

**CRO Communiqué**  
**Keeping you informed about CRO progress**  
**November 2013**

**Top Enrolling Physicians for October 2013**

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Bond (Phelps)	1	1.0	0	1.0
Dr. Bonebrake (Cox)	5	2.0	2.0	4.0
Dr. Carlson (Mercy Spfld)	8	2.3	4.0	6.3
Dr. Finnie (Mercy St. Louis)	2	0	1.0	1.0
Dr. Hanson (Mercy St. Louis)	1	0	0	0
Dr. Hu (Mercy St. Louis)	1	0	0.5	0.5
Dr. Luedke	1	0	1.0	1.0
Dr. Mirza (Mercy St. Louis)	1	0	0.5	0.5
Dr. Pinheiro (Mercy Spfld)	1	0	0	0
Dr. Rodgers (Mercy St. Louis)	1	0	0.5	0.5
Dr. Snider (Mercy Spfld)	1	1.0	0	1.0
<b>Total</b>	<b>23</b>	<b>6.3</b>	<b>9.5</b>	<b>15.8</b>

October has been another slow month for CRO enrollments. With five months of our grant year behind us we have earned 40.1 treatment credits and need to be at 54.2 to be on track to reach our grant year target of 130 treatment credits. We have earned 51.7 cancer control credits and need to have earned 58.3 control credits to be on track to meet this year cancer control target of 140. Attached is ‘CRO’s Patient Registration Summary’ updated through October.

**NCORP Grant**

We continue to wait for the release of the NCORP grant. The latest we have heard is it will be released before Christmas. The government shut down may have added to the delay.

**CRO Fall Steering Committee Meeting**

CRO’s fall Steering Committee meeting is being planned for Thursday, November 21<sup>st</sup>. Joseph M Anderson, MD FCAP from Redwood City, California will speak on Genomics in Cancer treatment the past, present and the future. Attached is a flyer regarding this meeting. Please RSVP to (417) 269-4520 by Monday, November 18, 2013.

**CRO in the news**

The government shut-down is now behind us, but many in the Ozarks were wondering how that affects cancer research in our area. KOLR 10 news did a story on Wednesday, October 16<sup>th</sup> featuring CRO’s director and research patient, Rhoda Hastings who is currently participating in a trial. Below is the link to the story. <http://www.ozarksfirst.com/story/cancer-clinical-trials-stopped-due-to-shutdown/d/story/Y49cD3iSXUO-B7iSITbsqw>

**Profile Study**

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’ is our study to profile this month. Duloxetine hydrochloride may lessen muscle, bone, and joint pain caused by hormone therapy. It is not yet known whether duloxetine hydrochloride is more effective than a placebo in treating patients with muscle, bone, and joint pain caused by hormone therapy. This randomized phase III trial studies how well duloxetine hydrochloride works compared to a placebo in treating muscle, bone, and joint pain in patients with early-stage breast cancer receiving hormone therapy. To be eligible for the trial patients must be women with histologically confirmed estrogen receptor (ER)-and/or progesterone receptor (PgR)-positive invasive carcinoma of the breast with no evidence of metastatic disease, have completed mastectomy or breast-sparing surgery, have aromatase inhibitor (AI)-associated musculoskeletal symptoms that began or increased after starting AI therapy; new musculoskeletal pain must not be due specifically to fracture or traumatic injury, be post-menopausal and have Zubrod performance status of 0-2.

## **New Studies Approved in October, 2013 Opened with IRBs**

**CALGB 50801** A Phase II Trial of Response-Adapted Therapy Based on Positron Emission Tomography (PET) for Bulky Stage I and Stage II Classical Hodgkin Lymphoma (HL)

Participating sites: Mercy Springfield (MO043) and Mercy Rolla (MO185).

**NSABP B-50-I** A Randomized, Multicenter, Open-Label Phase III Study to Evaluate the Efficacy and Safety of Trastuzumab Emtansine Versus Trastuzumab as Adjuvant Therapy for Patients with HER2-Positive Primary Breast Cancer who have Residual Tumor Present Pathologically in the Breast or Axillary Lymph Nodes following Preoperative Therapy

*Industry study with site visit scheduled for December. Unable to register until site visit completed.*

Participating sites: Mercy Springfield (MO043) and Cox Health (M0042)

**RTOG 1221** Randomized Phase II Trial of Transoral Endoscopic Head And Neck Surgery followed by Risk-Based IMRT and Weekly Cisplatin versus IMRT and Weekly Cisplatin for HPV Negative Oropharynx Cancer

Participating sites: Mercy Springfield (MO043)

## **New Studies Opened in October with the CIRB**

**SWOG S1207** Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e3 Breast Cancer Study- evaluating everolimus with endocrine therapy

Participating sites: All CRO sites

## **Studies sent to Cox & Mercy IRB's for Permanent Closure in October 2013**

**GOG-0130F** A Phase II Evaluation of Ixabepilone in the Treatment of Recurrent or Persistent Carcinosarcoma of the Uterus. - Closed 08/26/2013

**NSABP P-5** Statin Polyp Prevention Trial in Patients with Resected Colon Cancer - Closed 09/10/2013

**RTOG 0913** Phase I/II Trial of Concurrent RAD001 (Everolimus) With Temozolomide/Radiation Followed by Adjuvant RAD001/Temozolomide in Newly Diagnosed Glioblastoma - Closed 09/12/2013

**CTSU ECOG E1505** A Phase III Randomized Trial of Adjuvant Chemotherapy with or Without Bevacizumab for Completely Resected Stage IB-IIIA Non- Small Cell Lung Cancer (NSCLC) - Closed 09/20/2013

**GOG-0254** A Phase II Evaluation of SU11248 (Sunitinib Malate) in the Treatment of Persistent or Recurrent Clear Cell Ovarian Carcinoma - Closed 09/30/2013

**SWOG S0806** A Phase I/II Trial of Vorinostat (SAHA) (NSC-701852) in Combination with Rituximab-CHOP in Patients with Newly Diagnosed Advanced Stage Diffuse Large B-Cell Lymphoma (DLBCL) - Closed 10/01/2013