



Connecting Hope  
and Medical Science

# Focus ON THE Search

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

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## Enrolling in a Clinical Trial

Whenever treatment is needed for cancer, clinical trials may be an option. There are pros and cons: **PRO:** If a new treatment is proven to work and you are taking it, you may be among the first to benefit. **CON:** New treatments may have side effects that doctors do not expect or that are worse than those of standard treatment. **PRO:** You have the chance to help others and improve cancer treatment. **CON:** Even if a new treatment has benefits, it may not work for all patients.

General criteria for entering a trial often include:

- Having a certain type or stage of cancer
- Having received a certain kind of therapy in the past
- Being in a certain age group

The National Cancer Institute (NCI), drug companies, medical institutions, and other organizations sponsor clinical trials. NCI maintains the most complete database of clinical trials at [www.cancer.gov/clinicaltrials](http://www.cancer.gov/clinicaltrials). CCRP's website maintains a listing for clinical trials open at CCRP.

### Research Protocol

Every trial has a person in charge, usually a doctor, who is called the principal investigator. The principal investigator prepares a plan for the study, called a protocol, which is like a recipe for conducting a clinical trial.

The protocol explains what the trial will do, how the study will be carried out, and why each part of the study is necessary. It includes information on:

- The reason for doing the study
- Who can join the study
- How many people are needed for the study
- Any drugs they will take, the dose, how often, and side effects
- What medical tests they will have and how often
- What information will be gathered about them

**Coming next issue: Questions to Ask** if you are thinking about taking part in a clinical trial.

## 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.



## What's New from CCRP

### First Trial Participant Advisory Council Meeting a Big Success

Nearly 60 trial participants and family members attended the September 13th initial meeting of the Trial Participant Advisory Council. Additionally, many participants outside the Denver area also expressed interest in joining the council. For participants outside the Denver area, in 2008 CCRP will explore the possibility of forming advisory councils at CCRP affiliate sites.

The next step for the council is to set up work groups. The idea is for work groups to take on specific topics and/or

activities and then for all groups to come together for one or two general meetings per year.

**On Thursday, October 25th, we held a "Volunteer Fair" at CCRP for all who were interested to learn more about the opportunities within the various work groups and to make their selection of a specific work group.** For details, contact Stacy Kadota at 303-777-2663 or skadota@co-cancerresearch.org.

## Understanding Cancer and Cancer Treatment Terms

- Cancer begins in *cells*, the building blocks that form *tissues*. Tissues make up the *organs* of the body.
- Normally, cells grow and divide to form new cells as the body needs them. When cells grow old, they die, and new cells take their place. Sometimes, this orderly process goes wrong. New cells form when the body does not need them, and old cells do not die when they should. These extra cells can form a mass of tissue called a growth or *tumor*. Tumors can be *benign* or *malignant*.
- Most cancers are named for the tissue site where they start. When cancer spreads and forms a new tumor in another part of the body, the new tumor has the same kind of abnormal cells and the same name as the primary tumor. Doctors sometimes call the new tumor "distant" or *metastatic disease*.
- *Neoadjuvant treatment* is radiation and/or chemotherapy given before surgery to shrink tumors so that they can be more completely removed by surgery and prevent the cancer from coming back. *Adjuvant treatment* is radiation and/or chemotherapy given after surgery when there is no obvious disease present, but there is a chance that a small number of cancer cells have already spread.



### Examples of Advances Made by Cancer Clinical Trials

- The Study of Tamoxifen and Raloxifene (STAR) is a clinical trial designed to see how the drug raloxifene (Evista, an osteoporosis drug) compares with the drug tamoxifen (Nolvadex) in reducing the incidence of breast cancer in postmenopausal women who are at increased risk of the disease. One of the largest breast cancer prevention studies ever (with 14,000 participants), STAR took place at more than 500 centers across the United States, Canada, and Puerto Rico. CCRP enrolled 366 women in the STAR study and was one of the top five enrollment sites.
- As a result of this trial, on September 14, 2007, the U.S. Food and Drug Administration approved the use of raloxifene (Evista) for the prevention of invasive breast cancer in certain groups of high-risk women.

## This Issue's Featured Clinical Trial

### E5202 Stage II Colon Cancer

- E5202 is a clinical trial to (1) determine if certain molecular observations identified in some colon cancer cells may be used to help identify patients who are low-risk and would not require chemotherapy after surgery from those at high-risk of having a recurrence and would be more likely to benefit from receiving chemotherapy after surgery, (2) compare the effects of a combination of chemotherapy drugs given with and without a new drug (Avastin) in patients considered to be at high risk for recurrence of cancer, and (3) create a tissue repository that can be used in the future to help identify additional markers that may aid in making more personalized decisions for the treatment of colon cancer.
- Patients with low-risk markers will not receive any further treatment, but will be monitored through regular office visits. Patients with high-risk markers will be randomized to receive post-operative chemotherapy (Avastin).
- The Eastern Cooperative Oncology Group (ECOG) is coordinating this trial. For more information, visit [www.ecog.org](http://www.ecog.org).

### Resources

- Colon Cancer Alliance, [www.ccalliance.org](http://www.ccalliance.org)
- C3: Colorectal Cancer Coalition, [www.fightcolorectalcaner.org](http://www.fightcolorectalcaner.org)
- Colorectal Cancer Network, [www.colorectal-cancer.net](http://www.colorectal-cancer.net)

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