

ki:elements pioneers the speech-based assessment of neurological and psychiatric diseases. ki:e combines artificial

intelligence with natural language analysis and interpretation technologies. It offers digital biomarkers for a variety of clinical, before and in-trial usage scenarios.

The V3 framework established by the DiMe Society provides a unified evaluation framework for digital tools such as SBs.

— Authors of <u>Validation of</u>
<u>the Remote Automated</u>
<u>ki:e Speech Biomarker for</u>
<u>Cognition in Mild</u>
<u>Cognitive Impairment</u>



The Resource

- In Validation of the Remote Automated ki:e Speech Biomarker for Cognition in Mild Cognitive Impairment: Verification and Validation following DiME V3 Framework, authors from ki:elements leveraged DiMe's V3 Framework to evaluate a novel digital speech biomarker for cognition (ki:e SB-C).
- > Authors sequentially evaluated each phase of V3. They collected and statistically analyzed distinct data at each step and reported results for each phase:

Results

Verification: The SB-C could be reliably extracted using an automatic speech processing pipeline against manually corrected transcripts from trained clinical personnel.

Analytical Validation: In both languages (English and Dutch), the SB-C was strongly correlated with MMSE scores.

Clinical Validation: The SB-C significantly differed between clinical groups (including MCI and dementia), was strongly correlated with the CDR, and could track the clinically

meaningful decline.



Conclusion

Using the best practices for defined by the V3 framework, authors conclude that the ki:e SB-C is an objective, scalable, and reliable indicator of cognitive decline, fit for purpose as a remote assessment in clinical early dementia trials.

