



ALL ALS Consortium: A Natural History Study with Hybrid Options for Participation



Myah Stone, Emma Allen, Judith Chavira, Praveena Mohan¹, Courtney Igne², ALL ALS Consortium, James Berry², Robert Bowser¹

¹Barrow Neurological Institute, Phoenix, USA, ²Massachusetts General Hospital, Boston, USA

Introduction

The Access for ALL in ALS (ALL ALS) Consortium is a community of 2 clinical coordination centers, [Massachusetts General Hospital (MGH) and Barrow Neurological Institute (BNI)] and 35 research sites across the U.S. The ALL ALS Consortium was established by AMP ALS (Accelerating Medicines Partnership for ALS), a public-private partnership that is funded by the NIH. AMP ALS brings together the NIH, academic institutions, life science companies, foundations, patient-focused groups, and research nonprofits to accelerate therapeutic and biomarker development for ALS.

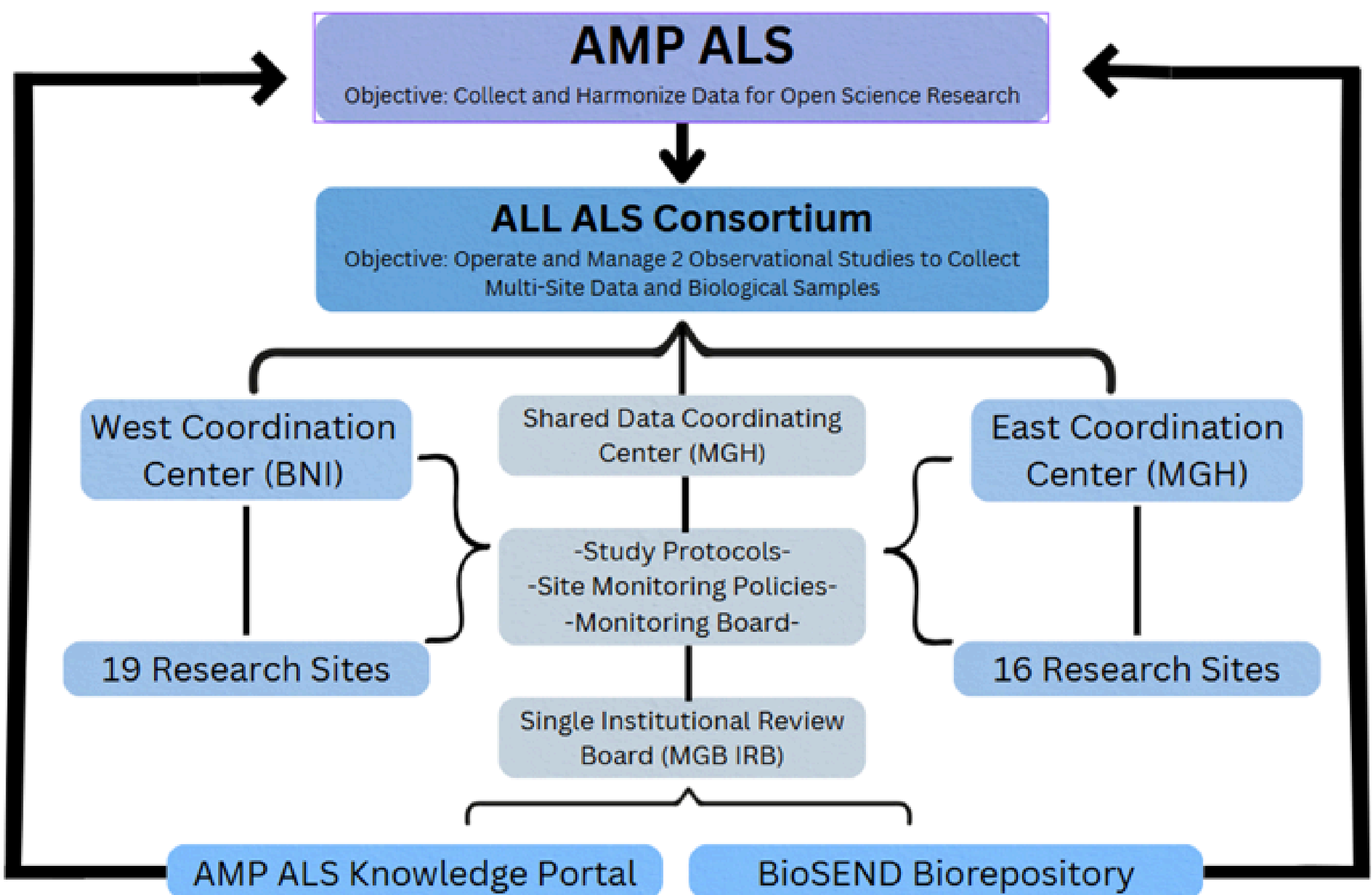


Figure 1. AMP ALS and ALL ALS Organizational Structure

ALL ALS consists of 2 observational research studies, ASSESS and PREVENT. Both studies collect longitudinal clinical data, biological samples, and digital health measures to share with researchers for biomarker research.

Objectives

- Enhance Cohort Representation:** Enable broad ALS community participation through onsite and remote recruitment strategies.
- Validate Clinically Meaningful Outcomes:** Assess whether participant-reported outcome measures—such as the ALS Functional Rating Scale-Revised (ALSFRS-R)—are meaningful and accurately reflect patient priorities and functional status.
- Advance Participant-Centered Engagement:** Increase accessibility and sustained involvement through proactive outreach, regular study updates, and communication strategies tailored to participant needs.
- Accelerate Data Integration:** Establish and share the largest harmonized ALS clinical dataset through the Accelerating Medicines Partnership (AMP®) ALS Knowledge Platform.
- Promote ALS Bioresearch:** Collect and share high-quality, data-integrated biospecimens through the BioSEND Biorepository to advance cross-disciplinary research and therapeutic development.

Methods

Eligibility Criteria:

ASSESS Symptomatic: Individuals diagnosed with ALS; can participate remotely or in-person. Remote participants must have access to internet-enabled devices and complete at-home blood collection.
ASSESS Control: Individuals without ALS or known ALS-associated genetic variants; in-person participation required.
PREVENT: Asymptomatic individuals at risk for developing ALS; in-person participation required.

Schedule of Activities & Assessments:

ASSESS Symptomatic participants complete onsite or remote visits every 4 months, ASSESS Control participants attend annual onsite visits, and PREVENT participants follow a hybrid visit schedule every 4 months. Across cohorts, assessments include physical tests (such as hand-held dynamometry, vital capacity, blood draws, and optional lumbar punctures), ALSFRS-R, symptom questionnaires, cognitive and speech evaluations, and digital health measures.

Results

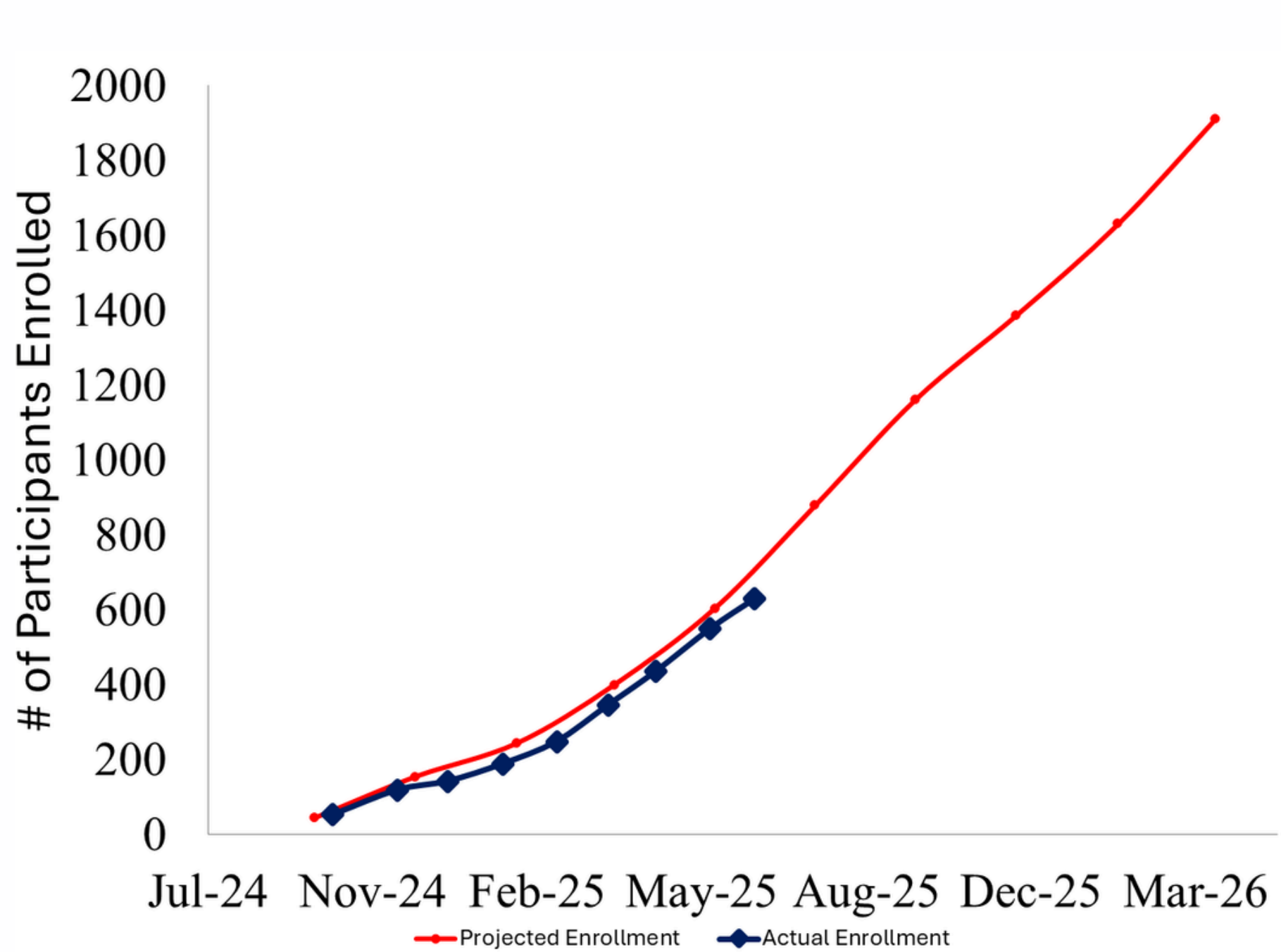


Figure 1. Projected vs Actual Enrollment.

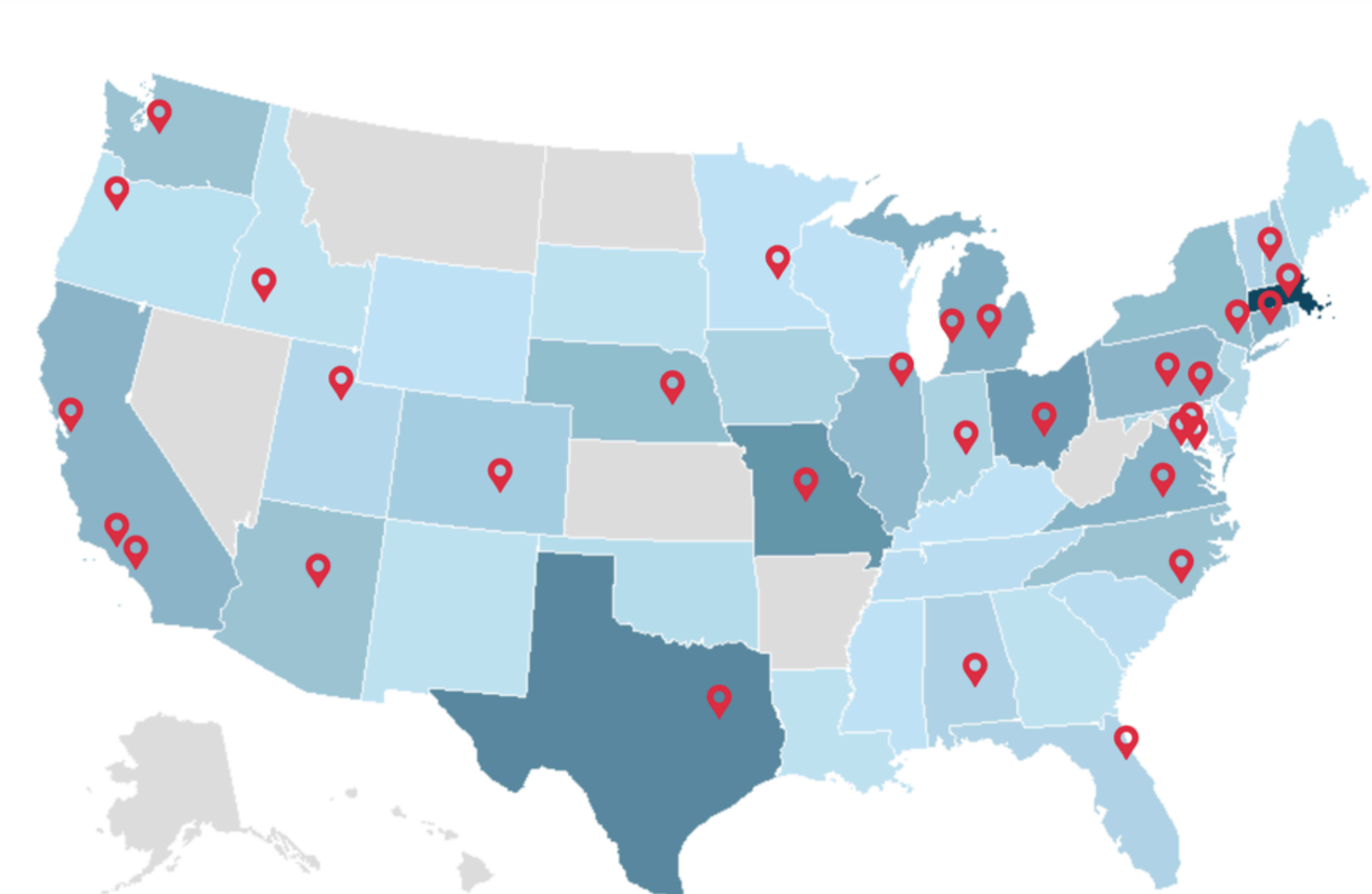


Figure 2. Geographic Distribution of Enrollment in the US. The darker the blue, the higher the number of participants enrolled in that state. Puerto Rico also has a participating site with local enrollment (not shown).

Table 1. Projected vs. Actual Enrollment in Years 1 (Sept 2024–Aug 2025) and 2 (Sept 2025–Aug 2026)

	Actual Enrollment (as of June 2025)	Year 2 Final Projected Enrollment Goals	Projected Enrollment (based off current enrollment rate)
ASSESS	416	940	672
PREVENT	212	120	311
Total	628	1100	983

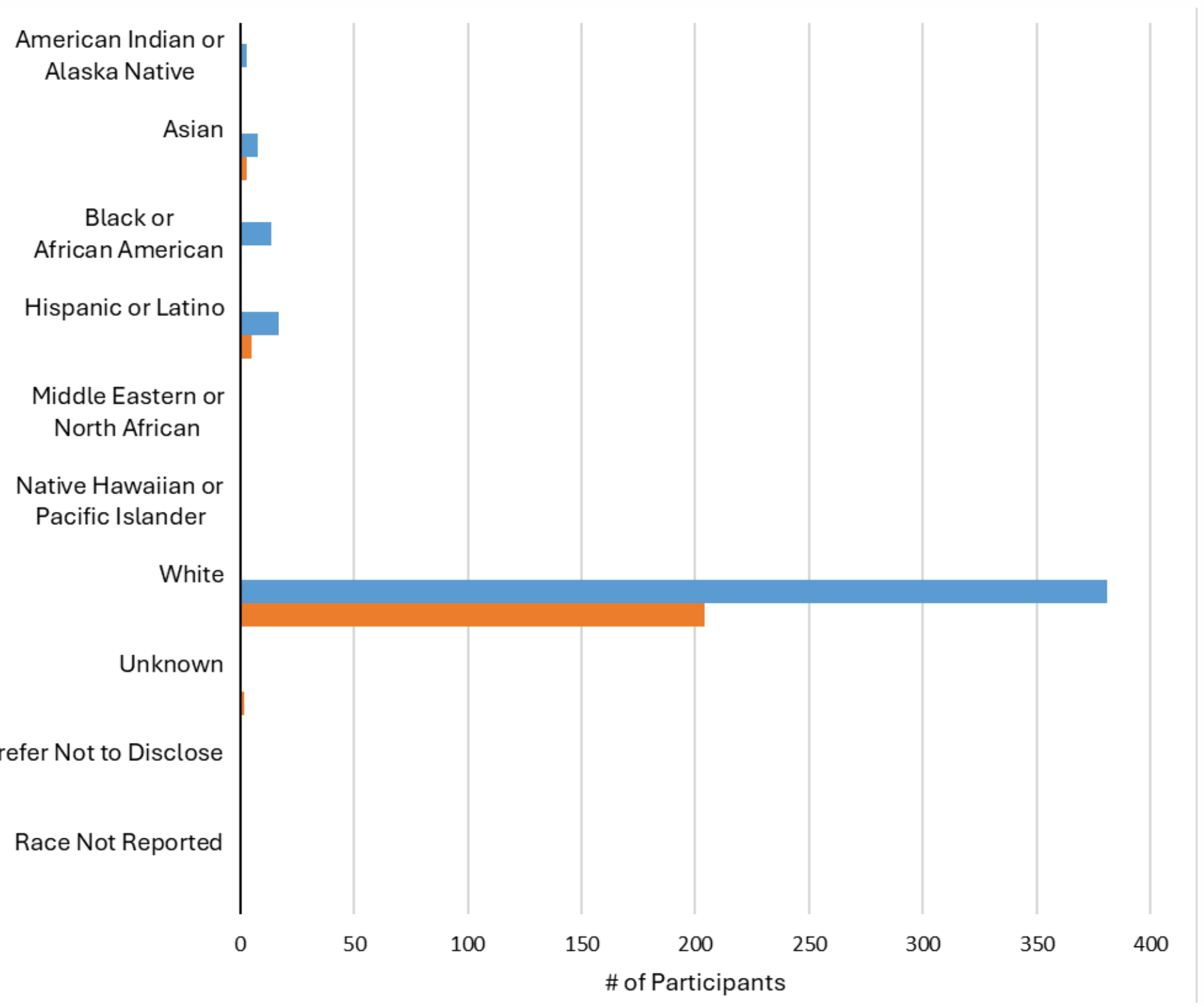


Figure 3. Participant's Self-Reported Race and Ethnicity. The majority of participants identify as White (93%), followed by Hispanic/Latino (3.5%) and Black/African American (2.2%).

Legend: ● ASSESS ● PREVENT

Results Cont.

Table 2. Participant Sex at Birth and Age

	Male	Female	18–30	31–50	51–60	61–70	Average Age
ASSESS	211	203	26	112	35	29	45
PREVENT	72	141	11	62	89	150	61

Discussion

As of June 2025, ALL ALS enrollment is nearing projected goals set by the Consortium and the NIH. Sites continue to accrue participants at a steady rate through site-led and consortium-led outreach. At the study-level, PREVENT has exceeded enrollment projections, suggesting a higher percentage of the at-risk community is willing to participate and engage in research than initially anticipated. These high enrollment numbers allow for an expanded collection of data and biological samples to support presymptomatic ALS research.

ASSESS enrollment remains below target. This was anticipated given ASSESS' ambitious enrollment goal. Nevertheless, outreach and recruitment initiatives are ongoing to improve future enrollment.

ALL ALS has successfully enrolled participants from 42 US states and Puerto Rico. The eight states that have not enrolled participants (AK, AR, HI, KS, MT, NV, ND, WV) lack in-state sites, highlighting potential barriers to long-distance site-enrollment despite remote participation options. Limited outreach beyond sites' patient registries may also contribute to these results.

The average age of individuals enrolled in ASSESS (61 yrs) is significantly higher than that of PREVENT (45 yrs). These averages align with ALS onset demographics (Longinetti & Fang, 2019). Both studies have enrolled more women than men, which is notable in ASSESS, given ALS is more prevalent in men (Longinetti & Fang, 2019, p.772). A breakdown of participant's sex in the ASSESS symptomatic and control cohorts may clarify this finding.

The high incidence of White participants compared to all other race/ethnicities suggests that ALL ALS must make more intentional efforts to enroll across a broader demographic by instituting outreach efforts outside of the sites' clinical environment.

Future Directives

- Increase general recruitment and retention through new and on-going initiatives led by the Consortium, sites, and organization partners, including in states with little to no interest.
- Ingress ALL ALS data in the AMP ALS Knowledge Portal for sharing amongst researchers.
- Implement a digital health sub study amongst a subset of clinical research sites for ALL ALS.

References

- Berry JD, Paganoni S, Harms MB, Shneider N, Andrews J, Miller TM, Babu S, Sherman AV, Harris BT, Provenzano FA, Phatnani HP, Shefner J, Garret MA, Ladha SS, Tsou AY, Mohan P, Igne C, The ALL ALS Consortium, Bowser R. (2024). Access for ALL in ALS (ALL ALS): a large-scale, inclusive, collaborative consortium to unlock the molecular and genetic mechanisms of ALS. *Muscle Nerve*, 70(6): 1140–1150. PMID: 39295118
- Longinetti E, & Fang, F. (2019). Epidemiology of amyotrophic lateral sclerosis: an update of recent literature [Review of Epidemiology of amyotrophic lateral sclerosis: an update of recent literature]. *Current Opinion in Neurology*, 32(5), 771–776. <https://doi.org/10.1097/WCO.0000000000000730>

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- Institutional Review Board at MGH.