

CRO Communiqué

Keeping you informed about CRO progress

June 2014

Top Enrolling Physicians for May 2014

| Physician | Patient Registrations | Treatment Credits | Control Credits | Total Credits |
|---------------------------------|-----------------------|-------------------|-----------------|---------------|
| Dr. Bergamini (Mercy St. Louis) | 1 | 0 | 1 | 1 |
| Dr. Bonebrake (Cox) | 1 | 1 | 0.5 | 1.5 |
| Dr. Donegan (Mercy St. Louis) | 2 | 2 | 0.5 | 2.5 |
| Dr. Graham (Phelps County) | 1 | 1 | 0 | 1 |
| Dr. Hanson (Mercy St. Louis) | 3 | 2 | 2 | 4 |
| Dr. Hu (Mercy St. Louis) | 1 | 1 | 0 | 1 |
| Dr. Nair (Mercy Spfld) | 2 | 2 | 0 | 2 |
| Dr. Oza (Good Samaritan) | 1 | 1 | 0 | 1 |
| Dr. Shunyakov (Central Care) | 1 | 1 | 0.5 | 1.5 |
| Dr. Vu (Freeman) | 1 | 1 | 0 | 1 |
| Total | 14 | 12 | 4.5 | 16.5 |

YEA! We did it! Thanks to all our investigators and research staff. CRO enrolled 259 individuals to clinical trials earning 205.4 credits for the past grant year (June 1, 2013 through May 31, 2014). This should allow us to receive \$4,000 per credit instead of \$2,500 per credit with the NCORP grant. CRO's year-end patient registration accruals are attached.

Status of the CCOP NCORP Program Transition

As we begin our new grant year on June 1, 2014 we continue to live in the world of uncertainty. We have received our grant score but do not know what the score actually means as other factors such as geographic location in addition to the score are being considered for awards. We eagerly await the announcement of the NCORP grant recipients scheduled for late July.

NCTN Overview

NCI's Division of Cancer Therapy and Diagnosis has posted an extensive overview of the National Clinical Trials Network at the following website address. <http://www.cancer.gov/clinicaltrials/nctn> This description provides a great overview of the new program.

CRO Steering Committee Dinner in St. Louis

CRO will have a CRO Steering Committee meeting on Thursday, June 18th in St. Louis. *Asad Dean, MD*, Hematologist / Oncologist at Texas Oncology in Ft. Worth, Texas will speak on "A New Treatment Option in Previously Treated Chronic Lymphocytic Leukemia and Mantle Cell Lymphoma". Please RSVP to 417-269-4520 by Friday, June 12th. Several CRO staff will be attending this event and conducting an internal auditing of Mercy St. Louis and Good Samaritan documentation before the program.

Study Profile

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" is our study to profile this month. Estrogen can cause the growth of breast cancer cells. Hormone therapy using tamoxifen citrate, goserelin acetate, leuprolide acetate, anastrozole, letrozole, or exemestane, may fight breast cancer by lowering the amount of estrogen the body makes. Everolimus may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. It is not yet known whether hormone therapy is more effective when given with or without everolimus in treating breast cancer. The purpose of this randomized phase III trial is to see how well giving hormone therapy together with or without everolimus works in treating patients with breast cancer. Placebo patients receive an approved endocrine therapy comprising tamoxifen citrate, goserelin acetate or leuprolide acetate, or an aromatase inhibitor (anastrozole, letrozole, or exemestane) for 2-5 years. Patients also receive a placebo PO daily for 1 year in the absence of disease progression or unacceptable toxicity. Thirty five hundred patients are being recruited for the study.

New Studies Approved in April, 2014 Through Cox and Mercy's IRB

None

New Studies Approved and Opened in April with the CIRB

GOG-0281- A Randomized Phase II/III Study To Assess The Efficacy of Trametinib (GSK 1120212) In Patients With Recurrent Or Progressive Low-Grade Serous Ovarian Cancer Or Peritoneal Cancer.

NRG-HN001- Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA)