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The Newsletter of the POINT Trial

Volume 3, Issue 2 2nd Quarter 2013

2013 2nd Quarter Recap

Dear Colleagues,

Enrollment Update

We reached an enrollment of 1,553 at the end of the second quarter of 2013, which included 61 subjects entered into the trial in May. We're at 37% of our target enrollment of 4,150; 150 sites are actively enrolling subjects.

Our original projections for the trial indicated we would be at nearly half (48.8%) of the 4,150 target by the end of June 2013. Enrollment in POINT began to fall off relative to projections starting in Q2 2011, and unfortunately, that trend has continued, as the graph to the right illustrates.

Expansion of the study to international sites is taking longer than originally projected; the first sites outside the US (Canada) are now expected to begin enrolling subjects in July, with Australia next, followed by the UK.

As you can see from the table on the right, only one new site was enrolled this quarter. While the NETT expects to bring on 20 more US sites, and the CRC, 4, we need to step up our efforts to recruit (and retain) subjects in POINT.

POINT DSMB Meeting

Recruitment, enrollment and retention were topics discussed in depth at the POINT DSMB meeting in New York on May 2, 2013. The POINT team and the DSMB reviewed the results of the first interim analysis, and while the DSMB has recommended that the POINT trial continue per its current protocol, it also recommended that enrollment expand to 5,840. It is important that we focus on this 40% increase in enrollment for POINT in both the US and OUS to meet this enrollment goal.

Focus on Enrollment and Retention

This 40% increase in enrollment will require greater focus and resources to attain. We will be coming to you over the next days and weeks as we develop strategies to implement at sites in response to this increase. We also welcome any strategies and ideas you might want to provide to help us meet this shared goal.

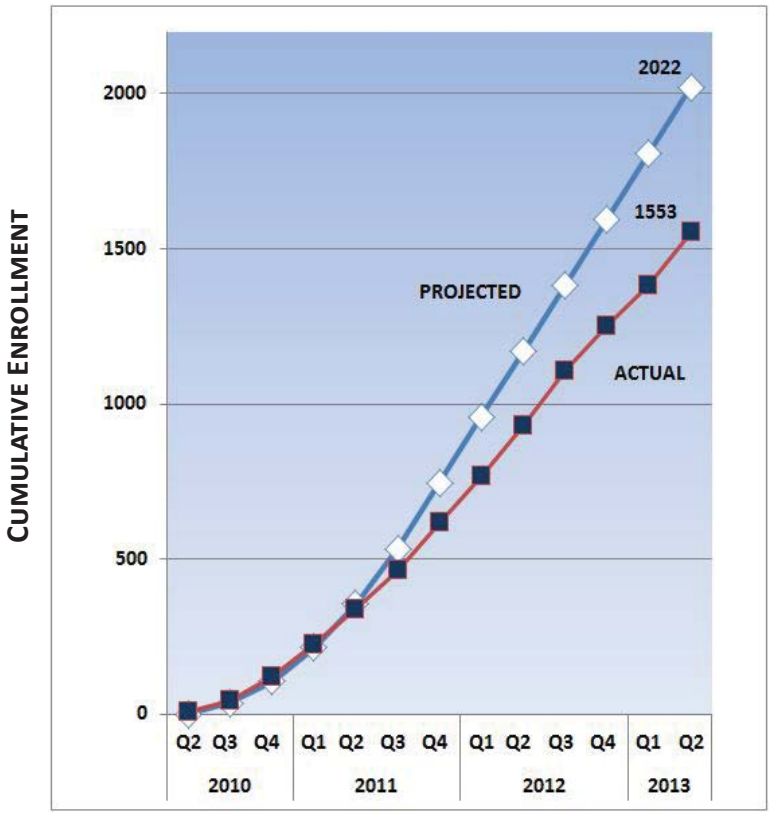
As always, please don't hesitate to contact us directly if you have questions or require more information.

Sincerely,

Clay Johnston MD, PhD, POINT Trial Principal Investigator
Don Easton MD, POINT Trial co-Principal Investigator

In This Issue

POINT Cumulative Enrollment
May 2010 through June 2013



Site Activations

Site (Hub)	City	State
UPMC - Presbyterian (UPMC)	Pittsburgh	PA

Top Enrollers (as of June 28, 2013)

Site (Hub)	City	State	#
Guilford Neurologic (CRC)	Greensboro	NC	75
Hospital of UPenn (UPenn)	Philadelphia	PA	64
OHSU- Oregon (OHSU)	Portland	OR	32
Detroit Receiving (Wayne)	Detroit	MI	31
Mayo Clinic Arizona (CRC)	Phoenix	AZ	30
Methodist Hospital (CRC)	Houston	TX	30
Temple Univ. Hospital (Temple)	Philadelphia	PA	30
Henry Ford (HFHS)	Detroit	MI	29
Advanced Neuro. Sp. (CRC)	Great Falls	MT	28
Abington Mem. Hosp. (UPenn)	Abington	PA	28
Kaleida Stroke Center, SUNY (CRC)	Buffalo	NY	28
Beaumont Hosp. Royal Oak (Wayne)	Royal Oak	MI	27
Regions Hospital (UPenn)	St. Paul	MN	27
Memorial Hermann Hospital (UTX)	Houston	TX	27
Univ. of Kentucky (Univ. of Kentucky)	Louisville	KY	27

Sites with 16-26 subjects enrolled: 18
Sites with 11-15 subjects enrolled: 17
Sites with 6-10 subjects enrolled: 39
Sites with 1-5 subjects enrolled: 74
Sites with 0 subjects enrolled: 12

NOTES FROM THE NINDS INSPIRE WORKSHOP

By Jens Leerssen, POINT Analyst, UCSF

The National Institute of Neurological Disorders and Stroke (NINDS) held an INSPIRE (Improving Neurology Subject [and Provider] Participation in the Research Enterprise) workshop on June 20-21 in Bethesda, MD. More than 120 stakeholders in neurology clinical research were in attendance.

Guest speakers, including Clinical Trial Specialist Jamie Roberts MA, CCRP (NIH/NINDS), Steven Mayo, PD, CCRA, PMP (Emissary International), Peggy Clark, RN, MSN, APRN (Univ. of Cincinnati), Barbara Tilley, PhD (Univ. of Texas), and Chris Speed (Newcastle Clinical Trials), shared their insights on meeting the challenges of recruitment and retention in neurology clinical trials through numerous presentations and round table discussions structured around the following areas:

Patient-Centered Study Design in Neurology: using newer technologies to streamline educational experiences and to improve communication channels towards understanding and responding effectively to subject concerns and interests.

Patient and Public Engagement: outreach, site selection, and simple and directly applicable materials to assist in study presentation and the enrollment process.

The State of the Clinical Research Enterprise: who the research audience is, how to reach them, and the importance and responsibility of community outreach and minority inclusion.

More than Just Metrics: Where the Quantitative Meets the Qualitative: successful approaches to structure goals, recognize and celebrate success, and to transfer effective strategies between sites.

In the course of the coming months, we look forward to including many of these ideas into POINT's approaches to increasing enrollment and retention.

A FOND FAREWELL TO TESS BONHAM

Many of you may know Tess Bonham as the Clinical Research Site Manager for POINT at the Neurological Emergencies Treatment Trials (NETT) Network at the University of Michigan. She has been a key team member since the start of POINT in 2010, and has contributed significantly to the progress and function of POINT.

Beginning in July, Tess will be moving to a new position in clinical research, focusing on trauma surgery trials.

We wish Tess the very best at her new position, and thank her for all of her hard work! After July 19th, any POINT inquiries for the NETT should be directed to: ***point-trial@umich.edu***.

COORDINATOR'S CORNER: Odds & Ends

POINT Biomarkers Ancillary Study Update

Thanks to all of you, enrollment for the POINT Biomarkers Ancillary Study is really moving along! Currently, we have a total enrollment of 127, with the NETT sites enrolling 81, and the CRC sites enrolling 46. We are working with the OUS Team and look forward to starting enrollment in the ancillary study at our OUS sites.

Please contact Trese Biagini, POINT Clinical Research Nurse, at
trese.biagini@ucsf.edu or (415) 502-7307 if you have any questions about the ancillary study.

iPad Usage for Consent in POINT

The second batch of iPads has been sent to top enrolling sites, but we have minimal use of the devices during the consent process (only 23 uses). Feedback on the iPads includes lack of usage from staff not being trained, and iPads not located nearby patients or locked in cabinets. We have some great feedback from patients' family members who found the video useful in understanding the trial and what participation in the trial meant for the patient. Mytrus, a clinical research registry based in San Francisco who created our interactive consent tutorial iPad app, has also created a step-by-step iPad startup video to help sites get their iPads up and running and to trouble-shoot any technical issues. They're also adding Mandarin and Spanish versions of the video that will be available in the near future. We encourage your enrolling team to use the iPads to aid in the consent process for improved consent and retention rates.

For any iPad questions, please contact:
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