

# Clinical Evaluation of Communication Brain Computer Interfaces in Amyotrophic Lateral Sclerosis: A Landscape Analysis

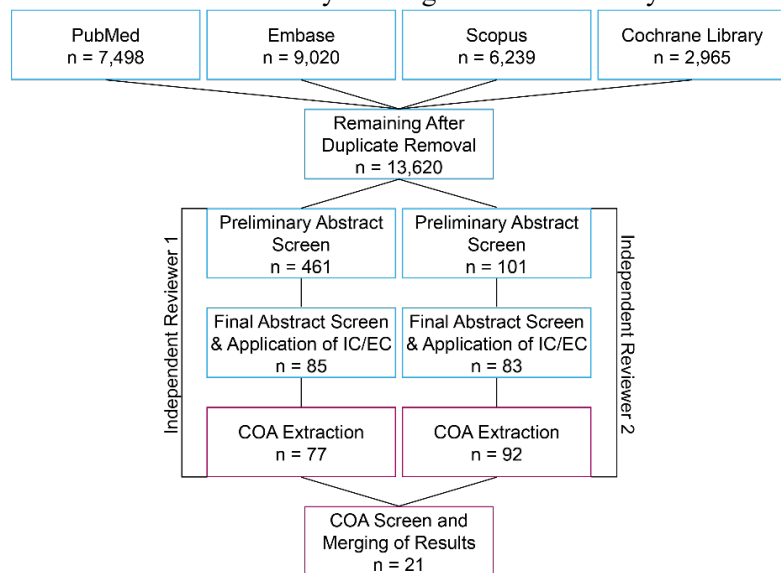
Melby, SR<sup>1</sup>, Asok Kumar JN<sup>1</sup>, McMullen DP<sup>2</sup>, Kellis, S<sup>1\*</sup>

<sup>1</sup>Blackrock Neurotech, Salt Lake City, Utah, USA ; <sup>2</sup>Office of Neurological and Physical Medicine Devices, CDRH, FDA

\*630 Kommas Dr, #200, UT-84108. E-mail: skellis@blackrockneuro.com

**Introduction:** Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative disease leading to severe paralysis and loss of communication, significantly impacting their quality of life. Communication brain-computer interfaces (cBCIs) offer a potential solution for paralyzed individuals, yet there are no standardized clinical outcome assessments (COAs) for evaluating their efficacy. This study conducts a landscape analysis, reviewing current communication efficacy approaches, COAs, and expert feedback to guide the development of cBCI-specific measures for ALS patients.

**Material, Methods and Results:** Through a project funded by the FDA's Rare Neurodegenerative Disease Grants Program (established under the Accelerating Access to Critical Therapies (ACT) for ALS act) we conducted a systematic literature review to identify existing measures that may be used or adapted to assess the effectiveness of cBCIs. Using a comprehensive and robust search filter, two independent reviewers screened 13,620 published manuscripts across multiple databases. From those papers, we identified 21 COAs relevant to cBCI in ALS patients (Fig. 1). Concurrent with the literature review, we conducted a series of structured interviews with key opinion leaders (KOLs) (n=15). KOLs confirmed the relevance of many of the COAs previously identified and provided valuable insight on the evaluation of communication in ALS and cBCI assessment. No additional COAs were identified during KOL interviews for inclusion. Finally, we assembled a panel of experts for an extended discussion on selected COAs. The panel reviewed 21 COAs, discussing their relevance, scale types, and applicability. It was concluded that while some metrics are useful, none were comprehensive enough for standalone clinical use, and modifications would be necessary for cBCI evaluation in ALS.



**Figure 1: Flow chart of comprehensive literature review processes and results after merging independent review results.** Blue bounding boxes indicate literature review and manuscript identification and screening. Magenta bounding boxes indicate clinical outcome assessment identification and extraction from selected papers.

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**Conclusion:** This study highlights the need for the development and application of comprehensive COAs for evaluating cBCIs in ALS patients. Through a comprehensive landscape analysis, we conclude that, although several relevant COAs exist in the scientific literature and current clinical practice that may be useful in the assessment of cBCI in ALS, none are suitable for use without some modification nor are any comprehensive enough for standalone use. Moving forward, patient-centered, adaptable evaluation approaches should be the primary focus guiding future development and validation efforts for metrics to assess cBCI efficacy and patient satisfaction.

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