The VERIFY STUDY

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

Newsletter March 2023 Issue 15

"Congratulations team, we've now recruited around 10% of the target sample size! The study protocol is bedding in and data quality is improving – Thank you!"

-Cathy Stinear, PhD

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
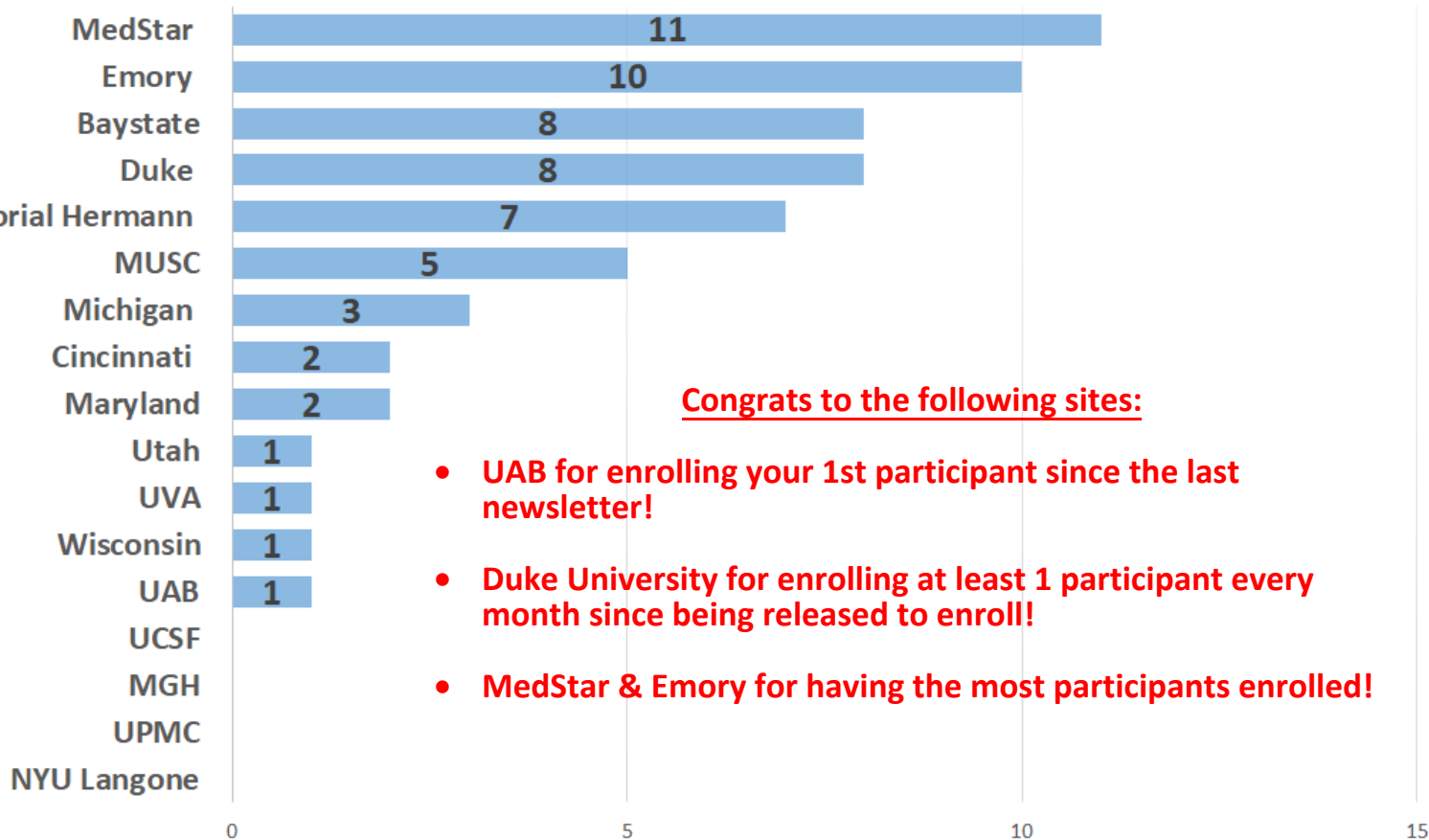- NYU Langone Medical Center

Study Reminders

- Protocol amendment v1.6 has been cIRB approved.
  - The updated virtual protocol training slides v1.6 is available on the DCU campus training website:https://dcu.musc.edu/campus/
    - Please ensure your study team reviews the updated protocol. Sites should document protocol trainings for study staff onsite in your regulatory binder.

- Study book/source documentation packet v6.0 is available in the toolbox tab of WebDCU.

- The updated pocketcards v3.0 are available in the toolbox tab of WebDCU. Sites can print these pocket cards and keep them on their TMS carts as a quick reminder of important study-specific information.

- The updated educational slide deck v3.0 is available in the toolbox tab of WebDCU. Sites can use this slide deck to help educate their site's clinical team about VERIFY.

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

Enrollment Updates

VERIFY TOTAL ENROLLMENTS: 60/657

| Site	Enrollments
MedStar	11
Emory	10
Baystate	8
Duke	8
Memorial Hermann	7
MUSC	5
Michigan	3
Cincinnati	2
Maryland	2
Utah	1
UVA	1
Wisconsin	1
UAB	1
UCSF	
MGH	
UPMC	
NYU Langone	

Congrats to the following sites:

- **UAB for enrolling your 1st participant since the last newsletter!**

- **Duke University for enrolling at least 1 participant every month since being released to enroll!**

- **MedStar & Emory for having the most participants enrolled!**

New enrollments since last newsletter

- MUSC, +2
  - PI- Dr. Heise, PSC- Valerie Salisbury

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

- Duke University, +2
  - PI- Dr. Feng, PSC- Tato Sokhadze

- UAB, +1
  - PI- Dr. Gropen, PSC- Tammy Davis

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

New: Issues Table in WebDCU
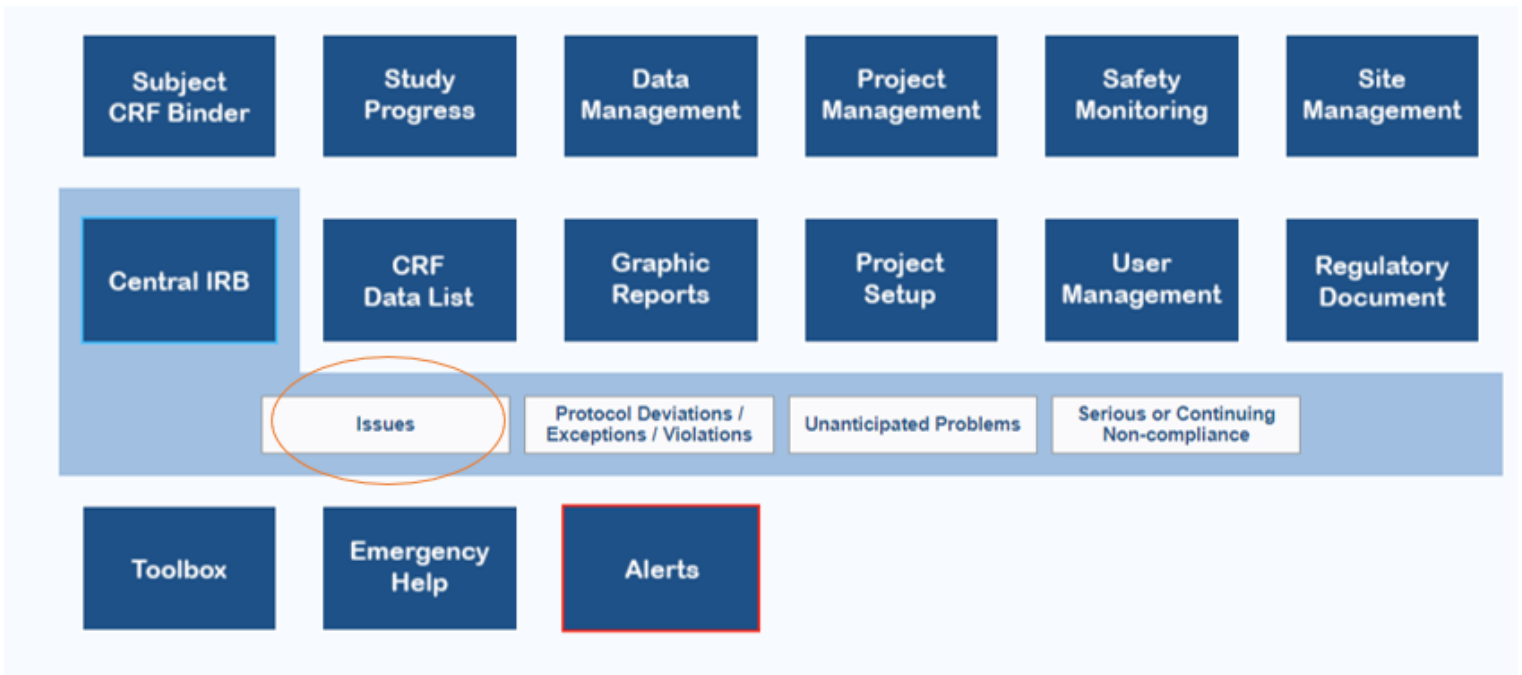
- The new Issues Table in WebDCU went live on 01Mar2023.
- Issues table training for sites occurred during the 28Feb2023 study coordinator webinar.
  - For those that were unable to attend the webinar, please feel free to review the webinar recording on the study's StrokeNet webpage: https://www.nihstrokenet.org/verify/webinars

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TMS Reminders

- New: TMS newsletters are being created and will be sent out periodically to the TMS operators, site PI and site PSC.
  - These TMS newsletters contain important information and reminders regarding the study's TMS procedure. Please be on the lookout for these newsletters!

- New: The VERIFY leadership team is working on creating quarterly meetings with TMSOs. These meetings will also contain important TMS related information. Meeting invites will be sent to sites.

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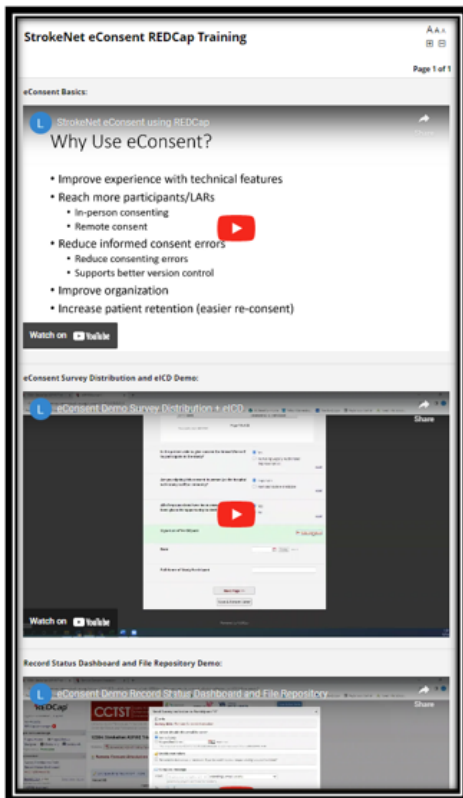 - The TMS safety checklist training is located here: https://verifytraining.blogs.auckland.ac.nz/tms-safety-checklist/

RedCap eConsent Training

Who should complete RedCap eConsent training?

- All sites using REDCap eConsent should ensure that all consenters have completed the following eConsent training:
  - https://redcap.link/StrokeNet_eConsent_Training

- VERIFY specific REDCap eConsent guide is available in the toolbox tab of WebDCU.

How should sites document RedCap eConsent Training for audit purposes?

- Completion of training certificate should be kept in your site's regulatory binder onsite.

REDCap- eConsent Download
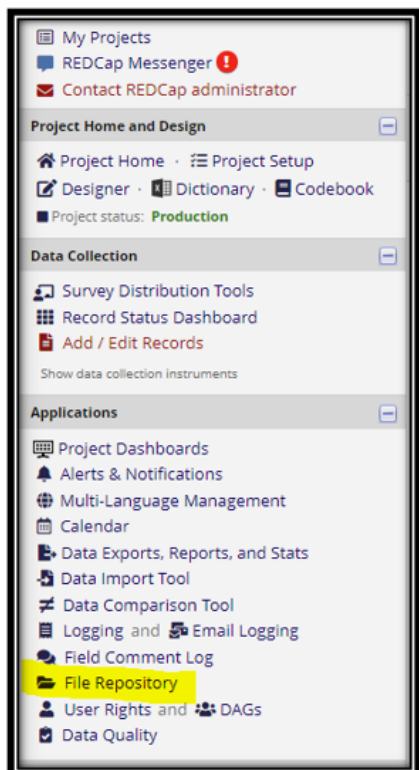
Correct Method for Downloading eConsents

- Completed consents should be accessed though the "**File Repository**" in REDCap.

  - Do NOT access completed consents from the "Record Status Dashboard"

    - This runs risk of having incorrect consents being printed (e.g., wrong version and/or date)

- Please review the eConsent guide for more details on this process
  - eConsent guide is located in the Toolbox tab of WebDCU.

FM & ARAT Experience Survey in RedCap

- The VERIFY leadership team strongly prefer that FM & ARAT are performed by PT/OT/MD; any exceptions require explicit prior approval from the VERIFY Study PIs.

- These assessments are complex and require experience.

- Since these assessments are the primary outcome measures, the VERIFY leadership team will only accept exceptions to staff who are not PT/OT/MD based on strong justification including prior experience performing these assessments.

The below FM & ARAT experience survey link will be sent to non-PT/OT/MD site staff and reviewed by VERIFY leadership team for review/approval.

https://redcap.link/ VERIFY_ARAT_and_FM_Survey

Webinars

- PI/CRC webinars occur on the 3rd Monday of each month, 4pm-5pm EDT. **Next PI/CRC webinar is on 03.20.2023.**
  - 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 03.28.2023**
  - https://ucincinnati.zoom.us/j/93360687517   Meeting ID: 933 6068 7517

Study Contact Information

CIRB- Regulatory contacts:

Betsy Casillo	betsy.casillo@advarra.com	513.619.1679
Kalli Beasley	beasleki@ucmail.uc.edu	

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

Email QUESTIONS to: verifystudy@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	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🚗		
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	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🚗					
Mount Sinai Hospital	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🚗						
Pennsylvania Hospital	🟩	🟩	🟩	🟩	🟩	🟩	🚗								
Penn State Hershey Medical Center	🟩	🟩	🟩	🚗			0								
Froedtert & Medical College of Wisconsin	🟩	🟧🚗	🟩		🟩	🟩	🟩								
Prisma Health Richland Hospital	🟩	🟧🚗	🟩		⬛	🟩	0								
University of Iowa Hospitals & Clinics	🟩	🚗	🟩	🟩							⬛				
University of Rochester Strong Memorial Hospital	🟧🚗		🟩	🟩	🟩		0								
Corewell Heath Butterworth Hospital	🟧🚗						0								