CRO Communiqué
Keeping you informed about CRO progress
March 2014

Top Enrolling Physicians for February 2014

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Bonebrake (Cox)	2	0	2	2
Dr. Bandi (Mercy St. Louis)	1	0	1	1
Dr. Carlson (Mercy Spfld)	1	0	1	1
Dr. Ding (Cox)	1	1	0	1
Dr. Brahmanday (Freeman)	1	0	1	1
Dr. Finnie (Mercy St. Louis)	1	0	1	1
Dr. Ludeke (Mercy St. Louis)	1	0	1	1
Dr. Sleckman (Mercy St. Louis)	1	0	1	1
Drs. Bumberry/Tiriveedhi (Mercy Spfld)	1	1	0	1
Total	10	2	8	10

Enrollments continue to be slow. CRO earned two treatment and eight cancer control credits during February. CRO has earned 66.1 treatment and 89.9 control credits this grant year. We must earn at least 200 credits by our grant year's end on May 31st to receive the higher level funding of $4,000 per credit as opposed to $2,500 per enrollment with the NCORP grant. Attached is CRO's updated patient registration statistics through February.

NCI Clinical Trials Network (NCTN)

The National Cancer Institute (NCI) has transformed a previous NCI-sponsored Clinical Trials Cooperative Group Program that funded several separate organizations into a consolidated and integrated program now call the NCI National Clinical Trials Network (NCTN). This new program becomes effective March 1, 2014. The overarching goal of the NCTN is to conduct definitive, randomized, late phase clinical treatment trials and advanced imaging trials across a broad range of diseases and diverse patient populations. It will comprise four adult network groups, one pediatric group and one Canadian collaborating clinical trials group that will generate trials for the network. Member institution of network groups can enroll patients on all adult phase III trials, randomized phase II trials, as well as select early phase trials, irrespective of the specific Network Group that is leading the trial (also known as Lead Protocol organization or LPO) in addition, select trials for adolescent and young adults will be open to all member institutions or sites.

Profile Study

NSABP B-50-I "A Randomized, Multicenter, Open-Label Phase III Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine Versus Trastuzumab as Adjuvant Therapy for Patients with HER2-Positive Primary Breast Cancer who have Residual Tumor Present Pathologically in the Breast or Axillary Lymph Nodes following Preoperative Therapy" is our profile study this month. This 2-arm, randomized, open-label study will evaluate the efficacy and safety of trastuzumab emtansine versus trastuzumab as adjuvant therapy in patients with HER2-positive breast cancer who have residual tumor present in the breast or axillary lymph nodes following preoperative therapy. Eligible patients will be randomized to receive either trastuzumab emtansine 3.6 mg/kg or trastuzumab 6 mg/kg intravenously every 3 weeks for 14 cycles. Radiotherapy and/or hormone therapy will be given in addition if indicated. This is a large trial with 1,484 women being enrolled.

New Studies Approved in February, 2014 Through Cox & Mercy Springfield's IRB's

SWOG S1310 "Randomized Phase II Trial of Single Agent MEK Inhibitor GSK1120212 Vs 5-Fluorouracil or Capecitabine in Refractory Advanced Biliary Cancer" (opened for all CRO components except Cox Branson)

New Studies Approved and Opened in February with the CIRB

NSABP B-52 **"**A Randomized Phase III Trial Evaluating Pathologic Complete Response Rates in Patients with Hormone Receptor-Positive, HER2-Positive, Large Operable and Locally Advanced Breast Cancer Treated with Neoadjuvant Therapy of Docetaxel, Carboplatin, Trastuzumab, and Pertuzumab (TCHP) With or Without Estrogen Deprivation"

Studies sent to Cox & Mercy IRB's for Permanent Closure in February 2014

GOG-0268 "A Phase II Evaluation of Temsirolimus (CCI-779) in Combination with Carboplatin and Paclitaxel Followed by Temsirolimus (CCI-779) Consolidation as First Line Therapy in the Treatment of Stage III-IV Clear Cell Carcinoma of the Ovary"