Leveraging Patient-Centric Data Analytics to Accelerate Clinical Trials

e are all familiar with the figures — it takes over a decade and \$2.6 billion to bring a new drug to market. While these objective statistics are daunting and do give pause, almost every life science professional will agree that they don't begin to tell the true story of the human element below their surface.

In the 10 to 12 years that it takes to develop a new drug, more than 16 million people in the United States alone will die from heart disease, cancer, respiratory disease, stroke, and Alzheimer's, resulting in debilitating healthcare costs, causing exorbitant rates of lost income, and creating untold grief. Fathers, mothers, friends, grandparents, children. Heartache, sorrow, financial hardship.

The life sciences industry has both the honor and burden of addressing this global problem. Fortunately, more than at any other time in our industry's history, we are well positioned to positively influence human health and change these statistics by leveraging technology — technology that barely existed when the drugs being brought to market today first entered development. Artificial intelligence (AI)-powered data analytics are simultaneously expediting clinical trials and putting novel, new therapeutics into the hands of the healthcare practitioners who treat and the patients who battle these debilitating diseases, faster than ever before.

AI-Fueled Data Analytics in Life Sciences

The life sciences industry is embracing and leveraging big data in unprecedented fashion. As a May, 2019 report by the Tufts Center for the Study of Drug Development indicates, biopharma is adopting and utilizing AI on numerous fronts:

- Over 60% of clinical operations functions leverage AI.
- AI is being deployed across therapeutic categories, including oncology, central nervous system (CNS), cardiovascular, immunology, rare diseases and metabolic/endocrine diseases.

- AI is also being leveraged in functions such as pharmacovigilance/safety/risk management (57%) and information technology (55%).
- Precision medicine and targeted therapies will further drive exponential AI utilization; 59% of respondents will expand AI staff through 2020.

However, despite this clear trend to accepting and adopting AI, biopharma is faced with some steep challenges before the industry as a whole can realize the optimal returns that will translate to therapeutic improvements for the patients who are in such desperate need. Lack of adequate staff skills, difficulty in adapting unstructured data, and insufficient budgets all hinder AI adoption and deployment in life science settings.

This is where data analytics partners can help. A qualified data analytics partner brings a variety of benefits to the table that enable sponsors to overcome these and other obstacles to leverage AI solutions that accelerate clinical trials. Unified, AI-enabled clinical data analytics platforms seamlessly integrate, curate, and animate unlimited sources of structured, unstructured and real-world data to deliver more actionable insights across a variety of therapeutic areas. Such platforms provide unprecedented control of an organization's data, and dramatically decrease the cost and time of drug development.

Sponsors can realize previously unattainable, enterprise-level views of the raw data across their disparate business silos, unleashing insights that provide the power to see around corners for confident business decisions that yield better business outcomes. By leveraging and optimizing Deep Learning/AI technologies that challenge the status quo and evolve data solutions to generate clinical insights in days versus months, drug development timelines can be reduced by up to 26 weeks, expediting the delivery of breakthrough therapies to the patients who so desperately need them.

Unique new AI-informed platform features extend the promise of these solutions even further. Virtual assistants shift the human-computer interaction paradigm by enabling context, domain, and intent-aware conversational



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user interfaces to provide rapid clinical operations insights. Advanced capabilities that track key performance indicators (KPIs) manage and help mitigate operational and financial risks, enabling decisions and course corrections before obstacles delay trials. And features designed specifically for tracking drug efficacy and patient safety enable simultaneous analysis of up to 50 variables, rendering the need for manual data analysis obsolete, and contributing to significant savings in clinical trial staff time and effort.

The technology outlined above, as well as the implicit expertise behind its development, are of course critical to any successful AI data analytics solution deployment. However, efficacious implementation of these advanced platforms hinges on a data analytics partner's ability to execute them rapidly and objectively.

Agility and Agnosticism

Analytics innovators embody what can be thought of as the two As: agility and agnosticism. These unique qualities ladder up to an eagle-eyed and streamlined view of the life science industry's raison d'etre: developing therapies to improve human health and cure disease. Data analytics organizations bring these attributes to their partner relationships, helping to ensure that platforms and solutions unfold correctly and are utilized optimally to maximum health outcomes.

Agility. Referring to both speed and flexibility, agility encompasses the ability of data analytics companies to offer both timely activation of solutions for their life science partners, as well as the ability to implement nimble and flexible platforms that maximize data and ensure cooperation and collaboration among various departments within a company. Groups are empowered to work together as a single team to resolve challenges quickly, in real time.

Unfortunately, a discrepancy exists in the

life science industry between the promise of data analytics activation timelines and the reality of inevitable, associated delays. Activation timelines that are not met lead to lost revenue and compromised clinical progress, frustrating sponsor partners and leading to dissatisfaction before a solution is even deployed. The newest AI-powered data analytics solutions are overcoming this problem, speeding the onboarding of biopharma partners, and enabling data analytics companies to offer implementation and activation guarantees.

Speed, without compromised efficiency or safety, is clearly of the essence in bringing new drugs to market for the patients who so desperately need them. The Leukemia & Lymphoma Society (LLS), the world's largest nonprofit dedicated to fighting blood cancers, recently partnered with a leading data analytics company to accelerate the development of novel acute myeloid leukemia (AML) therapies through its unprecedented Beat AML Master Clinical Trial. LLS will deploy a state-of-theart AI platform to enhance the operational and clinical conduct of the ongoing, multi-drug, multi-site precision medicine trial. Agility and speed are of critical importance to LLS. AI-informed data analytics will provide rapid insights into clinical data that will advance their study operations with the goal of expediting new treatments for a patient population that has not seen progress in decades.

The flexibility inherent in such agile solutions rectify previous inefficiencies in how data was managed and processed. Historically, the issue of agility around data falls into two key categories: too much data and not enough data. Patient monitoring devices are producing over 86,000 readings per day. An Intel study estimated that 70% of clinical trials will use wearable technology by 2025, and that there are 200 billion data points in a typical phase 2 trial that runs for six months with 100 patients. Conversely, there is not enough data, which leads to longer trial timeframes. A tremendous amount of unstructured data remains untapped, and it's estimated that 80% of healthcare data is unstructured. Not being able to access and use this data leads to delays in patient recruitment, site inefficiencies, and patient engagement and retention, all of which are of critical importance to clinical



trial success and therapeutic development. While pharma has a big data problem, it actually has a bigger text problem. There's lots of untapped wisdom sitting in biomedical texts and in electronic health records (EHRs) and medical notes.

Elligo Health Research is tackling this problem head on. Last year, Elligo partnered with a leading data analytics company to support its proprietary Goes Direct model, which engages physicians and their patients by first identifying patients using electronic health records and then providing their physicians with the infrastructure to conduct the research in their own offices, at no cost to them. AI-enabled analytics will accelerate the identification of eligible clinical trial patient populations and improve awareness of, access to, and participation in clinical trials for U.S. physicians and patients. The partnership will help resolve the challenges sponsors face when they must assemble vast amounts of data from disparate sources.

Virtual clinical trial companies are also partnering with data analytics innovators to flex their speed muscles. Designed to achieve better trial results at lower costs in faster timeframes, virtual clinical trials — as well as hybrid trials combining visits to traditional investigator-staffed sites with patient data from wearable and digital technology — can be greatly optimized by AI-powered analytics. Such partnerships benefit the emerging market virtual trial players, but the true winners will be the patients who have a more frictionless clinical trial experience and who ultimately are on the receiving end of the products developed through these research efforts.

Agnosticism. A crucial component that data analytics companies bring to any partnership, and one that is often overlooked, is objectivity. Data analytics partners have the ability to sit in the middle, between sponsors and CROs, life science companies and insurance organizations, disease and health. Like Switzerland on the global political stage, data analytics companies bring a wholly unbiased, non-partisan perspective to drug development, access and reimbursement, truly facilitating patients-first processes.

Such neutrality offers significant value at this particular moment in time. A certain degree of distress and distrust have accumulated among the various arms of the life sciences industry, as well as between life science organizations and external partners, such as insurance companies. In such situations, data analytics partners can function as a trusted third-party to adjudicate value-based contracts between payers and pharma, a trend that is increasingly being embraced by both industries. Due to a data-agnostic perspective, data analytics innovators are ideally positioned to help maximize benefits and minimize challenges for both pharmaceutical manufacturers and insurance companies when negotiating value-based contracts. Insights afforded by AI-powered platforms that gather data with a view of patients-as-priority can inform value-based arrangements that pay for therapeutic results, not prescribing activity. Such an ability paves an exciting, evidenced-based path forward for the life sciences industry.

The benefits of agnosticism are also apparent when one considers organizations like LLS. As the world's largest non-profit dedicated to fighting blood cancers, LLS has the luxury of focusing on outcomes versus bottom lines. When partnered with a data analytics innovator in its objective pursuit to realize its mission, as described above, LLS's power is amplified, its impact maximized and its results optimized.

AI-powered data analytics are empowering pharmaceutical and biotech companies to create and conduct patient-centric clinical trials that expedite the development and availability of therapeutics to improve patient health. By virtue of its agility and agnosticism, data analytics moves the clinical development needle forward, bridging industry challenges while retaining a focus that is squarely on patients, and bringing better drugs to market faster.



Saama Technologies is the advanced clinical data and analytics company, unleashing wisdom from data to deliver better business outcomes for the life sciences industry. Saama's unified, AI-driven clinical data analytics platform seamlessly integrates, curates, and animates unlimited sources of structured, unstructured, and realworld data to deliver actionable insights across all therapeutic areas.

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