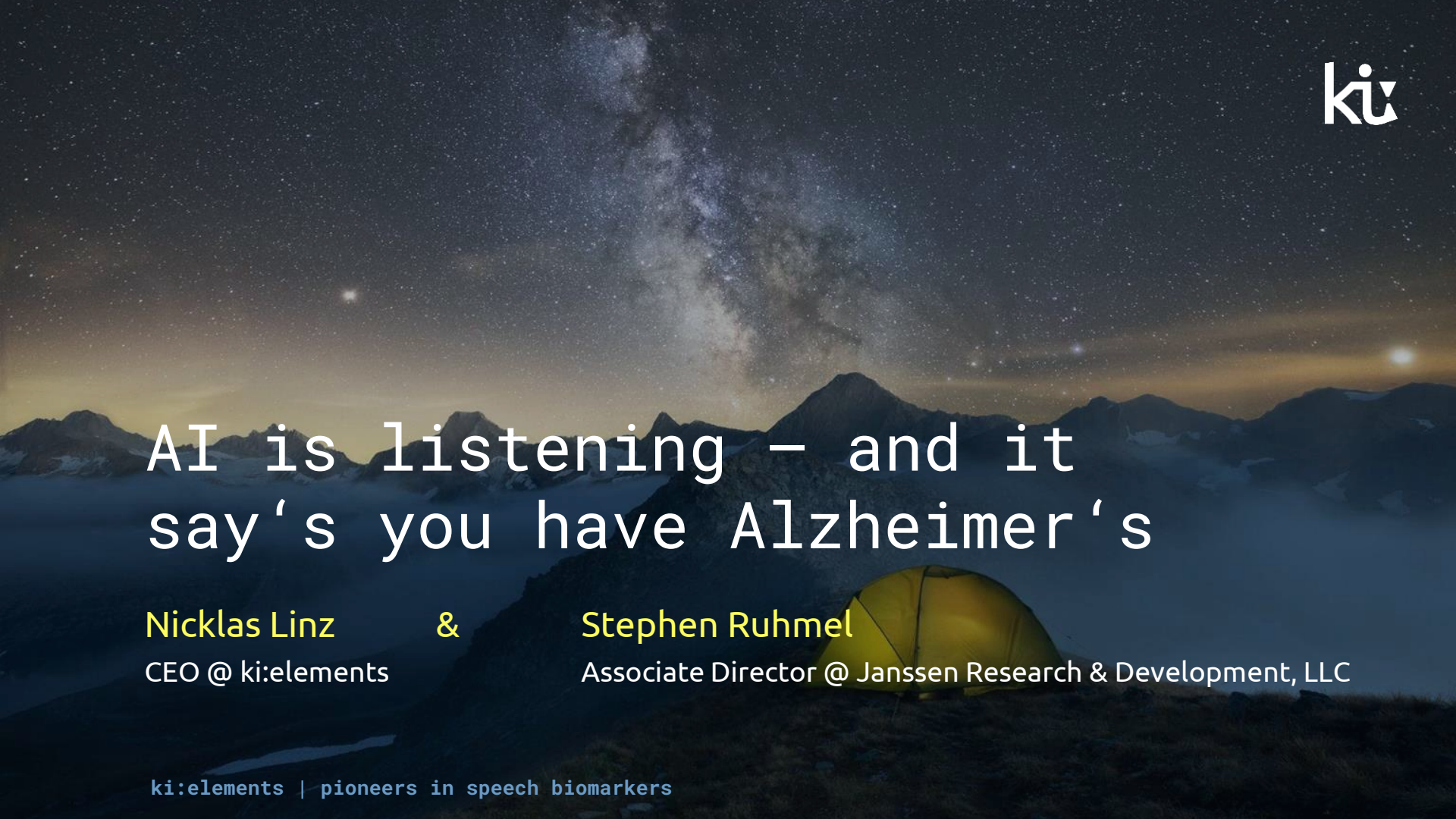

AI is listening – and it say‘s you have Alzheimer‘s

Nicklas Linz & Stephen Ruhmel

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Nicklas Linz

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Johnson & Johnson INNOVATION | JLABS

Stephen Ruhmel

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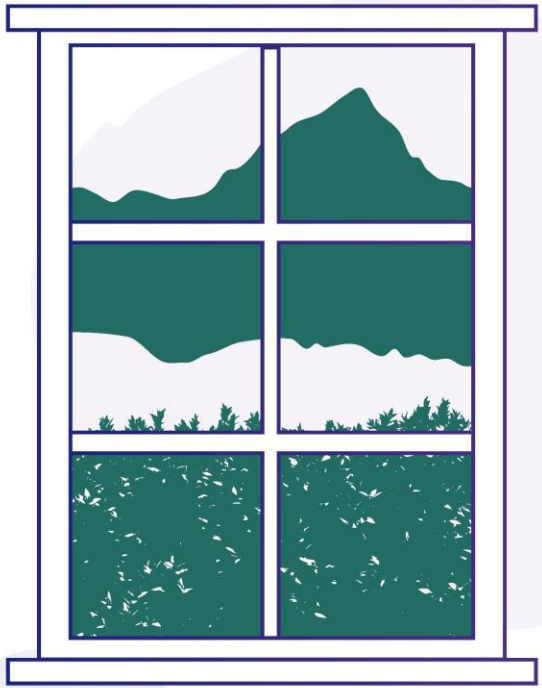



2022


ADD TO CART
72

The Alzheimer’s pandemic

Between 2000 and 2019, deaths from heart disease decreased 7.3% while deaths from AD have **increased 145%**

In 2020, caregivers provided an estimated **15.3 billion hours**of care valued at nearly $257 billion

In the United States, AD and dementia deaths have **increased 16%** during the COVID-19 pandemic

Neurodegenerative processes occur **20 years before** a patient’s first visit to the doctor.

Challenges to clinical trials in AD

Clinical trial recruitment poses significant challenges to drug development

80%

of trials fail to meet enrollment timelines

30%

of clinical trials' timeline is spent on patient recruitment

$5.9B

spent annually on clinical trial recruitment

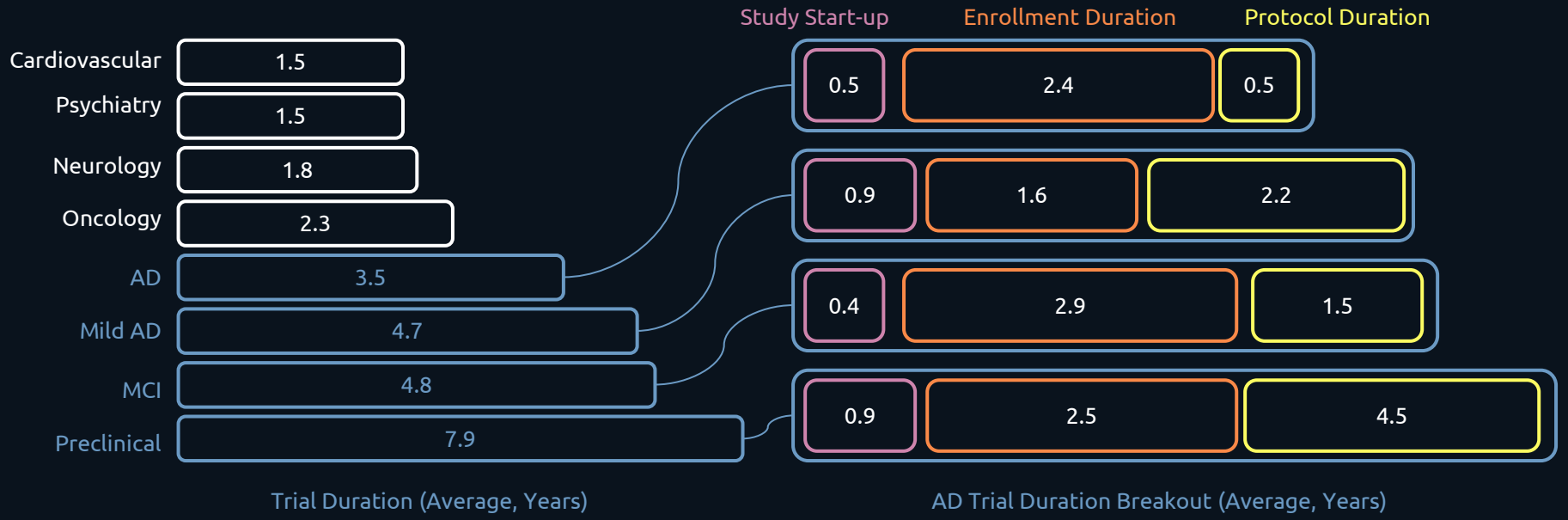
5%

or less of potential candidates enrolled in clinical trials

Reference: Johnson, Tesheia, et al. Using research metrics to improve timelines: proceedings from the 2nd Annual CTSA Clinical Research Management Workshop.Clinical and translational science 3.6 (2010): 305-308.
Ali, Z., Zibert, J. R., & Thomsen, S. F. (2020). Virtual clinical trials, Dermatology, 236(4), 375-382.
Bielski, R. J., & Lydiard, R. B. (1997). Therapeutic trial participants: where do we find them and what does it cost?. Psychopharmacology bulletin, 33(1), 75.

Enrollment duration as key barrier

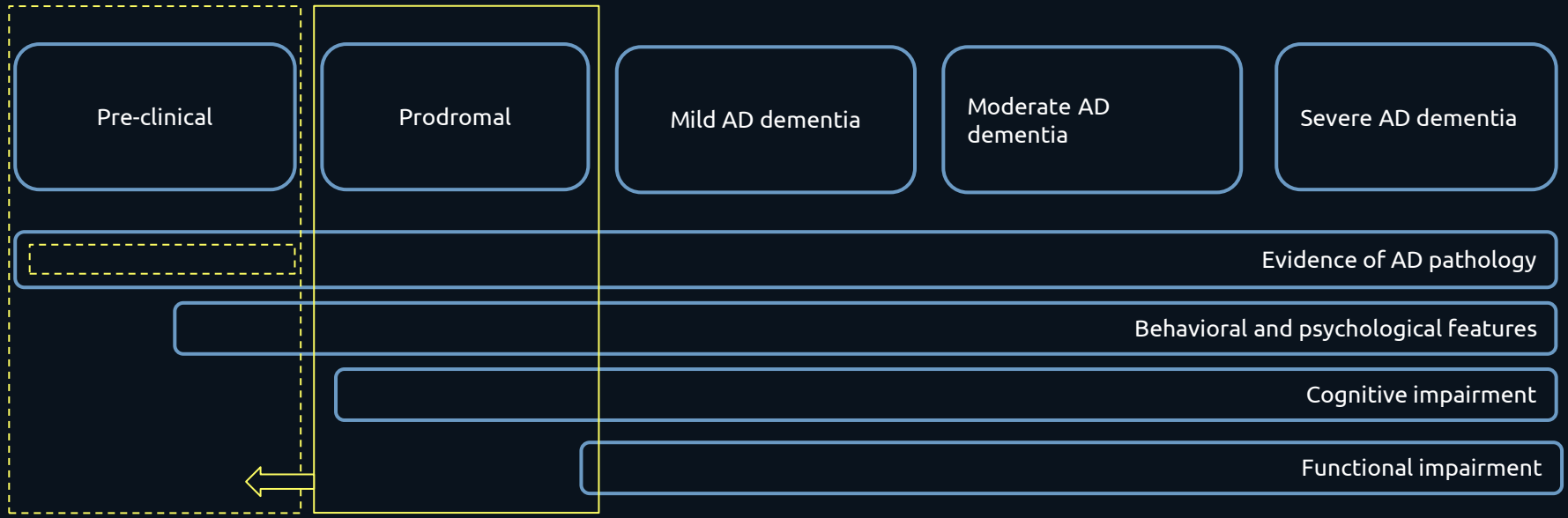
AD trials take longer time than trials of other disease areas



Reference: Goldman, D. (2020). Key Barriers for Clinical Trials for Alzheimer's Disease. USC Schaeffer Center White Paper, Aug, 17.

Enrollment tool as key barrier

It is difficult to find patients at pre-clinical stage of the disease



Trend of AD trials moving towards earlier stage of the disease, while no clinical manifestation could be detected and cheap, non-invasive tools are lacking to correctly target these candidates with high risks

Reference: A P Porsteinsson, Diagnosis of Early Alzheimer's Disease: Clinical Practice in 2021, J Prev Alzheimers Dis, 2021;8(3):371-386.

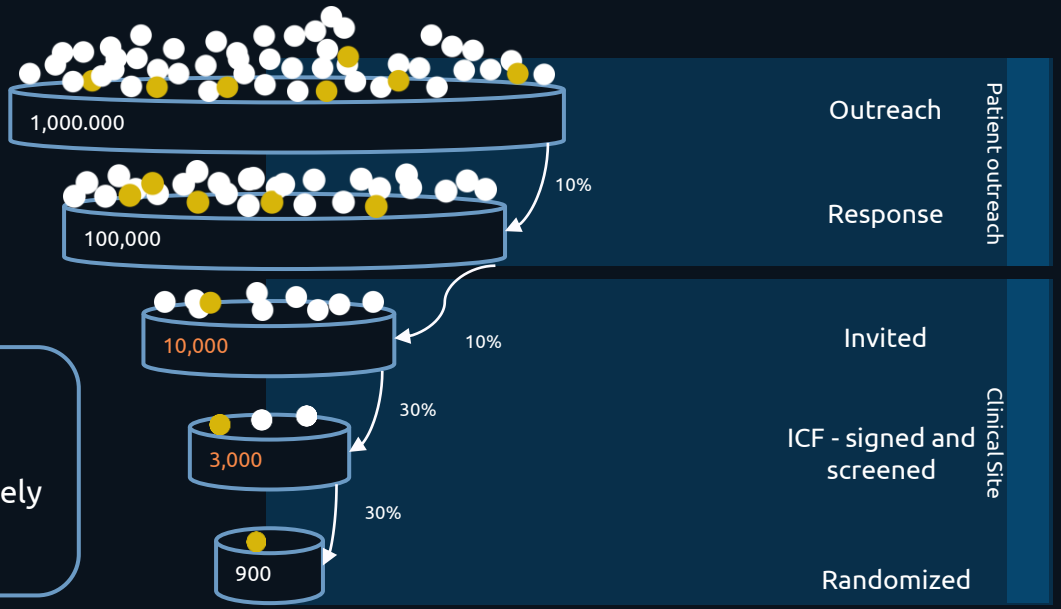
Identification of pain points

Time and cost consuming pre-screening procedures with low screen-in rate are the major pain points

Low successful screen-in rate of patients

Time and cost consuming pre-screening procedures

Lack of professional CROs having **in-depth understanding** of the therapeutic areas and keeping the communication transparent in a timely manner



Technical Framework

The ki:e SB-C harnessing AI and automatic speech analysis

Speech assessment protocol:
- Semantic Verbal Fluency
- Rey Auditory Verbal Learning

Speech collection front-end e.g. telephone or mobile app

Sensor collecting raw input: microphone

Automatically cut and prepared speech audio file

Transcription and feature extraction (e.g. semantic coherence)

Biomarker score calculation

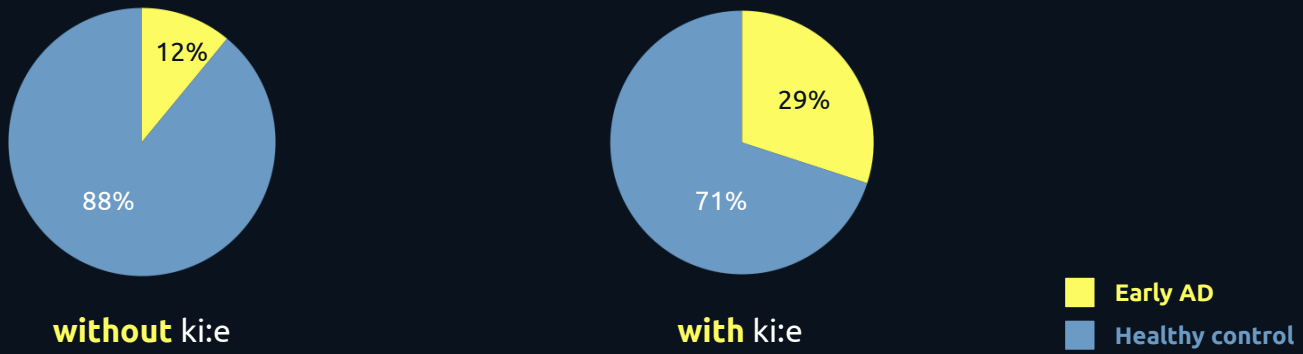
Ready-to-use speech biomarker:
- + cut-off informing diagnostic decisions
- + ML logic screening for MCI
- ...

H70 retrospective performance evaluation

Using ki:e Biomarker for screening can greatly enrich the MCI prevalence

Key messages

- ✓ Using ki:e SB-C, we are able to **improve MCI prevalence** from 11% (48/452) to 30% (37/123), thus greatly enriched the population by almost three-fold, reducing the full screening cost
- ✓ Using ki:e SB-C, out of all the excluded candidates, we are able to **correctly detect 97%** of them as true healthy population, reducing the invitation to site cost



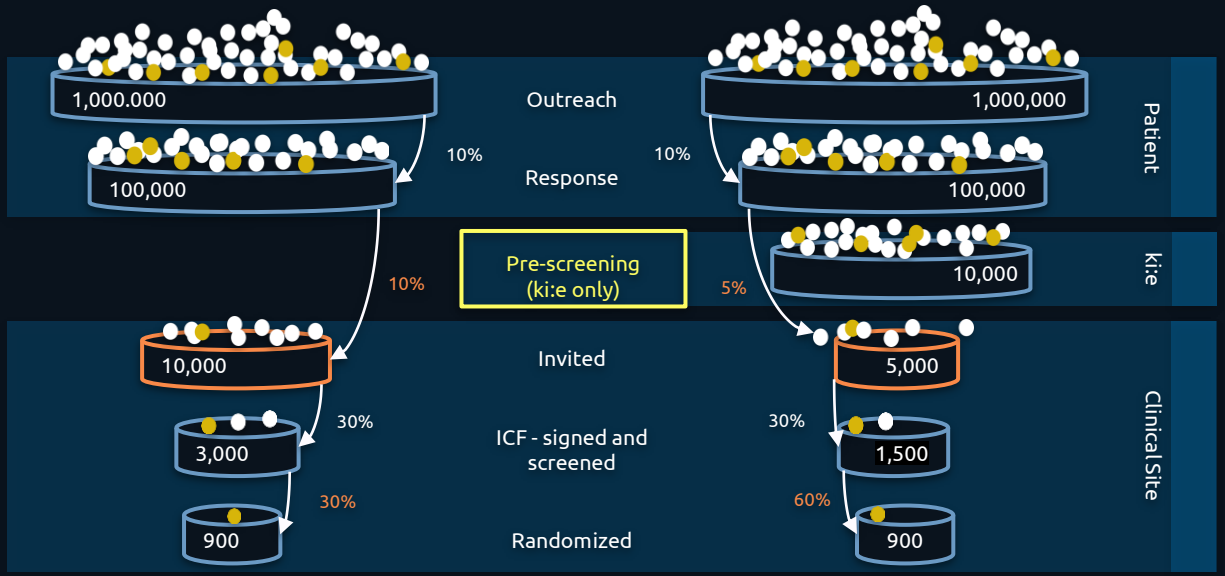
without ki:e

with ki:e

Proportion of patients who are suitable for MCI trials with/without using ki:e biomarker as a pre-screening tool (total=452 patients)

Our solution: Reducing recruitment cost

Use case in phase 2 trial – ki:e Biomarker could reduce the number of candidates invited to sites for screening by at least **50%**



Implementation in Autonomy


HITACHI

PET Scan to measure Tau

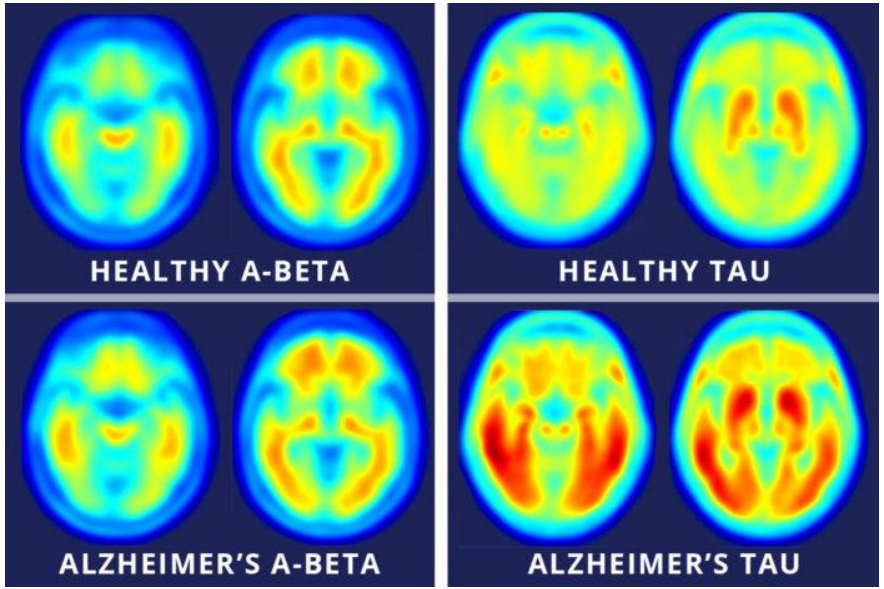


Image: https://medicine.wustl.edu/news/brain-imaging-links-alzheimers-decline-to-tau-protein/

Autonomy Study Pilot

Autonomy
ANTI-TAU ANTIBODY STUDY FOR ALZHEIMER'S DISEASE

Phone-based speech assessment

Integrated into recruitment funnel

Fully automated

Pilot sites

20 pilot sites
2,000 participants to take assessment
Sites are blinded to results

Recommendation to recruit

Automated "yes/no" recommendation to recruit into the study
Considers dementia (CDR) and cognitive impairment (MCI) in relation to Tau positivity

Measuring Success

01	**Specificity**	Number of successfully recommended participants who screened in
02	**Sensitivity**	Number of successfully *not* recommended participants who screen failed
03	**Participant Acceptance**	Proportion of eligible participants who consented to *and* completed the speech biomarker phone assessment
04	**IRB Approval**	IRB/Ethics approval of speech biomarker for pre-screening and recruitment
05	**Cost & Time Savings**	Cost/time to be avoided through lower proportion of screen fails

In the future...

Potential use as a novel endpoint to measure efficacy
Lower friction options (shorter instruments, existing voice interactions)
Case finding for therapies in market
Beyond research; as part of our day-to-day lives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