TAKEDA'S COMMITMENT TO INCLUSIVE AND EQUITABLE CLINICAL RESEARCH IN PSORIASIS


Photo courtesy of IFPA project "All the Colors We Are" March 2025

More than **7.5 million Americans** and **60 million[*] people** worldwide live with psoriasis, a chronic, immune-mediated inflammatory disease that leads to the development of thick, scaly plaques on the skin.[1-3]

PSORIASIS IS ASSOCIATED WITH A SIGNIFICANT BURDEN OF DISEASE

- Decreased quality of life[5]
- Stigmatization which can contribute to anxiety and depression[5]
- Loss of work productivity[5]
- Higher risk of comorbidities, such as cardiovascular disease, psoriatic arthritis and depression[6]

Reported psoriasis prevalence is similar between men and women, but it appears to differ by race and geography.[2]

HEALTH DISPARITIES IN PSORIASIS

People with skin of color[**] living with psoriasis experience[8]:

- **Lower rates of diagnoses**
- **Lower utilization rates of dermatologic care**
- **3x longer timeframe to diagnosis** than those with lighter skin tones
- **Lower biologic treatment rates** than those with lighter skin tones

Compared to White dermatology patients, Black and Hispanic patients were[10]:

- **more than twice as likely** to delay a doctor visit due to affordability
- **approximately 1.5 times more likely** to delay a specialist visit due to affordability

Based on a study of 16,986 U.S. dermatology patients from 2017-2022.

Patients in rural areas may have to **travel long distances** and experience **longer wait times** than those in urban areas. This can result in a delay in treatment.[8]

Psoriasis clinical trials are the least diverse (in terms of race, ethnicity, sex and geography) within dermatology – participants are predominantly white males.[9] The lack of diversity within clinical trials limits our ability to understand how different patient populations may respond in real-world settings.

AN ADDITIONAL CHALLENGE: LACK OF EPIDEMIOLOGY DATA

While psoriasis is one of the most common skin diseases in the world, more than 81% of countries don't have epidemiology data according to a 2020 study, making it difficult to understand the true impact of this chronic disease.

While there is relatively more epidemiology data from the U.S., underdiagnosis remains a significant challenge in underserved and underrepresented populations. Therefore, we do not have a consistent view of epidemiology of psoriasis in the U.S.[2]

> "A clear understanding of the global burden of psoriasis begins with comprehensive prevalence data from as many countries as possible. We are collaborating with like-minded organizations to build a strong evidence base, track comorbidities, assess the economic impact, and enable benchmarking across nations. By advancing research and data collection, we can drive meaningful change for people living with psoriasis worldwide."

Sicily Mburu, M.D., IFPA Scientific Officer

TAKEDA'S APPROACH TO REAL-WORLD REPRESENTATION IN US-BASED PHASE 3 PSORIASIS CLINICAL TRIALS

> "We recognized the limitations of available psoriasis epidemiology data in the U.S., especially the underrepresentation of various populations. So, we decided to unify data from multiple sources to paint what we believe is a more accurate representation of the psoriasis patient population in the U.S. We then used this collection of information to establish our enrollment goals for our clinical trials (in the U.S.)."

LaShell Robinson, Head, Global Feasibility and Trial Equity

Epidemiology data (from literature reviews, real-world evidence, etc.)

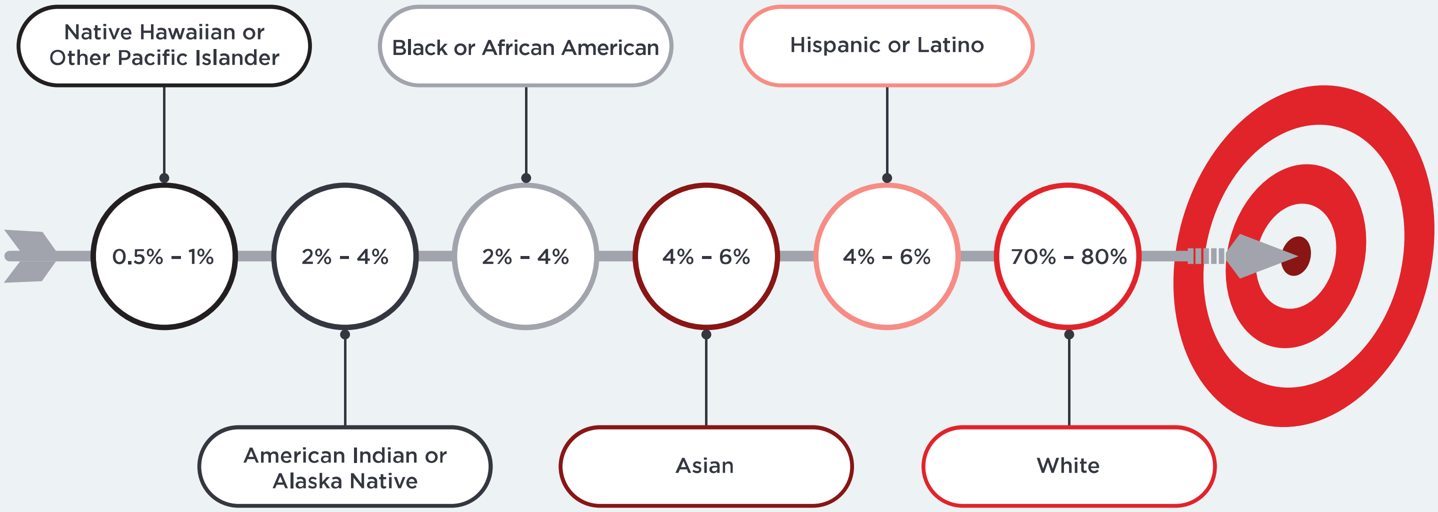
Clinical trial site reported data, gleaned during the feasibility process and site questionnaires

Claims data from insurers

Data from other countries

Our enrollment goals for the U.S. are rooted within these findings and what we estimate for the actual psoriasis population in the U.S. Takeda is working to publicly share the epidemiology estimates we have created.

Phase 3 Psoriasis Clinical Trial Targets (U.S.)



Native Hawaiian or Other Pacific Islander
0.5% – 1%

American Indian or Alaska Native
2% – 4%

Black or African American
2% – 4%

Asian
4% – 6%

Hispanic or Latino
4% – 6%

White
70% – 80%

Our team incorporated our tested strategy to **P.A.V.E. the way to clinical trials that better represent real-world patient populations**. We actively tracked our progress and pivoted as needed, striving to meet our goals without slowing down enrollment. We are proud we were able to meet or exceed nearly all of our goals.

Exceeded enrollment goals for Hispanic and Black populations, with Hispanic enrollment ***more than doubling*** and Black enrollment ***nearly doubling***.

Fell short of our Native American enrollment goals but exceeded representation in the U.S. population, based on recent census data, so we may have overestimated the prevalence in Native Americans.

Met our goal for Asian populations despite enrollment initially falling behind. We pivoted quickly and reached out to clinical trial sites located in areas with higher Asian populations to learn best practices and ensure our digital recruitment material resonated with Asian audiences to help meet our goals.

We did not establish enrollment goals for sex/gender because epidemiology data suggested equal opportunity, but ***ultimately enrolled fewer females*** than males in our trials.

Specific data from Takeda's Phase 3 psoriasis clinical trials will be shared by the end of 2025.

Based on aggregate clinical data of therapies approved for moderate-to-severe plaque psoriasis in the last 10 years, **we have had some of the highest rates of enrollment for Black and Hispanic populations.**[11]

"We've taken a closer look at psoriasis trials outside of Takeda's and have found that sex inequality within trials is a consistent trend and something the entire industry, including Takeda, can improve on. Moving forward, we will collaborate with others to increase the recruitment of women across all demographics to ensure real-world representation in our psoriasis clinical trials and beyond."

LaShell Robinson, Head, Global Feasibility and Trial Equity

MORE WORK TO BE DONE

Takeda is planning to expand our efforts globally, drawing on our U.S. strategy but also adapting accordingly to what is most appropriate per country or region and the respective patient populations.

"Our work to ensure our clinical trials better reflect the patient populations we aim to serve is an ongoing and collaborative process. We are partnering with other organizations around the world to increase understanding of how diseases and treatments affect different patient populations, encourage participation among historically underrepresented patient populations in clinical research and identify remaining unmet needs and opportunities for us to work together to advance more equitable psoriasis care for all."

LaShell Robinson, Head, Global Feasibility and Trial Equity

"By collaborating, patient advocates and industry can drive progress in reducing inequities in access to care and treatment, expanding data collection initiatives, and addressing health disparities in clinical trials."

Sicily Mburu, M.D., IFPA Scientific Officer

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*Considerable gaps exist on the incidence and prevalence of psoriasis, particularly in low- and middle-income countries. Only 19% of countries in the world have epidemiological data on psoriasis.[4]

**The term SOC refers to a diverse population of individuals of racial and ethnic backgrounds, including those who identify as Black or African, Hispanic or Latinx, Asian or Pacific Islander, American Indian or Native Alaskan, Indigenous Australian, Middle Eastern, biracial or multiracial, and non- White.[7]

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