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AI in Clinical Trials: An Incredible Voyage

Jonathan Burr
Senior VP, Clinical Platform Strategy
Saama Technologies

The 19th century English naturalist and seafarer Charles Darwin once said: "It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change."

He knew a thing or two about evolution.

So does the life-sciences industry — especially after last year when our ability to evolve was tested like never before, due to the global pandemic. COVID-19 created a maelstrom of change, stalling or halting clinical trials across the globe and forcing biopharma to immediately evolve to meet this global public health threat. Our industry delivered in record time by developing effective COVID-19 vaccines and, as a result, the future is beginning to look much brighter.

However, there is no guarantee of continued smooth sailing. The life-sciences industry must take every possible step to ensure the ongoing viability of clinical trials — in any situation. The clinical development process must be advanced and elevated in innovative and unprecedented ways in order to ensure that trials remain viable and can achieve their objectives. The solution lies, in great part, in the largely untapped potential of artificial intelligence (AI).

AI Informing Today's Clinical Trials

A lot of companies say they use AI in clinical development, and some do, but most biopharma companies largely employ AI in clinical research. The past decade has seen tremendous growth in industry adoption of valuable AI tools to inform research. AI typically comes into play with regard to performing manual, repetitive tasks, such as in drug screening, and copying data from one system screen to another. While there are a lot of opportunities for technology to help accelerate clinical development, AI remains largely under-utilized in clinical trials. As valuable as these resources are, they only just scratch the surface of this astounding technology.

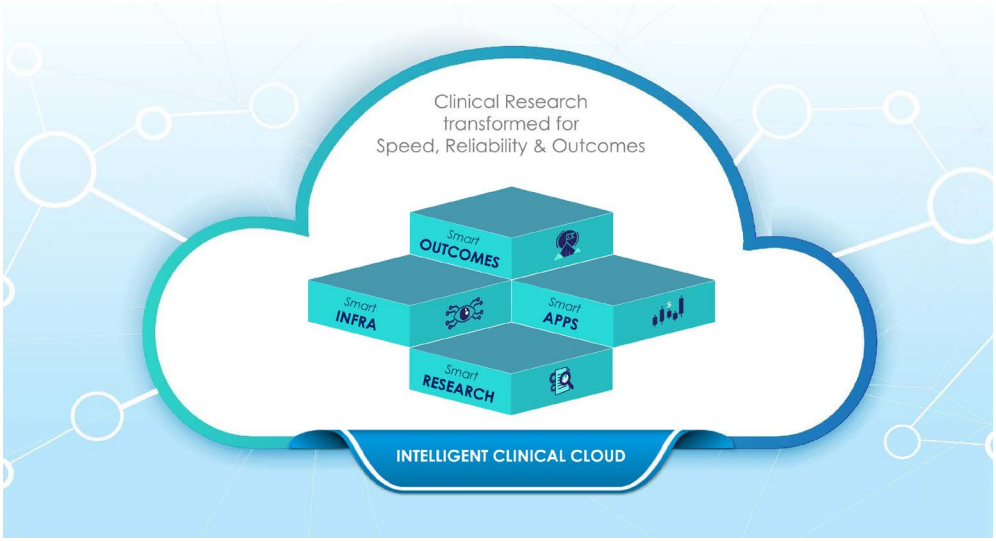
When we really lean into the potential of AI in drug development it becomes apparent what a powerful and exciting tool AI can be, when leveraged properly. Pfizer's development of its COVID-19 vaccine — the first to receive Emergency Use Authorization in the U.S. — is a prime example of AI in action. Pfizer applied AI to a number of stages of both vaccine trials and manufacturing. Significantly, the company leveraged a state-of-the-art ML tool to analyze data and find signals in its 46,000-person study and ensure that the data was available a mere 22 hours after primary efficacy case counts were met. This previously unheard of acceleration set a new industry bar for a process that historically takes about 30 days.

A similar path can be followed by forward-thinking biopharma as a new category of technology known as Intelligent Clinical Cloud (ICC) makes AI more viable in the clinical setting than ever before. This new category of purpose-built and intelligent infrastructure is bringing sustainable transformation for drug development via AI-based clinical insights and automation platforms that achieve scale, acceleration, and repeatability across therapeutic areas. AI can now go beyond simply making business processes more efficient to actually reducing cycle times of data as it flows into and informs decision-making, thereby improving the quality of those decisions with regards to business outcomes.

Such state-of-the-art automation platforms, infused with natural language understanding (NLU) and machine learning (ML), are informing real-time transactional systems for drug R&D. These solutions bring with them capabilities that include:

- Smart research to provide the reference framework and tools for sharing curated clinical insights
- Smart apps that are context-aware with humans in the loop to exchange insights across clinical processes and studies in a continuous learning mode
- Smart ops that are clinical-aware with clinical and operational data for scaling and automating complex tasks around onboarding, processing, and curating study data pipelines
- Smart outcomes that integrate traditional clinical workflows and processes

Though still fairly new, the application of AI to the data collected in clinical trials is yielding astounding insights. AI-powered chatbots harness natural language processing (NLP) and natural language understanding (NLU) to facilitate extraordinary conversa-



tional experiences for researchers with their clinical trial data. This ability to query data empowers researchers to overcome obstacles historically associated with clinical development. Increased efficiencies and cost savings are being realized related to critical outcomes such as patient recruitment, protocol adherence, prediction of study success, continuous process improvement, timely and accurate analytics insight, patient data privacy, and the ability to leverage previously untapped sources of data. By rendering these virtual assistants context-aware, AI reduces the cycle time needed for researchers to process and interpret data, accelerating the industry's ability to deliver safe and effective therapies.

AI is massively effective at reducing the "dead time" that bookends clinical trials, enabling sponsors to realize significant business benefits. By minimizing the study startup time prior to a patient receiving their first dose and compressing the time to FDA submission after the last study patient has been dosed, AI can positively impact sponsors' bottom lines. But these advantages are just the tip of the iceberg.

AI Re-Imagining Tomorrow's Clinical Trials

In terms of next-level clinical development efforts that will move today's clinical trial processes and biopharma business into tomorrow, AI will be integral to supporting the quantum, or next-generation, computing technology that will make the tantalizing possibility of in silico research a fact. Drug research performed by AI-powered computer simulation will truly revolutionize drug development. The concept of a full-body digital twin, while not yet a reality, is not all that far off. Already AI enables in silico research on individual organs, such as the liver, to assess safety and efficacy of potential drug candidates. The next step is a digital counterpart of the entire human body that enables clinicians to simultaneously evaluate how a prospective therapy will affect multiple organs. This digital twin would combine data from a spectrum of scientific and clinical resources to replicate human biology and its complex, interdependent systems. The ability to create digital twins would also catapult the concept of precision medicine to a new level by enabling personal patient models to be treated computationally with a variety of drugs to identify the therapy best suited for that individual.

The prospect of full-bodied digital twins translates to a world in which historical phases of clinical trials are no longer needed, and safety and basic efficacy of new therapies can be tested without the need for human volunteers. Analytics yielding such a clinical trial solution would ensure that, regardless of global health crises, clinical development would proceed uninterrupted and with a high degree of accuracy. New therapies would be introduced to the market having been tested and validated as safe and effective through AI. In silico research could conceivably yield drugs that could be brought to market for qualified patient engagement with a real-world testing label.

AI would inform this step of the process as well. Advanced active safety analytics engines currently available through cloud-based AI technology already use real-world surveillance and data to identify potential adverse events and safety issues associated with a particular drug. By mining resources like a patient's healthcare claims and electronic medical records (EMR), including their longitudinal history of medications, diagnoses, procedures, and labs, active safety analytics engines can flag new and unexpected safety signals that researchers might otherwise miss if not for the ability to leverage such real-world data (RWD). This powerful data science solution empowers drug developers to:

- Actively identify safety concerns during routine safety surveillance
- Understand the safety profiles of competitive products
- Identify all drugs associated with a specific outcome
- Explore potential causal relationships between drug/outcome pairs
- Respond rapidly and comprehensively to regulatory requests and potential findings

This AI-powered clinical trial solution renders moot sponsors' historical need to rely on voluntary, spontaneous reports and observational studies to understand a drug's safety profile after it reaches the market.

AI Redefined

AI in its purest form is ultimately a continuum of cognition. We've all seen the movies and read the books about the creation of cognitive-capable computers. Most of these stories usually involve some variation of AI taking over the world, to the detriment of humans. A much more compelling — and likely — scenario is one in which AI emerges as a previously unimaginable guiding solution, one that enables the betterment of humankind by helping to improve human health through drug discovery.

Though we are not quite there yet we are on our way and, like Darwin aboard the Beagle, we are guaranteed a thrilling voyage that yields unimaginable finds and opens up a universe of amazing possibilities. PV

Saama *is the No. 1 AI-driven intelligent clinical cloud company, enabling the life-sciences industry to conduct faster and safer clinical development and regulatory programs. Today, more than 50 biotech companies use Saama's award-winning Life Science Analytics Cloud (LSAC) platform on more than 1,500 studies, including many of the top 20 pharmaceutical companies.*

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