



Steering Committee (SC) Meeting Minutes

Meeting: January 11, 2018

Meeting called to order- 12:05pm | Adjourned- 1:05pm

Present: Lawrence Phillips (Atlanta), John Foreyt (Baylor) Michael Lewis (Central lab), Sangeeta Kashyap (Cleveland), Neda Rasouli (Colorado), Raneer Chatterjee (Duke), Rowena Dolor (Duke), Richard Pratley (Florida), Erin LeBlanc (Kaiser), Anne Peters (LA), Irwin Brodsky (Maine), Pauline Liao (Lenox Hill), Lisa Neff (Northwestern), Sun Kim (Stanford), Karen Johnson (Tennessee), Bess Dawson-Hughes (Tufts), Philip Raskin (UT Southwestern), Patty Sheehan (CC), Anastassios Pittas (CC), Myrlene Staten (NIDDK), Saul Malozowski (NIDDK) Ellen Vickery (CC), Paul Fuss (CC)

PPS Update

- Under review:
 - Dr. Aroda's, *Establishing an electronic health record-supported approach to recruitment in multicenter clinical trials: the vitamin D and type 2 diabetes (D2d) study experience*
 - Olivia Lovegreen's *Management of large multi-center trials in a challenging funding milieu*
- Waiting approval by SC (following meeting).
 - Dr. Leblanc's *Baseline Characteristics of the Vitamin D and Type 2 Diabetes trial (D2d)*
- Submitted to the ADA 2018
 - Dr. Leblanc's abstract *Baseline Characteristics of the Vitamin D and Type 2 Diabetes trial (D2d)*

Action: The CC will send an email for Dr. LeBlanc's baseline manuscript for your review and approval. Because this is a tier 1 publication, each site will contribute one co-author with the complete Research Group list appearing as an appendix

D2d Staff Retention

- **Timeline:** The study is projected to reach 508 diabetes events around May/June 2018. The CC will inform all sites ~2 months prior to reaching 508 events to start the end of study procedures. All sites will have 5 months from the end of study announcement to bring back all participants.
- **Budget:** All sites will receive year 5 funding as planned (no changes). Tufts anticipates establishing 1-year subaward amendments as of June 1, 2018, pending the NOA from the NIDDK. However, the length of the award may change depending on when D2d initiates end-of-study procedures. Subawards will be under the traditional payment model.
- Staff maybe concerned about job security and funding. PIs should assess staff understanding, assuage concerns and promote the importance of following D2d through to the end.

D2dOS

- ***The future of the study will depend - to a great extent - on the result of D2d, which depends on retention and adherence to study pills.*** If the result is positive, a follow-up study could be designed with participants continuing vitamin D long-term (D2dOS).



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- Need to establish good scientific aims for D2dOS. The grant discussed previously, (bringing screen fails who did not qualify due to meeting only 1/3 criteria) can be one of the aims of D2dOS. We will review progress with NIDDK in the Spring.

Non-diabetes Outcomes Update

- Committee reviewed cancer screening/cancer diagnoses entered in EDC across all sites (page 7).
- 410 cancer screening/cancer diagnoses have been entered in EDC, and 393 records have been sent to the CC.

Action: The CC will update page 7 and add an additional column that shows the total number of adjudicated cancers. We will review at next month's SC meeting.

Reports Reviewed.