The VERIFY STUDY

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

Newsletter August 2023 Issue 20

"The PIs wanted to highlight a fun fact about ourselves. I am a Bollywood singer and am part of a music band for the past 15 years!

I want to sing about the fact that we are seeing improvement in obtaining our primary data and want to thank everyone for working hard to ensure these measures are obtained. Please continue to do your best to collect this data and feel free to reach out to us with any questions."

- Achala Vagal, MD, MS

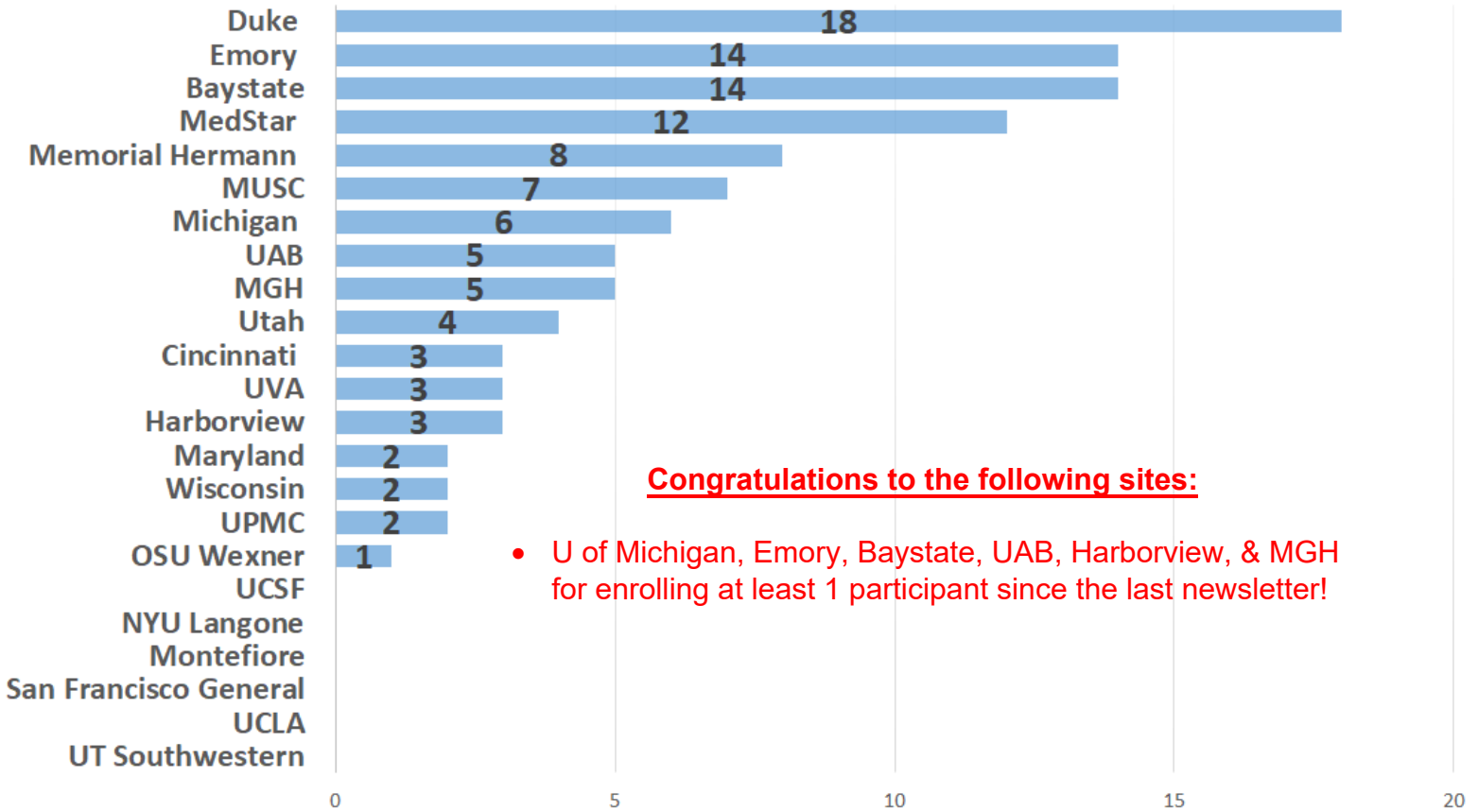**109**

Total Subjects Enrolled!!!

August

New enrollments since last newsletter

- U of Michigan +1
  - PI- **Dr. Krishnan** PSC- **Shannen Bolde**

- Emory, +1
  - PI- **Dr. Borich**, PSC- **Susan Murphy**

- Baystate, +2
  - PI- **Dr. Schlaug,** PSC- **Sirisha Nouduri**

- UAB, +2
  - PI- **Dr. Gropen**, PSC- **Tammy Davis**

- Harborview, +1
  - PI- **Dr. Mazwi**, PSC- **Mary Grace Asirot**

- MGH, +1
  - PI- **Dr. Lin,** PSC- **Julie DiCarlo**

CLAP CLAP

Enrollment Graphs

VERIFY TOTAL ENROLLMENTS: 109/657

Site	Enrollment
Duke	18
Emory	14
Baystate	14
MedStar	12
Memorial Hermann	8
MUSC	7
Michigan	6
UAB	5
MGH	5
Utah	4
Cincinnati	3
UVA	3
Harborview	3
Maryland	2
Wisconsin	2
UPMC	2
OSU Wexner	1
UCSF	
NYU Langone	
Montefiore	
San Francisco General	
UCLA	
UT Southwestern	

Congratulations to the following sites:

- U of Michigan, Emory, Baystate, UAB, Harborview, & MGH for enrolling at least 1 participant since the last newsletter!

Report: **Cumulative Enrolled by Month**

Legend: Target, Enrolled

(Graph: Subjects vs Month, 2023–2026)

WebDCU- Site Regulatory Reminders

- Please remember to obtain **expired** or **soon to be expired** training certificates from site personnel. These updated training certificates should be uploaded into WebDCU under the **People Document section.**

  - If there is a lapse in training between expired and updated training certificates, then a **note-to-file (NTF)** explaining that the site staff did not perform assessment while their training certificate was expired should be uploaded with the updated training certificate.

It is the site's responsibility to ensure that all site staff are up-to-date with training

People Documents

Action Research Arm Test (ARAT) Certification

Expired training

Current | Expired | Waived | Missing

WebDCU- Issues Table

For studies using Advarra as the cIRB, the **Issues Table** was created in WebDCU to report the following:

- Protocol Deviations, Violations, or Exceptions.
- Unanticipated Problems.
- Non-Compliance of cIRB Requirements
  - Serious or Continuing Non-Compliance
- Audit findings at your site.

When entering an event into the Issues Table, please use the following format:

- Describe the issue
- Describe how the issue was resolved or managed.
- Describe corrective measures or preventative actions that were put into place to minimize/ prevent the event from occurring again in the future.

Reminder: Staff Roles at Each Clinical Site

PREMISES FOR STUDY STAFFING:

1. Strongly preferred that FM and ARAT are performed by PT/OT
2. The study requires that FM at Study Visit 2 & 6 are performed by same person
3. Neither TMS operator nor TMS assistant should do 90-day FM or ARAT
4. Site PIs may not have daily availability at many sites
5. Individual variations to recommended model may be needed

STAFF MEMBERS TO BE TRAINED AND CERTIFIED AT SITES:
1. Site PI
2. 1° SC
3. 1° PT/OT
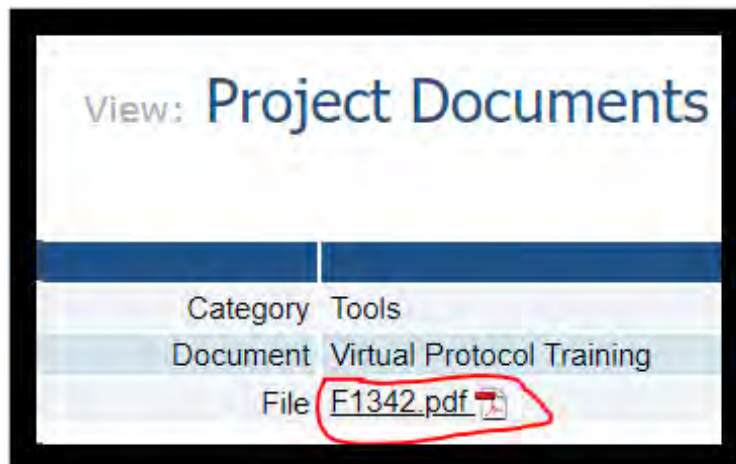4. At least one additional staff member(s) and more encouraged
   - 2° SC or 2° PT/OT

Please Train **2 People** for Each Sets of Trainings:
(1) TMS Operator (2) ARAT+FM, & (3) Other Behavioral Assessments

RECOMMENDED VERIFY SITE TEAM MODEL

| | Visit 1: Screening/Consent | Visit 2 & 3 (Inpatient) | | | | Visit 4: Post-TMS Hospital Assessment (DC Day or D5 Post-TMS, whichever is Sooner) | Visit 5: Post-hospitalization Phone Follow Up (30d) | Visit 6 (90d) (Outpatient) | |
		Baseline Clinical Assessments and MRI Facilitation (except FM)	FM	TMS Operator (TMS-trained)	TMS Assistant (no training)			FM and ARAT	Rest of Behavioral Assessments
1° SC	X	X		X		X	X		X
1° PT/OT			X					X	
2° SC or 2° PT/OT					X				
Site PI	Supervisory, may serve PT/OT or TMS role in some sites, or be available for backup in other sites								

Virtual Protocol Training Slides

- Reminder: The **virtual protocol training** slides are available in the Toolbox tab in WebDCU.

  - Information regarding study related trainings & how to access these trainings are located in this slide deck.
  - This slide deck can be a helpful tool when onboarding new study team members at your site.

View: **Project Documents**

Category	Tools
Document	Virtual Protocol Training
File	F1342.pdf

Missing Primary Data

Data as of 07Aug2023

- Of 73 patients who have reached 90 days post stroke onset
    - 29 (39.7%) have incomplete primary data
    - Either/both unusable or unobtained:
        - Biomarker - MEP status or MRI lesion 3D-T1 (n=13)
        - Primary outcomes - 90d FM/ARAT data (n=19)

The study was designed to tolerate **no more than 20%** missing primary data.

> o **Need to see improvement in obtaining primary data. We greatly appreciate your assistance in addressing issues that are under your control!**

Data MISSING?

Actions to Address Missing Primary Data

- **90-Day FM/ARAT**
  - ✓ Emphasize 90-day in-person visit for eligibility
  - ✓ Schedule 90d visit before DC
  - ✓ Coordinate 90d visit with SOC visits
  - ✓ Troubleshoot transportation
    - ❑ **Remember study willing to pay more than $40 for travel for participant or study team if necessary**
  - ✓ Keep in touch after DC
  - ✓ Collect alternate contacts for LTFU
  - ✓ Text/email/call them, at least 3 attempts
  - ✓ Remind of payment for their time
  - ✓ Check EMR and case worker if can't find them
  - ✓ Offer minimal visit for just FM/ARAT if resisting
  - ✓ Certified letter

- **RECAP of TMS Tips**
  - ✓ Maximize pt comfort and tolerability
  - ✓ Remember to do bilateral facilitation
  - ✓ Repeat TMS if needed

- **RECAP of MRI Tips**
  - ✓ Schedule early
  - ✓ Discuss with MRI tech
  - ✓ Remind clinical team of importance of this study

Webinars

- PI/CRC webinars occur on the 3rd Monday of each month, 4pm-5pm EDT. **Next PI/CRC webinar is on 08.21.2023.**

  - https://ucincinnati.zoom.us/j/99087999343   Meeting ID: 990 8799 9343

- CRC webinars occur on the 4th Tuesday of each month, 12pm-1pm EDT. **Next CRC webinar is on 08.29.2023**

  - https://ucincinnati.zoom.us/j/92697809888   Meeting ID: 926 9780 9888

Study Contact Information

CIRB- Regulatory contacts:
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CTA contact:
Aimee Nance   nanceae@ucmail.uc.edu   513.558.6566
Sasha Simms   simmssc@ucmail.uc.edu   513.558.3924

All other study questions:
Lisa Mundo, Prime PM   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
Houston Methodist Hospital													(car)		
Mount Sinai Hospital												(car)			
Lahey Hospital & Medical Center										(car)					
Prisma Health Richland Hospital				(black)						(car)					
Pennsylvania Hospital									(car)						
Penn State Hershey Medical Center									(car)						
University of Iowa Hospitals & Clinics						(car)						(black)			
Froedtert & Medical College of Wisconsin						(car)									
Corewell Heath Butterworth Hospital						(car)									
University of Rochester Strong Memorial Hospital	(car)						0								