

12 - EXPERIMENTAL, CLINICAL TRIALS

A clinical trial is a formal research project which is designed to answer defined questions about some aspect of medicine - usually a diagnostic technique or a therapy. A few of these research studies deal with health and physical improvement; but most deal with medical problems. These trials are conducted by government agencies, by universities, by pharmaceutical companies, by Health Maintenance Organizations, and, sometimes, by private physicians. Although direct governmental approval is not required in the U.S., the government has established guidelines for clinical trials, and they must be approved and monitored by a recognized "Institutional Review Board". The objective of such oversight is to help insure that the research has scientific merit, that the risk of damaging a participant is minimized, and, if there is possible damage, then the potential benefit is worth it. The common notion that one must be terminal before being admitted to an experiment is wrong. Indeed, end-stage medical situation usually do not qualify. Nor is it true that conventional treatment must have failed before participating in a clinical trail. Frequently, conventional and experimental modalities can be administered concurrently.

Although a patient may enroll in a clinical trial without the approval of one's primary physician, some kind of concurrence is advisable. If organized properly, there can be synergy between the two. However, you can assume that the patient or facilitator will have to do most of the ground work and coordination because treating physicians are usually not very interested in experimental treatments. If interested in what a clinical trial may have to offer, you will have already done the research in **Sections 1-4** and may have some idea about which clinical trials are



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being conducted; but you will need to refine your retrievals with the search commands which follow. If dealing with a cancer, then you will have already done the research in **Section 11** and have downloaded the clinical trials that are being conducted on the particular cancer of interest by the National Cancer Institute.

An essential site is the one which is dedicated specifically to clinical trials and is maintained by the National Institutes of Health. [<http://clinicaltrials.gov>]

The screenshot shows the ClinicalTrials.gov website. At the top, the logo "ClinicalTrials.gov" is displayed in a large, blue, serif font. Below it, the text reads "A service of the National Institutes of Health" and "Developed by the National Library of Medicine". To the right of the logo are three small images: a woman looking at a computer, a group of people in a clinical setting, and a man in a white coat. Below the images is the tagline "Linking Patients to". A navigation bar contains links for "Home", "Search", "Browse", "Resources", "Help", and "What's New". The main content area starts with a paragraph: "The U.S. National Institutes of Health, through its National Library of Medicine, has current information about clinical trials for patients, family members and members of the public. You may want to learn more about clinical trials and more about this Web site. Check often: ClinicalTrials.gov." Below this is a section titled "Search Clinical Trials" with a sub-header "Enter words or phrases, separated by commas:". There is a search input field, a "Search" button, and a "Tips" link. Further down, there are sections for "Search by Specific Information" (with a link to "Focused Search"), "Browse" (with links for "Browse by Condition" and "Browse by Sponsor"), and "Resource Information" (with links for "Understanding Clinical Trials", "MEDLINEplus", "NIH Health Information", and "healthfinder").

The “**Search**” function is standard; and for explanatory information, go to the sector “**Understanding Clinical Trials**”. There will be several monographs which are worthwhile printing and making a part of your files.

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The particular monograph, "What is a Clinical Trial?", covers the following issues:

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|---|--|
| <p>What is a clinical trial?
 What is a protocol?
 What are clinical trial phases?
 What protections are there for people who participate in clinical trials?
 What is informed consent?
 Who can participate in a clinical trial?
 Who sponsors clinical trials?
 What happens during a clinical trial?
 What is a placebo?
 What is a control or control group?</p> | <p>What is a blinded or masked study?
 What is a double-blind or double-masked study?
 What are side effects and adverse reactions?
 What are the benefits and risks associated with clinical trials?
 What should I know before I join a clinical trial?
 How should I prepare for the meeting with the research coordinator or doctor?
 What questions should I ask?
 Can I leave a clinical trial after it has begun?
 Will I be paid for participating in a clinical trial?
 Should I continue working with my primary health care provider if I participate in a trial?</p> |
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Before, after, or concurrent with the above procedures, go back into MEDLINE [<http://www.ncbi.nlm.nih.gov/PubMed>] and do the following retrievals as described in Section 3.

11 - RESEARCHING EXPERIMENTAL CLINICAL TRIALS	
SEARCH ROUTINES	THE KIND OF INFORMATION WHICH IS RETRIEVED
<div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">disease or therapy [MeSH]</div> <p style="text-align: center; margin: 0;">AND</p> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">Clinical Protocols</div>	<p>Clinical Protocols - Precise and detailed plans for the study of a medical or biomedical problem and/or plans for a regimen of therapy.</p>
<div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">disease or therapy [MeSH]</div> <p style="text-align: center; margin: 0;">AND</p> <div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;">Clinical Trials</div>	<p>Clinical Trials - controlled study designed to assess the safety and efficacy of new drugs, devices, treatments, or preventive measures in humans by comparing two or more interventions or regimens; prefer specific phase NTs.</p>

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11 - RESEARCHING EXPERIMENTAL CLINICAL TRIALS

SEARCH ROUTINES

THE KIND OF INFORMATION WHICH IS RETRIEVED

disease or therapy [MeSH]

AND

**Clinical Trial, Phase I
[Publication Type]**

Clinical Trial, Phase I [Publication Type] - clinical trials performed in a small number of subjects to assess the metabolism and pharmacokinetics of drugs and to evaluate safety of drugs, devices, diagnostics or techniques.

disease or therapy [MeSH]

AND

**Clinical Trial, Phase II
[Publication Type]**

Clinical Trial, Phase II [Publication Type] - A pre-planned, usually controlled, clinical study of the safety and efficacy of diagnostic, therapeutic, or prophylactic drugs, devices, or techniques based on several hundred volunteers, including a limited number of patients, and conducted over a period of about two years in either the United States or a foreign country.

disease or therapy [MeSH]

AND

**Clinical Trial, Phase III
[Publication Type]**

Clinical Trial, Phase III [Publication Type] - A pre-planned, usually controlled, clinical study of the safety and efficacy of diagnostic, therapeutic, or prophylactic drugs, devices, or techniques after phase II trials. A large enough group of patients is studied and closely monitored by physicians for adverse response to long-term exposure, over a period of about three years in either the United States or a foreign country.

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SELECTING AND ENROLLING IN A CLINICAL TRIAL

If a person has a serious medical problem and is under therapeutic management by a physician, then it is unlikely that one would enroll in a clinical trial without, at least, the acquiescence of one's primary physician. Hopefully, one has an innovative doctor who will not feel compromised by experimental therapies and research physicians being involved in your case and who will objectively consider whether or not a particular modality might be useful to you, in particular. The situation is, however, not necessarily a straight-forward matter of what is appropriate science and in the patients best interest, and expect to have to do some negotiation and diplomacy. If you are the patient, present the reports from the above research to your physician or, vice versa, to the patient if you are the physician. Decide the modalities of interest. From that point forward, it is best that your physician contact personally the principal investigator of the clinical trail, explain you patient profile, and, from there, determine you eligibility. Although it is appropriate that the physician make the contact, there is nothing wrong or impolite by the patient doing so. Frequently, experimental trials are multi-centered and there may be a participating facility close to you. And in some cases, your physician can become an investigator. Frequently, it is difficult to find the principal investigator; however, if you have a MEDLINE citation, the field entitled "**Author Affiliation**" (as below) is the address of the lead author of the article and that person either is or can identify the principal investigator.

Main Heading Fields	Example of the Data Entered
TITLE:	Treatment options in androgen-independent prostate cancer.
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