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Artificial intelligence can improve patients' experience in decentralized clinical trials

The clinical trials industry is undergoing a rapid transition toward decentralization, whereby some or all health assessments are performed remotely in participants' homes instead of in medical centers. This transition was accelerated by the need to continue running clinical trials during the COVID-19 pandemic. A decade ago, researchers collected initial evidence indicating that in-home participation can help to address the patient recruitment and retention challenges that have plagued the industry[1]. Research since then has continued to find that decentralization provides an opportunity to recruit larger, more diverse pools of patients[2].

However, for these potential benefits to be fully realized, further innovation is necessary to compensate for the increased responsibility that decentralized clinical trials place on participants. Shortcomings in digital health user interfaces have been identified by the National Academies of Sciences, Engineering, and Medicine as a key risk in decentralized trials[3]. The automation that artificial intelligence (AI) enables could fuel user interface improvements that would usher in the next generation of decentralized clinical trial applications.

In parallel with the movement toward decentralization, the amount of data collected from participants in clinical trials is increasing. A growing portion of this data collection involves participants individually completing surveys, diaries and other electronic clinical outcome assessments (eCOA) at home on a regular basis. Asking participants to engage in time-consuming data entry tasks can reduce their adherence to a trial's protocols or increase the number of errors that they make. Some trials use electronic notifications to remind participants when they need to complete eCOA tasks, but an excessive number of tasks and notifications can lead to participants dropping out or inputting inaccurate data[4].

This challenge can be addressed with reinforcement learning. Reinforcement learning is a domain of AI used for sequential decision making. It has been used to create chess-playing computers that beat the best human players[5]. These computers are trained to assess the state of the system in each turn (in chess, this is the configuration of the pieces) and take the action (moving one chess piece) that maximizes the probability of eventually achieving a goal (winning the game).

This approach has been implemented by Meta[6] to optimize notifications on Facebook, and it can be leveraged to improve participants' experiences in clinical trials. The goal would be to identify which notifications should be sent and when to send them to minimize total notifications while maximizing participants' completion of eCOA tasks. The 'state of the system' may be the time of day, the GPS location of the participant's data entry device, the number of notifications they have already received that day, and how they have responded to past notifications. The potential actions for the clinical trial mobile app may be to send a motivational message or a deadline reminder or to not send any notification at all, depending on the state of the system. This approach enables customization for each participant. Reinforcement learning can help participants fit eCOA tasks into their schedule while minimizing unhelpful notifications.

Patients are also increasingly asked to submit images and videos that they capture using a smartphone or tablet camera. This enables decentralized trials for dermatological, neurological and behavioral health interventions. In dermatology trials, participants are usually asked to submit images of their skin. Neurological and behavioral health trials may require participants to collect videos of them carrying out specific tasks[7]. However, it can be unintuitive for users to capture these images and videos with the required zoom, camera angle and lighting.

Computer vision is a domain of AI that enables the automatic assessment of images and videos. Many mobile banking apps use computer vision to coach customers to take photos of their checks for electronic deposits. If you hold the camera too far from the check or the lighting is too dark, the app will provide real-time advice about the required adjustments. The same could be done for user-submitted photos and videos in clinical trials; this approach has already been tested in telemedicine[8]. If a patient's entire body needs to be visible in the video, this could be confirmed automatically while the video is being captured in the trial's mobile application, allowing for immediate adjustments. If a skin photo appears overexposed, the user could be advised to turn off the flash. Empowering users to succeed quickly without needing to retake photos will improve their experience while reducing the time required for post-hoc, central quality control.

Efforts to decentralize the assessment of participants' mobility in clinical trials have largely relied on the use of wearable sensors. Some trials require participants to wear many sensors all over their bodies while performing specific mobility assessments to gather detailed information about their movement patterns[9]. Often the sensors must be oriented in a specific configuration to work properly. The process of applying these sensors can be time consuming, can require live guidance from clinical trial personnel via video conference, and remains error prone.

AI models designed for temporal data have the potential to enable more detailed measurements with fewer sensors. These models could be trained to infer how one body part is moving using data collected at a different body part, reducing the number of sensors needed to assess full-body movement patterns. In other cases, an AI model could be trained from a single sensor or small set of sensors to directly estimate a clinical outcome of interest. For example, research suggests that freezing-of-gait events in individuals with Parkinson's disease can be detected with just one sensor[10]. Replacing a full-body array of sensors with a single sensor opens the door to measuring mobility outcomes on a constant basis in a typical living environment so that even rare health events can be measured.

AI is already being used to enhance users' experience in customer-facing applications across many industries. Adopting this approach in clinical trials can empower more patients to enroll in trials, successfully complete those trials without undue burden, and submit high-fidelity assessments of their health throughout their participation.

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Competing interests

Both authors are employed by eResearchTechnology, Inc. (dba Clario).