

CRO Communiqué
Keeping you informed about CRO progress
March 2013

Top Enrolling Physicians for February 2012

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Biggers	1	0	1	1
Dr. Bond	1	0	1	1
Dr. Bonebrake	3	2	2	4
Dr. Carlson	13	5.8	9	14.8
Dr. Ellis	1	1	0	1
Dr. Gillett	1	0	1	1
Dr. Tiriveedhi	1	1	0	1
TOTALS	21	9.8	14	23.8

This has been another great month for accruals. We earned 9.8 much needed treatment credits and 14 control credits. Dr. Carlson earned us 14.8 credits this month. At this time, we are 11.1 treatment credits behind to be on track to meet our NCI target credits of 110 for this grant year. For control credits we are 13 credits above our NCI target of 80 for this grant year. Over all we are 1.9 credits ahead. This is great! Thanks to all of you for placing your patients on clinical trials.

NCI Revised Consent Form

The NCI's Consent Form Template for adult trials has been revised to result in shorter, more concise, consent forms for NCI-sponsored trials. The major changes that have resulted from this review include:

- A "lay" title in addition to the official study title
- Brief description of "usual care" to place research in context
- Text examples of various trial types and phases
- Section limits
- Risks described from a study participant's perspective
- Potential side effects listed using a table format in the "Risks" section

The February 15, 2013 version of the NCI Consent Form Template is attached and posted on the CTEP website at <http://ctep.cancer.gov/protocolDevelopment/>. It will be posted soon on the NCI's website at <http://cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/page3>.

CRO On Facebook

Cancer Research for the Ozarks has a Facebook page! This page will allow patients, health care workers and members of the community stay informed on events occurring around the Ozarks to raise cancer awareness and news released regarding new discoveries in the research community. Make sure to "Like the Page" and keep up with Cancer Research for the Ozarks!

NCORP Update

NCI shared some updated information pertaining to changes in how potential NCORP community sites will be designated on February 8th. It has been decided there will be only two designations: 1) NCORP and 2) NCORP – Minority and Underserved. There will be no tiers within the community components (e.g., no comprehensive or general components as previously presented). Applicants will be required to prepare the best response to the RFA for clinical trials and cancer care delivery research. If funding is sufficient, differential funding will be considered at peer-review and by program. Wortia McCaskill-Stevens, MD, with NCI wrote the concerns expressed by all stakeholders were heard. NCI's goal is to develop a successful research oncology program and a collaborative network within the cancer care community.

CRO Principal Investigator (PI)

Interviews with candidates for our CRO's Principal Investigator position will be held in March.

New CRO Affiliations

Much work is being done at CRO in preparation for the Mercy St. Louis CCOP to become our affiliate. May 31, 2013 is the date for this transaction to officially take place.

New Studies Approved in February 2013

Opened at Cox and Mercy Springfield

CTSUAAlliance A221101 A Phase III Randomized, Double-Blind Placebo Controlled Study of Armodafinil (Nuvigil) To Reduce Cancer-Related Fatigue in Patients with Glioblastoma Multiforme

RTOG 0913 Phase I/II Trial of Concurrent RAD001 (Everolimus) With Temozolomide/Radiation Followed by Adjuvant RAD001/Temozolomide in Newly Diagnosed Glioblastoma

RTOG 1205 Randomized Phase II Trial of Concurrent Bevacizumab and Re-Irradiation Versus Bevacizumab Alone as Treatment for Recurrent Glioblastoma

Studies Permanently Closed to Enrollment at Cox & Mercy in February 2013

NCCTG N0849 Randomized Phase II Trial of Extended Neoadjuvant Therapy for Locally Advanced Adenocarcinoma of the Esophagus, Gastroesophageal Junction, and Gastric CardiaA

NCCTG N0871 A Phase II Study of Carboplatin, Paclitaxel, and Everolimus in Previously Untreated Patients with Measurable Disease with Cancer of Unknown Primary (CUP)

SCUSF Pilot 2011-1 Treatment of painful radiation therapy-induced dermatitis in women treated for breast cancer with whole breast radiation following breast conserving surgery: A pilot study

Studies Temporally Closed to Enrollment at Cox & Mercy in February 2013

RTOG 0929 A Randomized Phase I/II Study of ABT-888 in Combination with Temozolomide in Recurrent (Temozolomide Resistant) Glioblastoma - Bevacizumab failure arm is closed permanently closed. Bevacizumab naïve arm is temporarily closed

GOG 127W A Phase II Evaluation of ABT-888 (IND #77840), Topotecan and Filgrastim or Pegfilgrastim in the Treatment of Persistent or Recurrent Squamous or Non-Squamous Cell Carcinoma of the Cervix