

Minutes from 6/5/14

Present: Bess Dawson-Hughes, Patricia Sheehan, David Robbins, Saul Malozowski, James Ware

1. Intent to treat group= all people who had a randomization number assigned.
Modified intent to treat group= all people who had a randomization number assigned and received study pills. *Had at least one dose of study pills.

Hopefully difference between ITT and MITT will be small.

If a randomization assignment was made in SPIRS the EDC randomization form should be completed.

All participants that have EDC randomization visit date and answered Yes to the question "Was a bottle of study pills assigned" (NEWBTLYN) will be in ITT group.

All participants in ITT that have Yes for the question "Confirm the bottle assigned was dispensed" (SDAISYN) at the randomization visit will be in the MITT group.

2. NIDDK Repository will be doing a review of the D2d study. Patty will ask the Central Lab, when based on current rate of enrollment the first set of samples will be shipped to the repository. Otherwise the Repository plan should answer all their questions

We discussed repository sample status. Patty informed committee that the lab will thaw -refreeze repository samples, and provide ancillary study investigators only the volume they require, not necessarily a full cryovial. We will add a question to the Ancillary Study application asking if a sample that was thawed and refrozen will be acceptable for the planned analyses. The revised application will be reviewed at the next ASES meeting, and the thaw refreeze issue will be discussed.

3. New site updates: all 3 new sites have submitted IRB applications.