EC Minutes from 10.2.14

Bess Dawson-Hughes, Saul Malozowski, Anastassios Pittas, David Robbins, Clifford Rosen, Patricia Sheehan, Jim Ware

DSMB Meeting

Taso shared the CC's presentation with the DSMB. CC can leave the call after presenting if the DSMB does not have any questions.

DSMB chair sent around D2d's informed consent and highlighted concerns.

EC's thoughts – hemoglobinopathy is not being collected by the study and is not routinely reported in research, therefore the consent should not be an issue.

If the Central Lab detects an extra peak and determines it is due to an E trait they tell the site they cannot evaluate the A1c sample. This is consistent with the GRADE study. *Do not bring up at DSMB meeting unless specifically asked.

CC should be prepared to answer questions regarding hemoglobinopathy and the current consent form.
Meeting will take place on a conference call line. Saul or Myrlene can call the CC on a separate line if the DSMB would like the CC to rejoin the discussion after presenting.

A1c Point of Care Analyzer

Simmons responded to Saul. Saul will try to set a teleconference time with him.
CC's thoughts – something is better than nothing. Simmons may be willing to loan sites the meters without any supplies. David knows of another manufacturer Saul can try to contact.
Action: [David] will send Saul contact information for another manufacturer.

Central Lab Closure

The Central Lab may be open to receive samples on Tuesday, December 23rd and December 30th. Patty has a follow-up call with the lab tomorrow.
EC's thoughts – cannot trust that samples will arrive on-time during the holidays. Ask the lab if they can come in for a half day on the 24th to process any samples that did not arrive on-time (Dec. 23rd).

Unblinded Sections of DSMB Meeting

Jim would like to have clinical representation during the unblinded sections of the DSMB meeting. Last meeting the DSMB asked about clinical features of individual cases that he was unable to answer.
EC's thoughts – can ask the DSMB if they have any questions regarding specific cases during the open session. Q: Did the DSMB want to be unblinded?

Reports

September – 61 randomized, same as August which is disappointing
570 randomized in total

Why was September so slow? Some well performing sites had a bad month. We should always be around 75-80 at minimum. Need to push low performing sites to get people in.

EC's thoughts – at the Investigator's meeting talk to sites about maintaining a steady recruitment pace over the long term.

New sites will be on next week's report.
All three new sites are sending out letters (last week – Cleveland, Kaiser), follow-up calls this week. Baltimore is sending letters and calling this week. CC is concerned with the pace at Cleveland. Baltimore should have its first screener soon.

Taso – need to get on sites, visit? Florida and Pennington turned around after visiting. We need to start those conversations with these sites. *Not focusing on UTSW.

Atlanta - slow, coordinator had a visa issue had to leave the country. The other coordinator has been out sick.
NY – new PI, needed new consent form, IRB has been slow. Taso and Patty spoke with Dr. Liao, Kamala and Mahmoud regarding using EMR and how to work through their own patients. Issues at both these sites have been resolved and recruitment should be back to normal.

Ancillary Studies
Gunstad - cognitive impairment study offered two options to sites if impairment was detected.
EC's thoughts – preference is to have his staff contact participant

Support and Education
Almost half of sites have held their first participant event.