ADPACE

ALZHEIMER'S DISEASE
Patient and Caregiver Engagement Initiative

Alzheimer's Disease Patient and Caregiver Engagement (AD PACE) is an innovative, patient and caregiver-driven collaboration spanning the public and private sectors. Aimed at identifying and prioritizing the needs and preferences of those living with and affected by Alzheimer's disease, AD PACE will ensure that the patient and caregiver voice is integrated into drug development, regulatory reviews, and reimbursement determinations.

WHAT WILL AD PACE DELIVER?

Over the next few years, AD PACE will develop a wide-ranging, scientifically rigorous understanding of what matters most to individuals across the breadth of the lived-experience with AD. Our intent is to be the authoritative 'patient and caregiver voice' that will inform and improve sponsors' product and clinical trial design, regulatory submissions and reviews, payer value models, coverage and payment determinations, and research on care and services.

WHY DO THIS AND WHY NOW?

Policy makers, regulators, and payers are moving with mounting force to assure that therapeutic interventions are approved based on a showing of efficacy against outcomes that are meaningful to patients and that approved therapies, when presented for determinations of coverage and payment, are shown to deliver value to the beneficiary. Defining what is clinically meaningful and what delivers value in Alzheimer's presents a particular set of challenges, made far more complex than in other conditions, because Alzheimer's takes hold long before symptoms appear and, when they do, involve cognitive impairment.

While there remains a dearth of therapeutic options for those who are diagnosed with, or at risk for, Alzheimer's, a wealth of promising agents are in the pipeline. This is the time to prepare for their introduction and to assure that regulators and payers understand the expectations and preferences of individuals at varying stages in the Alzheimer's lived-experience and are prepared to integrate these understandings into regulatory review and payment determinations.

HOW WILL AD PACE CAPTURE PATIENT AND CAREGIVER INSIGHTS?

This patient and caregiver voice will be delivered through direct interviews and surveys as well as

A-LIST

through the **A-LIST**, a growing online community of individuals with a demonstrated willingness to provide insights, opinions and elicited preferences to AD PACE. Today, the A-LIST engages over 6,000 members, including those living with Alzheimer's disease, other dementias, and mild cognitive impairment, as well as their current and former care partners and those at risk for the disease. These members actively engage in the A-LIST because they believe in the power of a collective voice and want their preferences heard on issues that span the entire scope of Alzheimer's disease.

WHAT ARE THE REGULATORY IMPLICATIONS OF AD PACE'S WORK ON ALZHEIMER'S DRUG DEVELOPMENT?

The *What Matters Most* study will provide information on the needs and preferences of those with and at risk for Alzheimer's that drug developers can use to support their submissions to the FDA. **FDA's Patient Focused Drug Development (PFDD)** initiative calls for the incorporation of the patient perspective in the drug development process. Armed with rigorously developed data from the *What Matters Most* study, drug developers and the FDA will have an improved and scientifically reliable understanding of outcomes that are clinically meaningful to patients and caregivers.

WHY IS AD PACE SUCH A PROMISING INITIATIVE?

As a patient and caregiver-led initiative, conducted in open collaboration with industry, other nonprofits and government, AD PACE is bringing the community together to perform work in a manner that looks at the full spectrum of disease; it is agnostic to any particular product in development. The AD PACE collaboration has the potential to streamline PFDD efforts in the Alzheimer's space, encouraging the sharing of knowledge, and leveraging past investments to accelerate patient experience data development.

WHAT OTHER ASSETS WILL AD PACE DEVELOP?

AD PACE will present a range of new assets to the community:

1 **The AD PACE Studies**, a set of integrated studies and surveys, beginning with a two part study, producing new knowledge on what matters most to patients and caregivers across the lived-experience with Alzheimer's.

2 **The A-LIST**, a persistent online community that will operate as a multi-modal means of identifying and engaging, directly and through partnerships, those with or at risk of the disease and caregivers.

3 **The AD PACE Data Commons**, an informatics platform that will house or link to datasets developed directly by AD PACE or accessed through collaborations. This repository that will provide access to a diverse range of data, including, e.g., raw data from AD PACE studies developed with common data standards and data elements, datasets contributed by sponsors and by partners, all to include, to the extent available and as examples, interview transcripts, survey guide lines, agency communications, and published studies, with the aim of establishing a searchable repository.

4 **The AD PACE Knowledge Landscape and Technical Assessment**, an overview of data sets and a technical assessment of the landscape of tools, scales and instruments used today to assess endpoints ("tools") that will inform the conduct of the *What Matters* and *What Matters Most* research and the GAP analysis.

5 **The AD PACE Gap Analysis and Tool Kit**, a set of tools (e.g. tools, scales, and outcome measures used in AD clinical trials) in use today that are confirmed to measure what matters most to patients, or are identified as in need of development, *de novo* or through adaptation of a current tool.

WHY NOW?

Alzheimer's afflicts more than 47 million people worldwide and nearly 6 million in the U.S.

Alzheimer's costs the world's economies more than $1 trillion annually. It is the most expensive disease in the U.S. with long-term care costs topping $277 billion annually.

Every 65 seconds someone develops Alzheimer's disease.

Women make up 2/3 of all Alzheimer's patients.

African Americans (2x) and Latinos (1.5x) are more likely to develop AD than whites.

Older veterans with TBI are 60% more likely to develop Alzheimer's.

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