

Finding Clinical Trials

A report on www.clinicaltrials.gov

I just experienced the frustration of trying to find clinical trials for a friend with recurrent colon cancer. We have all known patients who spent precious time and energy trying to find clinical trials on the internet. Even after an exhaustive search, they are never sure they have found all the trials available because there is no one place to find all the trials that are open and enrolling patients. In 1997 Congress required the Department of Health and Human Services (DHHS) Secretary to "establish a publicly accessible data bank of information about clinical trials for serious and life threatening disease and conditions." This law was enacted seven years ago but the database is still not comprehensive.

The first version of the databank, www.clinicaltrials.gov, was made public in early 2000 and contained mostly trials sponsored by the National Institutes of Health (NIH). Industry trials were the next step. The Food and Drug Administration (FDA) has provided guidance to industry including the information they should submit, the location of sites where the trials are open and enrolling patients and a contact person to provide information to people interested in participating in the trial. The FDA's Office of Special Health Issues presented a report on industry compliance at a recent FDA Science Forum. Forty-eight percent of industry's trials were in the www.clinicaltrials.gov databank. The report also contained concerns about the accuracy and completeness of the information industry provided to the databank.

If we want to increase accrual to cancer trials, having information in a central database is one step in getting the necessary information to potential participants. There is a need for advocates to demand enforcement of the law that requires all clinical trials for serious and life-threatening conditions be listed on the www.clinicaltrials.gov web site. Some advocates concerned about this problem have sent letters to Lester Crawford, Acting Commissioner for the FDA, questioning why he is not enforcing this legislation he is tasked with implementing. This issue is an agenda item for one of the workgroups at the Summit Series on Clinical Trials to be held on September 30th and October 1st outside of DC. We will update you on any new strategies that may come out of these discussions. --- *Contributed by Mary Lou Smith*

Research Advocacy Network mission:

To develop a network of advocates and researchers who can influence medical research from concept to patient care through education, support and collaborations.

Opportunity to Participate in RAN Research Initiative

Advocates in Action

RAN is introducing a web-based Communications training program soon. An advocate's best tool is to be able to communicate effectively. The Communications module is designed to help advocates have more confidence and purposeful in their communications with researchers. The module includes communication theory and simulates a meeting with researchers and advocates discussing a clinical trial. In conjunction with this initiative, RAN is sponsoring research to measure the efficacy of this program. Specifically, the study will identify and measure the barriers that may prevent knowledge transfer and how a "Best Practice" intervention may improve that transfer. RAN will use the research findings for future educational programs.

If you are interested in becoming a participant in this research, more information is available on the RAN website: <http://www.researchadvocacy.org>

Advocate SkillBuilders

EARLY STOPPING RULES

Early stopping rules or discontinuation guidelines are part of careful monitoring of clinical trials. Careful monitoring lets the researchers and sponsor learn about difficulties early and diminish the effect and minimize recurrences. Each clinical trial must have a protocol specifying how the trial will be conducted. The protocol establishes the "stopping rule" or outcome differences that must be seen between the treatment groups during an interim analysis causing the trial to be ended early. The size of difference depends upon the power, sample size and confidence. The early stopping rules look at harm, benefit and recruitment failure. Trials may be stopped early because:

- there is clear evidence of harm or harmful side-effects of the treatment
- there is no likelihood of demonstrated treatment benefit
- there is overwhelming evidence of the benefits of the treatment

Stopping rules can prevent over-reaction to random highs or lows in response or adverse event rates. Stopping rules by themselves are not enough to terminate a trial. The statistical computation must be taken in the context of new information, inaccuracy in assumptions and the limitations of any rule. The Data Safety Monitoring Board (DSMB) uses sample size and statistical power considerations to detect a clinically meaningful difference in safety and/or efficacy between the treatment arms and make a decision whether to stop a trial early. Statistical calculations are used to make these determinations. Interim analysis is timed based on the number of patients involved and the events observed. Significance levels are determined using a number of methods. These methods include O'Brien Fleming, Haybittle-Peto, Pocock, Boniferrani. The method should be stated in the protocol.

For more information on Clinical Trial Monitoring see the Advocate SkillBuilder series at <http://www.researchadvocacy.org>.

Calendar-What is Research Advocacy Network Doing?

September 2004

Sun	Mon	Tue	Wed	Thu	Fri	Sat
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

October 2004

Sun	Mon	Tue	Wed	Thu	Fri	Sat
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
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Network News

Network News is being sent to you as a courtesy. If you would like to discontinue receiving this publication, please send an email message to info@researchadvocacy.org and type "UNSUBSCRIBE" in the subject line. The newsletter is currently published 10 times /yr and includes articles on advocacy, research results and activities.

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Research Advocacy Network Activities

- **September 10**—Trainers—St. Louis Affiliate Susan G. Komen Breast Cancer Foundation Research Advocate Workshop, St. Louis, MO
- **September 12**—Northwestern University Town Hall Meeting, Chicago, IL
- **September 28-30**—North Central Cancer Treatment Group
- **September 30-October 1**—Workgroup Leaders at the Summit on Clinical Trials, Washington, DC
- **October 5**—Trainer at the Pennsylvania Breast Cancer Coalition Keystone Breast Cancer Conference Scientific Training
- **October 16**—Presentation at Columbus Affiliate of The Susan G. Komen Breast Cancer Foundation
- **October 20-24**—Facilitators for Lymph Science Advocacy Program (LSAP), National Lymphedema Network Conference, Reno, NV
- **October 28-31**—Public Responsibility in Medicine Conference
- **October 28-31**—Lynn Sage Breast Cancer Conference, Chicago, IL

**Research Advocacy
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- Advocate SkillBuilders
- Advocate Opportunities
- Fact Sheet Series: What It Means For Me
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Our mission: To develop a network of advocates and researchers who can influence medical research from concept to patient care through education, support and collaborations.

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