NOCTURNAL SCRATCH

Digital Measures Development

The Nocturnal Scratch project provided resources, including patient research, measure ontology, and clinical trial and payer best practices, to advance the broad acceptance of nocturnal scratch as an evidence-based, meaningful endpoint for atopic dermatitis (AD).

CPIMs serves as an opportunity for the Center for Drug Evaluation and Research (CDER), a branch of FDA, to engage in conversation about the meeting requester's proposal.

The Opportunity

- The Nocturnal Scratch consortium was working on the development of the nocturnal scratch measure.
- The team wanted to follow best practices for the development of a novel digital clinical measure to improve likelihood of regulatory acceptance.

The Resource

- The Nocturnal Scratch project team reviewed the Regulatory Quick Start Guide within the Pharma Exec Dossier of *The Playbook*: Digital Clinical Measures, which serves as a guide for interacting with the FDA regarding novel endpoint development.
- Ultimately, they leveraged the Critical Path Innovation Meetings (CPIM) pathway, a regulatory mechanism that is outside an individual drug development program.

The Impact

- By engaging with regulators through the CPIM pathway, as described in *The Playbook*, the Nocturnal Scratch project team was able to discuss the concept of the nocturnal scratch measure, its meaningfulness to patients, ontologies and context of use with members from FDA's Center for Devices and Radiological Health (CDRH) and CDER.
- From those conversations, the team **gained valuable learnings** early on in the project, which pointed them in the right direction for future measure development and helped them **mitigate potential issues**.
- Additionally, because CPIM meetings are agnostic to technology or drug, the team was able to discuss measure science **applicable for other future technology and trial uses.**