Digital Measurement of Nocturnal Scratch: **New Developments**

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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

Digital Measurement of Nocturnal Scratch: New Developments

June 4: Recent Regulatory Feedback
June 11: Updates from R&D on Algorithms and Tools
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Dr. Thorsten Vetter, MD
Senior Scientific Officer, Scientific Advice Office, EMA

Beth Kunkoski
Office of Medical Policy/Clinical Methodologies, CDER, FDA

Matthew Diamond, MD, PhD
Chief Medical Officer, Digital Health Center of Excellence, CDRH, FDA

Carrie Northcott, PhD
Head of Digital Sciences
Pfizer

Lada Leyens
Director and Member of the Board
DEEP Measures Oy

Michael Benecky
Senior Director Regulatory Affairs
UCB

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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; Ruth K. Freinkel, MD Professor
Sibel Health, Northwestern University

Sylvain Zorman, PhD
Director of Digital Health Sciences
ActiGraph

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Dr. Thorsten Vetter, MD, *Senior Scientific Officer, Scientific Advice Office,* EMA

Bray Patrick-Lake, MFS, *Digital Health Specialist, Digital Health Center of Excellence,* CDRH, FDA

Jeffrey Siegel, MD, *Office Director/Office of Drug Evaluation Sciences,* CDER, FDA

Christine Cong Guo, *Christine Cong Guo, Chief Scientific Officer,* ActiGraph

Tarik Yardibi, *Director, Sensing and Measurement,* Takeda

Carrie Northcott, PhD, *Head of Digital Sciences,* Pfizer

Bola Grace, PhD, MBA, *Senior Director, Digital Biomarkers,* GSK

Thomas Switzer, *Head of Digital Health, Early Clinical Development,* Genentech

John Batchelor, *John Batchelor, Science Liaison,* DEEP Measures Oy

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.*

DiMe Nocturnal Scratch project & CPIM meeting with FDA

Lucy Cesnakova
Digital Medicine Society (DiMe)

Nocturnal Scratch Initiatives
DiMe and DEEP

Carrie Northcott, PhD
Head of Digital Sciences
Biomeasures, Endpoints and Study Technologies (BEST)
Translational Clinical Sciences
Pfizer, Inc.

Atopic Dermatitis

- Atopic Dermatitis (AD) is a common chronic inflammatory skin disease with a prevalence of ~17-23% in developed countries, impacting both adults and children as well as their partners and caregivers.
- **Itch (feeling) *vs.* Scratch (action)** are terms often used interchangeably; however, they have different meanings. While often interrelated, they also are disassociated symptoms within the disease.
- AD is an “itch, that leads to scratching, and ultimately results in rashes” creating a vicious cycle.

- **Patient Perspective**

  The top burdensome symptoms that patients identified (parents on behalf of children) were:

  - **Dry, rough, leathery or scaly patches on the skin**
  - **Red, inflamed skin**
  - **Itchy skin**
  - **Scratching**

- Bylund S, Kobyletzki LB, Salstedt M, Svensson A. Prevalence and incidence of atopic dermatitis: a systematic review. *Acta Derm Venereol*. 100(12), 2020.
- Cesnakova, L. et al. A patient-centred conceptual model of nocturnal scratch and its impact in atopic dermatitis: A mixed-methods study supporting the development of novel digital measurements. Skin Health Dis. 3(5): e262, 2023.

Validation Framework for Novel Digital Endpoints (NDEs)

Digital medicine describes a field concerned with the use of technologies as tools for measurement and intervention in the service of human health

- Meaningful aspect of health that is **Important to patients**
- Establishment of **Meaningful change threshold**
  - Represents the amount of change in an endpoint measure perceived as important to patients and should be determined for each digital endpoint and given population under consideration
- Prospectively specified **Context of Use** (COU)
- Prespecified digital endpoint/s
- Validation framework for novel endpoints from **DHTs** require

  (1) Verification

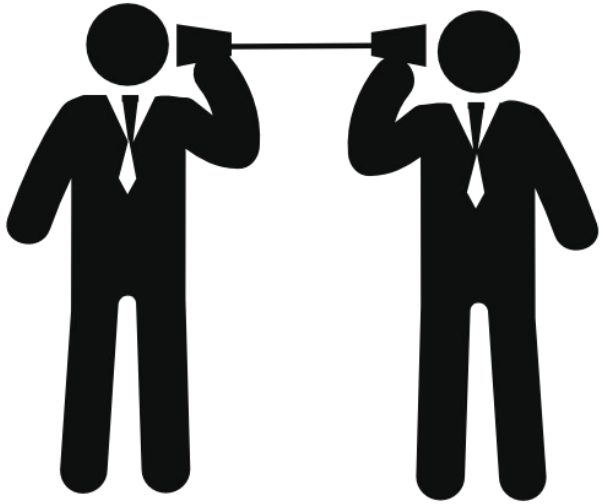
  (2) Analytical validation

  (3) Clinical validation

Digital Medicine (2020) 3:55 ; https://doi.org/10.1038/s41746-020-0260-4

Challenges

- Developing and Validating Novel Digital Endpoints for use are:
  - Costly
  - Timely
  - Language Challenges
  - Complex
  - The list goes on……



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NOCTURNAL SCRATCH

Digital Measures Development

DEEP Digital Evidence Ecosystem & Protocols

Founding Partners

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Pfizer

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Collaborating Partners

Advancing Innovation in Dermatology

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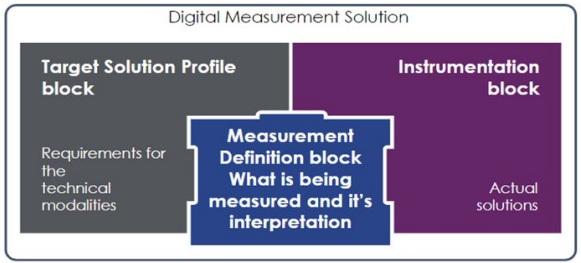
Digital Measures Development

- Patient Research
- Measure Terminology and Ontology
- Deployment to Clinical Trials
- Payer Acceptance

DEEP Digital Evidence Ecosystem & Protocols

Structured approach for robust validation of digital endpoint

- Elements could be reused for lifecycle management
- A catalogue of digital endpoint components



- The first series of questions centered around the measurement definition block for Nocturnal Scratch
- The second series of questions centered around Body of Evidence needed, Target Solution Profile and Instrumentation blocks:

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Digital Measures Development

FDA U.S. FOOD & DRUG ADMINISTRATION

DEEP Digital Evidence Ecosystem & Protocols

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- **Critical Path Innovation Meetings (CPIM)** (Critical Path Innovation Meetings (CPIM) | FDA)
  - The goals of the CPIM are to discuss a methodology or technology proposed by the meeting requester and for CDER to provide general advice on how this methodology or technology might enhance drug development.
  - The CPIM is a forum for FDA and stakeholders to discuss potential scientific advancements in drug development.

- **Innovation Task Force (ITF) Meetings** (Supporting innovation | European Medicines Agency (europa.eu))
  - Innovation Task Force (ITF) briefing meetings provide developers a forum for **early dialogue on innovative medicines** with EMA.
  - ITF briefing meetings:
    - cover regulatory, technical and scientific concerns arising from innovative medicines, technologies and methodologies;
    - enable informal exchange of information and guidance in the development process, complementing existing formal EMA procedures;

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Digital Measures Development

1. Concept of The Measure & Importance to the Patients
2. Ontology & Terminology of Nocturnal Scratch
3. Context of Use

DEEP Digital Evidence Ecosystem & Protocols

1. Conceptual Model for Nocturnal Scotch
2. Nocturnal Scratch Terminologies and ontologies
3. Context of Use
4. Body of evidence needed for Regulatory Validation of the Nocturnal Scratch Measure in Atopic Dermatitis
5. Body of evidence needed for the development of a new definition block for Psoriasis
6. Body of evidence needed for the development of a New Instrument

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Digital Measures Development

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Lucy Cesnakova

- DiMe Nocturnal Scratch project & CPIM meeting with FDA

Mike Benecky

- EMA's Innovation Task Force (ITF) briefing meetings under the EMA pilot conducted with EFPIA and DEEP consortium

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NOCTURNAL SCRATCH

Digital Measures Development

Advancing nocturnal scratch as a digital endpoint for atopic dermatitis

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NOVARTIS

Pfizer

ucb

Project Collaborators

Advancing Innovation in Dermatology Accelerator Fund

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gsk GlaxoSmithKline

LEO

Lilly

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Expert Partners:

National Eczema Association

GLOBAL PARENTS FOR ECZEMA RESEARCH
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Duke University

Harvard Business School

Boston University

Health Outcomes Insights
Getting targeted answers to patient behaviour and outcomes

Driving Adoption of Nocturnal Scratch as a Digital Endpoint & Improving Patients' Lives

Patient Research

Measure Terminology & Ontology

Deployment to Clinical Trials

Payer Acceptance

SKIN HEALTH AND DISEASE
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ORIGINAL ARTICLE | Open Access

A patient-centred conceptual model of nocturnal scratch and its impact in atopic dermatitis: A mixed-methods study supporting the development of novel digital measurements

Lucia Cesnakova, Keith Meadows, Stefan Avey, Judy Barrett, Brian Calimlim, Meenakshi Chatterjee, Sandra Goss, Katelyn R. Keyloun, Jérémy Lambert, Carrie A. Northcott ... See all authors

First published: 01 July 2023 | https://doi.org/10.1002/ski2.262

Published on 18.4.2023 in Vol 25 (2023)

Preprints (earlier versions) of this paper are available at https://preprints.jmir.org/preprint/43617, first published October 18, 2022.

Defining the Digital Measurement of Scratching During Sleep or Nocturnal Scratching: Review of the Literature

Will Ke Wang[1]; Lucia Cesnakova[2]; Jennifer C Goldsack[2]; Jessilyn Dunn[1, 3, 4]

Insights from FDA

Learnings from the Critical Path Innovation Meeting (CPIM) with FDA on digital measurement of **nocturnal scratch**

July 22 2022

Meeting Topics:

What is it?

Concept of the measure & importance to patients

How to measure it?

Ontology & terminology

How to use it?

Context of use

Main feedback items

- Measure the **most important and relevant concepts to the target population**. Use qualitative or quantitative research to obtain patient and/or caregiver input

- To establish **nocturnal scratch as an endpoint**, it is suggested to:
  - Showcase relevance of scratching in AD
  - Establish that scratching is part of the perpetuation of AD
  - Bring attention on relationship between itch and scratch

- From **clinician representatives**, nocturnal scratch is a useful proxy measure of itch and excoriation
  - Nocturnal scratch has significant **additive independent value** when connected with other measures - such as itch-specific PRO, ClinRO and ObsRO

Main feedback items

- Clinical validity of the tool is **dependent on the integrity of the sleep assessment**
  - Integrity around the sleep assessment is crucial

- **Nocturnal scratch, as defined, is differentiated from just scratch itself**
  - Changes in nocturnal scratch measurement must be attributable to changes in AD, not to changing sleep architecture

- When working with digital technologies, it is important that sponsors consider **data security** and the data privacy laws that could impact multinational trials during the technology development and potential use

Main feedback items

- **Nomenclature:** Digital measurement of nocturnal scratch seems to fit most to the description of clinical outcome assessment
    - However, the definition (digital biomarker or COA) would depend on the context of use of the measurement in a specific trial

- For **clinical validation**, it will be important to demonstrate that:
    - Changes in nocturnal scratch correlate with treatment effects and reduction in scratching will result in **improvement of the disease**
    - Measurement is validated in appropriate target populations - both adult and pediatric

- Part of clinical validation evidence may involve using an itch-specific PRO and/or a direct observation method measure to **anchor the change** in nocturnal scratch

Critical Path Innovation Meeting Topic: Advancing Nocturnal Scratch as a Digital Endpoint for Atopic Dermatitis

- The new measure shall be **rooted in patients' needs** and most important aspects of their lives
- The research and discussion about **connection between itch and scratch** is encouraged towards separation of these two phenomena, exploring their relationship and defining their specific unique roles in atopic dermatitis
- It is important to **conceptualize** the measurement of nocturnal scratch within the context of a specific research trial and validation

Critical Path Innovation Meeting Topic: Advancing Nocturnal Scratch as a Digital Endpoint for Atopic Dermatitis

- The research field must adopt **unified terminology** and measurement definitions to advance use of nocturnal scratch as a digital endpoint
- Clinical validation in **target populations**, including pediatrics, is crucial
- It is important to demonstrate that a **reduction in nocturnal scratching** correlates with treatment effects on atopic dermatitis
- **Collaboration** between stakeholders, as well as publishing and sharing the data, is encouraged to advance adoption of nocturnal scratch as a digital endpoint for atopic dermatitis

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THANK YOU

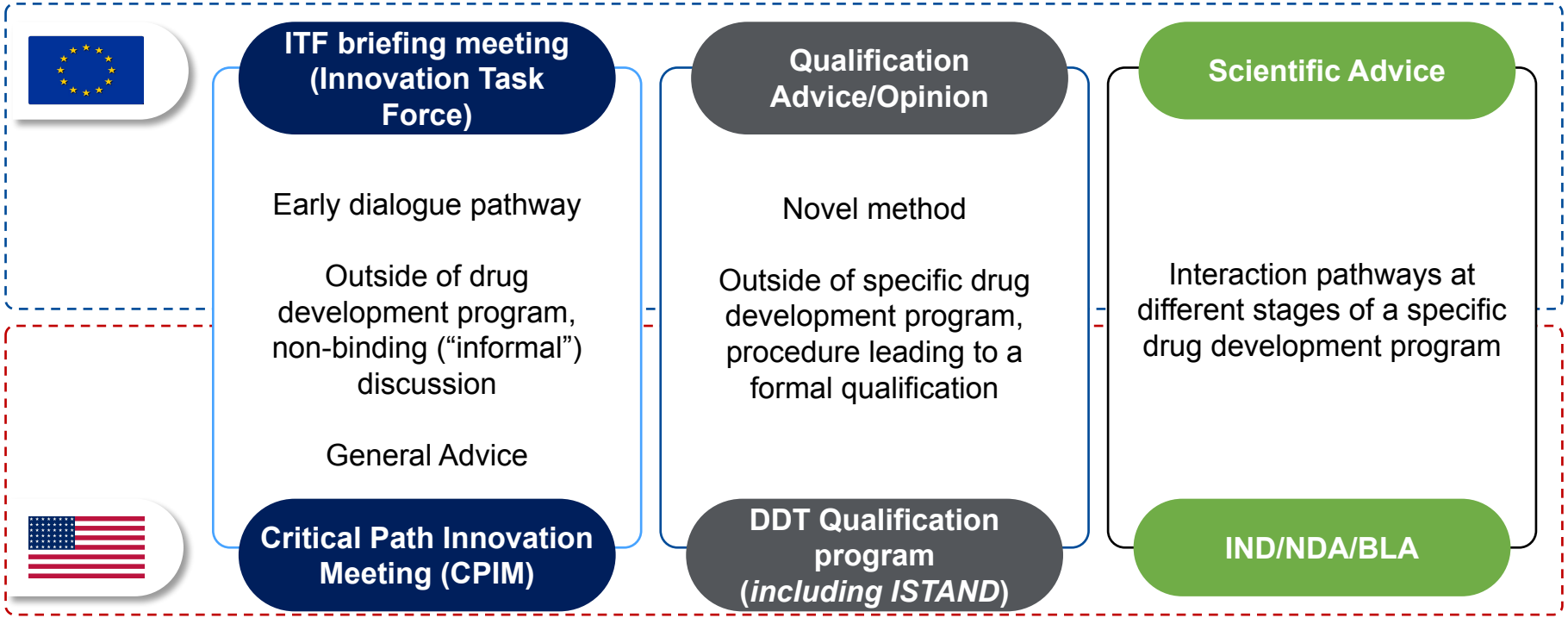
Lucy Cesnakova | lucy@dimesociety.org

@_DiMeSociety

linkedin.com/company/dime-society

Learnings from the DEEP-EFPIA-EMA Pilot

Procedures to seek regulatory acceptance or qualification



A complex environment at the interface of drug and technology regulatory frameworks (example from EU)

Multiple components and evidence with distinct regulatory considerations

The DHT: regulatory identity and documentation?

- Regulatory identity: Is it a medical device?
- Is the computerised system validated?
- Does it comply with privacy, security, GDPR, safety & environmental requirements?

The Data: quality and clinical operations?

- Has it been collected according to GxP principles?

The digital endpoint: meaningful, relevant and robust?

- Does it represent an outcome that is relevant for patients or is linked to the pathophysiology of the disease and can inform a regulatory decision?
- Is it sensitive to change?

Regulatory Stakeholders

The DHT: regulatory identity and documentation?	The Data: quality and clinical operations?	The digital endpoint: meaningful, relevant and robust?
CE Notified Bodies; HMA NCAs; EMA; Ethics Committees	Ethics Committees; HMA NCAs; EMA	EMA; HTA

Relevant Regulatory guidances

The DHT: regulatory identity and documentation?	The Data: quality and clinical operations?	The digital endpoint: meaningful, relevant and robust?
Medical Device Regulation Product specific EU legislation (Radio Equipment Directive EMA guideline on Computerised Systems and Electronic Data in Clinical Trials Draft RP on the use of artificial intelligence in the lifecycle of medicines	General Data Protection Regulation Clinical Trial Regulation ICH E6: Good Clinical Practice EU recommendation paper on decentralised elements in clinical trials	EMA Q&A: Qualification of digital technology-based methodologies to support approval of medicinal products ICH E9: Statistical principles for CTs Disease specific guidances for endpoints HTA guidances on endpoints

***Digital Endpoint** = precisely defined variable intended to reflect an outcome of interest that is statistically analysed to address a particular research question, that is derived from or includes a digital measurement (Definition in EMA Q&A) .*
Link to key resources from EFPIA digital endpoints sub-team.

BM= Biomarker COA = Clinical Outcome Assessment; DHT = Digital Health Technology; EC= Ethic Committees; EMA= European Medicines Agency; HTA= Health Technology Assessment Body; NCA= National Competent Authority; CT= Clinical Trial

The DEEP Model: From Innovation to Qualified Digital Measures

Standardized approach and reusability of data

Structured approach for robust validation of digital endpoint

Elements could be reused for lifecycle management

- To define technology changes to digital health tool
- To allow for extension of context of use

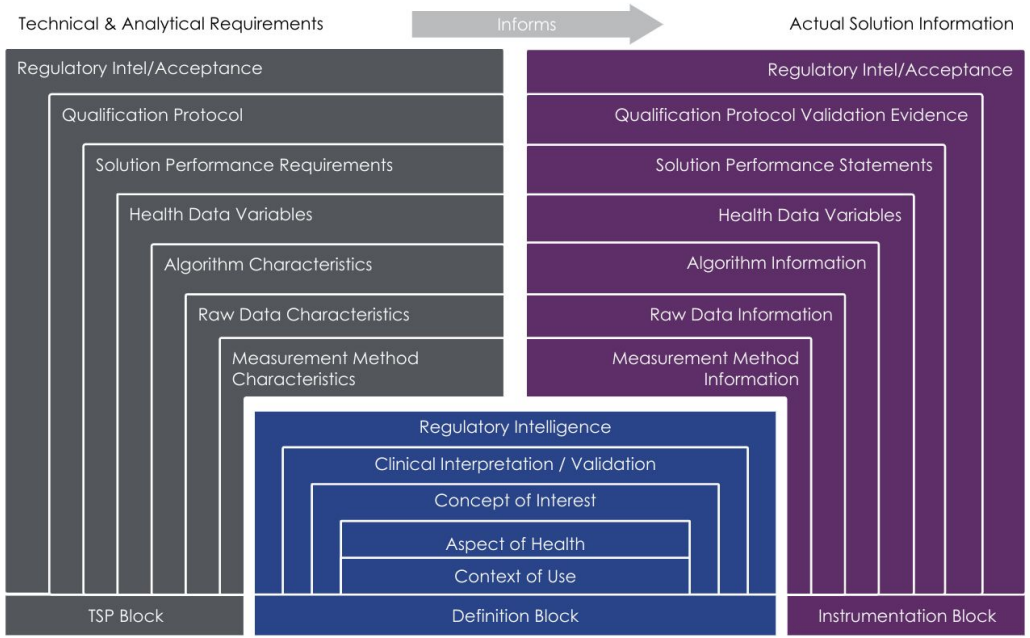
A catalogue of digital endpoint components

A platform for collaboration

Digital health is at the intersection of different regulatory frameworks

For multi-stakeholder co-creation of digital health methods

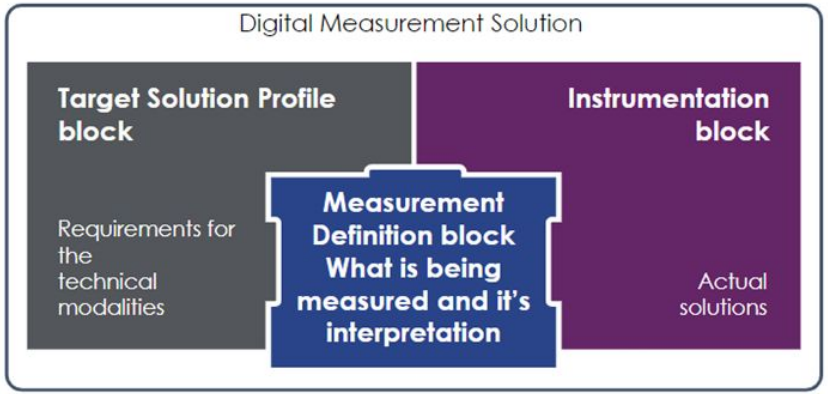
Involvement of the right experts

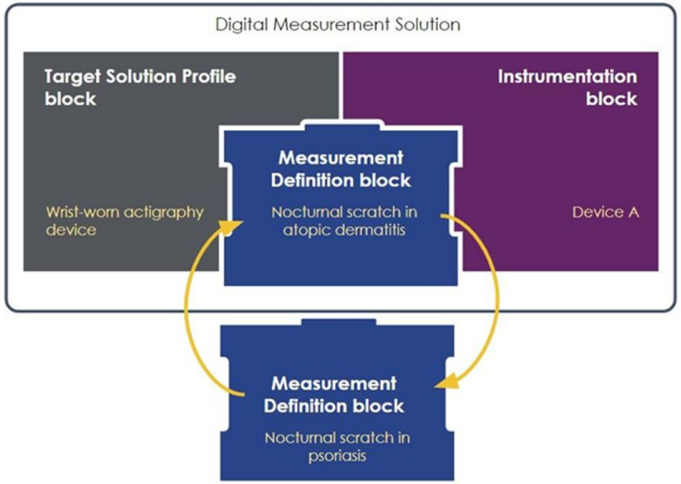


Exploring Optimizations to EMA's Qualification for Novel Methodologies Procedure (QoNM)

The Pilot: Applicant team requesting advice on nocturnal scratch measure in atopic dermatitis

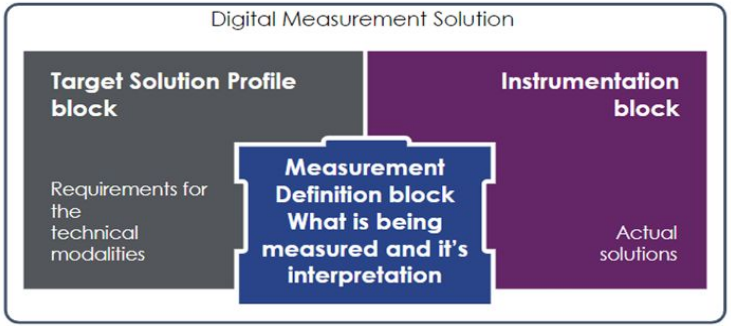
Ultimate Goal: Establish nocturnal scratch as a digital endpoint for atopic dermatitis





https://www.dimesociety.org/tours-of-duty/digital-measures-nocturnal-scratch/

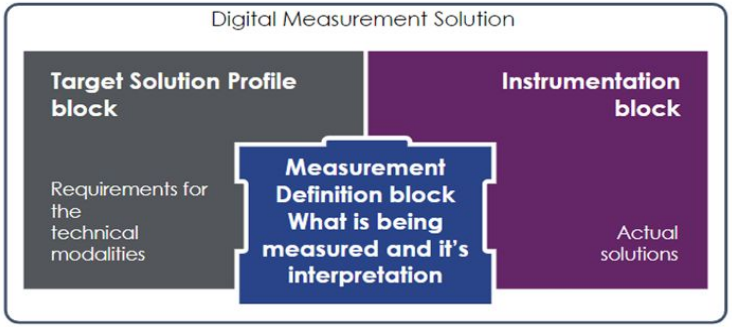
Goals for EMA ITF Meeting



- **The first series of questions centered around the measurement definition block for Nocturnal Scratch:**
  - **Conceptual Model for Nocturnal Scratch**
  - **Nocturnal Scratch Terminologies and Ontologies**
  - **Context of Use**

    Nocturnal Scratch as a secondary endpoint to measure efficacy of treatments of AD in pivotal confirmatory clinical trials in mild to severe AD patients 2 years and older.

Goals for EMA ITF Meeting (part 2)



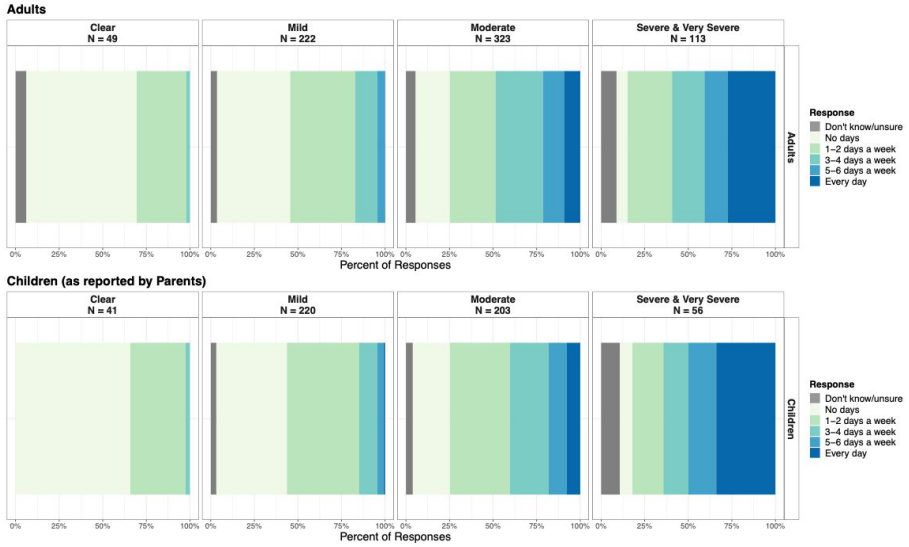
- **The second series of questions centered around Body of Evidence needed, Target Solution Profile and Instrumentation blocks:**
  - **<u>Body of evidence needed</u> for regulatory validation of the Nocturnal Scratch Measure in Atopic Dermatitis**
  - **Body of evidence needed for the development of a <u>new definition block</u> for Psoriasis**
  - **<u>Body of evidence needed for the development of a new instrument block</u> for current target solution profile (TSP)**

Meaningful Aspect of Health to Patients and Relationship to Disease

- The data collected as part of the DiMe study support a strong link between the severity of AD and the frequency of nocturnal scratch (as reported by patients).
  - "As the severity of AD increased, there was an increased bothersomeness, intensity, and frequency observed in all surveyed symptoms and effects" (Cesnakova et al. 2023)

Results from Survey Question 11:

"During the past two weeks, how often did you [observe your child] scratch at night because of your [their] eczema?"



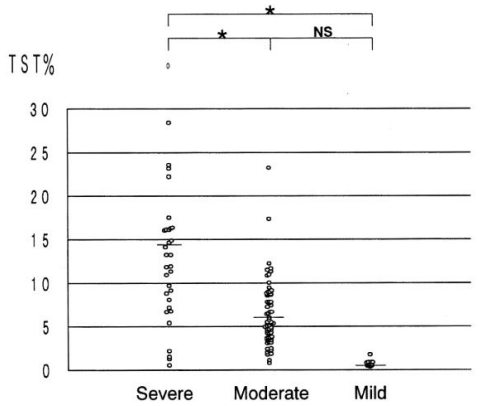


Figure 1. Percentage of total scratching time in the total recording time (TST%) and severity of atopic dermatitis. The severe group consisted of 12 patients with 32 recordings, the moderate group of 24 with 70 recordings, and the mild group of three with 10 recordings. Bars indicate the mean. *$P<0{\cdot}0001$; NS, not significant.

Figure from: Ebata, Aizawa, Kamide, Niimura. *Br J Dermatol*. 1999;141(1):82-86. doi:10.1046/j.1365-2133.1999.02924.x

Cesnakova, L. et al. A patient-centred conceptual model of nocturnal scratch and its impact in atopic dermatitis: A mixed-methods study supporting the development of novel digital measurements. Skin Health Dis. 3(5): e262, 2023 Dataset: https://datacc.dimesociety.org/digital-measures-nocturnal-scratch/#research

Body of Evidence Needed for Regulatory Validation of the Nocturnal Scratch Measure in Atopic Dermatitis:

Study	Activity	Objective	Summary
Qualitative study	Concept elicitation	Establish nocturnal scratch as an important concept that matters to AD patients	• 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	• 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	• 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	• Comparison to gold standard measure, e.g., videography and polysomnography
		Evaluate the reliability of DHT-derived nocturnal scratch measures	• 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	• Explore changes over time (e.g. relative rate of change over time)
	Clinical Validation	Evaluate correlations between proposed measures and other clinical outcomes	• Correlation of DHT-derived nocturnal scratch measures with: o PROs (e.g. NRS Itch) o 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	• Anchor-based methodology (e.g. using PGI-S as an anchor) as well as distribution-based methods as supportive. o Literature supporting the meaningful changes observed in standard sleep and scratch/lesion measures

Summarized outcomes

- **Conceptual Model for Nocturnal Scratch**:
  - **EMA ITF agreed that nocturnal scratch was a symptom of AD as well a valuable component of the disease to be targeted as an individual endpoint. In addition, these measures would add value in concert with existing endpoints.**
  - Questions were raised around the interrelationships between nocturnal scratch and itch, sleep disturbances, quality of life, and other domains of the disease which may not be fully elucidated by the DiMe study. Future studies were encouraged to provide quantitative evidence regarding the interrelationships between nocturnal scratch and other disease domains as part of the clinical validation package.
- **Nocturnal Scratch Terminologies and Ontologies:**
  - ITF acknowledged the Applicant's position and understood the reasoning and information provided; they also could envisage a more appropriate term. However, at this time **they are willing to accept nocturnal scratch as the term has been used in the scientific literature for quite a while and describes the majority of the population**, with the realization that there would be additional context provided by the sponsor.
- **Context of Use:**
  - **ITF agreed the potential is there and agreed with the proposed context of use, subject to additional detail that would be needed for individual use cases, e.g. with a view to demonstrating the ability to detect change and to characterizing the MCID.**
  - The sponsor would be required to provide the appropriate justification for their specific context of use of the endpoint. It is envisaged that additional evidentiary requirements would be needed, highlighting the clinical meaningfulness of the measure as well as the benefit associated if used as a primary or co-primary endpoint.

Summarized Outcomes (2)

- **Body of Evidence Need for Regulatory validation of Nocturnal Scratch Measure:**
  - **The ITF had no overarching concerns with the strategy proposed.**
  - The discussion centred on the use of natural history studies and discussions regarding the derivation of the minimally clinically important difference (MCID). ITF acknowledged that AD is not a progressive disease and is one that is often in flux and has "flares". In addition, it was agreed that analytical validation with patient coefficients of variation would cover variability of disease with respect to flares. ITF were open to alternative complementary methods to determine MCID, however, additional detail, context and discussion would need to take place.
- **Development of new definition block for Psoriasis:**
  - **The ITF acknowledged that they felt there was value in the stack model and that it was indeed helpful to be able to "re-use" data.**
  - However, ITF noted that there may need to be bridging data/comparability studies for new conditions; in this instance it was noted that there are different locations and scratching patterns that may be observed in psoriasis. Moreover within-patient coefficient of variation would be of value to capture. So, while in concept this is valuable, bridging studies would provide reassurance of the validation and will likely be needed.
- **Development of a new instrument block for current target solution profile (TSP):**
  - **ITF expressed positivity in the large potential for the described paradigm. ITF agreed that if a link between observed variability in analytical validation studies and technical performance characteristics was observed, then bench testing may be sufficient.**
  - However, ITF also noted that for more significant changes such as using a different DHT type to measure the same aspect of health, this may require additional validation. **ITF noted that it is desirable for Applicant to aim to develop DHT agnostic measurement solutions and the stack model is anticipated to support this.**

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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; Ruth K. Freinkel, MD Professor
Sibel Health, Northwestern University

Sylvain Zorman, PhD
Director of Digital Health Sciences
ActiGraph

Public Workshop

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

FDA

DIGITAL MEDICINE SOCIETY

June 26, 2024 | 11am - 3pm ET

June 27, 2024 | 11am - 3pm ET