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

September 2016

Cancer Research for the Ozarks

Top Enrolling Physicians for August 2016

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits
Dr. Carlson (Mercy Spfld)	1 + 2 industry	1.125	0.25	1.38
Dr. Donegan (Mercy St. Louis)	1	0.875		0.875
Dr. Ellis (Cox)	2	1.9188?		1.9188
Dr. Gillette (Cox)	1 + 1 industry		1	1
Dr. Luedke (Mercy St. Louis)	1	1	0.25	1.25
Dr. Miller (Freeman)	1	1		1
Dr. Oza (Mt. Vernon)	1	1.125		1.125
Dr. Raju (Mercy Spfld)	1			
Dr. Sleckman (Mercy St. Louis)	1 industry			
Dr. Tiriveedhi (Mercy Spfld)	1	1		1
Dr. Tummala (Mercy Spfld)	1	0.25		0.25
TOTALS	14	8.2938	2.25 1.5	13.01 12.25 7938 13.01 2.25 13.01

This is the first month of our 3rd grant year of our 5 year NCI NCORP grant. CRO's NCI credit goal for us this grant year (2016-2017) is 165 credits. To meet this goal we need to earn 13.75 credits a month. We are hopeful for a great enrollment year. This month we have ?? enrollments resulting in ?? credits. Our CRO Annual Report noting our accruals for grant year 2025-2016 will be coming out shortly. We are waiting verification from NCI regarding our total credits for the year.

CRO Steering Committee Meeting in St. Louis

On September 27, 2016 Dr. Joseph Fay will speak on "A Treatment Option for the Management of Multiple Myeloma in Patients Who Have Had One to Three Prior Therapies" at 6:00pm at 801 Chophouse in Clayton, Missouri. Dr. Fay is currently Director, Division of Immunologic Therapy for Cancer Baylor Institute of Immunology Research at Sammons Cancer Center, Baylor University Medical Center. He attended Harvard Medical School graduating with honors. He completed his Internship and Residency in Internal Medicine at Duke University Medical Center - Durham, North Carolina. He has extensive experience in research serving as Principal Investigator and authored more than 150 publications many of them addressing multiple myeloma. We hope to see our Component physicians and research staff at Mercy St. Louis, Good Samaritan and Phelps County in attendance. Please RSVP to Miriam Kelley (314) 251-6573 by Friday, September 23, 2016.

Cancer Care Delivery Research (CCDR) Study being Activated

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)". This study is currently being approved by the Mercy Springfield IRB. More information is available on the SWOG website at swog.org. 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 to begin consenting patients for participation.

ALLIANCE A011401

Alliance A011401 "Breast Cancer WEight Loss Study (BWEL Study)"was activated on August 29th. This randomized phase III trial studies whether weight loss in overweight and obese

women may prevent breast cancer from coming back (recurrence). Previous studies have found that women who are overweight or obese when their breast cancer is found (diagnosed) have a greater risk of their breast cancer recurring, as compared to women who were thinner when their cancer was diagnosed. This study aims to test whether overweight or obese women who take part in a weight loss program after being diagnosed with breast cancer have a lower rate of cancer recurrence as compared to women who do not take part in the weight loss program. This study will help to show whether weight loss programs should be a part of breast cancer treatment.

Patient Education

CRO staff have put together a one page educational flyer directing our patients to seek clinical trial education on our new website ozarkscancerresearch.org CRO staff in Springfield will be sharing this page with patients hoping this will assist our patients in answering questions regarding clinical trials and hopefully result in more patient participation. The education page will be attached the email with this Communique.

NCI's New Platform

The National Cancer Institute (NCI), in partnership with the White House Presidential Innovation Fellows (PIFs), announced a plan for re-designing how patients and oncologists find and understand information about available NCI-supported cancer clinical trials. To support this, NCI has launched Clinical Trials Ideas, https://cancerclinicaltrialsideas.cancer.gov, a website to gather ideas from patients, caregivers, advocates, health professionals and technical partners on how to make cancer clinical trials information more accessible. The goal is to ensure that patients and their care teams can access the information they need at the right time to strengthen participation in cancer research. While clinical trials may not be the best treatment option for every cancer patient, many patients, providers, and caregivers could benefit from understanding what options are available and having appropriate clinical trials offered and explained as an option in their cancer care. NCI is seeking ideas about how to make information about cancer clinical trials more accessible for doctors, patients, and caregivers. Can you help? Please share your ideas: http://go.usa.gov/xax65

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.

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.

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

ACTIVATION OF CIRB Protocols:

None

ACTIVATION OF Local Protocols:

None

CIRB Protocols reactivated:

ECOG-ACRIN EA1131 **"**A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Observation in Patients with Residual Triple-Negative Basal-Like Breast Cancer Following Neoadjuvant Chemotherapy

Closure through Local IRB:

Alliance A091305 – Temporary suspension A Phase 2 Randomized Study of Efatutazone, an Oral PPAR Agonist, in Combination With Paclitaxel Versus Paclitaxel in Patients With Advanced Anaplastic Thyroid Cancer

CIRB Closures:

GOG-0281 "A Randomized Phase II/III Study To Assess The Efficacy of Trametinib (GSK 1120212) In Patients With Recurrent Or Progressive Low-Grade Serous Ovarian Cancer Or Peritoneal Cancer" - closed to accrual in US effective 6/29/2016

S1400C Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer **" – Arm C temporarily closed**

CIRB Studies – Follow up terminated:

NSABP B-38 "A Phase III, Adjuvant Trial Comparing Three Chemotherapy Regimens in Women With Node-Positive Breast Cancer: Docetaxel/ Doxorubicin/Cyclophosphamide (TAC); Dose-Dense (DD) Doxorubicin/Cyclophosphamide Followed by DD Paclitaxel (DD AC -> P); DD AC Followed by DD Paclitaxel Plus Gemcitabine (DD AC -> PG)"

ACTIVATION OF CIRB 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 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