

Product Commercialization Program Fund (PCP Fund)

*Complete Scheme document including Proposal submission, Evaluation, Review Process and
Terms & Conditions*



Biotechnology Industry Research Assistance Council

1. Introduction

BIRAC is promoting product/technology development by Indian Start-ups in different areas of biotechnology through various funding schemes such as BIG, BIPP, SBIRI, PACE, IIPME, SPARSH, through various partnerships programmes like Grand Challenges India, National Biopharma Mission, WISH or as innovation awards like TiE Winer. BIRAC supported technologies are continuously monitored and measured for technology maturation on a BIRAC-TRL (Technology Readiness Level; http://www.birac.nic.in/desc_new.php?id=443) scale of 1 to 9. The existing BIRAC schemes support product development, extensive validation up to pre-commercialization. Once the technology/product has been successfully validated (\geq TRL 7) and is market ready, there are additional financial requirements for preparing the ground for market launch, test-validation in targeted markets and large scale commercialization, which are not covered under the existing funding programmes. To deal with the situation, BIRAC has launched the Product Commercialization Program Fund (PCP Fund) under the BIRAC Product Commercialization Program (PCP).

2. Objectives of PCP Fund

To hasten the market launching and large scale commercialization process of BIRAC supported products/ technologies from Start-ups having high commercial potential or societal impact by providing financial assistance by way of Grant-in-Aid assistance.

3. Eligibility

Products/Technologies developed by Indian start-ups with BIRAC support through its funding schemes, partnership schemes, through BioNEST incubation, awards or in any other means, or Products of high national relevance, recognized according by the steering committee, developed by start-ups with support from other sources of funding having $TRL \geq 7$ in the BIRAC-TRL scale and are ready for large scale commercialization in the next 6-18 months.

4. Areas covered

- Drugs (including drug delivery)
- Biosimilars
- Regenerative Medicine
- Vaccines
- Devices and Diagnostics.
- Agriculture
- Aquaculture/Fisheries
- Veterinary Sciences
- Industrial Biotechnology (covering Industrial Products & Processes)
- Secondary Agriculture)
- Bioinformatics & software (Including Artificial intelligence, Big Data Analysis, IoT's, software development etc.)
- Any other relevant areas in Biotechnology as and when identified by the relevant Steering Committee for Product Commercialization (SCPC) Committee

5. Duration of support

Maximum duration of support is 24 months

6. Application Process

As per the current practice, all ongoing BIRAC funded projects are monitored for their TRL on regular basis. Irrespective of the funding program or thematic area, all those projects that have reached TRL 7 or above will be considered.

Start-ups may also be recommended for Product Commercialization Fund (if the product is at TRL 7 or above) by BIRAC Technical Expert Committee, BIRAC internal PCU, Partner /BioNEST Incubators or by any other relevant authorities.

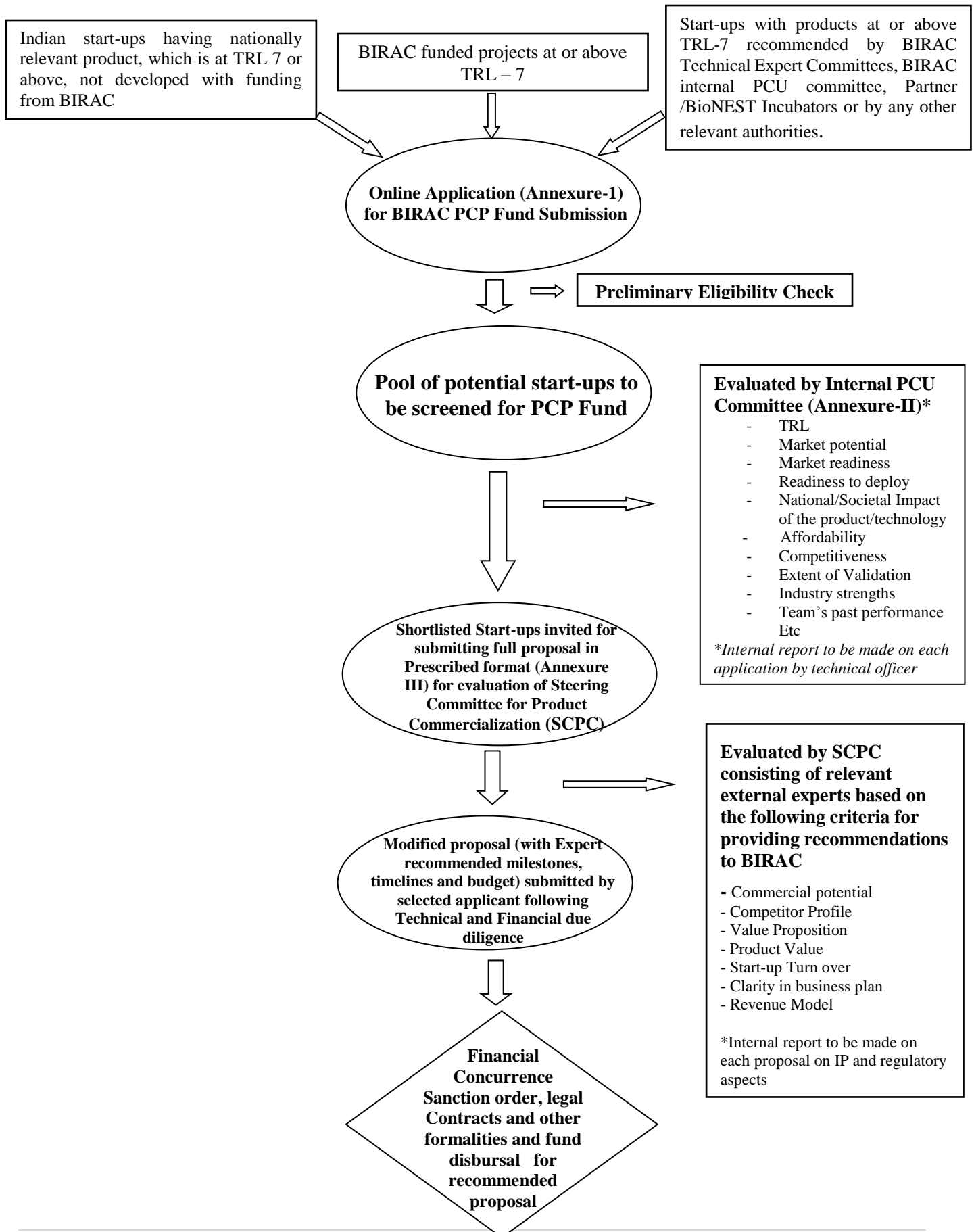
Indian start-ups having nationally relevant product which is at TRL 7 or above will also be considered, even if the product is not developed with funding from BIRAC.

In all the above cases Start-ups will have to apply for BIRAC PCP fund through submission of online application format available on BIRAC website (**Annexure-I**) which is open throughout the year.

6.1. Selection Process

1. The applications will be scrutinized quarterly by BIRAC Internal Product Commercialization Unit based on the Broad Evaluation Criteria (**Annexure-II**)
2. The BIRAC Internal PCU will screen the Products/Technologies which have reached Technology Readiness Level of 7 or above ($TRL \geq 7$) as per BIRAC TRL scale, based on the evaluation criteria placed at Annexure II
3. The PCU committee can select eligible products/technologies to be considered and invite them for submission of full proposal to BIRAC PCU as and when the evaluation is complete
4. Based on internal PCU recommendation the full proposal can be submitted in the prescribed format placed at **Annexure III**
5. The presentation of those who submitted the full proposals may be called for in the meeting of Steering Committee for Product Commercialization (SCPC). The committee shall look into project specific commercialization aspects including the following
 - Commercial potential
 - Competitor Profile
 - Value Proposition
 - Product Value
 - Start-up Turn over
 - Clarity in business plan
 - Revenue Model and
 - Other relevant information
6. Accordingly, the SCPC shall make the final recommendation to BIRAC on the funding support including the following
 - Extent of support
 - Expected Deliverables
 - Allowable core specific project aspects
 - Additional funding conditions
 - Monitoring parameters
 - Determination of benefit sharing

Process Flow Diagram



6.2. Sanction of PCP Fund Support

1. Technical and Financial Due Diligence will be done on case-specific requirements as per BIRAC norms.
2. The final recommendation of the SCPC will be placed for approval of the competent authority of BIRAC. The recommendation will have observation on all cardinal aspects of evaluation such as TRL, market potential, business plan, revenue model etc. Inputs regarding their evaluation can be undertaken in-house, or based on third party evaluation submitted by the Proponent, or through evaluation report of BIRAC's empaneled agencies.
3. It will be proceeded further for financial concurrence, legal concurrence and issuance of sanction order as per BIRAC norms.
4. The sanction order shall be appended with the format of the Grant Agreement (GA) containing grant-specific conditions.
5. After successful execution of the above documents and fulfillment of other formalities, fund disbursement will be initiated by BIRAC

6.3. Funding Process and Fund Disbursement

- a. The Grant-in-Aid assistance support (hereafter referred to as Funding) will be subject to pre-acceptance of associated conditions and execution of Grant Agreement as prescribed by BIRAC
- b. The fund allocation into different budget heads and break-up into installments will be done as per the recommendation from the expert committee with approval of the competent authorities.
- c. Usually the Allowable cost includes Equipment, Manpower, Consumables, Outsourcing towards CMO/Consultancy, Contingency (not exceeding 10% of total project cost), travel, certification etc. The Non-Allowable costs usually includes Legal cost and overheads, other allowable costs if any can be considered based on relevance and justification by the relevant committee.
- d. Fund release and disbursement will be based on a case to case discretionary recommendation by SCPC after accord of approval by competent authority of BIRAC.

6.4. Monitoring & Reviewing

- The PCP support shall be monitored regularly by the SCPC based on the quarterly progress report that will be submitted.
- Site visit shall be conducted towards the end of first year by BIRAC

7. Success of the Project

The success of the Project shall be determined by commercialization of the results of the Project. Market reach of results of the funded Project as products and/or services either through the fund recipient directly or through licensing, assignment or technology transfer of any of the interests to any third Party culminating in to monetary transaction and additional investments shall be considered as 'commercialization'. The Certificate of the Chartered Accountant in this regard will be considered for commencement and the quantum of such monetary transaction or extent of investments raised.

The site-visit that will be undertaken towards the end of the first year shall accordingly evaluate the Project for its prospective success or failure. If the SCPC ascertains the success and recommends the Benefit Sharing provisions, it becomes applicable as detailed later. Otherwise, in case of determination as “Project not viable for commercialization” by SCPC, the remaining sanctioned amount, if any, shall not be released and the fund recipient shall refund such unutilized Grant-in-aid amount that was already disbursed for the Project as on the date of the recommendation of the SCPC.

8. Benefit sharing

1. Benefit Sharing shall be equal to the amount of the Grant-in-aid disbursed for the Project (excluding refunded Grant-in-aid, if any) and additional 50% of such funding support cumulatively payable in eight or less yearly tranches.
2. Benefit sharing will be linked to occurrence of events as given below
 - i. The fund recipient entity successfully commercializes the product/technology supported through BIRAC PCP funding.
 - ii. Benefit Sharing can commence any time after the start of the Project subject to case to case recommendation of SCPC and based on project wise attainment of success
 - iii. Licensing/Assignment/ Technology-transfer of the Project developments to any third party where the Fund Recipient is not under taking direct market reach which also be treated as successful Commercialization and the Fund Recipient shall be liable for Benefit Sharing with BIRAC.
 - iv. If the Fund Recipient intent to transfer or sell/assign the interest of Project developments it shall take prior written permission from BIRAC before doing so. BIRAC reserves the right to realize the benefit sharing, in case of one time transaction as will be mutually agreed while granting such permission.
 - v. If the Fund Recipient licenses the interest of Project developments for periodical payments including Royalty, then the fund recipient can also continue to share the benefits as prescribed by BIRAC to be met from the periodical proceeds received from licensees/sub-licensees.
 - vi. In cases of significant changes such as public offering of shares, raising of venture funds, change in the share holding pattern, change in the legal entity status, receipt of notice under SARFESI/IBC, changes due to substantial expansion, merger and acquisition etc. , BIRAC reserves the right to enforce the benefit sharing obligation or the Surety Bond and recover the remaining benefit sharing committed for the project through the resolution or liquidation process as a receivable in favor of BIRAC.
3. For each financial year benefit sharing shall become payable to BIRAC within 60 (sixty) days of its closure.

9. Schedule for Benefit Sharing

From the start of the project	Percentage of the Benefit Sharing amount (i.e. 150% of the Grant)*
First tranche of the Benefit sharing #	Up to 10%
By the end of 2 nd year after the initial benefit sharing	Up to 20%
By the end of 3 rd year thereafter	Up to 50%
By the end of 4 th year thereafter	Up to 80%
By the end of 5 th year thereafter	100%
From 6 th year till the end of 8 th year	150%

NOTE:

* The Fund Recipient can share any amount more than such percentage till the total benefit sharing obligation of 150% of the Grant-in-aid disbursed is met any time earlier than the above stated timeline.

Benefit Sharing can commence any time after the start of the Project subject to case to case recommendation of SCPC and based on project wise attainment of success

10. Other Terms and Conditions

1. An entity that has already received Product Commercialization Fund once is not eligible for receiving the funds again for the same product
2. The PCP shall be governed by the specific GA and associated documentary requirements
3. Any deviation to the above specific guidelines can be undertaken after specific approval of competent authority

This guidelines can be revised by the BIRAC PCP Committee and SCPC as per needs basis to address additional/unforeseen conditions.

Disclaimer:- BIRAC, will not become liable for manufacturing, Commercialization and other product related liability.

Fund Recipient shall acknowledge the BIRAC support and its logo can be used on the final Developed Product as provided hereunder:-

“Developed with partial support from (BIRAC Logo)”.



11. Dispute Resolution:

In the event of any failure on the part of the Fund Recipient regarding commitment of the terms and conditions agreed for and if any differences arises between the Parties, BIRAC can invoke Arbitration clause mentioned in Grant Agreement for enforcing return of Grant-in-Aid assistance.

Note: Arbitration Clause:- In the event of any dispute or difference between the Parties hereto upon or in relation to or in connection with this GA, such dispute or difference, shall be resolved amicably and in good faith by mutual consultation. If such resolution is not possible, then the unresolved dispute or difference whatsoever arising between the Parties out of or relation to the construction, meaning, scope, operation or effect of this GA or the validity the breach thereof or in respect of any defined legal relationship associated therewith or derived there from dispute shall be submitted for arbitration to International Center for Alternate Dispute Resolution (ICADR), an autonomous organization working under the aegis of the Ministry of Law & Justice, Department of Legal Affairs, Government of India. The Authority to appoint the arbitrator(s) shall be the ICADR. The Arbitration under this Clause and provision of administrative services by ICADR shall be in accordance with the ICADR Arbitration Rules, 1996. The award made in pursuance thereof shall be binding on the Parties. The venue of arbitration shall be New Delhi and the arbitration proceedings shall be conducted in English Language. The provision of this Clause shall not become inoperative notwithstanding the GA expiring or ceasing to exist or being terminated or foreclosed.

-End of Document-