Establishing the Self-Driving Clinical Trial

Technology Networks: By Gary Shorter, Head of Artificial Intelligence at IQVIA Technologies

Artificial Intelligence (AI) has become an increasingly important part of modern life. From automating mundane tasks to holding the ability of predicting future trends and events, this technology has completely revolutionized the way we live, work and interact with the world. In the case of the healthcare industry, AI and Machine Learning (ML) have transformed how clinical developments occur.

Much like the new wave of driving automation, orchestration, digital workflows and the collection of data into digital forms make it possible for clinical trials to run on their own while offering patient personalization like never before. Thanks to the proliferation of health data and the development of these advanced technologies, today we have the power to establish the self-driving clinical trial — making the extraordinary possible for pharmaceutical organizations, hospitals, medical groups and, most importantly, patients. But what does this reality look like, and what does it mean for the industry? Let's explore the ins and outs of AI in clinical development.

The heart of successful clinical research: study design

Successful clinical research begins with study design. Strong protocols make or break successful research, as poorly designed ones can have disastrous consequences for the cost, efficacy and chances of success of trials. AI and ML create an optimal and efficient design that sets itself up from trained models — eliminating the need for manual design — which enables faster and more accurate setup while decreasing potential errors. In addition, validation processes provide the necessary inputs for designers to make any necessary tweaks before the study is ready to go-live.

ML can also evaluate different research options and outcomes in order to decide which approach will be most beneficial for regulatory bodies, insurers and patients. It can help to determine which countries and sites are best for the study, how to recruit participants and how to effectively launch the study — all based on historical data.

Automating the clinical development lifecycle

Once the design of the study is set up — the focus turns to the trial management aspect of research. From site selection and patient enrolment to quality monitoring and data management, AI and ML can alleviate the workload of organizers.

- **Site identification & patient recruitment**: One ongoing challenge in clinical trials is finding the right clinical trial sites that have access to enough patients who meet the criteria for inclusion and exclusion. As studies become more specialized, the goals for recruitment become more difficult and important, resulting in more expensive studies, longer timelines and a higher possibility of failure.

  AI and ML can reduce risks by locating the sites with the best potential for recruitment through mapping of patient populations and proactively seeking out sites that have a high probability of providing the largest amount of the right people for the study before sites are chosen. Models can be configured to examine factors like enrollment, safety, compliance and data quality, which vary depending on the type of trial and the interests of the CRO/Sponsor.

  Models can also be taught using data from past studies, allowing it to make predictions about which sites would be the most successful for a new project.

This allows sponsors to open fewer sites, speed up the recruitment process and reduce the chances of not having enough participants.

- **Pharmacovigilance (PV):** In PV (the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems), massive amounts of both structured and unstructured data must be integrated and reviewed to ensure quality and oversight. Technologies such as optical character recognition, natural language processing and deep neural networks are being used to format data more efficiently.

  In addition, AI and ML are being employed to automate manual intensive processes, such as translating and digitizing safety case processing and Adverse Drug Reaction (ADR) documents to aid risk assessments and study performance analysis. The tools also perform data listening tasks to identify adverse events by monitoring conversations on social media and other platforms, allowing project leads to improve patient safety while streamlining their work.

- **Clinical Monitoring:** To ensure proper research is conducted, clinical studies must be monitored constantly to identify and mitigate risks associated with patient safety, data accuracy and protocol adherence. A large amount of manual labor is used to assess risks associated with different sites and create "action items" to address those risks. AI and ML reduce the strain by automatically analyzing the risk environment and providing predictive analytics to generate more useful clinical monitoring insights. In addition, AI and ML can proactively determine which sites may face recruitment and performance issues, or which patients have a higher probability of Adverse Events (AEs).

- **Early Signal Detection:** The incorporation of advanced technologies has prompted the design of algorithms that can leverage medical information, such as symptoms and procedures, to precede diagnosis for patients. These algorithms can quickly go through the patient's information, suggest a course of action and immediately alert the doctor in real-time. This allows for more efficient and proactive care, as well as better integration for early-stage disease studies. One example is Alzheimer's Disease (AD) research, where historically, diagnoses are not made until the sickness has progressed beyond the initial stages.

The life sciences industry has evolved to the point where higher levels of data analytics are necessary for success — and how we handle this data across the board has become crucial for successful research.

Harnessing technology to transform clinical research

How we conduct research, expedite drug discovery, diagnose and treat patients have been completely revolutionized for the better. AI and ML enable more accurate and comprehensive decision-making, which, in hand, creates more meaningful and precise outcomes. But to reap the benefits, we must harness technology that can handle many elements — from global reach and high-level security in support of all regulatory needs to explainable and trusted use of AI that is unbiased and correct.

In addition, infrastructures must be able to store, digitize and use all content in a way that supports the user experience, which leads to several different approaches in the use of AI/ML — including the ability to utilize any known content coming from many different sources (video, documents, voice, devices, etc.), to analyze and generate useful insights and actions. Lastly, it's crucial to understand how the technology was trained, on what data, within which IT system, and how it is monitored and maintained by teams, to ensure it remains reliable and unbiased throughout its lifecycle.

As we continue to evolve the self-driving clinical trial, the future holds the promise of accelerated care and a more streamlined research environment. Let's make sure it is built properly, with clear guidance and proper validation.

About the author

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He holds an MSc and has served as a global biostatistics lead for multiple compounds in clinical trials. His 25-plus years of experience allows him to bring the same level of quality and domain expertise to the realm of AI, to ensure that quality AI tools are built and validated to the rigor of regulatory agencies' expectations.

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