

CRO Communiqué

Keeping you informed about CRO progress

May 2014

Top Enrolling Physicians for April 2014

| Physician | Patient Registrations | Treatment Credits | Control Credits | Total Credits |
|-------------------------------|-----------------------|-------------------|-----------------|---------------|
| Dr. Bechtel (Mercy St. Louis) | 2 | 2 | 1 | 3 |
| Dr. Bonebrake (Cox) | 1 | 1 | 0.5 | 1.5 |
| Dr. Carlson (Mercy Spfld) | 3 | 0 | 3 | 3 |
| Dr. Ellis (Cox) | 1 | 1 | 0.5 | 1.5 |
| Dr. Graham (Phelps County) | 1 | 1 | 0 | 1 |
| Dr. Hansen (Mercy St. Louis) | 2 | 0 | 2 | 2 |
| Dr. Holden (Mercy Spfld) | 2 | 2 | 0.5 | 2.5 |
| Dr. Pinheiro (Mercy Spfld) | 1 | 1 | 0.5 | 1.5 |
| Dr Raju (Mercy Spfld) | 1 | 1 | 0 | 1 |
| Dr. Verma (Cox) | 2 | 2 | 1 | 3 |
| Total | 16 | 11 | 9 | 20 |

This has been a good month for enrollments. Thank you! Ten physicians participated in earning 20 credits in April plus 0.2 follow-up credits. This gives us 186.4 credits for this grant year. Earning 13.6 additional credits by May 31, 2014 is well within our capability thus qualifying us for the additional funding with the NCORP grant. Please continue to be diligent with screenings and placing patients on trial. Earning 13.6 credits in May is critical for our funding. We will all benefit from additional funding with the NCORP grant. If CRO has more dollars then we can pass more dollars along to our components.

NCI 9-month Accruals for Grant Year 2013-2014

Below is a chart of the NCI 9-month credit accrual statistics (June 2013 – February 2014) for all CCOPs. At the end of February 14, CRO had earned 64.6 treatment credits and 89.9 cancer control credits. As noted below, CRO is in the top 20 CCOP's for total credits earned. We are doing a great job! Thank you for your hard efforts and support, it is paying off.

Achievement of 9-month Treatment Credit Accrual

63 CCOP/MCCOPs Range 1 –180

Achievement of 9-month Cancer Control Credit Accrual

63 CCOP/MCCOPs Range 1 - 161

Achievement of 9-month TOTAL Credit Accrual

63 CCOP/MCCOPs Range 0 -343

| Number of CCOPs/MBCCOPs (%) | 9-month Credit Accrual | Number of CCOPs/MBCCOPs (%) | 9-month Credit Accrual | Number of CCOPs/MBCCOPs (%) | 9-month Credit Accrual |
|-----------------------------|------------------------|-----------------------------|------------------------|-----------------------------|------------------------|
| 2(3%) | 95 - ≥ 100 | 8 (12%) | 95 - ≥ 100 | 20(31%) | 95 - ≥ 100 |
| 6(9%) | 76 - 94 | 3(5%) *CRO 89.9 | 76 - 94 | *CRO 154.5 | 76 - 94 |
| 12(19%) *CRO 64.6 | 51 - 75 | 9(14%) | 51 - 75 | 13(20%) | 51 - 75 |
| 21(33%) | 26 - 50 | 16(25%) | 26 - 50 | 12(19%) | 26 - 50 |
| 23 (36%) | ≤ 10 - 25 | 28 (44%) | ≤ 10 - 25 | 11(17%) | 26 - 50 |
| | | | | 8(12%) | ≤ 10 - 25 |

Status of the CCOP NCORP Program Transition

On April 10, 2014 CRO received a letter from Harold Varmus MD, NCI's Director in response to a letter sent by CCOP PIs regarding the lack of NCI funding support for the month of June, July and August, 2014. Dr. Varmus announced there would **not** be a funding gap before the NCORP program begins and the NCORP program is now scheduled to begin on August 1, 2014. **This is great news!** Much confusion and uncertainty remains but we will continue to enroll and care for our patients on clinical trials.

CRO Steering Committee

We will have a CRO Steering Committee meeting on Thursday, May 15th. Kelly McCaul, MD, Director of the Avera Hematology and Transplant Program in Sioux Falls SD will speak to us on "A New Treatment Option in Previously Treated Chronic Lymphocytic Leukemia and Mantle Cell Lymphoma". Please RSVP to 417-269-4520 by Friday, May 9th.

New Studies Approved in April, 2014 Through Cox and Mercy's IRB

GOG 0283 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

New Studies Approved in April, 2014 Through Mercy's IRB

ECOG E1412 "Randomized Phase II Open Label Study of Lenalidomide R-CHOP (R2CHOP) vs RCHOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients With Newly Diagnosed Diffuse Large B Cell Lymphoma"

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"

GOG 3004 SOLO-1 "A Phase III, Randomised, Double Blind, Placebo Controlled, Multicentre Study of Olaparib Maintenance Monotherapy in Patients with BRCA Mutated Advanced (FIGO Stage III-IV) Ovarian Cancer following First Line Platinum Based Chemotherapy

New Studies Approved and Opened in April with the CIRB

Alliance A091105 "A Phase III, Double Blind, Randomized, Placebo-Controlled Trial of Sorafenib in Desmoid Tumors or Aggressive Fibromatosis (DT/DF)

ECOG E1912 A Randomized Phase III Study of Ibrutinib (PCI- 32765)-based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)

ECOG E2112 Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Postmenopausal Patients with Hormone Receptor-Positive Advanced Breast Cancer