CRO Communiqué

Keeping you informed about CRO progress
August 2013

Top Enrolling Physicians for July 2013

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Bergamini (Mercy St. Louis)	1	0	0	0
Dr. Carlson (Mercy Spfld)	9	1.9	4.5	6.4
Dr. Finnie (Mercy St. Louis)	2	0	1	1
Dr. Hassan (Freeman)	1	0.1	0	0.1
Dr. Gillett (Cox)	1	0	1	1
Dr. Lafrancis (Mercy Joplin)	1	1	0	1
Dr. Jaboin (Mercy Spfld)	1	1	0	1
Dr. Raju (Mercy Spfld)	1	0	1	1
Dr. Rodgers (Mercy St. Louis)	2	0	1	1
Dr. Tiriveedhi(Mercy Spfld)	1	0	0.5	0.5
Dr. Tummala(Mercy Spfld)	3	1	1.5	2.5
Total	22	4.9	10.5	15.4

CRO has yet to receive our grant award for the current grant year. I inquired earlier this week and was told we would be receiving it any day now. Our enrollments continue to be low and concerning for the first two months of our grant year. Combining both months we have earned 14 treatment and 17.2 cancer control credits for a total of 31.3 credits.

CIRB

It is official – CRO received approval to begin using the CIRB on Monday, July 29th. CRO immediately began the transition to use the CIRB, but it will be September before actual approval with the CIRB will occur. The NCI CIRB currently reviews only Phase III trials. Other trials such as Phase II and our control trials will continue to be reviewed by the Cox and Mercy Springfield IRB's. The NCI CIRB Initiative has added a new CIRB to review NCI-sponsored early phase studies. This new CIRB is named the "Adult CIRB – Early Phase Emphasis". As a result of this addition, the existing Adult CIRB has been renamed the "Adult CIRB – Late Phase Emphasis" to differentiate the two Adult CIRBs. The Adult CIRB – Late Phase Emphasis will continue to review NCI-sponsored phase 3 studies.

Study Profile

SWOG S1202, "A Randomized Placebo-Controlled Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor (AI)-Associated Musculoskeletal Symptoms in Women with Early Stage Breast Cancer" is this month's profile study. The primary objective is to assess whether daily duloxetine decreases average joint pain in women with aromatase inhibitor-associated musculoskeletal syndrome (AIMSS), as measured at 12 weeks by the modified Brief Pain Inventory Short Form. Patients are blinded to receive the duloxetine or placebo. Women must have histologically confirmed estrogen receptor (ER) and/or progesterone receptor positive invasive carcinoma of the breast with no evidence of metastatic disease. They must have completed mastectomy or breast sparing surgery, and have recovered from all side effects of the surgery. Chemotherapy and/or radiation therapy must have been completed at least 28 days prior to registration.

CRO Affiliate Representatives Invited to Join CRO Executive Board

CRO Executive Board has extended an invitation to our affiliate's sites to appoint a physician representative to join the board meetings via the WebEx tool.

NCORP Grant

We are working to draft our NCORP grant application following previous CCOP U-10 formats as we have been advised by NCI. Release of the NCORP grant is believed to be in mid-September. With only 60 days from the grant releases to submission we hope to be well prepared for needed revisions and additions once the grant is released.

New Studies Approved in July, 2013
Opened at Cox and Mercy Springfield

Alliance A091201 Randomized Phase II Study Comparing the MET Inhibitor Cabozantinib to Temozolomide/Dacarbazine in Ocular Melanoma

ECOG E1Z11 A Cohort Study to Evaluate Genetic Predictors of Aromatase Inhibitor Musculoskeletal Symptoms (AIMSS) -

SWOG S1202 A Randomized Placebo-Controlled Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor (AI)-Associated Musculoskeletal Symptoms in Women with Early Stage Breast Cancer

Studies Permanently Closed to Enrollment at Cox & Mercy in July 2013

SWOG S1108 Phase II Trial of the Aurora Kinase A Inhibitor MLN8237, In Relapsed or Refractory Peripheral T-Cell Non-Hodgkin Lymphoma

Wake Forest 97609 Impact of Genomics and Exposures on Disparities in Breast Cancer Radiosensitivity

Studies Temporarily Closes to Enrollment at Cox & Mercy in July 2013

GOG-0231D A Phase II Evaluation of MLN8237 (IND#113149 NSC# 747888) in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus

Reactivation at Cox and Mercy in July

GOG 0260 A Phase II Evaluation of Elesclomol Sodium and Weekly Paclitaxel in the Treatment of Recurrent or Persistent Platinum-Resistant Ovarian, Fallopian Tube or Primary Peritoneal Cancer