AI and Healthcare:
From Potential to Powerful Solutions

In recent years, healthcare and pharma companies have been increasingly investing in the promise of artificial intelligence (AI), machine learning (ML), and other smart technologies. It's estimated that the global market for AI healthcare will grow to as much as $27.6 billion by 2025.[1] This growth is being driven by the opportunity and need to innovate and revolutionize areas like drug development, disease diagnosis, and treatment.

While we continue to see promising successes, some early projects have fallen short of the initial vision. Applications of AI and ML face difficult but surmountable challenges in healthcare. The landscape is defined by complexity, constantly changing regulations and demands from health authorities that require deep expertise to navigate. The stakes are high; in some cases, failure could lead to inaccurate recommendations or safety risks for patients.

Many life-sciences leaders believe their organizations lack the skills needed for consistently effective AI implementation. They also face mounting privacy and ethical concerns, and questions remain about the right balance of human involvement and insight with automated processes. Some leaders, while optimistic about the promise of AI, are still skeptical about how much it can really do for the industry.

In some cases, we have seen that technical expertise alone doesn't consistently deliver AI solutions that work for pharma. To succeed, these solutions must be led by companies that take an approach that integrates human science with breakthroughs in data science and technology — Human Data Science.

Human Data Science combines the best in technological and analytical capabilities with the right data and healthcare expertise to help companies make better, more insightful decisions. This approach can help enable the powerful AI-driven solutions life sciences companies are looking for and provide confidence that they have been purpose-built to accommodate the needs of the entire healthcare ecosystem — from patients and physicians, to payers and regulators and data privacy and ethics.

In an ideal world, the healthcare industry would be able to ensure we are reaching as many datapoints as possible to establish predictive models that help people, even before they become patients. At the outset of drug development, AI can comb through thousands of potential compounds to identify molecules that

have the greatest potential to deliver safe and effective treatments and new potential indications. As research moves forward, ML algorithms can prioritize which molecules to move forward using simulated trial outcomes and optimize site selection to accelerate progress. AI capabilities will continue to create opportunities to move to more personalized disease prevention and to ensure patients get the right diagnosis and treatments as early as possible.

The industry is beginning to scratch the surface of what AI can do for pharma. When companies take a holistic approach to AI, they will be even better positioned to advance human health. The following highlight just a few key examples of where AI solutions are showing increasing promise and beginning to deliver real value today.

Disease Screening

ML algorithms are built to answer specific questions such as, "which new patients are likely to develop this disease?" by learning the patterns in vast databases of patients who already have the disease. The more the algorithms are used in new patient data, the more accurate they become. But finding the best solution often requires more than just well-trained ML.

IQVIA conducted an early AI study of patients with tuberous sclerosis complex (TSC), a rare disorder that causes benign tumors to form throughout the body and cause seizures, kidney failure, epilepsy and death. Using a database of 5 million nonidentifiable patient records, the team tested four approaches to determine the impact of ML on accurate diagnosis. The approach that used a combination of both ML and clinical domain expertise achieved the highest accuracy at one-in-five patients accurately diagnosed with the disease.

While diagnosing rare diseases like TSC is often extremely difficult, it's the combination of the right data, ML and human healthcare expertise that will yield the most promise for patients. Even deep learning that relies less on domain experts is showing lift from incorporating domain knowledge into healthcare algorithms.[2]

In recognition of the increasing importance of AI in predicting disease, the FDA has proposed a new framework for modifications to AI/ML-based software and has already approved multiple AI-based algorithms for disease diagnosis.[3] As we continue to expand our use of algorithms in this

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area, even more important than applying domain expertise to the construction of algorithms will be feedback from experts on how to effectively operationalize any findings in clinical practice. Effective Human Data Science should ensure that the algorithms being generated ultimately benefit patients as well as physicians.

Clinical Trial Augmentation

Less than 14% of all drug development programs lead to approval.[4] The financial cost of trial failure can be enormous, and a failed trial could mean a potentially lifesaving drug isn't available to patients.

In studies where trial results are negative or inconsistent, AI-driven analyses can ensure sponsors are aware of the patient populations in a given trial most likely to experience positive outcomes from the drug. Using ML algorithms, it's possible to analyze trial data to identify predictive biomarkers in treatment populations who are experiencing these positive outcomes. These can be used at various points to inform trial design by identifying trends and outliers without bias. This approach can improve patient safety, reduce liability risks and increase approvals.

In a recent project, IQVIA worked with an emerging biopharma company running two phase III global trials to evaluate the safety and efficacy of a new drug versus standard of care for treatment of hospital-acquired bacterial pneumonia (HABP) due to gram-positive pathogens.

The company's own initial analysis found no overall treatment effect. However, an analysis using IQVIA's AI-driven approach retrospectively identified 26 biomarkers that were predictive of positive treatment effect. It also identified characteristics indicative of reduced treatment effect in the complement subgroup due to a safety

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concern that could be mitigated. Thanks in part to this analysis, the FDA approved the new drug with a black box label for challenging cases when alternative treatments are not suitable.

Site Selection Optimization

Identifying trial sites and gaining access to enough patients who meet inclusion and exclusion criteria are among the biggest obstacles in clinical research. Industry estimates indicate that well over half of all clinical trials face delays for these reasons. AI and ML solutions can mitigate these risks by mapping patient populations and optimizing protocol designs to predict which sites will deliver the most patients, then identifying the best avenues to recruit them.

In one global oncology study, IQVIA analyzed disease and region-specific healthcare data to more accurately locate patient pools then link them to research sites and physicians — even if those sites and physicians had never participated in clinical research. This allowed the sponsor to hone site-selection for better recruiting results. When companies effectively apply AI to optimizing their trials, they can experience up to 40% faster site identification and up to a 30% faster recruitment rate compared to using traditional methods.

Efficiency in Pharmacovigilance (PV)

The volume and complexity of adverse event (AE) data is increasing. From 2014 to 2015, the FDA saw a 32% increase in AE reports, and this trend is continuing.[5] Disparate and emerging global regulations, unstructured data sources and mounting pressures from payers and regulations have created the need for innovative solutions that both scale operations and improve cost efficiencies.

Healthcare has already begun to apply AI to PV applications to drive time and cost savings

while reducing errors through the basic automation of manual tasks. Innovations in cognitive computing and natural language processing (NLP) have enabled faster, more accurate identification of possible AEs from structured and unstructured data sources.

Expert PV intervention is essential to adjudicate each possible instance of an AE, but these automated approaches can reduce the need for PV review by 70%. Recently, a large pharmaceutical client successfully applied IQVIA's AI-driven auto-narrative template to thousands of case cycles from a portfolio of varied products. The change resulted in a 90% reduction in manual intervention, producing significant cost savings.[6]

The insights derived from using AI for PV tasks have led to faster assessment of subject, site and study risks and overall study performance by domain experts, enabling project leads to drive efficiencies while improving patient safety. Not only can this approach to pharmacovigilance reduce the need for human time and effort, the project lead's focus can be redirected to higher-value medical safety analysis or enhanced benefit-risk management.

Brand Management

When a product is approved for multiple indications, understanding why a physician prescribes it contributes to successful brand management. However, many brand performance data assets only report total prescriptions over time and can't track at an indication level.

To overcome this barrier, the IQVIA analytics team built an algorithm that analyzed electronic medical records and longitudinal prescription data to predict why a given drug was being prescribed for particular patient profiles. In 2018, a global healthcare company deployed an AI solution based on this algorithm to understand how their brand performed across different indications and against their competition.

The commercial team used the results to

more accurately target physicians with messaging for the disease they were most likely to treat. They were also able to track indications over time based on region and specialty, identify and address gaps in performance with enhanced resource planning and better predict future demands.[7]

AI's Promise For The Future

Leaders are understandably eager to benefit from fully automated data management systems and algorithms that can successfully diagnose rare diseases, identify highly specific patient populations, improve safety or speed time to market for a life-saving drug. And while that is all possible, realizing these visions requires the right combination of data volume and quality, technology, analytics and healthcare domain expertise.

One of the biggest challenges companies face in adopting AI has been convincing teams to change their approach and trust the insights these technologies deliver. It can be difficult to reconcile discrepancies between years of human expertise and the suggestions of an algorithm. AI works best as an augmentation to human expertise rather than a total replacement. By embracing AI as an integral part of Human Data Science, the healthcare industry will be better positioned to avoid past mistakes and realize the full potential and power of these capabilities to advance human health. **PV**

Editor's Notes:
[1] https://www.researchandmarkets.com/research/qtchdc/27_6_bn?w=12
[2] https://www.ijcai.org/proceedings/2019/0825.pdf
[3] https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device
[4] https://academic.oup.com/biostatistics/article/20/2/273/4817524
[5] https://www.ismp.org/sites/default/files/attachments/2018-01/2015Q4_0.pdf
[6] https://www.iqvia.com/library/white-papers/how-to-future-proof-your-pharmacovigilance-delivery-model
[7] https://www.iqvia.com/library/white-papers/leveraging-artificial-intelligence-and-machine-learning-to-drive-commercial-success

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