



[Sibel Health](#) is a medical device company that provides better health data for all® through their medical monitoring products, so that better decisions can be made.

We found the resources to be very helpful in informing our own engagements with the FDA around the scratch sensor work - particularly the surveys and voice of patient work.

— **Steve Xu, MD, MSc**
CEO @ Sibel Health,
physician, Clinical
technologist



The Problem

- » Sibel Health developed a wearable, wireless scratch sensor to automatically detect scratching using AI/ML algorithms.
- » The technology was accepted to the FDA's drug development tool (DDT) program and is currently undergoing qualification to act as an endpoint in clinical studies determining the efficacy of therapeutics for atopic dermatitis.



The Impact

- ✓ Having a shared terminology and ontology for nocturnal scratch facilitated conversation between Sibel, the FDA, pharmaceutical companies, and other stakeholders by ensuring that everyone had the same baseline understanding of the concept.
- ✓ Inputs from the patient study were critical in determining the outcome measure that would be most valuable to patients in drug development of the final version of the endpoint.



The Resources

- » DiMe organized a [Critical Path Innovation Meeting](#) between pharmaceutical companies, patient advocacy groups, dermatologists, members of the FDA, and digital health technology manufacturers like Sibel to discuss the digital measurement of nocturnal scratch.
- » During the Nocturnal Scratch project, DiMe and the partners also developed an evidence-based [ontology and terminology](#) of digital measurement of nocturnal scratch.
- » DiMe conducted a [mixed-methods study](#) that included interviews with both pediatric and adult atopic dermatitis patients and their family members. Patient interviews and surveys established the clinical meaningfulness of nocturnal scratch to patients.

