Ancillary Studies Evaluation Subcommittee (ASES)
Meeting Minutes

Meeting: March 9, 2015

Present: Bess Dawson-Hughes, Cyrus Desouza, Michael Lewis, Rich Pratley, Patricia Sheehan,
Absent: Chhavi Chadha (comments sent), Taso Pittas (in conflict), David Robbins, Cliff Rosen, Myrlene Staten

Meeting Minutes

1. Review of Letter of Intent – Dr. Fryburg (AS15-01)

This application proposes to investigate two methods of beta cell function tests to determine the best method for use in long-term, multi center studies.

Overall, this is an interesting question, although it does not specifically address a question of interest to D2d.

The following issues were brought up:

- The subcommittee does not believe that this study will interfere with the primary goals of D2d, but it does impose a significant burden on both sites and participants with three additional four hour visits and three additional two hour visits. The subcommittee wants to ensure that compensation provided to participants is adequate, and that added costs to the study sites are covered.
- Blood volume being collected – during the call, Ellen reported that the investigator confirmed that the 174 ml is the total volume of blood to be drawn in this 30-month ancillary study. After the call, however, we received a revised answer, indicating that that response was in error and that the 174 mL is what will be collected at pre-randomization, 18, and 30 months. The investigator indicated, however, that this number is being revised. [Note that the blood volume being drawn for the D2d measurements is 83 ml at pre-randomization and 7 ml on the 18 and 30 month visits.]
- The investigator wishes to recruit 30 participants from each of the vitamin D and placebo groups. Because participants and study staff are blinded to treatment assignment, the investigator will need to develop a plan with the study statistician to ensure that the recruitment goals are met.
- Because the first set of ancillary study visits would occur prior to and at randomization, in order to ensure that the recruitment goals are met, additional participants may need to be recruited to ensure the intended sample size is met, to account for the participants who do not qualify to randomize. Alternatively, the ancillary study could be presented to the participants at baseline and scheduled for visits once randomization eligibility has been confirmed.
- Due to the fact that this proposal will not be submitted for outside funding, it must be fully developed operationally before it is submitted to the ASES for review. This includes

identification of the sites to be involved and their agreement concerning logistical arrangements.

The application was approved for the PI to go forward with the ASES application, taking the above comments into consideration. The PI will need to work closely with the CC and study sites in the development of the protocol. Details on where the samples will be analyzed need to be included along with shipping details.

Next Scheduled Meeting: Monday, April 13th, 2015 at 3:00 pm EDT