
Cancer Research for the Ozarks

A Community Clinical Oncology Program

Springfield, Missouri

**The Year in Review
2013-2014**

Cancer Research for the Ozarks

The Year In Review 2013-2014

As I see it



Jay W. Carlson, DO
Principal Investigator

It is my pleasure to review some of the highlights of the past grant year for Cancer Research for the Ozarks (CRO). This last year, we experienced new challenges nationally and locally. On a national level, we had a very short stressful period of just 60 days to submit our grant through the new NCI Community Oncology Research Program (NCORP) process. We are still waiting for the final funding news. We also witnessed further integration of the NSABP, RTOG and GOG to the consolidated “NRG”. It is my perception that these national issues affected the availability of protocols for cooperative groups and that patient enrollment was lower because of this process. Locally, we also completed the integration of our new affiliates Mercy Hospital St. Louis in St. Louis, Missouri and Good Samaritan in Mt. Vernon, Illinois. We have improved the transparency of our CRO Board meetings for component PI participation through WebEx. CRO’s Executive Board made the decision to increase the accrual goals so that they were more in align with the American College of Surgeon’s research approaching accrual goals of 4% to 6% of the analytic cancer cases. As a team, we had great involvement and commitment earning 98 treatment and 107.4 control credits representing 75% and 77% of our Executive Board target, respectively. Forty-six CRO research investigators participated in making this happen! With this, we exceeded a threshold of 200 credits, a new benchmark set by the NCI that will allow us to receive additional funding for our registrations with the NCORP grant.

Our education program continues with offerings of national speakers on current oncology topics as part of the Steering Committee meetings. Investigators and staff have attended a variety of cooperative group meetings throughout the year. These are great opportunities to share our experiences with other like professionals, to learn about protocol results and to participate in discussions of upcoming protocols/studies.

The upcoming year will be a busy one as we increase our patient screening processes and evolve locally to adapt to the new NCORP processes. These reorganizations and “new rules” will continue to require considerable work for us to remain competitive in this new program. But I believe we can do it and that we are very well positioned to continue to provide outstanding investigative therapies for our patient population.

I want to thank all the participating providers and members of the CRO team for their outstanding work and commitment to our research efforts. CRO’s success is due to your dedication and strong belief that state of the art cancer treatment can only be achieved through clinical trials.

Progress Report

Marilyn Bauer, BSN, MEd, MHA, CRO Director

CRO's PI, Dr. Robert Carolla Retires

In the spring of 2013, Dr Carolla announced his plan to retire as CRO's Principal Investigator effective May 31, 2013. CRO is very grateful to Dr. Carolla for the inspiring leadership he provided for CRO during the previous five years. His great dedication to research and years of exceptional leadership have been instrumental in the success of CRO and in bringing other CCOP's to seek us out.

Dr. Jay W. Carlson, New CRO Principal Investigator

It was with great pleasure CRO announced Jay Carlson, DO accepted the position of Principal Investigator for Cancer Research for the Ozarks and Al Bonebrake, MD accepted the position of Associate Principal Investigator. Dr. Bonebrake and Dr. Carlson have a great interest in research and have been strong supporters of CRO with high clinical trial enrollments. Their knowledge and dedication to cancer research will lead CRO forward to embrace future opportunities.

CCOP Program Transitioning to NCORP

Approved in June 2013, the NCORP (NCI Community Oncology Research Program) will replace the Community Clinical Oncology Program (CCOP) Minority-Based Community Clinical Oncology Program (MB-CCOP) and the National Community Cancer Center Program (NCCCCP). NCORP adds Cancer Care Delivery Research (CCDR) to existing CCOP research priorities of treatment studies, cancer control and prevention studies, and increasing enrollment of underrepresented groups. Cancer Care Delivery Research (CCDR) is a new focus for the NCORP grant. Exactly what is involved with CCDR is unclear at this time. We anticipate CCDR will involve genetic counseling, disparities, quality care, survivorship, economic analysis and biospecimens.

NCORP Grant

NCI released the NCORP grant application on November 8, 2013. Applicants were given a very short time frame of 60 days to complete their applications. CRO's NCORP grant application was sent to NCI on January 6, 2014. CRO is well positioned to be an NCORP site and eager to participate in the new cancer care delivery research component of the grant. The new NCORP program will begin on August 1, 2014. CRO is anxiously awaiting the announcement of recipients.

New CRO Components

In March of 2013, the CRO Executive Board agreed to add Mercy Hospital St. Louis in St. Louis, Missouri and Good Samaritan in Mt. Vernon, Illinois as CRO components effective June 1, 2013 to ensure continued access to the patients served by these sites. With the addition of Mercy Hospital St. Louis and Good Samaritan, CRO expanded its access to patient populations by 38%.

The St. Louis Cape Girardeau CCOP had been an independent CCOP since the program's inception and had a prestigious history. Despite aggressive remedial

efforts from 2011 to 2012, NCI funding was terminated at the end of the 2012-2013 grant year for the Mercy St. Louis's CCOP.

CRO was also contacted by the Heartland CCOP in St. Louis regarding a partnership. After exploration this was not a workable option for CRO.

NCI's CIRB

In preparation for the NCORP grant CRO began networking with the CIRB in April of 2013. Since September of 2013, NCI's CIRB provides oversight for the majority of the cancer treatment trials from the NCTN (NCI Clinical Trials Network) Groups conducted at all CRO component sites. All CRO components now utilize the CIRB and CoxHealth or Mercy Springfield IRB's as their IRB of record. CRO is looking forward to using the CIRB as available for future trials. CRO will continue to use the CoxHealth and Mercy Springfield's IRB for MDAnderson, SunCoast, Wake Forest and NCI trials not covered by the CIRB.

CRO Components Representatives Invited to Join CRO Executive Board

In September 2013, CRO Executive Board extended an invitation to CRO component sites to appoint a physician representative to join the board meetings via the WebEx tool. This was done as a means to encourage greater collaboration and increased enrollments. Component research staff are invited to participate in the monthly CRO new study meetings also using the WebEx tool.

Congratulations to Dr. Carlson

Congratulations Dr. Carlson! Dr. Carlson was recognized at the CCOP PI and Administrators meeting at NIH on September 20th with a Platinum Certificate of Excellence for his contributions to NCI clinical trials during grant year 2012 - 2013. Dr. Carlson had 80 enrollments resulting in 69.2 credits during grant year 2012 - 2013.

Dr. Carlson National Study Chair

Dr. Carlson, CRO's PI is the National Principal Investigator and Study Chair for GOG-0269, "A limited access phase II trial utilizing bioimpedance to measure lower extremity lymphedema associated with the surgical management of a vulvar cancer." Dr. Carlson is the National Co-Chair for GOG-0244, "LymphEdema and Gynecologic cancer (LEG) study: incidence, risk factors and impact." He serves on the Ancillary Data Subcommittee and Cancer Prevention and Control Committee at GOG.

Basava Raju NRG Auditor

Basava Raju, CRO's Clinical Research Coordinator III has been selected to serve as an Alliance auditor. His first audit with Alliance will be in September 2014. Basava previously served as a SWOG auditor. Information gained from serving as a research base auditor is very beneficial for CRO. Many changes have been made at CRO as a result of knowledge gained from Basava serving in this manner.

CRO Steering Committee meetings

CRO's Fall Steering Committee meeting was held on Thursday, November 21st. Joseph M Anderson, MD, FCAP from Redwood City, California spoke on "Genomics in Cancer Treatment the Past, Present and the Future". Thirty-four attended this

evening of education and fellowship.

CRO Spring Steering Committee was held on Thursday, May 15, 2014 at TOUCH Restaurant. Dr. Kelly McCaul, MD, Director, Avera Hematology and Transplant Program at Avera Cancer Institute in Sioux Falls, SD spoke on “A New Treatment Option in Previously Treated Chronic Lymphocytic Leukemia and Mantle Cell Lymphoma”. Fifteen research physicians and staff attended this event.

Asad Dean, MD from Texas Oncology in Fort Worth, Texas will be the speaker at a CRO Steering Committee meeting on June 18th at 6PM in St. Louis. The title of this presentation is “A New Treatment Option in Previously Treated Chronic Lymphocytic Leukemia and Mantle Cell Lymphoma.” This event will be held at the Fleming Prime Steakhouse & Wine Bar. Several CRO Springfield staff will attend and Dr. Carlson will be available to speak with the group via WebEx.

CRO Screening Report

Another step CRO took in preparation for the NCORP grant was to update their screening processes. At the CCOP Principal Investigators and Administrators meeting in September 2012, participants were presented with a patient screening tool that collected data from patient screenings. CRO worked with its database developers to modify their current pre-screening tool to collect additional information making it comparable with the proposed screening tool presented by NCI.

CRO staff, including all component staff, now place data in the pre-screening tool of the database as they screen patients for clinical trials. The entered information is tallied for each CRO site monthly. After reviewing the report, the CRO Director sends it to the administrators and staff at each component noting any needed changes. The CRO Executive Board reviews compiled data and makes recommendations for change. From patient screening documentation, CRO hopes to be able to objectively evaluate opportunities to enhance enrollment to trials.

Acuity Tool Instituted at CRO

CRO started using a protocol acuity tool to assist in determining work load in January 2013. As new studies are reviewed by CRO, staff assigns the trial an acuity score. The 4 point protocol acuity tool has been piloted at several other CCOPs. CRO's Director is calculating accrual points to assess staff workload.

CRO On Facebook

Cancer Research for the Ozarks has a Facebook page! This page allows patients, health care workers and members of the community to stay informed on events occurring around the Ozarks to raise cancer awareness and news released regarding new discoveries in the research community.

Research Base Memberships

Seven research bases will be funded with the NCORP grant. Four adult cooperative and one pediatric (Children's Oncology Group) research bases are funded through the National Clinical Trials Network. These four are Alliance, ECOG-ACRIN, NRG and SWOG. The two cancer center research bases rumored to be funded are Wake Forest University and University of Rochester (URC).

CRO is affiliated with Alliance, NRG, SWOG, and Wake Forest University. We are working to affiliate with ECOG-ACRIN and University of Rochester.

Mercy St. Louis is the only CRO component working with the Children's Oncology Group (COG). The St. Louis Cape Girardeau CCOP received formal approval to join COG in June 2011 as part of their effort to increase accruals to NCI clinical trials. Mercy St. Louis was affiliated with COG prior to joining CRO as a component.

Research Base Meeting Attendance

Research Base meeting attendance is encouraged as approaching research changes and new trials are discussed. Marilyn Bauer, CRO's Director attended the PI and Administrators conference at NIH in Bethesda, Maryland on September 20, 2013. Dr. Robert Ellis and Dr. Brian Biggers attended the SWOG fall conference in Chicago on November 9 – 11, 2013.

Drs. Carlson, Bonebrake, Abdalla and CRO's Director attended the NRG meeting on February 5 – 7th in San Diego. Dr. Roger Holden and research nurse Michelle McKenzie attended the SWOG conference in San Franois on May 8 – 10, 2014. Marilyn Bauer, CRO's director attended the Alliance conference in Chicago on May 8-10, 2014.

Terry Fox Run

Terry Martin, a nurse anesthetist in Bolivar at Citizens Memorial Hospital, started a local Terry Fox Run to benefit CRO. Terry Martin was inspired by Terry Fox while a teenager as he struggled with the challenges of spinal bifida. The run was held September 28, 2013 at Southwest Baptist University in Bolivar. Terry Martin's plan is to make this an annual event to benefit CRO. This year's run raised \$750.

Bringing together CRO Components

As CRO has grown geographically, the need to bring together the components is recognized. While each of the nine CRO components (CoxHealth, Mercy Springfield, Mercy Joplin, Freeman Health System, Cox Medical Center Branson, Central Care, Phelps County, Mercy St. Louis and Good Samaritan) have the resources to support NCI-sponsored clinical trials research, CRO recognizes the need to provide ongoing training, education, outreach, and oversight to ensure maximum participation while ensuring patient safety especially as NCORP expands the scope of discovery. The following activities enhance component communication and coordination:

- Site PI's are invited to participate in the CRO Executive Board meetings via the WebEx tool.
- A monthly CRO Communiqu  listing trial enrollments, open and closed studies, study profiles and CRO events is sent to investigators, research staff, and others interested CRO.
- An annual CRO report is published and distributed at the end of each grant year.
- CRO Steering meetings are held biannually. These meetings consist of an update of CRO events and presentation with nationally recognized speakers.

- CRO Springfield staff travel to other components for internal audits and to encourage enrollments with investigators annually.
- CRO's Director sends a 'Marilyn's Message' to enrolling staff on a weekly or as needed basis
- CRO component research staff are invited to participate in the CRO monthly new study meetings via the WebEx tool.
- The CRO Administrative Office is available to assist all components including new staff orientation, assistance with the CREDIT database, checking eligibility criteria, etc.

The Springfield administrative office provides centralized coordination of administrative and quality assurance including regulatory compliance, research board coordination, internal and external monitoring and auditing, physician and staff credentialing, and general administrative management. CRO staff conducts regular site visits.

Quality

CRO rises or falls on the quality of its research and the reliability of its data and documentation. CRO's administrative team helps ensure the bar remains high. Basava Raju, CRO's Research Compliance Coordinator reviews all new CRO staff and new component staff documentation for the first six months or longer if needed. He performs an internal audit of local staffs charts quarterly.

Members of the Administrative team traveled to St. Louis to meet with the Mercy St. Louis staff and to conduct an internal audit on November 4, 2013. The same group performed an internal audit at Freeman Cancer Center in Joplin, Missouri on April 15, 2014. Research staff from Phelps County and other components frequently travel to Springfield for Basava to assist them and audit their documentation while they sit and observe. This is a great learning experience for new staff.

CRO Staff

CRO Springfield staff includes the director, office manager, regulatory compliance coordinator, clinical research coordinator, 4.5 registered nurses and 3 clinical research assistants.

CRO welcomed two new research nurses at the Hulston office this year. Janna Jones, RN in September 2013. Janna is a thyroid cancer survivor who had seven years of nursing experience. Michelle McKenzie, RN joined CRO in April 2014. Michelle has two years of oncology experience and is OCN certified. Michelle assumed a research position at Hulston as a nurse retired.

The four full time research nurses and two clinical research assistant who enroll patients in Springfield at CRO accrued 150 registrations this past grant year. This is approximately 25 registrations per staff. CRO's research nurses enroll to treatment trials and clinical research assistants enroll to cancer control trials under the guidance of the research nurses and clinical research coordinator. CRO's clinical research coordinator, PRN research nurse and follow –up clinical research assist

clinical staff as needed, staffing for vacations performing internal auditing and providing staff education on clinical trial documentation.

CRO Enrollments to Clinical Trials

CRO enrolled 259 patients to clinical trials in grant 2013-2014. 124 were enrolled to treatment trials and 135 patients were enrolled to cancer control trials. This resulted in 98 treatment and 101.8 cancer control trials credits for a total of 205.4 credits. Trial availability was sluggish this year as research bases were re-organizing and fewer trials were available.

Achieving Target Credit Goals

Grant year 6/1/2013- 5/31/2014 was unlike previous years for CRO enrollments to clinical trials. NCI assigned CRO target credits of 75 for treatment and 75 for cancer control. Knowing that NCI's expectation was much lower than in the past years and CRO had added two new components, CRO's Executive Board made the decision to increase CRO's target goals. The Executive Board set CRO's target treatment credit goal at 130 and cancer control credit goal at 140 for this grant period. CRO earned 98 treatment credits which was 75% of our Executive Board target. CRO earned 107.4 control credits which was 77% of our target accrual credits of 140 set by the Executive Board. Forty-six CRO research investigators participated in making this happen.

Achieving over 200 credits was a big goal for CRO this period as NCORP grant recipients will receive \$4,000 per credit if they have earned over 200 credits for the past three consecutive years. If recipients have earned less than 200 credits over the past years, they will be reimbursed at \$2,500 per credit with NCORP. Earning 205.4 credits made this goal a reality.

CRO's PI, Dr. Jay Carlson was the number one enroller this grant year. Dr. Carlson and his staff enrolled 61 patients earning 47.7 credits. Dr. Carlson registered 25.6% of CRO's total registrations this past year.

Credits are different from registrations. A registration is defined as one patient enrolled into one trial. Registrations tell us the number of patients in particular trials. Not all enrollments receive credit. Credits are the NCI value assigned to each trial registration. This past year, CRO had 238 registrations for credit, and 21 no-credit registrations, for a total of 259 registrations. Of that total, our nine components, (Mercy Joplin, Freeman Health, Cox Branson, Central Cares PA, Phelps County, Mercy St. Louis and Good Samaritan) contributed 109 registrations. Our components contributed 42% of our total registrations this grant year. Last grant year our components contributed 10.9% of our total registrations.

CRO Finances

CRO is supported by the generosity of our two sponsoring health systems, CoxHealth and Mercy Springfield. Since the beginning of CRO in 1987, these institutions have generously supported cancer research in our community by equally absorbing dollars not provided by our grant each year. CRO works hard to control expenses. The two tables below compare our FY 2012-2013 and FY 2013-2014 revenues. Accounting, lab, radiology services and office space for staff are just a few of the many benefits our sponsors provide for CRO which are not reflected in the numbers below.

CRO's grant award was amended as were other CCOP grants to include funding for June and July 2014. This was done due to the NCORP program starting on August 1, 2014. The additional funding was needed to eliminate a two month funding gap. The data below is for June 1, 2013 – May 31, 2014 funding only.

Revenues	Fiscal Year 2012-2013
Federal	726,587
Other	133,024
Total Revenues	859,611
Total Expenses	854,031
Remainder **	5,580

Revenues	Fiscal Year 2013-2014
Federal	\$724,590
Other	\$137,323
Total Revenues	\$861,913
Total Expenses	\$888,764
Deficit *	\$26,851

*The deficit is split equally between CoxHealth and Mercy Springfield
 Fiscal year 2013 -2014 – Deficit \$26,851
 **Fiscal year 2012-2013 – Remainder was \$5,580

Meeting the CRO Goals for 2013-2014.

Last year, CRO defined goals. Below are the goals and our progress in meeting these goals.

CRO Goals	Achievements
Goal 1. Increase accruals to NCI clinical trials	
<ol style="list-style-type: none"> 1. Exceed our NCI target treatment credits for the grant year by 1%. 2. Exceed our NCI cancer control credits for grant year by 2%. 3. Bring on board the St. Louis Mercy CCOP and Good Samaritan in Mt. Vernon, Illinois, as CRO components. Explore an affiliation with Ozark Medical Center in West Plains. 4. Explore collaboration with the Heartland CCOP in St. Louis. 5. Document 100% of patient screening for clinical trials in the CREDIT database. 6. Amend affiliate contracts to pay them \$500 per enrollment and if they exceed 3.5% of their past year's analytic tumor registry cases, pay them an additional \$500 per 1 credit registration. 7. Continue to update trials opened and closed each month in the CRO Communiqué. 8. Continue to profile a new study each month in the CRO Communiqué. 9. Update pocket list of studies available bi-monthly and deliver to investigators at all sites. 10. Successfully submit a NCORP grant application when the RFA becomes available. 11. When announced market the NCORP program to the Springfield and St. Louis community with print, 12. TV, radio and electronic media announcements. 	<ol style="list-style-type: none"> 1. CRO earned 98 treatment credits this grant year. We fell short of our Executive Board assigned treatment goal of 130 by 32 credits or 25%. We exceeded NCI goal of 75 assigned credits by 23 or 31%. 2. CRO exceeded NCI assigned control target credits of 75 by 32.4 credits or 30%. Earning 107.4 control credits, CRO fell short of our Executive Board assigned credit of 140 by 32.6 credits or 32%. 3. Mercy St. Louis and Good Samaritan in Mt. Vernon, Illinois became CRO components on June 1, 2013. 4. CRO explored this option but did not bring on Ozark Medical in West Plains. 5. CRO explored this opportunity but it did not result in an affiliation. 6. CRO staff document clinical trial screenings in the CRO CREDIT data base. Monthly screening data is reviewed for each site. 7. Affiliate (Component) contracts were revised to pay components \$500 per enrollment and if they exceed 3.5% of their past year's analytic tumor registry cases, pay them an additional \$500 per 1 credit registration. 8. Newly opened and closed trials are shared each month in the CRO Communiqué. 9. A new study is profiled in the monthly Communiqué when space is available. 10. CRO's pocket list of studies are updated and delivered every other month to investigators at all sites. 11. CRO's NCORP grant application was submitted on January 6, 2014. 12. The NCORP grant is scheduled to begin on August 1, 2014. CRO is anxiously awaiting notification of the award.

<p>Establish a BioSafety Committee at both Cox and Mercy Springfield allowing CRO to participate in vaccine trials.</p>	<p>13. The development of a Bio Safety committee was explored and is currently on hold at Mercy Springfield.</p>
<p><u>Goal 2. Improve communication efforts to keep CRO investigators and health care extenders aware of clinical trial availability</u></p>	
<p>14. Visit yearly with physicians and staff at each of our components to offer assistance and encourage enrollment to trials</p>	<p>14. Marilyn Bauer, Basava Raju, Debbie Cane and Sharon Brown traveled to St. Louis for a tour and internal audit with our Mercy St. Louis component on November 6, 2013. They traveled to Joplin for an internal audit and visit with Freeman on Tuesday, April 15, 2014. Research staff from other components traveled to Springfield for internal auditing of their documentation.</p>
<p>15. Hold twice yearly CRO Steering Committee meetings with national speakers on new cancer therapies and treatments.</p> <p>16. Invite affiliate research staff to join in on CRO's monthly review of new studies available using the WebEx tool.</p>	<p>15. On Thursday, November 21st Joseph M Anderson, MD FCAP from Redwood City, California spoke on Genomics in Cancer treatment the past, present and the future. On Thursday, May 15, 2014 at TOUCH Restaurant. Dr. Kelly McCaul, MD, Director, Avera Hematology and Transplant Program at Avera Cancer Institute in Sioux Falls, SD spoke on "A New Treatment Option in Previously Treated Chronic Lymphocytic Leukemia and Mantle Cell Lymphoma.</p> <p>16. In September 2013, CRO's Executive Board invited a physician representative from all seven CRO components to join our monthly or every other month CRO Executive Board meeting via the WebEx tool.</p>
<p><u>Goal 3. Ensure quality at CRO</u></p>	
<p>17. Successfully submit a NCORP (NCI Community Oncology Research Program) grant application when RFA available</p> <p>18. Convert IRB approval for all NCI cooperative groups Phase III and Phase II when it Becomes available to the CIRB</p> <p>19. Audit all new research staffs' (including components) documentation for the first six months of employment or as deemed necessary.</p> <p>20. Randomly select at least one patient record from each staff enrolling patients for quarterly internal auditing.</p>	<p>17. See # 11 above.</p> <p>18. CRO began using the CIRB for all available NCI studies in September of 2013.</p> <p>19. This is ongoing. Basava Raju, CRO's educational staff trainer reviews documentation for all new staff and component staff for the first six months of their time at CRO and randomly thereafter.</p> <p>20. Ongoing – See # 19 above.</p>

<p>21. Work for improved quality assurance at CRO and its COMPONENTS with:</p> <ul style="list-style-type: none"> • Maintain timely and accurate data submission. • Respond to queries in a timely manner to address those that occur. 	<p>21. On-going. During the first week of each month, delinquent data or un-responded queries are downloaded from the research bases websites for each research staff. The Director forwards the list to each staff member reminding them to respond to queries in a timely manner and to submit all delinquent data.</p>
<p><u>Goal 4. Promote CRO on a National Level</u></p>	
<p>22. Recruit a new PI for CRO</p> <p>23. PI and director to volunteer on NCI Committees</p>	<p>22. Jay Carlson DO became the PI and Al Bonebrake MD became the Associate PI for CRO on June 1, 2013 as Dr. Robert Carolla retired.</p> <p>23. Dr. Carlson serves on the Ancillary Data Subcommittee and Cancer Prevention and Control Committee at GOG/ NRG. Basava Raju is serving as an auditor for NRG. Marilyn Bauer has submitted her request to serve on the Alliance Prevention Committee.</p>

Cancer Research for the Ozarks grant year 2014-2015

Goals & Opportunities for CRO for Grant Year 2014 -2015

The CRO Executive Board met on June 11, 2014 and approved the following goals for grant year 2014- 2015.

Goal 1. Increase accruals to NCI clinical trials

- Obtain an NCORP grant
- Exceed NCI's treatment credit goal by 2% during grant year 2014-15
- Exceed NCI's cancer control credit goal by 2% during grant year 2014-15
- Develop Cancer Care Delivery Research at Cox and Mercy Springfield
- Explore "Trial Prospector" for patient screening when available
- Explore instituting a clinical trial educational course for patients such as Pre-Act
- 100% of all cancer patients be screened at all CRO component sites

Goal 2. Improve communication efforts to keep CRO investigators and staff aware of clinical trial availability

- Visit yearly with physicians and staff at each of our components to offer assistance and encourage enrollment to trials
- Hold twice yearly CRO Steering Committee meetings with national speakers on new cancer therapies and treatments
- Hold one CRO Steering Committee meeting in St. Louis allowing those far away to attend
- At least two CRO research staff will work with the economically poor (unrepresented group for our community)
- Explore concept of assigning different PIs for each research base

Goal 3. Ensure quality at CRO

- 75% of CRO's clinical research professionals will be credentialed as certified research professionals or oncology nurses
- Randomly select at least one patient record from each staff enrolling patients for quarterly internal auditing
- Work for improved quality assurance at CRO and its components with:
 1. Maintaining timely and accurate data submission
 2. Responding to queries in a timely manner to address those that occur

Goal 4. Promote CRO on a National Level

- When announced market the NCORP program to the Springfield community with print, TV, radio and electronic media announcements
- Encourage new investigators to become involved in NCI trials locally and at a national level
- Strive to have a CRO representative involved on committees at all NCI research bases

Protocol Reports: 2-Year Comparison of Registrations & Credits

Treatment

RESEARCH BASE	2012-2013 REGISTRATIONS	2012-2013 CREDITS	2013-2014 REGISTRATIONS	2013-2014 CREDITS
COG	-	-	6	10
CTSU	21	15.7	50	29.6
GOG	42	38.5	33	23.2
MD Anderson	0	0	0	0
NCCTG	3	3	1	1
NSABP	26	26.2	15	15.2
RTOG	1	1	10	10
SWOG	9	9.5	9	9
<i>SunCoast</i>	0	0	0	0
<i>Wake Forest</i>	0	0	0	0
Grand Totals	102	93.9	124	98

Cancer Control & Prevention

RESEARCH BASE	2012-2013 REGISTRATIONS	2012-2013 CREDITS	2013-2014 REGISTRATIONS	2013-2014 CREDITS
COG	-	-	9	9
CTSU	12	6.0	22	15.5
GOG	64	53.5	46	40.5
MD ANDERSON	0	0	0	0
NCCTG	7	6.8	0	0
NSABP (new)	19	17.2	10	7
NSABP (follow up visits)	14	2	21	2.3
RTOG	0	0	5	2.3
SunCoast	1	1	4	4
SWOG (new)	12	12	38	22.5
SWOG (follow up visits)	0	0	11	3.3
WAKE FOREST	11	11	1	1
Grand Totals	140	109.5	167	107.4

Registrations by Affiliate/Site (Follow up credits not included)

Component/Affiliate*	2012-2013 REGISTRATIONS	2012-2013 CREDITS	2013-2014 REGISTRATIONS	2013-2014 CREDITS
Central Care, PA	4	3.2	2	1.5
Cancer Hematology Center	41	42.4	49	33.2
Cox Surgeons	14	14	0	0
Ferrell-Duncan Clinic Gynecological	26	21.8	17	15
Freeman Medical Center (Joplin)	10	8.5	16	7.9
Good Samaritan	-	-	18	8.2
Mercy Joplin	3	3	2	2
Mercy Clinic Rolla	2	1.1	2	2
Mercy St. Louis	-	-	60	43.3
Phelps County Regional Medical Ctr.	3	3.2	6	5.3
Oncology Hematology Associates	40	32.5	31	23.2
Radiation Therapy Center Cox	2	2.1	1	1
Cox Medical Center Branson	5	2.3	0	0
Mercy Women's Oncology Care	80	69.2	61	47.7
Mercy Springfield's Radiation Oncology.	0	0.1	5	4
No Credit at Mercy	12	0	1	0
St. Louis Cancer & Breast Institute	-	-	21	11.10
Grand Totals	242	203.4	291 +1(0 credit)	205.4

All-inclusive 12-month Accrual for All Types of Protocols by Research Base

RESEARCH BASE	2012-2013 REGISTRATIONS	2012-2013 CREDITS	2013-2014 REGISTRATIONS	2013-2014 CREDITS
Children's Oncology (COG)	-	-	15	19
CTSU	33	21.7	70	43.6
GOG	106	92	79	63.70
MD ANDERSON	0	0	0	0
NCCTG	10	9.8	3	2.5
NSABP	45	43.4	25	22.2
RTOG	1	1	15	12.3
SWOG	21	21.5	47	31.5
Suncoast	1 + 6	1	4	4
WAKE FOREST	11	11	1	1
Total Reg. & Credits	234	201.4	259	199.8
<i>Industrial Trial Reg.</i>	7	0	1	0
<i>Plus follow-up</i>	14	2	32	5.6
Grand Total	<u>255</u>	<u>203.4</u>	<u>292</u>	<u>205.4</u>

*Credit + noncredit registrations

**Registrations totaled

Target Credits for CRO 06/01/2013 – 05/31/2014

130 Treatment Credits and 140 Cancer Control Credits

Patient Registrations by physician

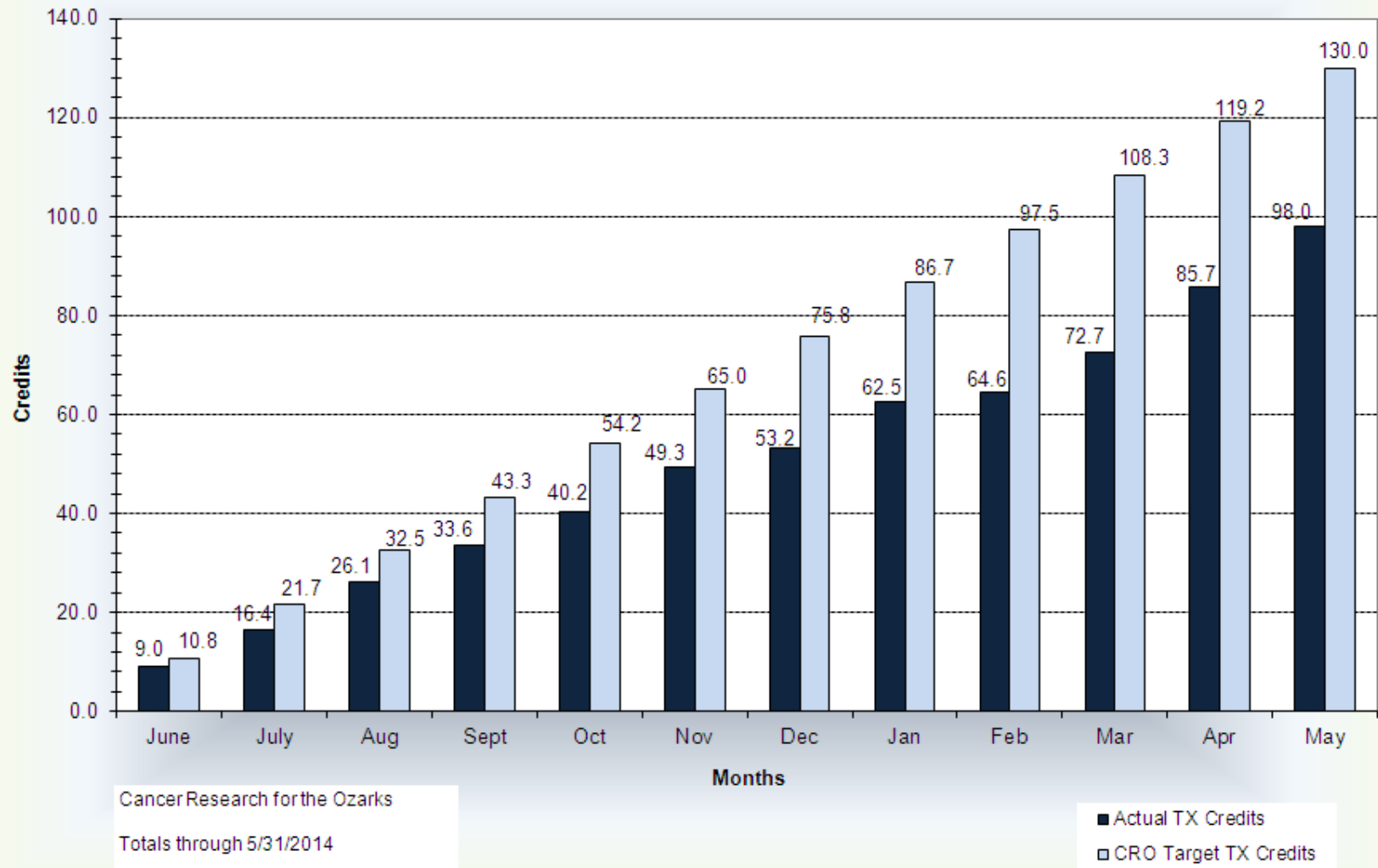
June 1, 2013 to May 31, 2014

	1 st Quarter		2 nd Quarter		3 rd Quarter		4 th Quarter		Total		Credits Earned
	c	n/c	c	n/c	c	n/c	c	n/c	c	n/c	
Abdalla	1	0	0	0	0	0	0	0	1	0	1.0
Anis	0	0	0	0	0	0	0	0	0	0	.1
Baglan	0	0	0	0	0	0	0	0	0	0	.4
Bandi	0	0	0	0	1	0	0	0	1	0	1.0
Bechtell	1	0	0	0	0	0	2	3	3	3	4.0
Bergamini	0	2	0	0	0	0	1	3	1	5	1.0
Biggers	0	0	0	0	0	0	0	0	0	0	.1
Bond	0	0	1	0	0	0	0	0	1	0	1.0
Bonebrake	2	0	6	0	5	0	4	0	17	0	15.0
Brahmanday	0	0	0	0	1	0	0	0	1	0	1.1
Braun	0	0	0	0	0	0	2	0	2	0	1.5
Carlson	21	0	19	0	17	0	4	0	61	0	47.7
Coplin	3	0	0	0	0	0	0	0	3	0	3.5
Creach	2	0	0	0	0	0	0	0	2	0	1.5
Croy	1	0	0	0	0	0	0	0	1	0	1.0
Cunningham	4	0	2	0	0	0	0	0	6	0	5.1
Ding	0	0	0	0	1	0	1	0	2	0	2.0
Donegan							3	0	3	0	2.5
Ellis	1	0	2	0	1	0	6	0	10	0	8.5
Finnie	4	0	3	0	3	0	0	0	10	0	7.2
Gillett	1	0	1	0	2	0	0	0	4	0	3.5
Graham	0	0	3	0	0	0	2	0	5	0	4.3
Hanson	0	1	2	4	3	2	6	5	11	12	14.0
Holden	3	0	1	0	0	0	3	0	7	0	6.3
Hassan	0	0	0	0	0	0	0	0	0	0	.4
Hoos	1	0	0	0	1	0	1	0	3	0	3.1
Hu	3	0	3	0	2	0	1	0	9	0	7.5
Huq	0	0	2	0	0	0	0	0	2	0	2.1
Jaboin	1	0	0	0	0	0	0	0	1	0	1.0
LaFrancis	1	0	0	0	0	0	0	0	1	0	1.0
Luedke	1	0	2	0	1	0	0	0	4	0	4.3
Miller	6	0	1	0	0	0	0	0	7	0	4.3
Mirza			1	0	0	0	0	0	1	0	.5
Nair	2	0	0	0	1	0	2	0	5	0	5.0
Needles	0	0	0	0	0	0	0	0	0	0	.6
Oza	6	0	4	0	0	0	1	0	11	0	8.2
Pinheiro	0	0	0	1	0	0	2	0	2	1	1.5
Raju	2	0	2	0	1	0	7	0	12	0	9.8
Rodgers	4	0	1	0	1	0	0	0	6	0	3.8
Shunyakov	0	0	0	0	0	0	2	0	2	0	1.5
Sleckman	0	0	1	0	3	0	0	0	4	0	4.0
Snider	0	0	1	0	2	0	0	0	3	0	2.6
Tiriveedhi	1	0	0	0	1	0	0	0	2	0	1.8
Tummala	4	0	0	0	0	0	0	0	4	0	3.1
Verma	0	0	1	0	0	0	4	0	5	0	4.0
Vu	1	0	0	0	0	0	1	0	2	0	2.0
Total	77	3	59	5	37	2	55	11	238	21	205.4

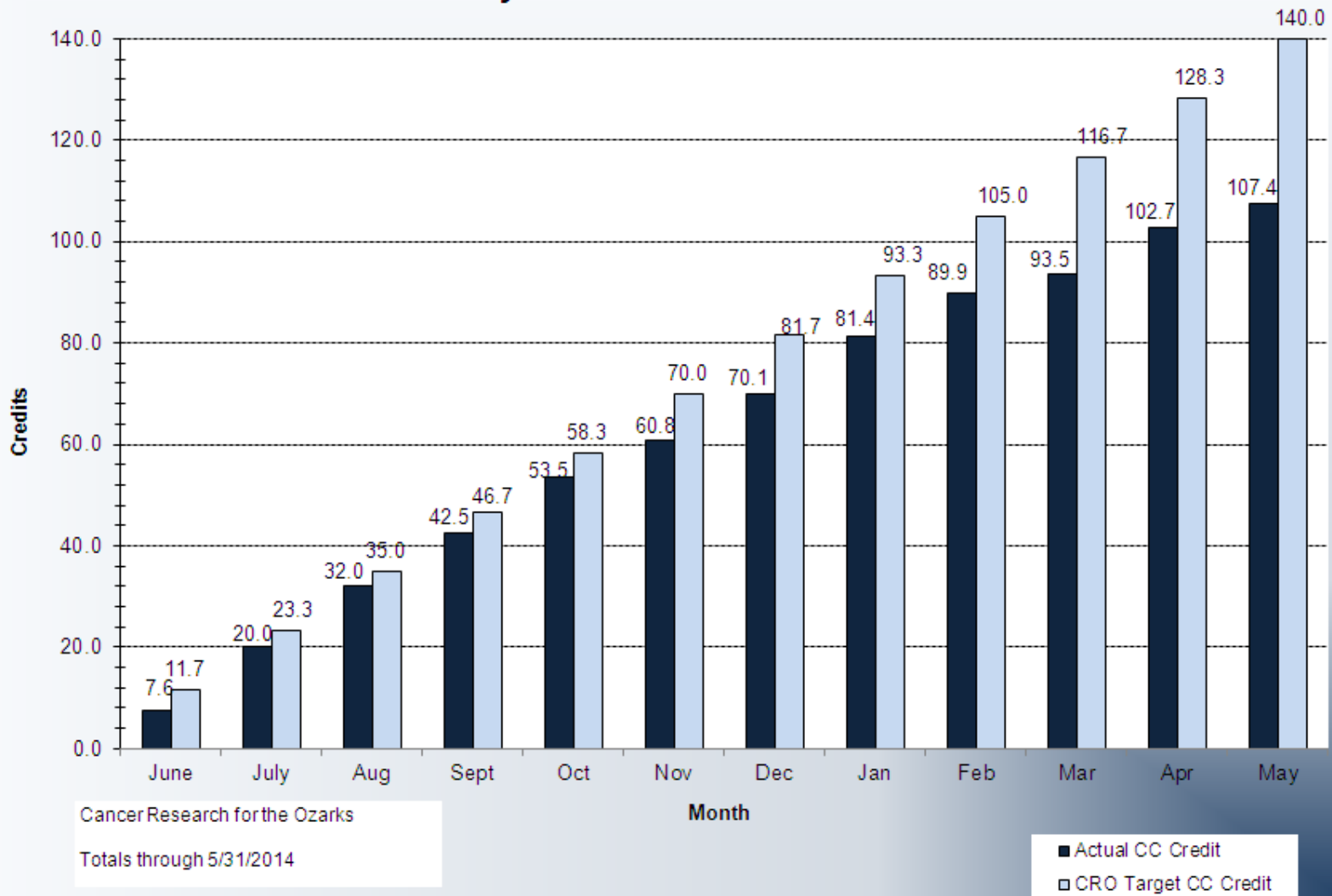
Top 9 Protocols by Registration

Rank	Protocol	Title	# Registrations	Credits
1.	GOG-0244	Lymphedema and Gynecologic Cancer (LEG) Study: Incidence, Risk Factors and Impact in Newly Diagnosed Patients	32	32 cc
2.	S0702	A Phase III trial of 6 versus 12 Treatments of Adjuvant Folfox plus Celecoxib or Placebo for Patients with Resected Stage III Colon Cancer	31	15.5 cc
3.	GOG-0235	A Prospective, Longitudinal Study of YKL-40 in Patients with FIGO Stage III or IV Invasive Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer Undergoing Primary Chemotherapy	14	4.2 Rx
4.	NSABP B-49	A Phase III Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Chemotherapy Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer	11	11 Rx.
5.	E1Z11	A Cohort Study to Evaluate Genetic Predictors for Aromatase Inhibitor Musculoskeletal Symptoms (AIMSS)	9	9 cc.
6.	ACCL1033	A Comprehensive Approach to Improve Medication Adherence in Pediatric ALL	8	8 cc
7.	NSABP B -43	A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma in Situ Resected by Lumpectomy	6	6 Rx.
8.	E5508	Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Non-Squamous NSCLC	5	5 Rx
9.	GOG 186K	A Randomized Phase II Study of NCI Supplied Cabozantinib Versus Weekly Paclitaxel in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer	5	5 Rx

May 2014 Treatment Credits



May 2014 Cancer Control



Cancer Research for the Ozarks Staff

Jay W. Carlson, DO, *Principal Investigator*

Albert Bonebrake, MD, *Associate Principal Investigator*

Marilyn Bauer, BSN, MEd, MHA, *Director*

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- Debbie Cane, AA, Office Manager
- Cynthia Dievert, Clinical Research Assistant
- Michelle McKenzie, BSN, Research Nurse
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- Rita Ritter, Clinical Research Assistant
- Marcia Thompson, BSN, Research Nurse
- Laura Winstead, BS, Regulatory Compliance Coordinator

Cancer Research for the Ozarks

*has a mission rooted in the spirit of collaboration
between CoxHealth and Mercy Springfield.*

*Inspired by our faith-based call to serve others, we seek to promote the
quality of life within the communities we serve by providing innovative
cancer research, education, and personal compassionate presence to our
patients, family members, and staff.*