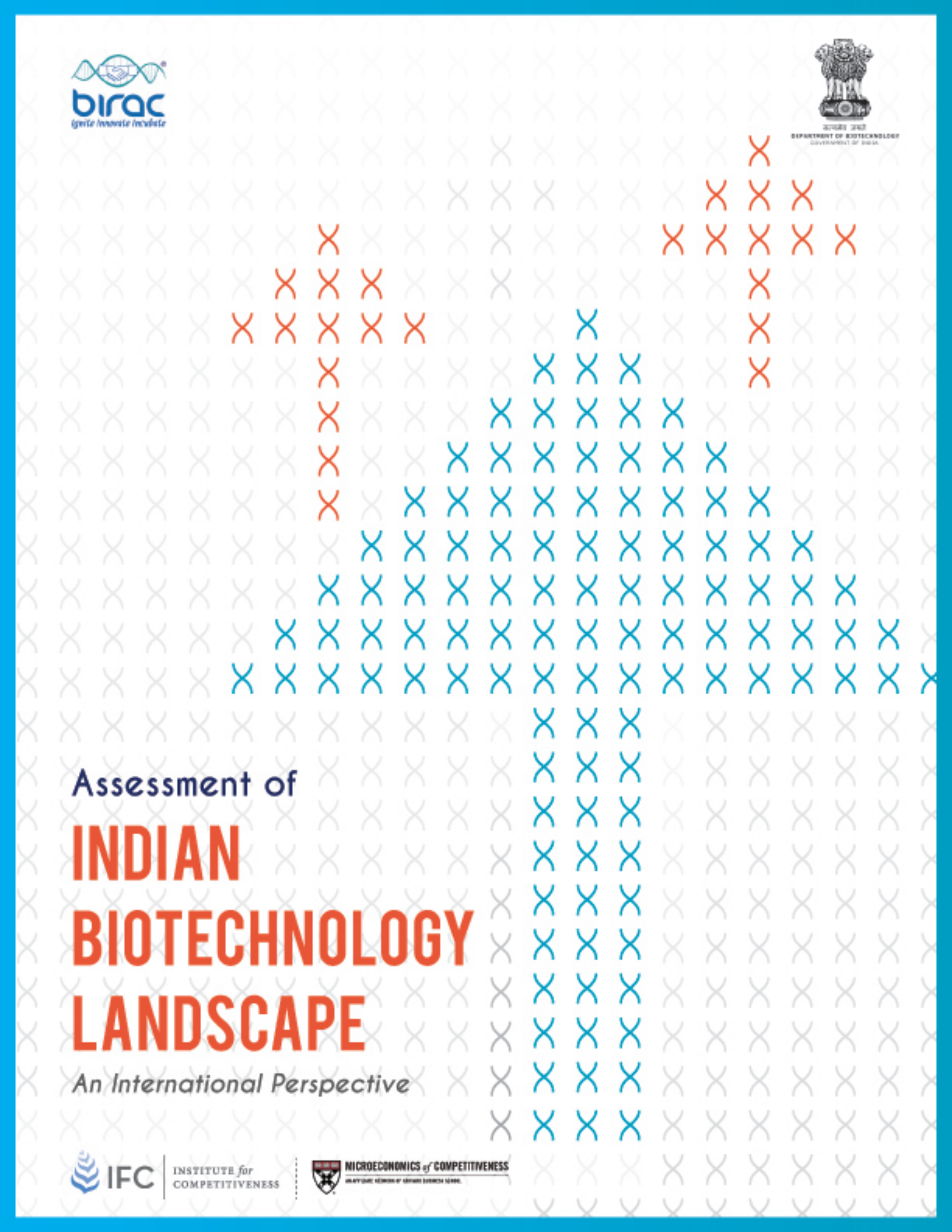

Assessment of

INDIAN BIOTECHNOLOGY LANDSCAPE

An International Perspective

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MICROECONOMICS of COMPETITIVENESS

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ASSESSMENT OF INDIAN BIOTECHNOLOGY LANDSCAPE

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Foreword

Dr. Renu Swarup

Secretary, Department of Biotechnology
Government of India

The biotechnology industry in India is entering a new era of growth. With forays into crucial sectors like pharmaceuticals, agriculture, industry, services and information technology, the biotechnology industry holds the potential to revolutionise the Indian economy itself and drive the country's growth agenda for decades to come.

Since its inception, the Department of Biotechnology (DBT) and Biotechnology Industry Research Assistance Council (BIRAC) its public sector enterprise have provided an enabling environment to the Indian biotechnology industry by promoting research and development in the field and improving capacity building across the country. The Department has strongly emphasised on facilitating a culture of cutting-edge research and innovation through its various initiatives towards empowering the industry with a world-class infrastructure and numerous public-private partnerships. DBT and BIRAC are committed to work alongside all aligned partners in the endeavour to create an innovation driven biotech ecosystem and amplify the growth of the Indian biotechnology to global excellence.

Biotechnology holds great potential to become the industry of the future. For instance, biosimilars can ensure the availability of affordable drugs and healthcare: genetically modified crops and bio-fertilisers can address the problem of food security: bio-fuels can provide a clean and cheap alternative to conventional fuel: bio-services can make India the hotbed for clinical research and development, etc. This industry holds immense potential to revolutionise the Indian economy.

India is among the top 12 destinations for biotechnology in the world, with approximately 3% share in the global Biotechnology industry. India is ranked 52nd according to the Global Innovation Index Report 2019. India is also the leader in the global supply of DPT, BCG and measles vaccines. Biotechnology sector is recognized as one of the key drivers for contributing to India's USD 5 Trillion economy target by 2024. As a result of the government's effort and support over the years, the Indian biotechnology industry has reached $51 billion in size, which has the potential to ensure significant economic growth and development to the citizens of the country. Global Bio-India 2019 is the most appropriate time to release the report on the Indian biotechnology sector to showcase how the biotechnology can play a key role in addressing the major challenges facing the country and contribute in its progress towards the Sustainable Development Goals in innovative ways.

A significant portion of the study report is devoted to making global comparisons and drawing insights from the best practices across the world. The recommendations that emerge from the report can potentially play a key role in guiding the approach of the government in driving policy making for the Biotech industry. The follow on second part of the study will be aimed to provide a concrete roadmap for the Indian biotechnology industry. I congratulate the entire team at the Department of Biotechnology and BIRAC in making this effort a successful one.

Message

Amit Kapoor

Chairman, Institute for Competitiveness

India has grown at a phenomenal pace in the last decade. It has already proved its mettle in Telecommunications, Smartphones and Automotive industries by becoming one of the world's fastest growing countries in these sectors and is expected to follow the same growth trajectory in other prominent sectors.

However, sustaining the high levels of economic growth as well as enhancing social well-being is a challenge that India faces today. It is axiomatic that innovation has the largest role to play in the long-term economic growth. That being said, the only way in which India can ensure continuous advancement is by targeting those sectors which would lead the way for a resource efficient as well as innovative economy. Interestingly, biotechnology is one such sector that can aid India to become a forerunner in innovation.

Often called as one of the sunrise sectors of India, the industry has already made considerable progress in providing a conducive environment for biotechnology innovation in the country. As a result, the biotech industry witnessed an upsurge in the number of start-ups in the recent years. The government has envisioned to make the biotechnology industry a $100 billion industry by 2025. This vision can only be met through long-term strategic planning which this study aims to provide.

The Biotechnology Landscape, 2019 is a two-part study which focusses on providing the stakeholders a roadmap for the future to make Biotech a $100 billion industry. It is a comprehensive report that analyses the current scenario of the biotech industry, highlights the challenges and issues that the industry faces and provides recommendations to overcome the hurdles.

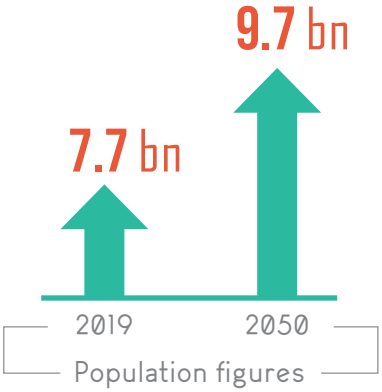
In addition, the study adjudges the performance of the Indian biotech industry vis-a-vis other top players. It also provides the myriad of investment opportunities. At present, India's share in the global biotech sector is around 3 percent but the study predicts that the share would increase to 19 percent by 2025 in the global biotech sector.

The Institute for Competitiveness is sincerely thankful to the Department of Biotechnology and Biotechnology Industry Research Assistance Council (BIRAC) for their constant support and invaluable feedback during the course of the project. I would also like to acknowledge the support of my team at the Institute for Competitiveness, including Aniruddh Duttaa, Chirag Yadav, Jatin Nair, Manisha Kapoor and Tanya Joshi in compiling the report. We are hopeful that the recommendations from the study will help the country in achieving the 2025 vision.

Content

Introduction

The world is confronted with potentially irreparable changes to its climate; unprecedented exploitation of natural resources through unsustainable development paths; and social upheaval caused by high unemployment rates and record high inequality. These issues would be exacerbated by the increase in population that is expected to reach 9.7 billion in 2050[1], up from the current figure of 7.7 billion. The well-being of our current and future generations depends on how these complex and inter-connected socio-economic challenges are tackled by the countries.



In the light of these challenges, the world needs policies that can not only bring economic prosperity for all but also guide our consumption and production processes to respect the ecological boundaries of our planet. We need to bring radical changes to the make efficient use of our limited resources. The only way for countries to ensure sustained growth and prosperity while tacking these challenges is to be more innovative and to focus on sectors that would pave way for an innovative and resource efficient economy.

The biotechnology sector, mainly due to its holistic nature, holds the potential to provide a solution these societal challenges. The use of biosimilars is helping millions of people around the world in battling life-threatening medical issues. Genetically modified crops are increasing acreage and are providing better yields to the farmers while reducing the dependence on heavy consumption of water and energy. Industrial biotechnology is being channelled to produce biofuels that can help in ensuring cleaner environment.

The Indian government, recognising the ability of biotechnology to drive India's socio-economic growth, is proactively working towards its development and is focused on

As early as 1986, India was the first country in the world to set up a department solely dedicated to biotechnology.

[1] The World Population Prospects 2019, United Nations https://www.un.org/development/desa/en/news/population/world-population-prospects-2019.html

promoting the large-scale use of biotechnology. Over the years, it has provided key support to enable the exponential growth of the Indian biotechnological industry. As early as 1986, India was the first country in the world to set up a department solely dedicated to biotechnology. Since then the country has aspired and made efforts towards becoming a leader in the biotech market by focusing on bio-innovation to address the challenges in healthcare, food and fuel security. Since its establishment, the Department of Biotechnology has made immense contributions to enable the exponential growth of the sector. From setting up Centres of Excellence to stimulate industry-academia interaction to the establishment of Biotechnology Industry Research Assistance Council (BIRAC) to encourage research and innovation within the sector, the department has made indispensable contributions over the years.

In fact, when the size of the biotechnology industry was merely $4 billion in 2011, it had set a target for it to touch $100 billion by 2025

These efforts by the Indian government reflect that the country recognises the fact biotechnology can revolutionise healthcare, agriculture, energy production and industrial processing. By transforming these sectors, it can contribute significantly towards employment generation, rural development, food security, wealth creation, and environmental sustainability. India has a vast pool of human capital, that clubbed with the recent advances in capacity building exercise: large outlays within the sector: and the partnership between private sector and the government can help in the future growth of this sector. However, the sector is still at a nascent stage compared to the developed biotechnology economies. The growth and development of the sector rests on taking steps to address the challenges in the current system. This include continuous investment in research, better knowledge transfer mechanisms, and establishing policy mechanisms that are conducive for the sector's growth and would help in achieving the ambitious target of $100 billion the sector needs to have a clear goal-oriented roadmap for the years to come.

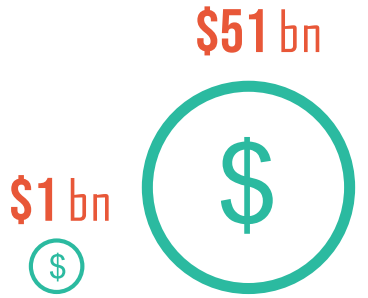
Against this backdrop, the study analyses the Indian Biotechnology landscape and provides a roadmap for its future. It starts by projecting the size of the biotechnology sector to get an idea about the rate of growth that is required to make it a $100 billion industry by 2025. The study then examines the strengths and weaknesses of the Indian industry by using the Diamond Model. This includes an in-depth understanding of the current Indian biotechnology ecosystem including the investment attractiveness capability, the IP regime, and industry-academia linkages. It then moves on to understand India's position vis-à-vis other emerging and developing biotech economies by calculating a Biotechnology Competitiveness Assessment. The assessment is based on three pillars, i.e. Enablers, Facilitators and Performance that would effectively point out the input-output relation in their respective Biotech industries. The indicators will be able to cover all the aspects of the global biotech industry and therefore will provide a clear picture about every country's individual performances. Based on these frameworks, the report provides a roadmap for the future.


250C

The Indian Biotechnology Landscape

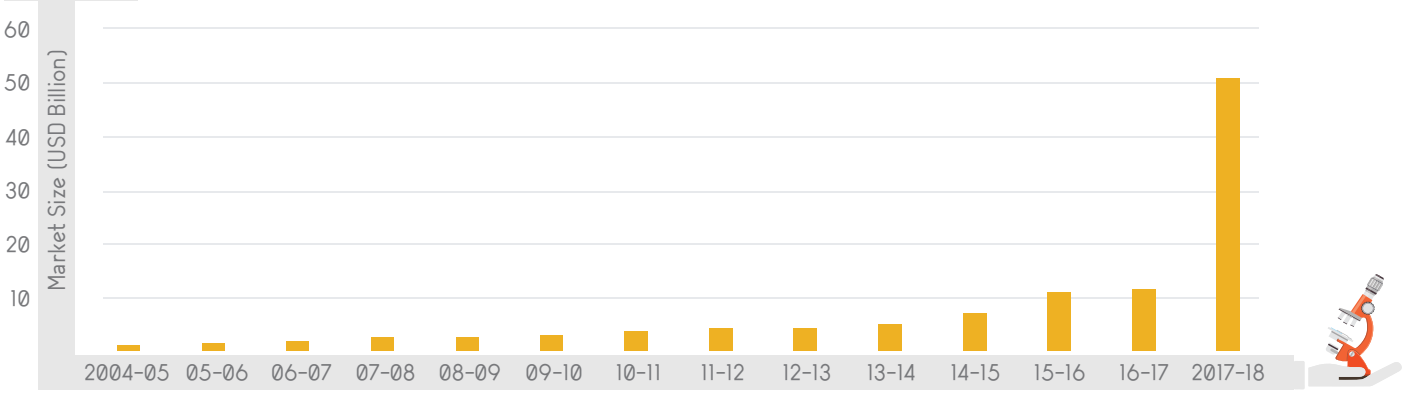
Size of the Industry

The biotechnology industry can be traced back to 1980s when the Government created Department of Biotechnology, India. From merely $1.1 billion in 2003, it has grown exponentially in size to a $51 billion industry as of 2018. The year on year growth rate of the industry is 14.7%. The growth of the industry is depicted in Figure 2.1. As of 2017, India accounted for approximately 3 percent share in the global biotechnology industry and stood among the top 12 destinations for biotechnology in the world.[2]



Size of the industry

Figure 2.1: Market Size of the Indian Biotechnology Industry (USD Billion)



Source: ABLE - Biospectrum Industry Survey, Make in India, Ministry of External Affairs, TechSci Research Global Industry Analysts Report GIA

[1] Invest India, Snapshot of the Biotechnology Industry https://www.investindia.gov.in/sector/biotechnology

The Department of Biotechnology has set an ambitious target for the industry i.e. to make a $100 billion industry by the year 2025.

The report defines three different possible scenarios for the growth of the biotechnology sector. The growth trajectories differ on the basis of the policy environment by the government, achievements and technology disruptions that could come from the businesses and the linkages between the different stakeholders in the industry. The different scenarios are explained in Table 2.1.

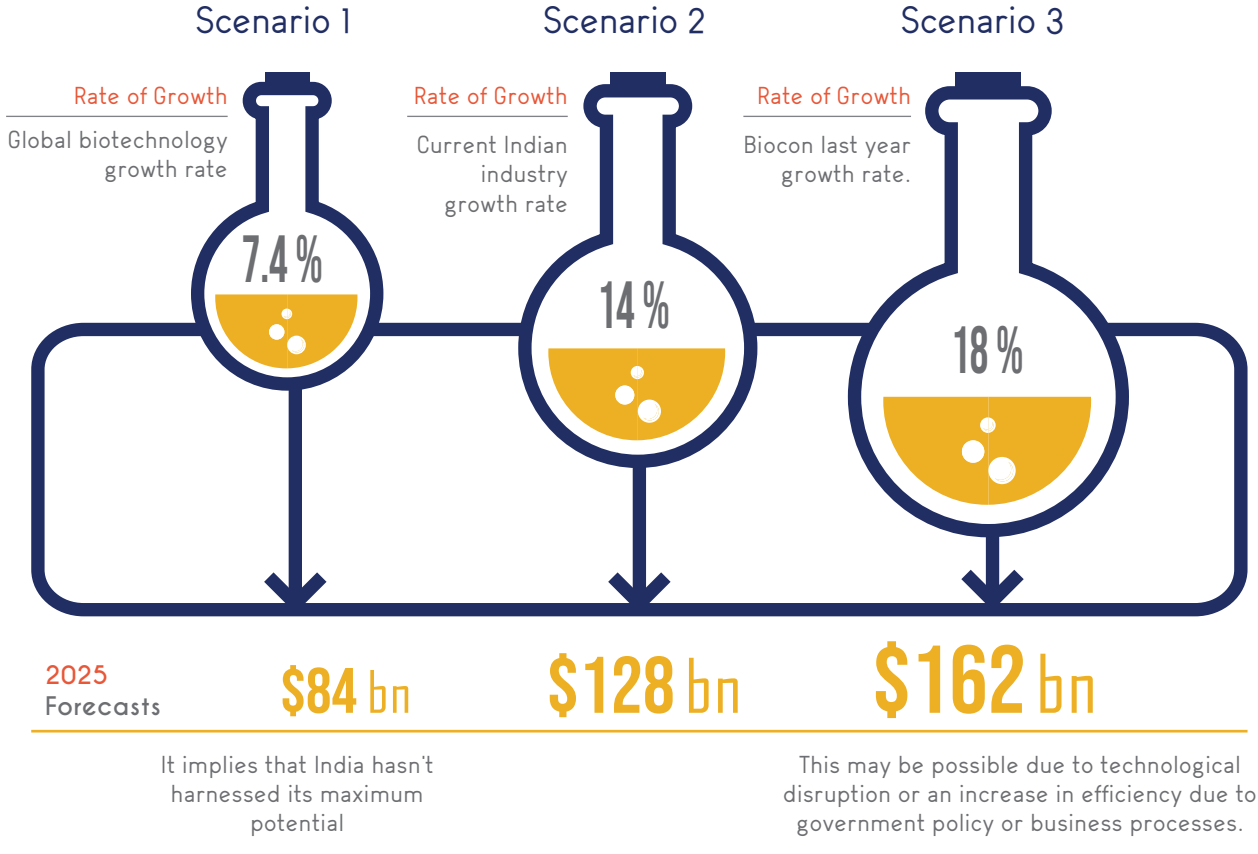
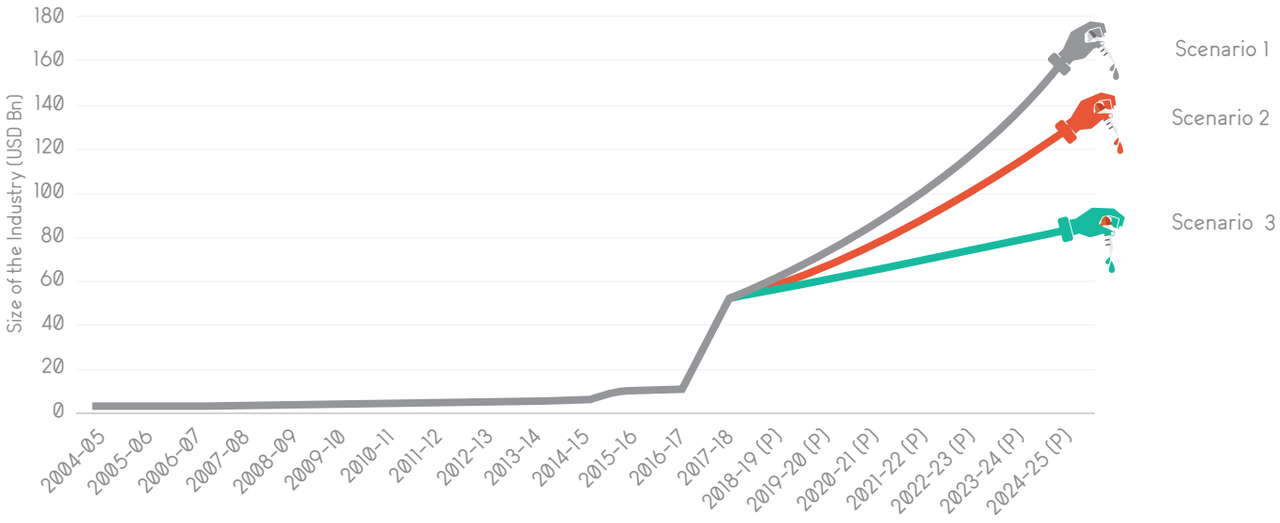


Figure 2.2: Projecting the Growth of the Industry



As mentioned above the Indian biotechnology industry has also become a prominent player in the global market. In the year 2017, it was around 3 percent of the global market. The Indian market, if it keeps on growing at the same growth rate of 14 percent (Scenario 2), it would reach $128 billion by 2025. In 2017, the global market was valued at $390 billion and is projected to grow at 7.4 percent yearly. Assuming the same rate of growth, the value of the global market would be $670.9 billion by 2025 (These projections are depicted in Figure 2.3).

The evolution of the global share of the Indian biotechnology industry is more clearly re ected in Figure 2.4.

The figure shows that the contribution of the Indian biotechnology industry in the global biotechnology market is expected to grow from 3% in 2017 to just over 19% by the year 2025[3].

[3] The actual figures of the Indian industry are available for the year 2018 while the actual gures for the global industry are available for the period 2017. So, in the year 2018 we are drawing comparisons between actual and projected gures. Therefore, one should take the global contribution of the Indian industry as the upper bound of the estimate. Some conservative estimates might provide different results.

Figure 2.3. Projected Growth of the Indian and Global Biotechnology Industry

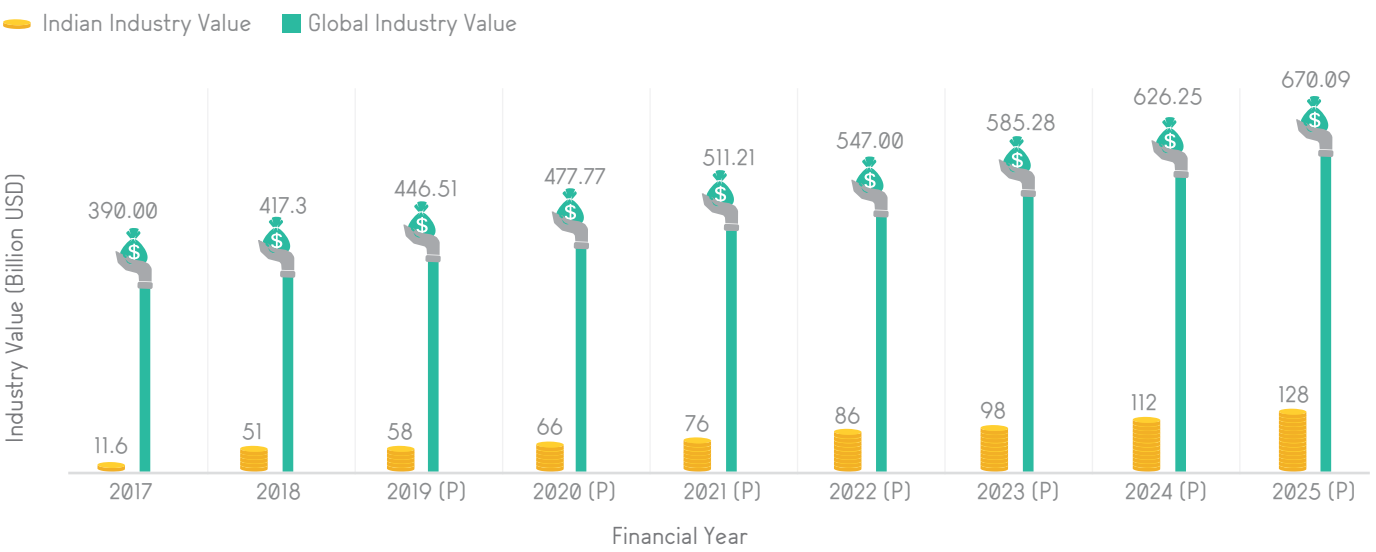
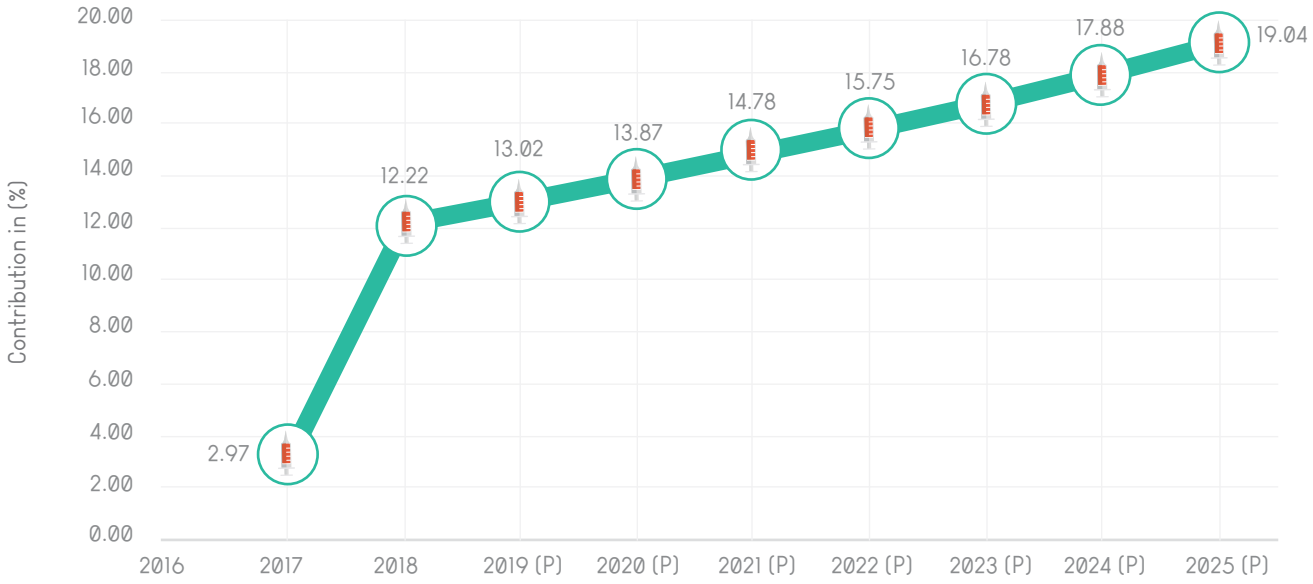


Figure 2.4. Projected Growth of the Global Share of the Indian Biotechnology Industry



The Competitiveness of the Indian Biotechnology Industry

It is important analyse the competitiveness of the industry to examine the strengths and weaknesses of the Indian biotechnology industry. The study uses Diamond Model by Michael E Porter to analyse the same.

The Diamond Model bases its assessment on four key elements:

Factor Conditions

It looks at factors that impact the productivity directly. These include factors of production: not just the conventional ones like land, labour, and capital but also specialized factors like skill set of labour, infrastructural facilities etc.

Demand Conditions

It examines the demand for the industry from local as well as international customers.

Context for Strategy and Rivalry

The element examines the level of competition in the market through indicators such as taxation policy, incentives, the rules for FDI etc.

Related and Supporting Industries

The proximity to upstream and downstream industries allows for easy exchange of ideas, access to local suppliers and more access to sophisticated infrastructure as compared to firms located in isolated areas.

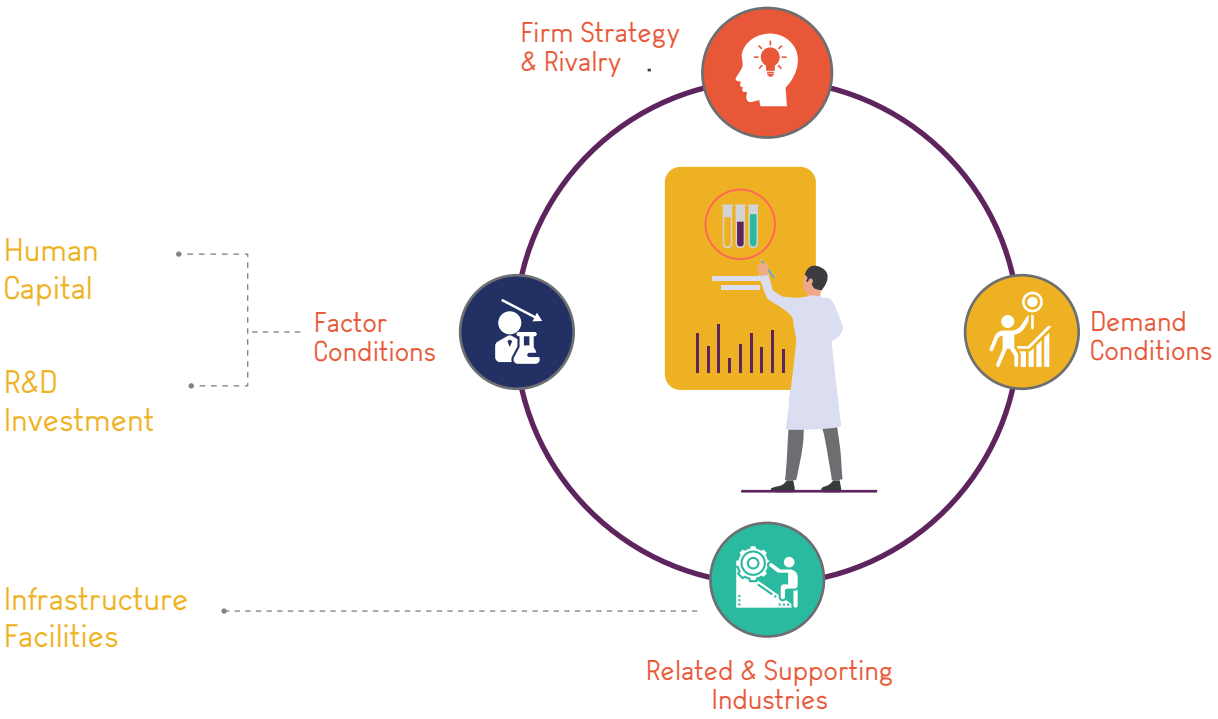
The table below shows the strengths and weaknesses of India under each of these elements. The green side shows areas in which India is already faring well, whereas the red side represents what is lacking.

Factor Conditions	Demand Conditions
• India is home to young minds has the potential to build a pool of affordable high-quality skilled workforce. • Industry-academia collaborative mission of department of biotechnology (DBT) in collaboration with World bank is an initiative for improving the linkages between industry and academia, the absence of which hinder research and developmental activities.	• Global biotechnology industry is growing at the rate of 7.4 percent and there is huge demand within each segment of the industry that Indians can cater to. • With an established IT system and infrastructure, growth in Bio-IT, an untapped segment, could propel the growth. • India's production of insulin could turn out to be the key, as the forecasted burden of diabetes seems to be big. • Biofuels could be of strategic importance given the increasing global energy needs.
• The educational curriculum does not prepare the students for the industry's demands. • Need for state-of-the-art research facilities across the country to boost R&D. • Lack of venture capital funding due to information asymmetry regarding the biotech industry.	• Low percentage of clinical trials conducted in India when compared to the rest of the world is a concern.

Context for Strategy and Rivalry	Related and Supporting Industries
• The National Biotechnology Development Strategy highlights underlying problems faced by the industry and provide recommendations. • States have introduced their own biotechnology policy documents to attract investments.	• Separate departments for Biotechnology, Scientific and Industrial Research, Science and Technology promote research, formulate policy and provide financial assistance. • Presence of bio-incubators, bio-clusters and biotech parks will help in multiplying the output, revenue and employment generation in the industry.
• Lack of coordination between departments and ministries which makes the system confusing.	

Issues and Challenges

The diamond brings out the following challenges in the Indian industry



Investment in Research and Development

India's expenditure on Research and Development, when compared to both developing and developed countries has been low. According to the UNESCO data,the expenditure on research and development (as a percent of GDP) in general has been 0.8% for India (depicted in Figure 2.5). The target set by the Economic Advisory Council to the Prime Minister (EAC-PM) for the year 2022 for such expenditure has been 2%.

India also falls short when it comes to the ratio of researchers per million inhabitants of the country. The number comes out to be 216.

In a populous country like India, there is an ever-growing educated workforce which implies there is immense potential for research and development activities. To develop the overall research sector of the country: India has to achieve the dual goals of creating a conducive research infrastructure and inculcating the behaviour to promote research among young graduates. And increasing expenditure on research must be channelized to achieve those two goals.

ACCORDING TO THE UNESCO DATA,

the expenditure on research and development (as a percent of GDP) in general has been

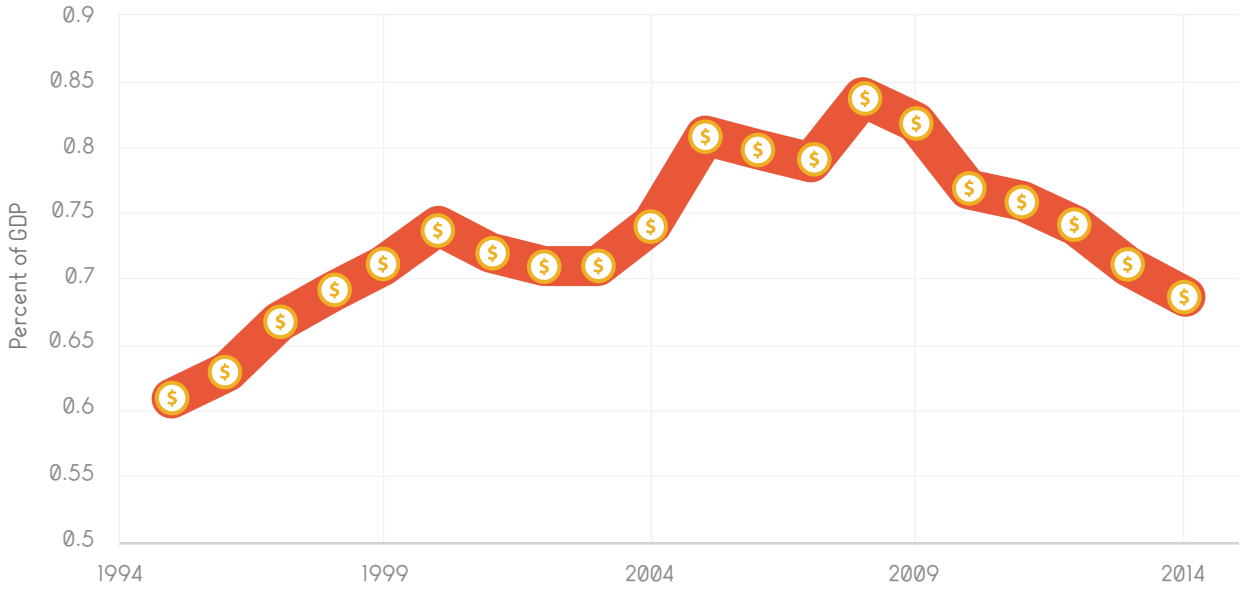
0.8% for India.

The target set by the Economic Advisory Council to the Prime Minister (EAC-PM) for the year 2022 for such

expenditure has been 2%.

As far as the biotechnology research and development is concerned, the government has taken a positive route. The Ministry of Science and Technology has received its largest-ever allocation of funds this fiscal year (2019-2020). DBT was one of the biggest beneficiaries as it received a budget of INR 2580 crores, which is a hike of INR 159 crores from the previous year.

Figure 2.5: R&D as Percentage of GDP



Regulatory Practices

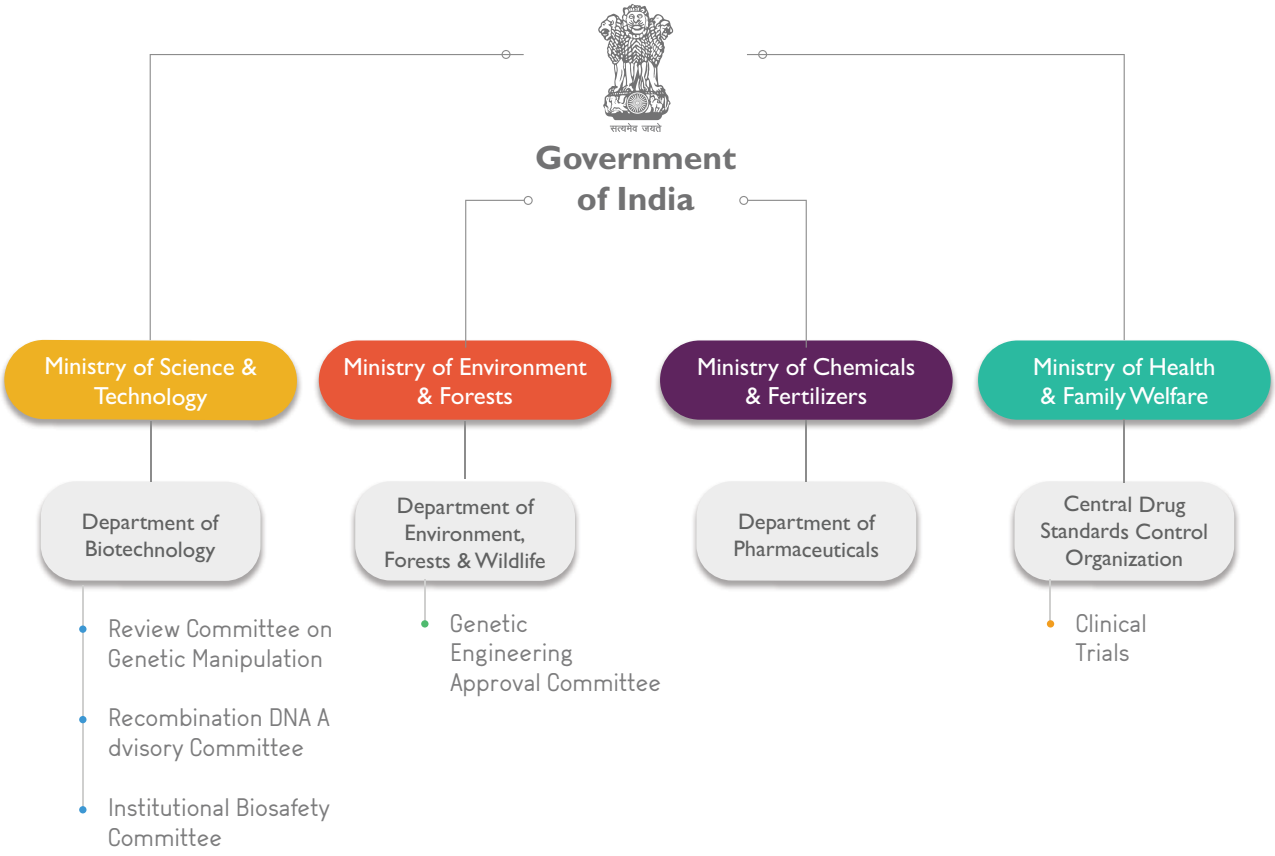
The Indian biotechnology industry is regulated by four main bodies – Ministry of Science and Technology, Ministry of Environment and Forests, Ministry of Chemicals and Fertilizers and Ministry of Health and Family Welfare.

The application policies concerning various above agencies often cause problems. Since different agencies are under different ministries, seeking approvals requires coordination from all the concerned ministries. The coordination between all departments and ministries hasn't been as strong as it should be. This often delays the rate of approvals and creates challenges in tracking of applications.

Figure 2.6 shown below presents the division of departments concerning biotechnology amongst various ministries. These departments also perform specific functions. The Department of Biotechnology under the Ministry of Sciences and Technology reviews issues related to genetic manipulation via the Review Committee on Genetic Manipulation. The committee covers the area of research as well as large-scale handling of hazardous microorganisms, Genetically Engineered (GE) organisms or cells and products thereof. While this particular committee overviews multiple stages of

development of GE organisms: its approval is carried out by another committee. Genetic Engineered Approval Committee (GEAC) under the Ministry of Environment, Forests and Climate Change have the responsibility concerning appraisal of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production with a perspective of their environmental impact. The committee also shares the responsibility for appraisal of proposals relating to the release of GE organisms and products into the environment including experimental field trials.

Figure 2.6: Departments concerning Biotech Approvals



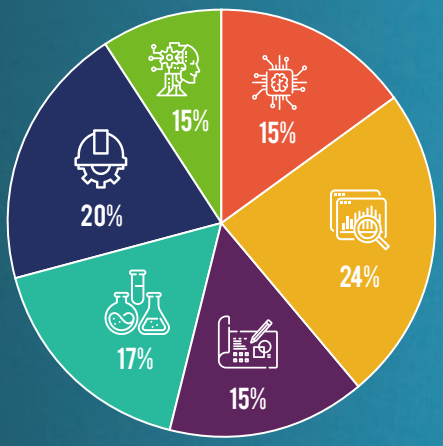
Therefore, in case of GE organisms, from its approval to its review, an applicant will have to move between two different ministries and two different departments. In such a situation, the applicant is dependent on smooth cooperation between the departments and the ministries. This could delay the process regarding use and commercialization of GE organisms.

There is a need to increase coordination between the departments and ministries to fasten the rate of assessment of applications.

Human Capital

India's working population is in an advantageous position. That is so because the country has a young workforce. This workforce has got massive potential and could contribute to the national economy in the coming decades. However, the focus should now be on improving the employability of the workforce. We need to align the demands of the industry with the university curriculum for the students to thrive in a competitive market. According to a skill-based survey conducted by UNDP, few job areas were identified that would dominate the future job markets and therefore, skill-based policies must be inclined in these areas and prepare the next batch of post-graduates for the same set of jobs.

Figure 2.7: Future Job Areas (Projected Percentage)



- Artificial Intelligence
- Analytics
- Design (Software, Hardware, Concept, etc.)
- Others
- Research and Development
- Robotics

Source: UNDP

Hence, industries must partner with universities to set curriculum, design courses, and impart knowledge so that fresh graduates can become more productive. The lack of linkages between industry and the universities needs to be addressed in order to tackle the low employability challenge.

The Government though has taken strong steps to address this gap. Under the Skill India project, several programs have been launched. Out of these schemes, Apprenticeship Training and Industrial Training Institutes are supposed to train the students and inculcate the necessary skills that the industries demand.

Infrastructure Facilities

The biotechnology industry's development is heavily dependent on the available infrastructure facilities such as physical (roads, rails, ports etc.) and research (incubators, instruments, animal breeding etc.) infrastructural facilities. India has made considerable progress on the physical facilities and should now shift its focus on improving the research facilities:

- The focus should be on providing world-class clinical trial infrastructure. For instance, India has just 1.3 beds per 1000 population.

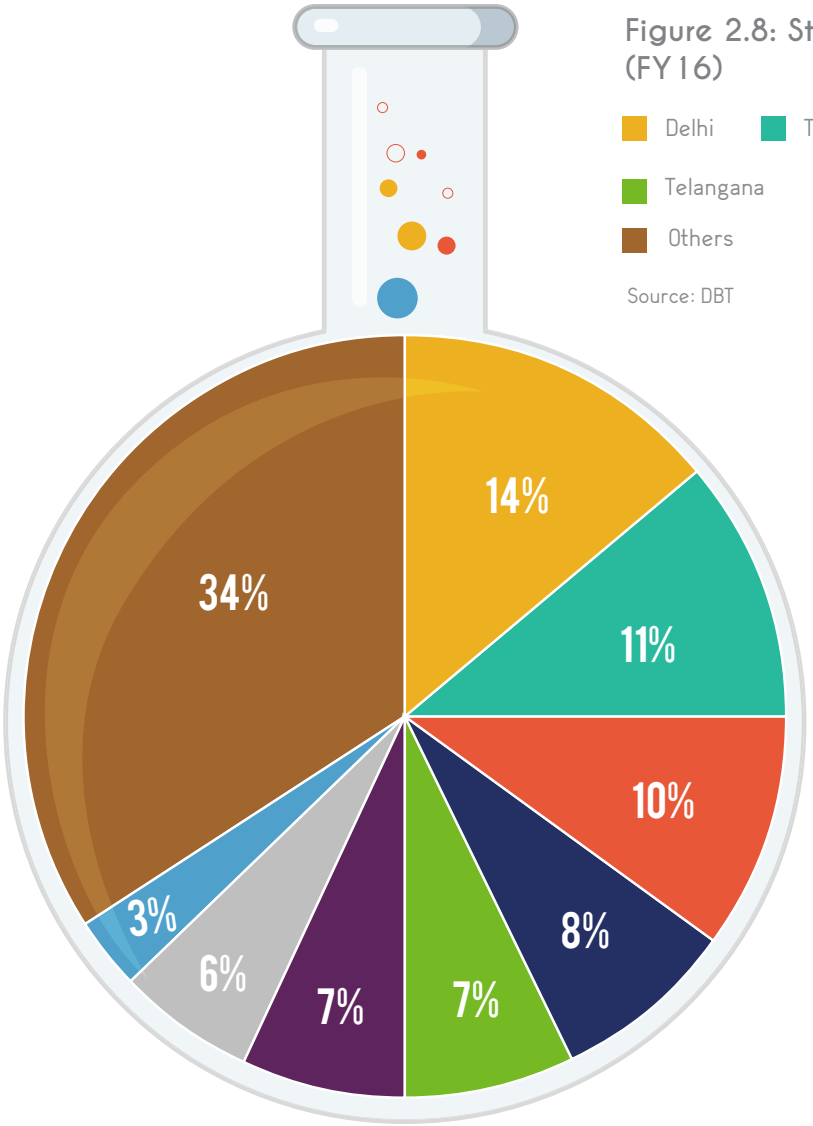
- It is commendable that bio-incubators are present around the country. But the size of these incubators is small compared with incubators in countries such as the US. US incubators employ about 20 times more than what an Indian bio-incubator can employ. This creates a difference in the productivity of the Indian companies vis-à-vis with companies from other countries.

- Electronic records are valuable for research purposes and a roadmap should be created for its adoption.

Contribution of States to the Biotech Industry: How Innovation and Clusters play a role?

Many states have their own specialized departments for biotechnology and also have released specific biotech policies. States such as Karnataka, Tamil Nadu have taken the lead in those regards. And therefore, they are some of the best performers in this particular industry. These states were allotted projects by DBT based on the available facilities to conduct research and work on such projects. The following chart presents the share of projects for different states in the financial year 2015-2016.

Figure 2.8: State-wise Biotech Project Distribution (FY 16)



Source: DBT

States such as Delhi, Tamil Nadu, Maharashtra etc have been some of the strongest performers in the sectors (as will be shown later) and therefore are allotted majority of projects.

The reason that these regions are the front-runners in the growth and development of India's biotechnology sector lies in their innovative potential. This depends on the institutions that are involved in the process of learning or that jointly or individually contribute to the development and diffusion of knowledge, new technology. Going by this idea, the main pillars of innovation landscape are government, the private sector and the higher education system.

The recent India Innovation Index, released by NITI Aayog, examines the innovation ecosystem of states and Union Territories. The comprehensive framework considers "enablers of innovation" – human capital, investment, knowledge workers, business environment, and safety and legal environment – as well as the "performance on innovation" – knowledge output and knowledge diffusion.

The states that have a strong innovation landscape are also the states that are contributing the most to the Biotech economy. These include states like Maharashtra, Karnataka, Delhi, and Tamil Nadu. These areas have established facilities that create a conducive environment for conducting business and the by-product of that is increased innovation, output and employment.

But other states have also stepped up with an effort to increase their project share in the coming years. For instance, Odisha state government released its first ever Biotechnology Policy in 2018 which would prioritize the thrust areas for basic as well as applied research and technology development with industry-academia-social interface. The policy also includes few fiscal and non-fiscal incentives along with initiatives to ease the process of conducting business.

There is a strong expectation that following Odisha's policy many states will do the same and therefore will focus on improving their performance. All the states in India are contributing to the biotech industry but clearly there are leaders and there are followers in the industry.

It is also important to understand that government, private sector as well the universities cannot work in isolation. The interactions between these actors such as adoption of new technologies by the industry, joint research by the private sector and research universities in the areas that can be commercialised or development of new courses in universities define the innovative capabilities of the region. These interactions become easier if these actors are in geographical proximity to each other. There is a lot of evidence to suggest that clusters[4] provide an environment conducive to innovation and knowledge creation.

They do so by offering advantages to firms in as compared to isolated firms. Cluster participation eases the process of learning and innovation as firms try to create a shared understanding of the industry and its workings. The relationship of firms within clusters allows them to directly observe other firms and universities.

[4] Clusters are defined by Michael E Porter as "geographically proximate group of interconnected companies and associated institutions in a particular field, linked by commonalities and complementarities. The geographic scope of clusters ranges from a region, a state, or even a single city to span nearby or neighbouring countries."

Figure 2.9: Biopharmaceutical Cluster in Indian States

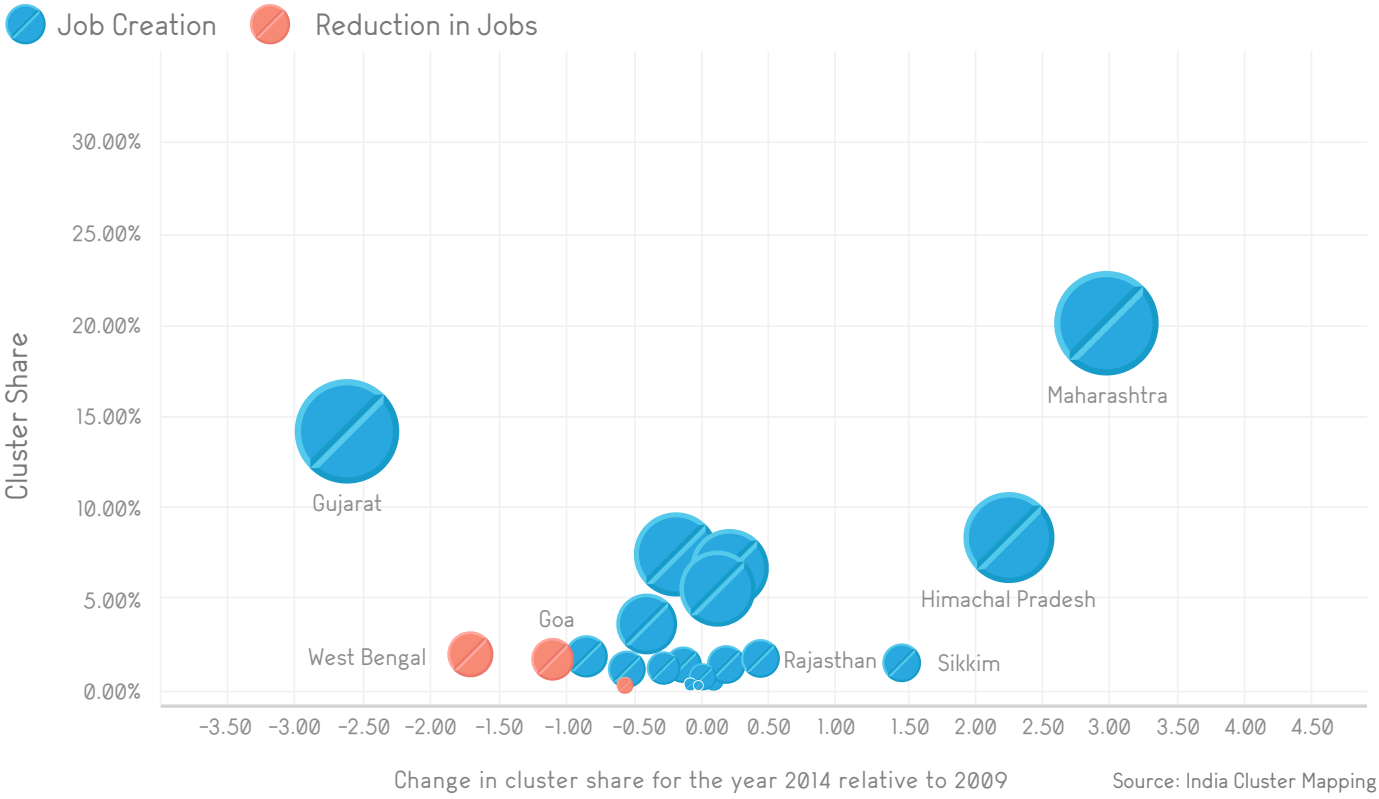


Figure 2.9 shows the presence of Indian biopharmaceutical cluster at the regional level. The cluster is mainly present in Maharashtra, Gujarat, Himachal Pradesh, Tamil Nadu, Karnataka, Uttarakhand. The graph also shows that the cluster is growing at the highest rate in Maharashtra, Himachal Pradesh, Sikkim and Rajasthan.

Beyond India's IP Regime

A strong IP regime is an important industrial tool for fostering innovation and economic growth in a country. Although it is undoubtedly an important cog in the innovation ecosystem, it is far from being the only determinant of strength or weakness. The majority of the recent debate regarding innovation in India has centered around its IP regime, particularly Section 3(d) of Patents (Amendment) Act of 2005 and Compulsory Licensing. Section 3(d) is mainly criticized by the industry for setting higher standards for innovation than TRIPS and thus hindering potentially beneficial incremental innovation. The notions that Section 3(d) effectively bars all incremental innovations and discriminates against western manufacturers have been proved inaccurate by many studies.

An Indian Pharmaceutical Alliance report details a list of 86 drugs up to the year 2010 that

despite relatively minor variations over pre-existing compounds, the patents were awarded in India, upon successfully demonstrating enhanced efficacy over the base formulation.[5] Also, during the three year period between April 2010 and March 2013, 77 percent of the total pharmaceutical patents awarded by India's Controller General of Patents, Designs and Trade Marks were granted to firms from the US and Europe, proving the lack of claimed bias.

In addition to Section 3(d), another important factor of India's patent regime is rights given to the Controller to suspend patent privileges in cases where the best interests of their citizenry are at stake as a result of force majeure or wilful exploitation of patent privileges by the patentee.[6] The right to grant compulsory licenses by the country is mentioned under Article 5A.(2) of the 1883 Paris Convention.

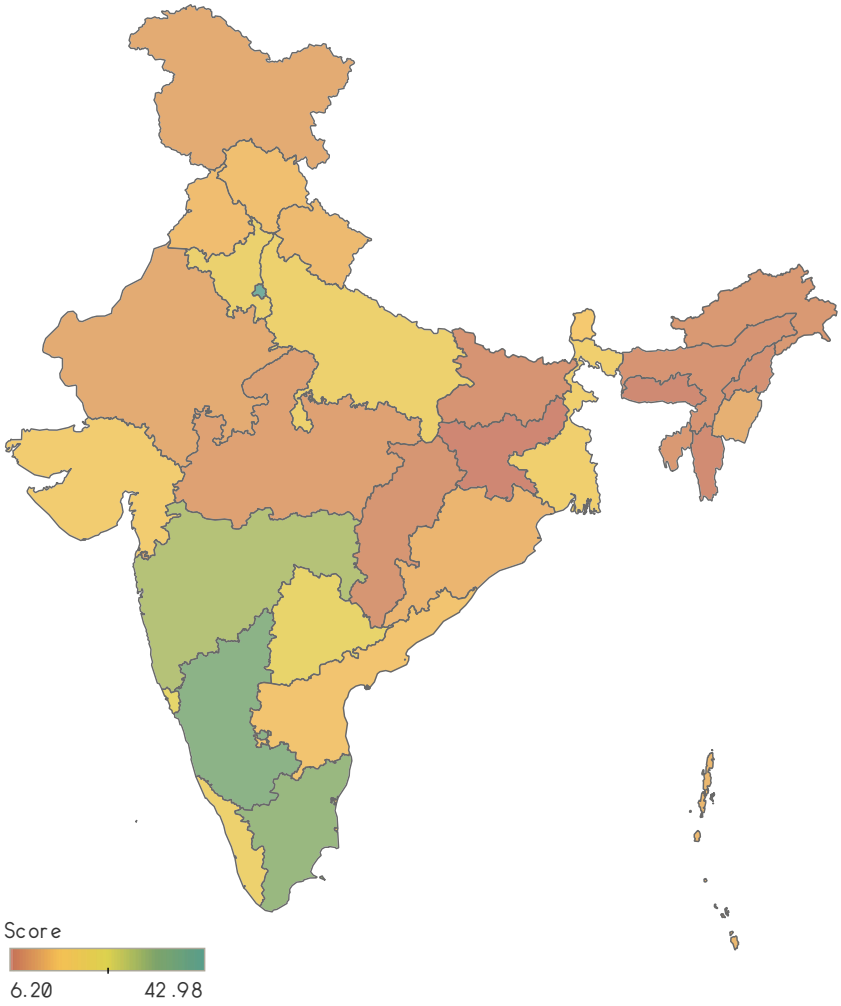
While the vast amount of discussion has been around India's IP regime, it is not the sole determinant of a strong innovation ecosystem in the country. A strong IP regime is a necessary but not a sufficient condition to foster innovation. Although the regulation across the country, there are significant variations across the states in terms of both the enabling conditions as well as the innovative performance. This feature of the Indian innovation ecosystem is highlighted in the recently released India Innovation Index 2019 by the NITI Aayog and the Institute for Competitiveness.

The index measures innovation across the Indian states and union territories as a function of both the inputs (enablers) for innovation and the output (performance). The index examines the enabling conditions in the country through a wide array of parameters ranging from the quality of human capital to the business environment to the public and private investments. The performance of the states and union territories is captured by both traditional indicators like patents, trademark and design applications, and India specific indicators like grassroots innovations.

The index's findings corroborate the multifaceted and complex nature of the country's innovation ecosystem. Given the same IP regime across the country, there is a vast disparity between the southern part and the rest of the country. The holistic policy approach, followed by the southern states, which were spearheaded by

focus of prioritising investment in innovation and creating the policy frameworks that encourage others to invest in innovation.

Figure 2.10: India Innovation Index Scores Across Indian States



Source: India Innovation Index 2019

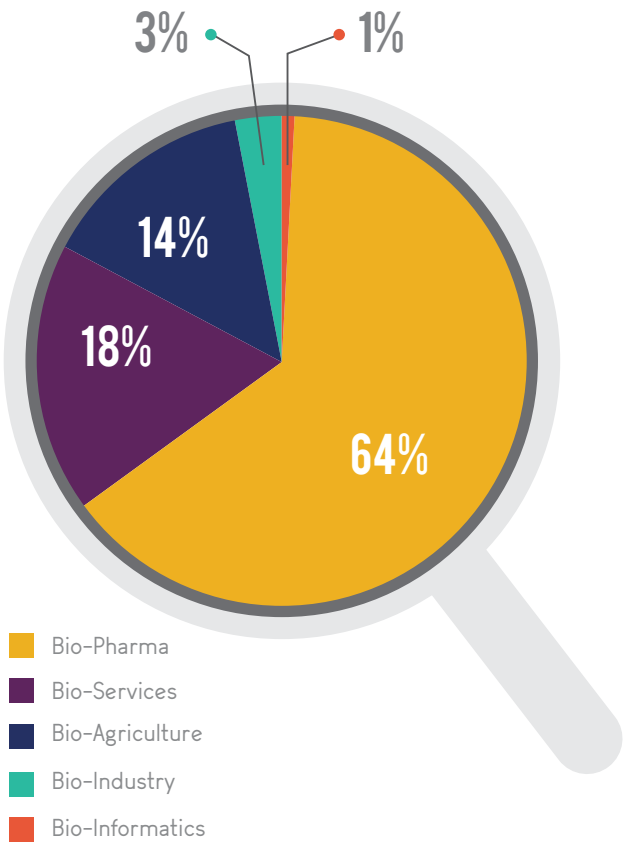
[5] James, T. C. (2009). Patent protection and innovation: Section 3 (d) of the Patents Act and Indian pharmaceutical industry. Indian Pharmaceutical Alliance.
[6] Khanna, A. R., & Singh, H. K. (2015). India's IPR Regime: Reconciling Affordable Access with Patent Protection.

Biotechnology: The Industry of the Future

Major Segments of Indian Biotechnology Industry

The biotechnology sector encompasses five segments that cater to different sectors; namely, biopharma, bio-services, bio-agriculture, bio-industry and bioinformatics (or Bio-IT). This section will assess the importance of each segment and how their performances can be improved. Each segment portrays the unique features that play a part in the functioning of the industry. But the Indian biotechnology industry is intricately interconnected such that there is constant interaction between all the segments. For instance, the production of biofertilizers is a culmination of output from both the bio-agriculture sector and the bio-industrial segment. Similarly, the product that Bio-IT provides is heavily dependent on the research and analysis of products generated by the other segments.

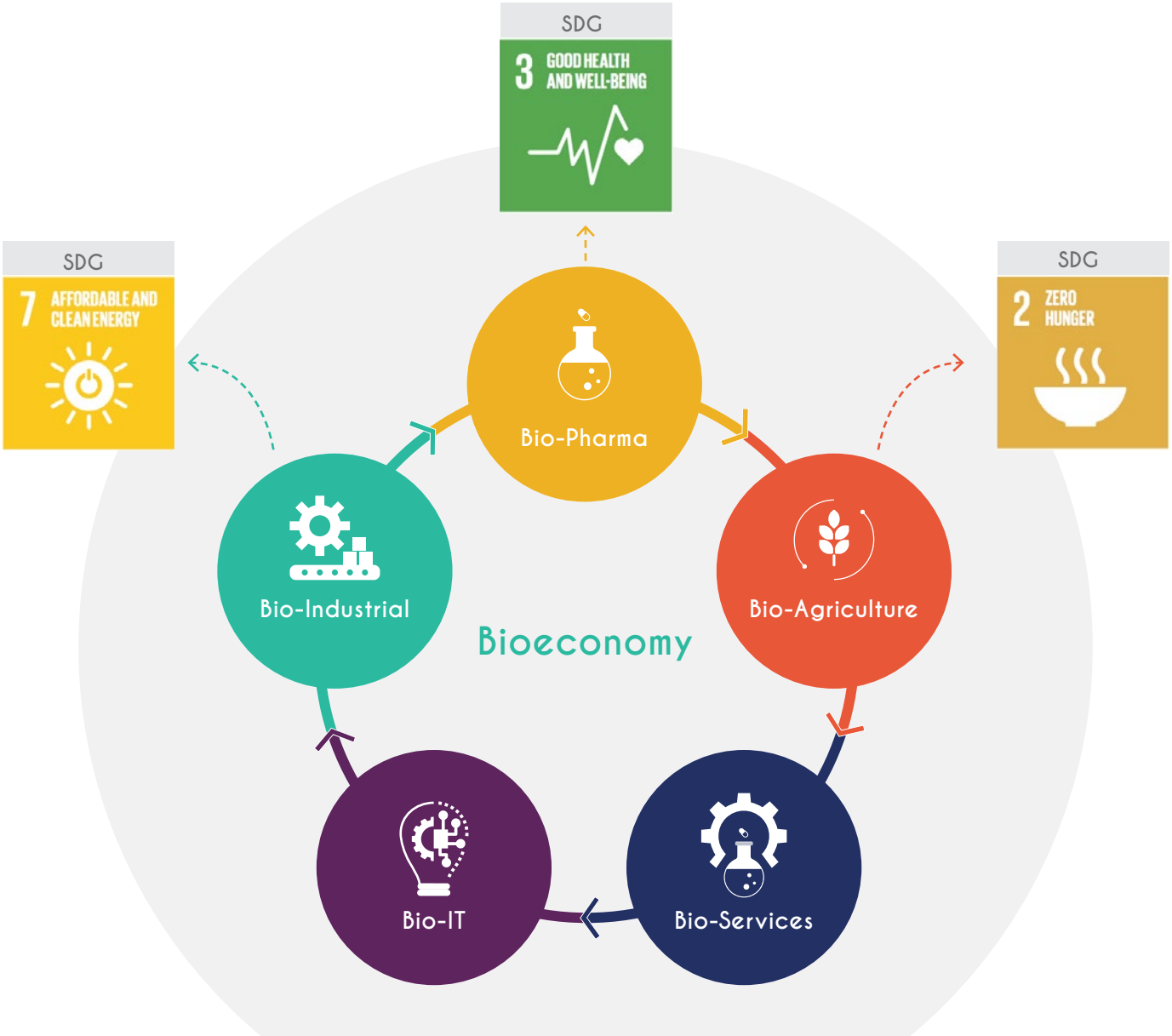
Figure 2.11: Percentage Share of Biotechnology Segments[7]



Source: ASSOCHAM, MakeinIndia, TechSci Research, 2016

[7] The numbers for 2019 have been released by Invest India, however they do not include the value for Bio-IT. Therefore, we are using the 2016 figures. Invest India numbers are: Biopharma (55%), Bioservices (16%), Bio-agriculture (22%), Bio-Industry (8%)

The above segmentation indicates that biopharma is the leading segment. This has always been the case but this year the contribution of biopharma has declined as compared to previous few years. The share of segments such as bio-agriculture, bio-services and bio-industrial has increased when compared to last year, which is on the lines of the global trend. Increasing use of industrial enzymes, biofuels, biofertilizers etc. have pushed the growth levels of these segments upwards. It is evident that the growth of the other segments has substantively led to the overall growth of the industry. The Indian biotechnology industry is not as dependent on the bio-pharma segment as it was earlier. With the other growing segments, the industry can expect further innovation, output and employment.



Bio-Pharmaceutical Segment

The traditional pharmaceutical companies focus on plant and chemical based compounds and manufacture drugs through chemical synthesis. Biopharmaceutical companies, on the other hand, offer solutions that are manufactured from living organisms. These solutions have been described by many as "one of the most sophisticated and elegant achievements of modern science". These biologics have offered therapeutic treatments where there was no cure available.

Ensuring health lives

The Sustainable Development Agenda, in its goal three, talks about ensuring health life for all. The targets within this broad objective include supporting the research and development activities to manage global health risks and ensuring the availability of essential medicines and vaccines for all by focusing on affordability. The Biopharmaceutical industry can play a key role in ensuring that the world makes considerable progress on this goal.

Today there is an increased emphasis on prevention rather than on cure, hence the relevance of vaccine is ever-growing. India can use that as a factor to increase its share in global vaccine production. In India, the private and the public sector have combined to work towards introducing new vaccine-based products in the market. For example, Bharat Biotech partnered with the DBT and manufactured a vaccine to combat ROTA Virus called ROTAVAC. ROTAVAC is an oral rotavirus vaccine and received its prequalification for safety and efficacy by the World Health Organization (WHO). There are 16 such Indian vaccines that have been prequalified by WHO. As of 2016, India had 12 major manufacturing facilities that manufactured vaccines for 150 countries around the world. India is a global leader in the supply of DPT and measles vaccine.

Biosimilars, the generic versions of biologics, also present an opportunity to ensure affordable drugs for all. India has the advantage in production and exports of biosimilars. According to a BIRAC report, India has 50 plus approved biosimilar products by US FDA. Moreover, Indian companies have strong experience related to production and export of pharmaceutical products around the world, that can help them in the process.

Bio-Agriculture

Bio-Agriculture is the third-largest segment in the domestic biotech industry. The bio-agriculture segment is an emerging scientific area that is useful for breeding nutritious, high-yielding and less resource input-demanding crops. It includes sustainable methods of agriculture practices such as the use of an improved variety of crops, biological substitutes of fertilizers, pesticides, etc. that enhance the quality of the yield and could be seen as an option to secure food supply.

Ensuring Food Security

India as a nation aims to match the standards set by the Sustainable Development Goals by the year 2030. Within these goals is the objective of ensuring zero hunger. This goal suggests that a country must end hunger, ensure sufficient intake of necessary nutrition and promote sustainable agriculture.

According to the World Nutrition Report (2018) by the World Health Organization, India does not perform well in indicators such as 'Adult Diabetes' (both male and female), 'Overweight in Adults' (both male and female) and 'Anaemia in Adult Women' and 'Wasting in Children'. In most of these indicators the people may be receiving food, but they may not be necessarily getting the sufficient amount of nutrition required.

Through the promotion of bio-agriculture segment, India can match the above goals and ensure food security as well as availability of nutritious food for all in the country.

In the past, biotechnology was used in agriculture to secure food supply during the Green revolution. This revolution set the tone for further experiments regarding the modification of cereal grains in India. Pusa Rice Hybrid 10 (PRH-10) is one of the success stories coming out of the post-revolution era.

Towards Sustainable means of Agriculture

India is on its way becoming the most populous nation in the world. Hence, the agriculture sector will have to bear the burden of feeding the whole population. The answer for such a challenge is sustainable means of agriculture. Sustainable forms of agriculture protect the biodiversity and provide higher yields with better nutritional value. World Bank also terms it as Climate Smart Agriculture, as it achieves the dual-objective of addressing the interlinked challenges of food security and climate change.

The tools to manage the above challenge is the introduction and use of agricultural inputs such as bio-fertilizers and bio-pesticides. These tools are by-products of the Bio-Agriculture segment. Biofertilizers are nutrient-mobilising microorganisms applied on seeds or soil to augment the content of nutrients in a form which can be absorbed by the plants. Unlike chemical/synthetic fertilizers, these biofertilizers are cost-friendly and do not leave chemical residue for the soil and the underground water.

Bio-Industrial

Industrial biotechnology involves the application of biotechnology for sustainable industrial processing and production of chemical products, materials and fuels. Biotechnological processing uses enzymes and microorganisms during industrial production that are employed in a broad range of sectors, including chemical and pharmaceutical, pulp and paper, human and animal nutrition, materials and polymers, textiles, energy, using renewable raw materials.

The enzymes used in the process of production have evolved in nature to become super biocatalyst, which facilitate and speed-up complex biochemical reactions. The enzyme catalysts are what make industrial biotechnology such a revolutionary new technology and one of the most promising segments. If developed to its full potential, industrial biotechnology might have a bigger impact on the world than biopharmaceutical and agricultural biotechnology.

Bio Fuels

India is highly dependent on imports of fossil fuels like crude oil for its energy requirements. Such dependency links the energy and financial situation of the country to the volatility of the external markets. To address these challenges, the Indian government is making concerted efforts to move towards the use of renewable energy.

Industrial biotechnology has immense potential to aid India's efforts on this front and provide new and innovative approaches to pollution prevention and resource conservation. Nothing illustrates the power of industrial biotechnology better than the production of biofuels.

Biofuels have been around longer than cars, but the cost effectiveness of conventional fuels have kept their usage to a minimum. But the worrying trends of climate change are giving a new urgency to the usage of alternative, clean fuels. Biofuels use uses chemical reactions, fermentation and heat to break down sugar and other molecules in plants. The resulting products are then refined to produce fuel that can be used in cars and other vehicles.

Therefore, higher investment in technologies like bio-fuels can aid India's move towards usage of renewable energy and address its concerns with rampant air pollution while reducing its global dependency on fossil fuels at the same time. It will also help India and the world achieve SDG 7 by 2030, which has given the world a target of achieving "Affordable and Clean Energy".

Industrial Applications

The application of biotechnology to industrial processes is also transforming how we

manufacture products and dispense waste. The best example of using biotechnology to reduce industrial pollution comes from the 1970s in the resolution of the problems caused by phosphate water pollution in the manufacture of laundry detergent. Biotechnology companies developed enzymes that could remove stains better than phosphates, which eliminated the usage of a polluting material and even improved the end product. The innovation in the segment can, therefore, allow production processes to become more environmentally friendly and cost effective.

Bio-Services

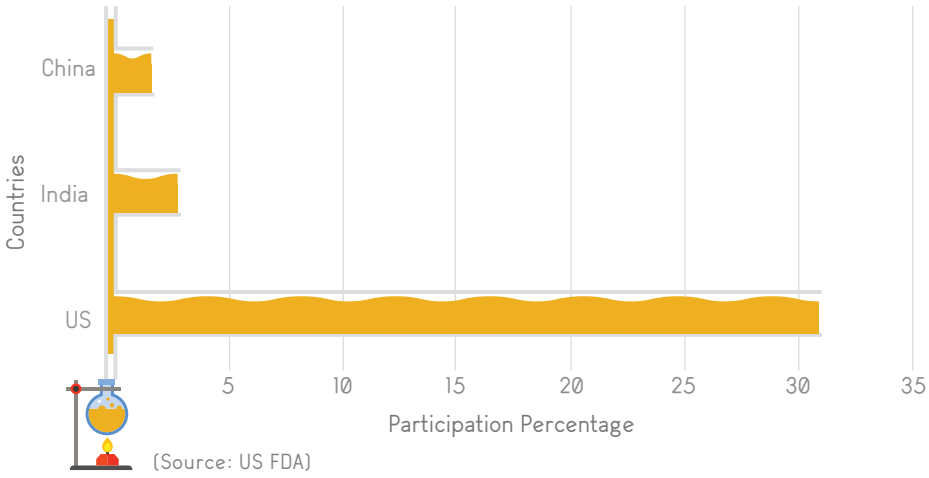
The majority of the bio-services market comprises the business of contract manufacturing and contract research. In relatively developed countries, due to escalating costs of production and stringent regulations, pharmaceutical companies turn to emerging countries for their services. These countries provide services such as contract manufacturing and research services (CRAMS) which reduce the costs and increase production rates for the said companies.

Making India the main destination for Clinical Trials

India is the second most populous nation in the world and according to the World Health Organization, accounts for about 20 percent of the global disease burden. India, therefore, is a perfectly suitable destination to conduct clinical trials for new drugs and medical techniques. As of February 2019, India accounted for only 1.2% of the clinical trials of the world. This figure has seen a decline as earlier, India used to account for 1.5% of such trials.

According to the US Food and Drug Administration (FDA), India was ranked 6th in the year 2015-16 for clinical trials' participation percentage. In fact, India is ahead of most of its contemporaries but the gap between India and US (first ranked) is really huge and it depicts the opportunity that has in terms of expanding the clinical trials. This is illustrated in Figure below.

Figure 2.12: The participation percentage for Clinical Trials (2015-16)



(Source: US FDA)

According to WHO, India has had the tightest regulatory system which has deterred the growth of the life sciences sector in the country. Recognising this in the NBDS 2015-2020, the government has introduced the following measures:

1. Introduction of an online window for submission and tracking of clinical trials
2. Creation of a dedicated cadre for regulation of clinical trials
3. Defined standards for accrediting clinical trials and principal investigators

Bio- IT

The interaction between the fields of biotechnology and information technology has led to the creation of a new segment called Bio-IT. The emergence of the segment can be attributed to the need for technology to make sense of the data that is being generated by hospitals, R&D labs, clinics etc. The volume of the data is increasing exponentially.

The segment, based on advances in computing and data science, extracts knowledge from biological data. It includes the collection, storage, retrieval, manipulation and modelling of data for analysis, visualization or prediction through the development of algorithms and software.

For a thriving bioinformatics segment, a superior IT sector is required, and India already has an established IT sector with State-of-the-Art facilities. Centre for Development of Advanced Computing, under the Ministry of Electronics and Information Technology, has created computing capacity through introduction of PARAM-Biochrome and Bio Blaze. These are advanced computing technology designed specifically to handle areas such as computational biology. This data has the potential to be used for national and regional development and can be used to address the poorest and the marginalised groups to ensure that "no one is left behind". It can be used to measure and track progress on the different development goals. The big data analytics can also develop high impact solutions that be used for development purposes.

The public private partnerships play a key role in this segment to ensure that the data is available across industries for research and development purposes. However, it would be important to ensure that while unlocking the value of data the parties are not violating human rights.

Global Comparison

The modern world holds immense potential for the growth of the biotechnology industry. The industry – which happens to be an amalgamation of biology as well as technology – is expected to save and improve lives across the world through advancements in biomedical, energy, and advanced food and industrial technologies. It can address a host of wide-ranging global challenges that relate to diagnosing, treating and curing diseases; ensuring a sustainable supply of safe and affordable food; and the development of biofuels, chemicals and other industrial products.

The industry is also entering its next S-curve of growth as the world has been working towards making a wide array of innovations – gene therapies, stem-cell treatments, antisense DNA, siRNA, CAR-T – into new and powerful therapeutic tools. But every country has different levels of capacity and capability to ride this curve based upon its underlying knowledge pool and market conditions.

While India has made numerous efforts over decades to develop its biotechnology industry, it is necessary to compare its position on a global scale. The Biotechnology Competitiveness Assessment is one such step as its overriding purpose is to assess India's biotech industry and its position amongst global competitors. It would shed light on countries that have competitive advantage over India and what can be done to catch up to the top-performers and even stay ahead of them.

The assessment evaluates a total of 20 countries which includes emerging biotechnology economies like Israel and China, as well as mature economies of the industry such as United States, Sweden, etc. Countries for comparison[8] comprise of economies from all major regions of the world and a broad spectrum of income groups as defined by the World Bank. The comparison is based on several indicators which mainly examines the capabilities and performance of the countries.

The Biotechnology Competitiveness Assessment carefully identifies the strengths as well as weaknesses of the current biotechnology scenario in the country, which, if focussed on would help the sector to grow with its full potential and achieve its target of becoming a $100 bn industry.

[8] Emerging: China, Egypt, India, Indonesia, Israel, Malaysia, Mexico, UAE, and Vietnam
Mature/Developed: Argentina, Australia, Canada, Japan, New Zealand, Singapore, South Korea, Sweden, Switzerland, United Kingdom, United States.

Framework

A comprehensive framework has been designed for the global comparison that would enable analysis as well as assessment of the sector. A direct comparison of a country's policy inputs with the biotechnology outputs are essential to gain a rich and detailed account of an economy's biotechnology environment.

The inputs comprise of factors such as human capital, investment in research and development, technology transfers, market incentives etc. They contribute to the development and sustained growth of the biotechnology sector. On the other hand, the output indicators adjudge the performance of the government and other stakeholders in building a successful biotechnology sector. Thus, while input indicators show the degree to which a conducive environment has been created for the growth of the biotechnology industry, the output indicators provide an account of the benefits that can be derived from the inputs. All these indicators together define the growth trajectory that the biotechnology sector follows.

The following figure provides the framework that has been used for making the comparisons between India and the World:

ENABLERS	FACILITATORS	PERFORMANCE
1. Human Capital	1. Technology Transfers	1. Clinical Trials
a. Number of Researchers per million of population (Full time equivalent)	a. Industry-Academia Linkages on R&D	a. Clinical trials per million population to date
b. Knowledge workers	b. Barriers to technology transfers of publicly funded and supported research	b. Clinical trials for biologics per million population to date
c. Quality of Research Institutions	c. State of Cluster development	
	d. Patents filed in 2 or more offices	
2. Investment in R&D	2. Regulatory Environment	2. Research Output
a. Expenditure on R&D as a percentage of GDP	a. Regulatory framework for Biopharmaceuticals	a. Biotechnology triadic patenting, share of global total average 1999-2013
b. Government spending on R&D	b. Regulatory framework for bio-agri	b. Scientific publications standardized for population
c. Business and private (BERD) sector spending on R&D	c. Regulatory Quality	c. Quality of academic publications
d. Universities spending on R&D		
3. Safety and legal Environment	3. Market Incentives	3. Biotechnology Output
a. Intellectual Property Protection	a. Biopharmaceutical pricing and reimbursement policies	a. Biopharmaceutical product launches, percentage available in country within 5 years of global product launch
b. Efficiency of legal framework in challenging regulations	b. R&D tax incentives	b. Biofuels production, percentage of global total
c. Efficiency of legal framework in settling disputes	c. Ease of Doing Business	c. Biotechnology crops, hectares under cultivation, percentage of total
d. Rule of Law		

The framework outlines three broad categories encompassing dimensions that provides a robust picture about the biotechnology sector. These dimensions are Enablers, Facilitators and the Performance measure.

Each dimension is then broken down into three components. The components are evaluated on the basis of 29 indicators ranging from the institutional and eco-system level (spending by different institutions on R&D, IP environment) to the more biotech specific factors (regulatory environment for biopharma and Bio-Agri, biopharma pricing and reimbursement policies) to the policy performance measures (biotechnology triadic patenting, biotechnology crops).
Enablers capture the factors necessary for the overall growth and development of an industry. These include human capital, investment in research and development, and strength of legal institutions. All these factors create an environment conducive for starting and operating any business.

Facilitators include advance factors that govern the long-term sustainability and profitability of the biotechnology industry. This dimension includes elements such as technology transfers, which talk about the industry-academia linkages, regulatory environment, and market incentives. They help in creating the conditions necessary for the development of the biotech capacity and promoting biotech innovation.

The third dimension "Performance" evaluates the output indicators of the biotechnology industry. It is further divided into three sub-dimensions – Clinical Trials, Research output, and Biotechnology output that together provide a comprehensive view of the performance of biotechnology industry in deriving benefits from the inputs.

The rationale for each dimension is given below:

ENABLERS	
1. Human Capital	The availability of human capital is the most basic yet the most crucial building block for the biotech sector. The economic growth of any sector/ country bears strong correlation with its human capital. Thus, the proportion of population employed in research, the quality of research institutions, knowledgeable workers, etc. play an instrumental role in creating conditions under which biotechnology innovation can take place.
2. Investment in R&D	Together with the skilled human capital, there is a need of competent infrastructure for research and development. Investment in R&D should not be the sole responsibility of the government: instead it should be shared by universities and businesses as well. Unavailability of adequate funds for R&D (for laboratories, clinical research, etc) would hinder the growth of biotechnology sector.
3.Safety and Legal Environment	The component assesses the quality of legal environment in the country. An ef cient legal environment helps in quicker settling of disputes and aids in challenging the present regulations in a better way. Along with that, the component stresses on the need to set strong regulations for the protection of Intellectual Property. These conditions are important for better functioning of private business and to incentivize them for innovation.
FACILITATORS	
1. Technology Transfers	This component looks into aspects that ensure the bene ts of research are transferred from public and government bodies to private businesses and from private-to-private businesses for developing commercially available technologies. It identi es the industry-academia linkages, barriers to technology transfers if any, state of clusters as well as patents led in two or more of ces, each of which are important for smooth innovation linkages amongst countries.
2. Regulatory Environment	The regulatory environment (consisting of ministries and departments that oversee the existing policies for biotech components in the economy) in a country or region is a major contributor in shaping incentives for innovation. A strong framework for biopharma as well as Bio-Agri segments creates the conditions for the production and sale of high-quality products and technologies

3. Market Incentives	This component consists of a broad range of market and commercial incentives from general R&D incentives to speci c policies aimed at biotech sectors such as pricing and reimbursement policies for biopharmaceuticals. Ease of doing business score can also have a profound impact on commercial and market incentives as it provides a holistic view of a country's business environment.
PERFORMANCE	
1. Clinical Trails	Clinical Trials help in discovering new treatments as well as new ways to detect diseases. They aim at diagnosing them and even reducing their probability of development. Thus, it is an important component to measure performance of a country in the biotechnology sector.
2. Research Output	From assessing the overall value and quality of a biotechnology patent to measuring the quality of academic publications, this component brings out the performance of a country based on outputs related to research.
3.Biotechnology Output	This component is speci c to biotechnology sector and its segments. It evaluates how are the segments performing in biotechnology crops, biopharma product launches and biofuels production. This is a very good measure of a country's biotechnology industry and its outputs.

The scores on each of the dimensions will help in identifying the areas in which India is lacking and where policymakers should focus on to make India a biotechnology hub. Detailed insights are provided by the framework that would help in identifying the relative strengths and weaknesses of each country and at the same time, provide learnings for India

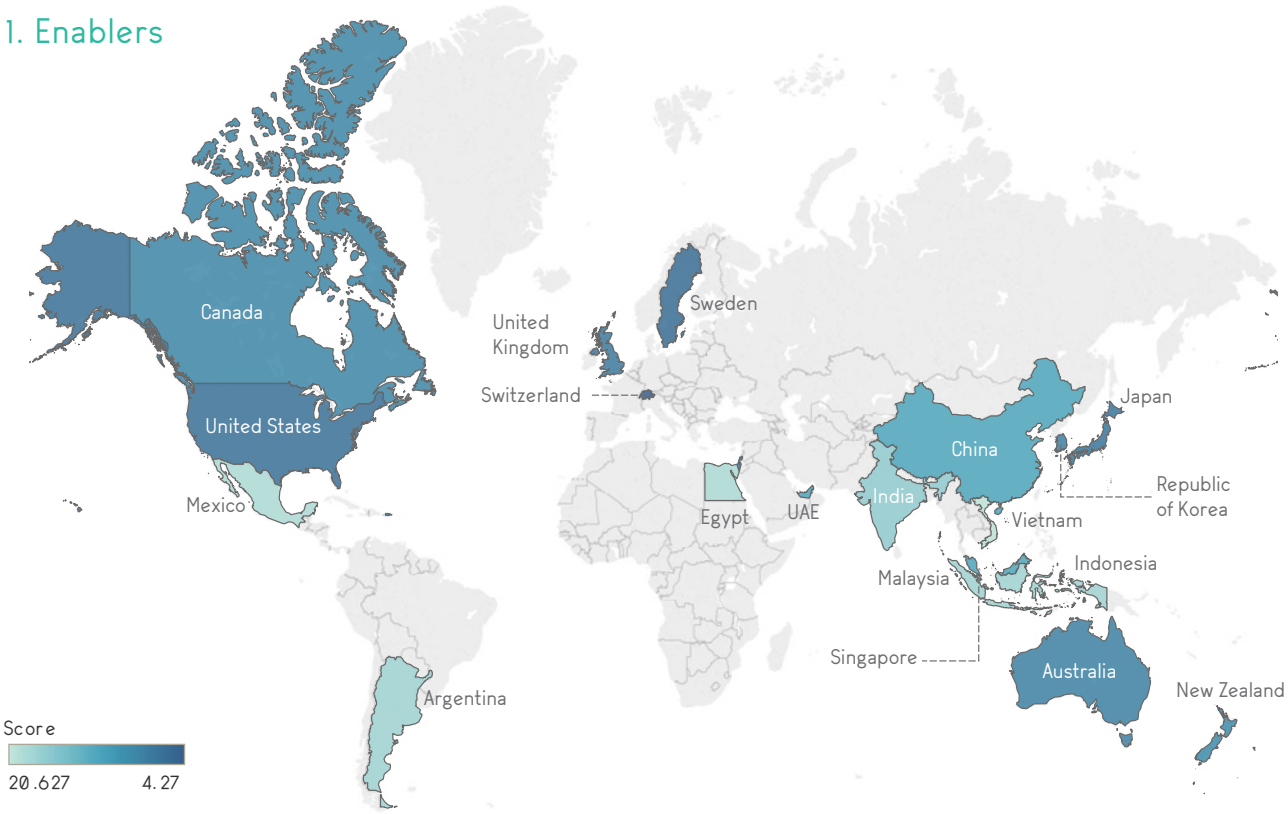
Results

The framework for adjudging the biotechnology competitiveness is not the end-product and is greatly limited by data availability. But it is an initial effort to assess the present biotechnology positives as well as negatives and to utilise it as a mapping dashboard of public expenditures, civil society, engagement and private sector investment. It can also be used as a tool to organize and structure strategic planning which would ensure continuous as well as sustained economic growth of the biotechnology sector.

The assessment scores the selected countries on the basis of their performance in each indicator. The scores range from 0-100 with 0 being the worst and 100 being the best score.

India has made considerable progress to improve its biotechnology landscape over the years. This assessment will help us in identifying the challenges that still remain, and would thus present us with the opportunity to work towards addressing these issues in order to utilise the full potential of our biotech industry.

1. Enablers



Countries are compared on the basis of three broad components under enabling environment dimension, which covers human capital, investment for research and safety and legal environment. The variation between the top and the bottom scores is least in this dimension.

It is, thus, interesting to note that Switzerland has been the top scorer, with an overall score of 74.27

Singapore, Sweden and United States have also been one of the best performers in the enablers.

Delving deeper into the components, it is observed that Republic of Korea is the best performer in human capital dimension. The country has the third largest number of full-time researchers (only to follow Israel and Sweden). Also, a significantly high scores in the indicator's knowledge workers and quality of research institutions has led the country to become the top scorer in this component.

REPUBLIC OF KOREA CONTRIBUTES NEARLY

4.3% of its GDP

to R&D; highest by any country.

Also, 80% of this expenditure is undertaken by private sector.

Superior performance in these two indicators has driven the overall score of the component "investment in R&D" in Korea's favour, making it the topmost scorer.

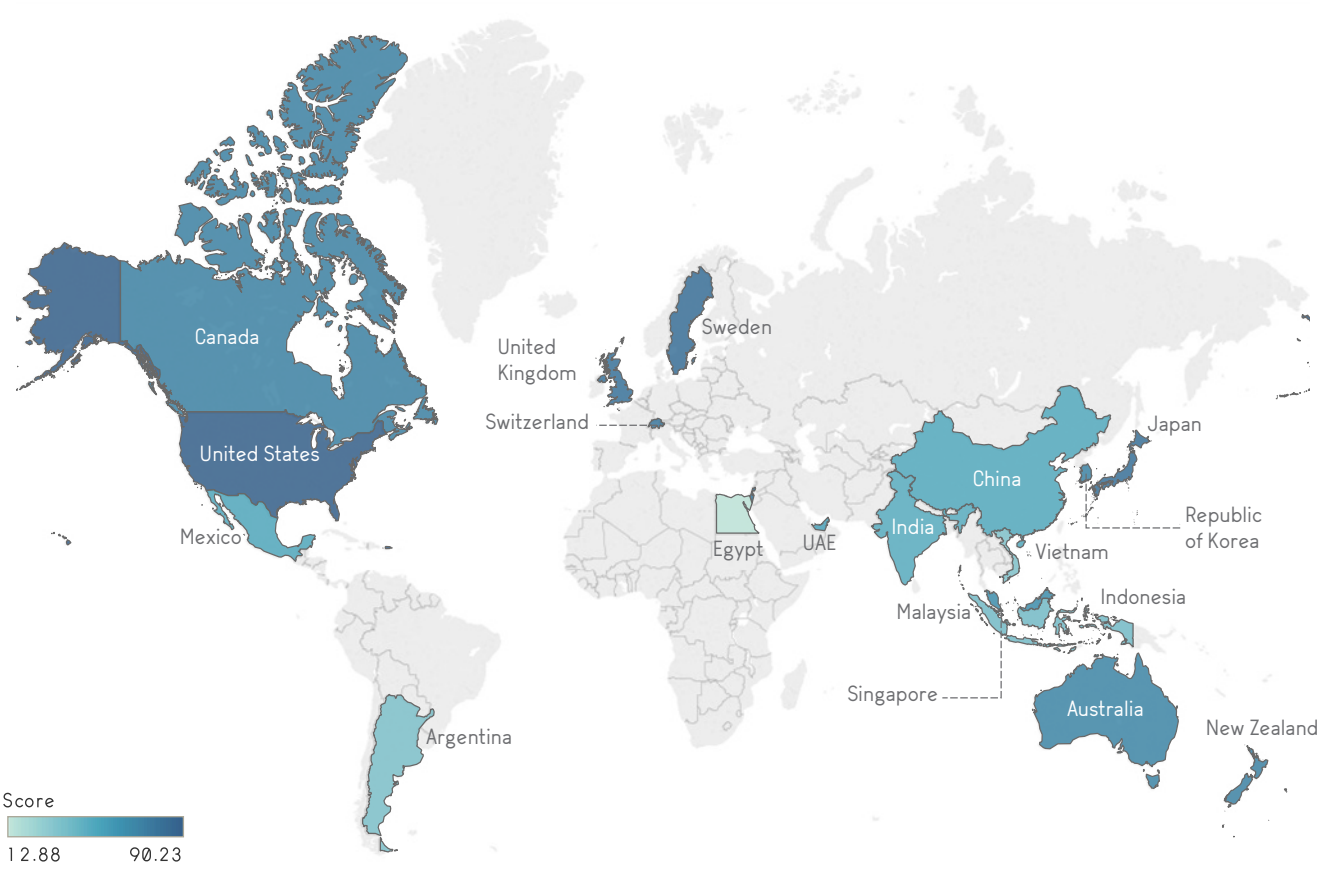
While looking at the scores of third component i.e. Safety and Legal Environment, it is interesting to note that Switzerland provides an overall amiable legal environment scoring as high as 94.70. Within the component, Switzerland provides an extraordinary framework for challenging legal regulations. Also, the country's performance in safeguarding the Intellectual Property (IP) has been commendable, only to follow Singapore. It is the exceptional performance of Switzerland in this component that has made it a top scorer in this dimension.

Having said that, Singapore safeguards the country's Intellectual Property (IP) in the most commendable manner and also provides the most efficient framework for solving disputes that arise either between businesses or between the business and the government. The worst performer in enablers is Vietnam with a score of 20.62 having weak quality of research institutions as compared to other countries. Also, the country's weak IP regime is also a major factor that has resulted in a low overall score.

HOW INDIA FARES

Though India performs better than Vietnam, Egypt and Indonesia, yet there is a significant difference in its score from that of the best performers indicating that India has substantial ground to cover in this dimension. India's performance in government spending on R&D along with legal efficiency in challenging regulations and settling disputes has been relatively better. The latter two indicators are crucial for the smooth functioning of private businesses and can help in improving India's rank in Ease of Doing Business (EODB) further.

2. Facilitators



The second dimension 'Facilitators' is an amalgamation of various advanced factors, which measure the growth potential of a country's biotechnology sector. Disparity among scores remain quite high with the United States of America performing exceptionally well in all the components and scoring 90.23. On the contrary, Egypt has the lowest score of 12.88, primarily because of the country's poor performance in all the components and even in many of the indicators. Singapore is performing well in most of the components and is the second-best performer in the dimension.

In the technology transfers component, Switzerland is the best performer followed by Japan and the US. However, according to the scores of the sub-pillar scores, the US has the best industry-academia linkage on R&D and Switzerland closely follows it. Both the countries have minimal barriers to technology transfers and have relatively widespread and well-developed clusters. However, the performance of US on the

indicator "filing patents in two or more offices" drags it overall performance downwards.

The component regulatory environment (including a regulatory framework for bio-pharmaceuticals, bio-agriculture and the overall regulatory quality) has least variation in its scores when compared to the other two components and all the countries perform a little better than other components but surely needs further improvement.

Also, the market incentives are high in almost all the countries except Egypt. All but Egypt and UAE provide tax incentives to encourage research in the country. Switzerland and US have relatively high scope of reimbursement and better pricing policies. Interestingly, even though New Zealand has topped Ease of Doing Business (EoDB) indicator, yet it needs to work on its pricing and reimbursement policies to gain an overall competitive advantage over other countries.

Disparity among scores remain quite high with the United States of America performing exceptionally well in all the components and scoring 90.23. On the contrary, Egypt has the lowest score of 12.88

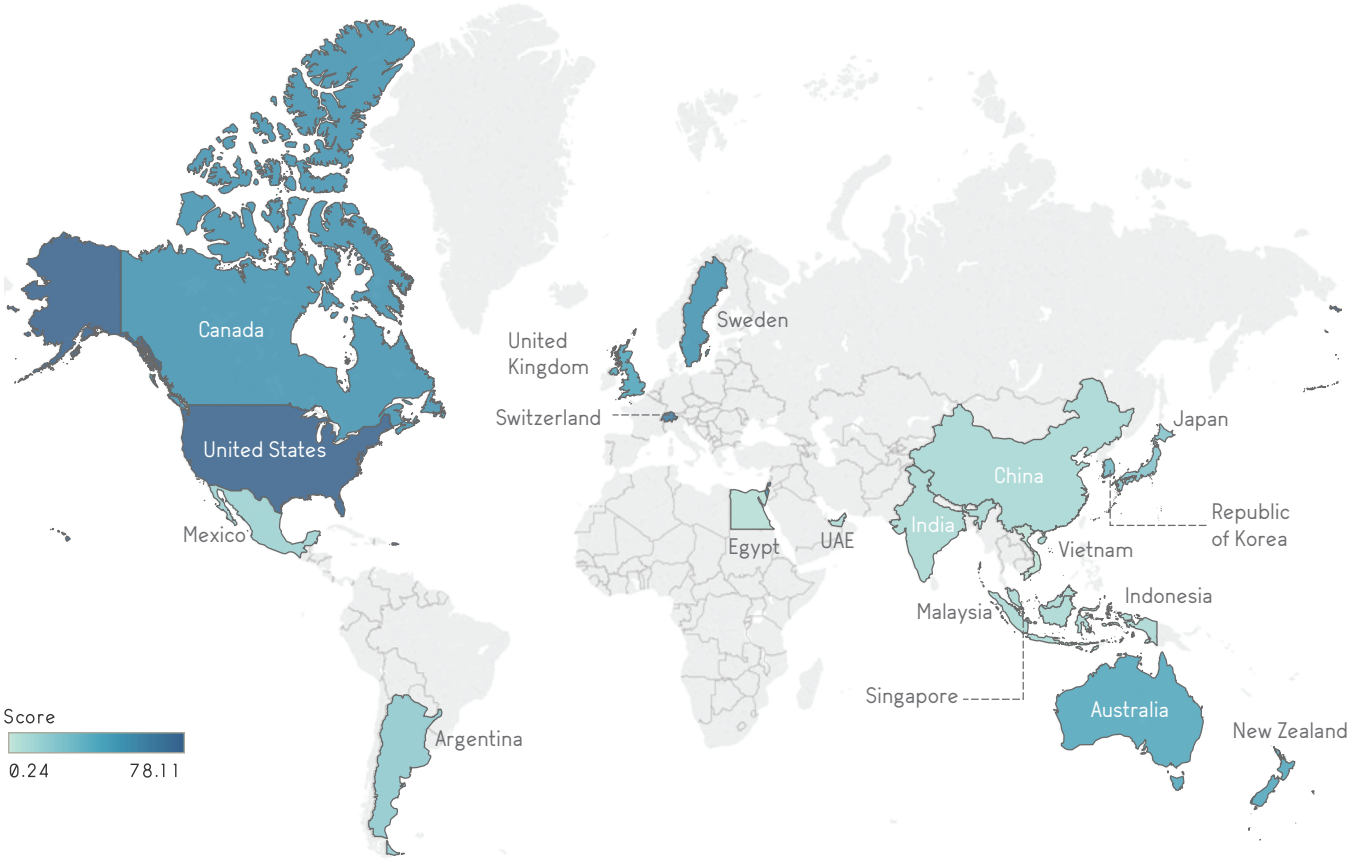
HOW INDIA FARES

Though, India's performance in this dimension with an overall score of 47.97, is better than the 'Enablers', the country needs to focus on improving all the three components in order to make a transition from emerging biotech economies to a mature one. As far as individual indicators are concerned,

India performs well in cluster development and with an improving EoDB rankings (77 in 2018 to 63 in 2019).

India also provides strong R&D tax incentives and has a defined regulatory framework for Bio-agriculture. Patent filing and barriers to technology are some issues on which India needs to pay immediate attention.

3. Performance



The performance of an economy's biotechnology sector is evaluated by the output score. It provides a clear view of whether the country has been able to draw benefits from its enabling as well as facilitating factors. Score of almost every country has been mediocre in this dimension. Even the average score is lowest amongst the three (28.30 as compared to 50.5 in enablers and 61.8 in facilitators). Also, maximum disparity is observed within this dimension as the scores range between 0.24 (worst) and 78.1 (best).

The United States of America has emerged as the top performer in the category while Vietnam is still struggling hard to make a mark. US, a mature economy, has been the only nation in this assessment to consistently perform well. Other mature economies do not have impressive scores and hence even these nations struggle deriving quality output from solid inputs.

Israel, an emerging biotech economy, has conducted the maximum number of clinical trials while Indonesia has the least. Also, an in-depth analysis of the research output, it is noted that Switzerland's quantity as well as quality of scientific and technical journal articles is relatively the best. However, the country doesn't fare good in triadic patenting indicator which is a perception of the overall value and quality of a patent. This indicator is topped by US.

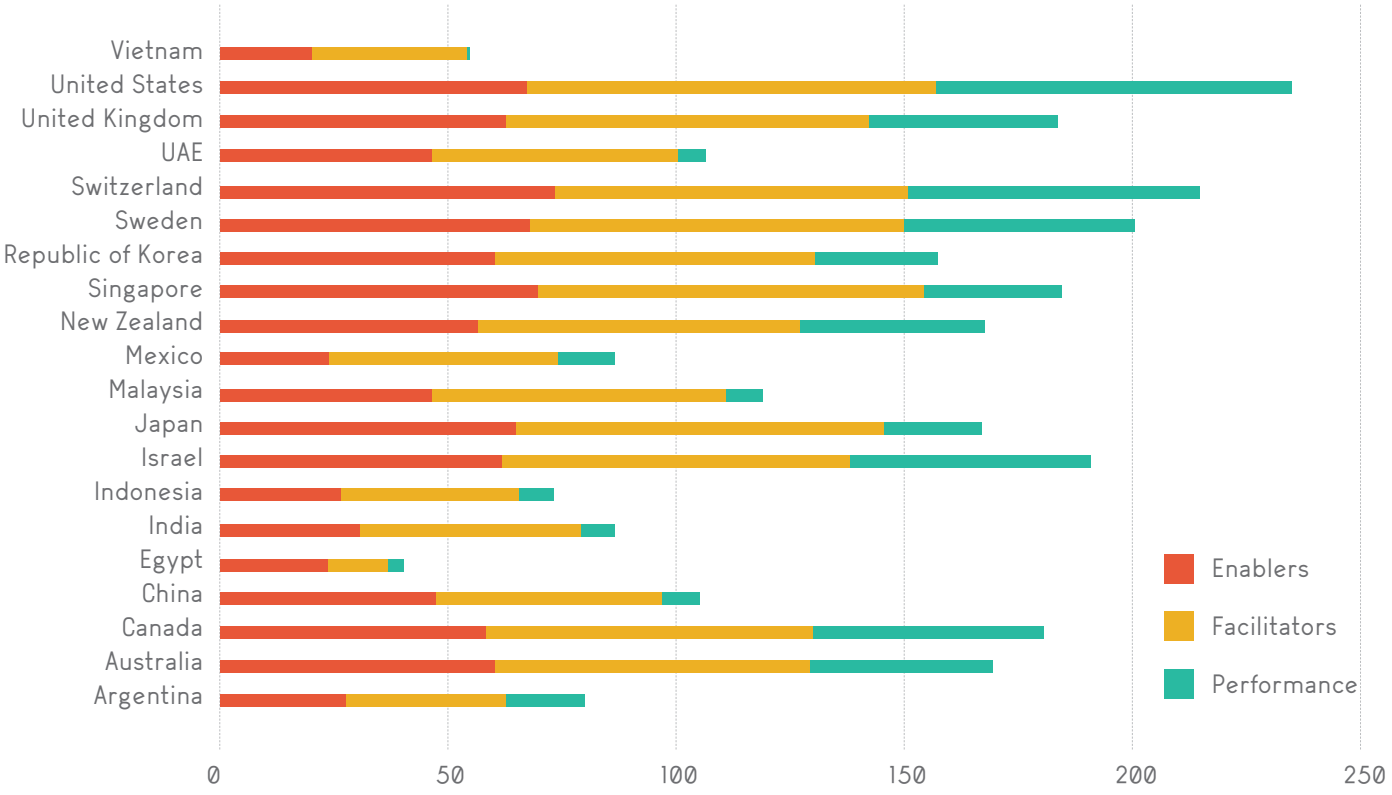
Apart from that, US performs remarkably well in the biotechnology output component. Whether it is the relative level of biopharma product penetration or country's percentage share in the total biofuel production or even the levels of biotechnology derived crops, US has been the leader. Only Argentina follows US with a considerable difference in scores (Argentina-41.73 and US- 100). Nevertheless, United Kingdom (50.6), Argentina (45.3) and Switzerland (44.4) have significant percentage of biopharma products and closely follow the United States (53.1).

HOW INDIA FARES

India has immense potential to improve its performance on this dimension but has not been able to translate the opportunities in its favour. Despite being the world leader in the production of BT cotton, India produces just 6.02% of hectares of biotechnology crops under cultivation. The capacity of the country in this category is largely underutilized. Also, in the clinical trials category, India's performance can improve if corrective actions are taken. India also has to improve on the scores for scientific publications and triadic patenting. There is an opportunity in improving scores for the indicator "Biofuel production" as it is expected that in search of cleaner sources of energy, the world will transition from fossil fuels to biofuels.

Overall Scores

The first inference that can be drawn by looking at the overall performance of countries on the assessment is that there exists a strong relationship between the Enablers, Facilitators and Performance. The United States of America is the top performance led by its outstanding performance in two of the three dimensions i.e. facilitators and performance. But countries such as Switzerland, Sweden, and Singapore provide the most conducive environment for basic factors constituted under enablers dimension.

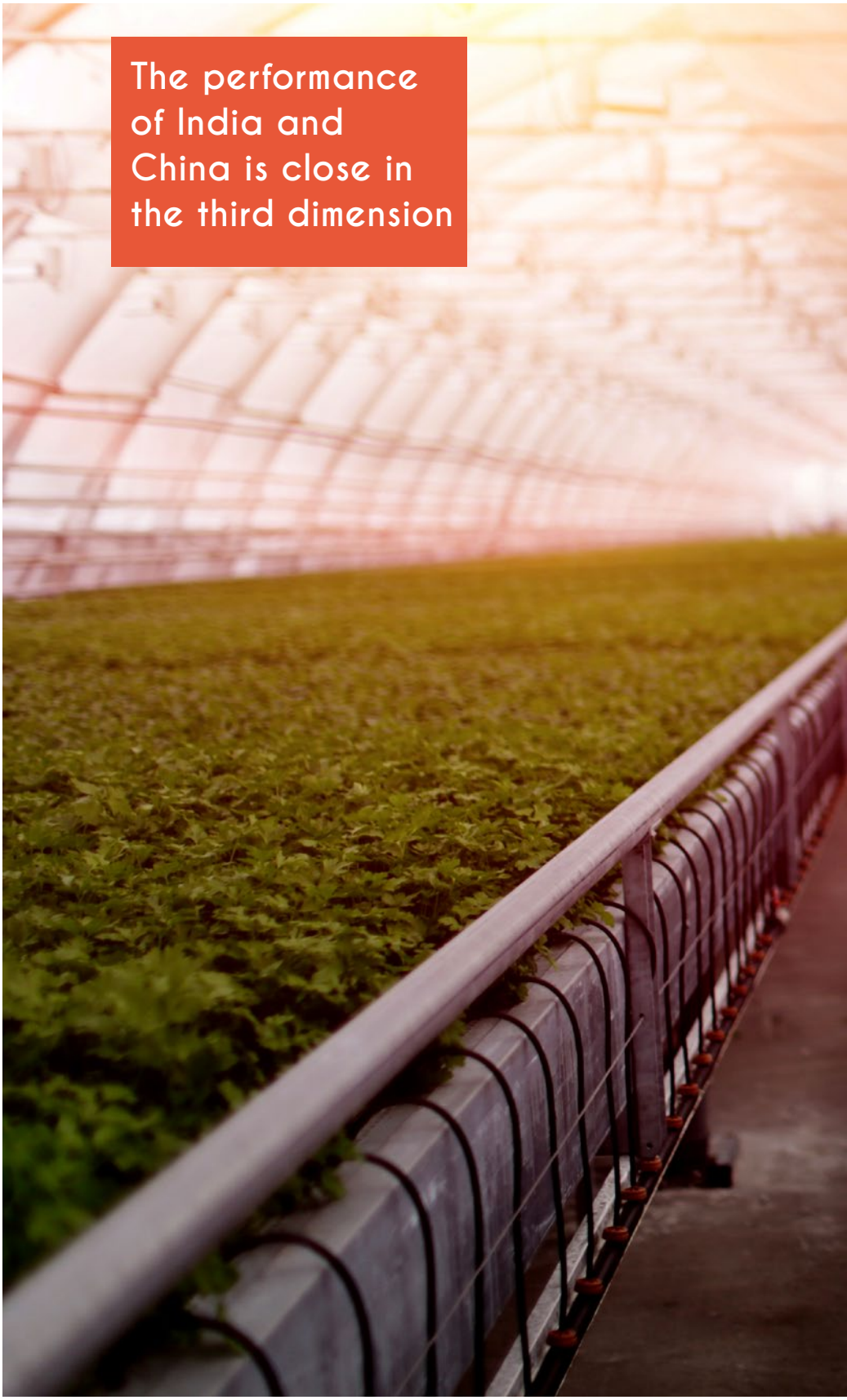


The facilitators dimension has a mix of both the types of markets in its top scorers. Relatively mature biotech economies like US, Japan, Switzerland have scored high in this dimension but emerging economies such as Israel and Singapore have outperformed a number of other mature economies. Though India's score in facilitators dimension is more than the other two, the country has surpassed nations such as Egypt, Indonesia, Vietnam and Argentina (a mature economy). Additionally, the gap between the scores of India and China is narrower than the first dimension.

When looked upon the third dimension, many countries have not fared well. The inputs have not been able to generate the desired outputs and serious attention needs to be paid by each country to all the factors that have been included in the dimension. Having said that, Vietnam has almost negligible score in clinical trials, research and the biotechnology output. The performance of India and China

is close in the third dimension as both of them have not fared well. Each economy has its own strengths and weaknesses. If the positives are utilized in an accurate way and negatives are worked upon with sincere efforts, each country can enhance its competitiveness vis-à-vis other economies.

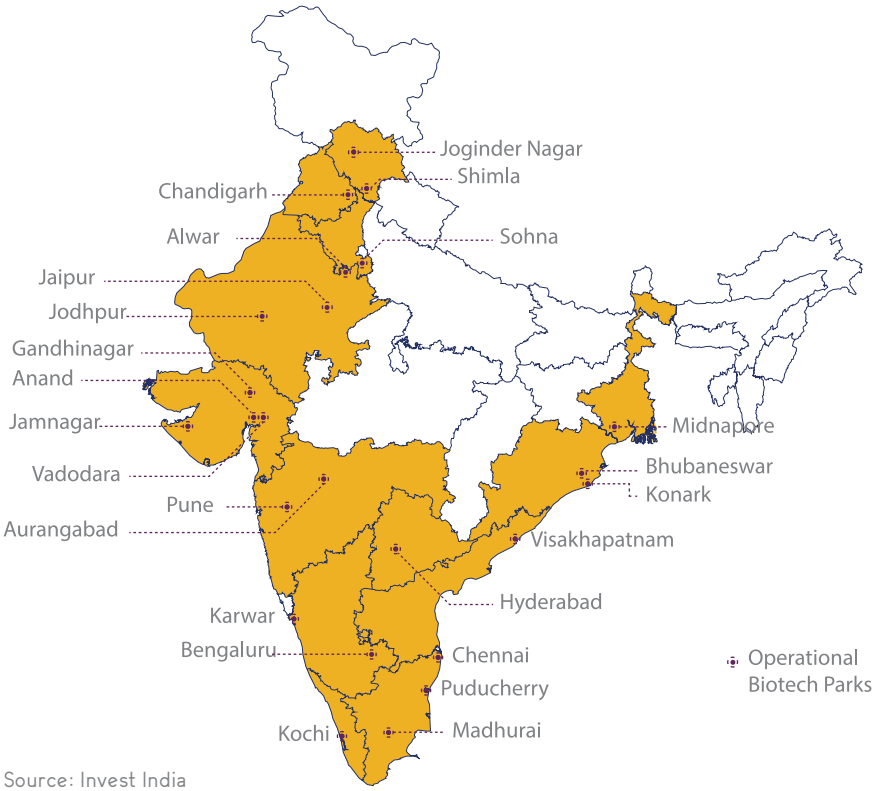
India must learn from the experience of other nations and constantly work on improving on its indicators where it is not faring well. Having said that, India is still an attractive prospect for investment. Indian biotech industry has plenty of promising avenues where unlimited potential can be tapped by investors. Hence, the next section will present how India is an attractive investment prospect.



Indian Biotech Industry as an Investment Prospect

Indian biotech industry has a promising future and it seems like an attractive prospect for future private investments. According to the recent BIRAC reports, the number of start-ups has been increasing in the last few years. This has led to a collection of 2600 plus biotech start-ups in India. This was possible due to a conducive environment created by the government through smart policies such as BioNest, Bioclusters and Biotech Park schemes. Such a development paves way for private investments on a larger scale.

Figure 3.1: Operational Biotech Parks around India



Source: Invest India

The NBDS clearly states the intention to promote private participation in the biotech industry. Government through this strategy has also shown keen interest in productive public-private partnership to amplify the innovation and output for the industry. India also has an established private share in the industry with some of the world's best companies based in the country. For instance, the growth of Biocon from a simple garage-based firm in late 1970s to one of the top biotech companies of the world today: must be an inspiration for private players in the industry.

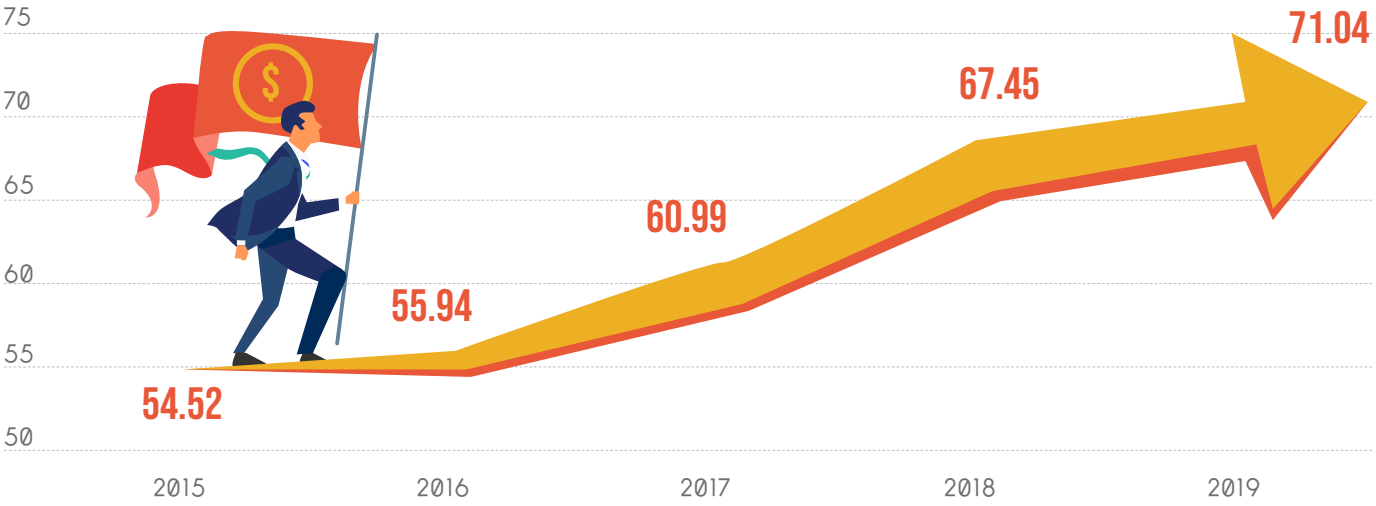
The above framework consists of indicators, that if improved, can create a platform where India can stand out as an attractive prospect. These selected indicators are crucial for increasing the private share of investment in the biotech industry in India:

1. Ease of Doing Business (EoDB):

This is one of the indices where India has shown significant progress in the last few years. India has worked on multiple factors that influence this index. For instance, providing one-window clearances for several industries, faster approval procedures and clearances. Improvement in settling disputes or allotting land for private business has also encouraged private players to enter the Indian market. Thus, improvement in general factors that ease the process of conducting business in India should increase the involvement of private firms in the biotech industry. In this year, India has made another big jump from previous rank of 77 to current rank of 63.

India has also managed to improve on its overall score, which means that the indicators that determine this index are improving significantly in the country.

Figure 3.2: India's EoDB Score



Source: World Bank

2. R&D tax incentives

R&D tax incentives are necessary to increase the rate of research towards innovation-based production. A large nation such as India, has been found private investment to be low with respect to R&D. This means that the brunt for spending for research is borne by the Government. Hence to indulge the private sector, tax incentives are the basic tools to attract research-based investment. India provides decent R&D tax incentives. According to Department of Scientific and Industrial Research (DSIR), for approved R&D centres, there is a super income tax deduction of 150% for dedicated R&D expenditure on both Operational expenses & capital expenses. Similarly, for R&D expenditure GST at lower slabs of 5% will be charged.

3. FDI Policy

The FDI policy for the biotech industry is a strong and an attractive one, which results in easy entry of private players into the Indian market.

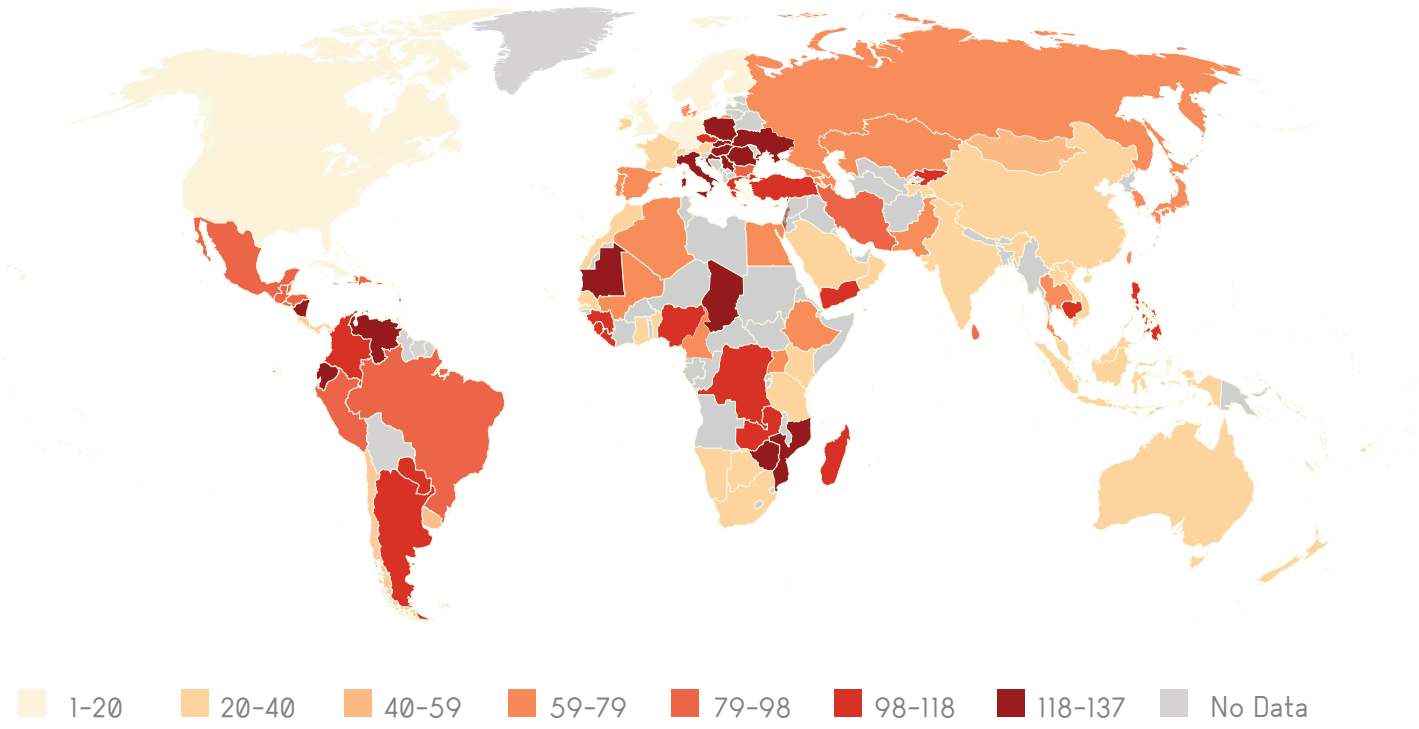
- 100% FDI is allowed under the automatic route for greenfield pharma.
- Under the government route for brownfield pharma in upto 74% FDI is under automatic route and beyond 74% is under the government approval route.
- FDI up to 100% is allowed under the automatic route for the manufacturing of medical devices.

It is clear that the FDI policy not only targets the biotech industry but also brings in related industries such as medical devices. Such investments along with presence of established clusters could create a strong supply chain for Biotech and allied industries.

4. Efficiency of legal framework in challenging regulations

The indicator "Efficiency of legal framework in challenging regulations" measures the efficiency of the legal system in case of handling disputes. In an efficient economy, strong synergy between the private and the public sector is necessary to amplify the growth of overall output and revenue. Yet, even in some of the most well-run economies, private sector and public sector clash over some disagreements. Too much of this, would drive away the private sector from the local markets. Thus, a mechanism must be present for the private businesses to challenge government actions or regulations through the legal system. India, in this respect has been improving constantly in the last few years. Acts such as Arbitration and conciliation act, Insolvency and Bankruptcy Code and Commercial courts act have ensured that there are specialized tools for private businesses to tackle regulations via legal means. This has also helped India in improving its above EoDB rankings.

Figure 3.3: Efficiency of legal framework in challenging regulations



Source: World Bank

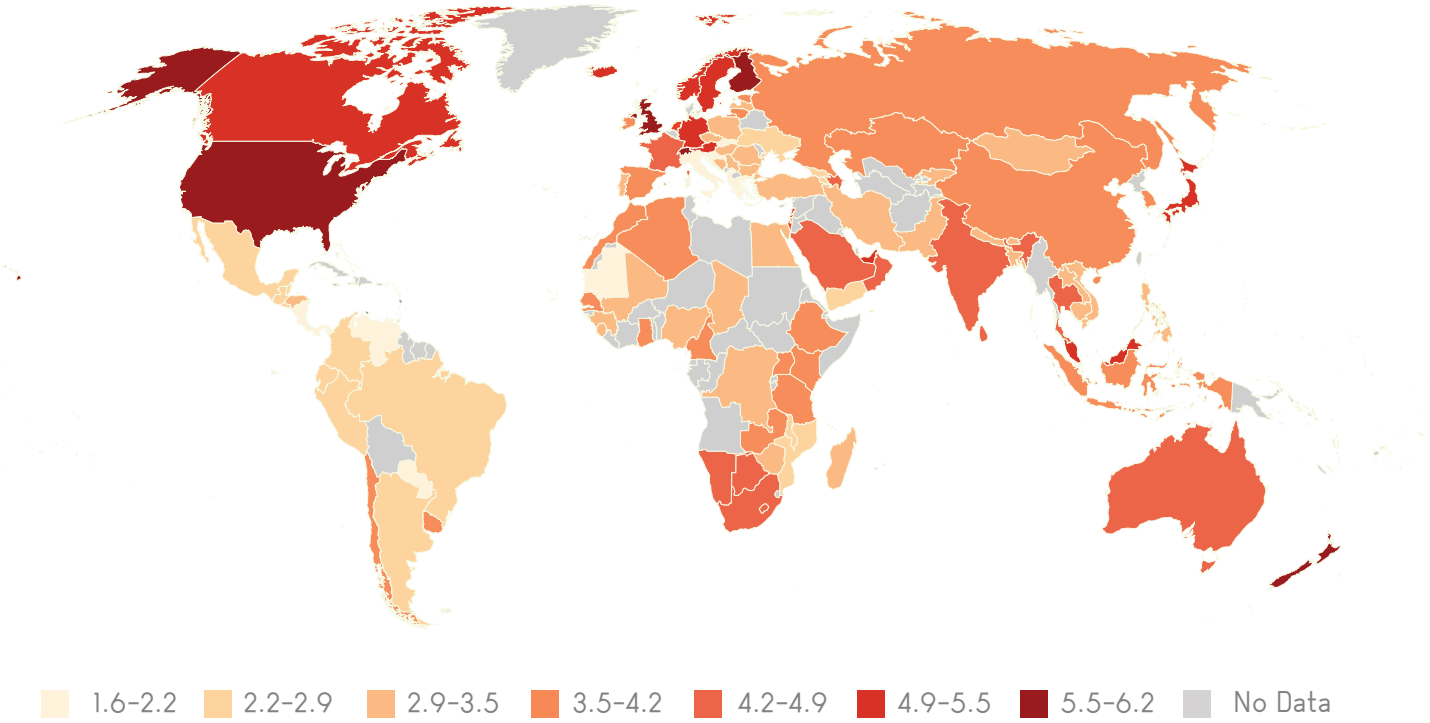
In the above map, rank 1 is the best performing country for the given indicator and similarly countries around rank 140 are the worst performers. India lies between the 20-40 bracket, which makes its position impressive in comparison.

5. Demographic Advantage

Continuing from the above point, settling disputes between businesses or between businesses and government is important to create a favourable business environment. If the disputes are cleared quickly and efficiently, it saves plenty of resources and time for private businesses.

The map below shows the efficiency of legal systems around the world in settling disputes for businesses. Countries with score 1 are the worst performers and countries with score 7 are the best performers. India lies somewhere in the middle, which suggests that it is in the right path to make it to one of the best performers. With the aforementioned legislative acts such as ICB, commercial courts etc. it streamlines the business-related legal problems and also fast tracks them towards proper settlements.

Figure 3.4: Efficiency of legal framework in settling disputes



Source: World Bank

6. Efficiency of legal framework in settling disputes

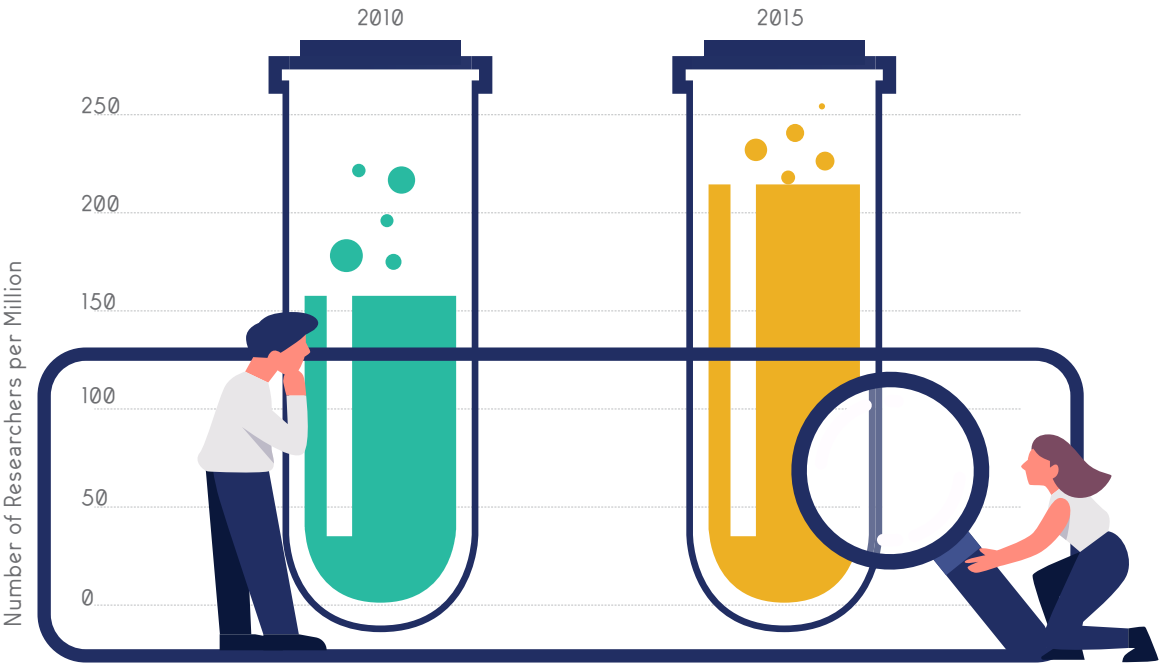
It is a well-known fact that India is currently in a phase where its working population (15-64 years) is at its peak. India can now tap the potential that this demographic range contains and improve on its productivity. This is evident from the number of researchers that have grown in the last few years.

With increasing literacy rates in all demographic divisions and increased investment in R&D, there is a strong expectation that the above number of researchers will improve exponentially. Also, the government has tried to strengthen the industry-academia linkage in biotech industry through the National Biopharma Mission. This would further enhance the research and innovation at the university level and would create a new and better prepared batch of young researchers for the industry.

The above indicators are essential for effective functioning of private businesses in any country. India has been rapidly improving in all these areas. And with a budding biotech industry, it indicates that India is now better prepared than ever to increase the private investment's share in the industry. With further improvement in the number of researchers and research infrastructure, it is inevitable that the industry will witness increased involvement of private sector.

India is on its way becoming the next Biotech hub and with existing policies and practices, the country's biotech industry could cross the 100 USD Billion mark by the year 2025. As mentioned before there are areas where India can improve and thus, the next section is targeted towards those areas. After identifying the challenges through India's low scores in some of the indicators in the above assessment: the next section will provide concrete recommendations that could help in tackling the underlying issues.

Figure 3.5: Researchers in full-time equivalents (FTE) per million population



Source: UNESCO

Policy Recommendations

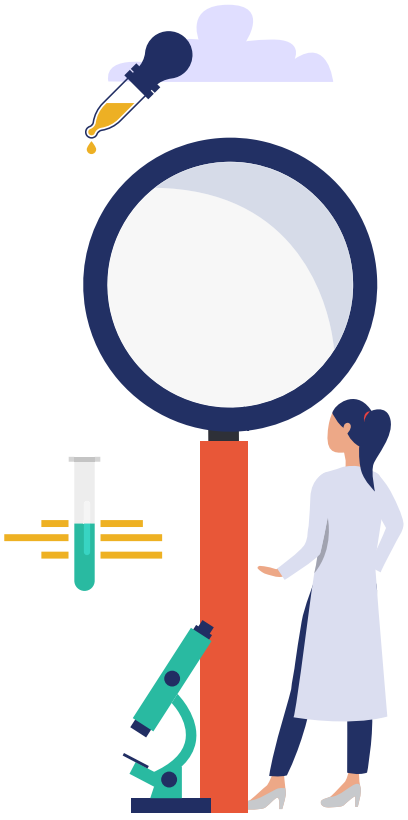
The study provides actionable insights that India can work towards to improve the growth of the biotechnology industry. These have been delineated in the following policy recommendations.

Derive value from Research and Development

Over time countries have realised the fact that long-term competitiveness can be sustained only through innovation. Many countries today have recognised the instrumental role that education, training of human capital and investment in R&D plays in the socio-economic growth of a country. They have been actively drafting policies and allocating finances to support education and research and development infrastructure. On the contrary, some countries continue to invest very little in it.

The framework used for global comparison earlier in the study captures the R&D atmosphere in each country under two different components. First, it captures the human aspect in the form of number of researchers and knowledge workers under the "human capital" component and then it captures the funding scenario under the "investment in R&D".

Despite having the most favourable demographic dividend and second largest population in the world, the number of researchers in India fall behind emerging biotechnology economies like Israel, South Korea etc., as well as developed biotech economies like the US and the UK.

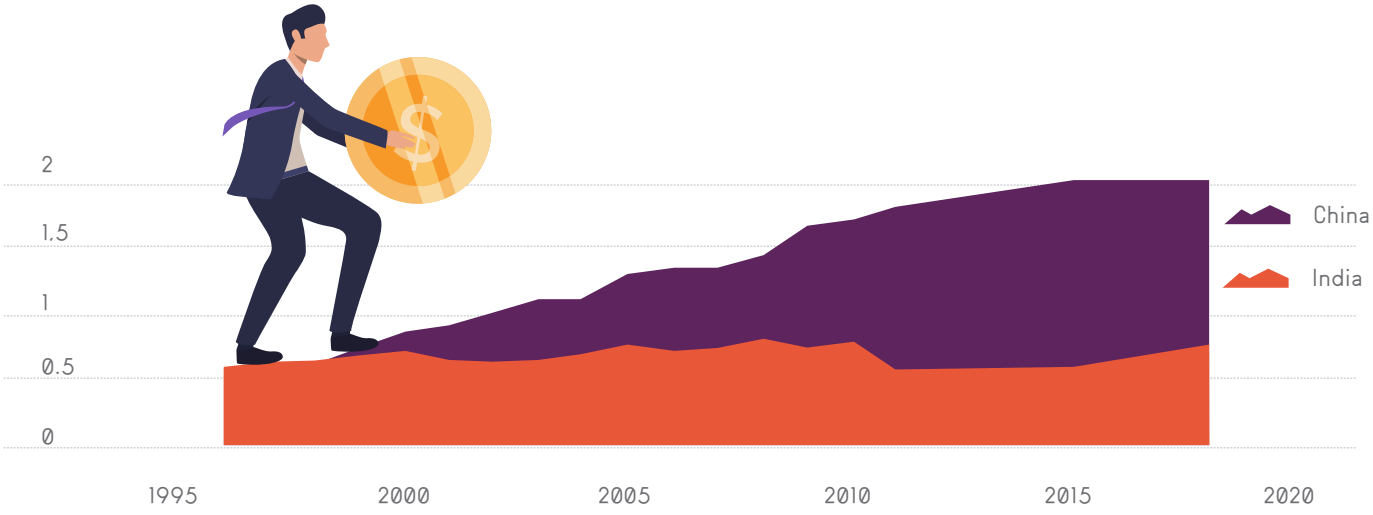


Israel, which is also a newcomer in the biotechnology sector, has shown immense progress in the past few years and houses the highest number of full-time researchers (8250). The country's scintillating performance is an outcome of various factors with early investment in R&D being one of the crucial ones.

Israel invests as much as 4.2 percent of its GDP in research, being the second largest spender after South Korea (4.3 percent). By comparison, India's spending on research is less than 1 percent of its GDP.

The story of Israel's huge investments in research dates back to 1993 when its government launched the "YOZMA" programme. This programme aimed to divert Israel's dependence on the public sector and trade and has been the most successful and original programme in the history of innovation in Israel. Yozma invested in new venture capital funds and attracted foreign investors by offering them insurance on risk. Collaborated efforts by Israel and South Korea in the field of research and huge spending in the sector, have contributed to the overall growth in both the economies.

China is also following the footsteps of these countries by bolstering investment in research. Today it spends nearly 2.1 percent of its GDP on research. Starting at almost similar levels of R&D spending, China has increased its spending with each passing year. To the contrary, India's spending on research has shown a downward trend. This is shown in Figure 4.1.



Source: Author's Depiction

Figure 4.1: Difference in R&D spending between India and China

The Indian government undertakes more than 60 % of the total research and development expenditure. This is in stark contrast with countries like Israel, US, China, Japan, Republic of Korea and Australia where more than 70 % of the spending is undertaken by the private sector on an average.

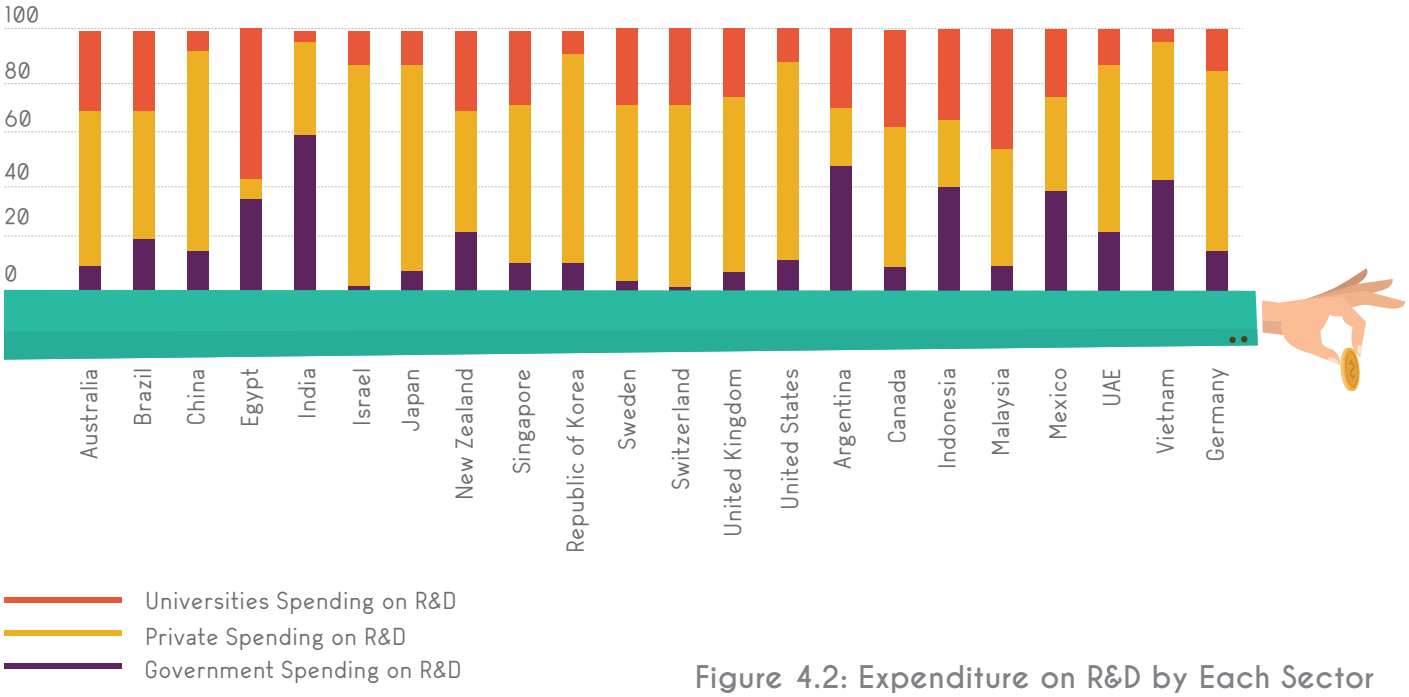


Figure 4.2: Expenditure on R&D by Each Sector

The figure depicts how much the government, private and universities contribute to the total research and development expenditure undertaken by the country. In terms of contribution by the government, India is at an advantageous position, but the private sector that needs to step up its level of research spending. The government should focus on identifying the possible reasons that are impeding private investment. Joint efforts by all the three sectors – government, industry and academia – would ensure overall growth of the biotechnology sector. The Indian government must engage with the other two stakeholders to identify the problems and correct them. Approach friendly steps taken by the government will lead to strengthening of the academia-industry-government bond and will lead to smooth transfer of knowledge and technology amongst all three.

The Indian government can provide R&D tax incentives to nudge investment in the right direction. Concentrated efforts would improve its basic environment essential not only to the biotech industry but for all the sectors individually and for the country as whole.

Improve Industry-Academia Linkages and the quality of Research Output

Universities and academic institutions are considered as the hub for innovation where researchers gather to share their ideas and develop new ones with cooperation. Also, university education signals that the degree/diploma holder is a part of skilled human capital.

Despite being the top scorer in quality of innovation among middle-income countries, industry-academia linkage is a challenge for India. There exists a lack of synergy between universities and industries over research and development activities. Both prefer to work in silos. A leading reason for this gap in knowledge transfer is a lack of clarity on ownership of intellectual property (IP) upon completion of research. This makes the industry hesitant to collaborate with universities for research. In addition, even if the two entities decide to collaborate, they have to overcome several hurdles such as contextual understanding due to lack of competencies and skill gaps across industries.

Since industry-academia linkages provide the basis for strong innovation system, universities must assure that R&D activities are oriented towards the market demand. There is a need to restore balance between the university education and their industrial implementation in order to achieve enhanced competitiveness as these issues often get reflected in the output. For instance, India's performance in research output is rudimentary and has immense scope for improvement. This can be linked to low share in the biological triadic[9] patenting, low number of papers published or the quality of those papers being sub-par.

Interestingly, as per Science and Engineering Indicators 2018 published by National Science Board, the number of research publications in India is following an upward trajectory. Though substantial difference exists between the publications' numbers when compared to US and China, however India has just surpassed Japan.

But even after this increased number of publications, the number of citations have not increased. Under top 1% cited publications in the field of Science and Engineering, India falls behind US, China and Japan by a considerable amount which can be clearly seen in the Figure 4.3. This poses a question on the quality of India's publications. So, it is imperative not only to increase the quantity but also the quality of research papers.

[9] Triadic patents are defined as a set of patents registered in three patent offices – the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO) and the Japan Patent Office (JPO).

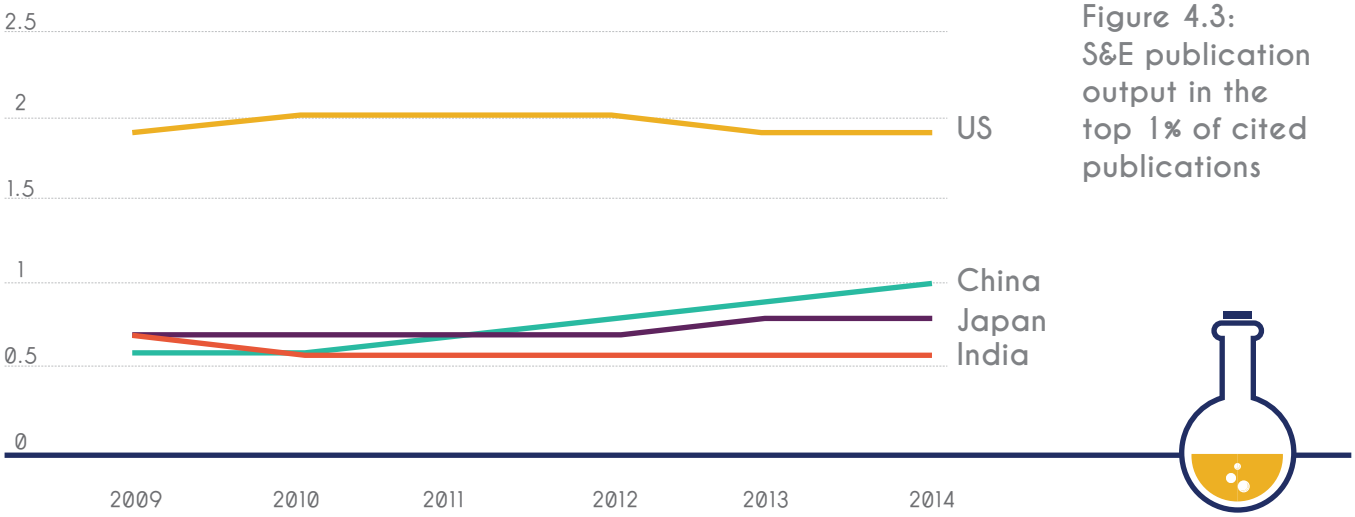


Figure 4.3: S&E publication output in the top 1% of cited publications

Source: Science and Engineering Indicators 2018

Thus, to improve the research output, countries must focus on bettering inputs such as industry-academia linkages and the quality of research institutions. China started working on its research institutions since 1949 and despite failing numerous times, the country kept on drafting policies that focused on research.

India has recently taken steps in the right direction. The country has launched its first ever Industry-Academia Mission under its National Biopharma Mission in order to boost biopharma development in the country. Also, the government has supported joint industry-academia Ph.D. programs.

Thus, with such programs, India will surely be able to overcome these challenges and improve not only the quantity but also the quality of its research.

Bio-crops and Biofuels-the way ahead

The biotechnology sector has brought immense economic as well as social benefits for India. Its presence has created deeper impacts on the Indian lives than often acknowledged. The sector contributed extensively in Green Revolution that used hybrid seeds to enhance farm yields, which made India self-sufficient

in food grains. Also, similar benefits were reaped in during White Revolution that enhanced India's dairy production through biotechnology interventions.

Despite having a history of using biotechnology in agricultural sector, the share of India in the number of hectares of biotech crops under cultivation is just 6 percent of the global land under cultivation of biotech crops. Having the second largest agricultural land in the world, India has the potential as well as resource to utilize this land and emerge as the biggest player in the biotech or genetically modified (GM) crops.

These GM crops have benefitted a number of developing countries and has created environmental benefits by significantly reducing carbon emissions. Also, the use of insecticides and pesticides has reduced. The year 2018 witnessed nearly 6 million of Indian farmers planting 11.6 million hectares of BT Cotton, making India the largest producer of BT cotton.[10] However, the country's scope of GM crops is limited to BT cotton only.

India needs to learn from Argentina as the latter followed a science-based approach to bio-agriculture regulation and has emerged as one of the global leaders in biotechnology crops.

[10] ISAAA Report, 2018.

The Argentine National Advisory Committee on Agricultural Biotechnology (CONABIA) is well established and highly regarded internationally.

Another major part of bio-agriculture industry is biofuel. Considering the present and future dependence on fossil fuels by India, biofuels can act as a cheap and environment friendly substitute. Currently, India produces merely 0.5 percent of the global output of biofuels. The country can draw lessons from the experience of countries like US and Argentina. An earlier shift made by US from fossil fuels to biofuel has made the country one of the topmost producers of biofuels in the world. Argentina, which is well-endowed with natural resources, got its first biofuel patented in 1928. By 2007, the country even had a dedicated law for biofuel use.

Realising the strategic importance that renewable energy sources like biofuel holds for India, the government launched a national biofuel policy which aims at blending 5 percent biodiesel in diesel by 2030 and 20 percent ethanol in petrol. Such effective policies are making India's transition towards biofuels relatively smooth. The national policy on biofuel along with use of biodiesels, ethanol and jatropha show a strong intent to increase production of biofuels. This policy will not only generate economic benefits for India by reducing its import dependence but will also push India towards a cleaner economy.

Easing the Regulatory Environment

The Indian biotechnology industry is regulated by four main ministries and their agencies as mentioned earlier in the study. Based on each Ministry's speciality, these agencies were constituted accordingly. The application policies concerning various agencies are often tedious and sometimes discourage potential investors. It might even delay the rate of approvals and tracking of applications.

It is commendable that the Government has established specialized departments for different areas of Biotechnology. There is a need to establish coordination between the departments and ministries to fasten the rate of assessment of applications.

Additionally, the regulatory environment for

biopharmaceuticals is particularly weak in the country. The country's drug review capacity is adequate, yet it is very inconsistent across various regions. Also, the delays in approvals and quality checks are quite long and make this regulation process extremely tiring for the biopharma companies.

In order to resolve these issues, there is a need of single window would streamline the whole application process. This could further boost the rate at which private firms invest into the Biotechnology industry.

Japan provides a perfect example where applications for approvals of new drugs (bio-pharma products) are put on the fast track in order to expedite the approval process as these are goods with substantial medical needs. India also needs to establish a similar set up that would speed up the application approval process and quality checks process.

Emphasis on Clusters

Clusters possess the ability to attract large number of companies, and generate employment, revenue and output. DBT has understood the importance of such clusters and as mentioned before created four full functioning bioclusters. To ensure that the benefits of such clusters can be maximized, India needs to learn from nations such as US.

For instance, in US there are specialized clusters just for Biopharma. There are multiple identified clusters spread across the country that emphasizes on production of biopharma products.

According to the data from the US cluster mapping, in 2016, biopharma alone created about 250,000 jobs. These clusters are far developed and therefore generate specialized jobs.

These clusters also share strong linkages with associated industries/sectors such as medical devices, business services etc which creates a solid production and supply chain.

India must identify new areas for the setup of biotech clusters. According to the data presented earlier in the study, the biopharma clusters in states and UTs like Sikkim and Jammu and Kashmir are performing well. Therefore, new bioclusters can be established here to further generate more output and revenue in an already flourishing market. The impact of these clusters will be long-term and will lead to multiplier effects in job and wage generation along with production of specialized output. Currently there are four full functioning bioclusters in states such as Karnataka, Delhi NCR.

These states have historically performed well in the industry. The new bioclusters must now be established in states who have the potential but never really performed well in the biotech industry. This process has begun as the government has planned to create a biocluster in Mohali, Punjab. According to the Institute for Competitiveness' paper on Indian cluster mapping: there is a strong positive correlation between presence of clusters and economic growth & innovation. Cluster based production quickens the innovation process and further creates ancillary industries which will then establish a consistent supply chain emphasizing on specialized goods.

Creation of Market Database

The biotech industry in India is an ever growing one. More start-ups are joining and expanding the share of output for the industry (according to the latest ABLE data). Hence it is necessary that a database must be maintained to identify such firms and record their contributions to the industry.

Maintaining a database will lead to better understanding of the market size and the rate of its growth. Furthermore, such collection of data can help in accurately calculate the segment-wise division of output and revenue of the industry. Biotech industry can therefore become a data driven industry where policy making will be dependent on accurate data. Policies arising from such practices will be more accurate and will cover all the grounds.

Countries like US, UK and Canada use cluster mapping and other such tools to calculate the market size and value the output generation of their respective biotech industries. A database could help BIRAC and DBT in formulating strong policies by understanding the underlying trends and problems that concerns the Indian biotech industry. While achieving a target of 100 Billion USD worth of output by 2025 is quite important, it is also necessary to ensure proper documentation of data.

These recommendations are based on the cross-country analysis done as a part of the assessment with a specific focus on the Indian biotechnology industry. And all these recommendations have so much relevance both today and also going into the future. Also, their impacts are going to be long term with multiplier effects throughout the economy. India has been faring well in some of the indicators and therefore the government must strengthen them to be on par with some of the mature biotech economies such as US, Singapore etc. Even in those indicators where India is not doing well, there is a strong potential to not just improve but further enhance India's position globally. These recommendations are based on ways to make India globally competitive and make its biotechnology industry one of the best in the world.

Appendix

I. METHODOLOGY

Following steps are followed to finally calculate the assessment scores.

1.Selection of the indicators

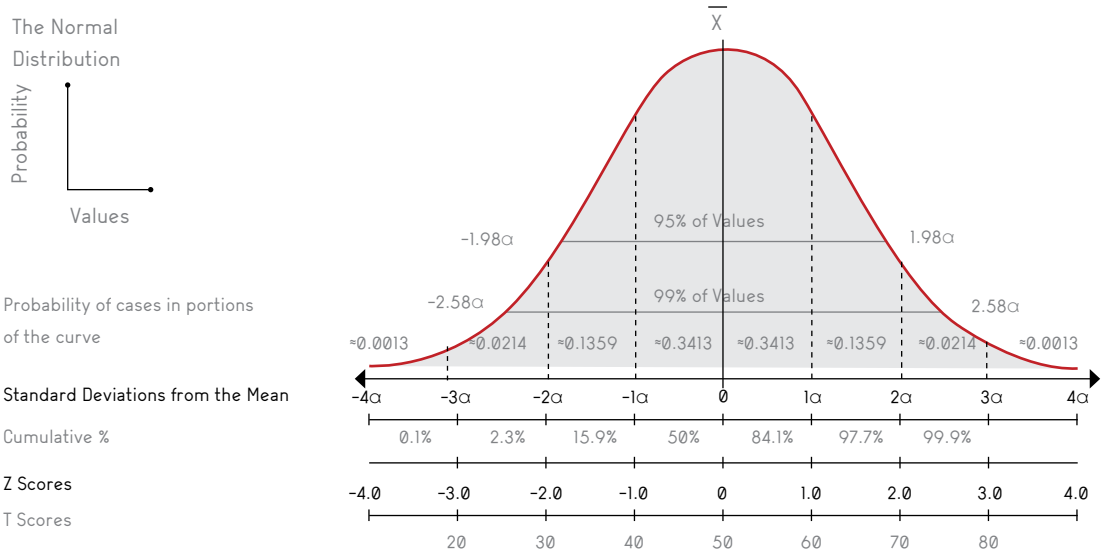
Indicators are carefully selected in a manner that they capture the entirety of the factors that could affect the growth potential of a country's biotechnology sector. These indicators focus not only factors specific to biotech sector but includes the factors that entail the overall competitiveness of a country.

2. Dealing with the data

A. NORMALIZATION

The indicators selected for comparison are not necessarily in the same unit. For instance, the life science graduates are in numbers whereas the legal scenario are a score. Also, R&D tax incentives are binary digits but universities spending on R&D are percentage. Thus, it is not feasible to compare them in their original units and a process is needed to transform them. Their conversion into same unit is necessary to draw insights. Hence, the normalization process transforms all the data into dimensionless numbers and makes them comparable.

Z-scores of the normal distribution are used3w for the process of normalisation. A z-score is the number of standard deviations a data point is from the mean. It ranges from -3 standard deviation to +3 standard deviation.



B. STANDARDIZATION

Using the formula given below, the indicators are standardized. This technique rescales the indicators with a mean of zero and standard deviation of one to make them comparable with each other.

where, Z is the z-score, X is the value of the indicator, μ is the mean and σ is the standard deviation.

$$z = \frac{x - \mu}{\sigma}$$

3. Score calculation

The final score of a country's performance in the Biotechnology Competitiveness assessment is based on the aggregation of the scores of three broad dimensions: Enablers and Biotechnology Landscape with Facilitators, Biotechnology Landscape and Performance.

Each dimension has been given equal weightage. This is primarily because the components they include are equally important to assess the overall performance of the biotechnology sector of each of the country.

The scores of each dimension are also further calculated by the aggregation of component scores and the score of each component is derived by averaging the indicator scores.

A clearer description of the same is given below:

A. COMPONENT SCORES

The dimensions of the assessment have components which further have indicators. Score of each component is calculated by averaging the score of indicators using the following formula:

$$\text{Components} = \sum (\text{indicator score})/\text{Number of indicators}$$

These scores will be transformed to a 0 to 100 scale. The calculation will be done using the following formula:

$$\frac{(X - \text{Minimum Score})}{(\text{Maximum Score} - \text{Minimum Score})}$$

where, X is the indicator score.

B. Dimension Scores

Each Dimension score is taken to be an average of its components using the following formula:

$$\text{Dimension}^{d} = \sum (\text{Component score})/\text{Number of components}$$

III. DEFINITIONS FOR INDICATORS

A total of 29 indicators has been used in the framework categorised under three dimensions. The rationale for each of the indicator is present below:

Dimension	Indicator name	Definition	Source
ENABLERS			
Human Capital	Number of Researchers	Researchers are professionals who conduct research and improve or develop concepts, theories, models techniques instrumentation, software of operational methods. R&D covers basic research, applied research, and experimental development.	World Bank*
	Knowledge Workers	Knowledge workers is a set of four quantitative indicators: employment in knowledge-intensive services; the availability of formal training at the firm level: R&D performed by business enterprise (GERD) as a percentage of GDP (i.e., GERD over GDP); and the percentage of total gross expenditure of R&D that is financed by business enterprise. In addition, the sub-pillar includes an indicator related to the percentage of females employed with advanced degrees. This indicator is measured in score.	GII-Global Innovation Index, 2019
	Quality of Research Institutions	The quality of scientific and research institutions is measured by the average score of the top three universities in the QS World University Ranking of 2016. It gives the average scores of the country's top three universities that belong to the top 700 universities worldwide.	GII, 2019
Investment in Research and Development	Expenditure on R&D as a percentage of GDP	Gross domestic spending on R&D is defined as the total expenditure (current and capital) on R&D carried out by all resident companies, research institutes, university and government laboratories, etc., in a country. It includes R&D funded from abroad but excludes domestic funds for R&D performed outside the domestic economy. This indicator is measured in USD constant prices using 2010 base year and Purchasing Power Parities (PPPs) and as percentage of GDP.	UNESCO
	Government Spending on R&D	Share of government in the total R&D spending undertaken by the country. It is measured in percentage terms.	UNESCO
	Business and Private Spending on R&D.	Percentage share of business and private (both profit and non-profit) in the total R&D expenditure.	UNESCO
	Universities spending on R&D.	Contribution of universities in the total spending on R&D, measured in percentage terms.	UNESCO
Safety and Legal Environment	Intellectual Property Protection	Measuring the extent to which the intellectual property is safeguarded. It is measured in scores.	GCI-Global Competitiveness Index, 2019
	Efficiency of legal framework in challenging regulations	How easy is it for private businesses to challenge government actions and/or regulations through the legal system. It is a score.	GCI, 2019

	Efficiency of legal framework in settling disputes	Measuring how efficient are the legal and judicial systems for companies in settling disputes. It is a score.	GCI, 2019
	Rule of Law	Measures how rule of law is experienced and perceived by the general public. It is an index and measures scores.	WJP Rule of Law Index, 20
FACILITATORS			
Technology Transfers			
	Industry-Academia Linkages on R&D	Measures the extent to which businesses and universities collaborate on research and development (R&D). It is measured as a score.	GII, 2019
	Barriers to technology transfers	Measures the extent to which laws and regulations or de facto practices act as barriers to technology transfer and commercialization activities of publicly funded and supported research. It is a score.	GIPC International IP Index, 2019
	States of Cluster Development	Score of how widespread well-developed and deep clusters are (geographic concentrations of firms, suppliers, producers of related products and services, and specialized institutions in a particular field).	GII, 2019
	Patents filed in two or more offices	A "patent family" is a set of interrelated patent applications filed in one or more countries or jurisdictions to protect the same invention. Patent families containing applications filed in at least two different offices is a subset of patent families where protection of the same invention is sought in at least two different countries. In this report, "patent families data" refers to patent applications filed by residents in at least two IP offices: the data are scaled by PPP$ GDP (billions). A "patent" is a set of exclusive rights granted by law to applicants for inventions that are new, non-obvious, and commercially applicable. A patent is valid for a limited period of time (generally 20 years), during which patent holders can commercially exploit their inventions on an exclusive basis. In return, applicants are obliged to disclose their inventions to the public in a manner that enables others, skilled in the art, to replicate the invention. The patent system is designed to encourage innovation by providing innovators with time-limited exclusive legal rights, thus enabling them to appropriate the returns from their innovative activity.	GII, 2019
Regulatory Environment	Regulatory framework for Biopharma	Measures all aspects of the regulatory framework in place for biopharmaceuticals, from product approval and manufacturing standards to clinical standards including the speed of market authorization; patent office backlogs; bioequivalence requirements for generic products; and the existence of a biosimilars pathway in line with international standards. It is measured in percentage.	BCI-Biopharma Competitiveness Index, 2017
	Regulatory framework for Bioagri	Examines the presence of regulatory authority for GM crops. It is binary (1 for presence of regulatory body, 0 otherwise)	IFC Research
	Regulatory Quality	Reflects perceptions of the ability of the government to formulate and implement sound policies and regulations that permit and promote private-sector development. It is measured in scores	World Bank

Market Incentives	Pricing and Reimbursement Policies related to Pharma	Assess the ability of the regulatory system in the economy to ensure that only high quality, safe biopharmaceutical products enter the market, yet do so in a timely manner. It is measured in percentage.	BCI, 2017
	R&D Tax Incentives	Examines the tax incentives available and provided in a given economy as a means of encouraging R&D. R&D incentives can be various tax incentives, credits, deductions, lower rates of taxation for specific forms of income (e.g. income derived from IP assets such as patent box schemes) and/or direct support mechanisms such as grants and subsidies for R&D activities. It is a binary (1if tax incentives are provided, 0 otherwise)	Building the Bio Economy, 2019
	Ease of Doing Business	Measures regulations that enhance business activities and those that constrain it. It is measured in scores.	Ease of Doing Business Index, 2019.
PERFORMANCE			
Clinical Trials	Clinical trials per million population to date	Number of clinical trials to screen, prevent, diagnose and treat disease	Building the Bio Economy, 2019.
	Clinical trials for biologics per million population to date	The number of dedicated trials conducted to test biologic drugs.	Building the Bio Economy, 2019.
Research Output	Biotechnology triadic patenting, share of global total average 1999-2013	Triadic patenting is defined as a set of patents registered in various countries (i.e. patent offices) to protect the same invention. According to OECD the triad includes three major patent offices: the European Patent Office (EPO), the Japan Patent Office (JPO) and the United States Patent and Trademark Office (USPTO). It is measured in percentage.	OECD
	Scientific publications standardized for population	The number of scientific and technical journal articles published from a given economy.	Building the Bio Economy, 2019
	Quality of academic publications	Measurement of the percentage of the country's scientific publications among the world's top 10% most cited publications.	Building the Bio Economy, 2019
Biotechnology Output	Biopharmaceutical product launches, % available in country within 5 years of global product launch	Comparison of relative levels of biopharmaceutical product penetration in the sampled economies. Specifically, it looks at the percentage of products available in each economy within five years of first global launch.	Building the Bio Economy, 2019
	Biofuels production, % of global total, 2017	Measuring each country's percentage share of the total amount of biofuels produced globally in 2017.	Building the Bio Economy, 2019
	Biotechnology crops, hectares under cultivation, % of total 2017	Comparison of levels of biotechnology derived crops in 2017.	Building the Bio Economy, 2019

*Latest Available Data.

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Institute for Competitiveness, India is the Indian knot in the global network of the Institute for Strategy and Competitiveness at Harvard Business School. Institute for Competitiveness, India is an international initiative centered in India, dedicated to enlarging and purposeful disseminating of the body of research and knowledge on competition and strategy, as pioneered over the last 25 years by Professor Michael Porter of the Institute for Strategy and Competitiveness at Harvard Business School. Institute for Competitiveness, India conducts & supports indigenous research; offers academic & executive courses; provides advisory services to the Corporate & the Governments and organises events. The institute studies competition and its implications for company strategy; the competitiveness of nations, regions & cities and thus generate guidelines for businesses and those in governance; and suggests & provides solutions for socio-economic problems.

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