



**October 2008: Cancer Clinical Trials – More Funding, Advocacy, & Education  
"Financial Assistance for Clinical Trials Participation"  
by Patrick G. Beatty, MD, PhD; Medical Oncologist, Montana Cancer Specialists;  
President, Montana Cancer Institute Foundation; Missoula, MT**

When investigators are designing clinical trials, and when physicians or physician groups are deciding whether to use a trial, it is important to be certain that not only are the trials medically appropriate, but also that the trial does not put any financial burden on the patient above what the patient would have been responsible for if s/he had not gone on trial.

Thus, clinical trials should not incur any extra expenses beyond expense of standard of care. For instance, if extra tests are required, they are paid for by the trial. If there are extra doctor visits needed, those should be paid for. In Montana particularly, if extra visits are required, many times the patient is reimbursed for travel.

Many clinical trials involve new medications: these are in general provided at no cost.

A patient who is considering entering a trial should address these issues. If the patient recognizes a cost, which the trial does not address, it is possible the investigator / sponsor could find a way to cover that expense.

**October 2008: Cancer Clinical Trials - More Funding, Advocacy, & Education  
"Cancer Prevention Research"  
By Benjamin Marchello, MD, Principal Investigator,  
Montana Cancer Consortium, Billings, MT**

Prevention of cancer is the ultimate goal of Oncology. No matter how effective our research is in perfecting diagnostic and treatment measures, there will always be some failures, as well as side effects and expenses for those who are cured. Not having cancer in the first place would be far better. Unfortunately, we are limited by our imperfect knowledge of the cause of cancer. We also are limited by the fact that we must "treat" many perfectly healthy people to prevent cancer in the few that would ultimately have developed the disease.

The most benign prevention strategy would be lifestyle change, but that would require cooperation of all individuals to make a difference. Stopping tobacco use would be a big step forward, but the users have to want to quit (it is a slow process.) Exercise is great but it would only reduce the cancer burden a little and is not possible for everyone. Diet change would be great if we knew the perfect diet! Then, of course, we have to tell everyone what to follow those recommendations and hope they do it. The research of lifestyle change is daunting. We would have to get thousands of people who feel fine to eat or do or give up what we tell them with no cheating/forgetting/giving up.

Preventive treatments have made some advances. Squamous cell carcinoma of the cervix can now be prevented by vaccination; however we have very few known virus connections with cancer that can be treated this way. There have been two large breast cancer prevention trials showing that high risk women can reduce their cancer risk by half with tamoxifen or raloxifene. That still is short of 100% protection for all women. There have also been two large prostate cancer prevention studies. The completed one shows significant reduction in high risk men with finasteride, but far from complete protection.

There are other ideas for prevention, but new studies are slow to develop. Treating healthy people means only minimal side effects can be tolerated. Also since in healthy people only a few cancers occur every year tens of thousands of people must participate to see any benefit. The National Cancer Institute currently feels this research is too expensive. Our hope lies in scientists finding new leads and in new funding opportunities appearing, which is a challenge in the current political and economic environment. That said, the future is prevention!

**October 2008: Cancer Clinical Trials – More Funding, Advocacy, & Education**  
**"How to Locate Relevant Clinical Trials"**  
**By Amanda R. Dinsdale, CCRC, Program Coordinator,**  
**Montana Cancer Consortium**

There are a number of ways to find information about participating in a clinical trial. The best first step is to consult with your physician. Ask your physician "Are there clinical trials that might be right for me?" Many physicians have a resource library or print information on clinical trials available in their office. Take the time to tour the resource library and review the available information.

There are a number of clinical trials websites you can search to find clinical trials available in your area. Cancer centers, clinics and hospitals often have websites where they list available clinical trials. Before you begin your search, identify what type of clinical trial you are looking for; treatment, symptom management, or prevention. When searching for a clinical trial it is good to know your medical history and disease name and stage so you can better search based on eligibility criteria. Depending on the questions the research is trying to answer, each clinical trial protocol clearly states who can or cannot participate in the trial. These guidelines are in place to ensure patient safety and accurate and meaningful study results. Common qualifications for entering a clinical trial include having a certain type and stage of cancer, having been previously treated with a certain kind(s) of therapy, general health status, and being in a certain age group.

When searching on the internet it is hard to know if you are viewing credible information. A useful tool for identifying credible web sites is Health on the Net (HON) Foundation. If you see this symbol on a website you know that that site has been identified as safe and credible. Health on the Net is the leading organization promoting and guiding the deployment of



useful and reliable online medical and health information, and its appropriate and efficient use. Created in 1995, HON is a non-profit, non-governmental organization, accredited to the Economic and Social Council of the United Nations.

When considering participation in a clinical trial it is important for you to ask questions and fully understand what is involved in the trial. Some clinical trials, particularly prevention trials, require a long term commitment from the participants. It is important for you to evaluate this time line and determine if it is a commitment you are willing to make. Once enrolled on a clinical trial, regardless of the type, it is very important for you to inform each of your physicians of your involvement. Keeping all of your healthcare providers on the same page helps to ensure your medical safety and produces better clinical trial compliance and ultimately better clinical trial results.

Listed below are a few web sites that have proven to be helpful when searching for clinical trials.

Web site: [www.cancer.gov/clinicaltrials](http://www.cancer.gov/clinicaltrials)

Information from the National Cancer Institute on how to find cancer clinical trials, what clinical trials are, recent research, and resources for researchers.

Web site: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

ClinicalTrials.gov provides regularly updated information about federally and privately supported clinical research in human volunteers. ClinicalTrials.gov gives information about a trial's purpose, who may participate, locations, and phone numbers for more details. The information provided on ClinicalTrials.gov should be used in conjunction with advice from health care professionals.

Web site: [www.emergingmed.com](http://www.emergingmed.com)

Provides a clinical trial matching and referral service for cancer patients.

Web site: [www.mtcancer.org](http://www.mtcancer.org)

Montana Cancer Consortium is a nonprofit organization whose mission is to bring state-of-the-art cancer treatment and prevention to Montana and Northern Wyoming through clinical trials sponsored by the National Cancer Institute.

Web site: [www.trialcheck.org](http://www.trialcheck.org)

A cancer clinical trial search engine brought to you by the Coalition of Cancer Cooperative Groups.



## **October 2008: Cancer Clinical Trials – More Funding, Advocacy, & Education "Clinical Trial Advocacy"**

**By James M. Burke, MD, Director of Clinical  
Research, Billings Clinic Cancer Center, Billings, MT**

In an era of ever shrinking dollars for medicine in general, cancer clinical trials are not immune. The two main sources for clinical trials are NCI (National Cancer Institute - federal government) and industry / Pharma (private funding). The private sector implementation of clinical trials is dictated by the investment atmosphere and fluctuates with the economy (and indirectly via public policy). NCI based trials reflect ever changing funding levels as allocated by congress. However, of late, the greatest change to clinical trial access has been the insurance industry. In an effort to squeeze more and more dollars from coverage, companies have begun to demonstrate a disturbing trend – denying coverage for clinical trials. Unlike Medicare which allows and covers clinical trial participation (for the time being anyway), private insurers can arbitrarily place barriers between patients and clinical trials. Although some legislation does exist on the state level to require clinical trials (about half the states) the federal government has no such requirements. Further, most state legislation does not affect small co-ops or collective insurance that is backed by so called re insurers. These insurers are not subject to state laws, but only federal law (they fall under the ERISA provisions). Unfortunately, most patients have no idea what their insurance will or won't cover at the time of diagnosis – and why would they? Who anticipates the need for participation in a clinical trial? The person answering the phone at the insurer's office may not know either. That "stream of consciousness" aside, what can you do to advocate for more clinical trial coverage?

- 1-lobby your federal representatives to back legislation that will be generally applicable to all states and eliminate loopholes to state mandates
- 2-review your insurance policy and question your insurer if "experimental" or "clinical trial" therapy is denied.
- 3-monitor Medicare legislation and protest any restrictions on clinical trial participation that may be proposed
- 4-back NCI proposals for new clinical trial funding
- 5-educate your friends and neighbors to the above as they come up; Number 2 can be done immediately.

Before the recent banking / economy crash a bill was before congress to boost clinical trials in cancer (see below- Access to Clinical Trials Act – sample letter to your rep). The bill has been "back burnered" for the moment but may resurface. I urge you all to review the basics of the legislation and contact your congressional reps.



*Reason: Access to Cancer Clinical Trials Act of 2008 (S. 2999 or HR 2676)*

*Dear Senator / Congressman X:*

*I am writing in support of the Access to Clinical Trials Act (S 2999 / HR 2676). As you know, cancer affects all of us –directly or indirectly. Although treatment is improving, many of the most common cancers remain incurable. Over the last several years, new treatments have made a huge impact on the prognosis for those diagnosed with this terrible disease. Clinical trials have played an essential role in advancing these new therapeutics. Unfortunately, the average drug requires approximately 10 years and 1 billion dollars in development costs before FDA approval. Only 2-3% of those diagnosed with cancer participate in clinical trials, thus increased participation in clinical trials may reduce the timeline to FDA drug approval. From a more immediate perspective, clinical trials provide access to the latest therapeutics before FDA approval – allowing those with incurable diseases access to potentially active interventions. Over the last several years, with a greater understanding of cancer biology, more and more of the drugs introduced to the clinic have shown anti-neoplastic activity, heightening the need for earlier patient access.*

*Although many states now mandate access to clinical trials, ERISA provides a loophole through which many insurers escape state jurisdiction. Only by changing federal law and closing the loophole in ERISA can access to clinical trials truly become equitable. The Access to Clinical Trials Act seeks to increase access to clinical trials by changing ERISA thus allowing clinical trials to move forward at a much faster rate and allowing more patients (who may not have 10 years to wait for FDA approval) access to potentially active drugs.*

*The insurance lobby will attempt to squash this legislation in the name of cost containment. Please take note that the Institute of Medicine and other academic institutions have studied the cost of participating in clinical trials compared to patients receiving standard care off trial (not participating in clinical trials). In the aggregate, these studies show no significant difference in cost. In many cases, the insurance industry stands to decrease costs for cancer care based on trial designs that provide free drug to patients on study. Most insurers that fall under ERISA would rather stay the course, refusing to acknowledge the body of evidence accumulated in regards to cost and clinical trials, and continue business as usual. Business as usual is not an acceptable response to the millions diagnosed each year with cancer. We must commit on a societal level to support progress towards curing this devastating disease.*

*Sincerely,  
(Your name)*



**October 2008: Cancer Clinical Trials – More Funding, Advocacy, & Education  
"Third Party Payers – Part 2"**

**by Grant W. Harrer, MD, Co-Principal Investigator of the Montana Cancer Consortium and Medical Director of the Sletten Cancer Institute, Great Falls, MT**

My September Forum essay discussed Cancer Clinical Trials as related to Third Party Payers. This month's essay continues that discussion. Remember that there are three parties at the proverbial table when healthcare costs are the issue ... the patient (the first party), the provider (the second party), and the payer (the third party). The third party payers include not only private insurance companies, but also certain government organizations, e.g., Medicare.

Required reading should be: [www.cms.hhs.gov/ClinicalTrialPolicies](http://www.cms.hhs.gov/ClinicalTrialPolicies) which provides the following summary of the Medicare policies on clinical trials with the associated links to the relevant documents (I have underlined the points I feel are especially important):

"Clinical trials are research studies designed to evaluate the safety and effectiveness of medical care. They are key to understanding the appropriate use of medical interventions of all types and informing payers about what services to cover. Only a very small percentage of American seniors participate in clinical trials, although the elderly bear a disproportionate burden of disease in the United States.

On June 7, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health and Human Services to "explicitly authorize [Medicare] payment for routine patient care costs...and costs due to medical complications associated with participation in clinical trials." The Health Care Financing Administration (now the Centers for Medicare & Medicaid Services, or CMS) responded to the executive order with the clinical trial policy national coverage determination (NCD) issued on September 19, 2000. The 2000 policy may be found through the link below labeled, "2000 Clinical Trial Policy".

CMS began a reconsideration of that 2000 NCD to address several issues about the policy on July 10, 2006. We issued a final decision memorandum on July 9, 2007 that preserves the status quo of the 2000 CTP with the exception of the following changes:

1. Clarification that items that are covered outside the trial are covered inside the trial
2. Addition of Coverage with Evidence Development (CED)

On July 19, 2007, CMS began a reconsideration of the 2000 CTP which proposes that the CTP be renamed the Clinical Research Policy and that a process be established that clinical research study sponsors/principal investigators must use to certify to CMS that their study meets the scientific and technical standards described in the proposed policy.

Based on a thorough review and consideration of comments from the public and the recent enactment of the Food and Drug Administration Amendments Act of 2007 (FDA AA 2007), the

313 West Mendenhall  
P.O. Box 6446  
Bozeman, Montana 59771



Phone: 406-587-8080  
Fax: 406-556-1050  
[www.CancerFamilyNetwork.org](http://www.CancerFamilyNetwork.org)

Agency decided that no change to the July 9, 2007 policy was appropriate at the time. On October 17, 2007, CMS closed the reconsideration with a final decision memorandum that retained the July 9, 2007 policy."

One of the main underpinnings of this policy is that participation in clinical trials generally does not cost more than standard medical care. In fact, by providing closer monitoring of both effectiveness and side-effects, money can be saved by detecting side-effects earlier than would otherwise be recognized, discontinuing the use of interventions that are not working, and identifying patients most likely to respond to a given treatment.

Private health insurance companies such as BCBS typically follow similar policies. Some companies do not, out of ignorance, lack of foresight, or greed.

In many spheres of health care, insurance companies have used Medicare as the gold standard for developing their own policies ... I believe that insurance company clinical trial policy should take Medicare's lead as well. We need a federal mandate for clinical trials coverage ... the template is provided here and already available to those with Medicare coverage!

**Audience: please send us some tough questions!!! This series of essays has now come to a close, but feel free to contact any/all of us on these issues in the future.**