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The Newsletter of the POINT Trial

Volume 6, Issue 3 4th Quarter 2016

2016 4th Quarter Recap

Dear Colleagues,
Happy New Year 2017!

Study Enrollment Update
We closed out 2016 with an enrollment of 4132, including 487 subjects from sites outside the US. This took us to just over 70% of our goal of 5840 subjects. Keep up the good work!

POINT ISC 2017: Houston, TX
The UCSF POINT Study Team will be hosting a reception for Principal Investigators and Study Coordinators during the International Stroke Conference (ISC) in Houston, TX on February 21, 2017, at the Marriott Marquis. See page 2 for more details. 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, have been sent out by email. Please RSVP by February 10th.

December 2016 DSMB Meeting
We met with our Data and Safety Monitoring Board by teleconference on December 16, 2016 to review all interim data from the trial. The DSMB did not identify any concerns regarding safety or study implementation, and thus recommended the study proceed as planned.

WebDCU™ Update
WebDCU™ was updated to replace the paper Delegation of Authority (DOA) log with an electronic DOA (eDOA) for POINT. All information about personnel and regulatory documentation is now housed within the POINT database. Please keep the paper DOAs at your site.

Don't hesitate to contact us directly if you have questions or require more information. We're looking forward to a great new year for POINT, and appreciate all your hard work on the trial.

Sincerely,

Clay Johnston MD, PhD, POINT Principal Investigator

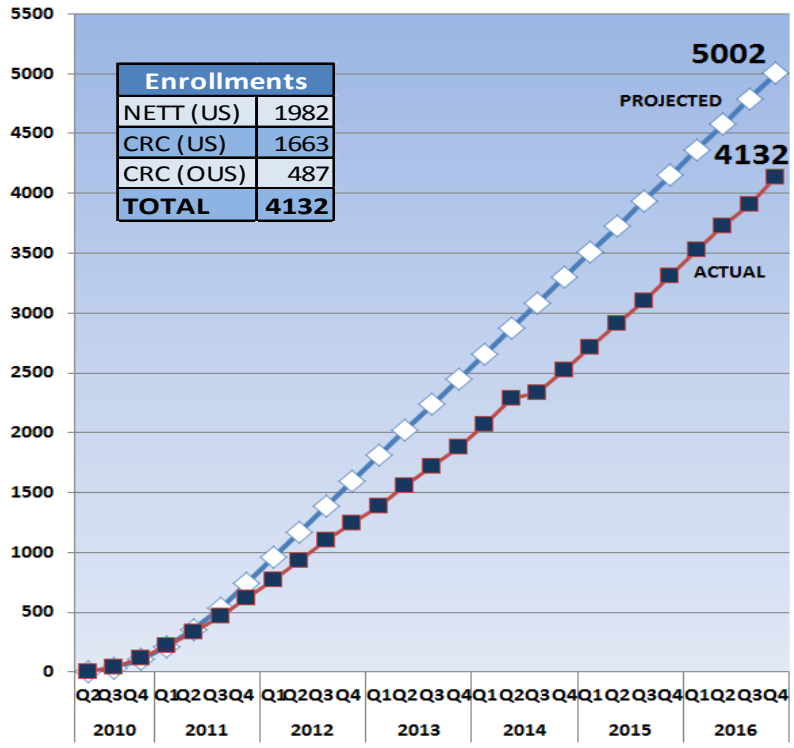
Don Easton MD, POINT co-Principal Investigator

Anthony Kim MD, MAS, POINT co-Principal Investigator

In This Issue: Coordinator's Corner: Preventing Study Drug Crossover

POINT Cumulative Enrollment

May 2010 through December 2016



Hot Enrollers for 4th Quarter

Hub	Site	#
CRC	University of Alberta Hospital, *Edmonton, AB, CAN*	13
NETT	Grady Memorial Hospital, *Atlanta, GA*	9
CRC	Pierre Wertheimer Hospital, *Bron, FRA*	8
UPENN	Hospital of the University of Pennsylvania, *Philadelphia, PA*	7
CRC	Hospital del Mar, *Barcelona, ESP*	7
CRC	Santa Creu and Sant Pau Hospital, *Barcelona, ESP*	6
Texas	Valley Baptist Medical Center - Harlingen, *Harlingen, TX*	6
CRC	Vall d'Hebron Hospital, *Barcelona, ESP*	6

Top Enrollers (as of December 31, 2016)

Hub	Site	#
CRC	Guilford Neurological Associates, *Greensboro, NC*	118
UPENN	Hospital of the University of Pennsylvania, *Philadelphia, PA*	116
CRC	Benefis Hospitals Inc, *Great Falls, MT*	90
Stanford	Stanford University Medical Center, *Stanford, CA*	78
CRC	University of Alberta Hospital, *Edmonton, AB, CAN*	74
NETT	Grady Memorial Hospital, *Atlanta, GA*	66
OHSU	Oregon Health and Science University Hospital, *Portland, OR*	62
NYP	NYP Columbia University Medical Center, *New York, NY*	61
Wayne	Detroit Receiving Hospital, *Detroit, MI*	61
CRC	Buffalo General Medical Center, *Buffalo, NY*	60
Temple	Temple University Hospital, *Philadelphia, PA*	57
Wisconsin	Froedtert Memorial Lutheran Hospital, *Milwaukee, WI*	53
CRC	Northwestern Memorial Hospital, *Chicago, IL*	53
CRC	Santa Creu and Sant Pau Hospital, *Barcelona, ESP*	53

Send your feedback and suggestions for future newsletters to POINTOperations@ucsf.edu.

International Stroke Conference 2017: Houston, TX

POINT is hosting 2 events during the ISC on Tuesday, February 21, 2017.

PI Reception for Site PIs and Coordinators:
5:30-7:00pm CT (3:30-5:00pm PT, 6:30-8:00pm ET)
Marriott Marquis Houston
Level 4, Texas Salon F Foyer

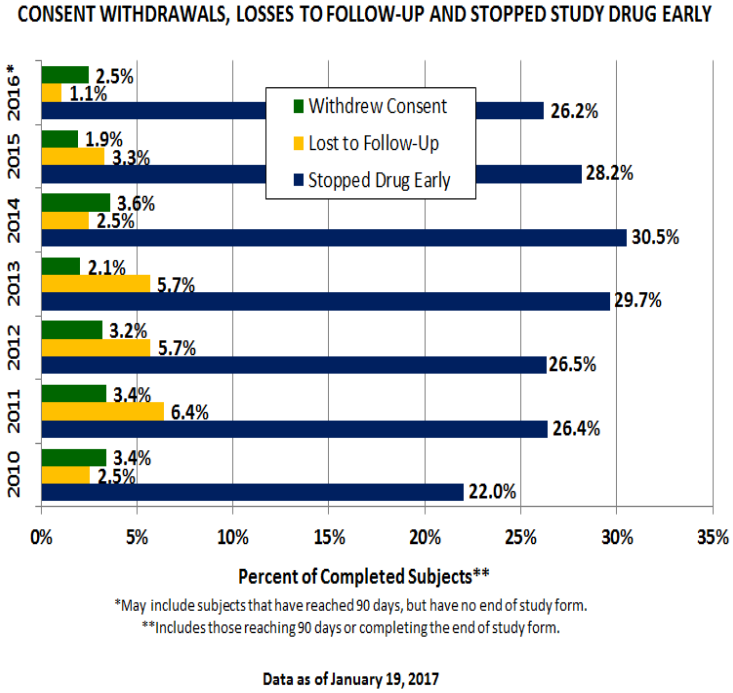
Advisory Committee Dinner Meeting:
7:30-9:00pm CT (5:30-7:00pm PT, 8:30-10:00pm ET)
Hampton Inn Houston Downtown
Heights Conference Room

Also, join us for the POINT Poster Session on Thursday, February 23, 2017.

POINT Poster Session
6:15-6:45pm CT (4:15-4:45pm PT, 7:15-7:45pm ET)
Houston Convention Center
Hall E CTP10

Please check your email for these e-vites and RSVP.

For any ISC 2017 event questions, email us at ***POINTOperations@ucsf.edu.***



COORDINATOR'S CORNER

Preventing Study Drug Crossovers in POINT

Aaron Perlmutter, MPH, MSW - Data Manager, MUSC

Subjects are randomly assigned to one of two treatment arms: clopidogrel plus aspirin, or placebo plus aspirin. The primary analysis in POINT is intention to treat, or ITT, and includes all randomized subjects. The basic principle of ITT is that the effect of a treatment intervention can be best evaluated by the intention to treat subjects with the intervention to which they were randomized, regardless of whether or not they received or adhered to this allocated intervention.

One way to ensure that subjects can be correctly analyzed in the groups to which they were randomized is to **minimize crossover**. Crossover occurs in POINT when a subject is accidentally put into the opposite arm of the study to which he or she was randomized by being given a bottle of study drug different from the one assigned. This can dilute the treatment effect between the two arms of the study and have a significant impact on final outcomes.

To reduce randomization crossovers, the Randomization Form (CRF 10) in WebDCU™ includes a link to the **Randomization Verification Form (RVF)**. When clicked, the link opens a form that site personnel must print, take to the investigational pharmacy (or other study drug location) and complete when study drug is dispensed. This step reduces the chances of crossover by requiring site personnel to compare the **5-digit Study Drug ID** assigned automatically by WebDCU™ and pre-printed on the form, to the **5-digit Study Drug ID** on the bottle of study drug that is dispensed by the pharmacy. Verification that the two Study Drug ID numbers match must take place before the loading dose is given to the subject.

The Randomization Verification Form contains the following information:

- **4-digit Subject ID** pre-printed on RVF by WebDCU
- **5-digit Study Drug ID** assigned by WebDCU™ pre-printed on RVF by WebDCU™
- **5-digit Study Drug ID** on bottle retrieved from pharmacy/other drug storage location

The person completing the RVF will enter the 5-digit Study Drug ID from the bottle on the form, then sign and date the form, verifying that the WebDCU™ Study Drug ID matches the Study Drug ID on the bottle. The Randomization Verification Form should be filed with the other source documents for the subject.

Questions? Contact Aaron Perlmutter, at perlmutt@musc.edu or (843) 876-1261.