

NOCTURNAL SCRATCH



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



The Problem

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.



The Impact

✓ 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 Resources

- » 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.