StrokeNet Enrollment Update

ARCADIA	531/1100	TRANSPORT2	17/129
ARCADIA-CSI	105/500	I-ACQUIRE	31/240
Sleep SMART	362/3062	MOST	103/1200
SATURN	25/1456	CREST H	165/500
ASPIRE	8/700	CREST 2	1739/2480

*Enrollment as of 9-November 2020

StrokeNet Trial Updates

MOST
Multi-Arm Optimization of Stroke Thrombolysis

MOST Enrollment Update:
Total randomizations: **100**
Randomizations between 22Oct2020 and 04Nov2020: **5**
Sites released to enroll with at least one subject consented: **30**
There are now **70** sites that have been released to enroll, **59** of which are actively recruiting!

- Congratulations to the following sites that have randomized one or more subjects in the past two weeks! The **Wake Forest Baptist Medical Center** team randomized the trial's **100th subject**. Thank you to everyone for all your work on the MOST trial!
  - Wake Forest Baptist Medical Center – Dr. Bushnell and Karin Haski **(7 total subjects!)**
  - Sarasota Memorial Hospital – Dr. Concha and Jeanette Wilson **(6 total subjects!)**
  - Central DuPage Hospital – Dr. Sachdeva and Jennifer (Robin) Schmidt **(6 total subjects!)**
  - St. Louis University Hospital – Dr. Linares and Andre Guthrie **(2 total subjects!)**

- Congratulations to Dr. Fernandez and the DHR Health site which has been released to enroll!

The University of Glasgow inadvertently sent an additional video camera to all active sites who had already received one. Please follow the instructions sent from Ozzy Dincarslan on 27Oct2020 and return the extra camera to:

Iris Deeds
792 E McMillan St.
Cincinnati, OH 45206

REMINDER: Please utilize the **MOST Checklist for Preparing Event Packets** as the cover page for all Serious Adverse Events (SAEs) that require an event packet. The following SAEs require an event packet: Grade 5; Intracranial Hemorrhage, Asymptomatic; Intracranial Hemorrhage, Symptomatic; Major Hemorrhage Other Than Intracranial Hemorrhage.

Be sure to mark your calendar for the November **MOST Trial Investigator Call** scheduled for 23Nov2020 at 2:00 PM ET.

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.

Thanks again to everyone that attended our first monthly PI/coordinator webinar in October. The presentation and slides are available on the NIH StrokeNet website, https://nihstrokenet.org/fastest/webinars. Our next monthly webinar is scheduled for **Wednesday, November 18th at 2:00 pm ET**. We look forward to talking with you all then!

EFIC community-facing template materials, English and Spanish, are now available on WebDCU™, in the Toolbox under Project Documents. Sites can use the templated, approved language to build and customize EFIC community-facing materials that suit their site needs. The REDCap survey link is live on the NIH StrokeNet FASTEST page. Please reach out if you plan to use the REDCap survey and need access.

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, we now have **13** sites that have submitted EFIC plans to Advarra and are taking next steps to implement them! Since the last update -- **Greenville Hospital System, Mount Sinai West, Grady Memorial Hospital, and University of Alabama Hospital**

The ABC/2 and IVH Score Imaging Training is available. Look for more information coming soon!

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

TRANSPORT2

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) or Julia Gonzalez, (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!

I-ACQUIRE

Congratulations to the Philadelphia site for enrolling their first participant on 11/4!!
We now have enrolled 31 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
- Philadelphia, PA – **1** participant 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)

ARCADIA passes 2000 consented patients and adds first Canadian site!

We understand that enrollment in the time of COVID can present many challenges. This is why we are so grateful for your efforts and ask that you continue to plan to address challenges that exist or may arise as this impact changes in your area. Remember that we CAN consent (email, fax, mail), randomize and follow up using remote procedures and you can contact your participants in-person, by phone and via other telehealth methods permitted at the site. Your planning will need to include how the study blood draw will happen when the team cannot see the participant in-person after the consenting process and how these samples will be shipped to the CALM lab. Please reach out if you would like to discuss options. Some sites have been very resourceful and have worked out various options with their clinical and study teams.

We have randomized 529 participants, an increase of 6 in less than two weeks. A special thanks to the six teams that provided the last two weeks' randomizations: Intercoastal Medical Group - Hyde Park, Sarasota, FL; Tufts Medical Center, Boston, MA; University of Mississippi Medical Center, Jackson, MS; Henry Ford Hospital, Detroit, MI with a special congratulation for the University of Illinois Hospital, Chicago, IL for randomizing their first subject.

We still have 29 subjects who are eligible for randomization and pending that visit. We understand that not all can be randomized immediately; however, please continue to their randomization visit safely and per protocol.

We are currently at 2007 subjects enrolled/consented, an increase of 35 in the last two weeks, thanks to 27 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 NewYork-Presbyterian Brooklyn Methodist Hospital, Brooklyn, NY; OSU Wexner Medical Center, Columbus, OH; OU Medical Center, Oklahoma City, OK; Tufts Medical Center, Boston, MA; Vanderbilt University Hospital, Nashville, TN and Yale New Haven Hospital, New Haven, CT for enrolling 2 and 3 participants during this period!

We would also like to welcome the Hamilton General Hospital, Hamilton, ON, Canada team as the site was released to enroll during this period!

We currently have 124 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 1st 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 11 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) 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.

Webinar: Our next PI and coordinator webinar will be November 24th 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 to all the sites for your hard work in enrolling subjects into ARCADIA-CSI! We have hit our 100 participant milestone!

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 ENROLLLED
UNIVERSITY OF CINCINNATI
POOJA KHATRI & JENNIFER POWERS

6 PATIENTS ENROLLED
GREENVILLE HOSPITAL
PAULO ZORTEA & VICTORIA HOLT

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 or Stephanie Kemp, skemp@standford.edu with any questions.

- **ENROLLMENT HAS RESTARTED!**
  - StrokeNet Central Pharmacy resupplied study drug to sites with consented patients on October 13th.
  - Notify 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/

SATURN has 83 sites open for enrollment and has randomized 21 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 EST 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. These were shipped last week. 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
- MUSC Katie Stever steverca@musc.edu

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

SATURN is working to add REDCap central e-consent for those sites who are interested in e-consent. This will require an additional implementation form from each site to be submitted to the cIRB. More details to follow in the coming weeks.

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
- Sarah Marchina Prime Project Manager (BIDMC) smarchin@bidmc.harvard.edu

IMPORTANT STAURN CONTACTS:

- **Questions regarding eligibility or protocol implementation**
  - Email: 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.

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

October was a good month for Sleep SMART. We had 40 subjects randomized almost beating our record of 43 subjects randomized in a month. As of November 3, 2020, 1046 subjects have been enrolled and 360 subjects have been randomized.

Congratulations to the following sites for randomizing their first subject:
The University of Vermont (Christopher Commichau MD and Caroline Hall)
St. Louis University Hospital (Joanna Ramiro MD and Andre Guthrie)
Mary Free Bed Rehabilitation Hospital (Eric Geiser MD and Jennifer Dowsett)

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.

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, 80 sites have been released to enroll and conduct in-person activities and 97 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, 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.

CREST-H

Site Startup and Enrollment Updates: sites: **56**; enrollments: **165/350**

Recruitment continues on pace but we need all hands-on deck! CREST-2 has <800 patients left to recruit. We need 185 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!

In the setting of COVID, here's an idea to minimize exposure of patients:
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.

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.

From the CREST-2 Clinical Coordinating Center:

CREST-2

WE MET OUR OCTOBER GOAL! CREST-2 has met 5/6 monthly goals since establishing them in May – with your help! Let's raise expectations to the next goal, **25** per month through May. 51 of our 74 StrokeNet sites are ready to enroll again. We're counting on you!

Completion of CREST-2 Enrollment

70%

WINNERS
INOVA FAIRFAX HOSPITAL

Congratulations to the CREST-2 team at Inova Fairfax Hospital for randomizing the 15th patient for the month of October! Thank you to Inova Fairfax and all other sites that were able to contribute to CREST-2 in October! We have officially met our goal of 15 patients 5 out of 6 months since establishing them in May 2020. We look forward to raising the bar with raising our goals to 25 per month until mid-next year.

Dipankar Mukherjee, MD, CREST-2 PI at Inova Fairfax and Melissa Hockman, RN, BSN, Coordinator at Inova Fairfax, wearing their CREST-2 masks!

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

Did You Miss the 2020 NIH Virtual Seminar on Program Funding and Grants Administration?

Not to worry, the entire conference is still available to you on the event platform until Nov 19! The only thing missing is the immediate access to staff that the "live" event offered. Recordings of the presentations and related materials, as well as a plethora of resources from the Institute and Center Exhibit Hall booths await your exploration.
How to access seminar materials:
- Step 1: Register for the seminar at https://nihvirtualseminar2020.vfairs.com/en/registration.
- Step 2: Log-in with the email address you used to register.
- Step 3: Explore!

NIH Releases Final Policy on Data Management and Sharing

The Final policy applies to all research funded or conducted by NIH that results in the generation of scientific data. The Final Policy has two main requirements (1) the submission of a Data Management and Sharing Plan (Plan); and (2) compliance with the approved Plan. We are asking for Plans at the time of submission of the application, because we believe planning and budgeting for data management and sharing needs to occur hand in hand with planning the research itself. NIH recognizes that science evolves throughout the research process, which is why we have built in the ability to update DMS Plans,

but at the end of the day, we are expecting investigators and institutions to be accountable to the Plans they have laid out for themselves.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html

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 <u>MUST</u> 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, 9-December, 2020, <u>at 11:00 am ET.</u>**

The 11-Novemnber call has been canceled due to the Veteran's Day holiday.

Grand Rounds

Grand Rounds are a requirement for the NIH StrokeNet Trainees, however all are welcome to participate.
Thursday, 19-November, 2020
4:00 pm ET

Topic: Genomics of 6,000 Acute Ischemic Stroke Patients Reveals Genes Involved in Excitotoxicity

Presenter: **Jin Moo Lee, MD,** Washington University, St. Louis

Moderator: Devin Brown, 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 <u>MUST</u> 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 - <u>Panel Discussion</u>

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

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
Lab Website: https://dxc536.wixsite.com/cunninghamlab

See below for a full list of 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 https://www.nihstrokenet.org