



IFPMA

International Federation of Pharmaceutical
Manufacturers & Associations

Frequently Asked Questions

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1. IFPMA CLINICAL TRIALS PORTAL

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Q: Why is the pharmaceutical industry developing a portal for searching information on clinical trials?

The pharmaceutical industry recognizes that a broader access to clinical trial information can be of significant benefit to patients as well as to the medical community in that it can help to facilitate medical decisions about potential therapies. In a [joint EFPIA/IFPMA/JPMA/PhRMA position on the disclosure of clinical trial information via clinical trial registries and databases](#) that industry issued in January 2005, it committed to make information available on ongoing clinical trials (Clinical Trials Registries) as well as on results of clinical trials (Clinical Trials Results Databases). By providing a single user-friendly entry site, the IFPMA portal aims to facilitate patients' and doctors' searches for comprehensive information on clinical trials.

Q: What information can I find by use of the portal?

The new internet search portal establishes links to IFPMA member

company websites as well as other commercial and government-sponsored websites containing information on clinical trials provided by pharmaceutical companies. Firstly, the portal can be used to search the mentioned websites for information on newly initiated clinical trials that are performed to determine the therapeutic benefit of a given medicinal product. Here, patients (in conjunction with their healthcare providers) will find as well information on how to enquire about enrolling in the ongoing trial they are interested in. Secondly, the portal enables the user to find results of clinical trials conducted on medicinal products that have been approved for marketing. Industry committed to disclose these results in a non-promotional summary, regardless of the trial outcome.

Q: How does the portal work?

The portal gives the possibility to either search the available Clinical Trials Registries or the Clinical Trials Results Databases. Entering a search text, e.g. the name of a medicinal product or the term for a disease like 'cancer' or 'hypertension' will start the portal search engine which will then collect and display the sought information available on the websites that are connected to it.

Q: How can I print out my search results?

You will find that if you print your search results in Landscape format they will be more readable. In Internet Explorer you can do this by clicking on 'File' (in the top left-hand corner of your browser), then 'Print'; select the button called 'Preferences' and check the radio button marked 'Landscape', then select 'OK' and 'Print'.

2. CLINICAL TRIALS

The following frequently asked questions are important in understanding the unique process of clinical trials.

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Q: What is a clinical trial?

A clinical trial is a research study to answer specific questions about a new medical treatment (medicine/drug, medical device, new therapies, vaccines), or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether such new treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people.

Q: Why participate in a clinical trial?

Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research.

Q: Where do the ideas for trials come from?

Ideas for clinical trials usually come from researchers. After researchers test new therapies or procedures in the laboratory and in animal studies (preclinical studies), the treatments with the most promising laboratory results progress into clinical trials. By conducting clinical trials, more and more information is gained

about a new treatment, its risks and how well it may or may not work.

Q: Who sponsors clinical trials and where are they conducted?

Clinical trials are sponsored or funded by a variety of organizations or individuals such as physicians, medical institutions, foundations, voluntary groups, and pharmaceutical companies. Trials can take place in a variety of locations, such as hospitals, universities, doctors' offices, or community clinics.

Q: What is a protocol?

A protocol is a study plan specific to each clinical trial. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

Q: What is a placebo?

A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or treatment.

Q: What is a control or control group?

A control is the standard by which experimental treatments are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.

Q: What are the different types of clinical trials?

Interventional trials (also called **treatment trials**) determine whether new treatments, new combination of drugs, new ways of

using known therapies or new approaches to surgery or radiation therapy are safe and effective. These trials might ask a participant to take an experimental new drug or undergo surgery.

Prevention trials look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals, or lifestyle changes.

Observational trials address health issues in large groups of people. Trial participants may be asked to answer questions about their family histories or give blood samples, but they do not receive treatment for their diseases.

Screening trials test the best way to detect certain diseases or health conditions.

Quality of Life trials (or **Supportive Care trials**) explore ways to improve comfort and the quality of life for individuals with a chronic illness.

Q: What are the phases of clinical trials?

Clinical trials are conducted in phases. The trials at each phase have a different purpose and help scientists answer different questions:

Phase I (Most typical kind of study: *Human Pharmacology*):

Phase I starts with the initial administration of an investigational new drug into humans.

Although human pharmacology studies are typically identified with Phase I, they may also be indicated at other points in the development sequence. Studies in this phase of development usually have non-therapeutic objectives and may be conducted in healthy volunteer subjects or certain types of patients, e.g. patients with mild hypertension. Drugs with significant potential toxicity, e.g. cytotoxic drugs, are usually studied in patients. Studies in this phase can be open, baseline controlled or may use randomisation and blinding, to improve the validity of observations.

Studies conducted in Phase I typically involve one or a combination of the following aspects:

- a) Estimation of Initial Safety and Tolerability
- b) Pharmacokinetics
- c) Assessment of Pharmacodynamics
- d) Early Measurement of Drug Activity

Phase II (Most typical kind of study: *Therapeutic Exploratory*):

Phase II is usually considered to start with the initiation of studies

in which the primary objective is to explore therapeutic efficacy in patients. Initial therapeutic exploratory studies may use a variety of study designs, including concurrent controls and comparisons with baseline status. Subsequent trials are usually randomised and concurrently controlled to evaluate the efficacy of the drug and its safety for a particular therapeutic indication. Studies in Phase II are typically conducted in a group of patients who are selected by relatively narrow criteria, leading to a relatively homogeneous population and are closely monitored.

An important goal for this phase is to determine the dose(s) and regimen for Phase III trials. Early studies in this phase often utilise dose escalation designs to give an early estimate of dose response and later studies may confirm the dose response relationship for the indication in question by using recognised parallel dose-response designs (could also be deferred to phase III).

Confirmatory dose response studies may be conducted in Phase II or left for Phase III. Doses used in Phase II are usually but not always less than the highest doses used in Phase I. Additional objectives of clinical trials conducted in Phase II may include evaluation of potential study endpoints, therapeutic regimens (including concomitant medications) and target populations (e.g., mild versus severe disease) for further study in Phase II or III. These objectives may be served by exploratory analyses, examining subsets of data and by including multiple endpoints in trials.

Phase III (Most typical kind of study: *Therapeutic Confirmatory / Hypothesis-testing*):

Phase III usually is considered to begin with the initiation of studies in which the primary objective is to demonstrate, or confirm therapeutic benefit.

Studies in Phase III are designed to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication and recipient population. These studies are intended to provide an adequate basis for marketing approval. Studies in Phase III may also further explore the dose-response relationship, or explore the drug's use in wider populations, in different stages of disease, or in combination with another drug. For drugs intended to be administered for long periods, trials involving extended exposure to the drug are ordinarily conducted in Phase III, although they may be started in Phase II. These studies carried out in Phase III complete the information needed to support adequate instructions for use of the drug (official product information).

Phase IV (Variety of Studies: - *Therapeutic Use*)

Phase IV begins after drug approval. Therapeutic use studies go beyond the prior demonstration of the drug's safety, efficacy and dose definition.

Studies in Phase IV are all studies (other than routine surveillance) performed after drug approval and related to the approved indication. They are studies that were not considered necessary for approval but are often important for optimising the drug's use. They may be of any type but should have valid scientific objectives. Commonly conducted studies include additional drug-drug interaction, dose-response or safety studies and studies designed to support use under the approved indication, e.g. mortality/morbidity studies, epidemiological studies.

3. PARTICIPATION IN A CLINICAL TRIAL

For those considering participation in a clinical trial, the following frequently asked questions are important in understanding the role of the participant and the unique process of a clinical trial.

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Q: Who can participate in a clinical trial?

All clinical trials have rules about who can participate. Using inclusion/exclusion criteria is an important principle of medical research that helps to produce reliable results. The factors that allow someone to participate in a clinical trial are called "inclusion criteria" and those that disallow someone from participating are called "exclusion criteria". These criteria are based on such factors

as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy participants. It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe. The criteria help ensure that researchers will be able to answer the questions they plan to study.

Q: What happens during a clinical trial?

The clinical trial process depends on the kind of trial being conducted (See [What are the different types of clinical trials?](#)) The clinical trial team includes doctors and nurses and possibly social workers and other health care professionals. They check the health of the participant at the beginning of the trial, give specific instructions for participating in the trial, monitor the participant carefully during the trial, and stay in touch as appropriate after the trial is completed. Some clinical trials involve more tests and doctor visits than the participant would normally have during routine treatment for an illness or condition. For all types of trials, the participant is in contact with a research team. Clinical trial participation is most successful when the protocol is carefully followed and there is regular contact with the research staff according to the defined schedule.

Q: What is informed consent?

Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study. The research team also provides an informed consent document that includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. In case the participant is unable to sign due to illiteracy, the oral consent of the participant must be witnessed and the informed consent document signed and dated by a literate and disinterested person. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

Q: What kind of preparation should a potential participant make for the meeting with the research coordinator or doctor?

- Plan ahead and write down possible questions to ask.
- Ask a friend or relative to come along for support and to hear the responses to the questions.
- Bring a tape recorder to record the discussion to replay later.

Q: What should people consider before participating in a trial?

People should know as much as possible about the clinical trial and feel comfortable asking the members of the health care team questions about it, the care expected while in a trial, and any cost implications of the trial. The following questions might be helpful for the participant to discuss with the health care team. Some of the answers to these questions are found in the informed consent document.

- What is the purpose of the study?
- Who is going to be in the study?
- Why do researchers believe the new treatment being tested may be effective? Has it been tested before?
- What kinds of tests and treatments are involved?
- How do the possible risks, side effects, and benefits in the study compare with my current treatment?
- How might this trial affect my daily life?
- How long will the trial last?
- Will hospitalization be required?
- Who will pay for the treatment?
- Will I be reimbursed for other expenses?
- What type of long-term follow up care is part of this study?
- How will I know that the treatment is working? Will results of the trials be provided to me?
- Who will be in charge of my care?

Q: Does a participant stay in contact with a primary health care provider while in a trial?

Yes. Most clinical trials provide short-term treatments related to a designated illness or condition, but do not provide extended or

complete primary health care. In addition, with the primary health care provider being in contact with the research team, the participant can ensure that other medications or treatments will not conflict with the protocol.

Q: What are side effects and adverse reactions?

Side effects are any undesired actions or effects of drug or treatment. Negative or adverse effects vary from treatment to treatment but may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental treatments must be evaluated for both immediate and long-term side effects.

Q: What are the potential benefits and risks of participating in a clinical trial?

Benefits

Clinical trials that are well-designed and well-executed are the best treatment approach for eligible participants to:

- Play an active role in their own health care. Gain access to new research treatments before they are widely available.
- Obtain expert medical care at leading health care facilities during the trial.
- Help others by contributing to medical research.

Risks

There are potential risks to participating in a clinical trial.

- There may be unpleasant, serious or even life-threatening side effects to treatment.
- The treatment may not be effective for the participant.
- The protocol may require more of their time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.

Q: How is the safety of the participant protected?

The ethical and legal codes that govern medical practice also apply to clinical trials. In addition, most clinical research is regulated by

the authorities with built-in safeguards to protect the participants. The trial follows a carefully controlled protocol, a study plan which details what researchers will do in the study. As a clinical trial progresses, researchers report the results of the trial at scientific meetings, to medical journals, and to various government agencies. Individual participants' names will remain secret and will not be mentioned in these reports.

Every clinical trial must be approved and monitored by an Ethics Committee (called Institutional Review Board (IRB) in the U.S. or Independent Ethics Committee (IEC) in the EU) to make sure the risks are as low as possible and are worth any potential benefits. An Ethics Committee is an independent committee of physicians, statisticians, community advocates (lay persons), and other suitably qualified experts that ensures that a clinical trial is ethical and the rights of study participants are protected.

Q: Can a participant leave a clinical trial after it has begun?

Yes. A participant can leave a clinical trial, at any time. When withdrawing from the trial, the participant should let the research team know about it, and the reasons for leaving the study.

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INTRODUCTION: Definition of Informed Consent

You may already have experience with signing consent forms for other kinds of medical procedures, such as surgery, or for cancer treatments such as radiation or chemotherapy. However, informed consent for a clinical trial involves much more than just reading and

signing a piece of paper. Rather, it involves two essential parts: a process and a document.

The informed consent document provides a summary of the clinical trial (including its purpose, the treatment procedures and schedule, potential risks and benefits, alternatives to participation, etc.) and explains your rights as a participant. It is designed to begin the informed consent process, which consists of conversations between you and the research team. If you then decide to enter the trial, you give your official consent by signing the document. You will receive a copy and should use it as an information resource throughout the course of the trial.

The informed consent process provides you with ongoing explanations that will help you make educated decisions about whether to begin or continue participating in a trial. Researchers and health professionals know that a written document alone may not ensure that you fully understand what participation means. Therefore, before you make your decision, the research team will discuss with you the trial's purpose, procedures, risks and potential benefits, and your rights as a participant. If you decide to participate, the team will continue to update you on any new information that may affect your situation. Before, during, and even after the trial, you will have the opportunity to ask questions and raise concerns. Thus, informed consent is an ongoing, interactive process, rather than a one-time information session.

SAFEGUARDS: Informed Consent and the Larger System of Protections

Informed consent for clinical trials is just one part of a larger system in place to safeguard people who want to help researchers evaluate new practices that may improve treatment, supportive care, screening, and prevention, while perhaps benefiting from these new methods. This system ensures that clinical trials are conducted ethically, without undue risk to participants. Some of the resources that contribute to this system of protections are described below.

HISTORY

The History of Informed Consent and the System of Protections

Over the past half-century, the international medical communities have taken numerous steps to protect people who take part in clinical research. The following timeline provides an overview of some of the key events that have contributed to the development of

the current system.

1947 - The Nuremberg Code

Developed in response to the Nuremberg Trials of Nazi doctors who performed unethical experimentation during World War II, the Code was the first major international document to provide guidelines on research ethics. It made voluntary consent a requirement in clinical research studies, emphasizing that consent can be voluntary only if:

- participants are able to consent;
- they are free from coercion (i.e., outside pressure); and
- they comprehend the risks and benefits involved.

The Code also states that researchers should minimize risk and harm, make sure that risks do not significantly outweigh potential benefits, use appropriate study designs, and guarantee participants' freedom to withdraw at any time. The Nuremberg Code was adopted by the United Nations General Assembly in 1948.

1964 - Declaration of Helsinki

At the 18th World Medical Assembly in Helsinki, Finland, the World Medical Association adopted 12 principles to guide physicians on ethical considerations related to biomedical research. It emphasizes the distinction between medical care that directly benefits the patient and research that may or may not provide direct benefit. These guidelines were revised at subsequent meetings in 1975 (Tokyo, Japan), 1983 (Venice, Italy), 1989 (Hong Kong), 1996 (Somerset West, Republic of South Africa) and 2000 (Edinburgh, Scotland) and notes for clarification were added in 2002 (Washington) and 2004 (Tokyo).

1996 - ICH Guideline on Good Clinical Practice

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. ICH guidelines aim to harmonize differences in the drug development processes in these three major pharmaceutical regions. Many other countries like Australia, Canada and the EFTA states have subsequently adopted these recommendations.

In this guideline ICH states the principles and practices concerning protection of clinical trial subjects.

WHAT TO EXPECT

While the informed consent process varies among different research institutions and clinical centers, you generally should expect the following:

- **An initial meeting** during which a member (or members) of the research team provides you with the informed consent document and explains its content to you. This discussion may also include your specialist and primary care doctor, as well as a nurse, social worker, patient representative, and/or staff psychologist. You may wish to bring along a family member or friend for support, and to help you keep track of the information presented. This information should be given logically and at a comfortable pace, with plenty of time allowed for you to consider it and ask questions. You may be given a video, audiotape, or even an interactive computer program to help you better understand the information in the consent document.

If your child (e.g., under age 18) is the one who will participate in the clinical trial, you will go through this process on his or her behalf. More and more frequently, children over the age of 6 are being asked to give their "assent" to participation as well. If this is the case, you will be asked to give permission for your child to take part in the assent process. During this process, a child or teenager is provided with a form that explains, in concrete and age-appropriate terms, the purpose of the research, what they will be asked to do, and what procedures they will undergo. Usually, a nurse or other health professional also explains the information and gives the child a chance to ask questions. Then they are asked to indicate their assent either by signing the form or making a mark in a specific place.

- **Time to digest the information.** It can be very difficult to absorb this information in one sitting, especially at a time of emotional distress. You should be given a copy of the document so that you can take it home, review it as many times as you need, and discuss it with family, friends, social workers, clergy, a patient representative, or other trusted advisors.
- **Assessment of your understanding.** The research team should take some steps to ensure that you comprehend the information, either by having you fill out a questionnaire, asking you questions orally, or having you explain certain aspects of the trial in your own words. You also should alert team members to anything you do not understand. If you find



that the document is written in words that are too difficult for you, don't hesitate to let them know that.

- **Opportunities to ask questions.** Both during the initial meeting and in follow-up discussion(s), you should be given the chance to ask questions and raise concerns. Keep asking questions until you have all the information you need to make your decision.
- **Continuing updates on new information.** As the trial proceeds, the research team may discover new information that could affect your health, welfare, or willingness to remain in the study. They will share this with you and may ask you to sign a new informed consent document. Of course, you are free to leave the study if this information leads you to have doubts about continuing to participate.

WHAT WILL I FIND IN THE INFORMED CONSENT DOCUMENT?

While informed consent documents do vary from place to place, they should communicate all of the information described below in language that you can understand, with some help from the research team (if needed). The information covered should include:

Purpose [Why is this clinical trial being done?]

In this section, researchers explain why they are conducting the trial. Their reasons will depend on the type of disease and the trial type (i.e., whether they are investigating new prevention, screening, supportive care, or treatment methods). Researchers conduct treatment trials either because they have not found an effective treatment for a certain type of disease, or they are not sure which treatment method works best.

Description of Procedures [What is involved in the trial?]

This section describes the procedures that you will undergo, how frequently you will have them, and where they will take place (at home, in the hospital or clinical center, or in an outpatient setting). For treatment trials, this section should include:

- procedures that are part of regular disease care and may be done even if you do not join the trial;

- standard procedures being done because you are in the trial; and
- procedures that are being tested or evaluated by the trial.

If this is a "randomized" trial, then you will be assigned at random (by computer) into one of two or more study groups. People in the different groups will receive different treatments or treatment combinations, so that researchers can evaluate which is most effective. If this is the case, the document should make clear what procedures each group will undergo. It should also indicate what your chances are of being placed in any one group.

Duration [How long will I be in the trial?]

This section indicates how long the trial will last and whether it involves follow-up, and if so, for how long. It also includes information about any circumstances under which the researcher might remove you from the trial (for example, if your condition worsens or new information indicates you shouldn't continue). The document should make clear that you have the right to stop participating at any time, and it should describe any possible medical consequences of sudden withdrawal.

Risks [What are the potential risks of the trial?]

This section includes the foreseeable physical and nonphysical risks of participating in the trial. A nonphysical risk might be time away from work, while physical risks might include side effects such as nausea, vomiting, pain, or susceptibility to infection, among others. The document should indicate the likelihood of these risks occurring, how serious they may be, and whether they are more likely to be short-term (last only during the trial or shortly afterward) or long-term (last weeks, months, or even years after the trial is over). The document should make clear which risks are related to the investigational aspects of the trial. It also should include specific information about reproductive risks (Could participating make you infertile? Should you not get pregnant or father a child while on the trial? Can you nurse a child during the trial?).

Benefits [Are there benefits to taking part?]

The document describes any benefits to you or to others which may reasonably be expected. A trial may or may not involve direct medical benefits to you, but it might lead to new knowledge that can help others in the future.

Alternatives to Participation [What are my options if I don't participate?]

For treatment trials, this section describes what care options you have besides participating in the trial, such as other commonly-used therapies or no treatment at all.

Confidentiality

This statement tells you the extent to which your information will be kept confidential. It should inform you about any groups or organizations that may have access to your records for quality assurance and data analysis (e.g. the trial sponsor).

Costs / Additional Expenses [What are the costs?]

This section indicates whether participating in the trial will result in added costs to you or your insurance company. It also covers other cost issues, such as who will pay for emergency medical treatment in case of injury or illness, whether you will have to pay for drugs that become commercially available during the trial (if this is a drug trial), and whether or not you will receive payment for participating.

Participants' Rights [What are my rights as a participant?]

The document should specify that:

- your participation is voluntary;
- you can choose not to take part or leave at any time without penalty or loss of benefits; and
- any new information that might affect your participation will be shared with you.

Contact Information [Whom do I call if I have questions or problems?]

You should have a contact name and phone number (usually of a member of the research team) for getting answers to questions about the study or a research-related injury. You also should be given a phone number for the Ethics Committee or a patient representative, in case you have questions about your rights as a research participant.

Supplemental Information [Where can I get more information?]

This section lists additional resources that may prove useful as you make your decision, such as informational booklets, community organizations, and Web resources.

The Signature

Your dated signature represents your legal consent to participate in the trial. In case of illiteracy of the participant, researchers need to pay special attention that the trial information they give is understood by the participant and a literate and disinterested person must witness the oral consent of the participant and sign the document on behalf of the participant. If any of these sections appears to be incomplete or missing from the informed consent document, don't hesitate to ask for the information.

OTHER USEFUL TIPS

- Keep a copy of the informed consent document as a helpful resource for the duration of the trial. Ask for a copy if one isn't offered to you. You may also request a copy of the protocol (full study plan).
- According to Good Clinical Practice principles, no informed consent document may include any language that asks or appears to ask you to waive your legal rights, or that releases or appears to release the investigator, the sponsor, or the institution from liability for negligence.
- If you cannot understand the forms you are signing, don't be afraid to let someone know that you are having trouble. If you have difficulties reading the document at first, try not to get upset. Many people feel anxious about reading and signing

documents and communicating with physicians. Just take your time and ask for help when you need it.

MORE INFORMATION: Resources for Understanding Informed Consent

You may find that the informed consent process and conversations with your medical team are sufficient in helping you arrive at a decision. Or you may wish to gather more outside information before making up your mind. Other good sources of information include:

- local hospitals
- Ethics Committees
- patient advocacy and support groups
- library and Internet research.

Keep in mind that everyone's information needs are different. You should do whatever makes you feel most comfortable as you make this important decision.

*Source: based on clinicaltrials.gov, cancer.gov and ich.org
FAQ dated 20 July 2005*