

Jan / Feb, 2010

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# CCOP NEWS



A Community of Caring in Cancer Research

## Columbus Community Clinical Oncology Program

### 2010 CANCER CONTROL ACCRUAL

Cancer control accrual is an important focus area again this year. Our cancer control objective for the period of June, 2009, through May, 2010, is 120 credits, with a minimum of 50. Credits accrued for the first seven months of this period total 19.5, which is just 16% of our goal. We should have accrued 58% of our goal, or 70 credits, to be on course to achieving our objective. This leaves 5 months to accrue over 100 cancer control credits. Please remember to screen patients to determine eligibility for cancer control trials. Thank you for your support!

Below is a list of trials currently available along with accrual credits June, 2009—December, 2009.

Sponsor	Protocol Number	Description	Patient Accrual	Accrual Credits
CALGB	70604	A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer	1	1.0
CALGB	170601	A Phase III Double Blind Trial of Oral Duloxetine for Treatment of Pain Associated with Chemotherapy-Induced Peripheral Neuropathy (CIPN)	0	0.0
HLMCC	0501	Stress Management Therapy for Patients Undergoing Chemotherapy (Non-Hispanic enrollment closed 09/18/2007, open to Hispanic patients only)	0	0.0
NCCTG	N07C2	The Use of Wisconsin Ginseng (panax quinquefolius) to Improve Cancer-Related Fatigue: A Randomized, Double-Blind, Placebo-Controlled Phase III Study	2	2.0
NCCTG	N08C1	Paclitaxel-Associated Acute Pain Syndrome Natural History Study. Arm C closed to general population. Arm D closed.	2	2.0
NCCTG	N08C3	Phase III Double-Blind, Placebo-Controlled Study of Gabapentin for the Prevention of Delayed CINV (Chemotherapy Induced Nausea and Vomiting) in Patients Receiving Highly Emetogenic Chemotherapy	6	6.0
NCCTG	N08C7	Phase III, Randomized, Placebo-controlled, Double-Blind Trial of Flaxseed for the Treatment of Hot Flashes. Open to minorities only.	0	0.0
SWOG	S0424	Molecular Epidemiology Case-Series Study of Non-Small Cell Lung Cancer in Smoking and Non-Smoking Women and Men (Partial closure effective 07/15/2007)	1	0.5
SWOG	S0702	A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment	1	0.5
SWOG	S0715	Randomized Placebo-controlled Trial of Acetyl-L-Carnitine (ALC) for the Prevention of Taxane Induced Neuropathy, Phase III	0	0.0
URCC	0701	A Study of the Effects of Exercise on Cancer-Related Fatigue	0	0.0
URCC	U1105	Prevention of Delayed Nausea - A Phase III Double-Blind Placebo-Controlled Clinical Trial	2	2.0
		Other CC Credits	7	5.5
Totals			22	19.5

**OUR MISSION:** The Columbus Community Clinical Oncology Program (Columbus CCOP) strives to deliver state-of-the-art cancer care to patients in their communities through clinical trials. This allows individuals to remain in their own neighborhoods while receiving the latest and best in cancer screenings, diagnostic care and treatment plans.

Please send newsletter comments to [steveo@columbusccop.org](mailto:steveo@columbusccop.org)



Columbus CCOP Newsletter

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## DR. KUEBLER'S CCOP UPDATES

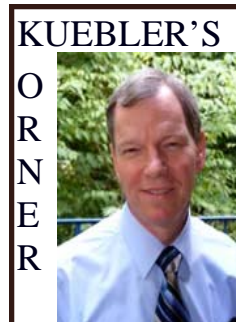
Hello, loyal CCOP members. I think we should have stated in our recent grant that snow can effect accruals. What a winter we are having! Actually, it appears we did quite well in the recent competitive grant renewal cycle. You are all responsible for this success. Thank you from all of us at the Columbus CCOP central office.

I hope everyone enjoyed the holidays. It's now back to work in pursuit of our goals for the year. You may have noticed more studies available for CNS malignancies. This is one of the areas where we would like to expand our protocol portfolio and thereby enhance accruals. We are also working to get more radiotherapists certified in order to participate in RTOG studies. Kudos to Riverside and Mt. Carmel hospitals for leading the way in this venture.

And now ... for the monthly sermon regarding cancer control trial accrual. Well ... this time it is getting serious. Let me share our accrual statistics: 19.5 credits to date. Our NCI expectation is 120. To say we need help in this area is an understatement. I know there are not that many cancer control trials available and eligibility may be somewhat restricted. However, I believe our biggest challenge is that we just don't think about these trials in our established patients. There are two trials dealing with nausea, one for stress management in patients on chemotherapy, one with fatigue and two concerning zoledronic acid. Finally, there is a study for the prevention of taxane induced neuropathy and one for the treatment of this symptom.

I ask that you include a commitment in your new year's resolutions to think about your patients symptoms and consider one of our cancer control trials. Let me know if there is anything we can do to help at the Columbus CCOP central office. Together we can improve our participation in this vital area of cancer research.

Thanks to all of you for your dedication. We've had a great 2009 and I look forward to more success in 2010.



Philip Kuebler, MD, PhD  
Columbus CCOP Principal Investigator

## MARK YOUR CALENDAR

**January 28, 2010: Multiple Myeloma:** This evening CME program will be presented by Dr. Don M. Benson Jr., MD, PhD. It will be held at the Worthington Inn and registration will begin at 6:00 PM.



**April 1, 2010: Melanoma:** This evening CME program will feature Dr. John Kirkwood, director of the Melanoma Program at the University of Pittsburgh Medical Center. It will be held at the Brio Tuscan Grille at Polaris. Registration will begin at 6:00 PM.



**June 24, 2010: 2010 ASCO Review:** This years program will again feature nationally recognized experts to present the most significant research presented at the national ASCO meeting. Be sure and mark your calendar!



You can view additional details and **register** at [www.columbusccop.org/events](http://www.columbusccop.org/events)

## **JANUARY IS CERVICAL HEALTH AWARENESS MONTH**

The National Cancer Institute estimates 11,270 new cases, and 4,070 deaths of cervical cancer in the United States in 2009. Cervical cancer is usually a slow-growing cancer that may not have symptoms but can be found with regular Pap tests (a procedure in which cells are scraped from the cervix and looked at under a microscope). Cervical cancer is almost always caused by human papillomavirus (HPV) infection.

The Ohio Department of Health, through funding by the Centers for Disease Control and Prevention, has a Breast and Cervical Cancer Project (BCCP). The project provides education, screening, re-screening, diagnostics and case management related to breast and cervical cancer. Eleven regional, multi-county projects implement the BCCP at the local level. Services provided include mammograms, Pap tests, office visits, clinical breast exams, colposcopies, breast ultrasounds, biopsies and other diagnostic procedures. The clinical services are provided through a network of more than 700 Ohio primary care physicians, nurse practitioners, gynecologists, surgeons, mammography facilities, radiologists, technologists/ technicians and cytologists. Eligibility requirements for this program can be found at:



[http://www.odh.ohio.gov/odhPrograms/hpr/bc\\_canc/bcanc1.aspx](http://www.odh.ohio.gov/odhPrograms/hpr/bc_canc/bcanc1.aspx)

## **COMMENTS FROM THE EXECUTIVE DIRECTOR**

### **DID YOU KNOW?**

Education Network to Advance Cancer Clinical Trials (ENACCT) is a national organization devoted to identifying, implementing and evaluating innovative community-centered approaches to cancer clinical trials education. They have received educational grants from multiple partners to adapt its successful clinical trial education programs to a Web-based format. "Your Role in Cancer Clinical Trials," is a series of free, one hour e-learning courses which enable patient advocates, community leaders, primary care providers, and cancer clinical trial staff to learn more about promoting and discussing all treatment options, including clinical trials, for every person diagnosed with cancer.

Some courses available for primary care providers and cancer clinical trial staff are:

- Your Role: Why Cancer Clinical Trials Are Important for My Practice (CEU provided)
- Your Role: Enhancing Your Recruitment and Retention Practices Among Medically Underserved Audiences (CEU provided)

To learn more please visit <http://www.enacct.org/>



Columbus CCOP  
Executive Director

## **IMPROVING OUTCOMES IN MULTIPLE MYELOMA**



Dr. Don Benson

The Columbus CCOP hosted a program Thursday evening, January 28th, at the Worthington Inn titled Improving outcomes in Multiple Myeloma: Optimizing Induction Therapy in the Transplant Setting. A great audience attended to hear Dr. Don Benson present. This was a CME event hosted by the CCOP and sponsored by OptumHealth through an educational grant from Celgene.





Please welcome the following people to the Columbus CCOP:

Dr. Alicia Terando recently joined the Columbus CCOP. Dr. Terando is a surgical oncologist affiliated with Grant Medical Center.

Joyce Cox, RN, has joined the Columbus CCOP team and is with Fairfield Medical Center.

## NCI TRIAL NEWS

The following trials are now open for accrual:

**GOG 0249:** A Phase III Trial of Pelvic Radiation Therapy versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin in Patients with High-Risk Early Stage Endometrial Cancer

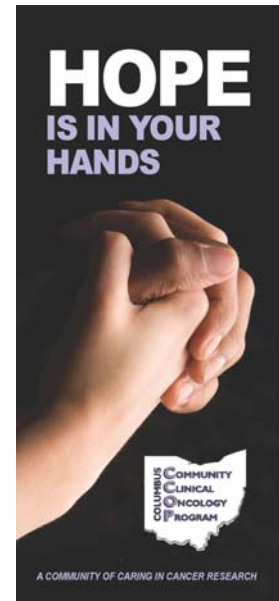
**GOG 0258:** A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs. Caboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma

**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

**RTOG 0815:** A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy with or without Short-term Androgen Deprivation Therapy for Patients with Intermediate-Risk Prostate Cancer

The focus on **cancer control** trials continues this year. Columbus CCOP members are asked to screen new patients to determine if they are eligible to participate.

**Protocols and consent forms can be found at [www.columbusccop.org](http://www.columbusccop.org)**



# CALGB 170601

## For Patients with CIPN Caused by Prior Treatment with Paclitaxel or Oxaliplatin

### CALGB 170601 Available Through the CTSU

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

#### Patient Population

See Section 4.0 for Complete Eligibility Details

- Patients with  $\geq$  grade 2 (using NCI-CTCAE v. 3.0 grading scale) sensory CIPN and an average neuropathic pain score  $\geq$  4 are eligible
- Patients must have CIPN resulting from past administration of paclitaxel or oxaliplatin (patients must not have received both agents)
- Patients must be  $\geq$  3 months beyond completion of paclitaxel or oxaliplatin chemotherapy
- Patients must **not** have pre-existing peripheral neuropathy from nerve compression injuries
- Patients must **not** have previously received or currently be receiving other neurotoxic drugs
- Patients with CNS malignancy are eligible, except those with leptomeningeal carcinomatosis.
- Patients with the following illnesses are eligible, provided they have no evidence of neuropathy from these illnesses at registration: diabetes mellitus, peripheral vascular disease, HIV infection, or a significant degenerative or familial neurologic disorder known to cause peripheral neuropathy
- Patients must **not** be receiving vitamin supplements in excess of recommended daily allowances
- Patients must **not** be taking, nor anticipate taking, any anti-depressants or anticonvulsants
- Patients may be receiving stable doses of analgesics for pain
- Patients may **not** be taking warfarin or heparin products
- Patients must **not** have known diagnosis of alcohol addiction/dependence within past 10 years
- Patients must **not** have a history of seizure disorder
- Patients must **not** have a history of narrow-angle glaucoma

**Number of Participants: 206**

#### Treatment Plan

See Section 7.0 for Complete Treatment Details

#### Patients Will Be Randomized to Study Drug or Placebo

(Note: This is a randomized, double-blind, crossover trial.)

- Patients will take 1 capsule (30 mg) of study drug (Duloxetine) or placebo daily for 7 days (week 1)
- Patients will then increase to 2 capsules (60 mg) of study drug or placebo daily for 28 days (weeks 2-5)
- Study drug or placebo will be tapered during week 6 (1 capsule/30 mg/day)
- Study drug and placebo will be discontinued during week 7 (no capsules for 7 days)
- Patients will then *cross over* to receive the alternative treatment, and sequence will be repeated for weeks 8 through 14

CALGB  
Protocol Chair:  
Ellen Lavoie Smith,  
PhD, ARNP, AOCN

#### Patient Enrollment

Non-CALGB Members: CTSU Patient Registrar 1-888-462-3009

#### Protocol Information

CTSU Help Desk 1-888-823-5923, CTSUcontact@westat.com, www.ctsu.org

**Please Enroll Your Eligible Patients!**