

# Monthly Update

16 – May 2019



## REMINDER!

### Monthly Coordinator Call

The coordinator call is scheduled for May, 16<sup>th</sup> at 10.30am

### Enrollment Update (as of 05/10/2019)

- **CREST 2** – 1400/2480
- **ARCADIA** – 211/1100 randomized; 861/4400 consented/not randomized
- **CREST-H** – 68/500

### StrokeNet Trial Updates



ARCADIA

**We've started this race and come from behind – let's not ease up now!**

**Thank you to each site for pushing thru the challenges!**

As of May 9, 2019, ARCADIA has 861 participants consented and 211 randomized. Enrollment is at 19% of the overall enrollment goal of 1,100 participants. This represents an increase of 26 consented patients and 9 randomized patients over the past 2 weeks! Please keep approaching potential subjects and don't lose momentum so that we can make this trial a success!

We truly appreciate the effort made by the 21 sites that have consented subjects in the last 2 weeks! We especially thank the two sites that consented two days in a row – AMAZING JOB Tufts Medical Center, Boston, MA and University of Alabama, Birmingham, AL!

We congratulate the University of Texas Health Science Center San Antonio, San Antonio, TX and University of Miami Hospital, Miami, FL for randomizing their first subjects! Your perseverance has paid off! Kudos also to the 7 veteran sites that randomized in the past two weeks: NYP Weill Cornell Medical Center, New York, NY; MedStar Washington Hospital Center, Washington, DC; Memorial Hermann Texas Medical Center, Houston, TX; University of Minnesota Medical Center Hospital, Minneapolis, MN; University of Utah Healthcare, Salt Lake City, UT; UF Health Shands Hospital, Gainesville, FL and Emory University Hospital, Atlanta, GA. We can't do it without you - great teamwork!!!

The University of Cincinnati Medical Center and United Hospital St. Paul have both randomized 10 subjects! There is still a tie for 2<sup>nd</sup> place between the University of Iowa and OHSU with 9 apiece. Who will unseat the enrolling leaders? Maybe it will be a veteran site or one of the newer sites? These sites are neck-to-neck and we challenge you to be the site that randomizes more than they have!

**ARCADIA is our race to win, let's make a committed effort to be part of its success!**

Our monthly per site randomization rate sits at 0.18 patients per site. We have released to enroll 122 sites, with several more US sites to join the ARCADIA team, including more VA sites almost ready. There are 72 sites that have randomized at least one patient, and 50 waiting to randomize their first; 110 have now consented at least 1 patient, and 12 have not yet consented any (including 6 new sites and 3 sites which are not active).

**Webinar:** Our next PI and coordinator webinar will be May 28th 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 at (<https://nihstrokenet.org/education>).

**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](mailto:Dempsey@neurosurgery.wisc.edu)

#### Co-I

Azam S. Ahmed, MD

Office 608-263-1410

[azam.ahmed@neurosurgery.wisc.edu](mailto:azam.ahmed@neurosurgery.wisc.edu)

### Clinical Research Manager

Stephanie M. Wilbrand, PhD

Office 608.265.9248

[wilbrand@neurosurgery.wisc.edu](mailto:wilbrand@neurosurgery.wisc.edu)

### Research Coordinator

Stephanie Armstrong, MS

Office 608.262-6493

[armstrong@neurosurgery.wisc.edu](mailto:armstrong@neurosurgery.wisc.edu)

### Research Coordinator

Glennie Mihalovic

Office 608.262-7481


[mihalovic@neurosurgery.wisc.edu](mailto:mihalovic@neurosurgery.wisc.edu)

FAX 608.263.1728

# Monthly Update

16-May 2019

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

| <br>CREST-2 | CREST-2      |             | CREST-2 StrokeNet |
|--|--------------|-------------|-------------------|
|  | CEA          | 735         | 265               |
|  | CAS          | 665         | 98                |
|  | <b>Total</b> | <b>1400</b> | <b>363</b>        |

**Recruitment:** CREST-2 ended April with 30 randomizations and we have 6 so far in May! We would like to highlight the **StrokeNet** sites: **The University of Chicago, Columbia University, and University Hospitals Cleveland Medical Center**, for randomizing since the last CREST-2 update!

If you haven't already done so, follow us on our **social media** accounts for updates on recruitment:



**May is Stroke Awareness Month!** : As most of you know, May is Stroke Awareness month! Check to see if your community may be holding any booth events. This effort can lead to **possible enrollments**! If you need any CREST-2 resources, please reach out to Kassondra.

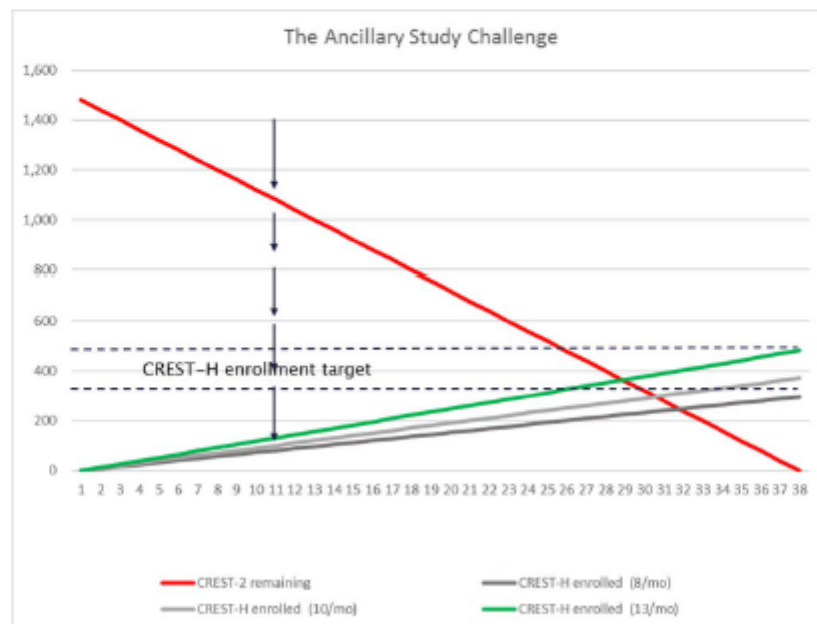
Guzman.Kassondra@mayo.edu

**Site Startup and Enrollment Updates:** sites: 45; enrollments: 68

Welcome St Boniface Hospital and Inova Fairfax!

**The Ancillary Study Challenge: Keep up with enrollments in the Parent Trial.** CREST-2 has just over 1,000 patients left to recruit (red line below). We had 8 CREST-H patients recruited in April, and 5 in May so far for a total of 68, so we need to recruit at least 10 per month to meet our enrollment targets. Please help us get there!

Remember to submit your test images for CT perfusion so CT can be used as a backup for MRP. Having CTP available as a backup will allow you to capture all potential CREST-H patients! Thanks.



If you are interested in becoming a CREST-H site, contact Randy Marshall [rsm2@columbia.edu](mailto:rsm2@columbia.edu), Ron Lazar [rlazar@uabmc.edu](mailto:rlazar@uabmc.edu), or coordinators Jaya Vijayan [vijayan.jaya@mayo.edu](mailto:vijayan.jaya@mayo.edu), or Kevin Slane [KJS4@columbia.edu](mailto:KJS4@columbia.edu) with any questions. Thanks!



TRANSPORT2

There will NOT be a PI and Coordinator call on Monday, May 13.

We would like to congratulate the University of Alabama for completing their CTA last week!  
Our count is now 12 sites with fully executed CTAs - **100%, yay!**

A huge thanks to all sites for working hard on their CIRB submissions. The following sites have been approved by the CIRB:

- MUSC
- Burke
- University of Kentucky
- Texas Medical Center
- Barnes Jewish Hospital
- MedStar
- University of Alabama
- USC Keck

Kelly will be reaching out to your site to schedule Readiness Calls. The Readiness call takes place of an in-person site initiation visit and will last about an hour. The PI and coordinator are required to be on the call, but we welcome anyone to join in on the call and ask questions.

Please reach out to your Regulatory Specialist to confirm that you have uploaded all of the necessary people documents.

Reminder to start identifying potential Training Subjects once you submit for CIRB approval. Don't forget to have the study coordinator to monitor the video recording process to ensure all movements are captured.

Thank you for your continued hard work to get TRANSPORT2 up and running!



I-ACQUIRE

We had an information packed I-ACQUIRE Investigator Meeting (IM) on Wednesday, May 1, 2019 at the Hilton Chicago O'Hare Airport. Thank you to all for your active engagement! We will have the protocol training slides from the meeting available on the WebDCU™ Training Center site soon... <https://webdcu.musc.edu/campus/>

Two people from each site who attended the Investigator Meeting will be reimbursed by their institution for their travel. Please keep your receipts in the event your institution requires them for reimbursement. Payment to your institution to facilitate reimbursements will be made first to those sites who have fully executed the CTA. For those sites who have yet to submit a signed CTA for full execution, please do so as expeditiously as possible so that reimbursement for attendance at the IM can be processed accordingly.

We are excited to announce the final clinical performance site who will be participating in the I-ACQUIRE Study:

- The Center for Advanced Pediatrics at Children's, Atlanta, GA

Our first PI and Coordinator Webinar is scheduled for Monday, 20 May 2019 at 2:00PM EST. This is the beginning of our monthly contact. For those who cannot join, the session will be recorded and available on the StrokeNet website. This was one of the two "best" times and we will also discuss rotating the monthly session in terms of days and times – and hope to have a definite schedule for our monthly calls established by June.

Update: the latter part of next week, clinical performance sites PI and PSC should receive a WebDCU™ access email so that work can begin in the regulatory database (submission of DOA and uploading of regulatory documents). We hope to be able to send you the approved protocol and ICDs late next week pending CIRB approval of an amendment so as to complete the regulatory packet documents. Thank you for your patience as we work through the processes.





The MOST team would like to thank all that were able to attend the Investigator Meeting (IM). We are extremely pleased with the level of engagement displayed. We also appreciate those who took the time to join us via WebEx.

The IM slides are posted in WebDCU™ under MOST/Toolbox/Project Documents. A Questions and Answers (Q&A) document from the IM is being drafted and will be posted in the Project Documents folder soon.

Training modules from the IM will be posted on the WebDCU™ Training Center site at: <https://webdcu.musc.edu/campus/>

Congratulations to the following sites for obtaining CIRB approval:

- Greenville Hospital System, Greenville, SC
- Loyola University Medical Center, Maywood, IL
- University of Michigan University Hospital, Ann Arbor, MI
- Barnes Jewish Hospital, St. Louis, MO
- North Shore University Hospital, Manhasset, NY
- University of New Mexico Hospital, Albuquerque, NM
- UPMC Presbyterian Hospital, Pittsburgh, PA
- Harborview Medical Center, Seattle, WA
- Temple University Hospital, Philadelphia, PA
- Wake Forest Baptist Medical Center, Winston-Salem, NC



**We are excited to say that our first site was released to enroll on May 9, 2019! Congratulations to UCSD Health La Jolla, La Jolla, CA!!**

Another milestone that we would like to achieve is to have 30 sites ready to enroll by the end of May and we are well on our way to meeting this milestone.

Congratulations to the following sites for having CIRB approval:

1. UCSD Medical Center-Hillcrest Hospital, San Diego, CA
2. Palmetto Health Richland, Columbia SC
3. UVA Medical Center, Charlottesville, VA
4. NYU Langone-Tish Hospital Medical Center, New York, NY
5. University of Illinois Hospital and Health Sciences System, Chicago, IL
6. Hoag Memorial Hospital Presbyterian, Newport Beach, CA
7. Mercy Health St. Mary's, Grand Rapids, MI
8. UPMC Presbyterian Hospital, Pittsburgh, PA
9. Memorial Hermann Texas Medical Center, Houston, TX
10. Harborview Medical Center, Seattle, WA
11. Novant Health Presbyterian Medical Center, Charlotte, NC

If we haven't already scheduled your site readiness call, and all of your Sleep SMART agreements are executed, we will be reaching out to your site in the very near future to get this scheduled.

Twenty-two additional sites have submitted to the CIRB and are awaiting approval. We encourage all other sites to work with the NCC Regulatory Compliance Specialists, Emily Stinson and Jennifer Golan, to complete the documents needed for CIRB submission and local IRB acknowledgement.

If your site has not yet completed the clinical trial agreement (CTA) and/or FusionHealth consignment agreement or DUA please continue to work diligently with your contracts/legal teams to get them finalized. All of these will need to be finalized before your site can be released to enroll.

## Reverse-to-Lyse Registry Opportunity!

The not-for-profit Hospital Quality Foundation (HQF) is collaborating with Boehringer Ingelheim to build an observational database of US and Canadian patients who have been managed with a "reverse-to-lyse" strategy. Eligible patients will have presented with an AIS despite dabigatran therapy, and are then given idarucizumab followed by rt-PA. Patients that go on to thrombectomy or other intervention after lysis are also eligible, but lysis after reversal must be the titillating treatment. Patients may be encountered prospectively but can also be entered non-prospectively, if they were treated after the pertinent institution added PRAXBIND to formulary. There is limited capacity for participating sites, so preference will be given to sites with an established record of using the reverse-to-lyse pathway. Data entry for the study is quite limited (in-hospital only) and includes no PHI; the study ("RE-VERSED AIS") has been approved by WIRB with waiver of consent and HIPAA. Interested sites should reach out to HQF at [re.versed.ais.hqf@gmail.com](mailto:re.versed.ais.hqf@gmail.com) to received more information.

## StrokeNet Meetings/Webinars

### Fall Network Meeting:

**Tuesday, 29-October, Atlanta, Georgia.** Meeting details will be forthcoming, but please **SAVE THE DATE!!!**

## Professional Development Webinar

*Professional Development webinars are a requirement for the NIH StrokeNet Trainees, however all are welcome to participate.*

**When: Wednesday, May 15, 2019 - 1:00 PM ET**

**Presentations: Validity of the Stroke Mimic Score in Bedside Stroke Code Evaluations  
Julian Duda, MD, UCSD**

Quantification and Optimization of Intraprocedural Time in Cerebral Endovascular Thrombectomy  
**Mariya Gusman, MD, Washington University**

Pilot study of induced hypertension for minimizing infarct progression in patients with acute large vessel occlusion ischemic stroke undergoing endovascular therapy  
**Nils Peterson, Yale University**

**Moderator: Shyam Prabhakaran, MD, University of Chicago**

- Trial Proposals status

| Project Name | Protocol PI  | Prevention/<br>Acute/Recovery | Status Update  |
|--------------|--|-------------------------------|--|
| PAST-TIME    | Jason McMullan, Opeolu Adeoye,<br>Nerses Sanossian | Acute                         | Review comments received; teams<br>planning next steps |

| Project Name | Protocol PI  | Prevention/<br>Acute/Recovery | Status Update   |
|--------------|--|-------------------------------|---|
| IMPACT       | Andrew Naidech   | Acute                         | Review comments received; teams planning next steps   |
| VERiTAS II   | Sepideh Amin-Hanjani   | Prevention                    | Review comments received; teams planning next steps   |
| SPLASH       | Jose Suarez, DaiWai Olson (contact PI)                                 | Acute                         | October 2018 submission<br>Study section review on 1-March, 2019<br>Waiting on summary statement    |
| CAPTIVA      | Brian Hoh, PI, Marc Chimowitz, Co-I                                    | Prevention                    | November 2018 resubmission<br>Study section review on 1-March, 2019<br>Waiting on summary statement |
| FURRTHER     | Bernadette Boden-Albala  | Prevention                    | November 2018 resubmission<br>Study section review on 1-March, 2019<br>Waiting on summary statement |
| ALISAH 2     | Jose Suarez  | Acute                         | February 2019 submission  |
| PreLIMBS II  | Sebastian Koch, Nestor Gonzalez, Neeraj Chaudhary                      | Acute                         | February 2019 resubmission  |
| TEST OF TIME | Schwamm, Wu, Urrutia, Barreto, Song, Warach                            | Acute                         | June 2019 submission  |
| PETITE       | Greg Albers  | Acute                         | June 2019 submission  |
| eBOOST       | Julius Fridriksson, Chris Rorden, Leo Bonilha, Jordan Elm, Mark George | Recovery                      | June 2019 submission  |
| IMAGING U    | David Hasan, Edgar Samaniego   | Prevention                    | June 2019 submission  |
| ERSIAS       | Nestor Gonzalez, Jeff Saver  | Prevention                    | June 2019 submission  |

| Project Name                         | Protocol PI   | Prevention/<br>Acute/Recovery | Status Update           |
|--------------------------------------|---|-------------------------------|-------------------------|
| COAST (CASH)                         | Adnan Qureshi   | Acute                         | June 2019 submission    |
| STEP-STONE                           | C. Meinzer, C. Derdeyn, P. Khatri                                     | Acute                         | October 2019 submission |
| FOCAS                                | Heather Fullerton, Mitch Elkind                                       | Prevention                    | In concept development  |
| TEACH2                               | Babak Navi, Scott Kasner, Mary Cushman, Mitch Elkind                  | Prevention                    | In concept development  |
| VERIFY                               | Pooja Khatri, Steve Cramer, Cathy Sinear, Achala Vagal                | Recovery                      | 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  |
| COAT<br>(TACOCAT)                    | Brett Cucchiara, Scott Kasner   | Prevention                    | In concept development  |
| SCOUTS<br>(ancillary to Sleep Smart) | Sandeep P. Khot,<br>Martha E. Billings                                | Recovery                      | In concept development  |
| Durand                               | Matthew Durand<br>Robert Dempsey<br>Allison Hyngstrom<br>John McGuire | Recovery                      | In concept development  |
| BLAST                                | James Meschia   | Prevention                    | In concept development  |



| Project Name                            | Protocol PI  | Prevention/<br>Acute/Recovery | Status Update                |
|---|--|-------------------------------|------------------------------|
| CAVIS                                   | Mark Harrigan  | Prevention                    | In concept development       |
| SPLIT                                   | Andrew Naidech   | Prevention                    | In concept development       |
| START                                   | Steve Warach, Truman Milling   | Prevention                    | In concept development       |
| ICAS                                    | David Hasan  | Prevention                    | In concept development       |
| Emokpae                                 | Lloyd Emokpae, Roland Emokpae,<br>Nelson Emokpae<br>(LASARRUS Clinic and Research Center)  | Recovery                      | In concept development       |
| PERFUSE-ICAS                            | S. Yaghi, P. Khatri, D. Liebeskind, S.<br>Prabhakaran  | Acute                         | In concept development       |
| SIMVICH                                 | C. Chen, A. Southerland, K. Johnston, B.<br>Worrall, N. Naval, D. Ding   | Acute                         | In concept development       |
| SCORE                                   | David Hasan  | Acute                         | In concept development       |
| URIC                                    | Enrique Leira  | Acute                         | SPAN Initiative              |
| MATRICES                                | Maarten Lansberg, Greg Albers, Albert<br>Yoo, Sam Zaidat   | Acute                         | On hold for EVT Platform     |
| ETHER                                   | Stephan Mayer  | Acute                         | On hold for EVT Platform     |
| SERENE<br>(ASSIST +<br>SEACOAST)        | Radoslav Raychev, Dimiter Arnaudov,<br>David F. Kallmes, (Radiology)<br>Alejandro Rabinstein, (Neurology)<br>Jeffrey Pasternak, (Anesthesiology)<br>Rickey Carter, (Biostatistics) | Acute                         | On hold for EVT platform     |
| HEMERA                                  | Italo Linfante, Raul Nogueira  | Acute                         | On hold for EVT platform     |
| NEPTUNE<br>(ARCADIA<br>ancillary study) | Ajay Gupta, Hooman Kamel   | Prevention                    | In concept development       |
| ARCADIA<br>ORACLE                       | Babak Navi   | Prevention                    | Hold ARCADIA ancillary study |

| Project Name | Protocol PI                  | Prevention/<br>Acute/Recovery | Status Update   |
|--------------|------------------------------|-------------------------------|---|
| RAFT         | Truman Milling, Steve Warach | Acute                         | In concept development; gathering preliminary data for a future application |



## Biweekly Update 10-May 2019

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

### StrokeNet Enrollment Update

CREST 2 – 1400/2480

CREST H – 68/500

ARCADIA –211/1100 randomized; 861/4400 consented

## Reverse-to-Lyse Registry Opportunity!

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## StrokeNet Meetings/Webinars

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## 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 **12-June, 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*

**When:** Wednesday, May 22, 2019 - 1:30 PM ET

**Presentation:** Fast Tracking the CTA Process – Let's Brainstorm!  
**Karen Rapp**, University of California at San Diego

Insight on How to Expedite the Approval Process for Both CTA and Local Review Boards  
**Chad Tremont**, University of Texas at Houston

**Moderator:** Dave Haney, Case Western Reserve University

To join the meeting: <https://nihstroketnet.adobeconnect.com/coordinator/>. 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: 434578

## Professional Development Webinar

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**When:** Wednesday, May 15, 2019 - 1:00 PM ET

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**Julian Duda, MD**, UCSD

Quantification and Optimization of Intraprocedural Time in Cerebral Endovascular Thrombectomy  
**Mariya Gusman, MD**, Washington University

Pilot study of induced hypertension for minimizing infarct progression in patients with acute large vessel occlusion ischemic stroke undergoing endovascular therapy  
**Nils Peterson**, Yale University

**Moderator:** Shyam Prabhakaran, MD, University of Chicago

## Grand Rounds

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

**When:** Thursday, May 30, 2019 - 4:00 PM ET

**Presentation:** Translational Research: Inflammation and Post-stroke Cognitive Decline  
**Marion Buckwalter, MD, PhD**, Stanford University

**Moderator:** Randy Marshall, MD, Columbia University

To join the meeting: <https://nihstroketnet.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

## Seminars and Conferences

### 2nd Annual Aspen Conference on Pediatric Cerebrovascular Disease and Stroke

July 15-19, 2019

Viceroy Snowmass Hotel  
Snowmass Village  
Aspen Colorado

Online registration for this conference is required.

Please visit <http://www.cincinnatichildrens.org/AspenNeuro> to register

## StrokeNet Employment Opportunities

For more information on additional StrokeNet employment opportunities, please visit:  
<http://www.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>