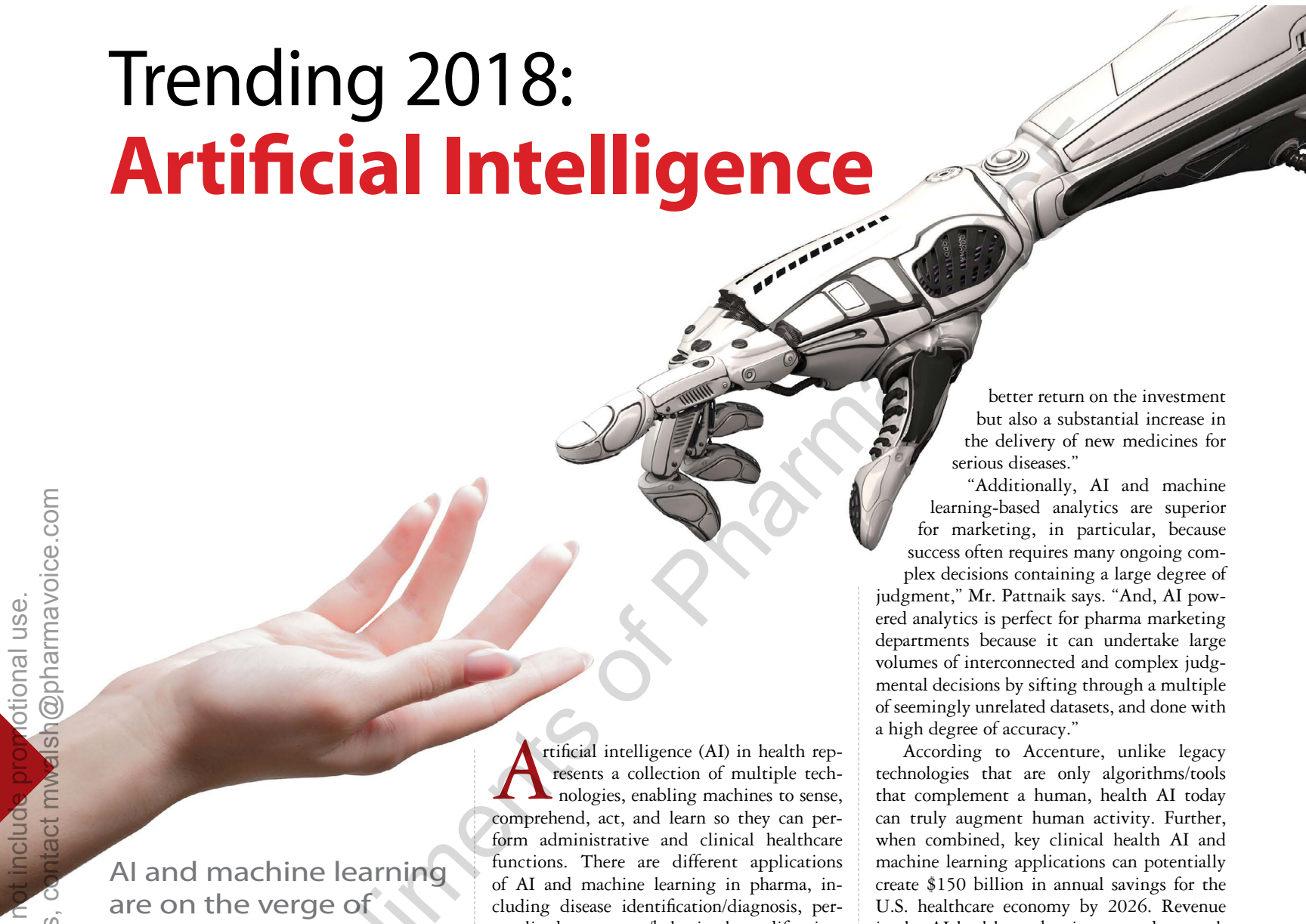
By Taren Grom

Trending 2018: Artificial Intelligence



AI and machine learning are on the verge of helping to transform many aspects of the life-sciences industry from R&D through commercialization. And while there is a lot of excitement around the technology and its ability to automate repeatable processes, there is also caution until its true power is completely understood.

Artificial intelligence (AI) in health represents a collection of multiple technologies, enabling machines to sense, comprehend, act, and learn so they can perform administrative and clinical healthcare functions. There are different applications of AI and machine learning in pharma, including disease identification/diagnosis, personalized treatment/behavioral modification, drug discovery/manufacturing, radiology and radiotherapy, smart electronic health records, epidemic outbreak prediction, sales, marketing, predicitive analytics, and so on.

According to Sudeep Pattnaik, founder and CEO of ThoughtSphere, AI and machine learning hold the key to bringing research and development in the pharma industry into the 21st century.

"They both present the pharmaceutical industry with a real opportunity for R&D to be done differently, so that it can operate more efficiently and substantially improve success at the early stages of drug development," he says. "The longer term value and benefits will mean that the vast resources and money used to develop drugs in the current process will be deployed more effectively to give not only a better return on the investment but also a substantial increase in the delivery of new medicines for serious diseases."

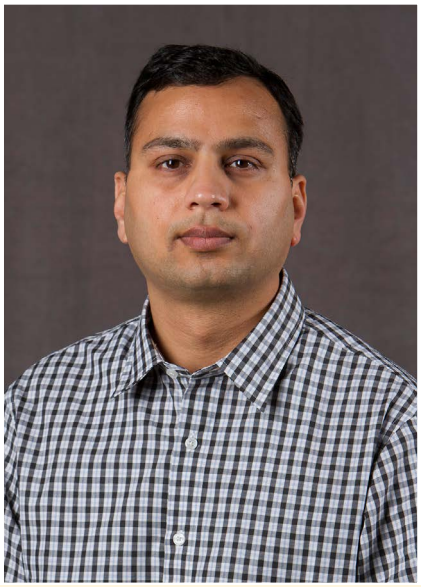
"Additionally, AI and machine learning-based analytics are superior for marketing, in particular, because success often requires many ongoing complex decisions containing a large degree of judgment," Mr. Pattnaik says. "And, AI powered analytics is perfect for pharma marketing departments because it can undertake large volumes of interconnected and complex judgmental decisions by sifting through a multiple of seemingly unrelated datasets, and done with a high degree of accuracy."

According to Accenture, unlike legacy technologies that are only algorithms/tools that complement a human, health AI today can truly augment human activity. Further, when combined, key clinical health AI and machine learning applications can potentially create $150 billion in annual savings for the U.S. healthcare economy by 2026. Revenue in the AI health market is expected to reach $6.6 billion by 2021, a CAGR of 40% and in just the next five years, the health AI market will grow more than 10 times. And as many as 74% of life-sciences executives believe AI will result in significant change or even completely transform their industry within three years.

Some of the biggest pharmaceutical companies are already turning to AI to improve their drug targeting strategies.

To improve the hit-and-miss business of finding new medicines, GlaxoSmithKline recently unveiled a $43 million deal to expand its AI capabilities (see sidebar: AI and R&D).

Other pharmaceutical companies, such as Johnson & Johnson, Merck, Novartis, and Sanofi are also jumping on the AI bandwagon to streamline their drug development and drug discovery processes.



Identifying the right business need for AI will help companies realize near term ROI while laying a foundation for broader deployment as the technology advances.

PRATIK MAROO
Cognizant Life Sciences

"In the near term, AI and machine learning have the potential to enable operations to be smarter, faster, and cheaper," says Jake LaPorte, Ph.D., head of digital development, Novartis. "This technology can automate steps of the clinical process and complete tasks in a matter of seconds, which if done manually can take humans days. At Novartis, we have found that by implementing a data-driven approach, we can pinpoint trial aspects that are of vital or strategic importance for humans to focus their attention upon, thereby enhancing our ability to make critical decisions on trial execution."

Sanofi Pasteur recently tapped Berg's AI capabilities to discover biomarkers that can help scientists learn more about individual flu vaccine responses.

In short, the goal is to learn about molecular features behind varying responses to flu shots out of data sets that are unmanageably large by traditional standards, according to release from the company.

Another burgeoning area of drug research where AI could provide value is in the rare disease space, where many rare diseases may go undetected until late stage symptoms surface, upon which a proper diagnosis can be determined.

"Early diagnosis of these rare diseases, without the excessive wait time would be paramount in accelerating treatment options," says Bruce Capobianco, senior director, RWE, ICON commercialization and outcomes. "Thanks to recent advances in technology, real-world data coupled with machine learning can help to facilitate early detection and significantly improve patient care."

Typically, physicians see only a small number of patients with rare diseases. Without having a significant research pool to work with, diagnosis and treatment take a considerable amount of time. Mr. Capobianco says with the breakthrough combination of RWD and machine learning, physicians have an intuitive predictive model, based from immense amounts of normalized data and associated computational intelligence, available to them for analysis to facilitate a better understanding and faster diagnosis of these rare diseases.

The ultimate goal is to harness modern supercomputers and machine learning systems to predict how molecules will behave and how likely they are to make a useful drug, thereby saving time and money on unnecessary tests.

Julie Ross, president of Advanced Clinical, agrees that pharma companies will benefit from AI not only in time and cost savings, as well as through increased safety and quality.

"By integrating AI with human-driven workflows, organizations will begin to function with more precision faster as a greater share of decision-making activity is transferred to AI applications," she says. "Companies will reassess workflows within their business lines, decipher which flows are heavily driven by human interaction and decision-making, and then combine that workflow with machine learning technologies to accelerate processes while reducing margin of error. As gaps in quality are narrowed using AI algorithms, organizations will increasingly see improvement in quality and safety of clinical trial conduct.

AI and R&D

PATRICK VALLANCE
President, Pharmaceuticals R&D, GlaxoSmithKline

If AI can identify threatening weather, translate language, and fly a drone, why can't it help us accelerate the discovery and development of new medicines?

At GSK, we believe it can. We are harnessing modern supercomputers and machine learning to enable us to develop medicines more quickly, with higher precision and quality, and at a reduced cost, by automating significant aspects of the drug discovery process.

The R&D process today generates more data than we can ever practically use. We run tens of thousands of chemical assays; we gather millions of data points from clinical trials. By applying computing power, we can rapidly interrogate and find patterns in huge amounts of data. What would take many years for humans to work through can take a computer only hours or minutes to review.

Computers can look for signals, patterns, minute connections within the data that could be the starting point for the development of new medicines that we might never spot. Ultimately, we believe AI can help us design a medicine by finding the best chemical compounds to make our molecule, then simulating how that molecule will interact with the desired target inside the human body and assessing the risk of off-target interactions.

Computer technology will never replace the expertise of our scientists. But we can use innovative technology to enhance our thinking and give us a better chance of success and a better starting point in the design of future medicines.

AI has the potential to reduce the expense of developing a medicine — more than $2.5 billion — and time — about six years from target to testing the molecule in humans for the first time. Our goal is to dramatically reduce this time, possibly to one year in future.

To focus our efforts, we have formed a new AI research unit at GSK to enhance our drug discovery processes using in silico technology — artificial intelligence, machine learning, and deep learning.

We believe the biggest benefit AI can bring to humankind is to help deliver more targeted treatments faster and at less expense. We are eager to prove that theory.

This application of AI will especially benefit pharma companies that manage manufacturing of product, packaging, distribution, and recalls — areas where consistent product quality is imperative."

Real-World Applications

The real-world applications of AI in pharmaceuticals are across several areas — sales and marketing, R&D, and payer and provider relations.

"The common applications in these areas all relate to analyzing unstructured data and creating the opportunity to provide actionable insights and to potentially predict an outcome with greater accuracy than a random sample of any other data sources," says Sundeep Bhan, co-founder and CEO of Prognos.

Within clinical trial research, Mr. Pattnaik says applying advanced predictive analytics in identifying candidates for clinical trials could draw on a much wider range of data than currently.

These sources potentially include social media and doctor visits, as well as genetic information. When looking to target a specific population. This would result in smaller, quicker, and less expensive clinical trials overall.

"Reports suggest big data and machine learning in pharma and medicine could generate a value of up to $100 billion annually, based on better decision-making, and optimized innovation, improved efficiency of research /clinical trials, and new tool creation for physicians, consumers, insurers, and regulators," he says.

According to Ms. Ross, real-world applications for AI in pharmaceuticals vary widely. From identifying potential candidates for clinical trials with advanced predictive analytics to streamlining clinical trial operations, AI is expanding the way in which humans and machines interact in clinical research.

The growing complexity of the healthcare stakeholder ecosystem is driving the production of increasingly diverse, unstructured, and difficult-to-integrate data sources, which is making it harder for life-sciences companies to get access to insights that are essential to their brand's success. Lance Scott, CEO of Zephyr Health, says this is particularly true for the commercial functions of these companies, including marketing and sales that frequently use different and outdated insights on the customer and market.

"Depending on the degree of human interaction within workflows for clinical trials or manufacturing of product," Ms. Ross says. "AI can augment or replace the need for human intervention in clinical research processes Many pharma companies are increasingly turning to an adaptive clinical trial approach to execute clinical trials. Through the assistance of machine learning, researchers and physicians can interpret enrollment and biological data in real time."

Ms. Ross says with this capability, clinical researchers can increase safety by adapting to the impacts of an investigative product through remote monitoring and real-time data access. Researchers can then add treatment arms, increase sample size, modify consent forms, and have deep and immediate insights into potential adverse events.

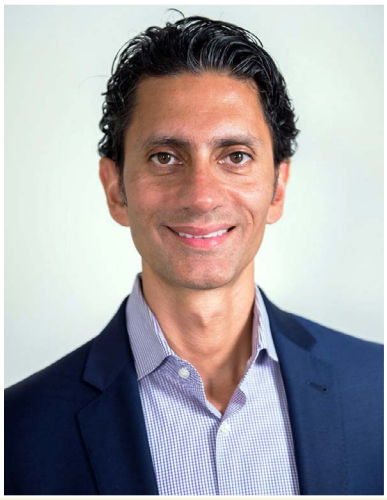
The Benefits of AI

Pharmaceutical companies can leverage AI to get the right patients the right care at the right time, says Randall Stevens, M.D., chief medical officer of Centrexion Therapeutics.

"Depending on how we leverage our vast data sources to understand what treatments a patient will benefit the most from, AI

> Advanced analytics platforms with AI are necessary to integrate this data and extract timely, relevant, and predictive insights.
>
> **LANCE SCOTT**
> Zephyr Health
> @zephyrhealth

> We have found that the use of machine learning and predictive algorithms has benefited the clinical trial process by improving how we leverage our vast clinical trial experience across multiple therapeutic areas.
>
> **DR. JAKE LAPORTE**
> Novartis

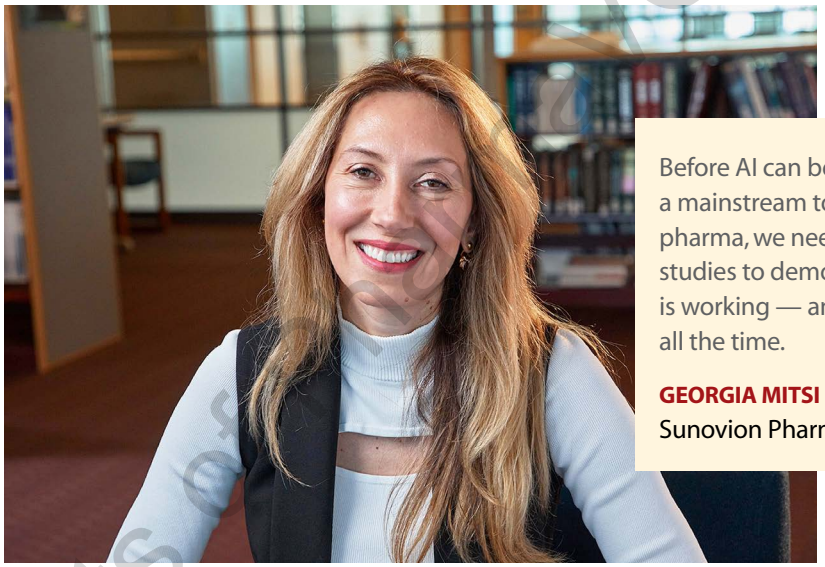


When healthcare AI is used on billions of clinical diagnostic, or lab, records available in real time, it can map out specific and complex patient journeys with a high degree of accuracy.

SUNDEEP BHAN
Prognos
@prognosAI

The scope of potential applicability of AI and RPA is extremely broad and will be determined by the ability of organizations to leverage these technologies and the readiness to change their organization toward effective use of these technologies.

DR. ISABELLE DE ZEGHER
Parexel



Before AI can become a mainstream tool for pharma, we need rigorous studies to demonstrate it is working — and working all the time.

GEORGIA MITSI
Sunovion Pharmaceuticals

can influence drug development strategies for pharma companies," he says. "Through the use of big data and analytics, we can understand in what diseases a medicine is most likely to have an impact and how to design clinical trials with specific patient populations and endpoints in mind, ultimately speeding pipeline progression."

Since the arrival and embracement of big data, pharmaceutical companies have struggled with harnessing the volume of data generated. One way they have found to deliver more focused solutions across a variety of functional areas is through AI.

"Principally, the main benefit from AI is helping pharmaceutical companies understand data in real-time," Mr. Pattnaik says. "AI is further enhanced by machine learning, when one field contained within AI that allows a machine to learn from data without needing rule-based programming."

Pharma companies could benefit from machine learning, together with AI, in driving the future success of the industry.

"By applying the right AI techniques to the right data, it becomes easier to plan effectively on the overall direction the company wishes to take, identify effective propositions for various segment types within a brand and, particularly when conducting clinical trials, allocate resources and budgets for optimum results," Mr. Pattnaik says. "Additional benefits for pharma companies include the areas of: fraud detection, which requires a fast-learning solution with the ability to continually evolve, and risk management that lends itself well to AI with its cognitive computing capabilities, as typical risk issues often include unlikely and/or ambiguous events."

The shift is on, as many pharma companies are diverging from marketing massive blockbuster drugs to engaging smaller pools of high-value patients, including oncology and rare and niche diseases, Mr. Bhan says.

"Biomarker testing helps determine a treatment regimen early in a patient's journey, and biomarker monitoring identifies patients who are failing a standard-of-care therapy and are candidates for the next-line therapy," he says. "When healthcare AI is used on billions of clinical diagnostic, or labs, records available in real time, it can map out specific and complex patient journeys with a high degree of accuracy. As such, it can identify relevant patient segments before a physician makes a treatment decision and, in some cases, before a therapy is even considered."

AI and robotic process automation (RPA) is a perfect application to drug development not just because it is a highly regulated process and by nature quite structured with many repetitive task, but because it is a data-intensive activity.

"RPA and AI can be of value in all phases of drug development and trial execution where there is a need to make decisions that can be better informed by learning from available knowledge or data," says Isabelle de Zegher, M.D., VP, integrated solutions, Parexel.

A few examples, she says, include: faster and more efficient identification of appropriate drug dosage based on modeling of the PK/PD characteristics of a drug; simulation of different protocol designs and execution scenarios; enhanced clinical trial supply management and forecasting of medicine demand during trial execution; and the extraction and curation of data from unstructured sources, such as electronic medical and health records and real-world data.

"RPA and AI can also bring value in all phases of a study execution where there is a well-defined, repetitive process, and specifically processes that are defined by regulatory

AI and Machine Learning

ALYSA LESEMANN
Senior Writer,
IBM Watson Health

The adjectives disruptive and radical have been used to describe artificial intelligence (AI), technology fascinating to imagine, though daunting when trying to predict its value, adoption, and lifespan.

In pharma, discussions of AI range from philosophical to practical. During a podcast for DIA 2017, Craig Lipset, Pfizer's head of clinical innovation, compares the state of today's radical technologies to when cloud computing was on the horizon. People found the cloud intriguing, but they needed time to acquire trust and confidence in it.

The power of AI lies in what it can do quickly, purposefully, and analytically with vast networks of disparate data. AI can extract and derive meaning from free text in EMR records, collect streaming information from patient devices, and correlate these datasets with insights gleaned from payer data. With this comprehensive level of automation, statistical models based on structured data will be replaced with machine learning algorithms, and new connections revealed by AI can lead to important medical discoveries.

Adverse events can be reported in structured and unstructured formats that AI can easily navigate. In pharmacovigilance and patient safety, tapping these resources helps identify and expedite correlation of risk indicators and can reduce administrative burden by alerting appropriate stakeholders.

AI has the potential to reduce timelines in drug research and enable companies to realize longer exclusivity of their patents and increased market opportunities prior to competition with generics. The technology also helps accelerate patients' access to innovative, efficacious and safe therapies.

Using machine learning, relevant information on a patient's health can be collected by phones, wearables, and other connected devices. Aggregating these datasets can help determine accurate and timely drug dosing based on an individual patient's need. In this way, AI can become a part of people's daily lives, inspiring their trust and confidence.

requirements and to which compliance must be flawless and auditable, such as management of site qualification document, pre-processing of numerous case safety reports, management of regulatory documents — such as CMC — to be reviewed and checked across different stakeholders and across different organizations; and more efficient management of eTMF and eCTD through automatic routing and workflow management documents," Dr. de Zegher says. "The scope of potential applicability of AI and RPA is extremely broad and will be determined by the ability of organizations to leverage these technologies and the readiness to change their organization toward effective use of these technologies."

According to Ms. Ross, implementing AI solutions may also provide speed for cost reduction, while maintaining regulatory compliance.

"If a drug typically takes five to seven years to bring to market, what would happen if AI was introduced into the clinical trial and manufacturing aspect of drug development?" she asks. "AI could both supplement human workflows and replace others. This hybridized approach to AI implementation for drug trials could reduce the time it takes drugs to reach the market, or rather speed up the process, thus reducing costs. If AI reduced the cost of a drug trial by just 10%, that's $160 million saved. The hope is that would also translate to lower drug costs that deliver new treatments and cures seven to eight months sooner, allowing us to identify and produce even more treatment/cures faster."

AI Providing Value

Mr. Bhan says pharma companies have traditionally informed their sales and marketing strategy based on medical claims and prescription data. Despite its high value, these data only show which physicians have already prescribed a therapy.

"When AI is used on utilization and real-time diagnostics data, it can stratify a large population by the likelihood of requiring a particular therapy within a certain period of time, such as three, six, or nine months," he adds. "As a result, brand teams can allocate promotional resources more efficiently and conduct highly targeted, timely physician outreach at the right time: when a physician has a relevant patient and is exploring treatment options, or before the patient needs therapy."

Further, Mr. Scott says an automated technology platform creates greater transparency in data assets by removing duplicative purchases, enhancing the value of purchased data through enrichment and analytics, and providing continuity across the entire product lifecycle.

"With the quantity and complexity of data available today, it's just not possible for life-sciences companies to interpret these data manually," he adds. "Advanced analytics platforms with AI are necessary to integrate this data and extract timely, relevant, and predictive insights."

Experts say machine learning, a type of AI, plays a crucial role in this.

"Solutions that incorporate machine learning increase the capability to process vast amounts of data — and to do so more precisely, reducing time-to-insights for targeted marketing programs," Mr. Scott says. "When these solutions are integrated into the commercialization strategy, sales and marketing have a deeper view of the customer. With this holistic view, the right message can be delivered to the right customer, at the right time.

Reports suggest big data and machine learning in pharma and medicine could generate a value of up to $100 billion annually, based on better decision-making, and optimized innovation, improved efficiency of research /clinical trials, and new tool creation for physicians, consumers, insurers, and regulators.

SUDEEP PATTNAIK
ThoughtSphere

This translates to better customer engagement — personal and nonpersonal — and improved market share with high-potential customers, otherwise known as the nirvana of sales and marketing."

Augmenting R&D decisions and de-risking clinical development is paramount to the success of any company, particularly those in biotech. Dr. Stevens says, the integration of AI platforms in combination with domain expertise will uncover hidden biological connections between drugs and targets and diseases.

"Using AI, we can draw from disparate data sources, distilling an association using predictive algorithms that experts can recognize and then translate into efficacy and safety findings," he says. "AI has the potential to revolutionize how we approach drug identification and development, shaving time and costs off of the process."

Pratik Maroo, chief digital officer, Cognizant Life Sciences, says while AI promises to transform healthcare, the life-sciences industry must invest carefully, and identify the areas in which AI will deliver near-term ROI.

"The industry is awash with AI initiatives: interest in cognitive computing, deep learning, conversational AI, and machine learning is growing," he says. " We see 80% of our clients investing in AI. Yet, very few have been able to demonstrate ROI."

He suggests that the following areas are the most likely to deliver near-term ROI from AI initiatives.

Improved R&D yield:

- Predict potential molecular combinations for drug development by analyzing historical basic research and clinical trial data
- Identify and recruit patients for trials by leveraging medical and genealogy data
- Enhance patient and investigator experience using conversational AI to deliver zero-touch experience
- Enhance safety signaling with real-world data

Increased message recall and customer experience:

- Better understand customer segments (patients and providers) by leveraging behavioral and social media data
- Suggest next-best course of action to energize communications based on unique understanding of provider
- Improve adherence through personalized therapy plans for patients, using conversational AI to deliver a zero-touch experience
- Prove outcomes and economic value of therapies using real-world data
- Enable self-diagnosis and facilitate more rich conversations and connections between patient and provide

Increased transparency in supply chain:

- Improve demand forecasting by leveraging nontraditional data sources
- Improve procurement-spend analytics to find new sources for raw material and services

"AI requires access to vast amounts of data to consume to keep learning," Mr. Maroo says. "This is difficult for life sciences, given regulatory compliance issues. Further, there is a noted lack of industry forums driving standards for data privacy, security, and interoperability. Nonetheless, identifying the right business need for AI will help companies realize near-term ROI while laying a foundation for broader deployment as the technology advances."

Experts at Medisafe say the pharmaceutical industry is in a perfect position to benefit from and learn a highly personalized approach to the patient experience and specific patient behav-

Pharmaceutical companies are considering AI to help them design new drugs, select genomic mutations, find patterns in real-world data to evaluate safety of their products and improve their understanding of the therapeutic market.

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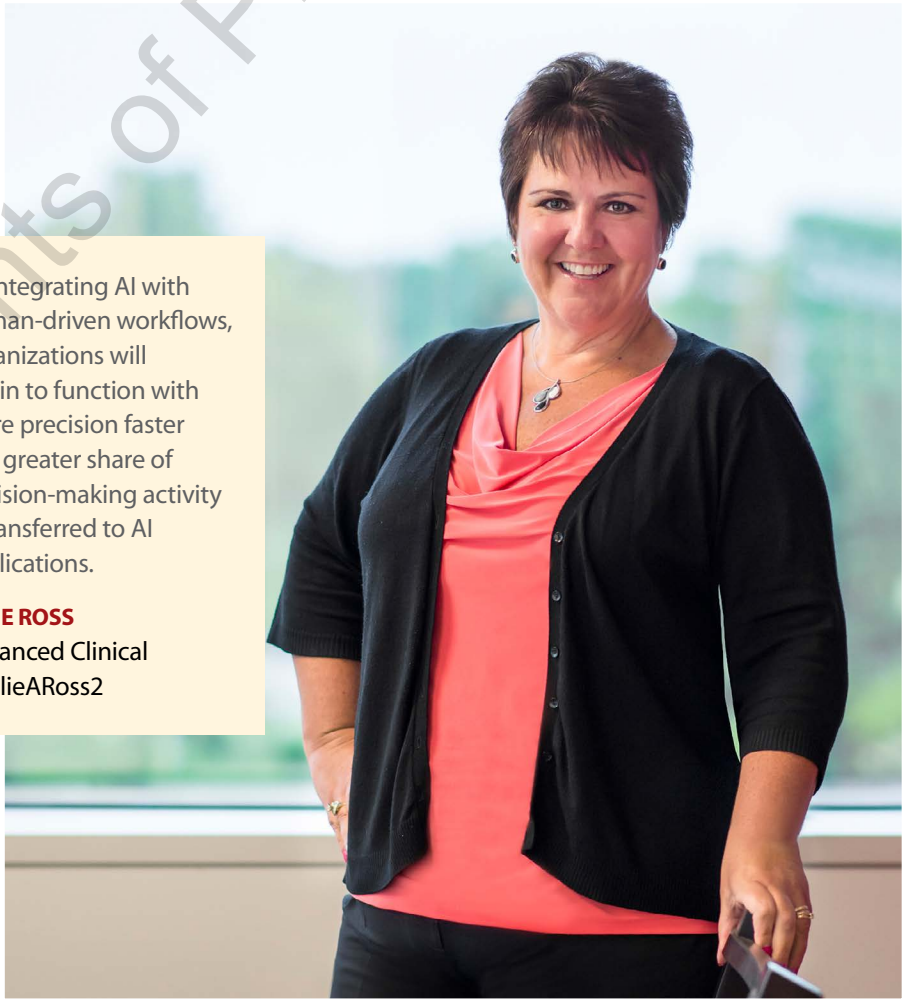


By integrating AI with human-driven workflows, organizations will begin to function with more precision faster as a greater share of decision-making activity is transferred to AI applications.

JULIE ROSS
Advanced Clinical
@JulieARoss2

ior by using AI. Companies of all types want to create better patient experiences and outcomes across the spectrum of care and AI empowers the accomplishment of this goal. Companies now have the ability to address patient issues and concerns in real time and improve their outcomes due to the intersection of the disruptive forces of social, mobile, cloud, big data, and AI all reaching a level of maturity and interoperability together.

At Novartis, machine learning and predictive analytic platforms are enabling a much more holistic, real-time view of its ongoing clinical trials.

"These efforts address challenges inherent in R&D productivity and enable us to manage trials more effectively and efficiently," Dr. LaPorte says. "In collaboration with Quantum Black, we've developed a platform called Nerve, to optimize clinical trial performance, including analyzing cost and quality predictors from a trial's outset. Nerve applies proprietary machine learning to spot patterns across data sets that enables us to: identify and explain levers of performance; test hypotheses and track improvement initiatives; and forecast key risk metrics. Nerve has already delivered a 10% to 15% reduction in patient enrollment times in pilot trials. Due to these promising results, we're now expanding the use of this technology to build new capabilities."

Even with advances in this area, Mr. Pattnaik says big pharma is still treading cautiously when it comes to AI as the technology has yet to demonstrate it can successfully bring a new molecule from computer screen to lab to clinic and finally to market.

Dr. de Zegher agrees saying pharma executives will have to consider where automation and AI can bring value in the context of how their organization currently operates.

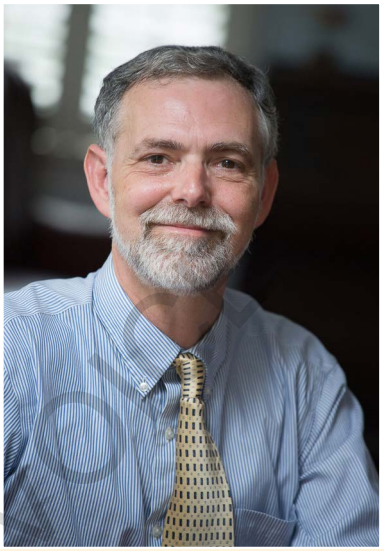
"Strategic thinking and readiness to include disruption in the business is important, and companies must think big and be open to change to reap the benefits AI can deliver."

Another challenge companies are facing with AI, Dr. de Zegher says, is the shift from human labor to digital labor. RPA and AI have a strong potential impact on an organization's processes, and therefore employee structure.

"A final challenge is access to data," she says. "With RPA and AI comes a significant amount of unstructured data. Companies will struggle to leverage insights from this data without a way to effectively aggregate and analyze it."

Georgia Mitsi, senior director, search evaluation and digital healthcare initiatives, at Sunovion Pharmaceuticals, believes that AI has not yet reached the maturity level to be incorporated in the regulated pharmaceutical environment.

"Before AI can become a mainstream tool for pharma, we need rigorous studies to demonstrate it is working — and working all the time," she says. "What if an algorithm even once makes the wrong prediction? That could become a liability for a pharmaceutical company. I believe in the power of innovation, but before technologies can become mainstream and part of the standard of care, we need validation."



Pharma companies can leverage AI to get the right patient the right care at the right time.

DR. RANDALL STEVENS
Centrexion Therapeutics

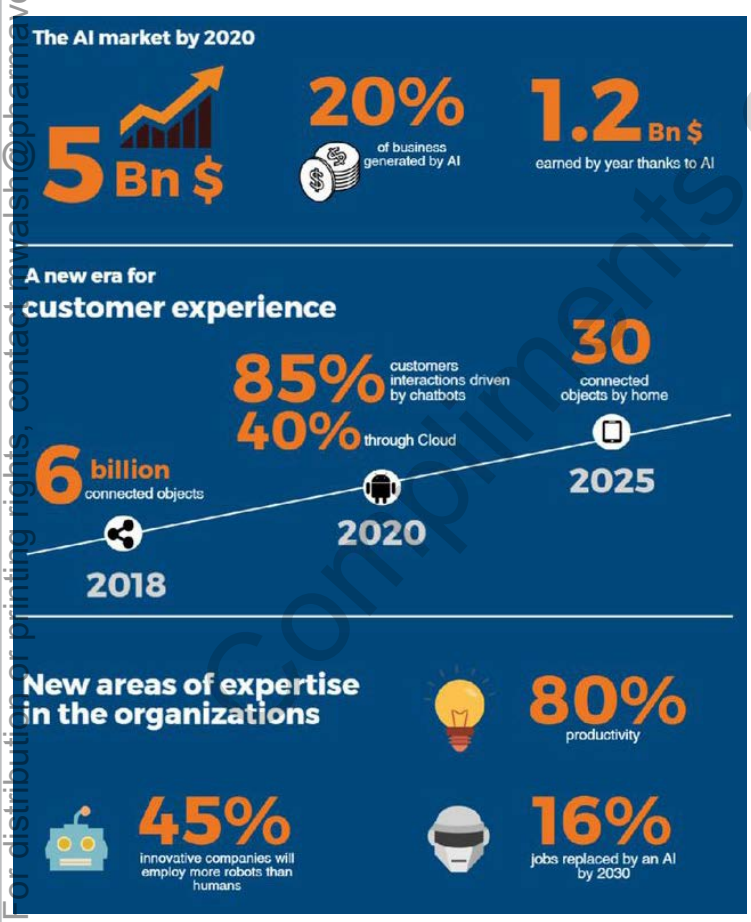
Mark Lambrecht, Ph.D., director, global health and life sciences practice at SAS, says while much has been recently reported on the value of AI, one thing is sure: the real analytical potential for healthcare and life-sciences organizations has not yet been realized.

"AI excels at automating certain tasks and making unbiased decisions on high quality clinical and behavioral data, eliminating human variation in clinical medicine," he explains. "There remains room for improvement in contextualizing observations from different sources, or understanding why a tumor has been observed, for example. Most pharmaceutical and healthcare organizations are now setting up groups to look for ways to apply AI in the drug-development and making processes.

"Pharma companies are considering AI to help them design new drugs, select genomic mutations, find patterns in real-world data to evaluate safety of their products and improve their understanding of the therapeutic market," Dr. Lambrecht continues. "Hospitals and academic medical centers use AI to drive automation in tasks that are prone to human error, optimize the patient experience, reduce treatment costs, and derive new clinical insights that can immediately be implemented at the point-of-care."

Even with advances in this area, Mr. Pattnaik says big pharma is still treading cautiously when it comes to AI as the technology has yet to demonstrate it can successfully bring a new molecule from computer screen to lab to clinic and finally to market.

A Solid Take-off for Artificial Intelligence in 2017



Source: Artificial Intelligence Stats