Coordinator Webinar and Round Table Discussion

September 27, 2017

Coordinator Call Announcements and Reminders

Next Coordinator Webinar :

- Round table Presenter: Kathleen Miller BSN, CCRC

  University of Minnesota

Discussion:

"Challenges and Opportunities for Research With a 24/7 Stroke Research Coordinator Pool"

  Wednesday, 25-October 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.

Project Updates
TELE-REHAB

<u>Study Updates:</u>

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

<u>Study Updates:</u>

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
ARCARDIA

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

Investigator Meeting Breakout sessions

➢ Physicians- Ancillary studies, publications and strategies for recruitment and medication adherence

➢ RCC manager and Site coordinators:

❑ WebDCU™

❑ ARCADIA Cores- Lab, ECG, ECHO- collection, shipping data entry

❑ Study Drug Accountability, shipping, storage, tracking

❑ CIRB –review submission documents

Study Start-up

- The Protocol Trial Agreements are being reviewed by legal at UC and will then go to NINDS for quick review.
- The first cohort of 30 sites will start receiving their PTA around mid October.
- IRB submission packets will go out to the first Cohort around the same time. (Minor edits to the protocol and ICF being made now)
- These documents will be sent out to the second Cohort 2-3 weeks after that and the 3rd and 4th Cohorts will follow in the same manner.
- This will allow NCC time to address any immediate trial agreement questions or issues before sending out another batch.

IRB submission Packet Contents

CIRB approved:
- Protocol
- ICF template with instructions for adding local language
- Pregnant Partner ICF Template
- Prohibited Medication List
- Wallet Card
- Subject Information Sheet
- Patient Visit Reminder Language for letter/email
- Certified Letter for Lost to Follow-up
- Primary Care Physician notification letter

Local Site Context Form (To be completed with your local HRPP, Office of Research, IRB or equivalent)

Readiness Calls

- There will be no **Site Initiation** visits.
- Instead of an in person visit, there will be a **Readiness Call** with each site.
- Ideally the site PI, Site primary coordinator and a pharmacy designee should be on the call at the very least. The RCC manager is also encouraged to be on the call with their sites.
- A copy of the checklist for the Readiness Call will be posted in WebDCU under ARCADIA/tools/project documents.
- RCC managers may need to assist newer sites on completing this checklist.
- Study drug will be shipped overnight to a site once the Readiness Call is complete and the site is officially released to enroll.
- Sites must have a current shipping address uploaded to Webdcu™ for study drug and lab supplies (lab supplies can be shipped once the PTA agreement is signed).

ARCADIA /Toolbox/Project Documents

WebDCU^{TM}

List: **Project Documents**

Help

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#	Category	Document	File	Version	Status	Document Date
1	Instructions	StrokeNet WebDCU User Manual	F1006.pdf	5	Current	18-May-2017
2	Regulatory	ARCADIA Regulatory Document Parameter Guidelines for WebDCU	F1008.pdf	1	Current	25-Apr-2017
3	Protocol	ARCADIA Protocol Amendment 1	F1009.pdf	1.1	Current	07-Jul-2017
4	Regulatory	CIRB approval letter for Amendment 1	F1010.pdf	1.0	Current	10-Aug-2017
5	MOP	ECHO Core Lab Manual	F1011.pdf	1.0	Current	08-Aug-2017
6	Instructions	ARCADIA Frequently Asked Questions List	F1013.pdf	1.0	Current	18-Sep-2017
7	MOP	Lab Manual	F1014.pdf	1.0	Current	21-Sep-2017

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):

<u>NCC Staff Members:</u>

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   Wenle Zhao, PI

Catherine Dillon, Operations Mgr. Jessica Griffin, Data Mgr.

CIRB Updates

<u>CIRB Team Members:</u>

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

Roundtable Discussion

StrokeNet Manager Breakout Session Planned for Atlanta Meeting

Network success over the past 5 years and plans for the future funding period:

NCC/NINDS Perspective- Leaders: Judy Spilker and Jessica Griffin

RCC PM Perspective: (ALL Managers who want to contribute to the discussion).

Operational Issues:

 Communications: Best practice ideas and challenges that still might remain. Observations regarding the NCC, RCC, Satellites and CPS sites including site engagement: Leaders: KINGA AITKIN, Preethy Feit and Kathleen Miller.

 Satellite growth Pro's and Con's: Leader: D. Haney.

Communication Challenges

in a Virtual Network

- Our StrokeNet Network is comprised of many entities each with its own distinct scope of work.
  - o NCC, RCC, Satellites,DCU, NIH-NINDS, Sponsors, cIRB

  - o Each partner entity has engaged personnel with expertise
    - Contracts
    - Project Managers
    - Clinicians
    - University and site departments: SPA, Finance, IRB
    - Administrative staff: communications

How can we direct the flow of information more effectively to improve performance?

- NCC to RCC
- NCC to Satellite
- RCC to Satellite
- NCC/RCC to prospective Satellites (those not yet involved in clinical trials)

Challenges of
Virtual relationships

- NCC, DCU communications to Satellites: High tech and low touch.
  - o Transactional (MTA, PTA, RA)
  - o Finances
  - o Granting WebDCU permissions

  - o Communication is primarily done by email or webinar.
  - o Satellites may never "meet" the end user.
  - o Expertise use of "lingo" may impede communication.
    - Satellites may be new to research and have less sophisticated internal capabilities.
    - Network participation is unfamiliar in itself.

RCC- Satellite Communication

o RCC PIs and PM are the faces of StrokeNet
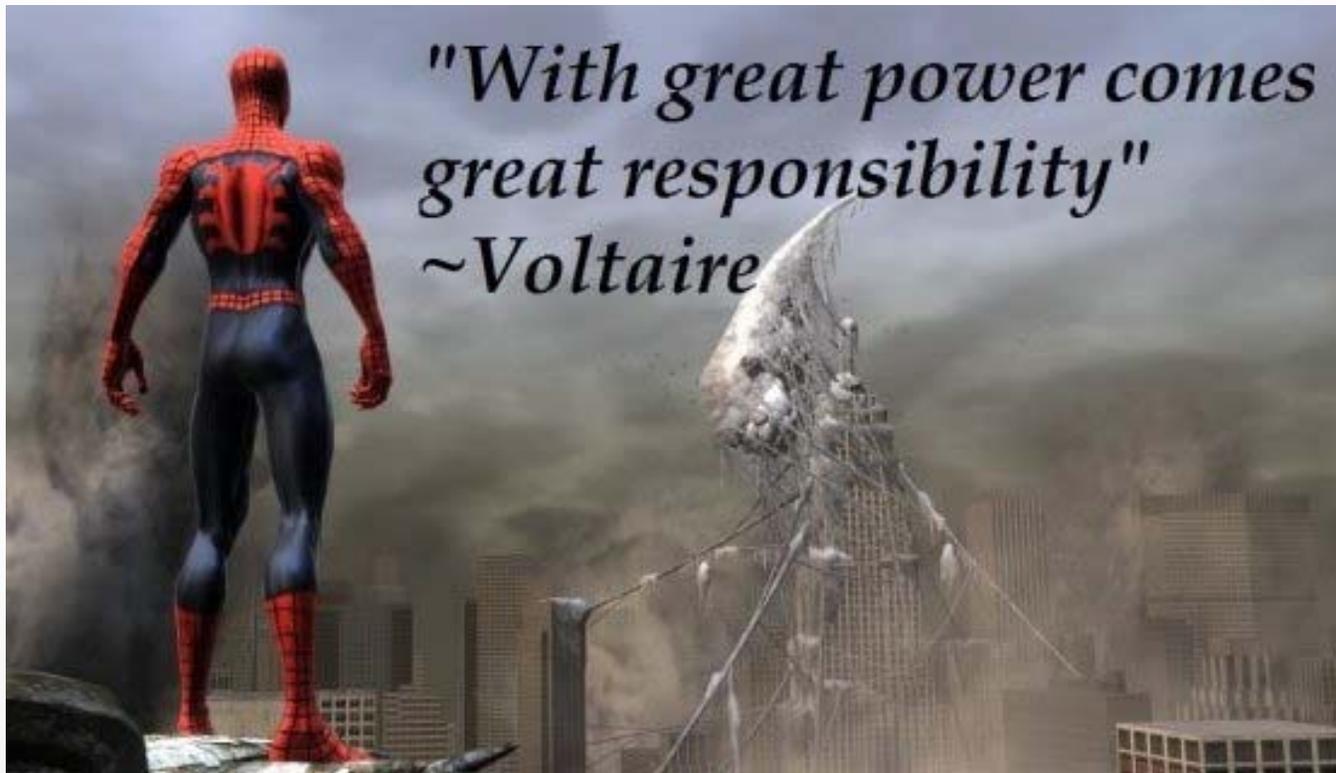
RCC- Satellite Communication

- **Knowledgeable**
  - o RCCs recruited the Satellite, have long standing working relationships, they "know" their sites.
  - o RCC PM has to know the ins and outs of all trials conducted at satellites sites

- **Available**
  - o More likely to pick up the phone to solve an issue or meet with them in person.

- **Proactive**
  - o Through regular, balanced communications

- **Engaging**
  - o find ways to motivate (e.g. incentives)- Preethy will cover

RCC- Satellite Communication

- Management SOP Outlines
  - o Frequency of communication
  - o Method of communication
  - o Expectations of satellites
  - o RCC responsibilities

Let's Tap the Potential of RCC Project Managers

- Keep RCC Project Managers (PM) in the loop with all communications at all levels
    - RCC PM may be able to provide information you need to resolve a matter very quickly with a phone call.
    - RCC PM can reach out directly to the correct person at the site. (Finance, IRB, PI)
    - NCC: Please inform us of situations where you perceive misunderstandings that are causing delays (ex: cIRB process)

General Communication

- Target the message to each audience
  - Biweekly bulletins have a lot of information that may include RCC action items.
    - Make it clear who is responsible for the action item.
    - Satellite coordinators who are trying to knock themselves out for StrokeNet have misinterpreted bulletin items and the "ask".
      - Feasibilities
      - Investigator meetings and StrokeNet meetings
    - Would it be possible to separate out information that StrokeNet sends to satellites v. RCC?

    - TIMING is EVERY THING
      - Please limit Friday afternoon communication drops
        - RCC's and Satellites have part time staff. Friday afternoon emails get less attention.

StrokeNet "Strong"

- To improve RCC performance with sites

- Include RCC project managers at every Investigator meeting(all clinical trials).
    - o RCC's are accountable for time to cIRB approval, time to first enrollment
    - o RCC's are accountable for site enrollments and data quality.
    - o RCC managers provide support to their satellites for logistics and problem solving
    - o RCC managers have less turnover than a satellite and will know the history for each satellite over the course of a trial.
    - o RCC can share suggestions as they engage with more than one site on a trial.

Engaging Sites without Trial Activity

- Educational Opportunities
- Patient characteristic data collection
- Other ideas?

Expanding Sites within the RCC
Pro's and Con's

- Sizing up your RCC : More is better vs. Lean and efficient.
- Site selections and what needs to be considered.
- RCC's with or without borders.
- Considerations: recruitment, study participation, costs.
- Administrative oversight, engagement challenges.

General Information and Updates

- Grant Renewal was due two days ago!

  Good Luck to all the RCC Sites

  - o Renewal reminders:
  - o This is an open Competition, Seamless Funding
  - o No more than 25 RCC Sites
  - o Still remains a 5 Year funding period
  - o Mechanism changing from U-10 to U-24
  - o Funding reduced from 250K to 200K.

General Information and Reminders

- Investigators meeting for ARCARDIA Trial Nov 17, 2017.
- IV meet and greet Nov 16th 7-9PM.
- No QAR due in October!
- Next months presenter Kathleen Miller
- Presenters for upcoming meetings.
- Agenda items for the LA Managers Breakout Session