JAMA Dermatology | Original Investigation

Improving Diversity in a Novel Psoriasis Study
VISIBLE as a Framework for Clinical Trial Quality Improvement

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IMPORTANCE Diverse racial and ethnic representation in clinical trials has been limited, not representative of the US population, and the subject of pending US Food and Drug Administration guidance. Psoriasis presentation and disease burden can vary by skin pigmentation, race and ethnicity, and socioeconomic differences. Overall, there are limited primary data on clinical response, genetics, and quality of life in populations with psoriasis and skin of color (SoC). The Varying Skin Tones in Body and Scalp Psoriasis: Guselkumab Efficacy and Safety trial (VISIBLE) is underway and uses strategies aimed at addressing this persistent gap.

OBJECTIVE To assess the innovative strategies used in the VISIBLE trial to recruit and retain diverse participants in a randomized clinical trial of psoriasis in participants with SoC.

DESIGN, SETTING, AND PARTICIPANTS This was an ad hoc quality improvement assessment of participant recruitment and retention approaches used by the VISIBLE trial. VISIBLE enrolled and randomized 211 participants (mean [SD] age, 43 [13] years; 75 females [36%] and 136 males [64%]) with SoC and moderate to severe plaque psoriasis from August 2022 to March 2023 to evaluate guselkumab treatment. The self-identified race and ethnicity of the participants was: 1 American Indian/Alaska Native (0.5%), 63 Asian (29.9%), 24 Black (11.4%), 94 Hispanic/Latino (44.5%), 13 Middle Eastern (6.2%), 1 Pacific Islander/Native Hawaiian (0.5%), 12 multiracial (5.7%), and 3 of other race and/or ethnicity (1.4%). Using a combination of objective (colorimetry to determine Fitzpatrick skin type) and self-reported (race and ethnicity consistent with SoC) parameters, VISIBLE sought to broaden inclusion of participants from various backgrounds.

RESULTS Observed improvements were that participant enrollment occurred approximately 7 times faster than anticipated (vs historical recruitment data for psoriasis studies); 211 participants (100%) self-identified themselves as a race or ethnicity other than White; and more than 50% had skin tone in the darker half of the Fitzpatrick skin type spectrum (type IV-VI). Innovations implemented by VISIBLE were (1) assessment of the natural history of postinflammatory pigment alteration and improvements over time using combined objective colorimetry and clinician- and patient-reported outcomes; (2) evaluation of genetic and comorbidity biomarkers relevant to participants with SoC; (3) a diverse demographic-driven approach to site selection (emphasizing investigator and staff diversity and experience with populations with SoC); (4) provision of cultural competency training to enhance participant enrollment and retention; (5) collection of patient-reported outcomes data in participants' primary language; and (6) periodic, blinded central review and feedback on investigator efficacy scoring to promote consistency and accuracy in evaluating psoriasis in participants with SoC.

CONCLUSIONS AND RELEVANCE VISIBLE is a unique study focused on addressing important knowledge and data gaps in populations of patients with psoriasis and SoC, with the goal of generating data to help improve clinical care and inform future best practices in diversity within dermatology research. The rapid study enrollment demonstrates that intentional and strategic approaches to clinical trial design and conduct can speed recruitment and bolster participation and retention of diverse populations in a dermatologic setting.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT05272150

JAMA Dermatol. doi:10.1001/jamadermatol.2024.5103
Published online December 11, 2024.

Supplemental content

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Underrepresentation of racial and ethnic minority groups in clinical trials has been a long-standing issue across therapeutic areas, including dermatology. The demographic composition of most skin disease trials does not reflect the diversity of the US population nor its disease epidemiology.[1,2]

The term *skin of color* (SoC) is used to describe the dermatologic characteristics of individuals of a race and/or ethnicity group other than White.[3] In the US, those who self-identify as American Indian or Alaska Native, Asian, Black, or Native Hawaiian or Other Pacific Islander (per the US Office of Management and Budget [OMB]), or report being of Latino or Hispanic ethnicity (in addition to an aforementioned race category) are generally considered to have SoC. However, these categories are not biological but rather social constructs. Populations with SoC are extremely heterogeneous, having a range of skin tones and other dermatologic characteristics, as well as diverse cultural and environmental backgrounds.[4,5] To date, populations with SoC have been underrepresented in dermatologic research and education, which contributes to disparities reported in diagnosis and treatment. Additionally, clinical trials have generally stratified participants based on the aforementioned socially constructed racial and ethnic categories without further consideration of skin characteristics.[6] However, methods are now available to more objectively characterize skin tone, allowing for application of evidence-based criteria to more accurately capture physiological attributes of different skin types.

The Varying Skin Tones in Body and Scalp Psoriasis: Guselkumab Efficacy and Safety trial (VISIBLE) is, to our knowledge, the first large-scale, randomized clinical trial dedicated to evaluating psoriasis and treatment outcomes in participants with SoC, including all skin tones, using a combination of objective and patient-reported parameters. This report discusses innovative strategies used in the ongoing VISIBLE trial to overcome barriers to recruiting and retaining participants with SoC and to address the unmet needs of diverse populations with SoC (**Box**).

Key Points

Question Can innovative clinical trial design overcome barriers to recruiting and retaining participants with psoriasis and skin of color?

Findings This quality improvement study found that the VISIBLE trial achieved broad diversity among its approximately 200 participants through self-identification of race and ethnicity and inclusion of all skin types. Innovative strategies used were colorimetry and enhanced photography to evaluate skin color, disease severity, and treatment response; centralized review of clinical photographs to ensure consistency across the skin-tone spectrum; and culturally sensitive and competent care and logistics support.

Meaning VISIBLE enrollment exceeded expectations, indicating that intentional and strategic approaches to study design and conduct can speed recruitment and bolster participation and retention of trial participants with skin of color.

Box. Overview of Strategies to Enhance Diversity in Dermatology Clinical Trials

During Trial Design
- Consult dermatologists with experience treating underrepresented populations
- Include minimum enrollment criteria for diverse participants (eg, >X% with SoC)
- Reduce frequency of in-person visits to minimize participants' time constraints
- Allow self-reporting of race and ethnicity to promote cultural and ancestral diversity
- Include objective measures of skin tone or pigmentation
- Use cross-polarized photography to better visualize erythema and other abnormalities in dark skin

Site Selection
- Use feasibility questionnaires to assess diversity of patient populations at potential study sites
- Use census and claims data to identify study sites with high proportions of underrepresented populations

Training for Investigators
- Provide cultural sensitivity training materials
- Develop training modules and quizzes that include images of disease across all skin tones

Recruitment
- Offer transportation services and reimbursement for missed work
- Translate all study materials into multiple languages
- Provide on-site translation services
- Use the broadest possible diagnostic criteria for inclusion
- Use referral networks, patient databases, posters, and advertising to promote enrollment

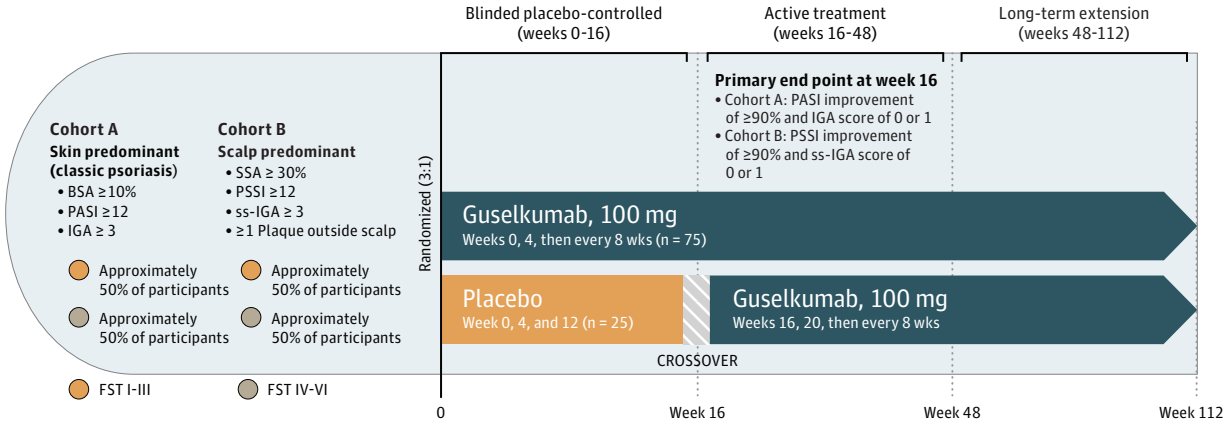
Abbreviation: SoC, skin of color.

Methods

This was an ad hoc quality improvement assessment of participant recruitment and retention approaches used by the VISIBLE trial. VISIBLE is a currently ongoing phase 3b, randomized, double-blind, placebo-controlled trial evaluating guselkumab safety and efficacy for the treatment of participants with SoC who have moderate to severe plaque psoriasis (cohort A) and/or moderate to severe scalp psoriasis (cohort B). The VISIBLE trial protocol is available in Supplement 1. VISIBLE followed guidelines of the Declaration of Helsinki and the International Conference on Harmonization of Good Clinical Practice. The institutional review board or ethics committee at each site and local health authorities in Canada and the US approved the protocol and any modifications. Participants provided written informed consent.

Eligible participants were recruited from 90 study centers in Canada and the US (eTable 1 in Supplement 2 provides the eligibility criteria). The final VISIBLE study population totaled 211 participants (mean [SD] age, 43 [13] years; 75 females [36%] and 136 males [64%]) whose self-identified race and ethnicity comprised 1 American Indian/Alaska Native (0.5%), 63 Asian (29.9%), 24 Black (11.4%), 94

Figure 1. The VISIBLE Study Design



BSA indicates body surface area; FST, Fitzpatrick skin type; IGA, Investigator's Global Assessment; PASI, Psoriasis Area and Severity Index; PSSI, Psoriasis Scalp Severity Index; SSA, scalp surface area; and ss-IGA, scalp-specific IGA.

Hispanic/Latino (44.5%), 13 Middle Eastern (6.2%), 1 Pacific Islander/Native Hawaiian (0.5%), 12 multiracial (5.7%), and 3 of other race or ethnicity (1.4%).

The co-primary end points in cohort A were the proportions of participants achieving an Investigator's Global Assessment of psoriatic lesions as clear (score=0) or minimal (score=1) and 90% or greater improvement per the Psoriasis Area and Severity Index at week 16. The co-primary end points in cohort B were the proportions of participants achieving a scalp-specific Investigator's Global Assessment score of 0 or 1 and 90% or greater improvement in Psoriasis Scalp Severity Index at week 16. A summary of the VISIBLE trial design is provided in the eMethods in Supplement 2 and in **Figure 1**.

Designing for Diversity

Championing Culturally Competent Care

VISIBLE was designed in consultation with more than 50 dermatologists specializing in SoC and approved by a steering committee of SoC experts in Canada and the US. These experts identified the following key areas to address in VISIBLE: the subjectivity of Fitzpatrick skin type (FST) classification[7]; lack of correlation between race or ethnicity and FST; and topics of particular relevance to populations with SoC, such as scalp psoriasis and postinflammatory pigment alteration (PIPA).

In a survey of individuals with SoC and self-reported psoriasis, culturally competent care was cited as a substantial unmet need.[8] In VISIBLE, 2 researchers (M. S. and A. R.) developed a cultural sensitivity training curriculum for site staff that encompasses topics including cultural awareness, competence, and knowledge; tips for study visits requiring an interpreter; and best practices when inquiring about self-identified race and ethnicity. Supplemental case-based cultural awareness advice was also available for sites and investigators, and another researcher (A. A.) developed training for efficacy assessment across all skin tones. Study materials were translated into 8 languages, based on site requests, and on-site translation services are available. Patient-reported outcomes materials may be translated into participants' primary languages.

Addressing Enrollment Barriers for Underrepresented Populations

Psoriasis prevalence has been reported to be lower among populations with SoC than among White populations.[8-10] However, it is likely that psoriasis prevalence among populations with SoC is underestimated due to selection bias, less health care utilization, and/or underdiagnosis.[8] Individuals with SoC are more likely to require a biopsy procedure for psoriasis diagnosis, and the time between presentation and diagnosis is generally longer compared with White individuals.[11] Delayed diagnosis and misdiagnosis may hinder enrollment in clinical studies. To proactively mitigate these potential barriers, VISIBLE eligibility criteria allowed 3 pathways for validating a diagnosis of psoriasis: an established clinical diagnosis (≥6 months); a positive biopsy specimen result; or an expert panel–confirmed psoriasis diagnosis based on clinical photographs.

Distrust of physicians, especially those in medical research, is common among underrepresented populations.[2] This may contribute to reluctance to try novel therapies or to participate in clinical trials.[12] To mitigate this distrust, VISIBLE considered study sites that were experienced in serving diverse populations, had investigators who represented populations with SoC, and/or reported having staff who were diverse. On-site discussions between the trial sponsor's (Janssen) representatives and dermatology practitioners helped identify potential trial sites. Additionally, steering committee members recommended trial sites with diverse patients and/or dermatologists experienced in treating populations with SoC for consideration. Each prospective site completed a feasibility questionnaire regarding the diversity of its overall population, of its population of patients with psoriasis, and of its investigators and staff; the number of languages spoken by personnel was also evaluated. All chosen sites were verified to have a diverse population of patients with SoC and psoriasis based on

sources including, but not limited to, census and claims data for each site location and on-site evaluation by the study sponsor's representatives. As a result of this approach, more than 50% of sites selected for VISIBLE were new to the sponsor.

Based on an analysis of data from ClinicalTrials.gov on 18 moderate to severe psoriasis trials with a study open date in 2015 or later that recruited 6610 participants, of whom 1062 (16.1%) self-identified as Asian, Black, or Hispanic, we calculated that the historical average recruitment rate (expressed as participants/site/month) of patients with SoC was 0.06 (eTable 2 in Supplement 2 lists the 18 trials). Using this calculation, it was estimated that more than 100 study sites would be needed to reach the target study population size within 1 year. To mitigate potential enrollment challenges, a multifaceted approach, including recruitment through referral networks, site-specific patient databases, posters, and traditional and online advertising, was used. To further facilitate enrollment and retention of an inclusive population, potential logistical barriers were addressed by offering transportation services and compensation for missed work. Additionally, constraints on participants' time were considered, and in-person visits occur less frequently in VISIBLE (approximately every 8 weeks in the first year and every 16 weeks in the second year) than in prior clinical trials of guselkumab (every 4 weeks).

Culturally Inclusive Self-Identification

Typical US Census definitions of race and ethnicity are not consistent with how some individuals prefer to self-identify.[5] For example, although individuals who self-identify as Cuban, Mexican, and Puerto Rican all fall within the Hispanic/Latino category per the OMB definition, these individuals have very different cultures and ancestries.[13] Individuals of Middle Eastern and North African descent are categorized by the US Census and OMB as White; however, there is increasing evidence that they may not consider themselves to be White.[14] For these reasons, VISIBLE inclusion criteria do not require that participants self-identify as a specific racial or ethnic category, but rather, allow them to report their race and/or ethnicity as they identify themselves.

Scalp Psoriasis

Scalp psoriasis is prevalent among populations with SoC[15,16] and is associated with reduced quality of life, regardless of overall psoriasis severity.[17,18] Additionally, hair characteristics (eg, follicle shape, density, and moisture content) can vary considerably among individuals with SoC, along with hairstyling and hair care practices, which merit special consideration when evaluating and treating scalp psoriasis.[19] To address the need for data on scalp psoriasis treatment in people with SoC, VISIBLE specifically includes a cohort of participants with predominantly scalp psoriasis (cohort B; Figure 1), but does not specify a minimum body surface area, instead only requiring at least 1 plaque outside the scalp to confirm the diagnosis of psoriasis.

Research to Address Unmet Needs of Populations With SoC

Skin Tone and Pigmentation

Given that a key objective of VISIBLE is to include a high proportion of participants with melanin-rich and/or darker skin tones, it was important to incorporate skin tone measurements that are easy to use and familiar to dermatologists. After consulting with approximately 50 SoC advisers, it was decided that objective colorimetry would be used, and results would be converted to the FST scale (type I-VI), which is most familiar to dermatologists.

Table. Determination of Fitzpatrick Skin Type Based on Individual Typology Angle and Melanin Index[12-14]

Fitzpatrick skin type	Individual typology angle (range, -90° to 90°)	Melanin index (range, 0 to 999 arbitrary units)
I	55° to 90°	<500
II	41° to 54°	
III	28° to 40°	500 to 599
IV	10° to 27°	600 to 699
V	-29° to 9°	700 to 799
VI	-90° to -30°	≥800

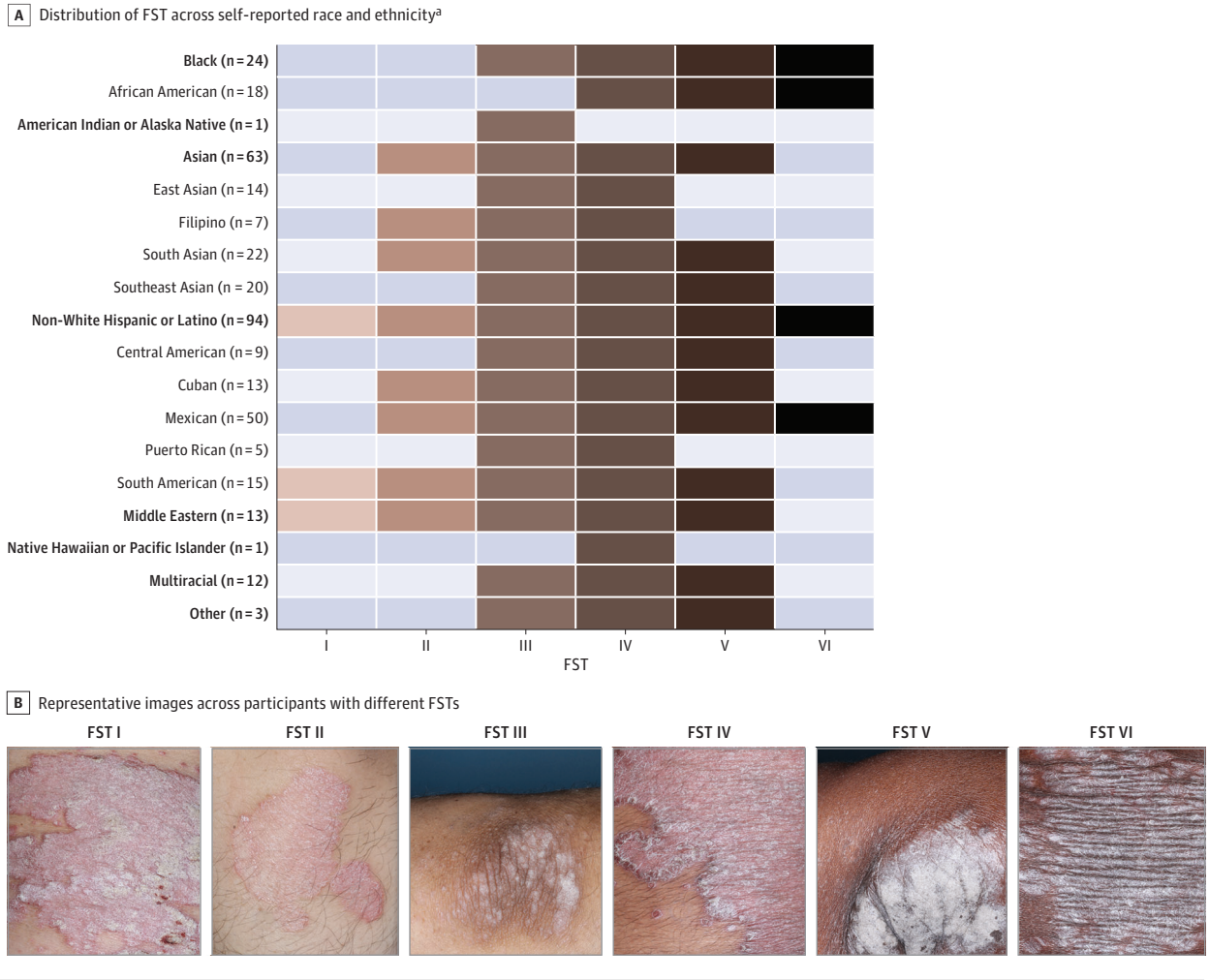
Traditionally, FST has been used as a proxy for skin tone and pigmentation, despite its original purpose to classify propensity of skin to tan or burn in response to sun exposure.[7,20,21] However, using visual assessment of skin tone and pigmentation to determine FST is imprecise and subjective.[22] Moreover, visual assessment of exposed skin pigmentation does not accurately estimate response to UV exposure or other stimuli (eg, inflammation) nor correlate with self-identified race and/or ethnicity.[22,23] To avoid the inherent subjectivity of FST assessment, objective colorimetry is used in VISIBLE to quantitatively determine constitutive skin tone and pigmentation of a non–sun-exposed area of skin based on individual typology angle (ITA) and melanin index. Colorimeter results are reported using the International Commission on Illumination L*a*b* color system, which measures skin lightness, erythema, and pigmentation.[24] ITA is calculated based on skin lightness and pigmentation.[24] ITA and melanin index values were converted to a I to VI scale similar to the FST, based on ranges shown in the **Table**.[24-26] If skin tone based on melanin index did not concur with ITA, skin tone was determined by ITA alone.

Although genetic predisposition may cause members of a particular race and/or ethnicity to trend toward darker skin tones, race and ethnicity are social constructs that do not directly correlate with skin tone, and prior studies have demonstrated how broadly particular race and ethnic groups can span the FST spectrum.[25] Because a goal of VISIBLE is to maximize diversity and inclusivity, the trial intentionally included participants of all skin tones. Consistent with previous studies, a wide range of skin tones can be seen across each self-identified race and ethnicity among participants enrolled in VISIBLE (**Figure 2**A and B). Furthermore, given that patient populations in previous psoriasis studies have been composed predominantly of participants with lighter skin, VISIBLE was designed with a minimum enrollment target of 50% of participants with FST IV to VI. The trial successfully recruited a study population in which approximately 70% of participants had FST IV to VI.

Enhancing Evaluation of Psoriasis Severity and Signs Across the Skin-Tone Spectrum

Although the visual appearance of psoriasis may be affected by constitutive skin pigmentation,[8,27] most medical re-

Figure 2. Range of Race and Ethnicity Categories and Fitzpatrick Skin Type (FST) Scores Across the VISIBLE Trial Population



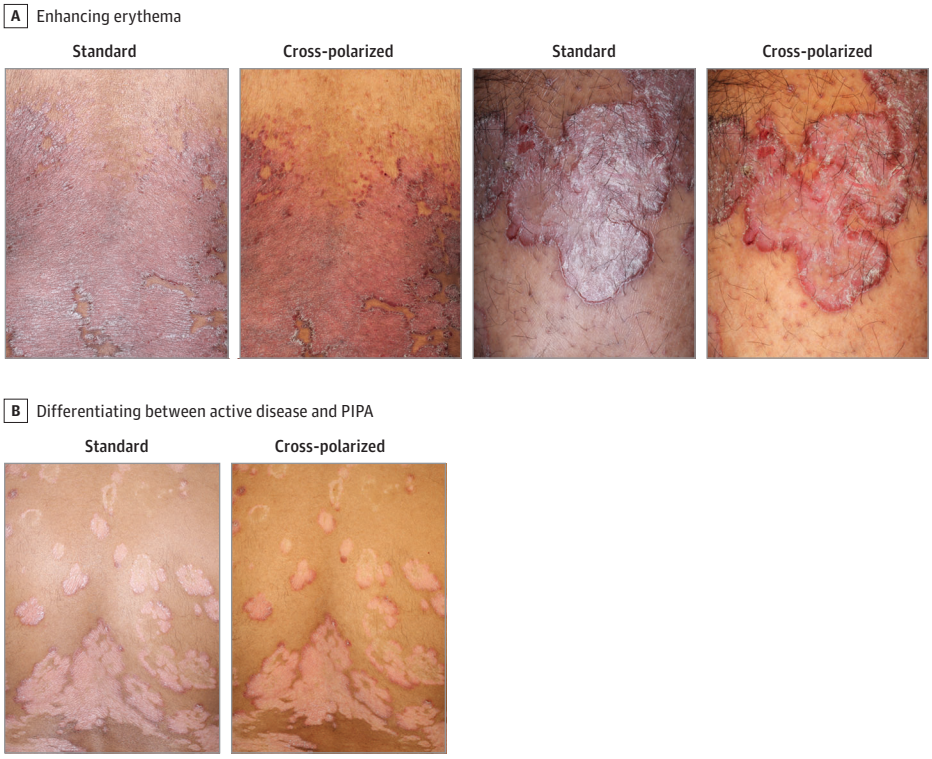
[a]Subcategories shown were reported in more than 5 participants.

sources contain images of individuals with lighter skin and plaques characterized by salmon-pink coloration and silvery scale.[8,28] The lack of representative psoriasis images in darker skin types may affect whether individuals perceive that they have psoriasis and should seek medical care, as well as clinicians' ability to recognize psoriasis, accurately determine disease severity, and evaluate treatment response in people with SoC. To promote consistent evaluations across VISIBLE investigators and study sites, dedicated training modules developed by experts in SoC (including A. A.), which included sample images depicting the entire range of psoriasis severity across the spectrum of skin tones (eg, lightly, intermediately, or darkly pigmented skin), were used along with a quiz to confirm investigator comprehension of ratings across skin tones. Additionally, a blinded panel of experts in SoC compared participant photographs and investigator ratings throughout the trial to ensure consistent assessment, and provided feedback and additional training, as needed.

Because erythema has a varied and nuanced appearance on melanin-rich skin,[8,29] psoriasis severity is more likely to be underestimated in individuals with SoC. Cross-polarized photography has been used to successfully assess changes in various inflammatory dermatologic diseases.[29] To support objective evaluation of disease severity in participants with SoC, clinical photographs are obtained at regular intervals, using both standard and cross-polarized lighting (**Figure 3**). In addition to decreasing glare and enhancing erythema, cross-polarized photography increases contrast between lesions and underlying skin, which is particularly useful for differentiating erythema from hyperpigmentation in individuals with SoC.[29] At the end of the study, VISIBLE will have approximately 20 000 standard and cross-polarized clinical images of psoriasis across diverse skin tones that can be used for both patient and clinician education.

Lastly, colorimeter and spectrophotometric measurements (for erythema and melanin, in particular) of lesional (≥2 lesions) and nonlesional skin are tracked throughout the study, provide objective measurements of improvement, and detect changes that may not be discernable to the human eye. The association between objective measurements and physician- and patient-reported measures of disease, as well as

Figure 3. Use of Standard vs Cross-Polarized Photography for Evaluation of Psoriasis Disease Severity



Participants with Fitzpatrick skin type VI and IV are shown in panels A and B, respectively. PIPA indicates postinflammatory pigment alteration.

histologic staining of inflammation and melanin, will be examined.

PIPA

Clearance of psoriasis plaques is commonly associated with PIPA, which may manifest as hyper- or hypopigmentation in an area previously affected by psoriasis. Although PIPA may affect all skin types, it is observed more frequently in people with darker skin tones, with increased risk of hyperpigmentation associated with FST of IV or greater.[30,31] PIPA may have a substantial impact on quality of life,[32-34] and patient surveys identify treatment of PIPA as a substantial unmet need.[32] Despite the importance of addressing PIPA, little is known about its evolution as psoriasis plaques clear or whether factors such as skin tone or constitutive pigmentation, race and/or ethnicity, and/or initiation or duration of treatment play a role in its progression. To collect much-needed data across all skin tones, VISIBLE is assessing PIPA using colorimetric devices and standard and cross-polarized photography (Figure 3), as well as patient- and physician-reported measures (ie, Skin Discoloration Impact Evaluation Questionnaire and Postinflammatory Dyspigmentation Area and Severity Index). Because it may take a prolonged period of time for PIPA to resolve, these data are being collected during a 2-year follow-up period.

Comorbidities

Epidemiologic studies have consistently demonstrated higher prevalence of metabolic syndrome and cardiovascular comorbidities among patients with psoriasis.[35] Furthermore, the prevalence of metabolic syndrome and cardiovascular disease varies across race and ethnicity groups.[36] The population enrolled in VISIBLE has a high comorbidity burden: more than 70% of participants have dyslipidemia, approximately 20% have diabetes, approximately 60% have hypertension, and more than 30% have metabolic syndrome; some of these comorbidities were identified at the time of enrollment in VISIBLE. To explore the impact of comorbidities on psoriasis outcomes in this population, VISIBLE is evaluating biomarkers for metabolic and cardiovascular disease. In addition, low vitamin D levels have been associated with higher risk for psoriasis,[37] and current literature[38] is not definitive on whether skin pigmentation impacts vitamin D production, although some evidence supports this.[39,40] Thus, VISIBLE is examining the associations between vitamin D levels and skin pigmentation and psoriasis response to treatment.

Results

Steps taken to promote recruitment of participants with SoC have yielded promising results. The study recruited faster than anticipated. In cohort A, the first participant was randomized in August 2022, and the last participant was randomized in February 2023. In cohort B, randomization occurred between September 2022 and March 2023. Based on our calculation that historically, individuals who self-identify as Asian, Black, or Hispanic have been recruited at a rate of 0.06 participants per

site per month in psoriasis trials, VISIBLE enrollment was completed approximately 7 times faster (0.4 participants/site/month) than historical data estimated. We anticipated a slightly higher rate compared to historical trials, given the detailed site selection process intended to bolster enrollment of participants with SoC; this rate exceeded our expectations.

Discussion

The VISIBLE study represents an advancement in clinical trial design, incorporating numerous strategies to improve diversity and participant retention (Box). The key novel methods and strategies included development of culturally sensitive investigator training, use of objective measures, inclusion of study sites with higher SoC representation that were new to the trial sponsor, and provision of transportation and translation services. Together these approaches resulted in the successful enrollment and retention of a diverse trial population. The strategies used in VISIBLE are consistent with recommendations in the literature,[41-43] in addition to the overarching efforts to continue to increase clinical trial diversity by reducing barriers to health care access and insurance, improving health literacy, reducing practitioner prejudice and bias, increasing awareness of clinical trials, and building trust in health care systems among racial and ethnic minority communities.[41-43]

Strengths and Limitations

Use of colorimetry in VISIBLE provides an objective method for quantitative measurement of constitutive skin tone and pigmentation and helps ensure uniformity of skin tone assessment across all sites. VISIBLE is also capturing novel data on pigmentation after psoriasis treatment and clearance of lesional skin. However, introducing new instrumentation and assessments into a psoriasis clinical trial poses challenges in data interpretation because results may not be fully understood or predictable. Because of uncertainty in interpretation and analysis of colorimeter data, FST is used as a reference to anchor colorimetry findings. The FST scale was chosen after discussions with experts in SoC who agreed that despite its limitations, FST is well known among dermatologists, even though traditional FST determination is subjective and not designed for skin tone assessment.

Without using quotas for enrollment by race and ethnicity, the final VISIBLE study population is consistent with reported demographic characteristics of the US population with psoriasis and SoC.[44] Allowing participants to self-identify race and/or ethnicity allowed for broad inclusivity; however, to have adequate power for statistical comparisons and analyses, some self-identities will be grouped together. Although the sample sizes in cohorts A (103 participants) and B (108 participants) are large enough to ensure sufficient statistical power for comparisons between guselkumab and placebo, VISIBLE is a relatively small study compared to most pivotal psoriasis trials. The VISIBLE study was developed with input from a diverse group of experts in SoC who agreed to use currently available yet imperfect scales and standards. We expect that VISIBLE will be one of many studies to continue to advance the field. Acknowledging its strengths and limitations will help to contextualize the trial results within the broader dermatology clinical trial landscape.

Conclusions

The findings of this quality improvement assessment indicate that VISIBLE is a unique trial focused on addressing key data and knowledge gaps pertaining to participants who have moderate to severe plaque psoriasis across a diverse range of skin types and race and ethnicity groups. Innovations in the VISIBLE study include broadening inclusivity via participant self-identification of race and ethnicity and participation of individuals representing a full range of skin types, using objective measures of skin tone and pigmentation (eg, colorimetry and spectrophotometry), and implementing enhanced photography with central review to complement investigator training and ensure consistent evaluations across the spectrum of skin tones. Data from VISIBLE will help address important clinical care gaps and inform best practices to drive inclusive clinical research in dermatology. Enrollment in VISIBLE exceeded expectations set by historic psoriasis recruitment data, indicating that strategic changes to clinical trial design can affect participation of diverse individuals, even in diseases traditionally considered to be less prevalent in those with SoC.

ARTICLE INFORMATION

Accepted for Publication: October 5, 2024.

Published Online: December 11, 2024. doi:10.1001/jamadermatol.2024.5103

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Park-Wyllie, Gao, Grimes, Shahriari, Yadav, Kindred, Taylor, Desai.
Statistical analysis: Rodriguez, Choi, Chan, Gao, Desai.
Obtained funding: Choi, Chan, Park-Wyllie.
Administrative, technical, or material support: Vashi, Rodriguez, Choi, Bronner, Yadav.
Supervision: McMichael, Rodriguez, Yeung, Choi, Chan, Grimes, Shahriari, Yadav, Kindred, Taylor.
Other–Lead investigator: Alexis.
Other–Editing: Alkousakis.

Conflict of Interest Disclosures: Dr Alexis reported grants (funds to institution) from Leo, Amgen, Galderma, Arcutis, Dermavant, AbbVie, Castle, and Incyte; advisory board/consulting fees from Leo, Galderma, Pfizer, Sanofi-Regeneron, Genzyme, Dermavant, Beiersdorf, Ortho, L'Oréal, Bristol Myers Squibb, Bausch Health, UCB, Arcutis, Janssen, Allergan, Almirall, AbbVie, Amgen, VisualDx, Eli Lilly, Swiss American, Cutera, Cara, EPI, Incyte, Castle, Apogee, Canfield, Alphyn, Avita Medical, Genentech, and Boehringer Ingelheim; speaker fees from Regeneron, Sanofi-Genzyme, Bristol Myers Squibb, L'Oréal, Janssen, J&J, and Aerolase; royalties from Springer, Wiley-Blackwell, Wolters Kluwer Health, and Elsevier outside the submitted work. Dr McMichael reported advisory fees and nonfinancial support from Arcutis, Galderma, Pfizer, Lilly, Rivian, Kenvue, Janssen, Sun Research, L'Oréal, and Incyte Research outside the submitted work. Dr Vashi reported consulting and/or advisory fees from L'Oréal, Janssen, and Canfield outside the submitted work. Dr Bhutani reported research funding from Amgen, Castle, CorEvitas, Novartis, Pfizer, and Regeneron and reported advisory fees from AbbVie, Arcutis, Aslan, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Galderma, Incyte, Janssen, Leo, Lilly, Pfizer, Novartis, Sanofi, Sun Research, Takeda, and UCB, and speaking fees from Amgen, Arcutis, Galderma, Janssen, Lilly and Leo outside the submitted work. Dr Rodriguez reported personal fees from UCB, Bristol Myers Squibb, Incyte, Sun Pharma, Lilly, Leo Pharma, AbbVie, and Arcutis, and grants from Leo Pharma outside the submitted work. Dr Yeung reported personal fees AbbVie, Novartis, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, JAMP, UCB, Leo Pharma, and Sun Pharma outside the submitted work. Dr Chan reported equity in Johnson & Johnson outside the submitted work. Dr Grimes reported consulting fees and/or grants from Incyte, Skin Better Science, L'Oréal, Pfizer, Laseroptek, AbbVie, Allergan, and Scientis, and equity in Mother Science/Versicolor Technologies outside the submitted work. Dr Shahriari reported consulting (honoraria) from AbbVie, Amgen, Apogee, Arcutis, Bristol Myers Squibb, Dermavant, Galderma, Pfizer, Incyte, Janssen, Leo, Lilly USA, Novartis, Sanofi-Genzyme, Regeneron, and UCB; speaker fees from AbbVie, Arcutis, Bristol Myers Squibb, Lilly USA, Janssen, Dermavant, Pfizer, Galderma, UCB, Sanofi, and Regeneron; and has served as an investigator for AbbVie, CorEvitas Psoriasis and Atopic Dermatitis Registry, Dermira, Cara, Dermavant, Novartis, Union, and Mindera outside the submitted work. Dr Yadav reported consultant/speaker/advisory board honorarium from AbbVie, Amgen, Aralez Bio, Arcutis, Bausch Health, BioJAMP, Bristol Myers Squibb, Byrdie, Cipher, Galderma, Incyte, Janssen, Kenvue, Leo, L'Oréal, Novartis, Paladin, Pfizer, Proctor & Gamble, Sanofi, Sun Pharma, UCB, and Unilever; and grants, research or clinical trial support from AbbVie, Amgen, Janssen, Sanofi, Lilly, and MoonLake outside the submitted work. Dr Kindred reported consulting, advisory and/or speaker fees from Lilly, UCB, Novartis, Sun, Janssen, AbbVie, Pfizer, Regeneron, and Sanofi; has served as an investigator and/or medical board member for Lilly, Aerolase, AbbVie, Pfizer, and Selphyl; and is a journal editor for Cutis outside the submitted work. Dr Taylor reported consulting, advisory, and/or speaking fees from Johnson & Johnson Innovative Medicine, AbbVie, Avita Medical, Beiersdorf, Arcutis Biotherapeutics, Hugel America, Biorez, Bristol Myers Squibb, Cara Therapeutics, Dior, Eli Lilly, EPI, Incyte, Estée Lauder, Evolus, Galderma, Glo Getter, Johnson & Johnson Innovative Medicine Advisory Board, LearnSkin, L'Oréal, Medscape, MJH Life Sciences, Pfizer, and Piction; equity in Glo Getter, Piction, Sanofi, Scientis US, UCB, and Vichy Laboratories; and grants from Allergan, Concert Pharmaceuticals/Sun Pharma, Croma Pharma GmbH, Eli Lilly, and Pfizer outside the submitted work. No other disclosures were reported.

Funding/Support: This work was supported by Janssen Scientific Affairs (Horsham, Pennsylvania).

Role of the Funder/Sponsor: The study sponsor was involved in the design and conduct of the study, and in the collection and analysis of the data. The authors provided the interpretation of the results and made the decision to submit the manuscript for publication.

Meeting Presentation: This research was presented in part at the 2024 American Academy of Dermatology Annual Meeting; March 8 to 12, 2024; San Diego, California.

Data Sharing Statement: See Supplement 3.

Additional Contributions: We thank the participants, investigators, and study personnel who made the VISIBLE study successful. Medical writing support was provided by Erica Chevalier-Larsen, PhD, and Cherie Koch, PhD (Janssen Scientific Affairs; Horsham, Pennsylvania) under the direction of the authors and in accordance with Good Publication Practice guidelines; these contributors were not compensated beyond a regular salary.

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