

EC minutes from 10.30.14

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

Physical Exams at Screening

PI (on behalf of a site PI) asked if physical exams can be skipped at screening unless there is a reason to perform an exam.

EC Decision – physical exams cannot be skipped at screening visits. It is important to make sure the PI sees participants before randomization.

Reviewed DSMB Report

The cut-off date for data is October 15th.

Important edits:

- Note that the current data does not include any contribution from the new sites. Reemphasize this point through presentation.
- Change figures to say 2014 instead of OCT 14, NOV 14, etc.
- Remove Tulane from figures.
- Make protocol deviation an appendix and sort by site.
- Separate the two Tulane participants who withdrew from consent from the rest. The DSMB already saw these people in the last report.
- Add a brief description for each SAE as an appendix. Categorize into systems and highlight those that are relevant and expected.

EC Comments:

- We may need to add more sites.
- Need to show projections to DSMB, especially as it relates to the budget, if we extend recruitment.
- Ask high performing sites for proposals on how they can expand. *Add to SC agenda.
- Send DSMB reports two weeks in advance and if they want additional items they will have time to request them.