

Thank you for joining the webinar!

We are admitting audience members from the waiting room.

Please allow a few moments for the webinar to begin.



Monthly EAP community Q&A webinar

January 9, 2025

EAP Webpages and Resources



Link to EAP Website:



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

About the Healey & AMG Center for ALS **Clinical Care & Resources** **Research Opportunities** **Platform Trial**

Home - Neurology - ALS - Research

Expanding Access to Investigational Products

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

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 >](#)

Expanded Access

- [Overview >](#)
- [EAP Opportunities >](#)
- [For Patients >](#)
- [News & Webinars >](#)

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 >](#)

EAPs Then and Now



2018

Single-center EAPs began at MGH Healey Center

2021 - 2022*

Multi-center companion EAPs at 9 sites of the HEALEY ALS Platform Trial

2022 - 2024

NIH funding

Trehalose – 25 sites
Pridopidine – 45 sites
RAPA-501 – 10 sites
CNM-Au8 – 7 + 1 virtual site

2024 - 2025

New NIH-funded EAP announced

Ibudilast

**ACT for ALS signed into law on Dec 23, 2021*



Pridopidine EAP 2

More info: clinicaltrials.gov
NCT06069934

[Status: No Longer Enrolling]

- 32 sites activated
- **201** participants enrolled
- 2 screenings planned or in progress



CNM-Au8.EAP.04

More info: clinicaltrials.gov
NCT06408727

- All 8 sites activated
- ~**180** participants enrolled



RAPA-501 EAP

More info: clinicaltrials.gov
NCT06169176

- 9 sites activated
- Enrollment ongoing



Ibudilast EAP

[Status: In Start Up]

- 10-25 sites
- Target enrollment: 200 ALS individuals
- **Webinar with Dr. Björn Oskarsson
February 13th**

Press Release (Sept 24, 2024)

<https://bit.ly/4hb98gq>



Educational Webinar Opportunities



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



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

Expanded Access Programs in ALS: What Have We Learned, Where Do We Go from Here?



Jinsy Andrews,
MD, MSc
Columbia
University



Suma Babu,
MMBS, MPH
Massachusetts
General Hospital



Richard Bedlack,
MD, PhD
Duke
University

Wednesday, January 15th 2025

1:00 PM - 2:00 PM ET

Patient Navigation

Central resource for people living with ALS

Two webinars
per month



Catherine Small

Phone: 833-425-8257 (HALT ALS)

E-mail: healeyalsplatform@mgh.harvard.edu

ALS Link sign-up:



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

Weekly webinar
registration:



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

Upcoming Webinars:

January 23rd – Monepantel/NUZ-001 Drug Science with Neurizon Therapeutics

February 13th – Expanded Access Discussion with Dr. Björn Oskarsson

February 27th – Platform Trial Learnings with Biostatistician Lori Chibnik, PhD



Allison Bulat