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
2016-2017

As I see it

Jay W. Carlson, DO
Principal Investigator

It is, once again, my great pleasure to review some of the highlights of the past grant year for Cancer Research for the Ozarks (CRO)! First, these highlights start with extending 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 clinical trials. Through the NCI's Community Oncology Research Program (NCORP) grant, CRO was awarded approximately $1.1 M for the operational expenses for this next year. Trial availability continues to be an issue, but this is improving. We achieved over 60% of the NCI's target accrual with the available protocols - meaning we did good, but our goal is to do better. Cancer Care Delivery Research (CCDR) remains a new NCI focus and there are several new CCDR protocols in the pipeline that will be available over the next year.

We are only able to do what we do through the tremendous team efforts of the different component sites. CRO has grown over the last year by adding Mosaic Life Care in St. Joseph, MO and Mercy Oklahoma City as new component sites. These additions have greatly increased the geographic footprint of CRO as well as the patient/provider pool for future enrollments.

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.

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 your local research staff or the CRO staff can help! Putting patients on protocols allows us to move the oncology mission forward while offering state of the art treatment to our patients.

Once again, I thank you for your research efforts and ask that you keep up the good work.

Progress Report

Marilyn Bauer, MHA, MEd, BSN - CRO Director

NCORP Program

CRO's third year as an NCORP continues to bring challenges as the NCORP continues to evolve and mature. Clinical trials continue to progress with increasing complexity and fewer in number. 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.

New Components

Heartland Regional Health Center dba Mosaic Life Care

Mosaic Life Care in St. Joseph, Missouri joined CRO for clinical trial participation in June 2017. Previously, this group had worked with the Kansas City NCORP. The Mosaic Oncology VP contacted CRO, in March 2017 and the process of bringing on this group proceeded. Mosaic is located approximately 250 miles from Springfield, and has approximately 1,000 analytic cancer cases yearly.

Mercy Oklahoma

Mercy Research's system wide restructuring presented additional opportunities for CRO. On Wednesday, May 3, 2017 Dr. Jay Carlson, CRO's PI and Marilyn Bauer, CRO's Director traveled to Oklahoma City to attend a Mercy Research Retreat. Dr. Carlson spoke to medical and radiation oncologists as well as administrators describing the NCORP program and the advantages for Mercy Oklahoma to work with CRO. The oncology physicians voted to join OZARKS NCORP and the transition is near completion. Formerly, Mercy Oklahoma partnered with the University of Oklahoma for oncology research trials. Mercy Oklahoma has approximately 2,000 analytic cancer cases yearly.

Mercy Ft. Smith

On the following Wednesday, May 10, 2017, Dr. Carlson and Marilyn took the same presentation to Ft. Smith, Arkansas where Mercy Ft. Smith is located. Mercy Ft. Smith previously worked with the University of Arkansas for clinical trial enrollments. There is definitive interest in becoming a CRO component, with the transfer expected in early 2018.

The addition of Mosaic, Mercy Oklahoma and eventually Mercy Ft. Smith will increase CRO's number of new cancer analytic cases per year from 8,200 to approximately 12,000. This is very exciting news for CRO as we continue to grow. The addition of these three new components is expected to have a positive impact on CRO accruals.

NCI Foundation Trials

At the request of our physician investigators, CRO began participating in Foundation trials. Foundation trials are sponsored by the individual research groups outside of their NCI grant. Monetary value for each trial is different. NCI credits are not provided for these trials, as they are not part of the NCORP grant. The regulatory requirements for these trials are stringent.

Mercy Research Re-organization

The Mercy health ministry consolidated their research programs and staff into a new, united entity to enable Mercy to leverage their collective talent and resources and to better ensure compliance with all applicable research regulations. As a distinct, non-profit arm of Mercy, Mercy Research is positioned to become a top-tier program for clinical research, product development and data analytics.

On October 16, 2016 JoAnne Levy became the Vice President of Mercy Research. JoAnne brings a wealth of operational experience to this new role, which will be invaluable as Mercy continues to strengthen and expand the new Mercy Research structure. For more than five years, JoAnne was a senior leader at ROI with oversight for supply chain operations and integrated sourcing solutions. She previously served for more than 15 years with pharmaceutical giant Covidien/Mallinkrodt where she held a variety of leadership positions in areas including legal, sales & marketing and supply chain logistics. Because of these varied experiences, JoAnne has exceptional skills in operational management, change management, contracting and industry relations. She is well versed in team building with central oversight. In addition to her strong work experience, JoAnne has an executive MBA and a law degree from Washington University in St. Louis. CRO staff were introduced to JoAnne during the January CRO Coffee on Wednesday, January 25th.

Institutional Review Board Changes

Mercy Research has moved all studies from Mercy locations doing research within the Mercy system to a single Mercy Institutional Review Board (MIRB). The function of the Mercy Institutional Review Board will be to review the Investigator Initiated Trials, Humanitarian Use Device, and Compassionate use studies. Mercy's IRB board now consists of nine representatives from all Mercy areas serving on a single virtual board. The Mercy Institutional Review Board (MIRB) began functioning in May 2017. Mercy Research will be using both an external IRB and the Mercy IRB. CRO will continue to use the NCI CIRB for NCI trials and MIRB or an external IRB as deemed necessary for Foundation trials.

PDX Supplement, Tissue + Blood (v3)

CRO received NCI approval for another Tissue + Blood collection supplement. This was CRO's third year to have been granted this supplement from NCI. This supplement was to collect 36 pairs of tissue and blood from patients with active solid tumors and lymphomas. This supplement was completed on August 7, 2017 when the 36th sample pair was submitted. There is particular interest from the NCI in less prevalent malignancies, such as Small Cell Lung, Pancreatic, Head & Neck, Ovarian and Bladder cancers, as well as Sarcomas, Melanomas, and Non-Hodgkin Lymphomas. CRO staff screened patients for eligibility and worked closely with investigators to collect the tissue following NCI guidelines for patients who consented to this protocol. This was another wonderful opportunity for CRO.

Cancer Care Delivery Research (CCDR)

Judy Hancock joined CRO as our Cancer Care Delivery Research Coordinator (CCDR) on August 15, 2016. Judy was a healthcare manager for the past 22 years, most recently at Dr. Carlson's office. She holds a M.S. in Health Administration and a B.S. in Business Administration. We were very excited to have Judy join us. She has taken an active role in CCDR by volunteering for research base committees and sharing her experience with S1415CD on webinars and at research base meetings.

On November 1, 2016, participation in CCDR studies opened for all components and sub-components named in the original NCORP grant application. Opening of CCDR to all NCORP sites has been well received with many sites eager to begin participating. CRO's Executive Board reviews and makes the decision to open a CCDR study.

CRO's first CCDR study activated was S1415CD, "A Pragmatic Trial to Evaluate a Guideline Based Colony Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia – Trial Assessing CSF Prescribing Effectiveness and Risk (TrACER)". The study was approved by Mercy Springfield's IRB on September 16, 2016. Three CRO sites (Oncology Hematology Associates, Mercy Springfield and Mercy St. Louis) were approved to participate in the Cohort arm of the trial. Each site was to enroll 52 patients.

CRO registered the first patient in the country to the S1415CD Trial Assessing CSF Prescribing Effectiveness and Risk (TrACER)) study at Mercy Springfield! As of August 1, 2017, CRO has enrolled 58 patients at Mercy Springfield & 16 patients at Oncology Hematology Associates (OHA) to the trial.

Since the Ozarks NCORP was very successful with recruitment for S1415CD at Mercy Springfield, SWOG asked CRO's CCDR Coordinator, Judy Hancock to represent Ozarks NCORP on the panel for the cohort group at the SWOG conference on April 27, 2017. Judy shared her experience with the study and answered questions from other sites.

NCI's Landscape survey was completed for all CRO Components and submitted on or before the deadline of April 21, 2017.

Mercy St. Louis is CRO's only component participating in Children's Oncology (COG) trials. They have opened ACCL15N1CD: Use of Evidence-Based Supportive Care Clinical Practice Guidelines in Pediatric Oncology. COG randomly selects and enrolls patients who were previously enrolled to a COG trial; therefore, consent is not required. This will be a rolling enrollment based on the total number of patients enrolled to all COG studies at our site. Mercy St. Louis has enrolled three patients to the study.

CRO Website Updated

An update to CRO's website was completed in August 2016. CRO's goal was to make our website more interactive and user-friendly for our investigators, patients and the community. The opening page has cancer disease sites listed. With one click, the protocols available for a particular disease type of cancer will open. A second click will bring up summary and eligibility criteria for the trial. We would like to see more of our investigators utilize our website to search for trials. This could possibly eliminate our need to put pocket cards with our trial listing and an abbreviated eligibility list together every other month. This is a time consuming task but well used by some physicians. Here is the link to our updated website http://ozarkscancerresearch.org/

Patient Education

Recognizing that fear of the unknown about research and clinical trials may be a deterrent for participation for some, CRO staff developed a plan to show potential trial candidates where they can find PRE-ACT clinical trial education on the CRO website while they are waiting in the physician office. We added a link to this training on the opening page of our website.

CRO staff also put together a one page educational flyer directing our patients to seek clinical trial education on our newly revised website: ozarkscancerresearch.org. CRO staff in Springfield share this page with patients in an effort to assist our patients by answering questions regarding clinical trials. We believe this will result in more patients understanding the importance of participation in clinical trials resulting in increased enrollments. CRO staff encourage the patients to review the information when they return home.

The patient education link was also added to a letter from the oncologists, which goes out to patients prior to their first visit, noting the physician's support of CRO and NCI clinical trials. CRO will continue to document patient screenings and assess if the PRE-ACT education makes an impact.

CRO's Facebook Page

Over the past, grant year, 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 publish or share relevant posts. We have shared information on the new trials we have open, news from our component institutions, survivor stories from patients who have participated in cancer research trials, and health tips. Investigators and staff have been encouraged to assist by sending us interesting facts, statistics and articles that they have read or heard.

CRO TV & Radio 30-second Ads

Marketing departments at CoxHealth and Mercy Springfield worked with CRO to produce marketing material for 30 second TV and Radio ads. CRO's goal was to educate our community regarding CRO services and thus increase trial enrollments. The 30 second TV ads began airing on November 21, 2016 with television stations KYTV (3/NBC), KOLR (10/CBS) and KSPR (33/ABC). The 30 second radio spots with KGBX-FM, KTTS-FM and KSGF-FM in Springfield; KHBZ-FM in Branson, Missouri and KKLB-FM in Monett, Missouri also began airing at the same time.

Our marketing campaign ran from November 21, 2016 through February 20, 2017. Our goal was to educate our community regarding clinical trials in hopes of increasing numbers of patients agreeing to clinical trial participation.

CRO Steering Committee Meetings

St. Louis Steering Committee Meeting

On the evening of September 27, 2016, Dr. Joseph Fay spoke on "A Treatment Option for the Management of Multiple Myeloma in Patients Who Have Had One to Three Prior Therapies" in Clayton, Missouri. Dr. Fay is currently Director, Division of Immunologic Therapy for Cancer Baylor Institute of Immunology Research at Sammons Cancer Center, Baylor University Medical Center. He attended Harvard Medical School graduating with honors. He completed his Internship and Residency in Internal Medicine at Duke University Medical Center - Durham, North Carolina. He has extensive experience in research serving as Principal Investigator and authored more than 150 publications many of them addressing multiple myeloma. Dr. Carlson, CRO's PI gave a brief update on CRO's status via WebEx. Approximately 20 physicians and research staff attended the meeting.

CRO's Fall 2016 Steering Committee Meeting

Dr. Jay Carlson, CRO's PI opened the fall 2016 Steering Committee meeting with an update of CRO statistics and activities on October 26, 2016. Dr. Joseph Lancaster spoke on "Personalizing Cancer Treatment with New, More Precise Clinical Diagnostic Tools". Twenty-eight attendees learned about new clinical diagnostics that are in the pipeline at Myriad Genetics and how the future of personalized cancer treatment may be impacted. Dr. Lancaster discussed the future of diagnostics; commitment to advancing science in both hereditary cancer and personalized genomics; and the most important topic of discussion was "how patient outcomes will be impacted".

CRO's Spring 2017 CRO Steering Committee Meeting

Gary Doolittle, MD, Professor of Medicine and Director of Telemedicine Services at The University of Kansas Medical Center spoke at the CRO 2017 Steering Committee meeting. His presentation was entitled "Dual Immune Checkpoint Inhibition for the First-line Treatment of Metastatic Melanoma". Dr. Doolittle is a Medical Oncologist who has been involved in research throughout his career and is well published.

Jennifer Walter, Nurse Practitioner, spoke following Dr. Doolittle on "OPDIVO for Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head & Neck." Jennifer is the Immuno-Oncology Clinical Liaison for Bristol-Myers Squibb. Jennifer has experience in community medical oncology. The meeting was held on Wednesday, May 17th in Springfield. Over 40 investigators and research staff attended the meeting.

CRO Staff Serve on National Committees

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

Person	CRO's Involvement with Research Base Committees
Jay Carlson, DO	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 4. Member of the Membership Committee for the GOG Foundation Trials
Basava Raju, MS. CCRP	Serves on the Alliance audit committee.
Daniel Pinheiro, MD	Serves on NCI's Head & Neck Steering Committee/Task Force (HNSC) his three-year term starts on October 1, 2017
Marilyn Bauer, BSN, MHA	1. Serves on the Alliance Prevention Committee 2. Serves on SWOG's CCDR committee

Dr. John Bumberry Co-Author

CRO investigator, John Bumberry of Mercy – Springfield is a co-author for ECOG study E4112 - Prospective Study of Magnetic Resonance Imaging (MRI) and Multi-parameter Gene Expression Assay in Ductal Carcinoma in Situ. CRO enrolled 15 patients to the trial and was entitled to be an accrual author. Dr. Bumberry placed eight of CRO's enrolled 15 patients on the trial.

Dr. Robert Ellis Co-Author

Congratulations to Dr. Robert Ellis of Oncology Hematology Associates who was 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. Shaun Donegan recognized for S1400 Enrollments

The leadership team for the S1400 ("Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer")(Lung-MAP) trial at MDAnderson recognized Dr. Shaun Donegan of Mercy St. Louis and the Mercy St. Louis staff for their S1400 enrollments. The MDAnderson team recognized that this trial takes a lot of time and commitment from Dr. Donegan and his team and wanted to acknowledge their efforts and dedication. Dr. Donegan has screened seven patients for this important precision medicine trial.

Dr. Irving Lafrancis Co-Author

Dr. Irving Lafrancis from Mercy Hospital Joplin has been granted authorship for an ECOG-ACRIN manuscript because NSABP/NRG Oncology at Ozarks CCOP had a high accrual for the study. The study is ECOG-ACRIN E1Z03, and the manuscript is titled "Quality of Life Companion Study for JMA27 (NCIC-MA.27): A Randomized Phase III Trial of Exemestane Versus Anastrozole in Postmenopausal Women With Receptor Positive Primary Breast Cancer". Dr. Lafrancis enrolled five of the 26 patients from CRO.

Dr. Daniel Pinheiro NCI's Steering Committees/Task Forces

Dr. Pinheiro has been elected to serve on NCI's Steering Committee/Task Force More than 40 nominations for 16 positions were received. Dr. Pinheiro will serve a three-year term starting October 1, 2017. Congratulations to Dr. Pinheiro!

Debbie Cane Earns CCRP

Debbie Cane, CRO's Research Quality Analyst passed the SOCRA Clinical Research Professional Certification Examination effective July 13, 2017. By passing the examination, Debbie is now designated a Certified Clinical Research Professional by SOCRA and entitled to use the "CCRP" credential after her name. Congratulations to Debbie!

Basava Raju – Alliance Auditor

CRO's Lead Certified Clinical Research Coordinator, Basava Raju served on the Alliance Audit Team that conducted an annual 3-year audit at Cancer Research Consortium of West Michigan (CRCWM) in Grand Lakes, Michigan on November 9 & 10, 2015. Basava Raju was also on the Alliance Audit Team as they reviewed documentation at Dartmouth College - Norris Cotton Cancer Center in Lebanon, New Hampshire on April 24 & 25, 2016. Basava's participation is a great opportunity for CRO to learn new and improved methods for CRO documentation and auditing.

Quality

NRG Off-Cycle Audit

NRG Oncology was at CRO performing an off-cycle audit on July 6 -7, 2017. The off-cycle audit was conducted due to the large volume of participants CRO has enrolled on NRG trials. One major deficiency was found and a corrective action plan was submitted.

Internal Auditing

This grant year with several new staff and several NCI research base audits much internal auditing has occurred at CRO. CRO's Lead Certified Clinical Research Coordinator has spent many hours, internally auditing Springfield staff's charts as

CRO's policy is to perform internal audits on all new staffs' documentation for at least the first six months of their employment. CRO's Office Manager has also spent many hours auditing the Regulatory Compliance Coordinator's 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 and co-worker illnesses. 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 Lead Certified Clinical Research Coordinator, Basava Raju, travels to these sites for internal auditing.

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 conferences 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 2016 – 2017 research base meetings is noted in the chart below.

Meeting	Dates	Attendance
NCI PI & Administrators	September 16 -18, 2016	Dr. Jay Carlson, CRO's PI, Albert Bonebrake, CRO's Associate PI, Judy Hancock, CCDR Coordinator, Debbie Cane, Office Manager, & Marilyn Bauer, CRO's Director
SWOG Fall	September 14 -17, 2016	Kristina Gardner, Clinical Research Professional, & Marilyn Bauer, CRO Director
Alliance	November 3-5, 2016	Marilyn Bauer, CRO Director
ECOG-ACRIN	November 10-12, 2016	Connie Roller, CRO's Clinical Research Assistant
COG Fall	September 14, 2016	Pam Harris, Lead Certified Clinical Research Nurse
COG Spring	March 29-30, 2017	Dr. Robin Hanson, Pediatric Oncologist and COG site PI
NRG Spring	February 7-10, 2016	Dr. Al Bonebrake, & Marilyn Bauer, CRO Director
SWOG Spring	April 26-29, 2017	Judy Hancock, CCDR Coordinator & Marilyn Bauer, CRO's Director
NRG	July 11-14, 2017	Drs. Jay Carlson, CRO's PI, Albert Bonebrake, CRO's Associate PI, Erin McCaig, Research Nurse

CRO's Director encourages staff participation in online trial specific webinars. Information is forwarded 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 during component webinars. CRO administrative staff attends all NCI NCORP administrative, CCDR and regulatory webinars.

CRO Enrollments to Clinical Trials

According to NCI, CRO enrolled 78 patients to clinical trials in grant year 2016-2017. Sixty three patients were enrolled to treatment trials and 15 patients were enrolled to cancer control trials. This resulted in 83.95 treatment and 17.22 cancer control trial credits for a total of 101.17 credits. Trial enrollment was sluggish this year as trials continue to be more complex and there are fewer trials available.

Achieving Target Credit Goals

NCI assigned CRO target credits of 82.5 for treatment and 82.5 for cancer control for grant year 2016-2017. CRO earned 83.95 treatment credits which was 102% of NCIs target (82.5 credits). CRO earned 17.22 control credits which was only 21 % of NCIs target (82.5 credits). Combined, CRO earned 101.17 credits or 61% of the set NCI Goal. Thirty-eight CRO research investigators participated in making this happen. In grant year 2015-2016, CRO earned 76.107 treatment credits and 30.264 cancer control credits totaling 106.371 credits which is 66% of the NCI assigned goal.

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 credits. Credits are the NCI value assigned to each trial registration. This past year, CRO had 78 registrations for credit, and 28 non-credit registrations, for a total of 106 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 35 NCI registrations. Our components contributed 49% of our total NCI registrations this grant year. Last grant year our components also contributed 49% of our total registrations.

Ongoing Accrual Stimulation Actions

CRO has seen historically low accruals this grant year and has taken many efforts to increase accruals to clinical trials including:

1. CRO staff screen all new patients and those coming in to investigator's offices to review scans, pathology, lab reports and discuss treatment options for clinical trial eligibility.
2. Trial accrual is a standing agenda topic at the CRO Executive Board, CRO Steering Committee, weekly CRO Huddle, and monthly CRO staff meetings etc. Accrual to trials is our top priority.
3. Dr. Carlson, CRO's PI sends e-mail messages to appropriate investigators as needed.
4. Trial specific flyers are developed, approved by the IRB and posted in patient care waiting areas for them to view.
5. 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 different trial is profiled each month in the CRO Communique

6. 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 and posted on our website.
7. Screening statistics are compiled each month and shared with the specific sites. The information is periodically reviewed by the CRO Executive Committee to ascertain if there is an area which can be impacted or improved upon in regard to increasing accrual to clinical trials.

CRO staff developed an action plan on October 20, 2016 to address low accruals. We continue to work to accomplish tasks on our plan and review the tasks each week at our huddles.

CRO Staff

CRO Springfield staff includes the director, research operations assistant/office manager, lead certified clinical research coordinator, research quality analyst, CCDR coordinator, senior clinical research coordinator, research coordinator, cancer research professional, one full time and one part-time BSN research nurse(s) and two clinical research assistants.

New CRO Staff

Leslie Morelock Herrell is CRO's Research Operations Assistant/Office Manager. Her first day at CRO was April 10, 2017. Most recently, Leslie was employed with Springfield Public Schools for several years, where she was responsible for administrative and financial duties and tasks. Leslie is located at the CRO Administrative Office.

Nicole Holman, is CRO's Clinical Research Assistant, who joined CRO on April 17, 2017. Nicole has worked at CoxHealth as a Radiology Tech Assistant/Phlebotomist. Nicole is working out of the CRO office in the Hulston Cancer Center.

Michelle Baker

Michelle joined CRO on July 3, 2017 as a long-term follow-up Clinical Research Assistant at the CRO Administrative Office. Michelle has many years of working in health care in various positions. Most recently, she worked in research with Zevacor Molecular.

Meeting the CRO Goals for 2016- 2017

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. Meet NCI's treatment credit goal during grant year 2016-17	1. Earned 83.94 treatment credits - 1.44 credits above NCI's 82.5 credit target for CRO.
2. Meet NCI's cancer control credit goal during grant year 2016-17	2. Earned 17.21 cancer control credits – 65.29 below NCI's target of 82.5 for CRO.
3. Develop Cancer Care Delivery Research at CoxHealth, Mercy Springfield and Mercy St. Louis	3. Hired Judy Hancock as our CCDR Coordinator in August 2016. CRO was selected to participate in S1415CD and enrolled the first patient in the country. A total of 74 patients were enrolled to this trial as of 8/1/17.
4. Screen 100% of all cancer patients at all CRO component sites	4. All local patients are screened and screenings are recorded in CRO's CREDIT database. All components have been encouraged to screen all oncology patients as well and document in CRO's CREDIT database.
Goal 2. Improve communication efforts to keep CRO investigators and health care extenders aware of clinical trial availability	
5. Visit yearly with physicians and staff at each of our components to offer assistance and encourage enrollment to trials.	5. Visited with investigators and staff at Mercy St. Louis on 9/27/16 – unable to visit with other sites due to staffing shortage & staff illness.
6. Hold twice yearly CRO Steering Committee meetings with national speakers on new cancer therapies and treatments.	6. October 26, 2016. Dr. Joseph Lancaster spoke on "Personalizing Cancer Treatment with New, More Precise Clinical Diagnostic Tools."
7. Hold one CRO Steering Committee meeting in St. Louis allowing those far away to attend	7. On September 27, 2016, Dr. Joseph Fay spoke on "A Treatment Option for the Management of Multiple Myeloma in Patients Who Have Had One to Three Prior Therapies" in St. Louis, Missouri.

Goal 3. Ensure quality at CRO	
8. 65% of CRO's clinical research professionals will be credentialed as certified research professionals or oncology nurses	8. 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. Debbie Cane became CCRP certified.
9. Randomly select at least one patient record from each staff enrolling patients for quarterly internal auditing	9. Chart audit is performed as time allows. Many charts are internally audited as new staff are oriented.
10. 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	10. 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 employment 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 respective staff member requesting a response to queries in a timely manner and to submit all delinquent data as soon as possible.
11. Stabilize staff turnover	11. Continues to be a goal for CRO.
Goal 4. Promote CRO on a Local and National Level	
12. Encourage new investigators to become involved in NCI trials locally and at a national level	12. CRO's PI and director visit with new physicians in Springfield to encourage enrollment to trials.
13. Strive to have a CRO representative involved on committees at all NCI research bases	13. 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.
14. Market CRO with 30-second TV and radio ads	14. The 30 second TV ads aired on local TV and radio stations from 11/21/16 through 2/28/17.

CRO Goals --- Grant Year 2017-2018

The CRO Executive Board approved the following goals for grant year 2017- 2018:

Goal 1. Increase accruals to NCI clinical trials to meet NCI 200 credit goal for GY 2017-2018

A. Track accrued credits and report to executive committee and components on a monthly basis
B. Complete transfer of Mercy Oklahoma and Mercy Ft. Smith to CRO
C. Monitor patient screening, and report to executive committee and components on a monthly basis to facilitate screening of 100% of CRO component cancer patients

Goal 2. Improve communication with CRO investigators and staff to increase awareness of clinical trial availability

A. Visit annually with physicians and staff at each component to offer assistance, obtain input regarding communication, and encourage enrollment to trials
B. Hold three CRO Steering Committee meetings annually (two in Springfield and one in St. Louis) with national speakers on new cancer therapies and treatments; the importance of cancer research and other topics of interest to CRO components
C. Include information regarding newly available clinical trials in CRO monthly communique

Goal 3. Ensure quality at CRO

A. Increase the number of CRO eligible staff who are credentialed in research or oncology to 65 percent
B. Perform quarterly internal audits on a minimum of one randomly selected record from each staff enrolling patients at all components
C. Monitor and develop quality assurance methods to ensure
    1. Timely and accurate data submission
    2. Timely response to research database queries

Goal 4. Promote CRO on both local and national levels

A. Encourage involvement of new investigators in NCI trials
B. Encourage CRO representation on committees at all NCI research bases
C. Utilize both purchased and PSA television and radio promotion of CRO clinical trials
D. Share CRO's social media efforts at NCI PI & Administrators Conference
E. Submit successful NCORP grant application

Treatment

RESEARCH BASE	2015-2016 REGISTRATIONS	2015-2016 CREDITS	2016-2017 REGISTRATIONS	2016- 2017 CREDITS
Alliance	7	11.644	14	18.66
COG	8	9. 275	9	10.97
ECOG-ACRIN	9	12.445	8	18.93
NCI	0	0.00	0	0.00
NRG	17	17.847	14	15.19
SWOG	22	24.896	18	20.20
Wake Forest	0	0	0	0
Totals	63	75.102	63	83.95

Cancer Control & Prevention

RESEARCH BASE	2015-2016 REGISTRATIONS	2015-2016 CREDITS	2016-2017 REGISTRATIONS	2016-2017 CREDITS
Alliance	6	6.750	4	5.19
COG	0	1.750	0	2.25
ECOG-ACRIN	15	16.000	9	2.38
NCI	0	0.364	0	2.13
NRG	1	2.000	2	3.77
SWOG	0	3.400	0	1.50
Wake Forest	0	0	0	0
Totals	22	30.264	15	17.22

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

RESEARCH BASE	2015-2016 REGISTRATIONS	2015-2016 CREDITS	2016-2017 REGISTRATIONS	2016-2017 CREDITS
Alliance	13	18.394	18	23.85
Children's Oncology (COG)	8	11.025	9	13.22
ECOG-ACRIN	24	28.445	17	21.30
NCI		0.364	0	2.13
NRG	18	19.847	16	18.96
SWOG	22	28.296	18	21.70
WAKE FOREST	0		0	0
Total Reg. & Credits	85	106.371	78	101.16
Industrial Trial Reg.	20	0.00	26	0
CCDR	0	0.00	74	0
Grand Total	85+ 20	106.371	178	101.16

*Credit + noncredit registrations **Registrations totaled

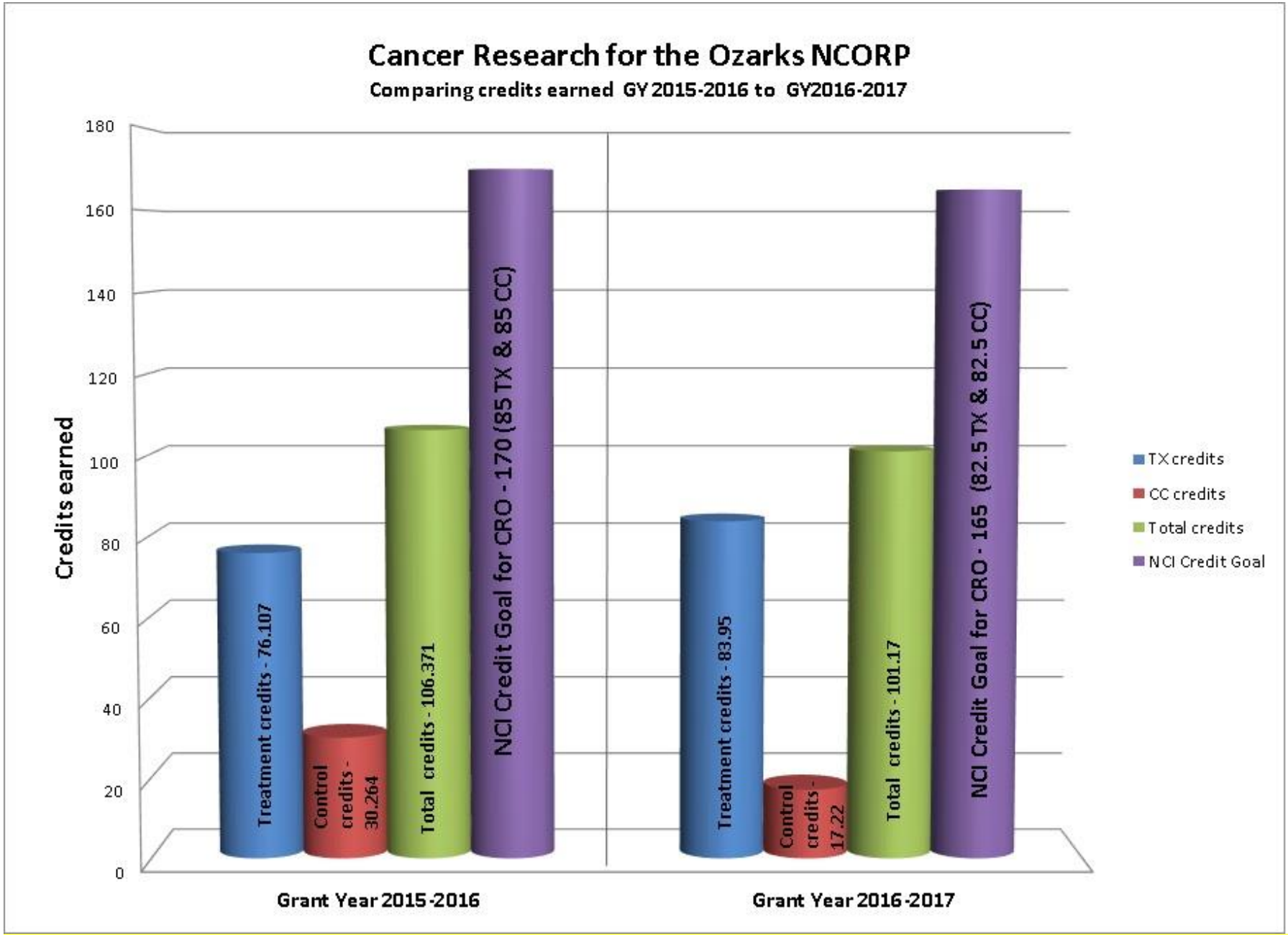
Registrations by Affiliate/Site

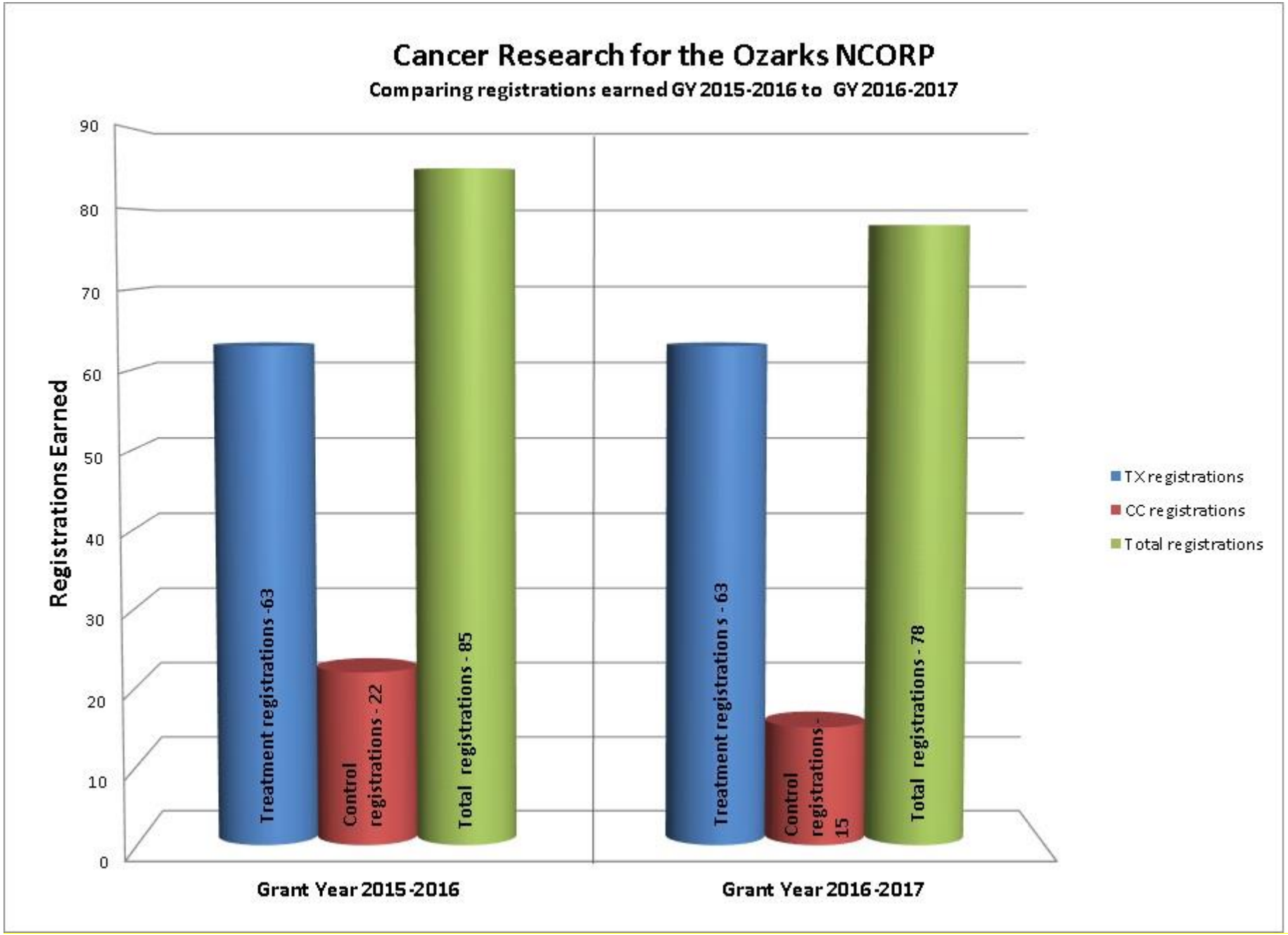
Component/Affiliate*	2015-2016 REGISTRATIONS	2015-2016 CREDITS	2016-2017 REGISTRATIONS	2016-2017 CREDITS
Central Care, PA	0	0.425	1	1.32
Mercy Springfield	30 + 2	36.830	16	25.76
Freeman Medical Center (Joplin)	4	5.290	1	2.64
Good Samaritan (Mt. Vernon, IL)	2	2.127	3	3.47
Mercy Joplin	0	0.065	1	1.21
Mercy Clinic Rolla	0	0.250	2	0.66
Mercy St. Louis	23 + 17	29.122	23	31.36
Mosaic Life Care	-	-	2	2
Phelps County Regional Medical Ctr. (Rolla)	8	8.391	4	3.21
CoxHealth System	13 + 10	17.370	22	25.92
Cox Medical Center Branson	0	0	0	0
St. Louis Cancer & Breast Institute	5	6.501	3	3.62
No Credit	20	0	142	0
Grand Totals	85 + 20	106.371	220	101.17

Patient registration to NON-Credit trials

August 1, 2016 to July 31, 2017

Protocol Name	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Annual
GOG-3005	2	1	0	0	3	2	2	0	1	1	0	0	12
PALLAS	2	0	0	0	1	1	2	3	1	4	0	2	18
9846 Tissue Procurement	0	0	2	10	7	0	1	3	4	4	3	3	33
SWOG S1415CD	0	0	1	7	10	13	5	9	9	8	4	7	74
Exceptional Responders	0	0	0	0	1	0	0	0	0	0	0	1	2
COG ACCRN07	0	0	0	0	1	1	0	0	0	0	0	0	2
	4	1	3	17	23	17	10	15	15	17	7	13	142


Cancer Research for the Ozarks NCORP
Comparing credits earned GY 2015-2016 to GY2016-2017
Credits earned
180
160
140
120
100
80
60
40
20
0
Treatment credits - 76.107
Control credits - 30.264
Total credits - 106.371
NCI Credit Goal for CRO - 170 (85 TX & 85 CC)
Treatment credits - 83.95
Control credits - 17.22
Total credits - 101.17
NCI Credit Goal for CRO - 165 (82.5 TX & 82.5 CC)
TX credits
CC credits
Total credits
NCI Credit Goal
Grant Year 2015-2016
Grant Year 2016-2017


Cancer Research for the Ozarks NCORP
Comparing registrations earned GY 2015-2016 to GY 2016-2017
Registrations Earned
90
80
70
60
50
40
30
20
10
0
Treatment registrations -63
Control registrations - 22
Total registrations - 85
Treatment registrations - 63
Control registrations - 15
Total registrations - 78
Grant Year 2015-2016
Grant Year 2016-2017
TX registrations
CC registrations
Total registrations

Top 10 Protocols by Registration

Rank	Protocol	Title	# Registrations	Credits
1.	**SWOG S1415CD**	"A Pragmatic Trial to Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia –Trial Assessing CSF Prescribing Effectiveness and Risk ("TrACER")"	74	CCDR 0 cc
2.	**DCP-001**	Use of a Clinical Trial Screening Tool to Address Cancer Health Disparities in the NCI Community Oncology Research Program (NCORP)	69	1.1625
3.	**EAY131**	Molecular Analysis for Therapy Choice (MATCH).	43 step 1 2 on trial	11.3
4.	**PALLAS AFT-05**	PALbociclib CoLlaborative Adjuvant Study: A randomized phase III trial of Palbociclib with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone for hormone receptor positive (HR+) / human epidermal growth factor receptor 2 (HER2)-negative early breast cancer	18	Foundation Trial 0 cc
5.	**A011401**	Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer	10 registered 9 on trial	10.425 RX & 2.25 cc
6.	**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	12	Foundation Trial 0 cc
7.	**A151216**	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)	11	4.95 Rx
8.	**AALL0932**	Treatment of Patients with Newly Diagnosed Standard Risk B-Precursor Acute Lymphoblastic Leukemia (ALL), A Group wide Phase III Study	6	6 Rx
9.	**ECOG-ACRIN NHLBI-MDS**	The National Myelodysplastic Syndromes (MDS) Study	6	1.875 cc
10.	**EAQ152**	A Randomized Study of Pre-disclosure Genetic Education v. Usual Care in Tumor Profiling for Advanced Cancer and a Pilot Study of Remote Genetic Counseling for Participants with Potential Germline Mutations Identified on Tumor Profiling	6	0.875 cc

Cancer Research for the Ozarks Staff

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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.