

NIA Update

ADC Directors' Meeting

Richard J. Hodes, M.D.
Director
National Institute on Aging

April 18, 2015

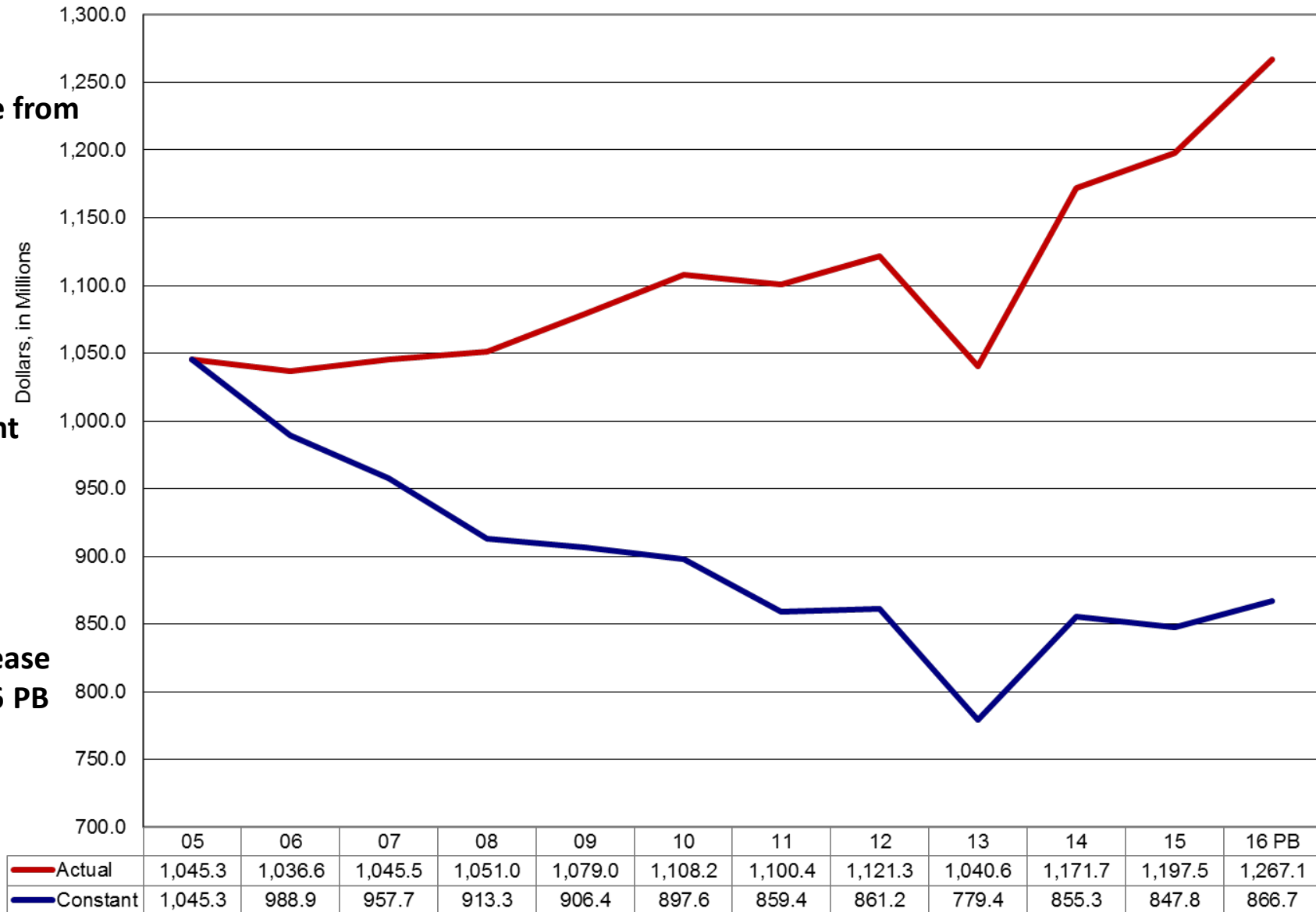


NIH/NIA Budget Update



NIA Appropriations FY 2005-2016 PB

Current versus Constant, FY05 Base Year



**Difference from
FY2005**

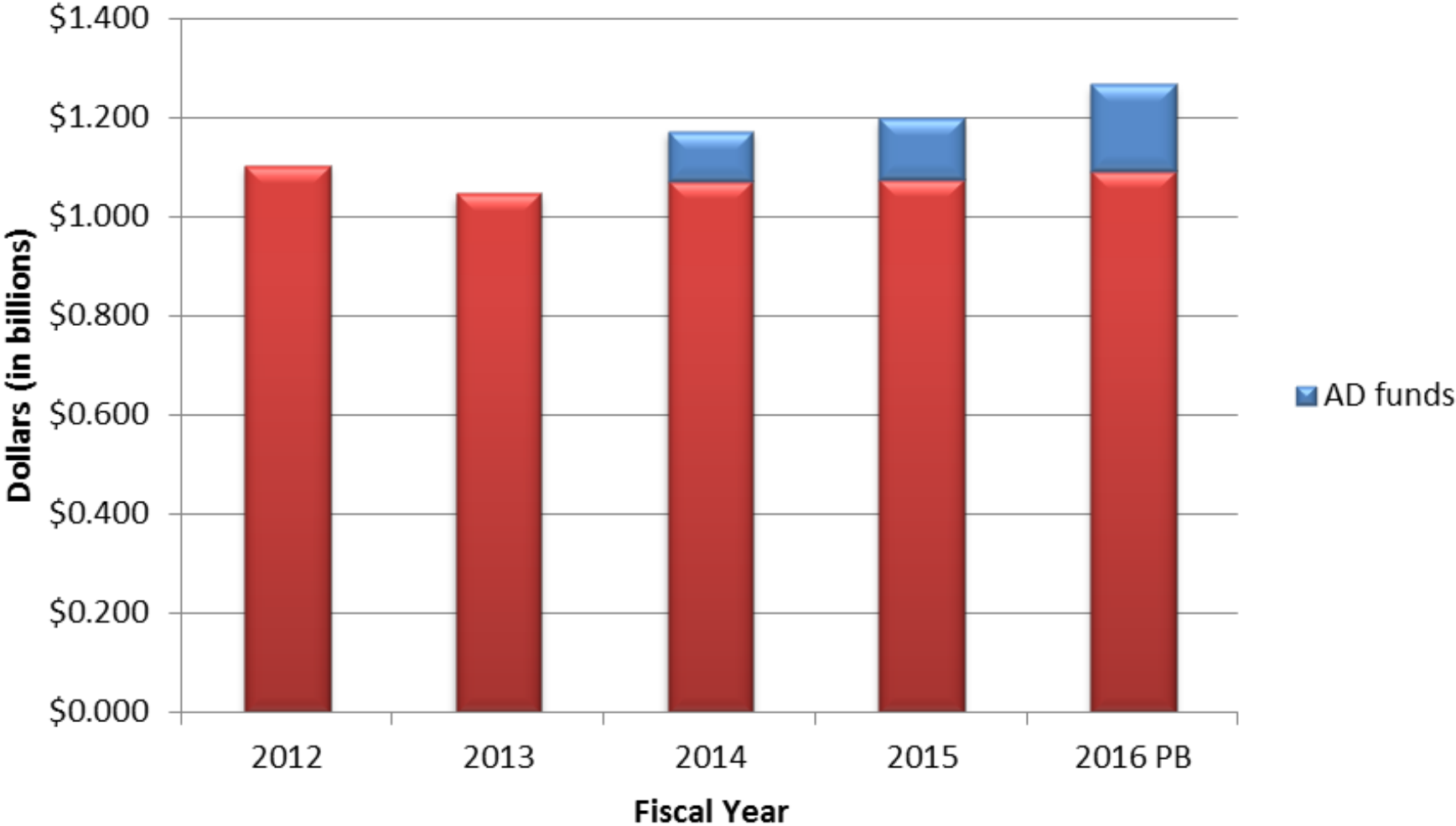
**In Current
Dollars:
\$221.8M
Increase**

**In Constant
Dollars:
\$178.6M
Decrease**

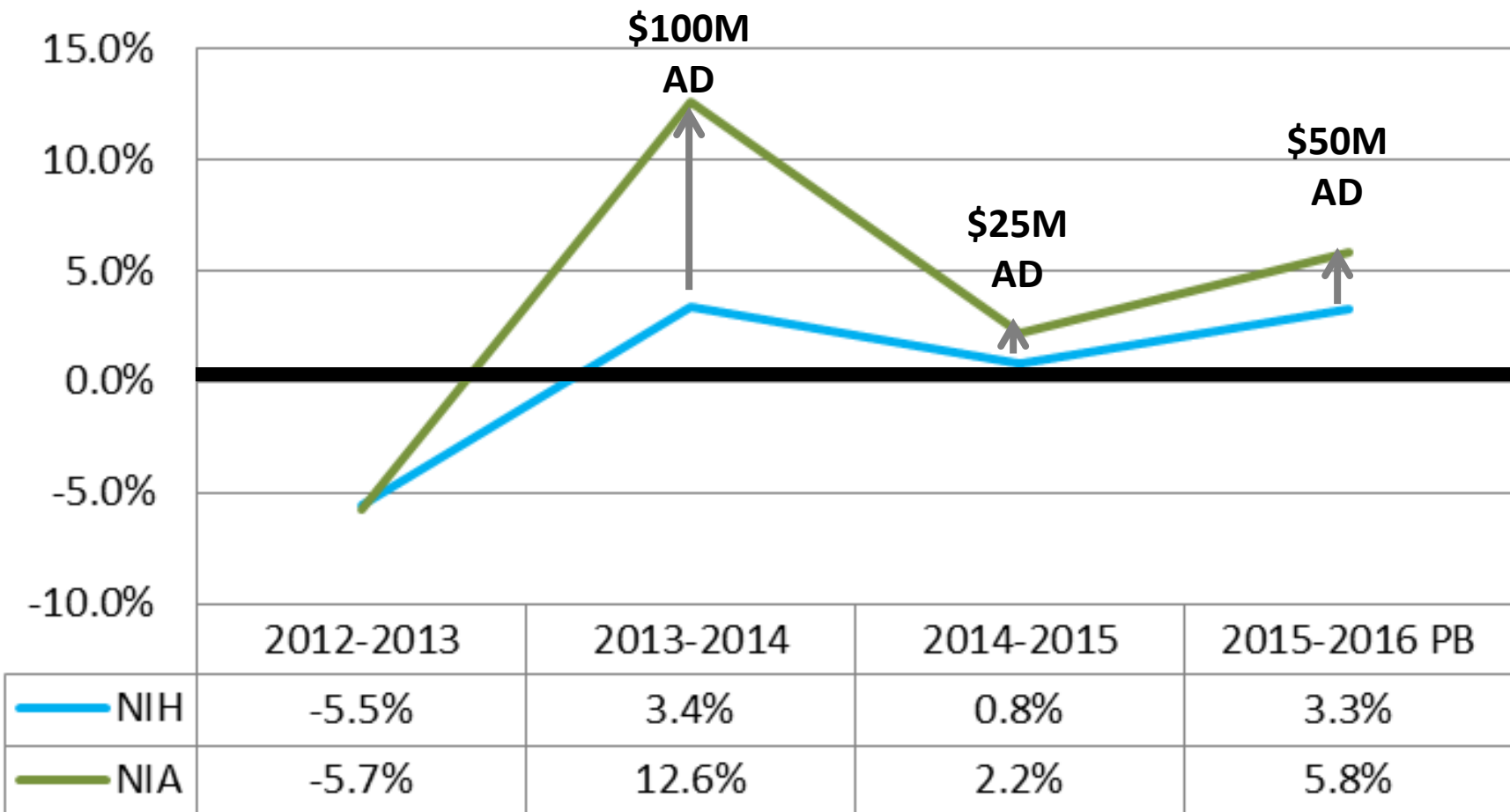
**17% decrease
FY05-FY16 PB**

	05	06	07	08	09	10	11	12	13	14	15	16 PB
Actual	1,045.3	1,036.6	1,045.5	1,051.0	1,079.0	1,108.2	1,100.4	1,121.3	1,040.6	1,171.7	1,197.5	1,267.1
Constant	1,045.3	988.9	957.7	913.3	906.4	897.6	859.4	861.2	779.4	855.3	847.8	866.7

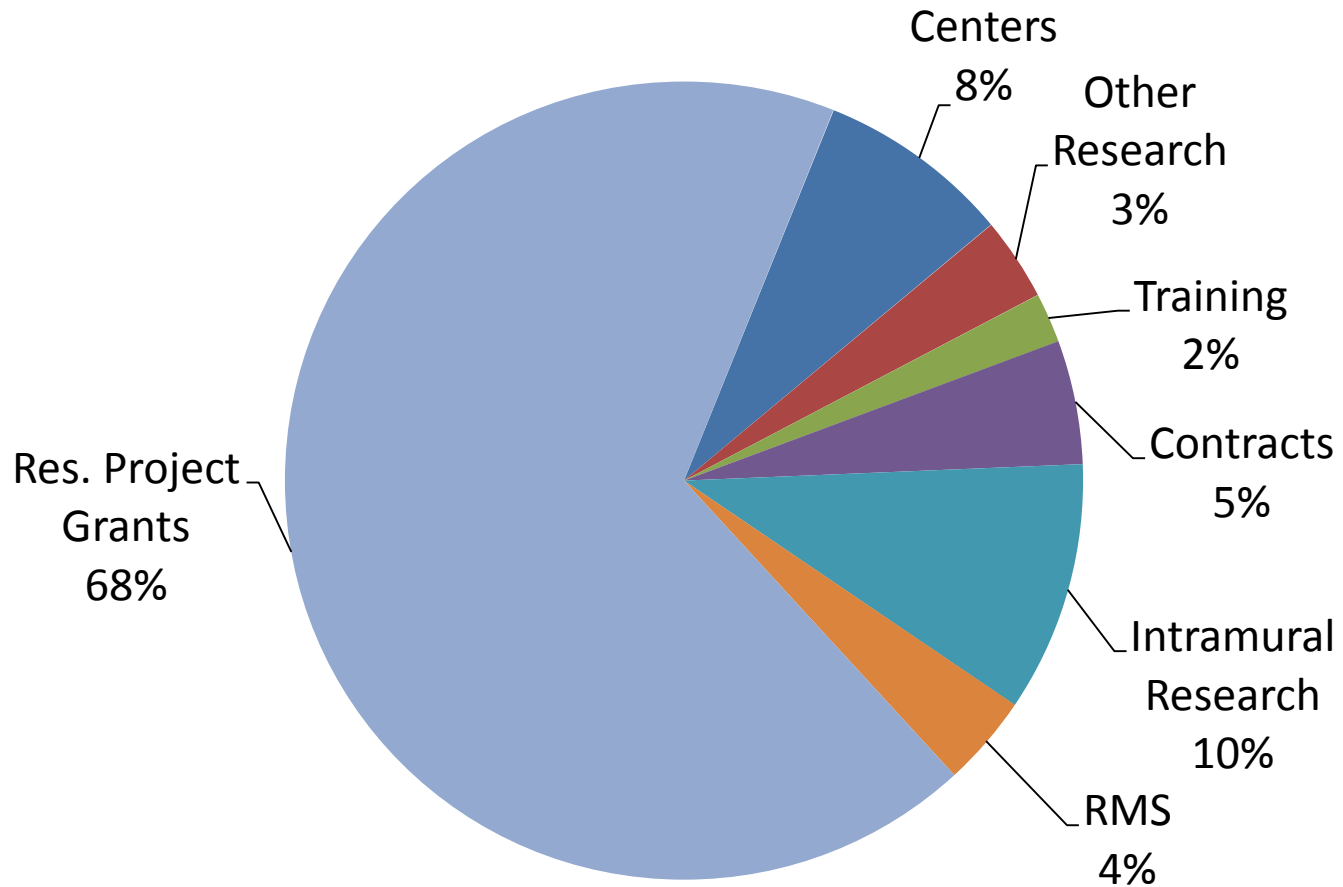
NIA Appropriations



NIH and NIA Percent Growth



Distribution of Obligations by Budget Category Fiscal Year 2014



Total NIA: \$1,171,656,075

NIA FY15 Budget Increase

- FY2015 Report language acknowledged the \$25,000,000 increase in NIA's budget.
- No specific earmarks for AD were mandated, but “a significant portion of the recommended increase for NIA should be directed to research on Alzheimer's.”
- Decisions about funding allocations should be determined by scientific opportunity and the quality of grant applications that are submitted for AD relative to those submitted for other diseases.

New Funding Policy – General Payline

Requested Direct Costs	<500k	500k or greater
All applications except N.I or E.S.I. R01s	7%	4%
N.I. R01s	10%	7%
E.S.I. R01s	12%	9%

New Funding Policy – AD Payline

Requested Direct Costs	<500k	500k or greater
All applications except N.I or E.S.I. R01s	11%	8%
N.I. R01s	14%	11%
E.S.I. R01s	16%	13%

AD Bypass Budget

SEC. 230. Hereafter, for each fiscal year through fiscal year 2025, the Director of the National Institutes of Health shall **prepare and submit directly to the President for review and transmittal to Congress, after reasonable opportunity for comment, but without change, by the Secretary of Health and Human Services and the Advisory Council on Alzheimer's Research, Care, and Services, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institutes) for the initiatives of the National Institutes of Health pursuant to the National Alzheimer's Plan, as required under section 2(d)(2) of Public Law 111–375.**

AD Bypass Budget

- Language in SEC. 230 of the FY2015 Appropriations Act requires a bypass budget for NIH Alzheimer's disease research to be submitted to the President/Congress.
- The HHS Secretary may review and comment, but not alter, the NIH budget submission.
- The budget will be estimated based on the NIH components of the National Alzheimer's Plan.
- NIH is in discussion re: how the development of the budget will proceed.

Possible Bypass Budget Timeline

- End of March – Preliminary recommendations available from 2015 AD Summit
- March – April – Submit recommendations to HHS for consideration in 2015 AD Plan
- May – 2015 AD Plan released
- May/June/July – NIH develops budget estimates based on elements included in 2015 AD Plan
- July – Proposed AD Bypass Budget is reviewed by the HHS Secretary, as well as the Advisory Council on Alzheimer's Research, Care, and Services
- Late July-August – AD Bypass Budget submitted to the President

ACCELERATING MEDICINES PARTNERSHIP (AMP)



Alzheimer's Disease Program



Target Discovery and Preclinical Validation Project

Suzana Petanceska

~2,500 brains
Clinical
Pathologic
Genomic
Epigenomic
RNAseq
Proteomic

Predictive Modeling



Data Integration

Experimental Validation

AMP-AD Knowledge Portal
Sage Bionetworks

Portal launched on March 4, 2015

Rapid and Broad Sharing of Data

Icahn School of Medicine

NY Stem Cell Foundation

Broad Institute

Rush University

Emory University

UCLA

U Florida ISB

Mayo Clinic

Biomarkers Project



Laurie Ryan

tau PET imaging
novel fluid biomarkers



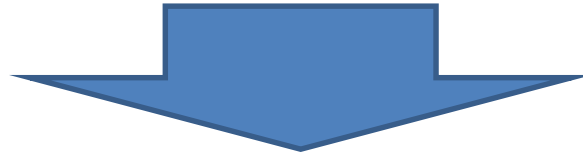
A4 DIAN API-ApoE4

Secondary Prevention Trials
anti-amyloid treatment





RFA AG13-013: Interdisciplinary Approach to the Identification and Validation of Novel Therapeutic Targets for AD



AMP – AD Target Discovery Consortium

Precompetitive Public Private Partnership

Government - Industry - Foundations

- A consortium of 4 multi-PI projects applying cutting edge systems and network biology approaches to integrate multidimensional human “omic” data (genomic, epigenomic, RNAseq, proteomic) from ~2,500 brains with clinical and pathological data, to discover, select and characterize novel therapeutic targets for AD and begin building predictive models.
- Rapid and broad sharing of data and analytical and research tools before publication.
- Data sharing and integration activities are coordinated by Sage Bionetworks through the collaborative data platform, [Synapse](#), an IRB approved environment where data can be stored, accessed and collaboratively analyzed.
- **AMP-AD Knowledge Portal (hosted on Synapse) launched and first wave of data released on March 4, 2015**

Integrated Network Analysis for Target Discovery and Validation

NIA U01 grants:

Pathway discovery, validation and compound identification for Alzheimer's disease*

Phil De Jager (Contact PI) *Broad Institute*

David Bennett *Rush University*

Integrative Biology Approach to Complexity of Alzheimer's Disease*

Eric Schadt (Contact PI) *Icahn Institute for Multiscale Biology at Mount Sinai & Dept of Genetics and Genomics Sciences*

A System Approach to Targeting Innate Immunity in AD*

Todd Golde (Contact PI) – *University of Florida*

Nathan Price – *Institute for Systems Biology, Seattle*

Nulifer Ertiken-Taner and Steven Younkin – *Mayo Clinic Jacksonville*

Discovery of Novel Proteomic Targets for Treatment of Alzheimer's Disease*

Allan Levey (Contact PI) *Emory University*

Administrative Supplements for Data Enablement and Data Integration

Lara Mangravite and Stephen Friend – *Sage Bionetworks*

Biomarkers for Treatment Responsiveness and Disease Progression

- A consortium of 3 NIA supported Phase II/III secondary prevention trials testing several anti-amyloid therapies. Through the AMP-AD partnership the imaging and fluid biomarker panels already included in these trials will be supplemented with tau PET imaging and novel fluid biomarkers.
- The goal is to explore the utility of tau imaging and novel fluid biomarkers for tracking responsiveness to treatment and/or disease progression.
- Baseline data from the trials will be made broadly available through the Alzheimer Association's GAAIN collaborative platform.

Biomarkers for Treatment Responsiveness and Disease Progression

NIA Clinical Trial Grants:

Alzheimer's Disease Cooperative Study (ADCS) Anti-Amyloid treatment in Asymptomatic AD Trial (A4 Trial)

ADCS, Reisa Sperling - Harvard Medical School

Dominantly Inherited Alzheimer Network (DIAN) Trial

Randall Bateman - Washington University

Alzheimer's Prevention Initiative APOE4 Trial (API APOE)

Eric Reiman , Pierre Tariot - Banner Institute

AMP-AD Biomarker Project: Trial Updates

As of February 17, 2015:

- For API APOE4 study preparation is ongoing with the goal of enrolling the first participant by the end of the third quarter of 2015
- DIAN-TU:
 - 115 participants screened
 - 70 participants randomized
- A4 Trial:
 - 992 participants screened
 - 57 participants randomized

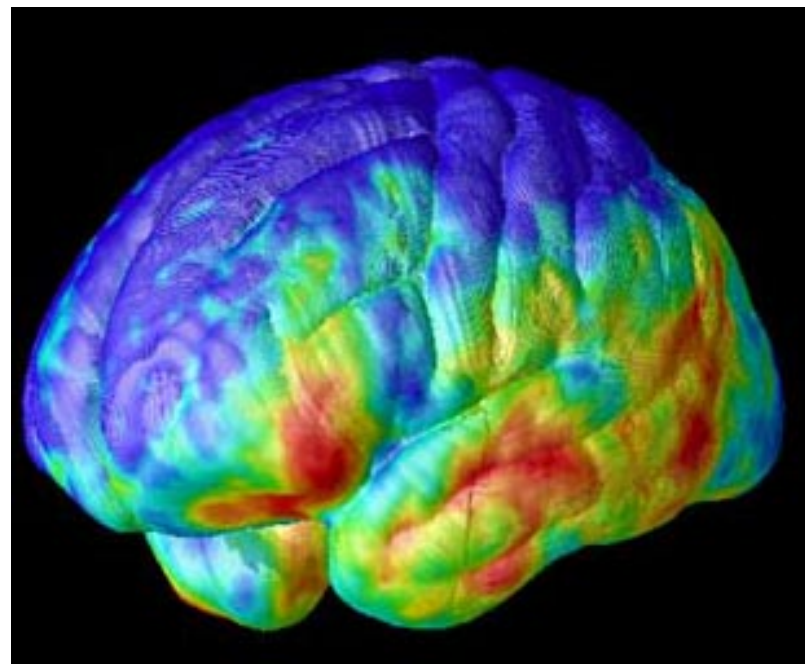
Alzheimer's Disease Research Summit 2015

- **February 9-10, 2015**

National Institutes of Health

U.S. Department of Health & Human Services

Bethesda, MD



Summit Agenda

- *NAPA Research Milestones: Process and Progress*
- *Plenary Lecture(s):*
 - Socioeconomic Burden of AD: Update on National and International Trends
 - Socioeconomic Burden of AD: Global Trends with a Focus on Developing and Under-Developed Countries
 - Deconstructing the Complexity of AD
- *Session I: Interdisciplinary Research to Understand the Heterogeneity and Multifactorial Etiology of AD*
- *Session II: Transforming AD Therapy Development: from Targets to Trials*
- *Session III: New Strategies for Prevention*
- *Session IV: Innovating disease monitoring, assessment and care*
- *Session V: Empowering Patients, Engaging Citizens*
- *Session VI: Enabling Partnerships for Open Innovation*