A 2017 Pulse on Artificial Intelligence in Life Sciences

Key insights from practitioners and technologists

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Artificial intelligence (AI) has the potential to reinvent the entire life sciences industry—from discovery to development, to the submission process and beyond, to delivery of the product and risk mitigation of the product on the market, including management of patient safety data.

“AI is happening now and is being brought into a whole range of different areas in life sciences, whether it’s data from wearables or novel delivery mechanisms,” says Jackie Hunter of BenevolentBio. “I don’t think there will be an aspect of the life sciences that won’t be affected by AI.”

Researchers are using the power of AI to mine data, and increasingly intelligent robotics will remove routine tasks from the lab and elsewhere in product development so as to free scientists to focus on more-bespoke, higher-level tasks, she says.
Innovation through AI

Although many AI applications are considered to be only in their infancy, Martin Gouldstone of Results Healthcare says, development has reached a point where software and hardware can create true, AI-enabled learning systems that are tailored for a specific purpose.

For many, the holy grail of AI in the area of life sciences is to put it to use in the discovery of new drug targets or even in new applications for existing drugs. Experts in the area say that’s not far off. “In the near term, we’ll see AI-discovered drugs come to market,” Gouldstone says. From a public health perspective, there is enormous interest in developing a suitably powerful tool that provides medical advice for the prevention of self-induced disease, Gouldstone adds.

“The technology for promoting wellness and compliance through AI-enabled technology is here,” Hunter says. “It’s the social component—meaning, whether people have the will to use AI-enabled technology to monitor their health and guide their lifestyles—that’s the bigger issue.”

Product delivery in remote regions is another exciting AI application. “For example, Zipline has used AI-controlled aircraft to deliver lifesaving medicines and blood products in Rwanda,” Hunter says. “The logistics of getting and distributing medicines will change. In fact, all along the value chain, AI can now be applied.”
From Artificial Intelligence to Regulatory Intelligence

There is growing interest in AI’s potential for harnessing and tapping into data that exists across a life sciences company in both structured and unstructured forms. Applying AI to mine real-world data outcomes in order to gain deeper regulatory insights enables companies to tap into data that currently remains untouched simply because it’s too difficult to do so.

“This is especially true of such areas as free text,” Hunter says. “But unstructured data could aid in early approval, which would lead to early adoption—with concomitant real-world outcomes. You could look for patterns and trends and clustering much more effectively. And then it comes down to personalised medicine: having better diagnostic criteria to stratify patients and to be able to think about approving drugs for particular subsets or clusters.”

“There’s growing awareness in big pharma that it’s important, and some companies are moving to create specialist roles to look out for this new technology and the ways it will help,” says Gouldstone. Mark Davies of BenevolentAI says that large pharma companies have a real opportunity to delve into historical data sets and extract new insights from data collected a long time ago—possibly from multiple sites around the world and from company mergers.

Christopher Rudolf of Volv Partners says machine learning can be deployed in decision making—for example, to analyse whether a drug is likely to get authorised. “At the other end of the spectrum, AI might be used for detecting anomalies in a company’s regulatory information management solution, such as by looking for gaps in the data that might be holding up regulatory approval,” Rudolf says.

“Typically, there are tens of thousands of pages in a submission, and it’s difficult to manually spot where data or metadata might not be stacking up. Teaching an AI system to assess previous, successful submissions enables the system to quickly learn patterns and to alert regulatory teams if it detects anomalies in the latest submission.”

One of the areas companies are investigating to see whether AI could manage data about their products is the Identification of Medicinal Products (IDMP), says Steve Gens of Gens and Associates. “About half of IDMP is in unstructured content—the summary of product characteristics, clinical reports, and manufacturing reports—and if handled manually, would require a person to search for correct reports, then to extract the data, and then to put it into an IDMP database,” he says. “For large companies with big portfolios in multiple markets, that’s an enormously complex and time-consuming task.” He adds that if AI can be applied to conduct the initial search and data gathering, then the manual task would simply be to verify the data before sending it to the regulatory authorities.

In its 2016 industry survey called Pursuing World Class RIM: Strategy, Measures and Priorities Gens and Associates found that about half of the 54 companies surveyed were investigating AI for purposes of the IDMP; about a third were monitoring what other companies were doing; and only 15% had no interest in AI for those purposes.
Tapping into the Patient Experience

To improve health-care delivery, more-extensive application of big data is expected when it comes to patients: data from patients in clinical trials, data from patients associated with clinical practices, and even data that patients gather from wearables. Such applications might include improved treatment modalities or better protocols by selection of therapeutic options based on a patient’s phenotype and by the mining of publicly available information on patients to influence decision making in R&D.

Gouldstone points to ongoing work by several organisations to better manage patients and disease progression. Even though its project has encountered several stumbling blocks, Duke University has used Watson algorithms to predict oncological diseases.

According to Hunter, AI has several potential applications in product safety—for example, in the use of algorithms to predict toxicity in clinical trial studies, which would give companies information for developing better molecules. There’s also the capacity to use AI to look at pathology specimens. “At the moment, a lot of the delays in toxicity studies are due to pathology reads,” she says. “If that function could be done automatically by using intelligent systems to recognise what’s normal and thereby free the pathologist to focus only on what’s abnormal, then that should expedite those studies.” She adds, however, that there are always questions as to whether the regulators would accept automation in toxicity studies.

Rudolf agrees, pointing to how AI is being applied to identify women whose Twitter posts indicate they have an increased risk of developing two relatively rare diseases: ovarian cancer and cervical cancer. Those identifications have produced accurate alternative diagnostic insights, and several companies are attempting to aggregate data from patient health records by using AI-derived ontological approaches that try to interpret unstructured content—for example, handwritten doctors’ notes.
More immediately, there is ongoing investigation of the deployment of AI for safety case process automation by applying AI to differentiate between low-risk and high-risk cases, to automate low-risk cases, and to have a safety expert manage high-risk cases, Gens says. “Case volumes on both the clinical and postmarketing sides are growing by around 15% each year,” he adds. “If you’re handling 500,000 cases per year—which is typical for larger companies—and on top of that you’re looking into social media networks for safety signals, that represents a huge increase in workload.”

The approaches companies take vary significantly. GSK for one has decided to take a progressive approach to social monitoring—and indeed to AI in general—and has established a pharmacovigilance centre of excellence to collect data from social media with a view to understand how its products are helping patients, to gather data on any adverse events, and to learn of potential misuse of its drugs. “AI won’t replace safety experts, but what it will do is remove many of the obstacles to the monitoring of safety signals not only in social forums but also in safety databases,” Anelli says.

According to Rudolf, regulators are starting to seek real-world evidence and patient-reported outcomes, and some companies are starting to introduce social listening and soft-data capture during phase 3 clinical trials as well as hard-data capture on devices so as to really create the evidence base for the time the product reaches the market. “Combining hard data and soft data early on improves prediction models, making it easier to pick up signals misuse of drugs and potentially help governments track how those drugs are being used or abused,” he says.

Using AI to gather data during clinical trials could feed into the entire life cycle, experts say. “If you look at some of the autonomous vehicles that Google’s building, which are continually collecting data and sending it back to build and refine models and improve the experience, those vehicles could equally be applied to wearables aligned with conducting clinical trials,” Davies says. “Through the use of AI, data would be collected, analysed, and fed back; would then go into the actual analysis from the trial data; and would then be used for monitoring and analysing adverse events.”

Hunter adds that the extension is for the data to facilitate more-adaptive clinical trials. “For example, currently, because of concern about bias, we don’t usually perform interim analysis,” she says. “Through AI, the independent safety-monitoring committee could get the data much more quickly, and there would be the potential for a blinded interim analysis at the machine level, which should get rid of the bias so that there might be no need to increase the power of the study. Therefore, there’s lots of potential in terms of new trial design.”

AI also has the potential to raise flags earlier on because it is especially good at picking up rare signals across a range of data. “You might see something that by itself doesn’t raise a flag to the naked eye—such as small increases in blood pressure that show up as blips—but if you see them consistently across all the sites, it could mean something,” Hunter says.
Tackling Regulatory Challenges

One of the barriers to integrating AI into the product life cycle—for example, to find safety signals—is the regulatory process itself, experts say.

“Regulators historically are very slow to react to change and progress, and the industry will have to work with such organisations as the US Food and Drug Administration and the European Medicines Agency to get them to recognise AI-enabled insights as a valid part of the reporting package,” Gouldstone says.

Hunter agrees, adding that many of the diagnostic tests currently required in the European Union and by the World Health Organization are out-of-date and that regulators are many years behind the technology.

“Self-learning AI systems that continue to learn as they get deployed in various situations present certain interesting challenges for regulators because the way those regulators might be calculating a certain parameter or determining a certain recommendation is highly likely to change over time,” Hunter says.

Intellectual property presents another challenge because any discovery made by means of AI will have to be quickly patented and protected, and Gouldstone says he’s not sure the patent system is equipped to keep up.
AI and the Future

AI clearly has an important role to play across life sciences products’ life cycles. AI experts in the industry are increasingly looking at ways to deploy machine learning so as to access the depth and breadth of regulatory data for evaluation of executable intelligence and for overcoming information challenges.

As more and more companies evaluate their structured and unstructured data and achieve beneficial outcomes from those evaluations—whether it’s enhancement of the submission process, successful mining of social media for learning about potential adverse events and other patient feedback, the discovery of new indications, or improvement in the manufacturing and supply chain process—the pace of AI adoption will gather speed.

About Volv Partners

Volv Partners’ mission is to enhance well-being for all people by accelerating science and reducing the costs of health care. Volv strives to accomplish that mission through close relationships with official organisations and institutions in the life sciences and with medical industries and partners that want to progress real-world evidence, foster adherence, and promote medicine and medical device safety agendas. Volv’s technology team combines its members’ substantial experience with expert application of the latest tools used in the real world. The team’s specialists created and have run highly valuable algorithms that have been adopted by the biotechnology sector and that are currently used extensively in the latest Web, cloud, machine-learning, and artificial intelligence technologies.

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