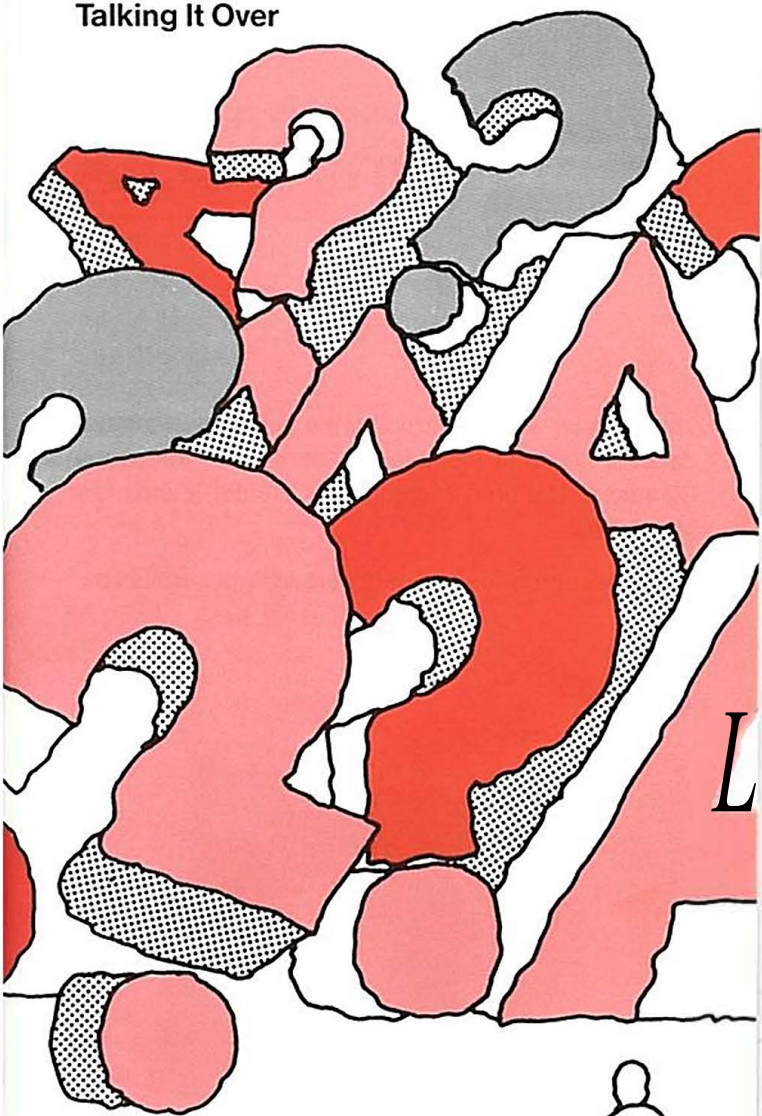
AIDS Clinical Trials

Talking It Over



U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Public Health Service
National Institutes of Health

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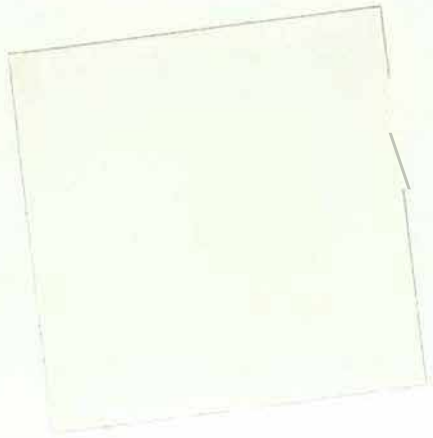
This booklet was prepared by the Office of Communications, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland.



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Acknowledgments

I : e National Institute of Allergy and Infectious Diseases and the medical centers that run clinical trials worked together to plan and produce this booklet. It was developed by talking to the doctors, nurses, and patients who take part in clinical trials for AIDS. They told us what people want and need to know when they're deciding whether a clinical trial is the right choice for them.

The people quoted in the booklet agreed to be part of this project to give others the benefit of their experiences. They are cited by first name only, to protect their privacy. NIAID gratefully acknowledges their important contribution to this project. NIAID would also like to thank the many persons who reviewed this booklet and provided valuable comments. We particularly acknowledge the National Association for People With AIDS for their assistance with recruiting reviewers for this booklet.

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Preface

"Clinical trials of experimental drugs are the only way to find out which drug works and which does not, and which drug is safe and which is not. All of us share a sense of urgency to see that safe and effective drugs to fight HIV infection and AIDS are discovered, tested, and made widely available as soon as possible."

Anthony S. Fauci, M.D.
NIAID Director

The National Institute of Allergy and Infectious Diseases (NIAID) is one of the National Institutes of Health, the research arm of the U.S. Public Health Service. NIAID scientists conduct research on AIDS, and NIAID also provides funding to scientists outside of government who are doing AIDS research.

One of NIAID's goals is to find ways to treat diseases caused by HIV (the virus that causes AIDS). NIAID is testing new treatments in people with HIV infection. These research studies are called clinical trials. Careful clinical trials are the fastest and safest way to find out which treatments work.

At hospitals across the country, NIAID has set up a group of research centers, called AIDS Clinical Trials Units (ACTUs), where these tests take place. All these ACTUs together make up the AIDS Clinical Trials Group (ACTG). In addition, doctors who are part of NIAID's Community Programs for Clinical Research on AIDS are conducting studies of AIDS drugs at hospitals and clinics in the communities where the impact of the AIDS epidemic is severe. NIAID is also conducting studies at the National Institutes of Health. Clinical trials sponsored by drug companies, other government agencies, and private research organizations are also taking place.

People with HIV can volunteer to take part in these studies, and that is what this booklet is about-to help you learn more about clinical trials. Is a research study right for you (or your loved one)? The information in this booklet gives you the facts that will help you make your choice.

Clinical Trials: Talking It Over

This booklet is for people who are thinking about taking part in a study to test new drugs for HIV (the virus that may lead to AIDS). This includes people who have:

- AIDS (acquired immune deficiency syndrome);
- Some symptoms of HIV (sometimes called ARC, or AIDS-related complex); or
- HIV, but no symptoms of disease.

Joining such a study, which is called a clinical trial, is a big step. You need to find out all you can about what a trial may mean for your care, for your daily life, for those close to you, and for other people with HIV, ARC, or AIDS.

In this booklet, doctors and patients who are in clinical trials talk about what trials mean to them. They answer basic questions most people have, such as:

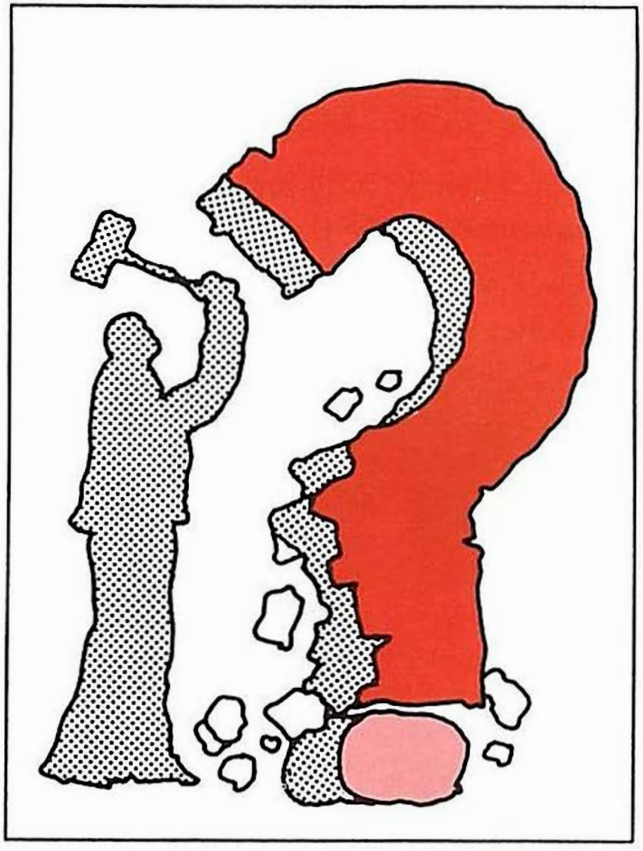
- What is the purpose of clinical trials?
- How do they work?
- What trials may be open to me?
- What is it like to be in one?

At the end of the booklet, you'll find a checklist of issues you should think about-and talk to your doctor or nurse about-in making up your mind. Page 23 explains common terms you may hear as you ask about clinical trials.

Clinical Trials: Research for Progress

Today there are more questions than answers about how to care for people who have the AIDS virus. The research studies known as clinical trials are a key step in getting more answers.

Dr. Daniel Hoth, director of the Division of AIDS at NIAID, explains how the studies can help. "Without clinical trials," he says, "finding a drug to treat AIDS would be like looking at a shelf with 20 bottles of medicine. You think some of them will work, but you don't know which ones. The purpose of clinical trials is to find out. Then doctors can give their patients only the drugs that will help, and only those that are safe to take."



How Studies for AIDS Have Helped

Clinical trials for AIDS are new. Many are still in an early stage, needing more patients or more data before they can get good answers. But already trials *have* led to better treatments.

"Thanks to well-run clinical trials," Dr. Elaine Eyster of the Hershey Medical Center notes, "we now have a treatment that helps some AIDS patients live longer: the drug AZT. Atter only a year and a half of clinical testing, the studies found that patients with AIDS and ARC clearly lived longer when taking AZT. Within 6 months of this proof, more than 4,000 AIDS patients began to benefit from the new treatment."

Every trial will not find a drug that works. But studies also help improve care by finding that a drug clearly does *not* work. And every trial answers more questions, which brings us closer to the goal: effective ways to prevent, delay the onset of, and treat AIDS.

How Do Clinical Trials Work?

"In doing clinical trials," notes Dr. Paul Volberding of San Francisco General Hospital, "we use the proven methods of science. The process is careful and exact. It can't always move as fast as we'd like and still give us results we can trust. But these methods have helped find good treatments for cancer, heart disease, and other infections. We can also rely on them to help us find better treatments for AIDS."

In early small studies, where the drug is being tested for safety and dose, each person who takes part gets the new drug being tested. In the larger trials that follow, doctors compare the new drug with another treatment to see which works better. These studies work like this:

- One group of patients gets the new drug.

- Another group gets a drug that is now used to treat the problem. If there is no drug that works for that problem, this group may get a look-alike pill that contains no drug (called a placebo).
- Doctors compare the progress of the two groups to see if the people who got the new drug had better results than people in the other group. Did their symptoms go away? Did they stay healthy longer? Did they have side effects from the drug? These are some of the questions clinical trials answer.

A key step in the process for patients is talking to research staff about what happens during the trial. Before you begin treatment in a study, the nurses and doctors explain why the trial is being run, risks you may face, how you may and may not be helped, what you will need to do, and how the study will work. Page 20 contains a list of questions you may want to bring with you when you talk to the staff. The list may help remind you of issues to raise.

You may also want to bring someone close to you to this meeting. Your loved ones may want to find out what the study will mean for your health and daily routine. And talking the issues over with them later may help you decide whether a study is right for you.

Research versus Treatment

Being in a clinical trial is different from being treated by your own doctor. In private treatment, the doctor's only aim is to help *you.* In a clinical trial, the doctors and nurses also want to help you. But the main goal is to find treatments that work for *many patients.*

Research studies differ from private treatment in three key ways.

1. *Trials follow strict guidelines.* They won't "bend the rules" for one patient, and they can't take short cuts. "We know what it takes to do a study right the first time," says Dr. Margaret Fischl of the University of Miami. "We have to be strict to get answers we can rely on. Then we can give the right drugs to the right patients more quickly- and save time and money that can be used to test other promising drugs."

2. *Trials may not always offer you a treatment that works.* In a study, no one knows if a new treatment will help, or how much it will help. You may not get the new drug, or the dose you get may not be what would help *you* the most. The treatment plan is set up to answer questions about the drug, such as which dose will work best or whether it should be given as a pill or a shot.

3. *Science sets a trial's length.* You may be in a study longer than you would like. Or it may end sooner than you'd prefer. A trial lasts as long as it needs to for valid results.

There's one more difference that can mean a lot. In private treatment, a patient can only help one person- himself or herself. In a clinical trial, he or she is helping to test new treatments that could bring a longer life and better health to many others.

Questions About ...The Availability of Clinical Trials

What types of drug studies are there for people with HIV?

Three types of drug studies with HIV patients are under way. These include studies of:

- Drugs that may control the virus that causes AIDS. Such drugs may be able to prevent or delay the onset of full-blown AIDS.

  Examples: AZT. foscarnet, dideoxycytidine, dextran sulfate

- Treatments that may strengthen the immune system. The AIDS virus weakens the immune system, and leaves the body open to other infections. This approach may "rebuild" the immune system and help the body fight off other infections.

  Examples: interleukin-2, alpha-interferon

- Treatments for the infections and cancers that attack AIDS patients. When these infections can be treated, patients have longer, more active lives.

  Examples: aerosol pentamidine to treat pneumocystis pneumonia;
  AZT plus interferon for Kaposi's sarcoma;
  foscarnet for cytomegalovirus infection.

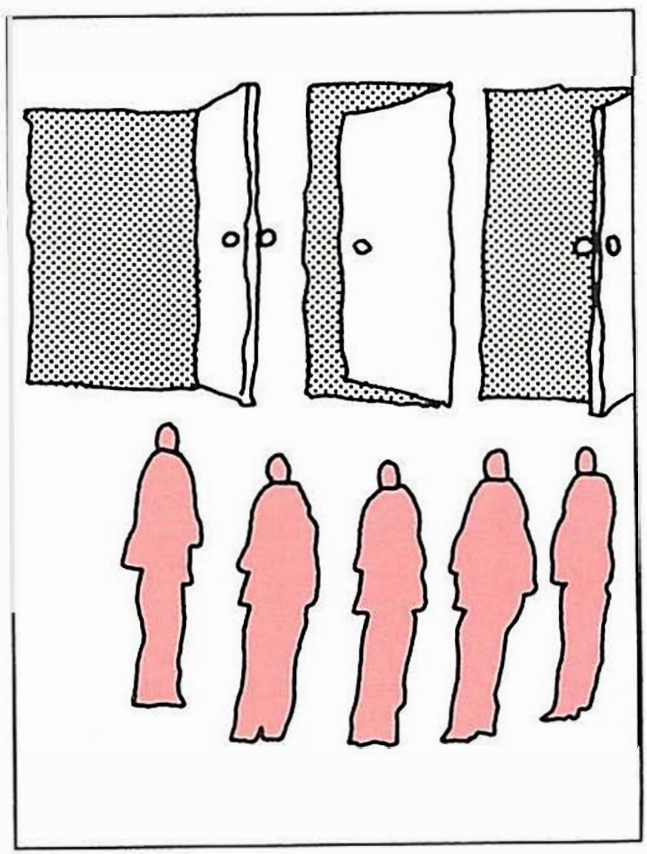
Can anyone with HIV join a clinical trial?

Each study tests a new treatment on groups of people who all have the exact type of problem d.octors think the new drug may help. Lab tests confirm whether a person has the health picture the study is looking for. Only people who match a study's exact needs will be right for that trial.

Why are trials set up in this way? "AIDS is a very broad disease," says Dr. Volberding. "It involves many types of patients and problems. To get results that have clear meaning, we focus on one patient group or one type of problem. For example, certain drugs may only work at one stage of the disease. A drug that helps a person with AIDS may not help a person with HIV but no signs of illness. When we define what we're looking at very tightly, then we know just how-and who-a new treatment can help."

Where do clinical trials for AIDS take place?

Most trials take place in large medical centers or hospitals. Sometimes private doctors and local clinics also test drugs.



Clinical Trials: Are You Eligible?

Referral: Patient finds out about a study from his or her doctor or other source. The patient or doctor contacts the research staff to find out if the study might be open to the patient.

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Counseling: Research staff explain the purpose of the trial, the risks, and what the patient will be asked to do.

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Testing: Patient takes a number of tests, such as physical exam, blood work, biopsy, or x-ray.

↓

Results:

Either:

Patient's test results meet the trial's needs.

↓

Outcome: Patient signs informed consent form and enters the trial.

Or:

Patient decides not to take part.

Or:

Patient's test results do not meet the trial's needs.

↓

Patient returns to private doctor or clinic for care. He or she may look for other trials.

Must I live near a clinical trial to take part?

Each trial has its own rules. "Studies often mean many clinic visits," Dr. Fischl notes. "We need to be sure that people who join won't drop out because it's too far or too hard to come once a week."

How can I learn what trials may be open for my problem?

See page 28 for places to call.

How do I find out if I'm eligible for a trial I'd like to Join?

The chart on page 8 briefly outlines how patients find out if they fit a trial's profile.

If you want to find out about getting into a trial, try to work with your doctor or AIDS clinic. The process often moves faster when a private doctor talks to a study's doctors about the medical issues. Then your own doctor can explain the fine points to you.

"If you don't fit one trial's needs," notes Debbie Katz, R.N., a special assistant at NIAID, "don't feel that you have 'failed the test.' New trials will continue to open."

Questions About ... Benefits and Risks of Trials

What are the benefits of being in a clinical trial?

Doctors and patients highlight five major benefits.

1. Patients have a chance to help others.

"I've never been a social activist," says John, a person with HIV. "But it means a lot to me now to know that I am part of a test that could help many people with HIV. Yes, I have a serious problem. But I'm trying to be part of the solution."

2. Trials offer access to top medical care.

"When I found out I had HIV," says George, "the doctor almost told me to go away, and to come back when I got sicker. In my research study, the doctors

and nurses are HIV experts. They give me the most up-to-date care. And the whole staff is warm and caring."

Bill, another patient, adds, "The key thing to me is all the tests we get in the trial. When you have this disease, you can worry about every cough or blemish. It really helps my state of mind to know I'm being watched with care."

Dr. Donald Armstrong of Memorial Hospital in New York talks about the value of the team approach. "Patients in a trial have doctors, nurses, psychologists, social workers, and pharmacists all working with them. This is comprehensive care."

3. *Joining means taking positive action.*

Kevin is a patient who has HIV infection with no symptoms. "From all I read," he says, "it seemed like it was just a matter of time before I became sick. I got into a trial because I felt I had to do something to try to help myself. Otherwise I was letting the disease take control of me."

4. *Patients may be among the first to be helped by a new drug.*

"When a new drug is proven to work, those in the study are the first to benefit," notes Dr. Volberding. "This chance to be helped is a chance many people are willing to take."

5. Some *costs are paid.*

"The tests and drugs that relate to a trial are paid for by the study," explains Dr. Armstrong. "At our center we charge only for care that isn't part of the research."

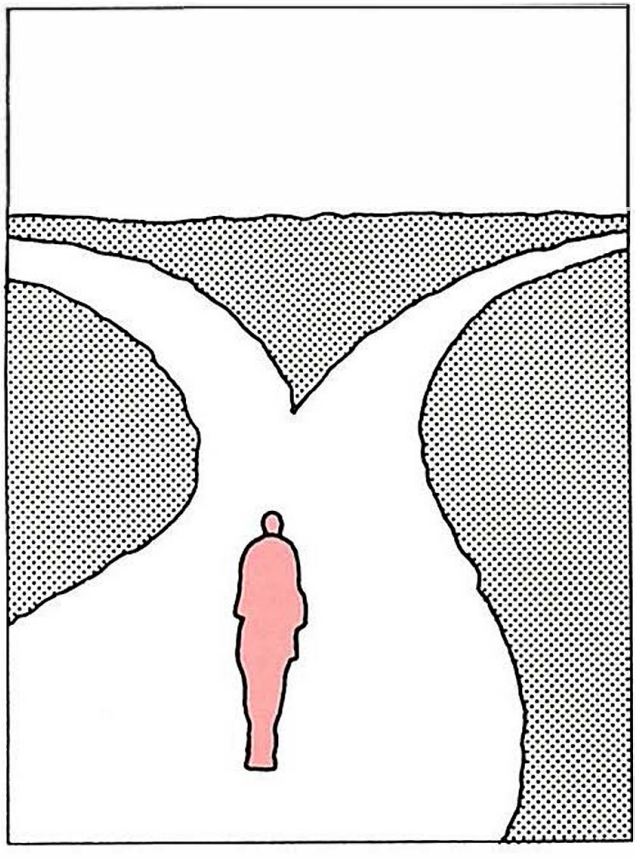
Every study offers some services free of charge. But each has its own policy about what is covered. State agencies and insurance companies also have different policies about what they will pay for. You should get all the facts before you enroll. Page 21 has a list of questions that can help you know what to ask about costs.

What risks might I face in a clinical trial?

Drugs used in clinical trials have already been through much testing in the lab. But when people first take a drug, there are still many "unknowns." Treatment in a trial can carry three major risks.

1. The treatment may not have benefits.

"The reason for clinical trials," Dr. Fischl underlines, "is to find out what will work and what will not. A new treatment may not help anyone. Or, because every person is unique, it may help some people but not all."



2 The treatment may be harmful.

Dr. Eyster says, "There is a chance that any drug may cause harm. A main reason for studies is to find out if people will be hurt by taking a new treatment.

"We watch people with great care. But there are always unknowns. Treatment could in fact make a person worse."

3 The drug may have side effects.

"The greatest fear people have," Joan believes, "is side effects. I worried that I'd feel worse from side effects, even if the drug was helping my disease."

Finding out a drug's possible side effects is one of the reasons clinical trials are held. Side effects in AIDS trials often do occur. "When they are serious," says Dr. Eyster, "we can take the patient off that drug, or the patient can decide to leave the study."

One patient talked about the side effects of all the drugs he takes. "I swallow my AZT pills and I get a headache. I take a shot of interferon and my arm aches. I inhale pentamidine and it makes me tired. Sure it's a bother. But would I rather give up on the chance to help and maybe be helped? No way."

Questions About ... Clinical Trials and Your Quality of Life

How much of my time will a clinical trial take?

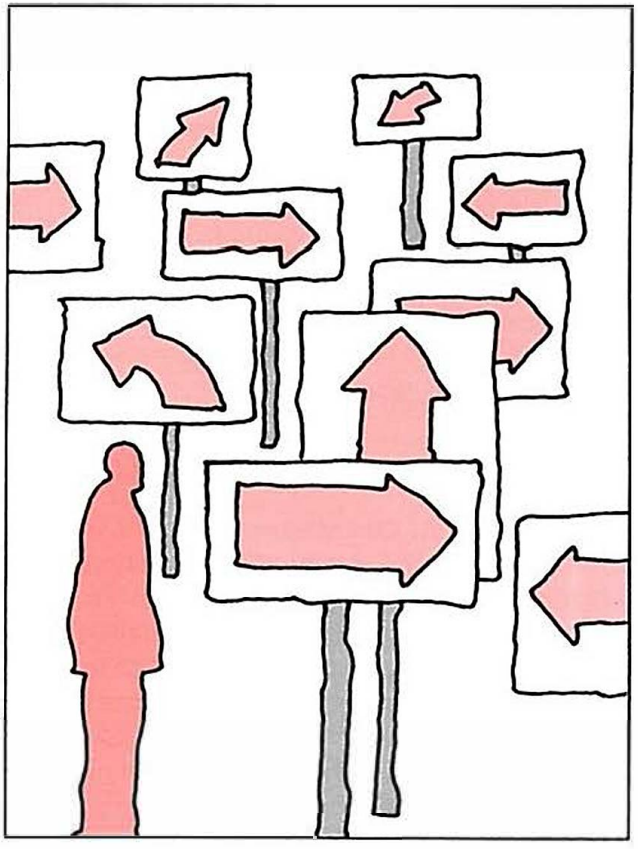
Every trial is different. It's a good idea to find out what the demands will be before you agree to take part.

In general, people visit the Clinic more often at first. Later, they don't need to come in as much. Earl says he started by coming in about twice a week. After 6 months, it was once every 2 weeks; now he goes only once a month.

How long does it take once you're there? It varies. But you can count on spending from one to several hours per visit.

Most studies see patients only during normal business hours. If you work, you may want to ask about how you can fit clinic visits into your work day. Study nurses may also have other ideas about how to make the visits easier. Ask them what has worked for other people.

When you think about time, don't forget to include travel time. Earl is only half an hour from his clinic by bus. But Maria is 130 miles from her center, a few hours by car.



Will I have to go through a lot of tests?

The number and kind of tests given vary from study to study. And some people do find all the blood tests a drawback. Yet research studies depend on tests.

"Careful tests and records," says Or. Armstrong, "are what research is all about. We need the facts to measure patient progress."

Can I still see my own doctor?

Most studies urge people to keep seeing their own doctor, if they have one. "Having HIV doesn't mean I have no other health problems," Linda says. "My own doctor treats these. He also talks back and forth with doctors from the study."

How will treatment affect my daily life?

Each trial has its own treatment plan. John has to take his pills six times a day, including during the night. He has to be careful not to take his tablet after greasy food. Kevin has to keep a daily record of any health problems or changes, no matter how small. He also writes down any non-trial drugs, such as aspirin, that he takes.

For some patients, it is hard to remember to take their medicine and keep their records. Others say it becomes second nature.

"My daily life is better because I take AZT," Earl believes. "I am staying well, so life is liveable."

Questions About ... Ethical Issues

I don't want everyone to know I have HIV. If I join a trial will others find out?

"All trials must set up strict systems to protect your privacy as part of the research plan," Or. Fischl replies. "At Miami, for instance, we use code numbers instead of names for all tests and records. The codes are locked in a safe. We never give out records, unless the patient signs a form that says he agrees."

Or. Eyster adds that at the Hershey Center, "People only find out who's in a study when the patients themselves talk about taking part."

Each center has its own system. Ask the research team at your center to explain how they will handle your records.

What safeguards protect people who take part in a study?

Five safeguards protect people who take part in drug studies.

1. Informed consent.

"This means we need to explain all about a study before a person agrees to enter," Dr. Volberding says. "We talk about the reasons for the study, risks and benefits that may occur, and what goes on during the trial. The people who want to join sign an informed consent statement. This says that they understand what's involved and that they agree to enter."

"The doctors and nurses will spend all the time you need to help you understand," comments Roy from New Orleans. "My group session lasted almost all day. We asked a lot of questions. But by the end, we knew what we were getting into!"

Page 20 contains a list of questions you will want to ask the doctor or nurse before you decide on a clinical trial.

2 NIA/0 review of the study.

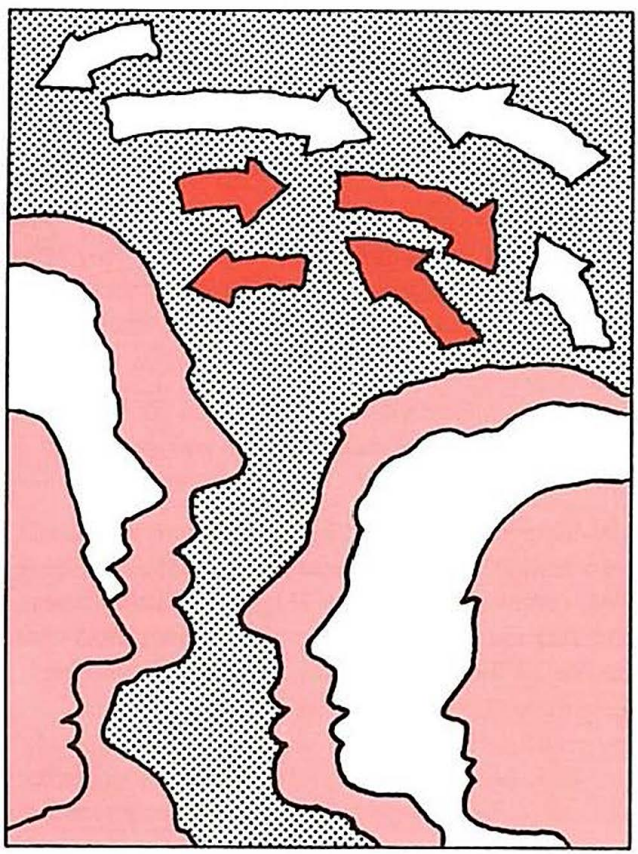
For the trials NIAID sponsors, experts in and outside NIAID review all study plans. They look at safety issues. And they make sure a trial is well-planned and uses the best methods of science.

3. Local review of a trial.

Before a trial begins, every hospital that takes part has the plans looked at by a special board. The board includes doctors, science experts. and others (such as clergy). They look at whether the promise of success is great enough to let people take the risks involved. They also check plans to protect patient safety.

4. Safety board review of a trial.

Many clinical trials have to show all their data to an outside, watchdog group. This safety board is made up of experts with no ties to the trial.



"The board reviews all a trial's data while it is still going on," explains NIAID's Debbie Katz. "They check to be sure that people are not being harmed by the treatment. In the trial that first proved AZT's value, the board stopped the study early. It was already very clear from the data that the drug had helped. With this proof, it would have been unfair to keep the drug from other patients."

5. Patient's right to stop treatment.

"A patient can leave a study at any time, for any reason," Dr. Eyster says. "Doctors also stop any treatment that is causing harm. For example, AZT makes some people very ill, even though others can take it with few problems. When AZT hurts a person, we lower the dose or we stop it."

"When I joined my trial," Kevin adds, "I was worried that I might be hurt by the new drug. But I figured, what did I have to lose? If I started feeling a lot worse, I would leave the trial."

Why do some trials give the new treatment to only some of the patients?

Studies that test new drugs often compare the progress of one group who gets the new treatment with that of a second group who does not. Dr. Eyster explains the reasons.

"To see why we need to compare, say for a moment that we *did* give each person in a study the new treatment. And say we saw some people improve. How could we be sure that people got better because of the new treatment? They could have improved on their own or for some other reason.

"When we compare, we see that a similar group of people who did not get the new treatment did *not* get better. Then we can feel sure that the new treatment made the difference."

Patient to Patient

"Don't be afraid of the drugs in trials. They may make you ill at first; and you may wonder why you're doing this to yourself. But half of it is your mental attitude. You have to work with it to make it work."

Earl

"I've known too many people who died taking some weird 'cure' they got from Mexico or somewhere. I've been in a research study for two years, and it isn't always easy. But the treatment makes sense."

Steven

"Since I found out I had HIV I've been in two studies. There was a 6-month stretch between them. During that time. I felt very alone, scared. paranoid ... it was the worst time in my life. Now I know how much being in a trial helps my mental health."

John

"Being in a trial means making some sacrifices, keeping up your end of the bargain. It's worth it to me. But you should get all the facts before you decide. There's no point in starting it just to drop out."

Maria

"How has the trial changed my life? I have HIV with no symptoms. For a while, I put being sick out of my mind. Of course, I was only fooling myself. But now I can't deny that I have a disease. The pills and the tests remind me of it everyday."

Kevin

"You've got to *do* something. Even if that only means finding out about all your options. You may decide not to join a trial. But you made a choice-you took control."

Linda

Almost all NIAID research studies today compare the new treatment with a drug already in use to see which works better. In a few cases, when there is no known drug that helps a problem, a study may compare the new treatment with a look-alike pill that contains no drug (placebo).

"Some people feel that it isn't humane to give a placebo in a disease like AIDS," Dr. Volberding says. "It's easy to understand their feelings. But, in fact, using a placebo can be the most humane choice. Because of its design, the test can be shorter. We find answers we can fully believe in. And fewer people need to be put at risk."

In all placebo studies, clinic staff tell people before they join that there is a chance of getting a look-alike drug. Then it is their choice whether or not to enter that study.

Why can't people in a trial take other drugs that may help them?

Sometimes they can. Each trial and each case is different. Steven, for instance, is taking AZT and interferon in his trial. His private doctor also gives him aerosol pentamidine, with the trial's agreement.

When other drugs are not allowed, it's because they could confuse the trial's results. "We could see people getting better and think it was due to the test drug," Dr. Armstrong notes. "But maybe the drug they took on their own was the reason.

"At our center. we believe doctors and patients have to talk openly about the 'other drug' issue," he adds. "Maybe we could have them go on a study where the drug they wanted *would* be allowed. At least if we know what they're taking, we can be smarter when we look at their results."

Thinking It Over...
Is a Clinical Trial Right for Me?

Are you thinking about joining a clinical trial? First, get all the facts you need to make your choice. Then be sure how *you* feel about the issues. Here is a checklist that can help.

The first part is a list of questions to ask your doctor and/or the staff of the trial you are looking into. The second part is a list of questions to ask yourself.

Questions to Ask the Doctor:

Facts about the study

- What is the purpose of the study?
- Who is running the study?
- Who is paying for the study?
- Who will review the results?
- What treatment(s) may I receive?
- Does the study use a placebo?
- Why do doctors believe that this treatment may work?
- How will the study keep my name and records private?

Risks and benefits

- Does the treatment have any known side effects?
- Are there any other risks?
- How may I be helped by the new treatment?
- What other options for treatment do I have?
- How do the pros and cons of my other options compare with those of the study?

What treatment will involve

- How long will the trial last?
- How often will I need to come to the clinic?
- How many times a day will I need to take a drug?
- What other things will I need to do?
- How is the drug given-as a pill, in a shot, or in another way?
- What tests will I need to take?
- Will I be able to see all my test results?
- Who will treat me in the study?
- Will a social worker (or other trained staff) provide support and help me deal with problems?
- Will I see the same doctor or nurse each time?
- Can I keep seeing my private doctor, if I have one?
- Where will I be treated after the study?
- If I take a drug that helps me, can I keep taking it after the study is over?

Costs

- What costs will be covered by the trial?
- What other costs can I expect?
- Does insurance usually cover the costs that a study does not pick up?
- What other help with costs is available?

Questions to Ask Yourself:

- Is helping to find better treatments for HIV important to me?
- Can I accept the changes a trial may make in my daily life?
- Am I committed enough to:
  - take the drug as often as I should?
  - go to the clinic as needed?
  - stick with a trial as long as it lasts?
- Am I willing to follow all of a trial's policies?
- Are the pros of taking part greater than the cons?
- Will I have the support of my friends and family?

Clinical trials. A research study in which people take part. A clinical trial tests new drugs and other treatments to see whether they help people get better. The research plan for a study is strict and follows the rules of science. Studies must be careful and thorough to give doctors and patients results they can trust.

Controlled study. A study in which doctors give the new drug being tested to one group of people. This group is often called the treatment group. They also give another drug, or no drug, to a second group of people with the same type of illness. This group is often called the control group. Then they compare the results of the two groups.

If people taking the new drug get better-and people taking the other drug (or no drug) do not-we know that the new drug works. Using a control group lets doctors be sure the new drug, and only the new drug, caused people to improve.

If the new treatment group does not improve more than the control group, we know that the new drug does not work any better than the treatment the control group was taking.

If many people in the treatment group get sicker, and people in the control group do not, we know that the new drug is not safe.

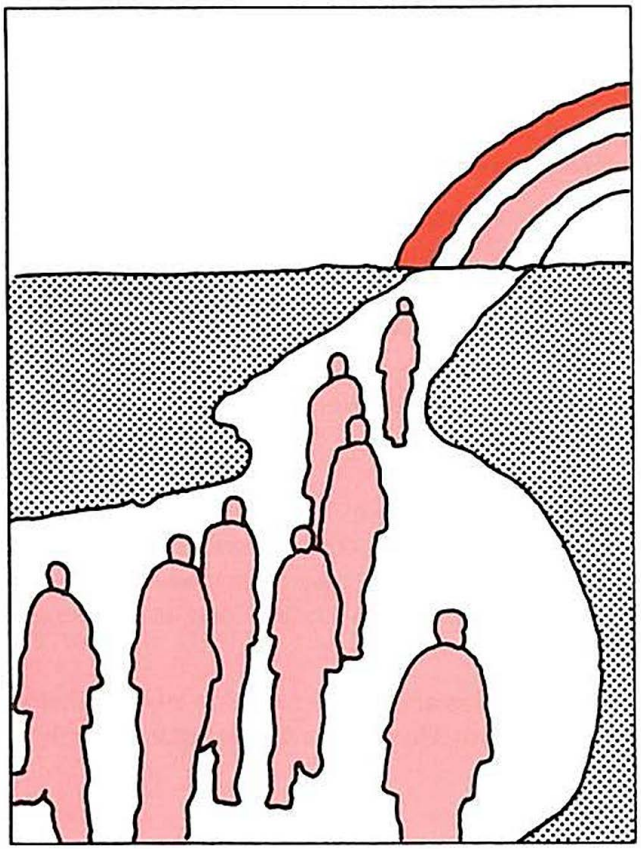
Double blind. A type of study in which neither the patient nor his or her doctor knows which treatment the patient is getting. It may be the new drug being studied. Or, it may be the "control" pill that doctors are using to compare results.

Some studies are "single blind." In these, patients do not know what treatments they are getting but their doctors do.

Why is blinding needed? When people take a pill that they believe will help them, they often see signs that they are getting better-even when they are not. The reverse may also be true. Doctors, too, may read the signs wrongly, because of what they *expect* to see.

When a study is blinded, no one expects a certain outcome. They see results as they are, with no false ideas to confuse them.

In all blinded studies, treatments are coded for safety. If a drug is harming a patient, the doctor can quickly find out which treatment it is.



Eligibility criteria. Key facts about a person's health that make a patient right, or not right, for a certain research study. Examples of these facts include: a person's age; what symptoms of HIV or other illness he or she has; results of certain lab tests; a person's overall health; and past treatments he or she has had.

To be right for a study, a person's health picture has to match all the study's needs fully.

First, you need to have all the health factors that are listed in the study's research plan (called *inclusion criteria).* Each person who takes part will have these same factors, so that doctors can compare like with like.

Second, the research plan lays out some health factors that people who take part in a study *cannot* have (called *exclusion criteria).* Often, this is done for safety. For instance, doctors may know or fear that the new drug will cause people with a certain illness or lab test result to get sicker. It would be wrong to allow them to take that risk.

Both the "must have" and the "can't have" checklists help doctors get clear research results. By working only with people who match these lists, doctors can be more exact about who a new drug will help, not help, or harm.

Informed consent. Each study paid for by NIAID must explain the project to all persons who ask about taking part. You have a right to know how you may be helped, if you may be harmed, or if you may have no change for the better. The research team should also tell you what joining a study will mean to your daily life: what tests you will receive, how often you'll need to come in to the clinic, costs, etc. (see checklist on page 20). After learning all about the study, you will decide whether or not to take part.

If the answer is "no," that's fine.

If the answer is "yes," you will sign a form that says you know the pros and cons of taking part and what the study involves.

Each study tries to do a good job of giving people the facts they need to make a sound choice. But if you are still unclear on any point, keep asking questions. It is your right-and you owe it to yourself to be sure.

Institutional Review Board (IRB). A group of doctors, science experts, clergy, and others who review a research plan. For all studies paid for by NIAID, each hospital doing the research must have an IRS. This board makes sure that the study protects patient safety. They will only approve a study if the benefit it may bring is likely enough and great enough to allow the risks people may face by taking part.

Placebo. A pill or liquid used in research studies that contains no drug (sometimes called a sugar pill). A placebo looks just like the real drug. This way, patients and their doctors in a blinded study don't know who is taking the new drug and who is taking the "no-drug" pill.

For HIV, studies only use a placebo if there is no proven treatment that doctors could use to compare with the new drug. Page 17 talks more about why some HIV studies need to use placebos.

Randomized study. A study that assigns each person by chance to the treatment group or the control group.

Why do studies put people into groups at random? This method keeps a study's results free of bias. For instance, doctors could "stack the deck" for a study without meaning to. They might assign people to groups based on their ideas about who would be helped most by the new drug, or based on some other point of view.

When the results came in, no one could be sure that the doctors' case-by-case choices didn't affect the outcome in some way. Then no one could be sure that other patients would get the same results from the treatment.

Steps in Drug Testing

The process of finding safe new drugs that work well is complex and includes many lab tests, trying out the drug in animals, and, if it shows promise. testing it in people. To protect patient safety, the U.S. Food and Drug Administration requires that drug testing in people be done in steps or phases. The drug must be found safe and/or effective in each phase before it can move on to the next.

Type of Trial	Number of Patients	Length	Purpose	Method
Phase 1	20-100	Several months	To see if drug is safe	All patients get the drug being tested.
Phase2	Up to several hundred	Several months to2years	To test effectiveness and short-term safety	In phases 2 and 3, doctors compare results for two groups; the first gets the drug being tested; the second gets another drug.or no drug.
Phase3	Several hundred to several thousand	1-4 years	To test safety, effectiveness. dosage level	

How to Find Out More

Ttiere are several places you can go to find out more about AIDS and AIDS drug trials.

- Your doctor. This is the place to start to learn about trials in your area.
- AIDS Clinical Trials Information Service (ACTIS). Staff will tell you about trials for AIDS patients and others infected with HIV. You can ask for a list of new drugs being tested, where the trials are, and who is doing the studies. English and Spanish are spoken. Call toll-free 1-800-TRIALS-A. Lines are open Monday through Friday 9:00 a.m. to 7:00 p.m. eastern time.
- The National AIDS Hotline (sponsored by the Centers for Disease Control). The hotline can give you basic facts about AIDS as well as tell you about AIDS support groups, clinics. and other services across the country. Call toll-free 1-800-342-AIDS. Spanish-speaking callers can dial 1-800-344-SIDA (7432). For deaf access, call 1-800-AIDS-TIY (243-7889). Lines are open 7 days a week, 24 hours a day.
- The National AIDS Information Clearinghouse (from the Centers for Disease Control) is primarily for health care and other professionals. Staff can tell you about AIDS organizations and materials they produce. English and Spanish are spoken. Call (301) 762-5111 (this is not a toll-free call).
- ***AIDS/HIV Experimental Treatment Directory,*** a booklet that is brought up to date four times a year, describes drugs that are being tested and tells where the tests are going on. Call the American Foundation for AIDS Research (AmFAR), (212) 719-0033.

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