



January 2017 Enrolling Physicians for December 2016

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	Tissue Procurement	Cancer Care Delivery Res.
Dr. Bonebrake (Cox)		0.50	0.1375	0.6375	6	
Dr. Carlson (Mercy Spfld)	3 (GOG 3005)	0.25		0.25	1	1
Dr. Creach (Mercy Spfld)			0.0125	0.0125		
Dr. Croy (Mercy Joplin)			0.0125	0.0125		
Dr. Dalia (Mercy Joplin)			0.0125	0.0125		
Dr. Donegan (Mercy St. Louis)	1	1		1		1
Dr. Goodwin (Mercy Spfld)						1
Dr. Hanson (Mercy St. Louis)	1	1.1		1.1		
Dr. Huq (Mercy St. Louis)	1 (PALLAS)	0.125		0.125		
Dr. Nair (Mercy Spfld)	1 (Exc Resp)					
Dr. Raju (Mercy Spfld)			0.0375	0.0375		1
Dr. Sleckman (Mercy St. Louis)	1	1.05	.25	1.3		
Dr. Snider (Mercy Spfld)		.25	0.0125	0.2625		4
Dr. Spencer (Phelps)	1	1		1		
Dr. Tiriveedhi (Mercy Spfld)			0.0375	0.0375		2
Dr. Toothaker (Phelps)	1		0.3125	0.3125		
Dr. Tummala (Mercy Spfld)			0.0250	0.0250		1
TOTALS	5 (NCI Reg)	5.275	0.85	6.125	7	11

December was a good month for tissue procurements and S14215CD enrollments. CRO had 7 tissue + blood specimens submitted, 11 patients enrolled to S1415CD and one Exceptional Responder submission. Our credits remain very low. We need to be at 66.66 credits and we have earned only 34.8375 credits. This is 52.27% of where we should be to reach NCI goal of 160 credits for us this year. Thanks to everyone for doing your best to get our credits up.

Mercy Research Re-organization

The Mercy health ministry has consolidated their research programs and staff into a new, united entity to enable Mercy to leverage their collective talent and resources and to better ensure compliance with all applicable research regulations. As a distinct, non-profit arm of Mercy, Mercy Research is positioned to become a top-tier program for clinical research, product development and data analytics.

On October 16, 2016 JoAnne Levy became the Vice President of Mercy Research. JoAnne brings a wealth of operational experience to this new role which will be invaluable as Mercy continues to strengthen and expand the new Mercy Research structure. For more than five years, JoAnne was a senior leader with ROi with oversight for supply chain operations and integrated sourcing solutions. She previously served for more than 15 years with pharmaceutical giant Covidien/Mallinkrodt where she held a variety of leadership positions in areas including legal, sales & marketing and supply chain logistics. As a result of these varied experiences, JoAnne has exceptional skills in operational management, change management, contracting and industry relations. She is versed in team building with central oversight. In addition to her strong work experience, JoAnne has an executive MBA and law degree from Washington University in St. Louis. CRO's Director, Marilyn Bauer will now report to JoAnne. CRO staff will meet with JoAnne during the January CRO Coffee on Wednesday, January 25th.

A011502 Profile study

"Aspirin in Preventing Recurrence of Cancer in Patients With Node Positive HER2 Negative Stage II-III Breast Cancer After Chemotherapy, Surgery, and/or Radiation Therapy" - This randomized phase III trial studies how well aspirin works in preventing the cancer from coming back (recurrence) in patients with human epidermal growth

factor receptor 2 (HER2) breast cancer after chemotherapy, surgery and/or radiation therapy. Aspirin is a drug that reduces pain, fever, inflammation, and blood clotting. It is also being studied in cancer prevention. Giving aspirin may reduce the rate of cancer recurrence in patients with breast cancer.

The primary objective of this trial is to compare the effect of aspirin versus placebo upon invasive disease free survival (iDFS). Primary objective To compare the effect of aspirin (300 mg daily) versus placebo upon invasive disease free survival (iDFS) in early stage node-positive HER2 negative breast cancer patients. Secondary objectives are:

- To compare the effect of aspirin versus placebo in early stage node-positive HER2 negative breast cancer patients upon distant disease-free survival, overall survival and cardiovascular disease.
 - To compare the toxicity of aspirin versus placebo in early stage node-positive HER2 negative breast cancer patients.
 - To assess adherence to aspirin and placebo among early stage node-positive HER2 negative breast cancer patients.
 - To bank tumor and germline deoxyribonucleic acid (DNA), plasma and urine collected at baseline and sequential plasma and urine collected 2 years later for future measurement of inflammatory markers.
 - To determine if there are subgroups of participants characterized by lifestyle factors associates with greater inflammation for whom there is greater benefit of aspirin versus placebo upon iDFS.
- Patients are followed up to 10 years after study enrollment.

ACTIVATION OF CIRB Protocols:

New Local Protocols:

None

CIRB Protocols:

NRG-GY008 A Phase II Evaluation of Copanlisib (BAY 80-6946), (IND #130822), A Selective Inhibitor of PI3KCA, in Patients with Persistent or Recurrent Endometrial Carcinoma Harboring PIK3CA Hotspot Mutations

SWOG S1513 Randomized Phase II Study of 2nd Line FOLFIRI Versus Modified FOLFIRI with PARP Inhibitor ABT-888 (Veliparib) (NSC-737664) in Metastatic Pancreatic Cancer

CIRB Protocols reactivated:

GOG-0286B – A Randomized Phase II/III Study Of Paclitaxel/Carboplatin/Metformin (NSC#91485) Versus Paclitaxel/Carboplatin/Placebo As Initial Therapy For Measurable Stage III Or IVA, Stage IVB, or Recurrent Endometrial Cancer - Phase III portion of this study opened 12/5/2016

Mercy IRB Protocols reactivated:

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

Closure through Local IRB:

GOG-0270 Groningen International Study On Sentinel Nodes In Vulvar Cancer (GROINSS-V) II: An Observational Study– closed 10/07/2016

ACRIN 6685 A Multicenter Trial of FDG-PET/CT Staging of Head and Neck Cancer and Its Impact on N0 Neck Surgical Treatment in Head and Neck Cancer Patients - closed to accrual eff 12/30/2016

CIRB Closures:

ECOG-ACRIN EAY131 Molecular Analysis for Therapy Choice (MATCH) - Sub-protocol N: suspended to enrollment 11/16/2016

SWOG S1318 – Cohort 2: temporary closure effective 11/15/2016

NRG-BN001 Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation With Concomitant and Adjuvant Temozolomide in Patients With Newly Diagnosed Glioblastoma – Photon Cohort (All CRO Sites) closed to accrual 12/20/2016

NRG-LU001 Randomized Phase II Trial of Concurrent Chemoradiotherapy +/- Metformin HCL in Locally Advanced NSCLC – Closed to accrual eff 12/15/2016

Here is to 2017! We are going to achieve great things by offering our community oncology clinical trials as we work towards finding a cure for cancer. Hope you all have a blessed 2017.

