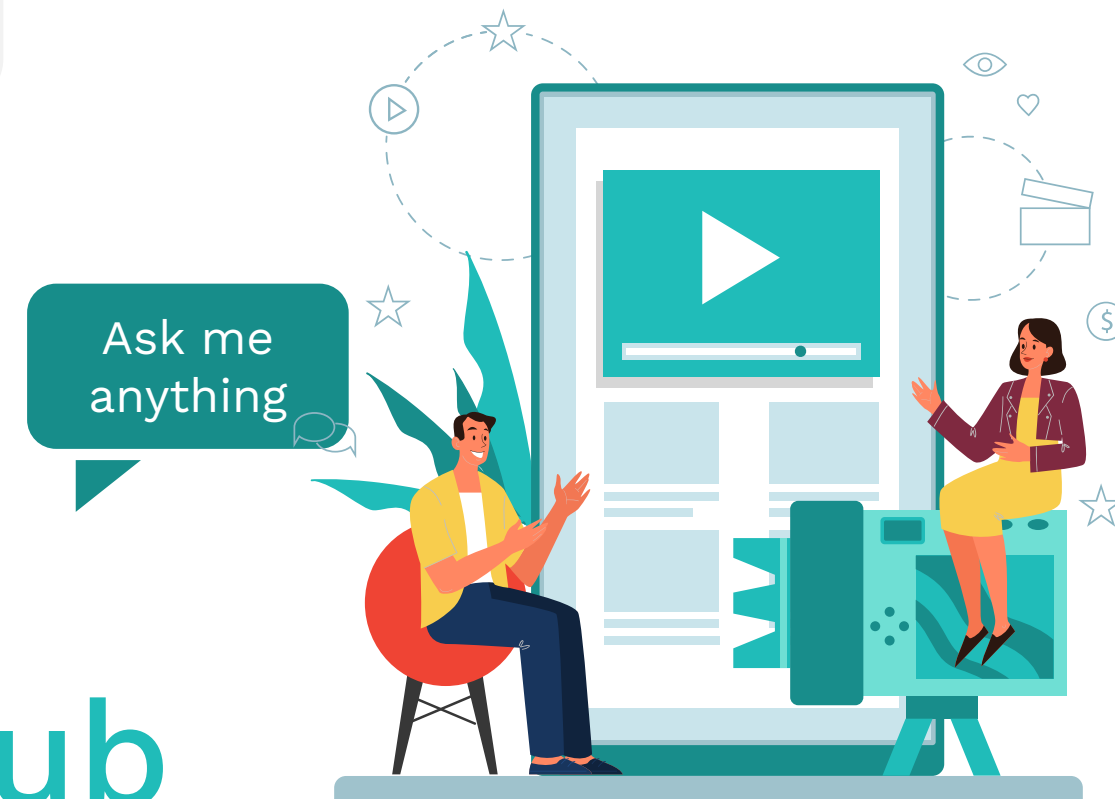




Virtual Journal club



Doina Sirbu
Medical Device Innovation Lead
UCB



Carrie Northcott, PhD
Senior Director, Digital Sciences &
Translational Imaging
Pfizer



Sylvain Zorman, PhD
Director of Digital Health Sciences
ActiGraph



Will Ke Wang
PhD Candidate
Duke University



Jessie Bakker, MS PhD
Program Director
DiMe
Moderator

Defining digital measurement of
scratching during sleep, or "Nocturnal
Scratch": A review of the Literature (JMIR)

Thursday, May 25th, 2023 | 12pm ET

But first, housekeeping

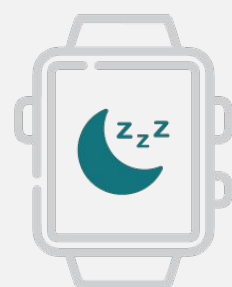
- Please note today's session is being recorded
- To ask a question for discussion during Q&A, please:
 - Either 'raise your hand' in the participant window and come off mute when the moderator calls on you, or
 - Type your question into the chat box
- Slides and recording will be available after today's session

Key Points

1. The why - setting the stage
2. Methods
3. Results
4. Discussion



NOCTURNAL SCRATCH



Digital Measures Development

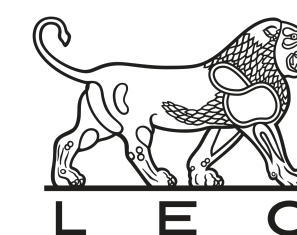
*Advancing nocturnal scratch
as a digital endpoint for atopic
dermatitis*

Founding Project Partners

abbvie



Project Collaborators



Expert Partners:



National
Eczema
Association



Harvard
Business
School



NOCTURNAL SCRATCH



Digital Measures Development



Patient Research

- Data and evidence from mixed methods research
- Conceptual framework



Measures Terminology & Ontology

- Data and evidence supporting technical definition
- Evidence-based ontology



Deployment to Clinical Trials

- 10 tools supporting successful operational implementation
- Case studies



Payer Acceptance

- Translating patient value to commercial value
- Modeling potential increases in drug utilization
- Key insights & action items



Terminology & Ontology

- **Ontology** - a set of concepts and categories in a subject area or domain that shows their properties and the relations between them.
- **Terminology** - the body of terms used with a particular technical application in a subject of study, profession, etc
 - **Terms** = names for material objects, but also the abstract entities (processes, properties, functions, etc)
 - Terms can be organized into **conceptual structures**, based on the relationship between them. For example: tables, chairs, cupboards, etc. can be grouped together as *furniture*.

Why is it important?



The Rapid Evolution of Digital Endpoints: Are We Headed in the Right Direction?

The number of unique digital endpoints being used in industry-sponsored trials of new medical products is skyrocketing, but is more always better?



Jennifer Goldsack
Jan 26 · 6 min read



“

When people buy a measuring instrument, they typically don't think of where the scale comes from.

Virpi Korpelainen, National Metrology
Institute, Finland

Ultimate goal: Scratch is a scratch is a scratch

*"The **evidence-based definition** of the measurement itself, its properties, and main outcome measures provide everyone with a powerful “dictionary” that can ultimately drive rapid acceptance of novel DHT-based measurements in clinical research by the patients themselves, clinicians, industry, technology developers, regulators, and payers."*

Methods

- Narrative literature review of definitions of **scratching** in patients with skin inflammation
- Targeted literature review of **sleep** in the context of the period during which such scratching occurred

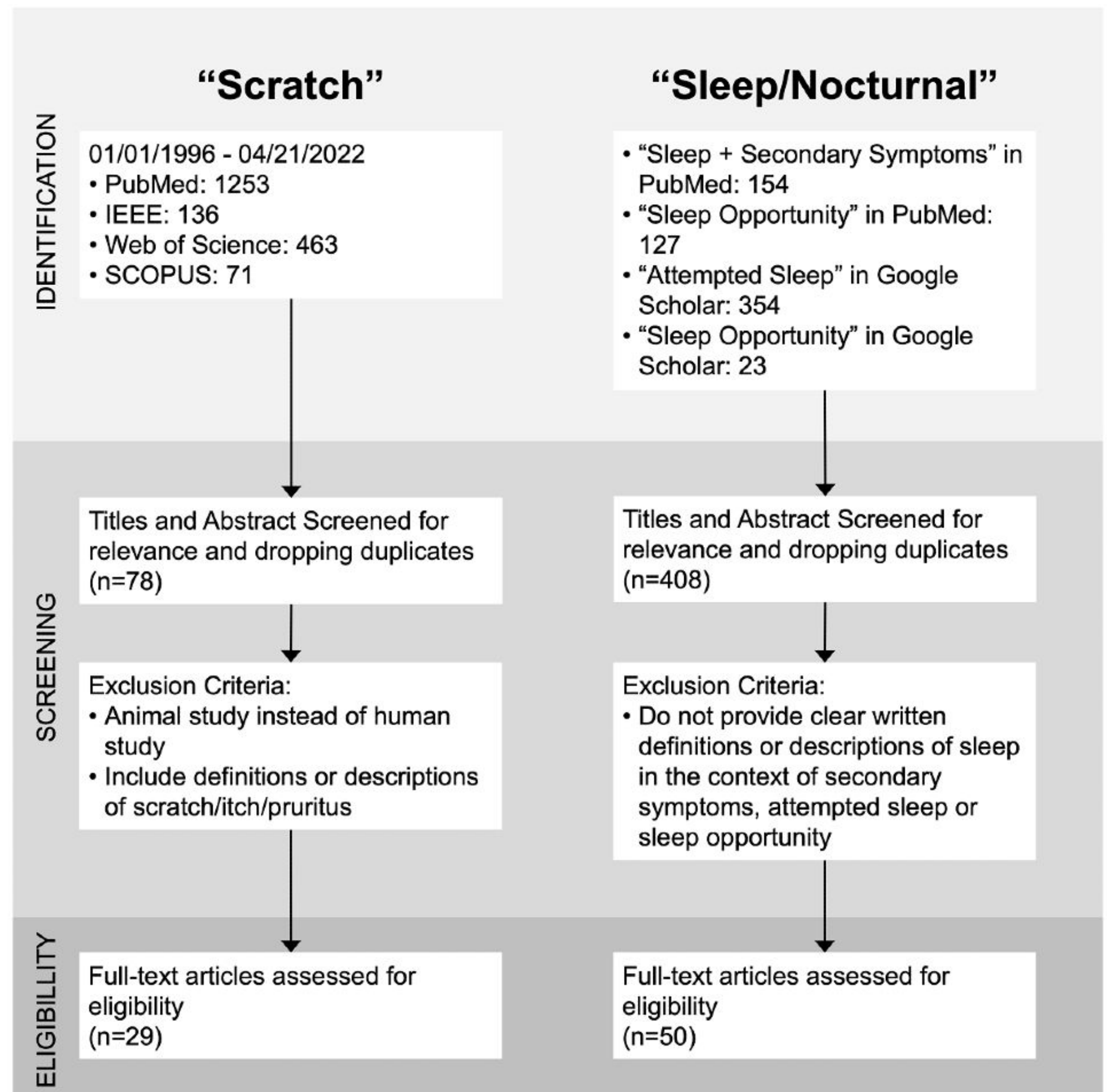
"Scratch" search strategy & criteria

- Dermatitis-related studies in humans
- Title search = ensured relevancy and that the publications discussed or examined scratch or related topics
- Include both "scratch" and "itch" in terms as they are often used incorrectly
- Limited 25 years in back (90s - maturing and proliferation of new accelerometry-based devices measuring movement and activity)

"Sleep" search strategy & criteria

- 3 search strategies - searching for:
 - Secondary sleep symptoms (cramp, pain, spasm, etc) with:
 - term for the sleep period (sleep, rest, nap, nocturnal, etc)
 - “sleep opportunity”
 - “attempted sleep”
- Title search → then screened the abstracts for the presence of a definition or description of sleep/sleep opportunity/attempted sleep **in the context of secondary symptoms** for a researched disease

Search pipeline



Results

- Scratch:
 - **29 of the found papers** contained a definition of scratch, itch, or pruritus*
**terms “itch” and “pruritus” were added due to the frequently interchanged use of the terms itch and scratch*
 - **2 of the found papers** had any description of sleep variables and their definitions for nocturnal scratching
- Sleep
 - **50 of the found papers** informed the sleep ontology

Results

- **Scratch search – extraction table:**
 - Author and year
 - Study participants (n)
 - Clinical outcome or calculated index (for scratching)
 - Device (used to measure scratching)
 - Scratch definition/terminology
 - Scratch detection method

Results: close look

- **Different description of scratching - examples:**

- An apparent action of rubbing or scratching to any part of the body with a rhythmical movement using hands or fingers and sometimes feet lasting >5 s
- Rhythmic movements >1 Hz without accompanying movements.
- Wrist activities 1-3 Hz
- Limb motion 1-3 Hz
- Burst of electromyographic activity of ≥ 3 s accompanied by a visible scratching motion
- Movement with frequency of 1-2 Hz
- Any skin contact movement that could reduce itch while not taking into account touching.
- Any repetitive rubbing or scratching of the body (including through fabric) performed with the hand or any part of the upper limb

Results: close look

- **Different outcome measure of scratching - examples:**
 - Total scratch time (mostly used)
 - Amount of accelerations >0.01 g
 - Wrist activity in 0-3 Hz range over the first 3 h of sleep
 - Total scratch records per “sleeping time”
- **Different definition of one scratching bout length:**
 - 5s
 - 3s
 - 2s
 - 1s

Results: Forming the ontology

- **The most used properties of measured scratching:**
 - **Characteristics** of the scratching movement
 - Examples: Speed, frequency (in Hz), pressure, force, acceleration, velocity [42], etc.
 - **Scratch Outcome** to be Measured
 - Examples: Total scratching time, amount of accelerations, wrist activity in 0-3 Hz
 - **Scratching tool** (or body part)
 - Body part or **area scratched**
 - Duration of **scratching bout** and minimum separation between bouts
 - **Method** or tool of recording scratch

Discussion: Terminology

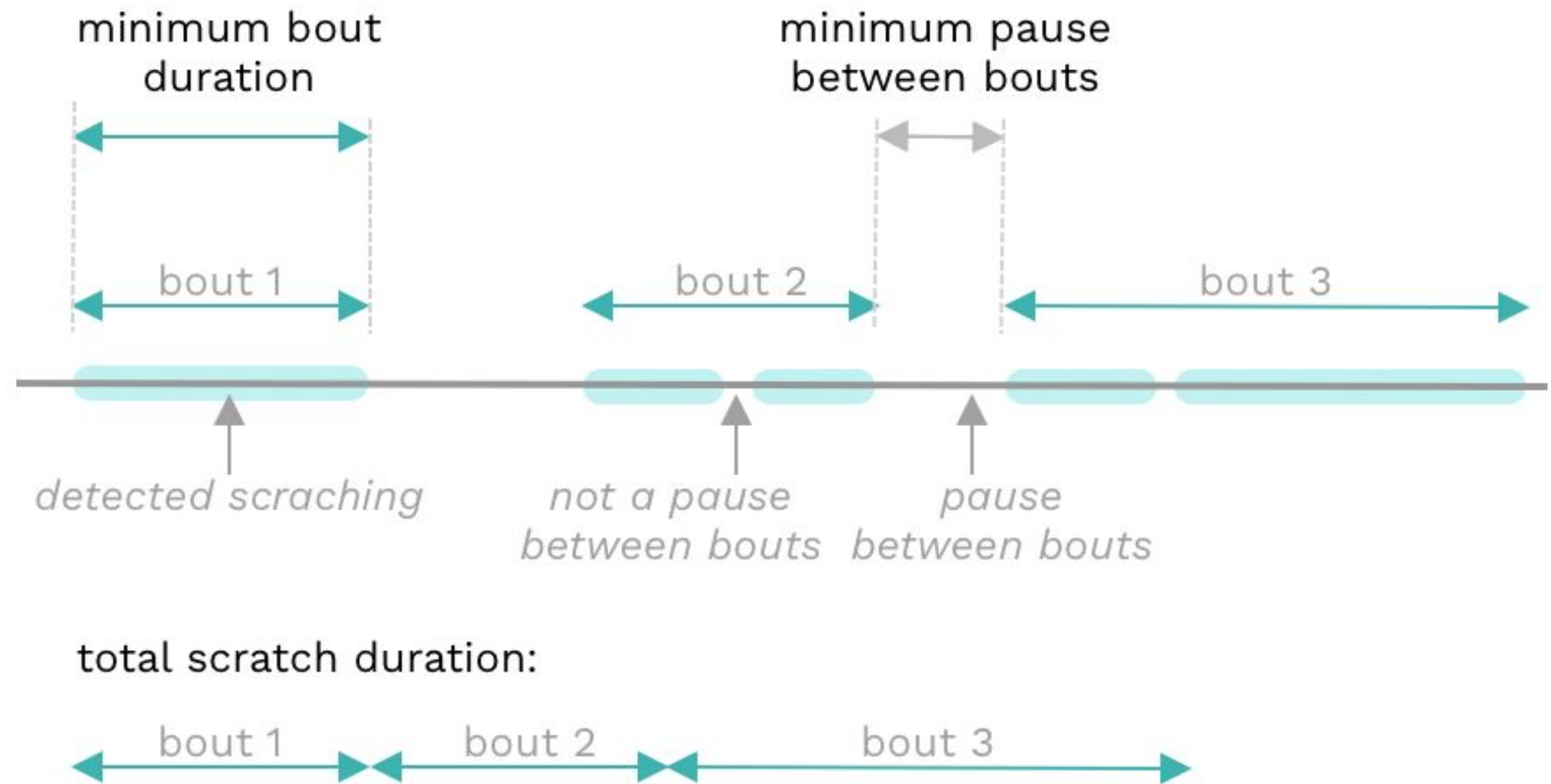
- **Definitions for scratching** and related variables **differed widely**
 - **Unified definition has never been proposed** - definition discerning it from the *sensation of itch* is often not provided in research studies or during interactions with patients.
 - For the purposes of the created ontologies, we propose a definition of both itch and scratch
- **The term “nocturnal”** is itself an exclusionary **misnomer**, though historically used to describe scratching during the time of sleep

Discussion: Ontologies

- Aid unified understanding among scientists and researchers
- Serve as roadmap for the development of standardized measurements
- Provide rich **list of properties** available to add to assessments:
 - We believe some of the properties should be **required** at all times:
 - Duration of **scratching bout** and min interval between bouts
 - Definition of the **sleep period** considered
 - **Measurement modalities** for scratch & sleep
 - Researchers can decide to add more advanced **optional** properties (e.g. REM or non-REM sleep, properties of scratching movement, etc.)

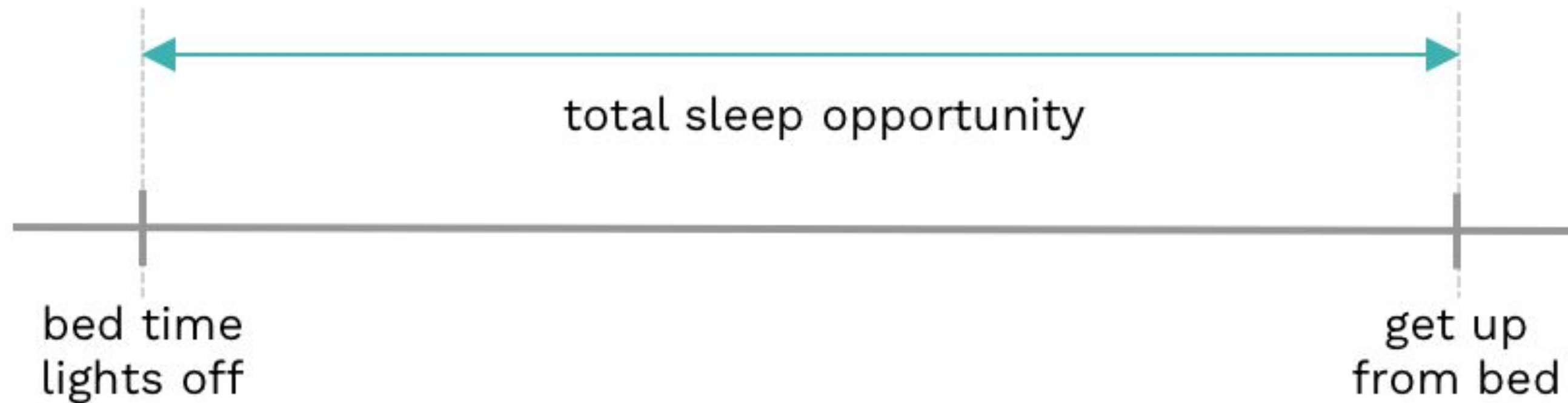
Discussion: Forming the ontology

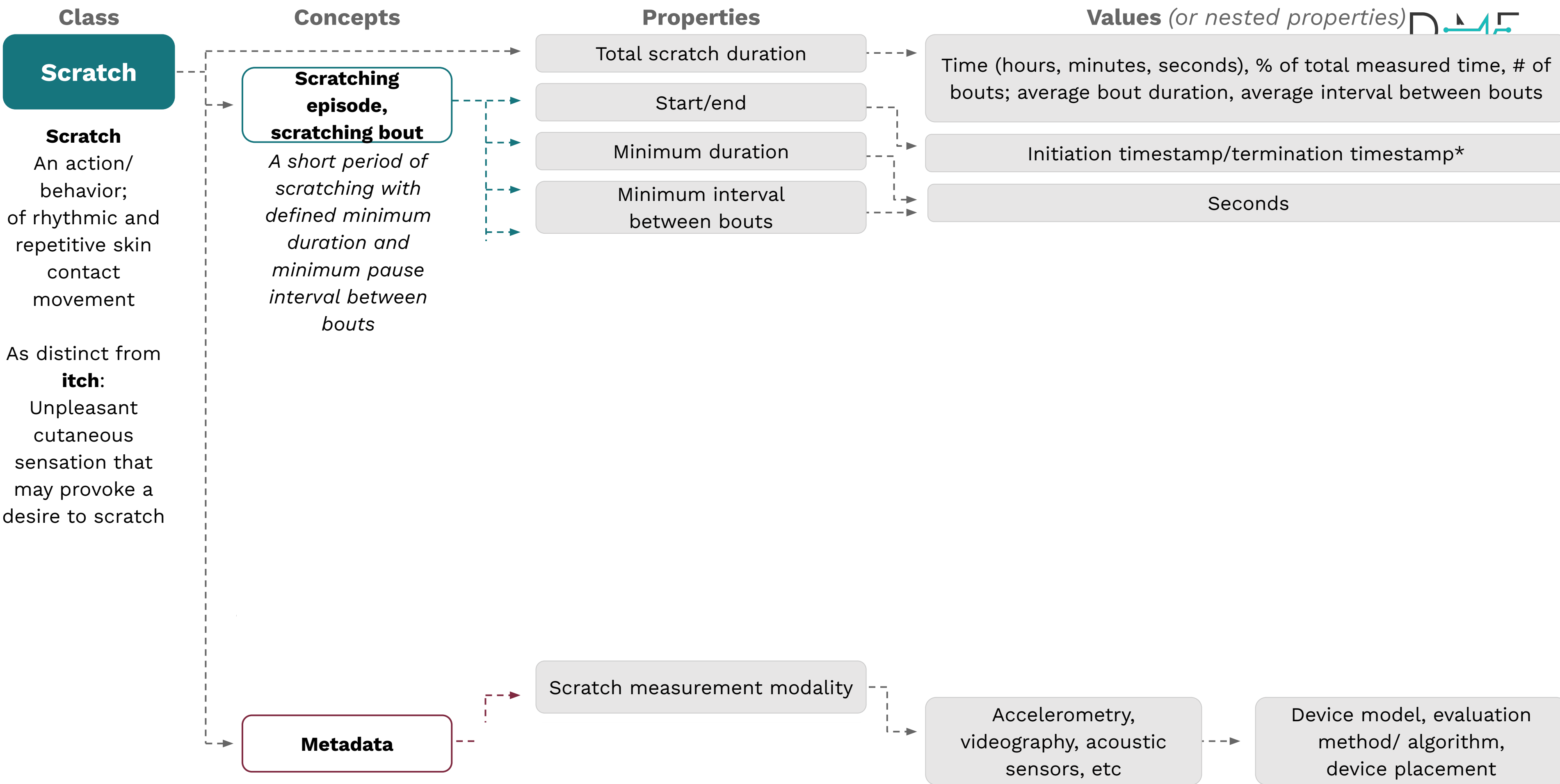
Scratching bout



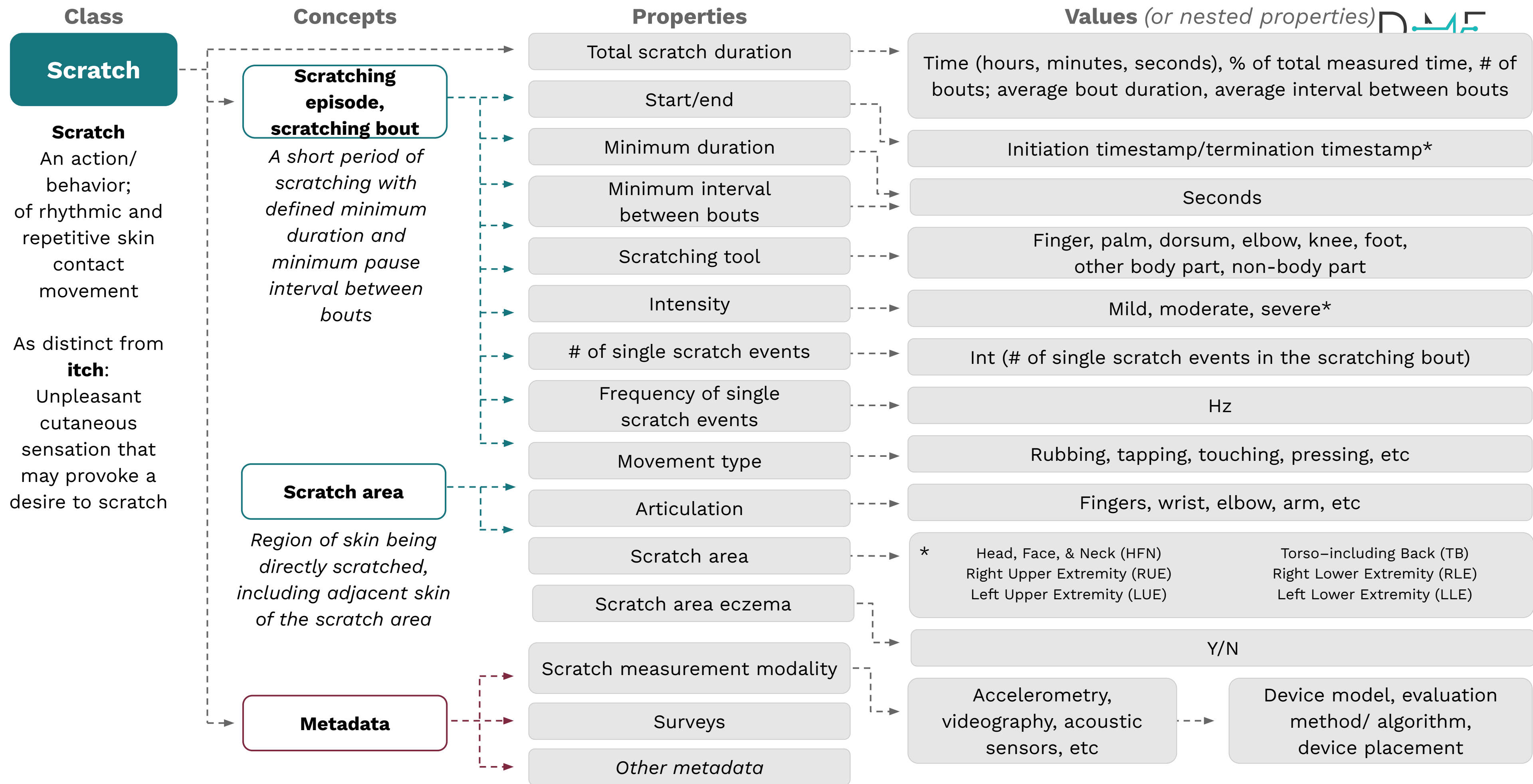
Discussion: Forming the ontology

Measuring sleep

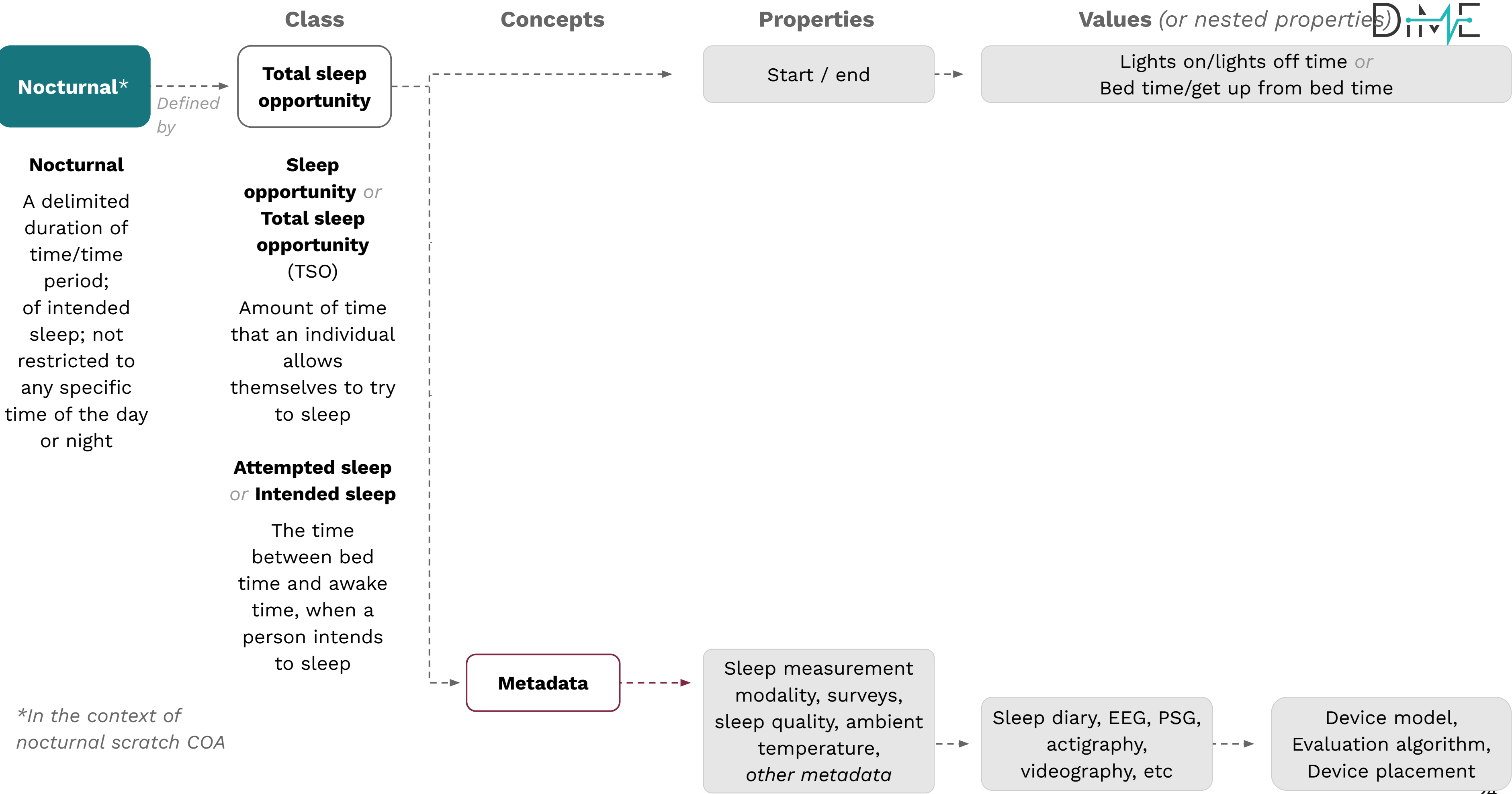


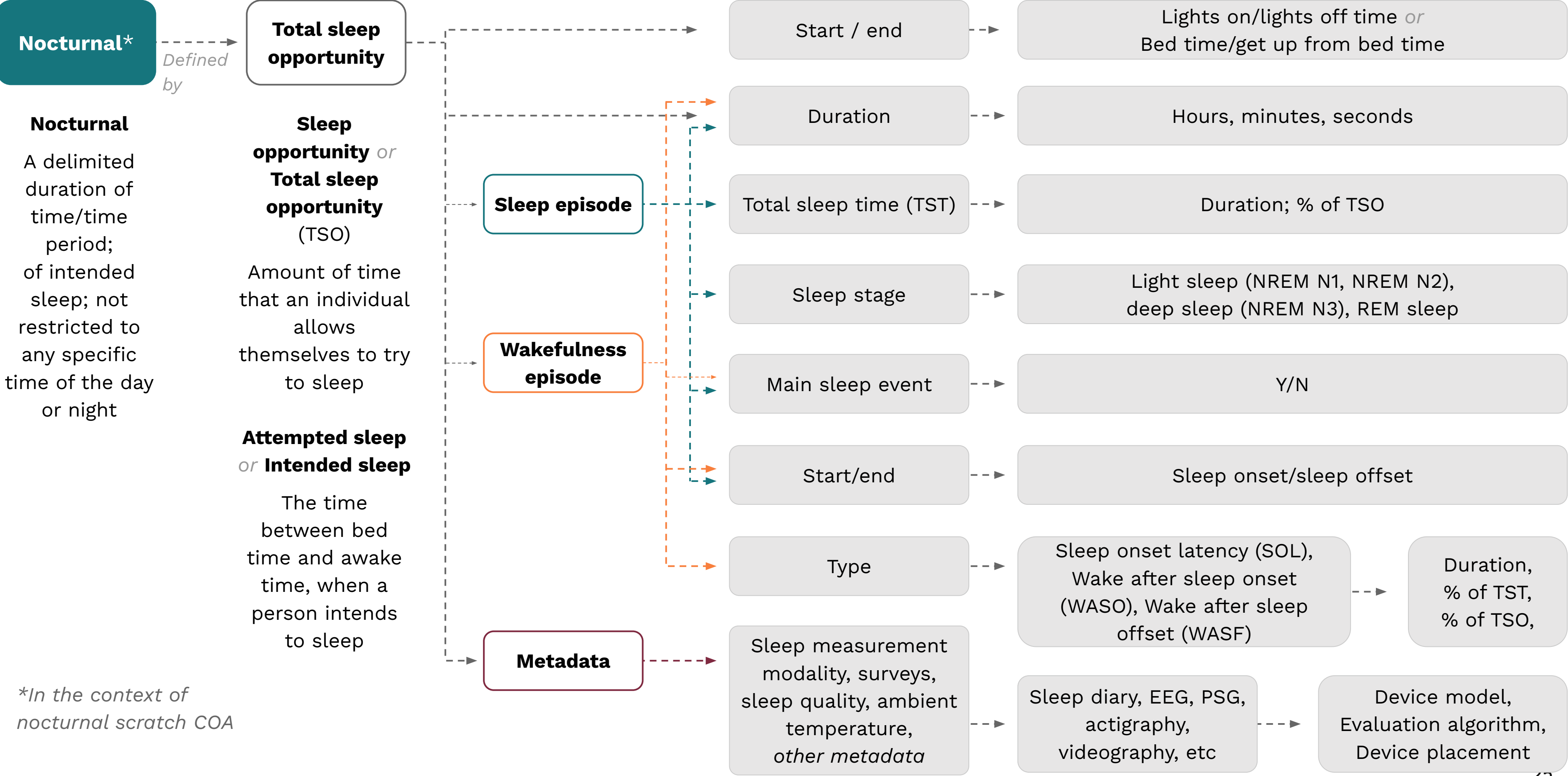


*Suggestion according to the literature



*Suggestion according to the literature 23





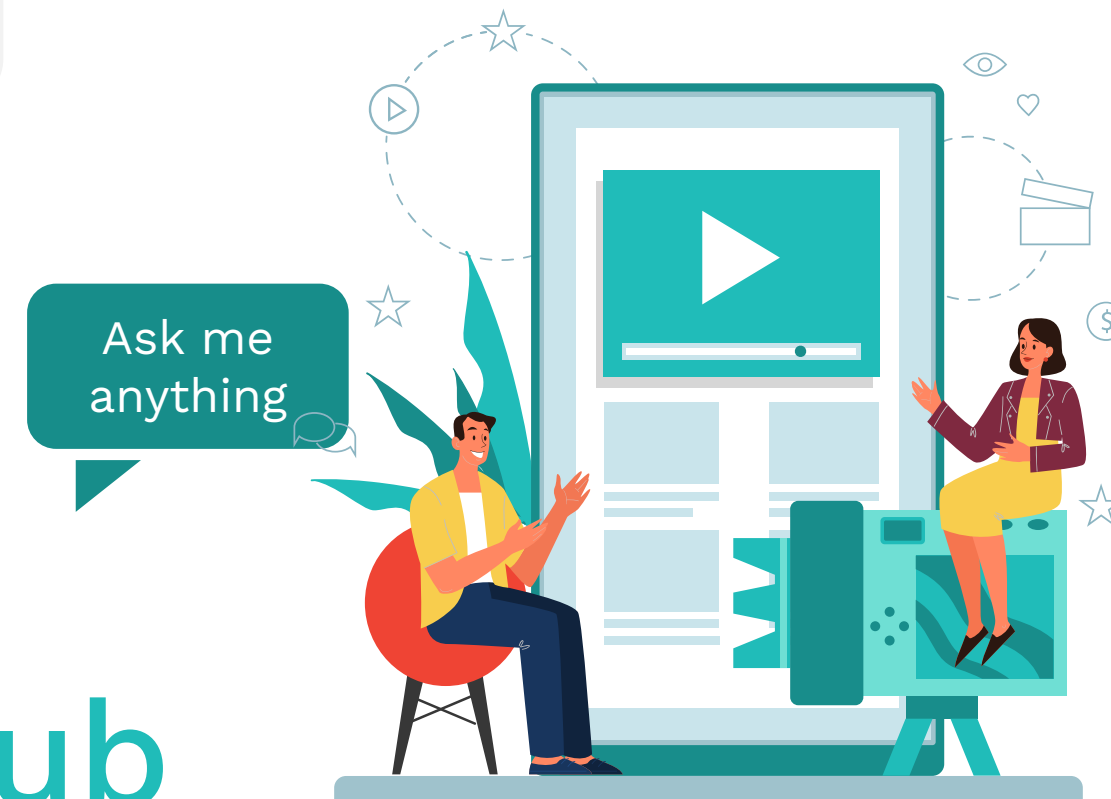
Discussion: Value for digital clinical measurement of nocturnal scratch (and others!)

A **digital clinical measurement** with **defined & unified terminology and properties**:

- Becomes technology agnostic
- Enable the creation of reliable verification or validation procedures
- Facilitate comparison of
 - performances among different tools and devices
 - measurements between patient subpopulations are comparable
- Adds valuable information about the patient populations
- Supports pre-competitive collaborations
- Enables better communication and sharing of results between stakeholders
- Makes adoption easier for all stakeholders

Discussion

Virtual Journal club



Manuel Spitschan, PhD
Assistant Professor /
Research Group Leader
**Technical University of Munich &
Max Planck Institute for
Biological Cybernetics**



Jessie Bakker, MS PhD
Program Director
DiMe
Moderator

How V3 might be applied to wearable
dosimeters and light loggers

June 13th, 2023 11 a.m. ET



Striding Past the 6MWT: Complementing Physical Activity Assessment with a Consensus Set of Digital Clinical Measures

Tuesday, June 27 at 11am-12pm ET



Dr. Alan Hamilton

Senior Director of Research
COPD Foundation

Panel Moderator



Candice Taguibao

Program Lead, PA Project
DiMe

Moderator



Bray Patrick-Lake

Senior Digital Health Specialist
**Digital Health Center of Excellence
CDRH, FDA**



Salma Ajraoui

Digital Practice Lead, Patient
Centred Solutions
IQVIA



Eric Mangin

Global Digital Analytics and
Technologies
MSD



Elena Ismailova

CSO
Koneksa



Kieran F. Reid, PhD, MPH

Director, Laboratory of Exercise
Physiology and Physical
Performance
**Brigham and Women's Hospital,
Harvard Medical School**



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