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*	☐	☐
B. Quantitative evidence of clinical validity in the target population. *See: The V3 Framework*	☐	☐

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	☐	☐
D. Primary sleep period	☐	☐
E. Sleep offset	☐	☐
F. Wake event	☐	☐

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	
Evidence	

B. Quantitative evidence of clinical validity in the target population

Description	
Evidence	

C. Sleep Staging

Description	
Evidence	

D. Primary Sleep Period

Description	
Evidence	

E. Sleep Offset

Description	
Evidence	

F. Wake Event

Description	
Evidence	