



**FNIH**

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Foundation for the  
National Institutes of Health

**Maria Freire, Ph.D.**  
**President and Executive Director**

Interagency Pain Research Coordinating Committee  
June 3, 2013

# IPRCC Mandate

*Section 4305(b) of the Affordable Care Act*

**“Make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.”**

So....



*'I'm going to explain Public,  
Private Partnerships until you  
feel drowsy and fall asleep'*



# Public Private Partnerships

## *Overarching Principles*

### What?

Mechanism to achieve a common purpose

Clear, defined goal with well-established milestones

### Who?

Multiple contributors

A matrix that is greater than the sum of its parts

Representation from industry, government, not-for-profits, philanthropies, etc.

### How?

Resource mobilization; sharing of assets and skills

Common governance, rules and legal framework

Nimble, transparent and accountable

# PPPs for Health

## *Examples*

### Knowledge Generation/Research

- ADNI

### Product Development

- TB Alliance

### Improvement of Access to Health Products

- GAVI

### Global Coordinating/Financing Mechanisms

- Global Fund ATM

### Health Services Strengthening

- Global Campaign for Microbicides

### Public Education and Advocacy

- National Call To Action To Promote Oral Health

### Regulation, Quality and Standards

- Anti-Counterfeit Drug Initiative





# FNIH

Foundation for the  
National Institutes of Health

*Building partnerships for discovery and  
innovation to improve health*

## **Purpose:**

- To support the NIH in its mission; and,
- To advance collaboration with biomedical researchers from universities, industry and nonprofit organizations.

## **Structure:**

- Established by Congress as a 501(c)(3) no-for-profit organization;
- Independent Board of Directors;
- NIH Director and FDA Commissioner *ex-officio* Board Members.

## **Highlights:**

- Raised >\$700 million since 1996;
- Supported >400 projects, ~100 currently active
  - research partnerships,
  - scientific education/training,
  - conferences/events, and
  - capital programs
- 94 cents of every dollar spent directly supports programs;
- 4-star Charity Navigator rating for past six years.

# Board of Directors

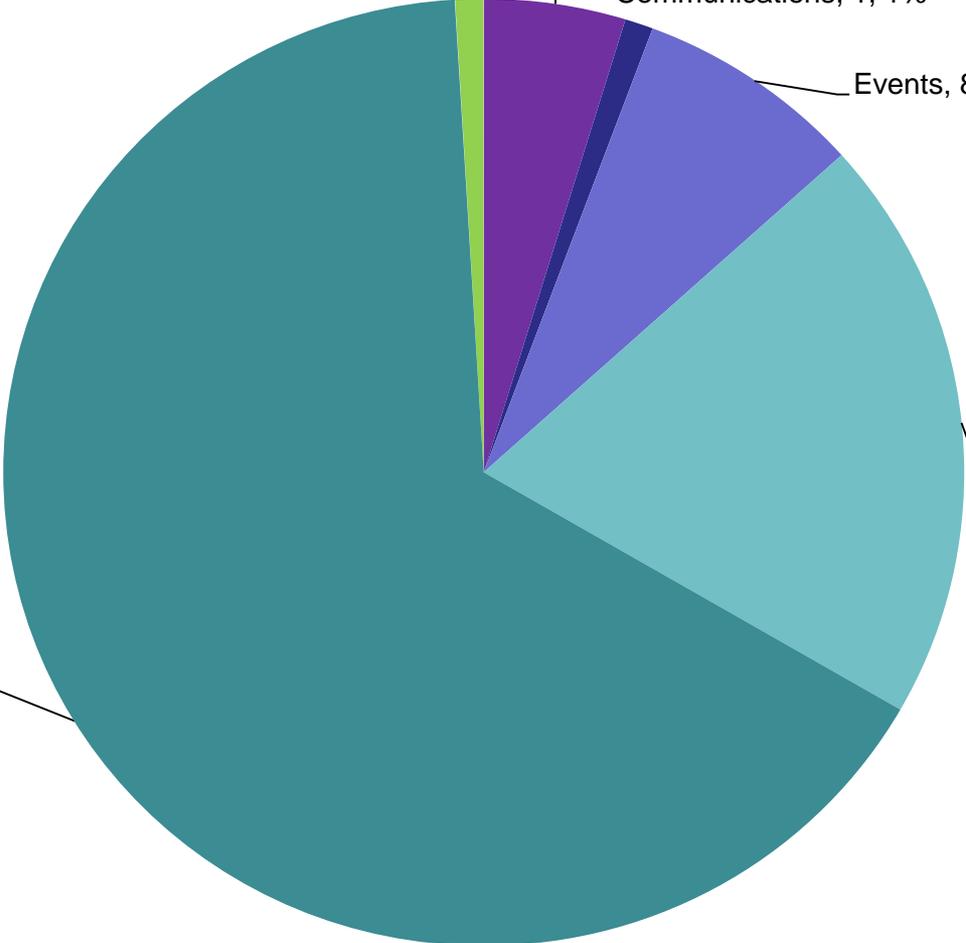
- Charles Sanders, MD – ret. GSK
- Mrs. William McCormick Blair – Lasker (Emeritus)
- Kathy Bloomgarden, PhD – Ruder Finn
- Mrs. William Cafritz – Kennedy Center
- James Donovan – Goldman Sachs
- Joseph Feczko, MD – retired Pfizer
- Maria Freire, PhD – FNIH
- Miles Gilburne – ZG Ventures
- Paul Herrling, PhD – Novartis
- Ronald Krall, MD – ret. GSK
- Sherry Lansing – Sherry Lansing Foundation
- Freda Lewis-Hall, MD – Pfizer
- Edison Liu, MD, PhD – Jackson Labs
- Ann Lurie – Lurie Investments, Inc.
- Joel Marcus – Alexandria Real Estate Equities
- Steven Mayer – ret. Human Genome Sciences & CoGenesys
- Paul Montrone, PhD – Perspecta Trust
- Martin Murphy, PhD – AlphaMed Consult
- Garry Neil, MD – retired Johnson and Johnson
- Steven Paul, MD – Weill Cornell Med College
- Hon. John Porter – Hogan Lovells
- Mrs. Jillian Sackler, DBE – AMS Found
- Mrs. Lily Safra – Safra Foundation
- Ellen Sigal, PhD – Friends of Cancer Research
- Solomon Snyder, MD – Johns Hopkins
- Nina Solarz - philanthropist
- Samuel Thier, MD – Harvard Medical School
- Anne Wojcicki – 23andMe

NIH Director/FDA Commissioner *ex-officio* Board members

# Portfolio

## 105 Active Projects

Other 1, 1%  
Capital Projects, 5, 5%  
Communications, 1, 1%  
Events, 8, 7%



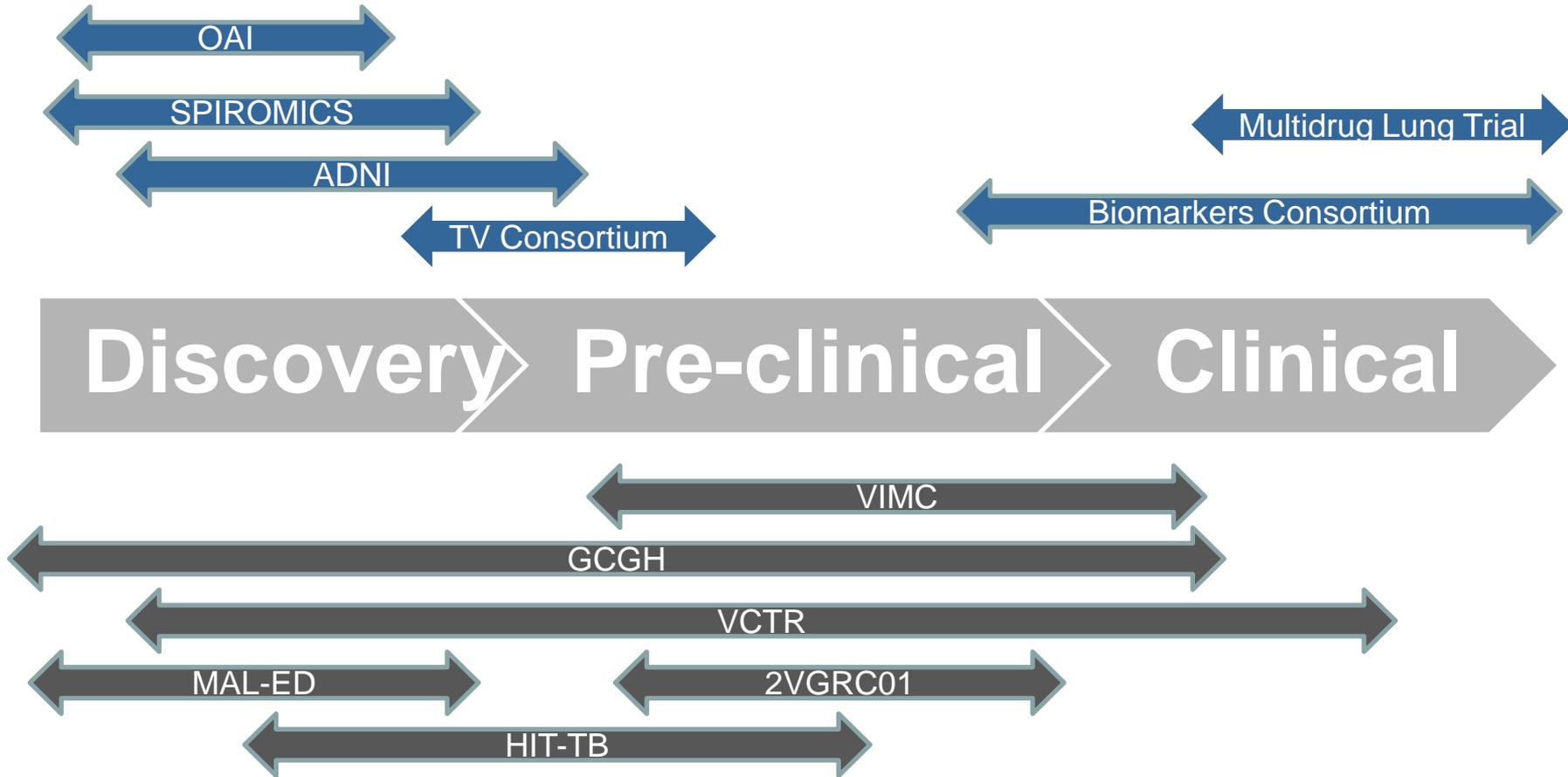
- Capital Projects
- Communications
- Events
- Education & Seminars
- Research Projects
- Not yet determined

Research Projects, 69, 66%

Education & Seminars, 21, 20%

# FNIH Partnerships

*in the R&D Context*



# Case Studies

# A Alzheimer's D isease N euroimaging I nitiative



## *A natural history study of normal cognitive aging, mild cognitive impairment (MCI) and early Alzheimer's disease*

- **Goals:**

- Establish a world-wide network to improve AD studies and clinical trials for disease-modifying treatments
- Optimize and standardize biomarker methods for early detection/disease progression
- Validate biomarkers for use in clinical trials

- **Partners:** NIA and >25 companies, foundations and agencies

- **Funding:**

- \$100M from NIA
- \$49M from partners through FNIH

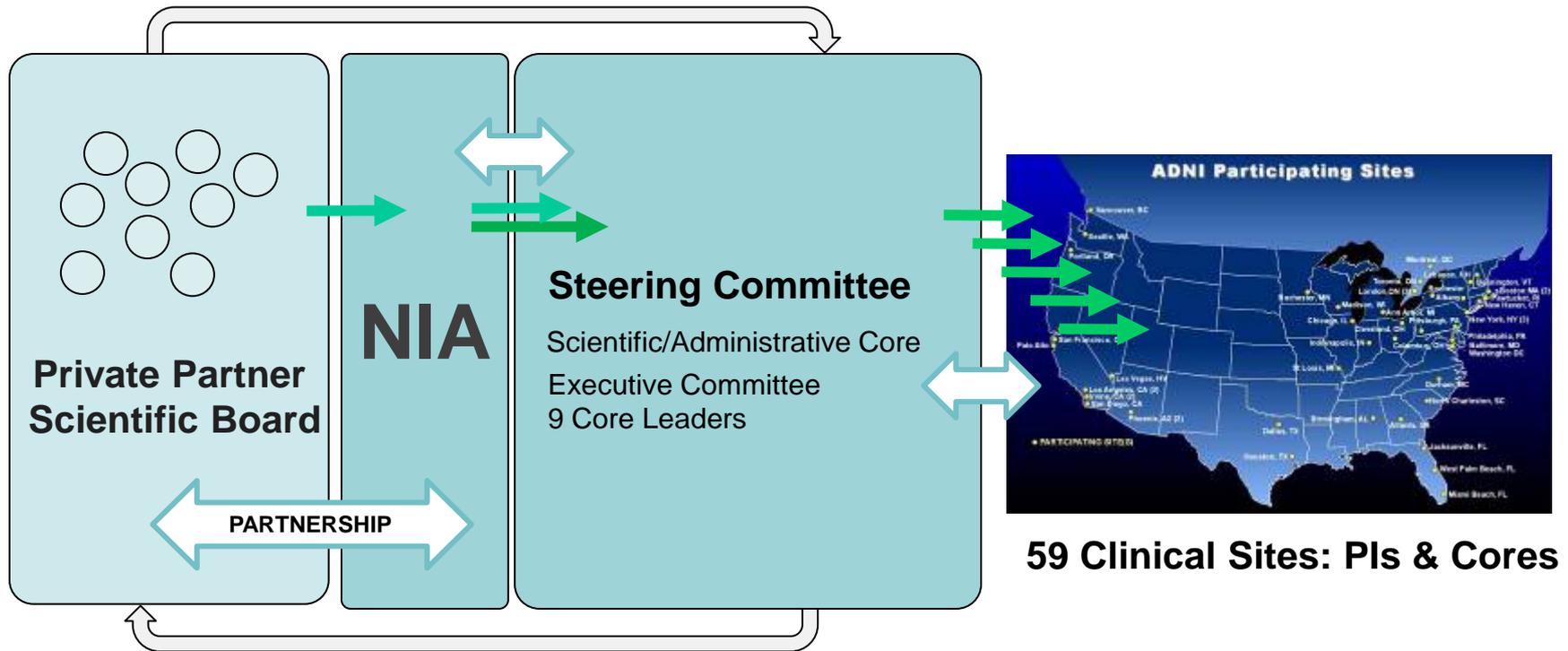
- **Structure:**

- ADNI is managed by NIA
- FNIH manages the ADNI partnership and convenes the Private Partner Scientific Board (PPSB)



# Alzheimer's Disease Neuroimaging Initiative

*A pre-competitive consortium*



**59 Clinical Sites: PIs & Cores**

- 1500 subjects enrolled
- Largest CSF collection in the field
- 329 publications to date
- Database of >166,000 PET & MRI images
- ~3.4 million downloads worldwide
- Alzheimer's Association & Brin Wojcicki Foundation: whole genome sequences of 818 ADNI participants



# A Alzheimer's D isease N euroimaging I nitiative

## Private Partner Scientific Board



BIOCLINICA™

biogen idec

 Bristol-Myers Squibb



Genentech  
IN BUSINESS FOR LIFE



Janssen  
Janssen Alzheimer  
Immunotherapy  
a Johnson & Johnson company

Johnson & Johnson



M S D  
Meso Scale Diagnostics, LLC.

NeuroRx  
RESEARCH

NOVARTIS



SYNARC  
Start here, finish first.™



Canadian Institutes  
of Health Research

Instituts de recherche  
en santé du Canada

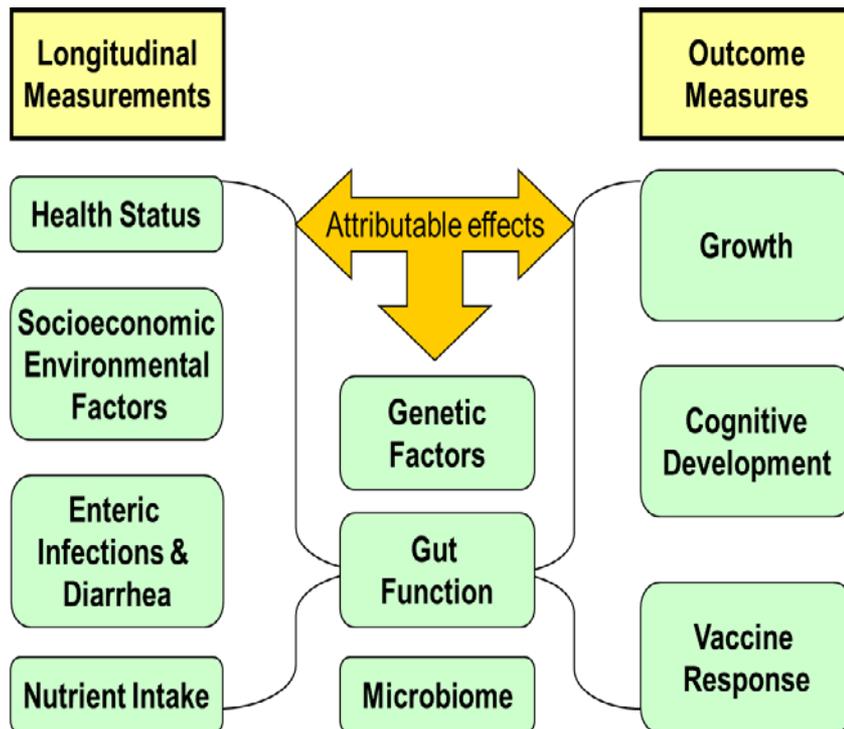
alzheimer's association®



Alzheimer's  
Drug Discovery  
Foundation

# MAL-ED

## *Etiology, Risk Factors & Interactions of Enteric Infections and Malnutrition and the Consequences for Child Health & Development*



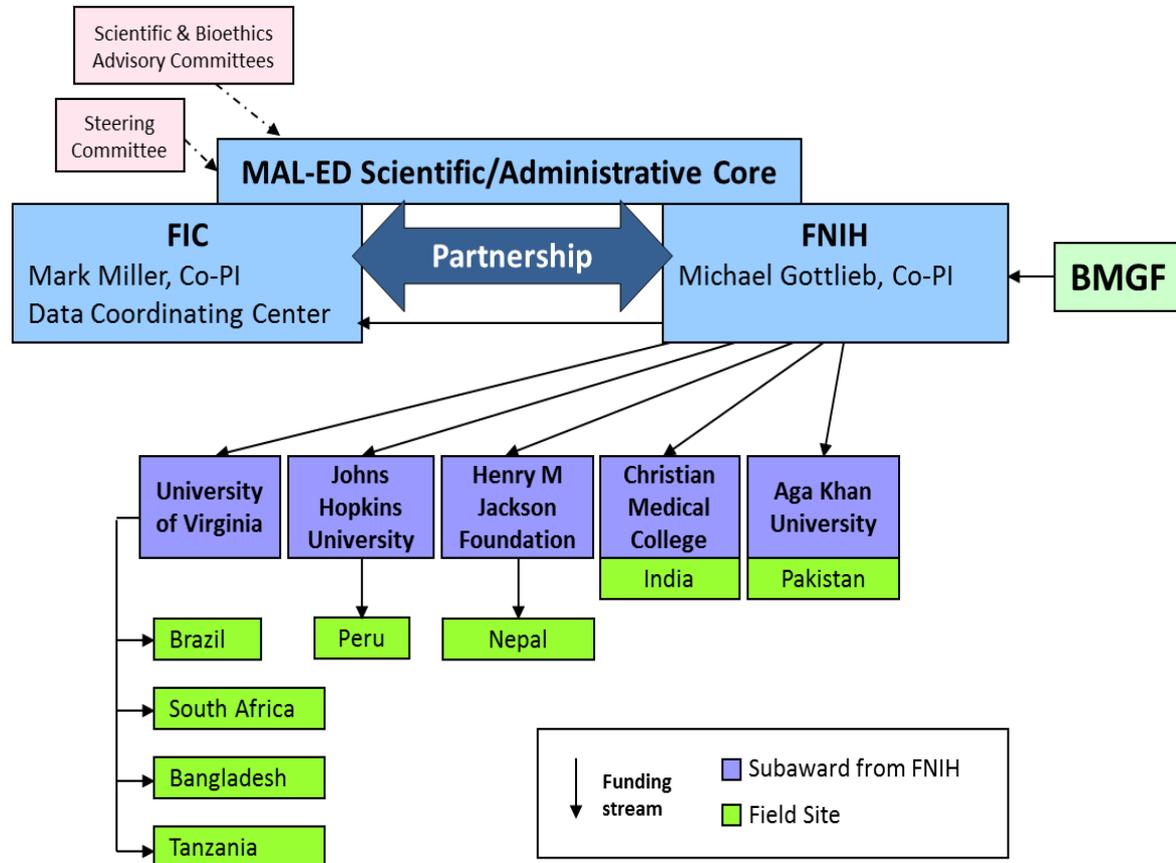
- **Goal:** Study birth cohorts in areas with high prevalence of malnutrition and enteric diseases to determine their relationship with gut function and inflammation and their effects on physical and cognitive development, and responsiveness to vaccines
- **Private Partner:** Bill & Melinda Gates Foundation
- **Funding:** \$40M
- **NIH Partner:** Fogarty International Center (FIC), Division of International Epidemiology and Population Studies

# MAL-ED

## Partnership Model

### FNIH provides:

- Co-leadership of international consortium
- Administration and financial oversight of non-NIH components in accordance with donor and regulatory requirements
- Executive management of governance framework for MAL-ED Network and “companion projects”



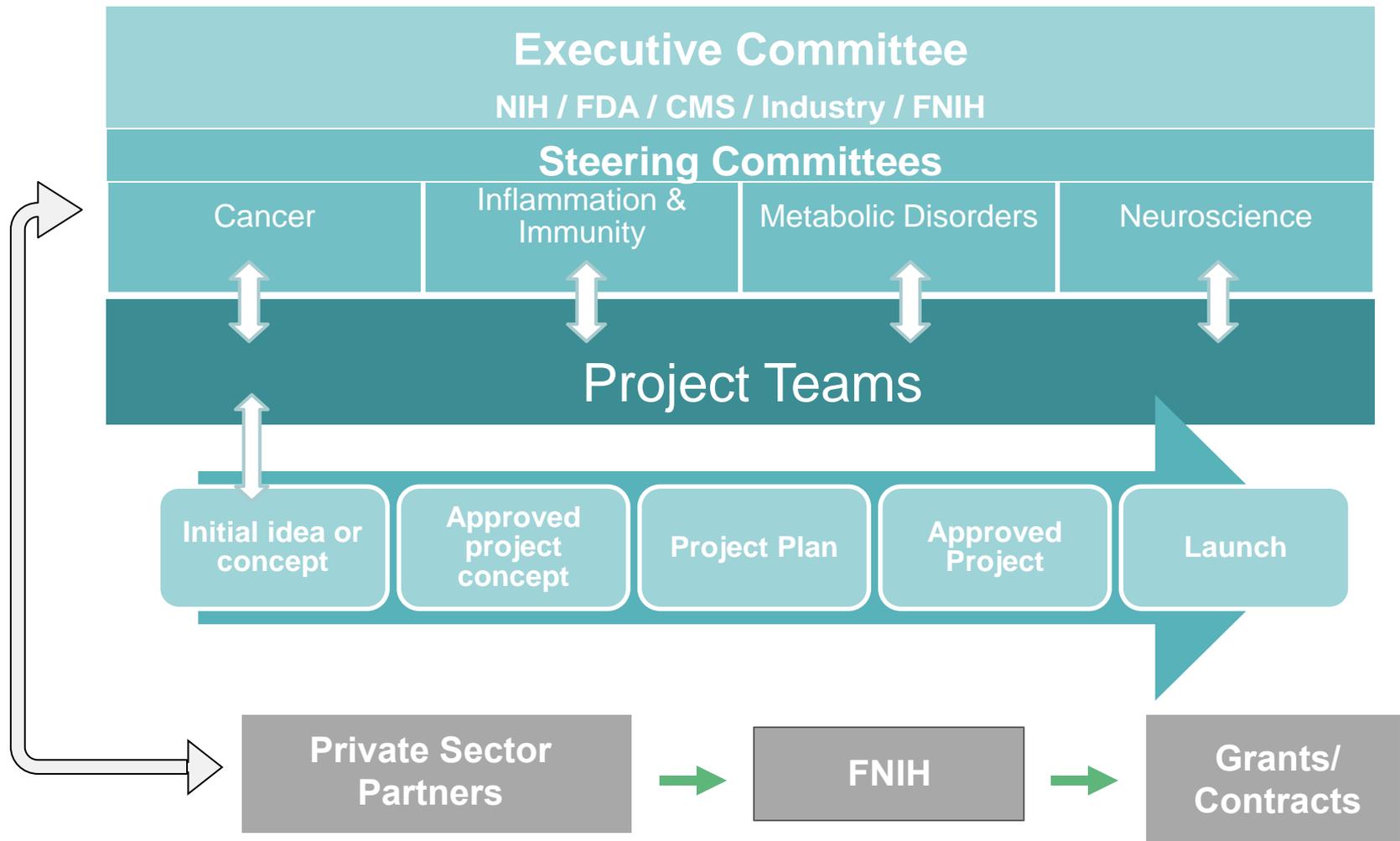
# The Biomarkers Consortium

*To enable improvements in drug development, clinical care, and regulatory decision-making.*



- **Goal:** To develop and qualify biomarkers using new and existing technologies
- **Founding Partners:** NIH, FDA, FNIH, PhRMA, BIO, CMS
- **Funding:** >\$50M
- **Functions:**
  - Qualifies biomarkers for specific applications in diagnosing disease, predicting therapeutic response or improving clinical practice;
  - Addresses a broad range of disease / therapeutic areas;
  - Generates information useful to inform regulatory decision-making;
  - Fosters the exchange of knowledge and expertise among industry, academics, and government leaders;
  - Pre-competitive; makes consortium project results broadly available to the entire scientific community.

# The Biomarkers Consortium



# FNIH PPPs

## *Competencies*



### Governance

- FNIH Board Members and staff play leadership roles

### Policy Management

- Provides a “safe harbor” for interactions between and among companies, government, academic entities
- Ensures projects meet NIH ethical and policy standards

### Program Management:

- Drive consensus across all stakeholders about what projects to conduct and how they should be executed

### Fundraising and Relationship Management:

- Directly solicits contributions
- Stewards and manages donor funds;

### Project Management:

- Ensures projects meet established deliverables and “go/no go” milestones

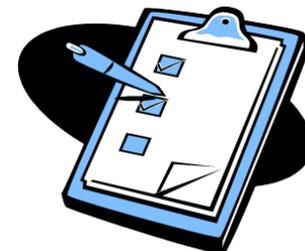
### Intellectual Property Management:

- Provides “pre-competitive” structures for handling intellectual property, including trusted 3rd party IP mechanisms

# Lessons Learned

## *General observations*

- Identify:
  - Scientific problem
  - Key players
  - Resources required
  - Neutral convener; trusted party
- Establish:
  - Clear goals and milestones
  - Effective mechanism to generate scientific consensus
  - Nimble infrastructure
- Facilitate:
  - Discussions with key opinion leaders and regulatory decision makers
  - Integrated approach to cross-sector partnerships
  - Communications; ensure all partners' voices are heard;
- Enable:
  - Sharing of data and expertise to collaboratively address medical needs
  - Resource mobilization
  - Manage grants, contracts, and projects; oversee and conduct research





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[www.fnih.org](http://www.fnih.org)