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.
Session 1: Overview of Current Infrastructure

Atul Butte, MD, PhD is the Priscilla Chan and Mark Zuckerberg Distinguished Professor and inaugural Director of the Bakar Computational Health Sciences Institute (bchsi.ucsf.edu) at the University of California, San Francisco (UCSF). Dr. Butte is also the Chief Data Scientist for the entire University of California Health System, the tenth largest by revenue in the United States, with 20 health professional schools, 6 medical schools, 6 academic health centers, 10 hospitals, and over 1000 care delivery sites. Dr. Butte has been continually funded by NIH for 20 years, is an inventor on 24 patents, and has authored nearly 300 publications, with research repeatedly featured in the New York Times, Wall Street Journal, and Wired Magazine. Dr. Butte was elected into the National Academy of Medicine in 2015, and in 2013, he was recognized by the Obama Administration as a White House Champion of Change in Open Science for promoting science through publicly available data. Dr. Butte is also a co-founder of three investor-backed data-driven companies: Personalis (IPO, 2019), providing medical genome sequencing services, Carmenta (acquired by Progenity, 2015), discovering diagnostics for pregnancy complications, and NuMedii, finding new uses for drugs through open molecular data. Dr. Butte trained in Computer Science at Brown University, worked as a software engineer at Apple and Microsoft, received his MD at Brown University, trained in Pediatrics and Pediatric Endocrinology at Children’s Hospital Boston, then received his PhD from Harvard Medical School and MIT.

Maria Carrillo, PhD, is Chief Science Officer at the Alzheimer’s Association. Under her leadership, the Association is the world’s largest nonprofit funder of Alzheimer’s research and an internationally recognized pioneer in convening the dementia science community to accelerate the field. Dr. Carrillo helped form the Association’s National Treatment and Diagnostic Alzheimer’s Registry, a national database that will be designed to continuously collect clinical practice data from health care providers caring for patients diagnosed with AD who are taking an FDA-approved disease modifying treatment.

Olin Janssen is a neuropsychologist and will soon defend her PhD thesis ‘Novel perspectives from existing data on Early Alzheimer’s disease pathology and dementia care use’. For her thesis she re-used existing data, and included different data sources and data types raging from biomarker data to registry data. She is currently working as a researcher on the Amyloid Biomarker Study.
Niranjan Bose, PhD, is currently the Managing Director (Health & Life Sciences Strategy) at Gates Ventures LLC, where he serves as the Science Advisor to Mr. Bill Gates. Prior to joining Gates Ventures in August 2014, he was the Chief of Staff to the President of the Global Health Program at the Bill & Melinda Gates Foundation. He was with the Gates Foundation from 2007 through 2014, which included a few years with their Enterics and Diarrheal Diseases (EDD) program strategy team, where he was responsible for managing a portfolio of investments, which included clinical development of enteric vaccines (rotavirus, cholera, enterotoxigenic E coli and shigella). Areas of expertise include infectious diseases, vaccines, biotechnology market research, strategy, management, and global health.

David Dore, PhD, PharmD, is a pharmacoepidemiologist who specializes in studying the post-marketing safety and effectiveness of medical products as they are used in customary clinical practice. He has over 15 years of experience with regulated post-approval safety studies (PASS) conducted with secondary data sources (e.g., healthcare claims), and he has developed expertise in novel data linkages and supplementary data collection to address biases in these studies. Additionally, Dr. Dore specializes in the development and research applications of large electronic health records (EHR) systems, which typically include a myriad of data types from various health systems. Dr. Dore has been on the faculty at the Brown University School of Public Health since 2008.

Barbara Entwisle, PhD, focuses on social, natural, and built environments and their consequences for demographic and health outcomes, and her current research examines migration processes in relation to the life course, household dynamics, and community contexts in the US, Southern Africa, and Northeastern Thailand. Dr. Entwisle examines population-environment interactions, and has leveraged data and tools assembled as part of the Nang Rong (Thailand) project. Dr. Entwisle presented at the NIH Common Fund’s 2018 BD2K Behavioral and Social Sciences and Big Data Workshop, presenting on Behavioral and Social Science Insights for Big Data Research.

Stephanie Monroe, PhD, is Executive Director of African Americans Against Alzheimer’s, the first national network created specifically to respond to the disparate impact of Alzheimer’s on African Americans. By working nationally, locally, and through strategic partnerships, African Americans Against Alzheimer’s is raising awareness of the critical need to engage, connect, and mobilize to advance our national commitment to ending Alzheimer’s by 2025. One of the primary focuses of the network is a community-based initiative that works at the grass roots level to bring Alzheimer’s out of the shadows, dispel myths about the disease symptoms, and encourage greater participation in clinical research designed to more effectively prevent, treat, and eventually cure this dreaded disease.
Session 2: Recruitment and Clinical Trial Uses of Real-World Data

Adrian Hernandez, MD, MHS, is Executive Director, Duke Clinical Research Institute, and Vice Dean of the Duke University School of Medicine. Dr. Hernandez received his medical degree from the University of Texas-Southwestern Medical Center in Dallas. He completed his residency training in internal medicine at the University of California in San Francisco. Dr. Hernandez completed his fellowship in cardiology at Duke University Medical Center Cardiology in Durham, NC, as well as his MHS.

Dr. Hernandez has research interests in improving cardiovascular health and accelerating clinical evidence through outcomes research, clinical trials, comparative effectiveness and health policy. Dr. Hernandez is a member of the American Society for Clinical Investigation and American Association of Physicians. He had led multiple large-scale patient-centered research programs, registries and clinical trials aimed at improving health across multiple conditions such as NIH’s Health System Collaboratory and PCORI’s PCORnet resulting in more than 700 peer-reviewed publications.

Michelle Tarver, MD, PhD, is the Deputy Director of the Office of Strategic Partnerships and Technology Innovation where she helps provide leadership for all scientific collaborative and emerging technology-related activities at the Center for Devices and Radiological Health (CDRH). Her office houses the Digital Health Center of Excellence which provides leadership to FDA on all matters related to digital health technologies. Under her leadership, the office is advancing efforts to include diverse and underrepresented perspectives in the evaluation of medical devices through the Health of Women program and the Pediatric and Special Populations program. Dr. Tarver provides strategic vision for collecting, analyzing and integrating the patient perspective in the development, evaluation and surveillance of medical devices, including digital health technologies. She leads collaborative efforts in fostering the development and evaluation of innovative medical devices that can address unmet public health needs.
Rema Raman, PhD, is a Professor of Neurology at Keck School of Medicine of the University of Southern California (USC) and the Director of Biostatistics and Recruitment at the USC Alzheimer’s Therapeutic Research Institute (ATRI). She is the lead of the Biostatistics Unit and the co-lead of the Recruitment Unit for the Alzheimer’s Clinical Trials Consortium (ACTC). Dr. Raman has focused her academic career in the design, conduct and analysis of clinical trials in neurology. Her primary statistical research interests are in correlated and missing data issues, design and analysis of efficient clinical trials and cohort studies, centralized and adaptive statistical monitoring approaches, recruitment and retention science and effective safety monitoring. Dr. Raman is co-director of the Institute of Methods and Protocols for Advancement of Clinical Trials in ADRD (IMPACT-AD), and the co-Chair of the ACTC Inclusion, Diversity and Education in Alzheimer’s disease Clinical Trials (IDEA-CT) committee.

Vincent Mor, PhD, has been Principal Investigator of over 40+ NIH funded grants focusing on the use of health services and the outcomes frail and chronically ill persons experience. He was recipient of a Robert Wood Johnson Foundation health policy investigator award and a MERIT award from the National Institute on Aging and is a member of the National Academy of Science Engineering and Medicine. He has evaluated the impact of programs and policies in aging and long-term care including Medicare funding of hospice, changes in Medicare nursing home payment and the introduction of quality measures. Dr. Mor was part of a team of researchers that developed and validated risk adjusted quality indicators for nursing homes and was the first to integrate Medicare claims and mandated clinical assessments into a research data base. This data resource is at the heart of the NIA funded Program Project Grant, "Changing Long Term Care in America” now in its third renewal and became the basis for a series of large, pragmatic cluster randomized trials of novel nursing home-based interventions. Dr. Mor is one of the PI's of the NIA funded Cooperative Agreement, the IMPACT Collaborative, designed to grow the field of investigators and health care systems undertaking pragmatic clinical trials designed to improve the lives of persons living with dementia and their care partners.

Malaz Boustani, MD, is a geriatrician, a neuroscientist, and implementation scientist with a goal of using insights from behavioral economics, complexity science, and network science to develop, implement and distribute an innovative, sustainable and scalable “Blue Print” of the 21st Century learning Academic healthcare delivery system. Dr. Boustani built a Clinical Aging Brain Care Learning Laboratory across two health care systems in Indiana; Indiana University Health, a statewide system that include 17 hospitals; and Eskenazi Health, a safety net health system serving the need of the underprivileged Marion County residents in Indianapolis. Through Dr. Boustani’s Clinical Laboratory, he led numerous observational and clinical trials studies totaling more than $70 million of funding from the NIH, AHRQ, and CMS.
Emily Largent, JD, PhD, RN, is the Emanuel and Robert Hart Assistant Professor of Medical Ethics and Health Policy. She holds a secondary appointment at Penn Law, is a Senior Fellow at the Leonard Davis Institute of Health Economics, and is affiliated with the Center for Health Incentives and Behavioral Economics. Dr. Largent’s work explores ethical and regulatory aspects of human subjects research and the translation of research findings into care with a particular focus on Alzheimer’s disease. In 2020, Dr. Largent was named a Greenwall Faculty Scholar; her faculty scholar project, “Autonomy on the Precipice of Cognitive Decline,” seeks to understand how our evolving understanding of Alzheimer’s disease affects patients and their families.

Corrie Painter, PhD, is the Deputy Director of Count Me In and is a research scientist at the Broad Institute of MIT and Harvard. A trained cancer researcher with a Ph.D. in biochemistry, she completed her postdoctoral work in cancer immunology, focusing on melanoma. In 2010, Painter was diagnosed with angiosarcoma. She has combined her cancer advocacy and scientific background to engage with patients in order to build and carry out patient-partnered genomics studies. She is also the co-founder of Angiosarcoma Awareness Inc.

Session 3: Secondary Data Uses of Real-World Data

Sebastian Schneeweiss, MD, ScD, is a Professor of Medicine and Epidemiology at Harvard Medical School and Chief of the Division of Pharmacoepidemiology in the Department of Medicine, Brigham and Women’s Hospital.

His research focuses on assessing the effectiveness and safety of biopharmaceuticals in clinical practice. He has developed analytic methods to improve the accuracy of estimating causal treatment effects of new drugs using complex digital healthcare databases. His work is published in >500 articles and is used for regulatory and coverage decision making around the globe. He is funded by NIH, PCORI, Burroughs Wellcome Fund, and FDA where he is also a voting consultant. He is Principal Investigator of the FDA Sentinel Innovation Center and co-leads the RCT-DUPLICATE initiative to understand when and how real-world evidence studies can reach causal conclusions to support regulatory and HTA submissions.
Maria Glymour, ScD, MS, research focuses on how to evaluate modifiable determinants of healthy aging experienced across the life course, with an emphasis on stroke and dementia risk. The challenges of disentangling causality from non-causal associations—an essential task to promote public health and health equity—have long been recognized. The last three decades of research methods, along with emerging data sources and growing computational power offer new opportunities. Dr. Glymour’s work seeks to harness these opportunities, especially in research evaluating social determinants of health, such as education, work, or income.

Dr. Maria Glymour  
Professor, Epidemiology & Biostatistics  
University of California, San Francisco

Mark W. Albers, MD, PhD, is a neurologist specializing in memory and olfactory disorders. His laboratory research focuses on elucidating the mechanisms of neurodegeneration, identifying novel drug targets that mediate neurodegeneration, and developing therapies to prevent neurodegeneration. He is leading a drug repurposing effort using real world data from Boston-based and UK-based electronic health record databases by emulated target trials, and he is the overall PI of the NADALS trial, the first basket trial in neurodegenerative disease. This drug repurposing trial will test the FDA-approved drug, baricitinib, in patient populations with either Alzheimer’s disease or ALS.

Dr. Mark W. Albers  
Assistant Professor of Neurology  
Harvard Medical School  
Wilkens Endowed Scholar, Dept. of Neurology  
Massachusetts General Hospital

Gabriel S. Eichler, PhD, is the VP and Head of Data for Novartis’s enterprise-wide R&D & Real-World data unification project, Data42. Dr. Eichler and his team are responsible for building the robust data infrastructure to seamlessly unify dozens of source systems inside and outside of Novartis with data42’s data lake. His team also oversees all semantics and other data policy-related activities of data42. Other roles he has played include as the Founder and Managing Director of Oak Health Partners, and has served as Data & Analytics lead at the Harvard Business School’s Kraft Precision Medicine Accelerator, VP of Products at GNS Healthcare and General Manager at PatientsLikeMe.

Dr. Gabriel S. Eichler  
VP & Head of Data, Data42  
Novartis

Julie M. Zissimopoulos, PhD, is Associate Professor at the University of Southern California, and Director of the Aging and Cognition Research Program and the Research Training Program at the Schaeffer Center for Health Policy and Economics. Dr. Zissimopoulos also directs multiple programs focused on reducing burden of Alzheimer’s disease and funded by the National Institute on Aging (NIA). Dr. Zissimopoulos’ current research focuses on economic costs of dementia, impacts of dementia on care partners, the use of and response to drug therapies for non-dementia conditions that influence risk of dementia, racial and ethnic disparities in diagnosis and health care treatment for dementia, and population measures of dementia using Medicare claims and survey data.

Dr. Julie Zissimopoulos  
Associate Professor  
PI, Center for Advancing Sociodemographic and Economic Study of ADRD and USC RCMAR  
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Kenneth Langa, MD, PhD, is the Cyrus Sturgis Professor in the Department of Internal Medicine and Institute for Social Research, a Research Scientist in the Veterans Affairs Center for Clinical Management Research, and an Associate Director of the Institute of Gerontology, all at the University of Michigan. He is Associate Director of the Health and Retirement Study (HRS), a National Institute on Aging funded longitudinal study of 20,000 adults in the United States. Dr. Langa is also Co-PI of the Harmonized Cognitive Assessment Protocol (HCAP) Network, whose goal is to develop international data resources for the study of Alzheimer’s Disease and Alzheimer’s Disease Related Dementias. Dr. Langa’s research focuses on the epidemiology and costs of chronic disease in older adults, with an emphasis on Alzheimer’s disease and other dementias.

Marina Sirota, PhD, is an Associate Professor at the Bakar Computational Health Sciences Institute at UCSF. Dr. Sirota’s research interests lie in developing computational integrative methods and applying these approaches in the context of disease diagnostics and therapeutics. Her primary focus is on leveraging and integrating different types of omics and clinical data to better understand the role of the immune system in disease. The Sirota laboratory is funded by NIA, NLM, NIAMS, Pfizer, March of Dimes and the Burroughs Welcome Fund. As a young leader in the field, she has been awarded the AMIA Young Investigator Award in 2017. Dr. Sirota also is the director of the AI4ALL program at UCSF, with the goal of introducing high school girls to applications of AI and machine learning in biomedicine.

Session 4: Discussion on Infrastructure Gaps and Opportunities

Shari M. Ling, MD, is the Centers for Medicare and Medicaid Services (CMS), Deputy Chief Medical Officer serving in the Center for Clinical Standards and Quality (CCSQ), responsible for assisting the CMS Chief Medical Officer in the Agency’s pursuit of higher quality health care, healthier populations, and lower cost through quality improvement. Dr. Ling's long-standing focus is on the achievement of meaningful health outcomes through delivery of high-quality beneficiary-centered care across all care settings, with a special interest in the care of persons with multiple chronic conditions and functional limitations, and reducing health disparities. Dr. Ling continues to serve as a part-time faculty member in the Division of Geriatric Medicine and Gerontology at Johns Hopkins University School of Medicine, and in the Division of Rheumatology, Allergy and Clinical Immunology at the University of Maryland.
Steven Farmer, MD, serves as Chief Strategy Officer in the Coverage and Analysis Group (CAG) at the Centers for Medicare & Medicaid Services (CMS). He joined CMS in 2017 as a Senior Advisor in the Center for Medicare and Medicaid Innovation where he assisted with development and refinement of value-based payment programs, with a particular emphasis on the Bundled Payments for Care Improvement Advanced model. He moved to the Coverage and Analysis group in 2019 where he leads an effort to streamline and accelerate evidence-based coverage policy development. He is a practicing non-invasive cardiologist.

Sudhir Sivakumaran, PhD, serves as the Vice President of the Neuroscience Program and Executive Director of the Critical Path for Alzheimer’s Disease (CPAD) consortium at The Critical Path Institute (C-Path). Dr. Sivakumaran oversees the overall strategic planning, management and execution of the objectives and goals of the Neuroscience Program and the individual consortia. Dr. Sivakumaran also leads the C-Path Industry Data Sharing Initiative aimed at acquisition and management of CDISC standardized high-relevance clinical trial and observational study datasets in Alzheimer’s disease. Together with the Quantitative Medicine Program, the Data Collaboration Center at C-Path, Dr. Sivakumaran leads efforts in the generation of novel regulatory-endorsed drug development tools (DDTs) by fostering relationships and engagement with industry, regulatory agencies (FDA, EMA), academia and patient advocacy organizations.

Penny Dacks, PhD, serves as AFTD’s Senior Director of Scientific Initiatives, leading strategy for AFTD’s research programs. She also serves as President of the FTD Disorders Registry, LLC on behalf of AFTD. Previously, she worked at the American Epilepsy Society, overseeing mission-related programs in research, medical education, and clinical activities. Before that she spent five years at the Alzheimer’s Drug Discovery Foundation, where she led development of CognitiveVitality.org and the Aging & Alzheimer’s Prevention Program to source and evaluate potential therapies. She trained in neuroscience at the University of Arizona and the Mount Sinai School of Medicine, Mount Sinai.

David Atkins, MD, MPH, has been Director of VA’s Health Services Research and Development (HSR&D) Service since 2013. In this role, he oversees a $120 million intramural health services research program aimed at improving the health of and care for 6 million Veterans receiving VA care. Under Dr. Atkins, HSR&D has moved to a research model that emphasizes close partnership with clinical and policy stakeholders within VA, in addition to a focus on translating research findings into broader implementation in a learning healthcare system. This effort has built on the HSR&D network of Centers of Innovation (COINS), new Consortia of Research (CORes) that bring researchers together in priority areas of Suicide, Virtual Care, Pain/Opioids and Care in the Community, a Research in Residence program that places researchers in clinical program offices, and an Evidence Synthesis Program producing a variety of evidence products for clinical and research use.
Russ Paulsen, MA, is a nationally recognized nonprofit leader and innovator. Under his leadership, a series of nonprofit programs and teams have saved hundreds of lives, helped rebuild and heal communities across the nation, and brought cutting-edge technology to public health and human services. Paulsen joined UsAgainstAlzheimer’s as chief operating officer in 2019. Since then, the organization built a web and telephone platform that delivers information tailored to where a specific user is on their Alzheimer’s journey; received its first-ever funding from the Centers for Disease Control and Prevention; and assembled a 100-organization coalition to set a national Alzheimer’s risk-reduction goal.

Mark A. Supiano, MD, AGSF, holds the D. Keith Barnes, M.D. and Dottie Barnes Presidential Endowed Chair in Medicine and is Professor and Chief of the Geriatrics Division in the University of Utah School of Medicine. In addition, he is the Executive Director for the University of Utah Center on Aging. He is a practicing board-certified geriatrician who has conducted patient-oriented research studies in older adults for more than 30 years. His research is focused in geriatric hypertension and the age-related physiological changes in the vascular system that contribute to the age-related increase in blood pressure, such as arterial stiffness, that are known to predict cognitive impairment. He currently is a member of the Systolic Blood Pressure Intervention Trial’s (SPRINT-MIND) Cognitive Outcome Adjudication Committee. He is also a member of the Steering Committee for the NIA clinical trial, “PRagmatic EValuation of eVEnTs And Benefits of Lipid-lowering in oldeR Adults” (PREVENTABLE; U19AG065188). This pragmatic trial is enrolling 20,000 people age 75 years and older to determine the role of a moderate-intensity statin in preventing dementia and prolonging disability-free survival as the trial’s primary outcome. He serves as the Chair of the trial’s Geriatrics Outcomes Assessment Subcommittee that developed and will be evaluating the trial’s cognitive and functional outcome measures. He has held many leadership positions in the American Geriatrics Society, and currently is a member of its Board of Directors.

Crystal M. Glover, PhD, is a social psychologist and mixed-methodologist at the Rush Alzheimer’s Disease Center and serves as an Assistant Professor of Psychiatry and Behavioral Sciences in Rush Medical College, and as Leader of the Outreach, Recruitment, and Engagement Core at the Rush Alzheimer’s Disease Research Center. Her areas of interest include health equity and health disparities; structural and psychosocial determinants of health; intersectionality as a conceptual framework and methodology; and social cognitive processes. She focuses on cognitive and healthy aging in inequitably included and understudied communities, such as African American/Black adults and Hispanics/Latinos. Dr. Glover has widely published her work in peer-reviewed scientific journals and presented her research at international and national scientific meetings.