CRO Communiqué
Keeping you informed about CRO progress
July 2014

Top Enrolling Physicians for June 2014

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Bechtel (Mercy St. Louis)	1	1	0	1
Dr. Bonebrake (CoxHealth)	1	0	1	1
Dr. Carlson (Mercy Spfld)	3	0	3	3
Dr. Donegan (Mercy St. Louis)	1	1	0	1
Dr. Holden (Mercy Spfld)	1	1	0	1
Dr. Klix (Mercy St. Louis)	1	1	0	1
Dr. Nair (Mercy Spfld)	1	1	0	1
Dr. Oza (Good Samaritan)	3	2	1	3
Dr. Rogers (Mercy St. Louis)	1	0	1	1
Total	13	7	6	13

Enrollments have been slow this month. CRO earned 7 treatment and 6 control credits in June. We will need to earn another 7 credits to receive $80,000 in funding for June and July. We are eager for several of our new studies to be activated.

Status of the CCOP NCORP Program Transition

No definite word that our NCORP grant has been approved however; we did get an email saying our grant has been selected for funding from the specialist handling our award. Additional information has been submitted as requested. We eagerly await the official announcement of the NCORP grant recipients scheduled for late July.

CRO Steering Committee Dinner in St. Louis

CRO held a Steering Committee meeting on Thursday, June 18th in St. Louis. Asad Dean, MD, Hematologist / Oncologist at Texas Oncology in Ft. Worth, Texas spoke on "A New Treatment Option in Previously Treated Chronic Lymphocytic Leukemia and Mantle Cell Lymphoma". Twenty-two attended the event including research physicians and staff from Mercy St. Louis and Good Samaritan. CRO staff conducted an internal audit with Good Samaritan and Mercy St. Louis charts prior to the meeting.

Study Profile – Exciting new trial!!

S1400 "Lung-MAP: Biomarker-Targeted Second-Line Therapy in Treating Patients With Recurrent Stage IIIB-IV Non-Small Cell (Squamous Cell) Lung Cancer" This screening and multi-sub-study randomized phase II/III trial will establish a method for genomic screening of similar large cancer populations followed by assigning and accruing simultaneously to a multi-sub-study "Master Protocol". The type of cancer trait (biomarker) will determine to which sub-study, within this protocol, a participant will be assigned to compare new targeted cancer therapy, designed to block the growth and spread of cancer, or combinations to standard of care therapy with the ultimate goal of being able to approve new targeted therapies in this setting. In addition, the protocol includes a "non-match" sub-study which will include all screened patients not eligible for any of the biomarker-driven sub-studies. This sub-study will compare a non-match therapy to standard of care also with the goal of approval. To learn more about this trial click on this link http://lung-map.org/healthcare-providers. This study is in pre-activation at this time. We are watching closely for it to be activated. Our staff can begin screening patients for the trial since patients must have their initial treatment prior to registration.

Alliance Appointments

CRO's Clinical Research Coordinator, Basava Raju has been appointed to serve on the Alliance audit committee. Basava's first audit with Alliance is scheduled for the fall of 2014. CRO's Director, Marilyn Bauer has been appointed to serve on the Alliance Prevention Committee. The Prevention committee is responsible for proposal development, proposal review, and/or manuscript writing. If you have an idea for a prevention trial please notify Marilyn at Marilyn.Bauer@CoxHealth.com

New Studies Approved in June, 2014 Through Cox and Mercy's IRB

Alliance A221301 Olanzapine for the Prevention of Chemotherapy Induced Nausea and Vomiting (CINV) in Patients Receiving Highly Emetogenic Chemotherapy (HEC): A Randomized, Double-Blind, Placebo-Controlled Trial

New Studies Approved and Opened in June with the CIRB

NSABP B-55 A Randomized, Double-blind, Parallel Group, Placebo-controlled Multi-center Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients With Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy - In Pre-Activation

SWOG S1400 Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer – In Pre-Activation

Closed Studies in June, 2014

SWOG 1115 Randomized Phase II Clinical Trial of AZD6244 Hydrogen Sulfate (NSC-748727) and MK-2206 (NSC-749607) vs. mFOLFOX in Patients with Metastatic Pancreatic Cancer after Prior Chemotherapy

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

GOG 0273 Chemotherapy Toxicity in Elderly Women with Ovarian, Primary Peritoneal or Fallopian Tube Cancer

GOG 0229L A Phase II Trial of AMG 386 (IND #111071), a Selective Angiopoietin 1/2 Neutralizing Peptibody, in Patients with Persistent/Recurrent Carcinoma of the Endometrium

Temporarily Closed Studies in June, 2014

SWOG S0819 A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer (NSCLC)