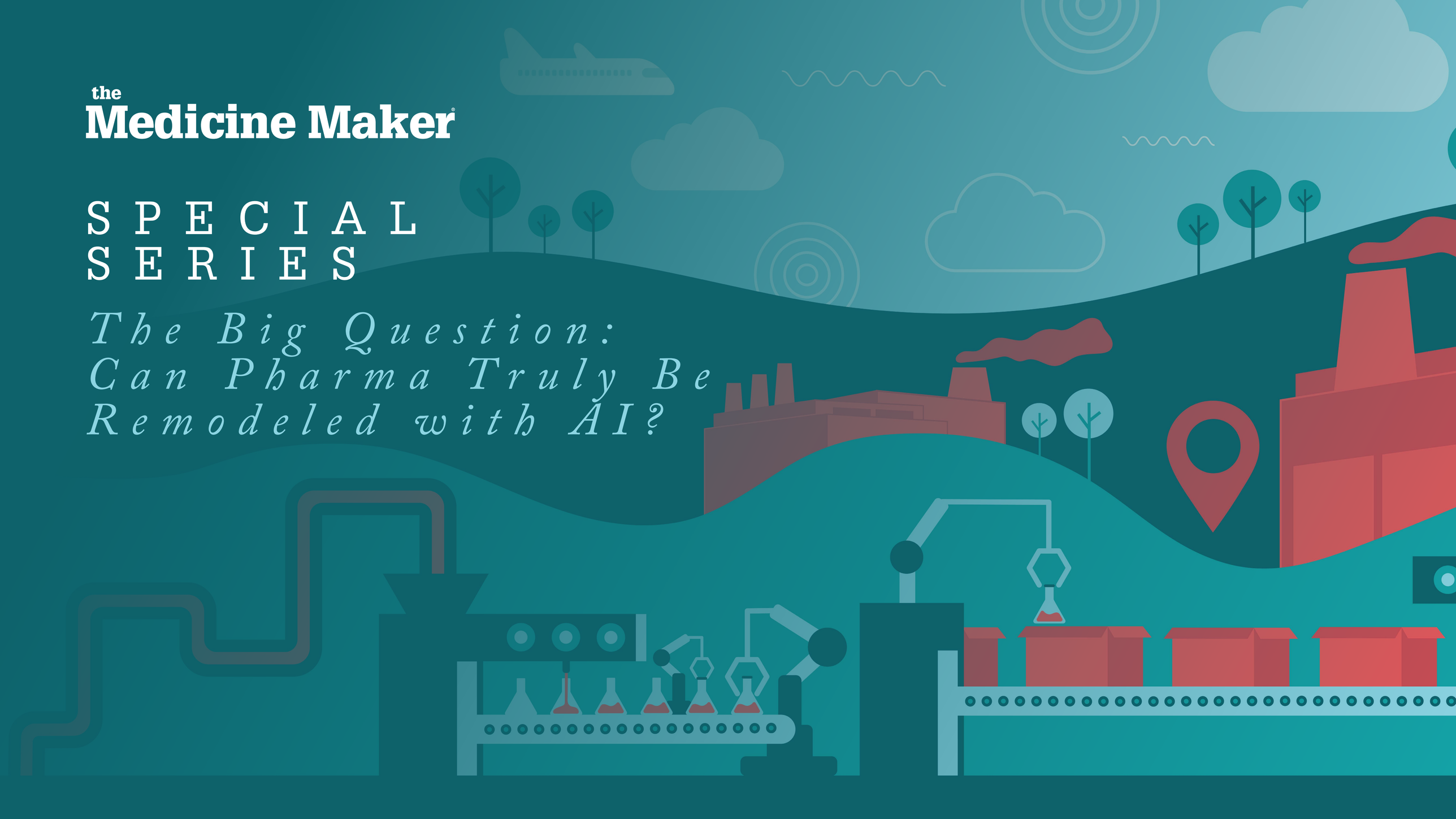
the Medicine Maker

SPECIAL SERIES

The Big Question: Can Pharma Truly Be Remodeled with AI?



INTRO

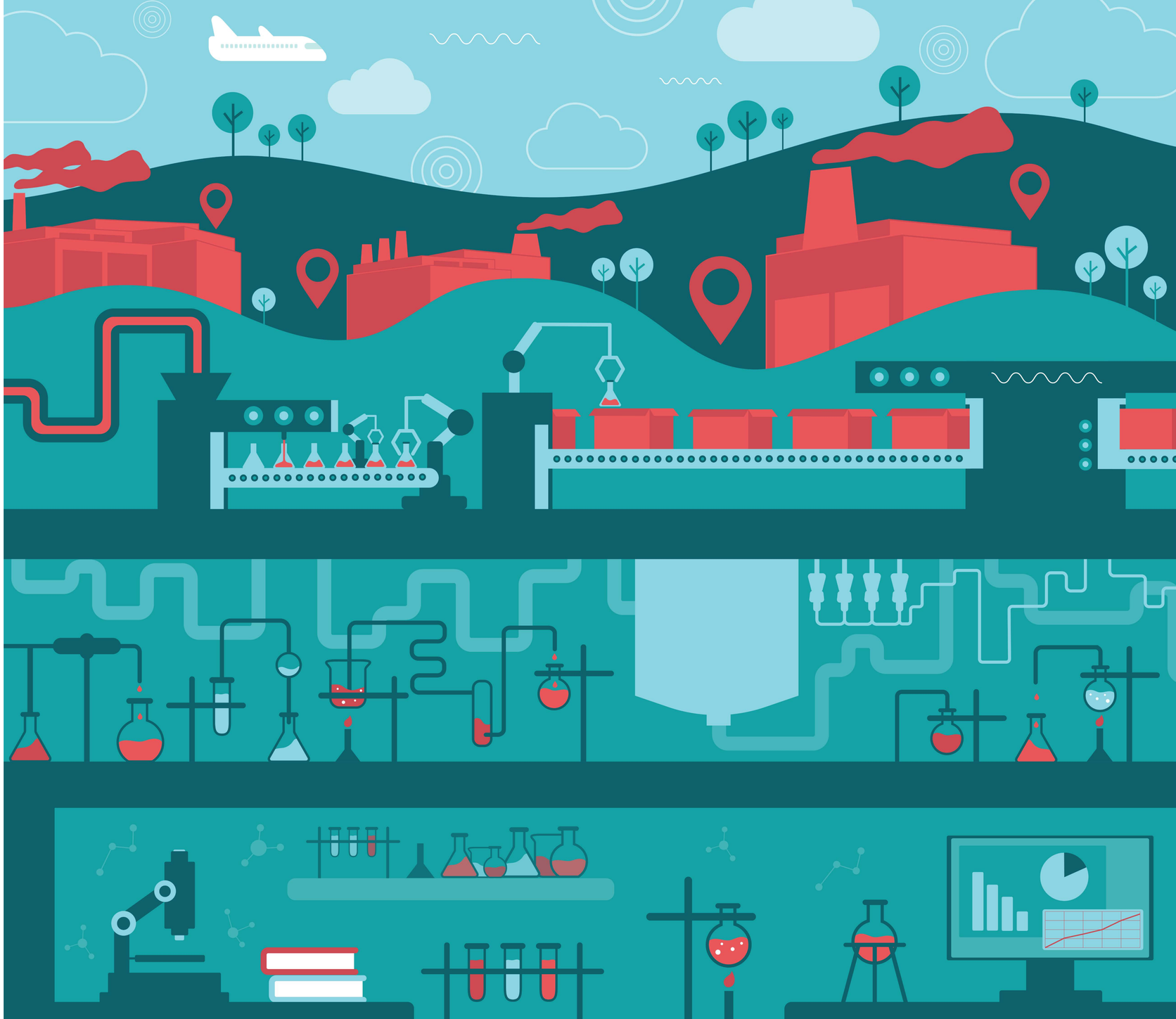
The Floor is Open

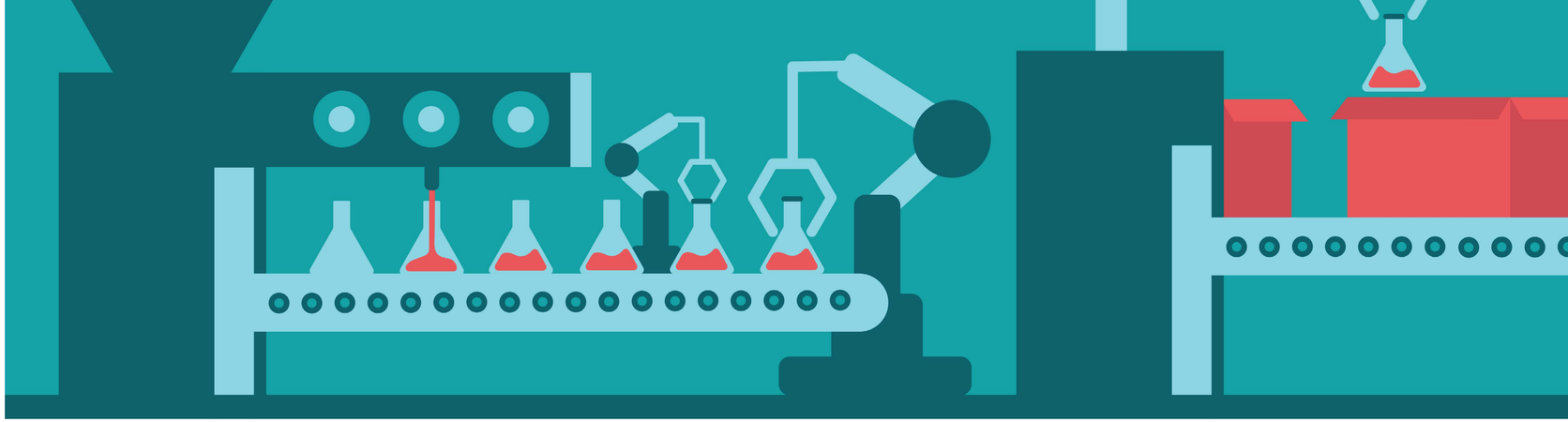
Perhaps the pharmaceutical industry's relationship with artificial intelligence will continue to grow from strength to strength – taking science to hitherto unimagined places. Perhaps algorithms and machine learning platforms will be slowly, subtly, but irreversibly integrated into the world of medicine making… We explore.

Welcome to The Big Question – a new series for The Medicine Maker that takes an in-depth look at a hot topic. First up: artificial intelligence (AI).

But why? AI is often touted in pharma circles as a great enabler that could streamline manufacturing processes, cut out the noise in the mountains of data produced and obtained by pharmaceutical companies, and reduce the risk of error. To this end, more and more companies are beginning to explore how they can implement AI technologies.

Our experts had vastly different interpretations and thoughts on the topic. Can AI technologies really help drive the industry to new heights or does the hype outweigh reality? Let's hear their views.





R & D

Intelligence by Design

By Maryam Mahdi, Deputy Editor

AI is finding its place in the pharma industry and companies of all sizes and across therapeutic areas are open to the possibilities its use might bring. Here, we speak to Marcelo Bigal, President and Chief Executive Officer at Ventus Therapeutics, Jo Viney, founder, President and Chief Executive Officer at Seismic Therapeutic, and Tommaso Biancalani, Senior Principal Scientist and Director, AI/ML at Genentech, about their AI journeys and why these systems are so important to the future of R&D.

Why are you personally so fascinated by AI?

Biancalani: I'm excited by the recent progress made in the field of "generative models." These are models that are capable of starting from a certain data sample and transforming it in a specific way. The classical examples are the filters on our phones that start with a photo of us and end by making us look older or younger. Can we do the same thing with medicine? For example, can we start from a known drug and ask the AI to transform it into a new one with fewer side effects? This would truly be game-changing in the healthcare space.

Bigal: In my view, small molecule drug discovery is an incredibly challenging pursuit that typically requires years of time, and the design and testing of thousands of molecules. Despite all the rigorous work, we frequently find that empirically identified "optimal" molecules fail in the clinic due to unoptimized potency, selectivity, or pharmacokinetic properties. The challenge of designing molecules that are fully optimized on potency, selectivity, and pharmacological properties is to get the physics right.

If we had the ability to model and determine the precise atomistic quantum physics parameters of protein-small molecule interaction, we could, in principle, design fully optimized molecules de novo with minimal chemical exploration. While this is not possible yet, I am fascinated with the opportunity to harness the power of machine learning and AI to make the dream of fully optimized physics-based drug discovery within our grasp. In theory, a physics-based AI approach could reduce the number of molecules under scrutiny from thousands to hundreds, and speed up the drug discovery process.

Viney: I've spent my entire career in autoimmune disease drug discovery – taking 13 drugs to the clinic at biotech companies. I am personally captivated by AI because I know from experience that developing drugs that target the immune system is difficult. When I began to understand the impact of machine learning to design better biologics and their capacity to advance them faster, I knew this was something I wanted to be a part of!

How has the use of AI in pharma changed over the years?

Biancalani: I see two main turning points. First, our ability to generate and store data exponentially increased in the last few decades (just consider that any pocket-portable USB stick can now contain many more books than the largest library in the world!). Second, the invention of the graphical processing unit (GPU) gave AI algorithms the power to manipulate large datasets – so-called deep learning.

Bigal: Machine learning has been part of drug discovery for more than two decades, with initial applications predicting physico-chemical properties of molecules and designing small libraries of chemical matter for a given target. In those days, lack of computational power made it challenging to widely apply these approaches to very large data sets, and also largely prevented scientists from even conceiving of other applications that we now see being developed. As Tommaso says, advancements in processing power, particularly with GPUs (driven by the gaming industry), have increased the scale of computational possibilities within practical time limits by at least 100-fold. Simultaneously, development of the deep-learning network architectures driven by natural language processing and image recognition has produced new machine-learning capabilities.

Of course, hardware and algorithm development were both required for software development, and thus together they represent a turning point in the application of machine learning to drug discovery. These advancements have led to a renaissance in computation-based drug discovery, revealing the potential for faster identification and optimization of potent and selective drug-like molecules for clinical testing.

Tommaso Biancalani

Marcelo Bigal

Jo Viney

I believe that machine learning will have its biggest impact when combined with and used to enhance novel physics-based methodologies for drug discovery and, as an industry, we are aggressively pursuing novel methodologies and algorithms, with the goal of ultimately identifying drug-like molecules completely in silico.

Viney: With all of the many steps and complexities in the drug development process, it has taken some time for drug developers to figure out how to integrate AI and machine learning within the process. AI is an amazingly powerful technology, but it does not stand alone from other analyses, experiments and insights from expert scientists that are key ingredients to discover and develop new medicines.

What are the biggest misconceptions about AI?

Viney: Related to my last point, perhaps one big misconception is that AI can operate as a standalone approach for drug discovery, design and optimization! Creating a new drug is a complex effort that requires many steps and inputs. In my view, AI can serve as a powerful technology so long as it is integrated with human insights that are essential to the process of creating new medicines.

Bigal: I agree with Jo. The biggest misconception about AI is that it can be a panacea applicable to all aspects of drug discovery – solving all challenges by itself. Like any tool or platform, it is well suited to some areas and not others. One fundamental challenge of AI is the need for sufficiently large data sets to train the algorithms. It is necessary that these training sets have far more data points than the query set. If this is not the case, then AI will have little to no impact on the problem. This is particularly acute in drug discovery, where the query set (chemical space) is over 1063, and the data points are many orders of magnitude less than that.

Another misconception is that AI and machine learning are the same thing. Machine learning is a very specific sub-field of AI. In fact, almost everyone doing work in this field is using machine learning (image processing, language processing, text processing, clustering, property prediction, and so on).

AI is not a black box that magically solves any problem it is applied to. It is a diverse set of powerful technologies that requires ingenuity, deep understanding of the problem, and large amounts of quality training data to develop a successful application.

Biancalani: AI cannot replace human scientists in target and drug discovery – but it can definitely help them. Today's datasets are so massive that humans cannot possibly "look" at all this data; we need computational methods to extract relevant patterns and information in an automatic fashion. AI offers the tools for doing just that.

Another common misconception comes from the name "artificial intelligence," which suggests that these algorithms possess (or can eventually exhibit) intelligentia in the same way a human does.

"AI is an essential tool or "lever" for R&D and the creation of patient-centric solutions, but it is just one part of the puzzle."

This is not correct. These algorithms can perform tasks that were typically performed by humans, but that doesn't make the software "intelligent." For example, a software that allows a vehicle to self-drive is very cool, but doesn't imply that the software "learns" or "thinks" in the same way a human does.

What is the hype versus the reality of AI?

Biancalani: AI is an essential tool or "lever" for R&D and the creation of patient-centric solutions, but it is just one part of the puzzle. There are other critical levers for R&D, including a deeper characterization of human biology, the ability to conduct experiments at exceptionally high resolution and massive scale, and the exploration and application of diverse therapeutic modalities. It's the interplay among these levers that has the potential to deliver a variety of benefits for patients.

AI is a great tool for navigating large datasets and finding insights that can inform the development of better medicines for patients. But we aren't at the stage where AI can create a medicine on its own. We still need scientists to validate these insights in the lab and to test the safety and efficacy of potential medicines in clinical trials.

Viney: The excitement surrounding AI in drug development is palpable, as it has emerged as a powerful new technology that can help us to design better drugs and advance them faster to patients. The reality is that there are a multitude of ways that AI can be integrated in the drug discovery process, and our industry is in the early stages of building new approaches to use AI and machine learning. There is so much potential in the future; AI can make major contributions to how we can improve and accelerate the process of creating new medicines.

Bigal: Many companies and scientists have set out to apply AI and machine learning to the entire drug discovery spectrum, from target identification, small molecule discovery, and optimization, to biomarker discovery and clinical trial design and execution. There has been a huge amount of hype from some of these companies, stating that they will solve all the challenges of drug discovery. However, in reality, many of the areas they claim they can impact do not have large enough training sets for this to be possible. In particular, the application of AI to identify new chemical starting points and optimize affinity of chemical matter using purely image-based approaches is an area where the hype outweighs the reality.

As I mentioned, the theoretical query set of small molecules is thought to be about 1063, yet the training set in the best of circumstances is likely less than a million compounds (10^6), if we combine all known small molecules with enough information to train on. Thus, applying AI and machine learning to this challenge is not feasible. One simply has to look at the molecules produced by some of these companies purported to use image-based machine learning approaches to realize that this is largely hype. In reality, they are simply making small modifications to pre-existing chemical matter, which a good medicinal chemist could do easily without any computational help.

The challenge of small molecule drug design is a function of physics. The laws of physics are universal and thus applying machine learning approaches to enhance and optimize physics-based parameters requires a far smaller data set to train on. I believe companies pursuing these types of approaches and platforms are the ones that should be able to realize the value of machine learning to this problem.

What advice would you give to others interested in using AI for pharmaceutical R&D?

Bigal: My advice would be to make sure that you understand the problem from the first principles and not just assume that AI can solve it. Find those areas to which AI approaches are best suited, where sufficient training sets exist, and focus on those areas. Drug discovery is an incredibly complex and difficult undertaking; don't assume there is one way to solve the challenges and instead think beyond AI to look for solutions. Importantly, never underestimate the need for experienced drug discovery scientists in your organization. Nothing can replace years of experience and a track record of success in developing drugs that address diseases of high unmet need. AI is only a tool to support those

scientists and cannot replace the years of experience and know-how that will remain a critical component for success.

Biancalani: Smaller enterprises, such as startup companies, often have sophisticated AI methods. However, to be successful in leveraging these methods to solve complex problems and accelerate R&D, you need both sophisticated AI and large datasets. Large datasets can be very difficult for a small company to access, but they may be able to access them through collaborations or partnerships with larger companies like Roche and Genentech.

What will pharma's future relationship with AI look like?

Viney: We have seen a lot of interest throughout the drug industry in AI and machine learning, and pharma companies are exploring different ways that AI can be used for specific drug modalities and in specific therapeutic areas. Like Tommasso says, it is important that companies maintain open dialogue with others who might be potential collaborators, while keenly focusing on advancing their own drug programs and developing drug product candidates to help patients.

The first AI-designed drugs are just beginning to enter the clinic, meaning we really are at the cusp of being able to see the power of the AI approach for accelerating and augmenting drug discovery and development. A decade from now, I hope we will be able to look back and see that this was an exciting time and a major turning point for medicine.

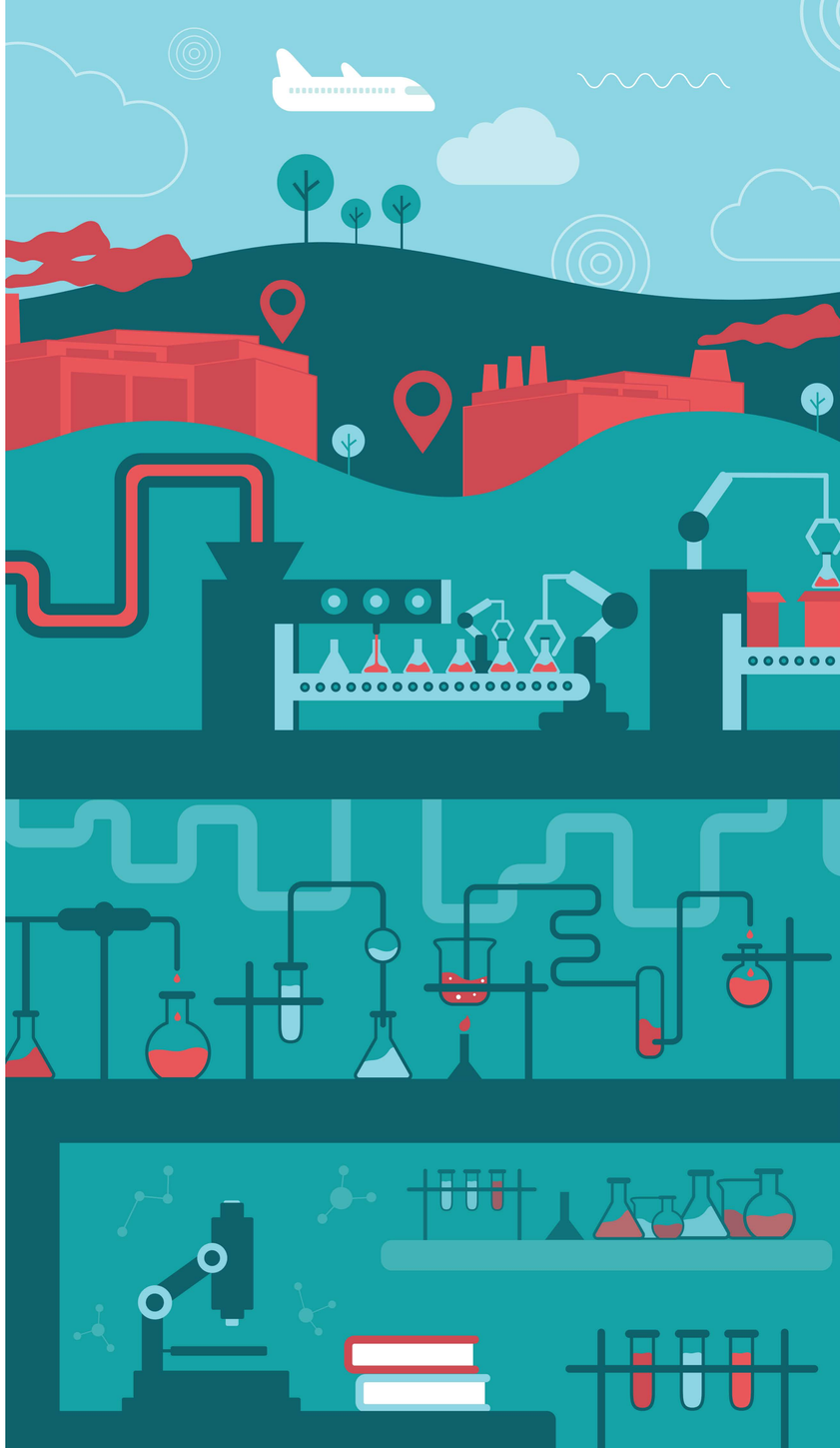
Biancalani: I believe AI can remodel every field where large datasets are present. This is an incredibly exciting time in the healthcare field. We are at an inflection point in drug R&D; science and technology are converging, and computational methods, such as machine learning, will be as essential as biology and chemistry to the future of medicine.

Thanks to this convergence, and the transformative scientific and technological advances in recent years, we have an opportunity to bring multiplicative, rather than incremental, benefits to drug discovery and development – and, most importantly, to patients.

Bigal: I think AI will continue to be a growing part of the pharma industry as we move beyond the hype and identify areas where AI can truly make a difference. With the continuing advancement of algorithms and hardware, we will continue to see innovative scientists think of new ways to apply this toolset.

It is important to remember that the concept of applying AI and machine learning to drug discovery is not new. Many of the concepts have been considered before only to fall by the wayside due to ineffective application, lack of computational power, weakness of algorithms, or the absence of enough data to train on. Though advancements in AI will make application to drug discovery more effective, I do not believe it will completely remodel the industry. At the end of the day, we are developing chemicals that have biological effects in complex organisms. The complexity of the human organism is still far beyond our understanding, and it would be naïve and arrogant to believe we have the knowledge to effectively model this in a computer to the point that it can replace experimental testing and hypothesis-driven science.

AI is an exciting new technology and we are in the hype cycle. Though some of the claims out there are for marketing purposes, there are many areas where the application of AI technology can genuinely increase throughput and efficiency of drug discovery, from target analysis with platforms like AlphaFold 2, to virtual screening of chemical libraries, to processing experimental results with image recognition. As we collect more data on biological interactions in organisms, we can envision AI helping to uncover complex patterns underpinning those interactions that would help us to understand disease mechanisms, select the most effective targets, rapidly identify and develop therapeutic molecules, and quantify effects of genetic variability to personalize treatments.



MANUFACTURE

Out With the Old

If the pharma industry wants to move ahead of the curve when it comes to manufacturing, it must do away with the legacy systems that hold it back

By Angelo Stracquatanio, Co-Founder at Apprentice Field Suite.

The life science industry is shifting toward more complex manufacturing, which can evidently be seen in the development of new biologics and cell and gene therapies. Despite these innovations, the approach to manufacturing critical drugs is stuck in the past; traditional methods – paper-based processes and legacy systems – can't hold up to the demands and pressures of new production methods.

Organizations must seek new ways to scale up and down to suit different batch complexities and sizes, identify how to handle new product introductions, and orchestrate flawless execution across teams and sites. Leading organizations are now embracing technologies, such as cloud computing, augmented reality, and AI, because modern, intelligent systems can bring them up-to-date and help them remain competitive in an ever-changing market.

In particular, AI tools can be used to augment decision-making with data-driven analysis. It can be built into the applications that decision-makers use daily, delivering usable insights that improve outcomes based on the data.

"Using AI, historical data can be analyzed to determine what may happen next and to help with process optimization."

Although some currently available pharma systems can provide historical data, what's currently missing is the ability to make predictions. Using AI, historical data can be analyzed to determine what may happen next and to help with process optimization. Organizations can also build AI models that simulate changes in process data to see how it would impact yield, quality, and efficiency, without having to run extremely time-consuming manual tests. Simply put, AI predictions can speed up these processes as the data already exists in one central system. In turn, organizations become less reliant on technical teams for data gathering, report analytics, AI modeling, and data requests.

On the shop floor, pharma organizations can even leverage AI to help machines make their own predictions or manage their own preventive measures. Operators can continue with confidence knowing that the shop floor can operate itself to increase speed and efficiency of production.

Though many in the industry are finally seeing the immense benefit of incorporating intelligent technologies and AI into their operations, there are only a few software providers capable of providing systems that are flexible enough to scale up and out with changing methods or deliver on the promise of pharma 4.0 connected systems. Traditional manufacturing technologies cannot easily (if at all) incorporate AI into their applications because of the level of technical expertise required to not only customize the platform, but also properly implement it and manage the AI models.

COVID-19 accelerated the immense uptick in adoption of new technology approaches in pharma, but there are few vendors who can adapt to the industry's changing needs and provide systems that are future-proof.

Perhaps the biggest drawbacks of these tools stem from a lack of understanding in terms of use cases and benefits. In my experience, some simply lack technical knowledge to use these systems effectively. Identifying how to apply this tech can be an issue for customers who aren't sure where to start, especially if those customers are using their own data scientists to maintain AI tools.

And for those who fear that there are risks associated with using AI for automation in such a highly regulated industry? I would remind them that there are guardrails that can be put into place. It's also worth noting that critical decisions will also always require human involvement. Overcoming many of these challenges comes down to appropriate education and support. By providing the right information, we can help each other on our journeys towards modern digitization. If you've not already embarked on your journey, now's the time!

Intelligent technologies, including AI, can increase operating efficiency, ensure process reliability, better track performance, and help you plan for the future. In a constantly changing landscape, the degree of digitalization will be a key differentiator. Even the FDA is investing in its own modernization plan, pushing out legacy systems and encouraging greater adoption of digitalization. In short, pharma needs to adopt new technologies to remain competitive and keep up with demand.

MANUFACTURE

Finding the True Meaning of Disruption

When it comes to innovation, keen and eager companies often describe their work as disruptive. But how many of the innovations making their way onto the drug development and manufacturing scene truly have the capacity to change the industry for the better?

By Noel Maestre, Vice President, Life Sciences at CRB

Disruptive is a term that is overused in the life science industry. It's often applied to marginal technological upgrades or even adapting a tried and true technology to a new application. That said, the current transformation in our industry is both exciting and unknown – and, by definition, disruptive.

Much like the scientific revolution currently being fueled by novel modalities, such as RNA, cell therapy and gene therapy, we are also seeing swift technological advancements. Pharma 4.0 is a complex ecosystem of tools, systems, and technologies that will amplify the industry's capabilities to a degree nearing science fiction. The age of lights-out, cloud-based, fully automated, and self-learning facilities is entering the biopharma industry, and progressing at a rapid pace.

As an industry, we must prepare for the profound changes the next two decades will bring in the form of curative therapies being manufactured in factories and processes that will have little resemblance to the ones we know today. Automation will help us get there. But it is our responsibility to harness the power of this revolution to make cures and therapies accessible to patients around the globe.

COMMERCIALIZATION

Making the Most of Big Data

Data is of massive value to all pharma processes and operations, but it is also of crucial importance to patient acquisition. But given the vast volume of data companies must trawl through, what is the best approach for finding the information that matters?

By Devesh Verma, Decision Science Principal and Brian Gibbs, Ph.D. Principal – Decision Science, at Axtria, Inc.

Pharma companies are in the business of bringing life-saving medications to the right patients at the right time. But if there are no patients, there is no pharmaceutical industry! Therefore, from a broad perspective, the patient challenge for the industry can be classified into two categories. The first challenge is to "acquire" the right patient on the brand, and the next challenge is to retain the patient so they can get optimal benefit from a given therapy.

Pharma medicines are produced with more specialized and novel agents than ever before, which, in turn, results in higher costs and poses reimbursement challenges from the payer community. However, payers are willing to pay for the medications that work effectively for patients, so the industry has to identify the right patient population for a therapy, and the point at which they become eligible.

What does this have to do with AI? Data is the foundation of building an ideal patient acquisition and retention strategy for any pharma company. As the world gathers greater amounts of data from connected devices (for example, health monitors, EHR, lab testing, and so on), an eligible patient for the right therapy can be identified much earlier in their journey. Data can also identify the profiles of patients who may be susceptible to poor adherence to therapy.

However, the industry's biggest struggle is connecting data across multiple sources and making it available to business stakeholders in real-time. Although connecting data sounds straightforward, when bringing together multiple systems, companies require a primary identifier, which is not readily available at the patient level due to privacy concerns. So, the question becomes, what can the industry do to learn and act on data in a compliant manner?

Machine learning may offer a solution. It is an application of AI that provides systems the ability to automatically learn and improve from experience with little or no explicit programming. Best-in-class organizations will have robust libraries of dynamic AI and machine learning algorithms that inform or directly drive action and provide endless opportunities to address complex questions more precisely and dynamically. Issues related to healthcare physician communication, promotional engagement, and patient behavior can all be predicted and acted upon using such systems.

But as with any algorithm, their ability to adaptively learn using streaming data and accelerated turnaround times is a significant risk. This particular challenge is referred to as "learning bias" and involves systems being trained on biased data. Though easily detectable by examining algorithm performance across learning iterations and closely profiling predictive errors, these steps need to be explicitly built into the AI/machine learning system (and usually require human intervention to diagnose and correct).

Therefore, algorithms should be developed with attention to bias in ways that may drive suboptimal or unethical actions. In many cases, algorithms may need to be simplified to provide explanation and understanding to inform stakeholders of the interventions that can help them avoid this type of predicted outcome.

Though this issue may seem daunting, the potential for AI and machine learning growth within the pharmaceutical and healthcare

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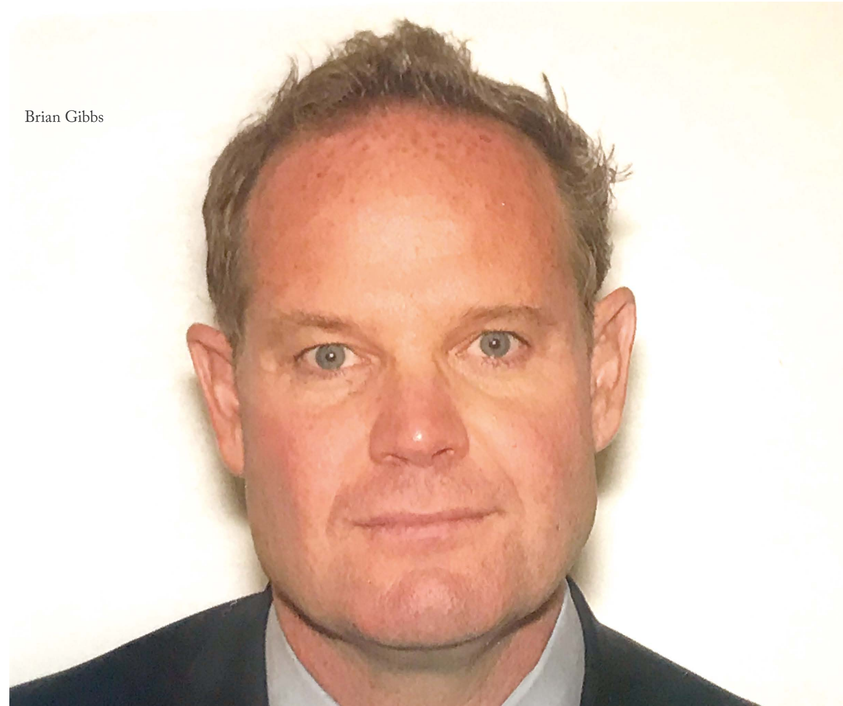
Devesh Verma


Brian Gibbs

sector is substantial. So much so that ample funds are being made available for expanding and investing in these technologies. The general perception is that there will be a strong return on investment upon their implementation.

Although a vast number of pharma business problems are amenable to machine learning-based solutions, there are also a significant number that are not and will continue to require knowledge, expertise, and judgment.

In our view, there are three necessary conditions for an AI or machine learning solution to generate high value for pharma organizations:

1. Domain expertise. Teams developing the algorithms must understand the nuances and complexities of the buying process in pharma in general, the differences across ecosystems, and specify their algorithms to capture these complexities.
2. Data expertise. Teams developing the algorithms must understand the vast data challenges in pharma, differences across regions or geographies, and have solid initial starting protocols for dealing with those challenges.
3. AI and machine learning expertise. Teams developing the algorithms must understand best practices for algorithm development, be able to scale the analytic process for numerous countries and dynamically evaluate results for precision and bias, and evaluate the tradeoffs between algorithm explanatory power and parsimony before having them operationalized to inform – or directly drive – action.

If companies can keep these factors in mind as they embark on their journeys, they should be able to reap the massive benefits that these digital solutions offer. Without them, they may find themselves inundated and overwhelmed with the highly valuable, yet unrefined data they own.

COMMERCIALIZATION

A Question of Security

As the industry embraces more AI-driven technologies, what cybersecurity considerations will have to be made? Vishal Salvi, CISO at Infosys, outlines what companies will have to learn to help keep their data and technologies safe in an increasingly digitized market.

Securing the bioeconomy is an ongoing challenge for companies across the life science and pharmaceutical sectors. Though companies from both sectors continue to innovate and adopt tools like AI to drive progress, the fact of the matter remains that pharma companies lag behind other businesses when it comes to the management of digital assets. This is also true of the industry's adoption of pertinent cybersecurity systems.

Last year, we spoke to Vishal Salvi, CISO at Infosys, and Charles Fracchia, founder BioBright and Vice-president of Data at Dotmatics, about the issue. But how have things changed since then? The industry certainly hasn't remained stagnant and as it grows and evolves, new vulnerabilities are sure to emerge.

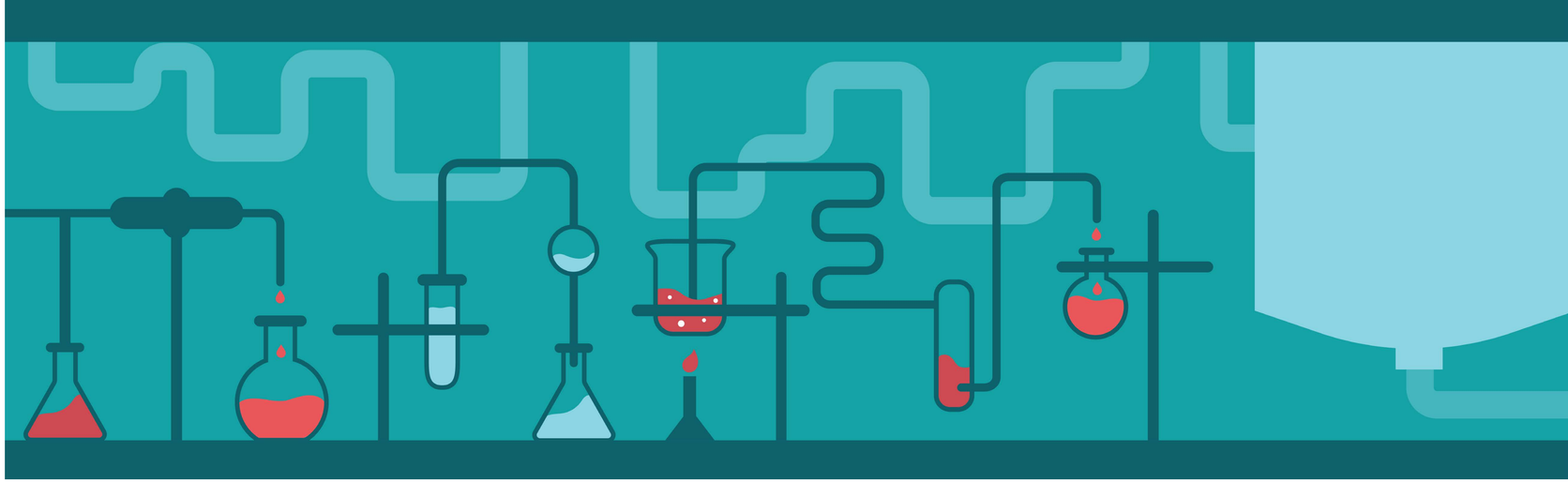
He joined us for our inaugural Big Question – an anthology of articles exploring whether pharma can be remodeled using AI – to share his thoughts on pharma's relationship with cybersecurity and how the increased use of AI will impact it.

THE PATIENT EXPERIENCE

Collaborating for a Cause

How Boston Scientific and IBM Research joined forces to use AI to help patients living with chronic pain

By Maryam Mahdi, Deputy Editor



Boston Scientific and IBM Research are collaborating to create an AI-based platform that provides doctors with personalized insights into patients' experiences with chronic pain – measuring and analyzing those experiences in a way that would not be possible without AI. By collating data from spinal cord stimulation therapy studies, the team are developing an approach that will "objectively and continuously measure chronic pain" in a bid to move medical assessment and treatment beyond arbitrary descriptors of pain level or strength.

We caught up with Rafael Carbunaru, Vice President of Research and Development, Neuromodulation, Boston Scientific, and Jeff Rogers, Global Research Leader for Digital Health at IBM Research, to talk about the platform and the role AI will play in the future treatment landscape for chronic pain.

Why is chronic pain such a complex problem for healthcare professionals to solve?

Carbunaru: For patients living with pain, finding the right treatment is a journey. The road to effective treatment can be further complicated for many as they are not aware of – or cannot access – the services and expertise of physicians and other healthcare professionals who specialize in the field.

Pain is also a subjective experience. So, when patients do access healthcare support, they may find it difficult to accurately describe what they feel. For example, if a physician asked a patient to rate their pain on a scale of 0 to 10, they may choose a number that doesn't accurately reflect their experience. It is also important to remember that with time and changing circumstances, the same patient may rate their pain very differently, despite the fact they still have to manage the same healthcare challenges.

This complexity leads to issues for the healthcare provider who may struggle to know when to intervene or when the patient has a good medical regime. The problem is further compounded when we acknowledge that patients may only visit their doctors a handful of times a year.

If patient data could be quantitatively addressed to provide a holistic picture of the patient landscape, we would be able to provide better support for all parties involved and help reduce the burden of chronic pain in society.

What's the story behind the partnership?

Carbunaru: For the past 18 years, we've been able to create therapeutics for chronic pain. Throughout this development, we remained in close contact with both patients and physicians. But we came to understand that managing pain is a unique therapeutic area. Pain is more than just a sensation; it affects many aspects of patients' lives.

Our goal was to help the patients who are living with this huge burden and help them achieve better health. And that's why we partnered with Jeff and his team at IBM Research. By combining Boston Scientific's experience in neuro-engineering, clinical studies, and patient contact with IBM's data science and AI know-how, we aimed to better understand the needs and experiences of the patients, who, on a global scale, live with pain.

We are collecting data on patients' mood, alertness, sleep, medications, pain level, and mobility to create a holistic profile of their experience. These factors work together to produce a single index that describes the fluctuating pain patient experience that we have called Pain Patient States. Though we are not developing a therapeutic agent, by building an understanding of patient states, we will be able to support physicians in making decisions with regard to patient care and even open the possibility to automatic therapy recommendations.

Rogers: As Rafael says, the partnership is all about better defining the patient experience. But how will we do that? Boston Scientific develops devices that can be used to create flexible and personalized therapies – the challenges they face is how to continuously choose the

optimal therapeutic interventions – while we use the data produced to make personalized projections of future outcomes to those interventions. The amalgamation of these two approaches is how we intend to improve patient outcomes by recommending the best projected intervention.

What impact will this collaboration have on the future of drug development?

Carbunaru: Some drugs that are used to treat pain can result in addiction – with long-term consequences for patients and their families. By creating a fuller picture of the millions of patients who live with chronic pain, we can highlight real individualized patient needs and thus point the way to new therapies and treatment approaches. And so, though our work is focused on spinal cord stimulation devices, it has the potential to be applicable to the entire pain management spectrum, including pharma. It could even help in improving therapeutic outcomes for other chronic conditions.

How has AI helped the chronic disease market to date?

Rogers: I think it has a lot of potential to help in this area, but it certainly hasn't had a broad impact yet. In the case of our current collaboration, AI has been a major driver in understanding the correlations in the data we have collected. It's really helping to shape ideas not only about the patient population but also individuals. We can begin to answer questions that address what a healthy Pain Patient State looks like for a particular person and create a tailored healthcare experience for them.

A patient's physiological and psychological state are affected by pain – and AI can give us a new platform to dissect the way these aspects of human health work together.

Carbunaru: AI is still a relatively new tool in healthcare. When you introduce something new – and very powerful – to the industry, there will, of course, be questions; some questions come from regulatory bodies and others from companies themselves.

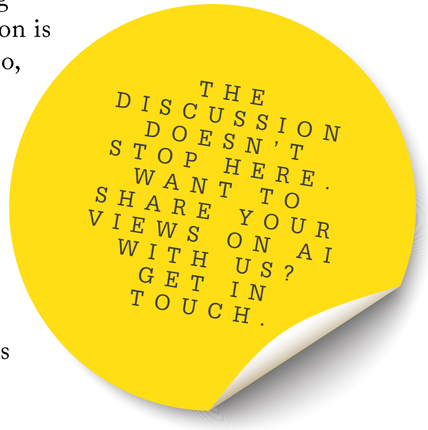
Although this may present challenges for some companies, it will definitely be a positive step forward as it will help bring new solutions to patients waiting for improved quality of life.

Is there a limit to what AI can achieve?

Rogers: It is not a silver bullet! Although AI has the massive potential to improve healthcare, like anything else, it doesn't solve all the problems experienced by patients, physicians, and other stakeholders within the sector. At best, AI is an augmenting set of tools to help enhance traditional healthcare approaches.

The FDA and other regulatory authorities have done a great job in thinking about the future use-case of AI. But, in my view, the healthcare community and the industry haven't clearly defined how far they can go with the technology.

Carbunaru: We're currently living through a period where innovation is happening at breakneck speed. So, the predictions we make today may fall short of what will happen five years – or even a decade – from now. For those of us working in R&D, we have to remain optimistic about creating a better world and helping patients achieve better health outcomes regardless of where AI may take us.



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Jeff Rogers