

The VERIFY STUDY

Validation of Early Prognostic Data for Recovery
Outcome after Stroke for Future, Higher Yield Trials

Newsletter April 2023 Issue 16



"We continue to have strong enrollment! It is important to remember that Day 90 visit is required in-person, so that our primary endpoint data can be collected. Ensuring that the contact information form is fully completed before the participant is discharged, is one way to help ensure the participant returns for in-person Day 90 visit".

Achala Vagal, MD, MS

Sites Released to Enroll

- University of Cincinnati Medical Center
- MedStar Washington Hospital Center
- Emory University
- UT-Memorial Hermann Texas Medical Center
- University of Michigan
- Medical University of South Carolina (MUSC)
- The University of Utah
- Baystate Medical Center
- UVA Medical Center
- Duke University Hospital
- Massachusetts General Hospital
- University of Maryland Medical Center
- UPMC Presbyterian Hospital
- University of Alabama
- UCSF Medical Center
- University of Wisconsin
- NYU Langone Medical Center



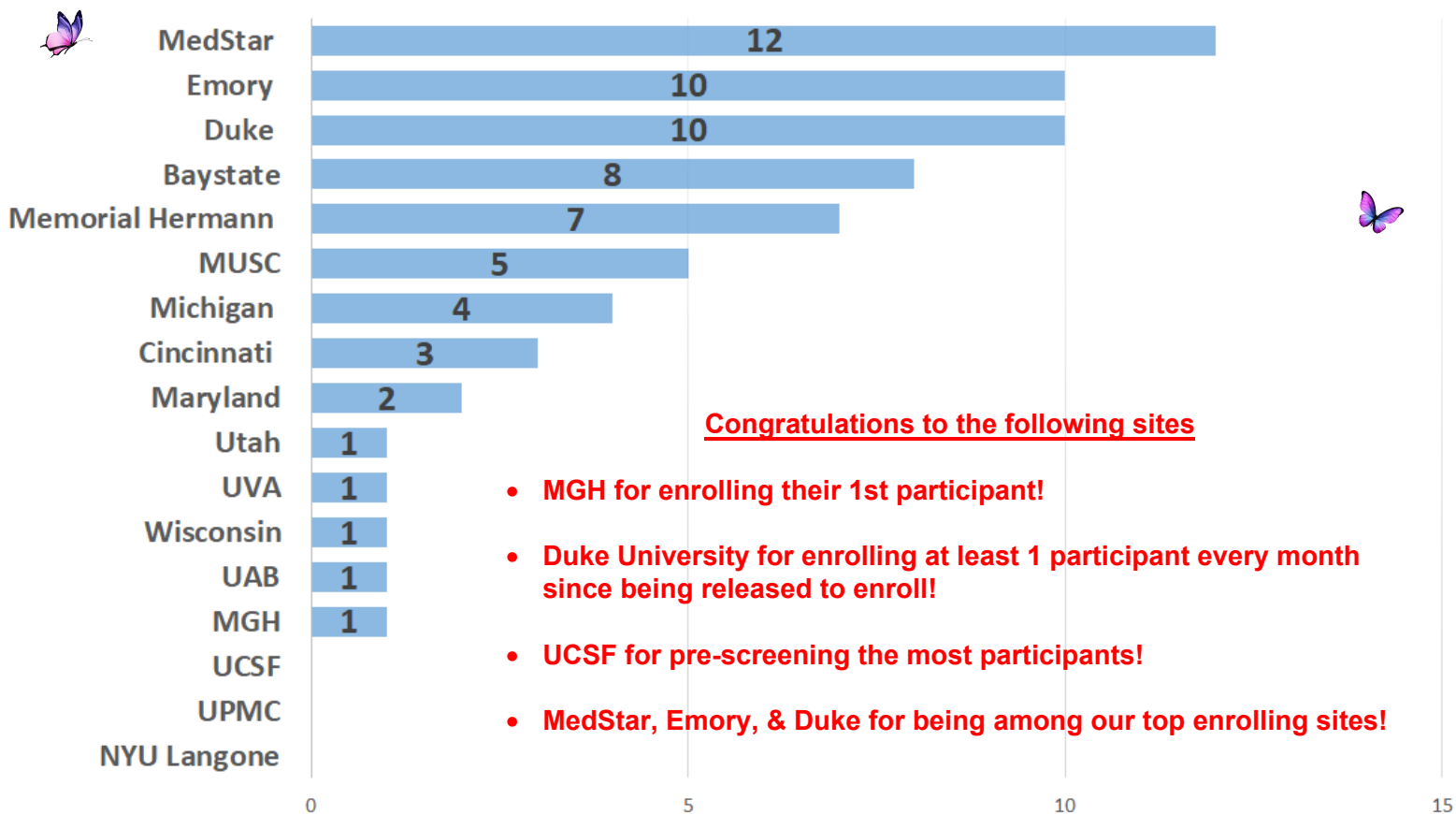
Protocol Amendment v1.6

Key Updates

- **Updated inclusion criterion #2:** Some bilateral stroke is permitted. The new wording is as follows: "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)".
- **Updated inclusion criterion #5:** Potential participants should be recruited/consented only if they are able to complete Day 90 visit in-person. The new wording is as follows: "Stated willingness to comply with all VERIFY procedures and availability for the duration of VERIFY, including Day 90 visit which must occur in-person".
 - Day 90 visit is required in-person to collect our primary endpoints
 - If not feasible to do in-person, despite full attempts, then some assessments can be completed remotely. Information for which assessments can be completed remotely is noted in protocol amendment v1.6, which is available in the Toolbox tab of WebDCU.
 - Since unable to collect primary endpoint data, then remote Day 90 visits are considered a minor protocol deviation, which is not reportable to the cIRB. However, minor protocol deviations can add up to major protocol deviations.
- **Added exclusion criterion #6:** Symptomatic stroke in any location within 30 days prior to index stroke.

Enrollment Updates

VERIFY TOTAL ENROLLMENTS: 66/657



Congratulations to the following sites

- MGH for enrolling their 1st participant!
- Duke University for enrolling at least 1 participant every month since being released to enroll!
- UCSF for pre-screening the most participants!
- MedStar, Emory, & Duke for being among our top enrolling sites!

New enrollments since last newsletter

- Duke University, +2
 - PI- **Dr. Feng**, PSC- **Tato Sokhadze**
- MedStar, +1
 - PI- **Dr. Edwardson**, PSC- **Jamal Smith**
- University of Michigan, +1
 - PI- **Dr. Krishnan**, PSC- **Shannen Bolde**
- University of Cincinnati, +1
 - PI- **Dr. Boyne**, PSC- **Erin Wagner**
- Massachusetts General Hospital, +1
 - PI- **Dr. Lin**, PSC- **Julie DiCarlo**



TMS Reminders



Enrolled Participants

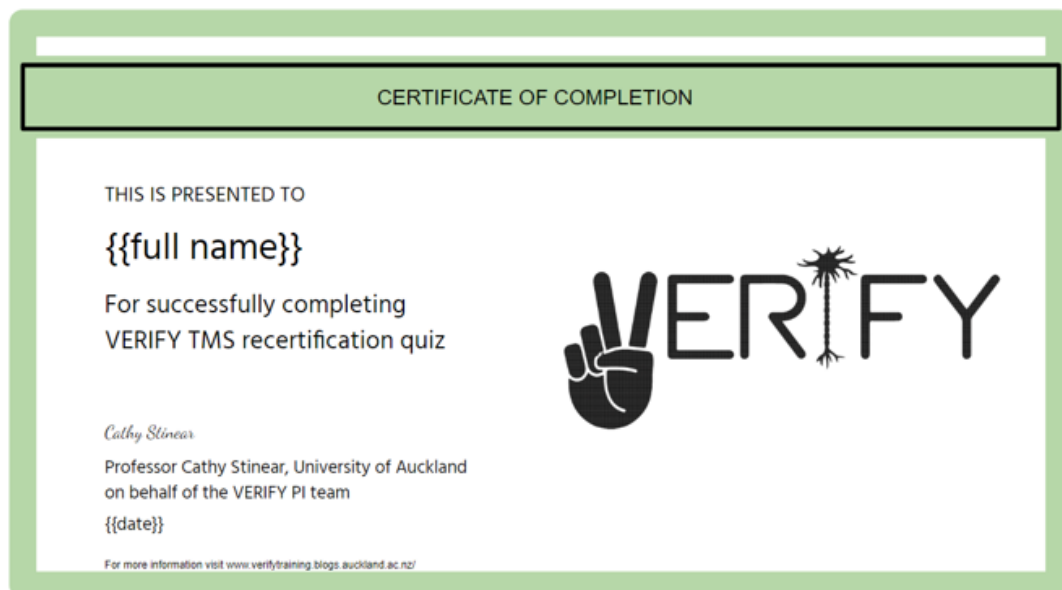
- Patient's asking to stop TMS before you can determine MEP status has led to undetermined MEP statuses for VERIFY patients. Tips for performing TMS with patients at high intensity can be found at:
 - <https://verifytraining.blogs.auckland.ac.nz/tms-stroke-patients/>
- To classify a patient as MEP- you need to check that no MEPs can be elicited while attempting all of the following **together**:
 - Increasing stimulator intensity to 100% MSO, **and**
 - Systematic movement of the coil to search for the optimal stimulation location, **and**
 - Participant performing bilateral facilitation
- If **any** of these are not performed then a patient cannot be called MEP- and they will have an **undetermined and unusable MEP status** which means they **can't be included in the primary study analysis**.



TMS Operator Recertification Training



- Retraining is required annually.
- Consists of a single short quiz.
- Once the retraining is completed, the certificate should be uploaded into WebDCU under the TMS training placeholder/ section.
- Certificate expiration date is 1 year from the time you complete the training.
- The recertification training is accessible through the TMS website
 - <https://verifytraining.blogs.auckland.ac.nz/>



Lost to Follow-Up



Ensure the contact information form is fully completed before the participant is discharged from the hospital.

- Record at least 2 additional people who can help reach the participant.
- Confirm with the participant how they like to be contacted:
 - Phone, Text, Email
- Confirm what time of day they prefer to be contacted
 - Morning, Afternoon, Evening



Schedule Day 90 visit with participant before they are discharged.



- In-home visits is an option if your institution allows (gas mileage is reimbursed).
- Transportation to a clinic visit from rehab/nursing facility is also an option (study will pay invoice for transportation cost).
- Write the time/date in their rehab diary or help the participant put the time/date on their calendar.

You might see whether a standard of care (SOC) clinic visit can be scheduled in the same timeframe as Day 90

- Can plan to complete Day 90 before or after SOC visit to help reduce burden on participant, if preferred.



Lost to Follow-Up: Documentation

- Sites should attempt to contact the subject 3 different times by phone, email or text.
- These times/dates should be documented in the electronic medical record (EMR) or subject binder.
- If the subject is unable to be contacted to schedule/complete day 30 or 90 visit, then the site should send a certified letter to the subject.

*****Follow-up/certified letter template has been CIRB approved and is available in the Toolbox tab of WebDCU.*****





Webinars

- PI/CRC webinars occur on the 3rd Monday of each month, 4pm-5pm EDT. **Next PI/CRC webinar is on 04.17.2023.**
 - <https://ucincinnati.zoom.us/j/96525424408> Meeting ID: 965 2542 4408
- CRC webinars occur on the 4th Tuesday of each month, 12pm-1pm EDT. **Next CRC webinar is on 04.25.2023**
 - <https://ucincinnati.zoom.us/j/93360687517> Meeting ID: 933 6068 7517



Study Contact Information

CIRB- Regulatory contacts:

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CTA contact:

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 Sasha Simms simmssc@ucmail.uc.edu 513.558.3924

All other study questions:

Lisa Mundo mundokl@ucmail.uc.edu



Race to Activation Tracker

Site Name	CTA Executed	CIRB Approved	DOA Approved	Investigator agreement form's uploaded	TMS Shipping Address entered	TMS Machine obtained	At least 1 TMSO online training Completed	Greenlighted 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
Harborview Medical Center															
Montefiore Medical Center															
Ronald Reagan UCLA Medical Center															
San Francisco General Hospital															
University of Texas Southwestern Medical Center															
Houston Methodist Hospital															
Lahey Hospital & Medical Center															
OSU Wexner Medical Center															
Mount Sinai Hospital															
Pennsylvania Hospital															
Prisma Health Richland Hospital															
Penn State Hershey Medical Center															
Froedtert & Medical College of Wisconsin															
University of Iowa Hospitals & Clinics															
University of Rochester Strong Memorial Hospital															
Corewell Health Butterworth Hospital															

