CRO Communiqué
Keeping you informed about CRO progress
October 2015

Top Enrolling Physicians for September 2015

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	Registered Exceptional Responders	Tissue Procurement Registrations
Dr. Carlson (Mercy Spfld)	1		1	1		0
Dr. Gillett (Cox)	1	1	0.25	1.25		
Dr. Ellis (Cox)	1	0.0125		0.0125		
Dr. Finnie (Mercy St. Louis)					1	
Dr. Hoos (Mercy Spfld)	1	0.06		0.06		
Dr. Rogers (Mercy St. Louis)	1	0.13		0.13		
Dr. Snider (Mercy Spfld)	1	1		1		1
Dr. Toothaker (Phelps)	1		1	1		
Dr. Tummala(Mercy Spfld)	1	0.13		0.13		
Dr. Verma						2
TOTALS	8	2.33	2.25	4.5825	1	3

Our accruals as noted above remain extremely low as we earned 4.5825 credits this past month. NCI's target accrual for CRO this year is 170 credits. To achieve this we must average 14.17 credits each month. Please continue to make every effort to place our patients on a clinical trial.

Tissue Procurement Supplement

All 100 of the blood specimens for phase I of the Tissue Procurement Supplement have been collected and processed. CRO is now working to accomplish the second phase of our tissue procurement supplement. Phase II involves the collection of 29 fresh tissue + blood specimens. This study is to collect 29 pairs of tissue and blood from patients with active solid tumors and lymphomas. There is particular interest from the NCI in less prevalent malignancies, such as Small Cell Lung, Pancreatic, Head & Neck, Ovarian and Bladder cancers, as well as Sarcomas, Melanomas, and Non-Hodgkin Lymphomas. CRO staff and component staff were trained during a webinar with NCI on September 23rd to carefully collect specimens. CRO staff will be screening patients for eligibility and will work closely with investigators to collect the tissue following NCI guidelines of the patients who consent to this protocol. This is another wonderful opportunity for CRO.

NCORP Graphic Identity Badge

NCI has a NCORP Graphic Identity Badge to use on websites and other digital materials, to identify us as being a part of this NCI cancer research network. The badge may be used on websites, social media, press releases, brochures, reports, slides, and patient and clinician materials. We are to share the badge with our components and subcomponents. Only the main NCORP site may request use of the badge and is responsible for ensuring that they are using the badge correctly.

CRO Fall Steering Committee Meeting in Springfield

CRO's Fall Steering Committee meeting will be on Monday, October 12, 2015. Dr. Gabriel Bien-Willner will be speaking on "Precision Medicine with NGS Testing". Gabriel Bien-Willner, MD is an Anatomic Pathologist with a Fellowship in Molecular Genetic Pathology. During his Post-Doc and Faculty positions at Washington University, his focus was on developing genomic technologies and applications to clinical practice, using next-gen platforms at the Center for Genome Sciences. Currently, Dr. Bien-Willner is Medical Director for Molecular Health where he frequently helps physicians make sense of patient's genomic information after the patients have had NGS testing performed. In addition to his Director position, Dr. Bien-Willner is also instrumental in bio-informatics pipeline design for NGS testing through Molecular Health's bio-informatics software suite. As an expert in cancer genetics/genomics, Dr. Bien-Willner continues to provide much needed support to physicians on how to make sense of big data/"data tsunami" that clinicians deal with every day. Please RSVP to (417) 269-4520 or Debbie.Cane@Coxhealth.com by Wednesday, October 7, 2015.

CRO listed on NRG website as top accruer

https://www.nrgoncology.org/About-Us/Membership/Outstanding-Site-Participation-Recognition

Study Profile

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" is our profile study this month. This randomized phase II trial studies how well dabrafenib and trametinib work in treating patients with stage III-IV melanoma that cannot be removed by surgery and contains a B-Raf proto-oncogene, serine/threonine kinase (BRAF) mutation. Dabrafenib and trametinib may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. Contrast-enhanced computed tomography (CT) scans of the neck, chest, abdomen and pelvis are required; a whole body positron emission tomography (PET)/CT scan with diagnostic quality images and intravenous iodinated contrast may be used in lieu of a contrast enhanced CT of the neck, chest, abdomen and pelvis; contrast may be omitted if the treating investigator believes that exposure to contrast poses an excessive risk to the patient; patients must have measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1; all measurable lesions must be assessed within 28 days prior to registration; tests to assess non-measurable disease must be performed within 42 days prior to registration; all disease must be assessed and documented on the Baseline Tumor Assessment Form (RECIST 1.1)

New Studies Approved and Opened in September 2015 with the CIRB

ALLIANCE A091401 Randomized Phase II Study of Nivolumab with or Without Ipilimumab in Patients with Metastatic or Unresectable Sarcoma

Reactivated Studies in September

ECOG-ACRIN E1A11 Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)
Reactivated 9/4/2015

SWOG S0931 EVERST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study
Reactivated 9/15/2015

New Studies Approved and Opened in September 2015 with Mercy Springfield's IRB

None

Temporary Closures:

None

Permanent Closures:

RTOG 1203 A Randomized Phase III Study of Standard Vs. IMRT Pelvic Radiation for Post-Operative Treatment of Endometrial and Cervical Cancer (TIME-C)
Closed to Accrual 8/27/2015

CIRB Closures:

None

Archived (no further follow-up)

SWOG S1202 A Randomized Placebo-Controlled Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor (AI)-Associated Musculoskeletal Symptoms in Women with Early Stage Breast Cancer
Will be closed to Accrual 10/1/2015 – all patients have completed follow up