

2014 2ND QUARTER RECAP

Dear Colleagues,

By now, you've noticed we skipped the POINT newsletter for the first quarter of 2014. We apologize for the gap in communication. There have been quite a few changes at the coordinating center at UCSF; we thought we'd wait until this current edition for an update.

Study Enrollment Update: Temporary Suspension

You should have been notified that POINT is suspending enrollment until we receive a shipment of active study drug to replace the inventory that expired. We have been working closely with the manufacturer Sanofi, which has been providing the active and placebo for the study at no charge. We ran into an unexpected delay due to a change in the bottle design, and expect the shipment next week.

We had our highest enrolling month ever in June — 85 subjects entered into the trial! We expect to be up and running again in late August, and will update you frequently as we get closer to the actual date. In the meantime, please continue to follow up subjects for their regularly scheduled visits, so we can bring the study back up without a hitch.

Before the new study drug arrives at your site, please be sure to *expire* the drug in WebDCU and to follow your local guidelines and practices to *destroy* the expired drug.

My New Role: Clay Johnston

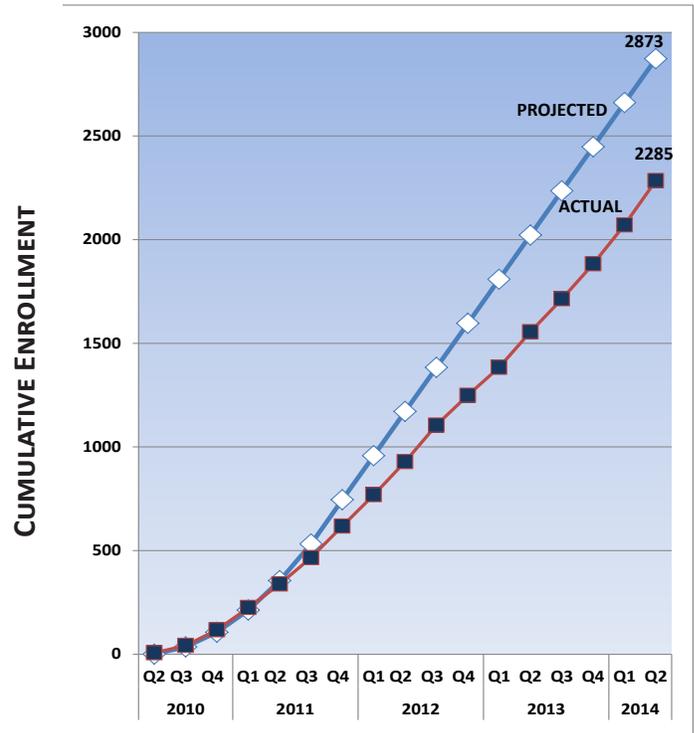
As of March 1st, I have accepted the position of inaugural Dean of the Dell School of Medicine at The University of Texas at Austin. In my new job, I will be building a medical school and hospital literally from the ground up. The first class of students will enter in the fall of 2016.

I will continue in my role as Principal Investigator on POINT, ensuring we meet and likely surpass our goals, with the continued support and commitment of the entire study team. Anthony Kim, a stroke neurologist at UCSF, will take on an expanded role in the study, working closely with Don and Mary. My new contact details can be found on the second page of this newsletter.

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 2014



POINT ENROLLMENT UPDATE: TOTAL = 2285

Hot Enrollers for 2nd Quarter

Place	Subjects	Site (Hub)
1	6	Hospital of the University of Pennsylvania (UPenn)
2	5	University of Calgary - Foothills Campus (CRC), Cleveland Clinic (CRC), Benefis Hospitals Inc (CRC), Massachusetts General Hospital (Mass General)

Top Enrollers (as of June 30, 2014)

Site (Hub)	City	State	#
Guilford Neurologic (CRC)	Greensboro	NC	92
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	42
Cleveland Clinic (CRC)	Cleveland	OH	41
Buffalo General Med Ctr (CRC)	Buffalo	NY	40
Detroit Receiving (Wayne)	Detroit	MI	39
Memorial Hermann (Texas)	Houston	TX	38
Regions Hospital (Minn)	Saint Paul	MN	38
Temple Univ. Hospital (Temple)	Philadelphia	PA	38
Methodist Hospital (CRC)	Houston	TX	37
Abington Memorial Hospital	Abington	PA	37

IN THIS ISSUE: Study Drug Replacement, POINT Vital Signs CRF, Clay Johnston's New Contact Information

Study Drug Replacement

As many of you may have already noticed, an alert regarding the study suspension was posted on the WebDCU™ POINT page as of the last week of June. Sites will be expected to destroy any remaining study drug. Prior to destroying study drug, sites will need to expire their supply in WebDCU™ per the instructions below.

REMINDER: Per the Monitoring Plan, please keep any study drug bottles that have been returned to you by subjects until your first monitoring visit.

How to remove expiring study drug from inventory in WebDCU™:

- 1) From the main menu page, click on [Drug Tracking], then on [Drug Expired].
- 2) Click the blue number in the first column of the 'List Record' table adjacent to the bottle number you are reporting as expired.
- 3) Click [Edit Record] at the top of the screen.
- 4) Click the checkbox to indicate that the study drug has been removed from inventory.
- 5) To finish, click [Save Record].
- 6) Repeat for all bottles of expiring drug in your current inventory.

REMINDER: Expired study drug should be destroyed on site following local guidelines for disposition of unusable study drug.

When the new study drug arrives at your site, it will need to be 'received' in WebDCU™. We expect the new shipment in July, and we will notify all active Primary Study Coordinators and Primary Drug Recipients as details emerge.

How to receive new study drug in WebDCU™:

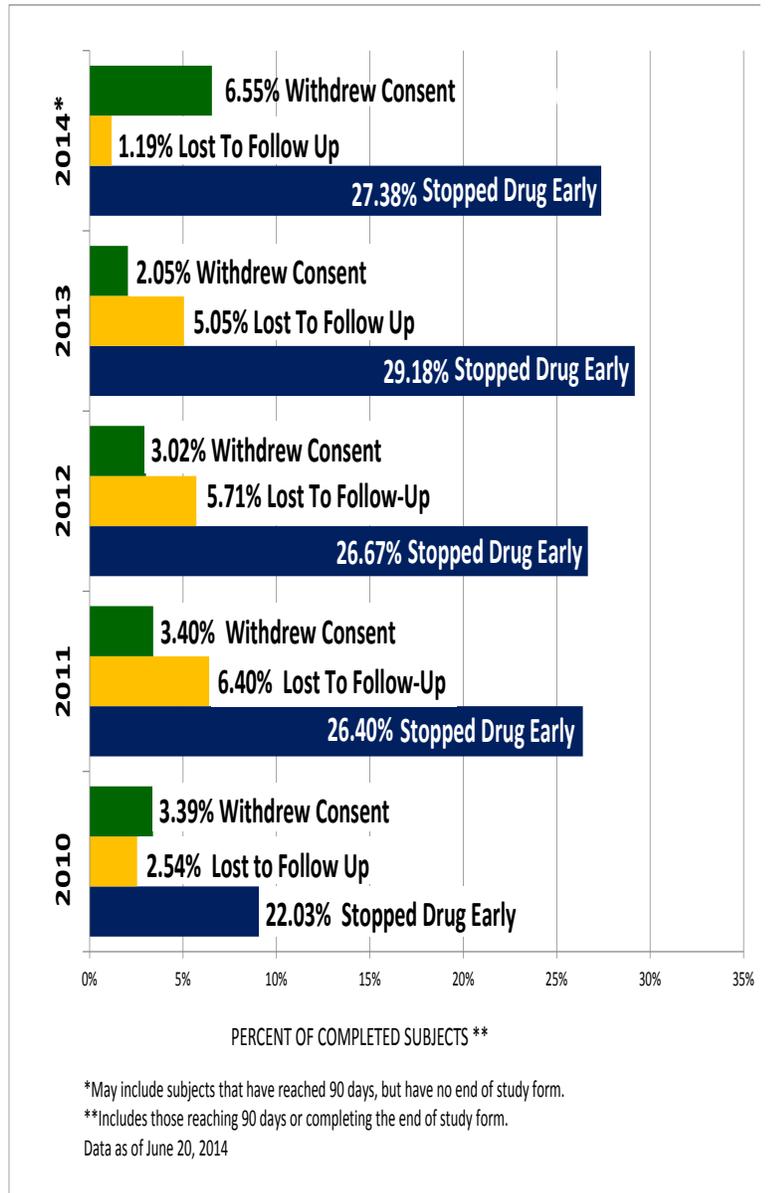
- 1) From the main menu page, click on [Drug Tracking], then on [Drug Receiving].

Note: You must "receive" the study drug before it will be available for randomization.

- 2) Click the blue number in the first column of the 'List Record' table adjacent to the bottle number you are receiving.
- 3) Click [Edit Record] at the top of the screen and enter the date the drug was received in WebDCU™.
- 4) To finish, click [Save Record].
- 5) Repeat for each bottle you are acknowledging receipt of in WebDCU™.

If you have any questions on expiring or receiving your drug inventory in WebDCU™, please contact Aaron Perlmutter (843-876-1261).

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



POINT Vital Signs CRF

Data collection guidelines for the Vital Signs CRF (Form 08) have been updated. Please see below, and the updated guidelines in the NETT Toolbox.

Form 08: Vital Signs

The vital signs CRF has instructions that say "enter the first measurements taken in the ED/clinic." If the first professional measurements of blood pressure after presentation with symptoms were taken at an outside hospital, these measurements should be entered on the Vital Signs CRF.

Clay Johnston's New Contact Information

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Department: Dell Medical School

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 Dell Medical School
 1400 Barbara Jordan Blvd
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Q1 & Q2 Site Activations

U.S. sites

University of Rochester Medical Center, Rochester, NY (CRC); NeuroTexas Institute, Austin, TX (CRC); Portland VA Medical Center, Portland, OR (OHSU); University of Toledo Medical Center, Toledo, OH (OSU); Yale-New Haven Hospital, New Haven, CT (Mass Gen); Winthrop University Hospital, Mineola, NY (CRC); Mercy Health West Hospital, Cincinnati, OH (UCincinnati); Marquette General Hospital, Marquette, MI (Wayne); Newton-Wellesley Hospital, Newton, MA (Mass Gen); OSF Saint Francis Medical Center (CRC); Mayo Clinic, Rochester, MN (UMinn); Saint Barnabas Medical Center, Livingston, NJ (CRC); Spectrum Health Butterworth Hospital, Grand Rapids, MI (Wayne); Northern Westchester Hospital, Mount Kisco, NY (CRC); Essentia Health-Fargo, Fargo, ND (UMinn); Desert Regional Medical Center, Palm Springs, CA (CRC)

O.U.S. sites

Auckland City Hospital, Auckland, NA, NZL (CRC); Montreal General Hospital, Montreal, QC, CAN (CRC); **Royal Adelaide Hospital, Adelaide, SA, AUS (CRC)**

*Sites highlighted in bold have accrued at least one subject as of 06/30/14