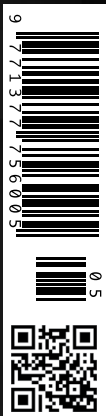




Labs and Drugs



440. Paul Timmers
Health Data Innovation Perspectives

445. Renato Cuocolo
Radiomics: Recent Trends and
Assessing Research Quality

456. Ekaterina Kldiashvili
eHealth for Morphology Laboratory
Practice

462. Maria C. Carrillo
Working Towards a World Without
Alzheimer's and All Other Dementia

468. Samna Ghani
Why is the Pharmaceutical Industry Not
Developing New Antibiotics?

472. Henrique Martins
The EU Health Data Centre: A New Total
Virtual Organisation

Working Towards a World Without Alzheimer's and All Other Dementia

◆ Author: Maria C. Carrillo | Chief Science Officer | Alzheimer's Association | USA

An overview of the goals and vision of the Alzheimer's Association and its commitment to advance vital research for the treatment, prevention and cure for Alzheimer's Disease.

Key Points

- The Alzheimer's Association is a leading voluntary health organisation in Alzheimer's care, support and research.
- The Alzheimer's National Registry for Treatment and Diagnostics (ALZ-NET) will gather clinical data and outcomes from U.S.-based patients treated with FDA-approved therapies for Alzheimer's disease in real-world practice.
- The Alzheimer's Association is focused on increasing public and private investment in research and is the world's largest non-profit funder of Alzheimer's and other dementia research.
- Since its inception, the Alzheimer's Association's Part the Cloud initiative has raised over \$60 million for Alzheimer's research, awarding grants to 59 clinical trials, which have gone on to receive \$940 million in additional funding from other sources.

What is the mission, vision and goals of the Alzheimer's Association?

The Alzheimer's Association leads the way to end Alzheimer's and all other dementia — by accelerating global research, driving risk reduction and early detection, and maximising high quality care and support. The Alzheimer's Association is the leading voluntary health organisation in Alzheimer's care, support and research.

- Our Vision: A world without Alzheimer's and all other dementia®
- Our Mission: The Alzheimer's Association leads the way to end Alzheimer's and all other dementia — by accelerating global research, driving risk reduction and early detection, and maximising quality care and support.

The Alzheimer's Association works on a national and local level to provide care and support for all those affected by Alzheimer's and other dementias. As the largest non-profit funder of Alzheimer's research, the Association is committed to advancing vital research toward methods of treatment, prevention and, ultimately, a cure. Finally, the Association is the leading voice for Alzheimer's disease advocacy, fighting for critical Alzheimer's research and care initiatives at the state and federal level.

What is the objective of The National Treatment and Diagnostic Alzheimer's Registry?

The Alzheimer's National Registry for Treatment and Diagnostics (ALZ-NET) will gather clinical data and outcomes from U.S.-based patients treated with FDA-approved therapies for Alzheimer's disease in real-world practice. ALZ-NET aims to monitor and report clinical and safety endpoints for patients treated with FDA-approved Alzheimer's disease therapies, including accompanying diagnostics, to track the long-term outcomes associated with these therapies in a real-world setting.

The Alzheimer's Association, American College of Radiology (ACR), American Society of Neuroradiology (ASNR), and the Department of Biostatistics, Brown University School of Public Health will partner to lead this important initiative. The scientific team will include a diverse group of leading academic experts in Alzheimer's clinical research and care, biomarkers, clinical trials, biostatistics and implementation research. Registry leadership will work with industry stakeholders and payers in developing and implementing the registry.

ALZ-NET will gather clinical data and outcomes from patients treated with FDA-approved therapies for Alzheimer's disease in real-world practice. ALZ-NET aims to monitor and report

clinical and safety endpoints for patients treated with FDA-approved Alzheimer's disease therapies, including accompanying diagnostics, to track the long-term outcomes associated with these therapies in a real-world setting. To that end, ALZ-NET will:

- Collect and archive diagnostic and safety neuroimaging studies, as well as genetic and fluid biomarker data and biosamples.
- Broadly share de-identified data with the research community and other stakeholders.

coverage for the scans, stating “the evidence is insufficient to conclude that the use of positron emission tomography (PET) amyloid-beta (Aβ) imaging is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of ... Medicare beneficiaries with dementia or neurodegenerative disease.”

CMS did find sufficient evidence that the use of PET Aβ imaging is promising: (1) to exclude Alzheimer's disease (AD) in narrowly defined and clinically difficult diagnoses, and (2) to enrich clinical trials seeking better treatments or preven-

ALZ-NET will gather clinical data and outcomes from patients treated with FDA-approved therapies for Alzheimer's disease in real-world practice

When you say this registry will be an FDA-approved-agent agnostic approach, what do you mean?

ALZ-NET will be designed to grow with scientific and medical advancements, and will be open to all FDA-approved Alzheimer's treatments. ALZ-NET will be a non-randomised, observational, multi-site, registry with an expandable platform that allows the addition of all approved drugs.

The registry will collect routine clinical practice data from healthcare providers. How do you plan to execute this? What would be the criteria for selecting the data sources?

ALZ-NET will leverage the Alzheimer's Association network of providers developed for the IDEAS and New IDEAS studies. We will provide educational support for clinicians in appropriate use of therapies, biomarker interpretation and safety monitoring. ACR and ASNR will provide education on PET and MRI interpretation for diagnostic and safety imaging studies.

ALZ-NET will recruit and collect longitudinal data through physician-submitted case report forms and payer claims, and will include collection and archiving of neuroimaging studies and biosamples. We will:

- Develop a multi-site network for patient enrollment and data collection.
- Collect baseline and longitudinal participant data, including measures of cognition and function and information about adverse events.
- Track health outcomes and resource utilisation via claims data.

Can you tell us a bit more about IDEAS (Imaging Dementia-Evidence For Amyloid Scanning)?

The original IDEAS Study was developed in response to the 2013 Centers for Medicare and Medicaid Services (CMS) National Coverage Decision on amyloid PET imaging in dementia and neurodegenerative disease. CMS did not provide

tion strategies for Alzheimer's. Under the National Coverage Decision, Medicare provides coverage for one amyloid PET scan per patient enrolled in an approved clinical study.

The Alzheimer's Association decided to lead an initiative to bring stakeholders together to develop a Coverage with Evidence Development programme. The IDEAS Study team was formed and protocol development began. The study opened in February 2016 and concluded recruitment in January 2018. The study engaged 946 dementia experts, who recruited Medicare beneficiaries from 595 dementia clinics and referred the subjects for imaging at 343 PET facilities across the United States. In total, 18,295 Medicare beneficiaries aged 65 and older meeting appropriate use criteria were enrolled into one of two sub-groups: (1) progressive, unexplained mild cognitive impairment (MCI), and (2) dementia of uncertain cause.

The IDEAS Study provided the strongest Phase IV data to date supporting the clinical utility of amyloid PET scanning. Results were published in JAMA in 2019 (Rabinovici et al. 2019).

Building on the momentum of the IDEAS Study, the Alzheimer's Association and the American College of Radiology, with manufacturing partners Eli Lilly and Co., GE Healthcare, and Life Molecular Imaging, launched the [New IDEAS: Imaging Dementia—Evidence for Amyloid Scanning](#) study.

The goal of the New IDEAS study is to determine if using a brain amyloid PET scan helps clinicians provide a more accurate diagnosis and make better treatment decisions, which would then inform or change a patient's treatment plan and improve their quality of life.

The New IDEAS study aims to be among the most racially and ethnically diverse Alzheimer's disease studies ever launched. At least 4,000 of the planned 7,000 New IDEAS participants will be Black/African American and Hispanic/Latino, populations historically underrepresented in dementia research. Participants will be enrolled over 30 to 36 months at 350 sites throughout the United States.

The vision of the Alzheimer’s Association is a world without Alzheimer’s and all other dementia. How will the Association make this happen, and what are your key strategies and future plans?

The driving force behind the Alzheimer’s Association [International Research Grant Program](#) is our desire to improve quality of life for people affected by Alzheimer’s. At present we are focused on increasing public and private investment in research and expanding our position as a respected global leader and the world’s largest non-profit funder of Alzheimer’s and other dementia [research](#) in order to accelerate progress toward our vision.

high-reward research aimed at uncovering underlying brain cell changes, timely diagnosis and new treatments for Alzheimer’s and all other dementia. In 2019, Bill Gates partnered with Part the Cloud and raised \$10 million to help further the cause.

Modifiable risk factors are estimated to contribute to nearly four in 10 dementia cases globally, and the Association is leading and funding studies in multiple countries to evaluate lifestyle interventions designed to reduce risk of cognitive decline. This includes the U.S. Study to Protect Brain Health through Lifestyle Intervention to Reduce Risk ([U.S. POINTER](#)), the world’s largest clinical trial testing whether multiple risk-reduction strategies can protect memory and thinking in cognitively unimpaired older adults at increased risk of developing

The Association works to identify and fund a wide range of the most promising projects, from basic discovery science to studies addressing social and behavioural aspects of Alzheimer’s and all other dementias

Together with our philanthropic partners, we are ensuring a profusion of new and diverse perspectives and cutting-edge projects to continue filling the drug development pipeline. The Alzheimer’s Association [International Research Grant Program](#) lies at the heart of our commitment to advance Alzheimer’s research. Since awarding our first grants in 1982, the Association has grown into the largest private, nonprofit funder of Alzheimer’s research. In 2021 we made our largest-ever total commitment in a single year. Our active commitments now total more than \$250 million, and they are powering more than 750 best-of-field projects in 39 countries.

The Association works to identify and fund a wide range of the most promising projects, from basic discovery science to studies addressing social and behavioural aspects of Alzheimer’s and all other dementias. The studies we’ve invested have enabled significant advances across the research spectrum in areas such as diagnosis, genetics, treatments, prevention, early detection and enhancing quality of life.

Since its inception, the Alzheimer’s Association’s [Part the Cloud](#) initiative has raised over \$60 million for Alzheimer’s research, awarding grants to 59 clinical trials, which have gone on to receive \$940 million in additional funding from other sources. With 100 percent of the proceeds from Part the Cloud going directly to Alzheimer’s Association research efforts, Part the Cloud funding allows the Association to propel bold,

memory decline and dementia.

To foster collaboration and facilitate the sharing of ideas and data across the globe, the Alzheimer’s Association has been increasing the number of research events we host worldwide. In addition to the Alzheimer’s Association International Conference® ([AAIC](#)®), the world’s largest and most influential international meeting dedicated to advancing dementia science, we now offer Neuroscience Next, AAIC Satellite Symposia, the Latinos & Alzheimer’s Symposium, the Tau Global Conference and more.

In partnership with the Alzheimer’s Impact Movement ([AIM](#)), a separately incorporated advocacy affiliate, the Association is the leading advocate for increasing federal funding for dementia research. Thanks largely to our leadership, Congress has been increasing the National Institutes of Health’s (NIH) annual budget for Alzheimer’s and other dementia research. It now stands at \$3.1 billion, a more than seven-fold increase since 2011.

Research funding and scientific [collaboration](#) fuel medical progress. They have changed the trajectory of heart disease, HIV and many cancers, and they will drive progress toward our vision of a world without Alzheimer’s and all other dementia.

Conflict of Interest

None. ■

REFERENCES

Rabinovici GD, Gatsonis C, Appgar C et al. [2019] Association of Amyloid Positron Emission Tomography With Subsequent Change in Clinical Management Among Medicare Beneficiaries With Mild Cognitive

Impairment or Dementia. JAMA, 321(13):1286-1294.