When prescribing therapies to treat atopic dermatitis, patients, payers, and health care providers want assurances that therapies yield patient-relevant improvements in conditions.

To date, existing measures in clinical trials do not capture a crucial dimension of the patient experience: scratch.

DiMe's 3Ps of Digital Endpoints Value resources recommend engaging with payers alongside regulators as soon as the decision to include a digital endpoint is made. Payers and regulators from the U.S. and Europe have been involved in the value workstream for DiMe’s nocturnal scratch project.

The integrated evidence plan (IEP) is at the core of the 3Ps of Digital Endpoint Value recommendations. An IEP “defines how the evidence will be generated within each clinical trial and real-world observational study, and how this will be leveraged to satisfy patient, physician, provider, payer, and regulatory requirements”.

By design, this project convenes all of these stakeholder groups to generate the evidence base to drive broad acceptance of digitally measured nocturnal scratch as a high-value, trusted endpoint for atopic dermatitis.

✓ By following the best practices described in DiMe’s 3Ps of Digital Endpoints Value, the nocturnal scratch project team are supporting payer acceptance of this new digital measure.

The DiMe Nocturnal Scratch project is the inaugural project in DiMe’s Digital Measures Development Program, driving broad acceptance of digital measurement of nocturnal scratch as a high-value, trusted endpoint for atopic dermatitis.

"Digital measurements must become another element of the overall clinical outcome assessments used for assessing effectiveness of potential new therapeutics,”

— Brian E. Winger, PhD., Senior Advisor for Digital Health, Eli Lilly