

Steering Committee Meeting Minutes 3/13/2014

Call to order - 12:02 pm / Adjourned 12:56 pm

Present: Maine, Tufts, Duke, South Carolina, Florida, Atlanta, Northwestern, Pennington, HealthPartners, Kansas, Baylor, Nebraska, Stanford, Ware, Central Lab, NIDDK

1. Review and Approval of D2d Design Manuscript

Emailed comments were incorporated. SC had no further comments/edits to main text.

Discussed authorship and how inclusive or exclusive it should be for the design manuscript.

Action: [Patty] will send out a poll with options of who should be listed as an author.

[Sites] need to add/remove staff from the circulated appendix as necessary and indicate how many calendar months of effort each individual has contributed to D2d.

2. Study Updates

125 randomized, all enrolling sites have randomized

Within four months, D2d has improved its screening to randomized ratio from 9:1 to 2.5:1

Once sites have completed 10 baselines, they will be sent all their lab results to decide if a site specific algorithm is necessary. Sites must submit the Site Specific Algorithm Proposal form to the CC for approval before any changes can be implemented. So far 4 sites have an approved site specific algorithm.

*Dr. Wong (Decision Analyst) determined that people with A1c below 5.5 do not become eligible after baseline.

Taso - the challenge has been that A1c from the central lab are higher than sites but glucose results are lower.

Lewis (Lab) - reasonable spread of variation, revisit analysis to see if trend continues

Saul - suggested publishing a methodology paper on the variability of A1c

Variability between screening and baseline lab results may also be due to participant lifestyle changes. Therefore sites should try to keep the screening and baseline visits as close as possible.

3. Need to Add 2-3 Sites/Satellites

Sites are encouraged to think about the possibility of adding a satellite site.

Saul - should there be a requirement point for sites to be able to add a satellite site?

Taso - sites that are close to 80% of their target or better (exceptions may be made)

Saul - consider adding recruitment graphs in the web portal

Action: [CC] will add a Recruitment Progress folder on the D2d portal