



NEWSLETTER **Fall 2000**

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Commonly Used Terms in Clinical Trials

Clinical trials: A carefully designed study of the effects of a drug or other treatment carried out on people.

Coordinator: An individual who manages the conduct of the clinical trial.

Consent form: A document that provides key facts about a clinical trial. This includes information about the study agent, tests that study participants may have, and possible benefits and risks. Although all participants in a clinical trial must sign a consent form, they can leave the study at any time. As a trial proceeds, there may be new consent forms.

Control group: In a clinical study, the group that receives either a placebo or a standard treatment that is being compared to the new treatment.

Double-blind: A method used to prevent bias in a clinical trial. Neither the participants nor the doctor knows who is taking the study drug and who is not—only researchers at a central office know.

Food and Drug Administration (FDA): A United States government agency that enforces laws on the manufacture, testing, and use of drugs and medical devices. All drugs and medical devices must be approved by the FDA before they can be used in the general public.

Follow up: Keeping track of the health of people who participate in a clinical study for a period of time during the study and after the study ends.

Informed consent: A process in which a person learns key facts about a clinical trial, including potential risks and

Understanding Clinical Trials of New Cancer Treatments

by Toni Rizzo

In the fast-paced competition of today's cancer drug market, the wonders of promising new drugs sometimes hit the popular media while they are still in the early stages of clinical testing. The public hears these drugs being touted as miracle cures by enthusiastic journalists or news anchors and see cured cancer patients giving testimonials to the drugs' effectiveness. Yet, when someone tries to learn more about these drugs he or she may not know where to start, especially when many experimental drugs have only a few numbers and letters for a name.

There are some new types of drugs that are showing exciting potential to slow or stop cancer growth, but none of these drugs is a cure-all and most are still being tested in clinical trials. New drugs must go through an extensive testing process to make sure they are safe and that they work for the disease they are meant to treat before they are approved for sale. The process can take many years to complete, from the start of the trial to final approval by the Food and Drug Administration (FDA).

It is possible to gain access to new cancer drugs by becoming a participant in a clinical trial, but gathering the necessary information on trials can be difficult and confusing. A basic understanding of how clinical trials work and familiarity with the terms used by doctors and researchers, can help someone who is considering joining a trial make an informed decision.

Phases of Clinical Trials

A clinical trial is a research study that tests a new drug or other treatment in people to determine whether it is safe and effective. Before a drug is tested in humans, years of preclinical experiments are done

benefits, before deciding whether or not to participate in a study. Informed consent continues throughout the trial.

Institutional Review Board (IRB): A group of scientists, doctors, clergy, and consumers at each health care facility that participates in a clinical trial. IRBs are designed to protect study participants. The group reviews and must approve the protocol for every clinical trial, as well as check to see that the trial is well designed, does not involve undue risks, and includes safeguards for patients.

Placebo: A tablet or capsule that looks like the study agent but doesn't contain any active ingredient. Some people call a placebo a "sugar pill." Placebos are rarely used in cancer trials.

Principle Investigator: A medical professional who oversees treatment of the participants in a clinical trial.

Protocol: The plan for a clinical trial. The plan states what the study will do, how, and why. It explains how many people will be in it, who is eligible to participate, what study agents they will take, what tests they will receive and how often, and what information is gathered.

Randomization: A method used to prevent bias in research. People are assigned by chance, often by a computer, either to receive the study agent (intervention group) or not (control group).

Side effect: Any undesired actions or effects of a drug or treatment. Experimental treatments must be tested for both short-term and long-term side effects.

Sponsor: The agency or firm responsible for financing the clinical trial.

Standard treatment: An FDA approved treatment currently in wide use for a particular disease.

Study agent: A drug, vitamin, mineral, food supplement, or a combination of them that is being tested in a clinical trial.

Finding Clinical Trials

Doctors, other healthcare professionals, and cancer support groups can help locate clinical trials for specific types of cancer. There are also internet resources for finding clinical trials and basic information about them:

CancerTrials: Comprehensive information on cancer trials. <http://cancerTrials.nci.nih.gov>

PDQ: Clinical trial search features a search form to look for clinical trials listed in the National Cancer Institute database. <http://cancernet.nci.nih.gov/trials.html>

CenterWatch: Clinical Trials listing service. <http://www.centerwatch.com/BACKGRND.HTM>

Benefits and Risks of Clinical Trials

There are possible benefits and risks of participating in a clinical trial. It is important to weigh these carefully and compare them with the benefits and risks of other treatment options.

Some of the **possible benefits** of taking part in a trial are:

* Access to new drugs or other treatments not available to the public

in the laboratory and in animals. If these tests are successful and the drug looks safe and promising, it is then tested in clinical trials. Clinical trials are normally done in three phases.

Phase I Trial

In Phase I trials, researchers test the safety of a new drug in a small number of healthy people. (Although some participants in phase I studies may have a type of cancer that does not have an "effective treatment," according to the National Cancer Institute web site.) The study is designed to determine how the drug is processed in the human body and what side effects there are at different dosages. Phase I studies usually last several months.

Phase II Trial

Once a drug is shown to be safe it is tested in larger numbers of people to determine its effectiveness and further study its side effects. Phase II studies may enroll up to several hundred people who have the disease the drug is intended to treat. The trials usually last several months to two years.

Phase III Trial

In Phase III trials, the drug is tested in several hundred to several thousand people. The purpose of Phase III trials is to learn more about the drug's effectiveness, side effects, the best dose to give, and the benefits of the drug over current treatments. These studies usually last several years and are often conducted at numerous locations nationwide and sometimes, worldwide. When the third phase of testing is successfully completed, the FDA carefully reviews all the findings from the trial and decides if the drug should be approved for sale.

Phase IV Trial

Phase IV trials, also called post-marketing studies, may be done after a drug is approved for marketing. These studies are done to obtain more information about the drug's safety and effectiveness, to compare it to other drugs on the market, and to study the quality of life of people taking the drug and the drug's cost-effectiveness.

How Clinical Trials are Planned

Clinical trials are usually sponsored by a pharmaceutical or biotech company, a government agency, or a research institution. The sponsor hires doctors to conduct the study. Doctors are usually paid on a per-patient basis. The medical care and treatment are often provided free, but this is not always the case. In some instances, medical insurance plans may pay some of the cost.

* Medical care provided by experts in leading health care facilities

* Close monitoring of treatment effectiveness and side effects

* Contributing to medical research

Some of the **possible risks** of taking part in a trial are:

* Side effects of the treatment that are unknown to the doctors

* Side effects may be worse than those of standard treatments

* The treatment may not work for everyone

* The trial may require more doctor visits, trips to the study site, hospital stays, and other inconveniences

* Health insurers may not pay for costs of experimental treatments not covered by the trial sponsor

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New Arrival at CRCMC Library

by Sara O'Donnell

*The Journey Through Cancer
An Oncologist's Seven-Level Program for
Healing and Transforming the Whole Person
by Jeremy Geffen, M.D., FACP*

This book was written by my former oncologist and good friend Jeremy Geffen. His approach to cancer care is patient centered, which is, unfortunately, a rare find in today's world.

I had the good fortune to have been under the care of Dr. Geffen during my treatment for breast cancer ten years ago. I firmly believe that a large part of my healing was due to the humane and heartfelt way I was treated. My care was delivered with great respect and always, always with love. Jeremy and I sat twice a month, across from each other in a small cubicle at UCSF, readying me for chemotherapy. In these sessions we spoke of our dreams. Mine was to assist others in this journey called cancer, helping them find resources and acting as an advocate for their individual needs. Jeremy's was to start a cancer center where patients could be treated as a partner in their healing, and where the healing that took place was more than just about the drugs they received. Here we both are, a decade later and our dreams are realized! Borrow the book from the CRCMC lending library, read it, and then recommend it to your oncologist.

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Guiding Hand

by Sara O'Donnell

Each trial is headed by a doctor called the principle investigator, who prepares a plan for the study, called a protocol. The protocol explains:

* The reason for the study

* How many people will be included in the study

* Who is eligible for the study

* What treatment will be given to study participants

* What medical tests participants will have

* What information will be gathered

How Participants are Protected

Clinical trials are carried out according to the plan in the protocol. An independent Institutional Review Board made up of doctors, other health care professionals, and community or patient advocates must approve the protocol and monitor every aspect of the study to make sure participants' rights and safety are protected.

Before enrolling in a trial, participants must sign an informed consent form. Informed consent is the process of learning important facts about the trial before deciding whether or not to participate. It is important to carefully read the informed consent form, ask the doctor or nurse any questions about the trial, discuss the information with family or friends, and be sure the information is understood and acceptable before agreeing to participate. The informed consent form should include details about the study plan, what will be done in the trial and for how long, the treatment given in the study, the possible benefits of participating, any possible risks, other available treatments, and the fact that the participant can leave the trial at any time.

What Happens in a Trial

Clinical trials may take place in a medical center, hospital, community clinic, or doctor's office. Participants in a clinical trial work with a team of doctors, nurses, social workers, and other healthcare professionals. Participants are given a complete medical exam and other medical tests to evaluate their health and the status of their disease and to determine their eligibility for the trial. Most Phase II and Phase III trials are randomized. This means that one group of participants will receive the experimental treatment and the other group will receive the standard treatment for the particular type of cancer. A placebo is almost never given in cancer trials for which standard treatments exist. These trials are also usually blinded, meaning that the participants and those on the research team, including the doctor, do not know who is getting the experimental treatment.

On May 28th of this year, we lost our founding board president, Mary Bradish O'Connor, to ovarian cancer, and I lost a friend. Her spirit is with us, but her physical presence at the office and in our lives will be missed for a long time to come.

Almost six years ago, when we were in the planning stages of CRCMC, Mary came to us with a generosity of spirit and commitment to open a resource center that would serve our communities with an open door and an open heart. Mary assisted in the practical aspects of fund raising to ensure that we could keep that door open, all the while reminding us of the emotional commitment to keeping an open heart.

Mary's involvement with CRCMC came from a place of true community spirit. At that point in time, Mary had not been diagnosed with cancer, nor had any of her family members or close friends. Six months after Mary came to us, she was diagnosed with ovarian cancer. Through her own struggle with cancer, she saw how her first-hand experience and individual journey could help others.

Always giving, always teaching, always staying true to her spirit—this was how Mary moved through cancer. She studied treatment options carefully and chose what fit best with her beliefs, embracing both eastern and western treatment options with a remarkable degree of thoughtfulness. Mary participated in our WeCAN! program, acting as a peer advocate for others, as well as facilitating the cancer support group for three years, stepping down from this role only months prior to her death.

As director of CRCMC, I am the one who receives most of the accolades for the Center's accomplishments. But truth be known, if it wasn't for Mary's wisdom and insight we would not have accomplished as much as we have in these last five years. She served as my guiding hand, helping to shape the vision and mission of the Center. Her spirit remains with us, but I miss her daily.

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Mendocino

by Mary Braddish O'Connor

We stood here years ago,
making promises before we had
a clue about love,
the price we pay
for saying yes. Before
we knew, we promised.

Whales swam far out,
blessing us, we thought,
with spouts of wedding lace

Trial participants are monitored carefully and may have more tests and doctor visits than they would if they were not in the study. Participants are expected to follow instructions carefully and stay in contact with the research team. If participants experience serious side effects from the treatment, they may be taken out of the trial to protect their safety.

[Deciding Whether to Participate](#)

People considering participating in a clinical trial should talk about it with their doctors, healthcare providers, cancer support groups, family and friends. They should learn as much as possible about their disease and the effectiveness and risks of available treatments. They should look into the credentials and experience of the facility involved in conducting the study. It might also be helpful to get information about the company sponsoring the study and any competing drugs that are being tested. Although lifesaving drugs are developed by pharmaceutical companies, it is critical to remember that these are profit-making companies and that doctors and research facilities are paid to conduct clinical trials. Most important of all, carefully weigh all your options and seek the advice of healthcare professionals before making a decision.

Toni Rizzo has undergraduate degrees in biology and education, as well as training and certification as a Cytologist (specialist in cancer cellular diagnosis), and an MS degree in communication. She has worked in hospitals for 15 years, including the University of Utah Health Science Center and Medical School where she was supervisor of the Cytopathology Laboratory and Instructor in the Cytopathology Degree Program. For the past 10 years she has been a freelance medical and science writer, with articles published in numerous journals and magazines, including National Geographic World. She also reports on medical conferences, writes continuing education programs, and medical training programs for pharmaceutical companies.

Toni moved to Fort Bragg one year ago from Salt Lake City, Utah. She has one daughter in college and lives with two cats. She considers herself to be a community activist and is particularly interested in healthcare issues, especially in environmental causes of cancer and other diseases.

Clinical Trial information contained in this article can also be found on the National Cancer Institute's Website at <http://cancerTrials.nci.nih.gov>. NCI can be contacted at 1.800.4.CANCER.

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while we toasted them
 from the rocky promontory,
 wild ocean all around.

They're back again (it's March
 again) and so are we,
 without wine and crystal,
 thinner now but just as happy,
 clearer about what a promise
 means. Last week a whale washed
 onto the beach, collapsed into herself
 until the last torn wave of the tail,
 the big eye emptied.

She might have said, except
 we already know (are learning),
 in this tough year, without future,
 without hope, the journey
 is all we have.

*Mendocino is printed with the permission of
 Marty Johnson.*

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Reflection and Celebration

by Sara O'Donnell,
 CRCMC Executive Director

CRCMC is celebrating its fifth anniversary this summer, and with that benchmark in time comes reflection as well as looking ahead to the future. This past year has been busy in terms of the numbers of participants we have served and the new services offered. Our organization has become a central, depended-upon, absolutely essential part of the life of our rural community.

One of the new services offered this year is Medical Consultation Planning, which was developed at Stanford University. CRCMC staff and volunteers received specialized training in communication facilitation and decision making by the developers of Consultation Planning. This has increased the tools that we as advocates have at our command to help patients navigate through the series of complex treatment decisions they face. CRCMC, along with the Humboldt Community Breast Health Project, are the first, and so far only, rural community-based organizations to use this technique.

In the tradition of sharing in the joys and sorrows of our friends and neighbors, we have presented folks with a unique caregiving approach, Share the Care, from the book of the same name by authors Cappy Capossela and Sheila Warnock. Share the Care is a practical team approach to providing care for loved ones.

We have received a grant to implement an educational and direct service program for lymphedema. Lymphedema is an accumulation of lymphatic fluid in the interstitial tissue that causes swelling. Secondary, or acquired lymphedema, can develop as a result of either a mastectomy or lumpectomy for breast cancer, in combination with axillary dissection, and often, radiation therapy. Through this project we are providing a series of educational programs to the medical community and to the community at large. This program will also provide access to physical therapy services to a number of uninsured or underinsured women who have undergone surgery for breast cancer.

We continue to train women to be part of our Women's Cancer Advocacy Network project (WeCAN!) through a training program designed by CRCMC four years ago. In that time, we have trained 115 women to act as advocates in seven Northern California counties. This program was recognized in 1996 as an innovative leader in patient navigation, by the State of California Department of Health Services Cancer Detection Section. Last year we trained 37 women from the far reaches of Humboldt County and Mendocino County, including the Hopland rancheria. We are proud of this program that encompasses the vision of our work, which is to ensure that quality care is equally available to all, regardless of income, and with proper respect for differences of culture, lifestyle and choice.

On the education front, we presented a well-attended public forum on genetically engineered foods, with speakers Dr. Marc Lappé, CRCMC advisory board member, and Britt Bailey. Lappé and Bailey are authors of the book *Against the Grain*. Not only was this an informative and lively presentation, it also brought high school students in to be part of the discussion. In fact, students made up one-third of the audience! We did an extensive outreach to the schools because we want to provide them with hope for their future, as well as our commitment to a cleaner environment and education on issues that directly affect them, such as an untainted food supply.

Currently, we are planning on expanding our services in Ukiah, from a volunteer basis to putting in place a paid staff position. This will be a major endeavor, but at the same time

provides an excellent opportunity to increase the quality and credibility of our present services and offer complete services to the inland section of our county, where two-thirds of the county population resides.

My hope is that someday our work will not be needed, that prevention will be foremost on the minds of research funders, governments and citizens of the world, and that the Precautionary Principle will be in place globally. Until then, there is much work to be done.

Come celebrate CRCMC's fifth year celebration with us on September 23rd; support our efforts with volunteer hours; stop by and visit; attend an educational forum; buy some raffle tickets; tell your friends and neighbors about our services; and come walk in solidarity with us on Big River Road on October 7, with the knowledge that 100 percent of the funds you generate will stay in Mendocino County assisting those in need.

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