

Monthly Update

05 – July 2019



School of Medicine
and Public Health
UNIVERSITY OF WISCONSIN-MADISON

REMINDER

Monthly Coordinator Call

The coordinator call is scheduled for August 15th at 10.30am

Neuro Teleconference Line:

USA Toll-Free: (877)848-7030

Access Code: 3386580

Enrollment Update (as of 07/03/2019)

- **CREST 2** – 1451/2480
- **ARCADIA** – 240/1100 randomized; 991/4400 consented/not randomized
- **CREST-H** – 84/500
- **Sleep SMART** – 10/3062
- **TRANSPORT2** – 0/129

REMINDER

Please remember to complete your **Annual Clinical Site Survey** – this is due August 1st, if you have questions please contact us.

This survey uses your data for site selection and participation in clinical trials for StrokeNet.

REVISED PLAN SIMPLIFYING MTA PROCESS

We have been trying to decrease the administrative work-load requirements for sites. Master Trial Agreements were part of initial RFA for StrokeNet but in retrospect have added additional work without a clear benefit since the clinical trial agreements contain the essential expectations of sites and coordinating centers for ongoing trials. Master Trial Agreements with the RCCs are already done and do outline the expectations for RCCs regarding sites in their networks which is helpful. While some satellites have also completed MTAs, many have not.

We had thought to use a very simple memorandum of understanding between RCCs and satellite sites in their networks rather than the longer and more complex Master Agreements so there was still clarity of which sites were in a regional network. This is important since productivity of RCCs are judged primarily by recruitment at regional network sites. However, any document requiring signatures between two institutions requires more effort and it was clear from your feedback that this attempt to make things simpler was making more work at some sites.

Thus, we have decided to make things as simple as possible. We will ask all RCCs to provide the NCC and the NDMC a list of all regional sites with the correct name, name of site PI and coordinator if appropriate. This will be updated yearly. This is important since some satellite sites that are currently with a legacy RCC may be transitioning to another RCC in the future. This list will then be used to attribute recruitments at a satellite with the associated RCC. The RCC will notify the NCC and NDMC of any changes regarding their Satellites and the Satellite's Clinical Performance Sites so the NDMC can update the WebDCU™ as appropriate. Updates for SS PIs, study coordinators, administrative and financial contacts are essential to efficient trial operations.

The RCC remains responsible for forwarding and bridging all major communications from the NIH StrokeNet (NCC/NDMC) — including newsletters, feasibility surveys, and educational opportunities — to each of their Satellites.

RCC and Satellites will continue to follow with the NIH StrokeNet Network Standard Operating Procedure ADM 09 RCC Management of Satellites and Performance Sites.

Thank you for your assistance and please call us if you have any questions.

Happy Fourth of July!! May the fireworks celebrate many enrollments in the weeks ahead.

Joe Broderick and Pooja Khatri on behalf of
The NIH StrokeNet National Coordinating Center

At the end, please find the latest bi-weekly StrokeNet newsletter and the dashboard.

RCC Contact Information

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Monthly Update



StrokeNet Trial Updates



ARCADIA

We're almost at 1,000 consented patients -- thank you all for making this possible!

As of July 3, 2019, 991 subjects have been consented at 114 sites and 240 subjects have been randomized at 77 sites. This is an increase of 36 consented and 10 subjects randomized in less than 2 weeks! Our enrollment is at 21.8% of the overall enrollment goal!

During the last two weeks, 26 sites have consented, and 10 sites have randomized eligible subjects. **We congratulate Buffalo General Medical Center (NY), Greenville Hospital System (SC) and Los Alamitos Medical Center (CA) on each randomizing their first subject!**

We have now released to enroll a total of 126 sites and are still working with other qualified sites to add them to the ARCADIA roster! Our randomization rate sits at **0.18 patients/ site/ month** based on our active sites. Please let us know of any excellent stroke sites that are interested in participating in this important trial.

Enjoy the holiday weekend and please keep approaching ESUS patients about the ARCADIA trial at your sites – Remember, every site's best effort is necessary for the trial to succeed!

Webinar: Our next PI and coordinator webinar will be July 23rd 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://nihstrokenet.org/education>).



Looks like July is going to be a great month for Sleep SMART!

Three additional sites released to enroll, seven subjects consented, and two subjects randomized already (as of July 3) this month!

We now have a total of 10 subjects randomized. Congratulations to the following sites for all their hard work and dedication:

1. Barnes-Jewish Hospital, St. Louis, MO-Eric Landsness MD, William Holt, and Jill Newgent-1 subject randomized
2. Prisma Health Midlands (Palmetto Health), Columbia, SC-Souvik Sen, MD and Jane Lim-3 subject randomized
3. UCSD La Jolla, La Jolla, CA-Dawn Meyer, NP, PhD, Theresa McQuaid, and Karen Rapp-1 subject randomized
4. UCSD Medical Center Hillcrest Hospital, San Diego, CA- Dawn Meyer, NP, PhD, Theresa McQuaid, and Karen Rapp-1 subject randomized
5. Brooks Rehabilitation Hospital, Jacksonville, FL-Parag Shah, MD and Taisiya Matev-2 subjects randomized
6. Cedars-Sinai Medical Center, Los Angeles, CA-Oana Dumitrascu, MD and Vicki Manoukian-1 subject randomized
7. University of Utah Healthcare, Salt Lake City, UT-Jana Wold, MD, Theodore Rock, and Kinga Aitken-1 subject randomized

If your site has not yet completed the clinical trial agreement (CTA) and/or FusionHealth consignment agreement or DUA please continue to work diligently with your contracts/legal teams to get them finalized before the end of July when the notice of award expires. Also continue to work on CIRB submission, create and submit your DOA and upload people and site regulatory documents. All of these will need finalized before your site can be released to enroll.


Important Reminder: If your site is running low on Nox T3 batteries, please contact Helgi Helgason directly at hgh@fusionhealth.com. In the future, you will be able to order batteries through the KOEO system.

The MOST team would like to thank the following sites for completing their site readiness calls:

- Stanford University Medical Center, Stanford, CA
- Yale-New Haven Hospital, New Haven, CT
- Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA
- UVA Medical Center, Charlottesville, VA
- University of Alabama Hospital, Birmingham, AL
- Northwestern Memorial Hospital, Chicago, IL
- University of Utah Healthcare, Salt Lake City, UT
- University of Wisconsin University Hospital, Madison, WI

Please make sure that your Institutional Pharmacy License is uploaded into WebDCU™ and enter your Pharmacy’s physical shipping address as well. Remember, the addresses must match or you will need to provide an explanation as to why the addresses differ to strokenetcpharm@ucmail.uc.edu

From the CREST-2 Clinical Coordinating Center:

 CREST-2	CREST-2	CREST-2 StrokeNet
CEA	761	277
CAS	690	103
Total	1451	380

Recruitment: we would like to highlight the CREST-2 study team at [Massachusetts General Hospital](#), [Kaiser Permanente Division of Research](#), [University of Alabama at Birmingham](#), and [Vanderbilt University Hospital](#) for randomizing since the last update! We are **249** patients away from our NIH-mandated goal of **1700 by February 2020**.

Medical Management Update: We are proud to announce that through your hard work we have **surpassed** the target systolic blood pressure goal of **<130 of 65%**! At **last follow-up**, the systolic blood pressure of **<130** is at **66.2%**!

Continuing Review Re-Approval Letters: All continuing review re-approval letters have been sent out! If you have not received yours, please contact your CREST-2 site manager.



Site Startup and Enrollment Updates:

sites: 47; enrollments: 84 (10 in June)

Welcome Ochsner Health Systems, our latest site to join!

With CREST-2 past the midway point, CREST-H needs to recruit nearly 1 of every two CREST-2 patients to meet our recruitment goals. Kaiser LA is on a roll, and Maine Medical, Mayo Rochester, Yale, Columbia, Iowa, and University Hospitals Cleveland remain leading enrollers. **THANKS!** If you have not done so already please submit your test images for CT perfusion. **Having CTP available as a backup will allow you to capture all potential CREST-H patients! Thanks.**

We are still recruiting additional sites. Contact Randy Marshall rsm2@columbia.edu, Ron Lazar rlazar@uabmc.edu, Jaya Vijayan vijayan.jaya@mavo.edu, or Kevin Slane KJS4@columbia.edu with any questions.



Reminder that our next PI and Coordinator call is scheduled for **Monday July 8th at 11am EST**. If anyone has topics they would like to discuss during the call, please send them to Kelly (krajeck@musc.edu).

If you already had your Readiness Call, please work to identify training subjects and schedule them for Rater & Trainer video certifications. This will be your last step to complete before your site is officially released to enroll. A few reminders:

- Coordinators- Please review your DOA and make sure all People Documents have been uploaded. If your site adds team members, don't forget to add them to the DOA and upload their documents.
- For mCIMT and Outcome Assessment training, we ask that you please make every effort to use a training subject who has had a stroke and has some UE deficits for certification.
- Be sure to have someone operate the camera during recording to ensure nothing is blocking the participant's movements.
- Please review the grading rubric that Drs. Rowe and Fritz posted in BOX to ensure you are meeting all the requirements BEFORE you start recording
- Raters – Don't forget to complete your self-assessment prior to informing Dr. Rowe that your videos are ready for review.

Please be sure to reach out to Kelly or any of the team members with any questions or updates regarding your site. If you feel you may need a refresher on any of the information covered during the Investigator Meeting, please reach out and we will be happy to schedule remote training sessions.

We look forward to enrolling our first subject soon!



Treating Therapist training in Roanoke, VA, (June 17-21, 2019) concluded on June 21, 2019. We would like to thank all in attendance during the four days of training.

There are 2 scheduled webinars for our Treating Therapists:

- ❖ Thursday, July 18 6:00pm EST – discuss fidelity and transfer packages
- ❖ Thursday, August 1 at 6:00pm EST – discuss and demo casting



Biweekly Update 5-July 2019

<http://nihstrokenet.org/coming-events>

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@crest2strokestudy



@CREST2_Study



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Joe Broderick and Pooja Khatri on behalf of
The NIH StrokeNet National Coordinating Center

Steering Committee Call

*Steering Committee Calls are a requirement for all NIH StrokeNet RCCs
(One representative per RCC required)*

The next Steering Committee call is scheduled for **10-July 2019, at 12 noon ET. Teleconference details: 1-877-621-0220, passcode 434578.**

NDMC News

PETITE Feasibility Survey

A feasibility survey for PETITE was sent out to the RCCs on 24-May. Please note that this is due by **17-June!**

Site Clinical Profile Annual Survey

The Site Clinical Profile Annual Survey for 2018 is now ready for data entry in WebDCU! RCCs – Please start working on completing this survey for each of the sites under your RCC. As a reminder, the data entered on these surveys are used for feasibility and site selection purposes. The data entered on these surveys should be for the 2018 calendar year. The 2016 survey is still available for viewing in WebDCU in case you need to refer back to what was entered for a site that year. We would appreciate completion by **1-August**.

Instructions for completing surveys in WebDCU:

- From the StrokeNet main menu page in WebDCU, click on [Project Management] and then [Site Clinical Profile Annual Survey]
- Click on the blue # link in the left hand column of the site and year (2018) that you want
- Once on the survey page, click [Edit Record] in the upper right hand corner of the screen
- Complete the survey and click [Save Record]. You are not required to enter all data at once.

If you have any questions or issues, please contact Jessica Griffin at simonsjl@musc.edu.

NINDS Clinical Trials Methodology Course

The CTMC is organized by the University of Michigan, in collaboration with the University of Iowa and Los Angeles BioMed

Upcoming webinar courses:

16-July 2019

Rare Disease Trials

Melanie Quintana

Unless otherwise specified webinars will generally be held on Tuesdays at 12PM ET: <https://bluejeans.com/7342322138>

For more information on fall webinar courses, please visit <https://nett.umich.edu/training/ctmc/ctmc-webinars>

StrokeNet Meetings/Webinars

Fall Network Meeting:

Tuesday, 29-October, Atlanta, Georgia. We anticipate up to **four** seats per RCC, with extra seats opening up after RSVPs are in, as in the past. There will NOT be a trainee meeting. Please send your RSVPs to Rose by **6-September**. On 9-September, we will open up the available seats on a first come-first served basis.

The RCC Network Coordinator should RSVP for all of the RCC members who will be attending. Each RCC may invite up to FOUR PARTICIPANTS, however, after RSVPs are in, additional spots will likely become available. Please RSVP to Rose, **no later than 1-October 2019**, noting your four participants and any names for the wait list. The NCC will reimburse two people from each RCC one night room and tax only.

While same day travel is possible in most cases, we have reserved a block of rooms for Monday, 28-October at the Atlanta Airport Marriott. We have negotiated a room rate of \$149 per night plus tax. Please book by **4-October 2019**. After that time, the group rate may not be available. These rooms are first come, first served, so act quickly. **Rooms not canceled 72 hours prior to arrival will incur a (non-reimbursable) cancellation fee.**

Please book your room via the reservation link below or call the hotel and ask to book in the StrokeNet Meeting room block:

<https://book.passkey.com/e/49950416>

Coordinator Webinar

Coordinator Webinars are a requirement for the NIH StrokeNet RCC Coordinators/Managers

Wednesday, July 24, 2019 - 1:30 PM ET

To join the meeting: <https://nihstrokenet.adobeconnect.com/coordinator/>. 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. 1 (877) 621-0220 Passcode: 434578

Professional Development Webinar

Professional Development webinars are a requirement for the NIH StrokeNet Trainees, however all are welcome to participate.

The next Professional Development webinar is TBD. Look for more information

Grand Rounds

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

The next Grand Rounds is TBD. We will keep you posted!

Seminars and Conferences

2nd Annual Aspen Conference on Pediatric Cerebrovascular Disease and Stroke

July 15-19, 2019

Viceroy Snowmass Hotel
Snowmass Village
Aspen Colorado

Online registration for this conference is required.

Please visit <http://www.cincinnatichildrens.org/AspenNeuro> to register.

StrokeNet Employment Opportunities

For more information on additional StrokeNet employment opportunities, please visit:
<http://www.nihstrokenet.org/education/employment-opportunities>

Postdoctoral Research Fellowship in Motor Recovery after Stroke

Focus: Probing motor recovery pathways with TMS and MRI

PI: Heidi Schambra, M.D.



A postdoctoral position is available Oct 1st in the Mobilis Lab of Dr. Heidi Schambra, in the Departments of Neurology and Rehabilitation Medicine at NYU. The Mobilis Lab aims to enhance

motor recovery after stroke using targeted physical training, noninvasive brain stimulation, and neuropharmacology. See www.mobilislab.com for our research areas and publications.

We are currently studying the role of a descending pathway in motor recovery after stroke. We are longitudinally evaluating its neurophysiology and neuroanatomy using TMS and advanced imaging techniques, respectively, in relationship to motor recovery in the paretic upper extremity. We expect the postdoctoral fellow to lead and develop this NIH-funded project.

We are seeking a motivated and enthusiastic candidate with primary interests in neurophysiology and neurorecovery. S/he must have PhD-level experience with TMS and behavioral testing in humans. S/he

must have the ability to work independently and with a collaborative interdisciplinary team, and should be comfortable working with healthy and stroke subjects. Experience with Matlab, Python, Igor, optical motion tracking, and/or Spanish language proficiency is a plus.

Specific responsibilities include:

- Acquiring and processing neurophysiology and behavioral data in human subjects
- Data analysis and synthesis
- Presenting findings at scientific meetings
- Writing and submitting manuscripts to peer-reviewed journals
- Contributing to grant proposals
- Mentoring students or visiting fellows

We will actively support the fellow's professional development of her/his academic research career. The postdoctoral fellow will also have the opportunity to learn about wearable sensor technologies, machine learning, diffusion kurtosis imaging, and transcranial electrical stimulation.

Interested candidates should submit (1) a CV, (2) a brief (2 pages or less) cover letter explaining their research experience, interests, goals, and available start date, and (3) the names, contact information, and roles of three references familiar with their research and academic work to Dr. Heidi Schambra at Heidi.Schambra@nyumc.org.



Baptist Health of Miami

Neuro Research Administrator (PhD)

<http://careers.baptisthealth.net/job/9788624/clinical-research-administrator-outcomes-research-ft-8a-4-30p-miami-fl/>

Full-time Vascular Neurology Faculty Position, Spectrum Health Medical Group

Title: Attending Vascular Neurologist

Field of Specialization: Stroke

Link to apply:

https://careers.peopleclick.com/careerscp/client_spectrumhealth/external/gateway/viewFromLink.html?jobPostId=123983&localeCode=en-us

Job Description: Spectrum Health's Department of Neurological Health is seeking to add a full-time vascular neurologist to their five board-certified vascular neurologist team. This new addition will participate in the Joint Commission certified Comprehensive Stroke Center at Butterworth Hospital in Grand Rapids, Michigan and support outreach to our surrounding regional hospitals. In addition to research opportunities, the position includes neurology residency and medical school teaching with faculty appointments through Michigan State University.

Spectrum Health Butterworth Hospital is a hub for regional stroke network in West Michigan.

Annual Stroke Volume: 1500+

Annual intravenous thrombolysis Volume: 150+

Annual Thrombectomy Volume: 150+

Requirements: MD or DO, BC/BE, ACGME-approved Vascular Neurology Fellowship

Contact: Christine Powers, Christine.powers@spectrumhealth.org
Full-time Neurocritical Care Faculty Position, Spectrum Health Medical Group

Title: Attending Critical Care Neurologist
Field of Specialization: Neurocritical Care

Link **to** **apply:**
https://careers.peopleclick.com/careerscp/client_spectrumhealth/external/gateway/viewFromLink.html?jobPostId=117639&localeCode=en-us

Job Description: Spectrum Health's Department of Clinical Neurosciences is seeking to add a full-time critical care neurologist to their fellowship-trained physician care team. This faculty member will participate in the Joint Commission certified Comprehensive Stroke Center and Level I Trauma Center at Butterworth Hospital in Grand Rapids, Michigan. In addition to research opportunities, the position includes neurology residency and medical school teaching with faculty appointments through Michigan State University. Robust Grand Round opportunities are available for CME/MOC and a Vascular Neurology Fellowship is also under development.

Leadership opportunity potential.

Spectrum Health Butterworth Hospital is a hub for regional stroke and trauma network in West Michigan.

Neuro ICU: 14 beds and growing

Annual Stroke Volume: 1500+

Annual intravenous thrombolysis Volume: 150+

Annual Thrombectomy Volume: 150+

Annual SAH Volume: 50+

Annual TBI Volume: 880

Requirements: MD or DO, BC/BE, Neurocritical Care Fellowship training

Contact: Christine Powers, Christine.powers@spectrumhealth.org



Lewis Katz School of Medicine

Department of Neurology
Lewis Katz School of Medicine at Temple University
Philadelphia, Pennsylvania
www.temple.edu/medicine

Summary of Opportunity

The Department of Neurology at the Lewis Katz School of Medicine at Temple University, is seeking applicants at the /Associate or Professor level to lead Temple's Stroke Division. The successful applicant will have completed a stroke fellowship and be BC/BE in neurology. The Stroke Medical Director, reporting to the Chair, will oversee the clinical, academic and research operations within the Temple Stroke Center.

The Temple University Stroke Center is a Joint Commission Comprehensive Stroke Center. The Stroke Service sees 800-1000 cerebrovascular related admissions per year. The program includes 2

neurointerventional faculty, and a 20 bed Neuroscience Intensive Care Unit staffed by stroke neurologists and neurointensivists. The program participates in the "Get with The Guideline's" Stroke Program and has consistently achieved Gold Plus and Target Stroke Honor Roll status. There is an active program of clinical trials through the StrokeNet Network (NINDS funded), a formal stroke prevention clinic utilizing evidenced based guidelines for risk factor modification. We are actively building our Stroke Teletstroke/Telemedicine network for acute stroke to neighboring community and rural hospitals.

In collaboration with the Department Chair and the organization's leadership, the successful applicant will be responsible for quality, safety and care provided on the stroke service and actively involved in performance improvement and cost containment initiatives. The Stroke Medical Director will provide leadership for regulatory and accreditation compliance and will co-direct the Temple Stroke Committee. The Director will be responsible for overseeing the residents for acute stroke care, share in the attending teaching schedule and help develop the stroke and acute care curriculum. He/she will maintain an outpatient practice and conduct research in one's area of interest. Stroke Telemedicine call has no in house obligations and will be shared with other attendings.

The Neurosciences Center at Temple University Hospital is one of the Philadelphia region's best facilities for the treatment of neurological disorders. A highly skilled and compassionate neurology and neurosurgery staff plus a state-of-the-art diagnostic center means access to advanced treatment options for patients with neurological disorders. Several of our physicians have been consistently selected by their peers as "Top Doctors," both locally and nationally. Working together, our neurologists and neurosurgeons use the latest protocols and state-of-the-art equipment, including the Leksell Gamma Knife® 4C, the Neuroblate® Laser Ablation System and the Elekta Synergy® S, to diagnose and develop individualized treatment plans for the full range of neurological problems.

Temple Health, one of Philadelphia's leading academic medical centers, is home to more than 1,000 physicians and scientists who share the mission of bringing innovative treatments to patients. Giving our patients access to some of the world's most advanced therapies — and helping them achieve outcomes once thought impossible — is the driving force for all our clinical care, research, and medical education.

Procedure for Candidacy

Interested candidates should submit a current curriculum vita and complete contact information to the following address: <https://bit.ly/2HexEz4>

Please address all applications to: Paul M. Katz, M.D., Director, Temple Stroke Program, C/O Michael Lester, Senior Director, Physician/Faculty Recruitment & Retention, Temple University School of Medicine, 3420 N. Broad Street, MRB 101, Philadelphia, PA, 19140, Email: michael.lester@tuhs.temple.edu

The University is especially interested in qualified candidates who can contribute through their research, teaching, and/or service to the diversity and excellence of the academic community. Lewis Katz School of Medicine at Temple University is an Affirmative Action/Equal Opportunity Employer and strongly encourages applications from women, minorities, veterans, and persons with disabilities.

Please share this with your clinical performing and satellite sites!

Contact: Jamey Frasure, PhD, RN, Director | NIH StrokeNet Coordinating Center | frasurjs@ucmail.uc.edu | 513-558-1742

<https://www.nihstrokenet.org>