Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

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Over the past few months, sites have put forth exceptional efforts towards enrollment and recruitment. Enrollment has started off strong in 2014, with 24 subjects enrolled in January, and 28 to date in February. Special congratulations to several sites who recently enrolled their first patient into SHINE: Valley Baptist, Long Beach, Summa, SUNY Downstate, and Kings County. Kudos to these sites.

Teams have also shown outstanding persistence in identifying patients who initially did not meet inclusion criteria but later reached eligibility. Many thanks to all sites who have shown such diligence and dedication.

The DSMB met earlier in January to review SHINE. The DSMB congratulated the team on the study's progress, and recommended the study continue as planned; no safety concerns were noted.

Also coming soon— a SHINE recognition point system will be introduced in the next few weeks. This point system is designed to highlight teams' hard work and exceptional efforts.
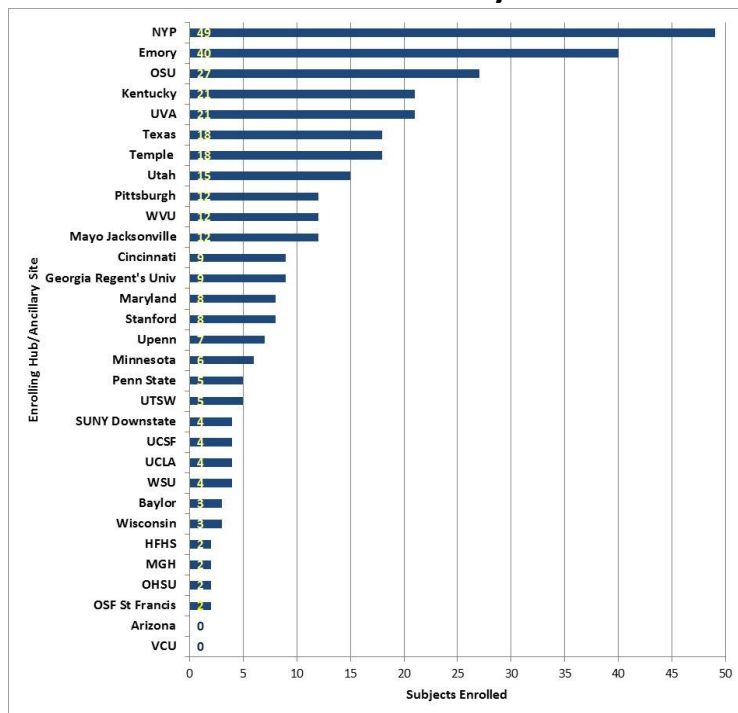
Thank you all for your continued commitment to the SHINE trial.

Karen C. Johnston, MD, MSc, SHINE PI
On behalf of the SHINE team

SHINE Enrollment Apr 2012—Feb 2014
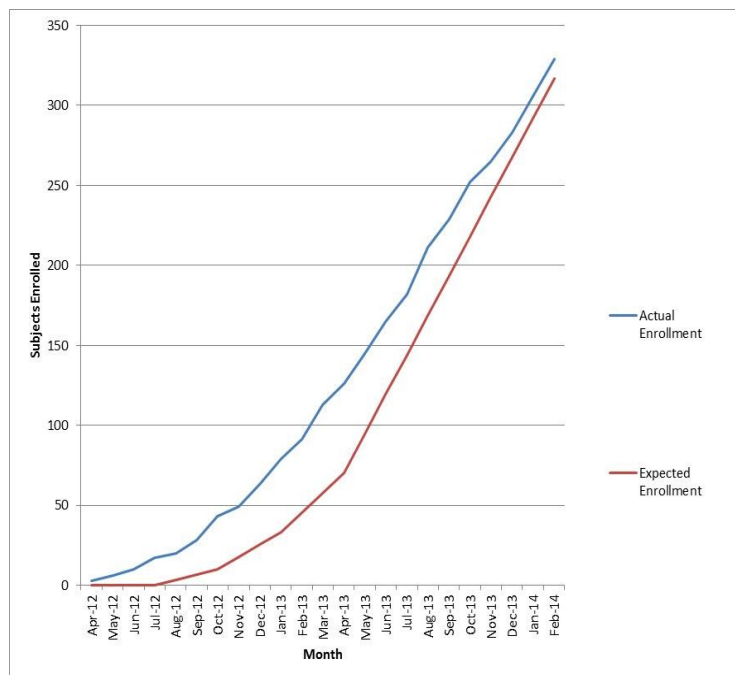
SHINE Enrollment by Site

*Data as of February 28, 12 noon ET

Meet Some of our SHINE Teams

Recent High Enrolling Sites
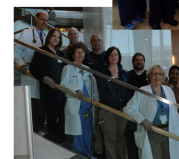

OSF

Stanford

SUNY Downstate

Valley Baptist

Overall Top Enrolling Sites

Ohio State

Columbia

Kentucky

Emory

The study teams listed above were featured on the SHINE ongoing clinical trials poster at the ISC for exceeding their previous highest monthly enrollment or as one of the lead enrolling sites for SHINE.

Thanks to all of the SHINE sites for their hard work!

Retention Tips and Strategies

As enrollment in the trial continues to steadily climb, we also want to make certain that we focus on retention and the importance of the study visits that happen after the treatment period ends. The following retention strategies can help foster a working relationship with enrolled patients which helps to ensure that we capture outcomes data.

During the hospital stay:

♦ **Engaging the study participant**— Be present and in contact with the study participant and their family as much as possible. Develop a positive relationship so that the participant and family feel comfortable approaching the study team with questions or concerns. Communicate the importance of what the they are contributing to.

♦ **Clearly explain their commitment to the study** — Remind them of the 6 week and 3 month appointments.

♦ **Contacts, Contacts, Contacts**— Obtain several phone numbers for the participant, family members, friends, neighbors, employers, or Primary Care Physicians. Note email and mailing addresses.

♦ **Provide hard copy resources**— Including appointment reminders and study team contact information.

♦ **Maintain a positive attitude**— In order for study patients to have a positive attitude about the trial, staff need to also have a positive attitude. Engage the clinical and nursing teams. Give positive feedback and encouragement.

In the follow-up phase:

♦ **Maintain personal communication between visits**

♦ **Be flexible and convenient when scheduling appointments**— Establish a working relationship with the clinic's scheduling team. Overlap study visits with other scheduled appointments. Offer to travel to the study patient's home if necessary.

♦ **Listen**—Be aware of concerns or sources of unhappiness or confusion with the participant.

♦ **Use medical records**— Patient lists may be helpful to see if a study participant has been admitted to the hospital between study visits.

♦ **Send educational and supportive study materials**— Send newsletters, clinical trials updates, notes of appreciation, etc. to keep the study patient and family informed and engaged.

Ways to locate lost subjects:

♦ **Use various modes of communication**— Utilize phone calls, emails, letters, etc.

♦ **Contact other sources close to the participant**— Locate a family member, neighbor, significant other, friend, or employer.

♦ **Contact the participant's physician**— Cross reference the participant's contact information with what their PCP (or other) has on file.

♦ **Use one of several search engines**:
   ♦ Search county public records online—
   ♦ http://www.whitepages.com
   ♦ http://publicrecords.onlinesearches.com/

Updates to the WebDCU Interface

WebDCU Home Screen
Click the WebDCU icon to access the home page. Here you can access individual trial portals (SHINE, POINT, etc.) and the NETT portal

Adding a Subject
The process to add a subject has not changed.
1. Select your spoke using the drop down box.
2. Enter the date.
3. Click "Add Subject"

Subject CRF Binder
Access subject CRF's to randomize a subject, and also access CRF's for the Baseline, Treatment Days, Week 6, Day 90, and End of Study visits

Screen Fail Logs
Find the Screen Fail Logs under the "Study Progress" Icon

Subject Visit
View completed and upcoming visit dates under "Subject Visit" within the "Study Progress" tab

Alerts
A red outline will appear when you need to address a query, such as a DCR

Actively Enrolling Sites
As of February 2014

Arizona	Arizona	SUNY	Maimonides
Baylor	Baylor*		Univ Hosp of Brooklyn*
Cincinnati	University Hospital*	Temple	Hackensack*
Emory	Emory University*		Temple*
	Grady Memorial*		Thomas Jefferson*
GRU	Georgia Regents*	UCLA	UCLA MC*
HFHS	Henry Ford*		Long Beach*
	Univ of Michigan*	UCSF	CPMC Davies
Kentucky	Univ of Kentucky*		CPMC Pacific
Maryland	Univ of Maryland*		San Francisco Gen*
Mayo Jax	Mayo Jacksonville*		UCSF Medical Center
MCW	Froedtert*	UPenn	Abington
MGH	Mass General*		Hospital of UPenn*
Minnesota	HCMC*	UT Houston	Austin Brackenridge*
	UMMC Fairview*		Austin Seton*
NYP	NYP Columbia*		Memorial Hermann*
OSF	OSF Saint Francis*		Valley Baptist*
OHSU	Harborview MC*	Utah	University of Utah*
OSU	Summa Akron City*	UTSW	UTSW-Zale*
	Wexner*	UVA	University of Virginia*
Penn State	Penn State Hershey*	VCU	VCU Medical Center
Pittsburgh	UPMC Mercy*	WSU	Beaumont Royal Oak
	UPMC Presbyterian*		Beaumont Troy
Stanford	Stanford*		Detroit Receiving*
SUNY	Kings County*		Sinai Grace
	Lincoln	WVU	WVU*

*indicates site with subject enrollment

Regulatory Document Reminders

Regulatory documents are required to be kept current for both spoke documents and people training documents during the course of the trial until study close out.

A Big Thank You to all sites for working really hard and keeping current with required training documents.

Sites' people documents and their statuses can be looked up in WebDCU in the NETT portal. Select "Regulatory Document", then "Required Docs People by Spoke". You can filter by status, team member's name, or expiration date.

I am glad to help with any questions you may have with regards to site regulatory compliance, training, etc.

Thank you all again!

— Arthi Ramakrishnan

Screen Fail Log Considerations

Screen fail logs are valuable tools for the study team to understand the patient population at your institution and help identify potential enrollment obstacles. Here are a few things to keep in mind:
1) Only include patients with:
   - A diagnosis of ischemic stroke
   - Present within 12 hours of symptom onset
   - A POC glucose level > 110 mg/dL
2) If you select "Other" as the reason, please provide a general comment to explain.
3) Submit your completed screen fail log by the 10th of the following month.

I-SPOT
Insights on Selected Procoagulation markers and Outcomes in stroke Trial

Total Enrollment: 33
I-SPOT Sites: 40

Many thanks to all participating sites for diligently screening and enrolling into I-SPOT!

— Hannah Reimer

Who to contact
Protocol questions - Amy Fansler - (434) 982-6027 or acf7h@virginia.edu
Regulatory & site readiness - Arthi Ramakrishnan - (734) 936-2454 or arthrama@umich.edu
Laptop questions- Amy Fansler - (434) 982-6027 or acf7h@virginia.edu
WebDCU support – Karen Briggs - (843) 792-3980 or briggsk@musc.edu
Education and training – Joy Pinkerton - (734) 232-2138 or joypink@umich.edu

24 hour emergency contacts:
SHINE Study Hotline – 800-915-7320 (Ext 1: PI on call, Ext 2: Safety Monitor)
WebDCU Emergency Randomization Hotline - 1-866-450-2016