

PANEL DISCUSSION

Pharmaceutical Industry Perspectives on Expanding African American Enrollment in Clinical Trials

Michelle Papka, PhD

Michael Irizarry, MD MPH

Tony Pearson, JD MPH



CRCNJ

The Cognitive and Research Center
of New Jersey, LLC

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Format

- Introduction: Michelle Papka, PhD
- Pharma perspective:
 - Eisai: Michael Irizarry, MD MPH
 - Lilly: Tony Pearson, JD MPH

Why is important?

What are they doing about it?

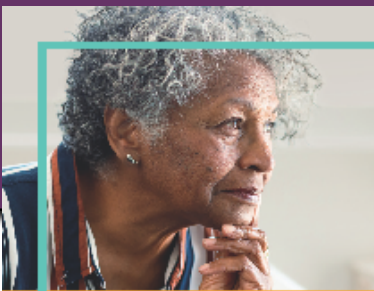
Impact of those Efforts

- Discussion: What else should we be doing?

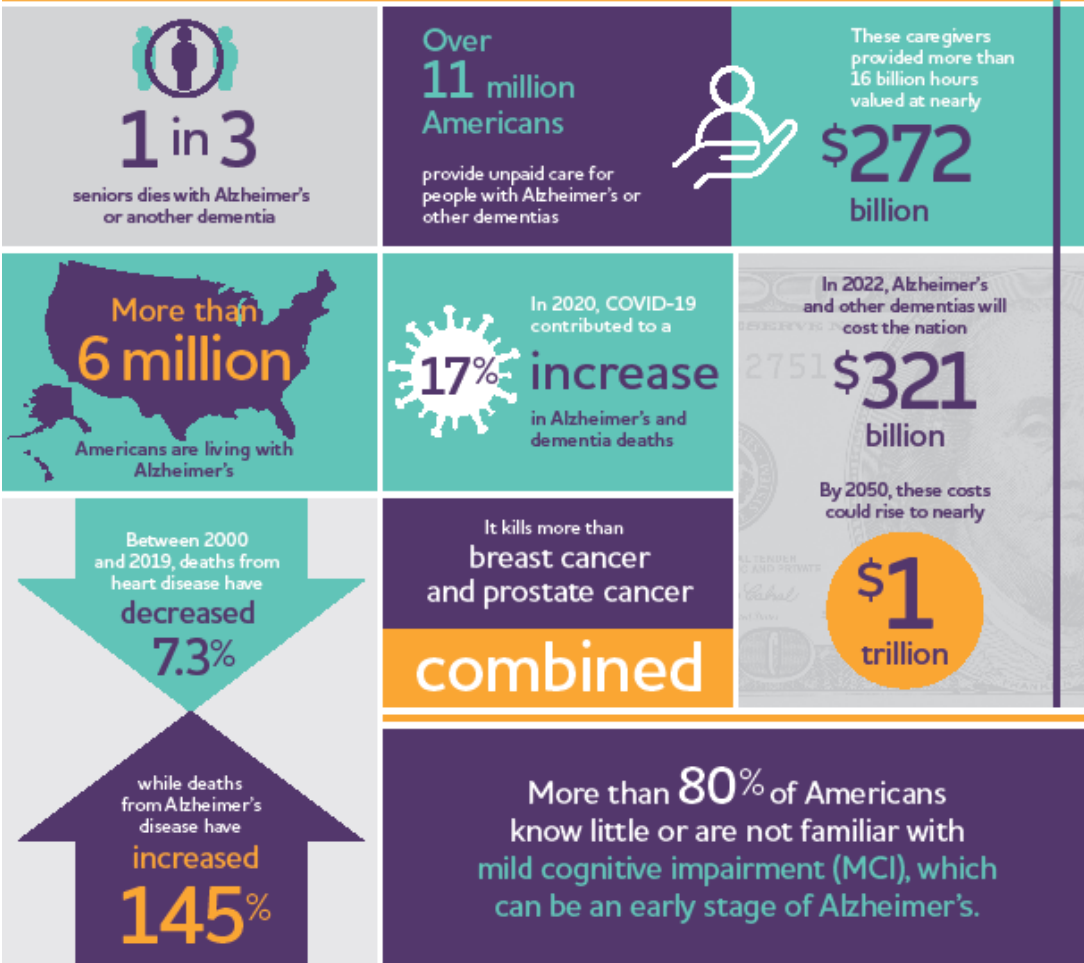


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2022 Alzheimer's Disease Facts and Figures



Focus on Black Americans:

- Twice as likely than older Whites to have Alzheimer's Disease
- 21.3% over the age of 70 are living with Alzheimer's
- Only 20% believe they have no barriers to excellent health care and support for AD/dementia
- 65% know somebody with Alzheimer's
- 55% think the significant cognitive decline is part of normal aging
- Disproportionate paid and unpaid caregiving costs

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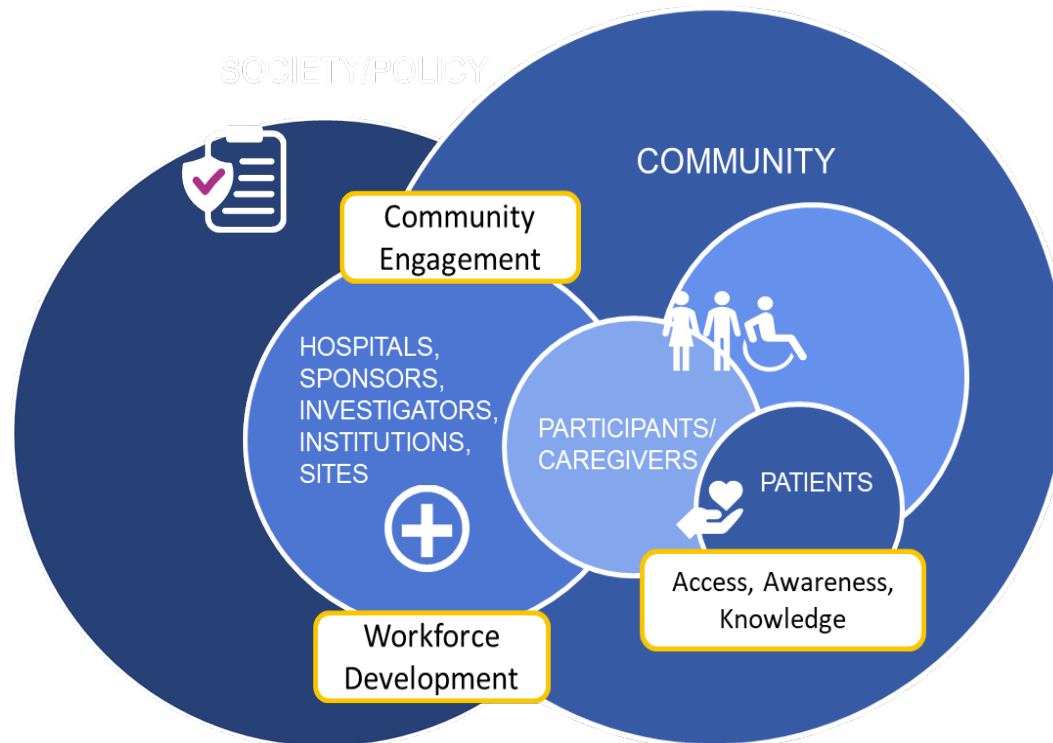
Reasons Cited By U.S. Adults for Not being Interested in Clinical Trial Participation

	White Americans	Hispanic Americans	Black Americans	Asian Americans	Native Americans
Don't want to be a guinea pig	49%	51%	69%	54%	51%
Treatment might cause sickness	37%	36%	45%	32%	18%
Time and cost might be too much	33%	26%	24%	43%	31%
Don't trust pharmaceutical companies	28%	22%	29%	19%	26%
Doubt there would be any benefit	26%	26%	21%	28%	36%
Might get placebo	17%	12%	14%	20%	9%
Don't trust medical research	10%	10%	24%	6%	16%
Unable to travel or get transportation	11%	11%	16%	19%	23%
Might not be treated fairly	3%	8%	22%	12%	10%



Mistrust Among Black Americans

- Past injustices



Individuals must be invited

Are Racial and Ethnic Minorities Less Willing to Participate in Health Research?

David Wendler^{1*}, Raynard Kington², Jennifer Madans³, Gretchen Van Wye⁴, Heidi Christ-Schmidt⁵, Laura A. Pratt³, Otis W. Brawley⁶, Cary P. Gross⁷, Ezekiel Emanuel¹

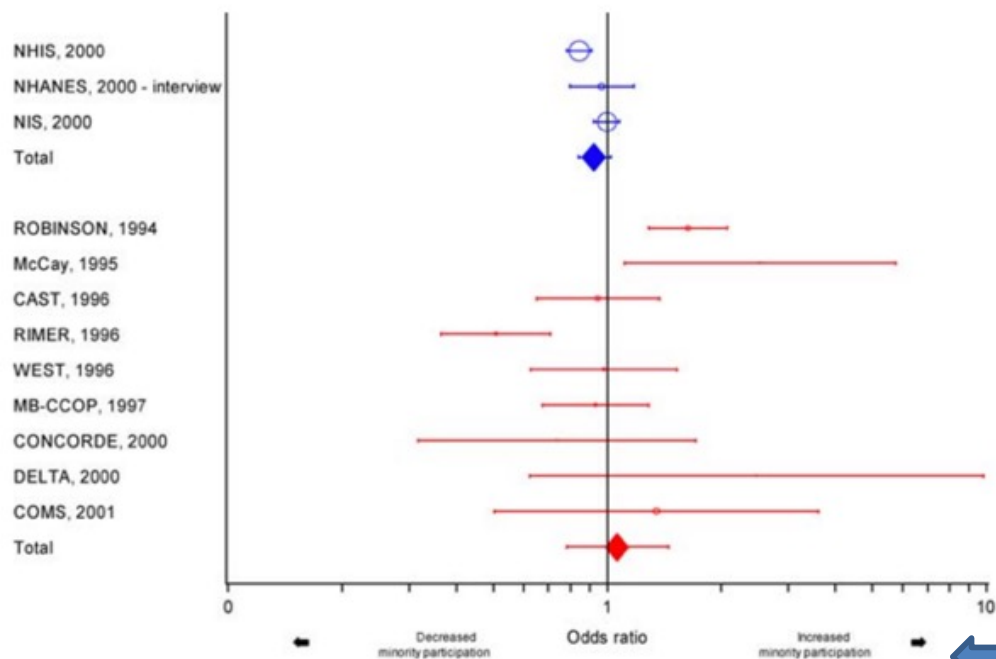


Figure 2. Comparison of African-American versus non-Hispanic White Consent Rates



From: <http://www.aral.com.au/ari/p-ywadsworth98.html>

Blue indicates interview and non-intervention studies; red indicates clinical intervention studies. The graph indicates that most studies found that African-Americans were equally willing to participate in research as non-Hispanic white Americans were. DOI: 10.1371/journal.pmed.0030019.g002

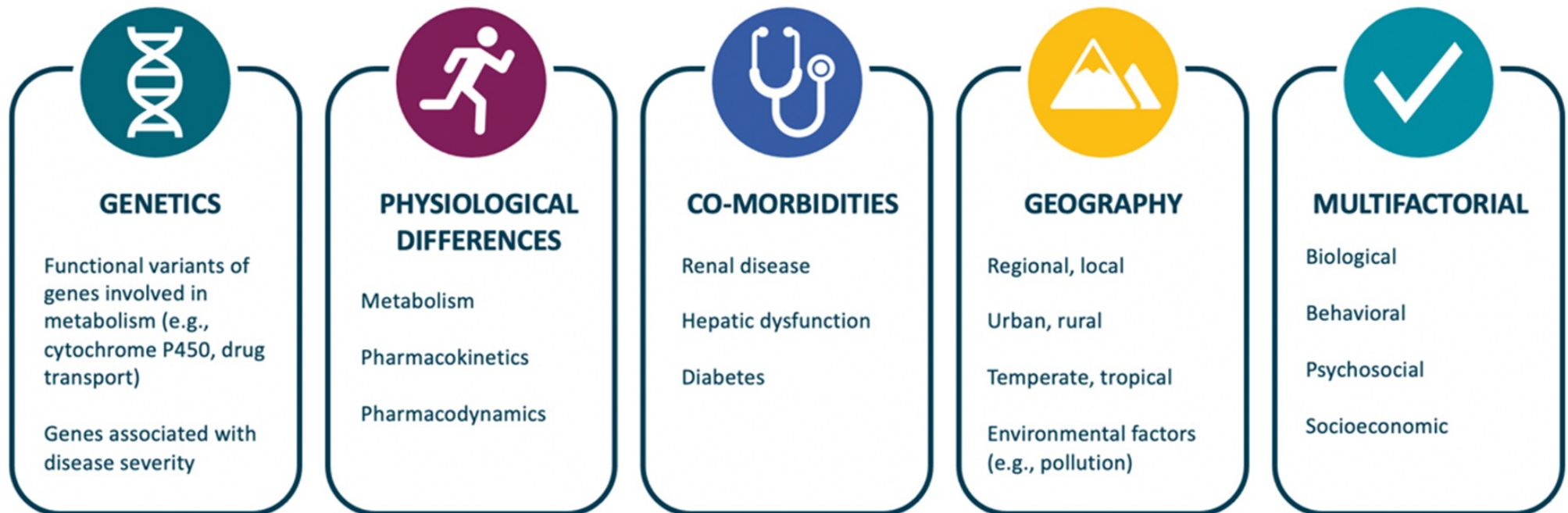


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Why do we need to enroll more African Americans in AD clinical trials?

Black Americans underrepresented in Alzheimer's clinical trials: 2% - <5%



Underrepresentation of African Americans in clinical trials results in ongoing healthcare disparities.

Expanding African American Enrollment in Clinical Trials

22 June 2023

Michael C. Irizarry, MD, MPH
SVP, Alzheimer Disease and Brain Health
Eisai, Inc



FOUR DECADES OF ALZHEIMER'S RESEARCH-NEVER GIVING UP

FOUR DECADES OF ALZHEIMER'S RESEARCH NEVER GIVING UP

Eisai's human health care *hhc* mission:

We give first thought to patients and their families and increasing the benefits health care provides.



Collaborations

to improve efficiency
and productivity



**Creation of
innovative medicines**

to fulfill unmet medical needs



Provision of solutions

to address gaps in
infrastructure



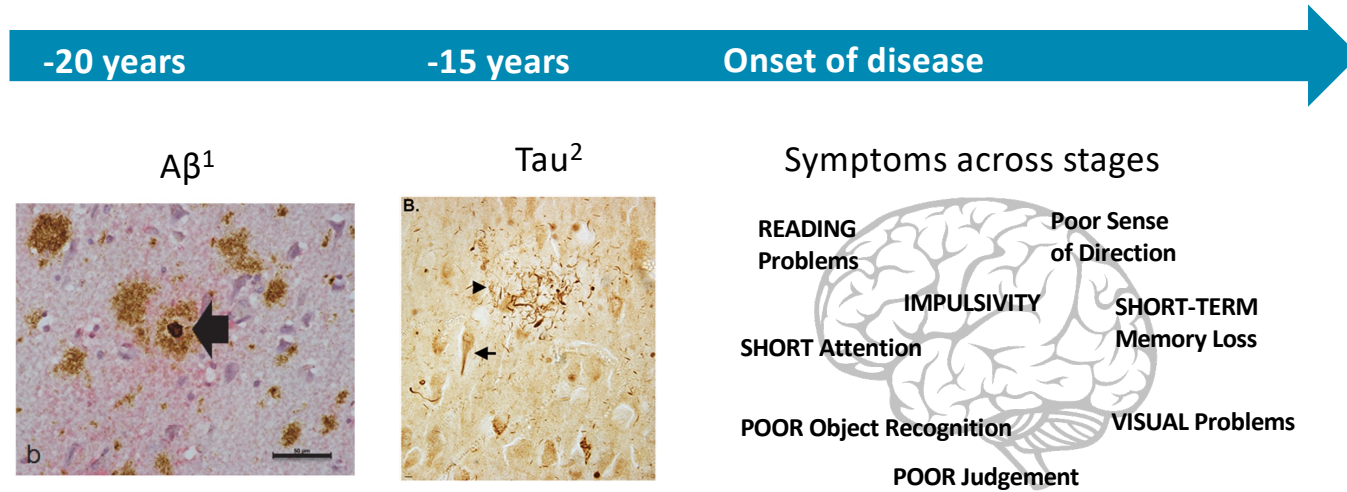
“ The primary focus of health care must always be the patient, the patient's family, and from a general vantage point, the public as a whole. These are the people we must serve. ”

– Haruo Naito, CEO of Eisai Co., Ltd.

FOUR DECADES OF ALZHEIMER'S RESEARCH – NEVER GIVING UP

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- AD pathologic changes in the brain start 15-20 years before the development of symptoms⁴
- AD is a continuum consisting of a preclinical stage and progressing to AD dementia³

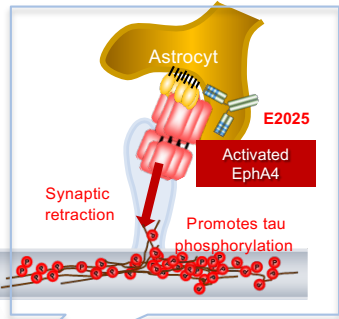
Areas of active investigation⁴: How are disease-modifying therapies interfering with the underlying pathophysiologic mechanism of disease?

AD, Alzheimer's disease.

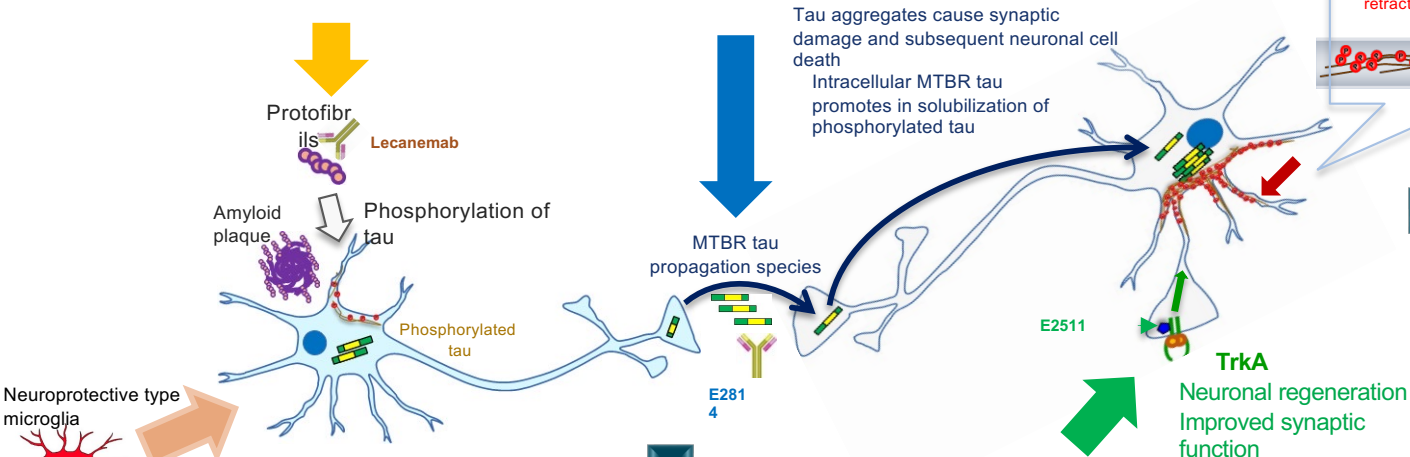
1. Mathur R, et al. *PLoS One*. 2015; 10:e0118463. 2. Day RJ, et al. *PLoS One*. 2015;10e0132637. 3. Jack CR, et al. *Alzheimers Dement*. 2018;14:535-562. 4. Bateman RJ, et al. *N Engl J Med*. 2012;367:795-804.

A
Lecanemab¹
 Aβ protofibrils clearance

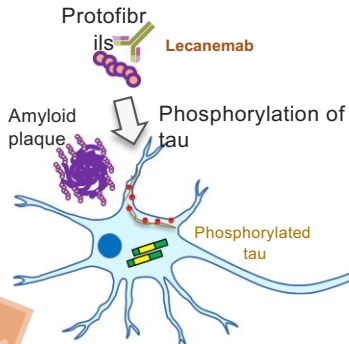
T
E2814 (Anti-MTBR²tau antibody)
 Pursuing expansion to sporadic AD, in-house Phase I study (effective dose study³) and Phase Ib/II study for DIAD⁴ are ongoing. In addition, Tau NexGen study⁵ is ongoing by DIAN-TU⁶



N
E2025 (Anti-EphA4⁷ antibody)
 Phase 1 Initiated
 Potentially regenerates the dendrites of damaged glutamate neurons and restores synaptic function



Neuroprotective type microglia

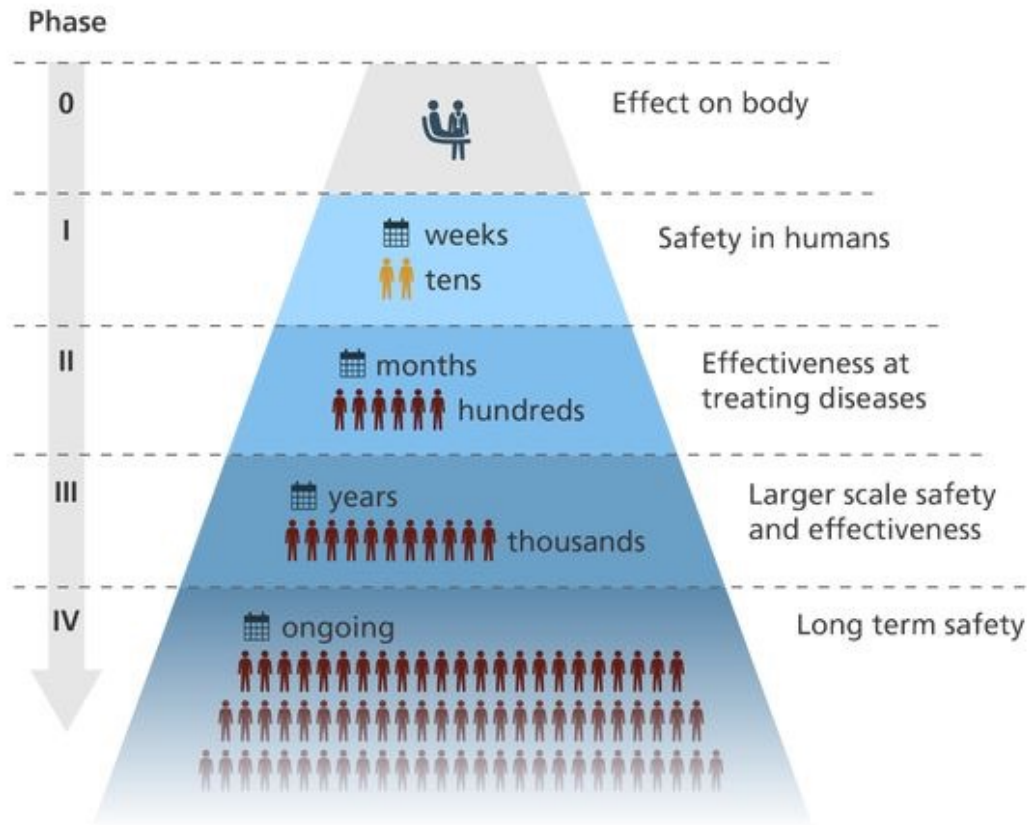


(1)
TREM2⁹ function coordination for neural immunotherapy for dementia (Immuno-Dementia) Non-clinical
 TREM2 is one of risk genes of AD and potentially suppress onset and progression of AD by restoring abnormal TREM2 function expressed in microglia, which associates with phagocytosis improvement

N
E2511 (TrkA⁸ binding synapse regenerant)
 Conduct research for biomarker, which potentially predicts drug efficacy in Phase 1 study
 Potentially restores synaptic function by activating TrkA and regenerates damaged axons of cholinergic neuron

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Clinical Trial Phases



<https://hubpages.com/education/How-are-drugs-developed-and-approved-The-drug-development-process>

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Eisai Initiatives to Facilitate Access to Clinical Trials

- Investigators and sites with access to diverse communities
- Engagement with community centers and faith-based groups
- Decentralized clinical trial activities
 - Home infusions
 - Remote cognitive assessments
 - Remote safety assessments
- Community-based screening
- Partnership with advocacy organizations



Ongoing engagement with Black Health Matters on a 12-month program that includes social media posts, health content and videos encouraging enrollment and 2 featured AHEAD Study videos/commercials

Black Health Matters @BHMinfo · Jan 30

Black people only make up less than 5% of #Alzheimer's trial participants, despite having a higher risk of developing the disease. Join the AHEAD Study and help contribute to one day perhaps finding a treatment to prevent it. Visit AheadStudy.org to learn more.

AHEAD STUDY AHEADStudy.org 1-800-AHEAD-70

There are benefits to participating in Alzheimer's research.

[Learn More](#)

Black Health Matters @BHMinfo · Oct 31

#Alzheimers still isn't preventable. Join the AHEAD Study to work with world-class memory researchers and investigational treatments. Find a #clinicaltrial near you at AheadStudy.org.

Alzheimer's on your mind?

Join a study that aims to help prevent it.

[Find out more](#)

AHEAD STUDY

AHEADStudy.org 1-800-AHEAD-70

Help us get AHEAD of Alzheimer's disease!

OUR STORY, OUR VOICES

READ ABOUT THE FACTS

[READ MORE](#)

[READ MORE](#)

[READ MORE](#)

Support for Diversity & Inclusion Activities in Alzheimer's Disease



UsAgainstAlzheimer's Brain Guide & Faith in Action Toolkit

- Brain Guide offers a private memory questionnaire and provides participants with resources just for them based on the answers provided.
- Faith in Action Toolkit provides brain health information and state-specific resources leaders of more than 30 churches can share with parishioners.



Bright Focus's Brain Info Live

- Programs offer brain health education in live, local, patient-facing events and virtual activities in rural south Georgia and Passaic County, New Jersey



Diversity & Inclusion

Alzheimer's Los Angeles is highly aware of the rich and vibrantly diverse nature of the large geographic area we serve, with dozens of distinct cultures and over 250 languages. We are committed to creating an environment that is open to discourse, listening, and learning from each other.

Alzheimer's LA Healthy Brain Initiative

- Educates the local African American and Hispanic communities about healthy lifestyle choices, understanding the difference between normal aging and the need for early diagnosis



Dementia Alliance of North Carolina Rural Outreach Initiative

- Increases education and access to dementia resources and support in rural counties in North Carolina

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Analysis of Eligibility Criteria for AD Clinical Trials

- 10,804 US participants screened across 4 AD Phase 2 and Phase 3 trials
 - 193 (2%) Hispanic and Black
 - 2,224 (25%) Hispanic and White
 - 696 (7%) Non-Hispanic and Black
 - 7,017 (65%) Non-Hispanic and White
- 2,444 Randomized
 - 34 (1%) Hispanic and Black
 - 412 (17%) Hispanic and White
 - 63 (3%) Non-Hispanic and Black
 - 1918 (78%) Non-Hispanic and White
- Higher rate of screen failures in Hispanic and Black groups was due to amyloid criteria (i.e. did not have Alzheimer's disease as the cause of cognitive impairment)
 - Hispanic and Black: 56% screen failure by amyloid criteria
 - Hispanic and White: 64%
 - Non-Hispanic and Black: 67%
 - Non-Hispanic and White: 32%

Grill J, AAIC 2022 and submitted

Conclusions

- Drug development in Alzheimer's disease has progressed rapidly with recent advances
 - Disease understanding
 - Experimental models of the disease
 - Biomarkers
- Increasing diversity in clinical trials is a priority
 - To be able to generalize the results of clinical trials to the real world population
 - Promote fair access to investigational therapies
 - Build trust in medical research, institutions, and therapies

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Eli Lilly: Tony Pearson, JD MPH