

SC Minutes from 1.12.17

Meeting Called to order- 12:02pm | Adjourned: 1:00pm

Present: Vanita Aroda (MedStar), Daniel Hsia (Pennington), Irwin Brodsky (Maine), Rowena Dolor (Duke), Betty Drees (Truman), Karen Johnson (Tennessee), Sun Kim (Stanford), Emilia Liao (New York), Erin LeBlanc (Oregon), Saul Malozowski (NIDDK), Myrlene Staten (NIDDK), Jean Park (MedStar-Baltimore), Anne Peters (LA), Lawrence Phillips (Atlanta), Anastassios Pittas (CC), Richard Pratley (Florida), Philip Raskin (UT Southwestern), Patty Sheehan (CC), Neda Rasouli (Colorado), Elizabeth Thomas (Colorado)

Discuss Question: What to do if participant has elevated Vit D level at PCP visit

- SC reviewed a recent case in which a participant at the Kaiser site had 25OHD level drawn at PCP visit and was told that it “it was too high” (91 ng/ml, local reference range is 20-80). The PCP recommended to reduce the current dose of vitamin D in half. No prior Vit D levels available. Currently not taking any additional vitamin supplements other than iron.
- The following were discussed
 - A high 25OHD level by itself is not toxic.
 - As long as safety labs (e.g. calcium) are fine, participant can continue on vitamin D.
 - Site PI may elect to check serum/urine calcium level more often than the protocol call for.
 - This case and suggested approach were added in the FAQ section of the MOP

Study drug adherence

- To promote adherence the SC discussed whether it would be acceptable for participants to take missed doses of study pill (e.g., take 2 the following day after forgetting to do so the previous day; take 7 study pills only at once if participant forgot the last 7 days).
- The rationale for such a proposal was to not give the participant the wrong impression that missing a few pills is ok.
- However, it was noted that
 - D2d evaluates daily dosing and study pills are formulated for daily dosing.
 - Infrequent high doses of vitamin D are not recommended.
- **It was concluded that no more than one a day should be made up at a time.**
- RCs should discuss with site PI and determine if it is appropriate to provide participant with instructions regarding taking two pills the day after a missed dose as some participants may find the instructions confusion or misinterpret them. .

Action: CC will update MOP 19: FAQ.

Maintaining staff motivation

- **Tufts:** Tufts site and CC team went out to dinner to celebrate end of recruitment.
- **Duke:** Site team went out for lunch and plan to also celebrate with their participants at next SEP event.

- **HealthPartners:** Chhavi cooked dinner for team.
- **MedStar:** Vanita discussed the importance of having a celebratory moment with staff and rewarding them for their efforts in achieving a great milestone in D2d.

QOL supplement roll out

- CC will send out the QOL protocol supplement. The QOL questionnaire will be given to participants who have upcoming M24 visits but *not for participants who already had their M24 visits.*

Data Variables and Availability

- A data variables PDF is now available on the portal and shows what D2d is collecting. The objective is to help generate ideas for ancillary studies and publications.

Action: Please contact the CC if you have any questions about the data.