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Biotechnology Innovation for Inclusive Growth

A Study of Indian Policies to Foster Accelerated Technology Adaptation for Affordable Development

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Abstract

This paper describes and analyzes a series of complementary policy initiatives in India to adapt and commercialize existing global biotechnologies to meet local needs in healthcare, agriculture, industry and the environment in a more affordable manner. This evolving approach has been implemented through six complementary elements, namely (1) translational research; (2) technology access through global consortia; (3) commercialization supported by public-private partnerships, broadly interpreted; (4) skills development; (5) regulation; and (6) institutional governance, including special purpose vehicles, for effective project management. The paper focuses on two public-private partnership initiatives, the Small Business Innovation Research Initiative and the Biotechnology Industry Partnership Program, which together have allocated more than US$70 million in public funding to almost 150 projects, contributing to a total public-private investment of more than $170 million over the past five years. The authors' key recommendation, to ensure effective resource use and better policy impact, is for these innovation-support initiatives to adopt more continuous monitoring with quicker feedback from learning to implementation, and more rigorous impact evaluation including approaches that allow the results of firms benefiting from support to be compared with an appropriate group of firms not benefiting from support.

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BIOTECHNOLOGY INNOVATION FOR INCLUSIVE GROWTH:

A STUDY OF INDIAN POLICIES TO FOSTER ACCELERATED TECHNOLOGY ADAPTATION FOR AFFORDABLE DEVELOPMENT

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I. INTRODUCTION

Indian economic growth has witnessed remarkable advancement over the last two decades. While the initial growth increase was triggered by economic reforms and a change in foreign direct investment policy that attracted global investment, a key driver of more inclusive growth is an innovation system that can apply solutions to challenges in health, agriculture, energy and environmental products, among others.[2] Affordable solutions in these areas have the potential to address the needs of all people and especially those in lower income groups. Such innovation-driven commercialization efforts should also help ensure longer-term competitive advantage to domestic enterprises as countries open their markets even more to global competition.

While many industrialized economies have implemented innovation policies and deployed resources focused on cutting-edge frontier research and its commercialization, some emerging economies have explicitly attempted to accelerate the technology catch-up process to benefit from technologies that are already developed and accessible. Frontier technology generation may indeed be the basis for a long-term growth path for some countries. However, countries with the required capabilities to adapt existing technologies to their local needs can stimulate more inclusive growth in the near to medium term, while also focusing on the creation of frontier technologies for the longer term.[3]

This paper explores how existing biotechnologies, adapted to meet heterogeneous local needs, can help support more inclusive growth. The paper describes six complementary types of policy initiatives taken by India's Department of Biotechnology (DBT) to support accelerated biotechnology adaptation: (1) focusing on translational research; (2) facilitating technology access through global consortia; (3) supporting commercialization through public-private partnerships (PPPs); (4) strengthening diversified skills development; (5) establishing required regulation; and (6) creating institutional mechanisms for effective governance.

The paper focuses in particular on two complementary PPP funding initiatives, the Small Business Innovation Research Initiative (SBIRI) for early-stage funding of SMEs, and the

[2] In a recent interview, Prime Minister Manmohan Singh emphasized the need to address the inclusive development needs of India through research, including communicable diseases, agriculture, technologies that conserve energy and save water, and environmentally-friendly technologies. See Singh (2012).

[3] This paper builds on one of the main conclusions of Dutz (2007), namely that India (and all countries) stand to gain more from catching up to the global frontier of knowledge through adaptation of existing technologies to meet local needs and affordability concerns than from trying to push out the global frontier through creation of new-to-the-world technologies. Based on a 2006 survey of roughly 2,300 manufacturing enterprises in 16 Indian states, applying existing technology in new settings is significantly more likely to be associated with increases in productivity than are efforts to create new-to-the-world knowledge.

Biotechnology Industry Partnership Program (BIPP) for viability gap funding of larger, higher-risk projects by all enterprises. These initiatives are still in early implementation, with SBIRI launched in late 2005 and BIPP in late 2008. However, there have already been 15 calls for proposals with 791 applications evaluated and 86 projects funded under SBIRI, and 16 calls for proposals with 474 applications evaluated and 61 projects funded under BIPP to early-August 2011. With US$72 million in public funding allocated across both initiatives, together with an additional $99 million in private investment by recipient enterprises, the initiatives have contributed to a total public-private investment of $171 million.

The purpose of the paper is to describe and evaluate, to the extent possible, the SBIRI and BIPP programs to-date, within the context of the broader six-element support framework for translational research and commercialization in biotechnology. The paper assesses output and outcome achievements based on available data, interviews of DBT staff, and interviews of beneficiary enterprises from a sub-set of funded projects. The paper describes what is known, and a way forward to learn more. A notable achieved outcome is India's first indigenously-developed oral rotavirus vaccine to prevent high children mortality from diarrhea, supported by both SBIRI and BIPP and by a global PPP consortium. It is the first time that an Indian company is bringing the vaccine to phase III trials, and India's first community clinical trial conducted directly through doctors and clinics, with the licensed vaccine to be sold to governments worldwide including UN procurement agencies at a price of $1.

Importantly, the paper also points to a key outstanding challenge, namely the adoption of more rigorous impact evaluation, and more continuous monitoring with quicker feedback of learning for improved implementation. Such monitoring and impact evaluation would help to assess the cost effectiveness of policies and outcomes relative to alternative solutions, to provide accountability, and to inform and build support from new prospective enterprise applicants and from society at large for any demonstrated (and not just presumed) positive benefits relative to costs of existing and future support initiatives in this area. It also would facilitate joint learning of how to best address emerging challenges through successive modifications of program design features driven by evidence-based analysis and debate, thereby improving the quality of public expenditures supporting innovation policy and providing a more solid foundation for future funding decisions.

The paper is structured as follows. The next section provides a succinct description of six complementary elements of an accelerated biotechnology adaptation program, and describes their implementation in India. Section III analyzes the two main PPP funding initiatives to implement the program in India, SBIRI and BIPP. A final section provides concluding remarks, including implications for other developing countries.

II. POLICIES TO FOSTER TECHNOLOGY ADAPTATION

II.1 Accelerated biotechnology adaptation

Biotechnology has many of the characteristics of a 'general purpose technology' (GPT) in that it drives growth by spreading over a range of important sectors of the economy and

stimulating them to innovate as well, including applications to healthcare and medicine, to agriculture and food products, to industrial processes including bio-fuels, and to environmental goods and services. Progress in the application sectors, in turn, can feed back into the GPT sector, providing incentives for further upgrading and advances in the GPT itself, and thereby setting up a self-sustaining positive feedback loop.[4]

Effective biotechnology transfer (from the vantage point of the entity creating a new technology) and absorption (from the vantage point of the entities adopting and adapting the technology to meet local needs) requires a set of steps to contribute to economic growth. Six complementary policy elements are:

1. **Translational research and validation**: Most applications of biotechnology typically need to be adapted and verified to meet specific needs in heterogeneous local contexts. While the frontier technology for the cost-effective production of a silicon wafer is largely invariant to location, most biotechnology applications need adaptation and verification to local biological variations including climate, soil type, and genetic variations in plants, animals and humans. 'Translational validation' refers to adapting a technology for local relevance, and then verifying the technology through a process whereby component technologies, aggregated and tested under laboratory conditions, are validated in the field to ascertain that they hold relevance as a complete solution with their efficacy and cost effectiveness confirmed at a commercially relevant scale.[5] Translational validation includes both proven technologies that are currently applied successfully in a particular context being validated for another context requiring closely-related solutions to be accomplished, as well as new technologies that are tested and modified under laboratory and field conditions to deliver value in the marketplace (see Box 1 for examples).

Box 1: Examples of translational validation

Existing technologies that can be accessed globally and aggregated are often not ready to be adapted and validated for local conditions. In health applications, while a number of candidate vaccines have been approved in industrialized countries, they are often not appropriate to the local context due to their high cost or their irrelevance to different needs. Similarly in the area of agriculture, while industrialized countries focus on large acreage grain crops for yield improvement, and on pest and weed mitigation with the development of genetically modified (GM) crops and molecular breeding, they often do not provide solutions to problems typical for tropical cropping regions. Productivity and plant quality are impacted by a number of local stress factors such as insects, pests and viruses (biotic or living factors) and drought, cloud cover, salinity, heat and submergence (abiotic or nonliving factors). Traditional breeding processes have taken years to integrate genes and develop plant

[4] See Trajtenberg (2009) for a discussion of GPTs as a driver of innovation in developing countries, and earlier discussions in Bresnahan and Trajtenberg (1995) and Helpman and Trajtenberg (1998).

[5] Translational research is an alternative to the traditional dichotomy between basic (or fundamental) and applied (and typically more short-term and incremental) research within specific scientific fields. It is a more interactive mode of research where multi-disciplinary and multi-skilled teams (with a great deal of interaction between academic research and industry practice) shorten the overall time frame of the basic-applied continuum to translate existing fundamental research results into practical solutions, seeking to move "from bench to bedside" or from lab experiments through clinical trials to point-of-use applications. See Goldblatt et al. (2010) and Woolf (2008); and see Popp (2011) and Dutz and Sharma (2012) on the need and required policy support for 'adaptive R&D' for green technologies (research and development required to adapt existing green technologies to fit to local soil, water, air, wind, sun and temperature conditions).

varieties that are resistant to such local stress factors. Adaptation of genetic engineering technologies allows the accelerated integration of useful genes in the crop genome and the development of traits that are preferred by local farmers to enhance crop yields and quality. However, validating transgenic technologies for their safety, efficacy and field-level performance is a time consuming and high investment process requiring specialized skills in verifying the technologies and integrating them in crops of interest.

As a concrete illustration, researchers at Cornell have discovered that the trehalose gene (a sugar with high water retention capabilities found in many animals and plants) has the potential to enhance stress tolerance in rice plants in conditions of drought, salinity and heat. Scientists have modified the gene in rice plants, which then possess enhanced tolerance to drought and salinity. These plants were tested by Cornell researchers in green-house conditions and were found to provide higher output of rice grains as compared to plants that were not genetically modified. The key element of translational validation relates to testing these plants in actual tropical drought-prone agriculture regions and validating the performance of the gene and its impact on the plant to provide higher yield under stress conditions. Validation of such performance in comparison with plants that are not genetically modified provides the true efficacy of the modified gene in inducing stress tolerance in rice plants. Further translational effort is involved in validating the efficacy of the gene to induce stress tolerance in other crops such as corn.

As another illustration, loss of value due to lack of post-harvest processing is common in most tropical regions. In India, an important fruit crop such as mango is subject to price fluctuations due to high seasonality, not being available year-round. There is potential to export mangos but such exports are again seasonal. A fruit such as the apple grown in US gets stored in 'Controlled Atmosphere Storage' (CAS) conditions, where careful control of reduced oxygen and carbon dioxide, raised humidity and lowered temperature provides longer shelf-life of up to one year, with researchers developing specific regimens for each variety in conjunction with growing and harvesting techniques, to achieve best quality (firmness, skin color, seed color, sugar level and flesh chlorophyll are regularly tested). Technologies such as CAS have the potential for translational adaptation for a large variety of horticulture products in tropical regions. These technologies need to be validated with research focused on developing storage parameters and protocols so that high-quality product availability is maximized over the year. Platform technologies such as CAS have wide scope for application in diverse environments once they are adapted to local conditions and validated through translational research approaches.

2. **Technology access**: Selecting, securing rights of usage and aggregating appropriate complementary pieces of technologies developed in the public and private innovation system within or outside the country into an accessible package to adapt to meet specific needs.

3. **Commercialization:** Supporting the process of introducing new products, production processes, organizational and marketing technologies into the market, from pre-commercial trials to commercial scaling-up to meet customer needs, driven by dynamic interactions between creators/adapters, entrepreneurial implementers, financiers and consumers.

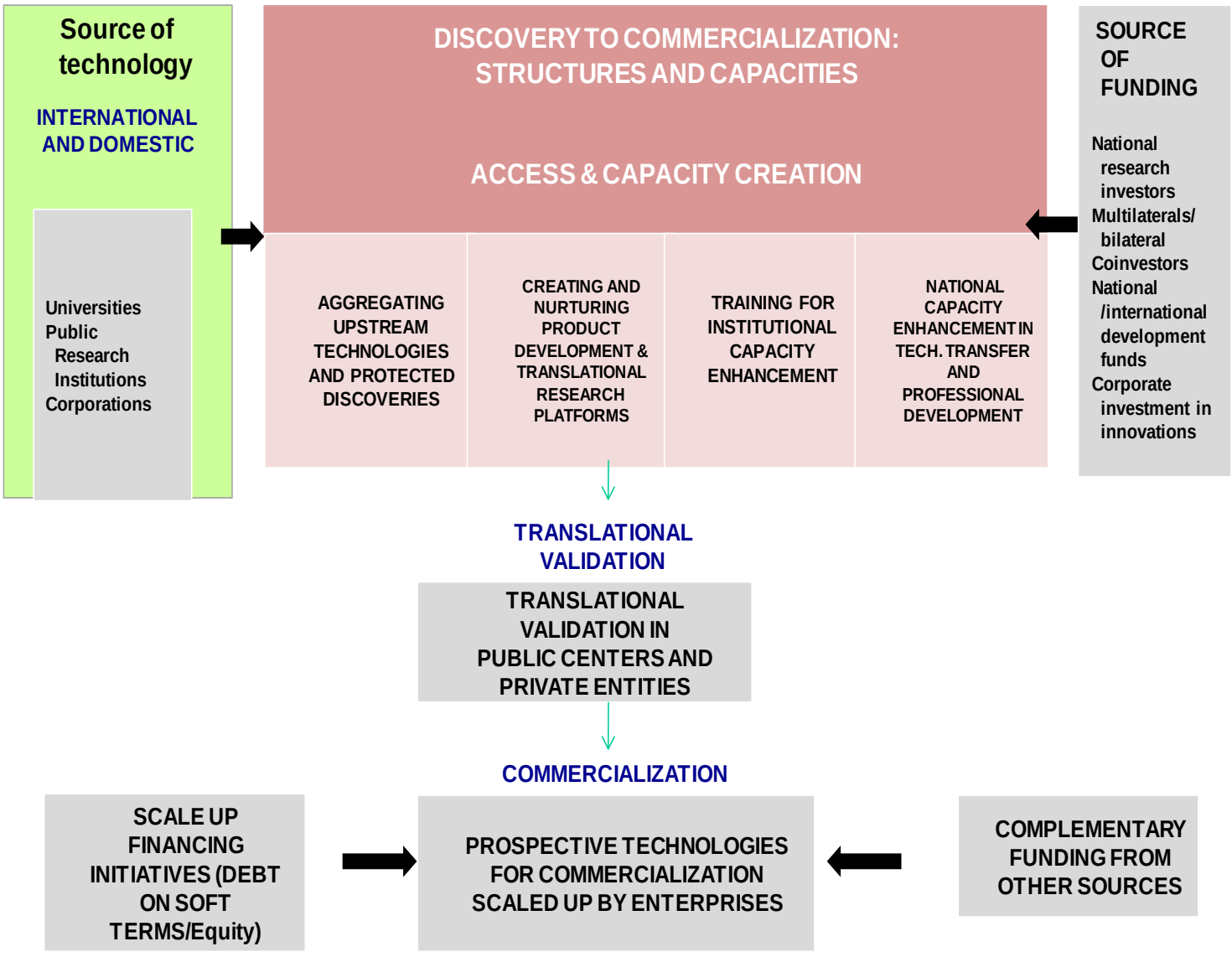
4. **Skills development:** Strengthening required education and skills, and nurturing cohorts of mentors with scientific, entrepreneurial and managerial capabilities to support enterprises in ensuring that the technology transfer and assimilation takes "root".

5. **Regulation:** Establishing the regulations and compliance frameworks required to ensure process (including trial subject safety) and product safety and that ethical issues are adequately addressed, and enhance public understanding and trust of new technologies so that local communities have the needed confidence to experiment and use the adapted and extended technologies based on informed decisions.

6. **Institutional governance:** Ensuring that appropriate institutional mechanisms are in place to yield effective resource use and desired policy impact, including transparency and required speed of execution in project management

These steps and supportive processes are depicted in Figure 1.

Figure 1: COMPONENTS OF BIOTECHNOLOGY ACCELERATION



II.2 Implementation experience in India

In 1986, the Ministry of Science and Technology created the Department of Biotechnology (DBT) to provide impetus to the development of the biotechnology sector in India. Over the past decade, DBT has been developing a more systematic approach to catalyze accelerated technology adaptation, through its own implementation of the six complementary policy elements.

(1) Focusing on translational research

Over the past years, DBT has focused on creating an innovation system where research at the discovery stage and at mid-levels of translational research can generate a pipeline of products. Early-stage research is the predominant engagement of the public research institutions but there was a need to complement this with mid-level translational research that would address affordable solutions. Translational research in the 1990s and early 2000s was not the foray of public researchers. The private sector had considerable interest in translational research but had little or no access to existing technologies and to professionals with diverse skills sets that could consolidate technologies and apply them to later-stage product-oriented development. Also, when science is moved from upstream to mid-level, the need to combine ethical practices, benchmarked product performance, process and product validation, regulatory validation and efficient product delivery strategies come to the fore. Finding sustainable solutions to these challenges requires the convergence of efforts by multi-disciplinary researchers. Research thus becomes driven by definitive outcomes, with the setting of milestones and the measurement of success through the socio-economic impact that follows from the delivery of goods and services.

Translational research to address issues impacting the livelihood of lower income communities is often more complex. It typically requires both domestic and global aggregation of technologies, their systemic validation with the engagement of public and private partners, and strategic commercialization of the products with a focus on their affordability to needy communities.

DBT initiated its focus on translational research around 2005. Its initial focus was confined to a couple of disease segments and a couple of crop stress factors. During the last five years, DBT consolidated this process and created sustainable frameworks that focused exclusively on translational research. One such framework is DBT's Grand Challenge Programs, announced in 2007 as part of its National Biotechnology Development Strategy.[6] Of these programs, the Vaccine Grand Challenge Program launched in 2008 is specifically intended to facilitate the accelerated development and validation of cost-effective new or improved versions of vaccines and delivery systems (such as vaccines that do not require refrigeration and needle-free vaccines).

[6] DBT adopted this approach inspired by the Grand Challenges for Global Health initiative to solve key health problems in the developing world announced by Bill Gates in 2003, and supported by the Bill & Melinda Gates Foundation, the US National Institutes of Health, the UK Wellcome Trust and the Canadian Institutes of Health Research.

Three specialized centers in translational research have been created to provide dedicated facilities and networking opportunities:

(i) Translational Health Science and Technology Institute (THSTI). Set up in early 2009, THSTI is an autonomous institute established by DBT made up of a series of labs and niche centers including a Vaccine and Infectious Disease Research Center, a Pediatric Biology Center, a Clinical Development Services Agency, and a Center for Bio-design and Diagnostic. The interim centers are located in Gurgaon in the south of Delhi area, and will move in about 18 months to a new 200-acre Biotech Science Cluster campus in Faridabad, in the State of Haryana. THSTI seeks to create an institutional environment for multi-disciplinary research to translate technological advancement into medical innovations for affordable healthcare solutions. The novelty is that the collaboration among research institutions, hospitals and companies is being built ground-up with a common governance to encourage practicing doctors to work with basic researchers and engineers for commercialization. THSTI is modeled on the Harvard-MIT Health Sciences and Technology (HM-HST) program for multi-disciplinary research founded in 1970, which integrates science, medicine and engineering in its academic and research activities to solve human health problems. THSTI is benefiting from a partnership with HM-HST, to oversee its development, and to mentor and train its faculty wherever necessary. Learning from India's first community clinical trial for a childhood vaccine for rotavirus infection (see Box 2) is expected to expedite THSTI's next product, a tuberculosis vaccine.[7]

(ii) Platform for Translational Research on Transgenic Crops (PTTC). While multinational corporations and larger domestic enterprises may have in-house ability to advance agricultural biotechnologies through the translation process, DBT created a specialized center for advancing the discoveries in public research institutions and small enterprises. In February 2009, DBT together with the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), a non-profit center supported by the Consultative Group on International Agricultural Research (CGIAR) based in Hyderabad, set up the PTTC to provide an effective interface between the lab and the land. The center has high quality personnel trained in validating gene performance, molecular integrity and the efficacy of transgenic crops developed by the public and private research system. PTTC is already operational and has identified early leads for advancement through translational validation. To complement the activities of the PTTC, DBT announced in February 2011 the establishment of a Crop Genetic Enhancement Network to spur the development of improved crop varieties. The Network is a globally-coordinated effort to bring in necessary genetic enhancement to analyze variances in crop genomics and to generate molecular markers – to enhance produce quality and reduce input costs. International partners would contribute to the initiative by pooling existing data and molecular markers and by collaboratively developing markers for further validation.

(iii) Translational research platform for processed foods. Another translational research center established in 2011 is a Bio-Processing Unit (BPU) at the National Agri-Food

[7] See Singh (2011).

Biotechnology Institute (NABI) in 'knowledge city' at Mohali in the State of Punjab, the breadbasket of India. NABI is establishing three centers of excellence for research and application at the interface of agricultural, food and nutritional biotechnology. The BPU will function in close linkage with other institutes, the agri-food industry and entrepreneurs to apply emerging bio-process application technologies to enhance the value of agricultural products.

(2) Facilitating technology access through global consortia

There was an absence in India of sufficient global connectivity for exploring contemporary science and its application. The absence of knowledge networking created a silo of confinement for national researchers. Infectious diseases needed a concerted global effort to engage multi-disciplinary talent drawn from various global locations in finding common solutions.

DBT conceived a span of global partnerships for Indian researchers to collaboratively learn to adopt best practices in technology generation, translation and commercialization. The stated goal was to walk shoulder to shoulder with global peers, gain excellence in research delivery as well as management of large research programs so that after a decade or so of partnership, India would gain global strength to contribute to the developing world in mitigating human illness and hunger. In such an effort, there was a need to reengineer Indian attitudes to collaborate with others and to contribute to global advancement. The emphasis on affordable technologies helped to pool talent, infrastructure, resources and the management ability to address these challenges.

There is an advantage in learning together and demonstrating best practices in the development of novel drugs for endemic diseases, and in clinically advancing the product to a deliverable mode. There was also a larger objective of linking domestic challenges to global challenges and addressing these with the power of collective responsibility and resource pooling. The pooling of intellectual property (IP) became a seamless and incidental effort, with all partners willing to pool IP and skills for accelerated solutions that could be commonly shared. The partnership frameworks, developed prior to the commencement of the collaborative programs, address key issues such as the methodology to transfer biological materials, IP co-creation processes and their protection, transfer of technologies, and impact evaluation.

A specific illustration of partnership frameworks is the Multi-party Agreement entered into by the partners within the Indo-Swiss Collaboration in Biotechnology (ISCB) consortium that binds every partner to a structured approach in research, IP protection, publication protocols, and adherence to certain project management practices (see Box 2). The experience sharing and exchange of best practices in research, project management, information management, joint publications, and a collective approach in priority setting and evaluation are some of the key gains from bilateral research programs initiated by DBT. These initiatives have helped to pool intellectual assets from partner countries that were pre-existing (background IP) for further advancement and application in the research programs, and share the intellectual

assets that were co-created by partners through collaborative efforts (foreground IP). The ISCB consortium arrangement further spelled out the manner in which the collaborating partners would donate technology to other developing countries that may gain from accessing the IP created by the consortium.

In biotechnology, quality of research and transparency in regulatory validation of efficacy and safety ultimately drive excellence in product delivery. DBT promoted global collaboration to elevate Indian research competency to global standards. The early results of such collaboration include an initial candidate in Phase III trials for infectious disease prevention (rotavirus), candidates in advanced field trials for crop yield improvement (pulse crops), and a number of other products in the pipeline. The genetically modified eggplant, supported by DBT for translational validation has already been approved by the regulatory agency, though its commercial release is withheld due to a political decision.

While international alliances are sometimes mistrusted for biased perspectives or unilateral gains by the partners, the DBT alliance model demonstrates that global alliances make technology and resource sharing possible for global gain. The focus on mid-level research partnerships with global alliances also facilitates sustainability of such efforts by focusing not just on one isolated issue but a suite of issues. The rotavirus vaccine, the most advanced candidate to be commercialized with international partnership nurtured by DBT, has the potential to deliver the vaccine at US$ 1 a dose, not just in India, but also in other developing economies. The vaccine is expected to start clinical trials in November 2011.

DBT continues to augment its joint footprint by partnering with more countries that have sound systems of discovery-led technology generation in the areas of health, agriculture, energy and environment. Global developmental funding partners such as the Bill and Melinda Gates Foundation and the Wellcome Trust, UK are co-investing with DBT in this development effort.

Box 2: Selected global collaborations

ISCB. The Indo-Swiss Collaboration in Biotechnology is DBT's longest established bilateral R&D program, jointly funded and steered with SDC (Swiss Agency for Development and Cooperation). It promotes research partnerships and adheres to an integrated value chain concept, namely continued support through to product development and application, with the main goal of contributing to poverty reduction. It was initiated in 1974. After an external evaluation in 1997, a 'new ISCB program' was launched in 1999 focusing on agricultural biotechnology (disease resistance in wheat, pest control in pulses, monitoring of pesticides, improvement of soil quality, and trans-sectoral topics), and involving more research institutions and broader stakeholders including the private sector, safety and health regulators, and representatives of ethics concerns. Over three phases (a first 5-year agreement of $15.2 million with DBT contributing roughly 30%, a 2nd phase to 2007 of $7.8 mn with DBT contributing 34%, and a 3rd phase to 2012 of $10.1 mn with DBT contributing almost 50%), ISBC has built considerable human capacity, generated licensable technologies for commercial dissemination, and demonstrated an excellent governance mechanism. The developed technologies have been externally reviewed and the private sector invited to license them. Sathguru Management Consultants guided the technology showcasing process. Licensees were identified through a transparent process. A consortium of licensees is now advancing the technologies for

commercialization. A ***Technology Advancement Unit*** (TAU) was opened in New Delhi in summer 2010 to facilitate and support technology transfer, including guiding project partners during the post-licensing phase. In a novel South-South cooperation, ISBC partners have now extended technology licensing support to Bangladesh to adopt the technologies to local conditions.

Wellcome Trust, UK. The ***Wellcome Trust-DBT India Alliance*** is a 5-year £80 million equally-funded competitive biomedical research fellowship program across the full spectrum of biomedical sciences, the largest international partnership that DBT has entered into to-date. Initiated in September 2008, it was modeled along the line of Howard Hughes Fellowship, the largest privately-funded science education initiative of its kind in the US, and was designed to support scientists at key stages of their research careers -- in fields such as neuroscience, cell biology, cancer diagnostics, genetics and infectious diseases prevalent in the developing world. A follow-on 5-year £45 mn equally-funded '***R&D for Affordable Healthcare***' initiative was launched in July 2010 specifically to support translational research projects that deliver safe and effective healthcare products for India and other low and middle-income countries at affordable costs, intended to address the funding gap from venture capitalists requiring a sufficiently large, demonstrable market with ability to pay. Projects covering any aspect of technology development for healthcare are considered, including diagnostics therapeutics, vaccines, medical devices, and regenerative medicine. Proposals drawing on the disciplines of the physical sciences, mathematics and engineering as well as biomedicine are equally encouraged. Funding agreements are negotiated on a case-by-case basis, with Wellcome Trust Grant Conditions applying, including ring-fencing of funds and fund release in tranches against the attainment of pre-agreed project milestones. One award in the pipeline is an ophthalmology project involving collaboration between the L.V. Prasad Eye Institute in Hyderabad and Sheffield University to develop new biocompatible materials for a stem cell-based therapy to restore sight in eyes where the cornea is damaged by chemical or burns injury.

Indo-US Vaccine Action Program (VAP). The Indo-US VAP was initiated in July 1987 for five years, and extended five times to-date up to July 2011. Its main aim was the development of joint R&D projects for new and better vaccines against major communicable diseases of importance to India; encompassing laboratory-based research, epidemiological studies, field trials, vaccine quality control, and delivery of vaccines. More than 50 projects have been initiated and implemented in the area of rotavirus, HIV, viral hepatitis, malaria, rabies, respiratory diseases, cancer immune-therapy, polio, typhoid and dengue. More than 500 Indian scientists have been trained in leading US institutions for vaccine development. Major successes include India's first indigenously developed oral rotaviral diarrhea vaccine (Human RotaVirus strain 116E, ROTAVAC), with successful completion of phase II trials and large phase III community clinical trials for safety and efficacy (conducted directly through doctors and clinics) currently underway on some 8,000 children in Delhi, Pune and Vellore. Indian licensing for ROTAVAC is expected during 2014 and WHO prequalification in 2015 for supply to UN agencies at a price of US$1. Bharat Biotech's rotavirus vaccine development project is a PPP between the Hyderabad-based company and DBT, the All India Institute of Medical Sciences (AIIMS) in New Delhi, the Indian Institute of Sciences in Bangalore, the Society for Applied Studies in New Delhi, the Translational Health Science and Technology Institute (THSTI) in Gurgaon, the Bill and Melinda Gates Foundation (which announced in March 2011 that it would give as much as $30 million in grants for the phase III trial), the international non-profit Program for Appropriate Technologies in Health (PATH), the Atlanta Center for Disease Control and Prevention, Stanford University, and the US National Institutes of Health. Bharat Biotech also received support from SBIRI (for phase II trials) and from BIPP (for phase III trials).

Other international collaborations established by DBT include with:
Australia. DBT and the Department of Innovation, Industry, Science and Research, Government of Australia in various fields of biotechnology.
Canada. International Science and Technology Partnerships in the area of convergent medical technologies, bio-pharmaceutical and health care research, and clean technologies.
Denmark. DBT and the Danish Agency for Science and technology in the areas of food, feed and bio energy.
ERA-net. DBT collaborated with the first ERAa-net project (European Research Area) named NEW INDIGO, aimed at fostering and coordinating scientific cooperation between the ERA and India.
EU. Development of functional foods and ingredients and valorization of by-products in food processing.
Finland. DBT-Academy of Finland and TEKES in the area of medical diagnostics.
Germany. Research partnership covering various facets of biotechnology research.
IAVI. DBT and the International AIDS Vaccine Initiative to develop next generation AIDS vaccine candidates.
Japan. DBT and AIST, Japan partnership for life science research.
Norway. Multicentric collaborative program on aqua health.
Sweden. DBT and Swedish Governmental Agency for innovation systems support research co-operation between Indian and Swedish scientists in the fields of biology, diagnosis and treatment of tuberculosis.
UK. Research collaboration between the National Institute of Immunology, New Delhi and Queens University, Belfast to advance cancer research and improve patient outcomes by discovering biomarkers for multiple types of cancer.
US. Contraceptive and Reproductive Health Research (CRHR) program.

(3) Supporting market-oriented research and commercialization through PPPs

Public-private partnership (PPP) is a concept that has evolved in India over the last decade in the area of infrastructure asset creation (public roads, ports, airports, power). It typically has involved public and private sectors co-investing in infrastructure assets with the private sector managing the assets under a well-specified contract with the objective of more cost-effective delivery of services. However, PPPs for co-creating intellectual assets, managing intellectual assets and commercializing the results need a model that is distinct from those generally adopted for infrastructure projects. Whereas the public research institutions possess the inter-disciplinary research skills to create new knowledge, the private sector has a deeper understanding of market needs and the economic relevance of products developed by application of technologies generated from public research. The private sector is typically more competent in addressing elements in the process such as product, clinical and regulatory validation, commercial risk assessment, strategic planning for market entry, product delivery forms with wide reach to needy household and farmer communities, and the harnessing of multi-disciplinary skills needed to convert product ideas to market-ready products. In most countries with a sound patent regime, the patent filings from the private sector far outweigh those from the public sector. The pooling of resources wherein the public sector invests largely in technology risk and the private sector invests largely in market risk-related

components can help innovation to reach needy communities in an accelerated manner with due sharing of risks and responsibilities.

Institutionalizing PPPs for the co-creation of intellectual assets is not an easy process as it requires the two divergent research systems to perceive value in each other to engage in such co-creation. DBT's experience with co-investment platforms for global connectivity has reportedly provided DBT the ability to structure the SBIRI and BIPP funding initiatives in order to create affordable solutions in the area of health and agriculture. Funding models implemented by other government science and technology funding agencies such as the Department of Science and Technology (Technology Development Board), and the Council for Scientific and Industrial Research (New Millennium Indian Technology Leadership Initiative, or NMITLI) do not have the same dedicated focus on health and agriculture-related commercialization needs with private entrepreneurs taking the lead.

DBT's ongoing objective is to create PPPs as an integral element of every research plan that is conceived to address frontier research areas, to enhance the likelihood of accomplishing technology commercialization. For the 12th five-year planning process (2012-2017), DBT has proposed that 30 percent of its anticipated augmented total budget flow to the private sector to engage in collaborative research, adaptation and validation for accelerated commercialization, including through scaled-up SBIRI and BIPP funding. This anticipated surge in support to the private sector is expected to help accelerate technology adaptation and commercialization.

(4) Strengthening diversified skills development

DBT also has focused on building a highly diverse talent pool within the public and private research system to excel in all stages of the innovation chain. The public talent pool was originally oriented to address exclusively early-stage research needs, but lacked the required diversity to carry out mid-level and later-stage translational research. The mid-level product-oriented research requires diverse disciplines of talent to engage collaboratively to adapt technologies, conceptualize the product forms and validate the efficacy of the product forms to suit consumer needs, including delivery within affordable costs.

The meeting points of health, agriculture, engineering and environment require a wide spectrum of knowledge communities to engage in collaborative application of knowledge. As an illustration, India typically loses a quarter of its agriculture produce to post-harvest losses. However, the talent pool to develop, validate and deploy simple value-addition technologies to preserve the post-harvest value of farm produce and to convert them into shelf-stable processed food was non-existent. Such an effort requires combining multiple disciplines such as farm engineering technologies, food science, food engineering, environmental engineering, market needs assessment, international trade and business skills. While many technologies are globally available and accessible for post-harvest value addition, the inability to translate such technologies or generate them indigenously denies India significant wealth creation. Similarly, generating energy from crops requires combining the knowledge of plant science, bioprocess engineering, environmental science, economics, and business. Validation of a

transgenic crop technology for a crop protection trait requires plant breeders, entomologists, plant pathologists, food safety specialists trained in assessment of the safety of proteins, and bio-safety specialists trained in environmental safety assessments. In the field of medical research, an interface of drug development researchers, clinicians, statisticians and epidemiologists is required to work together in validating relevance, safety and efficacy while devising novel strategies for delivery to reach vulnerable communities.

DBT has engaged in creating such capacity in areas beyond basic biology so that multi-disciplinary talent can engage in addressing translational research efforts. A two-pronged strategy was adopted: to re-skill existing professional scientists to engage in a more diverse arena of research; and to create new talent in young scientists to engage in inter-related multi-disciplinary research. There was also a focused effort to bring back well-trained researchers overseas of Indian origin with proven talent in multi-disciplinary areas to engage in public research institutions.

Every bilateral research program forged by DBT has envisaged capacity building through mutual exchange of research personnel as an essential element of the research capacity building process. In addition to the 2008 DBT-Wellcome Trust biomedical research fellowship program (see Box 2), there are number of other types of additional programs. The Ramalingaswamy Re-entry Fellowship program, funded by DBT, helps to attract Indian post doctoral fellows located abroad to undertake a sabbatical with Indian research institutions or universities by providing financial support (research funding and compensation) during their stint in India. The duration of the fellowship is for a period of 5 years, extendable for another 5 years. The Tata Innovation Fellowship program is a complementary scheme, supported by DBT and Tata, to recognize scientists with an outstanding track record in biological sciences and reward interdisciplinary work with emphasis on translation and innovation.

Another model funded by DBT and other supporters, initiated in 2001, is the Stanford-India Biodesign (SIB) fellowship program with the All India Institute of Medical Sciences (AIIMS) and Indian Institute of Technology (IIT) Delhi forming a partnership guided by Stanford University. SIB is based on the notion that innovation can be taught and learned if multi-disciplinary teams with engineering, medical and business background converge their ideas and engage in collaborative knowledge sharing. The competitive selection of young Indian students with an interest in the invention and early-stage development of new medical devices provides an opportunity to develop future science leaders. SIB's aim to catalyze the Indian medical technologies industry and reach out to India's medically under-served regions helps to deliver appropriate healthcare solutions to the needy. An appropriate functional system, including fellowships, innovation teaching, idea generation, product profiling, market analysis, commercialization, prototyping and validation support are all an integral part of this program. SIB already appears to have yielded successful results in terms of start-up ventures and products.[8] Seeing the benefit of this initiative, other IITs in the country have planned to adopt similar programs in their curriculum.

[8] The Jaipur knee, designed by SIB students, was selected as one of Time magazine's top 50 inventions for 2009. Two 2008 SIB Fellows started a company, ConSure Medical, which was recognized as one of the Top 75 startups in India to bet on by DARE magazine. Another invention by 2 SIB students at AIIMS, IntraOz, took

The partnership between DBT and the not-for-profit Association of Biotechnology Led Enterprises (ABLE) to provide exposure to graduating students in bio-entrepreneurship is another relevant initiative. A series of 3-day residential entrepreneurship development workshops was initiated in August 2011 across the eight north-eastern states of India, aimed at encouraging graduating B.E/B.Tech and Masters and doctoral-level students to take up life sciences entrepreneurship as a career option. The workshops are intended to strengthen business skills to enable graduates to start commercial biotechnology ventures, covering topics including technology sourcing, IP and patenting strategies, regulatory issues, as well as business models, accounting and finance.

There also appears to be a need for enhancement of technology management skills across multi-disciplinary functional competencies such as technology assessment, IP protection, technology valuation, and technology transfer licensing and post-license monitoring. DBT has supported the creation of the Society for Technology Management (STEM), an association of technology management professionals formed on the lines of the U.S. Association of University Technology Managers (AUTM). STEM is supported in carrying out capacity building efforts among practicing technology managers and prospective new entrants. DBT has nurtured and retained external talent wherever necessary in providing the vision for accelerating technology management skills in India.

(5) Establishing required regulation

As the policy focus moved to mid-level research to validate technologies and products, DBT began establishing the regulations and compliances frameworks required to ensure process and product safety and technological relevance. There was a consequent need to enlarge the pool of professional regulatory administration specialists by partnering with other regulatory agencies in countries that have established robust regulatory mechanisms. DBT's efforts have focused on establishing a sound system of regulation for pursuing research especially in agriculture biotechnology, bio-medical discovery-led clinical validation, and animal health-focused products. DBT established a number of frameworks for regulating the safety and efficacy of these technologies, with some of these regulations formulated on their own and some in collaboration with other national regulatory bodies that are responsible for specific aspects of regulations.[9]

DBT has proposed the Biotechnology Regulatory Authority Bill 2009 to establish an independent, autonomous, statutory agency to regulate the research, transport, import,

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first place in the India Innovation Pioneers Challenge 2009; it can help doctors administer drugs intravenously into the bone marrow of patients in trauma or having a heart attack.

[9] The various regulations, rules and acts introduced include: Recombinant DNA Safety Guidelines and Regulations, 1990; Revised guidelines for safety in Biotechnology, 1994; Revised Guidelines for Research in Transgenic Plants & Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998; Guidelines for Generating Pre-Clinical and Clinical Data for r-DNA Based Vaccines, Diagnostics and other Biologicals, 1999; Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated Genetically Engineered (GE) Plants, 2008; and Protocols for Food Safety Assessment of Foods Derived from Genetically Engineered Plants, 2008.

manufacture and use of organisms and products of biotechnology. Another initiative taken by DBT relates to creating a system of reward mechanisms for technology transfer and providing a legal mandate for technology generating agencies to license them to enterprises. This legislation, proposed on the lines of the Bayh Dole Act of USA, is intended to bring greater focus to the technology management process for publicly-generated technologies. The Public Funded R&D (Protection, Utilization and Regulation of Intellectual Property) Bill, conceived in 2007, has undergone considerable debate and discussions and is expected to be taken up for enactment by the national lawmakers in Parliament.

DBT has encountered challenges in bringing these regulatory frameworks to fruition. The recent withholding of approval for transgenic eggplant in India by the Minister for Environment highlights the complications in bringing consensus in regulatory processes. In principle, Indian ability to effectively regulate biotechnology-derived products in healthcare and agriculture should provide a competitive advantage given the lower costs in carrying out such validation, driven by abundant available scientific and clinical labor and the consequent lower total costs of various validation procedures. Currently, the cost of regulations in OECD countries typically leads the private sector to confine regulatory validation to products that have a sufficiently large global market potential. This is a key reason for large multinationals and industrialized country public research bodies not to advance research for neglected diseases, small acreage crops, and low-value agriculture products. If India gains sufficient regulatory capacity, then the products approved in India have the potential to reach other developing countries that have similar product needs in the areas of health and agriculture.

(6) Creating institutional mechanisms for effective governance

There was a perceived need by DBT to create institutional mechanisms that would accelerate translational research, covering project conceptualization, creation, management and monitoring, and that would provide for engagement of all involved partners, domestic, international, public and private. Such institutional mechanisms were expected to ensure transparency, speed of execution and effectiveness in management to increase the likelihood of success of the translational research programs.

A project management entity was conceived for each of the initiatives. Wherever needed, a special purpose vehicle (SPV) was created for the management entity to ensure efficiency, speed and transparency in governance and administration. Institutional frameworks were conceived and developed to suit the rules of engagement in mid-level research focused on the generation of affordable goods and services. The SPVs were tailor-made to the requirements of each initiative, depending upon the longevity and the depth of multi-party engagements in such initiatives. Each SPV had a distinct model of project management that focused on research effectiveness, resource management and governance. Specialists with project management ability and consultancy organizations with experience in global project management were retained to support the establishment of management structures that would provide able governance mechanisms. IP management, technology management functions, creation and adoption of project management tools, capacity to train scientists in effective

grant writing, and several other non-research related interventions required external talent to be sourced.

DBT's initial efforts to create SPVs arose from its bilateral engagement in global research partnerships. In their initial years of engagement, co-investors with DBT insisted on project management being vested with management entities based in the industrialized country partner country due to the project management skills they brought in. The bilateral engagements helped to create independent governance mechanisms with representation of experts, including scientists, administrators and technology management specialists from partnering countries. The engagements required collaborating partners to define a structured manner in which the funds would be deployed, research projects managed, and the results reviewed. Based on an examination of some of these governance models, they did not have a typical structure but were tailor-made to meet the needs of specific partnerships. The ISCB partnership described in Box 2, for example, is not managed by an independent legal entity, but by a Joint Action Committee, an apex body constituted with participation from academia, research administrators and industry from both countries. Separate project management units in Switzerland and in India provide the day-to-day management support for program implementation. Adequate external review mechanisms were established drawing on skills available in both countries. There appears to be a pattern whereby DBT's institutional frameworks initially have been catalyzed by their international partner programs, and then applied to provide a structured governance mechanism and administrative autonomy to domestic programs exclusively conceived by DBT.

III. ANALYSIS OF SBIRI AND BIPP

Over the past five years, DBT's total budget has gone up from $65 million in 2005-2006 to $275 million in 2010-11. This public support to biotechnology in India includes the creation and strengthening of physical capital, human capital and other forms of knowledge capital as well as institutional capabilities, plus a dedicated flow of public funds to enterprises in public and private sectors through two main PPP funding initiatives, SBIRI and BIPP.[10]

The purpose of this section is to describe and evaluate, to the extent possible, the impact of SBIRI and BIPP programs to mid-2011. A first subsection puts forward a framework for ex-post evaluation of these large public subsidy programs. A second subsection describes what we were able to find out. A third subsection recommends how to strengthen impact evaluation and continuous monitoring moving forward.

III.1 Principles for program evaluation

DBT's stated objective in supporting small and medium-size enterprises (SMEs) and larger domestic firms is to foster more inclusive growth by supporting all areas of biotechnology applications to healthcare, agriculture, industrial processes and environment, as well as bio-

[10] See DBT (2006, 2011).

medical devices and instruments, that would not otherwise be addressed by commercial enterprises due to the inherent technological and regulatory risks involved in advancing these products. Two matching-grant initiatives, SBIRI and BIPP, were conceived and created to address the complementary financing needs of private sector firms (SBIRI phase I and BIPP are matching-grant programs, while SBIRI phase II involves soft loans).

A rigorous methodological framework to evaluate the impact of SBIRI and BIPP support programs should ideally begin with a concise description of the logic of the programs, namely how each program is structured to resolve the problems (market failures and/or other objectives) it seeks to address and a clear articulation of what program success would look like, with measurable indicators for each element, going from required inputs and activities to achievement of outputs (whether deliverables were produced as intended) and outcomes (whether planned outcomes were achieved). DBT could be evaluated, for instance, on the cost effectiveness of policies addressing following objectives which stem from its mandate: (i) development of biotechnology capacity; (ii) generation of new (for India) biotechnologies; (iii) application of biotechnologies at commercial scale, and to meet affordability concerns; (iv) intellectual protection of Indian biotechnology; and (v) generation of profitable biotechnology-based enterprises. A full cost-benefit analysis should explore not only whether there are net gains for beneficiary firms (positive benefits net of all costs, relative to not participating in the program and relative to alternative approaches to achieve similar outcomes[11]) but also ensure that there are no concurrent negative displacement effects (on any other market participants that would not be as well off as before, due to the program).

For SBIRI and BIPP programs, the target population includes both the funded enterprises as direct recipients of program support, and also other private and public enterprises as indirect beneficiaries from learning, capacity building and linkage opportunities, and end-use consumers eventually benefiting from more affordable goods and services (to the extent that those benefits are not fully reflected in market prices paid for the goods and services). To be able to assess program results of funded enterprises, it would be desirable to analyze indicators of market-based validation of success, including: number of enterprises that receive a patent and that generate revenues from technology licensing; product sales or acquisition by a larger firm; indicators of whether projects getting soft loans are repaying and whether matching grants and soft loans are crowding-in additional resources, including additional private angel/VC-PE/commercial bank financing; employment generated; and changes over time in these variables, relative to the number of enterprises in trouble or failing – with an appreciation that too high a success rate could imply that not sufficient risky projects are being funded; and complementary measures of social benefits to end-use consumers, with households ideally broken down by income groups to the extent that meeting the needs of the poor is an explicit program objective. It also would be important to analyze indicators of public validation of success, including number of SBIRI projects that

[11] Alternatives should include both an evaluation of the more cost-effective measure of home-prepared water-salt-sugar solution relative to oral rotavirus to prevent diarrhea, and alternative policies such as offering large prize money in conjunction with large Indian corporate relative to matching grants and soft loans. Thanks to Apurva Sanghi for highlighting these types of alternatives for consideration in a full evaluation.

receive phase II funding and BIPP support, and that receive regulatory and clinical/field trial approval. It would then be desirable to link these outcome metrics to other factors (such as firm size and revenue at the time of funding, amount of support received per recipient together with other forms of public and private support, whether the project output was mainly intended for local use or also for export, etc.). More detailed publicly-available data on such program results would be a positive step forward.[12]

While more detailed information on actual program results is an important first step, the crucial issue in assessing program impact is comparing the observed result with the appropriate counterfactual. Program impact should correctly be defined as the difference between the observed outcome with intervention and the counterfactual, namely what would have happened without intervention. Impact evaluation should benchmark the change in the beneficiaries' performance over the program's support period with the evolution of the performance, over the same period, of a proper control group.[13] In the extreme case where a biotechnology entrepreneur would have commercialized a research-based discovery even without program support, there would be only direct program costs and no direct benefit. So it is important, in order to make an accurate case for existing program impact, to be able to quantify to what extent the observed outcomes exceed what would have happened absent SBIRI and BIPP.

In any such impact evaluation, it is also important to appropriately account for the positive externalities including learning effects and other spillovers from the bundle of support activities across the six-element support framework, including public investments in translational research centers, in facilitating global consortia, and in strengthening diversified skills development. It would be helpful to know which of these six elements worked better than others, and their prioritization for the allocation of scarce public resources. It also would be important to take into account positive spillovers from other public support programs that recipient firms may be benefiting from, including support for biotechnology research by India's CSIR (Council of Scientific and Industrial Research) and ICAR (Indian Council of Agricultural Research).

In addition to this traditional methodological framework to assess whether specific public programs to support innovation are impactful, three institutional design attributes for effective implementation that any such policy intervention should possess provide a complementary three-point test of good policy design: (i) *embededness*, whether mechanisms of strategic collaboration and coordination exist between government and the private sector to facilitate learning about where the most important market failures such as the largest knowledge spillovers lie; (ii) *carrot-and-stick incentives*, whether strong safeguards against bureaucratic capture exist that combine incentives to encourage investments in non-

[12] Scarcity of publicly-available data on program results is not limited to India. Twenty-five years after the onset of the US SBIR, the National Academies' recommendations still identified pressing needs for better data collection and analysis, emphasizing that SBIR program managers should give greater attention and resources to the systematic evaluation of the program supported by reliable data. See NRC (2008).

[13] See Cadot et al. (2011), Banerjee and Duflo (2011), and Lopez Acevedo and Tan (2011) for recent expositions of the desirability of rigorous impact evaluation to justify policy interventions and to improve their design.

traditional areas (carrots) with sufficient mechanisms to recognize failures and quickly phase-out support (sticks); and (iii) *accountability*, whether the intended beneficiary of innovation policy, society at large, has the information and ability to monitor the policymakers and bureaucrats to ensure that policy is responsive to its needs.[14]

III.2 Description of SBIRI and BIPP output achievements

This subsection describes what we were able to find out about SBIRI and BIPP. The analysis is largely descriptive, given that available DBT data coupled with interviews with DBT staff, DBT partners and beneficiaries were not sufficient to allow an assessment of the benefit-cost of resources spent.

(1) SBIRI: Early-stage funding of SMEs

The first PPP initiative created by DBT for domestic early-stage technology development and commercialization, launched in 2005, was the Small Business Innovation Research Initiative. It was modeled on the US SBIR (Small Business Innovation Research) program. A stated objective was to attract a greater number of SMEs to accelerate innovation by engaging in peer-reviewed quality research. Box 3 describes eligibility criteria for public support.

Box 3: Funding structure of SBIRI

SBIRI is open to SME Indian registered and majority-owned enterprises (start-ups and existing firms) that have an in-house DSIR (Department of Scientific and Industrial Research)-certified R&D unit, groups of such firms, and collaborations of such firm(s) with public R&D institutions. The enterprise must not have more than 500 employees engaged in R&D.[15] SBIRI operates in 2 phases, focusing on early-stage, pre-proof of concept funding:

Phase	Description and funding
I	For establishment of pre-proof of concept of innovation • 80% grant for project costs up to Rs 2.5 million (about $50,000) • 50% grant up to a maximum of Rs 5 mn for larger projects, with interest free loans up to 50% of remainder amount for total project costs exceeding Rs 10 mn
II	For product and process development • Soft loan with 1% simple interest rate for project cost up to Rs 10 mn • Soft loan with 2% simple interest rate for project cost up to Rs 100 mn (about $2 million) • Full grant to cover R&D costs of public R&D institutions.

SBIRI established a transparent, structured and time-bound evaluation process for the review of grant and loan applications. SBIRI widely advertised the 15 completed funding announcements to mid-2011, typically open for two months. The first call for proposals closed at end-October 2005, there were two in 2006, and subsequently three announcements

[14] See Rodrik (2007). The authors are grateful to John Speakman for highlighting the relevance of this three-point test for good policy design for evaluating these programs.

[15] Since the size limit of 500 employees applies only to the enterprise's DSIR-certified R&D unit, the overall size of supported enterprises can in principle be very large, significantly larger than any definition of SMEs.

per year (though only two in 2010, and one in 2011, with the 16th call responses to be taken up in October 2011 for review).

Building on the milestones that life-science firms typically set themselves, and the regimes they build for exchanging information with each other, the selection and monitoring processes are more probing and informative than is usual in private-sector applications for public support. There is a well-structured on-line application system. The proposals received are subjected to a three-step review process: (1) a primary review of the applications; (2) a presentation by the shortlisted applicants to a review committee; and (3) a visit to the site by an expert team. About half of the proposals are eliminated at the first step primary review. The remaining applicants are selected for presentation to a review committee evaluating the merits of the projects based on innovativeness and socio-economic relevance. Roughly half of the proposals that have been reviewed are chosen for the committee members to carry out a visit to the applicant's research site and interact with the project sponsor and the team. The review committee members allocate points for the anticipated ability of the enterprise to carry out the research, team competency, verification of linkages proposed, and the enterprise level managerial competency and commitment. However, evaluation does not put any weight on the past financial performance of the enterprise: enterprises that have negative net worth (erosion of their capital base) due to past losses are not penalized in securing the funding, as financial weakness is attributed to the early stage of technology advancement when expected revenues are not yet forthcoming. Each supported project is then monitored by a separate Internal Monitoring Committee, with half-yearly progress reports based on project visits by project investigators, typically including 1-2 external experts depending on the requirement.

Companies that have secured phase II funds have applied for them based on assurance of research results of phase I. Phase I recipients are required to clarify the level of investment needed for phase II and the research pathway for translational validation as part of their application for phase II funding. The overall span of repayment of the loan component to DBT is 10.5 years after the completion of the project, in ten equal annual installments with a moratorium of six months after conclusion of project execution. The beneficiary ventures have no moratorium on the accumulation of interest, with the interest liability accruing soon after the disbursal of funds.

Table 1 presents the total proposals received and approvals granted for each call for SBIRI proposals, across biotechnology application areas. In the six years since SBIRI's inception in mid-2005 to mid-2011, 15 batches of applications have been processed, 791 project proposals have been evaluated, and 86 proposals have been funded.[16] Over the first 10 batches (where there are no longer any outstanding applicants in waiting for final approval), an average of 15% of applicants have secured funding (84 out of 547 applicants). The success ratio has varied between a low of 11% (8 out of 71 applicants in the first October 2005 batch, no doubt

[16] To put these 791 proposals into perspective (the maximum number of submissions by the same firm has been three), India's pharmaceutical industry (a subset of all biotech industries) comprises some 250 established firms that account for approximately 70% of the products in the market, located on top of a fragmented based of an estimated 10,000-15,000 smaller producers; see Bruche (2012).

due to initial low quality in part driven by inexperience in grant proposal writing) and a high of 26% (10 of 39 applicants in the November 2006 batch).

To mid-2011, SBIRI has deployed $36 million, of which $5 million in grants and $31 million in soft loans, with a debt-to-grant ratio of roughly 6 to 1. Public SBIRI funding has leveraged an additional $33 million in private investment by recipient enterprises as their core contribution, for a total investment of $69 million across approved projects. The average public investment of about $420,000 per venture is roughly equivalent to the average of the US SBIR program.[17] This is due to the nature of projects supported by SBIRI not being restricted to pre-seed stage funding but also helping support follow-on project development seed funding requirements.

Table 1: SBIRI applications and approvals (as of June 30, 2011)

CALLS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Total
Closing date	Oct05	June06	Nov06	Mar07	July07	Nov07	Feb08	June08	Oct08	Mar09	June09	Dec09	May10	Oct10	Feb11	
Healthcare	38	49	17	25	22	22	21	29	13	35	26	24	16	26	23	386
Agriculture	15	19	4	12	9	15	8	12	4	10	9	18	11	10	8	164
Industrial Processes	5	19	12	6	6	8	3	6	12	11	9	7	7	3	7	121
Instrumen. & Devices	6	9	5	4	1	7	1	0	0	2	1	3	0	4	3	46
Environm.	1	1	1	2	2	5	2	4	1	1	1	0	1	4	2	28
Bioinfor-matics +								1	0	4	5	3	0	2	2	17
Food Bio-techn.+								2	1	0	3	2	0	2	1	11
Others	6	1	0	4	0	3	2	2								18
Total	71	98	39	53	39	60	37	56	31	63	54	57	35	51	47	791
Approved projects	8	18	10	7	6	7	7	7	4	10	2	0	0	0	0	86
RATIO	11.3%	18.4%	25.6%	13.2%	15.4%	11.7%	18.9%	12.5%	12.9%	15.9%	3.7%	0%	0%	0%	0%	10.9%

Source: DBT SBIRI database.

Note: Bioinformatics and Food biotechnology areas are tracked separately from the 8th batch onwards (prior to that, they were combined under 'Others'). Proposals received under batches 11 onwards are still under consideration, with 2 additional proposals under batch 11 and 4 proposals under batch 12 going through the final process of approvals, bringing the approved total to 92 as of September 30, 2011.

There has been an increase in the number of applications in the areas of bio-informatics and food biotechnology over time, leading to these areas being separately monitored as of June 2008. There is typically a time lag in granting final approval for some of the proposals due to the applicants not possessing recognition by the Department of Scientific and Industrial Research (DSIR) for their research facility, which is a mandatory requirement for SBIRI

[17] Since 1992, funding under the US SBIR phase I has typically been up to $100,000 while phase II awards have ranged up to $750,000, though it is not uncommon for awards to exceed these thresholds. US SBIR awards in fiscal year 2005 totaled $1.85 billion, with almost $1 billion being awarded by the Department of Defense. The average award size was roughly $315,000, with phase I awards averaging $110,000 and phase II awards averaging $760,000; see Table 1 in Link and Scott (2010).

funding to be secured. SBIRI allows companies that do not have DSIR recognition to apply, as long as they pursue such recognition while the application is being reviewed. Delays in securing such recognition have created a time lag in securing final approval. There are also other factors for time lags due to some of the conditions stipulated by SBIRI as a result of the review process not being fulfilled by the applicant before the announcement of the next call. Though SBIRI processes each of the calls and concludes the review process prior to the next call, there is some carryover of proposals that remain in the pipeline for approval for up to 2 years or more due to compliances being pursued by the applicants.

SBIRI has funded a heterogeneous mixed of ventures from very early-stage to well established companies. Of the 86 SBIRI-funded projects, 13 enterprises had annual revenues of US$ 25 million and above either on their own or combined with their group companies in 2010. Only 5 companies had annual group turnover of over $100 million.[18] The rest of recipients are smaller ventures, though all recipients have been in existence for three years or more prior to receiving approval. One of the reasons for SBIRI not to fund de novo start-up ventures is the need to secure DSIR recognition. Since DSIR does not grant this recognition to start-ups, the new ventures must take some time until their research facility is inspected and granted recognition by DSIR.

Table 2: SBIRI approvals relative to applications by area

Category	% of applications received to total applications	% of approvals secured to total approvals
Healthcare	49	51
Agriculture	21	25
Industrial Processes	15	15
Instrumentation and Devices	6	6
Environment	4	1
Bioinformatics, food biotechnology and others	5	2
Total	100	100

Source: DBT SBIRI database.

The composition of approved relative to proposed SBIRI projects across biotechnology application areas is provided in Table 2. Of the approved 86 projects, 51% have been in healthcare. Agriculture projects are second, with 25% of approved projects. Applications of biotechnology to instrumentation and devices cut across traditional disciplines, so they have

[18] To put these sales figures into perspective, again based on the pharma subset of all biotech industries, the top 10 Indian pharmaceutical companies by world-wide sales in 2009 ranged from $1.52 billion (Dr. Reddy's) to $498 million (Glenmark Pharma). See Bruche (2012), Table 1. According to the 2011 BioSpectrum–ABLE biotech industry survey, the size of the Indian biotech industry by revenues stood at roughly $3.5 billion (with bio-pharma accounting including diagnostics and devices accounting for 62%, bio-agriculture 14%, bio-industry 3.6%, bio-informatics 1.4%, and bio-services 19%). See http://biotechnews.co.in/April2011/toTheReaders.pdf.

been reflected as a separate category. Emerging segments such as bioinformatics solutions, food biotechnology and nanotechnology represent only 2% of approved projects to mid-2011.

In terms of type of innovation, about a third of funded ventures (27 of 86) are attempting new product development as their core stated objective, typically for a preventive or therapeutic solution in health care or a new transgenic crop in agriculture. The other funded ventures are seeking to develop new process approaches, devices or validation systems that can accelerate biotechnology development pathways.[19]

Table 3: Main source of technology for approved SBIRI projects

Area	Total projects supported	In-house technology source	Technology from domestic public research entities	Technology from foreign public research entities	Developed thru private-private collaborations
Health care	44	36	5	2	1
Agriculture and allied areas	21	12	4	1	4
Industrial process	13	11	2	-	-
Instrumentation & devices	5	5	-	-	-
Environment	1	1	-	-	-
Bio informatics and others	2	2			
Total	**86**	**67**	**11**	**3**	**5**

Source: DBT SBIRI database.

Table 3 describes the main source of technology for SBIRI funding recipients. Overall 78% of the funded projects relied on their own technologies for further advancement, validation and commercialization. Although in-house technology is by far the largest source of technology supported by SBIR to-date, this figure appears to be an overstatement, as evidenced by one of our detailed case studies (see Box 4), where the recipient company, SPAN Diagnostics, acquired and leveraged foreign intellectual assets through its prior purchase of a French company. Other companies may well have reported in-house technologies as the main source based on prior further development of existing technologies acquired from outside the firm, as well as access to technologies and research tools that are no longer protected due to expiration of the underlying patents. Of the 22% of projects reporting absorption of external technologies, the area of agriculture has experienced a far greater transfer of technology for further advancement (12 or 43% of agriculture projects) than in healthcare (18%) or industrial processes (15%). This could have been due to a relatively lesser engagement in translational research and technology transfer of the public research bodies in the area of bio-medical sciences. The agriculture universities and international agriculture research institutions as well as private collaborations appear to have supported technology transfer to private enterprises relatively more, by way of transfer of

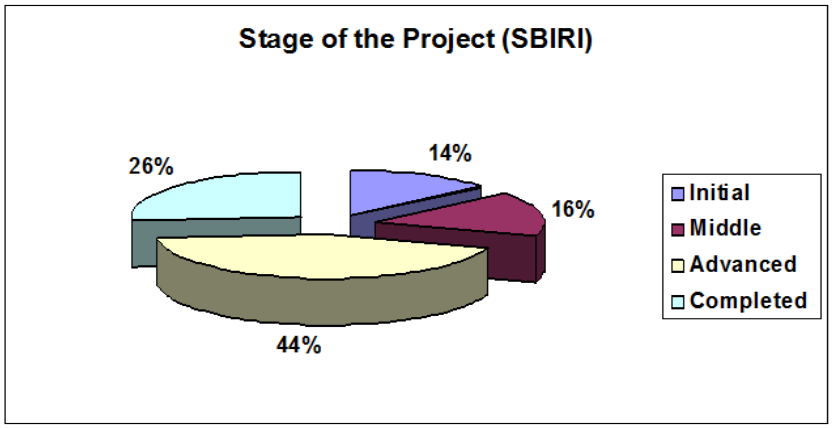
[19] A classification of all approved projects as either product development-oriented (D) or process-oriented (P) based on the hypotheses stated in the project titles is available from the authors upon request.

biological materials for further advancement, and validation for safety and commercialization. The low overall level of technology transfer from foreign research entities may be largely due to SBIRI currently not funding technology acquisition costs when the technologies are acquired from international sources.

Our direct contacts with a representative sample of 41 of the successful SBIRI applicants indicate that 14 of them have additionally had some form of academic collaboration to meet incidental technology-related needs, though not in the form of technology in-licensing.[20] Generally such collaboration related to product validation, use of advanced research infrastructure available with the academic partners, or process refinement support and scientific mentoring. This is a significant development as SMEs can derive considerable support in such partnering efforts with public research institutions and universities, accessing multi-disciplinary talent available within the public research system during their early stage of enterprise building. Access to quality research infrastructure is also a major gain for SMEs that do not have such facilities in-house.

In accordance with SBIRI policy, the IP generated from SBIRI funding is co-owned by DBT and the enterprise. The 41 beneficiaries did not indicate any disadvantage on account of this stipulation as the core element of funding is for commercialization. SBIRI likely retained this clause to ensure that if the IP created is not commercialized by the beneficiary ventures, SBIRI would have the right to take the technologies to market through alternate options.

Figure 2: Stage of advancement of a sample of approved SBIRI projects



Source: Authors' SBIRI sample database.

Figure 2 reports the degree of technology advancement of the sampled ventures. It is to be expected that over the 5 years of the program's life, a number of projects have been completed – and out of the 41 sampled projects, 10 are completed, namely have achieved

[20] To deepen the analysis of SBIRI, we selected and directly contacted 49 approved projects that were broadly representative of the various categories of funded projects, of which 41 provided additional qualitative responses on the nature of collaboration and on the stage of advancement of project, by telephone or in-person conversations with the CEO or head of research.

their objective and either already have products introduced in the market, are exploring marketing and scale-up options, or have completed clinical trials. Three of these ventures have generated new intellectual assets and have indicated their readiness to file patents. Among the 18 advanced-stage projects, there are reports of prototype testing, of animal experimentation completed and human trials beginning, and technologies in demonstration along with field evaluation and bio-safety studies. Projects at the initial and middle-stage include some with low or no revenue streams, not commensurate with the level of risk undertaken in the SBIRI-supported effort.

Over the next two to three years, it appears that SBIRI may be vested with projects that would either need to exit or may go "sideways" (barely managing to exist with low revenues), not realizing the objectives for which they were funded. It is natural for a number of such projects not to succeed. Indeed, the program would not be achieving its objective of support to higher-risk underfunded ventures if all funded projects were successful. Not all SMEs with high invention capacity will succeed on the technology side, and of those successful at research a number may not also possess the ability to reach markets on their own. Based on the sample interviews, we presume that the current more scientifically-oriented bi-annual review process may not help address these dynamic threats that enterprises face in introducing novel technologies to markets. There appears to be a missing mentoring and support mechanism to assist enterprises to modify the strategic elements of IP management (whether to in-license existing complementary technologies or seek to develop them in-house, whether to patent a new discovery or keep it as a trade secret, whether to out-license the IP to a larger domestic or international company or seek to bring it to market alone or through a consortium, how to actively protect own IP and minimize risk of patent infringement litigation), product development, regulatory validation, and product positioning in response to progress in research and evolving market needs. The SBIRI program could likely benefit by engaging in enhanced oversight and support in these critical complementary entrepreneurship-related areas.

Box 4: SBIRI case studies

1. SPAN Diagnostics: towards delivery of affordable disease diagnostics. Ahmedabad-based SPAN Diagnostics, an SME existing for over three decades, has sought to position itself as a manufacturer of affordable instruments for Indian and other emerging markets. SPAN acquired a French company that had intellectual assets in diagnostic applications. It then approached SBIRI to secure $450,000 to apply its design technologies to manufacture new generation chemistry analyzers.

Gaining confidence with this effort, SPAN also applied for a soft loan under the BIPP scheme for producing monoclonal antibodies and microbial antigens, based both on its own technology and some of the clones acquired from public partners from USA and Europe. BIPP provided about $500,000 for SPAN to establish the facility and create its own antibodies for its captive requirements as well as external marketing. Based on this support, SPAN currently has the whole range of technologies and the cGMP-compliant ('current Good Manufacturing Practices') facility to provide affordable solutions in disease diagnostics for a wide range of disease segments.

2. NavyaBiologicals: woman entrepreneur secures two patents towards commercialization. Bangalore-based NavyaBiologicals, an SME launched in 2006, developed technologies for a novel yeast expression platform for production of complex proteins. Dr. Rajyashri, a woman entrepreneur leading the company, wanted to test the proof of concept. SBIRI provided $100,000 to validate the platform. Rajyashri perceives this grant to have been the game-changer for her enterprise, helping in

'de-risking' the proof of concept stage. SBIRI then provided an additional $450,000 under Phase II funding to scale up the process of production of the proteins. The two patents secured by the company will help in commercialization. Navya is already a revenue-positive venture. Navya now has to go through the challenge of clinical validation of its products.

3. Shriram Bioseeds: advancing crop biotech innovation through a PPP. About 8.6 million hectares of India's land is afflicted with the twin problems of alkalinity and salinity, caused by extensive water logging, indiscriminate use of chemical fertilizers, and inadequate drainage – and aggravated by climate change. Genetically modified rice hybrids tolerant to both drought and salinity are, therefore, expected to not only increase food production in India but also improve income and prosperity of millions of small and marginal farmers. Drought tolerance technologies generally carry higher risk due to their inherent uncertain responses when exposed to environmental conditions.

Shriram Bioseeds, an India-based seed company, has built its research capacity to engage in exploration of novel genes for integration in crops that can improve crop trait properties. Bioseeds joined with ICGEB (International Center for Genetic Engineering and Biotechnology), an international UN-linked research organization with labs in New Delhi, to source genes and engage in collaborative research to generate hybrids with the needed tolerance to drought and salinity. SBIRI provided initial funding of $150,000, followed by a subsequent $300,000 to help the consortium members to advance the transgenic lines for translational validation for their efficacy. The partnership will move the technology forward if the field evaluation of the transgenic lines is successful in their trait evaluation.

(2) BIPP: Viability gap funding for larger, higher-risk projects

The Biotechnology Industry Partnership Program (BIPP) was conceived and put in place by DBT in 2008, as a complementary program to SBIRI to address national priority needs in the novel application of biotechnology to affordable solutions in healthcare, agriculture and the environment (green manufacturing and bio-energy). BIPP is intended to assist more established enterprises to address higher-risk discovery-led translational research for application-driven solutions. In these larger funding proposals with a conceivable span of 6 to 8 years from discovery to the market entry stage, the careful structuring of effective partnerships, mentoring support to industry partners, and the active engagement of public research partners to bring wider disciplines of research skills are all intended to help mitigate the higher risks. Best practices in research and milestone-based monitoring are essential elements required in all proposals. Box 5 describes eligible funding.

Box 5: Funding structure of BIPP

BIPP is open to Indian registered and majority-owned small, medium or large for-profit companies with a DSIR-certified R&D unit, groups of such firms, and collaborations of such firm(s) with public R&D institutions. Support is provided only for discrete novel applications to futuristic high-risk areas ('break-through research'), transformational technology and product development for the public good; no incremental development is supported. BIPP provides funds for four broad categories:

Category	Description
I	Areas with major social relevance but uncertain market-driven demand
II	High risk, discovery innovation research with relevance for making Indian firms globally competitive

III A	Evaluation and validation of already-existing products of high national importance promoting local innovation (clinical trials)
III B	Evaluation and validation of already-existing products of high national importance promoting local innovation (agriculture field trials)
IV	Shared cost major facilities, critical for enabling innovation

The scheme provides grants to biotech enterprises ranging from 30-50 percent of the R&D component as viability gap funding. Technology transfer, commercialization and licensing arrangements vary with the model of partnership and cost sharing. The contribution from the government and percentage of royalty is decided as per the Apex Committee recommendations based on the Technical Committee's evaluation, according to the following three models:

Models of operation	Investment, cost sharing and sharing of benefits
Government-supported privately-managed facility, with no conflict of interest.	• 100 % grant • User charge basis • Ownership with Government • Differential fee for public and private user
Public-supported in a public institution in partnership with a private investor who has no conflict of interest.	• Cost sharing with the firm • Up to 50 % grant • Shared profits • Ownership depending on contribution • Differential fee for public and private user
Specialized facility for discovery and innovation to be established, operated and managed by a single private enterprise.	• Soft loan as per SBIRI norms • User charge basis • Differential fee for public and private user • Should devote time for education and training of DBT-identified trainees for capacity building.

Building on the institutional learning from SBIRI, DBT formed an umbrella SPV called Biotechnology Industry Partnership Program (BIRAP) in September 2008, in partnership with the Association of Biotechnology Led Industries (ABLE)[21] and Biotech Consortium India Limited (BCIL).[22] The objective of BIRAP is to assist emerging biotech entrepreneurs and facilitate innovative R&D in existing SMEs and larger firms. BIRAP is the conduit for funding flows and management support for DBT's PPP schemes including BIPP. BIRAP also provides support to technology development programs such as the Stanford-India Biodesign

[21] ABLE is a non-profit industry association established in April 2003 representing biotech firms, investment banks, VC firms, leading research and academic institutes, law firms and equipment suppliers.

[22] BCIL is a public company established in 1990 by DBT and financed by the All India Financial Institutions (IDBI, ICICI, IFCI, UTI and selected corporate to facilitate commercialization of biotechnology by providing technology transfer, project consultancy, certification, information, bio-safety, training and project management services.

(SIB) fellowship program, and to other facilitation services such as biotech parks, incubators and IP management services.[23]

BIPP makes either general or special calls in areas of deemed major national relevance roughly every three months. The BIRAP Advisory Board is structured with experts brought from several disciplines and is a source of guidance in structuring the funding programs. The BIPP team carries out wide consultations with technical experts, academia and industry, and periodic studies by external experts to identify new areas for support under the special calls. The recent study of the Planning Commission of value enhancement opportunities for horticulture and grain crops, for instance, led to the announcement of a special call for funding such projects. The industry partnership platform established by DBT in partnership with FICCI (Federation of Indian Chambers of commerce and Industry) is another of the knowledge circles for idea generation.

All of the BIPP calls have been widely advertised. BIPP has adopted a three-stage application review mechanism and follow-on monitoring similar to SBIRI. Initial screening helps to weed out roughly 50% of the responses. Those shortlisted make a presentation to the committee of reviewers. A site visit follows for the expert teams to physically interact with the enterprise and to help improve the proposal. Attention is paid in the grant management process to proper documentation, scoring pattern, avoidance of conflict of interest, and timely decision-making. Supported projects are monitored by a separate Expert Monitoring Committee for each project comprising 2-3 technical experts, one financial expert, and one DBT officer, with periodic mandatory site visits.

BIPP has two types of benefit sharing when the ventures successfully commercialize technologies. The first relates to a grant with a stipulation of payment of 5% royalty on sales with a cap of twice the original quantum of funding by BIPP. The second is a fixed interest loan at 2% with a specified tenor for repayment of the debt on successful commercialization. The fact that 95% of the applicants have preferred the 2% interest-bearing loan to paying 5% royalty on grants suggests that financing terms may need re-calibration. It may be partly due to most of the BIPP grantees being existing revenue-earning entities with revenue streams emanating from their existing products, and may reflect industry confidence in bringing out the products into the market. BIPP confers the IP rights to the industry partners. For projects that are jointly developed by public and private partners, the benefit sharing arrangements for IP exploitation are structured in advance. BIPP reviews the "freedom to operate" rights of the developers prior to the award so that there are no major hurdles in background IP exploitation.

BIPP has carried out a periodic awareness raising efforts to enhance the level of response from the private sector and their public partners. A series of grant writing awareness seminars

[23] BIRAP is the first phase of a larger initiative called BIRAC (Biotechnology Industry Research Assistance Council), a new organization first envisaged by the government in 2007 while announcing its National Biotechnology Development Strategy. An in-principle approval for the setting-up of BIRAC was given by the Committee of Secretaries while approving the strategy in November 2007. In September 2011, the Prime Minister's Office asked for expediting the setting-up of BIRAC – to improve coordination between academia and private industry, and to be responsible for innovation management, operating all industry R&D schemes.

were conducted with active participation of industry and public researchers in major cities. Interactions with industry bodies, the global research community, and national policy planners further enhance the awareness of BIPP.

Table 4 depicts the total proposals received and approvals granted for each call for BIPP proposals, across biotechnology application areas. In the two and a half years since BIPP's inception in December 2008 to end-July 2011, 16 batches of applications have been processed, 474 projects have been evaluated, and 61 proposals have been funded. Of these 16 calls for proposals, 9 have been general calls and 7 have been special calls: H1N1 vaccine development (call number 4), bio-similars (officially-approved subsequent versions of more complex molecular biopharmaceutical products following patent expiry on the original product, call number 8), affordable healthcare products (no.9), anti-virals (no.10), priority agriculture areas (no.11), value addition to agricultural produce for food and non-food applications (no.14), and affordable healthcare technologies (no.16). Over the first 11 batches, an average of 16% of applicants has secured funding (60 out of 368 applicants). The success ratio has varied between a low of 4% (1 out of 26 applicants in the December 1, 2010 special call for affordable healthcare technologies) and a high of 24% (6 out of 25 applicants in the September 2010 special call for bio-similars).

Table 4: BIPP applications and approvals (as of August 1, 2011)

CALLS	1	2	3	4 *	5	6	7	8 *	9 *	10 *	11 *	12	13	14 *	15	16 *	Total
Closing Date	Dec08	June09	Aug09	Aug09	Dec09	Apr10	July10	Sept10	Dec10	Dec10	Dec10	Dec10	Mar11	Mar11	Aug11	Aug11	
Health-care	34	3	22	5	20	9	11	10	6	21	0	8	9	0	4	9	171
Agriculture	6	5	4	0	11	6	6	0	1	0	26	0	11	11	5	0	92
Clinical Trial	13	1	11	1	13	3	3	3	3	2	0	3	4	0	3	2	65
Ind. products & processes	2	1	6	1	7	1	3	8	6	0	0	0	3	7	0	0	45
Bio-medical devices and instruments	2	1	0	0	2	0	2	0	1	7	0	0	2	0	3	16	36
Infrastructure	0	12	7	3	1	0	2	4	3	0	0	0	0	0	2	0	34
Bio-energy	5	1	6	0	1	0	1	0	2	0	0	0	1	0	2	0	19
Field Trial	2	0	1	0	0	2	1	0	0	0	1	0	0	0	0	0	7
Environmental Biotechnology	0	0	0	0	0	0	0	0	4	0	0	0	0	0	1	0	5
Total:	64	24	57	10	55	21	29	25	26	30	27	11	30	18	20	27	474
Supported Projects	10	4	11	2	7	4	6	6	1	5	4	1	0	0	0	0	61
RATIO	15.6%	16.7%	19.3%	20.0%	12.7%	19.0%	20.7%	24.0%	3.8%	16.7%	14.8%	9.1%	0%	0%	0%	0%	12.9%

Source: DBT BIPP database; asterisks denote special calls (see text for details).

To mid-2011, BIPP has deployed $36 million, of which $13 million in grants and $23 million in soft loans, with a debt-to-grant ratio of roughly 2 to 1. Public BIPP funding has leveraged an additional $66 million in private investment by the recipient enterprises in the approved 61 projects as their core contribution, for a total investment of $102 million across approved projects. It is noteworthy that under a shorter span of time (two-and-a-half years versus five-and-a-half years for SBIRI), BIPP has leveraged roughly the same amount of public funding ($36 million) into twice as much additional private sector contributions ($66 million versus $33 million additional private investment under SBIRI).

The size of the funded enterprises is comparatively larger than SBIRI, with almost all recipient companies having sustained revenue streams from other products. Out of the 61 projects funded, 19 companies have current annual revenues of over $100 million (on their own or combined with group companies), 16 between $25 million and $100 million, and the rest of them less than $25 million.[24] The skewed distribution towards larger firms reflects the ability of beneficiaries to undertake larger research challenges leveraging their presence in the market and their ability to enlarge their research effort with support from BIPP. The projects, other than those relating to infrastructure development (2) have a development or validation phase of 3 to 4 years, prior to their readiness to go to the market.

The composition of approved relative to proposed BIPP projects across biotechnology application areas is provided in Table 5. The pattern of applications is relatively similar to SBIRI projects, with healthcare again the most important application area. Most healthcare projects are related to vaccine development for infectious diseases, reflecting India's comparative advantage in providing preventive care solutions for infectious diseases not just for its own population but for other developing regions of the world as well. However, in terms of approved projects, there is a marked skew in favor of clinical and especially field trials, highlighting the program's intent to help bring projects to commercialization. While overall roughly one in eight projects is approved, the approval ratio rises to one in six projects for clinical trials and better than one in two projects for agricultural field trials (where 5 out of 7 received projects were approved).

Table 5: BIPP approvals relative to applications by area

Category	% of applications received to total applications	% of approvals secured to total approvals
Healthcare	36	35
Agriculture	19	18
Clinical trials	14	18
Industrial products & processes	9.5	5
Bio-medical devices & instruments	8	5
Infrastructure	7	3
Bio-energy & environmental biotech	5	8
Field trials	1.5	8
Total	100	100

Source: DBT BIPP database.

[24] The reported figures are based on published figures and information from companies on unpublished revenues. Unpublished figures do not factor group revenues and stand-alone revenues of companies.

Box 6: BIPP case study example

Torrent Pharmaceuticals. This Ahmedabad-based pharmaceutical company discovered a small molecule and wanted to explore its application for diabetic-associated heart disease. The company decided to carry out the Phase II clinical validation with the help of domestic and international consultants. BIPP supported this application with two phases of funding totaling $3.2 million. The company however had to deploy its own resources to complement the BIPP support to carry out the package in domestic as well as international centers, as BIPP is restricted from supporting overseas clinical validation. However, the large support provided by BIPP to Torrent will help the company complete Phase II trials and advance the technology through Phase III validation. The key contributions of BIPP, in the words of Vijay Chauthaiwale, VP, Discovery Research Center, are "access to good quality reviewers, coupled with monitoring and progressive support commensurate with the progress of the project". The efforts of Torrent are representative of the ability of domestic enterprises to undertake international product development and the more comprehensive elements that are required when such efforts turn successfully to Phase III trials.

(3) Assessment of institutional design for effective implementation

The following assessment can be made in applying to the SBIRI and BIPP programs Rodrik's (2007) three-point test for good policy design.

Regarding embededness, namely whether mechanisms of strategic collaboration and coordination exist between the government and the private sector, the six-element support framework, and in particular the initiatives to facilitate technology access through global consortia, have enabled information to flow between the global private sector, the research community and the government. SBIRI and BIPP themselves are structured as contests that allow private sector firms to compete for public resources, which is typically useful for eliciting private-sector needs and priorities. However, there are a number of outstanding questions. In particular, it is not clear to what extent round-tables or advisory councils could be better utilized to elicit private sector needs and priorities for public goods, including the views of new entrants and entrepreneurs that are not part of the traditionally-canvassed constituency groups. More broadly, it would be useful to better understand and disseminate lessons learned regarding the types of public-private collaboration mechanisms that work best and why, so that the most useful experiences could be better documented and replicated to other sectors.

Regarding carrot-and-stick incentives, there does not yet seem to be a rigorous system in place that looks at emerging successes and likely failures, recognizes shortcomings, addresses them, and quickly phases out support to failures. The programs could benefit from more frequent monitoring and periodic evaluation. It could be helpful to be more explicit up-front on the specific criteria by which the programs will be judged a success, which helps ensure that emerging problems are addressed and guards against any subsequent inclination to modify criteria if outcomes and impact are not realized according to initial plans. Exploring ways to bring in additional market discipline as early as possible could also be helpful, including earlier compulsory seeking of additional private sector co-financing as a screen for research and early commercialization efforts being perceived by the market to be going in the right direction.

Finally, regarding accountability, a fundamental under-utilized tool is transparency. DBT should consider strengthening its M&E system and make findings publicly available. In particular, it would be helpful to have the logic of the programs and all indicators publicly available, including clearer statements of how each program is structured to resolve the problem it seeks to address with measurable indicators for each step from required inputs and activities to achievement of outputs and outcomes. Indicators of success should be publicly available, a data collection process should be in place that reflects positive as well as negative experiences (and makes the data available to researchers, so that the programs can benefit from more careful analyses), and evidence should be presented periodically, supported by regular external evaluations, on what has been achieved in terms of DBT's mission and mandate. A complementary governance issue to document, learn from, and share with other sectors, regards the management of various risks, including the risks of corruption and rent-seeking – such as how public and private interference in grant selection and in the structuring of the various approval committees was avoided, and whether more could be done in this regard.

III.3 Strengthening impact evaluation and continuous monitoring

DBT's deployment of resources in support of biotechnology applications appears to have generated significant outputs and outcomes. And there appears to be an opportunity for DBT to deploy additional resources over the coming years to accelerate biotechnology innovation. However, the case for additional resources, and the best allocation of these resources to their most effective use across biotechnology applications and support initiatives, is premised on a good understanding of the overall social impact of resources spent to-date. An important unresolved question is how significant program impact has been to-date from a social cost-benefit perspective, relative to what would have transpired absent public intervention, and relative to the opportunity cost of foregone benefits from otherwise allocating scarce public resources to alternative uses. As important is how to best structure a forward-looking effort of impact evaluation for continuous improvement of existing initiatives.

(1) Applying more rigorous impact evaluation in program design

One common approach to estimate program impact, referred to as ***quasi-experimental*** evaluation, takes advantage of available historical data on program outcomes. This is appropriate for circumstances where the evaluation was not built into the program design but is done afterwards. Quasi-experimental evaluation relies on appropriate econometric techniques for rigor. The typical empirical strategy of such a 'quasi-experiment' involves comparing the beneficiary or 'treatment' firms with a group of non-treatment or 'control' firms constructed after funding has taken place, with as close as possible relevant characteristics and likelihood for program participation so that the differences in outcomes of beneficiary versus control firms can be attributed to the program with a high degree of confidence. It is desirable to include several times as many additional control firms as treated

firms, to enhance the likelihood of good matches or as closely-comparable firms to the funded firms as possible.

In terms of appropriate firm-level outcome variables for measuring impact, other studies have examined employment growth and sales growth, and changes in productivity or changes in the efficiency with which firms convert inputs into outputs due to the program.[25] There are also other variables that capture intermediate outcomes along the chain of causality from treatment to outcomes that can be explored, such as patents, achieving the stage of clinical or field trials, or other variables that represent an accepted benchmark of intermediate success. Desirable data on firm characteristics at time of public funding and changes over time to control for in the analysis include firm location, age, size (number of workers and revenues), age of the CEO, education and training details (years of education of the owner, manager, and workforce), total sales, exports, sources of finance, linkages with other local firms/public labs/universities/global firms, and whether the firm benefits from other complementary public programs. Finally, to address the question of whether the additional social benefits of the programs are greater than the cost of the support, it would be desirable to complement this assessment with measures of social benefits to end-use consumers, with households ideally broken down by income groups to the extent that meeting the needs of the poor is an explicit program objective.

A second approach to estimate program impact is an ***experimental*** evaluation with random assignment or a randomized control trial (RCT), which is built into the program design before the program (or the next phase of the program) is implemented. Under RCT, firms in the treatment group receive assistance while those in the control group do not, with random assignment helping ensure that the two groups are similar. Such forward-looking program design with randomization provides the strongest foundation for causal inference.

A question could be raised whether RCT is appropriate to assess competitive matching grant funding where the best projects typically get funded, and whether the guiding principle of competition could be detrimentally affected if only one of every two (or two of every three…) equally-good projects are funded. Also, in a competitive grant scheme with random rejection, it could be claimed that there may not be a straightforward way for rejected submissions to challenge the results if it is not clear if the rejection was based on quality or on random selection. The latter concern can be addressed by making public which submissions exceed an announced threshold for quality, address any challenges on quality, and thereafter conduct a random draw among the most promising quality-based submissions. A public drawing can be open, transparent, and alleviate concerns about corruption. More

[25] Lerner (1999) assesses the long-run success of firms participating in the US SBIR program by examining the employment and sales growth of 1,435 enterprises over a 10-year period, with 3/5th of the enterprises chosen to closely resemble the awardees. He finds that SBIR awardees enjoyed substantially greater employment and sales growth than the matched firms, and were more likely to subsequently receive VC financing. However, the superior performance of awardees was confined to firms in regions with substantial VC activity. And the SBIR awardees receiving larger grants did not perform better than those receiving smaller grants, suggesting that awards played an important role in certifying quality but also that distortions of the award process occur. See also Wallsten (2000), Audretsch (2003), Gans and Stern (2003), Link and Ruhm (2009), and Link and Scott (2010).

broadly, it is not clear that governments should support the very best proposals if these enterprises are able to secure alternate market-based funding. From a development perspective, scarce public resources would be better directed towards the proposals where funds have the most impact at the margin – governments should be concerned with marginal rather than absolute returns, and ideally target those enterprises that will only succeed with public support.[26] Finally, and most importantly, it is critical to have credible evidence that scarce public resources are having a strong impact, and randomization is a powerful approach to generate such evidence.[27]

Including randomization across successful applicant SBIRI and/or BIPP firms moving forward would allow a systematic testing of a range of specific programmatic features that could help strengthen both programs, as well as provide a solid empirical foundation for the extent of impact from spending on these programs. Although in programs like SBIRI and BIPP the time to end-result can be relatively long, the focus of some or most of the testing and learning can be on quicker turnaround questions about how to improve project design to make interventions work better, such as testing different ways to improve program take-up, and testing the quality of different forms of technical assistance. To the extent that the sample size is relatively small, it will be important to focus on a few key features of the programs. For measuring relatively noisy outcomes such as research results, initial commercialization attempts and business profits, taking multiple measurements of such outcomes at relatively shorter intervals can, in principle, help to average out noise when estimating treatment effects and improve predictive power for future outcomes – especially in cases where the total cross-sectional treatment size is limited (McKenzie 2012). The following program features are illustrative of the types of areas about which very little regarding effectiveness is currently known, and that could be explored and then either be scaled up or phased out depending on their impact on outcomes:

- Variation in the level of the matching grant
- Variation in the time allowed for repayment of soft loans, including different periods of extension of the moratorium for repayment of debt obligations
- Different additional support mechanisms including: 'ignition' grants for very early-stage ventures who do not yet have research facilities with DSIR recognition and are not yet eligible for SBIRI funding; mentoring support on entrepreneurship development to help in the transition from science-based research to market-driven commercialization;

[26] We are indebted to suggestions by David McKenzie, including the desired focus on marginal rather than absolute returns. See http://blogs.worldbank.org/allaboutfinance/node/702

[27] Rodrik (2008) and Easterly (2011), among others, have emphasized that the utility of RCTs is often restricted by the narrow and limited scope of their application. Although RCTs are strong on internal validity (the quality of causal identification), they produce results that can be contested on external validity grounds (whether the results are generalizable to different settings – for a broader population of firms, a different location, a different industrial sector). This just serves to underscore the appropriate focus of the evaluation challenge, namely what is the best evaluation design that credibly teaches us something about how policy performs in an interesting context (and why a particular intervention works in a cost effective way or not); see http://blogs.worldbank.org/impactevaluations/a-rant-on-the-external-validity-double-double-standard.

financial support for firm-level investment in complementary intangible assets (for IP protection and associated legal support, for market intelligence, for software and databases, and for investment in worker and management skills upgrading), and funding for technology acquisition (for biomaterials, technologies and research tools developed by other local or international firms, or by public institutions, aggregated for sub-licensing)

- Additional mechanisms to achieve greater synergies between SBIRI and BIPP
- Additional mechanisms to allow detection of failure early-on, allowing a variety of strategic options for exit (including methodologies for recognizing failures, for salvage value creation, for the transfer of intellectual assets created for alternate use, and for the timely re-setting of objectives)

While it may be politically difficult for any government entity to propose full randomization in its design of a program moving forward, with the implication that some deserving program recipient firms end up as control firms rather than beneficiary firms, this approach does have the benefit of allowing maximum learning about the impact of program design features so as to help scarce public funding better achieve program objectives. Taking this political constraint into account, a few possibilities to consider include:

- With a larger number of smaller firms applying for the program, there is more potential for having clear selection rules that would allow some politically-acceptable degree of randomization among applicants
- "Encouragement design" techniques allow the benefits from randomization by sending additional information, brochures and other forms of encouragement to a randomly selected sub-set of firms.

(2) Applying 'diagnostic monitoring' principles for continuous improvement

A complementary approach to help improve the quality of public expenditures supporting innovation is inspired by a recent literature on institutional reforms for 'learning by monitoring' or 'diagnostic monitoring' for improved implementation: on how the diagnostic principles of systematic error detection and error correction for continuous improvement, as made famous by Toyota-style production systems, can be applied in different public policy contexts for programmatic improvement.[28]

From this 'diagnostic monitoring' perspective, the existing set of biotechnology support initiatives constitute an especially rich example of evolving programs where learning and improvement occurs through detecting and correcting 'mistakes' or identifying 'areas ripe for improvement'. In particular, the application selection processes of both SBIRI and BIPP programs, including enterprise site visits by expert selection teams, are more probing and informative than is usual in typical public support programs. The follow-on site visits by

[28] See, among others, Sabel (1996, 2005) and Sabel and Zeitlin (2011).

separate expert monitoring teams also are far more probing than customary. But at the next level of monitoring—the review of the procedures for monitoring and evaluating projects—there are difficulties, and hence room for improvement. For example, informal feedback on a confidential basis from a few of the project monitoring teams revealed that while the expert monitors adequately assessed the scientific and research capacities of the firms they were reviewing, they were not able to provide similar feedback on questions relating to the firms' entrepreneurial capacities and business organization. Did, for one example, the inventor know whether it would be better to seek help from a patent expert and try to patent his idea and commercialize it himself? To license out the idea? To seek to be acquired by a larger firm? Or, for another example, did the visited inventor realize that he was better at inventing than managing a business, and that he should find a more business-savvy partner who would be the more appropriate CEO of the incipient company? The monitoring experts responded that such matters were not under their remit, even though they realized that solutions to such questions would help make the programs more successful. More fundamentally, there does not seem to be any institutional routine for re-examining the remit of the monitors (or other key actors), and incorporating what they are learning about limits of the current form of organization into revisions that overcome them and improve performance. In short, it seems that DBT's initiatives are well on the way to becoming Toyota-style learning organizations, but could benefit from more rigorous and thorough-going application of the current organization of the principles they already embrace.

Our recommendation, accordingly, is for DBT to consider applying to its initiatives a more systematic set of the 'diagnostic monitoring' principles of error detection and error correction for continuous improvement -- going from (1) helping program recipients to detect and better address their own deficiencies early on, to (2) helping the programs themselves detect and better address deficiencies in the programs, strengthening the range of support initiatives in response to this continuous learning. For instance, a natural starting point may be to organize a meeting bringing a group of experts who have monitored existing program beneficiaries together, and explore the range of issues that an expanded set of initiatives could better help address. The goal of this meeting could be to assess the guidelines that monitoring experts currently operate under, and re-write the guidelines in light of the learning that emerges from the meeting, including possibly modifying or enlarging the composition of the monitoring teams. It would be useful to devise regular 'error detection and error correction' routines both at the level of the programs' interaction with firms, and at the level of how the programs themselves can be improved.

In terms of the complementary application of randomized experimental evaluation in program design, three separate types of firms could conceivably be compared as the program is expanded: a first set of control firms that do not receive any program benefits, a second group of treatment firms that receive existing SBIRI and BIPP program benefits, and a third group of treatment firms that receive the benefits of the enhanced 'diagnostic monitoring' treatment -- with some randomization of firms, for instance through a lottery selection (which could in principle mean that some selected firms under the programs become control firms

and thereby only benefit from the programs slightly later than others). This type of evaluation could help address the (current or future) expectation by funders of these programs to have a more rigorous basis for evaluating their impact and the direction of their further scaling-up.

IV. CONCLUDING REMARKS

This paper has described and analyzed public policy initiatives in India over the past five years (2006-2011) to foster biotechnology innovation for more inclusive growth. A key policy challenge for biotechnology industries is how countries seeking to grow more rapidly and in a way that is more inclusive can benefit from the existing global pool of technologies when these technologies cannot just be taken off the shelf and deployed but require adaptation and verification to local contexts. To meet this challenge, DBT has been developing a systematic approach to catalyze accelerated biotechnology adaptation centered on six interdependent and complementary implementation elements, namely (1) focusing on translational research, (2) facilitating technology access through global consortia, (3) supporting commercialization through PPPs, (4) strengthening diversified skills development, (5) establishing required regulation, and (6) creating institutional mechanisms for effective governance.

The paper has focused on describing and analyzing matching grant and soft loan funding support to-date under SBIRI and BIPP initiatives, based on available information and additional collected data on a sub-set of funded projects. Although there have already been significant funds disbursed and a few notable outcomes such as the development of an affordable oral rotavirus vaccine that is currently undergoing phase III clinical trials, there does not yet exist an empirical basis on which to assess program impact relative to what would have happened in the absence of SBIRI and BIPP.

The key recommendation of the paper is therefore for such innovation-support programs to adopt more rigorous impact evaluation. This includes making more historical data on program output and outcomes available, ideally in sufficient detail to allow ex-post quasi-experimental evaluations. It also includes considering the incorporation of some elements of randomization in program design. Such forward-looking program design would in principle allow a systematic testing of a range of program features that could help strengthen both SBIRI and BIPP, including variations in the level and repayment timing of matching grants and soft loans, and the desirability of additional support mechanisms such as ignition grants, mentoring support on critical elements of entrepreneurship development, financial support for investment in other complementary intangible assets, explicit funding for technology acquisition, and mechanisms for early-on failure detection and mitigation, including cut-off of funding when prospects for commercialization are deemed too low. Importantly, the paper also recommends applying principles of ‘diagnostic monitoring’ on an ongoing basis to detect and address program deficiencies, and thereby strengthen the range of support initiatives in response to this continuous learning.

It is hoped that this paper helps stimulate additional policy case studies and more rigorous empirical impact evaluation in the area of innovation policy implementation for inclusive growth. Two outstanding questions regarding the accelerated technology adaptation programs described in this paper are: (1) whether there exist alternative more effective approaches to foster rapid technology access, translational validation and commercialization than the six-element framework described here; and (2) how to best adapt and implement these programs, to the extent that they are characterized by positive benefit-cost ratios, to the specific technological capabilities and needs of other sectors in India and other developing countries.

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