Alzheimer's Disease and AD Related Dementias Research: Policy and Program Updates

2020 Spring ADRC Meeting
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May 1, 2020

NIH's Response to the COVID-19 Crisis: Funding Opportunities

- Across NIH, special funding announcements known as **Notices of Special Interest (NOSIs)** have been generated in response to the COVID-19 crisis. These NOSIs encompass:
  - **Administrative supplements** to existing grants
  - **Urgent revisions** and **emergency revisions** to existing grants
- The full list is available here: https://grants.nih.gov/policy/natural-disasters/corona-virus.htm.
- **The goal is to expedite review of applications and distribution of funds to assist in COVID-19 research.**
- **One example is NIA's NOSI:**

Notice of Special Interest (NOSI): NIA Availability of Administrative Supplements and Revision Supplements on Coronavirus Disease 2019 (COVID-19)

Notice Number: NOT-AG-20-022

Key Dates

Release Date: April 2, 2020
First Available Due Date: April 06, 2020
Expiration Date: May 01, 2021

https://grants.nih.gov/grants/guide/notice-files/NOT-AG-20-022.html

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Appropriations

FY 2020 Budget: Funding Increases Across the Board

$41.7 Billion for NIH

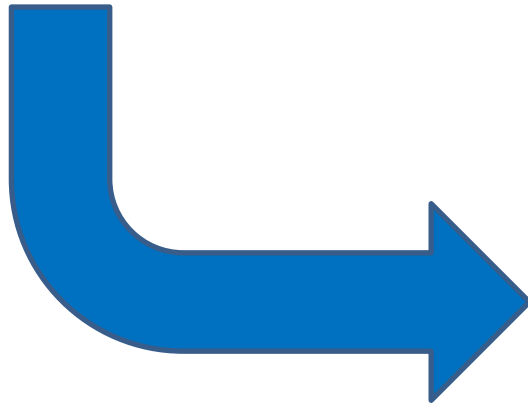→ **$500M for All of Us**
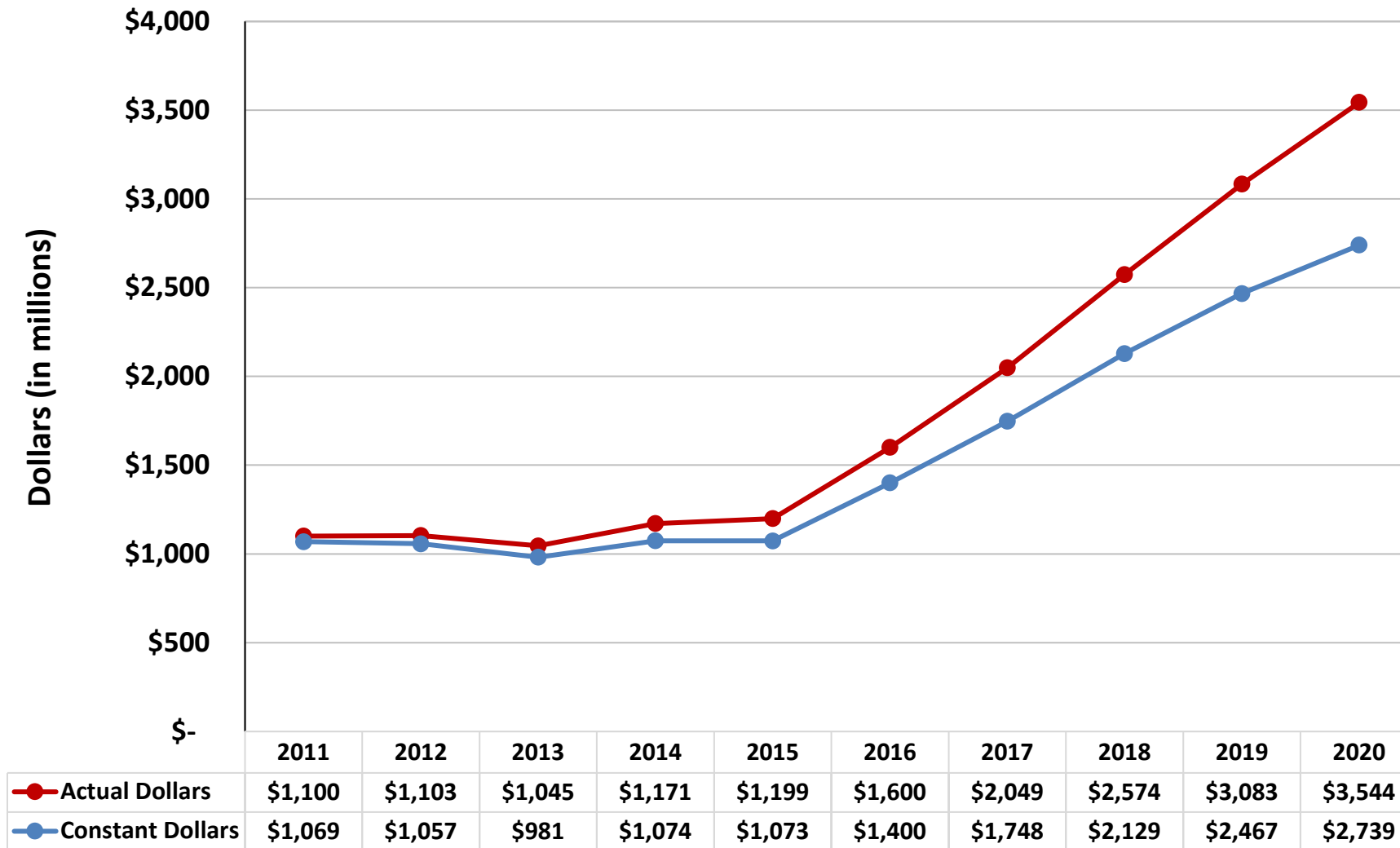
→ **$500M for BRAIN**

→ **$60M for Down Syndrome**

→ **$350M increase for AD/ADRD ($2.8B total)**

- **$3.54B for NIA**
- $110.3M increase for non-targeted NIA research
- **All divisions will benefit:**
  - DBSR
  - DGCG
  - DAB
  - DN

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NIA Appropriations
Fiscal Years 2011-2020

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Actual Dollars	$1,100	$1,103	$1,045	$1,171	$1,199	$1,600	$2,049	$2,574	$3,083	$3,544
Constant Dollars	$1,069	$1,057	$981	$1,074	$1,073	$1,400	$1,748	$2,129	$2,467	$2,739

Appropriations Budget Growth since FY 2011-2020
Actual Dollars: +$2,443.2M (222.0%)   Constant Dollars: +$1,670.7M (156.4%)

NIA AD/ADRD Appropriations

2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
National Alzheimer's Project Act (NAPA)	**$50 M*** redirected within NIH budget	**$40 M*** redirected within NIH budget	**$100 M** additional approp.	**$25 M** additional approp.	**$350 M** additional approp.	**$400 M** additional approp.	**$414 M** additional approp.	**$425 M** additional approp.	

$350M in additional appropriations as of 12/20/19

*One-year money
Years displayed are fiscal years

Policy Updates and Spending

Initial Allocations for Competing Research Grant Awards, FY 2020

CSR-Reviewed Research Applications			
	General Pay Line, <$500k	**General Pay Line, =>$500k**	**AD/ADRD Pay Line**
All applications except as noted below	11%	8%	28%
N.I. R01s	14%	11%	31%
E.S.I. R01s	16%	13%	33%

New Investigator (N.I.): An applicant who has not received a prior R01 award or its equivalent.
Early-Stage Investigator (E.S.I.): A new investigator who is within 10 years of finishing research training.
First-time Renewing: A former N.I. or E.S.I.'s first renewal application when the investigator has no other NIH grant support.
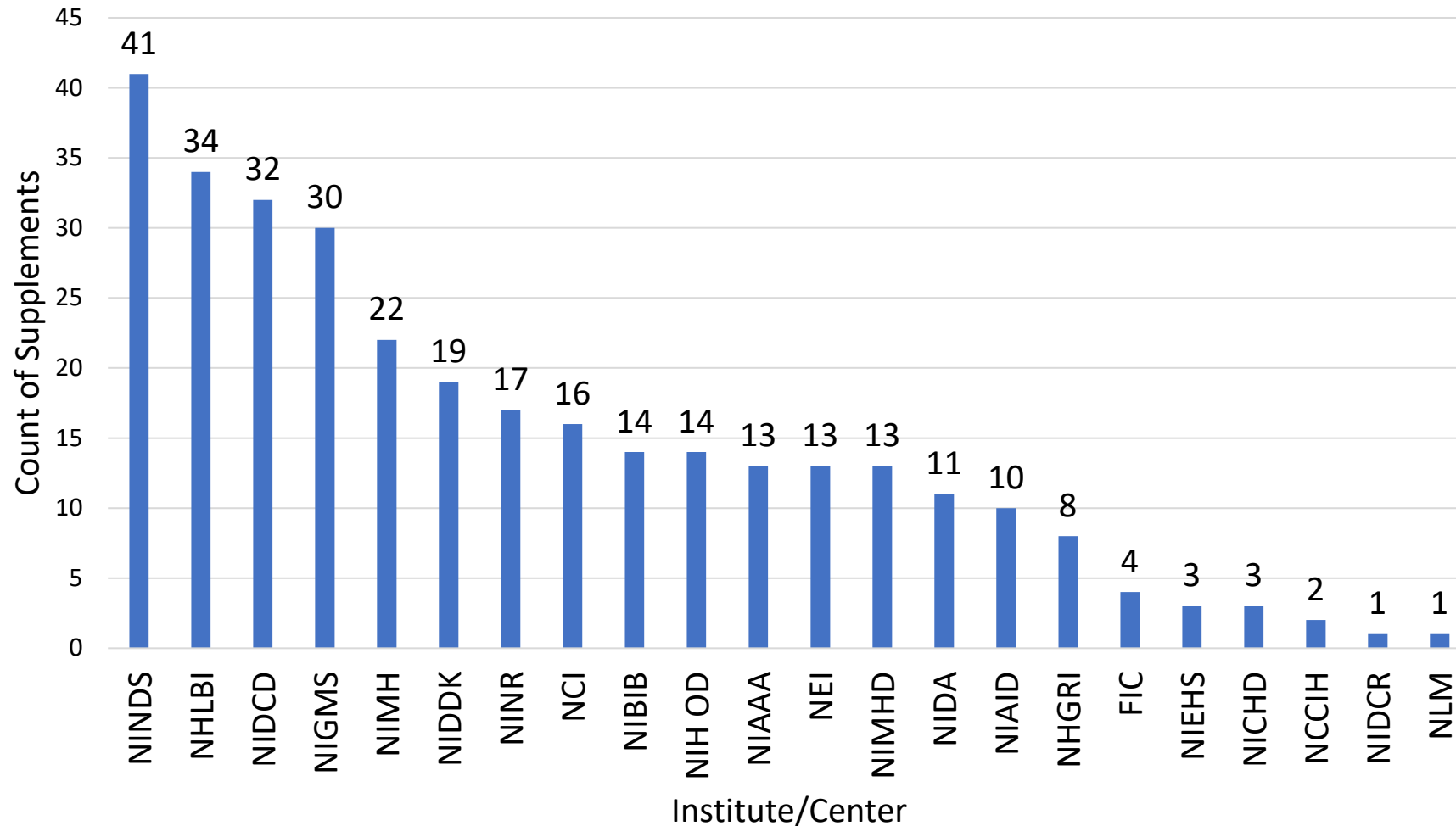*ADRD: Research on Alzheimer's disease and Alzheimer's-related dementias*
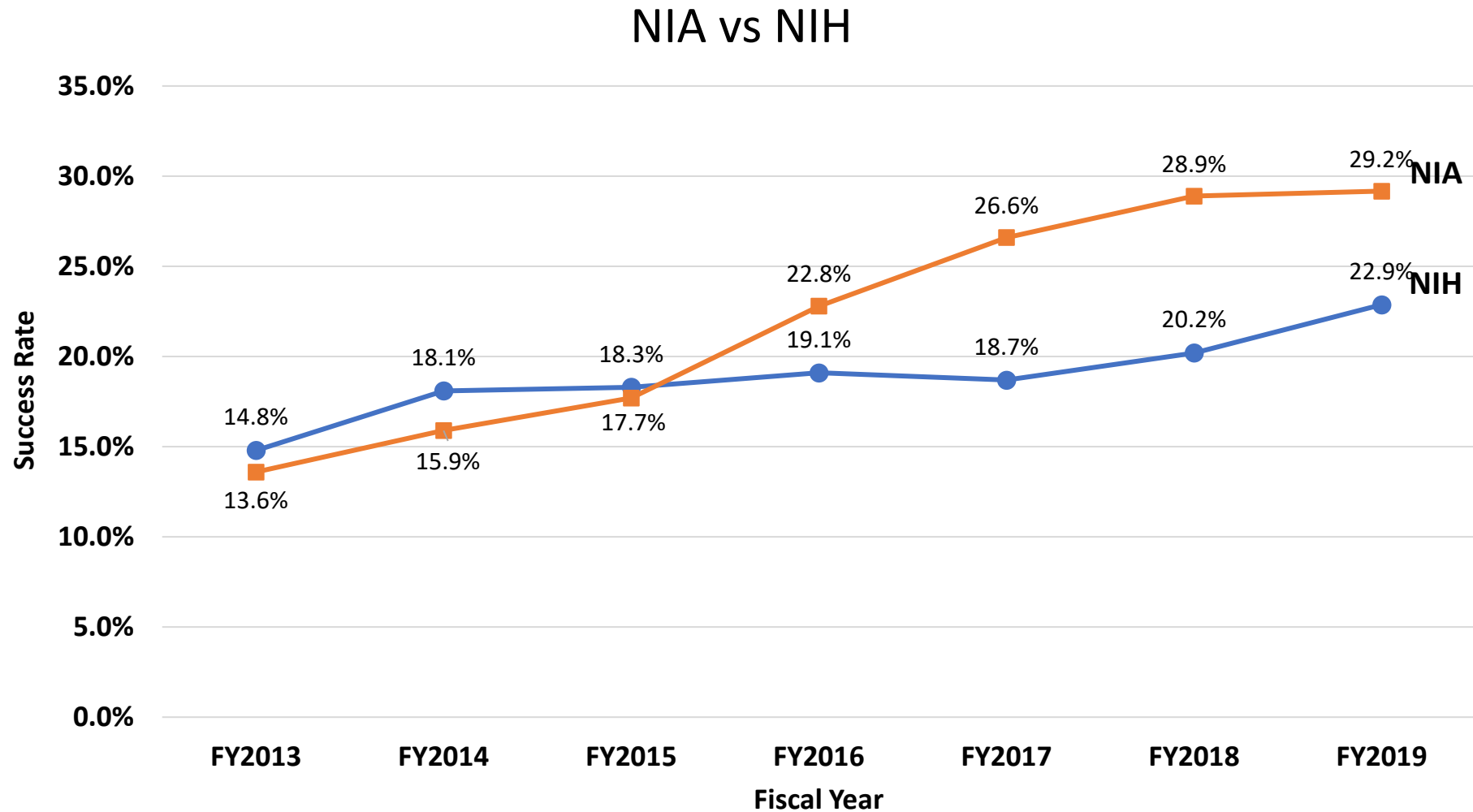
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FY 2020 Pay Lines

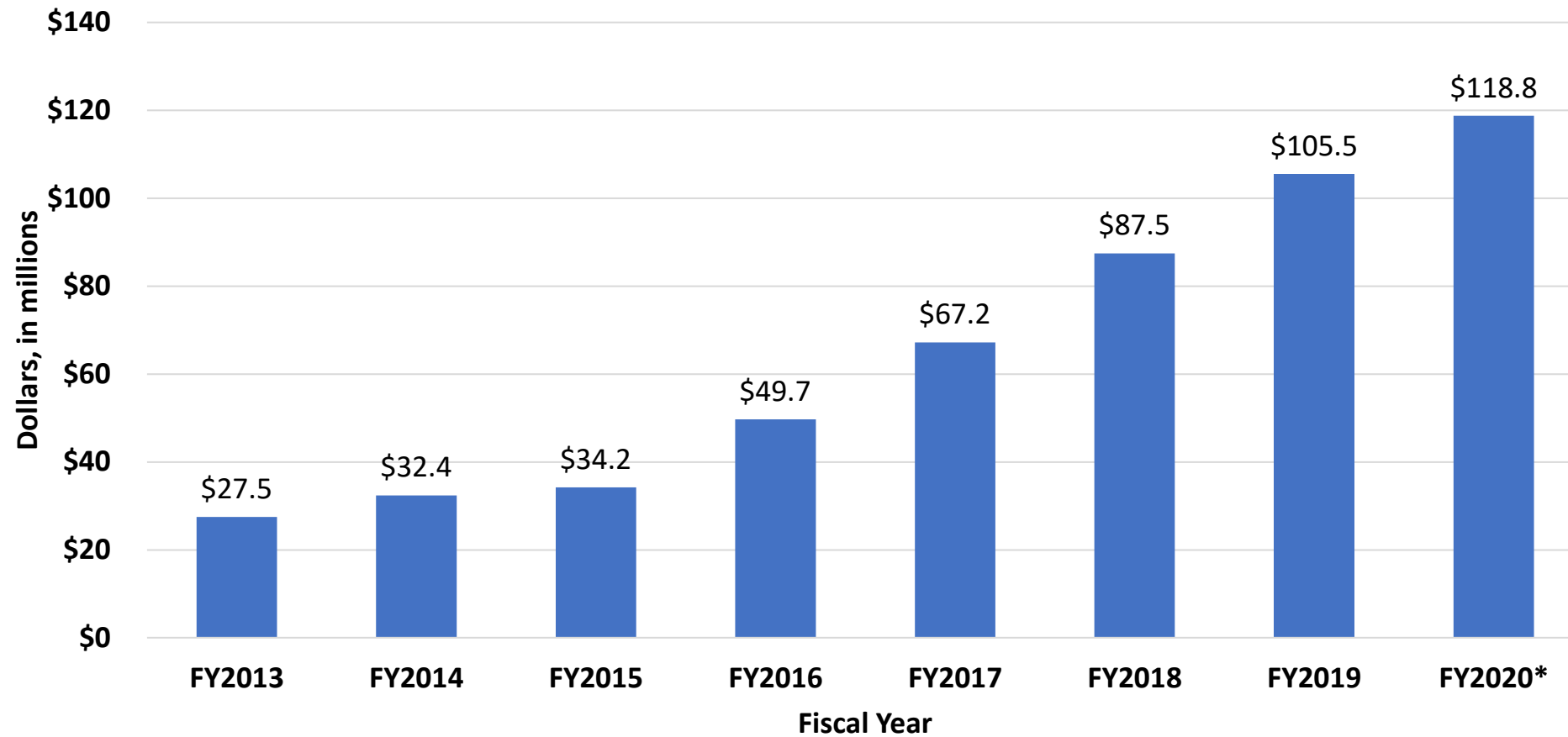| NIA-Reviewed Applications		
	General Pay Line	**AD/ADRD Pay Line**
Program projects (PO1)	20	40
Other NIA-reviewed research	20	40
Career awards	21	28

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FY19 AD/ADRD Supplements by Institute/Center
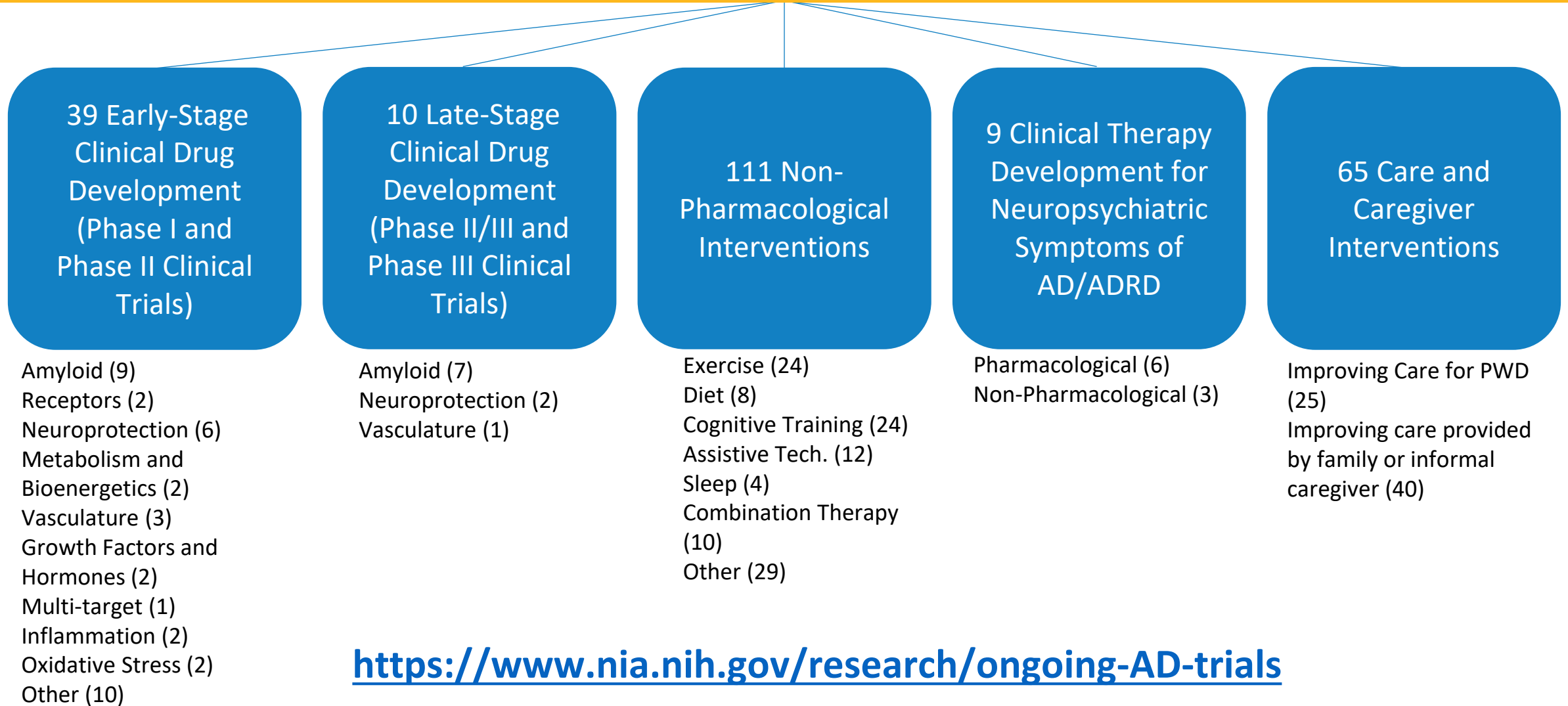
RPG Success Rates Over Time

NIA vs NIH

NIA SBIR/STTR Spending
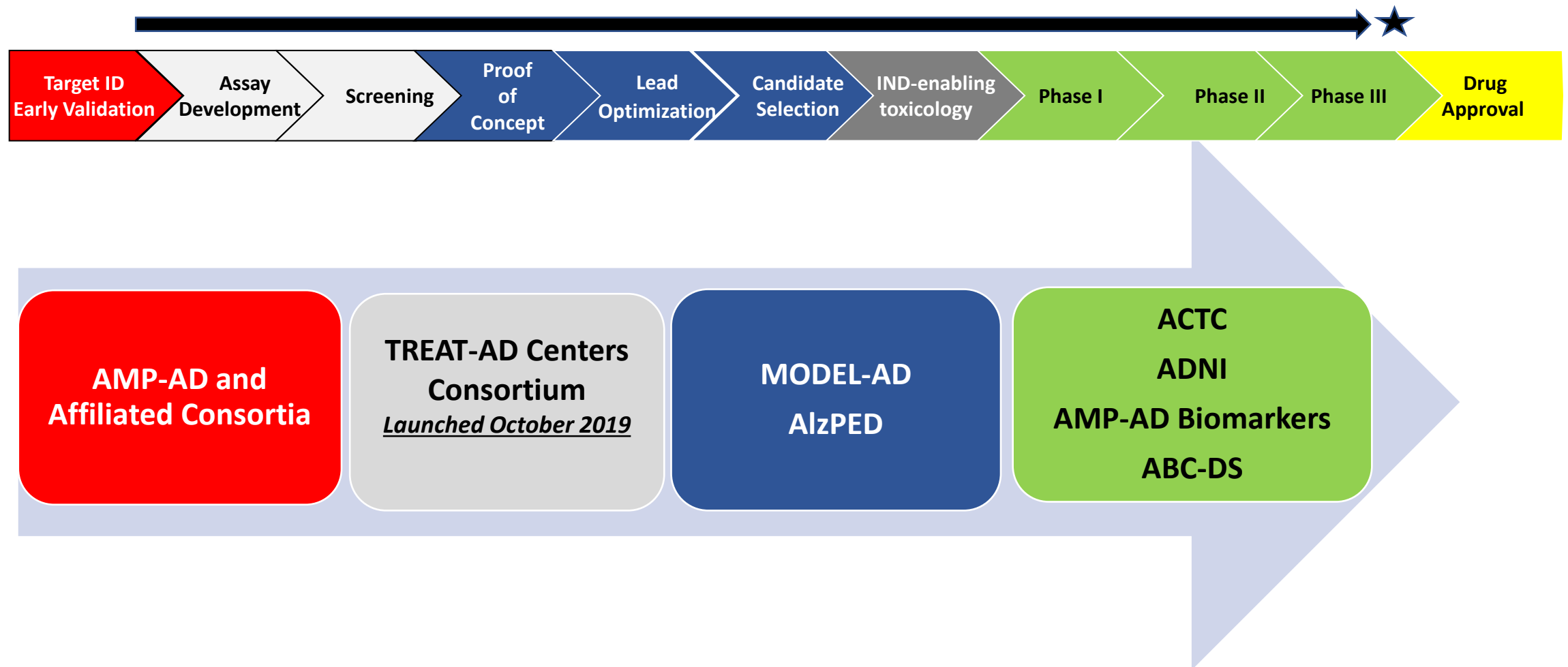

*FY2020 NIA SBIR/STTR Target as of 2/6/20

NIA Updates

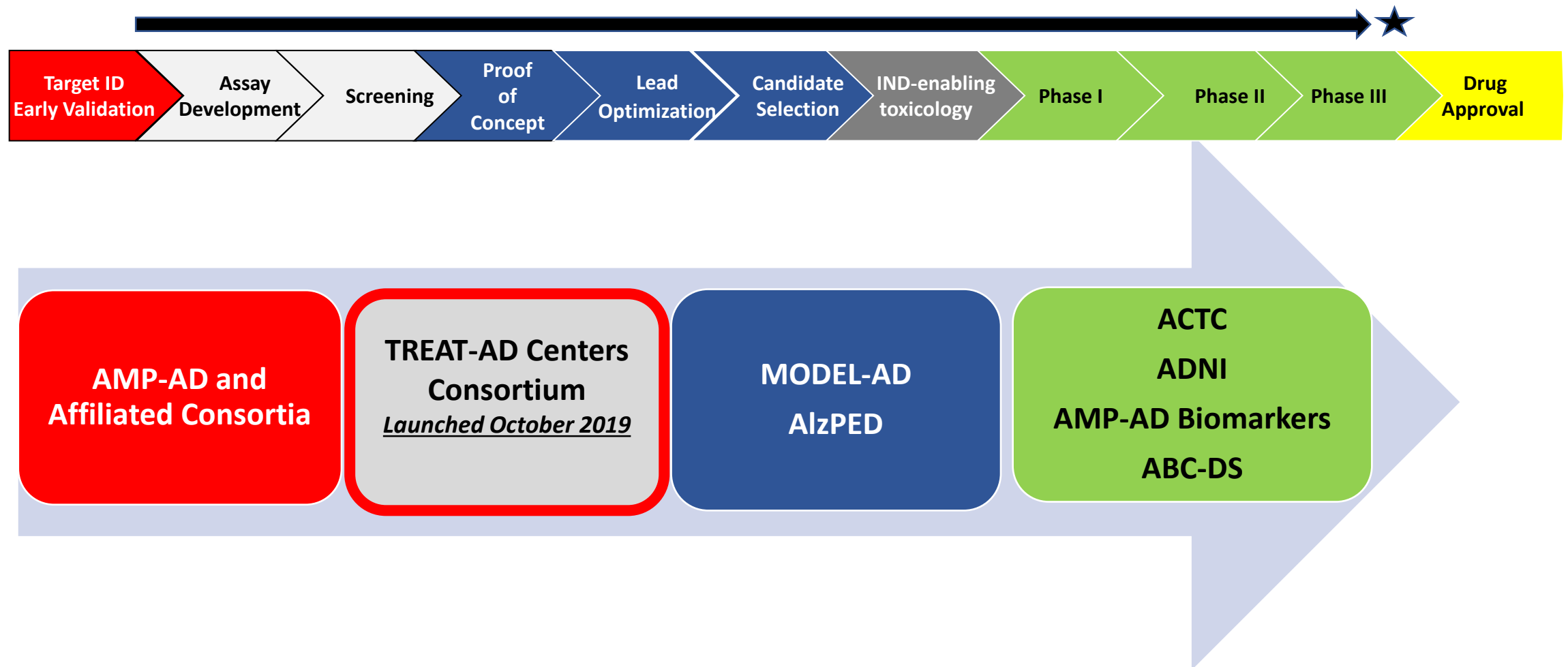# Active NIA AD/ADRD and Related Intervention and Prevention Trials (~230)

39 Early-Stage Clinical Drug Development (Phase I and Phase II Clinical Trials)

Amyloid (9)
Receptors (2)
Neuroprotection (6)
Metabolism and Bioenergetics (2)
Vasculature (3)
Growth Factors and Hormones (2)
Multi-target (1)
Inflammation (2)
Oxidative Stress (2)
Other (10)

10 Late-Stage Clinical Drug Development (Phase II/III and Phase III Clinical Trials)

Amyloid (7)
Neuroprotection (2)
Vasculature (1)

111 Non-Pharmacological Interventions

Exercise (24)
Diet (8)
Cognitive Training (24)
Assistive Tech. (12)
Sleep (4)
Combination Therapy (10)
Other (29)

9 Clinical Therapy Development for Neuropsychiatric Symptoms of AD/ADRD

Pharmacological (6)
Non-Pharmacological (3)

65 Care and Caregiver Interventions

Improving Care for PWD (25)
Improving care provided by family or informal caregiver (40)

https://www.nia.nih.gov/research/ongoing-AD-trials

NIA AD Translational Research Program: Diversifying the Therapeutic Pipeline

Multiple funding mechanisms support each step of the drug development process

| Target ID Early Validation | Assay Development | Screening | Proof of Concept | Lead Optimization | Candidate Selection | IND-enabling toxicology | Phase I | Phase II | Phase III | Drug Approval |

AMP-AD and Affiliated Consortia

TREAT-AD Centers Consortium
Launched October 2019

MODEL-AD
AlzPED

ACTC
ADNI
AMP-AD Biomarkers
ABC-DS

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Alzheimer Centers for the Discovery of New Medicines

- Two new research centers with funding expected to total more than $73 million.

- Designed to diversify and reinvigorate the Alzheimer's disease drug development pipeline.

- Will provide added infrastructure for developing high-quality research tools and technologies needed to validate and advance the next generation of drug targets.

https://www.nia.nih.gov/news/nih-funded-translational-research-centers-speed-diversify-alzheimers-drug-discovery

NIA Launches a Data Sharing Landing Page!

Data Sharing Resources for Researchers

There are a variety of data sharing policies, considerations, resources, and guidance available to support researchers in safely and efficiently sharing data from their studies. NIA also provides data resources to the Alzheimer's and aging research community.

To learn more about data sharing at NIH, see the NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources and the NIH Data Sharing FAQs,

https://www.nia.nih.gov/research/data-sharing-resources-researchers

https://www.nia.nih.gov/research/grants-funding/nia-specific-funding-policies#datasharing

AHRQ-National Academies Study on Dementia Care & Caregiving

- **Two parts:**
  - **Agency for Healthcare Research & Quality (AHRQ)**
    https://effectivehealthcare.ahrq.gov/products/care-interventions-pwd

  - **National Academies of Sciences, Engineering, and Medicine (NASEM)**
    https://www.nationalacademies.org/our-work/care-interventions-for-individuals-with-dementia-and-their-caregivers

- **Status:**
  - **AHRQ's Minnesota Evidence Based Practice Center** *released its draft evidence review on March 24, 2020*

  - **NASEM** *held a public workshop on April 15, 2020; an expert committee will deliberate recommendations for the NIH, expected in early 2021*

Implementation Tracking

AD+ADRD Research Implementation Milestones

Browse this database to learn more about research implementation plans and progress toward the goal of effectively treating and preventing Alzheimer's Disease (AD) and Alzheimer's Disease-Related Dementias (ADRD) by 2025.

150+ AD & ADRD Strategic Implementation Milestones

Across **15+** Research Implementation Areas organized under 8 Focus Areas (below)

Informed by recommendations from **350+** leading academic & industry experts, and public advocates

Participating at **6+** strategic research planning summits

https://www.nia.nih.gov/research/milestones

Alzheimer's Disease Research Implementation Milestones (number of milestones)	Milestone Implementation Status		
	Completed	In progress	To be initiated
Population Studies and precision medicine (8)		7	1
Research on Disease Mechanisms (11)	5	6	
Data Sharing and Reproducibility (6)		5	1
Translational Infrastructure and Capabilities (15)	3	9	3
Drug Development - Existing Targets (3)		3	
Drug Development - Novel Targets (8)	3	4	1
Drug Repurposing and Combination Therapy Development (5)	2	2	1
Non-Pharmacologic Interventions (4)		1	3
Biomarkers (9)	5	4	
Trial Design (6)	2	2	2
Enabling Technologies and Disease Monitoring (7)	1	5	1
Recruitment and Citizen Engagement (10)	2	6	2
Research on Care and Caregiver Support (11)	0	11	
Public Private Partnerships (10)	3	3	4
Portfolio Analysis Tools and Methods (1)		1	0
Total (114 milestones)	**26**	**69**	**19**

Ways to Stay Informed and Connected

Search all active NIA funding opportunities: **https://www.nia.nih.gov/research/funding**

Review the latest approved concepts: **https://www.nia.nih.gov/approved-concepts**

Subscribe to our blog and stay up to date on the latest NIA news: **https://www.nia.nih.gov/research/blog**

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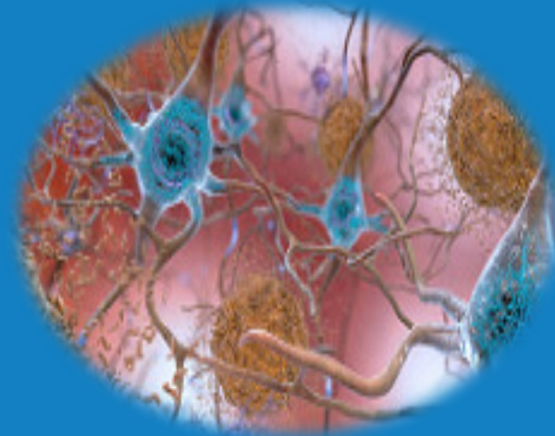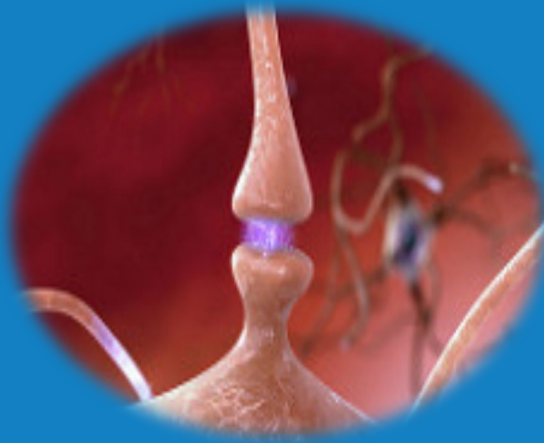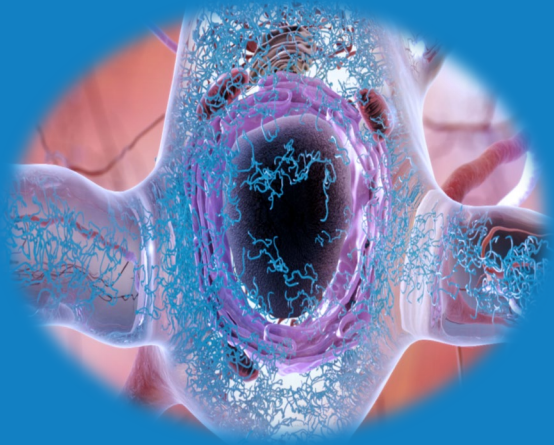
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