



Reminders

- At each contact, remind participants to call if they have been diagnosed with diabetes outside of the study.
- Pregnancy tests must be performed on all women of child-bearing potential at screening. If pregnancy test is not done because participant is not of child-bearing potential (post-menopausal, surgical intervention, male), select "Not applicable" in EDC.

Study Progress [4/30/14]

Screenings 925

Baselines 456

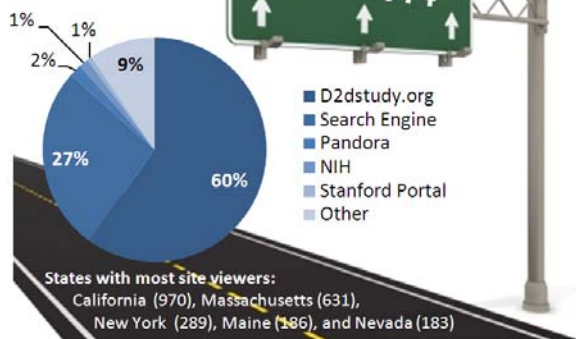
Randomizations **223**

April 67

April Showers Bring May Flowers

67 participants were randomized in April, surpassing our prior best month (March) by 16! We are on our way to meet our goal of 100 randomized participants per month.

Total Views
in April: 3,318



States with most site viewers:
California (970), Massachusetts (631),
New York (289), Maine (186), and Nevada (183)



Congratulations to our over achievers!

Met monthly goal:

- Duke – 96%
- HealthPartners – 96%
- Maine – 96%
- Stanford – 96%

Exceeded monthly goal:

- Nebraska – 133%
- Beth Israel – 120%



A record 110 baselines were performed in April, so going into May, we have 19 participants who are eligible for randomization and 11 participants with lab results pending – April baselines bring May randomizations!

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

Anastassios Pittas, MD, MS | D2d Principal Investigator | Coordinating Center (CC), Tufts Medical Center

Taso (pronounced like "taco" but with an "s") is the overall study PI and also serves as the Tufts site PI. In this dual role, he is deeply aware of the challenges encountered by both the CC and sites and this unique position allows him to contribute important insights towards the study's success. This dual role has also accelerated the rate his hair is graying and has contributed to widely fluctuating 'approval ratings' among D2d investigators... Taso was born and raised in Nemea, Greece (coordinates: 37.8167°N, 22.6667°E) and came to the U.S. to attend college. The idea for D2d originated in the summer of 2002 when he needed a project to meet the requirement for a study design class he was taking.



When he is not bugging the CC, Taso spends time with his spouse and two daughters. He prefers evolutionary appropriate ways to meet his vitamin D needs with the most popular ones being playing tennis and commuting to work on his bike. He is lucky enough to have a mother-in-law who makes the best baklava around which he frequently shares with the CC staff.

Questions? Please contact D2d Coordinating Center at d2d@tuftsmedicalcenter.org or 617-636-D2d2 (3232)



Follow-up Visits and Glycemia Results

Our first Month 6 follow-up visit occurred this month. The following summarizes how glycemia results are communicated to sites.

After the baseline visit, site staff are blinded to the actual HbA1c and glucose results until the participant meets the diabetes outcome. The outcome of each result will be communicated via email to site RCs and PIs. For each test, an email will be sent that says "D2d participant ##### had a negative/positive result" where negative means that the result did not meet the D2d criteria for diabetes and positive means that result met the D2d criteria for diabetes. Please include copies of these emails in the participant's source documents. After the visit, once all emails have been received for a specific visit, follow figure 18.2 in MOP section 18 to determine next steps.

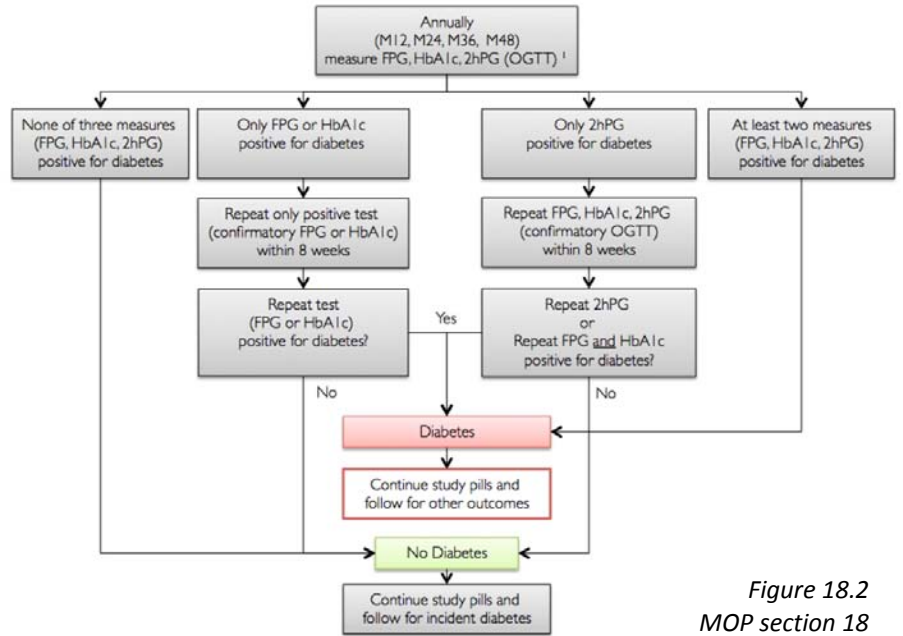


Figure 18.2 MOP section 18

If a participant meets the D2d criteria for diabetes either at a visit or by adjudication, all of the participant's past and future glycemia values will be made visible to the site.

Randomizations By Site

