



## Biweekly Update 20-November 2020

### StrokeNet Enrollment Update

ARCADIA	541/1100	TRANSPORT2	17/129
ARCADIA-CSI	111/500	I-ACQUIRE	34/240
Sleep SMART	369/3062	MOST	108/1200
SATURN	30/1456	CREST H	166/500
ASPIRE	10/700	CREST 2	1745/2480

\*Enrollment as of 20-November 2020

## StrokeNet Trial Updates



- **ENROLLMENT HAS RESTARTED!**
  - ASPIRE now has **10** randomized subjects!
  - Notify [ASPIRE@yale.edu](mailto:ASPIRE@yale.edu) if you consent a patient. Central Pharmacy will ship study drug supplies immediately.
  - Study drug resupply of all activated sites will begin 12/1/2020 and be completed by 12/22/2020.
- For sites still pending activation, please:
  - Upload/waive pending regulatory documents.
  - Enter addresses for study drug and lab kit shipments.
  - If CTA and cIRB approval in place, schedule readiness call.
- The ASPIRE/SATURN Investigator Meeting in New York has been postponed indefinitely. In lieu of the meeting, protocol training is posted on the WebDCU™ Training Campus <https://webdcu.musc.edu/campus/>



SATURN has 87 sites open for enrollment and has randomized 30 patients! We want to thank everyone for their efforts to screen recruit and randomize! We ask that sites continue to screen every ICH daily!

SATURN held the monthly PI/Coordinator webinar at 12:30pm ET on 10/29/2020. Please find the recording here: <https://www.nihstrokenet.org/saturn-trial/webinars> **for tips on how to optimize recruitment and enrollment.**

MGH sent out replacement blood tubes for the tubes which expired 10/31/2020 and will expire 11/30/2020. Sites will be replacing only the tubes, not the entire kit. SATURN reviewed process for replacing expired blood tubes in the lab kits on the most recent webinar. Please refer to the recording above. Please reach out with any questions about the labeling or updating WebDCU™:

- MGH Christina Kourkoulis [CKOURKOULIS@PARTNERS.ORG](mailto:CKOURKOULIS@PARTNERS.ORG)
- MUSC Katie Stever [steverka@musc.edu](mailto:steverka@musc.edu)

SATURN is actively looking to add sites; please reach out for further details.

SATURN has received approval for central REDCap eConsent and Remote Implementation and eConsent Forms were distributed to all US Sites for completion. Please return these forms as soon as possible.

SATURN is working to create a trial video for potential patients and their families. The video will be available as a YouTube link that the trial team can send to the patients and caregivers for viewing.

If you have any questions regarding SATURN and reopening enrollment at your site please contact:

- Kimberlee Bernstein NCC Project Manager [gammk@ucmail.uc.edu](mailto:gammk@ucmail.uc.edu)
- Sarah Marchina Prime Project Manager (BIDMC) [smarchin@bidmc.harvard.edu](mailto:smarchin@bidmc.harvard.edu)

#### **IMPORTANT SATURN CONTACTS:**

- **Questions regarding eligibility or protocol implementation**
    - Email: [SATURN@bidmc.harvard.edu](mailto:SATURN@bidmc.harvard.edu)
  - **SATURN Clinical Hotline**
    - Call 617-667-7000 and ask to page beeper #39636.
- \*\*\*Please tell the operator that you are calling about the SATURN trial.



### **ARCADIA Approaches 50% of Targeted Randomizations!**

It is almost Thanksgiving, and we are so grateful for how sites continue to push forward and even revise strategies to overcome the enrollment challenges posed on many fronts. Please continue to be flexible and remember that we CAN consent (email, fax, mail), randomize, and follow up participants using remote procedures when in-person processes are not possible or preferred. Letting potential participants know that they can participate from the comfort of their home (except for the blood draw) may be the difference between consent or refusal.

There are still have 33 subjects eligible for randomization and pending completing that process. We understand that not all can be randomized immediately; however, please continue to conduct randomization visits safely and per protocol.

We have randomized 540 participants, an increase of 11 in less than two weeks. A special thanks to the ten teams that provided the last two weeks' randomizations: Tufts Medical Center, Boston, MA; Memorial Hermann Texas Medical Center, Houston, TX; Central DuPage Hospital, Winfield, IL; UPMC Presbyterian Hospital, Pittsburgh, PA; Yale New Haven Hospital, New Haven, CT; University of Kentucky Hospital, Lexington, KY; Massachusetts General Hospital, Boston, MA and last but not least, thank you to the team at Emory University Hospital, Atlanta, GA for randomizing 2 subjects during this period AND having 100% retention rate!

We are currently at 2039 subjects enrolled/consented, an increase of 32 in the last two weeks, thanks to 26 sites, with some sites enrolling more than one during this period – thank you to all the site teams making this possible! A special thanks to the following teams for enrolling two subjects each during the last two weeks: Montefiore Medical Center, Bronx, NY; Swedish Medical Center, Englewood, CO; and University of Alabama Hospital, Birmingham, AL. Again, a big shout out to the whole team at Emory University Hospital, Atlanta, GA for consenting 3 subjects. Great job everyone!

We currently have 127 active sites that completed their re-start or started new since enrollment was resumed. We also have another group working towards being released to enroll for the 1<sup>st</sup> time. Let us know if you know of a good site that would like to participate in ARCADIA. We hope to continue to re-start sites as per the ARCADIA re-start plan for the 9 sites still pending re-release to enroll. We understand many of your sites cannot yet re-start, but those that can re-start enrollment, even if only remotely, please reach out to Rebeca ([ra2356@cumc.columbia.edu](mailto:ra2356@cumc.columbia.edu)) to review any pending items needed for your re-release. PLEASE do not start enrolling new subjects until your site has been officially re-released to enroll.

**Webinar:** Our next PI and coordinator webinar will be November 24<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://www.nihstrokenet.org/intranet/minutes/trial-webinars>

We hope you, your teams and families all have a safe, healthy and happy holiday next week.



Thank you to all the sites for your hard work enrolling subjects into ARCADIA-CSI during this difficult time!

The study team would like to welcome **Grady Memorial Hospital to ARCADIA-CSI!**

**Our top 3 enrolling sites are:**

9 PATIENTS ENROLLED

**UNIVERSITY OF IOWA**

ENRIQUE LEIRA & HEENA OLALDE

8 PATIENTS ENROLLED

**UNIVERSITY OF CINCINNATI**

POOJA KHATRI & JENNIFER POWERS

6 PATIENTS ENROLLED

**GREENVILLE HOSPITAL**

PAULO ZORTEA & VICTORIA HOLT

Congratulations to the following sites for enrolling their first subject:

**Mass General**

**Tufts Medical Center**

**We need your help enrolling patients into the ARCADIA-CSI substudy!** We have created form 515 to make screening a breeze. When a patient is randomized in ARCADIA, form 515 is posted in the patient's ARCADIA binder in WebDCU™. This form serves as the ARCADIA-CSI screening form and as a reminder to reach out to the patient to ask if (s)he would like to join ARCADIA-CSI. We currently have 128 forms pending completion.

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.



Thank you for your participation in Sleep SMART. We truly appreciate all your hard work, especially during this difficult time.

As of November 17, 2020, 1072 subjects have been enrolled and 367 subjects have been randomized. Congratulations to Curtis Benesch, MD, Emily Prentiss and the entire Strong Memorial Hospital team for randomizing their first subject on November 12, 2020.

**Two key reminders:**

1. Please complete all 3-month assessments within window. These can be done by phone, if needed. The 3-month mRS is a primary outcome for Sleep SMART!
2. Please complete a "warm transition" for intervention (CPAP) subjects some time prior to discharge. This contact between intervention subjects and the FusionHealth Care Team helps facilitate CPAP adherence post-discharge.

**SITE DOCUMENTS:** The placeholders in WebDCU™ for CIRB Approval (Protocol v5- 26Mar2020), CIRB Approval (Protocol v6-06Jul2020), Protocol Signature Page (Protocol v5-26Mar2020), and Protocol Signature Page (Protocol v6-06Jul2020) will all be archived in the near future. Please make sure that these documents are completed and uploaded, if applicable to your site. All site PI FCOI completed for continuing review should be uploaded in WebDCU™ to the StrokeNet CIRB Financial Interest Disclosure Form placeholder. The expiration date will be 24Nov2021.

**AMENDMENT:** Protocol v7.0 was sent to all sites on 20Oct2020. Please make sure the approval letter dated 12Oct2020 and the protocol signature page are completed and uploaded to WebDCU™ and your local IRB has been notified, if required.

**SITE IMPLEMENTATION FORMS:** The site implementation form is a document asking whether or not your site will be implementing remote consent procedures (including eConsent through REDCap). All sites need to complete the form and return to Kayla or Joelle.

**RE-OPENING:** If your site is ready to be re-released to enroll please email Kayla or Joelle for further instructions.

**Sites not previously released to enroll:**

If your site was not previously released to enroll, please continue to work toward site activation:

- CIRB submission
- Finalize the Clinical Trial Agreement and FusionHealth DUA and Consignment agreement
- Upload site and people documents to WebDCU
- Complete online trainings (<https://webdcu.musc.edu/campus/>)
- Complete readiness call (must have all contracts completed before this can be done)
- Please review the site to-do checklist found in the WebDCU™ toolbox

**Save the date-**Our next PI and coordinator webinar will be Monday, November 30, 2020 from 1-2 EST. We will go over study startup activities. This is for newer sites or sites that need a refresher.



**We now have enrolled 34 study participants. Everyone's hard work is greatly appreciated!**

- Boston, MA – 10 participants randomized
- La Jolla, CA – 5 participants randomized
- Columbus, OH – 5 participants randomized
- Roanoke, VA – 4 participants randomized
- Ann Arbor, MI – 3 participants randomized
- Cincinnati, OH – 3 participants randomized
- New Haven, CT – 3 participants randomized
- Philadelphia, PA – 1 participant randomized

**Save the date:** Upcoming PI/Co-I/Coordinator Webinar:

❖ Thursday 17 December (12-1pm ET)





Our next PI and Coordinator call will be on **Monday, 11/30/2020 at 11am ET**. If anyone has topics they would like to discuss during the call, please send them to Kristina Balderson ([Kristina.balderson@duke.edu](mailto:Kristina.balderson@duke.edu)) or Julia Gonzalez, ([Julia.jackson@duke.edu](mailto:Julia.jackson@duke.edu)).

11 sites have reopened to enrollment! Congratulations to MUSC, Burke, Baystate, Medstar, UAB, USC, Kentucky, Cincinnati, Moss, Emory, and Duke for being re-open to enrollment amidst the COVID-19 restrictions. Cleveland VA is under IRB review and UPMC is finalizing study start-up activities. We are hopeful that our remaining sites will be reopened to enrollment soon! There are 17 subjects randomized in the trial, 13 have completed the study and we have several subjects we are hoping to randomize this month.

For sites that are preparing to re-open to enrollment, please complete the WebDCU™ COVID Impact Assessment Form. By acknowledging that your site is ready to re-open, WebDCU™ will release your site to restart research activities. Once your site is ready to restart, a call will be scheduled with sites that will go over any reminders or tips for your first subject visit.

Thank you for your continued effort and flexibility during this time!



**Site Startup and Enrollment Updates:** sites: **56**; enrollments: **166/350**

**In the setting of COVID, minimizing exposure of patients is critical.**



CREST-H can be discussed in the context of consenting for CREST-2, at the time other imaging is being mentioned. In order to save the patient an extra trip to your medical center, you can have the patient verbally agree to the perfusion scanning, and then have them sign the CREST-H consent when they arrive at the scanner. Remember, consent signing must occur **AT THE SAME TIME OR AFTER** randomization into CREST-2.

Recruitment continues on pace but we need all hands on deck! CREST-2 has <800 patients left to recruit. We need 184 of them for CREST-H. We are working on 8 additional sites in the onboarding pipeline which will help the effort. Keep an eye out for asymptomatic carotid patients and let's keep the enrollment going!

Interested in becoming a CREST- site? 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:**



**Recruitment, Recruitment, Recruitment!** 2020 is quickly coming to a close and we want to ensure that CREST-2 enrollment finishes strong! **We need 40 more patients** by the end of 2020 to complete our enrollment goals. As 52 StrokeNet sites are ready to enroll again, **one patient randomized from each of these centers would allow us to surpass expectations.** Increase screening efforts, talk to your colleagues, and spread CREST-2 awareness wherever you can to get us to 1785 by December 31, 2020!



FASTEST is excited to continue study start-up! We would like to thank you for your continued efforts and hard work getting FASTEST ready to launch.

Thank you to everyone that attended our monthly PI/coordinator webinar this week, with the focus on **imaging training and managing blood pressure**. The presentation and slides are now available on the StrokeNet website,

<https://www.nihstrokenet.org/fastest/webinars>. Our next webinar will be **Wednesday, December 16<sup>th</sup> at 2:00 pm ET**.

The ABC/2 and IVH Score Imaging Training is available, <http://fasteststudy.com>.

Approved EFIC community-facing template materials, English and Spanish, are available on WebDCU™, in the Toolbox under Project Documents.

A few helpful reminders:

- Reach out to the NCC if you have not submitted an EFIC plan for review. We would like to hear from sites, even if your site is still developing a plan.
- When you are ready to initiate your EFIC plan, update your DOA log with your EFIC team.
- Reach out if you plan to use the central REDCap survey and need access.
- Update the EFIC forms in WebDCU™ as you complete EFIC activities.

Congratulations, we now have **15** sites that have submitted EFIC plans to Advarra and are taking next steps to implement them! Since the last update -- **Virginia Commonwealth University (VCU) Medical Center, Ronald Reagan UCLA Medical Center**

Please contact Pooja Khanolkar (Prime Project Manager), [khanolpa@ucmail.uc.edu](mailto:khanolpa@ucmail.uc.edu) or Julie Denlinger (NCC Project Manager), [denlinik@ucmail.uc.edu](mailto:denlinik@ucmail.uc.edu) with any questions.



### **MOST Enrollment Update:**

Total randomizations: **108**

Randomizations between 05Nov2020 and 18Nov2020: **8**

Sites released to enroll with at least one subject consented: **33**

There are now **71** sites that have been released to enroll, **61** of which are actively recruiting!

- Congratulations to the following sites that have randomized a subject in the past two weeks! The **University of Alabama Hospital**, the **Mercy Health Saint Mary's** and the **Santa Barbara Cottage Hospital** teams each randomized their **1<sup>st</sup> subject** in the trial. Thank you for keeping the MOST trial a priority!
  - University of Alabama Hospital – Dr. Bakradze and Tammy Davis (**1<sup>st</sup> subject!**)
  - Mayo Clinic Jacksonville – Dr. Huang and Jaya Vijayan (**5 total subjects!**)
  - Kaiser Permanente Los Angeles Medical Center – Dr. Sangha and Marissa Barron (**2 total subjects!**)
  - UCSD Medical Center - Hillcrest Hospital – Dr. Meyer and Ashley Nespodzany (**3 total subjects!**)
  - Mercy Health Saint Mary's – Dr. Farooq and Julie Bishop (**1<sup>st</sup> subject!**)
  - Santa Barbara Cottage Hospital – Dr. Nguyen and David Cunningham (**1<sup>st</sup> subject!**)
  - Sarasota Memorial Hospital – Dr. Concha and Jeanette Wilson (**7 total subjects!**)
  - Memorial Hermann Texas Medical Center – Dr. Barreto and Jamey Franklin (**10 total subjects!**)
- Congratulations to **Grady Memorial Hospital** who has been released to enroll!
- Congratulations to Dr. Banerjee and the **Medical University of South Carolina University Hospital** site which has been re-released to enroll!

A reminder to collect the **Consent Experience Survey** for each enrollment. The survey should be completed at the Day 3/Discharge visit by the patient or LAR who gave consent. Surveys can be completed in-person, or they may be administered over the phone. Please enter survey data in WebDCU™ under **Study Progress** ☐ **Informed Consent Survey**.

Please mark your calendar for the November **MOST Trial Investigator Call** scheduled for 23Nov2020 at 2:00 PM ET. As a reminder, the Most Trial Investigator Call invitations are sent to the principal investigator and all study coordinators at each site. If you would like your pharmacist(s) and/or other study team members to join the call, please be sure to forward the call invitation to them.

The **PI Hotline** is available 24/7 for any questions: **1-833-229-MOST**.

## **NIH/NINDS News**

### **Seeking Your Ideas on the NIH-Wide Strategic Plan for COVID-19 Research**

In less than a year, we have learned much about SARS-CoV-2 and COVID-19 disease. The NIH-Wide Strategic Plan for COVID-19 Research, released last July, has helped us get to this point. The Plan prioritizes conducting fundamental research; advancing diagnostics, treatments and prevention strategies; and redressing poor COVID-19 outcomes in health disparity and vulnerable populations. Cutting across all of these priorities is an emphasis on the importance of scientific collaboration, the research workforce, and data science as keys to the response.



From shifting public health needs to the unprecedented pace of biomedical discovery, everything about the coronavirus response is evolving. This goes for the plan as well, so too must it evolve.

We want your help on the next iteration of the Plan. A Request For Information (RFI) released yesterday seeks public feedback on the current Plan (NOT-OD-21-018). You or your organization can submit ideas here by **December 7, 2020**: <https://rfi.grants.nih.gov/?s=5f91a3efdb70000018003362>

If you have noted significant research gaps or barriers in the original Plan, let us know. Or perhaps you can share new resources that NIH can leverage to advance one of the plan's priorities. Maybe a new scientific technique has emerged that could revolutionize COVID-19 research, well send the suggestion our way. We look forward to receiving your thoughts on ways we can continue tackling coronavirus disease going forward.

<https://www.nih.gov/sites/default/files/research-training/initiatives/covid-19-strategic-plan/coronavirus-strategic-plan-20200713.pdf>

## Feasibility Survey Reminder

The REMAKE survey MUST be completed in WebDCU™ by **11:59pm ET on Thursday, December 3rd**.

### Please NOTE:

Questions 11, 12, 13 and 14 will be anonymized prior to results being sent outside of the NDMC. Please answer these questions honestly as they will be de-identified. Any late survey submissions, however, will not be anonymized. Please consider these questions without regard to the current situation at your institution or your current competing trials, but rather with a broad perspective given that this proposed trial would start in 1.5 years at the earliest.

## NIH StrokeNet RCC Manager Reminder

Please work with your RCC network sites to upload their CIRB approved documents to WebDCU™ as soon as possible after a protocol modification or the annual continuing review. The newly approved documents need to be posted and used after CIRB approval and document distribution.

## NIH StrokeNet Coordinator Webinar

*Coordinator Webinars are a requirement for the NIH StrokeNet RCC Coordinators/Managers however, all are welcome to attend*  
**Wednesday, January 27, 2021**  
**1:30 pm ET**

## Steering Committee Call

*Steering Committee Calls are a requirement for all NIH StrokeNet RCCs; Please invite satellite sites to attend*

The next Steering Committee call is scheduled for **Wednesday, 9-December, 2020, at 11:00 am ET.**

Please visit <https://www.nihstrokenet.org/intranet/minutes/trial-proposal-presentations> in regard to the REMAKE proposal presentation on 18-November.

## Grand Rounds

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

**Thursday, January 28, 2021**

**4:00 pm ET**

Topic: Stroke Transitional Care and How it Fits into The Continuum of All Stroke Trials, Both Acute, Prevention and Rehab/Recovery

Presenter: **Cheryl Bushnell, MD**, Wake Forest University

Moderator: Shyam Prabhakaran, 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**

## Professional Development Webinar

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

**Tuesday, December 8, 2020**

**4:00 pm ET**

Presentation: The Basic Science Underpinnings of Clinical Pediatric Stroke

Presenter: **Heather Fullerton, MD**, University of California San Francisco

Moderator: TBA

To join the meeting, please go to this URL: <https://nihstrokenet.adobeconnect.com/pdw/> Please enter as a guest, then your email address or complete name.

**To take part in the conversation you MUST dial in. 1 (877) 621-0220, Pass code Number: 190825**

# NIH StrokeNet Employment Opportunities

## **MetroHealth Rehabilitation Institute and Case Western Reserve University Research Associate**

We are seeking a research associate candidate to assist with ongoing non-invasive brain stimulation and neuroimaging studies for participants with chronic stroke and spinal cord injury in the department of physical medicine and rehabilitation at MetroHealth Rehabilitation Institute and Case Western Reserve University.

A minimum of a Bachelor's degree with three years of research experience in a laboratory setting is required. This is a full-time position.

### **For more information please reach out to David Cunningham:**

David Cunningham, PhD  
Assistant Professor  
Department of Physical Medicine and Rehabilitation  
Case Western Reserve University School of Medicine  
MetroHealth Rehabilitation Institute  
Cleveland Functional Electrical Stimulation Center  
Email: [Dxc536@case.edu](mailto:Dxc536@case.edu)  
Lab Website: <https://dxc536.wixsite.com/cunninghamlab>

See below for a full list of responsibilities and requirements:

### **Summary:**

Performs the most complex quantitative analytical procedures of research projects. Provides input and recommendation to the Principal Investigator regarding significant development and procedures. Works closely with the Principal Investigator; carries out complex research assignments of a non-routine nature. Upholds the mission, vision, values, and customer service standards of The MetroHealth System.

### **Responsibilities:**

1. Plans and carries out projects in accordance with general project plans.
2. Conducts analysis of samples. Utilizes new and innovative research techniques involving a high degree of skill and training.
3. Collects and analyzes data.
4. Records and maintains results for a particular experiment or closely related series of

experiments.

5. Evaluates adequacy of techniques. Studies and tests new procedures and analyzes outcome of tests.

6. Coordinates lab activities of entry level Researchers; supervises experiments, protocols and reports.

7. Supervises work activities by interviewing and recommending hires, preparing and conducting performance appraisals, and providing training and orientation for new staff.

8. Displays sensitivity to and understanding of various cultural, ethnic, racial, and socioeconomic backgrounds.

9. Performs other job-related duties as assigned.

**Qualifications:**

Other information:

**Required:**

Bachelor's Degree in Biology, Chemistry, or related science (i.e. Neurosciences, Biomedical Engineering, Kinesiology, Computer Science) or any equivalent combination of education, training, and experience in addition to the experience stated below.

Three years experience performing research work in a laboratory setting.

Ability to interact effectively with a wide range of cultural, ethnic, racial, and socioeconomic backgrounds.

**Preferred:**

Five years' experience performing research work in a laboratory setting.

Contingent on assigned department, experience in one or more of the following: Java, Pearl, C++, and MATLAB.

**Physical Demands:**

May sit, stand, stoop, bend, and ambulate intermittently during the day.

May need to sit or stand for extended periods.

See in the normal visual range with or without correction.

Hear in the normal audio range with or without correction.

Finger dexterity to operate office equipment required.

May need to lift to twenty-five (25) pounds on occasion.

Ability to communicate in face-to-face, phone, email, and other communications.

Ability to see computer monitor and departmental documents



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

**Please share your satellites and study teams!**

*Contact: Jamey Frasure, PhD, RN, Administrative Director · [frasurjs@ucmail.uc.edu](mailto:frasurjs@ucmail.uc.edu) <https://www.nihstrokenet.org>*