

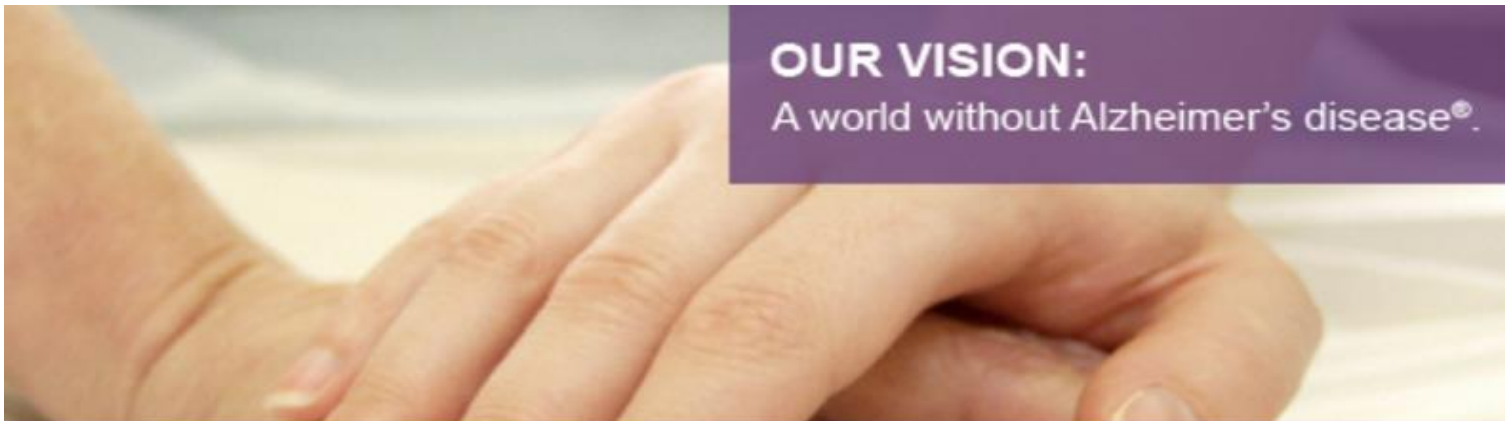


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Senior Director, Medical & Scientific Relations

# **Perspective from the Alzheimer's Association**



# IMAGINE



## 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.

# IMAGINE

## Desperate Need for Therapies To Stop or Slow Disease

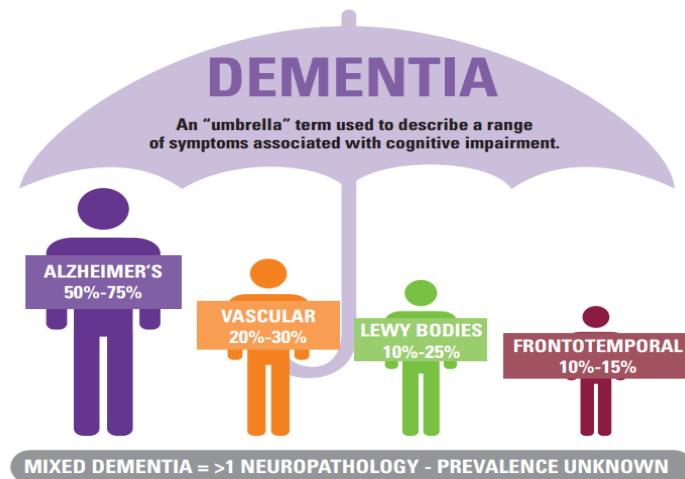
- Today, **5.4 million** Americans living with Alzheimer's; will triple by mid-century
- **Care:** Over **15 million** Americans providing care/ support for someone with Alzheimer's or related dementia
- **Cost:** **\$236 Billion** today; will exceed **\$1.1 Trillion** by mid-century



# IMAGINE

## Over 200+ Clinical Trials On-Going Today in the US

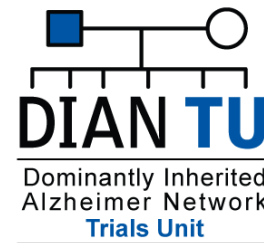
- Challenges include funding the pipeline and volunteers for clinical trials
- Recruitment challenges for Alzheimer's and related dementia trials around the world
- Need to facilitate ways to increase recruitment and design trials with innovative ways to decrease needed size and duration (i.e. adaptive design)



# IMAGINE

## 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



alzheimer's  
association®

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.

# alzheimer's association®

## DIAN-TU Pharma Consortium




**DIAN TU**  
Dominantly Inherited Alzheimer Network  
Trials Unit

\*Financial support has also been provided by anonymous sources.



**NATIONAL INSTITUTE ON AGING**  
*National Institutes of Health*  
U01 AG042791, R01 AG046179



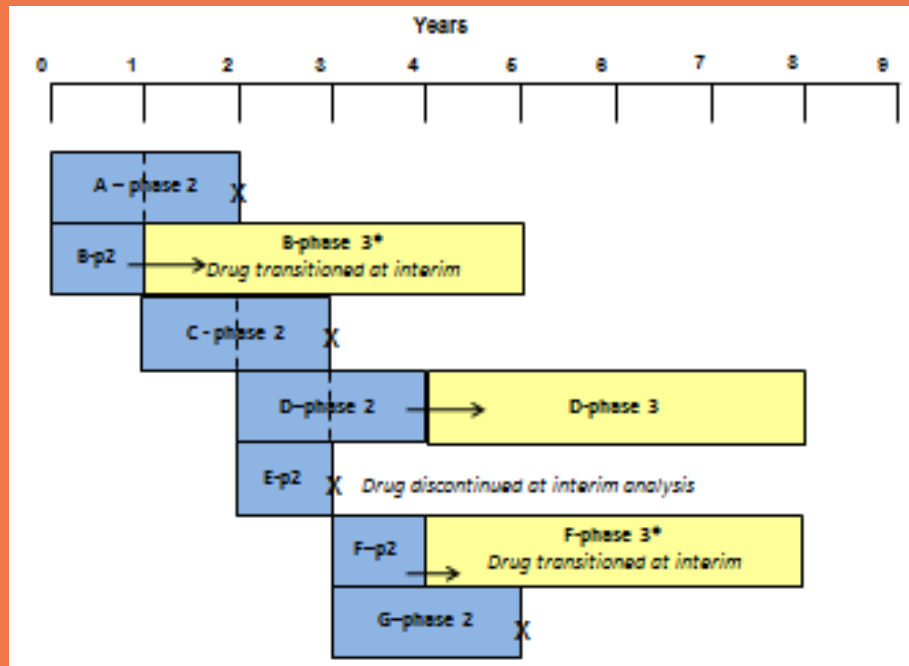





**DIAN-TU  
made  
possible  
through  
collaboration**

# IMAGINE

## ADAPTIVE DESIGN: DIAN-TU Model

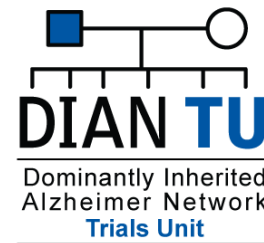


- Continuous addition of experimental drug (A, B, C, D ...) into phase 2 trial
- If experimental agent shows (+) biomarker profile, enrollment continues to phase 3 cognitive endpoint registration trial
- \* *Interim analysis may be performed at 1 year to determine if transition to phase 3 sooner*

# IMAGINE

## 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



alzheimer's   
association®



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## Challenges with Dementia Trial

### Recruitment

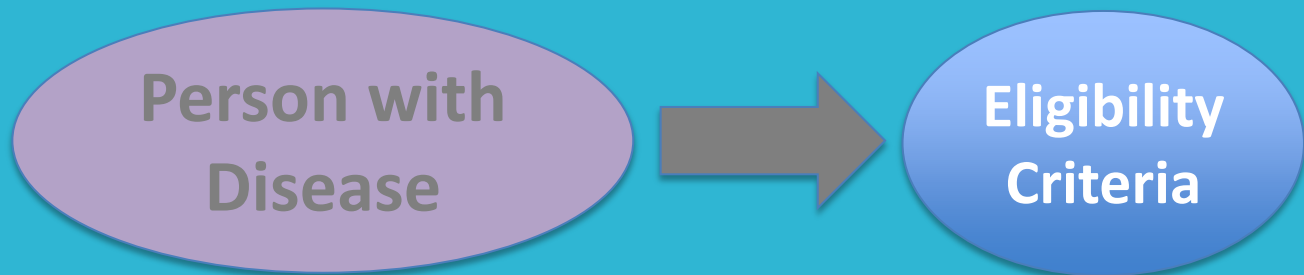
Person with  
Disease



IMAGINE

## Challenges with Dementia Trial

### Recruitment



# IMAGINE

## Challenges with Dementia Trial

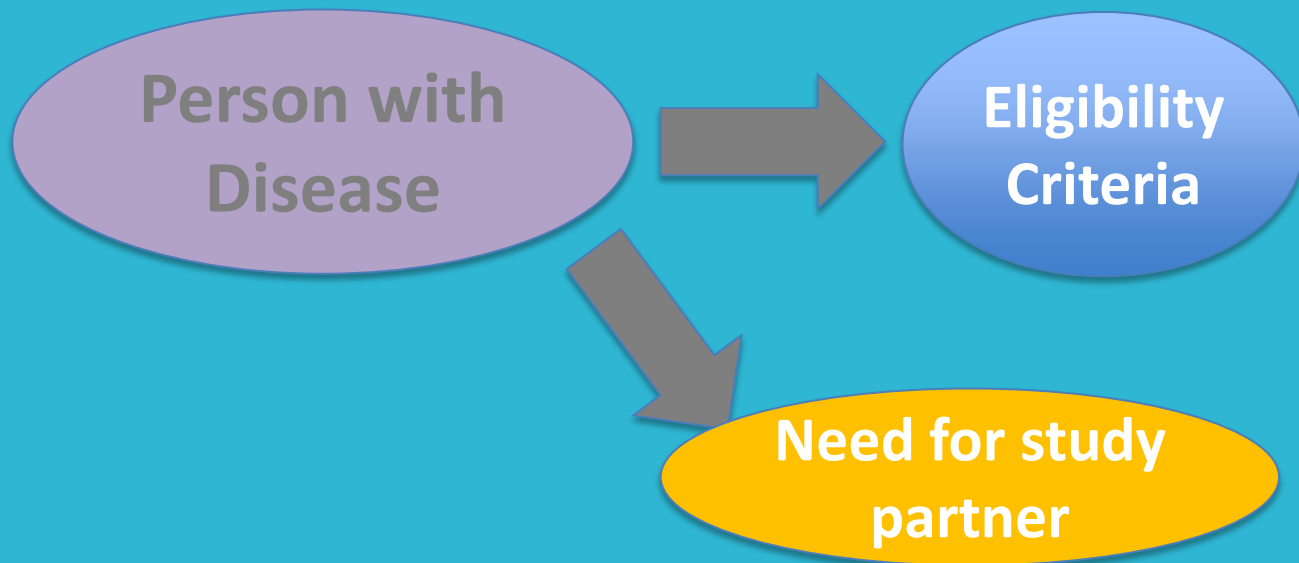
### Recruitment

- 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

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## Challenges with Dementia Trial

### Recruitment



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## Challenges with Dementia Trial

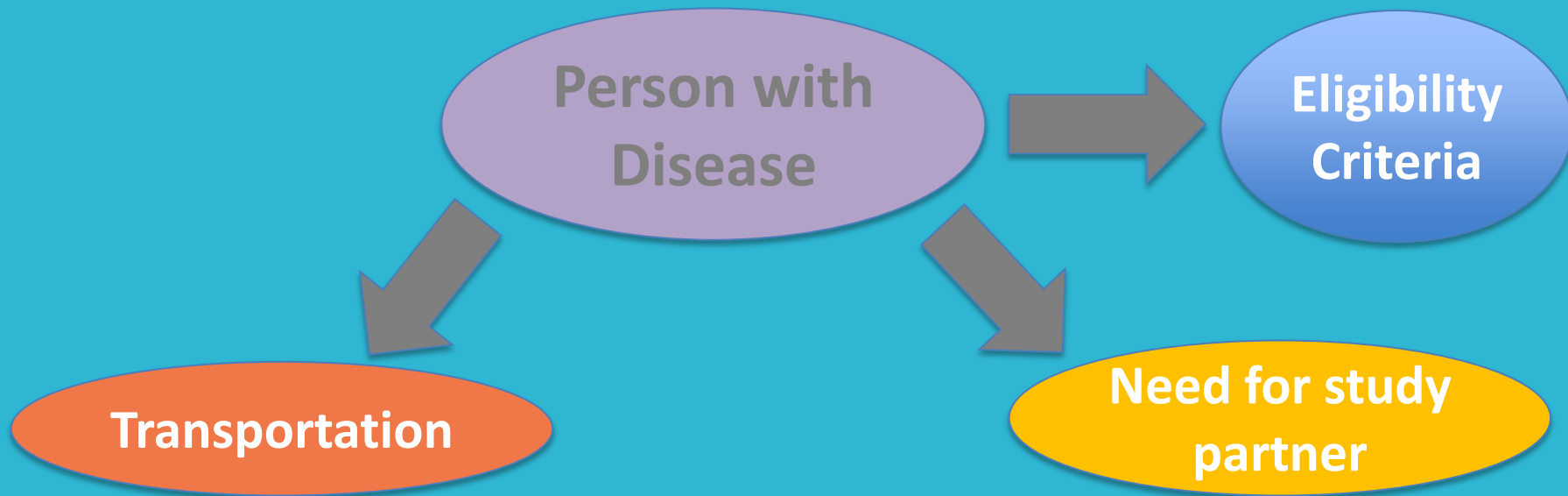
### Recruitment

- 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?**

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## Challenges with Dementia Trial

### Recruitment



# IMAGINE

## 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 chose not to participate given expenses of disease itself

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## Challenges with Dementia Trial

### Recruitment

Need to  
manage  
disease

Person with  
Disease

Eligibility  
Criteria

Transportation

Need for study  
partner





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## 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](http://Alz.org/10signs)



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## 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)

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## 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

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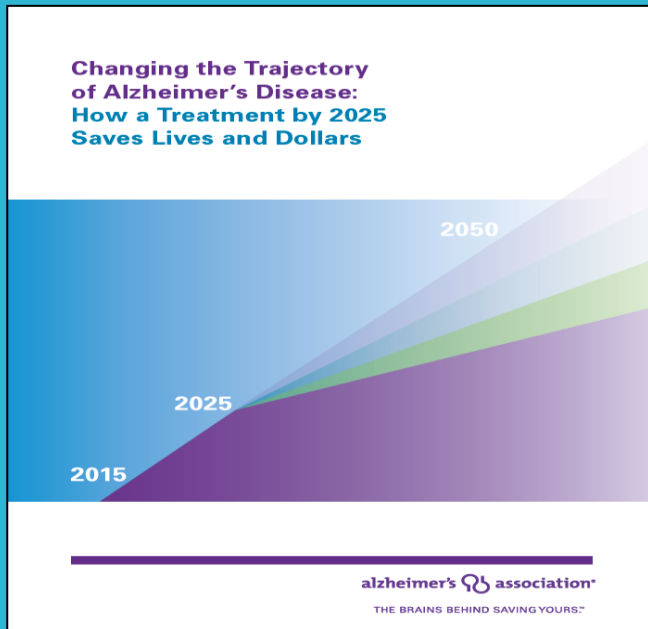
## IMPORTANCE OF COLLABORATION



- EPAD
- EMIF, DP-UK, GAAIN
- Collaboration for Alzheimer's Prevention (CAP) – A4, API, TOMMorrow, DIAN-TU
- Continue to link trials and patient perspective

# IMAGINE

## 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.**



**5.7**  
MILLION

people expected to  
develop Alzheimer's  
**would not in 2050.**



In total,  
America would save  
**\$367 billion in 2050.**

# IMAGINE

## 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