



FNIH

Foundation for the
National Institutes of Health

**Andrea Baruchin, Ph.D.
Senior Advisor to the President**

**Principles and Philosophies for Development of Ongoing
Partnerships to Support Food-Health Research**

June 5, 2014





My Agenda for Today

- Who and what is FNIH?
- Portfolio Overview
- Select FNIH Programs
- Lessons Learned





FNIH

Building partnerships for discovery and innovation to improve health.

Purpose

- To support the NIH in its mission;
- To advance collaboration with biomedical researchers from universities, industry and not-for-profit organizations.

Structure

- 501(c)(3) not-for-profit organization;
- Independent Board of Directors;
- NIH Director and FDA Commissioner *ex-officio* Board Members

Highlights

- Raised >\$750 million since 1996;
- Supported >400 projects, ~100 currently active;
 - research partnerships
 - scientific education/training
 - conferences/events
 - capital programs
- 94 cents of every dollar spent directly supports programs;
- 4-star Charity Navigator rating for past seven years.

Our role...

What we do, how we do it...



Identify:

- Important scientific problem
- Key players
- Resources required and sources of support
- Neutral convener; trusted party to provide safe harbor for discussions

Establish:

- Highest level of ethical standards
- Clear goals and milestones
- Effective mechanism to generate scientific consensus
- Nimble infrastructure and expert project management

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
- Management of grants, contracts, and projects; oversee and conduct research

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

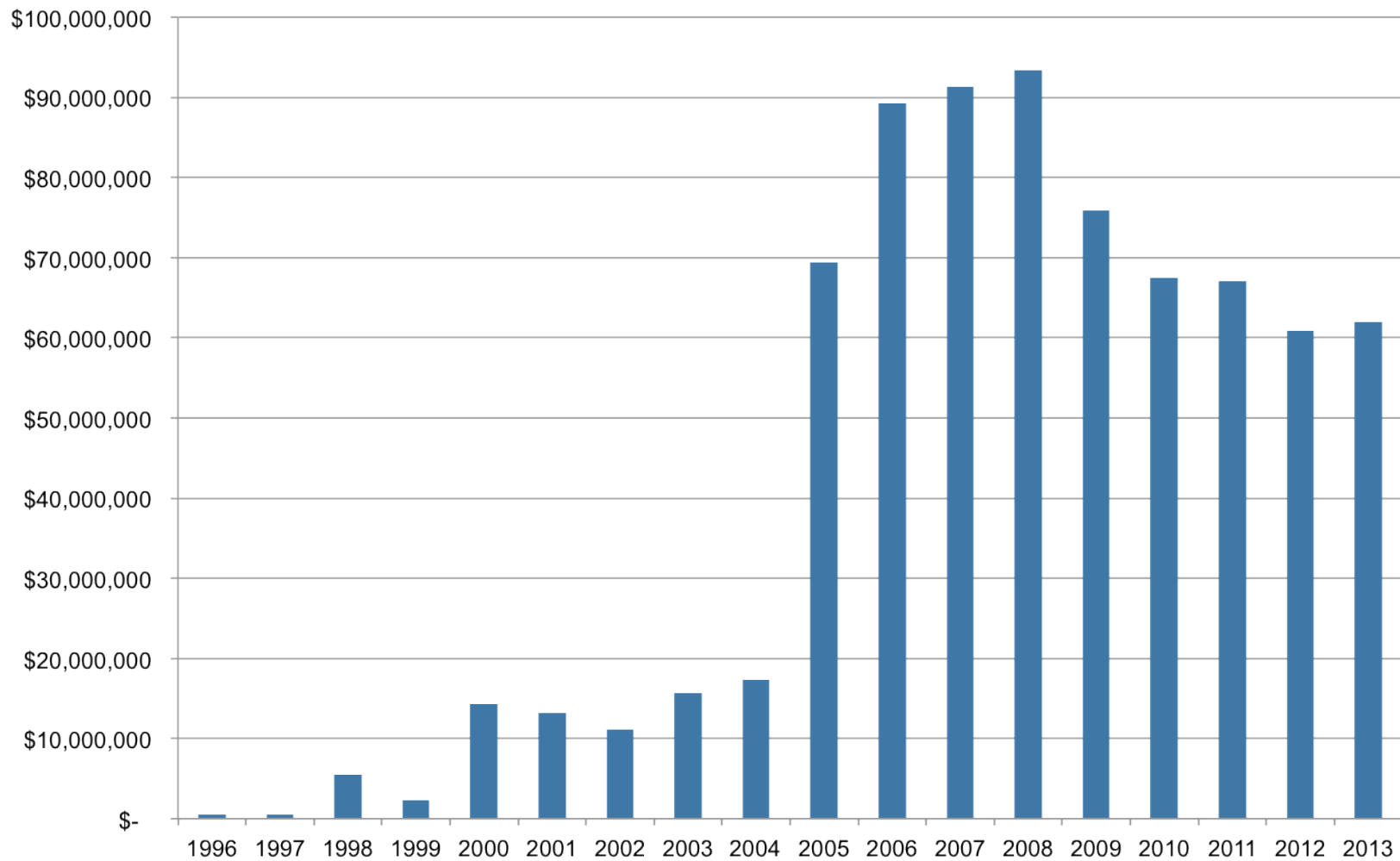
NIH Director/FDA Commissioner *ex-officio* Board members

Our Partners

- Government agencies
- Industry
- Associations
- Foundations
- Philanthropists
- Individuals & families

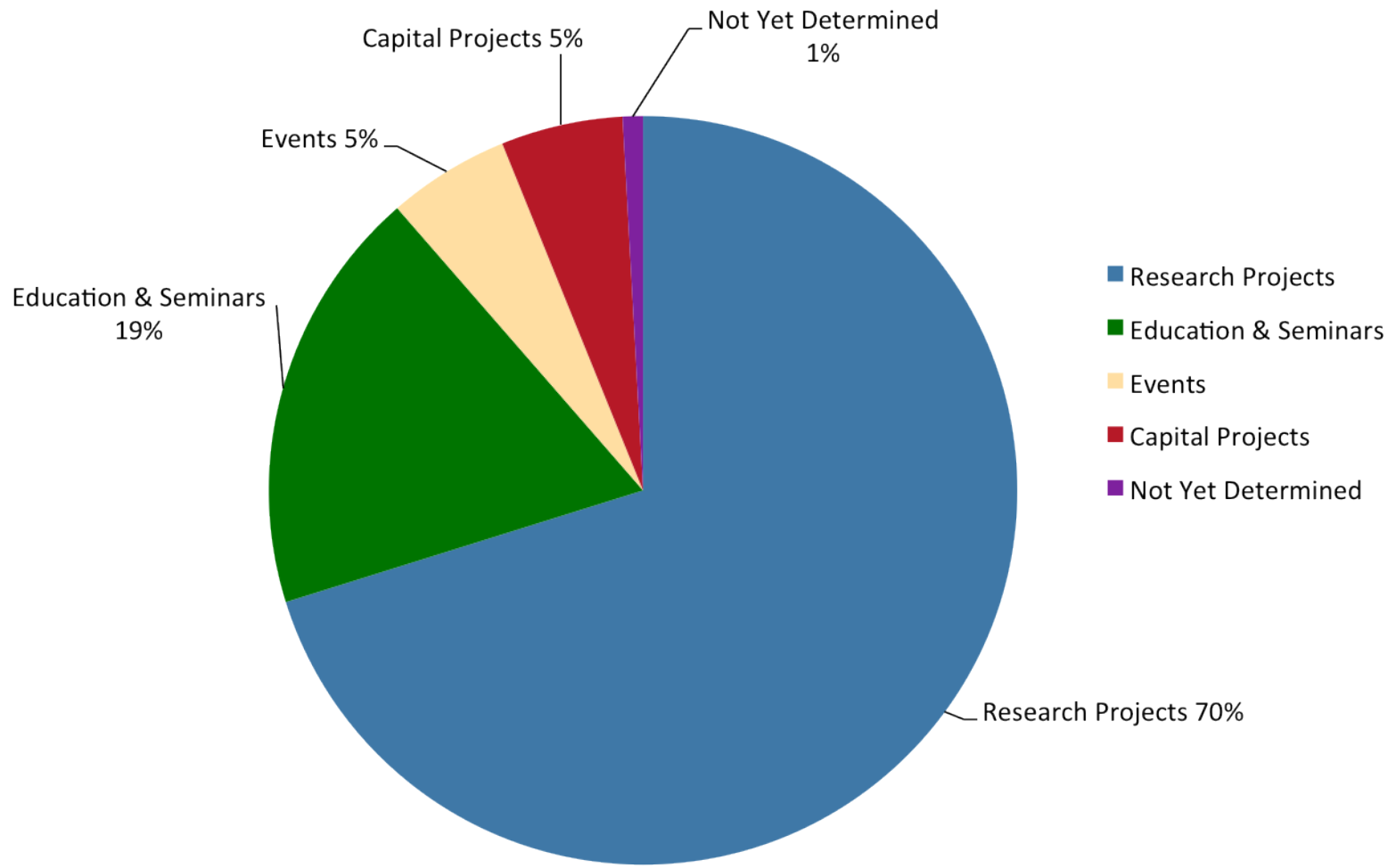


Fundraising Since Inception



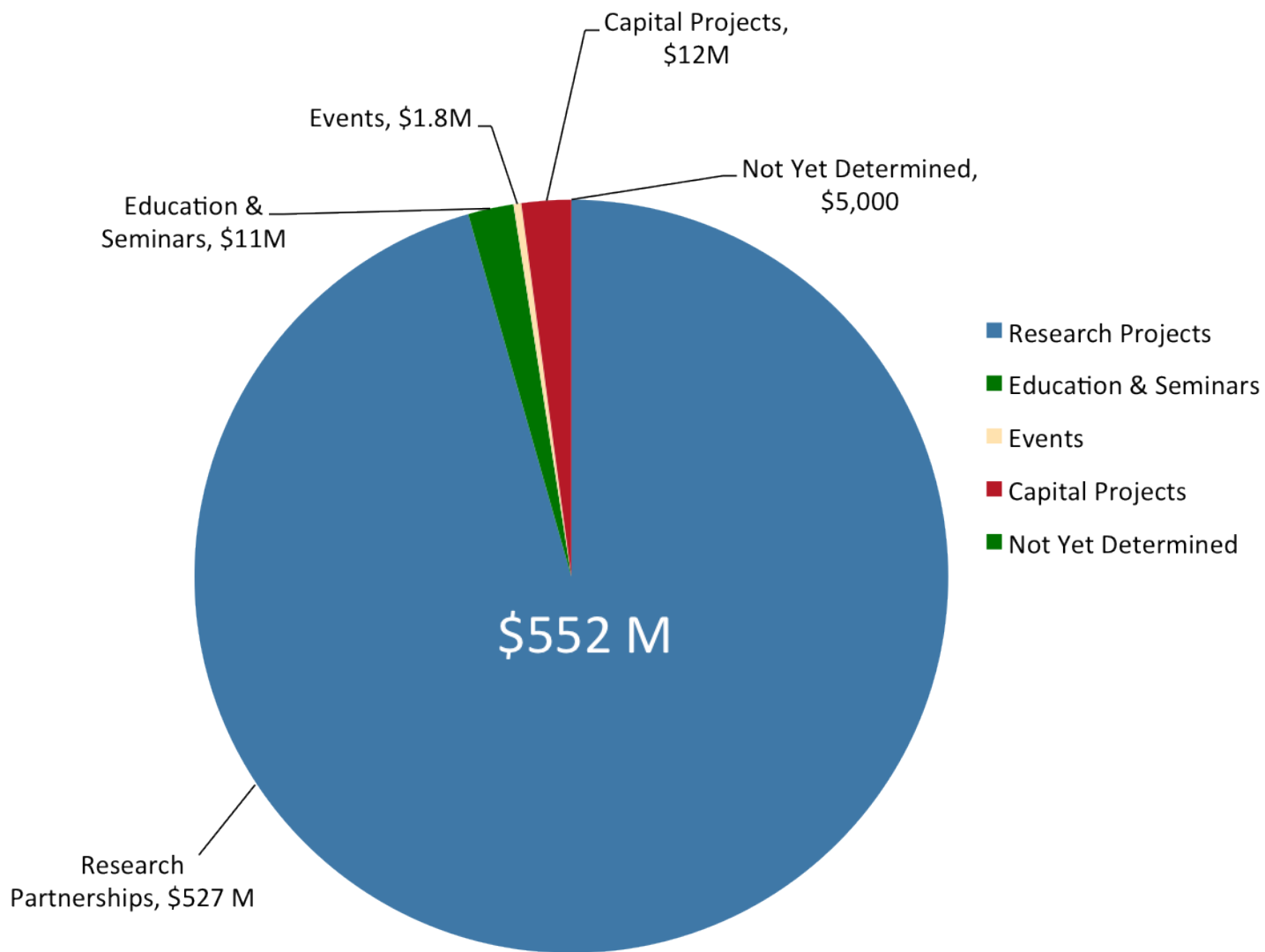
Current Portfolio

114 Active Projects

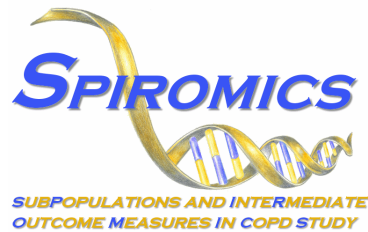
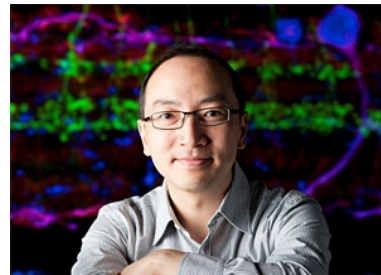


Funds Raised

Current portfolio – 114 Active Projects



Select FNIH Programs



Individual Donors



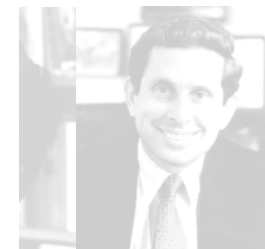
*The Dean R. O'Neill Renal Cell
Cancer Research Fund
and
The Dr. Edward T. Rancic Memorial
Fund for Cancer Research*



Support for Dr. Childs' laboratory
*Immunotherapies for renal cell
cancer*



- Boo!Run for Life each October
- Post-doc for 2-3 years in Dr. Childs NHLBI laboratory
- Total raised – over \$570,000
- Over 1000 donors

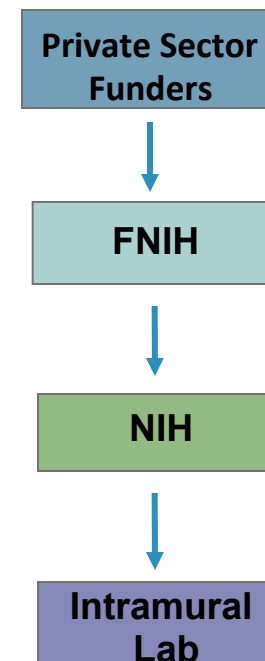


3 Small National Eye Institute Projects

- Research on uveitis and macular degeneration;
- Support for 2 NEI intramural investigators
- Funders: 3 industry partners
- Funding - <\$50K each

FNIH provides:

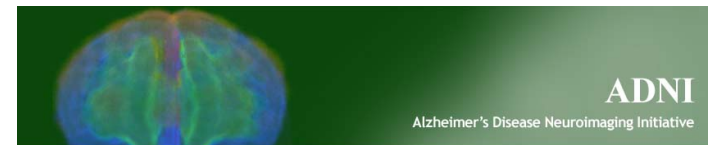
- Neutral third party “space” between funders and NEI;
- Additional fundraising, if necessary;
- Minimal administrative costs.



→ \$\$ Flow

ADNI

- \$150M natural history study of over 1200 participants:
 - normal cognitive aging;
 - subjective memory complaints (SMC);
 - mild cognitive impairment (MCI);
 - early Alzheimer’s disease (AD).
- Launched in 2004 at more than 55 clinical sites in the US and Canada.
- Facilitate the utilization and evaluation of neuroimaging and other biomarkers for use in clinical trials aimed at slowing the onset and progression of AD:
 - develop and standardize methods;
 - acquire data and make available to the research community;
 - form a collaborative network of clinical and imaging sites.



ADNI PPP Structure



Private/Philanthropic

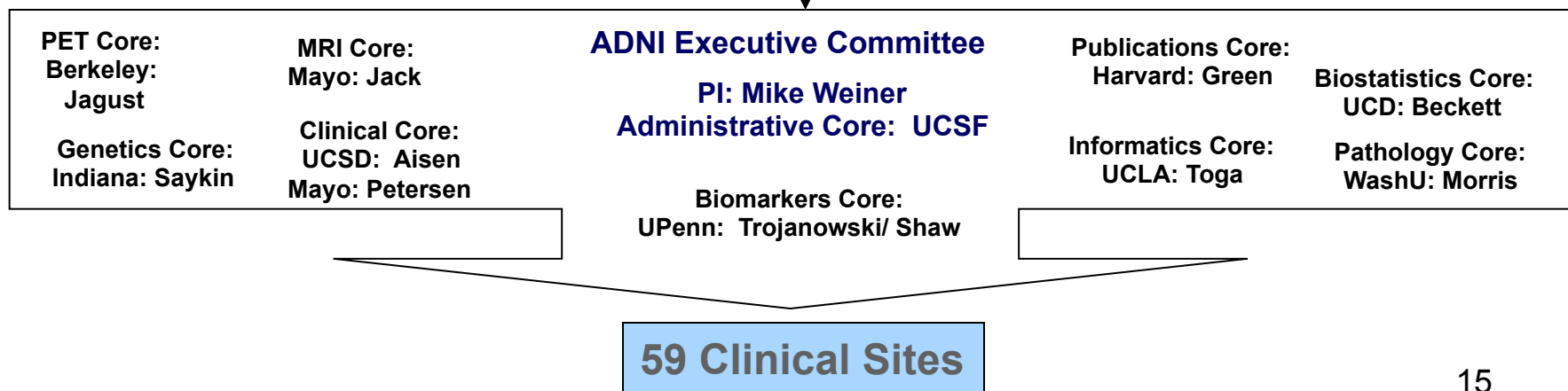


Erika Tarver, Renee Bullion, Andrea Baruchin

+
Public



John Hsiao, Laurie Ryan



Accelerating Medicines Partnership (AMP)



- An alliance among NIH, 10 biopharmaceutical companies, several not-for-profit organizations and FNIH to:
 - transform the current model for developing new diagnostics and treatments;
 - jointly identify and validate promising biological targets of disease.
- Beginning with three disease areas:
 - Alzheimer’s disease;
 - Type 2 diabetes;
 - Rheumatoid arthritis & lupus.
- \$230 million - split between NIH funds and those raised by FNIH.



Current AMP Partners



Alzheimer's disease

Type 2 Diabetes

RA & Lupus

Industry members



Government members



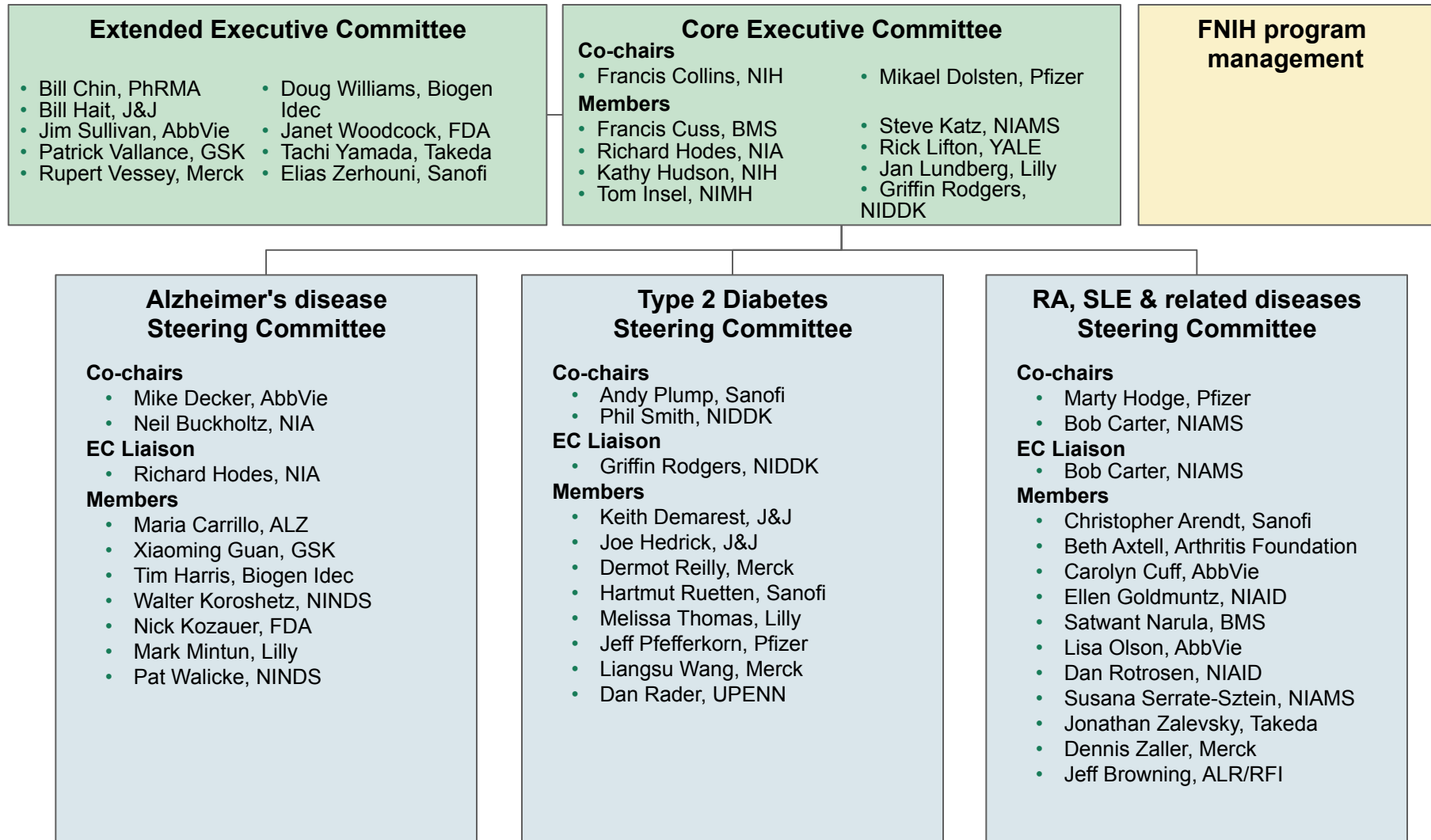
Non-profit members



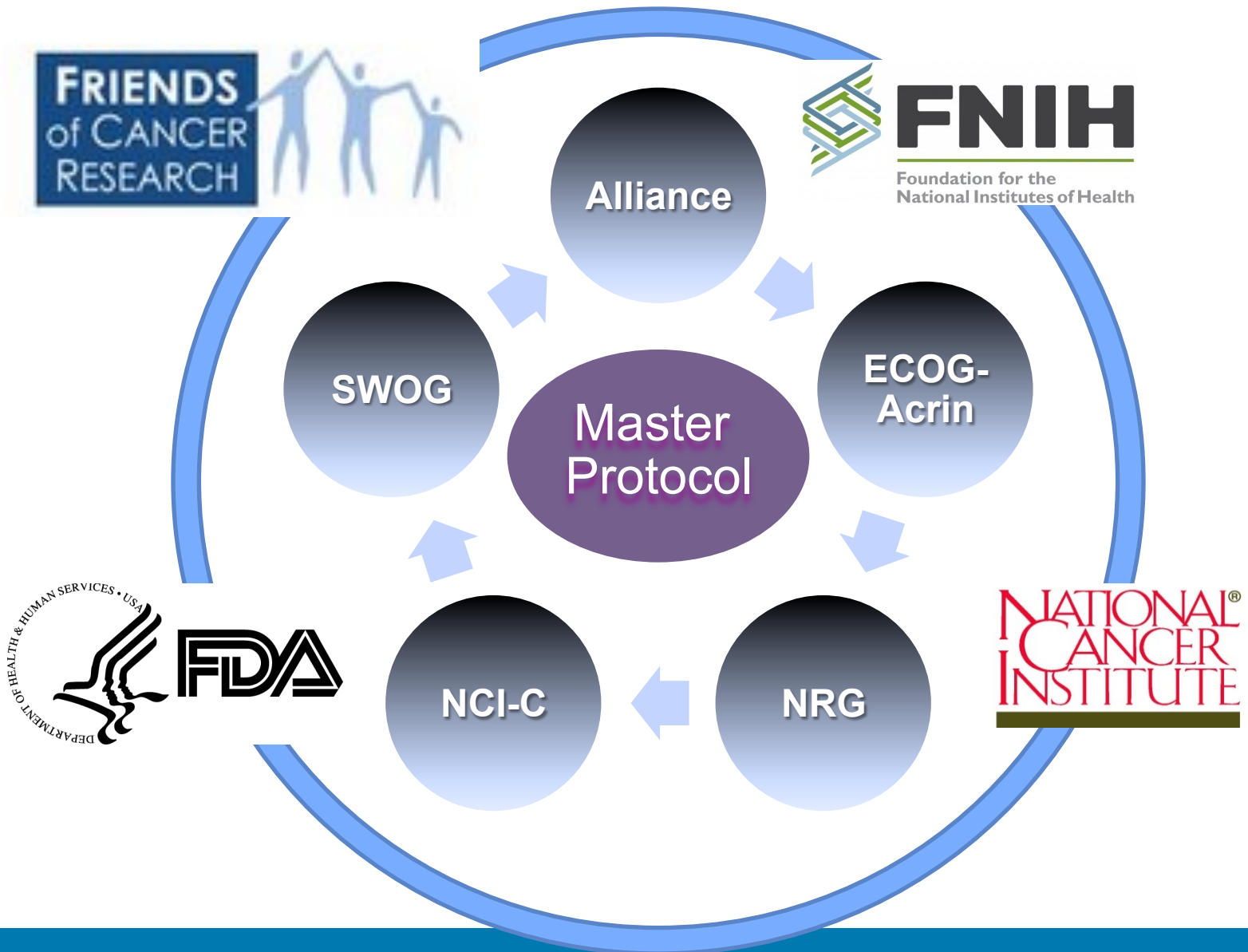
AMP Research Plans & Progress

Disease area	Research plan topics	Deliverables and Progress as of May, 2014
Alzheimer's disease	<p>Topic A: Validate biomarkers of disease within NIA-funded clinical trials</p> <p>Topic B: Conduct network analysis on human brain samples to identify genetic nodes and networks linked to AD</p>	<p>➔ NIA 5-year grants for 3 underlying clinical trials awarded in November 2013; trials underway</p> <p>➔ Three NIA 5-year network analysis grants awarded in November 2013; a fourth grant funded through FNIH was awarded in April 2014; data sharing platform in development</p>
Type 2 diabetes	<p>Phase 1: Create a knowledge portal containing comprehensive genotype/phenotype datasets in T2DM and complications</p> <p>Phase 2: Conduct targeted sequencing of high priority targets of interest</p>	<p>➔ Two NIDDK grant solicitations to fund the knowledge portal released April 2014; complementary FNIH scheduled for release by June 2014</p> <p>➔ FNIH RFPs for targeted sequencing scheduled for release in late 2014/early 2015</p>
Rheumatoid arthritis and lupus	<p>Phase 0/1: Collect blood and tissue and establish pathway/network maps of RA & SLE. Make all data available via a knowledge portal.</p> <p>Phase 2: Conduct additional focused analyses to stratify patient populations and validate potential therapeutic targets</p>	<p>➔ NIAMS grant solicitations to fund Phase 0/1 released March 2014.</p> <p>➔ FNIH supplemental grants to be released late 2014/early 2015</p>

AMP Governance



LUNG-MAP



Lung-MAP



- The problem – targeted therapies makes recruitment for cancer trials more costly and difficult;
- In squamous cell lung cancer, targeted drugs are predicted to work in only 5-20% of patients - requiring screening of huge numbers to meet trial accrual goals;
- Multi-arm Master Protocol with a common trial infrastructure;
- Screen large numbers of patients (>6000) for multiple targets by a broad-based next-gen sequencing platform - reduces the screen failure rate;
- 5 drug companies currently participating
- Designed to facilitate FDA approval of new drugs.



Lung-MAP Trial Arms for Treatment

Patients with
squamous cell
lung cancer

Tumor sample analyzed

Arm A

Arm B

Arm C

Arm D

Arm E

Tumor has
none of the
changes
listed here

Tumor
DNA has
PIK3CA
gene
mutation

Tumor DNA
has CCND1,
D2, CDK4
gene
mutation

Tumor DNA
has FGFR
gene
amplification,
mutation or
fusion

Tumors
contains
high levels
of c-Met
protein

Arm 1

Arm 2

Arm 1

Arm 2

Arm 1

Arm 2

Arm 1

Arm 2

Arm 1

Arm 2

50 %
Chemo-
therapy

50 %
MEDI
4736

50%
Chemo-
therapy

50 %
Pic-
tilisib

50%
Chemo-
therapy

50 %
Palbocic
lib

50 %
Chemo-
therapy

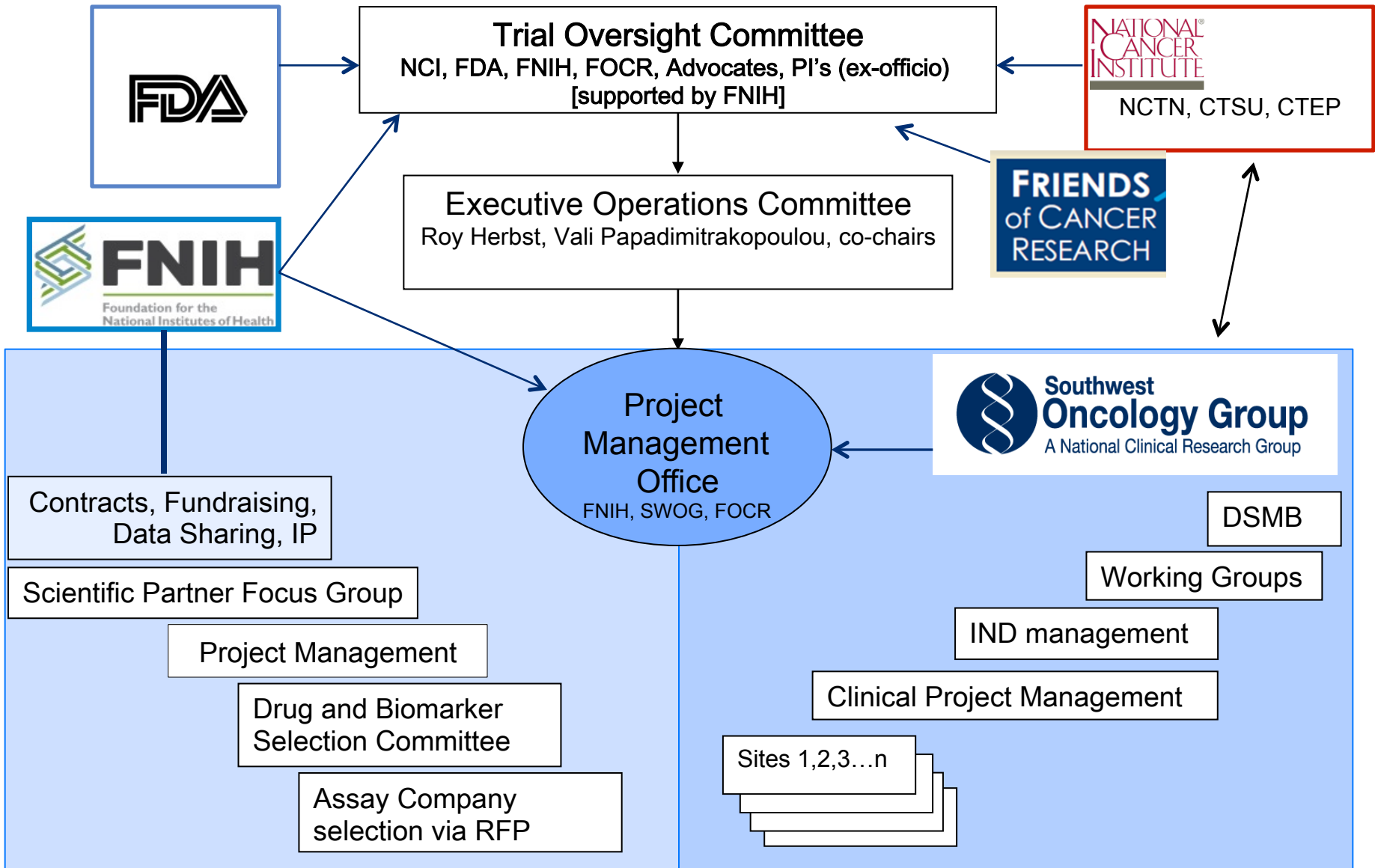
50 %
AZD
4547

50 %
Erlotinib

50 %
Rilotuma
mab+
Erlotinib



Lung-MAP Governance



Partnership “must-haves”

Lessons Learned

- A matrix that is greater than the sum of its parts;
- Well defined objectives, budgets, milestones and deliverables;
- Common governance, rules and legal framework;
- Realistic funding goals, expectations and timelines;
- Projects aligned with donor interest;
- Appreciation of the value of gifts;
- Collaboration adds complexity: *must “play nice with others!”*;
- Nimble, transparent and accountable.



*“When you’ve seen one
partnership...you’ve seen
one partnership.”*

