Informed Consent Ensuring Access to Anonymized Patient-Level Data and Biospecimens is Critical to Accelerating Innovative Alzheimer Disease Treatments

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Background

- Informed Consent Forms (ICFs) are a central requirement of clinical research in the USA, intended to ensure that prospective participants understand the risks and benefits of the study and the purpose of the research before they agree to participate. Typically, ICFs have evolved into lengthy and technical (15-40) pages designed to protect both the patients and the sponsors of the research study.
- Many ICFs do not discuss secondary research purposes or corresponding data sharing, leaving the research participant uninformed and data/samples may be lost in storage or are destroyed after the study has concluded.
- ICFs that restrict the distribution of data and samples have been an impediment to advancing Alzheimer disease (AD) understandings and treatments.
- Many projects rely on the sharing of data or samples and, in some cases, could not be accomplished because ICFs had been used that did not include provisions addressing potential data sharing.
- The Coalition Against Major Diseases (CAMD) is one of fourteen public-private-partnerships of the Critical Path Institute that is dedicated to delivering on the vision of the U.S. Food and Drug Administration's (FDA) Critical Path Initiative. It convenes diverse stakeholders (academia, non-profit patient-advocacy or research foundations, industry, and regulatory agencies) to collaboratively create tools and methods to advance new treatments for various stages of Alzheimer disease and related neurodegenerative diseases.

Objective

- Develop concise addenda to responsibly broaden data access of informed consent forms used for clinical trials.

Methods

- CAMD assembled a working group of individuals from industry, advocacy, and information technology backgrounds to draft addenda that would enable responsible data sharing.
- Addenda were designed for clarity and brevity with direct oversight from patient communication experts at the Alzheimer's Association, and Sage Bionetworks, the creator of eConsent.
- The addenda were reviewed by patients and care-givers from the **Alzheimer's Association – National Early-Stage Advisory Group (AA-NESAG)**.

Results

ICF Addendum to Ensure Future Data and Sample Sharing

Overview

The information collected in this study will be used to:

- see if the study drug works and is safe;
- compare the study drug to other potential or approved therapies;
- examine the relationship of the data and samples to that of other diseases;
- develop new tests;
- improve the design of future studies;
- advance the understanding of health and disease;
- accelerate other activities (e.g., creation of clinical tools that improve the delivery of innovative treatments by advancing basic and regulatory science).

You will not be identified in any publication from this study or in any data files shared with other researchers. Your identity will be protected as required by law.

When the information from this study is shared outside the study site, the information that identifies you will be removed. In addition, the Sponsor, like other Sponsors, provides access to clinical data that has been further de-identified so that outside researchers can use this data. Information that could directly identify you will not be included.

Your Rights: Data and Samples

You have the right to decide whether to participate in the study. If you decide to participate in the study, the following are groups with whom your study team may share your data and samples to improve new treatments or the conduct of clinical trials:

- Health authorities throughout the world [e.g., U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and other governing bodies that review clinical trials];
- Institutional Review Boards (IRBs) that oversee, and review the ethics of the research;
- The study Sponsor, and those working for or with the Sponsor, which may include affiliates of the Sponsor located in your country or other countries;
- Other groups: Examples of which include academic, government, or industry researchers; public-private partnerships; and/or external research collaborations. These entities will have oversight committees that will supervise the ethical use of the data and samples.
- At no time will the data or samples be allowed to be sold by an individual or group for profit.
- Your data and samples will be de-identified or anonymized. This means that your data or samples will not be linked with information that would allow any person or organization to determine that the data directly corresponds to you.
- The health information you contribute will be protected by U.S. federal law [the Health Information Portability and Accountability Act (HIPAA)].
- New results obtained with your data and samples will be reported back to the sponsor, and the results made publicly available.
- You have the right to withdraw your permission for us to use or share your information up until the time that your data and samples are de-identified and pooled together into a database. Your data and samples will be used and shared as described in this form.

Potential Benefits and Risks

Benefits

Allowing your de-identified data and samples to become available to research and regulatory organizations could advance new treatments. By giving approval now for your data and samples to be shared for research purposes, your valuable contributions have the best chance to be used as effectively as possible for research not only today, but also in the future as new research questions and technologies emerge.

Risks

Your de-identified or anonymized data may be shared for research purposes. Because your data and samples are de-identified (anonymized), the potential is extremely small that a person or organization could determine that it belongs to you. However, anonymity cannot be absolutely guaranteed. Experts in re-identification may in very rare cases be able to reverse the processes used to protect your identity and confidentiality.

Withdrawal of Consent

I understand I can withdraw permission to collect data/samples at any time but data already collected and pooled into the database will continue to be used. The study doctor/staff will discuss this with you.

Consent

I give permission to use and share my data and samples as described in this document.

Discussion

Patients with dementia and care partners from the **AA-NESAG** were "shocked" that their data and samples are not broadly shared:

"To me this is a no brainer. I am just learning now that this data was tossed out the window. I am shocked."

"I am getting emotional. It makes me angry to think that they could be using this [data] to find a cure."

"You always run a risk that your data or info will escape, but if it will further the cause of finding a cure/treatment, I think the benefit outweighs the risk."

"I don't think anyone protects information better than an ethical research organization."

With diverse feedback, concise addenda were created to enable data and sample sharing both within, and outside, future sponsored studies. Essential features include:

- The research purposes were intentionally not restricted to any single disease due to the many situations where data and samples collected for one disease may be useful to another.
- Data and samples will not be sold for profit. This concern was reiterated as an important concern by the **AA-NESAG** members and care partners.
- Specific examples of groups with whom a study team may share data and samples, with reassurance that these groups will have oversight committees to supervise the ethical use of the data and samples.
- Potential benefits and risks, in particular, the fact that anonymity cannot be guaranteed.

The addenda were made public as a **PERSPECTIVE** "*Concise informed consent to increase data and biospecimen access may accelerate innovative Alzheimer's disease treatments*", Alzheimer's & Dementia: Translational Research & Clinical Interventions 3 (2017) 536-541

Conclusions

- Data and sample sharing from clinical research is being increasingly recognized, with leading groups describing it as an ethical obligation to the participants who may have put themselves at risk in interventional clinical trials.
- With technological advances over the past 50 years, the data and samples collected in one study can often be used for secondary research purposes, reducing the costs, time, and patient-burden needed to develop effective therapies.
- Increasing the access of valuable anonymized patient-level clinical trial data has the potential to inform the foundational and regulatory science required to deliver innovative treatments for AD and, potentially, other neurodegenerative diseases.

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