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FROM THE ALZHEIMER'S ASSOCIATION INTERNATIONAL CONFERENCE 2022

**17 RECOMMENDATIONS FOR RESEARCHERS TO BETTER
COMMUNICATE WITH STUDY PARTICIPANTS
WHEN TRIALS END EARLY**

SAN DIEGO, AUGUST 2, 2022 – Participants in clinical trials can feel abandoned and adrift when their studies end early and they are the last to be informed, or they hear about it first from news or social media. A multidisciplinary workgroup convened by the Alzheimer's Association® today released 17 recommendations for clinical trial sponsors, researchers and staff about how to better communicate with study participants when trials stop sooner than expected.

The recommendations were announced today at the [Alzheimer's Association International Conference®](#) (AAIC®) 2022, in San Diego and online. They were simultaneously published online by [Alzheimer's & Dementia: The Journal of the Alzheimer's Association](#). (“Putting Participants and Study Partners FIRST When Clinical Trials End Early.” Emily A. Largent, J.D., Ph.D., RN, et al. DOI: 10.1002/alz.12732)

The Participant Follow-Up Improvement in Research Studies and Trials (Participant FIRST) workgroup, convened by the Alzheimer's Association in 2021, brought together stakeholders from the academic, industry, government and non-profit research communities, along with research participants and study partners, to establish recommendations for the Alzheimer's and dementia research community.

The workgroup's goals were to identify best practices for communicating with and supporting Alzheimer's research volunteers and their study partners who are directly affected by early stopping of clinical trials.

“Participants and study partners invest time, effort and hope in their research participation, and they should be treated with care and respect. On top of that, the experiences of today's participants may influence tomorrow's potential participants and their willingness to enroll in the next Alzheimer's clinical trial,” said Nancy Childs, Ph.D., workgroup participant, co-author of the journal article, and study/care partner for her husband, Mike.

There are a variety of reasons why research studies may end early. “No matter the reason, it is critical that a plan is in place to help guide interactions with participants and their study partners, and to respect the enormous commitment they have made to advancing research,” said Emily A. Largent, J.D., Ph.D., RN of the Department of Medical Ethics and Health Policy at the University of Pennsylvania Perelman School of Medicine, first author of the journal article and a co-leader of the workgroup.

The workgroup generated 17 key recommendations to guide study sponsors, funders, investigators and personnel spanning the pre-trial, mid-trial and post-trial time periods that focus on:

- Proactively allocating sufficient resources for orderly closeout if trials end early.
- Developing communication plans centered on research participants and their study partners.
- Helping participants and their study partners build and maintain support networks.
- If a trial stops early, rapidly informing study participants and their study partners.

“This type of culture change will require commitment from sponsors, funders, principal investigators, site investigators and study personnel,” said Rebecca M. Edelmayer, Ph.D., Alzheimer’s Association senior director of scientific engagement who co-led the workgroup and co-authored the journal article. “The Participant FIRST workgroup’s recommendations aim to assist the research community in taking intentional steps towards better supporting participants and study partners when clinical trials end early.”

“While these recommendations were developed with Alzheimer’s and dementia research at the forefront of workgroup members’ minds, they may be applicable more broadly to other fields of therapeutic research,” Edelmayer added.

17 key recommendations for better communication

Five pre-trial recommendations focus on accounting for the possibility of early stopping from the outset, particularly in budgeting and resource allocation, staffing, and communications plans. For example:

- Close-out budgets should cover a research coordinator’s time for a pre-specified period after the trial ends to ensure participants have a contact person and advocate at the study site.
- All communications should be clear and accessible to participants with cognitive impairment, culturally sensitive, and available in participants’ preferred language(s).
- An essential piece of the communication plan is a draft email that can be used to notify study participants and study partners if the trial ends early. The goal of this email is to reassure those who receive it that study personnel recognize there will be many questions and will follow up soon for a more in-depth discussion.

The workgroup also recommends establishing and guiding people to information resources such as the National Institute on Aging’s website (www.nia.nih.gov), which offers extensive clinical trials information, including a discussion of early stopping. Patient advocacy and research organizations such as the Alzheimer’s Association (www.alz.org/whentrialsend) and the Association for Frontotemporal Degeneration (<http://www.theaftd.org/research-clinical-trials/clinical-trials/>) also are recommended.

Three mid-trial recommendations include:

- Regularly updating contact information for participants and study partners.
- Reminding participants and study partners that clinical trials might end early.

Nine post-trial recommendations are more varied, and include:

- Ensuring that news releases announcing early stopping of clinical trials explicitly address participants and study partners.

- Site investigators and study personnel should immediately be notified that the trial is ending so they can answer participants' and study partners' questions consistently and correctly.
- Make initial contact with study participants by email as soon as possible, while ensuring privacy and confidentiality, with more personal contact by phone as soon as possible after that.

“Workgroup members, responding to guidance from study participants and care partners, agree that it is preferable for study participants to learn about early stopping from the research team at their study site, and the best method of notification is by telephone,” said Sarah Walter, program administrator at the Alzheimer’s Therapeutic Research Institute at University of Southern California, who co-led the workgroup and co-authored the journal article. “Participants and their families have developed close relationships with their research team, often over many months and years, and learning difficult news from someone they know and trust is important.”

In addition, the workgroup suggests study leaders leverage social media, collaborate with patient advocacy organizations, conduct a personalized close-out meeting, and share top-line results with participants and their study partners. According to the workgroup, responsibility for implementing the recommendations is shared across the many players responsible for coordination of the clinical trial: sponsor(s), funder(s), principal investigator(s), site investigator(s), and study personnel.

“Clear communication and coordination among these groups — and well-defined roles and responsibilities — will produce timely, seamless, effective support for participants and study partners impacted by early clinical trial termination,” said David S. Miller, M.D., M.A., clinical vice president at Signant Health, workgroup participant and a co-author of the journal article.

Research participants may feel adrift and unsafe

In 2018 and 2019, multiple Alzheimer's and dementia trials ended earlier than planned, including studies of verubecestat (APECS), Merck; atabecestat (EARLY), Janssen; crenezumab (CREAD 1 and 2), Roche; aducanumab (ENGAGE, EMERGE), Biogen/Eisai; and CNP520, Novartis/Amgen.

Many research participants and their study partners first learned about the trials' early and often abrupt ending through news coverage, rather than through direct communication from their study site. The understandable disappointment about the end of these trials — and how they learned about it — led to calls from the Alzheimer’s research community to identify better ways to communicate.

According to the authors: “Although systematic data on participants’ experiences of early stopping are lacking, there is anecdotal evidence that participants have a range of reactions when trials end.” They highlight three reactions — feelings of uncertainty, loss and vulnerability.

- When a trial ends early, many participants and study partners describe being plunged into uncertainty. They have questions about “what comes next?”
- Often, research participants and their study partners looked forward to study visits to socialize and find support. When a trial ends early, these valued relationships and interactions abruptly end, which creates a sense of loss.

- Having access to specialists and personalized care through a clinical trial can promote health and feelings of security. For some, the trial may provide access to health care that isn't otherwise available to them. Early termination of a clinical trial may precipitate feelings of vulnerability.

Why do clinical trials end early?

Clinical trials are research studies that closely monitor participants to test new interventions or drugs that may prevent, stop or treat diseases, including Alzheimer's and other dementia. Researchers develop a plan, called a protocol, for a trial before it begins. The protocol includes how long the study will last. A trial may be stopped early, however, for a number of reasons. The most common are:

- **Benefit.** One arm of a study is found to be clearly superior to the other, and continuing to expose participants to the inferior arm (and to research-related risks) cannot be ethically justified.
- **Safety.** Due to adverse events such as serious illness or death, risks to participants outweigh potential benefits of participation. The study is stopped to protect participants.
- **Futility.** Analyses suggest there is low probability that the trial will meet its prespecified endpoints, even if the study attains its full sample size. Termination of the trial may be recommended for ethical reasons or to conserve the sponsor's resources, time and money.

Alzheimer's & Dementia: Journal of the Alzheimer's Association

[*Alzheimer's & Dementia: Journal of the Alzheimer's Association*](#) bridges the knowledge gaps across a wide range of bench-to-bedside investigations. Content emphasizes interdisciplinary investigations related to: etiology, risk factors, early detection, disease modifying interventions, prevention of dementia and applications of new technologies in health services.

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The Alzheimer's Association International Conference (AAIC) is the world's largest gathering of researchers from around the world focused on Alzheimer's and other dementias. As a part of the Alzheimer's Association's research program, AAIC serves as a catalyst for generating new knowledge about dementia and fostering a vital, collegial research community.

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About the Alzheimer's Association®

The Alzheimer's Association is a worldwide voluntary health organization dedicated to Alzheimer's care, support and research. Our mission is to lead the way to end Alzheimer's and all other dementia — by accelerating global research, driving risk reduction and early detection, and maximizing quality care and support. Our vision is a world without Alzheimer's and all other dementia®. Visit alz.org or call 800.272.3900.

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Participant FIRST: Improving Communication With and Support For Participants in Trials That End Early

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