

Monthly Update

3-April 2018



REMINDER!

Monthly Coordinator Call

The next coordinator call is scheduled for **Thursday, April 19th 10:30am.**

Neuro Teleconference Line:

USA Toll-Free: (877) 848-7030

Access Code: 3386580

Enrollment Update

- **CREST 2** – 981/2480
- **Arcadia** – 2/1100 randomized; 18/4400 consented/not randomized
- **CREST-H** – 1/500

ARCADIA

Many readiness call need to be schedule.

Monthly webinars will begin for site investigators and coordinators. These will be held on the 4th Tuesday or every month at 2pm ET beginning 4/24.

HOTLINE: 1-877-427-2234

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

Trial Proposal Status:

- **DEFUSE 3 Closeout – Greg Albers**

Dr. Albers communicated that they have finished the final FDA report. There are currently 10 sub-studies in process, with two having been submitted (Marks and Lansberg). They are working with the DAWN trial on a HERMES like analysis.

- **Telerehabilitation in Patients with Stroke Closeout – Joe Broderick for Steve Cramer**

Dr. Broderick reported that the study continues to collect the equipment from sites and work on closing out the study. The goal is to present results at the ESOC in May, if they can finalize the data in time for that meeting. Dr. Broderick thanked everyone for their work on the trial.

- **MOST update – Ope Adeoye**

Dr. Adeoye said that preparations continue with the NCC and NDMC. Once they have an award, they can begin the contracting process. The goal for first enrollment is fall. The DSMB meeting is 22-March.

- **Sleep Smart update – Devin Brown**

Dr. Brown reported that the CIRB was reviewing their submission today. They are being reviewed by the DSMB next Thursday, along with MOST. Dr. Brown indicated that they are finalizing their sites, and if a site has enthusiasm for the study, coordinator availability and a respiratory therapist, they should contact her as soon as possible.

- **TRANSPORT 2 update – Wayne Feng/Gottfried Schlaug**

Dr. Schlaug reported that they are finalizing their sites, as well. They have identified 15 sites who have enthusiasm and the required equipment (equipment is not supplied, so sites must already have it), however, they will email the RCCs to see if there are other sites who would qualify and are interested. Their budget has been reduced to nine sites, so this will require their attention.

- **Trial Proposals status**

These proposals will be reviewed on 13-April:

- CAPTIVA
- FURRThER
- IWITNESS
- PRELIMBS
- SATURN
- TEMPO EMS

| Project Name | Protocol PI | Prevention/ Acute/Recovery | Status Update |
|----------------------------|---|---------------------------------------|--|
| TRANSPORT 2 | Wayne Feng, Gottfried Schlaug | Recovery | Approved for funding by Council February 2018 |
| CAPTIVA (CRISIS) | Brian Hoh | Prevention | October 2017 submission April 2018 study section |
| FURRTHER | Bernadette Boden-Albala | Prevention | October 2017 submission April 2018 study section |
| I-WITNESS | Lee Schwamm, Ona Wu, Steve Warach, Larry Latour, Shlee Song | Acute | November 2017 resubmission April 2018 study section |
| PreLIMBS II | Sebastian Koch, Nestor Gonzalez, Neeraj Chaudhary | Acute | November 2017 resubmission April 2018 study section |
| SATURN | Magdy Selim | Prevention | November 2017 submission April 2018 study section |
| Tempo-EMS | Nerses Sanossian, William Meurer, Jeffrey Saver, David Hess | Acute | November 2017 resubmission April 2018 study section |
| IACQUIRE (formerly IRIIS) | Warren Lo, Sharon Ramey | Recovery | March 2018 resubmission |
| FASTEST | Joe Broderick, Jim Grotto, Jordan Elm | Acute | June 2018 submission |
| ASPIRE (formerly SCORPION) | Kevin Sheth | Prevention | March 2018 resubmission |
| 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 |
|----------------------------------|--|-------------------------------|--|
| ARCADIA -CSI | George Howard, PhD Maarten Lansberg, MD/PhD Ronald Lazar, PhD Kevin N. Sheth, MD David Tirschwell, MD | Acute | June 2018 submission |
| IMPACT | Andrew Naidech | Acute | July 2018 submission |
| VERITAS II | Sepideh Amin-Hanjani | Prevention | July 2018 submission |
| 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 |
| SPLIT | Andrew Naidech | Prevention | In concept development |
| FOCAS | Heather Fullerton, Mitch Elkind | Prevention | In concept development |

| Project Name | Protocol PI | Prevention/ Acute/Recovery | Status Update |
|--|---|-------------------------------|---|
| 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 |
| Classen | Jan Classen | 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. |
| SCOUT | Sandeep P. Khot, Martha E. Billings | Recovery | In concept development |
| ARCADIA ORACLE | Babak Navid, MD, MS | Prevention | In concept development |
| CIAT RCT | Jerzy Szaflarski, MD | Recovery | In concept development |
| TACOCAT | Brett Cucchiaria, MD Scott Kasner, MD | Prevention | In concept development |
| CASH | Adnan Qureshi | Acute | In concept development |
| RISIS | Julius Fridriksson, 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 |
| ASSIST | David F. Kallmes, (Radiology) Alejandro Rabinstein, (Neurology) | Acute | In concept development |

| Project Name | Protocol PI | Prevention/ Acute/Recovery | Status Update |
|---|---|-------------------------------|---|
| | Jeffrey Pasternak, (Anesthesiology) Rickey Carter, (Biostatistics) | | |
| ARREST | Robert Brown, James Torner, David Hasan | Prevention | Decided not to submit 2-November 2017 section Pending Summary statement |
| 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. |
| ICTuS 3 | Pat Lyden | Acute | Indefinite hold. |
| NORRIS | Walter Kernan | Prevention | Not approved to move forward at this time. |

| Project Name | Protocol PI | Prevention/ Acute/Recovery | Status Update |
|--------------------|-------------------------|-------------------------------|--|
| 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 |



Biweekly Update 30-March 2018

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

StrokeNet Enrollment Update

CREST 2 – **981/2480**

CREST H – **1/500**

ARCADIA – **2/1100 randomized; 18/4400 consented**

StrokeNet Trial Updates



Congratulations to the team at University of Minnesota for randomizing the **second** ARCADIA patient!

A total of 18 subjects have been consented in the trial. Two subjects have been randomized and 4 more subjects are “eligible for randomization” so hopefully our numbers will be increasing very soon.

We need to schedule many readiness calls, so if we have requested your availability for a call, please respond to Daniel Velez dav2125@cumc.columbia.edu as soon as possible.

We are excited to see the trial moving forward and ask that you encourage your sites to continue working on their study start-up documents.

We will begin to have monthly ARCADIA webinars for all ARCADIA Site Investigators and coordinators. The Webinars will be held on the 4th Tuesday of every month at 2pm (ET) beginning on April 24th. We will send out more details soon. Please encourage your teams to participate.

As a reminder:

Call the ARCADIA Hotline @ **1-877-427-2234** for Eligibility questions or urgent clinical questions

Call the WebDCU™ Emergency Randomization Hotline @ **1-877-427-2234** for WebDCU™ Randomization issues

For other ARCADIA questions contact Irene Ewing the ARCADIA Project manager at irene.ewing@uc.edu

Thank you for all efforts on the ARCADIA Trial!



One new site greenlighted!



UPMC has been greenlighted for CREST-H enrollment. Several other sites are nearly there, including Houston Methodist, U Washington, Puget Sound VA, Mayo Clinic Rochester, and Overlake Hospital. Please keep moving ahead with your regulatory documents and test images. We are looking forward to ramping up enrollment over the next several weeks. Remember, **site reimbursement has increased to help with costs**. Thanks to all PI's and coordinators for all their hard work!



981 randomizations (495 CEA; 486 CAS)

1-March to present: 32 (24 CEA; 8 CAS)

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 **11-April, 2018 at 12 noon ET**. There will be a proposed trial webinar presentation:

Presentation: ARCADIA Cognition and Silent Infarcts (ARCADIA – CSI)

PI Presenter: **Maarten Lansberg, MD, PhD** – Stanford University Medical Center

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

To take part in the audio you must dial-in to: (877) 621-0220 Passcode: 434578

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.

WebDCU™ Regulatory Document Changes

To all Site Managers/Coordinators and Regulatory Document Coordinators – Please disregard any *new* regulatory document requirements that have populated in WebDCU™ until you receive further instructions. We are in the process of updating the database. Thank you!

NIH StrokeNet RPPR Information

RCCs will need to submit a Final-RPPR (Progress Report) no later than 120 calendar days *after* the period of performance end date (which is 7/31/2018). Earlier in the window is preferred for centers that will receive an award as an RCC for the 2nd cycle of NIH StrokeNet. Your Sponsored Research Office will work with you to complete the RPPR. All signing officials are aware of the timing/process. Please visit the links below for information and FAQs.

<https://grants.nih.gov/grants/rppr/index.htm>

FINAL RPPR (Section I) <https://grants.nih.gov/grants/rppr/faqs.htm>

NIH Research Methods Resources

The Research Methods Resources website provides investigators with important research methods to satisfy new application requirements. The NIH launched initiatives in 2017 and 2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the entire clinical trial lifecycle, from concept to results reporting.

Please visit the link below for helpful information and updated resources regarding clinical trial requirements, review criteria, etc. from the revised application guide for new applications in 2018.

<https://researchmethodsresources.nih.gov>

Coordinator Webinar

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

Topic: Trial Role Out with new Satellites, Best Practices

Moderator: **Devin Qualls**, Massachusetts General; **Heena Olalde**, University of Iowa; **Kinga Aitken**, University of Utah

When: **Wednesday, April 25, 2018 – 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:

2:00 pm: Identification of Biomarkers in Normotensive and Hypertensive Rats after Ischemic Stroke – **Ignatius Esene, PhD, University of Wisconsin**

2:30 pm: Difference in Culprit Plaque Characteristics and Locations between US and Chinese Stroke Patients: An in Vivo Study by Vessel Wall Magnetic Resonance Imaging – **Hiroko Watase, MD, University of Washington**

3:00 pm: Motor Behavior Pre-recovery: Single Joint and Multi Joint Control and Upper Extremity Use – **Jessica Barth, OTR/L, Medstar Research Institute**

When: **Monday, April 23, 2018 - 2:00 PM ET**

Moderator: David Liebeskind, MD, UCLA

Grand Rounds

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

Presentations: Post Stroke Depression - **Pam Mitchell, PhD, University of Washington**

When: **Thursday, April 26, 2018 - 4:00 PM ET**

Moderator: Shyam Prabhakaran, MD, Northwestern 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

StrokeNet CIRB Corner

61 ARCADIA performing sites have been submitted to the CIRB, and 48 of those have CIRB approval. Way to Go!

Please do not edit the questions or response options on the CIRB forms. Our forms are designed to meet the requirements of the electronic Protocol Administration System and provide what the reviewer's need to know regarding the sites. Therefore, the options provided on the forms for answers to the questions (such as yes or no) are the only choices that can be entered. When the form is modified by someone other than the CIRB, the answer options can have a great impact on completion in the electronic system, as well as the intent of the question and how it is viewed by anyone reviewing, monitoring, or auditing the site's information provided to the CIRB. If you have questions about how to respond to a question on a form, please feel free to contact the CIRB Liaison. Thank you for your cooperation.

StrokeNet Network Meetings and Important Info

16-October 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 from each RCC one night room and tax, up to \$250. Below is the reservation link which offers Congress rates. Please RSVP by **31-July**. The room

size is set, and we will not accommodate more than 5 people per RCC. There will be no Working Group or Training Core breakout sessions.

Venue:

Palais des Congrès
301 Saint-Antoine West (Entrance opposite the Westin Hotel)
Montreal QC
H2Z 1H2

<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 13 th 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/ |
| May 5, 2018 | UCLA Brain Attack! '18 Symposium |

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