

In war on Alzheimer's, group deploys new way to enlist

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By: Ron Leuty

Like the journey of a thousand miles, the path leading to an Alzheimer's disease treatment begins with a single step: Getting people through the doors of hundreds of clinical trial sites.

Now a program based at the University of California, San Francisco, is teaming up with a global foundation to build out a registry of current and potential Alzheimer's patients from which the right people can be quickly assigned to the right drug studies.



Michael Weiner of UCSF is the director of the Brain Health Registry, which in partnership with a global foundation hopes to sign up 40,000 people who can be shifted into the right Alzheimer's disease clinical trials at the right time.

The Brain Health Registry is a matter of time and money, said Dr. Michael Weiner, director of the registry and a professor of radiology and biomedical engineering, medicine, psychiatry and neurology at UCSF. It could potentially accelerate clinical trials by cutting down on the time it takes to enroll study participants.

"We think of a funnel where a lot of people come in and it leads to many smaller funnels, depending on the individual," Weiner said.

What's more, the one-stop-shop could reduce "screen fails," Weiner said, when patients are rejected for various reasons from a clinical trial. Those rejections can frustrate patients, he said, keeping them away from other studies.

Using a free website where people play games to determine the level of their cognitive skills, sign consent forms and build a profile, the registry over its first two years has signed up 36,000 people. Their names and information are held in a database, ready to be matched with the right clinical trials.

Those efforts are ramping up with the Brain Health Registry in January signing a partnership with the Global Alzheimer's Platform Foundation to bring another 40,000 people into the registry by the third quarter.

The focus initially is on clinical trial hubs such as the Bay Area, Boston and Providence, R.I., Las Vegas, Atlanta and South Florida. Patients return to the website every six months to continue testing and, depending on their skills or geography and the clinical trials enrolling patients, referral into a study.

While the foundation rolls out a national campaign, including public service announcements, the registry is at the ready to sign up Alzheimer's patients and their family members. Those relatives are an increasingly important part of Alzheimer's research since their baseline information can be collected and changes in the brain skills can be noted over years before other symptoms show up.

The matchmaking of trials and trial subjects is rarely easy; neither has the search for an effective Alzheimer's treatment.

Researchers don't quite understand what causes Alzheimer's. Is it the amyloid beta amino acids that tangle in patients' brains? Is it the protein tau that gums up neural connections? Both in combination with inflammation or something else? Not knowing can slow using or prescribing drugs that might at least alleviate the dementia and memory loss that marks the disease.

Those uncertainties have led to a number of clinical trial failures. But many studies lag simply because they can't enroll enough patients quickly enough, costing drug companies time and money.

"A lot of money and time is spent trying to identify Alzheimer's patients at various stages — screening them and getting their consent," Weiner said. "All of the large research projects are hugely slowed because of a lack of subjects, especially high-qualified subjects."

How can that be, given that more than 5 million Americans, according to the Alzheimer's Association, have the memory-stealing disease? Simple, Weiner said: As many as nine of every 10 people who sign up for a clinical trial never make it through the screening process because of exclusion criteria designed to give a study statistical balance.

Patients who are excluded from a study get frustrated, Weiner said, after sometimes spending hours being poked and prodded about their health. The registry is intended to put patients through screening just once.

The foundation "wants to accelerate the progress of Alzheimer's research to get effective treatments more quickly," Weiner said. "It sees the value of getting more people into the sites and reducing screen fails."



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