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The Newsletter of the POINT Trial

Volume 5, Issue 2 2nd Quarter 2015

2015 2nd Quarter Recap

Dear Colleagues,

Study Enrollment Update

The highest enrolling month in the quarter was April, with 69 enrollments, one of the most successful months yet. We closed out the second quarter of 2015 with an enrollment of 2,912 subjects, including 154 subjects outside the US. Seven sites were activated this quarter including Turku University Hospital, our first site in Finland.

DSMB Update

Funding, enrollment, and retention were the main topics discussed at the POINT DSMB meeting in Portland on June 8, 2015. The DSMB recommended that the POINT trial continue and emphasized the need to accelerate enrollment and reduce adjudication turnaround times. Strategies for retaining subjects and minimizing premature study drug discontinuations were discussed, especially for subjects who discontinue study drug in situations that are potentially avoidable. There are too many of these!

Premature Study Drug Discontinuation

With the big ongoing challenge of reducing premature study drug discontinuation (see page 2), we are pinpointing the potentially avoidable reasons for discontinuation and sharing the information with sites. We hope this allows you to concentrate on specific areas of improvement.

If you have suggestions for preventing early study drug discontinuation, please send them to Medina Sahak **(medina.sahak@ucsf.edu)**. Sometimes your ideas are the best ones and sharing them helps us all.

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

Sincerely,

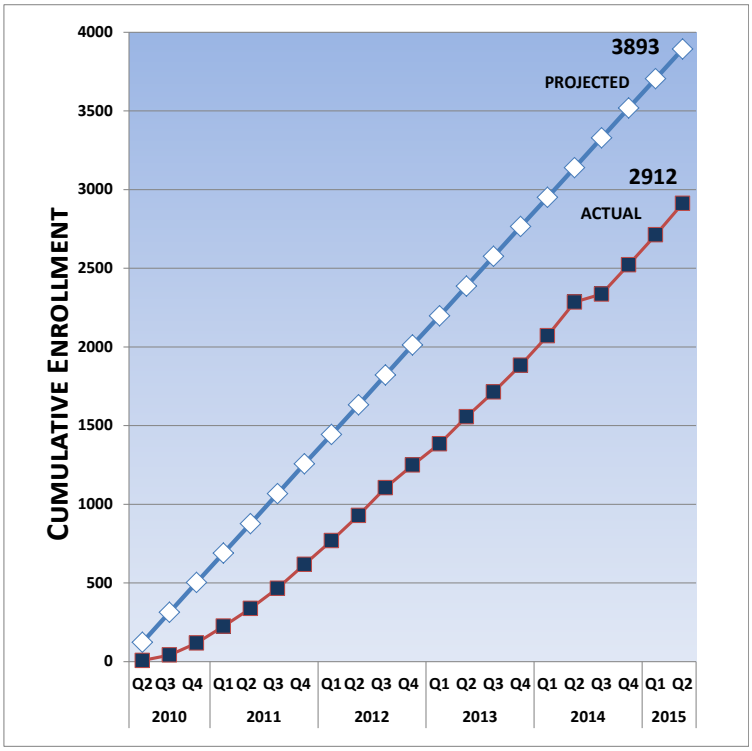
Clay Johnston MD, PhD, POINT Trial Principal Investigator

Don Easton MD, POINT Trial co-Principal Investigator

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

POINT Cumulative Enrollment

May 2010 through June 2015



POINT Enrollment Update: Total = 2912

Hot Enrollers for 2nd Quarter

Place	Subjects	Site (Hub)
1	8	Santa Creu and Sant Pau Hospital (CRC), University of Calgary Foothills Campus (CRC)
2	5	Hospital del Mar (CRC), Yale-New Haven Hospital (Mass General), Temple University Hospital (Temple), Detroit Receiving Hospital (Wayne), Sinai-Grace Hospital (Wayne), Hospital of the University of Pennsylvania (UPenn)
3	4	Stanford University Medical Center (Stanford), Abington Memorial Hospital (UPenn), Bethesda North Hospital (Cincinnati), Shands Hospital at the University of Florida (CRC)

Top Enrollers (as of June 30th, 2015)

Site (Hub)	City	State	#
Guilford Neurologic (CRC)	Greensboro	NC	106
Hospital of UPenn (UPenn)	Philadelphia	PA	95
Benefis Hospital (CRC)	Great Falls	MT	55
Buffalo General Med Ctr. (CRC)	Buffalo	NY	51
Stanford University (Stanford)	Stanford	CA	49
Columbia Univ. (NYP)	New York	NY	49
Detroit Receiving (Wayne)	Detroit	MI	48
Temple Univ. Hospital (Temple)	Philadelphia	PA	47
OHSU-Oregon (OHSU)	Portland	OR	47
Cleveland Clinic (CRC)	Cleveland	OH	44
Methodist Hospital (CRC)	Houston	TX	43
Memorial Hermann (Texas)	Houston	TX	43
Abington Memorial (UPenn)	Abington	PA	43

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

COORDINATOR'S CORNER: POTENTIALLY AVOIDABLE STUDY DRUG DISCONTINUATION

By Renee Kasperek-Wynn, Site Manager (NETT)

Early study drug discontinuation has been a major problem for the POINT trial. We are continuing to investigate strategies that will lessen potentially avoidable causes of subjects discontinuing drug. One major reason for study drug discontinuation is due to the Primary Care Provider (PCP) pulling the patient off study drug. Sites have reported that having the investigator make a call to the PCP on the day of enrollment has been most beneficial, as it ensures that the PCP is aware of trial objectives. This contact can also provide additional insight about the subject that can predict issues that may present in the subsequent study period. The timing (right away) and the mode (via call by investigator) can be important factors in how effective the contact to the primary care provider is.

Another potentially avoidable cause for early drug discontinuation is the subject declining to continue drug or the trial. Important strategies to prevent this include assessing the subject's comfort level, medical condition, and understanding of the trial. It has been noted that staff must take a great deal of time to adequately inform subjects and to encourage them to ask questions. Subjects may feel uncertain about aspects of the trial, and connecting with them on a personal level is an important factor in making them feel comfortable. Engage family members that are present at the time of enrollment, so they can provide support and also assist site staff in understanding subject's concerns that may arise during the trial. We have learned that many sites make contact with subjects much more frequently than the trial requires for collecting data. Call the subject at home upon discharge and also once or twice a month to keep them engaged and answer any questions.

A final strategy that has been highlighted by sites is the effort made to look at a subject's chart for red flags that may indicate non-compliance. This way, a discussion may occur with potential subjects up front that emphasizes their responsibilities prior to signing the ICF.

We are always looking for new strategies to help prevent subjects from coming off study drug early. If you have suggestions, please send them to Medina Sahak **(medina.sahak@ucsf.edu)**.

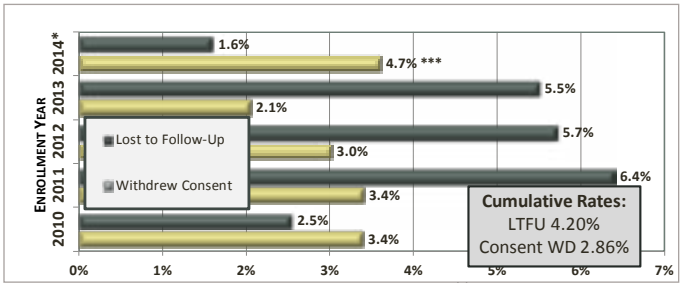
WebDCU Update

The POINT database in WebDCU™ will be undergoing an update in the fall, with the addition of an electronic Delegation of Authority Log (DOA) feature. Trainings were offered in early June for the new system. If you were unable to attend, please view the training video at https://vimeo.com/126930074.

Study Coordinators will be able to use the new system to assign roles and responsibilities to their new team members in the database directly from POINT, rather than in the NETT database. Regulatory document requirements for study team members will populate based upon the roles and responsibilities assigned to them in the DoA. The new module will allow coordinators to view the status of and upload documents in the same interface. Team members working on multiple NETT projects (e.g. SHINE, ESETT) will be able to share their general documents, such as CVs and medical licenses, across the studies.

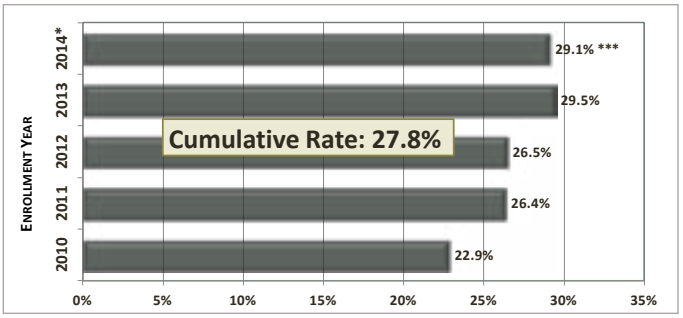
All previously active user accounts and uploaded documents will be switched over from the NETT database, so if you were using the database previously, you will not have to upload your documents again. If you have any questions after the new system is implemented, please contact Aaron Perlmutter **(perlmutt@musc.edu)**, Adam Henry **(henryad@musc.edu)** or Kristina Hill **(hilkri@musc.edu)**.

SUBJECT RETENTION: WITHDRAWN CONSENTS AND LOSSES TO FOLLOW UP



Data as of April 22, 2015

PREMATURE STUDY DRUG DISCONTINUATION: 2010-2014



Data as of April 22, 2015

Cumulative Rates*

Premature Study Drug Withdrawal

710 subjects– 27.8%

▷ Median Days on Drug: 7

▷ Unavoidable Causes – 15.3%

▷ *Potentially* Avoidable Causes – 12.5%

*2567 completed subjects

Top-Enrolling NETT Hubs (as of June 30, 2015)

Hub	*Total*	*Enrollments per 90 days*
UPenn	236	11.9
Wayne	134	6.6
Cincinnati	132	6.8
Minnesota	115	5.7

Q2 Site Activations

Rochester General Hospital, Rochester, NY (CRC); Footscray Hospital, Footscray, VIC, AUS (CRC); **Miami Valley Hospital, Dayton, OH (CRC);** University College Hospital, London, GBR (CRC); Luton & Dunstable University Hospital, Luton, GBR (CRC);Turku University Hospital, Turku, FIN (CRC); **Lincoln Medical and Mental Health Center, Bronx, NY (SUNY)**

***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. Also, check that your kits are properly labeled before you send them out. You can replace expired kits by contacting Jaeson Hackett **(hacketj@labcorp.com).**