CRO Communiqué Keeping you informed about CRO progress December 2011

I OP Enrolling Physicians for November 2011				
Physician	Patient	Treatment	Control	Total
-	Registrations	Credits	Credits	Credits
Dr. Bonebrake	4	3	1.5	4.5
Dr. Braun	1	0	0	S1,000.00
Dr. Carlson	10	2	.5	2.5
Dr. Ellis	1	1	0	1
Dr. Holden	1	0	1	1
Dr. Nair	5	3.5	1	4.5
Dr. Raju	1	0	1	1
Dr. Tiriveedhi	7	2.5	2.1	4.6

Discostata a fam

November has been a good month for enrollments. CRO earned 12 treatment and 7.1 control credits for a total of 19.1 credits. Dr. Tiriveedhi led the way this month with 4.6 credits and Dr. Bonebrake and Dr. Nair were right behind her earning 4.5 credits each. Thank you to all eight investigators who participated in placing patients on trials. Half way through our grant year 2011-2011 we have 54.3 treatment and 29.5 control credits. We are 5.7 treatment and .5 cancer control credits away from being on track to meet our NCI target goals of 120 treatment and 60 cancer control credits for the year.

Study Profile

NCCTG N10C2 "Double-Blind, Placebo-Controlled Study of Magnesium Supplements to Reduce Menopausal Hot Flashes" is a new cancer control study opened this month. Postmenopausal women with a history of breast cancer without malignant disease who are bothered by hot flashes qualify for this study. Hot flashes must occur greater than 28 times per week, be of more than 30 days duration and of sufficient severity to make the patient desire intervention. Postmenopausal is defined by absence of a period in the past 12 months, bilateral oophorectomy, women with at least one ovary without a uterus who are over 55 years of age, or FSH over 40 mIU/mL.

NCCTG Audit

CRO has been notified that NCCTG will be with us on February 2 and 3, 2012 to conduct an audit of CRO charts. Internal audits of NCCTG charts are currently occurring.

Cooperative Meeting Attendance

Dr. Carolla attended the first Alliance (ACOSOG, CALGB & NCCTG) meeting in Chicago on November 17 - 19, 20ll. Drs. Bonebrake and Carlson will be attending the next GOG meeting in San Diego, California on January 26-29, 2012. CRO is carefully monitoring our travel as our budget is lower this grant year due to funding cuts and increasing cost.

New Studies Approved in November 2011

Opened at Cox and St. John's

<u>NCCTG N10C2</u> Double-Blind, Placebo-Controlled Study of Magnesium Supplements to Reduce Menopausal Hot Flashes

<u>SWOG S0812</u> A Randomized Double Blind Placebo-Controlled Biomarker Modulation Study of High-Dose Vitamin D in Premenopausal Women at High-Risk for Breast Cancer, Phase IIB

<u>SWOG S1014</u> Abiraterone Acetate Treatment for Prostate Cancer Patients with a PSA of More Than Four Following Initial Androgen Deprivation Therapy, Phase II. **<u>WF 97609</u>** Impact of Genomics and Exposures on Disparities in Breast Cancer Radiosensitivity

Opened at Cox - Already open at St. John's

<u>SWOG S0816</u> A Phase II Trial of Response-Adapted Therapy of Stage III-IV Hodgkin Lymphoma using Interim FDG-PET Imaging – Credentialing must be completed at Cox for this study before enrollment can begin.

Opened at Cox Only

<u>GOG 229K</u> A Phase II Evaluation of BIBF 1120 (IND #113086) in the Treatment of Recurrent or Persistent Endometrial Carcinoma

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

<u>**GOG 256</u>** A Prospective Study of Cognitive Function During Chemotherapy for the Front Line Treatment of Advanced Ovarian, Primary Peritoneal or Fallopian Tube Cancer</u>