

Thank you for joining the weekly webinar!

We are admitting audience members from the waiting room.

Please allow a few moments for the webinar to begin.



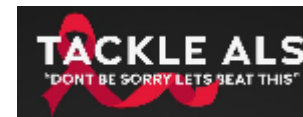
HEALEY ALS Platform Trial

Weekly Q&A – April 25, 2024



Healey & AMG Center

Sean M. Healey & AMG Center for ALS
at Massachusetts General Hospital



The AMG Foundation

Common protocol and shared infrastructure allow for operational and scientific efficiencies

**COMMON
PROTOCOL**

Regimen G

Regimen F

Regimen E

Regimen D

Regimen C

Regimen B

Regimen A

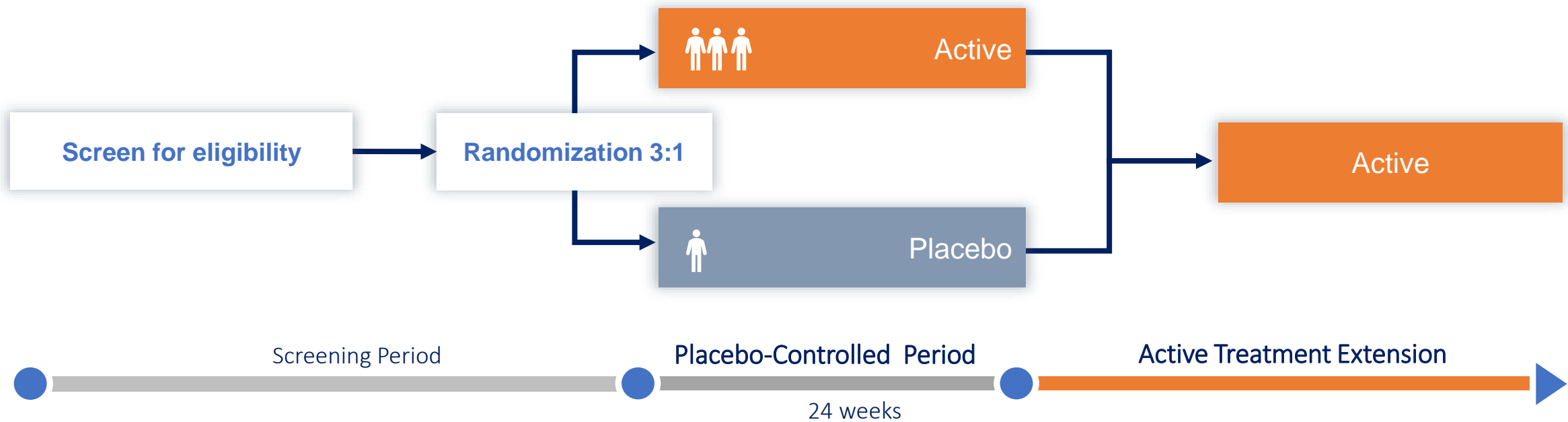
**1 Protocol
(Phase 2/3)
1 single IRB
Central Governance**

**7 Regimens
70+ Enrolling Sites
~1300 Participants**

Regimen: Active Study Drug + Matching Placebo



The objective of each regimen is to provide a go / no go decision to inform the clinical development program of the regimen study drug



Primary Endpoint (Placebo-Controlled Period)

Change from baseline through week 24 in disease severity as measured by the ALSFRS-R total score and survival

Safety, Secondary, and Exploratory Endpoints

(respiratory function, muscle strength, survival, biomarkers + regimen-specific endpoints)

Enrollment Update: Regimen F and Regimen G



<https://bit.ly/3JChDCq>

NEWS · 5 MINUTE READ · APR | 11 | 2024

The HEALEY ALS Platform Trial completes enrollment for testing investigational product ABBV-CLS-7262 from Calico Life Sciences

Thank You

for your partnership in ALS research

(as of 4/25/24)

Navigating Clinical Trial Opportunities



- **ClinicalTrials.gov** – clinicaltrials.gov/

- **NEW ALS TDI Trial Navigator** – www.als.net/als-trial-navigator/

- **ALS Signal (I AM ALS)** – www.iamals.org/get-help/als-signal-clinical-research-dashboard/

- **NEALS** – neals.org/als-trials/neals-affiliated

- **MDA** – www.mda.org/research/clinical-trials

- **ALSA** – www.als.org/research/finding-als-research-opportunities

- **International Alliance of ALS/MND Associations** – www.als-mnd.org/support-for-pals-cals/research/understanding-als-mnd-research/



NEALS Educational Webinars

Visit the **NEALS website** to explore upcoming webinars or view previous recordings



<https://bit.ly/3S4P0Sb>



May 8, 2024 / 4:00 pm–5:00 pm

An Overview of The ALS Better Care Act

Join Dr. Terry Heiman-Patterson, Dr. Kelly Gwathmey and Dr. Sabrina Paganoni, and as they discuss the importance of multidisciplinary care and the role of the ALS Better Care Act to ensure that quality care at Multidisciplinary Centers...

May 16, 2024 / 11:00 am–12:00 pm

Access for ALL in ALS (ALL ALS) Consortium

National Institutes of Health (NIH) funded “ALL ALS” consortium is a multi-institutional effort that aims to organize the ALS clinical research landscape in the US. ALL ALS is operating in partnership with several stakeholders...

Expanded Access Resources and Webinar Opportunities

Join us for updates about Expanded Access and EAPs **on the second Thursday of each month!**

(or view recordings online)



<https://bit.ly/3r6Nd2L>

Visit the NEALS website to explore upcoming educational webinar opportunities or view previous recordings



<https://bit.ly/3S4P0Sb>

Find more webinar opportunities and recordings through the **International Alliance of ALS/MND Associations**



<https://bit.ly/3Obj2m6>



EAP Webpages and Resources



Link to EAP Website:



<https://bit.ly/3uni3lc>

Navigation: About the Healey & AMG Center for ALS | Clinical Care & Resources | Research Opportunities | Platform Trial | Expanded Access | News & Events

Home - Neurology - ALS - Research

Expanding Access to Investigational Products

EAP Opportunities > EAP News & Webinars > Information for Patients >

Overview > EAP Opportunities > For Patients > News & Webinars >

Overview

At the Sean M. Healey & AMG Center for ALS, we are dedicated to developing effective treatments for ALS and to providing people with ALS access to experimental therapies through Expanded Access Protocol (EAP) programs.

EAPs are a pathway for people with a life-threatening condition or serious disease to gain access to an investigational medical product when they are not eligible for a clinical trial. These investigational products – drugs, biologics, or medical devices – are currently being studied, but not yet approved by the US Food and Drug Administration (FDA). Alongside traditional data, EAPs can also provide data that may be useful in developing new therapies.

We have built a dedicated team at the Healey & AMG Center to rapidly implement EAPs for people with ALS at Mass General and are working with several other research centers across the US.

Supporting Expanded Access

Expanded Access Protocol programs at the Sean M. Healey and AMG Center for ALS are funded by multiple sources, including contributions from donors like you. Thank you for partnering with us in the quest to discover life-saving therapies for individuals affected by ALS.

Give Now > Community Support >

EAP Opportunities
Current and upcoming expanded access protocols
Learn more >

EAP News & Webinars
Get the latest news and updates about expanded access protocols
Learn more >

Information for Patients
Common questions and helpful resources about expanded access
Learn more >

Patient Navigation

Central resource for people living with ALS



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Weekly webinar
registration:



<https://bit.ly/3r6Nd2L>

ALS Link sign-up:



<https://bit.ly/3o2Ds3m>

Upcoming Webinars:

May 2nd- Weekly Q&A webinar

May 9th- EAP Discussion with Shawn Sarbacker from Tech vs ALS



Allison Bulat