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
June 2016

Top Enrolling Physicians for May 2016

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	Registered Exceptional Responders	Tissue Procurement Phase II
Dr. Anis (Freeman)	1	1		1		
Dr. Bonebrake (Cox)	3+ 1 industry					3
Dr. Brahmanday (Freeman)	1	1		1		
Dr. Carlson (Mercy Springfield)	2	1		1		1
Dr. Croy (Mercy Joplin)	1		0.0125	.0125		
Dr. Frazier (Mercy St. Louis)	3		0.0375	0.0375		
Dr. Hanson (Mercy St. Louis)	1	0.1		0.1		
Dr. Hoos (Mercy Spfld)	1	1		1		
Dr. Lobins (CoxHealth)	1	0.125		0.125		
Dr. Oza (Mercy Spfld)	1	0.0125		0.0125		
Dr. Pinheiro (Mercy Spfld)	3					3
Dr. Raju (Mercy Spfld)	1	1		1		
Dr. Snider (Mercy Spfld)	1	.0375		.0375		
Dr. Spencer (Phelps County)	4	3	0.0125	3.0125		
Dr. Tummala (Mercy Spfld)	1		0.0125	0.0125		
TOTALS	26	8.1625	0.0875	8.4125		7

CRO earned 8.4125 credits from in May from 26 registrations. Six tissue plus blood specimens were obtained for our Phase II tissue procurements.

CRO Featured in 417 Magazine

CoxHealth's and Mercy Springfield's collaborative efforts with Enterprise Laundry, Ozarks Neuro Rehab Center and Cancer Research for the Ozarks) are profiled in the May issue of 417 Magazine. Here is the link http://www.417mag.com/417-Magazine/May-2016/Top-Doctors-2016/Working-Together/

CRO Logo

Here it is - CRO's new logo. CRO staff worked with our web designer to develop a logo for us. We hope to find many uses for it as we move forward.

Cancer Research for the Ozarks

Match Trial - EYA131

Enrollment of patients in the National Cancer Institute-Molecular Analysis for Therapy Choice (NCI-MATCH) phase II precision medicine cancer trial resumed on Tuesday, May 31, 2016. The trial is available in nearly 900 medical facilities nationwide. The trial opened to patient enrollment in August 2015 with 10 treatment arms and a goal to genetically screen 3000 patients for possible treatment in the trial. Enrollment of new patients was paused in November 2015 for a planned scientific review. The NCI-MATCH trial will determine whether treating patients with certain drugs or drug combinations that target changes in the tumor genes will shrink the cancer, regardless of its location in the body, such as the breast, lungs, etc. Changes in tumor genes are believed to drive cancer growth. Treatments that show promise in the NCI-MATCH trial can then advance to larger, more definitive clinical trials. During the pause in enrollment of new patients, investigators analyzed many facets of this innovative study that ignores the specific type of cancer in favor of looking for common genetic changes across tumor types. Here is the link to the interim analysis. http://ecog-acrin.org/nci-match-eay131/interim-analysis. Based upon this analysis, several changes to the trial design are now in effect:

- The number of available treatment arms increased from 10 to 24. Each arm tests treatment for a unique gene abnormality.
- The estimate for the percentage of patients who will match to the 24 treatment arms is 23 percent—about one in four or five—to reflect the actual percentage of individuals in the initial group with matching gene abnormalities, which was lower than expected. The original estimate was that about one in every three patients

might have a matching gene abnormality, based on data from other studies.

- The overall size of the trial increased from 3000 to 5000 patients for genetic screening, to include a larger number of patients given the lower-than-expected match rate.
- Physicians can now submit archived biopsy tissue samples in place of fresh tissue for genetic testing. This can occur if the biopsy samples were obtained within six months prior to enrollment on this trial and if patients have not received any intervening therapy that is considered to be targeted (e.g. against a particular target or multiple molecular targets) since the collection of the tumor sample. This can also occur in patients who received cytotoxic chemotherapy for up to four cycles, without the cancer responding to that treatment.

Study Profile

RTOG 0924 " Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial" This randomized phase III trial studies androgen-deprivation therapy and radiation therapy in treating patients with prostate cancer. Androgens can cause the growth of prostate cancer cells. Androgen deprivation therapy may stop the adrenal glands from making androgens. Radiation therapy uses high-energy x-rays to kill tumor cells. On Arm I, patients undergo high-dose radiotherapy of the prostate and seminal vesicles using intensity-modulated radiotherapy (IMRT)* or 3D-conformal radiation therapy (3D-CRT)* once daily, 5 days a week, for approximately 9 weeks. Patients may also undergo permanent prostate implant (PPI) brachytherapy or high-dose rate brachytherapy (I 125 or Pd 103 may be used as the radioisotope). On Arm II, patients undergo whole-pelvic radiotherapy (WPRT)* (3D-CRT or IMRT) once daily, 5 days a week, for approximately 9 weeks. Patients may also undergo brachytherapy as in arm I. Enrollment is expected in include 2580 participants.

Kristina Gardner

Kristina Gardner will be joining CRO on June 5, 2016 as a Cancer Research Professional. Kristina has a Baccalaureate degree in Biochemistry from Rice University, and a Master of Health administration degree from SMSU. She worked in research at MDAnderson in the past but most recently has been at Mercy Springfield as Nursing Operations Coordinator. Kristina will be devoting half her efforts at Mercy Springfield and the other half at CoxHealth. Welcome Kristina!

REACTIVATION OF Local Protocols:

GOG-0225 Can Diet and Physical Activity Modulate Ovarian, Fallopian Tube and Primary Peritoneal Cancer Progression-Free Survival? – reactivated for Dr. Bonebrake (Cox-Springfield) site only.
RTOG 1119 Phase II Randomized Study of Whole Brain Radiotherapy in Combination With Concurrent Lapatinib in Patients With Brain Metastasis From HER2-Positive Breast Cancer: A Collaborative Study of RTOG and KROG – reactivated following Amendment #4

CIRB Reactivations:

GOG-0281 A Randomized Phase II/III Study To Assess The Efficacy of Trametinib (GSK 1120212) In Patients With Recurrent Or Progressive Low-Grade Serous Ovarian Cancer Or Peritoneal Cancer
SWOG S1320 A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAF V600E/K Mutant Melanoma

Closure through Local IRB:

ECOG-ACRIN E4112 Prospective Study of Magnetic Resonance Imaging (MRI) and Multiparameter Gene Expression Assay in Ductal Carcinoma in Situ (DCIS) – closed to accrual 4/13/2016.
RTOG 1205 Randomized Phase II Trial of Concurrent Bevacizumab and Re-Irradiation Versus Bevacizumab Alone as Treatment for Recurrent Glioblastoma – closed to accrual 4/14/2016.

No further local IRB follow up:

GOG-0229J – patient follow up terminated
NRG-CC002 – Study closed to accrual; all patient follow up completed.
SWOG S0424 – Study closed to accrual; all patients have completed follow up or are deceased
SWOG S0720 – Study closed; all patient f/u complete
Wake Forest 97211 Study closed; all patient f/u complete

CIRB Closures: **Alliance A041202** Closed to new patient accrual 05/16/2016

No further CIRB follow up:

NSABP B-35, NSABP B-36 and NSABP R-04 will close to patient follow up effective 5/31/2016