and diverse group of biomarker experts through ongoing think tank meetings and workshops.

"Creating the standards and systems for successful biomarker development is complex but achievable through a new generation of networks of stakeholders that integrate knowledge to solve critical problems of this scale," stated Anna Barker, PhD, president, director, and cofounder of the NBDA; codirector of Complex Adaptive Systems and Professor at ASU; and former deputy director of the National Cancer Institute. "The NBDA was developed not just to relegate the flawed and fragmented approaches to biomarker development. . .but also to serve as a working example of what purposeful convergence of scientific knowledge and multisector collaboration can accomplish."

Effective high-quality biomarkers are critical to realizing the promise of personalized medicine. According to a press release issued at the launch announcement, the NBDA will be "disease agnostic" and is the first independent transsector organization to bring together key stakeholders from academia, the private sector, payers, and patients/advocates to address the current low rates of success in biomarker discovery, development, and validation. The NBDA will pursue its goals through a management construct– and systems-based approach that integrates biomarker knowledge networks from all of these stakeholder communities.

Powered by advanced genomic and other technologies, biomarker discovery has become a major focus for investigators working in nearly all areas of biomedical research. Despite detailed reports on thousands of biomarker discoveries over the past decade, the transition to clinical benefit has been slow and challenging. George Poste, PhD, interim chief science officer of the NBDA, codirector of Complex Adaptive Systems and Regents Professor at ASU, and former president of research and development for SmithKline Beecham, noted at the press conference that announcement of a biomarker discovery "does not mean that the technical process was robust, that the findings could be independently reproduced, or that they measure a meaningful change in biology that addresses clinically meaningful questions." The approval of protein biomarkers, for example, has changed little in the last 2 decades, with fewer than 1.5 approved on average per year by the Food and Drug Administration (FDA). Fewer than 100 biomarkers are in routine clinical use today. Materials released by the NBDA noted that "failure to develop and implement standards-based end-to-end systems approaches for biomarker development has also essentially stalled the advancement of the diagnostics industry, especially smaller biotechnology companies focused on molecular diagnostics. The explosion of genomics-based assays and other nonregulated laboratory-developed tests discourages companies from pursuing more rigorous, uncertain, and expensive FDA biomarker/diagnostic approval pathways. The undervaluation of biomarkers and reimbursement ambiguities further discourages investment in the field."

Anna Barker, PhD, NBDA president

The NBDA is already setting up workshops and demonstration projects to develop standards and/or create ideal pathways for 4 classes of biomarkers: genomic, proteomic, imaging, and complex (e.g., biosignatures) biomarkers. In addition, the NBDA is assembling a database of all guidelines, standard operating procedures, and standards developed on the collection, stewardship, and management of biospecimens. Once the database is complete to date, the NBDA will organize a consensus conference to identify standards for the field that can be agreed on by stakeholder communities.

"Creating and broadly implementing the standards (guidelines, standard operating procedures, best practices, etc.) needed to successfully discover and develop the effective biomarkers we need is not the job of the FDA, but it is the job of the affected stakeholders," said Barker. "A successful NBDA promises to reduce health care costs by accelerating drug development, empowering the diagnostics industry, and improving patient engagement and outcomes. Continuing to tolerate the failure of biomarkers means that the promise of precision medicine will never materialize for patients, and that would be tragic and costly." For more about the NBDA, its activities, and its "modular biomarker development pipeline" approach, see www.nbda-network.org/.

National Biomarker Development Alliance