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THE AWARE CONSUMER

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IN PHARMA
LIFE SCIENCES

OUT OF THE BOX
3D Printing of Pharma Products

IN FOCUS
Being Responsive To Change: Technological Advancement And Universal Health Care

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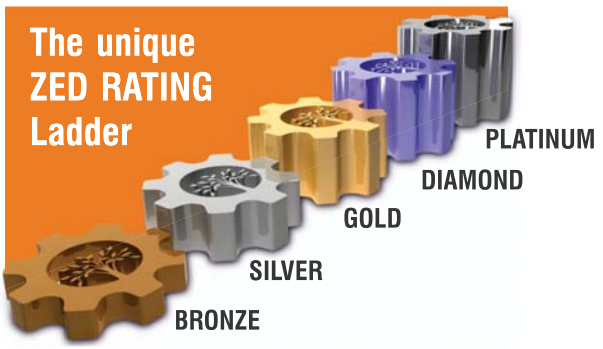
MAKE IN INDIA

QCI
Quality Council of India

ZED™
ZERO DEFECT • ZERO EFFECT

Certification Scheme

A roadmap to World-class manufacturing



HIGHLIGHTS

- A scheme by Ministry of MSME, Govt. of India
- Certification on the systems and processes of MSMEs
- Handholding MSMEs towards world class manufacturing
- Special emphasis on MSMEs supplying to Defence Sector
- Direct subsidy to participating MSMEs
- Creating a credible database of MSMEs for OEMS/CPSUs/Foreign Investors under "Make in India initiative"
- Quality Council of India (QCI) to function as the NMIU (National Monitoring and Implementing Unit) of the scheme

"Let's think about making our product which has 'Zero Defect'; so that it does not come back (get rejected) from the world market and 'Zero Effect' so that the manufacturing does not have an adverse effect on our environment"

SHRI NARENDRA MODI
Hon'ble Prime Minister

Free Registration at www.zed.org.in

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VIEW  POINT

BEJON KUMAR MISRA | bejonmisra@consumerconexion.org

Life Sciences: Commitment To Digital Transformation

AS IS TRUE for most industries, digital transformation is no longer a buzzword, but a strategic imperative for life sciences companies. While first movers would likely gain a competitive advantage, all of today's companies risk falling behind their competitors in delivering across all elements of the value chain if their strategies are limited to a few pilots and experiments. Life sciences companies have been fast followers in adopting new technologies, but waiting too long to commit could leave some companies with portions of their value chains disrupted in an ever more price-conscious segment.

Although many life sciences companies have been exploring the opportunities that digital technologies can offer, ranging from engaging with consumers through apps to using artificial intelligence to help improve operations, a recent survey by Deloitte with MIT Sloan Management Review finds that only 20 percent of biopharma companies are digitally maturing. The survey also shows that across industries digitally maturing companies are building new business models by successfully scaling lessons learned from early experiments, changing at all levels of the organization, and enhancing external collaboration.

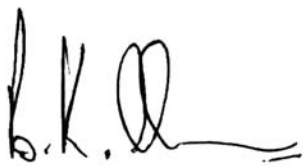
Pharma companies are thinking about how to organize their digital activities, and some are hiring chief digital officers (CDOs), often with experience in other industries, to lead transformation efforts. That said, we anticipate that the transformation may pose some challenges as well, especially in overcoming cultural barriers.

Technology is increasingly a strategic topic forpharma leaders, as digital and data analytics are exploited for competitive advantage. Many new opportunities exist—from screening potential research targets and using big data analytics in clinical trials, to leveraging digital to create more efficient processes and disruptive products and services that fully engage and provide value to key stakeholders.

Exploiting technology is a complex challenge. Pharma leaders are taking a more strategic approach to technology in several important areas: digital, big data and advanced analytics, simplified technology, capability building, and technology-enabled transformation.

The digital revolution is also an increasingly important topic in R&D and operations—from enabling new models of collaboration in research and efficiency in operations to creating disruptive “beyond the pill” solutions that allow patients and consumers to better manage their medical conditions.

An increase in R&D spend, patent publications and collaboration of Indian corporations with academia and global MNCs through a considerable number of deals, indicates that the Indian Pharmaceutical Industry is on the right path to enhance innovation and strategic growth across the globe.



Pharma leaders are taking a more strategic approach to technology in several important areas: digital, big data and advanced analytics, simplified technology, capability building, and technology-enabled transformation.

DESKTALK

Message from the Editor-in-Chief

POOJA KHAITAN
pooja@jagograhakjago.com

The Crucial Enabler Of Success

WE LIVE IN an age in which technology is moving at a rapid pace, creating new fields and disrupting existing models and processes, and Pharmaceutical industry is no stranger to this. Increasing use of innovative solutions and automation will drive the future of this industry and help to accelerate discovery, enhance productivity and enable regulatory compliance.

The Indian Pharma industry has grown manifold since independence and today is ranked among the major global players. This has been a result of several factors which together have provided the right environment for India's growth. However, given the fast pace of change, appropriate course corrections and suitable policy interventions are necessary for sustenance of future growth.

Some of the challenges besieging the process have been identified as lack of skilled manpower, inadequate finances, low technological base and limited access to new technologies. However, there is potential of nurturing an innovative ecosystem in India in order to transform India into a producer of innovative pharmaceutical products.

The pharmaceutical industry is under continuous pressure to discover and develop new drugs targeted toward increasingly complex diseases, which means the industry must use innovative technologies that will help them ramp up research and development, manufacturing and analytical capabilities while enabling them to be competitive and compliant. Today, there is much more time and cost pressure on the research and development of innovative medicines, particularly with regard to preclinical and early clinical research.

Many pharma companies are caught in a bind – they want to implement new manufacturing technologies, but they don't want to face the subsequent regulatory delays.

The winners in the digital arena will be companies that take an agile approach to strategy, digitize the core business, create disruptive products and services, capture value from data, and build capabilities and a differentiated ecosystem. Thus, technology is a crucial enabler of success in the commercial, operational, and scientific sides of the business.

INSIDE

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Beyond the Pill

Innovation Within Pharma

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UNLOCKING CONSUMER POTENTIAL
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Bejon Kumar Misra
PUBLISHER
Address: F - 9, Second Floor, Kailash Colony,
New Delhi - 110048
E-mail: bejonmisra@consumerconexion.org

EDITOR-IN-CHIEF
Pooja Khaitan

EDITORIAL CONSULTANTS
Praful D. Sheth
Bina Jain
Suman Misra
Manisha Bhatla
Pyush Misra
Shashank D. Sudhi
Shashi Bhushan

MANAGER CIRCULATION
Nirmal Dayal

DESIGNER: Galaxy
DESIGN CONSULTANT: Maanav Khaitan

WEB DESIGNER:
Manish Mohan
Ebrahim Bhanpurawala

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For any queries, please contact us at
pooja@jagograhakjago.com
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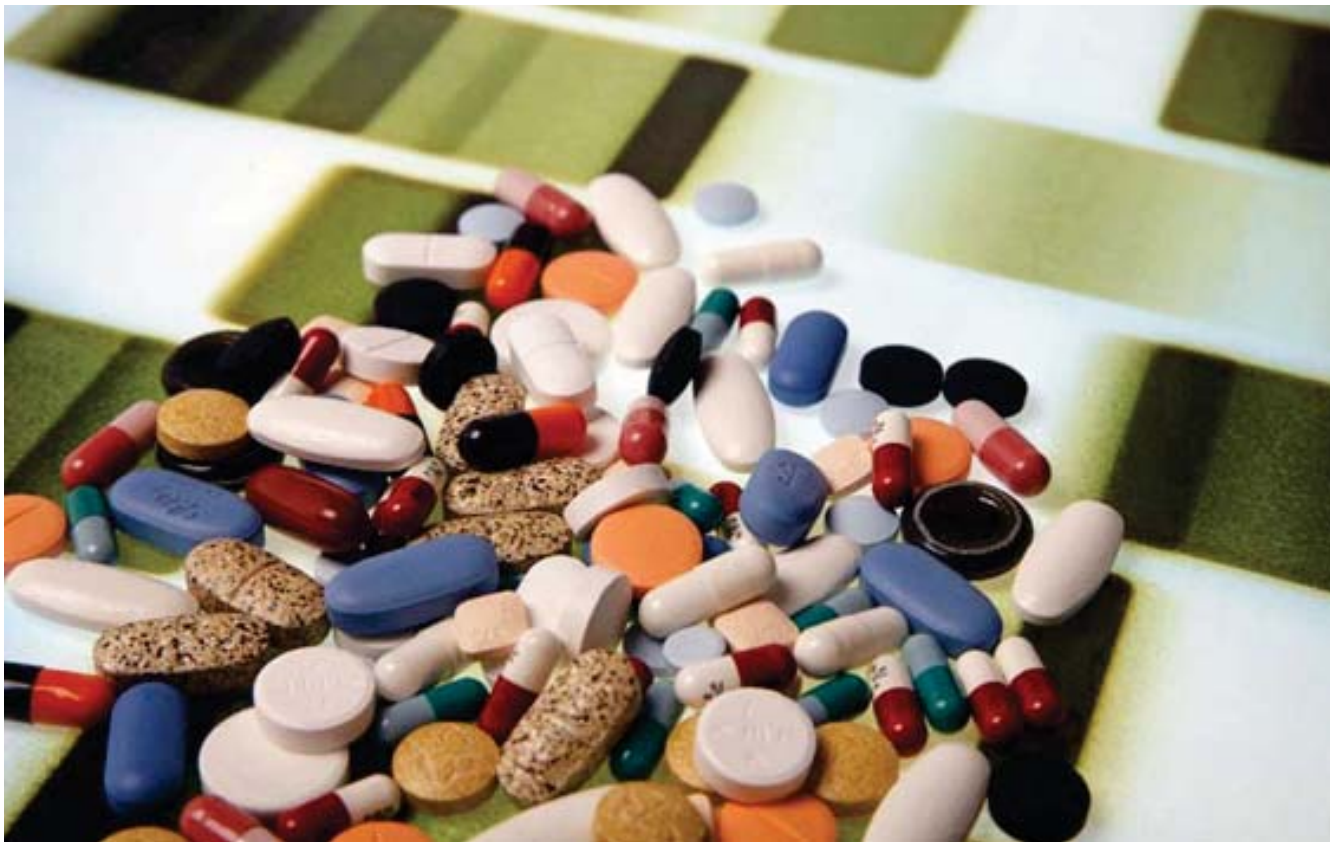
Dr. S.D. GUPTA
CHAIRMAN OF IIHMR UNIVERSITY, JAIPUR

"Despite capping of prices, demonetisation and GST implementation – all of which are perceived to impact the pharma sector adversely, this industry will continue to grow and the major growth engines will be domestic sales, exports, an ageing population, medical tourism etc."

ROUNDUP



INDIA TO BE AMONG TOP 5 PHARMA INNOVATION HUBS BY 2020

There are many attractive features that the existing Indian ecosystem can offer the life sciences industry, including development of new medicines

DATA BRIEFING

The Indian pharmaceutical industry is the eighth largest pharma market in value terms globally and is expected to touch

$55 billion.

THE CENTRAL GOVERNMENT is preparing for a multi-billion dollar investment in the pharma sector with 50 per cent public funding through its public private partnership (PPP) model to enhance innovation capability. According to the ASSOCHAM, the idea is to push India into top five pharmaceutical innovation hubs by 2020 and establish global presence by launching one out of every 5-10 drugs discovered in India at global level.

The Department of Industrial Policy and Promotion (DIPP) data suggests that the drugs and pharmaceuticals sector in India has attracted FDI worth USD 1,523 million during April 2014-March 2015. The Indian government has been very active in boosting growth and investment in pharmaceutical industry. It allows 100 per cent FDI (Foreign Direct Investment) under automatic route (without prior permission) in the pharmaceuticals sector. FDI favourably impacts the Indian pharma industry by providing access to more capital/funds for investing in R&D, which in turn, leads to creation of more IPR, highlighted the study titled 'IPR in pharmaceuticals: Balancing, innovation and access' jointly conducted by ASSOCHAM and TechSci Research.

The government has been actively undertaking policy initiatives for growth of the pharmaceutical industry. One such initiative is tax-breaks in the pharmaceutical sector. There is also a weighted tax deduction at a rate of 150 per cent for the research and development expenditure incurred.

Steps to streamline methods for development of a new drug molecule or clinical research have also been considered. The government has launched two schemes—New Millennium Indian Technology Leadership Initiative in 2003 and the Drugs and Pharmaceuticals Research Programme in 1994-95—which are specially targeted at pharmaceutical research, adds the study.

Additionally, industrial licenses are not essential in India for most of the pharmaceutical products. Hence, drug manufacturers are free to develop any drug upon approval by the Drug Control Authority. The act of protecting one's innovation through a patent has initiated investments from

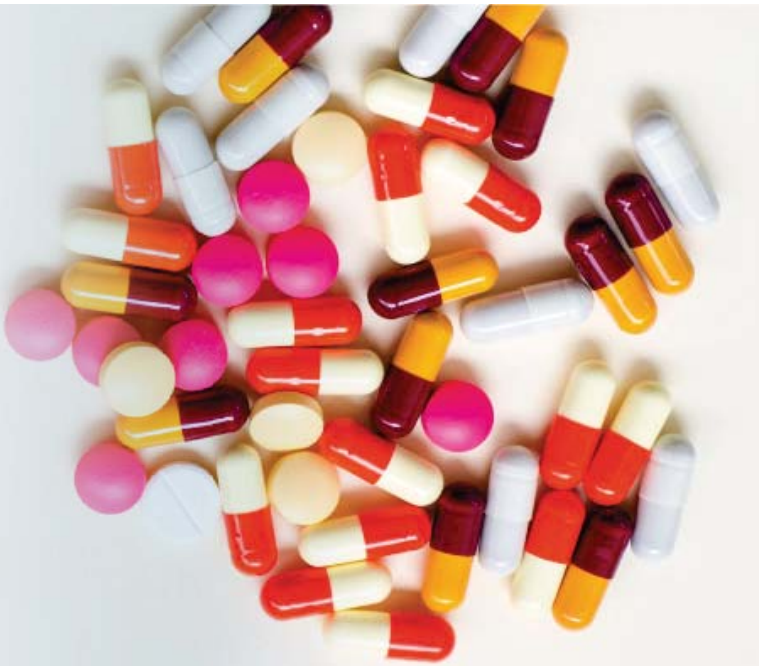
Introduction of NANOTECHNOLOGY

NANOTECHNOLOGY IS SIMPLY defined as the technology to manipulate the matter on the atomic and/or molecular scale. It is generalized to materials, devices and structures with dimensions sizes at the nanoscale of 1 to 1000 nanometers (nm).

Nanotachnology can be applied to many fields including sensors, biomaterials for tissue engineering, and nanostructures or 3D materials for molecular imaging and drug delivery among others. In medicine, nanotechnology is essentially a multidisciplinary field of physics, organic and polymer chemistry as well as molecular biology, pharmacology and engineering. These fields team up together to design a better and most opt treatment option for a disease using “the right drug, the right vehicle and the right route of administration”. In pharmaceutical industries, a new molecular entity (NME) that demonstrates potent biological activity but poor water solubility, or a very short circulating half-life, will likely face significant development challenges or be deemed undevelopable. There is always a degree of compromise, and such tradeoffs may inevitably result in the production of less-ideal drugs. However, with the emerging trends and recent advances in nanotechnology, it has become increasingly possible to address some of the shortcomings associated with potential NMEs. By using nanoscale delivery vehicles, the pharmacological properties (e.g., solubility and circulating half-life) of such NMEs can be drastically improved, essentially leading to the discovery of optimally safe and effective drug candidates.This is just one example which demonstrates the degree to which nanotechnology may revolutionize the rules and possibilities of drug discovery and change the landscape of pharmaceutical industries.

Even today various disease like diabetes, cancer, Parkinson's disease, Alzheimer's disease, cardiovascular diseases and multiple sclerosis as well as different kinds of serious inflammatory or infectious diseases (e.g. HIV) constitute a high number of serious and complex illnesses which are posing a major problem for the mankind. Nanomedicine is an application of nanotechnology which works in the field of health and medicine. Nano-medicine makes use of nano materials, and nano electronic biosensors. In the future, nano medicine will benefit molecular nanotechnology. The medical area of nano science application has many projected benefits

many multinational pharmaceutical companies in India. These MNCs are looking at India for its strength in contract manufacturing and as an attractive base for research and development (R&D), particularly for conducting clinical trials and other services.



The Government of India and the pharma industry have both shown growing focus to boost innovation.

Indian and foreign pharmaceutical companies are progressing with rising patented drug launches in India. The Indian Patent Office granted 2008 patents between 2010 and 2013. The Department of Pharmaceuticals has drafted Pharma Vision 2020 document, with an aim to establish India as a leading county for end-to-end drug manufacturing and innovation. This initiative by the government aims at providing support to Indian pharmaceutical sector through state-of-the-art infrastructure, internationally competitive scientific research personnel for pharmaceutical R&D and funding for research in the public and private sectors.

and is potentially valuable for all human races.

With the help of nano medicine early detection and prevention, improved diagnosis, proper treatment and follow-up of diseases is possible. Certain nano scale particles are used as tags and labels, biological can be performed quickly, the testing has become more sensitive and more flexible. Gene sequencing has become more efficient

with the invention of nano devices like gold nano particles, these gold particles when tagged with short segments of DNA can be used for detection of genetic sequence in a sample.

With the help of nanotechnology, damaged tissue can be reproduced or repaired. These so called artificially stimulated cells are used in tissue engineering, which might revolutionize the transplantation of organs or artificial implants.

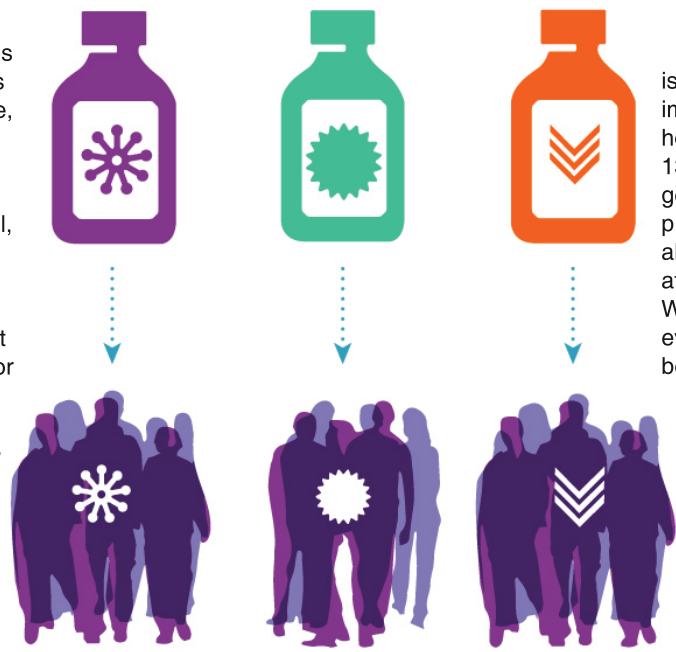
Nano medicine is a relatively new field of science and technology. By interacting with biological molecules at nano scale, nanotechnology broadens the field of research and application. Interactions of nano devices with bio molecules can be understood both in the extracellular medium and inside the human cells. Operation at nano scale allows exploitation of physical properties different from those observed at micro scale such as the volume/surface ratio.

Two forms of nano medicine that have already been tested in mice and are awaiting human trials; use of gold nano shells to help diagnose and cure cancer, and the use of liposome as vaccine adjuvants and as vehicles for drug transport. Similarly, drug detoxification is also another application for nano medicine which has been used successfully in rats. Medical technologies can make use of smaller devices are less invasive and can possibly be implanted inside the body, and their biochemical reaction times are much shorter. As compared to typical drug delivery nano devices are faster and more sensitive.

Nano materials have increased surface area and nano scale effects, hence used as a promising tool for the advancement of drug and gene delivery, biomedical imaging and diagnostic biosensors. Nano materials have unique physicochemical and biological properties as compared to their larger counterparts. The properties of nano materials can greatly influence their interactions with bio molecules and cells, due to their peculiar size, shape, chemical composition, surface structure, charge, solubility and agglomeration. For example, nano particles can be used to produce exceptional images of tumor sites; singlewalled carbon nanotubes, have been used as high-efficiency delivery transporters for biomolecules into cells. There is a very bright future to nano technology, by its merging with other technologies and the subsequent emergence of complex and innovative hybrid technologies. Biology-based technologies are intertwined with nanotechnology is already used to manipulate genetic material, and nano materials are already being built using biological components. The ability of nanotechnology to engineer matter at the smallest scale is revolutionizing areas such as information technology, cognitive science and biotechnology and is leading to new and interlinking these and other fields. By further research in nanotechnology, it can be useful for every aspect of human life. Medicine, regenerative medicine, stem cell research and nutraceuticals are among the leading sectors that will be modified by nanotechnology innovations.

UNDERSTANDING PRECISION MEDICINE

In precision medicine, patients with tumors that share the same genetic change receive the drug that targets that change, no matter the type of cancer.



PRECISION MEDICINE (PM) is a medical model that proposes the customization of healthcare, with medical decisions, treatments, practices, or products being tailored to the individual patient. In this model, diagnostic testing is often employed for selecting appropriate and optimal therapies based on the context of a patient's genetic content or other molecular or cellular analysis. Tools employed in precision medicine can include molecular diagnostics, imagingand analytics.

Over the last few years, precision medicine has gained more traction on a national and international scale. In 2015, President Obama announced a Precision Medicine Initiative to work on improving the field of medicine—first with cancer research, then expanding in a few years. The initiative defines precision medicine as “an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person.” It's often referred to using the phrase “N of 1” because of how individualized it is.

Precision medicine involves personalizing the field of medicine to improve it. This covers everything from individualized EHRs to treatments to medical devices and more. Genetic analysis helps find targeted treatments and medications that will work better for patients than those used through step therapy.

By having more targeted treatments, patients will have to try fewer inefficient and harmful medications. This field is called pharmacogenomics and is an important part of the PM movement. In cancer research, for example, the aim is to increase survival rates, target malignancies more accurately, and reduce medication issues. Using precision medicine to find the best medication can help extend lives.

Although the promise of PM is enticing, and broad implementation of multiplex hotspot testing is feasible, only 13-40% of patients enrolled into genotype-matched trials have presented with actionable alterations, which risks attenuation of treatment effects. With this in mind, the current evidence suggests that clinical benefits of biomarker-based treatment strategies may be limited. For example, a 2016 systematic review of 346 studies that compared phase 1 cancer drug trials with biomarker-based treatment strategies to trials without this approach concluded that a personalized approach resulted in a median progression-free survival of 5.7 months (95% CI 2.6–13.8) versus 2.95 months (95% CI 2.3–3.7). This review, however, did not assess risk of bias of individuals trials, or the overall quality of evidence for the outcomes they reported on, and was unable to assess effects on overall survival because of insufficient data.

There are policy challenges to the widespread uptake of PM, such as the regulation of genetic tests in such a way that encourages innovation but also protects patient confidentiality. Health and drug regulatory authorities need to establish clear guidelines for the identification and approval of personalized drugs and their related diagnostic tests for clinical use. Furthermore, the costs of developing and marketing new molecular targeted drugs are high, and may divert resources from the development of more clinically effective drugs. If health and regulatory authorities are to fund PM research, there should be independent assessors who regularly appraise the cost-benefit ratio of targeted drugs. Until there are more studies demonstrating clinical effectiveness of molecular targeted drugs, it may be difficult to justify their high costs.

Consumers, Beware

OVER THE PAST year, hacks on healthcare organizations have made for some significant headlines. But this recent surge of cybercrime is unsurprising. Advanced security services and protocols have difficulty making headway in industries like life sciences and healthcare where web-based systems and internal networks are late in coming. The rate of security adoption in these organizations lags in comparison to industries such as retail and finance.

The Unisys Security Index, which gauges the attitudes of consumers on a wide range of security-related issues, found that security concerns regarding identity theft and bankcard fraud top the list among consumers worldwide — even outpacing national security issues such as war and terrorism.

Fears about identity theft and card fraud affect all members of the life sciences and healthcare ecosystem, from pharmaceutical firms to medical device companies to hospital systems. Each of these players has access to tremendous amounts of personal health information. As such from a member and patient perspective, robust security is not an option, it is a necessity.

The average pharmaceutical or biotechnology company tends to have very strong internal security relating to their R&D intellectual property. However, this information is often shared with external agencies such as contract research organizations (CROs). In many cases, the level of security within the CRO is not on par with that of the pharmaceutical company. For that reason, pharma and biotech firms need to ensure not only the security of their own internal systems, but must also carry out due diligence with the CROs they interact with to ensure that appropriate security is maintained in all places at all times.

Medical device manufacturers have also been slow to incorporate security and privacy protocols in their devices and operating systems. As recently as three years ago, privacy and security concerns were addressed during the last stage of product development phase-gate processes. Effectively, the device was designed in full, then tossed over the wall to the regulatory department to determine what rules the device should comply with. Security provisions and protections in the hardware and software subsequently were added to meet necessary standards and laws.

If security is not engineered into a device all through the development process, then adding it on the backend can require substantial retooling. It can also result in less than optimal security in operation and effect, since it was not an intrinsic part of the design from inception. The fact remains that a substantial subset of the medical devices used today are either unprotected or have less-than-optimal security provisions in place. As hospitals connect these devices to their networks, they are often unknowingly introducing vulnerabilities into their systems.

Unsecured medical devices are the Achilles' heel for hospitals and healthcare systems. Globally, some 10 to 20 percent of medical devices in most hospitals are connected, and that number is growing rapidly. Unfortunately, as noted above, many connected devices older than two or three years have little to no device security. Even devices with protections are often not configured appropriately within the hospital network to actually insure security.

Hackers are exploiting this vulnerability ruthlessly. Ransomware is costing hospitals millions, while stolen data is damaging hospital reputations and patient trust worldwide. Nor is that the only cost to hospitals: being hacked ultimately can generate millions of dollars in fines and penalties from regulators.

Moreover, the greater acceptance of technologies such as IoT, cloud computing, artificial intelligence, and big data among pharmaceutical companies, is posing new security challenges. As a result, pharmaceutical companies are increasing their expenditure on various security products to prevent breaches, protect patient data, and secure sensitive information.

According to GlobalData's survey, 79% of pharmaceutical companies are currently making investments in identity & access management (IAM) solutions. Investments in IAM solutions among pharmaceutical companies are driven by the need to manage electronic user identities and ensure data privacy while avoiding any misuse of critical business information.

The survey further highlights that an equal proportion (75%) of pharmaceutical companies are currently deploying some form of backup & archiving and content & web filtering solutions to store as well as preserve their online information.

Although the pharmaceutical sector lags behind in implementing cyber security, the prevalence of data sharing is compelling companies to look for vendors that can provide integrated security operations and analytics to tackle anomalous behaviour. Additionally, organizations are striving to deploy IoT that can decrease human intervention and can achieve enhanced quality control, thereby offering more opportunity for IoT vendors in this sector.

The pharmaceutical sector is one of the biggest contributors to the world economy. After sluggish growth in 2016, the appreciating world economy in 2017 has had a positive impact on the growth of the pharmaceutical industry, leading to increased investments in core areas of ICT categories including hardware, software, and IT services.

SUPPORT THE CAMPAIGN

LOOK OUT FOR THE RED LINE

BE RESPONSIBLE

Medicines such as Antibiotics have a Red Vertical Line on their pack to indicate that these should be consumed only on doctor's prescription. Always complete the full course as prescribed by the doctor.

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Science And Innovation:

Pharma Digitalization

DIGITALISATION IS FUNDAMENTALLY changing the healthcare industry. The Pharma industry, as a core part of healthcare, is no exception to this. New technologies and innovations are already enabling pharma companies to improve medicine development and patient care.

At the same time, healthcare payers and other customers of pharma companies are demanding more and better data on the medication efficacy and improved patient quality of life. These demands cannot be fulfilled by purely traditional means.

Biomedicines, orphan drugs and advanced medical devices

Now that the era of conventional small molecule blockbuster medicines is about to end, the big pharma focus is shifting towards high value but lower volume products such as biomedicines, orphan drugs and advanced medical devices. The increasing price pressure caused by the tightening market price regulations and patent expirations is forcing pharma companies to challenge their current product and market strategies in order to survive.

Also, the global and heterogeneous regulation is increasing and bringing more complexity in compliance in product supply infrastructures and operations. For example, the US FDA's vision is quality manufacturing without the extensive regulatory oversight which will create completely new kinds of requirements in the product supply capabilities and systems.

One might say that Pharma business is undergoing a perfect storm: a concurrent transformation on multiple, unrelated areas changing the whole product lifecycle from early drug development to manufacturing and patient care. This transformation will not only challenge the incumbents but also create opportunities for new entrants outside of pharma business whose innovation and business clock speed are on a completely different level.

It is obvious that these market challenges and requirements can't be met with the current products,

Healthcare market challenges	• Innovations and competition outside of the pharma business • Increasing price pressure caused by the tightening market price regulations and patent expiries of major blockbuster medicines • Demand for better data on the medication efficacy and patient quality of life • New business models and ecosystems challenging the current way of business
Complex regulative requirements	• Diverse and fast changing global regulations in pharma manufacturing and sullpy chain compliances are demanding infrastructure changes beyond the current readiness and capabilities • The US FDA's a vision for the 21st century pharmaceutical quality manufacturing requires efficient, agile, flexible pharmaceutical manufacturing that reliably produces high quality drugs without extensive regulatory oversight
Increasing operational challenges	• Pharma companies are facing increasing challenges in production flexibility, competent resources, time-to-market and operational costs • Global production is highly distributed and non-standardized • Value network is very complex with a lot of partners and suppliers • Information paradox: there's a lot of it, but not accessible or usable.

Figure 1: Pharma digitalisation transformation drivers

business models and operations. Therefore the pharma business transformation is inevitable which will lead to the digitalisation of the pharma products, business models, operations and ultimately – the patient care. Enter the era of Pharma Digitalisation.

Indian Pharma industry is also experiencing a new wave of innovation and is adopting modern technologies and processes on par with the US and Europe. Technology has become a key differentiator and Digital technology stands tall as the major differentiator. This modern technology ranges from customer centric technology pertaining to the health care providers to the manufacturing and R&D focused technologies that would enhance productivity and enhance compliance. Digitalization can bring in major disruption in these two phases of research and development, especially in drug discovery. Digitalization has already made inroads into sales and marketing and has made significant positive impact on business.

Digitalization is the use of digital technologies and data to create revenue, improve business, replace/transform business processes and create an environment for digital business.

When companies are looking for exponential growth or to speed up the process of launch of new products, digital platforms become a very important ingredient of the organizations' resource portfolio. Digital platforms are sure to have a significant impact on the Pharma value chain especially in the manufacturing & Research and Development.

'Beyond the Pill' brings unprecedented opportunities

Companies have realized that it is very vital to collaborate both within and outside the company. The agility that is required in adapting to the latest trends is vital and defines the success or failure of the company. The industry is very knowledge intensive and with the amount of data and information pertaining to the processes that exists is quite astonishing.

The most profound part of the business transformation, called Beyond the Pill, is already cutting to their core businesses in clinical development and patient care. Pharma companies are facing immense challenges on improving patient outcomes at the same time with the intensifying competition and pricing pressures.

The next generation of pharma products already available vary from patient specific biomedicines to medical devices with the capability to provide patients real-time information about their condition, and collect patient data for care analytics to improve the treatment.

These new technologies not only can help companies to address several major care challenges—such as compliance and chronic disease management—but also can help them to create hundreds of billions of dollars in value.

This has already led the pharma manufacturers capitalising the Beyond the Pill business transformation. For example, pharma giants like Novartis, GSK and Novo Nordisk are already investing in partnerships and new

Figure 2: The New Pharma Reality external and internal drivers challenging the pharma industry

business models with technology companies such as Google, IBM and Qualcomm. Not to mention traditional device manufacturers like Apple, Samsung and Nokia who are already researching beyond the wellness products and looking to the patient care market.

All this will substantially improve the personal medication development and care processes where the patient and care data is the new source of innovation and competitiveness.

The new Pharma reality challenges future competitiveness

A study by NNE, a leading pharmaceutical engineering company, investigated global pharma companies' perspectives of the future successful pharma manufacturing sites. The study identified changing expectations of success moving from site stability to site agility with three key requirements:'

- Flexible production', a site's ability to accommodate changes in production demands,'
- Integrated quality', balanced and integrated quality systems; and
- Entering new domains', having the ability to quickly absorb knowledge to implement new practices.

This means that pharma companies already clearly perceive that their future competitiveness is at stake due to external and internal drivers.

In addition, the pharma manufacturing infrastructure implementations are already highly complex with an increasing number of connected equipment, and internal and external system integrations. The pharma ecosystem is highly networked with the pharma industry specific requirements eg, for the collaborative R&D data management and supply chain regulatory compliance reporting.

These fundamental pharma ecosystem, business model and technology changes are the factors leading to a new manufacturing and product supply industry transformation called the New Pharma Reality.

The Pharma digitalisation ecosystems

The New Pharma Reality and Beyond the Pill business transformations will affect the whole product life cycle, from R&D to product supply and patient care, and eventually it

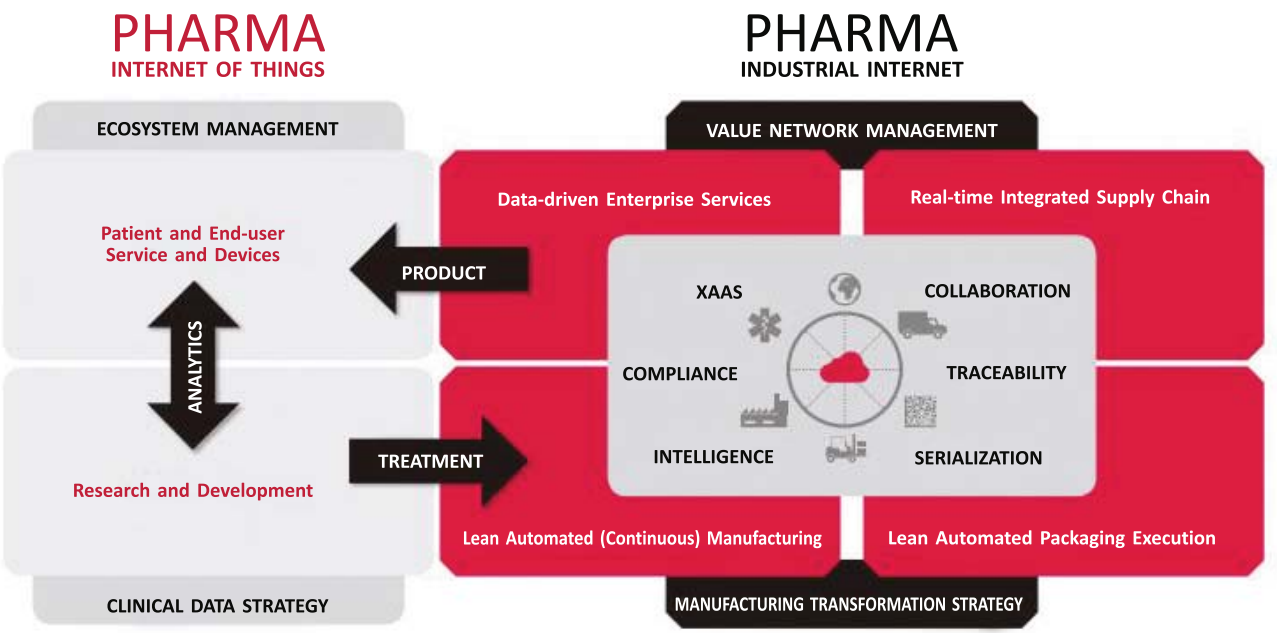


Figure 3: Pharma digitalisation ecosystems: Pharma IoT and Pharma Industrial Internet

will bring patients and their quality of life to the center of the pharma business. This industry transformation, Pharma Digitalisation, consists of two major concurrent and complementing digital ecosystems: Pharma IoT (Internet of Things) and Pharma Industrial Internet (or Industry 4.0 more generally).

The best way to conceptualise the Pharma Digitalisation is to describe it from the product lifecycle and product supply network point of view: how getting the medicines from development to patients will improve and change. This also helps with understanding the differences between Pharma IoT and Pharma Industrial Internet ecosystems.

Pharma IoT

Pharma companies have long ago realised that selling traditional medicines will not guarantee sufficient growth nor even sustain the competitiveness. This fundamental change moving Beyond the Pill typically arises from one or two realisations:

1) medicines alone are often not enough for patients to achieve optimal clinical outcomes, and
2) as the current product pipelines dry up, Beyond the Pill businesses can be valuable new sources of revenues.

This has created the interest for utilising the new technologies and business processes in development and patient care leading to Pharma Internet of Things or Pharma IoT.

Pharma IoT conceptualises the digitalisation of medical products and related care processes with smart connected medical devices and IT services (cloud, mobile, apps, etc.) in drug development, clinical trials and patient care. The outcome of the Pharma IoT in the development and clinical trials will be using the combination of advanced technologies and services for creating totally new kinds of disease treatment possibilities.

The fundamental difference between patient care Pharma IoT with other consumer IoT solutions is that

pharma solutions require regulatory compliance. This distinguishes the Pharma IoT solutions from general wellness and fitness applications where the software and hardware are basically free from the regulatory screening and hence can't be prescribed as a part of the clinical patient care.

Pharma IoT will enable the patients and healthcare professionals to use medicines with advanced sensor hardware and personalised care services and processes. It is clear that these new capabilities will facilitate new business opportunities for the pharma companies with the existing products as well as start-ups seeking for new disruptive platforms and business models.

Wearable technology

Good examples of the Pharma IoT solutions are the connected sensor wearables for Parkinson's disease and multiple sclerosis patients with the medication management improving the patient outcomes and the quality of life. In addition, the existing medical device products such as inhalers and insulin pump systems can be improved with sensor and connectivity technologies to collect data for further care analytics and personalised therapy.

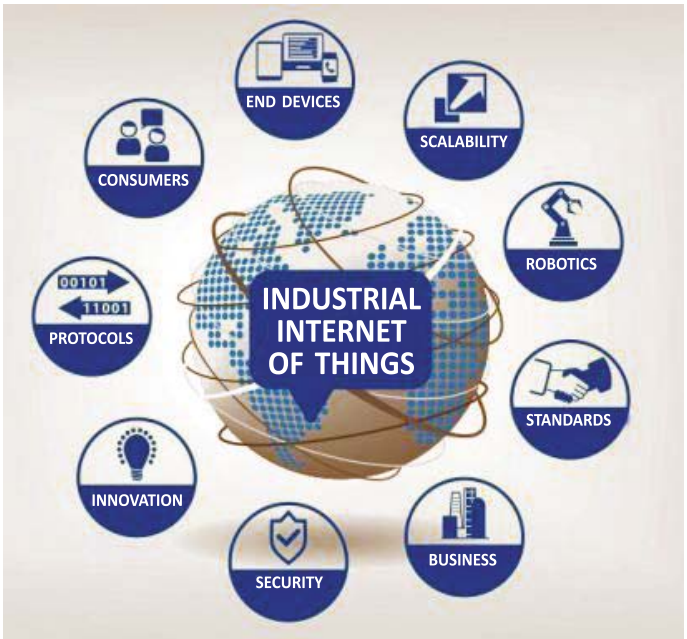
Machine learning and artificial intelligence (AI) will naturally find their way in the patient care as well. At some point of time there will be virtual clinical care service providers helping the patients to use the collected sensor data along with the artificial intelligence for improving the care outcome for example with Parkinson's or diabetes patients. Most probably there will be even 'just an app' for that. No doubt AI will also change the role and job descriptions of health care professionals in their everyday work.

At the same time, all this will enable substantially improve the personal medication and care processes where the patient care data is the new source of innovation and competitiveness for the pharma companies as the real world evidence.

And to make the transformation even more challenging, pharma companies need to take into account the forthcoming EU data protection and privacy legislation, which will give control of their care data to patients. For example, patients will be allowed to transfer their care and health data across the service providers leading to the emergence of totally new kinds of service platforms and business models.

Pharma industrial internet

Pharma Industrial Internet, like Industry 4.0, conceptualises the digitalisation transformation of the pharma product supply infrastructures from manufacturing the medicines to dispensing the medicines to patients. In other words, the industrial internet infrastructures manufacture and supply some or all medicine/sensor /device/apps/services/patient care processes capabilities



to the market whereas IoT is the ecosystem and market for utilising, analysing and monetising the use of the medical products and ultimately, patient care data.

The key infrastructures and capabilities in Pharma Industrial Internet are (Figure 3):

(1) manufacturing intelligence (continuous and automated 'lights-out' manufacturing);

(2) software controlled packaging execution (serialisation and automation/robotisation);

(3) integrated supply chain (traceability and collaboration); and

(4) enterprise back-end IT cloud based services (XaaS) utilising the data from the product supply (analytics, life-cycle management and regulatory compliance reporting).

In addition to the manufacturing and service infrastructures, Pharma Industrial Internet will enable drastic changes in business models and global manufacturing operations. With the high level of automation and real-time global ecosystem connectivity, the medicine manufacturing and packaging can become globally transparent and distributed in more controlled fashion given the regulatory constraints and requirements.

The third-party manufacturing and global product supply could be then managed centrally in real-time by the marketing authorisation holder, and yet the products can be traced and verified on a sales unit level throughout the supply network even up to the point of dispense and patient. In the longer term, this can lead to a platform economy where the ecosystem and innovation management will be the source of the competitive advantage rather than owning the manufacturing and product supply assets.

Pharma digitalisation facilitates the healthcare transformation

Ultimately, Pharma digitalisation will help the pharma business become more patient centric. Patients will gain more possibilities for better and cost-effective care outcomes.

For example, patients with diagnosed or potential heart conditions could have in the future small embedded wireless sensors to detect cerebral infarctions at an early

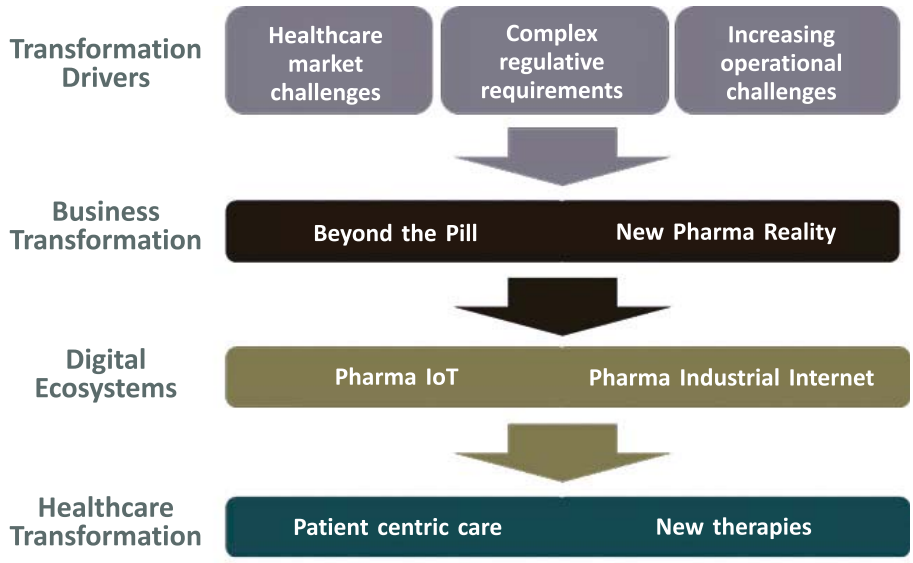


Figure 4: Pharma digitalisation facilitates the healthcare transformation

Smartphones and big data analysis, along with progress in robotics, new players in the media, IT industries have substantially changed the way we live and do business. By merging these technologies with the latest developments in medicine, including genomics, stem cells and stratified approaches, the speed of innovation can be accelerated significantly.

stage, and also overburdening and prolonged stress. The sensor data can be used for motivating patients to improve their lifestyles and habits leading to a better quality of life. This way the medication could be even avoided, and potentially the very expensive intensive care in a case of infarction. Not to mention the collateral costs and risks associated in the patient recovery process. The best and cheapest protection is indeed the disease prevention where the digitalisation will be an essential enabler for the patient centricity.

In addition, with digital solutions patients will be better informed and will be participating in their own care with the practitioners to ensure that care decisions respect patients' wants, needs and preferences. Digital collaborative services can bring transparency and facilitate patient centered activities in the care between the stakeholders while maintaining shared up-to-date data on the patient health and quality of life. This will lead to a better care results as well as patient engagement in the care process.

Pharma Digitalisation is transformation, not disruption

The Pharma industry is facing the biggest transformation since the rise of the modern medicines in the nineteenth century and the introduction of the manufacturing automation in 1980s. The transformation is already driven by the increasing global regulation, intensifying competition, demanding payer requirements and increasingly complicated product supply ecosystems.

At the same, completely new business opportunities are opening with new novel technologies and partnerships with high-tech companies. The future defining challenge will be how the inevitable very diverse and complex business requirements can be implemented with the current manufacturing, product supply networks and – most significantly – business models and products.

The good news is that no Uber or AirBnB like industry disruption is required to seize the digitalisation opportunities. Pharma companies simply need to start transforming into digital businesses to be competitive in the future.

After all, we should already know by now from the human history that it is not the strongest that survive, nor the most intelligent, but the ones most responsive to change.

India Innovation Trends:
PHARMACEUTICAL INDUSTRY

Dr. Mandakini Goel, PhD

THE PHARMACEUTICAL INDUSTRY strives for innovation as it is a major business growth driver. Innovation in this industry could lead to high monetary benefits in the form of Blockbuster drugs. For example – Obeticholic acid, a drug to treat chronic liver diseases is forecasted to generate $2.62 billion by 2020.

In the current scenario, innovation is the need of the hour in the Pharmaceutical industry, given the large and diverse patient pool, rising cost of treatments, and increasing risk factors of chronic diseases due to changing lifestyles in emerging countries like India. The Government of India (GoI) and the pharma industry have both shown growing focus to boost innovation. Multiple initiatives by the GoI to boost innovation and protect intellectual property rights and the increasing R&D spend by the corporate segment highlight this.

Success in innovation can be enhanced by increasing spend in R&D, protecting new ideas, monetizing patents, and by external collaboration. Leading pharmaceutical companies in India have increased their aggregate R&D spend. 46,000+ patents have been published in India between 2013 and 2015 with the focus on clinically and commercially viable drugs in various sub-technologies. The top 5 sub-technology categories indicating the applications of pharmaceuticals in India are covered in Figure 1.

Generic corporations such as Cipla, Dr. Reddy's Laboratories, and Cadila Pharmaceuticals feature in the top applicants list. It is worth noting that various Multinational Corporations such as Novartis, Sanofi, Roche, and Bristol-Myers Squibb have also filed patents in India. Top Indian patent filers such as Cadila Healthcare, Dr. Reddy's, Cipla, Sun Pharma, Wockhardt and Lupin have 100+ drugs in discovery phase and a sizable drug pipeline, which indicates growing inclination towards innovation.

Pharmaceutical companies are also exploring external collaboration in terms of in/out-licensing and Mergers & Acquisitions (M&A) as a key success factor. This is underscored by the fact that Indian companies have

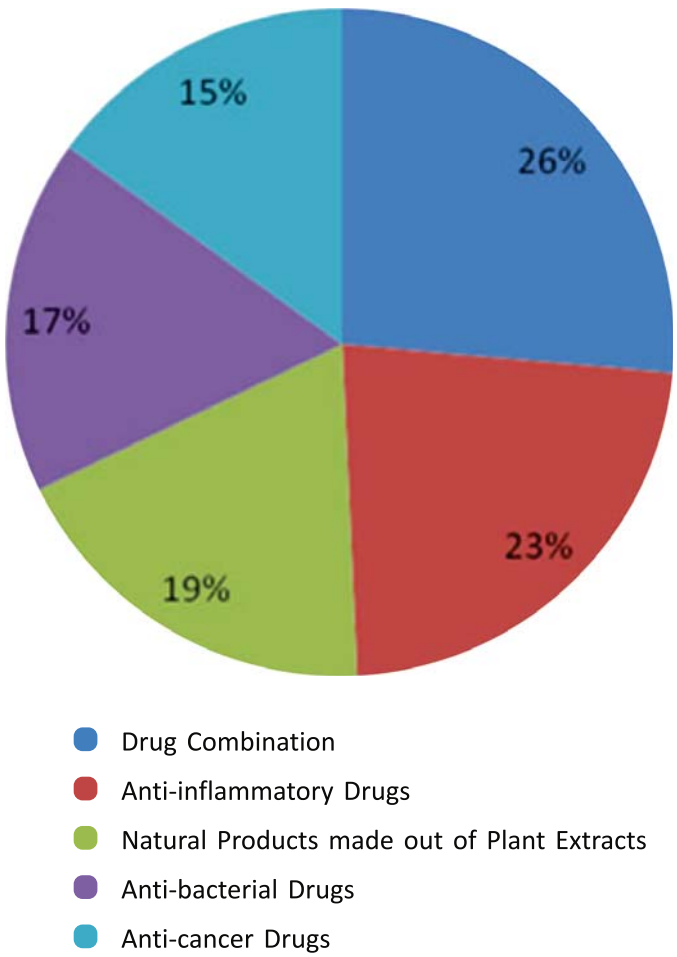


FIGURE 1: *Top Sub-Technology Categories in Pharmaceuticals in India*

Source: Derwent World Patents Index and Derwent Innovation

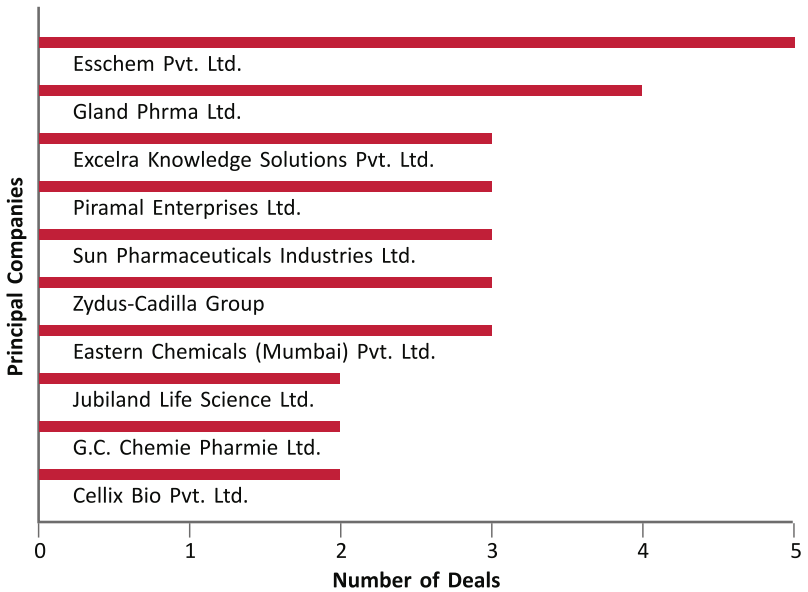


FIGURE 2: *Top 10 Indian corporations for collaborations*

Source: Cortellis Deals Intelligence

signed 55 deals in the last year. Of these 55 deals, 50 are currently active, 4 are completed and one deal was terminated. Of the 50 deals, 14 are in the context of drug-development Services, 11 are M&A (whole or in part) deals, 9 are related to drug-manufacturing supply, and 8 are for drug development and commercialization.

More than 50% of the drugs under development through these deals are in discovery phase. This indicates that most of the deals happen at an early stage of the drug discovery lifecycle.

The top 10 corporations that have entered into collaborations are as shown in Figure 2.

Faster And Better Treatments For Sick Patients Thanks To Technological Advancements

Drug shortages are the result of manufacturing and quality control issues. Obviously, if patients don't have the drugs they need, then they cannot receive the appropriate treatments. This means sick patients are not treated or they are prescribed less effective therapies.

Many of the technological advancements we see emerging aid in minimizing product failures and provide a greater assurance that products manufactured by biopharmaceutical companies will deliver expected performance. More and more manufacturing processes are becoming automated. Automation has been used in plenty of industries (automotive, manufacturing, etc.) for quite some time. Technology is just now becoming advanced enough to create automated systems for more complex manufacturing processes like pharmaceuticals and biopharmaceuticals.

Encouraging innovation in pharma manufacturing

Many pharma companies are caught in a bind – they want to implement new manufacturing technologies, but they don't want to face the subsequent regulatory delays. For many pharmaceutical companies, traditional manufacturing technologies no longer seem up to scratch. Faced with increasing cost pressures, they are seeking ways to speed up operations and to do more for less. This may mean automating processes that were previously manual, or deploying equipment that enables higher production yields.

This isn't just about cutting costs – through modernising their systems, they stand to improve product quality, too. For instance, a number of drugs companies are starting to rely on single-use equipment, which reduces the risk of contamination and subsequent batch recalls. Often, this is integrated into continuous manufacturing processes, which leads to greater product consistency as well as lower operating expenses.

This has clear ramifications for patient care. With almost two thirds of all drug shortages caused by manufacturing and quality issues, a small blip at the manufacturing plant can have devastating consequences further down the line. In this context, emerging technologies are looking increasingly attractive.

Most industries have welcomed technological advancements such as digitalization and automated systems with wide-open arms. However, it's not so easy to do with biopharmaceutical manufacturing (although we're getting there) because the manufacturing of biopharmaceuticals is extremely complex.

Biopharmaceuticals are larger and more complicated than small-molecule drugs/pharmaceuticals. To make biopharmaceuticals, biologists modify the DNA in cells and program the cells to fight specific diseases such as HIV/AIDS, cancer, diabetes and rare blood disorders. If something goes wrong at any stage of the manufacturing process, then it could mean thousands or millions of dollars lost in research and production costs. For the biopharmaceutical manufacturing process, there are many more quality control checks compared to the pharmaceutical manufacturing process.

India And The Future Of Life Sciences Innovation

There are many attractive features that the existing Indian ecosystem can offer the life sciences industry, including development of new medicines

INDIA IS KNOWN for many wonderful things. On the international stage, it is recognized as the fastest-growing economy in the world, and is well-known for its culture, exquisite cuisine and sense of community and family, among many other qualities. One thing it is less known for is the discovery and development of new medicines.

This will soon change.

The Indian pharmaceutical industry is a world leader in bringing generic drugs to the market in a cost-effective way. Rightfully referred to as the 'Pharmacy of the World', the Indian pharmaceutical industry is a strong manufacturing success story with significant global leadership in generic formulations and more than$15Bn of exports.Additionally, many Western pharmaceutical companies have established small-molecule development and manufacturing in India. More recently, Indian pharma companies have demonstrated the capability to develop biosimilars for global healthcare markets. These activities are highly valuable, providing essential and established medicines at more affordable prices to people around the world.

The future of India will go beyond generics and biosimilars.There are many attractive features that the existing Indian ecosystem can offer the life sciences industry and India will eventually play a critical role in the advancement of innovative medicines.

Improvements in genome sequencing have led to a better understanding of what causes and drives the progression of disease. Therapies based on translational strategies rationally target the mechanisms underlying the disease. Precision medicine combines both these ideals, by getting the right drug to the right patient at the right time. It is here that globally operating Indian pharmaceutical companies need to address unmet medicalworldwide.

Companies that are based in India but have substantial US operations are perfect examples of such innovators. Such companies are discovering new, cutting-edge precision medicines using state-of-the-art technologies, and hastening exploratory clinical studies in collaboration with major medical centres in India that provide unique access to treatment-naive patients. Public-private partnerships are further unlocking the potential of Indian biomedical research and development.

And people are taking notice.

The environment for highly innovative and cost-effective biomedical research has changed markedly. Today, there is much more time and cost pressure on the research and development of innovative medicines, particularly with regard to preclinical and early clinical research.

Big Western pharma is facing challenges in this regard. While the industry has the capacity and capability to develop drugs and commercialize them, and the economies of scale to do so profitably, these organizations often lack the agility and flexibility to innovate constantly in the increasingly competitive realm of life sciences discovery.

Many of the largest pharmaceutical companies in the world are relying on early-stage collaboration with start-up biotech firms and established academic labs to manage the

Innovation in the pharmaceutical industry has come a long way in the last few decades, but with the saturation of medical technology, a slowdown as is being witnessed now was definitely inevitable. Big pharmaceutical companies are suddenly looking to collaborate at all levels to spark innovation.

inherently risky prospect of drug innovation.

This type of early innovation will always be high-risk, but more importantly, will face progressive challenges of managing that risk in a nimble way. Essentially, it's about finding methods and processes that accelerate success and help unsuccessful projects "fail faster". The key to nimble risk management will flow from innovation hypotheses grounded in translational medicine, patient stratification and value propositions that convince investors, payers and regulators of the potential improvement and superiority in standards of care.

Sixty years ago, the total number of physicians in India was less than 50,000; today there has been a 16-fold increase to nearly 800,000 registered medical practitioners. Public health centres, the foundation of rural healthcare in the country, have increased from less than 100 to more than 23,000. This explosive growth is fertile ground for thought leaders, investors, regulators and medical centres to collaborate on developing the capabilities to nurture the type of start-up environment that will focus on innovation and better ways of healthcare delivery, with an eye on long-run rather than short-term profitability.

To capitalize on these opportunities, there are a number of steps that India can take. For example, incentives for start-up biotech firms, and commitment to rigorous global compliance standards that help increase trust in the Indian life sciences industry.

These trends are under way globally, but, in some respects, have yet to be initiated by experts with roots in India. Thought leaders must embrace a mindset that celebrates risk-taking and shows unwavering commitment to long-term objectives. By making investments in risky but nonetheless highly valuable emerging science, the global life sciences landscape will undergo an evolution as India transforms itself into a centre of excellence.

We have seen monumental progress in science and technology in recent years, most notably in the field of immuno-oncology for some of the hardest-to-treat cancers. These innovations didn't happen in isolation, but emerged from collaborative networks. Today, innovation occurs in a global village, not in a single country. With so much to offer the life sciences, India is poised to become a dominant player. The potential for this groundswell to materialize is happening today. It's exciting to be a part of it.

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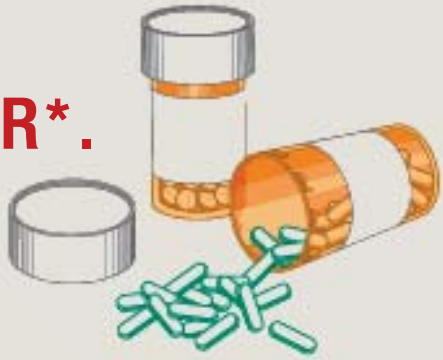

*International Policy Network

INNOVATE IN INDIA:

Injecting Innovation Into Indian Pharma

India's biotech industry is readying itself with a focus on innovation through higher investments in R & D, high-calibre scientists developing a host of Biosimilars & vaccines and building matching capacities to be cost competitive so as to replicate the success in API & generics manufacturing.

THE HON'BLE MINISTER Dr. Harsh Vardhan, formally launched the first ever Industry-Academia mission to accelerate biopharmaceutical development in India. The program named 'Innovate in India' witnessed an investment of USD 250 million with USD 125 million as a loan from World Bank and is anticipated to be a game changer for the Indian Biopharmaceutical industry. It aspires to create an enabling ecosystem to promote entrepreneurship and indigenous manufacturing in the sector.

India has been an active player in the pharmaceutical industry and has contributed globally towards making life saving drugs and low cost pharmaceutical products accessible and affordable for those in need. Be it the Rotavirus vaccine, heart valve prosthesis or affordable insulin, India has been a forerunner in these and many more. Despite, these advances Indian biopharmaceutical industry is still 10-15 years behind their counterparts in the developed countries and faces stiff competition from China, Korea and others. The lacuna primarily exists due to disconnected centers of excellence, less focus on translational research and staggered funding. There was an immediate need felt to focus on consolidated efforts to promote product discovery, translational research and early stage manufacturing in the country to ensure inclusive innovation.

Innovate in India (i3) is committed to addressing these gaps with a Mission to make India a hub for design and development of novel, affordable and effective biopharmaceutical products and solutions. The aim of the Mission is to “Enable and nurture an ecosystem for preparing India's technological and product development capabilities in biopharmaceuticals to a level that will be globally competitive over the next decade, and transform the health standards of India's population through affordable product development.”

As a flagship program of the Government of India in collaboration with World Bank, it promises to boost the growth curve for domestic biopharma in India by accelerating the translation of research concepts into viable products, supporting clinical validation, enabling sustainable networks for collaboration between industry and academia, and supporting entrepreneurial ecosystem amongst many others. Currently India has only 2.8% share in the global biopharmaceutical market, the program would elevate this to 5% resulting in an additional business opportunity of 16 Billion USD.

The Mission will provide a holistic and integrated approach to strengthen and support the entire product development value chain for accelerating the research leads to product development. This will help not only in immediate product development addressing public health needs, but will also help to create an ecosystem, which will facilitate development of a continuous pipeline of products.

Anticipated socio-economic impact

The Mission to be implemented by Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking of Department of Biotechnology will bring together expertise from national and international corridors to provide strategic guidance and direction to move promising solutions through the product development value chain. The program thereby stands unique in its approach as it becomes a cradle to innovate, co-create and co-facilitate scientific discoveries and offers young entrepreneurs an avenue to engage with the best in the industry.

Towards strengthening the emerging biotechnology enterprise in India, Department of Biotechnology (DBT) Ministry of Science & Technology has initiated the Mission Program entitled “Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals – Innovate in India (I-3) Empowering biotech entrepreneurs & accelerating inclusive innovation” (“Program”).

The Indian pharmaceutical industry is a world leader in bringing generic drugs to the market in a cost-effective way. Additionally, many Western pharmaceutical companies have established small-molecule development and manufacturing in India.

The program was approved by the Cabinet for implementation and formally launched by Hon'ble Minister for Science & Technology on 30th June, 2017 with a total cost US$ 250 million (of which 50% will be arranged through World Bank). Biotechnology Industry Research Assistance Council (BIRAC) setup by DBT is the Implementing Agency of the programme.biopharma1

The Legal Agreement with World Bank for flexible financing arrangements for this Mission of DBT was executed on April 24, 2018 between the project implementing agency – BIRAC a PSU of DBT, Department of Economic Affairs, Ministry Finance, Govt. of India and International Bank for Reconstruction and Development (on behalf of World Bank). This mission will mark the beginning of a new partnership between DBT and World Bank; it is envisaged that this programme will revolutionize the Biotech market. It will help deliver 6-10 new products in the next five years, create several dedicated facilities for next-generation skills, and hundreds of jobs in the process. It is anticipated that in the long term it would benefit the Indian population at large due to availability of affordable solutions and products relevant to Indian health needs.

The main aim of this Pan-India Programme is to make India a hub for design and development of novel, affordable and effective biopharmaceutical products and solutions. This Program would aid in enhancing India's innovation research and product development capabilities, especially by focusing on development of vaccines, biologics and medical devices for combating public health concerns. The Program would aid academic researchers (through enhancing their translation capability); empower bio-entrepreneurs and SMEs (by decreased cost and risk during early stages of product development) and the industry (by elevating their innovation quotient).

The programme will also bring isolated centers of excellence together, enhance regional capabilities and strengthen the current bio-clusters network in terms of capacities as well as quantity and quality of output. The Mission will strengthen and create shared infrastructure for product development and Centre of Excellences for knowledge generation and skill development for Technology Strengths and Technology Management. This mission will develop platform technologies for product validation, link institutions to strengthen clinical trial networks and build capacities in emerging areas.

This will be a great platform which will offer buoyancy as well as universal support to biotechnological innovation, and transform India into a global hub for cutting-edge biotechnology research and development. The programme will help deliver 6-10 new products in the next five years, create several dedicated facilities for next-generation skills, and hundreds of jobs in the process. Anticipated long-term impact would benefit the Indian population at large due to availability of affordable solutions and products relevant to Indian health needs.

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Super Technologies Changing Pharma Industry

Pharmaceutical industry is more reactive than pro-active in technology adoption, primarily because of tight regulations and domain complexities. As it is related with individuals health, all such data of these industries are very sensitive. Theft of such important data is a big risk, says **Mayur Parmar,** Drug Inspector, Food and Drug Administration.

Mayur Parmar

Drug Inspector, Food and Drug Administration

Q How innovations in technology space are changing the pharmaceutical industry?

As you know the pharmaceutical industry is the second most regulated industry after civil aviation industry, adaptation to new technologies has to go parallel with the regulation. However, the industry is continuously evolving and adapting with the latest technologies like IOT, 3-D printing, Cloud computing, smart manufacturing, etc. These innovations are still in pipeline phase and hold the potential to change the basics of the industry by offering value propositions such as improved patient and healthcare professional engagement, cost optimisation, faster time to market, higher productivity and improved service for patients. Moreover, as a regulator, I view it as a very good tool for enhanced compliance adherence.

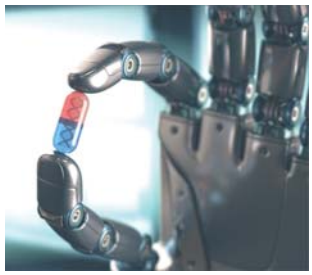
Q Information, research and new manufacturing techniques are some of the important drivers of growth for the pharmaceutical industry and theft of such important data can be a real-threat. So, how does company develop and implement potential security solutions to identify and mitigate such risks?

Well, pharmaceutical industry is more reactive than pro-active in technology adoption, primarily because of tight regulations and domain complexities. As it is related with the health of individual, all such data of these industries are very sensitive. Theft of such important data is a big risk. Implementation of this new ecosystem is not hassle free. It is imperative for a pharma company to conduct a detailed due diligence to analyse the people, process and technology readiness for such innovations. Data privacy, security and vulnerability management is something the company should work on.

Q What kind of latest innovations are you implementing in your manufacturing facilities and R&D Centres?

I am not directly involved with manufacturing facilities and R&D centres. However, I do visit such facilities for inspection. I see that many companies have started this transformation process toward these super technologies. I personally feel, if properly managed and regulated, the IOT will change the way of living of each and every individual of this globe. Well, not limiting to this, we can see lot of new changes like, Use of Auto-ID with AIDC (automated information data collection) for smart serialization, Real-time logistics visibility using RFID & sensors to capture and report parameters including temperature, smart warehousing and routing, Predictive maintenance of machines and equipment.

Q Artificial Intelligence (AI) and machine learning have brought a fundamental shift in drug development, how have these technological advancements brought in new opportunities to drug manufacturing or to bolster R&D efforts in the sector?



Honestly, I am hard pressed to think of areas where it will not be possible for AI to be a key driver. Now, with the advent of big data, companies are harnessing the power of AI to deliver more focused solutions in a variety of areas; AI helps them understand data in real-time. We can put machine learning under the broad umbrella of AI. On current date, we are just scratching the surface when it comes to AI and machine learning in pharmaceutical industry. I believe that AI can solve n number of problems related with the drug discovery process. The more than 10 year long process can be reduced to few 100 days with quite less expense. Apart from it, it has lot to do with genomics, cancer treatment and other frontiers of pharma

"There is no doubt that Cloud Computing offers an opportunity to the pharmaceutical community to innovate quicker, manage change faster and deliver new medicines to the market."

The University of Birmingham has chosen two additive manufacturing systems from engineering technologies company Renishaw as part of a new centre for custom medical devices.

industry. Even we should mention about the big players in this game like WATSON by IBM, DEEP MIND by Google etc. So, I feel that with these technologies tomorrow will be different than yesterday.

Q An adoption of cloud computing has granted pharmaceutical industry with enhanced scalability potential. Kindly apprise us on the major issues linked to the increased usage of cloud computing in the pharmaceutical industry.

There is no doubt that Cloud Computing offers an opportunity to the pharmaceutical community to innovate quicker, manage change faster and deliver new medicines to the market. According to few reports, nearly half of all pharma manufacturers are currently using a form of cloud-based infrastructure, or are at least considering it.

One can state many issues with this technology like Data security, Data migration issue, spying of private data, irreversible nature of data etc.

But the major issue I see as a regulator, with the cloud based infrastructure is Cloud Validation. It is undoubtedly a challenge, however by approaching Computer System Validation in a different way, organisations are demonstrating that it is possible to utilise the Cloud in our regulated environment and thus reap the benefits that this innovative technology offers. The future really does favour the brave " now is the time for pharma organisations to rise to the challenge.

Q How are you leveraging ICT to enhance your offerings and what could impact the growth of pharma – IT?

The government has to implement any change with great care. Still, all the governments of the world are now leveraging the benefits of ICT. E-governance is the talk of the town. The Government of India has done great in recent years for making governance smooth and easy. But I believe that much needs to be done. As an example, I would state about USFDA over here. The US Food and Drug Administration (FDA), with AWS, have used Cloud computing to reengineer the process for handling of their Adverse Drug Affects reports. By utilising AWS cloud, they have been able to quickly turn manual reports into machine readable information with 99.7 per cent accuracy, whilst at the same time reducing costs from $29 per page to $0.25 per page. Our current government is vibrant and accepting the innovation at ever-faster rate. I believe that there are huge possibilities for incorporation of these super technologies in government machineries and that will make betterment in the life of every citizen of India.

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Trends And Innovation In Indian Pharma Packaging

Yogesh Mudras leads and manages the entire India operations of UBM plc. At UBM India, Yogesh's repertoire of businesses is extensive and includes large format B2B exhibitions, conferences, seminars, Business Intelligence, and other properties that serve multiple key markets especially Pharmaceuticals. Here are edited excerpts of Managing Director, UBM India on the trends and challenges in pharma industry.

Yogesh Mudras

Managing Director, UBM India

Q Where is the Indian Pharmaceutical industry placed in the global map?

India is seen as a potential market for global pharmaceutical manufacturers and is ready to transform into a global pharmacy hub. It is the largest provider of generic drugs globally accounting for 20 per cent of global exports in terms of volume. The pharma industry has been growing at a compounded annual growth rate (CAGR) of more than 15% over the last five years, has significant growth opportunities and is likely to be in the top 10 global markets in value term by 2020, according to an industry report by PwC.

The various economic drivers and government policies like pharma parks, boosting the biosimilars and biologics sector, along with ancillary sectors, and reducing manufacturing costs are the key driving factors for the growth of the sector in the country. The 'Pharma Vision 2020', introduced to make India a global leader in end-to-end drug manufacturing, has boosted investments. The recent GST regime is a game changer for the sector, and will increase the focus on regional hubs by going for a unified tax structure. There is bound to be an efficient supply chain management, which is expected to reduce costs considerably.

Through our research in the sector, we believe that despite issues relating to compliance, infrastructure and pricing, the Indian pharma companies' confidence is now high and forecasts rapid growth for the Indian pharma economy.

Q What are the trends & innovations that you see in the Indian Pharma packaging industry?

Pharmaceutical packaging is one market across the globe which is advancing at a constant pace. Pharma packaging solution is an essential part of delivery system in the sector thatneeds to be reliable and speedy and deliver a combination of quality, tamper evidence, patient comfort and protection. It protects the medicine and drugs from various external environmental factors. Packaging is critical in pharmaceutical industry and is defined as a technique which allows containment of pharmaceutical product from the time of production in a unit till its use. According to the industry forecasts, the global market is growing rapidly and is expected to reach $ 158.8 billion by 2025.

Through our indepth research in the sector, we can say that the global markets are flooded today with duplicate drugs posing a threat to the pharmaceutical industry. To tackle this biggest challenge faced by the pharma companies, various tools and solution provider have developed track and trace technology to fight counterfeiting. These tools also play an important role in the supply chain process and help in avoiding the security lapses and works to the advantage of pharma companies by stopping the illegal counterfeit of medicines

Serialization continues to be a driving force for change in the pharmaceutical packaging segment to fight counterfeiting, theft, diversion, and false returns to manufacturers. New serialized labelling technologies on

display included printing 2D barcodes directly onto vials and onto pills and capsules. The effective serialization will cut down the counterfeiting of drugs in the supply chain

Regulatory authorities and tech-companies across the globe are working towards the implementation of policies and advanced technology that can bring down the illegal activities, safeguard the customers and support the industrial growth.

Q What are the growth opportunities and challenges in organising exhibitions and conferences in Indian Pharma industry in India ?

Every year, we introduce a new chapter to CPhI&P-Mec, UBM's flagship engagement platform, and the world's leading Pharmaceutical networking event. The show is the epitome of India's strength in the Pharma industry and has consistently grown to serve as an exclusive congregation of key global players across the pharmaceutical sector. To celebrate ten glorious years of CPhI-PMEC last year, the week-long India Pharma Week was introduced, catering to every need of the attendees through six streams of Business, Leadership, Knowledge, Innovation, Recognition & Networking. Ably supported by key governmental associations, the exhibition, grew even bigger and was held at two different venues in Mumbai: the traditional Bombay Exhibition Centre in Goregaon and the new venue- MMRDA grounds, BKC. CPhI& P-Mec India hasattracted 50,000 attendees from 94 countries across the globe. Last year, the event witnessed a record participation of 1,087 exhibitors from 21 countries and was spread over 65,000 sq. mts.

The India Pharma Week by UBM India stems from the proactive role it plays in driving key Governmental initiatives such as 'Make in India', 'Start-Up India, Stand Up India', and 'Skill India' connecting the global community to eke out solutions to challenges, and establishing superior standards within it. Through the various engagements under the India Pharma Week such

With this overarching theme of Ideate. Innovate. Integrate, UBM India is pleased to present the Pharma Connect Congress taking place on 12 December 2018 at India Expo Centre, Greater Noida, Delhi NCR.

as The CEO Roundtable, Women in Pharma, Pre-Connect Congress, Factory visit and The India Pharma Awards, different facets of the pharma domain are brought under spotlight and vital thought leadership garnered.

Q Your role in pharma packaging industry. What are your future expansion plans?

Pharma packaging plays an important role in drug efficacy, safety and patient experience. UBM India's signature confex (conference and exhibition), Innopack, stems from the proactive role it plays in driving key Governmental initiatives such as 'Make in India', and 'Skill India' connecting the global community to eke out solutions to challenges, and establishing superior standards within it.

It is the biggest platform for Pharma Packaging professionals to congregate, network, exchange ideas and knowledge, form future alliances and shape the future of the pharma packaging industry, all under one roof. Participants benefit from subjects centred round innovations in pharmaceutical packaging to enhance sustainability, and simplify usage for patients through adopting latest technologies including the future of 3D printing, advancements in Prefilled syringes, track and trace, serialization, packaging design and artwork.

UBM India provides the platform to more than 6500 members of pharmaceutical community from across the globe through this event. Such platforms connect buyers & sellers to network, understand the recent innovations and form future alliance, all under one roof. Professionals from various regions with different expertise get to exchange ideas and understand the know-how of each other's business. Speakers, exhibitors and audience engage through various activities and discussions around the recent trend, innovation and development in the sector during these exhibitions. The Innopack Awards is also eagerly awaited event in the calendar of pharma packaging industry professionals as it recognises and rewards innovations and excellence in the sector. Efforts are on to make it even more big and all-inclusive.

Another path-breaking expo on the packaging industry by UBM India is also on the cards and to be announced shortly.

Globally, UBM plc's Pharmapack is essential for industry insights and reimaging the capabilities of pharmaceutical packaging and drug delivery. It spans the breadth of the industry; from functional inks that incorporate electronic applications into packaging, to needle-free medicine delivery, to an app that scans packages to provide product information.

Q What new will be offered this year's India Pharma?

While India is renowned as the pharmacy hub of the world, and the Indian pharma economy lauded for its rapid growth, the industry is at a very crucial juncture in its growth trajectory. Certain challenges continue to surround it including a shortage of highly skilled talent. This year, we are shining the spotlight and handpicking young talent with a Paper presentation whereby a well-renowned jury panel picks top post graduate students to present their thesis on the pharma industry, and the winners will be feted during the Awards night. Besides, we also have included a special Masterclass, a new feature of the IPW, that will comprise prominent speakers from top organizations in a platform for knowledge sharing.

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Pyush Misra
Director,
Consumer Online Foundation

Using Big Data To Transform Pharma Industries

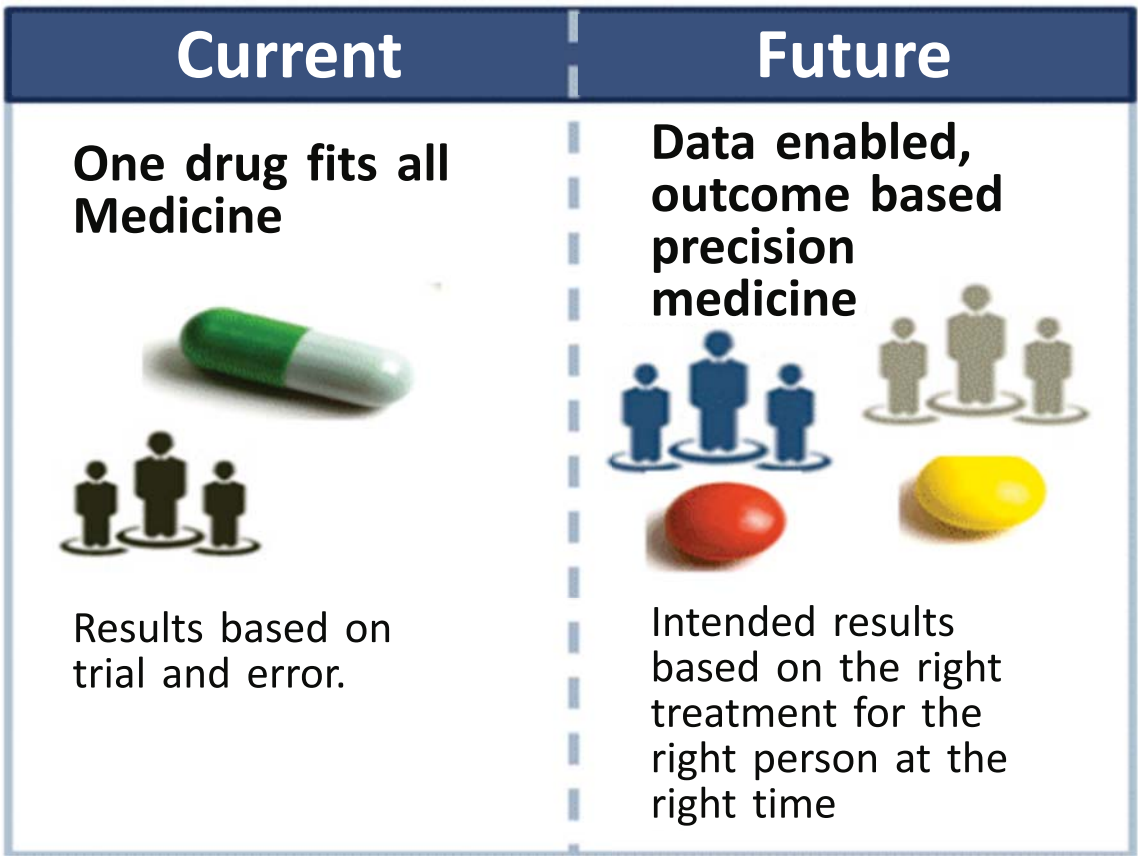
BIG DATA IS making enormous strides across several industries, including pharmaceuticals. With the collection of large amounts of data, companies can save money while increasing patient safety, managing risk, improving the efficiency of clinical trials and collaborating with other pharmaceutical companies to share innovations and data.

Although saving money hasn't been a priority for drug manufacturers in the past, with new healthcare reforms in action, many companies are looking at ways to stay within a budget. The development of a new drug costs an average of $500 million and the collection of large amounts of data.

There are five ways that Big Data is making major changes to the industry.

Predictive Modeling

Industries like agriculture use predictive analysis to forecast possible issues with heavy machinery. The pharmaceutical industry can use predictive modeling to qualify a particular drug for a patient based on the patient's genetics, diseases or disorders and lifestyle. This type of analysis also



takes into account the risk factors that could prove fatal to a patient.

Companies that specialize in Big Data analytics for drug discoveries use algorithms to analyze data in the cloud. Companies like Numerate are branching out to include programs specifically geared toward therapies for such conditions as cardiovascular and neurodegenerative diseases. With a targeted and personalized approach to care, patients will no longer take needless medications that don't improve their condition.

Clinical Trials

Using Big Data and predictive analysis, companies can conduct effective clinical trials. The patients selected for these trials can meet certain prerequisites found through multiple databases, and researchers can monitor the participants in real-time.

Big Data also has its place in predicting side effects for specific compounds before the clinical trial begins. Currently, there is a method that predicts drug toxicity in compounds. In the past, human trials may have found the toxicity too late. With the Proctor method analyzing 48 drug features, companies can save time, money and lives.

Industry Collaboration

Pharmaceutical companies can now use Big Data to work in collaboration with insurance companies, data management firms and scientists outside their company. By sharing information with insurance companies and providers in their network, a pharmaceutical company can widen its database for future clinical trials and predictive modeling.

Scientists working outside a particular pharmaceutical company can submit their findings regarding a compound to the company for analysis and testing. Data collection in the cloud makes sharing ideas and information accessible to the entire industry.

Pharmaceutical Sales and Marketing

The sales and marketing side of the pharmaceutical industry can benefit from the integration of Big Data analytics. Pharmaceutical representatives can focus on specific physicians in a geographical area with patients most likely to need the promoted medication based on predictive analysis.

Drug companies can save time and money by sending their pharmaceutical reps to only those physicians that require a visit. According to a 2013 survey, as much as 25 percent of marketing is now accomplished on a digital platform. Although drug rep visits are not obsolete yet, companies are finding that Big Data analytics can improve their return on investment.

Digital Apps

Pharmaceutical companies can now build a relationship with consumers through social media platforms and digital apps. This electronic data flow links all aspects of the industry, from patient follow-ups and R&D to electronic physician medical records.

Digital apps, wearable monitors, and other electronic devices provide companies with real-time monitoring of patients' health, and this information gives companies a first-hand look into patient compliance. Physicians, as well as companies, can receive instant feedback regarding patients through these apps and devices.

Why Big Data Growth Is Slow in the Pharmaceutical Industry

Cost is one of the largest factors in the slow growth and acceptance of Big Data analytics in the pharmaceutical industry. It's expensive to overhaul an entire infrastructure, so many companies are breaking changes down into small compartments in order of priority.

Patient privacy is another barrier prohibiting explosive growth in data sharing. Unlike data sharing in other industries, the pharmaceutical industry could potentially expose patient information. Drug companies must remain HIPAA-compliant while making changes and collecting data to avoid costly lawsuits and damage to their reputation.

Big data also has its own set of challenges. Leveraging big data to deliver quality care to patients while keeping it secure is a major challenge.The pharmaceutical industry will benefit from Big Data analytics as long they adhere to the regulations and laws and continue to protect patient privacy.

Data collection in the cloud makes sharing ideas and information accessible to the entire industry.

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TOP TECH TRENDS In Pharmaceuticals

BIOPHARMATREND SUMMARIZED several important trends affecting biopharmaceutical industry, namely: an advancement of various aspects of gene editing technologies (mainly, CRISPR/Cas9); a fascinating growth in the area of immuno-oncology (CAR-T cells); an increasing focus on microbiome research; a deepening interest in precision medicine; some important advances in antibiotics discovery; a growing excitement about artificial intelligence (AI) for drug discovery/development; a controversial but rapid growth in the area of medical cannabis; and continuous focus of pharma on engaging in R&D outsourcing models to access innovations and expertise.

Below is a continuation of this review with several more active areas of research added to the list, and some extended commentaries on the trends outlined above -- where relevant.

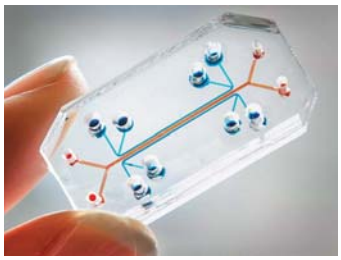
Adoption of Artificial Intelligence (AI)

With all the hype around AI nowadays, it is hard to surprise anybody with this trend in pharmaceutical research. However, it should be noted that AI-driven companies really start getting traction with big pharma and other leading life science players, with lots of research partnerships and collaborative programs. A potential of AI-based tools is now explored at all stages of drug discovery and development -- from research data mining and assisting in target identification and validation, to helping come up with novel lead compounds and drug candidates, and predicting their properties and risks. And finally, AI-based software is now able to assist in planning chemical synthesis to obtain compounds of interest. AI is also applied to planning pre-clinical and clinical trials and analyzing biomedical and clinical data.

It's likely that within the next decade, humans will no longer be pharmaceutical test subjects . Instead, cognitive computers will be used in biotechnology and genomic research. Rather than it taking months to see the effect of a particular drug on thousands of people, it will take seconds to see the effect of thousands of drugs on billions of simulations of the human body's physiology.

Intact, there's already one supercomputer program, Atomwise. This program has been used for similar purposes. It has the ability to search through existing medicines that could be re-purposed to more effectively treat diseases. Atomwise identified two drugs in less than 24 hours, that could reduce Ebola's infectiousness.

Organs (body)-on-a-chip



Microchips lined by living human cells could revolutionize drug development, disease modeling and personalized medicine. These microchips, called 'organs-on-chips', offer a potential alternative to traditional animal testing. Ultimately, connecting the systems altogether is a way to have the whole "body-on-a-chip" system ideal for drug discovery and drug candidate testing and validation.

This trend is now a big deal in drug discovery and development space and we have already covered the current status and context of the "organ-on-a-chip" paradigm in a recent mini-review.

While a lot of skepticism existed some 6-7 years ago, when perspectives on the field were articulated by enthusiastic adopters. Today, however, the critics appear to be in full retreat. Not only have regulatory and funding agencies embraced the concept, but it is now increasingly adopted as a drug research platform by both pharma and academia. Over two dozen organ systems are represented in on-chip systems. Read more about it here.

Bioprinting

The area of bioprinting human tissues and organs is rapidly developing and it is, undoubtedly, the future of

MNC Tie-ups In Developing Life Sciences Market

Tie-ups with MNCs will help the market scale up from merely replicating drugs to developing new ones

UNDER THE LEADERSHIP of Narendra Modi, the government has shown it understands the need to develop the country's innovative life sciences sector.

The Government is due to announce a major reform of intellectual property laws, which it sees as crucial for developing modern, high tech industries. Meanwhile, the Make in India campaign and the last Budget created a number of tax incentives and R&D initiatives aimed at increasing private and public sector research investment.

Such reforms are overdue.

Need to be creative

India's generic drug manufacturing industry constitutes a healthy 10 per cent of the volume of the global pharmaceutical industry, but only 1.4 per cent of the value. In fact, recent data from WIPO showcases a fall in the number of patents granted to resident Indians, particularly after 2007. All this, while the Indian pharmaceutical industry flourished under a trade restrictive market access regime, requiring foreign multinationals to abide by a stricter Section 3(d) clause of IPR Act, for them to get IPR protection in India.

If the pharmaceutical sector is to help propel India towards the next stage of economic development, it needs to be generating much more value, and that means creating medicines instead of just manufacturing copies of what's invented elsewhere.

The US pharmaceutical industry, largely comprised of innovative, R&D-focused companies, generates a direct output of $4,61,000 per employee in comparison to $1,49,000 on average for other sectors. In Europe, the pharmaceutical industry contributed an international trade surplus of $54 billion. It is no wonder western governments view these industries as major economic assets.

There is no reason why India cannot grow its own innovative bio-pharmaceutical sector. It has a well-developed scientific base, with a large number of highly skilled researchers and scientists. India is one of the six most bio-diverse countries, and its 7,517-km coastline has a wealth of marine organisms that could provide fertile territory for drug research.

The country's relatively liberal regulatory regime makes it a promising location for stem cell

A potential of AI-based tools is now explored at all stages of drug discovery and development -- from research data mining and assisting in target identification and validation, to helping come up with novel lead compounds and drug candidates, and predicting their properties and risks.

medicine. Founded in early 2016, Cellink is one of the first companies in the world to offer 3D printable bioink – a liquid that enables life and growth of human cells. Now the company bioprints parts of the body -- noses and ears, mainly for testing drugs and cosmetics. It also prints cubes enabling researchers to "play" with cells from human organs such as livers.

While 3D bioprinting is an extremely useful technology, it is static and inanimate because it considers only the initial state of the printed object. A more advanced approach is to incorporate "time" as the fourth dimension

research, cell engineering and cell-based therapeutic R&D. Meanwhile, its well-established strengths in information technology means it is emerging as a leader in the use of computer science, statistics and mathematics to analyse and interpret biological data — crucial for modern biotech research.

Change agents

While the Indian pharmaceutical industry is still dominated by the manufacturing of drugs invented by (mainly foreign) companies, things are starting to change.

India is now becoming a serious player in vaccine innovation, for instance, with Hyderabad's Bharat Biotech's innovative H1N1influenza and rotavirus vaccines and the two anti-malaria vaccines being jointly developed by Ranbaxy and Bharat Biotech. Domestic companies also promise much in active therapeutic proteins, protein and antibody production, and fabrication of diagnostic protein chips.

Patients are also benefiting from changes in the Indian industry. Bengaluru's Biocon is close to releasing an insulin product that can be consumed orally. If successful, it could spell the end of the daily injections regime for around 387 million people with diabetes worldwide, including 67 million in India.

While these are early signs of success, the industry has a long way to travel. While its 'R&D intensity' (the amount it invests in R&D as percentage of sales) has been rising for several years and now stands at 6 per cent, it is well short of the 20 per cent typical of western pharma companies.

India spends just 1 per cent of its GDP on R&D, with up to 80 per cent of that money coming from the Government. By contrast, about 75 per cent of research funds in wealthy countries come from the private sector. In addition to the reforms proposed by the Modi government, India's overall innovation ecosystem needs work. Last year, in total, India filed 1,394 patent applications in comparison to China's 25,539 patent applications.

In highly innovative countries, the academic and private sectors collaborate constantly in their research, each leveraging the advantages of the other. While there is some collaboration in India, the two worlds remain largely isolated from each other. Simple rule changes in this area could bring the two closer together.

Another challenge is to provide a domestic market for local innovations. Innovative countries tend to cover new drugs and technologies in their healthcare systems, for instance, which also improves the quality of care and health outcomes. Health insurance in India — where it exists — generally only provides for older, less effective medicines, making it difficult for R&D companies to get a foothold in the market. On an average, Indians spend around $160 on healthcare (annualised, per-capita figure), of which only 25 per cent is contributed by the Government — a figure lower than many Sub-Saharan African countries.

International alliances

These failings aside, one way to accelerate the transformation of Indian pharma manufacturers into R&D companies is for them to enter into international alliances with multinational companies. Such cross-border alliances import skills, finance and knowledge which are not always locally available, giving Indian companies a shortcut to upgrading their ability to conduct R&D.

This is already happening on a modest scale. Sun Pharma's February tie-up with Astra Zeneca to promote and distribute its new anti-diabetes drug in emerging markets is a case in point. But more tie-ups are needed to give Indian pharma a skills boost and bring new technologies into the country.

One thing foreign investors need in this sector is certainty over their intellectual property rights, which need to be clearly defined and readily enforceable. Despite the Government's focus on this area, recent Indian court decisions around patentability and compulsory licences make potential investors nervous, and could put the brakes on the sector's development.

The opportunity is there: it is up to Indian policymakers to grab it.

in the printed bio-objects (so called “4D bioprinting”), rendering them capable of changing their shapes or functionalities with time when an external stimulus is imposed. Here is an insightful review on 4D bioprinting.

Digitization of Medicine

Every company, in every industry is coming to the realization that a product or service isn't enough. A complete package must be offered and this package should be digitally friendly.

In the pharmaceutical industry, this trend is growing so quickly that there's a name for it, “Around the pill” digital offerings. These include everything from digital health apps to services and devices that can be bundled with the prescription.

Body Sensors

Body sensors can either be placed on a body or inside of it. They measure various critical vital signs. One sensor that's already being used is a digestible sensor. These are inside of a pill and track both the drug being digested and how well the drug is being absorbed by the body, especially effective in overseeing prescription adherence with major depressive disorders, and bipolar disorder.

AR and VR

Augmented drelaity is slowly creeping into every aspect of our lives, and that includes pharmaceuticals. Some pharmaceutical companies are looking at allowing patients to better connect with their prescriptions by translating the descriptions on the bottle into 3D.

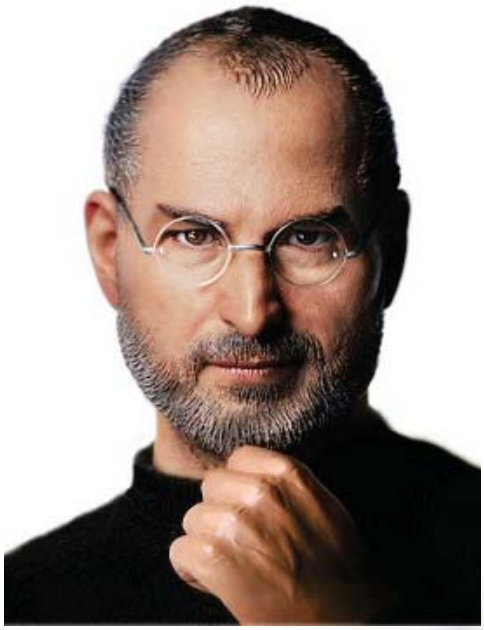
Instead of having to read a long, and nearly indecipherable pamphlet on how the drug works, patients could be much more engaged with a visual AR demonstration.

When it comes to VR, it's been believed that if the Pharma industry pursues and invests in the technology, more new streams of revenue from pharmacies that provide virtual reality treatments could be opened up.

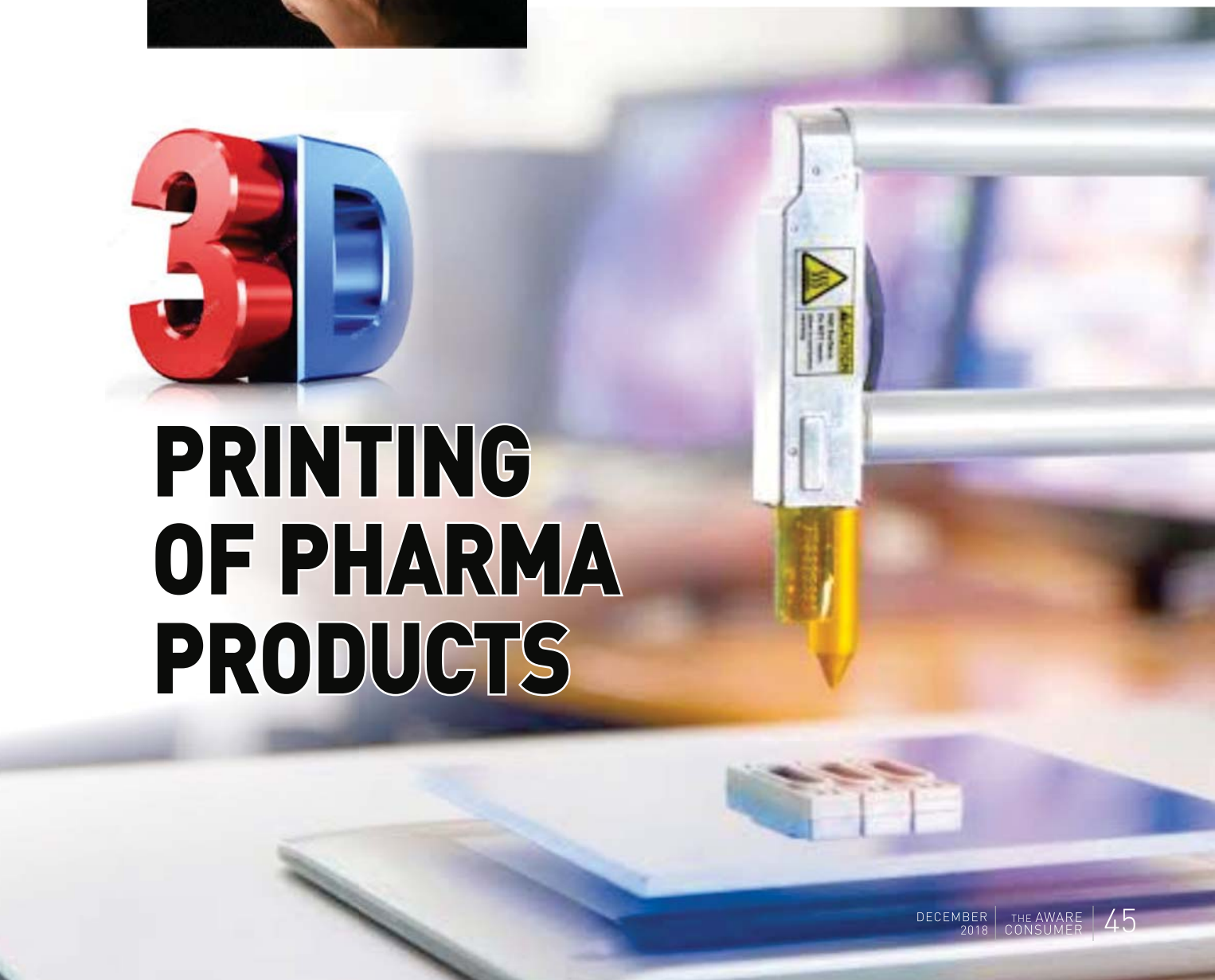
Precision medicine

Precision medicine is an approach that integrates clinical and molecular information to understand the biological basis of disease. This information can be obtained by converting DNA into data through a process called genome sequencing. Researchers can use this data to identify specific gene abnormalities, or biomarkers, to understand which types of patients a drug will be most effective for, and who is likely to experience severe side-effects. This can aid in the development of new targeted therapies and the repurposing of existing drugs.

Targeted therapies are tailored to the genetic makeup of individual patients so genomic testing is required to ascertain the most effective therapy before it is administered. This understanding of the relationship between a drug and an individual's genes enables doctors to administer the right drug for the right patient at the right dose, first time – leading to better outcomes and reduced adverse effects.



Steve Jobs once said, "The biggest innovation of the 21st century will be at the intersection of biology and technology." Every day, we see biology and technology become more and more integrated. In every industry, change is the only thing we can count on happening because it is inevitable. And when it comes to the research, design and production of biopharmaceuticals, change is rapid and ceaseless. Therefore, we must stay on top of the latest technologies to be successful.



3D PRINTING OF PHARMA PRODUCTS

THE 3D PRINTING methods gain an importance in the field of pharmaceutical and medical applications because of the possibility of rapid preparation of tailor-made objects which can be applied in personalized therapy or medicine. The introduction of 3D printing into the pharmaceutical technology particularly aims at the development of patient-centered dosage forms based on structure design. It is still a new research direction with potential to create the targeted release drug delivery systems in freeform geometries. Extensive research is conducted for oral dosage forms because that route of administration still remains the major and the favorite one. Some investigations are also focused on dosage forms for topical administration. The examples of 3D printed products demonstrate the growing interest in drug design by using different 3D printing techniques.

3D printing or additive manufacturing is a process of making 3 dimensional solid objects from a digital file.

The creation of a 3D printed object is achieved using additive processes. In an additive process an object is created by laying down successive layers of material until the object is created. Each of these layers can be seen as a thinly sliced horizontal cross-section of the eventual object.It all starts with making a virtual design of the object you want to create. This virtual design is for instance a CAD(Computer Aided Design) file. This CAD file is created using a 3D modeling application or with a 3D scanner. A 3D scanner can make a 3D digital copy of an object.

3D scanners use different technologies to generate a 3D model. e.g. time of flight, volumetric scanning, structured/modulated light.

Despite of the diversity of 3D process, preparation of 3D-printed object includes several stages:

- the design of 3D object with computer-aided design software and optimization of the geometry according to printer specification,
- the export of 3D model to a common and printer-recognizable file format e.g. STL which includes only 3D geometry in form of each vertex position data or OBJ in which additionally information about polygonal faces or color texture are coded,
- the import of the file to the software and generation of layers which will be printed; the height of the printed layer essentially influences the quality of the printed object as well as printing time,
- the fabrication of the object by subsequent application (or solidification) of the material layers dedicated to the specific printing method.

This technology benefits both the doctors as well as the patients and treats common as well as serious medical conditions, from chronic pain to epilepsy. These are developed as patient-specific formulations, thus making the medication customized and more effective, with lesser side effects and economical than standard drugs.

In April 2014, the Mata twins were born into an uncertain future. The sisters were connected from their chest to their pelvis with several shared organs, and it was deemed desirable to separate them. Faced with one the most complex separations ever for conjoined twins, their surgeons at Texas Children's Hospital in Houston, US, embraced the help of an unexpected rookie: a 3D printer.

The girls first underwent a series of computerised tomography scans. This data was used to print out colour-coded 3D models of the girls' organs and skeletons in exquisite detail. These models enabled the separation surgery to be planned and extensively practiced. At 10 months old, the girls were separated 18 hours into a 26-hour operation. 'This is the first time a separation surgery for twins with this particular configuration has been successful,' said one of their surgeons at the time. Along with the surgeons, 3D printing was hailed a hero.

And it isn't just for conjoined twin separation that 3D printing has earned its stripes in the operating room in recent years. Other types of complex surgeries have now been practiced this way, including a full-face transplant, and spine, brain and heart surgery. 3D printing is also increasingly being used to produce low-cost, made-to-measure implants including jaws, pieces of skulls, and hips.

To date though, healthcare's most prolific use of 3D printing is in the production of hearing aids. A silicone impression of a wearer's ear is scanned and the data used to print out personalised digital aids that fit in the ear, or soft earmoulds for behind-the-ear devices. A once labour-intensive process has been automated and produces snug earpieces that are both comfortable and prevent sound leakage.

DRUG PRODUCTION

3D printing is also starting to make a name for itself in medicine manufacturing. While it's hard to foresee the wholesale replacement of current tablet manufacturing processes, 3D printing is expected to find a place in certain niche medications and in personalised tablets.

There are reports of scientists developing 3D printed shapes which have been a challenge to manufacture conventionally e.g., 3D printed pyramid shaped tablets will become popular as they release medicament more rapidly than the conventional cylinder-shaped pills.

This technology is also known as pharmacogenetics, to make drugs specific to patients based on their DNA information.

What is the Technology Used in 3D Printing?

A computer algorithm is developed to design and calculate dosages specific to patients, based on their clinical and biological parameters. The algorithm generates 3D printable files which are then used for making 3D printed drugs.

The process involves producing a 3D object by building the medication on a substrate, using computer-aided design models. The material is ejected from a printer on a horizontal plane to create a foundation of the object. The printer then moves along the z-axis, and a liquid binder is sprayed onto the object to a specific thickness. This process continues based on computer defined instructions. This technology is also known as Additive manufacturing (AM), Rapid Prototyping (RP) or Solid free-form technology (SFF).

First 3D-printed Drug approved by U.S. FDA

3D printing into the pharmaceutical technology is still a new research direction with potential to create the targeted release drug delivery systems in freeform geometries.

Various techniques can be used to produce 3D printed pharmaceuticals or medications, e.g., Inkjet based fabrication, Direct-write, ZipDose, Thermal Inkjet printing, Stereolithography (SLA), and Fused deposit modeling (FDM).

Inkjet printing: This technique involves spraying droplets of combinations of active ingredient and excipient (ink) into a substrate. The sprayed ink then solidifies on a powder substrate.

ZipDose : This technology involves manufacturing a highly porous material which provides a personalized dose, with a high drug-load, low disintegration time and faster dissolution.

Thermal inkjet printing: This methodology facilitates dispensing extemporaneous solution of the drug on 3D drug scaffolds or films. It consists of a micro-resistor that heats a thin film of ink fluid, forming a bubble which expands to push the ink dropout out of a nozzle.

Material Jetting: In this case, a powder substrate is not required. The printers can print free-form structures that solidify drop by drop.

The company Aprecia uses its proprietary technology known as ZipDose technology to manufacture Spritam tablets, which are 3d printed tablets. It uses a combination of formulation science and 3D printing to produce easy-to-swallow and rapidly disintegrating formulations of drugs. With the help of this technology, the tablets disintegrate in the mouth with a tiny sip of liquid.

The process involves depositing a powdered blend to form the first layer. Next, the binding fluid is precisely deposited onto the first layer. This helps to bind the powder blend and prepares it to adhere to the next layer. This process is repeated several times, and the final product turns out highly solid yet highly porous.

Safety and efficacy of 3D printers:

The idea of individualized medicine whereby a patient's age, weight, race or organ function could inform doses and production has captivated medical community since 3D printing became a reality but the possibility of a printer defect or manufacturing malfunction remains a concern, as does placing responsibility for such an incident. Importantly, 3D printing manufacturers must be diligent about vetting their suppliers, as contaminated or defective materials may yield a faulty product and pose an even larger threat than the printers themselves.

3D printing technology has the potential to open doors in product development for pharmaceutical companies. It could help fulfill the promise of personalized medicine, a concept that is growing in popularity within the industry. For a firm considering a future in 3D printing, understanding risk exposures should be one of the first steps in determining whether it's a worthwhile investment. Pharmaceutical companies should work closely with their IT and manufacturing colleagues to understand the risk and then tap into insurance experts, their broker and underwriters to ensure that insurance coverage is properly crafted to address the risk exposures. 3-D printing technology in pharmaceuticals is an advanced drug delivery system that uses computer aided designs to create personalized drugs. Three-dimensional (3D) printing of drugs uses computer-aided designs to manufacture individualized pharmaceutical drug products. The 3D printing (3DP) technology is already being used in the pharmaceutical field to manufacture 3D printed customized prosthetics, surgical implants, medical devices and 3D bio-printed tissue. 3D printing technology for medications is an innovative and cost-saving technology to deliver medications with ease.

If you believe the hype, 3D printing is destined to transform every aspect of our lives at home, in hospitals and in our labs. Industrial and academic scientists are currently scrambling to develop viable tools of the trade to enable its continued charge into the pharmaceutical arena, but only time will tell whether 3D printing will live up its disruptive technology potential here.

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Department of Pharmaceuticals
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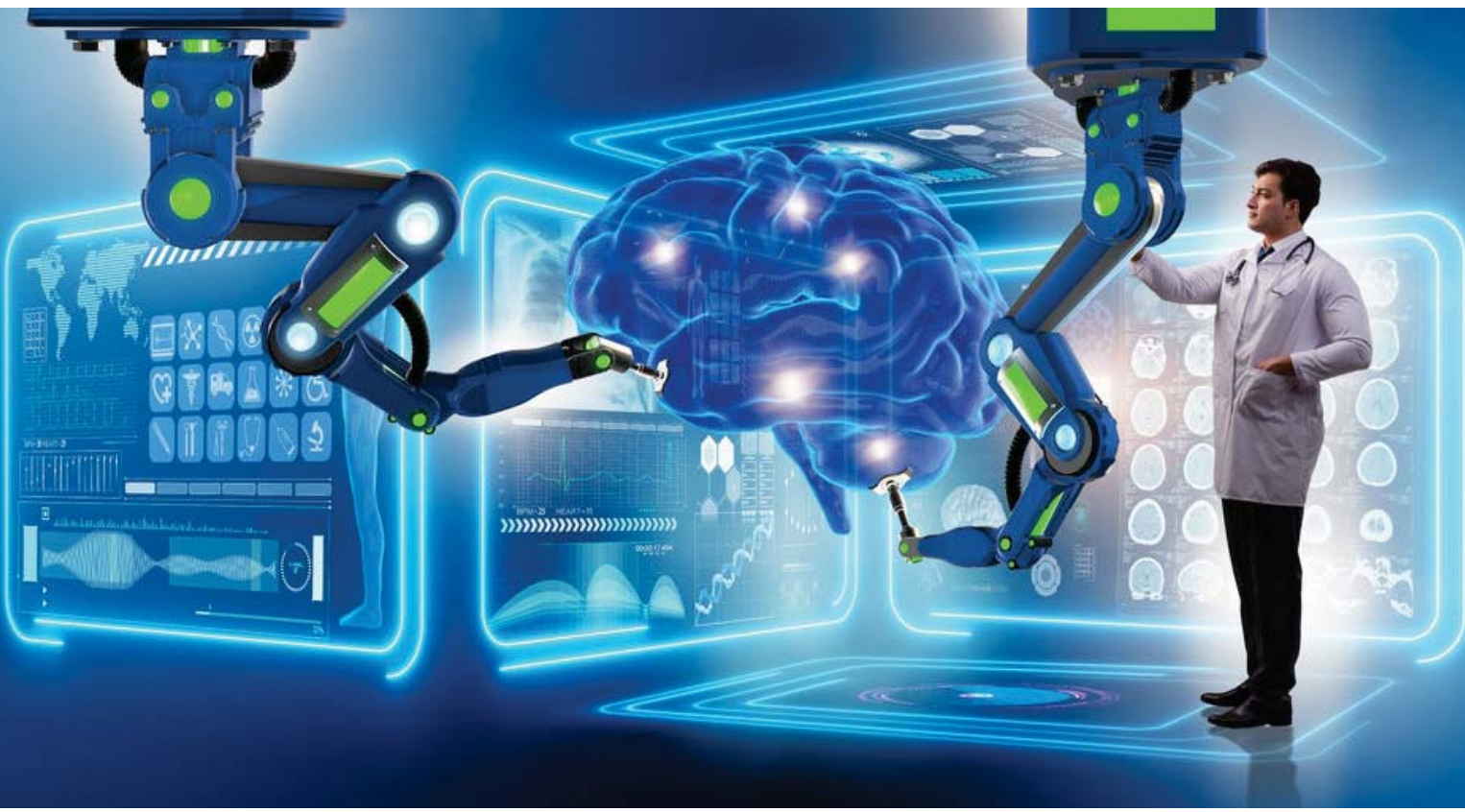
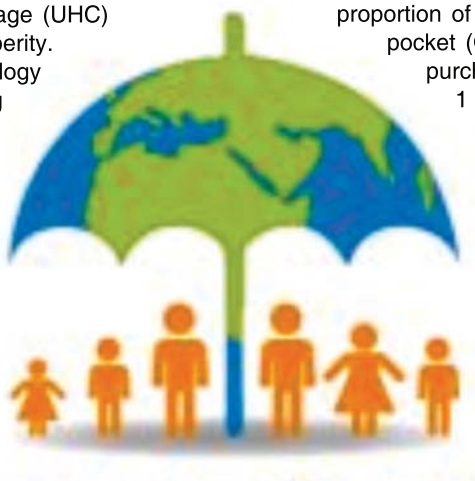
BEING RESPONSIVE TO CHANGE: TECHNOLOGICAL ADVANCEMENT AND UNIVERSAL HEALTH COVERAGE



ALMOST ALL COUNTRIES in Asia and the Pacific have embraced universal health coverage (UHC) as a pathway to greater national prosperity. Information and communication technology (ICT) is key to attaining and sustaining UHC as well as strengthening health-system accountability. ICT innovations in health—or e-health—are already in place in many countries in Asia and the Pacific offering lessons that can be replicated.



The goal of UHC is to ensure that all people obtain the health services they need without suffering financial hardship when paying for them.

Achieving UHC is important as the objectives of inclusive growth, sustainable economic development, and national and regional health security cannot be achieved without a healthy population.

The goal of Universal Health Coverage is to ensure that all people obtain the health services they need without suffering financial hardship when paying for them. This requires a strong, efficient, well-run health system; a system for financing health services; access to essential medicines and technologies; and a sufficient capacity of well-trained, motivated health workers.

Ensuring that every individual in this diverse nation obtains the needed health services without suffering financial hardship

The National Rural Health Mission (NRHM) launched by the Government of India seeks to provide accessible, affordable and quality health care to the rural population, especially the most vulnerable. It also sought to reduce the Maternal Mortality Ratio in the country from 407 to 100 per 100,000 live births. Infant Mortality Ratio from 60 to 30 per 1000 live births and the Total Fertility Rate from 3.0 to 2.1 within the seven year period of the Mission.

Now, the NRHM along with the recently launched National Urban Health Mission (NUHM) has been subsumed under the National Health Mission (NHM). Despite significant progress especially since the launch of NRHM, challenges remain:

The availability of health care services provided by the public and private sectors taken together is inadequate;

The quality of healthcare services varies considerably in both the public and private sector as regulatory standards for public and private hospitals are not adequately defined and, are ineffectively enforced; and

The affordability of health care is a serious problem for the vast majority of the population, especially at the tertiary level.

Out-of-pocket Health Expenditure as proportion of Total Health ExpenditureDue to the lack of extensive and adequately funded public health services, a large proportion of the population incurs heavy out-of-pocket (OOP) expenditure on services purchased from the private sector. Figure 1 shows that the OOP expenditure as a proportion of total health expenditure is a very high 61.7 per cent in India as compared to the global average of 20.5 per cent.

The total expenditure on health care in India, including public and private expenditure is broadly comparable to other developing countries at similar levels of per capita income. The total expenditure on health care (both public and private together) is 3.7 per cent of the GDP. Government Health Expenditure as proportion of GDP. However, according to the World Health Statistics 2013, public expenditure on health is very low constituting 28.2 per cent of total health expenditure According to the Government of India's 12th Five Year Plan, public health expenditure in India was only 1.04 per cent of GDP in 2011–12 as compared to the global average of 5.4 per cent.

How can Information and communication technology (ICT) help India to achieve UHC?

ICT innovations in health—or e-health—can help ensure that resources mobilized in the health sector are used more efficiently and effectively. This means reduced waste of resources, maximized coverage, and better quality health care provided at a lower cost.

ICT solutions can also help empower patients and communities to engage at all levels of the health system, as well as efficiently link health systems with important social protection programs.

Some examples of ICT in action include:

Short messaging service (SMS) - The ICT equivalent of the complaint and suggestion box, SMS systems enable a direct feedback link between patients and health authorities, with grievances or suggestions documented instantly and easier to track.

Dashboards - Akin to car dashboards, these visual devices help policy makers and implementing agencies identify programmatic areas in need of improvement.

Dashboards can also be designed to alert concerned bodies about unmet goals or operations that have veered off-course.

According to an e-book by Highmark examining top health care and coverage trends, increasing use of technology and the proliferation of employer-sponsored wellness plans have great potential to improve outcomes.

Geographic information systems (GIS) - These mapping devices are an invaluable means of analyzing UHC inefficiencies. Designed to depict geographically referenced data in a way that helps users visualize relationships, patterns and trends, GIS systems provide accurate information about access to quality health care services with data that is sufficiently granular to expose disparities.

Mobile data collection - Mobile applications can improve the tracking of health conditions in remote populations, enabling fieldworkers to upload data to a central server and then be easily retrieved for analysis.

What are the steps to introduce ICT into health systems?

Know your baseline.

Without ICT gap analysis it is impossible to know what policy and strategic changes need to be made.

Get everyone on board and bring your best team.

Political will and commitment is vital, e.g., through the establishment of an inter-ministerial committee on UHC to advocate for ICT investments in health.

Adapt, adopt, or develop tools.

Rather than reinventing the wheel by, e.g., developing new software or creating a mobile app when a solution already exists, it is better to identify tools available in the market, including technology based on open source software that allow for adaptation. For costlier solutions, joining forces with other agencies can yield economies of scale. Developing customized software and applications should be a last resort.

Commit to UHC, commit to integrated ICT systems.

This requires an ICT framework based on the principles of interoperability, with data sharing under agreed standards so systems and solutions can be interoperable.

Invest in unique ID systems and link CRVS to UHC.

Civil registration and vital statistics (CRVS) systems, whereby all live births result in the allocation and use of an individual unique identifier that remains with a person their whole life, and mortality data that includes the cause of death, are essential data for monitoring the health of the population.

Build institutional readiness and a skilled workforce.

Commitment at the highest level is vital for UHC with ICT, but capacity development is a process that must occur at all levels. Joint learning networks and communities of practice

are essential to share knowledge both nationally and with peers overseas.

Keep data safe and secure.

It can be a delicate balance between data sharing and individual privacy, but the two can both be comfortably accommodated as long as there is a sound policy for data security, privacy, and confidentiality in place. Systems can be set up in such a way that keeps private health information private and ensures data centers are adequately protected so only those that need access to any person's health record have it.

WHAT THE WORLD THINKS

At some point in our lives, we all need to see a doctor. For some, however, getting access to good, affordable health care is a real challenge.

In December, a report from the World Bank and World Health Organization (WHO) stated that at least half of the planet's population was unable to obtain essential health services.

Moreover, the report found that 800 million people spent at least 10 percent of their household budgets on health expenses for themselves, an unwell child or another family member. For nearly 100 million people, those expenses were described as being big enough to push them into "extreme poverty."

People in advanced, industrialized countries are living longer, and chronic disease rates among the elderly are on the rise in part because of lifestyle issues, such as obesity and inadequate exercise.

At the time, the WHO's director general, Tedros Adhanom Ghebreyesus, said it was "completely unacceptable that half the world still lacks coverage for the most essential health services."

He said that a solution existed in the form of universal health coverage, or UHC. Such a system would allow "everyone to obtain the health services they need, when and where they need them, without facing financial hardship."

The U.K.'s take on UHC, the National Health Service (NHS), has been running since 1948. Today, the NHS employs over 1.5 million people, and it's still guided by the three core principles that underpinned its launch — that it should meet the needs of all, be free at the point of delivery, and based on clinical need rather than a person's ability to pay.

As the NHS nears its 70th anniversary in July, efforts are underway to ensure that it continues to innovate. For example, a number of Academic Health Science Networks (AHSNs) have been set up to, in the words of NHS England, "deliver a step-change in the way the NHS identifies, develops and adopts new technologies."

Mike Hannay is chair of the AHSN. "We recognize that it can be really hard to get digital innovations into the NHS," he told CNBC's Nadine Dereza in an interview broadcast this week. "It's a real challenge for everyone."

"The only way that will happen is if there's a real need — too often we see innovations that are solutions looking for problems and what we really need are solutions that address real problems within the system," he added.

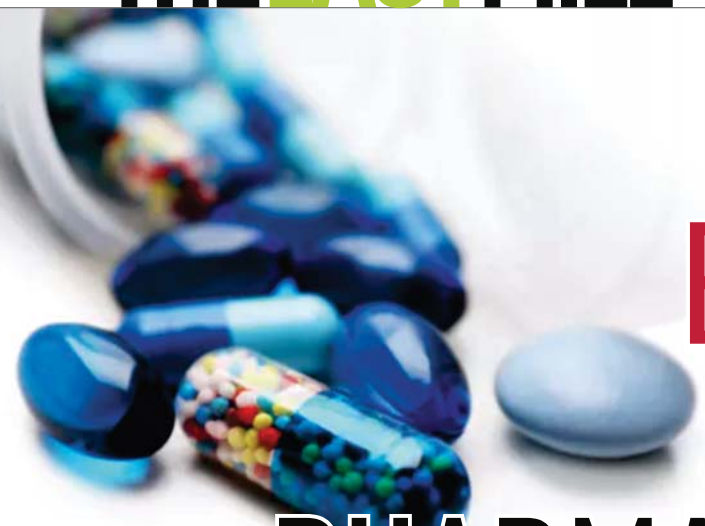
Hannay said that the AHSN often saw itself as a matchmaker, identifying challenges within the NHS and then working with clinicians, system managers and innovators to match problems to solutions.

One scheme looking to introduce new ideas to the health care system is the NHS Innovation Accelerator (NIA), which is delivered in partnership with all 15 of the AHSNs in England. As NHS England puts it, the NIA aims to speed up the uptake of "high-impact innovations for patient, population and NHS staff benefit."

In 2016, the business DrDoctor was chosen as an innovation fellow by the NIA. The company has developed technology that allows patients to view, change and schedule outpatient appointments on their computer, using an app on their smartphone, or via SMS.

"We've built it with patients in mind, and we've talked to people about what matters to them on the day," Tom Whicher, a founder of DrDoctor, told CNBC.

Mike Hannay, chair of the AHSN, described DrDoctor as a fantastic innovation. "It's all about patient-centred care, and making sure we put the patient right at the heart of what we're trying to do. And it drives down the cost of care as well."



ELEMENTS OF DISRUPTIVE PHARMA INNOVATION

"DISRUPTIVE INNOVATION" IS a powerful concept coined by Harvard Business School Professor Clayton Christensen, and has been in play in a variety of industries such as high tech, with the introduction of personal computers and cell phones initially, followed by the mobile internet, the cloud, and the internet of things, as well as in medicine, with the opening of medical clinics, competing with traditional doctor office practices.Disruptive innovation is an innovation that creates a new market and value network and eventually disrupts an existing market and value network, displacing established market-leading firms, products, and alliances

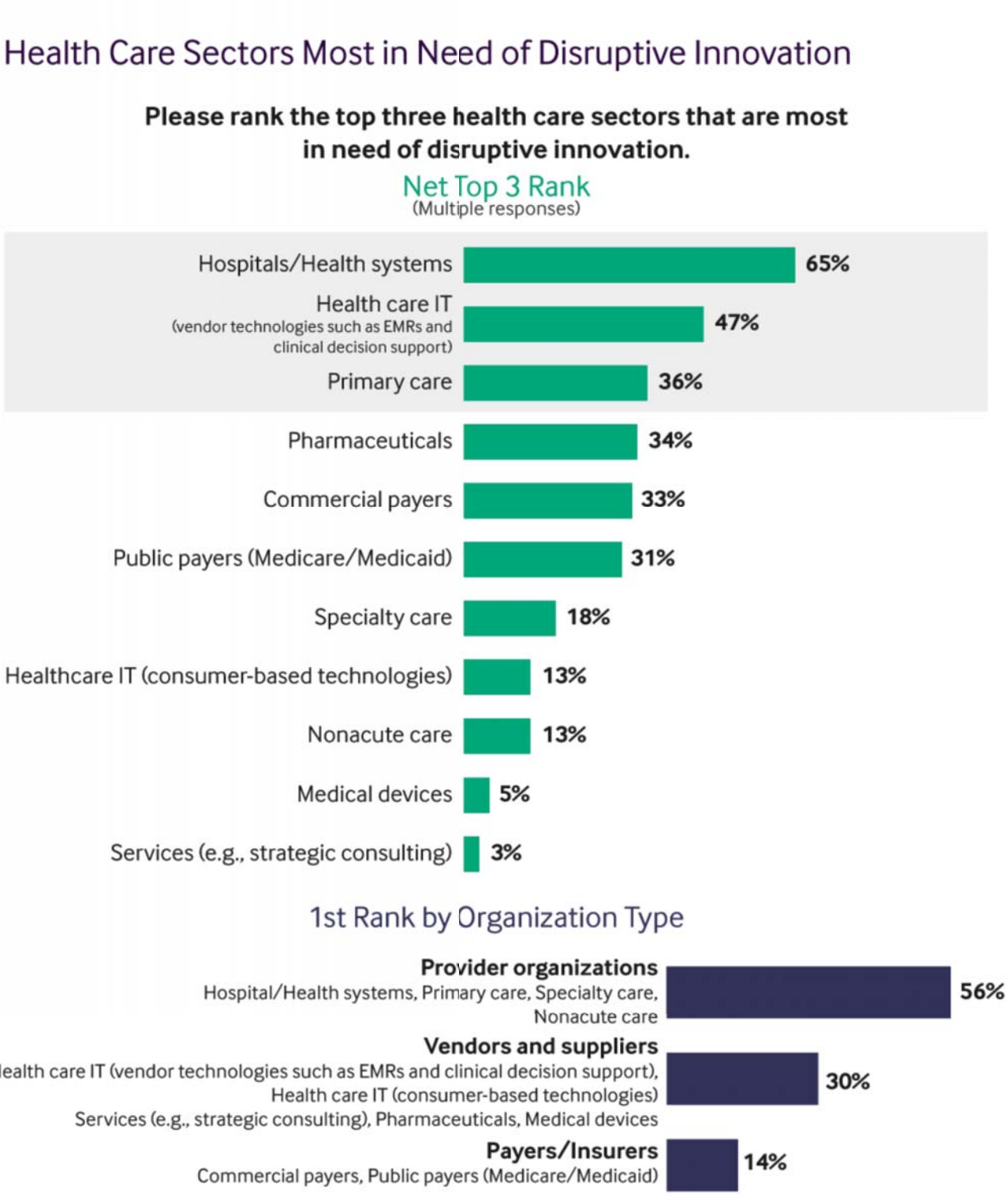
The ability to innovate, industry leaders agree, will be a critical factor in a pharmaceutical company's success in the future. Companies will have to embrace scientific advances and technologies to move new and innovative therapies forward.

Those involved in the drug discovery and development enterprise are open to change in order to achieve greater success, but there are variations in what that change will look like, and the NAM paper describes three very different versions of the future. The first vision suggests that the pharmaceutical industry go as far as shifting its focus entirely to healthcare delivery versus drug discovery and development, given all its accumulated knowledge in patient-centric issues. In turn, this would leave the space wide open for unimpeded innovative disruption of the drug discovery and development enterprise.

The second vision describes a more conventional disruption, that of employing technologies that will be paradigm shifting for medicine and clinical research, while the third addresses the emergence of a new and complex ecosystem arising from a new and innovative business model in the industry. One of the key issues to consider, however, is whether the innovative forces will come from within or outside of the industry (internal versus external disruptors). Considering what is at stake and the scale of the undertaking, it would seem there is room for a variety of industries to bring value to the enterprise.

The flip side of any new paradigm-shifting disruptive innovation is that it could be somewhat disadvantageous to already well-established companies in the industry and generate resistance. However, the introduction of a threat to the continued success of a few established companies may actually have the effect of prompting these companies to join in on the use of disruptive innovation. There is also a great deal of risk to companies choosing to take on innovative and potentially disruptive approaches. But in the spirit of creative approaches, companies find funding solutions and ways to mitigate costs with other enterprises, from government to other private entities and even individuals with available resources.

There is no doubt that disruptive innovation in a variety of industries has met with high levels of success, with the eventual adaptation of the more firmly entrenched companies to this approach. Furthermore, in-kind utilization of disruptive innovation within the pharmaceutical industry, while serving initially as a bane to some of the more well-established companies, could eventually prove to be the panacea urgently needed for greater success in developing therapies to treat and prevent human disease.

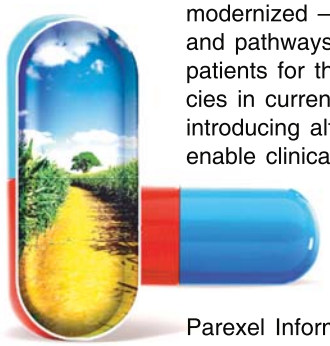

Health Care Sectors Most in Need of Disruptive Innovation
Please rank the top three health care sectors that are most in need of disruptive innovation.
Net Top 3 Rank
(Multiple responses)
Hospitals/Health systems 65%
Health care IT (vendor technologies such as EMRs and clinical decision support) 47%
Primary care 36%
Pharmaceuticals 34%
Commercial payers 33%
Public payers (Medicare/Medicaid) 31%
Specialty care 18%
Healthcare IT (consumer-based technologies) 13%
Nonacute care 13%
Medical devices 5%
Services (e.g., strategic consulting) 3%
1st Rank by Organization Type
Provider organizations
Hospital/Health systems, Primary care, Specialty care, Nonacute care 56%
Vendors and suppliers
Health care IT (vendor technologies such as EMRs and clinical decision support), Health care IT (consumer-based technologies) Services (e.g., strategic consulting), Pharmaceuticals, Medical devices 30%
Payers/Insurers
Commercial payers, Public payers (Medicare/Medicaid) 14%
Base = 519
NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

Pharma leaders believe their companies are enjoying a resurgence in innovation, according to a recent survey by KPMG. In fact, companies surveyed are confident that innovation is on the rise in their organizations, and more than half say they are satisfied with their portfolio's ability to address unmet medical needs. The survey also found that executives believe technology is at the heart of change. The use of data and technology is crucial to capturing and interpreting product information as it passes through the development process.

The industry is experiencing a technology revolution and customer expectations are having huge demands on what is possible, says James Streeter, senior director, life sciences product strategy, Oracle Health Sciences.

"The industry is looking to technology companies to handle all of the variant sources of data, as well as the large amount of data already produced to inform better study design and become more productive and efficient, while rationalizing costs," he says.

Industry leaders also say emerging technology is leading to radical change. Microchip modeling within clinical trials, 3D and 4D anatomical printing, and other sophisticated new and emerging technologies are expected to have the potential to disrupt the current research paradigm.



Challenges Impacting Innovation

With drug development cost estimates reaching between $800 million and $1.2 billion for each product, biopharmaceutical companies are trapped between pressure to reduce development costs and the need to ensure better outcomes and provide enhanced value for patients, all while navigating increasingly complex clinical trials, says Paula Brown Stafford, president of clinical development at Quintiles.

Furthermore, over the last years the amount of money invested in this field has dramatically increased while the number of new chemical entities (NCEs) brought to the market has lagged behind. This situation calls for a careful examination of the reasons accounting for the increase of overall R&D cost as well as for novel ways to optimise the process.

Pharmaceutical drugs form an essential component of the global healthcare system. They are needed even for preventive-prophylactic programmes. But the high price of innovative drugs and the lack of drugs in some important and specific disease areas is perhaps the greatest challenge for these systems.

As our understanding of diseases has become more sophisticated and as diseases have, in some cases, become more complex and difficult to treat due to the combined influences of unhealthy lifestyles, changing global environmental conditions and demographics, and constant exposure to harmful chemicals and infectious agents; and as important variables among the human population which affect both the nature and the experience of disease, such as gender-specificity, ethnicity, age, among others, are taken into consideration for drug discovery and development, there is an ever greater need to find more effective ways to develop drugs.

Unfortunately, achieving this goal is becoming more challenging every day given the increasing complexity of the process, the higher regulatory hurdles for drug approval, and the larger amount of information that needs to be taken into consideration and evaluated during the entire undertaking.

In our consumerist and pharmaco-dependent society, it is expected and demanded to have access to the best possible drugs with the lowest number of side-effects. However, like consumer goods, people get what they pay for. So, it is not surprising that access to the best drugs (for which more investment, capital and otherwise, have been needed) will require the payment of a premium. This, in fact, is becoming a novel trend in the industry

'In addition, companies are faced with incongruent regulatory requirements for drug approval, making it difficult to ensure compliance. We believe these challenges can be addressed — and clinical research modernized — by an equal focus on patients, processes, and pathways. By creating better ways to find the right patients for the right clinical trials, eliminating redundancies in current processes through standardization, and introducing alternative development pathways, we will enable clinical development transformation and help foster innovation across the industry," says Paula.

As disruptive technologies get cheaper, it is important for the industry to work with regulators to secure their approval and adoption," says Xavier Flinois, president of Parexel Informatics.

"The industry must prove to regulators that using these technologies will ensure fair trials and maintain patient safety," he says. "It is also important for individual stakeholders, especially those conducting the trials, to find a way to invest or provide investment capabilities that allow innovation through use of disruptive technologies. Partnerships between sponsors and third parties are essential because they allow for a focus on innovation and R&D spending."

One of the greatest challenges that the biopharmaceutical industry has to face today is the high cost of research and development (R&D). According to recent estimates by the Tufts Center for the Study of Drug Discovery and Development (TCSDD), it takes, on average, more than $2.558 billion (pre-tax, 2013 dollars) and 10-15 years to develop a new drug. Although these exact figures are controversial – and we should bear in mind that the actual expenditure depends on the drug and whether it is developed by a pharmaceutical or a biotech company – it is a fact that drug discovery and development is a very complex, difficult, unpredictable, risky and capital/labour-intensive endeavour.

Artificial Intelligence In The Development Of New Drugs

CUTTING-EDGE TECHNOLOGIES ARE increasingly entering pharma's Research & Development (R&D) processes as the use of Artificial Intelligence (AI) and machine learning in the early stages of drug discovery and development has the potential for various research needs.

Currently, AI and machine learning are two of the most-used buzzwords that are linked to digitization. Almost every industry has involved AI and machine learning technologies in their businesses as they seem to be applicable to every use-case. The possibilities seem limitless, and it looks like we just need to train machines to learn and evolve to enhance production and cost efficiency.

One of the key topics in 2018 is how AI can transform the current pharmaceutical industry. In fact, over the last years, pharma companies have been looking to Artificial Intelligence as a potential tool to help facilitate drug research, reduce development costs and enhance efficiency.

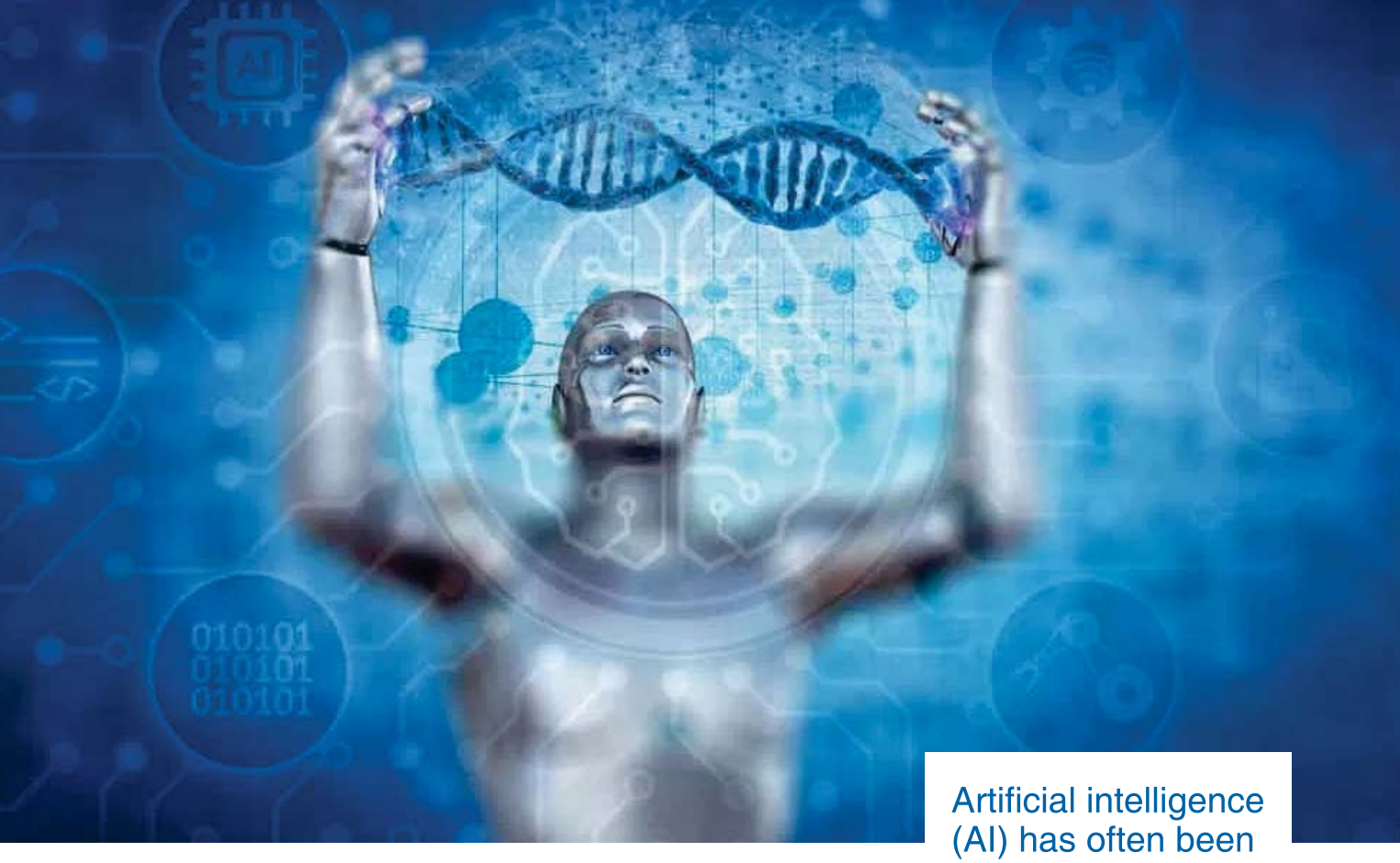
Drug development is becoming more and more inefficient. This can mainly be attributed to large average development costs (around $2b for a new approved treatment), low clinical trial drugs success rate (below 12%), and low ROI because of reduced healthcare expenditure and focus on rare diseases. About 15–20% of the development costs are in the discovery phase; 100s of millions of dollars. Reducing the cost and time of drug discovery and increasing the clinical trial success rate are thus imperative.

Using computer simulations for drug development, also known as in silico screening, design, and testing, have the potential to reduce costs and increase the success of drug pipelines. This idea is however not new. Methods such as homology modelling, molecular docking, quantitative structure-activity relationship modelling, and molecular dynamics simulations have been used since the 90s. But the advent of modern predictive analytic tools has now led to an exponential increase in the power of in silico. Artificial intelligence (AI) has often been used as a buzzword to describe different predictive analytic tools, such as predictive modelling, machine learning, and data mining, under one umbrella.

There is an increasing amount of pharma companies that are investing in artificial intelligence to enhance disease target identification, compound screening, de novo drug design, and potency/toxicity predictions. Currently, the healthcare artificial intelligence market is valued at around $0.7b and is expected to grow at a whopping CAGR of 53%, reaching $8b by 2022.

Drug discovery applications take up the biggest chunk of this market, namely over 35%. Other applications can be found in medical imaging, diagnostics, therapy planning, and hospital workflow. The performance of these predictive tools relies on three key components: the algorithm (i.e., the core infrastructure), the computing power (i.e., the engine), and the data (i.e., the fuel). Apart from cross-pollinating each other, there is rapid advancement in all three of these fronts, leading to un-precedent powerful tools that can be exploited to understand complex diseases and discover advanced treatments.

There is a lot of patient data available such as insurance data, public health data, mobile health data, patient reporting data, omics data, EHR data, familial data, and environmental data. This data does not only give insight into disease and treatment but also supports new



healthcare models such as outcome-based modes and patient-facing services. Data mining is often necessary because about 80% of healthcare data is unstructured. One of the main issues, however, is data protection and privacy. For example, Google DeepMind's agreement with the UK's National Health Service (NHS) to access kidney failure data led to a backlash due to issues with privacy laws. Companies such as IQVIA approach that problem by using vigorous privacy and security measures. IQVIA buys and curates data from pharmacy suppliers and EHR systems. Pharma companies can use their data to optimize their clinical development strategies.

With the advent of the Internet-of-Things (IoT), the amount of patient-specific data will increase at a rapidly accelerating pace. Although data mining will prove challenging, this could lead to an even better understanding of health and disease. IoT health solutions such as clinical-grade biometric sensors, home monitors, and fitness wearables will add to the vast amounts of data that can be used to predict novel disease targets and repurpose drugs.

Proteus Digital Health, for example, uses ingestible sensors on pills to not only track adherence but also track symptoms. Companies such as Quantus and MC10 produce clinical-grade wearable biometric sensors that track various vital signs.

There has been a lot of skepticism in recent years around whether artificial intelligence could deliver on its promise to improve drug development efficiency. It is now fair to say that there is indeed an incredible potential for disease target identification, compound screening, de novo drug design, and clinical prediction using these computational tools. This is not only evident by the increasing amount of technology providers, but also a large amount of adoption and testing by the pharma industry. Notably, BenevolentAI and Johnson & Johnson are taking a drug that was repurposed for sleepiness in Parkinson's disease through machine learning into Phase IIb clinical trials. While dozens of other pharma and biotech companies have already started collaborations with several AI companies aiming to monetize on advances in machine learning and supercomputing, it is important for companies to invest in the correct machine learning technology. Each algorithm has its strengths and weaknesses and is often optimized for specific purposes. With the ever-increasing computational power through supercomputers innovation, novel GPU-based AI accelerators, and elusive quantum computing, the impact of AI on drug development will only increase. We are furthermore only at the start of the data-era. With more and more data pouring in from advanced research (e.g., next-generation sequencing), healthcare digitization, and the Internet-of-Things, more insights will be gained over time. Soon, artificial intelligence will not only perform most parts of drug development — from discovery to clinical trials — but also find disruptive new treatments for complex diseases.

> Artificial intelligence (AI) has often been used as a buzzword to describe different predictive analytic tools, such as predictive modelling, machine learning, and data mining, under one umbrella.

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How Technology Innovation Impacts The Pharma Industry

IN THE PHARMACEUTICAL industry, one has to innovate keeping in mind the Right First Time concept because rewards for success are very high and the failure of innovation is linked to the very survival of the company. For every molecule, filing first for the patent pays a very high dividend.

For a start, the pharmaceutical industry is becoming more consumer-focussed, or rather patient-centric: “As patient well-being plays an ever-increasing role in drug approval, market access and reimbursement, pharmaceutical companies try to involve patients more in all the stages of value creation. New technologies, like artificial intelligence, biosensors and mobile apps provide companies with vast amounts of patient data, enabling more advanced analysis and, as a result, precision medicine, i.e. blockbuster drugs designed for the average patient will be replaced by treatments that take into account individual variations in genes, environment and lifestyle. These digital technologies will also change the firms' value propositions: combining drugs with biosensors that communicate with mobile apps to guide patients is no longer science fiction, and a far cry from just selling pills.”

The pharmaceutical industry is under continuous pressure to discover and develop new drugs targeted toward increasingly complex diseases, which means the industry must use innovative technologies that will help them ramp up research and development, manufacturing and analytical capabilities while enabling them to be competitive and compliant.

Researchers looking to simplify compound identification, quantitation and complex data analysis now have access to a wide range of software and cloud solutions designed to allow them to analyze, share and discover unique insights in several Pharma and drug discovery applications. As domestic and global Pharma multinational corporation (MNC's) increasingly collaborate with research institutes and start-ups to develop solutions in new drug delivery systems and targeted therapies, innovation in technology and laboratories using a Cloud platform are strengthening the way. Researchers and scientists are now able to connect, collect, upload, store, share and analyse data securely and remotely.

Another area of increasing use of automation is the use of robots to move biological or chemical samples

around to synthesize chemistries or to test pharmaceutical value of existing molecules. Laboratory processes are well suited for robotic automation as the processes are composed of repetitive movements and demand precision. Automation is also seeing growing usage in working environments which involve handling of hazardous compounds. With support from technologically advanced and innovative partners, the Pharma industry can shift gears and boost their efficiency and productivity throughout product life cycle.

Information, research and new manufacturing techniques are some of the important drivers of growth for the pharmaceutical industry and theft of such important data can be a real-threat. So, how develop and implement potential security solutions to identify and mitigate such risks?

Intellectual property is the bread and butter of the pharma industry. Therefore, it is imperative to protect the intellectual property using technology. Pharma industries have been using data leak prevention tools in their organisation to secure such data.

How technological advancements have brought in new opportunities for drug manufacturing and to bolster R&D efforts in the sector?

Currently, clinical trials are carried out on subjects. But in near future using Artificial Intelligence the trials may be conducted through simulation models. 3D printing will also help in proper diagnostic and accurate treatment of patients. Recently, new innovations like portable ECG machine that can fit into palm and send the ECG report to your doctor have also gained popularity. This will help patients to have early detection of heart disease.

The major issues linked to the increased usage of cloud computing in the pharmaceutical industry.

Presently, there are some regulatory requirements like the data should be stored within the country and proper backup schedule is acceptable to the data owner. However besides that, there should be more stringent SLAs (service-level agreements) with the vendor with proper exit clause. It should also be ensured that the data is recoverable in the format that you can read at the time of contract termination. Data security is another concern which needs to be looked into.

"Pharmaceutical companies realise the threats and have started to invest in digital healthcare and advanced analytics. As a result, we observe changes in the way those companies operate: how they interact with stakeholders, such as patients and payers, how they design their research and conduct clinical trials, and how they market their drugs," "But not only do technological advancements impact operations, they also change the business models. Or to paraphrase Novartis' new CEO, Vas Narasimhan: technologies enable reimagining Novartis as a medicines and data science company. Now, although the pharmaceutical industry has started to take serious initiatives and its conservative nature is slowly changing, it's still lagging behind other industries in adopting digital technologies."

At the production and packaging level, Pharma companies are leveraging advanced technologies and automation to address challenges such as sample under fill and overfill, detect metal contaminants and other dense foreign objects on the production line. Such solutions help them address the above issues on a running batch, thus reducing their downtime and help protect their brand image.

We live in an age in which technology is moving at a rapid pace, creating new fields and disrupting existing models and processes, and Pharmaceutical industry is no stranger to this. Increasing use of innovative solutions and automation will drive the future of this industry and help to accelerate discovery, enhance productivity and enable regulatory compliance.

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Pharma Gets Social

Social media has moved beyond being a fashionable word to one that is drawing renewed attention from the pharma and healthcare industries. The power of these tools and the impact that they can have not only on brand perception and, effectively, on sales, as well as the increasing interest of the regulators in social media is resulting in this shift. In addition, tools and technology and the growth of the data sciences industry have proven to be powerful enablers. As patient centricity becomes the cynosure of attention, the need to capture their views becomes necessary. Social media brings in a pragmatic component to clinical trials, supporting the world of evidence-based medicine (EBM). Patients themselves want to draw more informed decisions and want to be participants in the decision-making process on how their health is going to be managed.

It has been observed in studies that of the more than 74% of Internet users that engage on social media, 80% are looking for health information,with 90% of the younger media-savvy 18-to-24 year-oldsclaiming that they relied upon this source, using it twice as often as the more senior population. They shared health-related conversations and patient stories on diverse topics such as how someone coped with a chronic condition, views on diet and exercise, and their choice of physician.The most accessed online resources for health-related information included WebMD (56%) and Wikipedia (31%). Patients wanted doctors to actively share updates on the disease, new pipeline compounds, their experience with different drugs, etc., on social media and 60% claimed that they trusted what the doctors were posting.It becomes all the more important for healthcare professionals (HCPs) to share accurate information and timely updates with the patient community. It was not only patients who were leveraging social media, 60% of HCPs were also actively watching what their counterparts are sharing on health-related issues. Doctors themselves seemed to truly believe that social media is impacting the quality of care. Forty percent of patients also relied upon social media to assess how others were dealing with chronic conditions.

7 Ways That Pharmaceutical Companies Are Using Social Listening To Learn From

1. Market research

Social listening has been disrupting the traditional market research model for years and today it is being led increasingly by market researchers in pharmaceutical companies.

For example, one company was able to learn from online conversations among pharmacists dispensing products against generic prescriptions. By studying the language used to describe products, the brand team discovered which issues influenced a pharmacist's interaction with patients and, as a result, was able to choose the right words for customer messaging.

2. Competitive intelligence

The open nature of public social media means that you can learn as much about your competitors' products and services online as you can about your own. By listening to conversations among health stakeholders, you can find out how the messages and tactics of other brands in your therapy area are resonating with customers.

A company launching a product in a new, competitive class of drugs in Europe used social listening to compare customers' views about each of the products in its class across its launch markets. Through online conversations it rapidly learned about competitors' marketing tactics and was able to make informed decisions about its own customer engagement strategy.

3. Digital profiling

Not all social media conversation is equal. Understanding the online influence of individuals can help you decide how to respond to individual voices. In a recent study of 78,000 social media posts during the American Society of Clinical Oncology (ASCO) 2015 Annual Meeting, 230 of the most engaged online healthcare professionals were followed by more than one million people all over the world, of whom almost 40,000 were other healthcare professionals.

Many companies are using social media listening to understand their customers at an individual level, developing digital profiles of named key online influencers or 'Digital Opinion Leaders', which map out their online networks of influence, channel preferences and even brand advocacy behaviours.

4. Targeting rare disease

With billions of social media posts being published every day, social listening can identify and target very specific needs with great accuracy. This presents pharmaceutical companies with the opportunity to learn precisely where doctors are seeing patients with particular symptoms. For companies with medicines to treat rare diseases, the ability to geo-locate symptom conversations enables them to target messages to them anywhere in the world.

5. Clinical trials

Locating patients with particular diseases or symptoms can help identify potential clinical trial candidates. By listening to online conversations, companies developing or testing new medicines can track patient symptoms and also identify healthcare professionals who might support the trial. This approach enables companies to develop tactics for targeting and engaging candidates with other digital initiatives, such as Novartis' online clinical trials tool.

6. Medical Information

While caution still exists over adverse event discovery in social media listening, Medical Information teams in some pharmaceutical companies are using social listening to learn about patient experiences, proactively tracking conversations about product use. By learning from conversations about behaviours, some teams are identifying potential new indications for medicines. Others are using data on side effects to improve their understanding of a medicine's safety.

7. Congress strategy

Today's medical congress meetings take place not only on the ground at a conference venue but all over the world via social media. As one endocrinologist told me, if he could not be at this year's EASD meeting (the annual congress of the European Association for the Study of Diabetes) in person, he would simply take part via social media by following the congress 'hashtag' on Twitter. Indeed, one third of all social media content posted during this year's ASCO congress originated from outside of Chicago where the meeting took place.

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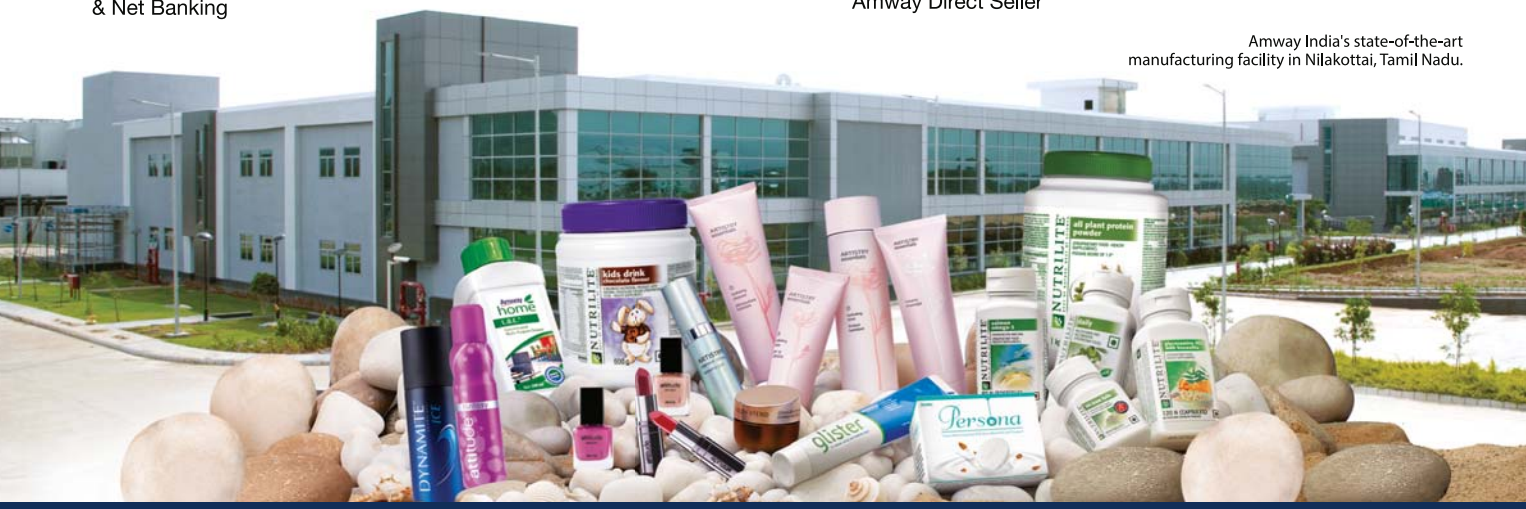

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