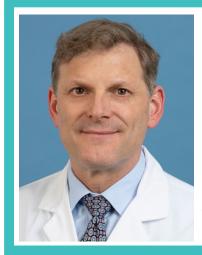


Newsletter June 2022 Issue 6



"Thanks to the many sites who have been working hard and are close to being cleared to begin enrollment. Strong work!"

- Steve Cramer, MD, MMSc

We are almost at lift off!

Remaining start up activities are moving full steam ahead. As always, thank you for working on getting these completed! Please do not hesitate to reach out with questions.

Key Action Items for Completion of Trainings

- > Online Training modules for all study staff
- Practical TMS training on healthy volunteers (congratsÁo U-Cincinnati for completing this!)
 - The last step for fast-track sites to have site readiness call and be released to enroll!!
- TMS technique check by VERIFY leadership/ consultants for standard TMS sites
 - The last step for standard sites to have site readiness calls and be released to enroll!!

Other Study Updates

•All TMS operators & TMS assistants need to be listed on the DOA. Only the TMS operators (not the assistants) need to complete the study's TMS training prior to performing the procedure on participants.

•All TMS operators are to upload their healthy volunteer training certificate in WebDCU under the People Document section. This is the only TMS training certificate that should be uploaded to WebDCU.

•ARAT scoring in VERIFY differs from the approach many examiners may have been using previously:

- 1) Previously, many examiners used a 5 second cutoff for task completion to distinguish a score of 2 (>5 sec) from a score of 3 (5 sec or less), but in VERIFY, the time cutoff to distinguish a 2 from a 3 varies from task to task.
- 2) Previously, many examiners scored a task based on a subject going from starting position (hands on table or lap, depending on the task) to completion of the task, but in VERIFY, a task is scored based on a subject going from starting position (hands on table or lap, depending on the task) to ending position (hands on table or lap, depending on the task).



✓ CTA/CIRB

- ✓ DOAs/Investigator Forms
- ✓ Trainings for TMS and Behavioral Assessments
- ✓ MRI Set Up
- ✓ Study Materials Shipping
- ✓ Site Readiness Call

	Study Contacts										
CIRB- Regulatory contacts:											
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CTA contacts: Sasha Simms	simmssc@ucmail.uc.edu	513.558.3924									
	0										
All Other VERIF	Y questions: Lisa Mundo mundo	oki@ucmail.uc.edu									

The first PI/Study Coordinator webinar is on <u>06.27.2022 from 4pm-5pm ET.</u> All site staff involved in the study should be in attendance. Zoom login details have been emailed to sites.

Email QUESTIONS to: verifystudy@ucmail.uc.edu

Race to Activation														
Site Name	CTA Executed	CIRB Approved	DOA submitted	Investigator agreement forms submitted for all PI/Sub'Is	TMS Shipping Address entered	TMS Machine obtained		Green Light to start HV training	TMS HV Training Completed	TMS Technique Check	MRI Phantom Approved	All WebDCU Documents upl <u>oa</u> ded	Site Activation Meeting Completed	Site Activated
University of Cincinnati Medical Center							7	7						
Emory University		13		13		1	3	3				C REPORT		
MedStar Washington Hospital Center							4	4						
University of Texas Southwestern Medical Center							2	2	6					
The University of Utah							2	2	And the second second					
NYU Langone Medical Center - Tisch Hospital							3	3	- Ga					
Medical University of South Carolina (MUSC)							1	1						
UT Houston-Memorial Hermann Texas Medical Center					1		2							
University of Michigan University Hospital							5		8.5					
UVA Medical Center							2		~	ŝ.	S	0		
Montefiore Medical Center		8				6000	1					1		
Baystate Medical Center						and the second second	600							
UF Health Shands Hospital					6		3							
University of Maryland Medical Center			500-											
University of Wisconsin University Hospital				6) 1				5	83 	10				
Duke University Hospital			6					-	1					
University of Alabama Hospital			- 6-			÷	1	4	22	6		5 10		
OSU Wexner Medical Center	1 A	11.2	6			·)								
Massachusetts General Hospital				20 50			2		63 62					
UCSF Medical Center		600					2							
Harborview Medical Center														
San Francisco General Hospital									.0					
Lahey Hospital & Medical Center	1. Sec. 1.	0.0	2				2		.0	63				
UPMC Presbyterian Hospital	States-		13	18			1		3					
Pennsylvania Hospital									19					
Houston Methodist Hospital							2		2					
Ronald Reagan UCLA Medical Center														
University of Iowa Hospitals & Clinics		2		24 24			3		85					
Penn State Hershey Medical Center	644													