The National Institute on Aging (NIA) is convening an exploratory workshop to learn what gaps exist in current real-world data infrastructure, and what opportunities lie in expanding availability of real-world data sources for aging and Alzheimer’s Disease and Alzheimer’s Disease and Related Dementia (AD/ADRD) research. Specifically, researchers will highlight gaps and opportunities to:

1. Securely access health data (e.g., EMR, claims, genetics, etc.) from private data providers and academic institutions to gain insight on AD/ADRD disease trajectory
2. Identify opportunities for developing a platform for an AD/ADRD digital cohort that serves as a diverse recruitment pool (i.e., Recruitment as a Service) for clinical trials across NIA extramural divisions (e.g., drug trials, prevention trials, dementia care interventions)
3. Analyze sensitive RWD through secure cloud workspaces while protecting privacy of the study participants
4. Collaborate in partnerships with health care and community health providers to enable rapid drug trials (RDT) to launch embedded pragmatic clinical trials (RePCT) for improving care for older adults with multimorbidity, including dementia

In attendance will be stakeholders from the National Institutes of Health, private industry, academia, and NIA funded investigators who have first-hand knowledge of real-world data and its application. Presenters and discussants are charged with identifying and prioritizing gaps and opportunities that exist in current real-world data infrastructure that require further exploration to support aging and AD/ADRD research.

May 4, 2022 Agenda

Introduction:

10:30 AM Welcome Remarks and Charge
Richard Hodes
Director, National Institute on Aging
Session 1: Overview of Current Infrastructure

10:40 AM  

**Session Plenary Speaker**

Gaps and Opportunities in Current Real-World Data Infrastructure

**Atul Butte**  
Distinguished Professor  
Director, Bakar Computational Health Sciences Institute  
University of California, San Francisco  
Chief Data Scientist, University of California Health System

11:00 AM  

**RWD Infrastructure, the Alzheimer’s Association National Registry, and Opportunities for Improved Patient Outcomes**

**Maria Carrillo**  
Chief Science Officer  
Alzheimer’s Association

11:15 AM  

**Real-World Evidence in Alzheimer’s Disease: The ROADMAP Data Cube**

**Olin Janssen**  
Researcher  
Maastricht University

Questions speakers will address:

- Provide overview of current RWD infrastructure.
- Discuss lessons learned from the infrastructure.
- Describe current gaps in integration and utilization of real-world data infrastructure that could limit AD/ADRD research.

11:30 AM  

**Key Barriers to Clinical Trials for Alzheimer’s Disease**

**Niranjan Bose**  
Managing Director  
Health & Life Sciences Strategy  
Gates Ventures

11:45 AM  

**Panel Discussion**

*Moderator: Jennie Larkin*

- David Dore  
  Principal Scientist  
  Exponent
- Barbara Entwisle  
  Professor, Sociology  
  University of North Carolina
- Stephanie Monroe  
  Executive Director  
  African Americans Against Alzheimer’s

12:05 PM  

**BREAK**

**15-MINUTES**
### Session 2: Recruitment and Clinical Trial Uses of Real-World Data

**12:20 PM**  
**Session Plenary Speaker**  
**Overview of Possibilities of Real-World Data for Clinical Trials and Patient Experience**  
**Adrian F. Hernandez**  
*Duke Health Cardiology Distinguished Professor*  
*Executive Director, Duke Clinical Research Institute*  
*Vice Dean, Duke University School of Medicine*

**12:40 PM**  
**Race and Ethnicity in Real-World Data Sources**  
**Michelle E Tarver**  
*Deputy Director*  
*Office of Strategic Partnerships and Technology Innovation*  
*Program Director for Patient Science*  
*Digital Health Center of Excellence CDRH, FDA*

**Questions speakers will address:**
- When is a RWD approach useful?
- How can RWD be used to recruit diverse study participants?
- How can RWD impact the patient experience—risks and benefits?
- What limits the integration of RWD into AD/ADRD clinical trials?

**12:55 PM**  
**Recruitment for Alzheimer's Disease Prevention Trials**  
**Rema Raman**  
*Professor Neurology*  
*University of Southern California*

**1:10 PM**  
**Recruitment for Dementia Care Trials**  
**Vincent Mor**  
*Professor of Health Services, Policy & Practice*  
*PI, IMPACT Collaboratory*  
*Brown University*

**1:25 PM**  
**Panel Discussion**  
*Moderator: Marcel Salive*

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<thead>
<tr>
<th>Lead Discussant</th>
<th>Assistant Professor</th>
<th>Deputy Director</th>
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<tr>
<td>Malaz Boustani</td>
<td>Emily Largent</td>
<td>Corrie Painter</td>
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<tr>
<td>Professor of Aging Research</td>
<td>University of Pennsylvania</td>
<td>Count Me In</td>
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<td>Indiana University</td>
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<td>Broad Institute</td>
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**1:45 PM**  
**BREAK**  
**30-MINUTES**
Session 3: Secondary Data Uses of Real-World Data

2:15 PM

Session Plenary Speaker
Which Scientific Questions can be Answered with RWD?

Sebastian Schneeweiss
Professor of Medicine, Harvard Medical School
Chief, Division of Pharmacoepidemiology, Department of Medicine,
Brigham & Women’s Hospital

2:35 PM

RWD Linkages: Possibilities for NIA Longitudinal Studies
Maria Glymour
Professor and Program Director
University of California, San Francisco

Questions speakers will address:
- For which applications are RWD most or least useful?
- How can real-world data be used for AD/ADRD research?
- What gaps exist in the current RWD infrastructure that limit the achievement of research and industry goals?

2:50 PM

Using RWD for Identifying and Validating Drug Repurposing Candidates for AD/ADRD
Mark W. Albers
Assistant Professor of Neurology
Harvard Medical School
Wilkens Endowed Scholar
Massachusetts General Hospital

3:05 PM

Unification of Clinical Trial Data
Gabriel S. Eichler
VP and Head of Data, Data42
Novartis

3:20 PM

Panel Discussion
Moderator: Nina Silverberg
Julie Zissimopoulos
Lead Discussant
Associate Professor
University of Southern California
Kenneth Langa
Professor of Medicine
University of Michigan
Marina Sirota
Associate Professor
University of California, San Francisco

3:40 PM

BREAK
15-MINUTES
Session 4: Discussion on Infrastructure Gaps and Opportunities

3:55 PM
Invited Comments
CMS Perspective: Shari M. Ling & Steven Farmer
Shari M. Ling        Steven Farmer
Deputy Chief Medical Officer    Chief Strategy Officer

Sudhir Sivakumaran
Vice-President, Neuroscience Program, Critical Path Institute

Penny Dacks
Senior Director of Scientific Initiatives, The Association for Frontotemporal Degeneration

David Atkins
Director of Health Services Research and Development, VA

Russ Paulsen
Chief Operating Officer, Us Against Alzheimer’s

Mark A. Supiano
Chief, Division of Geriatrics, University of Utah School of Medicine
Board of Directors, American Geriatrics Society

Crystal M. Glover
Assistant Professor of Psychiatry and Behavioral Sciences, Rush Alzheimer’s Disease Center

4:30 PM
Invited Commenter Discussion: Building equitable real-world data infrastructure that addresses wide-ranging stakeholder needs
Moderators: Partha Bhattacharyya and Lisa Onken, NIA

Session 5: Closing Panel

5:00 PM
Closing Panel: Prioritizing Gaps and Opportunities for Using RWD in AD/ADRD Research
Moderators: Patricia Jones and Nadezda Radoja, NIA

Discussants:
Malaz Boustani    David Dore
Kenneth Langa    Marina Sirota
Julie Zissimopoulos

ADJOURN: 5:30 PM