

STEPHANIE M WILBRAND

From: Beckmann, Rose (beckmare) <BECKMARE@UCMAIL.UC.EDU>
Sent: Friday, March 27, 2020 2:09 PM
To: Beckmann, Rose (beckmare)
Subject: NIH StrokeNet Biweekly Update 27-March 2020

Follow Up Flag: Follow up
Flag Status: Flagged



Biweekly Update 27-March 2020

StrokeNet Enrollment Update

ARCADIA	440/1100	CREST 2	1653/2480
Sleep SMART	253/3062	CREST H	139/500
TRANSPORT2	11/129	MOST	33/1200
I-ACQUIRE	22/240	ARCADIA-CSI	52/500
ASPIRE	0/700	SATURN	0/1480

StrokeNet COVID-19 Updates

Effective Tuesday, 24-March, 2020 **ALL** StrokeNet trials have suspended enrollments/randomizations. This move has been reported to the CIRB as a study-wide event by the Project Manager of each StrokeNet trial; individual sites **DO NOT** need to report this event.

For subjects who have already been randomized, please continue to perform follow-up visits, but do so remotely. This will also be reported to the CIRB as a study-wide event by the trial Project Managers.

We want you to know that the StrokeNet NCC and NDMC are still open for business. We would like to encourage all that have not yet been released to enroll, to continue to work toward site activation.

Should your institutional guidelines allow, please proceed with startup activities:

- CIRB submission

Coronavirus Disease 2019 (COVID-19)

Information for NIH Applicants and Recipients

The NIH is deeply concerned for the health and safety of people involved in NIH research, and about the effects on the biomedical enterprise in the areas affected by the HHS declared [public health emergency for COVID-19](#). Due to the potential exceptional impact, we want to assure our recipient community that NIH will be doing our part to help you continue your research. This is a rapidly evolving situation and we will provide updated guidance and information as it becomes available.

Guidance

- [NIH Late Application Policy Due to Public Health Emergency for United States for 2019 Novel Coronavirus \(COVID-19\) - NOT-OD-20-082](#)
- [General Frequently Asked Questions \(FAQs\) - Proposal Submission and Award Management Related to COVID-19 - NOT-OD-20-083](#)
- [Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19 - NOT-OD-20-086](#)
 - [COVID-19 Flexibilities for Applicants and Recipient FAQs](#)

Resources

- [NIH Website: Coronavirus Disease 2019 \(COVID-19\)](#)
- [CDC Website: Coronavirus Disease 2019 \(COVID-19\)](#) including its guidance for [Institutes of Higher Education](#) and [CDC Website: Centers for Disease Control \(CDC\)](#)
- [WHO Website: Coronavirus disease \(COVID-19\) outbreak](#)
- [General Information on NIH Extramural Response to Natural Disasters and Other Emergencies](#)

StrokeNet Trial Updates



Thank you to all on the frontlines – stay safe and healthy!

ARCADIA paused at 40% of target recruitment!

As you all know, all enrollment and randomizations have been suspended until further notice due to COVID-19. However, also for safety, we still need to continue to follow our already randomized subjects and send those still taking study drug their medication. IF you are shipping study drug and not handing it directly to the participants, then please remember to add the date they received the study drug to the corresponding CRF (F513) and not the date it was dispensed by your institution while noting in the comments that the study drug was shipped.

Please see our recent ARCADIA newsletter for March to see additional details and suggestions related to COVID-19. The slides from the recent webinar also include useful information about COVID-19 and will be available in WebDCU.

As of March 26, 2020, 1709 participants have been consented and 440 participants randomized at 101 sites. This is an increase of 12 consented and 3 subjects randomized in the past 2 weeks before the “pause” in enrollment/ randomizations came into effect. Our enrollment is at 40% of the overall goal.

Thank you to the 12 sites that consented and 3 sites that randomized subjects in the last two weeks. A special thanks to Capital Health Medical Center Hopewell, Pennington, NJ for randomizing their first subject!

We have now released to enroll a total of 144 sites, 134 of which were active prior to the pause. During the pause, we plan to continue 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.

Our thoughts and prayers are with all of you on the frontlines and our participants. Please keep safe!

Webinar: Our next PI and coordinator webinar will be April 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://nihstroketrials.org/intranet/minutes/trial-webinars>).



The ARCADIA-CSI Study Team is wishing all of our sites the best during this challenging time. We are thinking of all of you and hoping you and your families are staying safe and healthy.

As of March 17, 2020, ARCADIA-CSI has suspended enrollment. This information was submitted to the cIRB. The acknowledgment letter can be found in WebDCU™ in the Toolbox -> Project Documents.

The continuing review has been submitted to the cIRB. The continuing review is anticipated to go the board on April 21, 2020. When the study is approved, NCC Project Manager, Tashia Harris, will send out your documents.

During this Covid-19 shut down, please consider updating WebDCU™ and uploading documents that are still needed or have expired.

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



We would like to encourage all sites that have not been released to enroll to continue to work toward site activation. Should your institutional guidelines allow, please proceed with startup activities:

- CIRB submission
 - finalizing clinical trial agreement
 - uploading startup documents to WebDCU
 - receiving study drug and lab kits
 - remote protocol training
 - completing readiness calls
-
- 88 executed CTAs and 78 sites with cIRB approval
 - 26 sites released to enroll
 - The May 6-7 ASPIRE/SATURN Investigator Meeting is rescheduled for November 4-5, 2020; details in regard to hotel/travel arrangements will follow in the coming months.
 - The 1st ASPIRE Webinar will take place on 4/22/20 3-4pm EST
 - WebDCU Pointers for First Study Drug Shipment:
 - Enter address and contact person for study drug shipments in SITE MANAGEMENT>CLINICAL SITE
 - If you are using a pharmacy, upload Institutional Pharmacy License in Site Regulatory Documents and enter person with Pharmacist role on your DOA
 - If you are not using a pharmacy, waive Institutional Pharmacy License in Site Regulatory Documents and enter a note in your DOA, be sure a person has been assigned study drug dispensing (J) and accountability (I) roles
 - Site Readiness Calls should be scheduled if your CTA and cIRB approval are in place
 - New dates have been added to the online poll: <https://doodle.com/poll/rnnu37hfvmc>




Site Startup and Enrollment Updates: sites: **54**;
enrollments: **139**

We are at to **139** patients, **40%** of our target, and have begun to accumulate 1-year follow up scans. Let's keep the enrollment going!

As with other StrokeNet clinical trials, recruitment for CREST-H is on hold for now. Because the 1-year cognitive test is the primary outcome in CREST-H, however, we are making arrangements to obtain the 1-year telephone cognitive test for CREST-H patients, despite the Survey Research unit at University of Alabama Birmingham being temporarily closed. PI's and coordinators, please look for specific announcements coming up about this.

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	870	378 (44% of total)
	CAS	783	133 (17% of total)
	Total	1653	511 (31% of total)

COVID-19 Updates & CREST-2

CREST-2 Will Be Stopping Enrollment: The COVID-19 pandemic has already led to suspension of elective surgery and elective procedures at many if not most major medical centers. Accordingly, because of patient and health personnel safety, we have come to the conclusion that suspension of all CREST-2 enrollment should be instituted immediately. In the meantime, we would encourage you and your team members to continue your screening efforts and log them in the event that the patient may be eligible at a later time. We will let you know when enrollment may re-start.



On another note, CREST-2 was steady on track to surpass ACAS (n=1662) To the left is James F. Toole, MD, and Principal Investigator of ACAS. We appreciate your assistance during this difficult time but we look forward to exceeding ACAS when enrollment resumes.

Phone Call Follow-Ups: All sites are allowed to have their patients participate in phone call follow-up

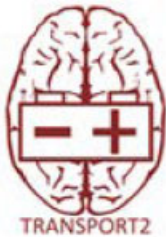
- Congratulations to the following sites that have been released to enroll since our last update!
 - **University of Utah Healthcare**, Salt Lake City, UT
 - Dr. Adam Dehavenon and Michael dela Cruz
 - **SUNY Upstate Medical University**, Syracuse, NY
 - Dr. Julius-Gene Latorre and Lena Deb
- As of 26-Mar-2020, there are **33 subjects** randomized and **54 sites** released to enroll, **17** of which have enrolled at least one subject.
- For sites are released to enroll please continue to complete screening logs in WebDCU™.
- The study leadership has submitted a notice to the CIRB to allow 90-day visits for enrolled subjects to occur remotely (phone, telemedicine/FaceTime) and to pause enrollments during the COVID-19 crisis. Individual sites do not need make these submissions to the CIRB. A recording of remote 90-day mRS interview conversations should be obtained using the provided video camera, even for audio only recording of a phone call, and uploaded for University of Glasgow review. If an audio only file is obtained, please contact Alastair Wilson, Alastair.Wilson@glasgow.ac.uk, to ensure the file uploads properly.
- For sites not yet activated, please note we will continue the site activation process including completion of regulatory documents, delivery of study drug and releasing sites to enroll. Our goal is to have as many sites ready as possible once we are able to return to usual procedures.
- Thank you all for your efforts!
- **The PI hotline is available 24/7 for any questions: 1-833-229-MOST**



In order to ensure the safety and welfare of human subject participants and research staff during the COVID-19 public health emergency, the SATURN and StrokeNet NCC leadership decided to hold enrollment into the SATURN trial until further notice.

In the meantime, we will continue the Site Readiness Calls during the enrollment-hold period, and urge all sites that are yet to complete trial start-up activities and paperwork to continue to work to complete the following items to be ready for activation once enrollment resumes:

- cIRB Submission – reminder to please send your documents to Emily or Jen at the NCC who will submit to the cIRB on your behalf
- Clinical Trial Agreement Execution – please follow-up with your institution to move this process along
- Protocol Training is available in WebDCU™ toolbox and on WebDCU™ Training Campus <https://webdcu.musc.edu/campus/>
- Study documents are available in WebDCU™ toolbox – including regulatory documents, regulatory parameters document, training materials, DRAFT CRFs, protocol appendices, Provider Information Sheets, Participant Information Sheets and MOP
- Reminder to enter site address into WebDCU™ for supplies – under Site Management>Clinical Site>click on your site to edit and enter address
- Reminder to acknowledge receipt of lab kits in WebDCU™ once received at your site
- Reminder to complete and submit site DOA in WebDCU™
- Reminder to upload approved Regulatory documents into WebDCU™
- Reminder to participate in the Doodle Poll once you receive the Readiness Call Scheduling email with the link



Reminder that our next PI and Coordinator call is scheduled for **Monday, March 30th at 11am ET**. If anyone has topics they would like to discuss during the call, please send them to Julia Gonzalez, (Julia.jackson@duke.edu).

On March 16, 2020, a letter was issued to sites regarding research study activities surrounding the COVID-19 pandemic. Subject randomization is currently on hold, but please continue to pre-screen patients in a remote setting. Subjects who are in the 45 and 105 day follow-up assessment stage, please contact Wayne Feng (wayne.feng@duke.edu) and Gottfried Schlaug (Gottfried.schlaug@baystatehealth.org) for subject retention and follow-up issues. We are exploring new alternative ways to complete patient assessment visits.

To date, Moss Rehab, University of Kentucky, University Southern California, Medstar, Emory University, and University of Cincinnati continue to enroll. MUSC, Barnes Jewish, Burke, University of Texas, University Alabama, and Baystate are all open to enrollment! There are eleven subjects randomized in the trial. Four have completed the study, and seven have completed the intervention phase and are in the follow-up period. Cleveland VA has a fully executed CTA and is working through their IRB submission. Duke has received CIRB approval, and is currently going through finance. UPMC is working through their IRB submission and has a signed CTA.

Thank you for your continued effort and flexibility during this time of uncertainty.

Steering Committee Call

*Steering Committee Calls are a requirement for all NIH StrokeNet RCCs
(one representative per RCC required)*

The next Steering Committee call will be the annual STROKENET NETWORK WEBINAR. The webinar will be held on **Wednesday, 8-April, 2020, from 12 noon – 3:00 pm ET**. Dial in: 513-621-0220; 1-877-621-0220; Passcode 434578.

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

Note, you must also dial in to join the conversation.

Coordinator Webinar

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

Wednesday, April 22, 2020 - 1:30 PM ET

Topic: NCC & NDMC – ICF Reminders and Changes to the WebDCU™ Unanticipated Event Reporting Module

Presenters: TBD

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

Thursday, April 23, 2020

Presenters:	1:00	James Giles, MD, PhD , Washington University Cost-Effectiveness Analysis of Transcarotid Artery Revascularization (TCAR) for Patients with Atherosclerotic Carotid Artery Stenosis
	1:30	Jacqueline Hirsh Greer, MD , Yale University Obstructive Sleep Apnea as a Risk Factor for Intracerebral Hemorrhage
	2:00	Maria Daniela Zambrano Espinoza, MD , Columbia University Effects of Clinically Meaningful Weight Changes on Premenopausal Women and Stroke Risk

Moderator: **Farhaan Vahidy, MD, MBBS, MPH**

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 **MUST** dial-in. (877) 621-0220 Passcode: 190825

Grand Rounds

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

Thursday, April 30, 2020

Topic: Feeding the Penumbra

Presenter: **Jeff Saver, MD, UCLA**

Moderator: **Randy Marshall, MD**

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

NIH StrokeNet Employment Opportunities

University of Cincinnati Vascular Neurologist

The Department of Neurology and Physical Medicine and Rehabilitation at the University of Cincinnati has new, exciting opportunities for **Vascular Neurologists** at Assistant, Associate, or Professor levels on both clinical and research career tracks.

The candidate will join an internationally renowned stroke program that includes:

- A highly collaborative, multidisciplinary team of 9 Vascular Neurologists, 7 Emergency Medicine Stroke Specialists, 9 Neurocritical Care Intensivists, 3 Interventionalists from Neurosurgery and Neurology, 2 Cerebrovascular Neurosurgeons, 6 Neuroradiologists, a large cohort of extremely experienced Research Coordinators, among others
- A JCAHO-Certified Comprehensive Stroke Center, including a 20-bed Neuroscience Intensive Care Unit and 10-bed variable acuity unit
- Multicenter, high-volume approach to acute stroke treatment and trial enrollment (550+ treated with reperfusion therapies in 2019), including a newly activated Mobile Stroke Unit
- A large, NIH-funded stroke research program, ranging from clinical trials in treatment, prevention, and rehabilitation/recovery, to epidemiology studies in health disparities and brain health, to molecular genetics
- A home to the National Coordinating Center (NCC) and a Regional Coordinating Center (RCC) of the NIH StrokeNet

The clinical practice would consist of a personally tailored combination of inpatient service, acute stroke call (including telemedicine), outpatient clinic, and teaching of residents and fellows from several different disciplines.

Exciting collaborative research opportunities are available for participation and growth, but not required.

MINIMUM QUALIFICATIONS: Must have an MD or DO, completed an ACGME-approved Vascular Neurology fellowship program, and be BE/BC.

HOW TO APPLY: Contact Pooja Khatri, MD, Director of the Vascular Neurology Division: pooja.khatri@uc.edu

The University of Cincinnati, as a multi-national and culturally diverse university, is committed to providing an inclusive, equitable and diverse place of learning and employment.

StrokeNet National Coordinating Center Project Manager - FASTEST

The NIH StrokeNet NCC is looking for a Project Manager for the FASTEST trial – a global trial – spanning the U.S., Canada, Germany, Spain, the U.K., and Japan; approximately 130 sites, including mobile stroke units; and approximately 860 subjects -- evaluating the use of recombinant factor VIIa to treat patients with spontaneous intracerebral hemorrhage within two hours of stroke onset/last known well. The trial will utilize exception from informed consent.

For detailed information about the position, and to apply, please visit <https://jobs.uc.edu/> and reference requisition number 44802.

For more information about StrokeNet employment opportunities, please visit

<http://nihstrokenet.org/education/employment-opportunities>

Contact: Jamey Frasure, PhD, RN, Director · NIH StrokeNet Coordinating Center · frasurjs@ucmail.uc.edu · 513-558 1742

<https://www.nihstrokenet.org>