NIH StrokeNet

PREVENTION | TREATMENT | RECOVERY

Coordinator Webinar

1/24/2024

MUSC MEDICAL UNIVERSITY of SOUTH CAROLINA

NIH

Funded by a grant from the National Institutes of Health

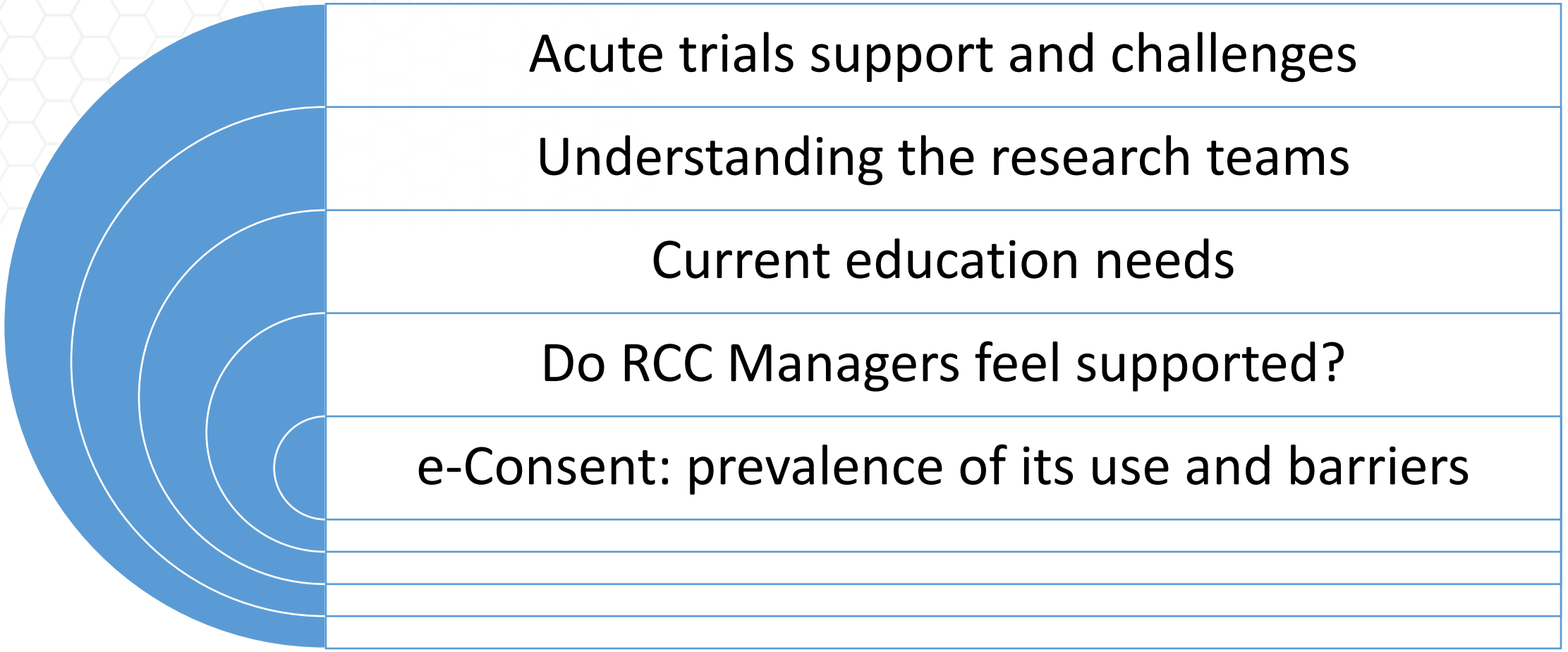
UNIVERSITY OF Cincinnati

Agenda for Today

- Update from the CRP Education and Training Core
- Brief StrokeNet Trial Updates
- Open Forum

Updates from CRP Education and Training Core

Discuss initial 5 take-aways from the RCC Manager calls



Acute trials support and challenges

9 RCC without 24/7 after hours coverage

- Not a dedicated 24/7 coordinator
- Not expected to come in over nights/weekend.
- No additional pay. Comp time is offered if the coordinator happens to stay after hrs
- IDS Pharmacy is expensive after business hrs
- Limited pharmacy hours
- Small team, no back-up coordinators

15 RCCs with 24/7 or limited after hrs coverage (7am-11pm or similar)

- Few sites have an actual call schedule for coordinators
- Higher salaries to compensate for on call
- Acute stroke recruitment is done remotely (clinicians are boots on the ground)
- Hard work/life balance for the 24/7 coordinators, lots of turn over
- Research pharmacy is 24/7
- The coordinator is on call 24/7 by their choice. No back up coordinator coverage

Understanding the research teams

- Have mix of RNs, CCRPs, non-licensed or certified research assistants, International medical graduates, post bac interns, etc.
- Clear career path- 3 levels of coordinators: 1. Entry level (e.g. RA1), 2. Experienced coordinators(e.g. RA2), 3.Research nurse coordinators.
- Some of the research coordinators do not have reliable clinical knowledge
- Most RCCs have CTSAs
- Optional training opportunities exist at most sites

Current education needs

- Short, pragmatic how-to videos and slides on basics (source documentation, how to make a correction, AE/SAE reporting, checklists)
- Reorganization of the existing resources and WebDCU Toolbox
- Re-naming of webinars, abstracting the education to a separate slide deck, # system to make it searchable by keywords
- One on one mentorship is helpful, should be consistent for all new RCC managers
- Strengthening stroke knowledge, SOC vs research, imaging, etc.
- Lunch and Learns, in person boot camps for coordinators/ managers where cases are discussed on a peer to peer basis
- Clear definition of roles and responsibilities between study team members (PI/SubI/fellow/manager/coordinators/trial specific central PM)

Do RCC Managers feel supported?

Yes- 21 RCC managers

- Engaged PIs who have great working relationships with Manager and team
- Supportive department that recognizes the hard work and prestige
- Weekly meetings with stroke attendings.
- Ability to work in a hybrid model has been helpful for work life balance.

No- 3 RCC managers

- Feels lost, did not get much education when transitioning to manager role.
- Concepts are a bit abstract.
- Past year has been hard.
- StrokeNet coordinator for a long time, regulatory duties are new and challenging
- Being understaffed.

e-Consent: prevalence of its use and barriers

Positives:

- Most RCCs and satellites have some version of eConsent currently approved for use
- Most sites are comfortable with remote consent and eConsent in the acute setting
- A few sites have dedicated tablets and are trying to use mostly eConsent
- Only 4 RCCs are paper only

Negatives:

- Challenging to use, especially in person, for older patients
- Some institutions strongly prefer paper for in person interactions
- Lack of dedicated tablet for research purposes

e-Consent needs

- Clear top to bottom expectation coming from StrokeNet
- Possibly providing a tablet to use for consent
- Educational session to increase comfort

StrokeNet Trial Updates

MOST

MOST
Multi-Arm Optimization of Stroke Thrombolysis

- MOST Clinical Database was locked 01Dec2023
- Currently in the process of closing sites
- Results from trial will be shared at 2024 International Stroke Conference in Phoenix, AZ on 07Feb2024 during Late-Breaking Oral Abstracts Session
  - Oral Presentations:
    - 12:14 PM MT: Multi-Arm Optimization of Stroke Thrombolysis Trial (Dr. Adeoye)
    - 4:45 PM MT: Outcomes of Patients With Endovascular Thrombectomy in the Multi-Arm Optimization of Stroke Thrombolysis Trial (Dr. Derdeyn)
  - Poster Presentation:
    - 7:00 PM MT: Argatroban And Eptifibatide In Addition To Intravenous Thrombolysis (Without Thrombectomy) In Acute Ischemic Stroke Patients (Dr. Grotta)
- Primary manuscript has been submitted, currently awaiting review

- Enrollments- 4,337
- Randomizations: 1,386/3,062 (45%)
- Planned Interim Analysis estimated to occur May 2024, anticipated DSMB recommendations June 2024
- Request for Continuing Review documents will be sent out early February
- Anticipate Kayla’s return early February

I-ACQUIRE

Perinatal Arterial Stroke: A Multi-site RCT of Intensive Infant Rehabilitation (I-ACQUIRE)

Principal Investigator: Sharon Ramey, PhD

This is a Phase III clinical trial to compare the efficacy of two dosages of a new infant rehabilitation protocol - I-ACQUIRE – to usual and customary forms of infant rehabilitation in infants who experienced Perinatal Arterial Ischemic Stroke (PAIS).

First Enrollment: 11/25/2019

Current Enrollment: Randomized 80.83% (194 / 240) of recruitment target.

TRANSPORT2

TRANScranial direct current stimulation for POst-stroke motor Recovery - a phase II sTudy (TRANSPORT2)

Principal Investigators: Wayne Feng, MD, MS;
Gottfried Schlaug, MD, PhD;
Caitlyn Meinzer, PhD

TRANSPORT2 is a phase II multi-center transcranial direct current stimulation (tDCS) dosing selection study based on the preliminary efficacy, safety, tolerability and feasibility.

First Enrollment: 9/9/2019

Current Enrollment: Randomized 91.47% (118 / 129) of recruitment target.

SATURN & SATURN MRI

- Current SATURN Subject Enrollment- **498/1456**
- Current SATURN Sites Released to Enroll –
  - **105 (97 US/ 8 Canada/ 0 Spain)**
- Current SATURN MRI Subject Enrollment- **176/894**
- Current SATURN MRI Sites Released to Enroll- **64**
- **SATURN has regulatory approval and executed CTA to move forward with 30 sites in Spain; the first site should be Released to Enroll by the end of the month**

ASPIRE

- Subjects in the ASPIRE trial are survivors of Intracerebral hemorrhage (ICH) who have atrial fibrillation (AF)
- Study is comparing anticoagulants in patients with AF after ICH
  - Subjects randomized to receive 5 mg apixaban BID or 81 mg ASA QD
  - Subjects are followed for outcomes up to 36 months
- Study target is 700 randomized subjects
  - Study is currently close to 40% total enrollment
- ASPIRE is still adding interested sites – ASPIRE@yale.edu
- Join us (with SATURN) for our ISC event –
  - Tues, Feb 6 @ 5:30 Sheraton Phoenix Downtown, North Mountain space

ASPIRE

FASTEST

- Current Subject Enrollment- **357 (100 US/257 OUS)**
- Current Sites Released to Enroll -**83 (47 US/ 36 OUS)**
- US sites CIRB approved **- 48**
- US MSU's Released to Enroll- **12 (10 US/ 2 OUS)**
- Continuing Review in the US completed **new exp. date 08Jan 2024**
- OUS countries working to complete annual review **Canada, Japan**
  - **EU complete.**
- v2 MOP released last week. **Now available in the Toolbox in WebDCU**
- 36 sites in US approved for EFIC **20 sites working to complete events**

CAPTIVA

- Subjects Randomized: **300**
- Sites Released to Enroll: **103**
  - Sites in startup: **15**
  - CIRB Approved/Submitted: **112/115**
  - CTAs Executed: **116**
- Continuing Reviews due February 16, 2024 (exp 08Mar2024)
- Canadian expansion underway – first site to open in March
- Welcome new CCC PM, Christina Marchese!

CAPTIVA CCC Hotline: 888-351-7776

***for urgent questions*

CAPTIVA-MRI

Comparison of **A**nti-coagulation and anti-**P**latelet **T**herapies for **I**ntracranial **V**ascular **A**therostenosis- **M**agnetic **R**esonance **I**maging

PIs: Dr. Adam deHavenon, Dr. Sepi Amin-Hanjani, Dr. Rano Chatterjee, Dr. David Liebeskind

- 9 sites have confirmed participation
- 4 sites have CIRB approval
- 3 sites have FE CTAs
- 2 sites have completed NOVA installation
- 1 site has completed their vwMRI Protocol Build
- We hope to have the first sites released to enroll in February
- CAPTIVA-MRI Investigator Meeting at ISC in Phoenix, Arizona for participating site PIs/Coordinators, February 7, 5-6 pm MST, please don't forget to RSVP

VERIFY

Validation of **E**arly Prognostic Data for Recovery Outcome after Stroke for Future, Higher Yield Trials (VERIFY)

Principal Investigators: Pooja Khatri, MD, MSc, UC
Steven Cramer, MD, UCLA
Cathy Stinear, PhD, University of Auckland
Achala Vagal, MD, MS, University of Cincinnati

First enrollment: 7/28/22

Current enrollment: 24.81% (163 / 657) of recruitment target

RHAPSODY-2

RHAPSODY-2

- We remain on pause.
- No word on whether or not USC has completed their investigation.
- We have been assured by NIH that we will be able to pay those sites who met the criteria for start-up payments prior to the 11/16/23 Stop Work order, but we have not been told when we will be able to do that.
- We will send out communication when we know more

SISTER

By the numbers

Sites Participating = 44

CDAs Executed = 42

cIRB Approvals = 10; pending = 5

CTAs Executed = 18

Dates to Remember

1/18/2024 – IM completed

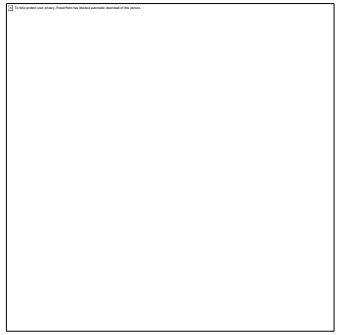
2/8/2024 – Mixer at ISC

3/6/2024 – Study Kick-Off Call

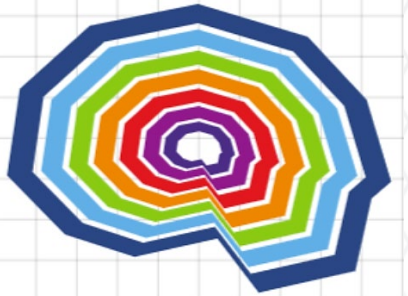
Updates

- Mods to PRIME protocol & ICF to be submitted per DSMBs recommendation which will cause mods to site's ICF
- Will start completing readiness calls at end of February and will ship drug immediately after the call
- WebDCU may not be totally ready when sites are released to enroll so may have to use paper documents for data collection
- May go to Canada, Europe & Australia for additional sites

SISTER is on X



STEP



- MUSC received the NOA and is working on the subcontracts
- The first 25 STEP sites have been selected and notified. The STEP PIs are actively engaged in selecting the remaining sites.
- The Master and Domain A protocols/consents/etc were submitted to Advarra on 1/19/23
- Actively working on the CTA, Parameters Document and the rest of the Regulatory Documents in preparation to send to the selected STEP sites.
- There will be a STEP presentation at ISC on 2/8 from 9:15-10:45

FOCAS

Focal Cerebral Arteriopathy Steroid (FOCAS) Trial

PI: Dr. Heather Fullerton

- 29 Sites (27 U.S. Sites and 2 Canadian Sites)
- **5 Sites Released to Enroll**
- 2 sites are expected to be Released to Enroll by the end of January
- An additional 13 sites are expected to be Released to Enroll in February/early March
- 14 CIRB approved; 3 pending submissions
- 13 FE CTAs
- Open Office Hours – January 24, 1 pm PST / 4 pm EST
- FOCAS Investigator Meeting, February 6 at ISC in Phoenix, Arizona – Time: TBD

Open Forum