Advancing Sleep Research: New Core Digital Measures & Resources

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Digital Health Measurement Collaborative Community
by DiMe

CORE MEASURES *of* SLEEP
Digital Measures Development

WEBINAR

Wednesday, April 24

11 am - 12 pm ET

RECORDINGS POSTED HERE

Agenda

- **Welcome & Housekeeping**
- Opening Remarks from NSF
- Background of Project
- Panel: Resources in Action
- Fireside chat: The importance of sleep staging
- Panel: The possibilities for and importance of the out of lab assessment of sleep
- Fireside chat: The real world impact of digital sleep measurement

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
    - **Type your question** into the chat box

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

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Joe Dzierzewski
Vice President, Research and Scientific Affairs
National Sleep Foundation

National Sleep Foundation

Joseph Dzierzewski, PhD

Vice President
Research & Scientific Affairs

NSF Serves the Public through its Sleep Health Mission and Goals

The National Sleep Foundation is dedicated to improving health and well-being through sleep education and advocacy.

Sleep health is accepted as a crucial measure of overall health.

The natural sleep/wake process is understood as the basis for healthy sleep.

Community, infrastructure, and environments respect sleep health.

Sleep science and insight are rapidly incorporated into accessible health products and services.

Sleep is Critical for Health and Performance

- Sleep is a fundamental part of our lives, strongly linked to brain and mental health, heart health, obesity, diabetes, immune function, and other public health priorities
- Sleep health and safety for wellness, selfcare, or medical conditions is in focus for the public, clinicians, industry, and policy makers
- Important to include NSF's guidelines and standards in new targeted resources for consistency across use cases

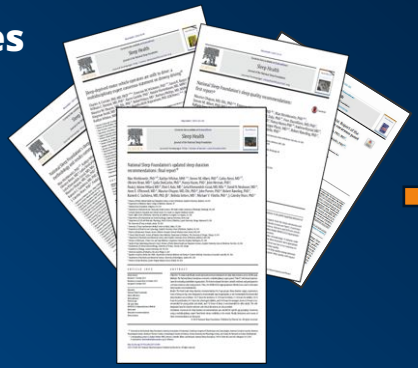
NSF Published Research and Guidelines

Setting the Standards

Translate science, data, and insights into recommendations for healthy sleep behaviors

Consensus guidelines

- Sleep duration
- Drowsy driving
- Sleep satisfaction
- Sleep quality
- Polyphasic sleep
- Sleep timing



Existing Standards Inform Multiple Use Cases

Consistent Sleep Measures Across Use Cases

1. Guidelines and standards exist
2. Consistency in application is key for progress
3. DiMe Core Measures of Sleep is a great example of appropriate application to expanded use cases

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CORE MEASURES *of* SLEEP

Digital Measures Development

Sleep disturbance greatly impacts quality of life and it's often the first indicator of a larger issue. Let's measure it the right way.

Project Partners

BAYER
BOSTON UNIVERSITY
DEFENSE INNOVATION UNIT
Duke
GSK
Jazz Pharmaceuticals
Lilly
National Sleep Foundation
NextSense
Revolutionizing Brain Health
SageBionetworks
Sage Therapeutics
Takeda
T.C. Demiroğlu Bilim University
UZ LEUVEN
VA | U.S. Department of Veterans Affairs

Digital Solutions Collaborators

Activinsights
BEACONBIOSIGNALS
BIOSTRAP
byteflies
dreem
Google
ŌURA
Primasun
sleep number
Softmatter
TNO innovation for life
VivoSense

Source: Sleep

We have our measures

Core Digital Measures of Sleep

Total Sleep Time

Initial Sleep Onset Latency

Wake After Sleep Onset

Number of Wake Events

Sleep Efficiency

Total Napping Time

Emerging Digital Measures of Sleep

Sleep Regularity Index

Symptomatology Impact on Sleep

Core Digital Measure of Sleep: Total sleep time (Duration)

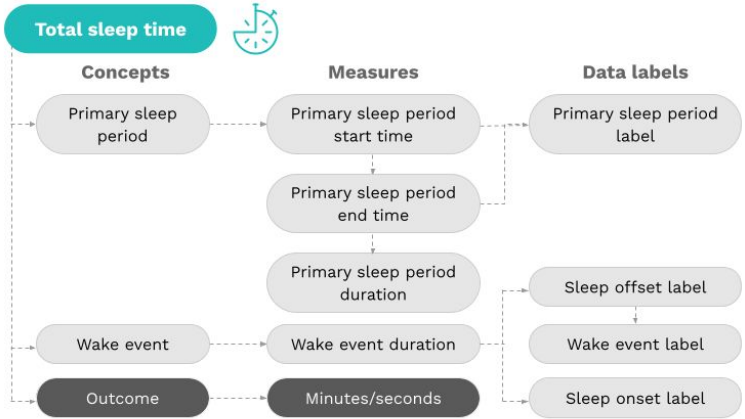
Also known as: *true sleep time, time spent sleeping*
Type: *Duration of time*

Definition: *The duration of time spent sleeping in the primary sleep period*

Total sleep time = (Primary sleep period) - (WASO)

WASO* = ∑ (Duration)

**Wake after sleep onset*



Measure considerations

Importance: Total sleep time is an important indicator of health and mortality.[1,2,3]

Measure derivation: The difference between the primary sleep period duration and the sum of all wake events in the primary sleep period (i.e., wake after sleep onset).

Optional deviations: By specifying what constitutes a confirmed wake event, users can ensure that the outcome of total sleep time is interpretable. With rationale, a confirmed wake event could be more or less conservative to meet the specific research goals.

Primary sleep period label

Description

A sleep period is a duration of time that an individual spends asleep in a single session. It may involve some number of brief awakenings, but the individual returns to sleep rather than terminating their sleep attempt. There could be several sleep periods in a given 24-hour period, but research and clinical practice is often concerned with activity within a primary sleep period, such as going to sleep at night and intending to wake up in the morning.

Label definition

A label for each epoch between:

- The first sleep onset Label=1 with a time attempting to sleep label=1
- The final sleep offset label=1 with a time attempting to sleep label=1

The final sleep offset is not included in the definition.

Where the time attempting to sleep label is not available, the In bed label can be used in its place. This substitution should be clearly noted.

Why is this important?

The primary sleep period label differentiates from the asleep label, as any sleep period can include brief periods of waking, provided the individual falls back asleep.

The primary sleep period label can therefore be used in conjunction with other labels and derived variables to determine, for example, the number of awakenings or the length of awakenings during the sleep period. It also allows the user to derive measures of other sensor-based symptomology or activity occurring during the sleep period.

Derived variables

Primary sleep period start time

Variable definition

The **timestamp** of the first epoch with the primary sleep period label.

Primary sleep period end time

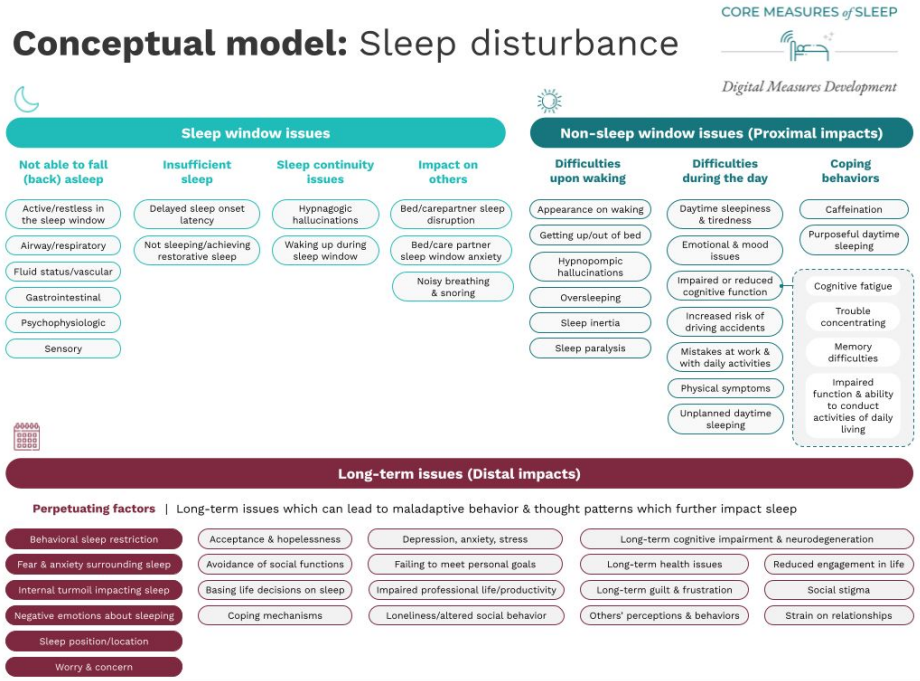
Variable definition

The **timestamp** of of the final epoch with the primary sleep period label.

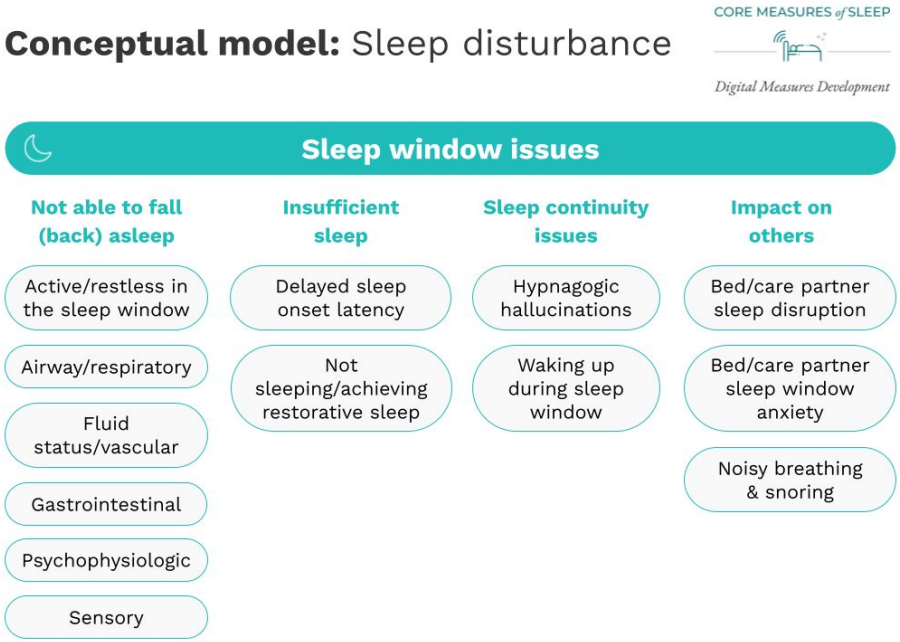
Primary sleep period duration

Definition: A **time duration (seconds)** calculated as the difference between the primary sleep period start and end times.

Our conceptual model was the basis for our digital core measures selection



Source: https://datacc.dimesociety.org/core-measures-sleep/



Source: https://datacc.dimesociety.org/core-measures-sleep/

We have resources for everyone!

DATACC by DME

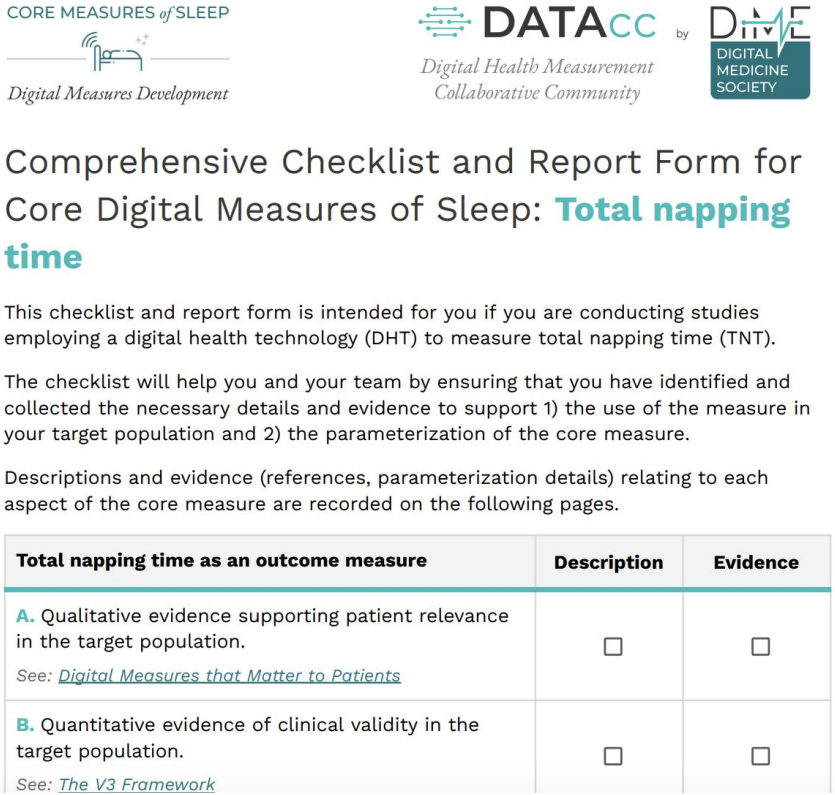
PROJECT HOME | ALL CORE MEASURES | KEY STAKEHOLDERS | LIBRARY OF DIGITAL MEASUREMENT PRODUCTS

Clinical researchers

Clinician & healthcare decision makers

DHT developers

Checklists and evidence report forms



CORE MEASURES of SLEEP
Digital Measures Development

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Digital Health Measurement Collaborative Community

Comprehensive Checklist and Report Form for Core Digital Measures of Sleep: **Total napping time**

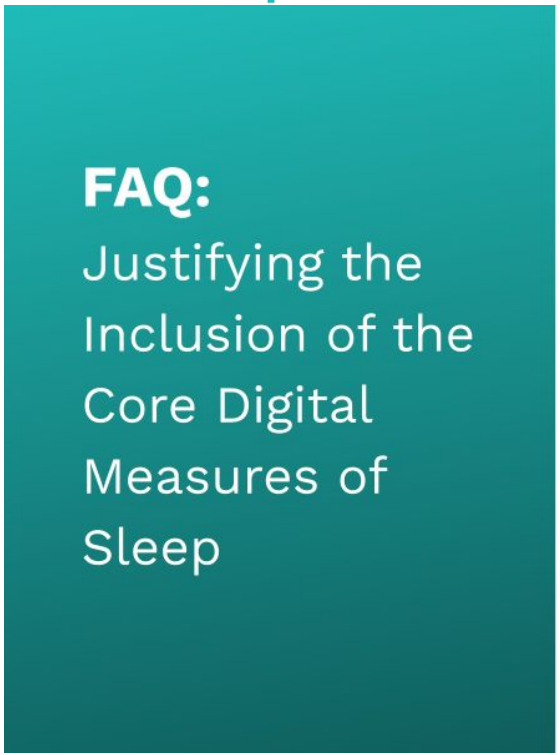
This checklist and report form is intended for you if you are conducting studies employing a digital health technology (DHT) to measure total napping time (TNT).

The checklist will help you and your team by ensuring that you have identified and collected the necessary details and evidence to support 1) the use of the measure in your target population and 2) the parameterization of the core measure.

Descriptions and evidence (references, parameterization details) relating to each aspect of the core measure are recorded on the following pages.

Total napping time as an outcome measure	**Description**	**Evidence**
A. Qualitative evidence supporting patient relevance in the target population. *See: Digital Measures that Matter to Patients*	☐	☐
B. Quantitative evidence of clinical validity in the target population. *See: The V3 Framework*	☐	☐

Arming you with the evidence you need to make a case for sleep



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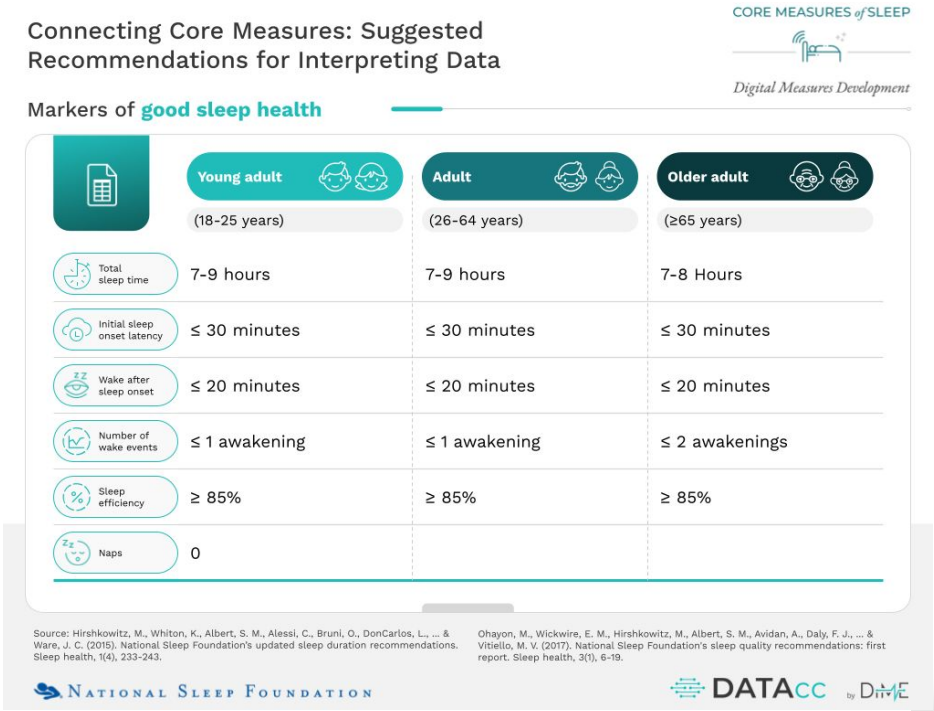
Resources for the general population and for clinicians



Connecting Core Measures: Suggested Recommendations for Interpreting Data

CORE MEASURES of SLEEP
Digital Measures Development

Markers of **good sleep health**

	Young adult (18-25 years)	Adult (26-64 years)	Older adult (≥65 years)
Total sleep time	7-9 hours	7-9 hours	7-8 Hours
Initial sleep onset latency	≤ 30 minutes	≤ 30 minutes	≤ 30 minutes
Wake after sleep onset	≤ 20 minutes	≤ 20 minutes	≤ 20 minutes
Number of wake events	≤ 1 awakening	≤ 1 awakening	≤ 2 awakenings
Sleep efficiency	≥ 85%	≥ 85%	≥ 85%
Naps	0		

Source: Hirshkowitz, M., Whiton, K., Albert, S. M., Alessi, C., Bruni, O., DonCarlos, L., ... & Ware, J. C. (2015). National Sleep Foundation's updated sleep duration recommendations. Sleep health, 1(4), 233-243.

Ohayon, M., Wickwire, E. M., Hirshkowitz, M., Albert, S. M., Avidan, A., Daly, F. J., ... & Vitiello, M. V. (2017). National Sleep Foundation's sleep quality recommendations: first report. Sleep health, 3(1), 6-19.

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Reimbursement for Clinicians: Getting paid for caring for your patients using digital measures of sleep

For the purposes of monitoring, diagnosing, and treating patients with sleep or sleep-related disorders, you as a healthcare provider (HCP) can perform a sleep assessment for your patients. There are several reimbursement avenues available to you for this assessment. However, the specific medical insurance codes for reimbursement and the associated activities need to be in line with guidelines to enable this process.

This document aims to offer you top-level initial guidance on the specifics of the reimbursement process if you wish to use digital health technology measures of sleep, such as the Core Digital Measures of Sleep, when treating your patients.

The full Payment and Coding Toolkit and Quick Start Guide is available should you be looking to adopt remote monitoring.

Remote patient monitoring (RPM) and remote therapeutic monitoring (RTM)

Remote patient monitoring, also called remote physiological monitoring, refers to the use of digital technologies to capture and analyze patients' physiological data, such as sleep metrics, blood pressure, glucose levels, or lung function.

Remote therapeutic monitoring refers to the use of digital technologies to collect and analyze data, including patient-reported measures, for the purposes of therapy

Special thanks to Joe and Shannon at NSF for their input into these

Vendor selection checklist to help you ask the right questions

Checklist:
Essential Questions for DHT Vendor Selection

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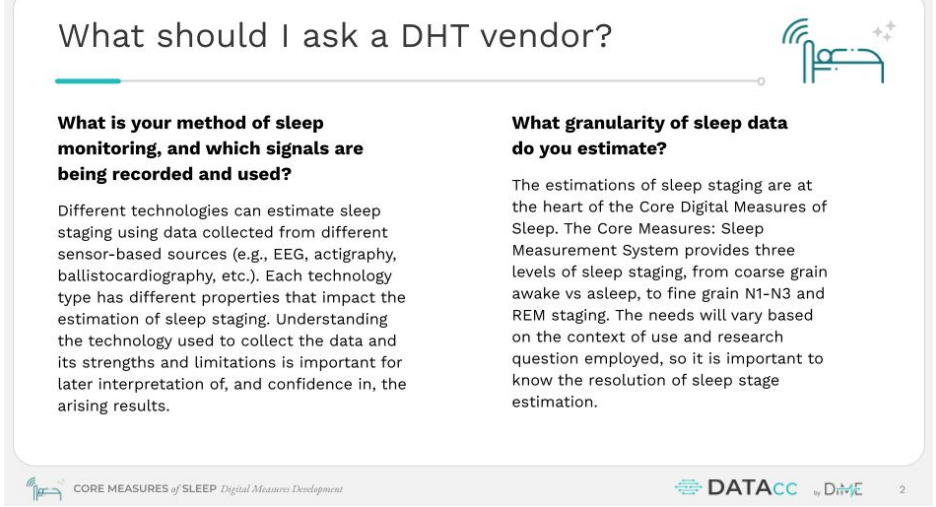
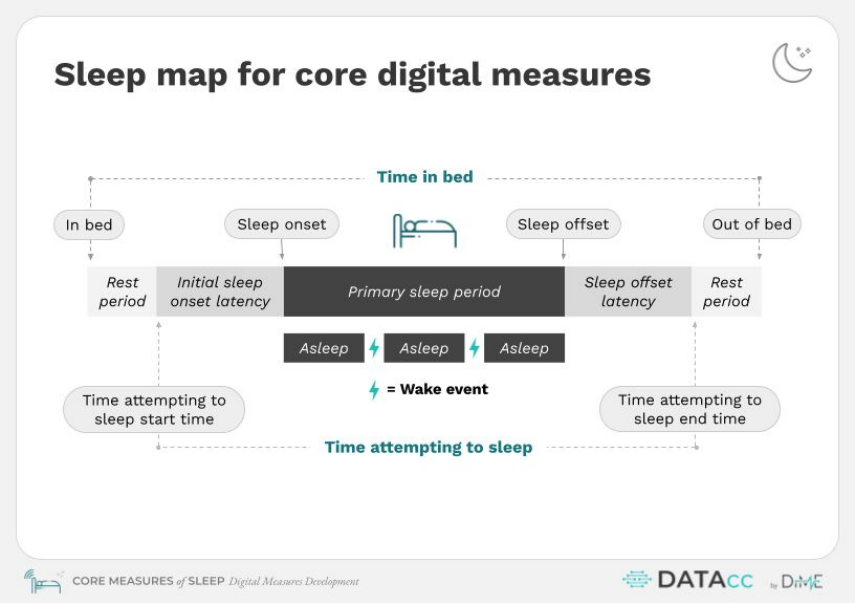
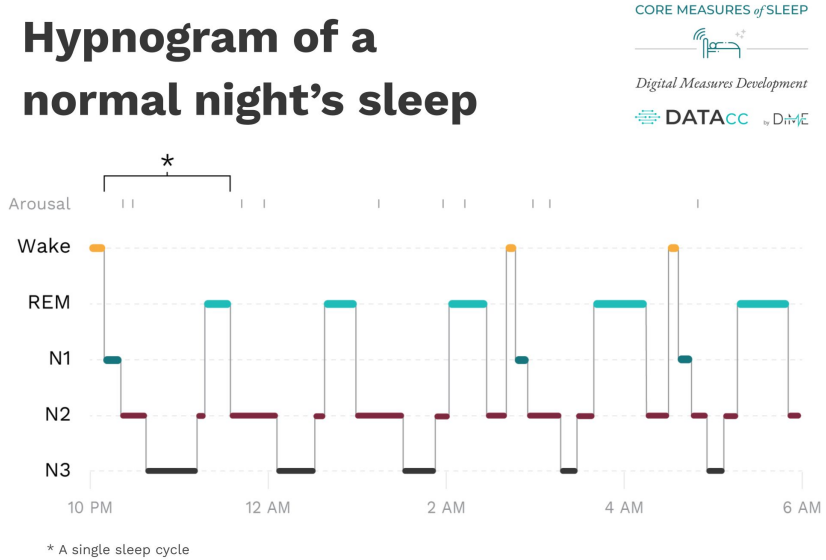


All the graphics we produced are available for you to use in your work





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Nina Shaafi Kabiri
Research Scientist
Boston University

Eric Nofzinger
Senior sleep medicine consultant
Jazz Pharmaceuticals

Katerina Placek
Senior Implementation Manager
Takeda

Jay Pathmanathan
Medical Director
Beacon Biosignals

Raul Torres
Principal Data Scientist
Takeda

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Michael Kremliovsky
Sr. Director of Medical Devices & eHealth
Bayer

Piper Fromy
Associate Program Director
Digital Medicine Society (DiMe)
Moderator

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Mark Aloia
Head of Sleep and Behavioral Sciences
Sleep Number

Bohdana Ratitch
Expert Statistician
Bayer

Sarah Averill Lott
Digital Medicine Society (DiMe)
Moderator

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Farah Hasan
Expert Advisory Board Member and Patient Speaker
Project Sleep

Piper Fromy
Associate Program Director
Digital Medicine Society (DiMe)
Moderator

DIGITAL MEDICINE SOCIETY

Building the **Business Case** *for* Digital Endpoints

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Join us in our next project as we convene leaders from across the field to **develop the business case** to support the development, adoption, and scale of digital endpoints!

Don't miss out on our next DATAcc by DiMe project – **scan the QR code** to share your interest and learn more!

Source: https://pages.insightly.services/digital_endpoints

Join us for an upcoming DiME Webinar

The DiMe webinar series hosts leading experts from across a variety of disciplines to discuss critical topics on digital medicine with our community.

Scan the code & learn more about our webinar series and to **register** for our next event!

Source: DiMe Webinar Series