Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

March 2018– Volume 6, Issue 2

IN THIS ISSUE

Spring is almost here and we are well into 2018. We enjoyed seeing many of you at the ISC in Los Angeles. We have now enrolled nearly 1100 subjects (total 1094) and are in the final stretches of the SHINE trial **#shinefinishline1400**. As per our recent discussions, our goal is for every site to enroll at least 1 subject every other month.

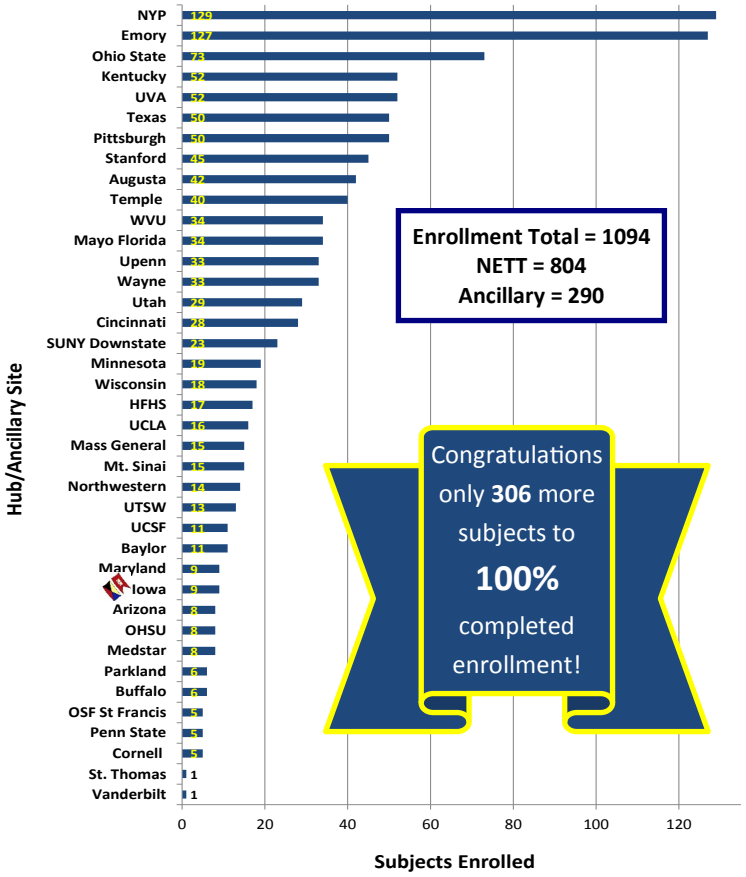
Please join us in extending our warmest welcome to our *newest* SHINE site, **Jackson Memorial Hospital** at the University of Miami! Currently, 45 sites are actively enrolling in SHINE. Kudos to all sites who met or exceeded their 2017 enrollment goals **(Augusta, Henry Ford, Univ. of Iowa, Ronald Reagan, and Northwestern)** and to all top enrolling sites **(Columbia, Grady, Henry Ford, Augusta and Stanford), and to all** actively enrolling sites! Thanks to all for your hard work.

Congratulations to our newest Bravo Zulu Flag Awardee: **University of Iowa!** In this issue, we are highlighting our 2018 enrollment goals, we share some best practices for retention strategies, and have some WebDCU™ reminders regarding team member changes. Lastly, a reminder regarding daylight savings time.

As always, we welcome your input on any issues or ideas related to SHINE. Thanks again for all your continuing efforts on SHINE.

Karen C. Johnston, MD, MSc, SHINE Administrative PI

SHINE Enrollment by Site through March 6th 2018



SHINE Population Demographics:

For those of you who missed the ISC's SHINE poster, below are the SHINE subject population demographics.

Characteristics	N = 1077
Median age (years)	66
Male (N, %)	585 (54%)
White (N, %)	689 (64%)
Black/African American (N, %)	310 (29%)
Hispanic or Latino (N, %)	166 (15%)
Past Medical History	
Diabetes mellitus type 2	855 (79%)
Enrollment Information	
Median eligibility glucose (mg/dL)	187
Median Stroke Symptom Onset to Randomization - minutes	423 (7:03 hours)
% Receiving IV tPA	676 (63%)
% Receiving IA mechanical treatments	132 (12%)
Stroke Severity	
Median NIHSS	7
NIHSS 3-7 (mild) (N,%)	546 (51%)
NIHSS 8-14 (moderate) (N,%)	314 (29%)
NIHSS 15-22 (severe) (N, %)	215 (20%)

2017's Enrollment Goal Achievers:

Hub	Site	#
Ancillary	Augusta	10
HFHS	Henry Ford	10
Ancillary	Univ. Iowa	5
UCLA	Ronald Reagan	5
Ancillary	Northwestern	4

2017's Top Enrollers:

Hub	Site	#
NYP	Columbia	20
Emory	Grady	19
HFHS	Henry Ford	10
Ancillary	Augusta	10
Stanford	Stanford	9

SHINE Bravo Zulu Award

Our sincere congratulations to the SHINE study team at the **University of Iowa,** this quarter's recipient of the SHINE Bravo Zulu flag. The Bravo Zulu flag is traditionally used by US Naval Forces to publicly recognize a job especially well done.

Kudos to the SHINE study team at the **University of Iowa** for exceeded their 2017 enrollment goal! This team always has a positive attitude, helpful team motivational strategies, and is extremely responsive to all queries. The SHINE leadership team thanks them for; their near perfect 90 day mRS retention rate and for their excellent data submission in window rate. It is this kind of commitment to the SHINE trial that will continue to make SHINE a successful study!

From left to right are the following: Daniel Anderson, MD; Jeri Sieren, RN; Erin Rindels, RN, MSN; Heena Olalde, RN, MSN; Sami Al Kasab, MD; Site PI: Kaustubh Limaye, MD

2018 SHINE Enrollment Goals

#SHINEfinishline1400

SHINE Enrollment How FAST Can we GO?

We have 45 sites actively enrolling, so *if all sites* enrolled <u>at least 1 every</u> other month ~ 22/month

#finishline **~14** *Months*

Heather M. Haughey, PhD, SHINE Project Director, 434-243-8065

Retention Strategies: Best Practices

The primary endpoint in SHINE is the blinded, in-person 90 day assessment of the modified Rankin Scale. The importance of capturing this blinded outcome is a top priority for the SHINE trial. We share the following suggestions and best practices as potential opportunities to improve retention:

- ***Introduce and emphasize the importance of follow-up at the time of initial discussion regarding SHINE trial participation*** – consider placing equal importance on acute management of blood glucose in the first 72 hours post-stroke and need for follow-up neurological assessment as requisites of study participation.
- ***Provide specifics of follow-up at time of consent*** – 6 week telephone follow-up & 90 day in-person follow-up.
- ***Explore potential barriers to follow-up at the time of consent*** – where does the patient live? How does the patient prefer to communicate? Email, text, phone? Does the patient have independent transportation or rely on alternative sources.
- ***Develop rapport with patient and family/friends during the course of acute hospitalization*** – identify the most reliable person to serve as a point of communication following hospital discharge. Establishing rapport during hospitalization may improve the probability of successful follow-up after discharge.
- ***At discharge, remind patient/family of importance and timing of follow-up*** – confirm best contact numbers, back-up numbers, email contacts and contact preference (phone, text, email).

Kevin Barrett, MD SHINE Recruitment PI

I-SPOT Status

Insights on Selected Procoagulation markers and Outcomes in stroke Trial

- 243 I-SPOT Subjects (94 IV tPA subjects)
- Enrollment Goals: 195 I-SPOT + 120 ISPOT-tPA for a total of 315 subjects
- SHINE subjects eligible for I-SPOT = 325
  - 240 Enrolled
  - 58 declined
  - 28 missed

Great job I-SPOTers!!

Thanks to the sites that enrolled this past month:

- Memorial Hermann
- Detroit Receiving
- NYP Columbia
- Augusta

Hannah Reimer, I-SPOT Project Manager

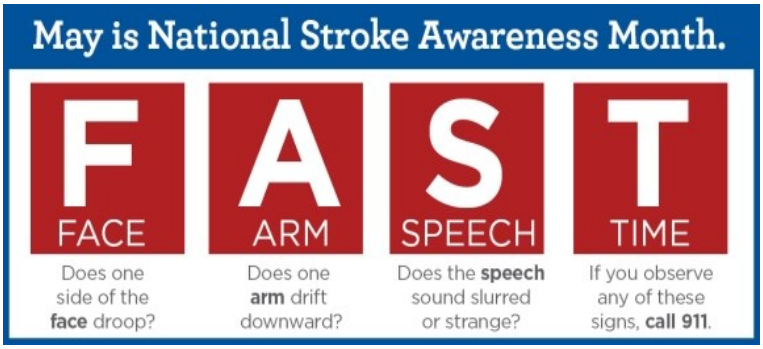
ISPOT study Hotline 1-774-234-7768

WebDCU™ Reminders: Team Members Changes

Add all new team members to 'Study Team Member Request' table and also 'Request User Permissions' as appropriate to their role. In addition, the team members will need to be added to the eDOA log with start date along with study responsibilities. After the eDOA is accepted, required trainings will populate in the database. Following these steps helps everyone ensure regulatory compliance for trainings and certifications are reconciled and current in the database for the new team member.

If a team member has departed, steps are posted in the SHINE FAQs to make them inactive and remove their access and permissions to WebDCU™ SHINE. In addition, follow local IRB guidelines for team member changes, as applicable. Upload the acknowledgement from IRB as "IRB Modification Notification". Link to regulatory database FAQs: https://nett.umich.edu/clinical-trials/shine/faqs#RegDatabase

Questions? Contact — Kavita Patel, pateka@musc.edu



SHINE and Daylight Savings Time

Daylight saving time begins on **Sunday, March 11th, at 2:00AM** local time, the time will spring ahead to **3:00AM**.

- If you have a subject on protocol please call the:
  - –SHINE Study Hotline 1-800-915-7320
  - –ISPOT study Hotline 1-774-234-7768
- Once a site randomizes we will reach out via phone & email

SHINE

WHO TO CONTACT

WebDCU™ Data → Information → Knowledge

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Askiel Bruno — abruno@augusta.edu Christiana Hall— christiana.hall@utsouthwestern.edu
Protocol, laptop & study drug stickers — Heather M. Haughey — hmh8f@virginia.edu; 434-243-8065
SAE reporting & regulatory — Ruth Lewis— rrlewis@med.umich.edu; 734-936-2454
Recruitment/retention — Katrina van de Bruinhorst — katrina.vandebruinhorst@utsouthwestern.edu; 214-648-9248
CRF completion/data management — Kavita Patel — pateka@musc.edu; 843-876-1167
Ancillary contracts/invoicing — Emily Gray— eaw8t@virginia.edu; 434-982-6773

24 hour Emergency Contacts:

SHINE Study Hotline — 800-915-7320
WebDCU Emergency Randomization Hotline — 866-450-2016
I-SPOT Study Hotline — 774-234-7768

I-SPOT