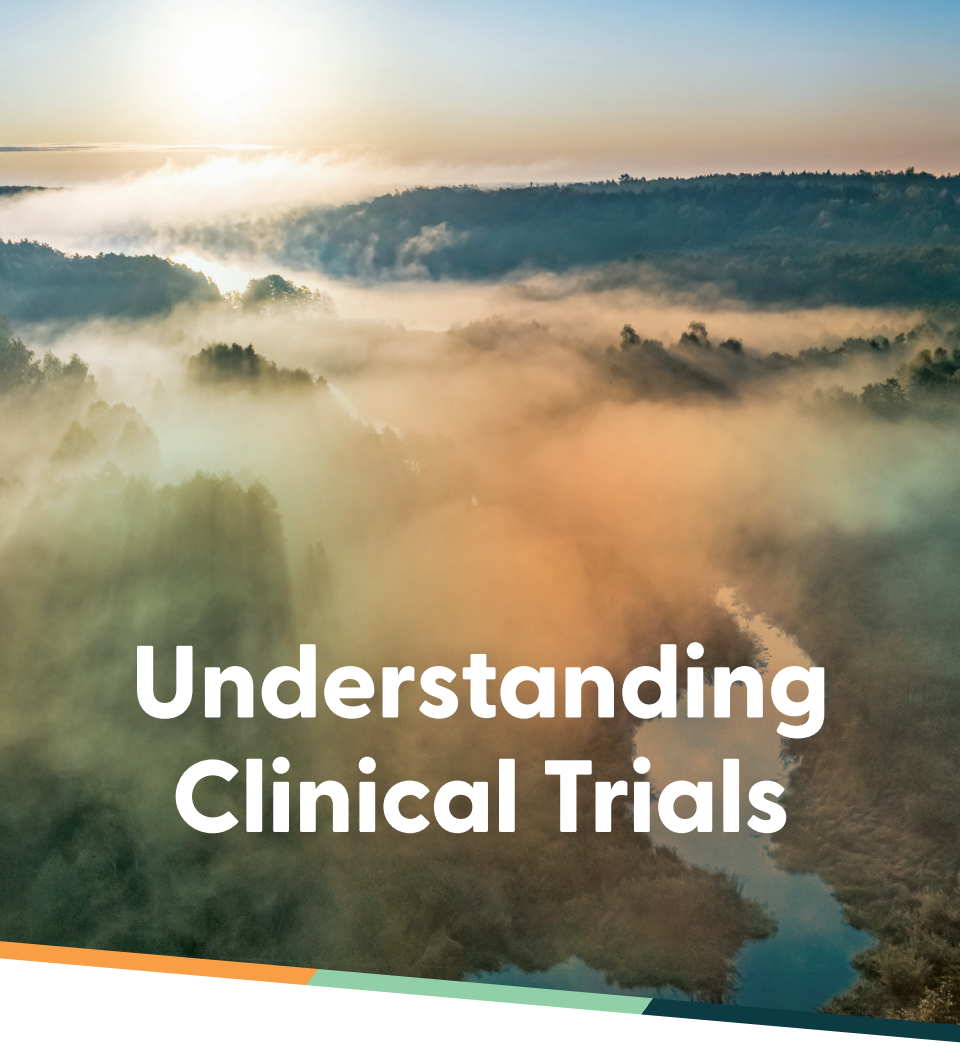

Understanding Clinical Trials

WISPer

From Breath to Breakthrough

Understanding Clinical Trials

Clinical trials offer hope for many people and are a chance to help researchers find better treatments for others in the future. The information that follows will provide you with a basic understanding of clinical trials. The more you know about clinical trials, the better prepared you will be when deciding if participating in a clinical trial is the right choice for you.

We encourage you to have conversations with your doctor about all your options, including clinical trials. Consider asking questions such as:

- Is there a clinical trial going on right now for IPF?
- What investigational medication or treatment is being studied?
- What are the potential risks and benefits compared to standard treatment?

What is a clinical trial?

A clinical research study, also called a clinical trial, is a carefully designed scientific evaluation of an investigational medication or treatment that is conducted by doctors and researchers.

Trials are conducted in four phases:

1. Phase 1 trials examine the safety of an investigational medication in healthy people.
2. Phase 2 trials involve the assessment of safety, efficacy, and establishing the appropriate dosing regimens in patients.
3. Phase 3 trials confirm the efficacy and safety findings from Phase 2 trials of an investigational medication in patients.
4. Phase 4 trials are conducted after an investigational medication has been approved to gather additional efficacy and safety information about how the drug performs 'in the real world' as opposed to in a controlled trial.

Who can enroll in a clinical trial?

All clinical trials have a set of guidelines called eligibility criteria that determine who can participate. The eligibility criteria are based on factors such as age, gender, the type and stage of a condition, previous treatment history, and other medical conditions. It is important to note that the eligibility criteria are not used to reject or accept people personally. Instead, the criteria are used to identify appropriate participants and help keep them safe.

Why should I enroll in a clinical trial?

You should only participate in a clinical trial if you and your healthcare provider feel comfortable with the details of the trial and believe it is a good option for you. When you participate in a clinical trial, you also help others by contributing to medical research.

Is it safe to be in a clinical trial?

Research is conducted for many years before an investigational medication advances to a clinical trial. Negative effects are possible. You will be fully informed of all known risks and the potential for unknown risks before you start. During the trial, your study team will carefully monitor your health and safety. You should report any concerns to your study physician.

What safeguards are in place?

An independent review board is involved in every clinical trial to help ensure the protection of participants. These can be called Institutional Review Boards (IRB) or Ethics Committees, depending on where you live. These boards are responsible for reviewing and approving research before it begins and for conducting regular reviews while the study is ongoing. Their revaluation involves a series of steps that include:

- Identifying the risks associated with the research, compared with the risks the participants would be exposed to even if not enrolled in the study
- Determining that the risks will be minimized as much as possible
- Identifying potential benefits of the research
- Determining that the risks are reasonable considering the benefits to the participants, if any, and the importance of the knowledge to be gained
- Assuring potential participants will be given a fair, accurate description of the risks or discomforts and the anticipated benefits of the research
- Determining intervals of periodic review of the study

Will the research help me personally?

The purpose of this study is to evaluate the safety and efficacy of an investigational medication in patients with IPF. A clinical trial may or may not help you personally, but it will provide researchers with valuable information about treating IPF in the future.

Will I be informed of the benefits and risks?

Each clinical trial has a well-documented plan, or protocol, about what you will need to know and what is expected. Your study team will keep you fully informed about the plan, including all known benefits and risks of the research. If there is a significant change in your health while you are participating, the study doctor will inform you and discuss your options, as your physical and mental health are of paramount importance. You are encouraged to ask any questions at any time. If you decide to participate, you will be asked to sign an informed consent form.

What do I have to do in a clinical trial?

Activities vary between clinical trials; however, most require regular medical examinations. Some trials involve taking either an approved or investigational medication, while others involve a procedure. Your study doctor will discuss these details with you. You may be asked to record information about how you are doing. You also may be asked to return for follow-up visits to evaluate whether the research is producing the intended results.

What if I change my mind?

You can withdraw from the study at any time, for any reason. Even if you begin the study, you can change your mind at any point. The study doctor will discuss your care options with you if you decide to withdraw from the study.

Will my information remain confidential?

Participant information is confidential; however, your provider may be required by law to share your information in certain situations. If information from the trial is published or presented at scientific meetings, your name and other personal information will not be used. The clinical trial sponsor, and regulatory agencies, also may review the research files and medical records.

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To learn more about this clinical trial, please visit **wispertrial.com**

WT0002-20250610-1

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