

# Monthly Update

01 – October 2019



School of Medicine  
and Public Health  
UNIVERSITY OF WISCONSIN-MADISON

## REMINDER

### Monthly Coordinator Call

The coordinator call is scheduled for October 17<sup>th</sup> at 10.30am

#### **NEW!!! Neuro Teleconference Line:**

- 1) Call into 733-4000 if calling from a UW Health phone, call (608)733-4000 if not calling from a UW Health phone
- 2) Enter the 4-digit Meeting ID (**9909**) followed by #

**PLEASE NOTE NEW DIAL-IN INSTRUCTIONS**

### Enrollment Update (as of 09/27/2019)

- CREST 2 – 1528/2480
- ARCADIA – 316/1100 randomized
- CREST-H – 111/500
- Sleep SMART – 55/3062
- TRANSPORT2 – 1/129

## Welcome!!

Please welcome our two new coordinators  
Jenna Bock and Victoria Harms will be coordinating several  
StrokeNet studies at UW

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

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# Monthly Update

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- Trial Proposals status:

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
ALISAH 2	Jose Suarez	Acute	September 2019 peer review
PreLIMBS II	Sebastian Koch, Nestor Gonzalez, Neeraj Chaudhary	Acute	September 2019 peer review
TEST OF TIME	Lee Schwamm, Ona Wu, Yuko Palesch, Caitlyn Ellerbe, Victor Urrutia, Andrew Barreto, Shlee Song, Steve Warach	Acute	September 2019 peer review
COASTAL	Adnan Qureshi	Acute	October 2019 submission
PETITE	Greg Albers	Acute	October 2019 submission
STEP-STONE	C. Meinzer, C. Derdeyn, P. Khatri	Acute	October 2019 submission
SPLASH	Jose Suarez, DaiWai Olson (contact PI)	Acute	November 2019 resubmission
CAPTIVA	Brian Hoh, PI, Marc Chimowitz, Co-I	Prevention	October 2019 A-1 submission
FOCAS	Heather Fullerton, Mitch Elkind	Prevention	ESC approved

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
VERIFY	Pooja Khatri, Steve Cramer, Cathy Sinear, Achala Vagal	Recovery	June submission
ERSIAS	Nestor Gonzalez, Jeff Saver	Prevention	Pending feasibility
PERFUSE-ICAS	S. Yaghi, P. Khatri, D. Liebeskind, S. Prabhakaran	Acute	Pending feasibility
COAT (TACOCAT)	Brett Cucchiara, Scott Kasner	Prevention	Pending feasibility
PAST-TIME	Jason McMullan, Opeolu Adeoye, Nerses Sanossian	Acute	Review comments received; teams Planning next steps
IMPACT	Andrew Naidech	Acute	Review comments received; teams Planning next steps
VERITAS II	Sepideh Amin-Hanjani	Prevention	Review comments received; teams Planning next steps
FURRTHER	Bernadette Boden-Albala	Prevention	Will resubmit; check to see if needs to go to ESC again.
TEACH2	Babak Navi, Scott Kasner, Mary Cushman, Mitch Elkind	Prevention	Deferred ESC approval
Rhapsody 2	Pat Lyden	Acute	Deferred ESC approval
IMAGING U	David Hasan, Edgar Samaniego	Prevention	Back in development
SPLIT	Andrew Naidech	Prevention	In concept development
SUCCESS	E. Sander Connolly Jr., John D. Lambris, Jan Claassen	Acute	In concept development
PRECISE MRI-T2	Natalia Rost, Shyam Prabhakaran, Rebecca Gottesman, Clinton Wright	Prevention	In concept development
Claassen	Jan Claassen	Acute	In concept development
CIAT RCT	Jerzy Szaflarski	Recovery	In concept development

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
SCOUTS (ancillary to Sleep Smart)	Sandeep P. Khot, Martha E. Billings	Recovery	In concept development
Durand	Matthew Durand, Robert Dempsey Allison Hyngstrom, John McGuire	Recovery	In concept development
GPAS	Jin- Moo Lee, Jonathan Rosand, Pooja Khatri, Steve Cramer, Carlos Cruchaga	Acute + Recovery	Processed by ESC separately
REMAKE	Sean Savitz, Larry Wechsler, Steve Cramer	Recovery	In concept development
THROTTLE	Kunal Agrawal, Brett Meyer, Steve Cramer	Recovery	In concept development
STARBURST	Stephen Page	Recovery	In concept development
BLAST	James Meschia	Prevention	In concept development
CAVIS	Mark Harrigan	Prevention	In concept development
START	Steve Warach, Truman Milling	Prevention	In concept development
SCORE	David Hasan	Acute	In concept development
IDDEAL	Syed Ali	Prevention	In concept development
CREST 3	Brajesh Lal, James Meschia, Gary Roubin	Prevention	In concept development
ARCADIA-G	Dana Leifer	Prevention	Post ESC
SIMVICH	C. Chen, A. Southerland, K. Johnston, B. Worrall, N. Naval, D. Ding	Acute	Post ESC
eBOOST	Julius Fridriksson, Chris Rorden, Leo Bonilha, Jordan Elm, Mark George	Recovery	On hold
URIC	Enrique Leira	Acute	SPAN Initiative
MATRICES	Maarten Lansberg, Greg Albers, Albert Yoo, Sam Zaidat	Acute	On hold for EVT Platform
ETHER	Stephan Mayer	Acute	On hold for EVT Platform

Project Name	Protocol PI	Prevention/ Acute/Recovery	Status Update
SERENE (ASSIST + SEACOAST)	Radoslav Raychev, Dimiter Arnaudov, David F. Kallmes, (Radiology) Alejandro Rabinstein, (Neurology) Jeffrey Pasternak, (Anesthesiology) Rickey Carter, (Biostatistics)	Acute	On hold for EVT platform
HEMERA	Italo Linfante, Raul Nogueira	Acute	On hold for EVT platform
NEPTUNE (ARCADIA ancillary study)	Ajay Gupta, Hooman Kamel	Prevention	In concept development
ARCADIA ORACLE	Babak Navi	Prevention	Hold ARCADIA ancillary study
RAFT	Truman Milling, Steve Warach	Acute	In concept development; gathering preliminary data for a future application



## Biweekly Update 27-September 2019

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

StrokeNet Enrollment Update			
ARCADIA	316/1080	CREST 2	1528/2480
Sleep SMART	55/3062	CREST H	111/500
TRANSPORT2	1/129		

### StrokeNet Trial Updates



ARCADIA

#### **ARCADIA Enrollment is Growing – thanks to everyone's dedication!**

As of September 26, 2019, 1235 subjects have been consented and 316 participants have been randomized at 90 sites. This is an increase of 51 consented and 15 subjects randomized in the past two weeks! Our enrollment is at 28.7% of the overall enrollment goal!

During the last two weeks, 37 sites have consented and 13 have randomized eligible subjects – thank you all!

**Congratulations to Moses H. Cone Memorial Hospital, NC and WVU Healthcare Ruby Memorial Hospital, WV for randomizing their first subjects.**

The competition on the leader board is ongoing. United Hospital has 14 randomizations and continues to pull ahead of University of Cincinnati which has 12 randomized subjects. Memorial Hermann Texas Medical Center has jumped to 3<sup>rd</sup> place with 10 randomizations and there is still room for a tiebreaker between the University of Iowa and OHSU to enroll beyond 9 subjects. Thank you all for your dedication and leadership!

We have now released to enroll a total of 132 sites, 121 are active, and we are still working on adding other qualified sites to the ARCADIA roster. Our randomization rate sits at 0.19 patients/ site/ month based on our active sites. Please let us know of any excellent stroke sites that are interested in participating in this important trial.

We want your enthusiasm for ARCADIA to continue to grow so that we can surpass last year's enrollments. Please keep approaching ESUS patients about the ARCADIA trial at your sites – Remember, every site's best effort is necessary for the trial to succeed!

**Webinar:** Our next PI and coordinator webinar will be October 22<sup>nd</sup> at 2 PM Eastern--save the date! We're asking that at least 1 person from each site attend the monthly webinar and pass the information along to their team. Also, please send suggestions for topics you'd like discussed.

If you miss out on a webinar, you will soon be able to find the slides on the StrokeNet website (<https://nihstrokenet.org/intranet/minutes/trial-webinars>).

-- The ARCADIA National Team

Brooks Rehabilitation Hospital is our top enroller with 32 subjects enrolled and 10 subjects randomized. Congratulations to Parag Shah, MD and Taisiya Matev!

Congratulations to the following sites for randomizing subjects in September:

1. Brooks Rehabilitation Hospital, Jacksonville, FL-Parag Shah, MD and Taisiya Matev
2. Prisma Health Midlands (Palmetto Health), Columbia, SC-Souvik Sen, MD and Phil Fleming
3. Barnes-Jewish Hospital, St. Louis, MO-Eric Landsness MD, William Holt, and Jill Newgent
4. SUNY Upstate Medical University, Syracuse, NY-Gene Latorre, MD and Lena Deb
5. UMPC Presbyterian Hospital Pittsburgh, Pittsburgh, PA-Sherry Chou, MD and Patricia Feineigle
6. Sarasota Memorial Hospital, Sarasota, FL-Mauricio Concha, MD and Jeanette Wilson
7. UCSD Medical Center Hillcrest Hospital, San Diego, CA- Dawn Meyer, NP, PhD, Theresa McQuaid, and Karen Rapp
8. University of Utah Healthcare, Salt Lake City, UT-Jana Wold, MD, Theodore Rock, and Kinga Aitken
9. Harborview Medical Center, Seattle, WA-Sandeep Khot, MD and Allison Kunze
10. Mayo Clinic Saint Mary's Campus, Rochester, MN-Eugene Scharf, MD and Amy Headlee-
11. Yale New Haven Hospital, New Haven, CT-Klar Yaggi, MD and Radu Radulescu
12. Eastern Maine Medical Center, Bangor, ME- Gillian Gordon-Perue, MD and Jessica Kneser
13. Beth Israel Deaconess Medical Center, Boston, MA-Jennifer Dearborn-Tomazos, MD and Sarah Marchina
14. Saint Luke's Hospital of Kansas City, Kansas City, MO-Suzanne Crandall, MD and Debbie Summers

We now have released to enroll a total of 47 sites. In order to schedule your site readiness call and release your site to enroll, the following need to be completed:

- FusionHealth Consignment and DUA executed
- CTA executed
- CIRB approval
- KOEO access confirmed and equipment received
- All required training completed and uploaded in WebDCU-<https://webdcu.musc.edu/campus/>

#### Important reminders:

1. When communicating with Greg Fletcher at FusionHealth regarding your Consignment agreement and DUA continue to also copy Kayla Novitski at [kcqossel@med.umich.edu](mailto:kcqossel@med.umich.edu)
2. Please remember to enter all subjects who meet criteria for enrollment, but decline participation, into WebDCU under Study Progress tab > Screen Failure Report.
3. Please remember to enter AEs into WebDCU as appropriate. If you have questions about what needs to be reported as an SAE and/or unanticipated event please reach out to Kayla or Joelle.

**Save the date-**Our next PI and coordinator webinar will be Monday, October 21<sup>st</sup> from 1-2 EST.




Reminder that our next PI and Coordinator call is scheduled for **Monday September 30th at 11am ET**. If anyone has topics they would like to discuss during the call, please send them to Kristina ([kristina.balderson@duke.edu](mailto:kristina.balderson@duke.edu)).

We are very excited that MUSC, University of Kentucky, Barnes Jewish, Burke, Emory, Moss Rehab, University of Texas, University of Cincinnati, and University of Alabama are open to enrollment! We have 1 subject randomized, 1 subject in screening and 5 screen failures. Hopefully, all 12 sites will be activated soon so we can catch up on our recruitment goals. LET'S GO TRANSPORT2 TEAM!!



**From the CREST-2 Clinical Coordinating Center:**

	<b>CREST-2</b>		<b>CREST-2 StrokeNet</b>
	CEA	803	287 (36% of total)
	CAS	725	106 (15% of total)
	<b>Total</b>	<b>1528</b>	<b>393 (26% of total)</b>

**Recruitment:** The CREST-2 Clinical Coordinating Center would like to thank all of the StrokeNet sites for their contributions to the trial thus far. As a reminder, our next recruitment milestone is **1700** randomizations by **February 29, 2020**. To achieve this goal we need **172** additional patients, which will require us to average **35** randomizations per month. Please continue to screen for CREST-2 patients and keep your team engaged.

**Medical Management Update:** Our latest report indicates that all the study risk factors show an improvement when compared to the baseline data. See table below.

Risk Factor	At Baseline (%)	At Last Follow Up (%)
LDL Cholesterol Level < 70 mg/dl	44.5	69.2
Systolic Blood Pressure < 130 mmHg	42.3	69.8
Smoking Cessation	79.1	82.1
HgA1c	46.7	49.6
Physical Activity	48.8	56.9
Weight	23.3	31.7

Currently we have 1351 patients (88.6%) participating in INTERVENT and 93 patients receiving study donated Alirocumab for the treatment of hypercholesterolemia.





**Site Startup and Enrollment Updates:** sites: **51**; enrollments: **111**

Shout out to Ochsner, St. Joseph's Barrow, and St. Boniface, three relatively new sites who just enrolled their first patient. Keep up the great work.

If you have not yet gotten approval for CT perfusion at your site, you will be receiving an email about this. We are making a big push for all sites to have both options. MRP is preferred because of the additional information regarding silent infarcts, white matter hyperintensities, microbleeds, and cortical thickness. For patients who cannot get MRI, however, due to a pacemaker, incompatible metal in the body, allergy to gadolinium dye, or claustrophobia, it is great to have CTP as a second option. Remember, the reimbursement is the same, and as long as they don't have an exclusion to CT such as allergy to iodinated contrast, they can get the CTP. **So help us please by getting test images uploaded for approval, so CTP can be an option at your site!**

We are still recruiting additional sites. Contact Randy Marshall [rsm2@columbia.edu](mailto:rsm2@columbia.edu), Ron Lazar [rlazar@uabmc.edu](mailto:rlazar@uabmc.edu), Jaya Vijayan [vijayan.jaya@mayo.edu](mailto:vijayan.jaya@mayo.edu), or Kevin Slane [KJS4@columbia.edu](mailto:KJS4@columbia.edu) with any questions.



The MOST Pharmacy Update Webinar on Monday, September 30 from 2-3PM ET.

Location: <https://nihstrokenet.adobeconnect.com/trials/>

**Pharmacy personnel who attend will satisfy their study-required training on the protocol amendment and will not need to complete a pharmacy training quiz at a later time.** PIs and Coordinators are invited but not required to attend. Updated protocol training will be released after the Pharmacy webinar. The webinar recording and the slide set will be available at: <http://nihstrokenet.org/most/most>

We have 14 sites approved on the protocol amendment for v3.1! Thank you to those teams who are working hard to reconcile regulatory documents in WebDCU™. We look forward to activating our first sites in October.

The webinar recording and the slide set will be available at: <http://nihstrokenet.org/most/most>



ASPIRE currently has 16 CTAs fully executed, and one site cIRB approved.

Congratulations to Maimonides Medical Center to be the first site to have a fully executed CTA and cIRB approval!



The I-ACQUIRE Team is excited to announce that enrollment is scheduled to open in mid-October. Sites continue to work hard to complete all training and certification processes by or before mid-October. Sites should be on the lookout for training dates for WebDCU webinar tutorials.

Congratulations to the following Clinical Performing Site (CPS) for having CIRB approval:

- Chicago, IL - Ann & Robert H. Lurie Children's Hospital of Chicago
- Cincinnati, OH - Cincinnati Children's Hospital Medical Center
- Columbus, OH - OSU Martha Morehouse Medical Plaza
- Houston, TX - Memorial Hermann-Texas Medical Center - Children's Memorial Hermann Hospital
- New Haven, CT - Yale New Haven Health Yale New Haven Children's Hospital
- Philadelphia, PA – The Children's Hospital Of Philadelphia (CHOP)
- Roanoke, VA - Fralin Biomedical Research Institute

Reminder the next I-ACQUIRE PI/Co-I/Coordinator Webinar is scheduled for **Wednesday 23 October 2019 at 12:00PM EDT**

## What's New in the WebDCU™?

The WebDCU™ has programmed a new email to be sent to trial sites when an invoice has been paid. This will be sent to all users in the 'Site Financial Manager' group. The email will include the invoice ID and the site name. If anyone at your site would like to receive this email, the trial Primary Study Coordinator can add people to the Site Financial Manager user group in WebDCU™. The NCC will no longer be sending emails with study invoices attached.

## PI? MPI? Co-PI? Co-I?

Help!! What's the difference between a PD/PI, Multiple PI, a Co-PI, a Co-Investigator????

**PD/PI:** When an individual has full responsibility & authority for the project.

**Multiple PI:** When there is more than one PD/PI with equal responsibility and authority for the project. NIH does not use the term Co-PI.

**Co-I:** Co-Investigators make significant contributions, but do not have overall responsibility and authority for the project. They are NOT considered PD/PIs.

## CIRB and Regulatory Update

Currently, per the StrokeNet Central IRB (cIRB) Reliance Agreement, your individual institution ensures that investigators and staff are qualified to work on studies and that financial conflicts of interest (fCOI) are identified and managed. The cIRB then verifies this information for all listed investigators at a given clinical site during its review of a specific clinical trial.

As of September 1, 2019, the cIRB will only perform these verifications for the Site Principal Investigator(s) at each of your sites for a given trial.

Site Principal Investigators should continue to submit documentation of relevant trainings and the StrokeNet study-specific fCOI forms with initial trial submissions, within 30 days of any change, site PI change modifications (when applicable), and annual continuing reviews.

Any fCOIs listing a positive disclosure for a given StrokeNet trial identified by your institution for other investigators or staff must still be submitted to the cIRB along with the locally approved management plans for the cIRB's records.

For NCC requirements, all trial clinical performance sites should have the Research Staff fCOI forms completed for each study team member. These forms must be available for review by monitoring staff either as electronic documents or as a paper document as part of your onsite documents and/or files.

The fCOI cIRB review process is described in the attached StrokeNet SOP ADM 02 *Reporting Conflict of Interest and Financial Disclosures*. The final signed version will be posted on the NIH StrokeNet website.

## 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-October 2019, at 12 noon ET**. Teleconference details: 1-877-621-0220, passcode 434578.

## Coordinator Webinar

*Coordinator Webinars are a requirement for the NIH StrokeNet RCC Coordinators/Managers*

The next Coordinator webinar is TBD.

## Professional Development Webinar

*Professional Development Webinars are a requirement for the NIH StrokeNet Trainees*

**Thursday, October 17, 2019 - 12:00 PM ET**

Topic: How to Give an Effective Scientific Presentation

Presenters: Farhaan Vahidy, MD, PhD, University of Texas, Houston

Moderator: N/A

To join the meeting: <https://nihstrokenet.adobeconnect.com/pdw/>. Please enter as a guest, then your email address or your first and last name.

To take part in the conversation you MUST dial in. 1 (877) 621-0220 Passcode: 190825

## Grand Rounds

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

**Thursday, October 24, 2019 - 4:00 PM ET**

Topic: Are Mobile Stroke Units Useful and Financially Viable?

Presenters: Andrei Alexandrov, MD, University of Tennessee Health Science Center

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

To join the meeting: <https://nihstrokenet.adobeconnect.com/grandrounds/>. Please enter as a guest, then your email address or your first and last name.

To take part in the conversation you MUST dial in. 1 (877) 621-0220 Passcode: 190825

## StrokeNet Meeting Information

**Tuesday, 29-October**, Atlanta, Georgia.

The NCC will reimburse two people from each RCC one-night room and tax only. RCC Network Manager, please send hotel receipts to Rose after the meeting. Include appropriate address to send reimbursement.

# 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 · NIH StrokeNet Coordinating Center · [frasurjs@ucmail.uc.edu](mailto:frasurjs@ucmail.uc.edu) ·  
513-558-1742  
<https://www.nihstrokenet.org>*