

CRO Communiqué
Keeping you informed about CRO progress
November 2012

Top Enrolling Physicians for October 2012

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Carlson	3	0	3	3
Dr. Ellis	2	2	0	2
Dr. Holden	1	0	1	1
Dr. Hoos	1	1	0	1
Dr. LaFrancis	1	1	0	1
Dr. Nair	1	0	1	1
TOTALS	9	4	5	9

This has been a slow month for enrollments as we had only nine. These nine enrollments earned us four treatment and five cancer control credits. At this time, we are 8.4 credits behind with treatment credits and 6.1 control credits behind to be on track to meet our NCI target credits for this grant year.

Study Profile

RTOG 1119 “Phase II Randomized Study of Whole Brain Radiotherapy in Combination With Concurrent Lapatinib in Patients With Brain Metastasis From HER2-Positive Breast Cancer: A Collaborative Study of RTOG and KROG” is our study profile this month. Patients must have pathologically proven diagnosis of HER2 invasive breast cancer with at least 1 measurable, unirradiated parenchymal brain lesion (≥ 10 mm) within 21 days prior to study entry. Patients may have progressive parenchymal brain metastases following stereotactic radiosurgery for 1-3 brain metastases, with at least 1 new measurable lesion. Adequate hematologic, renal, hepatic function within 21 days prior to study entry is also required.

CRO Audits

CRO staff have submitted Corrective Action Plans to GOG and SWOG for their routine audits conducted in August, 2012. NSABP have notified us they will be at CRO for their routine three year audit on January 7 & 8 2013. NCCTG have also notified us they will be returning for a re-audit at CRO on January 29, 2013.

Research Base Fall Meeting Attendance

Research Base attendance is encouraged as approaching research changes and new trials are discussed. Dr. Holden, Dr. Biggers and Basava Raju attended SWOG’s Fall conference in Chicago on Oct. 17-20, 2012. Robert Carolla and Marilyn Bauer attended the CCOP Principal Investigators and Administrators Meeting in Bethesda, Maryland on September 24 and 25, 2012. A plan for the new NCORP (NCI Community Oncology Research Programs) was the major topic of discussion. Many new changes are coming for CCOP programs as we transform to NCORP programs. NCI plans to have the new NCORP program developed for transformation to begin in December 2012.

New Research nurse

CRO welcomes Kathy Hodges as a new research nurse. Kathy has 17 years of oncology experience and is OCN certified. She is stationed at the Hulston office.

Changes at CRO

CRO staffs have started using a protocol acuity tool to assist in determining work load. As new studies are reviewed by CRO staff they will be assigned an acuity score. The 4 point protocol acuity tool has been piloted at several other CCOPs. We are also making changes in the CREDIT data base pre-study section which will allow us to collect additional information on patients screened for studies.

New Studies Approved in October 2012

Opened at Cox and Mercy Springfield

GOG-0231D A Phase II Evaluation of MLN8237 (IND#113149 NSC# 747888) in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus

RTOG 1119 Phase II Randomized Study of Whole Brain Radiotherapy in Combination With Concurrent Lapatinib in Patients With Brain Metastasis From HER2-Positive Breast Cancer: A Collaborative Study of RTOG and KROG

SWOG S1115 Randomized Phase II Clinical Trial of AZD6244 Hydrogen Sulfate (NSC-748727) and MK-2206 (NSC-749607) vs. mFOLFOX in Patients with Metastatic Pancreatic Cancer after Prior Chemotherapy

Studies Permanently Closed to Enrollment at Cox & Mercy in September 2012

CTSU CALGB 40603 Randomized Phase II 2 X 2 Factorial Trial of the Addition of Carboplatin +/- Bevacizumab to Neoadjuvant Weekly Paclitaxel Followed by Dose Dense AC in Hormone Receptor-Poor/Her2-Negative Resectable Breast Cancer