Identification of meaningful aspects of health connected to the symptom of nocturnal scratching in patients with atopic dermatitis

Qualitative semi-structured patient interviews to identify meaningful concepts of health related to nocturnal scratching

Performed qualitative interviews:
- adult patients with AD (n=15)
- adult caregivers or spouses of adult patients with AD (n=6)
- adult caregivers for children with AD aged 7-<18 years (n=14)
- and child patients with AD aged 7-<18 years old (n=14)

Transcripts of interviews were analyzed according to FDA guidance "Patient-Focused Drug Development: Methods to Identify What is Important to Patients"

The development of following quantitative survey
- will be informed by qualitative results
- will be distributed to 600 representative participants:
  - adult patients with AD (n=300)
  - adult caregivers for child patients with AD aged 7-<18 years (n=300)
Results

Most common reports about meaningful aspects of everyday life impacted by AD were:
- appearance of skin
- feeling of itch
- urge to scratch and awareness of scratching
- poor quality of sleep
- stress and anxiety

Summary of reports about nocturnal scratching and/or scratching during sleep:
- nocturnal scratching reported by all interviewed participants
- worsening of the itch sensation and urge to scratch in the evening and at night
- consistent observation of signs of nocturnal scratching in the morning (skin flakes, blood, new scratch marks, etc.)
- negative effects on sleep was a consistent finding across all cohorts

Summary of reports about impacts of nocturnal scratching:
- worsened skin condition
- worsening of daily mood
- feeling mentally and physically exhausted
- lack of energy
- increased stress level
Discussion

Preliminary qualitative data indicate a strong link between the nocturnal scratching and meaningful aspects of everyday life for patients with AD
  → in particular, the **impact of nocturnal scratching** on the appearance of skin, quality of sleep, daily mood and functioning, and mental health aspects
  → importance of a treatment to reduce nocturnal scratching together with other AD symptoms was consistently positive across all cohorts

A portion of the patients stated observing signs of nocturnal scratching in the morning without remembering the actual behavior
  → supports the **need of a passive measurement** supplementing the patient report

A major portion of participants reported willingness to use or wear a tool or a sensor for their own education as well as to support research of new treatments
  → indicates value of a **novel measure quantifying nocturnal scratching** by digital means
  → potential **challenges to overcome** in development of digitally measured nocturnal scratch appear to be: the value perceived by the patients, concerns about privacy or willingness to wear a digital tool or sensor on skin

Following quantitative survey will provide additional quantitative insights and will inform the development of specific quantitative digital measures of nocturnal scratch.