



## Clinician Partner Newsletter (Winter 2021) Updates for our collaborators

### For questions, please contact:

Lenore Jackson-Pope, RN, MSM, CCRP: [ljackson-pope@bwh.harvard.edu](mailto:ljackson-pope@bwh.harvard.edu)

Gad A. Marshall, M.D.: [gamarshall@bwh.harvard.edu](mailto:gamarshall@bwh.harvard.edu)

We have several Clinical Trials and Observational Trials open and enrolling for individuals who are cognitively normal, have Mild Cognitive Impairment (MCI) or have mild Alzheimer Disease (AD) dementia. If you would like a full list of studies open and enrolling, please email [ljackson-pope@bwh.harvard.edu](mailto:ljackson-pope@bwh.harvard.edu)

**COVID-19:** We are taking every precaution to protect our research participants, study partners, and staff. Should you have a patient or family member in need of additional information or resources, Mass General Brigham has set up a COVID-19 hotline for clinicians, patients and the public at 617-724-7000.

### Research news at Mass General Brigham

#### Can positive trial results for a potential new Early AD treatment be repeated?

**TRAILBLAZER 2 Study, for MCI and mild AD dementia:** Positive findings were noted in the TRAILBLAZER Study of Donanemab that we hope to repeat in the recently opened TRAILBLAZER 2 Study. Donanemab, is an investigational antibody that targets a modified form of beta amyloid. Recent results from Eli Lilly and Company's Phase 2 TRAILBLAZER-ALZ study, demonstrated significant clinical benefit over a period of 76 weeks using the Integrated Alzheimer's Disease Rating Scale (iADRS), a measure of global cognition and daily functioning, slowing decline by 32 percent. Donanemab also showed significant amyloid removal from the brain as measured by positron emission tomography imaging.

**TRAILBLAZER 2 Study** is a similar phase 2 clinical trial in which we will evaluate whether Donanemab is safe and effective and may slow cognitive impairment and reduce amyloid plaque buildup in people with early-stage Alzheimer's disease. Individuals age 60-85, with MCI or mild AD dementia may be eligible. Financial compensation is provided for each visit and reimbursement for parking and travel. If you would like to make a referral, please contact Allyson Pulsoni at [apulsoni@bwh.harvard.edu](mailto:apulsoni@bwh.harvard.edu)

#### Can a BCG vaccine help improve brain function?

**BCG Vaccine Pilot Study:** The aim of this study is to learn how the Bacillus Calmette-Guérin (BCG) vaccine affects immune and brain functioning in older adults who are cognitively unimpaired and older adults who may have trouble with memory and thinking. BCG has been given to billions of people around the world for prevention of tuberculosis, it is used widely in the United States as a treatment for bladder cancer, and its benefits are being explored for a number of other diseases.

Early studies suggest that BCG may also have some benefit for diseases that affect the brain. We are doing this study to learn more about how BCG affects immune and brain functioning in older adults. We hope that what we learn from this study may benefit people with memory and thinking problems in the future. This study may help direct future clinical trials for Alzheimer's disease. This study is looking for 4-5 more MCI participants (MoCA 18-25) age 55-80. They have to have no prior BCG vaccination or use in bladder cancer. For additional information: [ACTRUStudies@mgh.harvard.edu](mailto:ACTRUStudies@mgh.harvard.edu)

### Can we develop a treatment to prevent AD?

**AHEAD A3, 4-5: Alzheimer's Prevention Study:** The AHEAD Study is comprised of two different trials testing the same investigational drug (known as BAN2401, a monoclonal antibody against amyloid). Study participants are enrolled in one of two AHEAD trials based on whether they have intermediate or elevated levels of amyloid in their brain: Participants with intermediate amyloid levels take part in the AHEAD A-3 trial—the first pre-preclinical Alzheimer's disease trial. Participants with elevated amyloid levels take part in the AHEAD A-45 trial. Over the course of the study, the two different trial groups will receive intravenous (IV) infusions of BAN2401 or a placebo. The infusion process takes approximately 60 minutes. Infusions will take place every 2-4 weeks for about four years. At different points in the study, participants have PET scans to look at amyloid and tau in the brain.

#### Eligibility criteria:

- Healthy adults ages 55-80 who may have an increased risk of memory loss associated with Alzheimer's disease
- Have not been diagnosed with Alzheimer's disease or another dementia
- **Have elevated or intermediate levels of amyloid in their brains determined by brain imaging as part of the study**
- Have a close friend or relative who can serve as their study partner

#### Resources for professionals:

The team at CART and the MADRC are focused on providing our clinical partners with the resources they need. Our **Rapid Diagnostic Clinic** at Brigham and Women's Hospital is open and supporting clinicians in diagnosing patients. We can support you through an Epic referral if you're an in-house MGB provider or by email if you're a clinician external to the MGB system. Get in touch with us anytime at [BehavioralNeurology@bwh.harvard.edu](mailto:BehavioralNeurology@bwh.harvard.edu).

**See infographic attached to this email for links to professional resources.**

#### **Stay connected with MADRC News!**

Follow us on [Facebook](#) and [Twitter](#)! Subscribe to us on [YouTube](#)!