myTomorrows

ALS ASSOCIATION

# Why only 1 in 4 people living with ALS can realistically reach a recruiting trial

myTomorrows, in collaboration with the ALS Association | Direct patient outreach | Data collected August 2025 – June 2026

**A comparative analysis of timing, eligibility, and accessibility: The barrier is not trial availability. It is the time left to identify, evaluate and enroll before common enrollment windows close.**

**35** US ALS trials assessed

**280** People living with ALS profiled

**231** People living with ALS consulted

**55** Had viable trial option(s) (1 in 4 consulted)

## Background

Most people living with ALS never enter a clinical trial. Restrictive eligibility, distance from sites and rapid progression are widely cited as reasons – rarely quantified against a defined real-world population.

We asked how well an engaged, real-world ALS population aligns with the currently recruiting US trial landscape, and where access is actually lost.

## Methods

- **280 people** living with ALS profiled through direct outreach (age, geography, symptom-onset and diagnosis dates, functional status, travel preference)
- **35 US ALS trials** assessed from public registries (phase, geography, eligibility criteria, site status)
- Each person passed through five sequential access gates; attrition attributed to the first gate failed

## Cohort snapshot

(n =231 consulted)

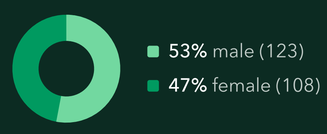


*Figure 1a. Sex*

Median age: **65 years**

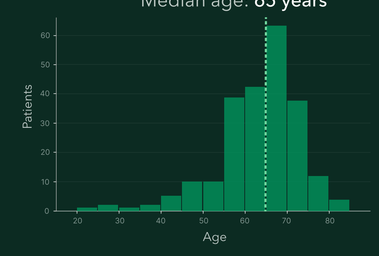


*Figure 1b. Age distribution*

## Key definition

**"Had viable trial option(s)"** = the person had at least one trial that is actively recruiting, has an open site they can reach, and for which they met symptom-onset, functional-status and trial-specific criteria at the time of assessment. It identifies options worth pursuing, not eligibility confirmed by a site.

## A 21-month diagnostic delay leaves about three months to access a trial

Among the 73 people who fell outside symptom-onset eligibility, the median time from first symptom to diagnosis was 21 months (mean 26.9). Against a 24-month enrollment cut-off, roughly three months remained at diagnosis for everything that follows.


*Figure 2. Time from symptom onset to diagnosis versus a 24-month enrollment cut-off, subgroup with symptom onset ≥24 months (n = 73).*

**21 months**
median symptom onset → diagnosis
(subgroup outside onset windows, n = 73)

**24 months**
most common enrollment cut-off from symptom onset

**~3 months**
remaining to be found, referred, screened and enrolled

**10-16 months**
typical diagnostic delays in ALS[1]
(leaving 8–14 months – still short of most referral-to-enrollment pathways)

## Where people drop off

Each person was passed through five sequential gates. Attrition occurred at every one. Most of it was not about whether a suitable trial existed.

| 280 | 231 | 158 | 128 | 55 |
|---|---|---|---|---|
| Profiled | Consulted | Within symptom-onset window | Open to a nationwide search | Had viable trial option(s) |

*Figure 3. 55 of 231 people consulted (23.8%) could realistically access a recruiting trial. Of the full profiled cohort of 280, 19.6%.*

No single criterion produces the gap between theoretical eligibility and real-world access. It is produced by delays accumulating in sequence – and every delay is subtracted from the same finite window.

## Three barriers account for most lost access

All three are the same currency. Diagnostic delay and referral lag are how people come to exceed onset windows – the figures overlap rather than sum.

**31.6%** Excluded: onset ≥24 mo (73/231) – Many ALS trials require enrollment within 24 months from symptom onset – excluding otherwise suitable patients.

**18%** Lost to referral lag – Time lost between diagnosis, referral, trial discussion and matching – the most modifiable of the three.

**14%** Lost to diagnostic delay – Time to a confirmed diagnosis consumes the eligibility window before trial conversations begin.

Some exclusions are not addressable through process: 7 people had a tracheostomy (4 otherwise within eligibility timelines); 14 had a cancer history, typically excluded within a 5-year look-back.

## What is not the barrier

Trial supply, genetics, geography and patient willingness were not the constraint.

**3.2%** had no match at all (only 9/280) – **~5 median** potential trial matches/person.

**32/35** trials were gene-agnostic – Around **70%** of those tested were negative for a pathogenic variant – genetics was rarely the bottleneck.

**33 states + DC** had recruiting sites – Within this cohort, only **4 states** – South Carolina, Mississippi, North Dakota, Oklahoma – left people (~10) with no reachable site.

**2.2%** were unwilling to travel (5/231) – **20** were open to participating anywhere in the world.

## What sponsors and sites can do

Five actions, mapped to the access they recover.

### Accelerate diagnosis and specialist referral

Earlier recognition of suspected ALS, faster referral to specialist care, and trial discussion at or shortly after diagnosis. Diagnosis often arrives too late for any trial conversation to take place.

→ Targets the time consumed before diagnosis

### Build standing referral pathways

Connect community neurologists, ALS clinics, advocacy organizations and trial centers before a site opens. Trusted clinicians shape participation decisions but have limited time and limited access to current trial information.

→ Targets the 18% lost to referral lag

### Identify and assess people earlier

Structured intake soon after diagnosis – onset and diagnosis dates, functional status, prior treatments, travel willingness – lets sites review pre-qualified candidates rather than unstructured inquiries. Patient navigation carries the search and the options conversation between clinic visits.

→ Protects the ~3-month residual window

### Fund travel and decentralize visits

Comprehensive travel reimbursement and concierge support, local laboratory testing, remote follow-up, home nursing, flexible visit schedules, and hybrid or platform designs. Publish real-time site status so people stop spending weeks on matches that were never live.

→ Targets the residual geographic and logistical gap

### Re-examine symptom-onset windows

Assess whether current onset limits balance scientific rigor against the reality of ALS diagnosis. Feasibility assessments should evaluate both the window and the time needed to move a person from identification to enrollment.

→ Targets the 31.6% excluded by onset windows

**Most people living with ALS do not lose access because no suitable trial exists. They lose access because diagnosis and referral delays consume the enrollment window before enrollment can begin.**

Read more here

[1] Richards D, Morren JA, Pioro EP. Time to diagnosis and factors affecting diagnostic delay in amyotrophic lateral sclerosis. Journal of the Neurological Sciences. 2020;417:117054. doi:10.1016/j.jns.2020.117054

**Limitations:** *Convenience sample of people actively seeking trial information; likely more motivated and better informed than the wider ALS population. "Had viable trial option(s)" is a matching construct – it does not verify site-confirmed eligibility, screening or enrollment. Onset and diagnosis dates are self-reported. Trial and site recruiting status is a point-in-time snapshot. No enrollment outcomes were captured. US trials only. The headline 24% is calculated on the 231 people consulted; for all 280 profiled it is 19.6%.*