Why consider taking part in a clinical trial?

A comprehensive guide for people living with pulmonary hypertension on clinical trials

What is a clinical trial?

A clinical trial is a carefully planned medical study that tests new ways to prevent, diagnose, or treat disease. Trials may involve new medicines, new combinations of existing treatments, new ways of using medicines, or new approaches to care and follow-up.

Clinical trials are essential because they help ensure that treatments are safe, effective, and truly beneficial for patients. Every treatment used in healthcare today has been tested in clinical trials.

Taking part in a trial is always voluntary, and your usual care should never be compromised.

Many patients also find that participating in research gives them a sense of contributing to progress for others living with the same condition.

"Together, we can build a stronger, more informed PH community"

PVRI IDDI Patient Engagement & Empowerment Workstream

pvrinstitute.org/clinicaltrials

How clinical trials are carefully tested

New treatments go through several phases before they can become widely available.

1. Researchers study safety and determine the appropriate dose
2. The treatment is tested in a small group of patients to explore whether it works and to further evaluate safety
3. Larger studies compare the new treatment with current standard treatments
4. After approval, ongoing studies monitor long-term safety and effectiveness

Each phase builds on earlier research, meaning treatments entering later stages have already undergone extensive scientific evaluation.

Why might participating in a clinical trial be beneficial?

Clinical trials are usually conducted at specialised centres with significant experience in managing the condition being studied.

Taking part in a clinical trial can offer several potential benefits.

- **Access to new treatments that are not yet widely available**
- **Close medical follow-up and regular monitoring**
- **Care at expert centres experienced in the condition**
- **Contribute to research that may help others with the same condition**
- **A chance to help improve care for future patients**

Studies have also shown that patients treated in clinical trial settings often benefit from structured follow-up and high standards of care.

It is important to understand that a clinical trial may not always provide a direct personal benefit, but it can still play a crucial role in advancing medical knowledge.

Your safety and rights as a patient

- You have the right to receive clear and understandable information
- You can ask questions and take time to decide
- You can withdraw at any time, without giving a reason
- Protecting your safety, dignity, and well-being is the highest priority in every clinical trial
- Independent safety monitoring committees review data during studies to ensure patient protection

Informed consent is a fundamental part of every clinical trial

Common misconceptions about clinical trials

Some people worry that joining a clinical trial means being treated as a “test subject.” In reality, clinical trials are highly regulated and designed to protect patients.

Participation is always voluntary

Treatments are carefully evaluated before reaching patients

Your health is monitored closely throughout the study

You can leave the trial at any time

A personal choice

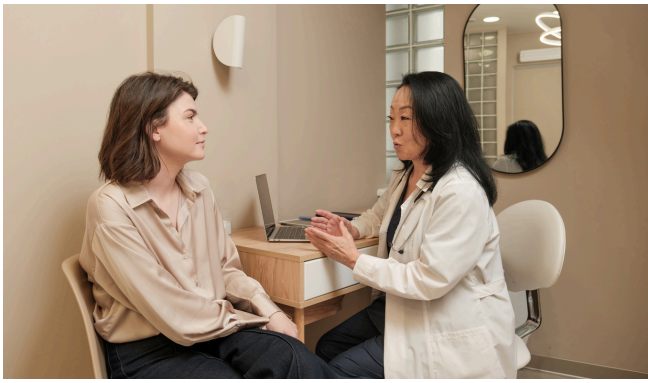
Deciding whether to join a clinical trial is a personal decision. Talking to your healthcare team, family, or a patient organisation can help you decide what feels right for you.

By considering participation, you are **helping shape better treatments and improve care for future patients.**

Patients as partners – not just participants

Patients are increasingly recognised as essential partners in clinical research. People living with a condition bring valuable real-life experience that cannot be learned from textbooks or data alone.

Your priorities, daily challenges, and treatment experiences help researchers design studies that are more relevant and feasible.



How patients can contribute to trial design

- Help shape trial design (visit schedules, endpoints, or study duration)
- Advise on outcomes that reflect what matters most in daily life
- Review patient information and consent forms to ensure they are clear and understandable
- Identify practical barriers to participation and suggest solutions

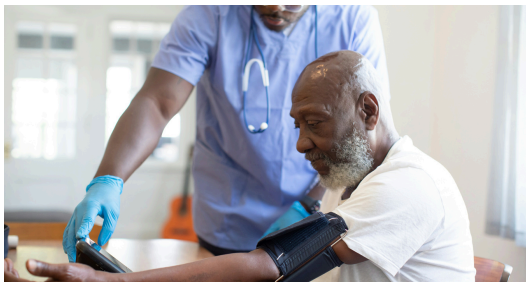
Patient organisations can also play an important role in ensuring that research addresses outcomes that matter most to people living with the condition.

Why patient involvement matters

When patients are involved early and meaningfully, clinical trials are more likely to:

- address real patient needs
- reduce unnecessary burden on participants
- improve recruitment and retention
- generate results that are meaningful for everyday life

This leads to better trials and better treatments.



A role for trained and informed patients

Some patients receive structured education about medicines development and clinical research through programmes such as EUPATI and similar initiatives. These informed patients can contribute effectively to discussions with researchers, clinicians, and industry partners.

A shared responsibility

Clinical research works best when patients, researchers, healthcare professionals, regulators, and industry collaborate.

Whether you contribute as a trial participant or as a patient partner in research design, your voice matters. Patients are not just subjects of research – they are essential partners in shaping the future of care.

Please note that trial appointments do not replace your regular clinic appointments or usual medical care.

Scan to access PVRI's patient resources