Minutes from 6/12/14

Call to order - 12:03pm / Meeting Adjourned - 12:57pm

1. Review of DSMB meeting
Meeting went well during the open session.
Executive Session conclusion: D2d is not doing well based on goals set. The issue of futility was brought up. Waiting for final report.

Taso - we set recruitment goals too high. Compared to other trials, we are doing well. We still want to finish recruitment in two years as planned. To help make this possible we have removed two sites and added 3 new sites for a total of 21 clinical sites.

DSMB pointed out that D2d has concentrated on underperforming sites and suggested we focus our efforts on sites that are doing well.

Budgets: Sites will receive larger core budgets for year 2 that can be used any way the sites finds appropriate (personnel, advertising, etc.)

The last two months we have reached roughly 65% of our goal.

2. Welcome New Sites
Cleveland Clinic - Dr. Sangeeta Kashyap
Kaiser - Dr. Erin LeBlanc
Baltimore - Dr. Vanita Aroda

3. Subcommittee Updates
Publications & Presentations - Design and Rationale paper is expected to be published in Diabetes Care, pending minor changes.

Recruitment & Retention - site presentations are complete. Going forward, the small group (original members) will meet on one Tuesday of each month to organize topics to present on at the next scheduled meeting. All staff are invited to attend the "presentations" monthly meeting. A few new members will join RRS. Emphasis will be placed on retention of participants and staff.
Retention thus far: 2 participants withdrew consent at the beginning of the study but we have had no missed visits.

Ancillary Studies - has received a few LOIs and applications. Two grants went to NIH that did not receive a funding score and one is still pending. *It is never too early to start thinking about ancillary studies.

Action: [Patty] invite new sites to join subcommittees.

4. How is the study going at sites?
Dr. Phillips [Atlanta] - getting better, switched from fingerstick A1c approach to using a database.
Dr. Desouza [Nebraska] - has noticed a shift in the Central Lab results.
Dr. Neff [Northwestern] - study has taken a toll on staff, current budget does not have the funding for site to re-hire a research assistant at their site.
Dr. Pittas [Tufts] - predicted 3.5:1 ratio and we are currently at about 4:1. Sites should continue to monitor their screening to baseline glycemia algorithm scatter plot and make adjustments as necessary. We are making changes in budgets for year 2.

Action: [All Sites] please review the year 2 budget with your administrator.

Keep an eye out - D2d is always looking for additional funding.