

Present: Bess Dawson-Hughes, Anastassios Pittas, Patricia Sheehan, Myrlene Staten, Jim Ware

1. Satellite D2d Clinic at Maine VA

Maine site approached VA to see if they can send letters to their patients informing them of the opportunity to join D2d. VA administration determined this was unacceptable after going back and forth (exploiting VA population).

Issues: Logistically/financial

Is this site going to help Maine reach its target or exceed its target?

Remarks:

Tulane - had to see patients at a VA hospital and dispense pills at a VA pharmacy.

Co-Investigator at VA that will allow Maine to access patient records.

Need more info from Maine site.

2. New Site Update

MedStar-Baltimore & Kaiser have IRB approval Cleveland Clinic - approval with stipulations; will probably be the first new site to start officially

3. Follow-up (Dr. Lewis and Santika)

Central Lab uses 7 controls in their assay. Are doing a relatively good job. Stuck with this level of variance.

David will ask Michael to carefully review data when any changes are made to pick up on any problems early.

4. Recruitment

37 enrolled; 18 waiting to be randomized; 47 waiting for baseline results

Action: move start date to mid Nov/December for reports

Activity has been coming from all different sites. Most baselines ever this week.

Dr. Robbins contact local chapter/national chapter who gave the Kansas site permissive to recruit through the ADA.

Large patient and family database of people interested in diabetes.

Monthly newsletter goes out, walk in September (can put up booth to recruit and distribute literature).

Getting a proposal from director for EC review and suggestions.

Action: Robbins will get contact name, ask whether it would make more sense for sites to go through their state chapter or for CC to get permission for everyone to recruit through the ADA.

5. Summary of Florida Visit

Taso and Myrlene visited the Florida site on Monday.

Biggest challenge is their central recruitment process; no dedicated RC.

Refocusing on D2d; hired new RC, solely for D2d.

Now have access to EMR

Other Announcements:

Next week - at least one nomination for True Blue (will include with meeting agenda)

Patty submitted manuscript (not many changes) we're waiting for new sites to become official.