VERIFY

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

Newsletter July 2024 Issue 30

HELLO July

Inside this issue:

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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
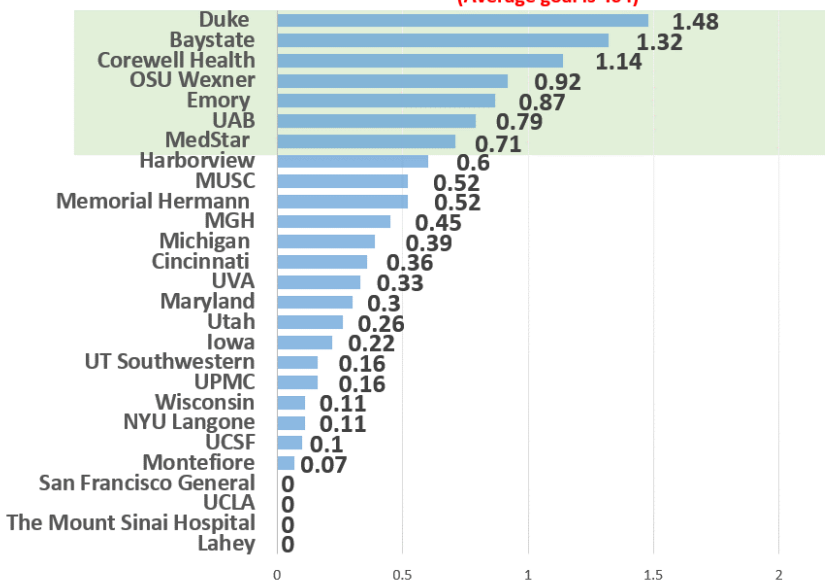Project Manager: Max Mays
maysmw@ucmail.uc.edu

Other Contacts:
ARAT/FM/RFA: Natalie Olivares
cramerlab@mednet.ucla.edu
MRI contact: Tyler Behymer
behymetp@ucmail.uc.edu
WebDCU contact: Natalia Hayes
hayesna@musc.edu

"I am honored to be a part of this fantastic team and contribute to this important study. Thank you to all of the assessors- keep using those stopwatches!"
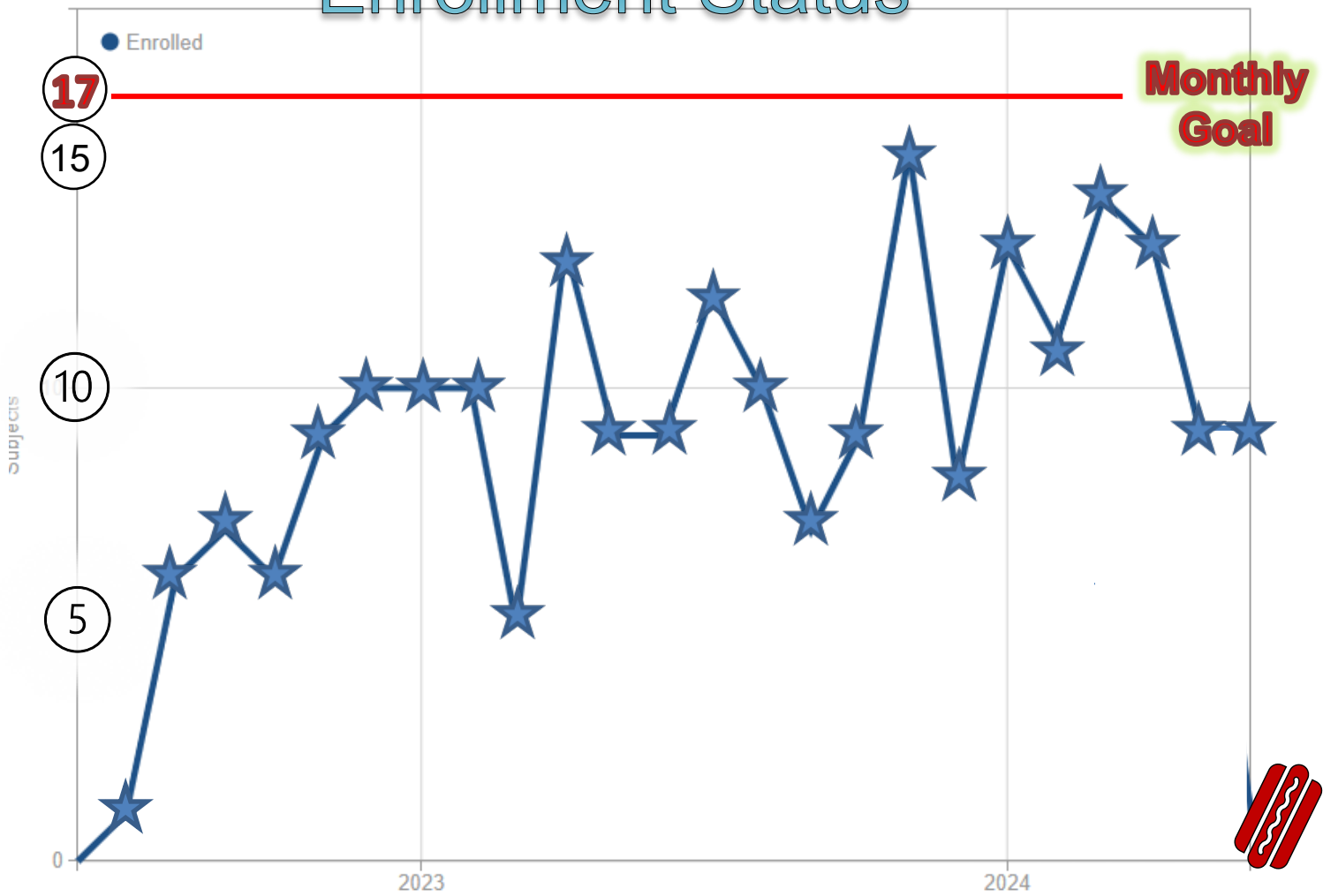
- Jessica Cassidy, PT, DPT, PhD
VERIFY SAFE/ARAT/FM data quality consultant

Enrollment Update

VERIFY SITE ENROLLMENT AVERAGE PER MONTH:
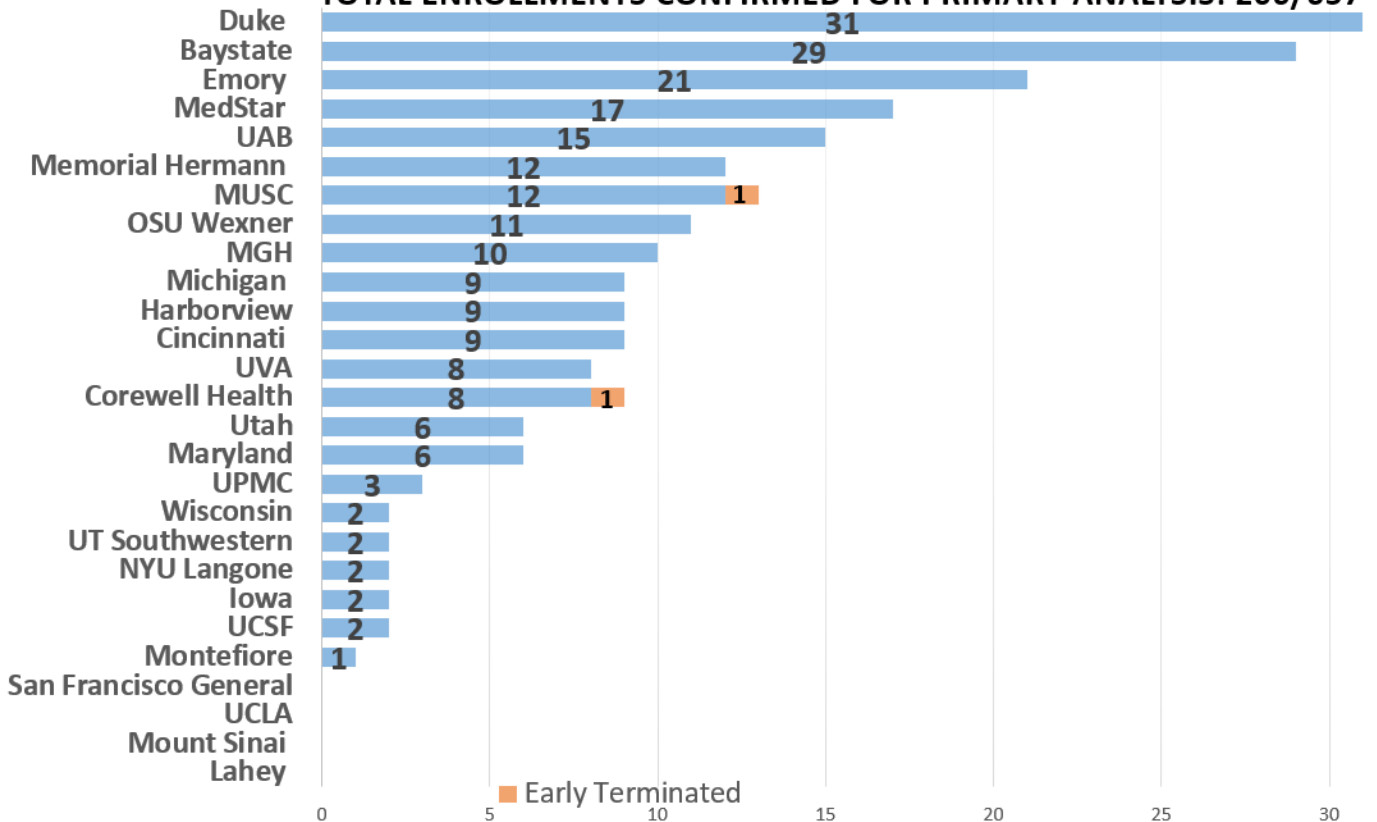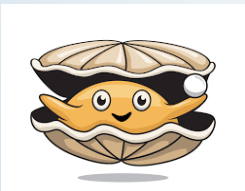(Average goal is .64)

Site	Average
Duke	1.48
Baystate	1.32
Corewell Health	1.14
OSU Wexner	0.92
Emory	0.87
UAB	0.79
MedStar	0.71
Harborview	0.6
MUSC	0.52
Memorial Hermann	0.52
MGH	0.45
Michigan	0.39
Cincinnati	0.36
UVA	0.33
Maryland	0.3
Utah	0.26
Iowa	0.22
UT Southwestern	0.16
UPMC	0.16
Wisconsin	0.11
NYU Langone	0.11
UCSF	0.1
Montefiore	0.07
San Francisco General	0
UCLA	0
The Mount Sinai Hospital	0
Lahey	0

Enrollment Status

Enrolled

17 — Monthly Goal

VERIFY TOTAL ENROLLMENTS: 227
TOTAL ENROLLMENTS CONFIRMED FOR PRIMARY ANALYSIS: 206/657

Site	Enrolled	Early Terminated
Duke	31	
Baystate	29	
Emory	21	
MedStar	17	
UAB	15	
Memorial Hermann	12	
MUSC	12	1
OSU Wexner	11	
MGH	10	
Michigan	9	
Harborview	9	
Cincinnati	9	
UVA	8	
Corewell Health	8	1
Utah	6	
Maryland	6	
UPMC	3	
Wisconsin	2	
UT Southwestern	2	
NYU Langone	2	
Iowa	2	
UCSF	2	
Montefiore	1	
San Francisco General		
UCLA		
Mount Sinai		
Lahey		

Early Terminated

Pearls of WISDOM
Advice and Suggestions

The MEP status determination for patients in WebDCU is final and should never be changed once entered

A Participant is considered "enrolled" only in the data collection system (WebDCU) **after** starting TMS (at least one stimulation is delivered) **OR** starting study-specific MRI pulse sequence (at least one MRI beep occurs). For sites that have the study-specific MRI sequence (3D-T1) as part of their SOC MRI, adding a "new subject" in the data collection system is based on starting TMS alone.

Regarding the Length of the Fugl-Meyer Scale (FMS) Recertification Training

For first time certification: participants must complete the Training module prior to accessing the Certification activities. VERIFY study personnel are assigned the FMS-ARMS Training Program activity, which can be accessed an unlimited number of times. The subsequent Certification activity contains 2 separate modules, each containing a patient case. The first module must be successfully completed to access the second module. Then the second module must also be successfully completed. Upon successful completion of the 2nd module, the participant receives an electronic certificate. The Certification and the Training Program can be accessed by the trainee (the GDPR/Privacy Wallet owner) at any time.

For subsequent recertification: participants are assigned a new pair of modules (2 new patients) for FM recertification. For VERIFY, the frequency of FM recertification is every 6 months. Subsequent recertification involves additional novel patient pairs (Certification B, Certification C, Certification D, etc). For FM recertification, the Training Program is optional, i.e., completing this module is not required to recertify.

Please note the following points:
- First-time participants must complete the Training Program before attempting certification.
- The Training program is recommended for review prior to recertification but is not required.
- Participants can proceed directly to the Certification module when it's time to recertify.

The below Figures outline in red what is required for first time certification (left) and for recertification (right)

🔖 UCLA- CA01 – Fugl Meyer – Certification A – Arm Motor Assessment	✕

TITLE	
UCLA- A001.1 – Fugl Meyer – Training Arm Motor Assessment – ENGLISH	not attempted
UCLA- A002.1 – Fugl Meyer – Certification A – Arm Motor Assessment – Patient 1 of 2	not attempted
UCLA- A003.1 – Fugl Meyer – Certification A – Arm Motor Assessment – Patient 2 of 2	not attempted

First Time Certification

🔖 UCLA- CB01 – Fugl Meyer – Certification B – Arm Motor Assessment	✕

TITLE	
UCLA- A001.1 – Fugl Meyer – Training Arm Motor Assessment – ENGLISH	not attempted
UCLA- A004.1 – Fugl Meyer – Certification B – Arm Motor Assessment – Patient 1 of 2	not attempted
UCLA- A005.1 – Fugl Meyer – Certification B – Arm Motor Assessment – Patient 2 of 2	not attempted

Recertification

Study Announcements

- **UPDATE:** **The VERIFY Source book as been updated! Please use the most updated version for protocol V2.0!**
    - ➢ Document available in the toolbox in WebDCU

- **REMINDER:** Data/imaging for all subjects must be entered and uploaded for all enrolled subjects regardless if they were early terminated or not!

- **REMINDER:** PI/CRC and CRC webinars are back on schedule to a regular monthly basis!
    - Please look to the webinar section for details!

- **ATTENTION:** **Virtual Investigator Meeting 2024**
    - Meeting occurred on June 4th
        -recording available here:
        https://www.nihstrokenet.org/trials/verify/webinars
        Password: Verifying

happy 4th of July

To Our VERIFY Family!!

☀️ Site Monthly Spotlight ☀️

June Achievements:

Top Enroller(s) with 1 enrollment each:

- Baystate Medical Center,
- Medical University of South Carolina,
- University of Alabama,
- University of Cincinnati,
- Harborview Medical Center,
- Corewell Health,
- UCSF Medical Center, &
- Montefiore Medical Center!!

Top Pre-Screener(s):
University of Utah!!

First Enrollment:
Montefiore Medical Center!!

VERIFY(ed) Extraordinary Team Member:

Dr. Cynthia Hung is the site PI at Montefiore Medical Center in NYC. She has not only taken on the responsibility of site PI, but also the roll of study coordinator, regulatory specialist, and TMS operator whenever necessary. She recently enrolled her first subject and ensured that both biomarkers were collected and useable. Thank you for all your hard work, Dr. Hung!

Do you have an extraordinary team member that you want to be recognized? Let us know by emailing verifystudy@ucmail.uc.edu and nominate them for the next newsletter!

Site Visits Highlights
(AKA Harry's 3rd Tour around the US)

MEMORIAL HERMANN

Corewell

University of Michigan

Site Visits Highlights

(AKA Harry's 3rd Tour around the US)

OSU

UVA

Baystate

Site Visits Highlights

(AKA Harry's 3rd Tour around the US)

MGH

Lahey

Race to Activation

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
Penn State Hershey Medical Center															🚗
Pennsylvania Hospital													🚗		
Strong Memorial Hospital												🚗			
Froedtert & Medical College of Wisconsin										🚗					
Prisma Health Richland Hospital				▬						🚗					
Birmingham VA Medical Center		🚗													
Keck Hospital of USC	🚗			▬											
Wake Forest Baptist Health	🚗														
Westchester Medical Center	🚗														

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: verify.study.tms@gmail.com
- 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 7/15/2024

  Meeting ID: 929 1999 7979   **Passcode: 708995**

  https://ucincinnati.zoom.us/j/92919997979?pwd=UEMrY2ZTTXgzbWJVTnBoQXR2ZlB2UT09

- CRC webinars occur on the 4th Tuesday of each month, 12pm-1pm EDT.
  Next CRC webinar is 7/23/2024

  Meeting ID: 952 3133 5017   **Passcode: 398747**

  https://ucincinnati.zoom.us/j/95231335017?pwd=T01mZUZaek01Vnh1anFPV3hiSVMzZz09

- **Past Webinars available:**

  https://www.nihstrokenet.org/trials/verify/webinars   **Password: Verifying**