



Connecting Hope  
and Medical Science

# Focus ON THE Search

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

## What's Inside

- History of Clinical Trials
- What's New from CCRP
- What is a Clinical Trial?
- This Issue's Featured Trial
- Examples of Advances Made

## History of Clinical Trials

Clinical trials have evolved over the last 250 years—from initial studies focusing on prevention of communicable disease and nutritional disorders in the 1740s to a current system of trials in many disease areas, involving numerous research institutions and with well-established ethics and guidelines.

- **1937:** Cancer clinical trials were formally inaugurated when President Franklin D. Roosevelt signed the legislation forming the National Cancer Institute (NCI), which mandated funding to support cancer research and training.
- **1955:** NCI began funding Cooperative Oncology Groups (COGs) in an effort to expand enrollment to more locations. COGs are groups of healthcare institutions that combine their resources in order to design and conduct clinical trials.
- **1971:** The National Cancer Act was passed, which expanded the research in oncology and began the war on cancer.
- **1983:** NCI started funding Community Clinical Oncology Programs (CCOPs),

to expand enrollment through community physicians in private practice.

**The Colorado Cancer Research Program (CCRP) is the only NCI-approved Colorado CCOP.** Through the CCOP network, community physicians work with scientists to conduct NCI-supported clinical trials. This collaboration helps to transfer the latest research findings to the community level.

Nationally,

- There are close to 5,000 cancer clinical trials underway in the United States.
- More than 22,000 new patients enter cancer treatment clinical trials each year.

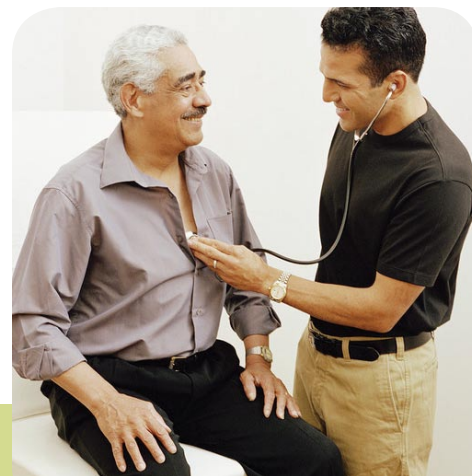
At CCRP,

- Over 100 Colorado community oncologists work through CCRP to enroll patients on NCI-sponsored trials.
- Today nearly 2,000 adults are active on CCRP trials.
- 17 hospitals throughout Colorado partner with CCRP.

## 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

### CCRP needs your help! Join the new Trial Participant Advisory Council.

Please consider joining the CCRP Trial Participant Advisory Council. The CCRP Board of Trustees is forming this new advisory council to bring the knowledge, skills, and perspectives of trial participants to the organization.

The Council will provide advice and recommendations on clinical trial recruitment, community education, what would be useful to know from the trial participant's perspective, and other appropriate items, as they emerge.

Greg DeCuir, CCRP Board member and current clinical trial participant, will chair the Council. Greg formerly worked for

the Metro Operations of the American Cancer Society.

**On September 13, 2007, CCRP will host a dinner and meeting to let you know more about the Trial Participant Advisory Council, why we need you, and the time commitment it will require to be on the advisory council.**

Please RSVP by returning the enclosed card or call 303-777-2663 no later than September 10th. We encourage you to come to the meeting and find out if this is an opportunity that suits you. We hope it does!

## What Is a Clinical Trial?

A clinical trial is one of the final stages of a long and careful cancer research process and the main way to make progress in treating cancer (see graphic below).

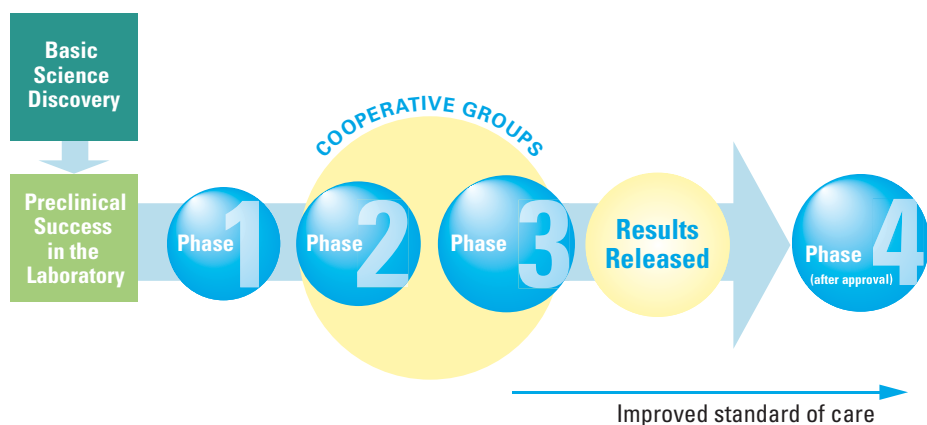
- Doctors perform clinical trials because they believe the drugs or techniques they are testing could be more effective or safer than the standard treatments. They have to show this belief scientifically and beyond a reasonable doubt so that the FDA will consider

approving the drugs/techniques for other people with the same cancers.

- People participate in clinical trials as volunteers to test new methods of prevention, screening, diagnosis, or treatment of a disease. They receive either the best treatment currently known for their cancer, or a new, and possibly more effective, therapy.
- Trials may be carried out in a doctor's office, clinic, or hospital.

### How Cancer Research Moves Into Patient Care

Clinical trials are conducted in a series of phases. Each phase is designed to answer a separate research question. Phase I trials evaluate safety; Phase II trials measure effectiveness; and Phase III trials test against the best existing treatment. In Phase IV trials, new users or long-term effects of the treatment are examined.



Source: Coalition of Cancer Cooperative Groups

### Examples of Advances Made by Cancer Clinical Trials

- A study that demonstrated the value of the drug tamoxifen in reducing the incidence of breast cancer.
- New medications for lung and colorectal cancers that extend survival and improve quality of life.
- A study that established an effective treatment program involving chemotherapy and radiation therapy for early lung cancer.
- Increases in the childhood cancer survival rate. Forty years ago, very few children diagnosed with acute lymphoblastic leukemia survived. Today, nearly all children with this type of blood cancer are treated effectively.

## This Issue's Featured Clinical Trial

### PACCT-1: TAILORx (Trial Assigning Individualized Options for Treatment) for Breast Cancer

TAILORx is a clinical trial of women with early-stage breast cancer to determine which patients with early-stage breast cancer would be more likely to benefit from chemotherapy. By identifying patients with early-stage breast cancer who are unlikely to benefit from chemotherapy, the trial will result in less use of chemotherapy.

- This trial uses a diagnostic test called Oncotype DX Assay to identify women who would most likely require chemotherapy and those whose cancer will most likely respond to hormonal therapy.
- Participants' cancers must be estrogen-receptor and/or progesterone-receptor positive and HER2/neu negative with no spread to lymph nodes and less than one centimeter in size.
- All chemotherapy and hormonal therapy medications used in this trial are commercially available and are not considered experimental.

The Eastern Cooperative Oncology Group (ECOG) is coordinating this trial. For more information, visit [www.ecog.org/general/tailorx.html](http://www.ecog.org/general/tailorx.html).

### Breast Cancer Resources

- Susan G. Komen for the Cure ([www.komen.org](http://www.komen.org)) Colorado affiliates in Aspen, Colorado Springs, Denver, and Greeley.
- 2006–2007 Colorado Breast Cancer Directory — available free of charge at doctors' offices or from the Colorado Cancer Coalition ([www.breastcancercolorado.org](http://www.breastcancercolorado.org), 303-692-2331)
- Y-Me National Breast Cancer Organization ([www.y-me.org](http://www.y-me.org))
- Organization name is BreastCancer.org ([www.breastcancer.org](http://www.breastcancer.org))
- Reader's Digest Health Resources ([www.rd.com/channel/breast-cancer](http://www.rd.com/channel/breast-cancer))

