Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

August 2014– Volume 2, Issue 4

IN THIS ISSUE

Congratulations to all on completing the first 3 years of the SHINE trial with us. We are excited to start the next phase of the trial with your continued hard work and support.

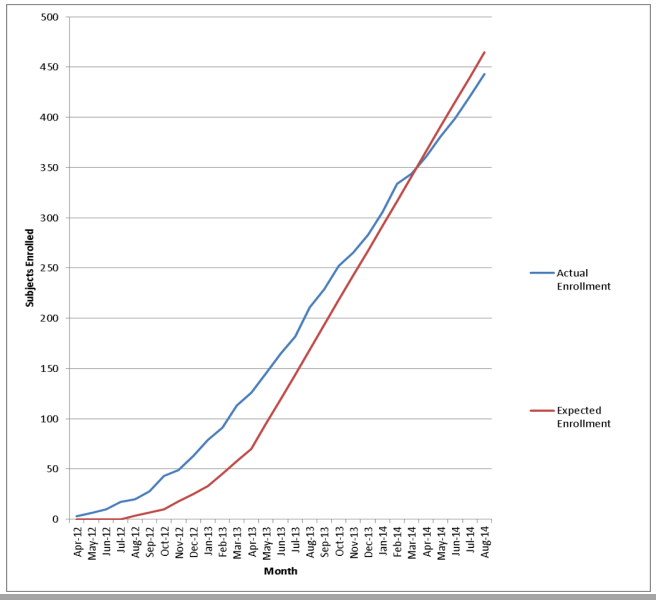
As we are entering into the 4th year of the trial, our focus will shift from start-up to supporting our enrolling sites. We are thrilled to have more than our originally planned 56 sites on board with a total of 62 activated sites to date and a total of 58 sites currently enrolling.

As we think about the next phase of the SHINE trial, we will also be counting on all of our sites to guide us. We feel fortunate to have recently had an opportunity to collaborate with Dr. David Wright who is PI of the Progesterone for the Treatment of Traumatic Brain Injury (ProTECT™ III) trial. David has great expertise and has been a wonderful resource in helping us think about the second half of the trial.

In this quarter's newsletter, we will highlight some of our trial and site-specific successes. We will share information on an NIH workshop on recruitment that we attended and updates on remote monitoring, regulatory reminders and adverse event reporting. Thanks again for all the hard work. I look forward to talking with each of your teams to get input on the continued success of the SHINE trial.

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

SHINE Enrollment—April 2012-August 2014



SHINE Bravo Zulu Flag

The Bravo Zulu flag has traditionally been used by US naval forces to indicate a job especially well done. The flag is awarded to SHINE sites in recognition of extraordinary contributions to the trial.

Emory SHINE Team

The Bravo Zulu flag is awarded to the **Emory team** this quarter in recognition of their continued dedication and exemplary efforts in the SHINE trial. Emory enrolled their 50th subject this quarter and is the second highest enrolling site in the trial. Our thanks as well to their fellows who have played a crucial role in recruitment. The Emory Midtown spoke was activated this quarter with a new enrollment at the Emory hub on the very same day. In addition, Emory reported the highest increase in retention percentages over the previous quarter. They consistently go above and beyond. Our thanks to **Vishal Patel, Alex Hall** and the entire team.

Karen C. Johnston, SHINE PI

Finger Stick Glucose Checks in SHINE

Due to known variations in blood glucose levels between capillary, venous and arterial sources, trial procedures have been updated to clarify the recommended blood source used for study point of care (POC) glucose testing. Capillary blood remains a **requirement** for the enrollment POC glucose test to determine eligibility and the preferred source of blood for POC glucose testing throughout the trial.

When there are concerns about the number of finger sticks or a subject withdrawing consent for study treatment, switching to venous blood samples for the remainder of the treatment period is permitted. When there is a choice of multiple veins, the vein closest to a hand should be used to obtain the samples. Once venous samples become the source of blood for the POC glucose checks, this should remain the source for the remainder of the treatment period. If venous blood cannot be reliably obtained, arterial blood may be used. Again, once arterial blood becomes the source, this should remain the source for the rest of the treatment period. Study teams are encouraged to call the trial hotline with questions.

Amy Fansler and Askiel Bruno
SHINE Project Director and SHINE PI

New SHINE Sites

Welcome to the newly activated **Emory University Midtown** and **University of Arizona Medical Center—South Campus**.

Actively enrolling sites: **58** Sites with at least one enrollment: **47**

Special Thanks to our SHINE Study Teams for their Recruitment and Retention Success Stories

MAYO JACKSONVILLE

At **Mayo Jacksonville,** local PI Kevin Barrett and coordinators Sothear Luke and Dale Gamble were able to capture the 90 day outcome in the evening on the final day of the window after countless attempts by their entire team to contact the patient.

SUMMA

At **Summa Akron City Hospital** (spoke of Ohio State), after multiple attempts, local PI Susana Bowling and coordinators Rachelle Scharsu and Kathy Cunningham were able to contact their SHINE patient. They assessed the mRS by phone but then learned that the patient recently started a new job and could not fit in a clinic visit with his work schedule. Dr. Bowling met him at a local YMCA one evening later that week in order to capture the all of the assessments in person.

KENTUCKY

Kudos also to the **Kentucky** Team, including the SHINE PI Roger Humphries and coordinators, Linda Dechtenberg and Joann Short, who enrolled 4 patients in 1 week — a SHINE trial record at their site. Their dedication and commitment to SHINE is exemplary.

These are just the type of activities that we are recognizing by awarding study teams with bonus points in the SHINE Recognition System. Please send along any stories similar of great teamwork and successful capture of outcomes to Katrina.vandebruinhorst@utsouthwestern.edu.

Katrina van de Bruinhorst and Amy Fansler, SHINE Recruitment Specialist and Project Director

The SHINE Recognition System has been restructured into two competitive divisions: Hub/Spoke complexes and individual sites. The way you earn points remains the same. As a reminder, points are assigned for enrollment, retention, CRF completion, updated regulatory documents, responses to DCRs, attendance on calls and bonus points. This two division system will reward Hub/Spoke complexes for outstanding work while also recognizing individual sites for excellent efforts.

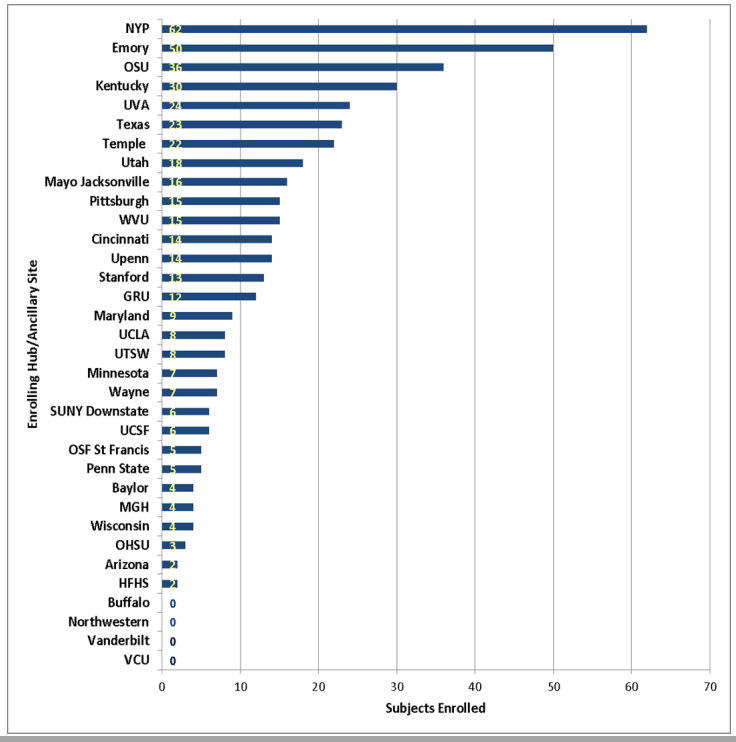
Final Standings—As of July 2014

1. **UT Houston—Valley Baptist, Seton, Brackenridge**
2. Emory/Grady— Emory University Hospital, EUH-Midtown
3. NYP Columbia
4. SUNY Downstate—Kings County, Maimonides, Lincoln
5. Stanford

1. **Columbia University Medical Center**
2. Stanford University Medical Center
3. Emory University Hospital
4. Grady Health
5. Valley Baptist Medical Center

Katrina van de Bruinhorst, SHINE Recruitment Specialist

SHINE Enrollment by Site



Fellows that are Making a Difference in the SHINE Trial

We have heard from many of our study teams that the fellows at their site play a critical role in their recruitment success. Including fellows in the screening and enrollment process not only has the potential to facilitate enrollment in the trial, but this contribution can play an important role in career development. Our thanks to the following fellows as we have heard from your site that they couldn't be doing what they do without you.

- Columbia University MC—Alex Merkler and Shadi Yaghi
- Detroit Receiving Hospital-Kushak Suchdev
- Emory—Kumiko Owada and Ali Saad
- Massachusetts General Hospital—Guido Falcone
- University of Virginia—Christina Chee and Prachi Mehndiratta

Katrina van de Bruinhorst and Amy Fansler
SHINE Recruitment Specialist and Project Director

Screen Failure Log Reminders

As a reminder, only potential candidates with a primary **diagnosis of ischemic stroke** and a **glucose >110mg/dL** that present within **12 hours of symptom onset** should be reported on the log. Screen Failure Logs are due on the 10th of every month.

Study Hotline Reminders

An investigator on call is available 24/7 for SHINE, and calls to the study hotline are always welcome. As a reminder, a call to the SHINE study hotline is **required** for any of the following:

- 3 BG<70mg/dL in 24 hours
- BG≥500mg/dL
- BG<40mg/dL

The PI on call can also address screening questions, safety concerns, meals or finger stick issues, protocol deviations, following up on wrong or missing entries in the laptop, timing of checks/dosing or other questions. Please don't hesitate to call.

SHINE Study Hotline – 800-915-7320
WebDCU Emergency Randomization – 1-866-450-2016
I-SPOT Study Hotline – 774-234-7768

Amy Fansler
SHINE Project Director

A trans-NIH workshop on Patient Enrollment and Retention in NIH -funded Clinical Trials was held July 25th in Bethesda, MD. This workshop was well attended by 200 participants who represented investigators, patient advocates, foundations, and many others. It was an opportunity to disseminate strategies to address and overcome challenges to enrolling representative populations, which has been a mission NIH has strived toward for the past 20 years.

Many investigators left this workshop empowered from learning about successful approaches to enrolling even the most challenging populations. Important next steps highlighted were: increasing awareness of clinical trials, incorporating patient perspectives in study design, adapting study designs to better accommodate patients needs, and simplifying the consent process.

Public participation is essential for the success of any clinical trial. In order to improve the health of populations, it will be essential to adopt patient-centered strategies to fortify the bridge that connects scientific endeavors to the values and needs of the patients.

Adrianne Haggins
SHINE Recruitment Team

Special congratulations to the following sites who enrolled their first I-SPOT subjects this quarter: **GRU, Austin Seton, Stanford, Detroit Receiving** and **UVA**. **NYP Columbia** enrolled 3 subjects this quarter almost tying Emory Hub for most enrollments total. **OSU** and **Cincinnati** also enrolled one more subject each. Many thanks to all these sites.

Please continue to enroll all I-SPOT eligible SHINE subjects!

Hannah Reimer
I-SPOT Project Manager

Updates from the NETT CCC and SDMC

Remote Monitoring—The NETT is excited to introduce remote monitoring in the SHINE trial. Remote monitoring allows a monitor to access and review medical records from the site to verify CRF submitted data. Remote monitoring will not replace in-person monitoring visits but may lengthen the time between visits and reduce the amount of time at the in-person monitoring visit. The first sites to participate include the Kentucky and UVA. WVU and GRU are in the process of establishing remote access.

In the near future you will receive a questionnaire requesting information about your ability to have remote monitoring access at your site. The NETT is very committed to initiating remote monitoring at every site and in all NETT trials and we're excited to travel down this new path.

Donna Harsh
SHINE Monitor

Site Activation and Regulatory Updates - We are getting close to initiating enrollment at all of our SHINE sites! Thank you to all sites for your diligence in completing the required trainings for new team members and uploading the regulatory documents. Missing and expiring document emails are sent on a bi-weekly basis to help with regulatory compliance as well.

Site IRB renewals approvals expire annually and continued renewal applications are required to be submitted usually about 40-60 days prior to expiration date for timely review at IRB. Kindly upload the IRB acknowledgements of CR submissions under "SHINE Full study IRB submittal V 2.0" to help us track the current status of submission at your site. We really appreciate the timely CR submissions.

Arthi Ramakrishnan
SHINE Site Manager

CRF Updates—An updated SHINE study book v9 was released in August 2014. Updates include changes to instructions and clarification of CRFs that address neurological worsening. These updates will be reviewed on the September 2014 NETT Study Coordinator call.

Kavita Patel
SHINE Data Manager

Who to contact

Protocol questions – Amy Fansler – (434) 982-6027 or acf7h@virginia.edu
Budget & contracts questions - Amy Fansler – (434) 982-6027 or acf7h@virginia.edu
General education and training – Joy Pinkerton – (734) 232-2138 or joypink@umich.edu
I-SPOT questions – Hannah Reimer – 215-707-5483 or hreimer@temple.edu
Laptop questions – Amy Fansler – (434) 982-6027 or acf7h@virginia.edu
Regulatory & site readiness – Arthi Ramakrishnan – (734) 936-2454 or arthrama@umich.edu
WebDCU support – Kavita Patel – (843) 876-1167 or pateka@musc.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
I-SPOT Study Hotline – 774-234-7768