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 – May 16, 2024
Common protocol and shared infrastructure allow for operational and scientific efficiencies

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

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

The HEALEY ALS Platform Trial completes enrollment for Regimen G evaluating investigational product DNL343 from Denali Therapeutics

Thank You for your partnership in ALS research

https://bit.ly/3JChDCq

Navigating Clinical Trial Opportunities

• ClinicalTrials.gov – clinicaltrials.gov/

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/
An Overview of The ALS Better Care Act

Hosted May 8, 2024 / 4:00 pm - 5:00 pm

- Establishes a single, flat $800 payment per visit to providers caring for patients with ALS on Medicare beginning January 1, 2025.

- Providing additional payment to ALS-related service providers will:
  - Improve access to care for patients
  - Extend survival
  - Catalyze clinical research
  - May offer financial savings due to improved outcomes (lower preventable costs)
Visit the NEALS website to explore upcoming webinars or view previous recordings.

https://bit.ly/3S4P0Sb

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...

June 12, 2024 / 12:00 pm–1:00 pm
Promising Alternative and Off-Label Treatments for ALS

In this educational webinar, Dr. Richard Bedlack of ALSUntangled will review what he considers to be the most promising alternative and off-label ALS treatments currently. These products, which include vitamins, supplements, and...
EAP Webpages and Resources

Link to EAP Website:

https://bit.ly/3uni3lc
First Participants Enrolled in the NIH-Funded Pridopidine and Rapa EAPs!

https://www.massgeneral.org/neurology/als/research/expanded-access-news

Press Releases

- **May 2024:** The Sean M. Healey & AMG Center for ALS and Rapa Therapeutics announce first participant enrolled in Expanded Access to RAPA-501 Protocol (EAP)

- **April 2024:** The Sean M. Healey & AMG Center for ALS and Prilenia Therapeutics Announce First Participant Enrolled in NIH-Sponsored ACT for ALS Expanded Access Protocol for Pridopidine

The Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital and Rapa Therapeutics have announced the first participant enrolled in the Expanded Access to RAPA-501 Protocol (EAP)
Patient Navigation
Central resource for people living with ALS

Phone: 833-425-8257 (HALT ALS)
E-mail: healeyalsplatform@mgh.harvard.edu

Weekly webinar registration:

ALS Link sign-up:

https://bit.ly/3r6Nd2L

Upcoming Webinars:
May 23rd - Weekly Q&A webinar
May 30th - Weekly Q&A webinar
June 6th - Canceled