

CRO Communiqué
Keeping you informed about CRO progress
November 2011

Top Enrolling Physicians for October 2011

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Ali	1	0	1	1
Dr. Bonebrake	4	1	2.5	3.5
Dr. Carlson	9	1.8	0	1.8
Dr. Tiriveedhi	1	1	0	1

Enrollments this month are down but there is promise of other patients in process of being registered to trials in the near future. We earned 3.8 treatment credits and 3.5 control credits during October. We are at 40.3 treatment credits and need to be at 50 to meet NCI's assigned target credit of 120 for this grant year. We have earned 21.5 control credits and need to have 25 to meet our assigned control credits of 60 for this grant year.

Study Profile

NCCTG N10C1 "Vaginal DHEA for Vaginal Symptoms: A Phase III Randomized, Double Blind, Placebo-Controlled Trial" is our profile study this month. Patients are randomized to one of three arms - DHEA 3.25mg, DHEA 6.5mg or a placebo vaginally, daily for 12 weeks at bedtime. Post menopausal women with a history of breast or gynecologic cancer (currently no evidence of disease) are eligible. Women must have significant vaginal complaints or dryness, and/or pain with intercourse (dyspareunia) or sufficient severity to make a patient desire therapeutic intervention. Vaginal symptoms must have been present for more than two months prior to randomization. Four hundred fifty six patients are expected to be enrolled.

Steering Committee Meeting on October 3, 2011

37 physicians, advanced practice nurses, research nurses and staff attended the CRO Steering committee meeting on October 3, 2011. Ravi Vij from Washington University School of Medicine in St. Louis spoke on multiple myeloma. Thanks to all of you who attended.

New CRO Staff Transition

On Wednesday, October 5, 2011, CRO Executive Board Administrators met to discuss CRO staffing. The decision was to take the opportunity with new staff coming on board to make some changes to better align staff with their strengths. Sharon Hodge transferred to St. John's on Wednesday, October 19th to assist in covering Dr. Carlson's office as well as helping Marcia cover Cancer Hematology Center. Amber Pierce RN joined CRO on Monday, October 17th at our Hulston office. Amber was the Assistant Nursing Manager at Cox on the oncology floor for many years and is familiar with the OHA physicians and staff. Sharon Brown is our new PRN nurse and will be assisting at both Cox and St. John's. We are very pleased to have both Amber and Sharon on board in their new positions. Our newly approved PRN nurse position will give us flexibility and better coverage for your research needs.

Phelps County's 1st enrollment

Congratulations to Dr. Ali and Krista Atkins who enrolled their first patient last week at Phelps County to HLMCC 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)".

New Studies Approved in October 2011

Opened at Cox and St. John's

GOG-0273 Chemotherapy Toxicity in Elderly Women with Ovarian, Primary Peritoneal or Fallopian Tube Cancer

NCCTG N10C1 Vaginal DHEA for Vaginal Symptoms: A Phase III Randomized, Double Blind, Placebo-Controlled Trial

SCUSF Pilot Z011-1 Treatment of painful radiation therapy-induced dermatitis in women treated for breast cancer with whole breast radiation following breast conserving surgery: A pilot study

Opened at St. John's

GOG -0127W A Phase II Evaluation of ABT-888 (IND #77840), Topotecan and Filgrastim or Pegfilgrastim in the Treatment of Persistent or Recurrent Squamous or Non-Squamous Cell Carcinoma of the Cervix

(already open at Cox)

Studies Permanently Closed to Enrollment at Cox & St. John's in October 2011

SWOG S0904 Phase II Study of Sorafenib and Erlotinib in Patients with Advanced Gallbladder Carcinoma or Cholangiocarcinoma.