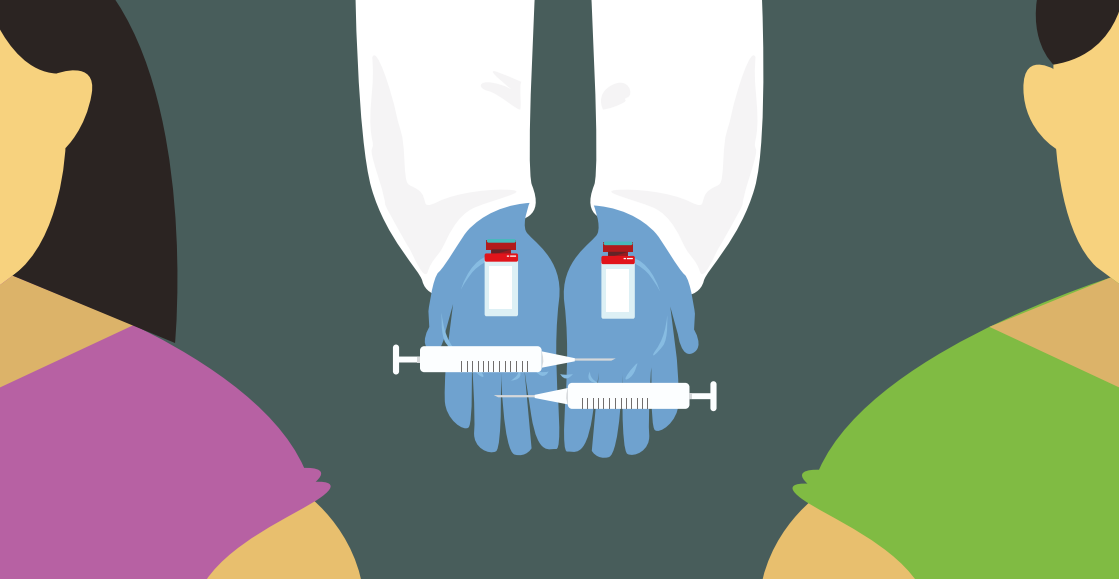
IFPA
GLOBAL LEADER IN FIGHTING PSORIATIC DISEASE

DESIGN IT RIGHT:

A checklist for diverse, equitable, patient-first trials

Building trust, expanding access, improving outcomes

BREAKING BARRIERS



Why does this matter?

Clinical research, including clinical trials, is essential to advancing our understanding of disease and identifying new treatment options. These efforts not only aim to improve symptoms but also to reduce overall disease burden and improve the quality of life of people living with disease.

Despite the large number of studies conducted worldwide, many individuals and communities remain underrepresented in clinical research. Representation in clinical trials is not optional – it is fundamental to achieving equitable and effective healthcare. Too often, research excludes or overlooks people based on age, gender, geographic location, skin color, disease presentation or comorbidities. This lack of inclusion results in evidence that fails to reflect real-world populations and perpetuates health disparities.

This checklist seeks to raise awareness and provide a practical foundation for clinical trial organizers to intentionally address these gaps. By ensuring that clinical research reflects the diversity of the populations it aims to serve, we can strengthen the relevance of trial outcomes and advance health equity for communities that are too often left behind.

The movement pushing for Diversity, Equity and Inclusion (DEI) of underserved and underrepresented groups in clinical research:

MRCT (Multi-Regional Clinical Trials) statement: “in the absence of diverse participation, individuals may not trust that data or conclusions apply to them, and they may be highly skeptical of the resulting evidence base”

The **WHA75.8** resolution and **WHO** Global action plan for clinical trial ecosystem strengthening, identify best practices for clinical trials.

ICH (International Council for Harmonization) continuously develops resources to improve design and reporting of clinical trials, with a special emphasis on patient centricity and diversity inclusion.

IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) note for guidance 2022 states 4 Principles that should be followed:

- The biopharmaceutical industry, as sponsors of clinical research, should commit to identifying barriers to participation by diverse groups in clinical research, and strive to implement strategies that help to reduce or overcome those barriers.
- Learning about and understanding the specific needs and challenges of diverse groups is a prerequisite to clinical trial population diversity and the benefits that follow.
- It is important to conduct clinical research in the widest range of populations that a potential therapeutic agent is intended to help.
- Diversity within the clinical research community, including sponsors, research teams, investigators, study coordinators, practice nurses, pharmacists, Institutional Review Boards, Ethics Committees, and others, can be a driver of greater diversity in patient participation.

World Health Organization

IFPMA

ICH harmonisation for better health

Good Clinical Trials Collaborative (goodtrials.org) is an example of an initiative that develops resources-such as tools and training courses-designed to enhance understanding of good clinical practice. One example is an evaluation tool that assesses whether the key principles of high-quality clinical research are appropriately implemented in a study.

The **INCLUDE Project**, by the NIHR (National Institute for Health Research), created a strategic roadmap and important questions on how to improve inclusion of underre-presented groups into clinical research.

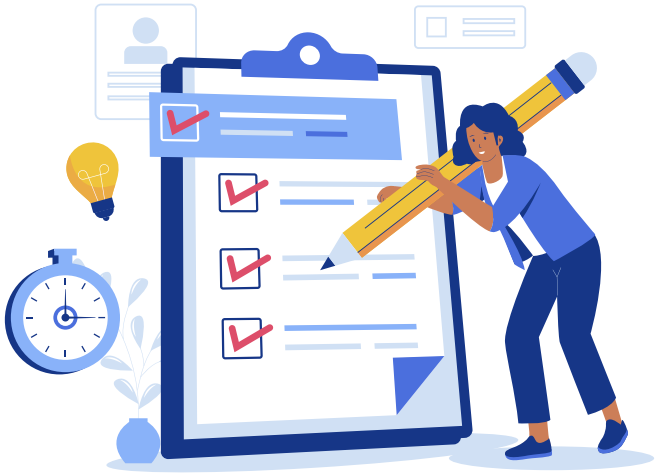
Both the **FDA** (Food and Drug Administration) in the United States and the **EMA** (European Medicines Agency) in the European Union have established action plans and regulations to ensure that clinical trial participants reflect the populations likely to use the treatment being tested.

Checklist

This checklist is intended as a practical tool to support thoughtful and inclusive trial design and conduct. It outlines aspirational considerations across the trial lifecycle – from study design to post-trial communication. Not all items will be feasible in every context, but the checklist is intended to encourage reflection, transparency, and continuous improvement in how trials are planned, implemented, and reported.

Study design

- ☐ Representation and diversity have been considered in the study design.
- ☐ The eligibility criteria reflect the real-world population affected by the condition.
- ☐ Community partners, patient organizations, or local leaders from diverse backgrounds have been invited to review the study plan.
- ☐ Potential biases in protocol design, e.g. insufficient participant diversity, have been assessed and addressed.
- ☐ Diversity goals are documented and will be revisited periodically throughout the trial.
- ☐ A DEI Lead – person or team – have been appointed to implement and monitor inclusion and equity throughout the study.
- ☐ A robust training plan for trial investigators and nurses is in place to ensure assessment knowledge and proficiency.



Population representation

☐ Underserved groups are meaningfully represented whenever relevant and feasible.

Groups by demographic factors

- ☐ Age extremes
  - ☐ Infants and children
  - ☐ Adolescents
  - ☐ Older people
- ☐ Pregnant and lactating women
- ☐ Male/female sex, non-binary, LGTBQ+
- ☐ Ethnic minority groups

Groups by health status

- ☐ People with physical disabilities
- ☐ People with multiple health conditions
- ☐ People with rare diseases

Groups by social and economic factors

- ☐ People living in rural or remote areas
- ☐ Indigenous communities
- ☐ Socioeconomically disadvantaged (unemployed, low income, ...)
- ☐ People in alternative residential circumstances (for example, migrants, refugees, unhoused, occupants of care homes)
- ☐ People with limited access to healthcare
- ☐ People who face language barriers
- ☐ People with limited digital literacy and access

☐ People with different skin tones and racial/ethnic backgrounds are meaningfully represented.

Groups by ethnicity

- ☐ White
- ☐ Hispanic or Latino
- ☐ Asian
- ☐ Black
- ☐ Middle Eastern
- ☐ Indigenous
- ☐ Multiracial/Mixed ethnicity

- ☐ Trial sites selected reflect geographic diversity
  - ☐ Urban/rural
  - ☐ Regional variation
  - ☐ Global representation, including underserved areas
- ☐ Countries were included on the basis of disease burden and not solely on the presence of existing research infrastructure.
- ☐ Consideration has been given to local healthcare systems, cultural norms, and regulatory frameworks.
- ☐ Digital access requirements are designed to avoid unnecessarily excluding participants. Where barriers are identified, an appropriate alternative plan will be developed and implemented to ensure equitable participation.

Recruitment strategies and patient experience

- ☐ The recruitment plans have been adapted to engage and enroll underserved communities.
- ☐ Clinical trial sites have been established to facilitate participant access to the study participants.
- ☐ The inclusion and exclusion criteria do not unnecessarily exclude individuals or populations.
- ☐ Community partners, patient organizations, or local leaders have been engaged to support recruitment.
- ☐ Study materials are developed using plain language principles to ensure they are understandable to non-experts and available in accessible formats.
- ☐ The materials shared with study candidates are written for a non-expert audience and in accessible formats.
- ☐ Study participants are treated with respect, in a culturally sensitive manner, and are not made to feel like study objects.

Practical barriers

- ☐ A contingency plan is in place to accommodate and compensate for logistical barriers, such as childcare support, caregiver assistance, time off work.
- ☐ Participant compensation is fair, appropriate across settings, and fully covers study-participation expenses.
- ☐ All participants are compensated equally, and travel expenses are fully reimbursed.

Informed consent

- ☐ Consent information should be presented in clear, plain language so that it is easily understandable by non-experts.
- ☐ Informed consent form and other resources are available in several languages to best accommodate for patient preferences.
- ☐ The participants are informed why they have been invited to participate. Unclear eligible criteria may increase fear, confusion and concern.
- ☐ The procedures, protocol, and potential risks are clearly stated and explained. Participants are encouraged to ask questions with regards to the study procedures.
- ☐ Sufficient time is given to candidates to read, understand, and discuss the informed consent form with peers or family members.

Intervention allocation

- ☐ To minimize allocation and assessment biases, a robust randomization system should be used, and double-blinding of participants and investigators is recommended.

Study adherence and compliance

- ☐ The study organizers have established protocols and tools to ensure participant retention and to mitigate withdrawal, as well as to manage potential study termination or suspension.
- ☐ Patient-centered routines are in place, with planned adaptations to accommodate the effects of the disease.
- ☐ There is clear and accurate information about the study duration and its expected completion.
- ☐ Clear information is given regarding what is expected after the study finishes (e.g. access to treatment and, if yes, for how long it will be provided).
- ☐ Study visit sites are selected to best accommodate participants, and follow-up visits are scheduled to minimize any unnecessary burden.
- ☐ Follow-up strategies should align with patient preferences, offering virtual visits or appointments at a local site whenever possible.

Endpoints and Patient Reported Outcome Measures (PROMs)

- ☐ Patient advocates and organizations are consulted to identify the patient reported outcomes most relevant to the study.
- ☐ The primary and secondary endpoints are designed to reflect the needs of patients.
- ☐ Outcomes pertaining to quality of life and mental health are assessed in the study.
- ☐ Clinical trial staff are trained to assess outcomes in all populations included in the study, including individuals with skin of color and the specific skin presentations of psoriasis, such as plaque clearing.

Analysis plan

- ☐ Subgroup analyses are pre-specified and recruitment goals are set accordingly.
- ☐ Specific disease presentations are carefully considered and interpreted when assessing outcomes (e.g skin phenotype in skin of color).
- ☐ Participant adherence, screen failures, and withdrawals are reported by subgroup with possible reasons.
- ☐ Interpretation, where applicable, addresses limitations.

Post-trial feedback to participants and communities

- ☐ Findings are shared with participants and are easily accessible.
- ☐ Community partners receive a debrief on the impact of their contributions.

Post-trial reporting and publication

- ☐ Participant demographics are clearly reported in publications and registries.
- ☐ Demographic characteristics and subgroup analyses are reported in the publications.
- ☐ Results are presented in sufficient detail and, when relevant, according to demographic and health factors, ethnicity, or other traits.
- ☐ Limitations related to representation are clearly stated.
- ☐ Lay summaries are provided and shared in accessible language(s) and formats.

For more information, check:

International Council for Harmonization (ICH) Guideline for Good Clinical Practice E6(R3)
International Council for Harmonization (ICH) General Considerations for Clinical Studies E8(R1)
WHO's Handbook for Good Clinical Research Practice (GCP)
WHO's Guidance for best practices for clinical trials (2024)
WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants (2024)
EFPIA (European Federation of Pharmaceutical Industries and Associations) Clinical Trial Data Sharing Ecosystem
Versavel et al., Contemporary Clinical Trials (2023)

IFPA in brief

IFPA is a non-profit organization dedicated to advocating for everyone affected by psoriasis and psoriatic arthritis. We unite national and regional associations, representing more than 100 million people worldwide.

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