

Alzheimer's Association Funding Program for Global Real-World Data Platforms (ALZ-RWD)

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1. Program Objective

The collection of Real-World Data (RWD) is integral to the discovery, evaluation and evolution of novel avenues for the diagnosis, prevention, treatment and care of Alzheimer's and other dementia. Furthermore, RWD can play a key role in the identification and understanding of health disparities, and the subsequent development and implementation of initiatives to advance health equity.

Real world data (RWD) platforms house data on patient health status and health care collected within real-world settings. To support the advancement of and opportunities for RWD platforms, the Alzheimer's Association is launching a peer-reviewed funding program to augment and accelerate global initiatives aimed at developing, expanding and aligning RWD platforms' infrastructure, data and impact.

2. Program Overview

In late 2021, the Alzheimer's Association launched the Alzheimer's Network for Treatment and Diagnostics ([ALZ-NET](#)) to connect clinical data from Alzheimer's patients to a network of medical professionals and researchers to encourage robust information sharing and education, and to drive innovation in the ways we care for and treat Alzheimer's disease and other dementia. To build on the global momentum in this field, the ALZ-RWD funding program aims to advance RWD by providing funds to develop, expand, and align RWD platforms' infrastructure, data and impact globally.

Potential projects will differ depending upon the specific aims and stage of development of the individual RWD platform. Eligible projects should relate to the following areas of focus, but other projects will be considered:

- Platform development (e.g., feasibility studies)
- Platform expansion (e.g., the addition of modules to existing platforms in order to collect RWD on newly-approved treatments)

- Platform utilization (e.g., site start-up payments to incentivize platform utilization, or the production of educational materials)
- Data collection (e.g., the addition of remote data collection or biomarker assessments, salaries for technical staff)
- Data integration and linking (e.g., with electronic health records)
- Data analysis and publication (e.g., research studies)

For all applications, priority will be given to proposals that enhance harmonization and collaboration across global platforms and have the potential to advance health equity (e.g., support ensures that a platform's population is representative of a defined community).

3. Funding and Award Period

The Alzheimer's Association has allocated up to USD \$5,000,000 to fund the ALZ-RWD Program over the next three years, and will accept submissions on a rolling basis.

As the scope and duration of funding will differ with each individual application, it is anticipated that funding will range from USD\$100,000 up to a maximum grant amount of USD\$1,000,000. Project duration is 12-24 months. Each RWD platform is limited to one unique award through this program's first iteration; with potential for follow-on funding.

Awarded projects will be evaluated on progress toward specific milestones; continued disbursement of funds is dependent on demonstrated progress toward key milestones.

Allowable costs under this award include:

- IT and related costs for platform establishment or expansion, including data access related fees
- Computer software if used strictly for data collection and/or analysis.
- Salary for the principal investigator, scientific (including postdoctoral fellows) and technical staff (including modest administrative support).
- Research supplies needed for the proposed studies.
- Support for travel to scientific and professional meetings, not to exceed \$5,000 over a two-year period.
- Open access publications fees.

Not allowable as direct costs under this award include:

- Computer hardware or standard software (e.g. Microsoft Office, mouse monitor, computer parts)
- Laboratory equipment such as freezers, ultracentrifuges, RT-PCR, Microscopy/imaging equipment
- Service contract fees of equipment
- Construction or renovation costs
- Tuition
- Rent for laboratory/office space
- Expenses such as Data Network Recharges and Computing and communication device support services
- General liability insurances, such as GAEL
- Wire and currency exchange fees

- Salary and/or compensation for Alzheimer’s Association Staff or current members of the Alzheimer’s Association Medical and Scientific Advisory Group (MSAG) and the International Research Grant Program (IRGP) Council. A complete list of MSAG and IRGP Council members can be found on our website alz.org/grants.

No indirect costs are allowed.

4. Eligibility

In order to be eligible for ALZ-RWD funding, proposals must

- Support the infrastructure, data and / or impact of a RWD platform that
 - Has, or plans to have, international, national or significant regional reach
 - Houses, or aims to house, data collected in real-world settings on patient health status and healthcare; including, for example, data from patient surveys, electronic health records (EHRs), administrative claims, digital health technologies and / or other sources
 - Comprises a physician or patient registry, or a cohort study; clinical trial databases are not eligible for this funding program
- Enhance alignment and collaboration between global platforms, including with ALZ-NET
 - Please note, the Association requires data sharing / connection (in line with international sharing laws) through GAAIN (gaain.org)
 - The ALZ-RWD funding program aims to complement ALZ-NET International - an initiative of the Alzheimer’s Association to convene global RWD platforms. Interested applicants are encouraged to email Claire Sexton (csexton@alz.org) for the latest information on activities and opportunities prior to any application
- Have the potential to advance health equity
 - For example, by ensuring that the platform’s population is representative of a defined community
- Include a Principal Investigator who is a full-time faculty member or full-time paid employee of the organization submitting the proposal.

Note: Investigators that have received Alzheimer’s Association funding for a related or other study and are currently delinquent in submitting required reports or have awards closed as “Incomplete” are not eligible to apply. For questions about eligibility, please contact the Alzheimer’s Association at grantsapp@alz.org and note that you are seeking clarification regarding the ALZ-RWD program eligibility.

Alzheimer’s Association grants are generally open to scientists and researchers across the globe; however, as a U.S.-based charity, the Alzheimer’s Association is subject to, and complies with, U.S. law. As a result, the Alzheimer’s Association cannot award, and will not award, grants in violation of applicable U.S. statutes and regulations. This means, among other things, that the Alzheimer’s Association cannot, and will not, fund any individual or entity (i) that is subject to U.S. comprehensive or targeted sanctions or if awarding funding would result in a violation of such sanctions, (ii) that is on the U.S. List of Specially Designated Nationals or entities owned or controlled by such persons, or (iii) when doing so is otherwise prohibited by U.S. laws related to combating terrorism.

5. Overview of Submission and Review Criteria

5.1. Summary

Pre-submission inquiries are welcome at any time and will be reviewed by the Alzheimer's Association with appropriate experts to evaluate the eligibility, feasibility, and potential impact of a proposal. Successful pre-submission inquiries will be invited to submit a full application, with deadlines discussed with applicant PI. Full applications will be reviewed by an expert group and panel for consideration to make recommendations to the Alzheimer's Association

If a submission is not accepted, the application is allowed up to two resubmissions.

5.2. Pre-Submission Inquiries

Pre-submission inquiries are welcome at any time via the [Pre-Submission Inquiry Survey](#), which collects information on

- The applicant team (PI, team, expertise)
- The RWD platform (name; country; status; brief descriptions of the platform, population and data sources; goals; team)
- The funding request (overview; brief descriptions of how support will have the potential to advance health equity and enhance alignment and collaboration between global platforms; current and potential sources of funding)
- Other relevant information.

5.3. Full Applications

For those invited to submit a full application, additional materials will be required. Templates, instructions and application deadlines will be provided after approval of the pre-submission inquiry.

5.4. Review Criteria

Applications will be reviewed by the Alzheimer's Association and a select panel of experts with special attention to:

- RWD platform infrastructure and data
 - Evaluation of the data sources (physician or patient registries, cohort studies, etc) and proposal strategy as well as the plans for storage and accessibility to the data.
- RWD Impact
 - Evaluation of the significant reach of the project (International, national or regional reach), overlap with existing or proposed RWD platforms. Is the platform representative of the population? Will there be a significant impact to the field/region?
- Alignment and collaboration between global platforms, including with ALZ-NET
 - Evaluation of plans to align and/or harmonize with other efforts, like ALZ-NET. Is the data sharing plan accessible and well described?
- Quality and adequacy of resources and budget

- Evaluation of the research team, technical expertise, institutional resources and facilities support. Is the timeline appropriate for the proposed work? Is the budget well justified?
- Priority for funding
 - If funded in part, is there an aspect/aim of the proposal that would be more of a priority over other parts of the proposal?

5.5. Budget

A "Budget summary" for the proposed research project is required and must be submitted with the application and within the allowable two-page limit. Your budget must not exceed USD \$1,000,000.00 (**direct costs only. Indirect costs are not allowed**) across all years. The minimum duration of the award is 12 months, and the maximum duration is up to 2 years.

Each project aim/work package should have a clearly defined budget associated, as projects may receive only partial funding.

5.6. Deadlines and Award Timeline

The first round of invited proposals will follow the timeline below. Pre-submission inquiry survey responses submitted after January 1, 2024 will be considered for the next round of funding.

- The Pre-Submission Inquiry Survey can be completed at any time.
- The first round of invited Applications will Opens: December 1, 2023 (Proposalcentral.com)
- Application Deadline: January 31, 2024 (No Exceptions)
- Application Review: February – June 2024
- Award Notifications: By July 14, 2024

For those invited to submit a full application, the full application must be received by 5:00 PM EST, January 31, 2024. Applications will not be accepted after this date. No exceptions will be made. No hard copies or emails will be accepted.

Award announcements will be made by July 14, 2024. For more information contact grantsapp@alz.org

It is imperative that you proofread your application before submission; you will not be allowed to make any changes to the application after the deadline or once applications are under review.

It is the responsibility of the applicant to ensure and verify that:

- The application is submitted by the receipt date/time deadline. Once submitted, you will receive a confirmation email from proposalcentral.com that your application was successfully submitted. If you do not receive a confirmation, click the Proposals tab and under the "Status" column, make sure it says Submitted and not In Progress, which indicates you have not yet submitted your application.
- The application is complete and accurate before submission. Only a single copy of an application will be accepted. We do not require signatures at the time of submission. The

signature page provided is for use should your institution/organization require signatures; we do not override any institutional policies and/or procedures. Please do not submit the signature page with your application.

- Revisions, additional materials, and/or reference, manuscripts, appendices, etc., are not allowed and, if attached, will be removed from your application.

6. Ethical and Regulatory Approvals and Reporting Requirements

If awarded for funding, the Alzheimer's Association requires that any necessary ethical and/or regulatory approvals are kept current, and may require specific reporting throughout the lifetime of the award. This includes, but is not limited to, the following:

6.1. Human Participants / Volunteers Ethical Assurances

Human participants / volunteers ethical assurances are not required at the time of application. Investigators have up to 90 days after receipt of their award notification to submit these documents. However, the Alzheimer's Association encourages investigators to initiate their certification applications on a schedule that recognizes that approvals at many institutions can take more than 90 days. We will accept only certifications that apply specifically to the funded project and must include the name of the awardee. An award letter will not be issued unless the appropriate certifications are in place and include the name of the awardee within the 90 days from award notification.

6.2. Diversity and Representation

Diversity and representation will be tracked throughout the duration of the grant and continued funding is contingent on progress towards advancing health equity. RWD platform populations should aim to be representative of a defined community – and consider diversity as appropriate, for example with regard to sex, gender identity, sexual orientation, socioeconomic status, race, and / or ethnicity. In addition, research studies utilizing the RWD platform must include appropriate inclusion or exclusion criteria.

6.3. Financial Responsibility

Funding is awarded to the institution and/or organization, not to the individual principal investigator. The principal investigator or a first-degree relative cannot be listed as the signing official or financial officer, or have checks sent to their attention if awarded.

6.4. Annual Scientific and Financial Reports

Interim Scientific and Financial Reports must be submitted at the end of each reporting period as long as the grant remains active. Final Scientific and Financial Reports must be filed within 90 days of the grant's end date. All reports must be submitted electronically via proposalcentral.com. The Financial Report must be approved and signed by someone with financial authority in the Office of Research and Sponsored Programs at the recipient's institution.

It is expected that award recipients will participate in Alzheimer's Association meetings and conferences, including the Alzheimer's Association International Conference (AAIC).

7. Additional Information

7.1. Review Process Overview

All proposals are subject to a multi-stage peer-review process carried out through an online system. In the first stage, applications are reviewed and rated by a minimum of three peer scientists with expertise in the proposed area of research. Reviewer conflicts of interest include (but are not limited to):

1. The Applicant trained with/or by the reviewer.
2. The Reviewer published with the Applicant in the last four (4) years. This excludes workshops or large consortia (e.g., ADNI, IGAP).
3. The Reviewer has been a co-investigator on a grant application or award with the Applicant in the last four (4) years.
4. Reviewer has a conceptual difference of opinion with the Applicant that will prevent a fair review.
5. Reviewer will receive financial benefit from the Applicant receiving an award.

The second stage includes further review and discussion of the scores and comments resulting from the initial review process. This second review will be carried out by an invited review committee to ensure fairness and equity in the initial review procedures and to make funding recommendations to the Association. Final recommendations from the review panel are shared with the Medical and Scientific Advisory Group (MSAG) and with the Alzheimer's Association for final approval in a coordinated manner. This multi-stage process is central to our award decisions and is designed to ensure both scientific rigor and fairness in the review of all submitted applications.

7.2. Appeals of Scientific Peer Review

To maintain a fair and rigorous review system, the Alzheimer's Association has a process for appeal of funding decisions. Appeals will not be considered for the pre-submission inquiries stage. Regarding full applications, an appeal is intended to address extraordinary circumstances. Appropriate reasons for initiating an appeal might include:

- Evidence that a reviewer has an undeclared conflict of interest.
- An egregious error or misunderstanding in the review process.
- Active malfeasance or demonstrable lack of due diligence.

The appeal process is not intended to provide a mechanism for routine protest of failure to receive a grant.

If an applicant believes an extraordinary circumstance has contributed to failure to receive funding, the principal investigator may send a two-page, double-spaced formal letter of appeal (Word document) to grantsappeals@alz.org. Any supporting documents included must be submitted as a PDF. **Appeals must be submitted within 2 weeks from the date your application outcome notification is sent.** Notification of action on the appeal will be made via email, usually within 90 days of the appeal deadline.

7.3. Nondiscrimination and Harassment Statement

The Alzheimer's Association is committed to providing an environment free from harassment and discrimination. Alzheimer's Association strictly prohibits harassment and discrimination based on race; creed; color; religion; sex; sexual orientation; national origin; ancestry; age; Veteran status; citizenship status; marital status; physical or mental disabilities; pregnancy, gender identity or expression (including transgender status); genetic information; and any other characteristic protected by federal, state or local law.

7.4. Multiple and Overlapping Submissions

Multiple submissions from one applicant are not permitted. This includes multiple submissions from the same group and/or collaborators. Overlapping submission with an existing Alzheimer's Association award is not allowed. Investigators who currently have an active Association grant may apply for this program if the projects are distinctly different; overlapping funding is not allowed.

7.5. Further information

Please contact the Alzheimer's Association at grantsapp@alz.org with any questions.