

CRO Communiqué
Keeping you informed about CRO progress
January 2014

Top Enrolling Physicians for December 2013

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Carlson (Mercy Spfld)	5	0.3	4	4.3
Dr. Finnie (Mercy St. Louis)	2	0	1.5	1.5
Dr. Hanson (Mercy St. Louis)	2	0	2	2
Dr. Hu (Mercy St. Louis)	1	1	0	1
Dr. Nair (Mercy Spfld)	1	1	0	1
Dr. Sleckman (Mercy St. Louis)	1	0	1	1
Dr. Jessica Snider (Mercy Spfld)	1	1	0.5	1.5
Total	13	3.3	9	12.3

Our accruals continue to be low. With seven months of our grant year behind us we have earned 54.3 treatment credits and need to be at 75.8 to be on track to reach our grant year target of 130 treatment credits. We have earned 68.6 cancer control credits and need to have earned 81.7 control credits to be on track to meet this year's cancer control target of 140. We are hopeful new studies will be activated soon as the research bases submitted their NCORP grant funding at the same time as CCOPs and this is now completed. Attached is "CRO's Patient Registration Summary" updated through December.

NCORP Grant

Our grant application was sent to NCI by UPS next day air today, January 6th. YEA! We are well positioned to be an NCORP site and participate in the new cancer care delivery research component of the grant. Funding announcements are scheduled to be made in September 2014. Thanks to everyone who participated in the grant application process. Many hours of hard work went into our 240 page application.

Profile Study

Alliance A011106 ALternate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A Phase III Study is a new study approved this month. This randomized phase III trial studies fulvestrant to see how well it works compared to anastrozole or fulvestrant and anastrozole together in treating postmenopausal patients with stage II-III breast cancer undergoing surgery. Estrogen can cause the growth of breast cancer cells. Hormone therapy, neoadjuvant treatment and using fulvestrant and anastrozole may fight breast cancer by blocking the use of estrogen by the tumor cells. It is not yet known whether giving fulvestrant alone, anastrozole alone, or fulvestrant and anastrozole together is more effective in treating patients with breast cancer. Patients must agree to provide the required research biopsies at baseline, week 4 and at surgery for biomarker and correlative studies. This is a large study with an estimated enrollment of 2820 by April 2016.

Time for Thanks

As the year concludes and holiday festivities are over, CRO wants to acknowledge and thank all of you who put in time and effort above and beyond the call of duty for CRO during 2013. Thanks go first to our physician investigators and research staff for enrolling patients to our clinical trials and for your commitment to caring for patients while conducting the research that will improve cancer care. At the end of 2013, CRO finished with a burst of frantic grant writing; special thanks to all who contributed to CRO's grant application, now completed.

New Studies Approved in December, 2013 Through Cox & Mercy Springfield's IRB's

CALGB 9665 The CALGB Leukemia Tissue Bank

SWOG S1211 A Randomized Phase I/II Study of Optimal Induction Therapy of Bortezomib, Dexamethasone and Lenalidomide with or without Elotuzumab (NSC-764479) for Newly Diagnosed High Risk Multiple Myeloma (HRMM)

New Studies Approved and Opened in December with the CIRB

Alliance A011106 ALternate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A Phase III Study

Alliance A041202 A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (= 65 Years of Age) With Chronic Lymphocytic Leukemia (CLL)

Studies sent to Cox & Mercy IRB's for Permanent Closure in December 2013

GOG 3001 A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of AMG 386 With Paclitaxel and Carboplatin as First-line Treatment of Subjects With FIGO Stage III-IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancers (Amgen Protocol #20101129) -This is an industrial study; we have been trying to negotiate a budget, but could not come an agreement.

WF 99311 Randomized Placebo-Controlled Phase 2 Pilot Study of Memantine (Namenda) for Smoking Cessation among Cancer Survivors
-study closed effective 11/06/2013