**Spring CaRE Wrap-Up**

**What are the results of my trial?**

Many clinical trial participants are curious as to why they do not hear about results of their clinical trials even years after their treatment ends and trial participation is over. The basis of the two CaRE meetings in May was to help explain the complexities involved in the clinical trial process.

Presentations were given by skilled members of the CCRP “family.” In Colorado Springs, Dr. Joel Ohlsen, retired Radiation Oncologist and CCRP Board Member, along with Cindy Winnenmiller, CCRP Clinical Research Associate presented. The Denver panel consisted of Dr. Nicholas DiBella of Rocky Mountain Cancers Centers-Aurora and member of the CCRP Board, Nancy Morton from CCRB, and Wendy Binyon, CCRP Clinical Research Associate. Vicki Tischer was the moderator at both sessions.

We used a single clinical trial, Combination Chemotherapy in Treating Women with Stage I, Stage II, or Stage IIA Breast Cancer and Positive Axillary Lymph Nodes (NSABP B-30), to demonstrate how long it can take to develop a research idea and protocol, open and conduct a trial, analyze data, and publish results. B-30 took over two years from the time the research concept made it to the National Cancer Institute’s (NCI) Steering Committee for review until the final protocol document was approved by NCI’s Institutional Review Board and final approvals to CCRP for activation.

A randomized trial comparing three different combinations of therapies for breast cancer (see table 1) B-30 was open for enrollment from 1999 to 2004, during which time data was collected. Following treatment, an enrolled patient’s health status was continually followed and reported for many years. Analysis of data probably began after the trial closed, but final analysis did not occur until 2010 and final results were published the same year. Those results indicated that overall survival (eight years) improved in the sequential AC-T group (Arm 1) compared to the AT (Arm 2) and the concurrent ACT groups (Arm 2): 83%/79%/79%. In addition, disease-free survival improved in AC-T arm (74%) vs. AT arm (69%) and ACT arm (69%). However, patients in Arm 1 exhibited more severe symptoms that those in Arms 2 and 3 despite their improved survival, and their quality of life scores were lower at six months. In Arm 1, with shorter duration of treatment, quality of life at twelve months showed no difference.

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<th>Arm #</th>
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*Commercial drug names: Adriamycin®, Cytoxan®, Taxotere®

Finally, we showed those in attendance the plan that the National Cancer Institute has developed in order to cut approval time by approximately twelve to eighteen months to demonstrate how long it can take to develop a research idea and protocol, open and conduct a trial, analyze data, and publish results.

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Following the second part of a multi-issue series that explains the process of opening a trial at Colorado Cancer Research Program (CCRP), enrollment and treatment of a patient and long-term follow-up post treatment.

### The Clinical Trial Process – Enrolling and Treatment of a Patient on a Clinical Trial

There are more than 125 Colorado physicians associated with Colorado Cancer Research Program who can enroll patients on CCRP cancer treatment, symptom control, or prevention clinical trials.

These physicians have an average of 65 trials available at any given time in which to enroll their patients, for nearly all cancer disease sites. All trials open for enrollment are listed online at www.co-cancerresearch.org. A critical point in the clinical trial process is the patient and physician discussing clinical trials as an option. As trials have become more complex, many patients become ineligible if certain treatments have already begun, or, in some cases, if surgery has already taken place.

Once a physician has deemed a patient eligible, and a patient agrees to participate, a Clinical Trials Coordinator will “consent” the patient. This process includes explanation of the trial, the potential risk, benefits of participation and having the patient sign an informed consent. From this point in time, the patient’s medical team has increased, from not only the patient’s physician and their staff who will monitor their treatment, but also include the Clinical Trials Coordinator, who will ensure that the protocol for the trial is being followed and that the patient health status will be reported to the trial sponsor.

One unique aspect of participation in a cancer clinical trial is that the investigational drug may be provided at no cost to the patient. Each trial has strict guidelines for drug administration; these guidelines must be followed. CCRP must ensure that the proper drug is ordered for each patient, that the dosages are correct, that any dosage reductions are followed, and unused drug is properly disposed of. The administration, delivery and storage of drug is not only highly regulated by government, but it is also critical that protocols are followed correctly. Failure to do so will deem that patient’s results on trial are not able to be used as part of the overall trial data. The process of insuring that drug delivery to the patient by the treating physician and his or her staff is monitored closely by Clinical Trials Coordinators and drug administration staff.

### Online Cancer Resources

**National Cancer Institute:**  
[www.cancer.gov](http://www.cancer.gov)

**National Comprehensive Cancer Network:**  
[www.nccn.com](http://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](http://www.asco.org)  
[www.cancer.net](http://www.cancer.net)

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

**CancerCare:**  
[www.cancercare.org](http://www.cancercare.org)

CancerCare programs include counseling and support groups, education, financial assistance and practical help.

**Steps in the Trial Process**

- **Patient Protection**
- **Enrollment and Treatment**
- **Long-Term Follow-up**

**Upcoming Events**

- **Free Men’s Health Screening**  
  Exempla Lutheran Medical Center  
  September 22, 2012

For more information call the AnswerLine at (303) 889-4595.

**Colorado Cancer Research Program (CCRP) - Summer 2012 - Issue 19**

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

Focus ON THE Search

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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
Park Adventist Hospital
Penneke-St. Francis Health Services
Porter Adventist Hospital
Presbyterian/St. Luke’s Medical Center
Rose Medical Center
St. Anthony Hospital
Sky Ridge Medical Center
St. Mary-Corwin Medical Center
Swedish Medical Center

CCRP’s Partner Hospitals

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<td>A GOG Intergroup Multicenter Phase III trial of Ovaplatin (Carboplatin) and Paclitaxel +/- NC1 Expressed: Bevacizumab (BEV). CA125, HCG, CA19.29 (Cohort 2) Compared with Paclitaxel and Bevacizumab (BEV) as First Line Chemotherapy in Patients with Muscular Epithelial Ovarian or Fallopian Tube Cancer (MDDC)</td>
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<td>Hodgkins Lymphoma</td>
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<td>Phase II trial of Response-adapted Chemotherapy Based on Pathway Entropy Scoring for Non-Hodgkin Stage I and II Hodgkin Lymphoma.</td>
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<td>Hodgkins Lymphoma</td>
<td>E2410</td>
<td>Phase II trial of Response-Adapted Therapy Based on Pathway Entropy Scoring for Non-Hodgkin Stage I and II Classical Hodgkin Lymphoma (HL)</td>
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<tr>
<td>Lung</td>
<td>A471/042</td>
<td>A Phase II, Multi-Cohort Study to Evaluate the Impact of Prophylactic Intensive on Dermatological and Gastrointestinal Adverse Events and Patient Reported Outcomes in Patients Treated with Dacarbazine (IF-025884)</td>
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<td>A Randomized Phase III study of Bortezomib, Rituximab, Dexamethasone, and Tamoxifene in Patients with Relapsed Waldenstrom’s Macroglobulinemia and Relapsed/Refractory Mantle Cell Lymphoma or Follicular Lymphoma (Phase II) and 2ndline/Relapsed Waldenstrom’s Macroglobulinemia (Phase II)</td>
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<td>SPI-ZEV-11-001</td>
<td>A Phase II, Optimal, Multicenter, randomized study of Sequential Zivitin (Brutonatin, Tuxade) versus Observation in Patients at Least 60 Years of Age with Newly Diagnosed Drug Resistant Lung II-C Cell Lymphoma in PET-Negative Complete Remission After R-CHOP or R-CHOP-Like Therapy</td>
</tr>
<tr>
<td>Pancrace</td>
<td>CALGB 408701</td>
<td>Randomized Phase II trial of Everolimus Alone versus Everolimus Plus Bevacizumab in Patients with Locally Advanced or Metastatic Pancreatic Neuroendocrine Tumors</td>
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For the most current information and details regarding these trials, please visit www.co-cancerresearch.org.

New CCRP Trials Opened (March – June 2012)

**This Issue’s Featured Clinical Trial**

GOG-261: A Randomized Phase III trial of Paclitaxel Plus Carboplatin versus Ifosfamide Plus Paclitaxel in Chemotherapy-Naive Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinoma (Mixed Mesodermal Tumors) of the Uterus or Ovary

- **Purpose:** Cancer patients may die a natural death but the growth of tumors can be complicated by killing them at different stages of the growth cycle and stopping them from dividing. With chemotherapy, this is best accomplished by using drugs that work in different ways. This clinical trial combines paclitaxel with either carboplatin or ifosfamide to determine which combination works better in treating patients with newly diagnosed uterine or ovarian cancer that is persistent (Stage I – IV) or recurrent when the patients have not before had chemotherapy. The study will enroll over 400 women in the United States and Korea. It is sponsored by the National Cancer Institute (NCI).

- **Eligibility:** At least 18 years old; stage I, stage II, stage III, or stage IV uterine carcinomas or ovarian carcinomas; no previous chemotherapy for this cancer; at least four weeks since external-beam radiation therapy; final eligibility for a clinical trial is determined by the health professionals conducting the trial.

The Clinical Trial Process — Enrolling and Treatment of a Patient on a Clinical Trial

continued from page 1

During a patient’s treatment, a Clinical Trials Coordinator will work in tandem with the treating physician, his or her nurses and other staff. Trial protocols may be up to 250 pages in length, and all portions of the protocol must be strictly followed. During this time, treatment progress, response to the treatment, and the patient’s overall health status will be charted and forwarded on to the trial sponsor. This occurs simultaneously for all patients enrolled on trials from across the country. Quite often, due to this reporting, it may be discovered that a portion of the trial should be changed. To decrease side-effects or other health related issues, changes can be made for many reasons, including protocol clarification or timing of health monitoring.

Currently CCRP has twenty-two (22) Clinical Research and Data Coordinators — called Clinical Research Associates — working with 125 oncologists around Colorado. In some instances Coordinators work from the CCRP office and travel to various treating offices; in other cases, providers hire their own coordinators.

In addition to the submission of patient health-status information to trial sponsors, the Clinical Trials Coordinator or Clinical Research Associates are also responsible for ensuring that all required specimens and biopsies are collected and shipped to the trial sponsor for further evaluation. Almost all trials that are being opened now require these submissions for further research.
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Congratulations to CCRP Research Staff
Late this spring, 5 CCRP staff and hospital affiliated coordinators earned the Society of Clinical Research Associates (SOCRA) certification of Certified Clinical Research Professional, increasing the total of CCRP’s staff with this certification to fourteen. The program offers an internationally accepted level of knowledge, education, and experience by which clinical research professionals will be recognized by the medical research community. CCRP applauds these individuals for their hard work and dedication to their patients and cancer clinical research.

Congradulations to: Bobbie Allen, RN (CCRP), Jeremy Fernandez (CCRP), Stacy Kadolak (CCRP), Kent Disney, RN (Exempla Lutheran Medical Center) and Shelley Lewyn (Penrose-St. Francis Health Services)

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.

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<td>A47471042</td>
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SOAPP Trial

SOAPP stands for Symptoms Outcomes and Practices Patterns, and the SOAPP trial is a survey of disease and treatment-related symptoms in patients with invasive cancer of the breast, prostate, lung, or colon/rectum. The clinical trial identification number is E2292. The trial is sponsored by the Eastern Cooperative Oncology Group.

• Purpose: To understand pain management patterns in outpatient oncology patients.

• Participants: More than 3,000 ambulatory patients with invasive cancer of the breast, prostate, lung, or colon/rectum participated in an initial assessment, which was a 25-item measure of pain, functional interference, and other symptoms. They completed a second assessment four to five weeks after the initial assessment.

• Conclusion: Most outpatients with common solid tumors must confront issues related to pain and the use of analgesics. There is significant disparity in pain treatment adequacy, with the odds of undertreatment twice as high for minority patients.

For further information, visit the SOAPP website (www.ecogsoapp. org) or contact ecogsoapp@ecogchair.org.
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Finally, we showed those in attendance the plan that the National Cancer Institute has developed in order to cut approval time by approximately twelve to eighteen months to speed up the process. In addition, some elements of the Community Clinical Oncology Program are undergoing changes and clinical trial designs may change in ways that, while maintaining scientific integrity, will speed up recruitment and the length of time it takes to conduct the trials themselves. In this way, we hope that we will be able to see analysis and results much more quickly than the ten years from initial enrollment to results publication of B-30.

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**Colorado Cancer Research Program (CCRP)**  
**Summer 2012**  
**Issue 19**

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**Connecting Hope and Medical Science**

2253 S. Oneida St., 3rd Floor, Suite B  
Denver, CO 80224-2522  
www.co-cancerresearch.org  
303.777.2063  
888.785.6789

**CCRP is a member of the Community Health Charities.**  
Please consider supporting CCRP in your workplace giving program.

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