

SC Minutes from 10/12/17

Meeting called to order - 12:04pm | Adjourned- 12:48pm

Present: Lawrence Phillips (Atlanta), Raneer Chatterjee (Duke), Neda Rasouli (Colorado), Richard Pratley (Florida), Chhavi Chadha (HealthPartners), Erin LeBlanc (Kaiser), Anne Peters (LA), Pauline Liao (Lenox Hill), Irwin Brodsky (Maine), Cyrus Desouza (Nebraska), Daniel Hsia (Pennington), Lisa Neff (Northwestern), Sun Kim (Stanford), Karen Johnson (Tennessee), Patty Sheehan (CC), Ellen Vickery (CC), Anastassios Pittas (CC), Saul Malozowski (NIDDK).

DSMB Recap:

- The DSMB meeting went smoothly and there were no concerns among safety or study progression. The DSMB recommended that the study proceed as planned (continue until 508 events occur)

Annual meeting will focus on planning for the future of D2d and end of study procedures.

- There will be an educational session about interim analysis to discuss/explain the different outcomes the DSMB considers and how these apply to D2d.
- The committee reviewed the Annual Meeting agenda for Sunday 10/22 and Monday 10/23.
- The committee suggested blocking out more time during the PI breakout for PIs who are currently working on papers or ancillary studies that are in development.

Action: The CC will work on expanding the PI breakout time for new development and existing papers.

Reviewed PR17-04 Chatterjee Proposal:

- The committee reviewed Dr. Chatterjee's tier 2 proposal: *The Effect of Vitamin D on Risk of Cancers: the Vitamin D and Type 2 Diabetes Study*
- The analysis plan explains the primary outcome is first diagnosis during D2d (i.e., since randomization) of any type of cancer (excluding non-melanoma skin cancers), and each participant with cancer is counted only once.
- One analysis will include the entire cohort and one analysis will be within each sex (among men; among women) as cancers may differ among sexes. Subgroups analyses identical to those completed for the diabetes outcome (by baseline 25[OH]D level etc.) will be conducted for the primary cancer outcome.
- Dr. Johnson and Dr. Phillips suggested censoring cancers collected from participants during the first year of participation due to the low effect on the intervention.
- Dr. LeBlanc explained that analyses will be conducted regardless of low power.
- DSMB suggested meeting with cancer specialists to discuss cancer outcomes in D2d.

Action: CC sent out a follow up email to the steering committee for approval/ disapproval on this proposal. Patty is organizing a meeting with a group from the Division of Cancer Prevention to further discuss this.

Bone Ancillary Study within D2d

- We will further discuss measure variables of interest for Bone outcomes at the annual meeting.

Reports Reviewed.