

Top Enrolling Physicians for August 2012

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Braun	1	0	0	0
Dr. Biggers	3	0	3	3
Dr. Carlson	4	4.5	1	5.5
Dr. Ding	3	1.3	0	1.3
Dr. Holden	1	1	0	1
Dr. Kent	1	1	0	1
Dr. Shunyakov	2	1.1	0.1	1.2
Dr. Skelley	1	1	0	1
Dr. Tiriveedhi	2	1	1.1	2.1
TOTALS	18	10.9	5.2	16.1

We are so close to being on target with our accruals. With a fourth of our grant year completed, we need to have 27.5 treatment credits to be on track to achieve our NCI target credits for this grant year. We have earned 26.4 – only 1.1 behind. We have 18.5 control credits and need to have 20.0 to meet NCI’s target for us – only 1.5 behind. Great job!

Study Profile

Wake Forest 97211 “A Feasibility Study of Donepezil in Female Breast Cancer Survivors with Self-Reported Cognitive Dysfunction Following Chemotherapy” is our profile study this month. For breast cancer patients, long term effects of great concern are the negative impact chemotherapy has on cognition, energy and mood which result in decreased quality of life. This study compares Donepezil, or Aricept which is known for its use with Alzheimer’s patients, to a placebo for what is commonly referred to as chemo brain. Eligibility requirements include: Female with history of invasive breast cancer treated with adjuvant chemotherapy between 1 and 5 years previously, no clinical evidence of recurrent disease, have received at least 4 cycles of cytotoxic chemotherapy and no history of hepatic or renal dysfunction or disease.

Cooperative Base Audits

Two GOG auditors were at CRO on Monday, August 20th for their required 3-year audit. Three SWOG auditors were at CRO on August 22nd and 23rd, plus a CTSU auditor was also with us on August 22nd. We have yet to receive a written report but were pleased that both groups found no alarming deficiencies and are planning to return in 3 years for their NCI mandated audit. No pharmacy issues were found and only minimal regulatory issues were noted.

Dr. Carolla SWOG Auditor

Dr. Carolla was in Columbus, Ohio serving as a SWOG auditor on August 28-30.

Financial Conflict of Interest Policy

Thanks to everyone for completing the training on FCOI disclosures.

CRO Website

Keep up to date with clinical trials available through CRO by visiting our website at Ozarkscancerresearch.org Our website is updated monthly.

Monthly Educational Conferences dates for August

No educational conference is scheduled for September at this time.

CRO Steering Committee Meeting

October 15, 2012 is the date for our fall CRO Steering Committee meeting. Steven Sorcher from Wash U will be speaking on colon cancer. It will be at TOUCH Restaurant and begin at 6PM.

New Studies Approved in August 2012

Opened at Cox and Mercy Springfield

CTSU ECOG E1411 Intergroup Randomized Phase 2 Four Arm Study in Patients ≥ 60 with Previously Untreated Mantle Cell Lymphoma of Therapy with: Arm A = Rituximab+Bendamustine Followed by Rituximab Consolidation (RB -->R); Arm B = Rituximab+Bendamustine+Bortezomib Followed by Rituximab Consolidation (RBV--> R), Arm C = Rituximab+Bendamustine Followed by Lenalidomide+Rituximab Consolidation (RB --> LR) or Arm D = Rituximab+Bendamustine+Bortezomib Followed by Lenalidomide+Rituximab Consolidation (RBV -> LR)

GOG 0225 Can Diet and Physical Activity Modulate Ovarian or Primary Peritoneal Cancer Progression-Free Survival?

GOG 0275 A Phase III Randomized Trial of Pulse Actinomycin-D versus Multi-day Methotrexate for the Management of Low Risk Gestational Trophoblastic Neoplasia

GOG 0277 A Phase III Randomized Trial of Gemcitabine (NSC# 613327) plus Docetaxel (NSC# 628503) followed by Doxorubicin (NSC# 123127) v. observation for uterus-limited, High Grade Uterine Leiomyosarcoma

GOG 0279 Phase II Trial Evaluating Cisplatin and Gemcitabine Concurrent with Intensity-Modulated Radiation Therapy (IMRT) for the Treatment of Locally-Advanced Squamous Cell Carcinoma of the Vulva

Wake Forest 97211 A Feasibility Study of Donepezil in Female Breast Cancer Survivors with Self-Reported Cognitive Dysfunction Following Chemotherapy

Opened at Mercy Springfield Only

GOG 0269 A Limited Access Phase II Trial Utilizing Bioimpedance to Measure Lower Extremity Lymphedema Associated with the Surgical Management of a Vulvar Cancer

Opened at Cox Only

GOG-0244 The Lymphedema and Gynecologic Cancer (LEG) Study; Incidence, Risk Factors, and Impact in Newly Diagnosed Patients

Studies Permanently Closed to Enrollment at Cox & Mercy in August 2012)

NCCTG N057K Phase I/II Evaluation of Everolimus (RAD001), Radiation and Temozolomide (TMZ) Followed by Adjuvant Temozolomide and Everolimus in Newly Diagnosed Glioblastoma