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07 Aug 2023 | **Interviews**

McKinsey Exec On Generative AI in R&D And Pharmacovigilance, Digital Twins

by Anju Ghangurde

McKinsey & Company's senior partner Vikas Bhadoria, in this first instalment of a wide-ranging two-part interview with *Scrip*, outlines a number of use cases to define where pharma currently is and the potential value that can be unlocked as industry adopts new technologies such as generative AI, digital twins and the metaverse.

New technologies like generative artificial intelligence (Gen AI) and digital-twins could potentially rewire the life sciences sector, with several promising use cases across the molecule-to-market continuum.

Vikas Bhadoria, senior partner, McKinsey & Company

The excitement, laced with some trepidation, over Gen AI across businesses and society at large has been quite extraordinary. Poster child OpenAI's chatbot, ChatGPT, drew one million users in just five days post launch - in comparison Netflix took an estimated three-plus years to garner a similar user base. (Also see "*ChatGPT Unleashed: Generative AI Use Cases Taking Off In Pharma*" - Scrip, 6 Jun, 2023.) (Also see "*The ChatGPT Revolution Comes To Pharma Business, Starting With Medical Congresses*" - Scrip, 22 Mar, 2023.)

Business executives too have taken to these new technologies, with recent studies suggesting significant use, across sectors, of Gen AI tools by the

C-Suite for work. (Also see "*'This Is The Way Of The Future': Digital Health Experts Share Thoughts, Experiences With Generative AI*" - Medtech Insight, 18 May, 2023.)

More widely, Gen AI is expected to deliver substantial productivity improvement across business functions and also alter the workforce.

In this first part of a wide-ranging interview with *Scrip*, Vikas Bhadoria, senior partner, McKinsey & Company, outlined use cases in areas such as target identification where the global management consultancy could help a pharma client deploy a "clinomics" approach to establish a proof-of-concept genomics platform for a single therapeutic area in under eight weeks.

Amgen, J&J, Takeda R&D Heads On The Era Of Human Data, Treating Disease Earlier

By Anju Ghangurde

04 Jul 2022
Big pharma R&D leaders discuss the confluence of technology and biotech driving insights into biology and how industry is doing in terms of identifying patients earlier in disease.

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Gen AI can also be effectively deployed for "customized communications, scripts and content," noted the McKinsey long-timer, who has worked in multiple countries/regions including India, China, Japan, Russia, the UK, North America and the Middle East.

R&D is where Gen AI's high-impact value gains potentially lie. It's also an area that's seen big picture action - for instance earlier this year, *Mitsui & Co., Ltd.* and AI chip giant NVIDIA teamed up for Japan's first Gen AI supercomputer for the pharma industry. Leading pharma companies and start-ups in Japan, reports said at the time, are expected to use the collaboration's Tokyo-1 NVIDIA DGX supercomputer to accelerate drug discovery.

McKinsey expects generative AI to have a significant impact on the pharmaceutical and medical-product industries - from $60bn to $110bn annually - it said in a recent report. The huge potential reflects the resource-intensive process of discovering new drug compounds; pharma companies typically plough in about 20% of revenues in R&D, with new drug development taking an average of 10-15 years.

Gen AI is expected to unlock significant value, improving both the speed and quality of drug discovery. Bhadoria, though, underscored the need for more detailed quality checks on AI-assisted processes going forward in the wide-ranging interview, which will also cover other areas such as drug shortages and quality compliance in its next instalment.

The executive, who leads the global management consultancy's Life Sciences Practice for India and the Pharmaceutical and Medical Products (PMP) Operations Practice in Asia, also touched upon the growing adoption of the "digital twin" technology across various functions in the pharma value chain including the first examples in planning and scheduling. (Also see "*Re-Configuring Pharma Operations Amid Pandemic Strains*" - In Vivo, 8 Apr, 2021.) (Also see "*McKinsey Exec On Technology Trends Reshaping Future Factories*" - Scrip, 9 Mar, 2022.)

"The models mimic all the constraints that exist, such as demand, lead times, and equipment capacities, but also shelf life, different market authorizations, number of people on shift on a given day, and batch sizes," explained Bhadoria.

Digital twins are already being deployed by some pharma firms as part of their smart manufacturing efforts. For instance, in 2021 *GSK plc* announced a successful proof-of-concept of a digital twin approach for vaccine manufacturing with *Siemens* and *Atos*, which uses machine learning and modelling to provide new insights for optimizing the development and manufacturing of vaccines. (Also see "*GSK CTO, Boehringer Exec On The Metaverse And Pharma's Foot In The Door*" - Scrip, 9 Mar, 2023.)

At an industry event in India earlier this year, a senior Siemen's executive referred to a GSK case study pertaining to the deployment of digital twins for the development and production of adjuvant technologies – a "real-time capable model" that has the ability to predict adjuvant particle size. Adjuvants are vaccine additives that boost the immune response; they also help lower the volume of antigen needed for each dose of vaccine, facilitating greater supply of these immunization shots when demand spurts.

Q **McKinsey's recent report on Gen AI suggests that it could deliver potential value of 15-25% of operating profits for pharma when deployed across areas like R&D, content for commercial reps, etc. Any early use cases that have demonstrated high value?**

A The use of AI can help accelerate drug discovery and design at unforeseen speed and also enable better customer engagement with use cases across the complete value chain.

We've seen use cases for target identification and lead screening. In silico target identification is the process of using data-driven algorithms to discover novel molecular entities with potential causal links to a phenotype of interest. We have helped a pharma client deploy the clinomics approach, to establish a proof-of-concept genomics platform for a single therapeutic area in less than eight weeks,

identified about 200 preliminary variants of interest in the pipeline. These variants were mapped to protein targets of interest in the client's internal datasets, generating an "end-to-end" discovery pipeline.

Similarly, deployment of AI-enabled deep learning models helps prioritize hit/lead screening libraries and automate analysis of millions of microscopy images from high-throughput screening assays. These models have significantly improved screening efficiency - around 80% of hits identified by screening approximately 20-50% of compounds based on virtual screening prioritization.

Then there are use cases for customized scripts or clinical notes by customer segment. Apart from using Gen AI for customer relationship management, creating training modules etc., it also has the potential to create customized communications, scripts and content to match the structure for sales reps leading to high quality interactions with their customers/healthcare providers. It can also be used for speech recognition to help doctors transcribe and analyze their conversations with patients and drafts clinical notes. It is expected that the application of Gen AI within the marketing and sales function has the potential to generate a productivity lift of 4% of global functional spending, or $490bn.

Q **There's talk around the potential of Gen AI in pharmacovigilance in terms of adverse event identification across multiple sources, real time insights etc. Can Gen AI be effectively trained to recognize facts, fiction and everything in between? For instance, in the COVID-19 vaccines arena there were equal loads of misinformation/scaremongering as there was science-based evidence and some blurring of the lines as well.**

A Pharmacovigilance (PV) requires monitoring the effects of pharmaceutical products, surveillance of known side effects, as well as sifting through large volumes of data to identify and act on emerging, previously unknown side effects.

Independent third-party research has shown that an important caveat here is heterogeneity of PV data, that are derived from a multitude of medicines, including vaccines, and, as a result, describing very different types of adverse drug reactions and adverse effects of vaccines, that have different mechanisms of actions, can be challenging.

Significant human feedback will be needed to train these Gen AI models using previously analyzed PV data and introduce capabilities to identify unexpected outcomes. There is also an increased need to verify whether generated content is based on fact or inference, thus requiring a new level of quality control.
Gen AI models can be trained to perform PV tasks given the large volume of data, high degree of uncertainty and need to learn from data. This will mean a phased adoption including significant training, building and improving models with increasing accuracy, followed by piloting with data where outcomes are known. After multiple successful "cold" trials, such models can be launched for PV tasks with necessary human oversight.

Q **What about the big grey areas – inherent bias embedded in generative AI data, data privacy/security and IP aspects. (Also see "*BioAsia 2023: Leaders from Novartis, Apple Talk Innovation, Tech, Data Privacy*" - Scrip, 28 Feb, 2023.) (Also see "*Artificial Intelligence Legislative Activity To Start In Fall; Sen. Schumer Lays Out Principles, Process*" - Pink Sheet, 5 Jul, 2023.) Are there sufficient guardrails/effective governance efforts in place or are we looking at a potential flood of litigation?**

A Gen AI has increased the need to understand whether generated content is based on fact or inference, requiring a new level of quality control. Given it is early days for Gen AI, regulations and refinements are needed before Gen AI models based on internet data can be widely deployed.
Hence, regulations surrounding AI and Gen AI are being developed globally and will continue to evolve. These regulations may differ in scope but contain certain denominators such as common principles around transparency, explain-ability, privacy, fairness, accountability, etc. In fact, tech solutions focused on AI risk management to enable compliance and international organizations to advance global standards around AI are also coming up, such as the 2019 OECD Recommendations on AI, the first set of inter-governmental policy guidelines on AI, adopted by 42 countries and supported by the EU, which are influential in international policy setting though not legally binding.
While such regulations are coming up, organizations have also started self-regulation

through AI principles and guidelines, strategically keeping humans in the loop and ensuring security and privacy as top considerations for any implementation. Going forward, companies may need to implement new quality checks on processes that shift from humans to generative AI, such as representative-generated emails, or more detailed quality checks on AI-assisted processes, such as drug discovery.

Q **Digital twins in medicine are expected to revolutionize drug development, manufacturing, and the supply chains. (Also see "*Indian 'Lighthouses' Deliver Gains Amid Price Erosion, Rising Input Costs*" - Scrip, 3 Jul, 2023.) Where do you see things headed in terms of more precise diagnosis, personalized treatments, shorter pharmaceutical processes and informed input–output predictions for biochemical reactions etc.?**

A Digital twin technology has been adopted quite successfully across various functions in the pharmaceutical value chain such as quality control (e.g., automated lab scheduling, prevention of deviations/out-of-specification), manufacturing (for determining optimal changeover settings), supply chain (to predict upcoming bottlenecks through simulation of complex interactions between sub functions) and R&D (mimic process behavior).

As the industry learns and develops these models and the comfort around these grows, we will see deeper application of this technology. For instance, in manufacturing, going forward, we see pharma factories are connected to the IoT [internet of things] and a digital twin of the pharmaceutical production process, and supply chains are accessible from anywhere in the world. We see more reasons to build hubs with control towers to run planning, quality investigations, maintenance support, audits and operational excellence projects, increasing effective capacity by over 10% for planning manufacturing processes.

If we consider supply chain planning and scheduling as the product portfolio of pharma companies continues to grow and diversify, it increases the volatility of the supply chain from sourcing to sales. We have seen the first examples in pharma of digital twins for planning and scheduling. The models mimic all the constraints that exist, such as demand, lead times and equipment capacities, but also shelf life, different market authorizations, number of people on shift on a given day and batch

sizes. Today, planning and scheduling activities which involve 10% of the staff right now can be fully automated in the future. The main benefit, however, will be better utilization of the infrastructure, which currently shows an average utilization of only 40%.

In areas like technical development in R&D, process development and scale-up can be laborious and time-consuming. Chemistry, manufacturing, and controls (CMC) labs are already using digital twin models to mimic process behavior, filter and predefine experimental conditions, reduce the number of wet lab experiments. Digital twins of unit operations will be routinely used to optimize process parameters such as glucose concentration, cell density and acetate level in real time, as well as to select optimal HPLC [high-performance liquid chromatography] columns and predict formulation parameters. Digital twins could be combined into a digital twin of the entire lab, enabling the simulation of complete CMC processes across the value chain.

Q **What's your view on the metaverse and its potential in pharma, including around facilitating cross-border collaboration in medical research by creating easy-to-access virtual environments or generating a virtual patient based on clinical data to predict a specific outcome? Is it much hype for now given issues around the limited inoperability among virtual worlds and governance?**

A Potentially, pharma companies can use the metaverse to deliver enriched, immersive experiences to healthcare providers and patients through multiple use cases. The metaverse has introduced the ability to not only be present within a virtual world but to also engage with that world alongside other users.

However, metaverse applications are still in an early stage of development and use cases will depend on how easily stakeholders are able to adapt these. Before it is used for medical research collaboration or generating virtual patients, proper pathways and regulations need to be put in place. This is expected to evolve as we start seeing gains from successful use case deployment using metaverse.

Areas such as commercial are expected to see faster adoption, given lesser regulatory requirements compared to cutting edge medical research. For example, a medical science liaison could use a 3D model to explain to an oncologist the mechanism of

> action of a given drug. This could be a significantly higher level of interaction, increasing a pharma company's involvement and engagement with physicians.