



Steering Committee (SC) *Meeting Minutes*

Meeting: February 08, 2018

Meeting called to order- 12:06pm | Adjourned- 1:02pm

Present: Lawrence Phillips (Atlanta), Adline Ghazi (MedStar- Baltimore), Jean Park (MedStar), Michael Lewis (Central lab), Ranee Chatterjee (Duke), Erin LeBlanc (Kaiser), Anne Peters (LA), Irwin Brodsky (Maine), Pauline Liao (Lenox Hill), Chhavi Chadha (HealthPartners), Cyrus Desouza (Nebraska), Lisa Neff (Northwestern), Sun Kim (Stanford), Beate Griffin (Tennessee), Bess Dawson-Hughes (Tufts), Philip Raskin (UT Southwestern), Patty Sheehan (CC), Anastassios Pittas (CC), Myrlene Staten (NIDDK), Saul Malozowski (NIDDK) Ellen Vickery (CC),

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 take place (D2dOS).
- The committee reviewed D2dOS draft document and discussed the design of model 1 (all get vitamin D) vs. model 2 (preserves the two D2d groups but vitamin D group receive open label vitamin D and control group stops placebos, similar to DPPOS)
- The committee was in agreement that model one would be a good option assuming benefit among vitamin D and diabetes prevention. However, model 2 is a better study design with two issues: control will take vitamin D on their own; retention may be a problem. The focus should be on retaining the control group (whom will not be given vitamin D or placebo pills throughout the study).
- Saul suggested submitting both proposals to NIDDK for additional input.
- *Summary:* Model 1 is an ethical approach with no concern for safety but there was less enthusiasm in terms of study design. Model 2 was generally supported by the committee but with challenges recognized.

Action: The Use of EMR section and outcomes section needs to be further established. An updated version will be developed for further discussion at next month's meeting.

Other Outcomes Update

- Committee reviewed cancer screening/cancer diagnoses entered in EDC across all sites (page 7). Almost all sites have submitted or entered an event in EDC. The CC is working with sites that haven't done so.
- 514 cancer screening/cancer diagnoses have been entered in EDC, and 494 records have been sent to the CC and

Reports Reviewed.