

CRO Communiqué

Keeping you informed about CRO progress

December 2015

Top Enrolling Physicians for November 2015

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	Registered Exceptional Responders	Tissue Procurement Phase II
Dr. Cunningham (Cox)	1	1.03		1.03		
Dr. Donegan (Mercy St. Louis)	1	1		1		
Dr. Ellis (Cox)	4	3.27		3.27		
Dr. Hanson (Mercy St. Louis)	4	3.1	0.5	3.60		
Dr. Mirza(Mercy St. Louis)	1		1	1		
Dr. Snider (Mercy Spfld)	1	0.13		0.13		
Dr. Spencer (Phelps)	1		1	1		
Dr. Tiriveedhi (Mercy Spfld)	1	1.06		1.06		
TOTALS	14	9.59	2.5	12.09		

CRO earned 12.09 credits with 15 registrations in November. There were no new exceptional responders approved and no tissue procurements collected for the Phase II of this initiative. NCI’s target accrual for CRO this year is 170 credits. To achieve this we must average 14.17 credits each month. Four months into our current grant year CRO has earned 32.4 credits. To be on track to meet our 170 credit target goal we need to be at 56.66 credits. Please continue to make every effort to place our patients on a clinical trial.

Basava Raju – Alliance Auditor

CRO’s Clinical Research Coordinator II, Basava Raju served on the Alliance Audit team which conducted an annual 3-year audit at Cancer Research Consortium of West Michigan (CRCWM) in Grand Lakes Michigan on November 9 & 10th. Basava’s experience as a national auditor is helpful to CRO as what he acquires from this experience will make our program stronger.

Fresh Tissue + Blood Supplement

We currently have 3 paired specimens and one blood only specimen collected for the second phase of our tissue procurement supplement. Phase II involves the collection of 29 fresh tissue + blood specimens. CRO needs to collect 29 pairs of tissue and blood from patients with active solid tumors and lymphomas. There is particular interest from the NCI in less prevalent malignancies, such as Small Cell Lung, Pancreatic, Head & Neck, Ovarian and Bladder cancers, as well as Sarcomas, Melanomas, and Non-Hodgkin Lymphomas. This is another wonderful opportunity for CRO. Our accruals have not been going as quickly as hoped. Please make every effort to identify patients and assist CRO in being successful with this initiative. Our component sites will receive \$3,500 per paired submission.

Study Profile

S0931, “Everolimus in Treating Patients With Kidney Cancer Who Have Undergone Surgery” is our profile study this month. This phase III trial is studying everolimus to see how well it works in treating patients with kidney cancer who have undergone surgery. Everolimus may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth or by blocking blood flow to the tumor. On Arm I Patients receive oral everolimus once daily on days 1-42. Treatment repeats every 6 weeks for 9 courses in the absence of disease progression or unacceptable toxicity. On Arm II, patients receive oral placebo once daily on days 1-42. Treatment repeats every 6 weeks for 9 courses in the absence of disease progression or unacceptable toxicity. The primary objective is to compare recurrence-free survival in renal carcinoma patients randomly assigned to 54 weeks of everolimus versus 54 weeks of placebo after nephrectomy or partial nephrectomy.

New CRO Staff

Erin McCaig RN, BSN joined CRO as a part-time cancer research professional on November 30th. Erin most recently worked in Alaska as a pediatric hematology/oncology nurse case manager. Erin will be job sharing with Sharon Hodge RN who will be going part-time in January. Welcome Erin!

CIRB Trials Opened in November

SWOG S1505, "A Randomized Phase II Study of Perioperative mFOLFIRINOX versus Gemcitabine/nab-Paclitaxel as Therapy for Resectable Pancreatic Adenocarcinoma".

SWOG S1404, "A Phase III Randomized Trial Comparing High Dose Interferon to MK-3475 (Pembrolizumab) in Patients with High Risk Resected Melanoma."

Temporary Closures in November

ECOG-ACRIN EAY131 Molecular Analysis for Therapy Choice (MATCH) - Closed to Accrual Effective 11/04/2015

Permanent Closures in November

AOST1322 Phase II Study of Eribulin (NSC#707389, IND#122686) in Recurrent or Refractory Osteosarcoma - Permanent Closure to Accrual Effective 07/28/2015

CALGB 80702 A Phase III trial of 6 versus 12 Treatments of Adjuvant Folfox plus Celecoxib or Placebo for Patients with Resected Stage III Colon Cancer - Permanent Closure to Accrual 11/20/2015 – Follow-up only

SWOG S1203 A Randomized Phase III Study of Standard Cytarabine plus Daunorubicin (7+3) Therapy or Idarubicin with High Dose Cytarabine (IA) versus IA with Vorinostat (IA+V) in Younger Patients with Previously Untreated Acute Myeloid Leukemia (AML) - Permanent Closure to Accrual Effective 11/04/2015

Temporary Closures in November

ECOG-ACRIN EAY131 Molecular Analysis for Therapy Choice (MATCH) - Closed to Accrual Effective 11/04/2015

ECOG-ACRIN E3108 A Phase II Prospective Trial Correlating Progression Free Survival with CYP2D6 Activity in Patients with Metastatic Breast Cancer Treated with Single Agent Tamoxifen - Closed to Accrual Effective October 22, 2015 – Follow-up only

NRG-CC002 Pre-Operative Assessment and Post-Operative Outcomes of Elderly Women With Gynecologic Cancers - Closed to Accrual Effective November 2, 2015

RTOG-1010 A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma

Protocols Archived in November (no further follow-up)

ECOG-ACRIN E1808 A Randomized Phase II Trial of Sunitinib/Gemcitabine or Sunitinib in Advanced Renal Cell Carcinoma with Sarcomatoid Features - Closed to Accrual Effective November 10, 2015 - Request to Archive Memo 11/05/2015

GOG-0186J A Randomized Phase IIB Evaluation of Weekly Paclitaxel (NSC #673089) Plus Pazopanib (NSC #737754) versus Weekly Paclitaxel Plus Placebo in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma - Request to Archive Memo dated 10/29/2015

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 Closed at Component sites on 05/15/2015. Request to Archive Memo Dated 10/27/2015.

 **A Very Merry Christmas and Happy New** 
Year to you! Thank you for your commitment to
CRO clinical research.

From the Staff at Cancer Research for the Ozarks