Why are biofluid biomarker studies important for ALS Research?

Biofluid biomarkers are measurable changes in your body that can be observed in your blood, urine, and cerebral spinal fluid. These changes can indicate healthy or unhealthy processes happening in your body and may be a sign of an underlying condition or disease such as ALS.

Researchers conduct biomarker research to measure the effects of investigational drugs on people during clinical trials. Biofluid biomarkers are an integral part of this research and may:

- Lead to earlier diagnosis of ALS or other neurodegenerative diseases
- Predict and track disease progression more efficiently
- Demonstrate whether an investigational drug reaches its designated target
- Identify subsets of people who best respond to a certain investigational drug

Biofluid biomarker studies provide an opportunity for all people with ALS to participate in research and make important contributions to our scientific understanding of ALS.

Study of Longitudinal Microbiome in ALS

Enroll and participate from your home!

**Full Study Name:** Longitudinal Assessment of the Gut Microbiome in People with ALS  
**Study Length:** 5 years  
**Participants:** People with ALS, asymptomatic ALS gene carriers, healthy volunteers  
**Biomarkers:** Stool and blood samples  
**Purpose:** To collect and analyze stool samples and observe the relationship between the gut microbiome and the progression of ALS over time. Information collected in this study will further our understanding of ALS and contribute towards the development of novel therapeutics.  
**Principal Investigator:** James Berry, MD, MPH  
**Sponsor:** National Institutes of Health and Brigham and Women’s Hospital  
**Enrollment Contact:** Ethan Riddell, 617-643-4803, eriddell@mgh.harvard.edu; Jane Lim, 617-643-7828, jlim19@mgh.harvard.edu

Target ALS Biomarker Study

Coming Soon!

**Full Study Name:** Target ALS Biomarker Study: Longitudinal Biofluids, Clinical Measures, and At-Home Measures  
**Study Length:** 16 months for ALS participants, 12 months for healthy volunteers  
**Participants:** ALS and Healthy Volunteers able to have lumbar punctures  
**Biomarkers:** Blood, spinal fluid, urine  
**Purpose:** The goal of the study is to build a library of samples (blood, cerebral spinal fluid, and urine) and linked medical and genetic data. Collaborating researchers will have access to this information to advance their knowledge of ALS.  
**Principal Investigator:** Mark Garret, MD  
**Sponsor:** Target ALS  
**Enrollment Contacts:** Lily Walker, 617-643-7909, lgwalker@mgh.harvard.edu; Jane Lim, 617-643-7828, jlim19@mgh.harvard.edu

For more information: Contact the research coordinator(s) listed for studies you are interested in OR Judi Carey, Research Access Nurse, mghalsresearch@mgh.harvard.edu or 617-724-8995
Study of LAB PALS

**Full Study Name:** A Longitudinal Analysis of Biomarkers in Patients with ALS

**Study Length:** 4 years (16 in-person visits)

**Participants:** People with ALS, asymptomatic ALS gene carriers, non-ALS neurological disease, healthy volunteers

**Biomarkers:** Blood, urine, and cerebrospinal fluid

**Purpose:** We would like to see how biomarkers and cerebrospinal fluid (optional) change over time in people with ALS. A biomarker is a molecule that we can measure to diagnose or monitor a disease.

**Principal Investigator:** James Berry, MD, MPH

**Sponsor:** ALS Finding a Cure

**Enrollment Contacts:**
Anne Williams: awilliams120@mgh.harvard.edu
617-726-4284
Chloe Noll: cnoll@mgh.harvard.edu
617-724-7113

Study of DIALS

**Full Study Name:** Dominant Inherited ALS (DIALS) Network

**Study Length:** At least 5 years (annual visits with optional 6-month visits)

**Participants:** People who do not have any neurological symptoms, but have a first-degree relative with ALS caused by a mutation

**Biomarkers:** Blood, urine, and optional cerebrospinal fluid

**Purpose:** To study people at risk for developing ALS to further our understanding of underlying early disease changes. The information collected in this study may lead to development of treatments that target the earliest changes in ALS and allow for possible disease prevention.

**Principal Investigator:** James Berry, MD, MPH

**Sponsor:** ALS Finding a Cure, ALS Association, Philanthropy

**Enrollment Contacts:** DIALS@mgh.harvard.edu, or call Gavi Forman at 617-724-7928

Stay Connected to ALS Research

Sign up for the MGH ALS Link to Stay Connected to Research:

https://lp.constantcontactpages.com/u/saTzwlp/ALSLink

View Currently Enrolling ALS Trials at the Healey Center:

https://www.massgeneral.org/neurology/als/research/als-clinical-trials