



Connecting Hope
and Medical Science

Focus ON THE Search

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

Winter 2010 ■ Issue 11

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What Happens When a Clinical Trial Is Over?

Clinical trial participants are always eager to learn about the results of their clinical trials. Here is a brief summary of how you can follow-up on the results of your trial(s).

- After a phase I or phase II trial, researchers look carefully at the data collected during the trial and decide whether to move on to the next trial with the treatment, or stop testing the treatment because it is not safe or effective
- After a phase III trial, researchers must look at the data and decide if the results have medical importance.
- After all trials, researchers inform the medical community and the public of the trial results. In most cases, the results of trials are published in scientific or medical journals.

To find out if the results of a trial you participated in have been published:

- Ask the doctor or nurse in charge of your treatment.
- Find out the official name of your trial and search for the trial in the PubMed database of medical publications. If you have trouble locating the trial or searching for it, the research librarian at a university or medical library may be able to help.
- Use the NCI Clinical Trials Search Form (<http://www.cancer.gov/clinicaltrials/search>) to search for the trial among the closed protocols listed in the NCI's registry of clinical trials. Go to "Trial Status/Phase"

and click on "Show Search Options." Under "Trial Status," click the button next to "Closed." Thousands of closed protocols have reference citations for published results.

The ClinicalTrials.gov Results Database allows researchers to report summary results of their trials. Each researcher is responsible for ensuring that the information is accurate and complete. To search and find posted results information, use the Advanced Search page and set the Trial Results search field to "Studies With Results." When results are available publicly for a trial, the status column in the "List Results" tab (search results list) is annotated, "Has Results," and the results record tab is labeled, "Trial Results." When results are not available for a trial, the results record tab is labeled, "No Trial Results Posted." Results may not be posted for any of the following reasons:

- The trial is still ongoing
- The trial may not be subject to the Federal results reporting requirements
- The trial is completed, but the deadline for results reporting has not been reached
- The results have been submitted, but have not yet been posted (e.g., pending review by ClinicalTrials.gov)
- Submission of results information has been delayed with certification
- A request for extending the submission deadline has been submitted to NIH

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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 and for people who have been recently diagnosed with cancer.

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 Clinic Oncology Program, one of 50 such programs nationwide.

CCRP's Partner Hospitals

Boulder Community Hospital
Exempla Lutheran Medical Center
Exempla Saint Joseph 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
St. Mary-Corwin Medical Center
St. Mary's Hospital
Sky Ridge Medical Center
Swedish Medical Center

Did You Know....

- CCRP enrolls 300 new patients annually in cancer clinical trials.
- CCRP follows patients post-study for their lifetime, this is now over 2,000 individuals.
- CCRP enrolled over 500 patients on breast and prostate cancer prevention trials.
- CCRP has over 100 cancer clinical trials open, and over 50 actively enrolling patients.
- CCRP partners with over 120 community physicians in Colorado.

Proposed Colorado Legislation: Patients' Costs for Oral Chemotherapy Treatment

The emergence of clinically safe and effective, orally administered anticancer medication has significantly increased the treatment options for cancer patients. However, many barriers currently impede the adoption of orally administered treatment as mainstay cancer therapy.

While intravenously administered anticancer medications are typically covered under a plan's medical benefit (where most patients are only responsible for an office copay), orally administered anticancer medications are typically covered under a plan's pharmacy benefit (where patients are generally responsible for high out-of-pocket coinsurance).

House Bill 1202 will require private health insurance plans to cover the cost of oral chemotherapy at a cost that is affordable to patients. If an oral chemotherapy drug or an anti-nausea drug has an IV equivalent, the oral version of the drug should be covered under the patient's medical benefit rather than their pharmacy benefit. To contact your legislator about this bill visit <http://www.leg.state.co.us/>. At the time of printing, HB 1202 passed the House of Representatives and will now be considered by the Senate.

CCRP 2009 Top Enrolling Sites

CCRP recognizes these research coordinators and the physicians for their dedication to cancer research and cancer clinical trials:



Kaiser Permanente Colorado

Left to right: Michelle Gattshall, Allison Edwards, Tracey Way, Marianne Zbylski, Mabel Peters, Emily Moreno



Penrose Cancer Center at Penrose-St. Francis Health Services

Left to right: Dale Huffner, Cindy Gevara, Martha Brown, Shelley Lowen, Leigh Anne Obluda



The Cancer Center at Exempla Lutheran Medical Center

Left to right: Linda Fiske, Judy Lawler, Kent Disney

CCRP Gets National Recognition

Colorado Cancer Research Program was recently recognized as one of the top accruing sites in the United States to four breast cancer clinical trials sponsored by the National Surgical Adjuvant Breast and Bowel Project (NSABP): B40, B41, B43, and B44. For more information about NSABP, visit www.nsabp.pitt.edu.

Visit the newly revised 2010 Colorado Breast Cancer Resources Directory online at www.breastcancercolorado.org.



This Issue's Featured Clinical Trial

CALGB 10603 (for newly diagnosed acute myeloid leukemia)

- **Purpose:** Drugs used in chemotherapy, such as daunorubicin and cytarabine, work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Midostaurin may help daunorubicin and cytarabine work better by making cancer cells more sensitive to the drugs. Midostaurin also may stop the growth of cancer cells by blocking some of the enzymes needed for cell growth. It is not yet known whether combination chemotherapy is more effective with or without midostaurin in treating acute myeloid leukemia. This randomized phase III trial is studying giving daunorubicin and cytarabine with or without midostaurin followed by high-dose cytarabine and midostaurin to see how well it works in treating patients with newly diagnosed acute myeloid leukemia.
- **Treatment/Intervention:** Patients will be randomly assigned to one of two treatment groups. Patients in group one will receive a 7-day continuous infusion of cytarabine and an infusion of daunorubicin on days 1-3. They will also receive midostaurin by mouth twice a day in weeks 2 and 3. Patients in group two will receive a 7-day continuous infusion of cytarabine and an infusion of daunorubicin on days 1-3. They will also receive a placebo by mouth twice a day in weeks 2 and 3. Patients will undergo bone marrow aspiration in week 3. In week 4, some patients will receive a second course of treatment with cytarabine, daunorubicin, and midostaurin or a placebo. Some patients will then receive a three-hour infusion of high-dose cytarabine every 12 hours on days 1, 3, and 5. They will also receive midostaurin or a placebo by mouth as before. Treatment may repeat every 4 weeks for up to four courses. Beginning at least 2 weeks later, patients may receive midostaurin or a placebo by mouth twice a day for 4 weeks. Treatment may repeat every 4 weeks for up to 1 year.
- After finishing treatment, patients will be evaluated periodically for up to ten years.

Resources

- National Cancer Institute, www.cancer.gov
- American Society of Hematology, www.hematology.org
- Leukemia & Lymphoma Society, www.lls.org
- Cancer and Leukemia Group B, www.calgb.org

Schedule of Spring Trial Participant Advisory Council Meetings

Two TPAC meetings are scheduled for spring 2010. The topic will be focused on Hematologic Cancer Clinical Trials. For more information and to RSVP, please call CCRP at (303) 777-2663.

Colorado Springs

Wednesday, April 14, 2010, 6–8 PM
Penrose Cancer Center
2222 N. Nevada Ave
Conference Rooms A, B & C

Denver

Wednesday, May 5, 2010 6–8 PM
Brooks Conference Center
2253 S. Oneida St. (parking and entrance on west side of building)

What Happens When a Clinical Trial Is Over?

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Results Reporting Requirements

While results information may be submitted for any registered trial, U.S. Public Law 110-85 (Food and Drug Administration Amendments Act of 2007 or FDAAA), Title VIII, Section 801 mandates that a "responsible party" (i.e., the trial sponsor or designated principal investigator) register and report results of certain "applicable clinical trials" not later than one year after the "primary completion date" or date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. The law also allows the NIH to provide an extension of the deadline for submission of results information for an applicable clinical trial.

"Applicable clinical trials" generally include interventional trials of drugs, biological products, or devices that are subject to FDA regulation, meaning that the trial has one or more sites in the U.S, involves a drug, biologic, or device that is manufactured in the U.S. (or its territories), or is conducted under an investigational new drug application (IND) or investigational device exemption (IDE).

Resources for Clinical Trial Results

- ClinicalTrials.gov, <http://clinicaltrials.gov/ct2/info/results>
- National Cancer Institute, www.cancer.gov
- Food & Drug Administration, www.fda.gov
- American Society of Clinical Oncologists (ASCO), www.asco.org
- American Society of Hematology (ASH), www.hematology.org
- San Antonio Breast Cancer Symposium (SABCS), www.sabcs.org

Pamper for Cancer – Aveda Style

Join us for a fun event that leaves you looking and feeling fabulous while supporting CCRP. Enjoy hors d'oeuvres and cocktails while you receive a specially-priced hair cut, and 100% of services and 20% of retail sales benefit cancer research. The **\$35 hair cut** includes a stress-leaving scalp, shoulder and hand massage, as well as a makeup touch-up. Other services may be available.

March 19, 2010

5:00 – 9:00PM

Aveda Academy

1650 Market Street, Denver

SPONSORED BY:

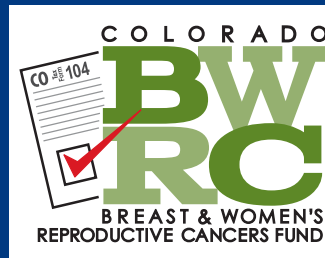


Call 303.777.2663 by March 15 to book and pay for your appointment.

Payments should be made to CCRP. (Sorry, no walk-ins.)

Colorado Breast and Women's Reproductive Cancers Fund (BWRC Fund)

You can make a difference for breast and women's reproductive cancers by selecting the check off fund on your Colorado income tax form. Donations fund a competitive grant program. Grants provide assistance for Coloradans who need help but don't qualify for existing programs and would otherwise "fall through the cracks." All funds stay in Colorado. For more information, visit <http://www.coloradocancercheckoff.org/>.



Drive for a Cure

Benefiting Colorado Cancer Research Program

**4th Annual Drive for a Cure
June 21, 2010 • Valley Country Club**

(303) 777-2663 or
golf@co-cancerresearch.org
for more info.

Vehicles for Charity

Donate your vehicle and support Colorado Cancer Research Program. Call Vehicles for Charity at **1-866-628-CARS** and select Colorado Cancer Research Program as the benefiting organization.



Online Cancer Resources

National Comprehensive Cancer Network: www.nccn.com

A website designed to educate patients with cancer to engage in more informed conversations with health care providers.

American Society of Clinical Oncology: www.asco.org

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

Cancer.Net: www.cancer.net

Provides information about cancer types, treatments, risk factors, genetics and clinical trials.

CancerCare: www.cancercare.org

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

CCRP is eager to provide you with information about topics in which you are interested. Have a topic you want us to cover? Have an event you want to let others know about? Please tell us what you would like to read about in *Focus on the Search* and we'll provide it. Call Todd at 303.777.2663 or e-mail us at ccrp@co-cancerresearch.org.

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