



Biweekly Update 14-August 2020

StrokeNet Enrollment Update

ARCADIA	474/1100	CREST 2	1692/2480
Sleep SMART	279/3062	CREST H	148/500
TRANSPORT2	14/129	MOST	63/1200
I-ACQUIRE	24/240	ARCADIA-CSI	60/500
ASPIRE	1/700	SATURN	9/1456

StrokeNet Trial Updates



Thank you for your participation in Sleep SMART. We hope you are doing well, especially during this difficult time.

AMENDMENT: All sites should have received protocol v6.0. Once the placeholders are available, please upload the CIRB approval letter and protocol signature page to WebDCU.

CONTINUING REVIEW: All sites should have received instructions for completion of continuing review documents. Please read the instructions before completing the documents. All documents need to be completed and returned to sicklejb@ucmail.uc.edu by September 4th.

RE-OPENING: On May 15, 2020, the CIRB approved our request to end the study-wide hold on in-person interactions, including enrollment, in Sleep SMART. Please report this to your local IRB, if appropriate. 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, 45 sites have been re-released to enroll and conduct in-person activities and 24 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

Sites that have already enrolled:

Don't forget these important reminders:

1. Who is considered a proxy in Sleep SMART (for the outcome assessments)? Someone who spends enough time with subject in the opinion of the study team member and proxy to estimate how the subject would have answered the question. Proxies should leave blank any question to which they don't feel capable of providing an informed response.
2. Recall that to be eligible for randomization after the run-in night, not only must CPAP use have been ≥ 4 hrs, and $CAI < 10$, but also, the subject must agree to continue on to randomization after run-in night exposure to CPAP. This requires the study team to ask the subject.
3. Please perform the 3- and 6-month follow-up visits by telephone (unless you have permission by Kayla or Joelle for in-person follow ups or your site is open for new enrollments) within the assessment window(!), by a blinded study team member: 90 days (-14 days, +30 days), 180 days (-14 days, +60 days).
 - If a blinded study team member is not available, but the assessment can still be done within window by an unblinded study team member, please take advantage of that opportunity and report performance by the unblinded investigator. If the assessments are completed by an unblinded study team member, an unanticipated event report will need to be completed in WebDCU
4. If the window for the 3-month visit ends and you have not been able to reach a subject, please continue to reach out to him/her until the 6-month window begins. Please pursue 6-month assessments out to 3 months past the 6-month assessment time point before considering the subject lost to follow-up.
5. If you can't get in touch with the subject by phone to schedule the outcome assessment, please check the consent form to see if you have permission to contact him/her by text or email. Alternative contacts may also be found in the back of the consent. Sleep SMART also has a letter template available on our website (<https://www.nihstroke.net.org/sleep-smart-trial/research-team>) and for those on the verge of being lost to follow-up, a lost to follow-up letter.
6. Please check your response to Q05 of F123 (Hospital Discharge form). If "no" please double check as most responses should be "yes." Please keep in mind that the question addresses quality of in-patient stroke care so it queries use of antithrombotics during the first 2 days after hospital admission. Also, antithrombotics include both antiplatelets and anticoagulants.
7. As a reminder, please ask subjects to answer PROMIS questions as they are written (do not provide specific instructions to attempt to eliminate the influence of COVID).
8. Please check "Alerts" in WebDCU to find unresolved queries.
9. Visit our website: www.nihstroke.net.org/sleep-smart-trial/research-team to review helpful materials.
10. If you missed one of our webinars, they are all available here: <https://www.nihstroke.net.org/sleep-smart-trial/webinars>
11. Recall that the informed consent checklist is mandatory to use for all enrollments.
12. Please complete the alternative contact information section of the informed consent document, and provide this information in KOEO.

13. Before hospital discharge, help initiate contact between intervention subjects and the Care Team: Program Care Team number in subject's cell phone if they agree, help them make a first call while they are still hospitalized, and remind them they can receive \$10 for another call completed after discharge but within the first week out of the hospital.
14. Remember to charge the Nox T3 internal clock quarterly.
15. All responses to Data Clarification Requests (DCRs) must be submitted within 5 days of query generation, except those associated with Serious Adverse Events, which must be answered within 24 hours of query generation. Site payments are contingent upon the subject's data being entered, submitted, and all DCRs addressed.
16. For stroke outcome events, please be sure to upload documentation in the outcome packets that provides information about new stroke symptoms, including focal neurological symptoms and signs on exam, and associated dates.
17. The 3- and 6-month mRS-9Q should not be completed using clinical notes. These questions must be directly asked of the subject (or proxy).

FusionHealth hands-on workshops: We conducted our first virtual hands-on workshop on July 29. Thanks to all who participated and made it a success! We will plan to have another workshop in the fall. Please let Kayla or Joelle know if you are interested in participating.

Save the date-Our next PI and coordinator webinar will be Monday, August 31, 2020 from 1-2 EST. We will be discussing remote consent options.



ARCADIA•CSI
Cognition & Silent Infarcts

Amendment V2 has been approved by the cIRB. The approved protocol and protocol signature page can be found in WebDCU in the toolbox. Complete the protocol signature page and upload into WebDCU.

The ARCADIA-CSI Study Team will be working on eConsent to be used during the study. Please let us know if your site will be using eConsent.

The study team would like to welcome **Mercy San Juan** and **United Hospital** to ARCADIA-CSI!

The following sites have been approved for Protocol Amendment V2 and are re-released to enroll:

- Intercoastal Medical Group
- UH Cleveland Medical Center
- St. Joseph's Hospital and Medical Center

All sites must complete the Covid 19 Impact Assessment Form in WebDCU prior to re-opening.

Sites still pending activation:

- Update **all** regulatory documents in WebDCU
- If you need to schedule your site readiness call – do so by contacting study team members below

Sites who were open prior to the Covid-19 pause:

- Update all regulatory documents
- Upload the approved continuing review documents

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

Site Startup and Enrollment Updates: sites: **55**; enrollments: **148/350**

Because of COVID, recruitment slowed, but we have enrolled 9 since reopening, bringing our total to 148, **42%** of our target. We are looking forward to reopening of the remaining CREST-H sites. Welcome to Lyerly Neurosurgery in Jacksonville, our 55th site. We have 8 additional sites in the onboarding pipeline.

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. Please feel free to contact Jaya, Kevin, or one of the CREST-H PIs with any questions about this. Remember, either MR or CT perfusion is acceptable as long as you have submitted and have approved a test image.

Interested in becoming a CREST- site? 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.



ARCADIA

Thank you for continuing to enroll in ARCADIA!

We appreciate everyone is working through the hot & stormy days of summer and all of the COVID challenges! Thank you for continuing to enroll in ARCADIA!

In the last two weeks, 24 sites have consented new subjects for a total of 1,800 consented participants, an increase of 30. A special thanks to the teams at Strong Memorial Hospital (NY) and Methodist University Hospital (TN) for consenting their first subjects!

Nine sites have randomized 10 subjects and now we have 472 randomized in ARCADIA. That is 32 more randomizations than when we were paused for COVID. A special thanks to the teams at: Oregon Health & Science University Hospital (OR), Jackson Memorial (FL), Northwestern (IL), Yale (CT), MedStar Georgetown (DC), Memorial Hermann Texas Medical Center (TX) and University of Alabama (AL). We also want to recognize Prisma Health Richland Hospital (SC) and Methodist University Hospital (TN) for randomizing their very first subjects! May this be the 1st of many more!

We have 98 sites throughout the US that have been released to enroll including 1 new site --welcome to the team at Ronald Reagan UCLA Medical Center in California!

We hope to continue to re-start sites as per the ARCADIA re-start plan and as possible at all the sites. 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) to review any pending items needed for your re-release. PLEASE do not start enrolling new subjects until your site has been re-released to enroll.

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

Webinar: Our next PI and coordinator webinar will be August 25th 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>



CREST-2 Enrollment

CEA	888
CAS	804
Total	1692

The world will never be the same because of COVID-19. That means CREST-2 will never be the same either. With our sites and our enrollment shutting down through the end of April, we had 0 enrollments in April and 5 in May. From June 1st through August 12th we have enrolled 34 patients, 1/3 of our usual rate but hopeful nonetheless. Special thanks to the StrokeNet sites that have re-opened and have contributed – with most of these sites enrolling more than 1 patient!

**Mayo Clinic Rochester – UPMC Altoona – Mayo Clinic Florida – Novant Health
Kaiser Permanente San Diego – UPMC Hamot – Oregon Health & Science University – VA Ann Arbor –
Ochsner Health – University of Iowa – Northwestern University – University of Alabama at Birmingham
– University of Florida Shands**

In addition to this, CREST-2 is **only 8** randomizations from having 1700 patients! This milestone would make us almost **70%** complete with recruitment. Please keep in mind our newly implemented COVID-19 recruitment goals:

- 15 randomizations per month through October 2020
- 25 randomizations per month through May 2021
- 30 randomizations per month through December 2022

Despite the challenges with the COVID-19 pandemic, **93** sites have been re-initiated for enrollment! We appreciate the continued effort that our sites have put into getting CREST-2 back up and running.



Congratulations!

All 12 sites have fully executed CTAs

9 sites have been released to enroll

- ❖ Houston most recently on 8/6/2020

5 sites have been approved to re-open (COVID-19)

- ❖ Boston, Cincinnati, Houston, La Jolla, and Roanoke

Total enrolled as of 8/11/2020 = **24**

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

- ❖ Thursday 10 September (12-1pm ET)
- ❖ Thursday 08 October (12-1pm ET)
- ❖ Thursday 12 November (12-1pm ET)
- ❖ Thursday 17 December (12-1pm ET)



Our next PI and Coordinator call will be on **Monday, 8/17/2020 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) or Julia Gonzalez, (Julia.jackson@duke.edu).

As sites are planning to reopen to enrollment, please take inventory of your supplies and contact either Julia Gonzalez or Kristina Balderson for restock. When reaching out, please indicate the number of supplies needed, contact, and shipping location with confirmation that someone will be able to receive these shipments. Home addresses are approved for receiving shipments during this time of remote working or limited time at the site. For other questions or concerns, please contact Julia or Kristina.

Please make sure you have completed your BlueCloud recertification training by logging into the website: <http://duke-transport2.trainingcampus.net>. Individuals who have expired or about to expire training have been sent reminder emails. **Note this is for the scoring of the Fugl Meyer, not the video training.** Annual renewal is now being tracked in WebDCU, which will notify coordinators directly when any of their staff have outdated training.

Congratulations to UPMC for being able to start the study team certification process! Congratulations to Baystate, Duke, Medstar, Kentucky, and UAB for being re-open to enrollment amidst the COVID-19 restrictions. We are hopeful that our remaining sites will be reopened to enrollment soon!! There are 14 subjects randomized in the trial. Six have completed the study and eight have completed the intervention phase but are in the follow-up period.

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



- Enrollment into the ASPIRE study was paused on July 8 due to a potential issue with study drug stability. We are working to get you a timeline for resumption of enrollment soon.
 - During this pause, we ask that all sites where enrollment is suspended to continue to screen and consent patients for ASPIRE if possible. Randomizations must be held until after the suspension is lifted.
- All sites must complete a Remote and Electronic Informed Consent Implementation form to be submitted to the cIRB via the ASPIRE NCC Project Manager. This form is posted in WebDCU > ASPIRE Toolbox
- 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:
 - Upload/waive pending regulatory documents.
 - Enter addresses for study drug and lab kit shipments.
 - If CTA and cIRB approval in place, schedule readiness call.
- ASPIRE next Webinar is August 26, 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



MOST Enrollment Update:

- Total randomizations: **63**
- There are now **66** sites that have been released to enroll, **52** of which are actively recruiting!
- Sites released to enroll with at least one patient consented: **23**
- Congratulations to the following sites that have randomized in the past two weeks!
 - University of Cincinnati Medical Center, **Site's ninth subject!** – Dr. Demel and Abby Vollmer
 - M Health Fairview Southdale Hospital, **Site's eighth subject!** – Dr. Benthoo and Megan Tessmer
 - Memorial Hermann Texas Medical Center, **Site's seventh subject!** – Dr. Barreto and Jamey Franklin
 - Wake Forest Baptist Medical Center, **Site's fourth subject!** – Dr. Bushnell and Karin Haski
 - McLaren Flint, **Site's third subject!** – Dr. Majjhoo and Marci Roberts
 - St. John Medical Center, **Site's second subject!** – Dr. Gordon and Lisa Shinder
 - University of Chicago Medical Center, **Site's first subject!** – Dr. Kramer and Vikrant Chauhan
 - SUNY Upstate Medical University, **Site's first subject!** – Dr. Latorre and Lena Deb
- Congratulations to the following sites that are released to enroll!
 - Ronald Reagan UCLA Medical Center
 - UPMC Presbyterian Hospital
 - UPMC Mercy Hospital
- Congratulations to the following sites that are re-released to enroll!
 - University of Mississippi Medical Center
 - Beth Israel Deaconess Medical Center

MOST Update:

- The August Investigator Call is on **Monday, August 17, 2020 at 2PM ET**. We look forward to speaking with everyone.
- Please complete and return the **Remote Consent Implementation Form** to indicate which method(s) of remote consent your team will use for MOST. This form must be completed for all sites, including those who elect not to use any form of remote consent. Return the form in an email to deedsss@uc.edu AND StrokeNetNCCreg@ucmail.uc.edu.

MOST Appreciated:

- For sites that are released to enroll please continue to complete screening logs in WebDCU™.
- For sites that have not been reactivated, please continue to update the COVID Impact Assessment in WebDCU™ with information on anticipated timelines for resuming research activities.

Thank you all for your efforts!

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

Coordinator Webinar

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

Wednesday, 26-August, 1:30pm ET

Topic: FASTEST Trial Presentation

Presenter: Pooja Khanolkar, MPH – FASTEST Prime Project Manager, University of Cincinnati
(Introducing) Julie Denlinger, RN – FASTEST NCC Project Manager

Moderator: Dave Haney, Case Western Reserve University

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

To take part in the conversation you MUST dial in. 1 (877) 621-0220 Passcode: 434578

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-September, 2020, 11:00 AM ET.**
Agenda TBA. Please note the new time going forward!!

Note: Wednesday, 14-October, 2020, is a regularly scheduled Steering Committee call. Please hold from 12 pm – 3pm ET on your calendars as this will be our **fall network meeting**.

RCC Coordinators/Managers

Please remember to upload your Notice of Award to your awardee folder on the www.nihstrokenet.org website.

Grand Rounds

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

**Thursday, August 27, 2020
4:00 pm ET**

Topic: Infectious Causes of Stroke in Adults and Children- COVID-19, Influenza, and Others

Presenter: **Shannon Agner, MD, PhD**, Washington University
Mitch Elkind, MD, MS, Columbia University

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

Professional Development Webinar

Professional Development Webinars are a requirement for the NIH StrokeNet Trainees

August 17, 2020

11:00 am ET

Presenter: **Jordan Elm, PhD**, Medical University of South Carolina

Presentation: Introduction to Biostatistics for Clinical Research

Moderator: TBA

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 <https://www.nihstrokenet.org>