



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: <u>Digital Measures that Matter to Patients</u>		
B. Quantitative evidence of clinical validity in the target population. See: <u>The V3 Framework</u>		

The parameters required for the calculation of total napping time can be supported by:

- 1. Descriptions of the algorithm output used for each of the necessary parameters, and/or
- 2. References to documented evidence (published manuscripts, technical specifications, etc.)

These elements are further described in the <u>Core Measures: Sleep Measurement</u> <u>System.</u>

Sleep measurement system variables	Description	Evidence
C. Sleep staging		



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D. Rest period	
E. Sleep offset	
F. Sleep onset	
G. Nap event	

When evaluating the quality of the evidence provided for the selected digital health technology, refer to the <u>EVIDENCE checklist</u>.

✓ **Once complete:** Store with study document for future reference. Submit with protocol registration, study report, or manuscript submission.

A. Qualitative evidence supporting patient relevance in the target population

Description	
Evidence	



B. Quantitative evidence of clinical validity in the target population

Description	
Evidence	

C. Sleep staging

Description	
Evidence	





D. Rest period

Description			
Evidence			

E. Sleep offset

Description			
Evidence			





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F. Sleep onset

Description		
Evidence		

G. Nap event

Description	
Evidence	



