



## Biweekly Update 23-October 2020

### StrokeNet Enrollment Update

ARCADIA	523/1100	TRANSPORT2	16/129
ARCADIA-CSI	98/500	I-ACQUIRE	30/240
Sleep SMART	347/3062	MOST	95/1200
SATURN	18/1456	CREST H	161/500
ASPIRE	4/700	CREST 2	1730/2480

## StrokeNet Trial Updates



- **ENROLLMENT HAS RESTARTED!**
  - StrokeNet Central Pharmacy resupplied study drug to sites with consented patients on October 13<sup>th</sup>.
  - Congratulations to **OSF St. Francis, UPMC Presbyterian Hospital, and Yale New Haven Hospital** for randomizing their consented 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 is on track for November
- 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/>
- ASPIRE next Webinar is October 28, 2020 3:00p-4:00p EDT <https://nihstrokenet.adobeconnect.com/trials/>  
To take part in the conversation dial 1 (877) 621-0220 Pass Code: 745694
  - Topic: Enrollment Challenges and Best Practices



SATURN has 80 sites open for enrollment and has randomized 18 patients!

SATURN will hold the next monthly PI/Coordinator webinar at 12:30pm ET on 10/29/2020. Please join us!

Please upload all outstanding CR documents to WebDCU™ and address any expired documents. Please be mindful of entering the correct effective and expiration dates for each document.

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

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)

#### **Questions regarding eligibility or protocol implementation**

- o Email: [SATURN@bidmc.harvard.edu](mailto:SATURN@bidmc.harvard.edu)

#### **SATURN Clinical Hotline**

- o Call 617-667-7000 and ask to page beeper #39636. Please tell the operator that you are calling about the SATURN trial.



ARCADIA

**ARCADIANS – let's push towards the randomization halfway point of 550!**

**We're almost there thanks to you!**

We still have some time left in October to pick up more randomizations. We have 26 subjects who are eligible for randomization and are still pending their randomization visit. That said, we want to make sure that these are done safely and per protocol so we understand that not all can be randomized immediately.

We have randomized 523 participants, an increase of 9 in less than two weeks. A special thanks to the nine teams that provided the last two weeks' randomizations: McLaren Macomb, Mount Clemens, MI; Mercy Health Saint Mary's, Grand Rapids, MI; Moses H. Cone Memorial Hospital, Greensboro, NC; Mount Sinai West, New York, NY; OU Medical Center, Oklahoma City, OK; UCSD Medical Center - Hillcrest Hospital, San Diego, CA; University of Cincinnati Medical Center, Cincinnati, OH; University of Iowa Hospitals & Clinics, Iowa City, IA and University of Kansas Hospital, Kansas City, KS –Thank you for your continued efforts!

We are currently at 1,972 subjects enrolled/consented, an increase of 42 in the last two weeks, thanks to 34 sites, with many sites enrolling more than once during this period – thank you to the site teams making this possible! A special thanks to St. Joseph's Hospital and Medical Center, Phoenix, AZ; UCSD Medical Center - Hillcrest Hospital, San Diego, CA; University of Cincinnati Medical Center, Cincinnati, OH; UPMC Presbyterian Hospital, Pittsburgh, PA, Yale New Haven Hospital, New Haven, CT and Northwestern Memorial Hospital, Chicago, IL for enrolling more than once during this period!

We would also like to welcome the St. John's Hospital, Springfield, IL team as the site was released to enroll this month!

We currently have 122 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 who would like to participate in ARCADIA. We hope to continue to re-start sites as per the ARCADIA re-start plan for the 12 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.

We understand that the enrollment challenges will change from site to site during this pandemic, but this is also a good time to assess performance from initial startup and see if there is anything that can be done to improve the enrollment at sites that have not been able to consent or randomize for a while prior to COVID. We will be reaching out to you and the RCCs about this in the coming weeks.

**REMINDER:**

CALM lab has finally moved to their new location. You can ship your samples to the new address:  
Dept of Pathology & Cell Bio, 630 W. 168<sup>th</sup> Street, P&S 15 401, NY, NY 10032, attention: Jane Netterwald, 212-305-4837.

We thank you for your continued support and effort during these challenging times, but together we can move forward in ARCADIA.

**Webinar:** Our next PI and coordinator webinar will be October 27<sup>nd</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>



**ARCADIA•CSI**  
Cognition & Silent Infarcts

Thank you to all the sites for your hard work in enrolling subjects into ARCADIA-CSI! We are 2 participants away from our milestone of 100!

The study team would like to welcome **NYP Columbia and Jackson Memorial 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:

Long Beach Memorial  
University of Kentucky  
UVA Medical Center  
Jackson Memorial

**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.

**Please complete the Covid19 Impact Assessment in WebDCU™ as soon as possible.**

Please contact Tashia Harris, [herndotl@ucmail.uc.edu](mailto:herndotl@ucmail.uc.edu) or Stephanie Kemp, [skemp@standford.edu](mailto:skemp@standford.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 October 21, 2020, 1007 subjects have been enrolled and 345 subjects have been randomized. Congratulations to the 17 sites who have randomized a subject in the month of October!!

**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 subjects some time prior to discharge. This contact between intervention subjects and the FusionHealth Care Team helps facilitate CPAP adherence post-discharge.

Protocol Amendment v7.0 was sent to all sites on 20Oct2020. The approval letter dated 12Oct2020 (for all sites listed on the letter) and the protocol signature page will need to be uploaded to WebDCU™.

**RE-OPENING:** In WebDCU™, please update the COVID Impact Assessment survey to reflect the current status of research at your institution and, if you are ready to re-start enrollments, to indicate confirmation (in 'general comments') of the statements in the memo dated May 15, 2020. Email Kayla or Joelle to let them know when your site is ready to be re-released to enroll. Pending NDMC queries may delay our ability to release you, so please catch up on these. **You will not be released to enroll until you receive official notice from WebDCU™.** Since our re-opening, 76 sites have been released to enroll and conduct in-person activities and 93 subjects have been randomized. If your site is not ready to enroll, but is able to complete in-person 3- and 6- month assessments, please contact Kayla or Joelle to seek permission for these limited in-person activities.



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, October 26, 2020 from 1-2 ET. We will review the protocol amendment v7.0 at that time in addition to other important reminders. As always, the webinar slides and recording will be available on our website for those who are unable to attend in real time: <https://www.nihstrokenet.org/sleep-smart-trial/webinars>

Thanks to everyone who attended the FusionHealth Virtual Hands-On Workshop on Wednesday, October 21, 2020. The Workshop was recorded and will also be available on our website for those who were unable to attend.



Our next PI and Coordinator call will be on **Monday, 11/09/2020 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 16 subjects randomized in the trial, 12 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!



## **Congratulations!** **We have enrolled 30 study participants!**

- Ann Arbor, MI – 3 participants randomized
- Boston, MA – 9 participants randomized
- Cincinnati, OH – 3 participants randomized
- Columbus, OH – 3 participants randomized
- La Jolla, CA – 5 participants randomized
- New Haven, CT – 3 participants randomized
- Roanoke, VA – 4 participants randomized

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

- ❖ Thursday 12 November (12-1pm ET)
- ❖ Thursday 17 December (12-1pm ET)

**Note:** The Treatment Implementation Center will be holding a Therapist Training session December 1 – 4, 2020 in Roanoke, VA. Please contact Mary Lou Schwarzer ([mary73@vtc.vt.edu](mailto:mary73@vtc.vt.edu)) for more information.



**Site Startup and Enrollment Updates:** sites: **56**; enrollments: **161/350**

Welcome to **Hartford Hospital**, our 56<sup>th</sup> site; they just received Green Light status to enroll! There are 8 additional sites in the onboarding pipeline. CREST-2 has <800 patients left to recruit. We need 189 of them for CREST-H. Let's continue the pace to meet our target. Keep an eye out for asymptomatic carotid patients and let's keep the enrollment going!

**In the setting of COVID, minimizing exposure of patients is critical.** We currently recommend that CREST-H 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.

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.

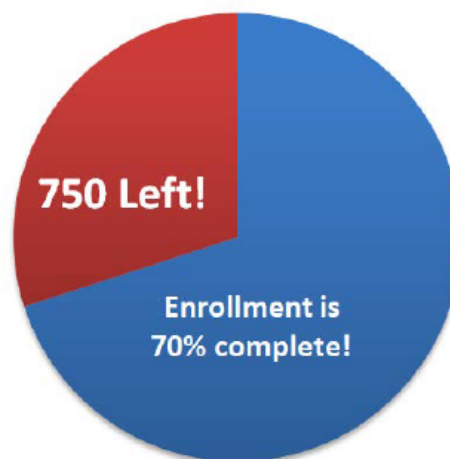
## **From the CREST-2 Clinical Coordinating Center:**



enrollment in December 2022.

**We have one more week left in October to meet our goal of 15!** There have been 10 randomizations thus far and we only need 5 more to meet our monthly goal. As a reminder, starting November the randomization goal will go up to 25 per month. **Enrollment is 70% complete!** Staying on track with these goals is essential to completing

**WE'RE COUNTING ON YOU!** We now have 108 sites re-initiated to resume enrollment, including 50 StrokeNet sites. If your site is ready to re-open for enrollment, please notify your site manager (if you have not done so already), so that we can make note of your site's status in CREST-2.



The SDCC has a data freeze scheduled for October 26<sup>th</sup> at 12 midnight central standard time (CST) to prepare for the upcoming DSMB report. Please enter and lock ALL outstanding AND current data by the date and time mentioned. If you have any questions, please reach out to your site manager or the SDCC.



## **MOST Enrollment Update:**

Total randomizations: **95**

Randomizations between 08Oct2020 and 21Oct2020: **6**

Sites released to enroll with at least one subject consented: **30**

There are now **70** sites that have been released to enroll, **58** of which are actively recruiting!

- Congratulations to the following sites that have randomized a subject in the past two weeks! Thank you for all your hard work on the MOST trial!
  - M Health Fairview Southdale Hospital – Dr. Benthoo and Megan Tessmer (**top enrolling site with 11 total subjects!**)
  - Central DuPage Hospital – Dr. Sachdeva and Robin Schmidt (**5 total subjects!**)
  - Sarasota Memorial Hospital – Dr. Concha and Jeanette Wilson (**4 total subjects!**)
  - UVA Medical Center – Dr. Chapman and Sonya Gunter (**2 total subjects!**)
  - The Jewish Hospital – Dr. Demel and Abigail Vollmer (**2 total subjects!**)
  - Houston Methodist Hospital – Dr. Misra and Jason Lee (**2 total subjects!**)

The October **MOST Trial Investigator Call** took place on 19Oct2020. A huge thank you to everyone that was able to attend. Topics for discussion included MOST trial updates, review of the eConsent process, including a live demonstration and data management updates. A recording of the webinar can be found at <http://nihstrokenet.org/most/webinars>.



Please note 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.

Please remember to update your Delegation of Authority (DOA) log when you update your FDA Form 1572 to change your principal investigator and/or to add new sub-investigators. In addition, if you update your DOA to add a new team member and their trial role includes obtaining informed consent, determining eligibility, administering the modified Rankin Scale and/or administering the NIH Stroke Scale, please ensure the new team member is also added to your FDA Form 1572. Please refer to the MOST Regulatory Document Parameter Guidelines for WebDCU™ located in WebDCU™ under the Toolbox tab within Project Documents for regulatory document requirements.

Please be sure to upload the CIRB approval letter that accompanies CIRB approved **translated** Informed Consent Forms, Participant Study Information Sheets and HIPAA Authorization Forms when uploading the documents in WebDCU™. The CIRB approval letter for **translated** documents should be uploaded in the CIRB Approved Administrative Amendments tab. The effective date will be the CIRB approval date within the letter and there is no expiration date required to be entered.

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



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 first monthly PI/coordinator webinar this week, with the focus on EFIC. We are pleased so many of you could join. The presentation and slides are now available on the StrokeNet website, <https://nihstrokenet.org/fastest/webinars>.

EFIC community-facing template materials are now approved by Advarra. Sites can use the templated, approved language to build and customize EFIC community-facing materials that suit their site needs.

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.
- Remember to update the EFIC forms in WebDCU™ as you complete EFIC activities.

Congratulations to the additional 2 sites (now a total of 8 sites!) that have submitted EFIC plans to Advarra and are taking next steps to implement them! -- **Central DuPage Hospital and UMASS Memorial Medical Center**

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



## Remote Procedures/eConsent Clarification

As a reminder for trials that are currently in the process of adding remote procedures including eConsent, (MOST, ASPIRE, SleepSMART and ARCADIA CSI) the Remote Informed Consent Implementation forms need to be returned to the NCC for CIRB submission. This form must be filled out and returned by all sites regardless of what procedures you will be using at your site even if you will not be using any remote procedures. **Sites should refer to study-specific guidelines for what methods are available when it comes to remote procedures including eConsent.** Please refer to SOP GCP 13, SOP ADM 24 or your trial specific SOP for more information on specific trial guidelines for remote procedures. For questions or more information please reach out to Emily Stinson [stinsoey@ucmail.uc.edu](mailto:stinsoey@ucmail.uc.edu) or your trial project manager.

## NIH/NINDS News

### Grant Submission Dates

Please make note: The NIH StrokeNet Clinical Trials and Biomarker Studies for Stroke Treatment, Recovery, and Prevention (UG3/UH3 Clinical Trial Optional) FOA, <https://grants.nih.gov/grants/guide/pa-files/PAR-20-285.html>, includes new submission dates:

**New Applications:** October 14, 2020; February 18, 2021; June 18, 2021; October 14, 2021; February 22, 2022; June 20, 2022; October 18, 2022; February 14, 2023, June 14, 2023 by 5:00 PM local time of applicant organization.

**Resubmission or Revision Applications:** November 18, 2020; March 22, 2021; July 14, 2021; November 18, 2021, March 22, 2022; July 20, 2022; November 18, 2022; March 14, 2023, July 23, 2023 by 5:00 PM local time of applicant organization.

### Required Submission of Financial Conflict of Interest Policy

Effective November 12, 2020, NIH funded recipients will be required to submit their publicly assessable Financial Conflict of Interest policy to NIH via the eRA Commons Institution Profile (IPF) Module (IPF Module). A PDF of the FCOI policy must be submitted by the institutional signing official (SO) via the IPF Module under a new tab labeled, "Policy Documents".

While the automated requirement goes into effect in November, NIH recognizes that recipients will need to modify their internal systems in order to comply. Therefore, applicants and recipients have until December 1, 2020, to comply with this requirement.

### Cyber Safety Reminders in regard to NIH-Funded Research

Please be reminded of the following important cybersecurity policies that apply to your NIH-supported research. These policies are designed to protect not only the NIH, but also you, your coworkers, your study participants, your institution, and your research. As healthcare and research institutions continue

to face mounting threats from cyberattacks, it's important that we all not only know how to protect sensitive information, but also make a personal commitment to keeping data safe.

When institutions like yours accept NIH awards, you also accept responsibility for protecting sensitive and confidential data as part of proper stewardship of federally funded research [[Section 2.3.12 of the NIH Grants Policy Statement \(GPS\)](#)]. This means, in part, that:

- **You must not house sensitive and confidential information about NIH-supported work on portable electronic devices.**
- **Data must be encrypted.**
- **Your institution must use proper controls to limit access to personally identifiable information.**
- **You and your institution should only transmit data when the security of the systems on the other side is known.**
- **You must take all reasonable efforts to prevent sensitive personal information, such as that held within online systems at your home institution, from being inadvertently lost, released, or disclosed.**

For awardees who collect, store, process, transmit, or use federal data, you must also make sure your information systems are protected from unauthorized access as required by the Federal IT Security and Management Act (FISMA) (see NIH GPS [Section 4.1.9](#)).

## November Coordinator Webinar - FASTEST

*Coordinator Webinars are a requirement for the NIH StrokeNet RCC Coordinators/Managers  
however, all are welcome to attend*

**Wednesday, November 18, 2020  
2:00 pm ET**

Due to the Thanksgiving Holiday, in place of the monthly RCC Coordinator webinar we invite you to attend the FASTEST Trial Monthly Webinar.

Please note the time and dial in information is different from the usual Coordinator webinar information. To join the meeting: <https://nihstrokenet.adobeconnect.com/fastest/> - Enter as a guest, then your first and last name.

**To take part in the conversation you MUST dial-in: 1 (866) 629-4752, Pass Code: 454907 - All phone lines will be muted, press \*6 to mute and unmute.**

## 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, 11-November, 2020, at 11:00 am ET.**

The 14-October Fall Network Webinar recording (and slides) can be accessed at [https://www.nihstrokenet.org/education/strokenet\\_meetings\\_presentations](https://www.nihstrokenet.org/education/strokenet_meetings_presentations).

## Grand Rounds

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

**Thursday, October 29, 2020**

**4:00 pm ET**

Topic: Patterns of White Matter Hyperintensities Define Underlying Causes of CSVD: An Unbiased Big Data Imaging Analytic Approach

Presenter: **Chia-Ling Phuah, MD, MMSc**, Washington University, St. Louis

Moderator: David Liebeskind, MD, UCLA

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*

**Thursday, November 12, 2020**

**2:00 pm ET**

Presentation: Finding & Negotiating your Perfect Job - Panel Discussion

Panel: **Karen Johnston**, University of Virginia  
**Larry Wechsler**, University of Pennsylvania  
**Shyam Prabhakaran**, University of Chicago

Moderators: Randy Marshall, Devin Brown

This will be a ZOOM meeting; stay tuned for details.

## NIH StrokeNet Employment Opportunities

*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>