KBITS

GOVERNMENT OF KARNATAKA

PRIMARY RESEARCH BASED PROFILING OF

BIOTECH SECTOR IN KARNATAKA

MESSAGE

India led by Karnataka has taken the lead in adoption of biotechnology as a sector with its strong emphasis on R&D, introduction of biotech products and also provision of biotech services. In the recent times the growth has been rapid owing to the vibrant ecosystem being created for entrepreneurship. Several thousand start ups have mushroomed across sectors- thanks to our Government's multi-sector start up policy- the first of its kind in India. Owing to State Government's strong support in creation of infrastructure, nurturing human resources required for the industry and enabling networking across sectors for convergence and collaboration, there has been an exciting environment to find solutions to societal challenges.

In view of the importance to keep track of the growth of the sector for identification of gaps and for strengthening of the domains required for innovation, a survey is highly useful. This is the essence of the document prepared by ABLE-CMR titled "Primary Research Based Profiling of Biotech Sector in Karnataka". The survey will help all who wish to seek collaboration in R&D institutions, set up start ups across the state and identify talent required. It must be noted that a task such as this will undoubtedly have gaps and it can only improve based on feedback from all stake holders.

I thank all who took part in the survey by ABLE-CMR, the members of the VGBT & other experts; members of the various academic institutions; startup companies and KBITS, Department of IT BT and S&T and who have been instrumental in providing input for this report.

17/11/17
BENGALURU, KARNATAKA

(PRIYANK KHARGE)
Hon'ble Minister
IT BT and TOURISM

PREAMBLE

India as a country is large in size equivalent to a continent, highly populous with close to 1.3 billion humans and billions of animals, highly diverse in culture, rich in natural diversity and growing at a vibrant rate of over 7% GDP in the face of several challenges it continues to encounter. But for the challenges seen in the sectors of Agriculture (Food, Feed, Fodder and Fiber), Nutrition, Health (infectious and lifestyle), Energy (non renewable and renewable) and Environment pitched against rapidly dwindling resources, the country would have easily reached a double-digit growth rate. A common relief thread that can actually stitch solutions to mitigate many of the challenges mentioned above lies in the area of Biotechnology. With this realization, the country led by Karnataka state is rapidly evolving in both organic and inorganic manner various measures to find answers.

Karnataka is progressing with path breaking activities in Academia, Industry and Start Up segments, with over 50% of India's 400 plus biotech companies based at Bengaluru and other cities of the State. Supported by various institutions of national and international stature, national and multinational biotech companies, and a highly proactive government (Karnataka State was the first one to create a separate ministry and department to embrace both Information Technology and Biotechnology domains), the Biotech Sector is pacing forward at a steady growth rate of around 20% CAGR.

In view of this, it is imperative to ensure there is a common accessible information resource of the various happenings in the Biotech Sector. With this objective, the Department of IT & BT supported by the Ministry of IT, BT & Tourism embarked upon commissioning a survey for profiling of the various activities in Academia, Industry and Start Ups in the Biotech Sector.

The Association of Biotech Led Enterprises (ABLE), a not-for-profit pan-India forum and a thirteen-year-old organization founded in Bengaluru, representing the Indian Biotechnology Sector,was identified as the most suitable entity to carry out a real-time survey of the activities in the Biotechnology space in Karnataka. The resulting document would then provide a window of opportunity to the government to identify gaps and work out solutions, be they may be in policy formulation, creation of infrastructure, nurturing of human resource, strengthening of networks for collaboration and so on.

ABLE in turn has identified a professional organization, CMR (CyberMedia Research) that specializes in primary market research, consulting and advisory services, with a track record of working with Government and Industry in the BT

and IT domains. The work of ABLE – CMR has resulted in detailed profiling of the Biotech Sector in Karnataka with help from academic institutions, established as well as start-up biotech companies and biotech experts.

The survey research findings reaffirm the leadership position of Karnataka in biotechnology. The biotech ecosystem in Karnataka comprises ~294 large, medium and small companies, including biotech startups. Building on its success stories in the biotech industry, Karnataka has emerged as India's biotech and medtech startup-hub, with ~65 biotech startups operating in Bengaluru, in domains ranging from BioAgri to BioPharma, BioServices to BioIndustrial, from MedTech to BioInformatics. 84% of the surveyed startups attributed the support of government funding for starting-up. KBITS is further fuelling the startup culture through dedicated startup funds. The culture for Intellectual Property (IP) and innovation in academic and research institutions is on the rise. 84% of the academic and research institutions in Karnataka have established Intellectual Property Cells, while 54% have established dedicated biotech startup cells/entrepreneurship cells.

It should be noted that a report of this nature could never be exhaustive and up to the minute in view of the dynamic nature of the sector and ever-changing global scenarios influencing all corners of the globe including Karnataka. A survey is only as good as the last spent minute before printing and must be taken in this spirit but must readily offer suggestions for continuous improvement.

The Department of IT & BT, Government of Karnataka compliments ABLE – CMR team ably supported by the officials of Karnataka Biotechnology and Information Technology Services (KBITS), Members of VGBT (Vision Group on Biotechnology) and colleagues in the BT sector.

Mr. Gaurav Gupta, IAS
Principal Secretary,
Department of IT, BT and S&T
Government of Karnataka, Bengaluru

ACKNOWLEDGMENTS

ABLE and CMR would like to express their sincere gratitude and appreciation to the stakeholders who provided their insights and suggestions during the course of this study. We sincerely thank all the stakeholders from industry (including ABLE membership), startups and academia, who responded to the survey and supported us with follow-on conversations, despite their busy schedules. The survey and the interactions gave us insights and perspectives that have helped shape this report.

Special thanks are due to the Karnataka Biotechnology and Information Technology Services (KBITS) for commissioning this important study to map and profile the biotechnology sector in the State. The senior leadership at KBITS, including, Ms. V. Manjula, IAS, Principal Secretary, KBITS; Ms. Tanushree Deb Barma, IAS, Managing Director, KBITS; and Dr. Jagadish Mittur, Head - Biotechnology Facilitation Cell (BFC) and team (Mr. Suchit Vasu and Ms. J M Rekha) at KBITS, supported us with their critical inputs, and guidance during the course of this study.

We would also like to place on record our sincere thanks to the ABLE leadership, including Ms. Kiran Mazumdar-Shaw, Hon. Non Executive Chairman ABLE, and Dr P.M. Murali, Hon. President, ABLE, for their constant encouragement and support.

During the preparation of this report, we received detailed and constructive feedback from several eminent biotech experts. We wish to express our grateful thanks and appreciation for the invaluable feedback received from the members of VGBT, in particular, Prof. G. Padmanabhan, Emeritus Professor, IISc; members of EGAB, in particular, Dr T.M. Manjunath; Dr Satya Prakash Dash, Head-Strategy, Partnerships, Entrepreneurship Development (SPED), BIRAC; Dr Anand Anandkumar, CEO, Bugworks Research Inc.; Mr G.S. Krishnan, Regional President, Novozymes South Asia; and, Dr Paul Kariath, Managing Director, Biotree. This report has benefited from their interest, enthusiasm, and their intellectual input.

Lastly, we would also like to place on record, our sincere thanks and appreciation to all the anonymous peer-reviewers for their in-depth comments, and helpful suggestions on the report.

Karnataka has taken immense strides in shaping the biotech industry of India, and is now replicating its success in the biotech startup sector. We are confident, and truly excited about the future of biotechnology in India and in particular, Karnataka.

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GM– Innovation and
Government Advisory,
CMR

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EXECUTIVE SUMMARY

The world's population is growing rapidly, with nearly all the growth coming from the developing world, where agricultural productivity is relatively low. By 2050, the world's population will be over nine billion. In particular, the current trajectory of population and economic growth in India and China requires new sustainable solutions to combat hunger and eradicate poverty, improve maternal health, to address climate and environmental issues, and more efficient environment-friendly means of manufacturing goods.

The deficit between available food supply and demand requires new imagination, and especially new tools to dramatically improve the quality of life.

Biotechnology delivers the technological tools and solutions that will help the world in addressing the grand challenges facing humanity – food, nutrition, health, energy, industry, environment, and livelihood security.

From new vaccines against emerging diseases and epidemics, to genetically modified and genetically engineered crops with great potential to increase productivity under different environmental pressures, and from developing environmentally friendly biofuels, to medical devices to solve India's unmet healthcare challenges – biotechnology is a powerful tool that will propel India and the world towards socio-economic progress.

Karnataka, the Biotech Capital of India, is home to one of the earliest and most thriving biotech ecosystems in India.

The biotech ecosystem in Karnataka comprises the biotech industry, including a large array of biotechnology enterprises, including large companies and mid-sized ones. Alongside the industry, is an array of new, promising biotech start-ups. The support for industry and startups comes from the strong biotech research base in Karnataka, comprising of many nationally and internationally renowned biotechnology research Institutions.

Driving the future growth of the biotech sector in the State is a proactive Government of Karnataka policy that was one of the first to foresee the potential of biotechnology, and came out with a slew of well-timed policies, offering incentives and concessions to stakeholders. In 2016, Karnataka announced the Startup Policy.

The Karnataka Biotechnology and Information Technology Services (KBITS), Government of Karnataka, commissioned a study "Primary Research-Based Profiling of Biotech Sector in Karnataka" to assist KBITS- Department of IT BT and S&T, Government of Karnataka, with a real-time indication of the status of the sector in order to suggest and implement changes to help further growth of the sector.

Towards this end, this study involved reaching out to three different sets of stakeholders – industry, startups and academia, each of whom, play a vital role in fueling biotech innovation in the State. The purpose was to get a stakeholder perspective on the key drivers, challenges, and opportunities in the segments they

operate in. In Karnataka, the biotech industry is spread across Bengaluru, Tumkuru, Mysore, Hubli – Dharwad, Mangalore, Manipal and other districts.

INDUSTRY

The Indian biotech industry commands 5% share of the global biotech industry, comprising of about 800 companies, and is valued at US$ 19Bgrowing at 25%[1]. The Government of India has to invest US$5Bwith intent to develop human capital, research infrastructure and biotech research initiatives to realize the vision of aUS$ 100B industry by 2025.[2]

The biotech industry comprises of five major segments: BioPharma, BioAgriculture, BioServices, BioIndustrial, and BioInformatics.

Biopharma is the largest sector contributing about 64% of the total revenue followed by Bioservices (18%), Bioagri (14%), Bioindustrial (3%), and Bioinformatics contributing (1 %).

On the back of increased domestic consumption, intensive R&D activities, fuelled by strong government policies, the Biotech Industry has grown over the last decade at 15%. The export market is the focus of the Biotech Industry that account for 50% of their revenues. This marks their clear focus on global markets.

The broad drivers for doing business for biotech enterprises in Karnataka include a conducive biotech hub- home to major biotech companies, good research infrastructure, and proactive Government Policy, including incentives.

Biotech companies operating in Karnataka perceive policy guidelines, and problems stemming from a stressed city infrastructure in Bengaluru, and ease of business. Despite the presence of world-class research institutions, Karnataka may be losing its advantage due to the lack of sufficient industry-academia interactions. The top five challenges facing industry include the following:

INDUSTRY: TOP CHALLENGES

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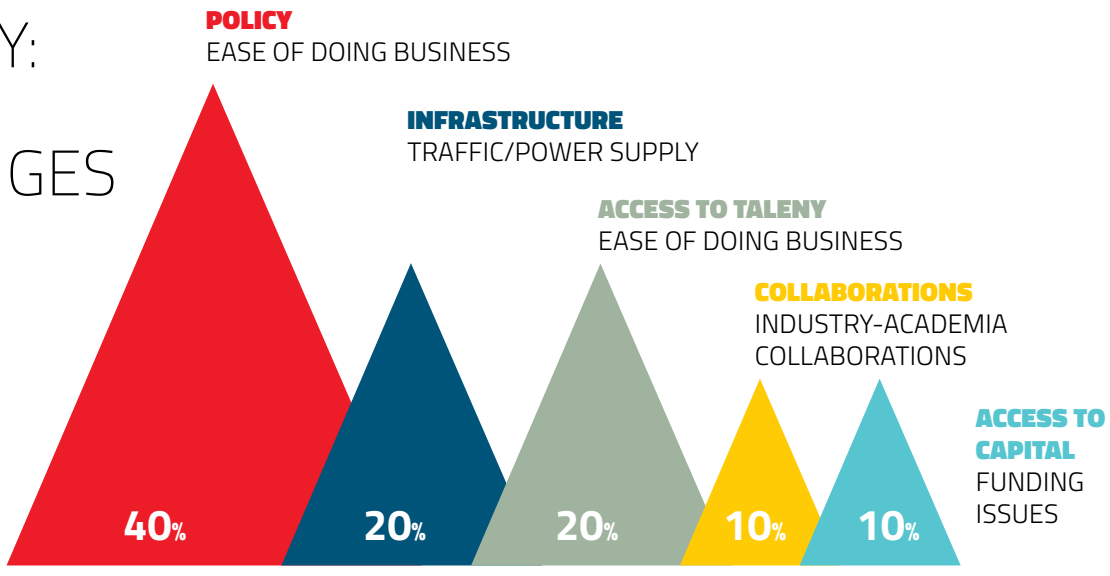

STARTUPS

The startup ecosystem is marked by the creation, growth and eventual success, or failure of new startups that aim to solve a specific problem area.

It is important to note that there are major differences between the world of tech startups, in general, and biotech startups.

In contrast to the tech startup world, where the rate of funding and formation of new companies has exploded over the past few years on the back of digital technologies, the biotech startup world represents a universe marked by incredible demand for funding, and the relative lack of venture capital available. The reason being that biotech sector is capital intensive. In the case of BioPharma startups, the risk of failure is high at several stages, across a long R&D timeline, comprising of basic research, preclinical, Phase I, II, and III, and market entry. For startups operating in the Medical Devices and BioServices segment, the time to market is relatively easier.

High-risk innovation requires risk funding, and Government will continue to have a major role as a facilitator. After the meltdown of ecommerce and food startups, there is a renewed interest in the investor community in resolving grand challenges of healthcare. 2016 marks the year when the biotech startup industry is an inflection point, with interest from VCs and PEs.

From a policy perspective, the Government of Karnataka has been spearheading new policy incentives and concessions to support the startup sector through dedicated funds, and making available biotech infrastructure for such startups.

STARTUPS: FUNDING SOURCES

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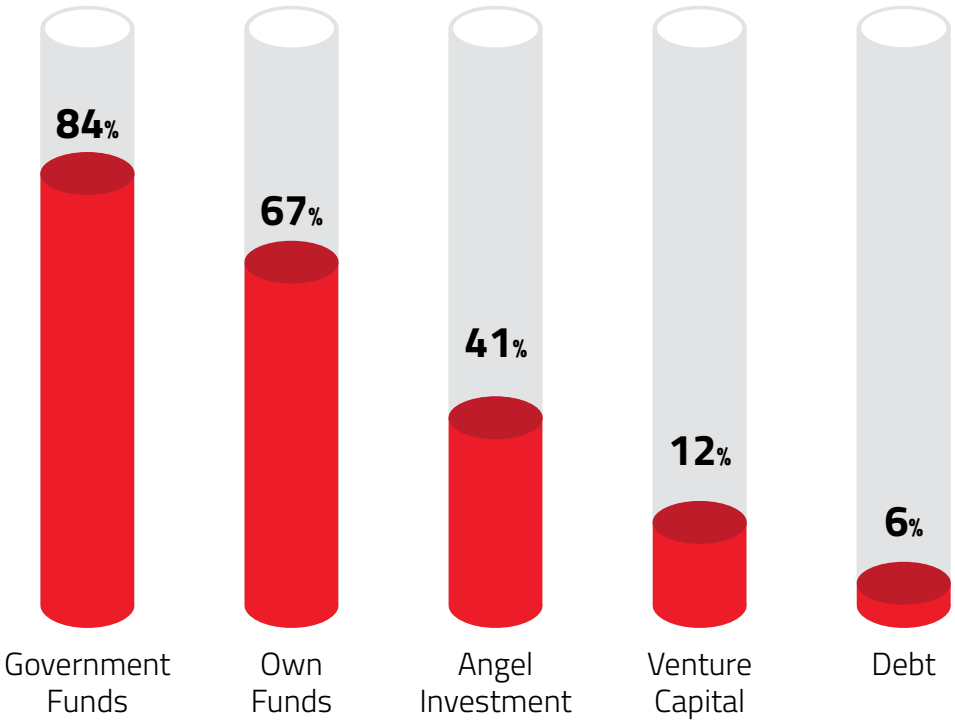


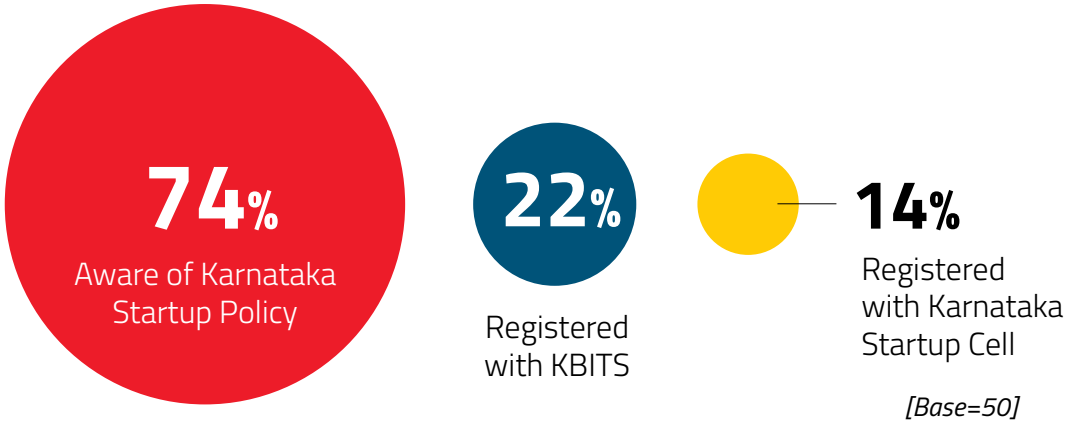
In Karnataka, entrepreneurs have started-up new biotech ventures, aided by Government funding, and dipping into their personal funds.

Typically, these entrepreneurs have come from varied backgrounds: Some have relocated to India after a PhD, or post-doctoral stint abroad; while others include seasoned scientists, who left their stable jobs in industry; and some others, fresh from university. One common thread that defines the startup community is the drive to solve critical challenges in India. These entrepreneurs are driven by possibilities, and have made the leap, by capitalizing on the strong industry and academia ecosystem in Karnataka. Despite of teething challenges, pertaining to funding and talent, they persist with their product development. Typically, such biotech startups employ <10 full-time employees, and are housed at incubators across the State. In addition to translational research, they are also contributing to capacity building.

There are more than 65 biotech startups operating in Bengaluru. It is important to note that some of these startups work at the intersection of general technology and biotech, and as such, cannot be slotted into one of the legacy biotech segments. One of the hottest technology areas is MedTech, which attracts entrepreneurs with its shorter gestation period, and clear path and time to market. MedTech signifies the convergence of Engineering, IT and Biotech, and involves development of medical devices or solutions that tackle some of the unmet challenges facing India. Beyond MedTech, there are startups working in technical domains, ranging from BioAgri to BioIndustrial, from BioPharma to Bioinformatics.

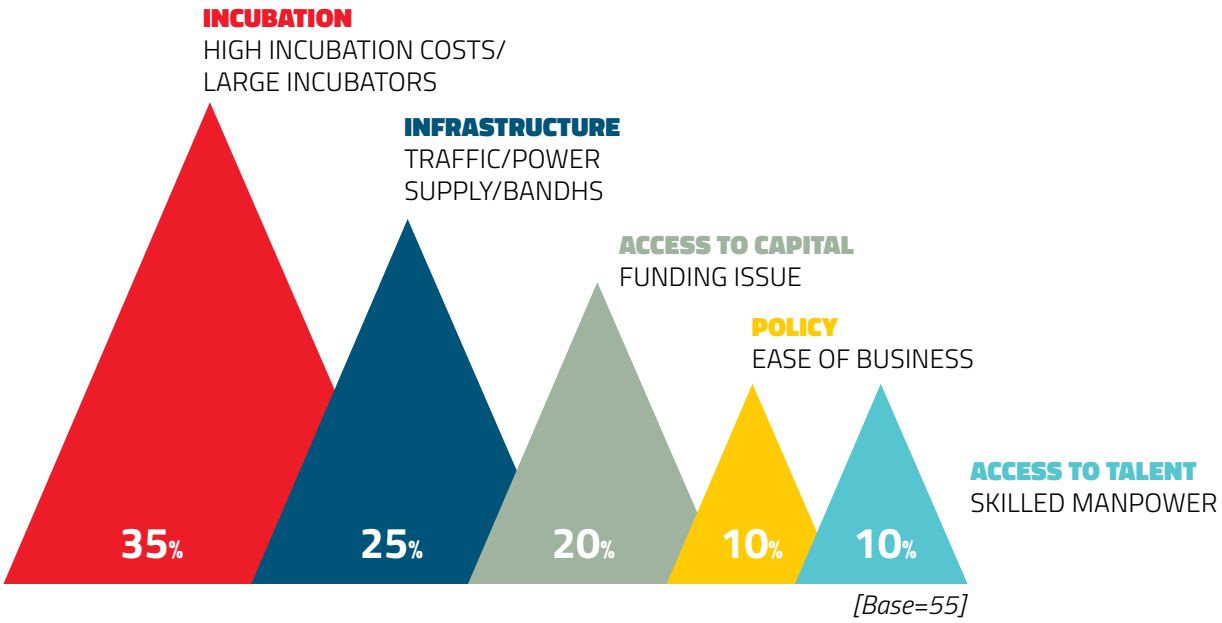
The awareness of KBITS and Karnataka Startup Policy is high. According to the KBITS Biotech Survey, there are a good percentage of startups that have either registered, or considering registration with the KBITS and the Startup Cell.

STARTUP AWARENESS ON KBITS AND KARNATAKA STARTUP CELL



Karnataka has a network of good early-stage incubators, including Bangalore Bioinnovation Centre (BBC); Centre for Cellular And Molecular Platforms (C-CAMP); Indian Institute of Science-Society for Innovation and Development (IISc-SID); International Centre for Innovation, Technology Transfer and Entrepreneurship (IN-CITE) Technology Business Incubator (TBI); Central Food Technological Research Incubator (CFTRI); and Agri Incubator Dharwad. However, they need to further strengthen the requisite infrastructure for startups to grow and become mid-sized biotech companies.

STARTUP: TOP CHALLENGES



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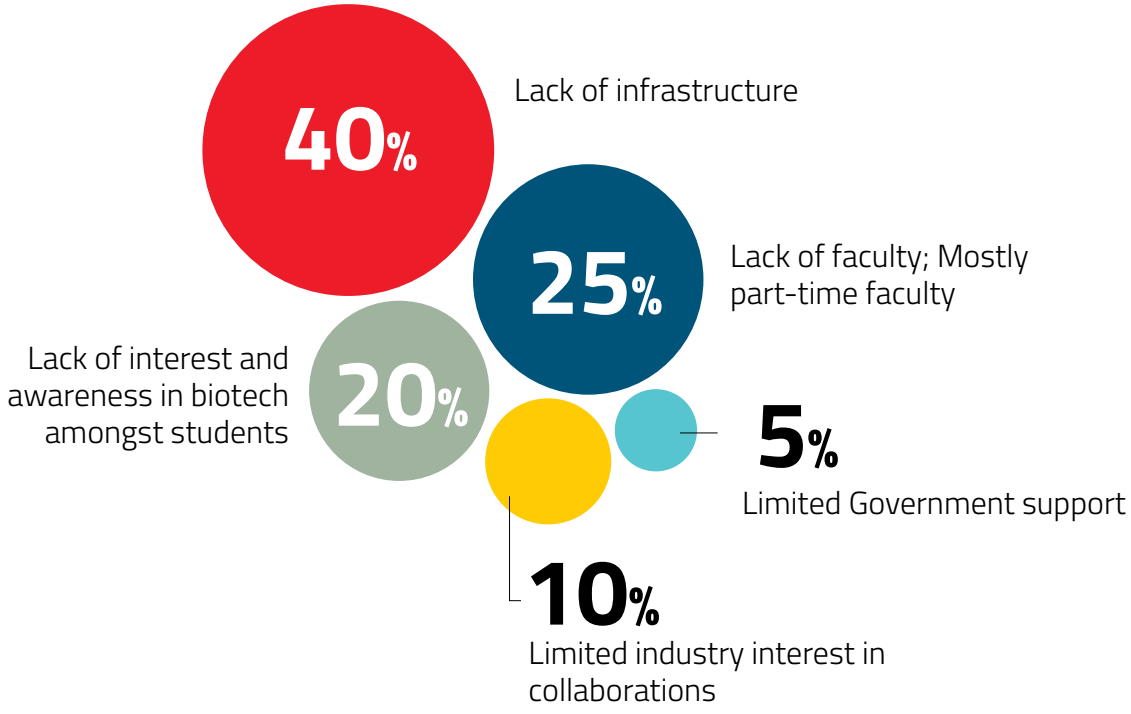
ACADEMIA

The Academia plays a critical role in supporting the growth of the biotech sector with supply of new quality skill-sets that are industry-ready and technology-aware. Karnataka is home to internationally renowned Centres of Research Excellence, such as Indian Institute of Science (IISc), Centre for Human Genetics (CHG), National Center for Biological Sciences (NCBS), University of Agricultural Sciences (UAS)/ University of Horticultural Sciences (UHS), Institute for Bioinformatics and Applied Biotechnology (IBAB), Institute for Agriculture Biotechnology (IABT), and Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR) that encourage industry collaborations. A few institutions have developed incubation units in their campuses, and allow faculty to startup, or partner with others to startup. In addition, these research centres also engage in collaborations with industry on translational research initiatives.

When one looks beyond these Centres of Excellence, a different story emerges. The ecosystem is marked by institutions that continue to supply talent to the industry with skill-sets that are no longer in demand. The syllabus has not kept pace with the changing technology trends. There has been a decline in the biotech enrolments at the UG and PG Level. Coupled with that, the faculties at such institutions are relatively less exposed to new technological advancements. In addition, the low pay-scales means that most of the staff at such institutions work part-time, and are unable to do justice to the changing needs. The infrastructure required for supporting biotech research at such institutions needs to be augmented.

CHALLENGES FOR ACADEMIA



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In conclusion, for India to achieve its target of $100B by 2025, it is important that that each of the stakeholders in the biotech ecosystem perform at their optimal level. Towards that goal, KBITS and its proactive policy initiatives would continue to play a critical role. In particular, KBITS should play a major role in enabling stronger industry-academia collaborations.

This survey report brings to you glimpses of how the biotech ecosystem is evolving, and the challenges and opportunities that mark the road ahead.

02

THE BIOTECH INDUSTRY

THE BIG PICTURE

INTRODUCTION

The world's population is growing rapidly, with nearly all the growth coming from the developing world, where agricultural productivity is relatively low. By 2050, the world's population will be over nine billion. The deficit between available food supply and demand is growing.

In particular, the current trajectory of population and economic growth in India and China requires new sustainable solutions to combat hunger and eradicate poverty, improve maternal health, to address climate and environmental issues, and deliver more efficient environment-friendly means of manufacturing goods.

India is facing new healthcare challenges arising from the emergence of new threats, ranging from the rise of antimicrobial resistance, to uncontrolled spread of diabetes and other lifestyle diseases, to emerging and re-emerging infectious diseases, for instance, Chikungunya and dengue.

For facing upto, and delivering on the grand challenges facing humanity, there is a need for new imagination, and especially new tools to dramatically improve the quality of life.

Biotechnology delivers the technological tools and solutions that will help the world in addressing the grand challenges facing humanity – food, nutrition, health, energy, industry, environment, and livelihood security.

From new vaccines against emerging diseases and epidemics, to genetically modified and genetically engineered crops with great potential to increase productivity under different environmental pressures, and from developing environmentally friendly biofuels, to medical devices to solve India's unmet healthcare challenges – biotechnology is a powerful tool that will propel India and the world towards socio-economic progress.

KARNATAKA: DELIVERING ON BIOTECH'S PROMISE

As a hotbed for biotech innovations, the biotech sector in Karnataka has shown an unequaled potential and limitless possibility in leading India in reaping the benefits of biotechnology.

The biotech sector in Karnataka has taken the lead in development and introduction of successful biotech products as well as services. For instance, some of the success stories in healthcare, agriculture and development that the State has contributed to include the following:

In Agriculture, the biotech sector has been consistently striving and delivering on new enhanced crop production technologies: through new hybrid, high yielding, insect and drought resistant crop varieties as well as creation of hybrids utilizing transgenic technologies; also through biocides and biofertilizers. Going up the agricultural innovation value chain, there is sectoral focus on the large-scale cultivation of seaweeds to develop biofuels, plant stimulants and animal feeds among others.

In responding to the Healthcare challenges, the biotech sector has been at the forefront of development of new innovative, targeted and personalized platforms and personalized disease treatment therapies; and to the first indigenous ELISA kits for the detection of HIV infection, Hepatitis C, and Japanese encephalitis; to development of portable, hand-held eye-screening device for common eye diseases; and microfluidics-based devices and diagnostics for different applications. In addition, the biotech sector supports research and development through first-in-class collaborative drug discovery services, from Hit generation, transformation of hits to leads, and lead optimization leading to development of drug candidates against known disease targets.

In responding to the challenges arising from ever-increasing Industrial pollution and waste management, the biotech sector has led to the development of new industrial enzymes that improve the efficiency of the effluent treatment process by convert complex compounds in industrial effluent into simpler forms; to the development of new processes to capture methane, largely from waste, into everyday products, ranging from plastic cups to high performance polymers such as stents and sutures.

Over the past five decades, three exciting phases have defined the scientific progress in biotechnology: The first phase was marked by revolutionary advancements in molecular and cellular biology that enabled understanding of cells and developments. Advances in genomics marked the second phase that enabled mapping of entire genome of an organism, and thus, identify the genetic foundations of many diseases. The third phase is marked by the convergence of scientific research, combining molecular and cellular biology with genomics, deploying fundamentally different conceptual approaches from engineering and physical sciences.[3]

Today, Karnataka is home to many exciting startups that are operating at the convergence of science and engineering to solve major healthcare challenges.

KEY BIOTECH SECTORS

There are five broad sub-sectors that encompass biotechnology: BioAgri, BioPharma, BioIndustrial, BioServices and BioInformatics sectors. Beyond these, and especially amongst startups, the focus is on MedTech that leverages engineering and biotech skill-sets.

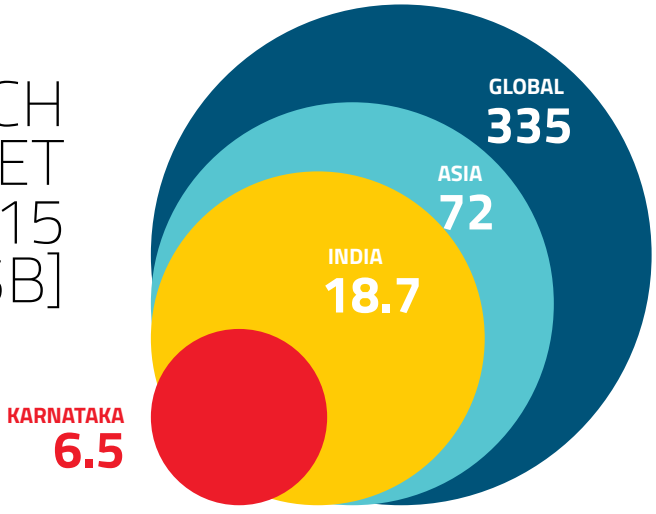
BIOTECHNOLOGY: KEY SEGMENTS

BioAgri	BioPesticides, BioFertiilzers, Hybrid Crops, Tissue Culture, Transgenics, Molecular Breeding
BioPharma	Vaccines, Therapeutics, Diagnostics
BioIndustrial	BioFuels, Enzymes, Nutraceuticals
BioServices	Clinical Trial Services, Custom Manufacturing, Custom Research
BioInformatics	Software & Database Services, Data Analysis
MedTech	Healthcare, BioPharma, Medical Devices

THE GLOBAL BIOTECH MARKET SIZE

An ever changing regulatory and risk environment, marked with economic uncertainties, and with an ever-increasing focus on delivering innovation and affordability to the demanding consumer, are some of the key trends that underpin

BIOTECH MARKET SIZE IN 2015 [IN US$B]



Note: The above estimates are limited to the biotechnology sector only. These estimates are in line with the ABLE's recent estimates of India's BioEconomy. ABLE estimates the Indian BioEconomy to be at US$35B, with BioPharma contributing US$18.9B, BioAgri contributing US$9.0B, BioInformatics (US$4.4B), BioIndustrial (US$1.9B), and BioServices (US$0.9B).[5]

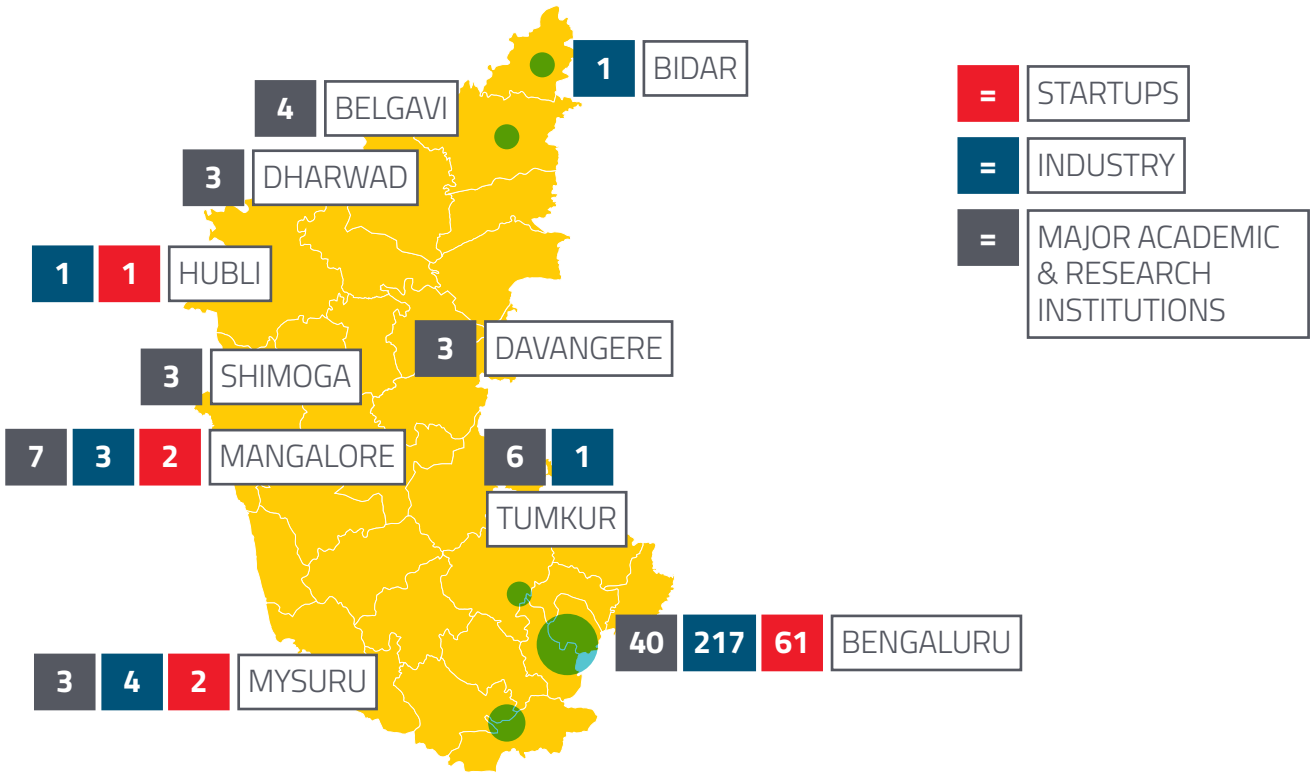
the global biotechnology market today.[4] Revenues for the biotechnology industry have grown over the past five years and global investments in biotechnology have increased consistently.

The global market for Biotechnology in 2015 is estimated by ABLE-CMR to be at US $335B, growing annually at a compounded annual growth rate (CAGR) of 11%.[6] Beyond the global markets of EU, and US, the growth in biotechnology sector is most prominent in Asia. With a biotech market size of US$ 72B, Asia is growing at a CAGR of 15%.[7]

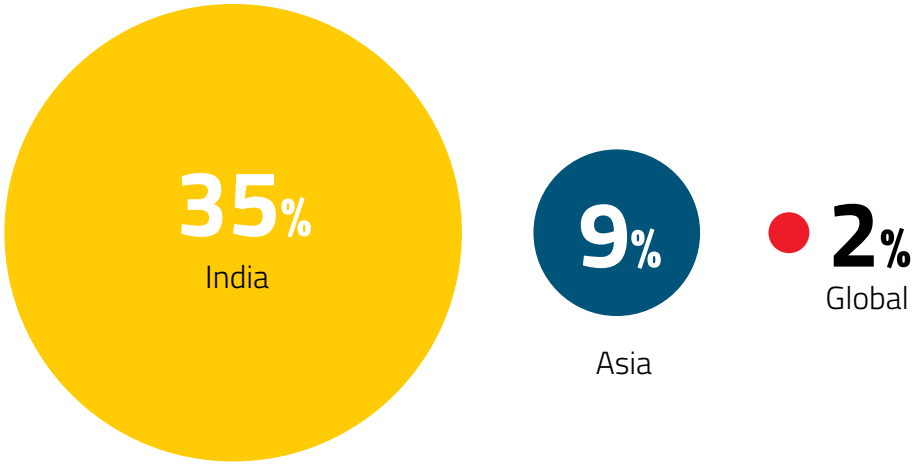
Within Asia, India is ranked second to China. With 17% of the world's population with increasing disposable incomes, India is an attractive bet for biotechnology industry.

The Indian Biotechnology Sector is showing strong growth potential, and is expected to develop further as an innovative manufacturing hub. The Indian biotech industry holds about 5% share of the global biotech industry, and is valued at US$ 18.7Bwith a CAGR of 25%. As the hub of biotechnology in India, Karnataka is growing at an impressive 35% CAGR, with a market size of US$ 6.5B.[8]

KARNATAKA BIOTECH MAP



KARNATAKA'S PIE OF THE BIOTECH MARKET 2015



KARNATAKA'S PIE OF THE BIOTECH MARKET

The biotech industry in Karnataka, comprising about 228 companies and about 65 biotech startups, holds about 2% market share of the global biotech industry.[9]

The major hubs for Biotechnology include Bengaluru, Mysuru, Hubli - Dharwad, Tumkur, and Mangalore, with new potential hubs under development, across the State.

The biotech industry in Karnataka has a 9% market share in Asia, while in India, it commands a impressive 35% market share.[10]

Karnataka is the preferred destination for biopharma and bioservices industry, especially, clinical trials, contract research and manufacturing activities. Karnataka is also strong on bioagri, medical devices and bioinformatics. Going forward, Karnataka will continue to develop its lead, and increase its market share in Asia and globally. Towards this end, the Government needs to continue developing its strong policy focus and policy implementation, with new emphasis on Medical Technology (MT), and especially on creation of large lab infrastructure, ecosystem linkages and access to capital.

POSITIONING KARNATAKA: REGIONAL AND GLOBAL BENCHMARKS

Given Karnataka's healthy pie of India's overall biotech market size, its imperative to identify benchmarks at the regional and global level for its future growth. Identifying and understanding the best practices adopted by other biotech nations to script their biotech success story will help Karnataka in its next phase of biotech growth story.

SO, WHAT CONSTITUTES A SUCCESSFUL BIOTECH NATION?

A thriving biotech ecosystem is one that is home to major academic research institutions; public and private biotech companies; has a network of incubation centres and bio-manufacturing facilities; provides access to funding through government grants or venture capital firms, and has good ecosystem linkage, providing access to service providers, mentors and human capital.

A successful biotech ecosystem is an example of an agglomeration economy. For instance, as one of the earliest biotech ecosystems in India, Karnataka is able

POSITIONING KARNATKA: REGIONAL AND INTERNATIONAL BENCHMARK

to attract new biotech market entrants - including established firms as well as new startup ventures. By co-locating in Karnataka, new market entrants able to leverage the supply channels – research institutions, industry, human capital, good infrastructure, and good regional and international connectivity. Hence, it is no surprise that Karnataka is known as the Biotech Hub of India.

When evaluating successful biotechnology ecosystems globally, the role of Government as facilitator and enabler stands out. Nations have built their biotech success stories through focused policy initiatives that spotted the biotech opportunity early and leveraged it. Here are some of the key success stories of a few countries that Karnataka needs to look at:

ISRAEL

Given that Karnataka is home to an early breed of medical technology platform and solution startups, Israel provides the right reference point for its future growth.

Israel is known as the Medical Device hub of the world, being home to more than 700 medical device outfits.[11] Israel is the world leader in medical device patents

per capita. The business environment is conducive, and this is seen in the many new R&D Centers that have been established by large medtech multinational companies. In Israel, one out of every three scientists is into life sciences, and medtech—the world's highest per capita ratio. It is because universities have been preparing tomorrow's human capital for careers in research and development.

The Israeli Government played a key role in developing Israel by spotting the biotech, especially medtech opportunity early, and acting on it. The Government invested on large biotech incubators, providing newly returned entrepreneurs with ready infrastructure, capital and tax incentives. In the last decade, the Israeli Government invested US $100M annually in the sector. This is a very high investment in a nation of only 8M people. The venture capital community in Israel is also active, providing funding support for medtech companies.

Lastly, in addition to a very sustainable biotech ecosystem, the regulatory framework in Israel is transparent, predictable and responsive.

SINGAPORE

Singapore is perceived as the best reference point in Asia for new healthcare and healthIT innovations. In Singapore, the business, research and policy environment provide the right market conditions for interactions and collaborations between all ecosystem stakeholders.

The policymakers realized the potential for emerging technology areas within biotechnology quite early, and acted on it. For instance, government and industry together develop and implement manpower initiatives in Singapore. The Sectoral Manpower Development Fund (SMDP)[12] for the Biologics Manufacturing industry is a good model for talent development. The SMDP collaborates with a variety of organization, and has the active support of industry. The Government has also taken the lead to support in awareness creation and capacity building through seminars and focused workshops, on themes such as regulatory pathways.

SAN FRANCISCO BAY AREA AND BOSTON

The San Francisco Bay and Boston have the largest concentration of biotech activity in the world, employing about 50,000 people in the biotech sector.[13] Both biotech clusters are seeing rapid growth in their established broad-based biotech industry segments. The focus in Boston is skewed towards pharmaceutical and BioPharma drug discovery, while it is more broad-based in the Bay Area. Both biotech clusters attract almost half of all the biotech investment made by US in biotech, and are the major drivers for global biotechnology innovation.

The Boston-area biotech hub[14] is among the largest and densest in the world, with 120 large and small biomedical companies based in a 1.5km radius, and supported by an ecosystem of academics, biosuppliers, venture capitalists, patent lawyers and other stakeholders.

The proximity of world class leading institutions such as MIT, Harvard University and others in the Boston Biotech Cluster is its greatest competitive advantage. In addition, the infrastructure for new biotech innovation is strong. For instance, one of the new projects is LabCentral,[15] a first-of-its-kind shared laboratory space designed as a launchpad for high-potential life-sciences and biotech startups, was built using State funding as well as Private Sector sponsorship from large pharmaceutical firms.

The Bay Area and Boston biotech clusters are successful owing to many leading research institutions, strong human capital, deep pool of venture capital, and a strong entrepreneurial start-up culture.

Even from a biotech startup innovation perspective, Bengaluru should be benchmarked against medical device hubs, such as Tel Aviv; biopharma, bioservices,

BENCHMARKING BENGALURU ON THE BIOTECH WORLD MAP

	BLR	SIN	BOS	TLV	SFO
PERFORMANCE	10	11	3	6	1
FUNDING	16	9	3	5	1
MARKET REACH	20	9	7	13	1
TALENT	17	20	12	3	1

MNote; BLR; Bengaluru; SIN; Singapore; BOS; Boston; TLV; Tel Aviv; SFO; San Fransisco

Source: The Global Startup Ecosystem Ranking 2015

and medical devices hub, such as Singapore, Boston and San Francisco.

All these cities have good connectivity, and a great entrepreneurial activity. The Government of Karnataka and KBITS can facilitate the biotech startup culture to boom, by following the examples of other major hubs, and investing strongly in efficient infrastructure, in ensuring greater interactions and collaborations between academia and industry stakeholders, and ensuring access to business mentorship for early stage startups.

SUMMARY

In summary, for Karnataka's next phase of biotech growth, speed and scale of government initiatives and most importantly implementation will be key.

By zoning key areas for biotech research and development, clarifying geography and land use decisions, Karnataka can encourage the development of large-scale, specialized biotech incubation units and attract new talent with seed

funding initiatives. Zoning land in advance for biotech would lead to more cross-collaboration between ecosystem stakeholders.

One of the challenges highlighted by the bioindustrial stakeholders in the KBITS Biotech Survey pertains to the conflicts arising from mushrooming residential areas near biotech zones, due to lack of awareness and misconceptions about "pollution". This must be addressed.

When new enterprises find a predictable and positive policy environment, they tend to stay in the region. Over a period of time, other ecosystem stakeholders start setting-up base in the ecosystem, and strengthen the research, business and financial expertise layers that mark any successful biotech ecosystem.

Building upon its biotech knowledge base, Karnataka, through its new Biotech Policy, can focus efforts on supporting new pilot plant and manufacturing facilities in the State for it to grow as a manufacturing hub.

GOVERNMENT OUTLOOK

Increasing investments, outsourcing activities, exports and the government's focus on the Biotech sector are driving Biotechnology in India.

Biotechnology in India is also benefitting from an increased emphasis on translational research that builds upon India's strengths of a vast pool of scientists, and an excellent network of national research labs.

Government is driving collaborations between industry and academia through its specialized industry-oriented arm, and supporting new ventures with funding, mentorship, guidance and infrastructure support.[16]

Some of the key policy initiatives undertaken by the Government of India include the following:

CENTRAL GOVERNMENT

NATIONAL BIOTECHNOLOGY DEVELOPMENT STRATEGY 2015-2020:

The National Biotechnology Development Strategy 2015-2020[17] was launched on December 30, 2015. The Strategy intends to establish India as a world class bio manufacturing hub by:

- Providing impetus to utilizing the knowledge and tools to the advantage of Humanity
- Launching a major well directed mission backed with significant investment for generation of new Biotech Products
- Establishing a strong Infrastructure for R&D and Commercialization, including 5 new biotech clusters, 40 Biotech incubators, 150 TTOs, and 20 Bio-connect centres.
- Creating India as a world class Bio-manufacturing Hub

NATIONAL INTELLECTUAL PROPERTY RIGHTS POLICY 2016

India's National IPR policy[18] was released in May 2016 with an aim to create awareness about IPRs as a marketable financial asset, promote innovation and entrepreneurship, while protecting public interest.

- Creating public awareness about the economic, social and cultural benefits of IPRs among all sections of society.
- Facilitating and enabling environment for creation of new IP, by leveraging and encouraging the vast scientific and technological talent pool.
- Modernizing and strengthen service-oriented IPR administration.
- Encouraging entrepreneurship, for building ecosystem linkages, for enabling Indian companies to commercialize their IP.
- Strengthening the enforcement and adjudicatory mechanisms for combating IPR infringements.
- Increasing the talent pool for skilled IP experts to facilitate the generation of new IPR assets and for commercializing them for development purposes.

NATIONAL STARTUP POLICY 2016

Startup India[19] is a flagship initiative of the Government of India, intended to build a strong eco-system for nurturing innovation and Startups in the country that will drive sustainable economic growth and generate large-scale employment opportunities. The Government through this initiative aims to empower Startups to grow through innovation and design.

KARNATAKA

KARNATAKA STARTUP POLICY 2016

The policy[20] aims to create a world-class startup ecosystem in the state through strategic investment and policy interventions leveraging the robust innovation climate in Bangalore by

- Stimulating the growth of 20000 technology based startups including 6000 product startups by 2020 in Karnataka;
- Achieving creation of 6 lakh direct and 12 lakh indirect new employments in the sector;
- Mobilizing INR 2000 Cr funding for investment in startups through Government intervention alone, by leveraging the Fund of Funds proposed to be put in place by the State Government.

BIOTECH SECTOR IN KARNATAKA

Karnataka was the first Indian State to bring out a policy for the Biotechnology industry in 2001. Subsequently, it also introduced the Millennium Biotech Policy II, a revised policy, in 2009, to build upon the achievements of the 2001 policy. This

policy encouraged the establishment of Biotechnology finishing schools across the State.

The Government of Karnataka s committed towards creating a supportive environment by enabling infrastructure, skill development and network opportunities through a holistic policy framework. The third version of the Biotech Policy will be ready soon. Industry Stakeholders in the KBITS Survey clearly indicated that the Biotech Policy in Karnataka is one of the best policies formulated in India. However, as per stakeholders, there have been some challenges in the actual, on-ground policy implementation. According to some industry stakeholders, the benefits from the policy have been hard to avail. However, there is continued optimism and confidence in the proactive policy initiatives of Karnataka.

SWOT ANALYSIS
KARNATAKA AS A BIOTECH HUB

- Earliest and most thriving biotech ecosystem.
- Excellent Research Base, with networks of centers of research eccellence.
- Strong Human Capital.
- Proactive BT policy environment.

- Infrastructure and funding constraints for mature startups to scale-up.
- Lack of networking platforms for biotech startups, except BangaloreBio.

- Growing recognition of R&D capabilities from Karnataka.
- Increasing base of medical devices and solutions startups, working in the confluence of IT, BT and MT.
- Increased focus on agricultural and other biotechnology segments.

- Intense competition for biotech investments at international and regional level.

BUSINESS ENVIRONMENT

A successful business environment is a combination of all the internal and external factors in the ecosystem – clients, competition, technology and policy that enablethe business operations of the industry.

Karnataka is one of the top five States in India having business investment potential, as ranked by the NCAER's State Investment Potential Index (N-SIPI 21) on five key parameters, namely, as being factor driven (labor), efficiency-driven (infrastructure), growth driven (economic climate; and political stability and governance), and perceptions driven (responses to the surveys).[21]

KARNATAKA VS OTHER STATES

As a first mover in the biotech sector, Karnataka has been able to leverage its strengths – location, talent, and infrastructure, to attract the best biotech companies and startups to set base in the State. Karnataka provides a unique thriving biotech environment because of the various elements that make the biotech ecosystem. However, it is prudent to note that new biotech entrepreneurs set-up operations in Karnataka due to a variety of reasons, going beyond the Government initiatives. Most biotech entrepreneurs in Karnataka originate from, or did their higher education in the State. This explains why they decided to set shop in Karnataka. While Karnataka is the leader in biotech sector, other Indian states are also stepping-up and aggressively chasing biotech investments.

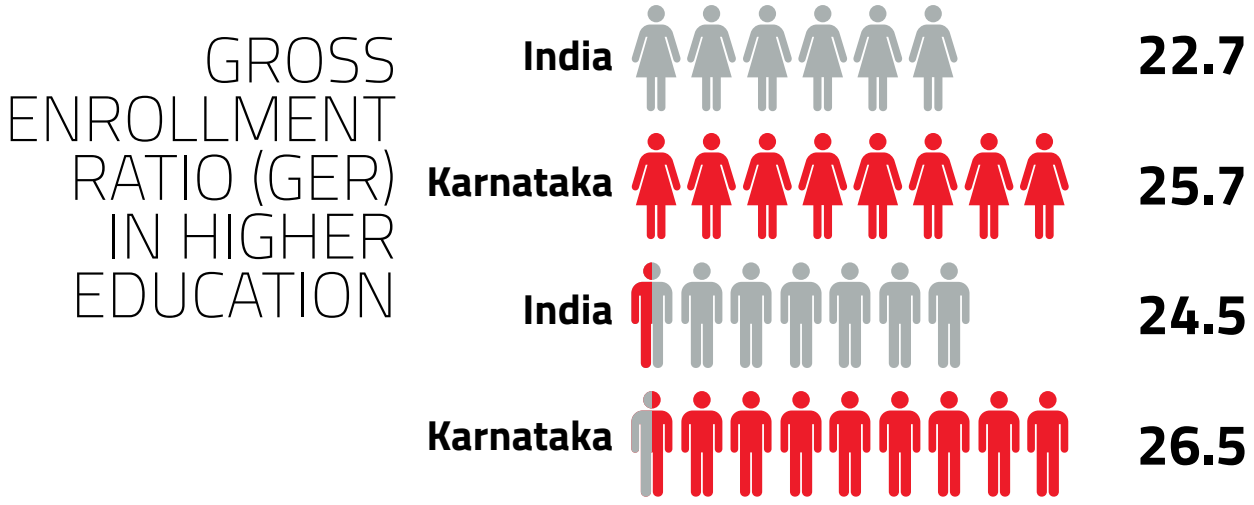
Here are the various parameters that define Karnataka, and assess its competition:

1.LOCATION

Karnataka is easily and well connected with the rest of India and most of the world. Bengaluru and Mysore continue to attract new biotech talent from outside the State, due to the locational advantage. Bengaluru has over the years emerged as the city of choice, and has constantly been rated high in the Mercer Quality of Living Survey.[22]

2. RESEARCH INFRASTRUCTURE

Karnataka has several higher education institutions and centres of excellence that support as well as fuel new biotech R&D. The vibrant biotech ecosystem in Bengaluru, over the years, has grown to provide the right setting for new biotech startup innovation, as well as for established companies. These research institutions enable research specialization across biotech domains.



Karnataka has a higher Gross Enrollment Ratio (GER) than the national average in Higher Education in the age group of 18-23.[23]

3. TALENT

Karnataka provides easy access to talent and mentorship. The industry participants in the KBITS Survey indicated that it is easier for new biotech talent to consider shifting to a cosmopolitan city, such as Bengaluru, rather than considering a move to other research hubs, such as Pune.

4. BIOTECH PARKS AND INCUBATION INFRASTRUCTURE

Karnataka is home to the newly established Bangalore BioInnovation Center (BBC), located within Bangalore Helix Biotechnology Park at Electronic City. In addition, the DBT-supported C-CAMP, and other sector-specific incubators being set up by KBITS in Karnataka, such as CFTRI Technology Incubator, and UAS Dharwad Agri Incubator, provide the right environment for new investment.

Emerging challenges for Karnataka include the stiff competition from other Indian States to attract biotech investment. For instance, Andhra Pradesh is setting-up a 200 acre, advanced medical devices manufacturing park in Vishakapatnam, that will have dedicated research and development as well as incubator centre.[24] In addition, Andhra Pradesh is also contemplating Food Parks in all its districts[25], and four incubation centres across the State.[26]

Telengana is in the process of setting-up a 12,500 acre "Pharma City" near Hyderabad.[27]

5. GOVERNMENT POLICIES

Karnataka was the first to launch a focused Biotech Policy at the state level, and which has been assessed by the biotech industry participants in the KBITS Survey as one of the best in India. Other major biotech states, including Gujarat, Maharashtra, Andhra Pradesh, Kerala, Telengana, have developed, or are in the process of developing their policy frameworks for Biotechnology and are ramping-up their focus in the Sector. Some of the States have been aggressively promoting their State too, through investment facilitation cells, dedicated Startup Cells, and Innovation and Startup Policy.

EDUCATION

Karnataka was one of the first states in India to introduce vocational education at +2 stage. Recognizing the importance of vocational education, Government of Karnataka established a separate Directorate of Vocational Education (DVE) to support the vocational education.

Today, Karnataka has one of the highest gross enrollment ratios (GER), better density of institutes and a good student pupil ratio that make it the first choice for

higher education.

In the higher education arena, State Universities in Karnataka have introduced the Choice Based Credit System (CBCS) at undergraduate and post-graduate level, adopting an interdisciplinary approach to learning, and providing a greater flexibility for students with a wide range of modules available in a single campus across various disciplines.

Karnataka also introduced the Millennium Biotech Policy II, a revised policy, in 2009, to build upon the achievements of the 2001 policy. Karnataka has the support of multiple initiatives from the State Government: Institute of Bioinformatics and Applied Biotechnology (IBAB) which intends to promote education, research and entrepreneurship in bioinformatics and biotechnology, Centre for Human Genetics (CHG) to promote education, research and awareness in this area which includes rare diseases &management; and Karnataka's Biotech Finishing School(BTFS), which plans to enhance the placement opportunities for fresh graduates. The establishment and encouragement of these Biotech Finishing Schools, has been an important step to make people also aware about this sector.

RESEARCH ENVIRONMENT

A successful research environment is one that provides a platform for new innovations to emerge, and enables collaborations between various stakeholders. The research environment in Karnataka is conducive for active research collaborations involving the biotech industry and academia.

For instance, Indian Institute of Science (IISc) is a premier public institution for scientific and technological research and higher education located in Bengaluru, India. Departments and centres in the Institute are broadly assigned to two categories: science and engineering. IISc collaborates with various government organizations like DRDO, ISRO, Bharat Electronics Limited, Aeronautical Development Agency, National Aerospace Laboratories, CSIR, Department of Biotechnology (Government of India) and Department of Electronics & Information Technology (Government of India). IISc also works in collaboration with private industry and research labs. Few organizations have been incubated by Society for Innovation and Development (SID) in the campus. IISc actively promotes and supports ventures by faculty, students and alumni.

National Centre for Biological Sciences (NCBS) is a research centre specializing in biological research. It is a part of the Tata Institute of Fundamental Research (TIFR) under the Department of Atomic Energy of the Government of India. The mandate of NCBS is basic research in the frontier areas of biology. The research interests range from the study of single molecules to ecology and evolution. In addition NCBS is engaged in a number of collaborative initiatives, such as inStem and the iBio; and also helps startups to access cutting edge instrumentation and software via C-CAMP.

Karnataka is home to many other Internationally renowned research institutions includingUniversity of Agricultural Sciences (UAS); University of Horticultural Sciences (UHS); National Institute of Mental Health and Neuro Sciences (NIMHANS); Mazumdar Shaw Center for Translational Research (MSCTR); Indian Institute for Horticultural Sciences (IIHR); Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR); Central Food Technological Research Institute (CFTRI); Rajiv Gandhi University of Health Sciences; Indian Veterinary Research Institute (IVRI), IIT Dharwad and several others.

TOTAL BUILT-UP LAB-SPACE IN KARNATAKA

According to the KBITS Biotech Survey, the Biotech Industry and Startups in Karnataka occupy a built-up lab space of 4.3 M. sq.ft.

This includes the lab facilities created by biotech industry for their R&D Centres, as well as the lab incubation space offered by public and private incubators in Karnataka, including C-CAMP, BBC, IBAB, CFTRI Incubator and others.

INDUSTRY-ACADEMIA COLLABORATIONS

A majority of the biotech organizations in the KBITS Biotech Survey indicated some level of collaboration with premium research centres in the State. The Indian Institute of Science (IISc) is one of the most preferred research partners for industry-academia collaborations, followed by other centres of excellence, such as NCBS, Manipal University, and UAS, with industry collaborations ranging from consultancy to joint research projects. For instance, IISC, NCBS, are engaged in industry collaborations focused on therapeutic development, ranging from initial screening of molecules to drug synthesis.

INDUSTRY COLLABORATIONS WITH ACADEMIA

PERFERRED RESEARCH INSTITUTIONS FOR COLLABORATIONS

- Indian Institute of Science (IISc)
- Manipal University
- National Centre of Biological Sciences (NCBS)
- Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR)
- University of Agriculture, Dharwad
- IBAB

[Base=148]

61%

OF INDUSTRY RESPONDENTS HIGHLIGHTED VARIOUS LEVEL OF COLLABORATIONS WITH ACADEMIA.

While it is encouraging to see such engagements, it is important to note that there is still a lot of ground to be covered for broadening and intensifying industry-academia collaborations.

CROSS-INDUSTRY COLLABORATIONS

A healthy biotech ecosystem is one that facilitates cross-industry collaborations, breaking the traditional silos. In Karnataka, the biotech ecosystem is conducive for such collaborations between various players within the ecosystem. So, large companies depend on multiple small companies based on varied functional requirements. In addition, some of the other collaborations include links with leading hospitals.

According to the KBITS Biotech Survey, the nature of biotech outsourcing ranges from pre-clinical research and development for lead identification, pharmacological studies, active ingredient manufacturing, QA services, regulatory services, leading upto clinical trials. For instance, there are active drug discovery collaborations involving multinational organizations and contract research organizations that specialize in designing molecules against specific targets using current drug discovery tools. It is important to note that a majority of the stakeholders consider such industry collaborations as sensitive information, and refused to specify their collaborators for the KBITS Biotech Survey.

ECONOMIC IMPACT OF BIOTECH ON KARNATAKA

Karnataka is the hub of biotechnology in India, with a critical mass of biotech companies and organizations. The biotech industry in Karnataka has access to a well-qualified human capital, sound R&D infrastructure, and comprising centres of research excellence that undertake cutting-edge biotech research, and with easy global connectivity through the Kempegowda International Airport (KIA) in Bengaluru.

BIOTECH MARKET IN KARNATAKA

Karnataka contributes US$6.5B of India's biotech revenues.[28] In 2015, the biotech exports revenues of Karnataka stood at US$4.91B, while the domestic revenues accounted for US$1.63B.[29]

Amongst the biotech market segments in Karnataka, Biopharma is the largest segment, contributing 64%, followed by BioServices (19%), Bioagri (14%), bioindustrial (2%), and bioinformatics contributing (3%).[30]

A majority of the respondents in Karnataka operate as limited liability companies.

In Karnataka, the breadth and depth of biotech is very broad, and includes all the major biotech segments. The biotech industry is home to about 228 biotech companies, that include large, established companies, to small and medium companies.

KARNATAKA BIOTECH MARKET SIZE US $6.5B

US$4.91B
EXPORTS REVENUE

US$1.63B
DOMESTIC REVENUE

MARKET SEGMENTS

US $0.78B	US $4.18B	US $1.24B	US $0.13B	US $0.19B
BIOAGRI	BIOPHARMA	BIOSERVICES	BIOINDUSTRIAL	BIOINFORMATICS

Karnataka's Biotech Market Size (ABLE-CMR Estimates)

TYPE OF COMPANIES

75%
Limited Liability Company

17%
Private Limited Company

7%
Single Person Business Activity

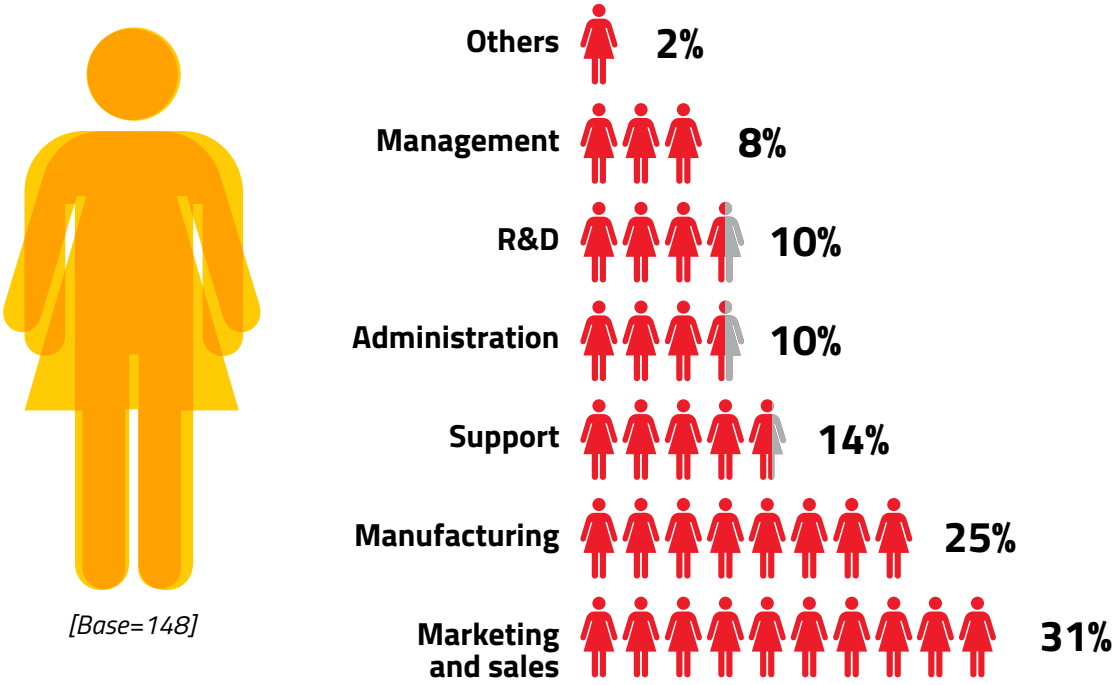
[Base=148]

1%
Joint Stock Company

There are about 65 biotech startups, and many more individual entrepreneurs. The biotech industry in Karnataka provides direct and indirect employment to an estimated 18998-plus people.[31]

In the biotech industry, the personnel perform various functional roles, including R&D, sales and marketing, manufacturing, and management and support functions,

FULL-TIME EMPLOYEES: BY FUNCTIONAL ROLES



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among others. In Biotech enterprises, the majority of full-time employees are distributed between marketing and manufacturing, and a limited number in R&D and other functions.

EMPLOYEE DIVERSITY: BY GENDER

According to the KBITS Biotech Survey 2016 findings, in the Biotech Sector, men occupy most of the positions at all levels. Women are very much underrepresented. The findings are in line with other such studies conducted in other geographies.

DIVERSITY AT THE WORKPLACE: BY GENDER

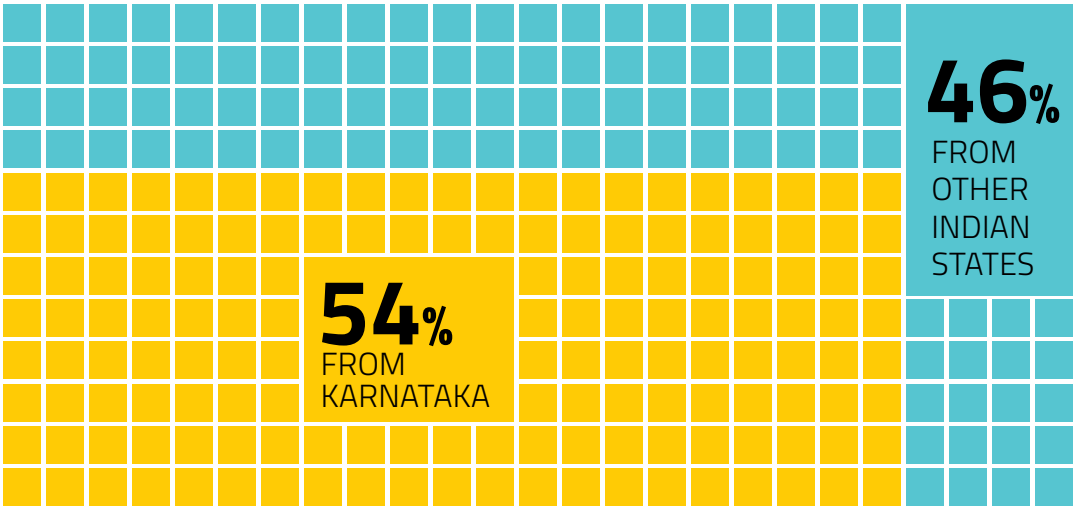
[Base=140]

In small biotech companies, the hiring procedures are unstructured and informal, with companies relying on human networks for referrals.[32]

EMPLOYEE DIVERSITY- BY GEOGRAPHY

In terms of geographic diversity, majority of the employees are from Karnataka. According to the KBITS Biotech Survey 2016 findings, there is a fair representation in the workforce of skilled professionals from other Indian States. Skilled biotech professionals prefer to relocate to Bengaluru, as compared to other locations in India. This is one reason why Bengaluru is emerging as the leading biotech startup hub too.

DIVERSITY AT THE WORKPLACE: BY ORIGIN



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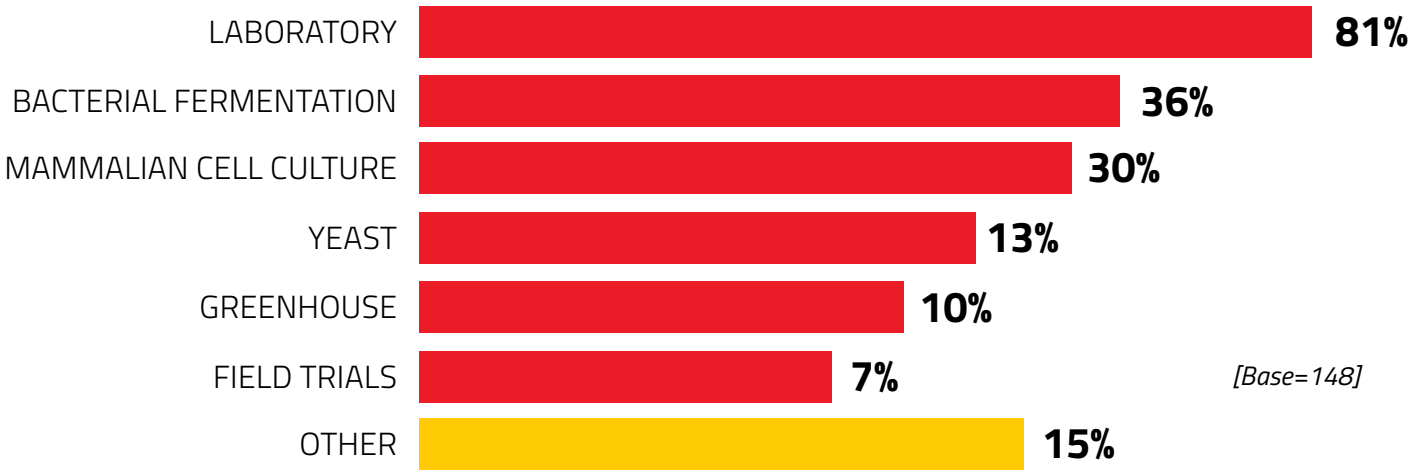
THE SCIENTIFIC TALENT BASE

Karnataka is placed second in terms of number of universities offering biotech courses at the undergraduate and post-graduate level, including engineering courses. Karnataka is home to a diverse range of specialized universities offering programs, ranging from Agricultural Biotechnology, to Biotech Engineering. At the PG Level, 80% of the colleges are offering Biotechnology programs. Every year, around 7,500 biotech graduates[33] are produced in Karnataka, graduating from top institutions including University of Agricultural Sciences (UAS), Indian Institute of Science (IISc), Manipal University, among others.

PLATFORMS/FACILITIES USED BY BIOTECH INDUSTRY

The Biotech Industry in Karnataka uses various platforms and facilities. The KBITS Biotech Survey 2016 findings indicate that the industry stakeholders from all biotech segments use the following platforms and facilities:

FACILITIES/PLATFORMS USED BY INDUSTRY



R&D AND MANUFACTURING FACILITIES IN KARNATAKA

According to the KBITS Biotech Survey 2016 findings, the Biotech Industry in Karnataka has well-established R&D facilities in the State. These R&D facilities range from 1000 to >200000 sqft. Only 6% of those surveyed indicated having an R & D facility in other Indian States, and <4% indicated having set-up an R & D facility outside India.

In terms of manufacturing facilities, 83% of the KBITS Survey respondents indicated having a manufacturing facility in Karnataka. 13% indicated having set-up a manufacturing facility in other Indian States, and <11% of the industry had manufacturing facilities internationally.[34]

R&D AND MANUFACTURING LOCATIONS

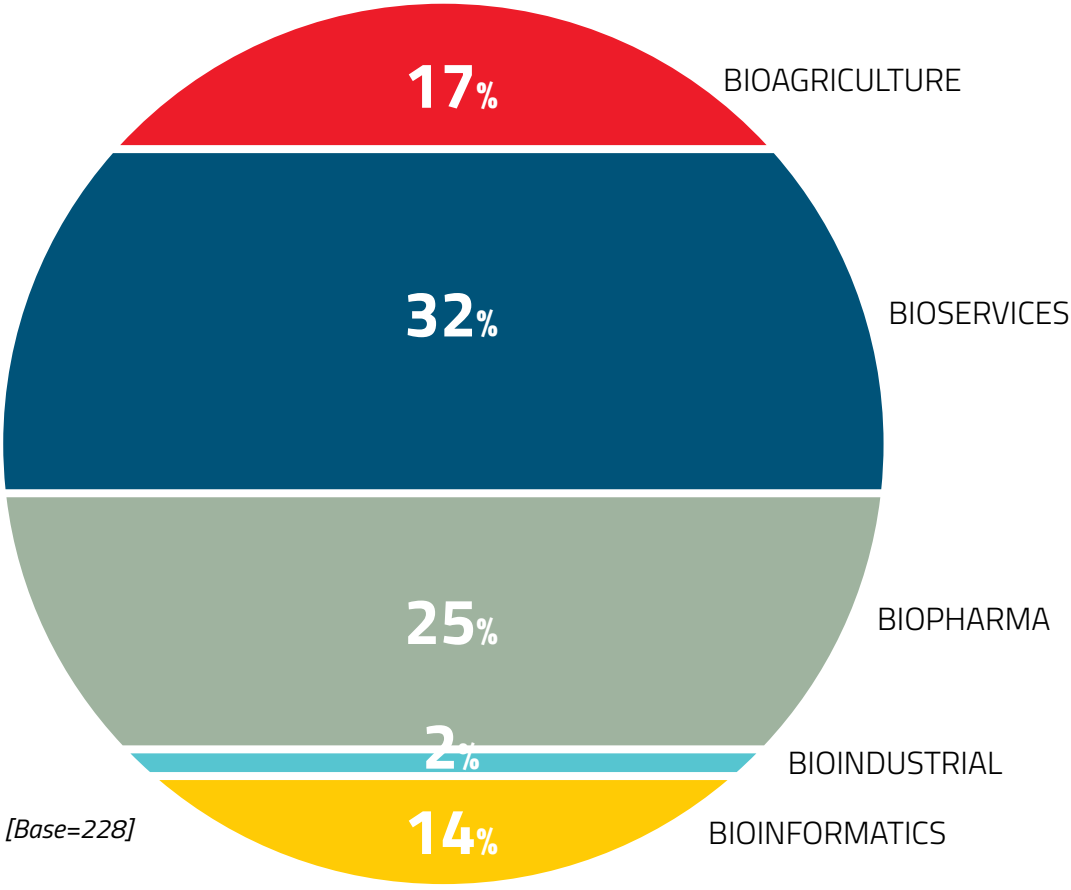
71%
Have R&D facilities in Karanatka

83%
Have manufacturing facilities in Karnataka

IP GENERATION BY BIOTECH INDUSTRY

In Karnataka, the biotech industry is more focused on generating IP at foreign Patent Offices, including the United States Patent and Trademark Office (USPTO), as compared to those at the Indian Patent Office. As per KBITS Survey findings, 1080 patents were granted overseas, as compared to 78 in India in 2015-16.

TYPE OF COMPANIES: BY SEGMENT



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INDUSTRY EXPECTATIONS FROM KBITS

One of the biggest challenges for the biotech industry in Karnataka, as per the earlier KBITS-sponsored ABLE- Biospectrum Biotech Survey 2016 findings, pertains to the uncertainties and lack of clarity on the regulatory processes and pathway. Coupled with that, there exists a perception pertaining to the challenges of government processes.

In BioAgri, the regulatory framework continues to be evolving, with uncertainties from policy perspective.

In BioPharma, the time period for new product development is the longest, with risk of the product failing to reach the market at the end of that period being very high. The lack of a clear roadmap and regulatory delays create uncertainties, leading to a financial impact on companies that are increasing their research and development (R&D) and expand product portfolio. However, the regulatory regime is undergoing change, with focus on improving transparency.[35]

In BioIndustrial, BioServices and BioInformatics segments, the regulatory uncertainties create similar challenges for the biotech industry.

From a policy perspective, industry has clear expectations from Government of India and Government of Karnataka.

In BioAgri, an unambiguous modern biotech application policy, decided on a case-to-case basis, would help in leveraging new technologies for development of agriculture.

Incentivization of biotech investments through tax-free capital gains, and policy incentives for those companies that undertake research for public good are also high on stakeholder's perspective.

Stakeholders also expect exemption from price control and preferential procurement of indigenously developed products and services by Government. Towards this end, industry believes a notification specifying 10% consideration for local companies in Government procurement would act as an incentive for growth of Biotech industry in Karnataka.

There is stakeholder expectation that the Government of Karnataka will support the set-up of Public Stem Cell Banking with international quality processing and make available of Stem Cell for common public.

Lastly, for small and medium sized companies, the expectation is for creation of large common instrumentation facilities and resources.

The expectation from KBITS is to foster capacity building and awareness workshops amongst SMEs and other stakeholders on regulatory processes. In addition, swifter approvals and clearances in Government processes would help biotech enterprises in doing business faster in the State.

With respect to human capital, all the key biotech segments face the challenges arising from shortage of industry-ready skilled workforce. The biotech graduates joining the workforce annually do not necessarily have experiential learning, and it requires a minimum of one year before they start contributing to the R&D of the company. The BTFS program of KBITS has been developing graduates with industry-ready skills, having sufficient exposure and practical experience. However, the challenge for skill development persists, and more such avenues for industry-ready skill sets should be developed.

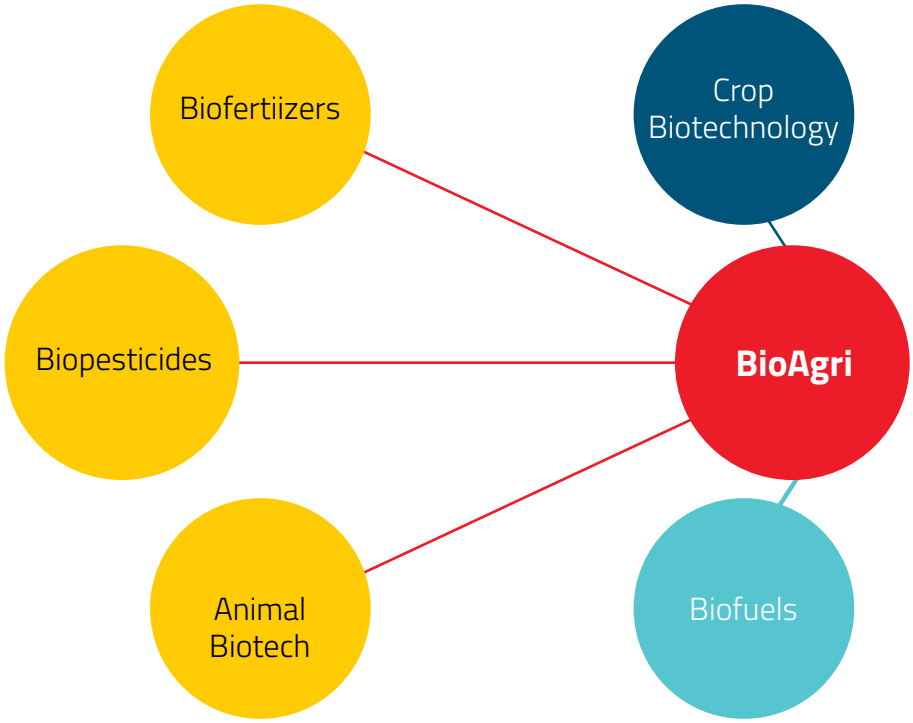
03

BIOAGRI

INTRODUCTION

Demand for food production has increased significantly due to rise in global population. This is one of the major drivers for growth in the agricultural biotechnology market. North America and South America are the leading geographic markets for agricultural biotechnology products. The market for transgenic crops occupies major share in the overall agricultural biotechnology industry, owing to rising demand for higher crop yield, and the limited availability of arable land. The global market for agricultural biotechnology is expected to grow to US$46.8 Billion by 2019 at a CAGR of 11%.

BIOAGRICULTURE: KEY SEGMENTS



According to the 2015 United Nations World Population Prospects report, India will surpass China by early next decade as the most populous country on Earth, with most number of mouths to feed. India is already classed as having a 'serious' hunger problem, according to the 2015 Global Hunger Index of the International Food Policy Research Institute. There is a danger that many of these new Indians will not have sufficient food, with deep concerns about under- and mal- nutrition.[36]

Karnataka recognized the scope of agricultural biotechnology quite early, and marked it as one of the most significant priorities in the state in its Biotech Policy.

BioAgri has a market size US$ 0.78B in Karnataka, contributing 12% of the total

biotech revenues.

Karnataka has six major soil types. Given the varied agro-climatic features, almost all cereals, pulses, oilseeds and commercial crops (fruits, vegetables, spices etc) are cultivated in different parts of the State. Many of these core crops need genetic improvement for higher productivity.

Technological advancements in DNA sequencing, genome editing, and synthetic biology are driving development of new products and applications in agriculture. The current research and development activities in transgenic research in India have led to the generation of a number of transgenic plants harboring genes of agronomic as well as quality traits, focused on increasing yield, nutrition, shelf-life, and building insect resistance. However, most of these technologies are on the shelf for lack of clarity on regulatory guidelines.

Bt Cotton is the only genetically modified crop approved in India for commercial cultivation. The success of Bt Cotton has led to the development of many new technologies for crop improvement through application of transgenic technology and marker-assisted breeding. Since 2002, 1128Bt Cotton hybrids have been developed, and adopted by 7.2 million farmers on 11.1 m.ha. area, accounting for 91% of total cotton area in the country. [37] The growth rate of Bt cotton in Karnataka has been observed to be gradually increasing since adoption, with Dharwad having the maximum growth in Bt cotton cultivation (88.65%) and Belgaum having the least growth at 8.17%.[38]

Beyond transgenics, "Precision Farming" is getting increased attention. Though one of the biggest producers of agricultural products, India has very low farm productivity. India's farm yield rates for rice and wheat —tonnes produced per hectare—is drastically lower than China and Brazil.[39]

Precision farming is a technology-based farm management system to identify, manage variability within fields for optimum profitability, analyze, protection of land resources and sustainability, is getting more attention. Precision Farming looks at management of variability of soil, water, nutrients, crop and environmental factors with the intent to expand the yield level with specific use of resources.[40]

GOVERNMENT OUTLOOK

For many years now, Indian agriculture has been driven by price incentives and input subsidies. Calling for a move from "input intensive" to "technology intensive" agriculture, there have been calls from Niti Aayog[41] and the Economic Survey 2015-2016[42] for adoption of high yielding Genetically Modified (GM) crops, citing a host of studies that have demonstrated significant net benefit of GM crops and countries such as Brazil and China have adapted to the new technologies.

The draft Biotechnology Regulatory Authority Bill (BRAI) Bill, 2013[43] was introduced in 15th Lok Sabha and was lapsed with the tenure of the same. The BRAI Bill 2013 has now been revised in line with the recent developments in

genetic engineering technologies and is expected to be reintroduced in Parliament.

With the approval from Government for field-testing of GM crops, the role of the DBT becomes more significant. DBT would encourage and support research on GM crops. To validate GM food, the DBT would establish a toxicological centre for testing toxicity, safety and biological contaminants and adulterants.

INDUSTRY OUTLOOK

MARKET DYNAMICS

There are some key trends impacting farming practices and agricultural biotechnology including precision farming (onine sensors, decision farming, yield increase etc.); new crop protection technologies (drought tolerance, disease resistance, GMO combination, nitrogen use efficiency); planting patterns (materials, feeds, food); and new farming models.[44]

DRIVERS

An ever-increasing population, growing demand for food production, coupled with shrinking arable land, is driving the growth of agricultural biotechnology. Public and private sector are developing new crop traits through industry-academia collaborations.

RESTRAINTS

While technology-based solutions for overcoming yield gaps hold promise, there are social challenges – pertaining mainly to lack of awareness. Alongside, there are fears pertaining to damage to beneficial insects and soil fertility. In addition, the mandatory requirement for No Objection Certificates from States to conduct confined field trials for GM crops has led to challenges.

It is important to continue with farmer outreach programs, leading to wider dissemination of improved seed varieties.

OPPORTUNITIES

BioAgri can be effectively employed to utilize waste or marginal lands to augment food production to meet the growing needs of population and at the same time preserving the natural resources by minimizing the use of agro-chemicals.

Some other potential areas of development include new crop irrigation systems, precision farming, new biofuels and biopesticides. Public-private partnerships offer opportunities to develop new approaches for integrated research and development and commercial supply chain-based solutions.

As Karnataka suffers from quite low yields per hectare, the scope for improved productivity in the State is substantial through the adoption of enabling technologies.

CHALLENGES

The key challenge for BioAgri is to foster innovation, promote entrepreneurship, and facilitate effective technology transfer to the end users. As new technological changes are introduced in the farm, it is essential to note that the social process of understanding and integrating new technology takes time. It is therefore essential to impart management skills at the farm level to give confidence to the farmers, and ensuring technological benefits are disseminated adequately across the farming community.

ROAD AHEAD

The agriculture sector in India is expected to generate better momentum in the next few years on the back of new Government policies, adoption of new crop technologies, and due to increased investments in agricultural infrastructure such as irrigation facilities, warehousing and cold storage. Factors such as faster adoption of technologies, reduced transaction costs and time; improved port gate management; and better fiscal incentives would contribute to the sector's growth.

R&D AND ACADEMIA OUTLOOK

Current R&D in crop biotechnology in India is focused on the biotechnology crops that can contribute to higher & more stable yields and enhanced nutrition. The current research and development activities in transgenic research in India has led to the generation of a number of transgenic plants harboring genes of agronomic as well as quality traits. In turn, the success of Bt Cotton has led to the study of transgenics in the State Agricultural Universities (SAU) and ICAR institutions, at the postgraduate and PhD levels.

Similarly, Marker-assisted selection (MAS) technology can be adopted as a complementary approach to transgenics, wherever feasible. The application of MAS technology enables scientists to select plant traits easily and faster at the seedling or even the seed stage, speeding up the breeding process.

The emerging gene-editing technology, involving precise manipulation of existing genes, is enabling crop modification for enhanced yield, and with more effective drought and disease resistance capabilities.

Going forward, the current R&D investments and funding in agricultural biotechnology research need to be scaled-up. The platforms available for bioagri entrepreneurship should be developed further, and dedicated space allocated in agricultural university campuses for new crop research.

The regulatory processes for technology development, validation and commercialization for R&D and academia should be clarified further. Capacity building workshops are required to develop awareness about the regulatory pathways, intellectual property protection and technology transfer.

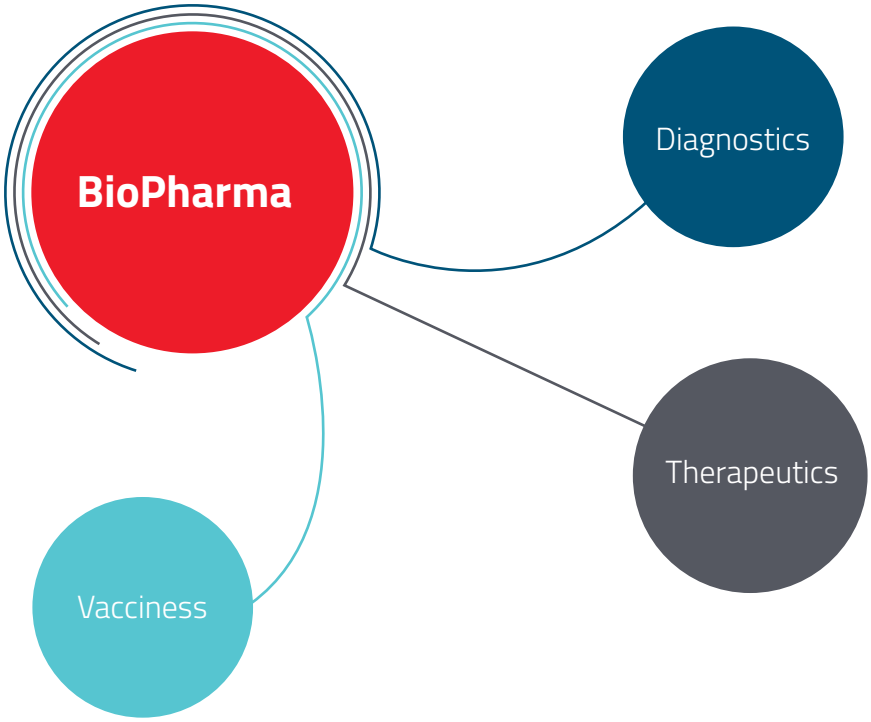
04

BIOPHARMA

INTRODUCTION

With an ever increasing burden of chronic diseases and an ageing world population, the global biopharma market is seeing rapid growth on the back of new technological innovations and supported by increasing R&D investments. The demand for specialized therapies will further fuel the growth of the biopharma segment over the long term. In an uncertain market environment marked by regulatory uncertainties and continued patent expirations, some Big Pharma companies have revamped themselves into pure-play biopharma enterprises.[45]

BIOPHARMA: KEY SEGMENTS



High burden of disease, good economic growth leading to higher disposable incomes, improvements in healthcare infrastructure and improved healthcare financing are driving growth in the domestic market.

Karnataka contributes 64% of the biopharma revenue of Karnataka totaling US$ 4.18B in 2015.[46]

GOVERNMENT OUTLOOK

The Government of India has unveiled 'Pharma Vision 2020' aimed at making India

a global leader in end-to-end drug manufacture. Approval time for new facilities has been reduced to boost investments. Many tax incentives aimed at pharmaceutical and biotech R&D and manufacturing have been provided under the aegis of the "Make in India" campaign and the 2014-15 government budget.

The new National IP Rights Policy lays the basis for necessary improvements to the system.[47] Regulatory framework needs to be streamlined, made transparent and flexible, to enable further growth of the BioPharma industry in India.

The Central Drugs Standard Control Organization (CDSCO) released the Biosimilar guidelines in 2016, which tweaks the 2012 guidelines.[48] The CDSCO also eliminated the need for repetitive pre-clinical/toxicological animal studies for drugs "already approved outside India."[49]

INDUSTRY OUTLOOK

MARKET DYNAMICS

The BioPharma industry continues to grow, aided by new technological innovations, arising from novel targeted therapeutics, new process technologies, and advances in cell line development.[50]

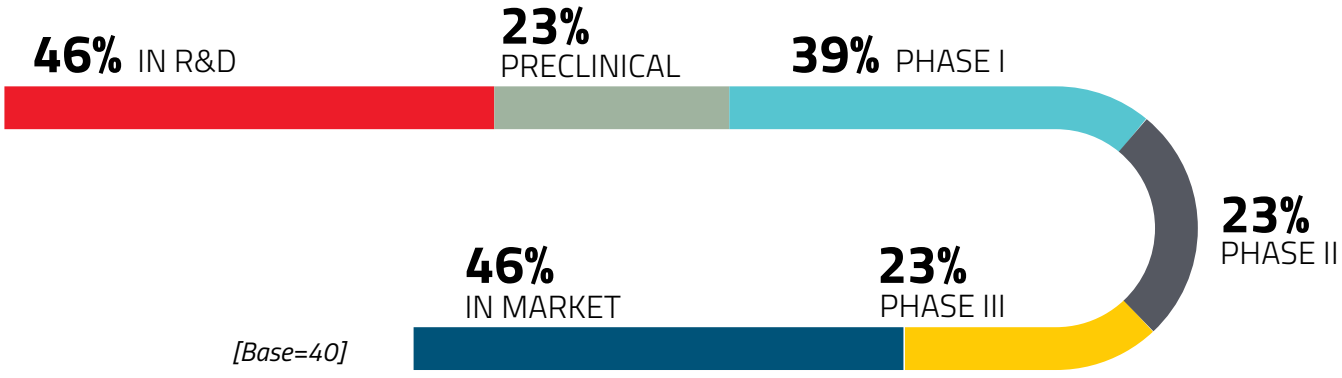
In a highly competitive market environment of therapeutics, key pre-requisite for Indian companies is attaining global quality, and key differentiator is speed and attaining first to market.

The development of new targeted and focused therapeutics has led a shift in the required manufacturing capacities, with more than 50% of the products in development requiring 5kl or smaller bioreactors.

BIOPHARMA PRODUCT PIPELINE

In terms of product pipeline, the products are spread across each of the stages, with 46% of the products in market, and an equal share of products in R&D. As per

PRODUCT DEVELOPMENT PIPELINE SNAPSHOT



the KBITS Biotech Survey findings, Biocon has 58 small molecules and 65 branded formulations in market, while it is engaged in the clinical development of MAbs and biologics (including Trastuzumab, Bevacizumab, Adalimumab)[51]; generic insulin and analogs (including rh-Insulin, Glargine, Aspart)[52], as well as novel molecules (including Insulin, Itolizumab, Fusion Proteins).[53] The survey findings further reveal that Kemwell Biopharma has two lead products in pipeline.

BIOPROCESS ENGINEERING

The biopharma production landscape is also witnessing changes with the rise of single-use technologies and continuous biomanufacturing processes. Today the BioPharma industry is looking at developing novel biomanufacturing solutions marked with low volumes, and yet to be technically able to produce the complex biologics.

Karnataka is home to the bioprocess equipment manufacturing industry that caters to the domestic biopharma industry, as well as exports a sizable portion of their products to major markets in Asia, Africa and Middle East.

As most of the equipment for biopharma industry is design built, Bengaluru with its right talent pool and enabling ecosystem comprising of chemical, mechanical, bioprocess and automation industries, has successfully emerged as a hub for bioprocess equipment manufacturing. Some of the major bioprocessing companies in Karnataka include Sartorius India, Merck Millipore, Biotree India and Biozeen.

As European and American manufacturers look for alternatives to expensive design built systems, the outlook for Indian bioprocess equipment manufacturing industry is very promising, given their increasing customer acceptance globally and their cost-effective solutions portfolio.

DRIVERS

The rise in availability, accessibility and affordability of healthcare, coupled with increased healthcare spends and extensive insurance coverage, have been the key growth drivers for BioPharma.[54]

BioPharma Companies are fostering rapid innovations, and investing in new and emerging opportunities, including new therapy areas.

RESTRAINTS

The complex, uncertain and time-consuming, regulatory pathways impede the growth of the biopharmaceuticals market. In addition, the biopharma industry suffers from the pressure arising from the high-end manufacturing requirements, coupled with the need for ensuring affordability.

OPPORTUNITIES

For both existing and new companies operating in the biopharmaceuticals segment,

the expiration of several biopharmaceutical patents represents significant market opportunities over the long-term, especially in monoclonal antibody (MAb) sector, and for those manufacturing Biosimilars.[55] Any company that is able to reduce the development costs effectively will be able to garner the market share.

CHALLENGES

The 2015 BioPharmaceutical Investment and Competitiveness Survey (BCI) found the continuance of critical gaps in IP protection in BioPharma. For innovator companies keen on participating in the India story, this hasbeen a historical challenge. Another problematic challenge is posed by enforcement, marked by drawn-out litigation and delays in getting timely remedies.[56]

While the biopharmaceuticals market has benefited from significant growth opportunities, Indian biopharmaceutical companies face challenges pertaining to the low manufacturing capacities, and including, for instance, the requirement of cold storage facilities.[57] In addition, the other key challenge pertains to availability of requisite skill-sets. For instances, companies have to suffer from high attrition rates, due to the limited supply of trained personnel in stem cells and regenerative medicine. Companies have to bear huge costs for training students with a general B.Sc. Biotech degree, as students with higher specialization are not adaptable to the needs of the industry, and lack the aptitude to develop new skills.

THE ROAD AHEAD

The BioPharma industry in Karnataka would benefit from a favorable and predictable business environment. The regulatory pathway needs to be streamlined and capacity building should be the policy focus for new BioPharma entrants. Going forward, India will ride on its success in vaccines and biosimilars to become the hub for global biologics including their development and manufacturing.

R&D AND ACADEMIA OUTLOOK

As the domestic demand for biopharmaceuticals in India continues to grow and the biopharmaceutical market expands, fueled by rising incomes and a growing middle class, Indian biopharmaceutical companies will have to scale-up their biopharmaceutical manufacturing and expertise. The growing expertise of biopharmaceutical companies to serve this domestic demand will enable them to build on their competencies, and cater more extensively to the western biopharmaceutical markets.

To compete globally, India will have to ramp up its R&D expertise in developing, manufacturing, and delivering affordable novel innovator drugs, in addition to continuing its focus on Biosimilars.

With a focus to further bolster the biopharma R&D innovation, Government needs to facilitate and scale-up industry-academia collaborations to accelerate

the pace of innovation. By focusing on establishment of early-stage translational research facilities in universities, KBITS can support academic and research institutions engaged in biopharma R&D to be better equipped to undertake and deliver on new product development.

KBITS should also scale-up its support for academic and research institutions by making available enhanced funding and mentorship. For instance, there are several academic research consortiums that are engaged in biologics and therapeutics research, the fruits of which are inaccessible to industry for further uptake. The cultural challenge for monetizing research in India needs to be surmounted.

The focus of academic and industry engagements need to be reoriented, with more stress on improving the quality, instead of increasing the scale of engagements. This would result in more fruitful outcomes for collaborative and joint research projects, IP acquisition by industry, academic and research inputs for improving regulatory frameworks, and more Greenfield consulting engagements by academic research scholars.

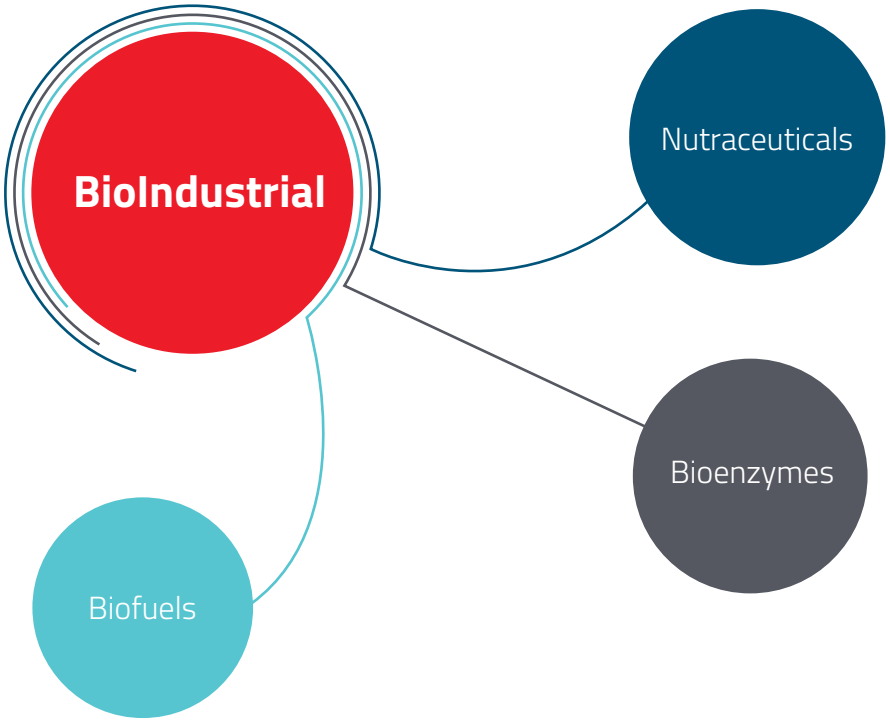
05

BIOINDUSTRIAL

INTRODUCTION

The BioIndustrial segment is growing rapidly with technological advances contributing to a rich pipeline of opportunities, including new products and newer ways to refining existing products and processes. The BioIndustrial segment holds the potential to create social and environmental advantages that combine economic growth with public good for making human lives better.

BIOINDUSTRIAL: KEY SEGMENTS



The global BioIndustrial market, according to some estimates, has already crossed US$140B. The market size for Bioindustrial segment in India is US $1.9B.65 % of the market is catered to by multinational enterprises. However, the share of domestic companies is on the rise, as these companies realize the huge potential of food enzymes. Towards this end, they are developing their R&D facilities and staff, establishing manufacturing plants, and a comprehensive distribution network. As a result, India today exports enzymes.

In Karnataka, BioIndustrial segment has a market share of US $.13B, commanding 2% of the total biotech market in the State.[58]

GOVERNMENT OUTLOOK

The Government is committed to developing India into a biomanufacturing hub. The National Biotechnology Development Strategy[59] emphasizes on bioindustrial applications. One of the key focus areas for DBT is Energy Bioscience, with emphasis on development of 2nd generation biofuels, and through establishment of a large scientist network dedicatedly working on biofuels. One of the initiatives of DBT in this domain includes development of biofuels from algae through harvesting and oil transesterification or direct conversion to bio-oil, through cost efficient, commercial scale technology.

Nutraceuticals, Herbals and Functional Foods in India are covered under the definition of food as per Section 22 of Food Safety & Standards Act (FSSAI), 2006.[60] There are no separate regulatory guidelines for approval or monitoring of nutraceuticals and functional foods in India. The regulatory regime for nutraceuticals is slowly evolving.

INDUSTRY OUTLOOK

MARKET DYNAMICS

The macro environment for Bio Industrial segment has changed from how it used to be a decade ago with consumers demanding quality products, to the industries adopting eco-friendly Biotech solutions. With growing environmental concerns globally and the Government of India's commitment on the initiatives to protect the environment, Industrial biotech segment plays a key role in shaping India's future. Today, the Government of India and the Ministry of Petroleum and Natural Gas have been driving the initiative to ensure Oil marketing companies add Ethanol to Gasoline to an extent of 10-20%,[61] which will not only reduce the dependency on imported crude, but will also enable progress towards a Bio-based economy. As part of this initiative, Oil marketing companies are setting up plants for the production of second generation (2G) ethanol (produced from non-edible agricultural residues).[62] The Industrial Enzymes play a very important role in this initiative, and have the potential to drive the industrial biotech business to an extent of two to three fold growth from today's levels.[63]

The enzyme business in the Detergent, Textile, Food, Feed and Technical industries continue to grow. With the growing middle class population and the demand for quality products, drives this segment further.

Two of the relatively younger sub-segments of the enzymes segment include pharmaceutical enzymes, and enzymes required for degradation of waste to usable products. This sub-segment is the focus of a small group of specialized manufacturers, and will take some time for growth and takeoff.

Nutraceuticals are seeing increasing demand from more conscious and health-

aware consumers who perceive that nutraceuticals can help fight inadequate nutrition, and the onset of many chronic diseases.

DRIVERS

The bioindustrial segment is seeing rapid growth, thanks to the increased demand for bioenyzmes and nutraceuticals. The increased number of technology applications drives the need for better regulatory approval mechanism to support new innovations, and support cost and resource optimization in production processes.

An increasing urban population, changing lifestyles, inadequate nutrition and increasing incidence of diabetes[64] are contributing to rise in consumption of nutraceuticals and functional foods.

RESTRAINTS

The raw materials for bioprocessing are becoming increasingly costly. Bioprocessing is still not as effective as chemical processing, resulting in high cost of bio-products. Bioprocessing that requires large amount of fresh water has had increasing concerns in many water shortage areas, or drought areas in India.[65]

OPPORTUNITIES

The industrial enzymes segment is largely export-driven and that is where most companies are focusing on. Many producers of consumer products are now committed to "green growth," which will require new enzymes and other chemical inputs, together with more sustainable production processes. If properly designed, bio-based production processes, including new bio-based inputs, can improve energy efficiency, water conservation, and, in some cases, reduce energy costs. The increased use of biomass as a feedstock for the production both of high-value, low-volume, bio-based chemicals and bioplastics and of high-value, high-volume, bulk biofuels and commodity chemicals provides new opportunities for innovation in sustainable agriculture.[66] Biotech companies are focusing on the manufacture of cellulosic enzymes that aid the production of bio-fuels. However, potential exists to explore technologies associated with bioenergy, Algae research and bioremediation. Lastly, rural India offers a vast market for those manufacturers who can demonstrate superior enzyme potential through new formulations, and differentiate their products in a nascent market.

CHALLENGES

Most fermentation processes are water-intensive, but new novel technologies exist to improve recycling. Scaling-up Bioindustrial operations is expensive, and industry is risk-averse.

Most importantly, despite the environmental and social benefits which industrial biotechnology products can bring, end beneficiaries are not adequately aware of its value proposition.

The industrial enzymes market is associated with high capital and operational costs. Investors are apprehensive about funding R&D activities, as the developed products' market performance cannot be pre-evaluated. Enzyme companies are also required to invest heavily in customer service and technical support, which puts a heavy strain on their budgets. In such a scenario, large manufacturers rule the roost, making it a challenge to maintain a healthy competitive environment.

THE ROAD AHEAD

Over the long-term, BioIndustrial segment will have a positive impact on quality of human life, both directly, (through nutrition, antibiotic replacement products, Urban & Rural waste conversion products) and indirectly, (through promotion of sustainable development).

R&D AND ACADEMIA OUTLOOK

The BioIndustrial segment offers myriad opportunities for focused translational R&D. For instance, the application of industrial enzymes can innovatively replace polluting chemical processes into eco-friendly processes that also deliver environmental sustainability. There is scope for R&D in essential and specialty chemicals that have a direct relevance in the Indian context.

To foster innovation and entrepreneurship in bioindustrial segment, there is scope to support centers of excellence for biomanufacturing to foster innovation and technology transfer through focused infrastructural facilities. There is continued government thrust for research on enzyme and protein engineering, metabolic engineering and synthetic biology; system biology, downstream processing and bioprocessing engineering, bio refinery approaches and life cycle assessment. The DBT is also supporting basic research projects on feedstock improvement and on algal biofuels (microalgae and macroalgae) Bioenergy centers would be supported for promoting commercialization of biofuels.

Ecosystem linkages connecting research and educational institutions, scientific agencies, recognized laboratories and public agencies need to be strengthened. In addition, attracting high skilled human capital for furthering public research in India is also critical.

Lastly, translational R&D would enable bioindustrial segment to respond to the grand challenges of today, pertaining to water, environmental protection, energy conservation and manufacturing sustainability.

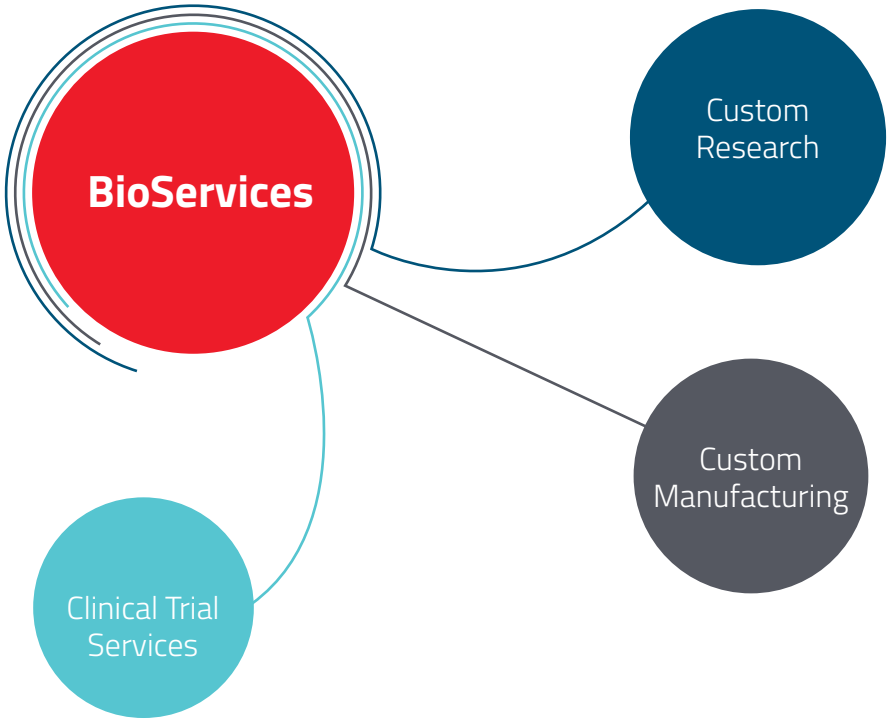
06

BIOSERVICES

INTRODUCTION

The Bioservices industry is a key segment of the global biotech industry. By 2020, the global contract research market is expected to reach $59.42 Bn. The Indian BioServices market is projected to become US$18 Bn by 2018, posting a strong growth rate of 18% - 20% during the period of 2014–18.

BIOSERVICES: KEY SEGMENTS



In Karnataka, BioServices has a market share of US $1.24B, commanding 19% of the total biotech market in the State.[67]

India has emerged as a leading destination for clinical trials, contract research and manufacturing activities owing to the growth in the bioservices sector. The demand for outsourcing clinical development, contract research in drug discovery and development and also discovery and development of other life science products, to contract research organizations (CROs) has been on the rise, thanks to the high costs associated with in-house R&D as well as the long timelines and chances of failure of clinical trials.

India is one of the world's best known low-cost manufacturing centres, with highest number of US Food and Drug Administration (FDA)-approved manufacturing plants outside the US. There are currently 10,500 manufacturing facilities, including 1,400 GMP approved production plants in India.[68]

India today represents a sixth of the global population and therefore a substantial proportion of the global health problems. Many of these are challenges faced elsewhere in the world but there are also issues and diseases that are unique to India, such as cervical cancer, infectious diseases, and the solutions to these problems can come more from India alone. Therefore, the Bioservices industry has a major role in developing solutions for the grand healthcare challenges facing India.

GOVERNMENT OUTLOOK

In India, the Central Drugs Standard Control Organization (CDSCO), under the Ministry of Health and Family Welfare (MoHFW), is the nodal agency that develops regulatory standards and regulatory measures for drugs, diagnostics and devices; laying down regulatory measures by amending acts and rules; and regulating the market authorization of new drugs – all in an effort to standardize clinical research in India and bring safer drugs to the market

With intent to improve the clinical trial landscape in India, the CDSCO has relaxed the existing rules and eased the clinical trial procedures in India.

Under the new norm announced by CDSCO, a clinical researcher will be allowed to perform as many trials as approved by the ethics committee, instead of the previous cap of three trials.[69]

The existing mandate for a clinical trial site to have atleast 50 beds has also been removed.[70] In addition, the rule for taking "no objection certificate" from the DCGI in case of addition or deletion of new clinical trial site or investigator.

In addition, the CDSCO may launch online grant of NOCs for conducting clinical trials soon, under SUGAM, an online solution for submission, application and grant of permission. The application can be submitted and monitored online which will reduce the time of clearance.[71]

INDUSTRY OUTLOOK

MARKET DYNAMICS

The BioServices Industry in India is driven by the availability of low cost, and high quality research fundamentals, with a strong regulatory support and good scientific talent base. The bio-services industry is expected to witness an impressive surge due to its lower operating cost than other biotech applications.

DRIVERS

Bioservices market is benefiting from the increasing generics utilization, significant patent expiries, as well as from the high quality, low cost-advantage of India that drives volumes and margins. The strong availability of study subjects across major therapeutic segments, and high level of ICH Good Clinical Practice (GCP) and US

Food and Drug Administration (FDA) standards compliance is also driving the market.

In addition to the traditional bioservices companies, the KBITS Survey reveals that new biotech startups are also developing their bioservices capabilities with intent to sustain their operations post 18 months of funding. With 2-3 FTEs, these startup firms continue to undertake research in their core area, and are transforming themselves into bioservices companies with competitive price offerings. This will shake the industry and lead to greater growth of the industry.

RESTRAINTS

For new market entrants with limited funds for development and manufacturing during early R&D phase, the evolving policy environment for contract manufacturing needs to be more conducive. A proactive policy that encourages contract manufacturing and collaboration would lead to many new startups to emerge. In the US, regulatory directives may negatively impact the growth of the Indian BioServices industry. Indian pharma companies have been issued various letters/notices by USFDA regarding non-compliance with the testing, hygiene and cGMP standards.

OPPORTUNITIES

Given India's vast and varied disease population with diverse gene pools, India represents a good opportunity for bioservices companies to expand their operations. As it stands, clinical research investment in India has been driven by cost-effectiveness, and capabilities available locally. Opportunities exist for further investments in research and development, with intent to reduce the timeline of various processes in the clinical trials pathway.

Indian contract manufacturing organizations are now becoming a more strategic partner for multinational pharma and biotech companies who look at them to bring new innovation, new technology, including 3D printing opportunities, new approaches and a global reach. For instance, the rising cost of manufacturing in Europe will translate into opportunities for Indian contract manufacturers.

CHALLENGES

India is no longer the low cost destination for Bioservices. The increasing costs, associated with manufacturing and labour costs, coupled with increasing competition from countries in Asia and Eastern Europe, are all posing challenges for the Indian bioservices segment.

The regulatory frameworks, and uncertainties associated with it, have been a major challenge to conduct clinical trials in India. In addition, several limitations still exist that either delay academic clinical research or curb its scope.

Some of the key traditional challenges for contract manufacturing have included

cultural differences, quality concerns, and lack of transparency in the manufacturing process. However, Indian bioservices firms have built on their success stories to address such concerns.

Skilled human capital is a challenge that compromises bioservices in India. Identifying and training medical professionals with a keen interest and aptitude in clinical and contract research is a challenge.

ROAD AHEAD

Looking into the future, the CRO industry will continue to grow at a rate of 20-30 % over the next three years, and the segment will also see the entry of a number of small-sized homegrown CROs into the market looking at Bioavailability/ Bioequivalence (BA/BE) studies. Also, being on the growth mode, Indian CROs will look at outbound acquisitions both big and small.

R&D AND ACADEMIA OUTLOOK

For India to tackle its unmet medical needs, academic and investigator initiated clinical research work is an imperative. Such research trials allow India to focus on neglected disease areas, such as cancer pertaining to head and neck, cervix, esophagogastric and gall bladder that are widespread but not been a priority for the industry. For instance, the industry focus is on breast cancer, lung cancer, prostate cancer and melanoma. An investigator-led research with existing drugs will enable to find more effective treatments for these cancers.

The Government regulators have been undertaking reforms to streamline the clinical trials and striving to create conducive environment for academia-led clinical trials. For instance, ICMR has developed norms to facilitate export of clinical samples for research collaborations. Finally, training in research is not an integral component of undergraduate and postgraduate medical school curriculum.[72]

The Wellcome Trust-Department of Biotechnology (DBT) India Alliance Clinical and Public Health Research Fellowship supports promising clinical research efforts in India, by identifying and supporting them.[73]

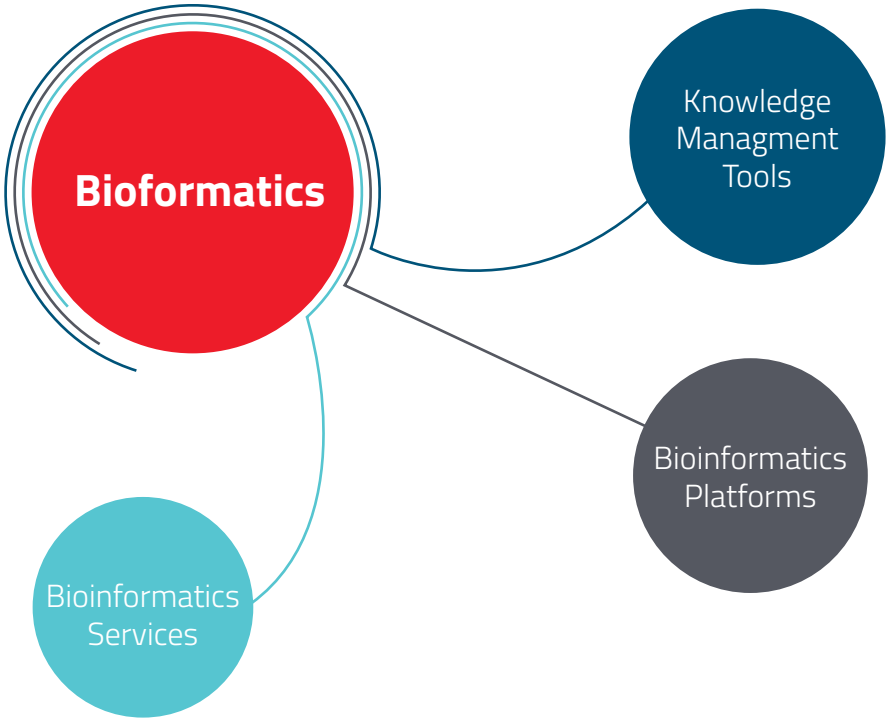
07

BIOINFORMATICS

INTRODUCTION

By 2020, the global market for bioinformatics is expected to reach US$ 12.48B. Bioinformatics sector is seeing rapid growth owing to the fast-declining prices of DNA sequencing, growing adoption rates of bioinformatics for database management during clinical trials, government encouraging the use of bioinformatics in drug discovery, and the emergence of chemogenomics. The future growth opportunities for Bioinformatics will come from the introduction of nanopore and cloud computing.

BIOFORMATICS: KEY SEGMENTS



US and Europe are the largest markets globally, and the fastest growing market for bioinformatics is APAC.

Bioinformatics is getting increased attention, owing to increase in public funding towards research and development (R&D) from the Government of India, decline in costs of human genome sequencing, increase in R&D investments by companies, and increase in the number of orders for contract research activities.

India's strong information technology base provides an enormous opportunity for companies in India and more so in Bengaluru to make rapid strides for exponential growth in Bioinformatics.

Bengaluru is a preferred destination for Bioinformatics start-ups. Several leading universities and biotechnology and information technology (IT) companies in the US and Europe, are looking at India and particularly Bengaluru for joint ventures, and access the large scientific manpower. In Karnataka, BioInformatics segment has a market share of US $.19B, commanding 3% of the total biotech market in the State.[74]

GOVERNMENT OUTLOOK

The new National Biotechnology Development Strategy (NBDS), covering the period 2015-2020, pushes a lot of stress on interdisciplinary sciences, with specific emphasis on human capital development at different levels, to creation of robust research infrastructure, and to making funding available for collaborative interdisciplinary research. With next-generation genomics emerging as a major platform that cuts across industry verticals, there is renewed focus on Bioinformatics. The Government Policy augurs well for the development of bioinformatics industry.

INDUSTRY OUTLOOK

MARKET DYNAMICS

The surge in drug discovery and drug development, leading to increased R&D activity, and increase in the growth of proteomics & genomics are driving the market growth. Increasing government support and greater use of bioinformatics in drug discovery and biomarkers development processes is fueling further market growth.

In 2014, Strand Life Sciences entered into a partnership with the Mazumdar-Shaw Medical Foundation (MSMF) to set up the Strand at Mazumdar-Shaw (SAMS) translational lab in the Mazumdar-Shaw Centre for Translational Research (MSCTR) at Bengaluru, with intent for making genomics-based diagnostics accessible and affordable.[75]

In late 2016, Syngene International Ltd acquired assets of Strand Life Sciences related to systems biology and pharma bioinformatics services among others.[76]

DRIVERS

With the growing use of bioinformatics in drug discovery and biomarkers development processes, and the increasing bioinformatics support in development of personalized medicines and clinical diagnostics, bioinformatics is experiencing good growth.

The traditional drivers for bioinformatics continue to be its skilled resources and cost advantage, driving bioinformatics outsourcing.

RESTRAINTS

One of the key restraints facing the Bioinformatics market is the saturation of the pharmaceutical sector, where most companies are developing in-house captive units. In addition, the lack of tools with multiplatform compatibilities and interoperability amongst data formats also restrains the market growth.

The advances in technology have led to a rapid generation of large volumes of sequencing data – from genomes of human, plants and disease causing bacteria, that could be used to answer some of the most important questions facing mankind.

The lack of skilled and trained professionals alongwith high costs are restraining the growth of the bioinformatics market. The challenge for bioinformatics stems from how best professionals in the biology and IT domains could bridge the gap. Today, much of the Bioinformatics training in India focuses on the use of bioinformatics software, and less on the understanding of the fundamental principles underlying the software. This, in turn, has led to a significant paucity of trained, high quality bioinformaticians with competence in exploiting genomic data and answering major biological questions.

OPPORTUNITIES

The growth in proteomics and genomics provides better opportunities for the Bioinformatics sector. Given the low cost of skilled labor and quality infrastructure available in India, bioinformatics services are getting a boost. As demand from the pharmaceutical industry increases, there is a greater demand for bioinformatics applications. These services are also relevant in analyzing public health data that would help in policy formulation and preventive measures.

CHALLENGES

The time required for developing a new bioinformatics application is about a year. It takes another year or so, before the product reaches the market. Most Indian companies operating in the Bioinformatics segment are small and medium-sized companies, having limited budgets to sustain products over the long-term.

As the bioinformatics industry globally consolidates with few companies having a vast market share, small bioinformatics enterprises will face further challenges. Given that pharmaceutical companies are developing in-house bioinformatics tools customized to their needs, the challenge for bioinformatics companies becomes tougher.

Lastly, the most critical challenge relates to the availability of skilled and trained professionals, trained in operating bioinformatics tools. A high rate of attrition coupled with rising wages would result in India losing its cost-competitiveness to other markets.

ROAD AHEAD

Genomics is rapidly changing the landscape of healthcare. Stepping into an era of data-driven health care, and personalized medicine, raw sequencing runs generate hundreds of gigabytes of data from a single measurement. The current clinical data management infrastructure is not enough to handle such enormous amounts of data. As a result, new and integrated better systems need to be deployed for unleashing the full potential of genomics. Translational bioinformatics has become an important discipline in the era of personalized and precision medicine, making an actual difference in patients' lives. The infrastructure, information technology, policy, and culture need to catch up with some of the technological advances.[77]

R&D AND ACADEMIA OUTLOOK

One of the major initiatives to foster bioinformatics in India was the Institute of Bioinformatics and Applied Biotechnology (IBAB), set-up by the Government of Karnataka. Since its inception, IBAB has benefited from consistent and escalating funding support from the Government of Karnataka and various departments of the Government of India. IBAB is playing a key role in fostering research and training in bioinformatics. In addition, IBAB enables entrepreneurship in Bioinformatics, through incubation of 20 new bioinformatics companies so far.

At the UG level, short-term training program modules will help create awareness and appetite amongst students for understanding and developing skills in bioinformatics. Such programs could have periodic follow-ups with students to enable experiential learning possible. In addition, the faculty requires capacity building to equip themselves with latest developments in bioinformatics. Such programs could include online course materials, as well as access for training at research institutions.

Some of the key thrust areas identified by the Government for research support include NGS data analysis, computational genetics, metagenomics, design of functional molecules, understanding nucleic acid, chromatin, protein structures and their interactions, marker assisted breeding, secondary metabolites, genome and proteome analysis.

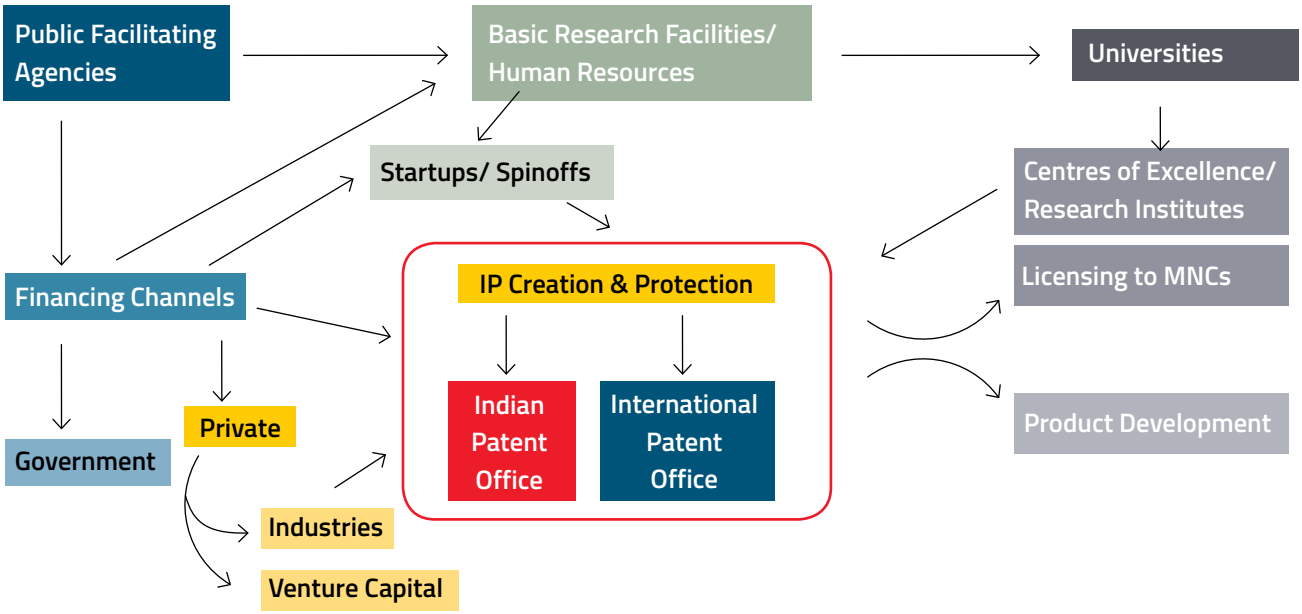
08

IP AND INNOVATION CULTURE

INTRODUCTION

India's ascent from a developing country to an emerging economic superpower has also witnessed a concomitant growth of high quality research publications. India was ranked 13th globally in the Nature Index, a database that tracks the affiliations of research articles published in an independently selected group of 68 high-quality science journals. The growth in research output has been achieved despite poor funding. The Government of India is incentivizing R&D through tax incentives that should increase research yield in the years to come.[78]

ECOSYTEM FOR TECHNOLOGY DEVELOPMENT



India's research ecosystem comprises of a diverse set of stakeholders, including the public sector that supports research funding, development of basic and advanced research infrastructure – including universities and research centres.[79]

As India grows, the interactions with global research institutions is on the rise, and in parallel, venture capital firms are showing greater interest in participating in the biotech story by funding new industry-academia linkages. In addition, the focus on intellectual property generation and commercialization/ technology transfer is on the rise.

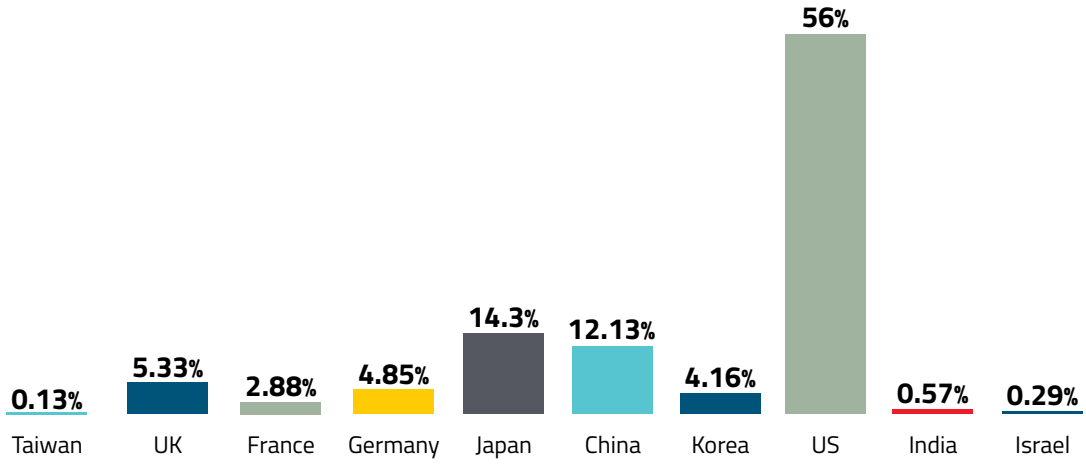
PATENTS AT NATIONAL AND INTERNATIONAL LEVEL

International patent filing is very expensive, and most Indian Universities and research institutions do not have this expenditure built into their budget. The Patent Office of India has an increasing backlog of pending patents. There are steps being

taken to appoint new patent examiners to deal with the backlog. However, the Patent Office staffs in India have the highest per capita workload (20 applications a month, as compared with 7 in Europe and China, 8 in the United States) at the lowest pay. In 2012 there were 123,255 pending patent applications, which has further increased to 246,495 in patent on-line applications.[80]

In terms of global publications in biotechnology and allied disciplines, India

INDUSTRIAL BIOTECHNOLOGY: PATENT APPLICATIONS (2003-2013)



accounts for 2-4%. Between 2000 to 2015, India had a 5.03% share in the total patent applications filed in biotechnology at the international level at WIPO.[81]

When it comes to patent applications, India is still lagging behind. There were only 83 patent applications in biopharmaceuticals filed by DBT-sponsored research institutions and universities between 2004 and 2010. Out of the 83 patents, only ten were granted. The number of technologies commercialized from these patents was even lesser. A similar trend was seen in BioAgri and BioIndustrial sectors, with only 10 patents granted out of 63 applications during the same period.[82]

While international patent protection can afford many strategic and economic advantages, the high costs of patent filing and its maintenance are definitely barriers at the international level.

Karnataka is ranked 4thamong all states in India in terms of the number of patent applications filed in 2009-10 with 755 applicants out of 7044 Indian applicants. Further, Karnataka ranks 2ndwith 12.4 patent applications per million populations.[83]

According to the KBITS Survey, the biotechnology industry in Karnataka, including the biotechnology startups, filed 410 patent applications at the Indian Patent Office and 1662 patent applications globally during 2015-16. A similar

BIOTECH PATENT FILING TRENDS (2015-16)

Number of Patent Application (India)	**410**
Number of Patent Granted (India)	**78**
Number of Patent Application (Overseas)	**1662**
Number of Patent Granted (Overseas)	**1080**

[Base=294

trend is observed in terms of patents granted, with higher grants overseas.

At the State Level, the Karnataka State Council for Science and Technology (KSCST), at the Indian Institute of Science, set-up a Patent Information Centre (PIC) in 2005 as a service centre to render IPR related services among S & T community. Its objectives include awareness generation on IP in the state, providing advisory services to inventors, universities, and government departments on IP, as well as to set-up IP Cells at colleges.

In 2015-16, the PIC received 40 queries concerning IPRs. In addition, five patent applications were filed and one design application was registered. The applicants include individual innovators and students and faculty members from engineering colleges.[84]

BIOTECH INCUBATION CENTRES AND RESEARCH PARKS

A thriving biotech ecosystem is one, which enables continuous interactions amongst its various stakeholders for new technology development and economic development. One such avenue comprises of the Research parks and biotech incubation centres. These centres provide space for technology incubation, prototyping, and pilot testing, and, in the process, facilitate interactions and collaborations between academia and industry. Biotechnology parks facilitate innovation, product development, advancement and commercialization.

In India, the Central as well as State Governments have taken the lead to establish biotech parks.

Karnataka possesses world-class research infrastructure, comprising of centres of excellence in biotechnology research. Some of the key research institutions in

Karnataka include Indian Institute of Science (IISc); National Centre for Biological Sciences (NCBS); Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR); National Institute of Mental Health & Neurological Sciences (NIMHANS); Central Food Technological Research Institute (CFTRI); Institute of Agriculture Biotechnology (IABT); Institute of Bioinformatics and Applied Biotechnology (IBAB); and Centre for Human Genetics (CHG) among others.

Karnataka is home to various types of incubators, ranging from those that provide infrastructural and specialized facilities, such as C-CAMP, and accelerators that provide techno-commercial mentoring and proof-of-concept funding beyond the early stage, including accelerators such as EVA and InnAccel.

THE BENGALURU BIOINNOVATION CENTRE (BBC), BENGALURU

The BBC, set-up by KBITS, aims to be a state-of-the-art incubation center catering to the needs of start-ups in the broad areas of Life Sciences. It is located within Bengaluru Helix Biotechnology Park at Electronic City in Karnataka. The Center is a modern incubation centre with central instrumentation facility in a 10-acre campus with total built up area of above 50,000 sq.ft. The Center is nestled between thriving academic institutions like Institute of Biotechnology and Applied Biotechnology (IBAB), Centre for Human Genetics and the upcoming area for anchoring Big Companies/MNCs. Thus, the center provides a crucial link within the developing biocluster, the Bengaluru Helix Biotech Park. BBC today houses over 19 companies.

THE CENTRE FOR CELLULAR AND MOLECULAR PLATFORMS (C-CAMP), BENGALURU

The Centre for Cellular and Molecular Platforms (C-CAMP) in Bengaluru Is located within the campus of the National Centre for Biological Sciences (NCBS).C-CAMP focuses on developing and making available state-of-the-art technologies and providing training on these technologies to academia and industry; and building a thriving ecosystem to stimulate innovation and promote bio-tech entrepreneurship in India. C-CAMP has funded around 50 life science start-ups/spin-offs, of which 11 are currently incubating at C-CAMP campus.

THE INSTITUTE FOR STEM CELL BIOLOGY AND REGENERATIVE MEDICINE (INSTEM), BENGALURU

The Institute for Stem Cell Biology and Regenerative Medicine (inStem) focuses on collaborative basic and translational research in stem cell biology and regenerative medicine. inStem's mandate to allow this cross- disciplinary, multi-pronged approach to research, straddles the divide between clinical and laboratory research in stem cell biology. At inStem, the research projects get support from the state-

of-the-art facilities at NCBS and C-CAMP.

INSTITUTE OF BIOINFORMATICS AND APPLIED BIOTECHNOLOGY (IBAB), BENGALURU

IBAB facilitates the incubation of bioinformatics startups in India, by providing startups with support and mentoring through the incubation process. IBAB has incubated almost 20 start-ups since 2002.

INNACCEL, BENGALURU

InnAccel is a MedTech-specific accelerator that fosters the development of novel medical devices and diagnostics from India.

IKP EDEN, BENGALURU

IKP-EDEN™ is a membership-based Do-It-Yourself fabrication studio and a startup accelerator. Building on the vast experience gained from helping Med-Tech startups and from managing scientific research facilities, IKP is leveraging its expertise to support engineering and hardware product design startups.

ESCAPE VELOCITY ACCELERATOR (EVA), BENGALURU

EVA provides infrastructural support, expert guidance and mentorship to life sciences and healthcare startups, enabling fundable startups to come into their own. The EVA's network of mentors offers technology, funding and market-access relationships.

INTERNATIONAL CENTRE FOR INNOVATION, TECHNOLOGY TRANSFER AND ENTREPRENEURSHIP (IN-CITE), NARAYANA HRUDAYALAYA, BENGALURU

IN-CITE is a Technology Business Incubator (TBI) funded by the National Science & Technology Entrepreneurship Development Board (NSTEDB) and Department of Science & Technology (DST), Government of India. INCITE-TBI focuses on medical technology, and is housed in Kiran Mazumdar Shaw Cancer centre inside the NH Campus.

MANIPAL UNIVERSITY TECHNOLOGY BUSINESS INCUBATOR (MUTBI), MANIPAL

MUTBI is one of the 54 TBIs funded by the National Science & Technology Entrepreneurship Development Board (NSTEDB) and Department of Science & Technology (DST), Government of India. It was set up in 2010 and its thrust areas are Information Technology (IT) in Healthcare, Agriculture, Renewable Energy and Energy Conservation Systems, and MEMS/Nanotechnology.

NUTRI/NUTRACEUTICAL AND PHYTOPHARMACEUTICAL PARK (N2P2 PARK), MYSURU

N2P2 is being established in close collaboration with CFTRI, Mysuru, to provide incubation platforms for entrepreneurs focused on nutraceuticals and phytopharmaceuticals. The Park provides 8000Sq.Ftarea for incubation. In addition, incubates benefit from attractive policy incentives, and access to high quality mentorship, R&D support, equipment and mentorship.

EHEALTH TBI, BENGALURU

The eHealth TBI was established in 2008, and is supported by the National Science & Technology Entrepreneurship Development Board (NSTEDB) and Department of Science & Technology (DST), Government of India. The thrust areas for eHealth TBI include Biopharma, Medical Devices and healthcare.

AGRI-BIOTECH PARK (ABP), DHARWAD (UAS –D)

The ABP is focused on fostering incubation within specific technology areas within agricultural biotechnology. The ABP provides incubation space for 10 teams, and provides 30 acres for field trials.

MARINE BIOTECH PARK (MBP), MANGALURU(KVAFSU)

MBP is being established in close cooperation with KVAFSU, and focused on incubating startups in bioenergy, nutrition and pharma.

ANIMAL BT PARK/VIVARIUM, BIDAR(KVAFSU)

Established in collaboration with KVAFSU, and focused on fostering incubation for vaccine production, embryo transfer, bioinformatics and stem cells.

09

THE STARTUP CULTURE IN KARNATAKA

INTRODUCTION

A startup ecosystem has three key characteristics: Access to Capital, Access to Know-how and an entrepreneurial mindset that always challenges the status quo. Successful entrepreneurs are those who are adept at tying all three characteristics together, creating best practices, surmounting the challenges to build the institutions that become the pillars of an entrepreneurial economy.

Karnataka provides the right ecosystem for new biotech startup innovation. This is due to the presence of pioneering industry giants, Biocon, Richcore, Kemwell, etc. and the centres of research excellence – IISc, NCBS, JNCASR, IIHR and UAS. In addition, a conducive policy environment in Karnataka, helped spawn many new startups. These startups were commandeered by entrepreneurs who left their jobs at established companies, or by those who have returned after post-doctoral studies in the West. The ecosystem also includes bright PhD scientists taking the lead in solving a grand challenge.

The entrepreneurs behind these nascent, early-stage startups are good scientists who have excellent research skills and are passionate about their science. To a certain, limited extent some of these startups have an understanding of their pathway, and time to market. However, most of the other entrepreneurs face difficulties wearing both the scientific and the market hats, and struggle a lot in defining their end market, and their go-to-market strategy.

The major driver for most of the new entrepreneurs has been on doing public good through social entrepreneurship, and has not been on making capital through IP monetization. The research, unfortunately, therefore remains entrapped in the academic world, without any serious efforts by the entrepreneurs to reach the market. Beyond the grant of INR 50 Lacs and 18 months, startups are forced to adapt to uncertain time to market. In some instances, they tend to focus on survival rather than risk-taking. One emerging trend is of startups turning into bioservices providers with 2 to 4 FTEs, to support their operations till the PoC is complete, and they are closer to the market.

In contrast to the tech startup world, where the rate of funding and formation of new companies has exploded over the past few years on the back of digital technologies, the biotech startup world represents a universe marked by incredible demand for funding, and the relative lack of venture capital available. The new Biotech innovation is capital intensive, spread over several years, and fraught with risk of failure at several stages, across a long R&D timeline, leading upto market entry. As such, for investors, while IT shows a clear potential and timeline for return on investment, in biotech, it is not the case.

However, 2015 marked an important inflection point for biotech startups. Since 2015, startups operating in the hot e-commerce and food delivery segments started experiencing a shakeout, with many promising startups closing down.[85] Alongside, the rise of diabetes and other chronic diseases in India led to an increased focus on a few grand challenges in healthcare.

Hitherto, uninterested VCs and angel investors have started making efforts to understand the biotech space, and started showing some appetite for investment too.[86] Some of the established startups have attracted VC funding, and interest from angel investors, who want to associate themselves with startups tackling grand challenges in healthcare.

For KBITS, this is an opportunity to emulate the Israeli innovation model for fostering and facilitating biotech startup innovation.[87] KBITS can further build on its biotech startup success story by:

1. Building large-scale infrastructure that a mature biotech startup can have access to.
2. Scaling-up funding available for successful entrepreneurs beyond the initial PoC.
3. Providing avenues for networking and mentorship for startups.

THE STARTUP ECOSYSTEM IN KARNATAKA

The sources of biotech innovation in Karnataka can be traced to the excellent academic infrastructure in Karnataka, supported by enlightened and proactive policies, and the strong presence of homegrown and foreign biotech MNCs in the State.

Karnataka is home to many nationally and internationally renowned biotechnology research Institutions. The network of national research laboratories, centers of academic excellence and several other institutes in medical science, educational and training institutes offering degrees and diplomas in biotechnology, bio-informatics and biological sciences have given a boost to the biotech sector. Given the strong research environment in Karnataka, the ecosystem is favorable to the development and growth of new biotechnology startups.

THE FIRST VS SECOND WAVE OF STARTUPS IN KARNATAKA

FIRST WAVE	SECOND WAVE
The first wave of startup entrepreneurs included seasoned R&D professionals who left their careers at large companies such as Biocon and AstraZeneca.	The second wave of startup entrepreneurs included enthusiastic PhD and post-doc scientists from Bengaluru and overseas, who zeroed on an unmet need, and embraced entrepreneurship.
They were self-funded, and leveraged their experience, knowledge, and industry connect to solve some of the unmet health challenges.	They benefited from the excellent early- stage incubators in karnataka, and had access to mentorship and capital through government grants.

Government support to biotech startup innovation includes the funding support available through national biotech funding programs, Biotechnology Ignition Grant (BIG)[88];Contract Research Scheme (CRS)[89]; Small Business Innovation Research Initiative (SBIRI)[90], and Biotechnology Industry Partnership Programme (BIPP)[91];and at the State level, through the Grand Challenges - Karnataka[92] and the Idea2POC funding program.[93] Supporting these funds are specialized incubators offering platforms for new entrepreneurs to startup – Bengaluru Bioinnovation Center (BBC), and C-CAMP. Karnataka offers a dedicated startup cell[94] that provides mentorship, incentives and concessions for new startups, a dedicated startup booster kit and a dedicated fund for fostering startups. In 2016, Karnataka announced a new "Startup Policy" for the State.[95]

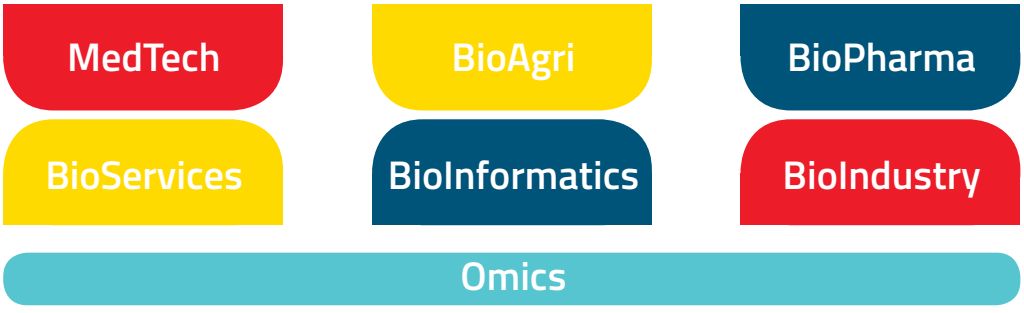
Karnataka also benefits from the strong presence of biotech industry in the State. Many homegrown and multinational companies have established their operations in Karnataka, seeking access to the research talent available in the State. These biotech companies are the sources for new biotech innovations, and new entrepreneurial ventures.

The biotech startup ecosystem in Karnataka comprises of startups that are addressing myriad challenges, and are spread across disciplines. For instance, the breakdown of silos, and convergence between life sciences, physical sciences and engineering, is leading to new research in life sciences at the molecular level supported by the technological advances from the engineering sciences. Such research comprises of skill-sets from bioengineering, synthetic biology, systems biology, and computational biology.

One of the hottest technology areas is MedTech, which attracts entrepreneurs with its shorter gestation period, and clear path and time to market. MedTech signifies the convergence of IT and Biotech, and involves development of medical devices or solutions that tackle some of the unmet challenges facing India.

Beyond MedTech, there are startups working in technical domains, ranging from BioAgri to BioIndustrial, from BioPharma to Bioinformatics. For survival, most pure-play startups have also transformed themselves as bioservices providers. Cutting across all the domains, is the layer of Omics.

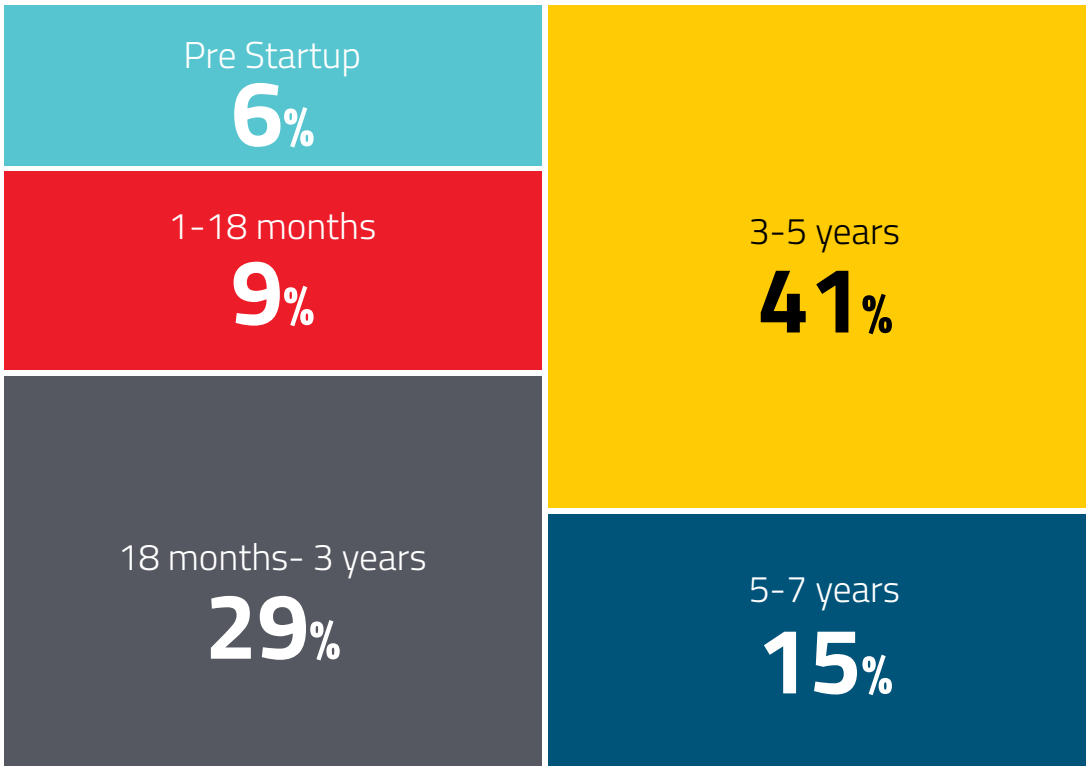
THE BIOTECH STARTUP ECOSYSTEM



A majority of the startups surveyed in the KBITS Biotech Survey 2016are currently in a stage, between 3 years to 5 years. 15% of the startups are <18 months old.

To support and sustain their operations, many of these startups are reinventing themselves as bioservices providers, while continuing to chart their path to market with their novel research and development. The entrepreneurs, who set base in Karnataka, and especially Bengaluru, chose to do so, because of the personal connection with the State, and to tap the excellent mentorship and support available. Bengaluru has been cited as an excellent avenue for early-stage research. However, from a cost-perspective, many startups are not averse to considering Mysore, Pune or other such locations. The advantage that Bengaluru has is its salubrious climate, presence of world class Institutions, social infrastructure and its ability to attract new talent from the rest of India.

STARTUPS: STAGE OF BUSINESS



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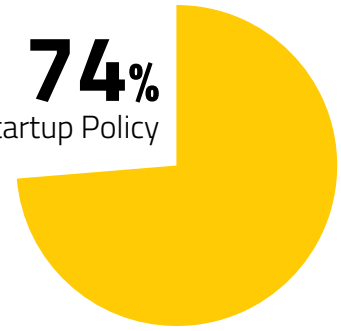
AWARENESS OF KBITS AND KARNATAKA STARTUP POLICY

According to the KBITS Biotech Survey 2016 findings, the awareness of Karnataka

STARTUP AWARENESS ON KBITS AND KARNATAKA STARTUP CELL



74%
Aware of Karnataka Startup Policy

14%
Registered with
Karnataka Startup Cell

22%
Registered with KBITS

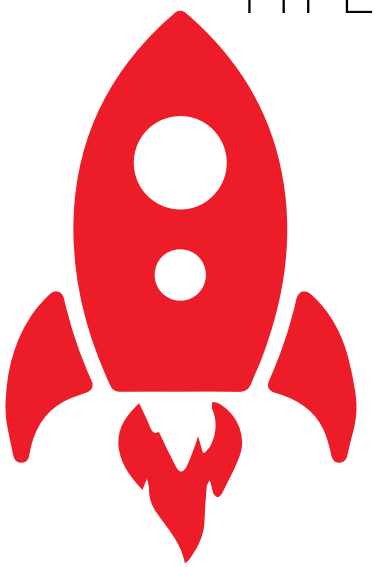
[Base=52]

Startup Policy is high amongst biotech startups. There are many startups that are still planning to undertake registration with KBITS or the Karnataka Startup Cell. However, indicators point to a higher rate of registration going forward.

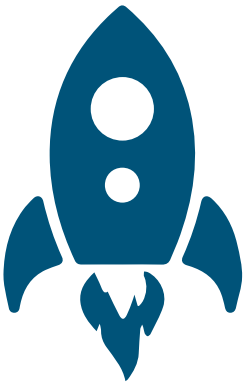
TYPES OF STARTUPS

53%of the startups in Karnataka are incorporated as limited liability companies, as per the KBITS Biotech Survey findings.

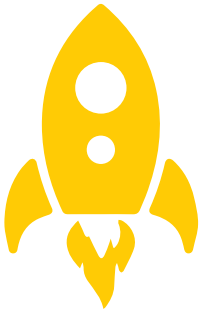
TYPE OF STARTUPS



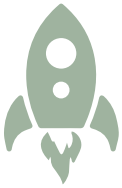
53%
Limited Liability Company



27%
Single Person
Business Activity



16%
Joint Stock Company



4%
Others

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ACCESS TO CAPITAL

The KBITS Biotech Survey 2016 findings indicate that government funding and personal funds are what most entrepreneurs turn to, while starting up.

The launch of BIG scheme by the BIRAC enabled many scientists to become entrepreneurs. The long life cycles and uncertainty and risk in the timeline have led VCs to show little or no interest in funding early stage startups. Only a few established biotech startups have been able to garner interest and some funding from VCs.

While BIRAC and KBITS are supporting a lot of early-stage startups, the funding available is not necessarily till the last mile. Very few startups are able to secure the follow-on Government funding. As such, access to capital remains the key issue till startups figure their way to market.

STARTUPS: FUNDING SOURCES

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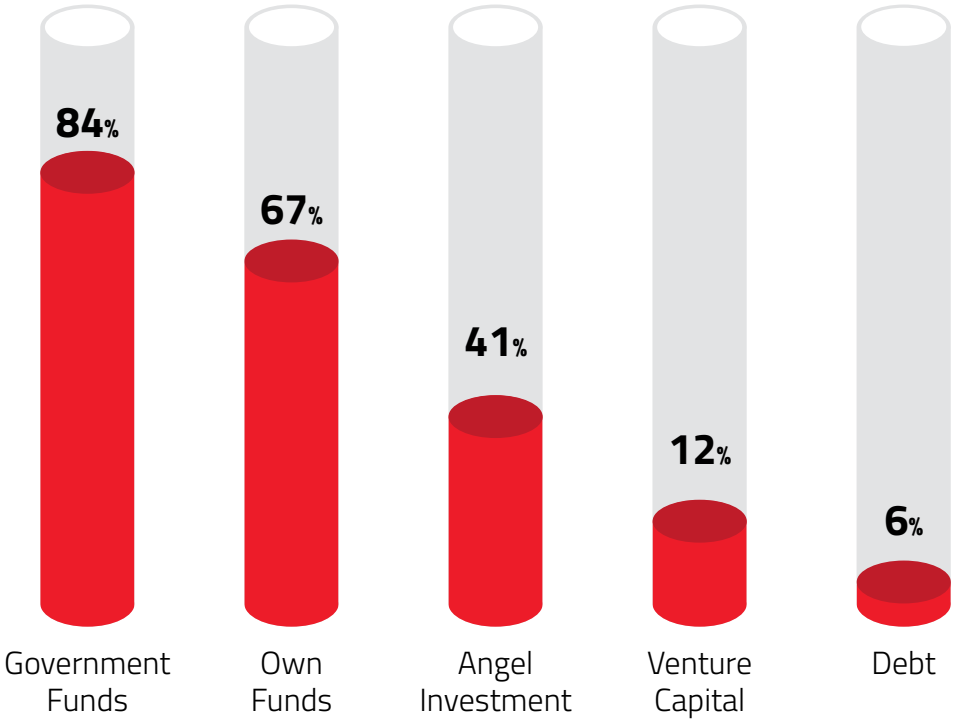


It would be helpful to have a provision of risk funding or next stage funding for all the start-ups, which may not have the funds to proceed further after receiving the initial grant, for establishing proof of concept.

ACCESS TO FUNDING: THE IMPACT OF 51% INDIAN OWNERSHIP RULE

The access to biotech funding in India is mostly restricted to Government funding, some angel investment, and a few venture capital firms. As such, capital remains a big challenge for new startups to sustain and grow to the next stage.

The avenues and opportunities for securing funding from biotech venture capital firms from overseas are high.

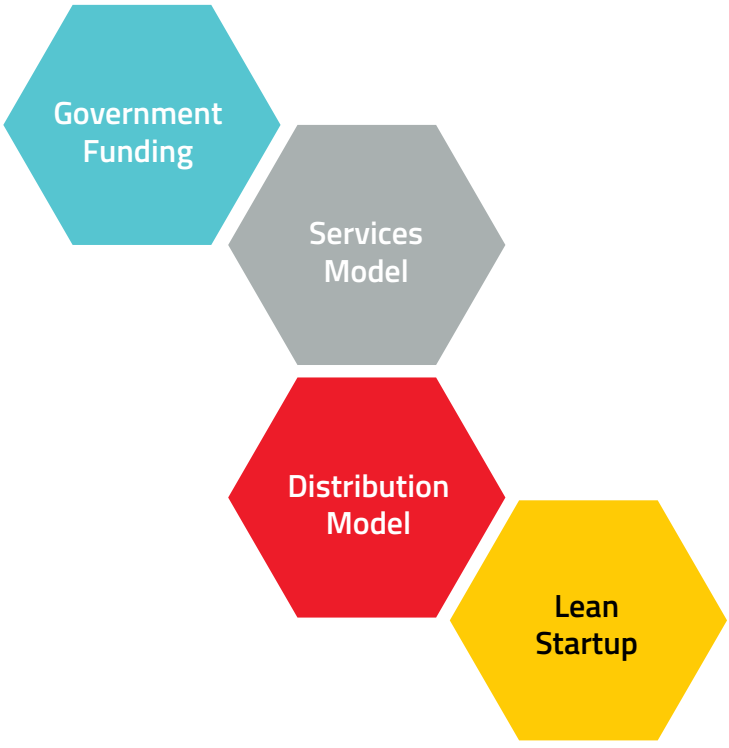
According to the KBITS Survey, most of the startup founders believe that the 51% ownership rule in Startups restricts access to Venture Capitalists (VCs) and other funds located outside of India.

Medtech startups believe that most of the grants from such funds are of higher amounts, and are linked to equity in the startup.

SURVIVING THE PATH TO MARKET

Once the 18 months of funding run out, startups seek to survive their path to market through various models.

SURVIVING THE PATH TO MARKET



These include the following:

1. GOVERNMENT FUNDING MODEL

Some startups continue to rely on government grants only to negotiate their path to market. So, from a PoC stage to an advanced technical PoC stage, its most government funding that helps startups sustain, till such time the startups are able to visualize the path to market.

2. SERVICES MODEL

Many of the startups continue to focus on their main R&D, and have developed services model to sustain them till they identify and negotiate the path to market.

3. DISTRIBUTION MODEL

Some startups even contemplate a distributorship model for new products and services, while persisting with their R&D to sustain themselves till they negotiate the path to market.

4. LEAN MODEL

Lean startups develop their R&D and product development by not scaling-up and only managing with the limited human capital they started with.

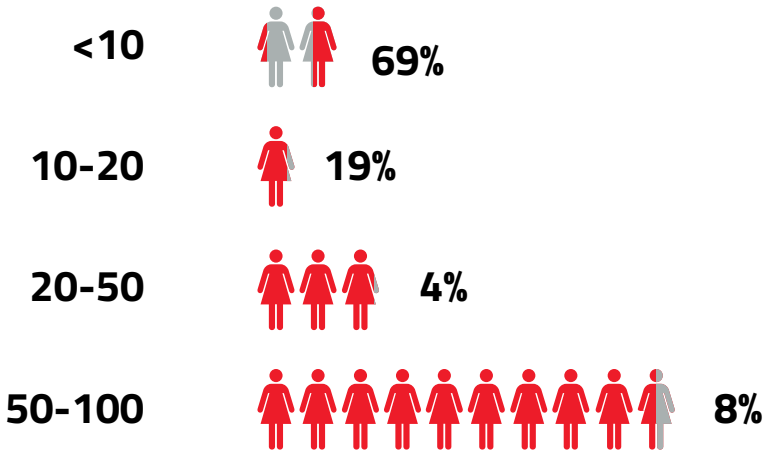
EMPLOYMENT IN STARTUPS

The biotech startup sector provides employment to 998-plus biotech professionals. A majority of the startups employ < 10 full-time employees. Only 12% of the startups employ 20-100 employees.

STARTUP REVENUES

As per the KBITS Survey, a majority of the startups in Karnataka have an annual turnover of < INR 1 Crore. There are a few startups, which have attained growth over the past few years, and have seen revenues of INR 5 Crore. However, these are very few.

ORAGANIZATIONAL SIZE OF STARTUPS: BY EMPLOYEE



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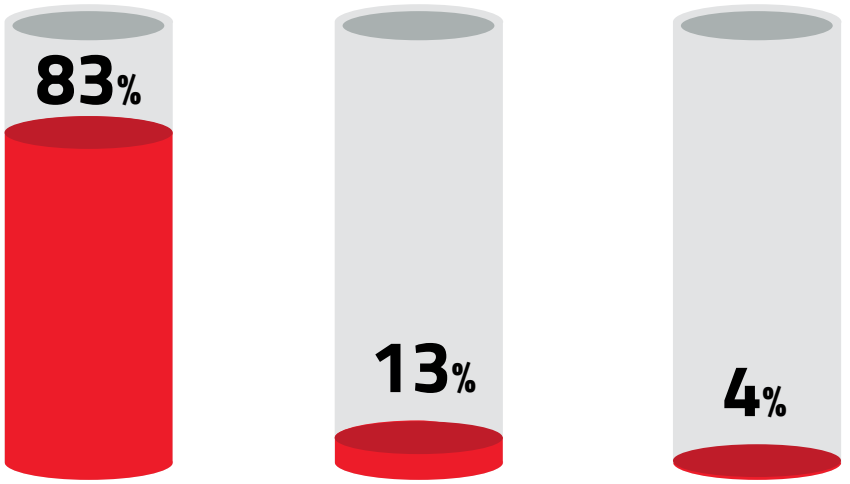
STARTUPS: ANNUAL TURNOVER
(APRIL'15-MARCH'16)



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STARTUP SET-UP

72% of the startups operate from a rented/leased facility, and only 23% have their own facility for their operations.

STARTUPS AND PATENTS

IP is accorded much importance by startups. As per the KBITS Survey, 67% of the startups surveyed have applied for patents.

33% of the startups indicated not filing for any IP. Most of such startups focus on downstream technology applications, or services.

STARTUPS: PATENTS FILING

33%
Have not filed for patents

67%
Have filed patents

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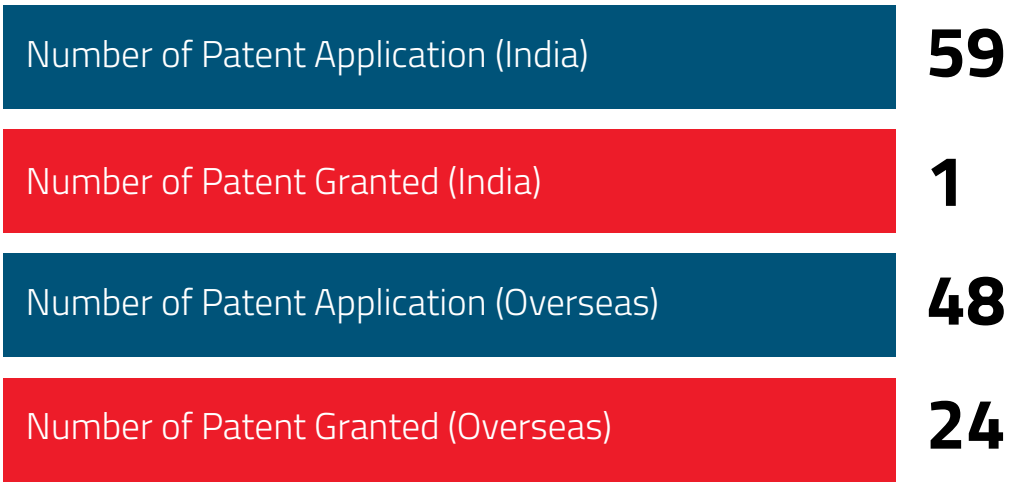
According to the KBITS Survey, biotech startups applied for 59 patents at the Indian Patent Office, and 48 patents overseas in 2015-16.

PATENT FILING TRENDS (2015-16) AMONGST STARTUPS



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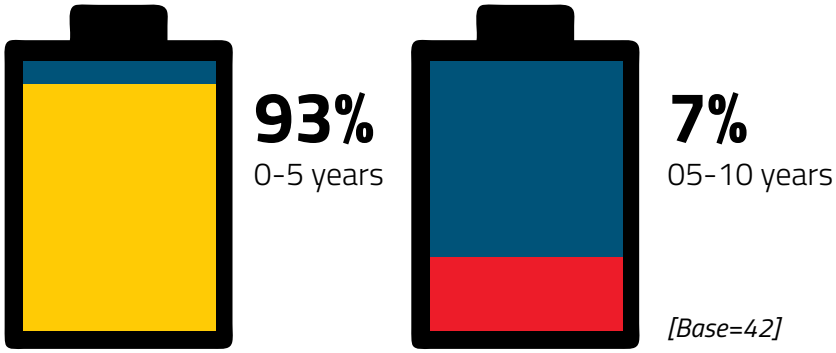
STARTUP: TIME TAKEN FOR ATTAINING BREAK EVEN

According to the KBITS Survey, of all those startups that have achieved break even, they have done so within a span of 5 years. This is indicative of a very vibrant ecosystem with the right support infrastructure.

NEW STARTUPS: ESTIMATED TIME FOR ATTAINING BREAK EVEN

An overwhelming majority of the new startups (93%) in the KBITS Survey anticipate achieving break-even within the first five years. However, there is a caveat to this finding: Most of the early-stage startups are yet to find their path to market, or

ESTIMATED TIME TO ACHIEVE BREAK-EVEN



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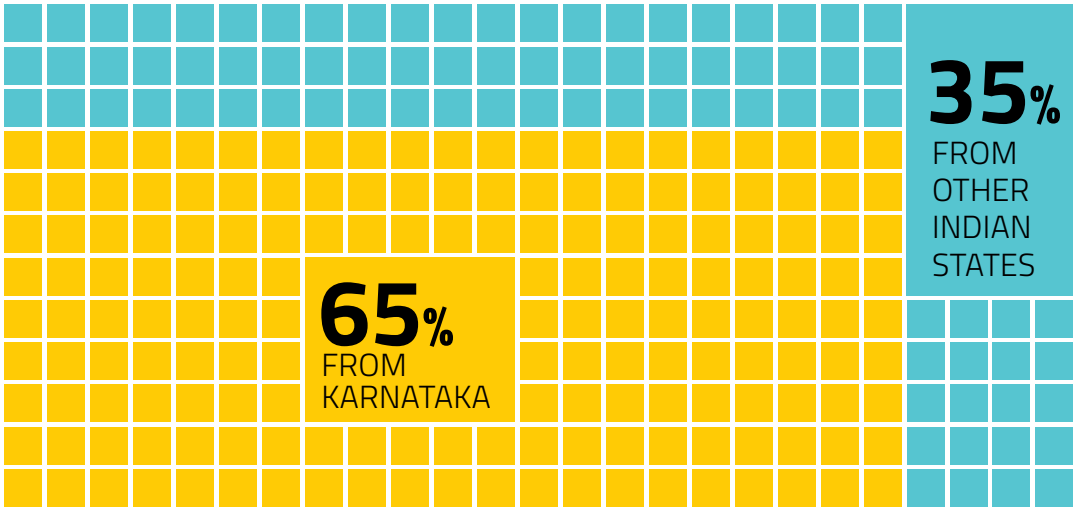
yet to develop a technical proof of concept. The biggest hurdle for such startups is that while they have relatively easier access to scientific and technical mentorship, there are only fewer avenues for securing business mentorship and guidance. This translates into challenges for biotech startups to define their end consumer, and their potential channels to market.

STARTUP DIVERSITY AT THE WORKPLACE

As part of the KBITS Biotech Survey, startups were asked to comment on the diversity at their workplace. Specifically, the Survey looked at Gender, Geographic Origin, and Category for the employees working in a startup.

DIVERSITY AT THE WORKPLACE: BY ORIGIN



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As per the KBITS Survey, the Startup Workplace is mostly male-centric, with only 34% females.

DIVERSITY AT THE WORKPLACE: BY GENDER

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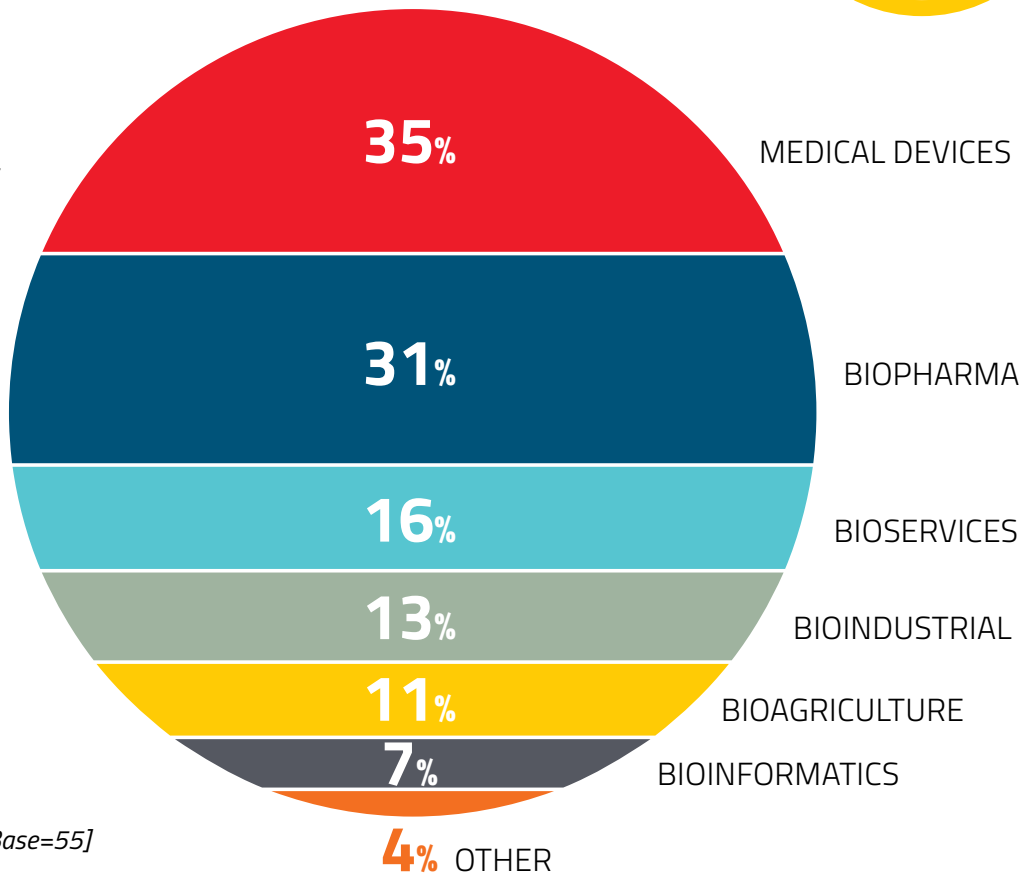
TYPE OF STARTUPS: BY MARKET SEGMENT

According to KBITS Biotech Survey findings, the types of startups in Karnataka includes the following:



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GOVERNMENT POLICY

- The Government of India announced a Startup Policy to accelerate spreading of the Startup movement in healthcare, and other sectors.[96]
- The Government of India aims to scale-up the number of start-ups to 1500 in biotechnology sector so as to further the growth of the biotech sector.[97]
- The Government of India is planning to launch a venture capital fund of INR 1,000 Cr. under the department of pharmaceuticals, to support start-ups in the research and development in the pharmaceutical and biotech industry.[98]
- The Government of Karnataka has launched the KITVEN FUND 3, for a biotechnology-dedicated fund, with corpus of INR 50 crore.[99]
- Karnataka-based biotech startups will get financial support from the Government of Karnataka for domestic and foreign patent filings.[100]
- The Government of Karnataka, through its Startup Policy, also offers a marketing incentive that covers 30% of the actual marketing costs including travel incurred in international marketing through trade show participation.[101]

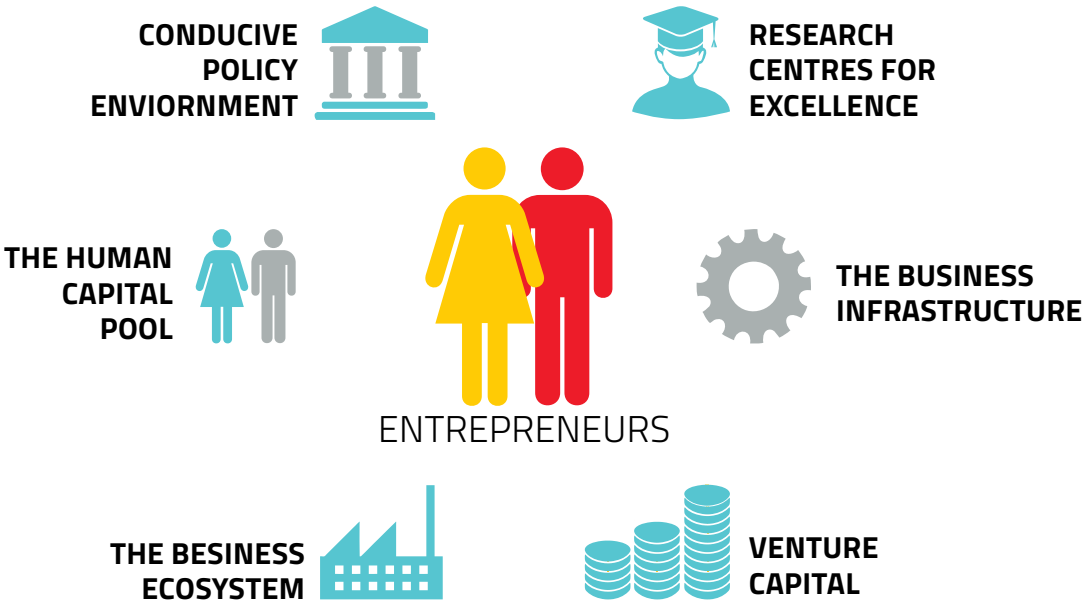
ENABLING FACTORS FOR BIOTECH STARTUPS

Karnataka is home to India's biotech industry majors, biotech startups and research institutions of excellence that together create a business environment, highly conducive to the successful creation of new startups across verticals.

The Business Ecosystem in Karnataka is one where large companies and startups co-exist symbiotically in a thriving and viable ecosystem. Large companies provide the platform from where new expertise, new entrepreneurs, and eventually, new startups emerge. For startups, the large companies provide the market for their service and product offerings, as well as for human capital.

The Human Capital Pool in Karnataka is very deep, with talent available locally as well as those willing to re-settle from other parts of India, and from overseas. The breadth of expertise available is vast, cutting across specializations.

ENABLERS FOR THE BIOTECH STARTUP ECOSYSTEM



The Business Infrastructure in Karnataka is very strong, and includes an array of business support service firms, law firms, accounting firms, market research firms, business advisors, and mentors that have experience in supporting startups at all stages of business incubation.

The Venture Capital market in Bengaluru is competitive and has an understanding and interest in biotech, and is more mature than in other regions.

The Research Centres of Excellence, comprising IISc, UAS, JNCASR, NCBS, CFTRI, Manipal Institute of Technology among others, support Karnataka in basic scientific and translational research, creating inter-connected and interpersonal networks of communities of expertise.

Lastly, the conducive policy environment in Karnataka, has helped spawn many new startups. An excellent network of mentors and key resources that provide the necessary support to entrepreneurs, on themes ranging from intellectual property filing, to market-making, from regulatory guidance to research monetization.

BIOTECH STARTUPS: A FEW ILLUSTRATIVE EXAMPLES

Startup	Established in	Focus Area
Achira Labs	2009	Developed a proprietary lab-on-chip platform to perform rapid, quantitative and multiplexed immunoassays (protein tests) at a low cost
Affigenix Biosolutions	2012	Engaged in developing innovative biologics, and providing cost effective research services and solutions to meet the specific and ever-changing regulatory landscape
Azooka Life Sciences	2015	Developing safe DNA/ RNA fluorescent stains for applications in biological sciences and genomics.
Bhami's Research Laboratory	2013	Developed proprietary novel crystallization technology for the purification of proteins especially monoclonal antibodies from cell culture, transgenic sources or plasma/ serum etc.
Bugworks	2014	Design of novel solutions for prevention and treatment of Infections caused by superbugs.
BioMoneta	2014	Novel infection control technologies to clear microbial contamination from air and surfaces in ICU settings.
Coeo Labs	2014	Develops innovative medical devices with focus on Emergency, Trauma an d Critical Care.
DF3D Creations	2014	Develops 3D medical models and software to support medical models for surgical planning.
Geniron Biolabs	2013	Animal healthcare start-up developing diagnostic kits for animal diseases, contraceptive vaccines, preclinical services, and custom antibody production services.
Indio Labs Pvt. Ltd.	2012	Developed a new generation of advanced medical technologies that would empower physicians, including the BioScoop™ and BxSeal™ technologies for soft tissue biopsy.
Interpretomics	2009	Big Data startup focused on cloud based software system for next-generation genomics data analysis and interpretation.

Startup	Established in	Focus Area
Pandorum Technologies	2011	Incubated at C-CAMP, the Pandorum technology platform is being utilized to design and manufacture functional, 3D living human tissues for medical research and various other applications.
Pradin Technologies	2013	Developed innovative solutions for value healthcare, including fetal monitors, ECG re-recorders, vision charts for refraction tests.
QTLomics Technologies	2013	Combines the power of traditional and Marker Assisted Breeding Programs with contemporary cutting edge genomic tools to catalyze the hybridization of desirable traits in the crop.
Liveon Biolabs	2011	Delivers on preclinical/non-clinical research requirements of drug discovery and pharmaceutical industry
Sattva Medtech	2014	Developing next-generation fetal health monitoring devices
Sea6 Energy	2010	Aims to derive ethanol fuel from seaweed (particularly red seaweed) that can replace non-renewable energy sources commonly derived from fossil fuels.
Shilps Sciences	2013	Developed solutionsto encapsulate cells in droplets and manipulate them, including cell analysis equipment, and atomic force microscope
String Bio	2013	Developed solutions to capture methane from everyday waste, through IP protected biocatalysts, fermentation processes and downstream purification technologies.
Viravecs Labs LLP	2014	Development of stable cell line development and viral vector production.
Yostra Labs	2014	Developed medical devices for diagnosis of diabetic peripheral neuropathy and diabetic foot ulcer.
Zumutor	2015	Developed platform technologies to deliver novel therapies for disease areas including oncology, rheumatoid arthritis, diabetes and metabolic disorders.

STARTUP CHALLENGES:

▪ For startups working on Medtech and other novel technology areas, the access to funding, and path to market is unknown. It is a journey fraught with risk and uncertainties. Pushing ideas beyond proof-of-concept to validation and scale remains a challenge for most startups beyond the first 18 months. According to BIRAC, only 20-30% of the start-up companies are successful in getting the next stage funding.

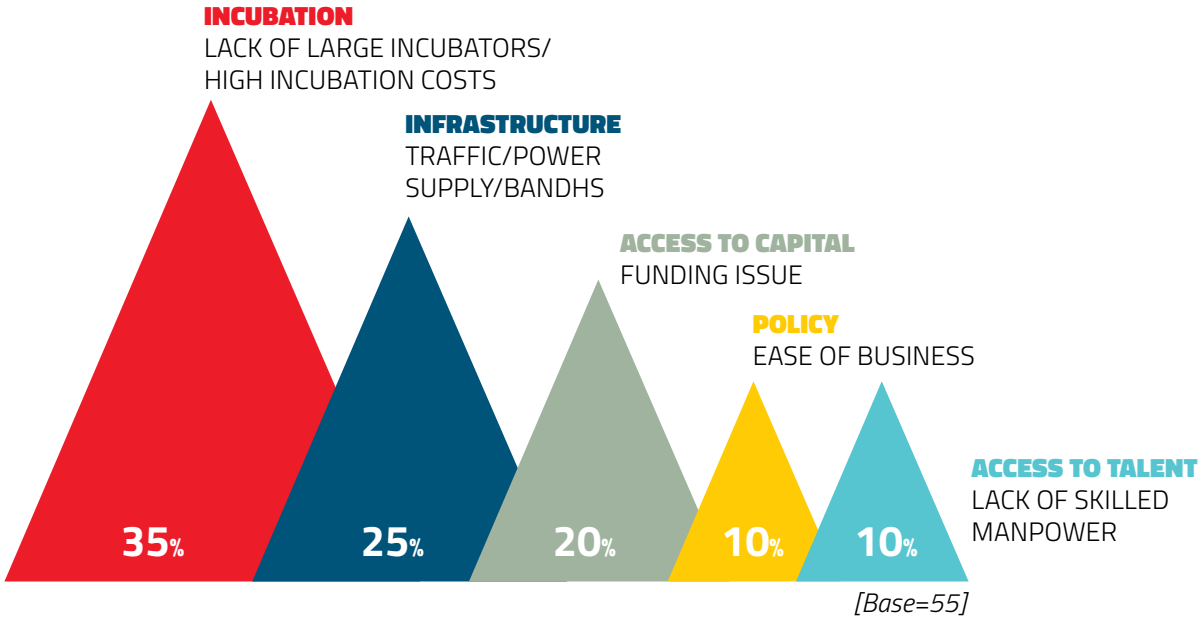
▪ The biotech startup founders are mostly from a scientific background. Some biotech startups do have a mix of technical and scientific skills. However, most entrepreneurs struggle to define their end-market, and their approach to market. As such, there is a need for startups to hire CEO with business acumen and biotech experience.

▪ The uncertainties and lack of awareness on the regulatory landscape remains a big challenge for startups. Startups are looking for expert guidance on regulatory processes.

▪ The avenues for getting mentorship and guidance are few. Startups depend on the Government of India supported biotech incubation centres for mentorship and guidance. While access to quality scientific mentorship is high, the access to mentors with business skills is limited. In addition, identifying such mentors with in-depth expertise on market development is a challenge. In essence, the access to knowledge networks remains a big challenge.

▪ Funding is the biggest challenge for biotech startups in Karnataka. Most

STARTUP: TOP CHALLENGES



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biotech startups depend on their own funds, and those from angel investors and government funding for their journey from initial idea to proof-of-concept stage. Beyond the PoC stage, the journey to market is fraught with risk and uncertainties.

- Biotech startups in Karnataka are incubated in centres of excellence, and other incubators. There is a perception amongst startups that the cost of incubation is very high and prohibitive for startups.
- The interaction of startups with established homegrown and foreign biotech companies is very limited. There is a perception amongst startup community that dedicated avenues for facilitating such interactions would be helpful.
- The talent gap is a challenge that the startup industry is facing. There is paucity of technical and soft-skill sets amongst fresh graduates.
- Lastly, very limited incubation space availability becomes a hindrance to allow the established startups to move from small to the medium category.

SUGGESTIONS TO KBITS:

1. The IT and BT sectors inhabit different worlds, and one single Startup policy should not address both sectors. While IT offers a clear visibility on returns on investment, the pathway for biotech startups is uncertain, and has a long journey from technical PoC stage to the market. There exists a perceived need amongst biotech startups for a Biotech Startup Policy that addresses the requirements of the biotech startups. Similarly, there is a need for a separate MedTech vision that addresses the medtech startups.
2. There is a clear need for awareness generation on State policy incentives, as most biotech startups indicated being unaware of available funding from Government of Karnataka, and in instances, where they did become aware, it was much closer to the funding deadline.
3. To encourage startup culture in State Universities across Karnataka, seed funding should be provided to scientists between 50 lakhs to 1 crore.
4. State Universities lack the experience in establishing and managing startup incubators, and infacilitating startup culture. As such, there is a need to prepare a network of business mentors for guiding startups at State Universities, especially those specializing in Agriculture.
5. A provision of risk funding or next stage funding for all the start-ups, which may not have the funds to proceed further after receiving the initial grant, for establishing proof of concept would be helpful.
6. A clear pathway with detailed processes for assessing startups for initial funding based on merit, novelty and marketability of the product should be established, so that their next stage funding chances are improved.
7. BengaluruBio India conference offers an excellent platform for networking and learning for SMEs and established companies. According to some early-stage biotech startups, the BengaluruBio was not an appropriate platform for them.

Instead, a focused biotech startup platform would benefit such startups, and will re-emphasize the image of KBITS as a facilitator. Such a platform would provide knowledge networks and linkages to markets, finance, human capital, regulatory guidance. Most importantly, such a platform would facilitate interactions between entrepreneurs at the early stage, and successful startups that have transited beyond the technical PoC stage.

8. The Idea2POC program in the Karnataka Startup Policy offers funding for INR 50 Lacs. According to biotech startups, while this is a good initiative, the funding offered is not adequate for biotech.
9. Currently, funding is available for new startups and established startups. There is a need for gap funding (between early-stage DBT funding and mature/late stage VC funding) for those startups that are in between.
10. The funding agencies have excellent technical acumen, and vast scientific knowledge. However, biotech startups feel there needs to be more understanding with respect to the go-to-market approach, and marketing.
11. There needs to be more advocacy for creating clarity in the regulatory environment. Work with the Central Government to ease the regulatory pathway, and create awareness of the regulatory procedures for startups.
12. It is important to create common facilities and resources for prototyping and instrumentation available to startups.
13. Efforts must be put into making land and funding available for setting up commercial ventures for those start ups, which are successful in developing commercially viable products/technologies.
14. Biotech startups in Karnataka are incubated in centres of excellence, and other incubators. There is a perception amongst startups that the cost of incubation is very high and prohibitive for startups. Alongside the human capital at such incubators should be agile, and responsive to the needs of the startup community.
15. Nurture existing Incubation facilities like C-CAMP, by investing for more capacity building.

10

EDUCATION AND SKILL DEVELOPMENT

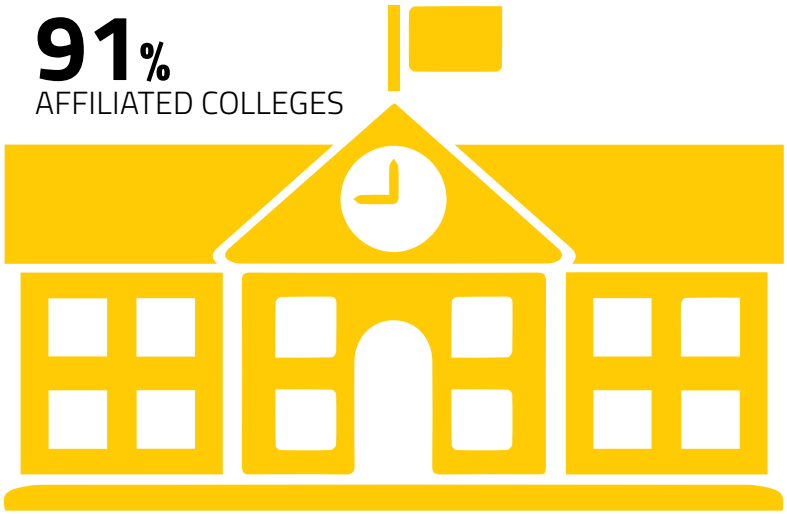
THE EDUCATION INFRASTRUCTURE IN KARNATAKA

Karnataka is placed second in terms of number of universities offering biotech courses at the undergraduate and post-graduate level, including engineering courses. Karnataka is home to a diverse range of specialized universities offering programs, ranging from Agricultural Biotechnology, to Biotech Engineering. At the PG Level, 80% of the colleges are offering Biotechnology programs.

UNIVERSITY EDUCATION

Karnataka is ranked first in India in terms of total number of state public universities, with 25 public universities. It also has 5 Agricultural universities, the highest in India. In comparison to the India's average of only 25 colleges per lakh population, Karnataka has 44 colleges per lakh population. However, the average enrolment per college in Karnataka is only 436, considerably lower than the national average of 715. The Pupil-Teacher-Ratio (PTR) of colleges in Karnataka is 10.1 students per teacher, which is higher than the all-India average of 14.9.

TYPES OF COLLEGES



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5%
RECOGNIZED CENTRES

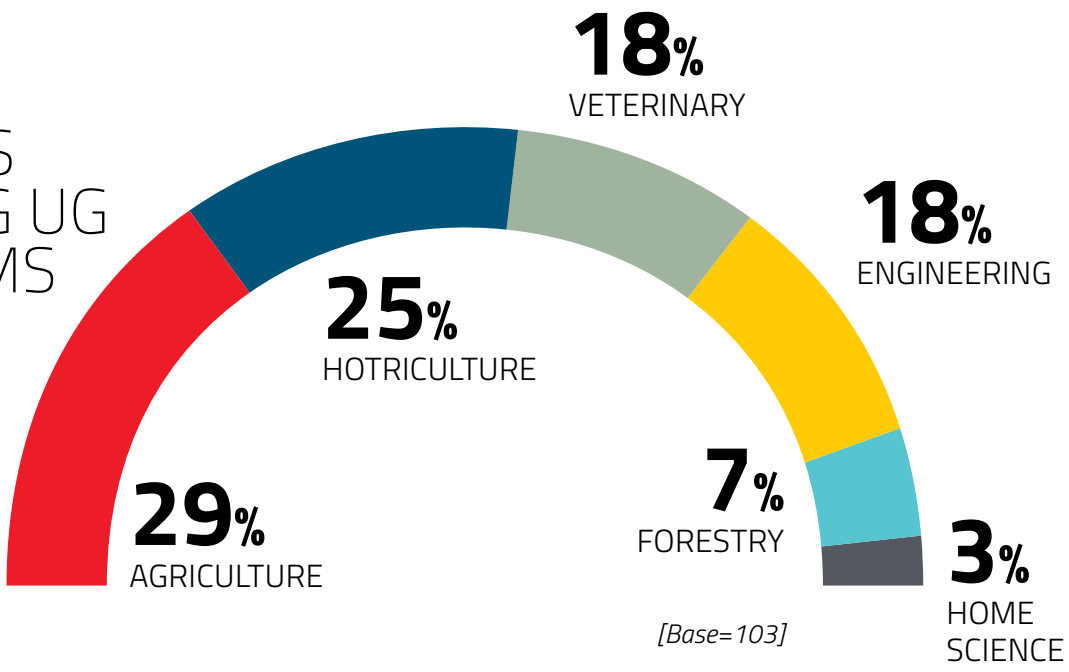
3%
CONSTITUENT/ UNIVERSITY COLLEGES

1%
PG/OFF-CAMPUS CENTRE

The colleges in Karnataka comprise predominantly of affiliated colleges, followed by recognized centres, university colleges, and off-campus centres.

In terms of gender, enrolment is skewed, as 58% comprises males, while only 42% of the enrolment is females, indicating gender disparity. The total number of teaching staff and non-teaching staff in all colleges in Karnataka is estimated to be 1.39 lakhs and 0.98 lakhs, respectively. But the ratio of teachers per college and non-teaching staff per college are 43.3 and 30.7, respectively, which is lower when

COLLEGES OFFERING UG PROGRAMS



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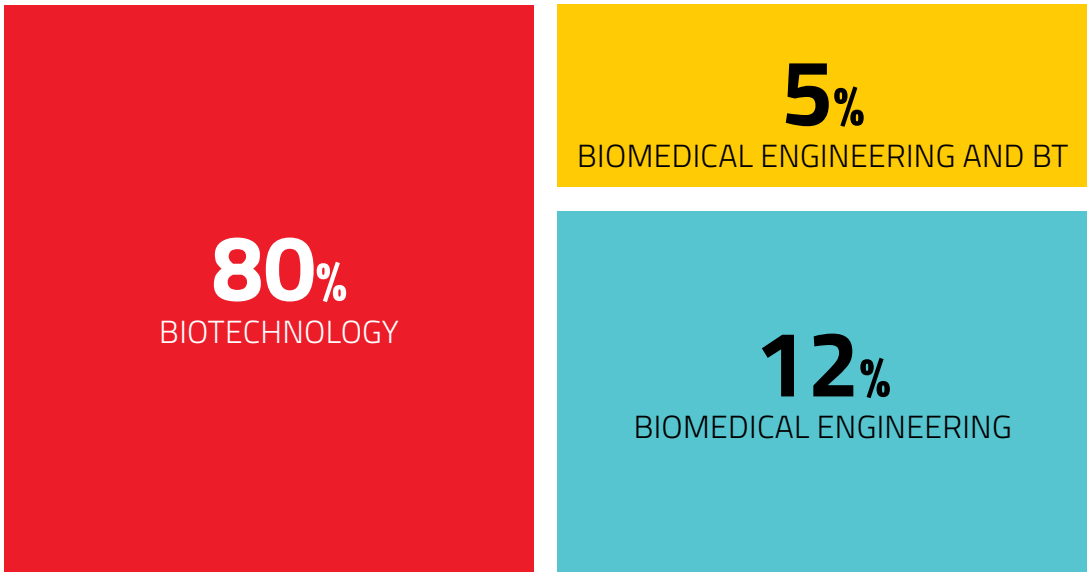
COLLEGES OFFERING PG PROGRAMS



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compared to all India average of 47.9 and 32.9.[102]

At the UG Level, Karnataka offers biotech programs across agricultural biotechnology, biotech engineering and other streams, including forestry and horticulture.

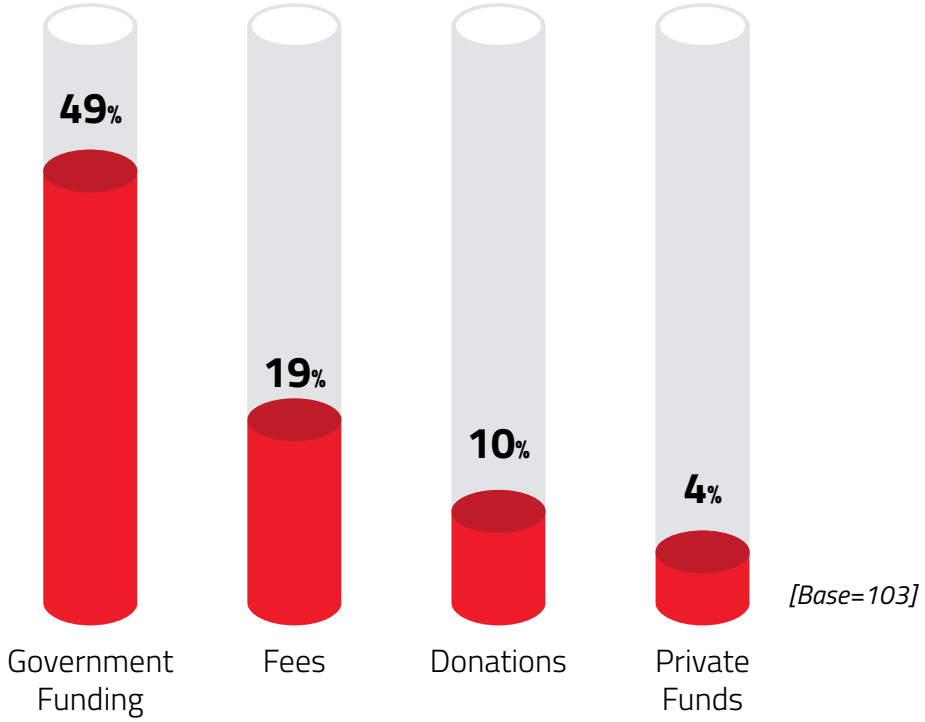
At the PG Level, the biotechnology programs include general biotech programs, dual-degree programs in biomedical engineering and biotechnology, as well as in pure biotech engineering.

FUNDING SOURCES FOR RESEARCH

Government is a major source of funding for research programs at universities. The funding comes through competitive grants for which universities vie for potential research projects, are evaluated and only the most promising receive funding.

In addition to government funding, stakeholders indicated donations from philanthropic agencies for driving the research programs at universities. In most cases, student fees are what contribute to research initiatives at institutions. Lastly, private funds also contribute to the research programs to a small extent.

SUPPORT FOR RESEARCH PROGRAMS AT ACADEMIA



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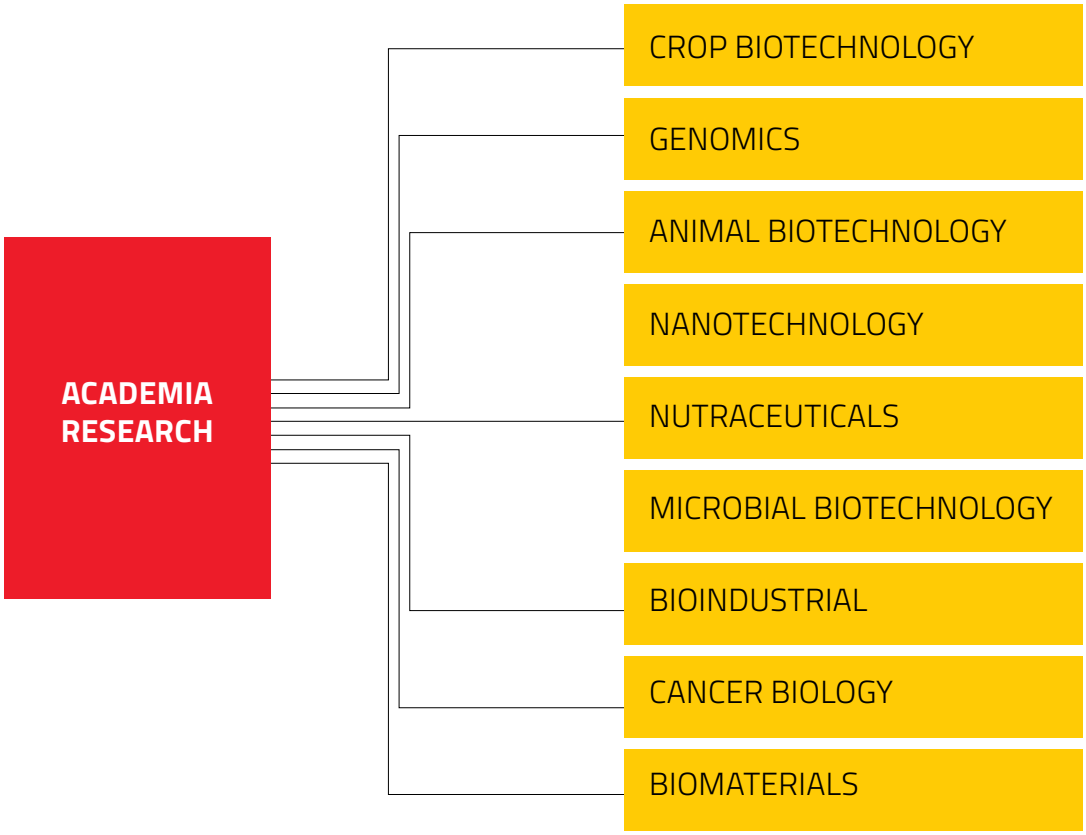
MAJOR AREAS OF RESEARCH

Universities are the centres of basic and translational research. Academic and Research institutions in Karnataka undertake specialized and cross-disciplinary research across a range of focus areas in Biotechnology- ranging from crop biotechnology to genomics, from bioinformatics to biofuels. The research faculties have diverse research interests that shape the research projects at the research institutions.

Some of the major research areas are illustrated below. This is not a complete list of all research focus areas.

SELECTED AREAS OF RESEARCH



TRENDS IN RESEARCH PUBLICATIONS

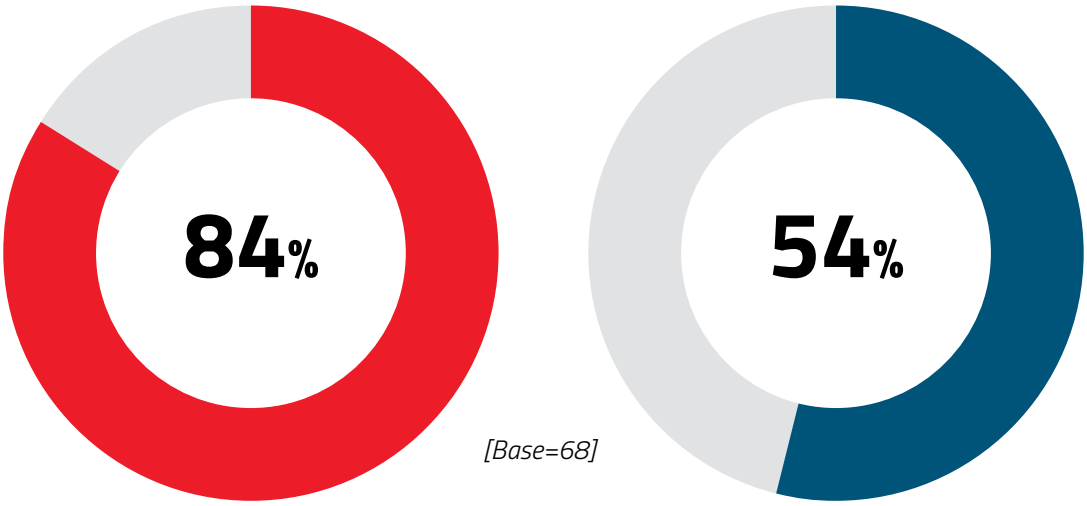
One of the important indicators of scientific growth in fundamental research is in the form of research publications. The number of research publications contributed by a nation towards the global output is considered as one of the indicators of the research strength of a nation.

According to the KBITS Survey, academic and research institutions are focusing more on publishing research papers in international publications, as compared to national publications. This reflects a developing trend amongst stakeholders surveyed in the KBITS Survey, and is a good indicator of highly meritorious progress in research outputs.

FOSTERING TRANSLATIONAL RESEARCH

The academia faces some key challenges when fostering an innovation-based translational research culture. These include a traditional focus on publishing research, low awareness of IP and Innovation issues, and severe funding constraints to focus on innovation.

ESTABLISHMENT OF IP/STARTUP CELLS



The centres of research excellence in Karnataka exhibit higher level of collaborations with industry, and increased propensity for filing patents. The faculties at such institutions also have varying degrees of academic freedom to participate in industry-sponsored research, or academia-industry collaborations. There is increased level of translational research at such centres. This, in turn, translates into new biotech startups incubated on campus.

Going beyond the centres of excellence, the KBITS Biotech Survey finds that academic and research institutions in Karnataka are responding to the changing world realities by beginning to focus on translational research.

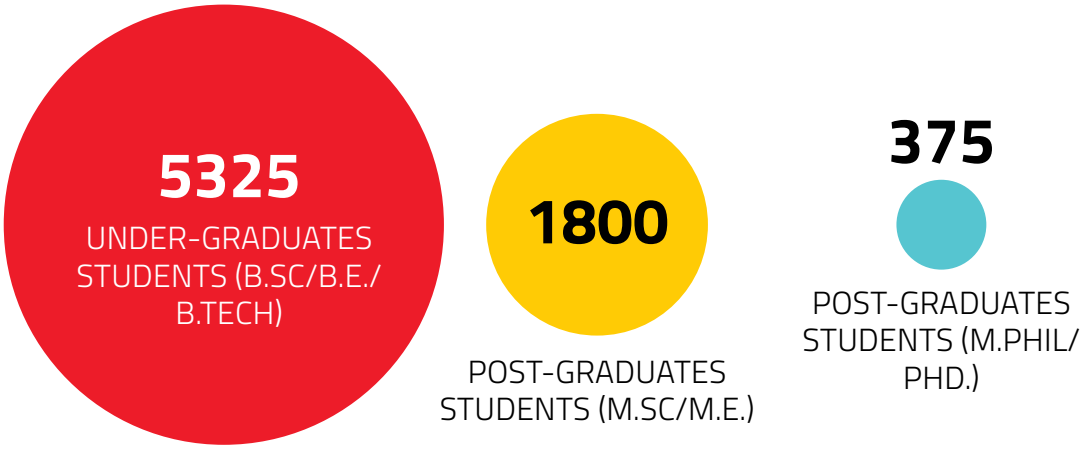
While the focus continues to be on basic research, the Survey points to a healthy number of research institutions that have established IP/Technology Transfer Cells, and Startup Cells to foster entrepreneurship.

This trend needs to be evaluated over the long-term to see the shift in innovation culture, and how much it does.

BIOTECH GRADUATES IN KARNATAKA

According to the KBITS Biotech Survey, 7500 biotech graduates from Karnataka enter the workforce annually.

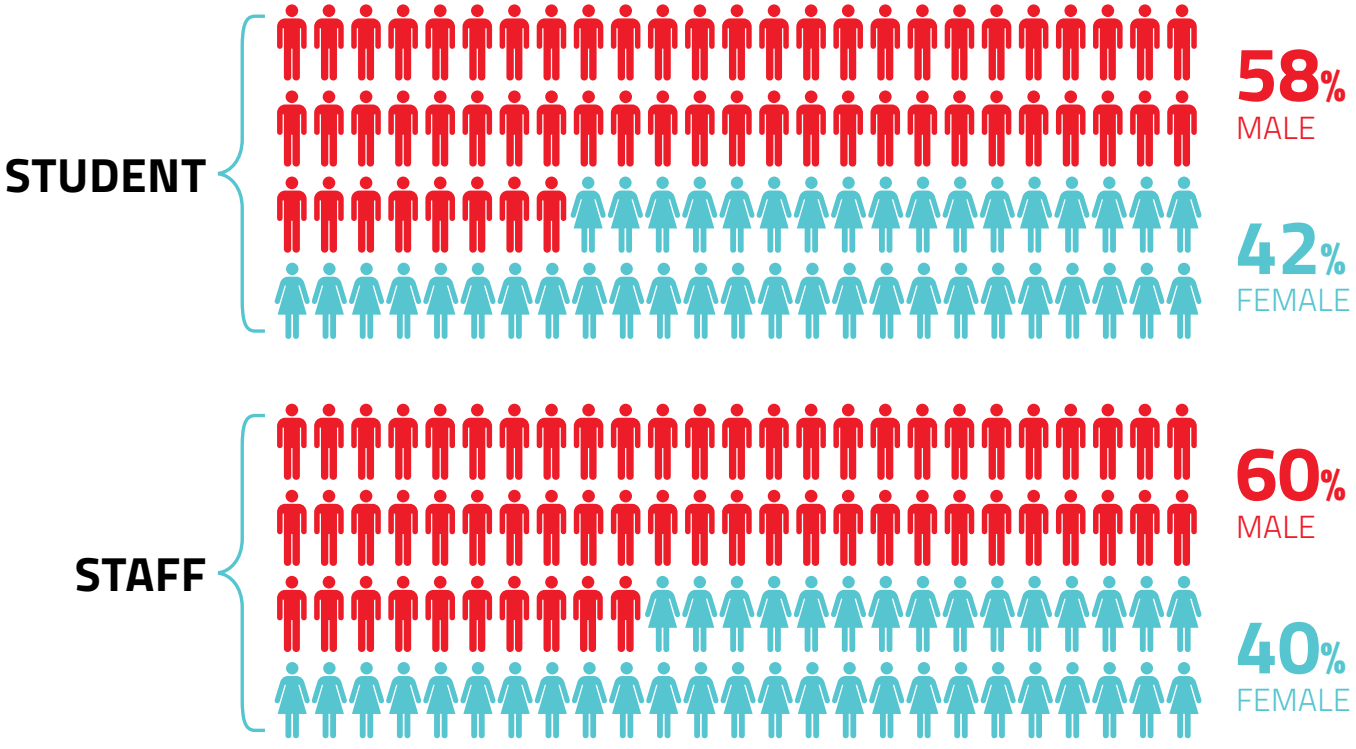
BIOTECH GRADUATES IN KARNATAKA



DIVERSITY IN ACADEMIC AND RESEARCH INSTITUTIONS

The academic institutions in Karnataka provide employment to approx. 817 professionals as staff.

DIVERSITY OF STUDENTS AND STAFF: BY GENDER



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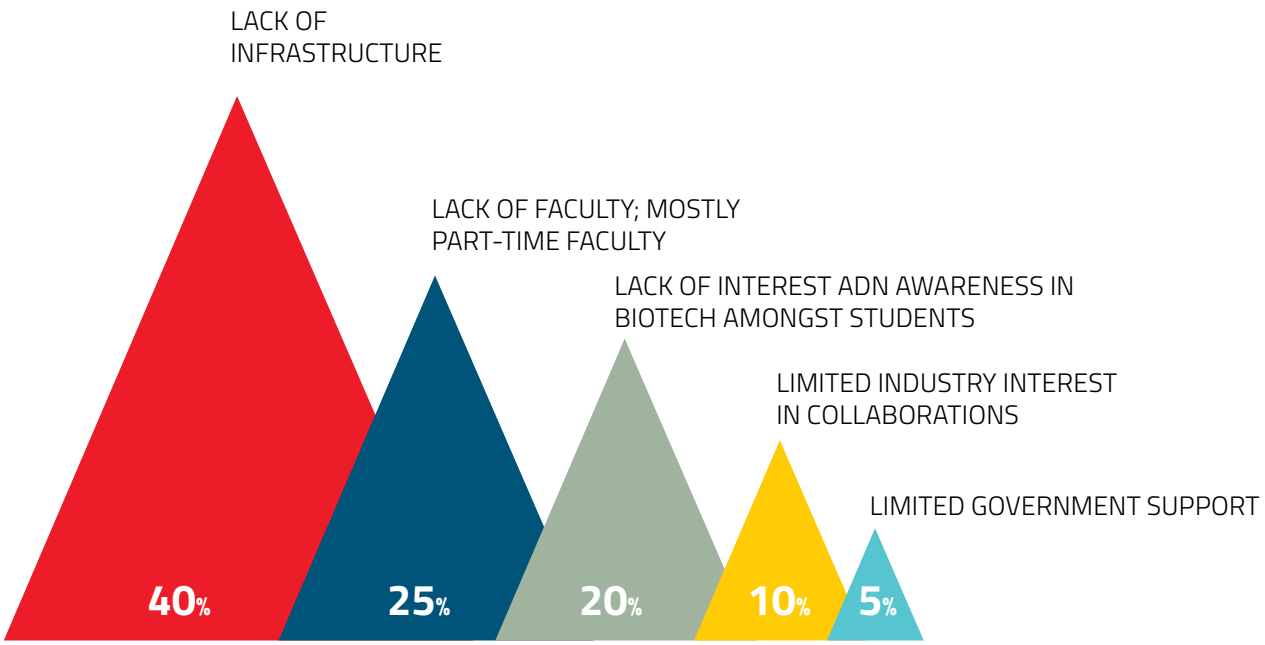
The gender diversity at student and staff level amongst academic institutions in Karnataka is slightly tilted towards males, with good representation of women too.

In terms of geographic diversity, majority of students and staff are from Karnataka.

Beyond the centres of excellence, the existing infrastructure in universities is perceived by the academia as being too limited to support biotech research. The supporting lab infrastructure is rudimentary due to the severe financial constraints that colleges find themselves in.

According to Survey respondents from academia, there is drastic reduction in number of students interested in pursuing biotechnology programs at the UG level. The lack of awareness of challenges in the nation and the lack of awareness of the role biotechnology can perform to find solutions to challenges amongst students are the reasons attributed to the decline in admissions. In addition, biotechnology does not command the same buzz or brand equity that ICT does. All of these reasons are contributing to the limited interest in biotechnology courses at UG level. Even beyond UG, there is very limited interest in pursuing academic and research careers through PG specializations.

CHALLENGES OF ACADEMIA



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The diminishing interest from students to pursue biotechnology programs translates into a similar challenge for retaining full-time faculty. In addition, the low salaries translate into limited or no interest from faculty to continue with full-time careers. Most teachers pursue other opportunities to support themselves financially.

There is a perception amongst academia of limited industry interest in research collaborations. While this may not be true of the centres of excellence such as IISc, NCBS, JNCASR and UAS, this perception is more prevalent amongst academia located beyond the biotech hotspot of Bengaluru.

Lastly, while there is acknowledgment of government support, there is also some perception of the support being limited from government for academia. The expectation is for increased government funding for infrastructure upgradation and for research lab equipment. All of the above, points to an increased need for awareness generation by the KBITS for sensitization on initiatives aimed at academia.

According to the KBITS Survey findings, to encourage the culture of research and innovation, a culture of incentives should be introduced to encourage the faculty contribution through research and publications. In addition, more focused faculty-exchange programs across universities in Karnataka and other regions should be available. Short-term faculty retraining programs would help the faculty with keeping abreast with latest technologies and trends, and would help them in tailoring pedagogy.

VOCATIONAL EDUCATION

The economic progress of the state is directly related to the development of Technical and Vocational Education System.[103] States that have invested and made progress in skill development have been able to attract higher private investments. [104]

Karnataka was the first state to introduce vocational education in India.[105] By integrating vocational education into higher education, and supporting it with additional capacities across research institutions, the State is contributing to creating awareness amongst students of opportunities and career pathways available for them to pursue.

Industry plays a strategic role in ensuring the growth of vocational training system as no government can accomplish desired goals and show results without the active participation of industry.

The key challenge for vocational education is the absence of sufficient theoretical backing provided for the information given in a course. In other words, without experiential learning, the learner cannot understand the nature and responsibilities of various skill-sets. A vocational education in rural Karnataka that focuses on agriculture or dairy farming would ensure that such vocations are sustainable over the long-term, and contribute to the development of a professional base. This,

in turn, will contribute to a culture of entrepreneurship leading to higher farm incomes and reduction in poverty levels.

SUPPLY OF BIOTECHNOLOGY SKILLS

The challenge for finding, attracting and retaining human capital is more defined now, than ever before, with only a small number of highly educated and experienced personnel available for key roles.

Regulatory affairs, clinical research and project management are skill areas experiencing excess market demand, which correspond to occupations that constitute a small fraction of the employment within the biotechnology sector. On the other hand, scientific expertise is a skill set experiencing meager market demand corresponds to occupations that contribute to the largest proportion of employment in the role of biotechnology sector.

For instance, one of the findings of the KBITS Study is that there are no specialized programs for stem cells and other new topics (for example, role of Microfluidics in Cell Biology; and Neurosciences). The current workforce is more exposed to technology domains such as plant pathology, fermentation, microbial technology etc. Given that, stem cell research companies have to depend on training new resources at a high cost.

ROADMAP FOR IDENTIFYING JOBS WITH CLEAR PATHWAYS

For economic growth and societal development, skill development is essential. When one looks at the changing demographic dividend of India, skill development is imperative to ensure industry-ready skills for >12 million youths entering the workforce annually.

The key drivers for economic growth include skills and knowledge that can help in adapting to the changing business and world realities. In imparting quality skill training to the youth, there are several challenges that are faced by the government.

The current capacity and capability of the existing skill training ecosystem is meager and under stress. So, the first challenge for Government is to increase the current capacity to ensure availability and accessibility of skill development initiatives for all. The other challenge relates to making training content relevant to changing industry needs. Besides core technology expertise, familiarity with other needs such as Biosafety, Teamwork, Accountability, Meeting deadlines, etc. are very important. While doing so, there is a need to ensure that the priorities of school education and skill development initiatives of the Government are aligned. Lastly, institutional mechanisms for enabling research infrastructure development, accreditation, and adequate investment for skill development need to be forged.

Karnataka faces the challenges arising from a severe scarcity of highly and suitably trained research personnel, as well as the emergence of new educated

workforce with little or no industry-ready job skill-sets.

The performance of a skill development ecosystem is dependent on multiple dimensions and attributes, and the interactions that drive them.

An ideal skill development ecosystem is one that makes learning and skill development available and accessible to citizens from all communities in the local contexts they live in. And also, learning how to learn with easily accessible resources.

SKILL DEVELOPMENT ECOSYSTEM- KEY ELEMENTS

- ACCESSIBILITY AND AVAILABILITY
- FACULTY UPGRADATION
- QUALITY IN EDUCATION
- INDUSTRY ORIENTATION
- EDUCATION INFRASTRUCTURE
- MANAGEMENT AND GOVERNANCE

Faculty, infrastructure, industry interface and curriculum development are the key dimensions that define the quality in technical education. Pedagogy and curriculum design, teaching assessment and delivery are the key factors that need to be addressed continuously.

The existing education infrastructure needs to be expanded to meet the requirements of the industry as well as the increasing number of new students graduating from schools. The expansion of the education infrastructure will cover both technical infrastructure, including new IT requirements and biotech lab requirements, as well as physical infrastructure, including smart (electronic) classrooms and recreational facilities.

The shortage of competent and permanent faculty is a major impediment in maintaining and delivering quality education. One of the findings of the KBITS Survey is the lack of exposure of faculty to changing technological developments. Capacity building for faculty through faculty development programs and faculty exchange programs needs to be developed.

For enabling industry-ready workforce, it is important to develop and sustain industry linkages by tailoring curriculum to industry requirements, and by enabling

greater industry-academia collaborations through on-the-job skill development programs as well as through faculty development programs. Measured against this challenge, the BTFS program has had a positive impact in Karnataka on enabling the workforce (see below).

INVESTMENT IN SKILL DEVELOPMENT: KARNATAKA VS. OTHER STATES IN INDIA

Karnataka is one of the first states in India to focus on specific skill development in biotechnology, by recognizing the challenges arising from the mismatch of skill-sets, and lack of experiential learning. While other States have also started offering skill development programs, Karnataka has been able to leverage its biotech ecosystem better and, as such, make an impact with its skill development initiatives.

BIOTECHNOLOGY FINISHING SCHOOL PROGRAM

The Millennium Biotech Policy-II of the Government of Karnataka set-up in 2011 the Biotechnology Finishing School (BTFS) to impart skill development by providing appropriate course content and duration to equip students with industry-ready skill sets. It is a two-semester program with the first one focusing on learning more about a particular domain of biotechnology (e.g. Protein Expression & Scale-up) in a class room and academic type of laboratory in a host institution and the second one as an intern in a relevant biotech company to learn more from the industry perspective.

With intent to bridge the gap between industry requirements and quality of graduates, the now-renamed Biotechnology Finishing School program, Biotechnology Skill Enhancement Program (BiSEP) provides students with the experience of real-life industry-oriented experience working on challenges, which are not covered in regular academic curriculum.

The BTFS Program was started in 2011 at 12 host institutions in Karnataka and have been offering PG Diploma courses since then. The program has gained acceptance and popularity amongst biotechnology students, and has received a good response from the industry in terms of job internships and job placements. They have increased steadily from year to year. So far, >800 students have taken up the course with placement record of ~75%.

INDUSTRY PERSPECTIVES ON BTFS

The BTFS program provides practical exposure and experiential learning to equip biotech students with practical skill-sets that enable them to take up jobs in the biotech industry.

The biotech industry has been encouraged with the quality of students graduating from the course, and appreciative of the skill development initiatives

undertaken.

Through the BTFS, biotech students are able to get hands-on experience in an industry environment. They are also able to gain experience in understanding industry expectations and requirements.

Industry is able to assess and evaluate the technical and soft-skills of the trainees during the training period, and match it with their skill requirements. This also helps them in cutting short the time required for new talent acquisition.

Though the industry and government invest so much in skill development, there is a perceived mismatch between the aspirations and aptitude of the trainees to pursue a serious career in Biotechnology:

Some trainees join the program, as they may not have found other job options at the time.

In the case of other trainees, once placed, they eventually drop out to pursue higher studies, or shift to a different career altogether within 1-2 years.

A third category of trainees comprises of those who, once placed, seriously pursue their biotech careers. However, their lack of a PhD degree acts as a barrier for further career growth post 5-6 years.

The industry perceives that there is continuous need to reorient skill development initiatives.

For BTFS Program to be more successful and to have more impact, KBITS must focus on alternative career pathways for fresh graduates, and tailor newer initiatives to suit the industry requirements as well as the aptitude of the newly enrolled students.

The BTFS can also have a specific focus on biotech startup sector. The startup sector has a felt need for new interns and research students.

A steering mechanism has to be devised to identify committed students aspiring a career in biotechnology.

While the focus on developing skill-sets for novel R&D has been a key focus for skill development, the reality is that R&D functions account for only 10-15% of the workforce. As such, there is a perception that there should be increased focus and efforts for skill development on other important biotech functions, including marketing, communication, regulatory affairs, intellectual property management, industrial processing, and clinical roles, among others.

Beyond the Government initiatives in skill development, the challenge for identifying candidates with industry-ready skill-sets continues to be huge.

INDUSTRY INITIATIVES IN SKILL DEVELOPMENT

The challenge for the industry stems from the lack of candidates arising from general degree courses such as BE, B.Sc., MSc., MTech and so on with industry-ready skills. There is a huge gap between the availability of qualified human capital and the changing industry needs. In addition, students specialized in a particular

technical domain, face challenges in adjusting and learning new skills on the job. Only few graduates are able to secure an employment of their choice, and the rest make adjustment and find unrelated career opportunities in the BPO sector, and bemoan the higher salaries that the ICT sector pays.[106]

At the UG level, the absence of necessary laboratory infrastructure translates into graduates with very inadequate knowledge skills for industry. For instance, the technicians working in stem cell research are few and availability of new skill sets is tough. This leaves the industry with a challenge to either hire general Biotechnology students, or hire fresh lab technicians and train them. The dearth of fresh available talent means the talent gap gets compounded. This, in turn, translates into companies having a challenge in retaining existing candidates. Attrition remains a challenge for industry. Industry must take a lead role in forecasting future needs and initiate appropriate programs in colleges offering courses in life sciences. It would serve the industry well, if they have a long-term memorandum of agreement to ensure a reliable supply of high caliber graduates.

Across domains, from BioPharma to BioIndustrial, the challenge also stems from the long cycles of upto a year to get candidates skilled and contribute. Given the tough project timelines, industry can rarely adjust and accommodate such long cycles for training new candidates.

To address the evolving skill requirements of the industry, it is important to move beyond theoretical knowledge, and equip students with practical project training in specialized biotechnology domains.

The Biotech Finishing School (BTFS) Program in Karnataka imparts industry-focused, industry-ready professional skills to increase the employability.[107] These institutes aim at imparting professional skills to biotech graduates to make them employable across the sector. In addition to the BTFS, the Biotech Industry in Karnataka actively promotes skill development through specific initiatives, including Industry Biotech Finishing Schools; Competency Training Programs, and Training Programs on topical themes, including: Bioinformatics, Systems Biology, Stem Cells, Intellectual Property Management.

While BTFS and other avenues equip students with industry-ready skills, the challenge for industry continues to be the absence of experiential learning, and the long lag for new employees to start contributing productively to the R&D process and timelines.

ACADEMIA INITIATIVES IN SKILL DEVELOPMENT

Complementing the industry initiatives and those spearheaded by Government, the academia also undertakes new initiatives for skill development. These include practical lab training, industry exposure trips and industry training programs, workshops for soft skills as well as technical skills in new technology areas, guest lectures, and conference visits at national and state level.

Research Lab sessions and hands on training is being given more emphasis across institutions with opportunities for biotech students to undertake in-house research projects.

Academia also provides technical skills in nanotechnology, molecular modeling, drug discovery and genomics, as well as in biofertilizers.

KEY ECOSYSTEM CHALLENGES

There is a declining interest amongst students for pursuing biotech programs at UG and PG level. The number of students enrolling for biotech programs is continuing to dip over the last few years. According to academia stakeholders, beyond the UG level, the number of students undertaking MSc and PhD programs shows further dip.

Funding is a critical challenge for academia, given that biotech research is capital intensive. The existing infrastructure in research institutions is limiting and is not conducive for enabling biotech research. Stakeholders indicated a lack of funding, or availability of limited funds for acquiring new high quality research instruments for research labs. The cost of such instruments is very high, and is not affordable for most institutions. In most instances, the funding grant available is not sufficient to meet the actual laboratory infrastructure requirements of academic institutions. As such, there is a need for continuous communication between research institutions, and funding agencies as well as policy makers.

Pedagogy in universities is not evolving to keep pace with the evolving technologies, and needs of industry. The slow rate of change or up gradation of academic syllabus in universities causes severe limitations for fulfilling industry skill requirements.

Stakeholders also indicated limited fora for interactions between industry and academia, posing a challenge for the uptake of translational research. In the absence of such interactions, the faculty at academic institutions do not get avenues to learn, or get adequate exposure to new technologies and research trends. There is a high attrition rate amongst qualified faculty that adds to the challenge. Given the low salary levels, the teaching staffs tend to move in search of new jobs.

In order to bring increased attention and focus on biotechnology at all levels, it is critical that the key leadership at political, administrative and academic level is able to tackle prioritized challenges through biotech solutions.

SUGGESTIONS TO KBITS:

1. Experiential learning models should be built-upon at the classroom as well as through industry exposure, by streamlining and complementing existing KBITS initiatives for skill development.
2. Industry-Academia Platforms should be further enabled to support the continuous learning and professional development of academicians and scientists

in Karnataka. Such platforms would support and contribute to the learning around new technologies, and enable wider adoption of best translational research practices.

3. Capacity building for faculty through faculty development programs and faculty exchange programs needs to be further refined and developed.

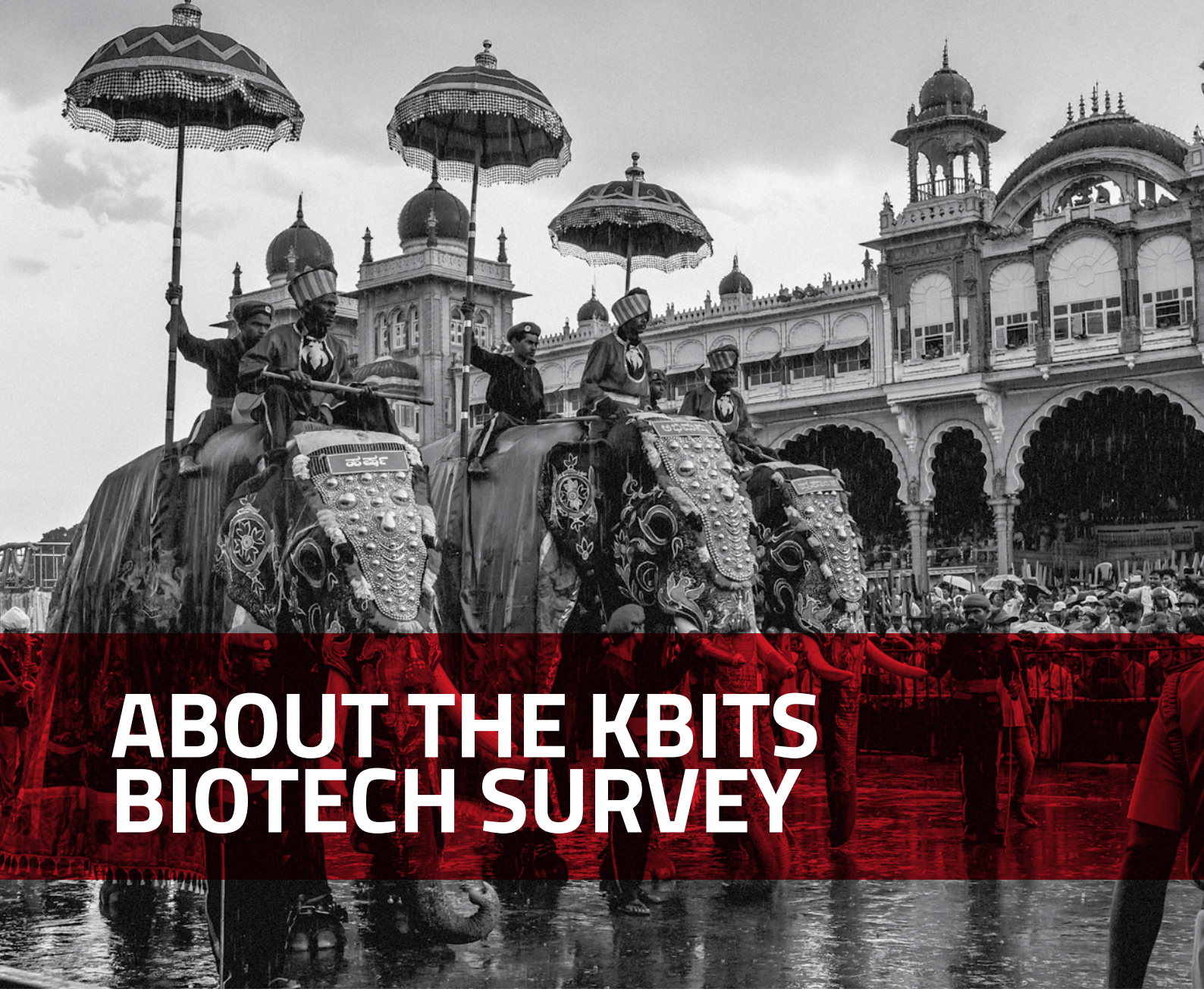
4. Biotech research, being capital expensive, requires continuous funding support. The funding mechanisms by State Government should further support and augment vital research infrastructure at academic institutions.

5. Platforms to support continuous dialogue between academic institutions and funding agencies would support in garnering insights on pressing funding challenges faced by academia in furthering biotech research.

6. Customized Skill development pathways would support retention of trained talent, and in turn, contribute to meaningful employment metrics over the long-term.

7. Continuous quality audits of higher learning centres in terms of student intake, and research outputs should be further augmented, to bolster the research capabilities of the industry.

8. Going beyond the focus on R&D, the focus of skill development initiatives should also include providing biotech students with adequate exposure and incentive to prepare and opt for career pathways in other equally important biotech functions, including marketing, communication, regulatory affairs, intellectual property management, industrial processing, and clinical roles, among others.



ABOUT THE KBITS BIOTECH SURVEY

The KBITS Biotech Survey 2016 is a study by ABLE and CMR in Karnataka, to assist KBITS- Department of IT BT and S&T, Government of Karnataka, to suggest and implement changes to help further growth of the biotech sector.

The survey was conducted from June 24, 2016 to September 1, 2016 through online, telephonic and face-to-face interviews, reaching out to about 420 stakeholders from industry, startups and academic/research institutions.

There were three different survey questionnaires, aimed at the industry, startups and academia, dealing with the individual stakeholder profiles and their perspectives on the biotech ecosystem.

The results discussed in this report are based on the responses of 307 stakeholders, comprising 148 companies, 104 academic and research institutions, and 55 startups. The respondents included CEOs, CSOs, CFOs, VPs, Directors, Academic Heads, Deans, Entrepreneurs, and other senior personnel.

ABBREVIATIONS USED IN THIS REPORT

APAC	Asia-Pacific
BA	Bioavailability
BBC	Bangalore BioInnovation Center
BE	Bioequivalence
BIG	Biotechnology Ignition Grant
BIPP	Biotechnology Industry Partnership Programme
BIRAC	Biotechnology Industry Research Assistance Council
BiSEP	Biotechnology Skill Enhancement Program
BRAI	Biotechnology Regulatory Authority Bill
BT	Biotechnology
Bt	Bacillus thuringiensis
BTFS	Biotechnology Finishing School
C-CAMP	Centre for Cellular And Molecular Platforms
CAGR	Compounded Annual Growth Rate
CDSCO	Central Drugs Standard Control Organization
CFTRI	Central Food Technological Research Incubator
cGMP	Current Good Manufacturing Practice
CHG	Centre for Human Genetics
CMO	Contract Manufacturing Organization
CRO	Contract Research Organization
DBT	Department of Biotechnology
DCGI	Drug Controller General of India
ELISA	Enzyme-linked Immunosorbent Assay
EU	European Union
FDA	Food and Drug Administration
FSSAI	Food Safety & Standards Act
FTE	Full-Time Equivalent
GCP	Good Clinical Practice
GER	Gross Enrollment Ratio
GM	Genetically modified
HIV	Human Immunodeficiency Virus
IABT	Institute for Agriculture Biotechnology

IBAB	Institute for Bioinformatics and Applied Biotechnology
ICT	Information and Communication Technology
IHP	The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IIHS	Indian Institute for Horticultural Sciences
IISc	Indian Institute of Science
IN-CITE	International Centre for Innovation, Technology Transfer and Entrepreneurship
IP	Intellectual Property
IT	Information Technology
IVRI	Indian Veterinary Research Institute
JNCASR	Jawaharlal Nehru Centre for Advanced Scientific Research
KSCST	Karnataka State Council for Science and Technology
KVAFSU	Karnataka Veterinary Animal And Fisheries Sciences University
MAS	Marker Assisted Selection
MOHFW	Ministry of Health and Family Welfare
MSCTR	Mazumdar Shaw Center for Translational Research
MT	Medical Technology
NBDS	National Biotechnology Development Strategy
NCAER	National Council of Applied Economic Research
NCBS	National Center for Biological Sciences
NGS	Next Generation Sequencing
NIMHANS	National Institute of Mental Health and Neuro Sciences
PE	Private Equity
PG	Postgraduate
PoC	Proof of Concept
PTR	Pupil-Teacher-Ratio
R&D	Research and Development
S&T	Science and Technology
SBIRI	Small Business Innovation Research Initiative
SID	Society for Innovation and Development
SIPI	State Investment Potential Index
SMDP	Sectoral Manpower Development Fund
TBI	Technology Business Incubator
UAS	University of Agricultural Sciences
UG	Undergraduate
UHS	University of Horticultural Sciences
US	United States
VC	Venture Capital
WIPO	World Intellectual Property Organization

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KBITS

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