



Clinical Trials in Pulmonary Fibrosis

A clinical trial is a research study that tests whether or not a treatment works. The effect of the treatment on each person is closely monitored and the information is used to understand whether the treatment is safe and effective and how to improve it. Clinical trials are particularly important when treatment options are limited, such as for Pulmonary Fibrosis (PF).

People who take part in clinical trials are volunteers. Clinical trials are approved and monitored by an Ethics Committee, to make sure that participants are safe and their rights are protected.

Why should you consider taking part in a clinical trial?

Clinical trials have made a big contribution to new treatment options for people with PF. Although laboratory research is important to invent new treatments and understand how they work, clinical trials are vital to understand whether these treatments are beneficial when used in people. If you take part in a clinical trial, you may

get access to a new treatment whilst it is still in the testing phase, however, there are no guarantees that it will be successful or make you feel better. Taking part in a clinical trial may offer more frequent monitoring and contact with your healthcare team. You will also contribute to better treatment options for people with PF in the future.

One of the most common clinical trials is a **randomised controlled trial**. This type of trial compares different treatments to find out which one works best. If you participate, you will be randomly allocated to one treatment or the other (like flipping a coin). Some trials involve a 'placebo' treatment; if you are randomised to the placebo group, you will receive something that looks identical to the real treatment but has no active ingredients. These features are an important part of a trial as they help make sure that the results are accurate.

It is important to note that some of these trials are done in addition to "Standard of Care". This means that clinical trial participants can enter a study if they are already receiving and continuing the best available treatment (the 'Standard of Care'). For example, most participants in PF clinical trials will already be receiving an antifibrotic

medication (e.g. nintedanib or pirfenidone) which they can continue through the course of the trial. They take the trial drug in addition.

Pros

- Early access to new treatments
- Frequent monitoring by your treating doctor
- May help other people in the future
- Opportunity to contribute to scientific knowledge
- PF trial participation may help family members if the condition is inherited

Cons

- May be allocated placebo treatment
- Frequent clinic / hospital visits
- Extra assessments, such as blood tests

What does taking part in a clinical trial involve?

Each clinical trial has different requirements, but there are some common features.

You will first be given a 'participant information and consent form' which provides a comprehensive outline of the purpose of the study, what you can expect and the potential benefits and risks.

You should read the information and consent forms carefully, and consider having family, friends, or your GP read it as well.

If you remain interested in the study you will be asked to sign and date the consent form, to provide your written informed consent to participate.



After providing consent, but before starting any trial treatment, the researchers will assess whether you are eligible based on your stage of disease, age, medical conditions or other factors.



The researchers will keep in touch with you during the trial to monitor your wellbeing and check for any side effects. You should also maintain contact with your treating healthcare team whilst on the trial for ongoing care.



Detailed assessments of your health and wellbeing will be made, before you start the treatment and at regular intervals during and after treatment. You may need to attend a hospital or clinic for these assessments.



During the trial, you can help by letting the researchers know of any changes to your health or medications, attending the assessments and filling out the forms as requested.

Taking part in any clinical trial is voluntary, which means you are free to withdraw at any time, without ongoing treatment being affected.

Trials can be conducted in different formats, including in-person, via telehealth (teletrials), or virtually.

What questions should you ask if you are considering a clinical trial?

After reading the participant information and consent form, you will be given an opportunity to ask the researchers and your healthcare team some questions, so you might want to consider:

- Is there a placebo arm?
- How long will I be in the trial?
- How often will I need to go to the hospital/clinic?
- What additional tests will I need?
- What are the benefits and side effects I might experience?
- Will I have to stop any of my current treatments?
- What happens to my treatment when the trial is finished?



FURTHER INFORMATION AND SUPPORT

Contact Lung Foundation Australia for more information, to access our support services and join our mailing list for regular updates and latest news.

Lung Foundation Australia Services

- Information and Support Centre
- Lung disease information resources
- Education webinars
- Support groups and peer-to-peer connections
- Referral to pulmonary rehabilitation and Lungs in Action exercise programs
- E-newsletter

External Links

- Centre of Research Excellence in Pulmonary Fibrosis: cre-pf.org.au
- Pulmonary Fibrosis Australasian Clinical Trials Network (PACT): pactnetwork.com.au
- Australasian Interstitial Lung Disease Registry: sydney.edu.au/medicine-health/our-research/research-centres/aildr.html

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