Case study

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Multimodal digital measures demonstrate greater responsiveness and sensitivity to disease progression and treatment effects than traditional clinical scales

🕕 About Modality.Al, Inc.

<u>Modality.AI</u> created Tina, a virtual guide that interviews patients with neurological conditions such as amyotrophic lateral sclerosis (ALS), Parkinson's, or schizophrenia. Tina analyzes what patients say and do to inform clinical trial sponsors about how their interventions affect disease progression.

🇳 The opportunity

- 4 out of 5 clinical trials fail today, leading to billions of dollars of lost opportunity for developers of drugs and other interventions.
- Inadequate or non-sensitive assessments (often completed in the clinic, biased, and error-prone) are a key reason for this.
- Robust, sensitive, easy-to-use digital assessments can provide a remedy.





The current clinical standard scale for ALS assessment, the ALS Functional Rating Scale-Revised (ALSFRS-R), is a categorical scale that is not sensitive enough to track fine-grained changes in ALS disease progression. This adversely impacts clinical trials, which may fail due to the lack of sensitive assessments.



• Modality's objective digital measures extracted from different modalities (speech acoustics, orofacial movement, natural language) provide more frequent, continuous-valued, sensitive measurements of ALS disease progression. They can, therefore, be more reliable than categorical scales.





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The impact

- Timing-related speech measures are very responsive at detecting a clinically meaningful change in both bulbar and non-bulbar ALS, with changes detected as early as 4 and 9 weeks, respectively (Neumann, Kothare & Ramanarayanan, 2024). This could allow clinical trial designers to reduce trial durations.
- Certain speech measures such as canonical timing alignment, speech duration, word count, and percent pause time are sensitive enough to track bulbar decline even when no patient-reported clinical change (i.e., the ALSFRS-R speech score remains unchanged).
- The responsiveness of these measures is stable even at a small sample size, potentially allowing for sample size reduction in clinical trials (<u>Neumann, Kothare &</u> <u>Ramanarayanan, 2024</u>).

— David Suendermann-Oeft

CEO, Modality.AI

This case study was adapted from the paper "<u>Multimodal speech biomarkers for remote monitoring of</u> <u>ALS disease progression</u>" by Michael Neumann, Hardik Kothare, and Vikram Ramanarayanan (2024), published in *Computers in Biology and Medicine*.



