IFPA
GLOBAL LEADER IN FIGHTING PSORIATIC DISEASE

BEFORE YOU JOIN A STUDY:

A practical guide for participation in clinical trials

BREAKING BARRIERS

Why does this matter?

This guide is designed to help you talk with your doctor about clinical studies and treatment options that may be available to you, including new treatments that are not yet on the market in your country. It includes helpful topics and suggested questions you can use during your appointment. Since healthcare professionals do not always proactively inform patients about trials, you may need to raise the questions yourself. This document was designed to support open and honest conversations with your healthcare team and to help reduce any worries, fears, or doubts you may have about clinical trials.

This guide is part of the Breaking Barriers project. You should use this guide together with the Glossary that explains common words and terms used in clinical trials in simple language. Our goal is to help you feel informed, confident, and empowered to ask questions and explore access to innovative treatments.

It is important to remember, you and your doctor know your medical history and personal situation best. Your doctor can help you understand whether a clinical trial may be right for you and guide you in making the decision that feels most suitable for your health and treatment journey.

Before you begin

Clinical research and trials are not equally available to everyone. Barriers include limited country representation, a low number of trial sites, particularly outside major urban centers, and strict recruitment criteria. Nevertheless, you should feel encouraged to discuss your options with your doctor, as there may be a study available to you. Patient advocacy groups can also help you learn about clinical trials and support you if you choose to participate.

NOTE: Download the Glossary as it will help you understand some of the terms used in this document.

Other supporting documents are available online that help you understand clinical trials, for example Trial Nation (trialnation.dk) and EUPATI (https://toolbox.eupati.eu/resources/patient-toolbox/patients-involved-clinical-trial-design/)

Are there any studies for me?

First, you can check online if there are clinical trials in your country. Several registries exist, some that include information on clinical trials globally (for example clinicaltrials.gov or trialsearch.who.int) and some that are country specific.

Global / International Registries

- ISRCTN – ISRCTN registry (UK/ international)

North America / Caribbean

- GCM Medical – Puerto Rico

South America

- ReBec – Brazil
- REPEC – Peru
- RPCEC – Cuba

Africa

- PACTR – Pan African
- SANCTR – South Africa

Asia

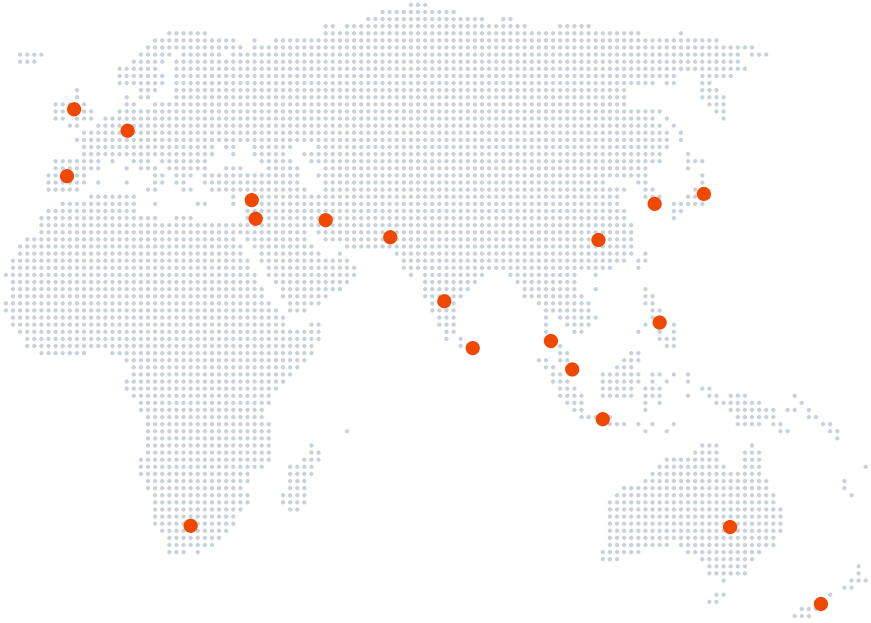
- ChiCTR – China
- ITMCTR – China (Traditional Medicine)
- CRiS – Republic of Korea
- jRCT and RTC Portal – Japan
- CTRI – India
- CTRP – Pakistan (functionality uncertain)
- SLCTR – Sri Lanka
- HSA Clinical Trials Register – Singapore
- INA Registry – Indonesia
- National Medical Research Register (NMRR) – Malaysia
- Philippine Health Research Registry – Philippines
- IRCT – Iran
- LBCTR – Lebanon
- National Clinical Trials Registry – Jordan

Europe

- CTIS Portal – EU/EMA (euclinicaltrials.eu)
- EU-CTR – EU Clinical Trials Register (clinicaltrialsregister.eu)
- DRKS – Germany
- REEC AEMPS – Spain

Oceania

- ANZCTR – Australia and New Zealand



Knowing if clinical studies are being conducted in your country is important information to use during the discussion with your doctor. Write your findings below.

When you are ready to talk about this topic, we have listed below a few questions that you can ask at the time of the visit. We recommend you prepare beforehand and write down your thoughts and questions.

It may be a good idea to take someone with you to your appointment. You could ask your partner, a family member, or a close friend to accompany you. They are important for moral support, ask questions that you may forget to ask, and take notes from the appointments. Make sure you invite someone you can trust.

Is there a clinical study in psoriatic disease that I can participate in?

Prepare by writing down when you first developed psoriasis, where it shows, any comorbidities you may have and when they started, your treatment history and current psoriasis treatment.

What types of clinical research or trials might be relevant to my condition? Write down what you have found in the online registries.

Am I likely to be enrolled (considering the eligible criteria: age, diagnosis, treatment history)?

Are there any reasons I would NOT be eligible?

If there is a study for you:

What is the study aiming to learn?

What type of study is it?

☐ Observational ☐ Interventional

If it is an interventional study (clinical trial), what is the phase of the trial (Phase I, II, III, or IV), and what does it mean for me?

Why should I participate in the study?

What are the potential benefits for me and my disease?

For observational studies, how will my participation improve care (for me and for others in the future)?

For interventional studies, how does this treatment compare to other treatment options? Is it safe?

What are the possible risks and possible side effects, and how will they be monitored and managed?

Treatment details

In addition to the new treatment, will I receive any other treatment?

If I do not receive the treatment being studied, will I receive a placebo or standard treatment instead? How long is the duration of placebo will last? Will I have access to the treatment at any point?

Will I need to change any of my lifestyle habits?

What types of tests will I need to do to be included and during the study?
(for example: blood tests, skin biopsies, surveys or questionnaires)
Will there be costs that are not covered by the study sponsor?

How often will I need to visit the clinic or hospital? Will the visit times be flexible to accommodate my daily life and commitments (work, family, other responsibilities)?

Privacy and personal data protection

What personal or health information will be collected?

How will this information be protected and used? Will it be shared? If so, with whom?

Study support and contact person

Is my participation voluntary? When am I expected to enter the study, and when will it end?

Is there a designated contact person who can answer my questions or concerns during the study, including in case of emergency or side effects?

Will I be compensated for the time spent participating in the study? If applicable, is there financial support for childcare, transportation to and from the trial site, caregiver support, or other related expenses?

What happens during and after the study?

Will I receive updates or results from the research? Will I be informed if any changes occur to the study (for example, early termination)?

Can I leave the study at any time? What will happen to me and my treatment options if I decide to withdraw?

Are there any circumstances under which the study team will require me to leave the study? If yes, ask for clarification.

When the study is completed, will I continue to have access to the treatment being tested? If yes, for how long? Will I continue to have access to the study team?

After my participation in the study, can I request documents or lab results so my primary doctor can know how to proceed with my care?

Participation agreement

What should I do if I decide to participate in the study (next steps and expected timelines)?

Will I receive printed documents to review in my own time? These may include general study information and the informed consent form. Can I review them at home with my family? When will I be expected to sign the consent form?

Participating in a clinical study can feel both exciting and overwhelming. On the one hand, you may get access to promising new treatments before they become available. On the other hand, these therapies are still being evaluated and have not yet received approval from regulatory agencies.

This guide, and the other resources from the Breaking Barriers project, are designed to help you better understand clinical research, explore your options, and feel more confident starting informed conversations with your healthcare provider about whether a clinical trial may be right for you.

We hope you find this guide useful and you use it when you feel ready to discuss clinical trials with your doctor.

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.

Visit: ifpa-pso.com

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

GLOBAL LEADER IN FIGHTING PSORIATIC DISEASE

www.ifpa-pso.com | info@ifpa-pso.com

BREAKING BARRIERS