IFPA

BREAKING THE MYTHS:

Clinical trials and psoriatic disease

BREAKING BARRIERS

Clinical trials are the type of studies that test new treatments or procedures and evaluate their effects on health outcomes. Clinical trials are carefully designed and need to be approved by an official governmental body before they start. Even though there is a general understanding of what clinical trials are, for those whom the studies are meant to help, it is not so clear.

Several myths and barriers prevent people living with disease from participating in clinical trials, and society from understanding the real barriers they face.

This brochure aims to raise awareness of these misconceptions and provide clarifying information.

Myth 1: “Clinical trials are dangerous”

The reality

The Four Phases of Clinical Trials

Phase 1:
Early human testing
Focus: Safety

Phase 2:
Testing effective-ness
Focus: Effectiveness

Phase 3:
Confirming results at scale
Focus: Strongest Evidence

Phase 4:
After approval
Focus: Long-term Monitoring

Clinical trials are structured in 4 phases (Phase I to Phase IV), and only if the previous phase of the study shows positive results can the study move to the next.

Before a new treatment is tested in healthy volunteers (Phase I), extensive research is conducted in laboratories and in laboratory animals. These pre-clinical studies evaluate how the treatment works and assess potential risks. Only when these studies demonstrate acceptable safety and promising results can clinical trials in humans begin.

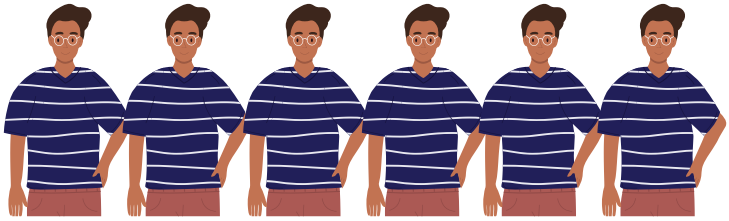
The first two clinical trial phases, especially phase I, primarily focus on safety, ensuring the new drug or procedure does not cause harm. While some risks may exist, participants are closely monitored by a medical team throughout the study.

The later phases (Phase II and III) evaluate how well the treatment works, how it compares to existing treatments, and monitor longer-term safety.

Key takeaways

- All treatments carry some risks, but clinical trials are carefully designed to minimize them.
- Treatments are approved only after years of research showing that their benefits outweigh their risks.
- Every approved treatment available today was once tested in clinical trials.
- Even after approval, treatments continue to be monitored for long-term safety.

Myth 2: “Clinical trials are conducted in small and homogeneous groups of people”



The reality

A new treatment can only be approved by the regulatory authorities if its efficacy and safety are clearly demonstrated in a large group of people, often several thousand participants. Contrary to the myth, it is essential for clinical trials to include participants with diverse characteristics so that results apply to the broader population the treatment is meant to be prescribed to.

Psoriatic disease affects people worldwide – across all ages, races, ethnicities, and backgrounds – and often co-exists with other conditions (comorbidities). Clinical trials should reflect this diversity.

Key takeaways

- Early phases involve small groups to test safety.
- Later phases involve thousands of participants to confirm that the treatment works and is safe.
- Diversity in clinical trials helps ensure treatments are safe and effective for everyone.

The reality

While some trials may offer options for people who have exhausted existing treatments, most clinical trials test new or improved therapies. For psoriatic disease, this may include new topical treatments (creams), oral medications (pills or tablets), biologics (injectables), or treatments that work faster or more effectively than current options.

Participating in a clinical trial may provide access to innovative treatments and closer medical monitoring — especially when certain treatments are not yet available locally. Not all medicines work the same way for everyone. Differences in genetics, disease type, and other factors mean that multiple treatment options are important to increase the likelihood of efficacious treatment options for everyone.

Key takeaways

- Clinical trials test the safety and effectiveness of all new medical treatments.
- Some trials (especially Phase I) may include healthy volunteers.
- Clinical trial does not mean last resort.

Myth 4: “Clinical trial participants are treated like guinea pigs”

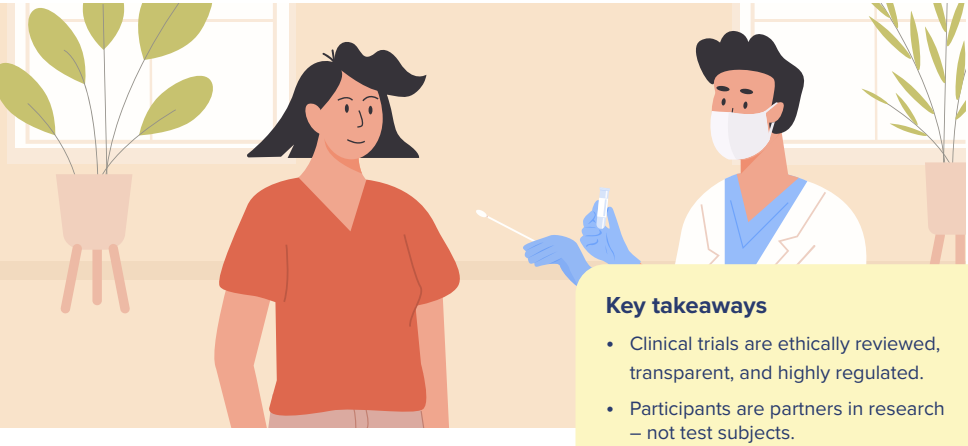
The reality

This myth may stem from concerns about safety or from historical injustices that created mistrust in certain communities. In the past, some populations were overrepresented in early-phase trials and underrepresented in later-phase research, contributing to fear and stigma.

Today, clinical trials are strictly regulated and reviewed by independent ethics committees and regulatory authorities to protect participants’ rights and safety.

Participants are carefully monitored by medical professionals, and clear action plans are in place if side effects occur.

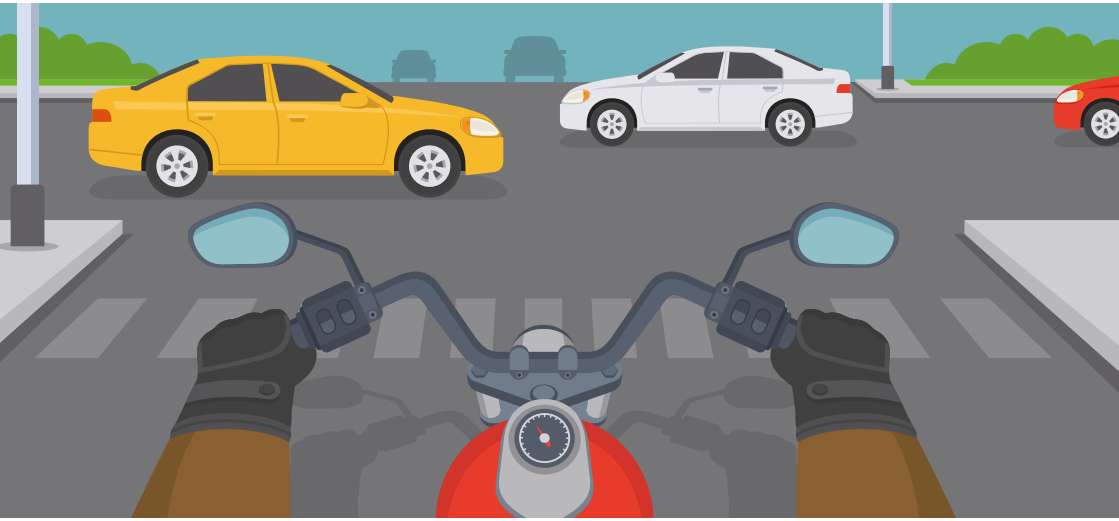
In recent years, patient organizations, civil society groups, and regulatory agencies have developed guidelines to strengthen patient involvement in research. Patient Research Partners now help design studies and define outcomes that reflect patients’ real needs.



Key takeaways

- Clinical trials are ethically reviewed, transparent, and highly regulated.
- Participants are partners in research – not test subjects.

Myth 5: “If I join a trial, I may lose control over my health”



The reality

Before joining a clinical trial, participants receive detailed information about the study, including the treatment being tested, how monitoring will be done, and how long the study will last. This information is provided in the informed consent form, which must be reviewed and signed before participation begins.

Participants can ask questions at any time and decide not to participate in the study.

Key takeaways

- Participants remain in control of their health throughout the study.
- They can leave the trial at any time, for any reason.
- Access to a dedicated medical team may in fact be positive, as it may help participants better understand and manage their condition.

The reality

Clinical trial sponsors usually cover all study-related costs, including doctor visits, tests, and treatments. Many trials also reimburse travel or other expenses related to participation.

However, compensation for time off work, loss of income or childcare may not always be offered. Details about costs, reimbursements, and time commitments are explained in the informed consent form. Participants are encouraged to ask questions if anything is unclear.

Key takeaways

- Study-related medical costs are typically covered by the sponsor.
- Reimbursement policies vary – always review the informed consent carefully.
- Participants should feel comfortable discussing potential expenses with study staff.

The reality

One major barrier to participation is that many people do not know where to find information about clinical trials or may find the language difficult to understand. This barrier is made worse because most clinical trials take place in only a few countries (mostly in Europe and North America) and many regions do not have any clinical trial sites at all.

Healthcare professionals and patient organizations can help identify available studies. Joining a clinical trial is not always simple. Participants must meet strict eligibility criteria related to age, health status, medical history, location, and other factors.

Participation may require multiple visits to the study site, which can affect work, school, or family responsibilities. Without adequate logistical or financial support, these requirements can create participation barriers.

A significant hinder for patients to join clinical trials is the language used in the informed consent form and supporting information. When the participant is unable to fully understand what the study entails, there is less willingness to take part in it.

Key takeaways

- If people cannot find trials, they cannot join them.
- Healthcare providers and patient organizations can help identify opportunities.
- Clear communication and practical support improve access.

Myth 8: “Clinical trials are available to everyone”

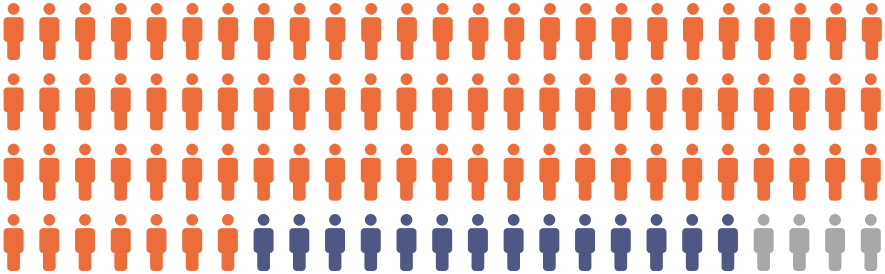
The reality

Clinical trials are not equally accessible to all populations. Many barriers – including strict eligibility criteria and geographic limitations – prevent certain groups from participating. The almost exclusive presence of clinical trial centres and infrastructures to main urban areas and in a small number of countries perpetuates the inequalities.

As a result, some populations remain underrepresented in research, and findings may not apply equally to everyone living with the disease.

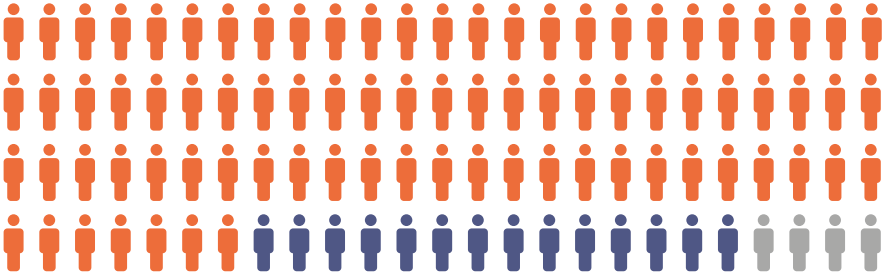
SoC – Participants in psoriasis clinical trial

84% are white



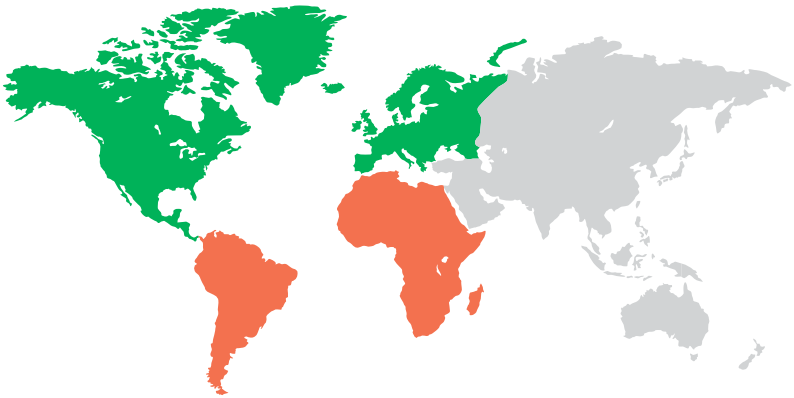
SoC – Participants in phase III psoriasis clinical trial

14% are non-white whereas only 4% are black



Global representation – Where clinical studies are conducted

- **90%** are in Europe and North America
- **4%** are in Africa and South America

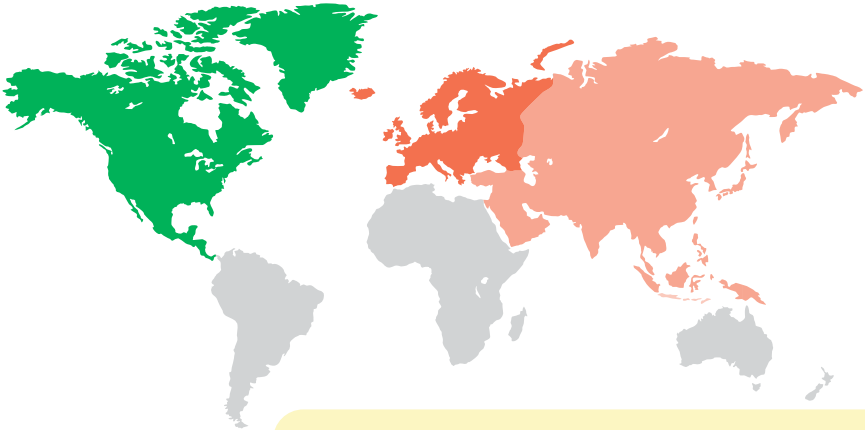


Underserved groups

Children, older adults, people with comorbidities or disabilities.

Pregnancy: the total number of clinical research studies that included pregnant people are:

- **13** in North America
- **4** in Europe
- **1** in Asia



Key takeaways

- Many populations remain underrepresented in research.
- When diverse groups are excluded, treatments may not be proven safe and effective for everyone.
- Although inclusion guidelines exist, implementation has been slow.

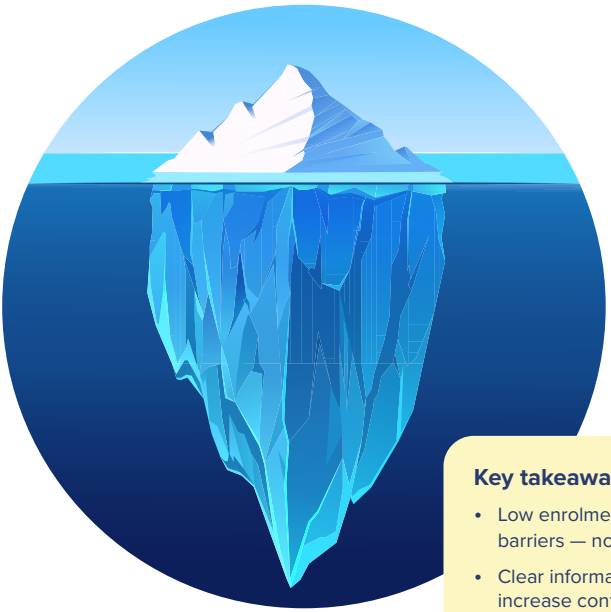
Myth 9: “Enrolment is low because people do not want to participate”

The reality

Approximately 80% of clinical trials in all disease areas fail to enrol participants on time. This is not because people are unwilling – studies show that interest in participating is generally high.

Barriers include lack of awareness, complex information and limited patient-friendly trial information materials, sociocultural barriers and practical challenges, fear of procedures or side effects, and limited patient-centered study design. Historically, trials have not always considered patient priorities, quality of life outcomes, or the practical burden of participation.

Ways to improve participation include the use of positive awareness campaigns, simplified and patient-centred communication strategies and expanding trial sites beyond major urban centres.



Key takeaways

- Low enrolment often reflects access barriers — not lack of interest.
- Clear information and realistic expectations increase confidence and participation.

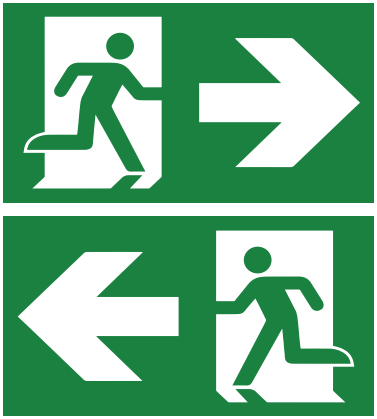
Myth 10: "Once agreed to join the study, participants cannot leave"

The reality

Participants who decide to leave the study may be asked to provide a final assessment of their symptoms and feedback that can help improve future studies.

Key takeaways

- Participants can leave a clinical trial at any time, for any reason.



Breaking Barriers

Addressing gaps and reducing stigma and underrepresentation in clinical research for psoriatic disease

Diversity matters in psoriatic disease research. Yet too many communities remain underrepresented in clinical trials, limiting understanding, slowing innovation, and leaving people without equal access to effective care.

Breaking Barriers is IFPA's new global project that explores why participation gaps persist, and how we can close them. Through collaboration among people living with psoriatic disease, researchers, and healthcare professionals, we aim to identify the social, cultural, and structural barriers that prevent inclusion in clinical research and to help remove them. As a part of this project, we have developed accessible educational materials about clinical research and inclusion. Check the QR code for more information.

IFPA in brief

IFPA strongly believes that the best way to find information and further resources is to get connected to a patient association.

Our priority is to connect IFPA's global members all around the world. Visit IFPA's members page for a list of member associations: **ifpa-pso.com**.

We encourage you to contact local associations for support in living with psoriatic disease – IFPA continues to stress the importance of the patientprovider relationship when making any treatment decisions and that the patient should remain at the center of decisionmaking processes. The decision to switch between treatments should be made on an individual basis and only with the full, informed consent of both patient and provider.

IFPA is a non-profit organization uniting national and regional associations from around the globe.

At IFPA, we envision a world without suffering from psoriatic disease. To achieve this, we focus on empowering our members, improving living conditions for people living with psoriatic disease and raising awareness.

Find out more about World Psoriasis Day, an IFPA-promoted annual advocacy campaign where members and supporters organize activities to raise awareness on psoriasis and psoriatic arthritis.

Visit: ifpa-pso.com

IFPA
GLOBAL LEADER IN FIGHTING PSORIATIC DISEASE

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