



Thank you!

Thank you to all who attended, presented, and contributed to the important dialogue at the fourth D2d Annual Meeting. Presentation slides are posted on the portal.



Study Progress [9/30/2016]

Screenings 6906

Baselines 3716

Randomizations **2215** **September: 60**

The Final Countdown[®]: Recruitment Challenge

We need to randomize 168 participants by the end of November. The DSMB is meeting in early December and we have to meet our recruitment goal by then! To up the ante, the CC is hosting a Final Countdown recruitment challenge.



At the end of each month (October and November), site teams will be acknowledged for their successes and continued motivation. The top five sites in each category below will receive a special surprise:

- Number randomized
- Percentage improved from the prior month (compete against yourself!). For example, if in September you randomized 1 participant and in October you randomize 3, this is a 300% improvement and would likely be in the top five.

When will recruitment end?

Please continue recruiting full steam ahead until you receive an email alert from the CC that will be sent when D2d has reached the magic number of 2,382.

Each week, the CC reviews reports on the overall study progress. Two numbers we follow closely are the number of participants randomized and the number of participants eligible who are awaiting randomization. When the number

randomized + **awaiting randomization** equals 2,382, the CC will send out an email alerting sites that active recruitment should stop. At that time, active recruitment efforts, such as sending letters, phone calls, and advertisements, should cease.

After active recruitment stops, participants who have a SCR or BAS visit scheduled will complete the visit and proceed to a BAS or RAN visit, if eligible. It will be at the discretion of sites to decide whether or not to proceed with a screening visit for potential participants in the midst of pre-screening. Sites will be reimbursed for all randomization visits.

This approach balances the need to meet our enrollment target with fairness to participants who have been contacted about the study. This will likely result in a slightly higher number of participants randomized than the initial 2,382 (~2,410), which will make up for some of the early participant withdrawals. The CC has written a letter to notify site IRBs of the anticipated number randomized.

SCR visits	BAS potential	BAS visits	Awaiting BAS labs	Awaiting RAN	RAN visits	RAN goal
6842	22	3679	29	12	2191	2382

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



Adverse Event Reminders

Ascertainment of adverse events was discussed during the Research Coordinator breakout session at the Annual Meeting.

- Using medical records
 - In order to ensure consistent collection of adverse events at all sites, the primary method for collecting adverse events should be *per participant report*. Per MOP section 4: inquire if there have been any changes in the participant's health, including any contact with health care system (e.g. physicians, hospitals) at each visit. Details should be collected on positive responses. If a participant reports starting a new medication, the RC should inquire what the indication is and determine if it could be an adverse event.
 - Review of the medical record may provide additional information or clarity regarding an adverse event, however, this should be done after a participant reports something relevant.
- Defining "hospitalization" for determination of Serious Adverse Event
 - Admitted to an inpatient floor regardless of time in hospital.
- Missing end dates
 - At each contact, unresolved adverse events should be reviewed for resolution.
 - A list of adverse events without end dates will be sent with monthly reports.
- Revision to source documentation
 - In order to ensure adequate follow-up on participant changes in health and adverse events, a revision has been made to the follow-up source documentation. A small check box with the text "Follow up on previously reported adverse events" has been added. Thank you to MedStar for this suggestion.

True Blue Recipient: Dalya Abou-El-Seoud, Northwestern University



Dalya Abou-El-Seoud (far right) is the D2d Coordinator from the Northwestern site. She joined the team in May 2014 to assist the primary site coordinator with participant recruitment in retention. In recent months, Dalya has taken a prominent role in the D2d Northwestern site management.

From the nomination by fellow coordinator Jenny Lewandowski and site PI Lisa Neff:

Dalya Abou-El-Seoud is the recruitment AND retention guru at the Northwestern University site in Chicago. Since she started in May 2014, Dalya has played a huge role in improving Northwestern's study enrollment as well as retaining participants. She has made particularly spectacular efforts with a few of our earliest participants whom we've struggled to retain and has had a 100% success rate in helping us keep these participants involved in the study. Dalya's positive attitude and huge heart have made her a favorite of our participants and we truly don't know what we'd do without her!



(left to right) Jenny, Lisa, Dalya

Congratulations Dalya!