



Study Progress [12/31/2016]

Screenings 7127
Baselines 3950
Randomizations 2398
December 49

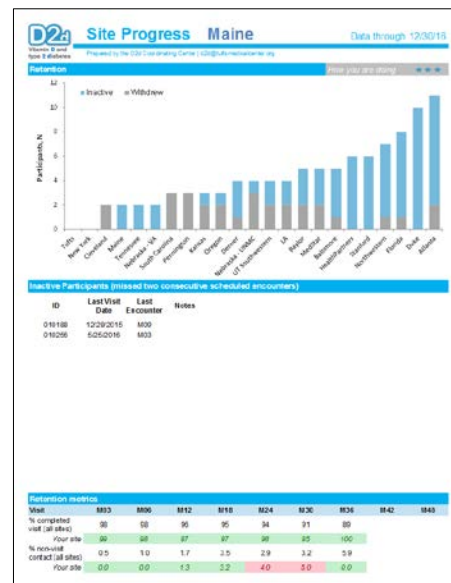
Active recruitment is done!

Participants who have a screening or baseline visit scheduled will complete the visit and proceed to a baseline or randomization visit, if eligible. The goal is have all participants randomized by the end of January. Exceptions or delays must be discussed as early as possible with the CC.

New Site Progress Report

With recruitment completed, the focus has shifted to retention. To assist your site in maximizing protocol fidelity and retention, the CC has developed a new site progress report, which will be circulated monthly. The report was developed based on input from coordinators and PIs.

If there is additional information that would be helpful to include, please contact the Coordinating Center.



Meet the D2d study team | D2d individuals, sites, components that make a difference

D2d Site | Lenox Hill Hospital, New York, New York

New York City is one of the most diverse cities in the world. Although it is known for being a very cosmopolitan city, that diversity has allowed us to recruit people from all backgrounds. The New York site was challenged with a substantial structural reorganization last year. However, we were able to seamlessly transition nearly all D2d participants from Mount Sinai Beth Israel Medical Center (MSBI) to our new home at Lenox Hill Hospital. The team is energized to ensure a smooth transition for the previously randomized participants and engage our newly recruited participants. Our goal is to retain all of our participants, and we are motivated by their commitment to D2d.

The team at Lenox Hill consists of Dr. Pauline Liao, who has been instrumental in participant retention through her warm and approachable demeanor. Dr. Liao is always willing to address concerns with a smile and reassurance. Co-investigator, Dr. Leonid Poretsky, is an integral resource to D2d and a visionary in diabetes research. Dr. Mahmoud Hassan previously worked with D2d participants at MSBI and plays an invaluable role in overseeing and maintaining the logistics of the study. Karina Ziskovich joined the D2d team as a Research Coordinator and contributes tremendously in all aspects of the study; her eagerness and enthusiasm has enabled us to recruit more patients at our new site, and she has been a wonderful asset to the team.

We are all thrilled to take part in this remarkable study and look forward to keeping our patients happy and healthy.



Karina Ziskovich, Pauline Liao, Mahmoud Hassan

Questions? Please contact D2d Coordinating Center at D2d@tuftsmedicalcenter.org or 617-636-D2d2 (3232)



DSMB follow-up and excerpts

The DSMB meeting took place on December 13th. The members expressed no concerns and high enthusiasm for the end of recruitment. The letter from the DSMB for submission to site IRBs is located on the D2d web portal under Protocol and Regulatory. The baseline data to the right was part of the DSMB presentation.

As part of the DSMB review, there was discussion regarding the responsibility of the study in identifying and acting upon high blood pressure readings. As a result, the source documents have been modified and the PI or study physician should be notified of a blood pressure greater than 160mmHg systolic and/or 100mmHg diastolic at a study visit. Additionally, the PCP letters for follow-up visits have been modified to also provide the blood pressure reading.

Baselines Characteristics (as of 9/30)

Number	2215
Demographics	
Age, mean (SD), years	59.4 (9.9)
Female sex, No. (%)	983 (44.4%)
Primary Race, No. (%)	
American-Indian / Alaska Native	11 (0.5%)
Asian	116 (5.2%)
Native Hawaiian or Other Pacific Islander	5 (0.2%)
Black or African American	564 (25.5%)
White	1476 (66.6%)
Other	43 (1.9%)
Ethnicity	
Hispanic or Latino	214 (9.7%)
Laboratory - Glycemia, mean (SD)	
Fasting plasma glucose, mg/dL	107.8 (7.5)
2-hour post-load glucose, mg/dL	137.2 (34.2)
Hemoglobin A1c, %	5.91 (0.21)



Manual of Procedures Updates: Please read the updated MOP sections on the D2d study web portal

Chart Area

Diabetes Outcomes - by time

