# The Department of Biotechnology, Government of India – communicating impact is important

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The Government of India's investment in science and technology (S&T) has been hovering between 0.6% and 0.86% of the gross domestic product (GDP) for some time[1]. Several reports, including a recent economic survey[2], have argued for an increase in investment. Typically, these studies have highlighted the levels of investment in S&T in advanced economies, implying that to be in a similar advanced economy, India requires investment in science. Indeed, a causal link between investment in science and economic growth has been well-documented in many contexts, notably in the United States, the European Union and the United Kingdom[3,4]. The rise of the 'younger' knowledge-driven economies such as Israel, South Korea, Taiwan and Singapore is often cited, to illustrate how even smaller countries can punch well above their weight[3–5]. The dragon in the room is, of course, China. At the time of the Tiananmen Square events, following the tumultuous and disruptive cultural revolution, science in China seemed certain to stagnate. Today, China is a science superpower in technology and is fast catching up with the West in fundamental sciences too[6].

In this background, India needs to analyse and introspect its many successes, missteps and the directions science has taken in the country. Only such analyses, done in each sub-sector, will indicate how current and future investments should be focused to provide an advantage in a scientific world that is both ruthlessly competitive and yet requires the size and quality of India's ingenuity to address the many problems our planet faces.

This note examines the role played by the Department of Biotechnology (DBT), Ministry of Science and Technology (MoST), Government of India (GoI) in the past 36 years in the biotech sector, highlighting some successes as learning pointers and suggesting steps that may further increase the impact of research and development on our economy and society.

Incubated as the National Biotechnology Board (NBTB) at the Department of Science and Technology in 1982 and established as a Department under MoST in 1986, DBT became the catapult propelling life sciences research to the forefront of science in India and a major driver of science-led economic growth in the country.

From its inception, DBT has helmed the growth of the biotech sector and played a crucial role in its growth. This has been done by well-managed investments in capacity building, infrastructure, developing regulatory processes and providing support to the industry over the years. These efforts have placed the Indian biotech sector at the centre stage globally with a significant rise in quality publications, patents, technology development, start-ups and major industry[7–11].

DBT has impacted the life sciences and biotech sectors through four broad sectors. First, the development of nation-wide capacity through human capital and infrastructure development. Second, in developing regulatory rules and guidelines for the sector, in collaboration with other Government agencies. Third, the seeding and growth of specialized research programmes in universities and research institutions. Fourth, stimulation of the start-up and industry ecosystem. All of these programmes have had important national and international collaborations.

Some major 'success stories' are briefly illustrated below, where support from DBT had positively impacted economic growth in various sectors.

## Human capital and the impact of teaching, training and research

Several centres of research excellence and programmes training skilled human resources in fundamental life sciences were established. Generous funding for setting up state-of-the-art laboratories and facilities was provided in basic biology, agricultural, medical and environmental sciences[7,8]. The M.Sc. biotech programme started in 1985 continues to be the route for talented students going into academia and research in this sector.

Several universities and research centres established across the country, such as at the Indian Institute of Science, Bengaluru; Madurai Kamaraj University; M. S. University, Baroda; Anna University, Chennai; Jawaharlal Nehru University, New Delhi; University of Delhi South Campus; Pune University; University of Hyderabad, Centre for Cellular and Molecular Biology, Hyderabad, and Institute of Microbial Technology, Chandigarh have provided a skilled and competitive workforce for industry and academia alike[7–9]. Tracking the career paths of DBT-supported researchers is important for policies on job creation and employment.

## Research and development in health and agriculture sectors and the causal impact on industry

### *Health*

Early initiatives and efforts by DBT in setting up the India–USA Vaccine Action Programme in 1987, and establishing the public sector unit Bharat Immunologicals and Biologicals Corporation Ltd (BIBCOL) in 1989, primarily for the supply of oral polio vaccine to combat poliomyelitis, spurred the nascent vaccine industry in the country. The development and introduction of the low-cost hepatitis B vaccine in 2002 and its success brought to the fore the potential of vaccine development in India. Interestingly, this also saw friction between academia and industry, but was critical learning in setting the stage for vaccine development in the country and introducing affordable healthcare to the world[12].

The first 'Make in India' vaccine 'ROTAVAC' (rotavirus vaccine) was introduced into the National Immunization Programme in 2015. With over 20 years of support by DBT in its development, working with international partners (the DBT–USA Indo–US Vaccine Action Programme, World Health Organization, Bill and Melinda Gates Foundation) and the Indian company, Bharat Biotech International Limited, showed how multi-institutional global collaborations could be steered to completion. The success of ROTAVAC put into place a vaccine development system which was leveraged in the speedy development of 'Covaxin' by Bharat Biotech in collaboration with the Indian Council for Medical Research. DBT has partly supported the ZyCoV-D vaccine from Cadilla Zydus and the mRNA vaccine from Gennova. These examples and the mega-manufacturing capacity of

Serum Institute of India Pvt Ltd, make our country a vaccine powerhouse[13,14]. The vaccine and the booming diagnostic industry, with many products in the market, have been substantially supported by DBT's Biotechnology Industry Research Assistance Council (BIRAC) (see below), and this support has contributed substantially to the emergence of the much-touted 'sunrise' biotech sector. The biotech industry as it stands today is a US$ 43.5 billion industry, contributing about 2% of GDP; about 2.7 million people are employed in high-skill areas of manufacturing and research and development (R&D)[15,16].

According to the *Reserve Bank of India Bulletin*[16], 'The country can also use the pandemic to elevate the sector's position in the global supply chain by standing as a reliable exporter of pharmaceuticals. Furthermore, the sector globally being highly research-intensive, a long-term approach towards shifting the focus to R&D (in academia–industry partnership mode), without depending much on joint ventures and higher incentives for R&D in Production Linked Incentive (PLI) scheme should be explored.'

### *Agriculture*

Cotton production was traditionally challenged by bollworm infestation. The genetically modified *Bt* cotton contains genes from the bacteria, *Bacillus thuringiensis*, making the cotton plant resistant to bollworm attack. This insect resistance leads to savings in chemical pest control and higher yields[17]. The introduction of *Bt* cotton was nothing short of an epic battle won against many lobbies, with GoI taking a bold decision in 2002 to approve its first genetically modified (GM) crop, i.e. *Bt* cotton, for commercial cultivation. DBT played a crucial role in introducing *Bt* cotton by facilitating the import of GM seeds, undertaking field trials and working tirelessly to obtain regulatory approvals[18]. The cotton industry exploded and India is now the largest producer of cotton (6,188,000 million tonnes/year), from being the third largest global producer in 2002. The total export of cotton is pegged at US$ 30 billion[19].

Another striking example of success in agricultural research is the commercial release of Improved Samba Mahsuri (ISM) rice variety in 2008. Samba Masuri (SB) rice has fine grains with good cooking and taste quality, and is a commercially popular variety. It is, however, susceptible to pest and disease infestation. DBT took up the problem of pest infestation and provided financial support to the Council of Scientific and Industrial Research Centre for Cellular and Molecular Biology (CSIR-CCMB) and the Indian Council Agricultural Research-Indian Institute of Rice Research (ICAR-IIRR) to develop the ISM rice variety, which would be resistant to bacterial leaf blight (BLB), the major infestation. ISM was released in 2008 and was found to be resistant to BLB even under severe infestation experienced in 2014–15; it consequently saw increased adoption by farmers by 2016. 'It was estimated that the value of the total produce was Rs 1,249 crore (based on 2016 prices). The trait value is Rs 240 crores, and it represents the value that farmers obtained by cultivating ISM instead of SM and the estimated reduction in loss that was prevented due to the adoption of ISM owing to its BLB-resistant trait[20]' with an internal rate of return (IRR) of 61.2%.

Research investments in allied areas of agriculture were equally significant in the economic expansion of the agriculture sector. Livestock plays an important role in the Indian economy. About 20.5 million people depend upon livestock for their livelihood. DBT has supported the development of better cattle breeds, artificial insemination, disease control in cows, buffalos, sheep, goats, deer, pigs, dogs and other animals, in addition to nutritious and healthy feed for animals and fishes. This provides better tools for managing the health and productivity of the largest population of livestock in the world which India houses. Livestock sector contributes 4.11% of GDP and 25.6% of total agricultural GDP.

Brucellosis is a major zoonotic disease caused by the *Brucella* species, which remains an uncontrolled problem in developing countries, including India. The major clinical manifestations of brucellosis in animals are infertility, repeat breeding, retention of placenta, abortion and stillbirth. Bovine brucellosis is endemic in India, causing severe economic loss to the tune of US$ 3.4 billion every year to the livestock industry. Humans get infections from infected animals and contaminated animal products, causing undulant fever, orchitis, chills, fatigue, and joint and muscle pain[21]. Vaccination for prevention and control of brucellosis in livestock in India will reduce the prevalence of Brucella infection to below 2% in cattle and below 3% in buffaloes in 20 years of implementation of a disease control programme. Depending on the vaccination coverage/efficacy, the net present value (NPV) could vary from US$ 4.16 billion to US$ 8.31 billion for intervention[22].

DBT initiated the development of a vaccine against brucellosis as a 'Network Project on Brucellosis' in 2012; the technology was commercially transferred in 2020 (ref. 23).

Aquaculture was given a major thrust by DBT and many cell lines, diagnostics and good farming practices were supported, standardized and promoted. India is now the second largest producer of fish in the world. Aquaculture's share in total fish production has grown from a third to half in 20 years, India is now the second largest aquaculture producing country[14,24,25].

The documentation of cost benefits accruing from the adaptation of *Bt* cotton, ISM rice variety and vaccination of livestock against brucellosis provides persuasive stories for enhanced support to science in all respects – financial, easy regulatory policies and successful delivery to the target group.

### *Industry and start-ups*

The establishment of BIRAC was a much-needed steer in the future direction of DBT. Partnership with and support to the industry brought about a robust ecosystem in the biotech enterprise. BIRAC, through its various industrial and entrepreneurial development schemes and programmes, has facilitated the growth of start-ups. Much has been written about the success of BIRAC[9,11,26]. It has provided direct employment to more than 30,000 people, with a conservative estimate of indirect employment to about 1,500,000 people. Various start-ups, companies and centres supported by BIRAC have been successful in commercialization of their products and technologies[11,26]. Documenting and analysing the economic benefits and contribution to the GDP of the biotech sector in India should also be a task that BIRAC must take on urgently.

### *International collaboration*

Few enterprises in the world are as thoroughly internationalized as science: with decided and emphatic global impact[27]. Strategic international cooperation and partnerships developed over the years have made life sciences research globally competitive. Apart from bilateral partnerships with all major countries, DBT is perhaps the first Government agency to partner with

**Annexure 1.** Budget analysis – science funding by the Government of India (FY 2020–23) by Chagun Basha, Senior Technical Specialist, Office of the Principal Scientific Adviser to the Government of India (GoI)

- These 12 scientific ministries/agencies cover up to 93% of scientific (including R&D, tech development and services) expenditure of the GoI.
- The Department of Biotechnology (DBT) accounts for ~2.9% of the overall scientific funding by the GoI. It also is the second largest extramural funding agency in the country.
- Percentage share of DBT expenditure in the overall Ministry of Science and Technology expenditure is 21.9%.

(Rupees in crores)

| Agency | FY 2020–21 | | FY 2021–22 | | FY 2022–23 (BE) | |
|---|---|---|---|---|---|---|
| | Percentage of share | Scientific budget | Percentage of share | Scientific budget | Percentage of share | Scientific Budget |
| Department of Scientific and Industrial Research[1] | 5.6 | 4,198.82 | 5.2 | 5,297.72 | 5 | 5,636.46 |
| Defence Research and Development Organization[2] | 21.7 | 16,145.74 | 18.1 | 18,337.44 | 19.2 | 21,330.20 |
| Department of Atomic Energy[3] | 20.5 | 15,196.24 | 22.4 | 22,707.21 | 20.5 | 22,723.5 |
| Department of Biotechnology[4] | 3 | 2,259.10 | 2.9 | 2,961 | 2.3 | 2,581 |
| Ministry of Electronics and Information Technology[5] | 7.2 | 5,396.3 | 9.4 | 9,581.25 | 12.9 | 14,300 |
| Ministry of New and Renewable Energy[6] | 3.5 | 2,643.3 | 7.6 | 7,681.8 | 6.2 | 6,900.68 |
| Ministry of Earth Sciences[7] | 1.7 | 1,274.54 | 2.3 | 2,369.54 | 2.3 | 2,653.51 |
| Department of Science and Technology[8] | 6.6 | 4,893.56 | 5.1 | 5,240 | 5.4 | 6,000 |
| Department of Space[9] | 12.7 | 9,474.41 | 12.5 | 12,642 | 12.3 | 13,700 |
| Department of Agricultural Research and Education (DARE), Indian Council of Agricultural Research[10] | 10.1 | 7,553.77 | 8.4 | 8,513.62 | 7.6 | 8,513.62 |
| Department of Health Research (DHR), Indian Council of Medical Research[11] | 4.2 | 3,124.59 | 3 | 3,080 | 2.8 | 3,200.65 |
| Ministry of Environment, Forest and Climate Change[12] | 2.6 | 1,966.92 | 2.4 | 2,520 | 2.7 | 3,030 |
| Total | | 74,127.29 | | 100,931.58 | | 110,569.62 |

[1]Demand No. 91, Department of Scientific and Industrial Research, Ministry of Science and Technology, Notes on demands for grants, 2022–23.
[2]29th Report, Demands for Grants (2021–22), Standing Committee on Defence.
[3]Demand No. 3, Department of Atomic Energy, Notes on demands for grants, 2022–23.
[4]Demand No. 90, Department of Biotechnology, Ministry of Science and Technology, Notes on demands for grants, 2022–23.
[5]Demand No. 27, Ministry of Electronics and Information Technology, Notes on demands for grants, 2022–23.
[6]Demand No. 71, Ministry of New and Renewable Energy, Notes on demands for grants, 2022–23.
[7]Demand No. 24, Ministry of Earth Sciences, Notes on demands for grants, 2022–23.
[8]Demand No. 89, Department of Science and Technology, Ministry of Science and Technology, Notes on demands for grants, 2022–23.
[9]Demand No. 95, Department of Space, Notes on demands for grants, 2022–23.
[10]Demand No. 2, Department of Agriculture Research and Education, Notes on demands for grants, 2022–2023.
[11]Demand No. 47, Department of Health Research, Notes on demands for grants 2022–23.
[12]Demand No. 28, Ministry of Environment, Forest and Climate Change, Notes on demands for grants 2022–23.

non-government science organizations/philanthropies. In 2009, it partnered with the Wellcome Trust (WT) to set up the DBT–Wellcome Trust India Alliance, a model for grantsmanship and promotion of excellence in biomedical research. The Alliance was perhaps one of the first and most successful examples of foreign direct investment (FDI) in R&D in India, with an equal joint commitment of DBT and WT of up to UK £ 16 million per year, amounting to a total of INR 1296 crores/UK £ 160 million over a 10-year period to be invested in India and Indian research. After 10 years, in March 2019, DBT became the senior partner, with twice the contribution to that of WT, with the Cabinet Approval of GoI.

DBT became an associate member of the European Molecular Biology Organization (EMBO) in 2015 and contributing member of the Human Frontier Science Programme (HFSP), allowing Indian scientists to compete globally and emerge as global leaders.

The idea of establishing an Institute of Marine Biology and Biotechnology to tap the vast unexplored potential of the abundant coastline of India was seeded with an Memorandum of Understanding between DBT, Pierre and Marie Curie University (UPMC; now Sorbonne University) and the National Centre for Scientific Research (CNRS), Government of France in 2015, which eventually evolved into the National Deep Ocean Mission, approved by the Cabinet in 2021 to be steered by the Ministry of Earth Sciences, GoI. CEPI (The Coalition of Epidemic Preparedness Initiative) was established in 2016 and launched in 2017, with DBT as a founding member along with WT, the Bill and Melinda Gates Foundation, the Government of Norway and the World Economic Forum. DBT set up the partnership organization, Ind-CEPI. Both these initiatives, i.e. Deep Ocean Mission and CEPI, have been established with foresight for the prosperity and well-being of India; CEPI has proved valuable during the recent SARS-CoV2 pandemic.

International collaborations and science diplomacy are under-utilized skills in India. Science diplomacy can be enlisted to meet a range of national domestic needs, from exercising soft power to serving economic interests to promoting innovation, and needs more support and encouragement from the Government[28]. Scientific prowess of a nation is a major metric of its economic growth; joint collaborative research allows showcasing the strengths and the country's scientific capacity and capabilities to the

world, at the same time allowing knowledge exchange and mutual economic benefits. DBT has established many successful bi/multilateral collaborations and Indian scientists in life sciences research are globally acknowledged; thus, impact analysis must be considered.

The evolution of DBT should be a casebook study for setting up Government departments moving from foundational support for human resource capacities to large ambitious projects. Moving rapidly to innovation, enterprise, and a start-up ecosystem, DBT is now placed at the centre stage globally for collaborations and partnerships.

No one would have envisaged that a tiny department such as DBT, with a budget of approximately US$ 400 million (approx. Rs 3000 crores) – a small fraction of the total national S&T funding – would have a disproportionate impact on the growth of science in the country. (See Annexure 1 for detailed budget allocation to various scientific ministries/departments, GoI.) Forward-thinking leadership with forthcoming Government support and the willingness to take risks at the right opportunity have been crucial in building an ever-expanding sector for the economic development of India over the years.

However, DBT's contribution to science-driven growth is sporadically documented and in-depth studies of this sector are needed. This lack of deep-dive documentation is detrimental for science, putting it on the back foot when queried about the impact of science, although experts know of many impactful contributions.

Science is and will remain a major fulcrum for the economic growth of a country. This will mean that both science funding agencies and scientists will have to communicate well to build trust and allow the monetization of their science. The Government on its part should not be hesitant in supporting science at all levels. As stated above, timely support to the vaccine industry and *Bt* cotton has reaped major benefits to India. GoI should place trust in science, put a flexible governance structure in place and allow science to flourish. Industry and academia partnerships are imperative for monetizing knowledge and helping accelerate the economic growth. Commerce of S&T cannot be neglected or viewed with suspicion; the financial growth of individuals, institutions and industry reflects a nation's economic growth. It is also an equitable model of economic expansion.

Over-regulation of technologies without careful analysis of the cost benefits is detrimental to sustainable economic growth and societal benefit. *Bt* cotton would never have been a success story if the emphatic decision was not taken in 2002. Due to delayed decision making, India has squandered several possibilities. We must not overlook the numerous opportunities presented by new technologies such CRISPR gene editing, particularly in the low hanging field of agricultural science. Easy, smooth regulatory processes with foresight and open data sharing are hallmarks of a confident and self-assured emerging scientific superpower, essential for facilitating rather than inhibiting research.

The much-acclaimed success of the COVID-19 vaccine resulted from an unusual and nimble coming together of Government, academia, rapid regulatory response, industry and international partnerships. This is the most important take-home lesson of the pandemic; the pursuit of science and its rewards is not solitary and for quick accelerated results, all stakeholders, viz. government, academia, industry and international partners must work together as a single unit, as a norm and not as an exception. The outcomes of Indian R&D can grow exponentially with: (a) GoI and industry conferring more trust and confidence in Indian science; (b) GoI putting structures in place for ease of financial disbursement, data-sharing and regulation, and (c) industry stepping up to define research questions which are of interest to them, reaching out to the vast network of research institutions to leverage and invest in the enormous capacity of state-of-the-art infrastructure and brilliant minds.

These are the often-repeated wish list of the scientific community. Therefore, the onus of building trust and confidence in its capacity to deliver on scale lies with the scientific community. Both scientists and funding agencies must provide solid empirical data/evidence for the impact that a flexible and nimble science support system has on the socio-economic growth of the country. Science and its rewards must be communicated evidently well. Well articulated documents providing evidence on the economic benefits that research and development brings to a nation will become powerful tools in influencing decision-makers for increasing investment in promoting science and its pursuit.


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