The Biomarkers Consortium is a public-private partnership managed by the Foundation for the National Institutes of Health (FNIH) helping to innovate and accelerate the new era of precision medicine by fostering a precompetitive consortium that involves the public and private sectors. Composed of several disease-focused efforts, the consortium’s central aim is to identify, develop, and qualify measurable indicators of biological and pathological processes—biomarkers—to advance specific applications for diagnosing disease, predicting therapeutic response, and improving clinical practice using new and existing technologies. Current core disease areas of focus include cancer, inflammation and immunity, metabolic disorders, and neuroscience.

Mission

The Biomarkers Consortium acts as a neutral third-party consortium architect and coordinator with a mission to provide a framework for biomedical researchers, regulators, and healthcare providers to develop and qualify biomarkers that can be used to accelerate the delivery of new technologies, medicines, and therapies for the prevention, early detection, diagnosis, and treatment of disease.
The Biomarkers Consortium goals include the following:

- fostering the precompetitive exchange of knowledge and expertise among industry, academic, and government leaders
- employing rigorous, inclusive governance and program management with clearly defined goals and milestones for biomarker-based projects that address a broad range of disease and therapeutic areas
- qualifying biomarkers for specific applications in diagnosing disease, predicting therapeutic response, and improving clinical practice using new and existing technologies
- generating information useful to inform regulatory decision-making
- providing and promoting broad access to consortium project results to the entire scientific community

Consortium History

The Biomarkers Consortium was launched by NIH, FNIH, U.S. Food and Drug Agency (FDA), Centers for Medicare & Medicaid Services (CMS), BIO, and PhRMA in October 2006 with the purpose of capitalizing the potential of biomarker-based studies.

The consortium demonstrated proof of concept of its collaborative approach with the completion of the Adiponectin Project in 2008. This project validated that the protein biomarker Adiponectin, a hormone derived from fat cells, is a robust biomarker predictive of glycemic efficacy in Type 2 diabetes. The study’s success was attributed to the consortium’s ability to combine significant trial data from multiple pharmaceutical companies with analytical and scientific expertise from public- and private-sector partners.

Structure & Governance

The Biomarkers Consortium is governed by an Executive Committee, which reports to the FNIH Board of Directors. The Executive Committee is supported by Steering Committees on four core disease areas: cancer, inflammation and immunity, metabolic disorders, and neuroscience.
Members of each Steering Committee represent academia, government, industry, and nonprofit/advocacy organizations and are led by co-chairs representing two of the following three sectors: academia, government, or industry.

The consortium employs program staff, including a director and four scientific program managers that are subject matter experts in each of the therapeutic areas. Project Teams are formed for approved projects and are responsible for developing a robust project plan that includes a budget, milestones, data access rules, intellectual property management, and other administrative functions. Key leaders from academia and industry and all project funders are represented on the Project Team. FDA and NIH members are on all consortium project teams and committees.

Financing

The Biomarkers Consortium is a membership-based organization with more than 30 industry, biotechnology, and nonprofit organization members. The financing is based on a tiered membership option that is divided into both scientific and supporting membership. Contribution levels are based on organization type and annual research and development spending.

Scientific members may nominate and serve on each Steering Committee or individual Project Team, nominate a member for the Executive Committee Industry Positions (when a vacancy is available), participate in project prioritization, development, and execution from the earliest stages, gain early access to project results, and have the opportunity to directly partner with FDA, NIH, and other key cross-sector experts.

Supporting membership is offered to corporations, firms, advocacy groups, and other philanthropic organizations that wish to support biomarker development but may not desire to contribute to project governance. Membership does not require members to fund specific projects developed by the Biomarkers Consortium. Projects are funded based on the discretion of each potential funder, and funding opportunities are offered broadly to all potential stakeholders.

Intellectual Property

The Biomarkers Consortium has developed general principles relating to intellectual property (IP)
aspects of the consortium (http://www.biomarkersconsortium.org/policies_ip.php). These guidelines outline the management of preexisting data and IP as well as new data and inventions that arise from consortium projects. The purpose of these principles is to facilitate the precompetitive use of data and technologies while ensuring adequate incentives and compliance with relevant requirements of antitrust law.

These principles are applied in the context of individual project plans via language that is specific to the individual consortium project and consistent with individual stakeholder missions and interests in public health. All participants must agree to implement the IP and data sharing principles of the Biomarkers Consortium as part of project execution.

**Patent Engagement**

The interests of patients are actively represented in consortium operations through the participation of patient advocacy foundations such as

- Alzheimer’s Association
- Arthritis Foundation
- JDRF
- CHDI Foundation
- Autism Speaks
- Avon Foundation

**Data Sharing**

Consortium principles (http://www.biomarkersconsortium.org/policies_ip.php) call for data to be shared as immediately and broadly as possible, consistent with achievement of the scientific goals of each project. Data sharing within consortium project teams varies based on the specific goals of each project and the types of data under review. Many of the project teams use SharePoint, web-based portals, secured email, and face-to-face meetings to communicate information over the course of the project.

The consortium allows project teams to establish comprehensive data access plans that define which
data arising from the project will be made publicly available, when, and how; a publication plan if appropriate; and scope, mechanisms, and methods of data access.

Impact/Accomplishment

For all of the Biomarkers Consortium efforts, impact is measured by the ability to achieve specific interim and final milestones in each project and broad release of results through publications and educational outreach.

In late 2012, the consortium completed the first phase of its Sarcopenia project, a collaboration designed to generate the first evidence-based comparison of candidate criteria for clinically important muscle weakness. The conclusions from the first phase of this work have been submitted as an insert of seven manuscripts for publication in the Journal of Gerontology Medical Sciences.

Another effort of the consortium is the development of The I-SPY 2 TRIAL (Investigation of Serial studies to Predict Your Therapeutic Response with Imaging And moLecular analysis 2), a clinical trial that is examining the benefits of adding investigational drugs to standard chemotherapy before surgery. The trial is validating a new model for adaptive clinical trials, using molecular diagnostics that can track the efficacy of therapeutic candidates for advanced breast cancer. Its findings have led to a draft guidance document that was published in the New England Journal of Medicine by FDA on new methods to conduct breast cancer drug trials with the ultimate goal and impact being the adoption of an adaptive trial design by clinical trial sponsors outside of the I-SPY 2 effort.

Links/Social Media Feed

Consortium homepage: http://www.biomarkersconsortium.org/

Twitter: @FNIH_Org

LinkedIn: Foundation for the National Institutes of Health (FNIH)

Facebook: FNIHorg
Points of Contact

David Wholley
Director, The Biomarkers Consortium
Email: biomarkers@fnih.org

Sonia Pearson-White
Scientific Program Manager, Cancer
Email: SPearson-White@fnih.org

Steve Hoffmann
Scientific Program Manager, Inflammation & Immunity
Email: SHoffmann@fnih.org

Maria Vassileva
Scientific Program Manager, Metabolic Disorders
Email: MVassileva@fnih.org

Judy Siuciak
Scientific Program Manager, Neuroscience
Sponsors & Partners

Alzheimer’s Association
American Diabetes Association
Amgen
Arthritis Foundation
AstraZeneca
Autism Speaks
Biotechnology Industry Organization
California Dairy Research Foundation
Centers for Medicare & Medicaid Services
CHDI Foundation
Daiichi-Sankyo, Ltd
Dairy Research Institute
Eli Lilly and Company
Foundation for the National Institutes of Health
Foundation of Health and Improvement & Technology
Johnson & Johnson
Juvenile Diabetes Research Foundation
Merck & Co., Inc.
Mitsubishi Tanabe Pharma Corp
Myraid RBM
National Institutes of Health
Pfizer, Inc.
Pharmaceutical Research and Manufacturers of America
Prevention of Organ Failure (PROOF) Centre of Excellence
Radiology Association of North America
Sanofi S.A.
Takeda Pharmaceuticals
U.S. Food and Drug Administration
US Pharmacopeial Convention