

## CRO Communiqué

### Keeping you informed about CRO progress

### December 2014

#### Top Enrolling Physicians for November 2014

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Carlson (Mercy Spfld)	3	0	3	3
Dr. Cunningham (Cox)	1	1.6	0	1.6
Dr. Ellis (Cox)	1	0.2	0	0.2
Dr. Huq (Mercy St. Louis)	1	0	1	1
Dr. Klix (Mercy St. Louis)	1	1.6	0	1
Dr. Oza (Good Samaritan)	2	3.2	0	3.2
Dr. Sleckman(Mercy St. Louis)	1	0	1	1
Dr. Tiriveedhi (Mercy Spfld)	1	1.72	0	1.6
Dr. Tummala (Mercy Spfld)	2	1.1	1	2.72
Dr. Verma (Cox)	1	1.72	0	1.72
<b>TOTALS</b>	14	11.64	6.1	<b>17.64</b>

Thank you for your continuing support of CRO and NCI clinical trial enrollments.

#### **Cancer Care Delivery Research (CCDR)**

Cancer Care Research Delivery is the new component of the NCORP program. NCI announced on their first PI first webinar held on November 24<sup>th</sup> that concepts for CCDR studies will begin being submitted by the research bases in January 2015. Wortz McCaskill-Stevens, NCI's Director said on the call that no CCDR studies are currently open. At CRO the job description has been written and the position for a Cancer Care Delivery Coordinator has been posted at Cox. We are anxious to fill this position and orient them to our program before the first CCDR studies are released.

#### **Study Profile**

E2112 trial: A Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Postmenopausal Patients with Hormone Receptor-Positive Advanced Breast Cancer is this month's profile study. The purpose of this randomized phase III trial studies exemestane and entinostat to see how well they work compared to exemestane alone in treating postmenopausal patients with hormone receptor-positive breast cancer that has spread to nearby tissue or lymph nodes or another place in the body. Estrogen can cause the growth of breast cancer cells. Endocrine therapy using exemestane may fight breast cancer by lowering the amount of estrogen the body makes. Entinostat may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. It is not yet known whether exemestane is more effective with or without entinostat in treating breast cancer. This trial for patients with breast cancer requires 600 enrollments.

#### **ASCO Clinical Trial Workload Assessment Tool**

**NEWLY RELEASED!** CRO is exploring this user-friendly online resource aimed to help research administrators assess clinical trial-associated workload based on the complexity of research protocols and the number of patients assigned to staff. The tool enables administrators to more effectively monitor and manage staff capacity, productivity, and needs. The tool also provides site-specific, individual staff-specific, and protocol-specific reports. The tool is available for free at [workload.asco.org](http://workload.asco.org).

#### **Welcome to Gina Dill**

Gina Dill, BSN will be joining CRO on December 15<sup>th</sup> as a research nurse at Hulston Cancer Center. Gina's personal experiences and past work in oncology will be assets for our program. Welcome Gina!!

A Very Merry Christmas and Happy New Year to you!  
 Thank you for your commitment to CRO clinical research.  
 From the Staff at Cancer Research for the Ozarks



## **New Studies Approved in November, 2014 Through Mercy's IRB**

**ECOG-ACRIN E3612** - A Randomized Phase II Trial of Ipilimumab with or Without Bevacizumab in Patients with Unresectable Stage III or Stage IV Melanoma

*\*Now approved with Mercy Springfield, Mercy St. Louis, Mercy Joplin, STLCBI, Good Samaritan and Mercy Rolla.*

## **New Studies Approved and Opened in November with the CIRB**

**AOST 1322** - A Phase II Study of Eribulin (IND# 707389, NSC# 707389) in Recurrent or Refractory Osteosarcoma: An Intergroup NCTN Phase II Study

**NRG-BN001** - Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation With Concomitant and Adjuvant Temozolomide in Patients With Newly Diagnosed Glioblastoma (Group I)

**NRG-HN002** - A Randomized Phase II Trial for Patients with p16 Positive, Non-Smoking Associated, Locoregionally Advanced Oropharyngeal Cancer

**SWOG S1406** - Randomized Phase II Study of Irinotecan and Cetuximab with or Without Vemurafenib in BRAF Mutant Metastatic Colorectal Cancer

## **Closed Studies in November, 2014**

**CALGB 90601** – 12/02 A Randomized Phase III Study of Gemcitabine, Cisplatin, Bevacizumab or Gemcitabine, Cisplatin, and Placebo in Patients with Advanced Transitional Cell Carcinoma

**GOG-0244** – 11/17 The Lymphedema and Gynecologic Cancer (LEG) Study: Incidence, Risk Factors and Impact in Newly Diagnosed Patients

**GOG-3004** – Closure to screening closed 11/14 A Phase III, Randomised, Double Blind, Placebo Controlled, Multicentre Study of Olaparib Maintenance Monotherapy in Patients with BRCA Mutated Advanced (FIGO Stage III-IV) Ovarian Cancer following First Line Platinum Based Chemotherapy

**NSABP B-43** – last day for pre-entry specimen is 12/05 - A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma in Situ Resected by Lumpectomy

**SWOG S1117** – closed 11/15 A Randomized Phase II Study of Azacitidine in Combination with Lenalidomide vs Azacitidine Alone vs Azacitidine in Combination with Vorinostat for Higher-Risk Myelodysplastic Syndromes (MDS) and Chronic Myelomonocytic Leukemia (CMML)