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The Newsletter of the POINT Trial

Volume 4, Issue 3 — 3RD Quarter 2014

2014 3RD Quarter Recap

Dear Colleagues,

Welcome back to the POINT Trial! We greatly appreciate your efforts to begin enrolling POINT subjects again.

Study Enrollment Update

We finished our first month post-hiatus with over 50 subjects entered into the trial! Given that we've just begun enrolling after a two-month break, this is definitely good!

Three new sites were activated this quarter, including two in the US (Beth Israel Deaconess Medical Center in Boston, and Alexian Brothers Medical Center in Elk Grove Village) and an additional site in Australia (The Northern Hospital, Epping, VIC).

iPad Project Update

In an effort to increase consent and retention rates, we began supplying iPads with a POINT app for an instructional video and quiz to some actively enrolling sites during the first quarter of 2013. The devices were meant to assist in the education of patients considering participation in the POINT study.

iPads have so far been distributed to sixty-seven sites which expressed interest in using them with their patients during enrollment. Of those, thirty-nine have used the POINT app at least once, so it isn't possible to draw any meaningful conclusions regarding the effectiveness of the POINT app as a supplement to the consent process due to the relatively small amount of data available on iPad usage. Nevertheless, we did find potential evidence for an association between watching the iPad video and consenting to participate in the POINT trial.

We plan on testing the validity of these preliminary findings by conducting a short pilot study of the POINT app at a limited number of sites. The results will be reported here once they become available.

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

Sincerely,

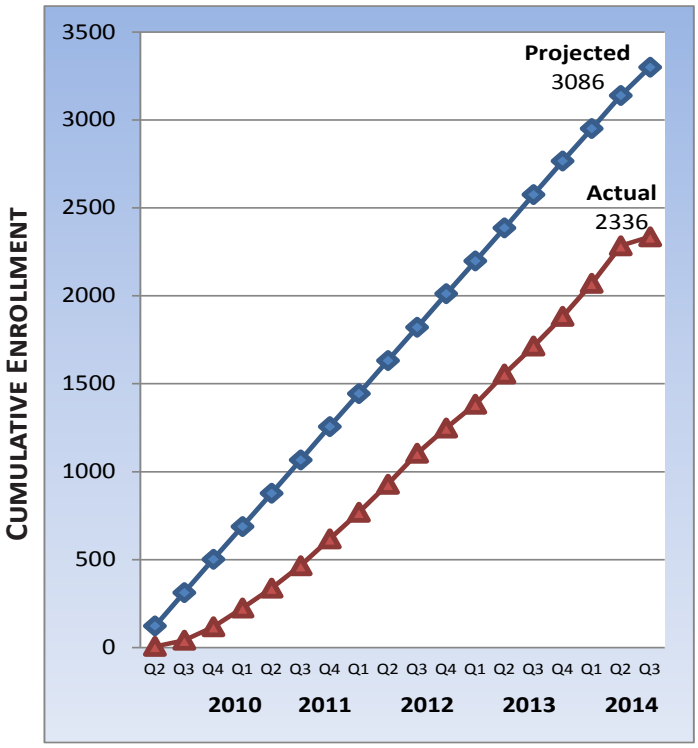
Clay Johnston MD, PhD, POINT Trial Principal Investigator

Don Easton MD, POINT Trial co-Principal Investigator

Anthony Kim MD, MS, POINT Trial co-Principal Investigator

POINT Cumulative Enrollment

May 2010 through September 2014



POINT Enrollment Update: Total = 2336

Hot Enrollers for 3rd Quarter

Place	Subjects	Site (Hub)
1	5	Stanford U (Stanford)
2	4	Barnes Jewish (Cincinnati), Shands Hospital (CRC) Methodist Hospital (CRC), Weill Cornell Med Ctr (CRC)

Top Enrollers (≥39 enrollments as of September 30, 2014)

Site (Hub)	City	State	#
Guilford Neurologic (CRC)	Greensboro	NC	93
Hospital of UPenn (UPenn)	Philadelphia	PA	85
OHSU- Oregon (OHSU)	Portland	OR	44
Benefis Hospitals (CRC)	Great Falls	MT	44
Columbia Univ. (NYP)	New York	NY	43
Cleveland Clinic (CRC)	Cleveland	OH	41
Buffalo General Med Ctr (CRC)	Buffalo	NY	41
Methodist Hospital (CRC)	Houston	TX	40
Detroit Receiving (Wayne)	Detroit	MI	39
Memorial Hermann (Texas)	Houston	TX	39
Stanford U (Stanford)	Stanford	CA	39

COORDINATOR'S CORNER: Enrollment and Retention Tips from the Cincinnati Hub

By Gina Neshewat MPH CCRP, Clinical Research Project Manager (NETT) and Irene Ewing, Cincinnati Hub Research Coordinator

In terms of enrollment, the Cincinnati Hub has always done very well. However, their performance this first month after the hiatus has been truly exemplary with nine enrollments. We recently had a chance to discuss study subject enrollment strategies with Irene Ewing, the Primary Study Coordinator for all of the sites within the Cincinnati Hub. We'll feature the second part of our conversation with Irene in next quarter's newsletter. Below are her answers to the first set of the questions we had for her:

1) How did you train your sites for POINT re-enrollment? Our team is located at the Hub and we meet weekly to discuss all stroke trials. Before a study starts and periodically during the trial, we set aside time in this meeting to retrain on trials. We periodically go out to meet with emergency department physicians and nurse educators, and in service them on trials. The nurse educator follows up with individual nurses. We also meet with each local pharmacist and train them on the trial. We provide a group training for pharmacies if they are open to that.

2) What challenges have you faced? Since our team physically covers 12 hospitals and does telemedicine with more, it can get very busy with multiple calls at one time. The coordinators who take calls have been trained to go out first when the physician is busy to evaluate the patient and talk to him/her about the study or show the video. This can either speed up the enrollment when the physician gets there, or rule out a patient more quickly.

3) Cincinnati has several smaller and larger hospitals and medical centers. Any advice for our smaller hospitals who are having difficulty with enrollment? Our situation is a bit different than some places since we have been going to these facilities for a long time. We do have a nurse coordinator/educator go out to visit all the spoke hospitals on a regular basis to do stroke education, and to give them an update on the current trials. You have to be visible. Any time one of our team goes to an emergency department, we almost always get a call the same day for a possible stroke.

4) What about advice for larger hospitals with competing trials? It is vital to know what other trials are being done and work with the departments/investigators to arrange some kind of rotation. We have a weekly Emergency Medicine Research Interest Group that meets to discuss any new trial that will be taking place in our ED. This avoids any surprises and allows time to collaborate on how the overlapping trials will be handled. We have done odd/even days and we have done alternating enrollments regardless of day.

5) Barnes Jewish Hospital (site Principal Investigator and Primary Study Coordinator pictured right) ended the third quarter with only 8.3 percent of their patients having discontinued study drug prematurely, and a 90-day enrollment rate of 2.2 subjects. What do you believe are some key factors contributing to their exceptional performance?
I know that they have recently instituted a follow-up policy. They continue to follow a patient up to the 12 hour mark. For example, if the patient doesn't qualify when they first see them, they continue to check back until they are out of the window. Communication with the patient and their primary care physician/neurologist is key for avoiding early drug discontinuation. If the patient becomes worried about being in the study it goes a long way to make them feel better when their private doctor knows about the study and supports it.

Dr. Heitsch (left) Rachel Sargent (right)

A Fond Farewell to Peggy Wayneyer

Peggy joined our (the Cincinnati Hub) NETT team in 2009. She immediately proved herself to be hardworking and dedicated. She always goes the extra step to make sure everything is done properly. She comes in after hours, even when she is not on call, to help with enrollments or follow-ups. She has personally enrolled 25 of the POINT patients at our local Hub-Spoke complex, and she has done 90% of the follow-ups. We have to thank Peggy for our low lost-to-follow-up rate as she often goes to patients' homes when they won't come to the clinic. While she admits she is directionally challenged, she always manages to find the right house! We are saddened that Peggy will be retiring at the end of November to spend more time with her family, particularly her grandchildren in Columbus, and working in her garden. Peggy is a bright spot on our team and she will be dearly missed!

Peggy Wayneyer (left) Dr. Kleindorfer (center) Irene Ewing (right)