NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

CRO Communiqué
Keeping you informed about CRO Progress

October 2016

Cancer Research for the Ozarks

Enrolling Physicians for September 2016

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Bechtel (Mercy St. Louis)	1	1.1		1.1
Dr. Carlson (Mercy Spfld)	1 + 1 industry	1.05	0.25	1.30
Dr. Dalia (Mercy Joplin)			0.0125	0.0125
Dr. Donegan (Mercy St. Louis)		0.0375		0.0375
Dr. Hanson (Mercy St. Louis)	1	1		1
Dr. Hu (Mercy St. Louis)		0.25		0.25
Dr. Lobins (Cox)		0.2625		0.2625
Dr. Nannapaneni (Cox)	1		0.3125	0.3125
Dr. Verma (Cox)	1	0	0.3125	0.3125
Dr. Pinheiro (Mercy Spfld)	1	0.25		0.25
TOTALS	6	3.95	20.8875	13.01 24.8375 13.01 2.25 13.01

September has been a very slow month for registrations and credits as noted above. We need to average 13.33 credits each month to meet NCI's goal of 160 credits for CRO this grant year. CRO is also making adjustments on how we count registrations and credits to better coincide with NCI. Registrations are based on only one registration per person and tissue screenings are not registrations. We will be checking each month to see if what our enrolling staff put in the NCI's OPEN data base coincides with what is in our CREDIT database.

CRO Annual Report for grant year 2015-2016

The second year of CRO's five year NCI NCORP grant ended on July 31st. During grant year 2015-2016 CRO had 85 NCI registrations which earned us 106.371 (76.107 treatment & 30.264 cancer control) NCI credits. We earned 88% or our NCI treatment credit goal but only 36% of our cancer control goal. Overall we earned 63% of NCI targeted credits for this period. More details for grant year 2015-2016 can be found in CRO's Annual Report which is attached.

PDX Supplement, Tissue + Blood (v3)

CRO has received NCI approval for another Tissue + Blood collection supplement. This is our third year to have been granted this supplement from NCI. This supplement is to collect 36 pairs of tissue and blood from patients with active solid tumors and lymphomas. There is particular interest from the NCI in less prevalent malignancies, such as Small Cell Lung, Pancreatic, Head & Neck, Ovarian and Bladder cancers, as well as Sarcomas, Melanomas, and Non-Hodgkin Lymphomas. CRO staff will be screening patients for eligibility and will work closely with investigators to collect the tissue following NCI guidelines of the patients who consent to this protocol. This is another wonderful opportunity for CRO. CRO component sites are encouraged to participate and will receive $3,000 for each submitted and approved pair.

CTSU's Updates on Three NCTN Precision Medicine Trials

The **Lung-MAP *(S1400**: A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer)* precision medicine trial is making strong progress. After a major revision in December, 2015, Lung-MAP accrual has spiked, with nearly 900 advanced stage squamous cell lung cancer patients registered to date and with nearly 800 open sites across the U.S. Lung-MAP is currently testing five targeted treatments and immunotherapies on squamous patients who have failed at least one line of therapy. Note that patients can be prescreened for the trial during treatment (prior to trial enrollment) before they have

progressed. Lung-MAP was featured in the NCI booth at the ASCO 2016 meeting in June and will be promoted at the 15th Annual International Lung Cancer Congress in Huntington Beach in August. Look for a new online public awareness campaign, powered by lung cancer advocacy groups, this fall. CRO has submitted tissue from 13 patients for this study and 6 have been registered to treatment arms of the study.

The **ALCHEMIST** portfolio now includes a new treatment trial, EA5142*, Adjuvant Nivolumab in Resected Lung Cancer (ANVIL)-a Randomized Phase III Study of Nivolumab*, which was activated on May 6, 2016. This new study, along with the other ALCHEMIST treatment trials (A081105 and E4512), is available for patients who have been registered and screened on A151216 and have completed standard of care adjuvant chemotherapy with or without radiation. Among patients with non-squamous cell lung cancer, patients with an EGFR (+) result will be assessed for A081105 and patients with an ALK (+) result will be assessed for E4512. Non-squamous cell patients with a negative result for both EGFR and ALK, and squamous cell patients will undergo PD-L1 testing if their site has IRB approval for EA5142 at the time of A151216 pre-registration. These patients can then be assessed for the EA5142 trial (in those sites that have EA5142 open for patient enrollment). Patients from sites without IRB approval for EA5142 at the time of A151216 pre-registration will be followed on A151216 and will not be tested for PD-L1. Note: Non-federal funds are now available for EA5142, check the funding sheet for details. CRO has 11 patients registered to A151216 (ALCHEMIST Screening trial). One patient has been registered to A081105 (ALCHMIST treatment).

NCI-MATCH/EAY 131 Enrollment of new patients for tumor testing continues to be brisk for NCI-MATCH/EAY 131, the multi-arm phase II signal-finding precision medicine trial that resumed screening on May 31, 2016, after a pause for an interim analysis. The trial currently has 24 arms, to which it is expected that one in every four to five screened patients will match. The size of the trial has increased to 5,000 patients for screening (up from 3,000) and screening reimbursement is now higher (check the EAY131 Funding Sheet posted on the Match protocol page on the CTSU website). As a result of substantial increases in laboratory capacity, the current median turn-around time for sites to receive tumor profiling results is 13 days. Other recent changes: submission of fine needle aspirate specimens is required in all cases, and sites are now required to submit images (already being collected as standard care) to a central archive for radiomic research. If fresh tissue cannot be obtained, archived tissue obtained â‰¤ (6) six months prior to registration can be submitted for testing in certain cases. Check the master protocol, section 3.1.6.3 for more information. When selecting patients for screening, *please* be sure to consider only those able to withstand being off treatment for up to six weeks (estimated specimen-to-drug interval). Look for five more treatment arms this fall. Seventeen CRO patients have had tissue submitted and the CRO's first trial registration is in process.

Cancer Care Delivery Research (CCDR) Study has IRB Approval

S1415CD, "A Pragmatic Trial to Evaluate a Guideline Based Colony Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia – Trial Assessing CSF Prescribing Effectiveness and Risk (TrACER)". More information is available on the SWOG website at swog.org. The study was approved by the Mercy Springfield IRB on September 16, 2016. Oncology Hematology Associates, Mercy Springfield and Mercy St. Louis will be participating in this trial. This is the first CCDR study in which CRO is participating. We are anxious for this trial to be activated.

CRO Steering Committee Meeting in St. Louis

Dr. Joseph Fay spoke on "A Treatment Option for the Management of Multiple Myeloma in Patients Who Have Had One to Three Prior Therapies" in St. Louis. Dr. Fay is currently Director, Division of Immunologic Therapy for Cancer Baylor Institute of Immunology Research at Sammons Cancer Center, Baylor University Medical Center. Eighteen physicians and research staff from Mercy St. Louis and Mercy Springfield were in attendance.

ACTIVATION OF CIRB Protocols:

ALLIANCE A011401 Randomized phase III trial evaluating the role of weight loss in adjuvant treatment of overweight and obese woman with early breast cancer

SWOG S1416 "Phase II Randomized Placebo-Controlled Trial of Cisplatin with or without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer" – 1.0 Treatment credits plus some specimen submission credits

SWOG S1507 "A Phase II Trial of Trametinib with Docetaxel in Patients with Kras Mutation Positive Non-Small Cell Lung Cancer (NSCLC) and Progressive Disease Following One or Two Prior Systemic Therapies" 1.0 treatment plus specimen

APPROVAL OF Local Protocols:

Alliance A061202 A Phase I/II Study of Pomalidomide, Dexamethasone and Ixazomib vs. pomalidomide and Dexamethasone for Patients with Multiple Myeloma Refractory to Lenalidomide and Proteasome Inhibitor-based Therapy" Open to phase II portion – 1.0 treatment credit

SWOG S1415CD: "A Pragmatic Trial to Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia –Trial Assessing CSF Prescribing Effectiveness and Risk ("TrACER")

Closure through Local IRB:

GOG-0283 A Phase II Trial of DCTD-Sponsored Dasatinib (NSC #732517 IND #73969) In Recurrent/Persistent Ovary, Fallopian Tube, Primary Peritoneal, Endometrial, or Endometriosis-Associated Clear Cell Carcinoma Characterized for the Retention or Loss of BAF250a Expression Temporarily- closed to accrual on 08/10/2016.

CIRB Closures:

A031201 Enzalutamide With or Without Abiraterone Acetate and Prednisone in Treating Patients With Castration-Resistant Metastatic Prostate Cancer- closed to accrual effective 08-31-2016

A011106 ALTernate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A Phase III Studytemporary- closure effective 8-30-2016

A031201 Enzalutamide With or Without Abiraterone Acetate and Prednisone in Treating Patients With Castration-Resistant Metastatic Prostate Cancer-Closed to Accrual effective 8-31-2016

AOST1521 A Phase 2 Study of GPNMB-targeted Antibody-Drug Conjugate, CDX-011 (Glembatumumab Vedotin, CR011-vcMMAE; IND# 128248, NSC# 763737), in Recurrent or Refractory Osteosarcoma-Temporary closure effective 8-11-2016