point–ers

The Newsletter of the POINT Trial

Volume 3, Issue 3 — 3rd Quarter 2013

2013 3RD QUARTER RECAP

Dear Colleagues,

Study Enrollment Update

We closed out the third quarter of 2013 with an enrollment of 1,714. The highest enrolling month in the quarter was August, with 62 enrollments. As of the end of September, we were at 29% of our recently revised target enrollment of 5,840 subjects enrolling at 158 sites. Eight new sites were activated this quarter, including the first sites in Australia and Canada. University of Alberta in Edmonton, Canada enrolled the first international participant in the study in August. Welcome to all our new sites!

Focus on Enrollment and Retention

While it's important to add new countries and sites to the study, it's equally important to make sure we keep subjects enrolled in the study for the full 90 days. Here's a quick snapshot of where we are now in terms of ways subjects leave the study or stop taking study medication.

Completed Subjects through 9/24/2013*	Stopped Study Drug Early	Lost to Follow Up	Withdrew Consent
	25.4%	4.9%	3.3%
*Includes subjects reaching 90 days or completing EOS form.			

As you can see, we need to work hard to reduce attrition, and we hope you will share any strategies and techniques you've developed to manage attrition at your site. For your reference, tips for minimizing premature discontinuation of study drug, compiled by Gina Neshewat, the new NETT POINT Site Manager, can be found on page 2.

POINT ISC 2014: San Diego, CA

It's that time again! The UCSF POINT Clinical Coordinating Center will be hosting a Reception for Principal Investigators and Study Coordinators during the International Stroke Conference (ISC) in San Diego, CA on February 12, 2014. This is a great opportunity to meet POINT study team members, share enrollment ideas and discuss any study issues. Invitations to the reception, including directions to the venue, will be sent out by email in the next few weeks, so remember to RSVP!

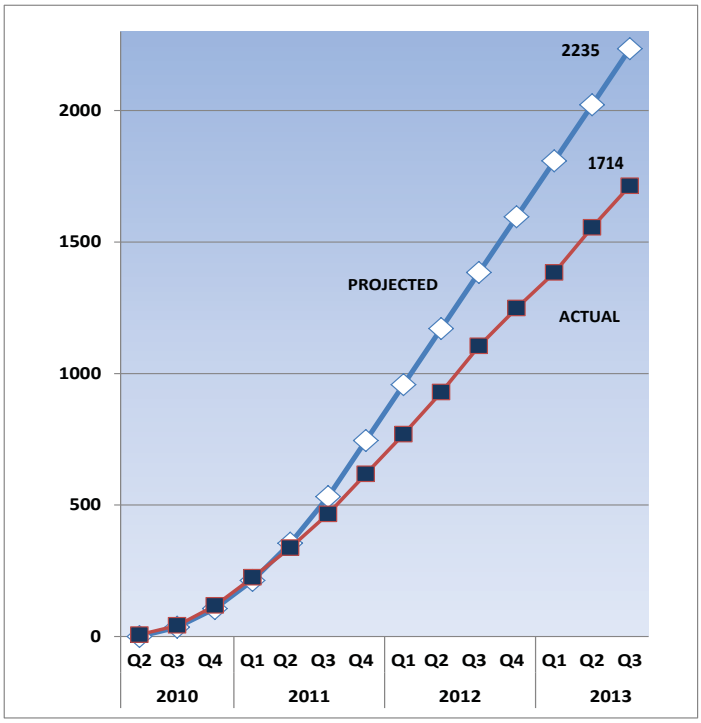
As always, please don't hesitate to contact us directly if you have questions or require more information.

Sincerely,

Clay Johnston MD, PhD, POINT Trial Principal Investigator
Don Easton MD, POINT Trial co-Principal Investigator

IN THIS ISSUE

POINT CUMULATIVE ENROLLMENT
MAY 2010 THROUGH SEPTEMBER 2013



POINT ENROLLMENT UPDATE: TOTAL=1714

Hot Enrollers for 2nd and 3rd Quarter

Place	Subjects	Site (Hub)
1	12	Oregon Health & Science University (OHSU)
2	10	Allegheny General (CRC), San Francisco General (UCSF)
3	9	Hospital of UPenn (UPenn), Abington Memorial (UPenn), Barnes Jewish Hospital (Univ. of Cincinnati), Advanced Neurology Specialists (CRC)
4	8	Temple University Hosp. (Temple Univ.), Methodist Hospital Houston (CRC), Northwestern University (CRC), Sparrow Hospital (CRC), Buffalo General Med. Ctr. (CRC)
5	7	Loyola University Chicago (CRC)

Top Enrollers (as of September 30, 2013)

Site (Hub)	City	State	#
Guilford Neurologic (CRC)	Greensboro	NC	78
Hospital of UPenn (UPenn)	Philadelphia	PA	67
OHSU- Oregon (OHSU)	Portland	OR	38
Methodist Hospital (CRC)	Houston	TX	34
Temple Univ. Hospital (Temple)	Philadelphia	PA	34
Abington Mem. Hosp. (UPenn)	Abington	PA	32
Advanced Neuro. Sp. (CRC)	Great Falls	MT	32
Detroit Receiving (Wayne)	Detroit	MI	31
Memorial Hermann (Texas)	Houston	TX	31

Sites with ≤ 30 subjects enrolled: 149

COORDINATOR'S CORNER: Study Drug Adherence Tips

By Gina Neshewat, NETT Site Manager

An essential component of POINT success is study drug adherence. The graph on the right shows the rate of subjects who stopped taking study drug early, before the full 90 days of their participation. As you can see, we need to address this issue ***now*** to prevent additional premature study drug discontinuations. Below are a few tips provided by Stanford, Minnesota and Cincinnati Hubs on how their Spokes maintain overall high study drug adherence in POINT. ***Remember*** - even if subjects stop taking study drug, they should be encouraged to **stay in the study** and to **complete all the follow-up visits**.

Periodic calls between study visits:

- Call subject after discharge to confirm he/she was sent home with study bottle *and* has aspirin at home.
- Call 1 to 3 days after hospital discharge, in addition to the 7-day contact, to inquire about study drug adherence.
- Call about every 4 weeks between scheduled contacts, especially around weekends and holidays.

Provide as much contact as possible, so the subject feels comfortable contacting you with any questions or concerns.

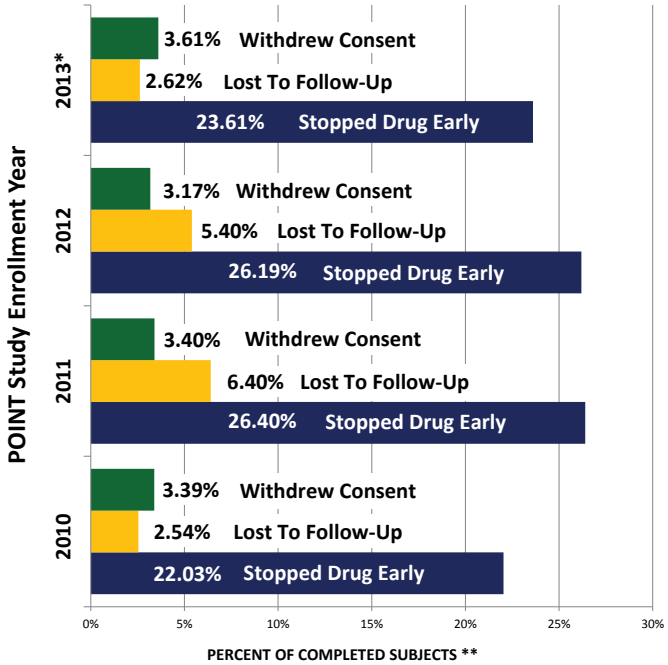
- Visit subjects before they're discharged to remind them about taking study drug and aspirin every day.
- Provide the names and phone numbers of several coordinators to call with any questions or concerns.
- If approved, provide transportation or offer to pay for mileage for study follow-up visits.

Keep in contact with subject's clinical care team, so they understand the POINT Trial and the importance of study drug adherance and avoiding prohibited medications.

- Talk with subject's nurse every day while subject is in the hospital.
- Site PIs call the PCP to explain the study and inform of subject's participation.
- Let subject know that you will be notifying his/her PCP.
- Fax/email PCP letter and study information as soon as possible: https://sitemaker.umich.edu/nett/point_toolbox
- Give a copy of PCP letter to subject to bring to PCP follow-up visit.

Please contact Gina Neshewat at: ***neshewat@med.umich.edu*** or (734) 647-1619 for any questions on study drug adherence.

WITHDRAWN CONSENTS, LOSSES TO FOLLOW-UP, AND STOPPED DRUG EARLY



*May include subjects that have reached 90 days, but have no end of study form.
**Includes those reaching 90 days or completing the end of study form.

Q3 Site Activations:

Jersey Shore (CRC), Neptune, NJ; **University of Alberta (Harrison), Edmonton, AB, CAN;** Mercy General (UCSF), Sacramento,CA; Mercy San Juan (UCSF), Carmichael, CA; San Jose Regional (Stanford), San Jose,CA; Aurora St. Luke's (Wisconsin), Milwaukee, WI; Fletcher Allen (CRC), Burlington, VT; **Royal Melbourne (NTA), Parkville, VIC, AUS**

ODDS & ENDS: QVSFS and Outcome Event Visits

Questionnaire for Verifying Stroke-Free Status (QVSFS)

Accurate identification of stroke and TIA status is fundamental to the POINT Trial. The Questionnaire for Verifying Stroke-Free Status (QVSFS), an 8-item structured interview, was designed to identify stroke and TIA-free individuals. In POINT, the QVSFS is collected on **Form 14** at the 7-and 90-day follow-up contacts, and at all outcome event visits. While the QVSFS is designed to be easily understood by most subjects, when administering the questionnaire, please make sure the subject/relative/caregiver/friend understands that the questions refer to **events since last contact.** *The index or enrolling event should be excluded.*

Outcome Event Visits

An Outcome Event Visit should be conducted if a subject experiences an ischemic stroke, TIA or myocardial infarction while enrolled in the study. All other clinical outcomes/SAEs do not require outcome event visits and should be reported on **Form 19** of the last visit that was posted.

Please contact Aaron Perlmutter, Program Coordinator, Data Management at MUSC. ***perlmutt@musc.edu*** or (843) 876-1261 if you have any questions about these topics.

International Stroke Conference 2014: San Diego, CA

POINT is hosting 2 events during the ISC on Wednesday, February 12, 2014:

PI Reception for Site PIs and Coordinators: 5-7pm PST
Advisory Committee Dinner Meeting: 7-9pm PST

Please look for your e-vites to these events and be sure to RSVP.

Look for more ISC updates in next quarter's newsletter. For any ISC 2014 events questions, please contact:

Caitlin Glennon, Research Associate, UCSF: ***caitlin.glennon@ucsf.edu*** or (415) 502-7309