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Lilly, BMS, Microsoft On GenAI's Machine-First Approach Success, Cell Therapy Use, Regulation

Google, Apollo Partnership Progresses

by Vibha Ravi

Machines are now generating molecules that "no human would have imagined," heard delegates at the BioAsia 2024 summit in Hyderabad, as big pharma and tech leaders discussed the many ways in which AI is causing fundamental shift in R&D approaches.

The extent to which artificial intelligence (AI) and technology are fundamentally altering the research and development game came through during a panel discussion by *Eli Lilly and Company*'s chief information and digital officer Diogo Rau and *Bristol Myers Squibb Company* executive vice president and chief digital and technology office Greg Meyers, among others, at a recent event.

The panelists also discussed applications of generative AI, for instance in drawing insights from data generated by wearables and the challenges in using resulting data, as also use of AI in manufacturing and market access models.

Lilly's Rau narrated success stories with its AI-model based discovery that opened a hitherto unseen portal, overcoming limitations of human thinking in the drug discovery process. Similarly, BMS's Meyers mentioned how cell therapy candidates could benefit from early detection of adverse events like a cytokine storm, during a panel discussion expertly moderated by Jeremy Jurgens, managing director, World Economic Forum and head of forum's Centre for

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the Fourth Industrial Revolution.

As leading pharma companies, both Lilly and BMS have embraced the use of AI.Among Lilly's prominent partnerships are those with Google parent *Alphabet Inc.*'s digital biotech company Isomorphic Labs for small molecule therapeutics, *XtalPi, Inc.* to discover and narrow down potential candidates and *Fauna Bio* for discovery efforts in obesity. (Also see "*Lilly And Novartis Are First Pharma Partners For Alphabet's Isomorphic In Drug Discovery*" - Scrip, 8 Jan, 2024.)

Meanwhile, BMS has partnered ConcertAI, Owkin, Tempus and Paradigm to leverage AI for improving clinical study designs and reducing trials costs.

Understandably, the potential could be huge but only if drug candidates succeed in getting through rigorous trials, given the complexity of the human body. While science has made immense strides, *Merck & Co., Inc.* R&D head Roger Perlmutter's statement back in 2013 highlighting how little is understood about human physiology and "we don't know how the machine works", still largely holds true.

KEY TAKEAWAYS

- Eli Lilly has an AI-generated molecule in R&D pipeline
- BMS sees use in developing cell therapy candidates
- AI models are now training humans, opening up unseen portals
- BMS-Pfizer's alliance with Fitbit is paying off
- Wearables present opportunities, but also regulation challenges
- GenAI finds use in market access, manufacturing
- Microsoft says interoperability of healthcare systems no longer significant barrier to data sharing
- Google's partnership with Apollo Hospitals progressing well
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AI-Models Training Humans?

At BioAsia 2024 in Hyderabad, Rau spoke of machines generating molecules that "no human would have imagined."

He said last year Lilly took a few molecules that were machine-generated and "had really unique structures that didn't look like anything that we knew much about, they only were somewhat similar to three molecules in our database and even then, remotely similar."

These were taken to the laboratory, with the company asking the chemist "Tell us what's wrong

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with these molecules, so we can train our models better." And the chemist said, "hey, that's interesting! We hadn't thought about doing it that way.", he said.

"So, we decided to go make those molecules. One of them is still in the running as a candidate. One of the things that gets lost in the whole discussion around AI and drug discovery is not just how we train our models, but how our models train our humans," Rau observed.

In Bengaluru, where Lilly opened a global capability centre in 2016, the team in India worked to develop in silico a preservative that could work in a broad temperature range and stabilize a drug during the latter's production process.

"This is a very laborious process in wet labs.... and it turns out it [preservative] was better than anything that our scientists were thinking. And is probably an ironic switch from all of the thinking that we did," he added.

While this doesn't imply machines will replace humans soon, as an apocalypse scenario and a few Hollywood movies might predict, it does illustrate that machines could overcome the boundaries of human thinking and knowledge to present new R&D candidates.

Lilly's CEO David Ricks also believes AI is one of the most exciting technological developments and has been quoted as saying "I can only think of two other things in my adult life that would compete with it. One of them was an iPhone, and another was when we first started to visualize the internet."

The Signature, Wearables Game

Meanwhile, BMS's Meyers indicated how early detection of disease signatures or adverse reactions are informing drug discovery and wellness efforts.

Earlier at the event, BMS CEO Christopher Boerner had highlighted India's potential in driving AI-led drug discovery after inaugurating a R&D facility in Hyderabad, which is set to be its largest site outside of the US. *(See sidebar)*

Speaking of cell therapies and the cytokine release mechanism triggered by immuno-oncology therapy candidates, he said "We're seeing that a very simple wearable like something similar to a Garmin [watch] can give you potentially hours and hours of early warning indication" of such a response.

BMS' Boerner Bets On AI-Driven R&D In India, Points To Potential For MS, Lupus Drugs

By Vibha Ravi

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Indicators like heart rate variability and respiration rate could show that cytokine release syndrome might be occurring and that could be a life-or-death opportunity to intervene.

So “rather than hospitalizing patients for cell therapy [or] for dosing to be a burden, let’s send them home and give them a wearable device. It could be really transformational for them, and also transformational for healthcare systems, which can't afford to give up a bed space.” (Also see "*BMS CDTO Meyers On Gen AI Use Cases, Long-Range Planning Models*" - Scrip, 8 Mar, 2024.)

04 Mar 2024
Bristol Myers Squibb CEO Christopher Boerner is looking to India to house the the company’s largest R&D site outside of the US, channeling the country's IT expertise to expand its AI-driven small-molecule research. He also wants to bring its drugs to treat multiple sclerosis and Lupus to India.

Read the full article here

In 2019, Bristol-Myers Squibb-*Pfizer Inc.* Alliance had partnered *Fitbit, Inc.* on the effort to drive timely diagnosis of atrial fibrillation (AFib) to prevent strokes in high-risk individuals and in 2022, Google-owned Fitbit received clearance from the US Food and Drug Administration (FDA) for photoplethysmography algorithm to identify AFib.

“We think that that tool has probably prevented 10s of 1000s of strokes worldwide, which is obviously very exciting. And the other thing is, there's a heart condition called hypertrophic cardiomyopathy.....if you hear of young people who sort of die over playing football, this is that kind of a disease,” said Meyers.

FDA has also now cleared an algorithm that uses a simple 12-lead electrocardiogram to detect signatures of this disease, which even the most experienced cardiologists often miss, with the average patient going two to three years being misdiagnosed, he added noting how machine-led detection can beat human decisions or experience at times.

Tackle Pain Points In Wearables

Scott Burgett, director, Garmin Health Engineering spoke about the pain points experienced by the wearables industry. While Garmin is “very invested” in making high quality watches and biosensors, wearable devices are not medical devices but consumer devices.

Although they have very high-quality sensors, Garmin doesn’t want to make them medical devices, “because if we did it would take us three or four years to do a single watch. Our product development cycle takes between 12 and 16 months and we have to do that to stay relevant in the market. So, we can't be regulated,” he said. (Also see "*AIRIS 2024: Global Cooperation A*

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Challenge For Regulation Of AI Products" - Pink Sheet, 5 Mar, 2024.) (Also see "*Artificial Intelligence: Industry Wants FDA To Boost Access To Databases, Clarify Use In Assessing Drug Efficacy*" - Pink Sheet, 7 Sep, 2023.)

At the same time, the watches generate huge amounts of data and "we have to somehow get into the hands of people who can use it" like those who write generative AI. "So we are solving some of those problems with just our connectivity solutions." However, Garmin has to figure out ways of getting the data into medical records and distil the information to make it actionable by a healthcare practitioner.

SAS Director On AI App Factory In 2024, Digital Twins And India Plans

By Vibha Ravi

12 Jan 2024
With an app factory to create fit-for-purpose, AI-driven applications, SAS hopes to help customers that include AstraZeneca and Novo Nordisk, to up their game in 2024, director Mark Lambrecht tells *Scrip* in this interview in which he also speaks about the current limitations of digital twins

Read the full article here

Sangita Reddy, joint managing director of Apollo Hospitals said the data generated by wearables like Garmin watches could have "transformational value in early predictions", citing the example of an Asia-specific cardiovascular disease risk scoring created by Apollo which is now sitting at the back-end of one of the large, personal wearables device companies.

Don't Miss The AI Bus

An audience member raised the question of such wearables generating non-anonymized data which could find its way into the wrong hands. "How does the health ecosystem ensure a layer of security and transparency is provided? How do we deal with the blind spots?" he asked.

In response, both Rau and Meyers said waiting for regulatory agencies to catch up with the applications of AI and draft guardrails or regulation around its use could lead to precious time being lost.

"You can't figure out all the blind spots in advance, they are blind spots after all, and the worst thing that you can do is wait until you think you figure them all out before you try out new technologies. You don't know what to expect and trying to make rules in advance is kind of crazy," said Rau.

Strongly advocating learning on the go, he added "people ask me what I am the most worried about with AI. The thing I'm most worried about is that people get too scared to use it. Our big opportunity is to take little steps, we're going to make some mistakes, we're going to skin our

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knee, but let's pick it up and keep learning from it."

BMS' Meyers said while building guardrails, it's important to keep in mind that patients are waiting for treatment. "If you're a 35-year-old mother of three, and you've been diagnosed with multiple sclerosis, and you realize that you're going to end up in a wheelchair, the last thing you're thinking about is data security and privacy. You want the healthcare system to get its act together and figure out how to come to market with new therapies," he emphasized.

"We kind of get a little bit in our own headspace around the IT stuff here at the end of the day. This is technology that can make a meaningful difference," he added citing the example of an average cancer patient where the first two to three lines of therapy fail simply because "we do not as physicians, doctors and scientist understand enough about the physiology of the disease."

If AI can help with this, companies should be empowered to use it else "we're not helping patients."

Microsoft On Interoperability, Provenance

Meanwhile, Sriram Rajamani, corporate vice president and managing director of *Microsoft Corporation* arm Microsoft Research India, spoke about how technology has advanced to an extent that different healthcare and hospital systems are able to talk to each other to enable insights drawn from effective data mining and analysis.

"One thing we see more and more is the fact that data is in islands. They are in different data formats in hospitals. But technology has improved so much now that these things can be interoperable, particularly with AI. We can break across silos and reason across data formats," he said.

Urging sharing of data to help build trust in AI models, he said no one person has access to data from all over the world.

"I think sharing is essential for trust so that these models are representative of what your

How Boehringer, Lilly Are Taming The GenAI Dragon For Regulatory, Commercial Content

By Vibha Ravi

05 Oct 2023
Heads of AI, global commercial services and human pharma services at Boehringer and Eli Lilly discuss at a recent summit ways to use generative AI like ChatGPT for commercial and regulatory content while tackling challenges like data protection, hallucination and CXO buy-in

Read the full article here

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concerns are. If you look at the population of the world, you have to have representative data from your community, people whose genetics are similar to yours in order to have reasonable predictions that make sense to you," Rajamani added.

It's also essential that while data is shared in conformance with policy, "we share with confidence and be intentional about it. And technology now provides you the ability to do that," he added.

Besides, data provenance is key to building trust in AI models. "The AI model doesn't document itself on what data it has been trained on so the metadata and the provenance has to be stored. That's the only way to get real confidence on data integrity. And as the data is used for multiple things you have to track where the data is within AI."

"You have to watermark what was generated, you need to track and record provenance of data. Those hygiene things are so important," Rajamani emphasized.

Gen AI For Market Access

Phani Mitra, chief digital and information officer at *Dr. Reddy's Laboratories Ltd.*'s pointed to AI opportunities in R&D, manufacturing and market access models that could make medicines accessible and affordable to a larger population.

In silico digital twinning helps save costs and time as the process of transfer from lab to the plant is becoming more complex, increasing the potential for failures as one scales up. "So, there are a lot of AI-led interventions that we are thinking of in that space, where you can predict the scale of outcomes, even without taking it to the plant" apart from use cases around yield optimization, he mentioned. (Also see "*Scrip Asks...What Does 2024 Hold For Biopharma? Part 4: Transformative Technology*" - Scrip, 30 Jan, 2024.)

Generative AI is also being used to cut go to market time. As "you take it [a product] to more and more regulatory bodies across the globe, the amount of work that's involved is a huge drag on productivity and time to market. So generative AI for us plays a big role" in creating effective and timely regulatory documentation.

Elaborating on more use cases in the company, he added "If we are able to combine access with digital health

Adopt Unilever Model, Tech To Prevent 'India Plus One' Situation – CRDMO CXOs

By Vibha Ravi

13 Mar 2024
CRDMO CXOs sketch a promising landscape for the Indian industry, highlighting technology, scale and talent, particularly

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interventions, there is an opportunity for us to explore what that patient data and patient support programs can do for drug discovery itself" while qualifying it with a comment that it's a "slightly unexplored use case right now."

millennials and Gen Z, as key factors in a SWOT analysis - while cautioning that a global 'China plus one' strategy could turn to a 'India plus one' too.

Read the full article here

Apollo-Google Partnering

Sangita Reddy, joint managing director of Apollo Hospitals, highlighted instances of data aggregation and analysis helping its healthcare chain that has 73 hospitals, over 5000 pharmacies, 300-plus clinics, over 1,100 diagnostic centres and 200-plus telemedicine units.

"Analyzing about 5 million [health] records, we've created a clinical intelligence engine using AI. When you embed that on top of every EMR [electronic medical record] data capture, you are increasing accuracy," she said.

Speaking about the company's AI-enabled projects, Reddy said "One of my favorite ones is a project where we've created X-ray analysis for automatically picking up TB [tuberculosis]. We hope to be able to give it to all government hospitals free of cost."

Through its digital platform Apollo 24/7, Apollo Hospitals aims to enhance the healthcare experience for users, with home delivery of medication and improved clinical decision making. It also runs a 'ProHealth' program backed by a predictive algorithm to capture the patient's health status, predict potential health risks and individualize health checks.

In September 2023, Apollo Hospitals announced a partnership Google Cloud to provide AI-powered telemedicine and online doctor consultation facilities countrywide.

Reddy pointed to a global shortage of healthcare workers in response to Jurgens' question on whether AI would displace human workers or help them.

"At the moment, I see both happening. But I'm very clear about this - AI will augment the healthcare worker. It will displace certain mundane, repetitive tasks which the healthcare worker needs to do, therefore enabling them more time to spend with patients and not have the kind of overworked, difficult environment that many healthcare workers face."

"So, it's augment, it's assist, it's enhanced quality, it's not displace," she underlined.

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