The Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) is committed to data and biospecimen sharing and promotes collaborative, high quality dissemination of DIAN-TU trial findings in a timely, accurate, and just manner while protecting trial integrity and participant confidentiality. To further these goals, the DIAN-TU has established policies related to the use of DIAN-TU data and biospecimens, publication, authorship, and citations of support. These policies provide structure to the data and biospecimen request and publication processes, ensure protection of trial integrity, provide respect for intellectual contributions, define standards regarding security and confidentiality, ensure appropriate acknowledgment of support and key stakeholders, and provide a mechanism for tracking productivity. They adhere to the NIH Policy for Data Management and Sharing, the Collaboration for Alzheimer’s Prevention data sharing principles¹ and the International Committee of Medical Journal Editors (ICMJE) criteria for authorship.

This document includes the following policies:

- DIAN-TU Data and Biospecimen Sharing Policy
- DIAN-TU Publication Policy
- DIAN-TU Authorship and Citation Policy

These policies apply to anyone (all DIAN-TU Study Team Members and non-DIAN-TU researchers) using or requesting use of DIAN-TU data and/or biospecimens for scientific analyses and all DIAN-TU related publications and communications. DIAN-TU Study Team Members are considered to be those who work or have worked on DIAN-TU trials (e.g. DIAN-TU Core leaders and members, Industry Collaborators, site PIs, partner sites PIs, referring physicians). The complete list can be found at https://dian.wustl.edu/our-research/funding/.

Any deviation from the DIAN-TU Data and Biospecimen Sharing, Publication, Authorship, and Citation Policies may result in actions to further limit the risk to DIAN-TU trials and participants, including barring violators from future data or biospecimen requests, institutional involvement to rectify deviations, and legal action.

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I. INTRODUCTION AND GENERAL INFORMATION

In general, all public and scientific communications (manuscripts, presentations, press releases, interviews, public website postings, etc.) must be submitted to, and reviewed and approved by the DIAN-TU before they are published, presented, or appear in public. In addition, access to DIAN-TU data and biospecimens is dependent upon review and approval by the DIAN-TU. Reviewers include, but are not limited to, members of the DIAN-TU Leadership, Administration, Clinical Operations, and Biostatistics teams, subject matter experts, and Industry Collaborators (see section II.C for details on the review process).

Because some data and biospecimens are generated from DIAN-TU clinical drug trials testing an Industry Collaborator’s therapeutic compound, Industry Collaborators may choose to review data and biospecimen requests and manuscripts related to their therapeutic compound(s) or other proprietary materials prior to publication to ensure protection of the applicable Industry Collaborator’s confidential information or its interest in intellectual property. This includes all public and scientific communications (manuscripts, presentations, press releases, interviews, public website postings, etc.).

A. Funding Requirements

DIAN-TU trials and projects are global studies supported by federal, philanthropic, and industry funding and adhere to country-specific regulations and funding source requirements for data and biospecimen sharing.

i. Regulatory and Funding Agency Requirements

Data and biospecimens generated from the DIAN-TU trials will be shared and administered in accordance with the policies of Washington University and National Institutes of Health (NIH) including the Bayh-Dole Act of 1980 [https://grants.nih.gov/grants/bayh-dole.htm], NIH Policy for Data Management and Sharing, the RFA-AG-04-011 [https://grants.nih.gov/grants/guide/rfa-files/RFA-AG-04-011.html], and the Health Insurance Portability and Accountability Act (HIPAA) [https://www.hhs.gov/hipaa/index.html]. In addition, the DIAN-TU will follow the European Commission General Data Protection Regulation (GDPR, https://gdpr-info.eu/) and country-specific regulations regarding data and biospecimen sharing. Some restrictions to data and biospecimen access relate to protection of confidentiality and privacy of DIAN-TU trial participants and their families, trial integrity, the intellectual property of the DIAN-TU trials Industry Collaborators, and available quantities of residual biospecimens for research.

ii. Industry Collaborator Agreements

The DIAN-TU Trial Industry Collaborators recognize the value of shared data, and language to allow for data and biospecimen sharing is included in agreements with Industry Collaborators. This language may include rights for an Industry Collaborator to have an opportunity to review data and biospecimen requests and manuscripts related to the Industry Collaborator’s study drug(s) or other proprietary materials prior to publication to ensure protection of the applicable Industry Collaborator’s confidential information or its interest in intellectual property.

B. Informed Consents

The DIAN-TU trial participant informed consent documents specify the following points regarding data and biospecimen sharing. These points are also reviewed with the participant during the consent process.
• Data and biospecimens collected during study participation may be used for other research and shared with Washington University researchers, other research institutions and companies in accordance with country-specific regulations.

• Data collected during study participation may be shared with large data repositories for broad sharing with the research community.

• Data and biospecimens collected during study participation will be coded to prevent disclosure of protected health information (PHI) and any research health information, in compliance with HIPAA regulations, European Union (EU) Data Protection Directive, and country-specific regulations.

• Data and biospecimens collected during study participation will be shared in such a way that the participant cannot be directly or indirectly identified.

• The DIAN-TU will work to minimize the risk of disclosing mutation status in publications and presentations. However, publications/presentations could reveal a pattern of symptoms, a relationship between chronic/acute disorders, etc. related to mutation status. If a participant doesn’t currently know their mutation status, there is the possibility that by reading publications related to DIAN-TU trials (journal articles, presentations, popular press coverage), the participant may deduce or guess (correctly or incorrectly) their mutation status.

• US participants relinquish any proprietary interest in the data or specimens they provide in the course of this research.

• Proprietary interest of non-US participants may vary in accordance with country specific regulations.

• Participants may withdraw from the study at any time. No new information or biospecimens will be collected, but the information and biospecimens that were already collected will continue to be used for the study.

• Data and biospecimens collected during study participation will be kept indefinitely and any data and biospecimens collected prior to withdrawal from study may still be used.
II. DATA AND BIOSPECIMEN SHARING POLICY

Qualified researchers may obtain access to de-identified biofluid biomarker, imaging, clinical, cognitive, genetic, and neuropath data and biospecimens generated from DIAN-TU trials or DIAN-TU related activities for the purpose of scientific investigation or planning clinical research studies per the requirements and processes outlined in this policy. This policy adheres to the Collaboration for Alzheimer’s Prevention data sharing principles (Weninger, 2016) and the NIH Policy for Data Management and Sharing. This policy applies to anyone using or requesting use of DIAN-TU data and/or biospecimens for scientific analyses planned for dissemination through publications, presentations, books, abstracts, grants, etc.

Any deviation from the DIAN-TU Data and Biospecimen Sharing Policy may result in actions to further limit the risk to DIAN-TU trials and participants, including barring future data or biospecimen requests, institutional involvement to rectify deviation, and legal action.

Productivity of data and biospecimen requests will be a criterion for future requests, such that investigator teams with high publication and result generation will be given priority, while investigator teams with low productivity will be de-prioritized.

A. Data & Biospecimens Available for Request

DIAN-TU Trial data consists of extensive imaging, biofluid biomarker, genetic, clinical, and cognitive data at baseline and annual visits (over 5000 variables per participant per visit). Neuropathology data is also available from brain autopsies of DIAN-TU participants. The DIAN-TU Trial Data Dictionary provides a description of the available trial data and associated variable names. Biospecimens include plasma, serum, cerebrospinal fluid, DNA, and brain tissue. Contact DIAN-TUDataRequest@wustl.edu for the DIAN-TU Trial Data Dictionary and details regarding available biospecimens and collection methods. Please note that biospecimens and raw imaging data have more sharing limitations and requirements than other data.

The DIAN-TU Trial Platform is designed to continuously add drug arms and allow for pooling of placebo. To ensure trial integrity with this design, data will be frozen or locked as follows:

**Baseline (and screening) Data** for a drug arm will be frozen (cleaned and validated) within 6 months after enrollment for that drug arm is complete.

**Cognitive Run-In Data** will be frozen (cleaned and validated) with the associated baseline data (i.e., within 6 months after enrollment for that drug arm is complete).

**Study Data (post randomization data)** will be locked (cleaned and validated) within 6 months after the last patient’s last study visit.

B. Priority of Access

To respect intellectual contributions of DIAN-TU Trial investigators and collaborators, availability of data is as follows:

i. **Baseline Data (pre-drug) and Cognitive Run-in Data**

**DIAN-TU Study Team Members:** Baseline data and associated Cognitive Run-In data will be available to qualified DIAN-TU Study Team Members once the data freeze is complete.

**DIAN-TU Study Team Members are considered to be those who work or have worked on**
DIAN-TU trials (e.g. DIAN-TU Core leaders and members, Industry Collaborators, site PIs, partner sites PIs, referring physicians). The complete list can be found at https://dian.wustl.edu/our-research/funding/.

Non-DIAN-TU Researchers: Baseline data and associated Cognitive Run-In data will be available to qualified, non-DIAN-TU researchers 12 months after the baseline and Cognitive Run-In data freeze is complete.

ii. Study Data (post randomization/drug) in Data

DIAN-TU Study Team Members: Study data will be available to qualified DIAN-TU Study Team Members after a drug arm and its placebo are closed and the regulatory process is complete.

Non-DIAN-TU researchers: Study data will be available to qualified, non-DIAN-TU researchers after the earlier of either regulatory approval of the tested treatment or 18 months after the completion or early termination of the trial.

iii. Biospecimens

1. Biospecimen access is prioritized based on:
   a. The needs of the specific drug arm/trial and proper conduct of the study, which includes the appropriate retention of biospecimens in sufficient quantities for analyses during ongoing trials as well as for confirmatory testing after trial completion.
   b. The needs of the DIAN-TU and Industry Collaborators, which includes meeting grant and related project aims.

2. Residual biospecimens stored for future research (baseline and post-randomization) will be made available to the research community at the time the associated data are released, and then only in accordance with all applicable requirements of Industry Collaborators, participant consent and country-specific regulations. Requests for biospecimens from the DIAN-TU trial are required to have drug or treatment specific hypotheses that can only be addressed with DIAN-TU samples. For hypotheses that are independent of treatment effects, DIAN observational or other cohort samples should be considered.

3. Biospecimens from DIAN-TU participants cannot be used for exploratory research. Investigators seeking access to this resource must first demonstrate the hypothesized effect in biospecimens from sporadic AD compared to cognitively normal controls, unless a mutation specific effect is hypothesized.

4. Regardless of where biospecimens are banked, these materials (tissue, fluids, etc.) remain under the authority of the DIAN-TU. Investigators receiving DIAN-TU biospecimens acknowledge this authority and will only use the materials in accordance with the ways approved by the DIAN-TU.

Disclaimer: Screening for infectious agents is NOT performed on biospecimens provided by the DIAN-TU Trial Cores at Washington University School of Medicine. The requesting investigator must take appropriate precautions.

iv. Data Generated after Database Lock

New data generated after database lock of a trial drug arm will be made available to requestors as follows:
Newly generated baseline data: 12 months after the latter date of either generation or trial completion.

Newly generated post-randomization data: 18 months after the latter date of either generation or trial completion.

C. Data and Biospecimen Request and Review Process

Requests for DIAN-TU data and biospecimens can be submitted electronically via the DIAN-TU resource sharing website (https://dian.wustl.edu/our-research/for-investigators/diantu-investigator-resources/). A DIAN-TU Data and Biospecimen Request Form may also be requested from DIANTUDataRequest@wustl.edu. If not submitted electronically via the DIAN-TU resource sharing website, request forms must be submitted via email to DIANTUDataRequest@wustl.edu.

Applicant information will be available to other registered data users so that other data users can see what analyses are underway. This should help applicants decide whether to join in research already underway, compete with these projects, or select another research topic.

Investigators seeking access to DIAN-TU biospecimens are strongly encouraged to contact and discuss their grant and data and/or biospecimen request proposal with the relevant DIAN-TU Core Leader in advance of submitting a request. Such questions should address biospecimen collection protocols, types of biospecimens available, availability of resources, etc. If a significant amount of resources of a Core will be required, investigators should discuss including support for these resources in their proposal with the Core Leader. Please avoid questions that would require database inquiries (i.e., how many samples have XX?).

- **Plasma, serum, or cerebrospinal fluid (CSF) and related data** - Biomarker Core Leader, Dr. Anne Fagan, fagana@wustl.edu
- **Autopsied brain material and related data** - Neuropathology Core Leader, Dr. Richard Perrin, rperrin@wustl.edu
- **DNA-Genetics biospecimens and data** - Core Leaders, Dr. Alison Goate, alison.goate@mssm.edu and Dr. Carlos Cruchaga, cruchagac@wustl.edu
- **Cognitive data** - Cognition Core Leader, Dr. Jason Hassenstab, hassenstjabj@wustl.edu
- **Clinical data** – Clinical Core Leader, Dr. Eric M. McDade, ericmcdade@wustl.edu
- **Imaging data** – Imaging Core Leader, Dr. Tammie Benzinger, benzingert@wustl.edu
- **Statistical data** – Biostatistics Core Leaders, Dr. Chengjie Xiong, chengjie@wustl.edu and Dr. Guoqiao Wang, guoqiao@wustl.edu

i. Request Content and Submission

1. **Requesting researcher information** including name, contact information, and institutional affiliation.

2. **Intended use of the data and/or biospecimens**, for example
   a. Abstract submission for presentation
   b. Academic publication
   c. Pilot data for grants
NOTE: If you are submitting a grant proposal that will use DIAN-TU resources, you must submit a letter of intent to DIAN-TUDataRequest@wustl.edu NO LESS THAN 60 DAYS PRIOR TO THE GRANT APPLICATION DEADLINE. See Section II.C.12 for more details.

d. Data exploration
e. Other (define)

3. Brief description of the project:
   a. Specific aims/hypothesis
      i. For hypotheses that are independent of treatment effects, consider DIAN Observational Study or other cohort data.
      ii. For biospecimen requests, demonstration of preliminary data from sporadic AD or dominantly inherited AD is required.
   b. Study design
   c. Statistical Analysis plans

4. Data variables/biospecimens requested including characteristics and preferences (e.g., format for data, volume of biospecimens)
   a. Requests for DIAN-TU biospecimens should detail the associated data elements to accompany the samples.
   b. Variables/biospecimens requested should be listed in a table format.
   c. For raw imaging data, justification of why raw data versus the processed data is required.
      NOTE: Access to samples will be limited and based on availability of samples, the needs of the related DIAN-TU trial, the needs of the DIAN-TU and Industry Collaborators, the applicability of the proposed research request to the DIAN-TU aims, the necessity of DIAN-TU samples for the proposed research request, and other criteria listed in section II.C.ii.4).

5. Institutional review board (IRB) approval (if applicable): Provide documentation of Institutional Review Board (IRB) or Ethics Committee (EC) approval valid for the analysis of DIAN-TU Trial data or exemption (i.e., acknowledgment from the IRB/EC that receiving coded data without access to other identifiers is not considered "research" requiring review).

6. Plan for data and biospecimen security/protection - provide assurance of ability to secure dataset and/or biospecimens in accordance with the most stringent protections possible compliant with local IRB/IEC and country-specific data protection regulations for such sensitive data (e.g. Health Insurance Portability and Accountability Act (HIPAA) for US sites, GDPR for EU sites, etc.).

7. Funding support (all expenses incurred will be covered by the applicant)

8. NIH-style biosketch or CV

9. Agreement to the DIAN-TU Data and Biospecimen Sharing, Publication, Authorship, and Citation Policies

10. Agreement to general terms and obligations of resource usage
    a. Datasets to be shared will be encrypted and password protected.
    b. The data will only be used for research purposes, and the recipient will not attempt to identify any individual participant.
c. Recipients of DIAN-TU data and/or biospecimens agree to only use the data/biospecimens in accordance with the ways approved by the DIAN-TU.

d. No sharing of data or biospecimens with a third party are allowed.

e. Data generated by recipients of DIAN-TU biospecimens must be provided back to the DIAN-TU to support the NIH requirements of reproducibility of findings and to further enhance the DIAN-TU database. The requestor should provide acknowledgements for the funding and work along with the dataset. The DIAN-TU will ensure future users of this data include appropriate acknowledgments in publications.

f. All data provided by the DIAN-TU will be destroyed when analyses are complete. Residual samples must be returned to the DIAN-TU.

g. Notify the DIAN-TU of publication acceptance and provide a copy of the publication to the DIAN-TU Data Request Manager so that the DIAN-TU may report productivity derived from our resources to our funding agencies.

h. Notify the DIAN-TU of funding resulting from this research with details (grant title, sponsor, number, dollar total, and dates) so that the DIAN-TU may report productivity derived from our resources to our funding agencies.

i. If the requestor is associated with the DIAN-TU Trial (e.g., a Core or Performance Site), the core/site leader must identify an individual within the core/site who will receive the data and conduct the analyses. This individual must not have contact with participants nor play any role in data processing that involves interpretation or judgment to avoid un-blinding of study personnel or biasing of the data.

11. Required after approval, but prior to receipt of data and/or biospecimens

a. Fully executed Data Use Agreement

b. For biospecimens, a fully executed Material Transfer Agreement which follows the NIA Biospecimen Task Force guidelines related to material transfer agreements.

12. Grant Applications

Approval by the DIAN-TU Data and Biospecimen Request Review Committee need not precede submission of your grant application, but it is strongly recommended. For approved requests, the DIAN-TU can provide a letter of support to accompany your application stating that the DIAN-TU resources you have requested are available and your request for these resources has been approved. If your request is under review, the DIAN-TU can provide a generic letter of support stating that the DIAN-TU resources may be available to you should your data request and grant application be approved. If you have not yet submitted a request, you can still receive the generic letter of support, but you will need to submit a letter of intent to the DIAN-TU Data Request Manager NO LESS THAN 60 DAYS PRIOR TO THE GRANT APPLICATION DEADLINE.

Common Obstacles to Approval

- Inadequate background/justification.
- Poor description of biospecimen requested.
- Failure to include a list of data variables requested in table format. Putting this information in paragraph form will significantly delay the fulfillment of your request and may result in the omission of desired variables.
- Failure to consult the appropriate Core Leaders in advance of submitting a request.
ii. **Request Review Process**

The DIAN-TU follows the principles of productivity (with recognition of the investigator who develops a research idea and does the work to publish it), transparency, fairness, and inclusiveness. In addition, it is most important that early data sharing (before trial completion) not impact the integrity of the trial or threaten regulatory approval of a treatment for AD. Lastly, because of our unique population (dominantly inherited AD), special care has to be taken to ensure even blinded data doesn’t reveal a participant’s mutation or treatment status or give a perception of a participant’s mutation or treatment status. The following process flow diagrams outline the steps for data and biospecimen sharing and includes steps to ensure trial integrity, protection of participant confidentiality, and contractual compliance.
DIANTU Biospecimen Request Process Flow

1. **Analysis Requestor**
   - After consulting with the relevant Core Leader(s), requestor submits biospecimen request.
   - Submit proposed analysis, rationale, SOP, etc.
   - Complete and return agreement.

2. **Data Analysis Request Manager**
   - Notify requestor and request additional information if needed.
   - Route to Review Committee for trial integrity check.
   - Appropriate use of specimens and data, specimen availability, and approval for request.
   - Route to Industry Collaborator(s) for review and approval.

3. **Scientific Review**
   - Requestor provides list of approved and initiated data use and material transfer agreements.
   - Requestor approves.

4. **Data Analysis/Statistical Team**
   - Generate data file or analyze data per request and provide to Data Request Manager.
   - Combine new data with existing DIANTU dataset.

5. **Biospecimen Management**
   - Pull and ship samples to requestor per the material transfer agreement.
   - Return or destroy residual samples per protocol.
1. Data and biospecimen requests will have an initial review by the DIAN-TU Data Request Manager for validity and to ensure the request is complete. If more information is needed, the Data Request Manager will ask the requestor for additional information or clarification of the request.

2. If the request passes the initial review, the Data Request Manager will route the request to the relevant DIAN-TU Industry Collaborators for review and feedback and to the DIAN-TU Data and Biospecimen Request Review Committee for review and approval/denial:

   **DIAN-TU Data and Biospecimen Request Review Committee**
   - DIAN-TU Director or Associate Director (Randall J. Bateman, Eric. M. McDade, or David Clifford) or designee
   - DIAN-TU Project Arm Leader(s) for the drug arm of the data and/or biospecimens requested
   - IQVIA Biostatistics (Ryan Thompson or designee)
   - DIAN-TU Biostatistics (Guoqiao Wang and Chengjie Xiong)
   - Subject Matter Experts (Related Core Leaders or designated consultants)
   - DIAN-TU Clinical Operations (Susan Mills or designee)
   - DIAN-TU Administration (Anna Santacruz or designee)

3. A documented form of approval from each of the above individuals will be filed with the request documentation. If consensus is not reached regarding the request, further review by the DIAN-TU Director/Principal Investigator may be required.

4. Requests will be reviewed based on the following criteria:
   a. Appropriateness of the investigator’s qualifications and resources to protect the data.
   b. Scientific merit and feasibility (e.g., availability of DIAN-TU resources to fulfill the request, burden on staff)
   c. Risk to trial integrity
   d. Risk of unblinding to mutation status (e.g., requests on a single participant, family, mutation, etc.)
   e. Risk of unblinding to treatment assignment (e.g., requests on a single participant, family, mutation, etc.)
   f. Appropriateness to DIAN-TU goals/themes
   g. Drug arms are not being compared to one another
   h. For biospecimen requests
      - Demonstration of preliminary data from Sporadic AD or Dominantly Inherited AD
      - Demonstration of the need for trial or drug related effects
      - Burden on DIAN-TU biospecimen resources
      - Plan to account for the potential of drug interference
   i. For raw imaging requests, appropriate justification of why raw data is needed vs. the processed data.

5. Requests will also be compared to prior approved data/biospecimen requests to determine
whether or not a similar request has already been received. If that is the case, the requestor will be notified so that they may pursue collaboration; however, that does not preclude the requestor’s eligibility to receive the dataset.

6. The Data Request Manager will send results of the review via email to the requestor and, for approved requests, determine the process for the data analyses. Data analyses may be performed in one of two ways:
   a. Data will be provided to the requestor, and the requestor performs the analyses. The requestor will provide the statistical code to the DIAN-TU Biostatistics Core for reproducibility purposes.
   b. The requestor works with the DIAN-TU Biostatistics Core to develop or finalize the analysis plan and statistical code. The DIAN-TU Biostatistics Core performs the analyses and provides the results to the requestor. The DIAN-TU Biostatistics Core will continue to work with the requestor on the analyses as needed.

   This latter option will be used when sharing of actual data poses a risk to trial integrity. For example:
   - Sharing of individual participant level data with DIAN-TU Study Team Members or others who need to remain blinded to participant treatment status during a treatment extension period.
   - Sharing of DIAN-TU trial study drug data during other ongoing studies of that study drug (e.g. study drug trials in sporadic AD).

   This latter option may also be used if a requestor does not have access to statistical resources or prefers to use the DIAN-TU Biostatistics Core resources for analyses.

7. Once a determination is made regarding the analyses/data sharing process, the Data Request Manager will do the following:
   a. If the data will be transferred, the Data Request Manager will notify the DIAN-TU Biostatistics Core and/or IQVIA to prepare the dataset and coordinate the data transfer. The Biostatistics Core personnel will prepare a file containing only the data elements requested, together with a participant identification number (not the DIAN-TU ID#, but identifier recoded to protect confidentiality) so that questions about particular individuals can be resolved without the investigator's knowledge of the participant’s identity.
   b. If the analyses will be performed by the DIAN-TU Biostatistics Core, the Data Request Manager will notify the DIAN-TU Biostatistics Core and coordinate communications between the Biostatistics Core and the requestor to finalize the analysis plan.
   c. For biospecimen requests, the Data Request Manager will notify the relevant DIAN-TU Core to prepare and coordinate the biospecimen transfer.

8. Along with notification of data/biospecimen request approval, the Data Request Manager will provide the requestor information regarding publication and authorship (see sections III and IV, the DIAN-TU Publications Policy and Authorship and Citation Policy).

iii. Request Tracking and Follow-up

1. Requestors are expected to submit for publication within 12 months after receipt of data or samples. Requests will expire after 3 years or upon publication acceptance, whichever comes first. Given appropriate justification, requests may be extended or approved for updated
datasets. Requests may be renewed under the following conditions:

a. Scientific justification for continuation of the approved project
b. Scientific justification for a need for an updated data freeze
c. Demonstration of productivity with prior datasets (e.g. Conference Abstracts and Publications)
d. Demonstration of continued compliance with DIAN data and tissue sharing policies

NOTE: Should DIAN-TU Leadership determine that the request does not have sufficient scientific justification for extension or that the request has deviated from the original approved project, then a recommendation will be communicated to the requesting investigator to submit a new request.

2. The Data Request Manager will contact the recipient at least semi-annually for application information updates. These requests will also solicit responses to the following queries about manuscripts:

a. Title of each manuscript in development
b. Lead (or senior) author of each manuscript in development, and contact information for that author
c. Status of each manuscript in development, i.e. in development, in submission, or in press/published
d. Citation of each published manuscript
e. Upload a file of each published manuscript

3. Publications will be provided to the DIAN-TU for review in accordance with the timelines set forth in the DIAN-TU Publication Policy (Section III). The Data Request Manager will work with the DIAN-TU Medical Team (PALs, Medical Director, DIAN-TU Director, DIAN-TU Associate Director) to check publications for potential unblinding issue and risks to trial integrity and DIAN-TU Administration to ensure compliance with the DIAN-TU Publication, Authorship, and Citation Policies (Sections III and IV). The DIAN-TU will not attempt to evaluate the scientific merit of proposed analyses, nor evaluate proposed abstracts from requests by non-DIAN-TU researchers. However, DIAN-TU Study Team Member requests for proposed analyses, abstracts, presentations, etc. will be reviewed for scientific merit and statistical validity.

The Data Request Manager will also provide the publication to the relevant DIAN-TU Industry Collaborators for review if required or appropriate. Review timelines for the DIAN-TU Industry Collaborators will be in accordance with the DIAN-TU Publication Policy (section III) and requirements of related Industry Collaborators. Expedited review can be requested, but may not always be granted.

4. The number, type, and disposition of the requests will be tracked by the DIAN-TU Data Request Manager and a data sharing report will be generated for progress and final reports to the National Institute on Aging (NIA) and other funding groups supporting DIAN-TU activities.

5. **Estimated Timelines for Requests**

a. 30-60 days for the data-only request review process
b. 90-120 days for the biospecimen request review process (reviewed semi-annually, with more extensive review)
c. 30 days from the time of request approval for provision of dataset and/or biospecimens

iv. Protection of Confidentiality

Despite the absence of personal information in the dataset, the possibility of deductive disclosure of participant identity remains because participants are associated with specific institutions, and the dataset contains detailed demographic information, as well as detailed prospective information about their disease and mutation status, living situation, etc. The following precautions to ensure confidentiality in shared datasets will be taken:

1. Each requested dataset will be stripped of DIAN-TU identifiers and re-coded with randomly-generated dummy IDs prior to release. The code linking a participant’s identity to data will be maintained only at the DIAN-TU site where the participant is enrolled. This link will only be accessible to research staff on a need to know basis. Any research data that goes outside of the study group will be coded with a second unique identifier (which is different from the study ID, another unique identifier) to limit the risk of loss of confidentiality.

2. Datasets will be transferred only with encryption and password protection by the CRO or Biostatistics Core.

3. A participant’s drug status (active or placebo) will not be provided with baseline data.

4. If the requestor is associated with the DIAN-TU Trial (e.g., a Core or Performance Site), the core/site leader must identify an individual within the core/site who will receive the data and conduct the analyses. This individual must not have contact with trial participants nor play any role in data processing that involves interpretation or judgment to avoid un-blinding of study personnel or biasing of the data.

5. Recipients agree to follow the guidelines listed in the DIAN-TU Publication Policy (Section III.B) for display of DIAN-TU data. The DIAN-TU Medical Team (PALS, Medical Director, DIAN-TU Director, DIAN-TU Associate Director) will review figures prior to publication/presentation to ensure results as displayed are not unblinding.

6. Recipients of DIAN-TU data agree to only use the data in accordance with the ways approved by the DIAN-TU and this policy.

v. Unusual Situations

It is expected that most users of DIAN-TU data will follow these guidelines/requirements in good faith and that most analyses will be of reasonable quality. While the DIAN-TU will review manuscripts for unblinding issues and risks to trial integrity, the DIAN-TU does not intend to review manuscripts for scientific quality, preferring to let the peer-review process sort out quality. It is recognized that DIAN-TU data may even be used to support publications with conflicting results. However, we do anticipate the possibility of some unusual circumstances:

1. Egregiously Poor Manuscripts. If a review of a proposed manuscript reveals that it is egregiously poor in terms of language, writing, or scientific credibility, the DIAN-TU can recommend to the authors that it not be submitted without significant revision. If the authors choose to submit the manuscript anyway, the DIAN-TU will have three options:
   a. Request that the acknowledgement credit be withheld;
   b. Request that the authors publish a statement to the effect that while DIAN-TU data were used, the DIAN-TU did not find this manuscript of sufficient merit to warrant submission for
publication; and/or

c. Revocation of privileges to use DIAN-TU data in the future.

2. **Failure to Follow the Data Use Agreement.** If users violate the Data Use Agreement, the sole sanction available to the DIAN-TU will be to revoke access to the DIAN-TU data.

3. **Fraudulent Use of Data.** Should the DIAN-TU discover an attempt to publish DIAN-TU data obtained fraudulently (i.e., stolen data), the data user will be sanctioned through NIH communication with them and/or their academic supervisors. As soon as the DIAN-TU becomes aware of any breach of the Data Use Agreement, immediate steps will be taken to cure the breach or end the violation. This may include discontinuing the user’s data access and/or reporting the violation. The DIAN-TU will revoke access to the DIAN-TU data and may limit or terminate any participation in the DIAN-TU studies and take legal action as needed, including but not limited to causes of action for damages and injunctive relief.
III. PUBLICATION POLICY

The DIAN-TU Publication Policy defines the DIAN-TU’s requirements and processes for publishing, presenting, and communicating findings from DIAN-TU data and DIAN-TU related activities. This policy applies to all public and scientific communications related to the DIAN-TU, including without limitation: manuscripts, abstracts, poster presentations, lectures, interviews, public website postings or other dissemination of results or analysis of any data or biological specimens derived from DIAN-TU activities.

DIAN-TU Study Team Members and non-DIAN-TU researchers utilizing the DIAN-TU data or biospecimens for or discussing DIAN-TU related activities in public and scientific communications must abide by this policy as well as other policies established by the DIAN-TU regarding the use of DIAN-TU resources. DIAN-TU Study Team Members are considered to be all those individuals who work or have worked on DIAN-TU trials (e.g. Core Leaders, Industry Collaborators, site PIs, partner sites PIs, referring physicians). The full list can be found at https://dian.wustl.edu/our-research/funding/. The DIAN-TU Director/Principal Investigator shall make the final determination regarding any disputes related to analyses, authorship or other issues related to publications or presentations that are the subject of this Publication Policy.

Any deviation from the DIAN-TU Publication Policy may result in actions to limit the risk to the integrity of DIAN-TU trials, well-being and personal data of DIAN-TU Trials participants; such actions could include barring violators from future data or biospecimen requests, institutional involvement to rectify deviations, and potential legal action.

A. Public and Scientific Communications Requirements

All public and scientific communications (manuscripts, abstracts, poster presentations, lectures, press releases, interviews, public website postings, etc.) must be requested, reviewed, and approved by the DIAN-TU before they are published, presented, or appear in public.

NIH open access policies must be followed and a PubMed Central ID# must be obtained for all DIAN-TU published manuscripts.

i. Manuscripts, abstracts, posters, and lecture presentations

1. Manuscripts, abstracts, posters, and lecture presentations must adhere to the authorship requirements defined in the DIAN-TU Authorship and Citation Policy (Section IV).

2. Manuscripts, abstracts, posters, and lecture presentations must adhere to the acknowledgment requirements defined in the DIAN-TU Authorship and Citation Policy (Section IV) and the Data Use Agreement, including acknowledgement of National Institute on Aging (NIA) of the National Institutes of Health (NIH) support using the NIA-NIH grant numbers for the DIAN-TU, the other financial sponsors of the DIAN-TU, and the DIAN-TU Study Team.

3. Manuscripts, abstracts, posters, and lecture presentations must follow the Requirements for Display of DIAN-TU Trial Data (Section III.B) for generating figures and tables.

4. Manuscripts, abstracts, posters, and lecture presentations must be submitted to DIAN-TUDataRequest@wustl.edu for administrative and statistical review, and Industry Collaborator review as required. Publications including DIAN-TU trial study drug data or findings will need to be reviewed by the relevant DIAN-TU collaborators (e.g. study drug/investigational product owners). Documents must be submitted for review per the following schedule. Expedited review can be requested, but may not be granted.
a. *Manuscripts* must be submitted to the DIAN-TU at least 60* days prior to submission to a journal to allow time for review and response to recommended edits. If an *Industry Collaborator* is a co-author, they should be included in the manuscript development to minimize the review time by their company communications team.

*NOTE: Manu*script*ts including MK-6240 tau imaging data must be submitted 90 days prior to submission.*

b. *Final versions of presentations or posters* must be submitted to the DIAN-TU at least 10 business days prior to submission to a conference or the presentation date to allow time for review and response to recommended edits. If an *Industry Collaborator* is a co-author, they should be included in the presentation or poster development to ensure a final version is submitted to their company communications team and minimize review time.

c. *Final versions of abstracts* must be submitted to the DIAN-TU preferably 10 business days, but no shorter than 5 business days prior to submission to allow time for review and response to recommended edits. If an *Industry Collaborator* is a co-author, they should be included in the abstract development to ensure a final version is submitted to their company communications team and minimize review time.

The DIAN-TU will not attempt to evaluate the scientific merit of proposed analyses, nor evaluate proposed abstracts from non-DIAN-TU Study Team Member requests, but will review the statistical analyses for rigor and reproducibility. However, DIAN-TU Study Team Member requests for proposed analyses, abstracts, presentations, etc. will be reviewed for scientific merit. The DIAN-TU will review all manuscripts and presentations for unblinding issues and risks to trial integrity, in addition to administrative review of manuscripts to ensure appropriate acknowledgments.

5. Author must inform the DIAN-TU of acceptance or rejection of the manuscript, abstract, poster or lecture presentation.

6. A final copy of the manuscript, abstract, poster, or lecture presentation must be provided to the DIAN-TU as follows. Final copies will be shared with appropriate stakeholders. If permitted by the journal or publication venue, a version of the publication or link to the publication may be made available online at the DIAN-TU website.

a. *Manuscripts*: A copy of the final manuscript and supplemental materials must be provided to the DIAN-TU Data Request Manager upon acceptance by the journal. In addition, the complete citation of the published manuscript must be provided to the DIAN-TU including the PubMed Central ID.

b. *Abstracts*: A pdf copy of the final abstract will be provided to the DIAN-TU upon submission of the abstract to the conference or related venue.

c. *Posters and Lecture Presentations*: A pdf copy of the final poster or presentation will be provided to the DIAN-TU prior to presentation date.

ii. **Press Releases**

Please contact DIAN-TUDataRequest@wustl.edu immediately after a decision to have a press release is made. Depending on the nature and content, press releases may require review and approval from multiple parties including Washington University Medical Public Affairs, DIAN-TU
Leadership, Industry Collaborators, the NIH, and other supporters of the DIAN-TU. Any media requests referencing a specific drug should and will be directed to the respective Industry Collaborator.

iii. Other Communications (interviews, media inquiries, public website postings, etc.)

1. The DIAN-TU, DIAN-TUDataRequest@wustl.edu, should be notified of these communications at least 2 weeks prior to the appearance or posting to allow sufficient time for review and approval. Depending upon the nature of the communication, multiple approvals (e.g. Washington University Medical Public Affairs, DIAN-TU Leadership, Industry Collaborators, the NIH, and other supporters of the DIAN-TU) may be required. Respective Industry Collaborators must be notified of media inquiries before any answers are provided to members of the media.

2. The notification for communications related to DIAN-TU activities should indicate:
   a. Nature of the communication (interview with site PI, site staff or participant, web posting, etc.)
   b. Venue and audience
   c. Media group when applicable (e.g. journal/newspaper name, radio or television station)
   d. Date of communication
   e. Description of information to be shared

3. While interviews, media inquiries, and website postings do not usually have authors, they should adhere to the acknowledgment requirements defined in the DIAN-TU Authorship and Citation Policy, Section IV.

4. Communications should follow the Public Communication Guidelines, Section III.C.

5. After the communication has occurred, the author/presenter/interviewee should send DIAN-TUDataRequest@wustl.edu a web link for or copy of media communications and website postings to share with appropriate stakeholders. If appropriate, the DIAN-TU will post links to the communications on the DIAN-TU website.

B. Requirements for the Display of DIAN-TU Data

All data relative to genetic status or treatment status must remain blinded in all research publications. To prevent unblinding to genetic or treatment status when displaying DIAN-TU trial data:

i. Present all data so that no DIAN-TU participant, family member, or researcher could assume s/he is represented as an individual or by an individual data point. Regardless of whether it is possible for a participant to draw such conclusion with certainty, data should be displayed in a manner so that participants would not be led to make assumptions about their own data.

ii. Descriptions of the datasets should be sufficiently vague to maintain confidentiality. Absolutes in reference to the timing and content of the datasets should be avoided. For example, state “DIAN-TU data that were deemed useable, approved by study monitors, and that passed all quality control measures were included in these analyses.” Avoid Maximum/Minimum, outliers or unique reports.

iii. Avoid displaying pedigree data in any way that participants and/or pedigree members could learn or make assumptions about information about their mutations or who is affected in their families.
iv. Pay careful attention to all information relating to mutation or treatment status.

v. In all descriptions and depictions of DIAN-TU data, use extreme care with regard to age, age at onset, parental age of onset, estimated years to onset (EYO), and age ranges.

vi. Strongly consider avoiding scatter plots that use age, age at onset, parental age of onset, estimated years to onset (EYO) or other metrics that would be known to participants. Omit the x-axis values or use averaged LOESS curves. “Jitter” may not obscure the data sufficiently to prevent participants from making assumptions about the data.

vii. Displaying extreme values in isolation from other data should be avoided.

viii. Geographic information as it relates to participant data (including any portion of participant zip codes) should not be referenced in publications or displayed with DIAN-TU data.

ix. Do not use dates (e.g. dates of assessments) that could be identifying.

x. Ns of 1 should be avoided. At a minimum, cells should contain at least 3-5 individuals so that there is ~50% chance of mutation status.

xi. Example figures

---

### Table 1. Characteristics of the Study Participants. *

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Carriers (N=88)</th>
<th>Noncarriers (N=40)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age — yr</td>
<td>39.1±10.3</td>
<td>39.5±8.9</td>
<td>0.92</td>
</tr>
<tr>
<td>Male sex — no. (%)</td>
<td>36 (41)</td>
<td>17 (42)</td>
<td>0.85</td>
</tr>
<tr>
<td>Education level — yr</td>
<td>13.9±2.5</td>
<td>15.0±2.5</td>
<td>0.04</td>
</tr>
<tr>
<td>Cognitive status — no. (%)†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptomatic</td>
<td>43 (49)</td>
<td>1 (2)</td>
<td>0.29</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>45 (51)</td>
<td>39 (98)</td>
<td></td>
</tr>
<tr>
<td>Positive for apolipoprotein E</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ε4 allele — no. (%)</td>
<td>22 (25)</td>
<td>9 (22)</td>
<td>0.69</td>
</tr>
</tbody>
</table>

* Plus–minus values are means ±SD.
† Participants were defined as asymptomatic if they had Cognitive Dementia Rating scores of 0 (no cognitive decline) and as symptomatic if they had scores greater than 0.
C. DIAN-TU Public Communications Guidelines

i. Sites should not allow media groups or others to take photos or video of the drug, drug label, drug administration, or any trial documents to prevent release of any confidential information, and to prevent misconceptions or negative perceptions regarding the administration or effects of drug (e.g., participants wincing or indicating pain through facial or other expressions).

ii. Here is a link, https://www.youtube.com/watch?v=TiEj5lsHd48, to a video made by the Seattle chapter of the Alzheimer’s Association about autosomal dominant AD and includes one of the DIAN-TU trial participants. It gives an idea of what can be recorded. Additional media regarding the DIAN-TU trial can be found on the DIAN-TU website, http://dian-tu.wustl.edu/news/.

iii. Although the names of the drugs are available on clinicaltrials.gov, there may be country specific issues with mentioning the drug by name depending on the context. For example, in the UK, to avoid code violations with the Prescription Medicines Code of Practice Authority (particularly clauses 3 (Marketing Authorization) and 26 (Relationships with the Public and the Media) in the 2019 ABPI Code of Practice), if a press release or public communication relates to use of a drug or product before it has been approved, the product/drug name cannot be mentioned, company logos cannot be used and no claims can be made about the drug’s efficacy.

iv. Filming an infusion after insertion of the needle is acceptable as long as the product name is not visible.

v. Send a link to any interview to DIAN-TUDataRequest@wustl.edu when released so it can be shared with DIAN-TU Collaborators and posted to the DIAN-TU website.

vi. Notify the DIAN-TU of the date of any interview or media release. The DIAN-TU needs to inform DIAN-TU Collaborators in advance so they can be prepared to answer questions that may result from the interview/media release.
IV. AUTHORSHIP AND CITATION POLICY

The overarching considerations for DIAN-TU publications are scientific and medical productivity, collaboration, inclusiveness, and recognition. The purpose of this Authorship and Citation Policy is to provide guidance and instructions for authorship and appropriate acknowledgment and citation of the source of the data, funding, in-kind support, and the DIAN-TU Study Team. DIAN-TU Study Team Members are considered to be all those individuals who work or have worked on DIAN-TU trials (e.g. Core Leaders, Industry Collaborators, site PIs, partner sites PIs, referring physicians). The list can be found at https://dian.wustl.edu/our-research/funding/. This policy applies to all public and scientific communications of any DIAN-TU data or DIAN-TU-related activity.

Communications include but are not limited to press releases, interviews, public website postings, presentations (includes poster and/or accompanying abstract) or manuscripts that contain or discuss unpublished DIAN-TU data or DIAN-TU-related activities. DIAN-TU Study Team Members and non-DIAN-TU researchers utilizing the DIAN-TU data or biospecimens or discussing DIAN-TU related activities in public and scientific communications must abide by this policy as well as other policies established by the DIAN-TU regarding the use of DIAN-TU resources. If you are unsure if your communication requires adherence to the DIAN-TU policies regarding communications and use of DIAN-TU resources, please contact DIAN-TUDataRequest@wustl.edu for clarification.

All public and scientific communications (manuscripts, presentations, press releases, interviews, public website postings, etc.) must be requested, reviewed, and approved by the DIAN-TU before they are published, presented, or appear in public.

Any deviation from the DIAN-TU Authorship and Citation Policy may result in actions to limit the risk to the integrity of DIAN-TU trials, well-being and personal data of DIAN-TU Trials participants; such actions could include barring violators from future data or biospecimen requests, institutional involvement to rectify deviations, and potential legal action.

A. Authorship

Authorship is based on the International Committee of Medical Journal Editors (ICMJE) criteria. Please see the ICMJE website, http://www.icmje.org/, for more details.

The DIAN-TU Director/Principal Investigator or Associate Director adjudicates all disputes related to analyses, authorship, etc. A grievance process (beginning with notification to the DIAN-TU Principal Investigator) will hear any authorship issues that arise.

i. Manuscript Authorship

When non-DIAN-TU Study Team Members use DIAN-TU Trial data or biospecimens, an invitation to respective DIAN-TU Study Team Members to participate in the manuscript development is encouraged, but not required. DIAN-TU Study Team Members leading a manuscript are required to send an invitation to participate to respective DIAN-TU Study Team members. DIAN-TU Study Team Members have extensive experience in the implementation, performance, and analysis of DIAN-TU data and can enhance external analyses and manuscripts. Requesting investigators should review current data requests posted on the DIAN-TU Trial website (https://dian.wustl.edu/our-research/for-investigators/diantu-investigator-resources/) to determine if there is already a similar request in progress. If a similar request already exists, the requesting investigator should contact the lead author regarding collaboration. Other DIAN-TU Study Team Members may also
communicate their desire to collaborate when a data or biospecimen request is reviewed. Please contact DIANTUDataRequest@wustl.edu for the list of DIAN-TU Study Team Members who should be invited to co-author.

Special Instructions for Manuscripts led by a DIAN-TU Study Team Member

DIAN-TU Study Team Members leading a manuscript must send an invitation to collaborate (meriting authorship) on the manuscript to other DIAN-TU Study Team Members who significantly contributed to the study and data collection (e.g. study specific Core Leaders, Industry Collaborators, site PIs, partner sites PIs, referring physicians). The invitation must be sent at the time of the data request to give the other investigators the opportunity to fully engage in the analyses and writing of the manuscript. Please contact DIANTUDataRequest@wustl.edu for the list of DIAN-TU Study Team Members who should be invited to collaborate.

In addition to the named authors, manuscripts by DIAN-TU Study Team Members must include “for the Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU)*” as an author in the author byline of the manuscript (after the named authors) with the asterisk referring to the following statement and website link that will list the names of the DIAN-TU leadership, key contributors to the DIAN-TU trial platform design and/or organization, Industry Collaborator, scientific and philanthropic collaborators, as well as collaborators from each DIAN-TU performance site (the site Principal Investigator (PI) and other individuals designated by the site PI).

*Data used in the preparation of this article were obtained from the Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU). As such, the study team members within the DIAN-TU contributed to the design and implementation of DIAN-TU and/or provided data but may not have participated in the analysis or writing of this report. A complete listing of the DIAN-TU Study Team Members can be found at dian.wustl.edu, DIAN-TU Study Team.

If the DIAN-TU group author cannot be used because of journal policies, then, at a minimum, the DIAN-TU Study Team should be listed in the acknowledgments with a link to the DIAN-TU Study Team page on the DIAN-TU website. In addition, a list of the DIAN-TU Study Team members and their contributions to the study should be listed in the supplemental materials. Please refer to the DIAN-TU Study Team page on the DIAN-TU website for the complete list of the DIAN-TU Study Team Members which includes federal, philanthropic, and scientific funding agencies, Industry Collaborators, study leadership, core leaders and teams, institutional study partners, and study performance site investigators and personnel.

ii. Abstract Authorship

The categories and authorship rules for abstracts accompanying presentations are as stated for the manuscript authorship but may have limitations on the number of authors permitted. If authorship is limited or impractical to include all authors in the abstract authorship list, then “The DIAN-TU Study Team” would be listed as an author with a link to the full study team list on the DIAN-TU website.

iii. Press releases, interviews, media inquiries, and presentations

Press releases, interviews, media inquiries, and presentations without published abstracts usually do not have authors. When presentations are accompanied by published abstracts, the authorship
rules for the abstracts are the same as for other types of publications, as described in this document.

iv. Arbitration

When conflicts exist regarding DIAN-TU publications, written summaries of the conflict submitted by those involved will be reviewed by the DIAN-TU Administration Core and/or Data Request Manager. The DIAN-TU PI will adjudicate the resolution. Any DIAN-TU Trial investigator who wishes to opt out of any automatic authorship listing may do so by emailing their opt out request to DIAN-TUDataRequest@wustl.edu.

B. Citations and Acknowledgements

i. Designation of DIAN-TU Study Team Members in Supplements to Publications:

DIAN-TU publications should recognize the non-author DIAN-TU Study Team members and their contributions to the study. All DIAN-TU Study Team Members should be listed in the acknowledgments and a link to the web page where lists of personnel can be found should be also included. If space is limited, a list of the DIAN-TU Study Team members and their contribution to the study should be listed in the supplemental materials. Please refer to the DIAN-TU Study Team page on the DIAN-TU website for the complete list of the DIAN-TU Study Team Members which includes federal, philanthropic, and scientific funding agencies, Industry Collaborators, study leadership, core leaders and teams, institutional study partners, and study performance site investigators and personnel. The Administration Core will be responsible for maintaining the list of all current DIAN-TU Study Team members for inclusion in publications and will update this list as needed on the DIAN-TU website.

ii. Required language to include with the Methods section of publications

The following language should be included in the Methods Section of the publication to accurately acknowledge data gathering by the DIAN-TU personnel. Depending upon the length and focus of the article, it may be appropriate to include more or less than the example below, however, inclusion of some variation of the language shown below is mandatory.

*Data used in the preparation of this article were obtained from the Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU). The DIAN-TU was launched in 2011 as a public-private partnership, led by Principal Investigator Randall J. Bateman, MD. The primary goal of the DIAN-TU is to implement effective, safe and efficient clinical trials that have the highest likelihood of success in advancing overall treatments as well as scientific understanding of dominantly inherited Alzheimer’s disease. For up-to-date information, see https://dian.wustl.edu/*. 

iii. Required language to appear in the Disclosures section of publications related to Solanezumab

For publications pertaining to the DIAN-TU research that speaks to solanezumab or Eli Lilly and Company, in relation to the solanezumab license with WU, i.e. any publication using DIAN-TU trial data from the solanezumab drug arm or in any publication in which solanzumab is specifically identified or the solanezumab arm of the DIAN-TU-001 trial is identified (e.g. a discussion of study design that includes an overview of the DIAN-TU-001 solanezumab study design or a publication covering all of the different approaches and therapeutic arms throughout all of DIAN-TU) AND the publication is authored by Drs. David Holtzman, Randall J. Bateman, or Barbara Joy Snider, the
following disclosure is required:

Dr. David Holtzman, Department Head of Neurology where the research is being conducted, is an inventor on patents for one of the treatments (solanezumab), which has been tested in the DIAN-TU clinical trials. If solanezumab is approved as a treatment for Alzheimer’s disease or Dominantly Inherited Alzheimer’s Disease, Washington University and Dr. Holtzman will receive part of the net sales of solanezumab from Eli Lilly, which has licensed the patents related to solanezumab from Washington University.

If the publication is about solanezumab in the DIAN-TU trial, but does not include Drs. David Holtzman, Randall J. Bateman, or Barbara Joy Snider as co-authors (on the manuscript, poster, abstract, etc.), the disclosure is not required.

iv. Required language to appear in the Acknowledgments section of all publications on the DIAN-TU trial data and DIAN-TU related activities

All manuscripts should include one of the following statements for acknowledgement of funding sources:

1. General DIAN-TU and/or DIAN-TU Trial Platform (not drug specific or all drugs)

Research reported in this publication was supported by the National Institute on Aging of the National Institutes of Health under Award Numbers U01AG042791, U01AG042791-S1 (FNIH and Accelerating Medicines Partnership), R1AG046179, R01/R56 AG053267, R01AG053267-S1. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. This research was also supported by the Alzheimer’s Association, Eli Lilly and Company, F. Hoffman-LaRoche Ltd., Janssen Pharmaceuticals, Avid Radiopharmaceuticals (a wholly owned subsidiary of Eli Lilly and Company), GHR Foundation, an anonymous organization, Cogstate, and Signant. The DIAN-TU has received funding from the DIAN-TU Pharma Consortium. We acknowledge the altruism of the participants and their families and contributions of the DIAN, DIAN Expanded Registry, and DIAN-TU research and support staff at each of the participating sites (see DIAN-TU Study Team) for their contributions to this study.

2. Publications including the DIAN-TU Trial Platform Solanezumab and Gantenerumab drug arms

Research reported in this publication was supported by the National Institute on Aging of the National Institutes of Health under Award Numbers U01AG042791, U01AG042791-S1 (FNIH and Accelerating Medicines Partnership), R1AG046179, R01AG053267-S1. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The research for the DIAN-TU-001 trial, solanezumab and gantenerumab drug arms, was also supported by the Alzheimer’s Association, Eli Lilly and Company, F. Hoffman-LaRoche Ltd., Avid Radiopharmaceuticals (a wholly owned subsidiary of Eli Lilly and Company), GHR Foundation, an anonymous organization, Cogstate, and Signant. The DIAN-TU has received funding from the DIAN-TU Pharma Consortium. We acknowledge the altruism of the participants and their families and contributions of the DIAN, DIAN Expanded Registry, and DIAN-TU research and support staff at each of the participating sites (see DIAN-TU Study Team) for their contributions to this study.

3. Publications including the DIAN-TU Trial Platform Atabecstat drug arm
Research reported in this publication was supported by the National Institute on Aging of the National Institutes of Health under Award Numbers R01/R56 AG053267 and R01AG053267-S1. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The research for the DIAN-TU-001 trial, atabecestat drug arm, was also supported by the Alzheimer’s Association, Janssen Pharmaceuticals, GHR Foundation, and an anonymous organization. The DIAN-TU has received funding from the DIAN-TU Pharma Consortium. We acknowledge the altruism of the participants and their families and contributions of the DIAN, DIAN Expanded Registry, and DIAN-TU research and support staff at each of the participating sites (see DIAN-TU Study Team) for their contributions to this study.

v. Publications led by a DIAN-TU Core Team Member

For publications led by a DIAN-TU Core Team Member, the following statement should be added to the acknowledgement statement:

This manuscript has been reviewed by DIAN-TU Study investigators for scientific content and consistency of data interpretation with previous DIAN-TU Study publications.
## V. VERSION HISTORY

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<th>Description</th>
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<td>12-Jan-2021</td>
<td>New policy</td>
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