

CRO Communiqué
Keeping you informed about CRO progress
January 2013

Top Enrolling Physicians for December 2012

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Bonebrake	1	0	1	1
Dr. Carlson	7	1.6	4.5	6.1
Dr. Cunningham	1	0	1	1
Dr. Ellis	4	2	2	4
Dr. Nair	1	2.5	0	2.5
Dr. Pinheiro	1	0	0	0
Dr. Raju	3	1	2	3
Dr. Tiriveedhi	1	1	0	1
TOTALS	18	8.1	10.5	18.6

Enrollments have increased this month for cancer control, but we continue to get further behind with treatment credits. In December, we had 19 registrations earning us 8.1 treatment and 10.5 control credits. This grant year, we have earned 51.1 treatment credits and need to have 64.2 to be on target to meet our NCI target this grant year. We have earned 46.4 control credits and need to be at 46.7 to be on target to meet our NCI target credit. We are just 0.3 credits behind for control but 13.1 credits behind with treatment credits. CRO staff, Dr. Carolla and affiliate staff, met on November 28th to share ideas to increase our enrollments. An action plan was developed. Steps of the plan are currently being explored and put in place.

Study Profile

This month's study profile is RTOG 1010 "A Phase III Trial Evaluating the Addition of Trastuzumab to Tri-modality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma." This study is tri-modality involving treatment with surgery, medical oncology and radiation oncology. Patient must have a histologically confirmed primary adenocarcinoma of the esophagus that involves the mid (up to 25 cm), distal, or esophagogastric junction. They must have confirmed HER2 positivity before randomization can occur. Those randomized to Arm 1 receive radiation (50.4 Gy), paclitaxel, carboplatin, and trastuzumab. This will be followed by surgery 5-8 weeks after completion of radiation, then maintenance trastuzumab, every 3 weeks for 13 treatments. Those randomized to Arm 2 receive radiation (50.4 Gy), paclitaxel, and carboplatin. Followed by surgery 5-8 weeks after completion of radiation

Freeman Regulatory Work

Beginning January 17, 2013 CoxHealth will become the Intuitional Review Board (IRB) for newly opened studies at Freeman. CRO's regulatory staff is busy preparing for this transformation.

Happy New Years!!!
May 2013 be filled with many
blessings and many NCI clinical
trial enrollments.



New Studies Approved in December 2012

Opened at Cox and Mercy Springfield

GOG-0186K A Randomized Phase II Study of NCI Supplied Cabozantinib Versus Weekly Paclitaxel in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer

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

GOG 0280 A Phase II Evaluation of the Potent, Highly Selective Poly (ADP-Ribose) Polymerase (PARP)-1 and -2 Inhibitor Veliparib (ABT-888) (IND#77840) (NSC #737664) in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Patients Who Carry a Germline BRCA1 or BRCA2 Mutation

CTSU ECOG E3805 CHAARTED: Chemhormonal Therapy Versus Androgen Ablation Randomized Trial For Extensive Disease in Prostate Cancer