

CRO Communiqué
Keeping you informed about CRO progress
May, 2011

Top Enrolling Physicians for grant year 6/1/2010 – 5/31/2011

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Bonebrake	20	17	1.5	18.5
Dr. Williams	14	12	2	14
Dr. Ellis	12	9	2.5	11.5
Dr. Holden	10	8.3	1.5	9.8
Dr. Raju	10	4	5.5	9.5

April was a low month for enrollments. We had 8 enrollments earning 5 treatment credits and 1.5 cancer control credit. With one month remaining for this grant year it does not look hopeful for us to meet our NCI target credits. At this time we have 96.4 treatment credits and 49.2 cancer control credits. By the end of May we need to have 120 treatment credits and 70 cancer control credits to meet NCI target. Thus we need to earn 23.6 treatment and 20.8 cancer control credits during May to meet our NCI target.

Study Profile for April - May

SWOG S1005 "A Phase II Study of MK-2206 (NSC-749607) as Second Line Therapy for Advanced Gastric and Gastroesophageal Junction Cancer" is our study profiled this month. Eligibility criteria require patients to have histological or cytologically confirmed adenocarcinoma of the stomach or gastroesophageal (GE) junction that has progressed after first-line regimen, or is recurrent within 6 months after receiving adjuvant therapy. Previous adjuvant (chemo) radiotherapy is permitted. Prior concurrent chemotherapy with radiation is not considered one prior regimen. Patients must not have known brain metastases. This study is going to St. John's IRB in May and was approved by Cox's IRB in April.

Exploring Phelps County as CRO Affiliate

CRO continues to talk with Phelps County Regional Hospital in Rolla regarding an affiliation to enroll patients into research trials. CRO's affiliate contract is currently being reviewed by administrators at Phelps County. It would be great to add them as our fifth affiliate. Phelps County currently has two medical oncologists, Dr. Bond and Dr. Nevils and plan to add another medical oncologist later this year. They also have a radiation oncologist, Dr. Mary Graham.

New CRO Investigators

Dr. Jay Carlson has joined CRO as an investigator. He will be joining St. John's as a GYN oncologist on May 2, 2011. Dr. Carlson is coming to us from Des Moines, IA where he has been a very active participant in GOG protocols for years including sitting on different committees. He is the national study chair for GOG 269 and national study co-chair for GOG 244 which are targeted to open after the upcoming July meeting. He is responsible for beginning the CCOP program in Des Moines and enrolled 81 patients on GOG protocols in the 9 months from April through December 2010. We are also working with Dr. Braun the new radiation oncologist at St. John's along with Dr. Bond, Dr. Nevils, and Dr. Graham to become CRO investigators. CRO is most excited to have new investigators join us as we continually need research champions.

New Studies Approved in April 2011

Opened at Cox and St. John's

GOG 0261 A Randomized Phase III trial of Paclitaxel plus Carboplatin versus Ifosfamide Plus Paclitaxel in Chemotherapy-Naive Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus or Ovary

Opened at Cox Only

GOG 0247 Patient, Physician and Nurse Factors Associated with Entry onto Clinical Trials and Completion of Treatment for Women with Primary or Recurrent Invasive Carcinoma of the Uterine Corpus or Uterine Cervix, All Stages – **previously opened at St. John's**

GOG 0268 A Phase III Evaluation of Temezirolimus (CCI-779) in Combination with Carboplatin and Paclitaxel Followed by Temezirolimus (CCI-779) Consolidation as First Line Therapy in the Treatment of Stage III-IV Clear Cell Carcinoma of the Ovary - **previously opened at St. John's**

SWOG S1005 A Phase II Study of MK-2206 (NSC-749607) as Second Line Therapy for Advanced Gastric and Gastroesophageal Junction Cancer

Opened at St. John's Only

GOG 0136 Acquisition of Human Gynecologic Specimens and Serum to be Used in Studying the Causes, Diagnosis, Prevention and Treatment of Cancer

GOG 0235 A Prospective, Longitudinal Study of YKL-40 in Patients with FIGO Stage III or IV Invasive Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer Undergoing Primary Chemotherapy

GOG 0249 A Phase III Trial of Pelvic Radiation Therapy Versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High Risk, Early Stage Endometrial Cancer

GOG 0263 Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy

Studies Closed April

CTSU CALGB 170601 A Phase III Double Blind Trial of Oral Duloxetine for Treatment of Pain Associated with Chemotherapy-Induced Peripheral Neuropathy (CIPN)

CTSU ECOG E1697 A Phase III Randomized Study of Four Weeks High Dose IFN-a2b in Stage II-A Melanoma

RTOG 0841 Efficiency of Screening for Depression in Cancer Patients Receiving Radiotherapy

SWOG S0424 Molecular Epidemiology Case-Series Study of Non-Small Cell Lung Cancer in Smoking and Non-Smoking Women and Men