

Monthly Update

9-August 2017



REMINDER!

Monthly Coordinator Call

The next coordinator call is scheduled for **Thursday, August 17th at 10.30am**

Neuro Teleconference Line:

USA Toll-Free: (877) 848-7030

Access Code: 3386580

Enrollment Update

- **IDEF** – 264
- **MISTIE III** – 504
- **CREST 2** – 672
- **Telerehab in Stroke** – 102
- **DEFUSE 3** – 182, enrollment complete
- **POINT** – 4586

RCC24 is currently enrolling in MISTIE III, POINT, and Crest2.

Multiple sites have yet to sign their SOPs. This is mandatory and we will be contacting those sites to have them signed ASAP.

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

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

Arcadia should begin enrolling in the early fall. All cohorts have been announced. The investigator meeting will be Sept. 13 in Atlanta.

DEFUSE-3 has been permanently closed due to a high likelihood of efficacy in the endovascular treatment arm.

At the end, please find the latest bi-weekly StrokeNet newsletter and 2018 Grand Rounds schedule from the National Coordinating Center.

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Trial Proposal Status

| Project Name | Protocol PI | Prevention/ Acute/Recovery | Status Update |
|------------------------|---|-------------------------------|---|
| MOST | Opeolu Adeoye, Andrew Barreto, Joe Broderick, James Grotta | Acute | Awaiting summary statements from June 2017 study section review |
| I-WITNESS | Lee Schwamm, Ona Wu, Steve Warach, Larry Latour, Shlee Song | Acute | Awaiting summary statements from June 2017 study section review |
| Sleep SMART (C-PAP) | Devin Brown | Prevention | Awaiting summary statements from June 2017 study section review |
| IMPACT | Andrew Naidech | Acute | July 2017 resubmission |
| TRANSPORT | Wayne Feng, Gottfried Schlaug | Recovery | July 2017 resubmission |
| ARREST | Robert Brown, James Torner, David Hasan | Prevention | July 2017 resubmission |
| VERITAS II | Sepideh Amin- Hanjani | Prevention | July 2017 submission |

| | | | |
|----------------------------------|----------------------------|------------|----------------------|
| ASPIRE (formerly SCORPION) | Kevin Sheth | Prevention | July 2017 submission |
| ACQUIRE (formerly IRIIS) | Warren Lo, Sharon Ramey | Recovery | July 2017 submission |

| Project Name | Protocol PI | Prevention/ Acute/Recovery | Status Update |
|---------------------|--|-------------------------------|----------------------------|
| CAPTIVA (CRISIS) | Brian Hoh | Prevention | October 2017 submission |
| FURRTHER | Bernadette Boden-Albala | Prevention | October 2017 submission |
| ALISAH 2 | Jose Suarez | Acute | November 2017 resubmission |
| PreLIMBS II | Sebastian Koch, Nestor Gonzalez, Neeraj Chaudhary | Acute | November 2017 resubmission |
| SATURN | Magdy Selim | Prevention | November 2017 resubmission |
| PICASSO | Marc Chimowitz | Prevention | Redesigning as Phase I |
| 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 |
| SEACOAST 1 | Radoslav Raychev, Dimiter | Acute | In concept development |

| Project Name | Protocol PI | Prevention/ Acute/Recovery | Status Update |
|---|--|-------------------------------|------------------------|
| | Arnaudov, David Liebeskind, Jeffrey Saver | | |
| TESLA | Albert Yoo, Sam Zaidat | Acute | In concept development |
| ASSIST | David F. Kallmes, (Radiology) Alejandro Rabinstein, (Neurology) Jeffrey Pasternak, (Anesthesiology) Rickey Carter, (Biostatistics) | Acute | In concept development |
| DEFUSE 4 | Maarten Lansburg, Greg Albers | Acute | In concept development |
| START | Steve Warach, Truman Milling | Prevention | In concept development |
| Deep TMS Treatment of Stroke (Israel - Industry) | Abraham Zangen | Recovery | In concept development |
| SPLIT | Andrew Naidech | Prevention | In concept development |
| FOCAS | Heather Fullerton, Mitch Elkind | Prevention | In concept development |
| PAST-TIME | Jason McMullen, Opeolu Adeoye | Acute | In concept development |
| PRECISE MRI- T2 | Natalia Rost, Shyam Prabhakaran, Rebecca Gottesman, Clinton Wright | Prevention | In concept development |

| Project Name | Protocol PI | Prevention/ Acute/Recovery | Status Update |
|--|--|-------------------------------|---|
| STEPSS (Dose Response Aerobic Exercise in Subacute Stroke) | Sandra Billinger | Recovery | Regrouping after review. |
| RISiS | Julius Fridrikson, Ron Lazar, Ed Jauch, Jordan Elm, Leonardo Bonilha | Recovery | PPIs unsure whether they will resubmit. |
| Tempo-EMS | Nerses Sanossian, William Meurer, Jeffrey Saver, David Hess | Acute | Triaged at November 2016 Study Section |
| 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 |
| 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 |

| Project Name | Protocol PI | Prevention/ Acute/Recovery | Status Update |
|--------------------------------------|-------------------------|-------------------------------|---|
| | | | 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. |
| URIC | Enrique Leira | Acute | Inadequate data to support the trial in its current form. Needs published work prior to submission. |
| ICTuS 3 | Pat Lyden | Acute | Indefinite hold. |
| NORRIS | Walter Kernan | Prevention | Not approved to move forward at this time. |
| 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 |

Monthly Update

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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=30 | Min=30 Max=301 Med=78.5 | Min=92 Max=195 Med=147 | Min=97 Max=298 Med=197.5 | Med=1 | Med=15 | Med=168 | Med=35 |
| DEFUSE 3 | 5/7/2014 | -6 | 31 | 162 | 11/10/2014 | | | | | |
| | 1/26/2015 | 58 | 58 | 92 | 97 | 1 | 15 | 168 | 35 | 5/6/2016 |
| ICTUS 3 | 6/4/2014 | 89 | 30 | 155 | 3/5/2015 | | | | | |
| | 8/13/2014 | -1 | 50 | 155 | 3/5/2015 | | | | | |
| MOST | | | 7/5/2015 | 131 | 11/13/2015 | | | | | |
| | | 12/11/2015 | 177 | 156 | 11/8/2016 | | | | | |
| | | | | 6/23/2017 | | | | | | |
| IMPACT | 6/2/2015 | 20 | 106 | 147 | 3/1/2016 | | | | | |
| | | | 7/5/2016 | 126 | 11/8/2016 | | | | | |
| | | | 7/11/2017 | | | | | | | |
| PreLIMBS | 7/23/2015 | 21 | 54 | 147 | 3/1/2016 | | | | | |
| Tempo-EMS | 2/22/2016 | 25 | 80 | 155 | 11/8/2016 | | | | | |
| 3/23/2016 | 14 | 61 | 155 | 11/8/2016 | | | | | | |
| I-WITNESS | 3/23/2016 | 14 | 301 | 142 | 6/23/2017 | | | | | |
| Prevention (40.9%) | 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 | 298 | 5/1/2017 | 3/10/2017 | | |
| | SleepSMART | 11/3/2015 | 22 | 76 | 150 | 7/8/2016 | | | | |
| | | | | 3/3/2017 | 112 | 6/23/2017 | | | | |
| | ARREST | 11/3/2015 | 22 | 76 | 150 | 7/8/2016 | | | | |
| | | | | 7/11/2017 | | | | | | |
| | SATURN | 2/3/2016 | 21 | 224 | 10/5/2016 | | | | | |
| | VERITAS II | 8/10/2016 | 84 | 251 | 7/11/2017 | | | | | |
| ASPIRE | 10/21/2016 | 25 | 238 | 7/11/2017 | | | | | | |
| Recovery (18.2%) | CAPTIVA (formerly CRISIS) | 6/7/2017 | 42 | 7/19/2017 | | | | | | |
| | FURRTHER | 6/13/2017 | 36 | 7/19/2017 | | | | | | |
| | RISIS | 12/15/2015 | 45 | 128 | 156 | 11/8/2016 | | | | |
| | STEPSS | 4/29/2016 | 56 | 103 | 195 | 4/18/2017 | | | | |
| TRANSPORT-II | 7/25/2016 | 36 | 36 | 195 | 4/18/2017 | | | | | |
| | | | | 7/11/2017 | | | | | | |
| ACQUIRE (formerly IRIIS) | 3/17/2017 | 35 | 81 | 7/11/2017 | | | | | | |



Biweekly Update 4-August-2017

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

StrokeNet Enrollment Update

Telerehabilitation in Stroke – **103/124**

iDEF – **268/294**

MISTIE III – **503/510** (expanding to 510 to ensure 500 eligible subjects enrolled)

CREST 2 – **706/2480**

StrokeNet Trial Updates



DEFUSE 3 was permanently discontinued last week based on the DSMB review of the data and their finding of a high likelihood of benefit in the endovascular group. The final results will be presented at the International Stroke Conference in January. In the meantime, we will be surveying the sites to determine interest and feasibility of a possible application for funding of an extension study to evaluate the efficacy of endovascular therapy inpatients with large core and large mismatch. Thank you to all sites for their dedication to this study! Site close-out instructions will be coming soon.



The ARCADIA team would like to remind those planning to attend the Investigator meeting on September 13th in Atlanta to confirm as soon as possible. For those unable to attend, an online training will be available after the Investigator meeting.

ARCADIA PLEASE NOTE: If you are an ARCADIA PI or Coordinator, and have indicated that you will be attending the meeting, you have been placed on a rooming list for the night of 12-September. You will NOT need to make a reservation. You will give the front desk your name at check in. If you are also attending the StrokeNet meeting, please DO NOT book both of your nights via the StrokeNet link. If you have done so, you

can confirm with us that you are on the rooming list for the ARCADIA meeting, and cancel the second night on your StrokeNet reservation. StrokeNet must pay for unused rooms, so please be aware. For questions about the meeting, please contact Irene Ewing <irene.ewing@uc.edu> or Rose Beckmann <rose.beckmann@uc.edu>. The ARCADIA Investigators also encourage colleagues to contact Dr. David Tirschwell <tirsch@uw.edu> with ideas for ancillary studies

37 in July
**Up from 28
in June**
45 per month needed



From the CREST-2 Clinical Coordinating Center:

706 randomizations (344 CEA; 362 CAS)
3 randomizations so far in August (2 CEA; 1 CAS)
123 active centers of which 52 are StrokeNet Sites



Scott Silverman, MD
Site PI

Greg Tirrell
Coordinator

*Congratulations to
Massachusetts General Hospital
for Enrolling **3** patients in July!*



CREST-H

CREST H Update:

The protocol is being finalized, and the next wave of site recruitment is about to begin. If you are a CREST-2 site that has recruited at least one CREST-2 patient, keep your eyes peeled for an invitation to join CREST-H!

Randy Marshall, On Behalf of the CREST-H Co-PIs Ronald Lazar, David Liebeskind, Sander Connolly.



The Telerehabilitation Trial is up to 103 patients randomized towards our goal of 124. This study promises to teach us about new roles for home-based telehealth. Enrollment is ongoing. Thanks for your hard work! For non-emergent questions: telerehab@uci.edu.



From The iDEF Team:

We hope that you have weathered the arrival of the new staff in July. There were four iDEF enrollments in July. Thank you to the sites that enrolled a subject in July, including Columbia, Duke, Loyola, and UNC. Three of the four enrollments occurred in the last week of July, so hopefully August will be a good month for the trial. You have enrolled **268** of the **294** subjects needed to complete the trial—**91** percent! We need your help to enroll the last **26** patients and finish recruitment on time. Thank you!

NDMC Survey Reminder

REMINDER! The **MOST Site Selection Survey** was sent for your review and completion on 2-August. **This survey MUST be completed in WebDCU™ by 11:59pm ET on Wednesday, August 16th.**

This survey should be completed for any sites that are interested in participating in MOST.

If you have any questions about how to complete the survey or if you have any issues with WebDCU™ please contact Jessica Griffin at simonsjl@musc.edu. Thank you!

Steering Committee Call

The next Steering Committee call will be **9-August, 2017, at 12 noon ET**. Agenda to follow.

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 a log in, please contact your RCC Network Manager/Coordinator to request one for you.

Coordinator Webinar

There next Coordinator Webinar will be **Wednesday, 23-August, at 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

Presentation: Writing your CV and Biosketch – Dawn Kleindorfer, MD
University of Cincinnati

When: Wednesday, August 16, 2017 – 1:00 PM ET

Moderator: TBA

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.

Note: To view the 2017-2018 Grand Rounds series schedule please visit:
<http://nihstrokenet.org/webinars>

Presentations: Post-Stroke Outcome Measures – Pam Duncan, PhD, PT
Wake Forest University

When: Thursday, August 31, 2017 – 4:00 PM ET

Moderator: Harold Adams, MD, University of Iowa

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: The NIH StrokeNet fall meeting has been scheduled for **Tuesday, 12-September** in Atlanta, GA. It will be held at the same location as last year, the Atlanta Airport Marriott. Please see the attached travel and logistics email. RCC Coordinators please **RSVP with your 5 attendees by 11-August, 2017**. You can reserve your room for 11-Sep via the reservation link below, at \$129 per night plus tax. Once the block has been satisfied, rooms will be reserved at the current rate. Note, the block is almost full!

ARCADIA Investigator Meeting:

The ARCADIA Investigator Meeting will be held **Sept. 13th** in Atlanta following the StrokeNet meeting. See the above ARCADIA update for details or contact Irene Ewing, at Irene.ewing@uc.edu.

2018: The International Stroke Conference is scheduled to be held in Los Angeles, California. We would like to propose having our network meeting at a Los Angeles Airport hotel in order to alleviate the very costly downtown LA hotel rates. We would negotiate a rate and reserve a room block for Sunday night, 21-January, and Monday night, 22-January.

Upcoming Conferences and Seminars

Upcoming NIH Seminars:

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>

2017-2018

NIH StrokeNet Grand Rounds Schedule

All Webinars begin at 4:00PM Eastern Time

| Date | Topic | Speaker | Institution | Moderator |
|---------|--|---|---|-------------------|
| July 27 | Use of Robotics in Stroke Recovery | Joel Stein, MD | Columbia University, Weill Cornell Medicine | Farhaan Vahidy |
| Aug 31 | Post-Stroke Outcome Measures | Pam Duncan, PhD, PT | Wake Forrest | Harold Adams |
| Sept 28 | Acute Reperfusion Therapy as in Dawn & DEFUSE 3/ Wake up Strokes | Raul Nogueira, MD | Emory University | David Liebeskind |
| Oct 26 | Predicting Stroke Recovery/PREP Algorithm | Cathy Steinar, PhD | University of Auckland | Randy Marshall |
| Nov 30 | International and US Stroke Disparities | Ralph Sacco, MD | University of Miami | Lori Jordan |
| Jan 18 | TCD Embolus Detection / Measurement of Carotid Plaque Burden Hemodynamics | David Spence, MD Randolph Marshall, MD | Robarts Research Institute Columbia University | Dawn Kleindorfer |
| Feb 22 | Sex Differences in Stroke | Louise McCullough, MD, PhD | University of Texas, Houston | Farhaan Vahidy |
| Mar 22 | Gloves Off for Acute Stroke Management; Fellow Case Presentations to Two Stroke Experts | Larry Wechsler, MD Jennifer Majersik, MD | UPMC University of Utah | Randy Marshall |
| Apr 26 | Stroke Prevention with the Expanded use of NOAC and use of Anticoagulants | Scott Kasner, MD | University of Pennsylvania | Shyam Prabhakaran |
| May 31 | Post Stroke Depression | Pam Mitchell, PhD | University of Washington | Cemal Sozener |

<https://nihstrokenet.adobeconnect.com/grandrounds/>

Please log in 15 minutes prior to start time of 4:00 pm EST

Please enter as a guest, then your first and last name.

If you have any issues viewing the presentation, please log out, then log back into the meeting room.

In order to join the conversation you must dial (877) 621-0220 Passcode 190825

Please hold questions until the end of the presentation. All lines will be muted, press *6 to mute and unmute.

If you have never attended an Adobe Connect meeting before: Test your connection: https://nihstrokenet.adobeconnect.com/common/help/en/support/meeting_test.htm