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Advancing Representation in Dermatology Clinical Trials: Ethical, Scientific, and Regulatory Imperatives for Inclusion Across all Fitzpatrick Skin Types

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Abstract

Underrepresentation of darker Fitzpatrick skin types in dermatology clinical trials remains a persistent scientific and ethical problem in the United States. Although the U.S. population has become markedly more diverse, clinical evidence in dermatology continues to be generated using samples disproportionately composed of individuals with lighter skin types. This imbalance raises concerns regarding diagnostic accuracy, therapeutic efficacy, and safety assessment across the full spectrum of skin phenotypes. The recent growth of the field of skin of color dermatology has highlighted the limitations of dermatologic knowledge derived primarily from light-skinned participants and has prompted renewed attention to inclusive research design. In this paper, we examine why certain Fitzpatrick skin types are systematically prioritized in dermatology trials, describe the scientific and clinical consequences of this imbalance, and evaluate how diversity oriented methodological practices, regulatory expectations, and specialty level developments can strengthen both the internal and external validity of dermatology research. Drawing from bioethics and regulatory perspectives as well as clinical dermatology expertise, we propose an updated framework for improving representation, advancing patient equity, and ensuring that dermatology research more accurately reflects the population it intends to serve.

Keywords: Diversity; Inclusion; Skin of Color; Fitzpatrick; Clinical Trials

Abbreviations

FDA: Food and Drug Administration; NIH: National Institutes of Health; IRBs: Institutional Review Board.

Introduction

Dermatology relies more than most medical specialties on the visual interpretation of clinical signs, diagnostic patterns, and morphological changes [1-12]. Historically,

dermatology clinical trials have disproportionately enrolled participants with mid-range Fitzpatrick skin types (III–IV), while individuals with the lightest (I–II) and darkest (V–VI) skin types have often been under- represented [4,8,13]. This pattern has been documented across multiple disease areas, including melasma [8], acanthosis nigricans [13], and psoriasis [4], though recent efforts, such as the VISIBLE psoriasis study, illustrate how intentional recruitment strategies can broaden representation across the full spectrum of skin phenotypes [4]. Studies across inflammatory dermatoses, pigmentary disorders, psoriasis, atopic dermatitis, acne, and cutaneous oncology demonstrate that darker Fitzpatrick skin types are included at lower rates than their prevalence in the general population would predict [1,4,14]. Although this pattern has been documented for more than two decades [1,2,14], the demographic composition of the United States has shifted significantly in the same period [3], widening the gap between research participants and real-world patient populations.

The consequences of this disparity are increasingly well understood, with underrepresentation of darker Fitzpatrick skin types limiting the generalizability of clinical trial findings and potentially affecting diagnostic accuracy, therapeutic efficacy, and safety assessments [4,8,14]. Diagnostic scales such as erythema indices, photographic severity ratings, and automated imaging tools are often calibrated for lighter skin, which can reduce accuracy and reliability when applied to darker Fitzpatrick skin types [15-17]. Similarly, therapeutic studies may fail to capture relevant safety or efficacy outcomes if pigmentation, dyschromia, scarring tendencies, and post-inflammatory responses are not adequately represented [4]. These limitations affect both clinical practice and public health, and raise ethical and regulatory concerns regarding justice, beneficence, and equitable distribution of research burdens and benefits [2,14,18,19].

Recent growth in the subspecialty of skin of color dermatology has created new emphasis on improving representation in research [19,20], expanding clinician expertise, and identifying the ways in which structural, methodological, and regulatory factors have historically limited inclusion. Despite this progress, many dermatology trials continue to overrepresent lighter skin types for reasons related to recruitment practices, institutional location, trial design, diagnostic scale selection, and long-standing assumptions about the generalizability of lighter-skinned cohorts [2,14,15].

This paper examines the origins and persistence of this imbalance, evaluates its impact on the scientific validity of dermatology research, and proposes a set of ethical, regulatory, and methodological principles to support meaningful inclusion of all Fitzpatrick skin types in clinical trials. Drawing from the authors' combined expertise in dermatology, bioethics, and institutional review board governance, the analysis situates the issue within the broader discourse on equitable research conduct and considers the growing role of the skin of color subspecialty as a driver of evidence-based reform.

Background

Diversity in clinical research has long been recognized as a critical determinant of both generalizability and social value, with ethical and methodological imperatives underscoring the need for inclusive participant populations [21-23]. In dermatology, underrepresentation of darker Fitzpatrick skin types has been repeatedly documented across a variety of conditions, including psoriasis, atopic dermatitis, acne, and pigmentary disorders [1,4,14]. Historically, clinical trials have prioritized lighter skin types for reasons including convenience of recruitment, concentration of academic dermatology centers in predominantly light-skinned populations, and reliance on diagnostic tools validated primarily in these populations [1,4,14].

Ethical and regulatory frameworks reinforce the importance of representative participation. The Belmont Report, the Declaration of Helsinki, and subsequent guidance from the FDA and NIH emphasize that the social value of research is contingent on producing knowledge that is generalizable to populations who will ultimately receive interventions [24-27]. Underrepresentation of certain Fitzpatrick skin types not only undermines external validity but raises ethical concerns regarding justice and equitable distribution of research benefits and risks [2,15,24].

Recent initiatives within dermatology, particularly the growth of the skin of color subspecialty, have sought to address structural and operational barriers to inclusion. These initiatives include training investigators to recognize dermatologic presentations in high-melanin skin, improving cultural competency in recruitment strategies and developing diagnostic scales validated across the full Fitzpatrick spectrum [16,28]. Such advances underscore that the problem is not simply one of participant availability, but also of methodology, training, and oversight.

Quantitative Landscape of FST Representation

Empirical studies have quantified the gap between trial enrollment and population demographics in the United States. A 2022 analysis of dermatology clinical trials found that participants with Fitzpatrick skin types I–III constituted approximately 75–85% of trial enrollees, while those with skin types IV–VI, who represent nearly 40% of the U.S.

population, accounted for only 10–25% of participants [1]. The enrollment disparity was most evident in clinical trials focused on inflammatory dermatoses such as psoriasis and atopic dermatitis, as well as in pigmentary disorders and studies assessing adverse events from therapeutics with pigment-altering effects [1].

The aggregate data reported by Chen V, et al. [1] highlight several persistent inequities in dermatology clinical trials [1]. Participants with lighter Fitzpatrick skin types (I–III) continue to dominate study populations, whereas those with darker skin types (IV–VI) remain markedly underrepresented despite increased awareness and guidance from funding agencies [29]. Measurement and diagnostic limitations further exacerbate this gap; endpoint tools such as erythema scoring and photographic assessment scales are less reliable in high-melanin skin, reducing diagnostic precision and potentially influencing outcome assessment [30,31]. The clinical consequences are nontrivial: therapeutic efficacy and adverse-event profiles may vary by skin type, and reliance on instruments calibrated for lighter skin tones risks misclassification of disease severity or response [1,31]. Collectively, these factors undermine both the external validity and the equity of dermatologic research.

Collectively, these findings underscore that clinical trial results derived predominantly from lighter Fitzpatrick skin types may not be fully generalizable to the broader U.S. population, highlighting the need for methodological and operational strategies to improve representation in dermatology research.

Discussion

The persistent underrepresentation of darker Fitzpatrick skin types (FST IV–VI) in dermatology clinical trials reflects not only technical limitations in measurement and trial design, but also broader ethical and regulatory considerations, underscoring the intersection of methodology, policy, and justice [1,2]. The empirical record shows that many trials either omit FST reporting or include minimal participation from darker skin types [1,2,31], even when those populations bear disproportionate dermatologic burdens. The absence of data on darker Fitzpatrick skin types (FST IV–VI) not only limits the generalizability of trial results but also undermines the evidentiary foundation for evaluating therapeutic safety and efficacy, thereby creating patterns of implicit exclusion that perpetuate inequities in dermatologic care [1,2,31].

Measurement and evaluation constitute the first layer of this ethical and scientific challenge. Dermatology trials that rely predominantly on visual endpoints, such as erythema scoring or the Investigator Global Assessment, often use instruments whose limited reliability compromises their validity for participants with darker skin tones (FST IV–VI) [30,32]. This introduces systematic measurement error that disproportionately impacts FST V–VI populations, increasing the risk of misclassification of disease severity and misestimation treatment response [30,32]. Objective metrics such as spectrophotometry, colorimetry, or cross-polarized imaging have been validated in smaller studies, yet their adoption in dermatology clinical trials remains limited [15,33]. Integrating validated objective measurement tools is essential to uphold both scientific accuracy and ethical legitimacy, ensuring that dermatology trials meet rigorous bioethical standards for the inclusion of participants with darker Fitzpatrick skin types (FST IV–VI) [15,33].

Measurement limitations in dermatology trials are not merely technical challenges; rather, they carry significant ethical and regulatory implications. IRBs have a responsibility to ensure that studies generate valid, generalizable evidence while protecting participants from harm. When clinical evidence is derived from non-representative samples, these limitations can skew inferences, potentially overestimate therapeutic efficacy and underestimate adverse effects for underrepresented populations, thereby raising concerns about justice and equitable treatment in research [30,33-35]. Pigmentary disorders such as melasma and post-inflammatory hyperpigmentation may manifest and respond differently across Fitzpatrick skin types. However, some clinical trials do not sufficiently stratify participants by skin type or report disaggregated outcomes, which can obscure important differences [36-38]. This transforms a question of design into a question of justice: whose outcomes are considered worthy of being measured [34-36].

From a methodological perspective, representativeness is inseparable from validity [1]. Trials that fail to include a demographically and phenotypically diverse participant base risk producing findings that lack generalizability and, by extension, scientific integrity. Ethical oversight requires IRBs to ensure that a study's design can generate knowledge applicable to the populations who will ultimately receive the interventions being tested [18,35]. This obligation extends beyond procedural compliance; it reflects a broader commitment to justice, ensuring that the benefits and burdens of research are distributed equitably across all patient populations. Trials should be powered and stratified to detect clinically meaningful differences across FSTs, and techniques such as oversampling or adaptive enrichment can achieve this without excessive cost. In such instances, the ethical challenge for IRBs and investigators alike is to recognize how methodological constraints may inadvertently limit the social value of research. Addressing these gaps is not only a matter of scientific rigor but also of fulfilling the fundamental ethical principles of justice, beneficence, and

respect for persons, which ensures that all populations stand to benefit equitably from the knowledge research produces.

Operational barriers including, limited recruitment sites, language discordance, and historical mistrust, are real but surmountable [1,39,40]. Many dermatology trials, like other clinical research studies, are often conducted at academic centers, which may predominantly serve lighter-skinned populations. Expanding recruitment to community clinics and minority-serving institutions could help diversify enrollment and build trust, consistent with strategies identified in broader clinical trial research [1,39,40]. Such operational strategies should be treated as methodological necessities rather than optional enhancements.

The expansion of skin-of-color expertise through the skin-of-color subspecialty offers a mechanism for structural reform in dermatology, providing a foundation for more inclusive trial design, broader enrollment, and greater trust among underrepresented populations [28,41]. Specialists trained in recognizing conditions in high-melanin skin can contribute to protocol design, endpoint selection, and recruitment strategy. Specialists trained in diagnosing and managing conditions in high-melanin skin can meaningfully influence protocol design, endpoint selection, and recruitment strategies. Their involvement highlights that underrepresentation can be meaningfully addressed through intentional expertise and inclusive design [42,43]. Integrating these experts into advisory panels could make inclusion structurally routine rather than aspirational.

Ethically, inclusion in dermatology research extends beyond mere representation to reciprocity. When FST IV–VI populations are underrepresented in trials, yet results are generalized to them, the contributions of participants are unevenly distributed, creating a moral and ethical imbalance that raises concerns of justice and fairness in research [18,44]. Equity in participation ensures equity in benefit, and IRBs play a crucial role in safeguarding this principle through deliberate, thoughtful protocol review [18,44]. Where investigators claim inclusion is infeasible, IRBs may consider requiring documentation of recruitment efforts and a remediation plan along with ongoing monitoring to ensure that corrective actions are implemented and that enrollment goals for underrepresented FST populations are actively pursued.

Digital health tools, including AI-based diagnostic systems, amplify the consequences of non-representative data. Models trained primarily on lighter skin tones risk reduced accuracy and misclassification when applied to FST IV–VI populations, reproducing inequities in diagnostic performance and clinical decision-making [45,46]. Trials evaluating such tools should document dataset composition and algorithmic performance stratified by Fitzpatrick skin type to ensure fairness, scientific validity, and ethical integrity. This practice aligns with the ethical obligations of IRBs and investigators to prevent harm, promote justice, and ensure that technological advances benefit all patient populations equitably.

Policy implications of underrepresentation in dermatology trials are substantial. The FDA guidance encourages, but does not mandate, diversity in clinical research, leaving implementation up to sponsors and investigators [14,26]. Explicit Fitzpatrick skin type reporting requirements would provide enforceable standards, improving transparency, accountability, and comparability across trials [2]. Funders and journals could reinforce these norms by requiring disclosure of FST distributions in publications, thereby incentivizing inclusion and enabling IRBs and investigators to evaluate whether studies adequately represent the populations who will ultimately receive the interventions. IRBs have an ethical responsibility to consider these reporting and inclusion standards during protocol review, ensuring that study designs promote justice, fairness, and equitable access to the benefits of research.

Cost and feasibility are valid considerations in dermatology clinical trials, but they do not ethically justify the exclusion of FST IV–VI populations. Expanding recruitment networks, training evaluators in skin-of-color assessment, and using objective measurement tools may increase trial resources, but these represent implementation challenges rather than ethical exemptions [1]. Adaptive trial designs, such as stratified randomization, oversampling, or seamless designs, alongside collaborative consortium infrastructures, can mitigate additional costs while preserving scientific rigor and generalizability [47]. By proactively addressing operational barriers, investigators and IRBs can uphold the core bioethical principles of justice and equity while ensuring that trials yield broadly applicable, valid evidence.

Ultimately, ethical and scientific imperatives converge; dermatologic research that excludes darker FSTs produces incomplete knowledge and perpetuates inequity. IRBs must treat inclusion as intrinsic to validity and ethical integrity. This requires changes in protocol design and review processes that translate aspirational goals into concrete, measurable commitments. Diverse inclusion is not an optional feature of dermatology research; rather, it is foundational to credible, just, and ethically overseen science.

Conclusion

Addressing underrepresentation of darker Fitzpatrick skin types in dermatology clinical trials is both a scientific and ethical imperative. Ensuring adequate inclusion across all skin types strengthens the validity and generalizability of trial findings, improves diagnostic accuracy, and promotes

equitable distribution of research benefits and risks [1,14]. Operational strategies that include diversified recruitment, objective measurement tools, and adaptive study designs are necessary to achieve meaningful inclusion [26,47]. IRBs play a central role in enforcing these standards and ensuring that study designs reflect population diversity while upholding bioethical principles of justice, equitable research, and responsible research conduct.

Declaration of Interest

The authors report no conflicts of interest.

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none

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