

# HEALEY ALS Platform Trial

Weekly Q&A – June 30, 2022



## Healey Center

Sean M. Healey & AMG Center  
for ALS at Mass General



The AMG Foundation

# Guest Speaker

**Gale Kittle, RN, MPH**

Director, Outcome Measurements Training  
Barrow Neurological Institute, Phoenix AZ



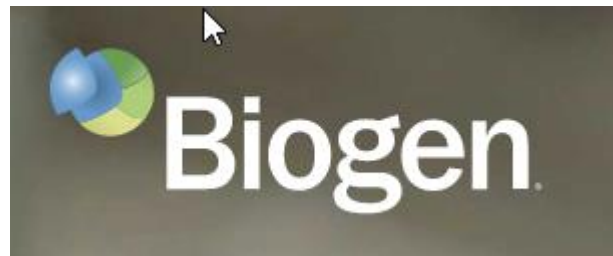


# Barrow Neurological Institute Clinical Research Organization

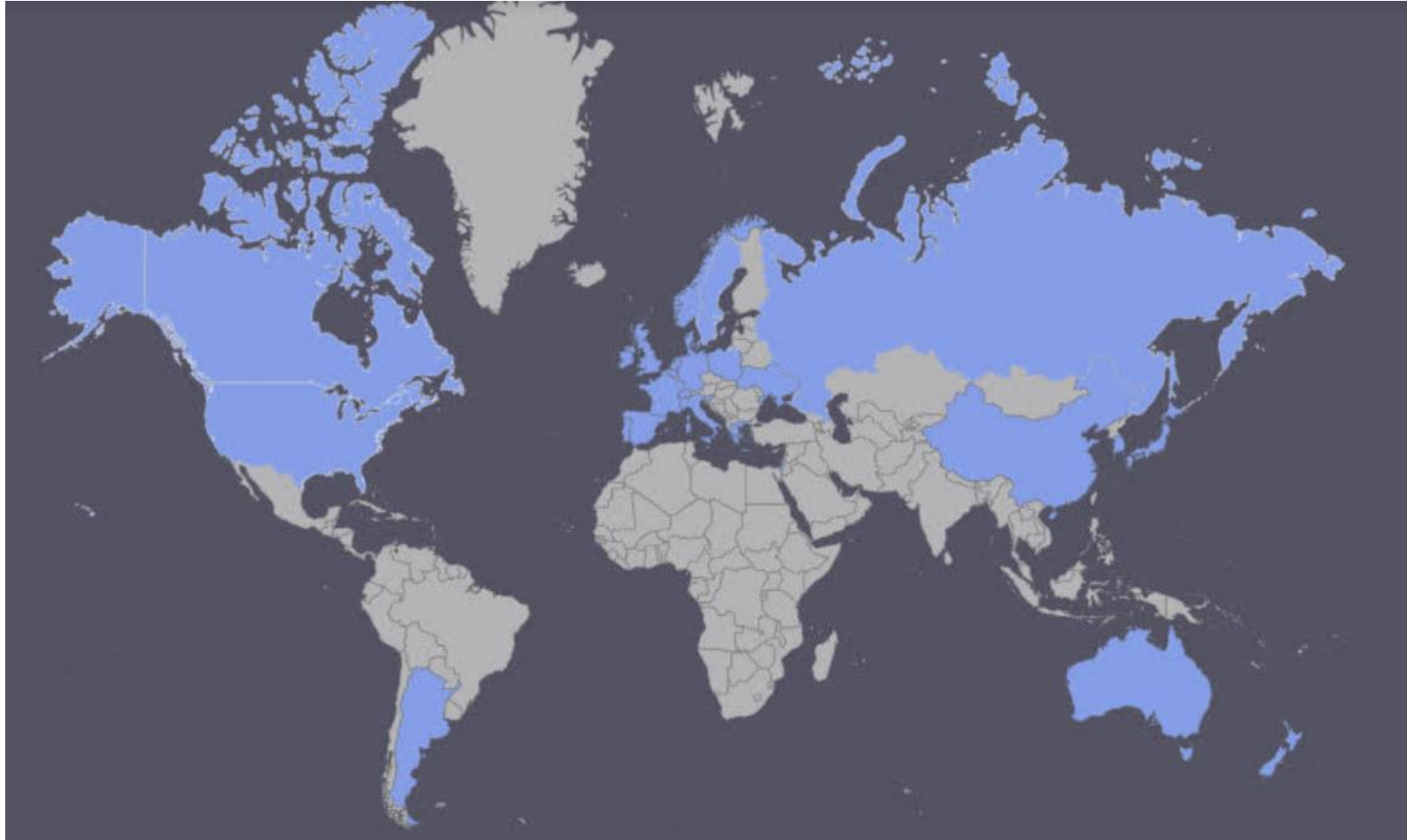
- Outcomes and Clinical Monitoring team specialized in Neurological Disorders.



BNI Outcomes Center: Phoenix, AZ



Trained/certified more than 1,400 evaluators  
in 27 countries





# Core Outcomes Team



Gale Kittle, RN, MPH  
Director/Trainer



Jenny Hamilton,  
BA, CCRC  
Project Manager



Marlee Lovett,  
BS  
Research  
Assistant



Jasi Torres, BS  
Research Assistant

# Platform Trial Outcome Measures

ALSFERS-R



Vital Capacity

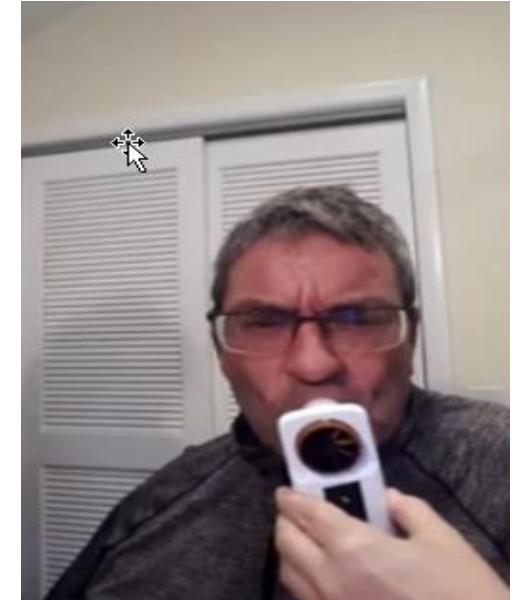


HHD



(Hand-held Dynamometry)

Home Spirometry



# Training and Certification

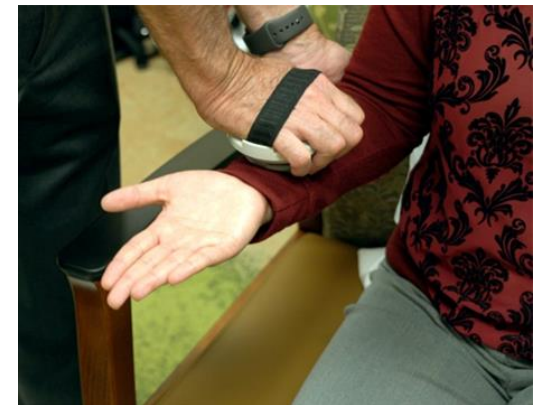


## Training

- Investigator Meetings: In-person or virtual
- Self-accessed webinar on training portal
- Real life or video practice/demonstrations

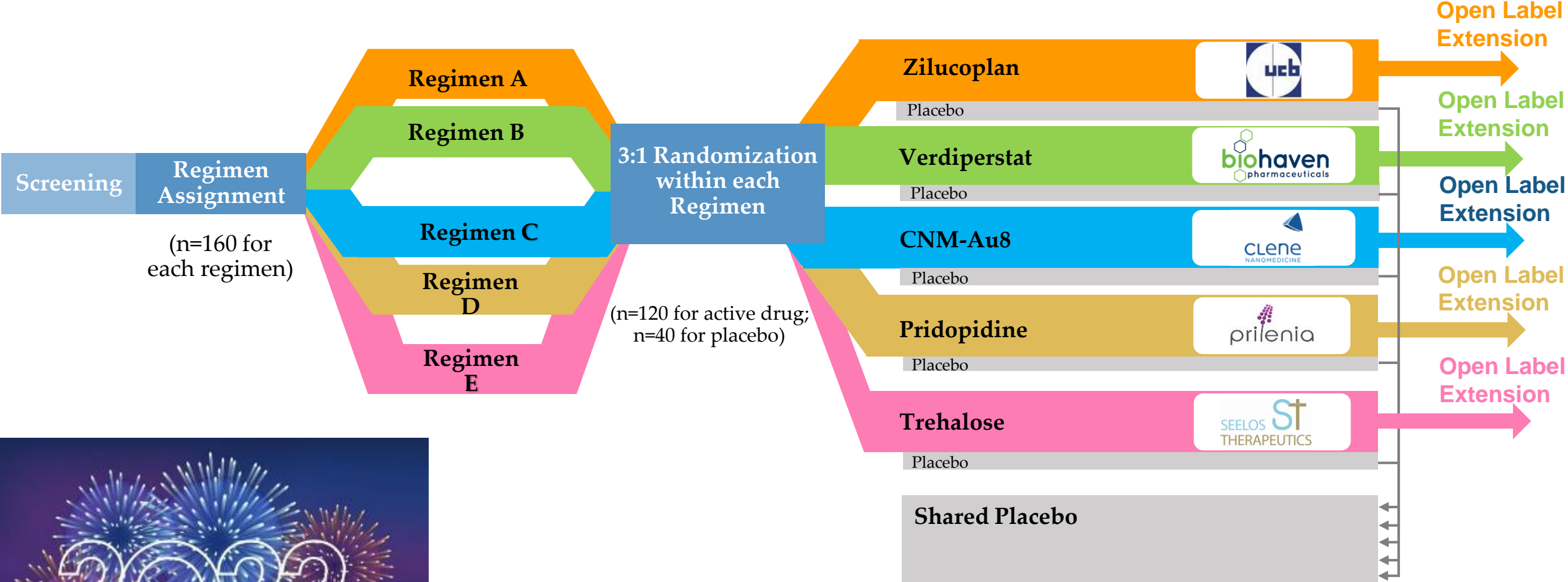
## Certification

- Perform practice assessments
- Must meet specific criteria for reliability requirement
- Retests and one-on-one training if required
- Regular certificate renewal (annually or every two years)





# The HEALEY ALS Platform Trial is a Perpetual Adaptive Trial



# Enrollment Updates (as of June 30, 2022)

- **83** individuals have signed informed consent
- **55** individuals have been randomized within Regimen E

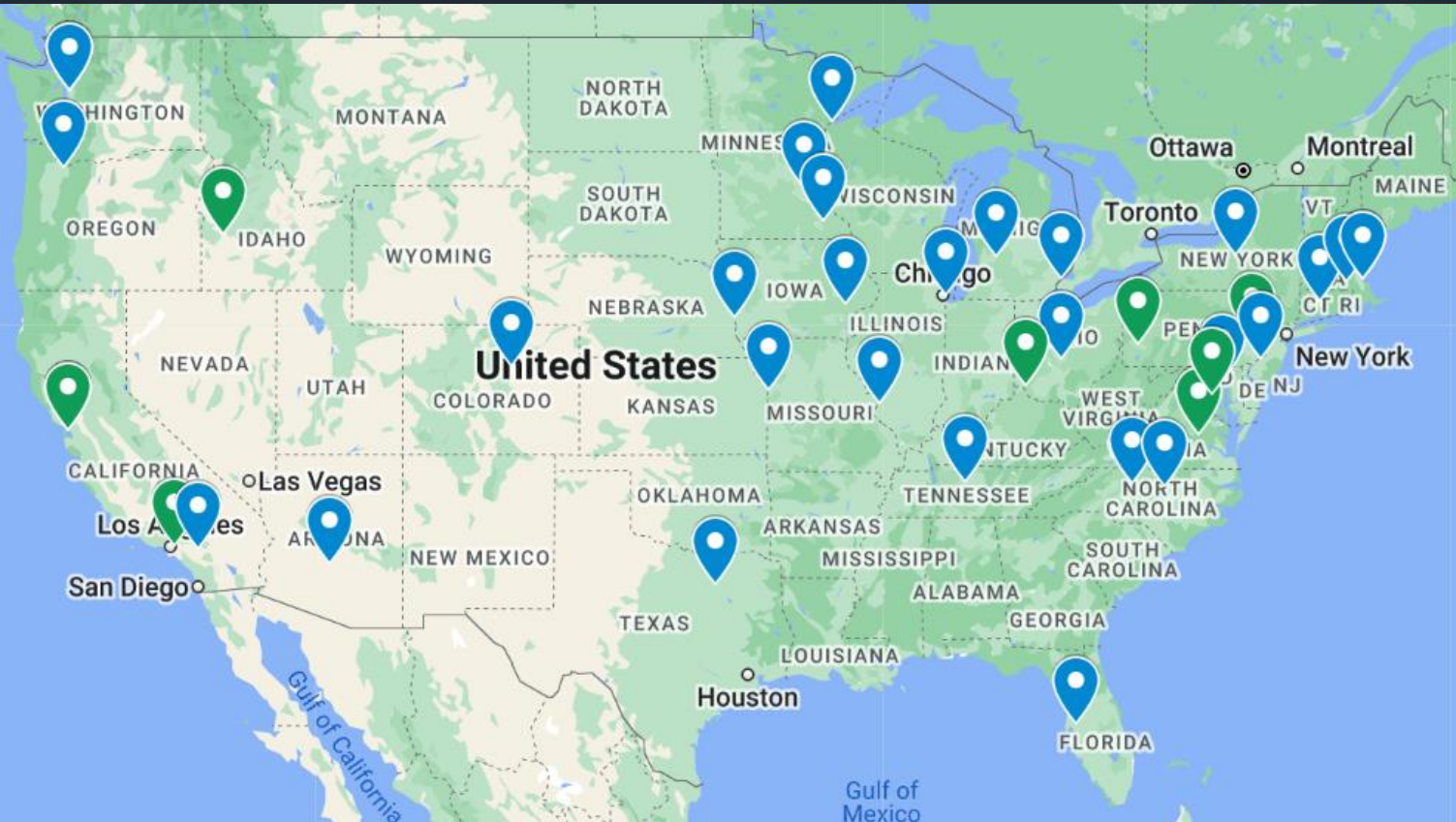
*Thank You*

**This breakthrough trial would not be possible without your participation**

Your **partnership** in research is what keeps us filled with passion, dedication, and the commitment to uncover new promising treatments for ALS

**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**

# 38 Sites Currently Activated for Regimen E



(as of 6/30/22)

*Sites in blue participated in previous regimens. Sites in green (underlined to the side) are new additions to the Platform Trial!*

- Lehigh Valley Health Network
- Mass General Hospital
- University of Kansas
- University of Maryland
- California Pacific Medical Center
- Northwestern University
- Virginia Commonwealth University
- University of Nebraska
- Washington University
- Wake Forest University
- Hospital for Special Care
- Saint Alphonsus Regional
- University of Massachusetts
- Duke University
- Barrow Neurological Institute
- Georgetown University
- Texas Neurology
- Beth Israel Deaconess Medical Center
- SUNY Upstate
- Spectrum Health
- Henry Ford Hospital
- Essentia Health
- University of Southern California
- University of South Florida
- University of Colorado
- Providence Brain and Spine
- University of Minnesota
- Loma Linda University
- University of Iowa
- Swedish Medical Center
- Ohio State University
- University of Cincinnati
- Thomas Jefferson University
- UC San Francisco
- Mayo Rochester
- University of Washington
- Vanderbilt University
- UPMC

Site Map & Contacts:



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



# Patient Navigation

## Central resource for people living with ALS



Catherine Small

Phone: 833-425-8257 (HALT ALS)

E-mail: [healeyalsplatform@mgh.harvard.edu](mailto:healeyalsplatform@mgh.harvard.edu)

Weekly webinar  
registration:



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

ALS Link sign-up:



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

### Upcoming Guest Speakers:

**July 7<sup>th</sup>**- James Berry, MD, MPH (Discussion about Biomarkers)

**July 14<sup>th</sup>**- Eufrosina Young, MD (Investigator at SUNY Upstate, New York)



Allison Bulat