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Big pharma piles into machine learning, but what will it get out of it?

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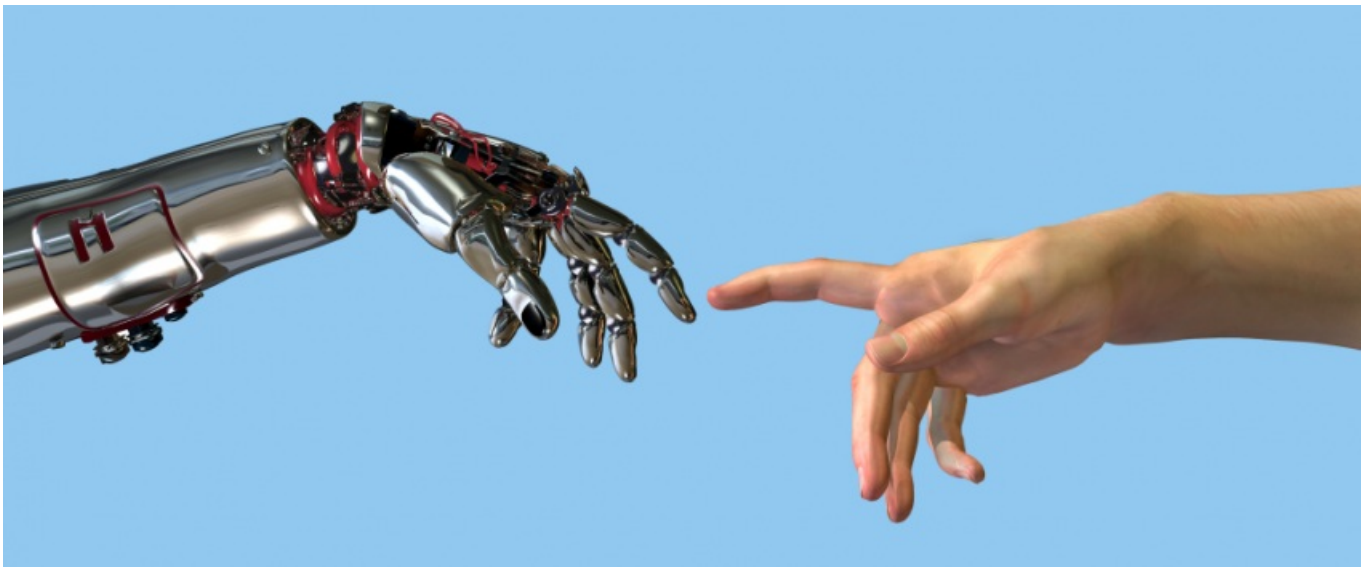

Big pharma is using machine learning to improve the drug development process – but can the tech live up to the hype?

Machine learning has been a buzz phrase in biopharma for some time now, even though some in the industry still struggle to define it. Many wonder whether the reality of artificial intelligence can live up to its hype and, if it does have a serious role to play, whether regulators are ready to embrace its use.

But it cannot be denied that data-mining has become widespread, with uses ranging from study recruitment to alerting regulators to clinical trial fraud. Perhaps most importantly, big pharma has embraced these technologies. Nevertheless, there is still a perception that at least some big pharma groups are jumping on the AI bandwagon without a clear idea of what they want to achieve.

Medidata, which specialises in AI for clinical trials, offers a glimpse into the new reality, counting 18 of the top 25 pharma companies as clients. And its chief executive, Tarek Sherif, has a warning to late adopters, telling *EP Vantage*: “In the next 10 years the companies that are most aggressive about adopting digital strategies will be the ones that are ultimately successful.”

He obviously has a vested interest, but others are taking matters seriously, too. The AI Summit in London in June, for instance, for the first time included a dedicated pharma track featuring many of the sector’s big players.

Low-hanging fruit

Its potential remains to be proven, but AI advocates see a vast array of applications for technology that can analyse and learn from reams of data, ranging from identifying potential new drug targets, to monitoring adverse events linked with approved products, to streamlining clinical trials.

And, once a trial is completed, machine learning could be used to find errors or inconsistencies in data that would otherwise lead to delays or regulatory knockbacks. This could include identifying outliers at sites whose unusual results could be down to issues as serious as fraud – sites creating patients that do not exist and falsifying data just to get paid – or something more benign like manual error.

In the past, companies usually only noticed such discrepancies once a study had closed, causing delays, but perhaps not disasters. “If your biostats team picks it up there’s still time, potentially, to deal with it,” said

Medidata's Mr Sherif.

Worse off were companies that did not spot anomalies before sending data packages to regulators, resulting in studies having to be re-run. Medidata has a technology called Trial Assurance that pinpoints inconsistent trial data in real time, something Mr Sherif says can be used while studies are still blinded.

Once identified, problem trial sites can be addressed before they affect the final results. Alan Louie, an analyst at IDC Health Insights with a particular focus on AI, described Trial Assurance as "a very effective tool to reduce the amount of time it takes to lock up the study and submit it to regulators. It's being adopted pretty quickly."

Ready for prime time?

Still, machine learning might not yet be ready for prime time. The sector has recently been hurt by reports that one big machine learning player, IBM Watson, was using algorithms that were causing incorrect cancer treatments to be recommended.

Another AI specialist, GNS Healthcare, is unperturbed by the Watson revelations. The company's co-founder and chief commercial officer, Iya Khalil, described Watson's technology as "a rudimentary way of doing machine learning".

She told *EP Vantage*: "A big part of the IBM Watson thesis was to use expert knowledge to drive learning, but that knowledge is incomplete. Watson got its name by beating someone at chess – starting from a point where we already knew the rules. In medicine and biology we don't know what the rules are."

Were it not for such snafus the potential of such technology would be clear. "For me, the biggest win across the entire pharma industry is shortening clinical trial times," Alex McMullan of Pure Storage told *EP Vantage* on the sidelines of the AI Summit. The company provides machine learning technology across various sectors, including pharma.

AI could have an impact at the trial recruitment stage, a potential bottleneck in drug development. At the AI Summit, Raphaël Pousset-Bougère, Ipsen's vice-president of big data and analytics, noted that biopharma spent 30% of its clinical trial time finding patients.

The French company is using AI to speed up recruitment, for example by identifying trial sites that are most likely – or unlikely – to hit their patient targets. Another application for machine learning could be reducing dropout rates, which can reach 30%, according to Medidata.

IDC's Mr Louie told *EP Vantage*: "Machine learning tools are very effective in identifying characteristics of patients who may be ready to drop out; then you can intervene and prevent that from happening."

And AI could have a place in the era of personalised medicine, with GNS's Ms Khalil describing how an analysis of a phase II study could be used to select the best responders for phase III.

But is this approach not already widespread? "Machine learning makes the process faster," she replied. "And in some cases it can't even be done without machine learning. For scenarios where the answer's really simple, where it's one mutation or one gene, you don't need machine learning. But these diseases are complex – often many factors are important. There are just too many possibilities to sift through."

Regulatory caution

A separate considration is whether regulators will be reluctant to embrace these kinds of technologies. "Regulators don't move that fast," said Mr Louie. "They're cautious to make sure there are no flaws in the methodologies such that a patient could get hurt."

Medidata is, predictably, more optimistic, with Mr Sherif noting that regulators themselves are interested in the company's Trial Assurance tech. "It could become a self-perpetuating thing: if the FDA is using it you're going to want to have your data checked before you get it to the FDA, because you don't want them to find something you didn't."

Pure Storage's Mr McMullan is even more bullish: "We're transitioning towards trusting the computer, trusting the model. I think in many cases we need to hurry the hell up." He added that safety simulations are commonplace in other industries, pointing out that in Formula One, for example, "most crash testing is done by computer now".

The recent Watson debacle might have given regulators another reason to tread carefully, but the buzz around machine learning in biopharma is unlikely to abate in the near future. With big companies like Novartis talking up a digital revolution, smaller players are sure to follow suit.

Mr Sherif highlighted Roche and Celgene as other large groups that have been particularly aggressive in the space. And the machine learning goldrush does not look like slowing down anytime soon, with Mr McMullan

noting: “The most common question I’ve been asked in the last two years is: how do I get started in AI?”