

Biweekly Update 22-November 2019

http://nihstrokenet.org/coming-events

StrokeNet Enrollment Update					
ARCADIA	364/1080	CREST 2	1579/2480		
Sleep SMART	116/3062	CREST H	118/500		
TRANSPORT2	4/129	MOST	3/1200		
I-ACQUIRE	7/240	ARCADIA-CSI	2/500		

StrokeNet Trial Updates



Thank you to each of our wonderful sites in ARCADIA!

As of November 21, 2019, 1394 subjects have been consented and 364 participants randomized at 93 sites. This is an increase of 41 consented and 13 subjects randomized in the past two weeks. Our enrollment is at 33.1% of the overall enrollment goal. Our randomization rate is at **0.20** patients/active sites/month.

Congratulations to the Lenox Hill Hospital, NY and McLaren Macomb, MI for consenting their first subjects and Eastern Maine Medical Center, Bangor, ME for randomizing their first!

The competition on the leader board is ongoing. United Hospital has 14 randomizations and continues to pull 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 and Oregon Health & Science University Hospital, Portland, OR take 4th place with 10 randomized subjects each. Thank you all for your dedication and leadership!

We have now released to enroll a total of 136 sites, 126 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.

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 November 26th 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 (<u>https://nihstrokenet.org/intranet/minutes/trial-webinars</u>).

The ARCADIA team wishes all our coordinators and investigators a wonderful Thanksgiving holiday!

-- The ARCADIA National Team

Sleep SMART

As of November 21, 2019, 381 subjects have been enrolled and 116 subjects have been randomized.

Brooks Rehabilitation Hospital and Sarasota Memorial Hospital are tied for first place, each with 12 subjects randomized! Prisma Health Midlands (Palmetto Health) is a close second with 11 subjects randomized.

Congratulations to the following sites for randomizing their first subject(s) during the month of November:

- 1. University of Cincinnati Medical Center, Cincinnati, OH-Sheva Coleman, MD and Sadie Caldwell
- 2. Memorial Hermann Texas Medical Center, Houston, TX-Sudha Tallavajhula, MD and Chad Tremont
- 3. WVU Healthcare Ruby Memorial Hospital, Morgantown, WV-Mouhannnad Azzouz, MD and Jay Sherman
- 4. Virginia Mason Medical Center, Seattle, WA-Fatima Milfred, MD and Ellie Fox
- 5. Mercy Health Saint Mary's, Grand Rapids, MI-Muhammad Farooq, MD and Julie Bishop
- 6. St. Cloud Hospital, St. Cloud, MN-Fareed Suri, MD, Dawn Bauerly-Pieper, and Melissa Freese

Important reminders:

- 1. A good number of potential sites are still not making progress towards release for enrollment because a clinical trial agreement (CTA) and/or FusionHealth Consignment agreement or DUA are still mired somewhere in a hospital contracts office. If this applies to you, please consider stirring the water to the best of your ability. Phone your contracts office, explain that Sleep SMART is moving on without you at this point, that the trial needs your participation, and that your hospital is losing a good opportunity for your physicians, staff, and patients as well. Ask them for a promised deadline by which contracts will be reviewed, if not approved. If they have questions or need to speak to someone about contract concerns, ask them to contact Dr. Brown, Dr. Chervin, or Ms. Kayla Novitski.
- 2. Please remember to enter all subjects who meet criteria for enrollment, but decline participation, into WebDCU under Study Progress tab > Screen Failure Report.
- 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.



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

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, and Baystate are open to enrollment! There are four subjects randomized in

the trial. All 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, University Southern California, 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 I-ACQUIRE team is excited to announce that 3 sites are released to enroll and 2 of the sites have randomized subjects.

- Roanoke, VA Fralin Biomedical Research Institute 3 participants randomized
- Boston, MA Boston Children's Hospital has 4 participants randomized

I-ACQUIRE Treating Therapist Training When: Tuesday, December 3 – Friday, December 6, 2019 Where: Fralin Biomedical Research Institute in Roanoke, VA Please contact Laura Bateman (<u>laurapb2@vt.edu</u>) for full details and to reserve a spot.

The I-ACQUIRE site directory will be updated monthly. You can download a copy at WebDCU/I-ACQUIRE/Toolbox/Project Documents



- The MOST team would like to thank and congratulate the following sites that have been released to enroll study participants:
 - o The Jewish Hospital, Cincinnati, OH
 - o WellSpan York Hospital, York, PA
 - o Houston Methodist Hospital, Houston, TX
- With 13 sites released to enroll so far, we have enrolled 3 participants in our study and we are looking forward to many more enrollments as we close out 2019!
- For study participoant eligibility questions don't forget to call the MOST hotline at: 1-833-299-MOST (6678)
- The MOST Continuing Review (CR) is has been submitted to the CIRB. Thanks to all of the clinical performing sites for the timely submission of their CR documents
- Reminder: Please submit Screen Failures in WebDCU™ under Study Progress-Screen Failure within 5 days of screening

From the CREST-2 Clinical Coordinating Center:

	CREST-2		CREST-2 StrokeNet
	CEA	830	358 (43% of total)
	CAS	749	130 (17% of total)
$\underline{CREST-2}$ –	Total	1579	408 (31% of total)

<u>Recruitment:</u> CREST-2 needs StrokeNet. As the year is ending, please keep in mind our next recruitment milestone of 1700 by February 29, 2020. If you need any help with recruitment resources, reach out to the CREST-2 Clinical Coordinating Center.

<u>Clinican Study App</u>: The CREST-2 Clinician Study App is officially here! We are so excited that our partnership with the Recruitment Innovation Center at Vanderbilt University has resulted in this very resourceful tool. As a reminder, the app will have necessary study information such as eligibility criteria, study windows, and more! Your CREST-2 site manager will be sending out your site specific link to your app with instructions on how to add it onto your devices by December 31st.









A Lifespan Partner

Rhode Island Hospital A Lifespan Partner

Site Startup and Enrollment Updates: sites: 52; enrollments: 118

Welcome to our latest Green lighted center: Miriam/Rhode Island Hospital!

Don't forget to schedule the 1-year follow up scans for your patients who are hitting their 1-year visit. You would have received an email as to whether your patient is requested to return for a follow up scan after the baseline scan was done.

ENROLLMENT TIP:

 Timing of consent can be a challenge because sometimes CREST-2 randomization doesn't happen until after the patient leaves your office. <u>Solution</u>: You can get *verbal* consent to participate in CREST-H during the CREST-2 enrollment, 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.

If you have not yet done so, please have CT perfusion approved in addition to MRP at your site if possible. Although MRI is preferred because of the additional information regarding silent infarcts, white matter hyperintensities, microbleeds, and cortical thickness, CTP is an second option for those who cannot undergo MRI. Remember, the reimbursement is the same, so as long as they don't have an exclusion to CT such as allergy to iodinated contrast, they can get the CTP. So help us please by getting test images uploaded for approval, so CTP can be an option at your site!

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

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, <u>sirline@musc.edu</u>.

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 a trial proposal presentation via the following link: <u>https://nihstrokenet.adobeconnect.com/steering/</u> To take part in the audio you **MUST** dial in at **(877) 621-0220**, Passcode Number: **434578**

Presentation: RHAPSODY2 **Presenter:** Patrick Lyden, MD, Cedars Sinai Medical Center

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: <u>https://nihstrokenet.adobeconnect.com/pdw/</u>. 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. 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: <u>https://nihstrokenet.adobeconnect.com/grandrounds/</u>. 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!

NIH StrokeNet Employment Opportunities

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

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: <u>https://umphysicians.wd1.myworkdayjobs.com/umpcareers/job/Minneapolis-MN-UMMC---East-Bank/Stroke-Neurologist_R0007593</u>

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