

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 – February 1, 2024



Healey & AMG Center

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



als FINDING a CURE™



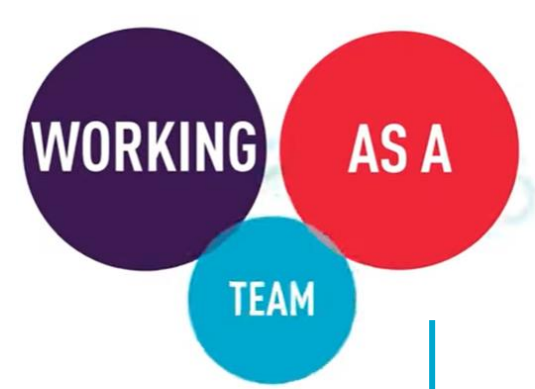
Calico



THE ARTHUR M. BLANK
FAMILY FOUNDATION



The AMG Foundation



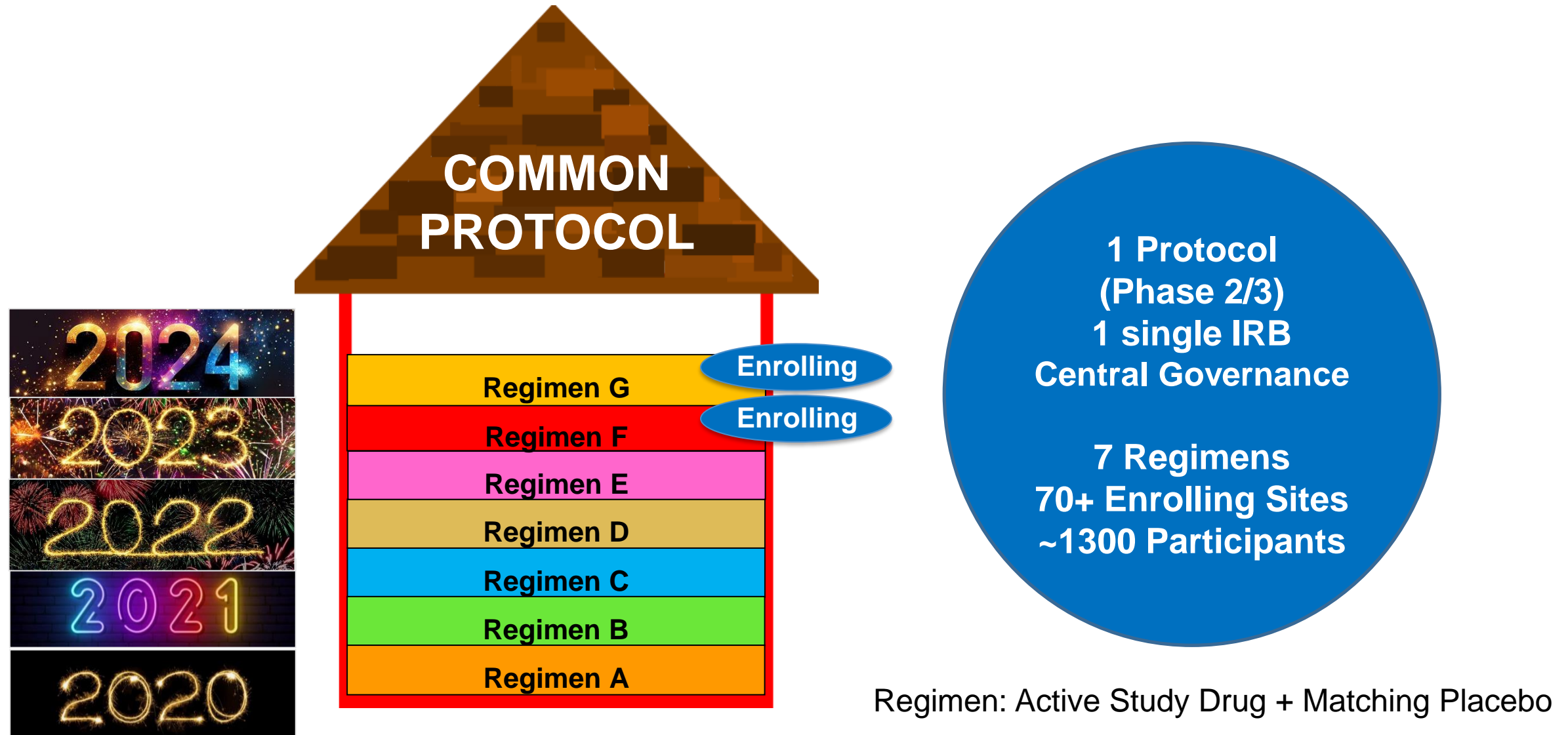
This trial is **dedicated to all people living with ALS**, their families, and friends. Your **partnership** in research is what keeps us filled with passion, dedication, and the commitment to develop new treatments for ALS

This breakthrough trial would not be possible without your participation.

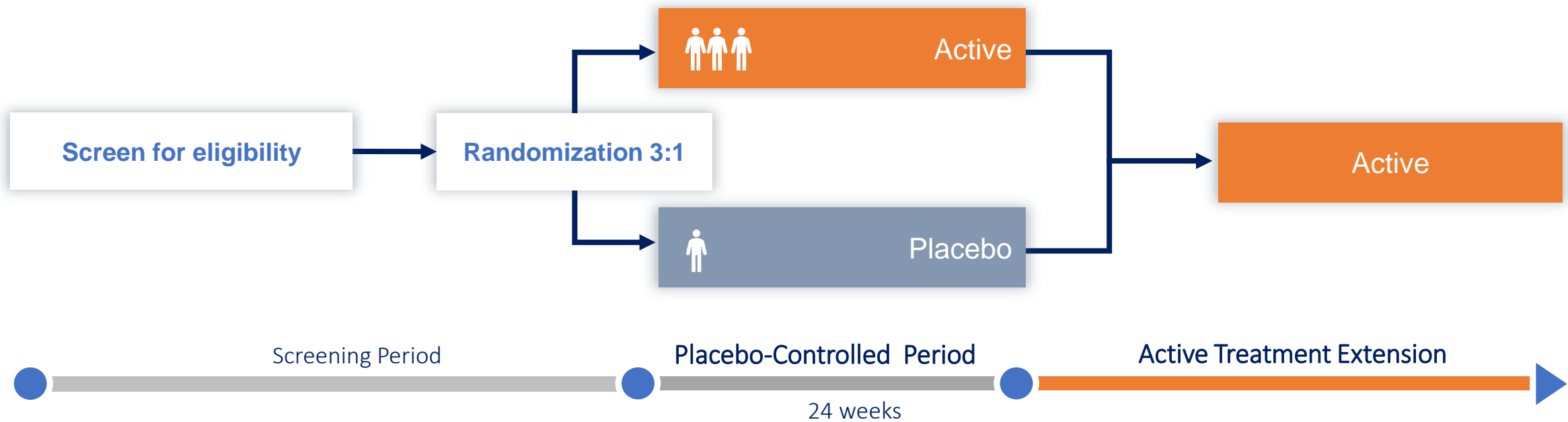
Every research participant, whether on the active drug or placebo, plays a critical role in making the hope of finding a cure for ALS a reality

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



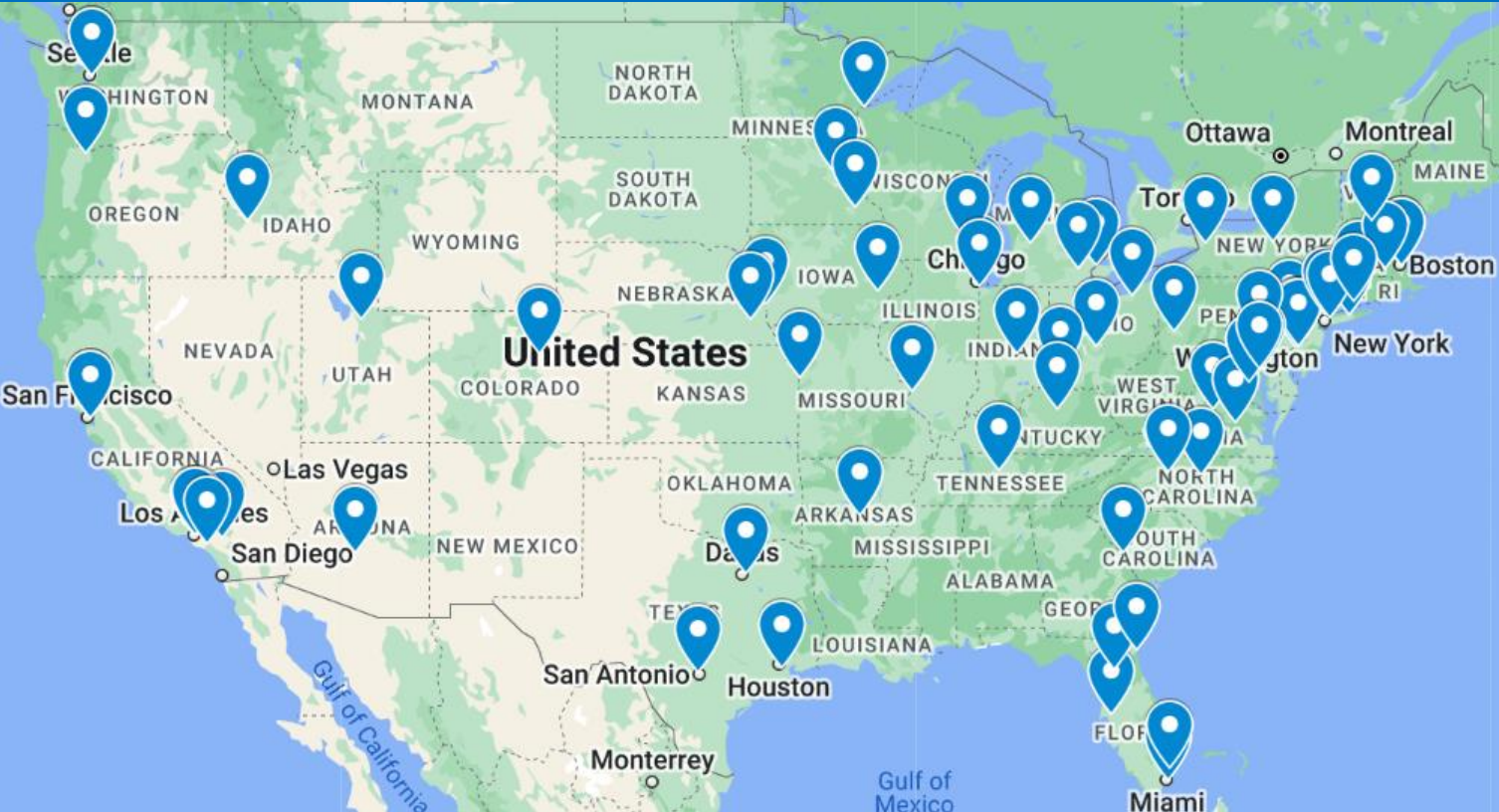
Primary Endpoint (Placebo-Controlled Period)

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)

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

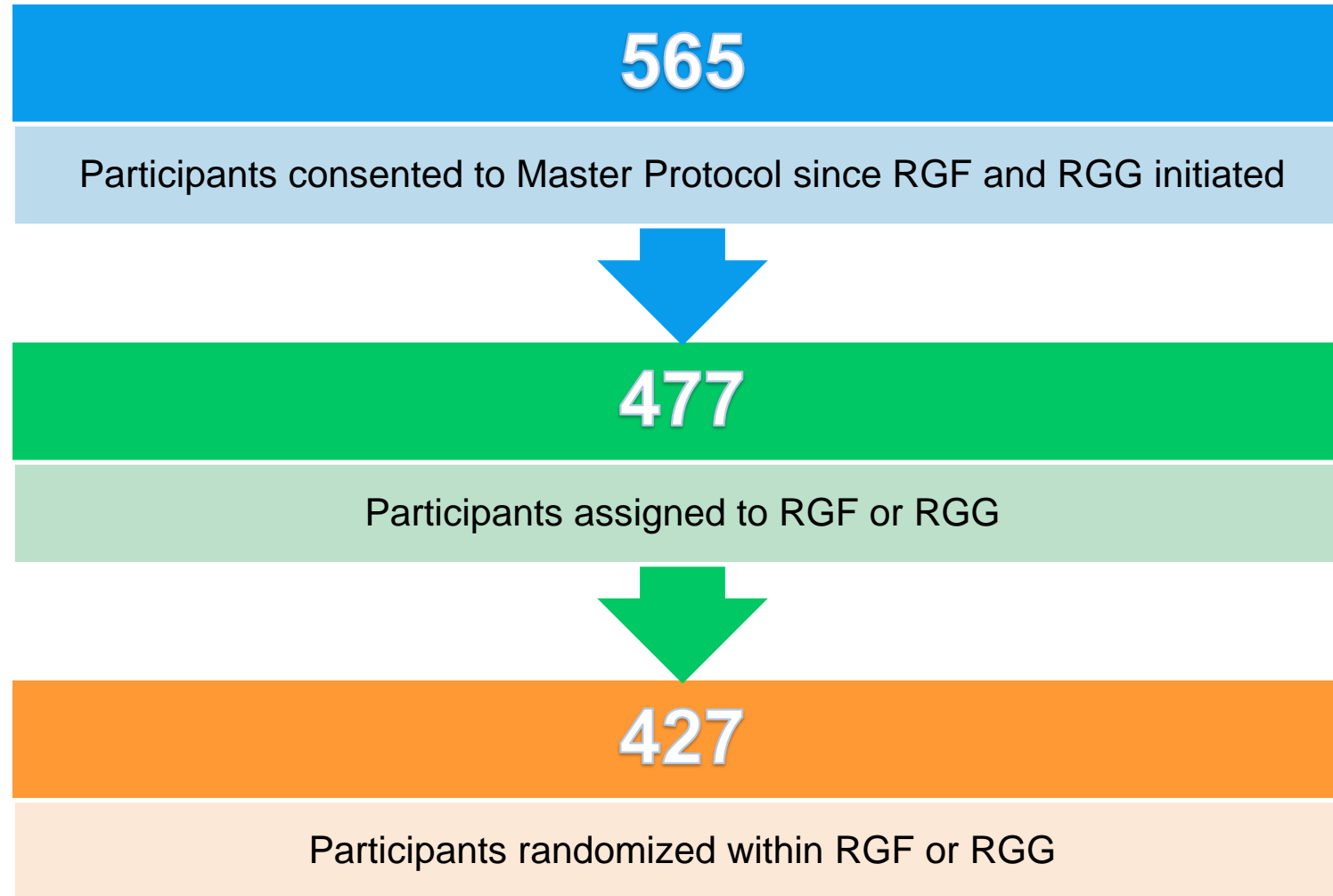


Contact a study team near you to discuss enrollment opportunities



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

Enrollment Update: Regimen F and Regimen G

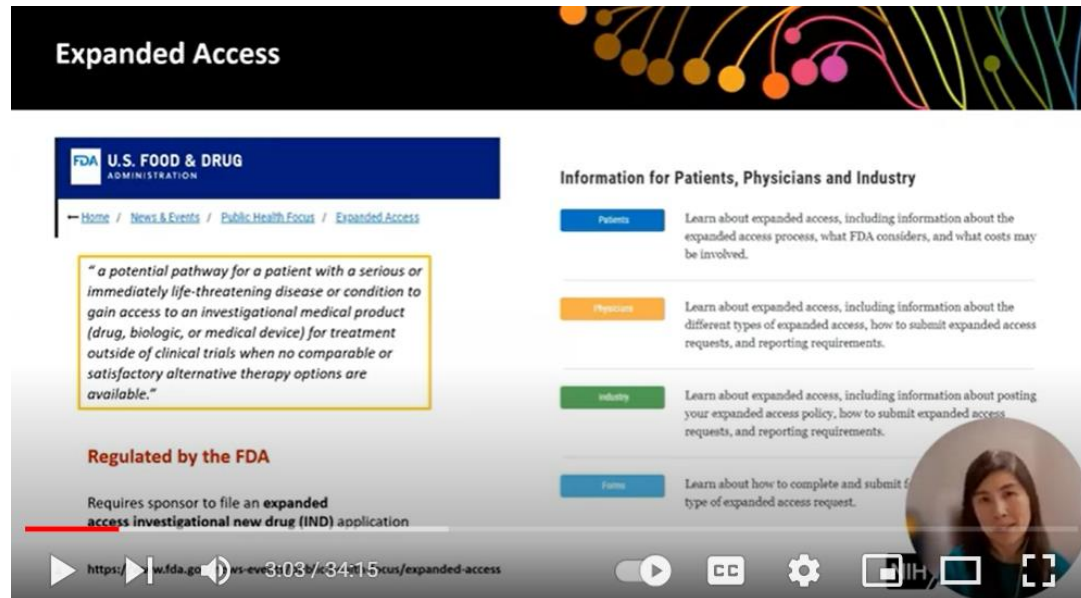


Thank You

for your partnership in ALS research

(as of 2/1/24)

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 are four sections: Patients, Physicians, Industry, and Forms, each with a brief description of the information provided. A video player is visible at the bottom of the screenshot.

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>

November 9, 2023 –
EAP Update with Dr. Suma Babu (MGH)
Recording: <https://bit.ly/48HAE0y>



February 8, 2024 –
Thurs 5:00-5:30 EST
EAP Update with Dr.
Rick Bedlack (Duke)
and Gwen Petersen



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>



The ALS Association/Northeast ALS Consortium Educational Webinar

ALS Treatments: Riluzole, Radicava, and Relyvrio



Monday,
March 18th
4:30pm EST

Moderator: Senda Ajroud-Driss, M.D., Northwestern University

Register Here:



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

*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:

February 8th- EAP Discussion with Dr. Rick Bedlack (Duke) and Gwen Petersen

February 15th- Weekly Q&A and Platform Trial Update

February 22nd- Genetics Discussion with Dr. Mark Garret (MGH)



Allison Bulat