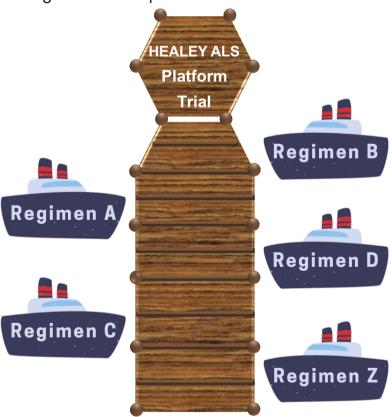
# HEALEY ALS Platform Trial

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 drugs using a shared platform.



Visit our website to learn more about current and future regimens:







## **Trial Highlights:**

#### **Multicenter Trial**

More than 70 Platform Trial sites across the US are working together to enroll about 160-240 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 24-week randomized controlled trial (RCT).

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

Participants will continue into the ATE for their regimen upon completion of the RCT. During ATE, participants know that they are receiving the active study drug. ATE is also called Open Label Extension (OLE).

View map and contact info for participating research centers:

https://bit.ly/3IICv9t



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?

The 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 platform trial will remain open until safe and effective treatments are found for all people living with ALS.

#### What phase is this research trial?

The Platform Trial is a late-stage trial (Phase 2/3), so data derived from the trial, if positive, could be used to support the approval of new medication.

# How are investigational products chosen for this trial?

The 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 one regimen, and then randomized to active drug or placebo within that regimen.

#### What is Active Treatment Extension?

After completing the 24-week randomized controlled trial, 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.

# Learn more about what to expect in the trial process:



https://bit.ly/3ExRal8

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



https://bit.ly/3xC6RXK

Additional questions? Register to attend the Weekly Q&A Webinars:



https://bit.ly/3DvkJTa