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THE ECONOMIC TIMES
SMART PHARMA
VIRTUAL SUMMIT 2021

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June 23, 2021

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FOREWORD

Sudarshan Jain, Secretary General IPA

The importance of India's pharmaceutical industry to India and the world can be judged from two sets of data. In 1969, medicines carrying the "Made in India" tag accounted for just 5 per cent of the domestic market; MNCs made up the remaining 95 per cent. In 2020, Indian companies made more than 80 per cent of all medicines sold in India[1].

Globally, Indian pharmaceutical companies provide over 60 per cent of the various vaccines the world demands; they meet 40 per cent of the demand for generics in the USA and provide 25 per cent of all medicine consumed in the UK[2].

India has the largest number of USFDA-approved plants outside the USA – more than 600 – nearly 1,400 WHO-GMP-compliant plants, and 252 approved by the European Directorate of Quality Medicines[3]. That is a testament to the quality of the medicines Indian companies make who supply over 80 per cent of antiretroviral drugs used to combat HIV/AIDS. Their medicines save millions of lives, and are affordable for millions of others.

The Covid-19 pandemic presented an unprecedented challenge. The industry responded, adjusting quickly to working under restricted conditions, and stepping up to play a key role in supplying essential medicines – like paracetamol, hydroxychloroquine (HCQs), APIs, etc – to more than 100 countries across the world to support them in fighting the pandemic. There has been a strong support of the government in dealing with the challenges and helping the industry in its endeavours of maintaining sustainable supply both in India and globally.

Covid-19 also presents opportunity for the industry to adapt and innovate as it races to achieve its goals outlined in IPA's Vision 2030 – The Way Forward document. Two deserve mention: to be a $120 billion dollar industry (from $42 billion now) by 2030, and to have at least two patented, original molecules developed by Indian companies from their own R&D.

To realise these goals, companies have to increase thrust on innovation and accelerate digitisation across the spectrum of manufacturing activity, from raw materials sourcing to the laboratory, testing quality and safety at the processing plant, to packaging and delivering medicines ready for human use. At this year's ET-IPA SMART Pharma Summit, industry leaders discussed the way forward.

Management experts have expanded and interpreted 'SMART' for different sectors. Below is the one relevant in the current context that the pharmaceutical industry operates in.

1. https://www.investindia.gov.in/siru/india-pharmacy-world
2. https://www.ibef.org/industry/pharmaceutical-india.aspx
3. https://www.pharmamanufacturing.com/articles/2019/making-the-case-for-indian-generic-manufacturing/
4. https://www.investindia.gov.in/siru/india-pharmacy-world

SAFETY

This is a core element in the way people live their lives now. To be safe – and responsible – this summit was held virtually. Everyday behaviour – washing hands frequently, sanitising all surfaces, wearing masks – is now designed to emphasise safety. Similarly, the industry, has to extend that to manufacturing processes and materials sourcing. Two panels at this conference will discuss how to do that even more effectively.

MARKETING

Even before Covid 19, studies showed that health-related questions on Google were 7 per cent of all searches; that amounted to 70,000 questions a minute, or more than a billion questions a day[5]. This emphasises the importance of patient centricity. It's time to reimagine marketing to go beyond distributors, pharmacies and the supply chain and make patients – and their doctors – the focus. As we move on beyond this pandemic, rethinking marketing should be high on our agenda.

ACCESS

How can medicines be made more accessible to patients who need them? The burden of non-communicable diseases (NCDs) is not restricted to urban. True, Indian pharmaceutical companies have made medicines very affordable using their innovation capabilities, but access goes beyond affordability. Improving access is the key to the growth of our industry. IPA's **Vision 2030 – The Way Forward** highlights opportunities for and challenges to growth; improving access is a continuous, ongoing conversation.

RESEARCH

The industry has to significantly up its game on drug research and development. Building the capabilities to invent, not just innovate, new medicines should be very high on every company's agenda; R&D should be coded into their organisational DNA. IPA envisages that Indian companies will create and market two patented drugs that will be in use globally by the end of this decade.

5. https://www.beckershospitalreview.com/healthcare-information-technology/google-receives-more-than-1-billion-health-questions-every-day.html

TECHNOLOGY

This is the all-pervasive factor in everything pharma companies do. If R&D is one strand of organisational DNA, this should be the second. The theme of this conference is digital technology, and its transformative power, to radically change everything from drug discovery in the laboratory to getting the medicine into the patient's body. Every step on that journey uses digital technology; it is the glue that holds it all together.

The themes in many of the day's discussions will initiate new conversations, extend ongoing ones, and perhaps take yet others into new and exciting territory. All of them will together set the foundation for much-needed reflection and action.

VIRUSES, VARIANTS AND VACCINES

Professor S S Vasan,
Project Leader, Australian Centre for Disease Preparedness (ACDP)
Commonwealth Scientific and Industrial Research Organisation (CSIRO)

BACKGROUND

Viruses constantly change; their genetic variations are called mutations. As the virus spreads to more people, the more chances it has to mutate. Some variants transmit the disease more effectively than others. There has been a lot of discussion in scientific circles and in the public space about whether some variants are more dangerous than others. Some experts have wondered about the effectiveness of current vaccines against the more highly transmissible variants which cause more severe forms of the disease.

SUMMARY

Professor Vasan's talk focused on three broad areas: the virus-variant-vaccine relationship, the status of Covid-19 vaccine research, and the potential future trajectory of vaccine research in India.

He presented a fascinating narrative of how, beginning with decoding the genetic sequence, scientists isolated different forms of the virus in different countries, developed vaccine candidates using different technologies, conducted pre-clinical research studies, ran clinical trials of the vaccine candidates, applied for and got authorisation to produce them.

Vaccine efficacy is a priority. Initially, studies found that the efficacy of the Inovio vaccine – a DNA vaccine – was not impacted by the variants. But much more recently, as more variants emerged, studies suggested that the beta variant reduced 'neuralisation efficacy'.

There are four variants that scientists are working on; alpha (from the UK), beta (from South Africa), gamma (from Brazil) and delta (from India). Most labs around the world worked to model vaccines in animals: monkeys, ferrets and transgenic mice; Professor Vasan's team worked on ferrets.

Professor Vasan said that his team continues to track the spread of the different variants to assess transmissibility. "What you find is that as it gets hotter, the new variant starts to spread faster than the non-variant." He said that this kind of intelligence or analytics can be acquired using tracking.

There were more than 327 vaccine candidates to begin with, he said; there were failures, too. Many firms ended their own searches, but joined others who persisted in search of theirs. The vaccine discovery story is also one of collaboration between companies that are usually rivals. Many of those joint efforts still continue.

His team also worked on nasal spray delivery systems for the AstraZeneca-University of Oxford vaccine, and found that in ferrets, it worked really well. "That study is now being taken to humans by Imperial College," said Professor Vasan. "This could well be how this particular vaccine is delivered in the future, if the human trials prove to be successful."

The third vaccine his team worked with is Mynvax, being developed at the Indian Institute of Science (IISc) in Bangalore. It's not going to be on the market very soon, but it can be a better product. Professor Vasan said it was thermostable at 37 degrees Fahrenheit – which means it can be kept in a household refrigerator; even at 100 degrees Fahrenheit (about 35 degrees Celsius), it will not break down for at least an hour-and-a-half.

No high-tech cold chain systems are required for storage, making the vaccine affordable and easily transportable. It's been tested against all four known variants of the virus, and has been efficacious against all of them. The data shared with the audience is currently under review, Professor Vasan said.

His final note was to address the suggestion that we do not test enough in India. He pointed out that even though we use two or three kinds of tests to detect Covid-19, the quality of metadata was actually pretty good. Multiple affordable tests could actually reduce the false negatives without incurring a huge cost.

Last, but not least, another option for testing in India was using waste-water epidemiology, collecting waste water from the public toilets. That way, he pointed out, results would identify local spread of all viruses, not just Covid-19, and quarantining and lockdowns could be localised effectively. That, after all, is a good way of using our 'jugaad' (hacks) abilities.

Key Takeaways:

- Viruses will mutate as they spread, creating variants
- Some variants spread faster; some genetic mutations have greater transmissibility
- Vaccines to treat the most prevalent forms of the virus are pursued
- Collaborations between scientists, academics and pharmaceutical firms are common

INTEGRATED QUALITY MANAGEMENT IN PHARMA

Phanikar Bhaskar Krishna,
Head – Product Management Group,
Caliber Technologies

BACKGROUND

In the pharmaceutical industry, companies emphasise quality across the entire spectrum of activity. Medicines don't just prevent or treat disease, they change the way people live their lives, and often, the lives of the people around them. Quality is therefore critical to living a healthy and fulfilling life.

Producing quality drugs is the purpose of every responsible pharmaceutical company. From the raw materials, through the production process to the medicines doctors prescribe and patients take, quality underpins everything a company does. The best outcomes are achieved when quality is optimal.

We live in the age of the fourth industrial revolution, a time when digital solutions applied to manufacturing processes make huge improvements in product quality. The basic principle here is that by connecting machines and systems, we can create intelligent networks along the value chain that can control and reinforce each other, making big leaps in quality. In other words, digitalisation enables integrated quality management.

SUMMARY

One thing that pandemic has brought home clearly is the need for accelerated digitisation in the pharmaceutical industry. As Mr Krishna puts it, it's time for pharmaceutical companies to become smart, sustainable and future-ready. Quality in the pharmaceutical industry has three dimensions: regulatory compliance, operational efficiency and automation.

The Covid-19 pandemic demonstrated the need for bringing medicines to patients and the market faster, without compromising on quality. So regulatory agencies like the FDA will focus on assessing and analysing data, and there is a tremendous amount of it.

Across the system, there is data from supplier quality management, laboratory data like out of trend (OOT), operational technology (OT), process deviations, batch wastage, personnel qualifications to market complaints. But most of this is maintained in silos.

"To build a strong resilient organisation, we have to move from silo-based information management systems to integrated quality management. Data and process must talk to each other," says Mr Krishna.

Data has to integrate and interface across the system where needed, implying better inter-departmental information exchange. This builds better quality metrics and a system that enables better and faster decision-making. Each company is a unique entity, meaning that each organisation develops its quality management system to meet its specific needs.

All organisations are a complex of subsystems; to illustrate how an integrated quality management system works, consider what happens when changes are made to the quality assurance system. They have to be documented, which means a change in the document that lays out the relevant process change. That means having to train people top make the change, and a change in the training system.

In an integrated system, Mr Krishna says, automation takes care of necessary information and data exchanges, enables discussion between relevant departments and implements the changes across the system. Similar changes can be affected in the laboratory that would need changes across the rest of the company. There are several such possible interactions.

Quality assurance necessitates that the data used and compiled in each sub-system or department be 'clean': in other words, it has to be accurate, available and actionable, Mr Krishna said. Analytical studies helps identify gaps, weaknesses and trends. Clean data ensures accurate interpretation and fast decision-making.

"Above all," he said, "integrated quality management needs a change in organisational culture."

Key Takeaways:

- Digitisation enhances quality management
- Integrated quality management (IQM) is critical for a pharmaceutical enterprise
- It can dramatically improve health outcomes
- Companies should adopt integrated quality management sooner rather than later

SPOTLIGHT SESSION: DIGITAL TRANSFORMATION IN PATIENT CARE: BUILDING A RESILIENT ENTERPRISE

Rehan Khan,
Managing Director, MSD Pharmaceuticals

BACKGROUND

The adoption of digital technologies restructures relationships. In healthcare, digitisation has transformed relationships between doctors, patients and pharmaceutical companies.

Scientists who study technical change and societal progress say this digital transformation is the consequence of what they call general-purpose technology: something that branches out and boosts performance across sectors and industries.

We are at the beginning of the fourth industrial revolution. The first – the steam engine – mechanised production; the second – electricity – scaled up the assembly line to mass production. The third – computing – created programmable controls for manufacturing. The fourth uses digital technologies to create 'smart factories', enabling components, people and machines to communicate as a network in ways that makes production autonomous.

SUMMARY

There are clear trends that show how the internet and internet technologies have become indispensable in unexpected ways. India's digital adoption had already hit an inflection point in 2017, when data prices dropped and internet access skyrocketed.

To show how deeply it is embedded, Mr Khan cited reports identifying the most searched words on the internet in the last few months: self-care, wellness, relaxation, virtual meditation, and 'peaceful playlist'. Health and wellness top of mind for everyone.

We read about connected devices that change patient behaviour. Many of us wear Apple watches, Fitbits etc., which monitor everything, from counting the number of steps we take to sleep patterns, and checking our daily activity levels. They help our doctors provide better care, and insurance companies to provide better cover for health risks.

Telehealth has grown exponentially. Telephone consultations have almost doubled and video consultations have nearly tripled from pre-pandemic times.

"They have overcome barriers to access that prevailed for years in our country," Mr Khan said.

There is an enabling policy ecosystem with new guidelines for telemedicine now, with initiatives like e-Sanjeevani OPD, a patient-doctor teleconsultation service set up by the Ministry of Health and Family Welfare.

A review of the trends in the use of digital communications technologies provides pharma companies a sense of what is possible for patient engagement. According to the McKinsey Global Institute report Digital India published in April 2019, prices of data have dropped by 95 per cent since 2013[6] in India. That made internet access cheaper and easier. Three things acquire greater significance: voice, video and vernacular languages.

India has more than 1 billion cell phone connections, of which 700 million are smartphone connections. So, voice has become the preferred option to search online. The second thing that has changed tremendously is online video. Initially, it was used for entertainment, but now its use for knowledge and information sharing has exploded.

Until now, pharma companies communicate in English to doctors and for patient education; occasionally we will use one or two languages. But leveraging data and mobile technologies in vernacular languages is significantly important. And this is the biggest opportunity for us to engage, and not just communicate, with patients.

SO, WHAT SHOULD WE FOCUS ON?

- Viruses will mutate as they spread, creating variants
- Some variants spread faster; some genetic mutations have greater transmissibility
- Vaccines to treat the most prevalent forms of the virus are pursued
- Collaborations between scientists, academics and pharmaceutical firms are common

"This will enable us to provide better patient care, better access, better availability, and better affordability," Mr Khan says.

MSD has entered into a partnership with Microsoft to use AI and machine language to support early diagnosis for lung cancer. This is one example of how access to data and to tech solutions will benefit all stakeholders: patients, doctors, research communities, and decision makers. For the pharma industry, digital-driven strategies are about the patient.

Key Takeaways:

- Digitisation should target patient engagement and benefits
- India is one of the fastest adopters of digital technologies in telehealth/telemedicine
- Companies have to focus on voice, video and vernacular languages for more effective patient engagement
- Pharma companies should work with and collaborate with the health start-up ecosystem to help establish innovation pathways

6.https://www.mckinsey.com/~/media/McKinsey/Business%20Functions/McKinsey%20Digital/Our%20Insights/Digital%20India%20Technology%20to%20transform%20a%20connected%20nation/MGI-Digital-India-Report-April-2019.pdf

CIO PANEL: THE OVERHAUL – FROM RAW MATERIALS TO PHARMACIES

THE PANEL

Jitendra Mishra,
VP and Group Chief Information Officer (CIO), Alembic Pharmaceuticals

Anjani Kumar,
CIO, Strides Pharma

Sekhar Surabhi,
President and CEO, Caliber Technologies

AVPS Chakravarthi,
Global Ambassador, World Packaging Organisation

Sreeji Gopinathan,
Global CIO, Lupin

MODERATOR

Shirish Belapure,
Senior Technical Adviser, IPA

BACKGROUND

In a March 2020 article by McKinsey & Co, the authors laid out the scope of the challenges Chief Information Officers (CIOs) face in creating organisational transformation with digitisation. The article used its 2018 IT Strategy survey to make its case, and identified three critical vectors:

- Reimagine technology's role in the organisation: As a business/innovation partner
- Reinvent technology delivery: end to end automation and platform as a service
- Future-proof the foundation: flexible architecture, data uniquity, cybersecurity

In its *Digital Maturity is Paying Off* survey – also in 2018 – BCG found that across healthcare, med-tech firms were the most digitally advanced; hospitals and providers were also making quick decisions on digitisation. Pharma and biotechnology firms seemed laggards. All three, however, scored highly on having business strategy driven by digital.

Where pharma lagged was in digitising the core. The survey showed there was a low degree of process digitisation, especially in the supply chain. There was no systematic approach to leveraging partner ecosystems and the wealth of data they had. Some reasons were:

- Managing the regulatory burden is complicated. Agencies such as the USFDA and EMA regulate pharmaceuticals and devices differently
- Scalability is a concern. Collecting data across regions, multiple therapies
- Cost of building/maintaining a digital health IoT platform. Estimated costs for building a digital health IoT platform - $50 million. Annual maintenance is high, too.

But that was 2018. Things have changed dramatically since then. Overhauling and digitising of the supply chain is under serious consideration by several companies.

SUMMARY

Not surprisingly, the shadow of the Covid-19 pandemic hangs over all discussions related to healthcare. It has prompted a fresh evaluation of the different parts of the ecosystem, in particular, the elements at the core: medicines, or pharmaceuticals.

"Things that have haven't happened in the last 10 years have happened in the last one," Shirish Belapure of IPA said, while setting the stage for the panel discussion. "It has changed the way pharma companies look at digitisation. How far-reaching are changes going to be?"

Different parts of the industry, from raw materials through manufacturing, quality control, packaging and distribution to pharmacies, have been affected to varying degrees. Industry experts and others are asking whether there is a case for an overhaul of the entire system.

Some of the work has been underway for some time now, even if certain parts have moved slower than others. Panellists addressed some important, even crucial questions about course correction and changes to medium-term strategies companies are undertaking.

Their discussions addressed the following questions:

- How did the pandemic increase attention to digitisation?
- What will the Internet of Things (IoT) change in pharma manufacturing?
- How do CIOs go about building a connected supply chain? Is there an ERP strategy?
- What tools do CIOs deploy in developing this 'smart manufacturing'?
- How do CIOs manage regulatory changes in implementing their digitisation strategy?

Panellists agreed that automation had been gaining traction in the two years leading up to the pandemic in 2020. They also agreed digitisation is imperative, more so now than ever before. A clear driver for greater and faster digitisation is regulatory compliance, especially with the USFDA and the EMA rules.

Both agencies upgrade their quality metrics often.

"If companies are looking at meeting the quality requirements in future, they have to think of automation with wings," Surabhi Sekhar of Caliber Technologies pointed out. "The other big advantage of digitisation is clean data. Cleaner the data, the lower regulatory oversight is."

Issues in manufacturing quality have severe financial implications. Companies are therefore looking at digitisation that will reduce equipment downtimes, changes in the climate conditions, and ensuring that the right people are taking the right actions at the right time.

IoT's positive impact on quality is talked about a lot. Predictive maintenance, for example, anticipates potential issues and works to head them off. The process uses sensors that monitor conditions like temperature, track line maintenance schedules, etc. As a bonus, they also track utility and material consumption. All this adds up to better quality.

"We are doing IoT with data analytics, artificial intelligence, machine learning to look at production yield," said Sreeji Gopinathan of Lupin.

In other words, IoT is used around critical process parameters. "But we are still distant from being a mature market for implanted devices and smart pills in India."

Pharmaceutical companies, however, have tended to be more reactive than proactive about digitisation, given the intensity of regulation they are subjected to. Panellists pointed out that they were therefore careful about how they engaged with digitisation.

But there is little doubt that business is being driven digitally now. Remote applications have been enabled, along with cloud-based platforms. Jitendra Mishra of Alembic provided an example of his company's experience of warehouse management, which was done manually earlier. Using digital signatures and other tools for a contactless environment, and with minimal manpower at factories, machines are accessed and the process managed remotely.

We use digital platforms to collaborate across functions, with our auditors, and regulatory agencies, which has enabled us to speed up the manufacturing process, Mishra said. "Done correctly, digitisation can speed up time to drug discovery and time to market."

How connected do supply chains have to be? A pharma company is made up of 3 triangles: the ERP or enterprise resource planning which integrates manufacturing processes across multiple units; the MES or manufacturing execution system and the QA/QC system, which validates process and product quality.

"The biggest and most important part of all three triangles is the data layer," said Anjani Kumar of Strides Pharma.

"It's about identifying actionable data. With today's cloud warehouse data lakes (vast pools of raw data), you have a lot of ready-to-use tools to generate business use cases, recommend action, etc. The era of ERP for supply chain solutions is over, he said.

Given the emphasis – in manufacturing and regulatory – on quality, packaging is key. It is the final stage of the supply chain that preserves drug efficacy. Packaging also innovates, for pills, injectables, sprays and devices.

"IT- or digitally-enabled packaging and sustainable packaging solutions matter because of the impact of packaging material on the environment," Chakravarthi AVPS of the World Packaging Organisation said. "Like the rest of the supply chain, packaging has also evolved in technological capability."

Any overhaul of the system will have to account for the evolution of 'smart' manufacturing. There is much talk on moving from batch to continuous manufacturing in regulatory circles. Shop floors may have to be designed, and capital expenditure budgets also overhauled.

Smart manufacturing, panellists agreed, was a matter of collaboration and engagement. It is achieved by harnessing actionable data from different devices, machines, using it to check them for consistency with data from other devices.

Data science and analytics make no sense if the data is not clean, is not the right data and available in adequate quantity. When regulation and audits move online and become remote, trust can become a challenge. This is where good data – clean data and plenty of it – becomes crucial.

Regulators use indicators to measure and reassure themselves that pharma manufacturing companies are turning out products that meet the highest standards of quality and patient safety. There are two that are worth noting: continuous process verification or CPV, and computer system validation or CSV.

We now live in a different time, said panel members: from BC (Before Corona) we are moving to AD (after Digitisation). Shirish Belapure, who moderated the lively discussion, had the final word. "IT is no longer a support function in the pharma industry," he said. "It's an integral one."

Key Takeaways:

- Covid-19 accelerated the inevitable re-evaluation of pharmaceutical manufacturing
- New regulatory requirements in global markets added their impetus
- The pharmaceuticals industry, once a laggard, is catching up on digitisation
- Given regulatory change frequency, and complexity, we have to learn quickly

CASE STUDY: IS AI, THE SILVER BULLET IN DRUG R&D?

Vishal Dhupar,
Managing Director, South Asia, NVIDIA

BACKGROUND

Artificial Intelligence (AI) has been increasingly used in various segments of the pharmaceutical industry. This includes drug discovery and development, repurposing, improving pharmaceutical productivity, and clinical trials, among others things, to reduce the time for achieving targets.

In the recent past, there has been a drastic increase in data digitisation; challenges include acquiring, scrutinizing, and applying that knowledge to solve complex clinical problems. AI can handle large volumes of data, using a variety of advanced tools and networks that mimic human intelligence.

At the same time, it does not replace human intervention in the process AI utilizes systems and software that can interpret and learn from input data to make or reach independent decisions to accomplish specific objectives. Applications are continuously extended in pharmaceutical industry settings.

In his talk, Dhupar took the audience through the complex maze of AI in drug discovery.

SUMMARY

A simple way of understanding AI is as software writing software. It's using an algorithm called deep learning, which some also call machine learning, that runs on 'supercomputers'. The basic idea is that you can teach a computer to do certain tasks.

It's important to define three things: the algorithm (deep learning), the GPU (the graphics processing unit or the supercomputer equivalent of a central processing unit or CPU, the brain of a PC) and domain experience, represented as data.

It is also important to understand the scale of the challenge. In 2020, the WHO reported that global spending on healthcare was $8.3 trillion: that almost 4 years of India's GDP, or 10 per cent of the entire world's GDP. Yet, there are thousands of diseases for which scientists have been unable to find treatments for. Which is where AI comes in.

In healthcare, the amount of data is so vast and complex that no human can understand it completely. Imagine that on any day, there are terabytes of data from genomic sequencers, electron microscopy, and high content screening systems. That can add up to petabytes of data per year from a single hospital (a petabyte is equivalent to 500 billion pages of printed text). AI algorithms process that volume of data.

Drug discovery before AI was a long and expensive process, characterised more by failure than by success. It's a process driven by and managed through human oversight in the laboratory. It took scientists 10 years to discover and bring a drug to market; on average about 90 per cent of attempts to find a therapy ended without being able to find one.

"Drug discovery is almost the best illustration of Murphy's Law in action," said Mr Dhupar. "It's hard to estimate the total amount of money and effort that has been lost."

In the last two years, transformer-based neural network architecture models have become available. Deep Learning is a kind of machine learning, based on recognising data patterns. Deep Learning is inspired by the human brain and how it perceives information.

It allows researchers to leverage self-supervised training and avoids the need for large label datasets. Deep Learning extracts more features, and working with a huge amount of data can perceive the way human beings do.

Unsupervised learning, uses machine learning algorithms to analyse and cluster unlabelled datasets by discovering hidden patterns or data groupings without human intervention. In silico medicine – the use of computational chemistry – has pioneered this method, and recently announced a novel preclinical drug using generative models. Like Schrodinger.

What about healthcare delivery? A complex series of data points feeds clinical decisions, and often decisions have to made in real time. Data flows from health records, medicine, imaging instruments, large tests, surgical procedures. That needs an entire ecosystem, algorithms that can predict, see what's unseen, and help make quick, complex decisions.

AI extends to diagnostics and sensor technology inputs too. In surgery, a firm developed an endoscopy visualisation system. Others are working on third generation genomic sequencing models even of viruses like Covid-19.

The healthcare industry continues to change rapidly. Data is very, very distributed. Federated learning is necessary to develop robust algorithms, and at scale. Instruments that see inside our bodies and perform surgeries are becoming intelligent sensors for AI. Collaboration and partnerships will be the norm. The future is challenging, but also promising.

Key Takeaways:

- AI is becoming essential to the pharmaceutical industry
- Its applications go beyond R&D, to diagnostics, surgery and patient care
- Devices and wearables are becoming ubiquitous

FIRESIDE CHAT: WHERE ARE WE NOW?

#DIGITAL INNOVATION IN PHARMA – THE PANDEMIC AND BEYOND

Sudarshan Jain,
Secretary General, Indian Pharmaceutical Alliance (IPA)

Sanjeev Navangul,
Managing Director and CEO, Bharat Serums

Rajaram Narayanan,
Managing Director, Sanofi India

THE PANEL

Rahul Guha,
Managing Director and Partner, BCG.

MODERATOR

BACKGROUND

Look around you; there are so many examples of the digital transformation in healthcare: Telemedicine and artificial intelligence (AI)-enabled medical devices are just two instances that are reconfiguring pharma companies interact with health professionals and patients, how data is shared and how decisions are taken about therapies and outcomes.

This is where, in the opinion of many, innovation lives. How can digitisation improve access to doctors for patients, in a country where they are in short supply? Apart from access, reducing human error, improving outcomes and reducing costs are high priority. This side of the digitisation equation is where doctors and patients drive digitisation priorities.

Research by DMN3, a B-to-C direct response marketing firm in the USA, found that of the people who went online looking for health information

- 47 per cent researched doctors
- 38 per cent researched hospitals and health facilities
- 77 per cent booked appointments

This is in a country of 315 million people. Even with half that number in India, the absolute numbers would be incredible. It's as if people are looking for on-demand healthcare.

We are all familiar with wearable devices, from measuring physical activity in diabetics to hand-held ECGs to detecting breast cancer with a patch. From a world in which we took a physical once a year/quarter, we now use continuous monitoring systems. People – and patients – want preventive care in the digital age.

And then there's AI. Think chatbots, virtual assistants and Japanese nurse robots, or those like Moxi, a friendly droid in the US that assists nurses with routine tasks like fetching and stocking patient supplies. Other speakers at this summit will delve in personalised medicine, accelerated drug discover and other applications.

The experts on this panel talk about digitisation and the changing contours of pharma company interactions with healthcare providers (doctors and hospitals) and with patients.

SUMMARY

Many assumptions we had before the pandemic have since been upended completely. Doctors and patients rely on digital information sources more than they ever did before, and the pandemic has created or generated so many new business models. It has also changed the nature of the discourse between pharmaceutical companies, healthcare service providers, and patients and their families.

Before the pandemic, healthcare was based on personal interaction with a provider, like a doctor or a patient; it wasn't unusual to walk into a doctor's office and occasionally find a medical representative there, waiting to meet the doctor. That interaction model has changed at a very fundamental level.

As a consequence of developments over the last 15 months, organisations now measure themselves on a digital maturity index. Put another way, companies have begun to assess to the degree to which they have integrated an ecosystem in which they apply digital thinking to all internal and external processes.

"We have done as much in the last 15 months as we have in the last five years," said Sudarshan Jain, IPA Secretary General. "We are on WhatsApp, we do email and webinars, but that's only part of the story. We still don't know how well we are doing. I think we are still at the early stages, and have a long way to go on this digitisation journey."

Company experience seems to bear that out. The value of the personal interaction with the doctor was typically 5 per cent knowledge transfer and 95 per cent share of voice/visibility. In the last 18 months, there's been a rapid re-adjustment of approaches. Companies had to aim for share of mind, and integrate field force staff into other roles within the organisation.

Firms had to change the metrics they used to measure performance. SFE, or sales force effectiveness didn't quite cut it any more. Rather than basing it on time spent with the doctor, companies had to search for and focus on insights-based interaction. Internally, that required a break-down of organisational silos to draw upon knowledge and action.

"When it came to CME (continuous medical education) programmes, everything we taught, professed or learned, we had to throw out of the window," said Sanjeev Navangul of Bharat Serums.

"Teams responded quickly. People focus on the content of conversations, probing for answers about what patients need or want, and what the patient experience is."

Participants agreed that these changes were a good thing, and that they are happening quickly is encouraging. Integrating the supply chain into the context of these conversations is also helping behavioural change, but they are wary of calling it transformation. For that, there is still some way to go.

So how is the future going to play out? According to Rajaram Narayanan, engagement will revolve around two themes. The first is that the access pharma companies will have is likely to be restricted to physicians. The second that physicians' access and usage of digital has gone up and dramatically, and will stay that way.

There are six drivers, which means developing different, even multiple capabilities.

- A combination of face-to-face and digital
- Content has to be interactive and infographic
- Engagement will be across multiple channels
- Engagement will not be HQ-managed, but orchestrated by field force
- Every contact needs to extract value – the role of medical is important here
- Engagement has to be responsible, because digital can be intrusive

"One point to remember is that we will still have the physician at the centre, we will still have the individual rep at the centre," said Narayanan. "That is the model we want and create, but capabilities for the future are going to be very, very different."

What about patient connect? This may not have been in the forefront, but companies are realising that the patient is critical to the ecosystem; most companies have always known that but it has taken on new meaning in a digital world. Companies start with the desired patient outcome and build the ecosystem around the patient accordingly.

"That has changed the stakeholders in the ecosystem are," Navangul said, in response to the moderator's question. "It's no longer just the patient or the doctor, it's the nutritionist, the physical therapist, the counsellor, who's invested in the system. Digitisation will increase stakeholders, and companies will have to engage with them too."

There has been a mushrooming of business models for patient centricity over the last few years.

"How can digital platforms play a role here, keeping mind about the potential for digitisation to be intrusive," wondered Rahul Guha.

There are two current roles that companies play, first through patient support programs that several of them run; the second is driven by patients' demand for information who take greater direct interest in their own care. The healthcare system itself has clearly changed. "It's no longer about who owns the doctor or the customer," said Sanofi's Narayanan. "It will take 4 or 5 organisations to come together to add value for patients."

To do that, there has to be recognition that when the patient's journey – as we call it – begins, some element of the healthcare industry accompanies her: from diagnostics to physician to drug company to pharmacist, etc. Keeping the patient at the centre of focus will force companies to be aware of the entire journey; data and digitisation help with that.

Guha summarised his two key takeaways about the future that digitisation and innovation in the pandemic and beyond: one, that content is king, and two, collaboration not competition is going to be the hallmark of patient engagement in the future.

"And that future is now," said Sudarshan Jain.

Key Takeaways:

- Face-to-face communication with doctors for medical reps is no longer important
- Patient engagement for companies has taken on new significance
- Engagement with physicians will be the primary engagement vector
- It will be a mix of personal and digital, involve medical and other teams
- Every contact/instance will have to deliver value

THE PHARMACEUTICAL THREAT LANDSCAPE: STAYING AHEAD OF CYBER VIRUSES

Vivek Srivastava,
Regional Sales Director, India and SAARC, Crowdstrike

BACKGROUND

Ever since the Covid-19 pandemic hit in March 2020, cyberattacks in India have gone up by almost 80 per cent. A report by the Ministry of Electronics and IT reported that until August 2020, Indian companies were hit by almost 7,00,000 cyberattacks.

In May 2021, a survey by Barracuda Networks, a cybersecurity firm, found that 81 per cent of Indian companies reported they had been hit by a cyberattack in the last year. As most people began working from home, the vulnerabilities in our IT infrastructure and networks became apparent.

Media reports say that India is second only to the US in terms of cyberattacks; the problems that surfaced in the pandemic were not restricted to a few; all major economies were targeted. Reports say firms in 2020 globally paid ransom of $20 billion to thwart attacks.

Are pharmaceutical companies prime targets? Yes, because they collect and store large amounts of sensitive and personal data. They also possess incredibly valuable data on pharmaceutical and medical advances and technologies. The industry follows strict privacy guidelines in safeguarding protected health information.
As pharma companies worldwide continue to embrace digital transformation, cybersecurity and risk mitigation should become a very high priority. Data suggests that almost 90 per cent of healthcare organisations have experienced data breaches, and nearly half of them suffer multiple attacks each year.

SUMMARY

The cyberthreat landscape has changed, just as the pharma landscape has changed, says Mr Srivastava. The players – or adversaries – have changed, the tradecraft has changed and the motivations have changed.

"Human psychology – and understanding their psychology – is key," he says. "It's like hand-to-hand combat. You understand the sequence of their moves, their training, the style and thus anticipate their next moves."

After years of watching, tracking and observing them, the list has been pared down to about 150 plus players, motivated by different reasons. More than half of them can be classified as state-sponsored or work for rival nations, so their motivation isn't monetary. It also means their resources are considerable.

The second group are the e-crime vendors, who want to monetise the information they manage to get. About 30 per cent – or 43 of the 150+ players – are focused specifically on the pharmaceutical sector. They have been very successful, so it has paid off for them in monetarily too.

A third set of players are those whose primary target is intellectual property rights, or IPR-related data. "Over the last 12 months, as we lived through the pandemic, and through the frantic search for vaccines, their value has gone up considerably," Mr Srivastava says.

Tracking indicates that the primary adversaries in the pharma space are of Chinese origin, and are likely to be state-sponsored. More recently, Russian, Korean and Iranian players are emerging. The sophistication of the attacks, however, is a step up from past experience.

Many of the breach searches are looking for minute details, not the 'secretive' information. They are tracking activities that are normally overlooked as being important, and searches that are undetected by traditional methods for leads and trends that constitute small pieces of evidence.

So how do companies respond?

- First, and foremost, break away from outmoded defences. Most defences are built to detect malware; more than half the breaches are malware free. The adversary is a very sophisticated state.
- Second, focus has to be on increased breach protection.
- Third, speed of the essence; only the fastest will survive a cyberattack. Think of the breaching process as happening in phases, on a scale of one to ten.
    - To stay ahead, security infrastructure should detect the attack in one minute, investigate it in 10, respond to and repel the attack in 60 minutes.
    - The time taken by an attacker to access to a company's environment and move laterally through the system is the breakout time.
    - That breakout time for a Russian adversary is about an hour, for a Chinese attacker is about couple of hours. Companies have to be very fast, it's the key to survival.
- Go beyond focusing on prevention technology, cover the entire attack life cycle.
    - Build the expertise, the processes, the skill set to detect low and stealthy
    - Put processes in place to respond to detected breaches, quickly contain them.

There are a couple of important questions companies need to keep asking.

- Number one, are they breached?
  - Experience shows that every third organization in the world is breached, and many don't detect the breach for months togethe
- Second, are they mature?
  - Companies have the infrastructure, the people and the skills. Testing the security infrastructure improves detection and remediation times

As long as the answers are satisfactory, it'll keep companies ahead in the game.

Key Takeaways:

- The cyberthreat landscape has changed significantly in sophistication
- State players have increased the ability to avoid detection
- Pharma firms have to replace outmoded technology with modern methods

UNDERSTANDING DISEASE STATES THROUGH DIGITAL SENSORS/WEARABLES

Dr Anand Subramony,
Vice President, External Innovation and Novel Technologies, AstraZeneca

BACKGROUND

Innovative wearable technologies have heightened interest in new means of data collection in healthcare, and biopharmaceutical research and development. Many applications for wearables have been identified, in a number of therapeutic areas.

With smartphones, there has been a complete change in how people communicate with each other, access media/content, and interact with that content. But most noticeably, in healthcare, wellness and beyond, this shift has led to a complete change in the expectations surrounding reporting of health-related events.

Wearable technologies – sensors with software applications (or apps) on smartphones and tablets – can collect health-related data remotely, outside the doctor's office or diagnostic lab. Other technologies, such as smart-cap bottles, monitor medication adherence, using a sensor and app-based data collection in combination.

These applications can also be adapted for drug development in early- and late-stage clinical trials. Collecting data from trial participants using wearables in natural settings can fundamentally change clinical trial design; they wouldn't have to be kept pharmacology units while the data collected.

Sensors can provide objective measures of what are mostly subjectively reported outcomes, like pain or fatigue; they could replace self-reporting. The fact that they can be done at home, and that the measures are simplified, makes them a very attractive option.

SUMMARY

Pharma is changing, from the way research and development is done to the use of digital technology in drug development. The changes are being driven by a numb er of factors, among the first of which is that it's no longer about making medicines and selling them. That's only part of the job; we live in a world that calls for total solutions.

Second there is a shift towards precision medicine made possible by biotechnology, the use biomarkers and other technologies to see how patients respond to particular medications. The third one is digital health. Digital technologies have had a huge impact on other industries and it is pharma's turn now. The one common thread running through all these changes is that they have improved outcomes for patients.

Drug development is a long and expensive process; it usually takes about 13 years and $2.6 billion to bring a drug to market, and that's just the successful ones. The company enjoys a captive market for a short time – it's come down from 6 to 2 yeas now – thanks to regulatory changes and competition.

To create something novel, understanding patient needs is key. Since patient care involves caregivers – and prescribers – they need to be considered too. The pandemic has also changed certain things irrevocably; without being able to access hospital and lab facilities, the need for solutions that can be delivered where the patient is gains importance.

The pandemic has accelerated other changes: lab automation, robotics in production, the use of data analytics and AI to develop medicines faster. Last but not least, the use of digital tools like apps and sensor technologies that can be used in the daily course of patients' lives by building delivery around their schedules.

Take ECG measurement. "It's very laborious; you go to the doctor's office, set up through nine terminals, use sensitive adhesives that you need to put the leads and wires on your body," Dr Subramony points out. "This has been completely transformed by a company that created a hand-held ECG device."

When it comes to clinical trials for a medication under development, he says, trial participants are given a 'trial in a box" with detailed instructions, compliance needs – and perhaps a device for monitoring. "This is our new normal," says Dr Subramony. "it's a paradigm shift, away from the way we used to do clinical trials."

Real time monitoring helps in creating feedback loops during a trial, for example, and dosages can be scaled back, adjusted and so on. Digital is transformative, but patient engagement is also crucial. Sensor preferences have to be understood, and training may be necessary in many cases.

Drug discovery has evolved from laboratory process to a cross functional collaborative enterprise that brings together data scientists, doctors, traditional pharmacists and technology developers. And the patient is the better for it.

Key Takeaways:

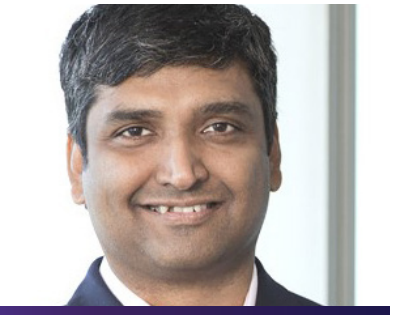
- Pharma is no longer a laboratory process driven industry
- Technology and pharmaceutical science interact in a number of ways
- Monitoring devices enable better oversight of patient response and adherence
- Digital technology enables visible patient centricity

LEADERS PANEL: HOW TECHNOLOGY IS BRINGING PATIENT CENTRICITY TO LIFE

THE PANEL

Satish Reddy,
chairman, Dr Reddy's Laboratories

Dr Murtaza Khorakiwala,
Managing Director Wockhardt



V Simpson Emmanuel,
Managing Director and CEO,
Roche Pharma India

Vani Manja,
Managing Director, Boehringer Ingelheim India

MODERATOR

Vikas Bhadoria,
Senior Partner McKinsey & Co

BACKGROUND

Defining patient centricity tends to be intricate, even complicated. With so many stakeholders, and the breadth and variety of stakeholder-patient interactions, coming up with an easy-to-grasp, encompassing idea of patient centricity is hard.

According to a study by Deloitte published in January 2020 there was no common, widely accepted definition for patient centricity. Most people the study's authors interviewed, however, agreed on what it was not:

- **It was not public relations or externally focused,** even when firms partnered with outside organisations
- **It was not just about better engagement with patients in clinical trials,** though getting patient input into the trials studies is essential
- **One size doesn't fit all**; patient centricity looks different for each company

Defining patient centricity tends to be intricate, even complicated. With so many stakeholders, and the breadth and variety of stakeholder-patient interactions, coSome experts prefer to talk about 'patient-centric approaches, defined thus: a patient centric approach is a way healthcare systems establish a partnership among providers, patients and their families to align with patient wants, needs and preferences.

In some countries – such as the USA – patient-focused drug development (PFDD) is part of the regulatory apparatus. The 21st Century Cures Act (called the Cures Act for short) requires the USFDA to report on the use of patient experience data in regulatory decision making.

The PFDD Program is staffed and run by the FDA's Center for Drug Evaluation and Research (CDER). It was set up to facilitate incorporation of relevant patient input. Based on the Program's work, the FDA is developing a series of guidance notes on the methodology to be used in collecting patient experience data.

ming up with an easy-to-grasp, encompassing idea of patient centricity is hard.

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SUMMARY

There are usually as many perspectives on patient centricity as there are people. For many, what it is end-to-end outcomes, convenience and accessibility. Company leaders define it as organisational purpose, about making medicines available to whoever needs it, and making them affordable.

"How do you make it easier for patients to manage their condition or disease better? That's among the questions we ask ourselves as companies," according to Satish Reddy of Dr Reddy's Laboratories.

Companies differ in the way they answer that question, depending upon the particular area they focus on. For some, it is about the specific problem the medicine made by a pharma company is supposed to treat. "We look at the value we bring through innovation in meeting patient needs," said Ms Vani Manja of Boehringer Ingelheim. "Patient centricity is the north star we navigate by."

As manufacturers, pharma companies take care not to substitute their own capabilities for the physician's expertise, or the clinical system, especially when it comes to chronic ailments.

"We supplement the system by empowering the patient, as one aspect of the management of her disease," Murtaza Khorakiwala of Wockhardt points out.

"In doing so, we factor other elements of disease management: lifestyle, behaviour, etc."

Technology comes in here, by integrating all the information about the patient – physiology, behavioural patterns, therapy adherence behaviour, diet, all the many factors that have an effect on the disease and how it is managed. All of that information is fed back into the process of making the medicine more efficacious and almost customised.

Digitalisation is prevalent to a greater or lesser degree across the value chain and the process, from drug discovery to when it is used by patients. A recurrent theme through this summit has been how Covid-19 has accelerated and brought a laser-like focus on digitisation. Everybody agrees that it is the way of the future, and that companies have to catch up quickly. Everyone is also clear that it aligns with the patient centricity principle.

"To reiterate what Satish (Reddy) said, it stems from our very purpose, which is to do now what patients need next," said Simpson Emmanuel of Roche Pharma.

"It is at the core of what we do. We are also clear that it's a continuous process; it's not a destination we reach. It never stops."

From that perspective, patient centricity encompasses a fairly large area. Taken to its fullest extent, patient safety, quality, clinical effectiveness, even reduced hospitalization and reduced wasteful expenditure are all achievable through a patient-centric healthcare ecosystem.

New therapies to treat severe cases of Covid – such as antibody cocktails – have pushed regulators to speed up the approval processes, look at clinical data that companies have to present in real time. There has been a rush to go in for collaboration on different levels: across development, manufacturing and go-to-market strategies.

Different functions within companies – regulatory, quality, strategy, medical affairs and communications have all had to come together in new and unusual clusters. "The supply chain had been both disrupted by events, and sometimes intentionally to keep the process flowing," Emmanuel of Roche explained.

Panellists were emphastic that the transformation process has been underway for some time already; what has changed is the speed and the visibility. Responding to the demands of addressing the pandemic, technology and data have been leveraged to a hitherto unheard-of extent.

"Companies are connecting the various dots using digital technologies," said Ms Manja. "This is not something that's restricted to the pandemic, but will extend to all the other NCDs – diabetes, cardiovascular diseases, oncology, etc." The sense of urgency she added, has to be sustained.

Which brings the discourse to the question of organisational culture change. That's been happening and continues to happen at the commercial side of companies. It's been slower on the development or R&D side, for example.

Creating an enterprise-wide view of patient centricity is where technology can play a significant role. Satish Reddy of DRL provided an example, the use of an app to assess and measure treatment for cancer in South America that showed patient experience was not uniform. So the company launched a digital platform which used patient insights to help hospital teams, diagnostics and patient support groups to change the experience.

How much of these changes can be driven from within the company, and capabilities built? The panel said people are oriented towards the familiar, to ways that are task oriented, not stopping to think about where those tasks will take them. The thing to do is break down silo mentalities; we have abundant skillsets, Emmanuel said, but need to change the mindsets.

The mindset change is not just about changing organisational culture, but instilling one of learning. It's not about how much you know, but about what you don't know. Secondly, in a world of rapid changes – there is unspoken acceptance that this is not going to be our last pandemic – agility is going to make a big difference. Responding and adapting quickly is going to matter a lot, said Khorakiwala.

All of which goes to show how different companies perhaps perceive patient centricity. The healthcare system as a whole is bigger than the sum of its parts, however. What should a patient-centric ecosystem look like?

The leaders on this panel – and on others at this summit – acknowledged implicitly that the pandemic exposed the inadequacies of healthcare systems around the world. Significant gaps in perceptions among different players about the others outside their sphere exists everywhere. So in planning our post-pandemic future, systems thinking will be essential.

The response to the pandemic has a huge silver lining: the collaborations, knowledge and capability sharing between companies in an industry that is perceived – often correctly – as highly competitive, has been enlightening and inspiring. That augurs well for the future. Med-tech players, start-ups, public-private and academic partnerships will all have to come together into an integrated ecosystem to make it sustainable, Ms Manja pointed out.

Management studies often paint large conglomerates as ecosystems, especially when they contain several large key pieces of adjacent industries. In healthcare that would be having hospitals, pharma companies, retail pharmacy chains and health insurance companies as part of a conglomerate. They can set up partnerships and collaborations for other elements.

The reality is that no one company can own every piece of the puzzle; conglomerates can teach us interesting lessons about building integrated ecosystems but the larger lesson is perhaps about the importance of collaborations unified by a single objective: in this case, patient centricity. It's about building a value proposition where the highest value is what the patient receives, Reddy said.

This is a conversation that can probably can go on for days, McKinsey's Bhadoria said, in summing up the discussion. "It gives us two things to take away: a good feeling and positive vibes of what is possible in building a patient-centric ecosystem, and secondly, a sense of the considerable challenges involved."

There is a substantial agenda out there, and a lot left on the table for further discussion.

Key Takeaways:

- Patient centricity has always been there, but not in the foreground
- Companies have incorporated it into their mission and purpose, sometimes explicitly
- It is not expressed as what companies do but how they do them
- It's a way of being, not an objective to be realised
- Collaboration, co-operating and coherence are ways that will define its future course

THE VIRTUAL TWIN EXPERIENCE

Guillaume Kerboul,
Director of Life Sciences, Dassault Systems

BACKGROUND

When disaster struck the 1970 Apollo 13 mission to the moon when it was in orbit, it was the existence of mirrored systems on Earth – a 'twin' of Apollo 13 – that enabled NASA to improvise and bring the astronauts safely back home. The concept of digital twins has been around since 2002; it was the advent of the Internet of Things (IoT) that accelerated their adoption across industries, including life sciences.

Essentially a digital or virtual twin is visual representation of a real, physical object. A computer program uses real world data to create simulations that can predict how a product or process will perform.

The program integrates artificial intelligence, machine learning, big data and software analytics to build virtual models that can mirror products, processes and manufacturing to drive innovation. In healthcare, it can also model patients using smart sensor technology.

SUMMARY

The 'avalanche of data' and data digitalisation has democratized science and technology, Kerboul said in his presentation. This wealth of data and digital technologies is put together to create a 'virtual twin' experience.

There are four areas in pharma that can leverage virtual twin technology: product (drug design), process (getting the biology right), manufacturing plant (quality) and patient (response to the drug).

For more than a decade, models and virtual representation of the molecule that is the drug have been used, along with the visual representation of those targets. Researchers define the target product profile, and play with those models.

"You can literally create tailor-made compounds based on the virtual twin of the drug, virtual twin of the targets, but also the virtual twin of the full chemical or biological library," Kerboul explained. "It's a way that transforms drug discovery using a virtual representation of the drug."

The next stage is the process. The El Dorado in pharma manufacturing is the idea of a 'golden batch', a repeatable process by which companies arrive create one with optimal yield and quality. Information is culled from the analytics of the batch process to define and find the golden batch, and create its virtual twin. With a virtual twin, companies can reach optimality by modelling it and displaying it.

The third stage is plant-level production. Typically, companies order the various pieces of equipment, which take a few months to arrive. Time is also taken up in commissioning, validating and qualifying the plant. "The process is long, expensive and there is a risk of losing data," Kerboul said.

What some companies are doing is recreating the line in their facility; they model not just the equipment itself, but its behaviour as well. Using the example of a company making pre-filled syringes, Kerboul explained how simulations with a digital twin can model or predict ways in which machines can behave.

Even without the actual physical machine, the company can optimize the best filling rate, and set the best parameters to get production without a single loss. Design the plant, take the optimal filling condition as input, simulate equipment behaviour, do qualification, validation, even the commissioning of the line, the debugging, and the factory acceptance test.

"This is what you do on the virtual twin of the line," Kerboul said. "You can use the virtual twin to check and optimize and validate the way operators are using the line, which is really interesting when you do changeovers, and cleaning processes that take a lot of time."

Last, but not least, companies build virtual twins of patients. An ideal patient can be modelled; so can the effect of the drug on the patient using a virtual twin. Sensors on real patient help create models of patient behaviour. There are a few examples of modelling some organs, and the way the devices or drugs interact with them.

Patients in clinical trials can be modelled; so can the design and management of a trial to gather data that can be leveraged. The objective is to accelerate the value of those clinical trials, reduce the risk, and optimize outcomes. Given the current challenges of enrolling people into control arms, virtual twins use synthetic control arms made up of virtual patients, using data from past trials, to serve the same purpose.

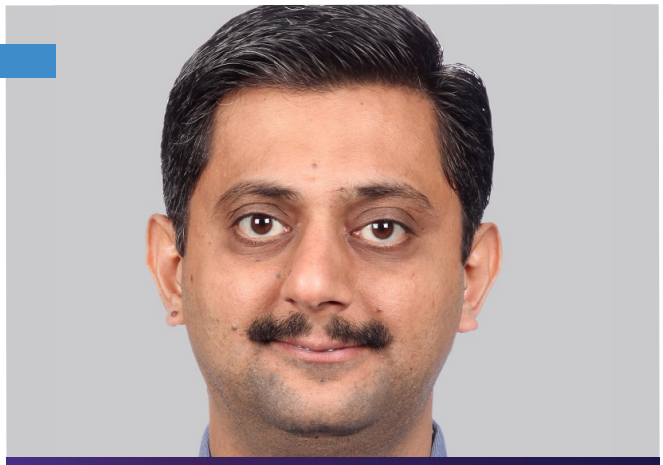
"The challenge is to do this in a robust way, and to generate and collect physical clinical development evidence, and insights," Kerboul said. He cited the example of Medicenna, a company which pioneered data development of synthetic control arms; the company is now working closely with the USFDA to create synthetic control arms to make virtual twins of the population that are as real as possible.

This is not the technology of tomorrow, Kerboul said. With virtual twins, the future is now.

Key Takeaways:

- Virtual twinning is going to be a game-changer across the spectrum of pharma
- From drug design to clinical trials, virtual twinning perfects pharma manufacturing
- Virtual twins bring together data analytics, AI, machine learning in IoT
- Being able to model the entire spectrum raises the bar on quality massively
- The impact on patient outcomes can be significantly visible

HOW TECHNOLOGY IS REVOLUTIONISING CLINICAL TRIALS: WHAT'S NEXT?



Dr Chirag Trivedi,
Clinical Study Unit Cluster Head, India & South East Asia, Sanofi

BACKGROUND

In April 2020, the newsletter Clinical Research News estimated that more than a third of all clinical trials do not enrol to capacity. All that changed with Covid-19. In a business where awareness was low, the search for a vaccine brought a rush of volunteers, according to Robert Goodwin, Head of Operations Center for Excellence for Global Product Development at Pfizer.

Volunteers who came in were sent home with an e-diary in their phones as an app that would record how they were feeling. The e-diaries made it easier for the doctors involved in the study. Instead of driving to a clinic, doctors just did video calls. Telemedicine took the trial to the patient.

Even before Covid-19 accelerated the process, technology was revolutionising clinical trials in different ways:

- It enables direct-to-patient strategies; companies can match patients to trials
- Data capture is easier with wearables; patient data drives trials
- About 8 billion data points are created per patient through the entire clinical trials process, which calls for automation
- Blockchain technology can addresses data privacy concerns

SUMMARY

The Covid-19 virus is still evolving; There are four transmissible variants so far (with one or two more emerging), and researchers continue to learn more. Information is still pouring in, Dr Trivedi points out, and uncertainties persist. Collaborating doctors and institutions are putting it all together and sharing it, with the help of digital technologies.

Typically, a vaccine takes about 8 years to develop and be approved. Covid-19 vaccines were developed rapidly, put through the clinical trials process, approved and injected into people within a year. That was the result of bringing together the biopharma industry, academia, scientists, researchers, etc, who looked at the technology platforms that were available and went ahead and leveraged them.

Digital technology was a big part of this. “We quickly got together to change the clinical trial protocols, introduced pandemic-related changes since physical visits of patients weren't allowed,” Dr Trivedi said. “Patients were kept in the safety of their homes, and medicines delivered, and blood samples collected, because data was important.”

Lab collections were done at home. Drugs that are typically infused at hospitals were also delivered at home. Home health care and study medications were administered at home. Virtual consulting, tele consulting, doctor-patient interactions were all arranged.
There was monitoring, remote visits where appropriate, and remote audits.

What are the lessons from Covid-19 for the future? First of all, clinical trials had to be made pandemic-proof. New protocols were created and approved them without compromising the quality or integrity of the trial process. In fact, they were strengthened.

Second, the industry has put together a technology ecosystem that will support changes that were made and maintain system integrity. Collaboration between pharma researchers, microbiologists and data scientists, is leading to patient-centric solutions.

Third, digital technology will allow the deployment of digital bio-markers. One example is the six-minute walk test usually done for a Covid-19 patient to assess lung function. If during the walk there is a drop in oxygen levels, and it falls outside a defined range, then the concern is addressed by taking appropriate measures.

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Cardiac function biomarkers can be tracked with a hand-held ECG machine, a digital ECG through the variables like blood pressure monitoring for example. This becomes easier to manage. More importantly, data becomes available on a real-time basis.

Digital technologies enable continuous monitoring, as compared to the once in a quarter in-person visit to your doctor. Potential adverse events become more predictable and clinical decisions can be taken to prevent the event and reduce the risk.

Wide scale adoption of digital technologies and creating e-medical records will create a data source with which data analytics can inform therapy, policy and patient care. Real world data sources of high quality and adequate quantity can have far-reaching impact on clinical trials management and design.

“But we will also have to keep ethical considerations and data security in mind all the time,” said Dr Trivedi. “That's going to be very important.”

All stakeholders – the biopharma industry, regulators, ethics committees, technology partners, hospitals, and the entire healthcare system will have to come together, strengthen the ecosystem and protect it. For digitisation to work effectively that will be critical.

Key Takeaways:

- Digital technologies speed up development, e.g., the Covid-19 vaccines
- Clinical trials can be made pandemic-proof, and patient participation easier
- Can strengthen system integrity, which is critical across the ecosystem
- Enhance the accuracy of biomarkers via continuous monitoring

ADOPTING AI AND MACHINE LEARNING TO UNLOCK THE FULL POTENTIAL OF PHARMA

Manikandan Balasubramanian,
Associate Partner, Intelligent Automation & Artificial Intelligence Practice, EY LLP

BACKGROUND

A 2019 report by RBC Capital Markets said that approximately 30 per cent of the world's data volume is generated by the healthcare industry. By the end of 2020, the report said that on a per capita basis, people will have 1,400 digital device interactions every day; that number is expected to reach nearly 5,000 by 2025 .

During the course of this summit, speakers and panel discussants have shared the many ways that digitisation in the pharma industry can lead to amazing transformations across the spectrum of companies' capabilities, from drug discovery to patient monitoring in critical trials. Much has been said about artificial intelligence (AI) and its use in pharma.

AI in pharma – and other industries – is narrowly focused; the objective is to solve a task or a related set of them using automation and algorithms. There are three broad types: one is the data science algorithms designed by people to apply analytics to evidence collected in the past. For example, researchers could take population-based outcomes from therapy together with an individual patient's medical history and recommend drug combinations and options.

The second type is machine learning; it uses neural networks, which are modelled on thinking in the human brain, but reaches decisions faster. Data-driven algorithms make software applications much more accurate in predicting outcomes, without needing programming.

And finally, there is deep learning; while also based on neural networks, it has additional capabilities in combining calculations and signals. In medicine, for example, deep learning can be used in diagnostics; it can analyse images and radiological scans, look at pathology data and historical treatment to reach conclusions and make recommendations.

SUMMARY

Automation and AI have been the topics of discussion in boardrooms across the country, according to a survey that EY conducted in 2020 with 400 CXOs and CIOs. Around 95 per cent of respondents in the survey said that their organisation was actively contemplating automation and AI initiatives, according to Balasubramanian.

He identifies two crucial drivers in the economics of the pharma business: a) how quickly you can get a new drug to the market, and b) what the cost is going to be. For most new drugs, the time n from discovery to market is 8 – 12 years, and the cost is about $2.5 billion; 90 per cent fail to make it.

In recent times, technology giants have started entering healthcare and pharma, with acquisitions; Amazon acquired PillPack (a retail pharmacy that delivers), Google bought Fitbit and Apple acquired health data start-up Gliimpse. Data and technology are central to the business of healthcare.

Pharma companies are deploying technology and automation to various parts of the manufacturing process. People on other panels and in other presentations have referred to it.

Drug discovery and development is an area where there is a tremendous amount of data that is already available. The human genome has been decoded, so there is a lot of data that helps with the ability to discover treatments for diseases through genetic therapy. The data available about behaviour that predicts rare diseases and hitherto-hard-to-treat conditions can be used with AI to reduce the cost of development for example.

“There’s a very interesting example around using speech recognition to determine potential onset of Alzheimer’s disease conditions,” Subramanian said. “Depression, based on the way the patient talks, the kind of words someone uses, so on and so forth are also indicators.”

At the other end of the process, patient enrolment for a clinical trial is hugely challenging; 86 per cent of clinical trials are unable to find enough candidates. AI can help find people looking for a new therapy, and with AI, improving the efficiency of clinical trial processes generates significant savings.

Outcomes from patient and doctor engagement can similarly be enhanced using AI and natural language processing or NLP. With Covid-related restrictions, field force personnel have had to find other ways of maintaining the doctor connect, which is where AI and machine learning come in.

A certain degree of automation already exists in a number of support functions like finance HR and IT. In finance, for example AI is used to look at reconciliation and working capital improvement for example; in HR, it can be used to assess the likelihood of how long talent or a particular candidate is likely to stay with the organisation.

Many pharma organisations have applied AI and machine learning to certain specific areas like parts of the production process; for those who haven’t yet started, some time spent thinking about the focus of AI would be time well spent.

“Many organisations have embarked on back-office conversions or BOCs, and the initiatives have fizzled out,” said Subramanian. “It’s important to show quick wins. The business impact doesn’t have to be 10x, it can be incremental.”

Second, an important consideration for companies is building their own data. Data is power in the pharma industry. Third, having high quality data science talent is going to be crucial. The demand for it is high across every industry, so competition for talent will be fierce.

Fourth, as organisations look to leverage capacity and learning from one area to others within the same organisation. So, developing an enterprise-wide structure of responsibility and governance of AI initiatives suggests a hub and spoke model works well.

"Establishing an enterprise platform for AI, encouraging reuse, skilling, looking at talent, looking at partnerships is typically a centralised responsibility," Subramanian said. "The embedded organizations within business functions are focused on generating demand."

Finally, awareness about AI and machine learning should be democratised through the organisation. People plug in and build their own AI models, so due diligence and adherence to internal policies on AI use become important, given the value and sensitivity of the data different parts of the company generates, and the legal implications around its use.

Artificial Intelligence and Machine Learning also demand responsibility.

Key Takeaways:

- The potential for AI and machine learning is limited only by creativity
- AI operates at multiple levels across the organisation
- Data is power
- Even support functions like finance, HR and IT can be plugged into AI
- Organisations must be clear about why they want to use AI, and for what

ACCELERATING DIGITISATION IN PHARMA WITH LOW-CODE PLATFORMS

Venkanna Chowdhury Manne,
CEO and Founder, Amplelogic

BACKGROUND

Pharmaceutical companies in India are at different stages of their digitisation journeys. The Covid-19 pandemic has challenged them to assess how much further they have to go on the digitisation journey, and forced them to start reconsidering their long-term planning schedules for digitisation, forcing some to move faster than envisaged.

In 2019, Pharmaceutical Manufacturing's Smart Pharma Survey had raised concerns that the industry's enthusiasm for the digital 'revolution' was declining. The pandemic changed all that. Wired magazine quoted Novartis CEO Vas Narasimhan from a 2020 interview as saying digital investments that "previously seemed like nice-to-have experimental areas that may transform us in five years" suddenly became "things that were fundamental".

A very significant part of India's pharmaceutical manufacturers have automated large parts of their production. Automation mean transferring process functions and entire process sequences from human to technical systems. From this perspective, most are compliant with the global GMP, or Good Manufacturing Practices, standard.

Digitisation is the next step up. It collects information generated by various processes with the organisation – including the automated ones - applies digital technology tools like AI for advanced insights such as assessing risk tolerance, anticipating future points of interest, and providing intelligent, customized recommendations.

SUMMARY

Before companies embark on their digitalisation journeys, they have to figure out how ready they are. Companies differ in size, scale and are at different levels of automation.

The first thing to look for when it comes to digitisation is business process excellence in the laboratory. This is where the time taken for sample testing is turned around, and algorithms are picked on the basis of the number of samples to be tested etc.

Capacity planning is the next thing. How many machines in the manufacturing line are underutilised, and how many are over-utilised? Firms take into consideration product quality review (PQR) data, and other quality metrics. They also look at resources planning: Employee Skill Evaluation for example, estimates of employee contribution, etc., using predictive analytics.

Organisations are a collection of systems integrated into a structure, so companies looking to digitise would tend to look for solutions that support their integrated architecture. Buying world class solutions – an eQMS system for quality, for example – for different processes can be tempting; the challenge is in integrating them into an existing system, which can be a complex and expensive task.

There is another reason to evaluate digitisation decisions thoughtfully. Pharmaceuticals is an industry where regulatory change is frequent, so many changes will mean new reporting requirements and reconfiguring digitisation solutions. There are multiple regulators too, from the USFDA, the EMA and our own CDSCO.

Low code platforms are a good option for Indian pharma companies. Simply defined, low-code is a software development approach that requires little to no coding in order to build applications and processes. It uses visual interfaces with simple logic and drag-and-drop features instead of extensive coding languages.

They are intuitive tools – much like iPhones – that let users with no formal knowledge of coding to create applications for many purposes. Non-professionals can use low-code platforms to create apps of varying complexity to meet business needs, automate processes, and accelerate digital transformation.

"You can create your own kind of workflows, and also the dashboards," said Mr Manne. "You can define your own organizational hierarchies; whenever there is a change in your organizational structure, you don't need to put lots of money to make the change."

These platforms can be hosted on a Cloud, On Premise – meaning on your IT infrastructure on factory premises, or used for Hybrid hosting (On Premise and a public or private Cloud). One example that illustrates this is how you handle complaints, for example. The response to the complaint can be hosted on a Cloud where both the complainant and the regulator have access, without sharing access to you own systems. This meets with the CSV (Computer System Validation) requirement that the EMA sometimes ask for.

Low code platforms can develop 80 per cent of the needed applications in four to five days. "Once you have this solution, you can visualize it, and can see if you like the experience of using the system," Mr Manne said. "You don't have to wait until after the OQ, or operational qualification, process."

It's as simple as that: drag and drop it on the checklist.

Key Takeaways:

- Digitisation is no longer about when, but about how
- Companies are also at different stages of digitisation readiness
- The approaches companies take depends on how big their operations are
- As the industry is heterogenous, there is no one-solution-fits-all fix
- Digitisation will be a step-by-step, process-by-process exercise

DIGITAL TRANSFORMATION OF THE PHARMA SUPPLY CHAIN: LESSONS LEARNED FROM THE PANDEMIC

THE PANEL

Prasad Deshpande,
Global Head – Supply Chain, Biocon

Swapn Malpani,
Joint Global Supply Chain Head, Cipla

Vickram Srivastava,
Head of Planning – Global Supply Chain, Sun Pharmaceuticals

Saurabh Gupta,
Senior VP and Head – Supply Chain, Lupin

Anand Garg,
VP and Head – India Supply Chain, Dr Reddy's Laboratories

MODERATOR

Jaydev Rajpal,
Partner, McKinsey & Co

BACKGROUND

Over the last 15 years, experts have been raising red flags over the lack of transparency and compromised security in the pharmaceutical supply chain. In 2013 the EU enacted that Falsified Medicines Directive, and the US enacted the Drug Supply Chain Security Act (DSCSA).

Indian pharma companies exporting to the USA were originally required to become fully compliant with the DSCSA by 2018, but then given an extension until the end of 2019. The EU had established a similar deadline – February 2019 – for Indian companies to meet the reporting requirements of the FMD.

Since then, the Covid-19 pandemic has only accelerated the need for Indian companies to digitise rapidly and meet the compliance requirements of their most important markets.

Digitisation can persuade companies to look for additional solutions to bring efficiencies into their supply chain management.

Digitising the supply chain has several advantages. It brings greater visibility to the different parts, helps identify processes that can be improved , and inventory management can be more real-time oriented. All this brings the much-talked-about 'agility' in the supply chain.

Implementing digitised solutions in supply chain management has its fair share of challenges too. Relocating existing records from legacy systems to new platforms can be daunting; third party expertise may have to be hired to help with integrating the data, while also ensuring that risk of losing data is minimised.

SUMMARY

Reflecting on the last 15 months since the start of the pandemic, McKinsey's Jaydev Rajpal talked of how companies across sectors were confronted with the largest health and economic crisis in recent history. Extraordinary measures were taken to protect people and maintain operations at the same time, despite shortages of workers, and/or raw materials.

"We have faced serious challenges across the supply chain, and responses have been varied," Rajpal said, as he invited panel members to share what surprised them most, and how they addressed the many demands placed on them.

In some senses, the pharma industry was readying for disruptions, especially in accessing APIs, because of the trade tensions between the USA and China. "It was the suddenness with which it happened that surprised most firms, in spite of being prepared," said Prasad Deshpande of Biocon.

Uncertainty is the bane of any supply chain manager, and it was no different this time. From the laboratory, through the shop floor to the distribution networks, the uncertainty was very unsettling. But people stood up to the challenge, said Swapn Malpani of Cipla.

For others it was a 'black swan' event, a term made famous by Nassim Taleb about the global financial crisis of 2009. Some firms, instead of trying to re-engineer business processes, fell back on business continuity plans that were put in place as part of earlier scenario planning exercises.

Since both the supply and demand sides were disrupted, they linked the two chains, looked for local vendors when global suppliers from another part of the world failed to meet their needs, innovated and completed the regulatory validations that are required for making life-saving medicines rapidly, and continued to meet commitments. "We are the pharmacy of the world after all," said Vickram Srivastava of Sun Pharma.

Panellists agreed that that many were unprepared for the scale of the disruption. Moving material became problematic, cross-country supplies stopped, shortages in inputs were sharp. Transportation was a challenge. Uncertainty reigned. But they reorganised quickly, looked at realistic lead times, worked on inventory management, reassessed demand

"We moved to concurrent planning, adapting rapidly," said Saurabh Gupta of Lupin. "I think it was a surprise, but we learned quickly too. Now, we expect uncertainty and account for it. We've gotten a good lesson from this experience, not one we are likely to forget soon."

Three or four things have come to the forefront as a consequence of the pandemic's effects. On the materials procurement side, where cost was a driver, the weight assigned to greater sustainability and reliability has been factored in. Even on the drug development side, processes have been speeded up.

From a three-month rolling plan basis, companies have shifted to weekly planning reviews. E-pharmacies are being looked into seriously as part of the distribution chain. "Government support has been invaluable in all this," said Anand Garg of Dr Reddy's Laboratories. "Whether it's registering an API or a new vendor, approvals are quick and smooth."

Some context on digitisation is in order here. Since 2017, McKinsey has been tracking progress of Industry 4.0, the annual survey of global manufacturing companies. The survey found that 94 per cent of respondents said Industry 4.0 helped them keep their operations running during the crisis, something that you are also reflecting on. And 56 per cent said technologies had been critical in their response.

Not surprisingly, two-thirds also said that they were more optimistic about prospects of digital technologies, compared to a year ago. The pandemic has improved acceptance of digital technologies. One other interesting takeaway was that the pandemic also forced companies to re-evaluate the progress of their own organisations' digital maturity.

The number of people who said that they had scaled up digital technologies was actually down by 40 per cent.

"So how are Indian pharma companies thinking about digital analytics and automation?" Rajpal wanted to know. "What challenges do organizations foresee as leading these discussions?"

Participants agreed that they had to invest in digitisation and invest early. Some had actually started four or five years ago, but other things like blockchain technologies captured their attention. They did, however, invest in AI-related analytics to better predict demand. Today's pharma organisations are complex, so managing complexity of processes is helped vastly by digitisation, so that investment will continue, if cautiously. "But it should however, be need-based, and not just because it's the latest buzzword," said Cipla's Malpani.

Some companies are now looking at the entire enterprise as a whole. They are no longer thinking about investing in a better ERP, or MES, or Quality Assurance, though they are critical parts of the system. Instead, they are looking across the company and at systems integration; they are looking at IoT solutions for maintenance, systems to track shipments and consignments that will use a system of alerts.

"When it seemed like we were over the pandemic in February, and doctors began to see people in person again, the momentum seemed to slow a little," said DRL's Garg. "Then came the second wave and we were back to having only 50 per cent of staff at the facilities. My one word of advice: don't lose momentum."

Participants in this panel, like those in others, agree that the supply chain generates an incredible amount of data that can be mined for a number of purposes. The data comes from multiple sources, and needs to handled and managed. Panel members concurred that the sense of purpose and urgency on this front cannot be lost.

"First of all, this is not a plug and play system, so we examine requirements carefully," said Lupin's Gupta. "You have look at strategic intent and stakeholder buy-in. Then you execute. You generate actionable insights that you can use effectively. This involves change management, and communicating so that it impacts frontline performance is key."

So, what's next for digital technologies? Their application is the laboratory – in the development and discovery business is not talked about very much, but it's a conversation we must have in greater depth, Biocon's Deshpande said with emphasis.

"Two decades ago, we lost the API market to China, when we chose to go for generics and formulations," he said. "Today we are talking about biosimilars and biotechnology. That's a whole different, new area where technology plays a big role. It is greater value. So yes, we need to stay on top of this."

Panel members agreed that rebuilding our API capability would take 7 to 10 years. The government will play a role here, to create the policy framework and incentives. It will be a long, drawn-out process, but members believe it's essential, because it is intimately tied to retaining our position as the world's pharmacy.

"Without technology, we cannot build an R&D ecosystem that will help the industry live up to the promise of the 4Ds: discover, design, develop and deliver," said Srivastava of Sun Pharma.

Indian pharma needs to innovate, make complex drugs, to invent new molecules. None of this will be possible if we don't use digital technologies throughout the ecosystem.

That's what the country needs: a new, technology-driven pharma industry.

Key Takeaways:

- The supply chain is critically dependent on digital technology
- Deploying digital technology in the supply chain is essential to our national health
- It is important for keeping the industry agile and adaptable
- The use of digital technology in the supply chain delivers benefits beyond the firm
- Government support to incentivise its use is key

AFTERWORD

Archana Jatkar,
Associate Secretary General IPA

It was enthralling to sit and listen to the various speakers and panel discussions at this year's ET-IPA Smart Pharma Summit. The ideas, the depth of expertise and the knowledge of the speakers and presenters has been educational, informative and completely absorbing.

I'd like to extend my warmest thanks to all the speakers and presenters who made the time from their very busy schedules to participate in this summit and give us the benefit of their knowledge and experience.

For me there have been four takeaways from this summit.

First, it was a great mix of depth and breadth. The individual presentations, case studies and keynote addresses delved deep into the topics chosen and teased out the intricacies and the important details that bettered our understanding of the topics. The panel discussions gave us the perspective of leaders who see these issues in unique ways. Their interactions explored nuance and finesse in important ways, while providing a wide-angle view.

Second, I realise this is just the beginning of a conversation on a topic that is critical to the industry's development and fortunes. There are more questions that will keep those who were listening engaged on these topics for some time to come. Each of the topics deserved at least twice the time allotted, which augurs well. It opens room for more conversations.

Third, this has to be an ongoing conversation. In fact, there have to be several ongoing conversations, for each of the topics. There is a wealth of information and detail waiting to be discovered and explored. I hope we can organise some of them in the coming months for the people with particular interests in them.

Fourth, patient centricity is going to be central to all public discourse in healthcare and pharma. As the various sessions that dealt with it or touched upon it showed, it has several layers, each of which deserves greater attention than we could give it in this event.

I believe these are conversations that can include more stakeholders: physicians, patient advocacy groups and policymakers. Their perspectives can inform and enlighten, while they would themselves gain from such engagement.

For those who like science fiction this reminded me of the serial Star Trek, the fictional voyage of a spaceship into the universe. I find its mission exciting. Allow me to quote Captain James T Kirk of the Starship Enterprise: "To explore strange new worlds. To seek out new life and new civilizations. To boldly go where no man has gone before!"

I'd like to think of this as the start of such a journey.

Once again, my heartfelt thanks to The Economic Times for Hosting the ET-IPA Smart Pharma Summit, to all the speakers, presenters and panel discussants, the moderators and last but not least, all of you in the audience who signed in to watch this virtual summit. It's my fervent hope that next year, I'll get to greet all of you in person.

Until then, stay safe and keep well!

ANNEXURE: SPEAKERS AND PANELLISTS

S S Vasan has been conducting research and preclinical evaluation of vaccines against viruses that require high levels of physical containment. He has been Head of Public Health at Oxitec, a part of Oxford University that was spun off as a separate biotech company, and is Honorary Professor of Health Sciences at the University of York in the UK. Currently, he is leading a project on the preclinical development of Mynvax, a protein-based vaccine at the Indian Institute of Science at Bangalore, and on antibody therapies.

Phanikar Bhaskara Krishna is a product manager at Caliber Technologies, with nearly two decades of experience at almost every level of the quality assurance process, including product management and development.

Rehan Khan is Managing Director at MSD Pharmaceuticals India Region. He has been MD and Executive Director of Abbott India Ltd, and spent over a decade working in Europe and the US with Novartis, Accenture and with Venture Media LLP. He has also been an entrepreneur and founder of First Penguin Capital, a Dubai- and Singapore-based early stage fund that invests in health and consumer tech start-ups.

Jitendra Mishra is VP and Group Chief Information Officer (CIO), Alembic Pharmaceuticals. He has twenty-five years at the national and international levels, in multicultural settings as an expert in different areas of information technology (IT), from IT infrastructure to cloud computing and emerging technologies. Before Alembic, he spent 12 years at GSK.

Anjani Kumar is CIO, Strides Pharma. An engineer, his experience traverses three continents – Africa, the Middle East, North America and India. He has worked at IMB for 14 years, and at Nissan Motors as regional CIO. He is a prolific writer and sought-after speaker on digital innovation across industries.

Sekhar Surabhi is the founder, President and CEO, Caliber Technologies, which he founded in 2001. His experience in quality assurance and developing integrated quality management solutions spans more than 3 decades.

AVPS Chakravarthi is CEO and managing director at Ecobliss India, a leading pharmaceutical packaging company with core expertise in packaging innovation. He is Global Ambassador for the World Packaging Organisation.

Sreeji Gopinathan is Global CIO, Lupin. He has headed information systems at Reckitt Benckiser, been a senior director at Philips and also worked at Proctor & Gamble, and the Indian Space Research Organisation. He had worked in multicultural environments in the Netherlands, the UK and India

Shirish Belapure is Senior Technical Adviser, IPA. He has been managing director at Zydus Hospira Oncology Private Limited, a joint venture between Zydus Cadila and Pfizer. He has also served as President – Global manufacturing – at Zydus Cadila.

Vishal Dhupar is MD – South Asia at NVIDIA. He has over 30 years of experience in the ICT industry. He has taken companies to leadership positions in diverse businesses: engineering design, security, networking and data storage. Vishal has worked at DCM, Digital Equipment, SGI, Autodesk, Sun Microsystems, Symantec and now Nvidia in India.

Sudarshan Jain is Secretary General, Indian Pharmaceutical Alliance (IPA). His experience covers four decades across the breadth of the pharmaceutical industry in India. He was most recently managing director at Abbott Healthcare Solutions; he has been at the senior-most levels in Johnson & Johnson and other leading Indian pharma companies.

Sanjiv Navangul is Managing Director and CEO, Bharat Serums. He has spent most of the last 30 years heading some of the most well-known names in pharma: managing director of MSD Pharmaceuticals in the Philippines, managing director, Janssen (the pharmaceutical arm of Johnson & Johnson). He has served on the board of Johnson & Johnson.

Rajaram Narayanan is Managing Director, Sanofi India, which he joined in 2014 as Country Head and General Manager. Over the last 4 years, he has led the strategic reorientation of the company in accelerating growth in key therapies, setting up new business models and transforming market operations. He has worked at Unilever for 18 years, and before joining Sanofi he was CMO at Airtel.

Rahul Guha is Managing Director and Partner, BCG and leads the consulting firm's healthcare practice in India. Before joining BCG, he was the co-founder of Nautilus Software Solutions and chief technology officer at valuepay.com, leading product development.

Vivek Srivastava is Regional Sales Director for India at Crowdstrike, a cybersecurity company that provides endpoint security, threat intelligence and cyberattack response services.

Dr Anand Subramony is Vice President of Novel Technologies at AstraZeneca and has spent almost two decades working on similar novel technologies at companies like Johnson & Johnson, Novartis and Dr Reddy's Laboratories.

Satish Reddy is chairman, Dr Reddy's Laboratories (DRL), a company that he has been part of for nearly 30 years He oversaw its transition from a manufacturer of APIs to a vertically integrated generics player and DRL's global expansion into Russia China and other emerging markets.

Dr Murtaza Khorakiwala is Managing Director Wockhardt. He has a medical degree and is a businessman. His experience is both rich and diverse; he practiced medicine, founded an IT start-up, and ran the UK arm of Wockhardt before returning home to first become executive director, and then managing director, of Wockhardt India.

Simpson Emmanuel is Managing Director and CEO, Roche Pharma India. He has spent the last 20 years of his career in the pharmaceutical industry. He joined Roche India in 2014 and has led different functions in the company, from sales and marketing, to strategic planning, market access and patient support programmes.

Vani Manja is Managing Director, Boehringer Ingelheim India (BI). She joined the company in 2011 in the US, and before taking charge of the South Asia operations of BI, she was head of the Go-To- Market division at the company's headquarters in Germany. She has worked in leadership positions across strategy, operations, marketing and sales. Before coming to BI, she has worked at Becton Dickinson and McKinsey & Co.

Vikas Bhadoria is Senior Partner McKinsey & Co. Since joining the firm in 2000 he has worked across the world in the pharmaceuticals and medical products practice including in China, Japan, Brazil, Russia, North America, Germany and South East Asia.

Dr Chirag Trivedi is Clinical Study Unit Cluster Head – India and Southeast Asia at Sanofi. He has worked in clinical trials at Sanofi for almost 16 years, specialising in them for his entire career. He has served as President of the Indian Clinical Research Society for five years.

Manikandan Subramanian is Associate Partner at EY LLP. He has worked on automation, AI and machine learning for several years. His expertise covers the gamut of ongoing AI work in the pharma industry, and the value it can add to companies who are initiating or exploring the scope for digitisation.

Venkanna Manne is founder and CEO of Amplelogic. He has close to 25 years of experience in developing software solutions to manufacturing challenges and digitisation.

Prasad Deshpande is Global Head – Supply Chain, Biocon. His work experience of 26 years in supply chain management and procurement had been gathered in a number of countries including the USA, Belgium, Singapore and India. At Biocon, he oversees central engineering and manages environment, health and safety projects.

Swapn Malpani is Joint Global Supply Chain Head, Cipla. Before joining Cipla in 2016, Swapn has worked in GSK, Johnson & Johnson and Dr Reddy's Laboratories (DRL). His experience covers a diverse set of industries, from pharmaceuticals, medical devices, consumer products and food.

Vickram Srivastava is Head of Planning – Global Supply Chain, Sun Pharmaceuticals. He has over 15 years of experience working in the logistics, heavy engineering and life science industries across Southeast Asia, the Middle East and India. He is considered a thought leader in his field.

Saurabh Gupta is Senior VP and Head – Supply Chain, Lupin, leading global supply chain operations to ensure optimal resource utilization. His responsibilities include operational excellence, project management, production planning and control, and vendor management.

Anand Garg is VP and Head – India Supply Chain, Dr Reddy's Laboratories. For the last 8 years, he has been responsible for end-to-end demand and supply planning from In-house plants, third-party and loan licensing partners. He has also worked with EY, Accenture, PwC and Capgemini.

Jaydev Rajpal is Partner, McKinsey & Co. A 20-year veteran in the pharmaceutical industry, he leads McKinsey's pharmaceutical and medical products practice in Asia in various functional areas including strategy, performance, compliance, quality and operations.

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