http://nihstrokenet.org/coming-events

StrokeNet Enrollment Update

ARCADIA	406/1100	CREST 2	1604/2480
Sleep SMART	188/3062	CREST H	129/500
TRANSPORT2	7/129	MOST	14/1200
I-ACQUIRE	14/240	ARCADIA-CSI	27/500

StrokeNet Trial Updates

Looking forward to ISC ARCADIA presentations and posters next month!

As of January 30, 2020, 1581 subjects have been consented and 406 participants randomized at 97 sites. This is an increase of 34 consented and 9 subjects randomized during the last two few weeks of January. Our enrollment is at 36.9% of the overall goal.

Thank you to the 30 sites that consented and 9 sites that randomized subjects in the last two weeks. A special congratulations to the University of New Mexico Hospital and the Mayo Jacksonville teams for randomizing their first subjects! You helped us reach and now surpass the 400th randomization!

Enrollment has been going strong at the top enrolling sites: United Hospital has 15 randomizations, University of Minnesota Medical Center Hospital has 14, the University of Cincinnati which has 13 and Emory has been gaining ground with 12 randomizations. Thank you all for your dedication and leadership! We need everyone to keep enrolling and follow their example to make ARCADIA a success.

We have now released to enroll a total of 140 sites, 132 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 February 25th 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 & ARCADIA: We 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 hour:

- **Wednesday, 19-Feb, at the JW Marriott, Room Platinum E/F from 6:30-8:30pm.**

We also have presentations/posters – come by and see what your efforts have helped produce:

- **Wednesday, February 19, 2020 @ 09:33 AM - Room 515A**
  - **Platform Presentation:** Mitch Elkind MD - Predictors of Atrial Cardiopathy Among Patients In the ARCADIA Trial: An Analysis of the First 924 Patients
    - This is part of Session A4: Diagnosis of Stroke Etiology Oral Abstracts 0845 - 1015 am
      - There will be other presentations related to ESUS and atrial cardiopathy at this session.
- **Thursday, February 20, 2020 @ 6:30 - 7:00 pm - Hall H –**
  - **Ongoing Clinical Trials Posters II:** Hooman Kamel MD - Atrial Cardiopathy and Antithrombotic Drugs in Prevention After Cryptogenic Stroke
- **2 Additional ARCADIA posters – information to follow**

Sleep SMART

As of January 29, 2020, 569 subjects have been enrolled and 188 subjects have been randomized.

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

1. Brooks Rehabilitation Hospital, Jacksonville, FL-Parag Shah, MD and Taisiya Matev-20 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-13 subjects randomized
4. Barnes Jewish Hospital, St. Louis, MO-Eric Landsness, MD, Will Holt, and Jill Newgent-11 subjects randomized
5. Moses H. Cone Memorial Hospital, Greensboro, NC-Pramod Sethi, MD, Rizwan Sabir, and Glynda Reaves-11 subjects randomized

Thanks to everyone who attended our second of four hands-on FusionHealth workshops on January 23, 2020. Hopefully, you found it to be extremely beneficial! The next workshop will be held April 16, 2020 at the Airport Marriot in Atlanta. Kayla will be sending an email invite soon.

Don't forget these important reminders:

1. **All components** of the 3- and 6-month outcome assessments should be conducted by a **blinded** study team member.
2. Please use 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 and is available on our website: https://www.nihstrokenet.org/sleep-smart-trial/research-team. This will help avoid consent errors. Common errors include: misuse of an LAR, lack of a witness when needed, use of non-IRB-stamped consent, consent conducted by personnel not listed on DOA.
3. Please remember to enter all subjects who meet criteria for enrollment, but decline participation, into WebDCU under Study Progress tab > Screen Failure Report.
4. 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, ACS, and deaths) (within 5 days of awareness of event)
5. 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.
6. 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.
7. 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.
8. 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.
9. The baseline NIH Stroke Scale should be done after the subject is enrolled.
10. All required 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 to complete the required tasks.

Save the date-Our next PI and coordinator webinar will be Monday, February 24, 2020 from 1-2 EST.

- Congratulations to **UCSD Medical Center, San Diego, CA** and **Regions Hospital, St. Paul, MN** for randomizing their first subjects.
- Thank you to the following sites that have been released to enroll:
  o UVA Medical Center, Charlottesville, VA
  o Massachusetts General Hospital, Boston, MA
  o Central DuPage Hospital, Winfield, IL
- The MOST team is looking forward to seeing you at the **International Stroke Conference** next month:

MOST Coordinator Lunch Meeting	StrokeNet Social Hour	MOST Poster
Wednesday, February 19, 2020 12:00 – 2:00 PM PT JW Marriott at LA Live Platinum F-G *RSVP to Iris Deeds no later than 31-Jan-2020 (deedsss@uc.edu)	Wednesday, February 19, 2020 6:30 – 8:30 PM PT JW Marriott at LA Live Platinum F-G *RSVP to Iris Deeds no later than 31-Jan-2020 (deedsss@uc.edu)	Thursday, February 20, 2020 6:30 – 7:00 PM PT Los Angeles Convention Center Hall H

- As of 27-Jan-2020 there are **14 subjects** randomized and **32 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**.

Congratulations to the I-ACQUIRE New Haven site for randomizing their first participant this week!

We now have **7** sites that are released to enroll and a total of **14** 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** participant randomized
- Columbus, OH - OSU Martha Morehouse Medical Plaza
- New Haven, CT - Yale New Haven Children's Hospital - **1** participant randomized
- Philadelphia, PA - Children's Hospital Of Philadelphia (CHOP)
- Roanoke, VA - Fralin Biomedical Research Institute - **3** 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 27 February (12-1pm ET).

Reminder that our next PI and Coordinator call is scheduled for **Monday, February 3rd 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 seven subjects randomized in the trial. six have completed the intervention phase. There are five 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!

CREST-H

<u>Site Startup and Enrollment Updates</u>: sites: **54**; enrollments: **130**

We are up to **130** patients, **37%** of our target, and have begun to accumulate 1-year follow up scans. Let's keep the enrollment going!
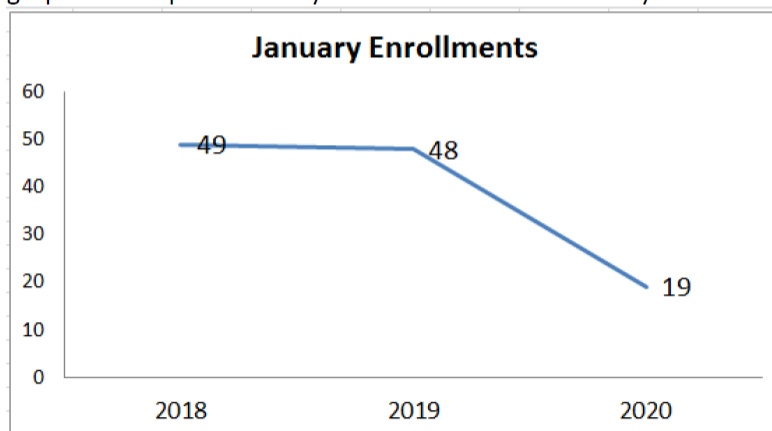
ENROLLMENT TIPS:
Discuss CREST-H during the CREST-2 enrollment process. Patients love to hear about cognition and the possibility of obtaining more information about brain blood flow (and the extra $100 to participate doesn't hurt). Consent for CREST-H can be signed **on the day of randomization into 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.

<u>From the CREST-2 Clinical Coordinating Center</u>:

	CREST-2	**CREST-2 StrokeNet**
CEA	854	370 (43% of total)
CAS	769	131 (17% of total)
Total	**1623**	**501 (31% of total)**

<u>Recruitment:</u> **CREST-2 needs StrokeNet.** Our recruitment milestone is **1700** by **February 29, 2020**. We need **77** patients with **22** days left to go. Please see below the graph that depicts January enrollments for the last 3 years – a worrisome trend.

January Enrollments

The Clinical Coordinating Center will be sending a survey out to all CREST-2 coordinators to get a better idea of recruitment challenges at your site. We strongly encourage your participation and feedback... and **we need some new enrollment tactics** that will further the success of CREST-2. Please keep an eye out for an email from Dr. Brott regarding this survey.

SATURN 🪐

SATURN is very excited to continue study start-up! 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 were due to be returned and uploaded to WebDCU by January 24th 2020. Please address any outstanding regulatory documents at your sites 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! We anticipate enrollment to begin March 2020.

SATURN and ASPIRE are having a joint Investigator Meeting! Save the date to go out soon!

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

ASPIRE

- 80 Sites with CTA in place, 59 sites with cIRB approval.
- Readiness Calles have been completed with 12 sites.
- Study Drug will start being shipped to sites the week of February 3, 2020.
- ASPIRE and SATURN will be holding a joint investigator meeting. A save the date will be sent out to participating sites shortly.

ARCADIA•CSI
Cognition & Silent Infarcts

ARCADIA-CSI has enrolled 27 subjects overall, and ten subjects in the month of January. Keep up the great work!

The following new sites have been released to enroll:

➢ OSU Wexner Medical Center, Columbus, OH
➢ UMASS Memorial Medical Center, Worcester, MA
➢ Utah Valley Regional Medical Center, Provo, UT
➢ Hartford Hospital, Hartford, CT
➢ Beth Israel Deaconess Medical Center, Boston, MA
➢ Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA
➢ Chandler Regional Medical Center, Chandler, AZ

Please stop by the StrokeNet Social Hour at the JW Marriott on Wednesday, 19-February, anytime between 6:30-8:30pm, if you are attending the ISC. We would love to say "thanks!" in person!

Site Payment Information

The primary study coordinator at your site can request access to the WebDCU™ payment module information for your site personnel by requesting they be added to the "Site Financial Manager" user group. A request can be made via the [User Permission Request] table in WebDCU™ or you can send an email to the trial-specific DCU Data Manager to request this access. To have access to this user group, the person does NOT need to be on the site DOA.

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. The call will include a webinar discussion in regard to the agenda for the February 18th EVT Platform Workshop.

To join the meeting: **https://nihstrokenet.adobeconnect.com/steering/**

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://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

The next PDW is scheduled for 10-February. Look for an email from Jeanne Sester with details.

Grand Rounds

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

Thursday, February 27, 2020 - 4:00 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 <u>MUST</u> dial-in. (877) 621-0220 Passcode: 190825

StrokeNet Meeting Information

The **EVT Platform Workshop** organized by the NINDS will be held on Tuesday, 18-February, 2020, at the JW Marriott, from 3-5:30pm PT, in Plaza I. SPACE IS LIMITED due to the size of the room, so **please RSVP** to Rose by 7-February, at the latest.

There will be a StrokeNet social gathering at the JW Marriott in Los Angeles on Wednesday, 19-February, from 6:30-8:30pm in Salons F-G. As in past years, there will be a cash bar. Please RSVP to your study Project Manager or Rose ASAP. For planning purposes, please RSVP ASAP!

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	• Johns Hopkins University School of Medicine • University of Maryland, Baltimore County	**REGISTRATION NOW OPEN!** **Venue:** Renaissance Harborplace Hotel - Welcome Page https://regionalseminars.od.nih.gov/baltimore2020/welcome/ **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/ **Note:** The ListServ information below is also a great way to receive the latest updates!
October 28-30, 2020	Nashville, TN	• Tennessee State University	**REGISTRATION OPENS LATE JANUARY!** Check back for the link and more information as it becomes available!

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