CRO Communiqué
Keeping you informed about CRO progress
October 2014

Top Enrolling Physicians for September 2014

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Ali (Phelps County)	1	1.6	0	1.6
Dr. Bonebrake (Cox)	2	0	2	2
Dr. Craft (Mercy St. Louis)	1	0	1	1
Dr. Croy (Mercy Joplin)	1	0	1	1
Dr. Donegan (Mercy St. Louis)	1	0	1	1
Dr. Ellis (Cox)	1	2	0.4	2.4
Dr. Holden (Mercy Spfld)	1	1.6	0	1.6
Dr. Hoos (Mercy Spfld)	1	0	1	1
Dr. Kosuri (Mercy St. Louis)	1	2.18	.40	2.58
Dr. Nair (Mercy Spfld.)	1	1.8	0	1.8
Dr. Shunyakov (Central Care)	1	1.6	0	1.6
	12	10.78	6.8	**17.58**

Our enrollments are better than last month but still lower than we like to see them. We must achieve a minimum of 16.66 or 17 credits per month to obtain 200 credits a year and keep the higher NCI level funding which is evaluated yearly. Thank you for your continuing support of CRO NCI clinical trials.

NCI Administrative Supplement for Blood Samples

Good news! CRO submitted an application to receive additional funding for submitting 100 blood samples to NCI to assist in the development of a tissue repository in early August. We received notification that we were one of five NCORP programs accepted for this project and awarded $48,510. We await further information to begin our campaign to collect de-identified blood specimens to be used for the NCI tissue repository. We believe it will begin in January 2015. All CRO Components will be asked to participate in collecting blood samples and be reimbursemed for their submissions.

CRO Steering Committee Meeting

Mark your calendars for 6pm on Monday, October 13th for CRO's next Steering committee meeting. The meeting begins at 6pm at TOUCH restaurant. Larry Geier MD will be our speaker. Dr. Geier has 30 years of clinical experience in Oncology. From 2007-2014, Dr. Geier served as the Director of Clinical Genetics, Kansas City Cancer Center. During this time, he presented 17 Clinical and Scientific Abstracts on Hereditary Cancer Testing at ASCO, ASBS, and other conferences. Uniquely, he has tested over 200 patients using a 25-gene panel, and can expertly compare and contrast this approach to "single syndrome" testing using scientific data, case studies, and clinical experience. Also an entertaining speaker, Dr. Geier's unique experience positions him to expertly present this important component of precision medicine from a scientific, clinical, and practical perspective. Please let Debbie know if you plan to attend by Friday, October 10th at 269-4520.

Interim Analysis for CALGB/SWOG 80702 "A Phase III Trial of 6 Versus 12 Treatments of Adjuvant FOLFOX Plus Celecoxib or Placebo for Pts With Resected Stage III Colon Cancer"

INTERIM ANALYSIS: This trial is part of an international collaboration, called IDEA for International Duration Evaluation of Adjuvant Chemotherapy. IDEA is testing non-inferiority of the duration of adjuvant therapy for colon cancer to determine if 3 months of therapy is not substantially worse than 6 months of therapy (that is "inferior"). In May, 2014 the IDEA team conducted a single, prospectively specified interim analysis after reaching 50% of the required number of disease-free survival events to test for futility. The IDEA Data Monitoring Board (DMB) concluded "based on the interim analysis results, the futility boundary for non-inferiority was not exceeded." Thus, the DMB's review determined that the trial's data do not--to date--indicate that 3 months is substantially worse than 6 months of adjuvant therapy (i.e., the non-inferiority research question is still pending and not yet answered). Featured article about the trial posted on NCI's cancer.gov at: http://go.usa.gov/pTzj. Over 1,800 of the 2,500 patient enrollment goal for this trial has been achieved it is expected to complete accrual by the end of 2015.

Study Profile

Alliance A221304 "Doxepin and a Topical Rinse in the Treatment of Acute Oral Mucositis Pain in Patients Receiving Radiotherapy With or Without Chemotherapy" The purpose of this study is to test whether a mouthwash made with a drug called doxepin can reduce the pain caused by mouth sores resulting from radiation therapy. A number of mouth rinse preparations exist for patients with treatment-related oral mucositis pain such as the DLA rinse, an over-the-counter medication. This study will evaluate the effects of doxepin compared to DLA (diphenhydramine, lidocaine and antacids)

and placebo. Doxepin is approved by the Food and Drug Administration (FDA) for the treatment of depression, anxiety, long-term pain management, as well as management of rash. This study is in pre-activation but should be released any day.

New CRO Investigators

Welcome to Sanur Dalia MD at Mercy Joplin and Bruce Ellerin MD at Phelps County. Dr. Dalia is a medical oncologist. DR. Ellerin is a radiation oncologist. We look forward to working with both gentlemen to enroll their patients in research studies.

New Studies Approved in September, 2014 Through Mercy's IRB -(Opened at Cox in August)

ECOG-ACRIN E7208 - A Randomized Phase II Study of Irinotecan and Cetuximab with or without the Anti-Angiogenic Antibody, Ramucirumab (IMC-1121B), in Advanced, K-ras Wild-Type Colorectal Cancer Following Progression on Bevacizumab-Containing Chemotherapy

New Studies Approved and Opened in September with the CIRB

ARST 1321 - Pazopanib Neoadjuvant Trial in Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (NSC# 737754, IND# 118613**)**

NRG-LU001 - Randomized Phase II Trial of Concurrent Chemoradiotherapy +/- Metformin HCL in Locally Advanced NSCLC

SWOG S1314 - A Randomized Phase II Study of Co-Expression Extrapolation (COXEN) With Neoadjuvant Chemotherapy for Localized, Muscle-Invasive Bladder Cancer

SWOG S1320 - A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) AND Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma

SWOG S1300 - A Randomized, Phase II Trial of Crizotinib Plus Pemetrexed Versus Pemetrexed Monotherapy in ALK-Positive Non-squamous NSCLC Patients Who Have Progressed Systemically After Previous Clinical Benefit From Crizotinib Monotherapy

Closed Studies in September, 2014

SWOG S0812 A Randomized Double Blind Placebo-Controlled Biomarker Modulation Study of High-Dose Vitamin D in Premenopausal Women at High-Risk for Breast Cancer, Phase IIB. Study closed effective 08/15/2014.

GOG-0258 A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel Vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma. Study closed effective 7/28/2014.

RTOG 1016 Phase III Trial of Radiotherapy Plus Cetuximab Versus Chemoradiotherapy in HPV-Associated Oropharynx Cancer. Study closed effective 7/31/2014