

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	<input type="checkbox"/>	<input type="checkbox"/>
B. Quantitative evidence of clinical validity in the target population. See: The V3 Framework	<input type="checkbox"/>	<input type="checkbox"/>

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 [Core Measures: Sleep Measurement System](#).

Sleep measurement system variables	Description	Evidence
C. Sleep staging	<input type="checkbox"/>	<input type="checkbox"/>

D. Rest period	<input type="checkbox"/>	<input type="checkbox"/>
E. Sleep offset	<input type="checkbox"/>	<input type="checkbox"/>
F. Sleep onset	<input type="checkbox"/>	<input type="checkbox"/>
G. Nap event	<input type="checkbox"/>	<input type="checkbox"/>

When evaluating the quality of the evidence provided for the selected digital health technology, refer to the [EVIDENCE checklist](#).

- ✓ **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	<p><i>Example placeholder text:</i></p> <p><i>Patients with [insert condition] report [insert]. This has been described by patients to be important to the patient population as it leads to [insert].</i></p> <p><i>Can include patient quotes to support descriptions. References can be numbered.</i></p>
Evidence	<p><i>Fill in references:</i></p> <ol style="list-style-type: none"> 1. <i>Insert</i> 2. <i>Insert</i> 3. <i>Insert</i>

B. Quantitative evidence of clinical validity in the target population

Description	<p><i>Example placeholder text:</i></p> <p>The clinical presentation of patients with <i>[insert condition]</i> leads to/includes <i>[insert]</i>. This has been evidenced in research showing <i>[insert]</i>. The clinical impact of this in the population is <i>[insert]</i>.</p> <p><i>[Where the study is generating evidence for the link between the selected core digital measure and the clinical interpretation in the population, an evidenced rationale for this hypothesis can be presented instead.]</i></p>
Evidence	<p><i>Fill in references:</i></p> <ol style="list-style-type: none"> 1. <i>Insert</i> 2. <i>Insert</i> 3. <i>Insert</i>

C. Sleep staging

Description	<p><i>Example placeholder text:</i></p> <p>The DHT selected to measure total napping time estimates sleep staging at the <i>[specify level - coarse grain, medium or fine grain]</i> in line with the Core Digital Measures of Sleep.</p>
Evidence	<p><i>Example placeholder text:</i></p> <p>Evidence for the estimation of sleep staging is detailed in the following material:</p> <p><i>Fill in references:</i></p> <ol style="list-style-type: none"> 1. <i>Insert</i> 2. <i>Insert</i> 3. <i>Insert</i>

D. Rest period

Description	<p><i>Example placeholder text:</i></p> <p><i>The DHT selected to measure total napping time uses a rest period outside the primary sleep period as described in the Core Measures: Sleep Measurement System. The technical definition of a rest period for the selected DHT is...</i></p>
Evidence	<p><i>Example placeholder text:</i></p> <p><i>Evidence for the estimation of the primary sleep period is detailed in the following material:</i></p> <p><i>Fill in references:</i></p> <ol style="list-style-type: none"><i>1. Insert</i><i>2. Insert</i><i>3. Insert</i>

E. Sleep offset

Description	<p><i>Example placeholder text:</i></p> <p><i>The selected DHT has been evidenced to estimate a confirmed sleep offset, as e.g., the first epoch with a sleep offset label in a series of at least five 30-second epochs with a sleep offset label.</i></p>
Evidence	<p><i>Example placeholder text:</i></p> <p><i>Evidence for the estimation of a sleep offset is detailed in the following material:</i></p> <p><i>Fill in references:</i></p> <ol style="list-style-type: none"><i>1. Insert</i><i>2. Insert</i><i>3. Insert</i>

F. Sleep onset

Description	<p><i>Example placeholder text:</i></p> <p>The selected DHT has been evidenced to estimate a confirmed sleep onset as e.g. the first epoch with a sleep offset onset in a series of at least five 30s epochs with a sleep onset label.</p>
Evidence	<p><i>Example placeholder text:</i></p> <p>Evidence for the estimation of a sleep onset is detailed in the following material:</p> <p>Fill in references:</p> <ol style="list-style-type: none"> 1. Insert 2. Insert 3. Insert

G. Nap event

Description	<p><i>Example placeholder text:</i></p> <p>The selected DHT has been evidenced to estimate a nap event in line with the Core Digital Measures of Sleep as an epoch with a sleep onset label=1 and rest period=1.</p> <p>A nap duration is estimated as the time duration (seconds) between</p> <ul style="list-style-type: none"> • A sleep onset time associated with a nap event label=1 • The sleep offset time of the following epoch with sleep offset label=1
Evidence	<p><i>Example placeholder text:</i></p> <p>Evidence for the estimation of a wake event is detailed in the following material:</p> <p>Fill in references:</p> <ol style="list-style-type: none"> 1. Insert 2. Insert 3. Insert