

Monthly Update

8-April 2017



REMINDER!!!

Monthly Coordinator Call

The next Coordinator call is scheduled for **Thursday, April 20th at 10.30am**

Neuro Teleconference Line:

USA Toll-Free: (877)848-7030

Access Code: 3386580

Enrollment Update

- **iDEF** – 158
- **MISTIE III** – 457
- **CREST 2** – 549
- **Telerehab in Stroke** – 84
- **DEFUSE 3** – 159
- **POINT** – 4132 – no update since February

Reminder to review and complete SOP and COI forms!

We also emailed a Clinical Profile Annual Survey that should be completed as soon as possible.

RCC24 is currently enrolling in Defuse 3, MISTIE III, POINT and Crest-2

**Everyone has been busy with enrollments and activating new studies.
Keep up the momentum!**

We have one site visit coming up with in April, and four more being scheduled!

The renewal grant will be submitted in the fall. Participation is more important than ever!

**At the end, please find the latest bi-weekly StrokeNet newsletter.
National Coordinating Center.**

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E. New Project Development Progress

| Type | Project | NINDS Grant Submission | | | | | Project Initiation | | | |
|--------------------|-------------------------|--|---------------------------|-----------------------------|--------------------------------|------------|-------------------------|---------------|---------------------|------------------------|
| | | Concept Synopsis Approved by NINDS ESC | Feasibility Assessment | Grant Submit to NINDS | Scientific Peer Review | Awarded | Protocol Submit to CIRB | CIRB Approval | First Site Released | First Subject Enrolled |
| | Summary | | Min=6 Max=89 Med=25 | Min=30 Max=301 Med=78 | Min=92 Max=195 Med=148.5 | Med=97 | Med=1 | Med=15 | Med=168 | Med=35 |
| DEFUSE 3 | 5/7/2014 | -6 | 31 | 162 | 11/10/2014 | | | | | |
| | | 1/26/2015 | 58 | 92 | | 97 | 1 | 15 | 168 | 35 |
| ICTUS 3 | 6/4/2014 | 89 | 30 | 155 | 3/5/2015 | | | | | |
| MOST | 8/13/2014 | -1 | 50 | 155 | 3/5/2015 | | | | | |
| | | | 7/5/2015 | 131 | 11/13/2015 | | | | | |
| | | 12/11/2015 | 177 | 156 | 11/8/2016 | | | | | |
| 6/2/2015 | 20 | 106 | 147 | 3/1/2016 | | | | | | |
| | | 7/5/2016 | 126 | 11/8/2016 | | | | | | |
| PreLIMBS | 7/23/2015 | 21 | 54 | 147 | 3/1/2016 | | | | | |
| Tempo-EMS | 2/22/2016 | 25 | 80 | 155 | 11/8/2016 | | | | | |
| ALISAH 2 | 3/23/2016 | 14 | 61 | 155 | 11/8/2016 | | | | | |
| I-WITNESS | 3/23/2016 | 14 | 301 | 2/1/2017 | | | | | | |
| Prevention (35.0%) | PICASSO | 10/16/2014 | 55 | 53 | 144 | 6/25/2015 | | | | |
| | | | | 3/5/2016 | 124 | 7/7/2016 | | | | |
| | ARCADIA | 3/6/2015 | 21 | 80 | 150 | 11/12/2015 | | | | |
| | | | 1/27/2016 | 37 | 125 | 7/7/2016 | | 3/10/2017 | | |
| | SleepSMART | 11/3/2015 | 22 | 76 | 150 | 7/8/2016 | | | | |
| | | | | 3/3/2017 | | | | | | |
| | ARREST | 11/3/2015 | 22 | 76 | 150 | 7/8/2016 | | | | |
| | SATURN | 2/3/2016 | 21 | 224 | 10/5/2016 | | | | | |
| VERITAS II | 8/10/2016 | 84 | 11/2/2016 | | | | | | | |
| ASPIRE | 10/21/2016 | 25 | 11/15/2016 | | | | | | | |
| Recovery (20.0%) | RISIS | 12/15/2015 | 45 | 128 | 156 | 11/8/2016 | | | | |
| | STEPSS | 4/29/2016 | 56 | 103 | 10/5/2016 | | | | | |
| | TRANSPORT-II | 7/25/2016 | 36 | 36 | 195 | 4/18/2017 | | | | |
| | ACQUIRE (formerly IRIS) | 3/17/2017 | | | | | | | | |

Active Inactive Awarded 30 # of days since previous milestone

All information is generated based on data currently in the database. Data may not be verified or validated. The report is generated to assist in trial operations only, and is not valid to support any statistical analysis of study data. Unless noted, the Data Coordination Unit (DCU) assumes no responsibility for the use of this report. This report may contain protected health information covered by the Health Insurance Portability and Accountability Act (HIPAA). You are prohibited from disclosing this information without the specific written consent of the person to whom it pertains. Anyone using this data specifically assumes responsibility for maintaining the confidentiality of the protected data.



Biweekly Update 31-March 2017

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

StrokeNet Enrollment Update

Telerehabilitation in Stroke – **83/124**
DEFUSE 3 – **152/476**
iDEF – **239/294** subjects
MISTIE III – **456/500** subjects
CREST 2 – **546/2480** subjects

StrokeNet Trial Updates



ARCADIA

From the ARCADIA Team: Stay tuned! We will be announcing the next wave of sites very soon! Information in regard to the dates/times of investigator meetings will be shared when final. We look forward to working with you on a successful launch of our trial! Contact Irene Ewing with any questions, irene.ewing@uc.edu.



From the DEFUSE 3 Team: March has been our strongest month so far with 26 patients randomized! Total randomized to date: 152. Great work everyone!

Friendly reminder: All neurointerventionalists listed on your site DOA, who are designated the responsibility of “Perform Endovascular Procedure”, must re-review the endovascular training module on the WebDCU Training Campus (<https://webdcu.musc.edu/campus>). After reviewing the training module, each investigator must print, complete and sign the Endovascular Training Attestation Form, paying careful attention to the check boxes on the form. Please upload all new attestations by **April 10, 2017**. Please contact Stephanie Kemp with questions, skemp@stanford.edu.



From the Telerehab Team: Enrollment continues well, and many sites are achieving the 0.67 patients/site (2 patients every 3 months) target. We are grateful for everyone's good work on this project!



From the CREST-2 Clinical Coordinating Center:

546 randomizations as of 3/29/17 (253 CEA; 293 CAS)
123 active centers of which 49 are StrokeNet Sites

Welcome to the following new CREST-2 Sites in March

*St. John Clinical Research Institute, Anna Wanahita, MD, Site PI
Tulsa, OK Kelli Bradshaw, Coordinator*

*Louis Stokes Cleveland VA Medical Center Cleveland, OH Gilles Pinault, MD, Site PI
Deborah Nogle, Coordinator*

*University of Florida Health Shands Gainesville, FL Anna Khanna, MD, Site PI
Rosie Kizza, Coordinator*

St. John Clinical Research Institute is a StrokeNet satellite of the University of Texas Health Science Center, Houston, TX.

Louis Stokes Cleveland VA Medical Center is a StrokeNet Clinical Performing Center of Case Western Reserve University, Cleveland, OH

University of Florida Health Shands is a StrokeNet satellite of University of Miami.

We're happy to have you all aboard CREST-2!



From the iDEF Executive Committee - Recruitment in iDEF is going well thanks to your hard work & commitment to the study. We are on target to finish recruitment this fall. As of March 28nd, 238 subjects have been enrolled. Only, 56 more subjects to go! Please, continue your hard work.

Steering Committee Call

The next Steering Committee call will be a **webinar on 12-April, 2017, at 12 noon ET:**

Proposed Trial Presentation:

“Efficacy of Infant ACQUIRE Therapy for Infants with Symptomatic Arterial Ischemic Stroke at Birth”

Trial PIs: Sharon Landesman Ramey, Ph.D. Virginia Tech Carilion Research Institute,
Virginia Tech

Warren Lo, M.D. - The Ohio State University and Nationwide Children’s
Hospital

Please invite your pediatric StrokeNet community to this call, as well as your Satellite sites.

To join the meeting:

<https://nihstrokenet.adobeconnect.com/steering/><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 Number: (877) 621-0220 Pass code Number: 434578

Minutes from the 8-March call are attached, but can also be accessed via the www.nihstrokenet.org website. After log in, click on the “Minutes” tab, then at the dropdown menu, select “Steering Committee”.

<https://www.nihstrokenet.org/intranet/minutes/steering-committee>. If you need a log in, please contact your RCC Network Manager/Coordinator to request one for you.

NDMC News

The StrokeNet Site Information Form has been revamped! The new form will be completed on an annual basis and has been renamed the ‘Site Clinical Profile Annual Survey’. You will receive an email early next week with instructions on how to complete the annual survey. This survey will need to be completed for each of your RCC’s sites using data from 2016. You will have 6 weeks to complete the annual survey in WebDCU™. One of the goals of this survey is for StrokeNet to have up-to-date data on each site available to help assess the feasibility of upcoming trials. This will help to not only reduce any redundancy on feasibility surveys, but also reduce the number of

questions on those surveys going forward. If there are any questions, please contact Jessica Griffin at simonsjl@musc.edu.

Publication News

We are happy to share the attached paper by the Recovery Working Group, published recently in the journal of Stroke:

Stroke Recovery and Rehabilitation Research: Issues, Opportunities, and the National Institutes of Health StrokeNet. Cramer SC, Wolf SL, Adams HP Jr, Chen D, Dromerick AW, Dunning K, Ellerbe C, Grande A, Janis S, Lansberg MG, Lazar RM, Palesch YY, Richards L, Roth E, Savitz SI, Wechsler LR, Wintermark M, Broderick JP. *Stroke*. 2017 Mar;48(3):813-819. doi: 10.1161/STROKEAHA.116.015501.

QAR Reminder

The next Quarterly Activity Report for RCCs, covering the period from 16-December, 2016 through 15-March, 2017, is due **1-April, 2017**. Thanks to all who have already submitted! Any questions, contact Jamey Frasure at frasurjs@ucmail.uc.edu.

NINDS News

NIH Clinical Center Grand Rounds, Great Teachers Lecture Series

Archived presentation: Topic: The Changing Face of Informed Consent

Speaker: Christine Grady, PhD, MSN, Chief, Department of Bioethics and Head, Section on Human Subjects Research, Clinical Center

<https://videocast.nih.gov/Summary.asp?File=22170&bhcp=1>

PROCESS FOR REQUESTING CARRYOVER

WHEN TO SUBMIT

When funds are needed and FFR has been received and accepted. Since there is often some time lapse between FFR submission and acceptance, it may be helpful for grantee to send the GMB specialist an e-mail when the FFR is submitted.

Requests are reviewed and processed as they are submitted. For end of FY requests, submissions should be submitted by the end of **MAY** to ensure processing before the close of FY.

*The award period ends July 31, so all requests must be submitted by the end of May and it can take up to 60 days so be sure to plan ahead. If sites overspend without approved carryover, the NINDS may not be allowed to release the

funds. *GMB is not able to process carryover requests while they are preparing new awards for StrokeNet so end of May is firm.*

WHAT TO SUBMIT

Email an attachment signed by Business Office & PI to the NINDS GMB Specialist with a copy to the Administrative Program Official to include the following:

- Scientific Justification (explain scientific need for \$ requested)
- Plan for use of funds (including timeline for use of requested funds)
- if request is for >25% of current yr \$, explain why funds were not fully expended in the prior year

Detailed budget for carryover requested amount only (including F&A) with itemized budget justification indicating how the funds will be spent - use budget form pages <http://grants.nih.gov/grants/funding/phs398/phs398.html>

APPROVAL PROCESS

GMB Specialist will review & obtain the Administrative Program Official's concurrence.

PLEASE NOTE: This process may take up to 60 days.

PROCESS FOR REQUESTING RELEASE OF RESTRICTED FUNDS

WHEN TO SUBMIT

- When the performance milestone specified in your NGA has been reached.

WHAT TO SUBMIT

- Email an attachment signed by Business Office & PI to the NINDS GMB Specialist with a copy to the Administrative Program Official.

- Include the following:

a) Specify the milestone(s) accomplished.

b) Indicate when the milestone was reached and provide supporting documentation (eg. enrollment reports or other related materials).

c) Request release of funds or lift restriction.

APPROVAL PROCESS

- GMB Specialist will review and obtain the Administrative Program Official's concurrence.

- If approved, a revised NGA will be issued removing restrictions.

PLEASE NOTE: This process may take up to 30 days.

Coordinator Webinar

There next Coordinator Webinar will be Wednesday, 26-April, 2017, at 1:30 pm ET.

This webinar will be a refresher in regard to navigating the WebDCU database, as well as the www.nihstrokenet.org website. Coordinator attendance is required, and RCC personnel participation encouraged. Look for an Outlook meeting invitation soon!

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: **1:00 PM** – Mellanie Springer, MD MSc – Montefiore
Race-Ethnic Disparities in Hospital Arrival Time after Ischemic Stroke

1:30 PM – **Chen Lin, MD** – **Northwestern University** – Tract-Based and Voxel Based Lesion-Network Mapping to Predict Recovery after Ischemic Stroke

2:00 PM – **Katherine Jacoby, MD** – **University of Minnesota** – Stroke Knowledge and Health Literacy in a Diverse Non-English Speaking Population

When: **Monday, April 17, 2017 – 1:00 PM ET**

Moderator: David Tirschwell – University of Washington

To join the meeting: <https://nihstrokenet.adobeconnect.com/pdw/> **To take part in the conversation you must dial in. 1 (877) 621-0220 Passcode Number: 190825**

Grand Rounds

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

Presenter: **Babak Navi, MD** – **Weill Cornell**

Presentation: Cancer and Stroke

When: **Thursday, April 20, 2017 – 4:00 PM ET**

Moderator: David Tirschwell, MD – University of Washington

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 2017

Pencil us in for **Tuesday, 12-September in Atlanta, GA, for the fall network meeting. Same location as last year, the Atlanta Airport Marriott. We have negotiated a very reasonable rate room rate, details to come. We will keep you posted!

Upcoming Conferences and Seminars

Upcoming NIH Seminars:

May 3-5, 2017

New Orleans 2017 – NIH Regional Seminar
<https://regionalseminars.od.nih.gov/neworleans2017/>

October 25-27, 2017

Baltimore 2017 – NIH Regional Seminar
<https://regionalseminars.od.nih.gov/baltimore2017/>

*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>