Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

September 2017 – Volume 5, Issue 4

IN THIS ISSUE

Dear Colleagues,

As fall begins we are excited to share with you some information and updates on the SHINE trial that we think may be useful.

In this issue of the newsletter, we highlight and congratulate all of you for your excellent work on achieving and maintaining such great data quality and outstanding subject retention.

Congratulations goes out to our *newest* Bravo Zulu Flag awardees, OSU Summa Akron, and to our top enrollers this quarter who are: Grady with 6, OSU with 5, Henry Ford with 5, Augusta with 4, and Stanford with 4, **congratulations!**

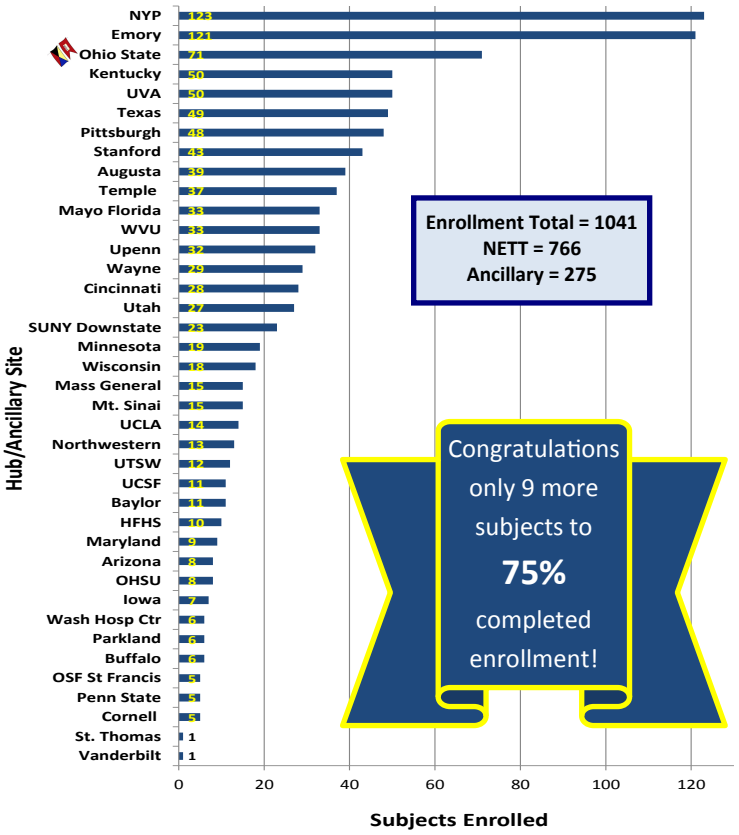
We are also highlighting a new WebDCU™ CRF summary table and some helpful reminders regarding WebDCU™, I-SPOT, and don't forget daylight savings time!

Currently, we have 44 sites actively enrolling in SHINE, including 31 NETT sites and 13 SHINE Ancillary Sites.

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

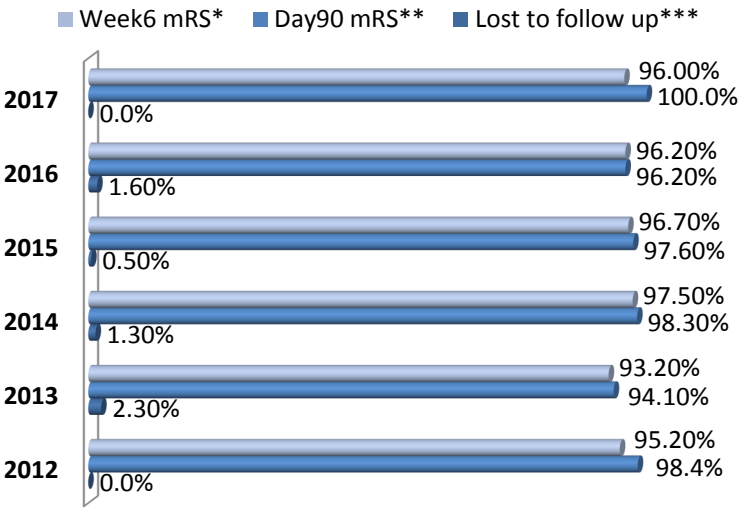
Karen C. Johnston, MD, MSc, SHINE Administrative PI

SHINE Enrollment by Site through SEPT 29st 2017



Retention Metrics by Enrollment Year

We have continued to have very strong retention. Thanks to all our teams and keep up the great work.



Percent of Subjects Data Collected in Window

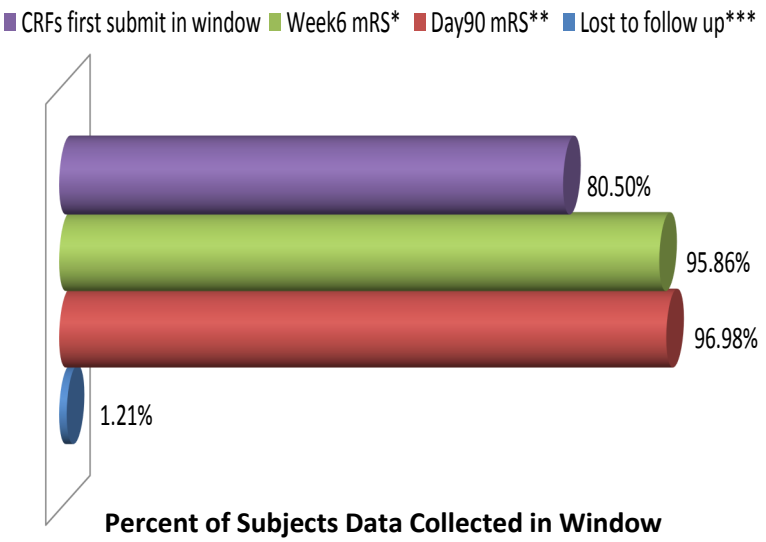
*Subjects with Week6 mRS or EOS, or > 56 days in Study

**Subjects with Day90 mRS or EOS, or >120 days in Study

***subjects with EOS form

Cumulative Data Metrics through Sept. 21st 2017

Outstanding data capture results shown below. Thanks to all our teams for your great work and dedication to SHINE.



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SHINE Bravo Zulu Award

Our sincere congratulations to our SHINE study team at **OSU Summa Akron City Hospital**, this quarter's recipient of the SHINE Bravo Zulu flag. The Bravo Zulu flag is traditionally used by US naval forces to publically recognize a job especially well done.

The SHINE study team at **Summa Akron** is always responsive to queries and always has a positive attitude. The SHINE leadership team thanks them for their high 90 day mRS retention rate, timely data submission, and enrolling the **1000th patient**! It is this kind of commitment to the SHINE trial that will continue to make SHINE a successful study!

From left to right: Linette Mercer BSN,. RN., Dr. Susana Bowling, Robin Roth BSN., RN. and Rachelle Scharsu BSN., RN.

SHINE Treatment Protocol Reminders

CONTROL GROUP – Treatment Protocol Reminders

BG target: 80-179 mg/dL
Glucose checks: q1-q3 hours (+/- 15 min)
Drip: IV saline drip – 0, 4 or 5 mL/hr
SQ injections: SQ insulin (human regular per sliding scale) and basal insulin (only at 48 hrs if indicated)

Timing of checks
Q1 hr – Do one check when ready to start IV saline (Q0) and then check hourly for next four hours (Q0, Q1, Q2, Q3, Q4)
Q3 hr – Then transition to q3 hour schedule (3, 6, 9, 12, 18, 21, 24)

Dosing
Adjust **IV saline** with EACH glucose check
Give **SQ insulin ONLY** at dosing times (**6, 12, 18, 24**)
- If hourly check is within 30 mins of next dosing time, give dose (i.e. if check is due at 11:41, you're within 30 min → give dose)
- If you cross a dosing time during the hourly checks, give dose (i.e. 1st check 05:20, 2nd check 06:20 → give SQ dose as crossed 6AM)

Level changes
All patients on Level 1 for first 24 hrs
Level changes assessed every 24 hrs from **time of randomization**
If latest 2 glucose checks are ≥180, advance to next level
Level 3
- Includes a one-time dose of SQ glargine/Lantus as close as possible to 48 hrs after randomization
- Dose =40% of total SQ insulin (count all 4 dosing times) given in prev 24 hrs

Meals
60 gm CHO/meal plus protocol approved snacks
HOLD meal until after glucose check/SQ dose (6, 12, 18)
Dysphagia diet/bolus tube feeds must also be 60 gm CHO
Continuous tube feeds ~180 gm CHO daily

Pauses
- Stop drip and document in study laptop & med record
- Upon return, restart protocol based on if check/dose missed

INTERVENTION GROUP – Treatment Protocol Reminders

BG target: 80-130 mg/dL
Glucose checks: Timing -q1-q2 hrs recommended by GlucoStabilizer® (+/- 15 min)
Drip: IV insulin per GlucoStabilizer®
SQ injections: SQ meal insulin (or saline if NPO)

Timing of checks – q1hr per GlucoStabilizer® until BG stabilized (may change to q2hrs then)

Dosing
Adjust **IV insulin** per recommendation of GlucoStabilizer®
Subcutaneous injections
- If NPO or on continuous tube feeds, give 0.05mL normal saline SQ at glucose check closest to 0900 and 2100
- If PO or on bolus tube feeds, give meal insulin per GlucoStabilizer®

Meals
60 gm CHO/meal plus protocol approved snacks
Dysphagia diet/bolus tube feeds must also be 60 gm CHO
Continuous tube feeds ~180 gm CHO daily
Estimating meal consumption
- Assesses meal tray ~20 minutes after start of meal
- Estimating PO meal consumption, then use Cover Carbs function
  - All or nearly all→ Enter 60
  - None or nearly none→ No entry in GlucoStabilizer®
  - Partial→ Enter 30
- Do NOT enter any numbers other than 30 or 60
- Dose immediately based on GlucoStabilizer® recommendation

Pauses
Stop drip and document in study laptop & med record
Upon return, restart protocol based on following
- If <3 hours since stop drip, Select 'Resume drip' (most recent drip run) and follow recommendation from GlucoStabilizer® for timing of next check/dose
- If ≥ 3 hours, Select Start a new drip; when ready to start insulin infusion, do a check and enter in GlucoStabilizer®

https://nett.umich.edu/sites/default/files/docs/shine_treatment_protocol_reminders.docx

Please call Heather M Haughey with any questions!

WebDCU™ News

There is a new table that has been added to WebDCU. It can be located by clicking on [Data Management] —> [Site CRF Data Entry Summary]. This table provides valuable information regarding data timeliness and accuracy.

WebDCU™ Reminder—Upload documentation

- **IRB submissions:** Study updates, Administrative items, Consent revisions, & Continuation reviews
- **IRB outcome notices**
- **Licenses, Curriculum Vitae, & Training Certifications**

Questions? Contact Ruth Lewis: rrlewis@med.umich.edu

WebDCU™ Reminder—Update team member changes

- Revise & submit Delegation of Authority Log (DOA)
- Request permissions to be granted or ended

Questions about WebDCU? Contact Kavita Patel: pateka@musc.edu

Also, please send team member email updates to Rusty Andres: randres@med.umich.edu

I-SPOT

Insights on Selected Procoagulation markers and Outcomes in stroke Trial

Total Enrollment:215
IV tPA subjects: 71

Review of I-SPOT Inclusion/Exclusion

INCLUDE

- Subjects (or LAR) who consent to I-SPOT
- IntraVENOUS tPA subjects are permitted

EXCLUDE

- Subjects with known moderate or severe hepatic insufficiency
- Prior or concurrent thrombotic or hypercoagulable condition
- Current or planned use of full dose anticoagulation from baseline to the 48 hour sample collection
- IntraARTERIAL tPA
- Any IntraARTERIAL therapy (mechanical thrombectomy)

Questions call the I-SPOT hotline: (774) 234-7768
Hannah Reimer, I-SPOT Project Manager

SHINE and Daylight Savings Time

Daylight saving time begins on **Sunday, November 5th, at 2:00AM** local time. Because the time change will affect management of the trial protocol, the SHINE PI's on call are ready to help support our study teams. Please contact the study hotline (800-915-7320) if you have an enrolled study patient during this time.

Windows Updates

Please maintain a schedule to check and update the laptops monthly and at the time of each enrollment. Please contact Heather M Haughey @ 434-243-8065; hmh8f@virginia.edu if you have any questions or concerns.

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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
SAE reporting & regulatory — Ruth Lewis — rrlewis@med.umich.edu
Recruitment/retention — Katrina van de Bruinhorst — katrina.vandebruinhorst@utsouthwestern.edu
CRF completion/data management — Kavita Patel — pateka@musc.edu
Ancillary contracts/invoicing — Emily Gray— eaw8t@virginia.edu
I-SPOT— Hannah Reimer— hreimer@temple.edu

24 hour Emergency Contacts:
SHINE Study Hotline — 800-915-7320
WebDCU Emergency Randomization Hotline — 1-866-450-2016
I-SPOT Study Hotline — 774-234-7768