

SC Minutes from 03.09.17

Meeting called to order – 12:02pm | Adjourned – 12:51pm

Present: Lawrence Phillips (Atlanta), John Foreyt (Baylor), Michael Lewis (Central Lab), Neda Rasouli (Colorado), Rowena Dolor (Duke), Chhavi Chadha (HealthPartners), Erin LeBlanc (Kaiser), Pauline Liao (Lenox Hill Hospital), Irwin Brodsky (Maine), Cyrus Desouza (Nebraska), Lisa Neff (Northwestern), Daniel Hsia (Pennington), Pat O’Neil (South Carolina), Sun Kim (Stanford), Bess Dawson-Hughes (Tufts), Philip Raskin (UT Southwestern), Patty Sheehan (CC), Anastassios Pittas (CC), Ellen Vickery (CC), Paul Fuss (CC), Myrlene Staten (NIDDK), Saul Malozowski (NIDDK).

D2d Future Plans / Interim Analysis Plans

- Sites that have participants who were randomized early in study will have M48 visits due this fall.
- Committee discussed next steps for the D2d study.

Action: Patty and Taso will provide document to sites for IRB submission that will allow participants to extend their participation past M48. In addition, Taso will provide a summary of the next steps and plans.

- When 70% of events occur, an Interim Analysis will be conducted with results provided to the DSMB and NIDDK.
- If PIs have any suggestions for future plans i.e. (continuing the D2d study as an outcome study or an observational study) please let the CC know.

Action: SC members are encouraged to think of and propose ways to get the most out of the D2d study. The discussion will continue at the next SC meeting in April.

Reviewed Dr. Kashyap’s Proposal

- Committee requested to further review, send comments, and vote for approval at next month’s meeting in April.

Reviewed Reports.