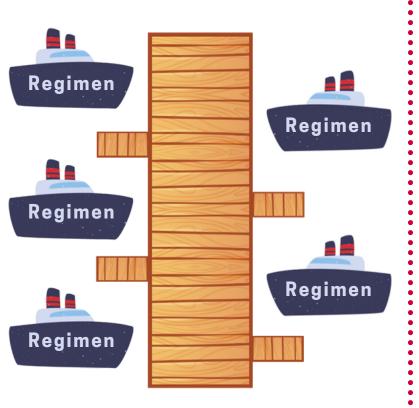
## NEALS Northeast Amyotrophic Lateral Sclerosis Consortium\*

# HEALEY ALS Platform Trial

A nationwide network of research centers in the Northeast ALS (NEALS) Consortium are partnering with the Sean M. Healey & AMG Center to conduct this first-of-its-kind platform trial for people living with ALS. The mission is to find answers as quickly as possible by testing multiple study drugs using a shared platform.



Visit the 'Study Drugs' webpage to learn about each regimen:

https://bit.ly/31EKT98



### **Trial Highlights:**

#### **Multicenter Clinical Trial**

Approximately 80 sites across the US are working together to enroll about 160-300 participants per regimen, depending on the regimen.

#### 3:1 Active Drug to Placebo Ratio

Participants have a 75% chance of receiving active study drug, and a 25% chance of receiving placebo during the 36-week randomized controlled trial (RCT).

#### **Active Treatment Extension (ATE)**

Participants will continue into the ATE for their regimen after completing the RCT. During ATE, all participants know that they are receiving the active study drug. The duration of ATE may vary for different regimens.

View trial details and eligibility criteria on ClinicalTrials.gov:

https://bit.ly/4hhlGSg



For general questions about the HEALEY ALS Platform Trial,

Contact the Patient Navigator

healeyalsplatform@mgh.harvard.edu 833-425-8257 (HALT ALS)

## **Frequently Asked Questions**

#### What is a platform trial?

A platform trial tests multiple investigational products in different participants using a common master protocol. New investigational products can be added to the platform; this means more opportunities to find groundbreaking therapies in a faster timeframe.

#### Why use a platform trial approach?

Platform trials are designed to decrease the time it takes to find effective therapies, reduce the number of participants on placebo, and increase access to research by conducting the same trial at multiple locations. The HEALEY ALS Platform Trial will remain active until safe and effective treatments are found for all people living with ALS.

#### What phase is this clinical trial?

The Platform Trial is a Phase 2/3 clinical trial, so data from the trial, if positive, could be used to support the approval of a new medication.

## How are the investigational products chosen for this trial?

Investigational products are selected by a team of experts after careful review of the pharmaceutical company and the science behind the study drug. Each investigational product is believed to have an equal chance of success for all forms of ALS based on available scientific evidence.

#### What is meant by the term 'regimen'?

A regimen is designed to test the safety and efficacy of one specific investigational product. Participants in the trial are randomly assigned to a regimen, and then randomized to active study drug or placebo within that regimen.

#### What is Active Treatment Extension?

After completing the 36-week randomized controlled trial (RCT), the Active Treatment Extension (ATE) allows participants to receive the active drug for the regimen to which they were assigned. The duration of ATE may vary.

## Stay Connected to the Platform Trial

Investigational products will be added to the HEALEY ALS Platform Trial through support by pharma, foundation partners, philanthropy, federal, and other fundraising initiatives.

View map and contact info for participating research centers:



https://bit.ly/3IICv9t

Sign up for the ALS Link to receive research news and updates via email:



https://bit.ly/3CqGbhb

Register to attend Platform Trial Q&A Webinars:



https://bit.ly/3DvkJTa