NIH StrokeNet

PREVENTION | TREATMENT | RECOVERY

Funded by a Grant from the National Institutes of Health

Coordinator Webinar and Round Table Discussion

November- 15, 2017

Coordinator Call Announcements and Reminders

Next Coordinator Webinar :

- No Coordinator call for December.
- Januarys call will be held as the in-person meeting in LA.
- Februarys call still TBD

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

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:**

"How to manage a Research Team"

Today's Host:

Kinga Aitken, MPH CCRP
UT StrokeNet, Research Associate
Department of Neurology
University of Utah School of Medicine

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Our Team

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My Role

- Bridge the gap
- Create and Implement Processes
- Ensure:
  - Sound conduction of all trials
  - Regulatory maintenance
  - Financial oversight
  - Training
- Keep team motivated

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Processes and Responsibilities

Coordinators

- Each coordinators is a lead on several trials
- Rotate in taking call (nights and weekends)
  - Responsible for successful, correct enrollment
  - Hand-off to lead coordinator
- Rotate on a weekly basis for subacute trial screening

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Enrollment

- Collaborative effort
- Enrollment packet
  - Latest v. ICF
  - Inclusion/ Exclusion form
  - NIHSS
  - +/- drug order
  - Imaging
- ICF script

  (for internal use only!)
- Enrollment binder

Name of study: ***
Subject`s initials: ***
DOB: ***
Consent provided by: patient/ LAR
Is reconsent necessary (when initial consent obtained from LAR): Y/N*
Consent obtained: in person/ fax-phone
Consent version: *** (date or version #)
Date: *** Time: ***
Study ID: ***

Consent was thoroughly reviewed with ***on ***, including study procedures, risks and benefits, other options for treatment, and that participation is voluntary with the right to withdraw at any time without consequences. Ample time was given for decision making; all questions were answered by the enrolling physician, *** and site coordinator, ***. Subject eligibility per Inclusion and Exclusion criteria with data available at time of consent was confirmed by the enrolling physician. *** was able to sign the consent form on *** at ***. A signed copy of the Consent was provided to ***. No study procedures were performed prior to the completion of the consent process.

Signature of person who verified the above items were completed, ***
Date: ***

Signature of Enrolling Physician, ***
Date: ***

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Acute Trials

Time since onset (hrs)	NIHSS		
	<5		
	Odd days	Even days	>=5
0-3	1- [redacted] 2- [redacted]	1- [redacted] 2- [redacted]	1- [redacted] 2- [redacted]
3--6	1- [redacted]	1- [redacted]	1- [redacted]
6+	1- [redacted]	1- [redacted]	1- [redacted] 2- [redacted]

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All Trials

Stroke Center Study Summary Card			
ACUTE STUDIES	**SHINE**	**DEFUSE 3 (on hold)**	**CHARM (coming soon)**
Age	≥ 18 (no upper age limit)	18-90	
NIHSS	3 - 22	≥6	
Time to Enrollment	≤12 hrs	IR initiated in 6-16 Hrs from LKW	
Other Eligibility	POC glucose: >110 w/DM, ≥150 w/o DM, upper limit 400	ICA or MCA-M1 occlusion; Target Mismatch Profile on CTP or MRI	
PI	Dr. Wold (Pg) (Cell)	Dr. de Havenon (Cell)	Dr. Majersik (Pg) (Cell)
STUDY HOTLINE	800.915.7320 Ext. 1	1-844-250-9300	
To determine eligibility, please contact:			
Kinga Aitken, StrokeNET Research Associate,			
Crystal Neate, Study Coordinator,			
Ka-Ho Wong, Study Coordinator,		Updated 6/12/2017	

Stroke Center Study Summary Card				
Type	**Recovery**	**Preventative**		
Study	**MEMANTINE**	**CREST 2**	**Navigate (ESUS)**	**ARCADIA (start-up)**
Age	≥18 (no upper age limit)	≥35	≥50	
NIHSS	<20	N/A (mRS= 0 or 1)	N/A	
Time to Enrollment	3 days- 8 weeks	screen within 180d of last DUS; randomize 30d after screening; procedure within 14 d of randomization	screen within 6 wks of stroke onset randomize at end of screening	
Clinical Dx	Supra-Tentorial Stroke or hemorrhagic (ICH) stroke	Asymptomatic High Grade Cervical Carotid Artery Stenosis	TIA, AIS, not lacunar	
Other Eligibility	Fugl-Meyer UE ≤50 and/or LE ≤28	No TIA or stroke ipsilateral to the stenosis ≤180 days of randomization	No Afib on ECG or episodes of AF lasting 6 min or longer after ≥24 Hrs cardiac monitoring	
PI	Dr. Majersik (Pg) (Cell)	Dr. Majersik (Pg) (Cell)	Dr. de Havenon (Cell)	Dr. Peter Hannon
STUDY HOTLINE	N/A	Clinical Coordinating Center 1-800-506-4981	Clinical Coordinating Center 1.800.607.2528	

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Post-Enrollment checklist

- For coordinators

Post Enrollment Checklist

- ✓ Give pt a copy of the signed/ dated consent form
- ✓ Put together statement of consent process
- ✓ Add EPIC note- use .studyconsent smartphrase
- ✓ Enroll pt in uTRAC
- ✓ Scan ICF and statement process into the shared drive
- ✓ Place copy of ICF into Kirby`s Inbox to be scanned into the Media tab of the pt`s chart in Epic
- ✓ Email update to the team re. the new enrollment

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Follow-up

- Study specific templates

Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis (CREST2) an RCT

Visit follow-up ***

Interval Medical History: ***

QVSS: ***
NIHSS: ***
mRS: ***
Blood Pressure: ***; ***; ***
Mean Blood Pressure: ***
Carotid Ultrasound: ***
Labs: ***
Medications were reviewed with pt.
Medications of study interest: ***
AE/SAE of study interest:

Comments: ***

Regulatory

- eBINDERS

GlobalHealthTrials.org

Regulatory Binder Table of Contents

Please file the following behind each of the corresponding tabs.

1- Study Logs	• Master Subject Log—list all subjects screened, regardless of their enrollment status • Randomization, screening and enrollment reports • Enrollment confirmation faxes • Site Visit Log—signatures of monitors, auditors, all other personnel performing a site visit • Clinical Trials Responsibility Log—list name, signature, and initials of all personnel who perform study-related procedures
2- Protocol	• Protocol • Amendment(s) • Signature page(s) for the protocol and any amendments
3- Investigator Drug Brochure	• Investigator drug brochure and signed receipt form • IND Safety Reports
4- Informed Consent	• IRB approved versions of consent forms (blank forms) • Signed informed consent forms (if filed elsewhere, please provide memo stating the location of the signed forms)
5- Competent Authority Regulatory Approval Documentation	• Initial notification/approval (not applicable for US and Canada) • Ongoing notification/approval (not applicable for US and Canada) • Interim/annual reports (not applicable for US and Canada) • Signed agreement between Investigator/Regulatory Authority (not applicable for US and Canada) • Other regulatory related documents (not applicable for US and Canada)
6- IRB/IEC Approvals	• IRB/IEC approval letter (original) or Research Ethic Board Attestation (Canada) for protocol, for consent form(s) and any amendments identified by protocol number and/or title and date of approval • Patient recruitment advertisement approvals and corresponding IRB/EC letter(s) • IRB/IEC membership information and/or general assurance number
7- IRB/IEC Communication	• IRB/IEC correspondence—letters of submission and approval notices • IRB/IEC notification of and responses to serious adverse events at your institution • Documentation of submission of safety reports to IRB/IEC and IRB/IEC responses • Progress reports and annual IRB/IEC renewals • Close out/final report notice
8- FDA 1572/Regulatory Forms	• Form FDA 1572 and updated forms • Financial disclosure for all principal and sub-investigators
9- Curricula Vitae (CV)	• Curricula vitae for all principal and sub-investigators and site staff • Medical licensure number, medical specialty, and board certification number (if applicable) for all principal and sub-investigators
10- Drug Accountability*	• Study-agent accountability logs • Study-agent order forms • Study-agent shipment records • Disposition and/or return of unused or damaged study kit records
11- Laboratory	• Laboratory accreditation/certification for all laboratories listed on the Form FDA 1572 • Lab normal ranges for all tests performed in study

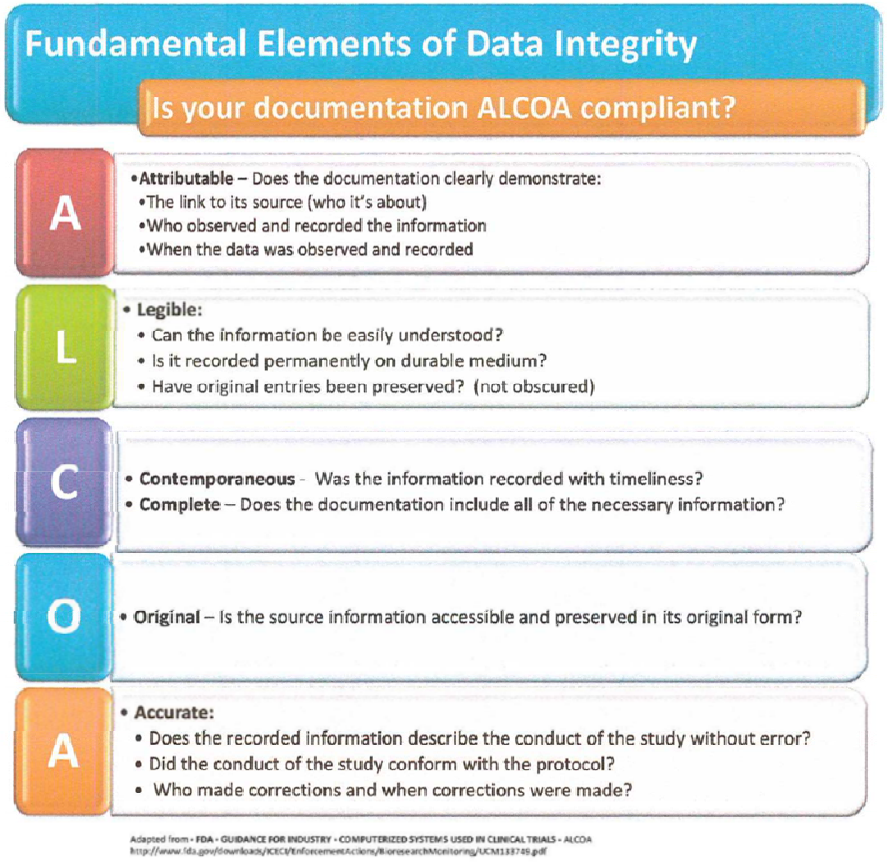
*Maintain drug accountability in the pharmacy manual over the course of the trial; at trial completion, file all records here or place a note stating the location of the forms.

GlobalHealthTrials.org

Regulatory Binder Table of Contents

12- Serious Adverse Events	• Master serious adverse event (SAE) reporting form and instructions for completion • Completed patient SAE forms—if filed elsewhere, insert a note in this section indicating where they may be found. • Related correspondence
13- Training	• Site initiation visit (SIV) attendance log • Trial-related training certificates
14- Trial Agreements	• Signed Clinical Trial Agreement (If Clinical Trial Agreement is filed elsewhere, insert a note in this section indicating where the contract is located) • Signed Confidentiality Disclosure Agreement (If CDA is filed elsewhere, insert a note in this section indicating where the CDA is located)
15- Regulatory Inspections/Audits	• Correspondence relating to inspections and audits
16. Guidelines	• ICH Guidelines • Declaration of Helsinki • Country specific regulations/guidelines (where applicable)
17. Country-Specific Documents	• REB attestation (CA) or equivalent • Qualified Investigator Undertaking • Clinical Trial Site Information Form
18. Correspondence	• Study related communication (letters, memorandums, written documentation of telephone conversations, facsimiles, newsletters, and copies of electronic correspondence) between the site and sponsor, coordinating center, contract research organization, etc. • Monitoring report copies

Data Integrity



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Training

- Consenting Training for MD
  - Yearly
  - Role play
- One on one WebDCU training
- Upkeep the skills of coordinators
  - RATS classes
  - One-on-one IRB, regulatory and uTRAC trainings.
- On site nurse training
- Weekly educational hour

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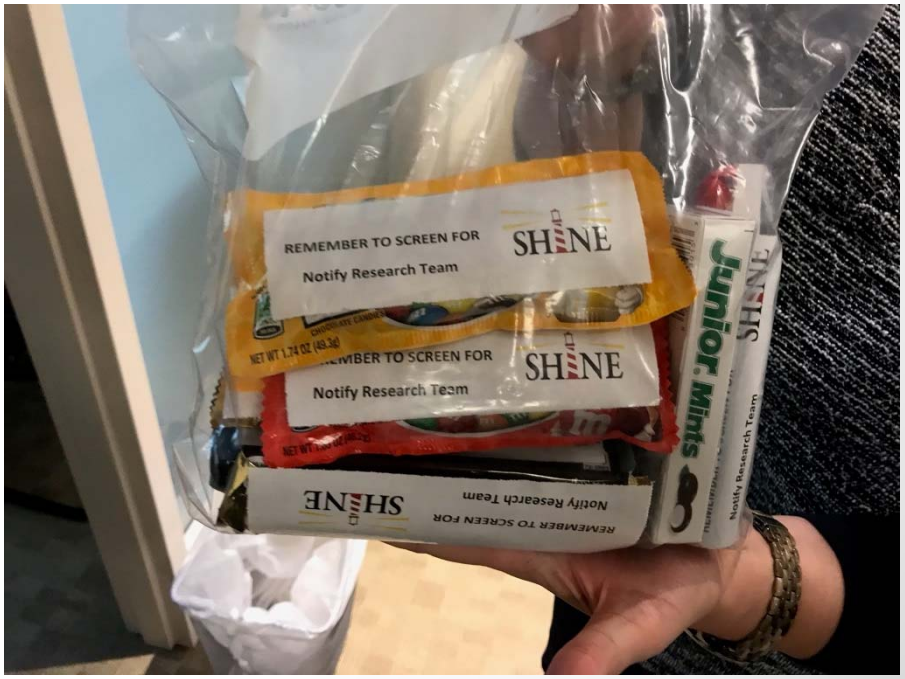
Motivation

- Recognition of excellent work
- Team building events



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Thank you!
Questions?

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General Information and Updates

- 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.
- Carry-over funding is possible.

General Information and Reminders

- Help Wanted:

Presenters for upcoming meetings in LA.

- Agenda items for the LA Managers Breakout Session.