

## CRO Communiqué

### Keeping you informed about CRO progress

### May 2015

#### Top Enrolling Physicians for April 2015

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	To Date Registered Exceptional Responders
Dr. Bechtel (Mercy St. Louis)	1	2	0	2	
Dr. Carlson (Mercy Spfld)	1	0	1	1	
Dr. Ellis (Cox)	1	1	0	1.06	2
Dr. Finnie (Mercy St. Louis)	1	0.96	0	0.96	
Dr. Holden (Mercy Spfld)					2
Dr. Hoos (Mercy Spfld)	2	1	1	2	0
Dr. Raju (Mercy Spfld)	1	1.1	0	1.1	1
Dr. Verma (Cox)	1	1.08	0	1.08	
<b>TOTALS</b>	8	7.14	2	9.14	5

Nine months into our grant year CRO has earned 122.66 credits. We are hoping for a brighter (more enrollments) final quarter of this grant year. We do know other NCORP programs are struggling with enrollments this grant year as well.

#### **NCI Administrative Supplement for Blood Samples**

Our first webinar for the NCI Administrative Supplement for Blood Samples was held on April 23<sup>rd</sup>. We hope to begin collecting samples the week of May 11th. All CRO research staff and component staff were invited to participate in the launch meeting. This is a non-credit trial. Component sites will receive payment for each specimen submitted. Patients will be consented and reservations will need to be made in Medidata Rave to assure there is a spot for submissions on the day the blood is to be collected. Ten collection kits have been received and we will be sending to sites participating this week.

#### **NRG Final Audit Report**

On February 17-19 the NRG group (formerly NSABP, RTOG, and GOG) audited our Ozarks NCORP. **The results were excellent.** No IRB deficiencies were noted. Pharmacy review found only one major deficiency. Patient case review consisted of 49 patients. Only 5 major deficiencies and 3 lesser deficiencies were noted. CRO's corrective action plan for deficiencies has been developed and submitted. The Alliance Research Group will be at CRO on June 4<sup>th</sup> and 5<sup>th</sup> for their 3-year audit and ECOG-ACRIN will be with us on October 21<sup>st</sup> – 23<sup>rd</sup> for their first audit at CRO.

#### **Study Profile**

Alliance A011203 "Tamoxifen Citrate or Z-Endoxifen Hydrochloride in Treating Patients With Locally Advanced or Metastatic, Estrogen Receptor-Positive, HER2-Negative Breast Cancer" is our profile study for May. This randomized phase II trial studies how well tamoxifen citrate works compared with z-endoxifen hydrochloride in treating patients with breast cancer that has spread to nearby tissue or lymph nodes or other parts of the body and has estrogen receptors but not human epidermal growth factor receptor 2 (HER2) receptors on the surface of its cells. Estrogen can cause the growth of tumor cells. Hormone therapy using tamoxifen citrate or z-endoxifen hydrochloride may fight breast cancer by lowering the amount of estrogen the body makes. It is not yet known whether tamoxifen citrate or z-endoxifen hydrochloride is more effective in treating patients with breast cancer.

#### **CRO Steering Committee**

June 11<sup>th</sup> is the date for our next CRO Steering Committee meeting. Sigrun Hallmeyer, MD, from Chicago will be our speaker. The title of Dr. Hallmeyer's presentation is "Expanding Treatment Options In The Treatment Of Metastatic Melanoma". Please make plans to attend. More information will be coming as we learn more regarding our speaker.

## **Institutional Review Board**

Mercy Springfield will be the local IRB for all CRO components. This transaction will be completed on May 15, 2015.

## **Upcoming NCI Trial Webinar:**

1. **Cancer Control Trials:** Presentations on ECOG-ACRIN E4112 and Alliance A011104 will take place on **Thursday, May 7<sup>th</sup> from 4 – 5 pm ET.**
  - **ECOG-ACRIN E4112**, *Prospective Study of Magnetic Resonance Imaging (MRI) and Multiparameter Gene Expression Assay in Ductal Carcinoma In Situ (DCIS)*
  - **Alliance A011104**, *Effect of Preoperative Breast MRI on Surgical Outcomes, Costs and Quality of Life of Women with Breast Cancer*

**Potential Attendees:** Radiologists, medical and radiation oncologists, breast surgeons, RT facility personnel (physicists, etc. – credentialing issues), radiology facility personnel, research staff, any practice staff involved in patient referrals, etc.

## **New Local Protocols in April 2015**

**ECOG-ACRIN E4112** - Prospective Study of Magnetic Resonance Imaging (MRI) and Multiparameter Gene Expression Assay in Ductal Carcinoma in Situ (DCIS) Opened 04/17/2015 at Mercy Springfield, Mercy St. Louis and Mercy St. Louis Cancer & Breast Institute

## **New CIRB Protocols in April 2015**

There are several protocols for which we are currently waiting for CIRB Approval:

**9846 Tissue Procurement** - Patient-Derived Models Tissue Procurement Protocol for the National Cancer Institute (NCI)

**Alliance A011203** - A Randomized Phase II Trial of Tamoxifen versus Z-Endoxifen HCl in Postmenopausal Women with Metastatic Estrogen Receptor Positive, HER2 Negative, Breast Cancer

**ECOG-ACRIN EA8141** – A Prospective Phase II Trial of Neoadjuvant Systemic Chemotherapy Followed by Extirpative Surgery for Patients with High Grade Upper Tract Urothelial Carcinoma

**NRG-GY001** - A Phase II Trial of Cabozantinib (XL-184) (NSC #761968) in Women with Recurrent, Clear Cell Carcinoma of the Ovary, Fallopian Tube, or Peritoneum

**SWOG S1403** - A Randomized Phase II/III Trial of Afatinib Plus Cetuximab Versus Afatinib Alone in Treatment-Naive Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer (NSCLC)

## **Closed Protocols in April 2015**

**Alliance A031203** - Randomized Phase II Study Comparing Cabozantinib (NSC #761968 and IND #116059) with Commercially Supplied Sunitinib in Patients with Previously Untreated Locally Advanced or Metastatic Renal Cell Carcinoma - Closed to Accrual on 04/06

**ECOG-ACRIN E2212** - A Randomized, Double-Blinded, Placebo-Controlled Phase II Study of Adjuvant Everolimus Following the Resection of Metastatic Pancreatic Neuroendocrine Tumors to the Liver - Closed to Accrual on 03/30

**ECOG-ACRIN E1311** - A Randomized, Placebo Controlled Phase II Trial of Afatinib (BIBW2992) as Adjuvant Therapy Following Chemoradiation in Patients with Head and Neck Squamous Cell Carcinoma at High Risk of Recurrence - Closed to Accrual on 03/31

**GOG-0260** – A Phase II Evaluation of Elesclomol Sodium and Weekly Paclitaxel in the Treatment of Recurrent or Persistent Platinum-Resistant Ovarian, Fallopian Tube or Primary Peritoneal Cancer - Closed to Accrual on 03/16

**SWOG S1201** - A Randomized Phase II Pilot Study Prospectively Evaluating Treatment for Patients Based on ERCC1 (Excision Repair Cross-Complementing 1) for Advanced/Metastatic Esophageal, Gastric, or Gastroesophageal Junction (GEJ) Cancer - Closed to Accrual on 04/01