The VERIFY STUDY

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

Newsletter September 2023 Issue 21

118

Total Subjects Enrolled!!!

September

"Hope you had a good summer, VERIFY Team! Summer months are always an uphill hike for maintaining recruitment – new trainees, fewer strokes, more vacations. Yet, we've done it with a steady 10/month—go team! I'd like to challenge every site to enroll one patient in the next 4-6 weeks to start off the fall and help us with the necessary ramp up– are you in?? Let's plan for a beautiful fall."   -Pooja Khatri, MD, MSc
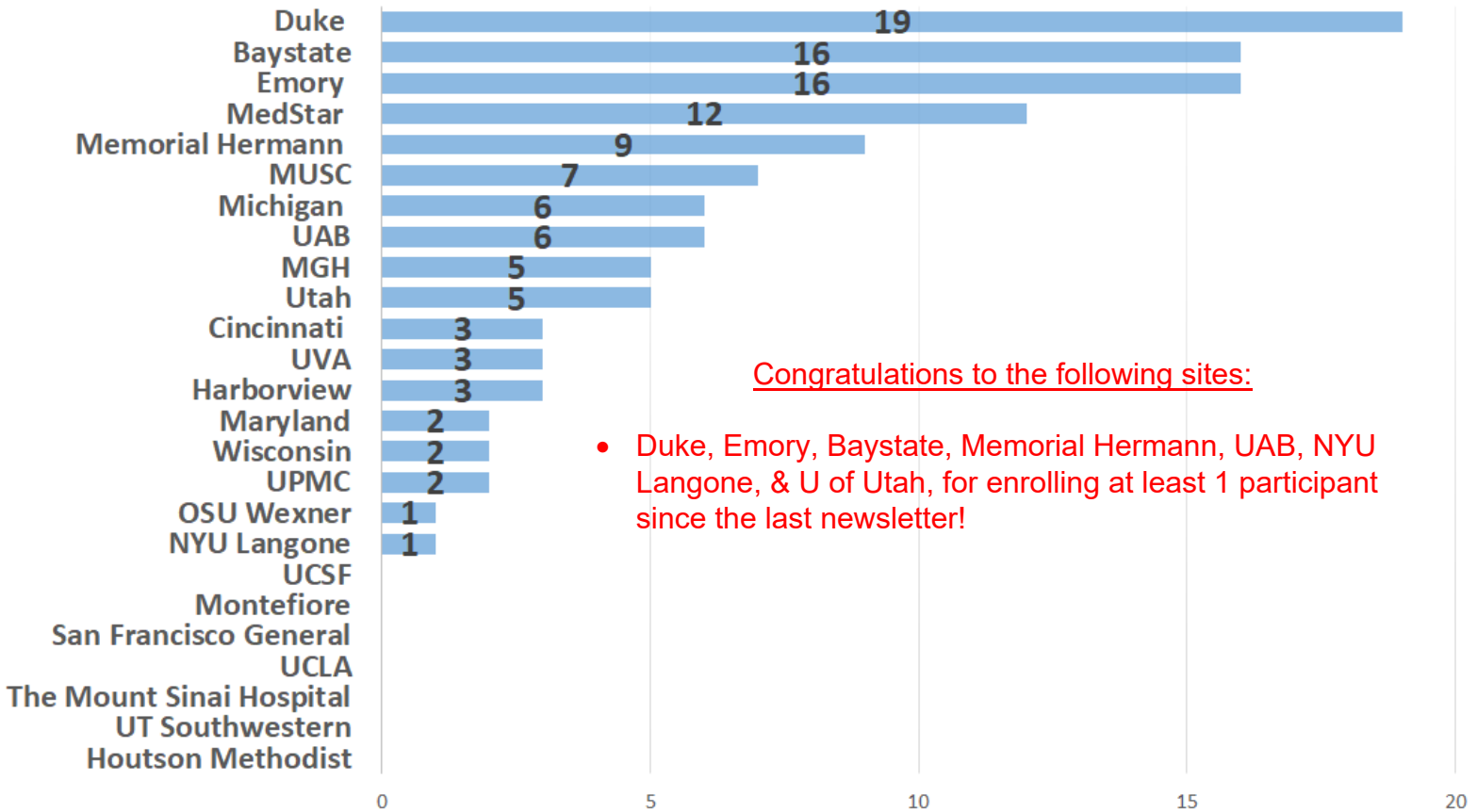
New enrollments since last newsletter

- Duke, +1
  - PI- **Dr. Feng**, PSC- **Tato Sokhadze**

- Emory, +2
  - PI- **Dr. Borich**, PSC- **Susan Murphy**

- Baystate, +2
  - PI- **Dr. Schlaug,** PSC- **Abraham Madjidov**

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

- UAB, +1
  - PI- **Dr. Gropen**, PSC- **Mitzi Roberts**

- NYU Langone, +1
  - PI- **Dr. Schambra**, PSC- **Yasmeen Mahady**

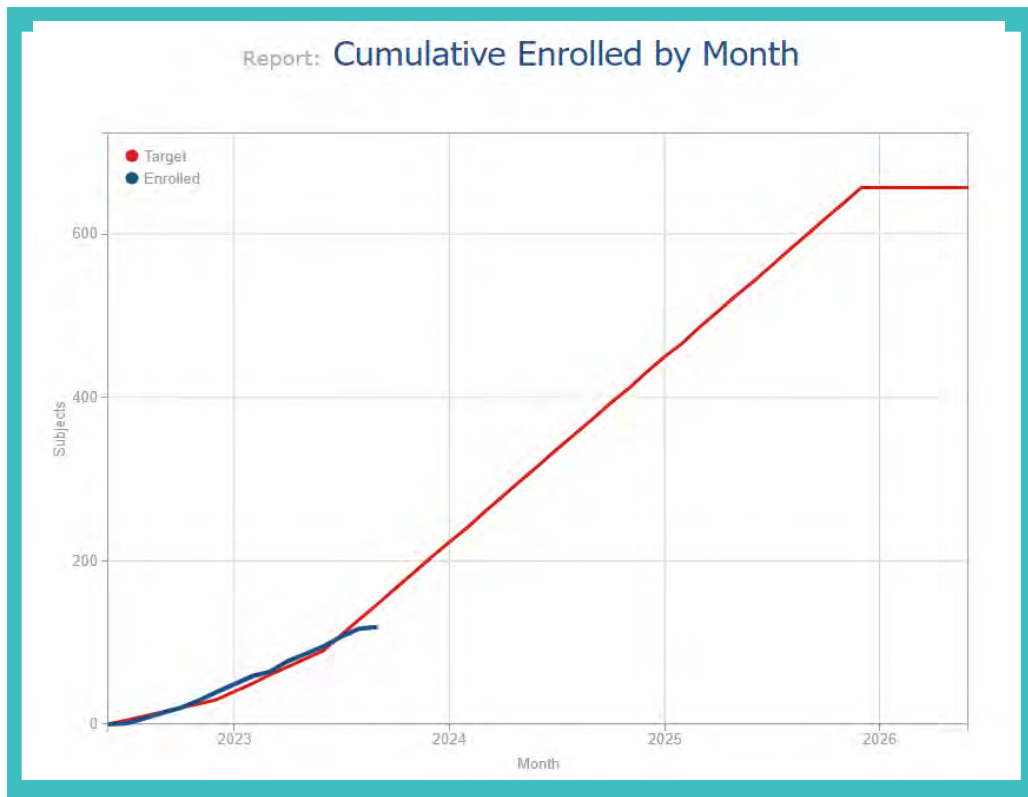- Utah, +1
  - PI- **Dr. Richards** PSC- **Megan Gardner**

CLAP CLAP

Enrollment Graphs

VERIFY TOTAL ENROLLMENTS: 118/657

Site	Enrolled
Duke	19
Baystate	16
Emory	16
MedStar	12
Memorial Hermann	9
MUSC	7
Michigan	6
UAB	6
MGH	5
Utah	5
Cincinnati	3
UVA	3
Harborview	3
Maryland	2
Wisconsin	2
UPMC	2
OSU Wexner	1
NYU Langone	1
UCSF	
Montefiore	
San Francisco General	
UCLA	
The Mount Sinai Hospital	
UT Southwestern	
Houtson Methodist	

Congratulations to the following sites:

- Duke, Emory, Baystate, Memorial Hermann, UAB, NYU Langone, & U of Utah, for enrolling at least 1 participant since the last newsletter!

Report: **Cumulative Enrolled by Month**

Patient Facing Rehab Diary Instructions

- V@Ápatient facing rehab diary instructionsÁ@ç^Áa^^}Á&ÜÓÁ¾]¦[ç^åÈ

  - This document is available in the Toolbox tab of WebDCU.

  - Sites can provide this instruction sheet to participants when giving them the rehab diary (~ visit 4).

TMS Study Hotline

TMS questions
- Urgent (during procedure)
  - Call or text hotline at :
    (833)337-2227

- Non-urgent questions
  - Email us at
    verify.study.tms@gmail.com

Reminder: TMSOs should include the TMS VERIFY email address (verify.study.tms@gmail.com) when emailing PMs/PIs about TMS issues. This way, the TMS team can communicate with sites ASAP.

- **Other consent/enrollment questions?**
  - Email VERIFY PIs (Pooja, Steve, Cathy, & Achala) and PMs (Lisa & Kalli).

VERIFY Principal Investigators
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- Steve Cramer
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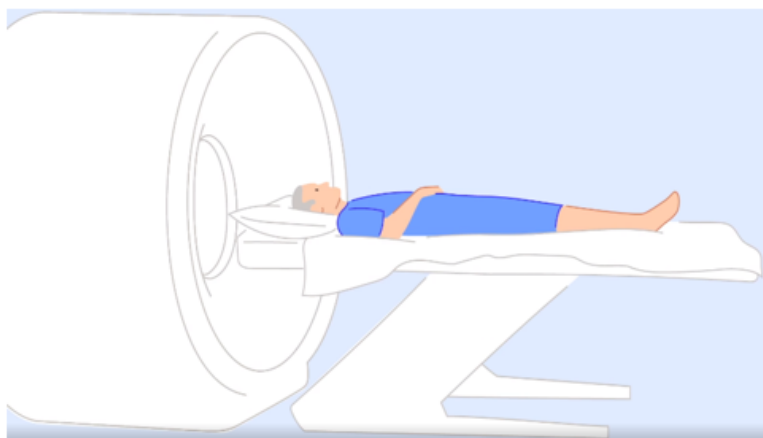
- Cathy Stinear
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- Achala Vagal
  vagala@ucmail.uc.edu

VERIFY Project Managers
- Lisa Mundo- Prime PM
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- Kalli Beasley- NCC PM
  beasleki@ucmail.uc.edu

MRI Issues Table Reminders

The below are MRI items that should be entered into the Issues table:

- MRI obtained outside of 24-168 hours from LKW

- Missing 3DT1 sequence (VERIFY Research MRI)

- No MRI obtained (SOC or Research)

- Involves patient safety

- Repeated noncompliance with the protocol – as determined by the study team

Pocket Cards v3.0

- 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.

- We will be shipping each site the following:
  - 20 one-page (back & front) pocket cards.
    - ➤ Purpose is to provide to your site's clinical care team (e.g., stroke physicians, fellows). This way they know what to look out for when seeing patients.
  - 3 of the entire 6-page pocket cards (8 ½" by 11") with 3 thumb tacks.
    - ➤ To be used by site staff, as a quick reminder of important study related information.

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

Spanish Versions of Assessments

The packet of Spanish versions of assessments is available in the Toolbox tab of WebDCU.

- Please note that if your site needs Spanish versions of the Star Cancellation Test, Pain Visual Analog Scale (VAS) and/or Rehab Diary, then please email the Cramer lab at cramerlab@mednet.ucla.edu.

General Information

The following Spanish versions of the assessments are included in this packet:

- ➢ Geriatric Depression Scale
- ➢ Motor Activity Log (MAL)
- ➢ NeuroQOL-Anxiety
- ➢ MoCA
- ➢ Fugl-Meyer
- ➢ EQ5D
- ➢ Star Cancellation Test
  - ○ Note: Please use printed test sheet that have been sent to your site. Do not use the example overleaf provided in this packet, as it is just for familiarization and not to be used with the patient.
  - ○ If your site needs Spanish copies of the Star Cancellation Test, please email the Cramer lab at cramerlab@mednet.ucla.edu.
- ➢ Pain Visual Analog Scale (VAS)
  - ○ Note: Please use printed test sheet that have been sent to your site. Do not use the example overleaf provided in this packet, as it is just for familiarization and not to be used with the patient.
  - ○ If your site needs Spanish copies of the Pain Visual Analog Scale, please email the Cramer lab at cramerlab@mednet.ucla.edu.
- ➢ Rehab Diary
  - ○ This is just a placeholder/reminder that the Rehab Diary is available in Spanish. If your site needs Spanish copies of the Rehab Diary, please email the Cramer lab at cramerlab@mednet.ucla.edu.
- ➢ NIH Stroke Scale (NIHSS)
- ➢ Modified Rankin Scale (mRS)
- ➢ Rankin Focused Assessment (RFA)
- ➢ Action Research Arm Test (ARAT)

Spanish version of the Lost to Follow-Up Letter Template

- Has been cIRB approved.

- Is available in the Toolbox tab of WebDCU.

VERIFY

Carta de seguimiento

(Fecha)

(Nombre del sujeto)

(Dirección del sujeto)

Estimado(a) (Nombre del sujeto):

Le estamos enviando esta carta como participante en el estudio VERIFY. Según nuestros registros, tenía programada una visita del estudio para el día (ingresar fecha). Intentamos comunicarnos con usted al [Insertar número(s) de teléfono] en tres ocasiones distintas y no lo conseguimos. Comuníquese con nosotros al [Insertar número(s) de teléfono] (y el nombre y título del contacto en el sitio)] para que podamos reprogramar su visita del estudio en persona o remotamente.

Si decidió detener su participación en el estudio, notifíquenos sobre su decisión para que podamos actualizar nuestros registros [y llevar a cabo cualquier procedimiento final del estudio]. Agradecemos su atención cuanto antes.

Atentamente,

[Insertar nombre del investigador principal]

(Firma)

Webinars

- PI/CRC webinars occur on the 3rd Monday of each month, 4pm-5pm EDT. **Next PI/CRC webinar is on 09.18.2023.**

  - 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 09.26.2023**

  - https://ucincinnati.zoom.us/j/96234616586   Meeting ID: 962 3461 6586

Study Contact Information

CIRB- Regulatory contacts:
Betsy Casillo   betsy.casillo@advarra.com
Kalli Beasley, NCC PM   beasleki@ucmail.uc.edu

CTA contact:
Wren Hanson hansonwm@ucmail.uc.edu

MRI contact:
Tyler Behymer behymetp@ucmail.uc.edu

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	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	🚗
University of Iowa Hospitals & Clinics	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	■	🚗 (red)			
Lahey Hospital & Medical Center	✔	✔	✔	✔	✔	✔	✔	✔	✔	🚗 (red)					
Prisma Health Richland Hospital	✔	✔	✔	✔	✔	■	✔	✔	✔	🚗 (orange)					
Penn State Hershey Medical Center	✔	✔	✔	✔	✔	✔	✔	✔	✔	🚗 (red)					
Pennsylvania Hospital	✔	✔	✔	✔	✔	✔	✔	✔	🚗 (red)						
Froedtert & Medical College of Wisconsin	✔	✔	✔	✔	✔	🚗 (orange)									
Corewell Heath Butterworth Hospital	✔	✔	✔	✔	✔	🚗 (orange)									
University of Rochester Strong Memorial Hospital	✔	🚗 (orange)					0								