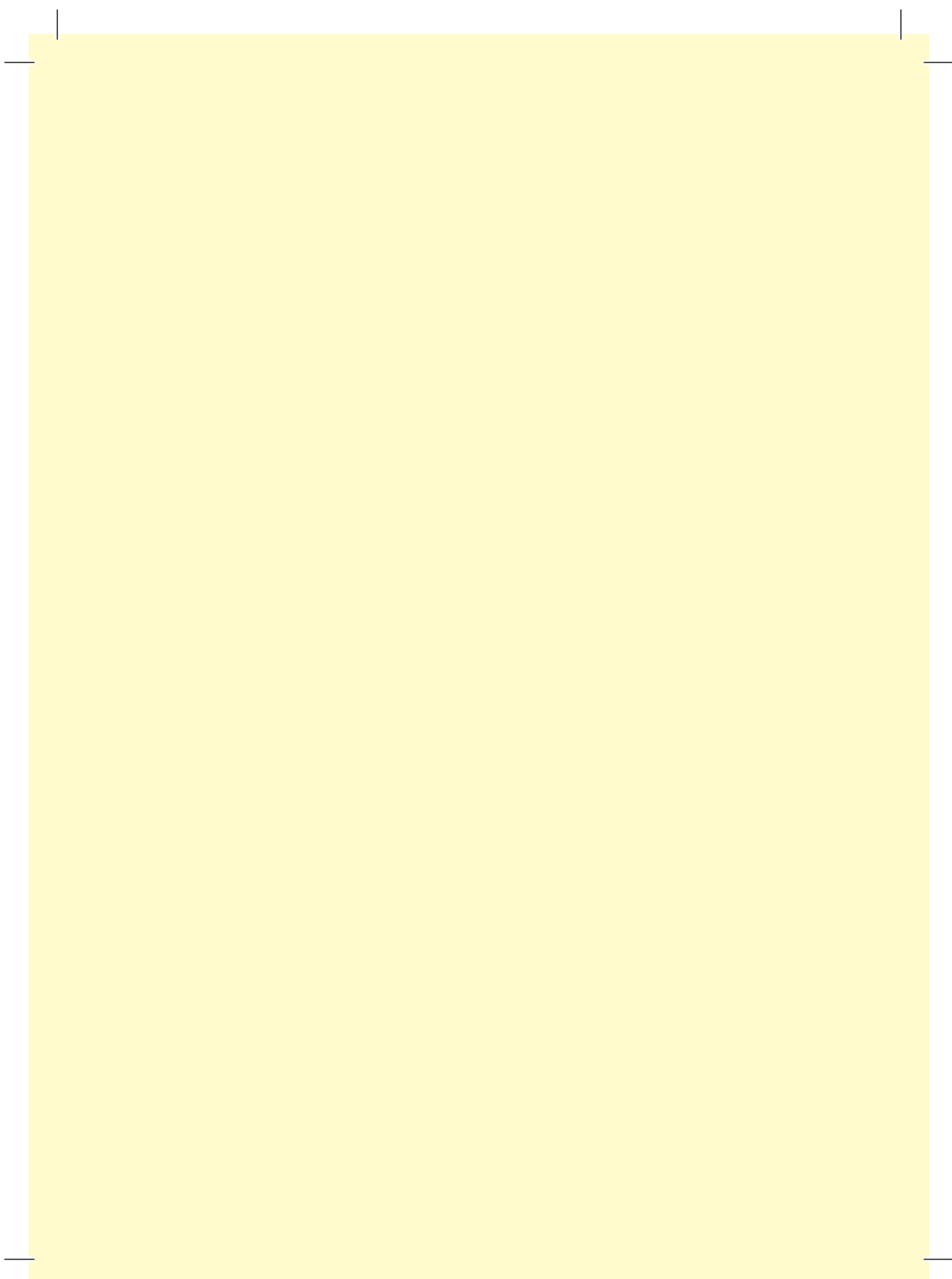




FAQ on Clinical Trials





Introduction

Patients with chronic diseases are often keen to volunteer to take part in clinical trials, hoping that their contributions will help research to discover new therapies that will help to treat or cure the condition affecting them. Taking part in a clinical trial often raises questions either for those in the trial itself or the family members or carers.

This booklet brings together some of the questions that are frequently asked by those thinking about joining a clinical trial. It aims to provide clear information in a straight forward way so that patients and their families can make informed decisions about taking part in a clinical trial if the opportunity arises.

The booklet has arisen as a result of a collaboration between the European Genetic Alliances Network (EGAN) and Roche. The content has been read by independent experts from the patient community and by those responsible for carrying out clinical trials. We hope that it is clear and accurate, but we welcome feedback on the content and suggestions for additional topics or other improvements that might be incorporated in future editions. Please send these to Alastair Kent (alastair@gig.org.uk).

This booklet is freely downloadable and maybe copied without limit provided the source is acknowledged.

Alastair Kent
President EGAN

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FAQ – clinical trials

1. What is a “clinical trial”?

A clinical trial is a research study in human subjects with the aim of answering specific questions about a new medical treatment (vaccines, new therapies or new ways of using known treatments). Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Pharmaceutical clinical trials are conducted in Phases. The trials at each Phase have a different purpose and each Phase looks at different areas (e.g. toxicity, dose finding etc).

2. What are Phase I clinical trials?

Phase I trials (sometimes called early treatment trials) aim to test the safety of various doses of a new drug. This includes looking at the side effects of a drug – for example, does it make people feel bad, raise their blood pressure etc? Phase I trials involve only a small number of people, who are usually healthy volunteers. In exceptional cases, for instance in cancer or HIV, patients who are at a very advanced stage of the disease may participate.

3. What are Phase II clinical trials?

Phase II trials test the new drug in a larger group of people who are ill, to see whether it has any effects suggesting that it might help them. As in Phase I, the number of participants is limited. Phase II trials also look at safety and at the right dose.

4. What are Phase III clinical trials?

Treatments only move into a Phase III clinical trial if Phases I and II suggest that a substance might actually be useful in ways that patients would regard as important. Phase III trials test new drugs in larger groups of people who are ill. Phase III trials compare the new drugs with whatever treatments are currently in use, or occasionally with a placebo. These trials look at how well the new treatment works in practice, and at any side effects. They usually last longer than Phase II trials – typically a year or more. Often several thousand patients in different countries will be involved in a Phase III trial. A large amount of participants is necessary because investigators have to be able to detect moderate but important differences between treatments.



'You can use the internet to find out more information about your condition'

5. What does “post marketing surveillance” – also known as Phase IV trials – mean?

Post marketing surveillance concerns the last and 4th Phase of a clinical trial. After a medicine has been launched, Health Authorities are often asking companies to provide additional data, collected from the actual use of the medicine in thousands of patients. Phase IV studies are designed to provide broader experience in evaluating the safety and effectiveness of the new medicine in larger numbers of patients, subgroups of patients, and to compare and/or combine it with other available treatments. These studies are designed to evaluate the long-term effects of the drug. Less common side effects may be detected at this stage.

Despite the vigilant tests carried out during clinical trials in the other three Phases, active post marketing surveillance of drug side effects is essential. Not all potential side effects of a medicine can be anticipated based on only several hundred to several thousand patients. Therefore, clinical trial sponsoring enterprises maintain a system of risk assessment programs to identify side effects that did not appear during the other trials. Information on adverse events that have been brought to the attention of the marketing authorisation holder are collated. This is also called “Pharmacovigilance” (i.e. the safety of medicines).

6. What is a “placebo”?

A placebo is a treatment that does not contain any active substance. It allows investigators to test for the ‘placebo effect’. This is a psychological response where people feel better even though they do not take a medicine with an active ingredient. By comparing people’s responses to the placebo and to the treatment being tested, the benefit of the treatment can be described.

7. Who is allowed to set up a clinical trial?

Clinical trials are designed by groups of medical and other specialists. The trial design is usually based on a thorough analysis of existing research, and a realisation that certain questions about treatment or symptom control need to be answered. It is discussed with medical staff, nurses, patients, statistical experts and support staff, as well as representatives from drug companies, to draw up the best possible trial design. The design for the study is known as the “protocol”.

8. Who regulates clinical trials?

In order to obtain an approval for a clinical trial, a company has to submit to national Health Authorities a so-called “study protocol” in which all the details of the study are described. This protocol is reviewed by the Health Authorities and also by an Ethics Committee, whose role it is to carry out research in the respect of dignity, rights, safety and well-being of the people who take part in medical research. If the Health Authorities and the Ethics Committee have not approved a protocol, then the study cannot go ahead. Any change to the protocol must also be approved by the Ethics Committee.

An Ethics Committee must have at least 5 members and is composed of health care professionals and investigators as well as members of the public.

The World Medical Association has also developed the so-called “Declaration of Helsinki”. This sets the ethical standards for research involving human beings, human material or identifiable data. Most investigators will state that their clinical trial protocol has been developed in line with these ethical principles.

In addition to this, The Food and Drug Administration (FDA) in the USA, the European Agency for the Evaluation of Medicinal Products (EMA) as well as multiple legislative texts at European Union level have very specific rules laid out to protect patients involved in clinical trials.

9. When and how is a trial approved?

Investigators are closely supervised by appropriate regulatory authorities. When beginning any study the doctor, or investigator, must ask approval from an Ethics Committee. The Ethics Committee is a committee of doctors and other medical personnel as well as lay people that have no ties to the study. Their role is to make sure that the study is as safe as possible and that the “informed consent” explains all of the important information to the patient.

10. What is an “informed consent”?

Except in exceptional circumstances you cannot be entered into a trial without signing a form saying that you have given your informed consent. If you sign this form, you confirm that you believe you have been given all the important facts about a trial, you understand them and that you have decided to take part in the trial of your own free will. An informed consent is not a contract and you may withdraw from the study at any time.

11. What will I find in an informed consent document?

While informed consent documents do vary from place to place, they should communicate all of the information described below in an intelligible language. The information covered should include:

a. The purpose of the clinical trial

In this section, investigators explain why they are conducting the trial. The reasons will depend on the type of disease and the trial type

b. Description of procedures

This section describes the ongoing procedures, how frequently they will be applied, and where they will take place (at home, in the hospital or clinical centre, or an outpatient centre). For interventional trials (see *Question 19* for an explanation on this type of trial) this section should also include procedures that are part of regular disease care and may be done even if the patient does not join the trial; standard procedures being done because the patient is in the trial; and procedures that are being tested or evaluated by the trial.

If it is a “randomised” trial (please see *Question 17* for an explanation of what randomised trial means) the document should make clear what procedures each group will undergo. It should also indicate the chances of being placed in any one group.

c. Duration of 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 the patient from the trial (e.g. if his condition worsens or new information indicates he shouldn't continue). The document should make clear that the patient has the right to stop participating at any time, and it should describe any possible medical consequences of sudden withdrawal.

d. Potential risks of the trial

This section includes the foreseeable physical and non-physical risks of participating in the trial. A non-physical 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 (infertility risk, etc.).

e. Benefits

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



'Bring plenty to do while you participate/have treatment, for instance a portable music player'

f. Alternatives to participation

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

g. Confidentiality

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

h. Costs / Additional expenses

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

i. Participant's rights

The document should specify that the participation is voluntary, the patient can choose not to take part or leave at any time without penalty or loss of benefits, and any new information that might affect his participation will be shared with him.

j. Contact information about whom to call in case of questions or problems

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 should be indicated. It also should be given a phone number for the Ethics Committee or a patient representative, in case the patient has questions about his / her rights as a research participant.

k. Supplemental information

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

l. The signature

The participant's dated signature represents his legal consent to participate in the trial. In case of illiteracy of the participant, investigators 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, the participant should not hesitate to ask for the information.

If English is not your native language, you should be able to obtain the consent documents in languages other than English. Because joining a clinical trial is an important decision, you should ask the investigator any questions you may have about the study before you make a decision.

It is also a good idea to take the consent documents home and discuss them with family members or friends. Talking about your options can help you to feel comfortable with your decision. If you decide to join the clinical trial, be sure to ask for a copy of the informed consent documents so you can review them at any time.

12. What are “eligibility criteria”?

All trials have guidelines about who can take part. These are called ‘eligibility criteria’, consisting of inclusion criteria (i.e. who is suitable to participate) and exclusion criteria. Not anyone who suffers from a particular disease can take part in any trial that studies this disease: the eligibility criteria for a lung cancer trial for instance might say that the only people who can take part are people who are at the earliest stages of their condition, who are over 18 but under 80, and who have no other health problems.

13. What are “inclusion criteria”?

Inclusion criteria help investigators decide who can join a trial. For example, some trials only include people of a certain age, or at a particular stage in their illness. You may have to have a medical examination before a trial (e.g. a blood test) to assess whether you are suitable to take part.



‘Talking things through with your family can help you to come to a decision everyone’s happy with’

14. What are “exclusion criteria”?

Exclusion criteria determine who won't be able to join a trial – for example, many trials exclude women who are pregnant to avoid any possible danger for the baby. Trials may also exclude people who are already taking a drug that may interact with the treatment being studied.

15. What does “blinding” mean?

Blinding means that whoever is assessing the effects of treatment will not know if they study patients on the treatment or patient on placebo. This helps to prevent bias. Sometimes patients will assess the effects of treatment, sometimes doctors will, and sometimes third parties will. Some or all of these people may be kept unaware of which treatment has been received. In a double blind trial, neither you nor the doctor will know which treatment you are receiving.

If you take part in a 'double-blind' trial, neither you nor your doctor will know which treatment you are receiving. The aim is to make sure that nobody's expectations affect the results of the trial.

16. What does “bias” mean?

When prejudices lead to incorrect conclusions about the effects of treatment, this is bias. It's really important to avoid bias in health research, as it can distort the results and could lead to unsafe or inefficient treatments being licensed for use, or useful treatments being overlooked. Investigators try to avoid bias by using randomisation and by blinding those administering the drugs and assessing the results of treatments.

17. What are “randomised” trials?

Most clinical trials are randomised trials. If you take part in a randomised trial, a computer, not a doctor, will decide which treatment to give you. This decision will be random. It will be due to chance alone, and not based on your doctor's decision.

Randomisation is the best way of ensuring that people in the different parts of a trial are broadly similar. By comparing similar groups of people, investigators can be sure that their trial is checking the difference between the treatments being studied, and not the differences between the people taking part.

Randomisation is important because investigators need to ensure that clinical trials are not biased. It is quite easy for people to be biased without realising it.

18. What is an “open label” trial?

In an open label trial, both you and your doctor will know which treatment you are receiving. In other words, this is the opposite of a double-blind trial.



'Hospital staff are there to look after you. Make sure you ask if you need something'

19. What are the different types of clinical trials that I can participate in?

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.

Diagnostic trials refer to trials that are conducted to find better tests or procedures for diagnosing a particular disease or condition. Diagnostic trials usually include people who have signs or symptoms of the disease or condition being studied.

20. How can I find out which clinical trials are going on?

Unfortunately, at the moment there is no easy way to find a clinical trial that may be suitable for you. The best thing to do is to discuss it with your own doctor to see if you can be referred.

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) has launched a user-friendly search portal allowing people seeking clinical trial information to search for comprehensive information on ongoing clinical trials or conducted by the pharmaceutical industry.

This portal enhances transparency and access to clinical trial information for patients and physicians through an easy-to-use online trial search engine and can be visited on <http://www.ifpma.org/clinicaltrials.html>. Information can be located by entering a disease and/or product name in the search fields.

Additionally IFPMA gives links to information posted on pharmaceutical company-owned websites and other commercial or government-sponsored websites containing information provided by pharmaceutical companies. In the US, the authorities have created a website (www.clinicaltrials.gov) where trials conducted in the US can be found.

21. How can I volunteer and participate in a clinical trial?

If you are interested in this, you should talk about it with your family doctor in order to understand the personal implications of participating in a clinical trial. Your doctor will contact the sponsoring company and put you forward. In general, companies have a close investigator relationship to a group of selected and accredited physicians who will conduct the study. In cooperation with your family doctor they will examine your case and decide about your participation. As the selection process and evaluation of eligibility criteria must be done under strict medical considerations that only a physician is able to fully appreciate, not the patient but his physician has to submit the application.

22. Can I contact a company directly to volunteer in a clinical trial?

No, this has to be done by your doctor. In general it is only possible to contact the company for information on contact persons on the specific ongoing clinical trials. They will indicate the responsible physicians of the study who decide about the participation.

23. Will I be compensated or paid for participating in a clinical trial?

For fundamental ethical reasons, the participation in clinical trials testing participants with illnesses is usually not paid/compensated. But on the other hand the sponsoring companies normally commit to provide the investigational medicinal product free for the duration of the study and the participants typically will get excellent care from the physicians during the course of the study and this care will also be free.

24. Why should I participate in a clinical trial?

There are various reasons for considering participation in a trial, such as suffering from a disease or scientific or personal interest.

At any rate, you should discuss this with trusted people among your family and friends as well as with your physician(s).

Please read also *Question 30*, which is related to this topic.

25. What questions should I ask before volunteering?

You might find it helpful to ask questions about a clinical trial before deciding whether to take part. You can ask your doctor or nurse, or the investigators running the trial. Some helpful questions might include:

- * What's the point of the trial? How will it help people?
- * What's known already from previous research?
- * Who reviewed and approved the trial?
- * Who is taking part in it? Why do you want me to take part?
- * How will this be different to the care I'm getting now and what are my options for treatment?
- * If the trial is testing a drug, how often must I take it, when and for how long?
- * Do you know anything about the potential *side effects*, risks or benefits?
- * How will the trial affect my daily life?
- * How often will I have to visit the clinic?
- * How far will I have to travel and will I have to make all the arrangements?
- * Will you give me food or drink if I've travelled a long way?
- * What will happen at these visits? Will I have extra tests?
- * What other medication can I take when I'm taking part in this trial?
- * Will I get regular check-ups? What happens if my condition gets worse?
- * What happens if something goes wrong?
- * How long will the trial last?
- * Who is running the trial?
- * Will I be told about the progress of the trial as we go along?
- * Will I be told about the results of the trial when it ends?
- * Who is funding the trial?
- * Will my expenses be paid e.g. for travel or childcare costs?
- * Is there anything I'm not allowed to do while I'm taking part in the trial?
- * Who will tell my GP that I'm on a trial?
- * How will my personal information be kept confidential?
- * Can I talk to other people taking part?
- * Who can I talk to if I have any more questions? (There should be someone available throughout the trial who can answer any further questions you may have)
- * What will happen if I do well on the trial treatment, and the trial has ended? Can I then continue?

26. What will happen to me during a clinical trial?

If you agree to join a trial, you may have more medical tests before you are given any treatment. This will allow the investigators to know where you started, so they can tell at the end of the trial whether there has been any improvement. These are called baseline measures.



'You will probably feel nervous when you first arrive at hospital/treatment centre. Friendly staff will be there to welcome you'

During the trial you may have more tests to see whether the treatment is working. These are known as outcome measures. This may involve more visits to the clinic than normal, or more tests than normal - for example, extra blood might be taken when you give a blood sample. Sometimes the tests are carried out as part of your routine care.

You may have to make some changes to your everyday life. This may include avoiding certain foods or over-the-counter medications like anti-histamines. You may also be asked to keep a diary. This could contain notes about how you are feeling after your treatment, whether you get a particular side effect, and how long it lasts.

As well as measuring the physical effects of a treatment, many trials now try to assess the impact on people's quality of life. For example, a 'quality of life' study might ask you about:

- * Your mood and general sense of well-being
- * Whether you feel more tired than usual
- * Whether you are managing to lead the life you would lead normally – going to work, looking after your family, or whatever you would normally do

You and your doctor might decide that you should stop taking part in a trial if your condition is getting worse and the treatment is not helping you. You can choose to leave at any point in a trial without giving a reason and without it affecting the level of care you receive.

Do not be concerned if you want to leave a trial because you are experiencing side-effects. The information will still be useful to others. The investigators may want to continue to follow your progress after the trial, even if you left early. This helps them to interpret the results of the trial accurately.

27. My physician won't put my name forward. What should I do?

Usually all search portals (e.g. IFPMA) indicate information about the responsible contact persons. On request they give specific information and advice on the particular study and make the best possible effort to put you in contact with the physicians who will conduct the study. Volunteers, whose family doctor doesn't provide support, should contact these physicians.

If necessary, they will contact the family doctor for further information about the patient's medical history.

28. Will taking part in a clinical trial affect the care I receive from my doctors?

No. You will be asked to come for regular check-ups and tests. Your doctors will have put your name forward and will therefore know that you are taking part in a clinical trial. This too will give you more opportunities to chat with them if you have any questions.



*'Usually your family can come and visit while you're having treatment'
(is this true?)*

29. Who decides whether elderly, incapacitated or children participate in a clinical trial?

The key concern is to ensure that elderly, incapacitated patients as well as children are protected. These patients can only be enrolled in a trial if an informed consent of the legal representative has been obtained. If no legal representative is available, then the patient cannot take part in the trial.

30. Will I have to stop taking my current medication? What are the risks and benefits of participating in a clinical trial?

You will usually be invited to take part in a clinical trial because you are a patient who needs treatment. You will then have a choice between joining a trial or carrying on with the treatment you would have been given anyway. This is not an easy decision. You will have to weigh up all the pros and cons of either option. It is important to consider what's most important to you and which option is most likely to give you the most benefits.

There are clearly many things to think about before taking part in a clinical trial. Some of the benefits and risks of taking part are listed below.

Possible benefits of taking part in a clinical trial

- * You may receive a new treatment before it is widely available
- * You may help to produce information of use to yourself and others with the same health problem
- * You can play a more active role in your own healthcare
- * Your treatment and progress may be monitored more closely

Possible risks of taking part in a clinical trial

- * You may experience unexpected side-effects
- * You may have to visit the clinic or hospital more often because you are being monitored more closely
- * You may have to undergo more tests (for example blood tests) than you would usually have in routine care
- * You may be given a new treatment that is less effective than the standard treatment. Or you may be given the standard treatment when the new treatment proves to be more effective.
- * You may find the new treatment works well for some other people, but not for you
- * You may not have access to the new treatment at the end of the trial, even if proves to be the best one

31. Can I withdraw from a trial?

You can change your mind and leave a clinical trial at any time—before the study starts, during the study, or during the follow-up period. Participating in research is always voluntary. Even if you decide to participate, you can always withdraw from the study without affecting your relationship with your doctor.

32. Will taking part in a clinical trial affect the care I receive from my doctor?

Absolutely not, in fact you will find that it is exactly the opposite that will happen. As described above, you may have to go and see your doctor more often than before, which will therefore give you more opportunities to ask him or her about the state of your condition, the treatment(s) you are given and your general well-being.

33. Will I find out the results?

It may be some time before the results of a trial become available. Some large trials involve thousands of people and can run for five years or even longer before every participant has been assessed. There may be years between when you take part and when the trial finishes.

At the end of the trial, the study sponsor (e.g. the company) should make the results available to everyone who took part. If not, you can always ask the investigator or your doctor to tell you about the conclusions. The results should provide more information about the possible risks and benefits of the different treatments that have been tested. They may help you and others like you to make more informed decisions about your healthcare.

Some investigators will also work with patient groups to ensure that the results of trials reach other patients. Investigators have a responsibility to publicise the results of their trial even if the results show that a new treatment doesn't work. They might do this at a conference, in a medical journal or in the press.

34. What will happen to my samples or information about me during and after the trial? Will others be able to look at it or use it for further research?

If you agree to join a trial, some people will need to be told that you are taking part. These people are:

- * Your GP, who is responsible for your healthcare on a day-to-day basis
- * The doctor and research team looking after you in the trial

The fact that you are taking part in a trial will be written in your medical notes. Investigators cannot tell anyone else that you are taking part in a trial unless you give your permission.

During the trial, all of the information collected about you will be kept confidential, as with any other medical records. When investigators publish the results of a trial, they are not allowed to include any information that would identify people - your name will not be used in any reports or publications.

The clinical trial protocol will define what is to be done with your samples and information. Specific sections within this document will detail for how long samples and information must be kept before they are destroyed. If samples and/or information are to be used further, then this will be either:

- * included in the original trial protocol
- * be part of the informed consent you will sign
- * be written up in a specific informed consent which you will also be asked to sign.

35. Is there someone I can ask if I have questions or problems that arise while I am in the trial?

If you have any questions or problems you should always ask the trial investigator first. They will be able to help you.

36. If the treatment works, will I be able to carry on getting it after the trial has ended?

It should be remembered that in most trials the different treatments are allocated randomly to the patients who enrol and neither you nor your doctor can choose which one you receive. Furthermore, most trials are also conducted 'blind' and neither you nor your doctor will know which of the treatments you are receiving until the end of the trial. If, at the end of the trial one treatment is found to be better than another, the opportunity to move onto the better treatment may be discussed with you, if it was not the treatment that you were receiving during the trial.

Clinical trial glossaries:

IFPMA website: <http://www.ifpma.org/clinicaltrials.html>

Roche website: <http://www.roche-trials.com/about/glossary.html#c>

US website: <http://www.clinicaltrials.gov/ct/info/glossary.jsessionid=E0E2ED626151A51917D61195F996FD92>

<http://www.nelh.nhs.uk/clinicaltrials/glossary.asp#eligibility>