



Coordinator Webinar and Round Table Discussion

October- 25, 2017

Coordinator Call

Announcements and Reminders

Next Coordinator Webinar :

- Round table Presenter: Kinga Aitken, MPH CCRP
UT StrokeNet, Research Associate
University of Utah School of Medicine
- Discussion: "How to Manage a Research Team"

"Wednesday, 15-November 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.

Upcoming StrokeNet Meetings:

- StrokeNet Meeting Monday, 22-January, 2018, ISC Los Angeles, California
- Plan Ahead: Montreal meeting Sept 2018.
- ARCADIA IV Meeting Nov-17, 2017 Atlanta, GA.

Project Updates

TELE-REHAB

Study Updates:

Study Project Managers: Lucy Dodakian, MA, OTR/L
Judith Spilker, RN, BSN

Study Investigator: Steve Cramer, MD

Data Manager: Kavita Patel



Project Updates i-DEF

Study Updates:

Study Project Manager: Aaron Perlmutter, MPH, MSW

Study Investigator: Magdy Selim, MD



Project Updates

CREST 2

Study Updates:

Study Project Manager: Mary Longbottom, CCRP,
CREST Director for Data Quality

Study Investigator: Tom Brott, MD

Project Updates

DEFUSE 3

Study Updates:

Study Project Manager: Stephanie Kemp, BS
Janice Carrozzella, MSN, CNP, RT(R), CCRA

Study Investigator: Greg Albers, MD
Data Manager: Jessica Griffin

Project Updates

ARCADIA

Study Updates:

Study Project Manager: Irene Ewing, RN, BSN

Study Investigator: Hooman Kamel, MD;
Mitch Elkind, MD

Data Manager: Cassidy Conner



ARCADIA Investigator Meeting Update

Atlanta Airport Marriott Hotel

- Free shuttle to and from the airport
- Nov. 16th 7-9pm Reception with appetizers and Cash Bar
- Nov. 17th 7am check-in and breakfast
- Meeting starts at 8am-Protocol review for entire group (will count as your protocol training)
- 1pm Breakout session

Project Updates

Recognized NIH Trials

Study Updates:

- POINT
- SHINE
- ATTACH 2
- MISTIE 3
- RHAPSODY



NCC Updates

(Forum for CC to communicate to coordinators information on reminders, common questions/issues, changes, suggestions, best practices, upcoming meetings, and for coordinators to ask questions):

NCC Staff Members:

Joe Broderick, PI

Jamey Frasure, Co-Director

Judith Spilker, Co-Director

Sue Roll, CIRB Liaison

Keeley Hendrix, CIRB

Diane Sparks, Contracts, Mgr. Kelly Reinert, Contracts, Asst.

Mary Ann Harty, Finances

Jeanne Sester, Training Coordinator

Rose Beckmann, Administration

Data Management Center Updates

(Forum for MUSC to communicate to coordinators information on reminders, common mistakes, changes, suggestions, best practices and for coordinators to ask questions):

WebDCU/MUSC Team:

Yuko Palesch, PI

Catherine Dillon, Operations Mgr.

Wenle Zhao, PI

Jessica Griffin, Data Mgr.

CIRB Updates

CIRB Team Members:

- Sue Roll, CIRB Liaison
- Keeley Hendrix CIRB Coordinator
- Jo Ann Behrle CIRB HPA



Roundtable Discussion

- **Today's Roundtable Discussion:** "Challenges and Opportunities for Research With a 24/7 Stroke Research Coordinator Pool".
- **Today's Host:**
 - Kathleen Miller, BSN, CCRC
 - University of Minnesota
 - StrokeNet/NETT Research Project Manager

Challenges and Opportunities for Managing a 24/7 Research Workforce

Kathleen Miller, BSN, CCRC
University of Minnesota

Department of Emergency Medicine and Neurology

StrokeNet Project Manager (2016 - present)
NETT Project Manager (2007-2017)



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Objectives

- Describe challenges to developing and managing a 24/7 research workforce within a university and a research network
- Identify potential opportunities to leverage resources within your institution and/or research network to create a 24/7 workforce
- List and discuss financial considerations
- Discuss staffing and other considerations



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“Necessity is the Mother of Invention”

- “When the need for something becomes imperative, you are forced to find ways of getting or achieving it.”^[2]
- *Many thanks to Irene Ewing (Cincinnati) and Katie Lamond (Penn) for their support and ideas.*



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The Need for 24/7 coverage

- NETT studies rely solely on emergency enrollments.
- NETT PI expectation of no missed enrollments.
- Need each site to be successful and contribute to overall Hub/RCC performance.



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Weigh the risk/benefits

Benefits

- Frequent enrollments can improve efficiency, support more staff
- Several ways to cost share.

Risks

- Study budgets are getting tighter.
- Studies end early and causes fluctuation in # of studies that need 24/7 coverage



Challenge: Sustainable funding

- Enrollments are primary funding source.
- 1-2 low enrolling studies cannot support 24/7 coverage
- A single site cannot likely support 24/7 coverage without other “costs”
 - Staff turnover due to burnout and/or lack of compensation for taking call.



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Requires Ongoing Investment

- Cultivate a well trained, seasoned staff.
- Takes time and money to on board new staff and to add new sites.
- Time to submit regulatory documents and trainings for multiple sites.
- Expense of on call pay (regardless of enrollments).



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Lack of enrollments have a cost too....

- If you don't enroll every 6 months....
 - It takes time and money to retrain entire research team.
 - May lose the study altogether at the site
 - Sponsor decision
 - Department's decision.



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Minnesota Model

- Created Internal Service Organization (ISO) within Department of Emergency Medicine (DEM) in 2010.
- ISO allows departments to contract with each other to provide professional services.
- Rates are established and approved annually based on actual costs.
 - Salaries, mileage, training



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ISO for 24/7 Workforce

- Full time/regular staff are hired through DEM or Neurology.
- On call only staff are “temp/casual”(non benefit).
- Work together to cover studies with 24/7 enrollments.



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24/7 Stroke Study Portfolio

- Stroke Studies: up to 3 sites within 12 mile radius of the university
 - ALIAS, ATACH 2, POINT, SHINE (for NETT)
 - DEFUSE 3 (StrokeNet)
 - Completed Industry: SWIFT PRIME, HEAT, LVIS



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Research Workforce Collaboration



**Department of Emergency Medicine
Medical School**
PI Michelle Biros, MD, MS
Co-PI Mustapha Ezzeddine, MD



**Department of Neurology
Medical School**
PI Mustapha Ezzeddine, MD
Co-PI Michelle Biros, MD, MS



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Opportunity: Leverage resources outside your department

- Collaborate with NETT or PECARN sites with coordinators providing 24/7 coverage
 - Experienced with stroke/neuro studies
 - Experienced with ED environment
- Collaborate with other departments that may provide or need 24/7 coverage (critical care, neurosurgery, trauma)
- Explore other networks at your institution



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Opportunity: Provide 24/7 service

- Develop your own workforce that could cover several of your RCC satellites after hours
 - Contributes to RCC overall success
 - Builds collaboration with the site
 - Hand on expertise from the RCC



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Opportunity: 24/7 coverage can become an asset

- Allows stroke investigators to take on new studies.
 - Ex: SWIFT PRIME (Business and Industry trial)
 - Experience with this study helped us get sites up and running faster for DEFUSE 3 since staff was knowledgeable.



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Neuro Expertise

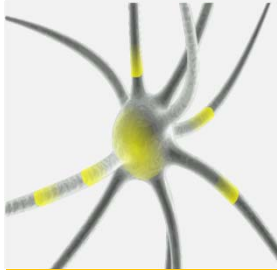
- Don't overlook value of your staff's neuro expertise in research
- Leads to other study coordination opportunities within your institution.
- Add studies that are less likely to need 24/7 coverage
 - Provides collaboration with other depts
 - Prepares you for future StrokeNet Studies



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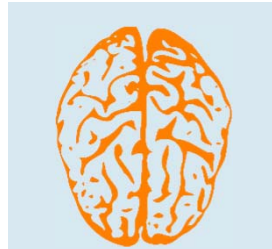
Who Do We Work With?



Neurology



Radiology



Neurosurgery



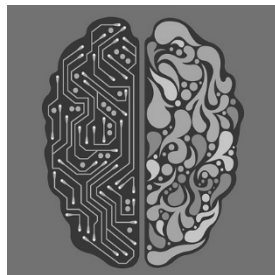
Experimental
Pharmacology



Physical Therapy



Epidemiology



Biomedical
Engineering



Kinesiology



Surgery



Dermatology



Think outside your box...

- Keep growing staff with neuro, ICU and ED expertise
- Add more studies to your portfolio
- Find existing research networks
- Develop an ISO so that other departments can use your expertise



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What next?

- The nitty gritty details...



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Cost Recovery: cost sharing

- 24/7 Studies share in the overall fixed cost (Roughly \$26,500/year)
 - Augment hourly pay: average \$3/hour
 - Includes 11 holidays at time/half
 - Monthly cost: \$2208
 - If three studies need 24/7 coverage
 - Cost to each study: \$720/month
 - If more than one site
 - Divide monthly cost (\$720) by # of sites



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Coordinator enrollment time

- Budget minimum of 4 hours for enrollment (our average time) or screen failure.
- Coordinator time charged to study ~ \$50/hour (ISO rate).
- Study is charged directly for coordinator time.



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Other costs for on call workforce

- Hiring, training - \$1500-2000 for first year/staff member. (Department expense)
- Extra administrative time for tracking detailed time sheets for billing
- Dispatcher/pager fees(\$110/month)



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How does staffing work?



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On call workforce expectations

- 12 hour shifts (7 pm – 7 am or 7am – 7 pm)
- Suggested # of shifts based for regular staff – averages 4 per pay period for .75 FTE
- Every 4th weekend (Friday 7 pm – Mon 7 am)
- One 3 day holiday weekend/year
- ON CALL only take the majority of after hours and weekend shifts.



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Regular coordinator staff

- Hired at 0.75 FTE (benefit earning)
- Hiring expectation to take “on call” shifts on regular basis
- Lead coordinators help to maintain expertise of all staff on studies
 - Take calls/texts from on call team as needed
 - Responsible for subject follow up



“On Call Only” workforce

- Hired as temp/casual employee.
- Paid for hours on call plus minimum of 4 hours when called to screen/enroll patients
- Scope of work: to get the enrollment done right!
 - Screen for eligibility, consent and complete randomization CRFs.
 - Hand off to lead coordinator after completing checklist.
 - Volunteer to perform blinded assessments



On call challenges

- Hire staff willing to take call
- Must be self directed staff member who can solve problems on the fly.
- Willing to travel to hospitals in the metro area and work seamlessly with staff
- Retaining experienced staff as their family needs change



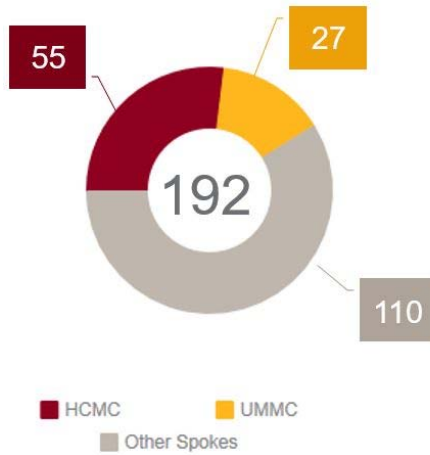
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Current NETT Studies

As of Oct 20, 2017 at 2:00 pm

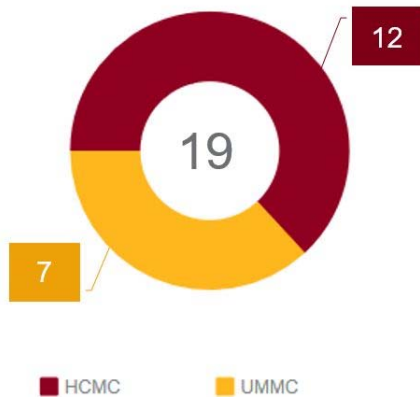
POINT Local Enrollment



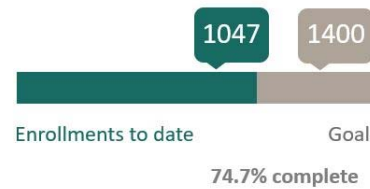
POINT International Enrollment



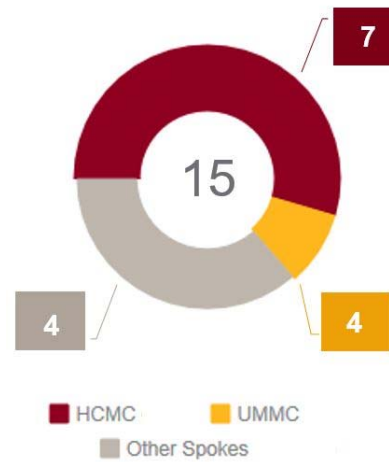
SHINE Local Enrollment



SHINE National Enrollment



ESETT Local Enrollment



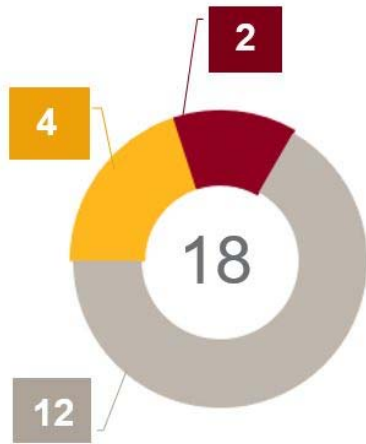
ESETT National Enrollment



Current StrokeNet Studies

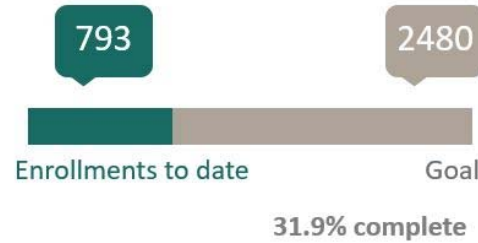
As of Oct 20, 2017 at 2:00 pm

CREST-2 Local Enrollment

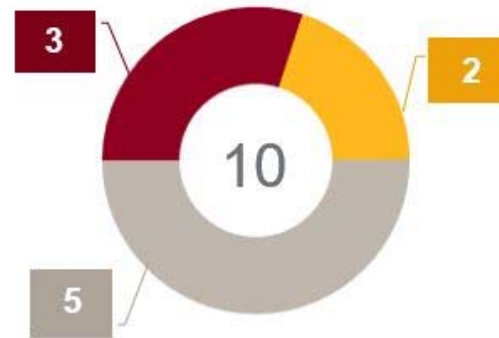


■ UMMC ■ HCMC ■ Other Sites

CREST-2 National Enrollment



DEFUSE 3 Local Enrollment



■ HCMC (30%) ■ UMMC (20%) ■ Other Sites (50%)

4 - HCMC – Consented not randomized
 3 – UMMC – Consented not randomized
 1 - Other Sites – Consented not randomized

DEFUSE 3 National Enrollment



Department of Neurology
 Medical School
 PI Mustapha Ezzeddine, MD
 Co-PI Michelle Biros, MD, MS



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**Thanks
for your
attention!**



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General Information and Updates

- Renewal Reminders:
 - No more than 25 RCC Sites, 7 new RCC sites have applied.
 - StrokeNet Educational Arm Trainee Awards:
- Some general principles for use of these funds:
- There is not a requirement to use these funds in Year 1. Unused funds can be requested for carryover in future years of the award.
- NIH StrokeNet is anticipated to become very active with the initiation of several large clinical trials. Your research staff may need additional training to properly manage these studies. The unused funds can be used to support these additional needs.
- The re-budgeting of funds designated for trainee salary support can't be approved for tuition or living expense stipends.
- Any questions about allowable use can be directed to Joanna Vivalda.



General Information and Reminders

- No QAR due in October!
- Next months presenter is Kinga Aitken.
- No December CC planned. January In- person Meeting.
- Presenters for upcoming meetings (Help wanted AD posted here).
- Agenda items for the LA Managers Breakout Session.

