BIOTECHNOLOGY

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Executive summary

1. GLOBAL POSITION

- India is among the top 12 biotechnology destinations in the world and the third-largest in Asia-Pacific. The country holds ~3% of the global biotechnology industry pie. The country is also the world's third-largest producer of recombinant Hepatitis B vaccine and second-largest producer of BT cotton
- The country is one of the world's leading suppliers of DPT, BCG & measles vaccines

2. STRONG START-UP ECOSYSTEM

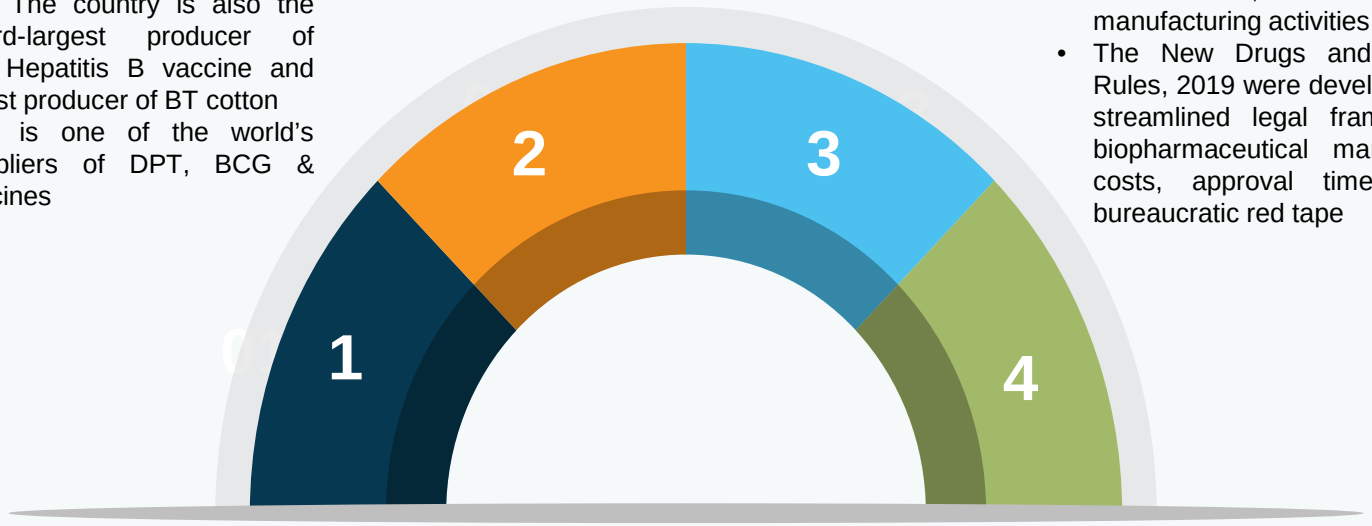
- India has a strong start-up ecosystem, originating from gradual improvements in the ease of doing business, proof-of-concept funds for start-ups and favourable government policies
- The biotechnology industry in India comprises >600 core biotech companies, >100 biotech incubators and >2700 biotech start-ups, which are estimated to reach 10,000 by 2024

3. STRONG GROWTH IN BIOPHARMACEUTICALS

- Biopharmaceutical is the largest segment that contributed ~58% to the Indian biotechnology market in 2019
- In June 2017, Department of Biotechnology, under the 'National Biopharma Mission', launched 'Industry-Academia Mission' to accelerate biopharmaceutical development in India

4. LEADING DESTINATION FOR CLINICAL TRIALS

- Bio-services, which accounted for ~15% of the Indian biotechnology market in 2019, is becoming a leading sector for clinical trials, contract research and manufacturing activities in the country
- The New Drugs and Clinical Trials Rules, 2019 were developed to create a streamlined legal framework for the biopharmaceutical market to reduce costs, approval timelines and cut bureaucratic red tape



Notes: *BT Cotton: Genetically modified pest resistant plant cotton, DPT: diphtheria, pertussis, tetanus, BCG: Bacille Calmette-Guerin*
Source: *Global Bio-India 2019, Biotechnology Industry Research Assistance Council*

Advantage India

Advantage India

1. Skilled human capital

- With a total population of 1.3 billion, 50% being under the age of 25, India has large pool of young and skilled workforce
- The government has come up with an industry-academia collaboration with the World Bank to accelerate discoveries and research for early-development of biopharmaceuticals

2. Infrastructure facilities

- Central and state governments have worked to set up several incubators and life science clusters across India.
- 9 DBT-supported biotech parks and 60 BIRAC-supported bio-incubators.
- Under the Union Budget 2021-22, the government announced plans to set up nine biosafety level-3 (BSL-3) laboratories through Pradhan Mantri Aatmanirbhar Swasth Bharat Yojana.

4. Epidemiological factors

- Patient pool expected to increase over 20% in the next 10 years, mainly due to rise in population
- New diseases & lifestyle changes to boost demand for drugs and devices

3. Policy support

- 100% under automatic route for greenfield projects for pharmaceuticals
- While 74% is permitted under automatic route for brownfield projects, 100% under government route is permitted for brownfield investments
- Mission COVID Suraksha was announced by the Government of India to accelerate the development and production of indigenous COVID vaccines.
- 100% under automatic route is allowed for the manufacturing of medical devices

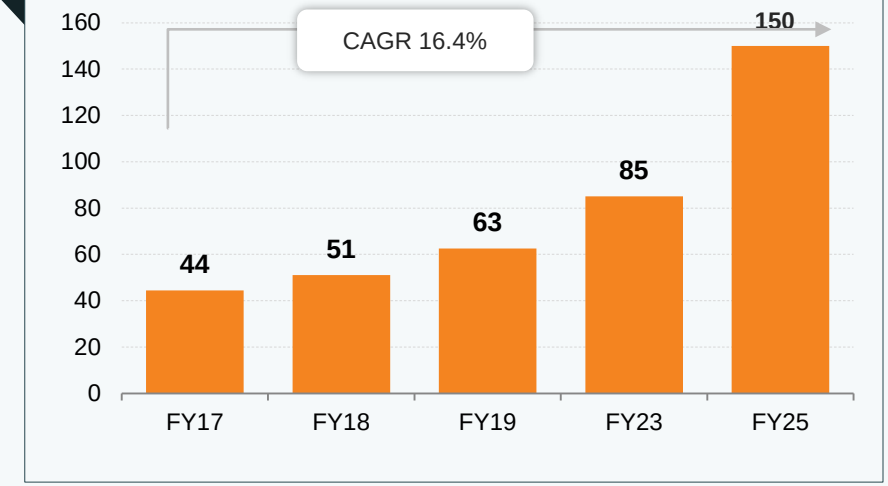
Source: *Department of Biotechnology, Press Information Bureau*

Market Overview

Biotechnology market

- The biotechnology sector in India is witnessing a strong growth trajectory and has proved to be highly inventive.
- India is among the top 12 biotechnology destinations in the world and the third-largest in Asia-Pacific.
- The Indian biotech industry holds 3% of the global market share
- The Indian biotechnology industry is likely to register a CAGR of 16.4% to reach US$ 150 billion in 2025.
- By 2025, contribution of the Indian biotechnology industry in the global biotechnology market is expected to increase to ~19% from 3% in 2017.
- The biotechnology sector, mainly due to its multidisciplinary approach holds the potential to provide an array of solutions for challenges in sectors such as health, agriculture, environment, energy and industrial processes.
- The biotechnology industry consists of 2,700+ biotech start-ups and is expected to grow to 10,000 by 2024. In 2020, India had >2500+ biotech companies.
- India has 665, the highest number, of FDA-approved plants outside of the US; 44% global abbreviated new drug applications (ANDA) and >1400 manufacturing plants, which comply with WHO requirements.

Indian biotechnology industry valuation (US$ billion)

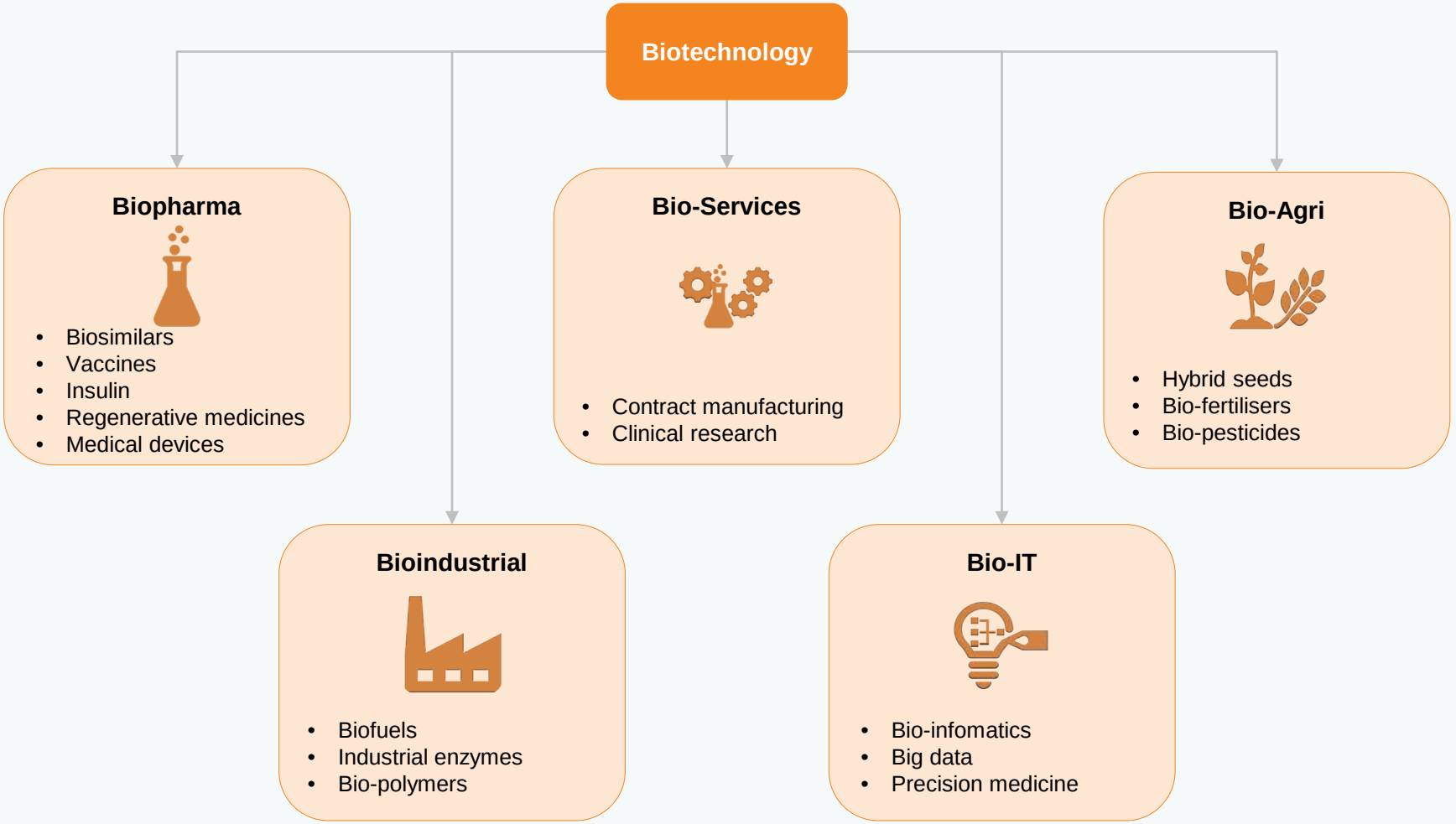


Indian bioeconomy at a glance (2020)

US$ 12 billion India's Biotech Industry Revenue	**1 million** India's Biotech Workforce
2,500+ Biotech Companies in India	**15,500+** Biotech Graduates Every Year

Notes: *FDA: Food and Drug Administration*
Source:*, DPT-BIRAC, Association of Biotechnology Led Enterprises (ABLE)*

Indian biotechnology sector is divided into five segments



Source: *Association of Biotechnology Led Enterprises (ABLE)*

Key players

	**Biocon**	Indian pharmaceutical company based in Bangalore that manufactures generic active pharmaceutical ingredients
	**Serum Institute of India**	Manufacturer of immuno-biologicals, which include Diphtheria, Tetanus, Pertussis, Hib, BCG, r-Hepatitis B, Measles, Mumps and Rubella vaccines
	**Panacea Biotec Limited**	Innovation-driven biotechnology company, undertaking research and development, manufacturing, sales, distribution and marketing of pharmaceuticals, vaccines and biosimilars
	**Dr Reddy's Laboratory Limited**	Integrated pharmaceutical company, providing affordable and innovative medicines
	**Wockhardt**	Global pharmaceutical and biotechnology organisation, manufacturing pharmaceuticals, biopharmaceutical formulations and active pharmaceutical ingredients
	**Jubilant Life Sciences Co**	Integrated global pharmaceutical and life sciences company, engaged in pharmaceuticals, life science ingredients, drug discovery solutions and India-branded pharmaceuticals
	**AstraZeneca Pharma India Ltd.**	Indian biopharmaceutical company based in Bengaluru that manufactures cardiovascular, renal and metabolic diseases, oncology, and respiratory medicines
	**Bharat Serums and Vaccines Ltd**	Indian pharmaceutical company based in Mumbai that manufactures plasma derivatives, monoclonals, fertility hormones, antitoxins, antifungals, anaesthetics, cardiovascular drugs and diagnostic products
	**Indian Immunologicals Ltd**	Indian biopharmaceutical company based in Hyderabad that manufactures animal and human vaccine including rabies, Hepatitis B, Diptheria and Influenza vaccines
	**Bharat Biotech**	Indian biotechnology company based in Hyderabad that engages in drug discovery, drug development as well as manufactures vaccines, bio-therapeutics, pharmaceuticals and health care products

Note: *News articles*

Recent Trends and Strategies

National and international partnerships

Two PSUs ink pact with Covaxin maker Bharat Biotech to manufacture COVID vaccines	Merck Sharp & Dohme (MSD) signs licensing pacts with 5 Indian drug firms for oral drug candidate for Covid-19	Bharat Biotech partners with Precisa Medicamentos to supply Covaxin in Brazil	ZyCoV-D, DNA vaccine candidate against COVID-19	Indian SARS-CoV-2 Genomics Consortium	Biotechnology University
In May 2021, Indian Immunologicals Limited (IIL) and Bharat Immunologicals and Biologicals Corporation (BIBCOL) inked technology transfer pacts with Bharat Biotech to develop the vaccine locally to boost India's vaccination drive. The two PSUs plan to start the production of vaccines by September 2021.	In April 2021, MSD, a drug firm, entered voluntary licensing agreements for investigational oral antiviral drug candidate 'molnupiravir', which is being studied for the treatment of Covid-19, with Indian drug firms—Sun Pharma, Cipla, Dr Reddy's, Emcure Pharma and Hetero Labs.	In January 2021, Bharat Biotech signed an agreement with Precisa Medicamentos to supply Covaxin, a coronavirus vaccine, to Brazil. Supplies to the private market would be based on receiving market authorisation from ANVISA—the Brazilian regulatory authority.	In January 2021, India's first indigenously developed DNA vaccine candidate against COVID-19, ZyCoV-D, by Zydus Cadila, has received approval by Drugs Controller General of India (DCGI), to conduct the Phase III clinical trials. The candidate has been supported by the National Biopharma Mission (NBM), under the sponsorship of BIRAC and the Department of Biotechnology, Government of India.	In December 2020, the government has launched the Indian SARS-CoV-2 Genomic Consortia (INSACOG), comprising 10 labs across the country. The purpose of INSACOG is to monitor the genomic variations in the SARS-CoV-2 on a regular basis through a multi-laboratory network.	In December 2020, the University of Edinburgh and Gujarat government signed an agreement to open a biotechnology university in the state by July 2021.

Notes: *BIRAC: Biotechnology Industry Research Assistance Council*
Source: *Company website, news articles*

Recent Developments

India allows 100% FDI under the automatic route (a non-resident or Indian company will not require any approval from the government) for greenfield pharmaceuticals and manufacturing medical devices.

2021

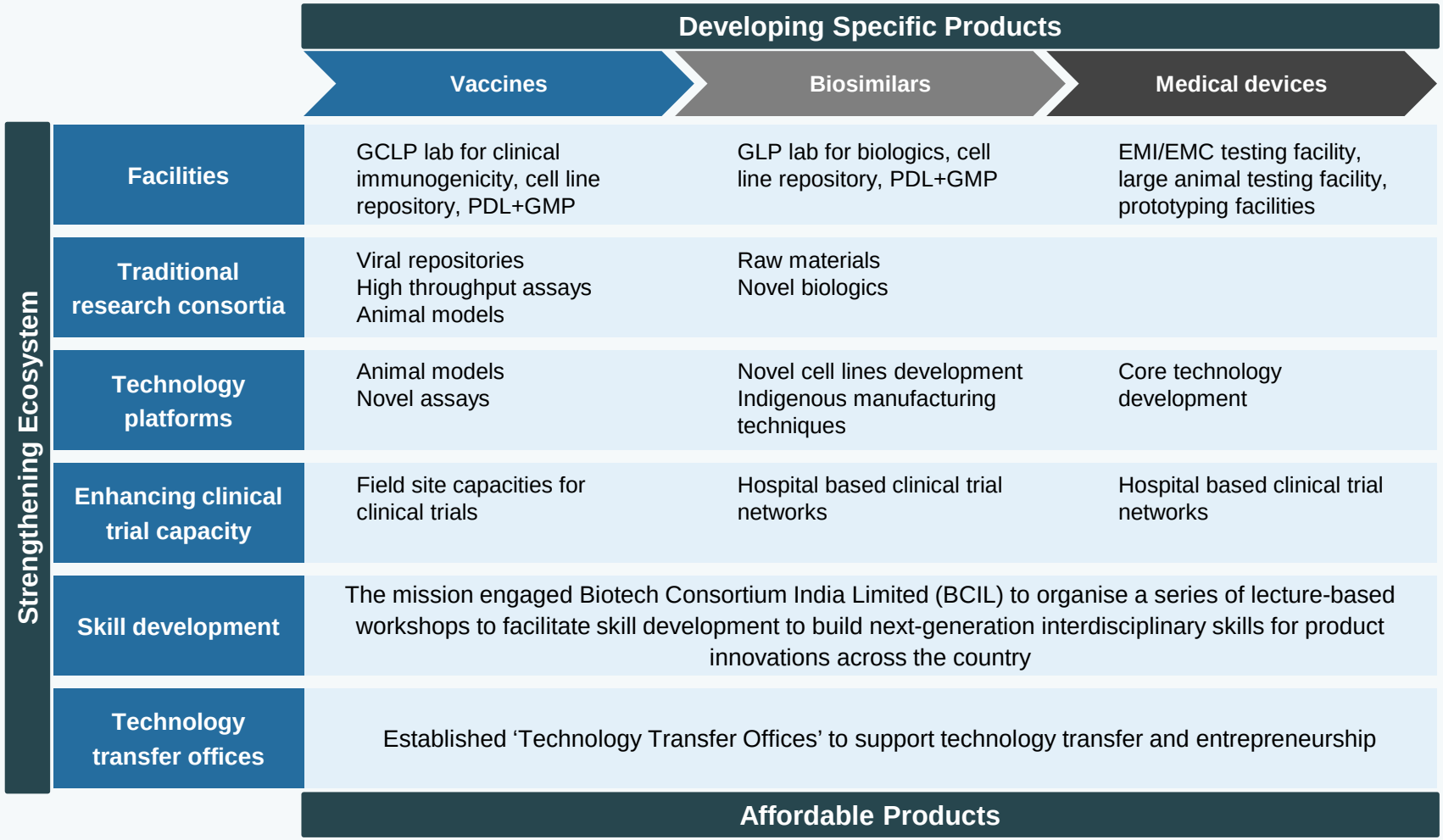
- **May 2021:** Under Atmanirbhar Bharat 3.0, Mission COVID Suraksha was announced by the Government of India to accelerate the development and production of indigenous COVID vaccines. To augment the capacity of indigenous production of Covaxin under the mission, the Department of Biotechnology, Government of India provided financial support in the form of a grant to vaccine manufacturing facilities for enhanced production capacities, which is expected to reach >10 crore doses per month by September 2021.
- **April 2021:** The Department of Biotechnology (DBT), Ministry of Science & Technology, approved additional funding towards clinical studies for India's 'first-of-its-kind' mRNA-based COVID-19 vaccine, HGCO19, developed by Pune-based Gennova Biopharmaceuticals Ltd.
- **April 2021:** Drug Controller General Of India (DCGI) gave a restricted emergency use approval to the Zydus Cadila's 'Virafin' for treating patients with moderate COVID-19 symptoms. Virafin is a pegylated interferon alpha-2b(PegIFN), which when subcutaneously injected to the patient in the early stages of infection, resulted in their faster recovery.
- **April 2021:** The CSIR-CMERI, Durgapur, indigenously developed an 'oxygen enrichment technology', which may be effective for treating COVID-19 patients. The oxygen enrichment unit can deliver medical air in the range of up to 15 litres per minute, with oxygen purity of >90%.
- **March 2021:** Gland Pharma Ltd. announced that it will produce 252 million doses of the Sputnik V COVID-19 vaccine in the third quarter of 2021.

2020

- **November 2020**: Bharat Biotech plans to produce 10 types of vaccines including malaria and COVID-19—with a total investment of Rs. 300 crore (US$ 40.54 million—at its upcoming unit in Bhubaneswar, Odisha.

Note: *CSIR-CMERI - Council of Scientific & Industrial Research-Central Mechanical Engineering Research Institute*
Source: *News Articles*

National Biopharma mission



Notes: *GCLP: Good clinical laboratory practice, GLP: Good laboratory practice, EMI: Electromagnetic interference, EMC: electromagnetic compatibility, PDL: preferred drug list, GMP: Good manufacturing practices*
Source: *Department of Biotechnology*

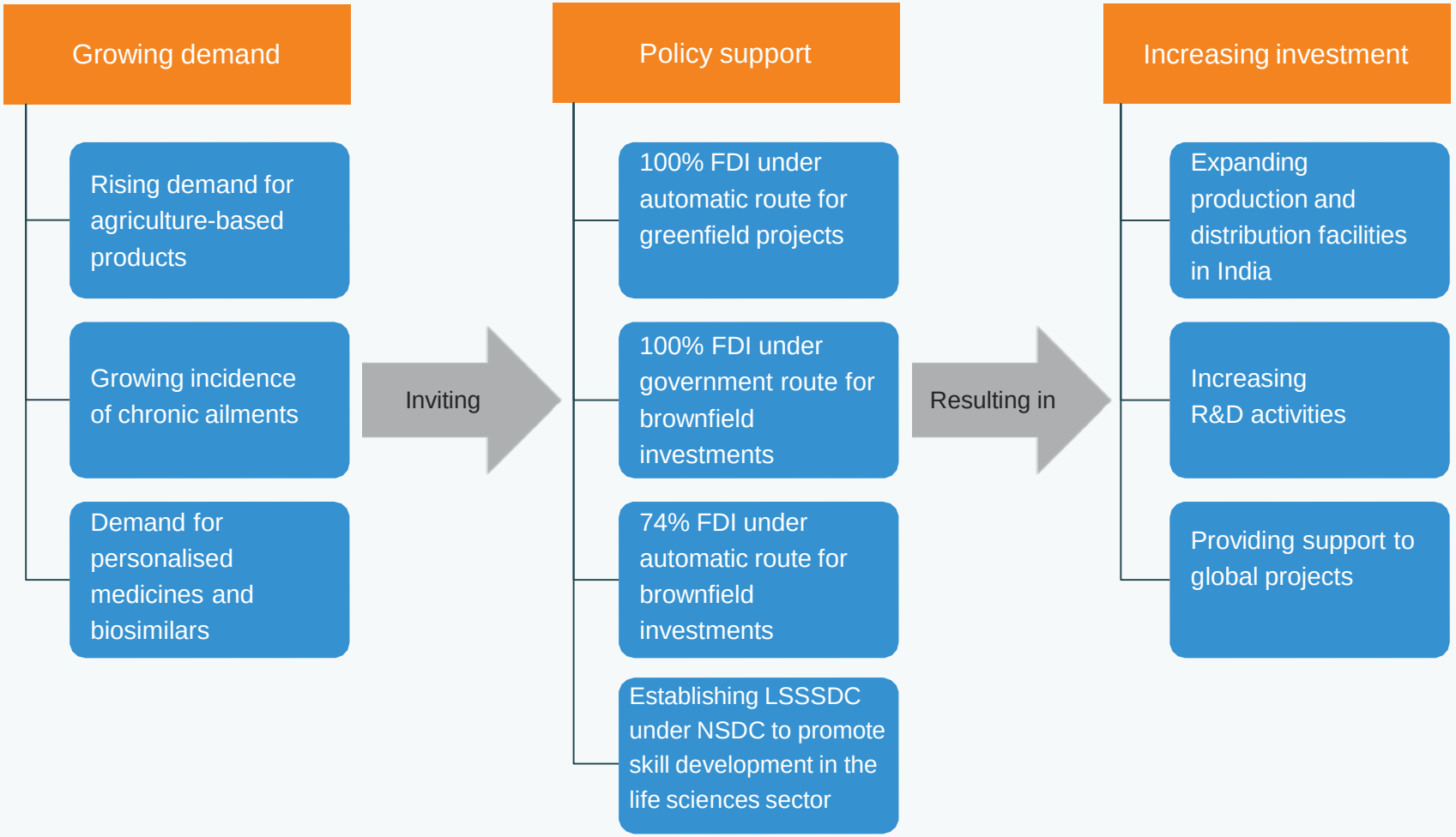
State-specific policies

South	
Andhra Pradesh Biotechnology Policy 2015-2020	Development of several infrastructure projects and industrial parks
Karnataka Biotechnology Policy 2017-2022	Strengthening the ecosystem required for boosting start-ups, accessing funds for R&D and product development, developing attractive incentives for investors and providing mentorship for growth
Telangana Life Sciences Policy 2015-2020	Development of suitable infrastructure to attract life science companies and become a leading investment destination in the sector
North	
Uttarakhand Biotechnology Policy 2018-2023	Aims to attract new investments worth US$709 million in the sector; generate employment opportunities for 5000 people by 2023
Himachal Pradesh Biotechnology Policy 2014	Aims to make Himachal a globally competitive destination for development of biotechnology products, processes and services
West	
Rajasthan Biotechnology Policy 2015	Aims to establish world-class research institutes and biomanufacturing infrastructure
Gujarat Biotechnology Policy 2016-2021	Aims to develop a robust biotechnology ecosystem in the state
East	
Assam Biotechnology Policy 2018-2022	Development of the biotechnology industry in Assam, following the growth of bio-agri segment in the state
Odisha Biotechnology Policy 2018	Aims to make Odisha one of the top biotech investment and innovation destinations in the country
Central	
Madhya Pradesh Biotechnology Policy 2003	Conservation and sustainable utilisation of bio-resources to promote socioeconomic growth in the state

Source: *State Government Website*

Growth Drivers

Strong demand and policy support driving investments



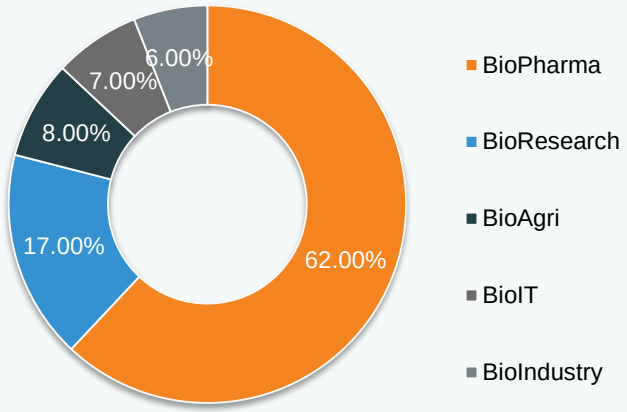
Notes: *LSSSDC: Life Sciences Sector Skill Development Council, NSDC: National Skill Development Corporation, R&D - Research and Development*

Source: *Department of Biotechnology, Association of Biotechnology Led Enterprises (ABLE)*

Ecosystem for start-ups

- The start-up ecosystem in India is strongly supported on the back of gradual improvements in the ease of doing business, proof-of-concept funds for start-ups and favorable government policies.
- BIRAC (Biotechnology Industrial Research Assistance Council), a public sector undertaking of DBT, partnered with innovative foundations and universities to focus on 'Make in India' and 'Start-up India' programmes.
- BIRAC established several industry-focussed schemes such as SBIRI, BIPP Biotechnology Ignition Grant, BioNEST, SITARE, PACE, SIIP, SEED, LEAP and Fund of Funds-AcE. BIRAC has supported 50 bio-incubators for potential entrepreneurs.

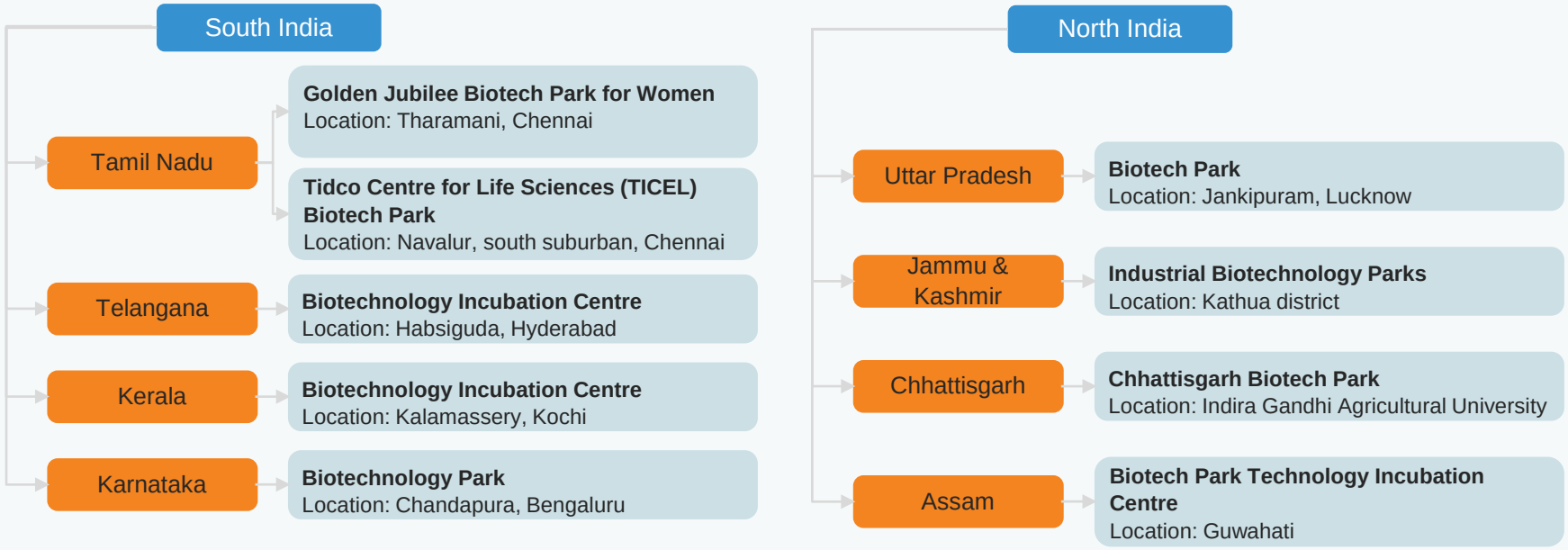
Sector-wise representation of startups-2019 (%)



BIRAC (Bio-Incubator)	
Incubators supported	60
Amount committed for BioNEST	US$ 3.31 million
Incubation area supported	640,349 sq. ft.
Incubatees supported	684
Resident incubatees supported	574
Non-resident incubatees supported	110
Total products/technologies commercialised	200
Total employment generated	3,500
Total IPs generated	250
Total trainings/workshops conducted	1,000

Source: *BIRAC*

Biotech parks



- Biotechnology parks and incubators are established across the country by the Department of Biotechnology (DBT), under the Ministry of Science and Technology, to translate research into products and services by providing necessary infrastructure support.
- These biotechnology parks offer facilities to scientists, and small and medium sized enterprises (SMEs) for technology incubation, technology demonstration and pilot plant studies to accelerate commercial development of biotechnology.
- The government, at present, supports nine biotechnology parks in various states, with the bulk being in the southern region.

"These parks are successfully accelerating the commercialisation of new technologies, nurturing and maintaining emerging ventures and assisting new enterprises to forge appropriate linkages with other stakeholders of biotechnology sector including academia and the government."

- Secretary, DBT

Source: *Association of Biotechnology Led Enterprises (ABLE)*

Opportunities

Opportunities in various segments

Under the Union Budget 2021-22, the government outlaid Rs. 1,660 crore (US$ 227.94 million) for biotechnology research and development.

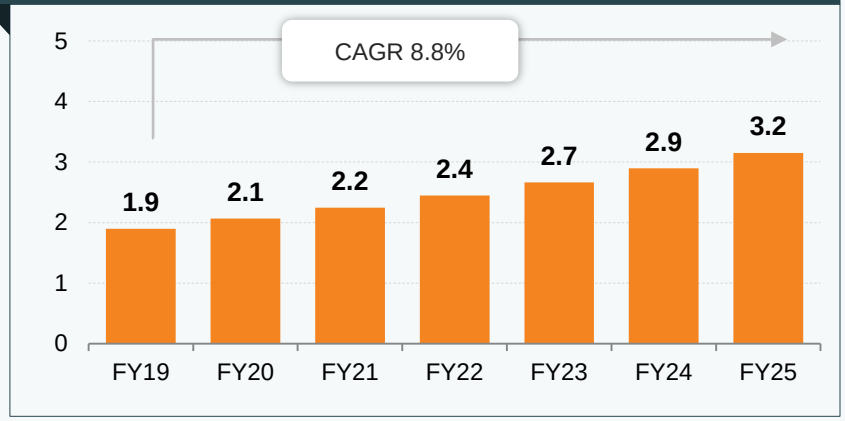
Bio-Services	Bioindustrials	Biopharma	Bio-Agri	Bio-IT
				
• India has potential for clinical trials due to a large and low-cost market • Clinical trials in India are regulated by the Central Drug Standard Control Organisation, which has reduced approval time to about 30-60 days, giving opportunity for market growth • The country also has the advantage of English-speaking researchers and required medical infrastructure to conduct medical research	• Biofuels and bioenergy are considered alternative resources and are gaining popularity in India • Rise in energy demand is leading to an increase in dependence on fossil fuel imports • As a result, companies can develop a strategy to reduce import dependence through biofuels and bioenergy	• The Indian biologics market is expected to register a CAGR of 22% from 2019 to 2025 to reach US$ 12 billion by 2025. • Growth of biologics provides opportunity for biosimilars in the market.	• India's Union budget 2021-22 states the government's plan to enhance farm productivity and focus on food security. • This will likely increase the importance of bio-agriculture, which will enhance efficient food production.	• Biotechnology has immense growth potential in the Bio-IT segment, given the rising need for technology to transform data generated by R&D institutes, clinics, hospitals, etc., into a defined format • India's IT industry is witnessing substantial growth and has the requisite IT infrastructure to cater to the needs of the global Bio-IT industry

Source: *Association of Biotechnology Led Enterprises (ABLE), Institute for Competitiveness*

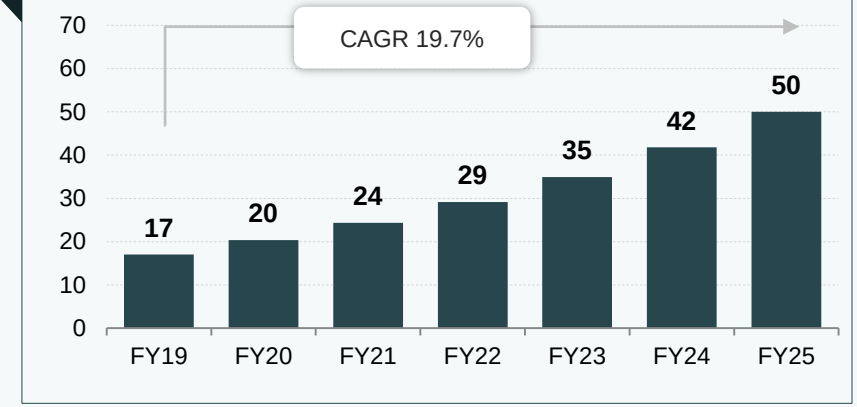
Key investment opportunities

- India is among the preferred destinations for clinical trials owing to a large patient pool, transformation of the healthcare market, well-educated physicians and cost competitiveness.
- The Union Ministry for Health and Family Welfare has reported new Drugs and Clinical Trials Rules, 2019, changing the regulatory landscape for approval of new drugs and conducting clinical trials in the country.
- The Indian Council of Medical Research (ICMR) has selected 12 institutes for clinical trial of the country's first indigenous COVID-19 vaccine.
- The Indian medical devices industry consists of MNCs and SMEs are expected to reach US$ 50 billion by 2025 with domestic manufacturers accounting for ~65%.
- India is among the top 20 markets for medical devices in India and 4th largest in Asian markets.
- India has six medical device manufacturing clusters where efficient manufacturing is done at lower costs.
- On April 13, 2021, the Union Government approved to streamline and fast-track the regulatory system for COVID-19 vaccines that have been approved for restricted use by the US FDA, EMA, UK MHRA, PMDA Japan or those listed in WHO Emergency Use Listing (EUL). This decision is likely to facilitate quicker access to foreign vaccines by India and encourage imports, including imports of bulk drug materials, optimise utilisation of domestic fill and finish capacity, etc.; this will boost vaccine manufacturing capacity and total vaccine availability within the country.

Clinical trials market in India (US$ billion)



Medical devices market in India (US$ billion)



Note: *US FDA - United States Food and Drug Administration, EMA - European Medicines Agency, UK MHRA – United Kingdom Medicines and Healthcare products Regulatory Agency , PMDA - Pharmaceuticals and Medical Devices Agency, Japan*

Source: *News Articles*

Upcoming biotechnology projects in India

Upcoming Biotechnology Projects	State Presence	Cost of the Project (US$ million)
Mangalapuram Bio 360 Life Sciences Park Project - Phase II	Kerala	56.56
Kupwara Biotechnology	Jammu & Kashmir	4.5

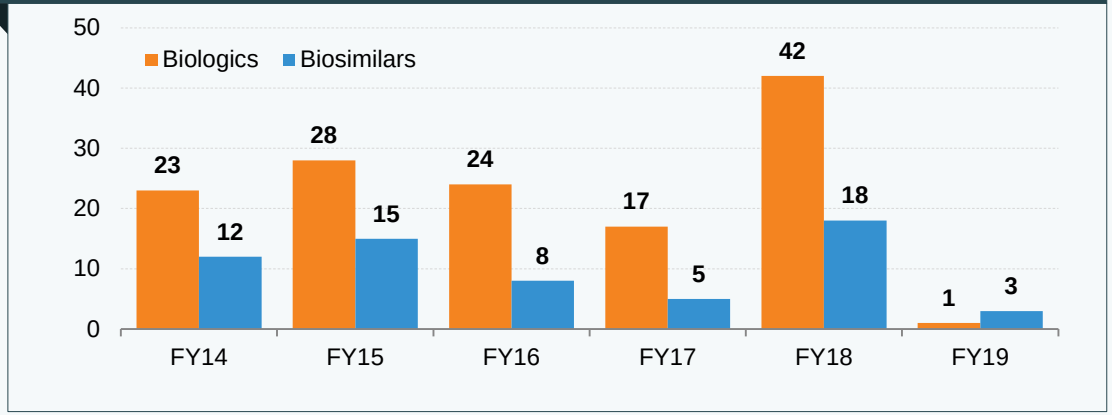
Source: *News Articles*

India: emerging hub for biologics and biosimilars

The global life sciences industry is shifting from chemical-based drug to biologics and biosimilars; India approved its first biosimilar as early as 2000.

- India's first biosimilar was approved in 2000 for hepatitis B. In 2019, there were approximately >95 approved biosimilars.
- Biologics economy in India was valued at US$ 7 billion in 2019 and is forecast to reach US$ 12 billion by 2025.
- In India, the biologics segment is led by Biocon Ltd., and has commercialised the biosimilars Trastuzumab and Pegfilgrastim among others in partnership with Mylan.
- Other players in the space include Dr Reddy's Laboratories, Intas Pharmaceuticals, Zydus Cadila and Lupin.

Number of biologics and biosimilars approved in India



Drug name	Originator company	Active companies	First launched
bevacizumab	Dr Reddy's Laboratories Ltd.	Dr Reddy's Laboratories Ltd	19-Aug-19
trastuzumab	Dr Reddy's Laboratories Ltd	Dr Reddy's Laboratories Ltd	26-Jul-18
pegfilgrastim	Lupin Ltd	Lupin Ltd	25-Jul-18
pegfilgrastim	Biocon Ltd	Biocon Ltd; Mylan NV	30-Jun-18
adalimumab	Hetero Group	Hetero Group	03-Jan-18
bevacizumab	Biocon Ltd	Biocon Ltd; Mylan NV	23-Nov-17
bevacizumab	Zydus-Cadila Group	Zydus-Cadila Group	30-Sep-17

Source: *Biologics Division, CDSCO, Association of Biotechnology Led Enterprises (ABLE)*

Opportunity in Biopharma

1. BIOSIMILARS

- India has >50 approved biosimilar products and the market is expected to reach US$ 2.2 billion by 2025
- Expiry of ~US$ 70 billion biologics drugs patent by 2020 will provide export opportunities
- Global companies are leveraging both generics to contain healthcare costs and Indian companies such as Biocon are positioning themselves to deliver affordable access to innovative and inclusive healthcare solutions

2. VACCINES

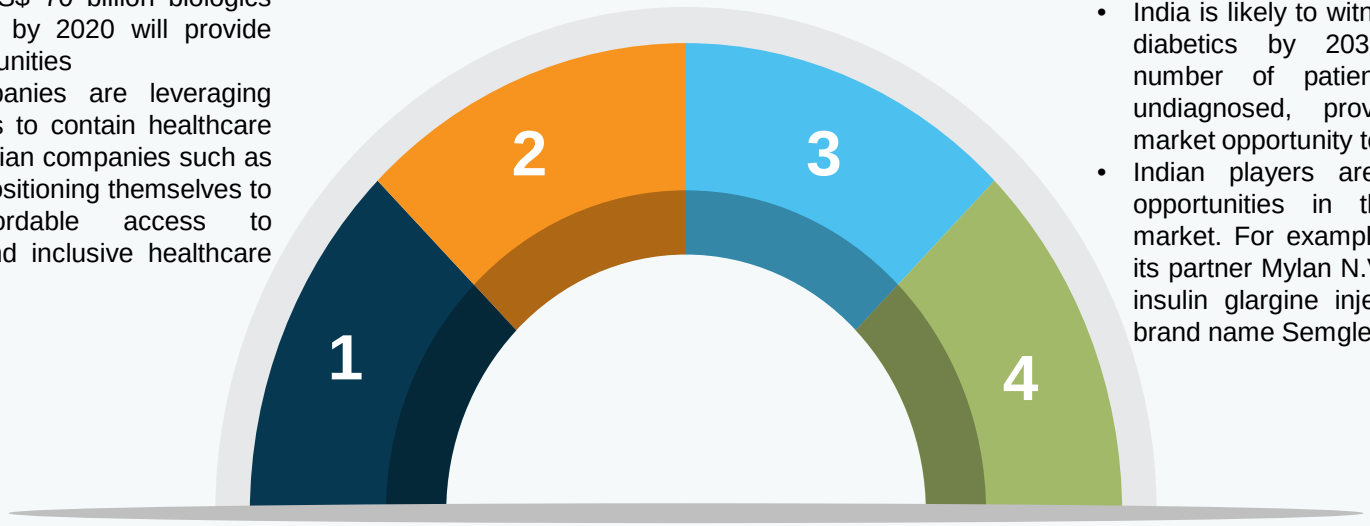
- India exports vaccines to about 150 countries
- The country covers 40-70% of the World Health Organisation (WHO) demand for DPT (diphtheria, pertussis or whooping cough, and tetanus) and BCG (Bacille Calmette-guérin) vaccines against tuberculosis, followed by ~90% of its demand for the measles vaccine

3. REGENERATIVE MEDICINE

- Several research institutes in India are investigating the use of stem cells to regenerate nerve, heart and adult muscle cells, and repair damaged bone tissues
- Rise in chronic disease incidences is driving the demand for regenerative medicine
- The Indian Council of Medical Research has issued the National Guideline for Stem Cell Research to promote clinical applications of stem cell research in ophthalmology, cardiology and spinal cord repair

4. INSULIN

- India is likely to witness >100 million diabetics by 2030. With rising number of patients, ~50% are undiagnosed, providing domestic market opportunity to the country
- Indian players are also creating opportunities in the international market. For example, Biologics and its partner Mylan N.V. launched their insulin glargine injection under the brand name Semglee in the US



Source: *BIRAC*

Key Industry Contacts

Key industry organisations

Agency		Contact Information
	Department of Biotechnology, Ministry of Science & Technology	6th-8th Floor, Block 2 CGO Complex, Lodhi Road New Delhi – 110 003.India Phone: 91-11-2436 2950 Website: www.dbtindia.gov.in
	Department of Science and Technology, Ministry of Science and Technology	Department of Science & Technology, Technology Bhavan, New Mehrauli Road, New Delhi-110 016 Phone: +91-11-26562122/25/33/44, 26567373, 26962819 Fax +91-11-26863847, 26515637 Website: www.dst.gov.in
	Biotechnology Industry Research Assistance Council (BIRAC)	1st Floor ,MTNL Building ,9 , CGO Complex, Lodhi Road, New Delhi-110003 Website: www.birac.nic.in, E-mail address: birac.dbt@nic.in Phone: + 91-11-24389600 Fax: + 91-11-24389611
	Council of Scientific and Industrial Research (CSIR)	Council of Scientific and Industrial Research, Anusandhan Bhawan, 2 Rafi Ahmed Kidwai Marg, New Delhi - 110001 Phone: +91-11-23737889 Website: www.csir.res.in
	Association of Biotechnology Led Enterprises	# 123/C, 16th Main Road,5th Cross, 4th Block, Near Sony World showroom / Headstart school, Koramangala, Bangalore -560034, India Phone: +91-80-41636853 Fax: +91-80-25633853 Website: www.ableindia.in, E-mail address: info@ableindia.org.in
	The Biotech Research Society, India	Biotechnology Division, NIIST, Industrial Estate P.O., Trivandrum 695019 Phone: +91-471-251 5279 Website: https://www.brsi.in/

Departments concerning biotech approvals

Government of India

- Ministry of Science & Technology
  - Department of Biotechnology
    - Review Committee on Genetic Manipulation
    - Recombination DNA Advisory Committee
    - Institutional Biosafety Committee
- Ministry of Environment & Forests
  - Department of Environment, Forests & Wildlife
    - Genetic Engineering Approval Committee
- Ministry of Chemicals & Fertilisers
  - Department of Pharmaceuticals
- Ministry of Health & Family Welfare
  - Central Drug Standards Control
    - Clinical Trials

Appendix

Glossary

- CAGR: Compound Annual Growth Rate
- Capex: Capital Expenditure
- CENVAT: Central Value-added Tax
- EHTP: Electronic Hardware Technology Park
- EPCG: Export Promotion Capital Goods Scheme
- FDI: Foreign Direct Investment
- FY: Indian Financial Year (April to March); So, FY10 implies April 2009 to March 2010
- LCD: Liquid Crystal Display
- R&D: Research and Development
- US$: US Dollar
- Wherever applicable, numbers have been rounded off to the nearest whole number

Exchange rates

Exchange Rates (Fiscal Year)

Year	Rs. Equivalent of one US$
2004-05	44.95
2005-06	44.28
2006-07	45.29
2007-08	40.24
2008-09	45.91
2009-10	47.42
2010-11	45.58
2011-12	47.95
2012-13	54.45
2013-14	60.50
2014-15	61.15
2015-16	65.46
2016-17	67.09
2017-18	64.45
2018-19	69.89
2019-20	70.49
2020-21	73.20

Exchange Rates (Calendar Year)

Year	Rs. Equivalent of one US$
2005	44.11
2006	45.33
2007	41.29
2008	43.42
2009	48.35
2010	45.74
2011	46.67
2012	53.49
2013	58.63
2014	61.03
2015	64.15
2016	67.21
2017	65.12
2018	68.36
2019	69.89
2020	74.18
2021*	74.94

Note: *As of April 2021*
Source: *Reserve Bank of India, Average for the year*

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