



## Biweekly Update 20-December 2019

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

### StrokeNet Enrollment Update

ARCADIA	381/1100	CREST 2	1596/2480
Sleep SMART	153/3062	CREST H	124/500
TRANSPORT2	5/129	MOST	6/1200
I-ACQUIRE	12/240	ARCADIA-CSI	13/500

## StrokeNet Trial Updates



**We wish all our PIs and Coordinators a Wonderful Holiday Season and New Year!**

**ARCADIA** As of December 18, 2019, 1476 subjects have been consented and 381 participants randomized at 94 sites. This is an increase of 43 consented and 8 subjects randomized in the past two weeks. Our enrollment is at 34.6% of the overall goal. Our randomization rate is at 0.18 patients/sites released to enroll/month.

**Thank you to the 38 sites that consented and 8 sites that randomized subjects in the last two weeks. Also, congratulations to Mayo Clinic, Jacksonville, FL for enrolling their 1<sup>st</sup> subject today!**

We have now released to enroll a total of 138 sites, 129 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 we get the needed approvals from the State Department.

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 28<sup>th</sup> 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>).



As of December 18, 2019, 464 subjects have been enrolled and 153 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-15 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

There is 3-way tie for 5<sup>th</sup> place among the following sites:

- Cedars-Sinai Medical Center, Los Angeles, CA-Oana Dumitrascu, MD and Vicki Manoukian-6 subjects randomized
- Moses H. Cone Memorial Hospital, Greensboro, NC-Pramod Sethi, MD, Rizwan Sabir, and Glynda Reaves-6 subjects randomized
- Harborview Medical Center, Seattle, WA-Sandeep Khot, MD, Allison Kunze, and Kaley Dugger-6 subjects randomized

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.

**Don't forget these important reminders as we move into the next year:**

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 remember to report AEs. If you need guidance, please refer to the Sleep SMART MOP.
3. 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.
4. 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.
5. 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.
6. 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.
7. The baseline NIH Stroke Scale should be done after the subject is enrolled.
8. Informed consent should be obtained ONLY by staff who have been delegated this responsibility on the DOA.
9. Double check the consent document to make sure all sections have been correctly signed/dated by subject/LAR and person obtaining consent. The subject/LAR must personally sign and date consent.
10. 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, January 27, 2020 from 1-2 EST.



ARCADIA•CSI  
Cognition & Silent Infarcts

The study team would like to thank all of our sites for working hard and we would like to wish you all a Happy Holiday Season!

Congratulations to our sites! We now have 13 subjects enrolled.

Congratulations to the new sites who are released to enroll:

- ✓ St. Joseph's Hospital and Medical Center
- ✓ NYP Weill Cornell Medical Center
- ✓ Wake Forest Baptist Medical Center
- ✓ University of Alabama Birmingham
- ✓ UVA Medical Center
- ✓ Harborview Medical Center
- ✓ Montefiore Medical Center

We now have 20 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:

- ✓ Henry Ford Hospital
- ✓ Ochsner Medical Center
- ✓ Hospital of the University of Pennsylvania
- ✓ Intermountain Medical Center
- ✓ Utah Valley Hospital
- ✓ UMass Memorial Medical Center

Please contact Tashia Harris, [herndotl@ucmail.uc.edu](mailto:herndotl@ucmail.uc.edu) or Stephanie Kemp, [skemp@stanford.edu](mailto:skemp@stanford.edu) with any questions.

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



We now have 6 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

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).



As of December 17, 2019, 6 MOST subjects have been randomized and 23 MOST sites have been released to enroll!

Thank you to the teams that have recently opened enrollment:

- University of Minnesota Medical Center
- University of Alabama Hospital
- University of Michigan University Hospital
- Hospital of the University of Pennsylvania
- Kaiser Permanente LA Medical Center
- University of Wisconsin University Hospital

Congratulations Dr. Sanjeev Sivakumar and the **Greenville Hospital** team, and Dr. Cheryl Bushnell and the **Wake Forest** team for enrolling their first subjects!

Reminders:

- Reach out to Iris Deeds ([deedsss@ucmail.uc.edu](mailto:deedsss@ucmail.uc.edu)) if you need I&E study cards sent to your site. Include your shipping address and the number of cards requested.
- The MOST Eligibility mRS Tool has been posted to the Toolbox in WebDCU.
- Call the MOST PI Hotline for eligibility or safety questions (**1-833-229-MOST**).

We appreciate the continued enthusiasm and hope that everyone enjoys the holidays!



Reminder that our next PI and Coordinator call is scheduled for **Monday, January 6th at 11am ET**. If anyone has topics they would like to discuss during the call, please send them to Kristina ([kristina.balderson@duke.edu](mailto: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. All five have completed the intervention phase and are in the follow-up period. Our first subject will complete the trial prior to the NEW YEAR! 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! Thanks for all of your hard work this year and happy holidays!



SATURN is very excited to continue study start-up!

CONGRATULATIONS to The University of California San Diego/12-112-1435 UC San Diego MC-Hillcrest! This is the first SATURN site to have a fully executed CTA and to submit to the CIRB! Way to go!!!

SATURN will host a webinar January 16, 2020 1-2pm to review CTA/CIRB Submission/Regulatory Database. Invitations will be sent to site study personnel.

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](mailto:gammk@ucmail.uc.edu)  
Wren Hanson Contracts [hansonwm@ucmail.uc.edu](mailto:hansonwm@ucmail.uc.edu)  
Emily Stinson Regulatory [stinsoev@ucmail.uc.edu](mailto:stinsoev@ucmail.uc.edu)  
Jen Golan Regulatory [golanjl@ucmail.uc.edu](mailto:golanjl@ucmail.uc.edu)



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


We had a productive annual CREST-2 PI meeting in Chicago. We were very grateful to *Navi Singha from Kaiser LA* for reporting best practices for enrollment. They are now tied for the lead in CREST-H enrollments. Here are a couple of suggestions:

**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](mailto:rsm2@columbia.edu), Ron Lazar [rlazar@uabmc.edu](mailto:rlazar@uabmc.edu), Jaya Vijayan [vijayan.jaya@mayo.edu](mailto:vijayan.jaya@mayo.edu), or Kevin Slane [KJS4@columbia.edu](mailto:KJS4@columbia.edu) with any questions.

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

	<b>CREST-2</b>		<b>CREST-2 StrokeNet</b>
	CEA	841	362 (43% of total)
	CAS	757	130 (17% of total)
	<b>Total</b>	<b>1598</b>	<b>492 (31% of total)</b>



from our family at the **CREST-2 Clinical Coordinating Center** to yours!

**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 **102** patients 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.

**We would like to give recognition** to the following **StrokeNet sites** that have randomized in December thus far:

- **Kaiser Permanente Division of Research**
  - PI: Mai Nguyen-Huynh, MD
  - Coordinator: Cristina Casias
- **Kaiser Permanente Los Angeles**
  - PI: Navdeep Sangha, MD
  - Coordinator: Catherine Lui
- **University of Washington at Harborview**
  - PI: David Tirschwell, MD
  - Coordinator: Hope Clark-Bell
- **San Francisco VA**
  - PI: Joseph Rapp, MD
  - Coordinator: Sandy Perez
- **Oregon Health and Science University**
  - PI: Wayne Clark, MD
  - Coordinator: Jon Foley
- **Novant Health**
  - PI: Don Heck, MD
  - Coordinator: Olga Dubangiu

## 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 Reminder

The feasibility survey for the RHAPSODY2 trial proposal must be completed in the WebDCU™ **by 11:59pm ET on Monday, January 6rd.** **\*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](mailto: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 **8-January, 2020, at 12 noon ET**. There will be a trial webinar presentation:

Presentation: Validation of Early Prognostic Data for Recovery after Stroke for Future, Higher Yield Trials (VERIFY)

Presenter: Pooja Khatri, MD, University of Cincinnati

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

To take part in the audio you **MUST** dial-in: **(877) 621-0220** Passcode Number: **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

**NINDS Clinical Trials Methodology Course (CTMC) is accepting applications for the 2020 cohort!**



**LABioMed**  
Los Angeles  
Biomedical  
Research Institute  
at Harbor-UCLA Medical Center



Dear clinicians and biostatisticians who work in the clinical neurosciences:

We are pleased to announce that the NINDS Clinical Trials Methodology Course (CTMC) is accepting applications for the 2020 cohort. The overarching goal of the CTMC is to help junior investigators develop scientifically rigorous, yet practical clinical trial protocols.

The course features a combination of distance learning activities and a residential course, along with small group mentorship from experienced clinical trialists and biostatisticians. Investigators from the NeuroNEXT and Strategies to Innovate Emergency Care (SIREN) clinical trials networks, along with other clinical trials experts, lead this course and serve as faculty. The residential part of the course is **required** and will be held July 20 – 23, 2020 in Ann Arbor, MI. Funding for travel (within the US) and accommodations will be provided for participants. Qualified applicants from clinical disciplines focused on neurological disease or injury, along with biostatisticians working on projects with clinical neuroscience researchers are encouraged to apply. All preliminary trial ideas are encouraged – the only requirement is that protocols are focused on the clinical neurosciences. Trainees should have content area mentors to assist them with the science and implementation of their project.

**The deadline for application submission is February 28, 2020 at midnight.** Application forms and additional details are available on the course website <https://nett.umich.edu/training/ctmc>.

Please contact [NINDS-CTMC-Info@umich.edu](mailto:NINDS-CTMC-Info@umich.edu) or William Meurer, MD, MS with any questions [wmeurer@umich.edu](mailto:wmeurer@umich.edu).

The NINDS Clinical Trials Methodology Course is supported by the NIH-NINDS grant **R25 NS088248** and is administered by the University of Michigan, the University of Iowa, and Los Angeles BioMed. Additional support is provided by the American Academy of Neurology.

## **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>

**Please share this with your clinical performing and satellite sites!**

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