NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

Monthly Update

8-February 2018

UW Health

School of Medicine and Public Health
UNIVERSITY OF WISCONSIN-MADISON

REMINDER!
Monthly Coordinator Call

The next coordinator call is scheduled for **Thursday, February 15th at 10:30am.**
Neuro Teleconference Line:
USA Toll-Free: (877) 848-7030
Access Code: 3386580

Enrollment Update

- **CREST 2** – 923
- **Arcadia** – 1
- **CREST**-H - 1

RCC24 is currently enrolling in Crest-2.
The CREST-H: 54 sites in the pipeline to become enrolling centers, several are nearing their green-light status. First site green-lighted with first Crest-H subject enrolled on 01/30/2018.

ARCADIA protocol amendment approved by cIRB 12/13/17.
All sites have received their start-up packages
3 sites are actively recruiting, with first subject enrolled on 02/01/2018

IMPORTANT!!!

This month's Coordinator Webinar will be focused on the ARCADIA startup, Irene Ewig (program manager) will be discussing the trial and Susan Roll (cIRB liaison) the IRB submissions.
PLEASE MAKE EVERY EFFORT TO ATTEND IF YOU ARE AN ARCADIA SITE!

Webinar is schedule for February 28, 2018 at 12:30pm-1.30pm (CST)
Dial-in information:
1-877-621-0220
Passcode: 434578

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

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Happy Valentine's Day

Trial Proposal Status

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
IMPACT	Andrew Naidech	Acute	November 2017 study section Pending summary statement
TRANSPORT 2	Wayne Feng, Gottfried Schlaug	Recovery	November 2017 study section Pending summary statement
ARREST	Robert Brown, James Torner, David Hasan	Prevention	November 2017 study section Pending summary statement
VERiTAS II	Sepideh Amin-Hanjani	Prevention	November 2017 study section Pending summary statement
ASPIRE (formerly SCORPION)	Kevin Sheth	Prevention	November 2017 study section Pending summary statement
IACQUIRE (formerly IRIIS)	Warren Lo, Sharon Ramey	Recovery	November 2017 study section Pending summary statement

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
CAPTIVA (CRISIS)	Brian Hoh	Prevention	October 2017 submission
FURRThER	Bernadette Boden-Albala	Prevention	October 2017 submission
I-WITNESS	Lee Schwamm, Ona Wu, Steve Warach, Larry Latour, Shlee Song	Acute	November 2017 resubmission
PreLIMBS II	Sebastian Koch, Nestor Gonzalez, Neeraj Chaudhary	Acute	November 2017 resubmission
SATURN	Magdy Selim	Prevention	No further information available since 04/18/2017
Tempo-EMS	Nerses Sanossian, William Meurer, Jeffrey Saver, David Hess	Acute	November 2017 resubmission
FASTEST	Joe Broderick, Jim Grotto, Jordan Elm	Acute	Tentative February 2018 submission
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
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 M	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
Deep TMS Treatment of Stroke (Israel - Industry)	Abraham Zangen	Recovery	In concept development
SPLIT	Andrew Naidech	Prevention	In concept development

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
FOCAS	Heather Fullerton, Mitch Elkind	Prevention	In concept development
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
STEPSS (Dose Response Aerobic Exercise in Subacute Stroke)	Sandra Billinger	Recovery	Regrouping after review.
RISiS	Julius Fridrikkson, 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.
SEACOAST 1	Radoslav Raychev, Dimiter Arnaudov, David Liebeskind, Jeffrey Saver	Acute	In concept development

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
ASSIST	David F. Kallmes, (Radiology) Alejandro Rabinstein, (Neurology) Jeffrey Pasternak, (Anesthesiology) Rickey Carter, (Biostatistics)	Acute	In concept development
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.

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
ICTuS 3	Pat Lyden	Acute	Indefinite hold.
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

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2-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	Med=168	Med=35
Acute (38.1%)	DEFUSE 3	5/7/2014	-6	31	162 11/10/2014					
		1/26/2015	58	58	92	97	1	15	168	35 5/6/2016
	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	37	125	298 5/1/2017		3/10/2017		
	SleepSMART	11/3/2015	22	76	150 7/8/2016					
				3/3/2017	112 6/23/2017					
	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					
	ACQUIRE (formerly IRIIS)	3/17/2017	35	81	114 11/2/2017					

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Biweekly Update
2-February 2018

http://nihstrokenet.org/coming-events

StrokeNet Enrollment Update
CREST 2 – **913/2480**
CREST H – **1/500**
ARCADIA – **1/1100**

StrokeNet Trial Updates

Great news! The first subject was enrolled in ARCADIA by the Columbia Team!
Congratulations to Dr. Eliza Miller and Daniel Velez.

We now have 3 sites actively recruiting: Columbia, Univ. Cincinnati and OSU Wexner, with more sites coming up within the next week or two.
We will begin sending out an ARCADIA newsletter once a month with study updates and tips.

Please continue to work with your contracts team to get your Protocol Trial Agreements signed if this has not been done.

It was great to see so many investigators at the ISC, and we want to thank everyone for their hard work and support as we embark on this important journey together!

The ARCADIA Team

The Telerehab Trial has completed enrollment and its final enrollees are now undergoing treatment.

Steven C. Cramer, MD

From the CREST-2 Clinical Coordinating Center:

923 randomizations (455 CEA; 468 CAS)
49 in January (27 CEA; 22 CAS)
2 in February (0 CEA; 2 CAS)
122 active centers of which **53** are StrokeNet Sites

StrokeNet Sites contributed 41% of the January 2018 enrollments!

January 2018 highest enrolling month to date.

Congratulations to the CREST-2 StrokeNet Sites enrolling in January 2018!

Site	Overall Total
San Francisco VAMC	17
Kaiser Permanente Los Angeles	15
Mayo Clinic Rochester	14
Ohio State University Medical Center	11
SUNY Buffalo	9
Oregon Health and Science University	9
University of Iowa Hospitals & Clinics	9
Emory University Hospital	8
Kaiser Permanente San Diego	7
University Hospitals Cleveland Medical Center	7
USC/ Keck Medical Center	6
Weill Cornell Medical College	6
Northwestern Memorial Hospital	5
University of Florida Health at Shands	4
University of Utah Hospitals and Clinics	4
Beth Israel Deaconess Medical Center	3
Miami Cardiac and Vascular Institute	2
Stanford University Medical Center	1

CREST-H **First patient enrolled!!!**

Of the 54 sites in the pipeline to become enrolling centers, several are nearing their green light status. One (Columbia University) was officially green lighted on January 18, 2018. The first CREST-H patient was enrolled today, January 30, 2018. Great to meet this milestone. Now only 499 patients to go…

Randy Marshall, On Behalf of the CREST-H Co-PIs Ronald Lazar, David Liebeskind, Sander Connolly.

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 **14-February, 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

The next Coordinator webinar is scheduled for 28-February, 2018.

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

Presentations:

2:00 – **Rasha Alkhatib, PhD – Northwestern** - Assessment of acute stroke services in a Palestinian public hospital: Towards implementing an evidence-based acute stroke unit

2:30 – **Neha Dangayach, MD – Mt. Sinai** - Promoting Neuroresilience in Aneurysmal Subarachnoid Hemorrhage patients with Grape Seed Polyphenol Extract: A Pilot Study

When: Thursday, February 15, 2018 - 2:00 PM ET

Moderator: Randy Marshall, MD, Columbia University

Grand Rounds

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

Presentations: International and US Stroke Disparities: **Ralph Sacco, MD, University of Miami**

When: **Thursday, February 22, 2018 - 4:00 PM ET**

Moderator: Farhaan Vahidy, MD, PhD, University of Texas at Houston

Note: To view the 2017-2018 Grand Rounds series schedule please visit:
http://nihstrokenet.org/webinars

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 CIRB Corner

Please use wet signatures or official digital signatures on documents, especially Conflict of Interest (COI) forms. We cannot accept cut and paste versions of signature. This will prevent documents being returned to sites for proper signatures.

COI form signatures should be accompanied by the printed version of the name associated with the signature.

Note for Continuing Reviews: When redacting participant information from the Informed Consent, do not redact the date of the participant's signature. We need to see the date the participant signed the consent along with the signature and date of the person obtaining consent.

NIH Inclusion Policy - Revision

Last month, NIH announced a revision (NOT-OD-18-116) to a decades-old policy originally conceived in response to concerns that children were not appropriately included in clinical research. These changes broaden the policy to address inclusion of research

participants of all ages, and as discussed at the last Advisory Committee to the NIH Director meeting, will apply beginning in **2019 to all NIH-supported research involving human subjects.** Please visit https://nexus.od.nih.gov/all/category/blog/open-mike/ for more information.

REVISED – NIH StrokeNet Concept Synopsis Proposal Form

To all prospective Protocol PIs: The initial determination of project suitability for StrokeNet will be made by the NINDS. Projects to be considered for funding and conduct within StrokeNet must follow the process defined below:

➢ Once the prospective applicant (i.e., Protocol Principal Investigator or PPI) is ready to proceed with a potential grant submission of a project to be conducted within the network, he/she should contact NINDS at StrokeNetInquiry@mail.nih.gov. The PPI will be invited to complete and submit the StrokeNet Clinical Study Concept Synopsis Form to the NINDS.

➢ The Concept Synopsis Proposal form has been revised and is available at http://nihstrokenet.org/documents.

➢ NINDS program staff will determine the completeness of the information provided and whether or not the proposed study is appropriate for the network. A telephone conference including NINDS program staff and the PPI may be scheduled to gather missing information.

➢ Projects deemed to be appropriate and complete will be presented to the NINDS Extramural Science Committee (ESC) for evaluation of the proposal's alignment with the overall mission and priorities of NINDS. If approved by ESC, the PPI may proceed with the development of the project and a grant application.

StrokeNet Network Meetings and Important Info

2018: The next NIH StrokeNet Network meeting will be held on Tuesday, 16-October, prior to the World Stroke Congress in Montreal. Look for details soon. We will reimburse two people form each RCC one night room and tax, up to $250. Below is the reservation link which offers Congress rates.

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

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

Upcoming Conferences and Seminars

April 13, 2018	Acute Stroke Management 13th Annual Conference for Nurses - Hilton Garden Inn Canonsburg, PA https://ccehs.upmc.com/liveFormalCourses.jsf
May 2-4, 2018	NIH Regional Seminar: Program Funding and Grants Administration – Washington DC https://regionalseminars.od.nih.gov/washingtondc2018/
February 27-28, 2018	OHRP Research Community Forum - San Diego, CA The federal Office for Human Research Protections (OHRP) is teaming up with University of California San Diego and local research institutions to host a Research Community Forum in San Diego, California.

Institutional review board (IRB) members, IRB administrators, clinical investigators, research scientists & support staff, sponsors, contract research organizations, government regulators and members of the research community are encouraged to attend. See attached flyer or register online at: https://www.regonline.com/SDRCF2018

February 23, 2018 7:00 am – 3:00 pm	UPMC Neuroscience Conference – Pittsburgh, PA Abstract submission opens **December 15, 2017** and closes February 9, 2018. Registration information to follow. Contact Therese Dawson at dawsont@upmc.edu with any questions.

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

NIH StrokeNet Employment Opportunities

MedStar Washington Hospital Center – Vascular Neurologist

MedStar **is** seeking an additional Vascular Neurologist to the largest Comprehensive Stroke Center in region.

- First in the Washington, D.C. region to be certified by the Joint Commission as a Comprehensive Stroke Center with ~1000 stroke inpatient visits per year
- A 926-bed not-for-profit, academic medical center located in the center of Washington, D.C.; the busiest and largest hospital in D.C. and a major referral center for area hospitals – also a Level I Trauma Center, Heart & Vascular Institute

- One of 10 hospitals in the MedStar Health system spanning D.C. and Baltimore, in addition to MedStar Health Research Institute, and MedStar Institute for Innovation
- Serves as a site within the NINDS StrokeNet Clinical Trials Network
- Serves as one of two sites of the NINDS intramural stroke program and its ACGME-accredited vascular neurology fellowship program
- One of the primary teaching sites for the Georgetown Neurology Residency Program
- Neurology is a joint department within the Georgetown University Dept of Neurology
- Opportunities for research and academic appointment commensurate with experience

Join a robust, multidisciplinary, stable and growing team comprised of board-certified physicians in Vascular Neurology, Neurology, Neurocritical care, Interventional Neuroradiology/Neuroendovascular Surgery, Diagnostic Neuroradiology, and Neurosurgery. Infrastucture includes a stroke-dedicated 3T MRI proximate to Emergency Department, neuroICU, a telestroke program, and outpatient stroke clinics. Interest in participation in clinical stroke trials is desired.

Minimum requirements include an MD or DO, eligibility for medical licensure in the District of Columbia and Maryland, and board-eligible/board-certified in Vascular Neurology.

Please feel free to share this posting with colleagues including fellows.

Currently accepting applications and scheduling interviews – please send a letter of interest and curriculum vitae to:

Amie Hsia, MD at amie.hsia@medstar.net

Vascular Neurology Faculty Positions at UW in Seattle

The Department of Neurology at the University of Washington is seeking two neurologists with expertise in vascular neurology to join the Comprehensive Stroke Center at Harborview Medical Center.

The Stroke Program at Harborview represents a dynamic environment to practice Vascular Neurology, both inpatient and outpatient. We care for ~800 stroke inpatients every year, including a disproportionate number of severe ischemic and hemorrhagic strokes. A TeleStroke program is in place and expanding. All patients are cared for by resident teams, and ICU patients are co-managed with the intensivists. You will interact with an outstanding and dedicated group of eight Vascular Neurologists, two Interventional Neurosurgeons, two Interventional Neuroradiologists, and an outstanding Emergency Department with a large, multidisciplinary and engaged team.

These are both full-time appointments and will be at the Assistant Professor rank (without tenure for reasons due to funding, job code 0113) in the clinician-educator academic

pathway, but candidates with exceptional qualifications may be considered for appointment at the rank of Associate Professor (without tenure for reasons due to funding, job code 0112) or Professor (without tenure for reasons due to funding, job code 0111).

Requirements include an MD or DO or foreign equivalent degree, eligibility for medical licensure in the State of Washington, and certification by the American Board of Psychiatry and Neurology in Neurology and Vascular Neurology. In order to be eligible for University sponsorship for an H-1B visa, graduates of foreign (non-U.S.) medical schools must show successful completion of all three steps of the U.S. Medical Licensing Exam (USMLE), or equivalent as determined by the Secretary of Health and Human Services.

Applicants should send a letter of interest and their curriculum vitae to:

Kass Klemz

Assistant to the Chairman

University of Washington Department of Neurology

Box 356465

Seattle, WA 98195

Email: kass@uw.edu

These positions are open until filled. University of Washington is an affirmative action and equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, age, protected veteran or disabled status, or genetic information.

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