The VERIFY STUDY

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

Newsletter January 2023 Issue 13

-Pooja Khatri, MD, MSc

We continue to ramp up: **12 pts were enrolled in December!**

Special thanks to Baystate who enrolled 6 in one month, and Utah for their 1st!

Look forward to several more screening sites in January!

Thank you all!!

Sites Released to Enroll

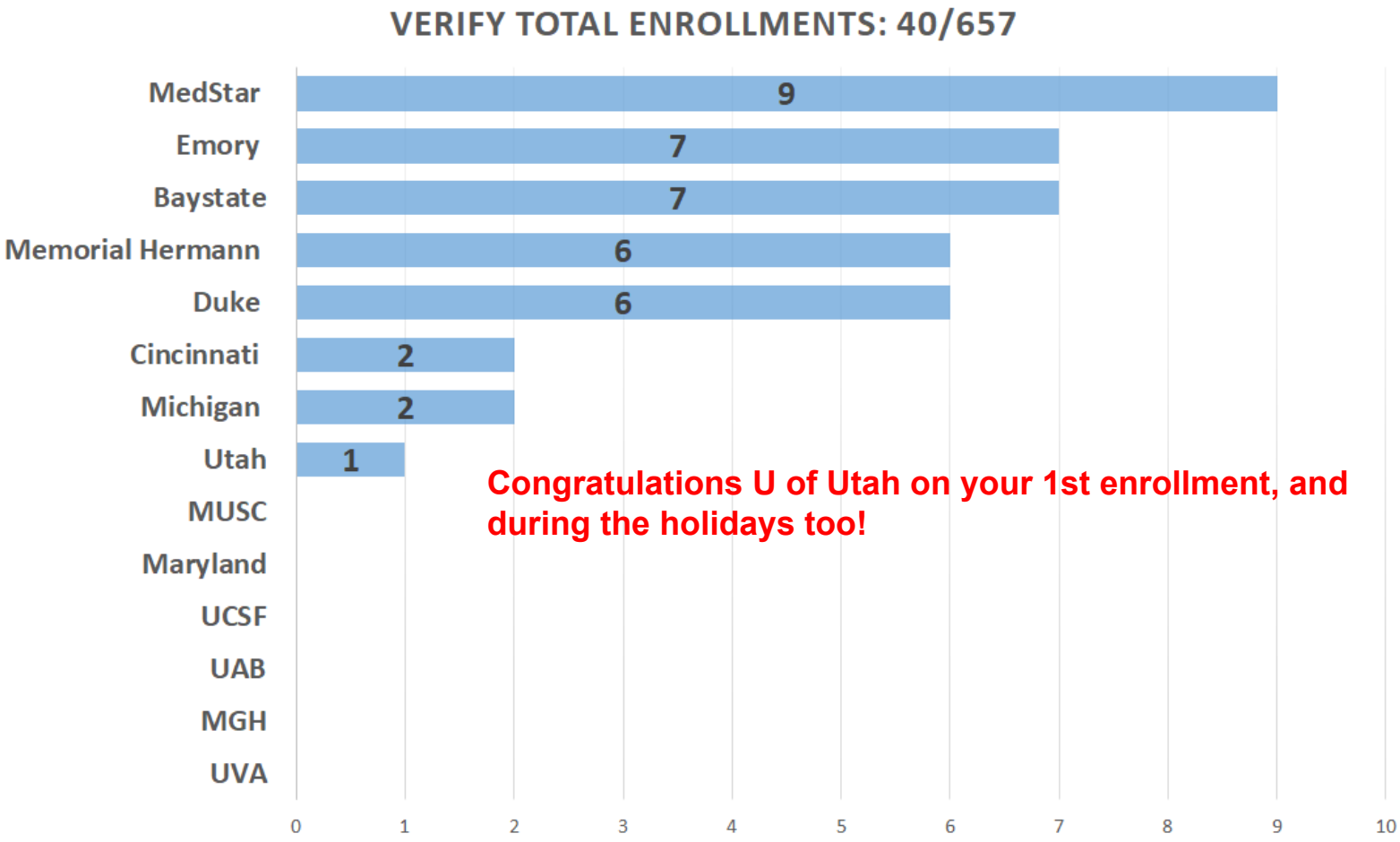
- University of Cincinnati Medical Center
- MedStar Washington Hospital Center
- Emory University
- UT-Memorial Hermann Texas Medical Center
- University of Michigan
- Medical University of South Carolina (MUSC)
- The University of Utah
- Baystate Medical Center
- UVA Medical Center
- Duke University Hospital
- Massachusetts General Hospital
- University of Maryland Medical Center
- UPMC Presbyterian Hospital *
- University of Alabama *
- UCSF Medical Center *
- University of Wisconsin*

* Indicates site activated since last newsletter

Study Reminders

- If a Spanish-speaking interpreter is needed to help consent a participant & your hospital is charging for this service, the study will cover this cost (up to $300 maximum per patient).
  - Please send invoices directly to Lisa Mundo at mundokl@ucmail.uc.edu & the study will DIRECTLY pay the translators.
- All sites using RedCAP eConsent should ensure that all consenters have completed the following training:
  - https://redcap.link/StrokeNet_eConsent_Training
  - In addition, the VERIFY specific RedCAP eConsent Guide is available in the WebDCU toolbox tab.
- A diagnosis of COVID-19 is not an exclusion in and of itself, but only if it leads to other exclusions.

Enrollment Updates



New enrollments since last newsletter

- Baystate +3
  - PI-Dr. Gottfried, PSC- Sirisha Nouduri
- MedStar, +2
  - PI- Dr. Edwardson, PSC- Jamal Smith
- Duke, +2
  - PI- Dr. Feng, PSC- Tato Sokhadze
- Michigan, +1
  - PI- Dr. Krishnan PSC- Shannen Bolde
- Cincinnnati, +1
  - PI- Dr. Boyne, PSC- Erin Wagner
- Utah, +1
  - PI- Dr. Richards, PSC- Megan Gardner

Are you audit ready? Tips for sites

- Ensure that a signature and delegation of responsibilities log is kept complete and up to date.
  - **Suggestions for sites:** The VERIFY study recommends printing the initial DOA from WebDCU & have the site PI sign/date the page. This will provide documentation of PI acknowledgment at the site level. In addition, please follow your site's local guidelines and standard operational procedures regarding the DOA.

- Ensure all stamped approval and approved documents for the sponsor and all sites are in the regulatory binders.
  - **Suggestions for sites: P**lease remember that your site should have a regulatory binder for the study onsite. This binder can either be physical (hard copy) or electronic. The stamped approved & approval regulatory documents should be kept in this binder at your site. This will help prepare your site for an audit.

- Ensure staff members update and/or take required training.
  - Suggestions for sites: Please ensure you are paying attention to emails from WebDCU and the Cramer lab about upcoming expiring trainings for your site staff.
    - The FM & ARAT require recertification every 6 months. The Cramer lab will send reminder emails at 1 month & 1 week prior to these trainings expiring.
    - It is the site's responsibility to ensure no assessment is performed by study staff with expired trainings.

****If a site staff performs an assessment with an expired training, it is a protocol deviation****

- Ensure a NTF is kept for staff members using modified or alternative names.
  - **Suggestions for sites:** If you have study staff with modified/alternative names, please write a note-to-file (NTF) noting this information. This way if your site is audited, the auditor will know that the alternative names are referring to the same person. A NTF template is available in the Toolbox tab of WebDCU. You are also more than welcome to use your own NTF template.

- Ensure all required study staff sign and date a COI, they are completed fully and accurately are kept in the regulatory file.
  - **Suggestions for sites:** Please remember that your site should have a regulatory binder for the study onsite. This binder can either be physical (hard copy) or electronic. All conflict of interest forms (COIs)/financial interest disclosure forms (fCOIs) should be kept in this binder. This will help prepare your site for an audit.

- Ensure lab directory CVs and laboratory normal values are kept with laboratory documentation.
  - **Suggestions for sites:** Your laboratory certifications (CAP/CLIA) can be kept onsite in your regulatory binder, under a tab titled "laboratory documentation". This will also help prepare your site for an audit.

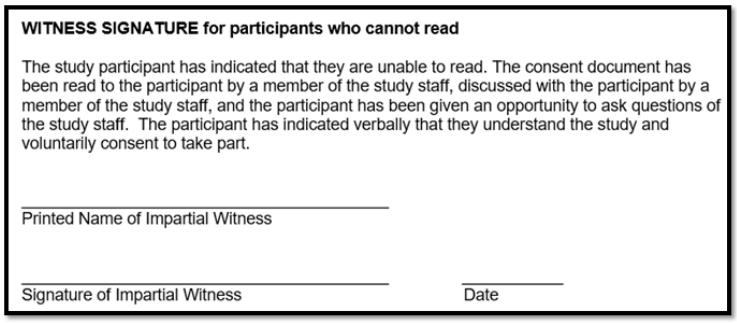
****Audit readiness is important, as the study & sites can be audited at anytime****

When to use a witnessed consent process

- When subject is cognitively capable of providing consent, BUT
  - Is illiterate
  - Is consenting using a short form
    - ❖ In VERIFY, short forms are only used if a Spanish consent form is not available at your site. Please note that not all sites will need a Spanish version of the consent form.
  - Is unable to physically sign AND date the consent
  - The participant should make their mark if able

- An impartial witness = **NOT** a study team member, a friend, family member, or the subject
  - An example of an impartial witness is a clinical nurse.

*****VERIFY does NOT allow Legally Authorized Representatives (LARs)*****

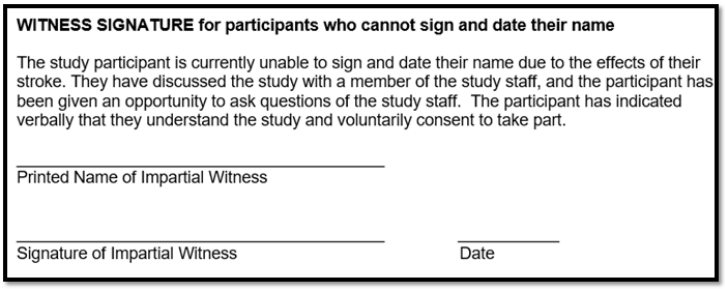


WITNESS SIGNATURE for participants who cannot read

The study participant has indicated that they are unable to read. The consent document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff. The participant has indicated verbally that they understand the study and voluntarily consent to take part.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness Date



WITNESS SIGNATURE for participants who cannot sign and date their name

The study participant is currently unable to sign and date their name due to the effects of their stroke. They have discussed the study with a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff. The participant has indicated verbally that they understand the study and voluntarily consent to take part.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness Date

The impartial witness must be present during the consent process & sign the consent documents in the appropriate areas.

Webinars

- PI/CRC webinars occur on the 3rd Monday of each month, 4pm-5pm EDT. **Next PI/CRC webinar is on 01.23.2023.**
  - 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 01.24.2023**
  - https://ucincinnati.zoom.us/j/93360687517 Meeting ID: 933 6068 7517

Study Contact Information

CIRB- Regulatory contacts:

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CTA contact:

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All other study questions:

Lisa Mundo	mundokl@ucmail.uc.edu

Email QUESTIONS to: verifystudy@ucmail.uc.edu