Strategies to optimize atopic dermatitis patient experience in clinical trial design utilizing digital measurement of nocturnal scratch

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A project by the

DIGITAL MEDICINE SOCIETY
Five main aspects
have been identified, enabling sponsors to form strategies to optimize the experience of patients with atopic dermatitis (AD) in clinical trials design utilizing digital measurement of nocturnal scratch

- Educating AD patients about the value of digitally measured nocturnal scratch
- Empowering AD patients in the trial & through the use of digital technologies
- Selection of the right technology to improve adherence & engagement
- Providing adequate training & support
- Minimizing the burden for AD patients in the trials
Educating AD patients about the value of digitally measured nocturnal scratch

Why does it matter to measure nocturnal scratching?

It is a measurement that does not rely on the clinician's, patient's, or caregiver's perception or observation that quantifies what happens outside of waking hours.

Measurement of nocturnal scratch has the potential to complement holistic overview of the physiology, functioning, feelings, and outcomes of the patients, complementing the perceptions, observations, and experiences measured by traditional measures of the disease:

- **Observation**: Appearance of skin
  - Signs and symptoms

- **Perception**: Subjective sensation
  - Itch

- **Experience**: Personal experience
  - QoL, sleep

- **Behavior**: Performed actions
  - Nocturnal scratch
Educating AD patients about the value of digitally measured nocturnal scratch

Why does it matter to measure nocturnal scratching?

Because it matters.

Our research showed that **nocturnal scratching** is a concept of interest that is important to patients with AD and connected to meaningful aspects of their lives.

The extensive patient input collected on the burden and experience of this symptom supports the intention to separate it as a **measurement** in clinical research or care.
Educating AD patients about the value of digitally measured nocturnal scratch

What can measurement of nocturnal scratching do for you?

*It is a measurement that does not rely on the clinician's, patient's, or caregiver's perception or observation that quantifies what happens outside of waking hours*

- Provide you with a "proof in hand" that validates your experience and quantifies your symptoms, and so empowers you to advocate for yourself with objective data in hand
- Provide you with more information about eczema symptoms' effects on your sleep and quality of life both daily and over a longer period time, while being easier to use than questionnaires or diaries that cannot fully account for the time you are asleep
- Help you talk to your doctor - about your eczema, lack of sleep, or effects on your everyday life
- Offer you a sense of control and ownership over your symptoms
- Provide you with insights that can lead to actions improving your physical and mental health
- Provide objective information about your or your child’s nocturnal scratching
- By measuring nocturnal scratching in a research study, you can help scientists to develop new drugs for eczema for you and people all around the world
- In a research study setting, you will always be provided a description of all data that will be collected from you, how it will be used, and who can access it in an informed consent form
Empowering AD patients in the trial & through the use of digital technologies

What are the long-term benefits of measuring nocturnal scratching in a clinical study?

By measuring nocturnal scratching in a research study, you can help scientists to develop new drugs for eczema for you and people all around the world.

If possible, share understandable data back to the patients in a plain language summary:

- Use CTTI's Decision Support Tool: Real Time Data Sharing with Study Participants to assess whether collected data should be shared with study participants in real time.
- To prevent creating biases in a trial, consider:
  - Sharing aggregates or simple insights that will not risk unblinding or jeopardizing the trial (e.g. streaks of nights measured, time measured, total scratch events, etc.)
  - Sharing the data, insights, or aggregates at the closeout of the trial.

Sharing the trial results back to the patients is not required, but this positive feedback loop can improve engagement and positive experience.

- Disseminating information about study results (via a publication, sharing a press release, etc.) can give the patients something to be proud of.
Selection of the right technology to improve adherence & engagement

Get the "right sensor to the right patient" - there may be individual preferences or access barriers that would make some sensors preferable over others

- For example, some people may have eczema on their hands or wrists and therefore tolerate wrist-worn sensors or patches worse than others

Consider technology literacy of the patients or caregivers

- Technology should be easy to set up, use and maintain
- Consider using a device that is ubiquitous (more familiarity with the device, less stigma associated with wearing or using the device)

For use in children, additional considerations apply

- Can any external part of the device enter the mouth? (e.g. for measurement in infants)
- Is the size of the device appropriate for use in children or infants?
- Will it interfere with social interactions of older children in school or with their peers, friends, or family members?
Selection of the right technology to improve adherence & engagement

If possible, include **reminders and notifications** in the technologies deployed for better experience, engagement, and adherence

If possible, enable **interactions with the device**
- Device itself can be used for communication - including "how tos", new information, instructions, etc.

If possible, provide opportunity to try out the device - a **trial run** - to patients to improve compliance in the early weeks of the trial
- Enable access to the technology to see how it's going to work before the clinical trial starts

**For more tips to select the right technology for the patients, please refer to** Part 3. of this toolkit that addresses **study population considerations for clinical trial design utilizing digital measurement of nocturnal scratch**
Providing adequate training & support

Training materials should address all concerns patients may have and may be asking about DHTs (privacy concerns, ease of use, skin irritation, etc.)

- Provide training materials in various formats (e.g. paper, mobile app, website, etc.) and make training materials visual & interactive
- For example, use of graphics, screenshots, video content, virtual assistant, e-learning, chatbots, etc.
- Create repository of important information, such as an online portal with Q&As, and keep it updated regularly
- Provide clarity to the patients about the "who, where, & how" of how tech support is provided and who can be contacted in case of any issues (both medical and technical)

The training materials should address practical aspects of interaction with the technology

- What's the level of setup and maintenance once a patient leaves the clinic? (e.g. charging, connecting to Wi-Fi, connecting to data hub/app on phone)
- Does the patient need to assess if the device functions correctly?
- Will there be notifications, warnings, alerts? In what frequency? How should the patient react to them?
- Can the device be interacted with beyond the intended use and desired functionality?
"Participation in a clinical trial can be an isolating experience."

Try and reduce the isolation element by applying some of the following strategies:

- If possible, ensure that dedicated personnel is available to the patients for an added human element when overcoming issues.
- Include proactive check-ins with patients.
- Offer materials and support in a patient's native language.
- Consider creating a community approach, such as connection to dedicated support lines, patient organizations, and groups of patients who are or were participating in the same or similar trials, and providing testimonials from other trials etc.
- Remember that an organized community offers larger value than random social media groups (established outside of the study participants or sponsors)
  - The patients in the trial may be seeking out connection on their own if not provided the information they need, and may find incorrect, biased or otherwise inapplicable information in this manner.
Minimizing burden for AD patients in the trials

- Look for ways to decrease number of required in-person visits at the clinic
- Refrain from too frequent & too long questionnaires and assessments in the trial
- Aim for lowest complexity of the device and its setup & maintenance
- Look for grouping functionalities in minimum number of devices (e.g. sleep, vitals, accelerometer, environment, etc.)
- Consider addressing heterogeneity of disease and patients - for example, provide multiple options to wear or use the technology, or offer a selection of different sensors if possible

For the study design, aim for the minimum required interaction:

- The smallest number of sensors that yield the necessary information
- The shortest wearing times that provide stable quantification of key variables
- Minimal required wear time can be calculated from previous studies where the participants had complete wear time compliance by simulating the effect of only having a portion of the data available

Minimizing burden for AD patients in the trials

Consider pros & cons of continuous use vs. use only at night:

Continuous monitoring

**Pros**
- Longitudinal data collection
- Better compliance (patient does not have to remember to switch or put the device on/off)

**Cons**
- Long wear increases stress of skin irritation
- Battery life may be shorter than study duration, increasing risk of missing data

Use only at night

**Pros**
- Lower risk of skin irritation
- Device may charge or process data when not in use

**Cons**
- Risk of lowered compliance (forgetting to switch or put device on/off)
- Higher data variability (not monitoring for the same time period every night)
Additional Relevant Resources

- The Playbook: How do we get patient input so we can select the right digital sensing product?
- The Playbook: Usability and Utility section (slides 139-145)
- CTTI: CTTI decision support tool on real time data sharing to patients
- CIOMS: Ethical framework for biomedical research
- DiMe: DATAcc Toolkit for Inclusive Deployment

Acknowledgements

DiMe and the project team would like to express their gratitude and appreciation to the experts that took a crucial part in development of these resources:

- Ashley Blua, Patient Ambassador, NEA
- Christine Pham-Cutaran, Patient Ambassador, GPER
- Wendy Smith-Begolka, Senior Vice President, Scientific and Clinical Affairs, NEA

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Digital Measures Development

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