

Comprehensive Checklist and Report Form for Core Digital Measures of Sleep: **Number of wake events in the primary sleep period**

This checklist and report form is intended for people conducting studies employing a digital health technology (DHT) to measure the number of wake events in the primary sleep period.

The checklist ensures users have identified and collected the necessary details and evidence to support 1) the use of the measure in their 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.

Number of wake events in the primary sleep period 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 number of wake events 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. Primary sleep period	<input type="checkbox"/>	<input type="checkbox"/>
E. Sleep offset	<input type="checkbox"/>	<input type="checkbox"/>
F. Wake 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>Example placeholder text:</p> <p>The clinical presentation of patients with [insert condition] leads to/includes [insert]. This has been evidenced in research showing [insert]. The clinical impact of this in the population is [insert].</p> <p>[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.]</p>
Evidence	<p>Fill in references:</p> <ol style="list-style-type: none">1. Insert2. Insert3. Insert

C. Sleep Staging

Description	<p>Example placeholder text:</p> <p>The DHT selected to measure # of wake events estimates sleep staging at the [specify level - coarse grain, medium or fine grain] in line with the Core Digital Measures of Sleep.</p>
Evidence	<p>Example placeholder text:</p> <p>Evidence for the estimation of sleep staging is detailed in the following material:</p> <p>Fill in references:</p> <ol style="list-style-type: none">1. Insert2. Insert3. Insert

D. Primary Sleep Period

Description	<p><i>Example placeholder text:</i></p> <p><i>The DHT selected to measure # of wake events in the primary sleep period in this study using the sleep opportunity window, per the DiMe Core Digital Measures of Sleep.</i></p> <p><i>-OR-</i></p> <p><i>The DHT selected to measure # of wake events in the primary sleep period in this study uses the In bed label as a proxy for the sleep opportunity window.</i></p> <p><i>-OR-</i></p> <p><i>The DHT selected to measure # of wake events in the primary sleep period in this study uses.....</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 the 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. Wake Event

Description	<p><i>Example placeholder text:</i></p> <p><i>The selected DHT has been evidenced to estimate a wake event in line with the Core Digital Measures of Sleep as an epoch with a sleep offset label=1 and primary sleep period=1.</i></p>
Evidence	<p><i>Example placeholder text:</i></p> <p><i>Evidence for the estimation of a wake event 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>