

## CRO Communiqué

### Keeping you informed about CRO progress

### February 2015

#### **Top Enrolling Physicians for January 2015**

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Donegan (Mercy St. Louis)	2	0.9	0	0.9
Dr. Craft (Mercy St. Louis)	1	0	1	1
Dr. Ellis (Cox)	2	2	0	2
Dr. Finnie (Mercy St. Louis)	1	0	1	1
Dr. Oza (Mt. Vernon)	4	0	4	4
Dr. Raju (Mercy Spfld)	1	1.12	0	1.12
Dr. Tiriveedhi (Mercy Spfld)	1	1.28	0.4	1.68
<b>TOTALS</b>	11	5.3	6.4	<b>11.7</b>

While our enrollments are up from December they remain low. We have earned 41.54 treatments and 40.58 cancer control credits credits at the end of January, half through our first NCORP year. This gives us 82.12 credits and leaves us falling short 27.88 to be on target to meet our 220 credit goal for the year but it is our understanding enrollments are low throughout the country.

#### **Study Profile**

Alliance A071102 – “A Phase II/III Randomized Trial of Veliparib or Placebo in Combination with Adjuvant Temozolomide in Newly Diagnosed Glioblastoma with MGMT Promoter Hypermethylation” is our profile study this month. This randomized phase II/III trial studies how well temozolomide and veliparib work and compare them to temozolomide alone in treating patients with newly diagnosed glioblastoma multiforme. Drugs used in chemotherapy, such as temozolomide, 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. Veliparib may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. It is not yet known whether temozolomide is more effective with or without veliparib in treating glioblastoma multiforme.

#### **Congratulations to Dr. Bonebrake**

An abstract for GOG#227G: “A Phase II Evaluation of Brivanib in the Treatment of persistent or Recurrent Carcinoma of the Cervix” is being prepared by John Chan, MD and is planned for submission to ASCO. Dr. Bonebrake had several enrollments to this study and will be added as a co-author. Congratulations!

#### **Establishment of New Cancer Prevention and Control CIRB**

The NCI CIRB Initiative announced the establishment of a new CIRB on January 14th, the Cancer Prevention and Control (CPC) CIRB. The addition of the CPC CIRB extends the benefits of centralized IRB review to investigators participating in studies sponsored by the NCI’s Division of Cancer Prevention. The CPC CIRB is expected to review studies developed by the DCP-sponsored NCORP and Consortia programs beginning in February of 2015. As with the existing CIRBs, the membership of the new CPC CIRB has been carefully selected to ensure that the CIRB has the expertise required to review studies sponsored by the NCORP and Consortia programs. Members have been selected based on their expertise in cancer prevention and control, ethics, patient advocacy, and protection of human subjects.

#### **NRG Audit**

CRO will have an NRG audit on February 17, 18 and 19<sup>th</sup>. Five NCI auditors will be at the CRO Administrative office over the three days. A total of 50 patient charts will be audited. Twenty drug accountability records and 39 regulatory records are also being prepared for review. This is the largest audit in CRO’s history. Efforts have been made to coordinate CRO component staff bringing charts and documentation to Springfield on either Tuesday or Wednesday.

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

CRO submitted and receive additional funding for submitting 100 blood samples to NCI to assist in the development of a tissue repository in August 2014. CRO was one of five NCORP programs accepted for this project and awarded \$48,510. CRO staffs leading this project have been invited to attend a webinar on February 19<sup>th</sup> to learn more about the study. We await further information to begin our campaign to collect de-identified blood specimens to be used for the NCI tissue repository. All CRO Components will be asked to participate in collecting blood samples and be reimbursed for their submissions.

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

Alliance A071102 - A Phase II/III Randomized Trial of Veliparib or Placebo in Combination with Adjuvant Temozolomide in Newly Diagnosed Glioblastoma with MGMT Promoter Hypermethylation

NRG - BR002 - A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer

### **Closed and Upcoming Closures in January, 2015**

CALGB 90601- A Randomized Phase III Study of Gemcitabine, Cisplatin, Bevacizumab or Gemcitabine, Cisplatin, and Placebo in Patients with Advanced Transitional Cell Carcinoma  
Closed to Accrual 12/02/2014

ECOG-ACRIN E1305- A Phase III Randomized Trial of Chemotherapy with or without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer  
Will close to accrual on 02/11/2015

NSABP B-47- A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer  
Will close to accrual at the end of January or beginning of February, no exact date has been released.

### **Temporarily Closed in January, 2015**

AOST1322 – 12/15/2014 Phase II Study of Eribulin (NSC#707389, IND#122686) in Recurrent or Refractory Osteosarcoma

GOG-0283 – 12/19/2014 A Phase II Trial of DCTD-Sponsored Dasatinib (NSC #732517 IND #73969) In Recurrent/Persistent Ovary, Fallopian Tube, Primary Peritoneal, Endometrial, or Endometriosis-Associated Clear Cell Carcinoma Characterized for the Retention or Loss of BAF250a Expression

### **Protocols Closed at Mercy due to zero enrollment**

Alliance A011104 - Effect of Preoperative Breast MRI on Surgical Outcomes, Costs and Quality of Life of Women with Breast Cancer

CALGB 80803 - Randomized Phase II Trial of PET Scan-Directed Combined Modality Therapy In Esophageal Cancer