Cancer Research for the Ozarks

NCI Community Clinical Oncology Research Program (NCORP)

Springfield, Missouri

NCI Community Oncology Research Program

A program of the National Cancer Institute of the National Institutes of Health

Together We Can CRO Find A Cure

Cancer Research for the Ozarks

The Year in Review
2015-2016

As I see it

Jay W. Carlson, DO
Principal Investigator

It is my great pleasure to review some of the highlights of the past grant year for Cancer Research for the Ozarks (CRO) and to once again extend my appreciation to the participating institutions, the enrolling providers and staff and especially patients – who have tremendous faith in their treating providers and agreed to enroll on these trials. Through the NCI's Community Oncology Research Program (NCORP) grant, we were awarded approximately $1M for the operational expenses for this next year and another $125,000 for ancillary tissue collection such that the organization remains strong. Like many NCORP's CRO enrolled fewer patients on clinical trials this last year, but was the leading NCORP program for fulfillment of ancillary tissue procurement protocols. Trial availability continues to be an issue, but this is improving. Cancer Care Delivery Research (CCDR) is a new NCI interest and the first CCDR trials are now opening. We would not have achieved our continued success without the integration of our component sites that span across the majority of Missouri.

This has been another busy year for the administrative staff as we have successfully completed numerous audits from different national cooperative research groups such as NRG, SWOG, Alliance and ACRIN-ECOG. As compliance and regulatory oversight has increased, the staff has done an amazing job at adjusting and meeting the requirements.

Our education program has continued to offer national speakers on pertinent oncology topics as part of the Steering Committee meetings. Investigators and staff have attended a variety of cooperative group meetings throughout the year. These have been great opportunities to share our experiences, to learn about protocol results and to participate in discussions of upcoming protocols/studies.

Over the last few years, there has been significant restructuring within some of the large cooperative groups. Protocol enrollments across the nation were down. But the restructuring is done, and the upcoming year may be challenging as the major cooperative groups are now focusing on enrollments again. Please continue to consider and offer protocol therapy to patients. We know it takes time to be knowledgeable about the protocols and to present them to patients, but this allows us to move the oncology mission forward while offering state of the art treatment to our patients.

Once again, I thank you and ask that you keep up the good work.

Progress Report

Marilyn Bauer, BSN, MEd, MHA, CRO Director

NCORP Program

CRO's second year as an NCORP continues to bring challenges as the NCORP continues to evolve and change. Clinical trials continue to progress with increasing complexity. The NCI credit system seems to have taken a different twist with enrollments resulting in fewer credits. The CCDR (Cancer Care Delivery Research) program continues to slowly evolve.

CRO is proud of our program and the opportunity it brings to our community. We are fortunate to have dedicated staff.

CRO Recognized by Alliance

CRO was one of the Top 50 highest accruing member institutions of the Alliance for Clinical Trials in Oncology during grant year 2014-2015. In recognition of this great achievement, Alliance awarded CRO with a funded travel spot for a hardworking research staff member to attend the Alliance's November 2015 and Spring 2016 Group Meeting.

CRO listed on NRG Website as Top Accruing NCORP Sites

CRO was recognized by the NRG research group for grant year 2014-2015 enrollments. NRG Oncology Outstanding Site Participation Recognition for the past grant year can be found at the following link. https://www.nrgoncology.org/About-Us/Membership/Outstanding-Site-Participation-Recognition Accrual totals are based on enrollments on NCTN and NCORP trials credited to NRG Oncology during the past grant year.

NCORP Graphic Identity Badge

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

NCI has developed a NCORP Graphic Identity Badge to use on websites and other digital materials to identify NCORPs as being a part of this NCI cancer network. The badge may be used on websites, social media, press releases, brochures, reports, slides, and patient and clinician materials. CRO is incorporating the NCORP badge as appropriate with marketing and social media efforts.

CRO Logo

Here it is - CRO's new logo. CRO staff worked with our web designer to develop a logo for us. We hope to find many uses for it as we move forward.

Cancer Research for the Ozarks

Cancer Care Delivery Research Coordinator (CCDR)

At the May 18, 2016 meeting, the CRO Executive Board approved the CCDR studies in which CRO will participate.

CRO submitted applications for participation in S1415CD "A Pragmatic Trial Evaluating a Colony Stimulating Factor Intervention in Standing Orders and the

Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia" being conducted by SWOG. SWOG is still accepting applications; however, the team has decided to move forward with the selection of components for the Cohort Arm as well as a subset of components for the first round of randomization in the Randomized Trial Arm (RT). Based on the information SWOG has received regarding CRO standing orders for CSFs, CRO's component sites CoxHealth - Oncology Hematology Associates (OHA), Mercy Hospital Springfield and Mercy Hospital St. Louis are eligible to participate in the Cohort Arm of this trial. We are anxious to learn more about this opportunity. This will be first CCDR trial in which CRO will participate.

Judy Hancock has been hired as the CCDR Coordinator for CRO. Judy will begin with CRO on August 15, 2016. Judy has been a Practice Manager for 22 years most recently at Mercy Clinic – Women's Oncology in Springfield. Judy holds a B.S. in Business Administration and a M.S. in Health Care Administration. We are delighted to have Judy with us at CRO.

NCI Tissue Procurement Administrative Supplement

In August 2014, CRO applied for and received an NCI Administrative Supplement grant "P9846 - Patient-Derived Models Tissue Procurement Protocol for the National Cancer Institute (NCI)." The project was to assist NCI in the development of a tissue repository. CRO was one of five NCORP programs accepted for this project and awarded $48,510 to collect and submit 100 blood specimens.

Patients with solid tumors and lymphoma were consented to participate. All CRO components were asked to participate in collecting blood samples for the project and reimbursed $450 for each specimen collected. CRO lead the country with their 100 submissions and on September 21, 2015, the study closed.

CRO was notified on August 10, 2015 they had the opportunity to apply for an additional tissue supplement involving submission of 29 paired fresh tissue + blood collections. Our original Tissue Procurement Supplement application was reworked and submitted. CRO was excited as this was another wonderful opportunity for our NCORP. Our application was written and submitted. CRO was notified they received the Phase II of this supplement, "PDX Supplement, Tissue + Blood (v2)" submission on October 8, 2015. CRO was awarded $150,119 for collecting the 29 paired specimens.
CRO submitted the last of 29 paired fresh tissue + blood collections required to complete "PDX Supplement, Tissue + Blood (v2)" on June 27, 2016. CoxHealth submitted twenty-one of the collections, Mercy Springfield submitted seven and Phelps County had one submission. Sixteen of our specimens were collected from Dr. Bonebrake's patients, CRO's Associate PI.

On June 21, 2016, CRO was notified they had the opportunity to participate in "PDX Supplement, Tissue + Blood (v3)" for the upcoming grant year 2016-2017. Our application has been written and submitted. This procurement opportunity includes the collection of 36 paired tissue + blood submissions. We are waiting to hear if our application submitted on July 18, 2016 is accepted.

Children's Oncology Group (COG) Report Card

Three-year report cards have recently been released for the 200(+) COG institutions. Mercy St. Louis received a solid ranking as there has been a steady improvement in enrollment numbers. Last year Mercy St. Louis' participation in therapeutic cancer treatment studies placed them in the **43rd percentile** of all COG centers! By way of comparison, Cardinal Glennon's enrollments were 38th percentile and St. Louis Children's (listed as Wash University) were 84th. In addition, their data submission was 100% current for each of the last three years which is a strong testament to the quality of our research support staff under Dr. Sleckman. Thanks to everyone at Mercy St. Louis who supports this important program.

CRO Marketing

Marketing departments at CoxHealth and Mercy Springfield are working with CRO to produce marketing material for 30-sec TV and Radio ads. Our goal is to educate our community in understanding clinical trials and their impact on finding new treatment. Our hope is to create awareness about CRO and thus increase trial enrollments.

CRO Website Update

An update to CRO's website has been completed. Our goal was to make our website more interactive and user-friendly for our investigators, patients and the community. Our website now includes trial schemas and eligibility criteria, a new patient education component and has a brighter look. Here is the link to our updated website http://ozarkscancerresearch.org/ Please take a look.

CRO Featured in 417 Magazine

CoxHealth's and Mercy Springfield's collaborative efforts with Enterprise Laundry, Ozarks Neuro Rehab Center and Cancer Research for the Ozarks are profiled in the May issue of 417 Magazine. Here is the link http://www.417mag.com/417-Magazine/May-2016/Top-Doctors-2016/Working-Together/

CRO's Facebook Page

Over the past couple of months, CRO has been diligently working to establish a Facebook "presence." The need to communicate with the public via social media is ever-increasing and it offers us an excellent opportunity to reach the public via a free format. To keep CRO's message and mission in front of the public, we will likely publish or "share" relevant posts several times per week. Recently we've shared information on the trials we have opened, news from our component institutions, survivor stories from patients who have participated in cancer research trials, and health tips. You can help by "liking" the CRO Facebook page and "sharing" it on your personal page. When you do that, one of your friends or family may "like" and "share" it as well – and we reach an even broader audience.

Cancer Care Professional

CRO started following the lead of other NCORP sites in opening our research nurse positions up to include graduates with a Bachelor's degree in a health-related field in August 2015. CRO leadership approved the change and job descriptions were revised to include this language at both CoxHealth and Mercy Springfield. During this time of huge nurse shortages, CRO had few applications for our nurse positions and we felt this was the time to make this change. Other NCORP programs have hired those with

a Bachelor degree in a health-related field and had great success. CRO has hired three Cancer Research Professionals who are doing a great job. One has a bachelor's degree in Respiratory Therapy, one has a BS in Biology and a Master's degree in Health Care Administration and the other was a family practice physician in India.

Dr. Robert Ellis Co-Author

Congratulations to Dr. Robert Ellis who has been named a co-author in "The Significance of Co-Expression of Epidermal Growth Factor Receptor (EGFR) and Ki67 on Clinical Outcome in Patients with Anal Cancer Treated with Chemo radiotherapy: An Analysis of NRG Oncology RTOG 9811". CRO enrolled 14 patients to this study.

Dr. John Bumberry Co-Author

CRO investigator, John Bumberry will be a co-author for EA study E4112 - Prospective Study of Magnetic Resonance Imaging (MRI) and Multiparameter Gene Expression Assay in Ductal Carcinoma in Situ. Cancer Research for the Ozarks entered 15 patients and is entitled to an accrual author. Dr. Bumberry placed eight of CRO's enrolled fifteen patients on the trial.

Basava Raju – Alliance Auditor

CRO's Clinical Research Coordinator II, Basava Raju served on the Alliance Audit team which conducted an annual 3-year audit at Cancer Research Consortium of West Michigan (CRCWM) in Grand Lakes, Michigan on November 9 & 10th. Basava Raju was on the Alliance audit team as they reviewed documentation at Dartmouth College - Norris Cotton Cancer Center in Lebanon, New Hampshire on April 24 & 25th. Basava's participation is a great opportunity for CRO to learn new and improved methods for CRO documentation and auditing.

SWOG Mentoring Workshop

CRO staff were invited by the Wichita NCORP to join them for a SWOG Mentoring Workshop in Wichita on Wednesday, February 17th. Debbie Cane and Marilyn Bauer attended the Mentoring Workshop Session. This was a great opportunity for our staff to network with the Wichita staff while receiving some great updates from the SWOG staff.

CRO Staff Serve on National Committees

CRO's current national research activities are noted in the below chart.

Person	CRO's Involvement with Research Base Committees
Jay Carlson DO, PI	1. PI & Study Chair for GOG 0244 which closed in 2014. He remains involved with data analysis. 2. Serves on the Alliance Community Oncology Committee 3. Chosen to serve on Cervical Task Force as a community oncologist by NCORP PIs
Basava Raju	Serves on the Alliance audit committee. Participated in audits with Cancer Research Consortium of West Michigan (11/9-10/15) and Darmouth College - Norris Cancer Center (4/24-25/16).
Victoria Wheelock, BSN	Participated in a 3-day SWOG audit at MD Anderson in January 2016.
Marilyn Bauer, BSN, MHA	1. Serves on the Alliance Prevention Committee 2. Serves on SWOG's CCDR committee

Quality

SWOG Audit

SWOG visited CRO on August 4-6, 2015. Four seasoned auditors reviewed 28 charts. No deficiencies were noted for regulatory, however, there was an issue with a past staff member not informing enrolling staff to re-consent patients as is required per CRO policy. These oversights lead to five of the major deficiencies. CRO will have a re-audit in one year with SWOG.

ECOG-ACRIN Audit

ECOG-ACRIN had an audit with CRO on October 21-23, 2015 with CRO. Four auditors reviewed thirteen charts. A corrective plan was submitted for deviations and approved. CRO staff was repeatedly complimented by our auditors for our well-organized chart documentation.

Statistics from the 2015 NCI audits with NRG, Alliance, SWOG and ECOG-ACRIN were compiled. Deviations for case reviews were assembled and put on a graft. The data was then shared with CRO staff and CRO Component staff during our January 2016 WebEx staff meeting. The two areas with the most deviations were errors in submitted data and adverse event reporting. Staff discussed ways to comply with submitting accurate and quality data such as having a peer double-check before submission, entering data as immediately as possible and so on. Adverse event deviations were followed by a discussion on ways to avoid these errors in the future. Resource material for adverse event reporting was also provided.

Internal Auditing

This grant year with several new staff and several NCI research base audits much internal auditing has occurred at CRO. CRO's Clinical Research Coordinator II has spent many hours internally auditing Springfield staff as CRO's policy is to internally audit all new staffs' documentation for at least the first six months of employment. CRO's Office Manager has also spent many hours auditing the Regulatory Compliance Coordinators work. CRO finds this to be an excellent teaching tool for new and seasoned staff.

Yearly, CRO attempts to conduct internal auditing at its component sites. This has not been possible this year due to CRO's staffing shortage. We do plan to conduct internal audits at all CRO component sites in the upcoming grant year. Phelps County and Central Care periodically bring their charts to Springfield or CRO's Study Coordinator, Basava Raju, travels to these sites for internal auditing.

CRO Steering Committee Meetings

Dr. Kent Shih from the Tennessee Oncology/Sarah Cannon Research Institute spoke at the CRO Steering Committee on: "An Overview of OPDIVO (nivolumab), An Immuno-oncology Agent Approved Across Multiple Tumor Types" in St. Louis on Tuesday, September 1, 2015. The event was held at Fleming's Prime Steakhouse & Wine Bar in St. Louis, Missouri. CRO enjoyed having our investigators and research staff from the St. Louis, Good Samaritan and Phelps County area with us. Sixteen investigators and research staff attended.

CRO's 2015 Fall Steering Committee meeting was held on Monday, October 12. Dr. Gabriel Bien-Willner spoke on "Precision Medicine with NGS Testing". Gabriel Bien-Willner, MD, is an Anatomic Pathologist with a Fellowship in Molecular Genetic Pathology. During his Post-Doctoral and Faculty positions at Washington University, his focus was on developing genomic technologies and applications to clinical practice using next-generation platforms at the Center for Genome Sciences. Currently, Dr. Bien-Willner is Medical Director for Molecular Health where he frequently helps physicians understand patients' genomic information after the patients have had NGS testing performed. In addition to his Director position, Dr. Bien-Willner is also instrumental in bio-informatics pipeline design for NGS testing through Molecular Health's bio-informatics software suite. As an expert in cancer genetics/genomics, Dr. Bien-Willner continues to provide much needed support to physicians on how to make sense of the big data/"data tsunami" that clinicians deal with every day. Thirty-two CRO investigators and research staff attended the event.

Dr. Monte Shaheen spoke on "An Immuno-Oncology Agent Approved Across Multiple Tumor Types, Opdivo (nivolumab), A Renal Cell and Lung Carcinoma Overview" on Monday evening, April 4th, 2016 at Ocean Zen during CRO's Spring Steering Committee meeting. Currently, Dr. Shaheen is Associate Professor of Medicine at the University of New Mexico Cancer Center in Albuquerque, NM. He completed his fellowship in hematology/oncology at Indiana University School of Medicine and is board certified. Dr. Shaheen has a strong interest in clinical trials having been involved with over 40 clinical trials including serving as the trial Principal Investigator. Formerly he was Founder and Director of Oncology Services at Providence Medical Group in IN. Since 2011, he has been the leader of the melanoma and sarcoma clinical working group at the University of New Mexico Comprehensive Cancer Center. Twenty-seven CRO investigators and research staff were in attendance.

Research Base Meeting Attendance

CRO's PI and Director encourage research base attendance and involvement with committees as this is where changes and upcoming trials are discussed. During CRO Executive Board meetings members were encouraged to attend meetings and get involved on a national level. Dr. Carlson contacted physicians to personally encourage their meeting attendance and involvement. CRO's Director has also contacted oncologists individually inviting them to attend research base meetings and encouraging their involvement in the groups according to their interest. CRO's attendance at grant year 2014 – 2015 research base meetings is noted in the chart below.

	Meeting Dates	Attendance
NCI PI & Administrators	August 27-28, 2015	Dr. Jay Carlson, CRO's PI, Albert Bonebrake, CRO's Associate PI, June Johnson, Adm. Director CoxHealth, & Marilyn Bauer, CRO's Director
Alliance	November 4-8, 2015	Basava Raju, CRO Clinical Research Coordinator
Alliance	April 27-30, 2016	Basava Raju, CRO Clinical Research Coordinator and Carol Antinora, Research Nurse
Children's Oncology	October 7-9, 2015	Pam Harris, Research Nurse

Group (COG)		
Children's Oncology Group (COG)	March 9 & 10, 2016	Dr. Robin Hanson
ECOG-ACRIN	November 12-14, 2015	Marilyn Bauer, CRO's Director
NRG	January 21-23, 2015	Drs. Al Bonebrake, Jay Carson, Abe Abdalla & Marilyn Bauer, CRO Director
NRG	July 13 -16, 2016	Dr. Al Bonebrake and Nicholas Perry
SWOG	October 8-10, 2015	Dr. Robert Ellis
SWOG	April 27-30, 2016	Erin McCaig, CRO Research Nurse, Swetha Mereddy, Clinical Research Professional, & Marilyn Bauer, CRO Director

CRO's PI and Director encourage staff participation in online trial specific webinars. They forward information electronically to encourage investigators and research staff at all components to attend. In addition to electronic notification, clinical trial webinars are promoted in the monthly CRO Communique and to research staff in the bi-monthly Marilyn's Message from CRO's director. CRO administrative staff attends all NCI NCORP Administrative, CCDR and regulatory webinars.

CRO Enrollments to Clinical Trials

According to NCI, CRO enrolled 85 patients to clinical trials in grant 2015-2016. 63 were enrolled to treatment trials and 22 patients were enrolled to cancer control trials. This resulted in 76.107 treatment and 30.264 cancer control trials credits for a total of 106.371 credits. Trial enrollment was sluggish this year as trials continue to be more complex and there are less trials available.

Achieving Target Credit Goals

NCI assigned CRO target credits of 85 for treatment and 85 for cancer control for grant year 2015-2016. CRO earned 76.859 treatment credits which was 90% of NCIs target (85 credits). CRO earned 30.264 control credits which was only 36 % of NCIs target (85 credits). Thirty-nine CRO research investigators participated in making this happen. In grant year 2014-2015, CRO earned 79.41 treatment credits and 58.83 cancer control credits totaling 138.24 credits.

Credits are different from registrations. A registration is defined as one patient enrolled into one trial. Registrations tell us the number of patients in particular trials. Not all enrollments receive credit. Credits are the NCI value assigned to each trial registration. This past year, CRO had 85 registrations for credit, and 20 no-credit registrations, for a total of 105 registrations. Of that total, our nine components (Mercy Joplin, Freeman Health, Cox Branson, Central Care PA, Phelps County, Mercy St. Louis and Good Samaritan) contributed 42 registrations. Our components contributed 49% of our total registrations this grant year. Last grant year our components contributed 46% of our total registrations.

Efforts to increase Trial Enrollments

Keeping with the national trend, CRO has seen historically low accruals this grant year and has taken many efforts to increase accruals to clinical trials including:

- Staff screens all new patients and those with follow-up scans coming in to our investigator's offices for clinical trial eligibility.
- Trial accrual is a standing agenda topic at the CRO Executive Board, CRO Steering Committee, staff meetings etc. We are always cognizant that accrual to trials is our first priority.
- Dr. Carlson, CRO's PI, sends email messages to appropriate investigators as needed. For example, when the MATCH trial opened Dr. Carlson sent an upbeat email to each CRO investigator encouraging enrollment.
- Developing trial specific flyers which are submitted to the IRB for approval when it may be helpful for patient recruitment. Currently, we are developing a flyer for the Wake Forest 97115 study.
- CRO staff developed an action plan in January 2016 to address low accruals. We continue to work to accomplish tasks on our plan and review the tasks each week at our Monday morning huddles.
- CRO's staff met for a coffee break to discuss the importance of site staff's role in presenting ICF/ trials to patients on May 3, 2016. Staff shared their views on the best approach and how important their approach in discussing the trial is to educate and encourage potential patient enrollment.
- A CRO annual report is compiled yearly to coincide with our grant year. This report is shared with our investigators, staff and others interested in clinical trial research.
- CRO updates investigators, staff and others associated with research with a monthly CRO Communique. Among other CRO happenings enrolling investigators are recognized each month for their enrollments through a chart noting their enrollment accomplishments. A trial is profiled each month in the CRO Communique.
- Enrolling staff are recognized in the Director's message "Marilyn's Message" for their enrollments for the month.
- Screening statistics are compiled each month and shared with the specific sites and the CRO Executive Board. The information is reviewed to see if there is an area which we can impact/improve to assist in accruing to trials

CRO Staff

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

The two full-time research nurses, two Cancer Research Professionals and two clinical research assistants who enroll patients in Springfield at CRO accrued 86 registrations this past grant year. This is approximately 14.33 registrations per staff. In addition they enrolled 14 to the tissue procurement blood initiative, 28 to the 9846 Tissue + Blood initiative and had 2 exceptional responders approved. CRO's research nurses/cancer research professionals enroll to treatment trials and clinical research assistants enroll to cancer control trials under the guidance of the research nurses and clinical research coordinator. CRO's clinical research coordinator, PRN research nurse and follow–up clinical research assistant assist clinical staff as needed, staffing for vacations, performing internal auditing and providing staff

education on clinical trial documentation.

Monthly Webinars for all Component members

In January 2016, CRO began having monthly webinars for all component staff. The goal is to make our NCORP a more cohesive and better program. NCORP staff are encouraged to submit topics for discussion and educational purposes. The webinars are held on the 4th Thursday of each month at noon.

Meeting the CRO Goals for 2015 - 2016

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

CRO Goals	Achievements
Goal 1. Increase accruals to NCI clinical trials	
1. Exceed NCI's treatment credit goal by 2% during grant year 2015-16	1. Earned 76.107 treatment credits – 8.893 below NCI's target of 85 credits for CRO
2. Exceed NCI's cancer control credit goal by 2% during grant year 2015-16	2. Earned 30.264 cancer control credits – 54.736 below NCI's target of 85 for CRO
3. Develop Cancer Care Delivery Research at CoxHealth and Mercy Springfield as the program becomes available.	3. Hired Judy Hancock as our CCDR Coordinator in July 2016. At NCI's request, added Mercy St. Louis as a CCDR site for CRO. Selected to participate in S1415CD at OHA, Mercy Springfield and Mercy St. Louis
4. Explore Telemedicine for clinical Trial enrollments	4. Information regarding trial enrollment via telemedicine was collected from Sanford NCORP of the North Central Plains in Sioux Falls, South Dakota & Montana Cancer Consortium NCORP in Billings, Montana and shared with CRO Executive Board on 12/9/15. After exploration, the decision was made to not become involved with telemedicine to enroll research patients at this time.
5. 100% of all cancer patients be screened at all component sites	5. All local patients are screened and screening recorded in CRO's CREDIT database. All components have been encouraged to screen all oncology patients as well and document in CREDIT.
Goal 2. Improve communication efforts to keep CRO investigators and health care extenders aware of clinical trial availability	
6. Visit yearly with physicians and staff at each of our components to offer assistance and encourage enrollment to trials	6. Internal auditing at St. Louis & Mt. Vernon on 6/18/14, Phelps County on 4/15/15. Central Care and Phelps County research nurses/cancer research professionals regularly meet with CRO Clinical Research Coordinator for documentation review. Internal auditing at Mercy St. Louis, Good Samaritan, Freeman Health System and Mercy Joplin did not occur this year due to NCI research base audits with NRG, Alliance, SWOG & ECOG-ACRIN and staffing shortages in Springfield.
7. Twice yearly CRO Steering Committee meetings with national speakers on new cancer therapies and treatments	7. On October, Dr. Gabriel Bien-Willner spoke on "Precision Medicine with NGS Testing". Dr. Monte Shaheen

	spoke on "An Immuno-Oncology Agent Approved Across Multiple Tumor Types, Opdivo (nivolumab), A Renal Cell and Lung Carcinoma Overview" on Monday evening, April 4th, 2016
8. Hold one CRO Steering Committee meeting in St. Louis allowing component investigators and outlying staff to attend	8. Dr. Kent Shih from the Tennessee Oncology/Sarah Cannon Research Institute presented An Overview of OPDIVO (nivolumab), An Immuno-oncology Agent Approved Across Multiple Tumor Types" in St. Louis on Tuesday, September 1, 2015.
9. Explore concept of assigning different PIs for each research base	9 Dr. Carlson asked different oncologists to present studies related to their area of expertise at the Mercy IRB
Goal 3. Ensure quality at CRO	
10. 75% of CRO's clinical research professionals will be credentialed as certified research professionals or oncology nurses. OCN certification is a goal for all local RNs	10. This continues to be a goal for CRO. All new staff are asked to strive for oncology/SOCRA certification within the first two years of employment at CRO.
11. Randomly select at least one patient record from each staff enrolling patients for quarterly internal auditing	11. Being done when time allows. Many charts were internally audited in preparation for research base audits.
12. Work for improved quality assurance at CRO and its components by: a. Striving for quality data submission b. Maintaining timely and accurate data submission c. Responding to queries in a timely manner	12. This is ongoing. Basava Raju, CRO's educational staff trainer reviews documentation for all new staff and component staff for the first six months of their service at CRO and randomly thereafter. During the first week of each month, delinquent data or un-responded queries are downloaded from the research base websites for each research staff. The Director forwards the list to each staff member reminding them to respond to queries in a timely manner and to submit all delinquent data.
Goal 4. Promote CRO on a Local and National Level	
13. Encourage new investigators to become involved in NCI trials locally and at a national level	13. CRO's PI and Director visit with new physicians in Springfield to encourage enrollment to trials.
14. Strive to have a CRO representative involved on committees at all NCI research bases	14. Dr. Carlson serves on the Ancillary Data Subcommittee and Cancer Prevention and Control Committee at GOG/ NRG. Basava Raju is serving as an auditor for Alliance. Marilyn Bauer serves on the Alliance Prevention Committee and SWOG's Cancer Care Delivery sub-committee.

Cancer Research for the Ozarks grant year 2016-2017

Goals & Opportunities for CRO for Grant Year 2016-2017

The CRO Executive Board approved the following goals for grant year 2016- 2017

Goal 1. Increase accruals to NCI clinical trials

- Meet NCI's treatment credit goal during grant year 2016-17
- Meet NCI's cancer control credit goal during grant year 2016-17
- Develop Cancer Care Delivery Research at CoxHealth, Mercy Springfield and Mercy St. Louis
- Screen 100% of all cancer patients at all CRO component sites

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

- Visit yearly with physicians and staff at each of our components to offer assistance and encourage enrollment to trials
- Hold twice yearly CRO Steering Committee meetings with national speakers on new cancer therapies and treatments
- Hold one CRO Steering Committee meeting in St. Louis allowing those far away to attend

Goal 3. Ensure quality at CRO

- 65% of CRO's clinical research professionals will be credentialed as certified research professionals or oncology nurses
- Randomly select at least one patient record from each staff enrolling patients for quarterly internal auditing
- Work for improved quality assurance at CRO and its components:
    1. Maintaining timely and accurate data submission
    2. Responding to queries in a timely manner
- Stabilize staff turnover

Goal 4. Promote CRO on a Local and National Level

- Encourage new investigators to become involved in NCI trials locally and at a national level
- Strive to have a CRO representative involved on committees at all NCI research bases
- Market CRO with 30-second TV ads and radio ads

Protocol Reports: 2-Year Comparison of Registrations & Credits

CRO Finances

CRO is supported, in part, by the generosity of our two sponsoring health systems, CoxHealth and Mercy Springfield. Since the beginning of CRO in 1987, these institutions have generously supported cancer research in our community by equally absorbing dollars not provided by our grant each year. CRO works hard to control expenses. The two tables below compare our FY 2014-2015 and FY 2015-2016 revenues. Accounting, lab, radiology services and office space for staff are just a few of the many benefits our sponsors provide for CRO which are not reflected in the numbers below.

CRO received $100,000 this grant year for Cancer Care Delivery Research (CCDR) activities. CRO spent $3,647 of the CCDR funding to interview applicants, hire a CCDR Coordinator, and attend CCDR research base meetings and webinars.

NCI's Administrative Supplement grant "P9846 - Patient-Derived Models Tissue Procurement Protocol for the National Cancer Institute" was another source of revenue for CRO this grant year. CRO was awarded $150,119 to collect 100 tissue samples for NCI.

The CCDR and unused funding and the open staff positions are the main reason for CRO's unused funding balance.

Revenues	Fiscal Year 2014-2015
Federal	$935,954
Other	$147,354
Total Revenues	$1,083,308
Total Expenses	$1,024,766
Remainder *	$58,542

Revenues	Fiscal Year 2015-2016
Federal	$1,092,680
Other	$131,299
Total Revenues	$1,223,978
Total Expenses	$1,193,576
Remainder *	$30,402

*If there is a deficit, it is split equally between CoxHealth and Mercy Springfield

Fiscal year 2015-2016 Remainder is $30,402
Fiscal year 2014-2015 -- Remainder is $58,542
Fiscal year 2013-2014 – Deficit $37,473

Treatment

RESEARCH BASE	2014-2015 REGISTRATIONS	2014-2015 CREDITS	2015-2016 REGISTRATIONS	2015-2016 CREDITS
Alliance	9	11.069	7	11.644
COG	7	7.500	8	9. 275
ECOG-ACRIN	25	26.490	9	12.445
NRG	3	3.426	17	17.847
SWOG	27	29.786	22	24.896
Wake Forest	0	0	0	0
Totals	71	78.271	63	75.102

Cancer Control & Prevention

RESEARCH BASE	2014-2015 REGISTRATIONS	2014-2015 CREDITS	2015-2016 REGISTRATIONS	2015-2016 CREDITS
Alliance	24	25.750	6	6.750
COG	1	2.000	0	1.750
ECOG-ACRIN	1	3.800	15	16.000
NCI			0	0.364
NRG	26	26.526	1	2.000
SWOG	0	2.100	0	3.400
Wake Forest	0	0	0	0
Totals	52	60.176	22	30.264

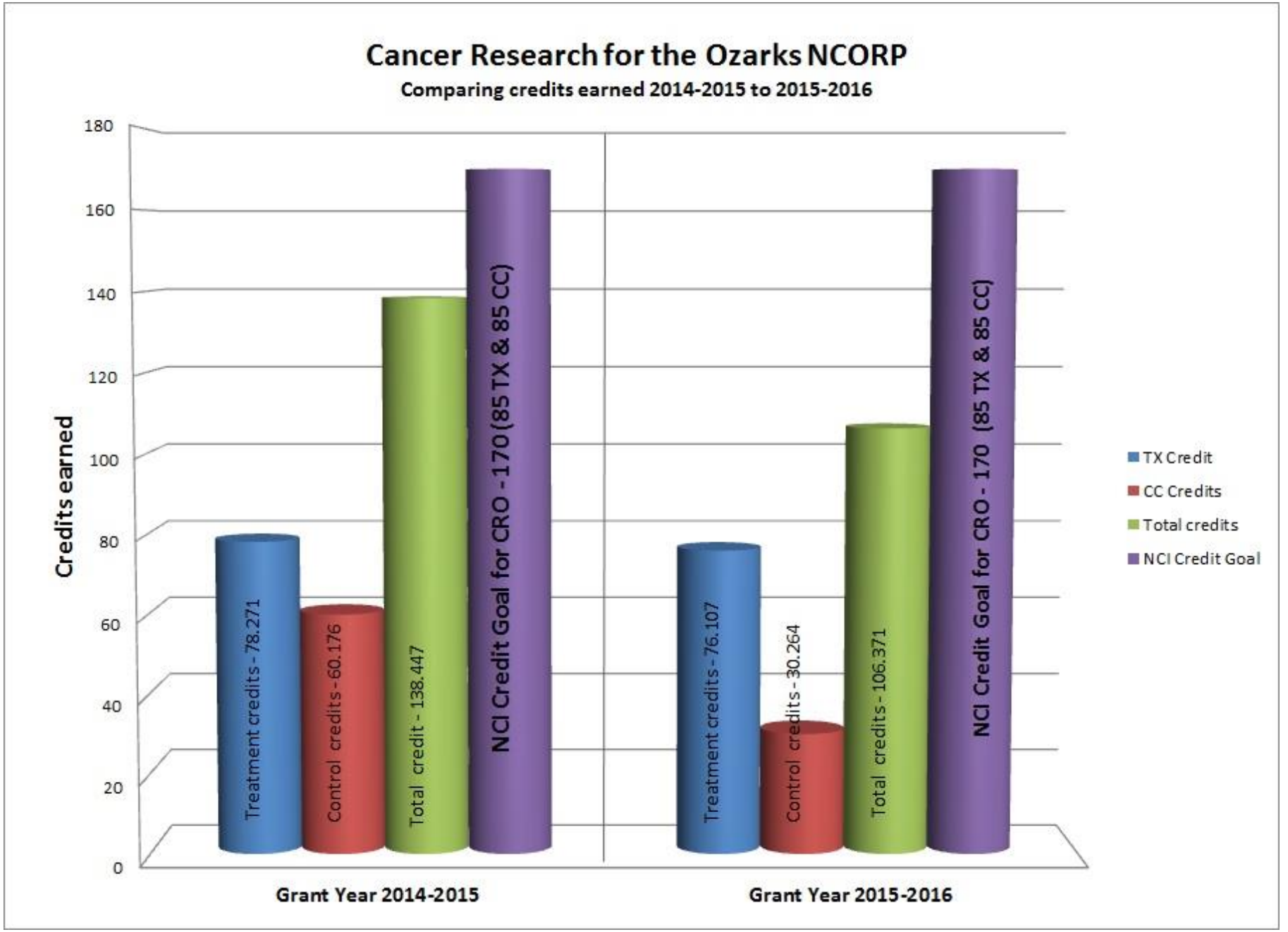
All-inclusive 12- month Accrual for All Types of Protocols by Research Base

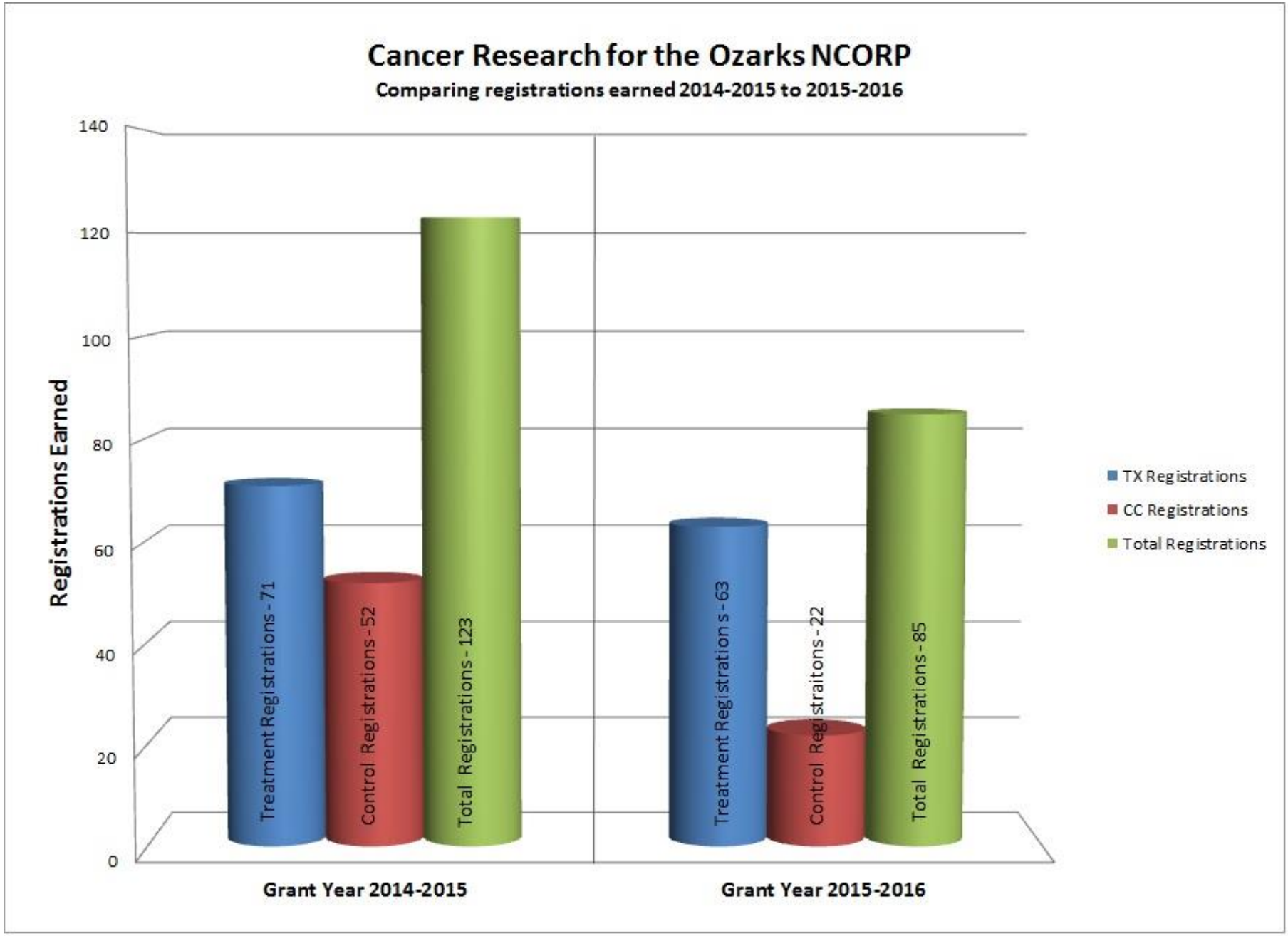
RESEARCH BASE	2014-2015 REGISTRATIONS	2014-2015 CREDITS	2015-2016 REGISTRATIONS	2015-2016 CREDITS
Alliance	33	36.819	13	18.394
Children's Oncology (COG)	8	9.500	8	11.025
ECOG-ACRIN	26	30.290	24	28.445
NCI				0.364
NRG	29	29.952	18	19.847
SWOG	27	31.886	22	28.296
WAKE FOREST	0	0	0	
Total Reg. & Credits	123	138.447	85	106.371
Industrial Trial Reg.	2		20	
Grand Total	123 + 2	138.447	85+ 20	106.371

*Credit + noncredit registrations **Registrations totaled

Registrations by Affiliate/Site

Component/Affiliate*	2014-2015 REGISTRATIONS	2014-2015 CREDITS	2015-2016 REGISTRATIONS	2015-2016 CREDITS
Central Care, PA	5	4.20	0	0.425
Mercy Springfield	48	34.23	30 + 2	36.830
Freeman Medical Center (Joplin)	8	5.28	4	5.290
Good Samaritan (Mt. Vernon, IL)	15	10.02	2	2.127
Mercy Joplin	7	2.37	0	0.065
Mercy Clinic Rolla	3	2.20	0	0.250
Mercy St. Louis	38	31.32	23 + 17	29.122
Phelps County Regional Medical Ctr. (Bolivar)	1	1.36	8	8.391
CoxHealth System	27	19.38	13 + 10	17.370
Cox Medical Center Branson	0	0	0	0
St. Louis Cancer & Breast Institute	7	6.15	5	6.501
No Credit	3	0	20	0
Grand Totals	184	137.74	85 + 20	106.371


Cancer Research for the Ozarks NCORP
Comparing credits earned 2014-2015 to 2015-2016
Credits earned
180
160
140
120
100
80
60
40
20
0
Treatment credits - 78.271
Control credits - 60.176
Total credit - 138.447
NCI Credit Goal for CRO - 170 (85 TX & 85 CC)
Treatment credits - 76.107
Control credits - 30.264
Total credits - 106.371
NCI Credit Goal for CRO - 170 (85 TX & 85 CC)
TX Credit
CC Credits
Total credits
NCI Credit Goal
Grant Year 2014-2015
Grant Year 2015-2016


Cancer Research for the Ozarks NCORP
Comparing registrations earned 2014-2015 to 2015-2016
Registrations Earned
140
120
100
80
60
40
20
0
Treatment Registrations - 71
Control Registrations - 52
Total Registrations - 123
Treatment Registrations - 63
Control Registraitons - 22
Total Registrations - 85
Grant Year 2014-2015
Grant Year 2015-2016
TX Registrations
CC Registrations
Total Registrations

Top 10 Protocols by Registration

Rank	Protocol	Title	# Registrations	Credits
1.	**E4112**	Prospective Study of Magnetic Resonance Imaging (MRI) and Multiparameter Gene Expression Assay in Ductal Carcinoma in Situ (DCIS)	15	15 cc
2.	**S1207**	Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e3 Breast Cancer Study- evaluating everolimus with endocrine therapy.	6	6 tx. + 1.25 Control
3.	**AALL0932**	Treatment of Patients with Newly Diagnosed Standard Risk B-Precursor Acute Lymphoblastic Leukemia (ALL), A Groupwide Phase III Study	4	7.52
4.	**A221304**	A phase III placebo-controlled, randomized three-arm study of doxepin and a topical rinse in the treatment of acute oral mucositis pain in patients receiving radiotherapy with or without chemotherapy	4	4 cc
5.	**NRG BR003**	A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or Without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer	4	4.1 rx.
6.	**A031201**	Enzalutamide With or Without Abiraterone Acetate and Prednisone in Treating Patients With Castration-Resistant Metastatic Prostate Cancer	3	3.1
7.	**E1A11**	Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)	3	3 tx & .85 cc.
8.	**GOG-3005**	A Phase 3 Placebo-Controlled Study of Carboplatin/Paclitaxel With or Without Concurrent and Continuation Maintenance Veliparib (PARP inhibitor) in Subjects with Previously Untreated Stages III or IV High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	3	GOG Foundation
9.	**NRG-GY004**	A Phase III study comparing single-agent olaparib or the combination of cediranib & olaparib to standard platinum-based chemotherapy in women with recurrent platinum-sensitive ovarian, fallopian tube, or primary peritoneal cancer.	3	3.193 tx. + .5 cc
10.	**RTOG 0924**	Androgen Deprivation Therapy & High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High-Risk Prostate Cancer: A Phase III Randomized Trial	3	3.102tx.

Cancer Research for the Ozarks Staff

Jay W. Carlson, DO, *Principal Investigator*

Albert Bonebrake, MD, *Associate Principal Investigator*

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

Debbie Cane, AA, Office Manager

Cynthia Dievert, Clinical Research Assistant

Kristina Gardner, BS, MHA, Cancer Research Professional

Judy Hancock, BS, MHA, Cancer Care Delivery Research Coordinator

Erin McCaig, BSN, Research Nurse

Nicholas Perry, BSRT, RT, Cancer Research Professional

Basava Raju, MS, BS, CCRP, Clinical Research Coordinator II

Andrea Reaves, Regulatory Compliance Coordinator

Rita Ritter, Clinical Research Assistant

Marcia Thompson, BSN, Research Nurse

Connie Roller, BA, Clinical Research Assistant

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.