

Meeting called to order- 12:03pm | Adjourned- 12:56pm

Present: Lawrence Phillips (Atlanta), Elizabeth Thomas (Colorado), Ranee Chatterjee (Duke), Chhavi Chadha (HealthPartners), Erin LeBlanc (Kaiser), Anne Peters (LA), Pauline Liao (Lenox Hill Hospital), Cyrus Desouza (Nebraska), Lisa Neff (Northwestern), Daniel Hsia (Pennington), Karen Johnson (Tennessee) Bess Dawson-Hughes (Tufts), Patty Sheehan (CC), Anastassios Pittas (CC), Myrlene Staten (NIDDK), Saul Malozowski (NIDDK).

Discuss option for patients with positive 2hpg who don't want to return for OGTT.

- Sites are facing challenging participants that don't want to return for an OGTT at a confirmatory visit if only the 2hPG is positive at the annual visits. The SC considered whether to allow patients who absolutely refuse to return for an UNCO-OGTT, to return and repeat the HbA1c and FPG only.
- The SC reviewed protocol figures 9.1.1 and 9.1.2 (Flow diagrams of laboratory evaluation for diabetes at annual and semi-annual visits).
- The SC agreed that it's better to collect these two measures rather than have the participant not come in at all.

Action: Allowing participants to not do the OGTT at the confirmatory visit will be evaluated on a case by case basis. Sites should contact the Coordinating Center if this situation occurs.

Non-diabetes outcome (CVD, Cancer) Update

- Four sites (Tufts, Kaiser, Duke, and Nebraska) are piloting this study supplement and have received IRB approval.
- Adjudication of CVD cases will require no (or very little) additional burden from sites since they will already have records collected from SAEs.
- Adjudication of pre-cancer and cancer cases will require some additional burden as additional questions will be asked at the participant's visits and data collection will be required.
- CVD and CA adjudication committees have been established.

Action: The Coordinating Center will provide power calculations at the next Steering Committee meeting in August.

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 DSMB is currently reviewing the revised protocol v1.9. Once this is approved, the CC will share both protocol and MOP changes regarding the end-of-study procedures.

Future of D2d, Natural history or prediabetes study

- Committee discussed the possibility of 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. 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.
- Taso has already submitted a LOI. Following approval, he will work on the ASES application and the grant due October 5, 2017. Pre-approval by NIDDK will be required to submit the grant.
- Several sites (Nebraska, Duke, Pennington, Kaiser, Northwestern, and Atlanta) expressed enthusiastic support. All sites were in support.

Reviewed reports.