http://nihstrokenet.org/coming-events

## StrokeNet Enrollment Update

| | | | |
|---|---|---|---|
| ARCADIA | 373/1100 | CREST 2 | 1590/2480 |
| Sleep SMART | 131/3062 | CREST H | 118/500 |
| TRANSPORT2 | 5/129 | MOST | 3/1200 |
| I-ACQUIRE | 9/240 | ARCADIA-CSI | 6/500 |

# StrokeNet Trial Updates

## ARCADIA

**Happy Holidays to All!**

As of December 5, 2019, 1433 subjects have been consented and 373 participants randomized at 94 sites. This is an increase of 39 consented and 9 subjects randomized in the past two weeks. Our enrollment is at 33.9% of the overall enrollment goal. Our randomization rate is at **0.19** patients/active sites/month.

**Thank you to the 23 sites that consented and 9 sites that randomized subjects in the last two weeks despite the holiday time off!**

The competition on the leader board is ongoing. United Hospital has 14 randomizations and continues to stay ahead of University of Cincinnati which has 12 randomized subjects. Memorial Hermann Texas Medical Center is in 3rd place with 11 randomizations and the University of Minnesota Medical Center, Oregon Health & Science University Hospital, Portland, OR and University of Iowa take 4th place with 10 randomized subjects a piece. Thank you all for your dedication and leadership!

We have now released to enroll a total of 137 sites, 128 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.

We're also in the process of adding 20-30 Canadian sites. These sites have enrolled in other ESUS trials and we're looking forward to bringing them onboard as soon as possible.

The CIRB continuing review has been completed and Pam has sent all sites their documents. Please make sure that you upload your new documents onto WebDCU.

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**: We will not have a webinar in December. Our next PI and coordinator webinar will be next year on 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).

Sleep SMART

As of December 5, 2019, 425 subjects have been enrolled and 131 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-14 subjects randomized
2. Sarasota Memorial Hospital, Sarasota, FL-Mauricio Concha, MD and Jeanette Wilson-12 subjects randomized
3. Prisma Health Midlands (Palmetto Health), Columbia, SC-Souvik Sen, MD and Phil Fleming-11 subjects randomized
4. Barnes Jewish Hospital, St. Louis, MO-Eric Landsness, MD, Will Holt, and Jill Newgent-9 subjects randomized
5. Cedars-Sinai Medical Center, Los Angeles, CA-Oana Dumitrascu, MD and Vicki Manoukian-6 subjects randomized
6. Moses H. Cone Memorial Hospital, Greensboro, NC-Pramod Sethi, MD, Rizwan Sabir, and Glynda Reaves- 6 subjects randomized

We also want to congratulate Henry Ford Hospital, Detroit, MI-Angelos Katramados and Teresa Wiegand for randomizing five (5) out of five (5) subjects enrolled.

Our first FusionHealth workshop took place on November 6, 2019 and was well received by all attendees. The next scheduled FusionHealth workshop will take place on January 23, 2020. We will also be hosting two additional workshops later in the year.

**Important reminders:**

1. A good number of sites eager to participate in Sleep SMART are not yet released for enrollment. Reasons vary, but barriers appear to include approvals at required administrative, legal or budget offices. If your site is in this situation, the Sleep SMART PIs are glad to speak to your site PI and research team to help brainstorm solutions for barriers you are facing. If you are interested, please contact Ms. Kayla Novitski, Prime Site Project Manager, at kcgossel@med.umich.edu to schedule a good time for the phone conference.
2. Please remember to enter all subjects who meet criteria for enrollment, but decline participation, into WebDCU under Study Progress tab > Screen Failure Report.
3. Please remember to enter AEs, SAEs, and protocol deviations/violations into WebDCU as appropriate. If you have questions about what needs to be reported as an AE, SAE, and/or unanticipated event please reach out to Kayla or Joelle.
4. All required people documents, including training, will need to be completed and uploaded in WebDCU before your site can be released to enroll.

**Save the date**-Our next PI and coordinator webinar will be Monday, December 16th from 1-2 EST.

# I-ACQUIRE

The I-ACQUIRE team would like to welcome the following Clinical Performing Site who will be replacing a site:

- Birmingham, AL – Children's Hospital of Alabama; PI: Tony McGrath, MD

We now have **5** sites that are released to enroll and a total of **9** randomized subjects:

- Roanoke, VA - Fralin Biomedical Research Institute - **3** participants randomized
- Columbus, OH - OSU Martha Morehouse Medical Plaza
- Boston, MA - Boston Children's Hospital - **5** participants randomized
- Cincinnati, OH - Cincinnati Children's Hospital Medical Center - **1** participant randomized
- Philadelphia, PA - Children's Hospital Of Philadelphia (CHOP)

Thank-you to all of our sites, they have been working hard!

**Save the date** – Our next PI/Co-I/Coordinator Webinar will be Wednesday, December 18 from 1-2PM ET.

Reminder that our next PI and Coordinator call is scheduled for **Monday, December 16th 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 **Five** subjects randomized in the trial. Four have completed the intervention phase and are in the follow-up period. There are several patients being screened or scheduled for screening this month. We are pleased that our new fully executed CTAs have been completed for MUSC, University of Kentucky, Barnes Jewish, Burke, Emory University, Moss Rehab, University of Texas, University of Cincinnati, University Southern California, Baystate and Medstar! We are very excited for all of the recent activity and hope to have a new enrollment very soon. Keep the randomizations coming, TRANSPORT2 team!

The study team would like to thank all of our sites for working hard to get ARCADIA-CSI up and enrolling!

Congratulations to UCSD Hillcrest and University of Iowa for enrolling their first subject!

Congratulations to the new sites who are released to enroll:

- ✓ Stanford University
- ✓ MUSC

We now have 6 subjects enrolled and 16 sites who have been released to enroll.

The study team would also like to congratulate the following sites for scheduling their readiness calls:

- ✓ Tufts Medical Center
- ✓ University of Miami Hospital
- ✓ Sanford Medical Center
- ✓ North Shore University Hospital
- ✓ Harborview Medical Center

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

- The MOST team would like to thank and acknowledge the following sites that have recently been released to enroll study participants. There are now 17 enrolling sites!
    - o Mercy Anderson, Cincinnati, OH
    - o Medical University of South Carolina University Hospital, Charleston, SC
    - o The Jewish Hospital, Cincinnati, OH
    - o Yale New Haven Hospital, New Haven, CT
    - o Abington Memorial Hospital, Abington, PA

- We have enrolled 3 participants so far and are looking forward to the 4th enrollment!

- Thank you for everyone's outstanding work preparing for enrollment. Our goal is to have all sites released to enroll by 31-Jan-2020.

**CREST-H**

**Site Startup and Enrollment Updates:** sites: **53**; enrollments: **118**

Welcome to our latest Green lighted center: San Francisco VA!

The Holidays are upon us, but we need to keep enrollment rolling!!

We hope to see StrokeNet CREST-H PIs at the annual PI meeting in Chicago December 7, 2019. Updates and new information will be discussed, including the possible inclusion of **TCAR** in CREST-2 and CREST-H.

ENROLLMENT TIP:
Discuss CREST-H during the CREST-2 discussion of imaging. Patients love to hear about cognition and the possibility of obtaining more information about brain blood flow. Timing of consent can be a challenge because sometimes CREST-2 randomization doesn't happen until after the patient leaves your office. Solution: You can get **verbal** consent to participate in CREST-H during the CREST-2 enrollment, then schedule the CREST-H MRI, and have the patient sign the consent when they arrive for their appointment at the scanner. This satisfies the requirement to have the CREST-H consent signed after CREST-2 randomization but does not require a separate trip to sign consent.

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.

**SATURN**

SATURN is very excited to begin study start-up! The NCC is distributing CTAs and Regulatory packets to sites this week.

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

Currently, there are 68 ASPIRE sites with fully executed CTAs; 43 sites have obtained cIRB approval.

The ASPIRE team, along with the NCC and NDMC, conducted a Regulatory/WebDCU™/Clinical Trial Agreement webinar on Thursday, 5-December, 2019. Look for this webinar to be posted to the StrokeNet website, on the ASPIRE page, at http://nihstrokenet.org/aspire-trial/home soon!

ASPIRE

**From the CREST-2 Clinical Coordinating Center:**

| | **CREST-2** | **CREST-2 StrokeNet** |
|---|---|---|
| CEA | 836 | 362 (42% of total) |
| CAS | 754 | 130 (17% of total) |
| **Total** | **1590** | **492 (31% of total)** |

**Recruitment: CREST-2 needs StrokeNet.** As the year is ending, please keep in mind our next recruitment milestone of **1700** by **February 29, 2020**. We need **110** patients left to go – we can do this! If you need any help with recruitment resources, reach out to the CREST-2 Clinical Coordinating Center.

**We would like to give special recognition** to the following **StrokeNet sites** that randomized in the month of November:

- **University of Pennsylvania**
  - PI: Michael Mullen, MD
  - Coordinator: Nichole Gallatti
- **OhioHealth Research Institute**
  - PI: Gary Ansel, MD
  - Coordinator: Amanda Bliemeister
- **Banner University Medical Center Tucson**
  - PI: Wei Zhou, MD
  - Coordinator: Joshua Black
- **VA Ann Arbor**
  - PI: Peter Henke, MD
  - Coordinator: Karen Belanger
- **University of Wisconsin**
  - PI: Girma Tefera, MD
  - Coordinator: Bridget Johnson

# NCC Winter Closure Days

The NCC will be closed from 23-December through 1-January. Business will resume as usual on 2-January.

# Feasibility Survey Updates

Feasibility surveys for the following *three* trial proposals, PERFUSE ICAS, ERSIAS, and COAT must be completed in the WebDCU™ by **Monday, 9-December, 2019.** 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 **11-December 2019, at 12 noon ET.   NOTE:** There will be two webinar presentations this month.  Log in via the following link: **https://nihstrokenet.adobeconnect.com/steering/**
To take part in the audio you **MUST** dial in at **(877) 621-0220,** Passcode Number: **434578**

**Trial Presentation:** RHAPSODY 2
**Presenter:** Patrick Lyden, MD, Cedars Sinai Medical Center

**Presentation**: Operationalizing Acute Ischemic Stroke Trial Enrollments
**Presenter(s):** Andrew Barreto, MD, UT Houston
Opeolu Adeoye, MD, University of Cincinnati
Joe Broderick, MD, University of Cincinnati
Jim Grotta, MD, UT Houston

# Coordinator Webinar

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

Look for more information about the January Coordinator Webinar soon.

# Professional Development Webinar

*Professional Development Webinars are a requirement for the NIH StrokeNet Trainees*

**Wednesday, December 11, 2019 - 2:00 PM ET**

Topic:       Consenting for Acute Stroke Trials

Presenters:   Jennifer Majersik, MD, University of Utah

Moderator:   Cemal Sozener, 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 <u>MUST</u> dial in. 1 (877) 621-0220 Passcode: 190825

# 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 <u>MUST</u> dial in. 1 (877) 621-0220 Passcode: 190825

# StrokeNet Meeting Information

The recording from the StrokeNet Network Meeting in Atlanta on 29-October can now be viewed on the website.  Look for 'NIH StrokeNet Meetings Presentations' under the education tab.

https://nihstrokenet.org/education/strokenet_meetings_presentations

**Coming soon:**  Information about the StrokeNet Trainee meeting at the ISC and the StrokeNet social hour!

# NINDS News

**Early Bird Rates for the Spring NIH Regional Seminar End 31-December!**

Don't miss out on the savings or the opportunity to learn about the NIH grants process directly from NIH experts next spring. From April 20-22, 2020, over 100 NIH & HHS experts will be on hand at the NIH Regional Seminar on Program Funding & Grants Administration in Baltimore, MD, ready to provide you with the latest policy and process information. What's the urgency to register?  Early Registration Rates end on December 31, 2019!  Register today at https://regionalseminars.od.nih.gov/baltimore2020/registration/.

**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.

**A Blizzard Ate My Application!  What Can I Do?**

NIH has your back. They have a standing natural disaster policy that can protect you in the event a natural disaster such as a hurricane or blizzard closes your institution close to an application due date.

If your institution closes due to an emergency, keeping you from being able to get your application in on time, document the reason in the cover letter of your application. Keep in mind that the delay in the submission should not exceed the time period of your institution's closure. Reasons for late applications are reviewed on a case-by-case basis, and no one at NIH can grant permission in advance for a late application.

**NIH/NINDS Federal Holidays**

The NIH/NINDS will be closed from Wednesday, 25-December through Wednesday, 1-January.  Have a safe and happy holiday!

# NIH StrokeNet Employment Opportunities

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

### UNIVERSITY OF MINNESOTA - VASCULAR NEUROLOGY POSITION SUMMARY - *Posting July 2019*

University of Minnesota Health seeks a board-certified or board eligible (BC/BE), fellowship-trained vascular neurologist to support our Stroke and Telestroke expansion across the M Health Fairview care system.  Our new Stroke Neurologist will join a network of academic physicians, fellows, residents, and APPs, providing care at our two comprehensive stroke centers, the University of Minnesota Medical Center and Fairview Southdale Hospital, in addition to inpatient telestroke services and emergent telestroke coverage at 10 spoke sites.

The M Health Fairview care system is committed to providing the best healthcare experience with focus on 'optimal health and well-being' for our patients.  We seek individuals who can provide highest-level patient-centered care aligned to the goals and objectives of the M Health Fairview organization to achieve exceptional patient outcomes.

*Scope of Practice:*

The Stroke Neurologist will be an integral team member in the development and implementation of a Stroke service line across the healthcare continuum within the M Health Fairview system. This position emphasizes in-person inpatient and telemedicine inpatient clinical setting including, but not limited to: rapidly diagnosing emergent stroke, administering thrombolytic therapies, and triaging patients who require transfer for endovascular, stroke, and neurocritical care at our comprehensive stroke centers. Additional areas of telestroke focus include ensuring the highest standards of secondary stroke prevention are accessible across the care continuum. In addition to clinical responsibilities, our program emphasizes the clinical education of our fellows, residents, and medical students. We also have a core commitment to clinical research, including our role as an NIH StrokeNet hub.

*Key Responsibilities include:*

- Provide direct inpatient care for patients with stroke and other complex neurovascular and neurological conditions
- Facilitate transfers to quaternary centers for Neurovascular, Neurosurgical, Neurointerventional, and Neurocritical Care through telestroke
- Prescribe lifestyle, medical, and interventional treatment to optimally reduce the risk of primary and secondary stroke.
- Participate in clinical research including pivotal local, national, and international trials
- Attend leadership meetings as deemed necessary
- Participate in processes that promote continuous improvement in patient care
- Collaborate with multidisciplinary teams throughout the continuum of care
- Additional opportunities for research and teaching may be available.

*Expertise, Credentials and Qualifications:*

Expertise should be comprised of a medical degree, graduate of an ACGME-accredited neurology residency, and vascular neurology fellowship. Prior telestroke experience is not required, but the individual should possess a strong interest in telemedicine and a desire to work collaboratively to provide for the stroke service needs of patients at M Health Fairview. A commitment to educating trainees and contributing to clinical research is essential.

*In addition, qualified applicants must also possess the following:*

- Medical Doctor (MD, DO)
- Current or eligible, unrestricted Minnesota State Medical License
- Board Certified Physician or Board Eligible Physician. If not yet certified, expectation is to acquire certification within 2 years of hire.
- Advanced knowledge of neurovascular care diagnosis and treatment

Link to apply: https://umphysicians.wd1.myworkdayjobs.com/umpcareers/job/Minneapolis-MN-UMMC---East-Bank/Stroke-Neurologist_R0007593

**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*