

CRO Communiqué

Keeping you informed about CRO progress

January - February 2012

Top Enrolling Physicians for January 2012

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Steven Braun	1		1	1
Dr. Bonebrake	2	1	1	2
Dr. John Buckner	4		4	4
Dr. Jay Carlson	10	5	2.5	7.5
Dr. William Cunningham	2	1.5	.5	2
Dr. David Croy	2	Pending randomization		
Dr. Helen Kim	3		3	3
Dr. Mohan Tummala	2	1	0.5	1.5

January was a great month for enrollments. The above numbers are for January alone during which time we earned 8.5 treatment and 12.5 cancer control credits. We are doing very well with cancer control credits with 52.6 credits, 7.5 above our target of 45.1 to attain our target of 60 for this grant year. We are not doing as well with treatment credits having earned 76.3 credits to date. We need to be at 90 to be on target to meet our goal of 120 for this grant year.

NCI 6-month CCOP Accrual Statistics

Below is a chart of the NCI 6-month accrual statistics (June 2011 – November 2011) for all CCOPs. The GREAT NEWS is CRO is doing amazingly well. At the end of November 2011, we were at 93% in meeting our treatment credits of 55.8 and at 96% in meeting our cancer control credits of 28.8. This placed us in the top category for cancer control achievements and the second from top with treatment accruals.

Achievement of 6-mo Treatment

Accrual Goals 64 CCOP/MCCOPs - Range = 5% -148%

Number of CCOPs/MBCCOPs (%)	Percentage of 6-month goal achieved*
9 (14%)	95 - ≥ 100%
15 (23%) *CRO 93%	76 – 94%
22 (34%)	51 – 75%
12 (19%)	26 – 50%
6 (9%)	≤ 10 – 25%

Achievement of 6-mo Cancer Control

Accrual Goals 64 CCOP/MCCOPs - Range= 2% - 261%

Number of CCOPs/MBCCOPs (%)	Percentage of 6-month goal achieved*
20 (31%) *CRO 96%	95 - ≥ 100%
9 (14%)	76 – 94%
15 (23%)	51 – 75%
17 (27%)	26 – 50%
3 (5%)	≤ 10 – 25%

Study Profile

CTSU NCIC-CTG MA.32 “A Phase III Randomized Trial of Metformin versus Placebo on Recurrence and Survival in Early Stage Breast Cancer”. We have recently been approved by National Cancer Institute of Canada (NCIC) to participate in this trial. Target enrollment is 3582 with 1266 enrolled at this time. This study is available for patients with invasive breast cancer who have been diagnosed and have undergone definitive surgical treatment for invasive breast cancer within the previous 12 months. Those enrolled may have received standard adjuvant loco-regional radiation, adjuvant endocrine treatment, trastuzumab or other biologics or bisphosphonates prior to or during study treatment. Chemotherapy (adjuvant or neo-adjuvant) if given, must be completed prior to randomization. Participants cannot be a known diabetic (type I or II) or have fasting glucose > 126 mg/dL. Each enrollment is worth 1 treatment credit and 0.5 cancer control credits if participant chooses to take part in the quality of life study.

NRG New Cooperative Group Name

The new cooperative group composed of NSABP, RTOG and GOG now has an official name. NRG (first letter of each of the individual groups) Oncology was chosen from over 300 entries sent by members. Not only does our name incorporate the first letter of each of the individual groups, but it also sets the momentum for the future: we are energy wrote Philip J. DiSaia, M.D., Group Chair.

New Studies Approved in December 2011 and January 2012

Opened at Cox and St. John's

GOG 0229K A Phase II Evaluation of BIBF 1120 (IND #113086) in the Treatment of Recurrent or Persistent Endometrial Carcinoma

SWOG S0927 A Randomized Placebo-Controlled Trial of Omega-3-Fatty Acid for the Control of Aromatase Inhibitor-Induced Musculoskeletal Pain and Stiffness in Women with Early Stage Breast Cancer, Phase III

SWOG S1108 Phase II Trial of the Aurora Kinase A Inhibitor MLN8237, In Relapsed or Refractory Peripheral T-Cell Non-Hodgkin Lymphoma

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

GOG 0229L A Phase II Trial of AMG 386 (IND #111071), a Selective Angiopoietin 1/2 Neutralizing Peptibody, in Patients with Persistent/Recurrent Carcinoma of the Endometrium

Studies Permanently Closed to Enrollment at Cox & St. John's in December 2011 & January 2012

CTSU CALGB 40503 A Randomized Phase III Trial of Weekly Paclitaxel Compared to Weekly Nanoparticle Albumin Bound Nab-Paclitaxel or Ixabepilone With or Without Bevacizumab as First-Line Therapy for Locally Recurrent or Metastatic Breast Cancer

CTSU CALGB 40502 Endocrine Therapy with or without anti-VEGF Therapy: A Randomized, Phase III Trial of Endocrine Therapy Alone or Endocrine Therapy Plus Bevacizumab (NSC 704865; IND 7921) For Women with Hormone Receptor-Positive Advanced Breast Cancer

CTSU ECOG E1A06 An Intergroup Phase III Randomized Controlled Trial Comparing Melphalan, Prednisone and Thalidomide (MPT) Versus Melphalan, Prednisone and Lenalidomide (Revlimid) (MPR) in Newly Diagnosed Multiple Myeloma Patients Who Are Not Candidates for High-Dose Therapy

GOG 0224 A Randomized Phase II Evaluation of Continuous Progestin Therapy Vs. Sequential Progestin Therapy in the Treatment of Endometrial Intraepithelial Neoplasia (EIN) From A Referred Cohort of Atypical Endometrial Hyperplasia (AEH) or EIN Patients That Desire Uterine Preservation

GOG-0229H A Randomized Phase II Evaluation of Continuous Progestin Therapy Vs. Sequential Progestin Therapy in the Treatment of Endometrial Intraepithelial Neoplasia (EIN) From A Referred Cohort of Atypical Endometrial Hyperplasia (AEH) or EIN Patients That Desire Uterine Preservation

GOG 0252 A Phase III Clinical Trial of Bevacizumab with IV versus IP Chemotherapy in Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma

NCCTG N08CA The Use of Glutathione (GSH) for Prevention of Paclitaxel/Carboplatin (TAXOL/CBDCA) Induced Peripheral Neuropathy: A Phase III Randomized, Double-Blind Placebo Controlled Study

NSABP C-11 A Phase III Study Evaluating the Role of Perioperative Chemotherapy in Patients with Potentially Resectable Hepatic Colorectal Metastases

RTOG 0617 A Randomized Phase III Comparison of Standard-Dose (60 Gy) Versus High-Dose (74 Gy) Conformal Radiotherapy with Concurrent and Consolidation Carboplatin/Paclitaxel +/- Cetuximab (IND #103444) in Patients With Stage IIIA/IIIB Non-Small Cell Lung Cancer

SWOG S0933 Phase II Study of RO4929097 (NSC-749225) In Advanced Melanoma