Artificial Intelligence: On a mission to Make Clinical Drug Development Faster and Smarter

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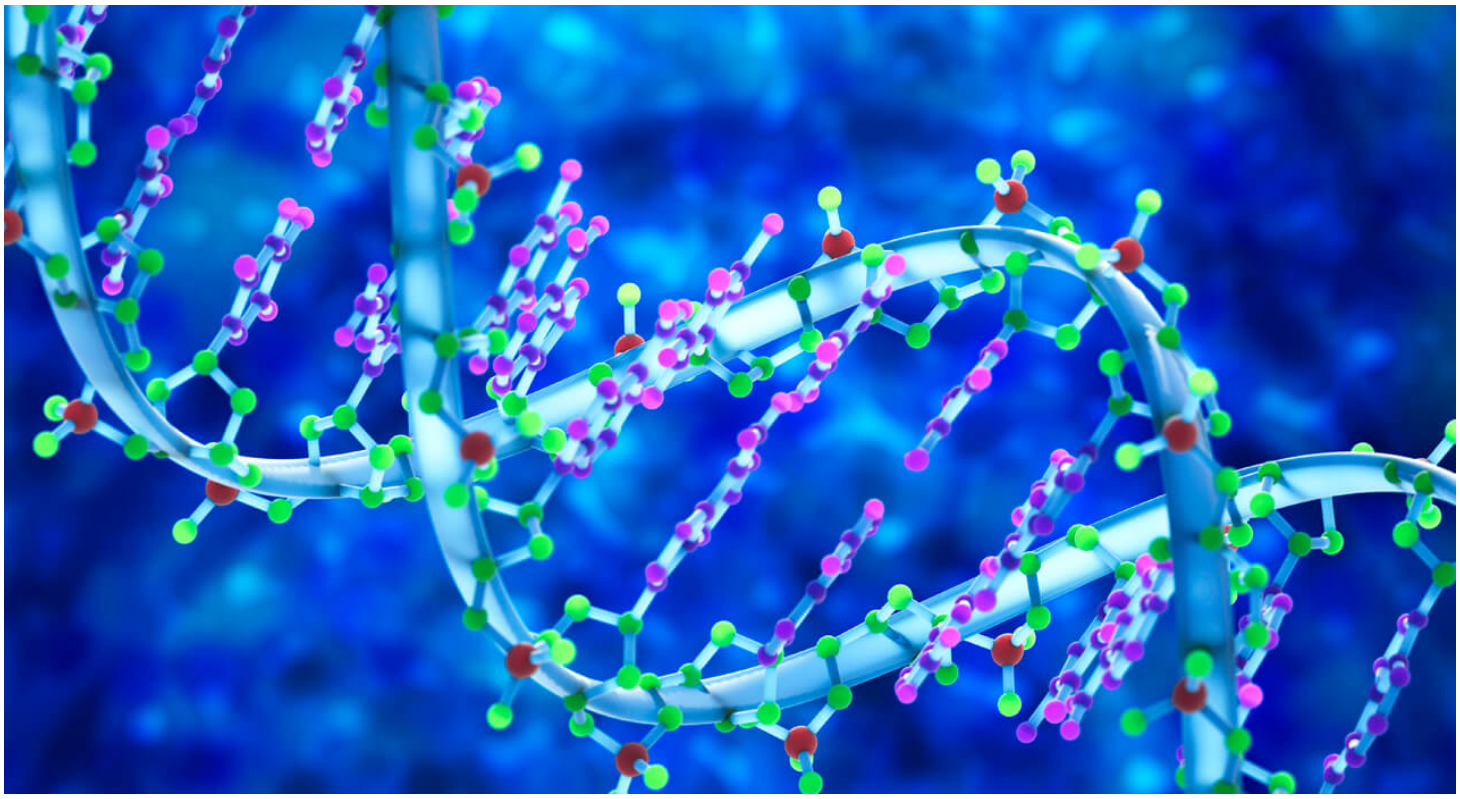

Just as Industrial Revolution-era factory builders developed machines to mass-manufacture drugs once ground by hand, today's pharmaceutical companies are turning to artificial intelligence (AI) to both speed and smarten the work of clinical development.

AI could assist pharma companies in getting medicines to market faster. AI today not only does flashy gene-sequencing work, it's being trained to predict drug efficacy and side effects, and to manage the vast amounts of documents and data that support any pharmaceutical product.

A quick primer: Artificial intelligence, or AI, is a blanket term for many advanced computing techniques. Two that matter to pharma companies are machine learning, which applies trained pattern-matching and statistical analysis to spot trends or predict outcomes, as well as natural language processing (NLP), which parses human-written words to deduce their meaning, and can also develop sentences that mirror human writing.

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The development and testing of a new drug creates terabytes or even petabytes of data at each stage. This new galaxy of information can contain additional insights previously not available to drug developers. It requires performing advanced math on huge volumes of data, but this is exactly where machine learning, a core of what we call AI today, excels.

Media scare stories about AI software seizing control of humanity are currently popular, but in reality employing AI is less like building a mechanical overlord than it is like training a super-intern. The software isn’t doing the thinking on its own, as portrayed in popular media. Human professionals train it and monitor its results for legitimacy. Machine-learning software — one of the most powerful techniques under the AI umbrella — is programmed and trained by experts, using huge sample data sets that have been painstakingly categorized by humans, to look for patterns and to call out those that matter, as defined by experts who’ve identified what counts as a good or bad result, or a notable finding.

The software then runs far, far, far faster and more accurately than an army of humans ever could, producing results that, again, are checked by experts to see if the software is properly evaluating the data to generate insights that help human developers make better-informed decisions and forecasts.

Such insights are valuable across the entire drug-development cycle. “We used to focus on storing and searching data,” says Boris Braylyan, Vice President and Head of Information Management at Pfizer. “Now we need to concentrate on true mining of our data for recommendations.”

Machine-learning analysis may also be able to improve the quality of regulatory submissions by identifying the most likely requests for information that government regulators may have and incorporating the answers from the get-go. “In the future we believe that AI may help us predict what queries regulators are likely to come back with,”

says Braylyan. “We may then be able to improve our submissions by predicting in advance what regulators are likely to ask, and coming prepared with those answers ahead of time.” This could save weeks of back and forth with regulators, when trying to get a drug to market.

Some of the smartest decisions for a pharmaceutical company include choosing which medications not to pursue. A drug that won’t be effective enough, or will have problematic side effects, pulls resources away from developing and delivering medications that could make life better for millions. “Using data to make faster decisions on a medicine’s potential,” Braylyan says, “would allow us to re-allocate resources, dollars, and expertise to the next promising candidate faster.”

Another fast-growing application of AI in clinical development is generating the myriad documents, tables, reports, and other content required as a potential new drug moves through development, testing, manufacturing, prescription and eventual use. Both regulatory requirements and a commitment to quality control require that each step of the process is thoroughly documented, so that other researchers, regulators, physicians, pharmacists and patients understand the drug’s effects, dosage and proper use.

“We produce tremendous amounts of information and content that we share with the public, with doctors, with regulators…and also internal documents that encapsulate our knowledge,” says Braylyan. “We are working to take the content created across the life cycle of a drug at Pfizer — from early analysis and predictions, lab data, and regulatory documentation, to test results and even the booklet that comes with a box of pills from the pharmacy — and both automate its creation, and ensure that it’s of high quality, using AI capabilities.”

The formal, structured nature of much of this content, and its focus on accurate data and correct terminology makes it an appealing target for automation. A computer program can calculate millions of data points in tables without error. And it can publish the same information in different documents at different technical levels and in different vocabularies for different audiences.

Exhibit A: The printed insert inside your prescription medicine box. “We call it the label,” Braylyan says. “It includes details on dosage, efficacy, side effects, potential interaction with other drugs, etc.” In the future, AI software trained and monitored by human experts will produce highly accurate labeling content for a new drug, and update it as the known information changes, in the blink of an eye, rather than requiring humans to do all the typing and confirming of each other’s work. The computer makes far fewer mistakes.

Pharmaceutical companies must produce hundreds of thousands of pages of reports and documentation for regulators. AI can help automate the production of much of that information, which comes from other, often computer-generated content, produced across the entire company and by external partners such as clinical research organizations, clinical trial sites, academic partners and investigators. “Natural language processing ensures that correct and consistent terminology is used,” Braylyan says, reducing errors and misunderstandings.

“We also need to analyze a tremendous amount of outside content not produced at Pfizer,” he adds. AI can quickly scan thousands of documents produced elsewhere for relevant information, rather than requiring them all to be read in full by a human being.

It’s still early in the game for AI as both research advisor and ultimate typist. But these concrete improvements hold promise for getting more effective drugs more quickly to the patients who need them.

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