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THE INDIAN BIOTECHNOLOGY INDUSTRY



\$ 100 billion

Vision by 2025



| Year | Growth Rate |
|------|-------------|
| 2008 | 36.8% |
| 2012 | 13.1% |
| 2016 | 57.1% |



800

Number of Companies

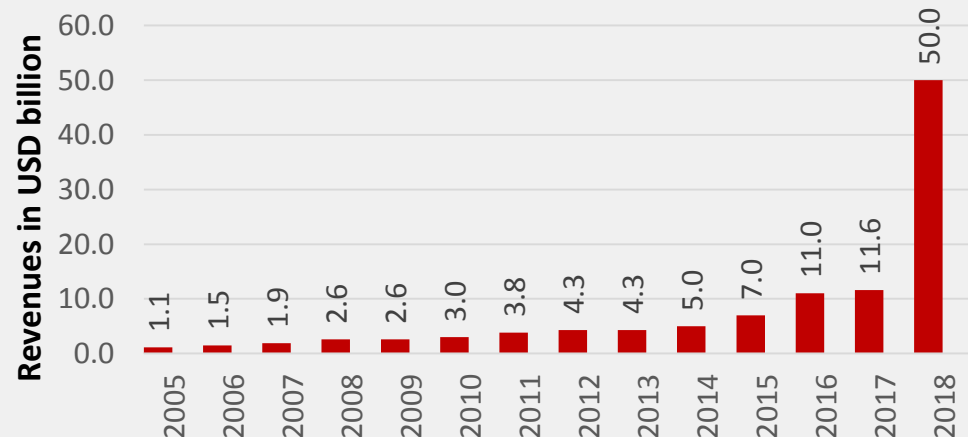
The biotechnology industry in India has been growing at a phenomenal pace. From merely \$500 million in 2003, it has grown exponentially in size to a \$11 billion industry as of 2016.

Globally, India is among the top 12 biotechnology destinations in the world.

In the last few years there has also been an explosive growth of start-ups within the industry. As of 2016, there were more than a thousand biotechnology start-ups in India.

INDUSTRY CATEGORISATION

| | |
|--------------------------|------------|
| Biopharmaceutical | 62% |
| Bioservices | 18% |
| Bioagriculture | 14% |
| Bioindustrial | 4% |
| Bioinformatics | 1% |



ROLE OF THE GOVERNMENT

1

As early as 1986, Rajiv Gandhi recognizing the potential of biotechnology in the country's development, set up the Department of Biotechnology with a modest budget of somewhere between 40 million to 60 million rupees.

2

The department has set up 17 Centres of Excellence in biotechnology at higher education institutions across the countries and has supported the establishment of 8 biotechnology parks.

3

The Department of Biotechnology set up the Biotech Industrial Training Programme. As a result of the programme, departments of biotechnology within existing institutions were created that has produced the current pool of biotech-skilled human resources that we witness today.

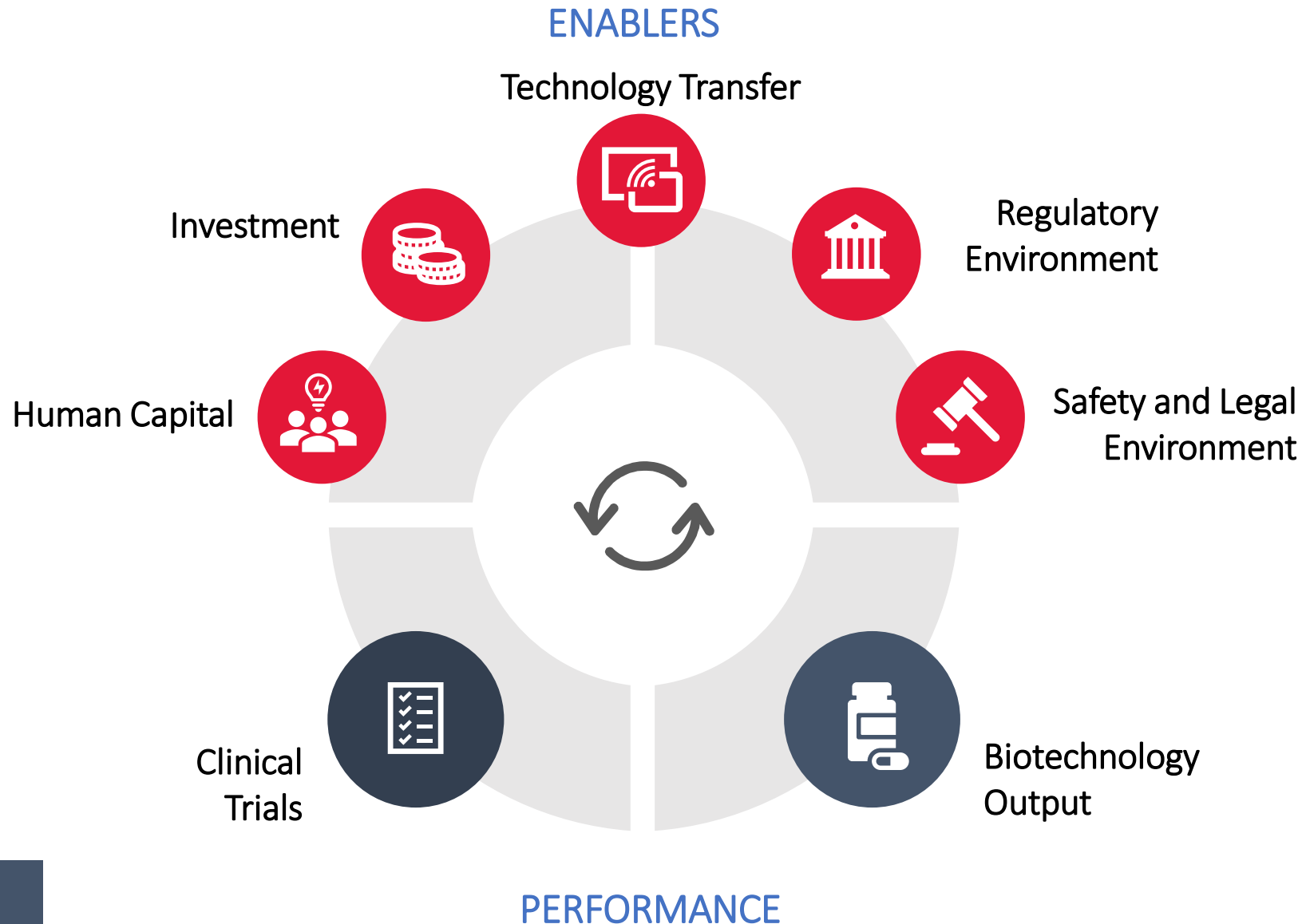
4

The biggest contribution of the department was setting up the Biotechnology Industry Research Assistance Council (BIRAC).

5

In its six years of existence, it has successfully supported 316 start-ups that have generated \$125 million in revenue through creation of 122 products and technologies

INDIA VS THE WORLD



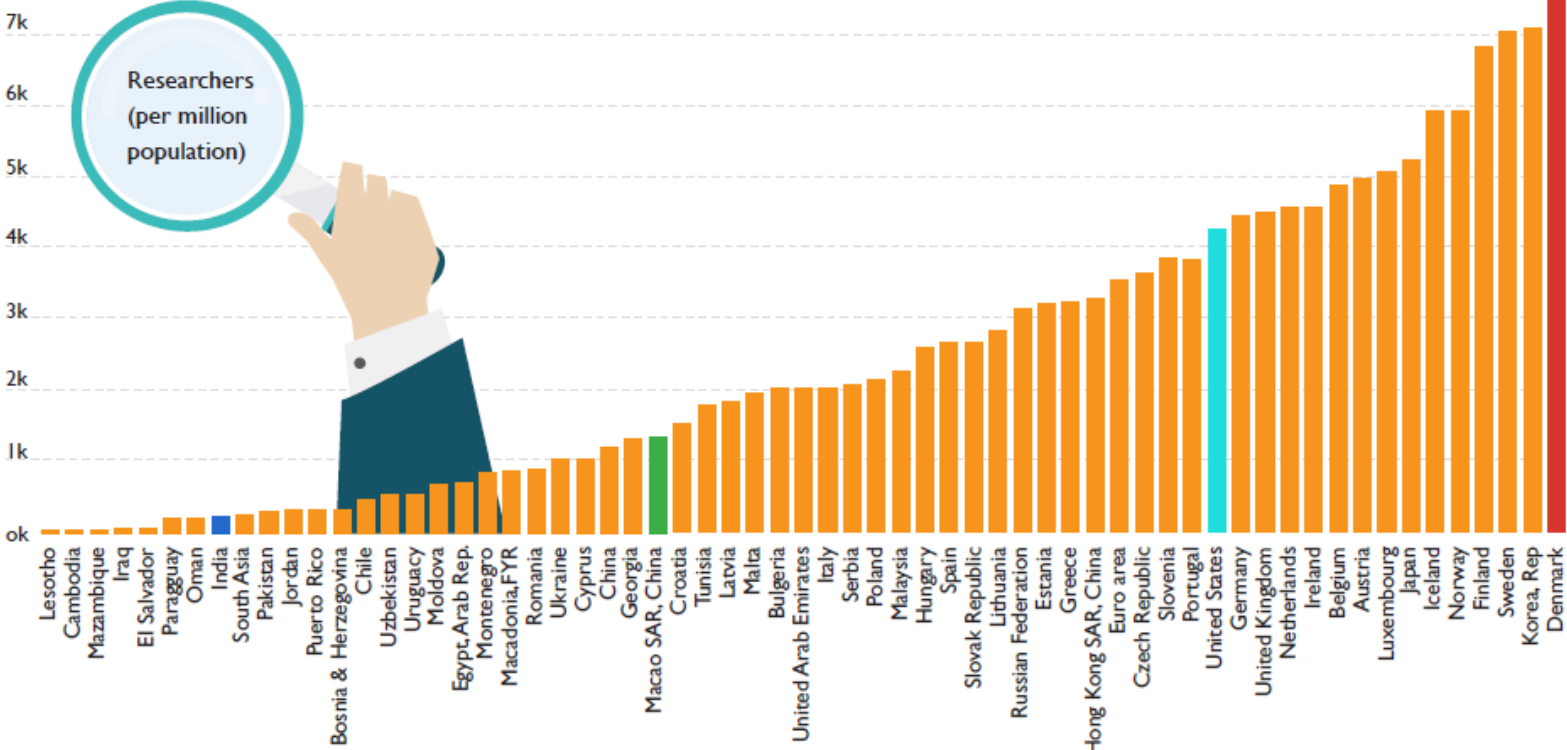
The assessment is done by looking at two types of measures – inputs and outputs.

The input indicators reflect the enablers such as human capital, policy landscape etc. that help to develop and sustain a successful biotechnology sector. Together these indicators measure the degree to which a country has created an environment conducive for the biotechnology sector to grow.

The output indicators measure whether the government, along with other stakeholders, has been able to build a successful biotechnology sector or not. Together these indicators reflect the benefits that the economies derive from the inputs in terms of biotechnology outputs, knowledge creation and exports.

ENABLERS

Human Capital

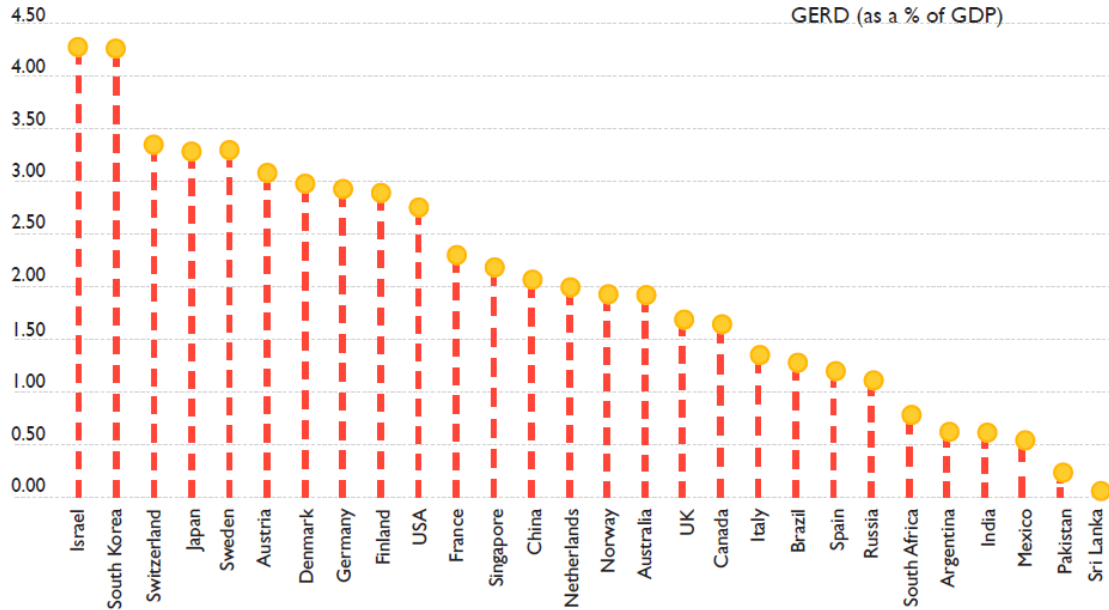


The number of researchers per million in India are 216, while China has 1177 researchers per million. For other mature economies such as South Korea this value stands at 7113. It's more striking that number of researchers in India are more than just 30 countries in the world.

ENABLERS

Investment

GERD (as a % of GDP)



Share in Investment



India devotes a paltry expenditure to research and innovation, especially when compared with the rest of the world. India presents a queer distinction from the rest of the world based on where most of the expenditure is raised. Compared to 77 percent in China, the share of private expenditure towards R&D in India is merely 43.5 percent.

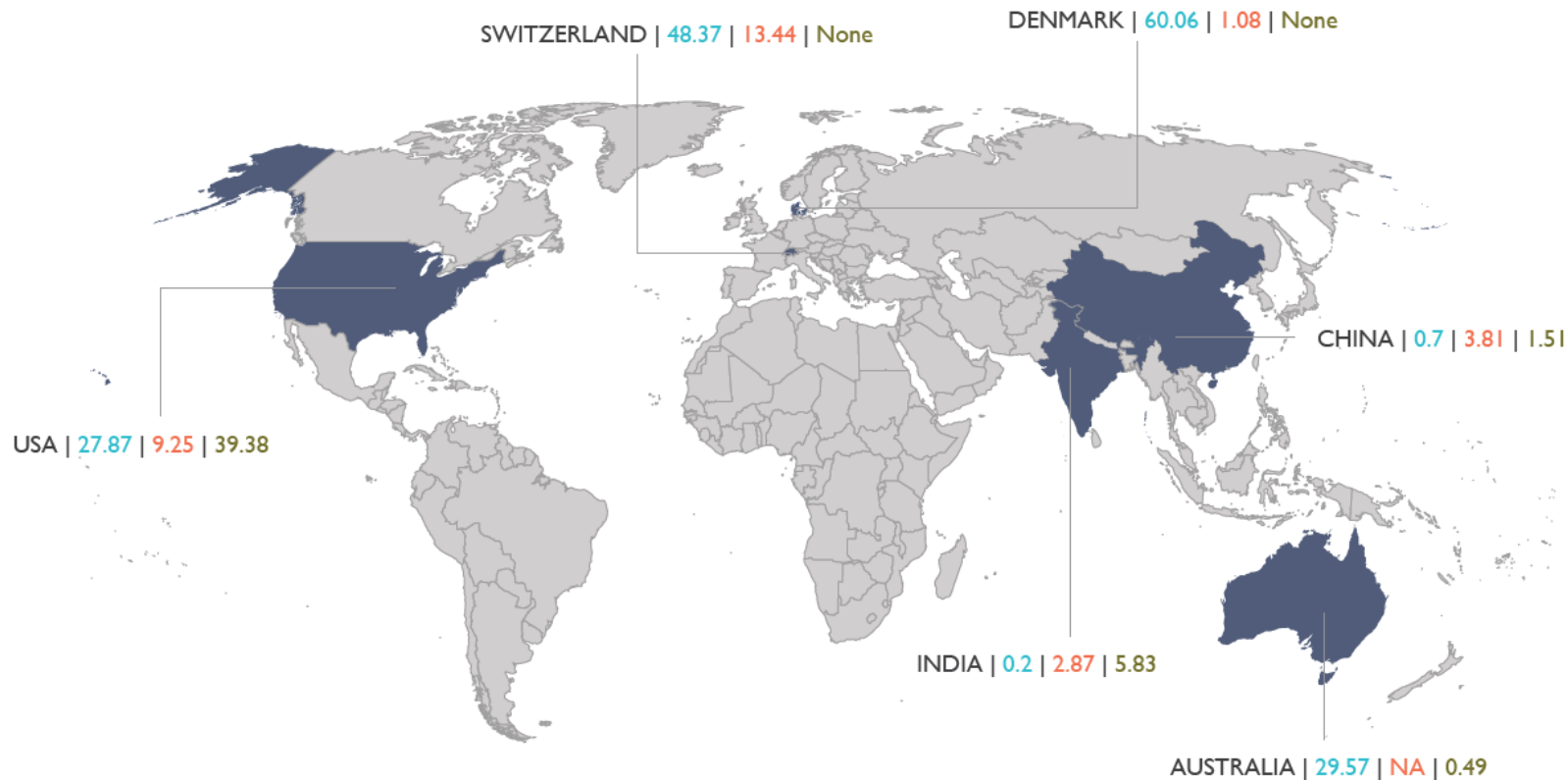
ENABLERS

Technology Transfer, Regulatory Framework and Safety & Legal Environment

| Aspect | Details |
|------------------------------|---|
| Technology Transfer | <p>Universities across the world are seen as hubs of innovation where experts from varied fields come together to share their ideas for developing new technologies, systems and processes. However, in the Indian universities the focus on research is quite abysmal and the linkages within different universities and industry academia linkages are missing.</p> <p>A conflict of interest is created when it comes to co-creating a product by industry coming together with academia. This happens because only 33 percent of Institutions of National Importance, 24 percent of central universities and merely 12 percent of state universities have an IPR policy.</p> |
| Regulatory Framework | <p>There is a feeling among the industry members that the Indian regulatory framework is unpredictable. For instance, some changes are made at a very short notice in an arbitrary manner. The government should work towards creating trust among the industry.</p> |
| Safety and Legal Environment | <p>The U.S. Chamber of Commerce Global Innovation Policy Center (GIPC) in their sixth edition of International IP Index analysed the intellectual property (IP) climate in 50 world economies.</p> <p>India, due to its higher patentability standards got a rank of 44.</p> <p>However, for the first time the country did not get placed in the bottom ten percent of economies measured. This is mainly due to the passage of guidelines to improve the patentability environment for technological innovations, as well as the implementation of some tenets of the National Intellectual Property Rights Policy.</p> |

PERFORMANCE

Clinical Trials and Biotechnology Output



- Clinical trials for biologics (per million population)
- Biopharmaceutical Exports (Percentage share of world exports)
- Biotechnology Crops (hectare under cultivation, percentage of total)

India has a huge potential for clinical trial activity due to its large and low-cost market. Despite these advantages, it currently hosts only 0.2 clinical trials per million population, which is among the lowest rates globally. This gap exists because of three main reasons:

- First, there is a lack of adequate resources for capacity building and infrastructure that is required to ensure high-quality clinical research system in the country.
- Second, India's patentability requirements remain outside established international best practices.
- Third, there are problems with the legal environment vis-à-vis clinical trial approval protocols as well as procedures for addressing trial-related injuries.

OPPORTUNITIES: INDIAN BIOTECHNOLOGY INDUSTRY

| SEGMENT | Biopharmaceutical | Bioservices | Bioagriculture | Bio-IT | Bioindustrial |
|-------------|--|--|--|--|--|
| OPPORTUNITY | <p>The share of biologics in the global prescriptions is on an upward trend. They are expected to contribute to almost 27% to global prescription sales by 2020. Given the growth of biologics, the opportunities for biosimilars are evident, especially when the 12 biologics products are expected to lose their patents in US by 2020.</p> | <p>India has the potential huge potential for clinical trial activity due to its large and low-cost market. Despite these advantages, it currently hosts only 0.14 clinical trials per million population, which is among the lowest rates globally.</p> | <p>Indian government's plans to enhance farm productivity and its focus on food security is clearly reflected in the Union budget. This focus will be conducive to the development of bio-agriculture.</p> | <p>Bio-IT is an emerging segment of the biotechnology industry and has immense potential for growth given the rising need for technology to transform data generated by R&D institutes, clinics, hospitals etc. into useful form. India has witnessed exponential growth in IT industry and has the requisite IT infrastructure for catering to the needs of global Bio-IT industry.</p> | <p>Biofuels and Bio-energy are gaining popularity as leading alternative resources. Presently, India is a net importer of fossil fuels, with the increasing rate of growth the demand for energy and our dependence on imports is also going to increase. Therefore, companies can strategize to reduce our dependence on fossil fuels through biofuels and bioenergy.</p> |

DIAMOND MODEL

Analysing the Competitiveness

UNIVERSITIES : Curriculum development along with industry exposure for students is necessary. Research output of the universities is not comparable to mature biotech economies.
INFRASTRUCTURE: Law research and development expenditure.
INDUSTRY ACADEMY LINKAGES : Technology transfer development of products and services that can be commercialized unemployable workforce are some of the challenges faced due to lack of linkages.

Factor
(Input)
Conditions

HUMAN CAPITAL : India is home to young and affordable high quality skilled workforce. However, talent retention is a major problem for the country.
VENTURE CAPITAL : The VC funding in Indian market is low due to the lack of technical know-how about biotechnologies.
ENTREPRENEURIAL ECOSYSTEM : Government efforts have significantly improved the ease of doing business in India.

Context for Firm
Strategy and
Rivalry

POLICY INITIATIVES: National biotechnology development strategy highlighted the major obstacles in India way towards becoming a global Biotech hub and listed down steps to address them. There is lack of coordination between different departments which makes the system confusing. There is lack of predictability and changes are made in the system at a short notice.
IP REGIME: Industry has a view that section 3(d) of the India's Patent Act sets a higher standard of patentability and impacts investment. The government needs to address Industries view on compulsory licensing.

Related and
Supporting
Industries

INSTITUTE FOR COLLABORATIONS : Government has set up Department of Biotechnology, Department of Science and Technology and Department of Scientific and Industrial Research for promoting research, formulating policy and providing financial assistance.
INCUBATORS AND BIOTECHNOLOGY PARKS : Central and the state government both have worked to setup incubators and biotechnology parks in India. However, biotechnology incubators in India smaller in size compared to mature economies such as US.

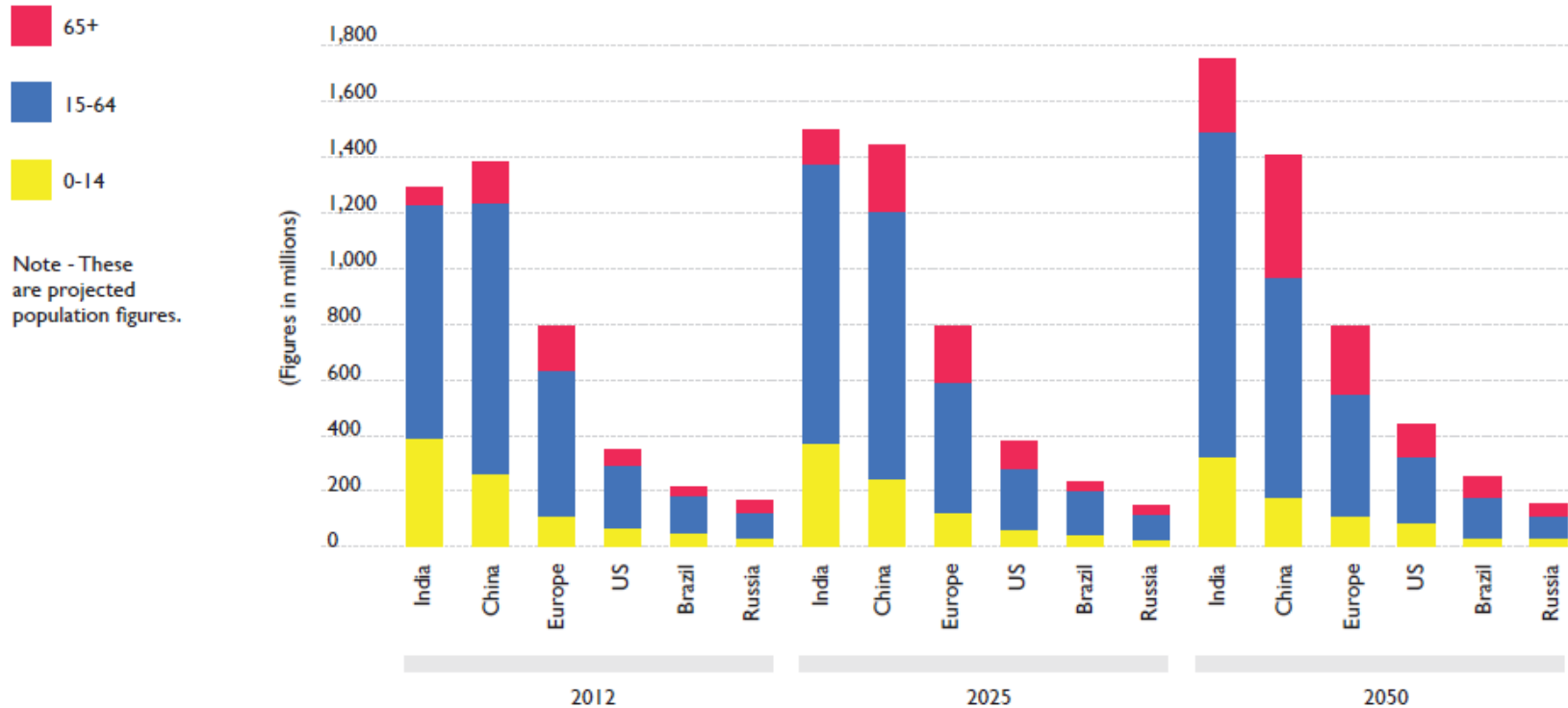
GLOBAL GROWTH: The Global Biotech industry is growing at the rate of 7.4 % and is expected to reach \$727.1 billion. Biosimilars are the biggest opportunity as many biologics are to lose patents exclusivity. India has a huge potential for Clinical Research given its population. India can tap the bio-IT market given its robust IT infrastructure and development of the IT industry.

Demand
Conditions

DOMESTIC DEMAND: The burden of diabetes is high in India and insulin is an opportunity that Indian players can tap. Large market for Healthcare with unmet medical needs. The focus of Indian government on agriculture and food security provides an opportunity for the players. Biofuels are of strategic importance to Indian given its increasing energy needs.

ADVANTAGE INDIA

Home to young affordable human capital



In India, more than 50% of the total population is below the age of 25 and almost 65% is below 35. The median age in India (26.5 years) is much below that of China (35.9 years) and the US (37.1 years). The effective utilization of this demographic advantage will provide India a competitive edge over all other emerging economies.

ADVANTAGE INDIA

Ease of Doing Business and Government Support

Ease of Doing Business:

In the recent years, the Ministry of Corporate Affairs have taken many steps to bring greater transparency in corporate structure and improve corporate compliance that has enhanced the efficiency of the processes under Companies Act, 2013.

- The amendments in Insolvency and Bankruptcy Code
- Establishment of National Financial Reporting Authority (NFRA)
- Streamlining the business processes
- Replacing the value-added tax with GST making the registration process faster
- Reducing the time and cost of export and import through various initiatives, including the implementation of electronic sealing of containers, the upgrading of port infrastructure and allowing electronic submission of supporting documents with digital signatures.



India moved up from 142nd to 77th position in four years.

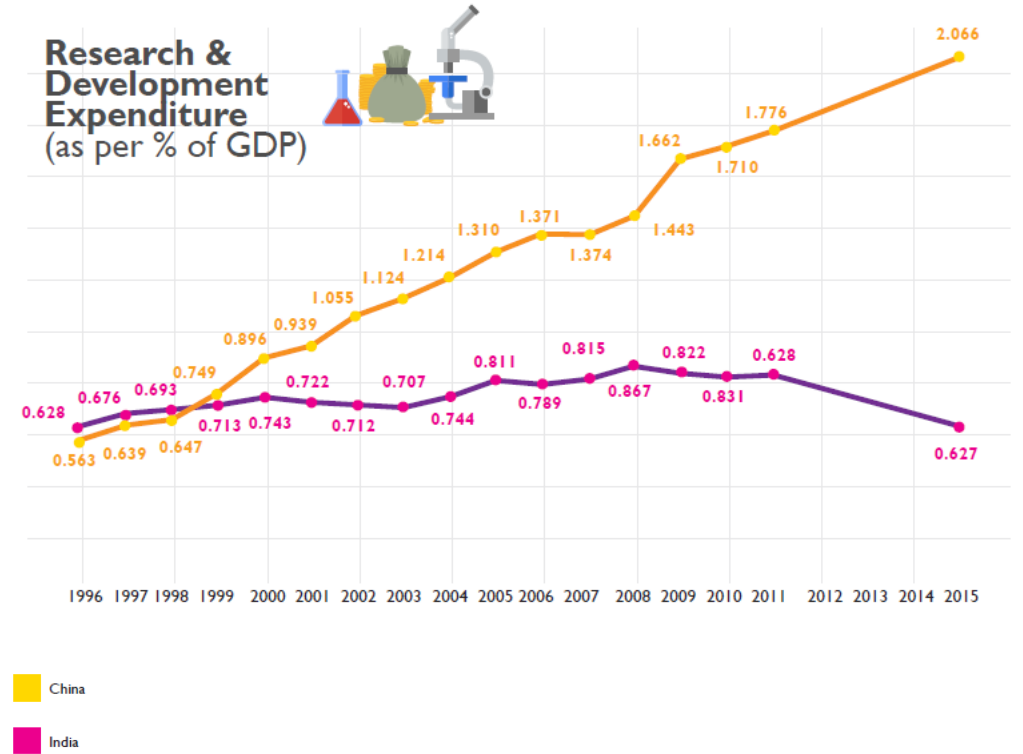
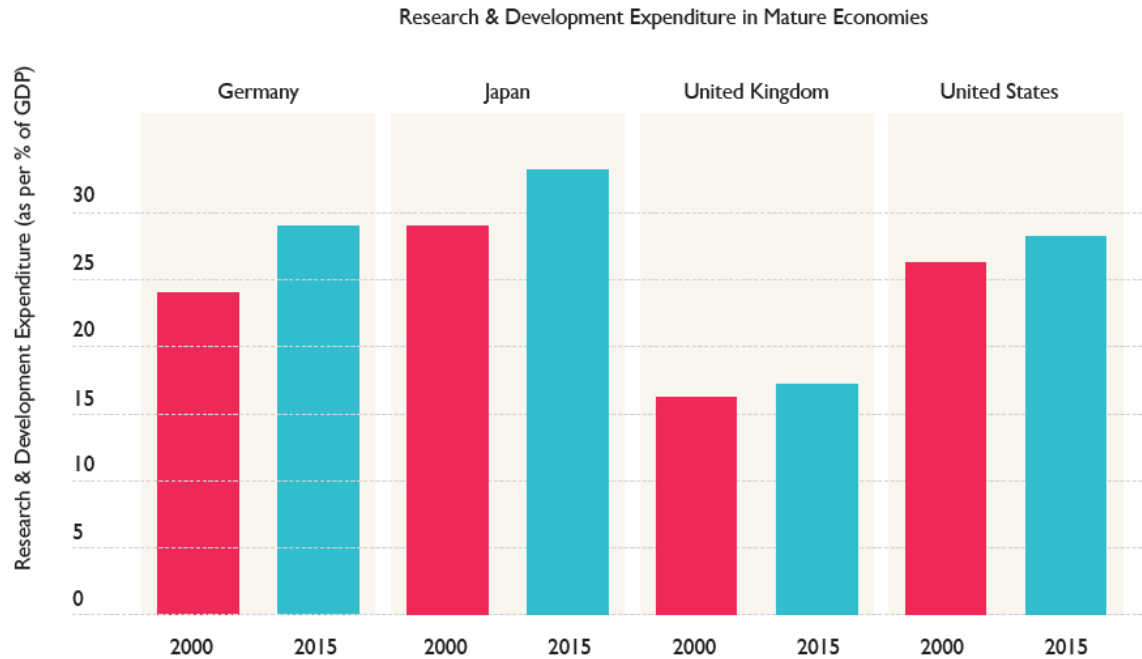
Government Support:

Various departments and ministries have played a pivotal role by setting up scientific research institutes to develop innovative solutions, opening incubators and technology parks to provide facilities to scientists and enterprises, focusing on bridging the infrastructural gap, and awarding research fellowships to promote commercial research.

National Biotechnology Development Strategy has recognised the challenges that are hindering the growth of the industry and is developing strategies to address these issues.

ISSUES AND CHALLENGES

Low Investment in Research and Development



India's research & development expenditure is low, not only compared to mature biotechnology economies such as Japan, and the US but also in comparison to emerging economies like China.

This becomes more worrisome for India since its competitor China has shown scintillating performance on this.

ISSUES AND CHALLENGES

India's IP Regime

| Aspect | Details |
|---|---|
| Section 3(d) of the Patents (Amendment) Act of 2005 | Section 3(d) is mainly criticised for setting a higher standard for patentability than mandated by TRIPS. The industry states that the fourth requirement of enhanced efficacy discourages incremental innovation and adversely impacts the environment for innovation on the whole. It is also possible that it is impacting foreign investment. However, this is compliant with the TRIPS regulations. |
| Compulsory Licensing | This gives rights 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. The issue is keeping many foreign investors out of the Indian markets. However, the government maintains the view that it has used this just once. Therefore, it is important for the Indian government and the industry to chalk out a plan of action that will be beneficial for both the innovators as well as the general public. |
| Regulatory Practices | <p>The Indian biotechnology industry is regulatory 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.</p> <p>The problem arises when some approvals are to be granted by two different bodies. For instance, Bio-Services fall under the purview of Ministry of Family and Health Welfare but the clinical trials in case of biotechnology are to be reviewed by the Department of Biotechnology. The lack of coordination between various departments create problems for the industry in form of tracking applications and obtaining approvals.</p> |

ISSUES AND CHALLENGES

Lack of Infrastructural Facilities

The growth of biotechnology industry requires access to world class physical (roads, rails, ports etc.) and research (incubators, instruments, animal breeding etc.) infrastructural facilities.

There are certain challenges that India face specially in terms of research infrastructure:

The biotechnology parks and incubators set up by the Indian government are smaller in size as compared to other economies. For instance, Biotechnology park in US employs around 20,000 – 50,000 employees while the strength of Indian incubators is 100-1500 employees.

India has limited animal breeding facilities, 71 to be precise and none of them has the capacity to be categorized as a large animal breeding facility.

There is a lack of clear roadmap for adoption of electronic records that hinders research.

ISSUES AND CHALLENGES

Lack of Skilled Human Capital

India has a young workforce, but it currently does not provide a competitive edge to the economy due to the lack of skills.

CHALLENGES

The education system is not industry oriented and hence produces students that have low employability rates. The industry has to invest in months of intensive training before freshly passed out students can become productive. This deficiency exists because of the weak linkages between the industry and the universities and the lack of co-ordination between the two on designing curriculums.

The focus on quantity instead of quality. The universities focus more on the number of hours taught and not on the quality of education imparted.

Due to these weak linkages, sometimes enough interest is not generated in the students to work in the biotech industry. This coupled with low compensation forces many students to seek employment in other areas.

VALLEY OF DEATH

Biopharmaceutical Industry

Valley of Death is the risk of failure in the transition of innovative products and services from discovery to marketization. The risk comes to play because biopharmaceutical is a highly capital-intensive industry with a long gestation period.



Source: DBT India

Most of the early research funding, often provided by universities or the government, runs out before the marketization phase, the funding for which is mostly provided by venture capitalists. It becomes difficult to attract further capital between these two stages because a developing technology may seem promising, but it is too soon to validate its commercial potential.

The failure rates coupled with the gap in resources has a huge impact on the commercialisation of innovative ideas. It will not be wrong to say that the industry is not constrained as much by the lack of innovative ideas as it is by the ability to process those ideas in usable forms.

PRICE CONTROLS

Biopharmaceutical Industry

Policymakers across the world are becoming more and more conscious about the costs of the drugs as questions are being raised on the pricing strategies of biopharmaceutical companies.

POLICY ACTIONS

Price Controls: This includes policies such as implementation of essential drug list, mandatory price cuts, reduction of mark-up for distributors etc.

Reimbursement Policies: This includes delisting of products on reimbursement lists, increase in patient co-pays etc.

Promoting biosimilars: These actions include providing incentives for to prescribe biosimilars etc.

Policymakers in India have also resorted to such measures in order to provide access to healthcare. These steps are much appreciated, especially in the light of the fact that 70 percent of the Indian population is driven towards private uninsured medical care due to the lack of an effective public healthcare system. However, these moves have several unintended consequences. The economies might benefit in the short term but the long-term effect of regulating the markets is a loss in the overall welfare due to two reasons. First, the decrease in profits due to price controls erode the incentive to invest in the research and development activities.

Second, controls might lead to a completely opposite corollary than what is expected i.e. higher healthcare costs with lower healthcare quality.

ACCESS TO HEALTHCARE

It goes beyond pricing

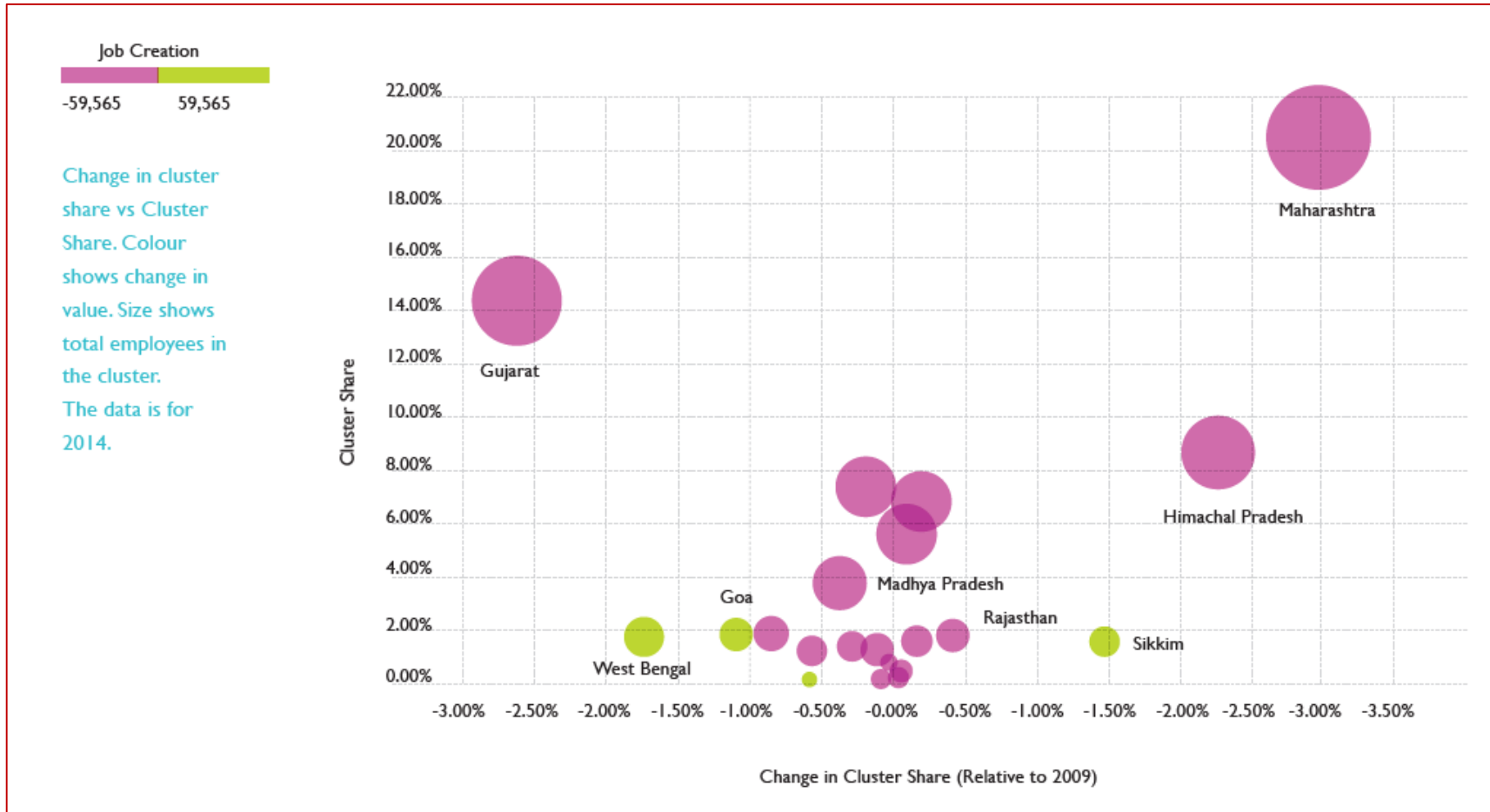


Some principles for looking at increasing access to healthcare

- Accessibility – The system should be accessible to the population with minimum delays
- Affordability – The system should be accessible with minimal costs possible
- Accountability – The system should be accountable to patient groups and citizens etc.
- Availability – The system should have availability of adequate medicines, medical equipment and healthcare professionals.
- Acceptability – The elements of the system should get accepted by the patient groups and citizens.
- Awareness – The system should try to reduce the information asymmetry between producers, patient groups, citizens etc.

One should keep in mind that the providing access to healthcare is more than a pricing issue. Therefore, governments need to work with the industry to adopt new strategies that not are not only aimed at providing affordable healthcare through price cuts but also encourage innovation.

BIOTECHNOLOGY CLUSTER

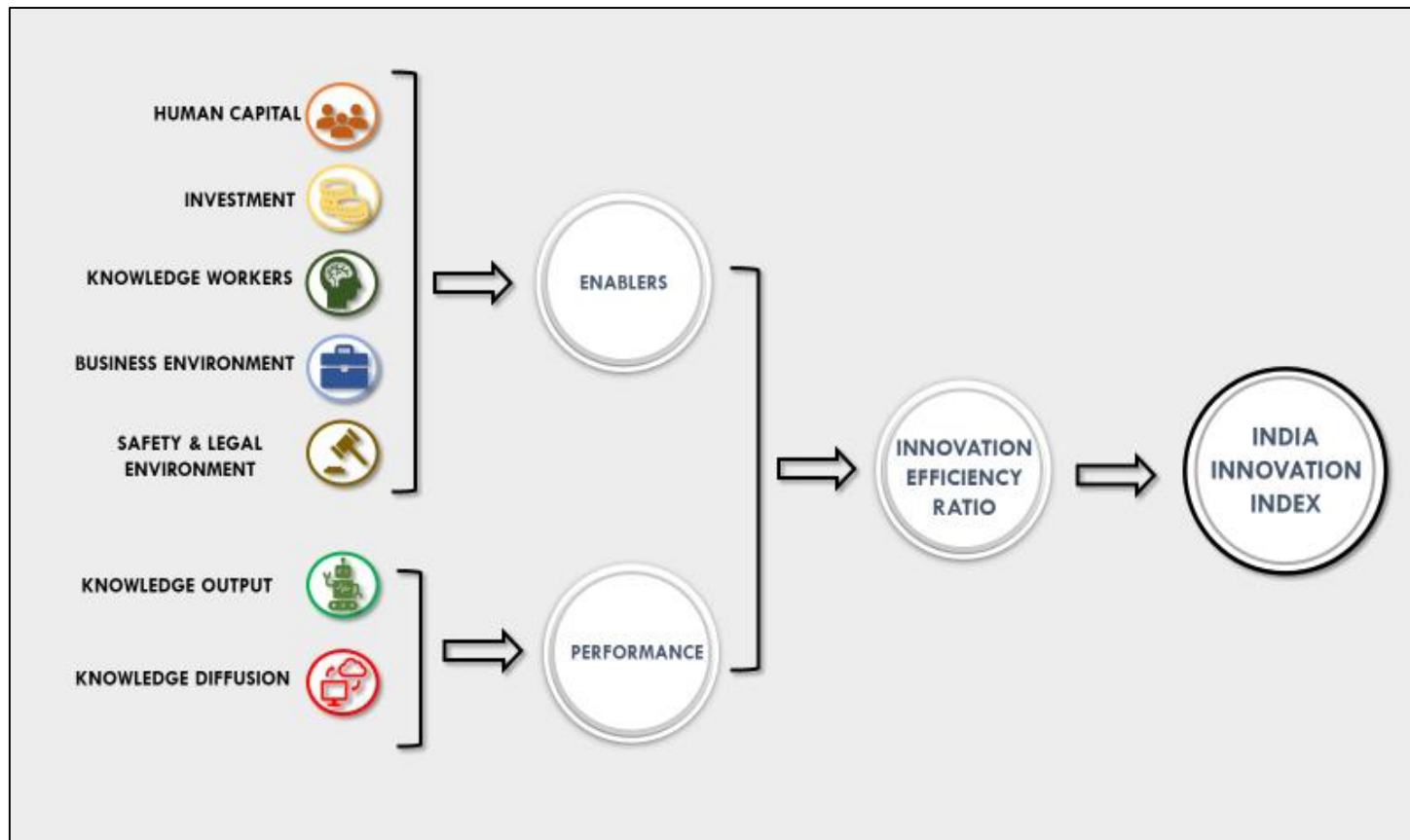


The cluster is mainly present in Maharashtra, Gujarat, Madhya Pradesh, Tamil Nadu and Karnataka.

However, if one looks at the change in cluster share then we can see that the cluster is growing in Himachal Pradesh, Rajasthan and Maharashtra.

INDIA INNOVATION FRAMEWORK

A state level study



There is a distinction between inputs and outputs while measuring innovation in an economy.

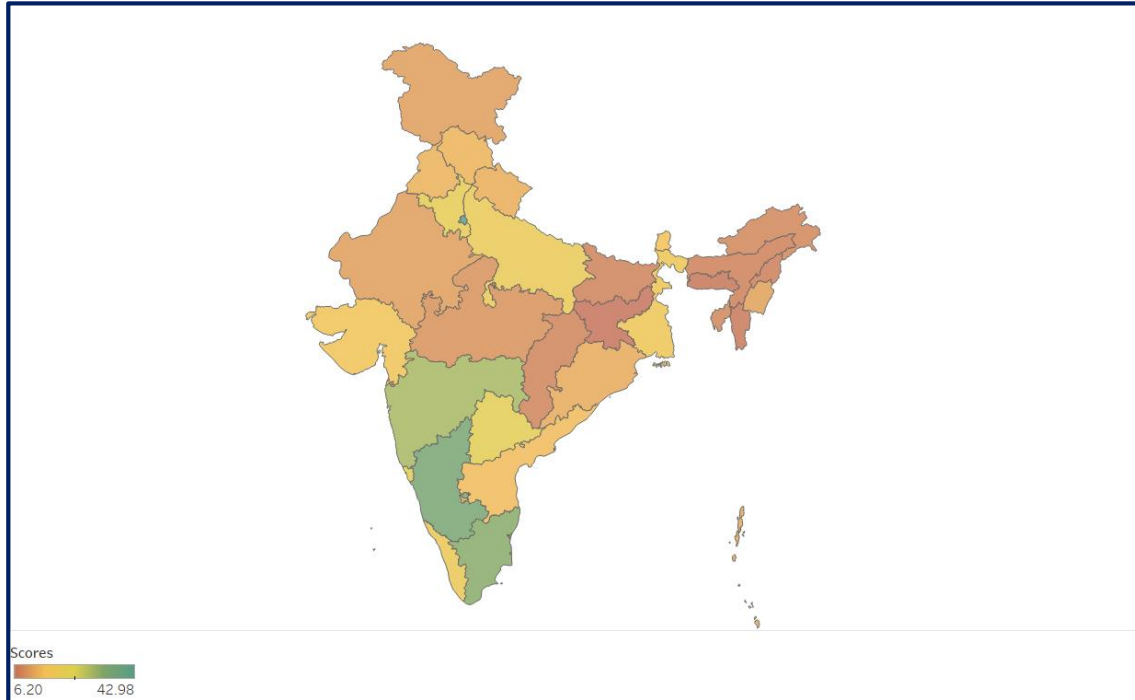
Inputs are aspects that enable an economy to stimulate innovation while outputs are the results of innovative activities within the economy.

India Innovation Index considers both enablers (inputs) and performance (outputs) as they are intricately related, one fuels the other.

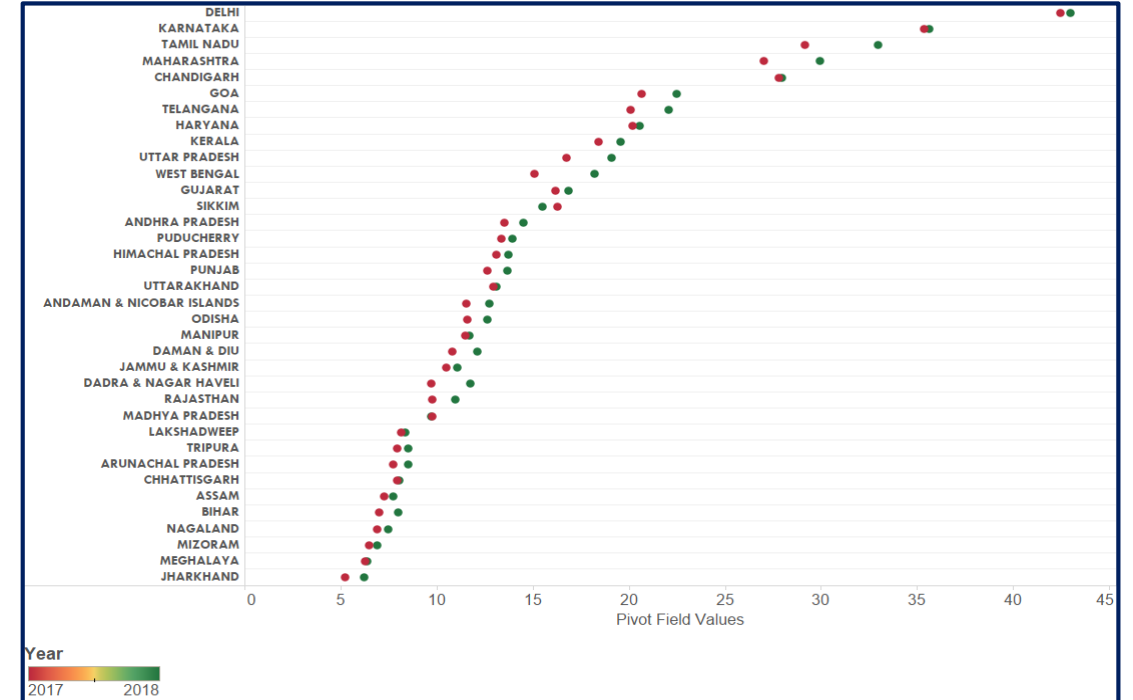
The Innovation Efficiency Ratio (ratio of performance score to enabler score) plays a key role here as it indicates the state's ability to efficiently leverage its investments and infrastructure to produce successful innovation output. The ratio inspects the balance, or lack of it in innovation ecosystem in a region.

INDIA INNOVATION INDEX: RESULTS

A state level study

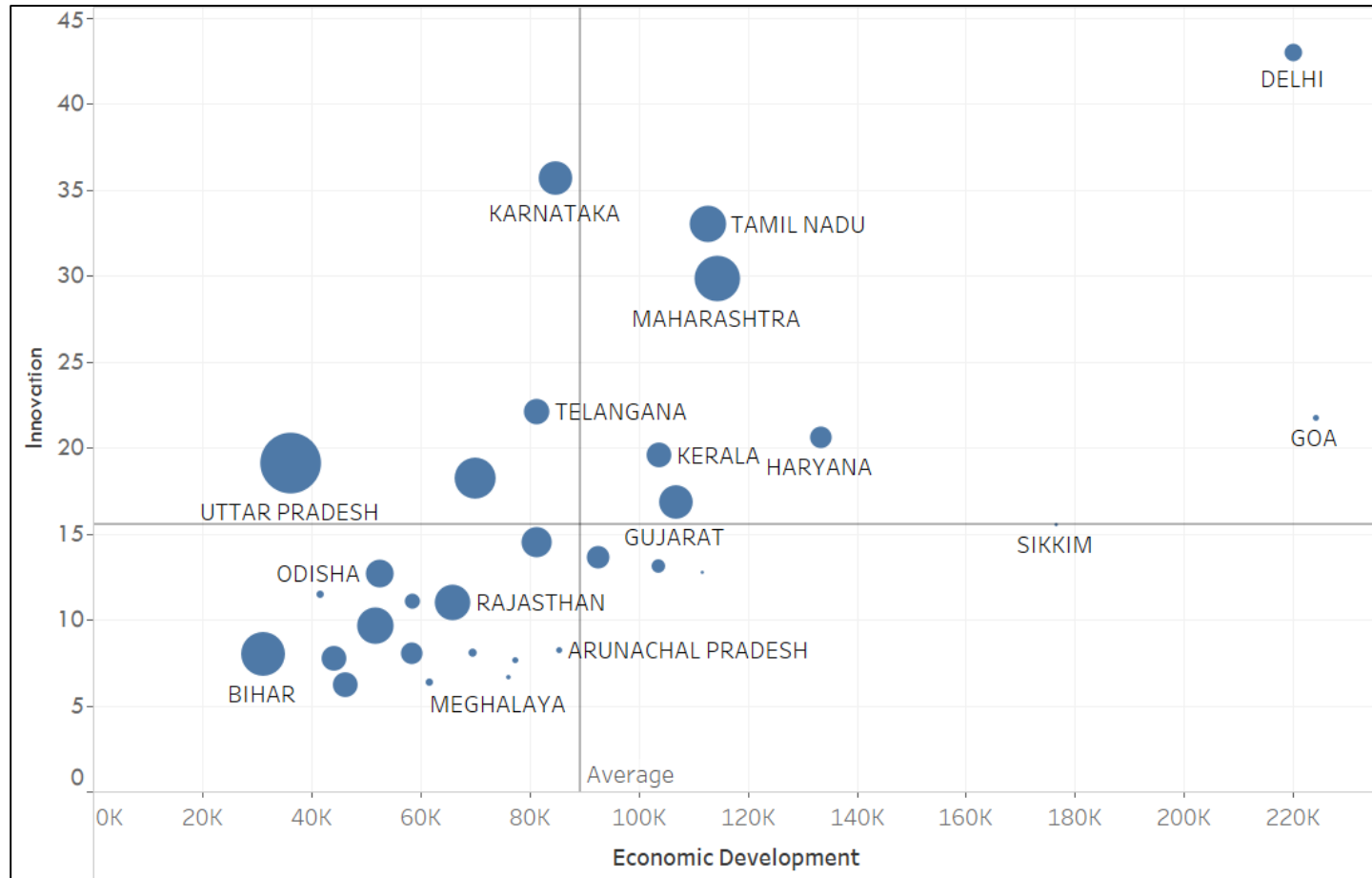


The states show variation across innovation scores with scores ranging from 42.9 to 6.2. Karnataka, Delhi, Tamil Nadu and Maharashtra are the best performing states.



Significant Improvement: Tamil Nadu, Telangana, Maharashtra and Goa
Lagging Behind: Sikkim, Meghalaya, Lakshadweep

INNOVATION AND ECONOMIC DEVELOPMENT



Economic Development is measured by per capita GDP

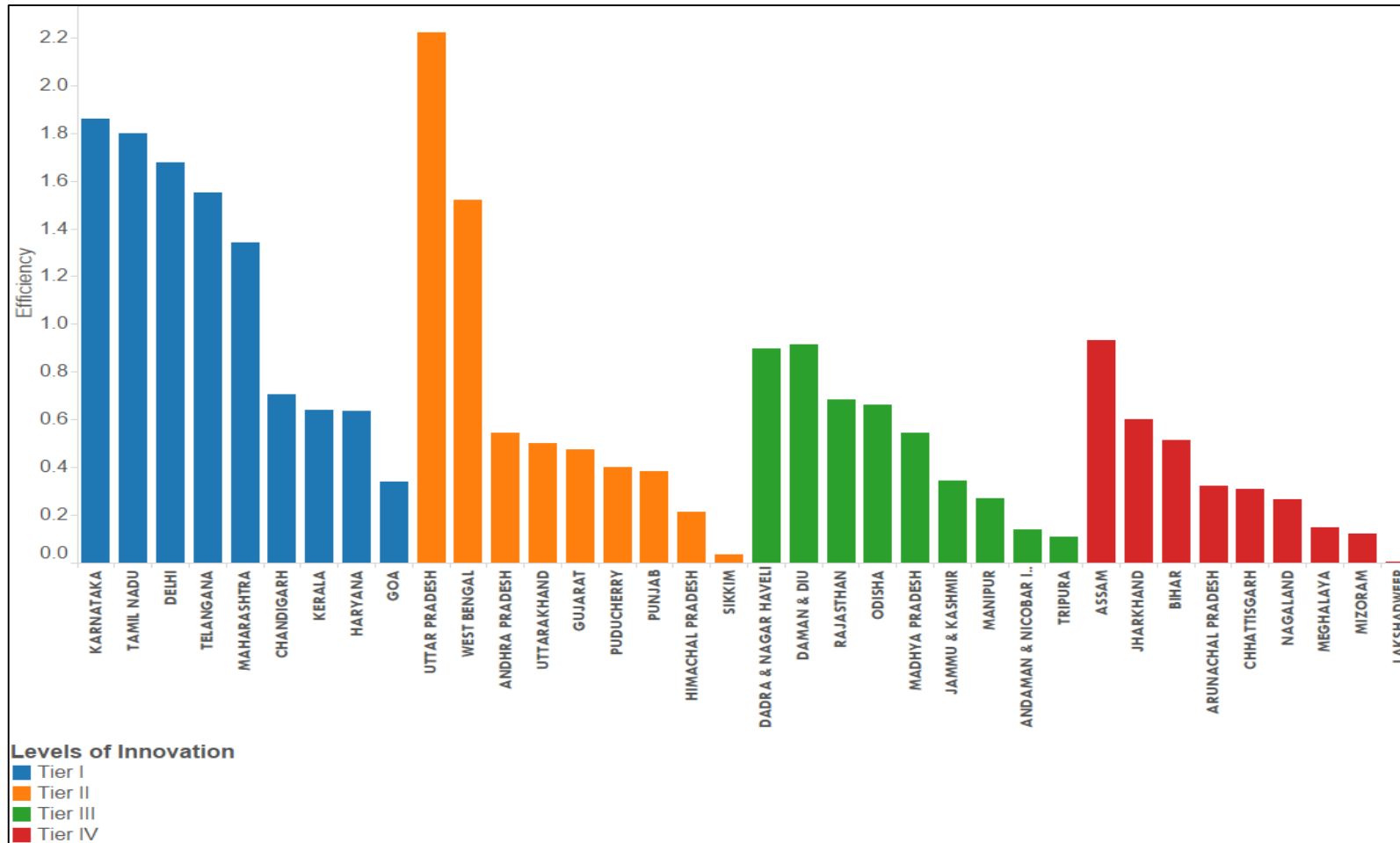
The link between innovation and growth is almost intuitive. A sustained economic growth is driven by growth in productivity of the factors involved in production.

Productivity in turn, arises from constant innovation that helps infuse efficiency into the production process.

A general upward trend between innovation and growth is apparent.

- The first quadrant carries states that have higher income than the national average and are also highly innovative. Delhi, Tamil Nadu, Maharashtra, Goa, Haryana, Kerala and Gujarat fall into this category.
- The second quadrant is an interesting category as it consists of states which have income lower than the national average but are more innovative than the average state.
- The states in the third quadrant need to work the most as their incomes are lower than the national average and are less innovative than the average Indian state as well. A majority of the states fall in this quadrant.
- The fourth quadrant, which consists of states that are richer than the national average but are not as innovative, comprises of only three states (Sikkim, Punjab and Uttarakhand) and one Union Territory (Andaman & Nicobar Islands).

INDIA INNOVATION: EFFICIENCY



- This graph examines the states' efficiency in leveraging its inputs for outputs.
- Karnataka, Tamil Nadu, Delhi, Telangana, Maharashtra, Uttar Pradesh and West Bengal are the most efficient states in the country with efficiency ratio above 1.

RECOMMENDATIONS

