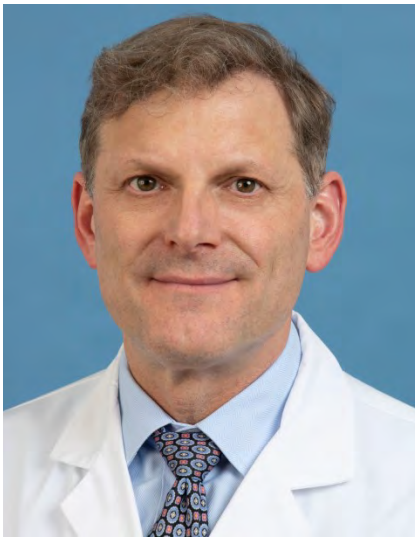
The VERIFY STUDY

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

Newsletter June 2023 Issue 18



"Thanks to all sites that are enrolling, and welcome to our newer sites. We appreciate the teamwork."

- Steve Cramer,MD, MMSc

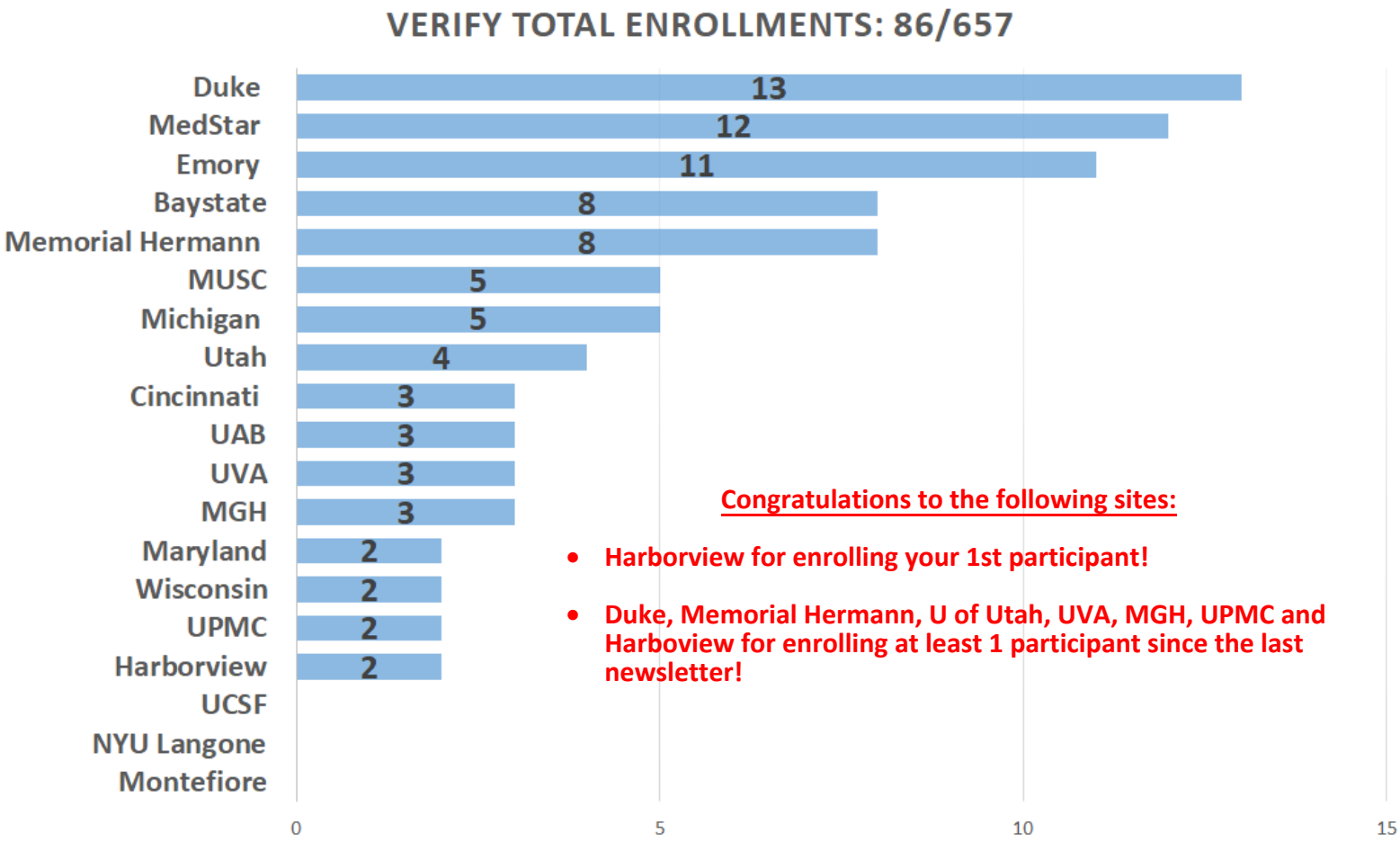
New enrollments since last newsletter

- Duke University, +1
  - PI- **Dr. Feng,** PSC- **Tato Sokhadze**
- Memorial Heramnn +1
  - PI- **Dr. Savitz,** PSC- **Emily Stevens**
- University of Utah, +1
  - PI- **Dr. Richards,** PSC- **Megan Gardner**
- UVA +1
  - PI- **Dr. Aldridge**, PSC- **Miah Perch**
- Massachusetts General Hospital, +1
  - PI- **Dr. Lin**, PSC- **Julie DiCarlo**
- UPMC, +1
  - PI- **Dr. Wittenberg,** PSC- **Jason Weimer**
- Harboview, +2
  - PI- **Drs. Tirschwell and Mazwi,** PSC- **Mary Grace Asirot**

Actions To Address Missing Primary Outcome Data (ARAT & FM)

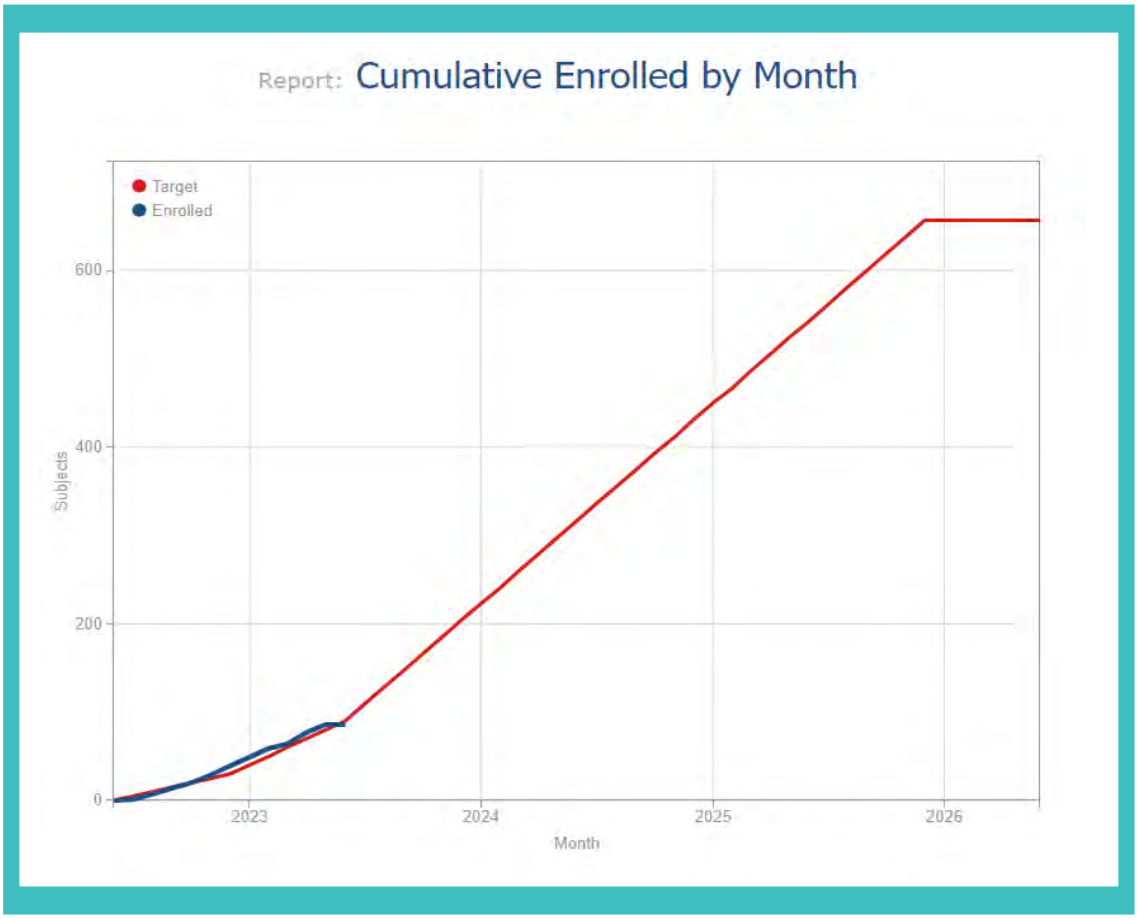
- Before consenting the participant, emphasize that the 90-day visit needs to occur in-person.
- Schedule the 90-day visit before the participant is discharged from the hospital.
- Coordinate the 90-day visit with standard of care visits.
- Troubleshoot transportation
  - **Remember the study is willing to pay for travel for participants or study team, if necessary.**
- Keep in touch after participant is discharged from the hospital.
- Collect alternate contacts for lost to follow-up.
  - Alternative contacts can be collected in the **contact information form.** A blank copy of this form is accessible in the Toolbox tab of WebDCU.
- Text/email/call them (at least 3 attempts required).
  - These attempts can be documented in the participant's binder.
- Remind participants about the payment for their time.
- If unable to reach participant, sites can check electronic medical record and/or case worker.
- Despite full attempts, if the participant is still hesitant on completing 90-day visit in-person, then sites could offer a shorter visit to complete just the FM and ARAT.

Enrollment Graphs



Congratulations to the following sites:

- **Harborview for enrolling your 1st participant!**
- **Duke, Memorial Hermann, U of Utah, UVA, MGH, UPMC and Harboview for enrolling at least 1 participant since the last newsletter!**



Patient Retention Tips

At the consent stage...

- The coordinator can present themselves as a resource
  - Allow the participant to contact you with any questions or concerns.
    - By text, phone or email (whatever the coordinator is comfortable with).
  - Be a listening ear – sometimes participants/families just like to feel they matter.
  - The participant may be in contact regarding topics that have nothing to do with the study- that's ok!
  - Explain that being a part of research means there are more eyes and hands involved with their care (coordinator, PI and other site study personnel).

- Emphasize the need for the 90-day in-person visit.
  - And that the study would pay them $150 for their effort plus transportation costs.

At hospital discharge...

- Fully complete the contact information form 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 would like to be contacted:
    - **Phone, Text, Email**
  - Confirm what time of day the participant prefers to be contacted
    - **Morning, Afternoon, Evening**

- Schedule the 90-day visit before discharge.
  - Consider **in-home visit** if your institution allows (all gas mileage is reimbursed; costs exceeding $40 may be invoiced).
  - Arrange **medical transportation** to a clinic visit from rehab/nursing facility if needed (study will pay invoice for cost).
  - Write the **time/date in their rehab diary** or help the participant put the time/date on their **calendar.**

- **Coordinate with a standard of care (SOC) clinic visit** if it can be done in the same timeframe as the 90-day visit.

- Provide the VERIFY **tote bag.**

After hospital discharge...

- Consider contacting your participants on a monthly basis.
  - Check-in to see how your participants are doing and whether there are any questions/concerns.

- Remind participants of the 90-day final visit during the 30-day phone call.
  - Mention the $150 reimbursement for their efforts to meet in-person for the 90-day visit.

- Troubleshoot any transportation issues.
  - Offer the option of completing the visit at the participant's home (if your site allows this).
  - Offer transportation assistance (such as taxi, uber, gas money and/or ambulance transport when needed for certain situations).

Addressing Challenges...

Not returning your phone call?

- Check the participant's electronic medical record (EMR) for standard of care visits scheduled, hospitalizations etc., on where you can meet them.

- Be persistent
  - Leave a voicemail informing them of the final visit and the $150 reimbursement. Include option to conduct home visit or send a cab.
  - Text them, as some participants prefer communicating via text rather than over the phone.
  - Attempt at least 3 different contact attempts by various means and document the contact attempts in the EMR or participant's binder.

- Contact additional people/family members that were provided on the contact information form.

- Check with their case managers to see if there are any alternate contacts.

Still unable to reach the participant?

- Review with the RCC project manager and then the VERIFY project managers to ensure that all options have been exhausted.

- Send certified letter as the final attempt and allow 7 days for the participant to respond.
  - The template for the certified letter has been cIRB approved and is accessible in the Toolbox tab of WebDCU.

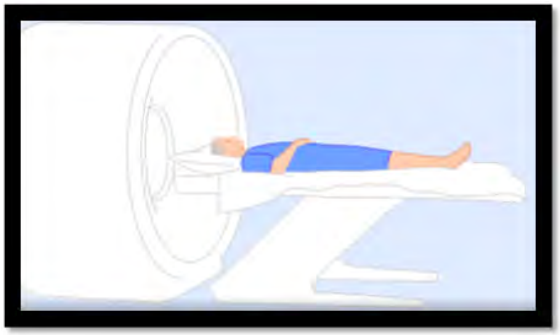
Got in touch but the participant doesn't want to do the final visit?

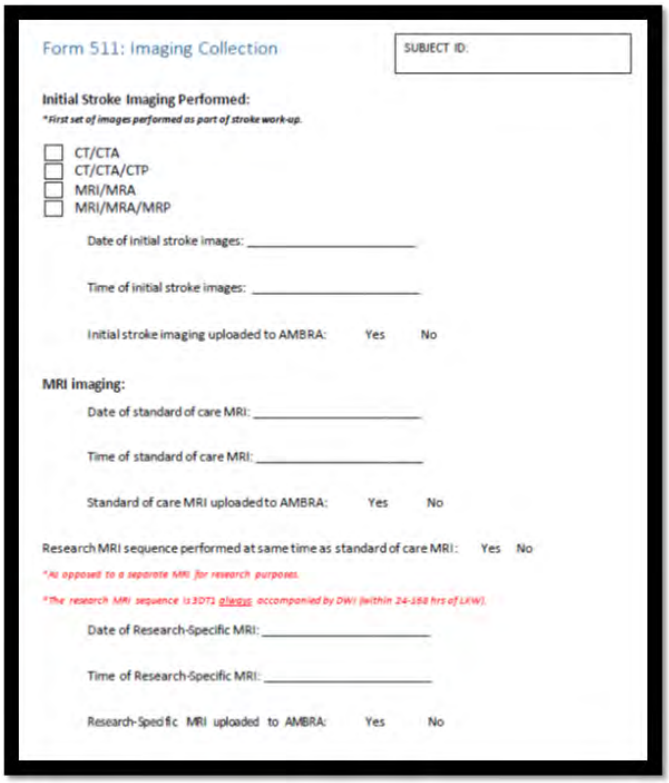
- Discuss barriers and offer solutions.

- Offer shorter visit for just the ARAT and FM (primary endpoints)

MRI Reminders- Scheduling

- Get in touch with the lead MRI tech ahead of time to understand the MRI process at your site.
- Right after consent: Call the MRI tech & give them a heads-up about the research MRI order or you can even stop by & put a "name to a face" with the MRI tech.
- After consent, call the MRI tech & remind them of the following:
  - Research scan is a paid scan.
  - Research scan is about 10 minutes in duration (3D-T1 & DWI).
  - Research scan needs to be completed prior to participant being discharged from hospital.
- **Always communicate with care team when ordering a research MRI scan****
- Enter the date/time of MRI into WebDCU by next business day after the procedure was completed.





Form 511: Imaging Collection

SUBJECT ID:

Initial Stroke Imaging Performed:

**First set of images performed as part of stroke work-up.*

- ☐ CT/CTA
- ☐ CT/CTA/CTP
- ☐ MRI/MRA
- ☐ MRI/MRA/MRP

Date of initial stroke images: _____

Time of initial stroke images: _____

Initial stroke imaging uploaded to AMBRA: Yes No

MRI imaging:

Date of standard of care MRI: _____

Time of standard of care MRI: _____

Standard of care MRI uploaded to AMBRA: Yes No

Research MRI sequence performed at same time as standard of care MRI: Yes No

**At opposed to a separate MRI for research purposes.*

**The research MRI sequence is 3DT1 always accompanied by DWI (within 24-168 hrs of LKW).*

Date of Research-Specific MRI: _____

Time of Research-Specific MRI: _____

Research-Specific MRI uploaded to AMBRA: Yes No

MRI Reminders- Imaging Submission Requirements

- If your institution requires you to remove PHI prior to uploading, please make sure that the date and time of image acquisition stays intact.
- All imaging **MUST BE** in native, uncompressed DICOM format.
- If compressed in zip format, must be extracted before uploading.
- Request initial/code stroke imaging, clinical MRI, and/or research MRI obtained for the participant during the stroke event.
- All imaging needs to be uploaded to Ambra within 5-7 days of acquisition.
- Complete the F511 'Imaging Collection' Form in WebDCU by next business day after procedure was completed (MRI Date/Time).

Reminder to Recruiting Sites: Below are the images that need to be submitted

- Initial acute clinical neuroimaging (CT/CTA/CTP or MRI/MRA/MRP)
- Standard of Care (SOC) MRI sequences
- Study specific MRI sequences at 24+ hours (if not part of SOC MRI)

Webinars

- PI/CRC webinars occur on the 3rd Monday of each month, 4pm-5pm EDT. **Next PI/CRC webinar is on 06.26.2023.**
  - 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 06.27.2023**
  - https://ucincinnati.zoom.us/j/93360687517 Meeting ID: 933 6068 7517

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