Steering Committee 12/12/13 Minutes

Call to Order-12:01pm / Meeting Adjourned-12:57pm

Present: Maine, Tufts, MedStar, Duke, Florida, Atlanta, Beth Israel, Tennessee, Pennington, HealthPartners, Kansas, Baylor, Nebraska, UT Southwestern, Phoenix, LA, Central Lab and NIDDK

1. Recruitment Update

Currently, D2d is not enrolling as targeted (4-6 participants/month/site) however it is expected that sites' enrollment will regress to the mean over time, meaning underperforming sites will improve.

2. Screened-Baseline-Randomization ratios are high

This is partially due to the variability between local and central lab results. To improve ratios, a protocol revision is proposed to allow sites to develop a site specific glycemia algorithm to allow participants to proceed to the baseline visit. Once sites have enough data the CC will work with individual sites to develop an algorithm.
Action item: this change was approved by the SC. The CC will circulate the final draft of the protocol for approval.

3. Combining Screening and Baseline Visit into One

If a person is known to have A1c or fasting glucose results available that qualifies them, it would save both time and effort if the screening and baseline visit were combined. The original logic against this method was that it is more cost effective to have multiple short visits than fewer long visits.
Action item: The CC will look into the operational aspects of this idea as an option that sites may use.

3. Pre-Screening Info

Widening BMI Range: Committee agrees BMI inclusion range should be widened.
Action item: The November Prescreening Failures Table was sent to SC members to break down the pre-screening failures due to BMI to determine what the new BMI range should be.
Action item: the CC will review data and propose changes to the BMI. Changes to the BMI inclusion range will require IRB approval but should not require any consent changes unless BMI ranges are specifically mentioned in sites' consent forms.

High Vitamin D intake outside of study: PIs and RCs need to educate both participants and PCPs that there is no evidence that 1000+ IUs of vitamin D is beneficial.
Action item: The CC will put together a generic letter that sites can send to PCPs describing the lack of evidence behind taking 1000+ IU of vitamin D.

History of Cancer: Several members were in favor of making the 5-year history of cancer time limit more flexible. It was proposed that the time frame be reduced from 5 years to 3 years with the caveat that the site PI could make a final decision with the approval by the CC or SOS chair. At the conclusion of the discussion, there was no consensus reached on this issue.
Action item: the CC will draft a protocol change to circulate for comments.

4. Repository Consent Rates

Consent rates are lower than expected. Repositories are extremely important for ancillary studies. Ideally we would like to see the repository consent signed by at least 95% of baselines. Many sites have reported success when presenting a participant with both consents together at the beginning of the screening visit.
Action item: the CC will talk to sites that have a low rates of repository ICF signed.

Note: The SC will meet on the 2nd Thursday of each month at 12pm EST. The call in information for all SC meetings will be:
Dial +1(619)550-0000
Access Code: 936-514-849