

CRO Communiqué Keeping you informed about CRO Progress

May 2017 Enrolling Physicians for April 2017



Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	Tissue Procurement	Cancer Care Delivery Res.
Dr. Bonebrake (Cox)	1	1.25		1.25		
Dr. Bumberry (Mercy Spfld)					1	
Dr. Carlson (Mercy Spfld)	1 + 1GOG 3005	0.575	1.025	1.6		1
Dr. Donegan (Mercy St. Louis)		0.250		.250		
Dr. Ellis (OHA)	1	1		1		
Dr. Huq (Mercy St. Louis)	PALLAS					
Dr. Kosuri (Mercy St. Louis)		0.0375		0.0375		
Dr. Nair (Mercy Spfld)		0.2625		0.2625		4
Dr. Oza (Good Samaritan)	1	1.2625		1.2625		
Dr. Sleckman (Mercy St. Louis)	1	1		1		
Dr. Snider (Mercy Spfld)					2	3
Dr. Tiriveedhi (Mercy Spfld)		0.2625		0.2625	1	2
Dr. Tummala (Mercy Spfld)		0.2625		0.2625		
TOTALS	5	6.1625	1.025	7.1875	4	110

CRO enrollments continue to be slow. All efforts to place patients on trial is encouraged. We obtained four Tissue & Blood specimens this month. This gives CRO 27 of the 36 specimens needed for this year's supplement. Our CCDR enrollments (S1415CD) continue to grow. Mercy Springfield has placed 44 and CoxHealth has placed 11 participants on this trial. Each site is to enroll 52 participants to this study.

Dr. Shaun Donegan recognized for S1400 Enrollments

The leadership team for the S1400 ("Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer")(Lung-MAP) trial at MDAnderson recognized Dr. Shaun Donegan and the Mercy St. Louis staff for their S1400 enrollments. The MDAnderson team recognized that this trial takes a lot of time and commitment from Dr. Donegan and his team and wanted to acknowledge their efforts and dedication. Dr. Donegan has screened seven patients for this important precision medicine trial! Thanks to all for your involvement in this important precision medicine trial.

Registration and Credential Repository (RCR)

A new online person registration **NCI Registration and Credential Repository** (RCR) process is under development at NCI. The new RCR application will require investigators, as well as other registration types of "non-physician investigator" and "associate plus", to submit their annual registration documents on line. All CRO Components will be doing their online registrations. In preparation for the transition, sites need to assure they have IAM accounts and updated Good Clinical Practice (GCP) Certificates for all investigators and staff. CRO Mercy Springfield and CoxHealth physicians will be receiving an email noting information needed and how to obtain the needed information. The first year with this transition will require additional efforts but once set up it will become easier.

Judy Hancock Serves on S1415 CD Panel at SWOG Meeting

CRO's CCDR Coordinator, Judy Hancock, participated in a two-hour session sharing her experience with the TrACER (S1415CD) trial on April 27th at the SWOG meeting in San Francisco. Judy will talk about her experience so far with the study and answered questions from other sites. Since the Mercy Springfield site has been very successful with recruitment thus far, SWOG asked Judy to represent Ozarks NCORP on the panel for the cohort group.

NRG Off-Cycle Audit

NRG Oncology will be at CRO performing an off-cycle audit on July 6 -7, 2017. CRO is preparing our NRG charts for possible auditing. The off-cycle audit is being conducted due to the large volume of participants CRO has put on NRG Foundation trials.

Spring 2017 CRO Steering Committee Meeting

Gary Doolittle, MD, Professor of Medicine and Director of Telemedicine Services at The University of Kansas Medical Center will be our speaker for the CRO 2017 Steering Committee meeting. His presentation is entitled "Dual Immune Checkpoint Inhibition for the First-line Treatment of Metastatic Melanoma". Dr. Doolittle is a Medical Oncology who has been involved in research throughout his career and is well published. Jennifer Walter, Nurse Practitioner, will speak following Dr. Doolittle on "OPDIVO for Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head & Neck." Jennifer is the Immuno-Oncology Clinical Liaison for Bristol-Myers Squibb. Jennifer has experience in community medical oncology. The meeting will be held on Wednesday, May 17th at 6p at TOUCH restaurant located at 1620 E. Republic Road in Springfield. Please RSVP to (417) 269-4520 by Friday, May 12th or to Marilyn Bauer at MarilynBauer@coxhealth.com.

SWOG S1507 Profile Study

SWOG S1507 "Trametinib and Docetaxel in Treating Patients With Recurrent or Stage IV KRAS Mutation Positive Non-small Cell Lung Cancer" is our profile study for May. This phase II trial studies how well trametinib and docetaxel work in treating patients with stage IV KRAS mutation positive non-small cell lung cancer or cancer that has come back. Trametinib may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. Drugs used in chemotherapy, such as docetaxel, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Giving trametinib with docetaxel may work better in treating non-small cell lung cancer. The PRIMARY OBJECTIVESof the study is to evaluate the response rate (confirmed and unconfirmed) to trametinib plus docetaxel in the entire study population of Kirsten rat sarcoma viral oncogene homolog (KRAS) mutation positive non-small cell lung cancer (NSCLC) patients following one or two prior systemic therapies.

Lisa Bogart

CRO's Cancer Research Professional, Lisa Bogart and husband Chris welcomed their baby girl at 5 am on Monday, April 17th. She weighed 7lbs 0.4oz and was 19in long. To Lisa and Chris Saoirse (pronounced Seer-sha) is perfect! Lisa should be back at work on May 29th.

New CRO Staff

<u>Leslie Morelock Herrell</u> is CRO's new Research Operations Assistant II. April 10 was her first day at CRO. Most recently, Leslie was with the Springfield Public schools with administrative and financial responsibilities. She will be at the CRO Administrative Office.

<u>Nicole Holman,</u> CRO's new Clinical Research Assistant, started on April 17th. Nicole has worked at CoxHealth as a Radiology Tech Assistant/Phlebotomist. Nicole will be working from our Hulston Office.

ACTIVATION OF CIRB Protocols:

New Local Protocols:

None

CIRB Protocols:

ECOG-ACRIN EA2161 A Phase II Study of MLN0128 (TAK-228) in Rapalog-Resistant Advanced Pancreatic Neuroendocrine Tumors (PNET)

Closure through CIRB:

EAY131 sub-study Q closed

Alliance A011203 – Closed to all Pre-registration 04/17/2017. Study Closed to all accrual on 05/19/2017.

Closure through Mercy IRB:

GOG-0283 – Closed to accrual 03/20/2017