



# Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

September 2018– Volume 6, Issue 4

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Dear SHINE Colleagues;

### Congratulations SHINE team on the completion of SHINE enrollment with 1151 subjects collected!

We have compiled a list of closeout FAQs and created a SHINE Site Closeout Checklist to be used by each site to document all closeout activities which can be found on page 2. As a reminder please be sure to respond to data queries promptly and reconcile all overdue CRFs, visits, and open rule violations.

We are working hard to have the data lock for the SHINE database occur by early to mid-November in order to present our results at the ISC in Hawaii. Please help us complete all study related activities to meet this deadline. We are preparing to support several people from each enrolling site to join us in Hawaii. We will have a final investigators meeting and we want you all with us as we anticipate being on

the platform to present SHINE primary results during the ISC meeting.

The SHINE Executive Committee graciously thanks all of the enrolling site teams and all of your patients who participated in the SHINE trial. We could not have done any of this without all of you. We thank you for all of your efforts over the last 6 years and are excited to celebrate the SHINE results with you.

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

## 2018's Top Enrollers

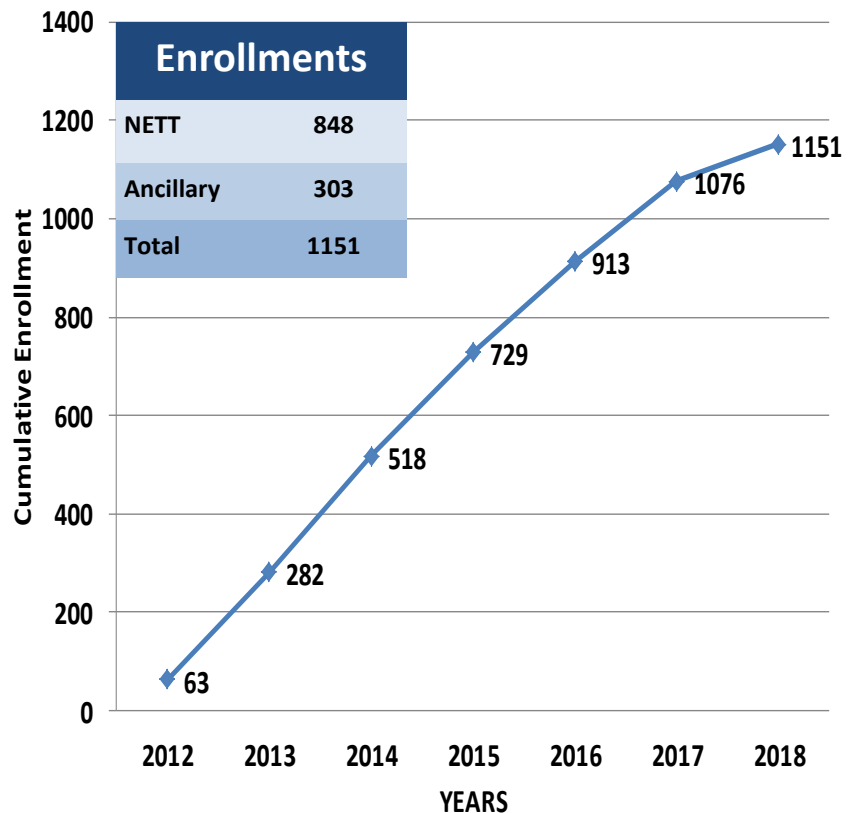
Hub	Site	#
NYP	Columbia	9
Emory	Grady	9
Ancillary	Augusta	7
Ohio State	OSU Wexner	6
Cincinnati	Univ. of Cincinnati	5

## Top 10 Enrolling Sites in SHINE

Hub	Site	#
NYP		136
Emory		135
Ohio State		79
Kentucky		54
PITT		53
UVA		53
UT Houston		51
Augusta		47
Stanford		45
Temple		44

## SHINE Cumulative Enrollment

April 2012 Through August 2018



**SHINE Team Picture Request:** Please send us pictures of PIs, coordinators, Nurses, etc.. send to [hmh8f@virginia.edu](mailto:hmh8f@virginia.edu)

## SHINE Closeout FAQs

### Q. When will the results be available?

A. Follow-ups will continue until all randomized patients have completed the study. Currently closeout activities are ongoing: data cleaning, site monitoring, sites submitting IRB updates to close SHINE to enrollment, but remaining active. We are targeting Early- to Mid-November for the database lock, and December for paper submission.

### Q. When will participants be told to which arm they were randomized?

A. Patient/patient contact SHINE Trial Results Letter templates will be provided to each site after database lock and all sites must send out these letters prior to publication of the manuscript Feb 6-8, 2019.

### Q. What is the SHINE dissemination plan for the primary results?

A. We hope to present the SHINE primary results at the ISC in Hawaii. We also plan to submit the SHINE primary results manuscript to the NEJM with hopes of the publication coming out on the same day as the ISC presentation.

## SHINE Site Closeout Checklist Items:

	Site Requirements
1	Notification of SHINE 'Closed to Enrollment' status has been submitted to the IRB
2	IRB acknowledgement that SHINE is 'Closed to Enrollment' has been uploaded into WebDCU™ as a 'IRB Notification - Site Close-out' document type.
3	Site acknowledges that continuing IRB approval will be maintained until after the primary paper is published.
4	eDOA has been revised to include <u>only</u> the Hub PI/PM, Site PI/PSC, & Team Members with regulatory/eDOA/follow-up/pharmacy responsibilities (remove appropriate team members when follow-up/pharmacy responsibilities completed)
5	Site acknowledges that the Site & People Regulatory Documents including CV, Professional Licenses, HSP/GCP Certifications are to be maintained for team members on the eDOA
6	All follow-up activities for active subjects enrolled prior to the closing of enrollment have been completed
7	All CRFs completed & submitted in WebDCU™
8	Screen failure logs completed & submitted in WebDCU™
9	All WebDCU™ queries (open DCRs & Rule Violations) have been resolved (Payments to sites are dependent on queries being resolved)
10	All trial data & records complete, accurate, legible, & valid
11	All monitoring action items have been responded to & closed
12	All monitoring reports have been reviewed & signed by Site PI
13	Site acknowledges all recruitment materials (posters, signs, notices, etc.) have been removed.
14	Pharmacy documentation is complete & accurate & a plan for storage is in place. Any SHINE drug held in reserve will be recycled or destroyed per local site procedures.
15	ASUS laptops have been recycled per local site procedures.
16	Dell laptops have been returned to UVA using the pre-paid UPS air bill provided by the UVA SHINE Project Director
17	I-SPOT lab kits have been recycled or destroyed per local site procedures.
18	All remaining I-SPOT samples have been sent to the I-SPOT Coordinating Center at Temple University Hospital. Please refer to your lab manual for specific shipping instructions.
19	Master subject list containing subject name, medical record number, date of birth, subject number, date of consent, date of randomization & end of study date is maintained in a secure electronic file/location titled 'SHINE Subject File / PI (name)' ( <b>truncated</b> )
20	Site acknowledges that records will be retained for a minimum of 6 years (or longer as required by local site procedures) from the approval date of the sponsor's final study report in accordance with contract or grant stipulations or until you are otherwise notified by NIH. ( <b>truncated</b> )
21	Storage location of hard copy study record:
22	Enrolled patients or patient's contact sent SHINE Trial Results Letter
23	Submit IRB termination application after primary paper published

**\*\* A link to your sites google closeout document was emailed to you! \*\***

# I-SPOT

## FINAL NUMBERS:

Total 270  
(86% of goal!)  
tPA 118 of 120;  
Non-tPA 152 of 195

THANKS TO ALL SITES WHO ENROLLED THIS PAST QUARTER AND TO EVERYONE WHO WORKED TO MAKE I-SPOT A SUCCESS!!

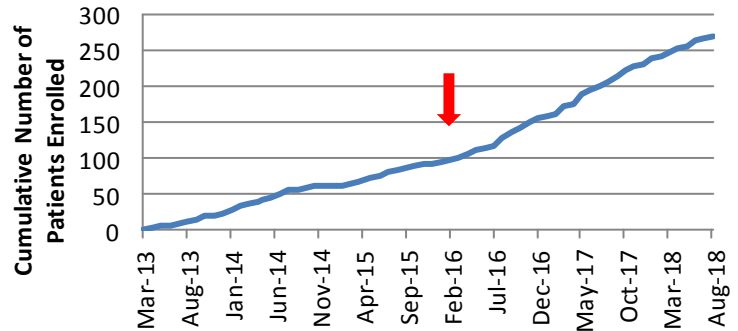
33 Sites enrolled at least one patient

### Top 10 Enrolling Sites in I-SPOT:

- |                           |                    |
|---------------------------|--------------------|
| 1. New York Presby. (41)  | 6. Temple (16)     |
| 2. Emory (35)             | 7. Cincinnati (12) |
| 3. Ohio State (27)        | 8. UT Houston (9)  |
| 4. Univ. of Kentucky (21) | 9. Mayo (8)        |
| 5. Augusta (18)           | 10. UPMC (8)       |

## Graph of I-SPOT enrollment

Arrow at start of tPA enrollment



## What do I do with the SHINE Laptops?

- All ASUS computers should be recycled at your local Institution as per your IT protocols.
- All Dell Computers need to be returned to UVA.
- All sites with Dell Computers please email Heather ([hmh8f@virginia.edu](mailto:hmh8f@virginia.edu)) the dimensions and weight of the shipping box and you will be sent a pre-paid UPS air bill.
- Thank you everyone!

Heather M Haughey, SHINE Project Director



## Please reconcile the following items:

- Open DCRs
- Rule Violations

## Please complete all:

- Past due visits (Please complete F14 End of Study after Day 90 visit is completed)
- Overdue CRFs
- Overdue Screen Failure Logs
- Pending Outcome Visits

For sites that have subjects with pending **90 day follow up visits**, you should have received an email from me which lists the earliest date of which this final visit can be conducted. Please schedule the visit at the date I provided you.

Thank you all for your efforts! Kavita Patel, SHINE Data Manager



## SHINE at the ISC 2019: Honolulu, HI

- SHINE anticipates presenting the primary SHINE results during the ISC, February 6-8, 2019 in Honolulu Hawaii.
- The SHINE team will host a final investigators meeting in Hawaii. The dates, location and specifics of that meeting will be shared as soon as finalized.

Heather M Haughey, SHINE Project Director

## WHO TO CONTACT

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 Retention — Katrina van de Bruinhorst — [katrina.vandebuinhorst@utsouthwestern.edu](mailto:katrina.vandebuinhorst@utsouthwestern.edu); 214-648-9248  
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