

CRO Communiqué
Keeping you informed about CRO progress
July 2015

Top Enrolling Physicians for June 2015

Physician	Patient Registrations	Treatment Credits	Control Credits	Total Credits	To Date Registered Exceptional Responders	To Date Tissue Procurement Registrations
Dr. Bond (Phelps County)						2
Dr. Carlson (Mercy Spfld)	1	1		1		4
Dr. Chobanion (Mercy St. Louis)	1		1	1		
Dr. Cunningham (Cox)						1
Dr. Dalia (Mercy Joplin)						13
Dr. Ding (Cox)						2
Dr. Donegan (Mercy St. Louis)						1
Dr. Ellis (Cox)					2	1
Dr. Finnie (Mercy St. Louis)	1	.92		.92		
Dr. Gillett (Cox)	1	1	.40	1.40		3
Dr. Hanson (Mercy St. Louis)	1	1		1		0
Dr. Hassan (Freeman)						1
Dr. Holden (Mercy Spfld)					2	
Dr. Hoos (Mercy Spfld)				0.10		3
Dr. Hu (Mercy St. Louis)						2
Dr. Jaboin (Mercy Spfld)						2
Dr. Kosuri (Mercy St. Louis)						1
Dr. Lafrancis (Mercy Joplin)						3
Dr. Luedke (Mercy St. Louis)						2
Dr. Nair (Mercy Spfld)						1
Dr. Nevils (Phelps)						1
Dr. Oza (Mt. Vernon)	1	0.04		0.04		
Dr. Raju (Mercy Spfld)					1	3
Dr. Rodgers (Mercy St. Louis)					1	3
Dr. Shah (Freeman)						1
Dr. Shunyakov (Central Care)						1
Dr. Sleckman (Mercy St. Louis)						2
Dr. Snider (Mercy Spfld)						4
Dr. Tiriveedhi (Mercy Spfld)	1	1		1		3
Dr. Tummala (Mercy Spfld)						3
Dr. Verma (Cox)						1
TOTALS	7	4.96	1.40	6.46	6	64

We have done an amazing job in collecting blood for our Tissue Procurement Administrative Supplement Collection. As noted above, we have submitted 64 of our 100 tissue samples. We are currently allotting kits for our longitudinal specimen collections and determining how many more registrations we have open before we have reached our 100 submissions. Thank you for making this project a true success. CRO has been the national leader with this initiative. Our accruals remain very low. We earned 6.46 credits this month. Ten months into our grant year we have earned 136.64 credits.

Clinical Trial Billing Webinar

CRO engaged Kelley Willenberg, a nationally recognized expert in clinical trial billing, to present a webinar for CRO research and billing staff on June 17th. Kelly gave a very informative presentation on clinical trial billing and research compliance including how to bill for patients who have Medicare Advantage plans. Forty-five research staff and their institutional billing representatives attended the call. We hope this will result in additional patients being placed on study who have Medicare Advantage plans.

Study Profile

EA1131 “Platinum Based Chemotherapy or Observation in Treating Patients With Residual Triple-Negative Basal-Like Breast Cancer Following Neoadjuvant Chemotherapy” is our profile study this month. This randomized phase III trial studies how well cisplatin or carboplatin (platinum based chemotherapy) works compared to observation in treating patients with remaining (residual) basal-like triple-negative breast cancer following chemotherapy after surgery (neoadjuvant). Drugs used in chemotherapy, such as cisplatin and carboplatin, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. It is not yet known whether cisplatin or carboplatin is more effective than observation in treating patients with residual triple negative basal-like breast cancer.

CRO Steering Committee Meeting

Michelle Hurchla Pyles, PhD was our speaker for our CRO Steering Committee meeting on Thursday, June 11th at Touch Restaurant. The title of Dr. Pyle’s presentation was “An overview of OPDIVO (nivolumab) in Metastatic Melanoma and Squamous NSCLC”. Approximately 25 physicians and research staff attended this event.

Alliance Audit

CRO had another great audit thanks to all CRO research staff. We think we will end up 3 non-compliances for pharmacy, two majors for regulatory and four majors for case reviews. Several of these issues were previously identified by internal auditing and have already been addressed. Until we get the final written report nothing is certain. Our auditors had many wonderful things to say about CRO. We heard compliments such your data quality is very good, your data is very organized and you make it easy to find information. I am feeling very proud of what we do at CRO. SWOG will be auditing us on August 4th, 5th and 6th.

New Studies Approved and Opened in June 2015 with the CIRB

EAY131- Molecular Analysis for Therapy Choice (MATCH)

(We are approved, but the protocol is still in pre-activation)

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

New Studies Approved and Opened in June 2015 with Mercy Springfield’s

IRB

Alliance A211201 - MA.32D - Change in Mammographic Density with Metformin Use: A Companion Study to NCIC Study MA.32

Upcoming Closures:

ECOG-ACRIN E2511 - Phase I and Randomized Phase II Double Blind Clinical Trial of Cisplatin and Etoposide in Combination With Veliparib (ABT-888) or Placebo as Frontline Therapy for Extensive Stage Small Cell Lung Cancer
Closing on 07/02

Temporary Closures:

GOG-0279 - A Phase II Trial Evaluating Cisplatin and Gemcitabine Concurrent with Intensity-Modulated Radiation Therapy (IMRT) for the Treatment of Locally-Advanced Squamous Cell Carcinoma of the Vulva

Temporary Closed on 06/15

ECOG-ACRIN E1A11 – Randomized Phase III Trial of Bortezomib, Lenalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite Duration Lenalidomide Maintenance in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)

Temporary Closed on 06/16

Permanent Closures:

SWOG S1310 - Randomized Phase II Trial of Single Agent MEK Inhibitor GSK1120212 Vs 5-Fluorouracil or Capecitabine in Refractory Advanced Biliary Cancer

Permanent Closure Notice dated 05/15/2015