INNOVATE KARNATAKA

GOVERNMENT OF KARNATAKA

K-tech

KARNATAKA

# Biotechnology Policy

(Draft)

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# ABBREVIATIONS

| | |
|---|---|
| ABLE | Association of Biotechnology-Led Enterprises |
| AI/ML | Artificial Intelligence and Machine Learning |
| AMR | Antimicrobial Resistance |
| AVGC | Animation, Visual Effects, Gaming & Comic |
| AVRDC | Anti-Venom Research and Development Centre |
| ARTPARK | AI& Robotics Technology Park |
| BBC | Bangalore Bioinnovation Centre |
| BFC | Biotechnology Facilitation Cell |
| BiSEP | Biotechnology Skill Enhancement Programme |
| BTFS | Biotechnology Finishing School |
| CAF | Combined Application Form |
| CAGR | Compounded Annual Growth Rate |
| C-CAMP | Centre for Cellular and Molecular Platforms |
| CHG | Centre For Human Genomics |
| CFTRI | Central Food Technological Research Institute |
| CLS | California Lifestyle |
| DLC | District Level Committee |
| DSAI | AI and Data Sciences |
| ESDM | Electronics System Design & Manufacturing |
| EDP | Entrepreneurship Development Program |
| FDI | Foreign Direct Investment |
| FTP | Faculty Training Program |
| GIFTS | GoK Incubator for Tech Start-ups |
| IBAB | Institute of Bioinformatics and Applied Biotechnology |
| IBAT | Institute of Agriculture Biotechnology |
| ICMR | Indian Council of Medical Research |
| IGICH | Indra Gandhi Institute of Child Health Hospital |
| IKF | Invest Karnataka Forum |
| 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 |
| LSSSDC | Life Science Sector Skill Development Council |

| | |
|---|---|
| MRI | Magnetic Resonance Imaging |
| NAIN | New-Age Incubation Network |
| NIB | National Institute of Biologicals |
| NASSCOM | National Association of Software and Services Companies |
| NCBS | National Centre for Biologics Sciences |
| NSDC | National Skill Development Council |
| NTU | Nanyang Technological University |
| NVEQF | National Vocational Educational Quality Framework |
| PoC | Proof of Concept |
| PPP | Public Private Partnership |
| RGUHS | Rajiv Gandhi University of Health Sciences |
| SBCC | State Biotechnology Co-ordination Committee |
| SIC | Strategic Investments Committee |
| SIR | Special Investment Region |
| TBI | Technology Business Incubators |
| UAHSS | University of Agricultural and Horticultural Sciences, Shivamogga |
| UAS | University of Agriculture Sciences |
| UHS | University of Horticultural Sciences |
| UMMID | Unique Methods of Management of Inherited Disorders |
| VGBT | Vision Group on Biotechnology |
| VGST | Vision Group on Science and Technology |

# 01

# STATE OF BIOTECHNOLOGY IN KARNATAKA

# STATE OF BIOTECHNOLOGY IN KARNATAKA

## 1.1 PREVAILING BIOTECH ECOSYSTEM

India is ranked third in the Asia-Pacific region and among the top 12 biotechnology destinations worldwide. About 3% of the world's biotechnology industry is accounted for by India.

The value of Indian Bioeconomy is USD ($) 80.12 billion, which registered a 14.1% growth from 2021. Indian Bioeconomy contributes 2.6% of the total GDP share. R&D expenditure in the field of Biotechnology has crossed $1 Billion, the sector has received $ 830 million as FDI in 2021. India has seen a huge surge in new start-ups with 3 new startups coming every day, in 2021 India registered 1,128 startups with cumulative number being 5, 365. India aims to be a $ 150 billion Bioeconomy by 2025 and a $ 300 billion by 2030. Karnataka being the Biotechnology capital of India will play a pivotal role in achieving this target.

Karnataka has been on the forefront of Indian Biotechnology Industry, owing to the prevailing ecosystem of the state. The Bioeconomy of the state grew from $ 16.44 billion to $ 18.91 billion in 2022. 155 new biotechnology startups were registered in the state in 2022, on an average a total of 13 biotech startups every day and a cumulative total of startups grew to 632. Karnataka's biotech R&D spent crossed $ 200 million. The state is also India's third largest ethanol producer and is the home to over 60 producers.

A good network of infrastructure, a huge talent pool, third largest GST collection, fifth in terms of ease of doing business and one of the highest FDI in India makes the state's ecosystem perfect for the growth of sector. Bengaluru, Karnataka's science capital and Asia's fastest growing Technopolis has developed into an ideal base for the biotechnology industry.

Karnataka is home to many renowned educational and research institutes, including the Indian Institutes of Sciences (IISC), National Centre for Biologics Sciences (NCBS), Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR), Rajiv Gandhi University of Health Sciences, the University of Agriculture Sciences (USA), Institute for stem cell science and regenerative medicines, Central Food Technological Research Institute (CFTRI), Defence Food Research Laboratory, University of Horticulture Sciences and others.

In past few years government has invested heavily on infrastructure including establishment of Bangalore Bio cluster, Bangalore Helix Biotechnology Park. Setting up bio-incubators in cities like Bagalkot, Mangalore, Mysuru and Dharwad catering to focused segments of biotechnology. Centre for Cellular and Molecular Platforms (C-CAMP), a DBT initiative located within the campus of the National Centre for Biological Sciences (NCBS) in Bengaluru, has been garnering appreciation right since its inception. DBT has also put in liberal support to another Bengaluru-based biotech startup hub Bangalore Bio innovation Centre (BBC) started by Government of Karnataka. Apart from this the state in recent years has witnessed tremendous developments in the form of DBT approving six private genomic sequencing labs and out of them four are from Karnataka. Government is also aiming to establish a pandemic preparedness centre

and Biobanking facility at BBC. Anti Venom Research Centre and Advanced biotech innovation centre for Aqua Marine will be established by Government of Karnataka in Bengaluru and Mangaluru respectively. Bangaluru Life science Park an industrial cluster developed on 52 acres with an investment of over 1000 Cr. KITS has shown keen interest in setting up the Bio Foundry in Bangalore Helix Biotech Park in electronic city, Bangalore.

State has built considerable resources and human capital to support biotechnology companies and a multi-disciplinary talent pool. 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 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.

IBAB is undertaking two distinct projects by state government synthetic biology group IBAB and Bio IT Centre. The Centre for Human Genomics has provided diagnostic and counselling services to 27,000 families with genetic disorders, the services are free of cost for BPL families. BBC has attracted a combine investment of 400 Crores and has a combined valuation of all the startups at Rs 1000 Crores. K-tech Centre of excellence established at C-CAMP, has started grand challenges on some of the major pain points faced by farmers in the State.

Strong government policy, availability of trained human capital and research base has made Karnataka, a preferred destination for global and domestic Biotech industries and investment in the country. Some of the largest Biotechnology companies such as Biocon, Syngene, Novo Nordisk, Novozymes, Bharat Biotech, Eurofin Advinus, Jubliant Biosys, Kemwell Biopharma, Millipore Sigma, Laurus Bio, Siemens Healthcare, Stelis Biopharma, Strand Genomics, Medgenome and Anthem Biosciences, are some of the major biotech companies with operations in state. Apart from these promising startups like Bugworks Research, Pandorum Technologies, StringBio, Vipragen Biosciences, Jiva Life Sciences, Fibroheal Woundcare, Immuneel Therapeutics, NESA MedTech, Zumutor Biologics have been successful in raising capital from the market in last 3-5 years and chart their growth strategies.

**The Bangalore Helix Biotechnology Park**

Bangalore Helix Biotechnology Park comprises premier academic and research institutions such as the Institute of Bioinformatics and Applied Biotechnology (IBAB), Centre of Human Genetics (CHG) and Bangalore Bio innovation 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 (In stem) and Cellular & Molecular Platforms ( C-CAMP)

## Karnataka Biotechnology Infrastructure Capabilities

| Educational & Research Institutes |
|---|
| • IISc |
| • NCBS |
| • JNCASR |
| • UAS |
| • InStem |
| • CFTRI |
| • DFRL |
| • UHS |

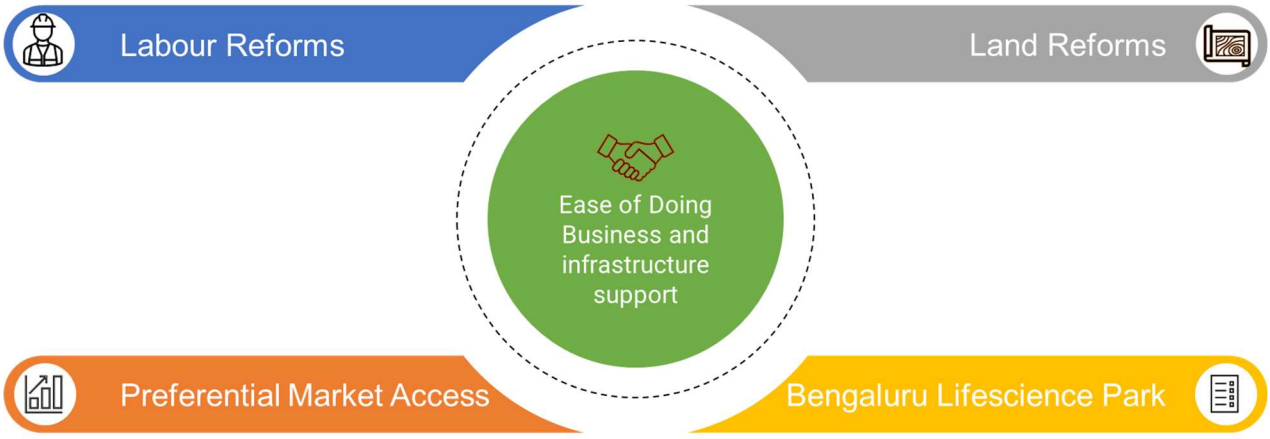
| Incubation Centres |
|---|
| ▪ C-CAMP |
| ▪ IBAB |
| ▪ Agri Incubation Center, Dharwad |
| ▪ Animal Biotech Incubation Center, Bidar |
| ▪ Marine Park/Incubation Center, Mangaluru |
| ▪ Nutraceutical & Phyto-Pharmaceutical Park, Mysuru |

| Promising Start-ups |
|---|
| • Bugworks Research |
| • Pandorum Technologies |
| • StringBio |
| • Vipragen Biosciences |
| • Jiva Life Sciences |
| • Immuneel Therapeutics |
| • Zumutor Biologics |
| • NESA MedTech |

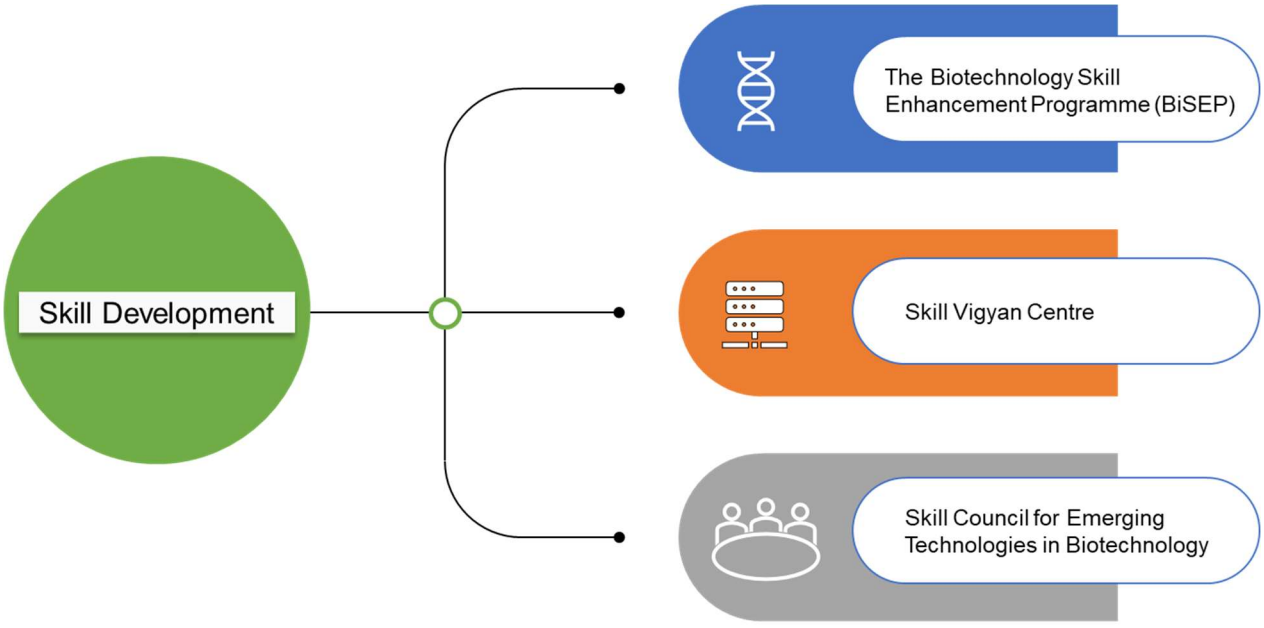
| Prominent Biotech Companies | | | | | | | |
|---|---|---|---|---|---|---|---|
| • Biocon | • Syngene | • Monsanto | • Stempeutics | • Novozymes | • Stand Life Sciences | • Avestagen | • Metahelix |
| • Laurus Bio | • Eurofin Advinus | • Stelis Biopharma | • Anthem Biosciences | • Medgenome | • Kemwell Biopharma | • Jubilant Biosys | • Millipore Sigma |

## Biotech Ecosystem in Karnataka

# 1.2 ACHIEVEMENTS OF KARNATAKA BIOTECHNOLOGY POLICY (2017-2022)

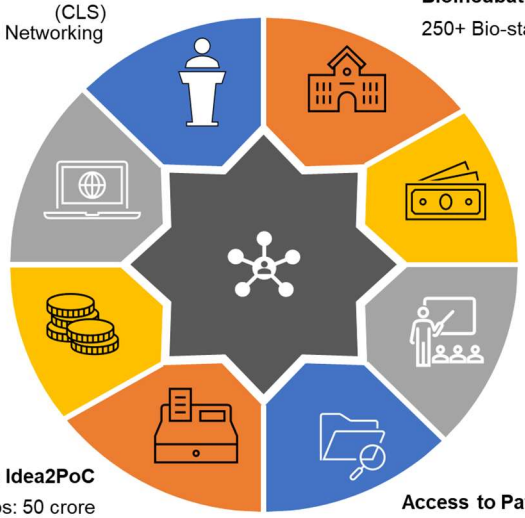



**Ease of Doing Business**




**Skill Development**

## Promote Startups & Entrepreneurship



**KITS collaboration with California Lifesciences (CLS)**
Mentorship & Networking

**Bioincubators**
250+ Bio-startups incubated

**Global Innovation Alliance program**
Collaboration with 30+ countries.

**Grand Challenges**

**KITVEN-3**
32 Cr funding: 7 BT Companies.

**K-SAP BIO50: Mentorship & Training**
50- Bio-startups

**Elevate Idea2PoC**
197 Bio-startups: 50 crore funding

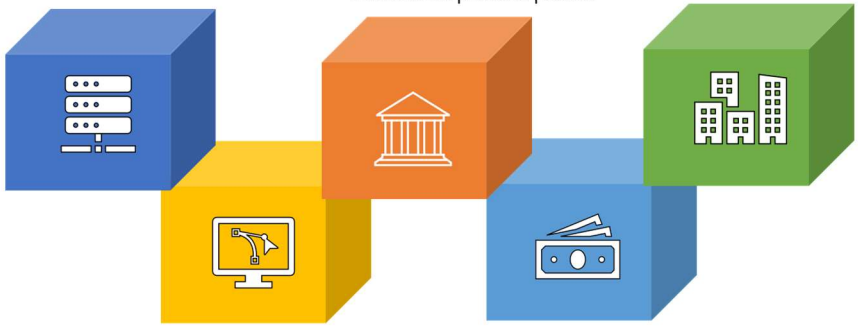
**Access to Patent Database and IP Support Cell at BBC**

## Leveraging IT Capabilities

**Bio-IT Centre**
- 1100+ students/faculties/clinicians/agriculturalist trained in NGS

**The Centre for Excellence for AI and Data Sciences**
- Air quality monitoring
- Understand pollution pattern

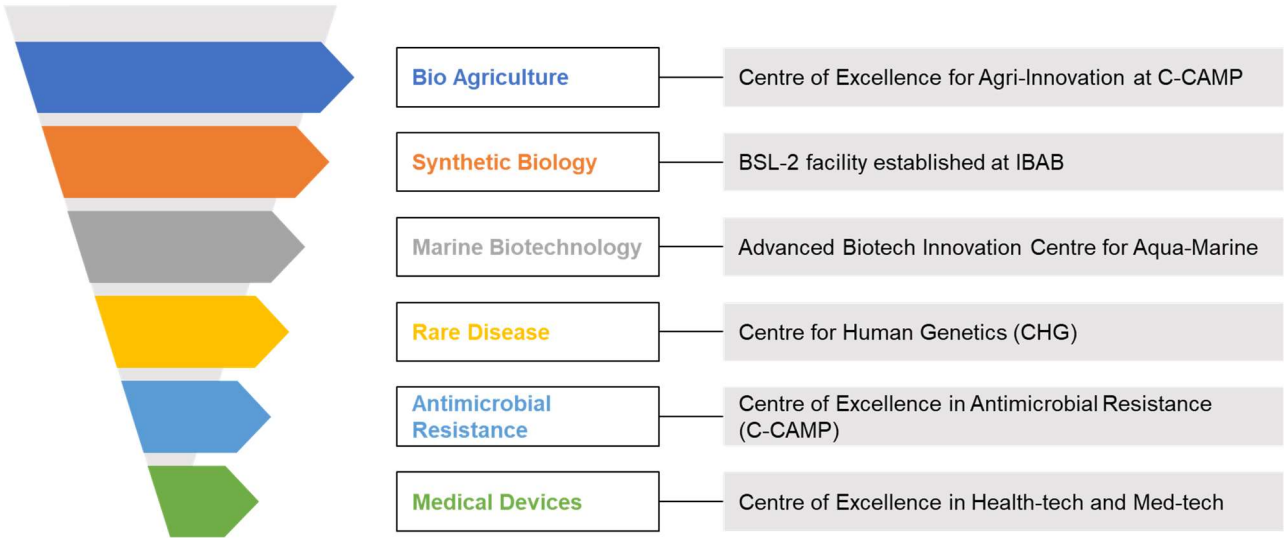
**The Centre for Excellence – IoT and AI**
- Support start-ups and Industry



**ARTPARK**
- One Health and Pandemic Prevention Data and Modelling
- Development of Platform for Research, Integrated Surveillance and Management of Health (PRISM-H)

**"Centre of Excellence Agri-Innovation programs"**
- Funding/incubation/acceleration support > 50 agritech startups

## Support for Emerging Technologies




### 1.2.1 Ease of Doing Business and infrastructure support.

a) Government re-constituted the Vision Group on BT & MNC Engagement Cell was established at Dept. of IT, BT and S&T.

b) Revamped eBiz platform with integrated and simplified process of seeking approvals from various departments. Introduction of Combined Application Form (CAF) and Self-Certification by the entrepreneurs. Relationship Managers for handholding investors

c) Online Monitoring of Disbursal of Fiscal Incentives enabled by Dept. of IT, BT and S&T.

d) Time Bound Grievance Handling through *Janaspandana* - Integrated Public Grievance Redressal System

e) Karnataka Strategic Investments Committee (SIC) as a guide to attract investments to the state.

f) Reconstituted Board of Invest Karnataka Forum (IKF) considering the current rapidly evolving global industrial landscape.

g) Online registration of property and property tax assessment

h) **Labour reforms:** simplified registration procedure, Increased transparency in inspection, Self-certification scheme Third Party Certification Scheme, allow women employees to work in night shift, permission commercial establishments to be open 24X7, separate minimum wages fixed for MSMEs and “Fixed term employment” added to encourage fixed term contracts.

i) **Land Reforms:** Sec 109 of the Land Reforms Act has been amended to make purchase and sale of farmland for industrial use, an easier exercise. Industries are now allowed to buy land directly from farmers and permission from Revenue Department deemed approved if authorities clear the application within 30 days. Industrial investments are exempt from Sec. 63, 79A, 79B, and 60, dealing with ceiling on land holding, and purchase of farmland by non-agriculturists, if the same had been cleared by the state’s high-level clearance committee or the state-level single-window clearance committee.

j) **Preferential Market Access** to startups provided by bringing in amendments in Karnataka Transparency in Karnataka Transparency in Public Procurements Rules, 2000

k) Bengaluru Life Sciences Park, an industrial cluster developed under PPP mode on 52 acres area at Bengaluru Helix Biotech Park, Electronics City, Bengaluru will have total built-up area of 50 lakhs sq. ft., with 30 lakhs sq. ft. specifically reserved for Biotechnology companies at the project's completion (with a ratio of 60% Biotech to 40% Non-Biotech area). The park will offer facilities such as an Incubation Centre, Built-to-suit Facilities, and Multi-Tenant Buildings. A building with a built-up area of 10.62 lakhs is now fully constructed and ready for occupancy. This park will provide the much-needed space for the biotechnology companies to expand and grow in the State.

### 1.2.2 Policy Interventions to create awareness about biotech-related programmes and gain public confidence and acceptance of biotech products.

The State Government has taken several steps to ensure that the policy framework is robust and futuristic in support of knowledge-based industry in the State which includes the fast-growing biotechnology industry. The State has come out with following the new policies namely, New Industrial Policy, E R&D Policy, New Startup Policy, R&D and Innovation Policy and has also established Karnataka Innovation Authority and Regulatory Sandboxes for regulating disruptive technologies. The Government of Karnataka has provided NoC to conduct confined field trials of genetically modified and herbicide-tolerant cotton and maize seeds at two universities of agricultural sciences in Karnataka.

### 1.2.3 Support for Skill Development.

The Biotechnology Skill Enhancement Programme (BiSEP), the modified version of the Biotechnology Finishing School (BTFS), aimed to educate and empower human resources to bridge the gap between academia and the biotech industry was started in 2018 in eighteen institutes spread across eight districts of Karnataka. Out of the 550+ students that enrolled in the programme, 485+ had successfully finished their training, with over 60% of them getting placed in industry.

A Skill Vigyan Centre was established in 2021 at Karnataka Innovation and Technology Society (KITS), with the support of Department of Biotechnology, Ministry of Science & Technology Government of India and under Faculty Training Program (FTP) and Entrepreneurship Development Program (EDP), implemented through seven partner institutes, 125+ teaching faculty and entrepreneurs have been trained in multidisciplinary areas of biotechnology.

A separate Skill Council for Emerging Technologies in Biotechnology has been constituted under the chairmanship of Minister for IT and BT, Government of Karnataka and members drawn both from Industry and academia. The council will provide guidance, policy advisory and specific action-oriented recommendations to bridge the skill gaps in emerging areas of technology.

## 1.2.4 Promote Startups & Entrepreneurship.

The State Government has continued to support the establishment of bio-incubators in different parts of the State under Technology Business Incubator scheme of Startup Policy and Biotechnology Policy. A total of 1.5 Lakhs plus incubation space has been created in five places viz., Bangalore Bioinnovation Centre, Bengaluru, GoK-Manipal BioIncubator, Mangaluru, Nutra Phytopharmaceuticals Incubation Centre, Mysuru, Institute of Agri Biotechnology, University of Agricultural Sciences, Dharwad and Centre for Biotechnology, University of Horticultural Sciences, Bagalkot. Nearly 250+ biostartups are incubated and availing the facilities made available at the incubators.

Siddaganga Institute of Technology, Tumakur and Basaveshwara Engineering College, Bagalkot along with NMAM Institute of Technology, Nitte, Udupi, Bapuji Institute of Engineering and Technology, Davangere, P A College of Engineering, Dakshina Kannada, Sri Jayachamarajendra college of Engineering, Mysuru, College of Agriculture, Vijaypura and KLE Dr. M S. Seshagiri College of Engineering, Belagavi having students pursuing biotechnology courses were encouraged and provided funds under NAIN to start their entrepreneurship projects and to avail initial funding under the programme. Boot camps and mentorship support were provided by BBC and C-CAMP.

ABLE as Knowledge Partner to GoK was asked to conduct awareness workshops and seminars in tier II and tier III cities to promote entrepreneurship. ABLE has already conducted such workshops/seminars in Belagavi, Mysuru, Mangaluru, Shivamogga etc.

K-SAP BIO50, Karnataka Start-up Advancement Program was started in collaboration with C-CAMP to enhance the likelihood of success for biotech startups through one-on-one mentoring, performance assessments, workshops, training and seminars, networking events, international partnering meetings and ancillary facilitation. 50 Biostartups have benefited from this program.

KITS had collaborated with Pune-based patent intelligence Platform and provided access to their patent search product “Patseer” for specific period to the winners of Elevate Idea2PoC (BT/Agri/Healthcare/Medtech/Diagnostics categories), BiSEP Host institutions, New Age Incubation Network organisations, TBIs and BioIncubators supported by GoK. Further, they were connected to Technology Transfer Office set up by DBT, GoI at C-CAMP and Patent Facilitation Cell at Bangalore Bioinnovation Centre to avail IPR services including patent search, drafting, filing, monetization, etc.

A total of 197 bio-startups have been funded under Elevate Idea2PoC scheme of Karnataka Startup Policy to tune of Rs.50+ crores. A sum of Rs.32 Crores has been invested in seven potential startups in the field of tissue engineering, nutrition, drug discovery and MedTech under BioVenture Fund (KITVEN – 3). The combined valuation of these seven companies is estimated at Rs.1500 crores upwards.

The Karnataka government launched the Global Innovation Alliance program in 2017 with the goal of establishing a forum for international cooperation on technology and innovation and making sure the state of Karnataka has a chance to demonstrate its capabilities as part of this global tech revolution. Currently, Karnataka is engaged in ongoing collaboration on projects with over 30+ GIA partners. Karnataka startups

are being introduced to the GIA country start-up ecosystem through the GIA Tech Engagement Meet, which aims to facilitate collaboration. Approximately fifteen GIA Tech Engagement Meetings have taken place with approximately twelve nations. GIA have also worked along with nations such as the UK, Australia, Germany, and others to enable Karnataka-based startups to take part in tech- and innovation-focused start-up initiatives introduced by these nations.

KITS, GoK started a unique International Acceleration Program in collaboration with California Lifesciences (CLS), USA that offered an unparalleled opportunity for Karnataka-based bio-startups to tap into the global market and receive invaluable guidance from seasoned professionals. The program's strategic collaboration with California Lifesciences adds further value, as it leverages the expertise and resources of one of the world's most influential biotech hubs. The program assisted bio startups in the life sciences sector by utilising the Bay Area's extensive knowledge in the creation and application of novel medical devices, diagnostic tools, therapeutics, and synthetic biology. The principal aim was to stimulate the expansion of biotechnology startups in Karnataka by utilising CLS's Silicon Valley expertise and network to assist Karnataka startups. A total of five start-ups in the field of life science, MedTech and healthcare were provided with expert mentorship program by CLS. All received technical, business, and market leads, indicating the valuable guidance they received. The mentor assigned to one of the startups has become an integral part of their advisory board, providing continued support for business development and investment. One of the startups even secured an export order, demonstrating the program's efficacy in promoting global business opportunities.

### 1.2.5 Support R&D addressing key societal issues by collaborating with various government departments to encourage projects that seek to provide solutions made possible by biotechnology.

To strategically shape the future of biotechnology in the areas having wide societal impact and increased bioeconomy, Anti-Venom Research and Development Centre (AVRDC), is being established as a collaborative initiative between KITS, GoK, IBAB and the Evolutionary Venomics Lab, Centre for Ecological Sciences, Indian Institute of Science at Bengaluru Helix Biotech Park. This centre will play a major role in developing advanced snakebite interventions and biodiscovery research from venoms, as well as provide various services invaluable for the manufacture of lifesaving antivenoms. In addition, IVRU will assist Forest Departments with wildlife forensics analyses of venoms and play a major role in snakebite education and outreach. The centre coming up in a total built-up area of 16,000 Sq. Ft. to have a serpentarium, venom extraction observatory, research lab, incubation facility and digital library.

### 1.2.6 Leverage IT capabilities for development of Bio-IT tools and solutions by fostering collaboration between the IT & BT ecosystems to develop new solutions & realize the potential of biological research and discoveries.

Bangalore India Bio and Bangalore IT eBIZ, the two flagship events of the Department were conducted annually since the beginning of this new millennium. In the year 2019, to bring together the convergence of

innovation in both the IT and BT domains and talk about exponential technology laws and the future of genomics, both the flagship events were combined as “Bengaluru Tech Summit” to really celebrate the "translational research" push that academia and industry in Bengaluru provides like no other city in South Asia.

Government of Karnataka continued support for training students and faculty in genomics by utilising the Next Generation Sequencing facilities, at the Bio-IT Centre of IBAB and actively collaborate with leading research organisation and hospitals to identify Karnataka specific genomic alterations that aid in cancer therapy and diagnosis of rare diseases, collaborate with genomic research companies to undertake translational research. The centre has introduced 2-year MSc course in Big Data in Biology, with emphasis on training students in AI/ML and applications in Biology that has 100% placements. More than 1100 students/faculty/ clinicians/agriculturists have been trained in NGS and single cell genome sequencing and analysis through hands-on workshops. Also has taken up sequencing and identification of unique variants in the Indian cohort which are probable drivers of cancer and drug targets, generated around 12.5TB data and has contributed to several publications in high impact journals.

Many Bio-IT startups who are working in the areas of applying AI, ML, NLP and Blockchain, other IT tools in solving some of the critical issues in the areas of drug discovery and disease diagnosis both in plants and animals are encouraged and funding extended under the Elevate Idea2PoC and Centre of Excellence Agri-Innovation programs.

The Centre for Excellence for AI and Data Sciences (DSAI) established by NASSCOM with the support of the Department of IT, BT and S&T has assisted Karnataka State Pollution Control Board with Intelligent Visualization air quality monitoring system deploying Deep learning and ML to analyse area-wise air pollution, weather, moisture levels to understand pollution patterns better. Karnataka Forest Department was assisted to optimize sales and operations of major forest produce by using AI analytics to forecast quantity required, type by seasons, species behaviour and best time to harvest and dispose. The centre has initiated discussion with the Department of Agriculture to set up Agriculture Experience Centre and development of Agricultural Stack for adoption with Startups. “AI for Good” program of DSAI has unlocked promising AI solutions to address some of the most common and complex problems in the areas of Healthcare, Agriculture, Natural Resources, Waste Management etc. Aindra Systems, Intello Labs, MyCrop, KisanRaja, Tricog Health, CropIn, JioVio Healthcare, TCS’s mKRISHI Platform, BKC WeatherSys, Accenture, IBM’s Watson for Oncology and Telerad Tech who participated in the program had utilised IT tools to solve critical challenges related to agriculture and healthcare.

The Centre for Excellence – IoT and AI, supported by the Department of IT, BT and S&T has developed programs to support startups and industry develop and deploy IoT and AI enabled solutions in the areas of Agriculture and Healthcare.

Department of Science & Technology (DST), Govt. of India and the Department of IT, BT and S&T has jointly supported establishment of ARTPARK (AI & Robotics Technology Park), a unique non-profit (section 8) organization promoted by the Indian Institute of Science (IISc) to foster innovations in AI & Robotics.

One of the focus areas is to drive AI through translational R&D in areas of Intelligent Healthcare. ARTPARK has initiated One Health and Pandemic Prevention Data and Modelling to understand the interlink and build predictive models using artificial intelligence for pandemic prevention. The outcome of the initiative will strengthen systems and assist healthcare policy makers with swift and specific decision making. One of the outcomes of this initiative is the development of platform for Research, Integrated Surveillance and Management of Health (PRISM-H) for disease surveillance in Karnataka that amplifies the State's dengue surveillance through an AI-based predictive model. ARTPARK has entered collaboration with ICMR as a national initiative to create gold-standard datasets representing India's diversity for improving access to and effectiveness of Medical Imaging in screenings and diagnostics to assist healthcare professionals.

### 1.2.7 Support for emerging technologies like Synthetic Biology, Marine Biotech, Medical devices, microbiome etc. to foster Bioeconomy.

The Government of Karnataka has supported the establishment of Synthetic Biology Group at IBAB to promote and strengthen research activity in Synthetic Biology. A state-of-art laboratory has been established with BSL 2 facility. Research projects initiated in the area of high socio- economic impact including production of high value metabolites and therapeutic proteins, development of a novel tunable synthetic yeast expression system expression of proteins and biomolecules, metabolic engineering of yeast cells to produce high value carotenoids by efficiently utilizing industrial bio-waste, engineering microbes to express a cocktail of gluten degrading enzymes for use in food industry & enzyme therapy, engineering human cells for biosensing and clinical applications and engineering mosquito cells to control transmission of virus infection. The collaborative research undertaken with industry includes engineering antibodies for therapeutic applications and engineering enzymes for bioproduction of a high value flavor and fragrance.

The Government of Karnataka has started Advanced Biotech Innovation Centre for Aqua-Marine in partnership with College of Fisheries, Mangaluru to support innovation and startups to develop value added products and functional foods from fish, bioactive compounds from sea weeds, nutraceutical and high-value byproducts from fish and Shellfish waste. The Centre when fully operational is expected to support 100+ startups formed by supporting innovative ideas generated by researchers, young professionals, and entrepreneurs.

KITS, GoK has established Centre of Excellence for Agri-Innovation in collaboration with Centre for Cellular & Molecular Platforms (C-CAMP) to promote deep-science/technology driven entrepreneurship in the Bio-Agri sector, leading to innovation, economic development, and job creation in the agricultural domain. The activity of the centre includes having Agri Immersion Programs, Grand Challenge, and hand holding them to become top global Agri-innovators of global scale. As part of this program, C-CAMP has promoted >50 agri startups with funding/incubation/acceleration support. Over 12 products have been commercialized and several start-ups have raised follow-on rounds of funding.

The Government of Karnataka has continued its support to the Centre for Human Genetics (CHG) which is engaged in advanced research, education, training, and services in human genetic diseases. It has pioneered services for rare diseases and research in Karnataka since 2003. Thousands of patients and

families have benefited from the diagnostic, counselling services and therapies it provides. CHG provides advanced training to doctors with MBBS and MD degrees and young scientists The Government of India, Ministry of Health has notified CHG as a Centre of Excellence for treatment of rare genetic disorders, one of only eight Centres in the country to receive this recognition. CHG has been selected listed by DBT, Government of India to implement its Unique Methods of Management of Inherited Disorders (UMMID) programme to assist the least developed districts of the country to manage the burden of Rare Genetic Diseases. It has also nurtured many focused on developing biotherapeutics for treating rare genetic disorders.

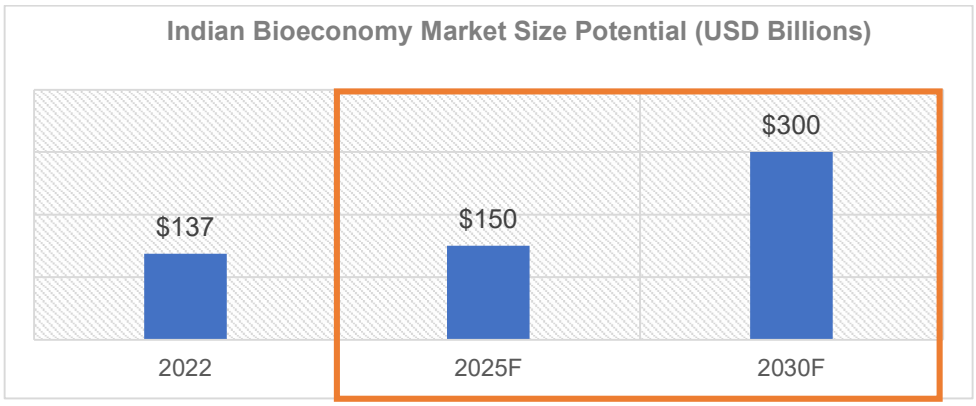
The Health and Family Welfare Department, Government of Karnataka has established Anti-microbial Resistance (AMR) Cell headed by Senior Medical officer. The department has also constituted the State Multi-Sectoral Steering Committee, State-level Technical Advisory Committee and District-level monitoring committee. Awareness programs and state-level actional plan under National Action Plan on Containment of AMR are taken under the directions of these committees. The Department of IT, Bt and S&T has been coordinating with the Health Department in providing necessary support and encouraging bioindustry and startups to come up with novel solutions. Bangalore Bioinnovation Centre (BBC) has joined as a new Partner of Amsterdam based AMR Insights. The Centre for Cellular and Molecular Platforms (C-CAMP) is setting up the Centre of Excellence in Antimicrobial Resistance innovation in Bengaluru under the aegis of the global India AMR Innovation Hub chaired by the Office of the Principal Scientific Adviser, GoI. The focus of the centre will be identifying and supporting, through funding and mentoring cutting-edge deep-science solutions across AMR and the larger health domain spanning food and agriculture, environment, and healthcare.

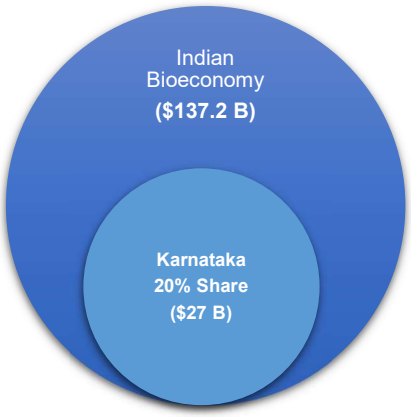
The Government of Karnataka has approved setting up a Centre of Excellence in Health-tech and Med-tech in PPP mode. The CoE is expected to boost innovation in the areas of medical biotechnology and indigenization of medical devices.

# 1.3 GROWTH POTENTIAL FOR BIOTECHNOLOGY IN THE STATE

The value of Indian Bioeconomy is $ 137.2 billion, which registered a 29% growth from 2021. Indian Bioeconomy contributes 4% of the total GDP share. R&D expenditure in the field of Biotechnology has crossed $ 1 billion, the sector has received over $ 580 million as FDI in 2022. India has seen a huge surge in new start-ups with 3.8 new startups coming every day, in 2022 India registered 1,391 startups with cumulative number being 6,755. India aims to be a $ 150 billion Bioeconomy by 2025 and a $ 300 billion by 2030. Karnataka being the Biotechnology capital of India will play a pivotal role in achieving this target.

Karnataka has been on the forefront of Indian Biotechnology Industry, owing to the prevailing ecosystem of the state. The Bioeconomy of the state grew to $ 27.1 billion in 2022. 155 new biotechnology startups were registered in the state in 2022, on an average a total of 13 biotech startups every day and a cumulative total of startups grew to 632. Karnataka's biotech R&D spent crossed $ 200 million. The state is also India's third largest ethanol producer and is the home to over 60 producers.



# 02

# POLICY OBJECTIVES

# Policy Objectives

The first two millennium Karnataka Biotech Policies laid the foundation for an advanced biotechnology ecosystem in Karnataka and the third policy focused on to provide direction and support to the sustainable development of thriving and world-class biotech ecosystem. Also, the past policies have laid solid foundation, and provided required support and impetus leading to a matured ecosystem which has now reached desired inflection point to bring the real 'Transformation'. Hence, the focus of this policy will be '***Transformation through impactful Implementation***' to take the growth from a liner to exponential level. This policy will synergize with the policies that the State already has in place viz., Industrial Policy, R&D and Innovation Policy, ER&D Policy and Startup Policy and at the same time be distinct in supporting the growth of the biotech sector in the State. This policy outlines the following principal objectives to create a comprehensive and supportive policy framework for the growth and development of the biotechnology sector in Karnataka, fostering innovation, job creation, and socio-economic progress:

1) **Simplify and expedite regulatory processes** for biotech companies, making it easier to establish and operate businesses in Karnataka. This includes faster approvals for setting up biotech industry and global research and development centres beyond Bengaluru.
2) **Attract domestic and foreign investments** by offering fiscal incentives and concessions. Encourage partnerships between public and private sectors for large-scale biotech projects.
3) **Support capacity building of biomanufacturing of new products** that support human health, climate, and energy goals, improve food security, and grow the bioeconomy of the State.
4) **Encourage research and development** initiatives that have a clear social impact. Provide grants, incentives, and infrastructure support for projects addressing critical societal challenges, such as healthcare, agriculture, and environmental sustainability.
5) **To support skilling and upskilling of workforce** in biotechnology by partnering with educational institutions to have a well-trained talent pool available for R&D and Industry.
6) **Promote cross-disciplinary collaboration and technology convergence** to stimulate innovation in the biotechnology sector. Facilitate partnerships between biotech companies, IT firms, and other industries to harness the power of data analytics, AI, and other emerging technologies in biotech.
7) **Establish a robust support ecosystem for biotech startups**. This includes augmenting existing funding mechanisms, establish incubators, accelerators, grow out space and mentorship programs to nurture and accelerate the growth of early-stage biotech ventures.
8) **Foster international collaborations and partnerships** in research, development, and technology transfer, enabling Karnataka to be a global biotech hub.
9) **Promote** biotechnological innovation and its adaption in rural Karnataka.
10) **Continue to support** research, development, and commercialization efforts in **emerging technology areas of biotechnology**.
11) **Encourage formation of innovative enterprises** in new age biotech sectors medical devices, diagnostic, cell and gene therapies and cures against rare diseases

12) **Preferential government procurement norms** for made-in-Karnataka biotech products and services.
13) With suitable incentives and encouragement, help **build Karnataka as a major global hub for the next big thing in Genomics,** called **"A crack in creation"** that is the ability of researchers to write on genomics i.e., edit, more accurate proofread and modify the genomes.
14) Build the base in the state for the next big thing emerging in biotechnology, that is the **combination of genomics and molecular biology** to boost tremendous advances in materials research, micro- and nano technologies for human health, food and energy security of the state.

The proposed objectives would be achieved by harnessing on some of the achievements and opportunities accomplished during the earlier policies and strategically implementing the key tenets of this policy.

**Policy Period and Applicability**

This policy shall be valid for a period of five years from the date of issue of Government Order or till a new Policy is announced.

# 03

# POLICY INITIATIVES

# Policy Initiatives

**3.1 Simplify and Expedite Regulatory Processes for Biotech Companies, Making It Easier to Establish and Operate Businesses In Karnataka. This Includes Faster Approvals for Setting Up Biotech Industry and Global Research and Development Centres Beyond Bengaluru**

A state's ability to flourish economically depends on its ability to create a conducive business climate. Karnataka has already put in place several measures that have made it one of the easiest states in India to do business in (EODB). In terms of business, a state like Karnataka, which has the most biotech companies and is one of India's fastest developing states, has the potential to overtake the other top states. Since the First Biotechnology policy was put into effect twenty years ago, the state's business attractiveness has increased thanks to an open and transparent business climate. The State government has undertaken several ground-breaking initiatives to draw in and keep some of India's biggest biotechnology businesses. A substantial amount of work has gone into streamlining and rationalising current procedures and utilising technology to improve governance and information distribution. Streamlining the administrative processes for businesses to invest in biotechnology which included single-window clearance, approval tracking system and a grievance redressal cell. Establishment of a web platform for dissemination of information related to the biotech sector. It presents a chance to draw in many foreign businesses to invest and conduct business in Karnataka. The policy will implement various initiatives as an endeavour to strengthen its position as a preferred destination for Biotechnology hub. An intensive exercise of mapping the entire business life cycle and the regulatory and compliance requirements at each stage has been carried out before concluding on the below Policy Initiatives -

**Policy Initiatives/Action Points:**

a. Leveraging the benefits of the existing policies under the KUM platform, E-Udyami and SAKALA Act and Reinforce attractiveness for business - Industry and Government to proactively collaborate and identify potential policy measures to further strengthen innovation and investment in the state to maintain its leadership position.
b. The Policy will aim to establish a standing Rapid Response Team of key agency representatives at the Biotechnology Facilitation Cell (BFC). Such team would meet regularly to guide industry about the latest regulatory requirements and provide recommended regulatory routes for compliance to the end users. The Rapid Response Team will also provide opportunities to cross-train regulatory staff members as guides that would reside within each agency to support the review of regulatory requirements.

**3.2 Attract Domestic and Foreign Investments by Offering Fiscal Incentives and Concessions. Encourage Partnerships Between Public and Private Sectors for Large-Scale Biotech Projects.**

India rank's 11th place in attracting FDI at the national level and Karnataka ranks 4th in attracting FDI at the state level. The Karnataka Industrial and ER&D policies combinedly facilitate greater investments in advanced manufacturing, research and development (R&D), innovation and to the create jobs. Further, the focus of the said policies is on Industry 4.0, R&D, Intellectual Property Rights (IPR), Technology Adoption and Innovation, Cluster Development Initiatives and Sustainable Industrialization. The plan is to align this policy to the same strategies to extend various benefits for the growth of biotech sector in the State. Biotechnology Industry by nature is capital intensive and requires sustain capital inflow to sustain and flourish. For the growth of the ecosystem, the policy would, therefore, plans to offer a special fiscal incentive and concessions to support and attract foreign investment.

a. **Moving beyond the capital, Bengaluru- Fiscal incentives Domestic and Foreign players for setting-up High-Tech Clusters beyond Bangalore (Zone 1 & 2)**
   The Policy will aim to support the concept of High-Tech Clusters or Biotech City wherein the developed industry would be encouraged to set-up their manufacturing units and support startups and SMEs with plug and play facilities in taluks coming under Zone 1 & 2. Government if required will consider amending the proposed Special Investment Region (SIR) Act to create, operate, and regulate such High-Tech Clusters in the State.
b. Subsidies for MSMEs- Government will also leverage and pass the benefits of Industrial Policy and ER&D policies to domestic and foreign biotechnology companies to boost bio-industrial innovations. The investment promotion subsidy will be based on 10 percent on turnover each year for a period of five years and limited to 20 to 30 percent of value of fixed assets (VFA). Other incentives include – exemption from stamp duty and concessional registration charges; reimbursement of land conversion fee; tax exemption on electricity tariff for MSMEs; and power subsidy for MSMEs.
c. The Policy will also align with other Departments to support Biotech players on the permissible Floor Space Index for the biotechnology units in biotechnology park.
d. To attract private investments from Indian and foreign entities, the Government shall consider strengthening Biotechnology Facilitation Cell at KITS and will choose an appropriate industry mascot that would act as a signatory to the state's success in the biotechnology sector, and would help with pitching to investors via roadshows, exhibitions, summits, conferences, etc.
e. Special incentives in alignment with Karnataka Industrial Policy and ER&D policy to domestic industries and overseas will be provided on case-to-case-basis.

### 3.3 Support Capacity Building of Biomanufacturing of New Products That Support Human Health, Climate, and Energy Goals, Improve Food Security, and Grow the Bioeconomy of The State Along with Making Karnataka as a Next Global Biomanufacturing and Clinical Trials Hub.

The first Karnataka Bioeconomy Report published in 2020 highlighted the strategic importance of concentrating on select domains. Notably, the report emphasized the pivotal roles of Bio-manufacturing and Vaccine Manufacturing in fortify Karnataka's leadership in R&D and manufacturing. Karnataka, a pioneering state in India, is embarking on an ambitious mission to establish itself as one of the largest biomanufacturing hub in the country for boosting the State's bioeconomy and reflecting its steadfast commitment to revolutionizing the healthcare and biotechnology landscape.

At this inflection point, State Government investment is critical to create large, shared, and scalable facilities that can be utilized by various growth-stage startups and companies who have products to take it to transitional stages of growth. Biomanufacturing infrastructure hubs could provide these critical facilities in locations across Karnataka, advancing manufacturing methods for complex new bioproducts and providing training opportunities for skilled workers. These hubs would be developed on public-private partnerships model, established in Bengaluru and other districts like Mysuru and Hubballi - Dharwad. The hubs would expand equitable access to job opportunities and enable better utilization of the unique natural resources and industrial capabilities located in different parts of the State. Further, the hub facilities would be designed for modularity and adaptability for a range of new products. The funding for these biomanufacturing infrastructure hubs would originate from public-private partnerships, and a substantial portion of the funding for the hubs would come from private industry.

Government of Karnataka will strategically focus on establishing a Bio foundry, a Novel Vaccine Hub, and advancing the state's prominence in clinical trials to solidify its global presence in the realm of cutting-edge biomedical research and development. Bio-foundry, will serve as a beacon of innovation, driving advancements in bioprocessing, synthetic biology, and related biotechnological domains. Vaccine Research & Pilot Production Facility for Next Generation Vaccines to serve as a pivotal nexus for the accelerated development and production of groundbreaking vaccines, addressing pressing global health challenges and bolstering the state's contribution to the international fight against infectious diseases. Complementing these two initiatives, Karnataka will be intensifying its efforts to become a global leader in clinical trials, by fostering a conducive environment for ethical and high-quality research, the state aims to position itself as a preferred destination for pioneering clinical trials, attracting leading researchers and fostering strategic collaborations with international healthcare institutions.

Initiatives:

a. **Establishment of Green-field Bio-foundry**

   A bio-foundry is a specialized facility that integrates principles of engineering, biology, and automation to streamline and accelerate the design, construction, and testing of biological systems. Essentially, it serves as a centralized hub for high-throughput biotechnology research, development, and innovation. Bio foundries aim to facilitate the rapid prototyping and optimization of biological systems, including the development of bioproducts, biopharmaceuticals, and various biotechnological solutions. Additionally, bio-foundries often serve as collaborative platforms,

fostering partnerships between academia, industry, and other research institutions to promote knowledge exchange and the translation of research findings into practical applications. The bio-foundry facility also addresses the growing demands of the growth-stage companies and to meet their requirements of GMP Pilot Plant & Scale-up facility.

The State proposes to set-up a green-field Bio Foundry at Bengaluru Helix Biotechnology Park as Joint Venture between Centre, under DBT initiative of "Fostering High Performance Biomanufacturing' and the Private Sector. The Private partner apart from investing in the project will also take on the responsibility of managing and operating the facility. This will be governed by an independent Board with representatives from Centre, State, and the Private partners.

b. **Vaccine Research & Pilot Production Facility**

The Government will support for the establishment of Vaccine Research & Pilot Production Facility on Viability Gap Funding basis to leverage all the capabilities that we have in our state in an integrated manner to pursue a vaccine development strategy starting with Covid19 and beyond. The facility (Biosafety Level 3) should focus on developing novel vaccines (nucleic acid (RNA or DNA), viral vectors, protein based (sub-units or virus like particles) plasmids, adjuvants - inactivated toxins, etc.) at a scale that can cater up to Phase 3 Clinical Trials. The facility must include an animal house to conduct pre-clinical vaccine testing may be dovetailed to DBT, GoI plans for the establishment of Centres of Excellence on New Emerging technologies (CONEs) for vaccine Adjuvants development. The facility estimated to cost approximately ₹250 will have private sector preferably a Contract Research Organisation (CRO) is involved, and the facility operated on commercial basis.

**c. Promote Karnataka as next Global Clinical Trials Hub**

India's average annual contribution to global clinical trials from 2010 to 2022 was approximately 4%, despite the country's large population. Following the regulatory changes post 2013, the top-20 pharma sponsored trials in India has increased by 10%. To increase the overall effectiveness of carrying out clinical trials, regulatory changes made after 2013 and the formative New Drugs and Clinical Trial Rules of 2019 have streamlined the approval processes, shortened the timelines by 30–40%, and added various exemptions and provisions. In India, private healthcare hospitals represent 60% of all hospitals. Private hospitals, which are mostly found in tier-1 cities, offer 87% of all services, 80% of all doctors, more beds, cutting-edge infrastructure, and patient access. Additionally, Tier-1 cities have much higher rates of disease prevalence, investigator density, and patient access to care. The healthcare market in Karnataka, is currently experiencing a dynamic and evolving landscape. Karnataka has significantly improved healthcare services, infrastructure, and technology in recent years, which has improved the state's population's general health.

The Karnataka Institute of Medical Sciences (KIMS), Hubballi, has been recently recognised by ICMR as a centre for clinical trials, making the institute the first and only government facility in Karnataka to be among the handful of such campuses across the country. The proposed Hospital

built within the existing IISc Bengaluru campus, will have the full advantage of the co-location with the science and engineering faculties and labs significantly shaping the technological innovation and advancements in near future. The availability of research funding and the booming biotechnology and pharmaceutical industries is another reason for the steady growth of Bengaluru as clinical research hub. Government will consider servicing a detailed study to chalk out the growth strategies and set-up support systems for setting up collaborative centres that can enable faster access to sites and patients for top pharma players for disease with high unmet need. This includes consider creating a single point ethics committee to have fast-track decision making and approvals, provide training to the ethic committee members evidence generation and use of real-world data and evidence in research and clinical practice and improve access to global clinical trials and support patient recruitment using real world data and evidence.

d. Government will support and incentivize setting up bio-manufacturing units related to CAR-T, mRNA Vaccines, AMR drugs, Biofuel and Alternate Foods. The proposed bio foundry and Biotechnology Growth Cluster would be utilized to support companies focusing on these domains.

Through these concerted efforts, the state is poised to emerge as a formidable global player, driving transformative advancements in biotechnology, vaccine development, and clinical research, while significantly impacting the global healthcare landscape with its innovative and progressive approach.

**3.4 Encourage Research and Development Initiatives That Have a Clear Social Impact. Provide Grants, Incentives, and Infrastructure Support for Projects Addressing Critical Societal Challenges, such As Healthcare, Agriculture, and Environmental Sustainability.**

Many advancements in the field of biotechnology stem from transformative discoveries made in academic research, which often originate from fundamental scientific exploration. Numerous thriving biotechnology companies worldwide draw substantial benefits from collaborating with academic institutions, highlighting the vital role of research and development in the life sciences domain. Prioritizing R&D activities in academic and research settings is crucial for generating innovative ideas and technologies. These, in turn, can be harnessed by private enterprises to create novel products and services, ultimately driving economic and societal progress. Current policy would place a strong focus on promoting interdisciplinary cooperation to tackle intricate issues that frequently involve interconnected contemporary research inquiries. By amalgamating expertise and know-how from various fields, including biology, chemistry, physics, medicine, engineering, and information technology, it would not only enhance the current knowledge repository but also generate fresh technologies to confront significant societal problems. To achieve this effect, the policy would adjust the current state funding structure to incentivize academic and research institutions that benefit from it to engage in collaborative research endeavours aimed at enhancing the well-being of a large population.

Initiatives

a. The policy will revitalize the knowledge environment at par with the growing bioeconomy will plan to set-up a Centre for Drug Discovery - for discovery and development of natural product-based drug utilising the state-of-art laboratory facility, Institute of Excellence at Mysuru established with the support of UGC/MHRD.
b. Establishment of Validation centres for nutrition claims with a focus to collect valid data on the phytochemical components of different Indian foods.
c. Nanobiotechnology Translational Research Centre - to facilitate and encourage scientists to move the knowledge outcomes with translational values for further validation and prototype development.
d. Strengthening the existing collaboration with the various other 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 Husbandry, Department of Health and Family Welfare, Department of Fisheries, Department of Ecology and Environment, local municipal bodies, etc., to develop and adopt latest biotechnological solutions 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.
e. Government will consider supporting pilot projects that aims to improve the yield of biofuels and bioenergy crops, produce novel enzymes used for waste treatment and processes such as bioremediation and improve agricultural crops to increase yield and improve nutritional value.
f. The Policy aim to address bio-remediation issue by promoting and incentivizing schemes to ensure less pollutants are released into the environment.

g. Research and Innovation is an outcome of interaction between industries, Universities, Research Institutions and Government. To enhance the synergy and seamless collaboration between the stakeholders, the proposed e-platform known as e-KRDIP will be utilized.

h. The proposed new organization called Karnataka State Research Foundation (KSRF) formed as part of Karnataka Research & Development and Innovation Policy will be mandated to support research projects in the field of biotechnology that addresses critical societal challenges related to healthcare, agriculture, and environmental sustainability.

i. A "Delivery Integrator" approach to coordinate cross-departmental activities that biotech may affect will be experimented. This will give state departments - a platform to collaborate effectively on shared problems and advance societal benefits more quickly.

**3.5 To Support Skilling and Upskilling of Workforce in Biotechnology by Partnering with Educational Institutions to have A Well-Trained Talent Pool Available for R&D And Industry.**

Unquestionably, Karnataka has a more diverse and highly skilled labour force than any other state, and its institutions are supported by research and academia. This is the state's largest bioeconomic edge. The Department of Skill Development, Entrepreneurship, and Livelihood was established by the Karnataka government to help young people gain the skills they need to find work and advance their livelihoods.

Using the Karnataka Skill Mission as a guide, this policy created these initiatives to handle the tasks of organising, regulating, standardising, promoting, putting into action, and overseeing skill development programmes pertaining to the biotechnology industry within the state. Given that 55% of the population is between the ages of 20 and 59, Karnataka has a favourable demographic dividend that would lead to faster economic growth, ensuring that young people are given the necessary skills. Skilled persons will then be able to find employment in the state as well as outside (including other countries) where there is demand for skilled workforce. The youth population of Karnataka population is about 52% of male, while the rest are female. The policy initiatives are cognizant of such ratios and therefore gender sensitive and have been taken into consideration giving priority to youth female in skill provision and promotion of employment among them. Government would leverage the natural competitive benefit the State has and will aim to foster the idea of entrepreneurship at school/ college level and provide them with a vision and back them fall back-option.

As part of the Millenium Biotech Policy – I, Government had supported for the establishment of Institute for Bioinformatics and Applied Biotechnology (IBAB) at Bengaluru, Institute for Agri Biotechnology at University of Agricultural Sciences, Dharwad and provided building and financial support for Centre for Human Genetics. The Policy will aim to create a larger vision of '**A vision to inspire and aspire'** to build strong and skilled workforce by developing IBAB and CHG together as a university of global standing by providing enhanced infrastructure and financial support. Similar such support will be provided for the Institute of Agri Biotechnology now coming under the Department of Biotechnology, UAS, Dharwad to start new graduate and post-graduate courses for developing trained human resource in emerging areas of Agri-Biotechnology including Gene Editing, Minichromosomal Technology Molecular Breeding, etc. The other initiatives planned are as follows:

a) The existing Biotechnology Skill Enhancement Program (BiSEP) shall be continued to support for development of skilled workforce. It will be restructured with an aim to create a highly trained candidates in specific areas of biotechnology.

b) The Policy will aim to sponsor various programs for global head hunting of scientist and create a platform for private companies to collaborate in attracting international expertise. The Policy will work on the ideology that bringing the best researchers in the biotechnology field would, in turn, attract the best students, junior researchers and faculty members.

c) The Policy to create a 'Bed to Bench' Research Investigator Award with the aim to promote the recruitment of number of highly qualified clinician scientists from abroad by incentivizing the private sector.

d) Special incentives can be extended to young scientists who are recipient of various prestigious grants and support them with rental discounts or concessions on national / international travel to attend event organised by the Department of IT, BT and S&T.

e) Polytechnic schools for skill development -The State has a total of 266 polytechnic colleges out which 85 are Government colleges. Policy will support to introduce biotechnology course in select Government and Government-aided Polytechnic colleges located in the Districts of Mysuru, Mangaluru, Hubballi – Dharwad, Raichur and Yadgir giving preference to Women Polytechnic colleges.

f) Stimulate industry and academia collaboration in skilling - Government seeks to bridge the gap between academic skills and needs of the biotechnology industry, by enabling State Universities/State Government University affiliated Autonomous Colleges to provide quality training and develop skilled human resources for the industry. Also, Industry to actively participate in designing curricula and standards for skill training courses, depute their industry members as faculty, make shop floor available for practical training and institutionalise paid apprenticeship. This policy will aim to develop industry designed courses and promote adaptation of the same across State's Government Universities and State Government University Affiliated Autonomous Colleges with NAAC 'A+' grade with CGPA >3.26. This will enable to support setting up of lab infrastructure in these academic institutions by industry. The host institute must develop the job-oriented training program of minimum three months duration in collaboration with one or more biotech industry having an annual turnover not less than 25 Crores.

   The selected State Universities or State Universities affiliated Autonomous Colleges, up to 10 colleges, will be reimbursed up to INR 10,000 per candidate for training and certification of selected students totalling to not more than 500 students per host institute during the policy period.

g) **Upskilling Program** - The Policy will aim to implement various upskilling programs like which would be like the theme of Continuous Professional Development Programs. Government will start an upskilling program for working professionals to encourage them to take timely action to reskill and upskill to seize the opportunities in the biotechnology industry, An amount upto INR 20,000/- shall be reimbursed to working professional, aged 25 years and above with not less than 2 years' work experience to undergo hands-on training in the advance biotechnological areas of Bioengineering, Genome Engineering & Editing, Cell Culture Techniques, Bioprocessing and Biomanufacturing, Molecular Diagnostics, Microbial Fermentation Techniques, Molecular Diagnostics, Immunology and Vaccinology, Big Data Biology, BioPrinting, etc., provided by organisations like IISc, IBAB,

CHG, IITs, IISERs, Autonomous institutions under DBT, GoI and Universities having NAAC A++ with CGPA >3.51.

h) The Policy aims to encourage regular update of curricula and courses in line with market demand and quality parameters. The department 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.

i) In line with the central government policy on the quality assurance framework, the state government will develop the quality criteria and align the same with the National policy at later point in time when it is finalised. The quality framework will set minimum standards and provide guidance for effective, valid, reliable, fair and transparent assessment in the context of NSQF. This would also facilitate certification and thereby improve status of skills training. Guidelines for accreditation of training providers based on training capabilities, infrastructure, and availability of trainers, ties with industry, etc., will be notified.

j) Industries will be encouraged to earmark funds for periodic skilling and up-skilling of personnel employed in the industry by utilising the space and infrastructure available in the government ITIs and polytechnics.

k) The Policy will aim to support establishment Competence Centres in association with an international training centre or MNC industry, to provide cutting-edge training for talent development with the newest digital and biomanufacturing skills in biotech and biopharma.

l) The Policy will act as a focal point and provide a platform for industry to establish partnerships with key science and engineering institutions in the State enabling the development of the new and more advanced methods needed to improve and expand biotechnological approaches and address some of the challenges of current bioprocessing and manufacturing methods. Technology Development and Transfer Support program will be initiated wherein all the research activities carried out as part of this program are in academic institutions, accompanied by the support of an industrial company that sees business potential in the achievements of the project. This incentive program provides financing applied research at academic institutes that has significant commercial value and IP generating capacity. The main goal is to reach significant milestones by the end of the project, which will enable the industrial company to sign a technology commercialization agreement with the research institution. This will also bridge the gap between academic knowledge and industry.

The academic institutions having recognition as a Research Centre by the State Universities or DSIR Certification is entitled to a grant of up to 50% of the approved budget towards non-recurring expenditure with a maximum scope of INR 10.0 Lakhs.

The research activities in the incentive program will have to compulsorily receive professional support by a registered biotechnology company as an Industry partner providing professional

guidance and in setting of research goals, as well as participates in the project by funding a minimum 30% of the total project cost. The balance 20% of the approved project can either be borne by Academic institution on its own or the industry partner can enhance its contribution to 50% of the approved project cost.

These grants may be availed by an entity, once, over the policy period. At the end of the research, the supporting company receives the first right to negotiate a commercialization agreement with the research institution. Such Industry and Academia partnerships should provide very specific training opportunities for doctoral students and increase the workforce for expertise at the bachelor's and doctoral level through industry immersive programs.

**3.6 Promote Cross-Disciplinary Collaboration and Technology Convergence to Stimulate Innovation in the Biotechnology Sector. Facilitate Partnerships between Biotech Companies, IT Firms, and Other Industries to Harness the Power of Data Analytics, AI, And Other Emerging Technologies In Biotech.**

Bengaluru is the Silicon Valley of India and Government will leverage this competitive advantage to its fullest. The impact of advance IT tools like AI, ML, Blockchain, Big Data Analytics, etc., on the entire value chain of Biotechnology industry is vital and can lead to faster and safer drug discovery and delivery systems and thus, being able to reduce cost and rolling out various biotechnology products. Karnataka's well established IT base, further backed by presence of large number of GCCs, which is effectively acts as a perennial source of trained human resource. Leveraging on this competitive edge, the Policy lays guidelines promoting cross-disciplinary collaboration to harness the synergetic relationships with the BT industry.

Policy Initiative:

a. The Government has proposed establishment of Karnataka Health Technology Laboratory (KHTL) at the cost of INR.8 crores. The Department of Electronics, IT & Bt will collaborate with the Department of Health and Famil Welfare in setting up KHTL and other Government Departments and industry players to set-up Centre of Excellence (CoE) or Technology Support Centres to encourage projects that promote cross-disciplinary collaboration and technology convergence.
b. The Policy will aim to set-up a Resource Centre with an industry partner or Association to provide access to computing and data sources used in Genomics, and DNA Synthesis and Fermentation. The identified partner will pool and subsequently distribute access to data used in biotechnology discovery applications for investigators and biotechnology startups.
c. Government will also plan to support Medical Colleges and Hospitals wherein a sizable collection of data from both clinical trials for drugs & diagnostic studies are there and it is made available to foster innovation by biotech industries and startups.
d. Technology Convergence: The Policy will also promote cross-disciplinary collaboration and technology convergence to stimulate innovation in the biotechnology sector by facilitating partnerships between biotech companies, IT firms, and other industries to harness the power of data analytics, AI, and other emerging technologies in biotech. The Policy will leverage the presence of ARTPARK, CoEs for Agri-Innovations, AI, IoT, Data Sciences, Robotics, Cybersecurity etc., for these purposes.
e. Data Privacy and Security: Provide platform and incentives to create and support in developing robust data privacy and security standards to protect sensitive genetic and healthcare data generated through biotech research. The incentive can be given to start-up companies working in these domains.
f. The Policy will continue to provide Bengaluru Tech Summit, as a common platform for various industries and startups to come together to set an agenda, identify cross-disciplinary challenges and collaborate to address such issues and through this policy and IT, Startup, E&RD and R&D and Innovation policies continue to support such innovation solution to mainstream product development.

**3.7 Establish a Robust Support Ecosystem for Biotech Startups. This Includes Augmenting Existing Funding Mechanisms, Establish Incubators, Accelerators, Grow Out Space and Mentorship Programs to Nurture and Accelerate the Growth of Early-Stage Biotech Ventures.**

Government is committed in creating a local environment that facilitates the acceleration of the product development to commercialization process that is critical to retaining the State's position as the premier biotech and life sciences innovation hub in India and the globe. The State has number of bio-incubators established with the support of Department of IT, BT and S&T. central agencies like NITI Aayog, BIRAC, DST, etc. and private who are supporting new businesses during their early stages. Through Elevate Idea2PoC, Grand Challenges, Seed Funding along with mentoring programs, the Dept. of IT, BT and S&T has been nurturing bio-startup ecosystem in the State. The City of Bengaluru, Karnataka has been among the top thirty startup ecosystems in the world for many years now (Startup Genome Report 2023).

Initiatives:

a. **Biotechnology Growth Cluster** - The Department of IT, BT and S&T will support for the establishment of a high-tech Biotechnology Growth Cluster (New industrial cluster with plug and play facilities as conceptualised in the Karnataka Industrial Policy) either by private investors or through PPP mode. This will act as a grow out space for maturing startups coming out of BBC, C-CAMP and other places where they can chart their next phase of growth and ensure innovation and productivity in emerging areas of Biotechnology continuous.

b. The Karnataka Startup Advancement Programme (K-SAP) implemented by C-CAMP will be re-structured and continued to support early-stage businesses in overcoming the "valley of death".

c. Karnataka Innovation and Technology Venture Fund -5 (KITVEN Fund-5) is a SEBI registered Category 1, Alternative Investment Fund (AIF) – Venture Capital Fund having target corpus of Rs.100 crore proposed to undertake investments in startup / SME companies catering to AI, ML, MedTech, EV, and such other Disruptive Technologies will be available for bio-startups developing products using disruptive technologies like gene editing, bioengineering, etc.

d. To encourage graduating students or professionals with experience to pursue entrepreneurship related to biotechnology business idea and to make pursuing entrepreneurship in the field of Biotechnology a lucrative and attractive career option, a fellowship of Rs.50,000/- per month for a period of 12 months will be given for them to become successful startups and minimize the risk faced by a budding entrepreneur. The state-supported incubators will hand-hold them and guide them along to convert the technology business ideas into business products.

e. A program to undertake valuation of select bio-startups (Department of IT, BT and S&T funded) interested to raise A series or scale-up funding will be initiated to assist them to understand their current standing or recommend possible avenues to improve.

f. In collaboration with incubators, training-plus-excellence programmes for entrepreneurs in fundamental and high-tech biomanufacturing techniques and technology business development will be initiated.

g. Since the entire ecosystem has matured and the various Angel Investors, PE / VC are investing in the young growth companies owned and run by technocrats, the policy will aim to incentive the efforts made by these companies to upskill their business acumen and skills. The Policy will provide certain incentives for attending various courses at the premier management schools like IIMs, XIME, IISc among others.

**3.8 Foster International Collaborations and Partnerships In Research, Development, and Technology Transfer, Enabling Karnataka to be a Global Biotech Hub.**

A platform called Global Innovation Alliance was launched during 2017 with an aim to tap the mammoth potential and growth of technology and innovation across the globe and to ensure State of Karnataka is provided an opportunity to showcase its strengths as part of this global tech revolution. This platform has grown over the years with mutual projects including biotech being implemented with countries like Australia, Finland, Germany, Netherlands, Japan, Switzerland, UK among others. Even considering the COVID-19 pandemic, constant communications were conducted with GIA partners to ensure their safety and concerns are addressed extending support to GIA government and industry partners present in Karnataka but to acknowledge the support lent by them to Karnataka during the challenging pandemic times.

The GIA countries have been participating in Bengaluru Tech Summit, the flagship technology conference of Government of Karnataka and dedicated track for Global Innovation Alliance (GIA) is created for facilitating international partnerships. Countries will host technology sessions for ecosystem connects, exchange of ideas and people, and deliberations on policy environment. This would be mutually beneficial where both countries would showcase their national capabilities and how they are shaping the public discourse on the rules and norms of emerging tech. The engagement with GIA partners will be continued focused on areas like Agritech, Bioinformatics, Healthtech, etc.

Initiatives

a. To support the growth of Karnataka's biotech and life science startup ecosystem, Government will continue to engage with international biotech hubs like Silicon Valley, Boston, Tel Aviv, etc.
b. Karnataka has been participating in BIO-USA, BIO-Japan and BIO-Korea and similar such events regularly and showcasing the biotechnology prowess of the state to international community. The Government intends to continue its participation and support for participation of startups and biotech companies in these events providing opportunity for fostering international collaborations.
c. Government has started to organize Global Innovation Alliance – Market Access Program (GIA-MAP) for Start-Ups. Few programs dedicated to biotech and life sciences startups will be organised under GIA-MAP.
d. Following the success of pilot K-tech – California Lifesciences Startup International Acceleration Program, a full-scale will be started with a target of supporting 100 biotech and life sciences startups during the policy period.

### 3.9 Promote Biotechnological Innovation and Its Adaption in Rural Karnataka.

Biotechnological tools enable the development of crops with enhanced resistance to pests and diseases, improved tolerance to environmental stresses, and increased nutritional content. Biotechnological advancements in veterinary science have contributed to improved livestock health, disease resistance, and production efficiency. Both are essential for rural economies heavily dependent on agriculture and animal husbandry. Biotechnological tools like gene editing, recombinant technology etc., aid in developing crops with improved resistance to pests and diseases. The development of portable and affordable diagnostic tools using micro-fluidic and other technologies has improved healthcare access in remote rural areas. Biotechnological tools are employed in the production of biofuels and biogas, providing rural areas with sustainable and renewable energy sources. This not only reduces dependence on non-renewable resources but also opens avenues for decentralized energy production in rural communities. Therefore, the integration of biotechnological tools and innovations in rural areas is integral to achieving sustainable development, enhancing agricultural practices, improving healthcare, and contributing to the overall growth of the bioeconomy of the State.

Policy Initiatives -

a. Government has already announced for the identification, evaluation and commercialization of grass-root innovations developed by farmers, artisans, labourers, technicians and others to solve local problems with an estimated budget of INR 5.0 crores. Centre of Excellence for Agri-Innovation at C-CAMP and Farm Innovation Centre at Bangalore Bioinnovation Centre will be utilised to identify biotechnological innovations developed by farmers and rural researchers and support them to successful business products.
b. A Rural Biotechnological Innovation & Application Centre will be set-up to support innovations having social impact and its scale-up in the areas of healthcare, agriculture and environmental sustainability and promote the concept of “Bio-Village”. Bio-Villages involves leveraging biotechnological innovations to address agricultural challenges, enhance healthcare, promote sustainable practices, and create economic opportunities, ultimately contributing to the holistic development of rural communities.
c. Theme-based workshops/seminars and awareness camps in support of rural technology development and its adaption will be continued to be held in zone 1 and zone 2 taluks with the support of ABLE and other organizations.

### 3.10 Definition of Biotech Companies and Extending Financial Incentives and Concessions for Attracting Investments in the Biotech Sector

#### 3.10.1 Definition of a biotech Company including Start-ups:

The definitions mentioned in the Karnataka Biotechnology Policy - III (2017-2022) continues to this policy. The companies that can be defined as biotechnology company must register with KITS, Department of IT BT and S&T, Government of Karnataka under Biotech Policy to avail the financial incentives and concessions announced in this policy.

#### 3.10.2 Fiscal Incentives and Concessions:

The fiscal incentives and concessions offered under the Industrial Policy 2020-2025 of the Commerce & Industries Department, Government of Karnataka shall be extended, where applicable, to the biotechnology industry and R&D centres in the state upon registration of Biotech Companies with KITS, Department of IT, BT and S&T, Government of Karnataka. To administer these and other incentives and concessions provided in this policy, the taluks in the state have been divided into four zones in Karnataka Industrial Policy 2020-2025 and the same would be followed where applicable. The scale of fiscal benefits and concessions available to the biotech industry under the Industrial Karnataka Biotechnology Policy 2020-2025 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 2020-2025. Some of the incentives available to the biotech sector under the Industrial Policy 2020-2025 of the Commerce & Industries Department of Government of Karnataka include:

a) Investment promotion subsidy
b) Exemption from stamp duty and concessional registration charges
c) Reimbursement of land conversion fee
d) Exemption on tax from electricity tariff
e) Interest subsidy on technology Up-gradation loan
f) Interest subsidy on technology adoption
g) Incentives for quality certification
h) Incentives for water harvesting / conservation measures
i) Investment subsidy for setting up of effluent treatment plants (ETPs)
j) Capital Subsidy for setting up STP.

#### 3.10.2.1 Incentives from the Department of Electronics, IT, BT, and S&T:

All the incentives and concessions extended by the Department of IT, BT and S&T to the companies in the biotech sector under the Karnataka Biotechnology Policy (2017 – 2022) will be continued under this policy. The process of applying and disbursal will be restructured and made more user industry friendly. The list of incentives and concessions extended to this policy are listed below.

#### 3.10.2.2 Biomanufacturing Unit Investment Subsidy:

Biomanufacturing Unit Investment Subsidy of maximum INR 10 Crore shall be available for the first five biomanufacturing enterprises with a minimum green field investment of 50 crores in Zone - 1 and Zone - 2

taluks and a minimum employment of 50 members. In case of units related to CAR-T, Vaccines, AMR drugs, Biofuel and Alternate Foods, additional 10% Investment Subsidy will be provided.

**3.10.2.3 Financial Assistance as Matching Grants for R&D:**

The Government would match the funding raised by the biotech company for R&D from Government of India as matching funds. Registered Biotechnology company getting funding support for R&D under any scheme of Government of India will be given matching funds to further increase the amounts available for them to undertake cutting edge research and development.

**3.10.2.4** Re-imbursement of up to 50% expenses incurred for procuring high end equipment's for undertaking cutting edge R & D by a DSIR recognised biotech company subject to a maximum of INR 10 lakhs per company applicable once during the policy period.

**3.10.2.5 Reimbursement of Costs for Preparation of Project Report or Valuation Report or Market Study:** Refund of cost incurred for preparation of project report for obtaining term loan or valuation of the Company for raising A-Series funding or market study costs up to a maximum of INR 3.00 lakhs.

**3.10.2.6 Power tariff Concessions:** A recommendation certificate from KITS, Department of IT BT and S&T to ESCOMs to help in power tariff concession.

**3.10.2.7 Interest subsidy (6%)** for Technology up-gradation for MSMEs for a loan of maximum of INR 100 lakhs for 5 years

**3.10.2.8 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 10 lakhs per case).

**3.10.2.9 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.

**3.10.2.10 Marketing Incentives:** reimbursement of 60% of the actual costs incurred for international marketing programs, subject to a maximum of INR 5 lakhs per year per company and 60% of the actual costs incurred for domestic marketing programs, subject to a maximum of INR 2 lakhs per year per company.

Department of IT BT and S&T will provide the following additional incentives to the companies under this Biotech Policy to support the growth of the Biotech industry in the State.

**3.10.2.11 Reimbursement of Lease Rental for Startups and MSMEs**

Biotechnology companies in all **zones**, taking on lease a minimum space of 10000 SQF and maximum space of 20000 SQF for their scale-up operations will be provided with lease rental reimbursements. *Reimbursement at the rate of INR 25/- per SQF will be provided to registered BT companies setup in all zones up to a maximum amount of INR 5 lakhs overall, for a period of 1 year, applicable once during the policy period).* This incentive will be applicable for spaces taken on lease rent for a period of 2 years and above only during the policy period.

#### 3.10.2.12 Employment Generation Incentive for Startups and MSMEs

Eligible registered biotech startups and MSME companies will be given the benefit for claim up to 50% of CTC with a ceiling not exceeding INR 50,000 per employee. The incentive will be available to the applicant for hiring Karnataka domiciled graduate or post-graduate with biotechnology as one of the major subjects of study who have joined the applicant biotechnology unit as a permanent / contractual employee and has successfully completed term of 1 year. This incentive is tied to each employee and can only be claimed once for each employee in their lifetime. Therefore, if a biotech company claims this incentive for any individual employee, and thereafter the same individual employee moves to another biotech company, this subsequent company cannot claim the assistance for this employee.

#### 3.10.2.13 Reimbursement of Internship Stipend:

The offering will provide reimbursement of internship stipend to biotechnology companies for hiring biotechnology students pursuing graduate or post-graduate courses as interns in the industry. The aim of this offering is to encourage industry-academia linkages, bridging the gap between academic skills and biotechnology industry requirements and develop skilled biotechnology talent pool. The offering will also help boost talent development in the biotechnology industry.

GoK will reimburse 50% of the internship stipend for interns per entity, for a maximum period of 6 months, up to INR 5,000 per month per intern, for a maximum of 1000 interns per year and 5000 interns over the policy period. The entity to offer internships to 33% women candidates and consider 50% of the total interns into full-time employment, to be eligible for this incentive.

**3.11 Encourage formation of innovative enterprises in new age biotech sectors medical devices, diagnostic, cell and gene therapies and cures against rare diseases.**

Given Bangalore's abundance of prominent biotech companies, medical device firms, and research centres specializing in rare disorders, Karnataka can strategically foster the creation of innovative enterprises in emerging biotech sectors such as medical devices, diagnostics, cell and gene therapies, and treatments for rare diseases.

a) To expand existing funding support provided by the Karnataka government to establish mechanisms or grants specifically dedicated to fostering international collaboration among students and researchers in the biotech fields.
b) Policy to aim at the formation of a strategic advisory panel consisting of experienced professionals, entrepreneurs, and experts in biotech fields. They can offer guidance and mentorship to college-level start-ups.
c) Strengthen Technology Transfer Offices within academic institutions to facilitate the commercialization of research findings and promote collaboration with industry partners.
d) To foster collaboration between domestic biotech companies, research institutions, and international counterparts to share knowledge, resources, and best practices.
e) To develop adaptive regulatory frameworks that accommodate the unique characteristics of emerging technologies, such as cell and gene therapies, fostering innovation while ensuring safety and efficacy.

### 3.12 Preferential government procurement norms for made-in-Karnataka biotech products & services.

a) To develop clear and comprehensive guidelines outlining preferential procurement norms for biotech products and services made in Karnataka.
b) Offer financial incentives, such as price preferences or discounts, to government agencies procuring biotech products and services produced within the state.
c) Provide tax benefits or exemptions to companies that meet the eligibility criteria for local procurement.
d) Establish a catalogue of locally produced biotech products and services, categorizing them based on their relevance to different government sectors.
e) Prioritize biotech products and services that demonstrate innovation, research excellence, and contribute to advancements in the field.

**3.13 With suitable incentives and encouragement, help build Karnataka as a major global hub for the next big thing in Genomics, called "A crack in creation" that is the ability of researchers to write on genomics, i.e. edit, more accurate proofread and modify the genomes.**

a) The policy will aim to develop a robust genomic data infrastructure that ensures secure storage, efficient processing, and ethical use of genomic data for research purposes.
b) To establish data-sharing protocols to facilitate collaboration between research institutions, both within Karnataka and on a global scale.
c) Policy to focus on Implementing comprehensive newborn screening programs to detect congenital anomalies early. To support funding for screenings for all newborns, ensuring that every child born with a congenital anomaly receives timely attention.
d) To create a regulatory sandbox for genomic editing technologies to allow for controlled experimentation and innovation while ensuring ethical and safety standards are maintained.

**3.14 Build the base in the state for the next big thing emerging in biotechnology, that is the combination of genomics and molecular biology to boost tremendous advances in materials research, micro- and nano technologies for human health, food and energy security of the state.**

a) To facilitate collaborative research initiatives between IINScT, IBAB, and other research institutions, universities, and industry partners. Foster a culture of interdisciplinary collaboration to address complex challenges in materials research, micro- and nanotechnologies.

b) To promote **Synthetic Biology** for Materials Production: Molecular biology techniques, including CRISPR, can be applied to engineer microorganisms for the sustainable production of materials, such as biofuels and bioplastics.

c) **Genomic Selection** in Crop Breeding: Genomic information can be used to select traits in crops, improving yield, resilience, and nutritional content. This contributes to food security by enhancing crop productivity.

d) **DNA-Based Sensors**: Genomic tools can be utilized to design DNA-based sensors for detecting specific biomolecules, pathogens, or genetic mutations, enabling early disease diagnosis.

e) **Nanomedicine**: Molecular biology can contribute to the design of nanocarriers for drug delivery, enhancing the targeted delivery of therapeutic agents to specific cells or tissues.

### 3.15 Continue to Support Research, Development, and Commercialization Efforts in Emerging Technology Areas of Biotechnology

#### 3.15.1 Bio-Agriculture

Karnataka, 123,100 km² of land, or 64.6% of the state's total area, are under cultivation. The state's overall agricultural productivity has increased significantly. The biggest contributor to the $1 billion Bio-Agri market in 2022 was Bt cotton. The Bt Cotton's contribution to the Bioeconomy of Karnataka stood at 5% share. Karnataka is also one of the leading states in Biofertilizer and pesticide usage. Karnataka, last year, has also issued NOC for confined field trials of two herbicide-tolerant GM crops: Bt Cotton and Bt Maize.

The state's arable land is mostly covered by semi-arid areas that are vulnerable to recurrent droughts, which can result in crop losses of up to 60%. There is an urgent need for the adoption of climate-resilient agriculture (CRA) to increase farm incomes and productivity over the long run while utilizing the natural resources that are already available through systems of crop and livestock production. Interestingly, the UAS, Dharwad has developed 24 novel crop breeds that are insect, salinity, and drought resistant. The state will continue the focus on the development of biotechnology procedures to address biotic and abiotic stressors impeding the state's agricultural production's growth and quality which includes phenomics, genetic engineering, genome editing, micropropagation etc.

Initiatives:

a) Genome Editing addresses the constraints of GM methods, facilitating enhancements in established local and regional crop types as opposed to introducing novel variants. Similarly, Minichromosomal technology does not alter the genes of plants in any manner, resulting in faster regulatory approval and acceptance by farmers. By using minichromosomal technology, agricultural geneticists can add dozens of traits to a plant. These traits can be agronomically beneficial ones like drought-tolerant and improved nitrogen usage. To support innovations and its adaptations, a specialised startup Hatchery for Genome Editing and Minichromosomal Technology will be established in one of the Agriculture Universities in the State. The Hatchery will function like incubators and support idea stage to startups and growth-oriented providing *access to training, technology, and semi-private workspace to grow their* businesses. The structure and the financing required for the initiative would be decided by a select committee constituting government representatives from the IT, Bt and S&T departments, agriculture scientists and industry experts.

b) The Centre of Excellence for Agri Innovation at C-CAMP will continue to come out with grand challenge calls to solve critical challenges faced by farmers by supporting innovative companies to build precision agriculture technologies based on big data analytics, simulation modelling, drone technology, pest-surveillance, and forewarning systems.

c) The Department of Agriculture will be launching soon the Navodyama scheme to fund startups for developing innovative agri-solutions, scale-up business and mentorship and acceleration programme The capacity of Bangalore Bioinnovation Centre and CoE for Agri-Innovation at C-CAMP capacity to support & hand hold the startups and a structured mentorship and acceleration program will be devised focusing on first generation agri-entrepreneurs selected under both Navodyama and Elevate Idea2PoC program..

### 3.15.2 Marine-Biotechnology

One of India's nine maritime states, Karnataka is endowed with an abundance of diverse aquatic resources in both the interior and marine domains. These water bodies are home to a diverse range of aquatic life that is highly valuable economically. The 320-km natural coastline of Karnataka is home to abundant corals, a variety of fish, and other economically significant aquatic species, all of which contribute to the region's rich marine biodiversity. The Karnataka Veterinary Animal & Fisheries Sciences University (KVAFSU) in its College of Fisheries in Mangalore and its centres in Bengaluru has been instrumental in conducting biotechnological research in aquaculture which includes generation of monosex, uniparental and polyploid populations, transgenic fish, molecular biology, enhanced feeds and health management, and the creation of natural products from marine organisms. Unique Marine Biotechnology Incubator has been established in Mangaluru to support innovative ideas and encourage growth of marine biotech sector in the State. Seaweeds have the potential to be highly interesting biotechnological sources since they produce a wide variety of secondary metabolites with a wide range of biological functions. The policy aims to give a special focus in seaweed cultivation for isolating bioactive metabolites that are valuable for food, pharmaceutical, cosmetic, nutraceutical and bio-based chemical industries.

Initiatives

a) The Departments of IT, BT, and S&T will continue to support Advance Biotech Innovation Centre for Aqua-Marine at College of Fisheries, Mangaluru to undertake aqua-marine biotech research to boost production and create novel marine bioactive and marine natural products with a special focus on bioprospecting of seaweeds to isolate bioactive products with industrial applications.

b) A Marine Biotech Cluster comprising of College of Fisheries, Advance Biotech Innovation Centre for Aqua-Marine, St. Aloysius College, Mangaluru University, Nitte University Centre for Science Education & Research, and nearby industries will be formed and support extended to conduct short-terms training programs to generate skilled human resources for marine agriculture, seaweed farming and processing, undertake genetic improvement programs for high yielding cultivars, establish demo seaweed cultivation and pilot processing plants for scaling up activities.

c) The Coastal Aquaculture Authority (Amendment) Act, 2023 has acknowledged the evolution of environmentally friendly aquaculture practices beyond shrimp farming, incorporating methods like cage culture, seaweed culture, marine ornamental fish culture, and more. The act has facilitated

for operation of aquaculture Units like hatcheries, Broodstock multiplication centers (BMC), and Nucleus Breeding Centres (NBC) within 200 meters from the High Tide Line (HTL).

d) Government would like to take advantage of the simplified regulatory processes and Ease of Doing Business that has been brought in the Coastal Aquaculture Authority (Amendment) Act, 2023 to generate employment opportunities and entrepreneurship in coastal regions by encouraging startups and industries for establishment of seed weed banks, seaweed cultivation, and marine ornamental fish cultures on an industrial scale and also through cooperatives benefitting small farmers, fishing community and SHGs, through profit sharing. The funding and the scope of support provided for this initiative will be decided by a committee headed by the Principal Secretary - Department of IT, Bt & ST, constituting members drawn from Department of Fisheries, Karnataka Veterinary Animal & Fisheries Sciences University (KVAFSU), ABLE and subject experts.

### 3.15.3 Synthetic Biology & Bio-derived Structural Materials

The size of the worldwide synthetic biology market was estimated at $ 13.09 billion in 2022, and it is projected to increase at a CAGR of 18.97% between 2023 and 2030. The engineering of biological systems at various scales, from molecules to animals, is the focus of this field to facilitate research and the development of new products. Alternative protein sources like plant-based meats (a solution for food security), insect gene editing (to eradicate malaria), large-scale microorganism production (for the removal of carbon dioxide), and quick vaccine development (such as mRNA vaccines) are a few potential applications for synthetic biology. Many major societal issues, like as climate change, biodiversity regeneration, sustainable manufacturing, and better food and health systems, could be addressed with the aid of synthetic biology. The synthetic group at IBAB Bengaluru, has successfully developed and established several tools, reagents and technologies useful for translational research activities and routinely uses them in the lab to generate new genes and customized genetic elements which include template-less PCR, DNA vectors, novel yeast expression vectors based on synthetic promoters and transcription activators to create a library of yeast strains capable of protein expression, cloning of multiple promoters, reporter genes, terminators, etc.

Initiatives

a) Karnataka would like to leverage the lead taken in establishing Synthetic Biology Group at IBAB by continuing the support to group for undertaking cutting edge research in creating synthetic biology tools and technologies having translational research and developing a pool of skilled and trained manpower in Synthetic Biology through education and training programs.
b) The Synthetic Biology Group will forge alliance with national and international agencies to promote responsible research and development in synthetic biology to create awareness related to biosecurity, biosafety, and ethical implications among the researchers in the State. This initiative can promote the safe and ethical use of synthetic biology technologies, fostering public trust and acceptance of these advancements.
c) To encourage talented students and innovative startups participate in greater number from Karnataka in the iGEM (International Genetically Engineered Machine) competition conducted by

iGEM Foundation, Cambridge MA, USA, a separate support funding scheme will be introduced. The funding and the scope of support required for this initiative will be decided by a committee headed by the Principal Secretary - Department of IT, Bt & ST, constituting members drawn from VGBt, ABLE and representatives from Karnataka State Higher Education Council, IBAB, IISc, NCBS, BBC and C-CAMP.

### 3.15.4 Medical Devices & Diagnostics

The Indian medical devices industry is valued at $ 10.22 billion as per the report published by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, with exports valued at $ 2.51 billion and the domestic market standing at $ 7.71 billion. A majority of this $ 7.71 billion domestic market is serviced by imports valued at $ 5.60 billion - which comprises 72% of the share. The size of the domestic medical device market is one-tenth that of its exports and is one-third that of the pharmaceutical sector in India. Although the medical device sector was called as a sunrise sector it still majorly remains import based.

In Karnataka, the combined sub-segment of Medical Devices and Diagnostics is a major contributor to its total BioEconomy. It accounted for 35 percent share of the state's BioEconomy. The Medical Devices and Diagnostics services as a subsegment generated $7 billion in value in 2022. Additionally, Karnataka is a major producer of PCR machines, medical IT, Insulin Pens, and Cardiac Stents and Implants. Manufacturers including GE Medical, Skanray, Biocon, and Bigtec Labs are developing these products.

Initiatives

a) Bangalore Bioinnovation Centre (BBC) has set-up a MedTech Accelerator with the support BIRAC under BioNEST programme. The facilty started in 2017 has supported many startups to turn their high potential Medtech concepts into innovative products by providing them build an investible start-up pitch, go-to market strategy and initiative commercial activities for their medical technology innovation. Also, the Department of IT, Bt and S&T under TBI Scheme of

   Karnataka Startup Policy has supported Society for Innovation and Development (SID), IISc to establish a MedTech & Geriatric Healthcare Technology Business Incubator (CPDMED TBI) to facilitate innovation and entrepreneurship in Medical Technology and Geriatric Healthcare. It provides for incubation support for new entities with innovative ideas, designs, or technologies. The facilities made available includes working space, EMI/EMC Pre-Compliance Testing, Usability Testing, Medical Simulations & Electronic Testing, Environmental Testing, Mechanical Testing, Chemical Testing and Biological Testing services. 50+ medtech and healthtech startups are incubated and testing services are provided to industry regularly. The activities of both the CPDMED TBI and MedTech Accelerator at BBC will be amplified by the proposed Centre of Excellence in Health-Tech and Med-Tech.

b) State has already announced setting up a Centre of Excellence in Health-Tech and Med-Tech at the estimated cost of Rs.50 crores. The same will be operationalised and augmented by dovetailing

with schemes announced by Department of Pharmaceuticals like the scheme for Promotion of Medical Device Parks, Human Resource Development in Medical Device Sector, Assistance to Medical Device Clusters for Common Facilities (AMD-CF), and Scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP).

c) Karnataka Innovation and Technology Venture Fund -5 (KITVEN Fund-5) is a SEBI registered Category 1, Alternative Investment Fund (AIF) – Venture Capital Fund having target corpus of Rs.100 crore. The Fund that has received a commitment from Government institutions proposes to undertake investments in startup / SME companies developing Disruptive Technologies and that includes MedTech. The investment in companies will be equity and equity related instruments adhering to the guidelines issued by the Securities & Exchange Board of India (SEBI) from time-to-time. Substantial portion of the funds has been earmarked for startups from tier-2/ 3 cites and women entrepreneurs.

### 3.15.5 AI / ML in Biotechnology

In the field of biotechnology, the integration of artificial intelligence (AI) and Machine Learning (ML) has huge potential to accelerate research, improve precision, and foster innovation. By 2030, most drug discovery processes will be conducted in silico through computer modelling or simulation. In the upcoming five to ten years, there will be an exponential rise in the number of companies leveraging AI for drug discovery, leading to the normalization of new drugs tailored to treat highly specific pathologies. AI technologies will also personalize medical treatments based on individual genetic, environmental, and lifestyle factors as AI-driven platforms can analyse patient data to provide tailored treatment plans and optimize therapeutic outcomes. AI-powered tools for mining and analysing large-scale biological datasets, such as genomics, proteomics, and metabolomics data is expected to uncover valuable insights and patterns, leading to a deeper understanding of complex biological processes and disease mechanisms. AI-based tools can also analyse molecular and cellular data to identify specific biomarkers associated with disease progression, prognosis, and treatment response, thereby facilitating early diagnosis and personalized therapies. Integrating AI technologies into bioprocessing can enhance process monitoring, control, and optimization, leading to increased production efficiency and cost-effectiveness in production of biopharmaceuticals, enzymes, and other biotechnological products. Optimization of agricultural practices, crop breeding, and genetic engineering can be fostered by AI-based systems that can analyse environmental data, predict crop yield, and identify genetic traits that enhance crop resilience and nutritional value, thereby contributing to sustainable agriculture and food security.

Initiatives

a) The Bio-IT Centre at IBAB, ARTPARK, CoE for AI & Data Sciences, CoE for IoT & Data Sciences and International Institute of Information Technology, Bengaluru all supported by Department of IT, Bt and S&T will be encouraged to develop AI tools and methodologies that is specifically useful for the biotechnology sector.

b) A dedicated Resource Centre to encourage and support Innovative startups applying or developing AI tools supporting biotechnology sector will be housed in one of the above-mentioned centres to support and create networking opportunities and learning from AI Experts and Practitioners. The Resource centre will also conduct acceleration program specifically targeted to support SMEs and startups working on AI-based products/services that align to biotechnology sector.

c) Government will support conducting "AI for Good" program jointly by the above-mentioned centres in consortia to identify and nurture startups and enterprises who have promising AI solutions to address some of the most common and complex problems faced that will include the biotechnology sector.

### 3.15.6 Antimicrobial Resistance

Antimicrobial resistance (AMR) has become a persistent global public health issue, with an estimated 10 million deaths annually by 2050. Although there are many contributing factors to AMR, there is no denying that antibiotic misuse has played a major role. Indian Council of Medical Research has taken initiatives to develop new drugs /medicines through international collaborations to strengthen medical research in AMR through AMR Research & International Collaboration. ICMR has also initiated an antibiotic stewardship program to control overuse or misuse of antibiotics.

The Health and Family Welfare Department, Government of Karnataka, the nodal agency has established Anti-microbial Resistance (AMR) Cell and in place are the committees constituted to control and monitor both at State and District levels along with having State-level Technical Advisory Committee.

Initiatives

a) To further the efforts of tackling drug-resistant infections in Karnataka, the Department of IT, BT and S&T will continue support the activities undertaken by the Department of Health and Family Welfare, and other stakeholders (including hospital networks) to establish an alliance in Karnataka against antimicrobial resistance with technological intervention where applicable. The department will continue to seek to enhance multi-disciplinary collaboration and public-private investments by means of competitive grand challenges for:
    i. Identifying high-risk strains and their resistance
    ii. Developing rapid diagnostics tests to differentiate between bacterial and viral infections.
    iii. Discovery and development of a sustainable supply of effective new antimicrobials
    iv. Developing informatics tools for linking human and animal diseases surveillance for better mapping and prediction of emerging diseases threat.
    v. Promoting the development and uptake of genomic technologies to improve appropriate, prompt, patient treatment.
    vi. Enhance understanding and supporting data for AMR containment through surveillance- establishing a referral laboratory.

vii. Support the creation of open and sustainable clinical trial networks globally, with our expertise and experience.

b) The funding support for promoting research activities and development of novel solutions in this area will be extended under the existing schemes/programs made available under the Startup, R&D and Innovation and ER&D Policies of the State.

### 3.15.7 Multi-Omics

In the past few decades, bioinformatics has been extensively utilised in many areas of biological sciences. It combines the principles of biology, computer science, mathematics, physics, and statistics to analyse and interpret biological data. In the field of genetics, bioinformatics plays a significant role in helping to sequence, annotate, and visualise genomes and their mutations. It facilitates the development of biological and genetic databases and text mining of biological writing. Genomics, AI and machine learning are ushering in a golden age of precision medicine, but the data used to drive research is heavily skewed towards genomes of European descent. To prevent further exacerbation of existing health inequalities, life sciences and healthcare organizations should take steps to address bias in the data. India's population of 1.3 billion is made up of over 4,600 diverse population groups, many of which are endogamous. These groups have unique genetic variations and disease-causing mutations that cannot be compared to other populations. By creating a database of Indian genomes, researchers can learn about these unique genetic variants and use the information to create personalized drugs and therapies.

The innovation of Next Generation Sequencing (NGS), often seen as the foundation of personalised medicine, has been successfully implemented in immunotherapy and oncology diagnostics. India has seen an increase in genome sequencing in recent years. Though lagging behind China and Korea in the Asia Pacific region, a lot of Indian startups and companies have started undertaking research in this new technique. Government bodies are also increasingly recognising the importance of these advancements and turning to genomic research to provide personalised healthcare for patients. The Department of Biotechnology (DBT) approved the inclusion of six private genomic sequencing labs into the Indian SARSCoV-2 Genomics Consortium (INSACOG). Four of these labs were from Karnataka. The Bio-IT centre in IBAB has attracted enormous funding from the Department of Electronics, IT, BT and S&T, GoK to train students and carry out research in the area of genomics, taking advantage of the NGS facility at the Centre.

Initiatives

a) To further expand Karnataka as a cluster for Advanced Genome Bioinformatics-Omics, the government will continue to make use of the existing infrastructure at IBAB and CHG.
b) The state is already working towards developing its genome database by utilising the rich biodiversity. The Genome Database will serve as the main repository for DNA, plant, and animal tissues, including those of Karnataka's endangered and commercially significant species.

c) Focused based training programs on genome-based data analysis that allows researchers to uncover valuable insights from the vast amount of data generated from sequencing a genome.
d) The government shall continue to promote large-scale omics and bioinformatics projects with special focus on single-cell genomics.

### 3.15.8 Cell and Gene Therapies

It is anticipated that the Cell and Gene Therapy market will almost triple in size over the next five years, rising from $5.3 billion in 2022 to $19.9 billion in 2027. CGT is developing at a very rapid rate. The Food and Drug Administration (FDA) approved the first CAR-T therapy just six years ago. There are currently six CAR-T products with FDA approval. Central Drugs Standard Control Organisation's (CDSCO) has granted marketing authorisation approval of the first humanised CD19-targeted Chimeric Antigen Receptor T cell (CAR-T cell) therapy product for relapsed/refractory B-cell lymphomas and leukaemia in India. Large biopharma companies are seeing the potential in this field and have invested in the development and commercialisation of these therapies. Several Indian companies are collaborating with global players to develop cell and gene therapies. Home grown companies like Stempeutics Research, Immuneel Therapeutics, Eyestem Research, etc., have either have products in the market or in advance stages of clinical trials. These companies coupled by the research and teaching that is going on in IISc., InSTEM, Manipal Institute of Regenerative Medicine, etc., has enabled to have strong cell and gene therapy ecosystem in Karnataka.

Initiatives

a) Recent advancements in molecular biology and genetics tools and technology have led to an increased demand for meticulously annotated and appropriately preserved cells and tissue samples. Government has therefore approved setting up of Biobank facility with a estimated budget of Rs.5 crores at Bangalore Bioinnovation Centre. The facility will be operationalised soon and the availability of a large collection of patient samples (with well-annotated patient clinical and pathological data) will be made available to the researchers, startups and industry which is a critical requirement to advance patient treatment.
b) Support for conducting short-terms skill upgrading training programs in Cell and Gene therapy will be provided to create talent pool to support the growth of the prevailing ecosystem.
c) To establish scale-up infrastructure for the start-ups to aid them till commercialisation stage under the proposed green field Bio Foundries (Bio Manufacturing Hub) at Bengaluru Helix Biotech Park envisaged in the Public Private Partnership (PPP) mode.

### 3.15.9 3D Bioprinting & Organoids

Organoids and 3D bioprinting are two cutting-edge technologies that have the potential to transform the fields of regenerative medicine, drug discovery, and personalized healthcare. When integrated, they offer a powerful combination for the development of complex, functional tissues, and organ models to replicate the cellular composition and microenvironment of diseased tissues to better understand disease progression and develop targeted therapeutic interventions.

The landscape of Drug Discovery is swiftly transitioning towards Non-Animal Methods (NAM), embracing 3D bioprinted models, organoids, and spheroids. These advanced models intricately mimic human physiology, incorporating the dynamics of microfluidics to emulate human biochemistry, molecular biology, and the pathophysiology of diseases. Despite a century of reliance on animal models in drug discovery, successful clinical translation has remained elusive. Consequently, the emergence of alternative non-animal dynamic 3D models presents promising avenues for futuristic drug development. Simultaneously, the rapid progression of Gene and stem cell therapies marks another significant paradigm shift, as researchers uncover more human molecular pathways responsible for disease initiation and progression, leading to the identification of novel early-stage disease targets. The versatile applications of 3D models extend to the construction of human organs for transplantation, such as those required for liver, heart, and kidney failures. Thus, human-derived 3D models represent a pioneering trajectory for the next five to ten years, offering novel approaches for disease diagnosis and therapies. 3D models find application in risk assessment across various sectors, including cosmetics, nutraceuticals, agrochemicals, and industrial pollution.

Initiatives

a) Government will support for the establishment of a *state-of-the-art* Organoids and 3D Bioprinting facility along with a multidisciplinary group of researchers, scientists, and engineers specializing in bioprinting, tissue engineering, biomaterials, and other related fields to drive innovation in this area. The multidisciplinary group will enable for the rapid evaluation of drug efficacy and toxicity that researchers and clinicians can harness to advance our understanding of human physiology, disease mechanisms, and personalized therapeutic interventions, ultimately leading to development of next-generation regenerative medicine solutions.

b) The funding and the scope of support provided for this initiative will be decided by a committee headed jointly by the Principal Secretary - Department of IT, Bt & ST and Department of Medical Education, constituting members drawn from IISc., InSTEM, NCBS, IBAB, ABLE and subject experts.

### 3.15.10 Space Biotechnology

The Indian space economy has the potential to grow to $44 billion by 2033 from its current value of $8.4 billion, and Karnataka's space ecosystem is ideally positioned to capitalise on this growth, ultimately capturing over 40 percent of the market share in the Indian space economy. To leverage its potential in the space sector and attract investment, State Government has plans to have a separate space policy to encourage innovation and manufacturing, with a focus on increased private participation, global collaboration, and partnerships. Karnataka has the inherent advantage of having a huge space sector with highest number of institutions related to the sector ISRO being the major one having its headquarters in Bengaluru, Karnataka.

Space biotechnology is a rapidly growing field that presents numerous opportunities for scientific exploration, technological advancement, and commercial development. DBT, GoI has identified Space Research as one of focus sub-sector under its new initiative for Fostering High Performance Biomanufacturing. The State would like to capitalise the presence of Human Space Facility Centre and Institute of Aerospace Medicine and focus on encouraging activities related to biological experiments in microgravity, bioengineering for long-duration space missions, biomedical research for space exploration, bioinformatics and data analysis in space biology and developing biologics to treat space-related health issues. All these areas significantly advance our understanding of life in space and drive innovation in the fields of medicine, agriculture, and environmental sustainability.

Initiatives

a) The State is proposed to set up green field Bio Foundries (Bio Manufacturing Hub) at Bengaluru Helix Biotech Park envisaged in the Public Private Partnership (PPP) mode with financial co-sharing to co-create integrated infrastructure for access by start-ups and research communities engaged in
b) Biomanufacturing. The facility to undertake space research (microgravity and radiation physiology) will be made available as part of the Bio Foundry.
c) The funding support for promoting research activities and development of novel solutions in this area will be extended under the existing schemes/programs made available under the Startup, R&D and Innovation and ER&D Policies of the State. Equity investment through Karnataka Innovation and Technology Venture Fund-5 (KITVEN Fund-5) will also be undertaken.

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