2025 SOCS MEETING THE CHALLENGE SUMMIT

Advancing Dermatology in Clinical Trials: Expanding Outcome Measures

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FDA

Thoughts from a Regulatory Dermatologist

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Disclaimers

This presentation reflects the views of the presenter and should not be construed to represent FDA's official views or policies.

Any representation of brand name drugs in this talk are for purposes of scientific discussion and specific comparison.

Presentation Outline

- What Skin Applied Products FDA Regulates
  (Drugs, Devices, Cosmetics)
- Why Population Representation Matters
- Examples: When Representation Is Necessary
- Examples: When Representation Is Not Necessary
- Guidances and Regulatory Tools Available Today
- Practical Considerations for Investigators and Sponsors

FDA Headquarters, Silver Spring, MD

FDA Campus

Human Dermatology Most Relevant FDA Components:

Center for Drug Evaluation and Research (CDER)

- Office of New Drugs (OND) – small and large molecules
- Office of Generic Drugs (OGD)
- Division of Dermatology and Dental Drug Products

Center for Devices and Radiological Health (CDRH)

Office of Cosmetics and Colors

When Representation Matters

- Skin disease prevalence differences
- Optical/diagnostic device validations
- Therapeutics with different responses (e.g. pharmacogenomics)
- Melanin related treatments (hydroquinone)
- Hyperpigmentation risk (including post-inflammatory)
- Hypopigmentation risk

Consequences of Partial Representation

- Ciclopirox (Loprox™) shampoo labeling
- Light-based therapeutic devices that have poorer performance
- Light-based diagnostic devices that are less accurate for patients with darker skin
- Artificial intelligence machine learning skin lesion diagnostics
- Antifungal studies conducted overseas that don’t address U.S. incidence

When It May Not Be Needed

- Products without plausible population-specific differences
- Bioequivalence studies where subject variability is minimized
- For generic drugs – the focus is on formulation
- Scientific justification over “checkbox” inclusion

Guidance Documents

Final Guidances that address study population representation:

- **Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products (January 2024):** standards for collecting and reporting of race and ethnicity data in clinical trials to ensure consistency and comparability across studies

- **Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs (November 2020):** trial designs, eligibility criteria, and enrollment practices to enhance representation of clinical trial populations. Who is most likely to use the medical product?

Draft Guidance: Diversity Action Plans to Improve Enrollment of Participants From Underrepresented Populations in Clinical Studies (June 2024): mandated by the Food and Drug Omnibus Reform Act of 2022 (FDORA), describes the required format and content of Diversity Action Plans for certain drug and device studies. It supersedes the April 2022 draft guidance and expands the scope of diversity considerations to include age group, sex, race, and ethnicity, as well as encouraging consideration of other factors like geographic location and socioeconomic status.

The FDA website for this guidance states the following:

> "Per a court order, HHS is required to restore this website to its version as of 12:00 AM on January 29, 2025. Information on this page may be modified and/or removed in the future subject to the terms of the court's order and implemented consistent with applicable law. Any information on this page promoting gender ideology is extremely inaccurate and disconnected from truth. The Trump Administration rejects gender ideology due to the harms and divisiveness it causes. This page does not reflect reality and therefore the Administration and this Department reject it."

Practical Considerations

- Population relevance for U.S. treated diseases
- Site demographics/site selection
- Recruitment practices
- Impact on enrollment
- Bench validation of devices prior to clinical studies – development of appropriate test methods for skin of color

Summative Conclusions

- Specific responsibilities when developing products for certain skin diseases to ensure representation – these include drugs, devices, and cosmetics
- When needed, assessment of safety and effectiveness in representative
- Population and skin type considerations may or may not matter depending on product/treatment specificities
- FDA guidance documents are available to provide framework considerations

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Thank You

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