

## Participating in an Alzheimer's Clinical Study: Perspectives on Involvement of a Person Living with Dementia and Her Study Partner.

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Presented by:

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NAPA Advisory Council Meeting

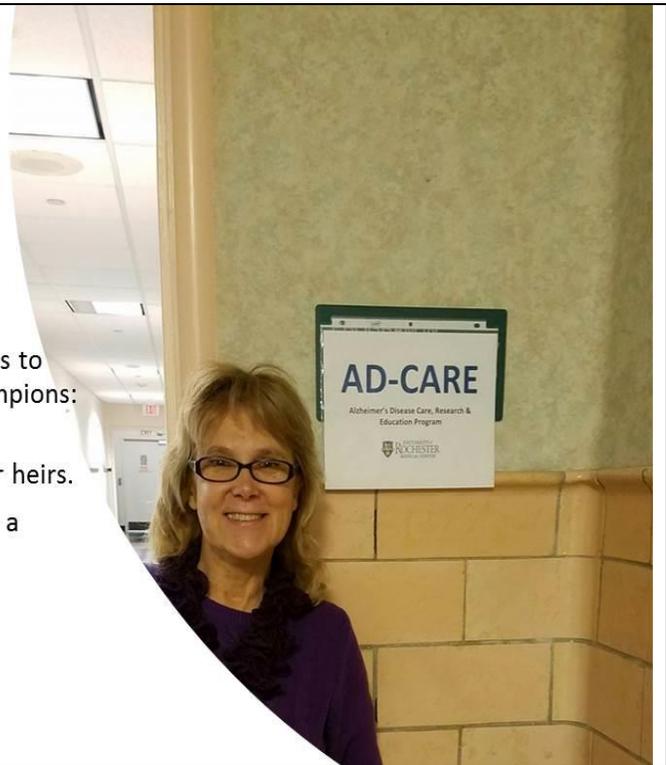
January 26, 2018



## Participating in Alzheimer's Clinical research...

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- May provide PLWDs with hope and strength.
- May help those living with a dementia diagnosis to move from feeling like victims to feeling like champions: from "Why Me to What Next"
- May not benefit the PLWD, but may benefit her heirs.
- May give our lives a purpose. We leave behind a legacy!
- Provides excellent medical care and access to procedures not yet available to general public.
- Will lead to treatments and to a cure!



## Requirements of an ADNI3 Study Partner:

- Must have direct contact with the subject at least one day (a minimum average of 10 hours per week.)
- Must be able to accompany the subject to all clinic visits or be available via phone to answer questions from study staff.
- Provide general information such as age, gender as well as relationship to the participant. Study partners will also be asked questions about the participant's health, memory, thinking function and emotional well-being in order to learn about changes in the participant.



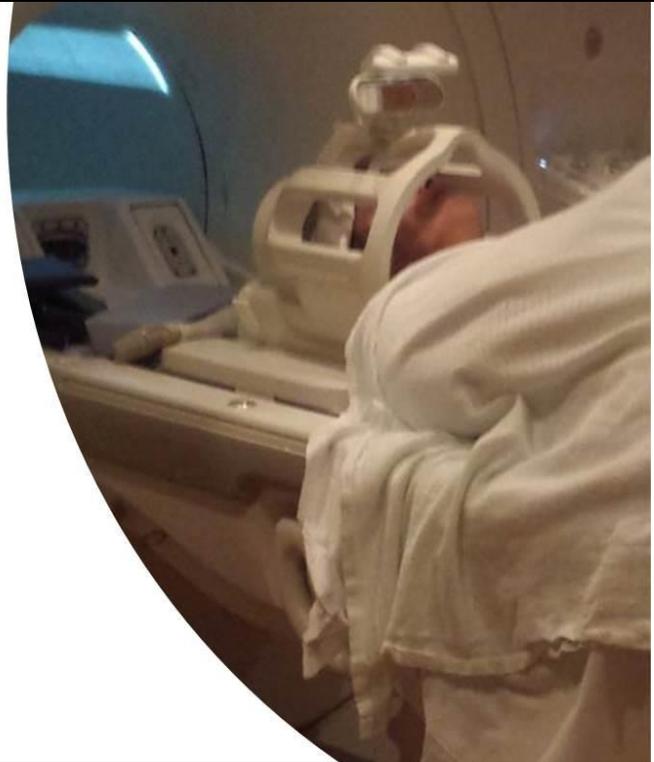
## Adventures and Challenges



## New Study Considerations: Possibilities vs. Challenges

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- Observational vs interventional study? Benefits vs. risks
- Distance from testing site. Should I move in order to participate?
- What if my current study partner isn't able to participate in a more demanding study?
- Should I participate in a study when I am no longer able to consent or able to work out the logistics? Another consideration: the time commitment.



## FULL EXPANDED LIST OF 2016 NAPA RECOMMENDATIONS

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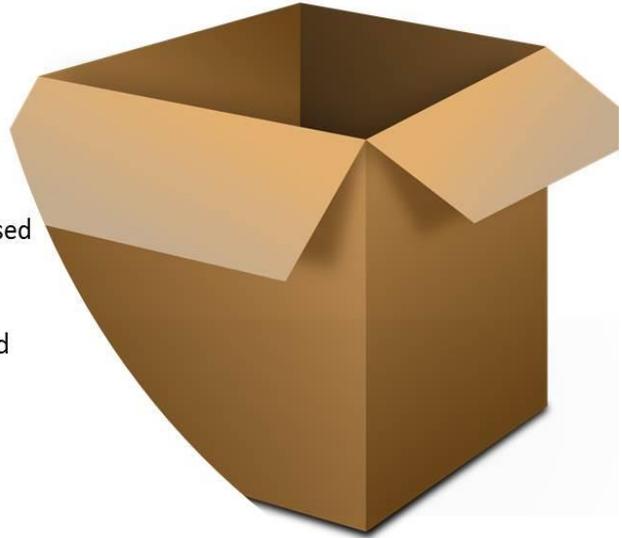
- A major area of emphasis for the 2017 National Plan should include the enhancement of recruitment efforts for randomized controlled trials for AD/ABRD
- A major challenge in the development of effective therapies for AD/ABRD has been the inefficient recruitment of participants in clinical trials.
- Emphasis should be placed on the enhancement of **diversity** and **inclusiveness** in these efforts.



## Think Outside the Box To Reduce Obstacles to Participation

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- Encourage PCP's to provide the newly diagnosed (and care partners) with information on the benefits of enrolling in clinical studies.
- Use faith communities to promote studies and host field research.
- Send researchers into the field (think Bookmobile).
- Provide vouchers for those in need to cover hotel, food and transportation costs.
- Promote non-familial study partners.



## Additional recommendations

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- Encourage Open House enrollment days at study sites (swabbing parties)
- Provide accommodations through technology
- Make appointment times convenient for PLWD and Study partner
- Develop outreach materials/education for diagnosing clinicians to help refer.



## References:

- For additional information on ADNI3, please visit <http://www.adni3.org/>
- For additional information on the AD-CARE Program at the University of Rochester in NY, please visit: <https://www.urmc.rochester.edu/alzheimers-care.aspx>
- For additional information on TrialMatch, please visit: [www. Alz.org/TrialMatch](http://www.Alz.org/TrialMatch) or call 800-272-3900



## January 26, 2018 -- Advisory Council Meeting #27

The meeting was held on Friday, January 26, 2018, in Washington, DC. The Research Subcommittee took charge of this meeting's theme, focusing on the process from targets to treatments. The Council heard speakers on the preclinical pipeline, the clinical trial pipeline, and the industry perspective. The meeting also included discussion of a driver diagram to guide the Council's future work, updates and a report from the October Care Summit, and federal workgroup updates. Material available from this meeting is listed below and is also available at <https://aspe.hhs.gov/advisory-council-alzheimers-research-care-and-services-meetings#Jan2018>.

Comments and questions, or alerts to broken links, should be sent to [napa@hhs.gov](mailto:napa@hhs.gov).

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### General Information

<b>Agenda</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Meeting Announcement</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Meeting Summary</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Public Comments</b>	<a href="#">[HTML Version]</a>

### Handouts

<b>Care Summit Report Themes</b>	<a href="#">[PDF Version]</a>
<b>NAPA Driver Diagram Draft Examples</b>	<a href="#">[PDF Version]</a>
<b>Outline for Care Summit Final Report</b>	<a href="#">[PDF Version]</a>

### Presentation Slides

<b>AbbVie's R&amp;D Vision for Alzheimer's Disease</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Care Summit Report</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Clinical Subcommittee Update</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Initiatives, Partnerships and Collaboration to Help Patients with the Highest Unmet Need: Dominantly Inherited Alzheimer's Disease Trials Unit (DIAN-TU) as a Case Example</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Long-Term Services and Supports Committee Update</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>

<b>NAPA Driver Diagram</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Overview of the Clinical Trial Pipeline for AD</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Overview on NIA Preclinical Pipeline</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Participating in an Alzheimer's Clinical Study: Perspectives on Involvement of a Person Living with Dementia and Her Study Partner</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Progress Since October</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Research Progress on Alzheimer's Disease and Related Dementias</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>
<b>Research Subcommittee Agenda: The Journey from Targets to Treatments</b>	<a href="#">[HTML Version]</a> <a href="#">[PDF Version]</a>

## **Videos**

<b>Updates since October meeting</b>	<a href="#">[Video]</a>
<b>NAPA Driver Diagram</b>	<a href="#">[Video]</a>
<b>Federal Updates</b>	<a href="#">[Video]</a>
<b>Public Comments</b>	<a href="#">[Video]</a>
<b>Research Subcommittee Agenda</b>	<a href="#">[Video]</a>
<b>Care Summit Update</b>	<a href="#">[Video]</a>

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