COMBINED PROJECT INFORMATION DOCUMENTS / INTEGRATED SAFEGUARDS DATA SHEET (PID/ISDS)
CONCEPT STAGE

Report No.: PIDISDSC19441

Date Prepared/Updated: 29-Jul-2016

I. BASIC INFORMATION

A. Basic Project Data

Country:	India	**Project ID:**	P156241
		Parent Project ID (if any):	
Project Name:	Innovate in India for Inclusiveness (P156241)		
Region:	SOUTH ASIA		
Estimated Appraisal Date:	08-May-2017	**Estimated Board Date:**	21-Jun-2017
Practice Area (Lead):	Trade & Competitiveness	**Lending Instrument:**	Investment Project Financing
Borrower(s):	Republic of India		
Implementing Agency:	Biotechnology Industry Research Assistance Council		

Financing (in USD Million)

Financing Source	Amount
Borrower	125.00
International Bank for Reconstruction and Development	125.00
Financing Gap	0.00
Total Project Cost	250.00

Environmental Category:	B - Partial Assessment
Concept Review Decision:	Track II - The review did authorize the preparation to continue
Is this a Repeater project?	No
Other Decision (as needed):	

B. Introduction and Context

Country Context

1. The Government of India (GOI) has identified the pharmaceuticals and biotechnology sectors as priority sectors under the Make in India initiative. The strategic importance of these sectors is twofold, as captured in GOI►(s Twelfth Five-Year Plan which specifically aims to foster the ►(better use of technology for innovative solutions to the country►(s most daunting development challenges►(, such as ensuring access to good quality healthcare. Accelerating growth in the biopharmaceutical industry would enable GOI►(s vision of faster, sustainable, and more inclusive growth, since health outcomes in India compare poorly with those countries at similar levels of development, and given the high burden from both communicable and non-communicable diseases facing India today. Despite India being a global manufacturing outsourcing hub for pharmaceuticals, especially generics , roughly 640 million Indians do not have access to essential medicines. Out-of-pocket health expenditures in India are among the highest in the world, making low-income households highly vulnerable to health shocks which have major impacts on mortality rates, access to education, and labor productivity.

2. India has the potential to build a knowledge-based bio-economy, at the intersection of economic and social value, by addressing public health priorities through innovation in healthcare biotechnology products. The availability of technical manpower, substantial spending on university level research in basic sciences, a mature generics pharmaceutical industry, and a set of emerging innovation hubs in the field have the potential to catapult India as a research-driven leader in a one of the fastest growing global markets . The global drug Research and Development (R&D) strategy has been changing significantly, and the focus is shifting from small molecules to biologics (seven out of the top ten best-selling drugs globally are biologics), making biopharmaceuticals the new wave of therapeutics. This sector also has a significant potential to sophisticate India►(s export basket through products of higher complexity, an indicator of economic diversification. Countries in Africa also lacking access to essential medicines are a particularly attractive market for exports in this area.

Sectoral and Institutional Context

3. Advancing India►(s healthcare biotechnology sector will require addressing a set of key constraints currently facing this sector. Specifically, the sector has limited funding for catalytic investments, lacks coordination and collaboration among stakeholders, and has some gaps in technology, skills, and regulations.

- Financing: In balancing risk and anticipated returns, healthcare product companies disproportionately allocate their R&D budgets to market segments that tend to be more profitable, giving rise to and perpetuating the so-called 90/10 gap and neglecting diseases predominantly affecting the poor. Adequately designed and executed, catalytic public investments provide a demonstration effect that fosters private sector ►(crowd in►(while equips biotechnology ecosystems with the tools to spur and sustain the innovation process over time. This is particularly important in India where Venture Capital (VC) funding is not available in this sector due to the long-term nature of the return on investment. While public funding is available, it is not sufficient given that the sector needs billions of dollars for product development.

- Coordination failures: currently, the sector lacks adequate coordination among all the actors in the product development ecosystem, which slows down innovation. Manufacturing capabilities currently lie within the larger private sector companies, and discovery/discovery validation capabilities lie within academia and research institutes. In addition, new ideas are being generated by entrepreneurs and startups who do not always have access to existing capabilities.

- Infrastructure: while adequate manufacturing facilities exist among India➢(s private sector players, these are not accessible to entrepreneurs and Micro, Small, and Medium Enterprises (MSMEs). Furthermore, not enough facilities exist to span the entire product development lifecycle in the healthcare biotechnology sector, namely for the discovery and discovery validation phases. Investment is therefore needed in technology, shared research and manufacturing facilities, and incubation space for entrepreneurs.

- Skills: India has many universities and programs that have produced skilled personnel in the biotechnology sector. Moreover, the brain drain suffered in the past has started reserving, whereby some researches trained abroad have started coming back to India thanks to the availability of research facilities and public funding. However, there are still gaps in applied technical and business skills in the critical areas of the product development life cycle and commercialization.

- Technology transfer: while significant research is being undertaken in India➢(s research institutes, the country lacks technology transfer offices (TTOs) that are dedicated to identifying research which has potential commercial interest and strategies for how to exploit it.

- Regulatory framework: while the Drug Controller General of India (DCGI) has put in place a regulatory framework for the development and commercialization of drugs, India➢(s regulatory process tends to be less efficient than global regulatory norms.

4. The combined efforts of the Biotechnology Industry Research Assistance Council (BIRAC) and the multifaceted expertise of the Bank can accelerate the transformation of India➢(s healthcare biotechnology sector. Housed in the Department of Biotechnology (DBT) in the Ministry of Science & Technology, BIRAC➢(s mission is to strengthen and empower emerging biotechnology enterprises by undertaking strategic research and innovation and also promoting nationally relevant product development needs with the purpose of catalyzing innovation-driven biotechnology enterprise and create an ➢(Indian Bio-Economy➢(. Supported by GOI, BIRAC has a successful track record of encouraging collaboration among stakeholders and providing a conducive environment for collaborative Research and Development (R&D), with a particular focus on the healthcare sector. The Bank can leverage its experience in financing and supporting the implementation of innovation, competitiveness, and public health projects as well as its knowledge of Public-Private Partnerships (PPPs) to help GOI unlock India➢(s potential for more innovation in healthcare biotechnology. This can have demonstration effects for future private sector funding in a sector that needs billions of dollars. The Project also has replication potential in other parts of the world (e.g. in Africa where there is also a large demand for affordable medicines).

5. Innovate in India for Inclusiveness therefore addresses the current market failures in the sector in order to increase India➢(s indigenous private sector innovation in healthcare products. BIRAC➢(s mission program aims to achieve the following:

- Promote collaboration through Product Development Partnerships (PDPs) targeting biopharmaceuticals, diagnostics, and devices addressing public health priorities;
- Strengthen infrastructure and technology for shared production and validation facilities;
- Develop skills and strengthen training facilities and tools in key areas;
- Set up Technology Transfer Offices (TTOs) in facilities across the country; and

- Raise awareness within GOI of global regulatory processes in the sector.
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The outcomes of this Project will be sustained beyond the Project►(s lifecycle, given the demonstration effects it will generate within the sector as well as the long-term nature of the innovation capacity building supported by the investment.

Relationship to CAS/CPS/CPF

6. The proposed Project is rooted in the ►(Integration►(and ►(Inclusion►(strategic engagement areas of the World Bank Group►(s Country Partnership Strategy (CPS) 2013-17. In terms of integration, the project will help to build the capacity of an indigenous biotechnology sector through the proposed investments with the potential to transform into a globally competitive sector. Inclusion refers to promoting human development, including health, to generate inclusive growth. It is also in line with India►(s 12th Five-Year Plan (FY2013-17), which calls for ►(faster, sustainable, and more inclusive growth►(focusing on health, poverty reduction, group equality, regional balance, empowerment, environmental management, and employment.

7. The Project also contributes to two CPS outcomes through developing a dynamic and empowered sector which will deliver affordable health care for all. Through strengthening key skills in the sector, the Project contributes to the CPS outcome on ►(improved demand-driven skills for productive employment►(. Through the PDPs, the Project also contributes to the outcome on ►(strengthened public & private health-delivery systems►(.

C. Proposed Development Objective(s)

Proposed Development Objective(s) (From PCN)

8. The proposed project development objective (PDO) is to increase indigenous private sector innovation in quality-assured, low-cost biopharmaceuticals, medical devices, and diagnostics which address public health priorities.

Key Results (From PCN)

9. The PDO level indicators will be the following:

►(¢ Number of products (vaccines, biotherapeutics, devices, and diagnostics) addressing public health priorities brought closer to market (i.e. advanced through the product development lifecycle or licensed for commercialization), of which number benefitting women;
►(¢ Cost reduction in products relative to similar available products (for products that reach commercialization within the project timeframe);
►(¢ Number of new IP registrations or product prototypes;
►(¢ Number of technologies licensed; and
►(¢ Number of active PDPs.

10. Progress will be measured through the following intermediate indicators:

►(¢ Number of beneficiaries (i.e. Indian companies and key actors in the sector);
►(¢ Number of people trained (of which, percentage who are women);
►(¢ Number of training courses/programs developed;
►(¢ Number of TTOs and incubators established;
►(¢ Number of shared facilities strengthened; and
►(¢ Number of internationally certified testing/validation facilities and biotech companies under the Project.

D. Concept Description

12. The Project will help bridge critical funding, skills, and infrastructure gaps and bring together the main players in the ecosystem (government, academia, and the private sector), so that India can introduce a larger number of healthcare solutions into the market more quickly than otherwise would be possible. On the one hand, the Project will promote Indian innovation and competitiveness in developing healthcare products. On the other hand, the Project will also facilitate access to life-saving healthcare products for people in the bottom 40 percent of the income distribution in India and elsewhere, addressing select public health priorities. This will not only build India►(s knowledge economy but also unlock the country►(s human potential for inclusive growth.

13. The proposed Project will finance the following four components:

Component 1 (USD120 million): Foster PDPs for the acceleration of the discovery-to-product commercialization process.
The burden of communicable and non-communicable diseases in India is high. Currently, products addressing these diseases are either not available or too expensive. Fostering and accelerating local product development is thus crucial. The Project will support partnerships facilitated by BIRAC which will bring together academia and the private sector to accelerate the low-cost development of select biopharmaceuticals, diagnostics, and devices which are already at advanced stages of the product development lifecycle.

The managed partnerships will bring together public sector funding with private sector expertise for the development of new technologies targeting local healthcare needs. Such partnerships facilitated by BIRAC as PDPs will focus on both preventive and therapeutic solutions to diseases with public health concerns. They help foster a non-competitive environment that brings together partners who would not otherwise work together, provide demonstration effects to encourage future collaboration, and fill critical funding gaps in the sector. PDPs have a successful track record globally, including in India where, with GOI►(s support, a PDP developed the vaccine for Rotavirus and managed to cut the cost by more than half.

The PDPs will focus on the following critical steps:
►(¢ Product development and scale up;
►(¢ Validation through pilot batches;
►(¢ Testing and clinical validation;
►(¢ Quality assurance and certification; and
►(¢ Product regulatory compliance for manufacturing and marketing.

The selection of products for development and scale up will be through a high-level technical consultation led by BIRAC that takes into account India►(s public health priorities. A detailed landscape analysis has been conducted to understand latest trends on disease incidence and healthcare R&D in India. Partnership focal points will be selected by a technical committee put together by BIRAC based on strength and competency in both research and product development and capacities in infrastructure and human resources. At present, about ten products are targeted for funding under this Project.

Component 2 (USD97 million): Strengthen shared infrastructure facilities for research and

manufacturing.
Currently, the infrastructure needed for discovery and discovery validation is almost exclusively in academia while the infrastructure needed for manufacturing is in the private sector. The project can help strengthen links along the value chain through investing in shared facilities for prototyping and manufacturing. This component will strengthen existing shared infrastructure facilities in India for the development, production, and validation of medical technologies and biotechnology products. This will include physical facility enhancement, mentorship, and technical assistance on international standards and global best practices.

Component 3 (USD15 million): Build and strengthen domain-specific knowledge, skills, and management.
This component will help bridge the skills gap to meet the industry➢(s requirements for trained personnel with applied technical and business skills in the critical areas of the product development life cycle and commercialization. Training will be provided in the following areas:
➢(¢ Analytical assays and bioprocess development skills;
➢(¢ Validation skills for regulatory approval;
➢(¢ Clinical trial study design and execution;
➢(¢ Program management and technical documentation;
➢(¢ Quality control and quality assurance;
➢(¢ Audit skills for regulatory compliance;
➢(¢ Manufacturing operations, maintenance and instrumentation verification skills; and
➢(¢ Business strategy and management capabilities for new ventures.

Component 4 (USD18 million): Provide technical assistance & capacity building for actors in the industry ecosystem and overall program management.
This component will provide technical assistance to BIRAC and other industry actors as needed to build capacity in the following areas, among others:
➢(¢ TTOs. This will include acquiring the institutional knowledge and know-how to birth a few TTOs in India for this sector attached to two or three key R&D hubs. The process will include Indian personnel doing internships in successful TTOs overseas as well as bringing key experts from overseas to embed them in the start-up TTOs in India. Domain expertise in technical, legal (patent writing skills), financial, and commercial aspects will be imparted to a core cadre of Indian professionals who will pioneer this subcomponent.
➢(¢ Regulatory framework. While the National Institute of Biologicals and the Drug Controller General of India provide the necessary certifications and approvals for new products, the regulatory process can be further streamlined. The Project will facilitate a review of these processes to align them with global norms. The Project will also facilitate greater coordination with other relevant Ministries (such as the Ministry of Chemicals and Fertilizers, responsible for pharmaceuticals policy in India, and the Ministry of Health and Family Welfare which is responsible for the safety and efficacy of medicines in India, and is responsible for product licensing, clinical trials, etc.).
➢(¢ Program management. BIRAC is already in the process of forming a dedicated unit of professional resources for this Project. They already have a lot of experience of successfully executing donor-funded projects, although this is the first Bank funded program.

II. SAFEGUARDS

A. Project location and salient physical characteristics relevant to the safeguard

analysis (if known)

B. Borrower's Institutional Capacity for Safeguard Policies

C. Environmental and Social Safeguards Specialists on the Team

Harinath Sesha Appalarajugari (GEN06)

I. U. B. Reddy (GSU06)

Samuel Thangaraj (GTC06)

D. POLICIES THAT MIGHT APPLY

Safeguard Policies	Triggered?	Explanation (Optional)
Environmental Assessment OP/BP 4.01	Yes	The Project components are not likely to involve major civil works/construction activities, but would involve renovation of existing buildings and / or establishing support infrastructure for carrying product development, pilot research and clinical trials. These could however involve generation of solid, liquid and air emissions while performing these activities / research. Appropriate assessments and mitigation measures will hence need to be designed relevant to the project activities. OP 4.01 hence has been triggered and is proposed to be categorized as ►(B►(.
Natural Habitats OP/BP 4.04	No	Based on the current information, the Project activities are not expected to cause impacts on the natural habitats. OP 4.04 is not triggered.
Forests OP/BP 4.36	No	Based on the current information, the Project activities do not involve substantial conversion of forest areas and impacts on the forest resources. OP 4.36, hence has not been triggered.
Pest Management OP 4.09	No	Based on the current information, the Project activities do not involve use of chemical fertilizers and aspects that require triggering OP 4.09.
Physical Cultural Resources OP/BP 4.11	No	Based on the current information, the Project activities do not involve impacts on Physical cultural resources. OP 4.11, hence has not been triggered.
Indigenous Peoples OP/BP 4.10	No	The Project area does not include Development Blocks/forest areas that are covered by The Scheduled Tribes and Other Forest Dwellers (Recognition of Forest Rights) Act 2006 and Panchayats Extension to Scheduled Areas Act, 1999 and where Scheduled Tribes live and where Scheduled Tribes targeted and oriented development

		plans are implemented. Hence OP/BP 4.10 is not triggered.
Involuntary Resettlement OP/ BP 4.12	No	Neither the Project Components nor its sub-components involve civil works/constructions that would require any land under any tenure System including Private and/or Government land. Though the Project may finance renovation and/or repairs to existing structures, it will not finance any civil work requiring any land now or in the future. The existing structures that are likely to be renovated are well protected research complexes and entry to these complexes are strictly restricted and regulated. In view of this, there is no possibility of any encroachments that will need to be cleared from these complexes resulting in loss of livelihood, etc. Hence OP/BP 4.12 is not triggered.
Safety of Dams OP/BP 4.37	No	Based on the current information, the Project activities do not involve construction of large dams and issues related to safety of dams. OP 4.37, hence has not been triggered.
Projects on International Waterways OP/BP 7.50	No	Based on the current information, the Project activities do not involve international waterways. OP 7.50, hence has not been triggered.
Projects in Disputed Areas OP/ BP 7.60	No	Based on the current information, the Project activities are not located in disputed areas. OP 7.60, hence has not been triggered.

E. Safeguard Preparation Plan

1. Tentative target date for preparing the PAD Stage ISDS

2. Time frame for launching and completing the safeguard-related studies that may be needed. The specific studies and their timing should be specified in the PAD-stage ISDS.

III. Contact point

World Bank

Contact: Bharatha Manju S. Haththotuwa
Title: Lead Private Sector Specialist

Borrower/Client/Recipient

Name: Republic of India
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Implementing Agencies

Name: Biotechnology Industry Research Assistance Council
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IV. For more information contact:

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V. Approval

Task Team Leader(s):	Name: Bharatha Manju S. Haththotuwa	
Approved By		
Safeguards Advisor:	Name: Maged Mahmoud Hamed (SA)	Date: 01-Aug-2016
Practice Manager/ Manager:	Name: Esperanza Lasagabaster (PMGR)	Date: 05-Aug-2016
Country Director:	Name: Genevieve Connors (CD)	Date: 09-Aug-2016

1 Reminder: The Bank's Disclosure Policy requires that safeguard-related documents be disclosed before appraisal (i) at the InfoShop and (ii) in country, at publicly accessible locations and in a form and language that are accessible to potentially affected persons.

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