

Monthly Update

1-May 2018



School of Medicine
and Public Health
UNIVERSITY OF WISCONSIN-MADISON

REMINDER!

Monthly Coordinator Call

The next coordinator call is scheduled for **Thursday, May 17th 10:30am.**

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

Access Code: 3386580

Enrollment Update

- **CREST 2** – 1006/2480
- **ARCADIA** – 10/1100 randomized; 34/4400 consented/not randomized
- **CREST-H** – 2/500

ARCADIA

About 38% of patients with ESUS are eligible, which is consistent with initial estimates.

34 sites released to enroll (out of 120). 95 PTA executed, 55 sites received CIRB approval. 39 readiness calls completed with 34 sites released to enroll.

CREST-2

1006 randomizations (508 CEA, 498 CAS) / 20 in April (11 CEA, 9 CAS)

122 active centers of which 50 are StrokeNet sites.

Accepting new sites for study

NINDS Twitter Chat

#BrainforLife Twitter Chat – May 2nd 1PM – 2PM ET

In observance of May, National Stroke Awareness Month, NINDS, Million Hearts, the American Stroke Association, and the American Academy of Neurology are co-hosting a Twitter chat to discuss stroke signs, the importance of keeping your brain healthy, and the latest stroke research.

Twitter/Facebook

NINDS will chat about new stroke research and what it may mean for treatment.

Join the conversation by using #BrainforLife.

Experts will answer your questions about stroke. Join @NINDSNews @MillionHeartsUS & @AAANPublic for #BrainforLife Twitter Chat.

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

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

Brooke Tashner

Office 608.261.1577

tashner@neurosurgery.wisc.edu

FAX 608.263.1728

Monthly Update

1-May 2018

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**

Dr. Broderick indicated that the database is locked. Results will be presented at the ESOC in May.

- **MOST update – Ope Adeoye**

MOST has been submitted to the CIRB, and the NINDS has indicated that the award should be issued in the next month or so, along with Sleep Smart.

- **Sleep Smart update – Devin Brown**

Sleep Smart was reviewed by the CIRB, awaiting comments. Dr. Brown reported that they have identified 109 of the 110 sites participating. She thanked everyone for their hard work moving things forward.

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

The study team is currently finalizing the protocol. Site selection survey was sent out yesterday, due May 8th.

- Trial Proposals status

These proposals were reviewed on 13-April:

- CAPTIVA
- FURRTHER
- IWITNESS
- PRELIMBS
- SATURN
- TEMPO EMS

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	October 2017 submission April 2018 study section
FURRTHER	Bernadette Boden-Albala	Prevention	October 2017 submission April 2018 study section
I-WITNESS	Lee Schwamm, Ona Wu, Steve Warach, Larry Latour, Shlee Song	Acute	November 2017 resubmission April 2018 study section
PreLIMBS II	Sebastian Koch, Nestor Gonzalez, Neeraj Chaudhary	Acute	November 2017 resubmission April 2018 study section
SATURN	Magdy Selim	Prevention	November 2017 submission April 2018 study section
Tempo-EMS	Nerses Sanossian, William Meurer, Jeffrey Saver, David Hess	Acute	November 2017 resubmission April 2018 study section
IACQUIRE (formerly IRIIS)	Warren Lo, Sharon Ramey	Recovery	March 2018 resubmission
FASTEST	Joe Broderick, Jim Grotto, Jordan Elm	Acute	June 2018 submission
ASPIRE (formerly SCORPION)	Kevin Sheth	Prevention	March 2018 resubmission
ALISAH 2	Jose Suarez	Acute	March 2018 resubmission
PAST-TIME	Jason McMullan, Opeolu Adeoye, Nerses Sanossian	Acute	June 2018 submission

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
ARCADIA -CSI	George Howard, PhD Maarten Lansberg, MD/PhD Ronald Lazar, PhD Kevin N. Sheth, MD David Tirschwell, MD	Acute	June 2018 submission
IMPACT	Andrew Naidech	Acute	July 2018 submission
VERITAS II	Sepideh Amin-Hanjani	Prevention	July 2018 submission
PHAST	Kate Amlie-Lefond, Michael Rivkin, Joan Cox Gill	Acute	In concept development
ETHER	Stephan Mayer	Acute	In concept development
iTREAT	Andrew Southerland	Acute	In concept development
RAFT	Truman Milling, Steve Warach	ACUTE	In concept development
CAVIS	Mark Harrigan	Prevention	In concept development
SERENE (ASSIST + SEACOAST)	Radoslav Raychev, Dimiter Arnaudov, David F. Kallmes, (Radiology) Alejandro Rabinstein, (Neurology) Jeffrey Pasternak, (Anesthesiology) Rickey Carter, (Biostatistics)	Acute	In concept development
DEFUSE TNK	Maarten Lansberg, Greg Albers	Acute	In concept development; needs more discussion with NINDS
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

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
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
Classen	Jan Classen	Acute	In concept development
SPLASH	Jose Suarez, DaiWai Olson (contact PI)	Acute	In concept development
HEMERA	Italo Linfante, Raul Nogueira	Acute	In concept development
STEPSS (Dose Response Aerobic Exercise in Subacute Stroke)	Sandra Billinger	Recovery	Regrouping after review.
SCOUT	Sandeep P. Khot, Martha E. Billings	Recovery	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
CASH	Adnan Qureshi	Acute	In concept development
Durand	Matthew Durand, Robert Dempsey, Allison Hyingstrom, John McGuire	Recovery	In concept development
RISIS	Julius Fridriksson, Ron Lazar, Ed Jauch, Jordan Elm, Leonardo Bonilha	Recovery	PPIs unsure whether they will resubmit.
URIC	Enrique Leira	Acute	Per ESC, on hold for now.
DEFUSE M	Maarten Lansberg, Greg Albers	Acute	On hold, in concept development, needs more discussion with NINDS

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
SEACOAST 1	Radoslav Raychev, Dimiter Arnaudov, David Liebeskind, Jeffrey Saver	Acute	In concept development
ASSIST	David F. Kallmes, (Radiology) Alejandro Rabinstein, (Neurology) Jeffrey Pasternak, (Anesthesiology) Rickey Carter, (Biostatistics)	Acute	In concept development
ARREST	Robert Brown, James Torner, David Hasan	Prevention	Decided not to submit 2-November 2017 section Pending Summary statement
CREST-P	Brajesh K Lal, Ronald Lazar, Randolph Marshall	Prevention	Pending score/critiques Score not in funding range
CREST-T	Brajesh K Lal, Ronald Lazar, Randolph Marshall	Prevention	Pending score/critiques Score not in funding range
PICASSO	Marc Chimowitz	Prevention	Redesigning as Phase 2, needs more data.
Bozoki study	Andrea Bozoki	Prevention	Discussed with ESC, have not received permission to move forward in its current form
DOSER	Alex Dromerick	Recovery	Discussed with ESC, have not received permission to move forward at this time Deferred
Contralateral Rehab	Jayme Knutson	Recovery	Discussed with ESC, have not received permission to move forward at this time More discussion needed
Ankle rehabilitation in acute stroke	Li-Qun Zhang	Recovery	In early stages of concept development Requested update 21-Sep Requested update 4-Nov *After RWG review, Dr. Cramer indicated this is in the PIs court; instructed him to seek out Dr. Janis in regard to the direction the proposal should take. PI did not respond to requests for update.
PATCH	Maarten Lansberg	Prevention	Inactive due to non-response from device company.
ICTuS 3	Pat Lyden	Acute	Indefinite hold.

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
NORRIS	Walter Kernan	Prevention	Not approved to move forward at this time.
ETOSHA	Tanya Turan	Prevention	Will not move forward in its current form.
Acute Biomarker	Robert Meller	Acute	Not coming into StrokeNet
SOPRANO	Karl Meisel, Wade Smith	Prevention	Not approved to move forward

E. New Project Development Progress

Type	Project	NINDS Grant Submission					Project Initiation				
		Concept Synopsis Approved by NINDS ESC	Feasibility Assessment	Grant Submit to NINDS	Scientific Peer Review	Awarded	Protocol Submit to CIRB	CIRB Approval	First Site Released	First Subject Enrolled	
	Summary		Min=-6 Max=89 Med=36.5	Min=30 Max=301 Med=78	Min=92 Max=195 Med=114	Min=97 Max=298 Med=197.5	Med=1	Med=15	Min=168 Max=325 Med=246.5	Med=35	
Acute (38.1%)	DEFUSE 3	5/7/2014	-6	31	162	11/10/2014					
			1/26/2015	58	92		97	1	15	168	35
	ICTUS 3	6/4/2014	89	30	155	3/5/2015					
	MOST	8/13/2014	-1	50	155	3/5/2015					
				7/5/2015	131	11/13/2015					
			12/11/2015	177	156	11/8/2016					
				3/1/2017	114	6/23/2017					
	IMPACT	6/2/2015	20	106	147	3/1/2016					
				7/5/2016	126	11/8/2016					
				7/11/2017	114	11/2/2017					
PreLIMBS II	7/23/2015	21	54	147	3/1/2016						
	9/18/2017		11/6/2017								
Tempo-EMS	2/22/2016	25	80	155	11/8/2016						
			11/6/2017								
ALISAH 2	3/23/2016	14	61	155	11/8/2016						
I-WITNESS	3/23/2016	14	301	142	6/23/2017						
			11/3/2017								
Prevention (42.9%)	PICASSO	10/16/2014	55	53	144	6/25/2015					
				3/5/2016	124	7/7/2016					
	ARCADIA	3/6/2015	21	80	150	11/12/2015					
			1/27/2016	37	125	298	5/1/2017	3/10/2017	325	1/29/2018	
	SleepSMART	11/3/2015	22	76	150	7/8/2016					
				3/3/2017	112	6/23/2017	2/7/2018				
	ARREST	11/3/2015	22	76	150	7/8/2016					
				7/11/2017	114	11/2/2017					
	SATURN	2/3/2016	21	224	195	4/18/2017					
VERITAS II	8/10/2016	84	251	114	11/2/2017						
ASPIRE	10/21/2016	25	238	114	11/2/2017						
CAPTIVA (formerly CRISIS)	6/7/2017	42	78	10/5/2017							
FURRThER	6/13/2017	36	78	10/5/2017							
Recovery (19.0%)	RISIS	12/15/2015	45	128	156	11/8/2016					
	STEPSS	4/29/2016	56	103	195	4/18/2017					
	TRANSPORT-II	7/25/2016	36	36	195	4/18/2017					
				7/11/2017	114	11/2/2017					
I-ACQUIRE	3/17/2017	35	81	114	11/2/2017						

Active Inactive Awarded 30 # of days since previous milestone



Biweekly Update 27-April 2018

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

StrokeNet Enrollment Update

CREST 2 – **1006/2480**

CREST H – **2/500**

ARCADIA – **10/1100 randomized; 34/4400 consented**

StrokeNet Trial Updates



ARCADIA

ARCADIA is picking up steam!

There are currently 34 subjects consented, 13 eligible for randomization, and 10 randomized. Thus far, then, about 38% of patients with ESUS are eligible, which is consistent with (if slightly higher than) our initial estimates. About half of the patients meet eligibility through the EKG criterion (increased P wave terminal force in lead V1) and about half through the NT-proBNP criterion; severe left atrial enlargement on echocardiography is a rare finding to date.

Study site start-up is also picking up. Thirty-four sites are enrolling (of a target of 120), while 95 sites have their protocol trial agreements and 55 sites have Central IRB approval. Our experience thus far suggests that the biggest impediment to achieving our numbers faster is a lag in getting regulatory and administrative documents (like contracts and IRB) through. Once sites are up and recruiting, they are finding the recruitment to be feasible and relatively easy. We encourage all ARCADIA sites that have not yet started recruiting to redouble their efforts to work with administrators to finalize documents so we can increase our numbers. Thanks for all your hard work!

From the CREST-2 Clinical Coordinating Center:



1006 randomizations (508 CEA; 498 CAS)
20 in April (11 CEA; 9 CAS)
122 active centers of which **50** are StrokeNet Sites



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

<u>Site</u>	<u>Overall Total</u>
Columbia University Medical Center, New York, NY	21
VA Puget Sound, Seattle, WA	12
Kaiser Permanente Division of Research, San Francisco, CA	6
University of Florida at Shands, Gainesville, FL	6
St. John Clinical Research Institute, Tulsa, OK	2
Stanford University Medical Center, Stanford, CA	2
Penn State Milton S. Hershey Medical Center, Hershey, PA	1



We doubled our enrollment in April: UPMC provided



patient #2!!

New site greenlighted!



Houston Methodist been greenlighted for CREST-H enrollment! Several other sites are nearly there, including U Washington, Puget Sound VA, Northwestern, UCLA, Mayo Clinic Rochester, Yale, and Overlake Hospital. Please keep moving ahead with your regulatory documents and test images. We are looking forward to ramping up enrollment over the next several weeks. Remember, **site reimbursement has increased to help with costs**. Thanks to all PI's and coordinators for all their hard work!

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 **9-May, 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: TBA

Moderator:

When: **Wednesday, May 23, 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 TWO Presentations are as follows:

When: **Tuesday, 1-May, 2018 - 2:00 PM ET**

2:00 pm: Secular Increases in Spontaneous Subarachnoid Hemorrhage during Pregnancy - **Kaustubh Limaye, MD, University of Iowa**

2:30 pm: Cerebral Small Vessel Disease in Patients with Spontaneous Cerebellar Hemorrhage - **Marco Pasi, MD, MGH**

3:00 pm: Identification of Biomarkers in Normotensive and Hypertensive Rats after Ischemic Stroke - **Ignatius Ngene Esene, PhD, Wisconsin Madison**

Moderator: Randy Marshall, MD – Columbia University

When: **Tuesday, 8-May, 2018 - 2:00 PM ET**

Presentations:

2:00 pm: Difference in Culprit Plaque Characteristics and Locations between US and Chinese Stroke Patients: An in Vivo Study by Vessel Wall Magnetic Resonance Imaging – **Hiroko Watase, MD, University of Washington**

2:30 pm: Motor Behavior Pre-recovery: Single Joint and Multi Joint Control and Upper Extremity Use – **Jessica Barth, OTR/L, Medstar Research Institute**

Moderator: David Liebeskind, MD, UCLA

Grand Rounds

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

Presentations: Stroke Prevention with the Expanded Use of NOAC and Use of Anticoagulants – **Scott Kasner, MD University of Pennsylvania**

When: **Thursday, May 31, 2018 - 4:00 PM ET**

Moderator: Cemal Sozener, MD, University of Michigan

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

NINDS Twitter Chat

#BrainforLife Twitter Chat – May 2, 1 PM – 2 PM ET

In observance of May, National Stroke Awareness Month, NINDS, Million Hearts, the American Stroke Association, and the American Academy of Neurology are co-hosting a Twitter chat to discuss stroke signs, the importance of keeping your brain healthy, and the latest stroke research.

Twitter/Facebook

- On Wednesday, May 2 from 1 to 2 p.m. ET, NINDS will chat about new stroke research and what it may mean for treatment. Join the conversation by using #BrainforLife.

- Experts will answer your questions about stroke. Use #BrainforLife to join.
- Let's chat about #stroke! Join @NINDSNews @MillionHeartsUS & @AANPublic for a #BrainforLife Twitter Chat.

Join us for a

Twitter Chat

Wednesday, May 2, 2018
1-2 p.m. ET

#BrainforLife



National Institute of
Neurological Disorders
and Stroke

*Stroke strikes fast,
you should too!*



SUDDEN TROUBLE SPEAKING



SUDDEN TROUBLE SEEING



SUDDEN TROUBLE WALKING



SUDDEN ONE-SIDED WEAKNESS



SUDDEN SEVERE HEADACHE

Revised StrokeNet QAR Template

The Quarterly Activity Report template has been revised as of 17-April 2018. Please use this version going forward (attached). The next QAR covering the period of 16-March – 15-June is due 1-July, 2018. If you have any questions, feel free to contact Jamey Frasure at frasurjs@ucmail.uc.edu. Thanks!!

Requirements for Registering and Reporting in ClinicalTrials.gov

The link below helps PIs understand and comply with ClinicalTrials.gov requirements. Included are resources, policies and a helpful decision tree to guide PIs through specific actions related to this regulation.

<https://grants.nih.gov/policy/clinical-trials/reporting/index.htm>

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

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

NIH StrokeNet Employment Opportunities

Augusta University (formerly the Medical College of Georgia)

The Department of Neurology at Augusta University (formerly the Medical College of Georgia) is seeking a Vascular Neurologist to join the Stroke Section at a certified Comprehensive Stroke Center. This section has a track record of excellence in clinical care, research, and education. In addition to providing clinical care to patients at Augusta University, this section also serves patients across the state through a tele-stroke network that provides emergency stroke care for 29 hospitals.

This position will provide coverage of the inpatient neurology service on a rotating basis, take call for the telestroke network, engage in stroke-related clinical research and provide oversight and mentorship for Vascular Neurology fellows, Neurology residents, and medical students. Investigator initiated research is highly encouraged.

The ideal candidate will have completed an accredited Neurology residency program and a Vascular Neurology fellowship, be board certified or board eligible in Vascular Neurology. Academic appointment will be commensurate with experience.

Interested candidates should send a CV and brief statement of interest to:

Jeffrey A. Switzer, DO, MCTS, FAHA
Director, Comprehensive Stroke Center
Professor
Department of Neurology
jswitzer@augusta.edu

University of Michigan

The Department of Neurology at the University of Michigan (UM) has an exciting opportunity for an outstanding VASCULAR NEUROLOGY clinician at the level of Assistant Professor to full Professor, in the college town of Ann Arbor, Michigan, a Forbes Top 20 Happiest Cities to Work.

The practice will consist of a balance across outpatient clinic, inpatient service, telestroke and ED call, teaching, and administrative roles. Collaborative research opportunities are also available.

The candidate will join a nationally renowned, highly collaborative, dynamic Multidisciplinary Stroke Program which currently includes 8 Vascular Neurologists, 5 Emergency Medicine Physicians who focus on stroke, 4 Neurocritical Care Intensivists, 2 Interventional Neuroradiologists, 2 Cerebrovascular /Endovascular Neurosurgeons, and many others. UM has a 15-bed NICU as well as a state-of-the-art inpatient stroke unit and a telestroke network. UM is a Joint Commission-certified Comprehensive Stroke Center with robust NIH-funded stroke research programs in diverse fields ranging from health disparities to molecular stroke research, including serving as a Regional Coordinating Center for StrokeNet.

Qualified candidates must have completed an ACGME-approved Vascular Neurology fellowship program, and be BE/BC. The Department is especially interested in qualified

candidates who can contribute to the diversity and excellence of the academic community.

Ann Arbor is a family friendly city known for its cultural offerings and high quality of life. Ann Arbor has been ranked highly as a preferred city because of its sporting, music, and active cultural life and welcoming natural setting. The Neurology residency and ACGME-approved Vascular Neurology fellowship offer the candidate the opportunity to work with highly motivated and skilled trainees.

Interested applicants should send a brief statement of interest and a copy of their CV addressed to Dr. David Fink, Chair, Department of Neurology by email to: Sarina Davis (sarinaw@umich.edu).

The University of Michigan is a non-discriminatory, affirmative action employer. Women and minorities are encouraged to apply.

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 | frasurjs@ucmail.uc.edu | 513-558-1742
<https://www.nihstrokenet.org>