

From: [Beckmann, Rose \(beckmare\)](#)
To: [Beckmann, Rose \(beckmare\)](#)
Subject: NIH StrokeNet Biweekly Update 28-February, 2020
Date: Friday, February 28, 2020 1:02:23 PM
Attachments: [image005.png](#)
[image006.png](#)
[image008.png](#)
[image010.png](#)
[image012.png](#)
[image014.png](#)
[image016.png](#)
[image018.png](#)
[image020.png](#)
[image030.png](#)



Biweekly Update 28-February 2020

<http://nihstrokenet.org/coming-events>

StrokeNet Enrollment Update

ARCADIA	427/1100	CREST 2	1642/2480
Sleep SMART	233/3062	CREST H	138/500
TRANSPORT2	11/129	MOST	24/1200
I-ACQUIRE	21/240	ARCADIA-CSI	38/500

StrokeNet Trial Updates



We enjoyed seeing many of our ARCADIA investigators last week at ISC. We also had the opportunity at ISC to present several abstracts, which were well-received. These focused on predictors of atrial cardiopathy among the ESUS patients consented and established that correlates of atrial cardiopathy include being female, age, black race, and other forms of cardiovascular disease. Interestingly, the predictors of P wave terminal force and of NT-proBNP differed from each other, suggesting that atrial cardiopathy may be a heterogeneous condition. We look forward to the opportunity to write up the results of these and other analyses as we continue towards completion of the trial.

As of February 27, 2020, 1657 participants have been consented and 427 participants randomized at 100 sites (of 142 sites that have been released to enroll). This is an increase of 26 consented and 5 subjects randomized in a bit less than two weeks. Our enrollment is at 38.8% of the overall goal.

Thank you to the 20 sites that consented and 5 sites that randomized subjects in the last two weeks.

A special thank you to Froedtert Hospital (WI) and Long Beach Memorial Medical Center (CA) for randomizing their first participants!

Enrollment has been going strong at the top enrolling sites: United Hospital and the University of Minnesota Medical Center have 15 randomizations a piece, the University of Cincinnati and Emory both have 13 and the University of Kentucky Hospital, Memorial Hermann Texas Medical Center and the University of Iowa Hospitals & Clinics have 11 each. Thank you all for your dedication and leadership!

We have now released to enroll a total of 142 sites, 134 are active, and we are still working on adding other qualified sites to the ARCADIA roster. We have quite a few sites working towards being released to enroll. However, please let us know of any excellent stroke sites that are interested in participating in this important trial.

Please keep approaching ESUS patients about the ARCADIA trial at your sites. Remember, every site's best effort is necessary for the trial to succeed!

Webinar: Our next PI and coordinator webinar will be March 24th at 2 PM Eastern--save the date! We're asking that at least 1 person from each site attend the monthly webinar and pass the information along to their team. Also, please send suggestions for topics you'd like discussed.

If you miss out on a webinar, you will soon be able to find the slides on the StrokeNet website (<https://nihstrokenet.org/intranet/minutes/trial-webinars>).



February has been a fantastic month for Sleep SMART! Forty-one subjects have been randomized this month surpassing our record of 36 subjects randomized December 2019.

As of February 27, 2020, 677 subjects have been enrolled and 233 subjects have been randomized.

The following sites remain at the top of our leader board for the most randomizations:

1. Brooks Rehabilitation Hospital, Jacksonville, FL-Parag Shah, MD and Taisiya Matev-25 subjects randomized
2. Prisma Health Midlands (Palmetto Health), Columbia, SC-Souvik Sen, MD and Phil Fleming-15 subjects randomized
3. Moses H. Cone Memorial Hospital, Greensboro, NC-Pramod Sethi, MD, Rizwan Sabir, and Glynda Reaves-14 subjects randomized
4. Sarasota Memorial Hospital, Sarasota, FL-Mauricio Concha, MD and Jeanette Wilson-13 subjects randomized
5. Barnes Jewish Hospital, St. Louis, MO-Eric Landsness, MD, Will Holt, and Jill Newgent-11 subjects randomized
6. University of Cincinnati, Cincinnati, Ohio-Sheva Coleman, MD and Sadie Caldwell-10 subjects randomized

Congratulations to the following 10 sites for randomizing their first subject in February:

1. Jackson Memorial Hospital, Miami, FL-Jose Romano, MD, Anny Rodriguez and Andrea Escobar
2. OSU Wexner Medical Center, Columbus, OH-Vivien Lee, MD, Luke Herren and Elizabeth Peters
3. University of Kentucky Hospital, Lexington, KY-Creed Pettigrew, MD and Pat Arnold
4. Buffalo General Medical Center, Buffalo, NY-Amit Kandel, MD and Annemarie Crumlish
5. Cox Medical Center, Springfield, MO-Jennifer Lynch, MD and Jessica Ratcliff
6. North Shore University Hospital, Manhasset, NY-Rohan Arora, MD and Leslie Wann
7. Greenville Hospital, Greenville, SC-Neel Shah, MD, Daniel Burch, and Ashley Pulido
8. Mission Hospital, Asheville, NC-Alex Schneider, MD and Tracy Nanney
9. Medical University of South Carolina, Charleston, SC-Christine Holmstedt, MD and Vicki Streets
10. John Muir Medical Center-Walnut Creek Campus, Walnut Creek, CA-Ok-Kyung Kim, MD and Melenie Aaron

Don't forget these important reminders:

1. KOEO and WebDCU do **NOT** communicate. Subjects should be always be added in WebDCU first! This will produce a subject ID that will then need to be entered in KOEO.
2. **All components** of the 3- and 6-month outcome assessments should be conducted by a **blinded** study team member.
3. Please continue to use the informed consent checklist at the time any new subject is enrolled. This checklist is available on our website: <https://www.nihstrokenet.org/sleep-smart-trial/research-team>.
4. Please remember to enter all subjects who meet criteria for enrollment, but decline participation, into WebDCU under Study Progress tab > Screen Failure Report.
5. Please remember to report AEs. If you need guidance, please refer to the Sleep SMART MOP. Please recall that the only AEs that should be reported between consent and randomization are:
 - All SAEs (fatal and non-fatal) that are definitely related or stand a reasonable possibility to be related to the Nox T3 sleep apnea test or the aCPAP run-in night procedures (within 5 days of event)
 - All non-serious AEs of special interest (see protocol 8.3.8) that are definitely related or stand a reasonable possibility to be related to the Nox T3 sleep apnea test or the aCPAP run-in night procedures (within 5 days of awareness of event)
 - Primary outcome events (ischemic stroke, ACS, and deaths) (within 5 days of awareness of event)

6. All responses to Data Clarification Requests (DCRs) must be submitted within 5 days of query generation, except those associated with Serious Adverse Events, which must be answered within 24 hours of query generation. Site payments are contingent upon the subject's data being entered, submitted, and all DCRs addressed.
7. Please review the [Data Collection Guidelines](#) for Sleep SMART located in project documents in WebDCU for how to complete CRFs. This should be the first place you look when you are not sure how to complete a form.
8. If the window for the 3-month visit ends and you have not been able to reach a subject, please continue to reach out to them until the 6-month window begins.
9. Don't forget to collect the IQCODE. This assessment should not be done by the patient. It should be completed by someone close to the subject.
10. The baseline NIH Stroke Scale should be done after the subject is enrolled.
11. Please remember to upload all CIRB Modification Letters to WebDCU in the CIRB Approved Administrative Amendments space holder.
12. All required site and people documents, including training, will need to be completed and uploaded in WebDCU before your site can be released to enroll. **Please continue to work diligently with your study teams on missing, expired or rejected documents.**

Save the dates—Our next PI and coordinator webinar will be Monday, March 23, 2020 from 1-2 EST and our next hands-on FusionHealth workshop will be held April 16, 2020 at the Airport Marriot in Atlanta. Detailed travel instructions have been sent to those selected to attend this workshop.



- **Congratulations to Dr. Josephine Huang and Jaya Vijayan at Mayo Clinic, Jacksonville, and Dr. Haitham Hussein and Jenny Koops at Regions Hospital, St. Paul for randomizing their second subjects this week!**
- **Congratulations to the following sites for being released to enroll this week!**
 - The University of Kentucky Hospital, Lexington, KY
 - WVU Healthcare Ruby Memorial Hospital, Morgantown, WV
 - Jackson Memorial Hospital, Miami, FL
- As of 27-Feb-2020, there are **24 subjects** randomized and **47 sites** released to enroll. We appreciate the continued effort towards of all sites preparing to be released to enroll.
- The MOST team would like to thank all that were able to make it to the MOST Coordinator Lunch as well as those who stopped by to view the MOST Poster during the ISC. It was great to see everyone!
- A special thanks and congratulations goes out to the following **16 sites** that met our goal and enrolled at least one subject prior to the ISC. You are MOST awesome!
 - Greenville Hospital System, Greenville, SC
 - Wake Forest Baptist Medical Center, Winston-Salem, NC
 - Saint Luke's Hospital of Kansas City, Kansas City, MO
 - Mayo Clinic, Jacksonville, FL
 - The Jewish Hospital, Cincinnati, OH
 - University of Cincinnati Medical Center, Cincinnati, OH
 - Houston Methodist Hospital, Houston, TX
 - Memorial Hermann Texas Medical Center, Houston, TX
 - Abington Memorial Hospital, Abington, PA
 - Regions Hospital, St Paul, MN
 - UCSD Medical Center - Hillcrest Hospital, San Diego, CA
 - University of Michigan University Hospital, Ann Arbor, M
 - Yale New Haven Hospital, New Haven, CT
 - Fairview Southdale Hospital, Edina, MN
 - Barnes Jewish Hospital, St. Louis, MO
 - Central DuPage Hospital, Winfield, IL
- **The PI hotline is available 24/7 for eligibility, safety or enrollment questions: 1-833-229-MOST**



We have **8** sites that are released to enroll and a total of **21** randomized subjects:

- Ann Arbor, MI - C.S. Mott Children's Hospital - **1** participant randomized
- Boston, MA - Boston Children's Hospital - **6** participants randomized
- Cincinnati, OH - Cincinnati Children's Hospital Medical Center - **3** participants randomized
- Columbus, OH - OSU Martha Morehouse Medical Plaza - **1** participant randomized
- La Jolla, CA - USC Health La Jolla - **4** participants randomized
- New Haven, CT - Yale New Haven Children's Hospital - **2** participants randomized
- Philadelphia, PA - Children's Hospital Of Philadelphia (CHOP)
- Roanoke, VA - Fralin Biomedical Research Institute - **4** participants randomized

Thank-you to all the sites they have been working hard!

Save the date – Our next PI/Co-I/Coordinator Webinar will be Thursday 19 March (12-1pm ET).



Reminder that our next PI and Coordinator call is scheduled for **Monday, March 2nd at 11am ET**. If anyone has topics they would like to discuss during the call, please send them to Kristina (kristina.balderson@duke.edu).

Moss Rehab, University of Kentucky, University Southern California, Medstar, Emory University, and University of Cincinnati continue to enroll. MUSC, Barnes Jewish, Burke, University of Texas, University Alabama, and Baystate open to enrollment! There are eleven subjects randomized in the trial. Two are in the intervention phase. Four have completed the study, five completed the intervention phase and are in the follow-up period. There are several patients being screened or scheduled for screening this month. Duke has received CIRB approval and we are working on adding UPMC and the Cleveland VA to the trial. They are working toward IRB approval. Keep the randomizations coming, TRANSPORT2 team! Thanks for all of your hard work!



Site Startup and Enrollment Updates: sites: **54**; enrollments: **138**

We are up to **138** patients, **39%** of our target, and have begun to accumulate 1-year follow up scans. Let's keep the enrollment going!

We had an excellent dinner meeting at the International Stroke Meeting in Los Angeles last Tuesday. Congratulations to **Mayo Rochester** for winning the CREST-H enrollment award, with a total of 9 enrollments in CREST-H, leading the pack. Runners up included Columbia and Kaiser LA with 8 each, and Novant, Main Medical, University of Iowa, and University Hospitals Cleveland tied for third with 7.

We are still recruiting additional sites. Contact Randy Marshall rsm2@columbia.edu, Ron Lazar rlazar@uabmc.edu, Jaya Vijayan vijayan.jaya@mayo.edu, or Kevin Slane KJS4@columbia.edu with any questions.



ARCADIA•CSI
Cognition & Silent Infarcts

If you haven't done so already, please submit your continuing review documents. The study will expire May 21, 2020 all documents need to be in by EOB February 28, 2020.

As of February 26, 2020, 38 subjects have been enrolled in CSI. Thank you to all of our sites who are working hard to get their CTAs and regulatory documents in.

The study team would like to give a shout out to our top 3 enrolling sites:

University of Iowa
Greenville Hospital System
University of Texas Health Science San Antonio

Thank you to all the sites that have consented and enrolled subjects over the past 2 weeks.

Congratulations to the new sites who are released to enroll:

- ✓ UH Cleveland Medical Center
- ✓ University of New Mexico Hospital

We now have 44 sites who have been released to enroll.

Important Reminders

- Please remember when you are seeing your ARCADIA subjects, don't forget about CSI!
- When a subject declines, state the reason in WebDCU

Please contact Tashia Harris, herndotl@ucmail.uc.edu or Stephanie Kemp, skemp@stanford.edu with any questions.



SATURN is very excited to begin enrollment next week! Several sites have both fully executed CTAs and cIRB approval and are being scheduled for Readiness calls beginning in February 2020.

Regulatory documents that required site action are due to be returned and uploaded to WebDCU ASAP. **Please address any outstanding regulatory documents at your site as soon as possible.**

RCC coordinators should follow up on all outstanding CTAs at this time. It is important to get your sites ready for release to enroll!

SATURN and ASPIRE are having a joint Investigator Meeting May 6th-7th at the TWA Hotel at JFK! Invitations went out this week.

Many study documents are posted on the WebDCU toolbox including regulatory documents, training materials, DRAFT CRFs and protocol appendices. Please remind your sites to utilize this valuable study resource.

If you have any questions regarding start-up please reach out to these contacts at the NCC:

Kimberlee Bernstein Project Manager gammk@ucmail.uc.edu

Wren Hanson Contracts hansonwm@ucmail.uc.edu


Emily Stinson Regulatory stinsoey@ucmail.uc.edu

Jen Golan Regulatory golanjl@ucmail.uc.edu



- Startup activities update:
 - Sites with an executed CTA: 83
 - Sites with CIRB approval: 73
 - Sites with CTA and CIRB approval: 63
 - Sites completed a readiness call: 35
 - Sites shipped study drug: 38
- First sites released to enroll will receive an email notification from WebDCU in the coming days!
- ASPIRE/SATURN Investigator Meeting May 6-7, 2020 at the TWA Hotel in New York – contact Laura Benken for any questions regarding this meeting, osinsklr@ucmail.uc.edu

From the CREST-2 Clinical Coordinating Center:

	CREST-2		CREST-2 StrokeNet
	CEA	863	375 (44% of total)
	CAS	779	133 (17% of total)
	Total	1642	508 (31% of total)

Congrats to Dr. Joe Rapp and team at the San Francisco VA for being the highest CREST-2 StrokeNet enroller this month!



**San Francisco VA
Health Care System** 

Continuing Review: It is time again to submit the CIRB continuing review for CREST-2. If you have received CIRB approval, the continuing review documents need to be submitted to the CIRB by **March 27th**. If you do not have CIRB approval yet, please disregard this message.

Please be on the lookout for an email from the CCC that outlines the required documents needed, which includes:

1. Updated StrokeNet COI forms from both CREST-2 and CREST-H team members
2. Completed research site continuing review form
3. De-identified copy of the last signed informed consent form
4. Current eDOA log generated and printed from WebDCU

The email will include additional information regarding these documents, as well as relevant attachments. These required documents will need to be submitted to your site manager by March 27th, who will then submit to the CIRB on your behalf.

Please note that due to the continuing review, the deadline for other submissions (adding/removing personnel, site specific consent changes, etc.) is **March 20, 2020**.

StrokeNet in the News!!!

I-ACQUIRE is a very newsworthy study! Take a moment to read this very interesting article in the Washington Post!

https://www.washingtonpost.com/health/some-infant-experience-strokes-in-utero-causing-physical-and-cognitive-problems-new-therapies-may-help/2020/02/21/25b1ca5a-3231-11ea-9313-6c8a89b1b9fb_story.html?itid=sf_health

Steering Committee Call

*Steering Committee Calls are a requirement for all NIH StrokeNet RCCs
(one representative per RCC required)*

The next Steering Committee call is scheduled for **11-March, 2020, at 12 noon ET**. Dial in: 513-621-0220; 1-877-621-0220; Passcode 434578.

Coordinator Webinar

Coordinator Webinars are a requirement for the NIH StrokeNet RCC Coordinators/Managers

Wednesday, February 26, 2020 - 1:30 PM ET

Topic: SATURN Trial Presentation

Presenters: Magdy Selim, MD, PhD – Beth Israel Deaconess Medical Center, Harvard Medical School
Kimberlee Bernstein, BS, CCRP – University of Cincinnati
Sarah Marchina, PhD - Beth Israel Deaconess Medical Center, Harvard Medical School

Moderator: David Haney, RT, Case Western Reserve University

To join the meeting: <https://nihstroketnet.adobeconnect.com/coordinator/>

Please enter as a guest, then your email address or your first and last name.

To take part in the conversation you MUST dial in. (877) 621-0220; Passcode: 434578

Professional Development Webinar

Professional Development Webinars are a requirement for the NIH StrokeNet Trainees

Presenters: 1:00 – 1:30 Kunakorn Atchaneeyasakul, MD
Intravenous tPA Delays Door-To-Puncture Time in Acute Ischemic Stroke with Large Vessel Occlusion
1:30 – 2:00 Ivy Nguyen, MD
Clinical Prediction Model for Recurrent Stroke in Patients with Symptomatic Intracranial Stenosis
2:00 – 2:30 Liming Dong, PhD
Prevalence and Course of Depression During the First Year After Stroke
Moderator: Harold Adams, MD

To join the meeting: <https://nihstrokenet.adobeconnect.com/pdw/>. Please enter as a guest, then your email address or your first and last name.

To take part in the conversation you MUST dial-in. (877) 621-0220 Passcode: 190825

Grand Rounds

Grand Rounds are a requirement for the NIH StrokeNet Trainees, however all are welcome to participate.

Wednesday, February 26, 2020 - 3:00 PM ET

Topic: Stroke Outreach to Underserved Communities – How to Make an Impact

Presenters: Olajide Williams, MD, Columbia University

Moderator: Cemal Sozener, MD, University of Michigan

To join the meeting: <https://nihstrokenet.adobeconnect.com/grandrounds/>. Please enter as a guest, then your email address or your first and last name.

To take part in the conversation you MUST dial-in. (877) 621-0220 Passcode: 190825

StrokeNet Regulatory Update

Site Binder Guidance for StrokeNet Studies:

The NIH StrokeNet National Coordinating Center has the following Standard Operating Procedures related to maintaining and storing onsite regulatory binders:

- ADM 2 Reporting COI and Financial Disclosures
- ADM 16 Network Process for Trial “Master” and “Site” Regulatory file Management
- ADM 21 Regulatory and Clinical Data Maintenance and Data Storage
- GCP 12 Regulatory and Clinical Trial Data Maintenance Storage

These SOPs can be found on the StrokeNet Website - https://nihstrokenet.org/sop_gcp. Please take a few minutes to review these SOPs. Feel free to contact Jen Golan (golanil@ucmail.uc.edu) or Emily Stinson (stinsoey@ucmail.uc.edu) with any questions. Thank you!

Reminder: Feasibility Survey Due Date

Just a reminder, the last day to complete the SATURN MRI feasibility survey is **Wednesday, 11-March**, by 11:59pm ET. Any questions, please contact Logan Sirline at sirline@musc.edu. ***PLEASE make it a priority to complete the survey and send the excel spreadsheet to Logan by the deadline.**

NINDS News

The National Institute of Neurological Disorders and Stroke (NINDS), and National Institutes of Health (NIH) recently assembled an external working group of international experts to update the Stroke v1.0 Common Data Elements (CDEs) based on user feedback and research advances. The updated and new documents are now available on the [NINDS CDE website](#) from **February 26, 2020 to April 8, 2020** for feedback from the stroke research and practice community. We hope you will take the time to review the draft CDEs and provide your comments prior to the general release.

To access and review the CDE recommendations please go to the website: <https://www.commondataelements.ninds.nih.gov/Stroke>

Please feel free to review and provide comments on as many domains as you wish. We look forward to your feedback and ask you to please submit your comments by **April 8, 2020**.

We hope that you will share this announcement with your colleagues and encourage them to provide feedback as well. Thank you for your time.

NIH StrokeNet Employment Opportunities

StrokeNet National Coordinating Center Project Manager - FASTEST

The NIH StrokeNet NCC is looking for a Project Manager for the FASTEST trial – a global trial -- spanning the U.S., Canada, Germany, Spain, the U.K., and Japan; approximately 130 sites, including mobile stroke units; and approximately 860 subjects -- evaluating the use of recombinant factor VIIa to treat patients with spontaneous

intracerebral hemorrhage within two hours of stroke onset/last known well. The trial will utilize exception from informed consent.

For detailed information about the position, and to apply, please visit <https://jobs.uc.edu/> and reference requisition number 44802.

For more information about StrokeNet employment opportunities, please visit <http://nihstrokenet.org/education/employment-opportunities>

Please share this with your clinical performing and satellite sites!

Contact: Jamey Frasure, PhD, RN, Director · NIH StrokeNet Coordinating Center · frasurejs@ucmail.uc.edu · 513-558-1742/<https://www.nihstrokenet.org>