Cancer Research for the Ozarks

A Community Clinical Oncology Program

Springfield, Missouri

The Year in Review
2012-2013

As I see it

Robert Carolla MD
Principal Investigator

It is my pleasure to review some of the highlights of the past grant year for Cancer Research for the Ozarks (CRO). We have added four new investigators to the roster which again demonstrates acceptance and growth by our group of dedicated physicians. We welcome our new affiliates Mercy St. Louis, Mercy Cancer and Breast Institute and Good Samaritan in Mt. Vernon, Illinois.

This past grant year we registered 85% of our NCI treatment credit accrual goal. Even more exciting is we exceeded our cancer control accrual by 29.5 credits. Overall we have registered 107% of the goal established by the National Cancer Institute. This is an outstanding accomplishment and again reflects the dedication of our investigators and loyal staff. I am pleased to recognize the accomplishments of the top investigators, Dr. Jay Carlson of Mercy and Dr. Al Bonebrake of CoxHealth.

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 opportunities to share our experiences with other like professionals, to learn of protocol results and to participate in discussions of upcoming protocols/studies.

The upcoming year will be a busy one as the staff prepares a new grant application for the soon to be announced NCI Clinical Oncology Research Program (NCORP). This is a reorganization of the community clinical oncology effort and will require considerable work for us to remain competitive in this new program. We look forward to negotiating and collaborating with other existing CCOPs to strengthen our NCORP application.

It is with mixed emotions that I announce my retirement as Principal Investigator of CRO. Dr. Jay Carlson has been selected as our new Principal Investigator and will be assisted by Dr. Al Bonebrake as Associate PI. I have no reservation about their ability to lead CRO forward and meet the challenges of the future.

I want to thank all members of the CRO team for their work and commitment to our CCOP. CRO's success is due to their dedication and strong belief that state of the art cancer treatment can only be achieved through clinical trials. I wish them all success in the future work of CRO.

Progress Report

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

Dr. Carolla Retires

Dr Carolla announced his plan to retire as CRO's Principal Investigator effective May 31, 2013. Under his guidance we received our 5-year NCI grant with a record score, added three new CRO affiliates and developed our CRO web site just to name a few accomplishments. We are very grateful to Dr. Carolla and Dr. Roger Holden for the inspiring leadership they have provided CRO the past five years. Their great dedication to research has been instrumental in the success of CRO and in bringing leading edge cancer research to the people of the Ozarks.

New CRO Principal Investigator and Associate Principal Investigator

It was with great pleasure CRO announced Dr. Jay Carlson accepted the position of Principal Investigator for Cancer Research for the Ozarks and Dr. Al Bonebrake accepted the position of Associate Principal Investigator. Dr. Carlson and Dr. Bonebrake have a great interest in research and have been strong supporters of CRO with high enrollments to clinical trials. We are confident their knowledge and dedication to cancer research will lead CRO forward as we embrace future opportunities. They begin their new appointments on June 1, 2013

New CRO Affiliations

CRO is adding three components of the St. Louis Cape Girardeau CCOP to our CCOP on June 1, 2013. The three affiliates include Mercy Hospital St. Louis, St. Louis Cancer and Breast Institute and Good Samaritan in Mt. Vernon, Illinois. These affiliations will increase our analytic cancer cases by 38%. The Heartland CCOP in St. Louis has approached CRO regarding collaboration. CRO is exploring this possibility.

Restructuring of CCOP's

NCI announced it is combining its community-based research networks to create a single network that builds on their strengths. The Community Clinical Oncology Program Network, including Community Clinical Oncology Programs (CCOPs), Minority-based Community Clinical Oncology Programs (MB-CCOPs), and the NCI Community Cancer Centers Program (NCCCP) will be united to create the NCI Community Oncology Research Program or N-CORP program.

On February 8, 2013, NCI shared some updated information pertaining to changes in how potential NCORP community sites will be designated. It has been decided there will be two designations: 1) NCORP and 2) NCORP – Minority and Underserved. If funding is sufficient, differential funding will be considered at peer-review and by program. Worta McCaskill-Stevens, MD, with NCI wrote NCI's goal is to develop a successful research oncology program and a collaborative network within the cancer care community.

Applicants will be required to prepare their best response to the RFA for clinical trials and cancer care delivery research. CRO will be preparing and submitting an NCORP grant request as soon as it is released. At this time, it is scheduled to be released in mid September 2013.

Screening for Clinical trials

As noted above, the CCOP program is in the process of transforming into the new NCORP (NCI Community Oncology Research Program) program. At this time, we are not sure of all the changes the new program will include, but we do know there will be a renewed emphasis on patient screening and enrollment. At the CCOP Principal Investigators and Administrators meeting in September 2012, NCI presented a patient screening tool that collects the data most likely required for patients screened for clinical trials. CRO has worked with our CREDIT database developers to modify the pre-screening tool in CREDIT to collect additional information making it comparable with the proposed screening tool presented at the meeting in September. From patient screening documentation we will be able to objectively evaluate and see where we can place a greater emphasis to enhance our enrollments.

Alliance Application

CRO submitted its application to join the newly formed Alliance cooperative group and was accepted as a member of the group. We have had multiple good CALGB and NCCTG trials in the past. With our recent addition of surgeons to our list of investigators, we look forward to participating in ACOSOG trials.

NRG Application

CRO has submitted our intent to join application to the newly forming NRG cooperative group. This cooperative group is composed of NSABP, RTOG and GOG. These three groups have provided many excellent trials for CRO in past years.

Congratulations Drs. Carlson, Bonebrake and Tiriveedhi

At the CCOP/MBCCOP Principal Investigators and Administrators Meeting at NCI in Bethesda, MD on September 23 & 24, Dr. Jay Carlson and his staff were recognized for achieving the highest enrollment of patients on NCI cancer treatment clinical trials and treatment plus cancer control clinical trials for all CCOP/MBCCOP programs for the second year in a row. Dr. Al Bonebrake and Dr. Lavanya Tiriveedhi were recognized for exceptional achievement in NCI patient enrollments. These physicians were recognized locally and presented their NCI plaques at our Steering Committee Meeting on October 5, 2012.

Dr. Carlson Appointed to GOG Committee

Dr. Carlson has been appointed to serve on the Ancillary Data Subcommittee and Cancer Prevention and Control Committee at GOG. His committee terms began at the January 24-27, 2013 GOG meeting in San Diego.

Dr. Jay Carlson GOG Study Chair

Dr. Jay Carlson is the 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 also the study co-chair for GOG-0244 "The Lymphedema and Gynecologic Cancer (LEG) Study: Incidence, Risk Factors and Impact in Newly Diagnosed Patients". At the end of May 2013, CRO has registered 41 patients to these two trials.

Dr. Carolla SWOG Auditor

Dr. Carolla was in Columbus, Ohio serving as a SWOG auditor on August 28-30, 2012. Dr. Carolla enjoys serving as an auditor and frequently returns with ideas that will assist in improving our own CCOP.

Financial Conflict of Interest Policy

On August 24, 2012 the US DHHS implemented revised regulations pertaining to the capturing and reporting of financial conflict of interest (FCOI). These regulations, changed significantly since 1995, included but not limited to a decrease to $5,000 in the value of equity interest in a public or non-public traded entity; disclosure of any reimbursed or sponsored travel; and a requirement for each investigator to complete FCOI training. These regulations apply to institutions that receive PHS/NIH grants or cooperative agreements. As a recipient of federal monies CRO must abide by these regulations. Policies were developed to assure compliance with these regulations at CRO and its affiliates. All CRO investigators and research staff completed a training course and submitted financial conflicts of interest as required.

Local Research Conference - "Community Based Research: The Time is Now"

CoxHealth and Mercy joined together to offer an educational and motivational research conference. The conference was held October 12-13, 2012 at McAuley Conference Center inside Mercy Hospital. The event featured a variety of topics, speakers and a lot of networking. Dr. Jim Atkins, Principal Investigator at the Southeast Cancer Control Consortium CCOP in Winston-Salem, NC was the key note speaker. Over 70 attended the one and a half day event.

CRO Steering Committee Meeting

Monday, October 15, 2012 was the date of our fall CRO Steering Committee meeting. Dr. Carolla opened the meeting with CRO updates and statistical information. Steven Sorcher MD from Washington University in St. Louis spoke on metastatic renal cell cancer. The title of his presentation was "Shedding Light on Second-line mRCC". The meeting was held at Touch Restaurant at 6PM. Thirty CRO investigators and research staff attended this event.

On Monday, April 22, 2013 at Touch Restaurant, Dr. Joseph Kim MD, a board certified surgical oncologist, currently serving as Associate Professor of Surgery and Director of Surgical Oncology Fellowship Program at City of Hope National Medical Center in California, spoke on "New Approval in Metastatic Colorectal Cancer (mCRC): A Case-Based Approach**".** Forty research investigators and staff attended this delightful evening.

NCI's CIRB

CRO is collaborating with the NCI Central Intitutional Review Board (CIRB). The Central IRB (CIRB) Initiative is designed to help reduce the administrative burden on local IRBs and investigators while continuing a high level of protection for human research participants. CIRB enables an investigator to enroll patients into NCI-sponsored clinical trials significantly faster than when employing a traditional IRB review. The CIRB Initiative is sponsored by NCI in consultation with the Department of Health and Human Services Office for Human Research Protections (OHRP). Currently the CIRB reviews only Phase III NCI studies; however, they plan to approve Phase II studies in the near future. Our application was

accepted and we expect to hear we have been granted access to CIRB studies at any time. Once we receive access we will begin using the CIRB for phase III NCI studies.

CRO will continue to use our local IRB's at CoxHealth and Mercy Springfield for Phase II NCI studies, all NCI trials from MDAnderson, SunCoast, Wake Forest and all industrial trials. Local consolidation of regulatory work is also occurring at CRO. On January 17, 2013 CoxHealth become the Intitutional Review Board (IRB) for newly opened NCI studies at Freeman. On May 17, 2013 Mercy Springfield became the IRB for Mercy Joplin NCI studies. On June 1, 2013 Mercy Springfield IRB's will be the IRB for NCI trials at Mercy St. Louis, St. Louis Cancer and Breast Institute and Good Samaritan.

CRO Web-based Monthly Educational Conference

This year we also set up CRO Web Based Conference Calls. We saw this as an opportunity to improve communications with our investigators and research staff. We developed and presented an interactive monthly web conference to discuss new studies and other things happening at CRO. Our target audience was our investigators, nurse practitioners and research staff including our affiliates. The meeting was conducted by use of the WebEx tool which is highly interactive with logon capabilities from home, iPhones, iPads, Blackberries and as well as video capabilities with a web-cam. CRO worked with our local health systems to obtain CMEs and CEUs for attending. We explored the best time to hold the conferences with our local oncologists. We set up the conference rooms at the medical oncology offices for our investigators and interested staff to join in as a group at 12noon and 5p on days selected by the physicians. Dr. Carolla presented new studies available to our CCOP and gave an educational update. Discussion and input from participants was sought. We hosted two calls per month to meet the preferences of the oncologists at Cox and Mercy Springfield May through September.

Due to lack of physician attendance it was decided to suspend these meetings in September. CRO resumed obtaining physician interest in studies by sending physicians written information regarding new trials and requesting their input.

While we have discontinued our WebEx meetings we have found the experience and the electronic WebEx tool to be an asset. CRO now invites all affiliate research staff to join us on the fourth Tuesday of the month when CRO staff in Springfield gathers to discuss new studies available for the next IRB meeting. Going forward we will use this tool for meetings with our affiliate investigators and staff.

CRO Affiliate Visits

Dr. Carolla, Marilyn Bauer, Basava Raju and Debbie Cane traveled to Rolla for a tour and visit with our Phelps County affiliate on April 24, 2012. We traveled to Joplin for an internal audit and visit with Freeman investigators and staff on Thursday, October 11, 2012. Encouraging enrollment is a major purpose of our affiliate visits.

Affiliate research nurses from Central Care PA in Bolivar, Phelps County Regional Medical Center in Rolla, and Cox Medical Center Branson periodically came to Springfield where the CRO Study Coordinator has reviewed their data submissions. Research staff at these affiliate sites are new in research. Having an experienced research staff review their work has been welcomed and a great learning experience.

Acuity Tool Instituted at CRO

CRO staffs have started using a protocol acuity tool to assist in determining work load. As new studies are reviewed by CRO staff they will be assigned an acuity score. The 4 point protocol acuity tool has been piloted at several other CCOPs.

Research Base Meeting Attendance

Research Base meeting attendance is encouraged as approaching research changes and new trials are discussed. Our GYN oncologists, Dr. Bonebrake, Dr. Carlson and research nurse Kathy Coleman attended the GOG conference in July 2012 in Philadelphia. Dr. Carlson and Dr. Bonebrake also attended the GOG conference on January 24-27, 2013 in San Diego. Marilyn Bauer, CRO's director, attended the NSABP/NRG meeting in San Diego on January 24-27, 2013.

Dr. Holden, Dr. Biggers and Basava Raju, CRO's study coordinator, attended SWOG's fall conference in Chicago on October 17-20, 2012. Dr. Robert Carolla and Marilyn Bauer attended the CCOP Principal Investigators and Administrators Meeting in Bethesda, Maryland on September 24 and 25, 2012. This is always a very informative meeting and we looked forward to learning how our CCOP program would be transformed.

Dr. Carolla, Dr. Holden, Kathleen Hodges and Basava Raju attended the SWOG conference in San Francisco on May 1- 4, 2013.

CRO On Facebook

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

Quality Assurance

Timely and accurate data submission is a very important ongoing goal at CRO. With the addition of a PRN research nurse to our staff this past year we are now able to devote the majority of our clinical research coordinator's time to internal auditing and staff education.

It is a CRO policy to internally audit one patient chart completely and three patient charts for eligibility quarterly for each staff placing patients on trial. Our clinical research coordinator is responsible for this auditing. He has worked with our new affiliate nurses at Skaggs, PCRMC and Central Care PA to audit and educate them on chart documentation for the past several months. Our plan is to audit these three new affiliates' documentation quarterly until they are secure with the process.

Our regulatory files are audited monthly by our office manager, who was previously our regulatory compliance coordinator. She randomly selects three regulatory protocols each month for auditing.

CRO Audits

Six NCI Cooperative Groups (GOG, NCCTG, NSABP, RTOG, SWOG, and SunCoast) were at CRO for their required 3-year audits this past year. CRO was pleased with audit results as no findings were significant enough to require a re-audit. Eighty-eight charts were

audited. CRO was consistently complimented for their drug handling and regulatory compliance, chart organization and completeness of documentation. Corrective action plans were submitted to address deficiencies noted. No deficiencies were noted on our RTOG audit.

CRO Accruals

This has been another interesting year for accruals. Forty-three percent of our enrollments have been to GOG trials. We are fortunate to have two very involved gynecological oncologists. Together they have accrued 106 of our 241 registrations on study, earning 91 of our 203.4 total credits.

Our affiliates accrued 26 registrations this grant year earning 20.6 credits.

CRO Staff

Our 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 Kathy Hodges in October 2012 as a new research nurse. Kathy has 17 years of oncology experience and is OCN certified. She is stationed at the Hulston office. Laura Winstead and Dana Morris joined CRO staff in April 2013. Laura is our Regulatory Compliance Coordinator. Dana is our Clinical Research Assistant responsible for long term follow-up and other duties.

The 4 full time research nurses and 2 clinical research assistants who enroll patients in Springfield at CRO accrued 206 registrations this past grant year. This is approximately 34.4 registrations per staff. Our 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. Our clinical research coordinator, PRN research nurse, and follow-up clinical research assistant assist our clinical staff as needed, staffing for vacations, performing internal auditing and providing staff education on clinical trial documentation.

Using our CREDIT database, our local and affiliate staff now record patient screening times. Our database shows 1558 patients were screened over the month of May 2013. Approximately 259 hours of staff' time was required to screen these 1555 patients.

Achieving Target Credit Goals

Grant year 6/1/2012- 5/31/2013 was a good year for CRO enrollments to clinical trials. We exceeded NCI assigned target credits. We earned 93.9 treatment credits which was 85% of our target accrual of 110 for treatment. We earned 109.5 control credits which was 137% of our target accrual credits of 80 for the year. Our total accrual was at 107% of our NCI assigned accrual goals. 28 CRO research investigators participated in making this happen.

Dr. Jay Carlson was our number one enroller this grant year. Dr. Carlson and his staff enrolled 80 patients earning 69.2 credits. Dr. Carlson has registered 33% of CRO's total registrations this past year.

Credits are different from registrations. A registration is defined by NCI. Not all registrations receive credit. Credits are the NCI value assigned to each trial registration. This past year, CRO had 228 registrations for credit, and 13 no-credit registrations, for a total of 241 registrations. Of that total, our affiliates in Joplin at Mercy, Freeman Health, Cox Branson, Central Cares PA and Phelps County contributed 26 registrations. Our affiliates contributed 10.7% of our total enrollments this grant year. Last grant year our affiliates contributed 9% of our total registrations.

CRO Finances

In 2008, Cancer Research for the Ozarks received a 5-year grant from the National Cancer Institute for $ 4,239,818 which supplied us with $566,009 this past fiscal year. Grant dollars go a long way, but do not completely support CRO.

CRO is supported by the generosity of our two sponsoring health systems, CoxHealth and Mercy Springfield. Since the beginning of CRO in 1985, 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 and has came a long way from fiscal year 2005-2006 when our expenses over grant revenue were $245,154. The two tables below compare our FY 2011-2012 and FY 2012-2013 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.

Revenues	Fiscal Year 2011-2012
Federal	$566.009
Other	$286,347
Total Revenues	$852,356
Total Expenses	$885,087
Deficit *	-$32,732

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

*The deficit is split equally between CoxHealth and Mercy Springfield
Fiscal year 2012 -2013 – Remainder is $5,580
Fiscal year 2011-2012 –Deficit $16,366 to each institution

Meeting the CRO Goals for 2012-2013

Last year, we defined goals. Below are the goals, and our report of progress toward meeting them.

CRO Goals	Achievements
Goal 1. Increase accruals to NCI clinical trials	
1. Meet our target treatment credits for this grant year.	1. CRO earned 93.9 treatment credits this grant year. We fell short of our NCI assigned treatment goal of 110 by 16.1 credits or 15%.
2. Exceed our cancer control credits for grant year by 5%.	2. We exceeded our NCI assigned control credits target goal of 80 by 29.5 credits or 37%.
3. Continue to work with surgeons at both Cox and Mercy Springfield to explore their interest in participating in clinical trials by July 1, 2012.	3. Drs. Biggers, Buckner, Bumberry & Woodall are CRO surgical investigators
4. Continue to publish trials opened and closed each month in the CRO Communiqué.	4. A listing of trials opened and closed each month is published in the monthly CRO Communiqué and on the CRO website.
5. Continue to profile a new study each month in the CRO Communiqué.	5. As space allowed a new study was profiled monthly.
6. Update pocket list of studies available bi-monthly and deliver to investigators.	6. Our pocket cards listing studies available & major enrollment criteria are updated every other month.
7. Explore development of a monthly web-based conference call meeting to discuss new studies and other CRO business by June 1, 2012. All CRO investigators and research staff including CRO affiliates would be highly encouraged to attend.	7. Conference calls were held monthly May through August then discontinued due to lack of physician attendance.
Goal 2. Improve communication efforts to keep CRO investigators and health care extenders aware of clinical trial availability	
8. Visit yearly with physicians and staff at each of our affiliates to offer assistance and encourage enrollment to trials.	8. Dr. Carolla, Marilyn Bauer, Basava Raju and Debbie Cane traveled to Rolla for a tour and visit with our Phelps County affiliate on April 24th. We also traveled to Joplin for an internal audit and visit with Freeman investigators and staff on Thursday, October 11th.
9. Hold twice yearly CRO Steering Committee meetings with national speakers on new cancer therapies and treatments.	9. On Monday, October 15, 2012 Steven Sorcher MD from Washington University in St. Louis spoke on metastatic renal cell cancer. On Monday, April 22, 2013 Dr. Joseph Kim MD New Approval in Metastatic Colorectal Cancer (mCRC): A Case-Based Approach.

Goal 3. Ensure quality at CRO

10. Audit all new research staffs' (including affiliates) documentation for the first three months of employment.	10. This is ongoing. Basava Raju is our CRO educational staff trainer who reviews documentation for all new staff and affiliate staff for the first three months and randomly thereafter. His internal auditing is a great educational tool for all staff.
11. Randomly select five patient records from each staff enrolling patients for quarterly eligibility auditing.	11. Ongoing see #10 above.
12. Quarterly conduct a complete audit on a minimum of one chart per enrolling staff	12. See above #10 and11
13. Maintaining timely and accurate data submission.	13. We were out of compliance with timeliness of Follow-up on treatment with SWOG which was at 15.38% in November 2012. 15% is considered out of compliance. An email was sent to all staff asking this information be addressed within a week. In December, we were at 15% for follow-up with treatment. Once again an email and individual conversations were held with out of compliance staff. The director continues to follow-up.
14. Training CRAs to develop data submission skills to assist RNs.	14. Ongoing – Since our CRA's now enroll to control trials they are kept busy and do not have time to assist RN with documentation.

Goal 4. Promote CRO on a National Level

15. PI and director to volunteer in NCI committees	15. An email was sent to Marge Good at NCI requesting how Dr. Carolla and Marilyn could become more involved. We have not been contacted to serve on committees however, with the new NCORP program underway they may not be adding to committee memberships.
16. Check into being an NCI grant reviewer.	16. An email was sent to Cynthia Whitman asking if Dr. Carolla could serve as a grant reviewer. We were not called.

Goals & Opportunities for CRO in Grant Year 2013-2014 are as follows:

Goal 1. Increase accruals to NCI clinical trials

- Exceed our target treatment credits for the grant year by 1%.
- Exceed our cancer control credits for this grant year by 2%.
- Bring on board the St. Louis Mercy CCOP and Good Samaritan in Mt. Vernon, Illinois, as CRO affiliates on June 1, 2013.
- Explore an affiliation with Ozark Medical Center in West Plains.
- Explore collaboration with the Heartland CCOP in St. Louis.
- Document 100% of patient screening for clinical trials in the CREDIT database.
- Amend affiliate contracts to pay them $500 per enrollment and if they exceed 3.5% of their past year's analytic tumor registery cases, pay them an additional $500 per 1 credit registration.
- Continue to update trials opened and closed each month in the CRO Communiqué.
- Continue to profile a new study each month in the CRO Communiqué.
- Update pocket list of studies available bi-monthly and deliver to investigators at all sites.
- Successfully submit a NCORP grant application when the RFA becomes available.
- When announced market the NCORP program to the Springfield and St. Louis community with print, TV, radio and electronic media announcements.
- Establish a BioSafety Committee at both Cox and Mercy Springfield allowing CRO to participate in vaccine trials.

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 affiliates to offer assistance and encourage enrollment to trials
- Hold twice yearly CRO Steering Committee meetings with national speakers on new cancer therapies and treatments.
- Invite affiliate research staff to join in on CRO's monthly review of new studies available using the WebEx tool.

Goal 3. Ensure quality at CRO

- Successfully submit a NCORP (NCI Community Oncology Research Program) grant application when RFA available
- Convert IRB approval for all NCI cooperative groups Phase III and Phase II when it becomes available to the CIRB
- Audit all new research staffs' (including affiliates) documentation for the first six months of employment or as deemed necessary.
- 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 affiliates with:
  1. Maintain timely and accurate data submission.
  2. Respond to queries in a timely manner to address those that occur.

Goal 4. Promote CRO on a National Level

- Recruit a new PI for CRO
- PI and director to volunteer in NCI committees

Protocol Reports: 2-Year Comparison of Registrations & Credits

Treatment

RESEARCH BASE	2011-2012 REGISTRATIONS	2011-2012 CREDITS	2012-2013 REGISTRATIONS	2012-2013 CREDITS
CTSU	33	23.2	21	15.7
GOG	103	59.3	42	38.5
MD Anderson	0	0	0	0
NCCTG	0	0	3	3
NSABP	5	5.4	26	26.2
RTOG	3	3.5	1	1
SWOG	18	20	9	9.5
SunCoast	0	0	0	0
Wake Forest	0	0	0	0
Grand Totals	**162**	**111.4**	**102**	**93.9**

Cancer Control & Prevention

RESEARCH BASE	2011-2012 REGISTRATIONS	2011-2012 CREDITS	2012-2013 REGISTRATIONS	2012-2013CREDITS
CTSU	8	6	12	6.0
GOG	39	24.9	64	53.5
MD ANDERSON	0	0	0	0
NCCTG	11	11	7	6.8
NSABP ***(new)***	23	19.6	19	17.2
NSABP ***(follow up visits)***	15	4.1	14	2
RTOG	2	1	0	0
SunCoast	2	2	1	1
SWOG ***(new)***	3	1.5	12	12
SWOG ***(follow up visits)***	0	0	0	0
WAKE FOREST	6	6	11	11
Grand Totals	**109**	**76.1**	**140**	**109.5**

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

AFFILIATE*/SITE	2011-2012 REGISTRATIONS	2011-2012 CREDITS	2012-2013 REGISTRATIONS	2012-2013 CREDITS
Central Care, PA	0	0	4	3.2
Cancer Hematology Center	44	38.9	41	42.4
Cox Surgeons	15	15.0	14	14
Ferrell-Duncan Clinic Gynecological	51	50.4	26	21.8
Freeman Medical Center (Joplin)	8	5.3	10	8.5
Mercy Joplin	2	1.5	3	3
Mercy Clinic Rolla	0	0	2	1.1
Phelps County Regional Medical Ctr.	9	6.5	3	3.2
Oncology Hematology Associates	24	21.2	40	32.5
Radiation Therapy Center Cox	0	0	2	2.1
Cox Medical Center Branson	5	2.8	5	2.3
Mercy Women's Oncology Care	92	35.8	80	69.2
Mercy Springfield's Radiation Oncology.	6	6.0	0	0.1
No Credit at Mercy	2	0	12	0
Grand Totals	**258**	**183.4**	**242**	**203.4**

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

RESEARCH BASE	2011-2012 REGISTRATIONS	2011-2012 CREDITS	2012-2013 REGISTRATIONS	2012-2013 CREDITS
CTSU	41	29.2	33	21.7
GOG	142	84.2	106	92
MD ANDERSON	0	0	0	0
NCCTG	11	11.0	10	9.8
NSABP	28	25.0	45	43.4
RTOG	5	4.5	1	1
SWOG	21	21.5	21	21.5
Suncoast	2	2	1 + 6	1
WAKE FOREST	6	6	11	11
Total Reg. & Credits	**256**	**183.4**	**234**	**201.4**
Industrial Trial Reg.	2	0	7	0
Plus follow-up	---	4.1	14	2
Grand Total	**258**	**187.5**	**255**	**203.4**

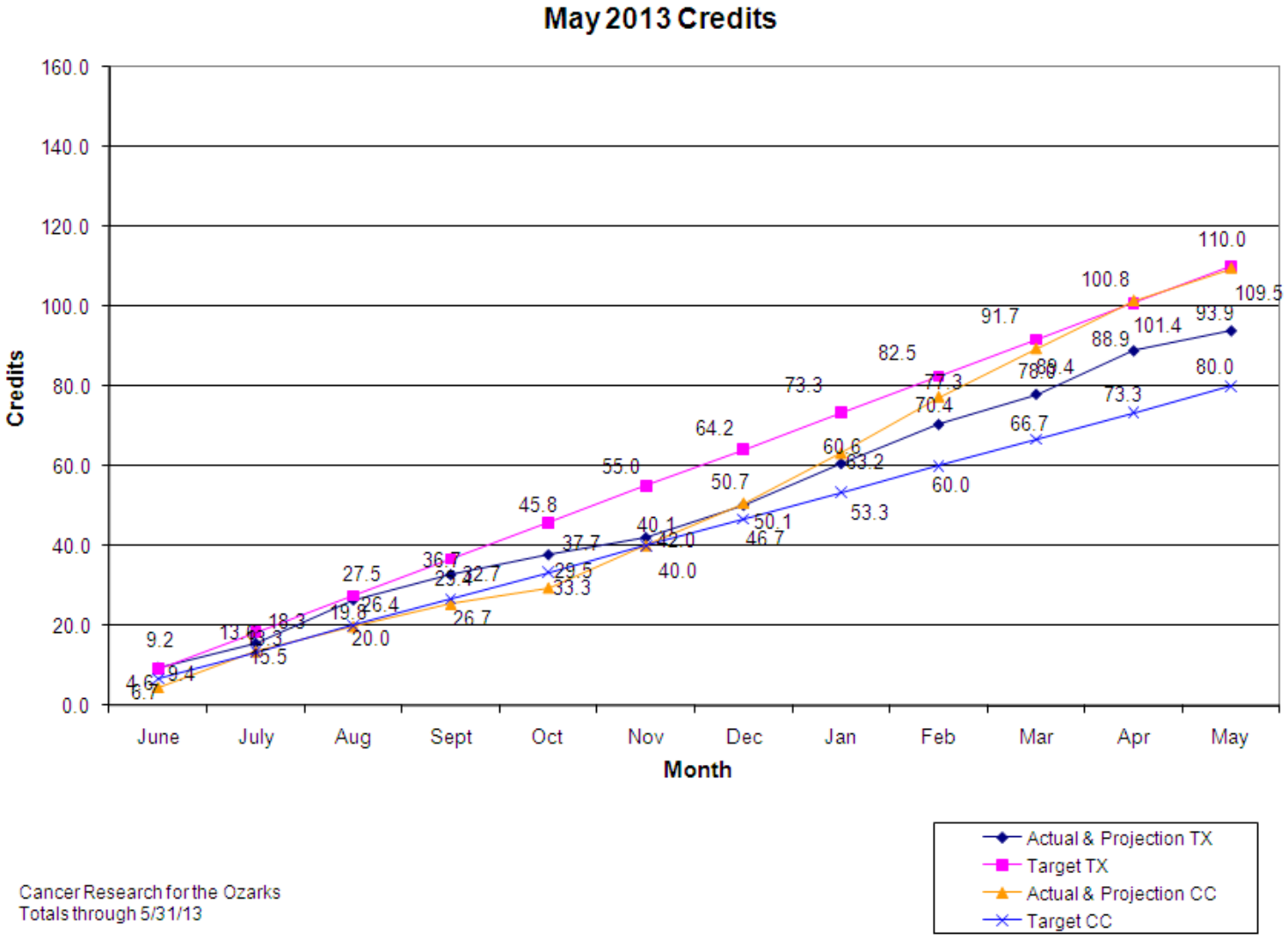
*Credit + noncredit registrations. **Registrations totaled.

Patient Registrations by Physician through May 31, 2013

	1st Quarter		2nd Quarter		3rd Quarter		4th Quarter		Total		Credits Earned for Registrations
	c	n/c	c	n/c	c	n/c	c	n/c	c	n/c	
Abdalla	0	0	0	0	0	0	0	0	**0**	**0**	**0.1**
Albritton	0	0	0	0	0	0	0	0	**0**	**0**	**0**
Ali, Yaqoob	0	0	0	0	0	0	1	0	**1**	**0**	**1.1**
Amir	0	0	0	0	0	0	0	0	**0**	**0**	**0**
Biggers	5	0	4	0	1	0	4	0	**14**	**0**	**14.0**
Bond	0	0	0	0	1	0	0	0	**1**	**0**	**1**
Bonebrake	2	0	7	0	7	0	10	0	**26**	**0**	**21.8**
Brahmanday	0	0	0	0	0	0	2	0	**2**	**0**	**1.5**
Braun	0	3	0	2	0	0	0	0	**0**	**5**	**0.1**
Buckner	0	0	0	0	0	0	0	0	**0**	**0**	**0**
Carlson	19	0	8	0	35	0	18	0	**80**	**0**	**69.2**
Clouse	0	0	0	0	1	0	1	0	**2**	**0**	**2.0**
Croy	0	0	0	0	0	0	1	0	**1**	**0**	**1.0**
Cunningham	1	0	0	0	3	0	0	0	**4**	**0**	**5.00**
Ding	5	0	0	0	0	0	2	0	**7**	**0**	**4.3**
Ellis	0	0	14	0	6	0	5	0	**25**	**0**	**18.9**
Gillett	0	0	1	0	2	0	1	0	**4**	**0**	**4.3**
Goodwin	0	0	0	0	0	0	5	0	**5**	**0**	**2.3**
Graham	0	0	0	1	0	0	0	0	**0**	**1**	**0**
Hassan	0	0	0	0	1	0	1	0	**1**	**0**	**1.1**
Holden	3	0	1	0	1	0	3	0	**8**	**0**	**8.1**
Hoos	1	0	4	0	2	0	1	0	**8**	**0**	**8.1**
Kent, Elizabeth	3	0	0	0	0	0	0	0	**3**	**0**	**2.5**
LaFrancis	0	0	1	0	0	0	0	0	**1**	**0**	**1.0**
Myers	0	0	0	0	0	0	0	0	**0**	**0**	**0**
Miller	0	0	0	0	2	0	0	0	**2**	**0**	**2.0**
Nair	0	0	1	0	1	0	0	0	**2**	**0**	**3.5**
Nanney	1	0	0	0	0	0	0	0	**1**	**0**	**1.0**
Nevils	0	0	0	0	0	0	0	0	**0**	**0**	**0**
Pinheiro	0	0	0	3	0	1	0	3	**0**	**7**	**0**
Raju	1	0	0	0	4	0	2	0	**7**	**0**	**7.1**
Ross	0	0	0	0	0	0	0	0	**0**	**0**	**0**
Sciortino	0	0	0	0	0	0	0	0	**0**	**0**	**0**
Shunyakov	2	0	0	0	0	0	2	0	**4**	**0**	**3.2**
Skelley	1	0	0	0	0	0	0	0	**1**	**0**	**1.0**
Tiriveedhi	8	0	2	0	3	0	1	0	**14**	**0**	**13.6**
Tummala	0	0	0	0	0	0	1	0	**1**	**0**	**1.0**
Driver	0	0	0	0	0	0	0	0	**0**	**0**	**0**
Vu	0	0	0	0	0	0	2	0	**2**	**0**	**1.5**
Zoghbi	1	0	0	0	0	0	0	0	**1**	**0**	**1.6**
Total	**53**	**3**	**43**	**6**	**69**	**1**	**66**	**3**	**228**	**13**	**203.4**

Top 10 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	38	38cc
2.	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	24	24 Rx.
3.	NSABP DMP-1	A Study to Evaluate Different Decision-Making Approaches Used by Women Known to be at Increased Risk for Breast Cancer	12	12 cc
4.	SWOG S1105	Randomized Trial of Text-Messaging Intervention to Reduce Early Discontinuation of Adjuvant Aromatase Inhibitor Therapy in Women with Early Stage Breast Cancer	11	11 cc
5.	GOG 0212	A Randomized Phase III Trial of Maintenance Chemotherapy Comparing 12, Monthly Cycles of Single Agent Paclitaxel or CT-2103(IND #70177), Versus No Treatment Until Documented Relapse in Women with Advanced Ovarian or Primary Peritoneal Cancer Who Achieve a Complete Clinical Response to Primary Platinum/Taxane Chemotherapy	10	10 Rx 5 cc
6.	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	10	3
7.	Wake Forest 99311	Randomized Placebo-Controlled Phase 2 Pilot Study of Memantine (Namenda) for Smoking Cessation among Cancer Survivors	10	10cc
8.	SCUSF Pilot 2011-1	Treatment of painful radiation therapy-induced dermatitis in women treated for breast cancer with whole breast radiation following breast conserving surgery: A pilot study	6	6 cc
9.	CALGB 80702	A Phase III trial of 6 versus 12 Treatments of Adjuvant Folfox plus Celecoxib or Placebo for Patients with Resected Stage III Colon Cancer	5	6.2Rx
10.	NCCTG N10C1	Vaginal DHEA for Vaginal Symptoms: A Phase III Randomized, Double Blind, Placebo-Controlled Trial	5	5 cc


May 2013 Credits
Credits
Month
160.0
140.0
120.0
100.0
80.0
60.0
40.0
20.0
0.0
June
July
Aug
Sept
Oct
Nov
Dec
Jan
Feb
Mar
Apr
May
Actual & Projection TX
Target TX
Actual & Projection CC
Target CC
Cancer Research for the Ozarks
Totals through 5/31/13

Cancer Research for the Ozarks Staff

Robert L. Carolla, MD, *Principal Investigator*

V. Roger Holden, MD, *Associate Principal Investigator*

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

- Sharon Brown, RN, Research Nurse
- Debbie Cane, AA, Office Manager
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- Cynthia Dievert, Clinical Research Assistant
- Dana Morris, Clinical Research Assistant
- Sharon Hodge, RN, Research Nurse
- Kathleen Hodges, RN, OCN, Research Nurse
- Basava Raju, MS, BS, CCRP, Research Coordinator
- 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.