

CRO Communiqué
Keeping you informed about CRO progress
February - March, 2011

Top Enrolling Physicians for grant year 6/1/2010 – 5/31/2011

Dr. Bonebrake	18 Registrations
Dr. Ellis & Dr. Williams	12 Registrations each
Dr. Raju	8 Registrations plus 1 no credit
Dr. Cunningham	7 Registrations

We had a great month with 16 treatment registrations in February. Dr. Bonebrake has pulled ahead of the race after putting 6 patients on study this month. We also had 2 enrollments from St. John's in Joplin and 1 from Central Cares in Bolivar in February. Currently, we have 85.3 treatment credits, 4.7 credits below where we need to be to meet NCI's target credit of 120 for this grant year. We have earned 39 cancer control credits. We need to be at 52.5 to be on target to meet the NCI assigned target credit of 70 for this grant year. As the numbers note we are desperately in need of cancer control credits.

Study Profile for February- March

NCCTG N09C6 "Randomized Double-Blind Study of Doxepin Rinse versus Placebo in the Treatment of Acute Oral Mucocitis Pain in Patients Receiving Radiotherapy with or without Chemotherapy" is our profile study this month. Eligibility criteria include currently undergoing a course of radiation therapy (with or without chemotherapy) for a malignancy which involves at least one third of the oral cavity mucosa. Patient must want relief of pain due to mucositis measured by a questionnaire. Performance status of participants must be between 0 – 2. This is a blinded cross-over study where one arm received doxepin swish initially followed by a placebo swish while those on the other arm receives the placebo first and then the doxepin swish. After the blinded portion of the study, patients have the option of continuing the doxepin rinse until completion of radiation therapy.

CRO Drugs Coming to CRO Administrative Office

Moving our research drugs to our administrative office continues to be a work in process. We have drafted a contract for a pharmacy/pharmacist to provide oversight of this endeavor. Once the contract is approved by legal and we find someone to provide this service we will bring the drugs over and begin ordering and receiving the drugs at our administrative office.

March 28th Steering Committee Meeting

We have had a change of speakers for our March 28th meeting. Mark Kozloff MD will speak on "The Use of Avastin-Based Therapy in Metastatic Colorectal Cancer: A Case Based Approach; New Advances in Gastric Cancer. Dr. Kozloff currently is program chairman for the Comprehensive Cancer Program at Ingalls Health System in Harvey, Illinois, lectures at Chicago Medical School and is an Investigator in Phase II studies at the University of Chicago. This CRO Steering dinner meeting will be on March 28th, 2011 at 6PM at Touch Restaurant. Tim England with Genentech BioOncology is assisting with sponsoring this event. Please let us know if you will be attending by calling (417)269-4520 by Thursday, March 24th.

New Studies Approved in January & February 2011

CTSU ECOG E3A06 Randomized Phase III Trial of Lenalodomidide Versus Observation Alone in Patients with Asymptomatic High Risk Smoldering Multiple Myeloma – opened at St. John's only

CTSU ECOG E1908 A Phase II Randomized Trial Comparing Standard and Low Dose Rituximab: Initial Treatment of Progressive Chronic Lymphocytic Leukemia in Elderly Patients Using Alemtuzumab and Rituximab – opened at Cox and St. John's

NCCTG N09C6 Randomized Double-Blind Study of Doxepin Rinse versus Placebo in the Treatment of Acute Oral Mucositis Pain in Patients Receiving Radiotherapy with or without Chemotherapy - opened at St. John's

RTOG 0839 Randomized Phase II Study of Pre-Operative Chemoradiotherapy +/- Panitumumab (IND #110152) Followed by Consolidation Chemotherapy in Potentially Operable Locally Advanced (Stage IIIA, N2+) Non-Small Cell Lung Cancer – Opened and waiting on credentialing at both Cox and St. John's

Studies Closed January & February 2011 :

GOG 229-I A Phase II Evaluation of Brivanib (BMS582664, IND #105029), in the Treatment of Recurrent or Persistent Endometrial Carcinoma

SWOG S0715 Randomized Placebo-Controlled Trial of Acetyl L-Carnitine for the Prevention of Taxane Induced Neuropathy

ECOG E5103 A Double-blind Phase III Trial of Doxorubicin and Cyclophosphamide Followed by Paclitaxel With Bevacizumab or Placebo in Patients With Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer