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AND ALTERNATIVE MEDICINE - USA

CLINICAL TRIALS: WHAT CANCER PATIENTS NEED TO KNOW



AIMaC
INFORMA PER AIUTARE
A VIVERE CON IL CANCRO

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Clinical trials: what cancer patients need to know

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Preface

Most people know little or nothing about clinical trials, their purpose, how to find them, and how they are carried out. This lack of knowledge may be why cancer patients do not join clinical trials and why doctors do not offer them as a treatment option.

A survey of 6000 adult cancer patients in the United States found that 85% of them did not know about clinical trials or were not sure that participating in them was a treatment choice for them. But 75% said that if they had known, they would have wanted to enter one. The reasons why patients did not take part in a trial included: they believed the 'new' treatment might be less effective than the treatment they were currently receiving, they were afraid they might receive a placebo, and they feared being treated as a 'guinea pig.'

On the other hand, patients who had taken part in clinical trials were very satisfied: 97% stated that they had been treated with great respect and that the treatment they received had been 'good' or 'excellent.' While they feared they might be 'guinea pigs,' the truth is that the treatment they received was the best available and under closer scrutiny than treatment patients normally receive.

Most of today's most effective standard treatments for cancer are based on previous clinical trials. Because of previous trials, many patients are living longer. In addition, post-operative care has improved, and the side effects of chemotherapy, which are often frightening for patients and their families, are fewer and can be better controlled.

This booklet gives information to help you decide if you wish to take part in a cancer clinical trial. It tells about the importance of trials, how they are carried out, and describes the rights and protections for patients.

Introduction

The results of cross-national clinical trials are important for all cancer patients throughout the world. The international conference Clinical trials: what cancer patients need to know (Rome, 20 April 2007) was organized within the framework of a project jointly promoted by Italy's National Institute of Health and AIMaC. The aim of the project is to develop new ways and means for providing information about clinical trials. The conference was attended by the foremost institutions engaged in the study and delivery of cancer treatment, such as the Italian Drug Agency (AIFA), the European Medicines Agency (EMA), the National Institutes of Health (NIH) of the U.S. Government and the World Health Organization (WHO), which contributed to the preparation of this booklet. The project is part of the cooperation set up among the NIH and ISS, envisaged in the Memorandum of Agreement signed by the U.S. Department of Health and Human Services and the Italian Ministry of Health.

Francesco De Lorenzo

Chairman

Italian Association for Cancer Patients, their families and friends – AIMaC

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Department of Therapeutic Research and Medicine Evaluation
Italian National Institute of Health

This booklet is for people with cancer, their families, and others who care about them.

It is divided into four sections, each answering one of the major questions patients and their families have about clinical trials:

1. What are clinical trials?
2. How are they carried out? How can I participate?
3. Should I take part in a clinical trial?
4. How can I get information about trials?

The first two sections provide background information on the important role clinical trials play in improving cancer care. The third helps you understand the advantages and disadvantages involved in taking part in a clinical trial. It describes your rights as a patient and protections that ensure your safety. Finally, part four offers ways to get access to ongoing treatment studies.

Part one

What are clinical trials?

Clinical trials are research studies that test new treatments in people with cancer. Research for new treatments begins in a laboratory, where scientists develop and test new ideas. If the approach seems promising, it may be tested in animals to see how it affects cancer in a living being and whether there are harmful effects. It is only after a long period of testing in the laboratory that a new treatment will be studied in cancer patients to see if it is safe and effective. A clinical trial is the final stage of a long, careful cancer research process, whose goal is to find better ways to treat cancer, extend patients' lives, and improve quality of life.



Besides new drugs, clinical trials also test new approaches to surgery or radiation therapy, and new combinations of treatments.

Types of Clinical Trials

Clinical trials have different goals ranging from prevention to diagnosis to treatment:

- **studies on prevention:** are aimed at seeing how life-style, diet, medicine, vitamins, and other practices may prevent people from getting cancer or lower their chances of getting it;
- **studies on screening methods and early diagnosis :** identify clinical and laboratory tests that help cancer to be found earlier in individuals who appear to be healthy;
- **diagnostic studies:** aim at making procedures more efficient and precise in identifying the disease and in monitoring it over time;
- **genetic studies:** aim at identifying genes associated with cancer and developing treatments to correct the defects of the gene (gene therapy);
- **treatment studies:** identify whether and in what ways new drugs, or biological, surgical, and radiological procedures can be used to make cancer treatment more effective;
- **palliative care studies:** address how to treat side effects, reduce physical effects, and provide social and psychological support for cancer patients.



There are different types of clinical trials.

This booklet focuses mainly on the clinical trials that test cancer treatments.

Why are clinical trials important?



Standard treatment: validated treatment deemed to be the best available cancer treatment.



Clinical trials are important for the development of new cancer treatments.



Cervix: the neck of the uterus.

Side effects: negative effects of the drugs also attack healthy cells. They cannot be separated from the benefits.

Quadrantectomy: surgical removal of a portion of the breast tissue (usually a quadrant, hence its name) together with a margin of surrounding healthy tissue.

Clinical trials contribute to our knowledge and progress against cancer. They transfer the results of biomedical research to clinical practice, that is to the treatment of patients. The most modern and most effective treatments now being used in treating cancer, called **standard treatment**, are based on previous study results.

Patients who take part in clinical trials get up-to-date care from cancer experts. They receive either a new treatment that is being tested or the best available standard treatment for their cancer. Of course, there is no guarantee that either the new treatment or the standard treatment will produce good results. New treatments may also have unknown risks. But if a new treatment proves effective or more effective than standard treatment, patients who have entered the study will be the first to benefit.

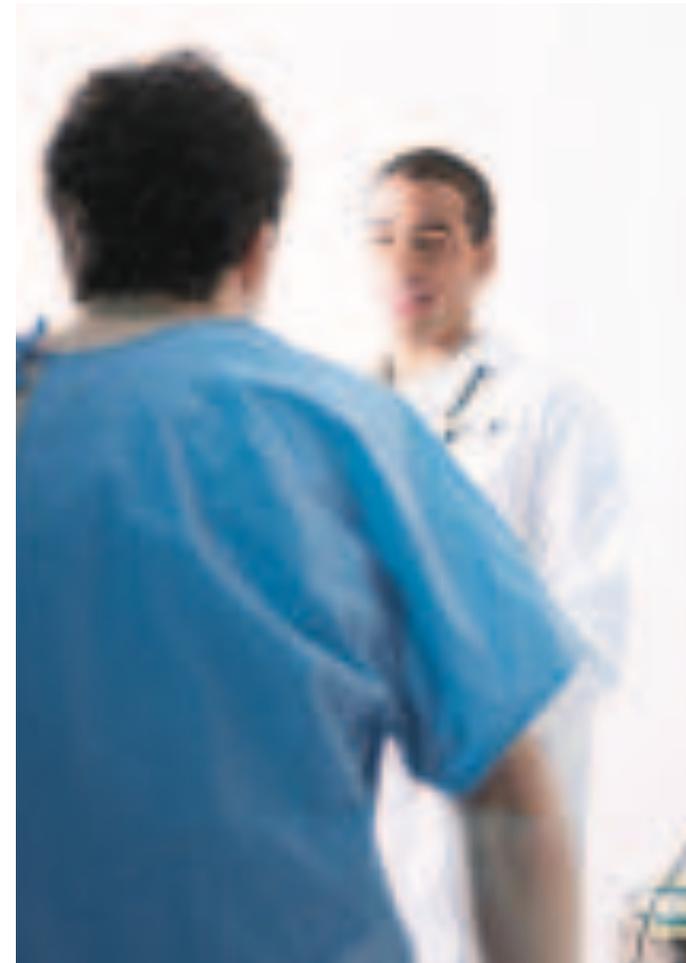
Progress in cancer treatment has been achieved through clinical trials

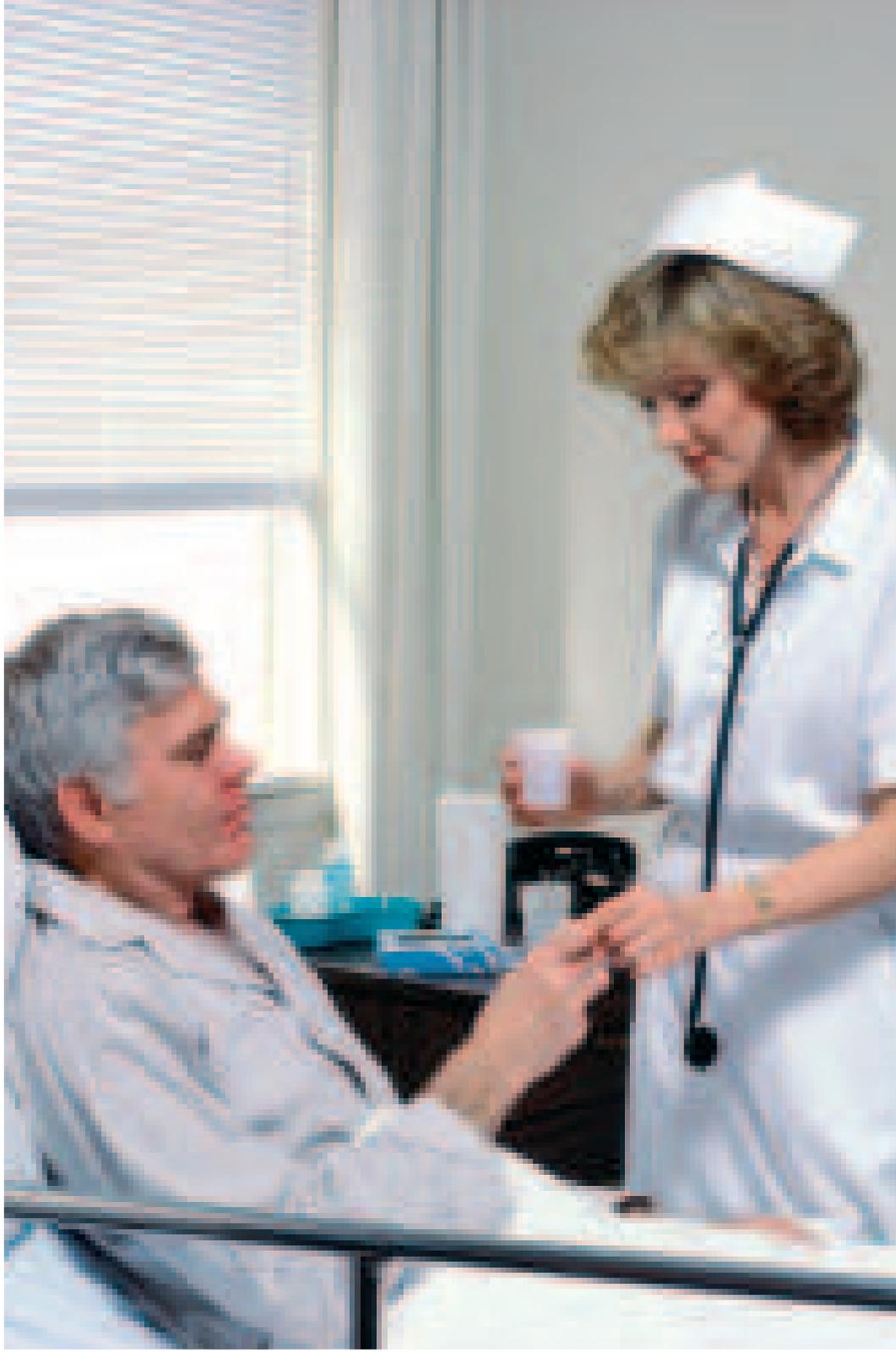
Clinical trials have enabled great progress to be made in the development of new cancer treatments. Some examples of this progress - chronic myeloid leukaemia, breast cancer, and cancer of the **cervix** - are briefly reported below.

Chronic myeloid leukaemia (CML): the results of clinical trials published in 2000 have revolutionized the treatment of this disease. A product, imatinib, better known under the brand name of Gleevec®, has greatly enhanced treatment and reduced **side effects**. The treatment, which uses molecules that are targeted exclusively to cancer cells, is now being studied for several other types of cancer.

Breast cancer: clinical trials have shown that in early stages of the disease, surgery to remove the tumour, or **quadrantectomy**, followed by radiotherapy, is followed by the same survival as did the more extensive surgery used in the past.

Cancer of cervix: five major clinical trials have shown that chemotherapy using the drug cisplatin combined with radiotherapy extends survival. In the past, this cancer was treated with surgery, followed by radiotherapy, or radiotherapy alone if surgery was not indicated.





Part two

How are clinical trials carried out? How can I participate?

In clinical trials, patients receive the study treatment and doctors observe and analyze the way they respond. Clinical trials have some risk for the people who take part. Each study takes rigorous steps to protect patients, and prevent and treat potential damage.

What is it like to receive treatment in a clinical trial?

When you choose to take part in a clinical trial, you receive your treatment in a medical centre qualified for cancer therapy. Your treatment team will include doctors, **research nurses**, and other professionals who work in close cooperation with the clinicians, such as **data managers** and **statisticians**. You will have more tests and see a doctor more often than you would if you were not taking part in a study. You will follow a treatment plan that your doctors will prescribe. You may be asked to help gather personal information, for instance, by keeping a log or by filling out forms about your health. In general, you will continue to be monitored even after your treatment is over.



Research nurses: nurses dedicated to the care of patients in clinical trials.

Data managers: people who deal with data collection.

Statisticians: people who deal with data analysis.

How is the research activity carried out? How are patients protected?



Protocol: detailed document that describes what will be done in the study and why (medical tests and their frequency). It includes the treatment plan.

Eligibility criteria: characteristics that patients must have in order to take part in a clinical trial.

Treatment plan: document that indicates what treatment will be carried out.



In clinical trials, a patient's well being is particularly important.

Approval by the Ethics Committee ensures patient safety.

1. Each clinical trial has an action plan (a protocol) that explains how it will work.

The **protocol** is a detailed action plan describing:

- how the trial is to be carried out;
- the reasons for the study;
- the purposes of the study and the criteria used to evaluate the results;
- the characteristics that patients must have in order to take part in the study (**eligibility criteria**);
- the number of patients who will be participating;
- the medical tests patients will get and how often they will take them;
- the **treatment plan**.

All the doctors who take part in the trial will use the same protocol. However, a patient's condition may, at any point, cause a doctor to make a change and, if necessary, stop treatment, taking the patient off the trial.

For the safety of the patients, the protocol of each clinical trial must be approved by the Ethics Committee at each hospital or other study site. The Ethics Committee must conduct a review to be sure the trial is scientifically appropriate, and must conduct an ethical assessment to assure that the interest of each patient is protected and that patients are not exposed to extreme or unethical risks. A study that is not appropriate scientifically would also not be appropriate ethically. The Ethics Committee is comprised of clinicians and 'lay people,' who include patient representatives, experts in ethics and law, clergy, as well as pharmacologists, statisticians, and other professionals.

2. Each clinical trial enrolls people who are alike in key ways.

Eligibility criteria specify the characteristics that all patients must have to be admitted to the study. The eligibility criteria are described in the protocol and differ from study to study, depend-

ing on the research purpose. They may include age, gender, type and stage of cancer, and whether cancer patients who have had prior cancer treatment, or who have other health problems, can take part.

Using eligibility criteria is an important principle of medical research. They help produce reliable results. During a study, they help protect patient safety so that people who are likely to be harmed by the study drugs or other treatments are not exposed to the risk. After the study results are analyzed, they help doctors know which patient groups will benefit if the new treatment being studied has proven to work. For instance, a new treatment may give good results for a certain type of tumour but not for another type, or may be more effective for men than for women.

3. Cancer clinical trials include research at three different phases.

- **Phase 1 studies** are the first step in testing a new treatment in human beings. In these studies, researchers look for the best way to give the new treatment. They try to define what the best doses are, in relation to the product's **toxicity**. They also watch for any harmful side effects. Because less is known about the possible risks and benefits in Phase 1 trials, these studies usually include only a limited number of patients. Eligibility criteria are particularly strict.
- **Phase 2 studies** focus on learning whether the new treatment has an anticancer effect (e.g., does it shrink the tumour?) and at what dosages. At the same time, the researchers continue to study the side effects. There are various types of Phase 2 trials. They can test a new product that has just completed a Phase 1 study, about which fairly little is known, and for which the researchers are still trying to identify the best dose. Or they can test well-known products to determine the effects on a specific type of cancer or on a specific group of patients.
- **Phase 3 studies** compare two (or more) treatments. The new treatment is tested against a standard treatment in different patient groups. At the end of an adequate **follow-up** peri-



All clinical trials must comply with a strict law of the Ministry of Health which reflects the most recent regulations issued by the European Union.



Toxicity: the drug may be toxic for some organs and tissues, and, depending on the level of toxicity, it may cause more or fewer side effects (cf. page 10).

Follow-up: period of observation during which the patient is checked and takes tests at regular intervals to assess the efficacy of treatment.

od, the comparison between the patients who have received the new treatment and those who have received the standard treatment provides data for objectively verifying the value of the new treatment. The researchers will know whether the patients who took the new treatment are living longer and whether they have a better quality of life.

In most cases, studies move into Phase 3 only after the treatment has shown promise in Phases 1 and 2. Phase 3 studies may involve hundreds or even thousands of patients who are enrolled by various research institutes at both national and international levels.

4. In Phase 3 studies, patients are assigned at random to receive either the new or the standard treatment.

Researchers assign patients by chance either to **the treatment group** (consisting of people who are receiving the new treatment) or to the **control group** (consisting of people being given standard treatment). Studies that use this method to distribute patients are called randomized trials. **Randomization** helps avoid bias so that the results are not affected by human choices or other factors not related to the treatments being tested.

In some randomized clinical trials neither the doctors nor the patients know whether they are in the treatment group or in the control group. This is another way to avoid bias because when patients know which treatment they are taking, it might change the way they react. This could bias the study by making the results look better than they really are.

When it is only the patient who does not know what treatment he is receiving the trial is called a 'single blind' study. When neither patient nor the doctor know what treatment is being taken, it is called a 'double blind' study.

Randomized, controlled clinical trials are the 'gold standard' for cancer research. That is, the results from these trials are the best evidence that a treatment works.



Treatment group: group of patients receiving the new treatment. Also called intervention group.

Control group: group of patients receiving standard treatment which is being compared against the new treatment.

Randomization: method whereby patients are assigned by chance to the treatment group or to the control group so the results are not biased by subjective or interfering factors.

Why do Phase 3 clinical trials compare treatment groups?

Comparing similar groups of people taking different treatments for the same type of cancer is a way of making sure that study results are real and caused by the treatment rather than by chance or other factors. Comparing treatments with each other often shows clearly which one is more effective or has fewer side effects. When no standard treatment exists for a cancer, some studies compare a new treatment with a **placebo**. You will be told if this is a possibility before you decide whether to take part in a study.

Your doctor can tell you more.

If you have any questions about how to take part in clinical trials and about how they work, ask the doctors, nurses, or other professionals who can help give you this information.

It may be helpful to bring this booklet with you and discuss points you want to understand better.

It may be rewarding to know that by taking part in a study, you are have a chance to help other patients to get better treatment. You may ask to be informed about the results of the study.



In Phase 3 clinical trials, all patients receive the best possible treatment.



Placebo: a tablet, capsule, or injection that looks like the drug or other substance being tested, but contains no active ingredient.



Part three

Should I take part in a clinical trial?

This is a question only you, those close to you, and your health professionals can answer. The information in this section can help you think about your choices and making your decision.

Looking at the benefits and drawbacks

Clinical trials are a good choice for most patients. But they are a treatment option that offers both benefits and drawbacks. It is useful to discuss these issues with your doctor and with your family.

Benefits

- Clinical trials offer high-quality cancer care. If you are in a study and do not receive the new treatment being tested, you will receive the best standard treatment.
- If a new treatment is proven to work and you are receiving it, you may be among the first to benefit.
- By looking at the benefits and drawbacks of clinical trials and your other treatment choices, you are taking an active role in a decision that affects your life.
- You have the chance to help others and contribute to improving cancer treatment.

Drawbacks

- New treatments under study are not always better than, or even as good as, standard care. They may have side effects that doctors do not expect or that are worse than those of standard treatment.
- Even if a new treatment has benefits, it may not work for you. Even standard treatments, proven effective for many people, do not help everyone.

Your Rights, Your Protections

Before and during a clinical trial, you have a number of rights. Among them:

- Taking part in a treatment study is up to you. It may be only one of your treatment choices. Talk about your options with your doctor. Together, you can make the best choice for you.
- If you do enter a study, the doctors and nurses will follow you carefully throughout the research to measure your response to treatment and to help control any side effects.
- If researchers find out that a treatment does not work you will



Doctors and health professionals can treat a person only if he/she agrees.



Informed consent: the right/duty to receive all available information in order to decide to receive a given treatment, such as to decide to take part in a trial.



Signing the informed consent form to take part in the study does not mean you cannot leave the study at any point in time.

be taken off the study right away. You may then be given other treatments by your doctor.

- You have the right to drop off the study at any time.

One of your key rights is the right to **informed consent**, which is provided for by law. Informed consent means that you must be given all the facts about the trial before you decide whether to take part. This includes details about the treatments and tests you may receive and the possible benefits and risks they may have. The doctor or nurse will give you an informed consent form that goes over the key facts. If you agree to take part in the study, you will be asked to sign this form.

In clinical trials, the informed consent process continues throughout the study. For instance, you will be told of any new findings regarding your clinical trial, such as new risks. Then you may be asked to sign a new consent form if you want to stay in the study. Signing a consent form does not mean you must stay in the study until the end. You can leave at any time and will have the opportunity of making other treatment choices.

Part four

How can I get information on clinical trials?

Patients and patient associations have contributed to many debates on clinical trials that have led to significant changes in terms of transparency and participation in the design and organization of clinical trials. Unfortunately, there are still major problems concerning lack of access to information, especially for Phase 1 trials.

In Italy

In Italy, it is required by law that all clinical trials on medicinal products be registered in the **National Observatory on Drug Clinical Trials (Osservatorio Nazionale sulle Sperimentazioni Cliniche dei medicinali (OsSC))** coordinated by the Italian Drug Agency (AIFA). The Observatory offers users a standard, but significant, selection of information from Phase 2 and Phase 3 clinical trials. The material is entered under the responsibility of the sponsors, their delegates, and their Ethics Committees.

The information is available on OsSC's website. Links will enable you to see a series of data on clinical trials currently under way in Italy. You also can see whether a trial is open for enrollment or is in a subsequent stage ('open' or 'closed').

Follow these steps:

1. go to <http://oss-sper-clin.agenziafarmaco.it/>
2. click on *Dati*
3. click on *Ricerca Sperimentazioni Cliniche* to register (optional)
4. click on *Ricerca Sperimentazioni Cliniche* again
5. proceed with your search by choosing between *Ricerca Guidata* (Structured search) by therapeutic area/pathology or geographic area and *Ricerca Libera* (Unstructured search)

The following information is available for each study or protocol:

- **EudraCT** code
- protocol code number
- title of the protocol



Osservatorio Nazionale sulle Sperimentazioni Cliniche dei Medicinali:
<http://oss-sper-clin.agenziafarmaco.it>



The European Clinical Trials Database, EudraCT: registers all the clinical trials carried out in the 25 Member Countries of the European Union since 1 May 2004. The database is confidential and is not accessible to the public.

- registration date
- sponsor
- stage of the study ("open" or "closed")
- therapeutic area (e.g. oncology or gynaecology)
- suggested therapeutic indication
- coordinating center and other participating centres

Thanks to cooperation with AIFA, AIMaC can provide further information that may help you better understand the data posted on the OsSC website. Call AIMaC helpline (toll-free number 840 503579; info@aimac.it) for assistance.

United States of America



National Institutes of Health (USA):
<http://clinicaltrials.gov>

In the USA, the National Institutes of Health has a **site** that is constantly updated; it records all the clinical studies, including Phase 1 trials, that are under way in the United States and in other countries around the world. At the present time, the site reports 250 trials under way in Italy, 95 of which are Phase 1 studies.

Cancer patient associations as information providers

The results of clinical trials on cancer have universal impact. Patient associations are interested in cooperating and coordinating cross-nationally. Providing patients with detailed and comprehensive information will facilitate their participation in clinical trials.

The main aim of the Clinical studies: What cancer patients need to know (Rome, 20 April 2007) conference was to bring together major institutions (AIFA¹, EMEA², ISS³, NCI⁴, NCCAM⁵, WHO⁶) and patient organizations (AIMaC, ECPC⁷, F.A.V.O.⁸) to share and make available the following information:

¹ Italian Drug Agency, ² European Medicines Agency, ³ Italian National Institute of Health, ⁴ U.S. National Cancer Institute, ⁵ U.S. National Center for Complementary and Alternative Medicine, ⁶ World Health Organization, ⁷ European Cancer Patients Coalition, ⁸ Italian Federation of Volunteer-based Cancer Organizations

- code identification number of the trial;
- person in charge of the clinical trial and clinical center where it is carried out, with contact names and addresses that patients can turn to for information;
- stage and type of the disease;
- phase of the trial and brief description;
- stage of patient enrollment;
- assurance that names of trials quote the drug or combination of drugs to be tested and the disease for which they are indicated.

Some questions you can ask your doctor

Finding answers and making choices may be hard for cancer patients and for those who care about them. It is important to discuss your treatment choices with your doctor, with the **oncologist** to whom your doctor may refer you, and with the medical team carrying out the clinical trial you consider entering.

Ask questions about the information you receive before signing the informed consent. Ask questions about any other doubt you may have. Being properly informed will help you to interact with your doctor in the best of ways.

You may want to take a relative or a friend when you go to the interview with your doctor. It might also be a good idea to take notes on the questions you ask and on the answers you get, or bring a tape-recorder to record what is said.

Here are some questions you may want to ask about:

The Study

- What is the purpose of the study? In what phase is this study?
- Why do researchers believe the new treatment being tested may be effective? Has it been tested before?
- Who sponsors the study, and who has reviewed and approved it?



Oncologist: a doctor who specializes in treating cancer.



No question about your health is foolish. It is of paramount importance to fully understand all the options that are available to you.

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20/4/2007 ROMA

STUDI CLINICI DI NUOVE TERAPIE CONTRO IL CANCRO:

UNA GUIDA PER I PAZIENTI

CLINICAL TRIALS: **WHAT CANCER PATIENTS NEED TO KNOW.**

8.30	Registration	13.10	European information on clinical trial: the EMEA point of view R. De Lisa (EMEA)
9.00	Welcome Presentation of the information tool E. Garaci (ISS) - F. De Lorenzo (AIMaC)	13.35	Discussion
9.30	International clinical trials registry platform T. Pang (WHO)	13.50	Lunch
9.55	The US Perspective Chair: S. Vella (ISS)	14.30	The Italian Perspective Chair: U. Tirelli (CRO)
10.00	Recruiting patients to cancer treatment trials in the United States M. C. Christian (NCI)	14.35	Problems with patient enrolment in clinical trials P. Casali (INT)
10.25	Disseminating clinical trials information to patients M. A. Bright (CIS)	15.00	Oncology clinical research in Italy: the AIFA perspective C. Tomino (AIFA)
10.50	Coffee break	15.25	Discussion
11.10	Clinical trials: what cancer patients want to know M. Morra (ICISG)	15.40	Coffee break
11.35	Outreach to patients C. Thomsen (NCCAM)	16.00	Round table: How to disseminate information on clinical trials? Moderator: D. Sassoli (RaiUno) The nurses' perspective: I. Carpanelli (AIO) The patients' perspective: E. Iannelli (F.A.V.O.) The psychologists' perspective: A. Meluzzi (Univ. di Siena) The physicians' perspective: G. Milillo (FIMMG) The oncologists' perspective: U. Tirelli (CRO)
12.00	Discussion	17.00	Floor discussion with members from cancer patient organizations
12.15	The European perspective Chair: S. M. Aloj (AIMaC)	18.05	Conclusions
12.20	Cancer trials as live savers: a patient's perspective on public cancer registries J. Geissler (ECPC)		
12.45	From general to specific information on clinical trials from the Dutch perspective C. Honing (KWF)		

