Monthly Update

12-December 2017

UW Health

School of Medicine and Public Health
UNIVERSITY OF WISCONSIN-MADISON

REMINDER!
Monthly Coordinator Call

The next coordinator call is scheduled for **Thursday, December 14th at 10:30am.**

Neuro Teleconference Line:
USA Toll-Free: (877) 848-7030
Access Code: 3386580

Enrollment Update

- **iDEF** – enrollment completed!
- **CREST 2** – 852
- **Telerehab in Stroke –** 122
- **POINT –** 4867

**RCC24 is currently enrolling in POINT and Crest2.
The CREST-H is hoping to green light their first set of sites in the next few weeks.**

Arcadia has a protocol amendment that the cIRB is reviewing on 12/13/17. We expect enrollment to start in the middle of January.

Warm wishes
for the Holiday Season!
Happy Holidays!

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 /
Outreach Specialist**
Jennifer Reckner
Office 608.262.7481
reckner@neurosurgery.wisc.edu

Research Coordinator / Admin Liaison
Jill Iwanski
Office 608.262.6493
Iwanski@neurosurgery.wisc.edu

Research Coordinator
Brooke Tashner
Office 608.261.1577
tashner@neurosurgery.wisc.edu

FAX 608.263.1728

Trial Proposal Status

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

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
SPLIT	Andrew Naidech	Prevention	In concept development
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.

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
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	Li-Qun Zhang	Recovery	In early stages of concept development Requested update 21-Sep

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
stroke			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.
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

Monthly Update

12-December 2017

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		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					

**Biweekly Update
8-December-2017**

http://nihstrokenet.org/coming-events

StrokeNet Enrollment Update
Telerehabilitation in Stroke – **122/124**
CREST 2 – **852/2480**

StrokeNet Trial Updates

The ARCADIA Start-up Investigator Meeting took place November 17 in Atlanta. Approximately 220 investigators and coordinators participated, and provided excellent comments and feedback on the study. The study team was gratified at the enthusiastic participation! Amendment 3 of the protocol, will be reviewed by the StrokeNet Central IRB on December 13. The Approved protocol will be sent out to all sites as soon as it is available. For questions about the regulatory process contact Irene Ewing, the Project Manager: Irene.ewing@uc.edu

For those who could not attend the meeting, and for other investigators and coordinators listed on sites' roster, a short training module will be available in WebDCU. All named sub-investigators and additional coordinators will need to complete this training before sites go live. An email will be sent out notifying sites when the training is posted.

ARCADIA will also plan to have a brief update meeting and social gathering on Monday January 22, 2018 from 5-7 PM immediately after the StrokeNet RCC meeting in Los Angeles at the same Manhattan Beach venue. This gathering will be open to all who are planning to attend ISC, but the study will not be able to provide funding for travel. Look for further Save the Date information in your email.

Finally, remaining sites should look out for emails with the protocol trial agreements. We expect Round 3 of PTAs to be sent in mid-December, and Round 4 in early January. We look forward to getting started with recruitment as soon as January!

ARCADIA wishes you all a happy holiday season!

We have enrolled 122 subjects toward our goal of 124. We are close to completing enrollment and are asking sites to do their best to enroll one more patient/site. For non-emergent questions: telerehab@uci.edu

Thank you - Steven C. Cramer, MD

From the CREST-2 Clinical Coordinating Center:

852 randomizations (415 CEA; 437 CAS)

120 active centers of which **50** are StrokeNet Sites

31 in November (15 CEA; 16 CAS)
6 in December (3 CEA;   3 CAS)

Congratulations to the CREST-2 StrokeNet Sites for Enrollment in November

- ✓ Louis Stokes Cleveland VA Medical Center
- ✓ Gundersen Clinic, Ltd
- ✓ UPMC Presbyterian Hospital
- ✓ Oregon Health & Sciences University
- ✓ Kaiser Permanente Medical Center Los Angeles
- ✓ Kaiser Permanente Division of Research, San Francisco
- ✓ SUNY Buffalo

 We currently have 54 interested sites: 145 investigators and coordinators from 48 sites have completed the CREST-H training webinar. We are hoping to green light our first set of sites within the next few weeks so that enrollment can begin. An additional 21 sites will be recruited over the next few months. We will be contacting RCC site PIs to help facilitate this. Thanks to all who are already on board. Please get those site enrollment documents completed!

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

Siekert Award to NIH StrokeNet Research Trainee, Eliza Miller!

CONGRATULATIONS to Emory University NIH StrokeNet Trainee, **Eliza Miller.** Eliza was the recipient of the Siekert New Investigator Award this year, for her ISC abstract: *Preeclampsia and Early Stroke Incidence in the California Teachers Study.*

IMPORTANT: Information for Clinical Trial Applications

**New Video Provides Overview of New NIH Policies on
Human Subjects Research and Clinical Trials**

This 15 minute video Overview of New NIH Policies on Human Subjects Research and Clinical Trials provides a succinct explanation of the various policy changes and what they mean for you.

https://grants.nih.gov/policy/clinical-trials/tutorial/story_html5.html?lms=1

Steering Committee Call

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

The next Steering Committee call will be **13-December, 2017, at 12 noon ET.**

Invited speaker:

> Patrick Lyden, MD, FAAN
> Chairman, Department of Neurology
> Carmen and Louis Warschaw Chair in Neurology
> Cedars-Sinai Medical Center

Dr. Lyden will speak to the group regarding his experience engaging industry with NIH funded trials.

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 a log in, 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

There will be no December or January webinar. We hope to see you at the in-person meeting in Los Angeles on 22-January.

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

There will be no December Professional Development webinar.

To join the meeting: https://nihstrokenet.adobeconnect.com/pdw/ **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.

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

There will be no December Grand Rounds webinar.

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

Upcoming Feasibility Survey

RCCs will be receiving the Feasibility Survey for the PAST-TIME Study on 2-January, 2018, with a due date of 17-January. Thanks in advance for your timely completion of this survey.

QAR Reminder

Just a reminder that your Quarterly Activity Report covering **16-June 2017 through 15-December 2017** will be due 5-January 2018. Relevant dates are attached, as well as the revised template. Please upload the QAR to your awardee folder on the www.nihstrokenet.org website. If you have any questions, contact Jamey Frasure at frasurjs@ucmail.uc.edu.

Thanks in advance for your compliance.

StrokeNet Network Meetings

2018: The International Stroke Conference is once again in Los Angeles, California. The NIH StrokeNet Network meeting will be held on **Monday, 22-January**, at the Manhattan Country Club http://www.manhattancc.com/home, adjacent to the Marriott Westdrift hotel in Manhattan Beach, CA. We will be reserving a block of rooms for 21 and 22 January at the Marriott. The room rate will be $194, which will include a $10 Uber card to help offset the cost of ground transportation; it is 3 miles from LAX, however, there is no free airport shuttle. This cost is significantly less than downtown LA hotels.

Look for the reservation link via email!

We will reimburse 2 people from each RCC *up to $500* each for two nights' room and tax with a receipt, in the event you prefer to stay downtown.

NOTE: For planning purposes, there will be breakout sessions for the Working Groups that afternoon, as well as a trainee meeting, time TBD. For those ARCADIA PIs and Coordinators attending the StrokeNet meeting, there will be a trial update given by the ARCADIA leadership team (tentatively 5:30-7:30pm). Appetizers will be served. Details to come.

K12 Neurorehabilitation and Restorative Neuroscience Training Network

The Neurorehabilitation and Restorative Neuroscience Training Network (NRNTN) provides outstanding research training and mentorship for clinical scholars in

neurorehabilitation and prepares rehabilitation clinician investigators for sustained and productive academic careers in neurorehabilitation. NRNTN is funded by the National Center for Medical Rehabilitation Research, NIH/NICHD.

This early career development and mentorship program seeks to prepare individuals with advanced neurorehabilitation related degrees (MD, MD/PhD neurologists, neurosurgeons, geriatricians, physiatrists and other physicians interested in neurorehabilitation, physical therapists, occupational therapists, speech language pathologists and others) who will be in a position to define the mechanisms underlying neural plasticity and recovery of function following CNS injury, to identify and implement methods to enhance that recovery, and to influence health care and policy to benefit individuals with disabilities. The NRNTN brings together a regional network of 8 leading academic clinicians and scientists in neurorehabilitation to provide mentored research training and career development for junior faculty level clinicians in neurorehabilitation.

The goal of the Neurorehabilitation and Restorative Neuroscience Training Network (NRNTN) fellowship is to prepare individuals for research careers that can include defining the mechanisms underlying neural plasticity and recovery of function following CNS injury, identifying and implementing methods to enhance that recovery, and/or influencing health care and policy to benefit individuals with disabilities.

The specific aims of the NRNTN fellowship are:

1) To provide outstanding research training and mentorship for clinical scholars in neurorehabilitation

2) To create a community of scholars

3) To prepare rehabilitation clinician investigators for sustained and productive academic careers in Neurorehabilitation

For further information, please contact:

Barbara Bregman, PT, P.h.D.
Program Director, Neurorehabilitation and Restorative Neuroscience Training Network
Georgetown University Medical Center
email: bregmanb@georgetown.edu

Sunju Barrie
Administrative Coordinator, Neurorehabilitation and Restorative Neuroscience Training Network
Georgetown University Medical Center
email: skb56@georgetown.edu

https://rehabmedicine.georgetown.edu/K12-webpage

NINDS Clinical Trials Methodology Course

The NINDS Clinical Trials Methodology Course is accepting applications for the 2018 cohort. The overarching goal of the CTMC is to help junior investigators develop scientifically rigorous, yet practical clinical trial protocols.

Course:

There is a combination of distance learning activities and a **required** residential course, along with small group mentorship from experienced clinical trialists and biostatisticians. The required residential part of the course will be held *August 20 – 23, 2018 in Ann Arbor, MI*. Funding for travel and accommodations will be provided for participants.

Who Should Apply?

Qualified applicants from clinical disciplines focused on neurological disease or injury, along with biostatisticians working on projects with clinical neuroscience researchers should apply. All preliminary trial ideas are encouraged, but it is **required** that protocols be focused on the clinical neurosciences. Trainees should have content area mentors to assist them with the science and implementation of their project. A small number of projects may qualify for additional work using clinical trial simulation.

Deadline:

The application submission deadline is February 28, 2018 at midnight, PST. Application forms and additional details are available on the course website: https://nett.umich.edu/training/ctmc. Early applications may be considered for early acceptance.

Have Questions?

Please contact NINDS-CTMC-Info@umich.edu or William Meurer, MD, MS with any questions wmeurer@umich.edu.

*The NINDS Clinical Trials Methodology Course is supported by the NIH-NINDS grant **R25 NS088248** and is administered by the University of Michigan, the University of Iowa, and Los Angeles BioMed. Additional support is provided by the American Academy of Neurology.*

Upcoming Conferences and Seminars

May 2-4, 2018	NIH Regional Seminar: Program Funding and Grants Administration – Washington DC Early registration closes 15-December!

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   UPMC Neuroscience Conference – Pittsburgh, PA
7:00 am – 3:00 pm   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

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 I NIH StrokeNet Coordinating Center I frasurjs@ucmail.uc.edu I 513-558-1742
https://www.nihstrokenet.org