

The Biomarkers Consortium

Advancing Medical Science

NIH ***FDA*** ***PhRMA*** ***BIO*** ***FNIH***



FOUNDATION
FOR THE
National Institutes of Health



February 2007

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FOR THE
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Foundation for the NIH (FNIH)

- n Established by Congress in 1990; incorporated in 1996
- n Supports the NIH mission
- n 501(c)(3) non-profit organization
 - Raised more than \$400M since 1996
 - 50+ projects
- n Non-governmental
 - Can directly solicit contributions
 - Has flexibility in donor relationships
 - Speed in making grants & contracts
- n NIH Director/FDA Commissioner: *ex-officio* Board members
- n Close relationships with NIH

Representative FNIH Partnerships

Biomarkers

- n **Alzheimer's Disease Neuroimaging Initiative (ADNI)**
 - 13 pharmaceutical and biotech companies, 2 non-profits; \$27M

- n **Osteoarthritis Initiative (OAI)**
 - GlaxoSmithKline, Merck, Novartis, Pfizer; \$18.7M

- n **Imaging Database Resources Initiative (IDRI)**
 - 8 imaging companies; \$1.2M

Genomics

- **Genetic Association Information Network (GAIN)**
 - n Pfizer, Affymetrix, Broad Institute, Abbott, others; \$24M

Global Health

- **Grand Challenges in Global Health (GCGH)**
 - n Bill & Melinda Gates Foundation, CIHR, Wellcome Trust; \$200M, managed by FNIH

The Biomarkers Consortium

Advancing Medical Science

Public Launch: October 5, 2006, National Press Club,
Washington, DC

Speakers:

Charles A. Sanders, MD (FNIH Chairman and
Chairman, The Biomarkers Consortium Executive
Committee)

Elias Zerhouni, MD (NIH Director)

Andrew von Eschenbach, MD (FDA Commissioner)

Caroline Loew, PhD (PhRMA Vice President of Scientific
and Regulatory Affairs)

The Honorable Jim Greenwood (BIO CEO)

What is a Biomarker?

- n A molecular, biological, or physical characteristic that indicates a specific, underlying physiologic state
- n Used in clinical practice to:
 - identify risk for disease
 - make a diagnosis
 - assess severity
 - identify the organs involved
 - guide treatment
- n Used in clinical research studies to assess
 - whether a drug is safe and effective
 - to learn more about health and disease
- n Helps the FDA judge whether a drug is safe and effective in treating disease

Biomarker Examples

- n Cholesterol is one of the most well-known biomarkers of cardiovascular health

- n Physical measurements:
 - body temperature (fever)
 - blood pressure (stroke risk)

- n Other biomarkers:
 - blood sugar level (diabetes)
 - antigens (hepatitis)
 - proteins (heart attack)
 - genetic variations (Huntington's disease)

Goals of the Biomarkers Consortium

- n Promote the discovery, development, and qualification of biomarkers
- n Accelerate delivery of technologies, medicines and therapies for prevention, early detection, diagnosis, and treatment of disease
- n Speed research
- n Ensure that safe, innovative, and effective new medicines and diagnostics are expeditiously developed
- n Make Consortium project results broadly available

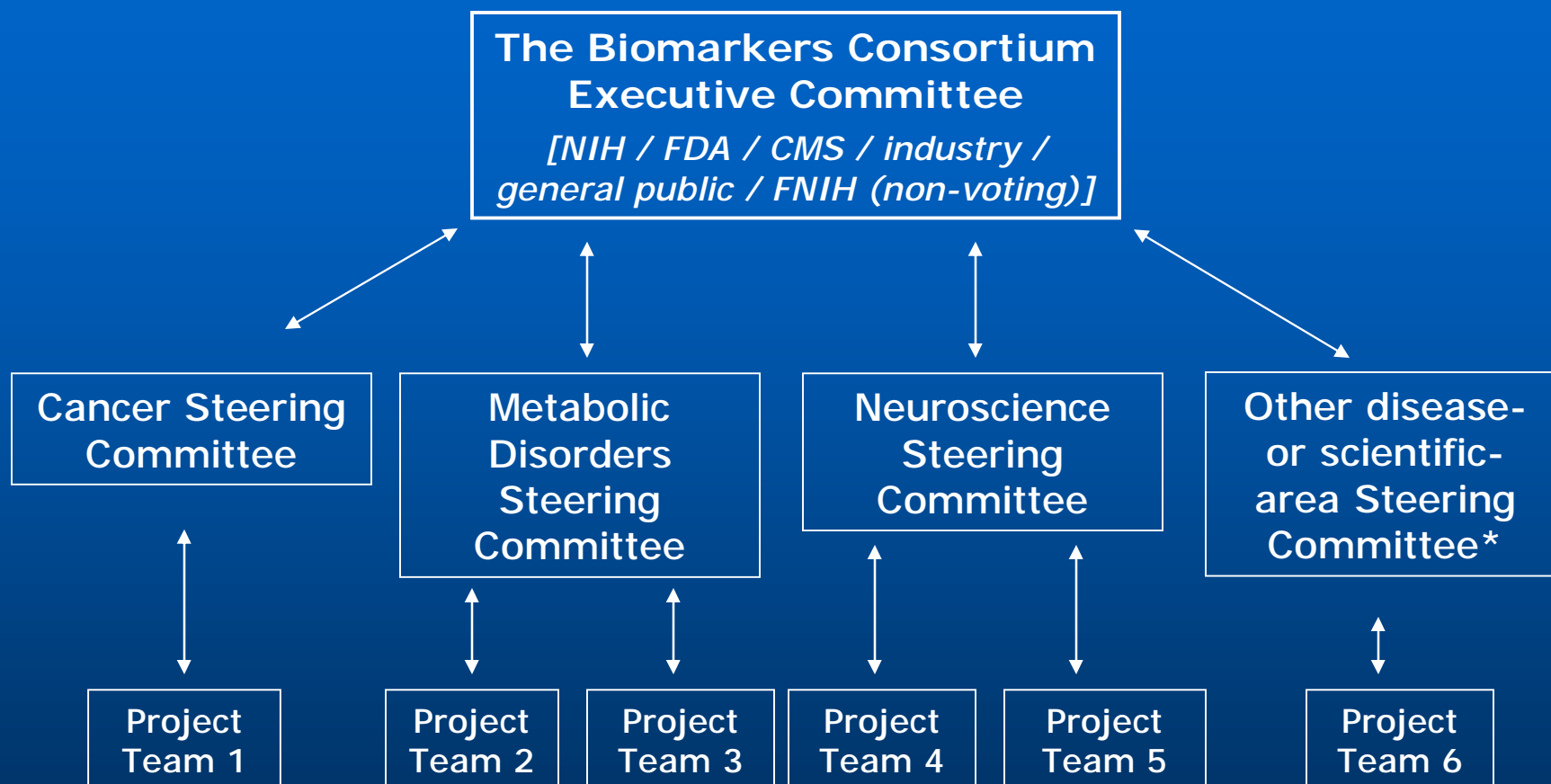
Executive Committee Composition

- n *Chairman:* Charles Sanders, Foundation for NIH (non-voting)
- n *NIH:* Thomas Insel, NIMH; John Niederhuber, NCI; Lawrence Tabak, NIDCR
- n *FDA:* Shirley Murphy, Office of Translational Science; Daniel Schultz, Center for Devices and Radiological Health; Janet Woodcock, Office of the Commissioner
- n *Centers for Medicare & Medicaid Services:* Peter Bach, Office of the Administrator
- n *Pharmaceutical industry:* Garry Neil, Johnson & Johnson; Perry Nisen, GlaxoSmithKline; Steve Williams, Pfizer
- n *Biotechnology/diagnostics industry* (temporary representative): Sara Radcliffe, Biotechnology Industry Organization
- n *Public member:* Mary Woolley, Research!America
- n *Foundation for NIH* (non-voting): Steven Paul, Ellen Sigal

Executive Committee Responsibilities

- n Establish and uphold necessary policies and procedures
- n Identify disease or scientific areas around which to establish Steering Committees
- n Approve project concepts and plans for potential execution by the Consortium
 - *Project concepts*: succinct descriptions of projects which, if approved, are referred to appropriate Steering Committee for development
 - *Project plans*: detailed descriptions of projects to be executed by the Consortium
- n Advise FNIH Board of Directors on financial commitments

The Biomarkers Consortium Governance



* *Steering Committees that may be established include those for cardiovascular and pulmonary disease and inflammatory, immunity, and infectious disease*

Founding Partners each have 3-4 seats on the Executive Committee

n *12 Seats composed of:*

- NIH
- FDA
- Pharmaceutical industry
- FNIH (non-voting)

n *Any founding partner can veto a project if all members representing the founding partner agree to do so*

Scope of Steering Committees

- n Therapeutic or scientific areas (i.e., cancer, metabolic disorders, neuroscience)
- n Identify, prioritize, and refine project concepts proposed by the Executive Committee, the public, or the Steering Committee itself
- n Recommend project concepts for Executive Committee approval
- n Assemble and oversee Project Teams to achieve each project's goals
- n Submit project plans for Executive Committee approval
- n Convene advisory groups and workshops, engage consultants, etc. as needed to inform the planning process

Steering Committee Co-chairs

n Cancer

- Anna Barker, National Cancer Institute
- Barbara Weber, GlaxoSmithKline

n Metabolic Disorders

- Bjorn Carlsson, AstraZeneca
- Myrlene Staten, National Institute of Diabetes and Digestive and Kidney Diseases

n Neuroscience

- Huda Akil, University of Michigan
- Scott Reines, Johnson & Johnson

Project Team Responsibilities

- n Develop detailed project plans for project concepts approved by the Executive Committee
- n Submit completed project plans for Executive Committee approval, via the relevant Steering Committee
- n With Executive Committee and FNIH Board approval and after funding is secured, develop project-specific guidelines and infrastructure and conduct the project

Initial Approved Project Concepts

Cancer

- n FDG-PET Lung and Lymphoma Projects (*approved for execution by the Executive Committee*)

Metabolic Disorders

- n Diabetes and Pre-Diabetes Biomarker Project
- n Evaluate the Utility of Adiponectin as a Biomarker Predictive of Glycemic Efficacy by Pooling Existing Clinical Trial Data from Previously Conducted Studies

Neuroscience

- n Whole Genome Association in Major Depressive Disorder: Identifying Genomic Biomarkers for Treatment Response
- n The NIH Intramural Program as a Generator and Incubator for PET Radiopharmaceutical Development

Project Concept Submission and Approval Process

1. Researchers are encouraged to submit promising project concepts via The Biomarkers Consortium Project Concept Submission Form (available at www.fnih.org)
2. The Executive Committee reviews each concept and may refer to a Steering Committee for development or create a Project Team if no appropriate Steering Committee exists

Focused and well-developed projects with private-sector funding partners already identified may follow a “fast track” mechanism

- Combines project concept & plan approval
- This option is not available if federal funds will be sought

Project Concept Submission and Approval Process (Con't)

3. Steering Committee will establish a Project Team to develop a detailed project plan

Project plan elements (where applicable):

- Goals and objectives
- Detailed scientific and management strategies
- Grants and contracts needed
- Human subjects, animal welfare, and other regulatory requirements
- Timeline
- Data sharing plan
- Project budget
- Other sources of support
- Potential funding partners

4. The project plan is reviewed by the Steering Committee, then to the Executive Committee for approval
5. Upon project plan approval, FNIH may seek the needed funding

Contributing Membership Program

- n Supports FNIH's central activities to operate the Consortium (\$2-2.5M per year):
 - Steering committees that promote biomarker development
 - Solicitation, selection, and further development of projects to be executed by the Consortium
- n Does not fund specific projects
- n Allows the involvement of various sectors of the healthcare enterprise in Consortium activities

Membership Levels

- n Private industry: \$5,000-100,000 per year, depending on annual sales
- n Non-profits/associations/advocacy organizations/individuals: \$5,000 per year
- n 10% discount for 3 year Contributing Member commitment

Contributing Membership Benefits to Private Industry

- n Participate in groundbreaking, collaborative initiative to identify and validate biomarkers
- n Elect representatives to serve with NIH, FDA, private industry, and others on the Executive Committee
- n Nominate technically qualified representatives to participate on all Steering Committees
- n Notification of opportunities to fund Consortium projects approved by the Consortium
- n Ongoing communications on Consortium activities

Non-profits, individuals, and all other contributors share all but the second of these benefits

Contributing Member Responsibilities

- n Pay annual membership dues (or fulfill multi-year commitment)
- n Consider funding specific Consortium projects
- n Consider participating in projects by sharing expertise, data, staff, or providing in-kind contributions
- n Consider providing employees on detail to staff Consortium or projects
- n Abide by the principles and policies adopted by the Consortium

Contributing Members

- n Alzheimer's Association
- n American Association for Cancer Research
- n American Society of Clinical Oncology
- n Association of Clinical Research Organizations
- n AstraZeneca
- n BG Medicine
- n Biotechnology Industry Organization
- n Boehringer-Ingelheim Pharmaceuticals, Inc.
- n Bristol-Myers Squibb
- n EMD Serono
- n GlaxoSmithKline
- n Johnson & Johnson
- n The Leukemia & Lymphoma Society
- n Eli Lilly and Company
- n Merck and Co., Inc.
- n Novartis
- n Novo Nordisk
- n Pfizer Inc
- n Pharmaceutical Research and Manufacturers of America
- n F. Hoffmann-La Roche
- n Society of Nuclear Medicine

Consortium Business Principles and Policies

- n These policies have been negotiated with principals and legal counsel representing FNIH, NIH, FDA, PhRMA and BIO:
 - Intellectual property and data sharing
 - Antitrust
 - Selection/award of grants/contracts
 - Confidentiality
 - Conflict of interest

- n Policies are available at www.fnih.org

Intellectual Property and Data Sharing Principles

- n Goal: facilitate the use of data and technologies in expanded biomarker efforts while ensuring adequate incentives to commercialize biomarker technologies
- n All participants will be granted a limited, non-exclusive, royalty-free and remuneration-free license to use each participant's pre-existing data and IP for research purposes in connection with a Consortium project
- n New data generated through Consortium activities will be handled according to the approved project plan
- n Data access rules are defined on a project-by-project basis, sensitive to human subjects and other protections

Antitrust Policy and Guidelines

- n Research activities are intended to be pre-competitive
- n Discussion to be focused on Consortium activities and projects
- n Agendas must be developed and followed for all meetings
- n Antitrust counsel must review all agreements and project plans prior to implementation

Selection and Award of Grants or Contracts

- n Applies to grants and contracts funded and managed by FNIH—Federal grants and contracts governed by Federal law
- n FNIH/Consortium conflict of interest and confidentiality policies apply
- n Solicitation and independent scientific review conducted by FNIH
- n Responders, awardees, and reviewers may or may not be Consortium participants
- n All decisions based on merit, not membership or involvement in the Consortium
- n FNIH responsible for award and post-award management

Next Steps - 2007

- n Convene Cancer, Metabolic Disorders, and Neuroscience steering committees co-chairs and members
- n Establish new steering committees as needed
- n Develop approved project concepts
 - Submit project plans to Executive Committee
 - Finalize funding and other agreements
 - Establish and convene project teams
 - Implement projects
- n Solicit, review, and act upon new project concepts
- n Continue outreach to organizations about contributing membership
- n Launch Biomarkers Consortium website
- n Maintain regular communications with contributing members

Contact Information

Foundation for NIH
One Cloister Court, Suite 152
Bethesda, MD 20814 (301) 402-5311

Director, The Biomarkers Consortium
C. Anthony Altar, Ph. D. (taltar@fnih.org)

Contributing Membership/Partnership Development
David Lee (dlee@fnih.org)

Steering Committees/Research Administration
David Wholley (dwholley@fnih.org)

www.fnih.org

www.biomarkersconsortium.org
(to be launched March 2007)