



KARNATAKA

BIOTECHNOLOGY Policy 2017-2022



SIDDARAMAIAH
CHIEF MINISTER

CM/PS/184/2017



VIDHAN SOUDHA
BENGALURU - 560 001

Date: 14-11-2017

MESSAGE



Karnataka was the first State in the country to introduce a Policy on Bio-Technology, when the Bio-Tech sector was in a nascent stage. The "Millennium Bio-Technology of 2001, followed by the" Millennium Bio-Technology Policy-II, in 2009, have been instrumental to a great extent in bolstering the development of an eco-system for the Bio-Tech sector to grow and flourish.

We are aware of the impact that Bio-Technology has on the society, especially in Agriculture, Health, Medical, Energy and Environment. We also recognize the need to continually change the policy to meet the changing needs of the sector.

Our Government is known for its pro-active policies aimed at promotion and growth of various sectors of the economy. We have announced a new policy for the Bio-Technology sector, to reinforce capacity building, Infrastructure development, research institutions for the emerging technology areas such as Anti-microbial resistance, Agri-biotechnology, Bio-informatics among others, which are expected to offer innovative solutions. We are grateful to the Vision Group on Bio-Technology, which has given inputs to our Government for the new policy.

I am confident that the Karnataka Bio-Technology Policy 2017-2022 will give a big boost to the various segments of the Bio-Technology sector.

(SIDDARAMAIAH)



MESSAGE



We are living in an era that is showing increasing stress on the planet owing to several factors such as the teeming population of humans and animals. This has led to deforestation, dwindling areas in crop cultivation, inadequate water resources, rapid urbanization, global warming all resulting in the looming effects of climate change. The trend to tackle these challenges has to be **IDEATE, INVENT** and **INNOVATE** leading to **STRATEGIC INVESTMENT**. This is the driving theme of our Government and is reflected in various initiatives that have been undertaken. The core solutions to the challenges threatening food security, healthy living owing to infectious and life style diseases, energy sufficiency and environment protection, reside in Life Sciences a discipline which is more popularly known as Biotechnology.

The Millennium Biotechnology Policy of 2001 and the second version of the policy in 2009 have enabled development of necessary infrastructure, institutions of higher learning and research, development of skills etc., for the growth of this sector in Karnataka. The Department of IT, BT and S&T, Government of Karnataka is continuously working in close association with Government of India, ABLE, IISc, NCBS, UAS and other institutions to take up policy initiatives.

The new Biotechnology policy 2017-2022 is designed to give an impetus to the growth of the bioeconomy in Karnataka. The new policy lays emphasis on strengthening of the ecosystem required to give a boost to the startups, access to funds for R&D and product development, attractive incentives for investment, and mentorship for further growth of the Biotechnology Sector in Karnataka. Attention for R&D and collaboration has been put on several emerging areas such as development of new technology platforms in Agriculture, Anti-Microbial Drug Resistance, Microbiome, Rare Diseases, Synthetic Biology, Animal & Marine Biotechnology amongst others. I am confident that the objectives listed in the policy will be achieved during the policy period.

I extend my gratitude to the chairperson and members of the Vision Group on Biotechnology (VGBT) and several other experts for their valuable suggestions to accelerate faster growth to make the state stronger for more investment in this sector. I am sure they will continue to guide and support Government initiatives for the growth of Biotechnology in Karnataka and beyond.

17/11/17
BENGALURU, KARNATAKA

Mr. PRIYANK KHARGE
Hon'ble Minister
IT BT and TOURISM



MESSAGE



Government of Karnataka has been spearheading efforts in the country and the region to establish a vibrant ecosystem to encourage further investment and growth of several sectors, namely Information Technology, Aerospace, Electronics Systems Design Manufacturing (ESDM), Animation Visual Graphics & Gaming & Comics (AVGC), Tourism and many more. The sector I believe that has the largest potential to make a sea change at levels most crucial for a healthy and secured living is Biotechnology. Embracing the domains of Agriculture and allied topics such as Horticulture, Sericulture, Floriculture; Health & Pharma; Animal Welfare; Energy and Environment, the field of Biotechnology steadily absorbing the innovations made around the world including Karnataka,

has made a huge impact on many societies for rendering better quality of living.

In the first ever Biotechnology policy released in India at the dawn of the millennium in 2001 and followed up with the release of the second policy in 2009, the guidelines triggered building up of institutional framework to spread awareness of the power of biotechnology; setting up of world class institutions such as IBAB (Institutions of Bioinformatics and Applied Biotechnology- Bengaluru), CHG (Centre for Human Genetics- Bengaluru); IABT (Institute for Agricultural Biotechnology - Dharwad); BBC (Bengaluru Bioinnovation Centre) and CFB (Centre for Biotechnology- Bagalkot); nurturing of human resources via these institutions and Biotechnology Finishing Schools (BTFS) to identify talent and building up of skills to serve the Biotech R&D and Industry segments; continuous promotion of national and international collaboration; and provision of concessions and fiscal incentives for investment.

In order to utilize the new developments in the rapidly advancing field of biotechnology for finding new solutions to the persisting challenges in the State and beyond as well as simultaneously aiming to capture a major share of the predicted bioeconomy target of ~100 billion USD in India or the predicted target of ~775 billion USD in the world (Global Market Insights Inc.), a new policy has been formulated. It is now compelling upon the Department of IT BT and S&T via its implementing partner KBITS (Karnataka Biotechnology and Information Technology Services) to further enhance "EASE OF DOING BUSINESS" and strengthen relationships with other relevant departments in the government; with the Vision Groups of Karnataka overseeing Biotechnology (VGBT), Information Technology (VGIT) and Science & Technology / Nanotechnology (VGST) as well as with many other experts drawn from academia, industry and the start-up sections of the society, to help us in successful implementation of the policy objectives.

17/11/17
BENGALURU, KARNATAKA

Mr. GAURAV GUPTA, IAS
Principal Secretary
Department of IT BT S&T and TOURISM





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ABBREVIATIONS

ABLE	Association of Biotechnology-Led Enterprises
AVGC	Animation, Visual effects, Gaming & Comic
BBC	Bangalore Bioinnovation Centre
BFC	Biotechnology Facilitation Cell
BiSEP	Biotechnology Skill Enhancement Programme
CAGR	Compound Annual Growth Rate
C-CAMP	Centre for Cellular And Molecular Platforms
CHG	Centre for Human Genetics
DLC	District Level Committee
ESDM	Electronics System Design & Manufacturing
FDI	Foreign Direct Investment
GIFTS	GoK Incubator for Tech Start-ups
IBAB	Institute of Bioinformatics and Applied Biotechnology
IBAT	Institute of Agriculture Biotechnology
IGICH	Indira Gandhi Institute Of Child Health Hospital
IISc	Indian Institute of Science
InStem	Institute for Stem Cell Biology and Regenerative Medicine
ITRI	Industrial Technology Research Institute
JNCASR	Jawaharlal Nehru Centre for Advanced Scientific Research
KAST	Korean Academy of Science and Technology
KBITS	Karnataka Biotechnology and Information Technology Services
KITVEN Fund	Karnataka Information Technology Venture Capital Fund
KSTA	Karnataka Science and Technology Academy
KSTePS	Karnataka Science and Technology Promotion Society
KUM	Karnataka Udyog Mitra
KVAFSU	Karnataka Veterinary, Animal and Fisheries Sciences University
LSSSDC	Life Science Sector Skill Development Council
MRI	Magnetic Resonance Imaging
NAIN	New-Age Incubation Network
NASSCOM	National Association of Software and Services Companies
NCBS	National Centre for Biological Sciences
NIB	National Institute of Biologicals
NSDC	National Skill Development Council
NTU	Nanyang Technological University
NVEQF	National Vocational Educational Quality Framework
RGUHS	Rajiv Gandhi University of Health Sciences
SBCC	State Biotechnology Co-ordination Committee
TBI	Technology Business Incubators
UAHSS	University of Agricultural and Horticultural Sciences, Shivamogga
UAS	University of Agricultural Sciences
UHS	University of Horticultural Sciences
VGBT	Vision Group on Biotechnology
VGST	Vision Group on Science and Technology

A close-up photograph of a microscope's objective lenses and eyepiece, set against a blurred background. A green circle with the white number '01' is overlaid on the center of the image. The image is framed by yellow borders on the top and sides, and a blue border at the bottom.

01

STATE OF BIOTECHNOLOGY IN KARNATAKA





1.1. THE PREVAILING BIOTECH ECOSYSTEM

1.1.1. Karnataka is the biotech capital of India underpinned by a robust ecosystem owing to the presence of prominent educational and research institutions as well as an array of biotech enterprises, including established companies and promising start-ups.

Karnataka has been at the forefront of biotechnology in India and is rightly known as the biotech capital of India. Over the years, the development of a strong ecosystem and modern infrastructure through a proactive policy framework enabled Karnataka to achieve sustainable development and become the flag bearer of India's biotechnology growth. Bengaluru, Karnataka's science capital and Asia's fastest growing technopolis, has developed into an ideal base for the biotechnology industry.

The state is home to many renowned educational and research institutes, including the Indian Institute of Science (IISc), National Centre for Biological Sciences (NCBS), Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR), Rajiv Gandhi University of Health Sciences, the University of Agricultural Sciences (UAS), Central Food Technological Research Institute (CFTRI), Defence Food Research Laboratory, University of Horticultural Sciences and others. There are several state and private universities and research institutions. The presence of these premier institutes has contributed significantly to a surge in R&D activities in the state, eventually translating into path-breaking innovation.

In the last two decades, the state made major investments in infrastructure to support the expanding ecosystem, including the development of Bangalore BioCluster, Bangalore Helix Biotechnology Park, as well as setting up of technology incubation centres in tier 2 and 3 cities to aid the advancement of biotechnology sector in the state.

The Karnataka government systematically built up considerable resources and human capital to provide biotechnology companies a multi-disciplinary pool of talented work force. The establishment of CHG, IBAB, and IBAT allowed the development of quality manpower in the fields of genetics, molecular biology and biotechnology. The Biotechnology Finishing School (BTFS) – a first-of-its-kind initiative in India – was launched in collaboration with the Department of Biotechnology (DBT). Under this programme, 12 biotechnology finishing schools were launched in the state to equip graduates and post-graduates with the necessary employable skills to make them job-ready. This programme has now been revamped and renamed in its second phase as Biotechnology Skill Enhancement Programme (BiSEP). Under the renewed plan, the focus would be on driving smart collaboration with the industry to align the skill sets of students to industry requirements as well as focusing on developing talent in tier 2 and tier 3 cities of the state.



EXHIBIT 1

KARNATAKA'S BIOTECHNOLOGY INFRASTRUCTURE CAPABILITIES

THE BANGALORE HELIX BIOTECHNOLOGY PARK

The Bangalore Helix Biotechnology Park comprises premier academic and research institutions such as the Institute of Bioinformatics and Applied Biotechnology (IBAB), Centre for Human Genetics (CHG) and Bangalore Bioinnovation Centre (BBC), a state-of-the-art incubation centre.

INCUBATION CENTRES

The government established two biotechnology incubation centres in tier 2 cities of Mysuru and Dharwad to promote research activities in food technology and agriculture, respectively, and is currently developing incubation centres in Mangaluru and Bidar for aqua-marine and animal biotechnology, respectively

THE BANGALORE BIO CLUSTER

The Bangalore Bio Cluster comprises three major institutions: National Centre for Biological Sciences (NCBS), Institute for Stem Cell Biology & Regenerative Medicine (InStem) and Cellular and Molecular Platforms (C-CAMP).

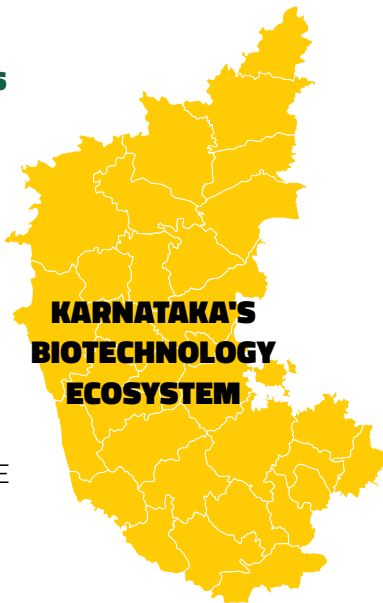
The availability of a strong research base and industry-ready manpower coupled with government support positioned Karnataka as the preferred destination for large global and domestic biotech investments in the country. Some of the large biotech companies in the country such as Biocon, Syngene, Novozymes, Monsanto, et al. are headquartered in the state. The state also has a thriving start-up ecosystem, particularly Bengaluru. Currently, Karnataka's biotech industry comprises ~380 companies and ~194 start-ups, together forming 60% of the biotech companies in India. The state also employs nearly 54% of the country's biotech workforce and contributed 35% of the total revenue generated by the Indian biotechnology industry as of 2015-16.



EXHIBIT 2

KARNATAKA'S BIOTECHNOLOGY
ECOSYSTEM AND ECONOMIC IMPACTRENOWNED
ACADEMIC
INSTITUTIONS

NCBS
INSTEM
IISC
UAS
IABT
JNCASR
IBAB
CHG
CFTRI
UHS
C-CAMP
BIO-IT CENTRE



INCUBATION CENTRES

- BBC, Bangaluru
- Agriculture Biotechnology Incubation Centre and Common Instrumentation Facility (Agri-BTIC_CIF), Dharwad
- Nutra - Phyto Incubation Centre & Common Instrumentation Facility (NPIC -CIF(m Mysuru
- Animal Biotech Incubation Center, Bidar*
- Marine Bio Incubation Center, Mangaluru*
- UHS Bangalkot Incubation Center*

PROMINENT BIOTECH COMPANIES (ILLUSTRATIVE)

Domestic Companies

- Aurigene Discovery Technologies
- Biocon
- Genotypic Technology
- Kemwell Biopharma
- Metaphelix Life Sciences
- Mitra Biotech
- Richcore Lifesciences
- Stempeutics Research
- Strand Life Sciences
- Syngene International

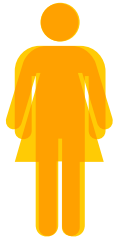
Foreign Companies

- E/I/DuPont India
- GE Healthcare
- Monsanto Holdings
- Novozymes South Asia
- Quintiles Research (India)

IN 2015-16, KARNATAKA ACCOUNTED FOR



35%

OF INDIA'S BIOTECH
INDUSTRY REVENUE

54%

OF INDIA'S BIOTECH
WORKFORCE

60%

OF BIOTECH
COMPANIES IN INDIA

7,500+

BIOTECH GRADUATES
EVERY YEAR



1.2. ACHIEVEMENTS OF THE MILLENNIUM BIOTECH POLICY – I AND II

1.2.1. The development of biotechnology sector in Karnataka has been aptly aided by the pragmatic policy initiatives of the state government over the years

Karnataka was the first Indian state to bring out a policy document for biotechnology in 2001. The Millennium Biotech Policy I focused on setting up the institutional framework required to spread awareness, attract investments and lay the infrastructural foundations necessary for sustainable development of the biotechnology sector. The state followed it up with the Millennium Biotechnology Policy II in 2009 to further expand the growth and role of biotechnology in the lives of the people, animals and the economy.

The two millennium biotech policies outlined several initiatives to strengthen the existing infrastructure through the development of incubation and common instrumentation facilities across Karnataka to accelerate innovation. These include the development of BBC in Bengaluru, and agriculture, nutraceutical / phyto-pharmaceutical technology incubators in Dharwad and Mysuru, respectively, to facilitate the development of biotech start-ups and provide them quality infrastructure facilities for R&D activities. Additional technology business incubators are being considered for establishment in universities and research institutions, across the State.

To focus on skill development, under the Millennium Biotechnology Policy II, the state established 12 biotechnology finishing schools. These institutions contributed to the development of industry-ready skilled workforce in biotechnology. In the second phase, the BTFS programme is being aligned with National Skill Development Council (NSDC) to design the course curriculum by assessing the skill demand of the industry. The programme was renamed 'Biotechnology Skill Enhancement Programme (BiSEP)' and is aimed at making students employable or self-employable after course completion.

Other key initiatives of the two millennium biotech policies include the establishment of premier research institutions such as the Institute of Bioinformatics and Applied Biotechnology (IBAB), Institute of Agriculture Biotechnology (IABT) and the Centre for Human Genetics (CHG). In recent years, the state has focused on the development of emerging areas, including synthetic biology and genomics through these institutions. The Government has approved a synthetic biology centre in IBAB, allocating INR 4.2 Crore over the next three years and a Bio-IT centre at a cost of INR 9.5 Crore over five years. Plans are also in place to leverage the existing infrastructure of IBAB and CHG to develop this cluster as a Centre for Advanced Genome Bioinformatics and facilitate the development of a genome databank for the storage of DNA of patients with rare diseases, endangered species and socio-economically important species in Karnataka. Other emerging areas, including the medical device technology, treatment of rare diseases and marine biotechnology, are being promoted by encouraging multidisciplinary collaboration, translational



EXHIBIT 3

ACHIEVEMENTS OF THE MILLENNIUM BIOTECHNOLOGY POLICY I AND II

CONSTITUTION OF THE VISION GROUP ON BIOTECHNOLOGY IN THE YEAR 2000



- Advise the government on policy initiatives
- Spearhead various initiatives to facilitate development of the biotech industry in the state
- Meet frequently to discuss progress and launch of new initiatives

ESTABLISHMENT OF PREMIER RESEARCH INSTITUTIONS



Establishment of premier research institutions including"

- IBAB (Bangalore) - www.ibab.ac.in
- CHG (Bangalore) - www.chg.res.in
- IABT (Dharwad) - sites.google.com/a/uasd.in/iabt/home
- CFB at UHS, Bagalkot - www.uhsbagalkot.edu.in

ESTABLISHMENT OF INCUBATION CENTRES



- State of the art incubation facility - Bangalore Bioinnovation Centre (BBC) - in Bangalore
- 2 technology business incubators, viz. Agri BT IC_CIF in Dharwad and NPIC_CIF in Mysuru

INDUSTRY-READY HUMAN RESOURCES



- Establishment of IBAB, IABT and CHG
- 12 BT finishing schools (BTFS) has been set up in the state; these completed the first cycle of 5 years.
- The program has now been revamped and renamed as "Biotechnology Skill Enhancement Programme (BiSEP)"; it has also been expanded to include 18 institutions spread across the state.
- Promotion of entrepreneurship
- 'Young Scientists' program under the B4 program

BIO-VENTURE FUND



- Setting up of KITVEN Fund III (Biotechnology), with a corpus of INR 50 Crores, in partnership with financial institutions. The fund is managed by Karnataka Asset Management Company Private Limited



research and establishment of virtual centres of excellence and incubation facilities specifically focusing on these areas.

The Karnataka government also provided a slew of fiscal incentives and concessions to biotech companies. These include rebate on stamp duty and exemption of entry tax, electricity duty and industrial power tariff. Additional incentives include investment promotion subsidy; subsidy for effluent treatment plants (ETPs); and financial support for patent registration, standardization and certification. Furthermore, the government set up funding programmes for biotech companies, including Bioventure Fund, Idea2PoC grants to start-ups etc.

1.3. GROWTH POTENTIAL FOR BIOTECHNOLOGY IN THE STATE

DBT, Ministry of S&T, New Delhi, has come out with National Biotechnology Development Strategy (2015-2020) after consulting with various stakeholders, to achieve target & vision of US \$ 100 billion by 2025.

Karnataka will play a prominent role to enable the country achieve its ambitious goal of USD 100 billion in biotech revenues by 2025¹.

The biotech industry in Karnataka commands an impressive 35% market share of the total Indian market, contributing USD 6.5 billion (INR 44,250 Crore) in 2015. The Government of Karnataka, through various initiatives detailed under the new biotech policy, envisions further increasing its market share and becoming a prominent biotech destination globally. Prevalence of challenges in most sectors will be the underlying factor to explore how biotechnology in convergence with other sectors can perform towards making Karnataka a health and wellness state.

India has an ambitious target of becoming a USD 100 billion (INR 681,350 Crore) biotech market by 2025. Karnataka would be the dominant contributor in achieving this. By implementing various initiatives envisaged under the new policy, Karnataka is expected to significantly increase its market share to 40–60% of India's biotech industry, reaching USD 40 billion (INR 272,500 Crore) to USD 60 billion (INR 408,800 Crore) by 2025. As part of its efforts to achieve this target, the government would continue to invest in quality foundations of science and technology so as to attract investments and develop Karnataka as a major bio manufacturing hub. More importantly, it would take the lead in leveraging its IT capabilities to develop Bio-IT technologies and solutions. Additionally, in its endeavour to become a globally competitive biotech hub and ensure international acceptance of its biotech products, the government would focus on strengthening its partnerships with global majors that can help accelerate innovations and inventions in life sciences.



EXHIBIT 4

INDIA AND KARNATAKA'S BIOTECH MARKET (2015-2025)

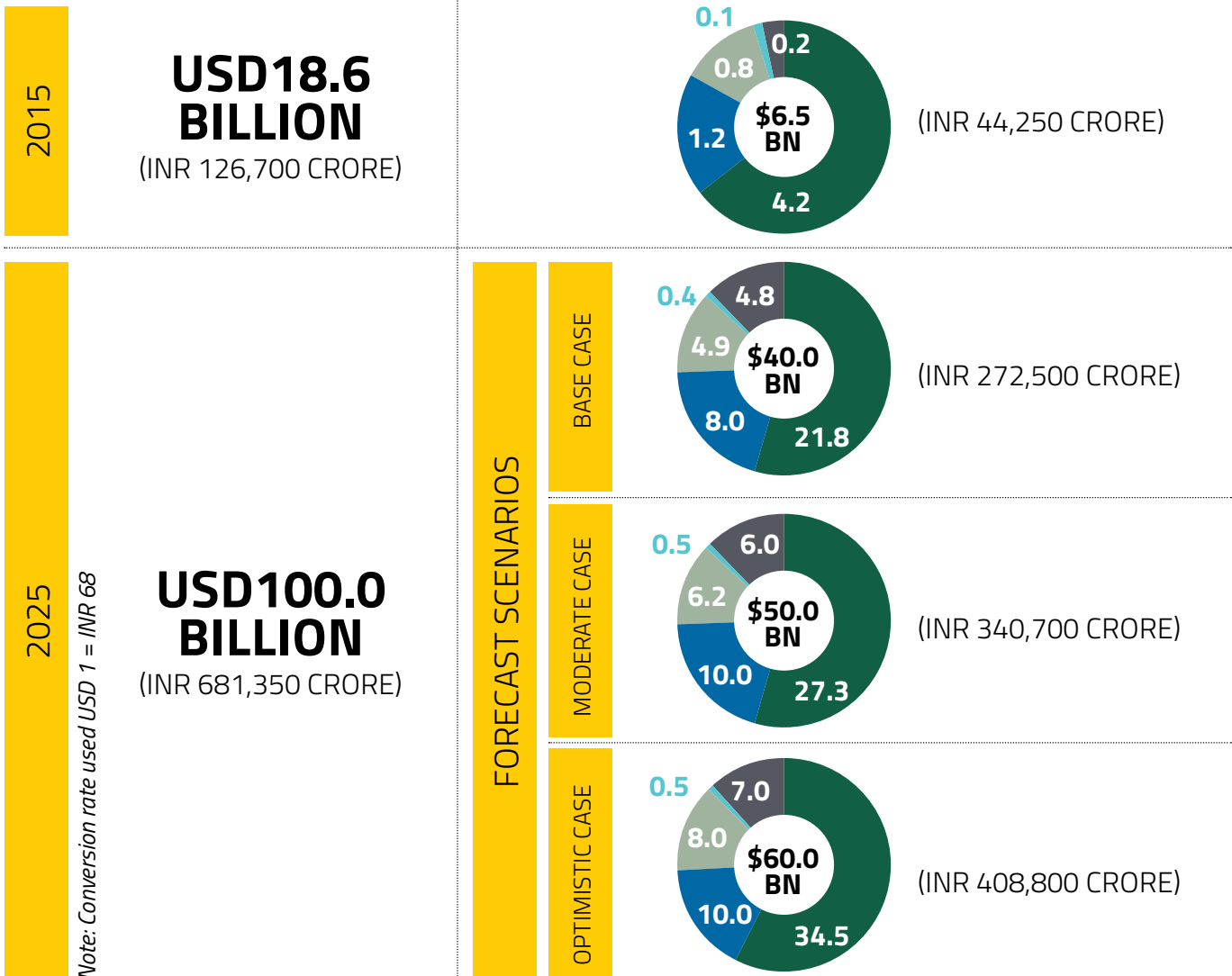


INDIA



KARNATAKA

- BioPharma
- BioServices
- BioAgriculture
- BioIndustrial
- BioInformatics



Source: Primary Research Based Profiling of Biotech Sector in Karnataka - KBITS, National Biotechnology Development Strategy 2015-2020, ABLE-Aranca Estimates



02

POLICY OBJECTIVES





The two Millennium policies laid the foundation for an advanced biotechnology ecosystem in Karnataka. The third iteration in Karnataka's biotechnology policy seeks to provide direction and support the sustainable development of a thriving and world-class biotech ecosystem. This would be achieved by exploiting existing technologies and opportunities; building an elite workforce; strategically shaping the R&D agenda to drive innovations; and using technology to address pressing social concerns related to agriculture, health, energy and environment. It would also offer a framework for developing essential resources and capacities to keep pace with the global biotech revolution.

The policy outlines the following principal objectives to maximise the potential of the state's bio economy:

- 1) Simplify administrative and clearance processes to create an enabling environment for the public and private sectors to invest across the biotech value chain
- 2) Realign the academic and training discourses to strengthen and retain human capital to meet evolving industry requirements and contribute to mitigating challenges
- 3) Conduct coordinated and integrated R&D with an emphasis on facilitating progress beyond the lab to address key prioritized societal issues
- 4) Invest in foundations of life sciences by creating technology platforms and encourage more effective multi-disciplinary collaborations to expand the scale and scope of biotechnology and its impact on the society and economy
- 5) Leverage IT and other technology (ESDM / AVGC) capabilities of the state to encourage development of Bio-IT tools and solutions
- 6) Institute funding mechanisms and mentorship programmes for biotech start-ups to stimulate innovations and discoveries that would benefit the society and growth of the bioeconomy
- 7) Extending financial incentives and concessions for attracting investments in the biotech sector
- 8) Foster the development of bioeconomy by supporting research and development (R&D) in emerging technologies



03

POLICY INITIATIVES

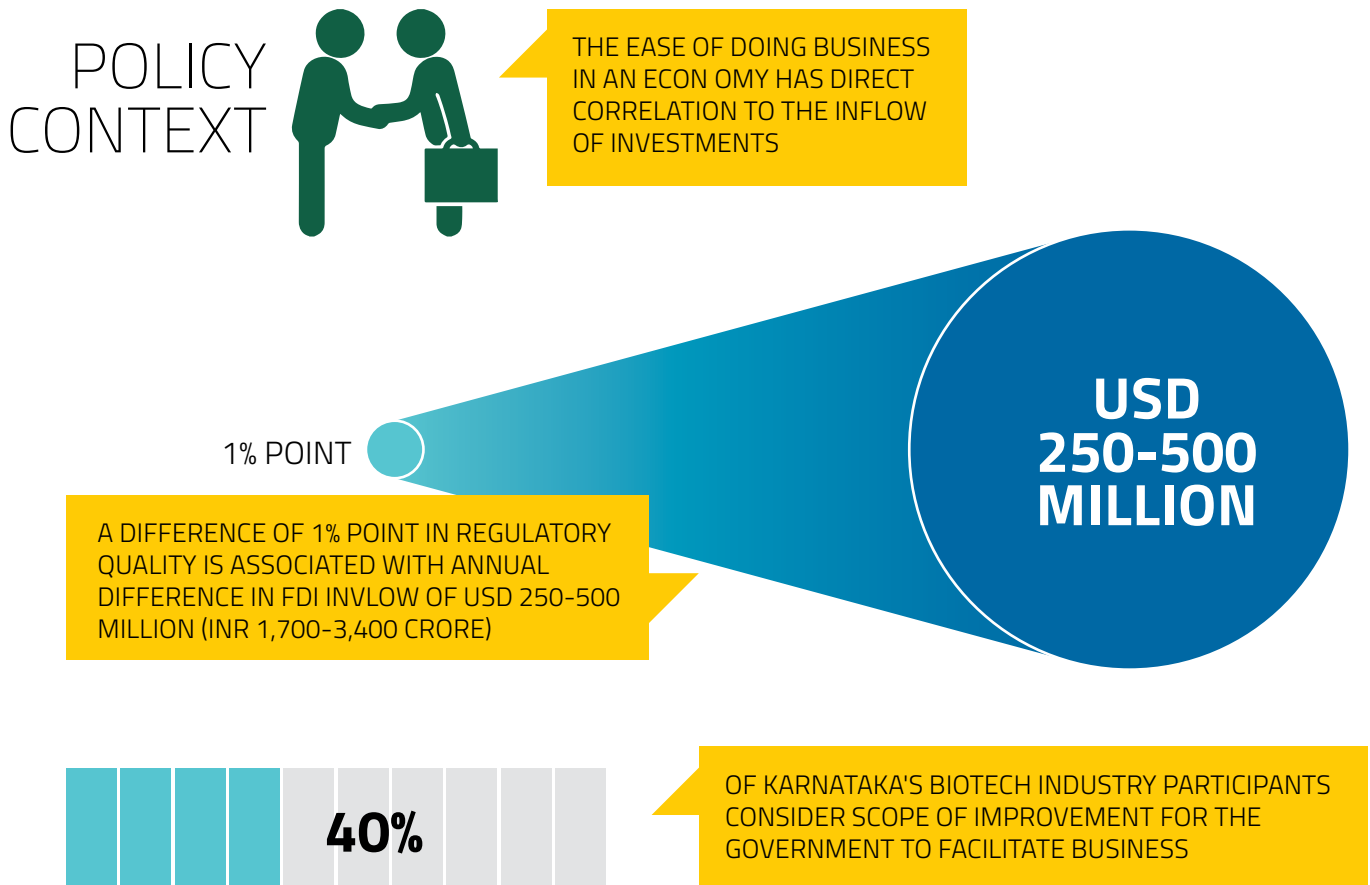




3.1. SIMPLIFY ADMINISTRATIVE AND CLEARANCE PROCESSES TO CREATE AN ENABLING ENVIRONMENT FOR THE PUBLIC AND PRIVATE SECTORS TO INVEST ACROSS THE BIOTECH VALUE CHAIN

Creating an open and transparent business environment is an essential prerequisite for sustainable growth in industries such as biotech. Business-friendly policies would help existing and upcoming enterprises to focus on improving productivity and innovation. A conducive business environment is also an important criterion for attracting investments into the state. Studies show a difference of 1% in regulatory quality is associated with an annual difference in FDI inflow of USD 250–500 million (INR 1,700–3,400 Crore)².

Although Karnataka is one of the largest recipients of FDI into the country, there is scope for improving the processes for setting up and operating enterprises. About 40% of the state’s biotech industry participants consider some scope of improvement for the government to facilitate business³. The state government has been working on the simplification and rationalisation of existing processes and leveraging IT to make dissemination of information and governance more efficient and effective.





3.1.1. Policy Initiatives/Action Points: Easing the process of setting up and operating business in the state for biotech companies by launching a revamped e-biz platform/interface

To improve the regulatory process for business and bring in transparency, the state, through Karnataka Udyog Mitra (KUM), launched the revamped eBiz platform aimed at simplifying and integrating the process of seeking approvals from various departments.

The online platform enables investors to file applications, make necessary payments, and track status and approval of applications. This platform would also ensure incentives available to biotech industries by the state government through various policies are provided through the portal. It is one of the first single-window systems to link all department approvals and make the entire process online. This system is in addition to a comprehensive interface (E-Udyami) already developed for investors to provide all information and support without any physical presence.

KUM established a dedicated central helpline and grievance redressal cell (which includes representation from the Department of IT, BT and S&T) to disseminate information to investors and ensure timely approvals and clearances. The timeline for completing the approval process is guaranteed under the Karnataka Guarantee of Services to Citizens Act (SAKALA Act).

3.1.2. Policy Initiatives/Action Points: Development of a central web portal for facilitation and dissemination of information related to the state's biotech activities

KBITS would develop and launch a biotech-specific portal, <http://itbt.karnataka.gov.in>, which would act as a gateway for enhancing knowledge and awareness among biotechnology stakeholders in Karnataka. Relevant information related to biotechnology infrastructure, research activities, skill development programmes, fiscal incentives and other state-supported programmes for the development of the sector would be accessible through the portal, which would be managed and updated periodically by the Biotechnology Facilitation Cell (BFC).

The whole spectrum of information, including details about the biotechnology policy, government initiatives and programmes, etc. can be accessed through the portal. In addition, it would facilitate discussions and exchange of information between stakeholder groups and encourage broad perspective discussions on various biotech topics.

BFC will also expand its engagement with the civil society, interest groups and other stakeholders by undertaking road shows, marketing and promotional activities on social media platforms in multiple languages and on ground (through road shows). This is done to create awareness about biotech-related programmes, and gain public confidence and acceptance of biotech products. A science communication strategy with the title "SCIENCE for SOCIETY" will be established.

An idea cell will also be set up within KBITS to act as an interface for biotech companies and other stakeholders to share new ideas/recommendations with the government.



3.2. REALIGN ACADEMIC AND TRAINING DISCOURSES TO STRENGTHEN AND RETAIN HUMAN CAPITAL, MEET EVOLVING INDUSTRY REQUIREMENTS AND CONTRIBUTE TO MITIGATING CHALLENGES

Karnataka accounts for more than 5%⁴ of the total undergraduate enrolments in India. About 28%⁴ of these enrolments are in the science stream. With 80% science colleges in the state offering biotech courses, Karnataka produces more than 7,500 biotech graduates each year⁵.

The easy availability of human resources, however, should translate into improved quality of workforce to meet evolving industry expectations and requirements. The establishment and successful implementation of BT Finishing Schools (BTFS) was an important step forward in developing industry-ready graduates. The current policy emphasises building on the success of BTFS by optimising the course structure and introducing additional initiatives to foster R&D and entrepreneurship and ensure availability of industry-ready and skilled manpower at different job levels.

POLICY CONTEXT



85%

RISE IN OVERALL BRAIN DRAIN FROM INDIA TO THE US IN THE LAST DECADE TO PURSUE HIGHER EDUCATION, VIZ. SPECIALISED PROGRAMMES AND DOCTORAL STUDIES



7,500+

BIOTECH GRADUATES PASS OUT IN KARNATAKA EACH YEAR

INDUSTRY SEEKS ADDITIONAL TECHNICAL AND BUSINESS TRAINING TO BE PROVIDED TO GRADUATES



80%

~80% OF POST GRADUATION COLLEGES IN THE STATE PROVIDE BIOTECH COURSES

THE FACULTY OF A MAJORITY OF BIOTECH INSTITUTES HAVE LIMITED EXPOSURE TO R&D AND NEW TECHNOLOGICAL ADVANCEMENTS

25%

IMPROVEMENT OF FACULTY STANDARDS IS CONSIDERED TO BE IMPORTANT BY ~25% OF INDUSTRY PARTICIPANTS TO IMPROVE THE OVERALL ACADEMIC DISCOURSE IN THE STATE



The teaching faculty at most biotech colleges has limited exposure to R&D and new technological advancements, impacting the overall quality of academic discourse in the state. Therefore, provision of reorientation courses and training of faculty at senior schools and colleges would be emphasised.

Increased activities must go beyond what is in the syllabi. These could include group discussions; learn how to learn; visits to places with ground realities (such as agriculture fields, farm yards, human and animal health hospitals, energy generation plants and waste recycling centres); bio-quiz competitions; creation of science prototypes; and identification of challenges wherein life sciences/ biotechnology can play a role.

3.2.1. Policy Initiative: Develop a skilled workforce attuned to the requirements of the industry and encourage entrepreneurship among biotech students through the Biotechnology Skill Enhancement Programme (BiSEP)

The BTFS programme was revamped and renamed Biotechnology Skill Enhancement Programme (BiSEP), aligning its curriculum with the National Vocational Educational Quality Framework (NVEQF) of the NSDC (National Skill Development Council).

The programme is aimed at bridging the gap between academic knowledge and its application in the industry and encouraging entrepreneurship among students enrolled under BiSEP. The programme would incorporate the following structural modifications:

Curriculum Upgrade: BiSEP would collaborate with Life Science Sector Skill Development Council (LSSSDC), CSIR-IICT or organisations empanelled with NSDC while designing the course curriculum and assessing students' skill sets. The curriculum would also be tailored to incorporate the latest industry trends and technological advances. Furthermore, the state government would constitute a committee of experts from relevant fields of Biotechnology who would periodically examine the syllabus in biotech institutions and suggest necessary modifications or additions. The courses would also integrate 'decision thinking', data analyses and oral/written communication skills to engage in scientific writing.

Internship Programmes: To impart industry-relevant training, the government would enable industry-academia collaborations through on-the-job skill development programmes under BiSEP. The programme would foster collaboration between the industry (including start-ups) and institutes to offer internships in relevant areas of expertise. This would be enabled through a mandatory partnership by each participating BiSEP college with one or more industry players. A programme to engage biotech industry and institutions and devise a scheme to attract fresh graduates with better salary structure will be explored.

Incubation Centres: BiSEP colleges would be encouraged to participate in the New Age Incubator Network (NAIN) programme — introduced under the Start-Up Policy — under which institutes would be provided assistance in setting up incubation facilities. These facilities would encourage students to start their own



entrepreneurship projects and avail initial funding under the programme. In addition, the participating students would be provided mentorship and consultancy services through the Virtual Incubation programme run through government-supported incubators in the state.

3.2.2. Policy Initiative: Facilitate training and development programmes for faculty to keep them abreast with the latest biotech technologies and trends

Faculty Development Programmes: Similar to the training programmes for students, the teaching faculty at colleges and post-graduate institutions such as State Agriculture Universities and Medical Colleges offering biotechnology courses within India and, where appropriate, outside India in collaboration with leading biotechnology institutions would be eligible for financial support for attending faculty development programmes. The programmes will have three modules, viz. basic, intermediary and advanced. These would be developed in association with leading science institutions such as IISc, NCBS, InStem, IBAB, IABT, UAS and others having expertise in particular areas of biotechnology. The modules would be designed to enable the faculty to keep abreast with the latest technologies and trends and help them tailor their pedagogy. The programme work would include online course materials and short-duration training and workshops at the aforementioned research institutions. The structure of the faculty development programme and financing would be decided by a select committee constituting government representatives from the Department of IT, BT, S&T, academicians and other relevant stakeholders.

Engagement with Teachers at Schools and Pre-university Colleges: The government, through existing programmes of Karnataka Science and Technology Promotion Society (KSTePS) and the Vision Group on Science and Technology (VGST) schemes such as Science Melas (public events), Lab-in-a-box programme, Karnataka Vijnana Vidya Jagruti and other teacher training programmes, would engage with teachers at schools and pre-university colleges to expose them to opportunities in life sciences. They, in turn, can impart this know-how to students to pique their interest in biotechnology.

3.2.3. Policy Initiative: Encourage fellowships and certificate programmes for Karnataka domiciled professionals and researchers to retain skilled human capital and provide commensurate career opportunities

Expanding enrolments under the KSTA Fellowship Programmes: The Karnataka Science and Technology Academy (KSTA) offers fellowships to meritorious students to pursue higher education in science. This programme would be extended to offer fellowships, specifically to students pursuing post-graduate education and research in life sciences.

Collaborating with Foreign organizations for Internships: The state would institute an international internship programme to support 50 young Karnataka domiciled students to undertake internships in foreign institutions. The duration of



the internships would be three to six months, with the selected students being paid a stipend for the duration of their internship. KBITS would pursue collaborations with international biotech companies and administer the programme. It would also explore partnerships with organizations such as Biopolis (Singapore), MUS-NTU (Singapore), ITRI (Taiwan), KAST (S. Korea) and others in South East Asia.

International immersion and internship would improve study experience, encourage exchange of ideas and knowledge and increase the number of work-ready students with global experience.

Short-duration Training for Professionals: KBITS would collaborate with premier institutions in the state to develop short-term specialized training programmes, specifically for working professionals to raise their general level of competency and skill sets. These trainings would also focus on providing specialised technical training in key emerging technologies.

These programmes would be a collaborative effort between premier institutes, including IBAB, CHG, InStem, IISc and industry participants. The financing required for the initiative would be decided by a select committee constituting government representatives from the IT, BT and S&T departments; academicians; and industry participants.

3.3. CONDUCT COORDINATED AND INTEGRATED R&D WITH EMPHASIS ON FACILITATING PROGRESS BEYOND THE LAB TO ADDRESS KEY PRIORITIZED SOCIETAL ISSUES

Most innovations in biotechnology are a result of convergent, breakthrough academic findings that evolve from basic science. Several globally successful biotech companies benefit from the research and support of academic institutions. Consequently, emphasis on R&D activities related to life sciences at academic and research institutions is especially important to yield ideas and technologies that private enterprises can leverage to develop new products and service lines and catalyse economic and social development.

This policy would lay particular emphasis on interdisciplinary collaboration to address the complex challenges that may often have interconnected modern research questions. The convergence of expertise and experience from diverse disciplines such as biology, chemistry, physics, medicine, and engineering plus information technology would result in the development of not only the existing knowledge library but also new technologies that address key societal challenges. To achieve this impact, the policy would modify the existing state funding framework to encourage beneficiary academic and research institutions to pursue convergent research activities aimed at improving the lives of millions.

3.3.1. Policy Initiative: Continued support to academic scientists and technologists for pursuing research activities related to life sciences

Improving Efficiency and Effectiveness of State Funding: The state provides several



grants to promote research activities. The emphasis now would be on introducing a mechanism that promotes a more effective utilisation of funds to address societal needs. To this effect, a share of the funding provided by the state to institutions for research activities needs to be earmarked to pursue strategic research projects with clear and defined outcomes, which would be put up in the public domain for licensing and other activities. This would be applicable for all schemes driven by the Department of IT, BT and S&T.

Promoting Interdisciplinary Research: Growth in biotechnology depends on the convergence and collaboration of multi-agencies and disciplines to develop tools and products with vast societal benefits. The state government would encourage research efforts that bring together researchers/institutions and professionals from diverse disciplines to develop innovative approaches in sequencing and characterising specific diseases; virtualize the drug development process; digitalise gene pool and blood banks to improve the fractionation process; These collaborations would also focus on accelerating the commercialization of advanced biotech products including new traits for crops, biofuels and development of tools for assessing experimental therapies, preventives and diagnostics especially of rare diseases, etc.

3.3.2. Policy Initiative: Initiate strategic partnerships with leading global biotech clusters to attract investment and R&D collaboration

To increase market share in India's biotech industry, Karnataka would enter into strategic collaborations with leading biotech clusters around the globe. These partnerships would be aimed at:

- Accessing biotech resources from developed clusters
- Promoting joint research work and transfer of knowledge and technologies
- Facilitating trade with leading bio economies around the globe

The state has developed strategic collaborations for academic research and knowledge exchange programmes with Boston (Boston – Bangalore Biosciences Beginnings - B4) and The Hague (to collaborate in the areas of technology for elderly, security, bicycle infrastructure, human genetics and start-ups), while partnerships with Spain and Australia are being discussed. Partnerships with other key international players such as the UK, France, Israel, South Korea and Japan will also be explored.

3.3.3. Policy Initiative: Development of a technology/research aggregator of biotech ideas to easily identify strategically important technologies and foster potential collaborations and commercialisation opportunities

Although several research projects related to life sciences are undertaken at academic and research institutions in the state, there is limited information on the research work conducted at these institutions. With the development of a dynamic repository consolidating the biotech research activity in Karnataka-based institutions, entrepreneurs, start-ups and other industry participants, investors,



collaborators et al. would be able to identify strategically important or marketable technologies and connect with researchers to either collaborate or license to take the technologies to market.

The information included on this AGGREGATOR PLATFORM would include:

- Description of research
- Status of research
- Credentials of researcher/institution

The aggregation of the research on this platform would expedite the transfer of technologies from research laboratories to the market.

3.4. INVEST IN FOUNDATIONS OF LIFE SCIENCES BY CREATING TECHNOLOGY PLATFORMS AND ENCOURAGE MORE EFFECTIVE MULTI-DISCIPLINARY COLLABORATIONS TO EXPAND THE SCALE AND SCOPE OF BIOTECHNOLOGY AND ITS IMPACT ON THE SOCIETY AND ECONOMY

The development of biotechnology is directly related to the introduction of new ideas and technologies in the market. To strategically shape the future of biotechnology, collaboration with multiple disciplines is required to benefit the broader bioeconomy. Such multi-disciplinary efforts can spawn research projects to address key scientific challenges across areas such as agriculture, health, environment and energy. Partnerships among government agencies, companies and other stakeholders will be instrumental in leveraging the financial and technical capabilities to generate solutions with a wide societal impact.

3.4.1. Policy Initiative: Collaborating with various government departments and agencies to encourage projects that seek to provide innovative solutions made possible by biotechnology

KBITS will actively seek to collaborate with government departments and agencies such as the Karnataka State Bio-Fuel Development Board (KSBDB), Department of Agriculture, Department of Health and Family Welfare, Department of Medical Education, Department of Animal Health and Fisheries, Department of Ecology and Environment, local municipal bodies, et al. to encourage the development of biotechnologies that focus on improving the quality of life and addressing societal needs. These solutions would target human health, food security, animal health and environmental sustainability, among others.

In partnership with the relevant departments, the Department of IT, BT and S&T will provide financial assistance to encourage pilot projects focused on enhancing the yield of biofuels and bioenergy crops, production of enzymes used for treatment of waste and processes (including bio-remediation and bio-magnification), design of new therapies using stem cells and tissue engineering, improvement in agriculture crops to increase yield and enhancement of nutritional value.



A “Delivery Integrator” model - similar to Department of Industrial Policy and Promotion - to coordinate activities across the departments that biotech may impact and critical. This will provide a platform for various state departments (that currently work in silos/isolation) to effectively address common challenges together and benefit the society at a faster scale.

3.4.2. Policy Initiative: Setting up a centralised biological and animal testing facility to support preclinical trials of biopharma and bioservices companies

The government will develop a dedicated biological testing facility well-equipped with latest technological equipment and authorized to provide certification to product testing procedures conducted by biotech companies. Additionally, this testing laboratory would act as a certifying authority similar to the NIB and maintain a databank of brain, blood samples and others, which can be used by companies for testing process. These databanks can also be used by biotech companies across the state on a pay-per-use basis.

The laboratories will be setup in Bengaluru (at IBAB) and Bidar (as an extension to the animal biotechnology facility being set up at the Karnataka Veterinary, Animal and Fisheries Sciences University - KVAFSU).

The investment necessary for setting up the facilities would be decided by a selection committee comprising government representatives from the Department of IT, BT and S&T and industry participants.

3.5. LEVERAGING IT AND OTHER TECHNOLOGY (ESDM/AVGC ETC.,) CAPABILITIES OF THE STATE TO ENCOURAGE DEVELOPMENT OF BIO-IT TOOLS AND SOLUTIONS

Bio-IT is critical to modern life science research and has significantly progressed in the last few decades. The use of computational tools to interpret large quantities of complex data emerged essential for research and broad development of the sector. As biotechnology continues to take advantage of increasingly large and more complex datasets such as human genome sequencing and proteomic profiles of cells, the ability to store, analyse, visualise and share data is a challenge. As the IT capital of India, Karnataka can leverage its IT capabilities to address these issues and develop interdisciplinary Bio-IT solutions. Major IT companies such as TCS, Infosys, Wipro, IBM, Intel et al. have built competencies to support proteomics, genomics, drug discovery, data analysis services and scientific data management systems. Nonetheless, a concerted effort focused on integration of synergies between the two domains could lead to the development of innovative solutions and new revenue streams and accelerate development of the market.

3.5.1. Policy Initiative: Foster collaboration between the IT and BT ecosystems to develop new solutions that will help stimulate the steps taken to realise the potential of biological research and discoveries

IT companies collaborating with biotech institutions or developing solutions that



have utility in life sciences would be provided access to facilities and services at state incubation centres such as BBC. Similarly, biotechnology-focussed companies will also be hosted at the NASSCOM start-up warehouse, Mobile 10X start-up hub and GoK Incubator for Tech Start-ups (GIFTS) to broaden the engagement between IT and biotech start-ups.

The Department of IT, BT and S&T will seek to expand the partnerships between the IT and BT ecosystems by bringing together industry participants from both the sectors to:

- Develop tools such as stem cell registry, digital genomics library and computerisation of blood banks to address the challenges in the life sciences domain
- Develop product lines with global relevance such as knowledge-/IT-enabled bioservices for processing global genomics data
- Industrialise biotech research using 3D bioprinting and artificial intelligence, among others
- Provide tertiary healthcare centres with effective technologies to develop biotech platform

The government will also consider providing financial support to collaborative projects with social relevance, such as developing gene banks, by establishing a corpus fund.

3.6. INSTITUTE FUNDING MECHANISMS AND MENTORSHIP PROGRAMMES FOR BIOTECH START-UPS TO STIMULATE INNOVATIONS AND DISCOVERIES THAT WOULD BENEFIT THE SOCIETY AND BOOST GROWTH IN BIOECONOMY

A significant portion of the funding required for the biotech industry is utilised for R&D of products and solutions. The state is home to over 200 biotech start-ups³, with majority of them requiring access to infrastructure and funds for R&D and product development. With new areas of research emerging, new start-ups are expected to bloom and state funding will be a critical catalyst driving research and allied activities.

The perceived high risk and long gestation period for biotechnology investments limits the venture capital funding compared with start-ups in other technology sectors receiving significantly high levels of funding in recent years. As per a KBITS survey in 2016, only a small percentage of biotech start-ups in Karnataka received funding from venture capitals and angel investors (9% and 7%, respectively).

For R&D, start-ups are required to leverage information from several databases providing information on patents and legal aspects, among others. This is critical for product development. However, these databases need to be subscribed to annually, are expensive and lead to additional costs for companies.

A key requirement from the industry is the need to impart business skills to scientists who are founders of start-ups and have limited exposure to business



requirements. Scientists with excellent research skills need to be equipped with business skills, ranging from preparing business plans and fund raising to developing sales and marketing strategies. As per the KBITS Biotech Survey 2016–17, majority of the start-ups faced difficulty in developing a business plan or go-to-market strategy. Although these start-ups have easier access to scientific mentorship through biotech incubation centres and life sciences institutions, avenues to gain business mentorship and guidance are limited.

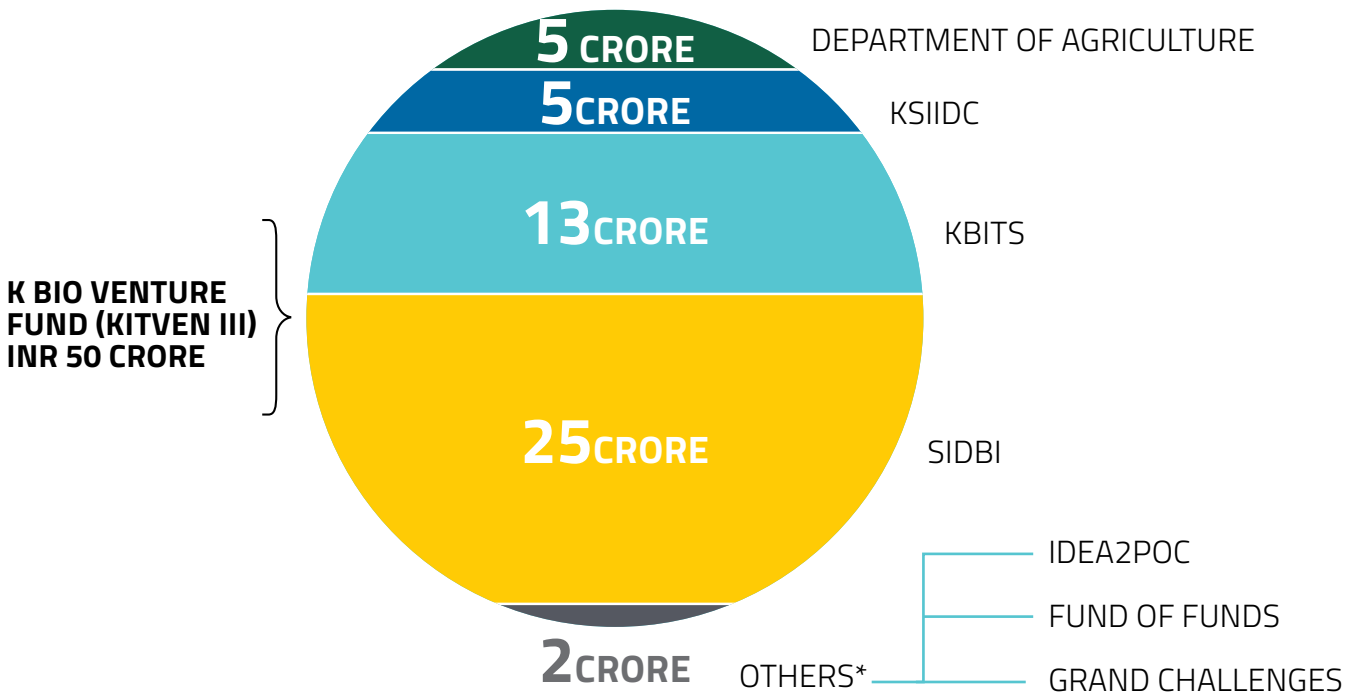
This policy will focus on addressing the funding gap by strengthening venture capital fund and incentivising innovations that can offer solutions to long-standing issues pertaining to the state of Karnataka. Support services such as provision to access relevant databases will help minimise operational costs for start-ups and enable access to mentorship cells that help hone business skills of scientists.

3.6.1. Policy Initiative: Karnataka’s biotech venture fund will effectively contribute to meet the funding requirement of emerging biotech start-ups

Setting-up and strengthening of K Bio-Venture Fund (KITVEN III): To narrow the funding gap, KBITS, in association with multiple state entities, set up KITVEN III - a bioventure fund, with a size of INR 50 Crore and further increase if appropriate. The commitment towards the current Bioventure funds comes from the following entities:

EXHIBIT 5

FUNDING AVENUES FOR BIOTECHNOLOGY COMPANIES IN KARNATAKA





Other enablers to the funding ecosystem:

- Funding for biotech start-ups will be complemented by other funds within the start-up policy such as Idea2POC (fund size of up to INR 50 Lakhs), Start-up Fund of Fund (INR 200 Crore), Grand Challenges among others.
- Technology business incubators (TBI) being set up in universities and R&D Institutions and New Age Incubation Network (NAIN) in colleges will further provide impetus to the biotech ecosystem in Karnataka.

3.6.2. Policy Initiative: Grand challenges focusing on biotech-led solutions to address societal challenges in the state

Introduction of Grand Challenges: KBITS, through the Grand Challenges Karnataka launched under the Start-up Policy of the government, will focus on new technologies or innovations that can offer solutions to some longstanding issues pertaining to the state of Karnataka. Grand Challenges Karnataka is aimed at channelizing innovations for social impact and, in the process, support the establishment and growth of start-ups. Grand Challenges around five well-defined priority queries will be taken up in the first phase. The programme is supported by the Karnataka Biotechnology and Information Technology Services (KBITS) as the funding agency and IKP Knowledge Park (IKP – Hyderabad & Bangalore) as the implementation partner.

The funding will be completed in two stages:

Phase I: Up to five innovators will receive Idea to Proof of Concept funding of up to INR 10 lakhs for six months for prototyping and testing innovative solutions in a real-world setting.

Phase II: After six months, the selected candidates will undergo one more round of selection. One of them will be selected for further funding of up to INR 50 Lakhs for 12 months to scale up the prototype.

The award agreement will be structured as a grant.

The programme will also work with the awardees for the duration of their project and beyond to ensure project implementation and extend mentorship, resources and networking opportunities. Through this KBITS-supported programme, IKP and other partners will provide the winning candidates access to networks and marketing channels to commercialise their innovations.

3.6.3. Policy Initiative: Provide access to scientific patent databases to start-ups, incubators and academic institutions as part of the start-up booster kit

Providing access to co-shared Patent and Legal databases: As part of the Start-Up Karnataka initiative, the government will provide start-ups access to co-shared patent and legal databases such as Thomson Innovation and Questel patent database. This will help biotech start-ups conducting extensive research and development and reliant on patent data globally for supplementing research activities.

This facility will also be extended to technology business incubators (TBIs), BiSEP and new-age incubation network (NAIN) institutions across the state.



Ready access to such expensive and relevant databases will stimulate innovation and contribute to industry growth. It is also expected to help prevent patent infringements, as start-ups will be able to search prior patents before filing for patents for their innovations.

3.6.4. Policy Initiative: Provide start-ups with business advisory services and facilitate access to private investors through a mentorship cell set up at incubation centres

Fostering Entrepreneurship Among Research Scientists: KBITS will set up a mentorship cell in association with the Association of Biotechnology-Led Enterprises (ABLE) to help scientists and founders of start-ups sharpen their business acumen and skills. The cell will comprise a committee or a pool of expert consultants and will be run at state-run incubation centres and new-age incubation networks. The cell is aimed at facilitating start-ups to develop:

Idea Validation: Guidance related to review of proof of concept, business idea validation, provision of feedback will be provided by expert consultants to start-ups.

Business Plan: Start-ups will receive support to develop an attractive business plan entailing the market, commercial and technical feasibility for the start-up's idea, and will help attract relevant funding from banks, private institutions, and venture capital funds.

Sales and Marketing Strategy: Following the successful development of the product/solution, start-ups will receive guidance to prepare a go-to-market strategy which will detail the sales and marketing efforts required to commercialize the product/solution successfully and access PE/VC funding for their ventures.

Start-up/Entrepreneur Education and Training Programme: This programme is aimed at providing education and training to start-ups and potential entrepreneurs through short-term courses, workshops, conferences, covering a wide area of subjects of relevance such as HR, finance, IP, management, leadership, and regulations. These programmes can be developed in collaboration with institutes such as IIM Bangalore.

IBAB, CHG & BBC (Bengaluru) IABT (Dharwad) and CFB@UHS (Bagalkot) can lead in coordinating such a programme, and this, in the form of a pitch document, can help start-ups develop a market entry strategy along with access to private equity/venture capital funding

3.7. DEFINITION OF BIOTECH COMPANIES AND EXTENDING FINANCIAL INCENTIVES AND CONCESSIONS FOR ATTRACTING INVESTMENTS IN THE BIOTECH SECTOR

3.7.1 Definition of a Biotech Company including Start-Ups:

A Biotech Company means and includes inter-alia a unit engaged in any of the following activities



- A. Any company (product development and/or service oriented such as clinical research and biotech contract research organizations) / laboratory initiating and carrying out work utilizing live cells / organisms (viruses, bacteria, lichens, algae, fungi, plants, animals, humans) - in other words "Living Systems" that are classified as Pro- / Eukaryotes; Plant Kingdom, Animal Kingdom including Humans.
- B. Any company / laboratory / individual working on the above with an objective to develop via R&D a product (proteins, enzymes, lipids and other biological molecules) or a process of benefit to the society in the areas of Agriculture (and its relevant areas namely Horticulture, Sericulture, Floriculture), Health, Energy and Environment.
- C. Any company / laboratory engaged in Omics work (Genomics, Proteomics, Lipidomics, Phenomics etc.), Bioinformatics, Genetic Engineering; Gene Editing; in-vitro / in-vivo analyses to determine functions; Enzyme Catalysis to produce products / processes.
- D. Qualification of a Biotech Startup company, in addition to the applicable terms and conditions outlined in the Startup Policy of Government of Karnataka (<http://itbt.karnataka.gov.in/pages/home.aspx>), is that the Startup registered / incorporated for not more than 4 - 7 years (depending on the nature of work, types of living systems used- the length of its growth cycle thereof; reagents / infrastructure required; area of application of the process / product and other factors that may determine the time and complexity required to proceed from one step to the next one.
- E. Startups utilizing Electronics – Engineering: Fabrication work for application in the four areas, namely, Agriculture (and relevant areas namely Horticulture, Sericulture, Floriculture), Health, Energy and Environment would need to justify for a 7-year qualification. Otherwise they would be qualified under 4 years or under.

Companies that can be classified in the above defined categories must register with KBITS, Department of IT BT and S&T, Government of Karnataka as per the terms and conditions of Biotech Policy and where applicable Start-Up Policy framework.

3.7.2: Fiscal Incentives and Concessions:

Upon registration of Biotech Companies with KBITS, Department of IT & BT, Government of Karnataka as outlined in section 3.7.1, the fiscal incentives and concessions offered under the Industrial Policy 2014-19 of the Commerce & Industries Department, Government of Karnataka (www.karnatakaindustry.gov.in) shall be extended where applicable to the biotechnology industry and R&D centers in the state. For the purpose of administering these incentives and concessions, the Taluks in the state have been divided into four zones in Karnataka Industrial Policy 2014-19 and the same would be followed where applicable. The scale of fiscal benefits and concessions available to the biotech industry under the Industrial



Policy 2014-19 varies based on the zones and the size of the enterprise (micro, small, medium, large and mega enterprises) as per the classification of Industrial Policy 2014-19 of the Commerce & Industries Department of Government of Karnataka. (www.karnatakaindustry.gov.in). Some of the incentives available to the biotech sector under the Industrial Policy 2014-19 of the Commerce & Industries Department of Government of Karnataka (www.karnatakaindustry.gov.in) include:

- a. Stamp duty exemption and concessional Registration charges
- b. Reimbursement of land conversion fee: 75- 100% depending upon the zone being used for set-up
- c. Tax exemptions as applicable
- d. Incentives for export oriented enterprises.
- e. Investment subsidy for setting up of effluent treatment plants (ETPs)
- f. Special incentives for enterprises coming up in low HDI districts
- g. Incentives for water harvesting / conservation measures
- h. Incentives for energy conservation

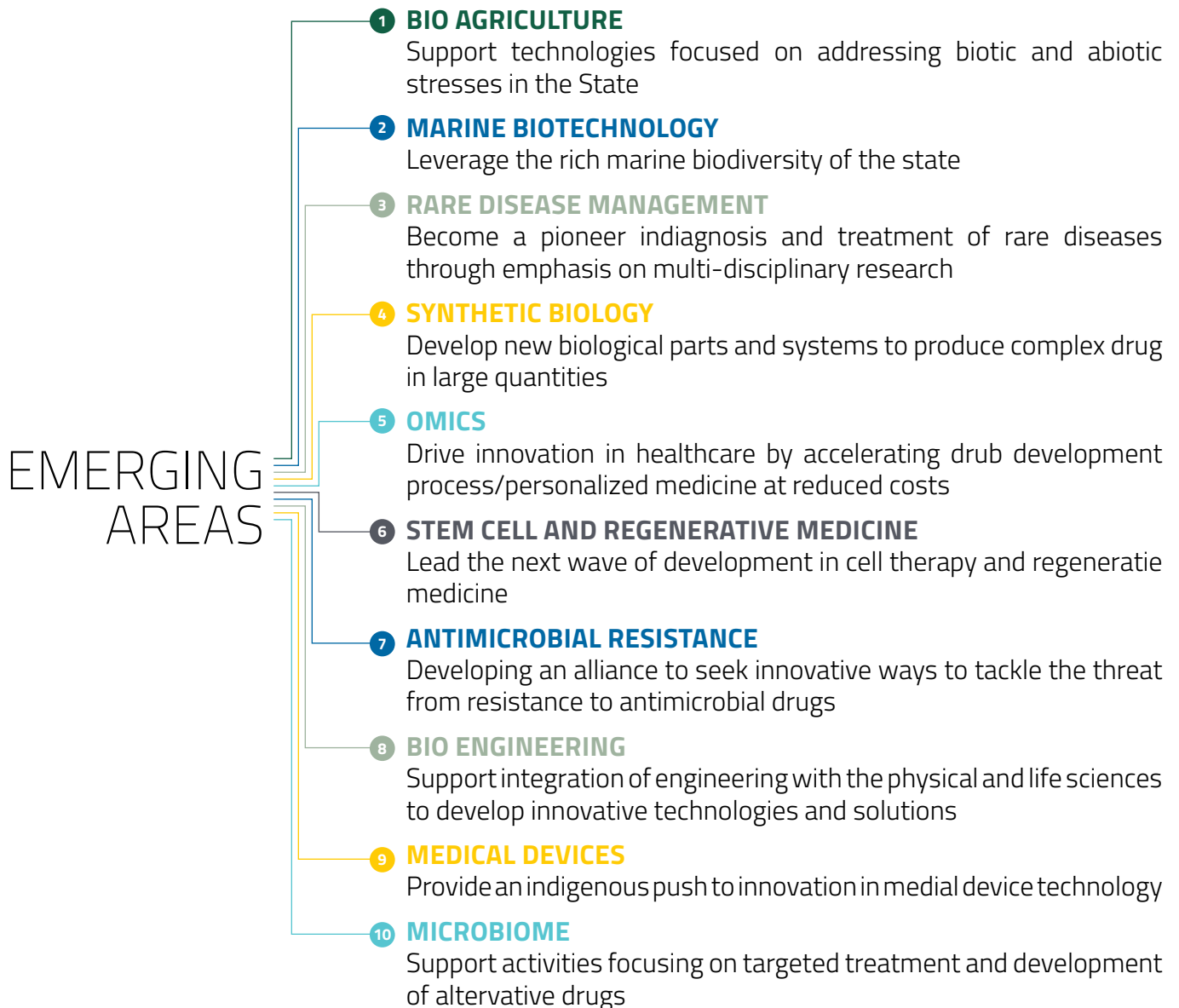
3.7.3: Incentives from the Department of IT BT and S&T:

The incentives available from the, Department of IT BT and S&T to the companies in the biotech sector classified under the Biotech Policy include:

- a. **Anchor Unit Subsidy:** Available for the first two manufacturing enterprises with a minimum employment of 50 – 100 members and a minimum green field investment of 50 Crores
- b. **Reimbursement of Costs for Preparation of Project Report:** Refund of cost incurred for preparation of project report, up to a maximum of INR 1 Lakh,
- c. **Power Tariff Concessions:** A recommendation certificate from KBITS- Department of IT BT and S&T to BESCO to help in power tariff concession.
- d. **Interest subsidy (6%)** for Technology up-gradation for MSMEs for a loan of maximum of INR 50 Lakhs for 5 years
- e. **Standardization Certificate:** Financial assistance of up to 50 % of the cost incurred in obtaining a standards certificate such as ISO / BIS / GLP /GMP / NABL (maximum of INR 5 Lakhs per case)
- f. **Patent Registration:** Financial assistance towards the cost of filing and prosecution of patent application up to a limit of INR. 2.0 Lakhs per Indian Patent awarded; and for awarded international patents on a single subject matter up to INR 10.00 Lakhs.
- g. **Marketing Incentives:** Reimbursement of 30% of the actual costs incurred for international marketing programs, subject to a maximum of INR 2 Lakhs per year per company.



3.8. FOSTER THE DEVELOPMENT OF BIOECONOMY BY SUPPORTING RESEARCH AND DEVELOPMENT (R&D) IN EMERGING TECHNOLOGIES



3.8.1. Bio Agriculture

Karnataka, with total cultivable land of 12.3 million hectares and constituting approximately 64% of the total geographical area, is a dominant agrarian state⁶. The state is also known for its dominant presence in horticulture, floriculture, sericulture, fisheries and animal husbandry. In fact, there is no crop in India which is not grown in Karnataka, thereby making it a representative sample of India. With nearly 65% of the state's population depending on agriculture as the main means of



livelihood, the state recognized the immense benefits that could be reaped out of agricultural biotechnology and marked it as one of the most significant priorities⁶.

The state has made significant progress in improving the overall agricultural productivity. However, in view of the increasing demand and decreasing resources, there is scope for further improvement with modern technological intervention. Karnataka, similar to several other states, faces some formidable challenges hampering the quality of agricultural produce in the state. Approximately 74% of the cultivable land in the state is under semi-arid tracts and prone to repeated drought, causing crop losses up to 60%⁶. There is an urgent need for the adoption of technologies such as phenomics to address this abiotic stress in tandem with other established technologies such as genomics, molecular breeding and other relevant ones. Apart from such abiotic stress, biotic factors such as attacks from pests, diseases and weeds are known to reduce yield by about 35% in most crops⁶. This translates into an annual crop revenue loss estimated at INR 11.4 billion. Additionally, Karnataka has a vast coastal tract of about 1.6 lakh hectares which is unsuitable for cultivation of crops due to high salinity. Some of these challenges can be addressed through biotechnology as already demonstrated in other countries and in India by adoption of Bt cotton to control cotton bollworms since 2002-03⁶.

Across India, technological advancements in genome editing, synthetic biology and DNA sequencing are driving new product innovation in agriculture. Additionally, the current scope of R&D activities in transgenic research led to the generation of a number of transgenic crops with higher productivity yield potential, prolonged shelf life, enhanced nutrition, insect/disease resistance, moisture-stress tolerance, etc. These technologies are anticipated to benefit agriculture and farmers and boost biotech education and business.

Policy Initiative:

The state of Karnataka would focus on providing the necessary support to companies operating in the agri- biotechnology segment. These steps would include:

- Allow owning or leasing of land by bio agriculture companies for performing field trials and other agriculture related activities. Also, the process of acquiring agriculture land by biotech companies will be streamlined. A cap will be imposed on the size of land to be allotted to these companies along with a mandate that it should be used only for the stipulated purposes. Focus would be on developing biotechnology processes to tackle biotic/abiotic stress that hampers the quality and growth of agricultural production in the state. Some of these technologies include:
 - Genetic Engineering
 - Phenomics
 - Marker-Assisted Selection
 - Micro-propagation (Bio-based systems for maintenance and augmentation of soil health)
 - Microbe based systems for increased crop productivity



- Constitution and activation of State Biotechnology Co-ordination Committee (SBCC) and District Level Committee (DLC) for:
 - Effective co-ordination between stakeholders
 - Facilitate smooth testing of biotech crops
 - Promote development & deployment bio-agriculture based technologies
- Support the functioning of the agri-biotech incubation centre set up within the premises of the University of Agricultural Sciences, Dharwad. The Department of IT, BT and S&T provided INR 6.5 Crore in the first phase to establish an incubation centre that can house six or more incubatees and a common instrumentation facility.
- Establish and support TBIs with focus on Agri and Agri-allied fields in institutions such as UAS / UHS / UAHSS across the state.
 - In collaboration with other relevant departments (Agriculture, Horticulture, Sericulture etc.,) set up a centralized cost-effective testing facility in a public system (SAU) for collecting test data of new traits/events to assess value for commercial use and Biosafety aspects
- The funding provided to K Bio Venture by the Department of Agriculture (of INR 5 Crore) will solely be utilised to support Agri-biotech ventures in the state

3.8.2. Policy Initiative: Aqua-Marine Biotechnology

The Indian fisheries and aquaculture plays an important role in providing nutritional security to the food basket, enhancing export of fish and fish products and providing employment to around 15 million people⁶. With a vast and diverse aquatic resources ranging from deep seas to lakes in the mountains and around 11% of the global diversity, India has shown sustained increase in fish production, reaching the current production level of over 10 million tonnes (which is around 4.5% of the global fish production)⁶.

Karnataka is one of the nine maritime states in India bestowed with rich and varied aquatic resources, both in marine and inland sectors. These water bodies harbour rich aquatic flora and fauna having great economic value. Rich corals, diverse fish and a plethora of economically important aqua species along the 320-km natural coast line represent the rich marine biodiversity of Karnataka. Fish production in Karnataka is around 3.8 lakh tonnes, with the marine and inland sectors contributing 60% and 40%, respectively⁶.

The application of biotechnological tools has the capacity to revolutionise fisheries sector by increasing fish production and biodiversity conservation. Several institutes in Karnataka are undertaking research activities on issues which have relevance for field application. For instance, The Karnataka Veterinary Animal & Fisheries Sciences University (KVAFSU) in its College of Fisheries in Mangalore - Bangalore is undertaking research on various aspects related to control of



reproduction. Research on selective breeding and use of molecular markers, chromosome set manipulation and sex reversal is being carried out at its centres in Hesaraghatta and Bengaluru. Similarly, the College of Fisheries at Mangaluru is pursuing biotechnological research on issues related to reproduction, aquatic and fish health management and fish processing.

Policy Initiative:

The Department of IT, BT and S&T will collaborate with KVAFSU and the Directorate of Fisheries to promote research in the field of aqua-marine biotech to increase yield, and develop novel marine bioactive products and marine natural products. Plans are underway to set up a centre for innovation and incubation at KVAFSU to explore the marine ecosystem and develop products relevant to bio-energy, pharma, nutrition, etc.

This facility would also be the primary interface for research efforts focused on the use of molecular markers to improve stock of commercially important and endangered species. The planned centre would also be a hub for improving collaboration between molecular biologists, marine biologists as well as with central research institutions such as The Central Marine Fisheries Research Institute to develop potentially commercially exploitable technologies/findings.

3.8.3. Rare Diseases Management

An estimated 720 lakh children and adults in India are affected by a rare genetic disorder, with Karnataka accounting for around 30–40 lakh people affected by many diseases⁷. The diagnosis of a rare disease takes about seven to eight years and entails significant out-of-pocket expenses, leading to financial hardships for patients and their families. Moreover, there is little emphasis on clinical research and innovations in the treatment and management of rare diseases. To address this socially relevant challenge, Karnataka developed a forward-looking Rare Diseases and Orphan Drugs (RDOD) Policy to emerge as a pioneer in this area.

Policy Initiative:

The Department of IT, BT and S&T will support the Department of Health and Family Welfare to facilitate:

- Networking between academia, research institutes such as The Centre for Human Genetics (CHG), Rajiv Gandhi University of Health Sciences (RGUHS), Indira Gandhi Institute of Child Health Hospital (IGICH) and biotech industry to enable “bench to bedside” translational research for rare diseases and other deficiencies which lie in genetic understanding. Particular emphasis will be placed on application of genomic sciences and other biotechnologies for effecting substantive health access for rare diseases affected communities. This could include collaborative projects to develop enzymes for replacement therapy and translational research in the fields



of gene editing, stem cell research and regenerative medicine therapies for treatment of rare diseases.

- Setting up of rare disease registries for robust surveillance, data collection and analysis for a set of prioritized rare diseases in Karnataka. Through such registries, monitoring, documentation and evaluation of care pathways and policies will be made possible.
- Access to genetic testing and analysis to allow for personalized and precision treatment according to disease genotypes and phenotypes.

The funding required for promoting the research activities would be decided by a selection committee comprising government representatives from the Department of IT, BT & ST, Dept. of Health, Directorate of Medical Education, hospitals and research institutions and other relevant stakeholders.

3.8.4. Synthetic Biology

The global synthetic biology market is estimated to be worth USD 5.2 billion as of 2015 and anticipated to advance at a robust CAGR of 23% from 2015–20⁸. Demand from existing applications in drug & vaccine development, particularly for bio-based polymers & bio-chemicals, are driving the market. The synthetic biology segment gained popularity in hazardous waste clean-up initiatives through engineered microbes. Engineered crops, through synthetic biology, would bridge the gap between supply and demand globally. Emerging applications across novel fields of research such as agriculture and bioremediation are expected to drive market growth over the coming years. Synthetic biology can play a prominent role in decreasing the demand for land, water and other valuable resources.

In India, the research activities related to synthetic biology and their application in industries are in nascent stages. Nevertheless, in line with the global trend, India witnessed the establishment of a few start-ups that are either providing services or manufacturing products based on synthetic biology technology. These start-ups are focusing on oligonucleotide, DNA fragment synthesis, butanediol (BDO) and other synthetic biology applications using bioinformatics. Advanced synthetic biology tools will also facilitate the fermentation processes for conversion of waste into green products In Karnataka; a few start-ups focusing on synthetic biology are predominantly present in Bengaluru. IBAB and BBC provide incubation facilities to start-ups which focus on synthetic biology.

Policy Initiative:

Karnataka will leverage its existing biotechnology and information technology infrastructure to facilitate the development of the synthetic biology segment. It allocated INR 9.85 Crores to be utilised over five years and plans are in place to set up a synthetic biology centre at IBAB. These funds will be spent for supporting research activities aimed at developing products of social relevance using the synthetic biology technology. This facility at IBAB will also be the hub for facilitating academic-industry partnerships in the area of synthetic biology.



3.8.5. Bioinformatics - Omics

Bioinformatics, an established interdisciplinary area within the broader science & technology domain, encompasses a systematic development and application of IT solutions to manage biological information. Bioinformatics facilitates discovery, development and implementation of computational algorithms and other software tools to understand the biological processes in order to address the various challenges faced primarily by the agriculture and healthcare sectors. Over the last decade, bioinformatics as a segment has significantly evolved globally owing to the increasing applications in drug discovery and biomarker development, resulting in its rising use in drug development and clinical diagnostics.

Bioinformatics has a wide range of applications in life sciences research, including genomics, proteomics, chemoinformatics, molecular phylogenetics and others. Of these applications, genomics commands the largest share with more than 20% of the bioinformatics applications developed in the last five years globally focusing on genomics and proteomics. In the short-term, the global genomics market is expected to gain impetus with the development of innovative technologies such as Next Generation Sequencing (NGS), advances in cell and single molecule imaging technologies and modelling software.

In line with the global trend, the application of genomics in India is expected to play a key role, particularly in areas such as agriculture and personalized medicine. Companies across industries, including cosmetics, pharmaceutical, FMCG and agro-biotech, are increasingly focusing on genomics and require bioinformatics applications and platforms to develop better therapeutics and products.

The evolution of new methods for high-throughput genotyping also provides an impetus to non-invasive measurements of the fine architecture of plants and the functional state of plant tissues. Plant Phenomics has practical applications in agriculture, where plant breeding and agronomy can benefit significantly from the development of new agricultural germplasm to support agricultural production. The convergence of genetics and physiology to reveal the molecular genetic basis of a wide range of hitherto intractable process could enable development of high-yielding genotypes of agricultural crops adapted to future climatic conditions.

Policy Initiative:

To achieve dominance in the emerging field of omics, the government will develop a state-of-the-art genomics infrastructure to enable Karnataka to achieve international competency and standards. The government will leverage on the existing infrastructure at IBAB and CHG to develop this further as a cluster for Advanced Genome Bioinformatics-Omics

Taking advantage of the state's biodiversity, the government will establish a dedicated programme for collection of floral, faunal and microbial biodiversity to establish Karnataka's Genome Database. Karnataka is endowed with a rich biological diversity, which includes over 3,000 species of plants, over 500 species of birds, 160 reptiles and 180 mammalian species. Also, with its 320-km coastline,



the state is home to nearly 500 species of fish. The Genome Database will act as the primary storage of DNA, plant and animal tissues, including that of endangered and socio-economically important species of Karnataka.

The government will promote large scale omics and bioinformatics projects at IBAB to compile, integrate and intelligibly analyse the collected genomes data through the use of modern technologies such as NGS. These projects will enable the study of various plants, animals and microbial species, that standard laboratory culture technique are not capable of, thereby providing valuable insights into the biodiversity of Karnataka. The studies will in turn assist in sequencing and characterising specific diseases and focus on biomarker studies for rapid identification as well as treatment for human inherited and rare diseases. Also, these studies will allow virtualizing many steps in the drug development process, thus helping accelerate clinical trials and reduce the cost. For instance, human genome and biological molecules will be analysed to create new information that will play an important role in drug discovery and delivering personalized medicines to patients. Similarly, analysing microbial genomes from soil samples can help improve crop productivity.

The funding required for these initiatives will be decided by a selection committee headed by the Principal Secretary - Department of IT, BT & ST, constituting representatives from other departments such as health, agriculture, etc. academicians and other relevant stakeholders.

3.8.6. Stem cell and regenerative medicine

Stem cell therapy and regenerative medicine is an emerging discipline that is anticipated to revolutionise patient care in the future. Currently, there are more than 770 regenerative medicine companies operating globally (including gene and cell therapies), of which ~15% are based in Asia⁹. There have been several research agencies and institutions in India (particularly in Karnataka) involved in stem cell research and regenerative medicine.

These companies cumulatively raised ~US\$5.2 billion in 2016, leading to undertaking of 804 clinical trials worldwide⁹.

Policy Initiative:

The Department of IT, BT and S&T will support programmes in stem cell biology and regenerative medicines with the aim of promoting basic and translational research in view of its potential application areas. The emphasis would be on proactively engaging with stakeholders involved in regenerative medicine and cell therapy to develop, promote and accelerate implementation of innovative regenerative medicine and cell therapy applications. Existing research institutions such as InStem and CHG can be the central hubs of excellence – and would work in co-ordination with hospital networks for promoting the field of regenerative medicine.

Additionally, the department will seek to establish a stem cell bank through public private partnerships to provide a repository of human embryonic stem cell



lines for use in research that may lead to clinical applications. Further, the state will seek to set up a coordination committee of experts to support the development, communication and implementation of technical processes and manufacturing scalability standards for gene therapy, cell therapy and other regenerative medicines.

3.8.7. Antimicrobial Resistance

Antimicrobial resistance in disease pathogens has increasingly become a matter of health concern globally. It is estimated 700,000 people die of resistant infections every year. By 2020, another ~10 million lives a year and a cumulative USD100 trillion economic output are at risk due to the rise in drug-resistant infections¹⁰. In India, antibiotic-resistant neonatal infections cause nearly 60,000 infant deaths every year¹¹. The magnitude of the problem has now lead to an alliance being developed at a global stage among various stakeholders such as hospitals, pharmaceutical and biotech companies, governments and multilateral agencies to tackle this issue.

In India, the Ministry of Health and Family Welfare drafted a national policy for containment of antimicrobial resistance in the country. More recently, the National Centre for Disease Control published guidelines for treatment of antimicrobial use in infectious diseases. Further, the central government has been encouraging biotech start-ups to seek innovative ways to tackle the threat faced by India from resistance to antimicrobial drugs by investing \$100,000 to start an India-focused seed fund to help groups in India compete for the UK-enabled Longitude Prize. It also collaborated with the Finnish funding agency, Tekes, to improve competitiveness of companies in the two countries through promoting collaboration in different phases of the knowledge innovation chain.

Policy Initiative:

To further the efforts of tackling drug-resistant infections in Karnataka, the Department of IT, BT and S&T will work with other government departments and stakeholders (including hospital networks) to establish an alliance in Karnataka against antimicrobial resistance with technological intervention where applicable. The department will also seek to enhance multi-disciplinary collaboration and public-private investments for:

- Identifying high-risk strains and their resistance
- Developing rapid diagnostics tests to differentiate between bacterial and viral infections
- Discovery and development of a sustainable supply of effective new antimicrobials
- Developing informatics tools for linking human and animal diseases surveillance for better mapping and prediction of emerging diseases threat
- Promoting the development and uptake of genomic technologies to improve appropriate, prompt, patient treatment



The funding required by promoting research activities and development of solutions in this area would be decided by a select committee constituting government representatives from the Dept. of IT, BT & ST, Dept. of Health and Family Welfare, hospitals and research institutions, and other relevant stakeholders.

3.8.8. Bio-engineering

Bio-engineering has been behind many of the contemporary, path-breaking healthcare solutions that are commonplace today such as ultrasound, MRI and other imaging techniques as well as development of artificial hips, knees and other prosthetic implants. As the paradigm shift from traditional schemes of healthcare towards a more technology driven model continues unabated, the importance of bio-engineering and bio-manufacturing to build, design and repair biological systems quantitatively has gained more significance. Moreover, the emerging trend of personalized medicines will continue to spur the development of innovative healthcare solutions for curing and preventing diseases.

Policy Initiative:

To fully integrate engineering with the physical and life sciences for the larger benefit of the society, the Department of IT, BT and S&T will encourage high-impact research in imaging, health informatics, and other interdisciplinary areas at the interface of biology and engineering. Of particular emphasis would be the development of medical technologies that are low-cost, effective and accessible to the wider society. Through the existing science and technology grants and funding avenues of the state, necessary support will be provided for research activities that advances knowledge of cellular and molecular disease mechanisms into precise medical diagnostics and therapeutics.

3.8.9. Medical Devices Technology

The medical devices industry is a multiproduct industry, producing more than 14,000 different types. The Indian market for medical devices and equipment is valued at US\$4.9 billion, which is approximately ~6% of the total healthcare market¹². A rise in the number of hospitals and the increased requirement for healthcare facilities creates a need for sophisticated devices and equipment, which can provide accurate treatment to individuals. More so, there is a mismatch between the design of certain technologies being imported and realities of clinical conditions and healthcare infrastructure in the country. Thus, India has much to gain from effective use of advanced medical technology.

The "Make in India" initiative of the Government of India identified medical device manufacturing as a sunshine sector. The government also formulated a draft "National Medical Device Policy-2015" to address headwinds (such as archaic regulatory standards, sub-standard quality of India-made products, high import dependency, Lakhs of tax incentives and unfavourable duty structure et al.) and encourage manufacturing in India. As a part of this policy, an autonomous



body - National Medical Devices Authority (NMDA) - is proposed to be set up with a mandate to provide single window clearances, develop medical devices parks, benchmark international practices, develop knowledge networks, revisit regulations, create an enabling environment and recommend incentives to encourage manufacturing of medical devices in India.

Policy Initiative:

In line with the plans of the centre, the state government amended the “Karnataka Industrial Policy 2014-19” to incorporate strategies and incentives aimed at promotion of medical devices manufacturing enterprises. These include:

- Establishing a medical devices park with comprehensive infrastructure facilities such as common facilities, calibration, testing and quality control through PPP mode
- Setting up a VC fund with a corpus of INR 25 Crore (with 26% contribution from state departments) specifically for medical devices ventures
- Provision of subsidies, help with regulatory costs, incentives and grants to build capacities, promote R&D and organise trade shows and events for promoting medical device manufacturing

The Department of IT, BT and S&T will collaborate with the Commerce and Industries Department for the provision and implementation of special packages for medical devices enterprises under the Industrial Policy 2014-19.

3.8.10. Microbiome

Microbiome research has been growing on the heels of technological development in DNA sequencing in the early 2000s. Research activities in the space gained momentum after the National Institutes of Health - a medical research agency that is part of the U.S. Department of Health and Human Services - initiated a study on the Human Microbiome Project (HMP) in 2007. The investments made under this initiative (USD 215 million between 2007-14) led to generation of nearly 50,000 files of publicly available sequencing data accessed by over 75,000 users from more than 178 countries¹³.

Currently at a nascent stage, the microbiome market is expected to witness continued growth as research institutions, universities and private companies allocate resources for advancing research in this field. Growing understanding of the importance of microbiomes in the human body has led companies to invest and venture into development of microbiome-based therapeutics and drugs.

Globally, the human microbiome research spending is expected to surge from ~USD 373 million in 2015 to ~USD 702 million in 2020¹⁴. The growth in research activity would be primarily driven by biotechnology companies engaged in research and clinical trials of novel drugs and probiotic supplements based on human microbiome research studies. Currently, there are over 55 companies around the world working on ~106 ongoing projects (focusing on targeted treatment and development of alternative drugs) from discovery to clinical stage¹⁵. Based



on the current research activity, it is anticipated that human microbiome based diagnostics are likely hit the market by 2021 and drugs for treatment of diseases such as diabetes, cancer and mental disorders by 2022¹⁴.

Policy Initiative:

The Department of IT, BT and S&T will seek to promote the integrated study of microbiomes across different ecosystems especially at premier research institutions such as CHG, NCBS and IBAB.

The emphasis would be on mapping of human microbiome and understanding the effects of micro-organisms on human health and a range of diseases. Support will also be provided for development of tools to predict the function of uncharacterised genes and enhance the understanding of chemical compounds produced in the biological pathways of microbes. New methods and solutions focusing on making changes in microbes to generating disease treatments and environmental improvements will also be encouraged.

The funding required by promoting research activities in this area would be decided the Dept. of IT, BT & ST in collaboration with the VGBT.



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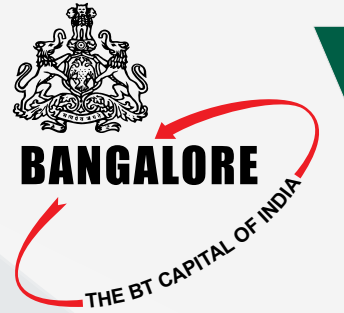
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“Most of the old cities represent the past of India.
They represent history, whereas
Bangalore represents the future that we are moulding...”

Pandit Nehru on his visit to Bangalore



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