Artificial Intelligence Improves PHARMA EFFICIENCY

As I consult with clients, I see that technology will ultimately be the driver behind pharmaceutical and biotechnology advancements in the coming decade. I believe that the use of artificial intelligence (AI) is a prime example of innovative efficiencies to come.

More than 15 years ago, when I was leading the arthritis therapeutic area at Searle/Monsanto and striving to get Celebrex to market as the first cox-2 inhibitor, pharmaceutical development was at an evolutionary stage. Manual processes were improving, but great strides in efficiencies were still needed. Six Sigma did not exist. Lean discovery and development programs were uncommon. Clinical development often moved slowly. Across the industry, discovery to market for one chemical entity took up to 15 years and cost hundreds of millions of dollars.

And it was this exact scenario that allowed my Searle/Monsanto team to capitalize on improving manual efficiencies. I was fortunate to lead a development team that believed we could do things better, smarter, faster and more accurately. By acknowledging our limitations, we were able to modify and improve our manual processes. For example, although we started clinical trials six months behind our competition, we beat them to market by six months without sacrificing quality. Because of the efficiencies our team implemented, we slashed a full year of development time for a drug that eventually generated more than $2 billion annually in revenue.

Fast-forward to today. The manual processes of drug development have been endlessly examined and study teams reconfigured. Efficiencies have been wrung from each and every thread of the manual processes, yet development times across the industry do not appear appreciably improved.

According to several reputable outlets, the current average for bringing a new chemical entity to market takes up to 15 years and costs $1.3 billion. Clearly, we still need drug development to be more efficient — faster, better, and of the highest quality. We owe it to the patients who depend on these critical drugs for their health and well-being.

Today we are in the next stage of improving drug development. We are transitioning from modifying manual processes to actively seeking and building technology components that will improve the manual efficiencies gained to date. And these technological advancements must allow us to seize the maximum benefit from both initiatives to deliver on our promises.

Technology Will Drive the Pharma Industry Forward

One highly advanced tool that leaps to the forefront of this discussion and illuminates the possibility of what technology holds for our industry is a clinical report writing tool based on artificial intelligence. In less than an hour, this tool can generate a first draft, company-, and regulatory-compliant Clinical Study Report (CSR) that is 80% to 90% complete.

Let that sink in for a moment.

In less time than most people take for a lunch break, there is a tool that successfully drafts a fully compliant, 80% to 90% completed CSR. This tool can reduce the time for completing each CSR by four to six weeks, and can reduce the internal resource utilization per study by about 250 hours and about $25,000.

I would have literally been first in line for a tool like this when at Searle/Monsanto. If I were developing a drug in today's market with the potential of Celebrex, I would no doubt implement a system that uses artificial intelligence, especially one that has shown the ability to save at least two months of time in getting an NDA to the FDA.

Blockbuster drugs in today's climate generate well more than $1 billion in revenue a year. The top 20 best-selling drugs of 2012 each individually accounted for more than $3 billion. The top drug alone had sales in 2012 of more than $9 billion, generating an estimated $24 million per day in revenue. If the technology, which is now available, had been used by only the top 10 drugs currently, the industry could have saved more than $5 billion in protected revenue.

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Impressive for sure. Yet when these figures are extended across our industry as a whole, the numbers become even more impressive. Approximately 6,000 sponsor-initiated clinical studies are started globally each year. If adopted across the industry, this one AI technology-based tool alone could cut up to 24,000 weeks of clinical development time.

And while the numbers are astounding, as a medical doctor and former vice president running several clinical teams in multiple therapeutic areas, I am extremely interested in what an AI technology could mean for internal resourcing, discovery, and development. As I reflect on my past experiences in drug development, I strongly believe my team would have been even more productive in developing new medicines with the added freedom that such technology provides. More medicines might have been developed and more patients positively impacted.

Putting AI to Practical Use

Clinical research organization technology has generally been used for purposes of clinical data management (CDM), but with the AI technology available today, through the use of new algorithms, as noted previously, there is one tool that can write clinical study reports by

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analyzing a company's specific templates and style guides and build a platform customized to specific writing and reporting conventions. The tool then "reviews" past studies and understands how best to build new CSRs quickly, accurately, and consistently.

It is the only artificially intelligent technology tool on the market, that I know of, with this degree of sophistication to recognize and understand the intricacies of vocabulary regardless of the source document. As a result, the system does not require a company to change the way it does business or learn a new methodology.

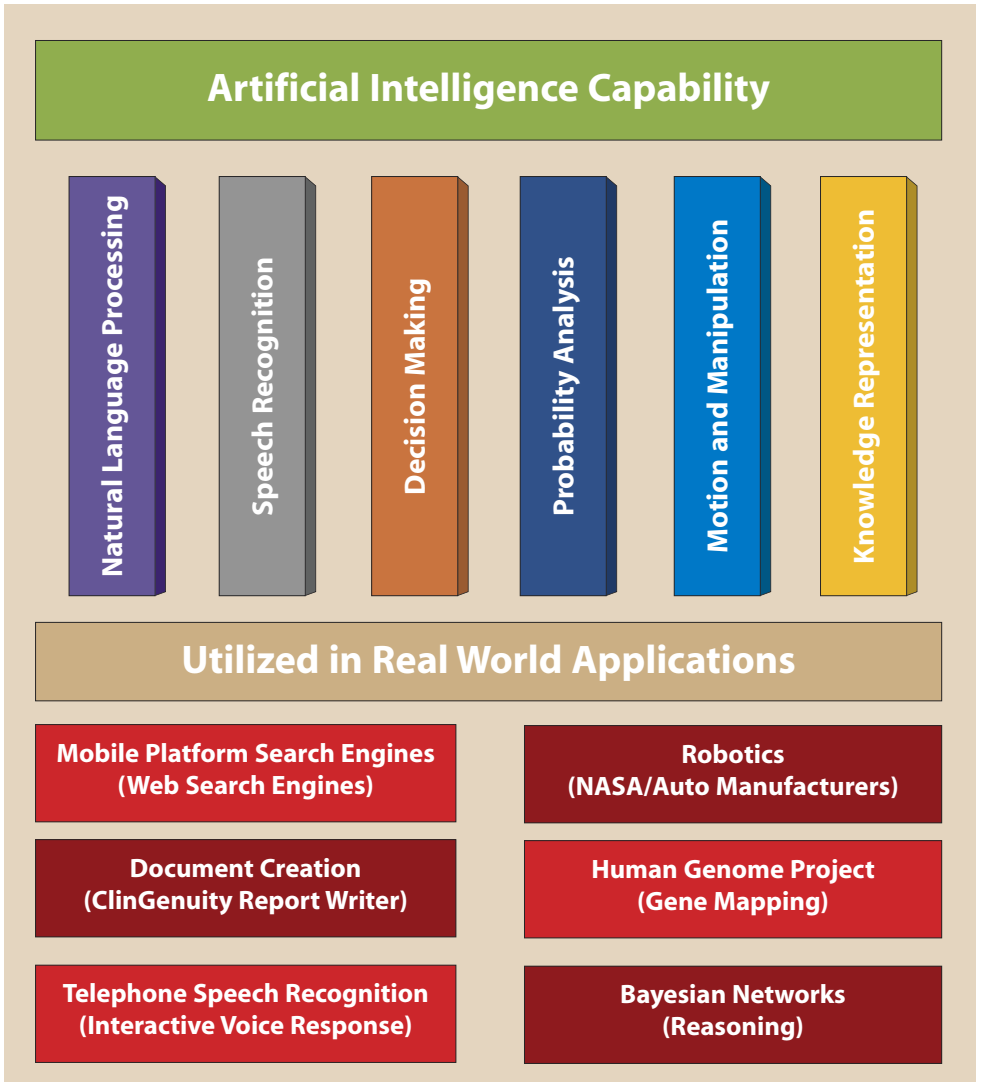
Simply stated, this tool honors what sponsors have intellectually done in the past: to automate what they plan to do in the future.

There will always be some writing that must be completed by a clinical person, but the vision is to identify what must be written by a clinical writer and have everything else done by AI.

There is a belief that almost all documents related to clinical trials will eventually use artificial intelligence.

On the patient side, companies will not only be able to get more drugs and devices to market quicker and cheaper through technology, but those cost-savings might allow the industry to reduce the cost of new drugs for consumers.

The reality of drug development is that it is labor intensive for clinical teams. Having the best technological tools mitigates labor and frees up teams to focus on strategizing and planning for the next innovative therapy.



Automating with Intelligence for the Future

Artificial intelligence aims to emulate intelligent behavior in computational processes and automate intelligence processes.

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I anticipate that true artificial intelligence systems will positively impact our industry beyond, and even exceed, our expectations. I fully expect to see other technology solutions to follow suit in transforming our industry for the better.

In fact, our company, ClinGenuity, is already building a full suite of offerings to target all regulatory documents that are involved in the drug development and approval process. Ultimately, that suite of offerings will provide the industry a comprehensive AI solution from automated e-protocols to submission documents. It's an exciting time to be a part of R&D and the transformation technology initiatives that are reshaping drug development. PV

WEBINAR

LEARN HOW ARTIFICIAL INTELLIGENCE CAN IMPROVE PHARMA EFFICIENCY
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ClinGenuity's *mission is to significantly reduce time and increase accuracy in study reporting processes for sponsor-based clinical trials, helping to accelerate the availability of important medicines to patients in need.*
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