

DERMATOLOGIST CONCORDANCE WITH A PRECISION MEDICINE TEST FOR THE SELECTION OF PSORIASIS BIOLOGIC TREATMENT

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ABSTRACT

In the United States, psoriasis affects >3%¹ of the population, leading to healthcare costs of >\$110 billion annually². The emergence of targeted biologic treatments has revolutionized the management of moderate to severe psoriasis patients, with impressive results. However, these clinical gains have come with a concomitant dramatic increase in spending on higher priced biologics. With the array of biologics available, physicians are required to implement a trial-and-error paradigm to match patient with the best drug. According to Joint AAD/NPF guidelines, predictive biomarkers for the appropriate biologic agent for patients are needed.³

A machine learning-based test (Mind.Px) has been introduced that predicts patient response to biologic drug class with a positive predictive value >91%.⁴ This test uses a dermal biomarker patch that allows for rapid and painless extraction of RNA. This 16-week randomized study was designed to assess the test utility in physician decision making and patient outcomes. Here, we report interim results of physician concordance with test results. In short, 51 patients from 14 sites were enrolled in the study; of these, 26 patients were randomized to the test informed arm and physicians were provided test results prior to biologic selection. After reviewing test results, 91.7% of the physician therapeutic choices (11 of 12 patients) were concordant with test results, despite formulary restrictions or physician preference. In contrast, only 62.5% of physician therapeutic choices (5 of 8) were concordant with test results in the treatment as usual arm. These results validate our reported, perceived clinical utility survey that showed 93% of physicians would follow test results, independent of drug preference.⁵ This test represents the first realization of precision medicine for psoriasis patients.

1 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(4):1029-1072. doi:10.1016/j.jaad.2018.11.057
 2 Pilon D, Teeple A, Zhdanova M, et al. The economic burden of psoriasis with high comorbidity among privately insured patients in the United States. *J Med Econ*. 2019;22(2):196-203. doi:10.1080/13696998.2018.1557201
 3 Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *JAAD*. VOLUME 80, ISSUE 4, P1029-1072, APRIL 01, 2019.
 4 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.
 5 Strober B, Parisi 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;31:1851-1860.

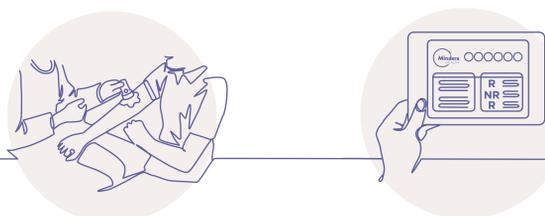


FIGURE 1. Overview of Mind.Px test¹

- Painless, minimally invasive test
- Patch placed on skin for **5 minutes**
- RNA is used to evaluate **over 7,000 biomarkers** per test sample ... comparable to a biopsy
- Predicts drug response to **better select biologic therapy**



FIGURE 3. Dermal Biomarker Patch (DBP) workflow.

STUDY DESIGN

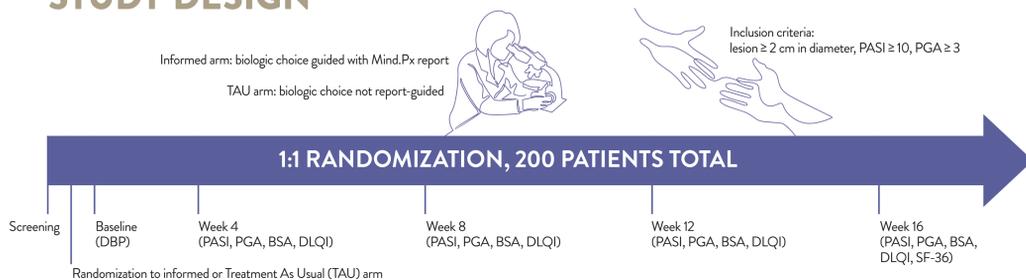


FIGURE 2. Design of MATCH clinical utility study

Assessments	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
	Screening 1-4 Weeks	Baseline/Randomization	Week 4 ±3 Days	Week 8 ±3 Days	Week 12 ±3 Days	Week 16 ±3 Days
Informed Consent	X					
Inclusion/Exclusion Criteria	X					
Demographics	X					
Clinician Demographics	X					
Mind.Px Dermal Patch	X					
Medical History	X					
Biologic Treatment History (previous & current; including response and questionnaires)	X					
Current Biologic Treatment & Biologic Treatment Trials Since Last Visit (including response and questionnaires)		X	X	X	X	X
Medication History (other than biologics)	X					
Physical Exam	X					
Vital Signs	X					
Randomization		X				
PASI	X	X	X	X	X	X
PGA	X	X	X	X	X	X
BSA	X	X	X	X	X	X
DLQI		X	X	X	X	X
SF-36 (patient reported)		X				X
Clinician Utility Questionnaire*		X (after)				
Adverse Events (AEs)	X	X	X	X	X	X
IP accountability	X					
Dose Changes		X	X	X	X	X
Switching		X	X	X	X	X
Regimen Augmentation		X	X	X	X	X
Discontinuation		X	X	X	X	X
Biologic Compliance		X	X	X	X	X

TABLE 1. Schedule of activities for MATCH study

* Performed at the baseline visit for subjects in the MND group only after receipt of Mind.Px report.

RESULTS

Previously, we reported that physicians are willing to utilize molecular information such as that provided by Mind.Px in their psoriasis biologic treatment paradigm.² Indeed, we found that physicians reported a desire to utilize Mind.Px results even if this differed from their initial clinical choice. We have initiated a prospective study aimed at conclusively proving the clinical utility of this test in a blinded patient cohort. Presently, we have enrolled 51 patients from 14 sites into this study; of these, 26 patients were randomized to the test informed arm and physicians were provided test results prior to biologic selection.

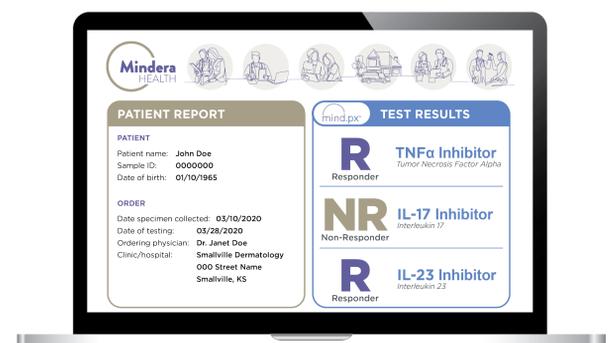


FIGURE 4. Sample Mind.Px test report received by physicians during the MATCH study.

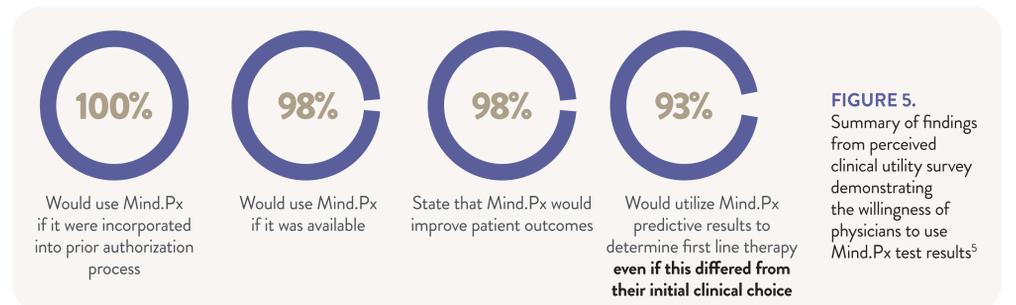


FIGURE 5. Summary of findings from perceived clinical utility survey demonstrating the willingness of physicians to use Mind.Px test results⁵

	Mind.Px informed	TAU
Concordant (%)	11 (91.7%)	5 (62.5%)
Not concordant (%)	1 (8.3%)	3 (37.5%)

TABLE 2. Preliminary concordance of physicians with Mind.Px test results

CONCLUSION

These preliminary findings from the MATCH study show that physicians who are provided a recommendation for biologic class use that recommendation in their decision-making process. It will be important to continue to monitor this metric, particularly for the drivers in those cases where Mind.Px informed physicians are not concordant with the test result (e.g., insurance formulary, physician choice, patient preference); to date, this has been a rare occurrence and generalized conclusions as to why non-concordance occurs cannot be drawn. Ultimately, clinical outcome measures in patients whose physicians have used Mind.Px results are needed to prove the clinical utility of this test and will be measured as patients complete the MATCH study. It is important to note that the willingness of physicians to follow Mind.Px is also in agreement with our previously reported survey study.²