

ALL ALS Study Updates

Robert Bowser, Barrow Neurological Institute

James Berry, Mass General Hospital

November 21, 2024





West Coordinating Center

- Located at Barrow Neurological Institute
- Contact PI: Robert Bowser



East Coordinating Center

- Located at Massachusetts General Hospital
- Contact PI: James Berry

AMP ALS

Accelerating Medicines Partnership Goal: Accumulate Data and Facilitate Open Science

ALL ALS Consortium



ALL ALS Goal: Generate prospective data/sample collection/sharing



19 Sites

Shared Protocols
OSMB
Steering Committee
Site Monitoring (BNI)

Shared DCC (MGH)
Single IRB (MGB)



Healey & AMG Center

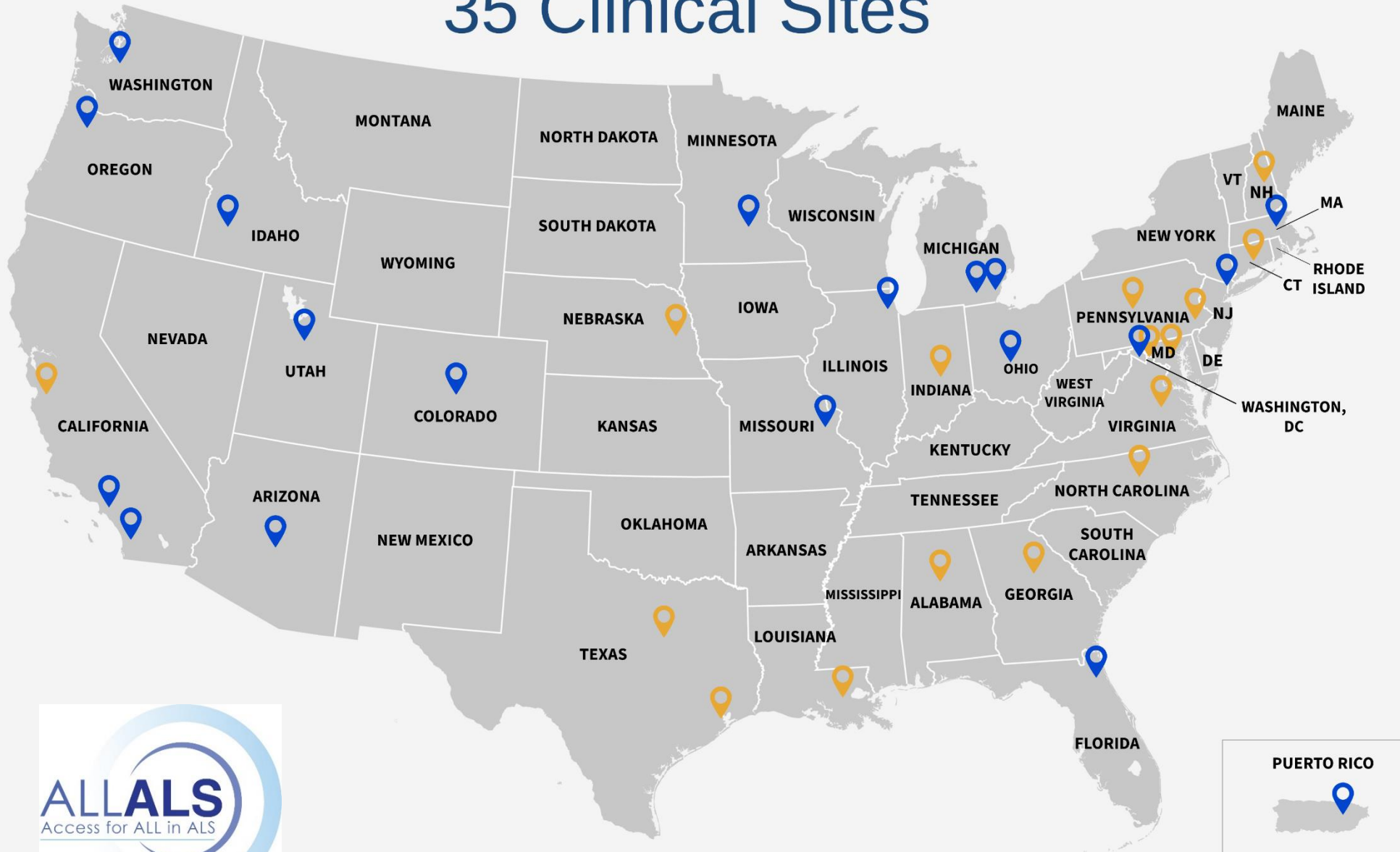
Sean M. Healey & AMG Center for ALS
at Massachusetts General Hospital

16 Sites

AMP ALS Knowledge Portal

NIH BioSEND Biorepository

35 Clinical Sites



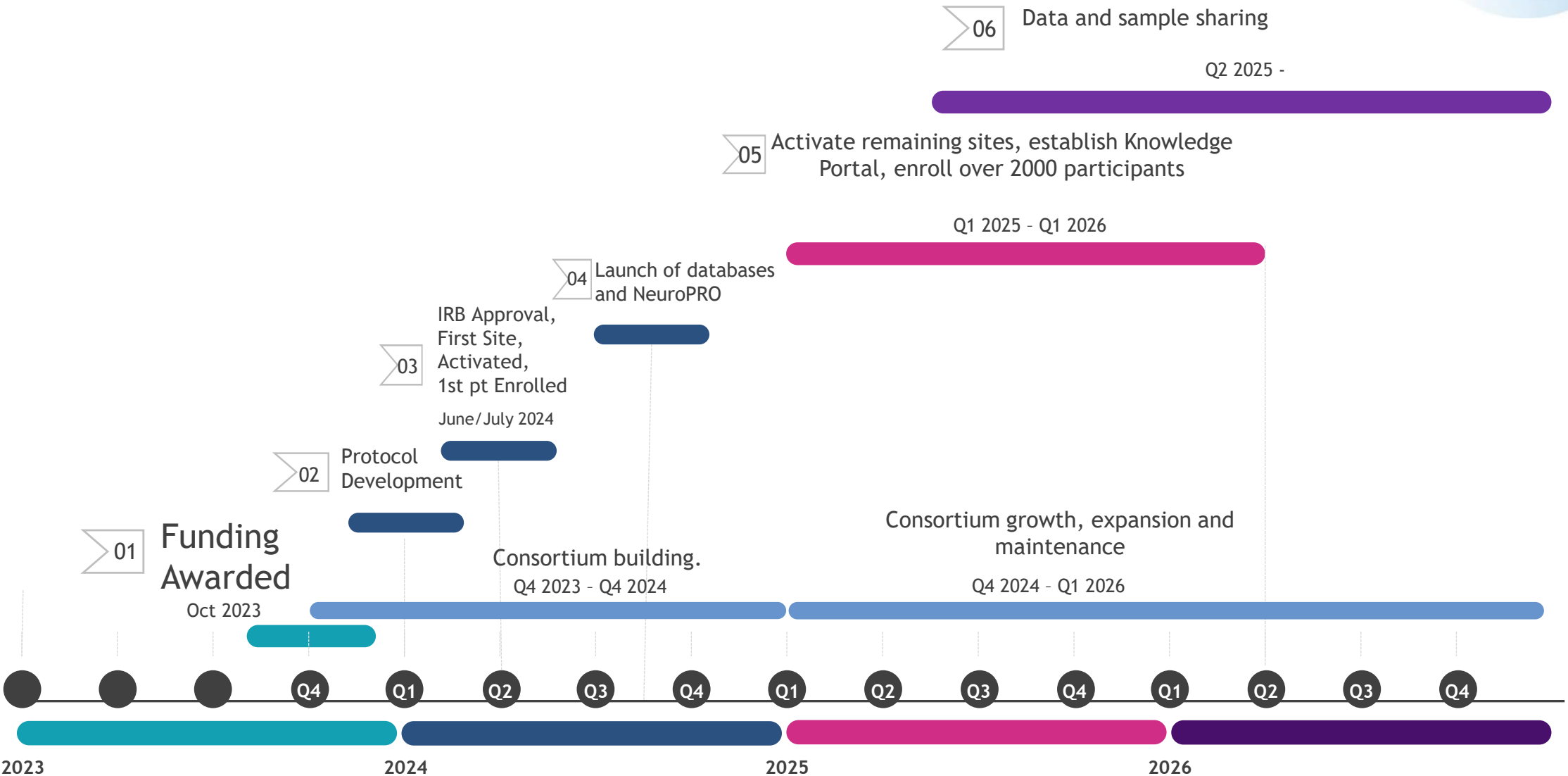
WEST

Barrow Neurological Institute*
 Columbia University
 Washington University*
 Georgetown University
 University of Washington*
 University of California, San Diego
 Northwestern University
 Mayo Clinic
 Massachusetts General Hospital*
 University of Colorado Denver
 Ohio State University*
 Universidad de Puerto Rico
 Saint Alphonsus Regional Medical Ctr
 Henry Ford Health
 University of Michigan
 University of Minnesota
 University of California, Irvine
 Providence Brain and Spine
 University of Utah

EAST

Texas Neurology*
 Virginia Commonwealth University*
 Temple University
 Pennsylvania State Medical Center*
 Duke University
 Dartmouth Hitchcock*
 University of Nebraska*
 Our Lady of the Lake Regional Medical Ctr
 Indiana University ALS Center
 Emory University
 Hospital for Special Care*
 University of California, San Francisco
 University of Alabama, Birmingham*
 Johns Hopkins University*
 Houston Methodist
 NIA/NINDS Clinical Research

ALL ALS Timeline



Participant Cohorts and Collections



Symptomatic people living with ALS

- On site visits
- Fully remote visits

Healthy Controls

- On site visits

Asymptomatic Individuals that harbor ALS gene variants

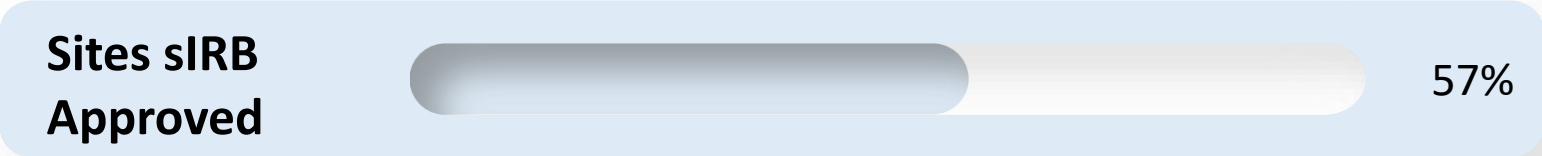
- Hybrid approach with annual on-site visits and additional remote visits

-
- Collect longitudinal biofluids
 - Linked to detailed clinical information.
 - Whole blood, plasma, serum, and cerebrospinal fluid (on a subset of participants)
 - Collect remote digital data each month
 - Speech recordings (Linus Health)
 - Questionnaires (NeuroPRO)

Site Activations



- 20/35 Sites have sIRB Approval
- 13/35 Sites Activated
- Sites activated within 4 weeks of sIRB Approval



Active Sites
Massachusetts General Hospital
Barrow Neurological Institute
Washington University
Texas Neurology
University of Washington
<i>Ohio State University</i>
<i>Johns Hopkins</i>
Virginia Commonwealth University
Penn State University
Hospital For Special Care
Dartmouth Hitchcock
University of Nebraska
University of Alabama

97 participants enrolled as of 11/20/24



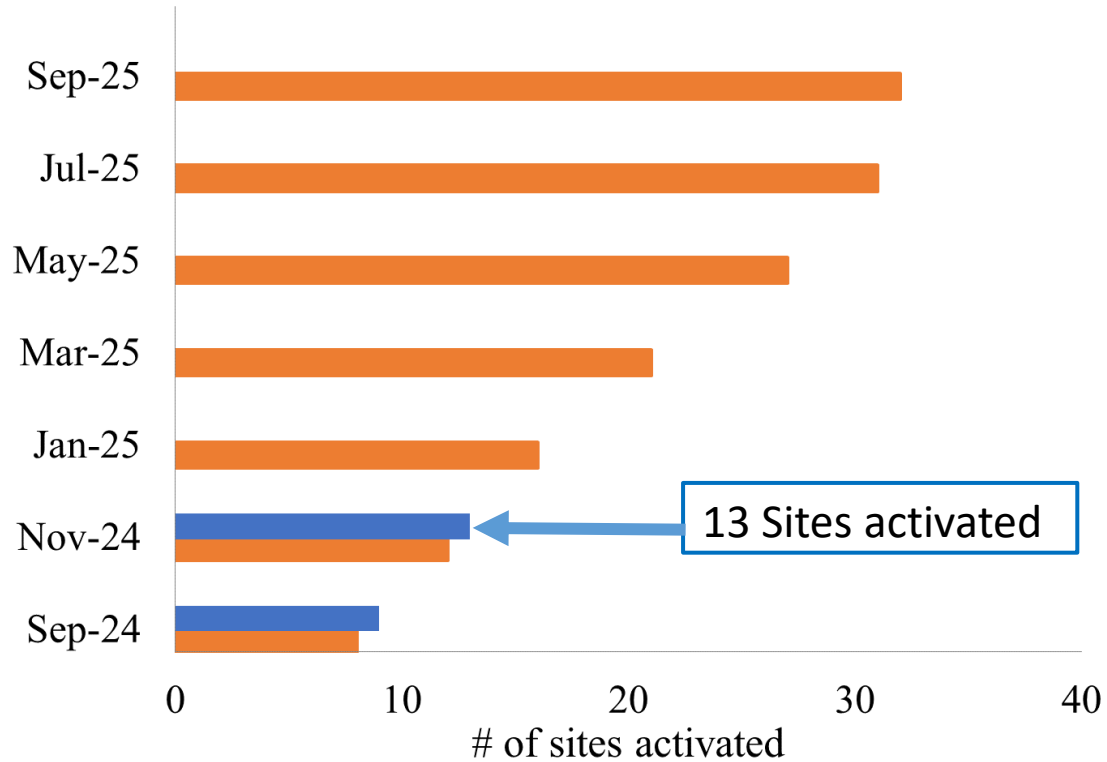
	Symptomatic Onsite	Symptomatic Offsite	Controls
ASSESS	31	0	12

	Main PREVENT Study	Genetic Testing Results Sub-Study
PREVENT	54	3

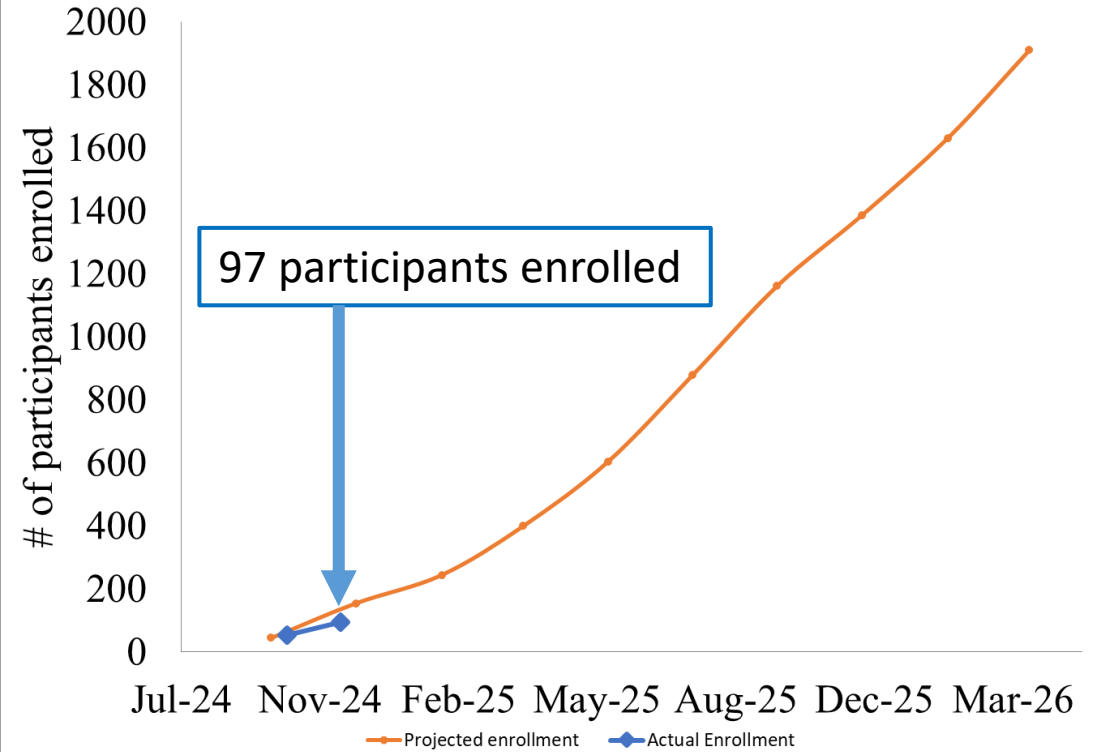
Activation and Enrollment



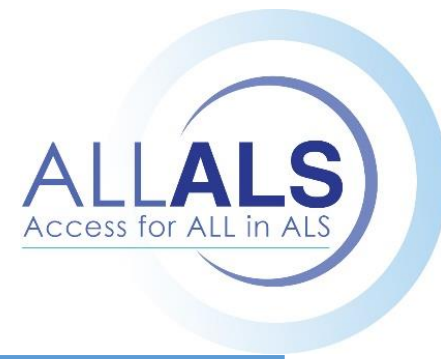
Activated- Projected vs Actual



Enrollment - Projected vs Actual



Year 2 Initiatives



Milestones	Planned	Achieved
Initiate quarterly ALL ALS webinars, initial webinar by 12/31/24	December 2024	11/21/2024
ALL ALS website launched by 12/31/24	December 2024	
21 Sites with sIRB approval	January 2025	
21 Sites activated	March 2025	
Each CCC hires Patient Navigator	March 2025	
Each CCC hires Outreach Manager	March 2025	
Develop Community Engagement Plan	March 2025	
Enroll participants in at least 8 states without a current clinical site	July 2025	
Outreach Coordinators complete 4 site engagements	September 2025	
740 Symptomatic Participants enrolled, w/133 providing CSF	September 2025	
120 Asymptomatic Participants enrolled, w/100 providing CSF	September 2025	
200 Control Participants enrolled, w/15 providing CSF	September 2025	

Study Innovations for ALL ALS



Creating a Speech Bank (Linus Health)

- Bank and share recordings with researchers for future research

eConsent (Florence)

- Use a purpose-built product to simplify/standardize remote consent

Biorepository (BioSEND)

- Make all samples available to the ALS research community

Website with Embedded Enrollment (Dojo)

- Spreads awareness, incorporates a patient interest form directly

Home Phlebotomy (PCM)

- Supports fully remote participation

Digital PROs (NeuroPRO)

- Delivers patient reported outcomes and links directly to study database

Broad Alignment with Other Studies

- ALL-FTD, Natural History Study, CDC, Target ALS, NIH Brain Bank, Precision ALS

ALL ALS Website



- Live Date planned for December 2024
- Participant Interest Form (PIF) embedded via RedCap.

ALLALS

Access for ALL in ALS

ABOUT

STUDIES

TEAM

PRESS/NEWS

PARTICIPATE

Access for ALL in ALS

Funded by the National Institutes of Health (NIH), the Access for ALL in ALS Consortium (ALL ALS), is a community of two coordination centers and 35 research sites across the United States, conducting a combined longitudinal natural history study and biomarker collection study for ALS.

ALL ALS research engages with people currently living with ALS, potential ALS gene carriers, and family members, friends, and community partners to better understand all stages of ALS disease progression.

About Us

ALL ALS STUDIES BY THE NUMBERS

8

Total Number of Active Sites

25

Participants Enrolled

45

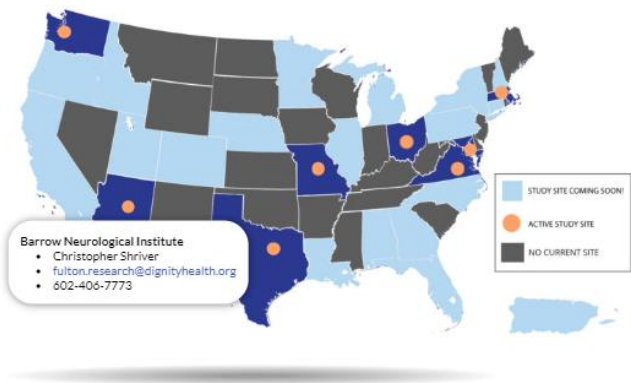
Number of Blood Samples

2

Number of CSF Samples

Where Can I Participate?

Study visits will be conducted during routine clinical visits or as stand-alone research visits, with either a combination of in-person and remote visits or entirely remote visits. Please see the map and site list below to find the study site closest to you!



ALL ALS Consortium Participant Interest Intake Form

If you wish for a member of study team to contact you about the ALL ALS consortium, please include your name and preferred contact information below:

Contact Information	
1) First Name	
2) Last Name	
3) City of Residence	
4) State of Residence	
5) Zipcode	
6) Phone number	 Include Area Code
7) E-mail	
8) Are you interested in participating in ALL ALS Consortium Studies?	☐
9) Questions/Comments for Study Staff	Expand

Track Study Progress

Find an ALL ALS Site

Complete a PIF

Participant Interest Form

Collected
using REDCap

ALL ALS Consortium Participant Interest Intake Form

If you wish for a member of study team to contact you about the ALL ALS consortium, please include your name and preferred contact information below:



Contact Information

1) First Name

2) Last Name

3) City of Residence

4) State of Residence

5) Zipcode

6) Phone number

Include Area Code

7) E-mail

8) Are you interested in participating in ALL ALS Consortium Studies?

9) Questions/Comments for Study Staff

Expand

Outreach and Patient Navigation



Patient Navigator

- Act as liaison between sites, coordination centers, and participants
- Assist in triaging and connecting remote participants to sites
- Develop materials for participant and community education



Outreach Program Manager

- Work with sites to develop recruitment and retention strategies
- Attend community events
- Present at webinars and meetings
- Track metrics and support efforts around DEI Initiatives

How to connect with ALL ALS

- **ClinicalTrials.gov**
 - ASSESS ALL ALS ([NCT06578195](https://clinicaltrials.gov/ct2/show/study/NCT06578195))
 - PREVENT ALL ALS ([NCT06581861](https://clinicaltrials.gov/ct2/show/study/NCT06581861))
- **NEALS Trial Finder** <https://tools.neals.org/als-clinical-trials/>
- **Website**
 - Url pending
- **Email Directly**
 - ALLALS_Info@dignityhealth.org

