

## RESEARCH LETTER

## Interim Clinical Utility Findings of a Transcriptomic Psoriasis Biologic Test Demonstrate Altered Physician Prescribing Behavior and Improved Patient Outcomes

Bruce E. Strober, MD, PhD<sup>1</sup>, Michael Bukhalo, MD<sup>2</sup>, April W. Armstrong, MD<sup>3</sup>, David Pariser, MD<sup>4</sup>, Leon Kircik, MD<sup>5</sup>, Sepideh Parhami, MS<sup>6</sup>, Paul Montgomery III, MS<sup>6</sup>, and Tobin J. Dickerson, PhD<sup>6</sup>

<sup>1</sup> Yale University School of Medicine, New Haven, CT

<sup>2</sup> Arlington Dermatology, Rolling Meadows, IL

<sup>3</sup> Department of Dermatology, Keck School of Medicine, University of Southern California, Los Angeles, CA

<sup>4</sup> Eastern Virginia Medical School & Virginia Clinical Research, Inc., Norfolk, VA

<sup>5</sup> Department of Dermatology, Icahn School of Medicine at Mount Sinai, New York, NY

<sup>6</sup> Mindera Health, San Diego, CA

### ABSTRACT

**Objective:** This study (MATCH) was designed to assess the clinical utility of a machine-learning based tool (Mind.Px) that predicts patient response to the most common biologic classes used in the management of psoriasis patients.

**Methods:** Psoriasis patients who were biologic naïve or switching biologic were enrolled into the study (N=112). At baseline, a dermal biomarker patch was applied to lesional skin and Mind.Px test results provided to physicians prior to biologic selection. The choice of biologic for each patient was recorded and in the case of physician non-concordance with Mind.Px test results, a questionnaire completed to determine the reason for non-concordance. Patients were evaluated at weeks 4, 8, 12, and 16 and statistical analysis between groups performed.

**Results:** Physician prescribing behavior was measured with and without the inclusion of Mind.Px test results. This data was compared to previously obtained data in which dermal biomarker patches were applied at baseline, but Mind.Px results were not provided to physicians at any point during treatment (N=180). Statistical analysis of concordance between the Mind.Px-informed and Mind.Px-uninformed groups within the MATCH study (84.4% vs 53.8%, respectively) showed that when given access to Mind.Px results, physician behavior was significantly altered ( $p = 0.0022$ ). Furthermore, improved clinical outcomes in those patients whose physicians were provided Mind.Px test results was observed. Specifically, this cohort reached PASI75 sooner than those who were not provided test results ( $p = 0.004$ ).

**Conclusion:** These results provide an interim measurement of the clinical utility of Mind.Px by demonstrating that physicians will utilize this test in psoriasis biologic decision making and by doing so, this leads to improved patient outcomes. These improved patient outcomes can potentially translate into tremendous cost savings for healthcare systems.

In recent years, dermatology research has seen an influx of molecular data that when combined with bioinformatic methods, makes the promise of precision medicine a reality.<sup>1</sup> Indeed, the need for precision medicine in the treatment of moderate-to-severe psoriasis patients was highlighted in the most recent AAD/NPF guidelines.<sup>2</sup> With the dramatic increase in spending on biologic drugs and an increasing array of biologic drugs available, physicians have been required to implement a trial-and-error paradigm to identify the best drug for a given patient.

A precision medicine test (Mind.Px) has been reported that predicts patient response to biologic drug class with a positive predictive value >91%.<sup>3</sup> This test uses a dermal biomarker patch that allows for rapid and painless extraction of mRNA from skin, followed by transcriptomic analysis and machine learning-derived classifiers to provide actionable results for clinicians. Here, we describe preliminary results from the MATCH study<sup>4</sup> that demonstrate a statistically significant difference in physician prescribing behavior when provided with Mind.Px test results, and measurable clinical benefit to those patients when concordant with Mind.Px results.

In the MATCH study, physician prescribing behavior was measured from a geographically diverse patient set with and without the inclusion of test results in the decision-making process (N=112; **Table 1**). Upon qualifying for the study, patients were randomized to either the informed or uninformed arms of the study. This data was compared to a previously reported data set in which dermal biomarker patches were applied at baseline,<sup>3</sup> but test results were not provided to physicians at any point during treatment (STAMP study, N=180). Concordance between the test-informed and test-uninformed groups within the MATCH

study was markedly different (84.4% vs 53.8%, respectively), where concordance was defined as when physician choice matches Mind.Px test outcome. Statistical comparison of these two groups showed that when given access to test results, physician behavior changed in a significant manner from those who used a standard of care treatment paradigm ( $p = 0.0022$ , Fisher's exact test); this trend was also observed when compared to the previously reported data set (84.4% vs. 62.8%,  $p = 0.0017$ ). Interestingly, the primary reason observed for physician non-concordance with test results came from payer formulary influence, suggesting that physicians were highly willing to use test results.

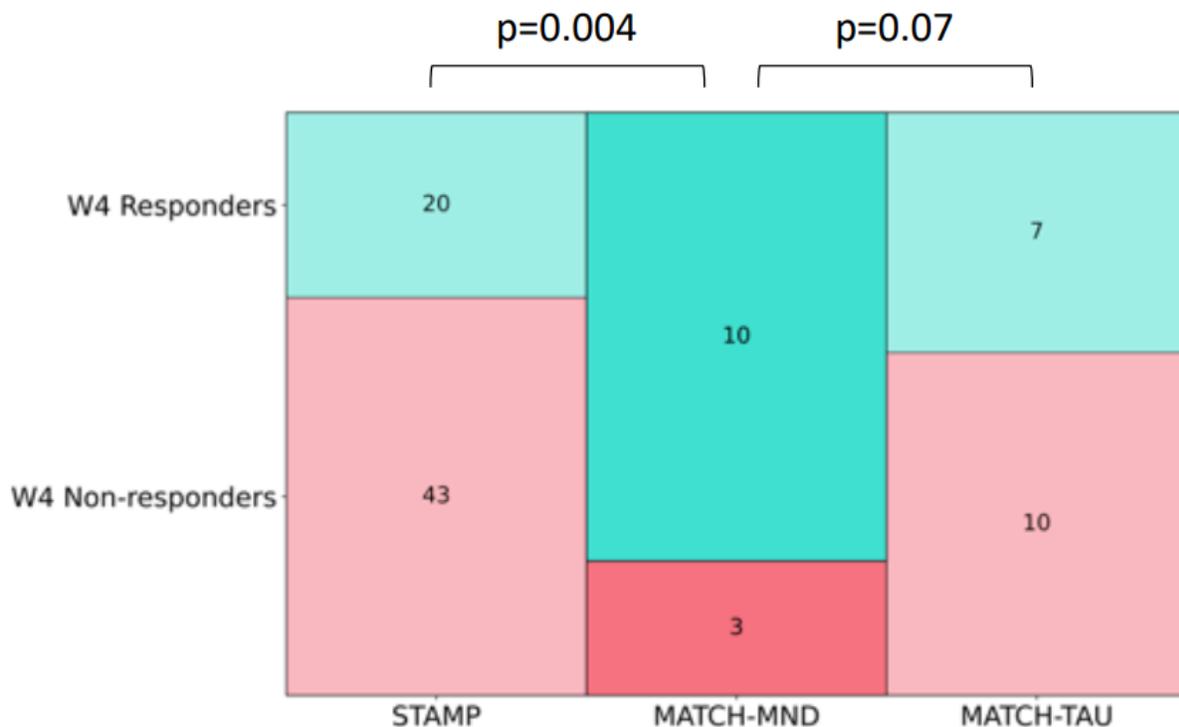
A critical component of the demonstration of clinical utility is to not only show physician usage of a test result, but also that by using the test, those patients have better clinical outcomes relative to those without test results. In an interim analysis, we have examined those patients who have completed the MATCH study and found that they showed improved clinical outcomes in those patients whose treatment was concordant with Mind.Px test results. In short, patients whose physicians were provided Mind.Px results reached PASI75 sooner than those who were not provided test results, and importantly, when compared against previously obtained observational data sets with identical inclusion/exclusion criteria,<sup>3</sup> statistical significance was observed ( $p = 0.004$ ; **Figure 1**).

These results validate our reported perceived clinical utility survey that showed 93% of physicians would follow the results of a precision medicine test for psoriasis biologic, independent of drug preference.<sup>5</sup> Future results from the MATCH study may continue to strengthen the clinical utility of this transcriptomic test by demonstrating that

**Table 1.** Physician concordance with Mind.Px results. Concordance is defined as when physician choice matches Mind.Px test outcome. Importantly, in the Mind.Px-informed arm six out of seven patients were discordant due to insurance formulary restrictions. The remaining patient was discordant due to patient biologic preference

	Mind.Px Informed	TAU
<b>Concordant (%)</b>	38 (84.4%)	21 (53.8%)
<b>Discordant (%)</b>	7 (15.6%)	18 (46.2%)

**Figure 1.** Mosaic plot comparing patients who have completed the MATCH study and those who completed the STAMP study.<sup>4</sup> Here, red boxes are non-responders at 4 weeks and green boxes are responders at 4 weeks, with the number of patients in a group shown in each box. MATCH-MND is the informed arm where patient test results are provided, and MATCH-TAU is a treatment as usual arm where test results are not provided to physicians. This analysis shows that by using Mind.Px results, patients reach clinical endpoints faster than patients in treatment as usual arms.



physicians will utilize a precision medicine test in psoriasis biologic decision making and that by doing so, patient outcomes are improved relative to the standard of care. By prescribing patients the optimal biologic the first time, this test can lead to improved patient outcomes, while also potentially translating into tremendous cost savings for healthcare systems. Precision medicine tools such as this have the potential to minimize the trial-and-error approach to the treatment of psoriasis, and provide physicians, patients, and payers with a powerful tool for improving the management of psoriasis patients.

While this interim demonstrates statistically significant changes in physician behavior and improved patient outcomes from this behavior change, the cohort of patients who have currently completed the study is limited. Future analysis as additional patients complete the study will be required.

**Conflict of Interest Disclosures:** Bruce Strober is a consultant (honoraria) for AbbVie, Amgen, Arcutis, Arena, Aristeia, Asana, Boehringer Ingelheim, Immunic Therapeutics, Bristol-Myers-Squibb, Connect Biopharma, Dermavant, Equillum, Janssen, Leo, Eli Lilly, Maruho, Meiji Seika Pharma, Mindera Health, Novartis, Pfizer, GlaxoSmithKline, UCB Pharma, Sun Pharma, Ortho Dermatologics, Regeneron, Sanofi-Genzyme, Ventyx, and vTv Therapeutics. He has received speaker honoraria from AbbVie, Eli Lilly, Janssen, and Sanofi-Genzyme. Dr. Strober is the co-Scientific Director of the CorEvitas (Corrona) Psoriasis Registry, the Editor-in-Chief (honoraria) of the Journal of Psoriasis and Psoriatic Arthritis, and has received research support from Dermavant, AbbVie, Corrona Psoriasis Registry, Dermira, Cara, and Novartis. Michael Bukhalo has served as a research investigator and/or advisor to Boehringer Ingelheim, Novartis, LEO Pharma, Eli Lilly, DUSA Pharmaceuticals, Merck, Allergan, Galderma, MedImmune, Centocor, and Celgene. April Armstrong has served as a research investigator and/or scientific advisor to AbbVie, Amgen, Arcutis, ASLAN, Beiersdorf, BI, BMS, EPI, Incyte, LEO Pharma, UCB, Janssen, Lilly, Mindera Health, Nimbus, Novartis, Ortho Dermatologics, Sun, Dermavant, Dermira, Sanofi, Regeneron, and Pfizer.

David Pariser is a consultant (honoraria) for Atacama Therapeutics, Bickel Biotechnology, Biofrontera AG, Bristol-Myers-Squibb, Celgene, Dermira, LEO Pharma, Mindera Health, Novartis, Pfizer, Regeneron, Sanofi, TheraVida, and Valeant. Dr. Pariser has also received research funding from Amgen, AOBiome, Asana Biosciences, Bickel Biotechnology, Celgene, Dermavant Sciences, Dermira, Eli Lilly, LEO Pharma, Menlo Therapeutics, Merck, Novartis, Novo Nordisk, Ortho Dermatologics, Pfizer, and Regeneron. Leon Kircik has served as a research investigator and/or scientific advisor to Abbott Laboratories, Abbvie, Allergan, Amgen, Amgen, Arcutis, Biogen-Idec, Bristol-Myers-Squibb, Boehringer-Ingelheim, Breckinridge Pharma, Celgene, Centocor, Cellceutix, Cipher, Combinatrix, Connetics, Coria, Dermavant, Dermira, Dow Pharmaceutical Sciences, Dr. Reddy's Lab, Eli Lilly, Galderma, Genentech, GlaxoSmithKline, Idera, Johnson & Johnson, LEO Pharma, Maruho, Merck, Medicis, Novartis, Promius, PharmaDerm, Pfizer, Merck Serono, Stiefel Laboratories, Sun Pharma, Taro, UCB, Valeant, and Xenoport. Sepideh Parhami, Paul Montgomery III, and Tobin Dickerson are employees of Mindera Health.

**Funding:** This study was funded by Mindera Health.

**Corresponding Author:**

Bruce Strober, MD, PhD  
 Phone: 860-322-2222  
 Fax: 860-322-6838  
 Email: brucestrober30@me.com

**References:**

1. Brownstone, N, Wu JJ, Strober BE, Dickerson TJ. Getting personal about skin: Realizing precision medicine in dermatology. *Dermatological Reviews*. 2021;2:289-295.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80:1029-1072.
3. Bagel J, Wang Y, Montgomery P III, et al. A machine learning-based test for predicting response to psoriasis biologics. *SKIN The Journal of Cutaneous Medicine*. 2021;5:621-638.
4. Strober B, Fox J, Jekowsky E, et al. Evidence threshold for a precision medicine test that predicts optimal response to a biologic agent in patients with psoriasis: A consensus panel. *J Drugs Dermatol*. 2022;21:630-636.

5. Strober B, Pariser D, Deren-Lewis A, et al. A survey of community dermatologists reveals the unnecessary impact of trial-and-error behavior on the psoriasis biologic treatment paradigm. *Dermatol Ther (Heidelb)*. 2021;11:1851-1860.