Quantitative Imaging Biomarkers Alliance

RSNA

THE biomarkers CONSORTIUM

OBQI: Unique HHS Partnership

The Oncology Biomarkers Qualification Initiative (OBQI) is a new and innovative collaboration among NCI, FDA, and CMS designed to qualify biomarkers for use in clinical trials – and ultimately speed better agents to cancer patients*

*Tri-partite MOU signed 01/23/2006

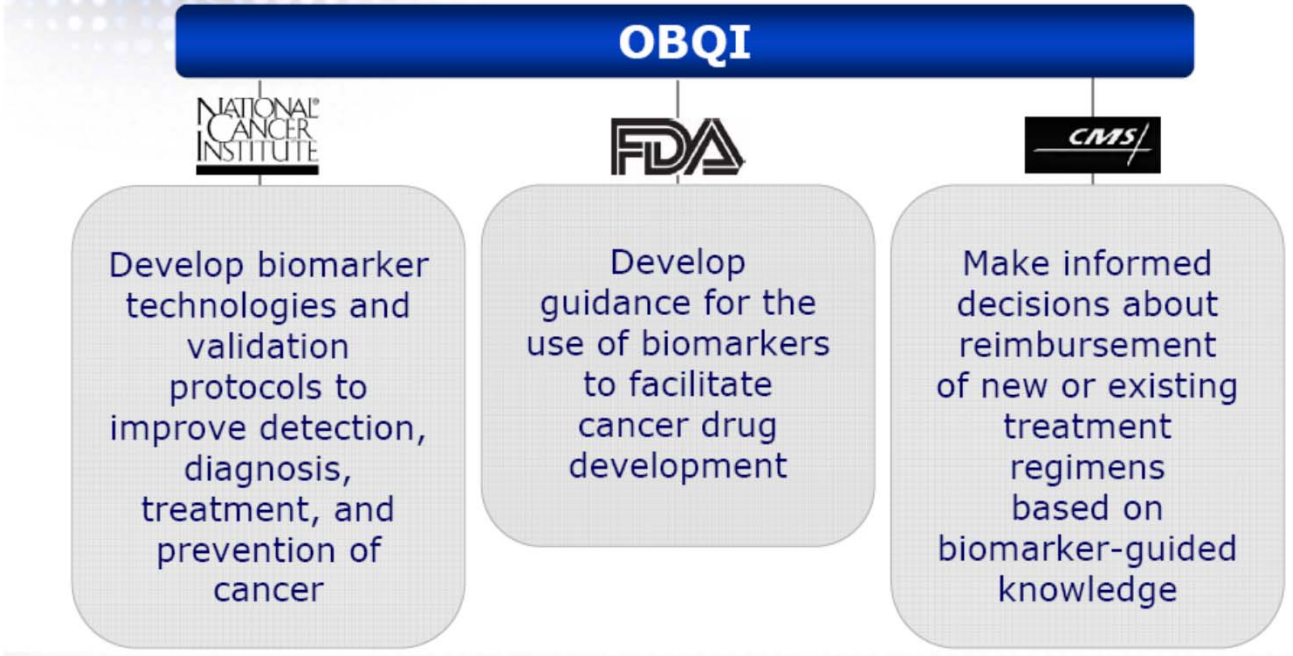
FOUNDATION FOR THE National Institutes of Health

Quantitative Imaging Biomarkers Alliance

RSNA

THE biomarkers CONSORTIUM

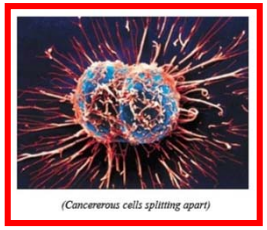
OBQI Coordinates Cross-HHS Goals for Biomarker Validation and Clinical Use



FOUNDATION FOR THE National Institutes of Health

The Biomarkers Consortium is led by an Executive Committee and organized around four Steering Committees

Cancer

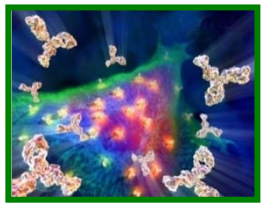


Gary J. Kelloff, MD,
NCI/NIH (Co-Chair)
David R . Parkinson, MD,
Nodality, Inc. (Co-Chair)

Caroline C. Sigman, PhD, CCS Associates, Project Manager
Sonia Pearson-White, PhD
Scientific Program Manager, FNIH

- *Accelerate Drug Development in all Cancers*
- *Circulating Tumor Cells (CTCs) as a Biomarker*
- *Improve and Standardize Imaging*

Inflammation & Immunity



Brian Kotzin, MD, Amgen Corporation (Co-chair)
Dan Rotrosen, MD, NIAID/NIH (Co-Chair)

TBN
Scientific Program Manager, FNIH

- *Rheumatoid Arthritis*
- *Transplantation*

Metabolic Disorders

Myrlene Staten,MD, NIDDK/NIH (Co-Chair)
David Kelley, MD, Merck & Co., Inc. (Co-Chair)

Maria Vassileva, PhD
Scientific Program Manager, FNIH

- *Atherosclerosis*
- *Beta Cell Function*
- *Microvascular Complications in Diabetes*
- *Functional Changes in Aging*

Neuroscience

Huda Akil, PhD, MA, University of Michigan (Co-Chair)
Husseini K. Manji, MD, FRCPC, Johnson & Johnson Pharmaceutical R&D (Co-Chair)

Judy Siuciak, PhD
Scientific Program Manager

- *Imaging in Alzheimer's Disease*
- *Markers of Depression and Anti-Depressant Response*

Quantitative Imaging Biomarkers Alliance RSNA

THE biomarkers CONSORTIUM

Joint Imaging Biomarker Qualification Committee

Gary J. Kelloff, MD (Co-Chair), NIH/NCI/DCTD Cancer Imaging Program
Daniel C. Sullivan, MD (Co-Chair), Duke University, RSNA
Monica Bertagnolli, MD, Brigham &Women's Hospital. CALGB
Ronald Boellaard, PhD, Nuclear Medicine, VU Medical University, Amsterdam
Laurence P. Clarke, PhD, NIH/NCI/DCTD Cancer Imaging Program
Claudio Dansky-Ullman, MD, NIH/NCI/DCTD/CTE/CIP
Constantine Gatsonis, PhD, ACRIN, Brown University
Otto Hoekstra, MD, PhD, Nuclear Medicine, VU Medical University, Amsterdam
Bruce Johnson, MD, Dana Farber Cancer Institute
Paul E. Kinahan, PhD, University of Washington
Michael Knopp, MD, PhD, CALBG Imaging Core Laboratory, Ohio State University
Mark G. Kris, MD, Memorial Sloan Kettering Cancer Center
Richard Little, MD, NIH/NCI/DCTD/CTEP
Michael F. McNitt-Gray, PhD, UCLA

FOUNDATION FOR THE National Institutes of Health

Joint Imaging Biomarker Qualification Committee (2)

David Mozley, MD, Merck Research Laboratories

James L. Mulshine, MD, Rush Medical College

Sonia Pearson-White, PhD, FNIH Biomarkers Consortium

David Raunig, PhD, Pfizer Global R&D

Lawrence V. Rubinstein, PhD, NIH/NCI/CTEP, Biostatistics

Lalitha Shankar, MD, NIH/NCI/DCTD/CTE/CIP

Lawrence Schwartz, MD, Columbia University, CALGB

Barry Siegel, MD, Washington University School of Medicine

Caroline Sigman, PhD, CCSA

Richard L. Wahl, MD, Johns Hopkins University

Wolfgang Weber, MD, University of Freiburg

Gundrun Zahlmann, MD, PhD, Roche, Inc.

CRO

Howard Higley, PhD, CCSA; Ying Tang, PhD, CCSA

RSNA/QIBA

Andrew Buckler, Buckler Biomedical, LLC

Quantitative Imaging Biomarkers Alliance RSNA

THE biomarkers CONSORTIUM

Biomarkers: Analytical & Clinical Validation

Biomarker validation is the process of assessing the assay and its measurement performance characteristics, and determining the range of conditions (including clinical settings) under which the assay will give reproducible and accurate data

Wagner *et al.*, Clin Pharm Therap 2007; 81: 104–107

FOUNDATION FOR THE National Institutes of Health

Quantitative Imaging Biomarkers Alliance RSNA

THE biomarkers CONSORTIUM

Biomarker Qualification

- Biomarker qualification is the evidentiary process of linking a biomarker with biological processes and clinical endpoints.

- Qualification is verification that the biomarker is "fit-for-purpose"

Wagner *et al.*, Clin Pharm Therap 2007; 81: 104–107

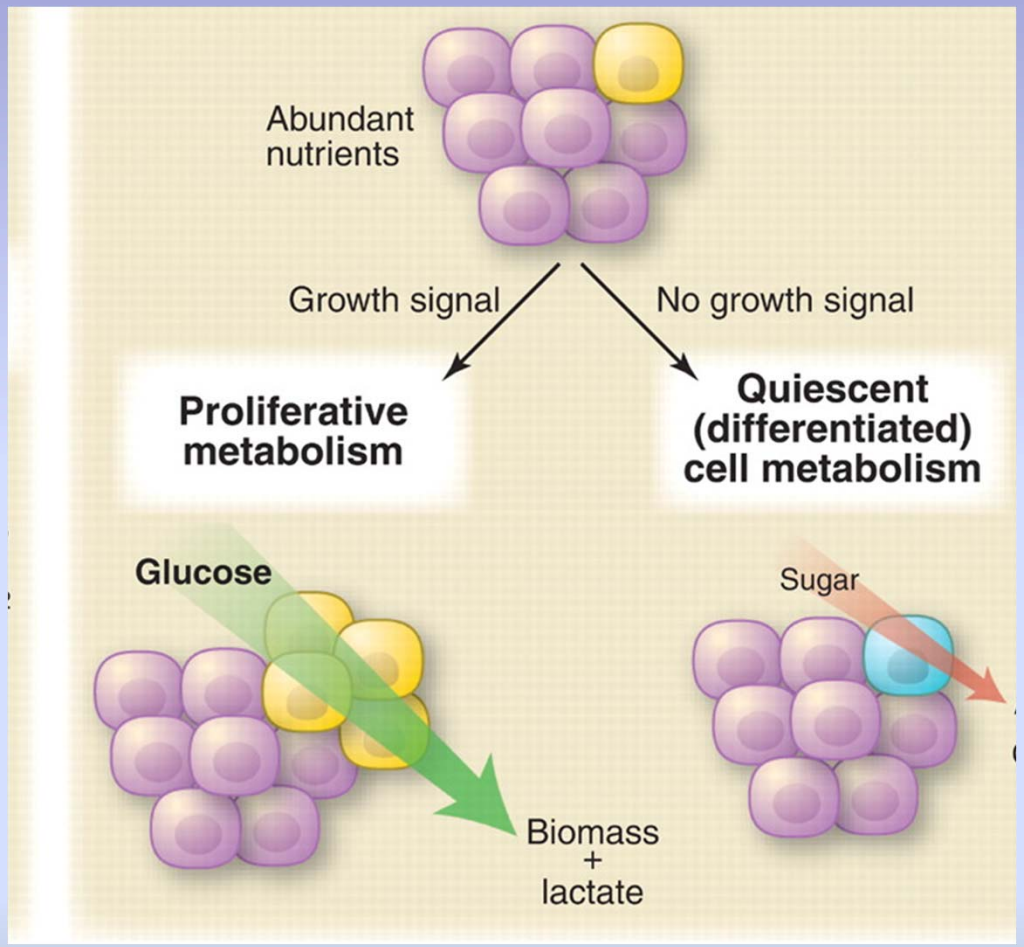
FOUNDATION FOR THE National Institutes of Health

Why FDG-PET

- FDG-PET exploits the reliance of tumor cells on glucose and glycolytic metabolism to image cancers (Warburg Effect, strong mechanistic rationale)
- FDG-PET data can be assessed visually, or analyzed semiquantitatively or quantitatively
- FDG-PET is approved for use in the diagnosis, staging, and restaging of a variety of cancer types, and in these applications can significantly impact the clinical management of disease
- In a number of clinical settings (*e.g.*, NSCLC, esophageal cancer, lymphoma), FDG-PET can provide an early measure of response to treatment with approved therapies
- With a few additional studies, FDG-PET could facilitate drug development and patient care by resulting in:
  - Shorter duration of Phase 2 studies to evaluate new drug/regimen
  - Accelerated approval in Phase 3 trials, with full approval contingent on evidence of clinical benefit (*e.g.,* PFS, OS after longer term follow-up)
  - Better patient care by ceasing ineffective therapies earlier

Kelloff *et al.* Clin Cancer Res 11: 2785–2808, 2005

Understanding the Warburg Effect: Metabolic Requirements of Cell Proliferation



Adapted from Vander Heiden et al., *Science* 324, 1029 -1033 (2009)

Published by AAAS

Science
AAAS

Value Proposition/Benefit for Partners in Public Private Partnership (PPP)

FNIH	• Nonprofit Convener and Partnership Builder
Diagnostics, Device Industry	• Companion Diagnostics, Imaging-based Biomarkers • Improved Business Model
Pharma	• More Efficient Drug Development and Approval Path • Better Early Response Criteria
FDA	• Provides for Evidence-Based Regulatory Policy
Academia, NCI	• Better Clinical Data • More Effective Treatment/Management
Patients/ Advocates	• Opportunity to Drive Path to Personalized Treatment • Potentially More Effective Treatment/Management
CMS	• Helps Define Reasonableness and Need