

CLINICAL TRIALS AS A TREATMENT OPTION FOR IDIOPATHIC PULMONARY FIBROSIS (IPF)

What Questions Should I Ask of the Physician (health care team) Conducting the Clinical Trial?

- What is the trial's purpose? Who is the trial sponsor?
- How do the potential risks and benefits of volunteering in this trial compare with treatments currently available?
- What is my time commitment? How often do I visit the trial site? How long is each visit?
- Do I pay any costs or fees? Do I get reimbursed for my time?
- If I have a problem (medical or other) during the trial, who do I contact, and how?
- If there is an unforeseen expense related to my participation in this trial, who is responsible for paying?
- Can I ever be taken out of the clinical trial?
- Can I withdraw from a clinical trial on my own and what steps would I have to take to do so?
- Is there a contract that explains the trial, the requirements, and my responsibilities? What steps should I take if I wish to withdraw from the trial?
- What steps do I take if the trial is stopped?
- What are my chances of receiving the experimental therapy versus placebo or control therapy?

What Is a Clinical Trial?

A clinical trial is a research study in human volunteers. Clinical trial results are used to answer specific questions about a medical condition, such as a potential treatment or cure. The results of these trials may help to identify a new treatment option for a given medical condition. These clinical trials generally have rigorously reviewed protocols and strict monitoring by internal and external oversight committees to protect the patient. An individual physician or a group of physicians can perform clinical trials.

I Want to Participate in a Clinical Trial. What Are my First Steps?

Tell your primary physician or pulmonologist about your interest in participating in a clinical trial. Discuss any concerns/issues related to your medical history. Let your primary physician or pulmonologist know if/when you begin participation in any clinical trial.

How Can I Become a Volunteer in a Clinical Trial?

Discuss your interest in volunteering in a clinical trial with your primary physician and any of your specialists (for example, your pulmonologist). Call a local university hospital or clinical trial center and ask to speak with someone about current and upcoming research projects at their facility. Keep in mind that not all volunteers will qualify to participate in a clinical trial.

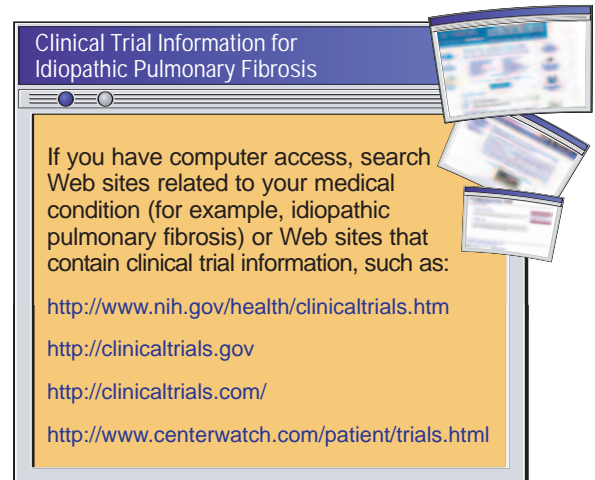
What Are the *Benefits* and *Risks* of Participating in a Clinical Trial?

Potential benefits of participating in a clinical trial include:

- Access to new research treatments before they are widely available
- Access to expert medical care at leading health care facilities at little to no cost
- An opportunity to help others by contributing to medical research
- Close monitoring of your health status by specialists

Potential risks involved with participating in a clinical trial include:

- Your participation in a clinical trial may take more time than a standard treatment approach, including travel to a study site or even hospital stays
- The treatment may not be effective for you. You may be assigned to a control group, which is a group of patients who do not receive the experimental therapy during the trial. Regardless of which group you are assigned (control or experimental), you will be closely monitored medically
- You may experience unpleasant or serious side effects to treatment
- You may be exposed to a substance not yet approved by the FDA as a treatment option. Alternatively, the substance could be approved for use, but not for the medical condition under study. Finally, this may be the first time the substance has been used in humans



Remember:

- Volunteering for a clinical trial is an important commitment, and often a rewarding experience
- Understand the different types of trials and requirements
- You are a volunteer helping to answer important medical questions. As a volunteer, you have the option to leave the trial at any time
- Be informed—**ask questions** and insist on answers before making your decision
- Your participation in a clinical trial is voluntary
- Feel comfortable before signing the informed consent—all questions are important, so please be sure you are well informed before starting a clinical trial