

EC Minutes from 7.16.15

Meeting Called to Order- 3:35pm | Adjourned-4:30pm

Present: Bess Dawson- Hughes, Saul Malozowski, Anastassios Pittas, David Robbins, Clifford Rosen, Myrlene Staten, James Ware.

Reports Reviewed

- 35 RAN (so far). Month activity looks promising.
- 69% RAN: BAS. Ratio- algorithm is working well.

Action: Change the "EOS" label on pages 3-4 to a more clarified label. Label change will be reflected on next week's EC reports.

Site Updates

- Tennessee - Seriously underperforming. Unanimous decision of EC for site to transition to performance based payments.
- UTSW - Activity has improved, and site should be looking to different sources to find subjects. Taso will send follow-up email [DONE].

Discontinuation of Study Pills

- Reviewed "study pill discontinuation for participant decision" document.
- Committee proposed adding more detail to those subjects that "withdrew study consent. For example, a subject may have withdrawn because they didn't get paid.

Action: Ellen will provide additional information for all participants that discontinued study pills and/or withdrew consent (no longer participating). Will use same format as in DSMB reports to maintain consistency in presenting data.

Next DSMB Report [due 10/30/2015, 2 weeks before meeting on 11/13/2015]

- Discussed cut-off day for DSMB report. The CC suggests including clean and complete data as of August 31st.
- Since reports will become more comprehensive as time goes by (e.g., inclusion of outcome data), we need to have enough time to prepare a good and complete report. The latest recruitment data (as of 10/30/2015) will be presented at the meeting.
- More detail on outcomes will be presented at the next DSMB meeting.

Action: A draft DSMB report will be circulated for review in the beginning of September with data as of August 31st, 2015.

Study Pill Potency

- Reviewed "D2d study pill testing results" document.
- Both Tishcon and the VA have measured the amount of Vitamin D in pills for all 3 lots. The % of target dose should be within 20% of target.
- Lots 2 and 3 are closer to 20% compared to lot 1.
- Committee agreed that all 3 lots are in good target dose range.

Truman Update

- Dr. Robbins reported that the Truman site is now fully staffed, have been working more efficiently, and have more screenings scheduled.
- Erica has been checking up on Truman this past week.

Action: Dr. Robbins will provide updates if needed.

Diagnosis of diabetes outside study/use of Metformin

- Committee discussed the importance of participants reporting being prescribed metformin by their PCPs and consulting with study site.
- Discussed the importance of reviewing protocol to follow with coordinators at each site and having PIs follow-up with PCPs, coordinators, and participants.

Action: CC will remind coordinators to give out wallet cards (which are available) to participants and where to access template within MOP for dealing with use of metformin.

Annual Meeting Ideas

- Saul suggested following up with Vanita about a guest speaker for meeting and focusing on retention.