



**ALS ASSOCIATION ROUNDTABLE**  
**INCREASING THE NUMBER OF, AND ACCESS TO,  
HIGH-QUALITY CLINICAL TRIALS IN ALS: A COMMUNITY  
DISCUSSION**

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October 19, 2022

## **ALS ASSOCIATION ROUNDTABLE PROGRAM OVERVIEW**

On October 19, 2022, The ALS Association (the Association) convened our eighth multistakeholder Roundtable. This hybrid in-person and virtual meeting focused on key elements of the need to build capacity for ALS clinical trials. Meeting participants were asked to consider the Association's unique role in expanding and sustaining the ALS clinical research ecosystem, identifying feasible and impactful actions to achieve the goal of more, better, and faster clinical trials.

### **KEY ROUNDTABLE THEMES**

During the Roundtable, three multi-disciplinary panels discussed key aspects of clinical trial capacity in ALS, including enhancing trial infrastructure, community navigation, and successful trial completion. Panelists addressed important questions to uncover potential action by the Association. Questions included:

#### **Panel 1: Enhancing Trial Infrastructure**

- How can we expand trial site capacity?
- How can we support and shepherd next generation of investigators?
- How should we leverage innovation and technology to make trials efficient?
- What other actions should the ALS Association take? What are other recommendations?

#### **Panel 2: Community Navigation for Trials**

- What can we do to help more people with ALS enroll in relevant clinical trials, and to enroll faster?
- What steps do we need to take with under-represented communities to ensure ALS trials are more diverse, inclusive, and robust/generalizable?
- What other actions should the ALS Association take to support navigation and faster enrollment?
- What other actions should the ALS Association take? What are other recommendations?

#### **Panel 3: Successful Trial Completion**

- How can we address logistical barriers to enhance enrollment & retention in trials?
- How can we address financial barriers to enhance enrollment & retention in trials?
- What should be done to better share results with trial participants?
- What other actions should the ALS Association take? What are other recommendations?

## Multiple important themes emerged throughout the day, including:

### Overarching

- Need to reduce burdensome travel to trials: There is a need to build ALS clinical trial capacity, especially to have more locations closer to more patients and incorporating remote monitoring where possible to reduce the need to travel as travel poses numerous challenges including cost, inconvenience to the patient and their family members, and stress.
- Need to increase genetic testing: The medical community needs further education about the critical importance of genetic testing to help identify relevant trials and match them to individuals first diagnosed with ALS.
- Need to increase patient understanding of the research process: The field could use more basic resources to help people with ALS understand what a trial involves as some people may lack understanding or trust in clinical research.
- Need to increase trial enrollment: Support activities to enhance clinical trial outreach and help patients find/enroll in clinical trials. Advance inventories of all ALS clinical trials sites and make clinical trial matching “concierge services” available to help people find and enroll in trials that match their situation and needs.
- Need to increase trial representativeness and quality: There is a need to ensure that ALS clinical trial populations are inclusive and diverse.
- Need to provide professionals working in ALS clinical trials with additional support, including enhanced staffing, more financial resources, and psychosocial services.

### Enhancing Trial Infrastructure

- Need to bring (and keep) more clinicians in the field of clinical research using appropriate incentives/dedicated time/payment structures.
- Fiscal pressures on health care institutions threatens the research ecosystem and often requires researchers to have to choose between seeing patients and undertaking clinical trials research.
- Address the real issue of clinician and staff burnout.
- Need to consider institutional incentives and other factors that facilitate or thwart ability to run clinical trials.
- Trial budgets are not as robust as they need to be to appropriately support the needed infrastructure for ALS clinical research (including coordinators, nurses, and other ancillary staff).
- Should seek to learn from cancer research to develop sustainable budgets and infrastructure.
- Association could invest in a coordinator program/help build a coordinator network.
- Need to focus on communities with greatest need.
- Broaden access to clinical trials using telehealth and remote monitoring.
- Engage with technology companies that are supporting clinical trials in new ways and bring them into help drive solutions for ALS.
- Need to look to VA system for potential learnings and models.



- Need to think globally, consider building a NEALS type of entity for other regions that the International Alliance could catalyze.
- Need to develop better measures to make trials faster and/or more powerful.
- There is a long-standing, unmet need for better scientific understanding of ALS, including biomarkers.
- Need to collaborate to develop new validated outcome measure tools.
- Need to find a balance between academic centers and community sites, including providing training and staffing support to a broader group of centers/potential trial sites, reducing the need for participants to travel.
- Industry is looking for sites that can enroll and accrue and conduct studies capably.
- Develop multi-disciplinary partnerships with the VA, particularly between local clinical trial sites and their local VAs.

## Community Navigation for Trials

- Need to help patients overcome significant burdens in enrolling in trials. The Association can assist in providing navigation and support, including understanding informed consent.
- Need to have engagement within the community – trial sites and coordinators need to build trusting relationships.
- Need to help people understand what a clinical trial is – language and culture must be considered within awareness and education efforts. It is necessary to “meet people where they are.”
- Need to couple education with awareness about impact of ALS and the value and benefits of being in a trial.
- Need to emphasize to all clinical trial stakeholders that any door is right door to get to an appropriate clinical trial (offer multiple options to find clinical trials, e.g., clinicaltrials.gov, matching service, provider education etc.).
- Association is developing a tool to email an individual once diagnosed and send them a link to a site the user can navigate and engage with as appropriate.

## Successful Trial Completion

- Need to do more to support trial sites in enrolling and encouraging trial sites to collaborate where possible.
- Need to address limited referrals to trials by health care providers and ancillary personnel.
- Expand awareness of trial opportunities among health care providers and incentivize them to spend time discussing trials with their patients.
- Need time for a coordinator to engage in understanding the trial rationale so they can share it with patients to help recruit them into the trial as well as educate them to be empowered in making an informed decision about staying in the study.
- Need to ensure trials are measuring meaningful outcomes.
- Evaluate and validate new endpoints.
- Need to address concerns with placebo controls in trial design.
- Expand use of natural history databases and other external controls.

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- Ensure trials have crossover and open label extension options.
- Need to consider what trial participation demands of patients (time, logistics, physical strain) to reduce burdens wherever possible. Facilitate input from people with ALS in trial design and advance use of remote monitoring and telehealth.
- Need to communicate with patients and families about results of trials – what was the impact of their participation? Need to show the value to participants so they might participate in another trial in the future and/or help to encourage and recruit others to participate in trials.

## NEXT STEPS

In addition to developing a detailed meeting summary from the Roundtable meeting, Association staff will engage with key stakeholders to review all recommendations made by participants and determine best next steps to prioritize those actions that can be operationalized into programs for the near-term and those that may require additional consideration, time, resources, and/or potential collaborations.



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