



Connecting Hope
and Medical Science

Focus ON THE Search

Clinical trials advancing the quest for cancer treatment, management, and prevention.

Colorado Cancer Research Program (CCRP) ■ Summer 2011 ■ Issue 16

Upcoming Events

■ **CaRE Colorado Springs**
October 11

■ **CaRE Denver**
October 13

■ **Men's Health Screening**
Exempla Lutheran
Medical Center
September 24

For more information,
call (303) 689-4595.

■ **Prostate Cancer Education Event**
North Colorado Medical
Center
September 22

For more information,
call (970) 350-6567.

**CCRP is a member of the
Community Health Charities.**

Please consider supporting
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How Trials Are Selected to Open at CCRP



In our last full issue, we visited with **Dr. Pajon**, CCRP's principal investigator, on the subject of "Reasons Why Clinical Trials Are Important." In this issue we talk to Dr. Pajon about "How Trials Are Selected to Open at CCRP."

"The trials selected depend upon the patient population our investigators see. We meet with our investigators on a regular basis and try to maintain a portfolio of clinical trials that covers what cancers are being seen in our patient population.

"After we review our patient population, we look and see what is available to us; not all trials are available.

- We look at the research groups we are aligned with through National Cancer Institute (NCI) Cooperative Groups which include: Eastern Cooperative Oncology Group (ECOG), National Surgical Adjuvant Breast and Bowel Project (NSABP), North Central Cancer Treatment Group (NCCTG), Gynecologic Oncology Group (GOG), and the NCI-supported Cancer Trials Support Unit (CTSU).
- We see what has recently been activated or open that targets our patient population.
- We review the requirements and consider whether or not our physicians can meet them.

- We begin the paperwork (e.g., what has to be sent to the institutional review board; reimbursement issues; special tests; insurance issues).
- Then, once the trial goes through all those loops and it is reviewed by the institutional review board (IRB), it gets activated.
- We will also occasionally do pharmaceutical (pharma) trials. In these instances, the pharma companies come to us and ask for our participation. We will only do these trials if we have physicians who are seeing patients for whom this drug is having a role and don't have competitive trials (i.e., two trials targeting the same patient population); that would dilute our effort.

"It takes a lot to activate a trial through all of our many partners. For example:

- We need a sufficient number of people to enroll. We call that "accrual."
- We need to keep track of accruals by tumor type and stage.
- Although we have 125 investigators who can potentially participate in our investigations to start and support clinical trials, in reality about 50 doctors do the bulk of the accruing to trials. There are a lot of doctors who have joined CCRP, but the commitment to the extra amount of time and effort that it requires (to support clinical trials) is not universally shared by everyone who is affiliated. It takes a lot of time for the doctor to present the concept of

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Focus ON THE Search

Focus on the Search is a quarterly publication of resources for people who are current or past participants in cancer clinical trials in Colorado, for people who have been recently diagnosed with cancer and those interested in cancer research.

Colorado Cancer Research Program (CCRP) is a non-profit organization, a partnership of 17 Colorado community hospitals, and their affiliated doctors, dedicated to the advancement of cancer research and care close to home. CCRP is a Community Clinical Oncology Program, one of 50 such programs nationwide.

CCRP's Partner Hospitals

Boulder Community Hospital
 Exempla Lutheran Medical Center
 Exempla Saint Joseph Hospital
 Littleton Adventist Hospital
 Longmont United Hospital
 McKee Medical Center
 Medical Centers of Aurora
 North Colorado Medical Center
 North Suburban Medical Center
 Penrose-St. Francis Health Services
 Porter Adventist Hospital
 Presbyterian/St. Luke's Medical Center
 Rose Medical Center
 St. Anthony Hospitals
 Sky Ridge Medical Center
 St. Mary-Corwin Medical Center
 St. Mary's Hospital
 Swedish Medical Center



The 2011 Robert F. Berris, MD, award was awarded to CCRP Principal Investigator **Eduardo Pajon, MD** (pictured with his wife Anita) for his 30-year commitment to cancer research. The award was also given to former CCRP enrolling physician **Dr. Catherine Azar**. Dr. Azar enrolled 300 patients during her time enrolling patients on CCRP clinical trials.

New CCRP Trials Opened (April 2011–July 2011)

Disease Site	Protocol No.	Title
Esophageal	E2208	Randomized Phase II Study as Second Line Treatment for Patients with Metastatic Esophageal or GE Junction Cancer.
Esophageal	RTOG 1010	A Phase III Trial Evaluating the Addition Treatment of HER2-Overexpressing Esophageal Adenocarcinoma.
Brain	N0577	Phase III Intergroup Study of Radiotherapy versus Temozolomide alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with 1p/19q Codeleted Anaplastic Glioma.
Liver	N0745	Phase I/II Randomized Study as First-Line Therapy in Patients with Locally Advanced or Metastatic Hepatocellular Carcinoma.
Colon	N0949	Randomized Phase III Trial as First-line Treatment in Elderly Patients with Metastatic Colorectal Cancer.
Gynologic	GOG-0186-I	Randomized Phase II Evaluation of in the Treatment of Recurrent or Persistent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma.
Breast	SWOG-1007	A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER-2 Negative Breast Cancer with Recurrence Score (RS) of 25 or Less.
Liver	E1208	A Phase III Randomized Trial in Unresectable Hepatocellular Carcinoma (HCC) in Patients with and without Vascular Invasion
Melanoma	E1609	A Phase III Randomized Study for Resected High-risk Melanoma.
Renal	S0931	EVEREST: EVERolimus for Renal Cancer Ensuing Surgical Therapy, a Phase III Study.
Cancer Control	N08C9	Phase III, Randomized Study in the Prevention of Acute Diarrhea in Patients Receiving Pelvic Radiation Therapy

For the most current information and details regarding these trials, please visit www.co-cancerresearch.org.

How You Can Be an Advocate for Cancer Clinical Trials in Your Community

The Education Network to Advance Cancer Clinical Trials (ENACCT) was founded to increase awareness and enrollment to cancer clinical trials in the United States. Clinical trials help to move basic scientific research from the laboratory into treatments for people. Unfortunately very few adults with cancer (less than 3 percent) participate in a clinical trial.

If you are interested in becoming an advocate for cancer clinical trials, we encourage you to visit ENACCT's website (www.enacct.org/yourrole) and take the free workshops on patient advocacy and cancer clinical trials. You may also contact Vicki Tosher, Community Outreach Coordinator at CCRP (303) 777-2663

This Issue's Featured Clinical Trial

N08CB — Calcium Gluconate and Magnesium Sulfate in Preventing Neurotoxicity in Patients with Colon Cancer or Rectal Cancer Receiving Oxaliplatin-Based Combination Chemotherapy

- **Purpose:** Chemoprotective drugs, such as calcium gluconate and magnesium sulfate, may prevent neurotoxicity (the tendency of some treatments to cause damage to the nervous system), caused by oxaliplatin. It is not yet known which administration schedule of calcium gluconate and magnesium sulfate is more effective in preventing neurotoxicity.

This randomized phase III trial is studying different administration schedules of calcium gluconate and magnesium sulfate and comparing how well they work in neurotoxicity in patients with colon cancer or rectal cancer receiving oxaliplatin-based combination chemotherapy.

Resources

- www.cancer.gov/cancertopics/types/colon-and-rectal
- www.cdc.gov/cancer/colorectal/

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clinical trials and why a particular one might be advantageous; time that is not paid for by anyone.

- Clinical trials also require time of Clinical Research Associates (nurses who do the interviewing of patients and enrolling, filling out the forms, etc.). Every patient in a clinical trial has a CRA.
- Getting patients to enroll is very time intensive; doing the reporting is also time intensive. and neither CCRP nor physicians are adequately compensated for this work. NCI is working on how to appropriately incentivize physicians to participate because lack of reimbursement is often the reason for lack of participation.
- But, in spite of the lack of reimbursement, CCRP has a cadre of doctors who are committed to clinical research and who will accrue patients. These doctors realize the value not only to science but to patients and themselves in enrolling people in trials. They truly contribute to advances in the treatment of patients with cancer. These people are not recognized well enough and that's unfortunate."

Drive for a Cure Raises over \$40,000!

CCRP would like to thank the sponsors of the tournament: **Rocky Mountain Cancer Centers, Catholic Health Initiatives Institute for Research and Innovation, Sherman & Howard, Parker Adventist Hospital, COPIC Financial, Longmont United Hospital, NuEnergy, and Wells Fargo Advisors.** A special thanks to the over 80 golfers that helped make this event a success!



Team Penrose at the **5th Annual Drive for a Cure** golf tournament, July 11, 2011.

CaRE (Cancer Research Education)

If you haven't heard, we **CaRE! Cancer Research Education** has long been a part of CCRP's programming: meetings held semi-annually in Colorado Springs and Denver to provide past and current cancer clinical trial participants and others interested in cancer research valuable learning opportunities about cancer research.

- Past topics have included presentations on the current status of specific disease, advances in cancer research, and the future of research and cancer.
- The next series of these meetings will be in Colorado Springs on October 11 and in Denver on October 13.
- If you are interested in attending, or would like to know more about upcoming topics at the **CaRE** series, please contact Vicki Tosher at (303) 777-2663.

We've updated the look of program announcements, in keeping with newsletter and website design. You, and the entire community, will soon recognize every piece of material coming from CCRP.

Patient Experiences: Barb Hansen



"I'm a member of the Patient Advisory Board here at CCRP and have had the privilege of attending the NCCTG (North Central Cancer Treatment Group)

Patient Advocate Symposium where the latest cancer research findings and clinical trials information were presented by many medical doctors and researchers. I was diagnosed with multiple myeloma (MM), a cancer of the plasma cells on December 1, 2006. I was treated at Rocky Mountain Cancer Center and after several months was informed that a study was available in which I might participate: clinical trial ECOG/CALGB 10104. After my family and I met with my doctor, Dr. Matous, to discuss the risks and benefits of the trial, I signed the consent papers. That study started in late 2007, and I'm pleased to say I continue to be in remission. Today I give back by serving on the patient advisory board at CCRP and also by being part of the First Connection Program of the Leukemia and Lymphoma Society where I talk to newly diagnosed patients with MM. I like sharing my story partly because I'm very thankful that there are many dedicated researchers, an organization like CCRP, medical personnel, and participants carrying out clinical trials. It was interesting for me to learn that the drug that my study uses, lenalidimide, is an analog or cousin of the drug

thalidomide that was popular back in the '60s but then banned because of the birth defects it caused when administered to pregnant women. Today's protocols with new drugs are extremely careful. They are so careful, in fact, that I've had three pregnancy tests at different intervals prior to being administered the drug — me, a person over 60 who's had a hysterectomy!

"I think it's empowering for a person to get involved in helping others either through clinical trials or being a patient advocate, such as through the Colorado Cancer Research Program. It has been for me. The information you gain from the experience of going through cancer with all its health-care visits, treatments, insurance paperwork, and the personal journey can be very valuable when shared with people facing cancer for the first time. I've had some wonderful conversations with people about things that I just took for granted after having been in treatment for almost six years now. It's very gratifying to be able to help someone learn new information or to help them put some fears to rest and also to just let them know you're walking with them, that they're not alone. I try to encourage others to take this step when they're ready. They will know when; it doesn't happen right away since people need time to heal. I also am a believer that helping others is part of the healing process, as it has been for me."

Cancer Control Clinical Trials

Cancer Control Clinical Trials are sometimes called supportive care research, palliative care research, or symptom management research. These trials work to reduce side-effects from cancer or cancer treatment. Common physical symptoms include pain, fatigue, loss of appetite, nausea, vomiting, shortness of breath, and insomnia. These trials work to improve quality of life. CCRP has various Cancer Control Clinical Trials open at this time. Ask your physician or call CCRP, 303-777-2663 or 1-888-785-6789, if you want additional information.

Online Cancer Resources

National Cancer Institute:
www.cancer.gov

National Comprehensive Cancer Network: www.nccn.com

A patient-oriented cancer website based on the NCCN Guidelines which set the standard of care for clinicians around the globe.

American Society of Clinical Oncology:
www.asco.org
www.cancer.net

Oncologist approved cancer information, including information on cancer research and advocacy.

CancerCare: www.cancer.org
CancerCare programs include counseling and support groups, education, financial assistance and practical help.



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