



Ancillary Studies Evaluation Subcommittee (ASES) *Meeting Minutes*

Meeting: December 8, 2014

Present: Chhavi Chadha, Bess Dawson-Hughes, Cyrus Desouza, Michael Lewis, Patricia Sheehan, Myrlene Staten

Absent: Sangeeta Kashyap (in conflict), Taso Pittas (sent comments), Rich Pratley, Philip Raskin, David Robbins (sent comments), Cliff Rosen

Meeting Minutes

1. Review of Letter of Intent – Dr. Kashyap (AS14-06)

This application proposes to investigate the relationship between vitamin D, metabolic syndrome and cardiovascular risk factors, and depressive symptoms. There is at least one study currently funded that is looking at the impact of vitamin D on depression. Whether this study will add substantial new information is unclear. Nonetheless, the subcommittee agrees the question is interesting, but requires further explanation for clarity and strength of proposal.

The following concerns were brought up:

- The aims are not clearly defined as written. The subcommittee suggests clarifying the time points at which the aims will be assessed (at baseline or longitudinally). The subcommittee suggest re-working the aims to determine whether:
 1. Vitamin D status is related to depressive symptoms in patients with pre-diabetes at baseline
 2. Vitamin D status is related to metabolic syndrome components and cardiovascular risk factors (inflammation and endothelial function) longitudinally
 3. Vitamin D status is related to depressive symptoms in patients with pre-diabetes longitudinally
 4. There is an interaction of vitamin D with depressive symptoms on cardiovascular risk
- Regarding the Beck depression questionnaire, question 9 clearly assesses suicidality. Develop a clear follow-up plan to use if participants express suicidal thoughts. One appropriate option is to refer such participants to their primary care or other physician. Question is below:
 - 0 I don't have any thoughts of killing myself
 - 1 I have thoughts of killing myself, but I would not carry them out
 - 2 I would like to kill myself
 - 3 I would kill myself if I had the chance
- Concerns were expressed regarding the experience of the applicant in coordinating multi-center FMD studies. Coordination involves recruiting sites with experience in the technique, developing a quality assurance program and monitoring the measurements throughout the study, site training in the procedure, etc
- Power calculations are needed to demonstrate that this study is feasible.
- The team would benefit from the addition of a depression specialist.

The application was approved for the PI to go forward with the ASES application, taking the above comments into consideration.

Next Scheduled Meeting: Monday, January 12th, 2015 at 3:00 pm EDT