

NIA Update

ADC Directors' Meeting

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NIH/NIA Congressional & Budget Updates



Public Law 113-76, 2014 Consolidated Appropriations Act



- Provides \$1 billion increase for NIH over the post-sequester funding level of FY2013
- Additional funds for NIA research - \$130 million more than last year, including a focus on Alzheimer's disease.

NIA Appropriations FY 2004-2014

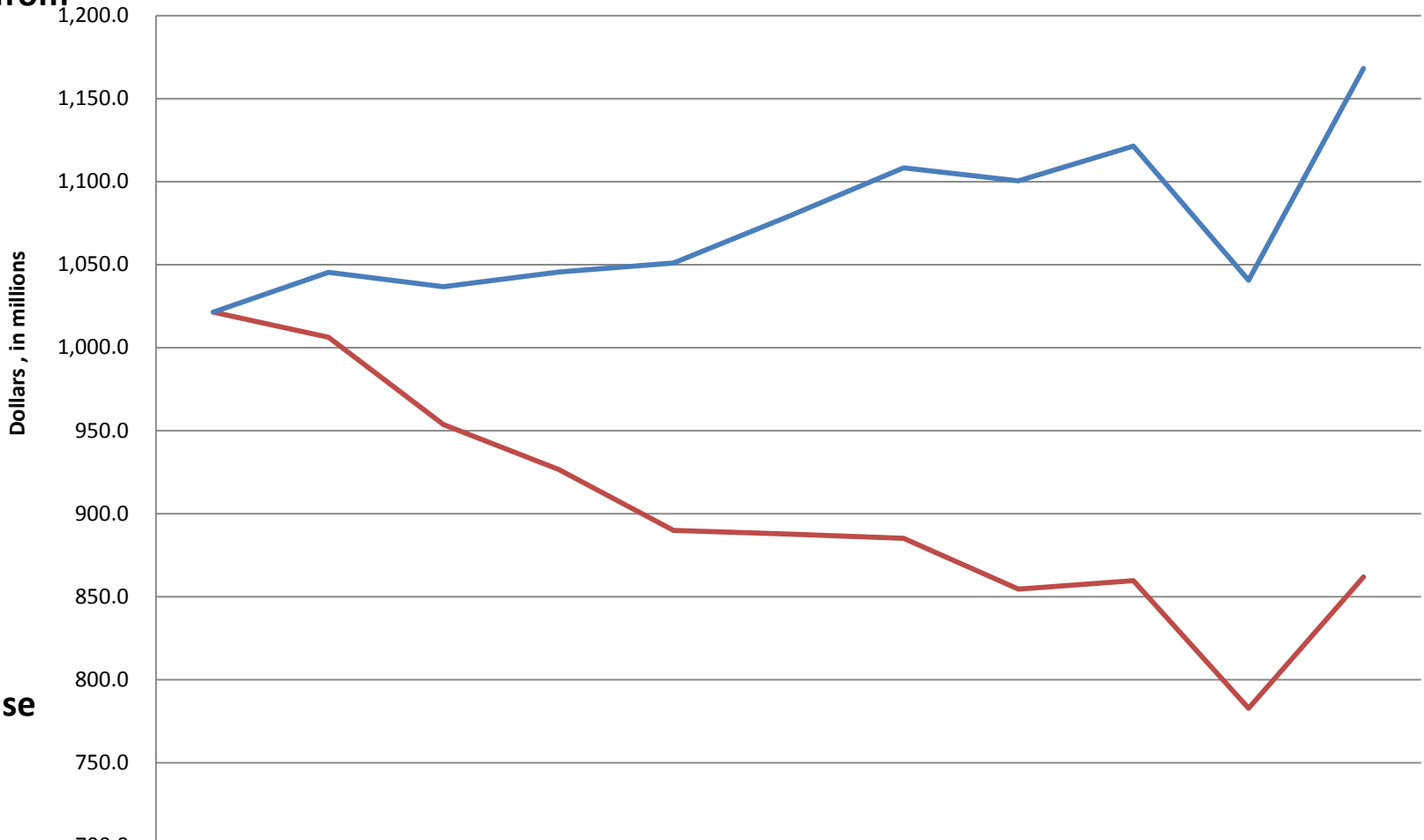
Current versus Constant, FY04 Base Year

**Difference from
FY2004**

**In Current
Dollars:
\$146.7M
Increase**

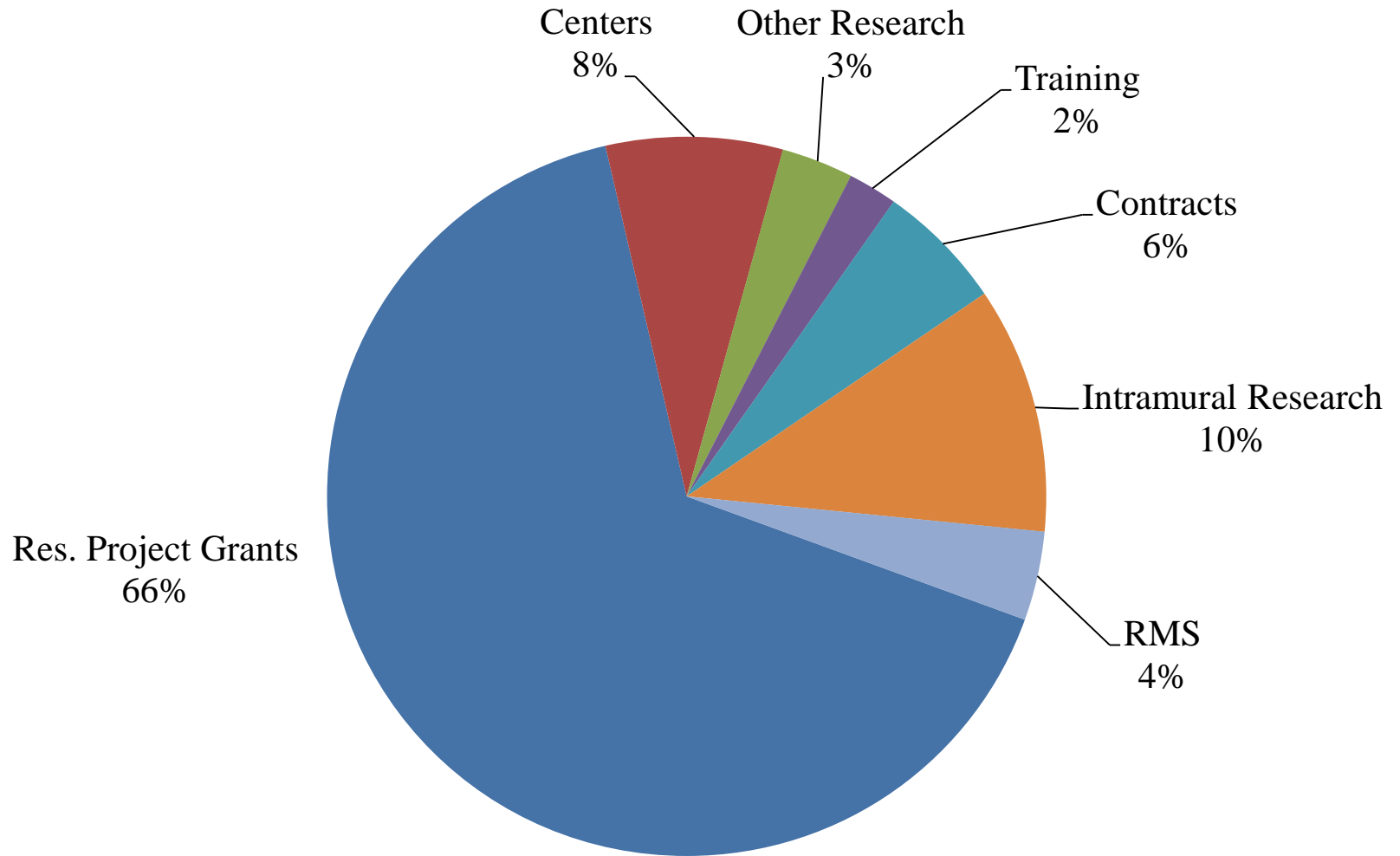
**In Constant
Dollars:
\$159.5M
Decrease**

**16% decrease
FY04-FY14**



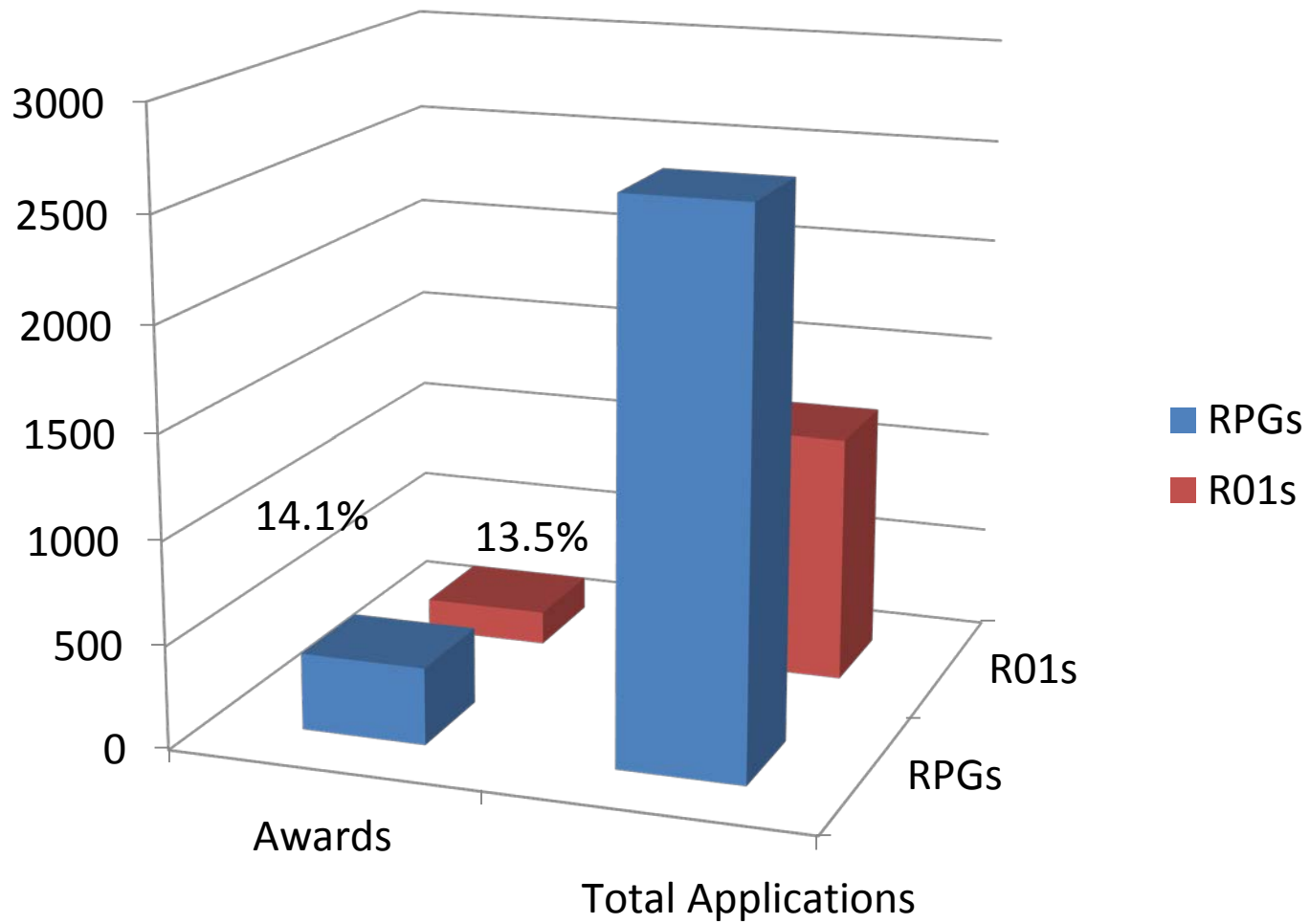
	04	05	06	07	08	09	10	11	12	13	14
Constant	1,021.4	1,006.2	953.6	926.7	889.9	887.6	885.2	854.5	859.6	782.8	861.9
Actual	1,021.4	1,045.3	1,036.6	1,045.5	1,051.0	1,079.0	1,108.2	1,100.4	1,121.3	1,040.6	1,168.1

Distribution of Obligations by Budget Category Fiscal Year 2013

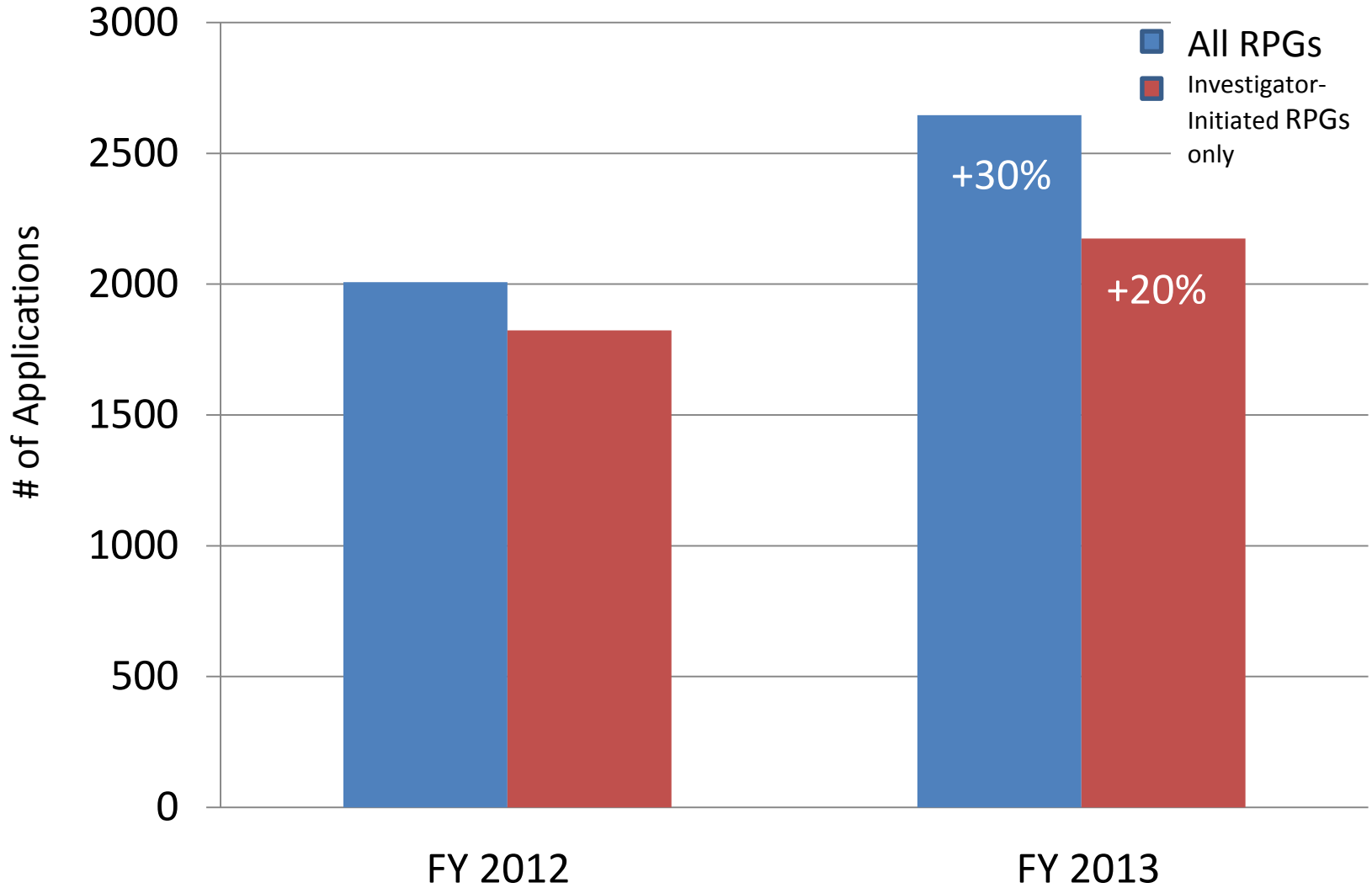


Total NIA: \$1,040,634,000

NIA SUCCESS RATE FOR FY 2013



RPGs APPLICATIONS FOR FY 2012 & FY 2013



New Funding Policy Changes

- 11th percentile funding line for most applications (for the fourth year in a row).
- Elimination of cuts to Type 5 awards beyond those made in earlier years.
- Available five point advantage for early-stage investigator R01 applications (and three points for other new investigators).

NIA RPG Percentile Paylines 2014

	<\$500K	≥\$500K
Established P.I.	11	8
Early Stage P.I. (R01 only)	16	13
Other New P.I. (R01 only)	14	11

Important Changes to Grant Resubmission Policy

- In 2009, the NIH changed its resubmission policy, from allowing two resubmission applications to one (an “A1” submission). If the A1 was not funded, any further applications had to be substantially different in content and scope in order to be eligible for submission as a “new” application.
- Following receipt of feedback from both new and established investigators, the NIH revised its policy effective April 17th, 2014:
 - After an unsuccessful (A1) submission, A “new” application will be considered *without* an association to a previous submission; i.e., the applicant no longer has to discuss how the application has changed or respond to previous reviews.
 - NIH still expects that applicants will nevertheless take advantage of previous reviewers’ comments to strengthen the applications for each submission.
 - NIH's policy for accepting overlapping applications remains in effect; i.e., NIH will not accept duplicate or highly overlapping applications *under review at the same time*.

Approach to FY14 Alzheimer's Disease Funding

- Funding high priority initiatives
- Funding high priority investigator-initiated projects that could not otherwise be supported.
- Aligning with priorities from NAPA and the AD Summit.
- Balance competing and non-competing funds

New NIA Alzheimer's Research Initiatives

- RFA-AG-14-012: Human Cell Reprogramming for Functional Genetics of Alzheimer's Disease (R01)
- RFA-AG-14-002: Optogenetic Tools for the Study of Neural Systems in Aging and Alzheimer's Disease (R01)
- PAR-12-183: National Institute on Aging Analysis of Alzheimer's Disease Genome Sequencing Project Data [U19](with new expiration date of January 1, 2015)
- Funding Opportunity Announcement for Planning Grants for Alzheimer's Disease Translational Centers for Predictive Drug Development:
<http://grants.nih.gov/grants/guide/rfa-files/RFA-AG-14-017.html>

Alzheimer's Disease Sequencing Project (ADSP)

National Alzheimer's Project Act – Treat/Prevent AD by 2025

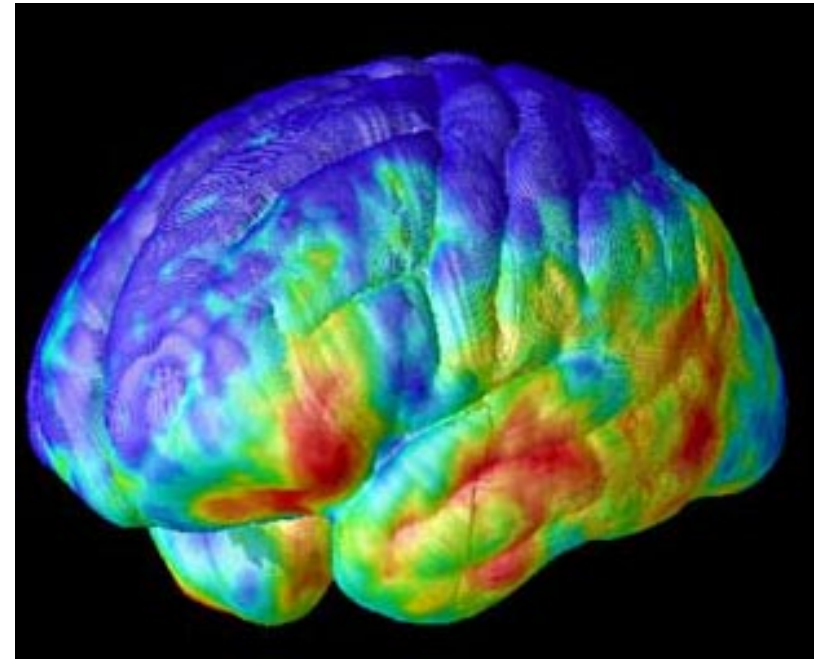
- NIA and NHGRI conducted a large scale sequencing project to identify AD risk and protective gene variants and to facilitate identification of new pathways for therapeutic approaches and prevention

Data Release Dates to Qualified Investigators:

- Whole genome sequence (WGS) data (582 subjects in 111 families) – complete March 2014
- Whole exome sequence data (5,000 cases and 5,000 controls) and from 1,000 additional cases - summer 2014

SAVE THE DATE

**Alzheimer's Disease
Research Summit 2015**



February 9-10, 2015

National Institutes of Health

U.S. Department of Health & Human Services

Bethesda, MD

Improving Grants Management & Review

- Maximizing efficiencies of core facilities
 - Integrating core facilities across NIH and finding efficiencies
- Analysis of Review Group Outputs (ARGO)
 - Using research tools to create a more dynamic structure for peer review that responds to changing trends in science
- Enhancing the NIH biosketch
 - Past performance of an applicant is often considered an important indicator of future success (during review)
 - The current biosketch format may rely too much on the impact factor of journals in which applicant has published
 - NIH seeks to better emphasize the applicant's actual contribution (including his/her role in past work) instead of the applicant's academic and research pedigree

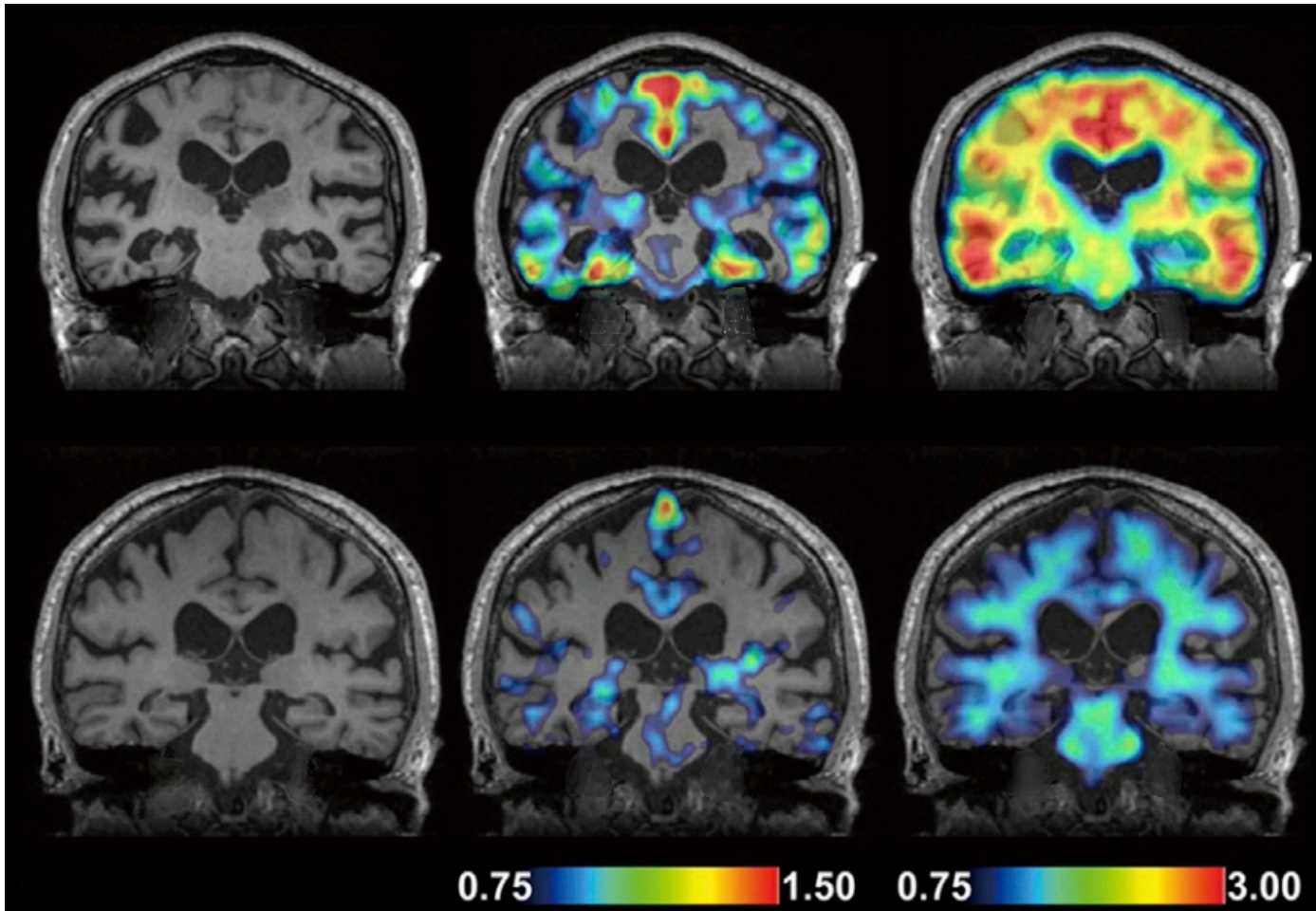
Diagnosing AD: Present and Future

MRI –structure

Tau

Amyloid

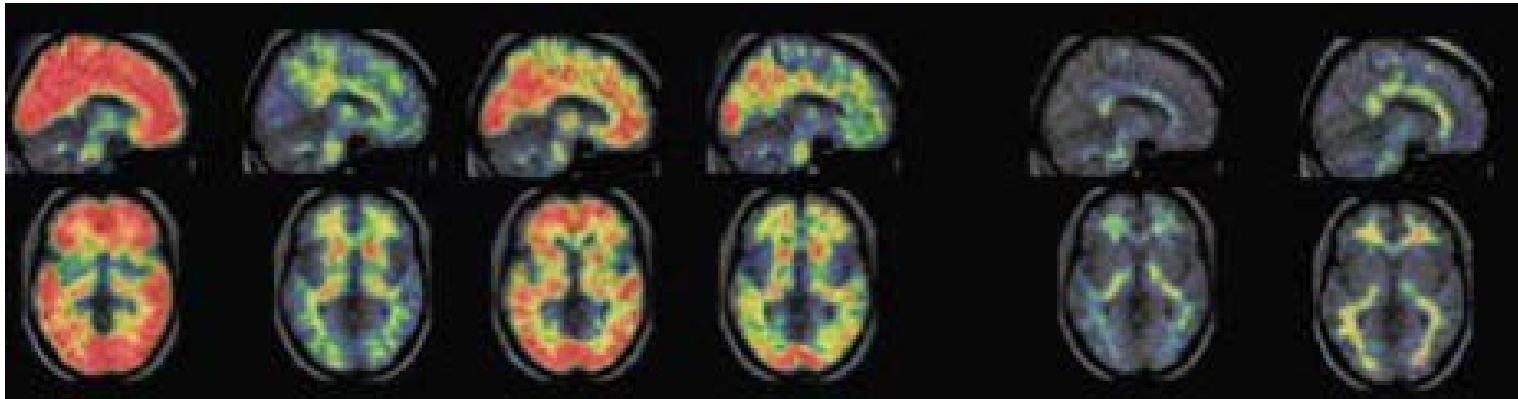
Alzheimer's
disease



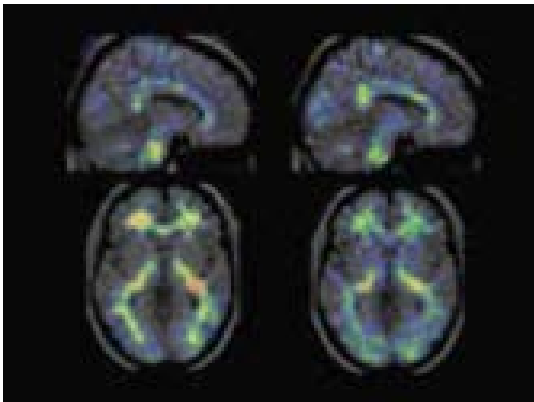
Amyloid PET Scans in *Presymptomatic* Early-Onset Alzheimer's Disease

Gene Carriers

Non-Carriers



Age 35-39 Years



Age 25-29 Years

Colombian Kindred

- N = 5000 living individuals from ~ 25 families
- 1500 with the *E280A (Glu280Ala) Presenilin1* mutation
- Autosomal dominant, 100% penetrance
- Median age of MCI = 44 years, dementia = 49 years

Double-blind, placebo-controlled trial for up to 60 months
- crenezumab 300 mg SC every 2 weeks

Accelerating Medicines Partnership (AMP)

www.nih.gov/amp

- Aims to distinguish targets of disease most likely to respond to new therapies
- 10 biopharma firms; several nonprofits

Government	Industry	Non-Profit Organizations
FDA	AbbVie	Alzheimer's Association
NIH	Biogen Idec	American Diabetes Association
	Bristol-Myers Squibb	Foundation for the NIH
	GlaxoSmithKline	Geoffrey Beene Foundation
	Johnson & Johnson	Lupus Foundation of America
	Lilly	Lupus Research Institute / Alliance for Lupus Research
	Merck	PhRMA
	Pfizer	Rheumatology Research Foundation
	Sanofi	
	Takeda	USAgainstAlzheimer's

aring

es best-

jects:

systemic

AMP

Alzheimer's Disease Scientific Design

- **Identification of theragnostic biomarkers that predict clinical outcomes:**
 - **Project A** will develop AD biomarkers and help qualify them for use in registration trials, to reduce the number of research participants and time it takes to evaluate and secure approval for promising therapeutic interventions.
- **Integrated network analysis in Alzheimer's disease brain tissue:**
 - **Project B** will expand the application of integrated network analysis (both RNA and proteomic studies) in human AD brain samples to identify biologic nodes and networks that are linked to the development or progression of AD.

AMP AD timeline

