

Monthly Update

8-June 2017



REMINDER! Monthly Coordinator Call

The next Coordinator call is scheduled for **Thursday, June 15**th **at 10.30am**

Neuro Teleconference Line:

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

Enrollment Update

iDEF – 254

Whealth

- **MISTIE III** 481
- **CREST 2** 638
- Telerehab in Stroke 94
- **DEFUSE 3** 182
- POINT 4350 no update since April

Reminder to review and complete SOP and COI forms!

RCC24 is currently enrolling in MISTIE III, POINT and Crest-2.

Everyone has been busy with enrollments and activating new studies.

Keep up the momentum!

The renewal grant will be submitted in the fall. Participation is more important than ever!

Arcadia should begin enrolling in the early fall! Marshfield and Aurora were selected in the third cohort! Congrats! There is one more cohort to be announced, so please let us know if you are interested.

DEFUSE-3 enrollments are on hold! The study is undergoing an interim analysis with the DSMB.

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

National Coordinating Center.

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Monthly Update

8-June 2017



Trial Proposal Status

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update	
CREST-H	Randy Marshall, Sander Connelly, Ronald Lazar, David Liebeskind	Prevention	Approved for funding	

ProjectName	Protocol PI	Prevention/ Acute/Recovery	Status Update
MOST	Opeolu Adeoye, Andrew Barreto, Joe Broderick, James Grotta	Acute	Resubmitted 17-March
IMPACT	Andrew Naidech	Acute	Resubmitting as new grant July 2017
STEPSS (Dose Response Aerobic Exercise in Subacute Stroke)	Sandra Billinger	Recovery	Pending summary statement
SATURN	Magdy Selim	Prevention	Pending summary statement
TRANSPORT	Wayne Feng, Gottfried Schlaug	Recovery	Pending summary statement
I-WITNESS	Lee Schwamm, Ona Wu, Steve Warach, Larry Latour, Shlee Song	Acute	Submitted February 2017
Sleep SMART (C-PAP)	Devin Brown	Prevention	Resubmitted March 2017
ARREST	Robert Brown, James Torner, David Hasan	Prevention	July 2017 re-submission
VERITAS II	Sepideh Amin- Hanjani	Prevention	July 2017 grant submission

ProjectName	Protocol PI	Prevention/ Acute/Recovery	Status Update
ASPIRE (formerly SCORPION)	Kevin Sheth	Prevention	July 2017 grant submission
ACQUIRE (formerly IRIIS)	Warren Lo, Sharon Ramey	Recovery	July 2017 grant submission
ALISAH 2	Jose Suarez	Acute	Re-submitting 5-November
PICASSO	Marc Chimowitz	Prevention	Redesigning as Phase I, with plan to submit in either July 2017 or October
PHAST	Kate Amlie- Lefond, Michael Rivkin, Joan Cox Gill	Acute	In concept development
CAPTIVA (formerly CRISIS)	Brian Hoh	Prevention	Targeting July 2017 submission; going back to ESC with revisions sometime in May
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
PreLIMBS II	Sebastian Koch, Nestor Gonzalez, Neeraj Chaudhary	Acute	Possible July 2017 submission

ProjectName	Protocol PI	Prevention/ Acute/Recovery	Status Update
SEACOAST 1	Radoslav Raychev, Dimiter Arnaudov, David Liebeskind, Jeffrey Saver	Acute	In concept development
TESLA	Albert Yoo, Sam Zaidat	Acute	In concept development
ASSIST	David F. Kallmes, (Radiology) Alejandro Rabinstein, (Neurology) Jeffrey Pasternak, (Anesthesiology) Rickey Carter, (Biostatistics)	Acute	In concept development; ASWG webinar 27-Feb
DEFUSE 4	Maarten Lansburg, Greg Albers	Acute	In concept development; ASWG scheduling discussion.
START	Steve Warach, Truman Milling	Prevention	In concept development; Prevention WG webinar 20-Mar
Deep TMS Treatment of Stroke (Israel - Industry)	Abraham Zangen	Recovery	In concept development
SPLIT	Andrew Naidech	Prevention	Will proceed to PWG
PRECISE MRI-T2	Natalia Rost, Shyam Prabhakaran, Rebecca Gottesman, Clinton Wright	Prevention	In concept development
RISiS	Julius Fridrikkson, Ron Lazar, Ed Jauch, Jordan Elm, Leonardo Bonilha	Recovery	PPIs unsure whether they will resubmit.

ProjectName	Protocol PI	Prevention/ Acute/Recovery	Status Update
Tempo-EMS	Nerses Sanossian, William Meurer, Jeffrey Saver, David Hess	Acute	Triaged at November 2016 Study Section
FURRTHER	Bernadette Boden-Albala	Prevention	Discussed with ESC, have not received permission to move forward in its current form
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
PreLIMBS	Sebastian Koch	Acute	Possible July 2017 submission with PreLIMBS II
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

ProjectName	Protocol PI	Prevention/ Acute/Recovery	Status Update
			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.
URIC	Enrique Leira	Acute	Inadequate data to support the trial in its current form. Needs published work prior to submission.
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

Health

Active Inactive Awarded 30 # of days since previous milestone

8-June 2017



Summary 2014 2014 2014 20 20 20 2015 22016 14		Feasibility Assessment Min=6 Max=89 Med=25 31 58 30 50 7/5/2015 177 147 3/1/201 126 11/8/201 54 80 155 11/8/201 301 2/1/201	162 155 155 131 156 16 16 147 155	S Grant Submission Grant Submit to NINDS Min=30 Max=301 Med=78 11/10/2014 92 3/5/2015 3/5/2015 11/3/2016 3/1/2016	Scientific Peer Review Min=92 Max=195 Med=148.5	Awarded Med=97	Protocol Submit to CIRB Med=1 15	Project II CIRB Approval Med=15 168	First Site Released Med=168 35 5/6/2016	First Subject Enrolled Med=35
72014 72014 72014 72014 72015 72016	-6 1/26/2015 89 -1 12/11/2015 106 7/5/2016 21 25 61	Min=-6 Max=89 Med=25 31 58 30 50 7/5/2015 1777 147 3/1/201 126 11/8/201 54	155 155 131 156 16 16 147 155	Max=301 Med=78 11/10/2014 92 3/5/2015 3/5/2015 11/13/2015 11/8/2016	Max=195	Med=97				
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3/2016		301 2/1/201							4	
PICASSO	10/16/2014	55		53 3/5/2016	144 6/25/2015 124 7/7/2016					
ARCADIA	3/6/2015	21 1/27/2016		80 37	150 11/12/2015 125 7/7/2016			3/10/2017		
SleepSMART	11/3/2015	22		76 3/3/2017	150 7/8/2016					
ARREST	11/3/2015	22		76	150 7/8/2016					
	2/3/2016	21	224	10/5/2016						
			16							
					156 11/8/2016					
STEPSS			103							
		36		36	195 4/18/2017					
	SATURN VERITAS II ASPIRE RISIS STEPSS	SATURN 2/3/2016 VERITAS II 8/10/2016 ASPIRE 10/21/2016 RISIS 12/15/2015 STEPSS 4/29/2016	SATURN 2/3/2016 21 VERITAS II 8/10/2016 84 11/2/201 ASPIRE 10/21/2016 25 11/15/201 RISIS 12/15/2015 45	SATURN 2/3/2016 21 224 VERITAS II 8/10/2016 84 11/2/2016 ASPIRE 10/21/2016 25 11/15/2016 RISIS 12/15/2015 45 STEPSS 4/29/2016 56 103	SATURN 2/3/2016 21 224 10/5/2016 VERITAS II 8/10/2016 84 11/2/2016 ASPIRE 10/21/2016 25 11/15/2016 RISIS 12/15/2015 45 128 STEPSS 4/29/2016 56 103 10/5/2016	SATURN 2/3/2016 21 224 10/5/2016 VERITAS II 8/10/2016 84 11/2/2016 ASPIRE 10/21/2016 25 11/15/2016 RISIS 12/15/2015 45 128 156 11/8/2016 STEPSS 4/29/2016 56 103 10/5/2016	SATURN 2/3/2016 21 224 10/5/2016 VERITAS II 8/10/2016 84 11/2/2016 ASPIRE 10/21/2016 25 11/15/2016 RISIS 12/15/2015 45 128 156 11/8/2016 STEPSS 4/29/2016 56 103 10/5/2016	SATURN 2/3/2016 21 224 10/5/2016 VERITAS II 8/10/2016 84 11/2/2016 ASPIRE 10/21/2016 25 11/15/2016 RISIS 12/15/2015 45 128 156 11/8/2016 STEPSS 4/29/2016 56 103 10/5/2016	SATURN 2/3/2016 21 224 10/5/2016 VERITAS II 8/10/2016 84 11/2/2016 ASPIRE 10/21/2016 25 11/15/2016 RISIS 12/15/2015 45 128 156 11/8/2016 STEPSS 4/29/2016 56 103 10/5/2016	SATURN 2/3/2016 21 224 10/5/2016 VERITAS II 8/10/2016 84 11/2/2016 ASPIRE 10/21/2016 25 11/15/2016 RISIS 12/15/2015 45 128 156 11/8/2016 STEPSS 4/29/2016 56 103 10/5/2016

All information is generated based on data currently in the database. Data may not be verified or validated. The report is generated to assist in trial operations only, and is not valid to support any statistical analysis of study data. Unless noted, the Data Coordination Unit (DCU) assumes no responsibility for the use of this report. This report may contain protected health information covered by the Health Insurance Portability and Accountability Act (HIPAA). You are prohibited from disclosing this information without the specific written consent of the person to whom it pertains. Anyone using this data specifically assumes responsibility for maintaining the confidentiality of the protected data.



Biweekly Update 26-May-2017

http://nihstrokenet.org/coming-events

StrokeNet Enrollment Update

Telerehabilitation in Stroke – 92/124 DEFUSE 3 – 182/476 iDEF – 254/294 subjects bouquet MISTIE III – 474/500 subjects CREST 2 – 631/2480 subjects

StrokeNet Trial Updates



From the ARCADIA Team: Cohorts 1-3 have been announced! Sites are still being considered for the final cohort.

An initial list of regulatory document requirements and instructions have been sent to RCC and site coordinators.

For Questions about this contact Erin Klintworth @ klintwor@musc.edu or Irene Ewing @ Irene.ewing@uc.edu.

If you haven't done so already, please identify your site PI and coordinator and send their contact information to Irene as soon as possible.

REMINDER TO SAVE THE DATE: the ARCADIA Investigator Meeting will be Wednesday, September 13, 2017 in Atlanta, immediately after the StrokeNet Network meeting. There will be a meet and greet reception on Tuesday evening, September 12. More details to come.



IMPORTANT Information from the DEFUSE 3 Team:

Pending an interim analysis by the DEFUSE 3 DSMB, the StrokeNet Central IRB requests suspension of enrollment in DEFUSE 3 patients who meet the DAWN selection criteria. This recommendation is *not* based on any review of DEFUSE 3 data. We anticipate a DSMB data review to occur very soon, and further modifications may occur at that

time.

As of now, **DO NOT** Enroll any subjects in the DEFUSE 3 study who meet the following criteria:

- 0-20 ml ischemic core and NIHSS ≥ 10 and age ≥ 80 years old
- 0-30 ml ischemic core and NIHSS ≥ 10, and age < 80 years old
- 31-50 ml ischemic core and NIHSS ≥ 20, and age < 80 years old
- Please note that DAWN did not include patients with:
- NIHSS 6-9
- Pre-stroke mRS= 2
- Ischemic core= 50-70 ml

These patients continue to be eligible if they meet our standard DEFUSE 3 enrollment criteria.

A protocol amendment with these eligibility changes will be submitted promptly. In the meanwhile, please ensure that the new eligibility criteria are adopted immediately. Feel free to contact me by phone or email if you have any questions. My cell phone is 650-888-0582. You can also reach me by email at albers@stanford.edu or Stephanie Kemp at skemp@stanford.edu

The RAPID maps are available to the DEFUSE 3 core lab in real time. The maps will be closely monitored to help ensure that DAWN eligible patients are not being enrolled in DEFUSE 3.

PLEASE NOTE: Until we can program the new criteria rules into WebDCU, PRIOR TO RANDOMIZATION you must call the DEFUSE 3 hotline (844-250-9300) to confirm patient eligibility based on the new selection criteria.



From the Telerehab Team:

Enrollment is currently **92**, and seems to have slowed at most telerehab sites. Please keep in mind that we are coming up on the *competitive* resubmission for StrokeNet RCCs for the next 5 years, and enrollment rates in clinical trials will be a critical factor. Please continue to do

everything you can to accelerate recruitment at your site, as this will not only help the trial to finish as quickly as possible, but will also be seen as a positive factor when your RCC undergoes review. Thank you for all your hard work!

As always, feel free to call or email the help lines if any questions arise. The 24 hour contact number at UC Irvine for emergency questions is (323) 539-8748. Email us with non-emergent questions at: telerehab@uci.edu



From the iDEF Executive Committee:

Enrollment is currently 254. Only forty to go!



From the CREST-2 Clinical Coordinating Center:

631 randomizations as of 5/23/17 (302 CEA; 329 CAS) **120** active centers of which **50** are StrokeNet Sites

Welcome to
University of Kansas Medical Center
Kansas City, KS

We're happy to have you aboard CREST-2!



Kamal Gupta, MD, Site PI Alyssa Boyce, Coordinator

ASPIRE Feasibility Survey Update

RCC PIs and Coordinators received an email from Jessica Griffin on 19 May in regard to an update to the ASPIRE Feasibility Survey; one question has been added to the original survey. Please login to your WebDCU account, click on the red StrokeNet button, go to Surveys, and then find your previously submitted Feasibility Survey 26: ASPIRE in order to edit the record. This must be completed by **Friday, 2-June**. If you have any questions, please contact Jessica at simonsil@musc.edu. Thank you!

Coordinator Webinar

There next Coordinator Webinar will be **Wednesday**, **28-June**, **at 1:30 pm ET**. Sherry Goldfarb, MPH, from the University of Michigan, will discuss a Study Rollout Checklist. 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

When: Wednesday, May 31, 2017 – 1:00 – 2:30 PM ET

Presentations: Personalized Neural Networks Associated with Correct Naming in

Post Stroke Patient – Ashley Wabnitz, MD, MUSC

Blood Pressure after Successful Endovascular Treatment in

Ischemic Stroke - Katherine Nearing, MD, Vanderbilt University

The Effect of Vasospasm Surveillance on Disposition in

Aneurysmal Subarachnoid Hemorrhage – Joseph Kim, MD, USC

Moderator: TBD

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.

The next Grand Rounds is TBA.

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

Steering Committee Call

The next Steering Committee call will be **14-June**, **2017**, **at 12 noon ET**. Dial-in is always the same, 1-877-621-0220, passcode 434578. You will receive notification if the call involves a webinar presentation.

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-

<u>committee</u>. If you need a log in, please contact your RCC Network Manager/Coordinator to request one for you.

StrokeNet Network Meetings 2017

Pencil us in for **Tuesday, 12-September in Atlanta, GA, for the fall network meeting. Same location as last year, the Atlanta Airport Marriott. We have negotiated a very reasonable rate room rate, details to come. We will keep you posted!

NOTE: The ARCADIA Investigator Meeting will be held **Sept. 13th** in Atlanta following the StrokeNet meeting. All participating sites will be invited to this meeting. Stay tuned for more details!

Upcoming Conferences and Seminars

Upcoming NIH Seminars:

October 25-27, 2017

Baltimore 2017 – NIH Regional Seminar https://regionalseminars.od.nih.gov/baltimore2017/

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

Educational Opportunities

STROKE ECHO EXTENSION FOR COMMUNITY HEALTHCARE OUTCOMES

When: Thursday, 22-June 12:00 – 1: 00 pm MST

Topic: LOOK WHO'S TALKING: STROKE AND STROKE PREVENTION IN

PREGNANCY

The Stroke Center, along with Project ECHO, is working together to create interactive, live video conferences to review interesting, recent stroke cases.

This is an easy and FREE way for your facility's staff and physicians to earn Continuing Education credits over a lunch hour!

To sign up, or for more information, please contact Jaleen Smith 801-585-1586 Jaleen.smith@hsc.utah.edu;

NIH StrokeNet Employment Opportunities

NIH/National Institute of Neurological Disorders and Stroke Vascular Neurology Fellowship Position Opening starting July, 2017

Vascular Neurology Fellowship Directors, the Vascular Neurology Fellowship at the NIH/National Institute of Neurological Disorders and Stroke, has an unexpected opening for a 2017-2018 position. With a focus on clinical practice and research, the ACGME-accredited Vascular Neurology Fellowship at the NIH/NINDS Stroke Program is designed for neurologists who seek to become experts in the management of cerebrovascular disorders. The program is oriented toward emergency management of stroke with emphasis in neuroimaging, thrombolysis, and other novel therapeutic and diagnostic approaches.

Interested persons should contact Pat Lyall (<u>LyallP@ninds.nih.gov</u>) or John Lynch (<u>john.lynch@nih.gov</u>)

UW Seattle Vascular Neurology Positions (2)

Assistant Professor, Associate Professor or Professor; all without Tenure

Search Number: AA17550

Job Details: 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.

See http://ap.washington.edu/ahr/academic-jobs/position/aa17550

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