Minutes from 5/1/14 Meetings

Present: Bess Dawson-Hughes, Saul Malozowski, Anastassios Pittas, David Robbins, Clifford Rosen, Patricia Sheehan, Myrlene Staten

Call to order - 12:01pm / Adjourned -

1. New Sites
Washington State University - EMR search based on MedStar's criteria yielded 273 eligible patients.
Patty - RC mentioned she did not fully understand the EMR search as she had never run one before, which was worrisome.
Taso - EMR does not seem like it would be a great method for this site. Recruitment for previous studies has never been very large, usually around 30-40 people.
Conclusion: Site will not proceed forward in application process.
Action: [Patty] contact PI to let her know site was not selected.

Cleveland Clinic - EMR search based on MedStar's criteria yielded 35,367 eligible patients.
Bess - are these people just from Cleveland, OH or all branches?
Myrlene - looks like site plans to cold mail, perhaps should get some PCPs on board and send letters on their behalf.
Taso - could cold mail first and follow-up with letters on behalf of the PCP.
Action: [Taso] ask site what hospitals/clinics were included in this search, have a discussion

The budgets for new sites so far have been average or below.
*If we want to add sites, we have to do it now to avoid budget implications.
Saul & Myrlene - add sites now (Cleveland Clinic, Kaiser, MedStar)

2. Options for Discontinuing Sites / Performance Based Payment
Tulane proposed a performance based payment option with no core payment (core payment would be wrapped into per/participant payment). *Tulane will not be sending any more invoices to the CC.
Myrlene - concerned these patients may not be treated the same as participants at "full time" sites.
*Ware previously mentioned that it would be best to completely drop participants who belonged to discontinued sites, but still consider them as having been enrolled into D2d.
Patty - Tulane has not screened a single participant since CC monitoring visit in March.

South Carolina
Patty - site has set up barriers, made it easier for the site vs. participants.

*Both Tulane and South Carolina have been warned that they need to enroll 6 participants by the end of May.
Conclusion: Give Tulane and South Carolina until the end of May to enroll 6 participants. If they are unable to make deadline, cut them.

Myrlene - Florida may also need to receive a letter if they do not turn things around soon.

3. Study Status
70 randomized; 1 randomized in May. Several sites did great in May.

Screening to randomization ratios have continued to improve, currently below 3 (average has been around 4.1).

Most sites appear to be using a diabetes risk questionnaire, especially sites that do not have access to EMR.

4. DSMB Report Plan
Next DSMB meeting is on May 27th. Plan to use data up until April 30th.
Add to report: ancillary studies, questionnaires, ratios, removing sites, adding sites (with a focus on EMR), and v1.6.
Protocol v1.6: changed waiting period from 12 to 8 weeks for people taking less than 2,000 IUs of vitamin D and lowered enrollment age of Native Americans from 30 to 25 years old.
Action: [CC] finalize v1.6 and distribute to sites before DSMB meeting.

CC will have first draft of report by end of next week, May 9th.
Quick EC meeting on Tuesday, May 13th at 1pm EDT.
Send reports on Thursday, May 15th to Saul --> DSMB.