

# Report of the IDEOM Meeting Adjacent to the GRAPPA 2024 Annual Meeting

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**ABSTRACT.** The International Dermatology Outcome Measures (IDEOM) organization presented updates on its patient-reported outcome measures (PROMs) for psoriasis (PsO), psoriatic arthritis (PsA), and other immune-mediated skin diseases at the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) 2024 annual meeting. The Hidradenitis Suppurativa working group reported on the IDEOM Musculoskeletal Questionnaire (MSK-Q), a PROM for MSK manifestations of psoriatic disease. Advances in PsA screening included integrating the Psoriasis Epidemiology Screening Tool (PEST) and 12-item Psoriatic Arthritis Impact of Disease (PsAID-12) questionnaires into the Epic electronic health record system to streamline detection and management of emerging PsA cases. The Connective Tissue Disease working group discussed upcoming trials and tools for addressing significant unmet needs in cutaneous lupus erythematosus. Finally, the Patient Satisfaction working group provided updates on the 7-item Dermatology Treatment Satisfaction Instrument (DermSat-7) and DermSat-11 for clinical trials and real-world studies. The DermSat-7 has been validated in a multicenter study of patients with PsO, whereas the DermSat-11 is currently undergoing validation. IDEOM continues to work to significantly improve patient outcomes and satisfaction in dermatology.

*Key Indexing Terms:* cutaneous lupus erythematosus, dermatology, GRAPPA, outcome assessment, psoriasis, psoriatic arthritis

## Introduction

International Dermatology Outcome Measures (IDEOM) is a nonprofit organization, established in 2013, dedicated to creating validated and standardized patient-reported outcome measures (PROMs) in the field of dermatology. The organization includes a diverse mix of patients, health economists, physicians, and representatives from regulatory agencies. IDEOM's goal is to enhance dermatologic research and treatment holistically to satisfy the needs of all aforementioned stakeholders.

IDEOM supports numerous ongoing initiatives to advance outcome measures in psoriasis (PsO), psoriatic arthritis (PsA), hidradenitis suppurativa (HS), connective tissue diseases (CTDs), cutaneous T cell lymphoma, itch, vitiligo, acne, and actinic kera-

toxis. During the IDEOM meeting at the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) 2024 annual meeting in Seattle, Washington, leaders presented updates on their ongoing projects on immune-mediated inflammatory dermatoses.

## Continued validation and current and future uses of the IDEOM Musculoskeletal Questionnaire

Dr. Joseph Merola presented updates on the IDEOM Musculoskeletal (MSK) Questionnaire (IDEOM MSK-Q) as an innovative instrument developed to assess MSK symptoms in patients with PsO regardless of PsA diagnosis.

The IDEOM MSK-Q consists of 9 items assessing 3 constructs: (1) intensity of MSK symptoms (pain, joint swelling, joint stiffness); (2) impact of MSK symptoms on health-related quality of life (HRQOL; work and/or school activities; family, social, and/or leisure activities; physical activity; sleep; emotional state); and (3) fatigue. Merola reviewed the need for the IDEOM MSK-Q, the development of the instrument, and early validation efforts. Current work includes validating the IDEOM MSK-Q as a means of capturing the intensity of MSK symptoms in psoriatic disease and their effect on HRQOL.

Recent construct validation efforts have been developed through a prospective longitudinal study using data from the Cohort for Psoriasis and Psoriatic Arthritis Registry (COPPAR). COPPAR collects data every 6 months on subjects, including assessments of skin and joint disease activity and a comprehensive set of patient-reported outcomes (PROs) covering various

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aspects of HRQOL, including the IDEOM MSK-Q. Additional information on demographics, lifestyle habits, comorbidities, medication usage, and family history are also collected.

A cross-sectional analysis of 245 patients registered in COPPAR was performed to compare patients' baseline IDEOM MSK-Q subscores alongside a robust set of corresponding instruments measuring similar or dissimilar but related constructs. There was a strong correlation between the IDEOM MSK-Q with instruments measuring PROs, HRQOL, and other aforementioned constructs, providing additional evidence that the IDEOM MSK-Q subscores demonstrate robust construct and known-groups validity. Current studies are evaluating the intrarater reliability, responsiveness, and cross-cultural validity of the IDEOM MSK-Q with several ongoing phase III and IV studies. The Preventing Arthritis in a Multi-Center Psoriasis At-Risk Cohort (PAMPA) trial (ClinicalTrials.gov: NCT05004727) and COPPAR clinical study (NCT03747939) already incorporate the IDEOM MSK-Q.

Future applications of the IDEOM MSK-Q may include its use as a screening tool for PsA, providing valuable insight into the transition from PsO to PsA. Its use for other diseases with MSK burden including HS, pustular PsO, and inflammatory bowel disease remains to be explored. These initiatives underscore the instrument's role in advancing our understanding of MSK symptoms in patients with PsO.

### **Screening for PsA and treating-to-target using the 12-item Psoriatic Arthritis Impact of Disease to improve clinical outcomes**

Dr. Alice Gottlieb reported updated findings of an ongoing study using the Psoriasis Epidemiology Screening Tool (PEST) and 12-item Psoriatic Arthritis Impact of Disease (PsAID-12) questionnaires for (1) screening for PsA, and (2) closely monitoring progress toward established treatment goals, or treating-to-target, to improve clinical outcomes.

PsA develops in up to one-third of patients with PsO and is undiagnosed in up to 41% of patients with PsO.<sup>1</sup> Prompt treatment of PsA is essential, as radiological damage presents in a significant proportion of patients within a median time frame of 2 years.<sup>2</sup> Whereas cutaneous disease typically precedes arthritis by 10-12 years, patients with mild psoriatic skin involvement can still develop debilitating PsA. Such findings highlight the role dermatologists can play in preventing disability through early detection and treatment of PsA.

In an effort to create a screening and treatment algorithm to address this need, Gottlieb applied IDEOM's MSK symptom framework in the Mount Sinai Health System to screen for MSK symptoms in patients with PsO and to evaluate PsA treatment effectiveness. This approach, based on outcomes from discussions at the 2020 IDEOM and GRAPPA meetings, involves patients with PsO completing the PEST via MyChart (Epic Systems) before their appointments. Patients scoring  $\geq 3$  on the PEST (ie, PEST-positive), indicating a high likelihood for PsA, and patients previously diagnosed with PsA by a rheumatologist subsequently complete the PsAID-12 on MyChart to assess MSK symptoms specific to PsA.

The data from these questionnaires are collected and converted to automatically displayed scores within Epic, which will prompt healthcare providers with recommendations for subsequent steps and best practices. A PsAID-12 score of  $\leq 4$  indicates a patient acceptable symptom state (PASS), supporting the continuation of the current treatment regimen. In contrast, a score  $> 4$  suggests an unacceptable symptom state, prompting healthcare providers to consider treatment modifications and/or referral to rheumatology.

Over 18 months, dermatology providers at Mount Sinai encountered 2341 patients with PsO, 37.9% of whom completed the PEST questionnaire. Of those patients, 24.5% were considered PEST-positive and subsequently completed the PsAID-12. A total of 62% of PEST-positive patients were within the target range, whereas 37.5% displayed an unacceptable PsAID-12 score. Of those patients out of the target range, 30.6% were referred to rheumatology and/or underwent therapeutic adjustment. In summary, IDEOM's MSK symptom framework demonstrates the effectiveness of the PEST and PsAID-12 as patient-centered screening tools and as benchmarks for clinical decision making.

### **Cutaneous lupus erythematosus: unmet needs and future collaborations**

Merola and Dr. Vibeke Strand highlighted significant unmet needs in cutaneous lupus erythematosus (CLE) and IDEOM's efforts to address them. CLE can frequently occur in patients without systemic lupus erythematosus (SLE), and up to 58% of patients with CLE do not progress to SLE.<sup>3</sup> There are limited treatment options and no US Food and Drug Administration (FDA)-approved medications for CLE, leaving patients reliant on systemic immunosuppressants or other limited therapies adapted from SLE therapies. Research is limited by the lack of consensus on classification, disease assessment, and regulatory agency-approved outcome measures.

Traditional SLE measures, including the Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) and the British Isles Lupus Assessment Group (BILAG) index, are not well aligned to measure CLE. These tools emphasize systemic symptoms of SLE, with limited dermatologic variables to describe skin-specific changes that are important in CLE. Drugs such as litiflimab, deucravacitinib, and anifrolumab are being evaluated in clinical trials using the Cutaneous Lupus Activity Investigator's Global Assessment revised instrument (CLA-IGA-R) and the Cutaneous Lupus Disease Area and Severity Index (CLASI) to more precisely assess the severity of CLE.<sup>4,5</sup> Merola and colleagues developed a provisional working core outcome set for CLE, ratified at an international meeting (the 5th International Conference of Cutaneous Lupus Erythematosus [ICCLE]) in Tokyo, including measures like CLASI-Activity (CLASI-A), CLA-IGA-R, CLASI-Damage (CLASI-D), Skindex-29+3 (CLEQOL), and patient global assessment of disease activity (PtGA).<sup>6,7</sup> Innovations such as RNA tape stripping for CLE<sup>8</sup> as well as more recent classification criteria<sup>9</sup> will help support clinical trials.

Collaborations with the Lupus Research Alliance (LRA), the FDA, and Outcome Measures in Rheumatology (OMERACT)

aim to advance these efforts. Strand presented updates from the OMERACT SLE working group, emphasizing the collaborative relationship between IDEOM and OMERACT in developing core outcome sets for CLE and SLE. To define the core domain set for SLE, a domain survey involving 100 patients with SLE at the University of Toronto and 145 stakeholders from 6 continents and over 26 countries highlighted differing priorities: disease activity, HRQOL, and functional ability were more important to stakeholders, whereas anxiety and sleep were more significant to patients. A scoping literature review is underway to refine candidate domains, definitions, and measurement instruments. Focus groups with a total of 36 patients with SLE from 5 continents identified 20 candidate domains, which will undergo the Delphi process for consensus, aiming for  $\geq 70\%$  agreement through 4 rounds from early fall 2024 to spring 2025. The goal is to establish a core domain set for SLE, with measurement instruments selected using the OMERACT Filter 2.2 and the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN)-OMERACT Good Methods Checklist.<sup>10</sup>

OMERACT and IDEOM plan to apply a similar process to CLE, aiming to establish a collaborative community of rheumatologists, dermatologists, patients, and stakeholders equipped with valid and feasible outcome measures. Their shared goal is to ensure improved and more consistent outcomes and treatment options for patients with CLE. IDEOM provides support for the mucocutaneous domains of the OMERACT SLE working group's efforts.

### Treatment satisfaction

Dr. April Armstrong presented updates on the 7-item Dermatology Treatment Satisfaction Instrument (DermSat-7) and the ongoing study for an 11-item version (DermSat-11) for patients with PsO. Patient perception of treatment is crucial for adherence and success. Therefore, these measures aim to capture patient satisfaction in both clinical trials and real-world studies.

The DermSat-7 measures patient satisfaction in clinical trials, focusing on effectiveness, convenience, and overall satisfaction. A multicenter cross-sectional pilot study with over 140 patients at Keck Medical Center, Brigham and Women's Hospital, and Mount Sinai validated this instrument. On day 1, patients completed the DermSat-7, 9-item Treatment Satisfaction Questionnaire for Medication (TSQM-9), Dermatology Life Quality Index (DLQI), and self-reported PtGA, whereas physicians provided Psoriasis Area and Severity Index (PASI), body surface area, and physician global assessment metrics. On day 14, the DermSat-7 and self-reported PtGA were readministered. Statistical analysis confirmed DermSat-7's validity, internal consistency, and reliability.

The DermSat-11, designed for real-world studies, includes an additional component for adverse effects, capturing undesired skin signs, symptoms, and sequelae on other organs. These elements, essential for real-world settings, are currently undergoing longitudinal validation at the University of California, Los Angeles.

Future efforts in partnership with the US National Psoriasis

Foundation will address patient satisfaction in clinical practice and in response to combination therapies. IDEOM is also adapting the TSQM-9 to reflect patient perception among those treated for both PsO and PsA.

### Conclusion

In conclusion, the updates presented at the GRAPPA 2024 annual meeting by IDEOM's psoriatic disease working group and CTD working group leaders reflect the organization's continued commitment to advancing PROMs for patients with dermatologic and rheumatologic diseases. Progress in developing, implementing, validating, and improving tools such as the IDEOM MSK-Q and DermSat underscores the organization's dedication to improving disease detection, treatment options, and HRQOL for patients. As we look forward to the IDEOM 2025 annual meeting, we are confident these efforts will remain influential in dermatology and rheumatology, driving a more collaborative, consistent, and patient-focused approach to care.

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### COMPETING INTERESTS

VS has served as a consultant for AbbVie, Alpine Immune Sciences, Alumis, Amgen, Aria, AstraZeneca, Atom Bioscience, Bayer, Blackrock, BMS, BI, Celltrion, Citryll, Equillum, Ermium, Fortress Biotech, Genentech/Roche, Gilead, GSK, Horizon, Ichnos, Inmedix, Janssen, Kiniksa, Lilly, Merck, Novartis, Omeros, Pfizer, R-Pharm, RAPT, Regeneron, Samsung, Sandoz, Sanofi, Scipher, Setpoint, Sorrento, Spherix, and Urica. AWA has served as a research investigator, scientific advisor, or speaker to AbbVie, Almirall, Arcutis, ASLAN, Beiersdorf, BI, BMS, EPI, Incyte, Leo, UCB, Janssen, Lilly, Mindera, Nimbus, Novartis, Ortho Dermatologics, Sun, Dermavant, Dermira, Sanofi, Regeneron, and Pfizer. LMPC has received honoraria from IDEOM. JFM is a consultant and/or investigator for Amgen, AstraZeneca, BI, BMS, AbbVie, Dermavant, Eli Lilly, Incyte, Moonlake, Novartis, Janssen, UCB, Sanofi, Regeneron, Sun Pharma, Biogen, Pfizer, and Leo. ABG has received honoraria as an advisory board member and consultant for Amgen, AnaptysBio, Avotres Therapeutics, BI, BMS, Dice Therapeutics, Eli Lilly, Highlights Therapeutics, Janssen, Novartis, Sanofi, Teva, UCB, and XBiotech (stock options for a rheumatoid arthritis project); and research/educational grants from Highlights Therapeutics, BMS, Janssen, and UCB, all paid to Icahn School of Medicine at Mount Sinai; and has received honoraria as an advisory. SR and BC declare no conflicts of interest relevant to this article.

### ETHICS AND PATIENT CONSENT

Institutional review board approval and patient consent were not required.

### PEER REVIEW

As part of the supplement series GRAPPA 2024, this report was reviewed internally and approved by the Guest Editors for integrity, accuracy, and consistency with scientific and ethical standards.

### REFERENCES

1. Mease PJ, Gladman DD, Papp KA, et al. Prevalence of rheumatologist-diagnosed psoriatic arthritis in patients with

- psoriasis in European/North American dermatology clinics. *J Am Acad Dermatol* 2013;69:729-35.
2. Gottlieb AB, Kircik L, Eisen D, et al. Use of etanercept for psoriatic arthritis in the dermatology clinic: the Experience Diagnosing, Understanding Care, and Treatment with Etanercept (EDUCATE) study. *J Dermatolog Treat* 2006;17:343-52.
  3. Curtiss P, Walker AM, Chong BF. A systematic review of the progression of cutaneous lupus to systemic lupus erythematosus. *Front Immunol* 2022;13:866319.
  4. Werth VP, Furie RA, Romero-Diaz J, et al. Trial of anti-BDCA2 antibody Litifilimab for cutaneous lupus erythematosus. *N Engl J Med* 2022;387:321-31.
  5. Werth VP, Merola JF, Wenzel J, et al. AB0609 Design of a phase 2, double-blind, placebo-controlled, global trial of deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor, in patients with active discoid and/or subacute cutaneous lupus erythematosus [abstract]. *Ann Rheum Dis* 2023;82:1506.
  6. Zhang AJ, Perez-Chada LM, Werth VP, Merola JF. Expert consensus achieved on a working core outcome set for cutaneous lupus erythematosus research in survey following the 5th International Conference on Cutaneous Lupus Erythematosus (ICCLE). *Lupus Sci Med* 2024;11:e001165.
  7. Guo LN, Perez-Chada LM, Borucki R, Nambudiri VE, Werth VP, Merola JF. Development of a working core outcome set for cutaneous lupus erythematosus: a practical approach to an urgent unmet need. *Lupus Sci Med* 2021;8:e000529.
  8. Merola JF, Wang W, Wager CG, et al. RNA tape sampling in cutaneous lupus erythematosus discriminates affected from unaffected and healthy volunteer skin. *Lupus Sci Med* 2021;8:e000428.
  9. Elman SA, Joyce C, Braudis K, et al. Creation and validation of classification criteria for discoid lupus erythematosus. *JAMA Dermatol* 2020;156:901-6.
  10. Maxwell LJ, Beaton DE, Boers M, et al. The evolution of instrument selection for inclusion in core outcome sets at OMERACT: Filter 2.2. *Semin Arthritis Rheum* 2021;51:1320-30.