

CRO Communiqué
Keeping you informed about CRO progress
March 2015

Top Enrolling Physicians for February 2015

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Donegan (Mercy St. Louis)	1	0.2	0	0.2
Dr. Carlson (Mercy Spfld)	1	0	1	1
Dr. Ellis (Cox)	1	1	0	1
Dr. Finnie (Mercy St. Louis)	1	0.2	0	0.2
Dr. Hoos (Mercy Spfld)	1	0	1	1
Dr. Miller (Freeman)	1	1.18	0	1.18
Dr. Oza (Mt. Vernon)	1	1	0	1
Dr. Pinhero (Mercy Spfld)	1	1	0.5	1.5
Dr. Sleckman (Mercy St. Louis)	1	0	1	1
Dr. Snider (Mercy Spfld)	3	0.2	2	2.2
Dr. Tiriveedhi (Mercy Spfld)	1	1.2	0	1.2
Dr. Tummala (Mercy Spfld)	1	1	0	1
TOTALS	14	6.98	5.5	12.48

Thank for all your efforts in putting each and every patient that qualifies on trial. Our enrollments remain low for February as noted above. We currently have 48.62 treatment and 47.08 cancer control credits. To be on track to make our 220 credit goal for the year we need to be at 64.17 for both treatment and cancer control credits.

NRG Audit

CRO had a great NRG audit. Seven different NRG auditors were at CRO on February 17, 18 and 19th. The auditors found no major deviations for regulatory or drug accountability. Only 4 major deviations which will require a written corrective action plan were noted. Three of the deviations were for treatment and for not reporting an adverse event. This was great considering 50 charts were reviewed. This is the largest audit in CRO's history. CRO staff were repeatedly complimented by our auditors for our well-organized chart documentation and for being an overall great site. Special recognition and thanks to all our research staff for their hard work each day. You are appreciated!!!

ECOG-ACRIN Audit

CRO will have its first ECOG-ACRIN audit on October 21-23, 2015. CRO will focus our internal auditing efforts of ECOG-ACRIN charts during the next several months.

Study Profile

NRG-BR002 "A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer" is our profile study for the month. The primary objective of the trial is to determine whether ablation (through SBRT and/or surgical resection of all known metastases) in oligometastatic breast cancer patients significantly improves overall survival. Participants are randomized to Oral and IV medications with palliative local treatment as needed (Standard of Care) or Oral and IV medications PLUS Ablative local therapy to all metastases (Experimental arm). Participants must have pathologically confirmed metastatic breast cancer within 270 days prior to registration, ≤ 2 metastases seen on standard imaging within 30 days prior to registration, maximum diameter of individual metastasis in any dimension ≤ 5 cm and maximum diameter of individual metastasis in any dimension ≤ 5 cm. Symptomatic bone metastasis is allowed if ablative therapy can be delivered. Sites for possible surgical excision include lung, liver, adrenal gland, bone, small intestine, large intestine, ovary, and amenable nodal disease sites. Surgical stabilization is allowed for a metastasis if it is followed by conventionally fractionated external beam radiotherapy. Patients with metastasis to the brain are ineligible.

CRO Exceptional Responder Enrollment

CRO has submitted data for 20 exceptional responder patients (11 from Mercy Springfield, 8 from CoxHealth and 1 from Phelps County). Two of Dr. Ellis's exceptional responders have been accepted. Four other submissions have been provisionally accepted which means a board of experts are reviewing them for final

approval. Eight submissions are pending and five have been excluded. Please let your research staff know if you have a patient who you think is an exceptional responder and they will work with you to complete the paper work and submit the tissue.

NCI Administrative Supplement for Blood Samples

Our first webinar for the NCI Administrative Supplement for Blood Samples was held on February 19th. We hope to begin collecting samples in March. All CRO Components will be asked to participate in collecting blood samples and be reimbursed for their submissions.

SWOG Cancer Care Delivery Research Sub-committee

Marilyn Bauer, CRO's Director will begin participating in the SWOG CCDR sub-committee.

New Studies Approved and Opened in February, 2015

Alliance A031201 - Enzalutamide With or Without Abiraterone Acetate and Prednisone in Treating Patients With Castration-Resistant Metastatic Prostate Cancer - Re-opened to Accrual on 02/16/2015

Alliance A091202 - A Phase II Randomized, Double Blinded Study of the Peroxisome Proliferator-Activated Receptor Gamma Agonist, Efatutazone vs. Placebo in Patients with Previously Treated, Unresectable Myxoid Liposarcoma Approved for use by CIRB on 02/13/2015

AEWS 1221 - Randomized Phase II Trial Evaluating the Addition of the IGF-1R Monoclonal Antibody Ganitumab (AMG 479, NSC# 750008, IND# 120449) to Multiagent Chemotherapy for Patients with Newly Diagnosed Metastatic Ewing Sarcoma - Approved for use by CIRB on 02/13/2015

NRG-CC002 - Pre-Operative Assessment and Post-Operative Outcomes of Elderly Women With Gynecologic Cancers Opened to Accrual on 02/10/2015

SWOG S1318 - A Phase II Study of Blinatumomab (NSC-765986) and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients \geq 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib (NSC-732517), Prednisone and Blinatumomab for Patients \geq 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL - Approved for use by CIRB on 02/13/2015

Temporarily Closed Protocols in February, 2015

Alliance A091201 - Randomized Phase II Study Comparing the MET Inhibitor Cabozantinib to Temozolomide/Dacarbazine in Ocular Melanoma - Temp. Closed to Accrual 02/06/2015

ECOG-ACRIN E2906 - A Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs. Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs. Observation in Newly-Diagnosed Acute Myeloid Leukemia in Older Adults (Age Greater Than or Equal to 60 Years) - Temp. Closed to Accrual 02/23/2015

SWOG S1222 - Fulvestrant Alone Versus Fulvestrant and Everolimus Versus Fulvestrant, Everolimus and Anastrozole: A Phase III Randomized Placebo-Controlled Trial In Postmenopausal Patients With Hormone-Receptor Positive Stage IV Breast Cancer - Temp. Closed to Accrual 02/24/2015

Closed Protocols in February, 2015

NSABP B-47 - A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer - Closed to Accrual on 02/10/2015

ECOG-ACRIN E1305 - A Phase III Randomized Trial of Chemotherapy with or without Bevacizumab In Patients with Recurrent or Metastatic Head and Neck Cancer - Closed to Accrual on 02/11/2015

RTOG 1221 - Randomized Phase II Trial of Transoral Endoscopic Head And Neck Surgery followed by Risk-Based IMRT and Weekly Cisplatin versus IMRT and Weekly Cisplatin for HPV Negative Oropharynx Cancer - Closed to Accrual on 02/11/2015