

Minutes from 6/19/14

Present: Bess Dawson-Hughes, Michael Lewis, Anastassios Pittas, David Robbins, Clifford Rosen, Patricia Sheehan, Myrlene Staten

Call to order - 3:33pm / Adjourned -

1. Glycemia

Up until recently sites had a good grasp on the glycemia at local vs. central lab. After about May 6th there was a shift in these values. Michael confirmed shift at the central lab, but not clear why (change reagent / recalibrate machinery). The variability is still within the expected range of the assay system. The Central Lab does not have any proposed specific action to take at this time. Going forward, the Central Lab will push to have lot changes further apart in time to avoid any future potential shifts and take greater scrutiny in analyzing data after reagent changes.

David Robbins' suggestions for Central Lab (sent via email):

- Consider research standards, which demand greater accuracy than clinical standards when accepting variability
- Consider sending sites standards to test. Is this feasible?
- Consider adding mass spec analyzer?

2. Year 2 Budget

Year 1 - 50% of personnel

Year 2 - 40% of year 2 budget to use any way the site wants, increase in core payment

Complaints from sites:

Comparing payments to those from industry studies; lag in payment

One problem is that sites are performing more baselines than anticipated.

Options:

#1 - Compensate sites for every baseline

#2 - Hire a new person to do month payments (currently 3 months)

Bess - give sites a lump sum up front that will cover costs of extra baselines (floating loan)

#3 - make randomizations worth more - this option was favored. However, at later discussions with research admin at tufts, this option was not considered optimal, as what sites really want is \$ up front.

3. DSMB

Minutes were more negative than expected, especially since concerns were not brought up in the open session. DSMB mentioned futility, based on low recruitment.

Mistakes:

- Setting monthly goals too high
- Saying recruitment started Oct 15th

Taso - looking to write a rebuttal

Bess - proposes adding an introduction to the monthly reports

4. Other

June has been a slow month - 39 randomized

Still waiting on year 2 Notice of Award - Office of Dietary Supplements has still not submitted their contribution.

New sites should be ready to contribute significantly sometime in August.