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The Newsletter of the POINT Trial

Volume 6, Issue 2 3rd Quarter 2016

2016 3rd Quarter Recap

Dear Colleagues,

Study Enrollment Update
August was our highest enrolling month of the quarter with 63 participants. Enrollment has been trending upward since the lull in June caused by new study drug and amendment 6 approvals, but we still are seeing lower than projected numbers. This is mainly due to the suspension of enrollment at international sites as they work on securing approval for amendment 6.0 from country and site regulatory bodies.

Since the implementation of Amendment 6.0, Australia, Canada, Finland, France, Spain, and the UK have received regulatory approval. Sites in these countries have started to enroll in POINT again, and we are thrilled to welcome them back into the fold! As the rest of our international sites come back into the trial, we look forward to an increase in our enrollment and a strong finish to 2016.

Upcoming DSMB Meeting
The POINT Study Team will be meeting with the DSMB by teleconference on December 16, 2016. As usual, funding, enrollment, and attrition will be the main topics of discussion. We are especially focused on continuing to bring down our rates of premature study drug discontinuation, withdrawal from the trial, and lost to follow-up prior to the meeting. We recognize that many of these situations are unavoidable, so we are focused on strategies that help us prevent the avoidable cases. A refresher on current LTFU practices can be found on page 2.

WebDCU Update
WebDCU will be undergoing some updates over the coming weeks. The primary goal of these updates is to replace the paper Delegation of Authority (DOA) log with an eDOA that lives in the POINT database. This means that all information about study personnel and regulatory documentation will be moved from the NETT database into POINT. In addition, all uploaded documents will be ported over from the NETT database, saving you from having to upload them again. For more details about this transition, please see the article on page 2.

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

Sincerely,

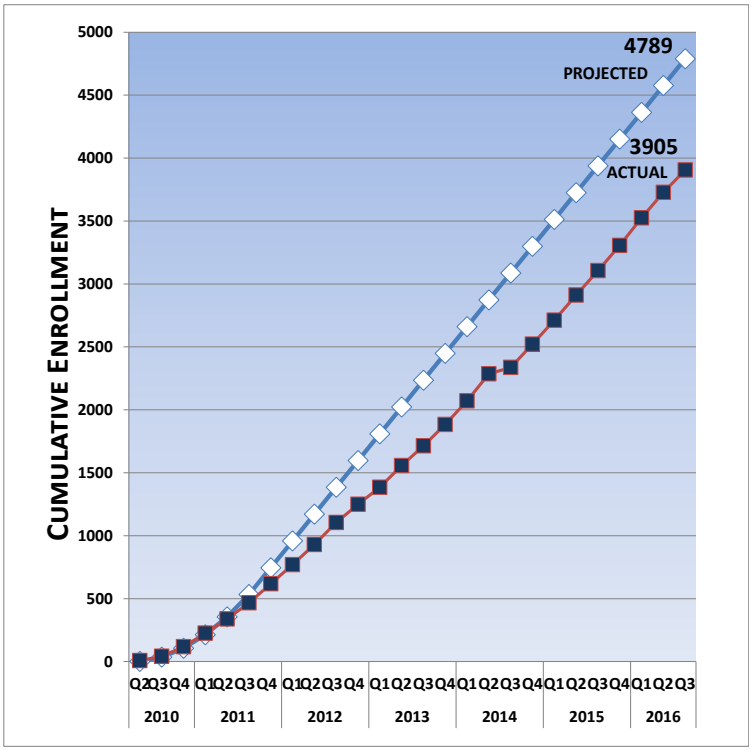
Clay Johnston MD, PhD, POINT Principal Investigator

Don Easton MD, POINT co-Principal Investigator

Anthony Kim MD, MAS, POINT co-Principal Investigator

POINT Cumulative Enrollment

May 2010 through September 2016



POINT Enrollment Update: Total = 3905

Hot Enrollers for 3rd Quarter

Place	Subjects	Site (Hub)
1	7	Benefis Hospitals (CRC)
2	6	University of Calgary (CRC)
3	4	University of Alberta Hospital (CRC), Bon Secours St. Mary's Hospital (CRC), Mayo Clinic Saint Mary's (Minnesota), Houston Methodist Hospital (CRC), WellSpan York Hospital (Upenn), OHSU Hospital (OHSU), Detroit Receiving Hospital (Wayne), Froedtert Memorial Lutheran Hospital (Wisconsin), Scripps Mercy Hospital San Diego (CRC), UCSD Medical Center (CRC), Massachusetts General Hospital (Mass General), University of Illinois Medical Center (CRC)

Top Enrollers (as of September 30, 2016)

Site (Hub)	City	State	#
Guilford Neurologic (CRC)	Greensboro	NC	115
Hospital of UPenn (UPenn)	Philadelphia	PA	109
Benefis Hospitals (CRC)	Great Falls	MT	88
Stanford Univ. (Stanford)	Stanford	CA	73
OHSU-Oregon (OHSU)	Portland	OR	61
Univ. of Alberta Hospital (CRC)	Edmonton	AB	61
Columbia Univ. (NYP)	New York	NY	60
Detroit Receiving (Wayne)	Detroit	MI	59
Buffalo General Med Ctr. (CRC)	Buffalo	NY	59
Grady Memorial Hospital	Atlanta	GA	57
Houston Methodist (Texas)	Houston	TX	56
Temple Univ. Hospital (Temple)	Philadelphia	PA	55

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

COORDINATOR'S CORNER: WEBDCU UPDATE

By Aaron Perlmutter, Data Manager, MUSC

At the end of October/beginning of November, we will be updating the WebDCU™ POINT interface for adding team members, completing the electronic Delegation of Authority log (eDOA), and adding regulatory documents.

After the update is implemented, new POINT study team members can be added within the POINT database instead of going to the NETT database like before. It will be possible to maintain an eDOA within WebDCU™ rather than tracking changes on the paper DOA. Additionally, all regulatory documents will be maintained within the POINT database, and a new "Site Reg Doc Status" page will show you the status of your Site and People Documents in a single view. Regulatory documents will be copied over from the NETT database, as will the study team members already on the project. There will be some steps for you to set up your team in WebDCU™, so we will be providing a user manual and a training video with detailed instructions on how to use the new functionality.

Please contact Adam Henry (**henryad@musc.edu**) or Aaron Perlmutter (**perlmutt@musc.edu**) with any questions or concerns.

LOST TO FOLLOW-UP REMINDERS

By Clay Johnston, MD, PhD, POINT Principal Investigator

While our rate for lost to follow-up (LTFU) is relatively low for 2016, 0.7%, we expect it to rise as more subjects reach the end of the study. As a reminder, if a participant cannot be reached for the 90 day visit, efforts to reach that subject can continue up to 150 days post-randomization. Documented attempts to contact the subject should be made, including at least three attempts by telephone and a letter sent via Certified Mail™ (or the equivalent in other countries). These attempts should be documented in the Comments section of Form 17 – End of Study in WebDCU™. The specific guidelines for documenting when subjects are considered LTFU are in the study protocol, section 9.4.2.1.

For our upcoming DSMB meeting, we are focused on highlighting the approaches we employ to reduce all of our attrition rates. If you have any strategies to lower these rates that you would like to share with us, please send them to **POINTOperations@ucsf.edu.**

International Stroke Conference 2017: Houston, TX

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

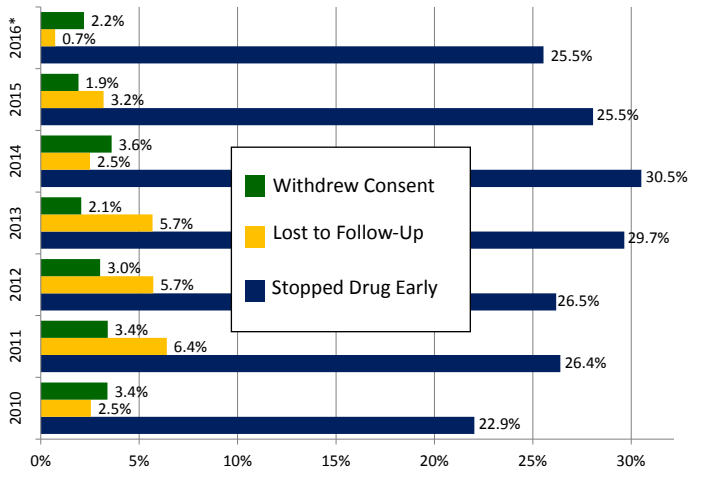
PI Reception for Site PIs and Coordinators: 5-7pm CT (3-5pm PT, 6-8pm ET)

Advisory Committee Dinner Meeting: 7-9pm CST (5-7pm PT, 8-10pm ET)

Location and additional details will be sent out in the coming months. Please check your email for these e-vites.

For any ISC 2017 events questions, please contact us at ***POINTOperations@ucsf.edu***

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



Percent of Completed Subjects**

*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 September 19, 2016

Top-Enrolling NETT Hubs (as of September 30, 2016)

Hub	*Total*	*Enrollments per 90 days*
UPenn	288	11.5
Cincinnati	181	7.1
Wayne	170	6.9
Minnesota	161	6.3

Enrollment by Country (as of September 30, 2016)

Country	*# Active Sites**	*Total Subjects*
AUS/NZL	9	56
CAN	8	148
FIN	2	14
FRA	1	16
GER	0	3
MEX	0	6
SPA	5	113
UK	2	47
US (CRC)	85	1609
US (NETT)	91	1893

*Some sites suspended pending Amendment 6.0 approval

ANCILLARY STUDY UPDATE

As you may know, the Mayo Clinic in Jacksonville, FL is preparing the genetic analysis for the POINT Ancillary Study. The summary statistics for the samples that have been collected so far have now been completed. Luca Farrugia, the research trainee working on the analyses, will be presenting these statistics during the next **NETT Study Coordinator Call**. **All CRC Coordinators are invited to join.** The details are below:

Date: November 1, 2016

Time: 10am PT/11am MT/12pm CT/1pm ET

Phone Number: 888-330-1716

Passcode: 5967697

The presentation will take approximately 10 minutes. Please look for an invitation with further details in your inbox. If you have not received an invitation, please contact your Study Manager or email us at **POINTOperations@ucsf.edu.**