OUR VISION:  A world without Alzheimer’s disease.

OUR MISSION: To eliminate Alzheimer’s disease through the advancement of research; to provide and enhance care and support for all affected; and to reduce the risk of dementia through the promotion of brain health.
Desperate Need for Therapies To Stop or Slow Disease

- Today, 5.4 million Americans living with Alzheimer’s; will triple by mid-century
- Care: Over 15 million Americans providing care/support for someone with Alzheimer’s or related dementia
- Cost: $236 Billion today; will exceed $1.1 Trillion by mid-century
Challenges include funding the pipeline and volunteers for clinical trials.
Recruitment challenges for Alzheimer’s and related dementia trials around the world.
Need to facilitate ways to increase recruitment and design trials with innovative ways to decrease needed size and duration (i.e. adaptive design).

Over 200+ Clinical Trials On-Going Today in the US
Example: Dominantly Inherited Alzheimer’s Network – Trials Unit

- PI: Dr. Randall Bateman, Washington University, St Louis
- Using adaptive design for last 4 years
- Enrolling DIAD individuals in phase 2 adaptive design, accelerate launch to phase 3
- Alzheimer’s Association provides unique virtual support groups and services
- Face to face at AAIC for families to interact
Through public/private support and partnership, the DIAN-TU has launched trials to provide advancement of treatments, scientific understanding and improvements in the approach to Alzheimer's disease drug developments.
ADAPTIVE DESIGN: DIAN-TU Model

- Continuous addition of experimental drug (A, B, C, D …) into phase 2 trial
- If experimental agent shows (+) biomarker profile, enrollment continues to phase 3 cognitive endpoint registration trial
- * Interim analysis may be performed at 1 year to determine if transition to phase 3 sooner
Example: Dominantly Inherited Alzheimer’s Network – Trials Unit

- Alzheimer’s Association funded launch DIAN-TU w/ $4.2 million & now $4.3 million for DIAN Next Gen using adaptive design studies
- DIAN-TU and DIAN NexGen sets stage next generation of clinical trials and adaptive design models, including combination therapy
Challenges with Dementia Trial Recruitment

Person with Disease
Challenges with Dementia Trial Recruitment

Person with Disease → Eligibility Criteria
Challenges with Dementia Trial Recruitment

• Many individuals with dementia take multiple prescriptions, commonly have other medical conditions.
• These can exclude them from eligibility to participate in clinical trials.
• In fact, studies have shown that only 10% to 27% of people with Alzheimer’s are eligible for trials.
Challenges with Dementia Trial Recruitment

Person with Disease → Eligibility Criteria

Need for study partner
Challenges with Dementia Trial Recruitment

• Most dementia clinical trials require study participant and a study partner
• Almost 2/3 of people who enroll in Alzheimer’s trials enroll with a spousal study partner
• Not all people with Alzheimer’s have a partner
• How can study sites be more flexible?
Challenges with Dementia Trial Recruitment

- Person with Disease
  - Transportation
- Eligibility Criteria
  - Need for study partner
- Challenges with Dementia Trial Recruitment

- Need for study partner
- Eligibility Criteria
- Transportation
- Person with Disease
Challenges with Dementia Trial Recruitment

- Person with dementia may not be able to drive; it is fairly common to lose driving ability.
- Requires person to depend on study partner or another for transportation.
- Transportation to/from study site could have socio-economic consequences that families may choose not to participate given expenses of disease itself.
Challenges with Dementia Trial Recruitment

- Need to manage disease
- Transportation
- Person with Disease
- Eligibility Criteria
- Need for study partner
Challenges with Dementia Trial Recruitment

- Need support as families learn to manage the disease
- Depending on trial population, opportunity to get families thinking about how to prepare for the future (financial, legal, care) (asymptomatic, early stage, moderate or late stage)
- Programming like “Know the 10 Signs” – identified by families as key to understanding aging versus Alzheimer’s

Alz.org/10signs
Challenges with Dementia Trial Recruitment

• Support groups – also huge need for both person with disease and the family
• Clinical studies do not need to meet these needs, but can help families connect to resources (Alzheimer’s Association, Alzheimer’s Europe, etc)
CLINICAL TRIALS CAN TREAT THE WHOLE PERSON

• Amount of time required; be creative or flexible on how you engage (in home, phone, skype, etc.) and flexibility of visit schedule (can informant come separately?)
• Distance of trial site; is there a more flexible way to engage?
• Person with dementia wants to be valued as a part of the study
• Language and messaging around the clinical trial
• Link person and family to support
IMAGINE IMPORTANCE OF COLLABORATION

- EPAD
- EMIF, DP-UK, GAAIN
- Collaboration for Alzheimer’s Prevention (CAP) – A4, API, TOMMorrow, DIAN-TU
- Continue to link trials and patient perspective
If we delayed onset by 5 years …

DELAYED ONSET
If we develop a treatment by 2025 that delays the onset of Alzheimer’s by just five years, then:

- Families would save $87 billion in 2050.
- In total, America would save $367 billion in 2050.

5.7 MILLION
people expected to develop Alzheimer’s would not in 2050.
Continue to Consider Perspective
Of Patient & Care Partner

• Desperate need for therapy to stop or slow progression of disease
• Language important in communicating about trial – timeline, trial design, etc.
• Opportunity for trial sites to consider how to be flexible, support the patient, their care partner