REMINDER!

Monthly Coordinator Call

The next coordinator call is scheduled for Thursday, October 18th 10:30am.

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

Enrollment Update (as of 09/28/2018)

- CREST 2 – 1163/2480
- ARCADIA – 96/1100 randomized; 347/4400 consented/not randomized
- CREST-H – 15/500

StrokeNet Trial Updates

As of September 27, 347 patients have been consented and 96 randomized (~9% of the target of 1100!). This represents an increase of 12 patients over the past 2 weeks since the last update. September represents our best month yet.

<table>
<thead>
<tr>
<th>Month</th>
<th>Patients Randomized</th>
<th>Patients Consented</th>
<th>Patients Not Randomized</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2018</td>
<td>8</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>April</td>
<td>11</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>May</td>
<td>19</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>June</td>
<td>17</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>July</td>
<td>19</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>August</td>
<td>19</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>September (through Sept 27)</td>
<td>20</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>96</td>
<td>20</td>
<td>72</td>
</tr>
</tbody>
</table>

The University of Iowa in Iowa City, IA remains in the lead for randomizations, with St. United Hospital in St. Paul MN, remaining close behind with 8 patients, and Oregon Health and Science University (OHSU) Hospital in Portland, OR is still just one back with 7. All told, 41 sites have randomized at least one patient, and 72 have consented for screening at least one patient. We continue to make progress on all these measures. Congratulations and thanks to all these sites for doing such a great job!

Sites that have not enrolled anyone in 3 months have been getting emails and calls from us to see if there are fixable reasons for this. Soon we will be asking for sites to do retraining as needed, and we may be reaching out for follow up training calls soon. We want everyone to succeed in this trial!

We look forward to providing more details and seeing the RCC teams in Montreal in October!

-- The ARCADIA National Team

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

We had 2 more site green lighted in the last 2 weeks, bringing our total to 30 sites and 15 patients enrolled. Welcome to Vancouver General Hospital and Weill Cornell. There are 32 more sites still in the pipeline to be green lighted and we will be pursuing more. UPMC is still leading recruitment with 4 enrollments, followed by UIowa with 3 and Michigan Vascular with 2. Fastest out of the gate was Gundersen Health, enrolling their first patient on the day they were green lighted!

Additional news reminder:
1. CIRB has now approved CT perfusion as an option in addition to MRI perfusion. This will permit more patients to be enrolled and give sites an additional option to work with.
2. Site reimbursement has increased by 30%, and patient remuneration higher as well, allowing more sites and patients to participate.

If you have an active CREST-2 site in your RCC that is not yet enrolling in CREST-H, let us know. Contact Randy Marshall rsm2@columbia.edu, Jaya Vijayan vijayan.jaya@mayo.edu, or Kevin Slane at KJS4@columbia.edu. We are still recruiting additional sites. Thanks!

Grand Rounds

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

Presentation: Perioperative & Periprocedural Stroke – Steven Messe, MD, University of Pennsylvania

When: Thursday, October 25, 2018 - 4:00 PM ET
Moderator: Cemal Sozener, MD, University of Michigan

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
NIH StrokeNet Coordinator Webinar:
When: October 24, 2018 – 1.30pm 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.

Important updates!!!

- Coming up 5 years of NIH StrokeNet
  The first Reliance Agreements have been sent out to sites. Thank you to those who have already returned them fully executed.
  Soon the Master Trial Agreements will be sent out, be on the look out for that.

Trial Proposal Status:

- MOST update – Ope Adeoye
  MOST has received Notice of Award, currently working on completing site selection and regulatory documents.
  Aiming for first enrollment in the Fall.
- Sleep Smart update – Devin Brown
  Notice of Award received, working on completing site selection. Aiming for first enrollment late Fall.

---

Dear Colleagues,
The Sleep SMART Investigator meeting will be held Friday, Feb. 22nd 2019 in Detroit, at the Airport Westin. A reception will be held the evening of Feb. 21st 2019.
Additional details will follow later, but please mark your calendars!
We look forward to working with all of you.

On behalf of the Sleep SMART Team,
Kayla & Joelle
<table>
<thead>
<tr>
<th>Project Name</th>
<th>Protocol PI</th>
<th>Prevention/Acute/Recovery</th>
<th>Status Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>FASTEST</td>
<td>Joe Broderick, Jim Grotto, Jordan Elm</td>
<td>Acute</td>
<td>June 2018 submitted</td>
</tr>
<tr>
<td>PAST-TIME</td>
<td>Jason McMullan, Opeolu Adeoye, Nerses Sanossian</td>
<td>Acute</td>
<td>June 2018 submitted</td>
</tr>
<tr>
<td>ARCADIA -CSI</td>
<td>George Howard, PhD, Maarten Lansberg, MD/PhD, Ronald Lazar, PhD, Kevin N. Sheth, MD, David Tirschwell, MD</td>
<td>Acute</td>
<td>June 2018 submitted</td>
</tr>
<tr>
<td>IMPACT</td>
<td>Andrew Naidech</td>
<td>Acute</td>
<td>July 2018 submission</td>
</tr>
<tr>
<td>VERITAS II</td>
<td>Sepideh Amin-Hanjani</td>
<td>Prevention</td>
<td>July 2018 submission</td>
</tr>
<tr>
<td>IACQUIRE (formerly IRIIS)</td>
<td>Warren Lo, Sharon Ramey</td>
<td>Recovery</td>
<td>August 2018 study section</td>
</tr>
<tr>
<td>ALISAH 2</td>
<td>Jose Suarez</td>
<td>Acute</td>
<td>August 2018 study section</td>
</tr>
<tr>
<td>ASPIRE (formerly SCORPION)</td>
<td>Kevin Sheth</td>
<td>Prevention</td>
<td>August 2018 study section</td>
</tr>
<tr>
<td>SPLASH</td>
<td>Jose Suarez, DaiWai Olson (contact PI)</td>
<td>Acute</td>
<td>October 2018 submission</td>
</tr>
<tr>
<td>CASH</td>
<td>Adnan Qureshi</td>
<td>Acute</td>
<td>October 2018 submission</td>
</tr>
<tr>
<td>I-WITNESS</td>
<td>Lee Schwamm, Ona Wu, Steve Warach, Larry Latour, Shlee Song</td>
<td>Acute</td>
<td>October 2018 resubmission A01</td>
</tr>
<tr>
<td>PreLIMBS II</td>
<td>Sebastian Koch, Nestor Gonzalez, Neeraj Chaudhary</td>
<td>Acute</td>
<td>October 2018 resubmission A01</td>
</tr>
<tr>
<td>Project Name</td>
<td>Protocol PI</td>
<td>Prevention/Acute/Recovery</td>
<td>Status Update</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-----------------------------------------------------</td>
<td>--------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>CAPTIVA (CRISIS)</td>
<td>Brian Hoh</td>
<td>Prevention</td>
<td>November 2018 submission</td>
</tr>
<tr>
<td>FURRThER</td>
<td>Bernadette Boden-Albala</td>
<td>Prevention</td>
<td>November 2018 resubmission</td>
</tr>
<tr>
<td>Tempo-EMS</td>
<td>Nerses Sanossian, William Meurer, Jeffrey Saver, David Hess</td>
<td>Acute</td>
<td>Hold for now</td>
</tr>
<tr>
<td>MATRICS</td>
<td>Maarten Lansberg, Greg Albers, Albert Yoo, Sam Zaidat</td>
<td>Acute</td>
<td>In concept development (no CSP on file)</td>
</tr>
<tr>
<td>DEFUSE TNK</td>
<td>Maarten Lansberg</td>
<td>Acute</td>
<td>In concept development, archive after 1-June 2018</td>
</tr>
<tr>
<td>ETHER</td>
<td>Stephan Mayer</td>
<td>Acute</td>
<td>On hold for EVD platform</td>
</tr>
<tr>
<td>PRECISE MRI-T2</td>
<td>Natalia Rost, Shyam Prabhakaran, Rebecca Gottesman, Clinton Wright</td>
<td>Prevention</td>
<td>In concept development</td>
</tr>
<tr>
<td>NEPTUNE (ARCADIA ancillary study)</td>
<td>Ajay Gupta, Hooman Kamel</td>
<td>Prevention</td>
<td>In concept development</td>
</tr>
<tr>
<td>Claassen</td>
<td>Jan Claassen</td>
<td>Acute</td>
<td>In concept development</td>
</tr>
<tr>
<td>HEMERA</td>
<td>Italo Linfante, Raul Nogueira</td>
<td>Acute</td>
<td>On hold for EVT platform</td>
</tr>
<tr>
<td>ARCADIA ORACLE</td>
<td>Babak Navid, MD, MS</td>
<td>Prevention</td>
<td>Hold ARCADIA ancillary study</td>
</tr>
<tr>
<td>Project Name</td>
<td>Protocol PI</td>
<td>Prevention/Acute/Recovery</td>
<td>Status Update</td>
</tr>
<tr>
<td>------------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>---------------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>CIAT RCT</td>
<td>Jerzy Szaflarski, MD</td>
<td>Recovery</td>
<td>In concept development</td>
</tr>
<tr>
<td>TACOCAT (COAT)</td>
<td>Brett Cucchiaria, MD Scott Kasner, MD</td>
<td>Prevention</td>
<td>In concept development</td>
</tr>
<tr>
<td>SCOUT (Ancillary to Sleep Smart)</td>
<td>Sandeep P. Khot, Martha E. Billings</td>
<td>Recovery</td>
<td>In concept development 25-April 18: Extensive feedback in recent weeks. Now at point where they are connecting that feedback with NIH and with the primary study (Sleep Smart)</td>
</tr>
<tr>
<td>WISC-R</td>
<td>Matthew Durand, Robert Dempsey, Allison Hyngstrom, John McGuire</td>
<td>Recovery</td>
<td>In concept development</td>
</tr>
<tr>
<td>ERSIAS</td>
<td>Nestor Gonzalez, Jeff Saver</td>
<td>Prevention</td>
<td>In concept development</td>
</tr>
<tr>
<td>BLAST</td>
<td>James Meschia</td>
<td>Prevention</td>
<td>In concept development</td>
</tr>
<tr>
<td>FOCAS</td>
<td>Heather Fullerton, Mitch Elkind</td>
<td>Prevention</td>
<td>In concept development</td>
</tr>
<tr>
<td>CAVIS</td>
<td>Mark Harrigan</td>
<td>Prevention</td>
<td>In concept development</td>
</tr>
<tr>
<td>SPLIT</td>
<td>Andrew Naidech</td>
<td>Prevention</td>
<td>In concept development</td>
</tr>
<tr>
<td>RAFT</td>
<td>Truman Milling, Steve Warach</td>
<td>ACUTE</td>
<td>In concept development</td>
</tr>
<tr>
<td>START</td>
<td>Steve Warach, Truman Milling</td>
<td>Prevention</td>
<td>In concept development</td>
</tr>
<tr>
<td>URIC</td>
<td>Enrique Leira</td>
<td>Acute</td>
<td>In concept development</td>
</tr>
<tr>
<td>SUCCESS</td>
<td>E. Sander Connolly Jr., John D. Lambris, Jan Claasen</td>
<td>Acute</td>
<td>In concept development</td>
</tr>
<tr>
<td>BrainPulse</td>
<td>Kyle Walsh, Shakeel Chowdhry, Julian Bailes, Andrew Russman</td>
<td>Acute</td>
<td>In concept development</td>
</tr>
<tr>
<td>Hasan – Intracranial Stenosis</td>
<td>David Hasan</td>
<td>Prevention</td>
<td>In concept development</td>
</tr>
</tbody>
</table>
StrokeNet Enrollment Update
CREST 2 – 1163/2480
CREST H – 15/500
ARCADIA – 96/1100 randomized; 347/4400 consented

StrokeNet Trial Updates

As of September 27, 347 patients have been consented and 96 randomized (~9% of the target of 1100!). This represents an increase of 12 patients over the past 2 weeks since the last update. September represents our best month yet.

<table>
<thead>
<tr>
<th>ARCADIA recruitment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2018</td>
<td>2 patients randomized</td>
</tr>
<tr>
<td>April</td>
<td>8</td>
</tr>
<tr>
<td>May</td>
<td>11</td>
</tr>
<tr>
<td>June</td>
<td>19</td>
</tr>
<tr>
<td>July</td>
<td>17</td>
</tr>
<tr>
<td>August</td>
<td>19</td>
</tr>
<tr>
<td>September (through Sept 27)</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>96</td>
</tr>
</tbody>
</table>

The University of Iowa in Iowa City, IA remains in the lead for randomizations, with 9; United Hospital in St. Paul MN, remains close behind with 8 patients, and Oregon Health and Science University (OHSU) Hospital in Portland, OR is still just one back with 7. All told, 41 sites have randomized at least one patient, and 72 have consented for screening at least one patient. We continue to make progress on all these measures. Congratulations and thanks to all these sites for doing such a great job!
Sites that have not enrolled anyone in 3 months have been getting emails and calls from us to see if there are fixable reasons for this. Soon we will be asking for sites to do retraining as needed, and we may be reaching out for follow up training calls soon. We want everyone to succeed in this trial!

We look forward to providing more details and seeing the RCC teams in Montreal in October!

-- The ARCADIA National Team

We had 2 more site green lighted in the last 2 weeks, bringing our total to 30 sites and 15 patients enrolled. Welcome to Vancouver General Hospital and Well Cornell. There are 32 more sites still in the pipeline to be green lighted and we will be pursuing more. UPMC is still leading recruitment with 4 enrollments, followed by U Iowa with 3 and Michigan Vascular with 2. Fastest out of the gate was Gundersen Health, enrolling their first patient on the day they were green lighted!

Additional news reminder:

1. CIRB has now approved CT perfusion as an option in addition to MRI perfusion. This will permit more patients to be enrolled and give sites an additional option to work with.

2. Site reimbursement has increased by 30%, and patient remuneration higher as well, allowing more sites and patients to participate.

If you have an active CREST-2 site in your RCC that is not yet enrolling in CREST-H, let us know. Contact Randy Marshall rsm2@columbia.edu, Jaya Vijayan vijayan.jaya@mayo.edu, or Kevin Slane at KJS4@columbia.edu. We are still recruiting additional sites. Thanks!

From the CREST-2 Clinical Coordinating Center:

2017 vs. 2018 Randomizations

Enrollment has not accelerated. At your own sites, please re-engage with your CREST-2 PI, your carotid surgeons, stenters and your ultrasound labs – and do anything else you can do to help!
Registration Open for [FDA's Clinical Investigator Training Course](#)

November 13-15, 2018

[Registration and Agenda](#)

Onsite attendance only. This event will NOT be webcast.

Registration closes on Nov 6, 2018, or when registration is full.

Experts from FDA’s Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), the University of Maryland and the University of Pennsylvania will provide a deep dive into the scientific background and practical methodology needed when conducting clinical trials.

In this intensive course, attendees will learn FDA regulations, ethical considerations, and the scientific principles to help them understand what is important when conducting clinical trials and preparing a submission for FDA review.

**About the Training Course**

Topics include:
- Preclinical and clinical science
- Statistical structure of trials
- Safety and ethical requirements
- FDA regulatory requirements related to the performance and evaluation of clinical studies
- Non-clinical, early clinical, and phase 3 studies
- Issues in the design and analysis of trials

After this course, the participant will be able to:
1. Explain the responsibilities of an investigator conducting a clinical trial
2. Describe what to look for in medical products being studied in a clinical trial
3. Describe the basic concepts of clinical trial design
4. Review clinical data for sources of bias and error

**Who Should Attend?**
Physicians, nurses, pharmacists and other healthcare professionals responsible for the conduct in clinical trials.

Location
Tommy Douglas Conference Center (TDCC)
10000 New Hampshire Avenue, Silver Spring, MD 20903

Speakers
FDA medical officers, FDA senior scientists, FDA senior experts, and guest lecturers from academia and patient advocacy will provide presentations.

Questions
Contact us with questions at ClinicalInvestigator@fda.hhs.gov or at 301-796-8946.

Continuing Education
This event is eligible for 12 credits towards a RAC recertification.

This training is part of a collaborative partnership between the University of Maryland, College Park and the University of Maryland, Baltimore, with support from the Food and Drug Administration (FDA), the University Of Maryland Center Of Excellence in Regulatory Science and Innovation (M-CERSI) focuses on modernizing and improving the ways drugs and medical devices are reviewed and evaluated.

Steering Committee Call

Steering Committee Calls are a requirement for all NIH StrokeNet RCCs
(One representative per RCC required)

Due to the network meeting at the World Stroke Congress in October, the next Steering Committee call is scheduled for 14-November, 2018 at 12 noon ET.

Just a reminder, minutes from all Steering Committee calls can be accessed via the www.nihstroke.net website. After log in, click on the “Minutes” tab, then at the dropdown menu, select “Steering Committee”.

Coordinator Webinar

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

The next Coordinator webinar is scheduled for 24-October, 2018
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, however all are welcome to participate.

When: Tuesday, October 9, 2018 - 12:00 PM ET
Presentation: Creating a Study Budget – Randy Marshall, MD, Columbia University; Stephanie Wilbrand, PhD, University of Wisconsin at Madison

To join the meeting, please go to: https://nihstrokenet.adobeconnect.com/pdw/

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

Grand Rounds

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

Presentation: Perioperative & Periprocedural Stroke – Steven Messe, MD, University of Pennsylvania

When: Thursday, October 25, 2018 - 4:00 PM ET
Moderator: Cemal Sozener, MD, University of Michigan

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 Network Meetings and Important Info

16-October, 2018: The next NIH StrokeNet Network meeting will be held prior to the World Stroke Congress in Montreal. We will reimburse two people from each RCC one night room and tax, up to $250.

The agenda is attached to this email.
6-February, 2019: Tentative social gathering at the ISC in Honolulu, Hawaii. Details TBD.

NOTE: Going forward, the NIH StrokeNet will have one in-person network meeting per year, in the fall. In the spring, there will be a half-day all-network webinar.

Upcoming Conferences, Seminars and Workshops

FDA Good Clinical Practice Workshop:
Data Integrity in Global Clinical Trials – Are We There Yet?

October 23-24, 2018 Tommy Douglas Conference Center, Silver Spring, MD

This forum will be delivered in hybrid format. When you register you will choose to attend either "In-Person Onsite" or "Virtually Online via Adobe Connect."

Registration is FREE:

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

NIH StrokeNet Employment Opportunities

Pre-doc / Post-doc Training Opportunity in Stroke Research at UTHealth

We are looking for driven, motivated and enthusiastic doctoral candidates and recent doctoral program graduates in epidemiology, bio-statistics or data science who have a strong quantitative background along with an understanding of research design and research methods. The UTHealth Institute for Stroke and Cerebrovascular Disease will provide support for the pre-doctoral / post-doctoral position at the NIH salary guidance levels for up to three years. The trainee will have a unique opportunity to apply their research and analytic skill set in epidemiological, population health, and clinical areas pertaining to stroke and cerebrovascular diseases. They will train with highly skilled and reputable clinical and research stroke faculty at the Stroke Institute of UTHealth. The program will be tailored to individual trainee’s background and career goals. Benchmarks of success will be determined based on research productivity (abstracts, manuscripts, grant submissions). Support will be provided for further training and certifications. UTHealth in partnership with its clinical affiliate, Memorial Hermann, is one of the largest stroke care providers in the world and has a strong and well-established track record of
research productivity and stroke training programs. Individuals interested in applying their skill set towards solving complex research questions in cerebrovascular disease are encouraged to apply.

This is a non-clinical training slot for folks who have Masters or PhDs in bio-statistics / epidemiology / bio-informatics or data science. Individuals will require a work authorization in the US. There are no citizenship or residency requirements.

Please forward:

1. CV
2. School Transcripts (Masters or PhD)
3. 2 letters of recommendation
4. Brief personal statement (not more than 1,000 words)

Email (Farhaan.vahidy@uth.tmc.edu) with application materials or for any questions.

Please share this with your clinical performing and satellite sites! Contact: Jamey Frasure, PhD, RN, Director NIH StrokeNet Coordinating Center I frasuris@ucmail.uo.edu I 513-558-1742 https://www.nihstroke.uc.edu
StrokeNet Enrollment Update
CREST 2 – 1163/2480
CREST H – 15/500
ARCADIA – 96/1100 randomized; 347/4400 consented

StrokeNet Trial Updates

As of September 27, 347 patients have been consented and 96 randomized (~9% of the target of 1100!). This represents an increase of 12 patients over the past 2 weeks since the last update. September represents our best month yet.

<table>
<thead>
<tr>
<th>ARCADIA recruitment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2018</td>
<td>2 patients randomized</td>
</tr>
<tr>
<td>April</td>
<td>8</td>
</tr>
<tr>
<td>May</td>
<td>11</td>
</tr>
<tr>
<td>June</td>
<td>19</td>
</tr>
<tr>
<td>July</td>
<td>17</td>
</tr>
<tr>
<td>August</td>
<td>19</td>
</tr>
<tr>
<td><strong>September (through Sept 27)</strong></td>
<td>20</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>96</td>
</tr>
</tbody>
</table>

The University of Iowa in Iowa City, IA remains in the lead for randomizations, with 9; United Hospital in St. Paul MN, remains close behind with 8 patients, and Oregon Health and Science University (OHSU) Hospital in Portland, OR is still just one back with 7. All told, 41 sites have randomized at least one patient, and 72 have consented for screening at least one patient. We continue to make progress on all these measures. Congratulations and thanks to all these sites for doing such a great job!
Sites that have not enrolled anyone in 3 months have been getting emails and calls from us to see if there are fixable reasons for this. Soon we will be asking for sites to do retraining as needed, and we may be reaching out for follow up training calls soon. We want everyone to succeed in this trial!

We look forward to providing more details and seeing the RCC teams in Montreal in October!

-- The ARCADIA National Team

We had 2 more site green lighted in the last 2 weeks, bringing our total to 30 sites and 15 patients enrolled. Welcome to Vancouver General Hospital and Weill Cornell. There are 32 more sites still in the pipeline to be green lighted and we will be pursuing more. UPMC is still leading recruitment with 4 enrollments, followed by U Iowa with 3 and Michigan Vascular with 2. Fastest out of the gate was Gundersen Health, enrolling their first patient on the day they were green lighted!

**Additional news reminder:**

1. CIRB has now approved CT perfusion as an option in addition to MRI perfusion. This will permit more patients to be enrolled and give sites an additional option to work with.

2. Site reimbursement has increased by 30%, and patient remuneration higher as well, allowing more sites and patients to participate.

If you have an active CREST-2 site in your RCC that is not yet enrolling in CREST-H, let us know. Contact Randy Marshall rsm2@columbia.edu, Jaya Vijayan vijayan.jaya@mayo.edu, or Kevin Slane at KJS4@columbia.edu. We are still recruiting additional sites. Thanks!

*From the CREST-2 Clinical Coordinating Center:*

### 2017 vs. 2018 Randomizations

![Graph showing enrollment comparison between 2017 and 2018](chart.png)

*Enrollment has not accelerated. At your own sites, please re-engage with your CREST-2 PI, your carotid surgeons, stentors and your ultrasound labs – and do anything else you can do to help!*
Registration Open for FDA's Clinical Investigator Training Course

November 13-15, 2018

Registration and Agenda

Onsite attendance only. This event will NOT be webcast.

Registration closes on Nov 6, 2018, or when registration is full.

Experts from FDA's Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), the University of Maryland and the University of Pennsylvania will provide a deep dive into the scientific background and practical methodology needed when conducting clinical trials.

In this intensive course, attendees will learn FDA regulations, ethical considerations, and the scientific principles to help them understand what is important when conducting clinical trials and preparing a submission for FDA review.

About the Training Course

Topics include:
• Preclinical and clinical science
• Statistical structure of trials
• Safety and ethical requirements
• FDA regulatory requirements related to the performance and evaluation of clinical studies
• Non-clinical, early clinical, and phase 3 studies
• Issues in the design and analysis of trials

After this course, the participant will be able to:
1. Explain the responsibilities of an investigator conducting a clinical trial
2. Describe what to look for in medical products being studied in a clinical trial
3. Describe the basic concepts of clinical trial design
4. Review clinical data for sources of bias and error

Who Should Attend?
Physicians, nurses, pharmacists and other healthcare professionals responsible for the conduct in clinical trials.

**Location**

Tommy Douglas Conference Center (TDCC)  
10000 New Hampshire Avenue, Silver Spring, MD 20903

**Speakers**

FDA medical officers, FDA senior scientists, FDA senior experts, and guest lecturers from academia and patient advocacy will provide presentations.

**Questions**

Contact us with questions at ClinicalInvestigator@fda.hhs.gov or at 301-796-8946.

**Continuing Education**

This event is eligible for 12 credits towards a RAC recertification.

This training is part of a collaborative partnership between the University of Maryland, College Park and the University of Maryland, Baltimore, with support from the Food and Drug Administration (FDA), the University Of Maryland Center Of Excellence in Regulatory Science and Innovation (M-CERSI) focuses on modernizing and improving the ways drugs and medical devices are reviewed and evaluated.

---

**Steering Committee Call**

*Steering Committee Calls are a requirement for all NIH StrokeNet RCCs  
(One representative per RCC required)*

Due to the network meeting at the World Stroke Congress in October, the next Steering Committee call is scheduled for **14-November, 2018 at 12 noon ET**.

Just a reminder, minutes from all Steering Committee calls can be accessed via the [www.nihstrokenet.org](http://www.nihstrokenet.org) website. After log in, click on the “Minutes” tab, then at the dropdown menu, select “Steering Committee”.

---

**Coordinator Webinar**

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

The next Coordinator webinar is scheduled for **24-October, 2018**

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, however all are welcome to participate.

When: Tuesday, October 9, 2018 - 12:00 PM ET
Presentation: Creating a Study Budget – Randy Marshall, MD, Columbia University; Stephanie Wilbrand, PhD, University of Wisconsin at Madison

To join the meeting, please go to: https://nihstrokenet.adobeconnect.com/pdw/
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

Grand Rounds

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

Presentation: Perioperative & Periprocedural Stroke – Steven Messe, MD, University of Pennsylvania

When: Thursday, October 25, 2018 - 4:00 PM ET
Moderator: Cemal Sozener, MD, University of Michigan

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 Network Meetings and Important Info

16-October, 2018: The next NIH StrokeNet Network meeting will be held prior to the World Stroke Congress in Montreal. We will reimburse two people from each RCC one night room and tax, up to $250.

The agenda is attached to this email.
6-February, 2019: Tentative social gathering at the ISC in Honolulu, Hawaii. Details TBD.

NOTE: Going forward, the NIH StrokeNet will have one in-person network meeting per year, in the fall. In the spring, there will be a half-day all-network webinar.

Upcoming Conferences, Seminars and Workshops

FDA Good Clinical Practice Workshop:
Data Integrity in Global Clinical Trials – Are We There Yet?

October 23-24, 2018 Tommy Douglas Conference Center, Silver Spring, MD

This forum will be delivered in hybrid format. When you register you will choose to attend either "In-Person Onsite" or "Virtually Online via Adobe Connect."

Registration is FREE: https://events-na12.adobeconnect.com/content/connect/c1/1315899612/en/events/event/shared/2026475943/event_registration.html?scoid=2026542041&_charset_=utf-8

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

NIH StrokeNet Employment Opportunities

Pre-doc / Post-doc Training Opportunity in Stroke Research at UTHealth

We are looking for driven, motivated and enthusiastic doctoral candidates and recent doctoral program graduates in epidemiology, bio-statistics or data science who have a strong quantitative background along with an understanding of research design and research methods. The UTHealth Institute for Stroke and Cerebrovascular Disease will provide support for the pre-doctoral / post-doctoral position at the NIH salary guidance levels for up to three years. The trainee will have a unique opportunity to apply their research and analytic skill set in epidemiological, population health, and clinical areas pertaining to stroke and cerebrovascular diseases. They will train with highly skilled and reputable clinical and research stroke faculty at the Stroke Institute of UTHealth. The program will be tailored to individual trainee's background and career goals. Benchmarks of success will be determined based on research productivity (abstracts, manuscripts, grant submissions). Support will be provided for further training and certifications. UTHealth in partnership with its clinical affiliate, Memorial Hermann, is one of the largest stroke care providers in the world and has a strong and well-established track record of
research productivity and stroke training programs. Individuals interested in applying their skill set towards solving complex research questions in cerebrovascular disease are encouraged to apply.

This is a non-clinical training slot for folks who have Masters or PhDs in bio-statistics / epidemiology / bio-informatics or data science. Individuals will require a work authorization in the US. There are no citizenship or residency requirements.

Please forward:

1. CV
2. School Transcripts (Masters or PhD)
3. 2 letters of recommendation
4. Brief personal statement (not more than 1,000 words)

Email (Farhaan.vahidy@uth.tmc.edu) with application materials or for any questions.

Please share this with your clinical performing and satellite sites! Contact: Jamey Frasure, PhD, RN, Director I NIH StrokeNet Coordinating Center I frasurejs@ucmail.uc.edu I 513-558-1742 https://www.nihstrokenet.org