

Data Safety Monitoring Board  
Comprehensive Cancer Center of Wake Forest University  
Meeting 06/17/09

Please find a summary below of the meeting of the Comprehensive Cancer Center of Wake Forest University Data Safety Monitoring Board on June 17, 2009. All members of the board (15) were present with the exception of three members.

**Protocol 60A02 - A Phase II Randomized Placebo-Controlled, Double-Blinded Trial Evaluate the Effects of Fruit and Vegetable Extracts on Intermediate Biomarkers in Head and Neck Cancer Patients**

Accrual for this study is closed with 134 total patients accrued. Samples need to be processed. The board anticipates having the results at the next DSMB meeting and the abstract is anticipated in September.

**Protocol 97202 – A Randomized Double-Blind, Placebo-Controlled Study of Oral Coenzyme Q10 to Relieve Self-Reported Cancer Treatment Related Fatigue in Breast Cancer Patients**

The final 11 patients were accrued and these last patients will complete the trial in September. The data will be reported at the next DSMB meeting.

**Protocol 98308 – A Randomized Double-Blind, Placebo-Controlled Trial of North American Ginseng Extract to Prevent Respiratory Infection and Reduce Antibiotic Use in Patients with Chronic Lymphocytic Leukemia**

This study accrued 293 patients in 120 days. Treatment ended in April, and follow-up visits ended in May. Over 35,000 diaries have been completed by the patients, and given the number, it will take some time to enter and process. Currently, data entry is approx. 1/3 of the way done. Retention is higher than expected, should be close to 90% (expected 80%). There have been twenty five AE's, of which 4 are possibly related to the study (2 AE's on each arm). Overall, it is a good example of a trial (on avg. 4.8 accruals per day) with CTSU accruing ~1/4 of the patients. The final report should be available at the next DSMB.

**Protocol 91105 – Phase III Double Blind, Placebo Controlled Study of Donepezil in Irradiated Brain Tumor Patients**

Accrual picked up a little bit since last DSMB: 4.7/month (expectation is 6/mo). Minority accrual ~10%. Three AE's reported in total, though none have occurred since the last DSMB. The Board suggested an interim analysis of AE's for the next meeting. Data will be reviewed again at the next DSMB.

**Protocol 97106 – A Randomized Study to Determine whether ArginMax Improves the Sexual Function and Quality of Life in Female Cancer Survivors.**

The study is closed except to minority accruals: 18 more pts are needed. Only 3 pts have been accrued over the last 6 mos. The RB is e-mailing the sites to identify issues with accrual – RB awaiting responses from the sites. Patients need to be accrued to the study

no later than June 1, 2010. RB is aware of the issues, and they have it on the agenda for their next RB meeting. Retention was a little better for minorities, while compliance was a little worse for minorities. No AE's since the last review

**Protocol 97405 – A Randomized Study of Soy Protein and Effexor on Vasomotor Symptoms of Men with Prostate Cancer**

Accrual was 1.7 patients per month at the last meeting. It is now at 2.3 per month, which is still below target of 4/mo. Per the last Board meeting, action was taken to address the issues. The RB feels good about the increasing accrual trends. Actions taken: conference calls were held with sites, education sessions held, contacted high-accruing sites to understand success factors: essentially they had urologists championing the study, the study was opened to the PHS family clinic, it was highlighted in the RB newsletter. Per Dr. Kelaghan, the study will be opened to CTSU sites in ~1 month. There is a 28% drop-out rate at 12 weeks; close to expectation of 25%, 97% compliance. Minority accrual is about 15%. There has been 1 AE that is unlikely to be related to the trial. Interim review will take place at 88 patients.