

Minutes from 5/8/14

Call to order - 12:01pm / Meeting Adjourned - 1:08pm

1. Subcommittee Updates

Recruitment and Retention - Chair: Vanita Aroda

RRS consists of a core group of members that met from October to November; since November, RRS has been open to all staff involved in recruitment. Recent meetings have consisted of 3-4 site presentations (available in the Recruitment Resource Center, RRC) on recruitment strategies that have been both successful and unsuccessful, and next steps. Best practices appear in the RCC on the D2d portal. From January to April, D2d % of target reached has increased from 29.5% to 59%.

Bray - southern sites have been performing more poorly than northern sites.

Taso - screened to randomized ratios between these two regions are about the same, southern sites need to screen more people.

Aroda - consider setting up a regional call for southern sites to discuss why certain methods are not working in the south and what can be done differently to improve recruitment.

Cyrus - consider EMR-based "clinical warning" for PCPs to alert them for patients who meet ADA criteria to screen patients with A1c and FPG.

Ancillary Studies Evaluation - Chair: Bess Dawson-Hughes

Overview of LOIs and Applications Received

2012 - 1 LOI

2013 - 7 LOIs --> 4 Applications --> 2 RO1s submitted in 2014

2014 - 4 LOIs --> 1 Approved, 1 for review today

Application: Biomarkers of cancer in the D2d trial - Joel Mason, U.DA Human Nutrition Research Center at Tufts University

Status - Application Unanimously Approved

*Consider holding X % of samples in reserve for future ancillary studies. [Saul] will inquire further by asking NIDDK Repository.

2. Save the date! - Investigator Meeting - November 17, 2014, Location TBD

Arriving on Sunday, November 16th - casual dinner

Monday, November 17th - finishing mid to late afternoon

3. Protocol v1.6 changes

- Inclusion age lowered to 25 years for people of American-Indian, Alaska Native, Native Hawaiian, or other Pacific Islander ethnicity.

- Wait period for washout if taking over 1,00 units/day now varies (8-12 weeks) depending on amount of vitamin D, as described in MOP.

4. Site Expansion

D2d is still far from reaching its target. Four sites have been evaluated and 3 were accepted - Baltimore, Cleveland Clinic, and Kaiser (Portland). All sites have access to EMR and will start after June 1st (year 2).

Larry - inquires about the possibility of more funding to help with recruitment

Cyrus - can successful sites be given more resources?

Taso - Sites need to prove success based on objective criteria. The CC is aware of challenges with the budget and will look into ways to help the sites.

Taso - The CC will reach out to successful sites to consider expanding their current enrollment goals. A successful site is one that meets at least 80% of its cumulative enrollment goals and has exceeded its monthly targets for at least 3 consecutive months.

5. D2d Study Status

Recruitment is continuing to improve each month. So far for the month of May, 17 participants have been enrolled.