

# Research/Clinical Trials

By Suzanne Lee, M.D., Patient Advocate, Center for Patient Partnerships

## 1. Doing research for a patient on a medical topic

a. **For cancer**—go right to National Cancer Institute website [www.cancer.gov](http://www.cancer.gov). Familiarize yourself with this site, there is an unbelievable amount of information here. You can also talk to a live person at 1-800-4-CANCER.

- Choose: type of cancer
- Choose: treatment—professional version. This will give you general information about the current standard treatment as well as links to useful articles.

b. **Surf the web**—there are good sites and there is a ton of junk. Check out associations for specific diseases--many are patient friendly and also have links to scientific data. See our resource list for recommended sites.

c. **Do a literature search**—[www.library.wisc.edu](http://www.library.wisc.edu)

-Choose: E-resource Gateway: Article Databases and More

-Enter: Pubmed

-PubMed is my favorite (Medline is another good choice). How effective your search will be is highly dependant on your input.

- For a specific author i.e. Peter G. Pryde, MD, you must enter the name in this format: pryde pg
- For a topic—start specific ie “treatment for stage 4 pulmonary hemangiopericytoma”. If you don’t get much broaden to “hemangiopericytoma” and even further to “soft tissue sarcoma” (ask Suzanne for advice). Every article will also have links to related articles.
- Find out who has published in your area of question—this may be a good future referral if the patient has a rare condition.
- Look for cutting edge research—published recently, different from standard therapy.
- Remember—these will be peer-reviewed articles, different from what you might find on google (which is a good place to start if you have no clue what something means). BUT, we are looking for scientifically proven research, not someone’s opinion.
- Follow links to full-article (sometimes these are not available on line, but can be ordered and sent to our library) and scan cited references for more useful info. Xerox useful articles for patient’s file or to send patient if appropriate.
- Do not get discouraged, this can be a very time consuming process, the answer will usually not jump out at you—keep looking, you are sometimes trying to find that needle in a haystack.

## 2. Be careful not to give medical advice

You can pass on information you found in your literature search along with a disclaimer such as, *“I found this interesting article out of Stanford, just published this year, showing promising results using a monoclonal antibody for your type of cancer. This sounds different from the treatment choices you have been offered. You could be eligible for this type of treatment. If you are interested, I could get you a copy of the article and you could run it by your doctor to see if you would be a good candidate.”*

### 3. Clinical Trials

When a patient has failed to respond to conventional therapy, or if the patient is undergoing conventional therapy and is wondering what the future holds, or if the patient cannot tolerate the side effects, or weighing the benefits/risks does not want conventional therapy, it is time to offer to help look into clinical trials.

- **First listen to the patient**—what do they want? Are they willing to go to the ends of the earth to find anything offering any glimmer of hope? Are they tired and sick and not wanting to travel, but if there happened to be a trial at their local Comprehensive Cancer Center using a therapy with no side effects they might consider it? Likely, they sit somewhere in between. We need to be careful not to project our values onto our patients.
- **University of Wisconsin Comprehensive Cancer Center**—[www.cancer.wisc.edu](http://www.cancer.wisc.edu)  
Select: Clinical Trial  
Select: UWCCC clinical trials listing. These are ordered by type of cancer.  
Phase 1's have there own section.
- **National Cancer Institute**—[www.cancer.gov](http://www.cancer.gov) is the most comprehensive site for trials.  
Select: Clinical Trials at the top of home page.  
Select: cancer type, stage, etc. and location  
Trials are ordered by phase (highest to lowest)  
Click on any underlined word: a pop up box will give you a definition (in case you don't know what kind of drug TC-18665 is or what an angiogenesis inhibitor is.  
Go to professional version, which is more detailed, but won't have underlined words.
- **Familiarize yourself with the different phases:**

**Phase I**: The first step in testing a new treatment in humans. These studies test the best way to give a new treatment (for example, by mouth, intravenous infusion, or injection) and the best dose. The dose is usually increased a little at a time in order to find the highest dose that does not cause harmful side effects. Because little is known about the possible risks and benefits of the treatments being tested, phase I trials usually include only a small number of patients who have not been helped by other treatments.

**Phase II**: A study to test whether a new treatment has an anticancer effect (for example, whether it shrinks a tumor or improves blood test results) and whether it works against a certain type of cancer.

**Phase III**: A study to compare the results of people taking a new treatment with the results of people taking the standard treatment (for example, which group has better survival rates or fewer side effects). In most cases, studies move into phase III only after a treatment seems to work in phases I and II.

**Phase IV:** After a treatment has been approved and is being marketed, it is studied in a phase IV trial to evaluate side effects that were not apparent in the phase III trial.

*Your search should be driven by the patient's desires in terms of phase, type of treatment, location, etc. For example, if your patient just wants some time off of chemotherapy, ignore the gobs of studies looking at various combinations of traditional chemo. Look for something different i.e. monoclonal antibodies, vaccines, interleukins, interferons and other biological therapies which stimulate the immune system or slow tumor growth or inhibit blood supply to tumors. There is no magic to this, go through each listing one at a time.*

- **Eligibility criteria:** If something looks promising and you have questions about your patient's eligibility, you can contact the center doing the trial with the patient's consent. If you don't have consent yet, you can still ask general questions. Eligibility criteria are published on the websites, but final acceptance into a study is at the discretion of the investigators. The eligibility criteria are often very detailed and confusing. The patient's doctor may get involved at this point. I frequently recommend the patient be seen at a Comprehensive Cancer Center (see below).
- **Medical records:** Patient's who are considering clinical trials should have a copy of their entire medical record. This will be required as will further testing and likely a visit to the center doing the trial if the patient is considered a good candidate.
- **Reporting your results to the patient:**

**Always review the results with me (Suzanne) before reporting your results to the patient.**

I frequently give the patient some options, then start a dialog. Some patients take the ball and run, some designate a friend or family member to make contact with the potential trial sites, other will want us to be more involved. Remember that clinical trials are works in progress and depending on the phase, may not be scientifically proven to be effective at all, or if effective, not necessarily better than standard therapy. Within a given phase we have no idea how effective one therapy would be over another, unless there are preliminary results published (check out pubmed). **Make sure you explain this to the patient.**

- **Caution!** *Keep in mind that the patient's status and the status of the trials are continuously changing. You may have found some fantastic trials, but the patient's condition may have rapidly worsened and he/she is no longer eligible, or the patient may have died. The trial sites are not always current. Many times you call the investigator and find that the trial is full, has moved to another stage with a new set of eligibility criteria, or has closed down due to toxicity. **Make sure you explain this to the patient.***

#### 4. Comprehensive Cancer Centers

These are the sites around the country affiliated with the NCI where the trials take place.

- For a listing based on location: [www.cancer.gov/cancercenters/centerslist.html](http://www.cancer.gov/cancercenters/centerslist.html)
- **Second opinions:** For patients living in rural communities with limited medical options, these are a great resource in terms of expert opinions, social services, support groups, etc. Patients can get a one time expert opinion and receive the bulk of their care at home with continued consultation from the CCC if appropriate. Patients with HMO's or PPO's with no in-network CCC coverage may be allowed to visit a CCC for an expert opinion and/or various levels of treatment.
- Because the CCC's are involved in clinical trials, they can help assess eligibility criteria as well as expedite a referral to a trial in another location.

#### 5. Alternative Therapies

You will be asked all sorts of questions about alternative therapies. Some of these may be helpful to a patient's healing, others dangerous and expensive.

- Check out [www.quackwatch.org](http://www.quackwatch.org) to see if a specific practitioner or therapy has been identified as being quackish. If I can't find anything too outlandish about a given therapy, and it seems harmless, I tell patients that they should run it by their physician to make sure it isn't contraindicated with current treatment.
- **Complementary and Alternative Medicine:** Often patients want to know about alternative treatments they can take instead of or in combination with conventional therapy. This is a good opportunity to educate a patient about evidence-based medicine (ie how therapies are studied, and shown to be effective for given conditions). Some alternative therapies have gone through the same rigorous testing as conventional therapies, and been proven effective for given conditions. Many times there is no proven conventional therapy for a given condition and CAM is a good option. CAM can also be used in conjunction with conventional therapy to help boost the immune system and/or limit side effects. The N.I.H. now has a CAM branch with many on-going trials, and lots of information on their website: [www.nccam.nih.gov](http://www.nccam.nih.gov)
- **CAM practitioners:** Many patients are already under the care of a CAM practitioner. We can also make referrals.