

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 – March 7, 2024

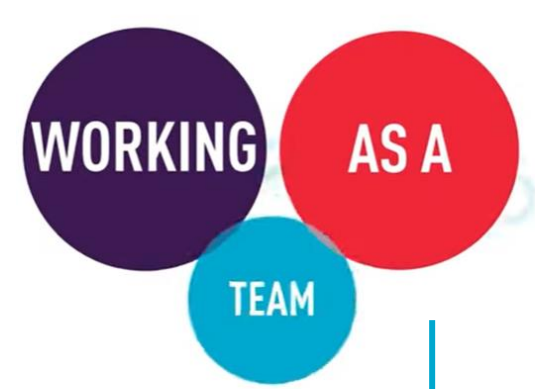


Healey & AMG Center

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



The AMG Foundation



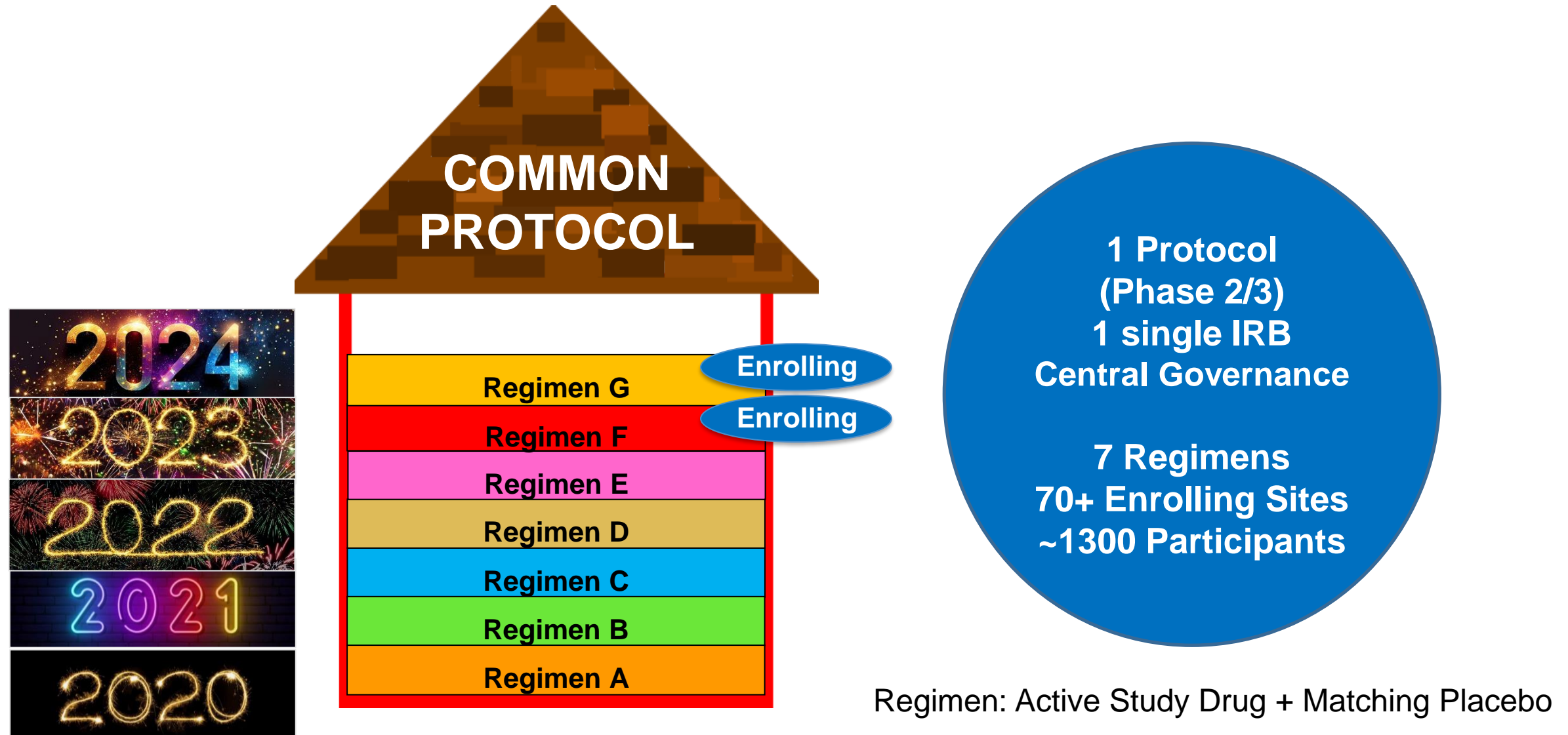
This trial is **dedicated to all people living with ALS**, their families, and friends. Your **partnership** in research is what keeps us filled with passion, dedication, and the commitment to develop new treatments for ALS

This breakthrough trial would not be possible without your participation.

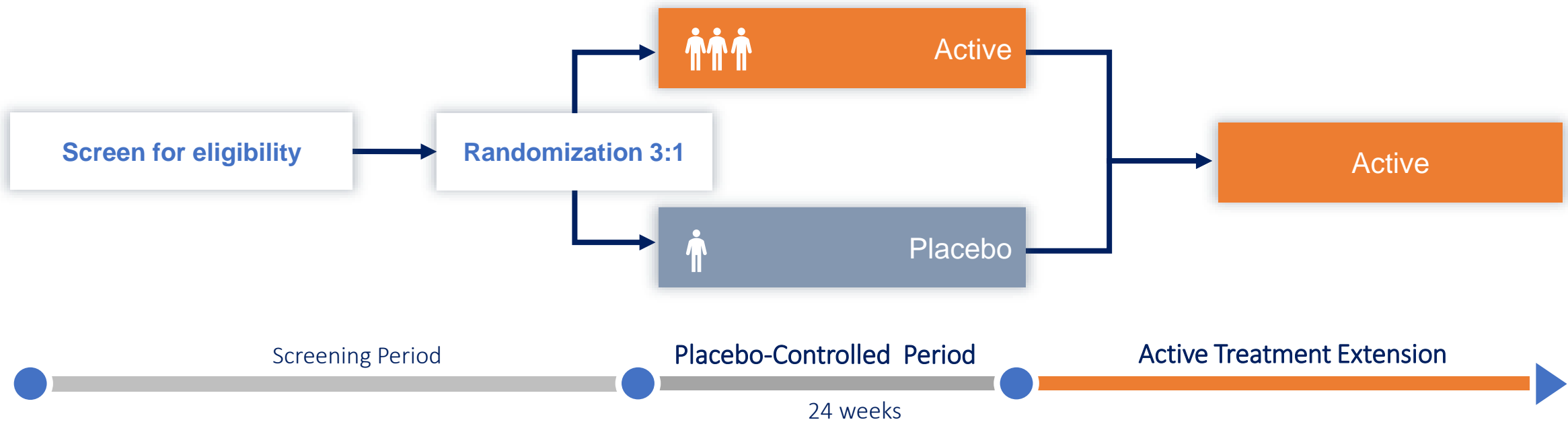
Every research participant, whether on the active drug or placebo, plays a critical role in making the hope of finding a cure for ALS a reality

Thank You

Common protocol and shared infrastructure allow for operational and scientific efficiencies



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



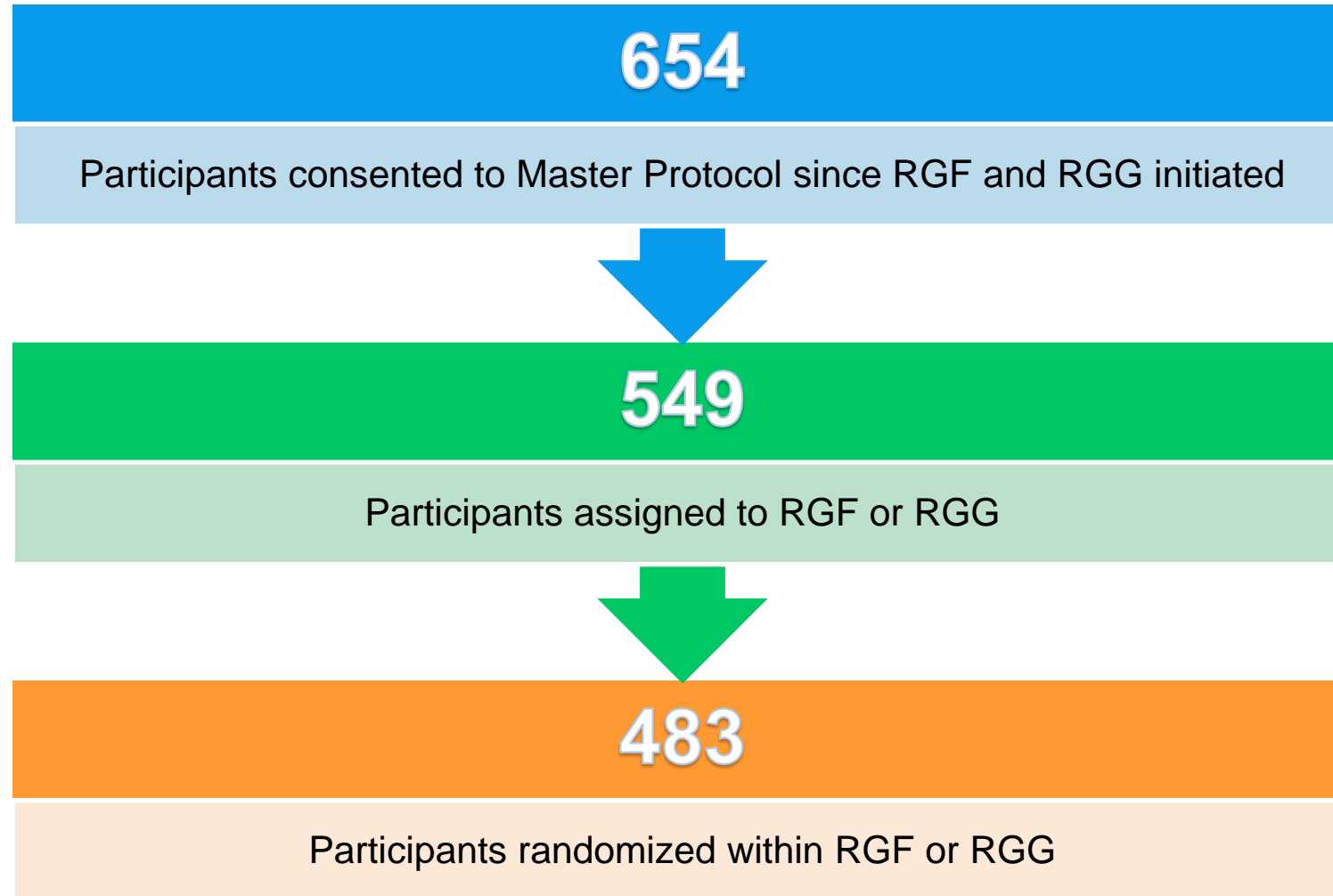
Primary Endpoint (Placebo-Controlled Period)

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

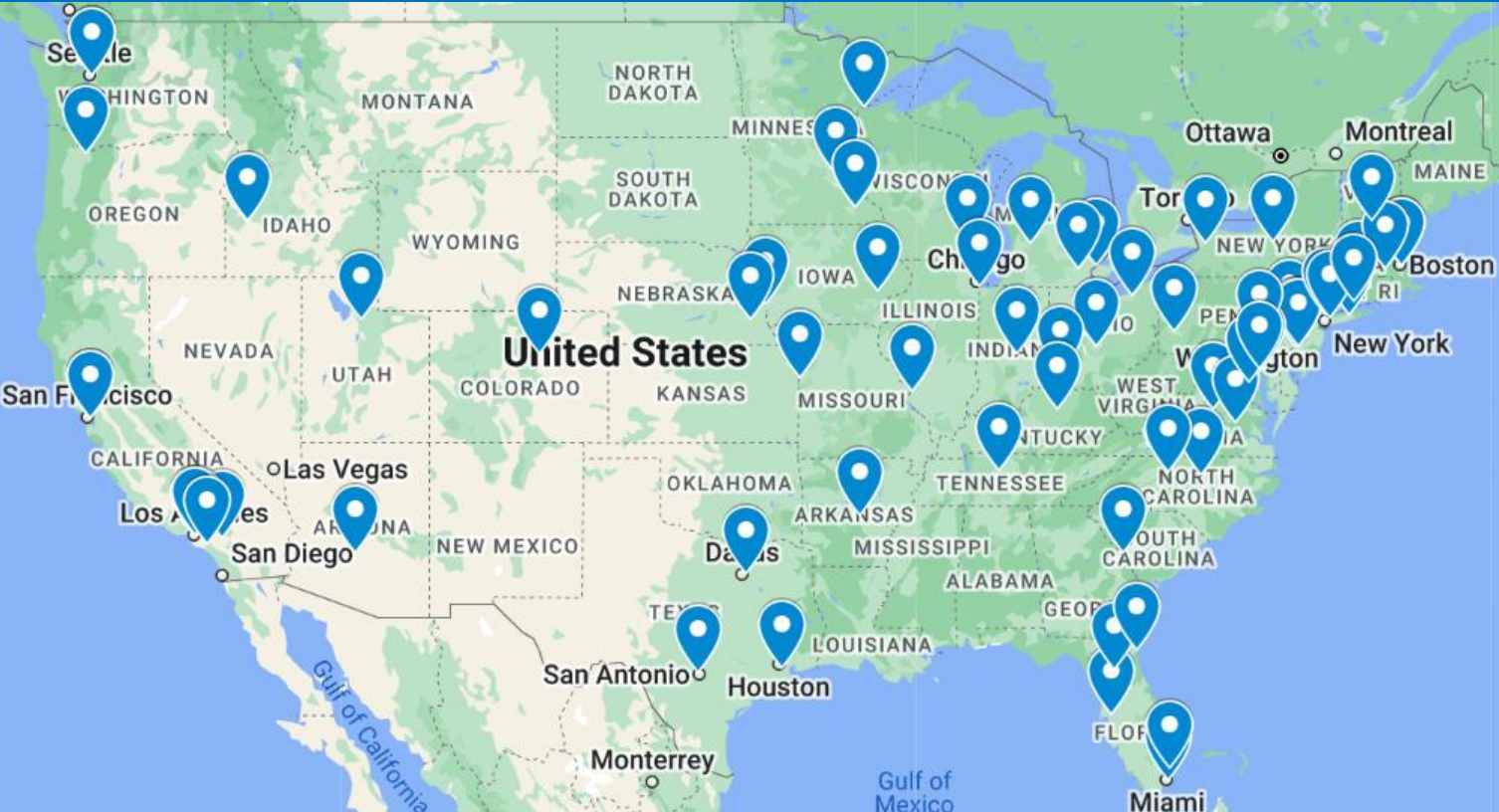


Thank You

for your partnership in ALS research

(as of 3/7/24)

Providing research access across a diverse network of 70+ NEALS sites

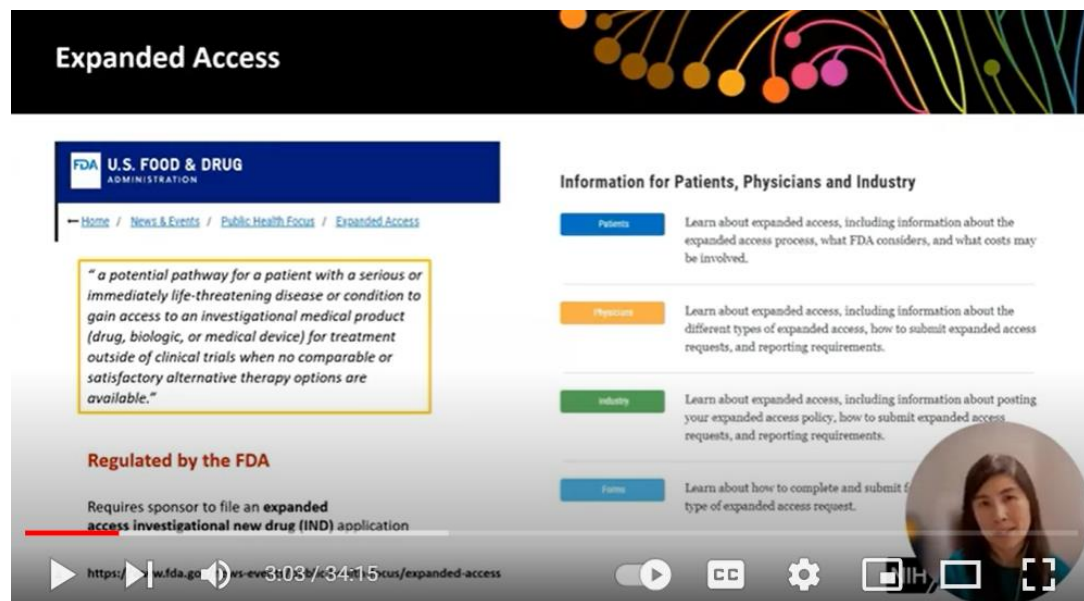


Contact a study team near you to discuss enrollment opportunities



<https://bit.ly/3g2NZr5>

Monthly Expanded Access Q&A Webinars



The screenshot shows the FDA's Expanded Access webpage. At the top left, it says "Expanded Access". Below that is the FDA logo and navigation links: Home / News & Events / Public Health Focus / Expanded Access. A quote in a yellow box reads: "a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available." Below the quote, it says "Regulated by the FDA" and "Requires sponsor to file an expanded access investigational new drug (IND) application". On the right, there is a section titled "Information for Patients, Physicians and Industry" with four sub-sections: Patients, Physicians, Industry, and Forms. Each sub-section has a brief description of the information provided. At the bottom of the screenshot, there is a video player interface with a play button, a progress bar, and a URL: https://www.fda.gov/oc/expanded-access.

February 8, 2024 –

EAP Talk with Dr. Rick Bedlack and Gwen Petersen

Recording: <https://bit.ly/49wySQn>

January 11, 2024 –

EAP Discussion with the NIH

Recording: <https://bit.ly/3HvfJCz>

December 14, 2023 –

EAP Update with Dr. James Berry (MGH)

Recording: <https://bit.ly/3UfCAJU>



March 14, 2024 – Thurs 5:00-5:30 EST

EAP Update with Dr. Jinsy Andrews (Columbia)

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>



Upcoming NEALS Educational Webinars

March 18, 2024

The Science Behind ALS Treatments: Riluzole, Radicava, and Relyvrio Description

Moderated by Dr. Senda Ajroud-Driss, this webinar for both clinicians and people living with ALS will review the 3 drugs that are currently FDA-approved in the United States for the general ALS population. Panelists, Dr. Lauren Elman,...

Register Here:



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

*Recording will later be available under
“educational webinars” on neals.org*

Patient Navigation

Central resource for people living with ALS



Catherine Small

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E-mail: healeyalsplatform@mgh.harvard.edu

Weekly webinar
registration:



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

ALS Link sign-up:



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

Upcoming Webinars:

March 14th- EAP Discussion with Dr. Jinsy Andrews (Columbia University)

March 21st- Weekly Q&A Featuring Karen Parada (University of Chicago)

March 28th- Weekly Q&A



Allison Bulat