Supporting patient participation

Sponsors and research teams should also consider what practical support is available to patients participating in trials. This may include:

- assistance with travel or accommodation when specialised trial centres are far from home
- clear points of contact for questions or concerns during the study
- flexible visit schedules where possible
- support from research nurses and study coordinators throughout the trial

Practical support can significantly improve trial accessibility and participation.

Accessible and meaningful patient information

Patient representatives can help ensure that information provided to patients should be clear, transparent, and accessible.

1 **Information materials use understandable language**

2 **The reading level is appropriate for the intended audience**

3 **The information reflects the realities of living with the condition**

The rise of empowered and educated patients

Patients today are increasingly informed and trained through structured education programmes such as EUPATI and similar initiatives.

Understanding of clinical research and drug development	Knowledge of regulatory and ethical frameworks	The ability to engage constructively with research teams

Empowered patients are ready to be credible, responsible, and solution-oriented partners.

A shared responsibility

Clinical research works best when patients, researchers, healthcare professionals, sponsors, regulators, and research delivery staff collaborate.

In addition to patients, research nurses, study coordinators, and other research staff bring valuable insights into how trials operate in real clinical settings.

Patients are not just participants in research – they are essential contributors to better trials and better treatments.

Scan to access PVRI's patient resources

Pulmonary Vascular Research Institute (PVRI) is the only charity (UK charity no. 1127115) fighting pulmonary hypertension on a global scale

PVRi

Why involve patients?

A comprehensive guide for trial sponsors and research teams on why patient involvement matters

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

PVRI IDDI Patient Engagement & Empowerment Workstream

pvrinstitute.org/clinicaltrials

Patients are experts – in living with the disease

People living with pulmonary hypertension (PH) are not medical experts, but they are experts in their own right. They understand what it means to live day to day with a rare, complex, and life-limiting condition – including symptoms, treatment burden, uncertainty, and impact on quality of life.

This lived experience provides insights that cannot be captured through clinical data alone.

Why meaningful patient involvement improves clinical trials

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

- Address questions that are relevant to patients' real needs
- Reduce unnecessary burden related to visits, procedures, and documentation
- Build trust between patients, researchers, and sponsors
- Select endpoints that reflect meaningful outcomes, not only physiological measures
- Improve recruitment, retention, and adherence

Patient involvement is not an obstacle to scientific rigor – it strengthens it.

Early patient involvement can also reduce costly protocol amendments, improve recruitment rates, and minimise delays in study timelines. Evidence suggests that incorporating patient insights early in trial design can generate significant efficiency gains for sponsors.

Moving beyond "tick-box" involvement

Too often, patient involvement happens late in the process – for example, reviewing documents once the protocol is already finalised. While valuable, this approach limits the real impact patients can have.

- Engaging patients early in trial design
- Involving them in defining research questions and priorities
- Listening to their concerns and acting on them
- Treating patient input as expertise, not validation

Finding and engaging patient partners

Patients can be identified and engaged through several channels, including:

Patient organisations and advocacy groups	Existing patient advisory panels
Patient education programmes such as EUPATI	Clinical centres with active patient communities

Working with patient organisations early can help ensure that the right patient perspectives are included from the start of the research process.

What patients can contribute

Well-prepared patient representatives can add value across the research lifecycle, including:

- ☑ **Protocol development (visit schedules, inclusion/exclusion criteria, feasibility)**
- ☑ **Selection of endpoints that reflect daily life and long-term impact**
- ☑ **Review of patient-facing materials to ensure clarity and transparency**
- ☑ **Identification of practical barriers to participation**
- ☑ **Advice on communication, consent, and follow-up processes**

Patient involvement helps ensure trials are designed for people, not just for systems