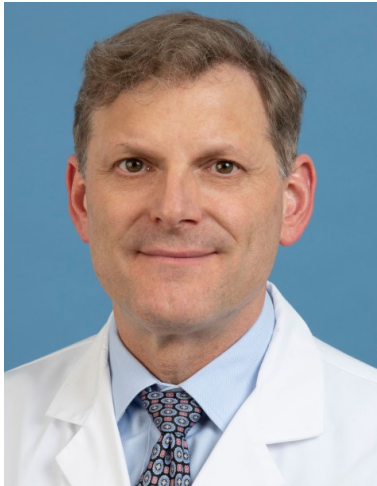# The VERIFY STUDY

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

Newsletter February 2023 Issue 14

Enrollments continue at a steady pace, with VERIFY now up to 17 sites. We are grateful for everyone's contributions as we try to establish valid biomarkers of stroke recovery. Thank you everyone!

-Steve Cramer, MD, MMSc

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*

* Indicates site activated since last newsletter
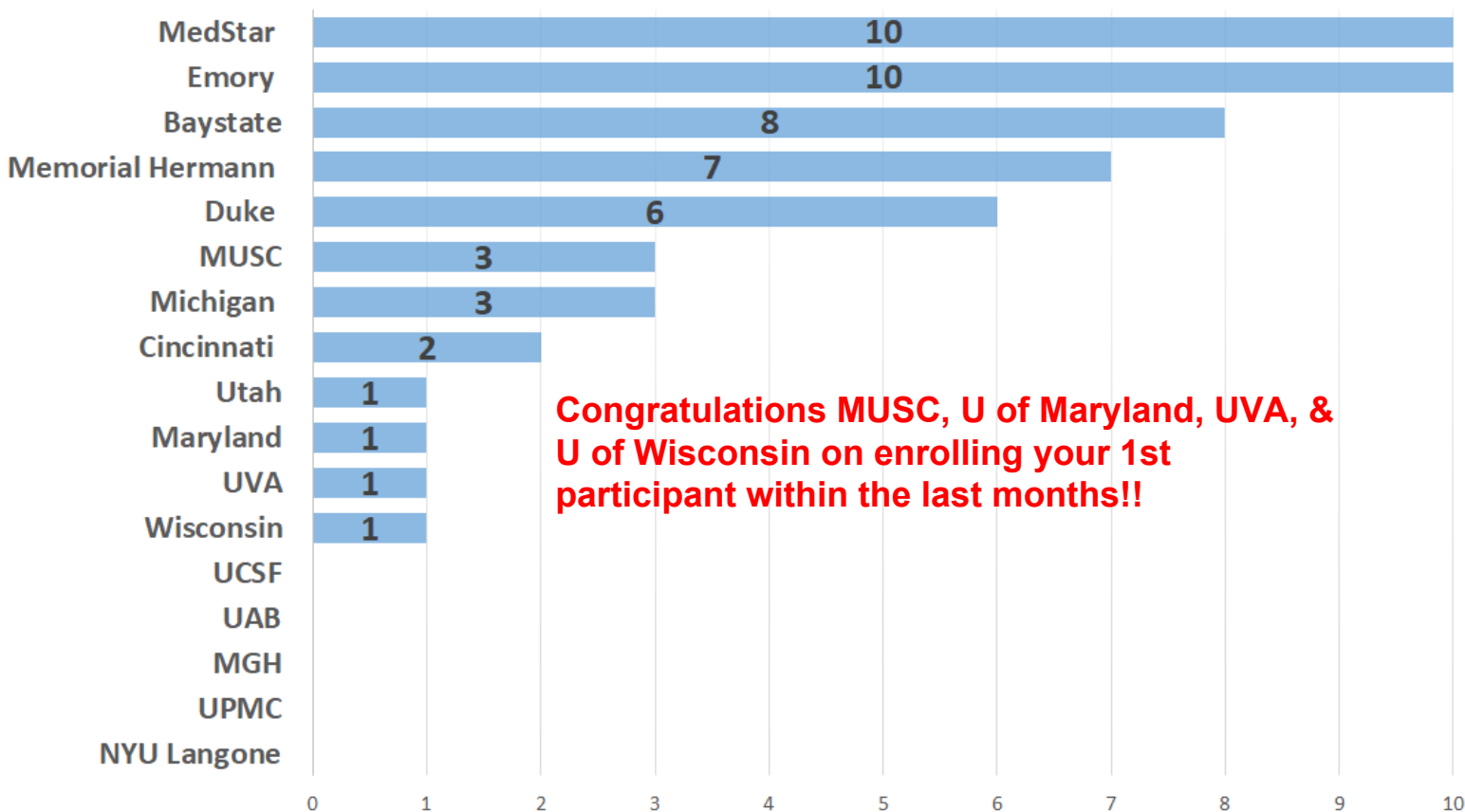
FEBRUARY

Study Reminders

- The FM & ARAT assessors and the patient/families should be blinded to the TMS MEP status.
  - The FM & ARAT assessors should <u>NOT</u> enter the TMS data into WebDCU, it will unblind them.

- Sites need to ensure phantom scans are completed every <u>6 months,</u> otherwise there is a risk of having unusable MRI scans from participants. Contact Tyler Behymer with any questions at behymetp@ucmail.uc.edu

- All sites using RedCAP eConsent should ensure that all consenters have completed the following training:
  - https://redcap.link/StrokeNet_eConsent_Training
  - In addition, the VERIFY specific RedCAP eConsent Guide is available in the WebDCU toolbox tab.

- The protocol training slides have been updated to reflect current study processes & the approved protocol v1.5.
  - These slides are accessible in the toolbox tab of WebDCU and on the DCU campus training website (https://dcu.musc.edu/campus/)
  - Please note: The protocol training slides will be updated again, once protocol amendment v1.6 is approved by the central IRB.

Enrollment Updates

VERIFY TOTAL ENROLLMENTS: 53/657

Site	Enrollments
MedStar	10
Emory	10
Baystate	8
Memorial Hermann	7
Duke	6
MUSC	3
Michigan	3
Cincinnati	2
Utah	1
Maryland	1
UVA	1
Wisconsin	1
UCSF	
UAB	
MGH	
UPMC	
NYU Langone	

Congratulations MUSC, U of Maryland, UVA, & U of Wisconsin on enrolling your 1st participant within the last months!!

New enrollments since last newsletter

- MUSC, +3
  - PI- Dr. Heise, PSC- Valerie Salisbury

- Emory, +3
  - PI- Dr. Borich, PSC- Susan Murphy

- Michigan, +1
  - PI- Dr. Krishnan, PSC- Shannen Bolde

- Memorial Hermann, +1
  - PI- Dr. Savitz, PSC- Emily Stevens

- Baystate +1
  - PI- Dr. Schlaug, PSC- Sirisha Nouduri

- University of Maryland, +1
  - PI- Dr. Braun, PSC- Bisola Amodu

- UVA Medical Center, +1
  - PI- Dr. Aldridge, PSC- Miah Perch

- University of Wisconsin, +1
  - PI- Dr. Ahmed, PSC- Sima Sayyahmelli

- MedStar, +1
  - PI- Dr. Edwardson, PSC- Jamal Smith

TMS Reminders

- Study coordinators should remind their TMS operators to use the <u>comments section</u> on the TMS source documentation if the TMS procedure did not go as planned. This will inform the TMS team that the site understood what they did during the TMS procedure (especially if there were issues with the data).

- TMS operators should <u>NOT</u> use their clinical judgment to determine MEP status. Please just follow the protocol.

- Both channels need to be negative to determine whether a participant is MEP negative.

- Any site staff completing the TMS safety checklist with participants <u>NEED</u> to have previously completed the TMS safety checklist online training module.
    - The TMS safety checklist training is located here: https://verifytraining.blogs.auckland.ac.nz/tms-safety-checklist/

- Sites can proactively schedule a time for themselves to enter the TMS data into WebDCU within 24 hours after the procedure. This will help ensure that the data is entered on time.

Webinars

- PI/CRC webinars occur on the 3rd Monday of each month, 4pm-5pm EDT. **Next PI/CRC webinar is on 02.27.2023.**
    - 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 02.28.2023**
    - https://ucincinnati.zoom.us/j/93360687517   Meeting ID: 933 6068 7517

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
Montefiore Medical Center													🚗		
San Francisco General Hospital											▩	🚗			
Harborview Medical Center											🚗				
University of Texas Southwestern Medical Center											🚗				
Ronald Reagan UCLA Medical Center										🚗					
Lahey Hospital & Medical Center										🚗					
Houston Methodist Hospital										🚗					
OSU Wexner Medical Center									🚗	▩					
Pennsylvania Hospital									🚗						
Mount Sinai Hospital						🚗									
University of Iowa Hospitals & Clinics		🚗									▩				
Prisma Health Richland Hospital		🚗			▩		0								
Penn State Hershey Medical Center	🚗						0								
University of Rochester	🚗						0								
Froedtert & Medical College of Wisconsin	🚗						0								