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.

The work that has been undertaken has already made great strides in understanding the significance of nocturnal scratching to patients and caregivers, how to make this endpoint a reality operationally, as well as alignment of terminology regarding this novel digital endpoint.

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- Nocturnal scratch is among the more advanced and promising applications of digital clinical measures as a drug development tool to date. Several organizations have developed robust algorithms and are initiating conversations with regulatory agencies to seek support for these novel measures.
- Despite this progress, challenges remain. Digitally measured nocturnal scratch is not yet broadly accepted, it has not been deployed in pivotal trials, and demonstration of the value remains unresolved.



- The <u>DiMe Measures that Matter</u> <u>publication</u> advises that incorporating patient input is a dynamic process; it should be conducted continuously throughout the measurement selection process. To that end, representatives from Global Parents for Eczema Research and National Eczema Association have been engaged in every aspect of the project as equal partners with pharma.
- The DiMe Measures that Matter framework has informed the development of a mixed methods study to collect evidence demonstrating the value of digitally measured nocturnal scratch to patients (adult and pediatric) with atopic dermatitis.



The Impact

- ✓ Measures that Matter has informed research that will advance broad acceptance of digitally measured nocturnal scratch and speed the development of new treatments for atipic dermatitis that address the symptoms that matter most to patients.
- ✓ It has also guided the first collaborative industry initiative to tackle the pre-competitive development of a clinical digital measure, and provided the blueprint for all of DiMe's current and planned Digital Measure Development Program projects.