NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

CRO Communiqué
Keeping you informed about CRO progress
February 2016

Top Enrolling Physicians for January 2016

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	Registered Exceptional Responders	Tissue Procurement Phase II
Dr. Bonebrake (Cox)						1 – blood only
Dr. Brahmanday (Freeman)	1	1		1		
Dr. Bumberry (Mercy Spfld)	2		2	2		
Dr. Carlson (Mercy Spfld)	1	1		1		
Dr. Clouse (Cox)						1- blood only
Dr. Donegan (Mercy St. Louis)	2	2.05		2.05		
Dr. Ellis (Cox)						1 – blood only
Dr. Gillett (Cox)						1 – blood only
Dr. Goodwin (Mercy Spfld)					1	
Dr. Luedke (Mercy St. Louis)	1	1	0.25	1.25		
Dr. Pinheiro (Mercy Springfield)						1
Dr. Tiriveedhi (Mercy Spfld)	1	1		1		
TOTALS	8	6.05	2.25	8.3		

CRO earned only 8.3 credits from 7 registrations in January. One tissue plus blood and 4 blood only specimens were obtained for our Phase II tissue procurements. NCI's target accrual for CRO this year is 170 credits. To achieve this we must average 14.17 credits each month. Half way or six months into our current grant year CRO has earned 48.2625 credits. To be on track to meet our 170 credit target goal we need to be at 85 credits. Please continue to make every effort to place our patients on a clinical trial.

EAY131 – Match Trial Update

The required interim analysis is well underway for this trial and a number of changes are being made to the MATCH trial at this time. ECOG-ACRIN and the NCI have determined that the pause on new patient enrollments needs to remain in place until all of the below activities are complete. Therefore, the enrollment pause, originally expected to lift in January 2016, has been moved to April or May 2016. The changes being made to the trial are as follows: expansion of laboratory capabilities; opening of 12-14 additional treatment arms; and scientific review of data from the first patient cases.

S1415CD - Cancer Care Research Delivery (CCDR) trial

S1415CD "A Pragmatic Trial Evaluating a Colony Stimulating Factor Intervention in Standing Orders and the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia" is being conducted by SWOG. This is CRO's first opportunity to participate in a CCDR trial. CRO has submitted applications for Mercy Springfield, Mercy St. Louis and Oncology Hematology Associate sites to participate in this opportunity. We are eager to learn if our sites have been accepted.

Colony-stimulating factor (CSF) is prescribed to patients undergoing a chemotherapy regimen which carries a high risk of febrile neutropenia (FN). FN is a serious, life-threatening complication which can result in hospitalization and death, and disrupt treatment, compromising the likelihood of remission or cure. Although evidence-based clinical practice guidelines for CSF are available, multiple studies show that between 55%-95% of CSF use is inconsistent with guidelines, including over- and under-use, exposing patients to unnecessary risks and costs. This pragmatic trial is designed to test an intervention to increase compliance with guidelines and generate evidence to assess the effectiveness of primary prophylactic CSF

(PP- CSF) on reducing rates of FN for patients receiving intermediate-risk chemotherapy regimens. The American Society for Clinical Oncology recommends PP-CSFs for patients on high FN risk (>20%) regimens, suggests consideration of PP-CSFs for intermediate FN risk (10-20%) regimens, and does not recommend PP-CSFs for low FN risk (<10%) regimens. Eligibility requirements include being over 18 years of age, having non-metastatic or metastatic breast cancer, non-small cell lung cancer, or colorectal cancer, being scheduled to receive first course of neoadjuvant, adjuvant, or palliative cytotoxic chemotherapy regimen. This includes newly diagnosed and recurrent disease.

Swetha Merddy

Welcome to Swetha Merddy who joined CRO on January 11th as a Cancer Research Professional. Swetha was a general practice physician in India and has been in the US for several years. Her family currently resides in Lincoln, Nebraska. She will be commuting to Springfield untill the end of the school year when her family will relocate to Springfield.

CIRB Trials Opened in January

None

Temporary Closures in January

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) -Temporary Closure to Accrual effective 01/06/2016. Memo distribution date 01/01/2016.

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) Closure to Pre-Registration Effective 12/28/2015

ALLIANCE A091105

A Phase III, Double Blind, Randomized, Placebo-Controlled Trial of Sorafenib in Desmoid Tumors or Aggressive Fibromatosis (DT/DF)
Suspension to Accrual effective 01/04/2016

ECOG-ACRIN EA1131

A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Observation in Patients with Residual Triple-Negative Basal-Like Breast Cancer Following Neoadjuvant Chemotherapy
Suspension to Accrual Effective 12/28/2015, CIRB Acknowledgement 12/29/2015

Permanent Closures in January

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