

PERSPECTIVE

The ADNI Administrative Core: Ensuring ADNI's success and informing future AD clinical trials

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Abstract

The Alzheimer's Disease Neuroimaging Initiative (ADNI) Administrative Core oversees and coordinates all ADNI activities, to ensure the success and maximize the impact of ADNI in advancing Alzheimer's disease (AD) research and clinical trials. It manages finances and develops policies for data sharing, publications using ADNI data, and access to ADNI biospecimens. The Core develops and executes pilot projects to guide future ADNI activities and identifies key innovative methods for inclusion in ADNI. For ADNI4, the Administrative Core collaborates with the Engagement, Clinical, and Biomarker Cores to develop and evaluate novel, digital methods and infrastructure for participant recruitment, screening, and assessment of participants. The goal of these efforts is to enroll 500 participants, including > 50% from underrepresented populations, 40% with mild cognitive impairment, and 80% with elevated AD biomarkers. This new approach also provides a unique opportunity to validate novel methods.

KEYWORDS

Alzheimer's disease, Alzheimer's Disease Neuroimaging Initiative, clinical trials, digital cognitive assessments, underrepresented populations

Highlights

- The Alzheimer's Disease Neuroimaging Initiative (ADNI) Administrative Core oversees and coordinates all ADNI activities.

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- The overall goal is to ensure ADNI's success and help design future Alzheimer's disease (AD) clinical trials.
- A key innovation is data sharing without embargo to maximize scientific impact.
- For ADNI4, novel, digital methods for recruitment and assessment were developed.
- New methods are designed to improve the participation of underrepresented populations.

1 | GOALS AND ACTIVITIES OF THE ADNI ADMINISTRATIVE CORE

1.1 | Overall structure and goals

The Administrative Core of the Alzheimer's Disease Neuroimaging Initiative (ADNI) provides overall study oversight, leadership, and coordination to ensure the success of ADNI and maximize its impact on the Alzheimer's disease (AD) field. The Administrative Core focuses on broad strategic directions to advance biomarker validation and use and provide insights for designing AD clinical trials.

1.2 | Organization/governance

The Administrative Core is led by the ADNI Principal Investigator Michael W. Weiner. It consists of (1) administrative staff managing scheduling, finances, and contracting; (2) scientists and research staff analyzing and publishing ADNI data across multiple domains, including imaging, biomarker, genetics, and clinical/neuropsychological data; (3) engineers overseeing data management and development and maintenance of the online, digital portal infrastructure for participant and study partner recruitment, screening, and assessment; and (4) project managers and study coordinators who configure and support the digital infrastructure. Strategic decisions about ADNI are made by the Steering Committee, comprising all Clinic Site Principal Investigators, all Core Principal Investigators, and National Institute on Aging (NIA) staff. ADNI Cores are described in Figure 1. Operational decisions are made by the Executive Committee, consisting of all Core Principal Investigators, industry and foundation representatives via the ADNI Private Partner Scientific Board (PPSB), and NIA staff.

1.3 | Coordination of ADNI activities

A key responsibility of the Administrative Core is to oversee and monitor all ADNI study activities, develop consensus, and devise a unified action plan. Weiner and his team oversee and coordinate the extensive and complex communication, interaction, and sharing of data and opinions among the Investigators and staff at the 65 clinical sites, Cores, and PPSB members. Weiner coordinates the ADNI Core Principal Investigators with industry through the PPSB. The Foundation

for the National Institutes of Health (FNIH) convened the PPSB in all ADNI phases through ADNI3. The Alzheimer's Association convenes the PPSB for ADNI4. The Administrative Core also helps facilitate the establishment of other ADNI-like studies around the world to build a worldwide network, including initiatives such as the Australian Imaging Biomarker & Lifestyle Flagship Study of Ageing (AIBL),¹ Worldwide ADNI,² ADNI-Depression,³ and Department of Defense (DOD) ADNI.⁴ For ADNI4, the Administrative Core also serves as a data collecting core, leading the ADNI4 digital operations, discussed below.

1.4 | Financial management

The ADNI Administrative Core has various financial responsibilities, including budget management, subcontract administration, expense tracking, and financial reporting. Furthermore, the core reconciles budgets, maintains updated financial accounting and projections, and ensures that budgets align with participant recruitment efforts. It also provides guidance and assistance in executing service and licensing agreements. Financial management encompasses coordinating funding from industry and foundations, especially for add-on projects. The Core also manages participant payments for activities conducted through the online digital portal.

1.5 | Online study infrastructure

The Engineering team within the Administrative Core is responsible for developing and maintaining the novel online infrastructure to support recruitment, screening, and longitudinal monitoring of participants and study partners in ADNI4. The Administrative Core built and maintains the ADNI online platform, using the Ebusu software developed for the Brain Health Registry (BHR; registered software with the University of California, San Francisco).^{5,6} The Administrative Core developed the necessary infrastructure to support various functions, including digital marketing, tracking of recruitment sources, managing the ADNI study website, conducting online screening to select and prioritize participants for further study participation (both remote blood tests and in-clinic assessments), and collecting longitudinal digital assessment data throughout the study. The Novoic Storyteller task, a speech-based digital assessment,⁷ is administered through a third party (Novoic, Ltd.) and integrated with the ADNI online platform

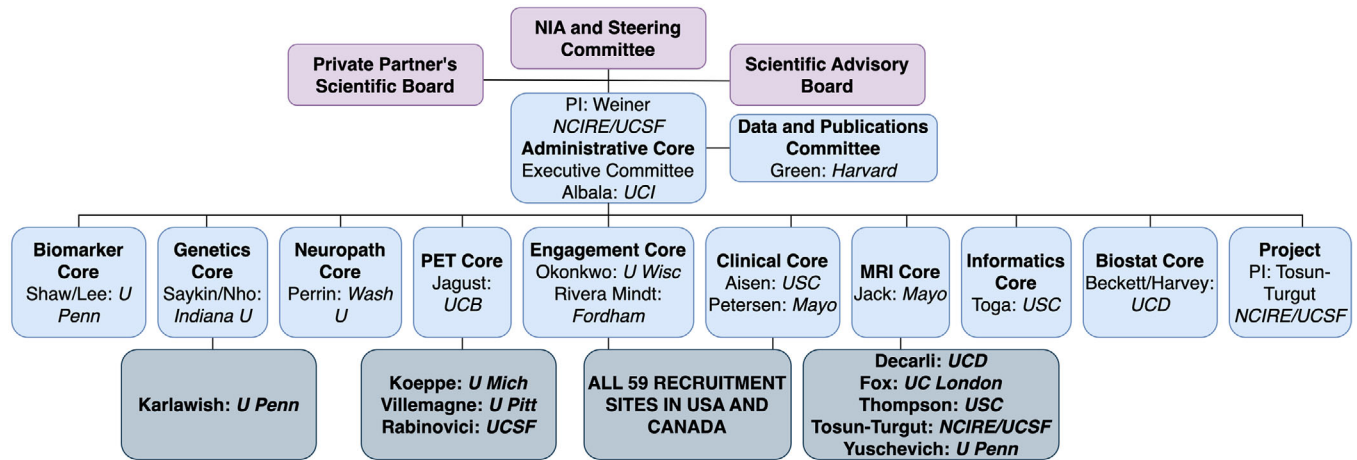


FIGURE 1 Overall organizational structure of ADNI. ADNI, Alzheimer's Disease Neuroimaging Initiative; Indiana U, Indiana University; MRI, magnetic resonance imaging; NCIRE, Northern California Institute for Research and Education; NIA, National Institute on Aging; PET, positron emission tomography; UC, University College; UCB, University of California Berkeley; UCD, University of California, Davis; UCSF, University of California San Francisco; U Mich, University of Michigan; U Penn, University of Pennsylvania; U Pitt, University of Pittsburgh; USC, University of Southern California; U Wisc, University of Wisconsin; Wash U, Washington University.

via an application programming interface. The Engineering team is responsible for linking remote assessment data with other ADNI data.

1.6 | Data sharing

A major innovation of ADNI, conceptualized by the Administrative Core, is widespread data sharing of the ADNI de-identified data set without embargo. Since 2004, ADNI has shared data with 47,735 individuals, resulting in > 5600 publications. Approximately 5% of these publications are authored by ADNI-funded investigators, while the remaining 95% are authored by individuals not directly funded by ADNI. The Informatics Core, led by Arthur W. Toga, PhD, leads the data sharing effort. It is responsible for de-identifying, archiving, and disseminating all clinical, biospecimen, genetic, and imaging ADNI data. Data are collated, maintained, organized, and shared through the Image and Data Archive (IDA) at the Laboratory of Neuroimaging (LONI) at the University of Southern California (USC). The website for accessing this data is available at <http://adni.loni.usc.edu/data-samples/access-data/>. The accompanying manuscript from the Informatics Core, authored by Toga et al., provides detailed information about the responsibilities of the Informatics Core and the ADNI website.

1.7 | Data and Publications Committee

The Data and Publications Committee (DPC), directed by Robert C. Green, based at Harvard University, is an integral part of the Administrative Core. The DPC serves three primary roles: (1) developing and proposing policy related to data access and publication, (2) screening all applications for access to ADNI data, and (3) reviewing all publications to ensure compliance with ADNI publication policy guidelines.

The DPC contributes to the establishment of policies promoting open data access by granting data access for all legitimate requests. Individuals requesting data access complete a brief online application form indicating their professional affiliation, reason for requesting access, or statement about the project area in which they are interested. The DPC individually reviews each application. All data users must complete a Data Use Agreement. After their request for data is approved by the ADNI DPC, they are provided full access to ADNI data via secure login to the IDA website. A publicly accessible table listing individuals with access to the data and their respective projects is provided to facilitate collaboration between data users (<https://adni.loni.usc.edu/study-design/ongoing-investigations/>).

Additionally, the DPC reviews manuscript submissions and requires all manuscripts using ADNI data to adhere to ADNI publication guidelines. ADNI publication guidelines are as follows: (1) recognition of organizations providing funding in the support acknowledgment section, (2) recognition of data collection by ADNI staff in the Methods section, and (3) a standard phrase of acknowledgment of ADNI in the author line. Accordingly, ADNI leadership and ADNI personnel obtain modest academic acknowledgment for the work they have done on behalf of all ADNI publications. Prior to manuscript submission, a member of the DPC reviews each manuscript using ADNI data for overall quality; however, importantly, it does not attempt to review manuscripts for scientific quality or duplication. Scientific review occurs at the level of publication to avoid practices that inhibit the use of ADNI data by the worldwide scientific community.

1.8 | Publications

The progress and achievements of ADNI have been described in a wide range of papers since its outset. Mueller et al.^{8,9} initially described ADNI's goals and structure. In 2010, ADNI was featured in special

journal issues of *Alzheimer's and Dementia*, and of *Neurobiology of Aging*. The first¹⁰ contained a series of papers outlining the achievements and future goals of the individual ADNI Cores, in addition to the roles and perspectives of the PPSB.¹¹ The second, introduced by Frisoni and Weiner,¹² contained the first significant collection of scientific results to emerge from the data generated by ADNI, and included a report on AD biomarker dynamics,¹³ an analysis of C11 Pittsburgh compound B positron emission tomography (PET) amyloid imaging,¹⁴ and methods for predicting future clinical decline,¹⁵ among others. A 2015 special edition of *Alzheimer's and Dementia*¹⁶ provided insights into industry perspectives and progress made by the ADNI cores and Worldwide ADNI in the intervening 5 years. Military risk factors for AD have been an area of increasing interest¹⁷ and were the focus of a 2014 special issue of *Alzheimer's and Dementia*^{18,19} highlighting the link between traumatic brain injury and cognitive decline. These papers have contributed to the three current DOD-ADNI studies which focus on exploring this link.^{20,21} Both the overall impact of ADNI until 2015, including the development of biomarkers, the standardization of methods, the establishment of Worldwide ADNI and other initiatives,²² and the ADNI3 study²³ have been described. Successive reviews of ADNI publications based on ADNI data,^{11,24–27} including the most recent review published in 2024,²⁸ comprehensively detail ADNI's contribution to understanding disease progression and improving clinical trials.

1.9 | Resource sharing

The Administrative Core provides administrative support and oversees the activities of the Resource Allocation Committees (RARCs). RARCs are responsible for reviewing applications to use ADNI's collection of participant biospecimens, including blood (plasma, serum, cells), DNA, urine, cerebrospinal fluid (CSF), and neuropathology samples obtained from autopsies of ADNI participants. Each RARC is a completely independent committee, appointed by the NIA, which establishes its own policies, rules, and functions. Members periodically rotate. Interested investigators, whether associated with ADNI or not, are encouraged to apply for access to ADNI biospecimens.

Instructions for requesting samples and the application form can be found on the ADNI LONI website at <https://adni.loni.usc.edu/data-samples/access-samples/>. After an initial summary statement reviewed by the NIA and subsequent approval, investigators are invited to submit a full application. Full applications are reviewed by the relevant RARCs and their recommendations are reviewed by the NIA, which makes final decisions. ADNI sends all samples to applicants using a unique code number that is blinded to participant codes. Requestors submit their blinded results to the affiliated ADNI Core (e.g., Biomarker Core for biofluid samples) for unblinding and facilitating uploading of the results to the ADNI database at LONI.

All individuals with ADNI data access can subsequently download the data and link it to additional ADNI data. Until recently neither ADNI investigators nor the laboratory performing the assay had any advance or exclusive access to the data. However, in 2024, the NIA revised

this policy to allow investigators analyzing samples to have exclusive access to their unblinded data for a 2-month embargo period. After that, the unblinded data become available to all investigators through the LONI website. This updated policy was implemented to encourage investigators to request ADNI biofluid, pathology, and genetic samples.

1.10 | Pilot projects

The Administrative Core plans and executes pilot projects to inform future ADNI phases. In ADNI3, the Core convened a Diversity Task Force to deploy culturally informed community-engaged research multi-pronged pilot efforts to improve the inclusion of Latinx and Black older adults into ADNI3.^{29,30} Efforts included (1) the establishment of an External Advisory Board, (2) modifications to the ADNI3 protocol and the digital pre-screener form, (3) selection of 13 Diversity Task Force sites, (4) deployment of local and centralized outreach efforts at the Diversity Task Force sites, and (5) establishment of a Community Science Partnership Board. Efforts increased the monthly enrollment rate of participants from underrepresented ethnocultural populations (URPs) by 268% (before: 1.1; during: 4.08) and resulted in 91 enrolled participants. Of these, 86 (94.5%) were from URPs (Latinx: 22 [25.6%]; non-Latinx Asian: 8 [9.3%]; non-Latinx Black: 55 [63.9%]; non-Latinx Other [non-White]: 1 [1.1%]). Several pilot studies conducted within the BHR, aimed at increasing URP inclusion through culturally informed digital recruitment, have informed the design of ADNI4. These include the California Latino BHR³¹ and the Community Engaged Digital Alzheimer's Research (CEDAR) study.^{32,33} A pilot study in BHR³⁴ to remotely collect blood for AD plasma biomarkers using local Quest Centers has informed the ADNI4 Remote Blood Study, as described below.

1.11 | Requests for proposals

The Administrative Core develops and disseminates requests for proposals to inform the protocol for future ADNI phases. In ADNI3, Requests for Proposals targeting innovative PET, magnetic resonance imaging (MRI), fluid, and digital biomarker methods were published on the LONI website. Investigators and vendors specializing in these fields were invited to submit proposals for including various methods and tools in ADNI4.

The Administrative Core was responsible for selecting digital assessments for ADNI4 from these proposals. ADNI received > 60 responses. ADNI and the Clinical Endpoints Working Group of the PPSB reviewed all proposals and provided recommendations regarding their inclusion in ADNI4. The PPSB process for providing recommendations about digital assessments is described in Sachdev et al., this issue. On the ADNI investigator side, this process included the following steps: (1) ADNI leadership, including Administrative and Clinical Core investigators, developed a set of key criteria needed for proposals to advance for consideration. The criteria included that the assessment measured cognition, including memory; could be completed remotely,

unsupervised; functionality across devices (e.g., mobile, tablet, desktop devices); low time burden < 20 minutes; ability to accurately distinguish diagnostic groups (cognitively unimpaired vs. impaired). Assessments not meeting these criteria were excluded from further consideration. (2) ADNI leadership then developed additional criteria for ranking the remaining, potential assessments. These criteria included availability in both English and Spanish; availability of normative data in diverse populations; brevity; strength of association with key, in-clinic assessment (e.g., Clinical Dementia Rating, delayed recall assessments); and evidence for usability and user acceptance. (3) Multiple ADNI Investigators ranked all potential assessments according to the criteria. Based on this process, Novoic Storyteller, a speech-based digital assessment,⁷ was chosen for inclusion in ADNI4. Calls for proposals regarding plasma AD biomarker assays were handled by the Biomarker Core, resulting in the inclusion of amyloid beta (A β 42/40), total tau, phosphorylated tau (p-tau₁₈₁, p-tau₂₁₇), neurofilament light, glial fibrillary acidic protein, from vendors including C₂N Diagnostics, Fujirebio, Roche, and Quanterix (see Shaw et al., this issue).

2 | NEW ADMINISTRATIVE CORE ACTIVITIES FOR ADNI4

2.1 | Novel recruitment, screening, and participant selection methods for in-clinic ADNI

In previous ADNI phases, participant recruitment primarily relied on site-level activities across all ADNI clinical sites. However, many initiatives and evidence now highlight the effectiveness of digital recruitment and assessment strategies, offering a highly scalable and valid approach for recruitment and assessment for AD clinical research studies.^{31,35–39} The ADNI3 Diversity Task Force effort described above, and multiple BHR initiatives for diverse, digital recruitment, have informed the development of new digital methods for ADNI4. ADNI4 is implementing a digital, online infrastructure for recruitment and assessment to enroll tens of thousands of participants into a Remote Digital Cohort. This effort is a collaboration among the Administrative, Engagement, Clinical, and Biomarker Cores.

Using a multitier prioritization process, subsets of Digital Cohort participants will be invited to enroll in a Remote Blood Cohort for plasma biomarkers, and to participate in ADNI4 in-clinic assessments. The overall goal is to enroll $N = 500$ new participants into in-clinic ADNI with the help of the remote cohorts and through direct-to-site recruitment efforts. The remaining $N = 500$ ADNI4 participants will consist of rollovers from past ADNI phases. The enrollment goals for new participants are at least 50% from URP groups (e.g., Black/African American and Latinx older adults, those with high school education or less), 40% with mild cognitive impairment (MCI), and 80% elevated brain amyloid across diagnostic groups. Data from the Remote Digital Cohort will be accessible to approved data users on the ADNI LONI website. Currently, speech files and transcripts of speech files from the Novoic Storyteller test are not being shared due to privacy concerns, including the ability to produce a voice print that could identify par-

FIGURE 2 Example of ADNI4 digital advertisement. ADNI, Alzheimer's Disease Neuroimaging Initiative.

ticipants, and the possibility that participants may inadvertently reveal identifying or private information in speech transcripts. Therefore, currently, only numeric scores related to the Storyteller assessment are shared on LONI. To maximize the future impact of speech assessments in the AD field, ADNI leadership is exploring methods to safely share speech files and transcripts while ensuring participant privacy. The ADNI Administrative Core recently convened a Speech Language Advisory Board, comprised of experts in the field, to address issues related to the speech and language assessment data.

2.2 | Digital advertising

ADNI4 is developing, deploying, evaluating, and optimizing national digital advertising efforts tailored toward URPs residing near ADNI clinical sites. Digital advertisements (Figure 2) direct potential participants to a recruitment website (Figure 3). ADNI4 collaborates with Alaniz Marketing, a company with experience in URP recruitment and engagement, to develop and execute advertising campaigns promoting enrollment into the Remote Digital Cohort. The Administrative

ADNI Alzheimer's Disease Neuroimaging Initiative

Think What You Can Do

Over 4,000 Alzheimer's research discoveries have been made thanks to participants in the Alzheimer's Disease Neuroimaging Initiative (ADNI) study.

You can make a difference too if you are between the ages of 55-90 and live in the U.S.

Fill out the form to join the ADNI4 Study

First Name

Last Name

Email

Month's Year of Birth

Postal Code

United States of America Postal Code

Phone Number

United States of America Phone Number

SUBMIT

Power In Participation

Structural racism exists in many aspects of life that contribute to dementia risk. There is evidence that missed or delayed diagnoses of Alzheimer's and other dementias are more common among Black older adults.

About The Study

ADNI is a landmark study of brain aging. ADNI is working to help increase the pace of discovery in the search to prevent, treat, and one day cure Alzheimer's disease.

We study changes in thinking and memory over time to help us learn more about brain health and Alzheimer's. You share data with the scientific community, leading to important discoveries.

Together, participants and researchers are increasing understanding to help lay a path forward for a better future.

LEARN MORE ABOUT THE STUDY

How It Works

It's free to sign up and be a part of Alzheimer's research.

- 1. Sign Up**
You can make a difference if you are 55-90 and live in the U.S. [ADNI4 Sign Up](#)
- 2. Create An Account**
Use your account to complete study tasks at a pace that is right for you.
- 3. Answer Questions About Yourself And Take A Memory Test**
We'll ask you to come back every 6 months for online questionnaires and memory tests. We may invite you to other phases of the study. Other phases may include blood tests and brain imaging, at no cost to you.

FILL OUT THE SIGN UP FORM

Why You Matter

New treatments are possible. Together, we can work towards a solution for all.

Alzheimer's is a brain disease that slowly destroys memory and thinking skills and eventually, basic functions. Currently, there is no way to prevent or cure it. But you can help change this.

Together, ADNI participants and researchers are increasing understanding of the disease for all. When you participate, you help find ways to live a healthier, longer life for you and the ones you love.

JOIN THE STUDY

Think What You Can Do

What if we could change the future of Alzheimer's and dementia for our children and grandchildren?

ADNI Alzheimer's Disease Neuroimaging Initiative

Do you have questions? See support and get help at [ADNI4 Support](#) (800-452-2210)

[ABOUT THE STUDY](#) [FAQ](#) [CONTACT](#)

This research was supported by grants from the National Institutes of Health and other sources. ADNI is part of the National Institutes of Health.

FIGURE 3 ADNI4 digital recruitment website. ADNI, Alzheimer's Disease Neuroimaging Initiative.

Core works closely with the Engagement Core to develop culturally informed approaches. The Administrative Core works closely with ADNI clinical sites to run digital advertisements appropriate for their regions' demographic composition, and with consideration of the site's capacity to enroll participants.

In addition to the focus on URPs, ADNI4 is aiming to enroll participants meeting diagnostic criteria for MCI and AD dementia. ADNI has developed advertising campaigns directed toward those with memory concerns. It is inherently difficult to directly enroll participants with cognitive impairments, motivating our development of an innovative "Loved Ones" advertising campaign directed at individuals who are concerned about their cognitively impaired loved one. The Loved Ones campaign is now in development and will be deployed and tested in the future.

Another digital recruitment source is AD registries, such as the Alzheimer's Prevention Registry (APR)⁴⁰ and the NIA Alzheimer's Disease Education and Referral (ADEAR) Center. They provide information about the ADNI study and provide a link to join the Digital Study through their participant communications.

2.3 | Tracking effectiveness

An essential feature of digital advertising is the ability to evaluate the effectiveness of specific advertisements. To facilitate this, the Administrative Core and Alaniz Marketing have established systems to track and report the results of digital marketing efforts. This includes the use of tracking URLs within our advertisements and national study registry listings which capture the amount of traffic received and leads gained via these links. Performance reports are generated and shared directly from Meta, the social media platform including Facebook and Instagram, by Alaniz Marketing. Furthermore, the Administrative Core's engineering team developed an internal dashboard to monitor various aspects of digital platform registration, account creation, enrollment into the digital study, and activity within the study tasks. These data are linked to the recruitment source if captured by the tracking URLs. The Administrative Core can leverage the internal dashboard and assess and monitor advertisement performance across different sites, including ad content and targeted audience.

2.4 | Digital assessment platform

2.4.1 | Participant platform

The online assessment platform for the Remote Digital Cohort includes a registration page, electronic informed consent document, and the following surveys: a questionnaire, a medical history questionnaire focused on major exclusionary criteria for in-clinic ADNI and self-report of cognitive impairment, memory concerns and changes questionnaire, the 12-item Everyday Cognition scale (ECog-12), the Novioic Storyteller test, and Study Partner information. To be eligible to join the Remote Digital Cohort, individuals must be between 55 and 90

years old, able to read English, and reside within 150 miles of an ADNI site. ADNI launched the first study recruitment website on June 20, 2023, and its first digital marketing efforts in September 2023. As of April 3, 2024, 3099 individuals were invited to the Digital Study and 595 enrolled and completed at least one survey question. Initial Digital Cohort results are described in a separate manuscript (Miller et al.) in this issue. Enrolled participants receive automated e-mail communications (e.g., reminders to finish tasks). Participants are asked to return every 6 months to complete follow-up tasks, including the ECog-12 and Novoic Storyteller tasks. Results from digital assessments (e.g., demographics, distance to sites, evidence for cognitive impairment) are used to select and prioritize participants for referral to the Remote Blood Study and in-clinic ADNI.

Individuals are prioritized as possibly impaired if they self-report diagnosis of MCI, AD, or dementia; indicate they have been prescribed a medication for cognitive impairment; or have Novoic Storyteller or ECog-12 scores indicative of possible cognitive impairment (ECog-12 score ≥ 1.36 ; Novoic Storyteller score ≤ 49.4 ; see Miller et al., this issue). As of April 3, 2024, 43 participants in the Digital Cohort have been invited to be contacted by clinical site staff for in-clinic ADNI4, and 22 of those participants have accepted the referral invitation.

2.4.2 | Study partner platform

The ADNI Study Partner digital platform was adapted from the Study Partner Portal of the BHR.^{37,41-43} The “My Study Partner” survey asks participants to identify someone to serve as their study partner and to provide the partner’s contact information. Participants are asked to identify a study partner who knows them well enough to provide information about their cognitive abilities and everyday functioning. There are no minimum requirements for the amount of time spent together. Details about the study partner’s relationship to the participant (e.g., relationship type, time spent together, whether they live together) are collected. Once participants provide the partner’s contact information, this triggers an automatic e-mail invitation to the potential study partner, inviting them to join. Study partners then register, create a digital account, provide electronic consent, and answer surveys separately from the participant. Study partner surveys include study partner basic demographics and relationship to the participant, the study partner version of the ECog-12, and study partner-report memory concern and changes questions. Enrolled study partners receive automated e-mail reminders to begin and finish tasks, and to return for follow-up.

2.5 | Remote blood study

Based on responses to digital assessments, proximity to Quest Diagnostics phlebotomy sites, and clinical site readiness to receive new participant referrals, a subset of participants from the Remote Digital Cohort are invited to the Remote Blood Study. The Remote Blood Study uses infrastructure for remote blood collection for AD plasma biomarkers, developed by BHR.³⁴ Participants receive an e-mail invita-

tion with a link to learn more about the study and join. After providing electronic consent, participants are provided with instructions for scheduling their blood draw at a local Quest Diagnostics site and an order sheet containing codes used to de-identify the blood samples from the point of collection. After the blood draw is complete, plasma and genetic samples are sent for analyses and sample banking to the Biomarker Core at University of Pennsylvania and National Centralized Repository for Alzheimer’s Disease and Related Dementias (NCRAD), respectively. ADNI aims to have plasma samples analyzed within ≈ 4 weeks and resulting AD biomarker data are returned to the Administrative Core to help inform referral selection of Remote Blood Cohort participants to the in-clinic ADNI study. Participants are compensated with a \$70 electronic gift card. Individuals in the Remote Blood Cohort who are not referred to in-clinic ADNI are asked to provide a blood sample every other year. To date, 160 participants have been invited to the ADNI Remote Blood Study and 66 have enrolled.

2.6 | Remote longitudinal monitoring cohort

Participants enrolled in the in-clinic ADNI with a diagnosis of CU or MCI are invited to complete digital assessments at 6-month intervals, using the same digital assessment platform as the Remote Digital Cohort. Assessments include brief demographic information, subjective memory concerns, ECog-12, Novoic Storyteller, and the option to invite a study partner. Participants who complete all study tasks are eligible to receive a \$25 eGift card. Study partners of in-clinic participants who join the ADNI online study and complete their tasks (such as ECog-12) are also eligible to receive a \$15 eGift card. Participants and study partners are encouraged to revisit the study website every 6 months to complete study tasks. To date, 90 participants have been invited to join the Remote Longitudinal Monitoring Cohort and 54 have enrolled and completed at least one questionnaire.

2.7 | Data management for the digital study

The digital assessment platform oversees and monitors the digital study activities described above, from online recruitment through pre-screening, enrollment, online data collection, blood collection, and referral to the clinical study. The study management system is called Ebusu.⁴³ Data collected by third parties is imported via API or bulk reporting via data exports. All data are available for inclusion in a customized dataset through which participants may be selected according to status as well as being tailored to specific tables and columns. An internal dataset comprising acquired and operational data is used to build reports and dashboards to monitor the recruitment and operations of the digital study. It is also used as described above, in Section 2.4, as the basis for selecting who to refer to the Remote Blood study and monitoring and tracking operations of the blood study. Ebusu also includes an “Investigator Portal” for site staff to manage their participants’ study activities related to the digital study and to receive referrals from the remote cohorts in a secure manner.

2.8 | Improving ADNI data infrastructure and the LONI website

The Administrative Core is working closely with the Informatics Core to redesign the ADNI website (<https://adni.loni.usc.edu/>). The redesigned website was launched in 2024. In conjunction, each Core (Clinical, MRI, PET, Biofluid Biomarkers, Genetics, Neuropathology) was asked to update the content that is presented on the ADNI LONI website related to their methodology, to improve information transfer. The redesigned website has clearer pathways for viewers to follow to learn more about the ADNI study from (1) the perspective of a prospective participant or (2) the perspective of a researcher interested in ADNI data and/or biological samples. Improved user flow, hierarchical presentation of information, and revised documentation are all being implemented with the goal of improving the overall user experience on the ADNI website, and connecting interested individuals with the key information they need about the ADNI study in a more straightforward way.

3 | SUMMARY

The ADNI Administrative Core oversees and coordinates all ADNI activities. A key innovation is data sharing without embargo to maximize scientific impact. For ADNI4, novel, digital methods for recruitment, screening, and assessment were developed. These new methods are designed to improve participation of underrepresented populations and achieve ADNI4 enrollment goals, including successful enrollment of those with cognitive impairment and elevated AD biomarkers. The long term, overall goal of the Administrative Core is to ensure ADNI's success and help design future AD clinical trials.

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CONFLICT OF INTEREST STATEMENT

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX

Collaborators:

A complete listing of ADNI investigators can be found at:

http://adni.loni.usc.edu/wp-content/uploads/how_to_apply/ADNI_Acknowledgement_List.pdf