Life Science Leader

HOW AI IS TRANSFORMING THE LIFE SCIENCE SECTOR - PART 2

How artificial intelligence has the potential to disrupt and revolutionize many aspects of clinical trials.

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6 WAYS AI IS TRANSFORMING THE LIFE SCIENCES (ALREADY)

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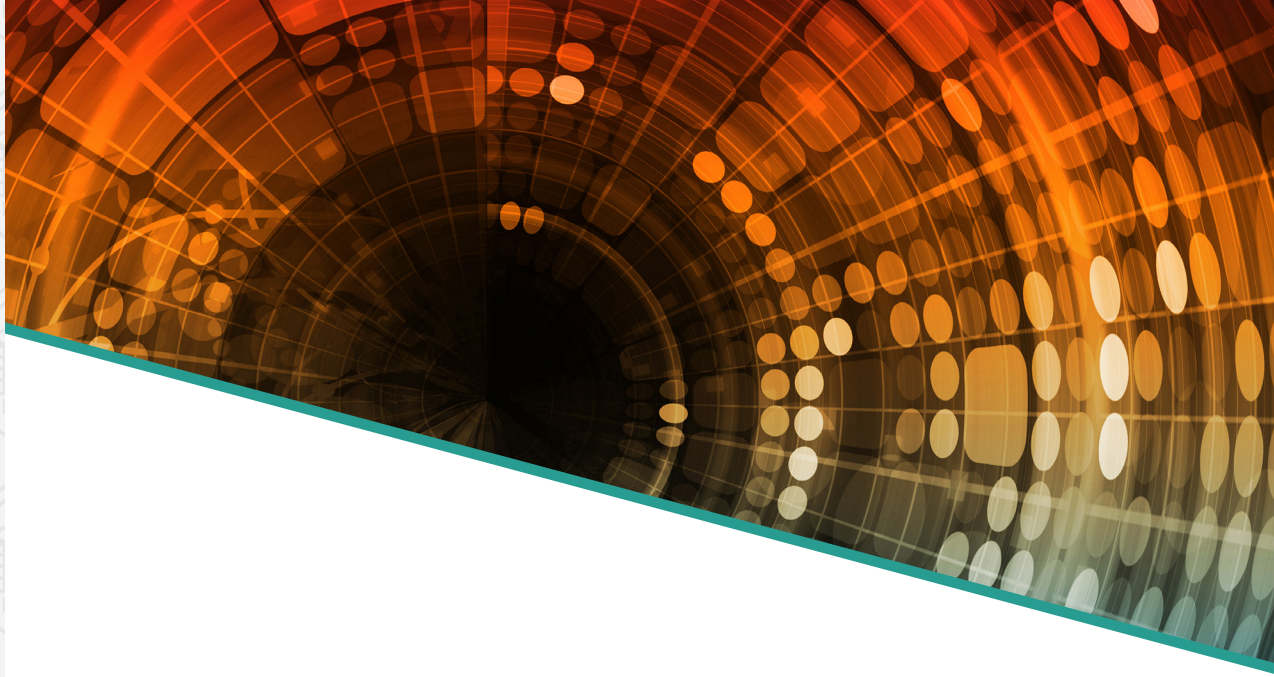

Most in the life sciences agree that artificial intelligence (AI) will reshape the sector from R&D through commercial. Although AI has only just left the starting gate and most activity is in exploratory phases, some benefits are starting to emerge. And there are pockets of early adopters trailblazing new approaches and seeking a competitive edge to accelerate products to market, improve patient outcomes and care, and drive cost efficiencies.

We have been studying AI early adopters and will explore how life sciences firms already apply AI in their organizations and how you can start to push your organization to explore a future not yet imagined.

UNDERSTANDING THE KEY COMPONENTS AND CAPABILITIES OF AI TECHNOLOGIES

Before we begin, it's important to have a common language and understanding of what we mean when we say, "AI." Is AI the same as machine learning? Where does robotic process automation fit? Oxford dictionary defines AI as "computer systems able to perform tasks normally requiring human intelligence such as visual perception, speech recognition, decision-making, and translation between languages."

From our perspective, AI can be viewed along a spectrum. On one end there is rule-based automation. At some point, someone said the water block in a toilet is artificially intelligent; it knows exactly when to open the valve to let water in and exactly when to stop doing that. That's an intelligent process. It is rule-based automation: if X, then Y. And there are people who say AI is just lots and lots of business rules, and if you have all the rules then you have a system that is intelligent. From our perspective that is where robotic automation, business process management systems, and rule-based management systems would sit. Think of this as things you get bored doing at work and would like to automate away.

Rupen Mehta
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On the other end, you have technologies such as natural language processing (NLP), machine/deep learning, chatbots, and virtual agents. NLP focuses on the interaction between computers and humans through language, from deriving meaning and sentiment from speech and text to generating language-based responses. Machine/deep learning uses historical facts to uncover patterns in that data, i.e., teaching an algorithm to recognize patterns and with the hypothesis that whatever happened in the past is a good predictor for the future. And AI mimics the cognitive functions of a human, building rules that are adaptable on the fly. In the end, AI is about making decisions. Yes, it's making sense of a visual image, a sound, or speech, but it's the decision-making that is important.

Stephen Moorehouse
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EXPLORING THE "ART OF THE POSSIBLE" FOR AI TO ACCELERATE PRODUCTS TO MARKET

There are numerous areas where the life science industry uses AI effectively today. The following sections describe six of those areas.

1. ADVANCING DIAGNOSTICS

Histopathology image analysis and automated diagnosis were ripe for AI, given the technological progress in digitalization of complete histology slides, which permit all microscopic magnifications. AI and pattern recognition, combined with complex algorithms and automated immunohistochemical measurement systems, have advanced pathologists' ability to oversee the analysis and concentrate on more-difficult cases.

2. ADVANCING RESEARCH OF NEW PRODUCTS

Life sciences companies are exploring how AI can be leveraged to identify new indications for existing products or research new candidates. Examples include, but are not limited to:

Using sophisticated learning algorithms to mine real-world structured and unstructured data to uncover insights can lead to the identification of new mechanisms of disease, potential new line extension, and design for preclinical experiments.
Knowledge gaps of how candidates act on proteins to aid design of new drugs can be filled.
Knowledge can be extracted in real time from commercial, scientific, and regulatory literature, allowing researchers to identify competitive white space, eliminate blind spots in research, and discover disease similarities.

3. ACCELERATING DRUG DEVELOPMENT

Across the industry, product development timelines range from seven to 10 years from discovery to launch, with sights set on reducing them to five to seven years. Advancements in AI and machine learning to reduce the time it takes to develop, manufacture, and launch new patient therapies support the goal of reducing overall product development timelines. Scientists are integrating research data, lab data, and clinical data, in combination with new information sources (e.g., social media and wearables) across the drug development spectrum, creating a holistic picture of the drug development candidate. Improving ways to acquire and mine data in

real time allows scientists to use AI and machine learning to make improved decisions faster, which will accelerate the product development and scale-up process.

4. DRIVING COMPLIANCE IN CLINICAL TRIAL TRANSPARENCY

Compliance is often a burden on companies and requires an approach to mitigate costs while meeting regulation. The European Medicines Agency's policies 0070 and 0043 are examples of regulations that have recently been introduced requiring companies to anonymize or redact patient information in clinical submissions. While generalist automation tools are available, many do not satisfy the accuracy needed to meet the policy's requirements. New applications are emerging utilizing advanced algorithms based on customized NLP technologies incorporating scientific-specific taxonomies and text-mining models. Using these advanced models, it is possible to identify keywords, phrases, and data patterns (such as adverse event dates) that may require redaction or anonymization. These new applications provide the higher level of accuracy required to meet the policy requirements while also automating manual activities.

5. IMPROVING CLINICAL SITE SELECTION AND ACCELERATING PATIENT IDENTIFICATION

Nearly 80 percent of clinical trials fail to meet their patient enrollment deadlines. Combining unanalyzed historical structured and unstructured clinical trial data into advanced AI models can improve and accelerate clinical site and patient selection decisions by highlighting high-probability targets. Continuing to use advanced AI models during active clinical programs enables real-time adjustment and course corrections. Engaging high-probability success targets at clinical trial onset in combination with a willingness to make real-time course corrections increases the likelihood of meeting patient enrollment timelines.

6. OPTIMIZING SUBMISSION DATES USING MACHINE LEARNING/PREDICTIVE ANALYTICS

Life sciences companies are responsible for up-to-date information on the safety

of their products. Pharmaceutical labels (e.g., package insert, patient information leaflets) are an important way to communicate safety information. When an update to the reference label is necessary for safety reasons, there are multiple considerations (e.g., artwork printing, production run dates) for submitting the local product label to the corresponding health authority. Most companies' SOP timelines that govern submission due dates are more stringent than what health authorities require, thus increasing workload and cost. Combining and connecting the appropriate data points with machine learning and predictive analytics can determine an optimal submission date.

HOW TO START INCLUDING AI AND AUTOMATION

AI represents an opportunity for life sciences companies to radically transform business at all levels — organization structures, processes, and people. However, given how extensive the opportunities are, an overall vision is needed to shape what you want to accomplish. We recommend companies to think big, start small, and scale fast.

THINK BIG

Identify what you want to achieve by employing AI and automation technology throughout the business. Setting a strategic direction is pivotal. Define your business needs and assess the maturity of your organization against your ambition. This identifies the gap and roadmap to reach the desired maturity. Scenario planning provides tools and techniques that help to actively explore, influence, plan for, and manage the future. It can help to explore plausible futures informed by current trends and emerging signals of change. This approach is most effective when it is highly personalized to your organization, function, or team's future, rather than a generic one.

START SMALL

Try it out; experiment. See what works and what needs adjustment. Prioritize use cases on effort and value, challenging them by defining clear hypotheses. Success-

ful use cases result in algorithms or models that can be quickly adopted as a new way of working.

SCALE FAST

Build upon the successes of your experiments. Excite the people and organization around your successes. Catalyze the change your organization needs to truly become data- and AI-driven, embrace this transformation, and expand and grow the number of AI initiatives.

Roles will change, skillsets will need to be learned or acquired, new business opportunities will present themselves, and new relationships with vendors and business partners will be required. The growth of AI in life sciences presents an opportunity to take advantage of newly available data and technologies. Patients should be optimistic that new therapies and medicines can be discovered, developed, and made available faster than ever before. ▪

AI SPEEDS PATIENT RECRUITMENT AT HEALTH QUEST

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Artificial intelligence (AI) has the potential to disrupt and revolutionize many aspects of clinical trials. One area in which it is already making an impact is patient recruitment. Mining electronic medical records (EMRs) for patients meeting inclusion and exclusion criteria can be tedious and time-consuming work but is a chore that seems ideal for an AI solution.

Health Quest is a four-hospital nonprofit system operating in New York's Mid-Hudson Valley and northwestern Connecticut. The group recently signed an agreement with IBM Watson Health to start matching its patients to clinical trials for which they may be eligible.

Health Quest began working with IBM Watson in early 2019 on a program to help with population health management. Health Quest needed access to real-time patient data to meet quality-based performance benchmarks and was able to use Watson Health to consolidate disparate data from across practices and departments. The result of that effort was the closure of gaps in care and the generation of $3.7 million in billing revenue.

"That success led us to start evaluating other ways that we could use the technology to become more efficient and effective," says Dr. Glenn Loomis, Chief Medical

Operations Officer at Health Quest. “One area that we felt would be an easy win for us was clinical trial matching. That refers to using the program (including natural language processing) to look through the medical records of cancer patients and determine what cancer trial they are a best match for.”

Glenn Loomis
Chief Medical Operations Officer
Health Quest

Although that may sound like a rudimentary task, Loomis states it is not. The old model was difficult and time consuming and required Health Quest to pay nurses to spend hours going through medical records and trial information, trying to determine which patients were the best fit for trials that were recruiting. Even if the nurses were successful in that endeavor, they were only qualifying patients for the trials they were aware of. There were many trials, including some that would be a better fit for the patient, that the nurses might simply be unaware of.

Ed Miseta
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“The clinical trial software will allow us to qualify more patients for more trials, and do it in a much timelier manner,” says Loomis. “We will also be matching them to the best possible trial for their particular cancer and for their particular circumstance. Some of those trials will be within our own organization and some may be trials that we are not offering. Regardless, we are looking for the trial that will provide each patient with the best possible treatment available and give them the best chance for an optimal outcome.”

PRECISION MEDICINE COMPLICATES RECRUITMENT

The growth of precision medicine treatments has certainly made clinical trials more complex. This has also put additional inclusion and exclusion criteria in place for pa-

tients. While the newer treatments being developed present a greater likelihood of success for patients, it also creates additional work for those attempting to locate patients.

Loomis notes this is a big part of the reason why hospitals require a lot of individuals working a lot of hours to comb through medical records in order to locate the right patients for a study. Even when you locate qualifying patients, there is no way to know if you are connecting them with the most optimal trial for their situation. What makes them the perfect candidate for a trial is dependent upon their individual situation, their type of cancer, and other conditions they may be dealing with. It is very difficult, if not impossible, for a human to be able to review and digest all that information.

The AI solution, called Watson for Clinical Trial Matching, is a cognitive computing system programmed to match patients to trials for which they may be eligible. Information on patients can be input, along with a complete catalog of all available trials and their inclusion/exclusion criteria. The system will then report the best available trial for that patient. That trial could be within Health Quest, another local hospital, or a large cancer center Such as MD Anderson in Houston. Clinical Trial matching has already been shown to cut patient screening time by 78 percent. In breast cancer trials conducted at the Mayo Clinic, it drove an 84 percent increase in enrollment in the first 18 months after implementation.

Health Quest always attempts to get patient consent upfront. Patients are asked in person or via email if they have an interest in participating in a clinical trial if one can be matched to their condition. Once the consent is received their records can be examined and matched to potential trials.

“At one time, many clinical trials were only available to patients at large hospitals and healthcare centers in major urban areas,” says Loomis. “We are very excited about the ability to now offer this same level of care to patients in the mid-Hudson Valley.”

SOLVE THE PATIENT RECRUITMENT BOTTLENECK

Patient recruitment remains a problem for researchers, but Loomis believes AI and efforts like the one underway at Health Quest will be a big part of the solution. A lot of time and money are spent trying to find trials that are the best match for a patient. Doing so in a more automated fashion makes that task far easier for both clinicians and patients.

“AI is helping us match patients to the right trial, but it will also make it much easier for us to get patients interested and involved in trials,” adds Loomis. ‘We know we have patients who would like to be involved with a trial, but for whatever reason are unable to locate the right trial. At times we also did not have enough resources to devote to helping patients find the right trial. AI will make that process easier for us and allow us to bring more trials to more patients.”

AI is part of a broader strategy for the Health Quest system. Loomis sees AI as a tool that will become a large disruption to both medicine and clinical trials. Health Quest is now making an active push to incorporate the technology into many aspects of its system to make the network more efficient and effective. Clinical trial matching is seen at this time as just the starting point for that strategy.

Loomis points out the fragmented nature of electronic health records as one area where AI can create efficiencies. He notes the technology can scan those records and provide information to clinicians at the point of care. He believes that is the area where AI has the potential to really shine. For example, a natural language processing engine scanning through all notes on a patient and providing insights to that information in one location. AI is also able to take that information, compare it to databases, and bring back recommendations for best practices.

“What we are doing now is a very early use case for AI,” says Loomis. “We are taking patient information and comparing it to trial information. I see this as a very early indicator of things we will soon be able to do in a much bigger way.” ▪

TALKING THE TALK: HOW AI-INFORMED VIRTUAL ASSISTANTS ARE CHANGING CLINICAL DEVELOPMENT

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The pharmaceutical industry as we know it today has roots that reach back to the apothecaries and pharmacies of the Middle Ages, when drug discovery largely involved sourcing plants and herbs for natural remedies and drug development and testing was an unstructured concept that relied on the hit-or-miss reactions patients experienced.[1] Failure was arguably more common than success and, unfortunately for the patients, treatment courses often did not yield optimal results.

The era of modern drug discovery and development arguably began with the breakthrough discoveries of insulin by Frederick Banting and colleagues in 1921[2] and penicillin by Alexander Fleming in 1928.[3] In almost a century since, and especially from the 1950s forward, clinical development has proceeded at breakneck speed, guided by rigorous and specified scientific protocols and aided by breakthrough technologies that enable and realize previously unimaginable progress.

AI MAKES RESEARCH FASTER, MORE EFFICIENT

One of the most exciting advances in clinical development is the relatively recent use of artificial intelligence (AI)-informed virtual assistants to guide and accelerate drug discovery. Until recently, analyzing the massive amounts of information

generated in any clinical trial required a considerable amount of labor-intensive, resource-consuming effort. Site- and patient-level data tracking was a cumbersome process, often requiring days to secure resolutions of queries. Needless to say, this belabored route had huge potential to negatively impact timelines and costs of clinical development.

The advent of advanced data analytics tools and solutions that leverage AI has changed the clinical development landscape. Leading data analytics companies have engineered cutting-edge, AI-informed virtual assistants that are changing the rate at and efficiency with which the life sciences industry conducts clinical research and propelling drug discovery and development to new heights. Such virtual assistants — think of them as the clinical development cousins to Amazon's Alexa, Apple's Siri, and IBM's Watson Assistant — do for drug development what those other chatbots do for our personal and professional lives: access information faster, enable progress, and accelerate productivity.

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In today's life sciences industry, such advantages are critical. Historically, pharma and biotech have had difficulty achieving clinical trial milestones, often experiencing a large chasm between targeted outcomes and actual results. The majority of global leaders in clinical operations rank patient recruitment (95 percent), site productivity (75 percent), and patient compliance (65 percent) as very important, but they are often unable to achieve these milestones. Only 47 percent report successful enrollment, 22 percent say their sites are productive, and 25 percent consider patient compliance efforts successful.[4]

AI-based virtual assistants are poised to change those outcomes. Virtual assistants are shifting the human-computer interaction paradigm, enabling clinical operations professionals to obtain more specific insights, faster than ever before, about the clinical trials they are running. Such knowledge goes a long way toward alleviating the planning, feasibility, and conduct challenges inherent in and pervasive throughout the drug development continuum.

THE ABILITY TO ASK DATA FOR ANSWERS

Through AI-powered virtual assistants, researchers can essentially "speak" to their data, asking questions and receiving responses about various aspects of study conduct. Because these virtual assistants are designed to focus exclusively on the domain, or subject area, of study conduct, they will not respond to extraneous queries about unrelated topics, such as the weather. They will, however, provide specific and detailed responses about a particular clinical trial. To properly answer a question, virtual assistants establish the context of a query, which is a combination of interpreting what a researcher wants to know (the intent of their question) with the full set of possible parameters or entities, such as names of people, organizations, locations, expressions of time, monetary values, etc. Once armed with such an understanding of the question at hand, which takes only seconds, virtual assistants mine available data about a trial to respond. As an example, if a clinical operations director wants to start their day by assessing the health of their portfolio of studies, instead of reaching out to a number of trial leads, he can simply ask his virtual assistant to display the portfolio risk chart. Follow-up questions about a particular study might include the following:

- What is the approved budget?
- What is the actual spend?
- How many subjects are enrolled?

These unique conversational experiences are much more dynamic than the traditional approach relying on canned analytics dashboards, and today's virtual assistants can remember the context of previous inquiries and seamlessly enfold new entities into the discussion to provide rapid clinical operations insights.

BENEFITS THROUGHOUT THE DEVELOPMENT SPECTRUM

The benefits to clinical operations professionals and the impact on trials are enormous. Delays in starting up a study can have major cascading downstream effects, so being able to monitor startup progress in real time can avoid multiple complications. Additionally, key performance indicators (KPIs) can be tracked and managed

to mitigate operational and financial risks, identifying obstacles and enabling decisions and course corrections before trial delays occur. 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. Increased efficiencies and cost savings can be brought to bear on 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.

AI-informed virtual assistants let pharma and biotech talk the talk — literally. Such unprecedented conversational experiences with clinical trial data are shifting the clinical development paradigm for good and for the better, overcoming obstacles historically associated with clinical development and enhancing the life sciences industry's ability to deliver safe and effective therapies.

AI-based technology was likely unfathomable to Banting and Fleming — imagine their reactions to actually being able to talk with their scientific data. And we've only just begun to scratch the surface of this amazing technology. We don't need to think about fast-forwarding 100 years to imagine or anticipate the next astounding technological advance for clinical development. The future is happening now, and it is more promising and exciting than ever before. ▪

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LEVERAGING AI TO ASSESS CLINICAL TRIAL TECHNOLOGIES

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As part of our ongoing series detailing an approach for the rapid assessment and prototyping of digital and other clinical trial technologies,[1] we introduce here the use of artificial intelligence (AI) and machine learning (ML) to optimize clinical study design and execution. The previous article presented the development of a ~70+ step configurable clinical study model that defines the time and costs associated with the individual steps that make up a "typical" clinical study, from clinical development planning (CDP) to clinical study writing (CSR) and that allows for user-defined customizations.[2] With this model, clinical study teams can identify those steps most amenable to "digital/technological" intervention(s) and the hypothesized ROI. Applying AI and ML concepts then allows an efficacy assessment of the proposed intervention(s) — a probability of success (POS) assessment, if you will.

WHAT ARE AI AND ML?

In its simplest definition, AI is the simulation of human intelligence by machines, and ML is getting those machines, or computers, to perform without explicit programming. In development for decades, these concepts have been popularized through the use of AI in such ventures as world-class chess competition, where IBM's Deep Blue supercomputer first beat the reigning world champion and Chess

Grand Master Gary Kasparov in 1997, and the television game show Jeopardy!, where in 2011, IBM's latest foray into AI, the Watson supercomputer, routed the best human contestants. More recently, with the advent of exponentially increasing availability of both data, i.e., Big Data, and computing power, AI has moved on to perhaps more practical applications ranging from self-driving cars and agriculture to medicine and finance. Estimates of current investments in AI development exceed $30 billion,[3] with projected ROI measured in the trillions.

The "engine" behind AI is ML — a subfield within data science. ML algorithms detect patterns and learn how to make predictions and recommendations by processing data and experiences, rather than by receiving explicit programming instruction. The algorithms also adapt in response to new data and experiences to improve efficacy over time.[4]

A detailed treatment of how AI and ML work is not the intent this article, but perhaps AI and ML may be best explained by summarizing what they can do. AI capabilities can be divided into five categories — with each category providing examples of usage scenarios (types of use cases).

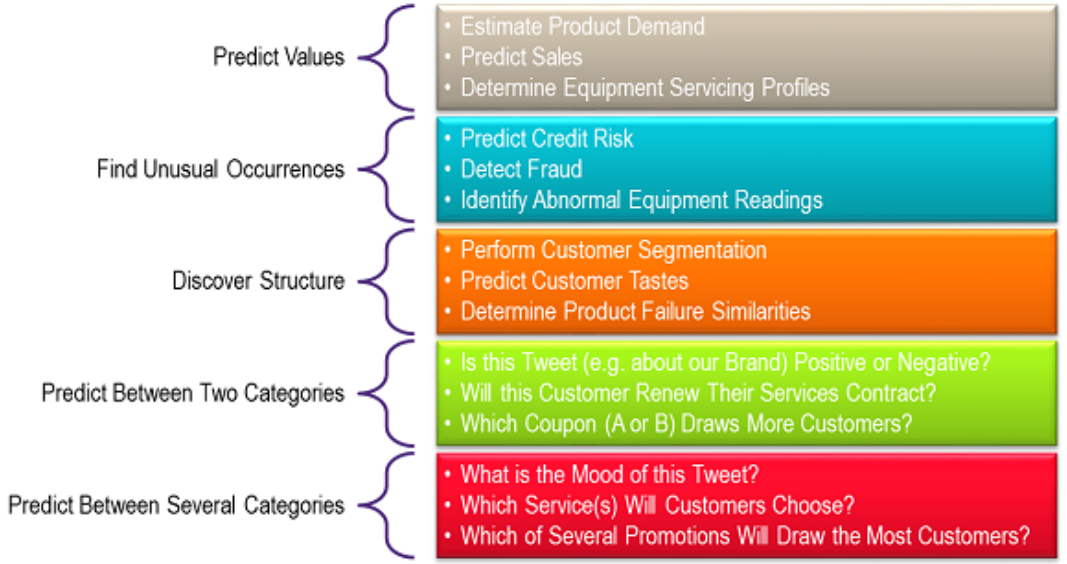

Image created based on information from the Microsoft Azure website.

DATA CONSIDERATIONS IN AI AND ML

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AI and ML data science techniques and technologies enable the detection of relationships and value levers within and across information and data that would be difficult or impossible to find using traditional business informatics tools or via descriptive analytics techniques. With AI, highly instrumented ML models can detect not just primary and secondary relationships across data objects and AI-detected concepts, but also tertiary and quaternary relationships and beyond. AI model evolution via inherent machine learning capabilities means that AI is able to unlock hidden values within and across data sets — whether it's your own data or the data of partners or subscription content providers.

Nate Regimbal
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Because of AI's ability to find relationships across data, clinical researchers can leverage AI use cases that utilize data both within and across data sources.

External data sources include public and subscription data such as:

- Freely accessible online databases like PubMed, SciFinder, DrugCentral, DrugBank, and more generic abstracting indices like Google Scholar
- Elsevier, Clarivate, Wolters Kluwer, Thompson Reuters, Frost & Sullivan, and other similar commercial subscription databases
- MedWatch/FDA AERS, EU-ADR
- Health authority correspondence data, e.g., regulations, guidances, and inspection and audit findings, etc.
- Social media sites such as Twitter, Facebook, WebMD blogs, and online patient forums
- Clinicaltrials.gov, EU Clinical Trials Register

Internal data sources are proprietary and affiliate data contained in clinical systems, such as EDC (electronic data capture), ePRO (electronic patient-reported outcome), CTMS (clinical trial management system), eTMF (electronic trial master file), and LIMS/LNs (laboratory information management system/laboratory notebooks).

APPLYING AI AND ML TO THE CONFIGURABLE CLINICAL STUDY MODEL

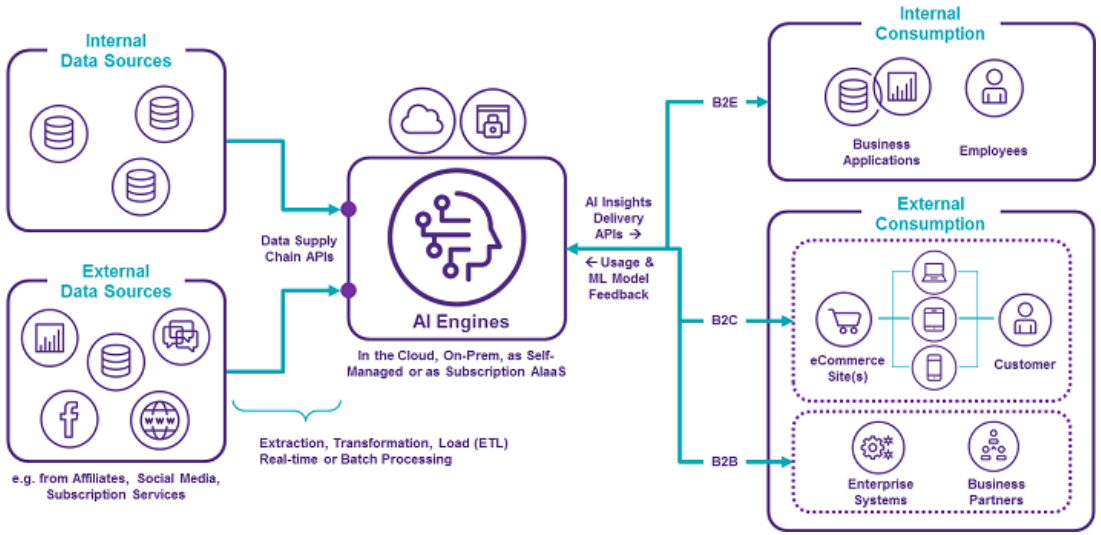
So how does one apply these concepts to our configurable clinical study model? In brief, once users have identified potential interventions, e.g., new technologies or potential levers through the clinical study model in a sensitivity analysis to quantify hypothesized ROI, they can assess the POS of the potential interventions using machine learning powered search to identify trends and insights from real world data and real world evidence to corroborate or refute the efficacy of the potential interventions. Take, for instance, the use cases of assessing the POS of streamlining a potential step in the clinical study process or a particular study design or cohort identification. Examples include:

- In designing a rare disease study of subcutaneous immunoglobulin for chronic inflammatory demyelinating polyneuropathy (CIDP), a disease that is estimated to affect only about 30,000 patients each year in the U.S.
- What can AI tell me about similar studies on CIDP, possibly with other interventions?
- What can AI tell me about the CIDP patient population in general?
- What can AI tell me about studies using subcutaneous immunoglobulin, in other populations/studies?
- What can AI tell me about rare disease studies in general?
- Using AI to identify very specific patient populations/target cohorts characterized down to the inclusion/exclusion level.
- Using AI to identify trends and insights in discrete process steps, e.g., site initiation or serious adverse event (SAE) reconciliation in a particular therapeutic area, disease indication, or study design, etc.

Demystifying AI via pragmatically answering the what, why, and how of AI can be

used to explore these use cases. Historically, this required significant financial and organizational investments in developing and implementing strategies and deploying a road map. However, due to recent and rapid technological and methodological advancements, lower touch alternatives now exist. Here we present one such rapid, low-cost approach — the minimum viable product (MVP).

The MVP approach leverages the Software-as-a-Service (SaaS) model to deliver AI-as-a-Service (AIaaS) using Agile methodology, negating the need for large investments in AI tools and platforms. In the MVP approach, internal and external data sources are first grouped together in a "data supply chain" and fed into the AI engine containing the focused use case-specific ML algorithms. These engines can run in the cloud or behind your firewall.



The outputs of the AI engines are then delivered to human users of existing or new use case-specific applications. The AI insights can also be sent to other systems. For example, if the AI models predict that a certain proposed digital intervention to a lever in the clinical study model will either fail or cause an increased risk of devia-

tions, the AI can send an alert to a user. The models can also instruct other systems and/or users to update contingency planning and CAPAs. Such would be a type of prescriptive analytics use case — utilizing AI-powered near-real-time optimization.

LEVERAGING THE OUTPUT

By leveraging this pragmatic AI approach, clinical research professionals can select the most relevant interventions to pilot either virtually in "conference room" exercises, in separate studies, or in real life by assigning different arms of a study to different technology or process interventions, analogous to different treatment arms but without the necessary statistical rigor or GxP implications. In this way, the hypothesized efficiencies can be confirmed or disproved in a quantifiable fashion without having to incur any switching costs associated with rolling out a new technology to an entire study or portfolio. Organizations can further assess the qualitative impact and cost through a very brief Net Promoter Score (NPS) survey of the user experience and behaviors of all stakeholders (e.g., patients, sites, sponsors), which can be combined with the quantitative pilot results in decision making. In our next and final article in this series, we will explore this NPS approach through a look at the change management aspects of introducing new (technological/digital/process) "interventions" into the clinical study. ▪

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ABOUT US

Life Science Leader magazine is an essential business journal for life science executives who work for everything from emerging biotechs to Big Pharmas. Our content is designed to inform readers of industry best practices and motivate them to implement those practices in their businesses.

Each month, *Life Science Leader* features interviews with executives from the leading pharma and biotech companies, including Pfizer, Merck, Daiichi Sankyo, Genentech, Genzyme, Eli Lilly, and Janssen, as well as the FDA and more. This exclusive thought leadership provides an in-depth look into industry trends and hot topics that will impact the growth of the pharma and biopharma markets.

As the market is continually growing and innovating, these insights provide readers with actionable information and strategies to implement when navigating the evolving clinical, manufacturing, entrepreneurial, and regulatory landscapes.

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