Poster ID – **P0007**

Augmenting Clinical Trials in Dermatology: A New Paradigm Using Generative AI and Dermocosmetic Interventions for Acne Remission Maintenance

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Introduction & Objectives

Generative **artificial intelligence (AI)** is increasingly used in healthcare, notably to create realistic artificial datasets, which help overcome patient recruitment challenges and improve statistical power in clinical trials.

Maintaining acne remission after oral isotretinoin treatment remains a key clinical consideration. Although isotretinoin is highly effective, some patients may experience acne recurrence following treatment completion. Assessing the long-term benefit of a dermo-cosmetic product in this setting demands large cohorts and extended follow-up, making patient recruitment a key barrier to generating robust clinical evidence.

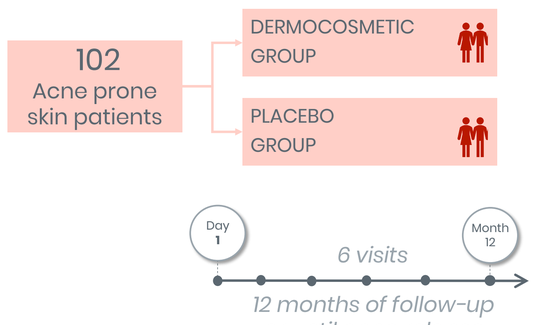
To address this challenge, AI-generated data, validated by both data scientists and expert dermatologists are used as a support tool to strengthen clinical evidence without replacing real-world data, ensuring full methodological rigor and clinical relevance.

Materials & Methods

A randomized, placebo-controlled clinical trial evaluated the efficacy of a dermo-cosmetic product (niacinamide and SMFE) in maintaining acne remission after oral isotretinoin treatment. 102 adolescents and young adults with acne-prone skin were randomly assigned to receive either the product or a placebo over a 12-month follow-up (6 evaluation visits).

Generative AI model: RHVAE (Riemannian Hamiltonian Variational Autoencoder)
For each real patient → 5 artificial patient profiles were created per treatment arm, maintaining balanced cohorts.

1. Randomized, placebo-controlled clinical trial



2. Generative AI by RHVAE model



102 real patients
510 artificial patients generated

Results

HOW ARE ARTIFICIAL PATIENTS GENERATED ?

Based on the real data, **the RHVAE generative model** learned the clinical patterns of the real recruited population across **over 1,000 variables.** It generated 5 artificial profiles per real patient, resulting in a total of **510 AI-generated patients.**

HOW DO WE ENSURE ARTIFICIAL PATIENTS ARE RELIABLE ?

Generated artificial datasets were evaluated against **a set of predefined fidelity** *(A, B)*, **diversity** *(C)* **and confidentiality** *(D)* **scores,** ensuring the quality and reliability of the artificial data.

A. Statistical Fidelity

Artificial patients show clinical distributions similar to real patients, with very small differences *(mean statistical distance: 0.006; max: 0.088).*

C. Patient Diversity

The model generates a wide variety of diverse profiles, not just copies of real patients *(37 iterations before collapse).*

D. Patient Confidentiality

No real patient can be re-identified from artificial data *(confidential ratio: 100%).*

B. Variable Interdependencies

Key clinical patterns and interdependencies between variables are preserved in artificial profiles, with real and artificial patients occupying a similar clinical space on PCA and a global multivariate statistical distance within acceptable thresholds *(0.031 - below 5%)*.

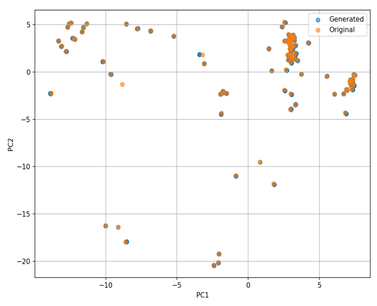


Figure 1. PCA projections of the original and AI-generated datasets show a similar overall distribution of patient profiles.



Figure 2. Covariance matrices of the original and AI-generated datasets show a close visual similarity.

HOW IS THE CLINICAL VALIDITY OF ARTIFICIAL PATIENTS CONTROLLED ?

The clinical validity of artificial patients was assessed through **a blinded review** in which expert dermatologists examined mixed real and artificial patient profiles, and no clinically significant differences were identified between the two types of profiles.

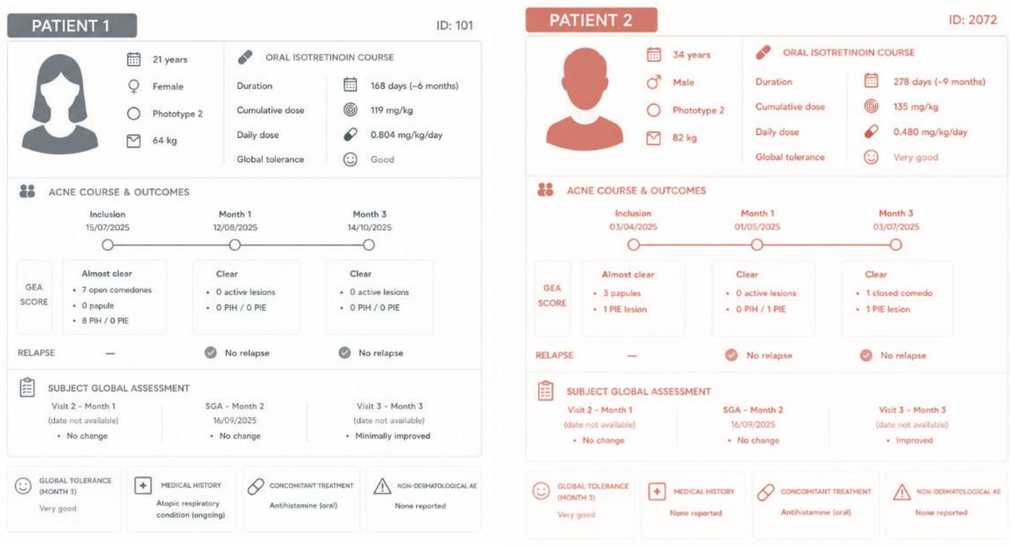


Figure 3. Examples of patient profiles: real or AI-generated, presented during the blinded dermatologist review.

Conclusions

Generative AI demonstrates its feasibility within the context of a dermo-cosmetic randomized controlled trial, especially in a field where enrolling large cohorts for extended follow-up periods remains a significant challenge.

Artificial cohorts reproduce real data structure while preserving confidentiality, thus paving the way for **augmented clinical trial paradigms,** providing that conclusions are always interpreted alongside real-patient results.

AI-AUGMENTED TRIAL: KEY ACHIEVEMENTS

- **x5 Sample Size**
- **Statistical Power**
- **Data privacy ensured**
- **Complementing real-world data**

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