

Meeting called to order – 12:03pm | Adjourned-12:37pm

Present: John Foreyt (Baylor), Elizabeth Thomas (Colorado), Ranee Chatterjee (Duke), Michael Lewis (Central Lab), Erin LeBlanc (Kaiser), Anne Peters (LA), Pauline Liao (Lenox Hill Hospital), Irwin Brodsky (Maine), Cyrus Desouza (Nebraska), Lisa Neff (Northwestern), Daniel Hsia (Pennington), Sun Kim (Stanford), Patty Sheehan (CC), Ellen Vickery (CC), Myrlene Staten (NIDDK).

Non-diabetes outcomes (CVD, Cancer)

- Committee reviewed the revised CVD and Cancer protocols that included power calculations sent to the committee on Wednesday 8/9.
- Four sites have been piloting the processes for the past few months and in response to their feedback the cancer questionnaire and the medical record collection requirements were modified to decrease the site burden.

Action: Patty sent out Non-diabetes outcomes IRB submission materials to all sites after the SC call.

DSMB and Interim Analysis

- 70% of the diabetes outcomes were reached at the end of June.
- The next DSMB meeting is scheduled for September 25, 2017 and the Interim analysis will be reviewed by the DSMB.
- The annual meeting in October will focus on end of study (EOS) procedures based on the outcome of the DSMB meeting.

Protocol v1.9 and EOS Procedures

- The amended D2d study protocol (version 1.9 | 2017.7.11) clarifies the plan for end-of-study visit. At the last D2d Data Safety Monitoring Board (DSMB) meeting in May 2017, the Board suggested we clarify and simplify the process for the end-of-study visit. This protocol change is in response to the Board's request and the changes have been approved by the DSMB and the Coordinating Center IRB at Tufts Medical Center.
- Once the study is about 2-3 months from reaching 508 outcomes, the CC will make an announcement to all sites that the next scheduled visits for participants should be their EOS visit.

Action: Patty sent out the revised D2d study Protocol. Sites are to submit it to their IRB.

Future of D2d, Natural history or prediabetes study

- As discussed at last month's SC meeting, Taso is developing a grant to bring back the cohort that was excluded after the baseline visit, to collect glycemia measures at 1 or 2 more time points. This could provide information on prediabetes progression in people that didn't meet D2d criteria previously.
- The scope of work and information for submitting grant was sent out on Tuesday 8/08 to all sites.

Action: If sites have any questions regarding budget, or logistics for the grant please email Taso or CC.

Reports Reviewed.