

Monthly Update

15-June 2018



REMINDER!

Monthly Coordinator Call

The next coordinator call is scheduled for **Thursday, June 21st 10:30am.**

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

Access Code: 3386580

Enrollment Update (as of 06/08/2018)

- **CREST 2** – 1052/2480
- **ARCADIA** – 29/1100 randomized; 106/4400 consented/not randomized, 44 patients are eligible for randomization
- **CREST-H** – 3/500



ARCADIA

This week has been extremely productive for ARCADIA! There are 7 new sites that have received CIRB approval, 8 enrollments and 4 randomizations!! As of June 8, 94 subjects have been consented, 42 are eligible for randomization, and 27 have been randomized. Thank you to United Hospital for consenting the most patients (9) and the University of Cincinnati for leading the way with the most randomizations (3)! We appreciate the hard work and enthusiasm from these two sites as well as all the other sites that have been actively consenting and randomizing. About 45% of consented patients are meeting our randomization criteria, so please don't be discouraged if a patient you consent does not end up qualifying for randomization—chances are the next one will.

We have many readiness calls that need to be scheduled so if your site has been CIRB approved please reach out to Daniel Velez dav2125@cumc.columbia.edu with your team's availability as soon as possible. If you have not yet submitted any regulatory documents or have questions about them, please reach out to Irene Ewing ewingi@ucmail.uc.edu to let her know the status of your site. We have several sites on the waiting list who continue to express enthusiasm about joining the trial, and we need to have a good sense of the status of our current sites as we make decisions about the waiting list.

We are looking forward to getting the full team on board and building on our progress so far. Thank you again for all your hard work and enthusiasm!

-- The ARCADIA National Team

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

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Trial Proposal Status:

- **DEFUSE 3 Closeout – Greg Albers**

DEFUSE 3 is very busy with substudies; there are approximately 10 in the works, with two almost ready to submit. Dr. Albers said that they hope to have 20 substudies from DEFUSE 3.

- **Telerehabilitation in Patients with Stroke Closeout – Joe Broderick for Steve Cramer**

Database is locked, results presented at ESOC in Sweden.

- **MOST update – Ope Adeoye**

MOST has received Notice of Award, currently working on completing site selection and regulatory documents.

- **Sleep Smart update – Devin Brown**

Notice of Award imminent, currently working on completing site selection and regulatory documents.

- **TRANSPORT 2 update – Wayne Feng/Gottfried Schlaug**

The study team is currently finalizing the protocol. Site selection survey completed.

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
TRANSPORT 2	Wayne Feng, Gottfried Schlaug	Recovery	Approved for funding by Council February 2018
CAPTIVA (CRISIS)	Brian Hoh	Prevention	Possibly November 2018 submission
FURRTHER	Bernadette Boden-Albala	Prevention	Waiting on summary statement to determine next steps
FASTEST	Joe Broderick, Jim Grotto, Jordan Elm	Acute	June 2018 submitted

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
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
IACQUIRE (formerly IRIS)	Warren Lo, Sharon Ramey	Recovery	July 2018 study section
ALISAH 2	Jose Suarez	Acute	July 2018 study section
ASPIRE (formerly SCORPION)	Kevin Sheth	Prevention	July 2018 study section
IMPACT	Andrew Naidech	Acute	July 2018 submission
VERITAS II	Sepideh Amin-Hanjani	Prevention	July 2018 submission
I-WITNESS	Lee Schwamm, Ona Wu, Steve Warach, Larry Latour, Shlee Song	Acute	November 2018 resubmission A01
PreLIMBS II	Sebastian Koch, Nestor Gonzalez, Neeraj Chaudhary	Acute	November 2018 resubmission A01
Tempo-EMS	Nerses Sanossian, William Meurer, Jeffrey Saver, David Hess	Acute	Tentative November 2018 resubmission A01
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

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
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
SPLASH	Jose Suarez, DaiWai Olson (contact PI)	Acute	In concept development
HEMERA	Italo Linfante, Raul Nogueira	Acute	In concept development
ARCADIA ORACLE	Babak Navid, MD, MS	Prevention	In concept development
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)

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CASH	Adnan Qureshi	Acute	In concept development
WISC-R	Matthew Durand, Robert Dempsey, Allison Hyngstrom, John McGuire	Recovery	In concept development
TESLA	Albert Yoo, Sam Zaidat	Acute	In concept development; needs more discussion with NINDS
START	Steve Warach, Truman Milling	Prevention	In concept development
SPLIT	Andrew Naidech	Prevention	In concept development
FOCAS	Heather Fullerton, Mitch Elkind	Prevention	In concept development
PHAST	Kate Amlie-Lefond, Michael Rivkin, Joan Cox Gill	Acute	In concept development
SATURN	Magdy Selim	Prevention	November 2017 submission April 2018 study section
CAVIS	Mark Harrigan	Prevention	In concept development
RAFT	Truman Milling, Steve Warach	ACUTE	In concept development
iTREAT	Andrew Southerland	Acute	In concept development
STEPSS (Dose Response Aerobic Exercise in Subacute Stroke)	Sandra Billinger	Recovery	Regrouping after review.
ERSIAS	Nestor Gonzalez, Jeff Saver	Prevention	In concept development
Meschia	James Meschia	Prevention	In concept development

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FOCAS	Heather Fullerton, Mitch Elkind	Prevention	In concept development
SPLIT	Andrew Naidech	Prevention	In concept development
CAVIS	Mark Harrigan	Prevention	In concept development



Biweekly Update 8-June 2018

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

StrokeNet Enrollment Update

CREST 2 – 1052/2480

CREST H – 2/500

ARCADIA – 27/1100 randomized; 94/4400 consented

StrokeNet Trial Updates



ARCADIA

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-- The ARCADIA National Team

From the CREST-2 Clinical Coordinating Center:



1052 randomizations (526 CEA; 526 CAS)

35 in May (12 CEA; 23 CAS)

5 in June (4 CEA; 1 CAS)

117 active centers of which **49** are StrokeNet Sites

Congratulations to these CREST-2 StrokeNet Sites for randomizing in June.

<u>Site</u>	<u>June</u>	<u>Overall Total</u>
University of Florida at Shands	1	9
University of Miami Hospital	1	6



We have 9 sites greenlighted for CREST-H enrollment, and the list below who are close. We are looking forward to ramping up enrollment over the next several weeks. Our goal is to recruit 75 sites. We have 53 interested so far. Contact Randy Marshall rsm2@columbia.edu or Kevin Slane kjs4@cumc.columbia.edu if you have a CREST-2 site in your RCC who is not yet signed up to participate! Remember, **site reimbursement has been increased**. Thanks to all PI's and coordinators for all their hard work!

Site Startup Updates

Sites close to being green lighted

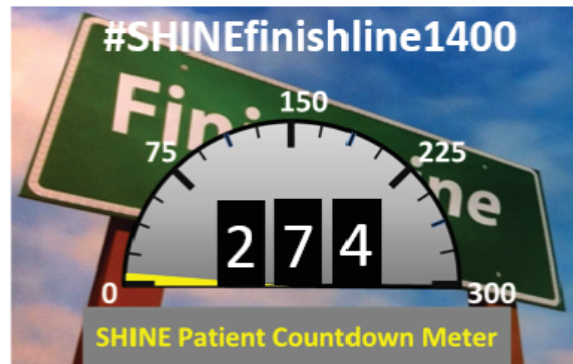
- Northwestern University
- VA Puget, WA
- UCLA
- Mayo Clinic, Rochester
- Yale New Haven, CT
- Overlake Hospital
- Huntsville Heart Center, AL
- SUNY Buffalo



Congratulations to our SHINE sites who enrolled in May:

Augusta University Medical Center = 2 enrollments
Kings County Hospital Center
NYP Columbia University Medical Center
OSU Wexner Medical Center
Henry Ford Hospital
Hospital of the University of Pennsylvania
UVA Medical Center
WVU Healthcare Ruby Memorial Hospital
UT Southwestern Medical Center

As of June 6th 2018, we are now 80% to goal, having enrolled 1126 out of 1400! Thanks to all of YOU, we are in the final stretch of enrolling in shine with only 274 subjects to go! Keep up the excellent work, and remember fingersticks should be repeated throughout the 12h window to catch all eligible subjects!



CIRB Corner

Congratulations to Michigan Vascular / McLaren – Flint on receiving CIRB approval for CREST-H 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 **13-June, 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". <https://www.nihstrokenet.org/intranet/minutes/steering-committee>. If you need log in access, please contact your RCC Network Manager/Coordinator to request one for you.

Coordinator Webinar

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

Topic: Q & A Post Renewal
Presenters: Joanna Vivalda, NIH/NINDS, Diane Sparks, UC NCC
Moderator: Dave Haney, Case Western Reserve
When: **Wednesday, June 27, 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

The next Professional Development webinar is scheduled for 23-August at 2:00 pm ET.

Grand Rounds

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

The next Grand Rounds presentation is TBA.

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. We will reimburse two people from each RCC one night room and tax, up to \$250. Below is the reservation link which offers Congress rates. **Please RSVP by 31-July**. There will be no Working Group, Trainee or Training Core breakout sessions.

IMPORTANT: RCC renewals will be confirmed in late May. In order to accommodate possible new RCCs, as well as former RCCs who may want to attend the meeting, it is possible that we may need to reduce the number of participants from each RCC to

THREE, instead of five. Please RSVP for your **THREE** foremost participants and up to **TWO** additional participants, if we have space available.

Venue:

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

<https://hotel.kenes.com/en/congress/WSC18>

<http://www.world-stroke.org/meetings/world-stroke-congress>

Upcoming Conferences and Seminars

We are happy to announce the first in our 2018 Webinar Series for the National Institutes of Neurological Disorders and Stroke (NINDS) Clinical Trials Methodology Course (CTMC). These webinars are open to all. Our course focuses on the design of early stage clinical trials for investigators focused on neurological illness and injury. Our past webinars and other lectures can be found at <http://neurotrials.training>

Please feel free to share this broadly amongst your professional contacts who are interested in clinical trials in the neurosciences. For your convenience, the attached appointment can be added to your calendar.

June 13, 2018 at noon EST

Specific Aims

Presented by Robert Silbergleit, MD

To join the Meeting:

<https://bluejeans.com/7342322138>

To join via Room System:

Video Conferencing System: bjn.vc -or- 199.48.152.152

Meeting ID : 7342322138

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

NIH StrokeNet Employment Opportunities

YALE SCHOOL OF MEDICINE DEPARTMENT OF NEUROLOGY POSTDOCTORAL JOB DESCRIPTION

GENERAL SUMMARY/ OVERVIEW STATEMENT:

The Division of Neurocritical Care at Yale has a track record of training outstanding postdocs who go on to successful high impact careers in biomedical research. This is an opportunity for a highly motivated individual with a background in biological or data sciences to perform cutting-edge research utilizing clinical trial, epidemiological, genetic and imaging data assembled from human subjects with stroke. Receiving general direction from [Dr. Kevin Sheth](#) and [Dr. Guido Falcone](#), and working in close collaboration with several investigators from across Yale and other institutions in the US, the incumbent will advance research work focused on acute stroke, both ischemic and hemorrhagic, with focus on clinical trial design and execution, neuroimaging analyses and population genetics.

Visa sponsorship for non-US applicants is possible

PRINCIPAL DUTIES AND RESPONSIBILITIES:

The postdoc will be responsible for project management, preparation of presentation materials, writing of manuscripts and grant applications, supervision of technologists and coordinators, presentations at local, national and international conferences. With broad support from Faculty members, the post-doctoral fellow will design and implement studies on the topics mentioned above, will analyze relevant data and lead the process of manuscript and grant writing. We are committed to tailor the training experience to the trainee's goals and career stage, providing the necessary background and tools to prepare her/him for competitive faculty or residency/fellowship positions.

QUALIFICATIONS:

- MD, PhD, ScD, DrPH, MPH or MSc (required)
- Proven experience in multi-tasking various assigned scientific/research projects (required)
- Training in Epidemiology and/or Biostatistics (preferred)

SKILLS / ABILITIES / COMPETENCIES REQUIRED:

- Time Management: Exceptional organizational skills and ability to organize time and priorities effectively, asking for direction when appropriate. Flexibility to handle multiple tasks and deadline pressures.
- Analytical Skills: Ability to conceptualize and conduct complex analysis of research data
- Capacity for independent work

- Critical Thinking/Decision Making: Ability to appropriately evaluate all aspects of a situation and to independently make appropriate and timely decisions.
- Interpersonal/communication: Excellent interpersonal/communications skills and a good command of English language, including medical and scientific terminology.
- Information Systems/Technology Skills: Exceptional computer skills (including operating systems, word processing, database, electronic mail, Internet, and spreadsheets).
- Experience with statistical and programing software (R, MatLab, SQL, Stata), preferred.

Please send CV and 3 professional references to:

Cathy Corso

Senior Administrative Assistant and Fellowship Coordinator

Yale University School of Medicine | Department of Neurology, Division of Neurocritical Care and Emergency Neurology

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

Please share this with your clinical performing and satellite sites!

Contact: Jamey Frasure, PhD, RN, Director | NIH StrokeNet Coordinating Center | frasuris@ucmail.uc.edu | 513-558-1742
<https://www.nihstrokenet.org>