Template Text: Standardized Rationale for the Use of the Core Digital Measures of Sleep

This document describes the intent and development of the DATAcc by DiMe's Core Digital Measures of Sleep. You can use it to provide justification for using these measures and the Core Measures: Sleep Measurement System (see below for example use cases). For scientific justification for including a given Core Sleep Measure, see the Justifying the Inclusion of Core Digital Measures of Sleep.

This document is written for you (clinical researchers, academic researchers and product developers) to lift the appropriate sections of text for supporting the use of the DATAcc core measures in your work. You are permitted to copy and paste text, and edit where necessary. The use of this text is intended to:

- Reduce your workload by eliminating the need to draft a justification where this has been determined a priori by DATAcc by DiMe.
- Drive broad adoption by reviewers of this text by reinforcing consistent, evidence-based messaging about the value of these core digital measures of sleep.

The intended use cases for this text include, but are not limited to, documents such as:

- Regulatory documents such as protocols, briefing books and other regulatory interactions
- Grant proposal submissions
- Ethics submissions
- User documentation
- Website-based information

Note the following information is written in the future tense. Please ensure the tense is corrected for your own purposes.

Core measures selection

This work's operationalization of sleep metrics will follow the DATAcc Core Digital Measures of Sleep specifications. Specifically, the following core measures will be included:

[Delete the following measures that you are not using]

- Total sleep time
- Initial sleep onset latency
- Wake after sleep onset
- Number of wake events in the primary sleep period
- Sleep efficiency
- Total napping time

Variables and labels used to derive these core measures will be configured and evidenced based on the accompanying Core Measures: Sleep Measurement System.

Background information

[Use the following text as an introduction to the rationale behind selecting the core measures set.]

The DATAcc Core Digital Measures of Sleep were devised as a method to standardize the conduct and reporting of sleep research and practice using sensor-based digital health technology. The project was driven by a pre-competitive group of experts, including digital health technology developers, pharmaceutical industry representatives, and academics. The selection of the Core Digital Measures of Sleep was based on an expert workshop to select a representative sample of therapeutic areas for study, a systematic literature review of patient-relevant concepts of interest relating to sleep and sleep disturbance, a narrative literature review of clinically relevant sleep parameters for sleep measurement, and a landscape analysis of available technology and its maturity, and finalized using a modified Delphi process for the refinement of the overall Sleep Measurement System and selection of the Core Measures.

The overall output of the project has two key components: recommendations for Core Digital Measures of Sleep and a supporting Sleep Measurement System. The Core Digital Measures of Sleep include six interpretable measures representing concepts that are broadly relevant across therapeutic areas:

- Initial sleep onset latency
- Wake after sleep onset
- Total sleep time
- Number of wake events in the primary sleep period
- Total napping time
- Sleep efficiency

The supporting Sleep Measurement System includes the component parts (variables) of the core measures, including the specifications for sleep stage measurement, derived variables relating to the Core Digital Measures of Sleep, and the related specifications for the epoch level data labels. This system allows the user to compile the core measures and other measures of interest in a consistent and reproducible manner. The system is equipped to allow the user to report on both technology-specific aspects of sleep measurement and any deviations from the definitions of the Core Digital Measures of Sleep.

Specification of and deviations from the Core Measures: Sleep Measurement System

[The system offers room for further specification of or deviation from the core measures and individual epoch level labels. Use this text to highlight specifics on your chosen measurement technology, or deviations you have made.]

The specification of the independent epoch level labels for *[insert core measures]* include the need to describe and evidence the measurement validity of all necessary parameters. The description, rationale, and associated evidence for each of the selected core measures can be reviewed in *[insert name and link to your completed Comprehensive Checklists and Report Forms for your selected core measures]*.

Some deviations from the core measures have been planned. Specifically, for the core measure *[insert core measure name]*, the adjustments to the definition of the core measure include *[e.g., using time in bed duration as the denominator for sleep efficiency, etc.]*. The rationale for this deviation is *[reason, e.g., the chosen technology, some specific about the patient population]*.