



Echo & Louie Beasley



Inside this issue:

- Introduction
- Enrollment Updates
- Site Monthly Spotlight
- Enrollment Challenge
- Study Reminders
- Race to Activation
- Monthly Webinar details

Got Questions?

TMS Questions:

Urgent (during TMS procedure)

Call or text TMS hotline at:

(833) 337-2227

Monday – Friday 0800 – 2100h EST

Non-urgent TMS questions Email:

verify.study.tms@gmail.com

Enrollment Questions:

verifystudy@ucmail.uc.edu

Please include VERIFY Enrollment Question in the subject line!!!

Study Questions:

Project Manager: Kalli Beasley

beasleki@ucmail.uc.edu

Project Manager: Max Mays

maysmw@ucmail.uc.edu

Other Contacts:

MRI contact: Tyler Behymer

behymetp@ucmail.uc.edu

WebDCU contact: Natalia Hayes

hayesna@musc.edu

Hello VERIFY Team!

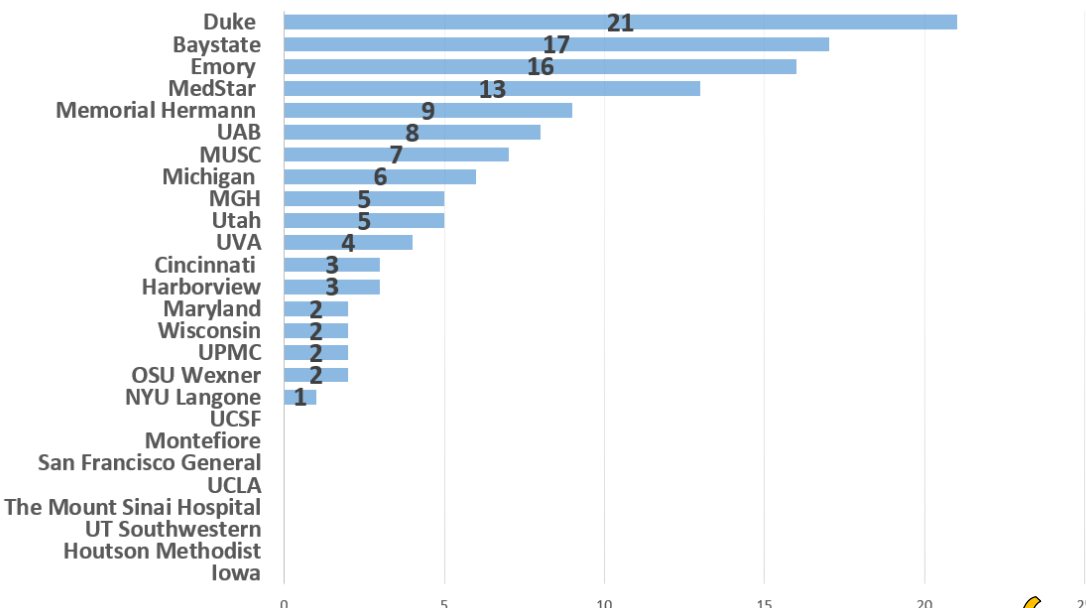
I am excited to move into my new role as the primary project manager for the VERIFY study!! Ever since my dad experienced a stroke in 2019, stroke clinical research has been something I am very passionate about. I hope to be a substantial resource to your team! I hope you all enjoy the pictures of my dogs above, Echo (6 yo Siberian Husky) and Louie (6m Bernedoodle).

- Kalli Beasley

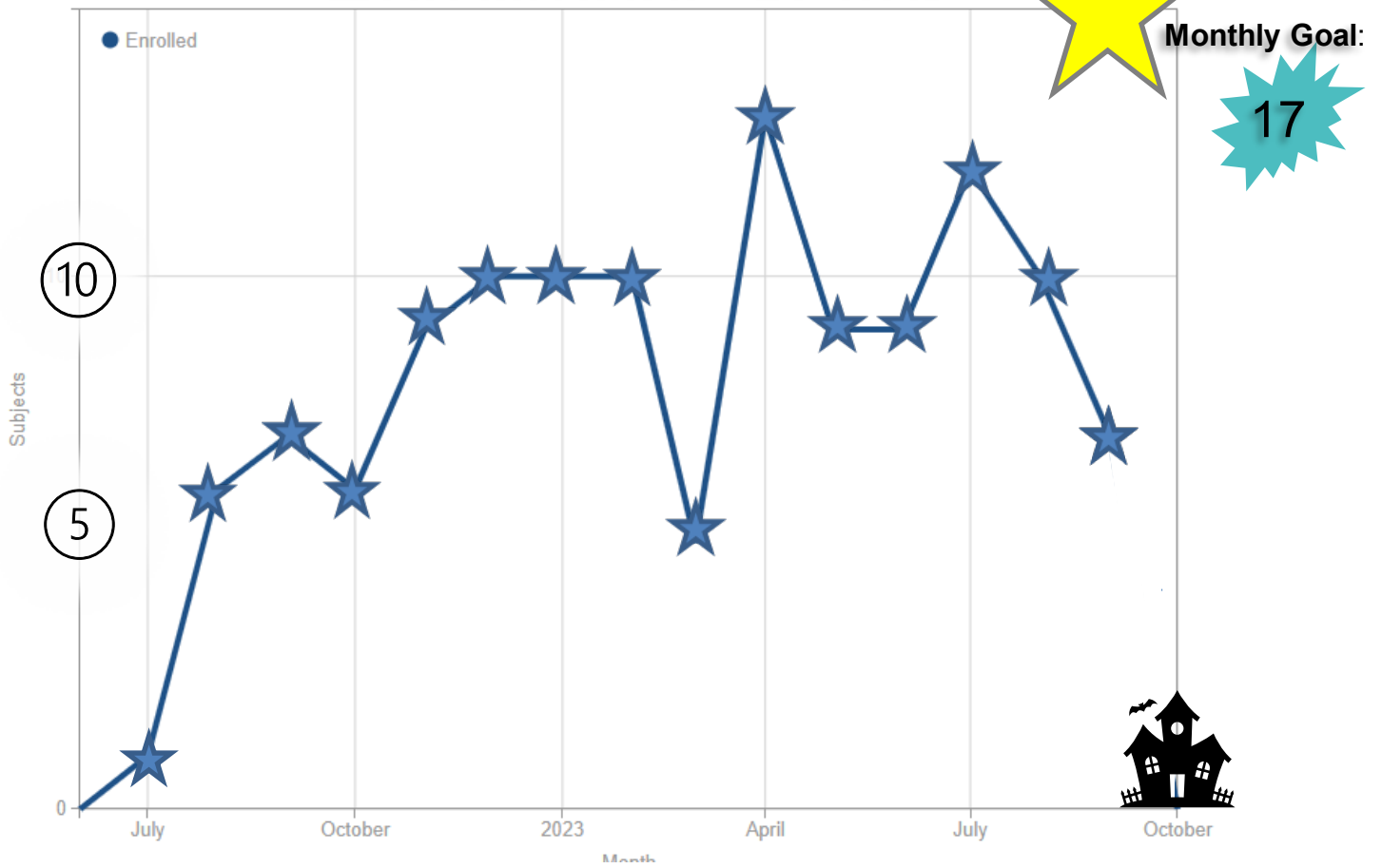


Enrollment Update

VERIFY TOTAL ENROLLMENTS: 126/657



Enrollment Status





Site Monthly Spotlight



September Achievements:

Top Enroller(s):

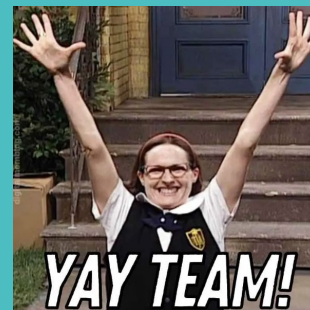
University of Alabama Hospital & Duke University Hospital

Top Pre-Screener:

Harborview Medical Center

Sites Activated:

University of Iowa



Enrollment CHALLENGE

1 enrollment per activated site by the end of October!!
(September 12th- October 31st)

Sites that complete the CHALLENGE
will receive VERIFY pins!!



You Can Do It!!!

Sites that have completed the CHALLENGE:

1. University of Alabama Hospital (2)
2. Duke University Hospital (2)
3. OSU Wexner Medical Center (1)
4. MedStar Washington Hospital Center (1)
5. UVA Medical Center (1)



Will your site be next?

Study Reminders



- **Have an enrollment question?**
 - Email: verifystudy@ucmail.uc.edu
 - ****Please include VERIFY Enrollment Question in the email subject line****
 - This will allow for the email to be automatically forwarded to study leadership and project managers

- **AE's are required to be reported until hospital discharge OR day 5 post TMS (if patient is still in the hospital).**
 - AE's are reported in the same location SAE's are in WebDCU
 - Examples of an AE include but are not limited too: petechial hemorrhages (captured by imaging), seizure, syncope and/or headaches (after TMS)

- **Remember-** if you are having trouble getting a patient back for the day 90-visit sites can offer a shortened in-person visit to obtain the FM and ARAT assessments!

- **Don't forget additional funds can be requested as needed to collect primary study data!**
 - This applies to baseline (MRI, TMS & FM) and day 90 visit (FM & ARAT)
 - Additional funds can be used for transportation costs such as but are not limited too: ambulance, medical transport, Uber/Taxi, additional milage (if cost exceeds \$40 that is already provided)
 - Must be approved prior by study team



Screening Tool - Pocket Cardsv3.0

- Pocket Cards are a useful tool that can help provide quick reminders of important study-specific information.
- Recommend that sites have a jpeg/picture of the pocket cards available on their phones.
- The most up-to-date pocket cards can be found in the **Toolbox tab** of WebDCU.

VERIFY Validation of Early Prognostic Data for Recovery Outcomes after Stroke for Future, Higher Yield Trials: A Biomarker Validation Study

Study Objective:

- To assess the most promising biomarkers of motor recovery after stroke
 - Validate in 557 ischemic stroke patients
 - Explore in 100 intracerebral hemorrhage patients
 - Outcomes (90-Day)
- Primary Outcome:
 - Fugl-Meyer (FM) scale
 - Action Research Arm Test (ARAT)
- Exploratory Outcome:
 - Motor Activity Log (MAL)
 - modified Rankin Scale (mRS)

Inclusion Criteria:

1. Age 18 years or older
2. Unilateral symptomatic stroke due to ischemia or intracerebral hemorrhage (Note: Bilateral acute stroke is permitted if the stroke that is contralateral to the index stroke is asymptomatic).
3. Motor deficits in the acutely affected UE, defined as a Shoulder Abduction and Finger Extension (SAFE) score ≤ 8 out of 10 points (i.e., excluding full or nearly full motor strength in both shoulder abduction and finger extension) within 48 to 96 hours of stroke onset (or time last known well).
 - a) SAFE score is determined by measuring the strength of shoulder abduction and finger extension, separately, each having a Medical Research Council grade from 0 to 5, then summing; scores range from 0 to 10.
4. Provision of signed and dated informed consent form within 48 to 96 hours of stroke onset, (or time last known well). Note: Participant is considered enrolled upon starting TMS (at least one stimulation is delivered) or starting study-specific MRI pulse sequence (at least one MRI beep occurs)
5. Stated willingness to comply with all study procedures and availability for the duration of the study, including Day 90 visit which must occur in-person.
6. Fluent in English or Spanish



Race to Activation

Site Name	CIRB Approved	DOA Approved	Investigator agreement form's uploaded	TMS Shipping Address entered	TMS Machine obtained	At least 1 TMSO online training Completed	Greenlight ed to start TMS HV Training	Uploaded TMS HV data to RedCAP	TMS HV Training Completed for at least 1 TMSO	TMS Technique Check	MRI Phantom Approved	All WebDCU Documents uploaded	Site Activation Meeting Completed	Site Activated
University of Iowa Hospitals & Clinics														
Lahey Hospital & Medical Center														
Prisma Health Richland Hospital														
Penn State Hershey Medical Center														
Pennsylvania Hospital														
Froedtert & Medical College of Wisconsin														
Corewell Health Butterworth Hospital														
Strong Memorial Hospital						0								

Is your site stuck?

Need Help Advancing in the Race to Activation?

- Virtual TMS Healthy Volunteer 1:1 sessions are being scheduled now!
Contact Harry Jordan to schedule your session:
h.jordan@auckland.ac.nz
- Having issues getting an MRI Phantom? We can help with that!
Contact Tyler Behymer to schedule a call or meeting:
behymetp@ucmail.uc.edu
- Have any other study related questions or issues?
Contact the Project Managers Kalli Beasley and Max Mays!!
beasleki@ucmail.uc.edu ; maysmw@ucmail.uc.edu

You got this!

Webinar Information

- PI/CRC webinars occur on the 3rd Monday of each month, 4pm-5pm EDT.
Next PI/CRC webinar is on 10.16.2023.
 - <https://ucincinnati.zoom.us/j/92919997979?pwd=UEMrY2ZTTXgzWJVTnBoQXR2ZIB2UT09>
 - Meeting ID: 929 1999 7979 Passcode: 708995
- CRC webinars occur on the 4th Tuesday of each month, 12pm-1pm EDT.
Next CRC webinar is on 10.24.2023
 - <https://ucincinnati.zoom.us/j/95231335017?pwd=T01mZUZaek01Vnh1anFPV3hiSVMzZz09>
 - Meeting ID: 952 3133 5017 Passcode: 398747

