ACTA SCIENTIFIC CLINICAL CASE REPORTS

Volume 5 Issue 5 May 2024

Editorial

AI and Clinical Trials: Recent Advances

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Received: March 05, 2024

Published: April 01, 2024

Artificial Intelligence (AI) has made tremendous advances in the field of clinical trials, offering the potential to address key challenges and transform the landscape of drug development. Recent developments have shown that AI, combined with big data, can lead to faster and more precise drug development, improved patient care, and enhanced regulatory oversight [1,2].

AI technologies make innovations possible, such as seamlessly combining phases of clinical trials, developing novel patient-centered endpoints, and collecting and analyzing Real World Data [1]. AI is also being used to speed up drug development journey by boosting the probability of successful trials and regulatory approval [4]. Major drug makers are leveraging AI to identify subjects for clinical trials quickly as well as reducing the sample size for clinical trials [3].

Despite these advancements, the adoption of AI for clinical development is still in its early stages, and there are challenges to be addressed, such as data limitations and reshaping clinical trial design [4]. Overall, AI's integration into clinical research is poised to revolutionize drug development, patient care and regulatory processes

Some specific AI tools used in clinical trials include:

- Patient Recruitment: AI is used to identify and screen potential participants based on inclusion and exclusion criteria, automate eligibility analysis, match potential participants to trials, and simplify trial searching capabilities [5].
- Trial Design Optimization: AI tools are employed to inform clinical trial design, resulting in the reduction of the number of trial participants and the facilitation of cohort selection [4].
- Data Analysis and Cleaning: AI is utilized for real-time monitoring, predictive analytics, data cleaning, and safety surveillance within clinical trials [5].
- Protocol Development: AI technologies aid in protocol development by reducing or replacing outcome assessments with more responsive and efficient measures, processing data from electronic medical and administrative records, and other sources to improve data quality and identify treatment efficacy more efficiently [1].

Artificial intelligence powering clinical development

Today AI can draw upon growing volumes of RWD (Real World Data). EMR (Electronic medical records) as well as claims data from various regions are widely available, also sources for novel data which includes but not limited to data omics panels, population-wide genomic studies, biobanks, patient registries, and imaging and digital pathology are increasing in number and diversity. Such sources reflect a significant change in patient's comfort in sharing their data for the purpose to upscale research and treatments by maintaining confidentiality and privacy, which includes technologies that enables the training of machine learning models which ensures respecting patient's confidentiality and privacy.

Additionally, various novel tools are used to systematically capture information from unorganized datasets. Giant language models (for example, BioGPT) are preferred to convert these unorganized physician's data into high-quality structured and organized database. On similar lines, such models are used to search the vast data pool of digital libraries such as published articles/literature and identify linking between biological parameters on a larger scale, which helps in creating and developing high-quality input for knowledge graphs which better represent the summary of available RWD (Real World Data) for a specific indication across various domains, which includes but not limited to targets, genes, proteins, phenotypes and pathways.

Majority of pharma companies use AI and RWD in clinical development only in selected situations and cases, and they in very rare

situations deploy both in combination. For example, one would prefer to use machine learning for selecting clinical trial sites and/or to predict or evaluate enrollment rates of trial participants. One might use Real World Data to measure prevalence of specific disease; for size of an eligible population, understanding the disease progressing (natural course of a disease) amongst untreated patients as well as by developing an additional control arm towards fulfilling the regulatory requirement. Similarly, while the level of funding and investment going into AI- enabled drug discovery companies have tripled in the last five years, that same trend is not true for equivalent companies in the clinical development space.

Four use cases that demonstrate the potential of AI:

Companies that are utilizing AI in combination with RWD get to see results with high impact. While RWD can be of high value by providing support to evidence in regulatory authority submission dossiers, the most successful companies focus their use of AI and RWD to make better and more informed decisions to support the success of clinical development programs in every step:

- At the stage of defining an asset strategy, AI and RWD can help in identifying which indications are most promising to pursue for novel assets. Several pharma leaders have identified multiple new indications for existing assets using such strategies, and an early- stage biotech firms have used AI and RWD to assess whether to shift its indication selection strategy towards a novel asset.
- AI and RWD can support decisions about the target patient population of a clinical trial, with subgroup discovery, refine subject's eligibility criteria for trial participation and help remove patients that are highly unlikely to benefit from the treatment, such process also will help in shortening the duration and cost of trials. One early-stage assessment can characterize "super-progressors" (that is, patients whose disease was likely to progress faster within the time frame of a clinical trial) and design a clinical trial with similar expected benefits and in an expedited time frame.
- For decisions about portfolio strategy, AI and RWD have helped companies in identifying the right combination of drugs towards the targeted indication or towards the right set of patient pool. One of the biopharma companies leveraged a prospective observational data set to generate evidence supportive of earlier positioning of its third-line treatment. Another was able to identify "super- responders" for several drugs in its portfolio, insights that helped the company position its assets optimally in a crowded indication.
- At the step of selecting and optimizing the end points of a clinical trial, AI and RWD can help a company identify patient attributes that closely track the primary end point over time. One biopharma company replaced a rare disease's existing end point, which was an infrequent event, with end points that occurred with greater frequency or could be measured with blood tests. This cut the length of trials by 15 to 30 percent [7].
- The use of artificial intelligence (AI) in diagnostics and imaging is undergoing extensive research and development. It has shown impressive accuracy and sensitivity in the identification of imaging abnormalities and promises to enhance tissue-based detection and characterization [8,9].

However, with improved sensitivity emerges an important drawback, namely, the detection of subtle changes of indeterminate significance [10,11].

In conclusion, AI is transforming clinical trials by enabling faster and more precise drug development, improving patient care, and enhancing regulatory oversight. AI technologies make possible innovations that are fundamental for transforming clinical trials, such as seamlessly combining phases of clinical trials, developing novel patient- centered endpoints, and collecting and analyzing Real World Data.

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