

The VERIFY STUDY

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

Newsletter July 2023 Issue 19



"Thanks everyone for ironing out the last wrinkles with TMS data collection, we're delighted with the high quality data coming in – keep up the good work!"

- Cathy Stinear, PhD



New enrollments since last newsletter

- Duke University, +5
 - PI- **Dr. Feng**, PSC- **Tato Sokhadze**
- Emory, +2
 - PI- **Dr. Borich**, PSC- **Susan Murphy**
- Baystate, +4
 - PI- **Dr. Schlaug**, PSC- **Sirisha Nouduri**
- MUSC, +2
 - PI- **Dr. Heise**, PSC- **Valerie Salisbury**
- OSU, +1
 - PI- **Dr. Hannawi**, PSC- **Myah Mahayri**
- MGH, +1
 - PI- **Dr. Lin**, PSC- **Julie DiCarlo**

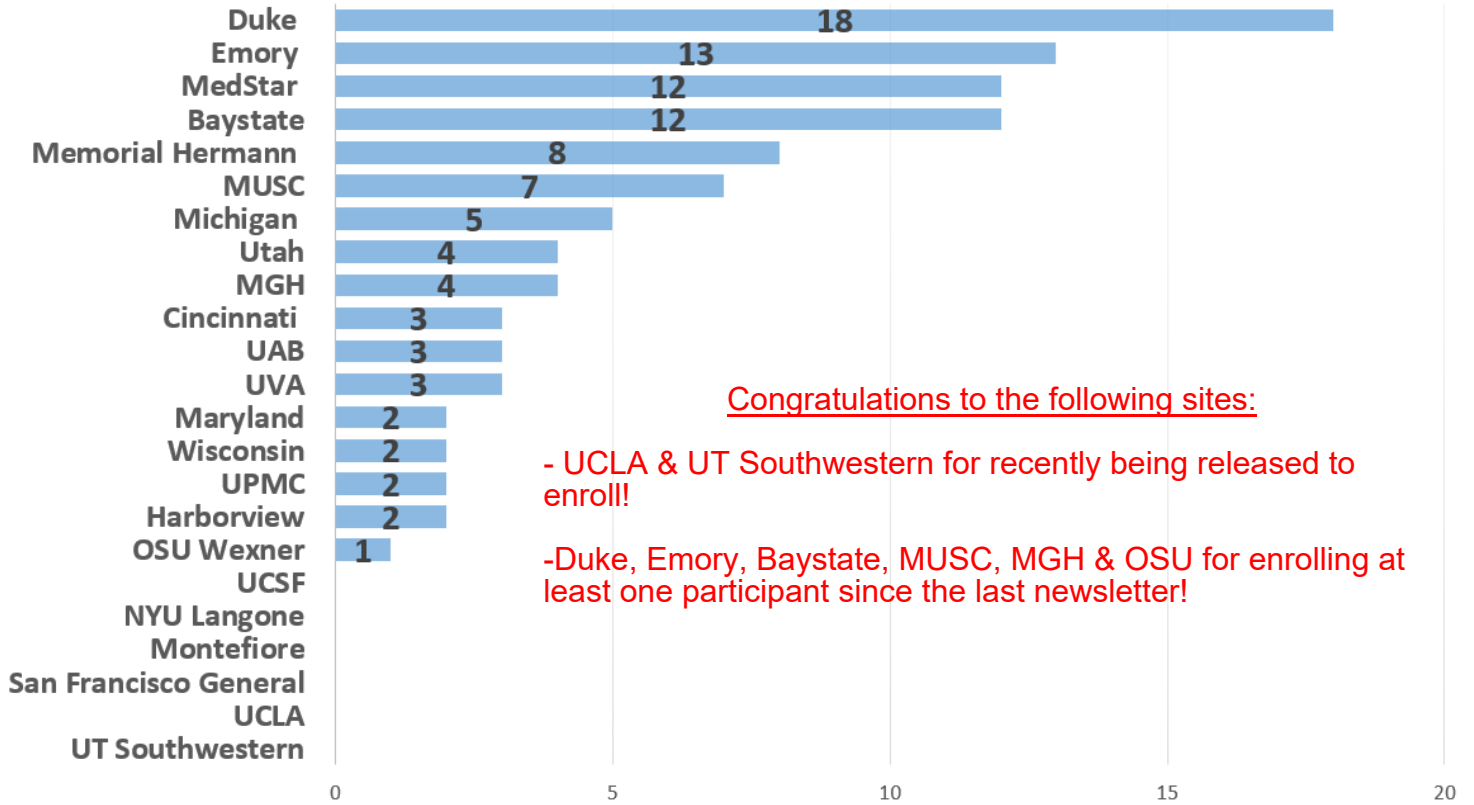
101

Total Subjects Enrolled!!!



Enrollment Graphs

VERIFY TOTAL ENROLLMENTS: 101/657



Congratulations to the following sites:

- UCLA & UT Southwestern for recently being released to enroll!

-Duke, Emory, Baystate, MUSC, MGH & OSU for enrolling at least one participant since the last newsletter!



Spanish Versions of Assessments

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
- EQSD
- 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)



VALIDATION OF EARLY PROGNOSTIC DATA FOR RECOVERY OUTCOME AFTER STROKE FOR FUTURE, HIGHER YIELD TRIALS

Spanish versions of study assessments
Version 1.0

- The packet of Spanish versions of assessments was emailed to sits on **15Jun2023**.
 - Packet is also available in the Toolbox tab of WebDCU.
 - Please noted 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.

- In the event that a **Spanish-speaking interpreter** is needed to help consent a participant, and your hospital is charging for this service, the study will cover this cost (up to \$300 maximum per patient).
 - If this service is needed, please follow the below guidance:
 - **Please send invoices directly to Lisa Mundo** at mundokl@ucmail.uc.edu and we will DIRECTLY pay the translators.
 - If you pay the translator directly, then UC will need to have a subcontract in place which will take time. So please do not pay the translator directly, and instead send us the invoices.



Studybook/Source Documentation Packet V7.0



VERIFY

VALIDATION OF EARLY PROGNOSTIC DATA FOR RECOVERY OUTCOME
AFTER STROKE FOR FUTURE, HIGHER YIELD TRIALS

STUDYBOOK

Version 7

[13 June 2023]

VERIFYSTUDYBOOK_V7_13JUN2023

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- The studybook/source documentation packet v7.0 was emailed to sites on 13Jun2023 and is also available in the Toolbox tab of WebDCU.


Reminder: This version should be used when collecting data for the study.

Toolbox

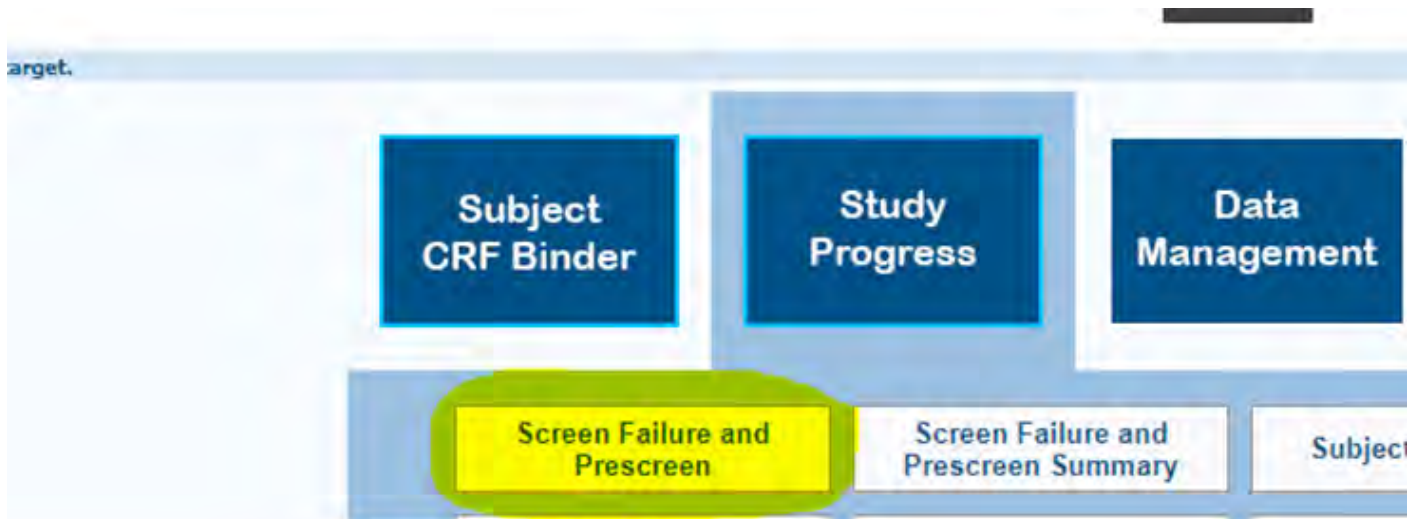
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Project Documents

View: Project Documents

Category	Instructions
Document	VERIFY Study Book- Source Documentation
File	F1420.pdf 
Version	7.0
Version Date	13-Jun-2023

Prescreen/Screen Failure Log



- Please enter **prescreen failure** (participants that were never consented in the study) and **screen failures** (participants that were consented but NOT enrolled in the study) into the prescreen/screen failure log in WebDCU.
 - This log is located in WebDCU under the **Study Progress** tab.
- Instructions on which participants to enter in this log are noted below.



Screening/Consent Workflow

1. Daily Chart Screening

- Identify all stroke patients (ischemic and ICH) in EMR with the following:
 - <36 hours of onset at admission
 - Some upper extremity weakness
 - Alert and able to consent themselves
 - No TMS & MRI contraindications
- Above subset of pts eligible based on full eligibility criteria?
 - **NO** → enter as a Pre-screen failure
 - **YES** → proceed to next step

2. Ask clinical team physician for the following:

- Confirm that patient has “some” weakness in shoulder abduction and/or finger extension?
 - **NO** → enter as a Pre-screen failure
 - **YES** → proceed to next step
- Mention study and ask if study team may approach
 - **NO** → enter as a Pre-screen failure
 - **YES** → proceed to next step

3. Patient consents?

- **NO** → enter as a Pre-screen failure
- **YES** → proceed to next step

4. SAFE score ≤ 8 ?

- **NO** → enter as a screen failure
- **YES** → proceed to next step

5. Remains eligible and 1st TMS stimulation or study-specific MRI is started?

- **NO** → enter as a screen failure
- **YES** → participant is now enrolled!

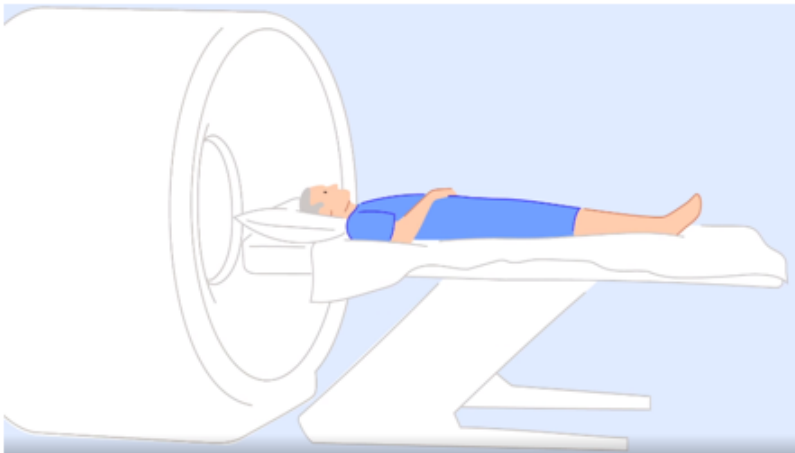
MRI Phantom Scan Reminders

Brief review of process:

- Phantom scan(s) of study-specific 3D-T1 sequence collected at study start up for site activation
- Phantom scan(s) are collected every 6 months (2 times per year) to ensure quality certification of MRI protocol over time.
 - This will help to prevent unusable MRI data
- Phantom scan(s) are needed after any scanner hardware upgrades and/ or software changes before scanning any new patient
 - Please notify the imaging team of any upcoming MRI upgrade if known in advance
- Email reminders will be sent out at every 5, 6, and 7-month window interval for upcoming phantom scans set to expire
 - If phantom scan not obtained after 7-month window, then activated site **will be placed on enrollment hold** until phantom is obtained.

As a reminder, **we are collecting phantoms of only the study-specific, 3D-T1 sequence (your site's ACR phantom is fine)**

- *Most institutions run their standard ACR phantoms at a scheduled time on a weekly basis*
- *Talk with your Radiology point of contact to determine your site's ACR phantom schedule*



➤ Contact **Tyler Behymer** with any imaging questions by

- Phone: 513-310-7472
OR
- Email behymetp@ucmail.uc.edu

