

Monthly Update

9-November 2017



REMINDER!

Monthly Coordinator Call

The next coordinator call is scheduled for **Thursday, November 16th at 10:30am.**

Neuro Teleconference Line:

USA Toll-Free: (877) 848-7030

Access Code: 3386580

Enrollment Update

- **iDEF** – 290
- **CREST 2** – 808
- **Telerehab in Stroke** – 117
- **POINT** – 4807

RCC24 is currently enrolling in POINT and Crest2.

The CREST-H protocol is being finalized.

The Arcadia investigator meeting is fast approaching on November 17.

Sleep-SMART and MOST were approved in September by the council. We do not have a timeline for these studies as they are not funded yet.

Six more trials were submitted for peer review!

At the end, please find the latest 2 bi-weekly StrokeNet newsletters and the dashboard.

RCC Contact Information

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Monthly Update

9-November 2017

Trial Proposal Status

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

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
ALISAH 2	Jose Suarez	Acute	March 2018 resubmission
URIC	Enrique Leira	Acute	Tentative 3-November ESC In concept development
FASTEST	Joe Broderick, Jim Grotto, Jordan Elm	Acute	Tentative 3-November ESC In concept development

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
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
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

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
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
FOCAS	Heather Fullerton, Mitch Elkind	Prevention	In concept development
PAST-TIME	Jason McMullan, Opeolu Adeoye, Nerses Sanossian	Acute	In concept development
PRECISE MRI- T2	Natalia Rost, Shyam Prabhakaran, Rebecca Gottesman, Clinton Wright	Prevention	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
CREST-P	Brajesh K Lal, Ronald Lazar, Randolph	Prevention	Pending score/critiques Score not in funding range

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

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status 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

8-November 2017



School of Medicine
and Public Health
UNIVERSITY OF WISCONSIN-MADISON

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	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 (43.5%)	URIC										
	DEFUSE 3	5/7/2014	-6 1/28/2015	31 58	162 92	11/10/2014	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					
			12/11/2015	7/5/2015	131	11/13/2015					
	IMPACT	6/2/2015	20	177	156	11/8/2016					
			3/1/2017	114	6/23/2017						
	PreLIMBS II	7/23/2015	21	106	147	3/1/2016					
	Tempo-EMS	2/22/2016	25	7/5/2016	126	11/8/2016					
	ALISAH 2	3/23/2016	14	7/11/2017	114	11/2/2017					
I-WITNESS	3/23/2016	14	301	142	6/23/2017						
Prevention (39.1%)	PICASSO	10/16/2014	55	53 3/5/2016	144 124	6/25/2015 7/7/2016					
	ARCADIA	3/6/2015	21 1/27/2016	80 37	150 125	11/12/2015	298	5/1/2017	3/10/2017		
	SleepSMART	11/3/2015	22	76 3/3/2017	150 112	7/8/2016 6/23/2017					
			ARREST	11/3/2015	22	76 7/11/2017	150 114	7/8/2016 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 (17.4%)	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 27-October-2017

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

StrokeNet Enrollment Update

Telerehabilitation in Stroke – **117/124**

iDEF – **290/294**

CREST 2 – **808/2480**

StrokeNet Trial Updates



The DEFUSE 3 manuscript has been submitted for publication and information about substudy proposals will be distributed next week. Final study results will be confidentially presented to investigators the evening before the ISC presentation. Please mark your calendars for the DEFUSE 3 Investigator Meeting on January 23 from 7-9:00 pm in Los Angeles.



We continue to make good progress on our start-up activities. We have a finalized protocol and MOP, which will be posted on WebDCU in the next week or two, and we have started to send out Protocol Trial Agreements to the sites in stages. On your end, if you haven't already RSVP'd for the ARCADIA investigator meeting in Atlanta on November 17, please email Daniel Velez (dav2125@cumc.columbia.edu) as soon as possible. We

look forward to seeing you all there!



Telerehab Trial

The large majority of patients with stroke do not receive acute reperfusion therapies, or receive them and are not helped by them, or have hemorrhagic stroke. New therapies are needed to improve outcomes in this population. Telehealth holds great promise in this regard. This study will provide substantial insights into the utility of a telehealth-based approach, and **we have only 7 more patients to enroll** before we reach our target of 124. For non-emergent questions: telerehab@uci.edu. Thank you—Steven C. Cramer, MD



From the CREST-2 Clinical Coordinating Center:

808 randomizations (394 CEA; 414 CAS)

CREST-2 **122** active centers of which **52** are StrokeNet Sites



CREST-2 StrokeNet Sites

Enrolling this Month



Overall

16	San Francisco VA Medical Center, San Francisco, CA
13	Mayo Clinic, Rochester, MN
11	OhioHealth Research Institute, Columbus, OH
10	Kaiser Permanente, Los Angeles, CA
9	Ohio State University Medical Center, Columbus, OH
7	Intermountain Medical Center, Murray, UT
6	Medical University of South Carolina, Charleston, SC
6	University Hospitals Cleveland Medical Center, Cleveland OH
3	Cedars-Sinai Medical Center, Los Angeles, CA
3	Vanderbilt University Hospital, Nashville, TN



CREST-H

CREST-H is in the process of preparing subcontracts with CREST-2 sites who will be participating in CREST-H. Recruitment of additional sites, particularly within StrokeNet group, is ongoing.

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



iDEF recruitment is at 99% - only **4 more subjects to go!!** Please make sure you are screening for iDEF!

Contact Jessica Griffin (simonsjl@musc.edu) with any iDEF-related questions.

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 **8-November, 2017, at 12 noon ET.**

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*

Topic: How to Manage a Research Team

Presenter: Kinga Aitken, MPH CCRP, Research Project Manager,
University of Utah School of Medicine

When: Wednesday, 15-November, 2017 – 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

Presentations: When & How to Incorporate a Statistician in a Study – Yuko Palesch, PhD, Medical University of South Carolina

When: Monday, November 27, 2017 – 3:00 PM ET

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

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>

Presentations: Predicting Stroke Recovery/PREP Algorithm – Winston Byblow, PhD, University of Auckland

When: Thursday, November 2, 2017 – 4:00 PM ET

Moderator: Randy Marshall, MD – Columbia University

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

Reminder: Year 5 Notice of Awards

RCC Coordinators, if you have not already done so, please log in to the www.nihstrokenet.org website and upload your Year 5 NOA to your awardee folder. Thank you!

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

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 Marriott Westdrift hotel in Manhattan Beach, CA. We will be reserving a block of rooms for 21 and 22 January. 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 information to follow soon.

We will reimburse 2 people from each RCC *up to \$500* each for two nights hotel with a receipt, regardless of where you stay, 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, 5-7pm). Appetizers will be served. Details to come.

Upcoming Conferences and Seminars

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



Research Assistant/Associate Professor
The Data Coordination Unit Department of Public Health Sciences
Medical University of South Carolina

The Department of Public Health Sciences at the Medical University of South Carolina invites applications for a Research Assistant or Associate Professor position in the Data Coordination Unit (DCU). The DCU specializes in the design of clinical trials and analysis of their data and in establishing, implementing and maintaining data and project management systems for multicenter clinical trials. The successful applicant must have a doctoral degree in biostatistics. Preference is given to candidates with an excellent background in statistical methodology, applicable to clinical trials, and a strong desire and

ability to collaborate with clinical trials colleagues. Expertise and research interests in one or more of the following areas are highly desirable: clinical trial methodology, adaptive clinical trial designs and/or Bayesian clinical trials designs, simulation studies. The successful candidate will have a focus on developing and sustaining independent and collaborative research and is expected to carry out methodological and collaborative research as part of the DCU and provide service to the community and the field of public health by meeting the following preferred characteristics:

- ❖ Prior experience in clinical trial development and collaboration;
- ❖ Ability to communicate and work with others within and outside the organization
- ❖ Understanding of the current and emerging issues in clinical trial design, implementation, and analysis methods
- ❖ Strong oral and written communication skills, and an overall professional demeanor
- ❖ Experience with or ability to develop proposals for grant submissions

Potential exists for a wide variety of areas of collaboration in clinical trials, especially in neurology and internal medicine areas.

To apply for the position, please visit the following MUSC website:

<http://careers.pageuppeople.com/756/cw/en-us/job/503014/univ-research-assistantassociate-professor-public-health-sciences>

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>



Biweekly Update 10 November-2017

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

StrokeNet Enrollment Update

Telerehabilitation in Stroke – **119/124**

iDEF – **293/294** (**ONE** more to go!)

CREST 2 – **823/2480**

StrokeNet Trial Updates



ARCADIA

The Nov 17th ARCADIA Investigator Meeting in Atlanta is fast approaching! If you have any questions about your travel to the meeting please contact Daniel Velez at Columbia dav2125@cumc.columbia.edu. The meeting agenda and travel reminders will be sent out to attendees next week.

All presentations will be posted for viewing after the meeting for those who cannot attend in person.

For questions about regulatory documentation collection or submission contact Irene Ewing, ARCADIA project manager irene.ewing@uc.edu



Telerehab Trial

The Telerehab trial has 119 patients enrolled and 5 more to go. Looking forward to learning the value of this home-based therapy for stroke survivors.

For non-emergent questions: telerehab@uci.edu

Thank you - Steven C. Cramer, MD



From the CREST-2 Clinical Coordinating Center:

823 randomizations (403 CEA; 420 CAS)

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



*11 CREST-2 StrokeNet sites
that randomized at least
one patient in October!*



CREST-H

We have recruited 48 sites to date. Site enrollment packets have gone out, and our training webinars started up this week. We need all StrokeNet RCCs with CREST-2 sites to participate to make this ancillary study a success. We will be contacting RCC site PIs to help facilitate this. Thanks to all who are already on board! Stay tuned for more updates...

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



iDEF recruitment is almost at 100% - only **1 more subject to go!!**
Thank you!

Contact Jessica Griffin (simonsjl@musc.edu) with any iDEF-related questions.

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Presentations: **Sex Differences in Stroke – Louise McCullough, MD, PhD, University of Texas at Houston**

When: **Thursday, November 30, 2017 – 4:00 PM ET**

Moderator: Lori Jordan, MD – Vanderbilt University

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

Reminder: Rules for NINDS/NIH Funding Acknowledgement of Posters

With the ISC approaching, now is a good time to clarify the use of the NIH/NINDS/NIH StrokeNet logos on scientific posters. The NIH StrokeNet logo includes the NIH mark, so please use our logo at the top or bottom of any scientific poster to recognize NIH StrokeNet support. This includes trainee posters, clinical trial posters, as well as any other work that is a result of StrokeNet support. **Note:** NIH guidelines require all materials that refer to research supported by NIH grants include the grant number somewhere within the document copy (other than the title). ***Please see the attachment for clarification.***

Thanks in advance for your compliance.

StrokeNet Network Meetings

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Look for the reservation link via email!

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Upcoming Conferences and Seminars

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
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- ❖ Prior experience in clinical trial development and collaboration;
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Potential exists for a wide variety of areas of collaboration in clinical trials, especially in neurology and internal medicine areas.

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<http://careers.pageuppeople.com/756/cw/en-us/job/503014/univ-research-assistantassociate-professor-public-health-sciences>

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>