Automated speaker verification for detecting identity anomalies and ensuring data integrity in multi-site CNS clinical trials

Submitter Michelle Worthington

Affiliation Brooklyn Health

SUBMISSION DETAILS

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What is the Methodological Issue Being Addressed? CNS clinical trial integrity is often compromised by intentional or unintentional anomalous site and participant behavior, such as duplicate enrollments. While some tools exist to mitigate this problem, these issues are difficult to detect via traditional monitoring methods. Automated speaker verification offers a scalable, objective solution to support quality management by analyzing acoustic signatures to confirm participant and rater identities over time and flagging recordings for secondary review.

Introduction Traditional study monitoring methods are often insufficient to detect sophisticated instances of site or participant anomalies, particularly in large-scale, multi-site clinical trials. As such, there is a critical need for objective, scalable, and automated solutions to ensure longitudinal data integrity. Existing models leveraging neural networks for speaker identification can recognize unique voice patterns in human speech. By creating digital voice profiles from recorded interviews, these tools can analyze and compare speakers over time. The implementation of these models offers a straightforward way to complement existing centralized quality management processes by identifying recordings that warrant further review, providing a powerful safeguard to ensure the integrity of clinical trial data. Here, we aim to develop and validate an automated speaker identification pipeline using an embedding-based speaker identification model, and evaluate flagged instances of ID anomalies.

Methods We evaluated our speaker identification model on data from an open-label observational depression study using MADRS interviews. Audio recordings were processed via an automated pipeline conducting transcription, diarization, and speaker audio separation. Recordings were then segmented into 30-second chunks and run through the ECAPA-TDNN framework, an existing speaker identification neural network, to extract speaker embeddings. We calculated intra- and inter-recording cosine similarities to identify the following cases of flagged speaker anomalies: 1) same participant IDs with different voices, 2) different participant IDs with the same voice, and 3) same rater IDs with different voices.

Results A total of 234 MADRS recordings were evaluated to assess model performance. Overall, 99.1% of pairwise comparisons across recordings were correctly identified as the same speaker, while 0.9% were identified as a different speaker despite being the same individual (cases of flagged speaker anomalies). Conversely, 3.6% of pairwise comparisons across recordings were incorrectly identified as the same speaker (cases of flagged speaker anomalies), whereas 96.4% were correctly identified as different speakers. These results demonstrate a high degree of

accuracy in distinguishing individual speakers, confirming the model's robustness in verifying speaker identification.

Conclusion Speaker embedding and identification models provide a highly scalable, robust framework for automating identity verification, essential for maintaining data integrity in global clinical trials. By reliably isolating identity anomalies, such as duplicate patient IDs or mismatched raters, this methodology supports quality management by flagging recordings for secondary review, significantly enhancing trust and security across diverse, multi-site study environments. This method could play an important role in ensuring consistent, high-quality data collection for global trials, ultimately strengthening the reliability of trial outcomes.

Co-Authors

Kieran McVeigh[1], Jacob Ouyang[1], Vijay Yadav[1], Anzar Abbas[1],
Michelle Worthington[1]

[1] Brooklyn Health

Keywords

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Guidelines I have read and understand the Poster Guidelines

Disclosures All authors are current or former employees of and hold equity in Brooklyn Health, a private company that developed and indirectly benefits from the model described in this abstract.

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