Cancer Research for the Ozarks

A Community Clinical Oncology Program

Springfield, Missouri

The Year in Review
2008-2009

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As I see it

Robert Carolla MD
Principal Investigator

The 2008-2009 grant year for Cancer Research for the Ozarks has been an exciting and challenging one, not only for the organization but for me personally. I became the Principal Investigator in June 2008 and have found this job to be a stimulating experience. I had no idea of the amount of work and time commitment that is necessary for the job, which makes me even more grateful for the strong leadership of Dr. Wendall Goodwin for more than 23 years. He has laid a very strong foundation for the organization, one that has allowed us to move forward in a positive fashion. All of us at CRO are grateful for his leadership and guidance.

Our number one activity for this year was the submission of a new grant proposal, which was accomplished in July 2008. It received a very high peer review score and at the end of May 2009, we received official notification of funding for the next five years with a total budget of $4.2 million. This is essentially what we asked for and is an affirmation by the National Cancer Institute that we have a quality organization, which is committed not only to research but also to patient safety. New investigators have joined CRO this year: Dr. Rajesh Nair and Dr. Chris Lewis at St. John's Clinic – Cancer & Hematology; Dr. Amir Anis and Dr. Elizabeth Kent of Freeman Healthcare in Joplin; and Dr. Joseph Carmichael and Dr. Brian Biggers of CoxHealth.

Our total treatment credits of 136 are 13.8% higher than the NCI guidelines, a significant accomplishment and one we should all be proud of. Although our cancer control credits fell short of our goal, we feel this is in part due to the paucity of protocols available. Our new affiliation with the North Central Cancer Treatment Group (NCCTG), from the Mayo Clinic Cancer Center, offers new and exciting opportunities not only in cancer control protocols but also protocols designated for cancer treatment.

Marilyn Bauer, executive director, has clearly outlined our goals for the next year. I would like to emphasize the goal related to the establishment of a community-wide institutional review board. We feel this is important to standardize the administration, allow wider participation of physicians in outlying communities of the service area and to achieve our goal of fiscal responsibility and independence.

I would like to personally thank the entire CRO staff and Dr. Roger Holden, who serves as Associate Principal Investigator. All of us at CRO look forward to an exciting year of further growth with the ultimate goal of becoming the top CCOP in the nation.

Progress Report

Marilyn Bauer, BSN, MEd, MHA, CRO Director

Dr. Carolla: New Principal Investigator

As of August 1, 2008, Dr. Carolla retired from full time practice at Oncology Hematology Associates. He has set up and organized office space at the CRO main administrative office. In his role as Principal Investigator (PI), he has been readily available to assist with protocol and regulatory processes. The transition of Principal Investigator responsibilities from Wendall Goodwin MD, who served as Cancer Research for the Ozarks (CRO) PI beginning in 1985 till June of 2008 has gone very smooth. Dr. Carolla's strong interest and involvement as an investigator prior to the PI position prepared him well for the CRO PI position.

New Investigators

We are happy to announce that several new physicians have become Investigators for CRO this year. Dr. Ernest (Chris) Lewis and Dr. Rajesh (Raj) Nair joined St. John's Clinic – Cancer & Hematology and completed requirements for the National Cancer Institute. Dr. Lewis has been an Investigator in another practice. Dr. Elizabeth Kent joined the oncologists at Freeman Healthcare. Most recently, she was a medical oncologist at Kansas City Cancer Center, in Overland Park, KS. Dr. Kent has also previously been an NCI investigator. Dr. Brian Biggers joined Crighton Olive Dunn Surgical Group as a breast surgeon. Dr. Biggers has a strong interest in research.

CRO physicians invited to participate in panel at CCOP meeting

Principal Investigator Dr. Robert Carolla and retired Principal Investigator Dr. Wendall Goodwin were invited to serve on a panel discussion at the national CCOP meeting in Washington DC on March 2, 2009. The topic was CCOP Principal Investigator Transition Plans. However, inclement weather in the Washington area prevented their reaching DC in time for the conference. Both were disappointed as they were excited to share their story.

Dr. Brian D. Biggers presented at SWOG spring conference

CRO Investigator Dr. Brian Biggers spoke to the surgery subcommittee at the April 2009 Southwest Oncology Group conference. His talk was about circulating tumor cells. He presented his data from Baylor, and is currently working on a validation study. Dr. Biggers is a breast surgeon with the Crighton Olive Dunn Surgical Group.

New Employees

Cynthia Dievert joined CRO on September 8, 2008 as a clinical research assistant. Cindy is based at St. John's. She is an LPN, and prior to this position had worked in St. John's surgical intensive care unit for fourteen years. Sharon Hodge joined the CRO team as a research nurse in December. Sharon was a clinical nurse specialist at St. John's Breast Center prior to joining CRO. Kathy Coleman joined us on June 1, 2009 as a research nurse. Kathy's background in risk management and leadership are well suited for research. Both Sharon and Kathy are based at CoxHealth.

Research Base North Central Cancer Treatment Group (NCCTG)

In August 2008, CRO submitted an application for affiliation to the North Central Cancer Treatment Group (NCCTG). In October we were notified by NCCTG that CRO was accepted. NCCTG offers a variety of cancer trials that can be significant for cancer patients in the Ozarks. NCCTG's high standards required a review of CRO's performance by a selection board which met in October. CRO feels fortunate to be affiliated with NCCTG since they only select those organizations they judge capable of meeting their standards for affiliation.

Consultant

In July 2008, Marge Good, director of the Wichita CCOP, visited CRO as a consultant. Under Marge's leadership the Wichita CCOP is currently ranked number three in the nation for enrollments. She is a well respected speaker in the CCOP and research world. Several excellent ideas for improving efficiency resulted from her visit. We have moved forward with a number of her suggestions.

New Protocol Review Processes

Historically, Cancer Research for the Ozarks Steering Committee met monthly to perform scientific reviews, discuss new protocols and determine which studies should be sent on to the IRBs at CoxHealth and St. John's. In September 2008, a new protocol review process was put into place. Currently, new studies are downloaded from research bases, and Principal Investigator Dr. Robert Carolla reviews each of them for feasibility. Appropriate studies are then forwarded to the Co-investigators at CoxHealth and St. John's in Springfield. After their review, Dr. Carolla collects their opinions and if the majority is favorable, the protocol is sent to the IRBs. CRO nurses also review new studies, give input and complete the CRO billing analysis form.

Quarterly Steering Committee Meeting

November 24th, 2008

With our new review process in place, our monthly CRO Steering Committee meetings have been less frequent and now include education as well as an update of CRO statistics. A variety of pharmaceutical companies have assisted in bringing nationally and regionally known speakers to Springfield for these meetings.

Bristol Myers Squibb assisted CRO in the first revised Steering Committee meeting held November 24, 2008 at Touch Restaurant. Our first speaker for the evening was Giovanni Antic PhD, a medical science liaison with Bristol Myers Squibb. He spoke briefly about metastatic colorectal cancer. Our featured speaker was James Atkins MD. He is the principal Investigator at the Southeastern Cancer Control Consortium, Inc. in North Carolina, which is the top enrolling CCOP in the nation. Dr. Atkins emphasized the importance of enrolling patients into clinical trials, stating "Choosing to enroll patients allows physicians the best opportunity to care for their patients." He commented that physicians not actively enrolling patients in clinical research often cite a lack of time. Dr. Atkins noted that in his experience, the use of clinical trials offers patients more than just standard care, garners increased peer respect for physicians and benefits society as a whole. Approximately 70 oncology physicians, nurse practioners and research staff were in attendance for this inspiring presentation.

March 4, 2009

The second CRO Steering Committee was held March 4, 2008, at Metropolitan Grill. Pharmaceutical company Genentech helped sponsor this meeting featuring Ramaswamy

Govindan, MD a noted physician from Washington University in St. Louis. Dr. Govindan is an expert in lung cancer. He discussed current information about lung cancer treatment and gave his futuristic outlook regarding this disease. Dr. Carolla reviewed current lung cancer and cancer control studies available at Cancer Research for the Ozarks. Approximately 35 were in attendance for this meeting.

The newly formatted Steering Committee meetings are building our research team and increasing camaraderie to our research community.

Review of studies with zero registrations

In an effort to become more efficient, CRO reviewed open studies with no enrollments, and evaluated the need to keep them open. Maintaining open protocols is time-consuming for both IRBs and the CRO staff due to the large amount of regulatory work required. In August 2008, CRO investigators at CoxHealth and St. John's had the opportunity to review a list of protocols with no registrations for at least one year. The review yielded 12 protocols not being used by physicians, and these protocols were archived. Going forward, physicians will have the opportunity to review protocol lists every six months to determine which should remain open and which should be archived. This review will also provide a reminder to physicians about the protocols available.

Protocol Pocket Cards

Pocket cards listing all open CRO studies with an abbreviated eligibility list were developed and first distributed at our November 24th Steering Committee meeting. The cards are color coded by disease site and fit easily into the pockets of lab coats. Positive comments regarding the usefulness and easy access to our studies have been reported by the physicians and nurse practioners. We have received requests for additional copies as they have become frayed or misplaced. The cards are frequently updated with new studies, revised eligibility criteria and study closures.

CREDIT (Clinical Research Environmental Data Information Tracking) Database

CRO staff, including affiliate staff from Freeman Healthcare and St. John's Regional Medical Center in Joplin, received training on the CREDIT database in January. CREDIT is specific to cancer research and has the capability to register, track and follow patients through protocols. It also features an Institutional Review Board component to manage IRB regulatory affairs, and a financial component to oversee billing and reimbursement. CREDIT is a web-based database now available to all CRO staff. The database should ease manual workload and allow the staff to have quicker access to their site-specific information. We continue to learn the capabilities of CREDIT and are very pleased to have been granted the opportunity to purchase this database.

NCI CCOPs 5-year grant award score announced

In July of 2008, CRO's 5-year grant request from the National Cancer Institute (NCI) was submitted. We were very pleased to receive a grant score of 139. To put this in perspective, the best score given is 100 and the worst score is 500. Dr. Joseph Kelaghan, NCI's grant specialist, stated "you nearly received the best score available." CRO's entire request for $4,239,818 was approved. This 5-year grant award provides funding for June, 2009 through May, 2014.

Staff Development

We requested and received the following PowerPoint presentations from NCI that are being used for staff development during our monthly staff meetings.

NCI PowerPoint Educational Presentations

1. Clinical Trial Protocol Development
2. Clinical Trial Designs and Protocol Development
3. Managing Data in Clinical Research
4. Documentation 101
5. Roles & Responsibilities of the Research Team
6. Roles & Responsibilities of the Sponsor
7. Types of Site Visits for Sponsored Clinical Trials
8. RECIST: Applying the Rules
9. Regulatory Binder
10. Adverse Events: Documenting, Recording, and Reporting

These presentations have stimulated discussions regarding CRO practices and have been positive education tools for new and experienced staff.

Marketing

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

EVENT	Date	Description
Leukemia & Lymphoma	5/27/08	Seminar hosted by The Leukemia & Lymphoma Society. Shirley Gordon, CRO research nurse spoke about the disease and options for patients.
GYN Support Group	9/12/08	Panel presentation including Drs. Bosscher, Albritton and CCOP director sharing CRO opportunities for research.
CoxHealth Expo	9/20/08	Wellness fair sponsored by CoxHealth
Cancer Survivors Group at CoxHealth	12/16/08	CRO director spoke to group of survivors about our department and the research opportunities we offer.
Multicultural Festival	1/19/09	Sponsored by Unite, a minority organization, featuring informational booths and entertainment.
A Time to Share	3/7/09	An educational & entertainment event sponsored by Breast Cancer Foundation of the Ozarks. CRO had a booth and CRO's investigators were featured speakers.
Missouri Public Health Nurses meeting	3/12/09	CRO director spoke to this group of nurses regarding. CRO services.
St. John's Women's Forum	4/21/09	Presentation by Dr. Gary Hoos, St. John's Clinic – Cancer & Hematology. CRO staffed a booth with information and visited with attendees. CRO was recognized as a sponsor of the event. Approximately 150 people attended.

Hispanic Health Fair	5/23/09	Pathways United Methodist Church has a Hispanic congregation. The parish nurse organized a health fair, and CRO participated with a booth. The majority of attendees spoke little or no English. CRO gave away Hispanic materials from NCI. More than 170 people attended.

Achieving Target Credit Goals

Each year 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 different from enrollments. Not every trial has credits attached, while other protocols may offer multiple credits. An enrollment is defined as one patient enrolled into one trial. Enrollments tell us the number of patients in trials. Not all enrollments receive credit. 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 100 cancer control or prevention credits. At fiscal year's end, Cancer Research for the Ozarks had accumulated 136.6 cancer treatment credits exceeding our target by 16.6 credits. Our cancer control credits for the year were 56.7. While we are disappointed our cancer control credits fell short, we know this was a problem for other CCOPs as well.

This past year, CRO had 167 enrollments for credit, and 13 no-credit enrollments, for a total of 180. Of that total, our affiliates in Joplin at St. John's Regional Medical Center and Freeman Health contributed 38 enrollments. This is significant number, and comprises 22.75% of our total enrollments.

CRO Finances

A National Cancer Institute federal grant for fiscal year 2008 – 2009 supplied CRO with $641,391 for expenses related to the provision of clinical oncology trials in our community. We are very fortunate and grateful to also have the support of Springfield's two major health care systems—CoxHealth and St. John's. CRO could not exist without the generosity of the administrations from both systems. Our sincere thanks to them.

One of CRO's ongoing objectives is to reduce expenses paid by our sponsors, while maintaining the quality of our work. This past year, we have succeeded in accomplishing this goal despite tough economic times in our country. As the table below shows our FY 2007-2008 deficit was $150,648 and our FY 2008-2009 deficit was $62,935.

Revenues	Fiscal Year 2007-2008
Federal	$586,474
Other	$79,174
Total Revenues	$665,648
Total Expenses	($816,296)
Deficit *	($150,648)

Revenues	Fiscal Year 2008-2009
Federal	$641,391
Other	$179,628
Total Revenues	$821,019
Total Expenses	(883,954)
Deficit *	(62,935)

*The deficit is split equally between CoxHealth and St. John's
Fiscal year 2006-2007 - $91,071 each
Fiscal year 2007-2008 - $75,324 each
Fiscal year 2008-2009 - $31,468 each

Meeting the CRO Goals for 2008-2009

Below are the goals established by CRO last year, and our report of progress:

CRO Goals	Achievements
Achieve CRO's NCI target treatment credits of 120 for grant year 2008-2009.	During 2008-2009, 127 patients were enrolled into treatment trials at CRO. CRO exceeded our NCI target goal accruing 136.6 cancer treatment credits.
Achieve CRO's NCI target cancer control credits of 100 for grant year 2008-2009.	During 2008-2009 CRO did not achieve our target cancer control credits. Forty patients were enrolled into cancer control studies earning 29.5 cancer control credits. An additional 27.2 control credits were earned with follow-up visits. Many efforts were made by the PI and CRO staff to find studies which would help us to meet this goal.
Prior to Dr. Goodwin's retirement, record CRO's history.	Prior to retiring from his practice and as CRO investigator, Dr. Goodwin shared the history of CRO in a power point presentation for CRO staff and IRB's at Cox and St. John's. The July 2008 issue of the Greene County Medical Society Journal honored Dr. Goodwin for his 23 years of cancer research with our CCOP, and his role as an oncologist in the community. The article discussed the history of CRO and role of CCOPs in cancer research, citing that one-third of all cancer research in the United States is conducted through CCOPs.
Continue with implementation of new staffing restructure to include cross training of staff	Cross training of staff at the both Cox and St. John's continues. Our study coordinator and one of our clinical research assistants (CRAs) have been trained at both Cox and St. John's. With a full staff on board at this time we will continue with this goal.
Survey physicians to define local barriers to patient enrollments amongst those who are qualified for trials.	In April 2008, medical oncologists at St. John's participated in a month long survey to assist CRO staff in identifying factors which could be changed to encourage trial enrollments. The survey provided information which eventually lead to the development of the CRO clinical trial pocket cards.
Bring in a motivational speaker to discuss measures to increase patient enrollment into research studies.	Dr. James Atkins MD, Principal Investigator at the Southeastern Cancer Control Consortium, Inc. in North Carolina, spoke to the CRO Steering committee in November, 2008. He emphasized the importance of enrolling patients into clinical trials and told the group that in his opinion, if their patient is not on a clinical trial then they are not receiving the best care possible.

Explore fund raising opportunities for CRO to off set cost to our sponsoring institutions	In February 2009 the Ozark Health Ventures LLC (OHV) board discussed CRO options for fundraising. Because OHV is a for-profit entity, CRO must exercise caution in any fund raising ventures. It was determined that unsolicited donations to CRO can be made to the Foundations of either CoxHealth or St. John's.
Prepare and submit our five-year grant request to National Cancer institute to assure CRO's future.	Our 5-year grant application was submitted on July 8, 2008. We received a grant score of 139 and the full $4,239,818 requested. This 5-year grant award provides funding from June 2009 through May 2014
Explore development of a web site for CRO.	A contract has been signed with Winnovate LLC to develop a website for CRO. We are in the process of writing content for the site at this time. The target date for completion is August 2009.
Implementation of a new database for CRO that currently is being developed for us at Cox.	In January, CRO staff received training on the CREDIT database. CREDIT is a web-based database and is available to all CRO staff and our Joplin affiliates. CREDIT is specific to cancer research and has the capability to register, track and follow patients through protocols. It also features an Institutional Review Board component to manage IRB regulatory affairs, and a financial component to oversee billing and reimbursement.
Enhance community awareness of CRO through presence at community events, media coverage of successful trials and other newsworthy occurrences, continuation of monthly email newsletter, and broad distribution of CRO video.	CRO has participated in 12 community events this past year. Monthly, the CRO Communiqué is distributed to health care professionals and others interested in research in our community. The one page newsletter addresses newsworthy occurrences in cancer research. Approximately 100 copies of the CRO video have been shared with individuals and groups this past year.
Work for improved quality assurance at CRO with 1. Quarterly inventory assessment of our pharmacy 2. Timely and accurate data submission to our cooperative groups 3. Addressing queries as they occur. Monthly reminders to be sent to each staff member. 4. Quarterly departmental chart audits.	Quality assurance continues to be a major goal at CRO. We have instituted quarterly inventory assessments of our pharmacy drugs, created monthly queries listings for each staff member to address, and included quarterly chart audits in our Standard Operating Procedures. Data submission continues to be an issue for CRO. With the stabilization of staff and freeing of our study coordinator to assist in this area we feel we will be able to meet these goals in the future.

Cancer Research for the Ozarks 2009-2010 Goals

It is important that we look toward the future. Goals & Opportunities for CRO in the next year are as follows:

- Exceed our target treatment credits of 130 by 7 enrollments or 5% for this grant year.
- Meet our target cancer control credits of 90 for this grant year.
- Complete development of a CRO website to be a user friendly site where health care professionals and community members have easy access to clinical trials available at CRO.
- Explore the feasibility of a Community IRB for CRO.
- Enhance community awareness of CRO through presence at community events, media coverage of successful trials and other newsworthy occurrences, continuation of monthly email newsletter, broaden distribution of CRO video.
- Greater participation of Principal Investigator and Administrator with CCOP and research base committees.
- Sponsor bi-yearly educational CRO steering committee meetings with an attendance of at least 50 for each meeting.
- Work towards a year of successful audits. CRO is expecting audits from six research bases this year.
- Explore the development of a volunteer ambassador program of past trial participants and the role they may provide for CRO.
- Work for improved quality assurance at CRO with:
  1. Timely and accurate data submission to cooperative groups
  2. Addressing queries as they occur. Queries are gathered monthly from our research bases and sent to the responsible staff member to complete.
  3. Quarterly departmental chart audits
  4. Stabilization of CRO staff
  5. Quarterly inventory assessment of our pharmacy

Cancer Research for the Ozarks 5-Year Goals (2008 – 2013)

In 2008 the following five-year goals were set for CRO by the CRO Executive Board and CRO staff. This longer time period will offer the opportunity to assess progress and make necessary adjustments to ensure we meet these important goals. It is interesting to review these goals and see the progress already made.

1. **Enhance** the health of our community and individuals with cancer by providing the latest NCI oncology research treatment trials. National statistics show that while 20 to 35% of all newly diagnosed cancer patients are eligible for clinical trials only 2 to 3% enroll in a trial. Our goal is to maintain our 5.8% rate of enrollment of all newly diagnosed adult cancer patients in our community on a clinical trial with 3.2% of those enrollments being into cancer treatment trials.
2. **Assist** in reducing the incidence of cancer and finding the cure for cancer by offering NCI cancer prevention and early detection trials in our community. Our goal is to maintain our 5.8% overall rate of enrollment with 2.6% of those enrollments being into cancer prevention and control trials.
3. **Provide** education to health care professionals and the communities within our geographical area about state-of-the-art-cancer care, including availability of NCI clinical trials, via website development and other marketing strategies.
4. **Monitor** our staffing mix as needed to keep pace with changing trends and with the goal of building a strong, efficient staff committed to research and teamwork.
5. **Identify** local barriers to accrual and develop plans to reduce them.
6. **Interact** with other CCOPs throughout the nation, specifically by attending research base meetings and CCOP administrators meetings to enhance network of opportunities available for CRO.
7. **Explore** the feasibility of establishing an oncology community IRB for CRO to enhance our efficiency and minimize expenses.
8. **Insure** quality is maintained including but not limited to:
   - Quarterly inventory assessment of our pharmacy services
   - Timely and accurate data submission to cooperative groups
   - Prompt query resolution within the month
   - Quarterly in-house departmental chart audits
9. **Develop** a volunteer ambassador program of past trial participants to share with those considering trial enrollments
10. **Explore** the feasibility for CRO to offset costs to our sponsoring institutions as we strive to become financially independent.
11. I**mplement** a new computer database for CRO (currently under development at CoxHealth).

Protocol Reports: 2-Year Comparison of Registrations & Credits

Treatment

RESEARCH BASE	2007-2008 REGISTRATIONS	2007-2008 CREDITS	2008-2009 REGISTRATIONS	2008-2009 CREDITS
CTSU	51	49.3	50	49.8
GOG	23	23.0	18	22.5
NCCTG			1	1.0
NSABP	31	31.0	26	30.5
RTOG	6	5.1	3	3.0
SWOG	21	21.0	29	29.8
Grand Totals	**133**	**130.4**	**127**	**136.6**

Cancer Control & Prevention

RESEARCH BASE	2007-2008 REGISTRATIONS	2007-2008 CREDITS	2008-2009 REGISTRATIONS	2008-2008 CREDITS
CTSU	13	9.3	6	3.0
GOG	11	6.0	11	5.5
MD ANDERSON	2	2.0	1	1.0
MOFFITT	33	33.0	1	1.0
NSABP ***(new)***	7	3.5	3	1.5
NSABP ***(follow up visits)***	59	17.7	56	16.8
RTOG	2	1.5	4	4.0
SWOG ***(new)***	9	5.5	1	0.5
SWOG ***(follow up visits)***	42	10.8	40	10.4
WAKE FOREST	6	6.0	13	13.0
Grand Totals	**184**	**92.3**	**136**	**56.7**

Registrations by Affiliate/Site

AFFILIATE*/SITE	2007-2008 TREATMENT	2007-2008 CONTROL & PREVENTION	2008-2009 TREATMENT	2008-2009 CONTROL & PREVENTION
CCOP	0	3	0	0
Cancer Hematology Center	23	36	54	20
Ferrell-Duncan Clinic	18	7	15	9
Freeman Medical Center (Joplin)	33	10	17	4
St. John's Regional Med Center (Joplin)	10	3	12	1
Oncology Hematology Associates	46	19	27	5
Radiation Therapy Center	1	0	0	0
Women's Oncology Care	2	4	2	1
St. John's Radiation Onc.	0	1	0	0
Grand Totals	133	83	127	40

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

RESEARCH BASE	2007-2008 REGISTRATIONS	2007-2008 CREDITS	2008-2009 REGISTRATIONS	2008-2009 CREDITS
CTSU	64+3	555.6	56+1	52.8
GOG	34	29.0	29	28.0
MD ANDERSON	3	3.0	1	1.0
MOFFITT	33	33.0	1	1.0
NCCTG			1	1.0
NSABP	38+22	34.5	29+9	32.0
RTOG	8	6.6	7	7.0
SWOG	30+68	26.5	30	30.3
WAKE FOREST	6	6.0	13	13.0
Total Reg. & Credits	**216+93**	**194.2**	**167+10**	**166.10**
Industrial Trial Registration			4	0
Plus follow-up	101 visits	28.5	96	27.2
Grand Total		**222.7**		**193.3**

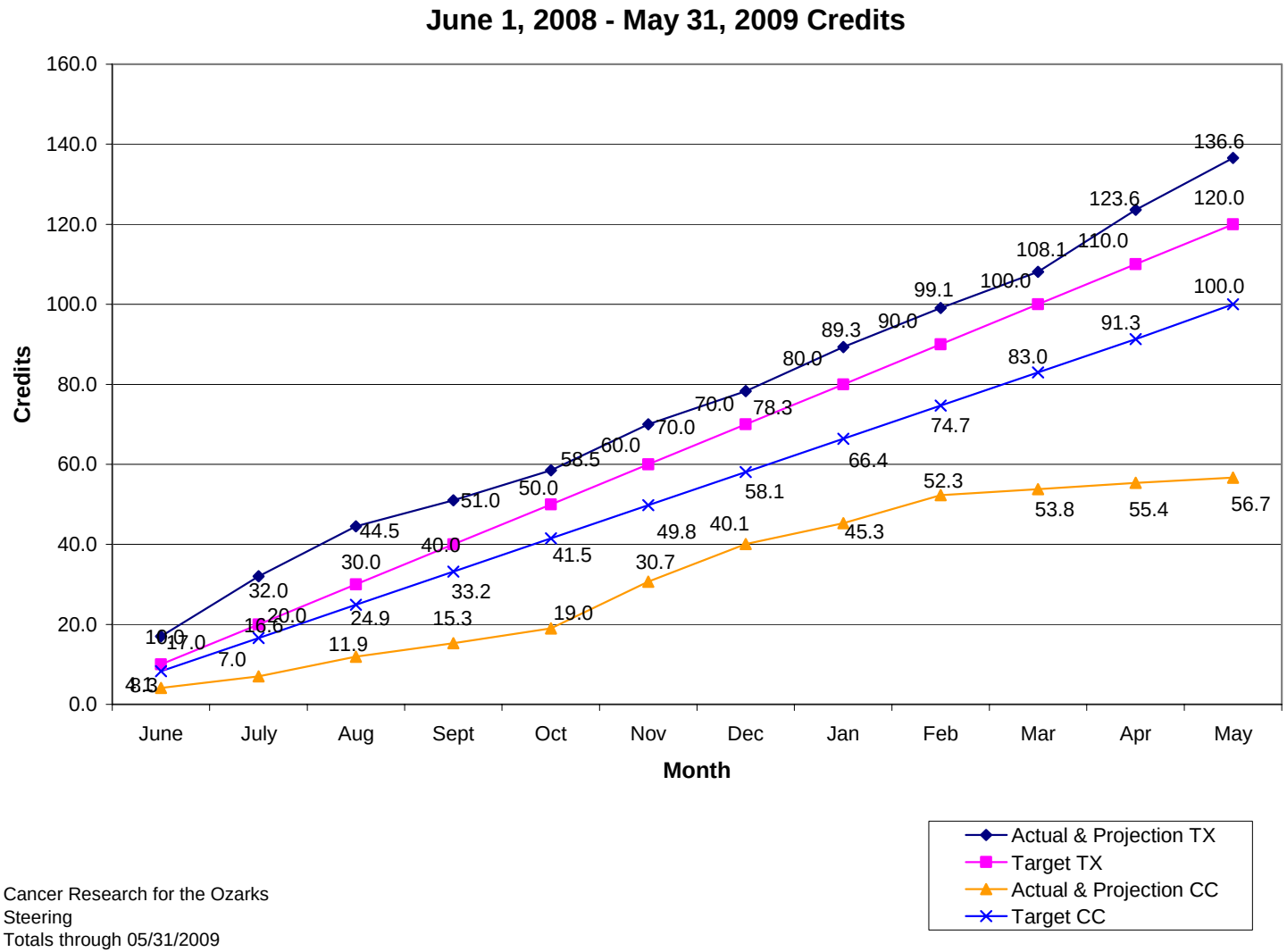
Patient Registrations By Physician June 1, 2008 through May 31, 2009

	1st QT		2nd QT		3rd QT		4th QT		Total	
	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
Albritton	0	0	0	0	0	0	0	0	0	0
Bonebrake	17	1	2	0	3	0	2	0	24	1
Bosscher	0	0	0	0	3	0	0	0	3	0
Carolla	2	0							2	0
Clouse	0	0	0	0	0	0	0	0	0	0
Croy	0	1	1	0	0	0	2	0	3	1
Cunningham	3	0	1	0	3	1	5	0	12	1
Ellis	2	0	6	0	7	0	2	0	17	0
Farber	0	0	0	0	0	0	0	0	0	0
Goodwin	1	0							1	0
Grant	0	0	0	0	1	0	0	0	1	0
Hassan	4	0	3	0	1	0	3	0	11	0
Holden	7	2	8	0	6	0	2	0	23	2
Hoos	0	1	4	0	2	0	4	0	10	1
Johnson, Jeffery	0	0	0	0	0	0	0	0	0	0
Johnson, Robert	0	0	0	0	0	0	0	0	0	0
Kent, Elizabeth							0	1	0	1
LaFrancis	5	0	0	0	0	0	2	0	7	0
Lloyd-Smith	0	0	0	0	0	0	0	0	0	0
Meyers, Duane							2	0	2	0
Miller	0	0	0	0	4	0	4	0	8	0
Nair	0	0	1	0	6	0	6	0	13	0
Pinheiro	0	0	0	0	0	0	0	0	0	0
Raju	7	1	4	1	3	1	0	0	14	3
Ross			1	0	0	0	1	1	2	1
Skelly	0	11	1	0	0	0	0	0	1	1
Tiriveedhi	2	1	3	0	5	0	3	0	13	1
Driver	0	0	0	0	0	0	0	0	0	0
TOTAL	50	8	35	1	44	2	38	2	167	13

Credit + noncredit registrations. **Registrations totaled.

Top 10 Protocols by Registration

	Number	Title	Registrations	Credits
1	CTSU E5103	A Double-blind Phase III Trial of Coxorubicin and Cyclophosphamide Followed by Paclitaxel With Bevacizumab or Placebo in Patients With Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer	17	17.00
2	SW0G S0307	Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer.	15	15.00
3	Wake Forest 98308	A Phase III Randomized, Double-Blind, Placebo Controlled Trial of North American Ginseng Extract (CVT-E0002; COLD-FX®) to Prevent Respiratory Infection and Reduce Antibiotic Use in Patients with Chronic Lymphocytic Leukemia	13	13.00
4	GOG 218	A Phase III Trial of Carboplatin and Paclitaxel Plus Placebo versus Carboplatin and Paclitaxel Plus Concurrent Bevacizumab (NSC #704865, IND #7921) Followed by Placebo, versus Carboplatin and Paclitaxel Plus Concurrent and Extended Bevacizumab, in Women with Newly Diagnosed, Previously Untreated, Suboptimal Advanced Stage Epithelial Ovarian and Primary Peritoneal Cancer	6	12.00
5	NSABP B-40	A Randomized Phase III Trial of Neoadjuvant Therapy in Patients with Palpable and Operable Breast Cancer Evaluating the Effect on Pathologic Complete Response (pCR) of Adding Capecitabine or Gemcitabine to Docetaxel when Administered Before AC with or without Bevacizumab and Correlative Science Studies Attempting to Identify Predictors of High Likelihood for pCR with Each of the Regimens	9	13.5
6	CTSU PACCT-1	Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning IndividuaLized Options for Treatment: The TAILORx TrialA Randomized	8	8.0
7	NSABP B-42	A Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five Years of Hormonal Therapy Consisting of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in Prolonging Disease-Free Survival in Postmenopausal Women with Hormone Receptor Positive Breast Cancer	7	7.00
8	CTSU E5202	A Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers	6	6.00
9	GOG 213	A Phase III Randomized Controlled Clinical Trial Of Carboplatin And Paclitaxel Alone Or In Combination With Bevacizumab (Nsc #704865, Ind #7921) Followed By Bevacizumab And Secondary Cytoreductive Surgery In Platinum-Sensitive, Recurrent Ovarian, Fallopian Tube And Peritoneal Primary Cancer.	6	4.5
10	NSABP R-04	A Clinical Trial Comparing Preoperative Radiation Therapy and Capecitabine with Preoperative Radiation Therapy and Continuous Intravenous Infusion (CVI) of 5-Fluorouracil (5-FU) in the Treatment of Patients with Operable Carcinoma of the Rectum	6	4.50



Cancer Research for the Ozarks
Steering
Totals through 05/31/2009

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*

- Stephanie Bryson, *Clinical Research Assistant*
- Rita Ritter, *Clinical Research Assistant*
- Debbie Cane, AA, Regulatory *Compliance Coordinator*
- Kathy Coleman*, BSN, Research Nurse*
- Shirley Gordon, BSN, *Research Nurse*
- Sharon Hodge, *Research Nurse*
- Cynthia Dievert, *Clinical Research Assistant*
- Basava Raju, MS, BS, CCRP, *Research Coordinator*
- Pat Stokes, BA, *Office Manager*
- 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.