



National Institute on Aging

Gaps and Opportunities for Real-World Data Infrastructure Stakeholder Workshop

May 4, 2022

Zoom Registration Link:

https://roseliassociates.zoomgov.com/webinar/register/WN_rhWyJDtYTd-60Te3LESVfA

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

Session 1**10:40 AM – 12:05 PM**

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*

11:30 AM

[Key Barriers to Clinical Trials for Alzheimer's Disease](#)*Niranjana Bose**Managing Director**Health & Life Sciences**Strategy**Gates Ventures***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.

11:45 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

Session 2
12:20 PM– 1:45 PM

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

Malaz Boustani

Lead Discussant

*Professor of Aging
Research*

Indiana University

Emily Largent

Assistant Professor

*University of
Pennsylvania*

Corrie Painter

Deputy Director

*Count Me In
Broad Institute*

1:45 PM

BREAK

30-MINUTES

Session 3:**Secondary Data Uses of Real-World Data**

Session 3
2:15 PM – 3:40 PM

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*

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
Wilkins 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
Research Scientist
Veterans Affairs*

Marina Sirota

*Associate Professor
University of
California, San
Francisco*

3:40 PM

BREAK**15-MINUTES****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?

Session 4: Discussion on Infrastructure Gaps and Opportunities

Session 4
3:55 PM – 5:00 PM

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

Session 5
5:00 PM – 5:30 PM

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
