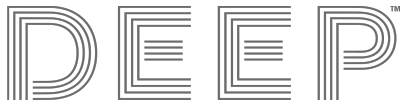


Digital Measurement of Nocturnal Scratch: New Developments



by DiME



DIGITAL EVIDENCE ECOSYSTEM & PROTOCOLS

June 4, 11AM ET
**Recent Regulatory
Feedback**

June 11, 11AM ET
**Updates from R&D of
Algorithms and Tools**

June 18, 11AM ET
**Processes, Validation
and Adoption**

But first, housekeeping

- Please note: **today's session is being recorded**
 - Slides and recording will be available on DiMe's webinar page after the session
- To ask a question for discussion during live Q&A, please either:
 - **'Raise your hand'** in the Reactions and the moderator will unmute you to ask your question live, or
 - **Type your question** into the chat box

**** Participants are not permitted to transcribe this webinar, violators will be removed from the session.*

Digital Measurement of Nocturnal Scratch: New Developments

June 4: Recent Regulatory Feedback

June 11: Updates from R&D on Algorithms and Tools

June 18: Processes, Validation, and Adoption



by DIME



DIGITAL EVIDENCE ECOSYSTEM & PROTOCOLS



Wendy Smith Begolka

Chief Strategy Officer: Research, Medical & Community Affairs, NEA



Dina Katabi

Professor & Co-Founder MIT, Emerald Innovations



Jaydev Thakkar

Chief Operating Officer Biofourmis



Steve Xu, MD

Board certified dermatologist, physician-engineer, CEO of Sibel Health; and the Ruth K. Freinkel, MD Professor at Northwestern University



Sylvain Zorman, PhD

Director of Digital Health Sciences ActiGraph



Carrie Northcott, PhD

Head of Digital Sciences Pfizer (moderator)



National
Eczema
Association

Patient Burden of the Itch-Scratch Cycle in Atopic Dermatitis

Wendy Smith Begolka, MBS

Chief Strategy Officer – Research, Medical & Community Affairs

wendy@nationaleczema.org

June 11, 2024

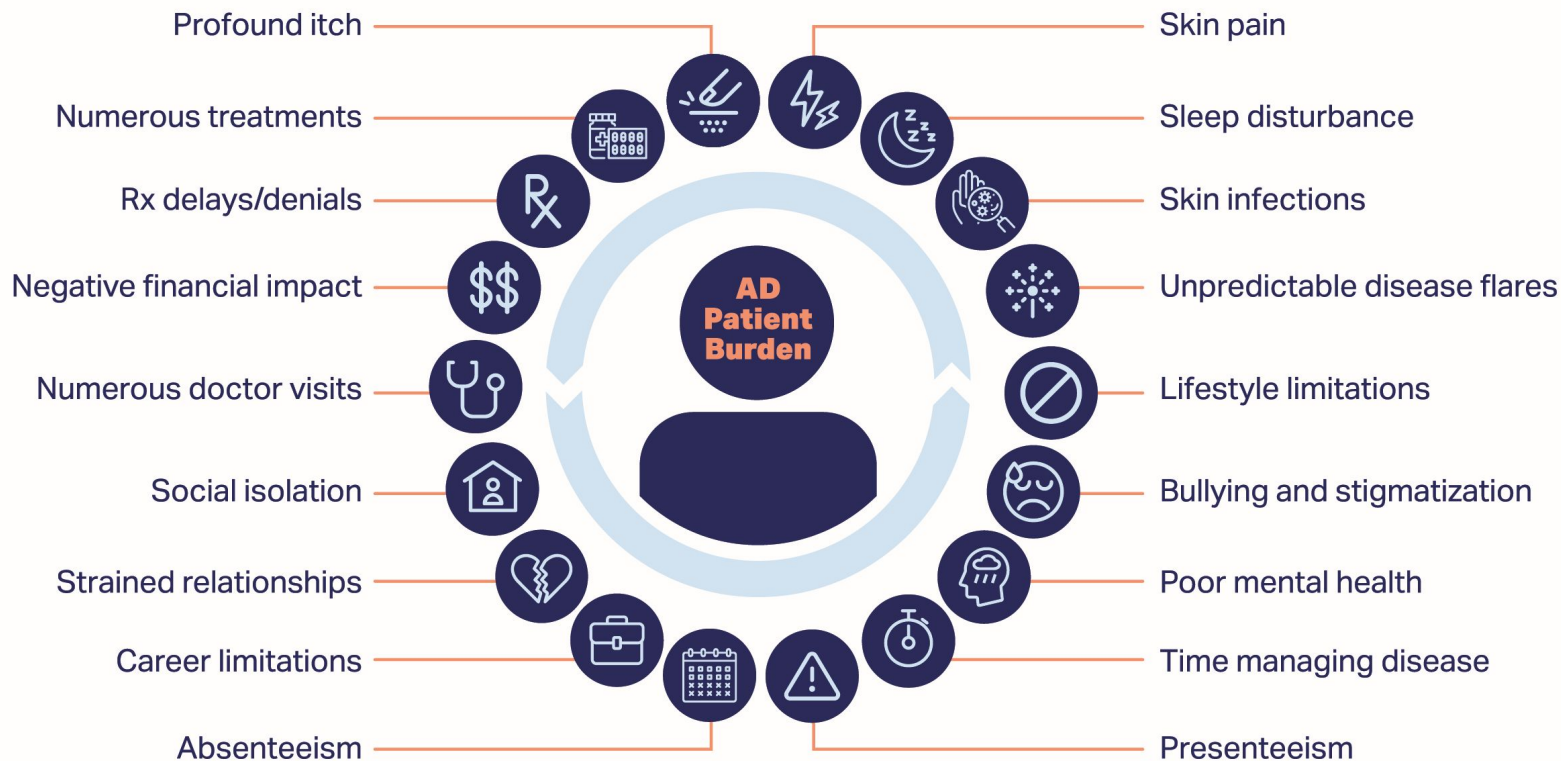
Atopic Dermatitis – Common, Chronic & Serious



- **Leading contributor to skin-related disability globally**
 - Ranks 15th among all non-fatal diseases
- **Affects over 31 million Americans of all ages and races**
 - 9.6 million children (<18 years)
 - 33% with moderate to severe disease
 - 16.5 million adults
 - 40% with moderate to severe disease
- **Typical onset at <5 years of age**
 - Persistence can occur childhood to adulthood
 - Can occur in adulthood for the first time
 - Second peak of prevalence after age 60



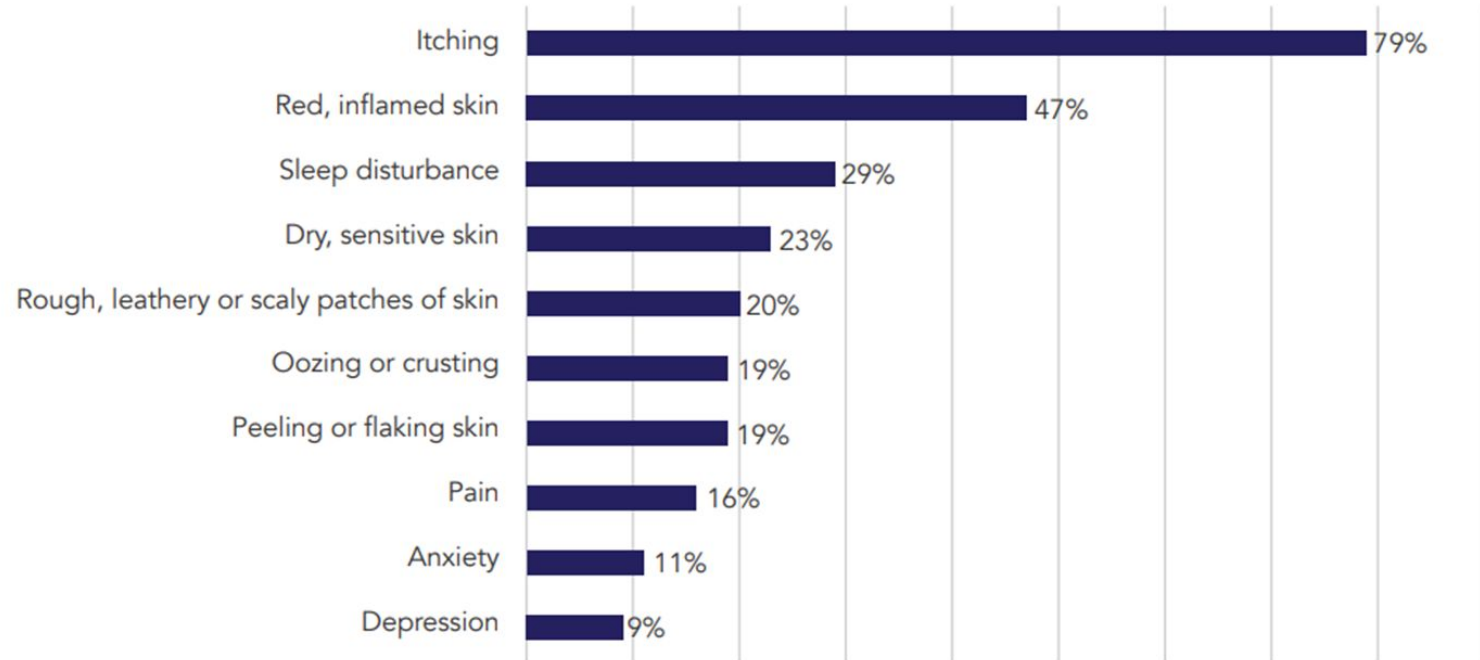
Patient Burden in Atopic Dermatitis (AD)



© National Eczema Association
<https://nationaleczema.org/surveys>

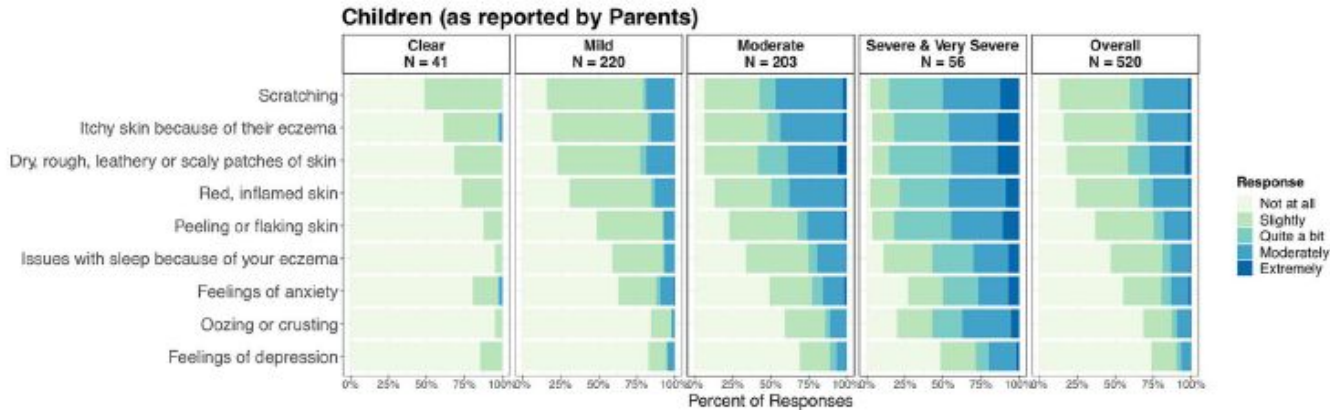
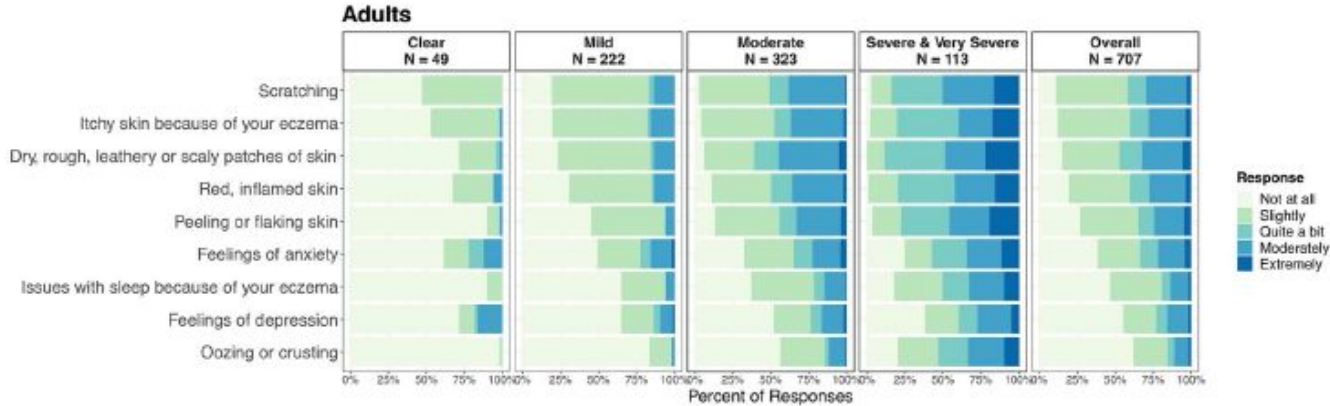


THREE MOST PROBLEMATIC ECZEMA SYMPTOMS



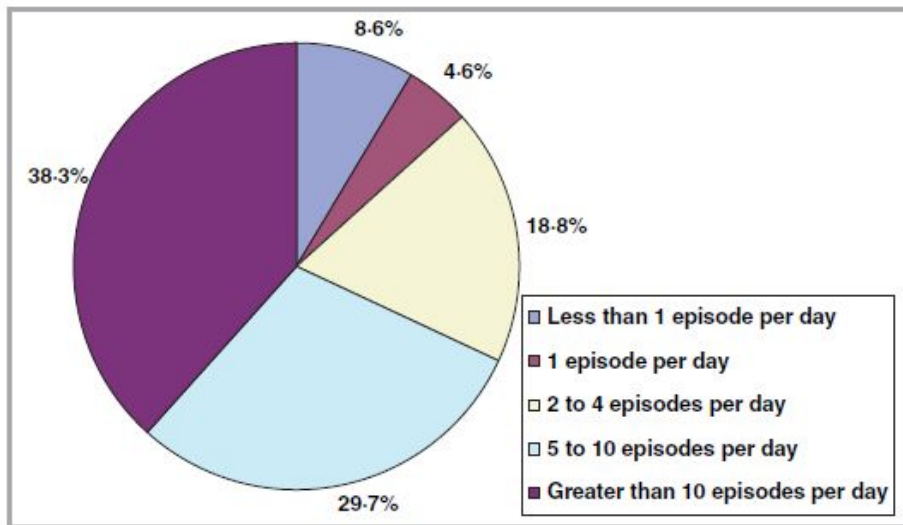
<https://www.morethanskindeep-eczema.com/>

Most Burdensome Symptoms of AD



Cesnakova L et al. Skin Health Dis. 2023;3:e262.

The Itch-Scratch Experience



Itch characteristic	No. of patients	%
Duration of itch		
< 6 months	11	3.6
6 months to 1 year	8	2.6
1–5 years	65	21.4
5–10 years	47	15.5
10–20 years	58	19.1
> 20 years	109	35.9
Associated symptoms		
Pain	178	58.6
Sweating	77	25.3
Heat sensation	162	53.3
Cold sensation	20	6.6
Other	57	18.8
Recent experience of scratching (–5 to +5 scale)		
Highly pleasurable (+4 to +5)	126	41.4
Moderately pleasurable (+2 to +3)	67	22.0
Neutral (–1 to +1)	36	11.8
Moderately unpleasurable (–2 to –3)	24	7.9
Highly unpleasurable (–4 to –5)	43	14.1
Blank	8	2.6

- >98% of individuals described their itch as ‘annoying’, ‘bothersome’, ‘unpleasant’ or ‘bothering’
- Participants reported itch/scratch more frequently at night, in the evening and during the winter

Dawn A et al. British Journal of Dermatology 2009;160; 642–644



“Whatever the causes, I’ve spent countless nights in the grip of itch, tearing at my skin to wake in the morning with crusty gashes on my hands, face, and elsewhere.”

“I still wake up unconsciously clawing at my skin. When I itch during the day I can find a distraction or I can try and control it, but there’s no control over scratching in my sleep.”

“I am a 50-year-old, lifelong sufferer. Most of you know the clinical definition of eczema, but please allow me to give you my personal definition of the disease. I call it torture. I endure endless bouts of itchy, torn open, bleeding, oozing, red, flaky skin from head to toe.”

“The itch is so bad that I bruise myself from scratching. Lost sleep has really affected my well-being. I am exhausted and sometimes don’t feel mentally prepared for the day.”

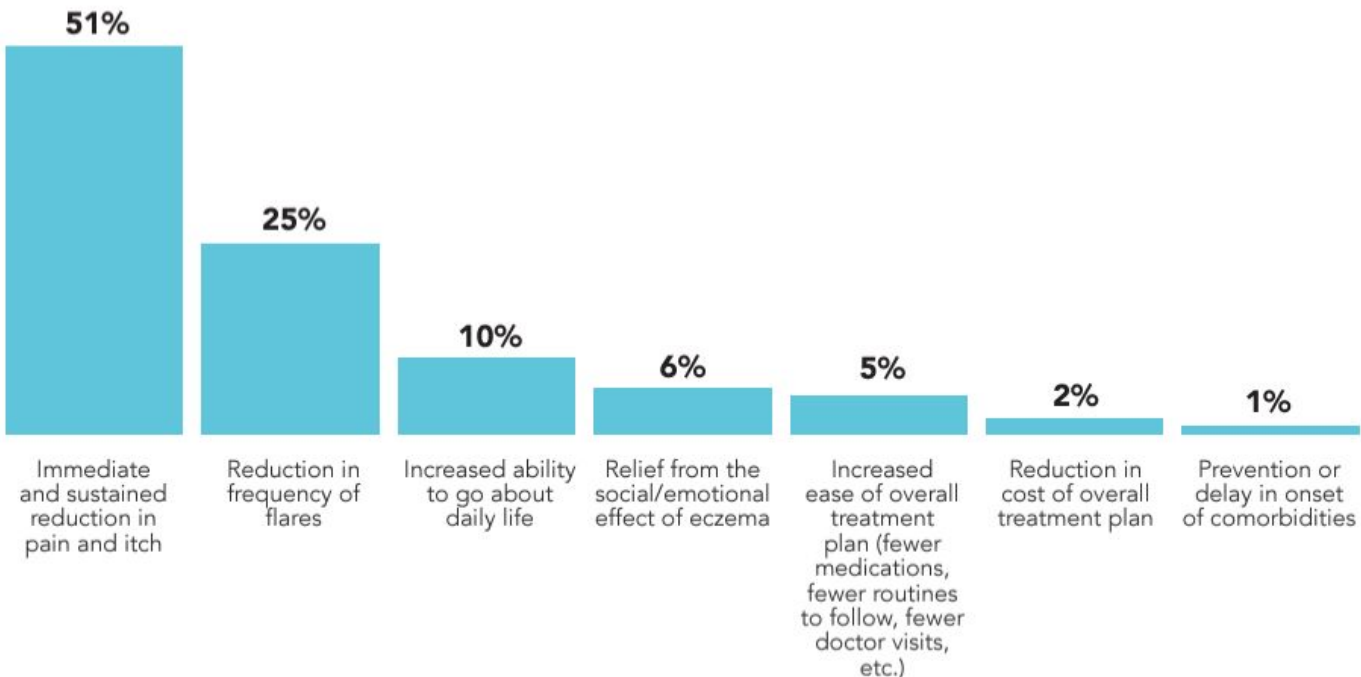
“At its worst, my eczema kept me from being able to sleep at night. I just wanted to scratch all night long since it felt like fire ants were walking all over my entire body. My skin was so itchy, hot and felt like it was going to burst.”

1. Yosipovitch G. *Living with Itch: A Patient’s Guide*
2. <https://www.morethanskindeep-eczema.com/>
3. <https://nationaleczema.org/focus-on-jim/>

Itch-Scratch Reduction #1 Treatment Goal



MOST IMPORTANT RESULT THAT A TREATMENT COULD PROVIDE PATIENTS WITH ECZEMA



<https://www.morethanskindeep-eczema.com/>



- **AD is largely a patient-reported disease**, however clinician-reported measures (ClinRO) predominate AD assessments.
- **Use of patient-reported outcomes (PROs) are increasing** (often itch or sleep) yet restricted to periodic care encounters.
- **Opportunity exists to complement care setting measures with real-world data** from patients and/or other disease tracking mechanisms to improve:
 - Self-monitoring and personal disease management
 - Shared decision making and clinician-supported disease management
 - Understanding of clinical trial and real-world treatment effectiveness and unmet needs



- **Standalone mobile health (mHealth) apps** – both general health and disease-related are becoming more widely available.
 - As of 2020 over 84M persons in the US have used apps with health and health-related content.¹
 - 12 eczema-specific mHealth apps available in the US
 - Tracking (w/ or w/o AI), education, shared decision making
 - EczemaWise by NEA²

1. *N Engl J Med* 2023;389:2100-2101
2. <https://www.eczemawise.org/>

The image shows a laptop and a smartphone displaying the EczemaWise app interface. The laptop screen shows a dashboard with various charts and data points, while the smartphone screen shows a similar interface with a focus on tracking and education. Above the devices, there are two award logos: 'eHealthcare LEADERSHIP AWARDS 2023 WINNER'.

Get to know your eczema.

You live with your eczema every day, but how well do you really know it? EczemaWise helps you see the bigger picture for better eczema management.

→ Try web now

Download on the App Store

GET IT ON Google Play



- **Wearable digital health technology** – both general health and disease-related.
 - 45% of Americans wearing some form of smartwatch as of April 2022.¹
 - 92% of smartwatch users reported that they used the devices to maintain/manage their health
 - Other sensor-based devices
 - Many also linked to an mHealth app for patient information



1. *N Engl J Med* 2023;389:2100-2101

Opportunities for Ongoing Patient Involvement



Observation

Appearance of skin
Signs and symptoms



Perception

Subjective sensation
Itch



Experience

Personal experience
QOL, sleep



Behavior

Performed actions
Nocturnal scratch

- **Patients have a significant role in AD care evolution**

- Determining what metrics are most meaningful in clinical trials and the real-world
- Willingness to use – stickiness, tolerability, and frequency of use
- Determining meaningful levels of change
- Use for self-monitoring and self-management
- Use to inform treatment decisions

Digital Measurement of Nocturnal Scratch

Jaydev Thakkar, COO, Biofourmis
June 11' 2024

Biofourmis Solutions Delivering Care Across the Continuum



**Hospital & Health
Systems**



**Payors & Risk
Bearing Entities**



**Life Sciences &
BioPharma**

BiofourmisCare

Technology-enabled solutions for care, anywhere*

BUSINESS
VERTICALS

BiofourmisConnect

Digital patient solutions to enable clinical trials, anywhere*

Acute Care

Deliver care to clinically-appropriate acute patients at home

Transitional Care

Enable patients to more easily move from acute to post-acute sites of care

Remote Patient Management

Help prevent decompensation post-discharge and reduce re-hospitalizations

FOCUSED
APPLICATIONS

Digital Clinical Trials

Onboard, manage, and communicate remotely with trial participants

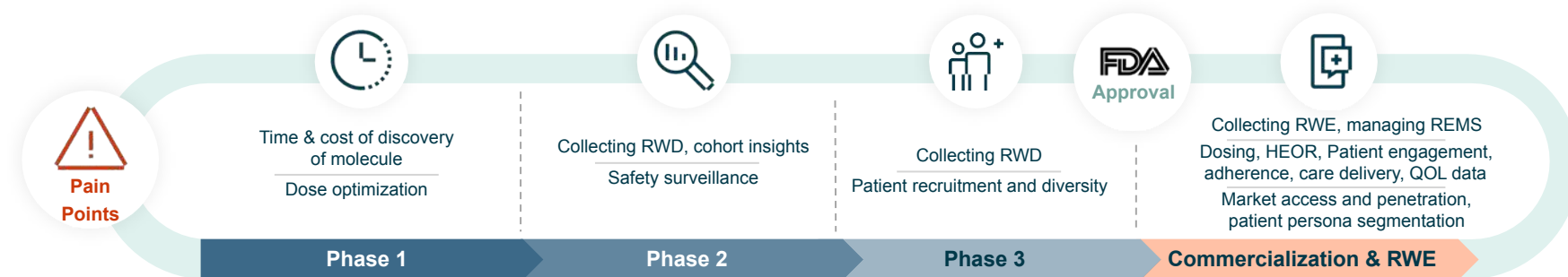
Digital Drug Companions

Technology and support services to promote participant engagement and retention

Digital Measures, Biomarkers & Endpoints

Harness physiologic data leading to more informed patient strategies

Opportunity to Optimize Drug Lifecycle Value



Co Development □ Digital Biomarkers | SaMD | Digital Companions

Clinical Development and Digital Trials

Commercial Validation & Market Access

Early-stage Candidates

- Precision medicine that uses biomarkers and AI/ML tools. **Allows dose titration and optimization personalized for each patient.**
- **Early evidence** to advance promising candidates, or “fail fast” unsuitable ones
- **Differentiation through SaMD development**

Mid/Late-stage Candidates

- Patient-centric digital biomarkers as surrogate endpoints to **speed clinical development**
- Remote/ decentralized monitoring for enhanced patient experience and **access to diverse population**
- Biosensor data for **improved assessment of efficiency, side effects, and outcomes**

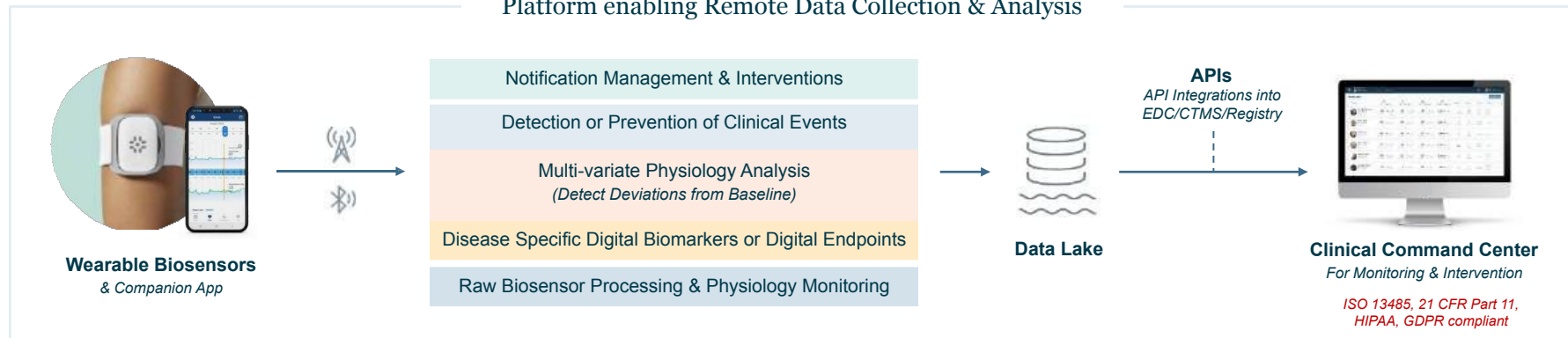
Marketed Drugs

- Integration into our disease-specific dynamic care pathways to **optimize care delivery**
- Observational data and surveillance to inform **FDA post-market drug safety monitoring**
- Outcomes data so reimbursement can be informed by the **outcomes of real-world patients**

Biofourmis Platform for Digital Clinical Trials

Combines integrated wearable biosensors, analysis/interpretation software (SaMD), continuous remote data collection, and digital endpoints to measure drug efficacy and safety.

Platform enabling Remote Data Collection & Analysis



Operational Infrastructure to support use of digital technologies



Measuring Nocturnal Scratch in AD

Scratch & Sleep Algorithm

Pharma and Tech commercial collaboration

The Technology



The Solution



The technology was developed by a major Pharma and has been licensed by Biofourmis to be an exclusive independent distributor to ensure competitive confidentiality and data privacy

Measuring Nocturnal Scratch and Sleep in AD

- **What:** Validated (in Atopic Dermatitis) nocturnal scratch digital tool to measure quantitatively, passively and in an unbiased manner **nocturnal scratching** (# of events and duration) and sleep quantity to provide endpoints with high accuracy, specificity and sensitivity
- **How:** Using sensor-generated data and validated algorithms, we collect essential information about patients' nighttime scratching, measuring and quantifying this behavior in real-time.
- **Who:** validated in patients from 2-75 years of age



Using digital health technologies to improve the lives of patients with Atopic Dermatitis

1

Development of
Nocturnal Scratch
and Sleep
Algorithms



2

Validation of
Nocturnal Scratch
and Sleep
Algorithms



3

Clinical Trial
Applications

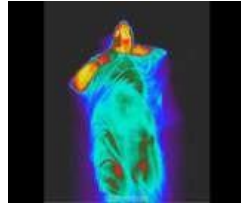


Development Nocturnal Scratch and Sleep Digital Health Measures

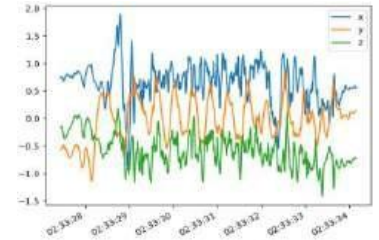
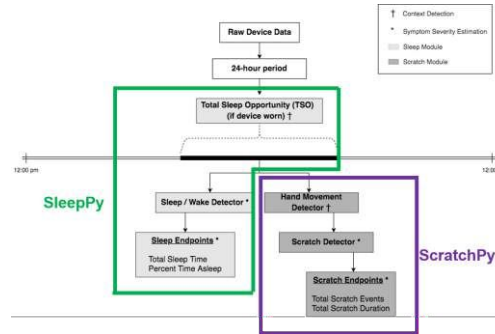
1

Development of Nocturnal Scratch and Sleep Algorithms

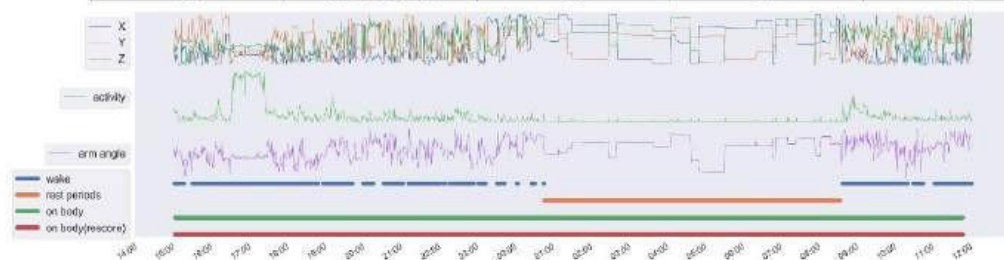
(Device agnostic algorithms)



Development of Novel Digital Measures



Total Sleep Time(minutes)	Percent Time Asleep	Wake After Sleep Onset(minutes)	Sleep Onset Latency(minutes)	Number of Wake Bouts
470.0	99.57627118644069	2.0	0.0	1.0



- Christakis et al. Journal of Open Source Software, 2019.
- Mahadevan et al, *Nature Digital Medicine*, 2021

Validation of Nocturnal Scratch and Sleep Digital Health Measures

2

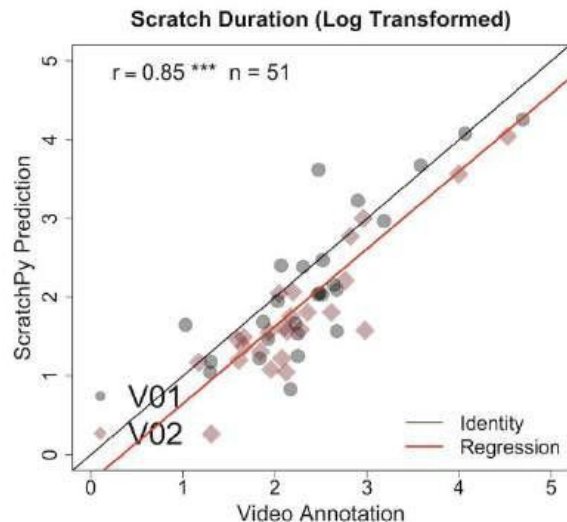
Validated Nocturnal Scratch and Sleep Algorithms

✓ -Correlation of Nocturnal Scratch to “ground truth” with video annotation

• Mahadevan, N, et al. Nature Digital Medicine, 2021

Accurately, measure Nocturnal Scratch and Sleep, compared with gold Standards

Nocturnal Scratch Duration- SQUAD



- 1) Scratch and Sleep Quantification in Atopic Dermatitis (SQUAD) ClinicalTrials.gov Identifier: NCT03490877
- 2) Monitoring of Scratch via Accelerometry in Children (MOSAIC) ClinicalTrials.gov Identifier: NCT03873220
- 3) Scratch Behavior Under Standard of Care (SOC) ClinicalTrials.gov Identifier: NCT03898427

Clinical Trials completed to validate the technology

- NCT03490877
 - Scratch and Sleep Quantification in Atopic Dermatitis (SQUAD)
 - Mahadevan et al. 2021 and Beck et al. 2021
 - N = 45
 - age: 31.7 ± 16.0 [12-75]
 - sex: 29 (64.4%) male, 16 (35.6%) female
 - race: 1 (2.2%) Asian, 23 (51.1%) Black / African American, 21 (45.7%) White
- NCT03873220
 - Monitoring Of Scratch Via Accelerometry In Children (MOSAIC)
 - Northcott et al. 2020
 - N = 41
 - age: 5.7 ± 2.9 [2-11]
 - sex: 18 (43.9%) male, 23 (56.1%) female
 - race: 22 (53.7%) Black / African American, 5 (12.2%) Hispanic / Latino, 9 (22.0%) Multiracial, 2 (4.9%) White, 3 (7.3%) Other
- NCT03898427
 - Scratch Behavior Under Standard of Care (SOC)
 - N = 120, ages 2-75, validation cohort
- Additional clinical trials exist in which SleepPy and ScratchPy algorithms are used for exploratory endpoints

Associated digital endpoints

Digital Measure	Type	Units	Description
TSO	Sleep	Minutes	Largest window of time where sleep is the intended behavior.
TST	Sleep	Minutes	Total time spent asleep during the total sleep opportunity window.
PST/Sleep Efficiency	Sleep	Percentage	Percentage of the total sleep opportunity window spent in the sleep state.
WASO	Sleep	Minutes	The periods of wakefulness occurring after defined sleep onset.
Number of Wake Bouts	Sleep	Integer	Number of times of wakefulness that occurred following sleep onset.
Total scratch events	Scratch	Counts	Total scratch bouts during the total sleep opportunity window.
Total scratch duration	Scratch	Minutes	Total time scratching during the total sleep opportunity window.

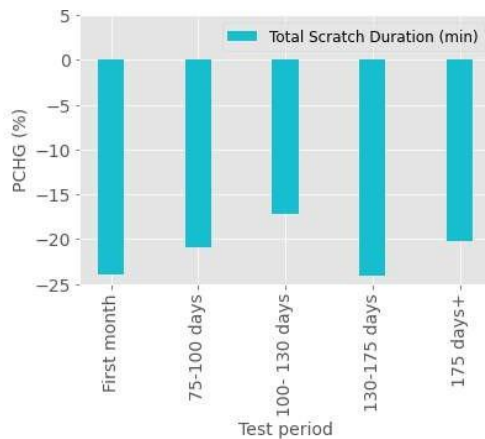
PST = percent sleep time; TSO = total sleep opportunity; TST = total sleep time; WASO = wake after sleep onset.

Drug-mediated Changes in Nocturnal Scratch and Sleep

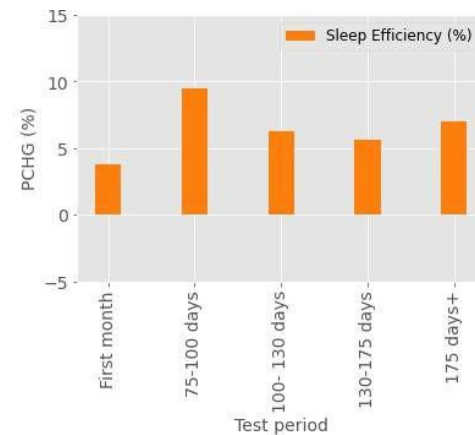
3

Clinical Trial Applications

✓ -Drug-Induced changes observed



□ Abrocitinib resulted in a general reduction in scratch duration.



□ Abrocitinib showed a general improvement in sleep efficiency.

Nocturnal Scratch and Sleep were Exploratory and Optional Endpoints
Limited participants (N=27), therefore descriptive analyses were completed

ClinicalTrials.gov Identifier: [NCT04345367](https://clinicaltrials.gov/ct2/show/study/NCT04345367)

- Di J, Christakis Y, Mamashli F, Kelekar A, Bruno J, Zhang Y, and Northcott CA. One scratch at a time: Nocturnal scratch and Sleep improvements in Atopic Dermatitis with Abrocitinib. EADV, Aug 2022

Did the participants find the devices comfortable?

- At the end of the studies the participants (or caregivers) were asked if they found the devices comfortable and their likeliness to wear the devices continually.
- **Patients with AD felt the devices were comfortable to wear.**

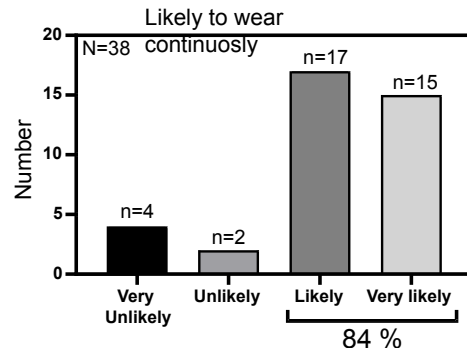
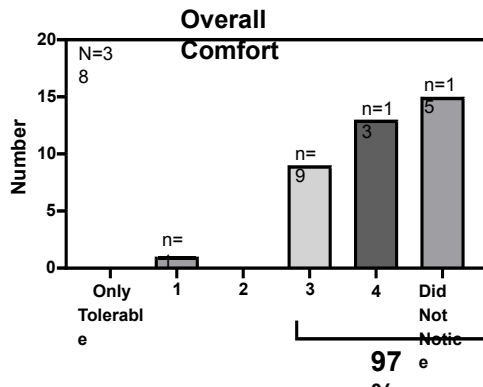
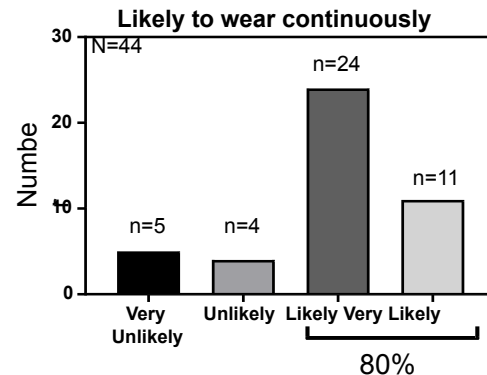
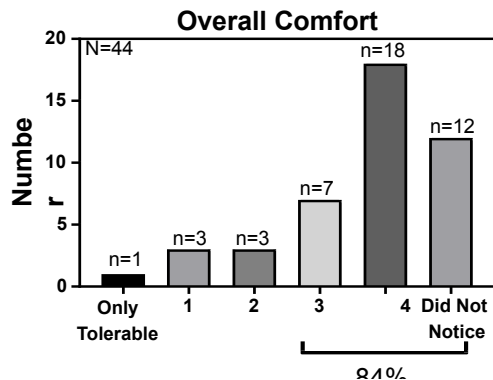
ADULTS

SQUAD; 12 – 75 years old



CHILDREN

MOSAIC; 2 – 11 years old

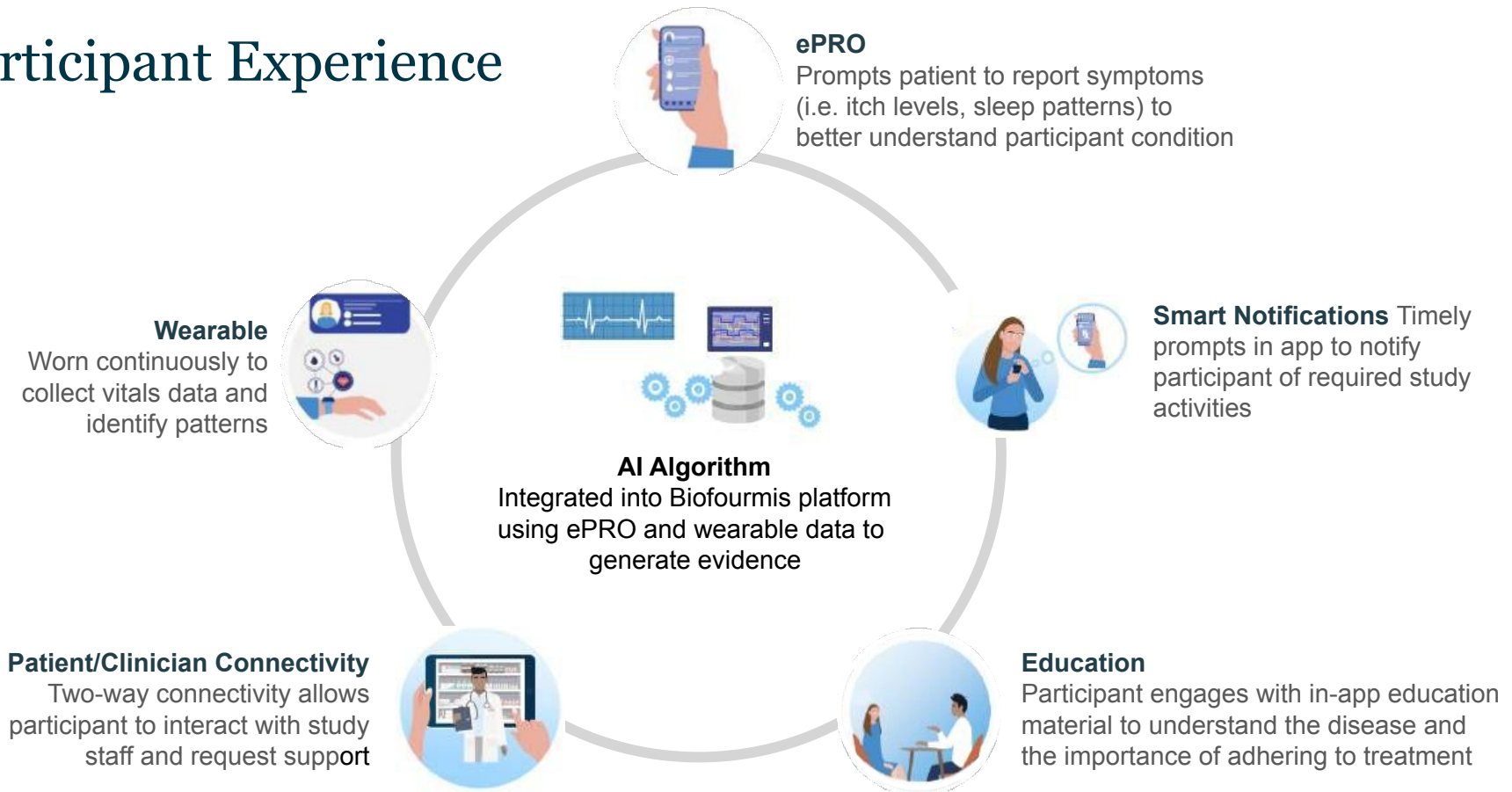


Validation Roadmap - Several Years of Work is Already Completed

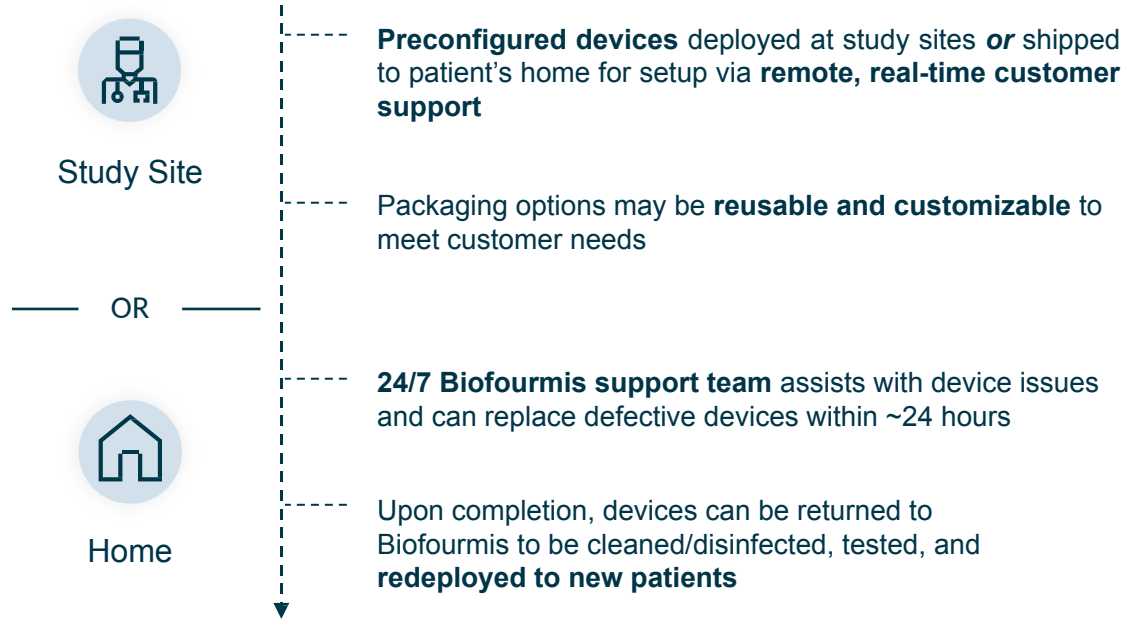
Study	Activity	Objective	Summary
Qualitative study	Concept elicitation	Establish nocturnal scratch as an important concept that matters to AD patients	<ul style="list-style-type: none"> Structured interviews with patients and their partners, further supported by survey data from patients and caregivers.
Feasibility & Analytical validation study (non-therapeutic) – evidence may be available from DHT manufacturers	DHT Feasibility	Demonstrate patient feasibility of deploying DHT to collect data in patients with AD	<ul style="list-style-type: none"> Patient feedback on the use of the DHT Evaluate compliance Understand barriers and facilitators for patients, for example through a structured questionnaire, to enable optimum deployment in future studies
		Demonstrate operational feasibility of deploying DHT to collect data in patients with AD	<ul style="list-style-type: none"> Clinical site feedback on the use of the DHT Identify operational issues arising from DHT deployment (e.g., technical issues, DHT-related adverse events (AEs)) Understand operational barriers and facilitators, for example through a structured questionnaire, to enable optimum deployment in future studies
	Analytical Validation	Assess the performance of DHT in measuring nocturnal scratch (duration, number of events) in patients with AD	<ul style="list-style-type: none"> Comparison to gold standard measure, e.g., videography and polysomnography
		Evaluate the reliability of DHT-derived nocturnal scratch measures	<ul style="list-style-type: none"> Within-patient coefficient of variation of nocturnal scratch measures over various periods of time
+Therapeutic study(/ies)	Analytical Validation	Evaluate the sensitivity to change of DHT-derived nocturnal scratch measures	<ul style="list-style-type: none"> Explore changes over time (e.g. relative rate of change over time)
	Clinical Validation	Evaluate correlations between proposed measures and other clinical outcomes	<ul style="list-style-type: none"> Correlation of DHT-derived nocturnal scratch measures with: <ul style="list-style-type: none"> PROs (e.g. NRS Itch) Skin lesions Primary/secondary efficacy assessments, e.g. EASI SCORAD or vIGA-AD
	Minimal Meaningful Change	Define minimum meaningful change that can be interpreted as treatment benefit	<ul style="list-style-type: none"> Anchor-based methodology (e.g. using PGI-S as an anchor) as well as distribution-based methods as supportive. <ul style="list-style-type: none"> Literature supporting the meaningful changes observed in standard sleep and scratch/lesion measures



Participant Experience



Biofourmis Logistics Services deliver complete device life-cycle management



(Sample devices shown to illustrate participant kit. Actual kits will vary dependent on study protocol and connectivity requirements.)

Biofourmis Vision:

Development of a commercial solution to analyze various data inputs such as skin images, environmental factors, lifestyle habits, and treatment history to provide personalized recommendations for managing Atopic Dermatitis

- 1. Personalized Treatment Recommendations:** By analyzing individual patient data, such as medical history, symptoms, environmental triggers, and treatment responses, the algorithm can provide personalized treatment recommendations tailored to each patient's specific needs. This can improve treatment effectiveness and patient outcomes.
- 2. Early Detection and Intervention:** Machine learning algorithms can identify patterns and early indicators of disease exacerbation or flare-ups based on patient-reported symptoms and environmental factors. This allows for early intervention and proactive management, potentially reducing the severity and frequency of flare-ups.
- 3. Educational Resources:** The patient app can provide educational resources about atopic dermatitis, including information about the condition, common triggers, lifestyle modifications, and treatment options. This empowers patients to better understand their condition and actively participate in their care.
- 4. Symptom Tracking and Monitoring:** Patients can use the app to track their symptoms, medication usage, and environmental exposures over time. The AI algorithm can analyze this data to provide insights into symptom patterns, treatment efficacy, and potential triggers, facilitating more informed discussions between patients and healthcare providers during clinic visits.

Thank you!

- For questions/inquiry: Jaydev.Thakkar@biofourmis.com



PIONEERING THE DIGITAL TRANSFORMATION OF
CLINICAL RESEARCH™

DECODE Nocturnal Scratch

Sylvain Zorman, Director Digital Health Sciences

[THEACTIGRAPH.COM](https://theactigraph.com)



Nocturnal scratch is cardinal to patient with eczema

1- “in bed, I left a **trail of blood, skin,** and tears”

2-“I still **wake up unconsciously clawing at my skin.** When I itch during the day I can find a distraction or I can try and control it, but **there’s no control over scratching in my sleep.**”

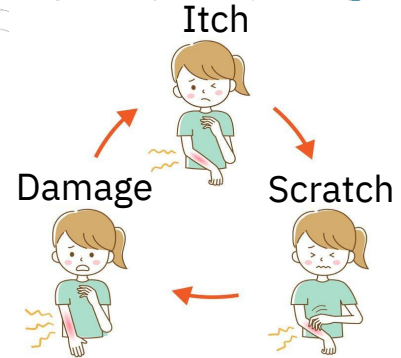
3-“I’d **wake every few hours, bloody and in tears** because I had ripped everything off in my sleep because **my skin felt like it was on fire**”



4-“Feel the heaviness of having **tear-stained eyes** whenever you hear your **child’s pained cries for relief** from yet another **bout of nightly scratching.**”

5-“I remember taking turns with my wife, **lying awake at night, holding Drew’s arms** down so he wouldn’t scratch and **peel the skin off his face and throwing away his bloodstained clothes** because we just didn’t want to wash them”

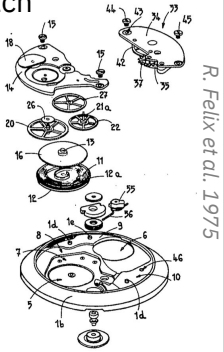
6-“When my son’s eczema was the most severe, he would **shed a pile of dead skin nightly.** He was in so much pain even the air hurt. His skin oozed and peeled. **He scratched, and it was very difficult to sleep. I would sleep with him to hold his hands down to not injure himself further.**”



Voice of the Patient

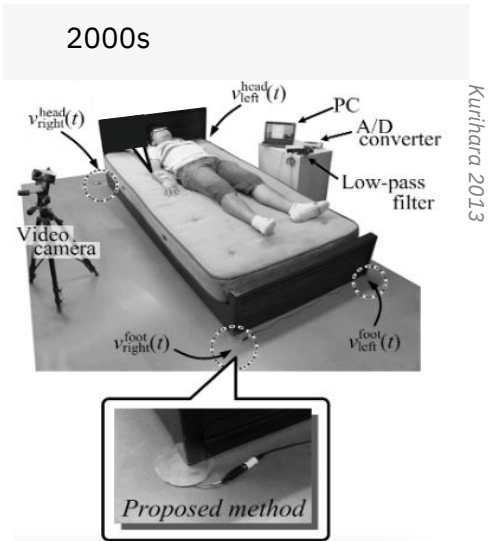
“Measure what is measurable, and make measurable what is not so” Galileo

1975: self-winding watch



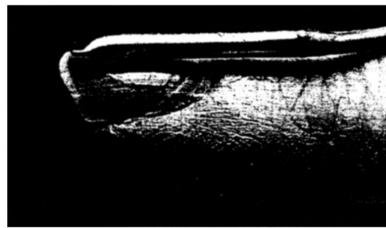
R. Felix et al. 1975

2000s



Kurihara 2013

1998: nail

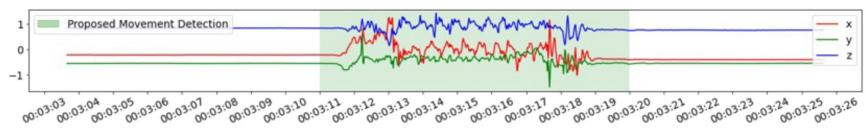


Molenaar 1998

Fig. 4 Transducer glued to a nail



+
Machine Learning



Ju 2023

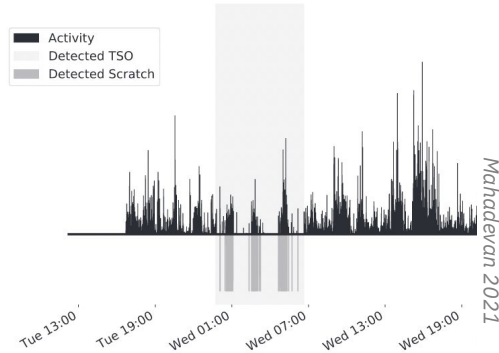
- High burden
- Low sensitivity
- Not scalable

Adoption of wrist actigraphy by pharmaceutical sponsors

Pharma initiatives

Past consortiums

Launched in 2023



Pharma Development:

- Pfizer (Mahadevan et al. 2021)
- Lilly (Ju et al. 2023)
- AbbVie (NCT04262791)
- Sanofi (NCT05235724)



NOCTURNAL SCRATCH



Digital Measures Development

Founding Project Partners	Project Collaborators	Expert Partners

ActiGraph™

DECODE
NOCTURNAL SCRATCH

Digital Endpoint Collaboration to accelerate Outcome DEvelopment in dermatological conditions

Technology agnostic approach

Delivering fit for purpose technology

Workstreams



Analytical validation study:

- ~60 participants (atopic dermatitis and psoriasis)
- comparison between wrist-based measure and video recording



Health authority engagements:

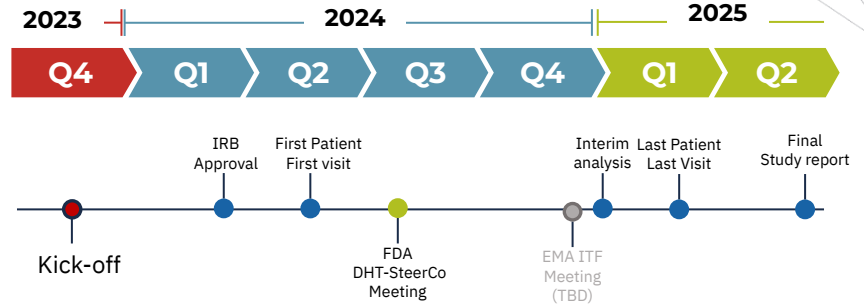
- FDA: DHT Steering committee
- EMA: Innovation Task Force meeting



Usability:

- Evaluate ways to maximize compliance
- Operational recommendations

Key Milestones



ActiGraph

DECODE
NOCTURNAL SCRATCH

Founding Project Partners

Janssen | pharmaceutical division of Johnson & Johnson

Takeda

Project Collaborators



Deliverables and benefits



Critical mass

- Consensus building
- Dissemination
- Cost reduction



Evidentiary dossier

- Verification
- Validation
- Usability



Regulatory buy-in

- Derisking future engagement
- Faster approval
- Lower the regulatory barrier



Thank you!



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Digital Measurement of Nocturnal Scratch New Developments

Advanced **Wearables** for Scratch Monitoring

June 11th, 2024

Measuring Itch: A Growing Number of Choices

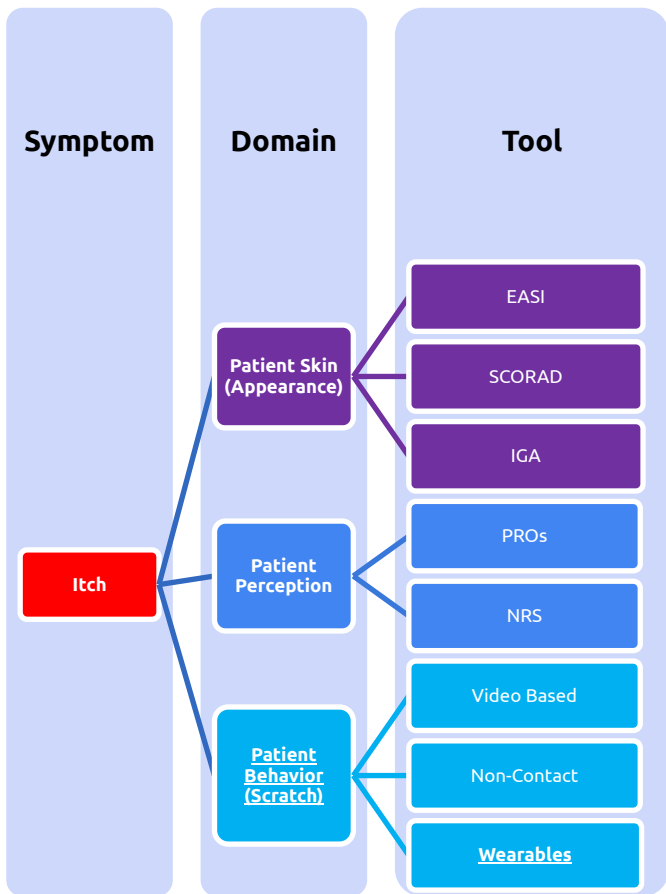
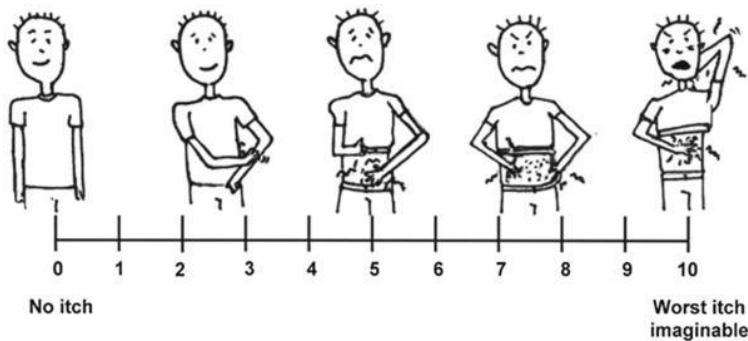
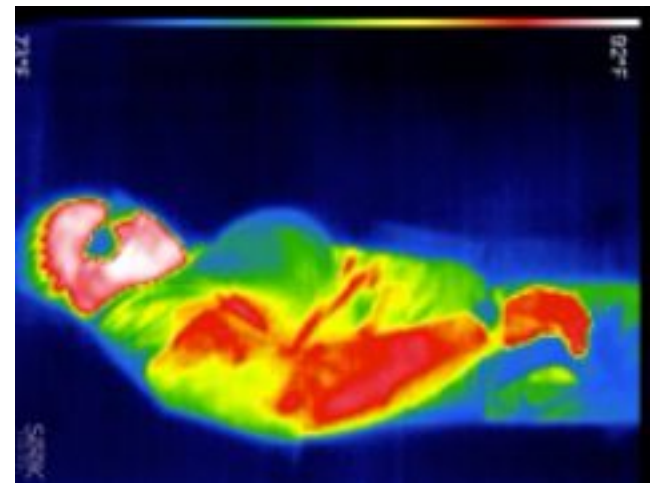


Table 1: Eczema Area and Severity Index

The EASI score rates the four involved regions (head and neck, trunk, upper extremities, and lower extremities) on a 0% to 100% scale for each region.¹⁷

Score	Description
0	Clear or no lesions
0.1-1	Almost clear
1.1-7	Mild disease
7.1-21	Moderate disease
21.1-50	Severe disease
>51	Very severe disease



Novel Digital Endpoints: ADAM™



Suprasternal Notch

Monitor patient health remotely with ten unique digital biomarkers such as swallowing and talking with a single device on a single body location.



Scratch and Sleep

A single device that can quantify scratching behavior such as scratch duration and intensity as well as standard sleep metrics.



Full Body Movement

Track body movements with a high degree of accuracy to characterize motor performance.

ADAM: Motion + Sound Sensing

Highly Specific and Sensitive for Scratch Sensing

High Frequency Accelerometer

- x, y-axis : 200 Hz
- z-axis : 1,666 Hz

Top Encapsulation

- Soft
- Stretchable
- Water-proof

Microcontroller

- Low power
- Wireless communication

Haptic Motor

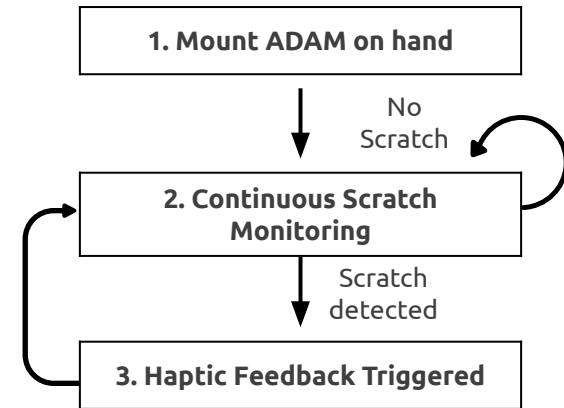
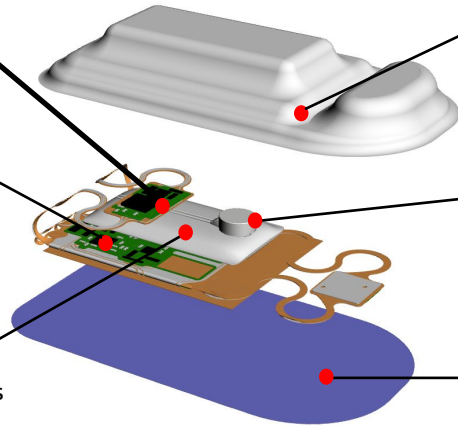
- ERM haptic motor
- Maximum of 10,000 RPM
- 1.4 G vibratory feedback

Rechargeable Battery

- Wireless charging
- Operation time : >35 hours
- Monitoring time : 1 week

Bottom Encapsulation

- Soft
- Stretchable
- Waterproof

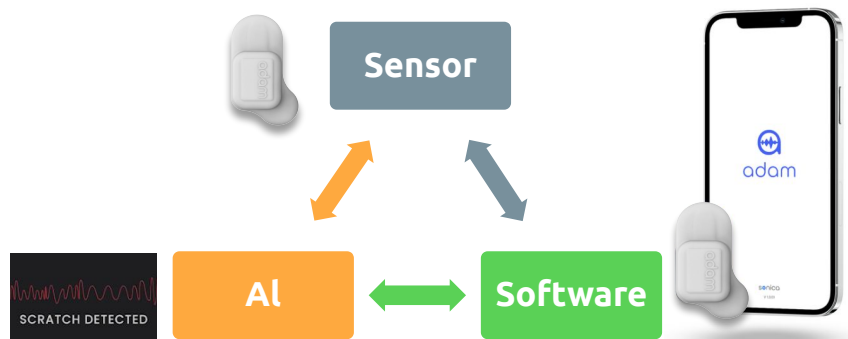


The Tech



Outputs

- Scratch events
- Scratch intensity
- Total sleep time
- Sleep efficiency
- WASO



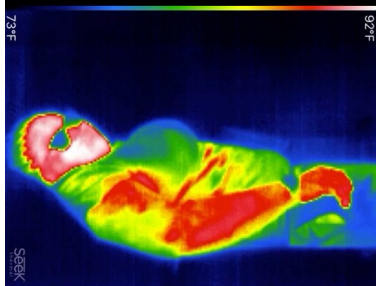
ADAM captures sleep and scratch metrics on a single device with AI and edge computing

The Validation

Pediatric AD: F1 83% | Sensitivity 84%

Motion Signal

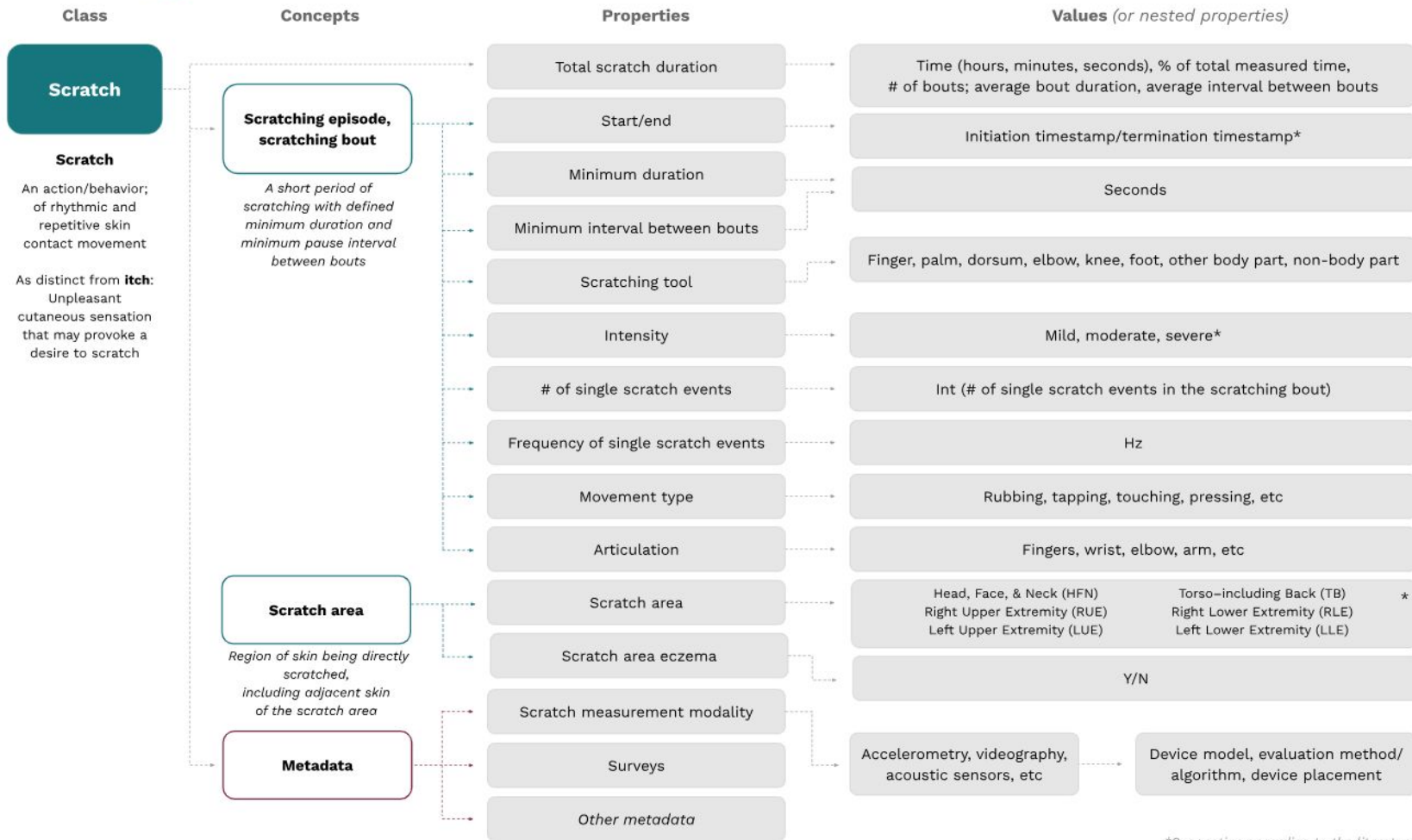
X
Y
Z



Likelihood of Scratch

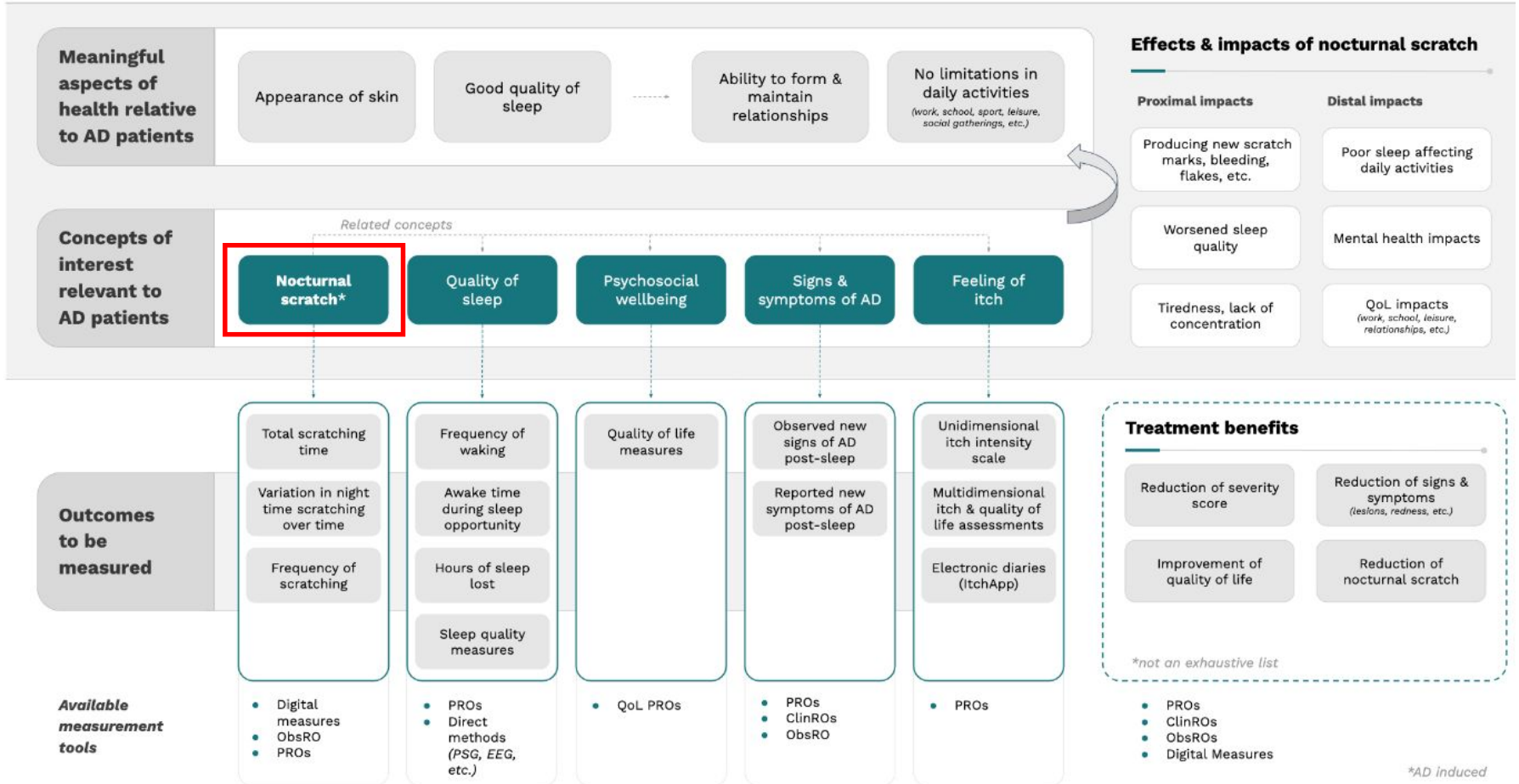
Adult AD: F1 90% | Sensitivity 93%

Ontology of "Scratch"



*Suggestion according to the literature

Measure What Matters: The Scratch and Itch Relationship



Scratch in AD Survey

**What do patients care about when it comes to scratching
beyond nocturnal scratching?**

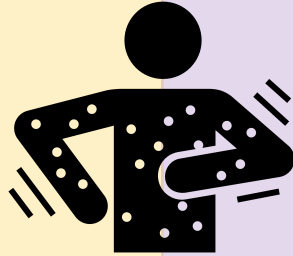
Characterizing Scratching Across 3 Key Domains



Intensity

How intensely does a patient scratch?

Awake



Events

How often does a patient scratch?

Asleep

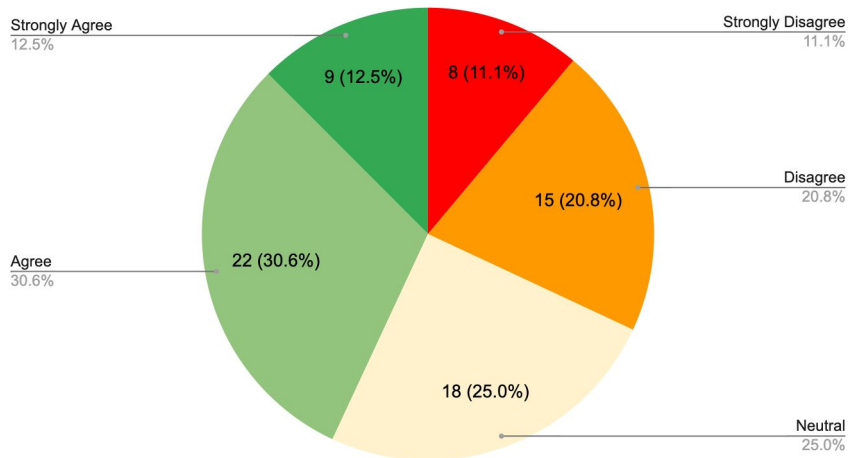


Duration

How long does a patient spend scratching?

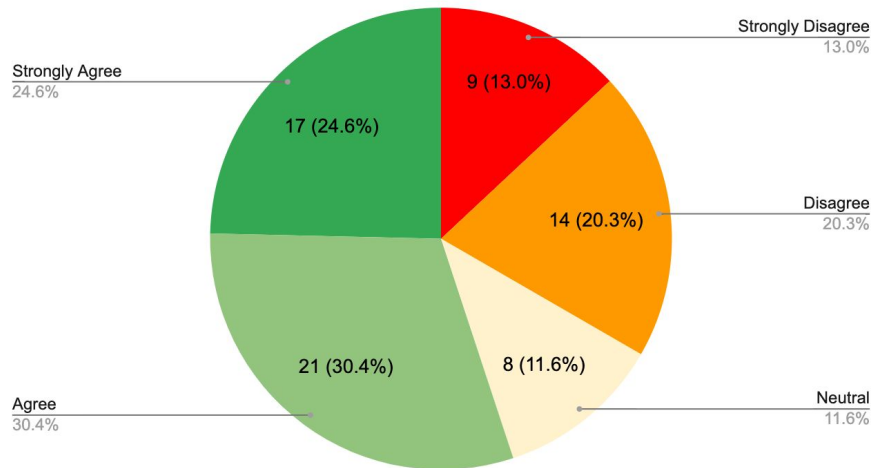
What Do Patients Care About When It Comes to Scratching (n=72 AD patients)?

Knowing how many times I scratch while awake would be meaningful



43% of AD patients agree or strongly agree that knowing how many scratch events in the day is meaningful to them

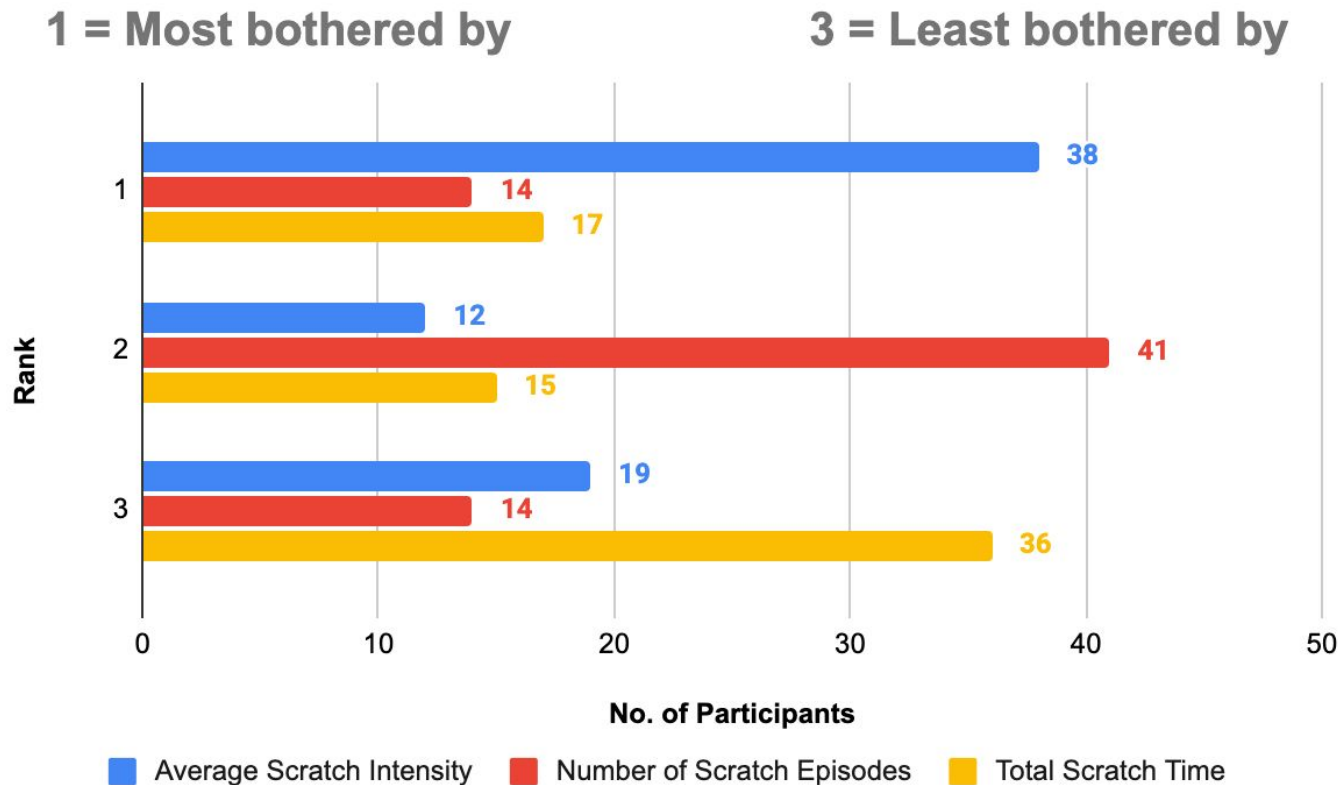
Knowing how many times I scratch while asleep would be meaningful



55% of AD patients agree or strongly agree that knowing how many scratch events at night would be meaningful to them

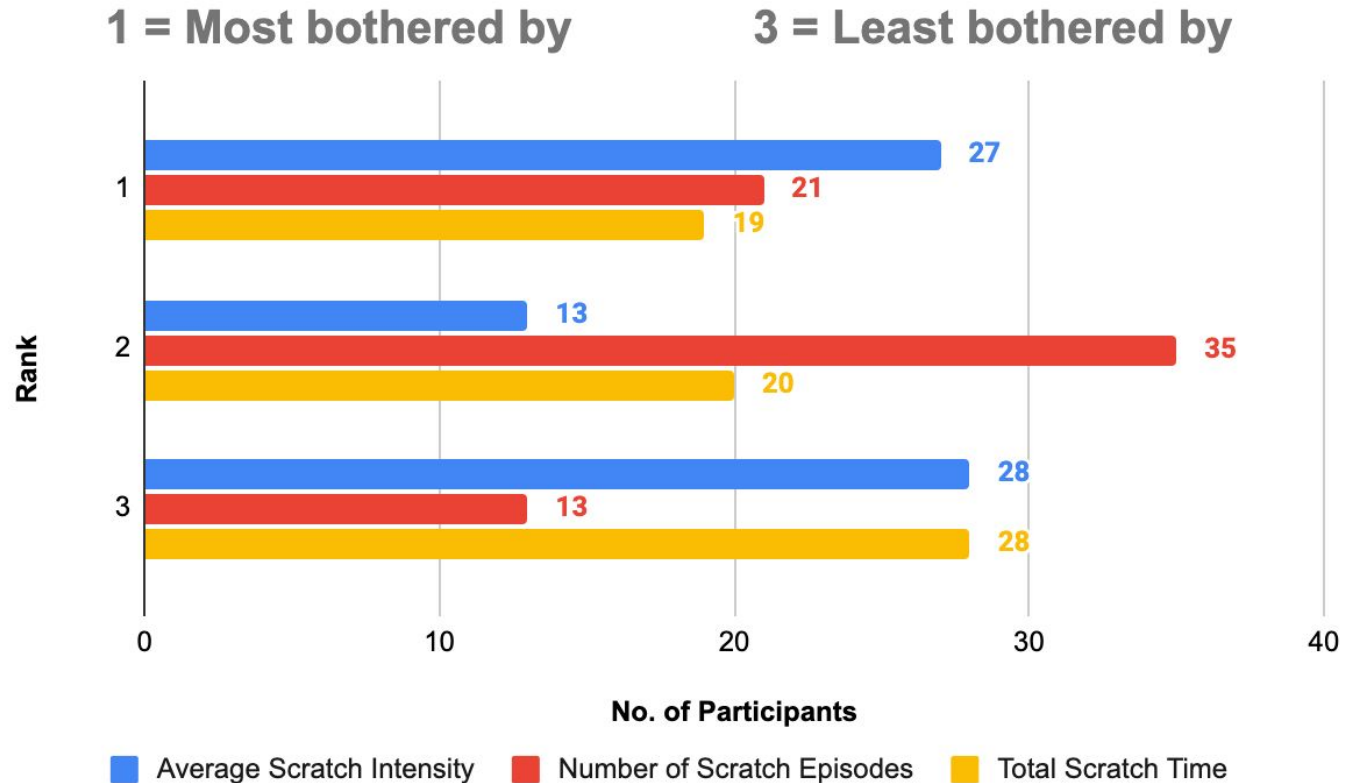
12% of respondents agreed or strongly agreed that nocturnal scratching would be meaningful to them compared to day time scratching

While awake, I am most bothered by ...



While awake, it was scratch intensity again!

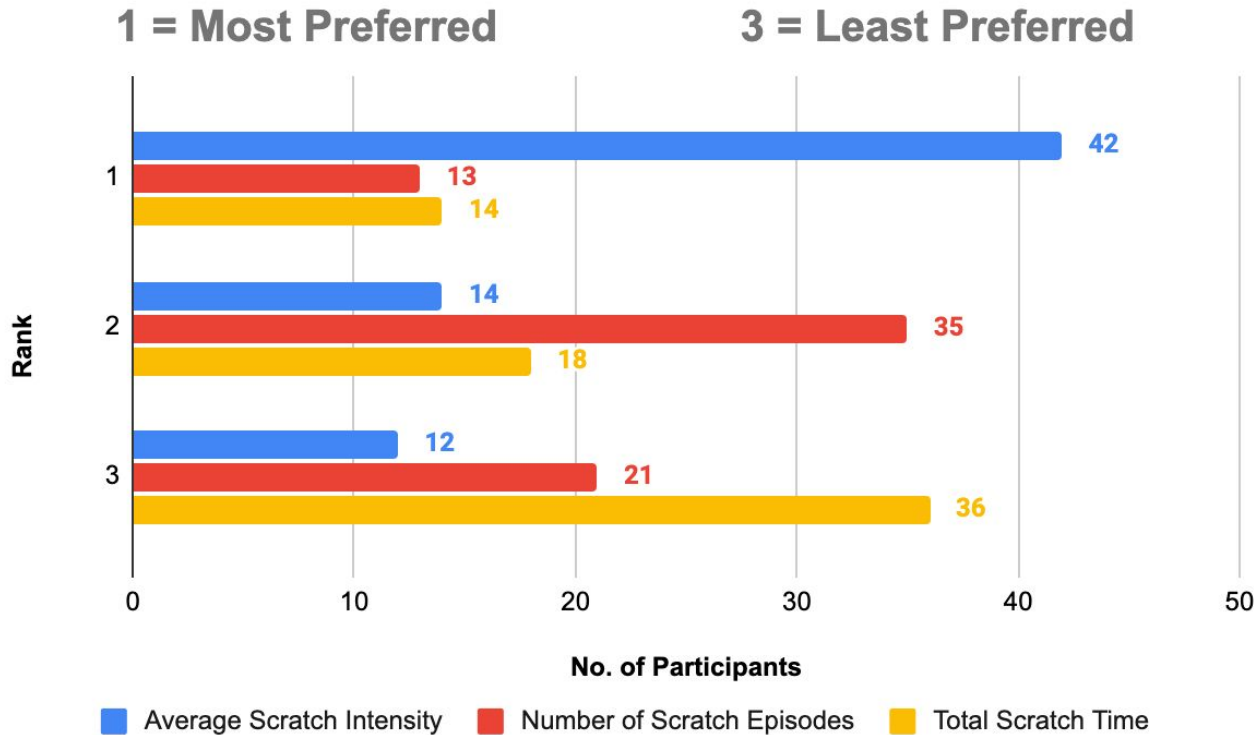
While asleep, I am most bothered by ...



While asleep, it was scratch intensity...

What Do Patients Care About When It Comes to Scratching (n=72 AD patients)?

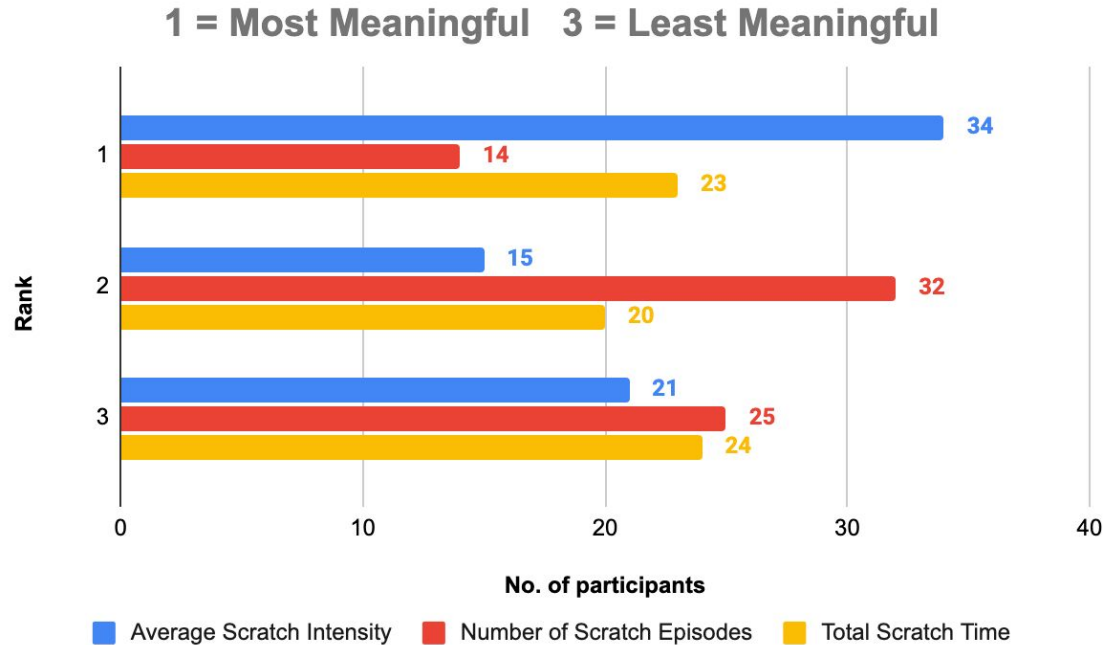
I would prefer a medical treatment that targets ...



The most patients ranked scratch intensity as what they would like a medical treatment to target

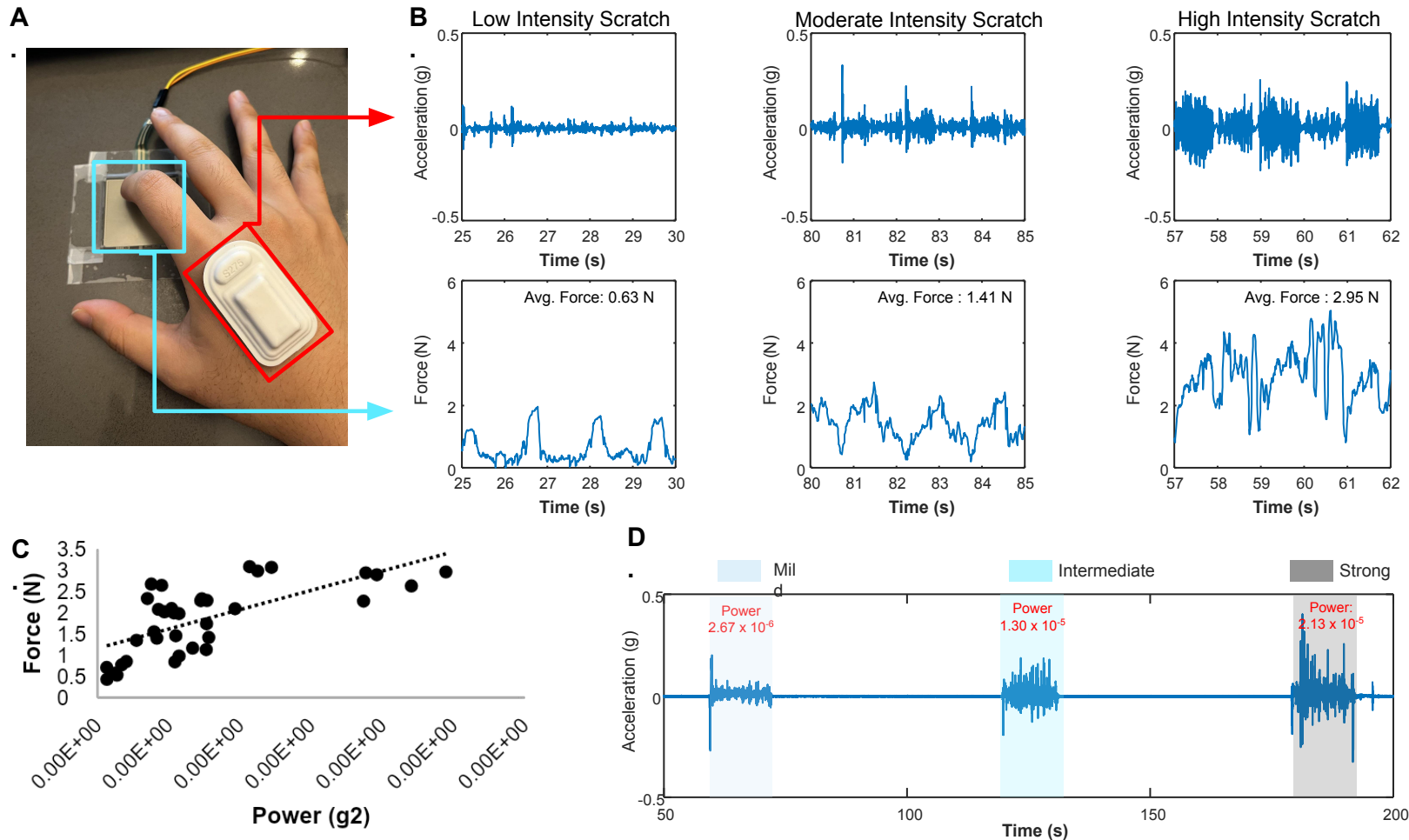
What Do Patients Care About When It Comes to Scratching (n=72 AD patients)?

The Most Meaningful Scratch Measurement



The most patients ranked scratch intensity as the most meaningful measurement

Scratch Intensity with ADAM: Translating Motion to Force

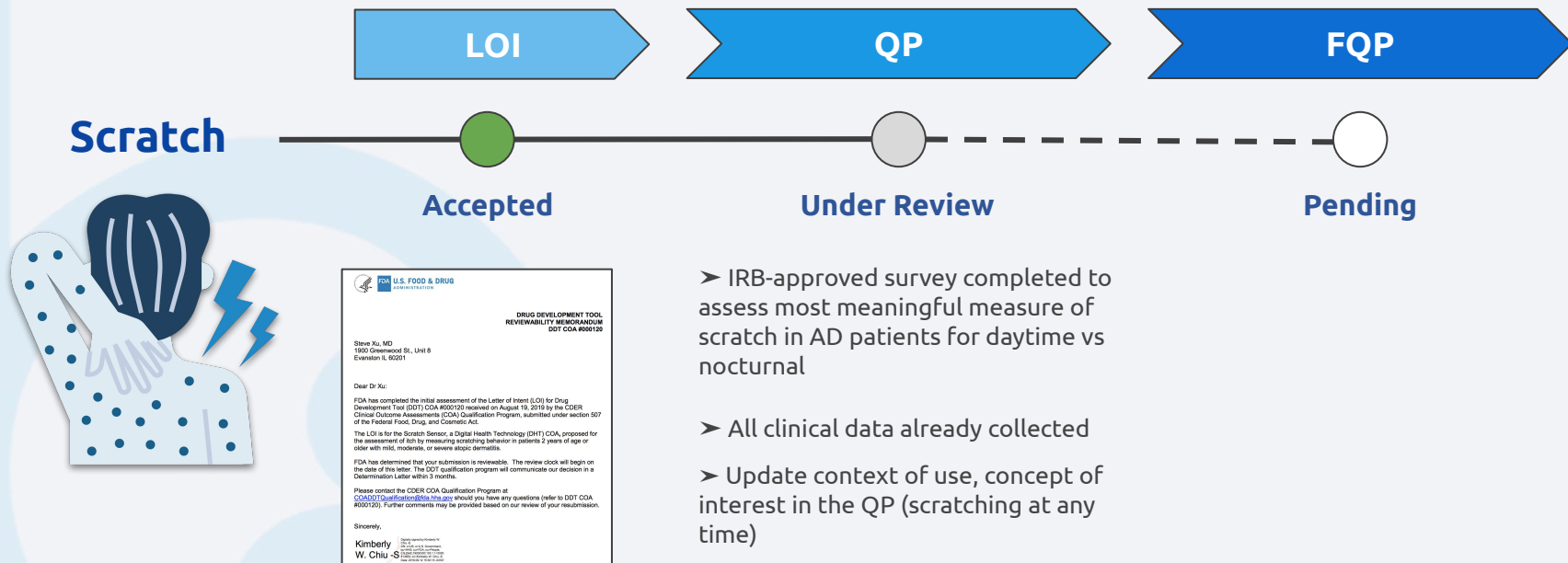


Global AD Scratch Validation Studies with ADAM



Study	Population	Subjects	Nights	Hours	Performance	Adherence*	Publication
Sibel Internal Validation Studies							
Algorithm Development	Volunteers	50	N/A	500	95% sensitive 100% specific	N/A	Unpublished
<u>Pediatric Validation</u>	Pediatric AD	11	46	378	84% sensitive 99% specific	83%	<i>Science Advances 2021</i>
<u>Adult Validation</u>	Adult AD	11	73	457	93% sensitive 100% specific	66%	<i>JAAD 2022</i>
Adult AD with Biofeedback	Adult AD	10	114	791	N/A	81%	Under Review
Total		82 total 32 in AD	233	2,126 hrs total 1,626 hrs AD		77% adherence rate to target	
Patient preferences for scratch domains	Pediatric and Adult AD	72	NA	NA	NA	NA	In preparation

FDA's DDT Program Status for Scratch



Conclusions

- To measure the symptom of itch, all three domains of skin appearance, patient perception, and patient behavior is important
- Measuring scratching as the defined behavior can be accomplished with a wide range of tools—wearables are the most common*
- Patients care about the entire spectrum of scratching behavior including scratch duration, scratch episodes, and scratch intensity for both daytime and nighttime periods
- Technologies that objectively measure scratching must be validated in well-conducted clinical studies

* Yang et al. Use of technology for the objective evaluation of scratching behavior: A systematic review. JAAD International. 2021.

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Of Nocturnal Scratch:**
New developments

June 18, 11 a.m. ET
**Processes, Validation,
and Adoption**

Public Workshop

Using Patient Generated Health
Data in Medical Device
Development: Case Examples of
Implementation Throughout the
Total Product Life Cycle



June 26, 2024 | 11am - 3pm ET

June 27, 2024 | 11am - 3pm ET

