

Public-Private Partnerships: The NIMH Perspective

July 22, 2010

Tom Insel, MD

Director, NIMH



NIH: Steward of Medical and Behavioral Research for the Nation



“Science in pursuit of **fundamental knowledge** about the nature and behavior of living systems... and the **application of that knowledge** to extend healthy life and reduce the burdens of illness and disability.”



Partnerships for Public Health

§ Biobanks

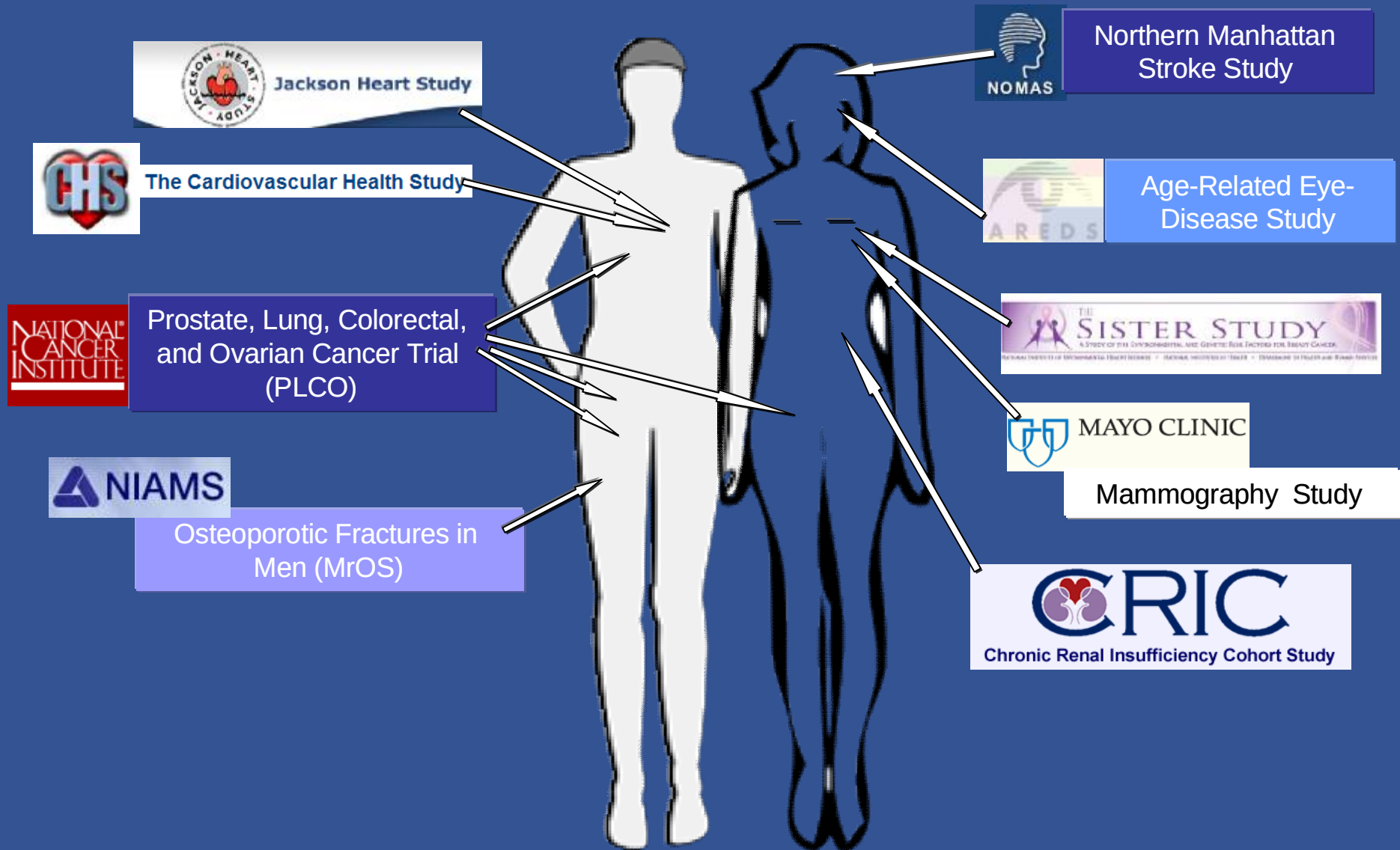
§ Biomarkers

§ Drug development

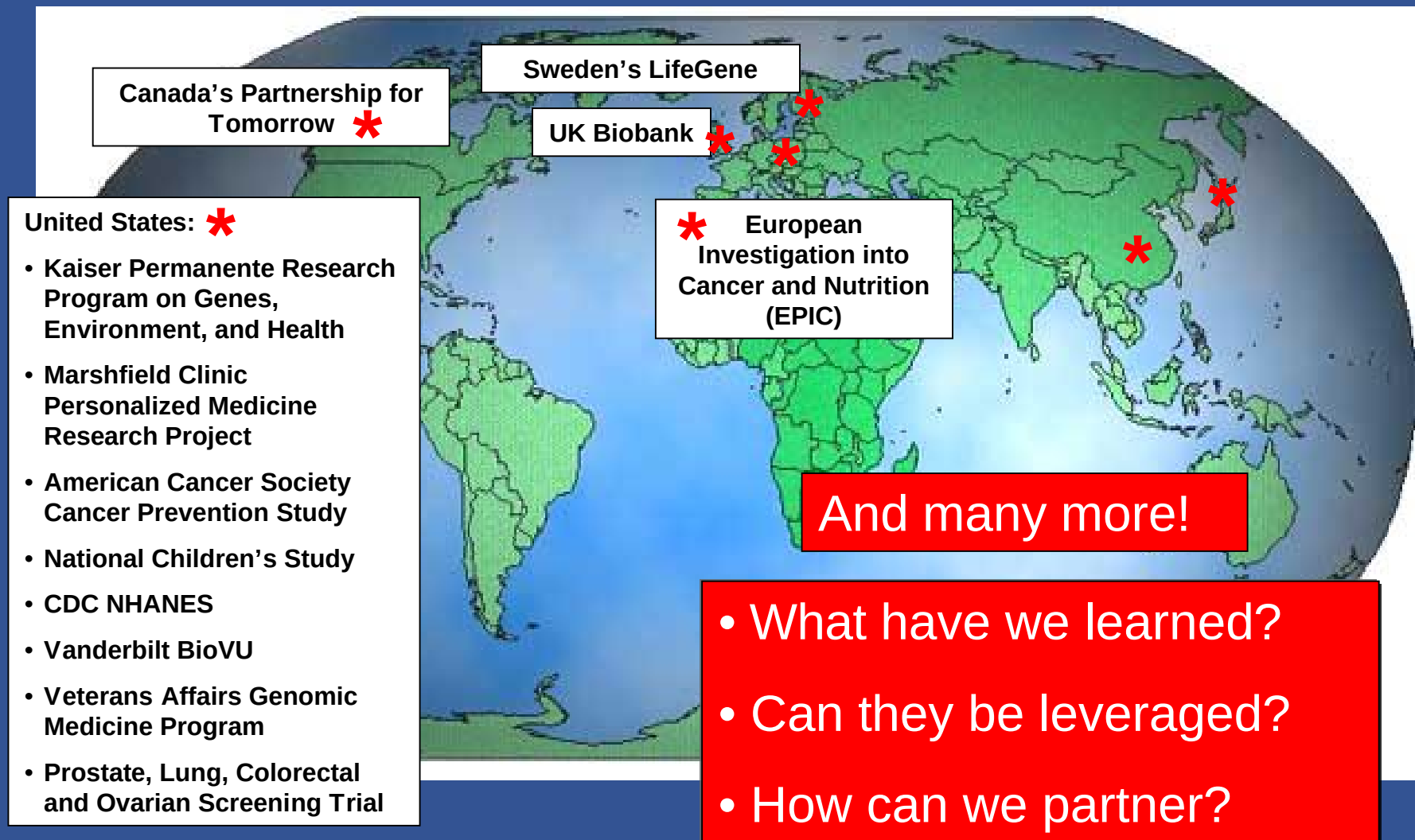
**Opportunities
and
Barriers**

Disease-Specific Cohort Studies

Important for defining disease risk



Large Ongoing Cohort Studies



New Tools Are Available



\$1000 Genome

Robotics and High-Throughput Processing



Computerized Questionnaires and Electronic Medical Records



Mobile Technologies



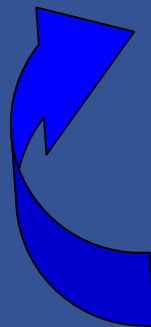
Large Biobanks

Components of Large Cohort Studies

Data Access for
Research Partners



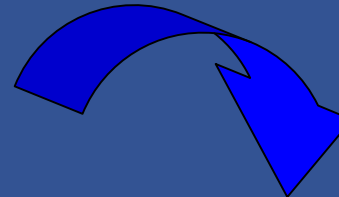
Follow-up



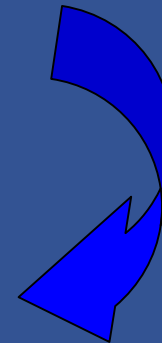
Biorepository



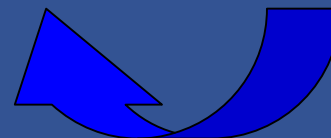
Lots of PLANNING!



Recruitment
and Consent



Questionnaire
and Physical
Assessment



Biobanks/ Large Cohort Studies

Opportunities:

Large scale efforts to look at risk and exposures prospectively
Repository can be mined in new ways as technology develops
Sampling of representative population

Barriers:

Costs
Consents for sharing
Standardization
Limitations of sampling



The screenshot shows the UK Biobank website. At the top, there is a navigation bar with links: Accessibility | Home | About Us | Site map | Health Professionals. The main header features the 'biobank' logo with the tagline 'Improving the health of future generations'. Below this is a section titled 'Improving the health of future generations' with a 'Welcome to UK Biobank' message. The text states that UK Biobank has reached its goal of recruiting 500,000 people aged 40-69 years to help tackle the diseases of the 21st Century. It provides information on how to confirm an appointment time or change it, and mentions that the assessment centres are open a week away. A list of links is provided on the left side of the page, including: Confirm appointment, Assessment centre locations, UK Biobank: what is it?, About assessments, Why is it important, Your questions answered, Our supporters, Meet the team, Ethical standards, Latest Developments, Research round up, GPs, Press, and International. A central banner reads '502,644 people are already helping. 12pm Wednesday 21 July 2010'. Below this is a video player showing a man in a white coat. On the right side, there is a section titled 'Your feedback is important to us. Tell us what you think' with a photo of a woman. At the bottom right, there is a logo for the Department of Health (DH).

Accessibility | Home | About Us | Site map | Health Professionals

biobank^{uk}
Improving the health of future generations

Improving the health of future generations

Welcome to UK Biobank

UK Biobank has reached its goal of recruiting 500,000 people aged 40-69 years to help tackle the diseases of the 21st Century. I thank you to everyone who has joined this pioneering and ambitious study.

If you have an invitation to our assessment centre in Wrexham, and you want to take part, we shall be delighted to see you. You can confirm your appointment time (or cancel it) online now. Just click the 'confirm' button below or above. A map and more information about your visit to an assessment centre are sent a week away. If you want more information or to change your appointment time, that's simple too - just call our Participant Resource Centre on the number on 0800 3 276 276 (Monday to Saturday 8am-7pm, calls are recorded). UK Biobank has Quality Management System Standard (ISO 9001:2008 accredited) and ISO 27001:2005 Information Security Management Certification.

If you are looking for more information about the project, just follow the links on the left.

Follow the latest news by watching the video below, or seeing our story on the BBC website. Read more about our latest achievement [here](#).

502,644 people are already helping.
12pm Wednesday 21 July 2010

Confirm appointment
Assessment centre locations
UK Biobank: what is it?
About assessments
Why is it important
Your questions answered
Our supporters
Meet the team
Ethical standards
Latest Developments
Research round up
GPs
Press
International

Your feedback is important to us. Tell us what you think

Department of Health

The FNIH Biomarkers Consortium



Abbott Laboratories	Academy of Molecular Imaging
Amgen	Advanced Medical Technology Association
Amylin	Alliance for Aging Research
AstraZeneca	Alzheimer's Association
BG Medicine	American Association for Cancer Research
Boehringer-Ingelheim	American College of Neuropsychopharmacology
Bristol-Myers Squibb	American Diabetes Association
Daiichi-Sankyo, Inc.	American Health Assistance Foundation
Eisai, Inc.	American Society of Clinical Oncology
Genstruct, Inc.	American Society for Clinical Pharmacology and Therapeutics
GlaxoSmithKline	American Society for Radiation Oncology
InfraReDx, Inc.	Arthritis Foundation
Johnson & Johnson	Association of Clinical Research Organizations
Eli Lilly and Company	Autism Speaks
Merck and Co., Inc.	Avon Foundation
Meso Scale Discovery	Battelle Memorial Institute
Metabolon, Inc.	Biotechnology Industry Organization
NextGen Sciences	CHDI Foundation
Orasi Medical, Inc.	Cystic Fibrosis Foundation Therapeutics
Pfizer Inc.	Federation of Clinical Immunology Societies
F. Hoffmann-La Roche	The Hamner Institutes for Health Sciences
Scout Diagnostics	The Immune Tolerance Institute, Inc.
Sepracor	International Society of Biological Therapy of Cancer
Takeda Pharmaceuticals	Juvenile Diabetes Research Foundation
XOMA, Ltd.	Kidney Cancer Association
	The Leukemia and Lymphoma Society
	Michael J. Fox Foundation for Parkinson's Research
	Ontario Cancer Biomarker Network
	Osteoarthritis Research Society International
	Pharmaceutical Research and Manufacturers of America
	Radiological Society of North America
	Society of Nuclear Medicine
	University of Illinois

The FNIH Biomarkers Consortium

Steering Committees:

Neuroscience, Cancer, Metabolic, Immunology

Goals:

Biomarkers for diagnosis (ADNI), treatment (I-SPY2), surrogate markers (FDG-PET for Ca)

Funding:

Industry + NIH

The FNIH Biomarkers Consortium

Opportunities:

Shared resources (pt samples, reagents)
Funding
FDA qualification

Barriers:

Culture clash
Discovery vs development
Industry representation
Process heavy
Stage of the science



Partnerships for Public Health

§ Biobanks

§ Biomarkers

§ Drug development

**Opportunities
and
Barriers**

Few Drugs in the Pipeline



Drug Development: Who and How?

- **Who?** Astra Zeneca, GSK leaving CNS in 2010. Lilly and Sanofi Aventis?
- **Who?** Biotech reduced due to reduced VC investment.
- **Who?** Analysis of pipeline reveals few novel ideas or molecular entities.
- **Who?** Cures Acceleration Network authorized in Health Care Reform

Patient Protection and Affordable Care Act

An Act

Entitled The Patient Protection and Affordable Care Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS

(a) SHORT TITLE.—This Act may be cited as the “Patient Protection and Affordable Care Act”.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

Subtitle A—Immediate Improvements in Health Care Coverage for All Americans

Sec. 1001. Amendments to the Public Health Service Act.

“PART A—INDIVIDUAL AND GROUP MARKET REFORMS

“SUBPART II—IMPROVING COVERAGE

“Sec. 2711. No lifetime or annual limits.

“Sec. 2712. Prohibition on rescissions.

“Sec. 2713. Coverage of preventive health services.

“Sec. 2714. Extension of dependent coverage.

“Sec. 2715. Development and utilization of uniform explanation of coverage documents and standardized definitions.

“Sec. 2716. Prohibition of discrimination based on salary.

“Sec. 2717. Ensuring the quality of care.

“Sec. 2718. Bringing down the cost of health care coverage.

“Sec. 2719. Appeals process.

Sec. 1002. Health insurance consumer information.

Sec. 1003. Ensuring that consumers get value for their dollars.

Sec. 1004. Effective dates.

Subtitle B—Immediate Actions to Preserve and Expand Coverage

Sec. 1101. Immediate access to insurance for uninsured individuals with a pre-existing condition.

Sec. 1102. Reinsurance for early retirees.

Sec. 1103. Immediate information that allows consumers to identify affordable coverage options.

Sec. 1104. Administrative simplification.

Sec. 1105. Effective date.

Subtitle C—Quality Health Insurance Coverage for All Americans

PART I—HEALTH INSURANCE MARKET REFORMS

Sec. 1201. Amendment to the Public Health Service Act.

“SUBPART I—GENERAL REFORM

“Sec. 2704. Prohibition of preexisting condition exclusions or other discrimination based on health status.

“Sec. 2701. Fair health insurance premiums.

“Sec. 2702. Guaranteed availability of coverage.



The Cures Acceleration Network (CAN)

- Goal: dramatically advance development of new treatments and cures for debilitating and life-threatening diseases by reducing barriers between laboratory discoveries and clinical trials
- Authorized budget for FY 2010: \$500M
- Will provide flexible funding mechanisms
 - Grant Awards: up to \$15M per award; potential additional funding in subsequent years
 - Partnership Awards: up to \$15M, requiring matching funds (\$1 for every \$3 awarded by NIH)
 - Flexible Research Awards: DARPA-like research authority

CAN provides a framework for integration *And for process engineering*



Cures Acceleration Network



NIH Molecular
Libraries
Initiative

NIH TRND

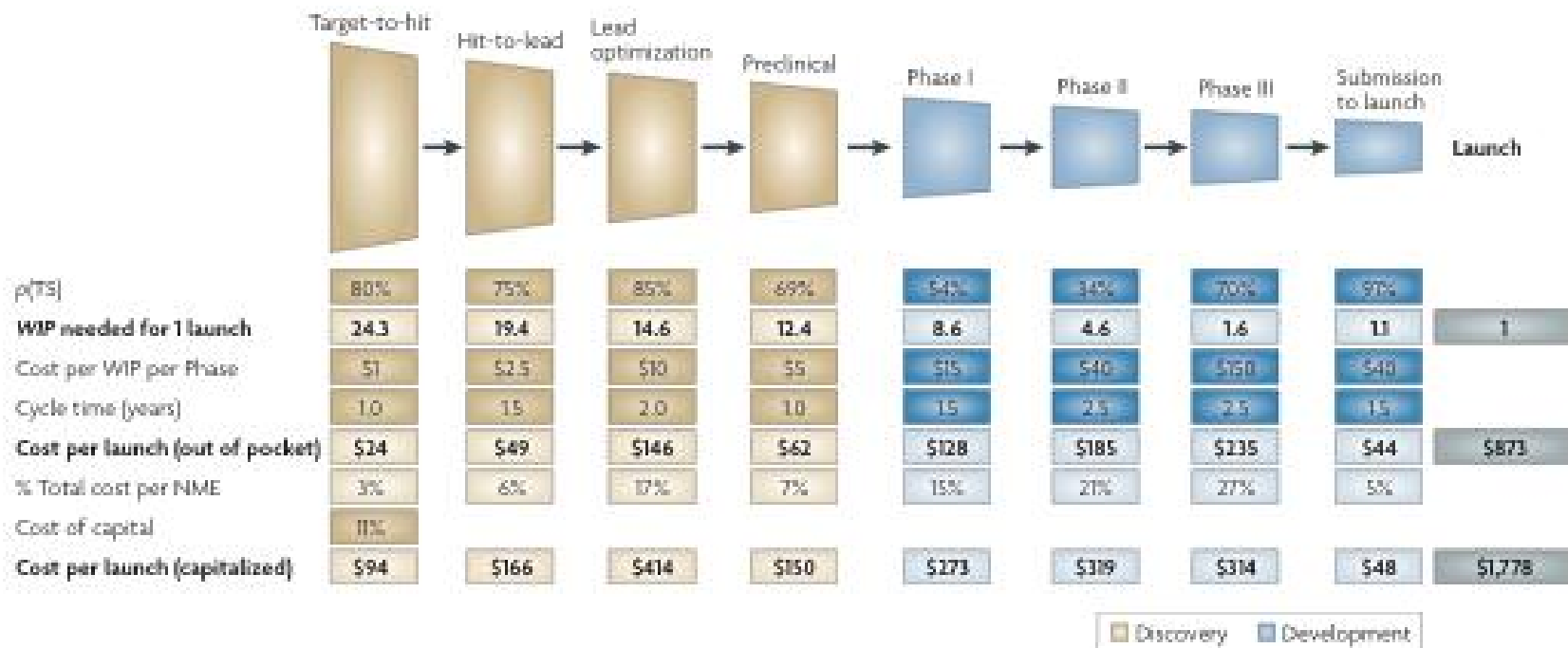
NIH RAID

NIH Clinical Center, CTSA

New NIH FDA Partnerships

How to improve R&D productivity: the pharmaceutical industry's grand challenge

Steven M. Paul, Daniel S. Mytelka, Christopher T. Dunwiddie, Charles C. Persinger,
Bernard H. Munos, Stacy R. Lindborg and Aaron L. Schacht



Nature Drug Disc 2010

Partnerships for Drug Discovery

Opportunities:

- Catalyzing discovery – empowering academia
- Repurposing of compounds
- Re-engineering



The New York Times

Barriers:

- Absence of expertise in academia/NIH
- Costs
- Premature intellectual property
- Creating hand-offs
- COI

- Ghost writing
- Biased reporting
- Driving health care inflation
- Marketing (influencing practice)

Psychiatrists' Relationships With Pharmaceutical Companies Part of the Problem or Part of the Solution?

Thomas R. Insel, MD

sicians. For instance, Eli Lilly consultants, etc) receiving mo

Partnerships for Public Health

§ Biobanks

§ Biomarkers

§ Drug development

Standardization

Integration

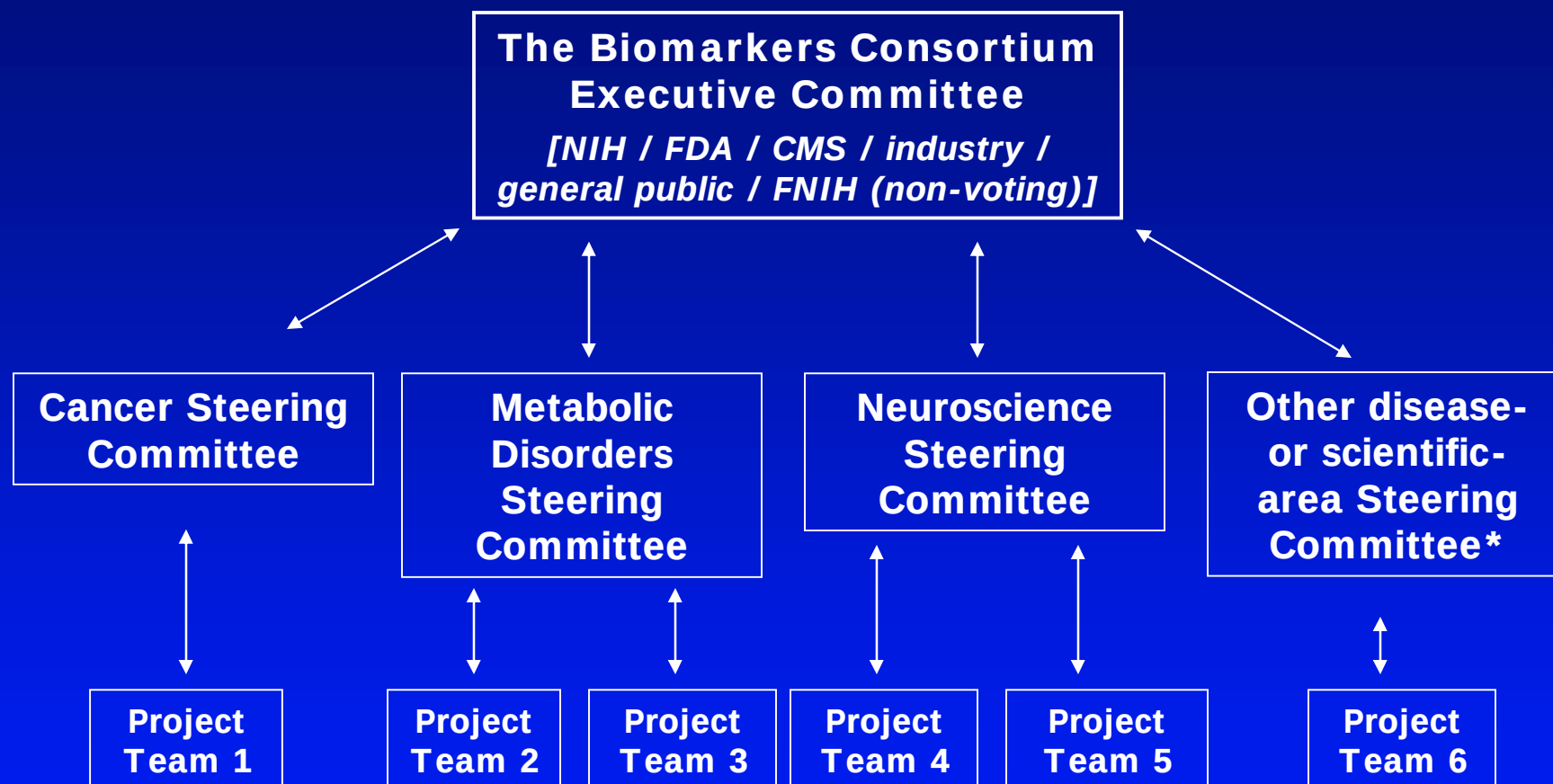
Sharing

GOOD PROCESS WILL NEVER

SUBSTITUTE FOR GOOD PEOPLE OR

GOOD SCIENCE — Steven Paul, Nature Drug Dev, 2010

The Biomarkers Consortium Governance



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

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**