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The Newsletter of the POINT Trial

Volume 7, Issue 3 3rd Quarter 2017

2017 3rd Quarter Recap

Dear Colleagues,

Study Enrollment Update
September was our highest enrolling month of Q3 with 61 participants. Enrollment has been trending upward since the lull at the beginning of the quarter. With the contributions at each of your sites, we continue to approach the projected monthly enrollment numbers of at least 80 participants per month needed to complete enrollment by late 2018.

As of the end of September, we had enrolled 4,741 participants, 81.2% of the 5,840 enrollment target for the trial. We're coming down the homestretch!

Upcoming DSMB Meeting
The POINT Study Team will be meeting with the DSMB by teleconference on December 18, 2017. Enrollment – with a particular focus on the United States – and retention will again be among the main topics of discussion. Our goal is to minimize premature study drug discontinuation, consent withdrawals, and lost to follow up. For strategies to prevent the avoidable cases in each of these categories, please see *Retention Tips and Reminders* on page 2.

POINT ISC 2018: Los Angeles, CA
The UCSF POINT Clinical Coordinating Center (CCC) will be attending the International Stroke Conference (ISC) in Los Angeles, CA. This year, it will be held earlier than usual from January 24-26, 2018. POINT will not be holding a PI Reception as we have done in previous years. Instead, we anticipate a larger celebration at the ISC 2019 when enrollment is complete.

We invite you to stop by the Poster Session in which POINT will be featured. It'll take place on Thursday, January 25th. Look for a reminder email in mid-November with the poster number and location.

Closing the Gap: 4800 Enrollments
In our 2nd Quarter 2017 newsletter, we shared that the NIH had placed a restriction on awarding the second half of our Year 1 funding until we reached 4800 enrollments.

At 4,741 enrollments, as of the end of September, we're really close to reaching the goal! Thanks for your contributions.

Sincerely,

Clay Johnston MD, PhD, POINT Principal Investigator

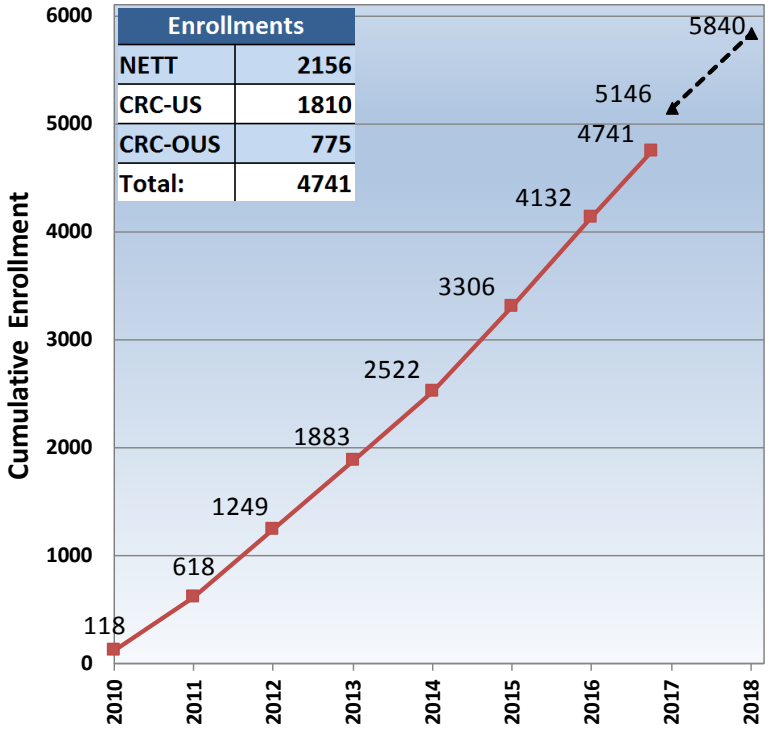
Don Easton MD, POINT co-Principal Investigator

Anthony Kim MD, MAS, POINT co-Principal Investigator

In This Issue: *Coordinator's Corner: Retention Tips and Reminders*

POINT Cumulative Enrollment

May 2010 through September 2017



Hot Enrollers for 3rd Quarter

Hub	Site	#
CRC	La Fe University Hospital, Valencia, ESP	7
CRC	University of Alberta Hospital, Edmonton, AB, CAN	6
CRC	Foch Hospital, Suresnes, FRA	5
CRC	Girona University Hospital, Girona, ESP	5
CRC	Benefis Hospitals Inc, Great Falls, MT	4
CRC	Helsinki University Central Hospital, Helsinki, FIN	4
CRC	Pierre Wertheimer Hospital, Bron, FRA	4
UPENN	WellSpan York Hospital, York, PA	4

Top Enrollers (as of September 30, 2017)

Hub	Site (US)	#
CRC	Guilford Neurological Associates, Greensboro, NC	122
UPENN	Hospital of the University of Pennsylvania, Philadelphia, PA	122
CRC	Benefis Hospitals Inc, Great Falls, MT	106
STANFORD	Stanford University Medical Center, Stanford, CA	84
EMORY	Grady Memorial Hospital, Atlanta, GA	75
OHSU	Oregon Health & Science University Hospital, Portland, OR	69
NYP	NYP Columbia University Medical Center, New York, NY	68
Hub	**Site (Outside of the US)**	**#**
CRC	University of Alberta Hospital, Edmonton, AB, CAN	104
CRC	Santa Creu and Sant Pau Hospital, Barcelona, ESP	72
CRC	University of Calgary - Foothills Campus, Calgary, AB, CAN	50
CRC	Vall d'Hebron Hospital, Barcelona, ESP	33
CRC	Foch Hospital, Suresnes, FRA	30
CRC	Miguel Servet Hospital, Zaragoza, ESP	29
CRC	Girona University Hospital, Girona, ESP	28
CRC	Helsinki University Central Hospital, Helsinki, FIN	28

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

COORDINATOR'S CORNER

Retention Tips and Reminders

by Karla Zurita, Enrollment Specialist, UCSF

Now that we're coming down the homestretch of the POINT Trial, we are focusing more than ever on reducing participant attrition. Although some cases of premature study drug discontinuation, consent withdrawal, and lost to follow-up are unavoidable, a few strategies can help to minimize the avoidable cases.

Premature Study Drug Discontinuation

Early study drug discontinuation by a participant's primary care physician (PCP) accounts for 40% of those coming off study drug before Day 90. An existing physician-facing strategy to minimize these discontinuations is the PCP letter sent after a patient's randomization, available on the NETT POINT Toolbox. The letter is intended to provide physicians with information about the trial, highlighting the importance of keeping a participant on the assigned intervention for the duration of participation in the study. Please make use of this letter, and the other materials in the Toolbox, when enrolling participants in POINT.

Withdrawal of Consent

To date, approximately 2.5% of participants have withdrawn consent in the study. If participants express that they wish to withdraw from the study, explore the level of participation that they would be willing to maintain. Do they want to discontinue only study drug? Would they be willing to be contacted by telephone or in writing? Are they refusing all follow-up visits?

Open, regular communication with a participant may provide insight into potential reasons that can be mitigated in time to prevent a consent withdrawal. When speaking with participants, try to gauge whether they are having difficulty complying with study drug; experiencing minor side effects; or anticipating any change in their life that could impact study participation.

Let's do our best to reduce this rate!

Lost to Follow-Up

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

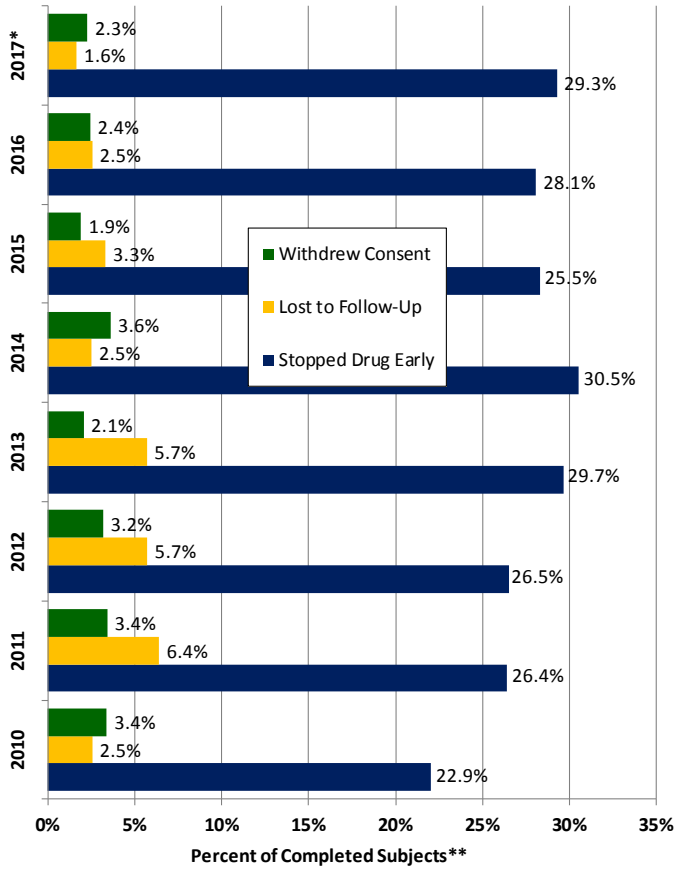
Remember that attempts to reach LTFU participants should continue through 150 days post-randomization. At least three attempts to contact the participant by telephone and a letter via Certified Mail™ must be documented in the Comments section of Form 17, End of Study on WebDCU™.

At the upcoming DSMB meeting, we will mention some of the approaches that have helped to keep attrition rates down. If you have any additional strategies to lower these rates that you'd like to share with us, please send them to karla.zurita@ucsf.edu.

End of Daylight Saving Time 2017

In the majority of the countries participating in POINT, daylight saving time (DST) ends on **Sunday, November 5th, at 2:00 AM local time.** Please remember that although we gain an hour on the clock, the 12-hour eligibility window for POINT candidates remains. Should there be urgent questions about participant enrollment around this time, please contact the POINT Hotline.

CONSENT WITHDRAWALS, 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 October 23, 2017

Cumulative Rates*

Premature Study Drug Withdrawal

1,305 Participants – 28.2%

Unavoidable Causes – 66.5%

Potentially Avoidable Causes – 37.8%

*4,286 completed the study. Data as of October 23, 2017

A Message from WebDCU™: Upcoming POINT Data Freeze AND Welcome Cassidy!

There will be a data freeze on Friday, November 3rd. Please continue to make sure your site is up to date with data by following the instructions that the WebDCU™ team provided by email for Open DCRs and Spoke Data Due, Visits Past Due, and Rule Violations.

Questions? Please contact Cassidy Conner at connerc@musc.edu or (843) 876-1105

Please note that effective October 1, 2017, Cassidy Conner will be the Lead Data Manager for POINT at MUSC. He is taking over for Aaron Perlmutter. Cassidy worked on POINT back in 2011, so the study is in good hands with him.

Best of luck, Aaron, and welcome back, Cassidy!