

The Biomarkers Consortium is a public-private biomedical research partnership managed by the Foundation for the National Institutes of Health (FNIH)

Special points of interest:

- The Biomarkers Consortium Year in Review
- 2009 Contributing Members
- Super Sessions at BIO 2008
- Project Development Process

Join the Consortium

The Biomarkers Consortium embraces government, industry, patient advocacy groups, and non-profit organizations, each of which has a stake in the identification, development and qualification of biomarkers.

As a group, we are addressing one of the most pressing needs in the diagnosis and treatment of disease: the development and qualification of disease biomarkers and surrogates. Organizations representing private industry (including the pharmaceutical, biotechnology, diagnostics, and information technology industries) and non-profit organizations (including associations, advocacy groups, trade organizations, and philanthropic organizations) that wish to support biomarker development are eligible to become contributing members.

Please take time to learn more about how you can [become a member](#) of The Biomarkers Consortium, including member [benefits](#) and [responsibilities, levels and types](#) of memberships, and a list of our [current members](#) by visiting our website at www.biomarkersconsortium.org

For more information, you may contact Paris L. A. Moore at pmoore@fnih.org.

To our members and subscribers:

Welcome to the first issue of *The Biomarkers Consortium Report*. On behalf of The Biomarkers Consortium, thank you for your interest in the Consortium as well as your involvement and efforts to moving forward the development of projects under the aegis of the Consortium - your support was an integral part of The Consortium's success in 2008.

The identification, development, and qualification of biomarkers is an increasingly essential element of predictive, preventive and personalized medicine. To meet this need, projects from The Biomarkers Consortium serve to develop and qualify promising biomarkers in order to help accelerate the delivery of successful new technologies, medicines, and therapies for prevention, early detection, diagnosis, and treatment of disease. The information and research results from Consortium projects are made publicly available and released as rapidly as possible to promote the use of biomarkers to improve public health. Through regular outreach efforts, like this newsletter, we will keep all of our partners and interested parties informed and up-to-date on current activities, the status of projects, and opportunities for involvement.

You can always find more information about the Consortium and its projects and activities on our website at www.biomarkersconsortium.org or via email at biomarkers@fnih.org. As we work together to build this uniquely powerful collaboration to coordinate and accelerate the development of biomarkers, the input of all of our partners as well as the general public is highly valued.

David Wholley
Director, The Biomarkers Consortium

Consortium Experiences A Transformational Year in 2008

Entering its second full year of operations in 2008, The Biomarkers Consortium significantly refined its strategy for identifying, evaluating and bringing forward new projects for execution, thanks to the leadership of its Executive and Steering Committees.

Early in 2008, The Consortium's Executive Committee agreed to refocus efforts on proactive identification of its "High-Impact Biomarker Opportunities" that address significant unmet medical needs, promise immediate practical impact on outcomes such as development of treatments and patient care, and can be accomplished within certain limits on timeframes and cost. This new focus has allowed the Consortium to internally develop priority projects within its four disease/therapeutic focus areas in cancer, immunity and inflammation, metabolic disorders and neuroscience as well as evaluate externally submitted projects more efficiently.

In 2008, the Consortium launched four new projects, in addition to the initial two Fluorodeoxyglucose-Positron Emission Tomography (FDG-PET) Lung and Lymphoma Projects launched in 2007, and developed a substantial pipeline of additional projects for eventual execution in 2009 and beyond:

[Evaluate the Utility of Adiponectin as a Biomarker Predictive of Gly-](#)

[cemic Efficacy by Pooling Existing Clinical Trial Data from Previously Conducted Studies](#) represents the first project to be completed by the Consortium. This project serves to help determine whether the protein adiponectin can serve as a predictive biomarker for glycemic control in Type II diabetes patients being treated with peroxisome proliferator-activated receptor agonists (PPARs). It is analyzing data pooled from randomized Phase II clinical trials provided by pharmaceutical companies Eli Lilly and Company, F. Hoffmann-La Roche, GlaxoSmithKline, and Merck & Co, Inc. Project results will be disseminated to the scientific community in mid-2009.

[Carotid Magnetic Resonance Imaging \(MRI\) Reproducibility Study via an AIM-HIGH \(Atherosclerosis Intervention in Metabolic Syndrome with Low HDL-cholesterol/High Triglyceride and Impact on Global Health Outcomes\) Substudy](#) looks at the reproducibility of non-invasive Carotid MRI in distinguishing vulnerable from stable atherosclerotic plaque. This project is conducting an 80-patient study at a total of 15 established imaging centers in conjunction with an ongoing clinical study sponsored by the Na-

tional Heart, Lung and Blood Institute. The Foundation for NIH has raised nearly \$1 million for this project from Abbott Laboratories, Merck and Co., Inc., and Pfizer Inc.

[Comparison of Two PET Radioligands Labeled With ¹¹C or ¹⁸F to Quantify the Peripheral Benzodiazepine Receptor, A Potential Biomarker of Inflammation](#) brings together resources from industry and the National Institute of Mental Health to assess the utility of two newly developed positron emission tomography



(PET) radioligands in quantifying inflammation in the central nervous system and the brain, with initial testing in Alzheimer's disease and atherosclerosis. Application of this work could extend to neurodegenerative and psychiatric disease and potentially to drug delivery. The Foundation for NIH has raised over \$500,000 for this project from Eli Lilly and Company, EMD Serono, F. Hoffmann-La Roche, GlaxoSmithKline, Merck and Co., Inc., and Pfizer, Inc.

[Use of Targeted Multiplex Proteomic Strategies to Identify Plasma-Based Biomarkers in Alzheimer's Disease](#) also focuses on Alzheimer's Disease, utilizing resources from another Foundation for NIH partnership, the Alzheimer's Disease Neuroimaging Initiative (ADNI). It is pursuing a tar-

2009

Contributing Members

Companies

Abbott Laboratories
 Althea Technologies
 AstraZeneca
 Avalon Pharmaceuticals
 BG Medicine
 Boehringer-Ingelheim Pharmaceuticals
 Bristol-Myers Squibb
 Digilab Biovision GmbH
 EMD Serono
 Genstruct
 GlaxoSmithKline
 GVK Biosciences
 InfraReDx
 Ingenuity Systems
 Johnson & Johnson
 Eli Lilly and Company
 Luminex Corporation
 Lundbeck
 Merck and Co., Inc.
 Metabolon
 Novartis
 Novo Nordisk
 Pfizer Inc
 F. Hoffmann-La Roche
 Rules-Based Medicine
 Scout Diagnostics
 Wyeth

Non-Profits/Advocacy Organizations/
 Trade Associations

Academy of Molecular Imaging
 Advanced Medical Technology Association
 Alliance for Aging Research
 Alzheimer's Association
 American Association for Cancer Research
 American Cancer Society
 American College of Neuropsychopharmacology
 American Health Assistance Foundation
 American Society for Clinical Pharmacology and Therapeutics
 American Society of Therapeutic Radiology and Oncology (ASTRO)
 American Society of Clinical Oncology
 Association of Clinical Research Organizations
 Autism Speaks
 Battelle Memorial Institute
 Biotechnology Industry Organization
 CHDI Foundation
 Cystic Fibrosis Foundation Therapeutics
 Federation of Clinical Immunology Societies
 The Hamner Institutes for Health Sciences
 Immune Tolerance Institute
 Juvenile Diabetes Research Foundation
 Kidney Cancer Association
 The Leukemia & Lymphoma Society
 Lupus Foundation of America
 Lupus Research Institute
 Michael J. Fox Foundation for Parkinson's Research
 Ontario Cancer Biomarker Network
 Pharmaceutical Research and Manufacturers of America
 Polo Ralph Lauren Foundation
 Radiological Society of North America
 The Ryan Licht Sang Bipolar Foundation
 Society of Nuclear Medicine
 Vanderbilt University

Consortium Experiences A Transformational Year in 2008 (continued)

geted approach to identify viable plasma-based biomarkers of Alzheimer's Disease, utilizing samples collected from the ADNI partnership. The funds needed to conduct this project are being provided through a surplus of funds raised for the greater ADNI partnership.

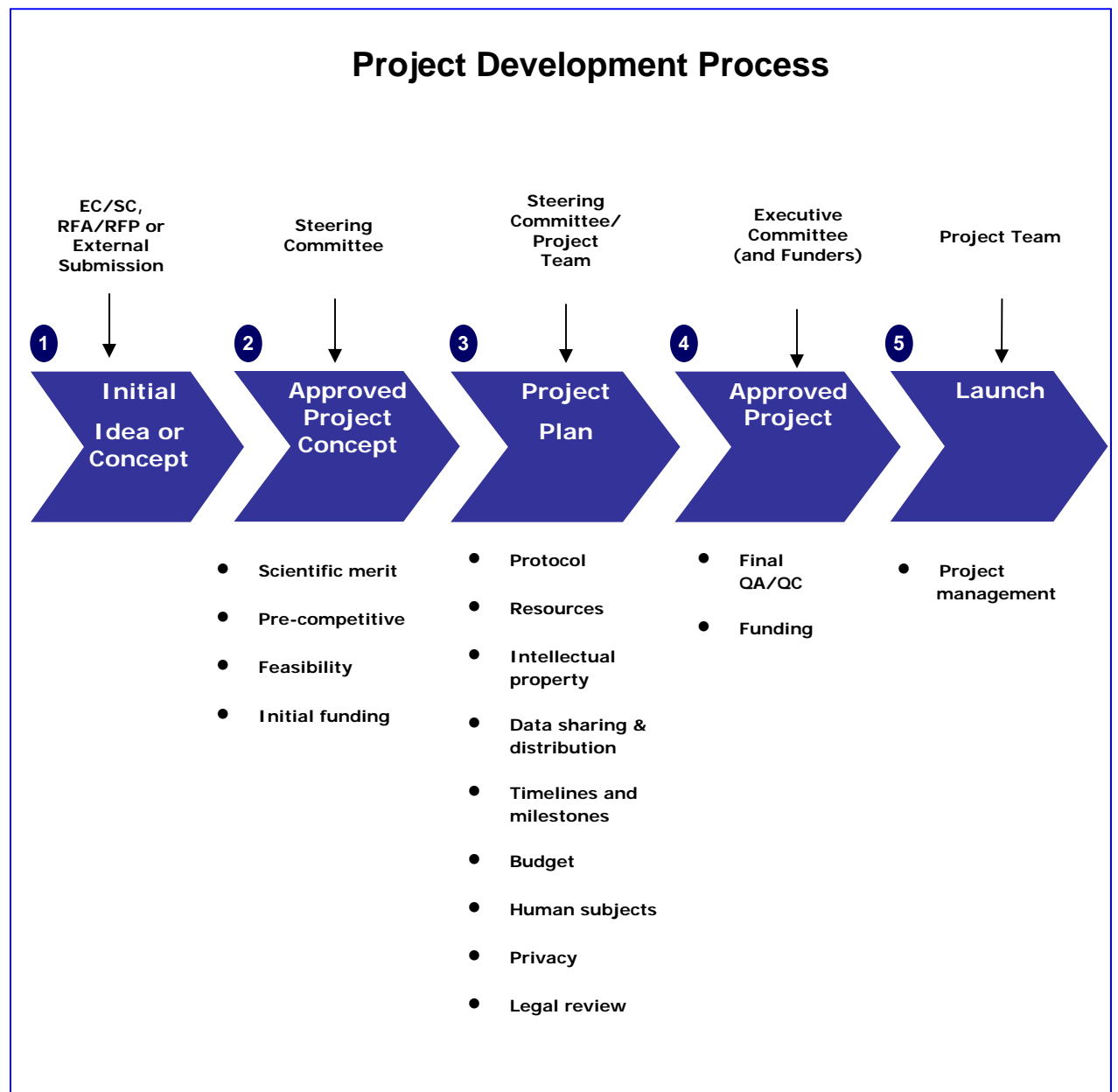
Circulating Tumor Cells as Biomarkers of Castration-Resistant Metastatic Prostate Cancer: Validation into Clinical Practice which was approved in late 2008 and is currently awaiting initiation, will characterize circulating tumor cells as biomarkers in metastatic prostate cancer.

By the end of 2008, over \$8 million had been contributed towards the Consortium's launched projects and a total of 60 organizations were participating in the Consortium's contributing membership program (27 companies and 33 non-profit organizations), representing over \$5 million in revenue used by the Foundation for NIH to operate the Consortium.

We would like to especially thank all of the organizations involved in the Consortium and the volunteer representatives that have been active participants on The Consortium's Steering Committees, Project Teams, and Working Groups. We look forward to their continued involvement as we develop new projects this year and beyond and continue to execute our existing projects.

**FROM CONCEPTION TO IMPLEMENTATION:
 How Biomarker Consortium Projects are Developed and Executed**

The Biomarkers Consortium has a well-defined process for developing its programs from basic ideas into fully realized, planned projects. Each phase is carefully vetted by components of the Consortium's governance structure, which includes an overarching Executive Committee (the primary governing body of the Consortium); four Steering Committees in cancer, immunity & inflammation, metabolic disorders, and neuroscience; and Project Teams that develop and implement each individual project. The graphic below illustrates this process. To learn more about the status of our current projects, go to www.biomarkersconsortium.org.



Progress Report:

Continued Growth and Success in 2009

This year, The Biomarkers Consortium is poised to pursue a diverse mix of new and exciting initiatives. This section highlights the current status of each Steering Committee's efforts.

Cancer Steering Committee

- The *FDG-PET Lung and Lymphoma Projects*, launched in 2007, have enrolled 78 patients to date and additional sites continue to be qualified for accrual.
- The *DCE-MRI Technique Optimization Study Using Prostate Cancer as a Model System* project plan was approved by the Executive Committee in February 2009.
- The Cancer Steering Committee pipeline includes three additional projects which are anticipated to be ready for Executive Committee approval by late 2009:
 - ⇒ *Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis (I-SPY 2): An Adaptive Breast Cancer Trial Design in the Setting of Neoadjuvant Chemotherapy*
 - ⇒ *Detection and Characterization of Circulating Tumor Cells in Prospective Cancer Treatment Trials – Neoadjuvant Breast Cancer*
 - ⇒ *Detection and Characterization of Circulating Tumor Cells in Prospective Cancer Treatment Trials – Metastatic Breast Cancer*

Neuroscience Steering Committee

- The *Comparison of Two PET Radioligands Labeled With ¹¹C or ¹⁸F to Quantify the Peripheral Benzodiazepine Receptor, A Potential Biomarker of Inflammation* Project was launched in January 2009.
- The *Use of Targeted Multiplex Proteomic Strategies to Identify Plasma-Based Biomarkers in Alzheimer's Disease* Project is underway; results will be disseminated by mid-2009. Also under development is the second phase of this project, that could look at identifying cerebrospinal Fluid (CSF)-based biomarkers in Alzheimer's Disease.
- A Project Team to develop the concept for *Placebo Data Analysis in Alzheimer's Disease (AD) and Mild Cognitive Impairment (MCI) Clinical Trials* has been recently formed. The proposed project would combine placebo data from a number of large pharmaceutical clinical trials, with the goal of creating datasets of 3,000-5,000 subjects for AD and MCI groups separately.

Metabolic Disorders Steering Committee

- A poster on the strategy and baseline results of the Adiponectin project was presented at the American Society for Clinical Pharmacology and Therapeutics meeting in March 2009; an abstract of the full results will be presented at the 69th Scientific Session of American Diabetes Association (ADA) in June 2009. A manuscript of the results has also been submitted for publication in *Clinical Pharmacology and Therapeutics*.
- The *Carotid MRI Reproducibility Study* has begun patient recruitment this spring and should have all scans completed by the end of 2009.
- The *Summit to Establish Guidelines for the Diagnosis of Sarcopenia* was approved for execution by the Executive Committee in February 2009.
- The Atherosclerosis Working Group will pursue two tracks for projects: *Mathematical Modeling of Biomarkers of Atherosclerosis and the Prediction of Clinical Events*, and *A Prospective Trial to Identify the Time Course of Change of Biomarkers of Atherosclerosis*. The working group will complete a strategy proposal outlining these ideas in more detail by mid-2009.
- The Consortium held a Beta Cell Function Symposium on April 15-16, 2009 in Washington DC. This event featured world experts in the field who will generate a consensus statement about the gold standards of measurement and identify the gaps in the field.
- A publication outlining the priorities of the Committee has been published in the April issue of *Diabetes* (an ADA journal) and the May issue of *Diabetologia* (an EASD journal).

Immunity & Inflammation Steering Committee

- In order to create project proposals that adequately reflect critical needs in immunity and inflammation, selected organizations are being surveyed to determine current interests levels within the area of inflammation and immunity biomarkers. Collaborations with other organizations such as the Arthritis Foundation are being explored to identify possible joint projects that could synergize with individual efforts at each organization.
- The Immunity & Inflammation Steering Committee has formed two working groups to develop project concepts in two critical areas: Markers of Immune Status and Markers of Accelerated Atherosclerosis in Rheumatoid Arthritis and Systemic Lupus Erythematosus.

For those readers whose organizations are Biomarkers Consortium contributing members, now is a good time to review your current Committee participation, as one of the benefits of membership is the ability to suggest participants to serve on Steering Committees. Participation also allows you and your organization to be part of the decision-making process concerning Consortium priorities and be part of the conversations that shape the future efforts of the Consortium.

**Stay Abreast of
Consortium Projects**

Get the latest news and information on activities developed by The Biomarkers Consortium. Subscribe to The *Biomarkers Consortium Report* today and ensure that you are one of the first to hear about Consortium events, projects and progress.

Feel free to encourage your colleagues and others with an interest in personalized medicine to learn about the activities and projects of The Biomarkers Consortium.



YES! I want to receive the latest news and updates on The Biomarkers Consortium. Send an email to: biomarkers@fnih.org

or visit

www.biomarkersconsortium.org

**CONSORTIUM FEATURED PROMINENTLY DURING TWO
“SUPER SESSIONS” AT BIO 2008**

The FDG-PET Lung and Lymphoma Projects, as well as other projects under development by the Cancer Steering Committee, were the topic of a well-attended “super-session” at the Biotechnology Industry Organization (BIO) 2008 International Convention in San Diego in June. Biomarkers were a strong theme throughout the conference, raising the Consortium’s profile among the biopharmaceutical community. A second “super-session”, attended by more than 400 people, focused on the role of public-private partnerships in biomarker development.

The Biomarkers Consortium’s Steering Committees

The success of The Consortium in moving projects forward is directly related to the work of each Steering Committee in developing priority projects within its disease/therapeutic focus area. The members of these Steering Committees are tasked with evaluating externally-generated projects more efficiently.

We would like to recognize the co-chairs of each Steering Committee for the exceptional work they have done in advancing the work and mission of The Biomarkers Consortium:

Cancer

Co-Chairs:

- Anna Barker, PhD, National Cancer Institute
- David Parkinson, MD, Nodality, Inc.

Inflammation & Immunity

Co-Chairs:

- Bruce Littman, MD, Translational Medicine Associates
- Daniel Rotrosen, MD, National Institute of Allergy and Infectious Diseases

Metabolic Disorders

Co-Chairs:

- Björn Carlsson, MD, PhD, AstraZeneca
- Myrlene Staten, MD, National Institute of Diabetes and Digestive and Kidney Diseases

Neuroscience

Co-Chairs:

- Huda Akil, PhD, MA, University of Michigan
- William Potter, MD, PhD, Merck and Company

The Biomarkers Consortium

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**THE
biomarkers
CONSORTIUM**

The Biomarkers Consortium is a public-private biomedical research partnership managed by the Foundation for the National Institutes of Health (FNIH)

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