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Future visions in clinical trials: The role of artificial intelligence and how it changes clinical research

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The synergy of advances in diverse areas of artificial intelligence holds considerable promise for improving the efficiency and efficacy of clinical trials. Of particular interest to Trials.ai is improving the design and execution of protocols. Poorly constructed protocols lead to poor research and costly amendments, protocol deviations, delays in obtained appropriate data and more.

Opportunities for Artificial Intelligence to Improve Outcomes: The Trials.ai system is designed to accept a protocol document, scan it and assess for opportunities and threats. This includes, for example, consistency between the time and events (T&E) table and the in-text description of events, and consistency between the synopsis and the body of the protocol. Natural language processing tools are helpful in this regard. Additionally, AI tools are used to scan completed protocols based on a similarity. Similar protocols coupled with published and internal data are mined to predict the degree of success from the proposed design as well as identify any problematic items.

Addressing Enrollment and Retention: Clinical trials often fail because of poor enrollment. Trials.ai can warn the study designer, for example, that particular inclusion/exclusion criteria may be too limiting for subject enrollment can save the sponsor considerable funds and time that can be invested in a better clinical design or an alternative effort. Clinical trials also fail because of poor subject retention. To address this, we have created and are refining what we call a Patient Burden Index (PBI), which is an AI-derived quantitative measure of the impact that the protocol design has on the subject. Protocols can then be scored based on their PBI, and alternative designs can be explored. We believe this is an entirely novel approach to improving subject retention and cooperation at all stages of a clinical trial.

Executing the Trial More Effectively and Efficiently: Once the trial has started, AI will play additional roles to help ensure a best outcome. In our case, our client partners provide a protocol that is uploaded into our system. The system then maps the T&E schedule into a dashboard-driven user interface that shows when each event is to be completed. With available personnel assignments and schedules, the system can also identify who is to do which task in support of which patient at which time. Practitioners are alerted ahead of time for events, which helps to reduce protocol deviations.

Biography

Trials.ai is Kim's 3ʳᵈ company yet her passion for fixing logistical problems with clinical trials drives her as if it were her first. Her expertise in organizational development enabled her build Corporate Development Programs for companies like Pfizer, Merck and Wyeth Ayerst. Ms Walpole understands the complex clinical trials space and the needs of sponsors, CROs and sites. Her goal is to use technology to as a catalyst for helping organizations in study design and execution so that patients can be exposed to better quality treatments, faster.

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Notes:

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