CRO Communiqué
Keeping you informed about CRO progress
November 2014

Top Enrolling Physicians for October 2014

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Bonebrake (Cox)	2	0	2	2
Dr. Carlson (Mercy Spfld)	3	0	3	3
Dr. Croy (Mercy Joplin)	1	1.68	0	1.68
Dr. Donegan (Mercy St. Louis)	1	2.14	.04	2.18
Dr. Hanson (Mercy St. Louis)	1	0.8	0	0.8
Dr. Holden (Mercy Spfld)	1	1.6	.16	1.76
Dr. Hu (Mercy St. Louis)	1	1.8	0	1.8
Dr. Raju (Mercy Spfld)	1	.25	0	.25
Dr. Shunyakov (Central Care)	1	1.6	0	1.6
Dr. Snider (Mercy Spfld.)	1	1.78	0.4	2.18
Dr. Tiriveedhi (Mercy Spfld)	1	0	1	1
Dr. Vu (Freeman)	1	1.6	0.4	2
TOTAL	15	13.25	7	**20.25**

October has been CRO's best enrollment month since becoming an NCORP program in August. Thank you!

Dr. Carlson Elected to Serve on the NCORP Cervical Task Force

Congratulations to CRO's PI, Jay Carlson who has been chosen to serve on the Cervical Task Force as a Community Oncologist by the NCORP PIs. The goal of the Gynecologic Cancer Steering Committee (GCSC) is to ensure that NCI supports the best-designed trials addressing the most important questions and leveraging the most significant scientific advances in gynecologic cancer. Dr. Carlson's role as a community oncology representative is to facilitate the development and evaluation of clinical trials that are attractive to patients and feasible in the community setting. His three year period began on October 1, 2014. You can learn more about the NCI steering committees here: http://www.cancer.gov/aboutnci/organization/ccct/steering-committees. The GCSC is one of sixteen steering committees formed in response to the recommendations of the Clinical Trials Working Group (CTWG). These committees leverage NCTN Group, SPORE, Consortia, and Cancer Center structures and involve the oncology community to address the design and prioritization of phase III and large phase II trials. The steering committees replace the CTEP concept review process for phase III and large phase II trials and provide a forum for strategic planning and prioritization.

Study Profile - Another Genetic trial for Lung Cancer

The Alliance for Clinical Trials in Oncology, in conjunction with NCI and ECOG-ACRIN Cancer Research Group, has launched the **Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials, or ALCHEMIST** – three trials to identify patients with early-stage lung cancer who have tumors that contain uncommon genetic changes and evaluate whether drug treatments aimed at those changes can improve their survival. As lead network group, the Alliance is coordinating two of the three trials, including the ALCHEMIST screening trial and the adjuvant treatment trial for patients with epidermal growth factor receptor (EGFR) mutations. All of the NCI-supported National Clinical Trials Network (NCTN) groups are participating in the trials. The three trials of ALCHEMIST are: ALCHEMIST - Screening component (A151216), ALCHEMIST - EGFR Treatment component (A081105) and ALCHEMIST - ALK Treatment component (E4512).

Participants enrolled in ALCHEMIST need to have been diagnosed with lung adenocarcinoma or other types of non-squamous, non-small cell lung cancer (or NSCLC), and must be planning to undergo surgery or have already undergone surgical removal of their tumors. In the ALCHEMIST screening trial, tissue from the participant's surgical resection will be tested in a central laboratory for genetic changes in two specific genes – EGFR and anaplastic lymphoma kinase (ALK). Participants with tumors found to contain EGFR mutations or rearrangement in the ALK gene will then be referred to one of the two randomized, placebo-controlled treatment trials evaluating specific drugs targeted against these genetic alterations, erlotinib and crizotinib, respectively. These drugs have been approved by the U.S. Food and Drug Administration (FDA) in the treatment of advanced non-small cell lung cancer in patients whose tumors contain the targeted molecular alterations; however, it is not known if these drugs will be beneficial for patients with early-stage disease. Those participants that receive standard therapy after their surgery (consisting of chemotherapy with or without radiation therapy, as prescribed by their treating physicians) will complete the therapy prior to participating in the ALCHEMIST treatment trials. We are excited to participate in this ambitious trial.

Exceptional Responders Pilot Study: Molecular Profiling of Tumors From Cancer Patients Who Are Exceptional Responders."

The Exceptional Responders Study is a new initiative to understand the molecular underpinnings of exceptional responses to systemic treatment in cancer patients. It was approved for CRO by the CIRB on October 29, 2014.
NCI asks clinicians to identify potential exceptional responder cases. An exceptional responder is a patient having an exceptional or complete response to experimental or standard cancer therapy for six months or more. This could be from patients enrolled in early phase clinical trials where fewer than 10% responded or could be from patients treated on later phase trials of single agents or combinations. It can also be from patients having exceptional responses from established cancer treatment. Potential cases for this study must be submitted to NCI for provisional approval before enrollment; see protocol for full details.

NCI plans to examine tissue and clinical data from up to 300 exceptional responder cases and will conduct genome sequencing analyses. The information will be stored in a controlled access database so that qualified investigators will be able to access it for further research.
The NCI press release for this study can be found here
http://www.cancer.gov/newscenter/newsfromnci/2014/ExceptionalRespondersInitiativeSept2014.
If you have an exceptional responder patient that you think may qualify please let the CRO staff know. They will work with you to consent the exceptional responder. If you have any questions, please contact the CRO office at 417-269-4520.

Welcome to Wendy Klafehn

Wendy Klafehn RN joined the CRO staff on Monday, October 27, 2014. Wendy will be at our Hulston office. She has most recently worked on the oncology floor at Mercy. We are delighted to have her with us.

New Studies Approved in October, 2014 Through Cox and Mercy's IRB

Alliance A221304 (in pre-activation) - 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
ECOG-ACRIN E1808 - A Randomized Phase II Trial of Sunitinib/Gemcitabine or Sunitinib in Advanced Renal Cell Carcinoma with Sarcomatoid Features
ECOG-ACRIN E3612 (only approved at Cox sites) - A Randomized Phase II Trial of Ipilimumab with or Without Bevacizumab in Patients with Unresectable Stage III or Stage IV Melanoma

New Studies Approved and Opened in October with the CIRB

ALCHEMIST protocols:
Alliance A151216 - Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)

Alliance A081105 - Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)

ECOG-ACRIN E4512 - A Phase III Double-Blind Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib Versus Placebo for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein

Closed Studies in October, 2014

SWOG S0709 A Phase II Selection Design of Pharmacodynamic Separation of Carboplatin/Paclitaxel/OSI-774 (Erlotinib; NSC-718781) or OSI-774 Alone in Advanced Non-Small Cell Lung Cancer (NSCLC) Patients with Performance Status 2 (PS-2) Selected by Serum Proteomics
Closed 09/15