

Tribal Consultation on the National Institute on Aging (NIA) Real-World Data (RWD) Platform

Friday, January 5, 2024 | 2:00 p.m. – 4:00 p.m. EST

This document provides an overview for Tribal leaders and community members as background for participation in the upcoming National Institutes of Health (NIH) **Tribal Consultation on the NIA Real-World Data Platform** on **January 5, 2024, at 2:00 pm EST**. Please register for the Consultation [here](#).

NIH Mission

The NIH mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

- NIH invests most of its \$45 billion budget¹ in medical research for the American people.
- NIH invested \$3.51 billion in Alzheimer's and related dementias research in 2022.²
- More than 80% of NIH's funding is awarded through almost 50,000 competitive grants to more than 300,000 researchers at greater than 2,500 universities, medical schools, and research institutions in every state.
- About 10% of the NIH's budget supports projects conducted by approximately 6,000 scientists in its own laboratories, most of which are on the NIH campus in Bethesda, Maryland.
- Located in Bethesda, Maryland, the NIH is a component of the U.S. Department of Health and Human Services and is composed of the Office of the Director and 27 Institutes and Centers, many of which have an organ- or disease-specific focus. The Office of the Director is the central office at NIH and is responsible for setting policy for NIH and for planning, managing, and coordinating the programs and activities of all the NIH components.

Purpose of Consultation

The purpose of this consultation is to foster ongoing collaboration and seek input about ways to include and share data between American Indian/Alaska Native (AI/AN) Tribes and communities and Alzheimer's and related dementias researchers as part of the NIA Real-World Data Platform, while honoring Tribal sovereignty and Tribal data ownership. Input from this consultation will be used to inform and shape development and planning of the Platform, with the goal of making sure that findings that may help improve outcomes for people with dementia and their families are applicable to AI/AN Tribes and communities.

¹ Based on historical distribution of actual FY 2021 obligations across extramural and intramural mechanisms that comprise the annual NIH budget.

² NIH Research Portfolio Online Reporting Tools (2023). *Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)*. <https://report.nih.gov/funding/categorical-spending#/>

Alzheimer's Disease and Other Dementias

There are many gaps in the scientific community's understanding of Alzheimer's Disease and other dementias. The trajectory of these diseases begins many years before symptoms start to appear. This makes it difficult to untangle the many biological, clinical, behavioral, and environmental factors that may contribute to dementia's onset. It also presents challenges for identifying and evaluating effective interventions. Moreover, there are persistent health disparities in the likelihood of developing some form of dementia and its prevalence among several communities, including AI/AN as compared to whites. A recent study estimated that 23% of AI/AN Medicare beneficiaries 65 and older may have dementia compared with 12% of their White counterparts.³ Furthermore, between 2014-2060, the number of AI/ANs aged 65 and older living with dementia is projected to grow over five times.⁴ To date, many of the studies and clinical trials examining dementia do not include individuals who adequately represent the populations experiencing disproportionately high rates of the disease.

Scientific advancement is needed to develop effective interventions to diagnose, delay, prevent, and treat dementia and to better understand the risk factors. Transforming the dementia research enterprise requires addressing some of its most widespread and costly problems: a) lack of data accessibility; b) lack of representation of historically marginalized groups among the research leadership teams; and c) links between complementary data sources that capture information from larger, more inclusive, and representative populations who are participating in research funded by NIA. Data accessibility is particularly important for aging and dementia research because data sufficient to answer pressing scientific questions cannot be captured solely through one discrete data source due to: (1) dementia's unique ethical considerations, particularly where smaller communities of AI/AN people may have a greater risk of their personal identifying information (PII) being disclosed and concerns related to respecting Tribal data ownership and sovereignty⁵ (2) insufficient understanding of if and how dementia can be prevented and when prevention interventions must begin; and (3) the long duration of care typically required by Alzheimer's Disease and related dementias. A central platform for data access would help researchers evaluate therapeutic treatments and behavioral interventions more rapidly, at lower cost, and help to assure that findings are applicable to more people, by potentially developing more effective community-level interventions or by personalizing therapeutic plans that take into account multiple individual factors.

Real-World Data

Real-world data is data relating to patient health status and/or the delivery of health care from a variety of sources that are collected in the context of the routine delivery of care such as

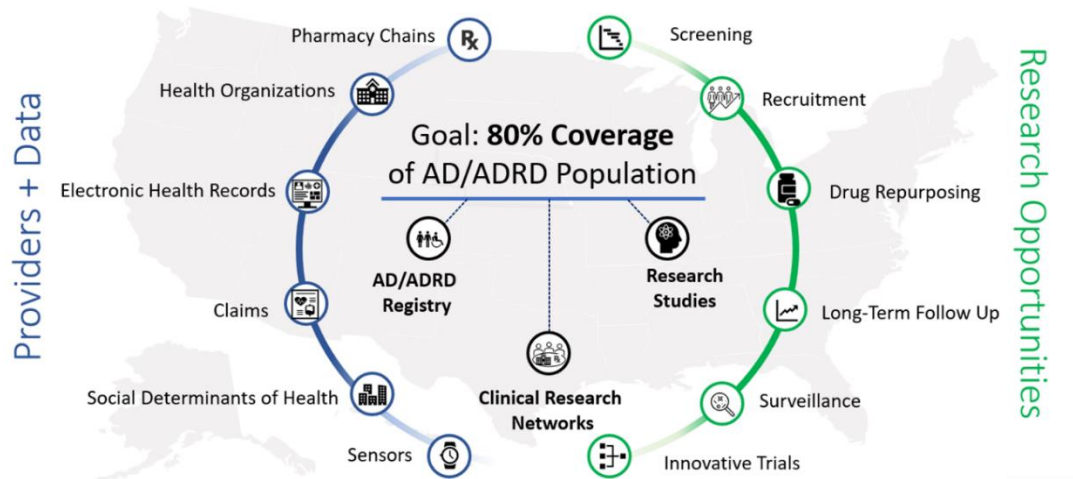
³ Moon HE, Kaholokula JK, MacLehose RF, Rote SM. Prevalence of dementia in American Indians and Alaska Natives compared to White, Black, and Hispanic Medicare Beneficiaries: Findings from the National Health and Aging Trends Study. *J Racial Ethn Health Disparities*. 2023;10(4):1527-1532. doi:10.1007/s40615-022-01338-y

⁴ Alzheimer's Association and Centers for Disease Control and Prevention. *Healthy Brain Initiative: Road Map for Indian Country*. <https://www.cdc.gov/aging/healthybrain/pdf/executive-summary-road-map-for-indian-country-508.pdf>

⁵ One example is Arizona State University researchers' use of blood samples from the Havasupai Tribe outside of what was agreed to in the consent process. In Mello MM & Wolfe LE. The Havasupai Indian Tribe case – Lessons for research involving stored biologic samples. *N Eng J Med* 2010(363)204-207. doi: 10.1056/NEJMp1005203

electronic health records; claims and billing data; patient-generated data in home-use settings; and data generated and collected from mobile devices and wearables (see Figure 1 below). Real-world data for healthcare research can be used to reduce research costs and participant burden while increasing research efficiency. It may also lead to the development of high-impact, scalable interventions that can be rapidly tested within a few months to a few years (instead of decades) to improve health outcomes for older adults, persons with dementia, and their families.

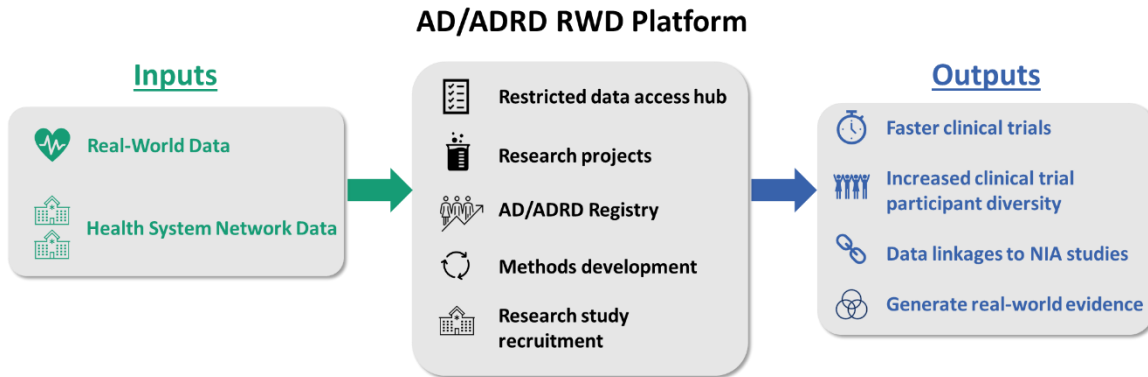
Figure 1– Overview of Platform Data Types and Research Opportunities



NIA Real-World Data Platform

NIA is in the process of planning for the development of the NIA Real-World Data Platform. The Platform will be a hub for real-world data representing 70%-90% of the total U.S. population, including those at risk of developing dementia, and approximately 80% of people living with dementia, providing a data resource to dementia researchers. Privacy-preserving linkages between real-world data sources and health system network data sources will help address the dementia research enterprise’s most widespread problems outlined above, which will aid in the development of interventions that are applicable to all people, including groups that are historically underrepresented in research. Figure 2 below depicts an overview of the data going into the Platform, the tools and capabilities it enables, and its potential research benefits.

Figure 2 – Platform Overview



Data for this initiative will be stored in three locations. First, private real-world datasets purchased for the Platform will be uploaded to a single, centralized longitudinal data warehouse. Second, a federated data environment will facilitate secure linkages between the centralized data warehouse and multiple research studies. In this type of environment, data are stored in multiple geographic locations rather than a single, centralized location. Third, a federally-approved Authority to Operate⁶ enclave existing outside the Platform will facilitate linkages between Platform data and Centers for Medicare and Medicaid Services data (and potentially other federal data sources).

NIA requires submitted applications for this initiative to have a plan for developing data access, privacy, and governance procedures. Applications must address how prospective researchers will gain access to the Platform with appropriate Institutional Review Board (IRB) and security oversight. They must also specify how data requests and access will be fulfilled, monitored, and terminated, and must provide only the minimum data necessary to complete their IRB-approved study. Applications must also outline a plan to continually engage with a wide range of communities in addressing data privacy, consent, and ethical issues and incorporate feedback into the Platform’s development.

In addition to outlining privacy-preserving requirements, applications must have a plan to minimize health disparities and serve communities that have been historically underrepresented in research. Applications must define strategies to facilitate more inclusive and diverse clinical trial recruitment via the Platform; strategize, execute, and evaluate ways to continually improve the representativeness of the population in the Platform; and facilitate research examining health disparities within populations with Alzheimer’s and other dementias.

AI/AN Data Sovereignty

An initiative of this type and scope requires careful consideration of the ethical collection and use of data. While applications for this initiative are required to have plans to make data private and secure, NIA also wants to ensure the Real-World Data Platform respects Tribal and AI/AN data sovereignty. During this consultation, NIA seeks your input on how to shape the Platform’s ability to secure and share data collected on AI/AN people.

⁶ This refers to security standards for information systems outlined in the Federal Information Security Management Act. See <https://security.cms.gov/learn/authorization-operate-ato> for more details.

Suggested questions for representatives of various AI/AN populations to consider:

- How should AI/AN data be collected, stored, and shared responsibly for Alzheimer's disease and related dementias research?
- How should NIA approach communication, outreach, engagement, and long-term inclusion and sustainable involvement in clinical research and trials?
- How would AI/AN communities want to be involved in data governance and access?
- How can the Real-World Data Platform team build and sustain meaningful partnerships with representatives of AI/AN communities?
- How should NIA approach data stewardship and governance for rural, urban, or non-reservation dwelling individuals who self-identify as AI/AN?

Additional Resources

- NIA Workshop Report: Gaps and Opportunities for Real-World Data Infrastructure
https://www.nia.nih.gov/sites/default/files/2022-09/workshop_report_nia-real-world-data-workshop.pdfhttps://www.nia.nih.gov/sites/default/files/2022-09/workshop_report_nia-real-world-data-workshop.pdf
- Memory Loss and Alzheimer's Disease in Native People
<https://alz.org/media/Documents/Memory-Loss-and-Alzheimer-s-Disease-in-Native-People.pdf>
- Still Here (video)
<https://vimeo.com/279478897/788d394e8f>