

CRO Communiqué Keeping you informed about CRO progress

July 2016



Top Enrolling Physicians for June 2016

	Patient	Treatment	Control	Total	Registered Exceptional	Tissue Procurement
Physician	Registrations	Credits	Credits	Credits	Responders	Phase II
Dr. Bechtel (Mercy St. Louis)	1	0.1		0.1		
Dr. Bonebrake (Cox)	4					4
Dr. Carlson (Mercy Springfield)	3	1 (No credit X2)		1		
Dr. Croy (Mercy Joplin)	1		0.0125	0.0125		
Dr. Dalia (Mercy Joplin)	2		0.0250	0.0250		
Dr. Ding (CoxHealth)	1	0.125		0.125		
Dr. Donegan (Mercy St. Louis)	2	1.125		1.125		
Dr. Finnie (Mercy St. Louis)	1	0.0625		0.0625		
Dr. Hanson (Mercy St. Louis)	2	1.1		1.1		
Dr. Huq (Mercy St. Louis)	1	1	0.25	1.25		
Dr. Kosuri (Mercy St. Louis)	1	0.125		0.125		
Dr. Oza (Good Samaritan)	1		0.0125	0.0125	`	
Dr. Pinheiro (Mercy Spfld)						1 blood only
TOTALS						4 + 1 blood
	20	4.6375	0.3	4.9375		only

CRO had 20 registrations equaling 4.9375 credits this month. Only the month of July left in this grant year.

Cancer Care Deliver Research

The SWOG study team for TrACER/S1415CD "A Pragmatic Trial to Evaluate a Guideline Based Colony Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor (CSF) Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia" are still accepting applications, however, the team has decided to move forward with the selection of components for the Cohort Arm as well as a subset of components for the first round of randomization in the Randomized Trial Arm (RT). Based on the information SWOG has received regarding CRO standing orders for CSFs, CROs components, CoxHealth South - Oncology Hematology Associates (OHA), Mercy Hospital Springfield and Mercy Hospital St. Louis are eligible to participate in the Cohort Arm of this trial. We are anxious to learn more about this opportunity.

<u>Tissue + Blood NCI Administrative Supplement</u>

CRO submitted the last of 29 paired fresh Tissue + blood collections required to complete "PDX Supplement, Tissue + Blood (v2)" on June 27, 2016. CoxHealth submitted 21 of the collections, Mercy Springfield submitted seven and Phelps County had one submission. Sixteen or our specimens were Dr. Bonebrake, CRO's Associate PI patients. This week CRO was notified they had to opportunity to participate in "PDX Supplement, Tissue + Blood (v3)" for the upcoming grant year 2016-2017. Our application is being written and will be submitted next week. This procurement opportunity includes the collection of 36 paired tissue + blood submissions.

Study Profile

EA2133 "Cisplatin and Fluorouracil Compared with Carboplatin and Paclitaxel in Treating Patients with Inoperable Locally Recurrent or Metastatic Anal Cancer" is our profile trial this month. This randomized phase II trial studies how well cisplatin and fluorouracil work compared with carboplatin and paclitaxel in treating patients with anal cancer that cannot be removed by surgery, has come back at or near the same place as the primary tumor, or spread to other places in the body. Drugs used in chemotherapy, such as cisplatin, fluorouracil, carboplatin and paclitaxel, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. It is not yet known whether cisplatin and fluorouracil are more effective than carboplatin and paclitaxel in treating anal cancer.

CRO's Facebook Page

Over the past couple of months, CRO has been diligently working to establish a Facebook "presence." The need to communicate with the public via social media is ever-increasing and it offers us an excellent opportunity to reach the public via a free format. To keep CRO's message and mission in front of the public, we will likely publish or share relevant posts several times per week. Recently we've shared information on the new trials we have opened, news from our component institutions, survivor stories from patients who have participated in cancer research trials, and health tips. You can help by sending us interesting facts, statistics and articles that you read or hear. Hopefully, we'll be able to turn that information into an upcoming post. You can also help by "liking" the CRO Facebook page and "sharing" it on your personal page. When you do that, one of your friends or family may "like" and "share" it as well – and we reach an even broader audience.

ACTIVATION OF CIRB Protocols:

<u>SWOG S1500</u> - A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET)

NHLBI-MDS - The National Myelodysplastic Syndromes (MDS) Study

<u>ECOG-ACRIN EA3132</u> - Phase II Randomized Trial of Adjuvant Radiotherapy with or Without Cisplatin for p53 Mutated, Surgically Resected Squamous Cell Carcinoma of the Head and Neck (SCCHN)

ACTIVATION OF Local Protocols:

<u>ECOG-ACRIN EA2133</u> An International Multicentre Open Label Randomized Phase II Advanced Anal Cancer Trial Comparing Cisplatin plus 5-fluorouracil (5-FU) versus Carboplatin plus Weekly Paclitaxel in Patients with Inoperable Locally Recurrent or Metastatic Disease – open at Mercy Springfield, Mercy STL sites, Mercy Rolla, Good Samaritan, Cox and PCRMC.

<u>GOG-3012</u> A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Niraparib Maintenance Treatment in Patients with HRD-Positive Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy – Non-NCI trial IRB approved for Mercy Springfield and Cox only

Closure through Local IRB:

<u>SWOG S1211</u> 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) – Temporary closed 6/2/2016

<u>Alliance A221304</u> A phase III placebo-controlled, randomized three-arm study of doxepin and a topical rinse in the treatment of acute oral mucositis pain in patients receiving radiotherapy with or without chemotherapy – Closed to accrual 5/16/2016.

<u>Alliance A091201</u> Randomized Phase II Study Comparing the MET Inhibitor Cabozantinib to Temozolomide/Dacarbazine in Ocular Melanoma – Closed to accrual effective 5/6/2016.

SWOG S1304 A Phase II Randomized Study Comparing Two Doses of Carfilzomib (NSC-756640) with Dexamethasone for Multiple Myeloma Patients with Relapsed or Refractory Disease – Closed to accrual 5/15/2016

CIRB Closures:

NRG-GY002 A Phase II Evaluation of Nivolumab, a Fully Human Antibody Against PD-1, in the Treatment of Persistent or Recurrent Cervical Cancer – closed to accrual 6/8/2016