

Monthly Update

7-September 2018



REMINDER!

Monthly Coordinator Call

The next coordinator call is scheduled for **Thursday, October 18th 10:30am.**

Neuro Teleconference Line: USA Toll-Free: (877) 848-7030

Access Code: 3386580

Enrollment Update (as of 08/31/2018)

- CREST 2 – 1142/2480
- ARCADIA – 76/1100 randomized; 270/4400 consented/not randomized
- CREST-H – 12/500
-

StrokeNet Trial Updates



ARCADIA is finishing the month of August strongly with 270 patients consented and 76 randomized!

ARCADIA Recruitment	
March 2018	2 subjects randomized
April	8
May	11
June	19
July	17
August	19
Total	76



1142 total randomizations of which 271 were from StrokeNet sites
30 in August of which 17 were from StrokeNet sites
117 active centers of which 49 are StrokeNet Sites

CREST-2
Congratulations to these CREST-2 StrokeNet Sites for randomizing since the last August update!

Site	August	Overall Total
Kaiser Permanente Los Angeles Medical Center	1	20
Massachusetts General Hospital	1	18
Oregon Health & Science University	1	17
OhioHealth Research Institute	1	17
Mayo Clinic Rochester	1	16
University of Florida Health at Shands	1	11
Emory University	1	10
University Hospitals Cleveland Medical Center	1	9
University of California, Los Angeles	1	6
University of Chicago Medical Center	1	3



RCC Contact Information

600 Highland Avenue
Madison, WI 53792

PI

Robert J. Dempsey, MD
Office 608.265.5967

Dempsey@neurosurgery.wisc.edu

Co-I

Azam S. Ahmed, MD
Office 608-263-1410

azam.ahmed@neurosurgery.wisc.edu

Clinical Research Manager

Stephanie M. Wilbrand, PhD
Office 608.265.9248

wilbrand@neurosurgery.wisc.edu

Research Coordinator

Stephanie Armstrong
Office 608.262-6493

armstrong@neurosurgery.wisc.edu

FAX 608.263.1728

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



Grand Rounds

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

Presentation: Community Education in Stroke – **Shyam Prabrakaran, MD**
Northwestern University

When: **Thursday, September 27, 2018 - 4:00 PM ET**

To join the meeting: <https://nihstrokenet.adobeconnect.com/grandrounds/> Please enter as a guest, then your email address or complete name. To take part in the conversation you must dial in, 1 (877) 621-0220 Passcode Number: 190825

NIH StrokeNet Coordinator Webinar:

Topic: TBA

Presenters: **TBA**

Moderator: Dave Haney, Case Western Reserve

When: **Wednesday, September 26, 2018 – 1.30pm ET**

To join Coordinator Webinars: <https://nihstrokenet.adobeconnect.com/coordinator/> Please enter as a guest, then add your first and last name or email address. For Audio: Dial-In Number: (877) 621-0220 Passcode 434578.

Please send suggestions for future coordinator webinar ideas to beckmare@ucmail.uc.edu.

Important updates!!!

- **Coming up 5 years of NIH StrokeNet**

The first Reliance Agreements have been sent out to sites. Thank you to those who have already returned them fully executed.

Soon the Master Trial Agreements will be sent out, be on the look out for that.

Trial Proposal Status:

- **MOST update – Ope Adeoye**

MOST has received Notice of Award, currently working on completing site selection and regulatory documents. Aiming for first enrollment in the Fall.

- **Sleep Smart update – Devin Brown**

Notice of Award received, working on completing site selection. Aiming for first enrollment late Fall.

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
FASTEST	Joe Broderick, Jim Grotto, Jordan Elm	Acute	June 2018 submitted
PAST-TIME	Jason McMullan, Opeolu Adeoye, Nerses Sanossian	Acute	June 2018 submitted
ARCADIA -CSI	George Howard, PhD Maarten Lansberg, MD/PhD Ronald Lazar, PhD Kevin N. Sheth, MD David Tirschwell, MD	Acute	June 2018 submitted
IMPACT	Andrew Naidech	Acute	July 2018 submission
VERITAS II	Sepideh Amin-Hanjani	Prevention	July 2018 submission
IACQUIRE (formerly IRIIS)	Warren Lo, Sharon Ramey	Recovery	August 2018 study section
ALISAH 2	Jose Suarez	Acute	August 2018 study section
ASPIRE (formerly SCORPION)	Kevin Sheth	Prevention	August 2018 study section
SPLASH	Jose Suarez, DaiWai Olson (contact PI)	Acute	October 2018 submission
CASH	Adnan Qureshi	Acute	October 2018 submission
I-WITNESS	Lee Schwamm, Ona Wu, Steve Warach, Larry Latour, Shlee Song	Acute	October 2018 resubmission A01
PreLIMBS II	Sebastian Koch, Nestor Gonzalez, Neeraj Chaudhary	Acute	October 2018 resubmission A01

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
CAPTIVA (CRISIS)	Brian Hoh	Prevention	November 2018 submission
FURRTHER	Bernadette Boden-Albala	Prevention	November 2018 resubmission
Tempo-EMS	Nerses Sanossian, William Meurer, Jeffrey Saver, David Hess	Acute	Hold for now
MATRICES	Maarten Lansberg, Greg Albers, Albert Yoo, Sam Zaidat	Acute	In concept development (no CSP on file)
DEFUSE TNK	Maarten Lansberg	Acute	In concept development, archive after 1-June 2018
ETHER	Stephan Mayer	Acute	On hold for EVD platform
SERENE (ASSIST + SEACOAST)	Radoslav Raychev, Dimiter Arnaudov, David F. Kallmes, (Radiology) Alejandro Rabinstein, (Neurology) Jeffrey Pasternak, (Anesthesiology) Rickey Carter, (Biostatistics)	Acute	On hold for EVD platform
PRECISE MRI-T2	Natalia Rost, Shyam Prabhakaran, Rebecca Gottesman, Clinton Wright	Prevention	In concept development
NEPTUNE (ARCADIA ancillary study)	Ajay Gupta, Hooman Kamel	Prevention	In concept development
Claassen	Jan Claassen	Acute	In concept development
HEMERA	Italo Linfante, Raul Nogueira	Acute	On hold for EVT platform
ARCADIA ORACLE	Babak Navid, MD, MS	Prevention	Hold ARCADIA ancillary study

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
CIAT RCT	Jerzy Szaflarski, MD	Recovery	In concept development
TACOCAT (COAT)	Brett Cucchiaria, MD Scott Kasner, MD	Prevention	In concept development
SCOUT (Ancillary to Sleep Smart)	Sandeep P. Khot, Martha E. Billings	Recovery	In concept development 25-April 18: Extensive feedback in recent weeks. Now at point where they are connecting that feedback with NIH and with the primary study (Sleep Smart)
WISC-R	Matthew Durand, Robert Dempsey, Allison Hyngstrom, John McGuire	Recovery	In concept development
ERSIAS	Nestor Gonzalez, Jeff Saver	Prevention	In concept development
BLAST	James Meschia	Prevention	In concept development
FOCAS	Heather Fullerton, Mitch Elkind	Prevention	In concept development
CAVIS	Mark Harrigan	Prevention	In concept development
SPLIT	Andrew Naidech	Prevention	In concept development
RAFT	Truman Milling, Steve Warach	ACUTE	In concept development
START	Steve Warach, Truman Milling	Prevention	In concept development
URIC	Enrique Leira	Acute	In concept development
SUCCESS	E. Sander Connolly Jr., John D. Lambris, Jan Claasen	Acute	In concept development
BrainPulse	Kyle Walsh, Shakeel Chowdhry, Julian Bales, Andrew Russman	Acute	In concept development
Hasan – Intracranial Stenosis	David Hasan	Prevention	In concept development



Biweekly Update 17-August 2018

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

StrokeNet Enrollment Update

CREST 2 – 1142/2480

CREST H – 12/500

ARCADIA – 76/1100 randomized; 270/4400 consented

StrokeNet Trial Updates



ARCADIA is finishing the month of August strongly with 270 patients consented and 76 randomized!

ARCADIA Recruitment	
March 2018	2 subjects randomized
April	8
May	11
June	19
July	17
August	19
Total	76

United Hospital in St. Paul MN continues to lead the way with 7 patients randomized.

Oregon Health and Science University (OHSU) and the University of Iowa are tied, each with 6 patients randomized.

We now have 88 sites released to enroll. It is vital that we get the rest of our sites activated so we have the full complement recruiting. Please get your readiness calls scheduled.

As we mentioned on the Webinar this week, some sites may begin to see warning notices (emails) about failure to consent any subjects.

If your site has been activated, but you are struggling to identify ESUS patients, please reach out to us.

We will include some best practices on the next ARCADIA Webinar which will be Sept. 25th at 2pm ET.

Thank you from the ARCADIA Team!!



1142 total randomizations of which 271 were from StrokeNet sites
30 in August of which 17 were from StrokeNet sites
117 active centers of which 49 are StrokeNet Sites

CREST-2

Congratulations to these CREST-2 StrokeNet Sites for randomizing since the last August update!

Site	August	Overall Total
Kaiser Permanente Los Angeles Medical Center	1	20
Massachusetts General Hospital	1	18
Oregon Health & Science University	1	17
OhioHealth Research Institute	1	17
Mayo Clinic Rochester	1	16
University of Florida Health at Shands	1	11
Emory University	1	10
University Hospitals Cleveland Medical Center	1	9
University of California, Los Angeles	1	5
University of Chicago Medical Center	1	3

Don't stop



ENROLLING!



We had 4 more sites green lighted in the last 2 weeks, bringing our total to 27 sites and 12 patients enrolled. Welcome to Maine Medical, U Wisconsin, Mercy St. Louis, and Kaiser Permanente Los Angeles. There are 27 more sites in the pipeline to be green lighted. Leading enrollment with 3 patients is UPMC, followed by U Iowa and Michigan Vascular with 2. Fastest out of the gate was Gundersen Health, enrolling their first patient on the day they were green lighted.

KEEP IN MIND:

1. CREST-H will soon be allowing **CT perfusion** as an option in addition to MRI perfusion. This will permit more patients to be enrolled and give sites an additional option to work with.
2. Site **reimbursement** will be **increasing by 30%**, allowing more sites to participate.

HELP US FIGURE OUT IF REVASCLARIZATION WITH REPERFUSION CAN HALT OR REVERSE COGNITIVE DECLINE... If you have an active CREST-2 site in your RCC that is not yet enrolling in CREST-H, let us know. Contact Randy Marshall rsm2@columbia.edu or Kevin Slane at KJS4@columbia.edu. We are still recruiting sites.

NINDS New Funding Announcements

New Funding Opportunity Announcements (application due date **December 13, 2018**):

RFA-NS-18-033

Stroke Preclinical Assessment Network (SPAN) to Support Translational Studies for Acute Neuroprotection (U01 Clinical Trial Not Allowed)

<https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-18-033.html>

The purpose of this funding opportunity announcement (FOA) issued by NINDS is to invite applications for network sites for the NIH Stroke Preclinical Assessment Network (SPAN). SPAN will facilitate testing of up to 6 promising neuroprotective drugs or interventions to be given prior to or at the time of reperfusion in experimental models of ischemic stroke (e.g., transient middle cerebral artery occlusion). The awarded network sites will become part of the network and will collaborate with the other awarded sites under the oversight and central coordination provided by the SPAN Coordinating Center (RFA-NS-18-034). Applicants for the network sites must propose a promising neuroprotective intervention to be tested within SPAN; awarded sites will test up to 6 interventions in parallel, including their own. If successful, this network will accelerate the identification of the most promising neuroprotective therapies for future pivotal clinical trials and span the gap between preclinical and clinical testing, in a cost- and time-effective fashion.

RFA-NS-18-034

Stroke Preclinical Assessment Network (SPAN) to Support Translational Studies for Acute Neuroprotection - Coordinating Center (U24 Clinical Trial Not Allowed)

<https://grants.nih.gov/grants/guide/rfa-files/RFA-NS-18-034.html>

The purpose of this funding opportunity announcement (FOA) issued by NINDS is to invite applications for the Coordinating Center (CC) for the NIH Stroke Preclinical Assessment Network (SPAN). SPAN will facilitate testing of up to 6 promising neuroprotective drugs or interventions to be given prior to or at the time of reperfusion in experimental models of ischemic stroke (e.g., transient middle cerebral artery occlusion). The CC will work with the awarded network sites (RFA-NS-18-033) and will provide centralized administrative oversight and coordination of all aspects of the network. If successful, this network will accelerate the identification of the most

promising neuroprotective therapies for future pivotal clinical trials and span the gap between preclinical and clinical testing, in a cost-and time-effective fashion.

NDMC Survey Reminders!

The **SATURN Site Selection Survey** was sent for your review and completion on 17-August.

Surveys **MUST** be completed in WebDCU™ or emailed to simonsjl@musc.edu by 11:59pm ET on **Tuesday, September 4th**.

NINDS News and Resources

All about Grants Podcasts

<https://grants.nih.gov/news/virtual-learning/podcasts.htm>

The Office of Extramural Research (OER) talks to NIH staff members about the ins and outs of NIH funding. Designed for investigators, fellows, students, research administrators, and others just curious about the application and award process, we provide insights on grant topics from those who live and breathe the information. **Episodes are available as mp3s for download via iTunes, or via RSS feed.**

The current podcast below is included under the **Preparing a Successful Grant Application** series:

Inclusion across the Lifespan policy

Starting January 29, 2019, NIH will begin implementing the Inclusion across the Lifespan policy, which requires the consideration of age, along with sex/gender and race/ethnicity, in applications that involve human participants.

In addition, you will find podcasts in many interesting and informative topics (and corresponding transcripts) in each of the podcast series below:

- Preparing a Successful Grant Application
- Getting to Know NIH and the Grants Process
- Advice For New and Early Career Scientists
- Submitting Your Application
- How NIH Grants Are Reviewed
- Life As An NIH Grantee (Post-Award Activities and Requirements)

CIRB Corner

Congratulations to **MetroHealth** on receiving CIRB approval for ARCADIA with no reviewer comments returned on their initial submission. Way to Go!!!!

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 **12-September, 2018 at 12 noon ET.**

Just a reminder, minutes from all Steering Committee calls can be accessed via the www.nihstrokenet.org website. After log in, click on the "Minutes" tab, then at the dropdown menu, select "Steering Committee".

Coordinator Webinar

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

Topic: TBA

Presenters:

Moderator: Dave Haney, Case Western Reserve

When: **Wednesday, September 26, 2018 – 1:30 PM ET**

To join Coordinator Webinars: <https://nihstrokenet.adobeconnect.com/coordinator/> Please enter as a guest, then add your first and last name or email address. For Audio: Dial-In Number: (877) 621-0220 Passcode 434578.

Please send suggestions for future coordinator webinar ideas to beckmare@ucmail.uc.edu.

Professional Development Webinar

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

Presentation: CV and Biosketch – **Lori Jordan, MD, Vanderbilt University**

When: **Monday, September 24, 2018 - 1:00 PM ET**

To join the meeting, please go to: <https://nihstrokenet.adobeconnect.com/pdw/>

Please enter as a guest, then your email address or complete name. To take part in the conversation you **MUST** dial in. 1 (877) 621-0220 - Passcode Number: 190825

Grand Rounds

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

Presentation: Community Education in Stroke – **Shyam Prabrakaran, MD**
Northwestern University

When: **Thursday, September 27, 2018 - 4:00 PM ET**

To join the meeting: <https://nihstrokenet.adobeconnect.com/grandrounds/> Please enter as a guest, then your email address or complete name. To take part in the conversation you must dial in, 1 (877) 621-0220 Passcode Number: 190825

StrokeNet Network Meetings and Important Info

The next NIH StrokeNet Network meeting will be held on Tuesday, 16-October, 2018, prior to the World Stroke Congress in Montreal.

RSVPs are in, and those on the waiting list have been notified. Please do not attend if you have not RSVPd; there will be *no extra seating*.

RCC Managers/Coordinators will meet directly following the general session. Please contact Dave Haney (David.Haney@uhhospitals.org) if you have agenda items you would like to add.

Venue:

Palais des Congrès
301 Saint-Antoine West (Entrance opposite the Westin Hotel)
Montreal QC
H2Z 1H2

NOTE: Going forward, the NIH StrokeNet will have one in-person network meeting per year, in the fall. In the spring, there will be a half day all-network webinar.

Upcoming Conferences, Seminars and Educational Opportunities

OHRP Exploratory Workshop: *Meeting New Challenges in Informed Consent in Clinical Research*

Livestream: Friday, September 7, 2018, 8:00 a.m. – 4:45 p.m. ET*

View the event: <https://videocast.nih.gov/live.asp?live=28334>

No registration required - International viewing supported

The HHS Office for Human Research Protections (OHRP) Exploratory Workshop is a new initiative to provide a forum for intellectual exchange within the research community on important issues related to human subjects protections. The workshop will bring together experts from diverse perspectives to discuss challenges for informed consent and innovative ways to address them. We anticipate that panel discussions will involve only invited speakers and moderators.

Sessions

- A. Laying the groundwork for meaningful informed consent
- B. Effectively presenting information to facilitate high-quality decision-making
- C. Pragmatic clinical trials (PCT) – challenges and innovations in getting informed consent
- D. Delivery room research and the challenges for informed consent
- E. Closing: Moderators panel

**For those unable to watch the Livestream due to time zone differences, the video and summary reports will be made available on the workshop website a few weeks after the event:* <https://www.hhs.gov/ohrp/education-and-outreach/exploratory-workshop/2018-workshop/index.html>

*For more information on these and other conferences and seminars, please see:
<http://nihstrokenet.org/in-the-news>

NIH StrokeNet Employment Opportunities

**Clinical Research Project Manager
NIH StrokeNet NCC
Department of Neurology
University of Cincinnati, College of Medicine**

The University of Cincinnati is a premier, public, urban research university; ranked as one of America's top 26 public research universities by the National Science Foundation. U.S. News has ranked UC in the Top Tier of America's Best Colleges. The Chronicle of Higher Education calls UC a "research heavyweight". Forbes, Delta Sky and Travel + Leisure magazines have named UC one of the most beautiful campuses. #HottestCollegeInAmerica

UC is one of the largest employers in the Cincinnati region, employing over 15,000 full time and part time faculty, staff and student workers. The College of Medicine, Department of Neurology, is looking for a Clinical Research Project Manager. This position will support the University's mission and commitment to excellence and diversity in our students, faculty, staff and all our activities.

Duties And Responsibilities Of The Position

1. Serve as the lead project manager on a NIH-funded trial for 0.5 FTE of this full-time position.
2. Works collaboratively with newly funded trial PIs during start-up activities in the pre-award period until a project manager is hired and trained.
3. Provides guidance to NCC project managers for establishing trial timelines and completion date targets and work flow and process guidelines.
4. Collaborates with NCC project manager to determine network project management and or site management services for new network trials.
5. Works with NCC project manager to oversee distribution of trial specific Medwatch or safety reporting information.
6. Contributes to the performance evaluation process of NCC project managers.
7. Works in collaboration with the CIRB liaison on CIRB and fCOI issues in StrokeNet trials.
8. Assists in the development of administrative and GCP network SOPs.
9. Participates in network governance as a member of the Executive and Steering committees.
10. May participate in working groups as a representative of NCC.
11. Serves and as a resource for PPI/sponsor and NCC project managers for the submission of regulatory correspondence, progress and safety monitoring, and reporting to regulatory agencies.
12. Participates, as needed, in clinical trial site assessments including but not limited to site initiation visits, closeout visits and regulatory or performance audit visits in conjunction with NDMC staff.
13. Participates, as needed, the development of trial specific protocols/amendments, MOPs, and educational and training needs.
14. Assume administrative director role for urgent matters and time sensitive activities when s/he is absent.
15. Attend trial DSMB meetings if project manager is unavailable.
16. Travel after normal business hours as required.

Skills and Characteristics Needed:

- Ability to see the complexities of projects and understand how each role at the NCC contributes to getting the necessary work done in a timely manner.
- Keeps supervisor and co-workers informed of necessary facts, related to job progress, projects, tasks, results, and/or problems.
- Shares knowledge and expertise regarding the process or procedure required to carry out specific duties and responsibilities.
- Adapts easily to changing situations.
- Ability to listen first, ask questions, and then facilitate to direct with the answers and solutions at hand.
- Promote cross-level and cross-functional collaboration within the NCC.
- Supports employees with clear direction and help with problem-solving skills if necessary.

- Attempts to lead with transparency and honesty.

Minimum Qualifications: Bachelor's degree required, preferably in related discipline or equivalent education/experience. At least five (5) years of directly relevant experience, preferably in an academic or clinical setting. *Degrees, Licensure, and/or Certification:* Appropriate certification strongly preferred

*The University of Cincinnati, as a multi-national and culturally diverse university, is committed to providing an inclusive, equitable and diverse place of learning and employment. As part of a complete job application you will be asked to include a **Contribution to Diversity and Inclusion** statement.*

The University of Cincinnati is an Affirmative Action / Equal Opportunity Employer / M / F / Veteran / Disabled.

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>