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National Institutes of Health Develops AI Algorithm to Identify Potential Volunteers for Clinical Trials

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Researchers from the National Institutes of Health (NIH) have developed an algorithm that harnesses AI to help accelerate the process of matching potential volunteers for relevant clinical research trials. The algorithm, called TrialGPT, is intended to help clinicians navigate the vast range of clinical trials available to patients by identifying potential matches and providing a summary of how that person meets the criteria for study enrollment. The team of researchers used a large language model (LLM) to develop an innovative framework for TrialGPT and compared the algorithm to the results of three human clinicians who analyzed over 1,000 patient-criterion pairs. The team also conducted a pilot user study, where two human clinicians reviewed six anonymous patient summaries and matched them to potentially suitable clinical trials. When clinicians used TrialGPT as a starting point, they spent 40% less time screening patients and maintained the same level of accuracy. The research team was selected for the Director's Challenge Innovation Award, which will allow the team to further assess the model's performance and fairness in real-world clinical settings. The researchers "anticipate that this work could make clinical trial recruitment more effective and help reduce barriers to participation for populations underrepresented in clinical research."

A tool similar to TrialGPT could be used by life sciences companies as they work to ensure that patient selection for their research studies is adequately diverse. One of FDA's priorities is to advance health equity by promoting clinical trial diversity. Participants in clinical trials should represent the patients that will use the medical products, but that is often not the case. FDA has issued recommendations to improve inclusion of underrepresented populations in clinical trials, including guidance in 2019 and 2020. Now under the Food and

Drug Omnibus Reform Act of 2022 (FDORA), sponsors must submit "Diversity Action Plans" for certain clinical studies in the form and manner specified by FDA. These Diversity Action Plans are intended to increase enrollment of participants who are members of historically underrepresented populations in clinical studies to help improve the strength and generalizability of the evidence for the intended use population. As part of the agency's June 2024 draft guidance regarding Diversity Action Plans, FDA offered examples of ways sponsors could satisfy the requirement to explain how the sponsor plans to meet specified enrollment goals, including community engagement, improving access by selecting sites that serve demographically diverse populations, employing clinical study decentralization when appropriate, and improving study awareness. One way to expand study awareness among clinicians and patients would be to employ an algorithm like TrialGPT.

Although all AI/ML-enabled medical devices would not necessarily be required to submit Diversity Action Plans under FDORA (the requirement only applies to device studies requiring an Investigational Device Exemption), FDA has repeatedly warned of the risk of the potential for bias in AI/ML-based medical devices. Perhaps another AI tool that helps to identify suitable study participants from underrepresented populations could be used to address algorithmic bias.

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