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The Newsletter of the POINT Trial

Volume 5, Issue 1 — 1ST Quarter 2015

2015 1ST Quarter Recap

Dear Colleagues,

Study Enrollment Update

The highest enrolling month in the quarter was March, with 70 enrollments! We closed out the first quarter of 2015 with an enrollment of 2,712 subjects, including 106 subjects outside the US, reaching over 46 percent of our target of 5,840 subjects. Five sites were activated this quarter. Included amongst these is Northwick Park Hospital, the third site in the UK. Northwick Park Hospital has enrolled 4 subjects since they were released to enroll in late January.

Weekly Performance Metrics Updates

This January, we began presenting POINT performance metrics related to study drug adherence on a weekly basis during the NETT Operations Committee conference call. Our study performance update, now a standing item on the agenda, has given us the opportunity to discuss on a regular basis any issues pertaining to enrollment and early study drug discontinuation with our partners at the NETT, CRC, and MUSC. We welcome any feedback that Study Coordinators might have regarding study drug adherence, so we will also be discussing this matter during the next NETT Study Coordinator Call on April 14, 2015. Please contact Rusty Andres (randres@med.umich.edu) for the dial-in details if you aren't on the e-mail list for this call.

POINT ESO 2015: Glasgow, Scotland

The POINT Study Team will be presenting a poster at the European Stroke Organisation (ESO) Conference on April 17 and 18 in Glasgow, Scotland. More information regarding the ESO poster sessions, including days, times and directions to the venue, will be sent out by email in the next few weeks.

POINT Recognition System

We are considering a recognition system that would provide sites with the opportunity to be rewarded for exceptional performance in terms of enrollment or study drug adherence. Please forward your suggestions/ideas for this new program to Sundary Sankaran (e-mail below). More details to follow in the near future.

Please don't hesitate to contact us directly if you have questions or require more information.

Sincerely,

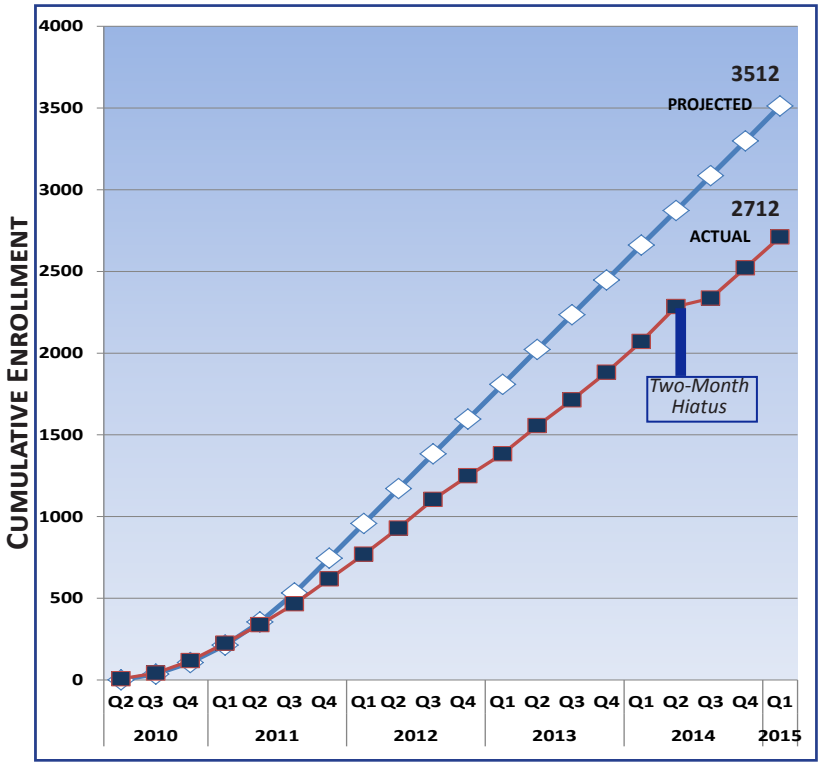
Clay Johnston MD, PhD, POINT Trial Principal Investigator

Don Easton MD, POINT Trial co-Principal Investigator

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

POINT Cumulative Enrollment

May 2010 through March 2015



POINT Enrollment Update: Total = 2712

Hot Enrollers for 1st Quarter

Place	Subjects	Site (Hub)
1	11	Santa Creu and Sant Pau Hospital (CRC)
2	6	University of Alberta Hospital (CRC)
3	5	Benefis Hospitals Inc (CRC), Guilford Neurological (CRC), Froedtert Memorial Lutheran Hospital (Wisc.), Shands Hospital at the University of Florida (CRC)
4	4	Buffalo General Medical Center (CRC), Grady Memorial Hospital (Emory), Northwick Park Hospital (CRC), Southern Illinois - Memorial Hospital (CRC), University of Florida Health Sciences, Jacksonville (CRC), Yale-New Haven Hospital (Mass General)

Top Enrollers (as of March 31, 2015)

Site (Hub)	City	State	#
Guilford Neurologic (CRC)	Greensboro	NC	106
Hospital of UPenn (UPenn)	Philadelphia	PA	90
Benefis Hospitals Med Ctr (CRC)	Great Falls	MT	52
Buffalo General Hospital (CRC)	Buffalo	NY	49
Columbia University (NYP)	New York	NY	47
OHSU Oregon (OHSU)	Portland	OR	47
Stanford University (Stanford)	Stanford	CA	45
Cleveland Clinic (CRC)	Cleveland	OH	44
Detroit Receiving (Wayne)	Detroit	MI	43

COORDINATOR'S CORNER: EARLY STUDY DRUG DISCONTINUATION PREVENTION TIPS

This past February, we surveyed some of our top-performing sites for ideas on strategies we might be able to apply at the site-level in order to decrease our rate of early study drug discontinuation. See table to the right. Below are some of the suggestions we have received so far:

"Contacting and consulting the PCP has also been beneficial as beyond medical history, he/she is usually able to provide insight as to medication compliance, personality, and predict issues that may present in the subsequent 90 days."

-Erica Eber, Stroke Research Nurse Coordinator
(NYP Weill Cornell Medical Center, New York, NY)

"We review the patient's medications very carefully for prohibited medications and other disease processes that might eventually lead them to prohibited medications within the 90days. Some patients, although willing to discontinue an NSAID or change a PPI to an H2 blocker for 90 days for example, we have found the patients usually want to revert back to their previous therapy for pain/relief."

-Patricia McNelis, Primary Study Coordinator
(Temple University Hospital, Philadelphia, PA)

"It is extremely helpful to have an additional point of contact when the POINT patient has been discharged. It is also helpful to have that person be fully informed of the study to help the POINT patient remember to take the study meds and stay on track."

-Dominica Randazzo, Primary Study Coordinator
(San Francisco General Hospital, San Francisco, CA)

"Part of the process is making potential subjects better understand the study. Study teams should present the facts about the TIA / minor ischemic stroke reoccurrence rate. Just because symptoms may have resolved doesn't mean patients are 'in the clear'."

-David McCane, Co-Investigator
(Methodist Hospital, Houston, TX)

"It's really helpful if the neurologist on-call can talk to the patient in person about the study or be available to talk to the patient about it over the phone. We make a point to communicate that our patients health is our and the treatment team's number one priority. We try to humanize the experience and connect with them on a personal level. I make myself very available through email and my cell phone to answer any questions or concerns any time."

-Christine Keller, Clinical Research Coordinator
(Stanford University Medical Center, Stanford, CA)

Study Drug Discontinuation:
Targeted Study Drug Adherence Training

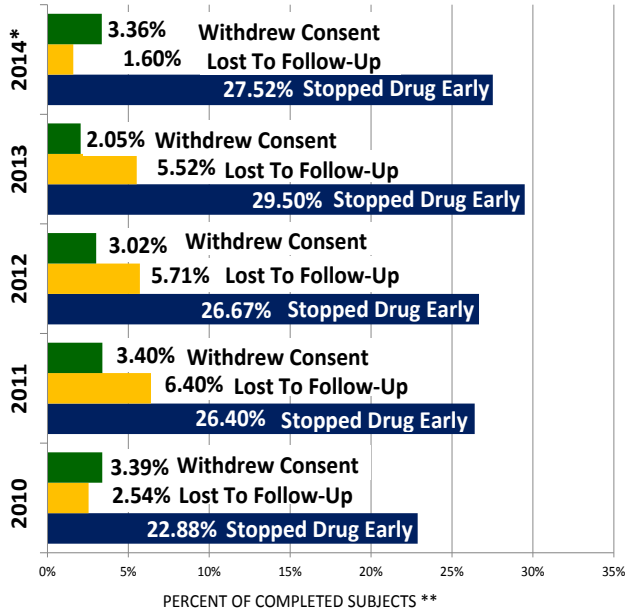
In an effort to improve study drug adherence amongst POINT subjects, we are planning a series of training sessions for sites with the highest rates of early study drug discontinuation. Some of the topics covered in the slide set to be presented during these training sessions include:

- The negative impact that early study drug discontinuation has on study participants, sites, and the sponsor
- A comparison between avoidable and unavoidable reasons for early study discontinuation
- Possible reasons subjects decide to discontinue study drug early
- Factors that may contribute to subjects adhering to study drug
- Strategies that site staff can employ to prevent POINT subjects from discontinuing study drug early

We also put together an online survey for site staff to provide their feedback regarding the issues above. Please follow the link below to access the survey:

https://www.surveymonkey.com/s/CG8B2QN

WITHDRAWN CONSENTS, 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 March 23, 2015 (Q1 2015 excluded due to insufficient data)

Top-Enrolling NETT Hubs (as of March 31, 2015)

Hub	*Total*	*Enrollments per 90 days*
UPenn	226	12
Wayne	121	6.5
Cincinnati	120	6.3
Minnesota	110	5.7

Q1 Site Activations

Long Beach Memorial Medical Center, Long Beach, CA (UCLA); Northwick Park Hospital, Harrow, GBR (CRC); St. Anthony Hospital, Lakewood, CO (CRC); Girona University Hospital, Girona, ESP (CRC); Miguel Servet Hospital, Zaragoza, ESP (CRC);

***Bold text indicates sites that have already enrolled subjects.**

Biomarker Specimen Collection Kits

Please remember to periodically check the expiration dates on any unused biomarker kits at your site. You can replace expired kits by contacting Brittney Whitworth **(Whitwob@labcorp.com)**.

Loading Dose Administration Outside the "12-Hour Time Window"

Recently a site stopped study drug permanently in a subject who never received the loading dose (LD) because "the patient was over the 12 hours."

Although we strongly encourage initiation of treatment within the 12 hour interval, and failure to do so in a randomized subject is a minor violation, initiation of the study drug treatment should proceed.

These patients are at high risk for an ischemic outcome well beyond the initial 12 hours and the primary goal of POINT is to determine whether the study drug can prevent that.

Look for an FAQ to be added to the Toolbox on this topic.