



Biweekly Update 17-January 2020

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

StrokeNet Enrollment Update			
ARCADIA	397/1100	CREST 2	1604/2480
Sleep SMART	172/3062	CREST H	129/500
TRANSPORT2	6/129	MOST	8/1200
I-ACQUIRE	12/240	ARCADIA-CSI	22/500

StrokeNet Trial Updates



Looking forward to ISC ARCADIA presentations and posters next month!

See the ARCADIA newsletter sent this week for details.

As of January 16, 2020, 1547 subjects have been consented and 397 participants randomized at 95 sites. This is an increase of 51 consented and 8 subjects randomized during the first few weeks of the year. Our enrollment is at 36.1% of the overall goal.

Thank you to the 39 sites that consented and 7 sites that randomized subjects in the last two weeks. And a special congratulations to the first VA site to randomize a subject in a StrokeNet trial – thank you VA Puget Sound Health Care System, WA!

We have now released to enroll a total of 140 sites, 131 are active, and we are still working on adding other qualified sites to the ARCADIA roster. 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 January 28th 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>).

ISC get together: We also look forward to seeing everyone at the International Stroke Conference, where ARCADIA will be participating with the other StrokeNet trial groups in an evening social gathering. See the newsletter for details.



Sleep SMART is off to a great start in 2020! Twelve subjects randomized since the beginning of the year.

As of January 15, 2020, 527 subjects have been enrolled and 172 subjects have been randomized.

Congratulations to the following sites with the most randomizations:

1. Brooks Rehabilitation Hospital, Jacksonville, FL-Parag Shah, MD and Taisiya Matev-19 subjects randomized
2. Sarasota Memorial Hospital, Sarasota, FL-Mauricio Concha, MD and Jeanette Wilson-13 subjects randomized
3. Prisma Health Midlands (Palmetto Health), Columbia, SC-Souvik Sen, MD and Phil Fleming-12 subjects randomized

There is a 2-way tie for 4th place between the following sites:

- Barnes Jewish Hospital, St. Louis, MO-Eric Landsness, MD, Will Holt, and Jill Newgent-9 subjects randomized
- Moses H. Cone Memorial Hospital, Greensboro, NC-Pramod Sethi, MD, Rizwan Sabir, and Glynda Reaves-9 subjects randomized

A special thanks goes out to the Sarasota Memorial Hospital team for their Christmas Day randomization!

The CIRB has voiced concern with the number of protocol deviations that have been reported related to deficiencies with the informed consent process and has asked us to provide a corrective action plan (CAP) that describes how we will provide clinical performing sites with additional training on the informed consent process. All site PIs and primary study coordinators are required to review the StrokeNet ICF training powerpoint slides that were sent by email on 1/16/2020 and provide attestation by 1/31/2020.

Don't forget these important reminders:

1. Please remember to enter all subjects who meet criteria for enrollment, but decline participation, into WebDCU under Study Progress tab > Screen Failure Report.
2. Please consult the informed consent checklist at the time any new subject is enrolled. This checklist was sent by email to participating sites on 1/16/2020.
3. 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 awareness of event for non-fatal; within 24 hours of awareness for fatal)
 - 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 and ACS) (within 5 days of awareness of event)
4. 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.
5. 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.
6. 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.

7. 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.
8. The baseline NIH Stroke Scale should be done after the subject is enrolled.
9. All required people documents, including training, will need to be completed and uploaded in WebDCU before your site can be released to enroll.

We are looking forward to our next hands-on FusionHealth workshop scheduled to take place on January 23, 2020. We will also be hosting two additional workshops later in the year.

Save the date-Our next PI and coordinator webinar will be Monday, January 27, 2020 from 1-2 EST. You should have already received a meeting invite. Please let Kayla or Joelle know if you have not received the invite.



The study team would like to thank all of our sites for working hard.

We now have 22 subjects enrolled!

ARCADIA•CSI
Cognition & Silent Infarcts

Congratulations to the new sites who are released to enroll:

- ✓ Henry Ford Hospital
- ✓ Memorial Hermann Texas Medical Center
- ✓ Tufts Medical Center
- ✓ Maimonides Medical Center
- ✓ Los Angeles County + USC Medical Center
- ✓ Mercy Health Saint Mary's
- ✓ Keck Hospital of USC
- ✓ Oschner Medical Center
- ✓ University of Miami Hospital

We now have 30 sites who have been released to enroll.

The study team would also like to congratulate the following sites who can now schedule their readiness calls:

- ✓ University of Wisconsin Hospital
- ✓ University of Mississippi Medical Center
- ✓ The Ohio State University Wexner Medical Center
- ✓ University of Cincinnati

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

We look forward to working with each of you as the study progresses.



Reminder that our next PI and Coordinator call is scheduled for **Monday, January 21st at 11am ET**. If anyone has topics they would like to discuss during the call, please send them to Kristina (kristina.balderson@duke.edu).

We are very excited that MUSC, University of Kentucky, Barnes Jewish, Burke, Emory University, Moss Rehab, University of Texas, University of Cincinnati, University Alabama, University Southern California, Baystate and Medstar are open to enrollment! There are six subjects randomized in the trial. Five have completed the intervention phase. There are four in the follow-up period. One has completed the study. There are several patients being screened or scheduled for screening this month. We are working on adding three new sites to the trial and they are working toward CIRB approval. We are excited for all of the recent activity and hope to have a new enrollment very soon. Keep the randomizations coming, TRANSPORT2 team! Thanks for all of your hard work!

Site Startup and Enrollment Updates: sites: **54**; enrollments: **129**


Welcome to Banner Health U Arizona!

ENROLLMENT TIPS:

Discuss CREST-H during the CREST-2 enrollment process. Patients love to hear about cognition and the possibility of obtaining more information about brain blood flow (and the extra \$100 to participate doesn't hurt). Consent for CREST-H can be signed **on the day of randomization into CREST-2**. Otherwise you can get **verbal** consent to participate in CREST-H during the CREST-2 enrollment, schedule the CREST-H perfusion scan (**MRP** or **CTP**), and have the patient sign the consent when they arrive for their appointment at the scanner.

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.

From the CREST-2 Clinical Coordinating Center:

	CREST-2		CREST-2 StrokeNet
	CEA	849	370 (44% of total)
	CAS	764	130 (17% of total)
	Total	1604	501 (31% of total)

Recruitment: Happy New Year! CREST-2 needs StrokeNet. As we move into the next year of CREST-2, please keep in mind our recruitment milestone of **1700** by **February 29, 2020**. We need **87** patients left and **33** days left to go. We know that with your support, we can accomplish this incredible milestone. If you need any help with recruitment resources, please reach out to the CREST-2 Clinical Coordinating Center.

Thank you to the CREST-2 team at Oregon Health & Science University for being the highest StrokeNet enroller with 15 patients being randomized in 2019!



Pictured: Wayne Clark, MD, CREST-2 Site PI; Jon Foley, CREST-2 coordinator

Congratulations Dr. Clark, Jon, and the rest of the CREST-2 team at Oregon Health & Science University!



We now have **7** sites that are released to enroll and a total of **12** randomized subjects:

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

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

Save the date – Our next PI/Co-I/Coordinator Webinar will be Thursday 23 January (12-1pm ET).



- The MOST Study Team would like to wish everyone a Happy New Year!
- Congratulations to **Mayo Clinic Jacksonville** for randomizing the first subject in 2020 and congratulations to **NYP Weill Cornell Medical Center** for being the first site released to enroll in 2020!
- Thank you to the following sites that have also been released to enroll in 2020:
 - o St. John Medical Center, Tulsa, OK
 - o Loyola University Medical Center, Maywood, IL
 - o Regions Hospital, St Paul, MN
 - o UCSF Medical Center, San Francisco, CA
- The MOST team is looking forward to seeing you at the **International Stroke Conference** next month:

MOST Coordinator Lunch Meeting Wednesday, February 19, 2020 12:00 – 2:00 PM PT JW Marriott at LA Live Platinum F-G <i>*RSVP to Iris Deeds no later than 31-Jan-2020 (deedsss@uc.edu)</i>	StrokeNet Social Hour Wednesday, February 19, 2020 6:30 – 8:30 PM PT JW Marriott at LA Live Platinum F-G <i>*RSVP to Iris Deeds no later than 31-Jan-2020 (deedsss@uc.edu)</i>	MOST Poster Thursday, February 20, 2020 6:30 – 7:00 PM PT Los Angeles Convention Center Hall H
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- As of 17-Jan-2020 there are **8 subjects** randomized and **29 sites** released to enroll. We appreciate the continued effort towards enrolling at least one patient before the ISC! The PI hotline is available 24/7 for eligibility, safety or enrollment questions: **1-833-229-MOST**.

It Just Makes Sense...

If your provider offers free long distance, please use the toll number (1-513-621-0220) when dialing in to the StrokeNet conference line. Use the toll-free number (1-877-621-0220) only when necessary.

Feasibility Survey Reminder

The feasibility survey for the VERIFY trial proposal must be completed in the WebDCU™ **by 11:59pm ET on Friday, January 31st.** ***PLEASE NOTE:** If the survey is not applicable for a particular site, the survey should not be completed.

If you have any questions, please contact Logan Sirline at the National Data Management Center, sirline@musc.edu.

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 **12-February, 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, January 22, 2020 - 1:30 PM ET

Topic: Study Updates 2020

Moderator: David Haney, RT, Case Western Reserve University

To join the meeting: <https://nihstrokenet.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

January Trainee presentations are TBA

Grand Rounds

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

Thursday, January 30, 2020 - 4:00 PM ET

Topic: Antiplatelets and the Clinical Implications of CHANCE and POINT

Presenters: Dawn Meyer, PhD, University of California San Diego

Moderator: Shyam Prabhakaran, MD, University of Chicago

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 Meeting Information

There will be a StrokeNet social gathering at the JW Marriott in Los Angeles on Wednesday, 19-February, from 6:30-8:30pm. As in past years, there will be a cash bar. Space is limited. Please RSVP to your study Project Manager or Rose ASAP. RSVPs must be in by **30-January, 2020**.

NINDS News

Upcoming NIH Seminars

Each year, the Office of Extramural Research (OER) sponsors the NIH Regional Seminars on Program Funding and Grants Administration. These seminars are intended to help demystify the application and review process, clarify Federal regulations and policies, and highlight current areas of special interest or concern. The seminars serve the NIH mission of providing education and training for the next generation of biomedical and behavioral scientist. NIH policy, grants management, review and program staff provide a broad array of expertise and encourage personal interaction between themselves and seminar participants. The seminars are appropriate for grants administrators, researchers new to NIH, and graduate students.

DATES	LOCATION	AMBASSADORS	PROGRAM INFO
April 20-22, 2020	Baltimore, MD	<ul style="list-style-type: none"> Johns Hopkins University School of Medicine University of Maryland, Baltimore County 	<p>REGISTRATION NOW OPEN!</p> <p>Venue: Renaissance Harborplace Hotel - Welcome Page https://regionalseminars.od.nih.gov/baltimore2020/welcome/</p> <p>Room Block: Great rates in the seminar room block. Get yours before they fill up. For more information, please visit https://regionalseminars.od.nih.gov/baltimore2020/hoteltravel/</p> <p>Note: The ListServ information below is also a great way to receive the latest updates!</p>
October 28-30, 2020	Nashville, TN	<ul style="list-style-type: none"> Tennessee State University 	<p>REGISTRATION OPENS LATE JANUARY!</p> <p>Check back for the link and more information as it becomes available!</p>

Updated Grant Application Instructions and Forms Coming in Spring 2020

NIH will require the use of updated application forms and instructions (FORMS-F) for due dates on or after May 25, 2020 ([NOT-OD-20-026](#)). A [preview of form changes](#) and clarification of how the changes impact research training grant, fellowship, and career development award applications ([NOT-OD-20-033](#)) are already available. Additional details will be posted early next year.

In the meantime, continue to use FORMS-E application packages for due dates on or before May 24, 2020 despite the expiration dates noted on each form. The NINDS is working with the Office of Management and Budget to renew forms and new expiration dates will be reflected when the FORMS-F application packages are posted.

What to Do if a Due Date Falls on a Weekend or NIH Holiday?

With the winter season upon us, remember that when a due date falls on a weekend, Federal holiday, or when Washington, D.C.-area Federal offices close (due to severe weather, for example), the application deadline is automatically **extended to the next business day**.

If you suspect Federal offices in D.C. are closed due to severe weather you can check OPM.gov to verify. Only when Federal offices in the Washington, D.C. area are listed as "Operating Status: CLOSED" is the application deadline automatically extended to the next day. See NIH Guide Notice NOT-OD-17-041 for additional details.

If your local winter weather is severe and results in the closure of your institution, then NIH submission policies regarding weather/other disasters apply.

NIH StrokeNet Employment Opportunities

Program Name: SUNY Health Science Center at Brooklyn Program
Director Name: Nikolaos Papamitsakis, MD
Sponsoring Institution: SUNY Health Science Center at Brooklyn
ACGME Code: 1883521080
Specialty: Vascular Neurology
Address: SUNY Downstate Med Center
Vascular Neurology Program Box 1274
450 Clarkson Ave, MSC 1213
Brooklyn, NY 11203

Contact info: Marjorie Maxwell (marjorie.maxwell@downstate.edu; T 718-270-4232; F 718-221-5761)

Program description: SUNY Downstate department of neurology offers a one-year ACGME accredited vascular neurology fellowship, with an optional second-year of clinical research. We are a major academic center in the New York City area, and the training site for the only medical school in Brooklyn. Training for the fellowship occurs at the University Hospital of Brooklyn (UHB), the Kings County Hospital (KCH) and Maimonides Medical Center (MMC). The stroke fellows provide acute stroke care in the inpatient setting, and are integral members of the outpatient stroke clinic. They also provide teaching to neurology residents and medical students. The stroke division participates in several clinical trials, offering ample opportunities for clinical research. We have currently one available stroke fellowship position starting on 7/1/2021.

*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 · frasurjs@ucmail.uc.edu ·
513-558-1742
<https://www.nihstrokenet.org>*