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The Newsletter of the POINT Trial

Volume 7, Issue 2 2nd Quarter 2017

2017 2nd Quarter Recap

Dear Colleagues,

Study Enrollment Update
We closed out the 2nd quarter with an enrollment of 4,586 participants, 79% of our 5,840 target. April was the strongest month of the quarter with 90 enrollments, including 46 participants from outside the US. Keep up the great work!

Study Drug Update
As of the end of June, Lot 6 study drug was restocked at all sites in the United States, New Zealand, and Canada, as well as at the depots in Australia, Mexico, and the United Kingdom. This new batch of study drug expires in October 2018. As a reminder, NETT sites should destroy the old supply (Lot 5) per local guidelines after the first monitoring visit has been conducted and sites have been instructed to do so. CRC sites should wait until authorization is given to destroy drug at the next monitoring visit, or when instructed to do so by the site manager.

June DSMB Meeting
We met with our Data and Safety Monitoring Board (DSMB) on June 30, 2017. Discussion topics included funding, recruitment, and preparation for study closeout activities. The DSMB did not identify any concerns regarding safety or study implementation, and thus recommended the study proceed as planned.

September 2017 Enrollment Target: 4800
The NIH placed an enrollment restriction on our Year 1 funding: 50% of the award was made available, with the remainder becoming available once a target of 4,800 participants has been reached.

We'd like to reach that target by the end of September 2017. Based on our performance over the last 9 months, we believe we can consistently enroll 80 participants each month for the next 3 months and reach this goal.

Thank you for your commitment to POINT throughout the years and as we reach the final stretch!

Sincerely,

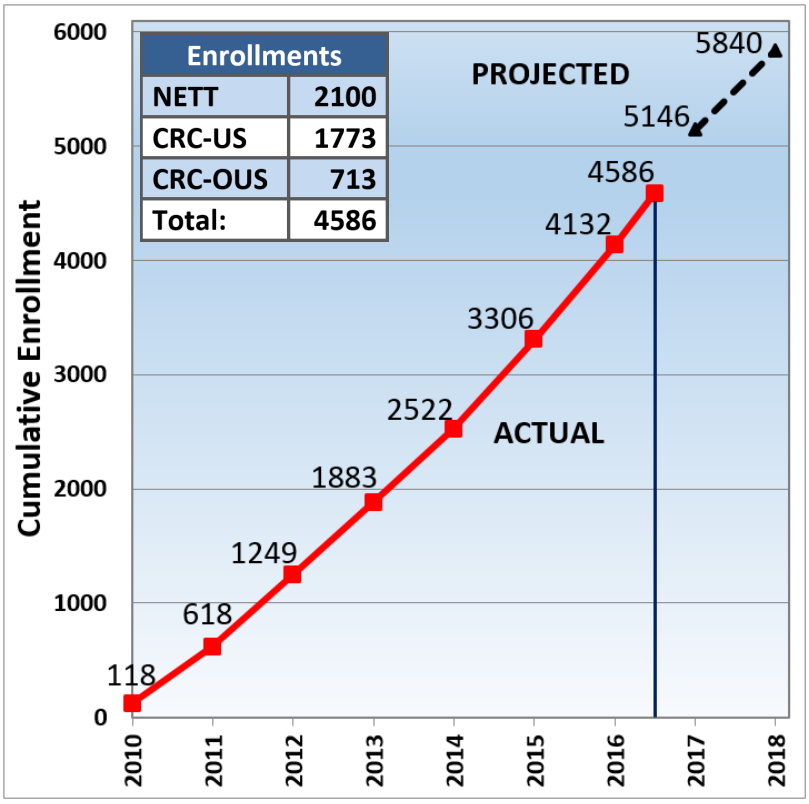
Clay Johnston MD, PhD, POINT Principal Investigator

Don Easton MD, POINT co-Principal Investigator

Anthony Kim MD, MAS, POINT co-Principal Investigator

POINT Cumulative Enrollment

May 2010 through June 2017



Hot Enrollers for 2nd Quarter

Hub	Site	#
CRC	University of Alberta Hospital, *Edmonton, AB, CAN*	15
CRC	Santa Creu and Sant Pau Hospital, *Barcelona, SPA*	9
CRC	Bichat-Claude Bernard Hospital, *Paris, FRA*	8
CRC	Helsinki University Central Hospital, *Helsinki, FIN*	8
CRC	Benefis Hospitals Inc, *Great Falls, MT, USA*	7
CRC	La Fe University Hospital, *Valencia, SPA*	7
MINNESOTA	Hennepin County Medical Center, *Minneapolis, MN*	6
CRC	Footscray Hospital, *Footscray, VIC, AUS*	6

Top Enrollers (as of June 30, 2017)

Hub	Site (US)	#
CRC	Guilford Neurological Associates, *Greensboro, NC*	120
UPENN	Hospital of the University of Pennsylvania, *Philadelphia, PA*	120
CRC	Benefis Hospitals Inc, *Great Falls, MT*	102
STANFORD	Stanford University Medical Center, *Stanford, CA*	83
EMORY	Grady Memorial Hospital, *Atlanta, GA*	72

Hub	Site (OUS)	#
CRC	University of Alberta Hospital, *Edmonton, AB, CAN*	98
CRC	Santa Creu and Sant Pau Hospital, *Barcelona, SPA*	69
CRC	University of Calgary - Foothills Campus, *Calgary, AB, CAN*	48
CRC	Vall d'Hebron Hospital, *Barcelona, SPA*	31
CRC	Northwick Park Hospital, *Harrow, GBR*	27
CRC	Hospital del Mar, *Barcelona, SPA*	27
CRC	Miguel Servet Hospital, *Zaragoza, SPA*	26

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

COORDINATOR'S CORNER

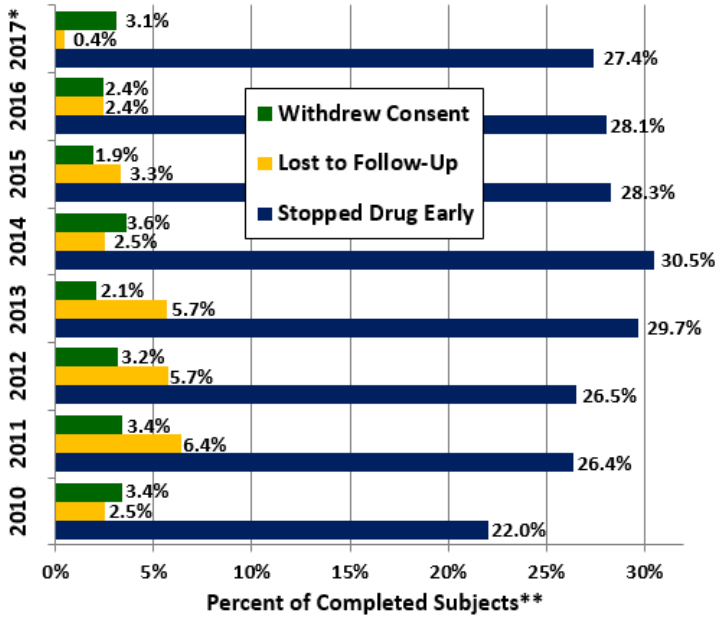
Keeping the electronic Delegation of Authority (eDOA) log current

The electronic Delegation of Authority (eDOA) log in the POINT database should accurately reflect your current study team members, their roles, and their responsibilities. Please adhere to these instructions:

1) **If a study team member is no longer participating in the POINT trial at your site**, an end date should be added to the eDOA under [DOA Submission] and any user groups should be removed for that person under the [User Permission Request] table.
2) **If a study team member joins the POINT trial at your site**, a [Study Team Member Request] should be made, the person should be added to the eDOA under [DOA Submission], and, if necessary, permissions to the database should be requested.
3) **If a study team member changes roles/ responsibilities at your site**, an end date should be added for the original roles/responsibilities on the eDOA under [DOA Submission] and a new entry should be added with all of the current roles/ responsibilities. The end date should be the same as the new start date.

For any questions on the eDOA, contact your Study Manager.

CONSENT WITHDRAWALS, LOSSES TO FOLLOW-UP, AND STOPPED STUDY 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 July 3, 2017

Reminder About the Use of Aspirin

A few questions about the use of aspirin in POINT have come up again. Sites in Germany requested clarification whether patients already taking a daily dose of aspirin of 50-325mg are still eligible for the trial. ***A patient on aspirin for any reason, and not taking prohibited medications, is definitely eligible for screening in POINT***.

Further clarification was requested about which patients would not be considered eligible for the study based on the following exclusion criterion:

> Anticipated requirement for long-term (>7 days) nonstudy antiplatelet drugs (e.g., dipyridamole, clopidogrel, ticlopidine), or drugs affecting platelet function (such as prior vascular stent or arthritis).

This exclusion does not apply to aspirin as it is a study drug. As stated previously, patients on aspirin for any reason who are not taking any prohibited medications can be screened for participation in POINT.

Additional examples of non-study antiplatelet drugs are nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, indomethacin, and naproxen.

As always, please reach out to us or to your Study Manager with any questions. For emergency enrollment guidance, call the 24-hour POINT Study Hotline at 1-866-94-POINT.

GCP Training Documentation for POINT Sites

Individual Good Clinical Practice (GCP) training documentation has historically been given a status of "waived" in WebDCU™ for our NETT sites. With the new NIH policy (effective January 1, 2017) requiring investigators and clinical trial staff of NIH-funded trials to be trained in GCP, we need to collect this documentation in WebDCU™ at NETT sites.

Please note that GCP training documentation for current NETT staff that was previously "waived" in the database has been programmatically updated to a status of "expired". You will need to upload a current GCP training certificate to WebDCU™ to replace these expired documents.

The CRC-EMMES has always required documentation of GCP training for its sites, which should continue to provide current GCP training certificates.

Send in Your Biomarker Samples!

Please send to LabCorp any refrigerated or frozen biomarker samples that are overdue. Study Managers will check in with sites that have samples marked as collected on WebDCU™ but are not registered at LabCorp. Refer to your lab manual for specific storage periods for the various temperatures.

Looking Ahead: Study Closeout Milestones

With only 20% of our 5840 enrollment target to go, it's time to begin looking ahead at the milestones for the study closeout period. Our Last Subject In (LSI) is expected in September 2018 - just over one year from now. We can't thank you enough for the great work that has brought the POINT Trial to this stage. Here's to continuing a successful trial!

2018

- **Last Subject In (LSI):** September 2018
- **Last Subject Visit (LSV):** 90 days after LSI

2019 Onward

- **Last Subject Follow-Up:** Up to 150 days after LSI
- **Database Freeze**
- **Final Analysis Report**
- **Primary Manuscript/ Publication**
- **Public Data Sharing**