Shaping the next generation of digital and data-driven healthcare, and sustainable practices

February 2023





Contents

1

Shift toward Intelligent Health Ecosystem to deliver personalized health experiences anytime and anywhere

Technology driven transformation across the pharma value chain to improve efficiency and outcomes

3

The ongoing revolution in personalized, patient-centric, virtual, and home-based care opening new opportunities and business models for MedTech companies

4

Need for life sciences companies to create long-term growth focusing on sustainability and Environmental, Social, and Governance (ESG) value-led model

06 12 22 26

Foreword

At EY, we are delighted to bring this report on "Shaping the next generation of digital and data-driven healthcare and sustainable practices" and launch it at the 20th BioAsia 2023 conference at Hyderabad. EY is proud to be the knowledge partner for BioAsia 2023 this year as well and this thought leadership report is dedicated to the themes of BioAsia around One Health, Health equity and Next Generation health focusing on health and innovation for all.

The years of the pandemic had resulted in lockdowns, choking of supply chains globally, patients not being able to get to treatment centers and vaccines, workers not being able to attend their place of work, shortages of resources and products, all adversely impacting the cost value equation. All these have resulted in bringing in awareness, and the need for health sciences companies, healthcare service providers to fast track their digital transformation journeys. Likewise, the patients, consumers and other stakeholders, having experienced convenience in entertainment and ecommerce, want no less and are demanding that manufacturers and service providers to catch up with these advancements. In this publication, we have tried to bring out critical aspects and the value digital, data and the emerging ecosystem are bringing on to the table, changing the way healthcare is delivered. Also, with a global focus on sustainable practices, the importance of ESG can never be understated. The dimensions that one should expect and prepare for are clearly brought out in the report. We thank our colleagues at EY and BioAsia leadership for their contribution and making this publication possible in a short time.

Lastly, we want to add our congratulations to the BioAsia leadership and the Government of Telangana for running this conference successfully at a Global level – and with the 20th edition, it is only getting stronger. We would like to congratulate them on yet another stupendous effort. Onwards and upwards.



Farokh Balsara EY LLP





Suresh Subramanian EY LLP



Hitesh Sharma EY LLP



to them.



Foreword

Healthcare and life sciences industry is becoming more and more digital, responsive, and focused on patients. Virtual care and digital models are transforming the industry like never before. Within two decades perhaps empowered customers, radically interoperable data, and scientific and technological advances will completely morph the healthcare system we know today. With the rising healthcare cost and shortage of workforce it an urgent need to drive efficacy of care and personalization, and better access

Advanced technology and new analytical tools are shaping this healthcare revolution to drive personalised care and better patient outcomes. Pharma companies are already using them in some way to deliver personalised care - artificial intelligence (AI), machine learning (ML), cognitive computing and big data processing, to make advances in the research and development of drugs or to automate operational processes and workforces. Data rich value chain and consortium of these technologies is likely to break down the silos and succeed in therapies where traditional medicine has largely failed, e.g. dementia. Lastly, technology continues to and will shift the perspective of how health is viewed by the consumer of the future. Consumers in future are likely to take full ownership of their own health and become fully empowered to decide the care path "best suited"

In this context, Government of Telangana has partnered with EY to organize the 20th edition of its flagship international convention - BioAsia, from 24-26 February 2023, with the theme of "Advancing for ONE: Shaping the next generation of humanized healthcare based on three pillars of 1.**One Health**: Integrating cross-sectoral ecosystems to safeguard the future 2.Next generation health: Harnessing research, disruptive technologies such as data, analytics, extended reality, AI and blockchain to deliver personalized healthcare & 3.Equity: Driving accessibility and affordability to quality healthcare for all. Over the years, BioAsia has been instrumental in shaping and building a vibrant life sciences ecosystem in Telangana led by technology and innovation. The event has brought together who's who across healthcare, research, start-up, pharma and technology and continues remain one of the most informative life sciences symposia in the country.



Shakthi Nagappan Director (Life Sciences and Pharma) Chief Executive Officer, BioAsia and Hyderabad Pharma City Ltd



Shift toward Intelligent Health Ecosystem to deliver personalized health experiences anytime and anywhere^{1, 2}

Healthcare and life sciences industry practices have changed beyond all recognition over the past century; yet the rate of change and adoption of digital or virtual care models which transform the way we manage health is now accelerating, arguably at an exponential pace.

The clinicians of the future may indeed become medical engineers and will be trained in artificial intelligence, big data, robotics and other emerging technologies and disciplines. They will remotely manage multiple patients at a distance with the help of artificial intelligence (AI), augmented reality (AR), nanobots and other powerful tools which are already growing rapidly today in technological maturity and commercial value.

The future physician (or "medical engineer")?

Replacing the traditional concept of a physician, the *medical engineer* of the future may, for example, oversee nanobots at an ICU container park to provide personalized care to high volumes of patients simultaneously



The healthcare revolution is not just an opportunity but an urgent and essential need. Our existing healthcare models are not sustainable in the long run. The cost of health spending continues to rise with the rapid worldwide growth of costly chronic diseases. Meanwhile, the global healthcare workforce faces a predicted shortfall of 18 million health workers by 2030, a gap which will accelerate the necessary adoption of digital technologies.

Yet while these trends are widely acknowledged, we now also have the tools for transformation, which will not only drive efficacy of care and personalization, but also, and equally importantly, better access and efficiency.

1. Published by Pamela Spence, EY Global Health Sciences and Wellness Industry Leader on 26 May 2022

2. EY report, "How you can create value in an intelligent health ecosystem"

66

Artificial intelligence driven healthcare may sound like a science fiction today, just like MRI was a science fiction about 40 years back – who would have imagined at that time that a machine would scan the brain cells.

. . . .

Chief Technical Officer of one of the top 5 India based multinational pharma company



Medical engineer hundreds of miles away from the actual patient and can monito and treat >50 patients at a time



Advanced nanobots performing medical intervention

Science and technology are the engine, data is the fuel

New technologies are already driving the evolution of health. Today, healthcare innovators are working on integrating cloud computing, sensors, virtual and extended reality systems, and fifth-generation broadband into our care delivery models. Just over the horizon, still more advanced technologies like quantum computing and an immersive metaverse are taking shape. There is no single new technology that holds the key to the future of healthcare. Rather, as these technologies continue to evolve and converge in the healthcare space, they are enabling the creation of a growing internet of medical things (IoMT).

Infographic 1: The future will be data-rich, and we will continue to see new technology drivers



In the future, this IoMT will extend itself everywhere. Our homes and working environments will be loaded with connected appliances, virtual assistants, motion sensors, remote monitoring tools connected to smart infrastructure. Beyond this, bioelectronic implants, smart clothing, ingestible sensors, and ultimately nanobots and smart dust will map the very surfaces and interior spaces of our bodies. The net effect of this ever-present IoMT will be to drive an unprecedented growth in the quantity and quality of healthcare data available.





Data – particularly the disparate, often unstructured data generated from our daily lives, which is often relevant to health outcomes – requires new analytical tools to turn it from raw information into actionable insights. This analytical power is now becoming available and applied to new previously unused data sources in creating new knowledge maps.



8

Data is the fuel behind personalized healthcare

The fundamental problem behind the asymmetry of wishful thinking and deployment in India is the un-availability of good data.

• • • •

Setting up strong data architecture is no longer an option, but the only way forward for India to do real disruptive innovation.

Al and ML algorithms depend heavily on good, curated data that sets the stage for next level of innovation. In India, we still use global informatics databases to understand genes, understand disease entities, understand targets. To build tools and drugs personalized for Indian patients, there is a need to spend sufficient time, effort, money, people, and resources to build a suitable Indian data set. To enable real innovation, we need to strengthen data generation at every level – academic research, drug discovery, and clinical research. We also need to create an ecosystem where there is a transparent sharing of information.

Another very important need for India to personalize healthcare and improve health outcomes is to focus on **'health outcomes data'**. If we track epidemiology, interventions, outcome, etc., and develop a database that is maintained at every individual hospital level and physician level that caters to a national grid, this can have many use cases. For example, with this database, insurance companies can understand coverage risk, policymakers can identify which areas of interventions are failing with the available therapies. This will also help at a planning commission level, for example, when we think about which hospitals need to be set up and what kind of infrastructure is required to cater to the epidemiological problems in a jurisdiction.

COO & Board Director of one of India's pioneer start-up in Cell & Gene and immuno therapy

-

-

Head Strategy & BD of one of India's pioneer start-up in Cell & Gene and immuno therapy

Data and digital-driven personalized health experience in India

Patients and families in India today are hungry for knowledge – they are much more aware and want to be a part of the decision making for their own care.

With the advent of more digital media and smart phones, many patients now have access to information at their fingertips. They are much more aware of what types of treatments are necessary. They review physicians online; they review practices and care online – there is a lot more 'zomatification' of healthcare in terms of experience for the patient.

With the pandemic, there has also been increasing awareness and shift from treatment towards wellness and prevention. Over the last few years, penetration of home care health services and the healthcare insurance have also gone up significantly in India - driven by both fear and awareness. This is further transforming the entire healthcare ecosystem. A good deal of health-tech start-ups are developing affordable solutions in targeted specialities such as diabetes, cardiology, and for wellness. These companies are focusing on technology as a platform and bringing everything together - for example, doctor consultation, lab tests and diagnostics, medicine delivery, and other value-added services. Instead of engaging with the patients when they are diagnosed, these companies are working on the idea of being a part of the entire wellbeing routine in terms of their mental, emotional, physical fitness. The penetration of wearables is also increasing, for example, wearables as simple as fitness watches to CGM devices (continuous glucose monitoring) for diabetes patients. Continuous collection and monitoring of this data can help in identifying early warning signals.

Life sciences companies are also now focusing on such digital solutions for the patients and physicians across the iourney. Companies have realized that if they effectively channelize the data collected through such tools, they can be a better partner in this entire journey, and hence have started focusing on gathering the data. Considering 'data equal to asset', companies are now willing to spend on the infrastructure for data collection and analysis.

Potential challenges in adopting and using digital tools in India

- Most of the information that patients have access to today is not India specific – a lot of the information actually is western literature or provided in a context that is different from Indian healthcare. There is a need to create an Indian ecosystem driven experience for patients.
- India is a multi-lingual country. The access of information may be restricted because of the type of language in which the information is communicated.
- Digital literacy and reach can be other barriers, for example, the urban population will be easily able to adopt the digital tools than the population residing in villages.
- ► A lot of different solutions for same purpose, or solutions that do not seamlessly onboard all stakeholders involved in healthcare delivery, may cause confusion for patients and physicians.
- Patients are reading about their own symptoms, doing the triaging themselves and deciding on their own whether they need to visit physician A vs. physician B. This can overload the system in favor of specialists and superspecialists rather than generalists.

Action items to strengthen digital health ecosystem in India

The first step is to make India specific information available for patients to use. Strong patient societies, for example, a lymphoma society or myeloma society can play a very important role here. These societies can create websites that disseminate impartial and unbiased information to patients in multi linguistic formats. Life sciences companies can also play an important role in providing the information about diseases and drugs.

There is also a need to set up a system that incentivizes patients to go to primary care first instead of directly going to super-specialty physicians.

President & Head, Global Demand & Supply Organisation of one of the top 5 India based multinational pharma company

-

-

-

COO & Board Director of one of India's pioneer start-up in Cell & Gene and immuno therapy

Head Strategy & BD of one of India's pioneer start-up in Cell & Gene and immuno therapy

Building an intelligent ecosystem that can personalize insights

The growing presence of AI within healthcare is reflected in the FDA approval of over 130 novel algorithms in 2021, including AI that detects cerebral aneurysm and an algorithm for calculating the number and size of ovarian follicles. These algorithms already offer tools to perform digital triage, optimize care pathways, provide behavioral coaching and real-time disease management, and execute deeper analysis of genomic and other extensive data sets.

As the world of healthcare data continues to expand, Al offers a means to connect, combine and interrogate these data differently and unlock actionable insights. The adoption of AI into care delivery will be a continuous learning process, in which our healthcare algorithms continuously grow in intelligence and value. This combination of human and computational power will offer more value and power than either alone. With the power of Al, we can begin to link the huge volumes of data generated and the vast array of technological tools being developed into a comprehensive, integrated smart health system.

This system will be built on layers of data integration and analysis, with interconnecting platforms linked by a data backbone. The personalized data cloud surrounding each individual patient will be fed into a data layer, which allows that patient's data to be compared to individualized baselines and to real-world data on comparable patient cohorts. From here, the system can begin to plan betterinformed targeted interventions - and learn from these interventions to continually refine care approaches for each patient.

This data-driven smart system will enable us to break down the silos between care settings and optimize decisionmaking across the patient journey. Most importantly, it will finally offer a way to deliver truly human-centric care.

Digital patient twin technology - the key to more personalized, equitable and efficient healthcare³

Digital patient twin technology that fuses together a wide range of data sources beyond the traditional medical record – from wearable sensors to air pollution levels – can forecast the future health of individuals and help enable health systems to provide better care for all. Using predictive analytics, health systems can identify the points in an individual's life where they might be at higher risk for developing new conditions or seeing existing disease progress and intervene in powerful ways to change the course of a person's health.

3. Published by Aloha McBride, Global Health Sector leader at EY on 8 March 2022



With the insights possible from digital twin technology, health systems can tailor each interaction with the patient – from the first outreach, through treatment and post - recovery.

"For consumers who are accustomed to personalization in most of their shopping experiences, they do not want to be treated along standardized care pathway protocols that treat all patients the same: they want healthcare that meets their specific needs, preferences, and personal circumstances.

Digital twin technology holds the potential to make healthcare more personal, more effective, more efficient, and more equitable."

Wearable sensors can be integrated with the digital twins to produce live data streams that alert clinical teams, caregivers, and the patient when action needs to be taken both inside the hospital and at home, enabling more exception-based care management.

Call-To-Action

The explosion in data and technological innovation offers us a way to reinvent care as a patient-centered, personalized health experience - how ready are life sciences companies to fit in this evolving integrated ecosystem?



Technology driven transformation across the pharma value chain to improve efficiency and outcomes^{4, 5}

The life sciences industry has already benefited from technological enhancements, and there is the promise of more to come. Drug development, clinical trials, manufacturing, and supply chain are some of the areas impacted by AI and machine learning (ML).

Research and Development (R&D): increasing efficiency and productivity with a focus on patient centricity

The rapid development and mass deployment of COVID-19 vaccines, including the pioneering mRNA vaccines, highlighted to stakeholders what the industry is capable of achieving. At the same time, new technological advances are opening up the possibility of the life sciences industry making other breakthroughs that will transform the health experiences of patients, while potentially saving millions of lives.

66

As the knowledge base evolves and we come to know more about the human body, there is always a quest to identify new targets and come out with new medications. All the technological advancement is increasing the pace of shift toward personalized medications.

R&D Head of one of India's leading pharma company

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 Cloud and edge computing Improve data aggregation and storage Allow affordable high-throughput screening Genetics and genomics Identify responders for oncology therapies Develop targeted therapies outside oncology Create individualized therapies Source: EY analysis Today: already in use This list is indicative and not exhaustive 4. EY Report, "Today for tomorrow: realizing the potential of Life Sciences 4.0"

5. Published by Arda Ural, EY EY Americas Industry Markets Leader, Health Sciences and Wellness on 2 July 2022

Data and technology (e.g., artificial intelligence (AI), machine learning (ML), natural language processing (NLP), etc.) can help life sciences companies develop treatments faster and more efficiently, reducing the costs of healthcare, while making it more accessible to patients.

Thanks to its ability to process and interpret large data sets, Al and ML can be deployed to design the right structure for drugs and make predictions around bioactivity, toxicity, and physicochemical properties. Not only will this input speed up the drug development process, but it will also help to ensure that the drugs deliver the optimal therapeutic response when they are administered to patients.

The fashion in which clinical trials have been designed and conducted has not materially changed over the last decades, until the pandemic brought about necessary change to help transform some components of the clinical trial process, such as study monitoring and patient enrolment. Decentralization of clinical trials, enabled by technology, can help in reducing the costs of conducting clinical trials while increasing patient convenience/ accessibility, improving equity in clinical trial recruitment, and enabling better data monitoring.



commonplace in the near future

India's role in the future of innovative and affordable cell & gene therapies

66

India has the potential to play an important role in making cell and gene therapies affordable by reducing input cost and process time across the value chain: right from developing the raw (input) materials, to manufacturing, and delivery of the treatment.

But this requires a significant amount of innovation. We need to invest in understanding new manufacturing technologies; We need to invest in reimagining the entire process of making autologous cell therapies differently than the current set of paradigms in the West; We also need to strengthen the entire start-up ecosystem.

The availability of cell & gene therapies in India actually put India on the map. The entire thinking that India could become a destination for advanced cell therapies and best care for patients globally reenergizes the entire Indian healthcare sector. This includes physicians, nurses, life sciences companies, funding agencies, insurance companies. Think about this new ecosystem - a new bubble that needs to be built from the ground up through a supporting government policy, funding mechanisms, innovative discovery, operational and delivery mechanisms that impact the cost value equation.

Reducing costs of research and delivery cannot be one person's job we need to become patient centric as a nation.

COO & Board Director of one of India's pioneer start-up in Cell & Gene and immuno therapy

Head Strategy & BD of one of India's pioneer start-up in Cell & Gene and immuno therapy

Manufacturing and supply chain: transitioning from manual processes to agile systems for delivering personalized drugs to patients

Several Internal/Operational, External and Macroeconomic factors are impacting the manufacturing and supply chain function of the life sciences companies and require urgent response. Amongst all the drivers, the COVID-19 pandemic had a significant impact on the value chain. Increasing pricing and inflationary pressures, and focus on ESG are other key drivers necessitating a shift in priorities. In addition, the move toward 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.

Industry factors impacting manufacturing and supply chain function

Medicines made affordable through efficient manufacturing

61% of adults worldwide agreed that many people in their country could not afford good healthcare

24X7 cGMP compliant and audit readiness

Foreign inspections by USFDA have increased by three times from 2009 to 2019 and surprise inspections have resumed

"Lights out" operations of plants with minimal physical intervention

An estimated 50 percent of existing work activities in the pharmaceutical- and medical-manufacturing industry could be automated

Capability to manufacture medicine with drugs tailored to individual patients

The global personalized medicine market size is projected to reach over US\$5.7 trillion by 2030 and expanding growth at a noteworthy CAGR of 11.6% from 2021 to 2030

End-to-end traceability with detection of low standard medicines and processes at every step from production to distribution of drugs

About 1 in 10 medical products in low- and middleincome countries is substandard or falsified

Safe workplace

Manufacturing worker safety is critical and involves preventing physical harm, chemical exposure, equipment hazards, and promoting well-being

> Carbon neutral, Water neutral and zero waste manufacturing

It is estimated that the pharmaceutical industry directly generates about 52 mega tons of CO2 equivalent per year – 55% higher than emissions from the automotive industry Advanced technologies and data can play a central role in maximizing efficiencies and improving agility across the value chain quickly, efficiently and effectively. Increased automation and connectivity in manufacturing and production processes results in greater efficiency, productivity, and agility at a lower cost:

- > By analyzing longitudinal data, AI and ML can identify systemic issues in the pharmaceutical manufacturing process, highlight production bottlenecks, predict completion times for corrective actions, reduce the length of the batch disposition cycle and investigate customer complaints.
- Furthermore, life sciences companies can improve their efficiency by applying AI to their supply chain management and logistics processes, aligning production with demand and with an Al-enabled sales and operations planning process.
- > Al and ML can also monitor in-line manufacturing processes to ensure the safety and quality of drugs. These interventions will give life sciences companies confidence that their manufacturing processes are operating at a high standard and not putting the organization in breach of regulations.
- > Disruptive technologies also allow manufacturers to produce personalized products on demand, resulting in greater customer satisfaction and increased market competitiveness.
- Companies can also improve the sustainability and resource efficiency of production processes by using advanced technologies, such as smart energy management systems and recycling technologies.

There are numerous advantages to investing in advanced technologies and data analytics capabilities, and all the benefits cannot be listed here. But in a nutshell, it is a critical and urgent investment for sustainable, longterm growth.



Disruptive technologies and manufacturing excellence: key to efficiency and agility











Manufacturing 4.0: digital technologies to drive cost, agility and quality

30%

70%

Shaping the next generation of digital and data-driven healthcare, and sustainable practices

404	0%			>95%	95%	%06<	>80%	Baseline	APS
	- č	Product recall reduction		~ 0 defects	>95%	>80%	>50%	Baseline	Product defects eductions
				>85%	85%	80%	78%	Baseline	Process reliability JEE
20%	• 0	Maintenance cost reduction	2 A	Unattended	8	16	24	Baseline	Jnplanned MTBF stops/day)
				Improving	%06<	>80%	>50%	Baseline	Process failures eduction
30%	0	Energy and water cost reduction		Improving	Improving	%06<	>50%	Baseline	Breakdown eduction
,				<2%	<6%	<8%	<12%	Baseline	Jnplanned Iowntime
	-			>98%	>98%	>95%	>93%	Baseline	On-time delivery

66

The next generation of digital and data-driven pharmaceutical supply chain manufacturing will likely be characterized by increased automation, data analytics, and greater connectivity. This can help improve supply chain visibility, reduce the risk of counterfeits, and increase efficiency.

Operations Head of India's largest CDMO

With the digitally enabled manufacturing units and supply chain, companies can leverage a large variety of data to move from gut-based decision-making to a more evidencebased decision-making. This can help them manage great complexities and high volumes at lower costs. For example, a digital twin can create a real time simulation of the entire manufacturing process. Such a 'digital factory' can allow companies to track the processes in real time, anticipate and predict potential failures, optimize quality and productivity, and get treatments to patients much faster.

Role of advanced technologies in making pharma manufacturing and supply chain patient centric, agile, and self learning



The life sciences industry likely has only scratched the surface of the potential for technology to shape its future for the better.

The industry is only in the early stages of deploying AI and ML in life sciences. And while we can already see their promise, the industry is likely to find numerous future use cases for the technology that we cannot even begin to conceive of today.



Call-To-Action

To achieve R&D transformation, global pharma companies are either partnering with health tech start-ups and academia or developing their in-house capabilities. How are you developing the required capabilities?

Call-To-Action

How do you plan to leverage data and technology advancement to reduce manufacturing and supply cost, while maximizing responsiveness?

Supply chain digitalization – progress in India



During the pandemic, companies realized that data-driven real time decision making, and agility are critical to smooth functioning of the supply chain. This has fast forwarded the adoption of tools and technologies across several areas.

Many pharma companies have significantly invested in the supply chain digitalization, and it has been a journey of sort. About 10 to15 years back, it was more about getting the basic data of sales and inventory movement. Then companies moved to making SAP and ERP a part of the transaction system. The next step was digitalizing procurement, production planning and scheduling. And now we are talking about digitalization of end-to-end planning and developing use case of analytics in the area of procurement and new product launch. Companies are re-looking at the entire process – right from demand planning to supply planning and scheduling – and automating steps where possible. This has resulted in significant benefits, such as improvement in forecasting accuracy, inventory planning, actual vs. requirement score, and decrease of entire planning cycle time by up to 3 to 4 days. Digitalization also offers the agility to supply chain to respond to market needs by leveraging simulation & what-if scenarios building capability of the tool.

The next step for us is to use the data and analytics in a way that contributes to company revenue and profitability. We use multiple data sources to understand the developments in the market. For example, we monitor industry trends, our competitors' activities, our customers' preferences, etc. This helps us in picking Early Warning Systems. However, all this data is available in silos. Connecting all this available information into a comprehensive database and transmitting it to the relevant stakeholders can enable real time and effective decision making – for example about raw material procurement, inventory calls on finished goods/input components, etc. – allowing us to respond immediately whenever there is any opportunity in the market.

Another important digitalization step is integrating the business plan (sales and revenue plan based on which the budget and P&L are created) and the supply chain plan (on which the entire ecosystem is working). This one integrated plan can then be used for making all decisions about investments, working capital requirements, etc.

-

President & Head, Global Demand & Supply Organisation of one of the top 5 India based multinational pharma company



3

The ongoing revolution in personalized, patientcentric, virtual, and home-based care opening new opportunities and business models for MedTech companies⁶ As digital technologies, data science and other fields continue to converge, the nature of MedTech innovation is shifting. The industry needs to focus its innovation on new opportunities, including delivering personalized virtual care in the home and other non-traditional settings. To secure their place in the changing ecosystem, companies should prioritize using innovation as a disrupter before they are disrupted by their competitors.

The COVID-19 crisis has expedited healthcare's move away from traditional institutional channels toward home-based settings – and this momentum continues.

The past few years suggest that virtual, flexible care delivery offers benefits and improved outcomes beyond merely the ability to adapt to, and cope with, the extraordinary demands of the pandemic. Studies have shown that hospital-at-home programs can help establish a more immediate and consistent connection between patient and provider to stabilize or improve chronic conditions, prevent hospital readmission after discharge,

Al is already optimizing insights from large quantities of health data that humans alone cannot compute with comparable precision



6. "In today's disruptive health care environment, how will medtech transform?", EY Pulse of industry medical technology report 2022

and mitigate the development of chronic conditions among relatively healthy patients. In addition, evidence shows that remote patient monitoring can reduce readmission rates, falls and adverse events while freeing up both hospital beds and healthcare professionals' time.

In response to the opportunities offered by these new care models, MedTech companies have innovated to deliver better outcomes, improve access to underserved populations and increase detection of underdiagnosed diseases. For example, Sonavi Labs has developed an auditory device that can identify the presence of lung issues without an X-ray.

The industry's largest players have also taken note and made moves to boost their virtual care capabilities. One recent example is Medtronic's August 2022 deal with BioIntelliSense to build its remote monitoring capabilities and provide continuous, connected care from in-hospital to home.

In addition, advanced technologies can also help in improving diagnosis of diseases earlier and with more accuracy. For example, AI and ML are effective at identifying characteristics in images that cannot be perceived by the human brain. As a result, it can play a vital role in diagnosing cancer. Research by the National Cancer Institute in the US suggests that AI can be used to improve screening for cervical and prostate cancer and identify specific gene mutations from tumor pathology images. There are already several commercial applications in the market. Going forward, AI may also be used to diagnose other conditions, including heart disease and diabetic retinopathy. By enabling early detection of life-threatening diseases, AI will help people enjoy longer, healthier lives.

	— Recent FDA approvals for AI —
	Feb 2022
138	Viz.ai wins approval for AI that detects cerebral aneurysm
	Jan 2022
	Caption Health: algorithm approved for cardiac imaging
	Jan 2022
	Follicle clarity: algorithm for calculating number and size of
2020-2021H1	ovarian follicles approved

23

The industry must continue to embrace these opportunities. There are still issues to address beyond the regulatory and reimbursement questions, including inequitable access to the digital infrastructure (such as broadband) that is required to deliver virtual care effectively. But, working with providers, patients and policymakers, the industry can address these challenges and play a key role in innovating healthcare delivery in ways that offer better outcomes for all stakeholders.

MedTech companies must build their capabilities to meet the patient and the provider where they are as health systems continue to evolve toward home-centered, interconnected, intelligent health ecosystems.

Call-To-Action

How are you adapting your innovation and business model strategy in light of the changing requirements of the evolving healthcare ecosystem?





Need for life sciences companies to create long-term growth focusing on sustainability and ESG value-led model

Stakeholder capitalism: the case for change

The definition of success in business has expanded to mean more than higher profits or better returns. There's a growing recognition that quarterly earnings no longer accurately reflect a company's entire value. Indeed, while those balance sheets may have captured more than 80% of a company's value in 1975, today's balance sheets reflect at most 50% of that corporate value.

These changes mean life science organizations must better articulate their value outside the innovative medicines they develop. In today's world, talent, data, trust, and innovation also contribute to financial success. And, as the life sciences industry continues to wrap services around products, intangible assets such as intellectual property, human capital, organizational culture, corporate governance, and public trust are growing in importance. We need new reporting frameworks to measure these intangibles and drive long-term results.

What has changed: stakeholders demand that companies measure sustainability in a defined and consistent way, and will hold them accountable in the future



Sustainability can be a source of value

Many of these intangible assets directly link to social and environmental initiatives that are part of a company's sustainability agenda. There is an increasing body of evidence demonstrating a link between sustainability and corporate performance. However, the exact linkage still needs to be understood. Indeed, research suggests that sustainability is a sign of resilience and is associated with a better risk-adjusted performance across a range of metrics.

Source: EY ESG Compass platform





Because of this, a growing percentage of investors are choosing to finance companies that prioritize sustainability goals. More than US\$450 billion in global green and sustainability-linked loan volume was announced in 2019, up 78% from 2018, setting a record.

Beyond sustainability metrics to building a culture of sustainability						
_	Now Leading practices today		Next Emerging practices tomorrow			
1	Strategy an	d gove	rnance			
From agenda to advocacy	Setting targets and steering committees established at C-suite level	0	Defining targets and steering committees at business or functional unit level (local ownership)			
From scorekeeper to business partner	Aligning management incentives with financial and human value		Linking C-suite and board compensation to pay with strategic nonfinancial objectives such as access to healthcare or environmental impact			
2	Engagement a	nd pric	pritization			
From engagement to co-creation	Consulting diverse stakeholders to surface new ideas/risks		Using more collaborative, inclusive, and strategic engagement across functions			
From responding to avoiding risks	Prioritizing materiality topics based on short-term impact to stakeholders and business		Embedding long-term horizon (scenario analysis) in materiality assessments that are co-created with stakeholders			
3	Measuring a	and rep	porting			
From execution to measurement	Developing inclusive business models to deliver on societal value	0	Measuring the impact of initiatives to reflect contribution in upkeep of public health, building trust and upskilling R&D talent while growing the business			
From segmentation to cohesion	Planning and reporting of sustainability practices is not in alignment with overall strategy planning	•	Planning and reporting is well integrated with business' strategic plans and budgeting process			

Defining and internalizing sustainability

For the life sciences industry, one key component of sustainability is the linkage between disease impact and the role innovative medical products and services play in reducing this burden, which has economic, societal, and individual costs.

For life sciences companies, the growing focus on access means there is a strong need to track and analyze efforts to support sustainable healthcare systems. Multiple sustainability parameters align with these needs. For instance, metrics, such as the "number of patients benefited", align well with the goal of improving health outcomes at the population level.

One challenge life sciences companies face is deciding which of the numerous sustainability frameworks to use to measure value. Because most frameworks are not specifically designed with life sciences companies in mind, at best, these models only approximate the value life sciences companies create. This value disconnect is one of the many reasons it is difficult to draw a direct line from a company's sustainability efforts to its financial performance. Separately, the wide variety of metrics in use is also problematic. Our analysis suggests that even within a single organization, various parts of a business may use different metrics to track sustainability efforts. That variability makes it difficult to assess the impact of sustainability programs at an enterprise level, let alone compare different companies.

However, as the focus on sustainability is getting stronger, the life sciences specific framework of key value drivers and metrics has started to take shape.

Common value drivers cited by CEOs

Responsible innovation (includes R&D, bioethics, etc.)	Access and affordability	Product qua and patient safety
Pharmaceuticals in the environment and anti-microbial resistance	Diversity in clinical trials	Employee learning and developmen
Business ethics, integrity, and compliance	Supply chain management	Cybersecuri and data privacy

Life sciences sector metrics - illustrative

	Quantitative Qualitative			
Supply Chain Management	Safety of clinical trial participants	Ethical marketing		
 Percentage of (1) entity's facilities (2) Tier I suppliers' facilities participating in the Rx-360* International Pharmaceutical Supply Chain Consortium audit program 	 Management process for ensuring quality and patient safety during clinical trials (1) Voluntary Action Indicated (2) Official Action Indicated Monetary losses as a result of legal proceedings associated with clinical trials in developing countries 	 Code of ethics governing promotion of off-label use of products Monetary losses as a result of legal proceedings associated with false marketing claims 		
Drug safety	Employee recruitment, development and retention	Counterfeit drugs		
 Products listed (FDA) MedWatch Safety Alerts for Human Medical Products database Fatalities associated with products as reported in the FDA Adverse Event Reporting System Number of recalls issued; total units recalled Total amount of product accepted for take-back, reuse, or disposal 	 (1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) midlevel managers, (c) professionals, and (d) all others Talent recruitment and retention efforts for scientists and research and development personnel 	 Methods and technologies used to maintain traceability of products throughout the supply chain Actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit product Code of ethics governing interactions with health care professionals List of products on the WHO List of part of its Prequalification of Medicines Programme (PQP) 		

*Rx-360 is a nonprofit international consortium which addresses pharmaceutical and medical device supply chain security in relation to public health concerns Source: EY ESG Compass platform

Source: EY ESG Compass platform

of lead	ling life sciences c	ompanies
ality	Climate change (climate, carbon and energy)	Impact on nature (water and waste management, natural resource use, biodiversity)
d nt	Corporate governance	Employee diversity, equity and inclusion
ity	Talent hiring and retention practices	Employee engagement and wellbeing

Sustainability agenda movement in the right direction

Traditionally, the focus for all companies across sectors has been on cost and quality. But while chasing low cost, somewhere companies can lose sight of something that is not getting measured - and this includes the impact on the environment and society.

The Government of India (SEBI) has made it mandatory for the top 1000 listed Indian companies to publish the ESG performance. This is a step toward making the companies not only accountable to the shareholders, but to all the stakeholders because we are talking about building a better world.

Life sciences companies had focus on ESG earlier as well, but it was not getting measured and communicated to the relevant stakeholders. But many Indian companies have now made a definitive progress in defining the ESG targets and setting up mechanisms to report progress.

There are also some guidelines by relevant authorities to work with the vendors. We work with MSMEs, and we also deal with large corporate vendors. As far as the large corporate vendors are concerned, they are already aware of ESG principles. The real challenge comes when we work with the MSMEs. We have started working with them to make them aware of the guidelines also supporting them to become compliant. We believe this being done by corporates over period of next two to three years will help in creating awareness and grass root changes in existing ways of working.

-

President & Head, Global Demand & Supply Organisation of one of the top 5 India based multinational pharma company



Beyond sustainability metrics to building a culture of sustainability

There is a critical need to have a single version of truth with real/ near time performance analytics to create actionable insights. Accordingly, the purpose and goal can be divided into four key pillars:

- 1. Scientific measurement and baselining
- 2. Benchmarking and continuous monitoring
- 3. Improving performance to enhance revenues and optimize cost and working capital
- 4. Effectively communicate the impact and value across all stakeholders

	How do we leverage d	ata as our ESG s	uperpower	
Go	oal <i>©</i>	Third party/ supply chain data	External data	Enterprise data
(\$	Measure: timely measurement of ESG KPIs with Governance & controls	40%-50%	10%-20%	30% -40%
	Monitor and benchmark: performance monitoring and improvement	 Supply chain - tier I and II Partner ESG data Traceability 	 Analyst inputs Rating agencies ESG intelligence 	 Enterprise resource planning / Economic data Human capital
	Improve performance and reporting: harmonization of data for reporting across various standards and frameworks	 Human rights/ Social Third party governance 	 Sector bench- marking ESG controversies 	Supply chainCorp governance
Î Î Î Î Î	Communicate - long term value creation journey			

Contextualizing data from ESG standpoint

There are four layers primarily to look at ESG data landscape:

ESG Standards and sectoral risk and Opportunities library (De-coding the ESG Alphabet Soup)

Last we tabulated, there are 500 + ESG framework and standards that have been evolving for the last 20 + years. They have existed from different stakeholder lens - investors, customers, societal and regulators. We are increasingly moving toward global harmonization and focus is more on sectorization & predictive data that is forward looking.

Source: EY ESG Compass platform

- Enterprise data: This is the data that an organization emits across its business model. It is primarily around buy, make, move and sell, including support processes like human resources, finance and governance processes
- **Third-party data:** The third layer is the third-party • data across its supply chain - suppliers, business partners, distributors, outsourcing service providers and customers - this third-party environment, social and governance data is key for traceability from cradle to cradle
- External data: Fourth layer is the external data that the outside environment is creating, like rating agencies, ESG controversies, competitor intelligence, sector benchmarking and corporate social data.

We believe that the third party and external intelligence is key to differentiating an enterprise's ESG transformation journey.

For any company, data acts both as a telescope and microscope in all key business decision making, and benchmarking is important to create competitive differentiation. Companies can look at benchmarking from two lens - outside in and inside out.

Certain select examples of ESG data analysis and benchmarking would include:

- Materiality themes and sector weightages: environmental, social and governance
- Benchmarking with key peers and competitor intelligence: KPIs, goals, targets
- Science-Based Target (SBTI) benchmarking: ~4,000+ companies for Net Zero analysis
- Climate risk scenarios: Task Force on Climate-Related Financial Disclosures (TCFD)

- Sector benchmarks and innovation: patents database, etc.
- ESG performance ratings: disclosures, performance, and risk ratings. About 25,000 to 30,000 companies are globally rated, including ~1000 Indian companies. governance and engagement with rating agencies, including proxy firms, is key
- Social and governance indicators

Environmental indicators: peer benchmarking - a case study

		Enviro	onmental in	dicators			
Category	Environmental indicators	Company A	Company B	Company C	Company D	Company E	Company F
	Scope-1 emissions	1,556	1,190	2,630	3,121	4,129	2,726
	Scope-2 emissions	1,110	1,430	1,870	2,060	2,520	2,921
Greenhouse gas (GHG) emissions	Scope-3 emissions	4,514	3,650	6,230	7,153	9,659	10,137
	% Renewable energy	-	8%	11%	-	24%	26%
	% Non-renewable energy	100%	92%	89%	100%	76%	74%
Water	Water positive	No	No	No	No	No	No
Waste management	Waste recycled	20%	13%	9%	-	-	
	Waste incinerated	80%	57%	91%	100%	38%	8%
	Waste to landfill	Zero/ nil	30%	Zero/ nil	Zero/ nil	62%	92%

Call-To-Action

Where are you on your sustainability and governance agenda?



Conclusions

Like the disruption in the retail, transportation, finance and other sectors, new data-driven technologies will fundamentally alter the way healthcare is imagined and delivered. The healthcare revolution and shift toward Intelligent Health Ecosystem is not just an opportunity but an urgent need.

. . . .

- The ubiquity of data and analytics is creating new opportunities for life sciences companies to rethink innovation and create personalized health outcomes that the wider ecosystem of health stakeholders is now demanding. Platforms that connect, combine, and share data will be central enablers of this future value creation.
- The life sciences industry has already benefited from technological enhancements, and there is the promise of more to come. Drug development, clinical trials, manufacturing, and supply chain are some of the areas impacted by advanced technologies, such as AI and ML.
- Digital and data have the potential to transform the functions of the life sciences value chain and make them more productive, cost efficient and agile.
- 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. Ongoing revolution in personalized, patient-centric, virtual and home-based care has the potential to open up new opportunities and business models for life sciences companies.
- Reinventing business is not a choice but is imperative. With disruption being the new normal, innovation will give high performing companies a competitive edge.
- As companies develop their long-term transformation and growth strategy, they need to ensure that it is based on a sustainability and ESG value led model.

Way forward

- How will your organization transform its business model to be innovative while being cost-effective?
- Will your organization build new capabilities • organically, by acquisition or by flexible partnerships?
- How will your organization establish sustainability as the foundation of its growth strategy?



EY India Life Sciences Offerings



. . . .



....

EY Life Sciences Contacts

Farokh Balsara

Partner & National Director, Consumer Products & Health Services, EY farokh.balsara@in.ey.com

Suresh Subramanian Partner, National Health Sciences Leader Suresh.Subramanian@in.ey.com

Hitesh Sharma Partner, National Health sciences and Healthcare Leader - Tax Hitesh.Sharma@in.ey.com

Kaivaan Movdawalla Partner, Healthcare Leader Kaivaan.Movdawalla@in.ey.com

Sumeet Chandna Partner, Customer & Growth Sumeet.Chandna@in.ey.com

Saikat Ghosh Partner, Supply Chain, Operations & Strategy Saikat.Ghosh@in.ey.com

Phalgun Rudrapatna Partner, R&D, Manufacturing, Supply chain & Operations Phalgun.Rudrapatna@in.ey.com

Abhijit Basak Partner, Strategy Abhijit. Basak@in.ey.com

Amit Gupta Partner, Merger & Acquisitions amit1.gupta@in.ey.com

Sunil Gangwal Partner, Transaction Diligence sunil.gangwal@in.ey.com Parag Gandhi Partner, Post Merger Integration Parag.Gandhi1@parthenon.ey.com

 $\bullet \bullet \bullet \bullet$

Rajiv Joshi Partner, Forensics & Quality rajiv.joshi@in.ey.com

Nitin Mehta Partner, Technology Risk Nitin.Mehta@in.ey.com

Divin Proothi Partner, Technology Risk Divin.Proothi@in.ey.com

Ram Deshpande Partner, Technology Consulting Ram.Deshpande@in.ey.com

Satyam Jha Partner, SAP, Tech consulting satyam.jha@in.ey.com

Prosenjit Sengupta Partner, Technology Consulting, Prosenjit.Sengupta@in.ey.com

Nitesh Mehrotra Partner, ESG Governance, Process & Digitization Nitesh.Mehrotra@in.ey.com

Rajni Sadana

Health Sciences & Wellness Leader, EY knowledge rajni.sadana@gds.ey.com

Shobhna Mishra Associate Director, Markets & Industry Insights shobhna.mishra@in.ey.com Tarannum Khan Brand Market & Communications

Shweta Sharma Editing Brand Market & Communications

Satish Singh Rajeev Birdi Design Centre Sanjay Sinha

Chief Technical Officer, Zydus Group

Prashant Sharma

Operations Head, Akums Drugs and Pharmaceuticals Ltd

Gaurav Suchak President & Head, Global Demand & Supply Organisation, Zydus Group

Dr Arun Anand COO & Board Director, Immuneel Therapeutics.

Prachi Dubey Head Strategy & BD, Immuneel Therapeutics

Dr Ravi Kumar Nityanandam R&D Head, MSN Laboratories

Functional area experts





Ambli BRT Road, Behind Iskcon

Elante offices, Unit No. B-613 & 614 6th Floor, Plot No- 178-178A Industrial & Business Park, Phase-I

A Block, No.4, Rajiv Gandhi Salai Taramani, Chennai - 600 113

IGI Airport Hospitality District Aerocity, New Delhi - 110 037

Hyderabad

THE SKYVIEW 10 18th Floor, "SOUTH LOBBY" Survey No 83/1, Raidurgam Hyderabad - 500 032 Tel: +91 40 6736 2000

Jamshedpur

1st Floor, Shantiniketan Building Holding No. 1, SB Shop Area Bistupur, Jamshedpur - 831 001 Tel: + 91 657 663 1000

Kochi

9th Floor, ABAD Nucleus NH-49, Maradu PO Kochi - 682 304 Tel: + 91 484 433 4000

Kolkata

22 Camac Street 3rd Floor, Block 'C' Kolkata - 700 016 Tel: +91 33 6615 3400

Mumbai

14th Floor, The Ruby 29 Senapati Bapat Marg Dadar (W), Mumbai - 400 028 Tel: + 91 22 6192 0000

5th Floor, Block B-2 Nirlon Knowledge Park Off. Western Express Highway Goregaon (E) Mumbai - 400 063 Tel: + 91 22 6192 0000

Pune

C-401, 4th floor Panchshil Tech Park, Yerwada (Near Don Bosco School) Pune - 411 006 Tel: + 91 20 4912 6000

Ernst & Young LLP

EY | Building a better working world

EY exists to build a better working world, helping to create longterm value for clients, people and society and build trust in the capital markets.

Enabled by data and technology, diverse EY teams in over 150 countries provide trust through assurance and help clients grow, transform and operate.

Working across assurance, consulting, law, strategy, tax and transactions, EY teams ask better questions to find new answers for the complex issues facing our world today.

EY refers to the global organization, and may refer to one or more, of the member firms of Ernst & Young Global Limited, each of which is a separate legal entity. Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients. Information about how EY collects and uses personal data and a description of the rights individuals have under data protection legislation are available via ey.com/privacy. EYG member firms do not practice law where prohibited by local laws. For more information about our organization, please visit ey.com.

Ernst & Young LLP is one of the Indian client serving member firms of EYGM Limited. For more information about our organization, please visit www.ey.com/en_in.

Ernst & Young LLP is a Limited Liability Partnership, registered under the Limited Liability Partnership Act, 2008 in India, having its registered office at 9th Floor, Golf View Corporate Tower B, Sector 42, Golf Course Road, Gurgaon Haryana 122002

© 2023 Ernst & Young LLP. Published in India. All Rights Reserved.

EYIN2302-008 ED None

This publication contains information in summary form and is therefore intended for general guidance only. It is not intended to be a substitute for detailed research or the exercise of professional judgment. Neither EYGM Limited nor any other member of the global Ernst & Young organization can accept any responsibility for loss occasioned to any person acting or refraining from action as a result of any material in this publication. On any specific matter, reference should be made to the appropriate advisor.

SS

ey.com/en_in

🎔 @EY_India 🛛 in EY You Tube EY India 🦵 EY Careers India 🤘 @ey_indiacareers