

Steering Committee Minutes from 7.10.2014

Present: Maine, Tufts, MedStar, Duke, Florida, Beth Israel, Northwestern, Tennessee, Baylor, Nebraska, LA, Stanford, Kaiser, Cleveland, NIDDK, Central Lab

1. Welcome New Sites

Kaiser Permanente NW - Dr. Erin LeBlanc

Cleveland Clinic - Dr. Sangeeta Kashyap

Baltimore - MedStar - Dr. Vanita Aroda

2. Notice of Awards - received

Sub-awards for year 2 have been going out.

Budgets

Year 1 - confusing, but managed conservatively and commensurate with effort.

Year 2 - sites get 40% of budget as core to be used in anyway the site sees appropriate. The remaining 60% is performance based.

3. Recruitment Reports

Slow start, which was to be expected.

Last 3 months D2d, has only been reaching 2/3 of its monthly goal.

Slow recruitment was a critical issue at the last DSMB meeting in May. Futility was even discussed, if recruitment goals were not met.

In June, all sites but one had at least one randomization. Screening to randomization ratios have improved.

Baseline to randomization ratio (currently at 60%, want around 80%)

4. Lab Variation

Some sites noticed a shift in lab results after the Central Lab's lot change on May 7th.

Lewis - because screening and baseline labs are draw on different days there is also biological variation to account in addition to the differences in methodologies and equipment.

Cyrus - suggests drawing samples for the screening and baseline together reduce biological variation within the samples

Combined Screening/Baseline visit can be done if sites have info on A1c from the last few months.

Under this approach, OGTT labs are processed and saved, but only sent to central lab if screening lab results come back as qualifying

Action [CC] - Gather data on whether A1c and fasting glucose correlate better in combined visits when compared to separate screening and baselines

Myrlene - ask participants not to fast for too short or too long and not to participate in strenuous activity before visits

5. Information to Capture Electronic Data Capture Add questions regarding gestational diabetes and menopause

Menopause - sub question (# of periods/year) Action [Sites] - email ideas to CC by the end of next week

6. Investigator's Meeting

Renaissance Capital View Hotel

Crystal City, Virginia

November 16-17