
Cancer Research for the Ozarks

A Community Clinical Oncology Program

Springfield, Missouri

The Year in Review
2010-2011

Cancer Research for the Ozarks *The Year In Review 2010-2011*

As I see it



Robert Carolla MD
Principal Investigator

This past grant year has been another one of growth for Cancer Research for the Ozarks (CRO). Twenty-eight physicians from Cox, St. John's and the Joplin affiliates have participated in patient registrations for research protocols. This broad range of acceptance by the medical staffs of all institutions confirms that CRO remains a major force in research in Springfield and Joplin. This past grant year we registered 88.4% of our NCI accrual goal.

Our mission statement seeks to improve the quality of life in the community served by these two health centers. I am pleased to report that we have expanded our service area significantly with the addition of Skaggs Cancer Center in Branson and Central Care Cancer Center in Bolivar as affiliates of CRO. Recently we have signed an affiliation agreement with Bond Clinic and Phelps County Hospital in Rolla; physicians of these two groups have signed on as CRO investigators. Our range of service which now encompasses all of southwest Missouri and south central Missouri allows even more patients access to the very latest in cancer treatment options. This is truly an exciting time for us all.

At the April meeting of the South West Oncology Group (SWOG), CRO-Ozarks Regional CCOP was recognized as a major contributor to the activities of SWOG during our 26 year existence. We are very proud of this designation and at last feel that we are receiving national attention for our efforts. Our organization has been dealt a setback with the devastating tornado in Joplin on May 22 which has seriously affected our research efforts at St. John's Regional Medical Center. Fortunately Rita Glaze, the St. John's research nurse, was spared any personal loss. Although Freeman Medical Center was spared direct damage from the tornado, Lois Crockett, a research nurse, suffered the loss of her home. Our hearts go out to all those affected in Joplin and we pray for some return of normalcy to their lives as soon as possible.

We also have continued the educational program of CRO with offerings of national speakers on current oncology topics quarterly. These programs have created a spirit of camaraderie between the investigators, research staff and the support staff of physician's offices. A recent speaker commented on the positive attitudes of our meetings and the sense of cooperation between all who participate. It is this kind of attitude which compels our organization forward and makes it as great as it is.

My thanks to CRO's dedicated staff and participating physicians.

Progress Report

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

CRO Outreach Results in New Research Affiliates

Formal agreements were signed with Skaggs Community Health Center in Branson, Missouri and Central Care Cancer Center in Bolivar, Missouri for an affiliation with CRO to enroll patients into research trials in March 2010. Both institutions elected to work with CoxHealth's Institutional Review Board for regulatory coverage. CoxHealth's IRB revised their policies to include coverage of the outlying community centers. Investigators and affiliate staff completed regulatory training and were accepted by the NCI to participate in research. Staff assisting the investigators at our new affiliate sites spent time with CRO research staff in Springfield observing and learning about research. CRO staff traveled to Central Care Cancer Center in Bolivar, Missouri on March 24th and November 9th, and to Skaggs in Branson, Missouri on March 31st to train staff that are assisting the physicians with trial enrollments. CoxHealth's business department held a training session with both sites on March 29, 2010 regarding billing procedures for research. Our new affiliates are now enrolling patients. This was an exciting event for Cancer Research for the Ozarks and oncology patients being cared for in our outlying communities.

We are currently working on an affiliation with Phelps County Hospital in Rolla. Phelps County physicians have applied for investigator status. CRO is looking for an agreeable date to visit Phelps County and begin training staff. Phelps County has obtained grant money to hire an RN devoted to assisting physicians with research. CRO continues to be open to future expansions to offer cancer patients in our rural communities the best care possible while increasing our enrollments to clinical trials at CRO.

Pharmacy Issues for CRO

The Missouri State Board of Pharmacy audited the commercial pharmacy of CoxHealth, which receives and dispenses all investigational drugs for CRO, on June 23, 2010. The auditor/inspector determined that the CoxHealth Pharmacist was in violation of a Missouri statute each time a research drug was received, since the drug suppliers were not licensed in the State of Missouri. Each violation constituted a misdemeanor; however, multiple misdemeanors could have elevated the charge to a felony. As a result, on August 18, 2010 CRO was required to stop enrollments of any new patients onto protocols that involved investigational agents. We continued to treat those patients already on study and to enroll to studies which did not involve Investigational New Drugs (IND) agents. Needless to say, this could have been a devastating blow to our CCOP program.

The Missouri Hospital Association, the Missouri State Board of Pharmacy, as well as the administrative and legal departments of our two parent institutions, CoxHealth and St. John's Springfield, worked diligently with the NCI and state legislators to help rectify this situation. On August 27, 2010 we were granted a temporary reprieve from the Missouri State Board of Pharmacy and resumed enrollments to clinical trials with provided drugs. The Missouri Pharmacy Board requested a change in the statute which requires legislative approval.

The Missouri Board of Pharmacy met on September 14, 2010 and adopted a rule to formalize its position that a drug distributor licensure is not required in the shipment of new

investigational drugs or biological products in Missouri. The board began working on final language which was presented at the Missouri Board of Pharmacy's January 2011 meeting.

CRO Accruals

September was a slow month for registrations due in part to our pharmacy issues as noted above. We had only 6 registrations for the month resulting in 4.3 treatment and 1.5 cancer control credits.

At our October 7, 2010 CRO monthly staff meeting, CRO staff along with our PI, Dr. Robert Carolla, brainstormed to develop an action plan, working hard to look at every opportunity we had to identify possible patients who would benefit from our NCI trials. Steps included in our plan were:

1. Dr. Carolla sent a letter to our investigators to encourage enrollments.
2. CRO's PI and Director visited with our medical oncologists asking their input and assistance on ways to increase our enrollments to clinical trials. Follow-up to each suggestion was pursued.
3. CRO staff worked with medical and radiation oncologists to place a letter from them in their new patient packets introducing them to clinical trials and noting the physician's support of clinical trials.
4. CRO staff reviewed our screening practices to assure we were reaching all eligible patients.
5. CRO Clinical Research Assistant (CRA) at St. John's began visiting patients once they had been roomed in the physician's office before the physician saw them to share cancer control trial information.
6. CRO developed a flyer promoting availability of multiple symptom cancer control trials to distribute to patients, display in elevators and waiting areas.
7. CRO staff began rounding in chemotherapy and radiation therapy departments at least daily to promote trials.
8. CRO's director met with the staff in physicians' offices to share information about CRO and answer questions about our services.
9. Staff placed "Ask your Doctor About A Clinical Trial" flyers in all patient exam rooms at the oncologists' offices.
10. CRO staff began spotlighting a protocol monthly making flyers to place at physicians' workstations and in their staff break rooms, presenting at tumor board and profiling in the CRO Communiqué publication
11. CRO worked with cancer support groups to share information about cancer research and the trials available.
12. CRO's staff sent letters and visited with surgeons requesting their support of clinical trials.

At years' end on May 31, CRO had accrued 104.1 treatment credits; only 15.9 credits below the NCI assigned target credits of 120 for this grant year. We earned 63.9 cancer control credits just 6.1 below our NCI assigned target credit of 70 for this grant year.

Enrollment to NCI oncology clinical trials are reduced nationwide, and have been for the past two years. It is believed that this is due to multiple reasons, including stricter eligibility requirements. For example, on NSABP P-5 "Statin Polyp Prevention Trial in Patients with

Resected Colon Cancer,” patients who are on statin drugs are ineligible. This is a roadblock as many of our patients are on cholesterol reducing medications. Numerous patients are ineligible for control trials because they fail just one of the criteria.

CRO Communiqué

CRO publishes a “*CRO Communiqué*” monthly. The Communiqué is distributed by email or in print to each of our investigators, administrators and others interested in our program. In this publication we share monthly accrual statistics, recognize the leading physicians in trial enrollments, profile newly opened studies, announce upcoming CRO events, and share CCOP news including the Institute of Medicine’s report on Cooperative groups. A list of recently opened and closed studies with in the last month is also included.

CRO Steering Dinner Committee meetings

Dr. Nora Bucher shared information on pharmacokinetically guided dosing using “Area Under the Curve” rather than traditional BSA dosing. Myriad Pharmaceutical Company assisted with the event which was held on September 27, 2010 at Metropolitan Grill. Dr. Carolla updated the group on CRO activities. Recognition plaques were presented to the three top enrolling physicians in grant year 2009-2010. Dr. Manjula Raju was the top enrolling investigator with 19 enrollments. Dr. Roger Holden was second with 18 enrollments, and Dr. Al Bonebrake was the third highest enrolling physician with 16 patients enrolled in clinical trials. Twenty-eight physicians, nurse practitioners and research staff attended the event.

Thirty-seven physicians and research staff attended the CRO Steering Committee meeting on Monday, March 28 at TOUCH Restaurant. After an update on CRO activities by Dr. Carolla, Dr. Brian Barnett gave a presentation on Adjuvant HER2 Breast Cancer Therapy with Herceptin. Dr. Barnett serves as Director of Medical Oncology at the Elliott Head Breast Cancer Center in Baton Rouge, Louisiana and previously served as an Assistant Professor at Tulane University Medical Center. Dr. Barnett has an interest in translational research and served as co-investigator in numerous tumor immunotherapy clinical trials while at Tulane. Genentech sponsored the event.

Dr. Carolla Auditor for Southwest Oncology Research Group (SWOG)

CRO’s Principal Investigator, Robert Carolla MD, traveled to Arkansas as a SWOG auditor at St. Edwards Mercy in Ft. Smith, and to the Highlands Oncology Group in Springdale on November 9 – 12, 2010. Information he gains from his auditing experience is an asset to CRO in preparing for our Cooperative Group audits and assists us to become an even better CCOP.

CRO Staff Receives Awards

Dr. Robert Carolla was recognized on Saturday, October 1, 2010 in Jefferson City, Missouri with a Missourian award. The prestigious Missourian Award acknowledges the most accomplished citizens of Missouri. Nominees have made an outstanding contribution to the state or nation in the fields of civics, business, art or politics.

CRO’s Director, Marilyn Bauer was recognized as one of “Springfield’s Most Influential Women” on September 24th, 2010. This event was sponsored by the Springfield Business Journal to recognize successful women who have demonstrated leadership and influence in

civic affairs. Twenty Springfield women were honored and recognized at a luncheon and live auction benefiting a women's charity.

New Research Investigators

Greg Nanney MD joined the medical oncology group at Cancer Hematology Associates at St. John's in Springfield. Dr. Nanney completed his investigator paper work and was able to begin enrolling patients onto trials upon his arrival in November 2010.

Jay Carlson MD joined St. John's as a GYN oncologist on May 2, 2011. Dr. Carlson came to us from Des Moines, Iowa where he has been a very active participant in GOG protocols including sitting on different committees. He is the national study chair for GOG 0269 and national study co-chair for GOG 0244 which are both targeted to open after the upcoming July meeting. He is responsible for opening the CCOP program at Mercy Medical Center in Des Moines and enrolled 81 patients on GOG protocols in the 9 months from April through December 2010. CRO is very excited to have Dr. Carlson with us.

We are also working with Dr. Steven Braun, the new radiation oncologist at St. John's along with Dr. Joseph Bond, Dr. Ruth Nevils, and Dr. Mary Graham from Phelps County to become CRO investigators. CRO is most excited to have new investigators join us as we continually need research champions.

Community Health Educator Grant Opportunity

In July 2010, the NCI announced the availability of an administrative supplement to NCI-sponsored grants and cooperative agreement awards that was pertinent to the National Outreach Network (NON). In response CRO developed a grant proposal and submitted the application on August 4, 2010. The intent of the grant was to expand community outreach capacity, by disseminating cancer information to diverse communities. CRO selected a health disparity project of working with prenatal patients at the Greene County Health Department's Women Infants and Children's (WIC) office on a tobacco cessation project. The grant was highly competitive with only 17 grants being approved. Even though CRO was not selected as a grant recipient, this was an opportunity to work with other community resources and educate them about cancer research.

Internal Audits at CRO Affiliates

Dr. Carolla, Basava Raju, Debbie Cane and Marilyn Bauer spent the day at St. John's in Joplin, Missouri conducting the first quality assurance audit at this affiliate site on August 17, 2010. This group, joined by Marcia Thompson, research nurse, traveled to Joplin again for an audit at Freeman Cancer Center on Wednesday, November 10. Patients' charts, regulatory files and the pharmacy drugs/storage were audited.

Our goal in doing internal audits is to provide optimal care for our research patients, prepare for better outcomes with our research base audits and make future audits less stressful. Internal auditing is a practice audit and a learning experience for all. It provides us a means to develop a closer relationship with our affiliates, and hopefully results in suggestions to make future research process audits go more smoothly.

CRO Drugs Moved to CRO Administrative Office

To improve work processes, research drugs were relocated from the Convenient Care Pharmacy to the CRO Administrative Office. After discussions with both the NCI's Pharmaceutical Management Branch (PMB) and the Missouri Board of Pharmacy, a plan to change the drug storage location was approved by the CRO Executive Committee on Monday, December 16th. The legal, compliance and pharmacy staffs at both CoxHealth and St. John's were consulted, and remote monitoring equipment was installed for the drug refrigerator. The actual transfer of the drugs occurred on June 2, 2011.

EF5 Tornado Destroys St. John's Medical Center in Joplin Missouri

We are most grateful that our Joplin research investigators, nurses and their families were safe following the EF5 tornado which struck their community on Sunday evening, May 22, 2011. Unfortunately, CRO's affiliate St. John's Medical Center was destroyed in the storm and one research nurse lost her home, car and possessions. The NCI was notified of the storms' destructiveness. We are keeping them updated as we hear news regarding the loss of drugs, research records and where patients will be continuing with their treatments.

Marketing

The following is a list of events and speaking engagements CRO has participated in the past 12 months.

<u>Event</u>	<u>Date</u>	<u>Description</u>
Cox IRB Presentation	10/21/2010	Marilyn Bauer spoke regarding CRO and and its service. 11 IRB members attended.
Oncology Hematology Assoc. Associates (OHA) Staff	10/28/2010	Marilyn Bauer spoke to OHA staff telling them of CRO's role and currently open studies. 18 were in attendance
Lung Cancer Support Group at CoxHealth	11/9/2010	Dr. Cunningham gave an update on the latest lung cancer treatments. CRO's Director spoke of the lung cancer clinical trials currently available and CRO's services.
Image Reborn Breast Cancer Support Group	1/12/11	CRO's Director spoke to this group of 37 breast cancer survivors about CRO services.
UNITE Multicultural Event	1/17/2011	CRO's Debbie Cane staffed a booth at this event giving out information to educate attendees regarding CRO. Approximately 200 attended the event.

Achieving Target Credit Goals

As with other CCOPs, low accruals to trials has been concerning for CRO again this grant year. Steps taken to increase clinical trial participation were discussed earlier in this report.

Yearly, the National Cancer Institute (NCI) sets credit goals for Community Clinical Oncology Programs (CCOPs). Credits are assigned to protocols and awarded to the CCOP when a patient is enrolled in a cancer treatment or prevention trial. Credits are also awarded for long-term follow up visits for patients in large cancer prevention trials. Cancer Research for the Ozarks' assigned NCI target credits for this fiscal year were 120 cancer treatment credits and 70 cancer control or prevention credits. At fiscal year's end, Cancer Research for the Ozarks had accumulated 104.1 cancer treatment credits and 63.9 cancer control credits.

Credits are different from enrollments. An enrollment is defined as one patient enrolled into one trial. Enrollments 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 173 enrollments for credit, and 7 no-credit enrollments, for a total of 180. Of that total, our affiliates in Joplin at St. John's Regional Medical Center, Freeman Health, Skaggs, and Central Cares PA contributed 16 enrollments. Our affiliates contributed 11% of our total enrollments this grant year. Last grant year our affiliates contributed 17.6 % of our total enrollments.

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 \$581,389 this past fiscal year. Grant dollars go a long way, but do not completely support CRO. We are very fortunate and grateful to also have the support of Springfield’s two major health care systems—CoxHealth and St. John’s.

One of our continuing objectives is to reduce expenses paid by our sponsors who help support our work. Of note, in fiscal year 2005-2006 *these* systems contributed \$245,154 in support of CRO. The two tables below compare our FY 2009-2010 and FY 2010-2011 revenues. This past year, despite less revenue from our NCI grant, CRO finished in the black with \$14,382 remaining in our account.

CRO could not exist without the generosity of the administrations from both systems. Our sincere thanks to CoxHealth and St. John’s. 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 2009-2010
Federal	\$681,390
Other	\$277,715
Total Revenues	\$959,105
Total Expenses	\$967,790
Deficit *	(17,372)

Revenues	Fiscal Year 2010-2011
Federal	581,389
Other	397,049
Total Revenues	978,438
Total Expenses	964,056
Remainder *	14,382

*The deficit is split equally between CoxHealth and St. John’s
 Fiscal year 2009-2010 - \$8,686 each
 Fiscal year 2010-2011 – Remainder \$7,191 plus to each institution

Meeting the CRO Goals for 2010-2011

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

CRO Goals	Achievements
Exceed our target treatment credits of 120 by 5% resulting in 126 treatment credits for this grant year.	CRO was fortunate to have achieved 104.1 treatment credits. Enrollments to clinical trials have been a struggle the past two years throughout the country due to the lack of trials and increased difficulty of conducting them.
Exceed our target cancer control credits of 70 by 5 % giving us 73.5 credits for this grant year.	CRO earned 63.9 cancer control credits this grant year. Enhancing our enrollments to clinical trials has been and will continue to be a major focus for CRO.
Educate cancer patients at Cox and St. John's while enhancing our enrollments into clinical trials by placing a letter into the new patient packets showing physician support of cancer research and introducing CRO to the patient.	A letter from the physicians at Cancer Hematology Center, Oncology Hematology Associates, St. John's Radiation Center and Cox's Radiation Center is now inserted into all new patient packets. The letter introduces new patients to Cancer Research for the Ozarks and lets the patients and their families know their physicians support NCI clinical trials.
Increased efforts to keep CRO investigators and health care extenders aware of clinical trial availability by: <ul style="list-style-type: none"> - CRO's PI sending a monthly letter to investigators informing them of new opened trials and those trials closed during the month. - Sharing a clinical trial (multidisciplinary if possible) at Cox's weekly tumor conferences - CRO staff to attend nurse practitioner meetings at Cox to share trials they can assist us in recruiting participants. 	In Aug. 2010, CRO began including newly opened and closed studies in their monthly CRO Communiqué. In November 2010, we began profiling a new or interesting study in the Communiqué. CRO staff screen all patients being presented at weekly tumor boards at both Cox and St. John's. CRO staff attends weekly tumor board meetings to network with other health care professionals and to discuss trials patients being presented qualify for. We have not yet had an opportunity to attend nurse practitioner meetings.
Capture patient screening information in CRO's CREDIT database for monthly analysis.	Great information is available from the CREDIT data base. We continue to learn and use the capabilities and functions of the data base as new capabilities are introduced.
Work with pharmacy to correct issues with handling of research drugs. Conduct internal audits monthly.	Monthly audits of CRO pharmacy drugs are performed by CRO's Study Coordinator. Monthly audits will continue with CRO research drugs as they are moved to the CRO Adm. office.
Explore feasibility of getting more surgical oncology trials at CRO	In May 2010, CRO explored the feasibility of getting more surgical oncology trials (ACOSOG) at CRO and found only 3 additional trials would be available to us if

	<p>we were to become affiliated with ACOSOG. With ACOSOG collaborating with NCCTG and CALGB to be one of the 5 cooperative groups, CRO will have access to all 3 groups via our affiliation with NCCTG.</p>
<p>Explore the development of a volunteer ambassador program of past trial participants and the role they may provide for CRO.</p>	<p>Consulted with other CCOP administrators including Connie Szczepanek from the Grand Rapids CCOP to network and research other CCOP ambassador programs. Information shared with the CRO Executive Board on 2/16/11. The board discussed the benefit of a program versus the time commitment. Decision to ask physicians and staff for possible past trial participants who would be good candidates to share their experience with trials and may be willing to explore the possibility of an ambassador program for CRO.</p>
<p>Establish internal audits of our affiliate charts and regulatory records</p>	<p>CRO staff performed internal audits at St. John's in Joplin on August 17, 2010 and Freeman in Joplin on November 10, 2010. Both audits revealed minor suggestions for improvements and an opportunity to network with our affiliates.</p>
<p>Work for improved quality assurance at CRO with:</p> <ol style="list-style-type: none"> 1. Timely and accurate data submission 2. Decrease queries and turnaround time to address those that do occur 3. Stabilization of CRO staff with no vacancies this next year 4. Quarterly departmental chart audits 5. Review and updating of Standard Operation Procedures at CRO 6. Continue to master the capabilities of our CREDIT data base 7. Continue with efforts to accurately track CRO finances 8. Job shadowing to assure coverage of all aspects of CRO business in case of an emergency 	<p>Quality assurance is an ongoing responsibility at CRO. Late data submission has been an issue for CRO this past year. Efforts have been made to prevent this from being an issue going forward.</p> <p>CRO has had no staff vacancies this past year. Stabilization of staff greatly helps efficiency and quality of data submitted.</p> <p>CRO's Standard Operating Procedures are continually being reviewed. A formal review of our SOP's was conducted in 2010.</p> <p>Having a dedicated and highly skilled person responsible for CRO finances and the CREDIT database has helped the financial stability over the past several years.</p> <p>An effort to train staff to cover for each other continues. This past year, one CRA has mastered the ability to submit data for our research nurses.</p>

Goals & Opportunities for CRO in Grant Year 2011-2012 are as follows:

Goal 1. Increase accruals to NCI clinical trials

- Exceed our target treatment credits for this grant year by 3%.
- Meet our cancer control credits for grant year.

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

- Publish trials opened and closed each month in the CRO Communiqué.
- Profile a new study each month in the CRO Communiqué.
- Network with physicians keeping them updated on new trials available.
- Update pocket list of studies available bi-monthly and deliver to investigators.
- Hold twice yearly CRO Steering Committee meetings with national speakers on new cancer therapies and treatments.
- Distribute pocket cards of open studies at tumor conferences at Cox and St. John's.

Goal 3. Increase new investigators and affiliate participation in clinical trials

- Contact surgeons to explore their participation in clinical trials by July 1, 2011.
- Explore the possibility of an affiliation with Phelps County Hospital in Rolla, Missouri. September 1, 2011 is a target date for an affiliation completion.
- Revise affiliate contract to require a minimum number of enrollments to remain involved with CRO.
- Require a minimum number of affiliate enrollments before RN staff is sent to research base meetings.
- Work with affiliates to encourage their enrollments to clinical trials.

Goal 4. Ensure quality at CRO

- Complete transfer of research drugs to the CRO Administrative Office by June 1, 2011.
- Re-evaluate the staffing structure at CRO by August 1, 2011.
Work for improved quality assurance at CRO with:
 1. Timely and accurate data submission
 2. Decrease queries and turnaround time to address those that do occur
 3. Quarterly departmental chart audits
 4. Train CRAs to develop data submission skills to assist RNs

Protocol Reports: 2-Year Comparison of Registrations & Credits

Treatment

RESEARCH BASE	2009-2010 REGISTRATIONS	2009-2010 CREDITS	2010-2011 REGISTRATIONS	2010-2011 CREDITS
CTSU	65	62.3	52	44.40
GOG	14	16.00	26	19.70
MD ANDERSON	0	0	0	0
NCCTG	8	8.00	4	4.00
NSABP	13	15.50	2	3.00
RTOG	1	1.00	5	6.00
SWOG	15	16.30	27	27.00
<i>Suncoast</i>			0	0
<i>Wake Forest</i>	0	0	0	0
Grand Totals	116	119.1	116	104.10

Cancer Control & Prevention

RESEARCH BASE	2009-2010 REGISTRATIONS	2009-2010 CREDITS	2010-2011 REGISTRATIONS	2010-2011 CREDITS
CTSU	10	7.0	20	17.0
GOG	11	5.5	18	13.0
MD ANDERSON	0	0	0	0
MOFFITT	0	0	0	0
NCCTG	17	17.0	1	1.0
NSABP (<i>new</i>)	6	4.5	1	1.0
NSABP (<i>follow up visits</i>)	17	5.1	29	9.6
RTOG	0	0	10	9.0
SWOG (<i>new</i>)	6	5.5	8	7.0
SWOG (<i>follow up visits</i>)	31	9.3	25	6.3
WAKE FOREST	1	1.0	0	0
Grand Totals	99 Includes f/u visits	54.9	112 Includes f/u visits	63.9

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

AFFILIATE*/SITE	2009-2010 REGISTRATIONS	2009-2010 CREDITS	2010-2011 REGISTRATIONS	2010-2011 CREDITS
Central Care, PA	0	0	3	3.0
Cancer Hematology Center	69	61.5	48	40.1
Ferrell-Duncan Clinic	16	14.0	28	26.0
Freeman Medical Center (Joplin)	16	15.0	7	5.3
St. John's Regional Med Center (Joplin)	14	14.0	4	4.0
Oncology Hematology Associates	50	46.1	47	46.0
Radiation Therapy Center	1	1.0	4	4.0
Skaggs Regional Medical Center	1	.5	0	0
Women's Oncology Care	9	7.5	30	20.7
St. John's Radiation Oncology.	0	0	3	3.0
Grand Totals	176	159.6	174	152.1

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

RESEARCH BASE	2009-2010 REGISTRATIONS	2009-2010 CREDITS	2010-2011 REGISTRATIONS	2010-2011 CREDITS
CTSU	75+1	68.1	71+1	61.4
GOG	25	21.5	44	32.70
MD ANDERSON	0	0	0	0
NCCTG	25	27.5	5+1	5.0
NSABP	19+8	25.1	3	4.0
RTOG	1	1	15	15.0
SWOG	21+0	30.8	35	34.00
Suncoast	0	0	0	0
WAKE FOREST	1	1	0	0
Total Reg. & Credits	167+1	159.6	173+2	152.1
<i>Industrial Trial Reg.</i>	8	0	5	0
<i>Plus follow-up</i>	48	14.4	---	15.9
Grand Total		<u>174.0</u>	<u>180</u>	<u>168.0</u>

*Credit + noncredit registrations. **Registrations totaled.

Patient Registrations by Physician through May 31, 2011

	1 st Quarter		2 nd Quarter		3 rd Quarter		4 th Quarter		Total	
	c	n/c	c	n/c	c	n/c	c	n/c	c	n/c
Abdalla	0	0	0	0	0	0	2	0	2	0
Albritton	0	0	0	0	0	0	0	0	0	0
Amir	0	1	0	0	0	0	0	0	0	1
Bonebrake	5	0	3	0	11	0	9	0	28	0
STJ Women's Onc	14	0	0	0	0	0	0	0	14	0
Carlson							10	0	10	0
Carolla	0	0	0	0	0	0	0	0	0	0
Clouse	0	0	1	0	0	0	1	0	2	0
Croy	0	1	0	0	1	0	0	0	1	1
Cunningham	4	0	0	0	3	0	1	0	8	0
Ding	1	0	0	0	2	0	0	0	3	0
Ellis	6	0	0	0	6	0	4	0	16	0
Farber	0	0	0	0	0	0	0	0	0	0
Gillett	0	0	2	0	2	0	0	0	4	0
Goodwin	0	0	5	0	0	0	1	0	6	0
Hassan	2	0	1	0	0	0	0	0	3	0
Holden	1	0	4	0	2	0	6	0	13	0
Hoos	2	0	0	0	0	0	0	0	2	0
Johnson, Jeff	0	0	0	0	0	0	0	0	0	0
Johnson, Robert	0	0	0	0	0	0	0	0	0	0
Kent, Elizabeth	1	0	0	0	0	0	0	0	1	0
Kim, Helen	0	0	0	0	0	0	3	0	3	0
LaFrancis	1	0	0	0	0	0	1	0	2	0
Myers	0	0	0	0	1	0	0	0	1	0
Miller	0	0	0	0	1	0	0	0	1	0
Nair	1	1	3	0	1	0	0	0	5	1
Nanney			1	0	3	0	2	0	6	0
Pinheiro	0	0	0	0	0	0	0	0	0	0
Raju	3	0	4	1	1	0	3	1	11	2
Ross	0	0	1	0	0	0	1	0	2	0
Shunyakov	0	0	0	0	2	0	1	0	3	0
Skelley	0	0	0	0	0	0	0	0	0	0
Tiriveedhi	0	0	3	0	3	0	4	2	10	2
Driver	0	0	0	0	0	0	0	0	0	0
Williams	3	0	5	0	4	0	4	0	16	0
Total	44	3	33	1	43	0	53	3	173	7

Co-Investigator Registrations

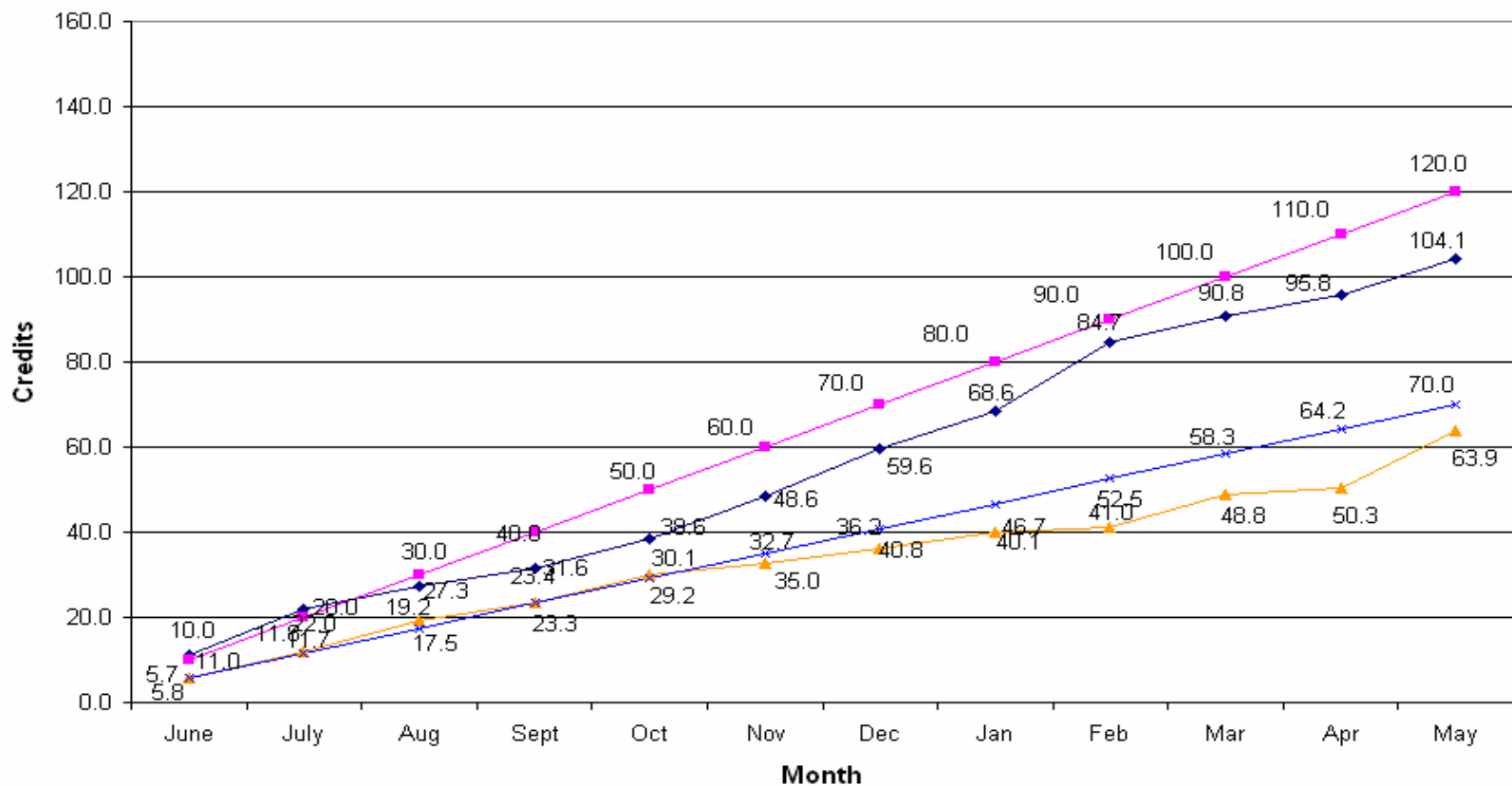
June 1, 2010 to May 31, 2011

	1 st Quarter		2 nd Quarter		3 rd Quarter		4 th Quarter		Total	
	c	n/c	c	n/c	c	n/c	c	n/c	C	n/c
Kim, Helen	0	0	0	0	0	0	0	0	0	0
Biggers, Brian	1	0	1	0	0	0	0	0	2	0
Abdalla, Ibrahim	0	0	0	0	1	0	0	0	1	0
	1	0	1	0	1	0	0	0	3	0

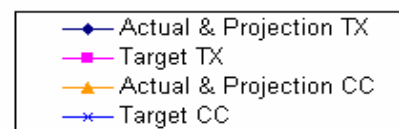
Top Protocols By Registration

	Number	Title	Registra- tions	Credits
1	SWOG S0904	Randomized Phase II Study of Docetaxel Followed by Vandetanib (ZD6474) vs. Docetaxel Plus Vandetanib in Patients with Persistent or Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Carcinoma	16	16.00 Rx.
2	CTSU E5103	A Double-blind Phase III Trial of Doxorubicin and Cyclophosphamide Followed by Paclitaxel With Bevacizumab or Placebo in Patients With Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer	14	14.00 Rx.
3	CTSU CALGB 70604	A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer	14	14.00 cc
4	GOG 0247	Patient, Physician and Nurse Factors Associated with Entry onto Clinical Trials and Completion of Treatment for Women with Primary or Recurrent Invasive Carcinoma of the Uterine Corpus or Uterine Cervix, All Stages	8	8.00 cc
5	RTOG 0841	Efficiency of Screening for Depression in Cancer Patients Receiving Radiotherapy	7	7.00 cc
6	GOG 0136	Acquisition of Human Gynecologic Specimens and Serum to be Used in Studying the Causes, Diagnosis, Prevention and Treatment of Cancer	7	0.7 Rx.
7	SWOG S0715	Randomized Placebo-Controlled Trial of Acetyl L-Carnitine for the Prevention of Taxane Induced Neuropathy	6	6.00 cc
8	CTSU 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	5.00 Rx.
9	GOG 0086P	A three arm randomized phase II study of Paclitaxel/Carboplatin/Bevacizumab, Paclitaxel/Carboplatin/Temsirolimus and Ixabepilone/Carboplatin/Bevacizumab as initial therapy for measurable stage III or IVA, stage IVB, or recurrent endometrial cancer	5	5.00 Rx.
10	NSABP B- 44-I	BETH Trial: A Multicenter Phase III Randomized Trial of Adjuvant Therapy for Patients with HER2-Positive Node-Positive or High Risk Node-Negative Breast Cancer Comparing Chemotherapy Plus Trastuzumab with chemotherapy Plus Trastuzumab Plus Bevacizumab	5	0

June 1, 2010 - May 31, 2011 Credits



Cancer Research for the Ozarks
Totals through 5/31/2011



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*

- Rita Campbell – Ritter, Clinical Research Assistant
- Debbie Cane, AA, Office Manager
- Kathy Coleman, BSN, Research Nurse
- Cynthia Dievert, Clinical Research Assistant
- Shirley Gordon, BSN, Research Nurse
- Lisa Hamilton, LPN, Clinical Research Assistant
- Sharon Hodge, BSN, Research Nurse
- Basava Raju, MS, BS, CCRP, Research Coordinator
- Stephanie Sekscinski, Regulatory Compliance Coordinator
- Marcia Thompson, BSN, Research Nurse

Cancer Research for the Ozarks

*has a mission rooted in the spirit of collaboration
between CoxHealth and St. John's Health System.*

*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.*