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
May 2016

Top Enrolling Physicians for April 2016

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	Registered Exceptional Responders	Tissue Procurement Phase II
Dr. Biggers (Cox)	1					1
Dr. Bonebrake (Cox)	2					2
Dr. Bumberry (Mercy Springfield)	2		1.0125	1.0125		
Dr. Ellis (Cox)	1	1.125		1.125		
Dr. Finnie (Mercy St. Louis	1	1.125		1.125		
Dr. Frazier (Mercy St. Louis)	6		0.075	0.075		
Dr. Goodwin (Mercy Spfld)	2	1.125		1.125		
Dr. Miller (Freeman)	1	0.3375		0.3375		
Dr. Pinheiro (Mercy Spfld)	1					1
Dr. Rodgers (Mercy St. Louis)	1	1.05		1.05		
Dr. Sleckman (Mercy St. Louis)	1	1	0.25	1.25		
Dr. Spencer (Phelps County)	1		0.0125	0.0125		
Dr. Tiriveedhi (Mercy Spfld)	1	1		1		
Dr. Verma (Cox)	1	0.125		0.125		
Dr. Westfall (Mercy St. Louis)	1		.0125	.0125		
TOTALS	23	6.8875	1.3625	8.25		4

CRO earned 8.25 credits from in April from 23 registrations. Four tissue plus blood specimens were obtained for our Phase II tissue procurements. Please continue to make every effort to place patients on a clinical trial.

Wall Street Journal Article

Follow this link to the April 12, 2016 issue of the Wall Street Journal to read a short article entitled "Clinical Trials Need More Subjects. http://www.wsj.com/articles/clinical-trials-need-more-subjects-1460407076

National Coverage Analysis Pilot -

The CTSU pilot for National Coverage Analysis (NCA) development is now underway. NCAs will be developed for new NCTN Phase III treatment trials and select Phase II trials as well as cross network NCORP cancer control and prevention trials activated after May 1, 2016. The NCAs will be reviewed and approved by the lead NCTN Network Group or NCORP Research Base and posted to the CTSU website under the protocol specific funding tab. Protocol amendments and protocol funding form updates will prompt a review and revision of the NCA documents as needed and they will be reposted to the CTSU website with a new version date. CTSU will make every effort to have the NCA available within 2 weeks after protocol activation. Depending on the complexity of the trial, some NCA reviews may require additional development time.

The NCAs are provided by the CTSU as a guidance tool for institutions to assist with billing compliance. Institutions that chose to utilize these tools are responsible for the verification and modification of the coverage analysis in compliance with their institutional guidelines and are ultimately responsible for modifications specific tor their local coverage determinations. Notification of new and updated NCAs will be included in the Bimonthly Broadcast under the NCTN or NCORP Trial Updates section. See below for NCA postings for the following trials: ALLIANCE - A071102, ALLIANCE - A081105, ALLIANCE - A151216, NRG - NRG-CC00, NRG - NRG-CC003, NRG - NRG-HN001, NRG - NSABP-B-55 and SWOG - S1500.

Study Profile

NRG LU001"Chemotherapy and Radiation Therapy With or Without Metformin Hydrochloride in Treating Patients With Stage III Non-small Cell Lung Cancer" is our profile study. This randomized phase II trial studies how well chemotherapy and radiation therapy given with or without metformin hydrochloride works in treating patients with stage III non-small cell lung cancer. Drugs used in chemotherapy, such as carboplatin and paclitaxel, 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. Radiation therapy uses high-energy x-rays to kill tumor cells

and shrink tumors. Metformin hydrochloride may shrink tumors and keep them from coming back. It is not yet known whether chemotherapy and radiation therapy is more effective when given with or without metformin hydrochloride in treating stage III non-small cell lung cancer.

ARM I: Patients receive paclitaxel intravenously (IV) over 1 hour and carboplatin IV over 30 minutes on days 1, 8, 15, 22, 29, and 36 and undergo radiation therapy (3-dimensional conformal radiation therapy [3D-CRT] or intensity modulated radiation therapy [IMRT]) once daily (QD) 5 days a week for 6 weeks. Beginning 28-42 days after completion of radiation therapy, patients receive consolidation chemotherapy comprising paclitaxel IV and carboplatin IV on days 1 and 22. Treatment with consolidation chemotherapy repeats every 3 weeks for 2 courses in the absence of disease progression or unacceptable toxicity.

ARM II: Patients receive metformin hydrochloride orally (PO) twice daily (BID) or thrice daily (TID) for 14 days. Beginning on day 15, patients undergo radiation therapy and receive paclitaxel and carboplatin as in Arm I, and receive metformin hydrochloride BID or TID for 6 weeks. Beginning 28-42 days after completion of radiation therapy, patients receive consolidation chemotherapy as in Arm I and metformin hydrochloride PO BID or TID for 10 weeks.

Sharon Hodge

Sharon has decided to fully retire. Her last day with CRO will be May 25th. She is looking forward to becoming move involved with her church and grandchildren. Sharon will be greatly missed. She has been with CRO for many years and her wealth of knowledge is something we all value. We will celebrate her retirement in the coming weeks.

Kevin Howk

Kevin Howk will be joining us on May 9th as a Cancer Research Professional. Kevin has a BA in psychology and a MS in pharmaceutical science. He has spent the last four years as a research assistant at the University of Arkansas for Medical Science. He has also been a pharmacy tech in the past. We are excited to welcome him to our team. He will be working with our staff at Mercy and training to assist at Cox also.

Trials Opened in March at Mercy Springfield

Alliance A221102 Randomized Double-Blind Placebo Controlled Study of Subcutaneous Testosterone in the Adjuvant Treatment of Postmenopausal Women with Aromatase Inhibitor Induced Arthralgias

 Approved at the 4/15/2016 IRB for Mercy Springfield, CoxHealth South Hospital, Central Care, Phelps County Regional Medical Center, Freeman Health System, Mercy Joplin, Mercy Rolla, Mercy Hospital St. Louis, STLCBI – South City, STLCBI - Ballwin, and Mercy Washington and Good Samaritan.

CIRB Reactivations

ECOG-ACRIN EA6134 A Randomized Phase III Trial of Dabrafenib + Trametinib Followed by Ipilimumab + Nivolumab at Progression vs. Ipilimumab + Nivolumab Followed by Dabrafenib + Trametinib at Progression in Patients with Advanced BRAFV600 Mutant Melanoma – Reactivation acknowledged by CIRB on 4/12/2016

Closures with Mercy Springfield

CALGB 50904 A Randomized Phase II Trial of Ofatumumab and Bendamustine vs. Ofatumumab, Bortezomib (IND #58443) and Bendamustine in Patients with Untreated Follicular Lymphoma

 Closed to accrual 4/5/2016

CIRB Clousures

SWOG S1406 Randomized Phase II Study of Irinotecan and Cetuximab with or Without Vemurafenib in BRAF Mutant Metastatic Colorectal Cancer– closed to accrual effective 4/1/2016