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

Appraisal Stage

Report No.: PIDISDSA20992

Date Prepared/Updated: 09-Mar-2017

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:	14-Mar-2017	**Estimated Board Date:**	30-May-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
Appraisal Review Decision (from Decision Note):	
Other Decision:	
Is this a Repeater project?	No

B. Introduction and Context

Country Context

n/a

Sectoral and Institutional Context

While India is recognized as a leading global manufacturer of high-quality generic drugs, industry gaps and market failures constrain its innovation capabilities, limiting its competitiveness and ability to address its disease burden. The Indian pharmaceutical sector accounts for about 2.4 percent of the global pharmaceutical industry in value terms and 10 percent in volume terms. India also accounts for 20 percent of global exports in generics, making it the largest provider of generic medicines globally. In 2014 Indian manufacturers provided nearly 60 percent of vaccine volume, representing just over 30 percent of the total value of procurement by the Global Alliance for Vaccines and Immunization (GAVI). However, the strategic focus of the global pharmaceutical and medical device industries has gradually shifted from reverse-engineering manufacturing towards product innovation, primarily thanks to breakthroughs in translational research, bio-manufacturing, and medical technology. With this shift, however, diseases that disproportionately affect low- and middle-income countries (LMICs) and the poor, many of which are public health priorities in India, are largely ignored as companies tend to allocate research and development (R&D) funding to high-profit markets.

Under this new paradigm, innovation capabilities, quality of research, and transparency in the regulatory validation of product efficacy become increasingly relevant for the long-term competitiveness of the industry. While India is a leader in innovation in South Asia, innovation in India is mostly incremental or imitative, as illustrated by the strong generics industry. India's output of patents and trademarks is small, business expenditure on R&D is low, and there is a limited skills base for innovation . With the exception of world-class players in a few sectors and localized centers of excellence, there is a low degree of novelty innovations in India, and the economy underperforms relative to other middle-income peers on several related indicators.

While India has strong capabilities and resources in basic research and manufacturing (figure 1), market failures limit its capabilities in pilot to market-stages of product development. To successfully transition towards world-class innovation in biopharmaceuticals and medical devices, India needs to overcome these market failures that currently undermine private incentives to invest in R&D and negatively affect the performance of innovative entrepreneurs. These are:

a. Investment in pilot-to-market stages of product development is perceived as too risky for private investors: lack of investment in product-oriented discovery and translational research limits innovation capacity (see Figure 1) and impedes the industry's ability to provide affordable solutions to neglected diseases that constitute public health priorities. Access to private capital (venture capital, private equity, etc.) is extremely limited at this stage due to the perception of high risk. While a few large companies have the means to fund product development and scale up, these investments can be prohibitively costly for smaller firms, and network and market financing failures can prevent their acquisition. Globally, substantial government grants are available for scale-up funding, especially in the European Union, the United States as well as Asian countries such as Korea, but the dearth of such options in India impacts the competitiveness of the industry and the ability for critical products to reach the market in a reasonable timeframe and at an affordable price.

b. Sub-optimal investment in public goods critical to translational research: India has strong and well-developed capabilities in the pre-validation and large-scale manufacturing stages where the industry's research and the bulk of private investment have focused; however critical technology and knowledge gaps exist in pilot-to-market stages of the product development lifecycle. India lacks the hard and soft infrastructure to support these stages of the value chain. First, firms and in particular Micro, Small & Medium Enterprise (MSMEs) lack access to technology and equipment tailored to specific needs across poorly developed stages of drug development, such as basic and applied research, clinical trials, and validation. Second, despite strides in developing strong capabilities in basic research, bio-manufacturing and medical services, India lacks a workforce – including scientists, researchers, staff

trained in a broad set of skills across the different stages of product development – equipped to provide the skills-base for a well-functioning innovation ecosystem. While infrastructure, technology, and human capital are critical to successful innovation and deliver substantial economic benefits, the levels of investment required and appropriability problems make it prohibitive for individual firms to pursue these investments. In countries that have been successful in building effective innovation ecosystems, partnerships among government, the private sector, and academia have eased access to these shared facilities and public goods.

c. There is a gap between private and social returns to collaboration: research shows that relative to other regions, a much larger share of innovation in South Asia (including in India) takes place in-house, limiting productive collaboration across firms and possibly explaining high rates of imitation instead of radical innovation. Cooperation to strengthen interactions and linkages across the various stakeholders in innovation processes is an essential pillar in the innovation ecosystem. Government organizations are ideally placed to build non-competitive collaborations towards accelerated and cost-effective product development, in which the division of risk-taking aligns with the social and private returns of participating actors. These include filling in process gaps between large companies with manufacturing expertise and the discovery and validation capabilities which currently lie within academia and research institutes.

d. Institutional failures in management of innovation systems: globally, successful experiences highlight the importance of strong and efficient institutional arrangements for knowledge creation and diffusion. In countries with well-functioning innovation systems, technology transfer offices (TTOs) assist stakeholders in the facilitation and adoption of new global innovations, technologies, and licensing models, manage intellectual assets, and provide relevant legal monitoring and support. Yet, India lacks TTOs that can identify research which has potential commercial interest and develop strategies to exploit it.

e. Private returns do not provide sufficient incentives for R&D in diseases of the poor: In the current market-driven R&D system, a high number of medicines for diseases that disproportionately affect populations in LMICs are not available or not affordable. Pharmaceutical companies are typically reluctant to invest in developing medicines for patient populations that do not represent a profitable market or for diseases predominantly affecting LMICs given the low and unpredictable expected private returns on investment. This "directionality" failure means that with regard to addressing societal challenges, governments have to provide direction and public funding of R&D is justified to achieve a socially optimal level of R&D. This can be done by influencing the incentives of and reducing the risk for the private sector of undertaking R&D activities deemed to have significant social benefits and thus delinking the price of solutions for public health priorities from their R&D cost.

India has recognized the need for strong innovation policies particularly in support of the biopharmaceutical sector. India's strategy, "Decade of Innovations 2010-20", aims at strengthening innovation capacities including by increasing gross expenditure on R&D to two percent of GDP by 2020. The Make in India initiative, an ambitious country-wide program launched in September 2014 to encourage manufacturing, identifies the pharmaceuticals, biotechnology, and medical device industries as priority sectors and aims at addressing a number of policy challenges and improving the business environment to foster India's competitiveness. Finally, the twelfth Five-Year Plan encourages states and central ministries to promote "R&D outputs leading to public and social goods" such as ensuring access to good quality healthcare and alleviating the burden of communicable and non-communicable diseases (NCDs).

To implement its strategy, the Government of India (GOI) created the Biotechnology Industry

Research Assistance Council (BIRAC) five years ago under the Department of Biotechnology (DBT). BIRAC has supported 539 companies (mainly start-ups and MSMEs) that are implementing 360 projects with funding support of over US$100 million and commitments of over US$160 million from the private sector. These projects have delivered 26 affordable products and 19 new technologies in addition to creating 53 new intellectual properties (IPs). BIRAC efforts can be broadly divided into three verticals: (i) providing innovation funding to entrepreneurs, small and medium enterprises (SMEs), start-ups and other biotechnology companies; (ii) supporting entrepreneurship through mentorship, capacity building, technology transfer facilities, and IP management; and (iii) developing strategic partnerships with national and international entities. BIRAC's schemes encourage collaboration among stakeholders and provide a conducive environment for collaborative R&D, with a particular focus on the healthcare sector (including drugs, devices/diagnostics, biosimilars, and vaccines/clinical trials). The proposed project would further BIRAC's work in transforming the biopharmaceutical and medical devices industries in India.

The World Bank (Bank) can leverage its experience in financing and supporting the implementation of innovation, competitiveness, and public health projects to help the GOI unlock India's potential for increased innovation. Drawing from global best practices adapted to the strategic and institutional context of India, the design of the project is based on a holistic approach to product-driven innovation in the biopharmaceutical and medical device industries. The project will focus on the sections of the biotechnology value chain where critical gaps impede the development of the industry exist (Figure 1). It will support concerted public-private efforts towards product development combined with upgrades in related soft and hard infrastructure to reinforce and sustain the transformation of the industry. Consortia of public-private stakeholders will be the recipients of grants to accelerate development and improve success rates of select products tackling major public health priorities. These consortia will also benefit from additional project support aimed at improving overall factor conditions in the business environment, which will be implemented in tandem with the product-driven initiatives. Namely, the project will support improved technical skills, advanced research-oriented facilities, and technology transfer processes which, combined, will foster improved innovation capabilities and collaboration within the ecosystem.

C. Proposed Development Objective(s)

Development Objective(s)

The proposed project development objective (PDO) is to facilitate innovation in biopharmaceutical products and medical devices that address public health priorities in India

Key Results

Number of products addressing public health priorities advanced at least one step on the product development pathway
Number of new intellectual property registrations or product prototypes
Number of technologies licensed for manufacturing or commercialization
Number of technology transfer offices established
Number of companies using shared facilities supported by the project

D. Project Description

Component 1 (USD 125 million): Strengthening the pilot-to-market innovation ecosystem

The interventions under this component will be targeted at critical gaps in infrastructure, human

capital, and technology transfer that have been identified as weak areas in the pilot-to-market innovation ecosystem for biopharmaceuticals and medical devices. The project will not address the overall regulatory and institutional framework for biopharmaceutical and medical devices in India, which has already undergone significant reforms in the last three years that improved its robustness, but will have targeted interventions within that framework to improve areas where gaps have been identified (Clinical trials and technology transfer).

The project will provide grant funding to support the creation of centers of excellence for validation, early stage bio-manufacturing, clinical development, training, and technology transfer. Funding will be used to procure specialized equipment, services, and technologies required for the different stages of the pilot-to market process. Grant recipients under this component will be primarily private and autonomous public entities, selected through open and competitive calls for proposal with transparent selection criteria. Grantees are expected to be top institutions from both the public and private sectors that already have a successful track record in the biotechnology space but lack specific capabilities required to enable faster, lower-cost validation, clinical development, and early stage manufacturing.

Component 2 (USD120 million): Accelerating the pilot-to-market process for specific products

The project will provide grant funding to consortia of private, public, and academic institutions, led by cutting-edge institutions in their respective field, to accelerate the development of low-cost, select vaccines, biopharmaceuticals, diagnostics and medical devices that address public health priorities in India. By extending financing to consortia, the project seeks to foster a more collaborative R&D environment which leverages the expertise of local and international players, from both the public and private sectors. Additionally, consortia present an opportunity to link MSMEs in the field with larger companies. This funding will be used by grantees to cover the cost of critical aspects of the product development process such as acquisition or licensing of proprietary technologies, equipment and specialized services as well conducting clinical trials and meeting other regulatory requirements. In addition to funding, the products supported under this component will benefit from access to the research infrastructure, scientific research tools, and a clinical trial network that will be developed under component 1, at reduced costs. Finally, the products directly supported by the Project will be those that address public health priorities, have market potential and are already in the critical validation to early bio-manufacturing stages of product development. In addition to reflecting the lower cost of development in lower market prices, the recipients of grants under this component will commit to delivering agreed quantities at agreed prices to the public health sector in India.

Component Name:
Strengthening the pilot-to-market innovation ecosystem
Comments (optional)

Component Name:
Accelerating the pilot-to-market process for specific products
Comments (optional)

Component Name:
Project management
Comments (optional)

E. Project location and Salient physical characteristics relevant to the safeguard analysis (if known)

The Project activities will be carried out in public and / or private research centers / organizations in urban areas / cities across India. Some of the possible project locations include biotechnology research and innovation centers in National Capital Region (NCR) of Delhi, Pune, Bengaluru, Hyderabad and Chennai. Specific organizations that will carry out research activities of the project, however will be finalized only after competitive selection of agencies during implementation. Joint teams of the World Bank and the implementing agency (BIRAC) visited some of the research and innovation centers of the organizations involved in bio-tech research in health sector, as part of the project preparation and to understand the potential safeguard issues related to the project activities. These visits indicate that the proposed activities of the project can be carried out in the existing product development or bio-tech research centers with procurement of additional equipment and deployment of new staff. Considering the above, the project does not impact any environmentally sensitive areas or locations, areas/ development blocks where Scheduled Tribes/Indigenous People live. The Project activities are also 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. The project activities however would involve generation of small quantities of solid, liquid, bio-medical and hazardous substances and air emissions. The Environmental Management Framework (EMF) developed for the project incorporates measures to assess magnitude and significance of these pollution sources and systems available with the agencies to manage them. Appropriate assessments and mitigation measures will be designed and incorporated by the agencies to address these issues, prior to the implementation of the project activities.

The project however, does not require acquisition of any Private Patta (titled) land or any Government land under different tenure system. This means, the Project does not trigger Bank's social safeguard policies – Involuntary Resettlement and Indigenous Peoples.

F. Environmental and Social Safeguards Specialists

Harinath Sesha Appalarajugari(GEN06)

Samuel Thangaraj(GSU06)

II. IMPLEMENTATION

The project will be implemented by BIRAC, a public sector unit under the Department of Bio-Technology (DBT), Ministry of Science and Technology, the GoI. BIRAC will serve as the Implementing Agency and will be led by a project management unit (PMU) within BIRAC. The PMU will be staffed by a dedicated Project Director (PD) as well as a mix of dedicated and part time officers and consultants including technical coordinators (one for each subcomponent), procurement, financial management, social, environmental and monitoring and evaluation specialists, a legal/compliance team, a communications team, a quality control officer and other administrative staff. In addition, a Steering Committee made up of senior DBT representatives (both civil service and career scientific officers) will provide strategic direction for the project and have final decision authority. A Technical Advisory Group made up of global and Indian academic and industry experts will provide scientific and technical guidance for the project. Most of the funding for the Project will be in the form of grants following open, competitive and transparent calls for proposals. The eligibility and selection criteria, application formats and other details of the calls for proposals as well as grant disbursement, implementation and monitoring is detailed in the Project Implementation Manual.

Environmental Safeguards Implementation: The project activities are expected to cause minimum or low environmental impacts. Some of the environmental impacts anticipated due to

the research and innovation initiatives of the project include: (i) generation of solid, liquid, biomedical and hazardous wastes in small quantities; (ii) air and noise emissions due to the operation and maintenance of various units and systems related to the project activity; and (iii) Bio-safety and Occupational Health and Safety Issues to the project staff while carrying out the research and product development activities related to the project.

Considering the minimum safeguard issues associated with the project, only OP 4.01 on Environmental Assessment, has been triggered. To address the requirements OP 4.01, an Environmental Management Framework (EMF) has been prepared, that provides procedures and guidance to address issues of environmental pollution due to the project activities and Environmental Due Diligence Process to understand the issues associated with the project activities. BIRAC will be responsible for EMF implementation and monitoring the implementation of Environmental Management Plans (EMPs) for the research and product development activities of the project.

A draft EMF for the project was prepared and disclosed locally as well as submitted for disclosure to the Bank's InfoShop on March 9, 2017.

III. SAFEGUARD 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, hazardous and biomedical waste and air emissions while performing these activities / research. OP 4.01 hence has been triggered and is proposed to be categorized as 'B'. Since specific research and product development activities and the agencies who will carry out these activities have not been identified at the time of appraisal, an Environmental Management Framework (EMF) has been developed, that sets out procedures and guidance to identify potential environmental issues associated with the project activities and formulate mitigation and management measures. The implementing agencies will use the EMF to carry out environmental due diligence of project activities and design appropriate mitigation and management measures.

Natural Habitats OP/BP 4.04	No	Based on the available information, the project activities are not expected to cause impacts on the natural habitats. OP 4.04 hence has not triggered.
Forests OP/BP 4.36	No	Based on the available 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 available 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 available 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 available 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 available 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 available information, the Project activities are not located in disputed areas. OP 7.60, hence has not been triggered.

IV. Key Safeguard Policy Issues and Their Management

A. Summary of Key Safeguard Issues

1. Describe any safeguard issues and impacts associated with the proposed project. Identify and describe any potential large scale, significant and/or irreversible impacts:
The project activities are not expected to cause large scale, significant / irreversible impacts. Some of the activities of the project which will be carried out by biotech research institutions / organizations, however could lead to generation of small quantities of liquid, solid, hazardous and bio-medical waste. In addition, issues of bio-safety and occupational health and safety are also anticipated due to the project activities. The EMF developed for the project outlines procedures and provides guidance to the agencies (who will be carrying out the product development and all other project activities), to address these issues and mitigation / management measures.
2. Describe any potential indirect and/or long term impacts due to anticipated future activities in the project area:
No indirect and / or long term environmental impacts are anticipated either due to the project or anticipated future activities in the project area. Some of the project activities however, would involve carrying out clinical trials on humans and animals. While these trials will be carried out as per standard protocols of clinical trials, the project has also developed a Clinical Research Validation and Management Framework (CRVMF) to address the issues related to clinical trials.
3. Describe any project alternatives (if relevant) considered to help avoid or minimize adverse impacts.
The project activities are aimed at facilitating innovation in biopharmaceutical products and medical devices that address public health priorities and hence the project is expected to contribute significantly to the public health sector in India. An analysis of the public health benefits and associated negative impacts (if any) will be evaluated during the selection of bio-pharma products and of the agencies who will carry out the research related to these activities.
4. Describe measures taken by the borrower to address safeguard policy issues. Provide an assessment of borrower capacity to plan and implement the measures described.
BIRAC, the implementation agency for the project has never worked with World Bank and / or any other multilateral agency, so far. The agency hence has no exposure to the safeguard policies and their implementation. However, the team at BIRAC has good expertise and analytical expertise, which makes them well positioned to quickly understand Bank processes and policies. The agency also has experience in working with development partners such as 'Gates Foundation' that gave them some exposure to process requirements of development agencies. Considering the above, the World Bank team has provided handholding support to

BIRAC in carrying out safeguard preparation work for the project. For the implementation phase, the PMU at BIRAC will hire a qualified and experienced environmental specialist who will be responsible for implementing the agreed EMF for the project and monitoring the implementation of environmental management measures in various product development activities to be carried out by the agencies. In addition, the training component of the project also includes modules of environmental management in bio-pharma research which will help all the stakeholders in understanding environmental issues associated with the sector and build their capacity to implement mitigation / management measures.
5. Identify the key stakeholders and describe the mechanisms for consultation and disclosure on safeguard policies, with an emphasis on potentially affected people.
The key stakeholders for the project include Department of Biotechnology, BIRAC, biopharma / biotech research agencies working on public health, various regulatory agencies, NGOs working in health sector and the people at large. Series of stakeholder meetings were organized by BIRAC as part of the development of the concept and preparation of the project. Another multi-stakeholder consultation is planned by BIRAC, prior to the finalization of the project. Inputs from these consultations have been incorporated in the overall project design and the development of EMF. A draft EMF for the project was prepared and disclosed locally as well as submitted for disclosure to the Bank's InfoShop on March 9, 2017.

B. Disclosure Requirements

Environmental Assessment/Audit/Management Plan/Other	
Date of receipt by the Bank	08-Mar-2017
Date of submission to InfoShop	09-Mar-2017
For category A projects, date of distributing the Executive Summary of the EA to the Executive Directors	
"In country" Disclosure	
India	09-Mar-2017
*Comments:*http://www.dbtindia.nic.in/wp-content/uploads/EMF_i3-BIRAC-draft-for-disclosure_Cleared_Clean.pdf	
If the project triggers the Pest Management and/or Physical Cultural Resources policies, the respective issues are to be addressed and disclosed as part of the Environmental Assessment/Audit/or EMP.	
If in-country disclosure of any of the above documents is not expected, please explain why::	

C. Compliance Monitoring Indicators at the Corporate Level

OP/BP/GP 4.01 - Environment Assessment						
Does the project require a stand-alone EA (including EMP) report?	Yes	[X]	No	[]	NA	[]
If yes, then did the Regional Environment Unit or Practice Manager (PM) review and approve the EA report?	Yes	[X]	No	[]	NA	[]
Are the cost and the accountabilities for the EMP incorporated in the credit/loan?	Yes	[X]	No	[]	NA	[]
The World Bank Policy on Disclosure of Information						
Have relevant safeguard policies documents been sent to the World Bank's Infoshop?	Yes	[X]	No	[]	NA	[]
Have relevant documents been disclosed in-country in a public place in a form and language that are understandable and accessible to project-affected groups and local NGOs?	Yes	[X]	No	[]	NA	[]
All Safeguard Policies						
Have satisfactory calendar, budget and clear institutional responsibilities been prepared for the implementation of measures related to safeguard policies?	Yes	[X]	No	[]	NA	[]
Have costs related to safeguard policy measures been included in the project cost?	Yes	[X]	No	[]	NA	[]
Does the Monitoring and Evaluation system of the project include the monitoring of safeguard impacts and measures related to safeguard policies?	Yes	[X]	No	[]	NA	[]
Have satisfactory implementation arrangements been agreed with the borrower and the same been adequately reflected in the project legal documents?	Yes	[X]	No	[]	NA	[]

V. Contact point

World Bank

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

Contact:Jorge A. Coarasa
Title:Sr Economist (Health)

Borrower/Client/Recipient

Name:Republic of India
Contact:

Title:
Email:

Implementing Agencies

Name:Biotechnology Industry Research Assistance Council
Contact:Dr. Renu Swarup
Title:Senior Adviser, DBT and MD, BIRAC
Email:swarup@dbt.nic.in

VI. For more information contact:

The World Bank
1818 H Street, NW
Washington, D.C. 20433
Telephone: (202) 473-1000
Web: http://www.worldbank.org/projects

VII. Approval

Task Team Leader(s):	Name:Bharatha Manju S. Haththotuwa,Jorge A. Coarasa	
Approved By:		
Practice Manager:	Name: Esperanza Lasagabaster (PMGR)	Date: 13-Mar-2017
Country Director:	Name: Junaid Kamal Ahmad (CD)	Date: 13-Mar-2017

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