

**CRO Communiqué**  
**Keeping you informed about CRO progress**  
**September 2015**

**Top Enrolling Physicians for August 2015**

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	To Date Registered Exceptional Responders	To Date Tissue Procurement Registrations
Dr. Abdalla (Cox)	1	0.13		0.13		0
Dr. Bonebrake	1	1		1		
Dr. Dalia (Mercy Joplin)						2
Dr. Hahs (Mercy St. Louis)	1		1	1		
Dr. Oruwari (Mercy St. Louis)	1		1	1		
Dr. Oza (Mt. Vernon)						1
Dr. Tiriveedhi (Mercy Spfld)	1	1		1		0
Dr. Tummala (Mercy Spfld)	1	0.14		0.14		
<b>TOTALS</b>				4.27	8	95

During the first year of our new NCORP grant, CRO earned 79.41 treatment and 58.83 cancer control credits for a total of 138.24 credits. Our accruals as noted above remain extremely low as we enter our new grant year. 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**

WOW! So proud of CRO! We have 97 tissue procurement submissions completed. This leaves CRO with 3 longitudinal submissions to collect when the patients reoccur. CRO led the nation with the 9846 Tissue Procurement supplement and did so well that we have been given another NCI supplement opportunity. We were notified on August 10th that CRO had the opportunity to apply for an additional supplement involving submission of 29 fresh tissue + blood collections. Each paired submission is rewarded with \$3,500. Our original Tissue Procurement Supplement application was re-worked and submitted. Lori Minasian, Deputy Director at NCI told me CRO was a slam dunk for the opportunity and we will be hearing more about it within the month. This is another wonderful opportunity for CRO.

**Study Profile – this trial is an Exciting Big Deal for Research**

NCI's trial, EAY131-Molecular Analysis for Therapy Choice (NCI-MATCH) phase II precision medicine trial is now open through the ECOG-ACRIN Cancer Research Group. Precision medicine refers to the tailoring of treatment based on the characteristics of each individual. As the largest precision medicine trial for cancer to date, NCI-MATCH seeks to determine whether matching certain drugs or drug combinations to people whose tumors have specific gene abnormalities will effectively treat their cancer, regardless of their cancer type. Treatment for this trial focuses on molecular abnormalities of patient tumors instead of the organ sites of the cancer.

NCI-MATCH (EAY131) will match patients with one of 22 treatments to test the use of each specific drug or drug combination targeted to a particular gene abnormality. The trial opened on August 17th with ten treatments, and the additional 12 treatments will be added to the trial within the next several months. nlamack@gog.org. Patients may also be eligible for screening if they have a rare type of cancer for which there is no standard treatment. All patients considering the trial will need to have a new biopsy and their tumor cells will need to undergo genetic testing to see whether they contain one of the gene mutations being studied. Trial researchers expect that about one-third of the patients screened will have one or more molecular abnormalities that match one of the 22 treatments being studied. If so, they will be further evaluated to determine if they are able to be treated as part of the trial. There will be 35 patients enrolled for each drug/drug combination being studied.

The trial's design calls for at least 25 percent of the 1,000-patient enrollment to be people with rare types of cancer. The inclusion of uncommon types of cancer in NCI-MATCH offers patients an unusual opportunity to

have their disease assessed to see if it has the same genetic abnormalities found in more common cancer types. It also offers researchers a unique opportunity to study the effectiveness of new treatments on rare diseases. As leader of the trial, ECOG-ACRIN is coordinating the genetic testing. It also supports all trial sites with training, laboratory services, trial assignments, biostatistical support, data management, auditing, quality control, and public awareness.

A NCI MATCH Trial NCORP Webinar will be held on Thursday, September 17, 2015 at 3pm Central Time  
Below is information for joining:

[Join WebEx meeting](#)

Meeting number: 739 300 832  
Meeting Password: NCIMatch#1

[Join by phone](#)

Dial In Number: 1-240-276-6338  
Your Cisco Unified MeetingPlace meeting ID: 739 300 832

**CRO Recognized by Alliance**

CRO was one of the Top 50 highest accruing member institutions of the Alliance for Clinical Trials in Oncology during grant year 2014-2015. In recognition of this great achievement, Alliance is awarding CRO with a funded travel spot for a hardworking Alliance research staff member (i.e., oncology nurse, fellow, or clinical research associate) to attend the upcoming Alliance November 2015 Group Meeting. Cindy Dievert had enrolled 11 patients to Alliance trials this past grant year and has been asked to attend the meeting.

**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](mailto:Debbie.Cane@Coxhealth.com) by Wednesday, October 7, 2015.

**New Staff at CRO**

Nicholas Perry will be joining CRO as our first Cancer Research Professional on September 14<sup>th</sup>. Nick holds a Bachelor's Degree in Respiratory Care from MSU where he participated in cell biology research. Currently Nick is a Respiratory Therapist at CoxHealth. Welcome Nick!

**CRO Steering Committee Meeting in St. Louis**

Dr. Kent Shih from the Tennessee Oncology/Sarah Cannon Research Institute will speak on: "An Overview of OPDIVO (nivolumab), An Immuno-oncology Agent Approved Across Multiple Tumor Types" in St. Louis on Tuesday, September 1, 2015 at 6:00 p.m. The event will be held at Fleming's Prime Steakhouse & Wine Bar • 1855 South Lindbergh Boulevard • St. Louis, Missouri. We look forward to having our investigators and research staff from the St. Louis, Good Samaritan and Phelps County area with us. Please let Marilyn Bauer ([Marilyn.Bauer@CoxHealth](mailto:Marilyn.Bauer@CoxHealth) or 417-820-4880) know if you will be attending by Wednesday, August 26<sup>th</sup>.

## **New Studies Approved and Opened in August 2015 with the CIRB**

**NRG-BR003** A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or Without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer

**NRG-GY003** Phase II Randomized Trial of Nivolumab with or Without Ipilimumab in Patients with Persistent or Recurrent Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer

**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

**NRG-CC001** A Randomized Phase III Trial of Memantine and Whole-Brain Radiotherapy With or Without Hippocampal Avoidance in Patients with Brain Metastases

## **Reactivated Studies in August**

**Alliance A091201** Randomized Phase II Study Comparing the MET Inhibitor Cabozantinib to Temozolomide/Dacarbazine in Ocular Melanoma

## **New Studies Approved and Opened in August 2015 with Mercy Springfield's IRB**

None

## **Temporary Closures:**

**GOG-0286B** A Randomized Phase II/III Study Of Paclitaxel/Carboplatin/Metformin (NSC#91485) Versus Paclitaxel/Carboplatin/Placebo As Initial Therapy For Measurable Stage III Or IVA, Stage IVB, or Recurrent Endometrial Cancer – *temporarily closed 7/13/2015*

**SWOG S0931** EVERST: EVERolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study  
*Temporarily closed 8/15/2015*

## **Permanent Closures:**

**ECOG-ACRN E2108** A Randomized Phase III Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Patients with Metastatic Breast Cancer  
*Closed to accrual 7/23/2015*

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

**SunCoast 0806** Phase II placebo-controlled trial of lisinopril and Coreg CR to reduce cardiotoxicity in patients with breast cancer receiving (neo)adjuvant chemotherapy with trastuzumab (Herceptin)  
*Closed to accrual 7/6/2015*

## **Archived (no further follow-up)**

**CALGB 9741** A Randomized Phase III Trial of Sequential Chemotherapy Using Doxorubicin, Paclitaxel, and Cyclophosphamide or Concurrent Doxorubicin and Cyclophosphamide Followed by Paclitaxel at 14- or or 21-Day Intervals in Women with Node Positive Stage II/IIIA Breast Cancer

**SWOG S0502** A Phase III Randomized Study of Imatinib, with or without Bevacizumab (NSC-704865), in Patients with Metastatic or Unresectable Gastrointestinal Stromal Tumors

**SWOG S9704** A Randomized Phase III Trial Comparing Early High Dose Chemoradiotherapy and an Autologous Stem Cell Transplant to Conventional Dose CHOP Chemotherapy (With Possible Late Autologous Stem Cell Transplant) for Patients With Diffuse Aggressive Non-Hodgkin's Lymphoma in the High-Risk International Classification Prognostic Groups