FDA APPROVAL OF ADUCANUMAB

• Aducanumab approved by FDA through accelerated approval pathway.

• FDA approved based on effectiveness of aducanumab in reducing amyloid plaques.

• Clinical trials limited to people diagnosed with mild cognitive impairment or early-stage Alzheimer’s.

• After initial broad indications, revised labeling to be consistent with testing

• Ultimately approved for Medicare coverage when utilized in a clinical trial
URGs more often experience missed or delayed diagnosis of dementia than Whites.

Proportion of missed or delayed diagnoses of dementia in claims data by race/ethnicity (yellow = missed/delayed)

LACK OF DIVERSITY OF STUDY POPULATION

In Biogen’s phase 3 trials, **89% of participants were White** and 9% were Asian.

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Source: November 6, 2020: Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee Meeting Announcement - 11/06/2020 - 11/06/2020 | FDA
LACK OF DIVERSITY OF STUDY POPULATION

In Biogen’s phase 3 trials, 89% of participants were White and 9% were Asian.

However, in the US population, Alzheimer’s prevalence differs by race and ethnicity.

WHY DIVERSITY MATTERS: MORE INCLUSIVE CLINICAL AND COMMUNITY-BASED RESEARCH

Increasing diversity in the scientific workforce is essential in the clinical research process to address the needs of underrepresented groups.

B/AA, Hispanic, and Native American physicians more likely than white physicians to practice in underserved communities (1).

Patients who have a choice are more likely to select health care professionals of their own racial or ethnic background (2).

Sources:


THE NEED FOR DIVERSE PERSPECTIVES IN SCIENCE

Published Monday, 3/20/23

The NIH UNITE Initiative

New Notices of Funding Opportunity

• Science Education Partnership Awards (SEPA) – 17 ICOs signed on
• Research With Activities Related to Diversity (ReWARD) (PAR-23-122)
• Instrumentation Grant Program for Resource-Limited Institutions (S10 - Clinical Trial Not Allowed) (PAR-23-138)

Concepts approved by NIGMS Council:
• Institutional Climate Assessment and DEI Action Plan Development Grants
• Research Capacity Building Program to Enhance Workforce Diversity.
New Notices of Funding Opportunity

*Concept approved by NIMHD Council:*

- Institutional Research Capacity Building Needs Assessment and Action Plan Development Grants
NIH Development of a Prize Competition for Institutional Excellence in Diversity, Equity, Inclusion, and Accessibility (DEIA)

• Transformative cultures, systems, projects, and processes
• Measurable change that led to a more inclusive environment
• Anticipate announcement of the competition early April 2023
CONTACT US

- Check out our website [diversity.nih.gov](https://diversity.nih.gov)
- Sign up for our [quarterly newsletter](#) and visit our [COSWD blog](#) for twice monthly updates
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