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
April 2016

Top Enrolling Physicians for March 2016

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	Registered Exceptional Responders	Tissue Procurement Phase II
Dr. Bond (Phelps County)	1	1		1		
Dr. Bonebrake (Cox)	3					3
Dr. Bumberry (Mercy Springfield)	4		2.025	2.025		
Dr. Ding (Cox)	1					1 blood only
Dr. Ellis (Cox)	3	2.125		2.125		
Dr. Finnie (Mercy St. Louis	1	1		1		
Dr. Frazier (Mercy St. Louis)	2		0.025	0.025		
Dr. Hahs (Mercy St. Louis)	1		1	1		
Dr. Nair (Mercy Springfield)	1				1	
Dr. Oza (Mt. Vernon	1	0.125		0.125		
Dr. Spencer (Phelps County)	1		1	1		
Dr. Tummala (Mercy Spfld)	1	0.125		0.125		
TOTALS	20	4.375	4.05	8.425	1	3 + 1 blood only

CRO earned 8.425 credits from in March from 20 registrations. This is up from previous months but still low considering NCI's target for CRO is 170 for the grant year which breaks down to 14.7 credits per month. One exceptional responder was approved. Three tissue plus blood and 1 blood only specimens were obtained for our Phase II tissue procurements. Please continue to make every effort to place our patients on a clinical trial.

Children's Oncology Group (COG) Report Card

Three-year report cards have recently been released for the 200(+) COG institutions. Mercy St. Louis, received a solid ranking as there has been a steady improvement in enrollment numbers. Last year Mercy St. Louis's participation in therapeutic cancer treatment studies placed them in the **43rd percentile** of all COG centers! By way of comparison, Cardinal Glennon's enrollments were 38th percentile and St. Louis Children's (listed as Wash Univ) were 84th. In addition, their data submission was 100% current for each of the last three years, which is a strong testament to the quality of our research support staff under Dr. Sleckman. Thanks to everyone at Mercy St. Louis who support this important program.

Alliance Audit Participation

CRO's Basava Raju was on the Alliance audit team as they reviewed documentation at Dartmouth College - Norris Cotton Cancer Center in Lebanon, New Hampshire on April 24 & 25th. Basava's participation is a great opportunity for CRO to learn new and improved methods for CRO documentation and auditing.

Spring 2016 CRO Steering Committee Meeting – This Coming Monday, April 4th

Dr. Monte Shaheen will speak on "An Immuno-Oncology Agent Approved Across Multiple Tumor Types, Opdivo (nivolumab), A Renal Cell and Lung Carcinoma Overview" on Monday evening, April 4th, 2016 at Oceans Zen beginning at 6pm. Currently, Dr. Shaheen is Associate Professor of Medicine at the University of New Mexico Cancer Center in Albuquerque, NM. He completed his fellowship in hematology/oncology at Indiana University School of Medicine and is board certified. Dr. Shaheen has a strong interest in clinical trials having been involved with over 40 clinical trials including serving as the trial Principal Investigator. Formerly he was Founder and Director of Oncology Services at Providence Medical Group in IN. Since 2011, he is the leader of the melanoma and sarcoma clinical working group at the University of New Mexico Comprehensive Cancer Center. Please RSVP to (417) 269-4520 or Marilyn.Bauer@Coxhealth.com

Dr. Robert Ellis Co-Author

Congratulations to Dr. Robert Ellis who has been named a co-author in "The Significance of Co-Expression of Epidermal Growth Factor Receptor (EGFR) and Ki67 on Clinical Outcome in Patients with Anal Cancer Treated with Chemoradiotherapy: An Analysis of NRG Oncology RTOG 9811". CRO enrolled 14 patients to this study.

CCDR at a Glance

The below link will take you to a one page glance at the CCDR page recently developed by NCI. I will also attach it to this version of our CRO Communique. https://applications.prevention.cancer.gov/ncorp-portal/ccdr-resources/CCDR%20-%20At%20A%20Glance%203-16-16.pdf

A221101 Trial - CRO's Profile Study

"Testosterone in Treating Postmenopausal Patients With Arthralgia Caused by Adjuvant Aromatase Inhibitor Treatment" is our study to profile this month. This is a randomized, placebo-controlled, phase III trial evaluating topical testosterone for the alleviation of aromatase inhibitor induced arthralgia. A parallel group design will be utilized for this two-arm study: topical testosterone vs. placebo. Patients are stratified according to baseline pain score (5-6 vs. 7-10) and age (< 50 vs. 50-60 vs. > 60). The primary objective is to determine whether testosterone will reduce AI-induced arthralgia and associated joint symptoms. The secondary objective is to explore whether testosterone will have an acceptable safety and tolerability profile, with particular reference to androgenic adverse events including acne, hirsutism, and alopecia. Patients must be post-menopausal, have no history of coronary artery disease and not be insulin-dependent diabetics. Women must be on Arimidex or Femara in adjuvant treatment of their breast cancer. Patients are on study treatment up to six months as defined in the protocol. The testosterone/placebo topical gel is self-administered at home daily using a Accu-Pen Dispensing Device. This protocol is worth 1 Cancer Control credit per registration. This trial is being presented at the April 15th IRB meeting for approval.

Trials Opened in March at Mercy Springfield IRB

PALLAS PALbociclib CoLlaborative Adjuvant Study: A randomized phase III trial of Palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+) / human epidermal growth factor receptor 2 (HER2)-negative early breast cancer
Approved at the 3/18/2016 IRB for Cox, Mercy Springfield, PCRMC & Mercy St. Louis

CIRB Protocols that Opened in March:

Alliance A221208 Randomized Phase II Study: Corticosteroids + Bevacizumab vs. Corticosteroids + Placebo (BeSt) for Radionecrosis after Radiosurgery for Brain Metastases

Alliance A061402 Solitary Plasmacytoma of Bone: Randomized Phase III Trial to Evaluate Treatment with Adjuvant Systemic Treatment and Zoledronic Acid Versus Zoledronic Acid After Definite Radiation Therapy

DCP-001 Use of a Clinical Trial Screening Tool to Address Cancer Health Disparities in the NCI Community Oncology Research Program (NCORP)

NRG-GY004 A Phase III study comparing single-agent olaparib or the combination of cediranib and olaparib to standard platinum-based chemotherapy in women with recurrent platinum-sensitive ovarian, fallopian tube, or primary peritoneal cancer

NRG-GY005 A Randomized Phase II/III study of the combination of Cediranib and Olaparib compared to Cediranib or Olaparib alone, or Standard of care chemotherapy in women with recurrent platinum-resistant or -refractory ovarian, fallopian tube, or primary peritoneal cancer (COCOS)

NRG-GY006 A Randomized phase II trial of radiation therapy and cisplatin alone or in combination with intravenous triapine in women with newly diagnosed bulky stage IB2, or stage II, IIIB, or IVA cancer of the uterine cervix or stage II-IVA vaginal cancer

Reactivation of Local Protocol in March:

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) - *reactivation approved by Mercy Springfield IRB* **See revision #10 for recent changes**

Temporary CIRB Closures in March

Alliance N1048 A Phase II/III trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision – *Quality of Life component closed effective 2/1/2016.*