

2015 4TH QUARTER RECAP

Dear Colleagues,

2015: THE YEAR IN REVIEW

Study Enrollment Update

We ended 2015 with 3,306 enrollments, which is over halfway (57%) to our target of 5,840 subjects. November was our highest enrolling month of the quarter (and year) with 78 enrollments. International enrollment increased in the last quarter with 54 enrollments from OUS sites, bringing us to a total of 250 subjects outside the US. We expect international enrollments will continue to increase with the addition of new sites and the end of enrollment in SOCRATES. For a more detailed update on OUS sites in the trial, please see the article on page 2.

DSMB Update

During the November 20th DSMB teleconference, study funding, new study drug, Lost to Follow-Up participants, and the pace of subject enrollment were the main topics of discussion. The DSMB recommended that the POINT trial continue, and asked that we work to improve the racial and ethnic diversity of the study population, and continue to reduce adjudication turnaround times.

LOOKING AHEAD TO 2016

NIH Funding Target

In the first quarter of 2016, we need to be very focused on our NIH funding restriction. Due to the enrollment milestone target placed on POINT by the NIH, we received only half of our total Y5 funding. We'll receive the remainder once the study reaches 3,500 enrollments; we've set the end of February 2016 as the deadline for getting to that goal. While we're pleased that our enrollment rate is increasing, currently averaging around 65 subjects enrolled per month, it's not enough to meet that target.

We're 194 enrollments away from our target. We need to enroll at least 97 subjects in January and in February to reach 3,500 by February 29th. We'll be sending monthly updates on our progress as we near the deadline.

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

Sincerely,

Clay Johnston MD, PhD, POINT Principal Investigator

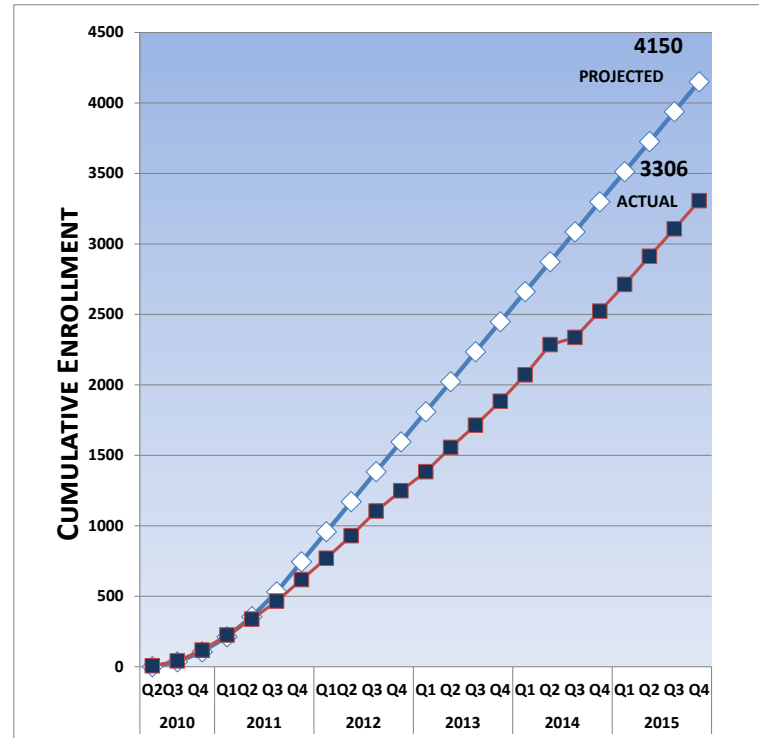
Don Easton MD, POINT co-Principal Investigator

Anthony Kim MD, MS, POINT co-Principal Investigator

**IN THIS ISSUE: COORDINATOR'S CORNER:
INTERNATIONAL SITES IN THE POINT TRIAL;
LOST TO FOLLOW-UP DATA COLLECTION**

POINT CUMULATIVE ENROLLMENT

MAY 2010 THROUGH DECEMBER 2015



POINT ENROLLMENT UPDATE: TOTAL = 3306

Hot Enrollers for 4th Quarter

Place	Subjects	Site (Hub)
1	11	University of Alberta Hospital (CRC)
2	8	Benefis Hospitals (CRC)
3	7	Grady Memorial Hospital (Emory), Stanford University (Stanford)
4	6	Vall d'Hebron Hospital (CRC)
5	5	Mayo Clinic St. Marys Campus (Minn)

Top Enrollers (as of December 31, 2015)

Site (Hub)	City	State	#
Guilford Neurologic (CRC)	Greensboro	NC	109
Hospital of UPenn (UPenn)	Philadelphia	PA	100
Benefis Hospitals (CRC)	Great Falls	MT	66
Stanford Univ. (Stanford)	Stanford	CA	60
Columbia Univ. (NYP)	New York	NY	54
Buffalo General Med Ctr. (CRC)	Buffalo	NY	54
Detroit Receiving (Wayne)	Detroit	MI	50
Temple Univ. Hospital (Temple)	Philadelphia	PA	50
OHSU-Oregon (OHSU)	Portland	OR	50
Abington Memorial (UPenn)	Abington	PA	47
Univ. of Kentucky (Kentucky)	Kentucky	KY	47
Univ. of Alberta Hospital (CRC)	Edmonton	AB	47
Memorial Hermann (Texas)	Houston	TX	46
Cleveland Clinic (CRC)	Cleveland	OH	46

COORDINATOR'S CORNER: INTERNATIONAL SITES IN THE POINT TRIAL

By Valeriya Lockwood, Site Manager (EMMES)

POINT has now successfully expanded to 43 sites in 9 countries. More international sites are activated every month. As you know, in 2013 the DSMB increased the overall enrollment goal by 40% from 4,150 subjects to 5,840 subjects. International sites were brought on to make up this increase of 1,690 subjects. This is a large gap to close; however, we believe we can meet this goal with the end of the SOCRATES trial and the addition of new international sites. We would like to provide a brief update on the status of international expansion and our expectations for 2016.

Country	First Site Initiated	Planned Sites	Current Sites	Subjects (12/31/2015)
Australia/New Zealand	Sep-2013	11	9	41
Canada	Oct-2013	13	10	103
Finland	May-2015	2	2	1
France	Sep-2015	11	1	4
Germany	Sep-2015	17	3	0
Mexico	Aug-2015	8	3	4
Spain	Mar-2015	10	6	67
United Kingdom	Oct-2014	12	8	30

Germany, France, and Spain were top international enrollers in SOCRATES, and we have plans to open up 28 new sites in these countries. Enrollment from these countries has already started to make a significant impact; Spain is the second highest international enroller for POINT after less than a year in the trial. In particular, we would like to highlight the efforts of Santa Creu and Sant Pau Hospital in Barcelona. This site averages at least two enrollments per month and does an excellent job of holding onto subjects. Keep up the good work!

We thank all participating and interested investigators and their study teams for the continuing efforts in opening the doors of their institutions in their respective countries. Your hard work is greatly appreciated, and we are grateful for your continued support of the POINT trial.

LTFU: DOCUMENTING ATTEMPTS TO CONTACT SUBJECTS IN WEBDCU

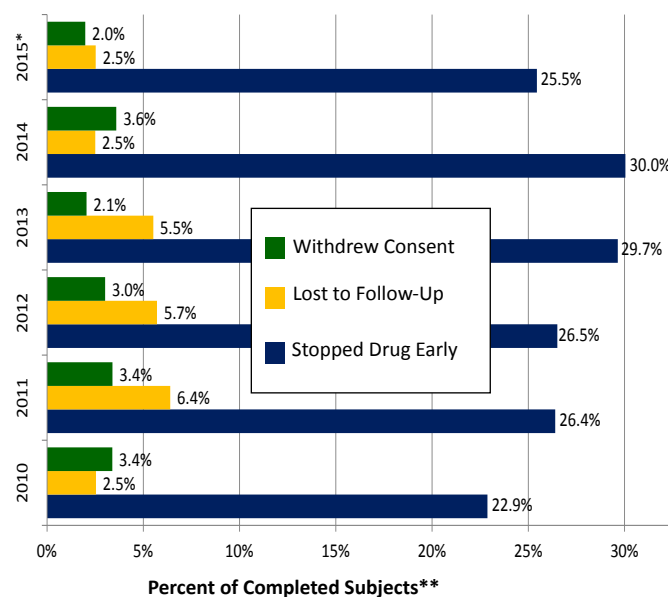
We do everything we can to collect follow-up information on POINT enrollments. Yet there are still some subjects we are unable to reach for scheduled contacts and as a result, about 4% of subjects are now considered to be lost to follow-up.

To help minimize that rate, it is critical to document attempted contacts in the subject's Form 17 – End of Study in WebDCU, using the guidelines set out in the study protocol (section 9.4.2.1). These include:

- At least three attempts to reach the subject by telephone
- At least 1 letter sent via Certified Mail™, with Return Receipt Service requested (or equivalent in other countries) for evidence of delivery to the participant's address, allowing a week for the subject to respond to the site.

If the subject has consented to allow alternative contacts to provide information for follow-up, please document attempts to reach those alternates in the subject's record as well. Please enter the dates and a description of your attempts in the General Comments section of Form 17. This information will be useful in providing feedback on the effectiveness of those guidelines and developing important metrics for the overall study.

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. Data as of December 11, 2015

Top-Enrolling NETT Hubs (as of December 31, 2015)

Hub	Total	Enrollments per 90 days
UPenn	259	11.8
Cincinnati	149	6.7
Wayne	145	6.7
Minnesota	135	6

Q4 Site Activations

ABC Medical Center Santa Fe, Mexico City, FD, MEX (CRC); University Hospital Frankfurt, Frankfurt, DEU (CRC); The Royal London Hospital, London, GBR (CRC); **Mercy Hospital, Springfield, MO (CRC)**; Los Robles Hospital and Medical Center, Thousand Oaks, CA (CRC); Helsinki University Central Hospital, Helsinki, FIN (CRC)

***Bold text indicates sites that have already enrolled subjects.**

IMPORTANT REMINDER

The current inventory of study drug expires August 31, 2016, and will be replaced with new active and placebo in May 2016. WebDCU will not allow you to randomize using expired study drug as of May 31, 2016 (90 days before the August expiration date). Please look for details on the restocking in the coming weeks.

International Stroke Conference 2016: Los Angeles, CA

POINT is hosting an ISC Poster Session on Thursday February 18, 2016 from 6:15-6:45pm

Please stop by to meet the UCSF PI's and study team. We look forward to seeing you there!

Location:
Los Angeles Convention Center
1201 South Figueroa Street
Hall H
Poster Number **CTP39**

For any ISC 2016 events questions, please contact:
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