

Participant Recruitment Plan

Our recruitment strategy is based on our experience with previous clinical trials i.e. ADOPT, and Vitamin D study conducted by Dr. Emilia Pauline Liao. All prior recruitment for these studies was done before the opening of the Friedman Diabetes Institute, whose mission is to provide state of the art education to all patients in need of such education (pre-diabetes and diabetes), including those who do not require endocrine care and remain in a primary care setting. Thus, we expect recruitment to be enhanced in the setting of the Friedman Diabetes Institute and General Medical Associates (GMA)

Recruitment will be targeted as follows:

1. We expect the largest number of participants to come from our own patient population and their relatives who are at high risk of diabetes. At the Friedman Diabetes Institute, the number of patients with pre-diabetes and diabetes seen at the Institute has significantly increased and in 2012, reached 4169 office visits. Using such a resource is highly effective in recruiting highly motivated and interested participants and will maximize retention and decrease the screened-to-enrolled ratio. Based on our database, 66% of patients at Friedman Diabetes Institute are over 45 years old, and near 75% of those have BMI >25.
2. We will also recruit from our endocrinology clinics where approximately 34,086 annual visits occur with an additional 20% of patients on the wait list to be seen by providers. The research coordinator and research assistant will recruit subjects also at General Medical Associates (GMA) where approximately 46,825 annual visits occur and where patients are seen by primary care providers. The research assistant will be located at GMA during peak patient visit hours and speak to identified subjects the same day regarding the study and further screening. We expect to screen and recruit the majority of our subjects from the General Medical Practice.
3. Electronic Recruitment: Friedman Diabetes Institute has an active website. A separate web page will be created for the D2d study, and posted on the FDI website with information to contact research coordinator. Providers at the Friedman Diabetes Institute participate in weekly tweeting on a specialized Diabetes Board that was created for FDI. During these tweets providers will discuss the D2D study and refer potential subjects to the research coordinator. We expect to recruit a number of subjects from these encounters. FDI staff also regularly participates in discussion on the FDI Facebook page and we will create a D2D interest page so that prospective subjects can contact us through Facebook. Information about the study will also be posted at other hospital web pages, which will link interested volunteers to the study's web site. Providers also participate in publishing regular blogs on sites such as Healthline.com and Everydayhealth.com. These blogs will also be used as a platform for the D2D study to recruit subjects.
4. The Endocrinology and General Medical Associates have recently transitioned to electronic medical records (ECW) and this will aid us tremendously in identifying subjects that are eligible for the study. Providers are able to refer patients electronically via ECW and a subject can be referred to the coordinators on the same day as their appointment giving the coordinators opportunities to speak to the patient while they are still in the provider's offices. Presentations will be made at both the Endocrinology Grand Rounds and GMA Grand Rounds which are attended by faculty, residents and fellows. Pocket cards will be given out with study inclusion criteria in addition to coordinators contact information, so that providers will be able to refer subjects to the coordinator directly and efficiently. Cost for the cards will be part of the materials and supplies cost of \$1000.

5. Hospital electronic and paper newsletters and flyers (“Monday Morning Update”; “Connections” - news and information for Continuum Health Partners). Strategy: a short advertisement will be created and posted in the newsletter weekly. Over 15,000 full-time equivalent employees of the Continuum Health Partners, including 7,000, at BIMC have access to these publications.
6. Friedman Diabetes Institute outreach locations – community centers, churches, “food banks”, etc. Strategy: At our regular outreach educational events (3-4 times a month), educators from the Friedman Diabetes Institute will explain the study objectives and terms of participation directly to the prospective research subjects. In addition, extra recruitment sessions will be scheduled at the most of our permanent outreach locations, including Latino Health Institute, Community Kitchen and Food bank For New York City, and other centers with high number of potential study participants. Outreach material will be printed specifically for D2D for a cost of \$2000
7. Advertisements in the local press. Since its opening FDI has built strong relationships with media outlets such as Health Magazine, Diabetes Living Magazine, Shape.com, DiabetesMine.com and Prevention Magazine and including television interviews in shows such as CBS Eye On New York, NY Nightly News (NBC Nonstop), Doctor Radio” SiriusXM. We will utilize these media outlets to create and raise awareness regarding the D2D study to generate potential subjects. We will also be advertising in New York’s premium local paper, “AM New York”, with a similar advertisement. In our previous studies we have been successful in generating near at least 20 responses per day with this approach. The cost of advertisements will be as follows:
“NY Metro” \$2000 for one a single placement advertisement. In order to be effective, we will need to repeat the advertisement at least 4 times (2000X4) for a total cost of \$8000
“The Daily News” \$2000 for a single placement advertisement. Repeating the advertisement 3 times (2000X3) for a cost of \$6000. For a total advertisement cost of 16,000 for the first year. We expect the cost of advertisement to be half of the first year (\$8000) for the second year and (\$2000) for the third year.

We anticipate to pre-screen approximately 500 subjects, screen approximately 400 and successfully enroll 100 subjects.