SC Minutes from 06.08.17

Meeting Called to Order- 12:04pm | Adjourned- 12:58pm

Present: Lawrence Phillips (Atlanta), Jean Park (Baltimore), John Foreyt (Baylor), Neda Rasouli (Colorado), Richard Pratley (Florida), Erin LeBlanc (Kaiser), Pauline Liao (Lenox Hill), Irwin Brodsky (Maine), Cyrus Desouza (Nebraska), Lisa Neff (Northwestern), Sun Kim (Stanford), Karen Johnson (Tennessee), Bess Dawson-Hughes (Tufts), Patty Sheehan (CC), Anastassios Pittas (CC), Ellen Vickery (CC), Paul Fuss (CC), Myrlene Staten (NIDDK), Saul Malozowski (NIDDK).

DSMB follow- up and plan for Interim Analysis

- The DSMB meeting was held on 5/23/17. An interim analysis will be done when 70% of the study's diabetes outcomes are reached. This will be prior to our next DSMB meeting in September, which will focus primarily on the results of the interim analysis.
- Based on the Interim Analysis Plan 4 possibilities could occur:
    - The study will continue as originally planned (continue until 508 events occur)
    - The study will stop because of a safety concern
    - The study will end because Vitamin D had a greater than expected result and shows benefit
    - The study will stop because of futility in relation to the primary outcomes
- The CC will share with all sites the final outcome and what the next steps are regarding planning end of study visits.

Committee Updates

- PPS- The following posters were submitted to the ADA:
    - Irwin Brodsky: *Reclassification of patients with prediabetes upon repeated testing: the vitamin D and type 2 diabetes (D2d) study*
    - *Daniel Hsia: The Hemoglobin Glycation Index (HGI) Influences Glycemic Classification: The Vitamin D and type 2 Diabetes (D2d) Study*
- ASES- A new LOI is under review. 193 participants have completed the QOL and none met the safety threshold.

Non-diabetes outcomes task force update

- The task force decided to pilot this study supplement at 4 sites and are in the process of obtaining IRB approval. Existing D2d study procedures and processes will be harnessed to obtain the data needed to adjudicate cancer and CVD outcomes.

Action: 4 sites will pilot the processes and we will report back on burden, power, etc. to the study group.

New business

- We discussed the possibility of developing a grant to bring back the cohort that were excluded after the baseline visit, to collect glycemia measures at 1 or 2 more time points. Sites could use EMR to find/ contact previous individuals that failed at BAS. This could provide information on prediabetes progression in people that didn't meet D2d criteria previously.