Today for tomorrow: realizing the potential of Life Sciences 4.0

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Foreword

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In our last report, *"Life Sciences 4.0: transforming health care in India"*, we discussed how the shift to an empowered patient consumer and the rise of data-driven platforms are reshaping the health care ecosystem in India as well as globally. This report, *"Today for tomorrow: realizing the potential of Life Sciences 4.0"*, explores how the evolving ecosystem is changing the life sciences value chain and creating new opportunities to capture future value through the development of personalized products and services and end-to-end solutions.

The ubiquity of mobile and peer-to-peer sharing tools is transforming consumers into super consumers, who demand convenient and seamless care. Growing awareness has shifted consumers' focus from mere treatment of diseases to its prevention. Wearables and sensors are shifting patient care from hospitals to homes. Telemedicine and online portals are making it possible to deliver personalized healthcare experience.

These changes require that India-based companies proactively shift their business models from supplying commodities to supplying innovations. Life Sciences 4.0 is all about the ability of life sciences companies to strategically evolve from one stage of business maturity to another at the right time and with the right capabilities. Strategic investments made today can help companies grow tomorrow.
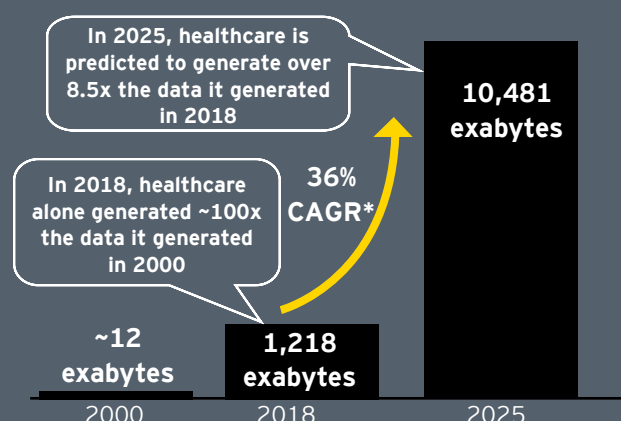
Life sciences companies in India have started taking small, experimental steps towards their 4.0 journey. Currently, activities are fragmented across the value chain.

With the shift in business models, the core expectations of each business function are also shifting. Keeping this transition in mind, there is a need for these companies to simultaneously equip themselves with right capabilities that can be adapted across the value chain. There is a need for companies to create a digital strategy that aligns with their short-term and long-term business goals and accounts for the organization's current talent capabilities and culture. Although the tactics employed at each company may vary, the report features some of the key steps that all companies can follow to successfully begin their transformation.

The digital and scientific advancement in Life Sciences 4.0 is reshaping the entire health care ecosystem globally. Availability of new technologies and abundance of data is altering the way care is delivered. Increasing awareness about disease prevention and management is changing the definition of the value delivered by health care, resulting in a shift in the expectations of all stakeholders. Life sciences companies need to prepare today to remain competitive tomorrow.

This report examines the ramifications for life sciences companies' market offerings and business models. We also explore a practical approach to build future capabilities across the business functions by implementing digital technologies.

Health data explosion***

In 2025, healthcare is predicted to generate over 8.5x the data it generated in 2018

In 2018, healthcare alone generated ~100x the data it generated in 2000

36% CAGR*

10,481 exabytes

~12 exabytes

1,218 exabytes

2000   2018   2025

Companies need to develop **capabilities to harness the power of data**

Number of USFDA-approved AI algorithms
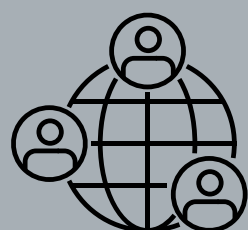
2015   2016   2017   2018   2019
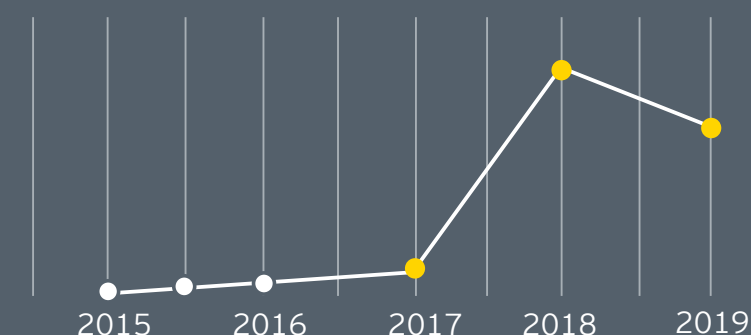
Over 60 algorithms were approved between 2018-2019. Majority of them were for diagnosis or disease monitoring in cardio and neurological therapy areas#.
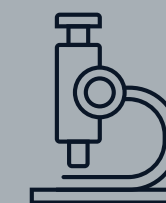
~70% of top 10 biopharma companies now have a chief digital officer#

880%
increase in M&A activity in cell and gene therapy deal totals to US$49 b between 2018-2019 from US$5b between 2014-2015#

The global cell and gene therapy market was valued at US$6b in 2017 and is expected to grow at a CAGR of 22% to reach ~US$36b by 2026

Life sciences M&A deal value was US$370b in 2019,
which broke the record for 2014 (US$335b)#

Top global life sciences incumbents* signed **~500** digital deals between 1 January 2014 to October 2019#

~50% of these deals were aimed at accessing tools and platforms for **virtual care, remote monitoring and improving research** and **development#**

Source: # EY analysis; **Coherent market insights; *** IDC, "The DataAge 2025," November 2018; Wired magazine, May 2019
*Note: Digital deals by top 40 life sciences companies (top 20 biopharma and top 20 medtech companies) from 2014 onwards were screened from various public domain sources. These deals include mergers and acquisitions, joint ventures or alliances and exclude PE/VC funding. Deal value for each year is a sum total of the disclosed values of all the digital deals captured in that year.
CAGR: Compound Annual Growth Rate

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Life Sciences 4.0 is shifting the ecosystem to the next stage of maturity. Where is the Indian pharma industry on its innovation journey?

Macroeconomic factors and Life Sciences 4.0 are transforming the entire healthcare ecosystem

For sustained growth, life sciences companies must embrace new business models

As Indian companies prepare to shift from supplying commodities to supplying innovations, they need to understand how new technologies will transform their business

Evolving health care and pharma market trends

This is an exciting time for the Indian pharma market. Overall industry revenue was US$38 billion in 2018[1] and the country is now the largest provider of generic drugs globally, fulfilling about 40% of the generics demand in the US and roughly 25% of all medicines in the UK. The country is also the supplier of over 50% of global demand for vaccines and 80% of global demand for antiretroviral drugs for Acquired Immune Deficiency Syndrome (AIDS)[2] .

These have been good days for generic companies, but this may be as good as it gets. Even though India's leading position in the generics market has been an important growth driver for most of the top companies, this market is becoming more difficult. Price controls and protectionism are common phenomena across all geographies. Buyer consolidation, intense competition, and increasing regulatory scrutiny are hampering India's dominance in the US generics market. As a result, there are potential pressures on both revenue and margins.

Based on EY survey with 20 leaders in Indian domestic and multi-national pharma companies, executive realize that these challenges can have an impact on their growth. Companies are, therefore, exploring new business models to achieve high sustainable growth.

> "
> The era of 25%-30% margins in generics is a thing of the past. That means innovation will differentiate one player from another.
>
> Strategy head,
> Indian pharma company

Large number of companies are investing in complex generics and innovative drug delivery devices. Most of the top Indian companies are intensifying their efforts to expand their geographic footprint, capture a larger share of the biosimilars market, and increase their presence in specialty and chronic diseases.

Some companies aim to launch the next-generation of innovative products, either through in-licensing the potential blockbusters or increasing their research and development (R&D) investments. For e.g., Alkem recently partnered with a South Korean drug maker, Dong A, for Evogliptin, a new class of a DPP4 inhibitors[3] . Similarly, Aurobindo Pharma completed a US$300 million deal to acquire seven oncology products from US-based firm, Spectrum Pharmaceuticals Inc[4] .

While opportunities to deliver new products grow, the industry is witnessing a boom in digital technologies. Synonymous with the Fourth Industrial Revolution, or Life Sciences 4.0, these digital technologies range from robotics to Internet-of-Things and Artificial Intelligence to analytics. This digital revolution is reshaping the entire health care ecosystem, bringing a set of new challenges and opportunities. There is a need for companies to invest in new capabilities related to customer engagement, personalization and data literacy to capture the future value in the evolving ecosystem. For instance, mobile-based apps have the ability to improve customer engagement, while a combination of wearables and Artificial Intelligence can deliver timely and personalized therapies to promote a lasting behavioral change. These new technologies, coupled with scientific advances, are generating massive amounts of data. These data have the potential to change every facet of health care, including the traditional drug and device business. The key challenge, however, is that the data sets currently reside in siloes in different parts of the ecosystem. For example, life sciences companies hold abundant clinical research data, hospitals store health record and imaging data, laboratories have diagnostic results, and pharmacies have important records of prescription usage. There is a need to integrate these datasets to derive holistic insights that can improve health outcomes. This need to integrate data will result in more partnerships between different health stakeholders in the future.

At present, in certain therapeutic areas such as diabetes, a combination of digital plus traditional life sciences offerings are already having a powerful impact. As early initiatives are scaled across geographies and therapy areas, the ability to improve health outcomes and access and lower costs will only be magnified.

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[1]The Indian pharmaceutical industry – the way forward", IPA, 2019. Available from: https://www.ipa-india.org/static-files/pdf/publications/position-papers/2019/ipa-way-forward.pdf;

[2]Pharmaceuticals", IBEF, October 2019

[3]Alkem partners with Dong A to launch anti-diabetic drug", BioSpectrum Asia, February 2018. Available from: https://www.biospectrumasia.com/news/49/10298/alkem-partners-with-dong-a-to-launch-anti-diabetic-drug.html

[4]Aurobindo acquires 7 oncology drugs from spectrum for $300 million", The Economic Time, January 2019. Available from: https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/aurobindo-acquires-7-oncology-drugs-from-spectrum-for-300-million/articleshow/67581241.cms

Changing role of life sciences companies with the evolution of healthcare ecosystem

As Indian companies prepare to shift from supplying commodities to supplying innovations, they need to understand how new technologies may change their business.

While it is impossible to predict the future, one useful way through which companies can evaluate the impact of a new technology or its capability is using the S-curve. In the early days of availability of technology, its novelty leads to lack of use cases and slow adoption. Once the user adoption grows, the technology also experiences rapid growth. But once the market saturates, growth once again plateaus. This evolution typically lasts 10-20 years (See Figure 1 for additional details).

Globally, technology is affecting all aspects of health care, including the stakeholders of life sciences companies, i.e., physicians, hospitals, payors (insurance providers), policy makers and patients. The drugs and devices are also evolving from traditional pills and bulky devices to digital therapies and self-learning software. As a result, the roles of manufacturers are changing – and so are the products and services expected to create future value.

Social media and smart phones have led to creation of a hyper-connected world, and that has started to change the way people absorb information and interact with each other. The availability of useful information at a person's fingertips has influenced customer behavior and expectations. With the rise of e-commerce, people can get almost everything delivered at their doorstep at the click of a button. This is one of the reasons that people now demand the same experience in health care.

The growing use of online services allow physicians and patients to comfortably access medical information (about drugs and diseases) online. People are now comfortable using wearables and sensors to track their health and fitness. They want to be empowered to make their own health choices using the data that is thus getting generated. In addition, they also expect to receive personalized solutions and services with measurable outcomes. Life sciences companies need to think about how they can engage these informed super consumers with appropriate information and services customized to them.

Figure 1: The S-curve of innovation

The "S-curve" of innovation represents an approach to innovation that can help companies navigate technology disruption. Organizations can use the S-curve to map how innovative their products are and accordingly take decisions to stay ahead of the curve.

Source: Ideagenius
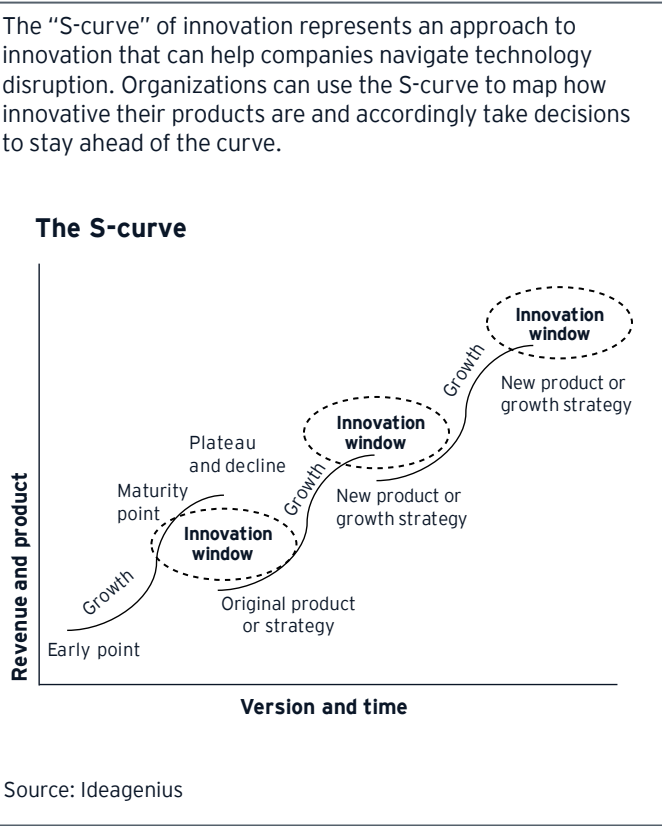
Figure 2: The traditional model of health is evolving rapidly

Source: EY analysis
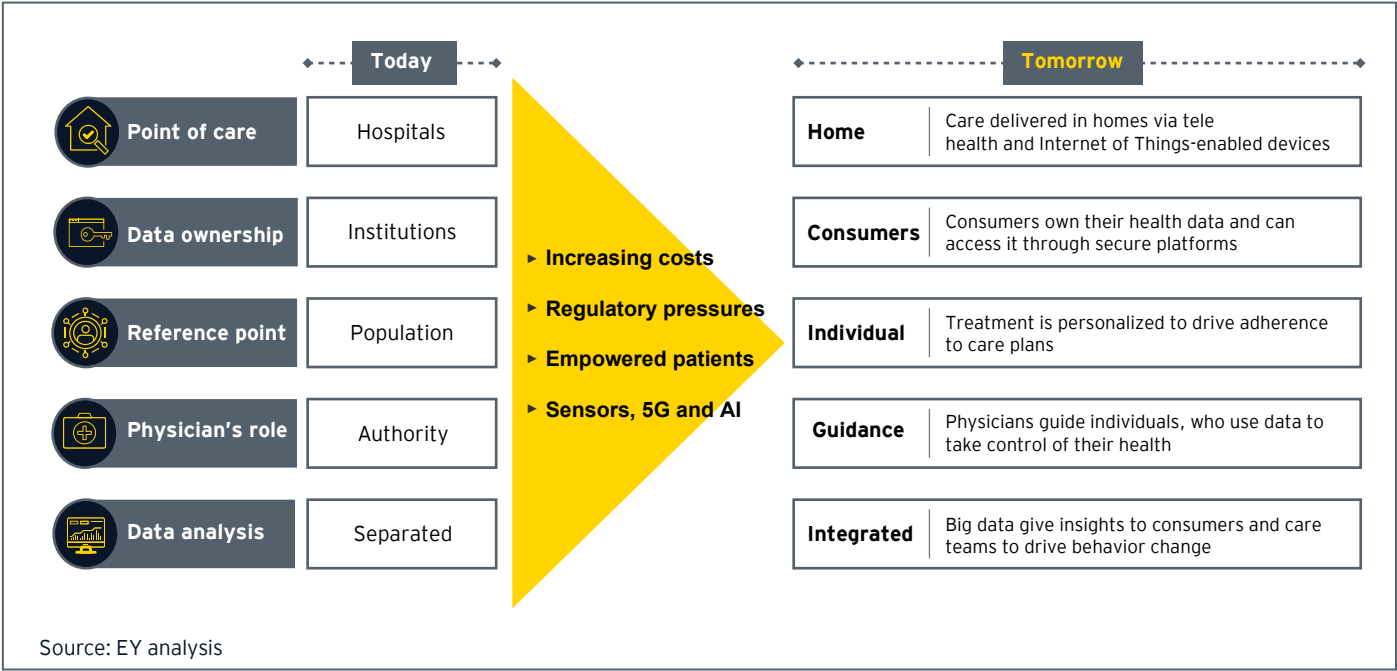
Need for life sciences companies to adopt new business models

Like the disruption in retail, transportation, finance and other industries, technology is fundamentally altering the way health care is imagined and delivered (Figure 2). The combination of smart devices, and sophisticated algorithms has made it possible to remotely diagnose, monitor and treat disease. This is leading to a shift in the health care delivery from hospitals and clinics to patients' homes. Consumers are being empowered to use their data to optimize their own health outcomes – much as they can access and use their own bank accounts. Secured platforms are helping the patients to share their health data with the physicians and care team conveniently.

With the increasing focus on personalization, there is a shift from a one-size-fits-all model of care, where treatments are developed for the entire population to tailor interventions for each patient. This is already a reality in the oncology and rare disease space, where individualized therapies can be made-to-order from a patient's own tissue (see figure 3). Such individualized therapies require new processes that embed the patient in the supply chain. These processes span more than the manufacture and supply of the therapy to how outcomes are measured, and payments are made. The first cell-based gene therapies, Kymriah and Yescarta, were approved in the US in 2017; soon cell and gene therapies will be manufactured and marketed in India as well. Companies need to plan ahead and ensure the entire product value chain is aligned to deliver such innovative individualized therapies in the future.

Figure 3: Operating model of Individualized Cell and Gene Therapies (ICGT)

Pointellis™

Safe, secure and timely individualized cell and gene therapies (ICGT)

23.6m new cancer cases could be diagnosed every year by 2030.

ICGT can dramatically improve patient outcomes and alleviate the burden of cancer and mutation-based diseases.

" 80% of data required is generated from our supply chain and 95% of the entire business needs it.

EY differences

Technology
Our Pointellis offering is designed to be robust, flexible, private and secure — and highly capable to meet the complex challenges of supporting leading-edge cancer care.

Network and partnership
We have a strategic partnership with Microsoft to collaborate on leading technology and processes and we have relationships with payors, providers and government, etc.

Experience
We have extensive cancer treatment experience, we are supply chain and manufacturing professionals and we are strategy consultants.

80% of data required is generated from our supply chain and 95% of the entire business needs it.

Current therapies
(from factory to patient)

Drug manufacturer — Drug distributor — Medical facility — Mass treatment

ICGT
(from patient to factory to patient)

ID patient — Draw and separate blood — Cryopreserve and ship — Manufacture CAR-T therapy — Finalize and ship CAR-T therapy — Receive treatment and prep — Administer treatment — Monitor and follow-up

Culture ↑ Thaw Freeze

The ICGT Digital Ecosphere
The Digital Ecosphere will have a wide range of necessary functional capabilities, information, services, data and analytics to expedite the timely flow of information and materials along the end-to-end value chain. This will enable ICGT to be provided at scale, helping patients receive the timely care they need.

Functional capabilities of the ICGT Digital Ecosphere:

Biometric chain of identity/custody: track and trace biopsy tissue and blood samples from point of care when the patient first enters the system, all the way through medicine administration

‣ Supply chain: allow for enrollment, scheduling, demand and capacity planning as well as coordination of logistics and delivery

‣ Funds allotment: manage the complexities of paying all who are involved with the treatment of a patient

‣ Patient engagement: share appropriate information and keep the patient engaged through the waiting process as well as provide disease management information

‣ Care management: provide those who treat and support critically ill patients with up-to-date information and decision support based on the wealth of data captured through the platform

‣ Health outcomes: measure more accurately and allow providers, health systems, payors and manufacturers to adapt treatment and improve clinical benefit

Data consumers: Patients | HCP | Drug manufacturers | Payors | Regulators | Other consumers

Native and third-party applications | Native stakeholder applications | Chain of custody and chain of identity | Supply chain | Patient engagement | Funds allotment | Care management | Health outcomes

Application programming interface (API)

Pointellis information exchange:
- Cyber protection – data verification and governance – access rights management
- Application programming interface (API) | Analytics and reporting
- Data preparation and reporting
- Data cleansing and standardization
- Data capture adaptors (minimum viable)

Data producers: Health care providers | Leukapheresis centers Genome sequencing | Cyro-preservation

Logistics providers | Manufacturer | Therapy administration | Therapy follow-up

Pointellis
Pointellis will enable and support the ICGT Digital Ecosphere with a secure, seamless information exchange "backbone" to help enable safe and accurate delivery of truly ICGT to patients at the right time and place, every time.

Components of the Pointellis information exchange include:

‣ APIs, middleware and micro-services to connect with the array of systems where data resides and is extracted

‣ A data capture layer to bring in data from sensors and systems

‣ Cross-platform compatibility, with flexible integration and interfaces enabling a broad catalog of future features

‣ Data storage optimized for the immediate functional needs of the Digital Ecosphere as well as new insights

‣ Analytics and reporting to translate data into meaningful insights to support decision-making

‣ Cybersecurity considerations built into a blockchain enabled foundation

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Digital technology is also changing the way treatments are given. Behavioral, economic, social and financial parameters can be used alongside traditional clinical metrics to design innovative solutions that nudge patient-consumers to take actions that are most likely to improve or sustain their health.

With the growth in the number of therapies and their distribution channels, companies need to think about ways to differentiate their offerings to enable patients better manage and prevent diseases and also help physicians treat more patients in individualized ways.

There has also been a shift from disease treatment to better management, and ultimately disease prevention. With increased awareness, people have started realizing the importance of health and wellness. This transition from sick care to well care will be profound. Therefore, companies need to understand how to engage with customers effectively using the right business model so as to intercept their diseases in the initial stages.

Case study in digital innovations for better health

The ICGT supply chain: In this treatment, the physician takes the blood or tissue sample of the patient, which is cryopreserved. It is then sent to the lab for sequencing and manipulation to create a custom therapy. The enhanced cells are shipped back to the treatment center for reinfusion into the patient.

The entire process – from vein to vein – can take few weeks and requires rigorous management to ensure a zero-defect supply chain and quality control. Highly specific nature of the material requires strict handling procedures and documentation at every stage and by every entity involved in the process.

Currently ICGT treats certain forms of cancer and rare diseases. As the science advances, the technology is likely to be used to treat a wider array of indications. EY's global solution, Pointellis™ links the patient, clinic, lab and logistics company while guaranteeing data security. It helps patients to get their individualized treatment quickly and securely.

Questions to ask:

‣ How will you personalize disease management for every person that takes your drug?

‣ As health care becomes more value-focused, how will you deliver, measure and get paid for the outcome of your drug?

‣ As therapies evolve from small molecules to biologics to personalized cell and gene therapies and digital therapeutics, what will be your next revenue stream?

We've already seen the importance of digital technologies in developed geographies and there lies a similar potential in the emerging markets as well. It is the right time for Indian pharma companies to understand where they are on the S-curve and develop strategies to stay ahead of the competition.

Some companies have already taken early steps in this direction. Cipla, for example, acquired a stake in Mumbai-based Wellthy Therapeutics in 2019[5]. Wellthy has developed a digital disease management platform for patients with diabetes and cardiovascular disease. Available in multiple languages, including regional dialects, the platform uses behavioral science, real-world evidence and Artificial Intelligence (AI) to provide real-time monitoring, coaching and advice to patients. It can also provide virtual clinical assistance to doctors.

The stake in Wellthy isn't Cipla's only effort to advance its S-curve. The company has also acquired a stake in the South African company, Brandmed, for its integrated solution to address outcomes and value-based care for patients with chronic lifestyle and non-communicable diseases such as hypertension, high cholesterol or asthma[6]. With these investments, the Indian company is developing capabilities to move from disease treatment to continuous monitoring and wellness.

Impact of delayed technological investments

Across many industries, there are numerous examples of businesses that closed their doors or were acquired because they did not keep pace with changing customer demands. That is one reason the Fortune 500 global list (an annual list published by Fortune that ranks companies by total revenues) is so dynamic. Our analysis suggests the list is only growing more volatile.

Disruption is the new normal. Innovation separates high performers by giving them a competitive edge. Life Sciences 4.0 is about the ability of the life sciences companies to strategically move from one stage of business maturity to the next at the right time and with the right capabilities. In the next chapter, we will discuss how the life sciences companies can leverage the new technologies across the value chain.

> "
> Companies will succeed not only by owning intellectual property, but because they have access to critical data and AI to analyze and drive insights from them. If acted upon, these insights can improve the health care experience, clinical decisions and outcomes.
>
> **Pamela Spence,**
> Global Health Sciences and Wellness Industry Leader

Key consideration for growth

As the industry continues to move in a direction where drug is just a part of overall patient care, what is your strategy to stay ahead on the S-curve?

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[5]Cipla to acquire 11.71% stake in Wellthy Therapeutics", The Economic Times, February 2019. Available from: https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/cipla-to-acquire-11-71-stake-in-wellthy-therapeutics/articleshow/68053804.cms?from=mdr

[6]"CIPLA MEDPRO ACQUIRES A STAKE IN CONNECTED HEALTH COMPANY BRANDMED", Cipla, April 2019, Available from: https://www.cipla.com/press-releases-statements/cipla-medpro-acquires-stake-connected-health-company-brandmed

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How can Indian pharma companies ride the wave of digital and data disruption today to remain relevant tomorrow?

New data-centric technologies can transform the business value chain

Companies are investing in technology to transform the customer experience, operational processes and business models

These investments must serve company's needs today and enable growth tomorrow

Potential of digital and data to reinvent the entire business value chain

As life sciences companies explore new business models, they need to equip themselves with the right capabilities – people, process, data and technology. It is expected that all business functions should be integrated with each other to allow smooth sharing of data and insights. They should operate at optimal efficiency and quality and should be competent to enable the growth of the organization in the future.

Let us now take a closer look at the current and potential future state of different business functions in a typical life sciences company.

▶ Sales and marketing

▶ Operations: research and development (R&D), supply chain and manufacturing (SC&M), quality and compliance (Q&C)

▶ Enabling functions: finance, human resources (HR)

Sales and marketing in 4.0: customer engagement is the key priority in the face of digital economy and changing expectation of the stakeholder ecosystem

Imagine a smartly-dressed medical representative (MR) trying to impress a physician about the benefits of a particular pharmaceutical brand. Then imagine a doctor prescribing the same medication to a patient. This is what a traditional successful sales pitch looks like.

Over the years, this story has changed. In the life sciences industry, product sales have traditionally been driven by constant interaction with doctors. At one time, MRs were the most important source of information for the doctors to learn about drugs. However, most physicians globally, and in India, now rely far less on MRs due to limited availability of time and increasing technology savviness. According to Publicis Worldwide, the average time an MR takes with physicians has decreased to less than 30 seconds per visit[7]. Physicians' are keen to understand about the science behind the drug, and they are comfortable consulting online resources like social streaming channels over conversations with MRs to achieve this objective. Therefore, the industry now needs creative ways to deliver relevant information about their drugs in a more engaging and personalized manner.

Increasing access to internet is also changing end consumers' needs. There is an increase of about 40 million new internet users in India annually[8]. With the convenience of e-commerce, people now prefer online platforms that can be accessed through mobile and web, to meet their daily needs, be it booking a cab, ordering food or conducting financial transactions. Consumers expect the same kinds of services in health care. This shift is redefining the role of the pharma companies and forcing them to play a larger role in disease management, instead of only manufacturing pills.

In health care, online services allow patients to access health-related information at any time of the day, irrespective of their location. This is transforming the consumers into super consumers. Every step, from consulting the doctor to delivery of medicines, can be done online. For e.g., a patient with a fever and sore throat wants to consult a doctor. The patient can book a tele-consult appointment. The physician can guide the patient to take several lab tests, for which results can be shared virtually with the doctor for the diagnosis. The physician can send a prescription for antibiotic to an e-pharmacy, and hours later, the medicine is delivered to the patient's address. Every step of this process is done virtually, giving rise to a digitally-based patient journey.

> "
> Today, with the kind of data that we capture, analytics is getting in through the play of decision-making and marketing function is going from intuition-based to evidence-based, i.e., going from how we feel the product needs to be promoted, to what the doctor wants to listen.
>
> Personalization will be the biggest differentiator, going forward, because physicians don't want to meet a me-too field representative.
>
> So, capability building is important, not just in terms of on-ground field representative, but also what kind of digital marketing activities and how you are doing it."
>
> Senior marketing executive, leading Indian pharma

[7]M. Sharma, "How digital technologies are reshaping pharma marketing in India", Indian Television, September 2019. Available from: https://www.indiantelevision.com/mam/marketing/mam/how-digital-technologies-are-reshaping-pharma-marketing-in-india-190905
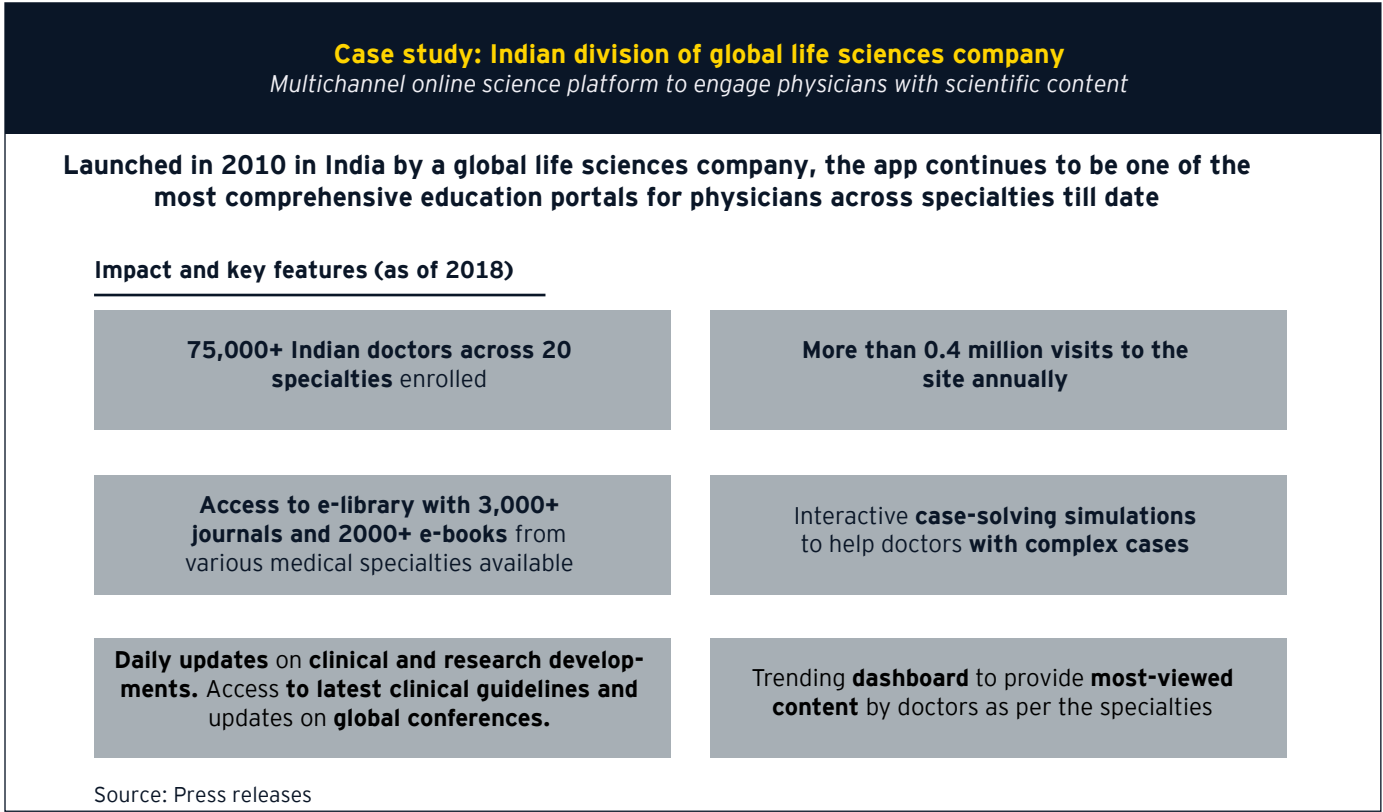
[8]Choudhary, "India adds 40 mn new internet users each year", Hindustan Times, May 2019. Available from: https://www.hindustantimes.com/business-news/india-adds-40-mn-new-internet-users-each-year/story-BjLUWWwS5Jh5TDkydhz8VJ.html

As the importance of e-portals, such as e-pharmacy, teleconsultation, etc. grows, companies should look at innovative ways to partner with them to get closer to the digitally-savvy patients. For example, one pharma leader shared during our survey that their company sponsored blogs on an e-pharmacy start-up portal that helped them reach more than a million patients in the last two years.
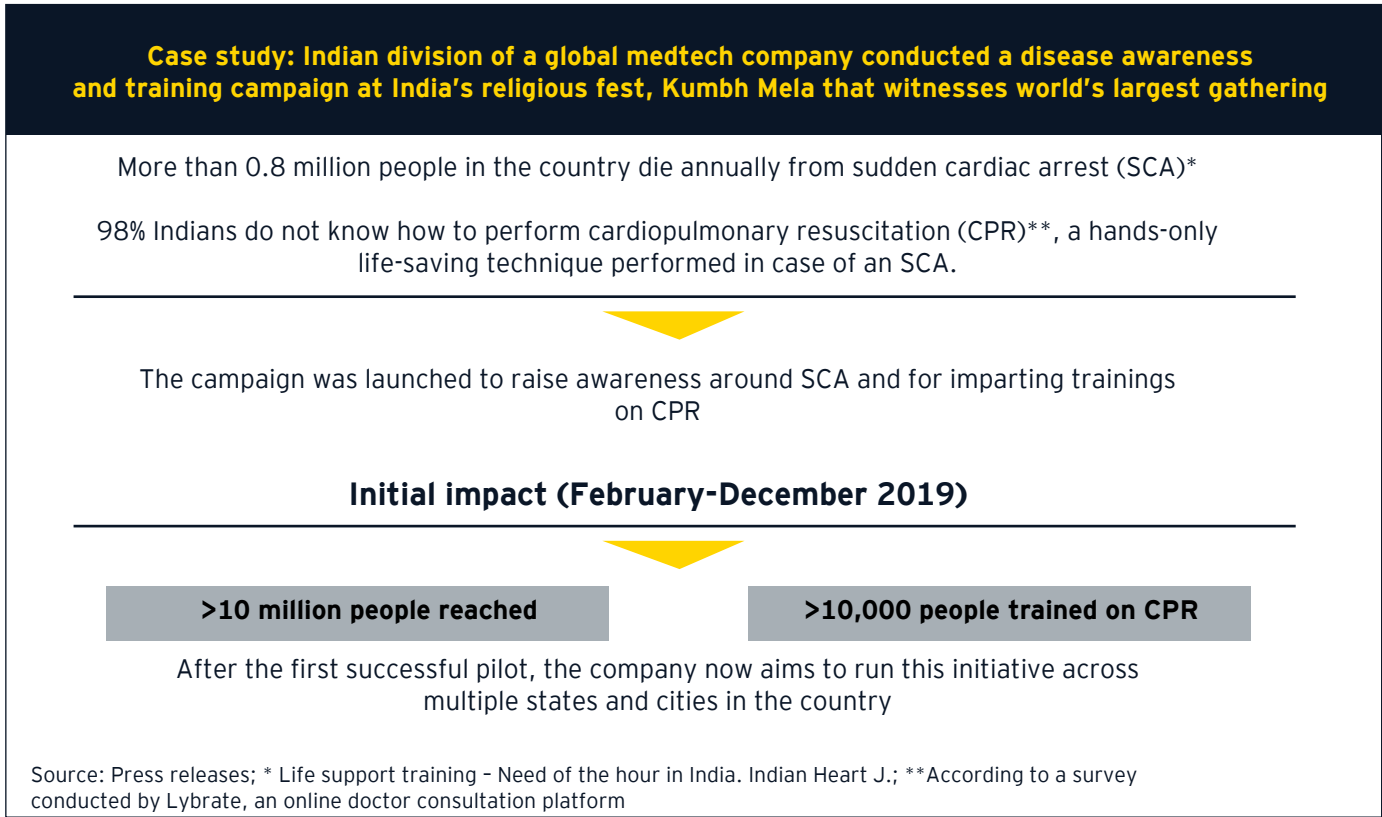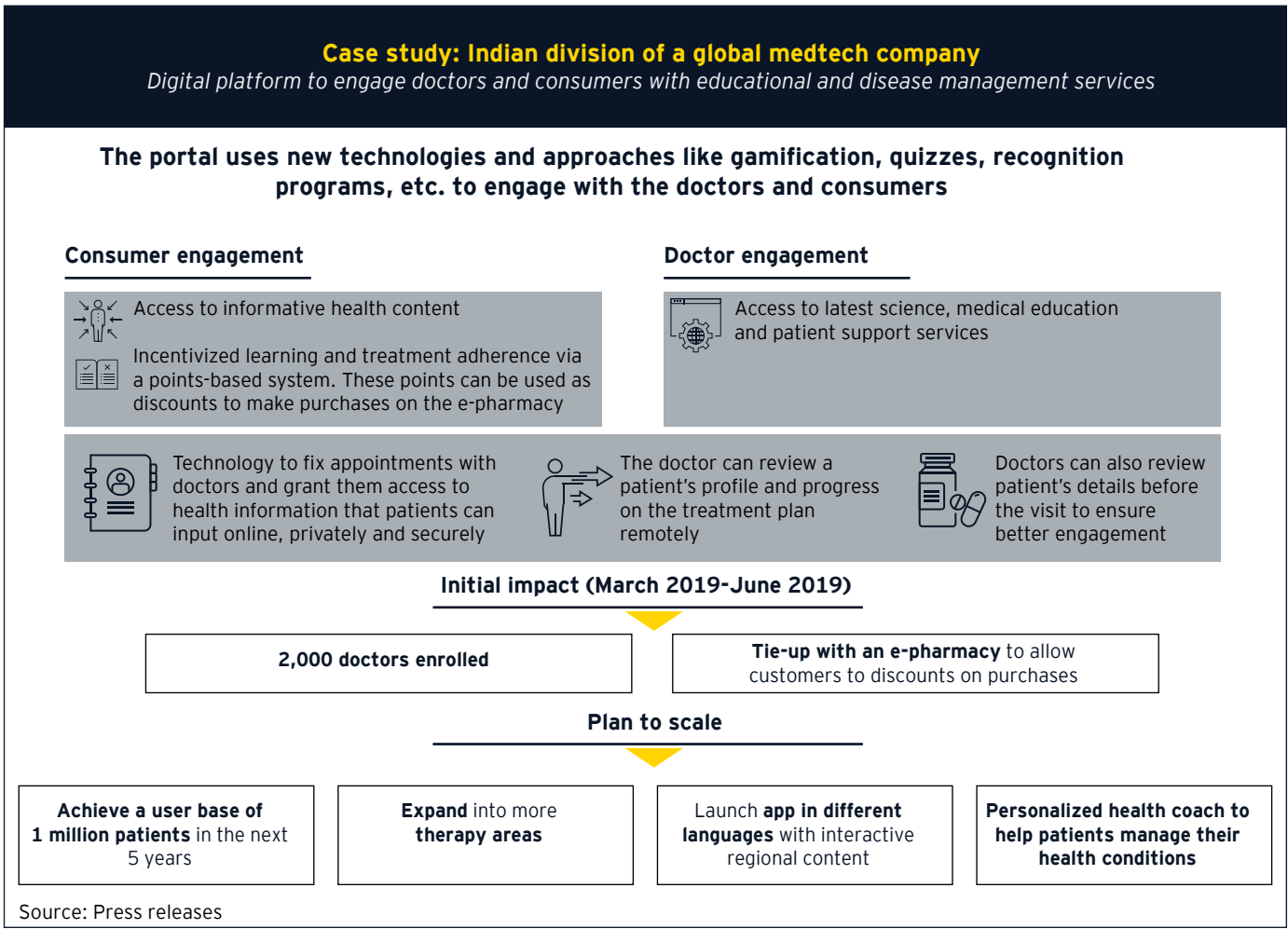
Indian life sciences companies are also experimenting with chat bots and apps to improve customer engagement and creating opportunities for personalized relationship management. These digital initiatives are aimed at increasing engagement with the three key customer segments – physicians, channel partners and patients. A recent report by Zenith indicates that India is the fastest-growing market in healthcare advertising spending, growing at an annual rate of 26%[9]. Companies are connecting with consumers via social networking sites, albeit with low levels of active engagement (see figure 4 some use cases).

> "
> In the pharma sector, customer and consumers have typically been different. In the current digital age, we need better consumer connect.
>
> CIO,
> leading Indian pharma company

Case study: Indian division of global life sciences company
Multichannel online science platform to engage physicians with scientific content

Launched in 2010 in India by a global life sciences company, the app continues to be one of the most comprehensive education portals for physicians across specialties till date

Impact and key features (as of 2018)

75,000+ Indian doctors across 20 specialties enrolled	**More than 0.4 million visits to the site** annually
Access to **e-library with 3,000+ journals and 2000+ e-books** from various medical specialties available	Interactive **case-solving simulations** to help doctors **with complex cases**
Daily updates on **clinical and research developments**. Access **to latest clinical guidelines and** updates on **global conferences.**	Trending **dashboard** to provide **most-viewed content** by doctors as per the specialties

Source: Press releases

[9] M. Sharma, "How digital technologies are reshaping pharma marketing in India", Indian Television, September 2019. Available from: https://www.indiantelevision.com/ mam/marketing/mam/how-digital-technologies-are-reshaping-pharma-marketing-in-india-190905

Case study: Indian division of a global medtech company
Digital platform to engage doctors and consumers with educational and disease management services

The portal uses new technologies and approaches like gamification, quizzes, recognition programs, etc. to engage with the doctors and consumers

Consumer engagement

- Access to informative health content
- Incentivized learning and treatment adherence via a points-based system. These points can be used as discounts to make purchases on the e-pharmacy
- Technology to fix appointments with doctors and grant them access to health information that patients can input online, privately and securely

Doctor engagement

- Access to latest science, medical education and patient support services
- The doctor can review a patient's profile and progress on the treatment plan remotely
- Doctors can also review patient's details before the visit to ensure better engagement

Initial impact (March 2019-June 2019)

2,000 doctors enrolled	**Tie-up with an e-pharmacy** to allow customers to discounts on purchases

Plan to scale

Achieve a user base of **1 million patients** in the next 5 years	**Expand** into more **therapy areas**	Launch app in different **languages** with interactive regional content	**Personalized health coach** to help patients manage their health conditions

Source: Press releases

Case study: Indian division of a global medtech company conducted a disease awareness and training campaign at India's religious fest, Kumbh Mela that witnesses world's largest gathering

More than 0.8 million people in the country die annually from sudden cardiac arrest (SCA)*

98% Indians do not know how to perform cardiopulmonary resuscitation (CPR)**, a hands-only life-saving technique performed in case of an SCA.

The campaign was launched to raise awareness around SCA and for imparting trainings on CPR

Initial impact (February-December 2019)

>10 million people reached	**>10,000 people trained on CPR**

After the first successful pilot, the company now aims to run this initiative across multiple states and cities in the country

Source: Press releases; * Life support training – Need of the hour in India. Indian Heart J.; **According to a survey conducted by Lybrate, an online doctor consultation platform

Walk the Talk

An interview with Udit Batra, CEO of MilliporeSigma

Udit Batra,
CEO of MilliporeSigma

One of the best aspects of my job is the opportunity to sit down with forward-thinking leaders in the life science industry. It's also one of the most challenging. The pressure to move beyond clichés and talking points is immense – and that pressure only grows with the stature of the executive.

I was therefore apprehensive when interviewing Udit Batra, member of the Executive Board of Merck KGaA, Darmstadt, Germany, and CEO of its life science business, MilliporeSigma. Udit is known to be one of the most exciting young leaders in the industry today.

To avoid claustrophobic meeting rooms, we conducted our interview as we strolled across the company's beautiful Peenya, India campus. Coffee in hand, we were literally "walking the talk" or maybe more appropriately "talking the walk!"

Q. What is your vision for MilliporeSigma?

Our purpose is to solve the toughest problems in life science in collaboration with the global scientific community. There are three areas we focus on.

First, given the sheer diversity of approaches that are now available to solve medical problems, we believe that the technologies for drug discovery and manufacturing will change. We have investigated approximately 60 technologies and are now backing about 11 with dedicated teams to further develop ideas used to analyze and manufacture cell and gene therapy products, for single proteins and for anti-body drug conjugates, to name a few.

Second, not only are we training our teams in the use of data and advanced machine learning techniques, but we are applying many of the latest approaches to our e-Commerce channel because we believe it can also serve as a collaboration platform.

Third, we deeply believe in a "seamless world." There is a lot to learn from the success of vaccination programs in Brazil, the application of digital technologies in China and the services in India before potentially rolling those out to the rest of the world.

Q. What is your vision for India?

When thinking about India, there are three parts to consider.

One part is "Service" – the IT Centre of Excellence in Bengaluru, with 600 professionals, has helped us diversify small and large IT applications, which we used to outsource.

Sigma-Aldrich had also built a shared service centre in Bangalore with 400 people. It is not just about doing transactional work such as finance and accounts but also regulatory filing using robotics. Competitive intelligence is centred around India. Lots of support functions for global success, like customer service, are based in India.

The second part is "Products" – 80 percent of the products produced from the life science plant in Peenya are for export. We are making components for bioreactors and mixers and these are the fastest-selling products in the fastest-growing market. These "made in India" products form a significant part of the supply chain.

Thirdly, considering there are incredible engineers coming out of India and given that there are stated ambitions to lead in many spaces, we have set up a number of application labs. For example, India is one of the nine countries where we have set up an M Lab™ Collaboration Centre. The M Lab™ is a real-time customer experience application lab showcasing instruments such as chromatography, filters, etc.

Q. Given the industry's larger push to adopt digital, how does the company aim to thrive in this brave new world?

First, we are the leading player for e-Commerce – in the life science world. From an India perspective, our rate is 1%, which is our average penetration rate. How can we create a better experience? We have already set up a collaboration with Alibaba, starting a flagship store on 1688.com in China, and, if all goes well, we would consider replicating elsewhere.

Second, we must have the analytics to solve problems. Digitization is not for the heck of it but for using advanced analytics to problem-solve. Customer analytics have been able to bring meaningful change in the sales trajectory of products.

Third, we must leverage software as a product and innovative business model. For example, we came up with a lab notebook, an application which is helping to track lab data. We would not have been able to do that had we not thought like a start-up as part of our "Promise Ventures" initiative.

Patients are increasingly using digital tools, including wearables, to monitor and manage their health. The number of wellness coaches, yoga instructors and nutrition experts with massive online followings via apps or other social channels has increased. The number of health apps alone is astonishing. By one estimate, there were more than 60,000 such apps on the Indian Android and iPhone Operating System (iOS) play stores as of January 2019[10]. As these new types of health influencers play an increasingly important role in helping people manage their health, companies need to think how they can engage with them.

The contract development and manufacturing organization (CDMOs) and clinical research organization (CROs) are also investing in digital capabilities to provide service excellence to customers. They are training all employees on the importance of customer centricity (see figure 4 some use cases).

Revamping the traditional sales force to improve its effectiveness

This strategic priority is about investing in the backbone of pharma sales, i.e., medical representatives (MRs). Life sciences companies in India are equipping their field force to meet the demands of today's hyper-connected world. These initiatives are aimed at fulfilling two primary objectives, namely, increasing efficiency and skill improvement.

The increasing number of representatives and brands has reduced access to time-strapped physicians. Thus, commanding a high share of voice via face-to-face meetings is becoming increasingly difficult. Life sciences companies are equipping their salesforce with digital tools such as iPads, activity planning and reporting portals to help them plan their field days more effectively. They are also providing virtual assistants to help resolve physicians' queries live.

To compete, sales representatives must also be more responsive to physicians' demands, and adept to meet their changing needs. Traditional classroom-based methods on disbursing information on products and diseases to technologically-sophisticated methods such as customized online training platforms may help sales representatives to achieve this goal. Life sciences companies are also providing training to sales representatives on soft skills pertaining to interpersonal communication. (see figure 4).

> "
> Customer centricity is about enabling your field force with the technology to build deeper relationships with their customers.
>
> We are evaluating a tool that will give specific pointers to the MRs about physicians' preferences and suggestions on what should be promoted.
>
> Head HR and strategy,
> leading Indian pharma company

Figure 4: Indian life sciences companies moving towards personalized engagement with internal and external stakeholders

Business priorities		Initiatives		
		Mainstream*	Recent	Emerging
Improving customer engagement	Doctor engagement	‣ Websites, webinars, e-mails	‣ Mobile apps on disease awareness and education ‣ HCP portals provide access to global journals and videos curated by experts	‣ Personalized content based on behavioral analytics
	Patient engagement	‣ Conducting disease awareness campaigns on specific days	‣ Mobile apps on creating awareness about diseases, educating the masses and ways to manage them ‣ Predictive modelling to ascertain online search patterns for targeted marketing	‣ Chatbots for answering patients' queries
	Retailer engagement			‣ Sharing knowledge on drugs and diseases as well as on other business specific topics, for e.g., on banned drug policies or drug return policies
	Customer service		‣ Automated end-to-end customer interaction portals ‣ Order-to-delivery project management software ‣ Interactive CRM tools and apps for seamless information sharing	
Improving sales force effectiveness	Increasing efficiency	‣ Access to laptops and iPads. e-detailing	‣ Planning and reporting tools for medical representatives	‣ Chatbots and virtual assistants to answer the queries of MR/doctor at the time of detailing
	Employee training	‣ Classroom sessions on products, disease, detailing, customer centricity, etc.	‣ Management and technical programs delivered via interactive online learning platforms and classroom sessions	‣ Online platform for customized on-the-go training needs

Mainstream: in use by Indian companies for long; Recent: adopted by digital leaders; Emerging: small scale pilots
Disclaimer: the list of initiatives is not exhaustive

Source: EY analysis
HCP: healthcare provider; CRM: Customer Relationship Management; MR: medical representative

[10]A. Ahaskar, "Health apps are getting doctors to your smartphones and doorsteps in India", Live Mint, January 2019. Available from: https://www.livemint.com/technology/apps/health-apps-are-getting-doctors-to-your-smartphones-and-doorsteps-in-india-1548949818374.html

Role of advanced technologies in making sales and marketing more customer-centric

Artificial Intelligence
- Maximize productivity of medical reps
- Develop digital assistants (chatbots) to address questions of patient and physician
- *Enable customized physician and patient engagement*

Augmented Reality and Virtual Reality
- Educate patients and physicians
- Train medical representatives
- *Provide immersive experience using mixed reality and increased brand differentiation*
- *Create virtual care companions*

Wearables and sensors
- Capture real-world data to demonstrate and understand customer behavior
- Enable monitoring and sharing of data, remotely
- *Provide preventive care by continuous and passive monitoring*

Digital therapeutics
- Assist in disease diagnosis, management and treatment
- Use gamification to encourage behavioral change
- *Used as a standalone therapy*

Online platforms
- Educate patients and physicians
- Identify patient influencers/micro-influencers
- Create patient communities
- *Enable bi-directional sharing of information*

Today: already in use
Tomorrow: evidence of initial use cases and expected to become commonplace in near future

Source: EY analysis
This list is indicative and not exhaustive

Key consideration for growth

How will your company refocus and readjust its sales and marketing practices to meet the needs of super consumers?

?

Operations

Similar to the sales and marketing function, research and development (R&D), supply chain and manufacturing (SC&M) as well as quality and compliance (Q&C) functions are also being disrupted by the advanced technologies in Life Sciences 4.0.

R&D in 4.0: redefining innovation by leveraging disruptive technology while maintaining a risk-optimized approach

The Indian pharma industry has already embarked on its journey toward launching innovator molecules. Almost all top companies are gradually stepping up the product value chain, which is reflected in their recent R&D spend and focus areas. As per EY's analysis, the average R&D spend by some of the top Indian pharma companies increased from 5.9% of sales in FY10 to about 8.8% during FY18.

> The first lever that you press when you want to change the business model is R&D.
>
> Senior official,
> leading Indian pharma company

> Going forward, it will be a differentiated drug delivery system or a differentiated molecule that will help businesses grow.
>
> Strategy head,
> leading Indian pharma company

R&D spending of top Indian pharma companies (in INR million)

Company	FY10	FY18	FY10 %	FY18 %
Sun Pharma	2,242	22,489	6%	8%
Lupin	4,119	18,510	8%	12%
Dr. Reddy's Lab	3,793	18,265	5%	13%
Cipla	2,627	10,740	5%	7%
Zydus Cadila	2,075	6,900	6%	6%
Aurobindo Pharma	1,015	6,665	3%	4%
Torrent	1,196	3,693	6%	6%

Legend: FY10 | FY18 | R&D spending as a percentage of revenue from operations

Source: Companies' annual reports and EY analysis
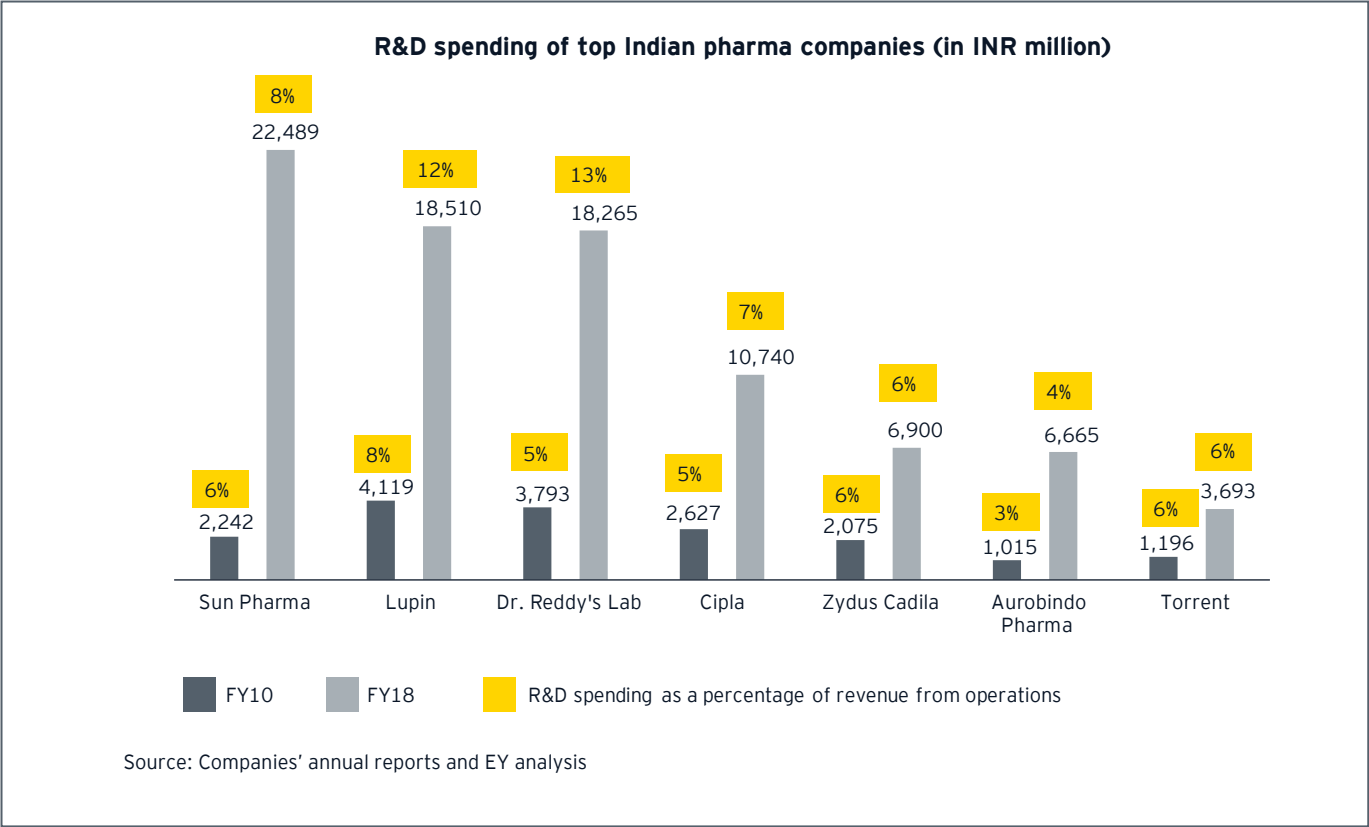
Emerging R&D models offering growth opportunities

Indian companies are currently involved in the following types of R&D models:

‣ Generics : R&D in generics has been a traditional focus area for a majority of India-based pharma companies.

‣ Complex generics, biosimilars, and specialty products: this is an emerging model. This category includes R&D in biosimilars and drug delivery innovations. This category is expected to bring sustained growth as the margins from vanilla generics go down. Companies are also focusing their research efforts on chronic diseases.

‣ New chemical entities: this category is popular among most leading multi-national pharma companies. Indian companies are beginning to improve their in-house novel drug development with the aim of launching new blockbusters.

Biosimilars now has low market penetration in India, but it is expected to improve due to rise in disposable income and consumer demand, and its acceptance among physicians. As companies increase their biosimilars pipelines, India is likely to capture about 8% of the global US$62 billion biosimilar market by 2025. In Indian context, biosimilars will constitute ~7% of the total pharma market by 2025[11]. Companies are undertaking both organic and inorganic routes to capture this lucrative market. Biocon, in 2019, earned INR15.2 billion or nearly 28% of its overall revenue from biosimilars[12] .

Developing new chemical entities puts the Indian companies in direct competition with global innovators. Zydus and Glenmark, as well as some of the large clinical research organizations (CROs) and contract development and manufacturing organizations (CDMOs) are already engaged in the research for new drugs.

About 30% (400 out of 1,200) of the scientists in Zydus are involved in new chemical entity (NME) research under its dedicated research arm, Zydus Research Centre[13] . In addition to launching innovative drugs, the company is also strategically focusing on drug repurposing. The company launched India's first indigenously discovered and developed NCE, Lipaglyn,

for type II diabetes in 2013. Since then, the company has continuously researched on Lipaglyn's usage in other indications, including non-alcoholic steatohepatitis (NASH), non-alcoholic fatty liver disease (NAFLD) and primary biliary cholangitis (PBC).

No matter which model Indian companies choose to invest, it is now critical that they use new technologies to improve the probability of success and efficiency as measured by R&D timelines and costs.

Role of technologies in refining R&D processes

Digital technologies such as Artificial Intelligence (AI) and Machine Learning (ML) have the potential to radically transform core drug discovery and development models, increase productivity and reduce overall R&D timelines. To achieve this transformation, global pharma companies are either partnering with health tech start-ups and academia or developing their in-house capabilities.

However, to harness these opportunities, companies are required to build new capabilities in the following areas:

1. Patient centricity: conducting faster patient-centric trials by engaging patients as R&D partners.

2. Data literacy: using data to design better clinical trials and streamline operations

3. Risk optimization: adopting risk-based methodologies to enhance quality and safety.

Virtual tools are also helping companies to map real-time data. In clinical trials, new software tools promise to reduce the complexity and costs of these studies. Remote monitoring solutions, for instance, bring clinical trial to patients, creating the possibility of virtual or site-less clinical trials.

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[11] "MARKET ANALYSIS & SEGMENT FORECAST FROM 2014 TO 2025", Grand View Research, 2018; "INDIA'S NATIONAL HEALTH PROTECTION SCHEME:AYUSHMAN BHARAT", SKP Group, 2019

[12] R. Shinde and D. Rajagopal, "Understanding the biosimilars opportunity for India", Economic Times, May 2019. Available from: https://economictimes.indiatimes.com/markets/stocks/news/understanding-the-biosimilars-opportunity-for-indian-pharma/articleshow/69335230.cms

[13] "Lipaglyn", Zydus, Available from: http://www.lipaglyn.com/about_zydus.html

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The majority of investments in R&D are done to accelerate the entire R&D process. It involves reducing the entire development time and gaining competitive advantage by bringing the drug to market more quickly.

Another important aspect of drug discovery and development division is that you have multiple choices. How do you ensure that you have a higher success rate or a better strike rate from the investments that you are making? This is where data analytics can play a significant role."

CIO,
leading Indian pharma company

These virtual trials are estimated to cost less than half as much per patient as traditional clinical trials. Other benefits include, increased recruitment rates and diversity as greater conveniences result in enhanced participation. Virtual trials also make it possible to collect a huge amount of patient data. For instance, in regular clinical trials, patient reported data is mostly collected when the patient comes to the site. However, in virtual trials, sensors and remote monitoring help the sponsor to collect data passively for the entire duration of the trial. It also increases patient adherence by allowing real-time tracking of progress and sending reminders to the patient, its family or caregivers about the treatment protocol. This reduces the potential for confounding trial data due to non-compliance.

Additionally, the use of real-world evidence (RWE) in clinical trials is accelerating. Sources such as patient registries, claims data and patient reported data are being used to inform clinical trial design, regulatory approvals and reimbursement decisions. Technologies such as wearables, smart phones and connected devices are important sources to capture this real-world data capture.

Redesigning R&D workbench for a leading specialty pharma company

Type of company

‣ A leading generic and specialty pharmaceutical company has manufacturing presence in India, Brazil and other Asian countries. The company has significant sales presence in the US, Europe, emerging markets and in India. The products to be launched by the company has increased manifold.

Requirement

‣ To attain sustainable, cost-effective transformational R&D processes that support emerging business models.

‣ To establish new product development systems to manage increase in scale and complexity.

‣ To implement new product launches and reduce launch timelines.

Solution provided

EY engaged with the client to provide the following:

‣ Designed and built a digital a digital tool to manage the new product launch process.

‣ Identified distinct propositions and value differentiators.

‣ Designed operating models across the business units involved in the new product development and implementation processes.

‣ Developed a roadmap with timelines and project control mechanisms.

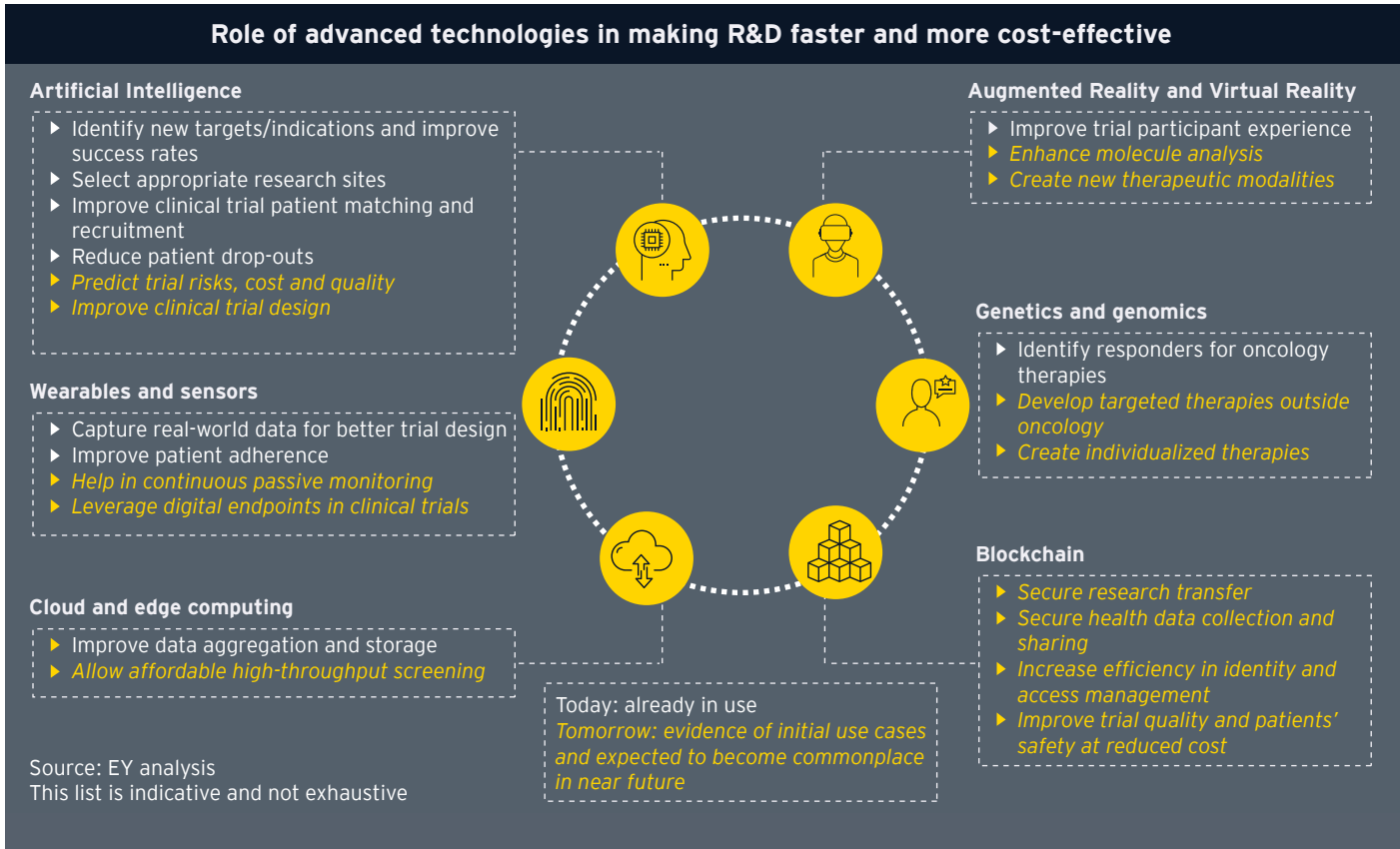‣ Automated project tracking and review mechanism to enable a virtual workforce in R&D functions.

Client's outcome

1 Reduction in new product launch (NPS) timelines

2 Integrated stakeholder management system

3 Better management of risks, costs, resources and timelines for critical launches

4 Digital solutions for new product launches

Role of advanced technologies in making R&D faster and more cost-effective

Artificial Intelligence

- Identify new targets/indications and improve success rates
- Select appropriate research sites
- Improve clinical trial patient matching and recruitment
- Reduce patient drop-outs
- *Predict trial risks, cost and quality*
- *Improve clinical trial design*

Wearables and sensors

- Capture real-world data for better trial design
- Improve patient adherence
- *Help in continuous passive monitoring*
- *Leverage digital endpoints in clinical trials*

Cloud and edge computing

- Improve data aggregation and storage
- *Allow affordable high-throughput screening*

Source: EY analysis
This list is indicative and not exhaustive

Augmented Reality and Virtual Reality

- Improve trial participant experience
- *Enhance molecule analysis*
- *Create new therapeutic modalities*

Genetics and genomics

- Identify responders for oncology therapies
- *Develop targeted therapies outside oncology*
- *Create individualized therapies*

Blockchain

- *Secure research transfer*
- *Secure health data collection and sharing*
- *Increase efficiency in identity and access management*
- *Improve trial quality and patients' safety at reduced cost*

Today: already in use
Tomorrow: evidence of initial use cases and expected to become commonplace in near future

Key consideration for growth

How can life sciences companies build platform capabilities to capture emerging opportunities in Life Sciences 4.0 for drug development?

?

Manufacturing and supply chain in 4.0: transitioning from manual processes to patient-centric agile systems

Most Indian pharma companies employ conventional systems for manufacturing and supply chain planning. However, the shift toward Life Sciences 4.0 is beginning to change their mindsets. Companies now realize that everyday factory equipment, people and processes must grow smarter, and supply chains need to evolve to be more resilient and globally integrated.

The Indian pharma industry boasts of a strong network of 10,500 manufacturing sites. However, most of these plants use traditional batch manufacturing processes resulting in longer production times and increased chances of error due to high human intervention. Inefficient manufacturing costs the industry millions of dollars every year according to an industry benchmarking report. Effective utilization is an area for improvement, which can alter the way companies avoid unnecessary capex.

Overall, the average drug manufacturing utilization rate in India is roughly 75%[14](across both API and formulation production facilities). This means 25% of capacity goes unused due to the inherent variability in processes. Other common factors that lead to inefficient utilization of capacity include high changeover times between different batches and products, ineffective scheduling and machine breakdowns. There is a strong need to analyze the bottlenecks on capacity and invest in solutions to target these bottlenecks and minimize capital expenditure (capex).

As per EY estimates, on an average, ~15%-20% capacity can be released through initiatives such as reducing cycle time variability, quality check turn-around time (QC TAT), changeover, lead times, etc.

Capacity utilization at Indian API and formulation plants

75% utilization with 25% inherent cycle time variability

- Total hours in a month: 100%
- Total occupied hours: 25%
- Batch-to-batch changeover: 13%
- Product-to-product changeover: 7%
- Productive maintenance + breakdown: 2%
- Equipment waiting time: 3%

Source: EY analysis
API: active pharmaceutical ingredient

[14]P. Kumari, "The API paradox of India's pharmaceutical industry", Trade Promotion Council of India, June 2019. Available from: https://www.tpci.in/blogs/the-api-paradox-of-indias-pharmaceutical-industry/

Pilot for improving the overall equipment efficiency (OEE) for a leading global generic company

Type of company
- A leading generic and specialty pharmaceutical company, headquartered in India, has significant sales presence in the US, Europe, emerging markets and India.

Requirement
- Granulation, compression and packing can contribute to high production loss, availability (manufacturing time) loss, performance (manufacturing speed) loss and quality (scrap or rework) loss. It may also be difficult to correctly track micro steps.

Solution provided
EY engaged with the client to provide the following:
- Designed the architecture of machine integration to capture the required data.
- Setup an on-premise/cloud solution and an alarm management system to efficiently monitor the OEE data in real-time.
- Created a dashboard to visualize the performance of the line, train client's team members on root cause analysis so as to take corrective actions.
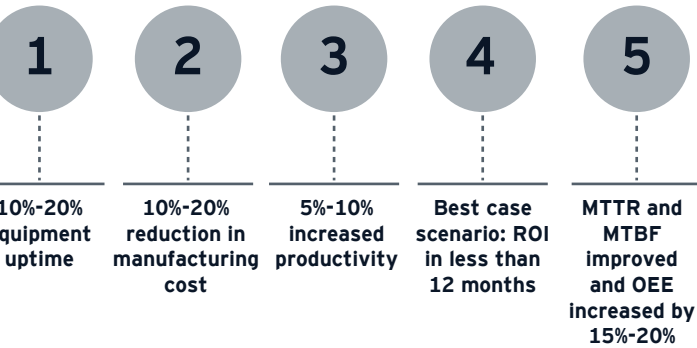
ROI: return on investment; MTTR: mean time to repair, MTBF: mean time between failures

Client's outcome

1. 10%-20% equipment uptime
2. 10%-20% reduction in manufacturing cost
3. 5%-10% increased productivity
4. Best case scenario: ROI in less than 12 months
5. MTTR and MTBF improved and OEE increased by 15%-20%

The supply chain also faces similar efficiency and serviceability challenges. Companies spend a significant portion of their revenue on transportation. Traditionally, companies have maintained high just-in-case inventories to prevent stoppage in the production cycle and loss of business through stockouts, and to meet urgent unforeseen demands. But these safeguards result in high cost. In most cases, it is difficult to monitor order-management in real-time. Demand and supply planning requires extensive and frequent manual intervention. Planning is mostly based on historical data trends and market intelligence, even though the health care market faces considerable demand variability due to a number of factors. These include how products are purchased (e.g., government tendering process), the impact of environmental conditions (e.g., linkage between air quality and respiratory disease) unpredictable transmission (e.g., seasonal flu) or changes in the competitive landscape (e.g., plant closures or openings of competitors).

"There is need for exility – efficiency with agility.

Consider an unexpected opportunity in the US market due to regulatory actions at another firm. In this situation, the company that is able to supply the product the fastest is more likely to win the bid vs. the company with the lowest cost. Hence, agility is critical.

Efficiency is also extremely important. Are you able to build plants that can do more with less? Are you able to churn out more throughput from your plant with less footprint? Are you able to reduce manpower? Efficiency will mean better yields and lower cost."

Manufacturing head,
leading Indian pharma company

India's distribution system is extremely fragmented, which also adds to the challenge. Based on the interviews with executives, most of the large Indian pharma companies have about 10,000 distributors. The number of retail pharmacies has increased from 125,000 in 1978 to about 900,000 in 2019[15]. The presence of large number of vendors and lack of integration across the network causes lack of product visibility, especially as the communication channels with distribution partners proliferate.

The move towards personalized medicine, increased product diversity and complexity (including complex biologics and cell and gene therapies requiring just-in time deliveries) and new models of delivering healthcare directly to the patients are also adding to the manufacturing and supply chain complexity.

The companies thus, need to think of innovative ways to be nimble and to deliver high-quality affordable drugs globally while still being profitable. With the kind of volumes that the Indian industry manufactures and supplies, it is not possible to achieve such levels of efficiency and agility with the conventional systems and processes.

This is where smart factories and IoT-driven integrated supply chains come in. These platforms allow all manufacturing units and the entire supply chain to be remotely interconnected. A combination of hard and soft sensors capture multiple data points in real-time, such as machine utilization and productivity, equipment health, process conditions, energy consumption, interplant logistics, product demands, inventory levels, batch status, supply chain shipments, and temperature controls during transport. With the products throughout the process, companies face a lower risk of quality deviation. Manufacturers can also use their proof of compliance with the process as a surrogate for achieving the overall quality, potentially reducing the need for spot testing during distribution. In essence, if companies are able to show that they can produce error-free products using these trackable processes, there is the potential for regulators to approve their use based on the manufacturing methods instead of measuring their intrinsic product qualities.

> "
> We are leveraging technology as an enabler to improve several aspects of our supply chain, such as inventory management and forecasting, customer service improvement, meeting customer demands with agility in our recent go-direct model and deriving customer insights for future collaborative innovation.
>
> Senior executive,
> leading medtech MNC in India

With the digitally-enabled manufacturing units and supply chain, companies can manage great complexities at lower costs, and leverage a large variety of data to move from gut-based decision-making to a more evidence-based decision-making.

Based on the discussions with industry leaders, the pharmaceutical industry has been taking cautious steps in implementing new supply chain and manufacturing technologies. This conservative approach is due, at least in part, to regulatory requirements to prove that any process modifications will not have a detrimental effect on product quality, and to some extent apprehensions in touching anything that is approved by the regulators.

Figure 5: Future of pharma operations: Artificial Intelligence to substantially increase supply chain efficiency with hyper-clock speed, real-time planning and execution

Source: EY analysis
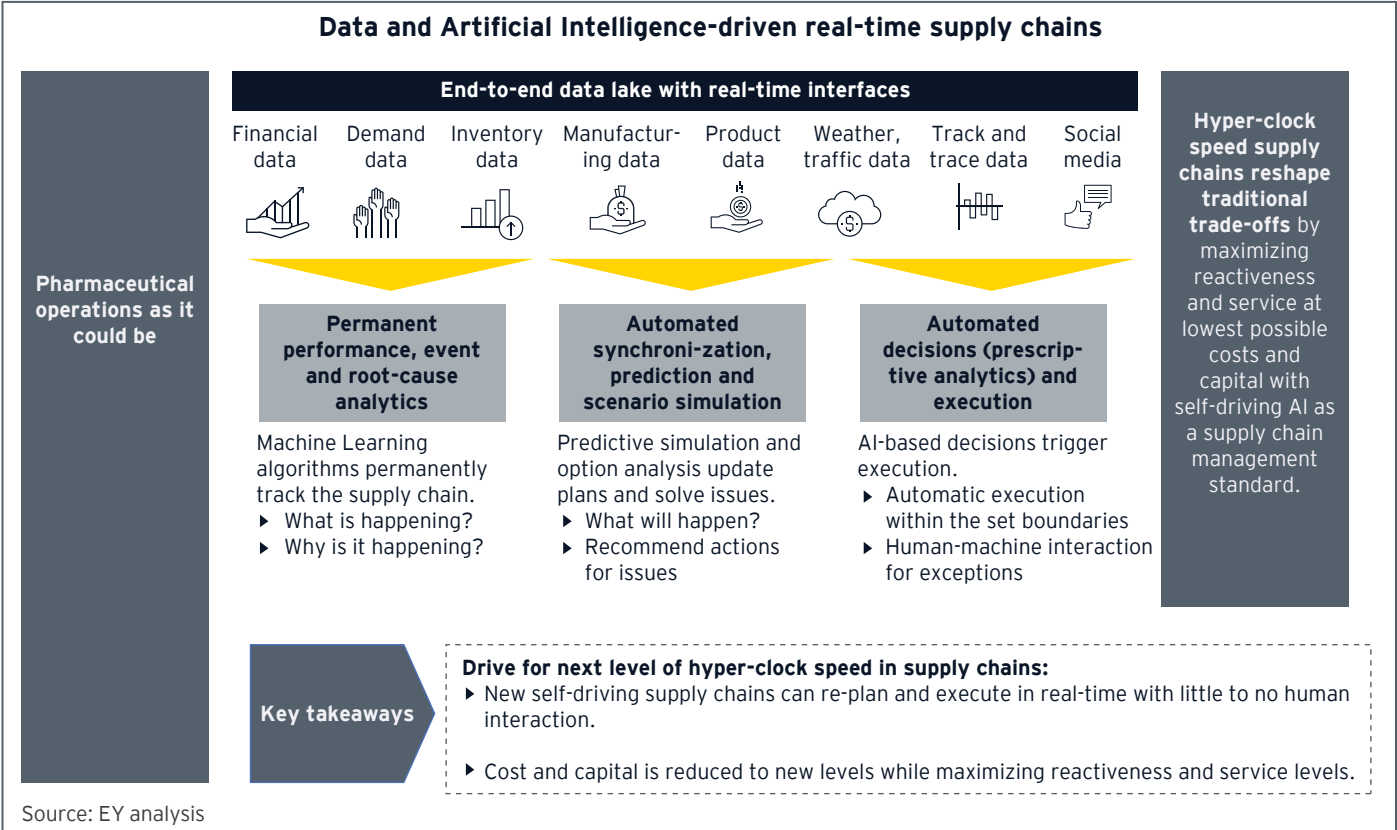
Figure 6: Steps to achieve lights out supply chain planning
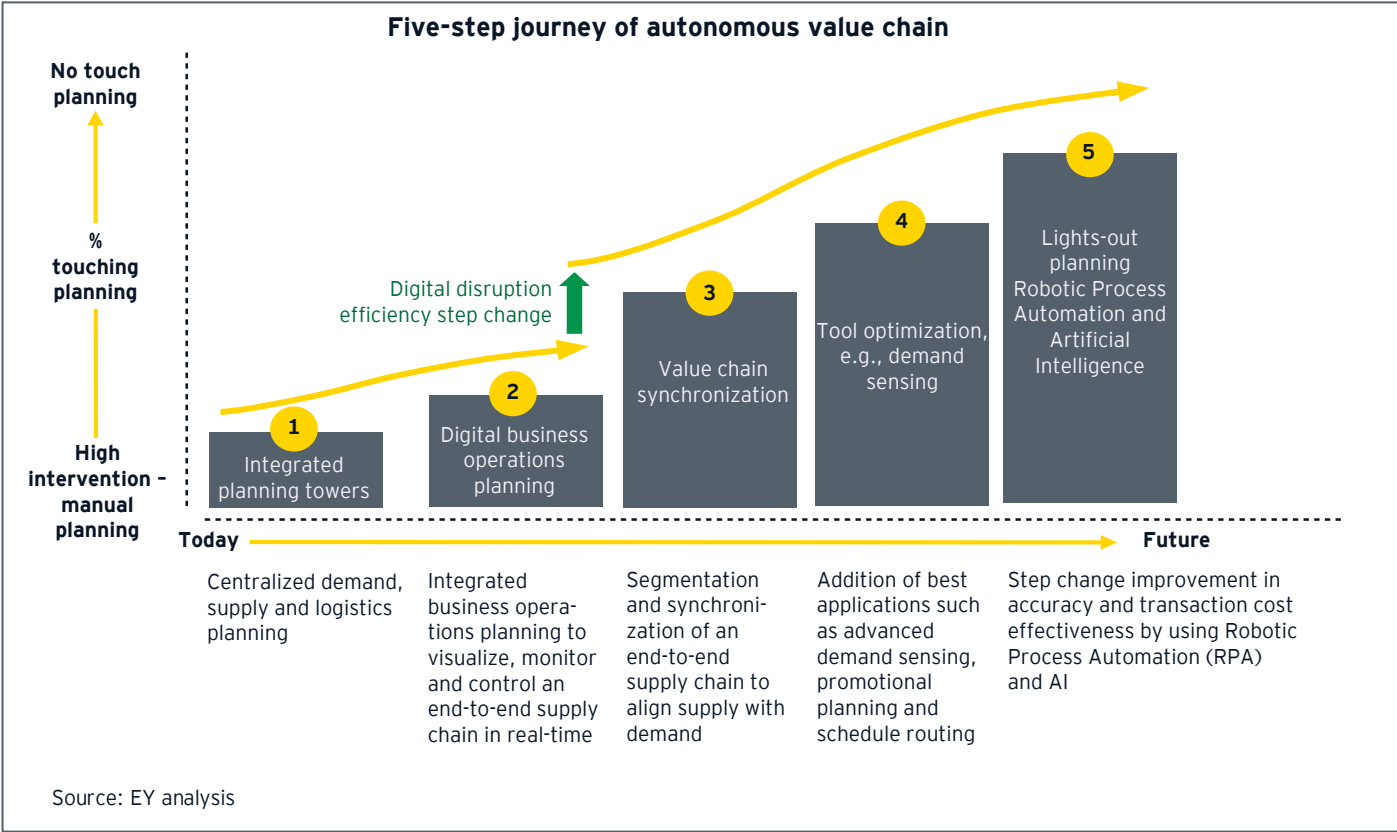
Source: EY analysis

To remain relevant in Life Sciences 4.0, organizations need to be more patient centric. That means executives must have greater visibility into their manufacturing and supply chains and the ability to use data to adapt them
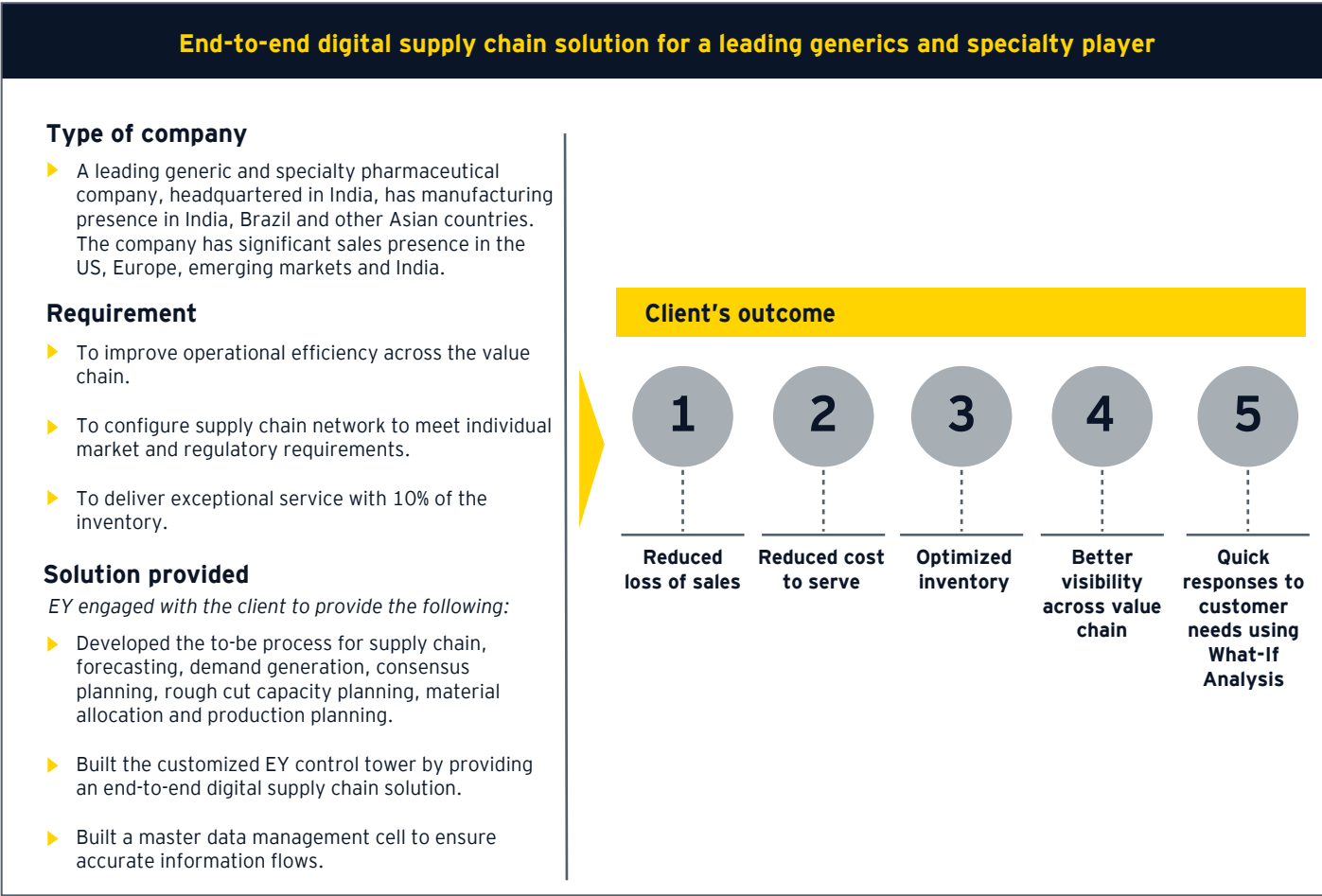
In the current scenario, a majority of Indian pharma companies have not invested in a tech-enabled supply chain. While there have been isolated instances of IoT in manufacturing, it has primarily been with an aim to improve regulatory compliance and not processes. (See Figure 7 for selected initiatives by Indian pharma companies.)

End-to-end digital supply chain solution for a leading generics and specialty player

Type of company
▶ A leading generic and specialty pharmaceutical company, headquartered in India, has manufacturing presence in India, Brazil and other Asian countries. The company has significant sales presence in the US, Europe, emerging markets and India.

Requirement
▶ To improve operational efficiency across the value chain.
▶ To configure supply chain network to meet individual market and regulatory requirements.
▶ To deliver exceptional service with 10% of the inventory.

Solution provided
EY engaged with the client to provide the following:
▶ Developed the to-be process for supply chain, forecasting, demand generation, consensus planning, rough cut capacity planning, material allocation and production planning.
▶ Built the customized EY control tower by providing an end-to-end digital supply chain solution.
▶ Built a master data management cell to ensure accurate information flows.

Client's outcome

1	2	3	4	5
Reduced loss of sales	Reduced cost to serve	Optimized inventory	Better visibility across value chain	Quick responses to customer needs using What-If Analysis

"
I do not see enough radical work being done for automating manufacturing and supply chain.

End-of-line packaging automation systems, dispensing automation, digital dashboards, etc. are the kind of things that the industry is trying to do today, but I don't think it is sufficient.

Manufacturing head,
Indian pharma company

Figure 7: Selected initiatives taken by Indian pharma companies across supply chain and manufacturing

Business priorities		Initiatives		
		Mainstream*	Recent	Emergin
End-to-end planning	Delivering the right product to the right patient at the right time at lower costs	‣ Advanced planning and optimizing applications to improve production planning, pricing, scheduling and shipping	‣ Cloud-based systems for collecting and sharing data	‣ Real-time insight for better demand forecasting, inventory management, using Artificial Intelligence and advanced analytics
Procurement	Inventory and cost optimization	‣ Email-based order management	‣ Enterprise Resource Planning (ERP) systems facilitate the flow of information within and outside an organization ‣ E-procurement	‣ End-to-end inventory management
Manufacturing excellence	Increasing productivity and efficiency	‣ PLCs to monitor batch execution and data	‣ Plants automated with DCS ‣ SCADA systems to automate large and complex processes ‣ MES to control complex manufacturing systems and data flows on the factory floor ‣ Maintaining paperless workflows and batch manufacturing records to reduce errors	‣ Smart factory (fully integrated manufacturing facilities with real-time monitoring and decision-making)
	Regulatory compliance		‣ QbD approach for API/ formulation and optimization of analytical methods ‣ Digital SoPs to reduce compliance errors ‣ Setting up automatic cartonators at filling and sealing units and automatic recording of batch data ‣ In-built systems for error-proofing	‣ Early warning signal system for OOS and OOT
Distribution and logistics	Cost optimization and efficiency	‣ Automated packing for shipments to increase efficiency	‣ Data analytics to manage stock expiry and wastage ‣ Engaging with online pharmacies as new distribution channels	‣ Efficiently manage drug distribution system ‣ Use of sensors
	Visibility and data integrity	‣ Customer relationship management (CRM) tools for managing and interacting with all stakeholders (customers, suppliers, vendors, etc.)	‣ Track and trace mechanism (sensors, beacons, etc.) for an end-to-end visibility	‣ Use of blockchain for real-time tracking and to track and trace medicines

Mainstream: in use by Indian companies for long; Recent: adopted by digital leaders; Emerging: small scale pilots
Disclaimer: the list of initiatives is not exhaustive

Source: EY analysis
PLC: Programmable Logic Controllers; DCS: Distributed Control System; SCADA: Supervisory Control and Data Acquisition ; MES: Manufacturing Execution Systems; QbD: Quality by Design; API: Active Pharmaceutical Ingredient; OOS: Out of Specification; OOT: Out of Trend; SoP: Standard Operating Procedure

Global case studies

A leading global pharma company aims to shrink costs and fatten margins with the power of robotics, AI and new-generation manufacturing technologies

The company targets saving half a billion euros in annual costs by 2022 by:

Reducing the lead time by six months by digitizing their processes	**Reducing cycle times by 20%** by shifting to second-generation manufacturing process
Cutting inventory levels by 20 days by using AI-based forecasting	**Reducing baseline by 20% in manufacturing procurement** by optimization of CMOs and suppliers

Source: Press releases
CMO: contract manufacturing organization

A leading global pharma company is investing to build an agile, cost-efficient manufacturing processes and supply chain using AI, IoT and ML

The company created Insight Centers to get real-time visibility across the manufacturing operations and distribution functions by

Continuous tracking of manufacturing lines to detect bottlenecks and make recommendations to improve accuracy and efficiency	Improving the forecast and tracking of potential issues that may hinder the quality and inventory
Digitally scanning images of sites and tracked individual items to spot potential risks or delays and improve manufacturing inspection	Experimenting with the collected data to develop new optimization models for product innovation and personalized treatments that are more complex to make

AI: Artificial Intelligence; ML: Machine Learning; IoT: Internet of Things
Source: Press releases

Key consideration for growth

How can your organization reduce manufacturing and supply cost while maximizing responsiveness?

Quality and compliance in 4.0: transformation from regulatory requirement to a precursor for growth

In 2018, the Indian pharma industry generated US$38 billion[16] in revenue, largely due to its ability to produce low cost, high quality drugs. As Indian companies continue to expand both their geographical footprint and their capabilities outside simple generics, it is essential that quality and compliance are embedded in the overall growth strategy.

An analysis of the US Food and Drug Administration's (FDA's) inspection citation dataset suggests the top issues in 2019 pertained to the failure to investigate the discrepancies and inability to follow the written procedures. These citations are indicative of the need to set up a robust system to document all the processes and data.

Due to recent data integrity and quality concerns, there has been a spike in inspections by global regulatory bodies, including the FDA, the European Medicines Agency, the UK Medicines and Healthcare products Regulatory Agency. The US is the major market for Indian pharmaceutical exports, and India has the second-largest number of USFDA-approved manufacturing plants outside the US (more than 523 drug manufacturing facilities, as of November 2019)[17]. In 2018 14% (174 inspections) of all global regulatory inspections by the USFDA occurred at Indian-based companies[18]. In 2019, the regulatory issued 19 warning letters, 46% of them were handed out to Indian pharmaceutical companies, the highest number in the last four years[19].

While these numbers are concerning, the intent of the companies is not to be nefarious. Companies rely on traditional manual processes due to which they face unintentional quality lapses. Many organizations use complex applications that are not interoperable and lack broader functional capabilities. Audit, change control, corrective and preventive action (CAPA), customer complaints and non-conformance identification processes are often handled manually. These companies also follow traditional compliance management systems that are based on outdated technology.

Increased regulatory scrutiny is set to be the norm...

...with the increase in the number of inspections
174 inspections in 2018 (14% of the global inspections by the USFDA)

...by reduction in gap between conducting inspections and issuing warning letter from **>10 months in FY16 to <7 in FY18**

Indian industry is aligned to meet global standards...

...with **reduced number of official action indicated (OAI)**

2017	15%
2018	4%
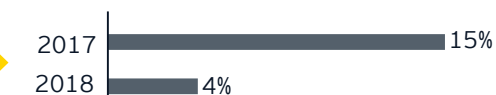
...highest number of ANDA approvals

36% ANDA approvals in the last decade awarded to Indian companies	**29%** increase in ANDA approvals to Indian companies in 2019 vs. 2018	**12 out of top 20** companies getting approvals in 2019 were Indian

Source: USFDA, press releases
USFDA: U.S. Food and Drug Administration; ANDA: abbreviated new drug application

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[16]The Indian pharmaceutical industry – the way forward", IPA, 2019. Available from: https://www.ipa-india.org/static-files/pdf/publications/position-papers/2019/ipa-way-forward.pdf

[17]"Pharmaceuticals", IBEF, October 2019

[18]V. Pilla, "Indian drug makers show improvement in USFDA inspection outcomes", Money Control, March 2019. Available from: https://www.moneycontrol.com/news/business/companies/indian-drug-makers-show-improvement-in-usfda-inspection-outcomes-3599091.html

[19]PB Jayakumar, "USFDA slaps 19 warning letters to Indian pharma firms in 2019; highest in 4 years", Business Today, December 2019. Available from: https://www.businesstoday.in/sectors/pharma/usfda-slaps-19-warning-letters-to-indian-pharma-firms-in-2019-highest-in-4-years/story/392859.html; B. Unger, "An Analysis Of FDA FY2018 Drug GMP Warning Letters", Pharmaceutical Online, February 2019. Available from: https://www.pharmaceuticalonline.com/doc/an-analysis-of-fda-fy-drug-gmp-warning-letters-0003; "ANDA approvals in 2019: Trends for the generics industry", Express Pharma, January 2020. Available from: https://www.expresspharma.in/drug-approvals/anda-approvals-in-2019-trends-for-the-generics-industry/; A. Pingle, "Indian pharma companies grab 290 final ANDA approvals from US FDA in 2018", Pharmabiz, January 2018. Available from: http://pharmabiz.com/ArticleDetails.aspx?aid=113233&sid=1

These developments indicate the urgency for Indian pharma companies to act. Companies need to shift from manual, people-dependent processes, to automated systems to minimize human errors. The digital quality management system (QMS) can integrate the entire product value chain, serving as a single version of truth for the entire organization. This system also minimizes the chances of errors as it presents accurate data that can be leveraged to identify and resolve past issues. Insights generated over time can be used to create algorithms for future preventive/predictive maintenance and to avoid quality lapses for products that are in the market and in pipeline.

Further, to scale their ambitions of expanding into new geographies, companies need to establish agile system that is compliant to varied regulatory requirements without creating complexities.

Given the increasing pressure to stay competitive and compliant, the Indian industry needs to embrace a more proactive mindset. Instead of viewing quality and compliance as a regulatory mandate, companies should consider them as an integral component of the company's culture and strategy.

Steps to strengthen quality and compliance

The recent efforts by government bodies and industry reflect the growing importance of adhering to regulatory and compliance requirements. The industry has started to recognize that the value of quality and compliance is not solely related to regulatory requirements but to their ability to become a major supplier of global pharmaceuticals.

Importantly, over the last five years, a quality culture has started to emerge. The All India Drug Control Officers Confederation has organized workshops to train drug inspectors in the country to match the international quality inspection standards. To further guide Indian drug developers in their efforts to improve quality excellence, the Indian Pharmaceutical Alliance (IPA) has also developed guidelines for data reliability, investigations, process validation and good documentation practices[20].

20 "Data Reliability Guidelines", IPA, 2017

" As compliance requirements get increasingly stringent, the only way to stay compliant is through automation. You want to have minimal human intervention because the higher is the human intervention, the higher are the chances of errors.

Compliance does come at a cost, but it is mandatory. There is a need to leverage advanced technology and make systems electronic.

Senior executive,
leading Indian pharma company

Besides government efforts, Indian pharma companies have also started to prioritize quality and compliance Most Indian companies now aim for 24x7 audit readiness. To meet those needs, they are upgrading their quality management systems and making them mistake-proof through automation and other digital interventions. These advanced systems more than reduce errors as they increase operational efficiency by standardizing and simplifying the processes. They also increase accountability via user identification and generate more accurate and shareable data. As a result, companies are more quickly able to identify and resolve issues and create systems capable of learning from past mistakes.

In addition to the new technologies, companies also need to conduct regular training programs for employees to build a culture of quality across the organization. These programs range from use of tools and the overall importance of adherence to quality mandates, as well as the implications of non-compliance for individuals and the entire firm.

Business priorities	Digital initiatives
Manufacturing	▶ Digital standard operating procedures ▶ Electronic batch manufacturing records (BMRs) to ensure data integrity ▶ Manufacturing Execution Systems (MES) for improving efficiency and productivity
Laboratories	▶ Laboratory information management systems (LIMS) for efficiency improvement, instrument and application integration, electronic data exchange, etc.
Overall quality control process	▶ Digital end-to-end quality management systems

Disclaimer: the list of initiatives is not exhaustive

Source: EY analysis

Case study of an Indian pharma company
A leading Indian pharma company undertook a transformation exercise to build a robust quality culture

7,800+ Employees coverd

16 Sites covered

Circle mentors and Implementation Champions (ICs) trained **124+**

938+ Circle representatives trained

6,500+ Frontline employees rewarded

5,000+ Ideas implemented to improve quality

Visual dashboards installed across Shop floors **227+**

25+ Culture Academy team members on-boarded

938+ Trainers enrolled to create quality-related awareness among frontline employees

213+ Circle mentors and ICs trained

Early Warning System (EWS) for leading global generic company

Type of company

▶ A leading generic and specialty pharmaceutical company, headquartered in India, has significant sales presence in the US, Europe, emerging markets and India.

Requirement

▶ To have a robust quality check system to address data integrity challenges.

▶ To configure review process to meet regulatory requirements and create transparency.

▶ To create preparedness across hierarchies for achieving quality excellence

Solution provided

EY engaged with the client to provide the following:

▶ Tracked anomalies generated from huge volumes of logs in a quality control laboratory

▶ Automated current manual review process in quality control laboratory

▶ Developed interactive dashboards to effectively report the anomalies

▶ Built a flexible and customizable architecture to suit the requirements of various manufacturing facilities

*Title 21 of the Code of Federal Regulations

Client's outcome

1
100% logs were analyzed automatically, anomalies were identified and closed

2
Transparency in reporting

3
Closure of data integrity issue

4
Planned compatibility with 21 CFR norms*
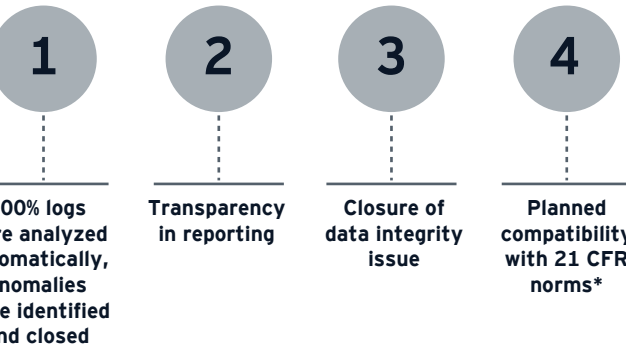
Role of advanced technologies in making pharma manufacturing and supply chain patient centric, agile, and self learning

Artificial Intelligence

▶ Preventive/predictive maintenance, demand
▶ planning, inventory management, quality control/management
▶ *Automated synchronization, prediction and scenario simulation*
▶ *Prescriptive analytics and execution*

Wearables and sensors

▶ Track and manage remotely
▶ Improve workforce efficiency and safety
▶ Monitor assets in real-time

Cloud-based platforms

▶ Data storage and management
▶ *Integrated manufacturing and supply chain network*

Online platforms

▶ Online pharmacies
▶ *Direct-to consumer delivery of medicines*
▶ *Supply chain safety information exchange across geographies*

Augmented Reality and Virtual Reality

▶ Improve workforce efficiency
▶ Enhance employee training experience
▶ *Provide remote assistance to on-site workers*

Blockchain

▶ *Track and verify drug quality*
▶ *Label management*
  Chain of custody for individualized therapies

3D printing

▶ *Print personalized dosages*

RPA*

▶ Automate areas of manual intervention
▶ *Develop end-to-end autonomous networks*
▶ *Enable automated decisions and execution*

Today: already in use
Tomorrow: evidence of initial use cases and expected to become commonplace in near future

Source: EY analysis
This list is indicative and not exhaustive

Key consideration for growth

Where does quality and compliance stand on your organizational strategic agenda?

Enabling functions in 4.0: transitioning from cost centers to strategy value providers

Employees spend a vast portion of time doing tediously repetitive tasks that make their jobs unsatisfying. If these are automated, back office employees can focus on higher value tasks. Additionally, employees from core business functions spend a lot of time on administrative activities such as uploading expenses and applying for leaves, which reduce their productivity and potentially result in lost revenue. Since these activities are considered non-productive work, they might lead to errors due to disaffection. A recent survey (conducted by OnePoll) involving 10,000 Indian workers revealed that on an average, they spend more than three hours a day on manual, repetitive computer tasks that do not add value for the business. Further, 52% of millennial respondents highlighted that they could be more productive if there were fewer administrative tasks[21] .

Digital technologies enable organizations to slash costs by automating functions that reduce the number of full-time employees (FTEs) and improve processing efficiency. Besides cost savings, these technologies allow employees to focus more on value-adding activities.

Our primary research suggests that currently digitization of enabling functions is mostly focused on finance and human resource activities in the top Indian pharma companies.

Creating an agile finance function

In the current scenario, where data is the new currency, stakeholders expect more accurate, real-time and detailed information. This is forcing finance departments to rethink their approach towards enterprise reporting. Investing in a robust Enterprise Resource Planning (ERP) system empowers finance departments to analyze information based on multiple dimensions (e.g., product, region, customer type) in real-time. This provides true data-driven insights that allow employees to make fact-based decisions across the value chain, including the product marketing strategy, channel allocation and staffing requirements. Automating the processes involved with collecting and collating of data helps in reducing the need for operational support in managing information flows.

> " Investments are being made on how we can save the time of sales representatives. The MR needs to invest time in talking to the doctor rather than reporting about work. We are automating systems, such as travel reimbursement or leave encashment, to reduce the efforts of the field force and save their time.

Senior marketing executive,
leading Indian pharma company

Digital evolution in HR function

Digital technologies can also significantly improve human resource (HR) processes. The introduction of technology in HR is primarily aimed at creating a working environment that focuses on personalization, motivation, recognition, and providing an overall compelling experience.

Based on a study undertaken by Mercer in 2019 (Mercer global talent trends 2019: life sciences), 89% of HR teams in life sciences companies globally invest in technology to improve the employee experience. HR plays a big role in the digital employee experience[22] .

One starting point could be the use of technology to enhance end user experience while onboarding. Globally, companies have also started using AI-based hiring platforms to identify a candidate based on the position. In addition to bringing efficiency to the hiring process, AI eliminates the inherent human biases which an HR might have while recruiting in person.

Enabling functions are traditionally viewed at as cost centers. However, the above examples suggest that investing in technology in the enabling function can uncover immense strategic value for the organization.

> " If you look at the HR function, attrition is a big issue in the pharma industry today, particularly among the field force. How do we make sure to improve our engagement with employees, so they stay longer with the firm? Another important area of improvement is their productivity. I think these are the places where the technology-based solutions can play a big role

Chief information officer,
leading Indian pharma company

Digital learning-driven productivity improvement tool

A US$230 million company and a leading life insurer in India, with a CAGR of 45%, had a target of becoming a top 3 player within three years. To achieve this objective, the company followed its board mandate and accelerated sales managers' (SM) productivity.

Solution provided

EY used its proprietary tool SalesPro to achieve following:

- ▶ **Customized, role-specific learning content:** learner-centric content design and production with a test/re-test function to assess learning

- ▶ **On-the-go digital platform:** provided a multi-platform involving adaptive learning and continuous user experiences.

- ▶ **Aligned support ecosystem:** provided a continuous post go-live activation of new skills with periodic stakeholder connect network and incentivized employees through gamification.

- ▶ **Predictive productivity analytics:** Deployed dashboards for monitoring productivity improvements and used algorithms to predict performance

CAGR: Compound Annual Growth Rate

Client's outcome

1 Productivity improved

2 Time-to-productivity became faster

3 Engagement increased and attrition reduced

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[21] "88% Indian professionals believe bots should be used for admin work", Hindustan Times, January 2020. Available from: https://www.hindustantimes.com/more-lifestyle/88-indian-professionals-believe-bots-should-be-used-for-admin-work/story-nWTTwcTsZNx3phKqCBoSON.html

[22] "MERCER GLOBAL TALENT TRENDS 2019: LIFE SCIENCES", Mercer, https://www.mercer.com/content/dam/mercer/attachments/global/Career/gl-2019-talent-trends-infographic-industry-lifesciences.pdf

Data sciences to identify, assess and recommend the right profiles using EY Talent Miner

Leading generic pharmaceutical company, headquartered in India, was facing issues with high attrition rates in its field force that led to high costs of bad hires

Solution provided

EY engaged with the client to provide the following:

▶ **Created dynamic predictive algorithms:** used advanced statistical methods to build predictive talent profiles that would stay longer and perform better in the company.

▶ **Upgraded hiring processes:** designed sales acumen-based online assessment as part of the shortlisting process and used integrated hiring algorithm and assessments into the hiring process to align interview processes.

▶ **Optimized candidate sourcing channels:** deployed algorithm to identify right candidates from multiple sourcing channels while connecting with passive candidates to expand the candidate pool.

▶ **Technology enablement and integration:** deployed cloud technology to integrate existing HRIS or ERPs, and digitized the hiring process to offer superior experience while improving HR and process efficiency.

HRIS: Human Resource Information System; ERP: Enterprise resource planning

Client's outcome

1 — Attrition reduction

2 — Optimized sourcing channels

3 — Reduced bad hiring costs
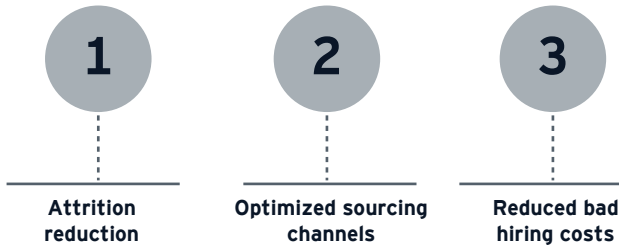
Key consideration for growth

How is your digital strategy enhancing the value of enabling functions?

?

3

While the digital journey is necessary for success, it may not always be easy. What is your strategy to deal with the challenges?

Every new endeavor comes with its own set of challenges

The top three challenges that Indian pharma companies face while implementing digital strategies are the regulated environment, driving change management and the availability of accurate data.

Though Indian companies have been slower than their global peers in adopting digital, they have the advantage of learning from the global failures and success while implementing their own digital strategies

Indian pharma's progress on their digital journey

EY's primary survey reveals that every company now understands the need for digital transformation. In the 4.0 world, though every company is at a different stage of digital maturity, all have started their journey.

According to industry leaders we surveyed, most Indian companies are already beyond the inertia stage. They understand that digital implementation is not just a fad, but a necessity to remain relevant and competent in the future. Most executives also agreed that the Indian industry is behind its multinational counterparts. While this could be seen as a disadvantage, it provides Indian companies the opportunity to learn from the experiments and experiences of their counterparts. This way, Indian companies have the ability to adopt validated best practices and avoid costly detours.

As a whole, the global pharmaceutical industry has been late in adopting digital technologies compared to other industries such as retail, banking and finance. A primary reason for this lag is the highly stringent regulatory and compliance requirements.

When we experiment with anything new, challenges emerge. Even some of the most digitally-advanced global companies have had to refine their strategies. Sanofi, for instance, recently revised its joint-venture with Alphabet's Verily Life Sciences, while Novartis has revamped its collaboration with Pear Therapeutics that focused on prescription digital therapeutic for opioid use disorder.

Key challenges that Indian pharma companies face in implementing digital

The following analysis is based upon EY's survey conducted with 20 leaders of top Indian domestic and multi-national pharma companies.

Top challenges faced by Indian pharma companies in implementing digital interventions

Challenge	Percentage
Regulated environment	71%
Change management (especially in large organizations)	57%
Unavailability of accurate/usable data	43%
Unavailability of skilled resources	29%
Lack of consensus between business, strategy and tech teams	29%
Huge initial investments with lack of visibility on ROI	29%
Lack of sustenance plan	14%
Data privacy concerns	14%
Inertia	14%

RoI: return on investment
Source: EY analysis. Executives of leading Indian life sciences companies were interviewed to draw consensus.

It was found that about 70% of respondents consider stringent regulatory and compliance requirements as a top challenge in implementing digital technologies in the pharma industry. Any new digital platform, software, technology, etc. requires compliance with the existing systems and the approval of the regulator. The fear of regulatory action and the complexity of getting fresh approvals sometimes discourages companies from implementing technologies, especially the disruptive untested technologies. Additionally, due to novelty of technology, the regulators may have limited familiarity with the risk profiles of specific technologies, leading to extended questioning. As a result, they may hold new technologies to higher safety and efficacy standards because of concerns about potential risks that aren't fully known. Companies shy away from making investments as they fear that increased regulatory oversight may lead to delays in launching or shipment of the products that already come with high implementation costs.

The second most cited challenge was change management. While an organization's top management may want to implement a digital change, they cannot do so without the support of each and every employee in the firm. Resistance due to lack of awareness among shop floor workers, for example, can lead to failure of any new digital tool despite evidence of success elsewhere. Disbursing information to the lowest possible level, particularly in large organizations, can be very challenging.

The third most cited challenge was data inaccuracy. While life sciences companies have access to abundant data, it is a challenge to ensure that the collected data is correct. In case it is not, finding the right data source becomes another challenge.

Additionally, it is also difficult for companies to get access to a skilled workforce that can understand both digital tools as well as the business function. Though India has a strong workforce in information technology, but it still lacks workforce that can understand advanced digital skills such as AI and Big Data.

Another area of concern is the lack of consensus between business, strategy, and technology teams. At times, these business functions may have different priorities and needs, which makes investing to drive change across the organization difficult.

In some cases, there may be a challenge in getting management buy in, especially where the initial investment is huge and there is limited visibility of return on investment. In the next chapter, we will see how companies can tackle these issues.

> **"**
> One of the things we need to understand is how to make people adopt the new technology or digital platform. Even though we know it is important, but people adapting from old systems to new is going to be always a challenge.
>
> Head of operational excellence, leading Indian clinical research organization

Key consideration for growth

How do companies tackle inherent systemic challenges to potentiate digital for meeting their business goals?

4

How do life sciences companies prepare today for tomorrow's cycle of disruption?

Organizations understand that it is imperative to adopt digital technologies to improve today's business and enable tomorrow's growth.

Organizations need to develop a digital strategy that maximizes the potential gains of the technology.

A transformative mindset that is human-centric and leverages technology to reinvent the business model is key to design an effective digital strategy.

Practical approach to develop organizational level digital strategy

In an effort to move up the value chain and continue to expand their geographic footprint, Indian companies need to make the systems simpler, efficient and agile. This is possible with the use of data and advanced digital technologies. Companies should perform diligence and invest in technologies according to their appetite for risk.

As organizations plan their digital agendas, it is important to bridge the gap between a technology's potential and its successful delivery, also known as digital effectiveness. Companies need to develop an exponential mindset that leverages technology for business model reinvention and empowering the workforce.

A new nucleus of value creation lies at the heart of digital transformation

Historical mindset

Exponential mindset

Scope

Efficiency

Scale

Technology

Human centricity

Business model reinvention

Sustainable competitive advantage

Dynamic competitive advantage

Source: EY analysis
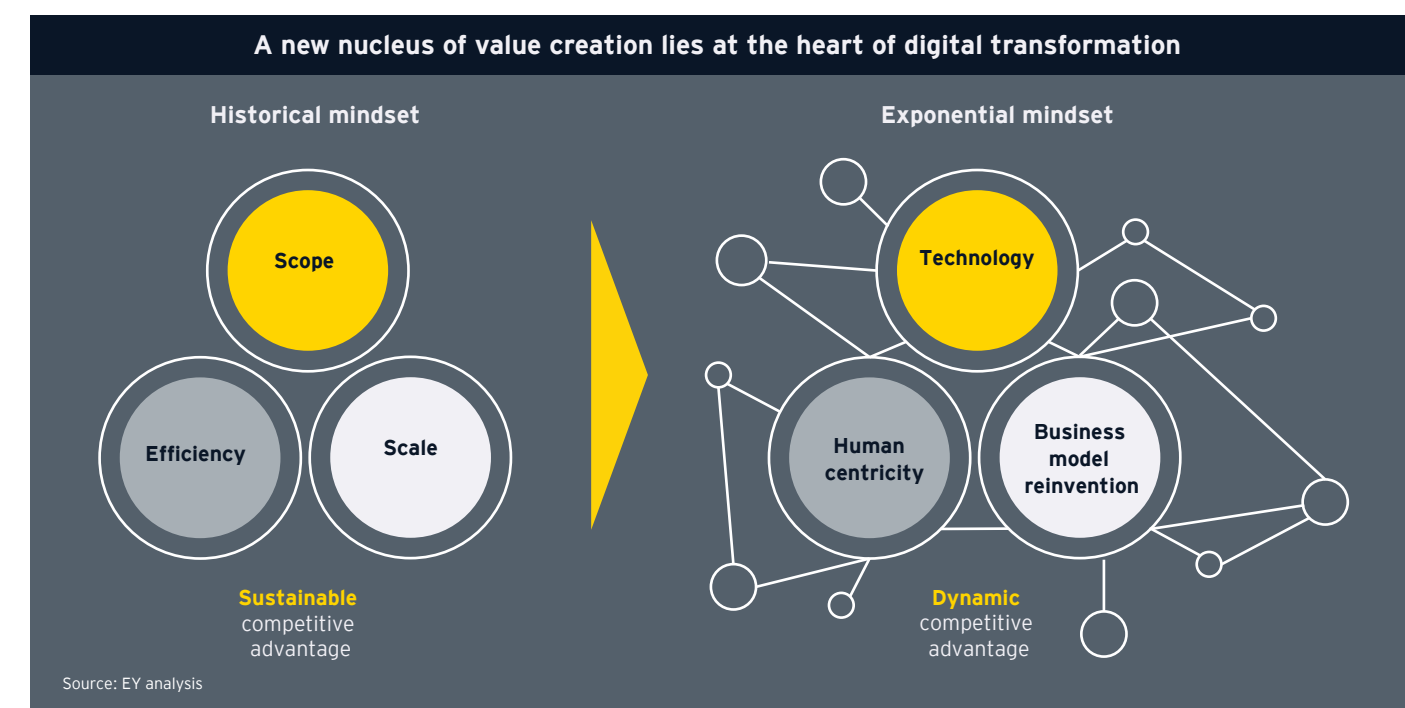
In this chapter, we aim to discuss best practices to increase digital effectiveness by designing and implementing a digital strategy that simultaneously addresses changing organizational needs.

Digital strategy approach

- **The Bridge** (yellow)
  See the future and plan with purpose

- **The engine room** (grey)
  Orchestrate and accelerate like a market leader

- **Innovation** (blue)
  Disrupt and create like a start-up

- **Design, test and iteration** (purple)
  Design, build and test like a scale up

- **Deployment hub** (green)
  Plan, invest and scale up like a venture capitalist

- **Digital factory** (dark grey)
  Accelerate and industrialise transformation

Define the digital vision

Start with leadership buy in: like any other transformation strategy, the role of leadership is critical for any digital transformation strategy. Senior management's commitment must be secured for digital investments to be successful. The leadership team of an organization must invest appropriate resources that are not just financial. The time spent in guiding the organization through the transformation is also essential. At this phase, the identification of "change managers", leaders focused on helping the top management enable the change, is a must. These individuals will have the day-to-day accountability for driving advances (discussed in detail later) on the digital front.

It is no accident that as companies have increased their digital transformation efforts, they have created a new leadership role, the chief digital officer (CDO) at the board level. Since 2016, about 50% of the top 20 biopharma have appointed CDOs to their organizations. These individuals have diverse backgrounds and may come from outside the traditional life sciences industry. They are accountable for defining and driving digital strategies and demonstrating the overall organization's commitment to the effort.

Align vision with the organizational goals: one of the many roles of a CDO is to help define the digital transformation vision closely aligned with the organization's overall business goals. The vision should clearly state what needs to be achieved, and why. Instead of following the hype around a new technology, initiatives should be directly linked to business value.

Executives should prioritize projects that align with a company's growth needs based on the answers to some simple questions. These are - what processes will improve? What metrics will be used to measure the improvements? How long will it take to implement the changes? What are the costs versus benefits related to the digital implementation? Besides this, an essential question is whether it is possible to estimate the potential costs associated if the technology is not implemented.

Each organization has different business objectives, capabilities and level of digital maturity. Based on an organization's objectives and timelines, digital transformation requires prioritization of certain projects over others.

The company should have the ability to sequence the digital strategy to drive maximum reward while minimizing the risks. Starting too many projects simultaneously may strain a company's financial and human resources. However, prioritizing the programs that are strategically of higher urgency may help companies to manage their resources and funds instead of closing the projects abruptly.

It is important to identify opportunities that allow the company to stay ahead of its competition on the S-curve of innovation. Categorizing projects based on the impact and effort can be helpful. Companies may initially want to prioritize projects that are lower in impact but are likely to generate tangible returns more quickly to drive enthusiasm and buy in from employees. Even though it may be fine to start with point solutions or projects for specific functional areas, the smaller initiatives should fit in the overall long-term strategy.

It is also important to have an appropriate cybersecurity strategy in place from the beginning to avoid making upgrades later that may be expensive.

Set clear and ambitious targets: since companies are more likely to meet goals that can be measured, it is important to define the desired return on investment (RoI) and the steps to reach this goal. This value proposition should be shared with all employees – by defining it concretely, workers have a greater understanding of the ultimate goal and are more motivated to achieve it. For e.g., when improving the supply chain function, companies could aim to achieve a certain level of efficiency as a result of automating a portion of work. Alternatively, a company might target the reduction of inventory costs by a set amount due to smart forecasting methods.
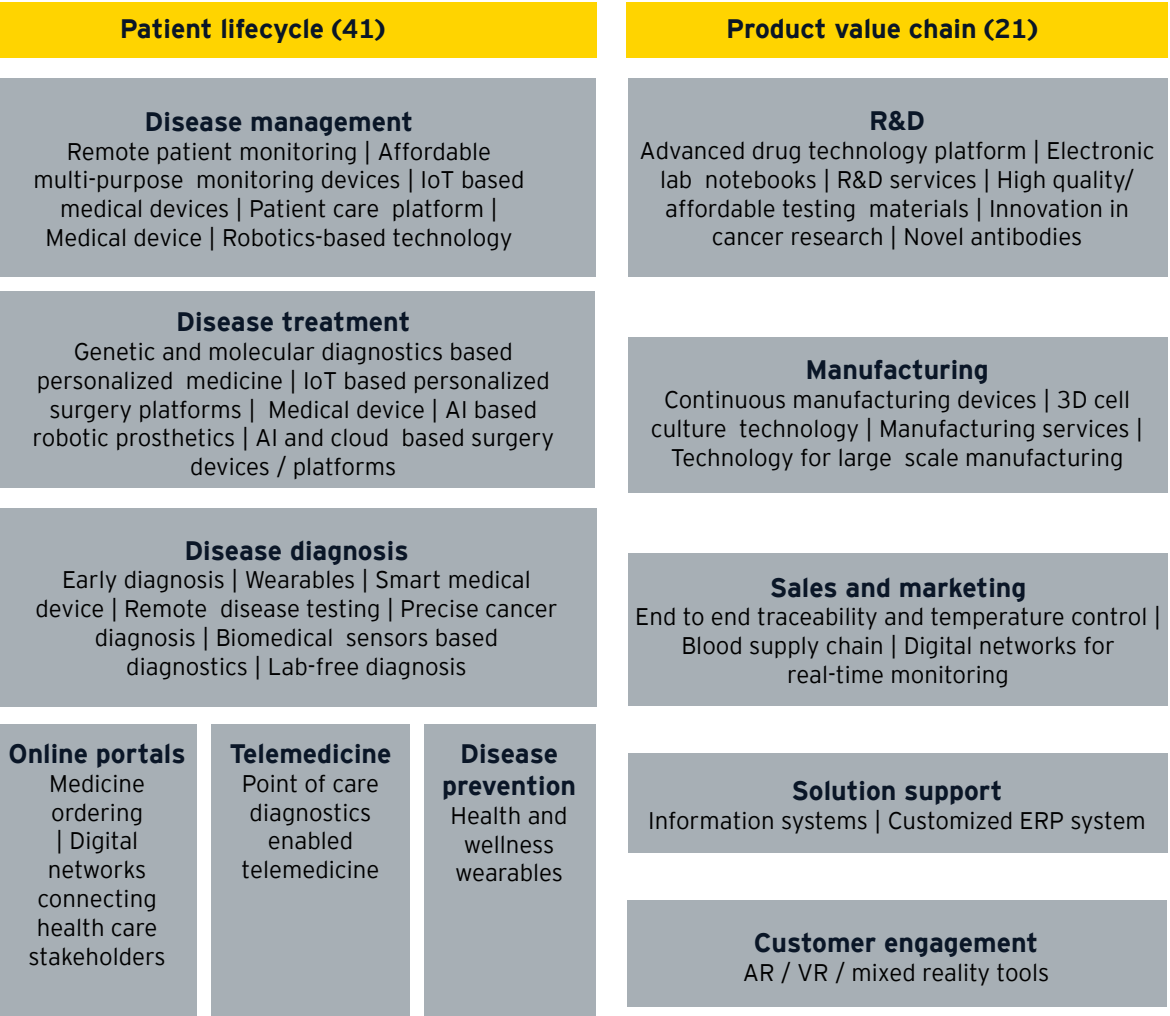
Companies should also continuously monitor their progress toward target goals and celebrate interim achievements. This helps employees understand the magnitude of the potential outcome for the business. In parallel, project managers must make the right business case to secure appropriate stakeholder buy-in and investment.

Assess organization capabilities: companies need to assess the capabilities of the current systems, processes, people, technology and data to identify gaps between these skills and what is needed to support transformation. They must determine how to fill these gaps, including where to invest internally and where to outsource, collaborate or acquire.

In most cases, these decisions are based upon what is important for businesses now and in the future. Companies can do this by defining core and non-core functions, assessing how critical the capabilities are for their value proposition. Maintenance costs are another important factor to consider, be it a human resource or a specific data analytics platform. For example, according to the EY survey, Indian life sciences companies recognize the importance of analytics. However, respondents also noted that they are not currently focused on hiring data scientists because they fear it may be difficult to keep them motivated longer-term in the absence of enough new projects over time. In such cases, companies like to partner with contractors. Companies are now more open to the start-ups to gain access to the needed talent or technology that is transformational (see figure 8 for EY start-up analysis across the product value chain).

Figure 8: Range of innovative solutions developed by the surveyed start-ups

Patient lifecycle (41)	Product value chain (21)
Disease management Remote patient monitoring | Affordable multi-purpose monitoring devices | IoT based medical devices | Patient care platform | Medical device | Robotics-based technology	**R&D** Advanced drug technology platform | Electronic lab notebooks | R&D services | High quality/affordable testing materials | Innovation in cancer research | Novel antibodies
Disease treatment Genetic and molecular diagnostics based personalized medicine | IoT based personalized surgery platforms | Medical device | AI based robotic prosthetics | AI and cloud based surgery devices / platforms	**Manufacturing** Continuous manufacturing devices | 3D cell culture technology | Manufacturing services | Technology for large scale manufacturing
Disease diagnosis Early diagnosis | Wearables | Smart medical device | Remote disease testing | Precise cancer diagnosis | Biomedical sensors based diagnostics | Lab-free diagnosis	**Sales and marketing** End to end traceability and temperature control | Blood supply chain | Digital networks for real-time monitoring

Online portals	Telemedicine	Disease prevention	Solution support
Medicine ordering | Digital networks connecting health care stakeholders	Point of care diagnostics enabled telemedicine	Health and wellness wearables	Information systems | Customized ERP system

Customer engagement
AR / VR / mixed reality tools

Size of the boxes is indicative of the total number of start-ups catering to the respective areas
Other areas: social network for doctors, Intelligent labor monitoring devices
Source: EY analysis based on primary survey sample set

Historically, acquisitions have been the fastest route to new technology and talent-related capabilities, especially if companies can create incentives to retain the know-how post integration. Roche's acquisition of Flatiron is an example of how one pharma used mergers and acquisitions (M&A) to buy instead of building new data capabilities. Roche acquired the real world data company and then kept it as an independent entity. This helped it access the capabilities it needed while also creating a structure that preserved the entrepreneurial and agile spirit of the start-up.

This shift to a more open, collaborative approach is essential for future success, especially in data-related projects. In the recent past, there has been a tendency to hold data. But it isn't about owning all the data. Success in the future will be about partnering with various organizations or stakeholders for having access to the data and then using it to drive insights.

Engage and execute

Change management is critical: according to the executives that participated in the EY survey, this is the second most important challenge. A shift in the mindset is needed to successfully implement any big change in old processes. While the C-suite is often well-versed and open in accepting the new technologies owing to their advantages, executives in the middle and lower management ranks may lack the awareness regarding the efficiencies by implementing digital technologies. Employees sometimes also have fears related to automation.

There is a need for leaders to dispel these fears and communicate the digital vision to the employees across all business functions and levels. The employees should be able understand what the initiative means for the organization and for them. These communications need to be initiated long before digital projects are initiated. Communication platforms that encourage two-way dialog, such as webcasts and internal social platforms, can be leveraged for effective communication.

Have a strong project team in place: it is important to have cross-functional teams with people from all the levels. Including people from all ranks and integrating the viewpoints from different parts of the value chain may help in generation of both strategic and practical ideas. This can also help companies to develop a more rounded view on how different solutions can address the business problem.

Establish transformation governance: once the team is in place, it is essential to define clear roles and responsibilities. Everyone should understand the expectations from them to map the implementation of the initiative while working with the leader.

Identify the key performance indicators and measures of success: it is important to note that the success in case of digital initiatives might not be directly linked to the revenue. Setting the KPIs aligned with the desired outcome from the technology, e.g. x% gain in efficiency in three months in case of implementing technology to improve efficiency will help in measuring success. It is also important to devote sufficient time to the initiative before assessing return-on-investment (RoI).

Identify intermediate milestones: in case of a long-term project, the milestone should give enough data to the project leader to decide if the pilot is running successfully or a change in strategy is required.

As the team develops the execution strategy, it is also important to design the sustenance plan to achieve complete potential of the initiative. Therefore, aligning a team to keep it live and scale it is essential. Generally, it has been seen that there is a lot of enthusiasm for projects at the beginning, but the efforts lose pace as the focus shifts.

While aiming for success, the team should also decide the action plan that might be required if things do not go as expected. Like defining success, defining what failure looks like – and when to decrease investment – is an important step.

Train people to use technology: it is difficult to transition from traditional ways of working to using a new technology. Thus, employee training is a critical aspect to improve their engagement and probability to achieve success.

Embrace transformation as a continuous way of working

Constant evaluation and adjustment: as more data is created from different digital and data implementation initiatives over time, the insights should be used to continuously assess further improvement needs. Companies must ensure that digital technology never gets outdated. To achieve this, it may also be necessary to update a project strategy based on the changes in the industry ecosystem or adopting new, more advanced technologies.

Over time, the data from initiatives across different areas should be integrated across the entire value chain to achieve the next level of transformation.

Transform culture: we discussed in the first chapter the need to remain ahead of the competition on the S-curve. This is only possible if companies continue to update their current systems and processes.

Employee training should be part of the culture to help them constantly evolve. Employees should be encouraged to develop new skills and be given the time to learn those skills. It is important to encourage employees and recognize their efforts despite failures. As the need for digital skills increases, it may make sense to create an independent digital centre of excellence to help develop programs across the organization.

Digital- and innovation-led KPIs should be established for the leadership, as well as the entire firm. Program managers and leaders should be held accountable for delivering on these KPIs. Other than achieving the initially defined project target, success metrics should also consider leaders' ability to scale a successful pilot programs across different parts of the organization. At times, success metrics could also be related to leader's agility in making a go/no-go decision.

Introduce organization level changes: in Life Sciences 4.0, functional silos can be challenging when companies are moving towards integrating digital capabilities across the entire organization. It is important for companies to encourage sharing of best practice between different departments to save time and benefit from the existing knowledge without recreating the wheel each time.

Key consideration for growth

How do design the most intelligent digital transformation strategy?

Conclusions

- Like the disruption in the retail, transportation, finance and other sectors, new data-driven technologies will fundamentally alter the way health care is imagined and delivered.
- As Indian companies prepare to shift from supplying commodities to supplying innovations, they need to understand the changes that new technologies may bring in their business.
- Reinventing business is not a choice but is imperative. With disruption being the new normal, innovation will give high performing companies a competitive edge.
- Digital and data have the potential to change the functions of the life sciences value chain.
- Companies are investing in technology to transform customer experience, operational processes and business models. These investments must serve the company's needs today and enable their growth tomorrow.
- Indian companies have the advantage of learning from global failures and successes while implementing their own digital strategies.
- A company's digital transformation vision should be closely aligned with the its overall business goals.
- As organizations plan their digital agendas, it is important to bridge the gap between the potential of a technology and its successful delivery.

Way forward

- How will your organization transform its business model to be innovative while being cost-effective?
- How will the platform-based investments you make today secure value tomorrow?
- Once you have started your transformation, how will you sustain it?

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