



# Currently Enrolling Biofluid Biomarker Studies

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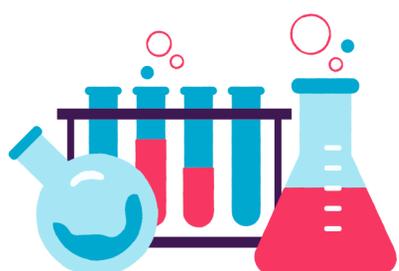
## Why are biofluid biomarker studies important for ALS Research?

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:** Kelly Fisher, 617-726-9094, [kfisher@mgh.harvard.edu](mailto:kfisher@mgh.harvard.edu); Jacqueline Topping, 617-643-6036, [jtopping@mgh.harvard.edu](mailto:jtopping@mgh.harvard.edu)

## Study of ALS Sample Repository (Living Library)

**Full Study Name:** ALS Sample Repository

**Study Length:** 1 in-person visit

**Participants:** People with ALS, PLS, other MND, healthy volunteers

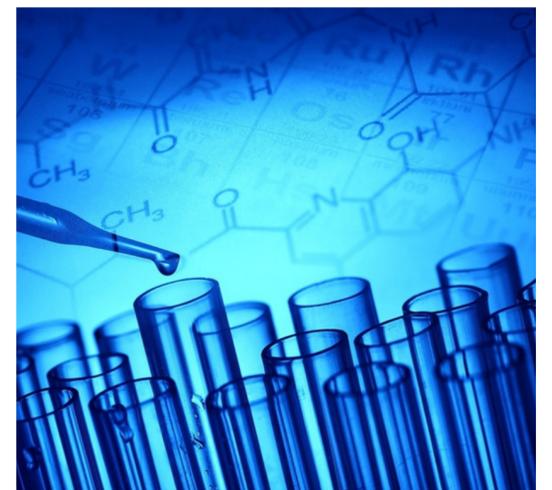
**Biomarkers:** Blood, spinal fluid, and/or urine samples

**Purpose:** To answer questions and support research related to cause, prevention, treatment, and heritability of ALS.

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

**Sponsor:** Hollister Lindley Fund

**Enrollment Contacts:** Alison Clark, 617-726-4284, [aclark51@mgh.harvard.edu](mailto:aclark51@mgh.harvard.edu); Kelly Fisher, 617-726-9094, [kfisher@mgh.harvard.edu](mailto:kfisher@mgh.harvard.edu)



### For more information:

Contact the research coordinator listed for studies you are interested in OR Judi Carey, Research Access Nurse, at [jcarey8@partners.org](mailto:jcarey8@partners.org) or 617-724-8995

## Study of LAB PALS

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

**Study Length:** 2 ½ years (7 in-person visits)

**Participants:** People with ALS, asymptomatic ALS gene carriers, healthy volunteers

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

**Purpose:** To test potential biomarkers over time which can be used to further uncover ALS pathophysiology, discover disease biomarkers, and identify new therapeutic targets. The biomarkers might help diagnose ALS sooner, monitor ALS progression, and teach us about potential causes and treatments for ALS. The samples we collect will be used to compare and analyze changes in immune cells and other changes in plasma and gene expression.

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

**Sponsor:** Holy Cross Hospital Inc.

**Enrollment Contact:** Chloe Noll, 617-724-7113, [cnoll@mgh.harvard.edu](mailto:cnoll@mgh.harvard.edu); Jacqueline Topping, 847-309-0806, [jtopping@mgh.harvard.edu](mailto:jtopping@mgh.harvard.edu)

## 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:** Kathleen Diana, 617-724-6346, [kdiana@mgh.harvard.edu](mailto:kdiana@mgh.harvard.edu); Allison Carey, 617-726-1559, [abcarey@mgh.harvard.edu](mailto:abcarey@mgh.harvard.edu)

## Study of Radicava Effects in ALS

**Enroll and participate from your home!**

**Full Study Name:** Radicava®/ (Edaravone) Findings in Biomarkers in ALS (REFINE-ALS)

**Study Length:** 6 cycles of IV Radicava (8 in-person visits) over 6 months

**Participants:** People with ALS

**Biomarkers:** Blood and urine samples

**Purpose:** To identify biomarkers that show how IV Radicava (edaravone) works in ALS patients. REFINE-ALS will measure the levels of distinct biomarkers involved in oxidative stress and in inflammatory response, neuronal injury or death, and muscle injury. Biomarker levels and ALS progression will be assessed before the first Radicava cycle and at specific times throughout the study.

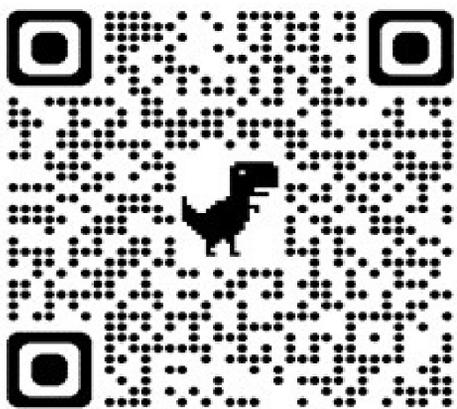
**Principal Investigator:** Suma Babu, MD

**Sponsor:** MT Pharma

**Enrollment Contacts:** Ryan Gifford, 617-724-0783, [rfgifford@mgh.harvard.edu](mailto:rfgifford@mgh.harvard.edu); Henry Rutherford, 617-643-6252, [hrutherford@bwh.harvard.edu](mailto:hrutherford@bwh.harvard.edu)

# Stay Connected to ALS Research

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View Currently Enrolling ALS Trials at the Healey Center:



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