



## Biweekly Update 9-October 2020

### StrokeNet Enrollment Update

|             |          |            |           |
|-------------|----------|------------|-----------|
| ARCADIA     | 514/1100 | TRANSPORT2 | 15/129    |
| ARCADIA-CSI | 82/500   | I-ACQUIRE  | 28/240    |
| Sleep SMART | 328/3062 | MOST       | 89/1200   |
| SATURN      | 16/1456  | CREST H    | 160/500   |
| ASPIRE      | 1/700    | CREST 2    | 1721/2480 |

## StrokeNet Trial Updates



ARCADIA-CSI  
Cognition & Silent Infarcts

Thank you to all the sites for your hard work in enrolling subjects into ARCADIA-CSI! We are now approved for eConsent. Please let us know if your site would like to use eConsent.

The study team would like to welcome **Buffalo General and Long Beach Memorial to ARCADIA-CSI!**  
**Our top 3 enrolling sites are:**

8 PATIENTS ENROLLED  
UNIVERSITY OF IOWA  
ENRIQUE LEIRA & HEENA OLALDE

7 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:

**Emory University**  
**UMass Memorial**  
**Abbott Northwestern**  
**Intercoastal**

**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@stanford.edu](mailto:skemp@stanford.edu) with any questions.



## **ARCADIANS continue to enroll despite the challenges – thank you!**

Our September randomization total was 25 participants which was a great monthly improvement since the COVID pause was lifted in June and even better than some pre-COVID months – you are amazing, now let's try to top that!

We have randomized 514 participants, an increase of 11 in less than two weeks. A special thanks to the eleven teams that provided the last two weeks' randomizations: Banner University Medical Center - Tucson Campus, Tucson, AZ; Greenville Hospital System, Greenville, SC; Mayo Clinic, Jacksonville, FL; Methodist University Hospital, Memphis, TN; Ochsner Medical Center - Main Campus, New Orleans, LA; Oregon Health & Science University Hospital, Portland, OR; UCSD Health La Jolla, La Jolla, CA; United Hospital, St. Paul, MN; University of Kentucky Hospital, Lexington, KY; University of Nebraska Medical Center, Omaha, NE and UPMC Presbyterian Hospital, Pittsburgh, PA. Thank you for your continued efforts!

We are currently at 1,930 subjects enrolled/consented, an increase of 34 in the last two weeks, thanks to 28 sites, with many sites enrolling more than once during this period – thank you to the site teams making this possible! A special thanks to Greenville Hospital System, Greenville, SC; Mercy Health Saint Mary's, Grand Rapids, MI; Methodist University Hospital, Memphis, TN; North Shore University Hospital, Manhasset, NY and Vanderbilt University Hospital, Nashville, TN for enrolling more than once during this period!

We would also like to welcome the Bon Secours St. Mary's Hospital, Richmond, VA as they have just been released to enroll this past week!

We currently have 119 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 15 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.

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.

Don't forget to email Rebeca and Pam about the challenges you've faced and how you've overcome them as we would like to show our gratitude to all the excellent investigators and coordinators we have on the team.

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>



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

As of October 7, 2020, 967 subjects have been enrolled and 326 subjects have been randomized.

Congratulations to Mayo Clinic Jacksonville (Brynn Dredla, MD and Eldina Stojadinovic) and University of Louisville (Tracy Ander, DO and Ann Jerde) for randomizing their first subjects!!

**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.

**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, 69 sites have been released to enroll and conduct in-person activities and 73 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 dates-**FusionHealth Virtual Hands-On Workshop will be Wednesday, October 21 2020 from 11-4 EST. A Zoom link invite will be sent the week prior to the workshop. All are welcome! And

Our next PI and coordinator webinar will be Monday, October 26, 2020 from 1-2 EST.



SATURN has 75 sites open for enrollment and has randomized 16 patients! This week we opened the first Canadian site, London Health Sciences in Ontario.

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

Please continue to update the COVID Impact Assessment with information on anticipated timelines for resuming research activities. Please reach out to the study team when your site is able to resume research activities. We will assist you with opening for enrollment when local restrictions allow.

Please upload all outstanding CR documents to WebDCU™ and address any expired documents.

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.



ASPIRE

- Randomization into the ASPIRE study was paused on July 8 due to an issue with study drug stability. We expect sites will start to receive new drug ASAP. We are encouraging sites to continue screening and consenting patients. Sites who have consented patients will be restocked first.
- Please remember to update the COVID-19 Impact Assessment v2 in WebDCU™ to alert us to any changes in local restrictions on screening or enrollment.
- For sites still pending activation, please:
  - o Upload/waive pending regulatory documents.
  - o Enter addresses for study drug and lab kit shipments.
  - o 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://nihstroketnet.adobeconnect.com/trials/> To take part in the conversation dial 1 (877) 621-0220 Pass Code: 745694





Our next PI and Coordinator call will be on **Monday, 10/19/2020 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)).

Eight sites have reopened to enrollment! Congratulations to Baystate, Medstar, UAB, USC, Kentucky, Moss, Emory, and Duke for being re-open to enrollment amidst the COVID-19 restrictions. Both Burke and MUSC are finalizing their institutional requirements for re-opening which should happen in the next couple of weeks. 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 15 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 28 study participants!**

- Ann Arbor, MI – 3 participants randomized
- Boston, MA – 9 participants randomized
- Cincinnati, OH – 3 participants randomized
- Columbus, OH – 1 participant 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:** Max Mays will be in contacting Study Coordinators to gather documentation for the 2020 I-ACQUIRE Continuing Review.

**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.



### **MOST Enrollment Update:**

Total randomizations: **89**

Randomizations between 24Sep2020 and 07Oct2020: **11**

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

There are now **70** sites that have been released to enroll, **57** of which are actively recruiting!

- Congratulations to the following sites that have randomized one or more subjects in the past two weeks! Great job teams!
  - M Health Fairview Southdale Hospital – Dr. Benthoo and Megan Tessmer (**top enrolling site with 10 total subjects!**)
  - Memorial Hermann Texas Medical Center – Dr. Barreto and Jamey Franklin (**9 total subjects!**)
  - McLaren Flint – Dr. Majjhoo and Marci Roberts (**7 total subjects!**)
  - Wake Forest Baptist Medical Center – Dr. Bushnell and Karin Haski (**6 total subjects!**)
  - Central DuPage Hospital – Dr. Sachdeva and Robin Schmidt (**4 total subjects!**)
  - SUNY Upstate Medical University – Dr. Latorre and Lena Deb (**3 total subjects!**)
  - University of Minnesota Medical Center Hospital – Dr. Benthoo and Megan Tessmer (**1<sup>st</sup> subject!**)
  - Vanderbilt University Hospital – Dr. Mistry and Drew Anderson (**1<sup>st</sup> subject!**)

Please mark your calendar for the October **MOST Trial Investigator Call** on 19Oct2020 at 2:00 PM ET. Topics for discussion include MOST trial updates, eConsent review and data management.

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



Welcome FASTEST sites! We would like to thank you for your efforts and hard work getting FASTEST ready to launch. We are pleased to begin adding to the Biweekly Update and are excited about our continued work together.

Thank you to everyone that attended the October 5<sup>th</sup> Virtual Investigator Meetings. We are pleased so many of you could join. The presentation and slides are now available on the StrokeNet website, <https://nihstroketenet.org/fastest/home>.

That brings us to our second announcement, we are officially on the StrokeNet website! We are working to populate the study pages with helpful information.

Lastly, we will begin our monthly PI/coordinator webinar this month. The webinar will be the third Wednesday of every month at 2:00PM ET. Look for the webinar invite coming soon!

Congratulations to **RCC 12 UCSD Health La Jolla and UCSD Medical Center - Hillcrest Hospital** on being the “FASTEST” and first sites to submit their EFIC plan to Advarra and start their EFIC activities! Congratulations as well to the other 5 sites that have also submitted their EFIC plans to Advarra! -- **North Shore University Hospital, University of Cincinnati Medical Center, Loyola University Medical Center, Memorial Hermann Texas Medical Center, and University of Chicago 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.



Sites: **55**; Enrollments: **160/350**

We 160 enrolled, representing 46% of our target. **Novant Forsythe, Kaiser San Diego, SUNY Buffalo, Wake Forest, Weill Cornell, and Kaiser Los Angeles** all enrolled in September. Thanks!!! We are still on pace to complete our target enrollments by the end of the study, but it will take dedication and perseverance!

**Tip of the month:** CT perfusion slots are often more accessible than MRP. Consider CTP if you need to obtain the CREST-H scan on short notice. Interested in becoming a CREST-H 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).

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



to end the year strong, considering our next recruitment goal is to have 25 randomizations per month starting November 1<sup>st</sup>. Staying on track with these goals is essential to completing enrollment in December 2022.

**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.



# 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](#)).

## Opportunity for Trainees

### 2020 NIH Virtual Seminar on Grants Administration and Program Funding

The National Institutes of Health invites you to take part in a unique (and \*FREE\*) opportunity to learn more about working with the NIH grants process, programs, policies, and staff at the 2020 NIH Virtual Seminar on Grants Administration and Program Funding.

Additional presenters and session information will be announced in the coming weeks. Registration is now open at <https://nihvirtualeseminar2020.vfairs.com/en/registration>.

Questions regarding this event may be addressed to [NIHRegionalSeminars@nih.gov](mailto:NIHRegionalSeminars@nih.gov).

## Coordinator Webinar

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

Due to the Fall network Webinar on 14-October, there will not be a Coordinator webinar this month. Please stay tuned for the November date and plan.

## 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 the Fall Network Webinar, scheduled for **Wednesday, 14-October, 2020, 12pm – 3pm ET**. Calendar invitations have been sent.

To join the meeting please log in to the webinar and also dial in in order to speak:

<https://nihstroketnet.adobeconnect.com/network/>

**1-877-621-0220 – Passcode 631088** - Please enter as a guest and then your first and last name. \*Please note, this is a different passcode than the monthly Steering Committee calls.

## 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, October 22, 2020  
2:00 pm ET**

Presenter: **Randy Marshall, MD**, Columbia University  
**Stephanie Wilbrand, PhD**, University of Wisconsin

Presentation: How to Prepare a Budget

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

## 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>