BIOTECHNOLOGY START-UP ECOSYSTEM IN INDIA

BCIL

Biotech Consortium India Limited
New Delhi

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1. INTRODUCTION

Biotechnology is a prominent knowledge-intensive industry in India today. It has significant potential to play a pivotal role in the rapid economic development of the country. With India ranking among the top 12 biotechnology destinations globally, and second in Asia after China; India is ready to leverage this advantage to be an important player in the global context.

Creation of enterprises based on biotechnology innovations - Bioentrepreneurship' is pitched to be one of the key drivers leading to job creation, improved productivity, increased prosperity, and a better quality of life. It provides immense opportunities for strengthening economy through innovative technologies in the area of food security, healthcare, clean energy, environmental issues, etc. In Indian context, the large population of educated young minds needs to be nurtured for entrepreneurship to enable them to excel in the global competitive scenario and for well-being of the society in general.

The Government of India has taken several initiatives in the recent years to foster innovation and entrepreneurship towards development of a robust economy. Some examples include 'Startup India', 'Skill India', 'Innovate in India', 'Make in India', 'Atal Innovation Mission', etc. Budgetary allocations to the biotech sector have also increased with the objective of creating an innovation ecosystem and nurturing start-ups. With the above objective, the Department of Biotechnology (DBT) has initiated several novel programmes and schemes to promote bioentrepreneurship amongst students, research fellows, young faculty and scientists. Several programmes of other government departments such as Department of Science and Technology (DST) and Department of Scientific and Industrial Research (DSIR) have also been developed and aligned to provide opportunities and support to promising innovation led entrepreneurship ideas. Multiple public-private partnered incubation centres have been set up in different parts of the country and are creating a dynamic atmosphere for the entrepreneurial minds in the domain. Incubators, accelerators, angel investors and venture capitalist funding are also acting as enablers to realize life sciences start-up dream of potential entrepreneurs.

Biotech Consortium India Limited (BCIL), New Delhi is a company promoted by DBT and the All India Financial Institutions. BCIL has been working in the area of innovation management, technology transfer, capacity building for entrepreneurship development through hand-holding support and information dissemination to stakeholders for more than 28 years. This publication is an effort to reach out to prospective entrepreneurs particularly young minds of the country to inform about the numerous policy initiatives of the Government of India including fiscal policy initiatives, funding schemes, infrastructure support, market facilitation etc. that contribute to developing an encouraging ecosystem for venturing into the field of biotechnology and contribute to the country-wide initiatives towards creation of a robust start-up ecosystem in the country. The second section of the book covers a practical step-by-step guide with an example of medical device start-up enterprise which can be referred to by the prospective entrepreneur to build teams, incorporate company, ideate, innovate and implement a technology through its start-up company for benefit of the society.

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2. START-UP ECOSYSTEM IN INDIA

2.1 INTRODUCTION

The Indian Startup Ecosystem, which traces its growth all the way back to the nineties, has taken quantum leaps to emerge as the 3rd largest in the world and has witnessed the launch of an estimated 20,000 startups over the years, just behind the US as per the Start-up India initiative being led by Ministry of Commerce and Industry, Government of India. Currently, there are around 4,750 technology led startups of the total number. As per the information available, 1,400 new tech startups were born in 2016 alone; implying that 3-4 tech startups were born every day. Indian entrepreneurs are building world-class technology startups, attracting global investor interest and churning out successes and unicorns at a rapid pace. A survey report by Innoven Capital reveals that cost of doing business, proximity to customers/ vendors and size of domestic market are the leading factors that make India appealing as a startup nation[1]. India is often called as "Young India" with over 7 million college graduates graduating from various fields per year and 55% of the youth prefer working in startups over corporates (as per a youth of the nation survey of 150K young Indians). [1]

The Start-up boom in India has been possible due to increase in investments, amenable cost of doing business, outsourcing activities, exports, size of domestic market and the government's focus on this sector. The Government of India has taken several initiatives in the recent years to foster innovation and entrepreneurship towards development of a robust economy. Some of their initiatives include 'Startup India', 'Skill India', 'Innovate in India', 'Make in India', 'Atal Innovation Mission', etc. India is also home to a strong pool of scientists and engineers capable of developing innovative and cost-effective solutions in production and manufacturing. Moreover, significant initiatives towards setting up and strengthening of national research laboratories, centers of academic excellence and several other institutes in different areas of science and technology have also given a boost to this sector. A

NASSCOM report of 2015 elaborated the status of Indian start-ups as shown in Figure 1.

The Indian biotechnology industry, a highly knowledge-intensive industry is on a strong growth trajectory and is expected to play a significant role as an innovative manufacturing hub. It is expected to grow at an average growth rate of around 30% a year and is poised to reach a USD 100 billion market size by 2025 (Make in India statistics). This is attributed to the growing demand for healthcare services, intensive R&D activities, strong government initiatives, fast-developing clinical capabilities with the country becoming a popular destination for global companies for clinical trials, contract research and manufacturing activities. As per the report, "India's Biotech Start-Ups Ecosystem" by the Association of Biotechnology Led Enterprises (ABLE), the bioscience sector has witnessed a constant dynamic situation with about 1022 startups being formed in this sector during a five-year period from 2012 to 2016 with investments worth Rs 18,700 crore from various sources.[2,3]
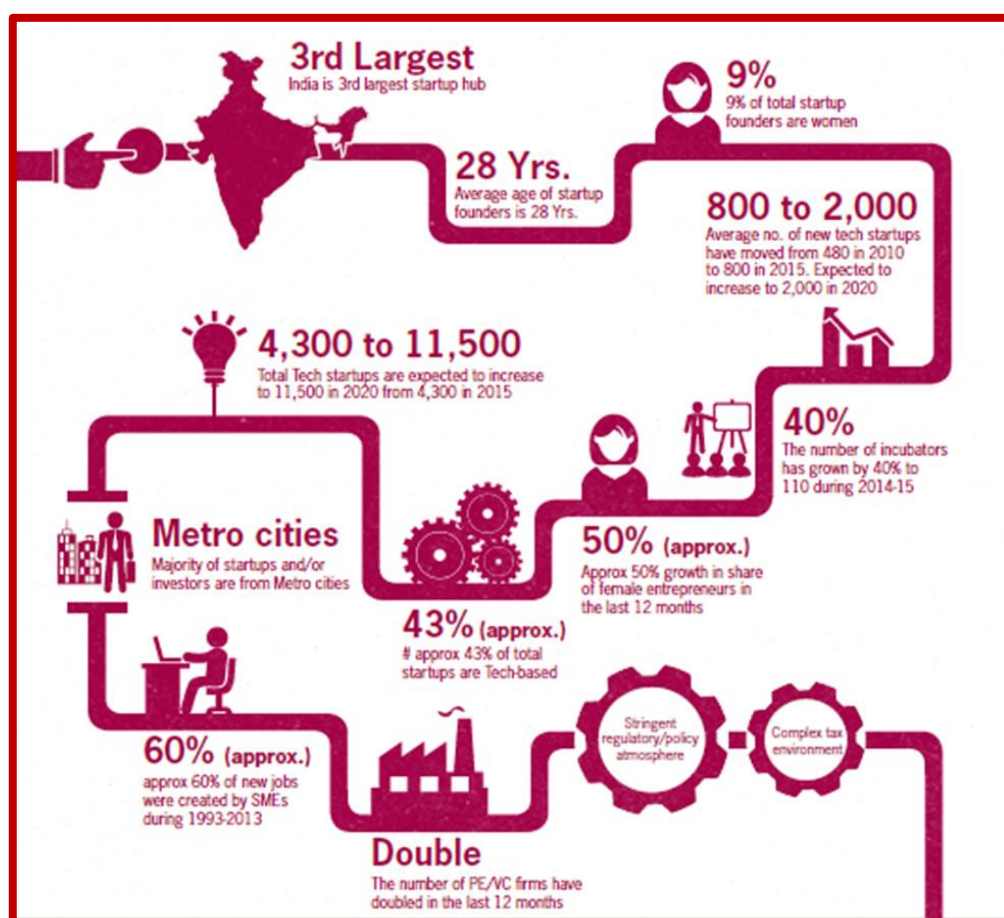

Figure1: Status of Indian Start-ups (Source: NASSCOM Start-up India report 2015)

At this surge of the start-up innovation ecosystem, this document will be helpful to the budding entrepreneurs as a resource guide. It will serve as a resource document for budding entrepreneurs and start-ups which includes information on the Government initiatives, programmes and schemes for promotion of bioentrepreneurship through innovation. The document provides an overview of the 'Startup India' initiative to elicit the interest of students and researchers for entrepreneurship.[4] The document also includes a compilation of information on various funding schemes/ programmes of different government agencies supporting various facets of innovation, infrastructure development and capacity building to foster entrepreneurship. The weblink details for the schemes/ programmes have also been provided for further reference.

2.2 START UP INDIA INITIATIVE

Startup India is a flagship initiative of the Government of India, intended to build a strong ecosystem that is conducive for the growth of startup businesses, to drive sustainable economic growth and generate large scale employment opportunities. The Government through this initiative aims to empower startups to grow through innovation and design.

With the intention to build a strong eco-system for nurturing innovation and Startups in the country, the Hon'ble Prime Minister launched Startup India Action Plan on January 16, 2016 in New Delhi. The Government through this initiative aims to empower Startups to grow through innovation and design and to accelerate spreading of the Startup movement.

In order to meet the objectives of the initiative, Government of India had announced an Action Plan that addresses all the key aspects of the Startup ecosystem. Several programs have been undertaken since the launch of the initiative. These programs have catalyzed the startup culture, with startups getting recognized through the Startup India initiative and many entrepreneurs availing the benefits of starting their own business in India. Figure 2 summarizes the start-up ecosystem in India.[5,6]

The 19-Point Startup India Action Plan envisages several incubation centres, easier patent filing, tax exemptions, ease of setting-up of business, a INR 10,000 Crore corpus fund, and a faster exit mechanism, among others.

The key objectives of the Start-up India Action Plan and its achievements with implications on the Biotechnology Startups are given below:

1. Policy for Reducing Compliance and Enabling Operations
2. Fiscal Policy Initiatives
3. Infrastructure Support
4. Funding Support Initiative
5. Intellectual Property Facilitation
6. Facilitating Public Procurement
7. Mission Programs to Boost Innovation and Startups
8. Biotechnology Sector Specific Initiatives

2.2.1 Policy For Reducing Compliance And Enabling Operations

This includes the following two key initiatives by the Government:

i. **Policy for Reducing Compliance**

ii. **Creation of Start-up India Hub**

The details about the above policies given below:

i. **Policy for Reducing Compliance**:

This initiative of the Government of India aims to reduce the regulatory burden on Startups thereby allowing them to focus on their core business and keep compliance cost low. Regulatory formalities requiring compliance with various labour and environment laws are time consuming and difficult in nature. Often, new and small firms are unaware of nuances of the issues and can be subjected to intrusive action by regulatory agencies. In order to make compliance for Startups friendly and flexible, the Government has introduced simplifications in the regulatory regime.

Accordingly, the process of conducting inspections has been made more meaningful and simple. Startups are now allowed to self-certify

compliance (through the Startup mobile app) with 9 labour and environment laws. In case of the labour laws, no inspections will be conducted for a period of 3 years. Startups may be inspected on receipt of credible and verifiable complaint of violation, filed in writing and approved by at least one level senior to the inspecting officer.

In case of environment laws, Startups which fall under the 'white category' (as defined by the Central Pollution Control Board (CPCB) are now allowed to self-certify compliance.[3]

The present status is as follows:

Acknowledging the long gestation period for Startups, the definition of the Startups has been amended where an entity shall be considered as a Startup for up to 7 years (from earlier 5 years) and a Biotechnology Startup for up to 10 years from the date of its incorporation/ registration. Also, scope of definition has been broadened to include scalable business model with high potential of employment generation or wealth creation. Additionally, no letter of recommendation from an incubator/industry association is now required for either recognition or availing tax benefits.

Numerous applications for Startup recognition are now being received by the DIPP. Out of the applications received, 14,036 have been recognised as Startups by DIPP. 91 Startups have been approved for availing tax benefits as of 3rd week of Nov, 2018. Compliance norms have been eased in order to reduce the regulatory burden on Startups thereby allowing them to focus on their core business.

Startups falling under the list of 36 "white" category industries will not require Environment clearance under 3 Environment related Acts viz. The Water (Prevention & Control of Pollution) Act, 1974; the Water (Prevention & Control of Pollution) Cess (Amendment) Act, 2003 and the Air (Prevention & Control of Pollution) Act, 1981.

Ministry of Skill Development and Entrepreneurship (MSDE) has issued advisory to states to allow Startups to self-certify compliance for a period of 1 year with the Apprenticeship Rules, 1992 of Apprenticeship Act 1961.[7,8]

As per the advisory issued by Ministry of Labour & Employment (MoLE) on 12 January 2016, Startups have been given the provision to self-certify compliance under 6 Labour Laws. MoLE has now increased the tenure of compliance of self-certification under 6 Labour laws from 3 to 5 years. 27 states have confirmed compliance viz. Andhra Pradesh, Assam, Chhattisgarh, Chandigarh, Daman & Diu, Delhi, Gujarat, Himachal Pradesh, Mizoram, Odisha, Punjab, Tripura, West Bengal, Uttar Pradesh, Haryana, Jharkhand, Madhya Pradesh, Maharashtra, Tamil Nadu, Telangana, Uttarakhand, Rajasthan, Karnataka, Bihar, Andaman & Nicobar, Arunachal Pradesh and Meghalaya.

The "Startup India Hub" has been envisaged by the Government to be a key stakeholder in this vibrant ecosystem which will have the following functions:

- Work in a hub and spoke model and collaborate with Central & State governments, Indian and foreign VCs, angel networks, banks, incubators, legal partners, consultants, universities and R&D institutions.
- Assist Startups through their lifecycle with specific focus on important aspects like obtaining financing, feasibility testing, business structuring advisory, enhancement of marketing skills, technology commercialization and management evaluation.
- Organize mentorship programs in collaboration with government organizations, incubation centers, educational institutions and private organizations who aspire to foster innovation.

Startup India hub was operationalised on 1st April, 2016 to resolve queries and provide handholding support to Startups. The hub has handled more than 1,14,000 queries from Startups through telephone, email and Twitter. To seek clarifications pertaining to Certificate of Recognition as a "Startup", Certificate of Eligibility to avail tax benefits, seeking information on incubators or funding now any startup can get in touch with the Hub on Toll- Free number: 1800115565 or Email ID: dipp-startups@nic.in. The hub has mentored more than 660 Startups for incubation, funding support, on business plans, pitching support, etc. Startup India Online Hub was launched to serve as an online platform where all the stakeholders of the Startup ecosystem can collaborate and synergize their efforts. Under this initiative, more than 2.7 lakh users have been registered so far.[9]

2.2.2 Fiscal Policy Initiatives

The following fiscal initiatives have been taken-up by the Government to foster start-up ecosystem in the country:

i.   **Credit Guarantee Fund for Startups**
ii.   **Tax Exemption on Capital Gains**
iii. **Tax Exemption to Startups for 3 years**
iv.   **Tax Exemption on Investments above Fair Market Value**

The details about the above initiatives and the key achievements so far are given below:

i.   **Credit Guarantee Fund for Startups:**

This initiative aims to catalyse enterpreneurship by providing credit to innovators accross all sections of society. In order to overcome traditional Indian stigma associated with failure of Startup enterprises in general and to encourage experimentation among Startup entrepreneurs through disruptive business models, credit guarantee comfort is being extended by the Government which is helping flow of Venture Debt from the formal Banking System.

Debt funding to Startups is also perceived as high risk area and to encourage Banks and other lenders to provide Venture Debts to Startups, Credit guarantee mechanism through National Credit Guarantee Trust Company (NCGTC)/ SIDBI has been rolled out with a budgetary Corpus of INR 500 crore per year for the next four years.

ii. **Tax Exemption on Capital Gains**

This initiative aims to promote investments into Startups by mobilizing the capital gains arising from sale of capital assets.

Due to their high risk nature, Startups are not able to attract investment in their initial stage. It is therefore important that suitable incentives are provided to investors for investing in the Startup ecosystem. With this objective, the Government envisages to extend exemption to persons who have capital gains during the year, if they have invested such capital gains in the Fund of Funds recognized by the Government.

In addition, existing capital gain tax exemption has also been extended for investment in newly formed manufacturing MSMEs/start-ups. Currently, such an entity needs to purchase "new assests" with the capital gain received to avail such an exemption. Investment in 'computer or computer software' (as used in core business activity) shall also be considered as purchase of 'new assets' in order to promote technology driven Startups.[12]

iii. **Tax Exemption to Startups for 3 years**

This scheme aims to promote the growth of Startups and addresses working capital requirements. During the initial years, budding entrepreneurs struggle to evaluate the feasibility of their business idea. Significant capital investment is made in embracing ever-changing technology, fighting rising competition and navigating through the unique challenges arising from their venture. Also, there are

limited alternative sources of finance available to the small and growing entrepreneurs, leading to constrained cash funds.

With a view to stimulate the development of Startups in India and provide them a competitive platform, the profits of Startup initiatives have been exempted from income-tax for a period of 3 years. This fiscal exemption shall facilitate growth of business and meet the working capital requirements during the initial years of operations. The exemption can be availed subject to non-distribution of dividend by the Startup.

iv. **Tax Exemption on Investments above Fair Market Value**

Under The Income Tax Act, 1961, where a Startup (company) receives any consideration for issue of shares which exceeds the Fair Market Value (FMV) of such shares, such excess consideration is taxable in the hands of recipient as 'Income from Other Sources'.

In the context of Startups, where the idea is at a conceptualization or development stage, it is often difficult to determine the FMV of such shares. In majority of the cases, FMV is also significantly lower than the value at which the capital investment is made. This results into the tax being levied under section 56(2) (viib) of the Income Tax Act, 1961.

Currently, investment by venture capital funds in Startups is exempted from operations of this provision. The same is extendable to investment made by incubators in the Startups.

The tax benefits include:

- **Tax Exemption:** The Finance Act, 2016 had made provision for Startups to get income tax exemption for 3 years in a block of 5 years, if they are incorporated between 1st April 2016 and 31st March 2019. In the Union Budget 2017-18, the Government has increased this period of profit-linked deductions available to the

eligible Startups to 7 years. To avail these benefits one must get a Certificate of Eligibility from the Inter-Ministerial Board of DIPP.

- **Tax Exemption on Capital Gains:** Section 54 EE has been introduced under the Finance Act, 2016 which provides for exemption of capital gain up to INR 50 lakhs arising out of transfer of long term capital asset invested in a fund notified by Central Government.

  Also, Section 54 GB of Income-Tax Act, 1961 has been amended to provide exemption from tax on capital gains arising out of sale of residential house or a residential plot of land if the amount of net consideration is invested in equity shares of eligible Startup for utilizing the same for purchase of specified asset.

- **Removal of Angel Tax:** Tax exemption on investments above Fair Market Value (or angel tax) has been introduced for Startups. Revised norms for claiming angel tax exemption has been provided through a notification dated 11th April 2018.

2.2.3 Infrastructure Support

The infrastructure support initiatives of the Government of India under the Start-up India action plan includes the following:

i.   **Setting-up of Incubators**
ii. **Research Parks**
iii. **Building Innovation Centres at National Institutes**
iv. **Setting up of 7 New Research Parks Modeled on the IIT Madras Research Park**

The details and key achievements for each of the above initiative is provided below:

i. Setting-up of Incubators

To ensure professional management of Government sponsored /funded incubators, Government under the Start-up India Action Plan envisages to create a policy and framework for setting-up of incubators across the country in public private partnership.[20,21]

India currently lacks availability of incubation facilities across various parts of the country. Incubation facilities typically include physical infrastructure, provision of mentorship support, access to networks, access to market, etc. Of all these features, physical infrastructure entails large capital investment which can generally be facilitated by the Government. However, requisite skills for operating an incubator are pivotal as well, for which expertise of the private sector needs to be leveraged. Considering this, Government is encouraging setting up of 35 new incubators in existing institutions. Funding support of 40% (subject to a maximum of INR 10 crore) is being provided by Central Government for establishment of new incubators for which 40% funding is being pooled by the respective State Government and 20% funding by the private sector. The incubator is being managed and operated by the private sector.

A grant of 50% (subject to a maximum of INR 10 crore) is being provided by Central Government for incubators established by private sector in existing institutions. The incubator is being managed and operated by the private sector.

The funding for setting up of the incubators is being provided by NITI Aayog as part of Atal Innovation Mission. Participating departments and agencies for setting up of new incubators includes Department of Science and Technology, Department of Biotechnology, Department of Electronics and Information Technology, Ministry of Micro, Small and Medium Enterprises, Department of Higher

Education, Department of Industrial Policy and Promotion and NITI Aayog.

Each of the above mentioned departments/agencies have entered into a standard MoU with identified private sector players for creation of academia-industry tie-ups for nurturing innovations in academic institutions.

ii. **Research Parks**

The objective of setting up Research Parks is to propel successful innovation through incubation and joint Research and Development (R&D) efforts between academia and industry. 8 Research Parks are being setup under Startup India initiative. Research Park at IIT Kharagpur is under construction and INR 100 crore has been released. The Research Park at IIT Gandhinagar is being set up by DST which has sanctioned INR 90 crore and disbursed an initial instalment of INR 40 crore. The remaining 5 are being set up by Ministry of Human Resource Development (MHRD) at IIT Guwahati, IIT Hyderabad, IIT Kanpur, IIT Delhi and IISC Bangalore with a budget of INR 375 crore. In addition, another Research Park at IIT Bombay is under construction and INR 34 crore has been released.

iii. **Building Innovation Centres at National Institutes**

By this initiative, the Government of India envisages to propel successful innovation through augmentation of incubation and R&D efforts.

In order to augment the incubation and R&D efforts in the country, the Government has envisaged to set up/ scale up 31 centres (to provide facilities for over 1,200 new Startups) of innovation and entrepreneurship at national institutes, including setting-up 13 Startup centres wherein annual funding support of INR 50 lakhs (shared 50:50 by DST and MHRD) is being provided for three years for encouraging student driven Startups from the host institute.

The Government has also planned Setting-up/ Scaling-up 18 Technology Business Incubators (TBIs) at NITs/IITs/IIMs etc. as per funding model of DST with MHRD providing smooth approvals for TBI to have separate society and built up space.[16,17]

iv. Setting up of 7 New Research Parks Modeled on the Research Park

To propel successful innovation through incubation and joint R&D efforts between academia and industry, the Government has envisaged to set up 7 new Research Parks with an initial investment of INR 100 crore each. The Research Parks will be modeled based on the Research Park setup at IIT Madras.

The IIT Madras Research Park endeavors to enable companies with a research focus to set up a base in the Park and leverage the expertise of IIT Madras. The Research Park breaks down the traditional, artificial barriers of innovation through its connectivity and collaborative interaction. This helps industry to create, integrate and apply advancements in knowledge. It leverages best practices from successful Research Parks such as those at Stanford, MIT and Cambridge.

The guiding principles behind the park include:
- Creating a collaborative environment between industry and academia through joint research projects and consulting assignments.
- Creating a self-sustaining and technologically fertile environment.
- Encouraging and enabling R&D activities and Startups that are aligned to potential needs of the industry.
- Providing world class infrastructure for R&D activities and incubation.
- Enabling development of high quality personnel and motivating professional growth for researchers in companies through part time Masters and PhD Programs.

The present status is as follows:

New incubation centres are being established under Atal Innovation Mission across India through financial support. The incubators will provide necessary infrastructure and assistance to Startups in their early stages of growth.

NITI Aayog has received applications for setting up Atal Incubation Centres (AICs) in public and private sector as well as scaling up of Established Incubation Centres (EICs). To establish new incubators in institutions as well as in the private sector, NITI Aayog has approved 22 institutes to establish new incubators with a total grant of INR 54 Crores.

A grant-in-aid of INR 10 crore is being provided to each Established Incubator Centre (EIC) for a maximum of 5 years to cover the capital and operational costs in running a centre. 8 established incubators have received a total scale-up grant of INR 34 crore so far.

2.2.4 Funding Support And Incentives-Start-Ups

One of key challenges faced by Startups in India has been access to finance. Often Startups, due to lack of collaterals or existing cash flows, fail to justify the loans. Besides, the high risk nature of Startups wherein a significant percentage fail to take-off, hampers their investment attractiveness.

In order to provide funding support to Startups, Government has set up a fund with an initial corpus of INR 2,500 crore and a total corpus of INR 10,000 crore over a period 4 years (i.e. INR 2,500 crore per year). The Fund is in the nature of Fund of Funds, which means that it will not invest directly into Startups, but shall participate in the capital of SEBI registered Venture Funds.

Key features of the Fund of Funds are highlighted below:

- The Fund of Funds will be managed by a Board with private professionals drawn from industry bodies, academia, and successful Startups
- Life Insurance Corporation (LIC) will be a co-investor in the Fund of Funds
- The Fund of Funds will contribute to a maximum of 50% of the stated daughter fund size. In order to be able to receive the contribution, the daughter fund should have already raised the balance 50% or more of the stated fund size as the case maybe. The Fund of Funds will have representation on the governance structure/ board of the venture fund based on the contribution made.
- The Fund will ensure support to a broad mix of sectors such as manufacturing, agriculture, health, education, etc.

The present status is as follows:

As per the Start-up India status report 2018, a 'fund of funds' of INR 10,000 crores to support innovation driven Startups has been established which is being managed by SIDBI. The corpus shall be released over two Finance Commission cycles, by 2025. FFS invests in SEBI registered   Alternative Investment Funds (AIFs) which, in turn, will invest in Startups. INR 600 crore has been released to SIDBI. Further, a letter of comfort for INR 1600 crore has been provided to SIDBI. Total commitments stand at INR 1611 crore to 32 AIFs. 170 Startups have received funding from various AIFs.

2.2.5 Intellectual Property Facilitation Initiatives

This initiative aims to promote awareness   and   adoption   of   IPRs by Startups and facilitate them in protecting and commercializing the IPRs by providing   access   to   high quality   Intellectual   Property   services   and resources, including fast-track examination of patent applications and rebate in fees.

Intellectual Property Rights (IPR) are emerging as a strategic business tool for any business organization to enhance industrial competitiveness. Startups with limited resources   and manpower, can sustain in this highly

competitive world only through continuous growth and development oriented innovations. For this, it is equally crucial that they protect their IPRs. The scheme for Startup Intellectual Property Protection (SIPP) is facilitating filing of Patents, Trademarks and Designs by innovative Startups. The details about the SIPP Scheme of the Government of India is placed at **Annexure 1.** Various measures being taken in this regard include:

- **Fast-tracking of Startup patent applications:**

  The valuation of any innovation goes up immensely, once it gets the protective cover of a patent. To this end, the patent application of Startups are being fast-tracked for examination and disposal, so that they can realize the value of their IPRs at the earliest possible.

- **Panel of facilitators to assist in filing of IP applications:**

  For effective implementation of the scheme, a panel of "facilitators" have been empanelled by the Controller General of Patents, Designs and Trademarks (CGPDTM), who shall also regulate their conduct and functions. Facilitators are responsible for providing general advisory on different IPRs as also information on protecting and promoting IPRs in other countries. They also provide assistance in filing and disposal of the IP applications related to patents, trademarks and designs under relevant Acts, including appearing on behalf of Startups at hearings and contesting opposition, if any, by other parties, till final disposal of the IPR application.

- **Government to bear facilitation cost:**

  Under this scheme, the Central Government bears the entire fees of the facilitators for any number of patents, trademarks or designs that a Startup may file, and the Startups have to bear the cost of only the statutory fees payable.

- **Rebate on filing of application:**

  Startups are provided 80% rebate in filing of patents *vis-a-vis* other companies. This will help them to spare costs in the crucial formative years.

The present status is as follows:

A panel of 427 facilitators for patent and design applications and 670 facilitators for Trademarks applications has been constituted for assistance in filing Intellectual Property (IP) applications and to fast track the process of patent filing and acquisition as on December 2018. DIPP bears the facilitation cost on behalf of Startups and also provides rebate in the statutory fee for filing application.

Under the SIPP scheme, Patent applicants have received the benefit of up to 80% rebate in patent fees and free legal assistance. Startups have also availed benefit of fees rebate in expedited examination filing fees (Form 18(A)). Trademark Rules, 2017 has been recently amended to provide 50% rebate in Trademarks filing fee to Startups. Overall, more than 2,000 Startup cases have been facilitated under the scheme.

2.2.6 Facilitating Public Procurement

Relaxed Norms of Public Procurement for Startups are being envisaged and are being implemented by the Government.

To provide an equal platform to Startups (in the manufacturing sector) *vis-à-vis* the experienced entrepreneurs/ companies in public procurement

Typically, whenever a tender is floated by a Government entity or by a PSU, very often the eligibility condition specifies either "prior experience" or "prior turnover". Such a stipulation prohibits/ impedes Startups from participating in such tenders.

At present, effective April 1, 2015 Central Government, State Government and PSUs have to mandatorily procure at least 20% from the Micro Small and Medium Enterprise (MSME).

In order to promote Startups, Government shall exempt Startups (in the manufacturing sector) from the criteria of "prior experience/ turnover"

without any relaxation in quality standards or technical parameters. The Startups will also have to demonstrate requisite capability to execute the project as per the requirements and should have their own manufacturing facility in India.

The present status is as follows:

To create a conducive ecosystem for growth of Startups and provide an equal platform to Startups vis-à-vis the experienced entrepreneurs/companies in public procurement, relaxed norms of public procurement for micro and small enterprises have been provisioned in the Procurement Policy of Ministry of Micro, Small and Medium Enterprises (MSME). Department of Expenditure has also notified that all Central Ministries / Departments shall relax condition of prior experience and prior turnover in public procurement to all Startups (whether MSEs or otherwise) subject to meeting of quality and technical specifications. Department of Public Enterprises has expanded the relaxation to Central Public Sector Undertakings (CPSUs). GFR 2017 has incorporated rules which provide for relaxation of conditions of prior turnover, prior experience and exemption from submission of Earnest Money Deposit (EMD) for Startup

2.2.7 Mission Programs To Boost Innovation And Startups

Various mission programs have been proposed to be initiated under the Start-up India Action plan of the Government. One of the key programmes being launched and is being implemented under this initiative is the **Atal Innovation Mission (AIM) with Self-Employment and Talent Utilization (SETU) Programme.**

This initiative aims to serve as a platform for promotion of world-class Innovation Hubs, Grand Challenges, Startup businesses and other self-employment activities, particularly in technology driven areas

The Atal Innovation Mission (AIM) shall have the following core functions:

- Entrepreneurship promotion through Self-Employment and Talent Utilization (SETU), wherein innovators would be supported and mentored to become successful entrepreneurs

- Innovation promotion: to provide a platform where innovative ideas are generated The main components proposed to be undertaken as part of the mission include.

- Entrepreneurship promotion:

- Establishment of sector specific Incubators including in PPP mode

- Establishment of 500 Tinkering Labs

- Pre-incubation training to potential entrepreneurs in various technology areas in collaboration with various academic institutions having expertise in the field

- Strengthening of incubation facilities in existing incubators and mentoring of Startups

- Seed funding to potentially successful and high growth Startups

- Institution of Innovation Awards (3 per state/UT) and 3 National level awards

- Providing support to State Innovation Councils for awareness creation and organizing state level workshops/conferences

- Launch of Grand Innovation Challenge Awards for finding ultra-low cost solutions to India's pressing and intractable problems

The present status is as follows:

- **ATAL INNOVATION MISSION:**

  As on December 2018, the guidelines for harnessing private sector expertise to set up incubators, organizing annual grand challenge for innovative solutions to problems faced by industry and those posed by Ministries as well as establishment of tinkering labs have been formulated and published on NITI Aayog's and Startup India's website.

- **ESTABLISHMENT OF TINKERING LABS**

  As per the Startup India Action Plan, more than 5000 Tinkering Labs are being established. NITI Aayog has selected **5441** schools for establishing

Tinkering Labs. Out of the selected, **2071** Tinkering Labs have received a Grant-in-Aid of INR **12** Lakh each.

2.2.8 Promoting Startups In The Biotechnology Sector

The Biotechnology sector in India is on a strong, growth trajectory. Department of Biotechnology endeavors to scale up the number of Startups in the sector by nurturing approximately 300-500 new Startups each year to have around 2,000 Startups by 2020. In order to promote Startups in the sector, The Department of Biotechnology shall be implementing the following measures along with its Public Sector Undertaking Biotechnology Research Assistance Council (BIRAC):

- **Bio-incubators, Seed Fund and Equity Funding:**
  5 new Bio-clusters, 50 new Bio-Incubators, 150 technology transfer offices and 20 Bio-Connect offices will be set up in research institutes and universities across India.

  Biotech Equity Fund – BIRAC AcE Fund in partnership with National and Global Equity Funds (Bharat Fund, India Aspiration Fund amongst others) has been set up to provide financial assistance to young Biotech Startups.

- **Encouraging and leveraging global partnerships:**
  Bengaluru-Boston Biotech Gateway to India has been formed. Letter of Intent has been signed between DBT, GoI and Department of IT, Government of Karnataka for the same. Through this initiative, a range of institutes in Boston (Harvard/ MIT) and Bengaluru will be able to connect to share ideas and mentor the entrepreneurs especially in the areas of Genomics, Computational Biology, Drug Discovery and new vaccines.

- **Amplification of Bio-entrepreneurship through BIRAC Regional Entrepreneurship Centres (BREC).**

  The BREC aims to impart bio-entrepreneurs with the necessary knowledge and skills required for converting innovative ideas into successful ventures. Department of Biotechnology shall set up 5 Regional centres or Mini-BIRACs shall be established in the next 5 years.

- **Technology Business Incubators (TBIs)**

  The objective is to propel successful innovation through augmentation of incubation and R&D efforts.

The present status is as follows:

- Under Biotech seed fund, INR 11 crore has been sanctioned and INR 7 crore disbursed to 11 Bio-incubators. A fund of funds with a corpus of INR 150 Cr has been approved. A total of 31 bio-incubators have been supported (sanction amount of INR 235 Cr) by DBT. The impact has been multi-fold as over 710 Startups have received benefits from these bio-incubators under various programmes like Biotechnology Ignition Grant, IIPME (Industry Innovation Programme on Medical Electronics), Sparsh, Grand Challenges, BioNEST, etc.

- 3 BIRAC Regional Centres have been operationalized in Hyderabad, Bengaluru and Pune.

- 4 (out of 5) bio clusters have been sanctioned INR 401 Cr by DBT. 4 entrepreneurs have joined the Harvard University, USA under Bharat-Boston Biotech Gateway.

- 15 Technology Business Incubators (TBIs) are being set up in top educational institutes. 11 TBIs have been approved and other 4 are in advanced stages.INR 42 crore has been sanctioned and INR 17 crore has already been disbursed to 11 TBIs.

Figure 2: Start-up Ecosystem in India

2.3   INITIATIVES BY GOVERNMENT OF INDIA MINISTRIES/ DEPARTMENTS

Besides the umbrella Start-up India initiative which promotes generation of start-ups in all domains, a wide spectrum of new programmes and opportunities have been initiated by the Government of India ministries and departments to foster a culture of innovation and entrepreneurship across a number of sectors in the country. These initiatives include funding schemes for generation of proof-of-concept, validation, contract research, infrastructure support, mentorship, support for intellectual property protection, handholding support for capacity building, etc. Several schemes also foster public-private

partnerships for facilitating expeditious translation of innovations from lab to market.

These initiatives also forge the engagement of all stakeholders ranging from academia, industry, investors, small and big entrepreneurs, non-governmental organizations to the most underserved sections of society. Recognising the importance of women entrepreneurship and economic participation in enabling the country's growth and prosperity, the government also seeks to bring women to the forefront of India's entrepreneurial ecosystem by providing access to loans, networks, markets and trainings. The section below provides a compilation of information on various schemes of Indian government agencies particularly relevant to science and technology.

2.3.1 Funding Initiatives

The Government of India through its scientific and industrial agencies offers an array of policies, initiatives and incentives for technology development, from early-stage development to full-scale commercialization, for the benefit of the biotechnology entrepreneurs. The Government grants are mostly in the form of grant-in-aid or soft loans. A number of national agencies i.e. Department of Biotechnology (DBT), Department of Science and Technology (DST), Department of Scientific & Industrial Research (DSIR), Council of Scientific & Industrial Research (CSIR), Ministry of Micro Small Medium Enterprises (MSME), National Research Development Corporation (NRDC), Defence Research & Development Organization (DRDO), Technology Information, Forecasting and Assessment Council (TIFAC), etc. have been supporting biotech start-up companies as well as academia in various areas of biotechnology with a view to strengthen innovative R&D and technology development. Several international India-specific Grand Challenges i.e. Wellcome Trust, Bill & Melinda Gates Foundation, Lockheed Martin Corporation, Grand Challenges Canada and bilateral/multi-lateral programmes with other countries also support innovative technology development in India.[10-16]

This section covers funding opportunities which can be availed through Government of India grants and private funding through VCs and Angel Investors.[19]

A. Government of India Funding Opportunities

B. Private Funding through Investors

A. Government of India Funding Opportunities

Some of the key funding schemes which can be availed by the company and key programme of the Government of India to promote bioentrepreneurs are given below:

i.   **Biotechnology Ignition Grant (BIG)**

1. The BIG scheme of the BIRAC, Government of India enables technology innovators and entrepreneurs to pursue a promising technology idea, and establish and validate proof of concept (POC) for the idea. By funding establishment and validation of POC, BIRAC wishes to help innovators and entrepreneurs advance an idea closer to eventual commercialization/implementation in the form of technology licenses or creation of start-up companies or raising investments for the company. The scheme aims to support high-risk technology ideas with considerable potential for impact. It aims to support projects that aim to establish or validate proof of concept for a promising and innovative technology idea and to promote the creation of new start-ups based on innovative technology ideas and/or to support early start-ups to establish and validate their technology ideas up to the POC stage. The funding of upto Rs 50 lakhs can be granted under this scheme. The weblink http://www.birac.nic.in/big.php could be accessed to view further details.

ii. **Biodesign Innovation and Translation**

Realizing the need to foster and promote development of indigenous affordable medical technologies in India and to promote entrepreneurship, Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India initiated and supported a handful of Biodesign Programs in India including Stanford-India Biodesign (SIB) Programme, Healthcare Technology Innovation Centre, IIT, Madras, Centre for Biodesign, Translational Health Science And Technology Institute (THSTI), Faridabad, Biodesign-Bioengineering Programme, India Institute of Science, IISc., Bangalore, and National Biodesign Alliance. Of these programmes, the model of Stanford India Biodesign Programme initiated in collaboration with Stanford University, USA in the year 2007 has been one of the most successful models, particularly in creation of 'First Generation Entrepreneurs'. This Program is aimed to focus on training of Indian Fellows at Stanford for 6 months followed by the second phase of fellowship in India wherein the Fellows apply their learnings from Stanford to identify the unmet medical needs specific to India. The Fellows further help in the wider dissemination of the knowledge gained, by training a team of interns in the Indian phase of their Fellowship. The SIB Program has been successful in training more than 50 fellows and interns each and development of novel biomedical technologies protected through a robust IP portfolio. Several products developed under the programme have been commercialized by the Fellows – turned entrepreneurs and are available in market. In view of the success of the program, the fellowship has now been indigenized with foreign fellows from leading universities in other countries such as Australia and Japan now coming to India for training in Biodesign. The programme has now been renamed as School of International Biodesign (SIB). For details, please visit http://www.dbtindia.nic.in/stanford-india-biodesign-sib-programme/.

Considering the large population of India and the corresponding unmet medical needs, this model may be a useful tool to alleviate medical device import dependency of India in an expedited manner.

iii. **Social Innovation Immersion Program (SIIP)**

SIIP is BIRAC's social innovation fellowship/award program aimed at creating a pool of biotech "Social Innovators" who can identify needs & gaps within communities and then can help bridge the gaps either through an innovative product development or services.

The immersion programme is a unique social innovation platform which provides the opportunity for clinical and rural immersion and also funding support for developing the prototype through mini kick start grant apart from the monthly fellowship to young social innovators.

The programme has already developed clusters across the nation on three thematic areas "Maternal and Child Health" "Ageing and Health" and "Waste to value".Most of the Social innovators who are mentored through the program have been successful in raising the follow-on funding or starting their own enterprise.The programme is implemented through BIRAC SIIP partners and is mentored through BIRAC SIIP knowledge partner (http://www.birac.nic.in/desc_new.php?id=395).

Till date, the programme has been successful in creating clusters in the domain of "Maternal and Child Health", "Ageing and Health" and "Waste to Value" across the nation, mentoring 35 social innovators, identifying and nurturing more than 70 novel solutions and developing 12 prototypes against society's most pressing problems.

iv. **Social Innovation Program for Products (SPARSH)**

This programme aims to foster development of technologies/ healthcare solutions which are affordable & relevant to societal health. The programme aims at promoting the development of innovative solutions to society's most pressing social problems. The scheme tackles major social issues and offer new ideas for widespread change. The scheme aims to invest in ideas and innovations that improve health care of all Indians and encourage affordable product development in the social sector.

The scheme intends to create a pool of social innovators in the biotech arena who will identify the specific needs and gaps in healthcare. The social innovators are provided financial and technical support for developing market-based solutions that have potential to bring cost effective health care breakthroughs to vulnerable populations in particular.

The scheme aims to identify and provide support to cutting edge innovations towards affordable product development that can bring significant social impact and address challenges of inclusive growth, provide support in the form of impact funding of biotech product innovations (with social goals) that can be scaled. It also aims to create and foster a pool of social innovators in the field of biotech and provide a platform to share the best practices, understand intricacies of business models in social innovation and network. Further details can be obtained from http://www.birac.nic.in/desc_new.php?id=110.

Till date, 7 prototypes, 3 products and 2 technologies of social relevance have been developed through this programme.

v.   **Sustainable entrepreneurship and enterprise development fund (SEED fund):**
SEED Fund is to help cover the first Valley of Death for Startups and help them to become investible. Bio-incubation allows harnessing of the entrepreneurial potential of startups by providing access to infrastructure, mentoring as well as networking platforms that the startups could use during their fledgling days. It helps the young entitites to survive by providing them specialised support services during the critical period of a business venture i.e. the start-up phase.

While the Bioincubators are able to support the "Space, Services and Knowledge" requirements of startups, wide gap exists in financial support required by a technology driven start up in the initial phase.

BIRAC's initiative -Sustainable Entrepreneurship and Enterprise Development Fund ("SEED Fund") primarily aims to address this need through the Incubators.

The basic idea of SEED Fund is providing Capital assistance to startups with new and meritorious ideas, innovations and technologies. This would enable some of these start-ups to graduate to a level where they will be able to raise investments from angel/Venture capitalist or they will reach a position to seek loans from commercial banks /financial institutions. Thus the proposed seed support is positioned to act as a bridge between promoters' investment and Venture/Angel investment. This is not an investment scheme, but, rather a support scheme to enable start-ups and incubator to attain sustainability.

Under Incubator SEED Fund, BIRAC provides Grant-in-aid Assistance to selected BIRAC funded incubators based on certain establishment and operational criteria. Initially BIRAC shall identify up to five incubators and expand further in due course. Each such selected incubator is granted up to 200.00 Lakhs for implementation of SEED Fund. Each incubator can design a selection process to screen & select startups for equity and operational funding through SEED Fund (e.g Accelerator program or Direct investment). The provisions stated above deal with the essential guiding principles of the initiative. For further details, please visit http://www.birac.nic.in/seedFund.php.

vi. **Accelerating Entrepreneurs (ACE) Fund:**
Biotech start up journey, especially for first time entrepreneurs, is full of hurdles, both technological as well as business related such as business plan and market entry strategies, navigating regulatory hurdles, connecting and pitching to VCs and networking with future stakeholders. There is a greater realisation within the biotech community regarding the importance of focused mentorship which can help accelerate nascent biotech start up. BIRAC is therefore designing and implementing an equity based fund for supporting entrepreneurs in

the valley of death. Biotechnology Innovation Fund – AcE (Accelerating Entrepreneurs) Fund is an equity "Fund of Fund" exclusively for Biotech Start-ups. AcE daughter funds are SEBI registered private funds to invest equity in start-ups for providing the risk capital to undertake innovation, research and product development (http://www.birac.nic.in/aceFund.php).

- The AcE Fund makes a maximum capital commitment of up to Rs 30 crores or up to 30% of the total aggregate capital commitment amount(i.e. fund corpus) in each AcE daughter Fund
- The assistance to a start-up is provided up to INR 7 crores against equity
- The AcE daugher fund invests at least twice the amount contributed by BIRAC's AcE Fund into Biotech/Life Sciences sector start-ups

vii. **Students Innovations for Advancement of Research Explorations (SITARE)**

This scheme is a collaborative effort of BIRAC with Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI), a non-profit organization based at Ahmedabad, Gujarat for fostering grass root level innovations at the university/college level among the students. This scheme entails the following two categories of grant awards:

- *BIRAC-SRISTI GYTI Awards*: 15 entrepreneurial ideas at the university level are selected from across India every year and nurtured for 2 years *in situ* with a grant of INR 15 lakhs each.

- *BIRAC-SRISTI Appreciation Awards*: Hundred (100) young innovators are awarded INR 1 lakh every year to take their innovations to next level. The objective is to inculcate the sense of entrepreneurship among the young students who can be motivated to take their innovations to commercial levels.

More information is available at http://www.birac.nic.in/desc_new.php?id=261.

viii. **E-YUVA**

This programme focuses on applied research and need-oriented (societal or industry) innovation among researchers and to catch them young, provide professional mentoring and support needed. BIRAC has a strategic action plan to foster the culture of innovation and techno-entrepreneurship in Indian Universities, leveraging the University Innovation Cluster (UIC) and Cluster Innovation Centre (CIC) model. Five University clusters as mentioned below have been identified to establish Cluster Innovation Centres:

- Anna University, Chennai
- Panjab University, Chandigarh
- Tamil Nadu Agricultural University, Coimbatore
- University of Rajasthan, Jaipur
- University of Agricultural Sciences, Dharwad

Further details could be viewed at http://www.birac.nic.in/desc_new.php?id=262.

ix. **Promoting innovations in Individuals, Start-ups and MSMEs (PRISM)**

The scheme aims at transforming an individual innovator into a successful Technopreneur by promoting, supporting, funding untapped creativity of individual innovators. PRISM is for budding students, professionals and common citizens interested in innovation and having an implementable and commercially viable, novel innovation. This scheme was earlier known as "Technopreneur Promotion Programme" (TePP). Thrust areas include green technology, clean energy, industrially utilizable smart materials, waste to wealth, affordable healthcare, water & sewage management and any other technology or knowledge intensive area. The maximum support for generating proof of concept and prototype development is Rs. 2.00 lakhs, for innovation

incubation is Rs. 20.00 lakhs; and for enterprise incubation is Rs. 50.00 lakhs. Specific details of the scheme are available at http://www.dsir.gov.in/#files/12plan/prism/prism.html.

x. **Patent Acquisition and Collaborative Research and Technology Development (PACE)**

This scheme of the DSIR provides catalytic support to industries and institutions for development and demonstration of innovative product and process technologies, traversing the journey from proof of concept or laboratory stage to pilot stage, so that they can be launched for commercialization. The scheme supports ingenious work and assists in development of new technologies or creative/innovative application of the existing technologies to solve unmet needs of industry. The scheme also strengthens the interface between industry, R&D establishments and academic institutions by supporting collaborative proposals. The scheme supports industry to develop and demonstrate the technology (either acquired technology or its own indigenous in-house technology) alone or in collaboration with R&D organizations/ academic institutions/ universities. The weblink http://www.dsir.gov.in/#files/12plan/pace/pace.html can be accessed for further information.

xi. **Techno-Commercial Support for Promising Inventions / Innovations**

This support is provided by the National Research Development Corporation (NRDC). There are number of value additions required for the laboratory scale technologies to be acceptable by the industry. The objective of this program is to provide essential support to the applicants for overcoming minor issues like testing of the product, authentication of results in field conditions, improvement of prototypes and preparation of comprehensive know-how document. Under this scheme, NRDC provides techno-commercial support to Indian inventors / scientists / technocrats / NRDC Awardees / NRDC Licensees, etc to make the developed technology marketable and

acceptable to entrepreneurs and industries. The techno-commercial support is provided for the following purposes:

i) Improvements in prototypes to make it commercially acceptable
ii) Carrying out process trials / field trials / testing / analysis
iii) Preparation of a pre-feasibility report
iv) Preparation of video or animation film about working of the invention
v) Preparation of comprehensive know-how document
vi) Demonstration of the technology (in deserving cases only)

Indian inventors, scientists, technocrats, etc. having promising, technically feasible & commercially viable invention/innovation are eligible to seek support under this scheme. Category-wise funding support in the range of Rs. 25,000 to Rs. 2 Lakhs can be availed (http://www.nrdcindia.com/english/index.php/technology-management/2014-03-27-09-50-15/techno-commercial-support).

xii. **New Generation Innovation and Entrepreneurship Development Centre (NewGen IEDC)**
The programme is managed by National Science and Technology Entrepreneurship Development Board (NSTEDB), of the DST.[18] NewGen IEDC aims to inculcate the spirit of innovation and entrepreneurship amongst the young S&T students, encourage and support start-up creation through guidance, mentorship and support. The programme is implemented for a period of 5 years in academic institutions to create a culture of entrepreneurship. A maximum of twenty new projects are supported in a year. Students are encouraged to take up innovative projects with possibility of commercialization. Few amongst the "Job-Seekers" are expected to be converted to "Job Generators" through the entrepreneurial route under this programme. Specifications of the scheme are available at http://www.nstedb.com/institutional/edc.htm.

B. Private Funding through Investors

i.   Venture Capital Funding:

Another source of funding for driving innovations is risk capital. Risk Capital is an option where the provider reduces the burden of risk of the entrepreneur and thereby bears some part of the overall risk involved in technology translation. Risk Capital is an important instrument for not only start-ups and innovative / fast growing companies but is also critical to those companies looking at growth. Risk capital substitutes promoter's contribution, thereby reducing the capital to be brought by the entrepreneurs.[19] As per an annual report on Indian venture capital and private equity on startups released by IIT-Madras, only 8.3% of startups are successful in getting funding. The percentage of funded companies globally is about 36 - 52%, against the Indian startups which are about 5-11%. For example the Tata Capital Innovations Fund is a venture capital fund managed by Tata Capital. The Fund invests in the range of US$ 2 million to US$10 million in early stage companies offering technology based solutions for Indian as well as global markets. The Fund's investment philosophy is to back the right entrepreneurial spirit by identifying investments which have a potential to create new growth opportunities; increase efficiency; bring affordability and accessibility to the industry or change the way business is conducted. The Government has also initiated a venture capital fund as public-private partnership to support entrepreneurships through innovative technologies such as the Bharat Innovation Fund, Micro Venture Innovation Fund (MVIF) and India Inclusive Innovation Fund. A list of key venture capital funding opportunities in India is provided in Table 1.

Table 1		
Key Venture Capitals and Angel investors in India		
Scheme	**Organization**	**Type of funding**
TEX Fund	SIDBI Venture Capital Limited	Equity
India Opportunities Fund	SIDBI Venture Capital Limited	Equity
Setu Ventures	Setu Ventures	Equity
Venture Factory	i2india Ventures	Equity
Infuse Venture Fund	I3E Trust	Equity
Seed funding	Villgro Innovations Foundation	Other
BSE SME Platform	BSE Ltd	Equity
Centre for Innovation Incubation and Entrepreneurship	Centre for Innovation Incubation and Entrepreneurship	Other
Support for International Patent Protection in E&IT	Department of Electronics and Information Technology	Other
Omnivore Capital Management Advisors Private Limited	Omnivore Capital Management Advisors Private Limited	Equity
Unitus Seed Fund	Unitus Seed Fund	Equity
TIFAC -SIDBI Revolving Fund for Technology Innovation	TIFAC – SIDBI	Debt
SAMRIDHI Fund	SIDBI Venture Capital Limited	Equity
Small Business Innovation Research Initiative(SBIRI) Phase II	Biotechnology Industry Research Assistance Council (BIRAC)	Debt
Micro Venture Innovation Fund (MVIF)	National Innovation Foundation (NIF)	Debt
Seed Fund	ICICI Knowledge Park (IKP)	Other
Various financing schemes	National Bank for Agriculture and Rural Development	Debt
Omnivore Partners	Omnivore Partners	Equity
Bharat Innovation Fund	Centre for Innovation Incubation and Entrepreneurship	Equity
Amity Innovation Fund	Amity Capital Ventures	Equity
BIRAC-CEFIPRA Partnership	Biotechnology Industry Research Assistance Council (BIRAC)	Equity
Global Innovation & Technology Alliance (GITA)	Global Innovation & Technology Alliance (GITA)	Other
NSTEDB Seed Fund	Entrepreneurship Development Center	Equity
TDB Seed Fund	Entrepreneurship Development Center	Equity

Various financing schemes	Department of Science and Technology, Govt. of India	Other
Seed Support System of NSTEDB, DST	IIT Kharagpur	Equity
NSTEDB and other Seed Support Scheme	SIDBI Innovation and Incubation Centre, IIT Kanpur	Other
Seed Support System of NSTEDB, DST	TBI - KIET Ghaziabad	Other
Seed Support System of NSTEDB, DST	KIIT Technology Business Incubator, Bhubaneshwar	Other
Seed Support System	Society for Innovation and Entrepreneurship SINE – IITB	Other
Utthishta Yekum Fund	Utthishta Management Advisors LLP	Equity
Angel Investment Network	Intellecap Impact Investment Network (I3N or I-cube-N)	Equity
VENTUREAST TENET FUND	Ventureast	Equity

The Bharat Fund, a public-private-academia partnership has been set up by Centre for Innovation Incubation and Entrepreneurship (CIIE) of IIM Ahmedabad. The fund aims to support and provide funding (grants, seed capital, venture capital) and business support to innovation-driven start-ups that solve real problems faced by the masses of India through technology-enabled and rapidly scalable solutions. This fund primarily focuses on healthcare and life-sciences sustainability and digital technologies.

Micro Venture Innovation Fund (MVIF) is the first and unique micro-venture risk fund in the world, which provides funding to grassroot innovators under a single signature on a simple agreement of understanding, without any collateral or a guarantor. MVIF invests in risk areas with a probability of high failure, investing in those technologies and products for which either market does not exist or may be very limited. Apart from the financial returns, one of the key criteria for selection of a technology for MVIF support is social return or social value created for the benefit of society at large. India Inclusive Innovation Fund focuses on providing risk capital

funding to enterprises that create and deliver technologies and solutions aimed at enhancing the quality of life at the bottom of the Pyramid; and subject to applicable law work with other funds with objectives similar to its own. The Fund supports investment at different stages of the enterprise development cycle – from early stages, through later phases of scaling-up of potentially successful solutions and business models.

ii. **Funding from Angel Investors**

Many prominent companies, including Google, Yahoo and Alibaba have come with funding support from Angel investors. Though, Angel investors generally invest lesser amounts than venture capitalists, this alternative form of investing generally occurs in a company's early stages of growth, with investors expecting upto 30% equity. They prefer to take more risks in investment for higher returns. Some examples of popular Angel Investors in India are Indian Angel Network, Mumbai Angels, Hyderabad Angels etc. Some of these active angel investors have invested in many successful startups. Table 1 above summarises the key VC and Angel investors in India.

2.3.2 Infrastructure Support

To promote innovations and investments in biotechnology, biotech parks, technology incubators and special economic zones have been set up in India to promote technology incubation and scale up as well as manufacturing activities by providing infrastructure support, facilities and incentives so as to minimize the above constraints for technology development, commercialization and large-scale manufacturing. The key infrastructure initiatives of the Government being implemented through various Departments are given below:

i. Technology Business Incubators (TBIs)

Technology Business Incubators not only facilitate the setting up of startups which are technology-based and knowledge-driven but also to nurture their growth by providing them with the necessary platform required for their growth and establishment as successful enterprises. TBIs emerged in the 1950s, and have proliferated around the world, often supported by governments as a means of spurring economic development. In India, DST, Government of India first invested in Science and Technology Entrepreneurs Parks (STEPs) in the 1980s, and then from the early 2000s, in Technology Business Incubators (TBIs). DST has so far funded over 60 TBIs. Most are based within academic institutions, but some are public-private partnerships with other types of 'host' organisations, such as the Indian Angel Network. India also has a growing number of private incubators, set up by entrepreneurs, investor networks and corporations.

Bioincubators Nurturing Entrepreneurship for Scaling Technologies (Bio-NEST), as scheme of the BIRAC, DBT provides incubation support focused on fostering the biotech innovation ecosystem in the country. Bio-NEST program provides support to establish bio-incubators either as a standalone entity or as a part of the academia. Through Bio-NEST, BIRAC has supported 36 bio-incubators so far creating a cumulative area of 391849 sq. ft. for budding entrepreneurs. Details of the scheme are available at http://www.birac.nic.in/bionest.php.

There are different types of incubators based on the way they deliver their services, in their organizational structure and in the type of clients they serve. The different types of incubation models available in India to support young entrepreneurs are listed below:

S. No.	Model	Key Features
1	Support-led incubation	Rolling application process, or one or more application deadlines each year. Tailored, individual support (sometimes alongside group or peer support) provided

		by staff or external mentors. Sometimes, but not always, time-limited. Seed funding sometimes provided.
2	Impact accelerators	Seed funding sometimes provided. Open, competitive application process. Upfront investment, usually in exchange for equity. Time limited (e.g. three-six months) with intensive support, including events and mentoring. 'Cohorts' of startups, rather than individual companies. Periodic graduation, with Demo Day/Investor Day.
3	Classic incubator workspace	Rolling application process. Office or desk space and access to shared facilities like meeting space. Strategic advice, coaching or mentoring. Seed funding or opportunities to apply for investment sometimes provided.
4	Co-working spaces	Flexible desk and meeting space. Opportunities to meet other ventures or entrepreneurs. Programme of events or learning.
5	Social venture academies	Modules or training delivered through classes specifically aimed at social entrepreneurs or ventures (but not part of a wider qualification like a degree).
6	Impact angel networks	Group of high-net-worth individuals looking to invest, sharing cost and process of search and due diligence. Investment, plus mentoring, support and connections.
7	Prizes and competitions	Widespread publicity for the prize and its aims. Shortlisting by competition organisers. Pitching or face-to-face 'final'. Follow-up support and publicity for the winners.

DST has instituted National Initiative for Developing and Harnessing Innovations (NIDHI) as an umbrella programme for nurturing ideas and innovations (knowledge-based and technology-driven) into successful startups. Under this umbrella, NIDHI-PRomoting and Accelerating Young and ASpiring technology entrepreneurs (PRAYAS) is a scheme to promote and accelerate young and aspiring innovators & startups. It is a pre-incubation support programme that allows the innovators to try their ideas without fear of failure, hence allowing them to reach a stage where they

have a ready product and are willing to approach incubators for commercialization. The programme facilitates prototype funding to an innovator for a maximum amount of Rs. 10 lakhs with a cap of supporting 10 such innovators per year. It also provides a dedicated fabrication lab facility to the innovators funded under this scheme for developing their prototype. The key objectives of this programme are as follows:

- To enable translation of an innovative idea to a prototype.
- To provide a platform for faster experimentation and modify approaches in the idea to market journey.
- To generate innovative solutions relevant to the local and global problems.
- To attract a large number of youth who demonstrates problem solving zeal and abilities to work on their new technology/knowledge/innovation based startups.
- To enhance the pipeline in terms of quality and quantity of Innovative start ups to the incubators.

Entrepreneurs-in-Residence (EIR) Programme is one of the programs introduced under NIDHI to inspire the best talents to be entrepreneurs, to minimise the risk involved in pursuing start- ups, and to partially set off their opportunity costs of high paying jobs. The NIDHI-EIR programme provides opportunities for innovative entrepreneurs to expand their networks and get critical feedback on their ventures in order to promote their entrepreneurial career goals and aspirations. It provides fellowship grant to budding entrepreneurs for pursuing a promising technology business idea. Selected entrepreneurs are eligible for a maximum grant of Rs. 30,000 per month for a period of 12 months. The objectives of programme are:

The National Science & Technology Entrepreneurship Development Board (NSTEDB) of the DST provides seed funds in aid to develop an innovative thinking among young brains to turn into successful entrepreneurs. It

facilitates a seed fund of Rs 2 crore under the scheme "Seed Support System for Start-ups in Incubators". The Seed Support is for incubatees who are physical resident units within STEP/TBI. The funds are meant for early stage funding for indigenous ideas and technologies requiring up-scaling and related work. Quantum of financial assistance to the incubated entrepreneur ranges from Rs. 2 lakhs to Rs. 50 lakhs.

ii. Biotech Parks

Bioclusters have been developed by many states with the vision of intrinsic academic and entrepreneurial strengths. Key features of these clusters are Biotech Parks, Biotech policies, fiscal Incentives like tax holidays, capital subsidies and energy concessions, centers of Biotech excellence, specific biotech development funds and incubators etc. Some of the bioclusters in India are Hyderabad, Bangalore and Pune bioclusters.

The concept of Biotech parks has evolved to support the entrepreneurs and technopreneurs initiating their own ventures in biotechnology. Biotech parks are built-up structures with common facilities for smooth initiation and conduct of business. The facilities include physical facilities in the form of office space, dry and wet laboratories, specialized equipment and instrumentation facilities, pilot plant and scale up units and good communication network. In addition, the park provides developed land at cost effective rate for carrying out manufacturing activity. These are suited for technopreneurs who have a technology but are unclear about the commercial viability of the technology. The presence of the core-shared facility helps in reducing capital costs for the clients in the Biotech park as they are able to use state of the art equipment in the facility without having to invest on their own in various fields. The biotech parks generally also have an incubation centre and business facilitation centre to help create economic value.

Both the Central and State Governments are making their earnest efforts to promote biotechnology activities in the country by setting up biotechnology parks, incubators as well as pilot projects through public

private partnership. DBT has supported several biotechnology parks and incubation centres located in different states for the promotion of Biotech start-up companies and the promotion of Public Private Partnerships:

- Lucknow Biotechnology Park, Uttar Pradesh
- Biotechnology Incubation Centre, Genome Valley, Hyderabad, Andhra Pradesh
- Biotechnology Core Instrumentation Facility (BTCIF) at TIDCO Centre for Life Sciences (TICEL), Chennai
- The Golden Jubilee Biotech Park for Women, Siruseri, Kanchipuram District, Tamil Nadu
- Guwahati Technology Incubation Centre (GBPIC) at Biotech Park, Assam
- Bangalore Biotech Park, Karnataka
- KRIBS BioNest, Kochi, Kerala (previously called KINFRA Biotech Park)
- Punjab Biotechnology Incubator, Mohali, Punjab

With the launch of the Startup India initiative, it was also planned by the Government of India to set up seven new research parks to boost innovation and entrepreneurship.

BCIL has assisted 15 State governments for establishment of biotech parks and also extended advisory to some of them. Biotech Parks are an effective platform for promoting biotech entrepreneurship and commercialization of innovative technologies.

iii. **Special Economic Zones (SEZs)**

The SEZs have been conceptualized to attract more capital to enhance economic activity in a location and step up exports. The benefits offered by the government to the developer and the unit-holders through exemptions from all types of taxes and levies have proven to be highly conducive and are the force behind private developers to set up and develop SEZs. The promotion of SEZs is expected to tackle wide range of structural

bottlenecks created by monetary, fiscal, taxation, trade, tariff and labour policies, apart from overcoming complex procedures and infrastructure deficiencies.

India was one of the first countries in Asia to recognize the effectiveness of the Export Processing Zone (EPZ) model in promoting exports, with Asia's first EPZ set up in Kandla in 1965. Subsequently, the SEZ Act, 2005 was enacted with the following salient features:

a) Satisfying the needs of all major stakeholders in an SEZ, including developers, operators, suppliers, residents, etc.,

b) Making provisions of single window clearance mechanism,

c) Providing attractive fiscal incentive package,

d) Establishing free trade and warehousing zones with a view to develop internationally competitive infrastructure facilities to augment import and export of commodities,

e) Setting up of off shore banking units, and

f) Facilitating public private participation towards development of infrastructure.

All details regarding the SEZs of India can be accessed at http://sezindia.nic.in/.

A detailed list of schemes for start-ups initiated by the Government of India is also provided at **Annexure 2.**

2.3.3 Other Platforms For Promotion Of Enterpreneurship

There are several other platforms for budding entrepreneurs to showcase their ideas, seek funding, collaborations and mentorship, some of which are:

a) *Hackathon*

A hackathon is a non-stop product development competition, where problem statements are posed to technology students for innovative solutions. It is a rapid prototyping solutions marathon build by a multi-disciplinary team.

Smart India Hackathon (SIH) is one of the initiatives of the Ministry of Human Resource Development (MHRD) and All India Council for Technical Education (AICTE), Government of India for development a comprehensive mass movement amongst potential entrepreneurs and promote innovate on all fronts. SIH is a unique Open Innovation Model for identifying new and disruptive technology innovations to solve the challenges faced in our country. Such platforms harness creativity and expertise of students; crowdsource solutions for improving governance and quality of life and provide opportunities to potential entrepreneurs. The 2019 version of SIH included the following subject areas:

- Smart Communication- Designing devices which would help in easing communication channels between various communication devices and points

- Healthcare & Biomedical devices- Designing devices that would help in managing healthcare better.

- Agriculture & Rural Development- Designing devices keeping in mind the need to enhance the primary sector of India - Agriculture and the lives of our Rural Population.

- Smart Vehicles- Creating intelligent devices to improve commutation facilities, quality of travel experience and overall travel safety features hardware.

- Food Technology- Creating state of art solutions to manage and process our agriculture produce.

- Robotics and Drones- There is a need design drones and robots that can solve some of the pressing challenges of India such as handling medical emergencies, search and rescue operations, etc.

- Waste management- Solutions could be in the form of waste segregation, disposal, and improved transportation system.

- Clean water- Creating state-of-the-art devices to improve distribution, management and purification of water.

- Renewable Energy- Innovative ideas that help manage and generate renewable sources more efficiently.

- Security & Surveillance- Creating state-of-the-art safety and security technologies for India.

- Miscellaneous- Technology ideas in tertiary sectors like Hospitality, Financial Services, Entertainment, Tourism and Retail.

b) B- plan Pitches

Business plan is a written document describing the nature of the business, the sales and marketing strategy, financial background, and containing a projected profit and loss statement. A business plan is also a road map that provides directions so that a business can plan its future and helps it to avoid bumps in the road. Business plan pitches and competitions are made in forum of investors and promising business plans are offered funding support in these pitches. Many successful businesses are known to have obtained their seed funding through business plan pitches.

c) Technology Fairs

Technology fairs are exhibitions for entrepreneurs in a specific industry to showcase and demonstrate their new products and services. Such fairs provide business opportunity packages for sale. Exhibiting at a trade fair/ trade show is an excellent way to find customers to help a business grow.

The above list of models of entrepreneurship promotion is not exhaustive and need-based development of new models is an ongoing process in all sectors across the world.

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3. BEST PRACTICES FOR MAKING A SUCCESSFUL START-UP IN INDIA

3.1   FORMING A CORE TEAM

3.1.1. Search for core team members prior to identifying a need or a solution in mind

If you already have an idea, make a note of it, keep it aside, and re-understand the problem with the team and see if everyone still arrives at the same solution. This may be difficult to do, but it is very important that everyone in the team believes in the solution and the need.

Often teams break or disintegrate because of unequal contribution toward the development of the device and yet hoping for equal ownership of the invention. This happens when 1 or 2 members initiate the idea and involve others later on, which gives rise to lots of conflicts. Secondly, when an individual already has an idea, the tendency is to look for team members as employees, where they work in an employer-employee relationship versus a team effort where everyone is contributing for a cause that all are passionate about. In the latter, the team members have a primary incentive of ownership to drive the development forward, which is more sustainable. In the former, the incentives of the employees are primarily monetary.

3.1.2. Identify key skills and roles that you will need in your core team

For any medical device, an engineer or a biomedical engineer, a product designer (preferably with a mechanical engineering background), a business graduate, and a clinician are required. Any 2, in any combination, is a good starting point. It is absolutely essential to have a core team of at least 2 people and preferably 3 or 4 people. 1 or 2 required skills can always be outsourced if the core team is only 2 members. Be clear about what role you are looking for. Co-founder? Advisor? Chief Executive officer (CEO)? Chief Technology Officer (CTO)? Clinical Director? Etc.

It is recommended to avoid engagement with students who are still attached to colleges as they may not be able to contribute on a long-term basis and with employees of existing companies if their involvement will lead to an automatic ownership of rights to their parent company.

3.1.3. Create your pitch for potential team members

A true entrepreneur must have the charismatic skill to draw people toward them and join them in their vision as well as mission. To form a core team, you will need to find people who can be aligned to your thoughts and are willing to work together as a team toward the same or similar goal. It is very important that there is clarity about what you want. For example, "I want to do something in maternal and child health care and improve lives of women and children in my country. I want to make a solution, form a company. and run it till it becomes an industry over the next 10–15 years. Would you like to join me as a partner in this journey? We can possibly change the lives of millions of babies."

It's fine if you have an aim to address a specific area within healthcare or if it is something as broad as, "I want to do something in healthcare and want to create my own pipeline of products." As long as you don't have a preconceived solution, you should be fine. For example, "I want to detect hearing loss in babies using image processing," or "I want to make monitoring of vitals portable in an ICU." Tell your potential team partner that you would like to find the problem together, understand it together, and solve it together in an equal partnership. Tell them that you believe their involvement will help identify a great need and generate a groundbreaking solution. It will be difficult to do that all alone.

3.1.4. Start your search with friends and family

Work with people you have spent good and bad times with and who understand you well. If there is someone in your friend circle or acquaintances that meets the skill requirement and profile, approach them first. They are probably more predictable to understand and are going to be easier to work with. It may affect your relationship if something unexpected happens, and

you must be aware of that possibility. But again, if they really wish well for you, they would probably understand eventually and work things out with you again in due course.

3.1.5 Expand your search through recommendations from friends and family

Ask for recommendations from friends and family for people who they feel would meet your requirements

3.1.6 Attend MedTech events/conferences, hackathons, engineering and medical conferences

There are many MedTech events that happen across India all year long that you must attend to meet like-minded people. Some events/keywords to look for while searching online are MedTech summits, medical device expos, hackathons, jugaadathons, etc. If you are a non-clinical person looking for interactions with doctors, attend medical conferences and strike conversations with doctors who were invited as speakers at the conference and talked about something that aligns with your interest or with doctors who presented posters or papers on topics of your interest. If you are a doctor, attend engineering conferences (IEEE or COMSNET events).

3.1.7 Join social media groups on medical devices, engineering, product design, and clinical groups

Join MedTech groups on social media platforms by liking their page on Facebook/LinkedIn or directly joining groups. On Facebook, you can hit like on pages by InnAccel, Stanford Biodesign, India Biodesign, CAMTech, etc. On Twitter, you can follow me on @DrJagdishChatur for updates on upcoming events. You can also look for what people in the MedTech community have joined and follow the same or join groups that have MedTech/Biodesign/invent in them.

3.1.8 Know when to kill the idea

If you have spoken to at least 10 different people and have made a sincere effort to see if you can find someone to join your team and it hasn't worked out, then evaluate the reasons for this, and see if you can work it out. If you cannot—

and have tried at least 2-3 different approaches over a maximum of 3 months and still no team could be created—then it is probably an indication to stop finding a team and closing the approach altogether. It may just be bad timing, bad luck, or an uninteresting project. It's always good to know sooner than later.

3.1.9 Try the employment route

If nothing works out, it's a valid reason to explore the next best option, which is hiring a team. If you are willing to put in some of your money (10-15 lakh INR), that's good enough to get a couple of good team members on board for a year. You can also apply for grants and gain some capital to hire people. I am not a big fan of this approach as it works well only for a few months or a year, but it has worked well for some people in the long run too. Remember, you will need a team for 3-5 years to get a medical device from idea to commercialization.

3.1.10. Install HiiiH (Team building) application

To solve this problem of identifying and meeting potential team members, I have been involved in the development of a unique software application called HiiiH (Healthcare Innovation in Indian Healthcare) that can help you find anyone (around you), right from a co-founder or CEO to consultants, advisors, and interns. It also allows networking among industry experts, keeps you updated with the latest information, and keeps you connected with Indian start-up companies. This app can be downloaded from Google Play Store and iOS App Store. For more queries on the app, reach out to jagdish@hiiih.in

3.2   IDENTIFYING A STRATEGIC FOCUS AREA

3.2.1 Consider the team's passion or interest as an important factor in selecting a focus area

 Members of the team must be passionate about a specific area of healthcare. These could be maternal and child health, ophthalmology, ENT, orthopedics, etc. If each member of the team has a different area of interest, select a focus

area where multiple fields come together to allow everyone's interest to be given a fair chance. For example, in trauma and emergency or in intensive care, patients with any kind of healthcare problem can be addressed with a primary focus on emergency or critical care. Similarly, community healthcare or paraclinical areas such as pathology or microbiology also cover a wide variety of healthcare problems.

Remember, being passionate is an important reason to ensure commitment and determination.

3.2.2 Select a strategic focus area that is neither too narrow nor too broad

A strategic focus area should be broad enough to include a spectrum of needs and at the same time should not be so narrow that it focuses on just one need. Each specialty, sub-specialty, or super specialty in the medical field can be a strategic focus area. Avoid broad areas like the entire field of medicine/healthcare or too narrow areas such as focusing purely on reducing ICU infections. In case you are interested in reducing ICU infections, select the entire ICU care or intensive care as the strategic focus area.

3.2.3 Consider recent trends and market interest

It is important to track what focus areas are getting traction in terms of funding (private/government), licensing deals, and company acquisitions. This information can be acquired from MedTech reports, news, and by attending MedTech conferences/summits. Also, try to find out what other start-up companies are working on and how well they are doing. I have created a website called www.medicaldevicesindia.in that lists most of the MedTech companies in India with their web links; it can be a good starting point to understand who is working on what and how crowded or isolated the focus area is.

3.2.4 Exclude solutions or technical areas from the focus area

Exclude solutions as the focus area. For example, internet of things (IoT), laser-based technology, etc. This will bias the team from the start, and you may develop a non-ideal solution for a need only because it allows the use of

a technology of your interest. Following a process becomes less meaningful if you have already decided what you want to make.

It is not possible to say beforehand what technology may be eventually used in the solution, but if you identify a good need, the solution criteria may allow the use of the technology of your choice. This would be the suggested way to move forward.

3.3. MAKING CLINICAL OBSERVATIONS

3.3.1 Enroll your team as a clinical observer at a teaching medical college/hospital

Most teaching hospitals/colleges have a student section that is generally responsible for enrolling students or visitors for observership. They typically have a standard application process where a request to be an observer at a particular department can be placed with the dean of the college, who forwards this to the concerned head of department for approval. Once approved, a fee (can range from INR 7000 to INR 30,000 per month) can be paid to officially enroll as a clinical observer. Note that most colleges do allow students or professionals from non-clinical backgrounds to become observers. It may be helpful to speak to the head of department in person before submitting an application so that the approval process is quicker, and all concerns or questions can be clarified beforehand.

Alternatively, you may ask a clinician if he/she is alright with you shadowing them for a few weeks, and they can suggest the most suitable way for you to engage with them. Some places may have different formalities or even no formalities.

3.3.2 Carry out clinical observations for at least 6 to 8 weeks

Typically, the first 8-10 days are spent simply understanding the routine and clinical workflow at a hospital, the functionality of a department, and the interpersonal relationships between various healthcare professionals. It is absolutely fine if no tangible observations come up during this time. It is usually in the latter half of the second week or the third week onward where

teams really understand what's going on and have the knowledge and insight to make meaningful clinical observations.

In my experience, 6-8 weeks of continuous observations show approximately 80% of all-important needs that are significantly frequent and critical enough to be worth solving. Toward the end of the 7th or 8th week of observations, teams tend to start noting a lot of repetitions of similar scenarios that have already been documented and very few new observations. This is a good indication to end the clinical immersion activity.

3.3.3 Watch the same observations as a team

Many teams believe it is more productive to split up and observe different things separately so that more observations are recorded. I think these teams miss the point. It's not important to get more observations but important to get meaningful observations that are better understood by the entire team. It is very important that all members or at least 2 team members observe the same observations together. It helps the majority of the team to get a first-hand experience and visual understanding of the problem and more importantly gets 2 or more perspectives on the same observation. The value of having a multidisciplinary team is high when they observe together and document what they see and perceive together. This can be different from a doctor's point of view when compared to a designer or an engineer's point of view. It is through these different perspectives that important details of an observation are recorded.

When individuals observe independently, only 1 person has a visual experience of the observation and may eventually become more passionate about the need when compared to others in the team. More importantly, an individual may miss out on certain details, which probably could have been picked up by someone else if they were making the observations together.

3.3.4 Target at least 100 different observations in a 6-8 week time frame

There is no hard and fast rule on the number of observations, and it is just as valuable if there are 15 or 40 observations. The 100 observations benchmark

is just to give an idea based on my personal experiences (while carrying out over 10 such clinical observation exercises). I found that teams were effectively able to record 100 unique observations on an average in 6–8 weeks. This is just an indicator to see if the team is doing enough and if any strategic changes need to be made in the process of finding observations.

A weekly review (2-3 hour) of the observations by an external clinical expert in the field will help clarify a lot of the questions that arise from these observations.

3.3.5 Focus on negative outcomes

Focus on events where there were undesirable measurable outcomes such as more than expected blood loss in a surgery, more than anticipated hospitalization for an illness, unexpected ICU admission in a trauma case, complications in procedures/surgeries, procedures that did not lead to expected cure or required repetition, preventable death, preventable disability or morbidity, etc.

Do not document observations where there was a potential for something to go wrong but nothing actually went wrong. These are not typically considered as observations because nothing undesirable happened even though it could have. There were risky moments in the observation, but they did not lead to anything untoward. These 'ifs and buts and could have happened, may have happened' observations lead to the development of solutions that will have the same 'ifs and mays' for adoption. For example, a doctor did not wash his hands before touching the patient, so the patient may develop an infection, or the doctor carried out a procedure without wearing gloves, and the patient may develop a complication. This will be a valid observation only if the patient develops a post-procedural infection, and there is clinical/scientific evidence to prove that this was indeed due to lack of hand hygiene.

It is my personal suggestion to avoid working on needs where the basic hypothesis itself needs proving and convincing as this may lead to a very challenging adoption of these technologies. I fully agree that these are

pressing problems that need to be solved and probably should be solved once there is a clear and scientific understanding of why these problems occur with substantial scientific evidence.

3.3.6 Document ideas or suggestions separately

There are always going to be people who give suggestions and advice on how you could focus on something better or work on something that they feel is more important. Do not dismiss these suggestions and ideas just because you are following an observation-based process. Do note these down and have further discussions on these with the person who made these suggestions. This will help in fully understanding the reasoning and basis of why these suggestions were made. They are often based out of some incident or event in the past.

It is probably fine to document retrospective anecdotes and events in the same format as these are observations that someone else has seen or experienced. The team needs to take their own judgment call on these observations. Another way would be to keep a note of these observations and document them formally once you see a similar event during the clinical immersion prospectively.

3.3.7 Collect all necessary information pertaining to each observation

There is a shortage of adequate clinical data in India, and therefore it is important to document these observations more comprehensively. A few lines about the observation are insufficient as further research and gathering of information at a later time is challenging. It is advisable to document the observation as a structured docket of information (observation docket) under the following headings -

- *Date, time, place of observation.*
- *Name of observer.*
- *Short title for the observation: A short title helps in easy referencing and retrieval of the observation. For example: Death due to cardiac tamponade.*

- *Observation: A 100-300 word description of the sequence of events that took place leading to the undesired or negative outcome. No suggestions, solutions, or assumptions are included in the observation. It is a factual description of what happened. For example: "An 18-year-old student sustained severe chest injuries after he came in between a truck and a wall while assisting the driver to reverse the truck. He was brought to the emergency room of the hospital with low blood pressure, raised jugular venous pressure (JVP), and difficulty in breathing. Multiple clinical blood tests were carried out before a cardiac tamponade (due to injury to the heart muscle, blood from within the heart chambers seeps between the heart and the heart wall at each pump, causing difficulty in pumping due to increasing pressure build-up at the wall of the heart, eventually causing the heart to stop pumping further blood) was suspected.*

  Pericardiocentesis (blood collected between heart and its outer cavity is drained out) done under USG (Ultrasound) guidance (16G needle) & around 20 ml of blood was aspirated. Arterial line inserted into pericardial space (space between the heart and its outer wall) under USG guidance & 10ml blood aspirated following which patient had a cardiac arrest & CPR (Cardiopulmonary Resuscitation) performed in accordance to ACLS (Advanced Cardiac Life Support) guidelines. The patient did not survive. Probable cause of death - cardiac tamponade or blunt injury abdomen or hemorrhagic shock. Autopsy Report - Death was due to 'cardiac tamponade' as a result of blunt trauma to chest." – Note that in this case, the team waited till the autopsy report arrived before completing the observation.
- *Problem: What was the reason because of which the negative outcome occurred? For example: Lack of early detection at the site of trauma for life-threatening cardiac injury due to collection of fluid in the pericardial cavity.*
- *Negative outcome – The undesired outcome that resulted in the observation because of the problem. For example: Death due to delayed detection of cardiac tamponade.*

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- *Frequency of negative outcome as per expert: How many times does a clinical expert see the negative outcome? It is crucial here to get the monthly or yearly incidence as a rough estimate for the negative outcome only. For example: An emergency medicine physician sees, on an average, 8 deaths due to cardiac tamponade per month due to delayed detection.*

- *Prevalence of target market – This is the number of people who will need the solution and are at risk of developing the negative outcome. So, as an example, this will be the number of patients who can develop cardiac tamponade or have a blunt chest injury, such as patients who have had chest injuries. This is the market that will buy the product.*

- *Criticality of negative outcome as per expert: Based on death, morbidity, disability, temporary discomfort, etc., the criticality of the negative outcome is assessed. For example: Death due to late detection of cardiac tamponade is very critical, but pain due to bone biopsy is less critical as the pain and discomfort are short-lasting and do not impact the procedure and outcomes significantly.*

- *Best available treatment worldwide: What technology is available today to address this problem today? For example: Portable echocardiography machine is the best technology available to detect cardiac tamponade at the site of trauma.*

- *Cost of best available solution: How expensive is the technology today? For example: Cost of portable echocardiography machine ranges from 3000-8000 USD.*

- *Reason for not having access to best available solution: Are the reasons affordability, lack of awareness, lack of suppliers, lack of clinical data, high skill requirement, high maintenance, high infrastructure requirement, etc.? For example: High cost, high skill requirement, and lack of awareness of the technology are reasons for the decreased adoption of portable echocardiography machines.*

- *Additional insights: Any opinions, thoughts, and assumptions understood by speaking with doctors or watching the observations. For example: In the cardiac tamponade case we understood that paramedics in*

ambulances reach the site of trauma, and patients die by the time they are brought to the hospital. Therefore, not only the detection, treatment through pericardiocentesis will also need to be provided by paramedics. The paramedics in India do not have that kind of therapeutic training, and even if they do, the perception within the public inhibits them from carrying out therapeutic life-saving procedures. This poses an important technology challenge, which directs the potential solution to be both diagnostic and therapeutic while maintaining low skill.

3.3.8 Consider these strategies to find meaningful observations

Depending on the strategic focus area, the volumes of meaningful observations may differ. For instance, areas where many procedures are performed or lots of critical conditions are dealt with probably will have more negative outcomes simply due to the nature of activities and circumstances that play in these areas. Whereas in areas that are predominantly consultation-based, it is difficult to relate actions to causes because these may occur in different frames of time or at different locations. The following strategies may be adopted to maximize the chances of making meaningful observations:

Watch procedures and surgeries: Procedures can be diagnostic or therapeutic. In either case, they have a definite start and a result at the end. The procedure may be successful or may fail, or may have complications during or after the procedure. Therefore, it is easy to understand and document these observations and take away conclusions from these.

In consultation, OPD or ward patients follow up patients for a while before concluding if it is a meaningful observation: If a patient is seen in the OPD and given medications, follow up with the patient a week later or at the next follow up to see if they have improved or worsened. If a patient was treated at the hospital as an inpatient, then do follow up every day to see if the patient is doing well for a few days or until time of discharge. Many times, the undesired outcomes are not immediate or difficult to identify. A patient in the ICU, in my opinion, is in itself an undesirable outcome as ICU admissions are

obviously due to things going horribly wrong unless they are under observation following a surgery. So, by just understanding what led them to get into an ICU and have a prolonged stay can in itself be a meaningful observation.

Collect anecdotes from doctors, nurses, patients: It is not mandatory that the undesired outcome needs to be visualized by you in real-time. That may not always be possible. The idea behind observations is to get in direct proximity to the person who has experienced or is experiencing something undesirable so that you can gather as much information as possible from that single incident or event. This way, it will help understand the clinical workflow and stakeholders in addition to the sequence of events that lead to the undesirable outcome.

Avoid general statements: While collecting anecdotal information, doctors, nurses, and other healthcare professionals tend to make general remarks or statements pertaining to clinical challenges and problems. For instance, they may say, "Lot of women have anemia during pregnancy and face complications during pregnancy." While this may be a valuable need to solve, in order to understand it better, it is important to know more details. If probed further to describe a case as an example, doctors may share a case where it will be possible to understand the age group of the patient, socio-economic background, hemoglobin levels before pregnancy, reasons why hemoglobin levels dropped during pregnancy, what was the exact complication in this case, why did it occur, how could it be avoided, and where is the real gap that leads to the problem. These details help in further research and create leads for further discussions. The solution generated from such in-depth understanding leads to development of more specific solutions.

Attend morning and evening rounds: This is a great way to understand the cases and learn from discussions between doctors. These rounds happen on a daily basis and are a very good way to track improvement and management strategies. This is a good starting point to identify important cases and understand gaps in management.

Attend night duties: Shadowing resident doctors during night duties is a great way to see cases that are typically emergencies and their management in an immediate setting. Resident doctors, being junior, understand the workflow better, are more approachable, and can spend more time in discussions.
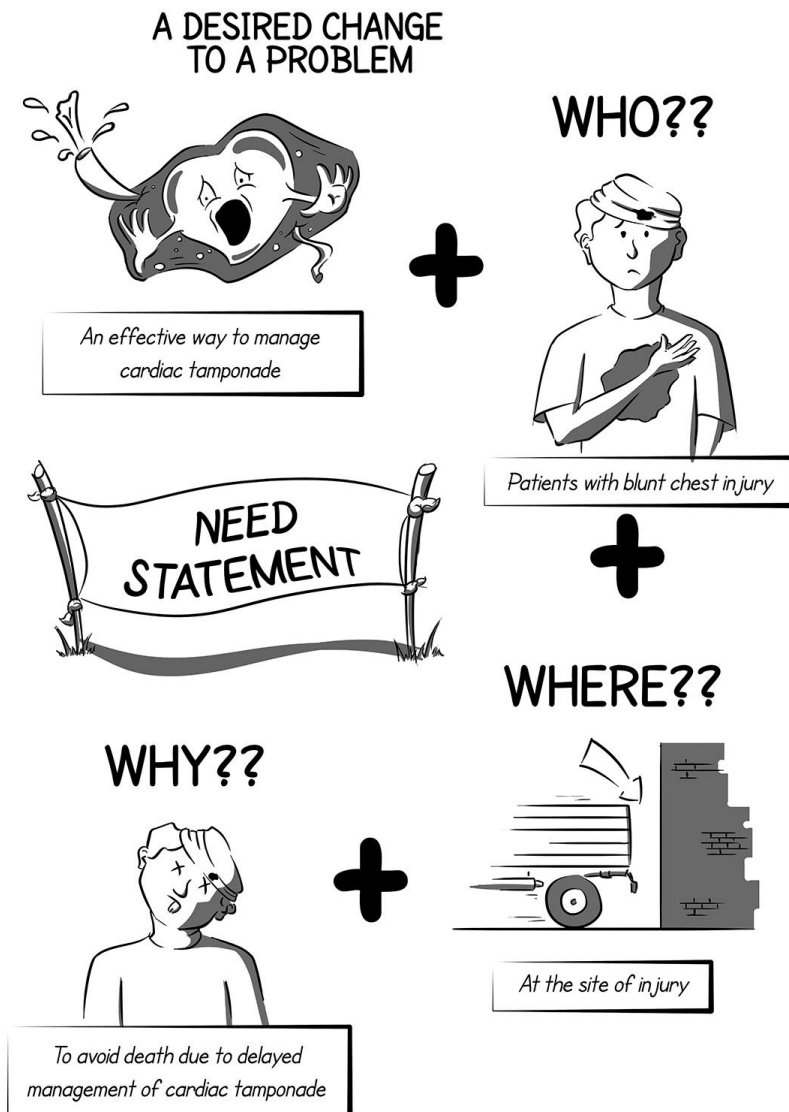
3.3.9 Expand immersion to other regions and areas for another 1-2 weeks

The first 6 -8 weeks give a great overview of the problems and needs that prevail at a single healthcare setting. Having understood these observations and the clinical domain, it is important to understand if these problems exist in different healthcare settings as well. Therefore, it is recommended that teams spend a day or 2 at primary healthcare centers, community healthcare centers, district hospitals, nursing homes, and corporate hospitals. This will help validate if similar problems exist in different healthcare settings and will give a perspective on how these problems are managed differently in these settings.

3.3.10 Validate or gather data by attending conferences and events

The more data gathered, the better. It is a good idea to keep a watch out for conferences or CMEs (Continuing Medical Education events) so that teams can attend them and speak with doctors to gather data on the frequency/criticality of cases seen in their settings. This will help in extrapolating market opportunity at a later point in time and also help in understanding the gaps that exist in their healthcare settings.

3.4. FORMING A NEED STATEMENT

A DESIRED CHANGE
TO A PROBLEM

WHO??

An effective way to manage
cardiac tamponade

Patients with blunt chest injury

NEED
STATEMENT

WHERE??

WHY??

At the site of injury

To avoid death due to delayed
management of cardiac tamponade

3.4.1 Identify all the components of a need statement from the observation docket

A need statement formula is, "*A desired change to the problem in who, where, and why.*"

A desired change to the problem: What needs to be changed today in order to ensure the problem is eliminated? Remember, this is not your decision and is derived from the understanding of the problem. For instance, in the cardiac tamponade example, we know that the solution for cardiac tamponade exists and can be performed if cardiac tamponade is diagnosed

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at the site of the chest injury (site of accident) and that this is not possible today because diagnostic tools are not available at the site. Therefore, there is delay in identifying the condition. In this case, the desired change becomes, *"A faster way to diagnose cardiac tamponade."* Here, the desired change is '*faster,*' and the problem is related to '*early identification of cardiac tamponade.*'

In the same example, if you find out in your research that by just identifying the cardiac tamponade at the site is still of no use because the paramedics will not be able to perform ultrasound-guided pericardiocentesis, then the need becomes *'an effective way to manage cardiac tamponade'* where effective implies here – easy diagnostic and therapeutic solution that can be used by a paramedic safely. Whenever the desired change includes words like 'better' or 'effective,' make a note in brackets explaining the parameters that will make the solution better or effective.

Who: Who is being affected by the problem today? In the same example, the who becomes 'patients with blunt chest injury' as these are the patients who need early diagnosis or management for cardiac tamponade.

Where: This really defines the solution because it takes into direct consideration the infrastructure and resources that may be available at the location of potential use. In the same example, the need is to have a more effective management for cardiac tamponade in people with blunt chest injury at the site of injury. This means that an ambulance that reaches this site must be capable of providing the solution or there must be a first-aid center nearby that can provide the solution. Therefore, when we think of concepts for this example, we must take into consideration the paramedic user skills, available resources, and infrastructure in an ambulance. Once this is figured out, the need can be solved.

Why: Most important reason for addressing the need. In the example that we have been using, the '*why*' is to avoid death due to delayed management of cardiac tamponade.

The need statement therefore becomes, in the example stated, *"An effective way (faster and easier) to manage cardiac tamponade in patients with blunt trauma to the chest at the site of injury in order to prevent delay in management and death."*

3.5   NEEDS FILTERING PROCESS
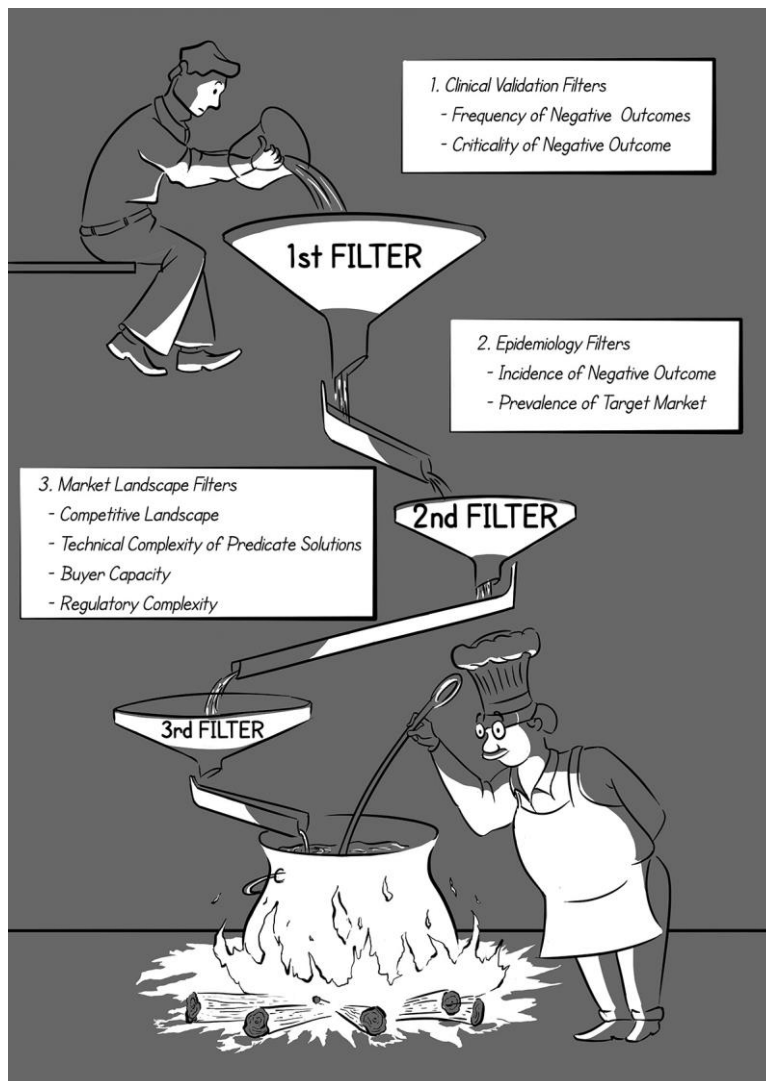
3.5.1 Ensure that you have all the necessary data before beginning the filtering process

The following information will be required to filter the 100-300 unique needs that have been identified:

- *Frequency of the negative outcome (per month) as per clinical expert.*

- *Criticality of the negative outcome as per clinical expert:* Recording what happens if the need is not addressed.

- *Incidence of negative outcome from literature search.*

- *Prevalence of the target market (the population at risk of developing the negative outcome) from literature search.*

- *Competitive landscape:* How many competing products (addressing the need) exist worldwide.

- *Technical complexity of predicate solutions:* How complex are the solutions that are addressing the needs today in terms of development and commercialization?

- *Buyer capacity:* Who is the buyer in the predicate (device that is addressing the need today) scenario (hospital/doctor/patient), and how good is the buying capacity?

- *Regulatory complexity:* For the most effective predicate product, how complex has its regulatory pathway been in terms of class of device or type of FDA approval and time taken to get regulatory approvals?

3.5.2 Eliminate redundant and similar needs

When teams observe together, each member documents his/her docket of information separately, and when a final consolidated list is created, there will be many similar needs. It is important to identify all similar observation dockets and consolidate it into 1 single docket. Any additional information on that particular observation must be included in 1 unique docket of information.

Careful attention must be taken to ensure that observation dockets with similar information such as negative outcomes, target market size, competitors, etc., must be included in 1 docket. For example, if a team member records an observation related to a child having pain while receiving intravenous (IV) fluid administration leading to delay in IV access and another team member records difficulty in accessing the IV line for fluid administration due to lack of identification of veins, these 2 observations

are identifying 2 reasons for delay in administering IV fluids in children. In such a case, both observations must be documented in the same docket as observation 1 and observation 2. The need statement should incorporate both situations. Such as a faster way to rehydrate children or a safer way to provide fluid replenishment in children.

3.5.3 1st level of filtering- Applying clinical validation filters

All need statements can be included in a worksheet (preferably an Excel sheet). All the filtering parameters can be tabulated in the same sheet in parallel columns. The first levels of filters are:

Frequency of the negative outcome (per month) as per clinical expert: The scoring is carried out in a 1,3,5 format. In order to assign what falls under 1,3, or 5, it is important to calibrate from the domain expert as to what is the commonest and the least common condition that they see in their practice and how frequent they are on a monthly (preferably) or yearly basis. From this range, it is possible to assign proportionately what falls under 1,3, or 5. For example, in the field of dermatology, if pimples or acne vulgaris is the commonest condition with a frequency of 200 cases per month and if a rare variety of skin cancer is seen once in a year, then the 1,3, and 5 scoring can be calibrated as follows:

Any negative outcome with a frequency of more than 100 cases per month is scored 5, more than 20 cases a month is scored 3, and anything less than that is 1. The team needs to decide, based on the inputs by the domain expert, on what seems to be a reasonable scoring system. If way too many needs (>70%) fall under any 1 category (1,3, or 5), then that is an indicator that the scoring is inappropriate. A typical indicator of good scoring is when 30-40% needs fall under 5, 10-15% fall under 3, and the rest fall under 1.

Criticality of the negative outcome as per clinical expert: The criticality of the negative outcome is assessed by the nature of outcome. For instance, if the negative outcome resulted in something that reversed completely or

subsided within 48 hours and did not leave any temporary or permanent disability or death, such a negative outcome falls under a low criticality score and would be scored as 1. Pain, discomfort, etc., typically fall under this category. We score negative outcomes that leave behind disability or long-term morbidity of up to 6 months at a moderate criticality score of 3.

If the negative outcomes lead to death, near death/life-threatening experiences, result in emergency procedures/ICU stays, or result in disability of more than 6 months, then such negative outcomes are given a score of 5 as highly critical needs. This kind of scoring really objectifies criticality in a manner such that only the most deteriorating negative outcomes filter up to the top and those which are transient or temporary in nature filter down into the list.

3.5.4 2nd level of Filtering- Applying epidemiology filters

The second level of filters are intended to understand if the problem/need identified exists in other setting or other parts of the country. This is important to gauge how many times negative outcomes could result due to shortcomings that are specific to a particular hospital or region. Searching the incidences of negative outcomes and the prevalence of the target market will help in understanding if the problem is due to an inherent gap that exists in many or majority of the hospitals. Typically, in my personal practice of applying these filters, I would give for each need/negative outcome a maximum of a 3-hour search of scientific and scholarly articles to determine these numbers.

If a negative outcome was indeed critical and high in incidence or prevalence, then there would be something in scientific literature about them. Not finding anything on a need, despite 3-4 hours of reasonable searching, indicates the problem is probably not that important or not that common. The second level filters are:

Incidence of negative outcome: Most negative outcomes are events or incidences. For example, excessive blood loss resulting in hypovolemic

shock or a cardiac arrest. These events last for some time and then leave behind morbidity. These are looked for in incidences as they are events that are short-lived. Now, how to decide scoring for this? The scoring is dependent on the prevalence of the target market. If the incidence of negative outcome is more than 10% of the prevalent pool, then that means out of 100 people who are at risk of facing the negative outcome, over 10 people actually do face the negative outcome. This is considered to be significantly high and is given a high incidence score of 5. If the incidence is less than 5% of the prevalent pool, the score given is 1, and if it is between 5 and 10, a moderate incidence score of 3 is given.

Prevalence of the target market (at risk for negative outcome): The prevalent pool is measured in comparison to the population of the country. As a reference marker, a market size of more than 10 million patients is considered significantly high. Another way to score this is by comparing the prevalent pool with the population. If the prevalent pool is more than 10% of the population of the country, it is given a high prevalence score of 5. If the prevalence is less than 5% of the population, it is scored 1, and if it is between 5 and 10 %, the score given is 3.

At the end of this filtering round, the top needs are critical and frequent enough as per clinician experiences but also significantly common and prevalent as per literature.

3.5.5 3rd level of filtering- Applying market landscape filters

The third level of filtering is designed to assess the market landscape for those needs which have already proven to be important both in terms of impact and magnitude. The following parameters are scored in this round of filtering:

Competitive landscape: In a competitive landscape, existing solutions that are addressing the same problem are searched for. This search is carried out at a global level, and the availability of the solution in India is also evaluated. If the competitive products that exist abroad are not available in India, they are

given a score of 5. If there are more than 3 competing technologies in India, the score given is 1, and if there are less than 3, the score given is 3.

Technical complexity of predicate solutions: This is to understand how complex an existing technology is that has tried to address the same or similar problem. The complexity of the technology is measured by the time taken to develop and test the device, the scientific research and basis for the technology, and the infrastructure and resources required to develop the technology. For instance, a stent is considered to be a highly complex technology as it requires a lot of intricate design, materials, testing, and infrastructure requirements. Such a technology is scored 3. This is because developing a highly complex technology is a reasonable strategy to protect the company from competitors as it may not be feasible for them to develop the same technology easily.

A simple device such as a tongue depressor or a stainless steel surgical tool or a simple disposable device can be considered to be a simple technology and be given a score of 1. This is because the protective element from new competitors is low as it would be easy for anybody to develop the technology. A moderately complex technology such as a portable ultrasound machine or a Doppler is considered moderately complex and is scored 5 because this category of device is ideal for a start-up, and at the same time, it is not that easy for a new competitor to develop.

Buyer capacity: It is important to understand in the present scenario, with the existing solutions, that the buyer is not only capable in terms of ability to pay but also the ability to make an educated decision to buy the technology. Here, there are only 2 scoring parameters. 1 for poor buyer capacity, and 5 for good buyer capacity. A hospital, a doctor, an insurance company, or a lab/clinic are all considered buyers with good buying capacity because they have the money as well as the education or background to make a scientific decision to buy the device. Study trials, efficacy data, safety data, affordability, economic advantage, etc., can be understood and interpreted considerably by these buyers.

Patients or patient relatives are considered poor buyers as majority of them do not wish to spend on healthcare, and their approach to buying a technology can be easily manipulated or changed by so many variable factors. A relatives' advice, word of mouth from a friend, so many alternative therapeutic options (Ayurveda, Unani, Yoga, Homeopathy, spirituality), etc., affect the decision of this buyer, and it is hard to predict what factors will lead to sustainable sales.

Regulatory complexity: We typically follow the European CE category of regulatory requirement to score the best existing technology which is presently being used to address the problem. A class 3 device is scored 1, a class 2a and 2b device is scored 3, and a class 1 device is scored 5.

At the end of this filter, the top 10 needs will all be critical, impactful (both from clinician experience and literature), and will have a lucrative market landscape for easy adoption if a suitable technology is developed.

3.5.6 Selecting 1 need from the top 10 needs

The team can take a decision based on their personal preference, interest, and passion to select any 1 of the top 10 needs, as any 1 of them would be worth solving. It is not necessary to always select the number 1 need. Strategic decisions based on whether there is a clinical expert more inclined toward a particular need or if there is a lot of grant and funding support in a particular need that has made it to the top 10 can be strategic reasons for selecting a top need.

3.5.7 Creating a needs specification document

A needs specification document is a consolidated write-up of all the information relevant to the clinical need, the problem, and the requirements for the solution. The importance of creating this document is for easy cross-referral and for knowledge sharing when new members join the team. A majority of this information is required for grant applications, business plan competitions, and investor pitches. Therefore, having this complied document

helps to create many other important documents that require a subset of this information in an easy and consistent manner.

The need specification document is typically a 20-30-page document that contains the following key elements:

The need statement: This is a single statement that incorporates what problem needs to be solved, in what way, in whom, why, and where.

The clinical observation: A detailed description of the observation as described before in the clinical observation section.

Disease state fundamentals: All relevant medical information pertaining to the need is documented here. The anatomy of the region, normal physiology, etiology or cause of the problem, and abnormal physiology or pathophysiology is documented in this section. The sources of information are medical textbooks, scholarly articles, or publications only. Typically, the clinician in the team takes the main lead in consolidating this information and takes responsibility to ensure that the rest of the team members understand this background information in detail.

For example – If the need is for a faster way to detect cardiac tamponade, the understanding of the anatomy of the heart, pericardial space, and mediastinum cavity is crucial. The normal physiology of the heart, what causes cardiac tamponade, and how it becomes abnormal when there is a cardiac tamponade must be well-understood. Also, how existing treatments work and their principles must be understood in great detail.

Treatment landscape: This section includes information on the current way the problem is being managed, what are all the other ways (in terms of devices, processes, surgeries, medications, etc.) that the problem is being or can be addressed today. In each treatment approach, what are the specific drawbacks and gaps that need to be filled.

For example- In cardiac tamponade, the treatment options include direct insertion of a needle into the pericardial space either blindly or under ultrasound guidance. The principle here is anatomical landmarks or ultrasound guidance. In each, there will be gaps related to skill, infrastructure requirement, cost, and accessibility. These need to be listed out very clearly.

Competitive analysis: There is a minor difference between this section and the one above. While in treatment landscape, all types of treatment options are considered, in competitive analysis, only technologies or products that are in the market that address the problem (globally or in India) are listed down in this section and specific drawbacks or gaps in each of them are analyzed.

Stakeholder analysis: All the stakeholders involved, directly or indirectly, with the need are listed down. Each stakeholder is categorized as influential/neutral/non-influential based on the decision-making role they play with regards to any solution that is addressing the need. Each stakeholder is assessed on how they are affected today (benefited positively or negatively) with the current state of solutions and how their benefits would change when the new technology that is being developed comes into play. This is crucial to understand to ensure that the novel solution that you are bringing does not negatively affect the key influential stakeholders.

There are 3 approaches to identify stakeholders, and teams are encouraged to use all 3 methods in order to get a comprehensive list of stakeholders. The first method is called 'following the flow of cash' – here, teams list in sequential order which stakeholders handle flow of cash from patient to end beneficiary for the solution that is addressing the problem today.

The second method is called 'following the flow of care' – here, the patient is followed from the time of identification of the problem till the time the patient is managed and has recovered to note down all the stakeholders who interacted with the patient throughout this duration of time.

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The third method is called 'following the flow of equipment' – here, the technology or medical device that is being used to address the problem today is followed from its procurement till the time it is stored or disposed of. Each method discovers new stakeholders that are often otherwise missed. Hence using all 3 allows teams to identify all-important stakeholders.

Market Size: The size of the market is the prevalent target market pool, which has already been noted during the filtering session. A deeper search is carried out to estimate more closely the market size within the country.

Market Landscape: This section assesses the current market or business model followed by technologies that are addressing the problem today. How are they reaching the target customer, and what type of medical device (disposable/reusable/capital/over-the- counter/physician sell, etc.) are they developing to address this? This is important to know in order to identify the preferred business model for the new technology that will be developed by your team. This will be a crucial selection criterion when concepts are generated in the next step.

Needs criteria: These are categorized into *'must-haves'* which are the specific measurable criteria a solution must meet in order to solve the need and *'nice-to-haves'* which are optional measurable criteria.

For example: In case of the need related to early detection or management of cardiac tamponade, some of the measurable criteria could be:

- The detection of cardiac tamponade must happen within 30 minutes since the onset of injury (basis should be scientific literature or expert clinician opinion)
- The solution must be usable by the skill level of a paramedic
- The solution must ensure that the patient's blood pressure does not fall below 100/60 mm/hg 90% of the time

Ideal solution statement: Just like the need statement helps to focus on what to solve, the solution statement helps to understand the outcomes the solution must achieve in order to solve the need.

For example: An early detection and management tool for cardiac tamponade that can be used at the site of injury by a paramedic within 30 minutes of the onset of surgery.

3.6   DEVELOPING NEEDS CRITERIA
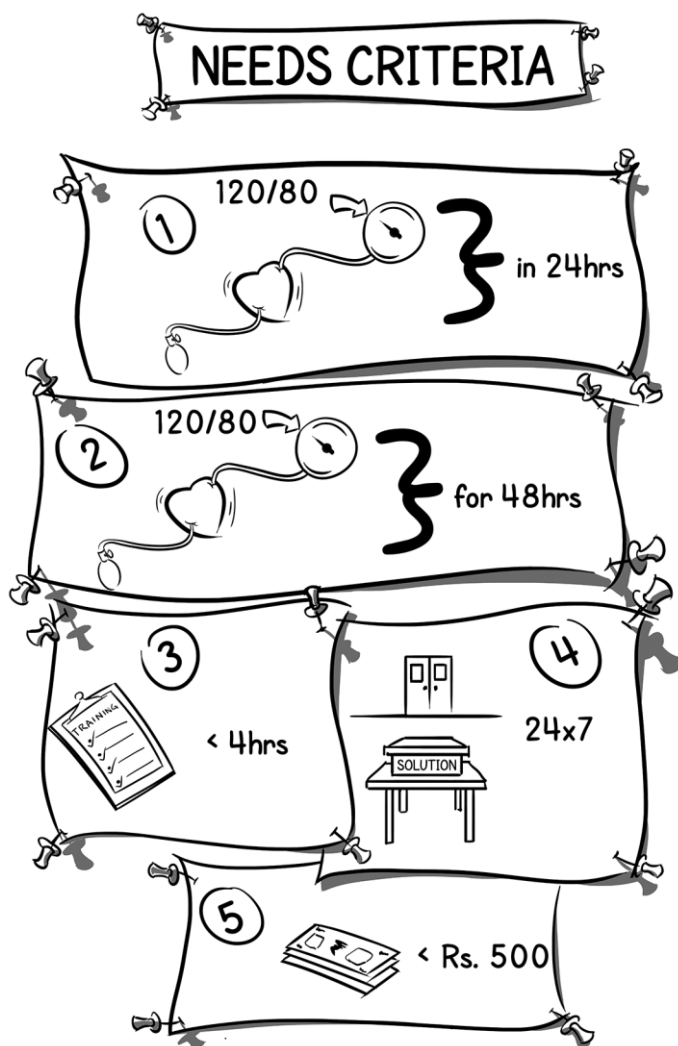
As mentioned in the previous section, needs criteria must be absolutely measurable since these are the criteria that you would bench your solution to. These criteria would form the basis of the benchtop testing and many of the clinical trial parameters. If the needs criteria are vague and non-measurable such as ease of use, comfort, etc., then these will be difficult to test later on.

Needs criteria must include only what the solution must achieve. It should not include technical requirements such as material must be plastic, it must have a handle, or it must be of a particular shape. This pre-biases the solution significantly and ends up being more like the requirement for a particular concept.

The following are common measurable or quantifiable criteria that can be used in the 'must-haves' or 'nice-to-haves' category: Time to intervention or diagnosis or procedure duration, hospital stay, blood loss, cost, skill requirement, infrastructure requirement (example: the solution must work and be maintained in areas where there is no power for over 8 hours), mucosal damage, visualization of certain anatomy at all times, reusability for certain number of times, portability, etc.

Example of needs criteria for a need statement: A faster way to rehydrate children in hypovolemic shock (low blood pressure due to loss of body fluid) at the emergency room of a tertiary care hospital in order to prevent end organ damage and death.

The 'must-haves' could be:
1. Blood pressure should be brought to normal within 24 hours since the onset of symptoms.
2. The restored blood pressure must be maintained for at least 48 hours after the intervention.

3. The solution should be implemented by a nurse, paramedic, or a doctor after minimal training (less than 4 hours of training).
4. The solution must be readily available at the emergency room at all times.
5. The cost to the patient must not exceed more than 500 INR for the solution that causes the rehydration which leads to restored blood pressure.

The 'nice-to-haves' could be:
1. Blood pressure should be brought to normal within 2 hours of the first point of care.
2. The solution should cost the patient less than 200 INR.
3. The solution should be readily available at all times at the first point of care.

There is no rule on the number of these criteria, but it is essential to restrict it to the minimum required to effectively solve the need. Do note that the more criteria you add, the more difficult it is to prove that the technology solves the need.

3.7 BRAINSTORMING AND CONCEPT GENERATION

3.7.1 Prerequisites

- The needs criteria and the need statement should preferably be written on a whiteboard/chart paper or be immediately accessible for reference during the brainstorming session as concepts that are generated will be shortlisted based on these criteria.
- 3-5 people are the recommended team size to be present in the brainstorming session. Less or more tend to be ineffective.
- A clinician from the field of interest should be present in the brainstorming session.
- The brainstorming team must be cross-disciplinary. At least 2 different disciplines must participate. This is to ensure elimination of biases.
- Keep coffee/tea, chocolates, etc., in the brainstorming session in order to have ready access to stimulants that improve thinking.

Rules:

- 1 person speaks at a time.

- When an idea is shared, no judgment or ridicule must be passed as this discourages the spirit of creative thinking.

- Once an idea is shared, the team must build on it and discuss it till its logical conclusion and only then move over to the next idea shared by someone else.

- Each brainstorming session should be a minimum of 45 minutes and maximum of 60 minutes in duration.

- Each idea is documented on a whiteboard or chart paper in words or drawings.

3.7.2 Method

In every brainstorming session, the ideas that are generated are categorized into concepts (an approach) and embodiments (different ways to achieve the same concept). For example, to replace fluid in a dehydrated child, a concept can be to provide fluid directly into the vascular system, and its embodiment could be injecting though needle/syringes, injecting through catheters, or injecting into the bone marrow which also communicates through the vascular system. Another concept could be to provide indirect absorption into the vascular system and embodiment could be through transdermal patches, buccal cavity patches, or through gastric absorption.

The primary focus in a brainstorming session must be to come up with as many concepts as possible and if embodiments come up for any particular concept, they must be documented under that particular concept.

Once 5-8 concepts are generated, each concept or its embodiment is evaluated with the needs criteria to see if it fits or if any further brainstorming should be

done to make that concept/embodiment meet the criteria. Those that cannot are eliminated and the ones that can are retained.

This process is repeated 3-4 times in different brainstorming sessions until 1 or 2 concepts consistently meet the criteria every time, and these are the ones that get selected for proof-of-concept generation.

3.7.3 Developing A Proof-Of-Concept

A proof-of-concept (POC) is the first prototype that shows that the fundamental principles that drive a concept work. For example, if the concept involves a certain type of suction mechanism, then one needs to demonstrate in the POC that such a suction mechanism can work and can be made.

The POC prototype does not need to look like the product that you envision, but by using available resources and off the shelve equipment, you are demonstrating that the concept you are proposing has a scientific basis to work.

The product designer and the engineers on the team typically take the lead to develop a POC, and it can take a month to 6 months to develop this based on the complexity of the device.

The clinician needs to be closely involved at this stage as this sets the foundation for further prototyping, and the clinical basis must be extremely accurate.

3.7.4 How To Validate An Existing Need Or Solution?

Many times, one may not follow a process from scratch as described in the previous sections. You may already have a solution in mind and maybe even a prototype. That is absolutely fine. You can still pause for a week and evaluate the need that you have chosen to see if it is worthwhile to take it forward.

All you need to do is document all the parameters retrospectively and take a decision on moving forward based on some criteria that I have suggested at the end of this section.

Document the following based on what has been described in the previous sections. For areas where you do not have complete information, gather them as you fill these out with clinicians and other experts. Attend conferences, events, or spend a week or 2 at a hospital if need be. It is better to know, sooner than later, the potential of what you are working on.

1. Need statement.
2. An anecdotal observation that represents the need you are addressing.
3. Clearly define the negative outcome you are trying to avoid/prevent/reduce/eliminate.
4. Incidence of negative outcome as per clinical expert (score 1, 3, 5).
5. Prevalence of target market as per clinical expert (score 1, 3, 5).
6. Incidence of negative outcome as per Indian literature (score 1, 3, 5).
7. Prevalence of target market as per Indian literature (score 1, 3, 5).
8. Competitive landscape (score 1, 3, 5).
9. Technical complexity of predicate (score 1, 3, 5).
10. Buyer capacity (score 1, 5).
11. Regulatory complexity (score 1, 3, 5).
12. Perform a stakeholder analysis and see if any influential stakeholder is negatively affected by your solution. If that is true, deduct 10 points from the score.
13. If the influential stakeholder who is negatively affected can be converted into being positively affected by making some changes in the prototype or business model, deduct 5 points rather than 10.

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If the total score is above 30, this is a need worth pursuing. If it is less than 30, even 29, do think about dropping the idea, and with the new information gathered through this research, look for other needs to solve.

If you are lacking team members, it is a good idea to see how and where you can find these team members now so that they can be a part of your journey. The HiiiH application can be used to bridge the gap.

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SCHEME FOR FACILITATING STARTUPS INTELLECTUAL PROPERTY PROTECTION (SIPP)

1. **Introduction**
   Intellectual Property Rights (IPRs) are emerging as a strategic business tool for any business organisation to enhance industrial competitiveness. Startups, with limited resources and manpower, can sustain in this highly competitive world only through continuous growth and development oriented innovations; for this, it is equally crucial that they protect their IPRs. The scheme for Startups Intellectual Property Protection (SIPP) is envisaged to facilitate protection of Patents, Trademark and Designs of innovative and interested startups.

2. **Vision**
   To protect and promote IPRs of startups and thus encourage innovation and creativity among them.

3. **Objective**
   The scheme of SIPP aims to promote awareness and adoption of IPRs amongst startups. Scheme is inclined to nurture and mentor innovative and merging technologies among Startups and assist them in protecting and commercialize it by providing them access to high-quality IP services and resources.

4. **Who can apply**
   Any startup recognised in terms of explanation 5 of the Notification GSR 180 (E) published in the Part II, Section 3, Sub Section (i) of the Gazette of India dated 17.2.2016.

   It is further clarified that an entity shall be considered a 'startup' if it meets the terms ad conditions laid down in the above mentioned notification.

   The startups covered under this scheme will not be required to obtain certificate of an eligible business from the Inter-Ministerial Bard of Certification.

5. **Appointment of Facilitators**
   For effective implementation of the scheme, facilitators shall be empanelled by the Controller General of Patent, Trademark and Design (CGPDTM). The CGPDTM shall regulate conduct and functions of empanelled facilitators from time to time.

   In case of any complaint by a startup about a facilitator or on getting information about professional misconduct through any source, the CGPDTM can remove the facilitator form he panel.

6. **Who can be a Facilitator**
   I   Any Patent Agent registered with the CGPDTM
   Ii Any Trademark Agent registered with the CGPDTM

Iii Any Advocate as defined under The Advocates Act 1961 who is entitled to practice law as per the rules laid down by Bar Council of India from time to time, who is well-versed with the provisions of the relevant Acts and Rules, and is actively involved in filing and disposal of applications for patents, trademarks and designs

iv. Government departments/organisations/agencies like TIFAC, NRDC, BIRAC, DEITy, DSIR etc.

7. Functions of Facilitators

Among other functions as may be decided by the CGPDTM, facilitators will be responsible for :

❖ Providing general advisory on different intellectual property rights to startups on pro bono basis,
❖ Providing information on protecting and promoting IPRs to startups in other countries on pro bono basis,
❖ Providing assistance in filing and disposal of IP applications related to patents, trademarks and Design under relevant Acts at the national IP offices under the CGPDTM
❖ Drafting complete provisional specifications of inventions of startups
❖ Preparing and filing responses to examination reports and other queries, notices or letters by the IP office,
❖ Appearing on behalf of startup at hearings as may be scheduled
❖ Contesting opposition, if any, by other parties, and
❖ Ensuring final disposal of the IPR application

8. Fees of Facilitators

Following fees structure will be applicable to the empanelled facilitators, for any number of patents, trademarks or designs that may be applied for by a startup. The facilitator shall not charge anything from the Startup or the entrepreneur, and this fees shall be paid directly to the facilitator by the Central Government through the CGPDTM.   This structure may be revised from time to time by the Department of Industrial Policy and Promotion.

(Figures in Rs.)

Stage of Payment		Patent	Trademark	Design
At the time of filing of Application		10,000	5,000	2,000
At the time of final disposal of Application	Without opposition	10,000	2,000	2,000
	With Opposition	15,000	5,000	4,000

Note: If any application is withdrawn or abandoned before disposal of application, facilitator shall be entitled to fees only for filing of application and not for disposal of application.

9. **Statutory Fees**

The cost of the statutory fees payable for each patent, trademark or design applied for in India or abroad by a startup after launch of this scheme shall be borne by the startup itself.

10. **Period of Scheme**

The scheme shall be run initially on a pilot basis, and shall be applicable for a period of 1 year from the date of launch of Startup India.

11. **Budget**

The budget for the scheme shall be provided from the funds available with the Department.

12. **Ownership of IPR**

This scheme shall be in no way transfer, either wholly or partially, ownership rights on the IPR created to the facilitator or the Government, and the Startup shall have full rights on the IP generated.

<u>Disclaimer</u>

The scheme does not in any way entitle the startup or the facilitator to grant or registration, as the case may be, of the IPR; the applications shall be disposed off as per the relevant laws and rules.

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DETAILED START-UP SCHEMES BY GOVERNMENT OF INDIA

Start-up Schemes by Government of India

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
Support for International Patent Protection in Electronics & Information Technology (SIP-EIT)	Department of Electronics and Information Technology (DeitY)	IT Services, analytics, enterprise software, technology hardware, Internet of Things, AI	Up to INR 15 Lakhs per invention or 50% of the total expenses incurred in filing and processing of the patent application upto grant, whichever is lesser.
Multiplier Grants Scheme (MGS)	Department of Electronics and Information Technology (DeitY)	IT Services, analytics, enterprise software, technology hardware, Internet of Things, AI	Limited to a maximum of INR 2 Cr per project and the duration of each project should, preferably, be less than two years. For industry consortiums these figures would be INR 4 Cr and three years.
Software Technology Park (STP) Scheme	Software Technology Parks of India (STPI)	IT services, fintech, enterprise software, analytics, AI	Sales in the DTA up to 50% of the FOB value of exports is permissible and depreciation on computers at accelerated rates up to 100% over 5 years is permissible.
Electronic Development Fund (EDF) Policy	Department of Electronics and Information Technology (DeitY)	IT Services, analytics, enterprise software, technology hardware, Internet of Things, AI, nanotechnology	Companies will get risk capital from "Daughter Funds" set up by Electronic Development Fund (EDF).
Modified Special Incentive Package Scheme (M-SIPS)	Department of Electronics and Information Technology (DeitY)	Technology hardware, Internet of Things, aeronautics/aerospace & defence,	Majorly provides capital subsidy of 20% in SEZ (25% in non-SEZ) for units engaged in

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
		automotive, non-renewable energy, renewable energy, green technology,and nanotechnology	electronics manufacturing.
Scheme to Support IPR Awareness Seminars/Workshops in E&IT Sector	Department of Electronics and Information Technology (DeitY)	IT services, analytics, enterprise software, technology hardware, Internet of Things, AI	Organisations are provided with a grant between INR 2 Lakhs to INR 5 Lakhs.
NewGen Innovation and Entrepreneurship Development Centre (NewGen IEDC)	NewGen Innovation and Entrepreneurship Development Centre (NewGen IEDC)	Chemicals, technology hardware, healthcare & lifesciences, aeronautics/aerospace & defence, agriculture, AI, AR/VR (augmented + virtual reality), automotive, telecommunication & networking, computer vision, construction, design, non-renewable energy, renewable energy, green technology, fintech, Internet of Things, nanotechnology, social impact, food & Beverages, pets & animals, textiles & apparel.	Provide a limited, one-time, non-recurring financial assistance, up to a maximum of INR 25 Lakhs.
The Venture Capital Assistance Scheme	Small Farmers' Agri-Business Consortium (SFAC)	Agriculture	The quantum of SFAC Venture Capital Assistance will depend on the project cost, location and the promoter's status.
Credit Guarantee	Credit Guarantee Fund Trust for Micro	Sector-Agnostic	Both term loans and/or working capital facility up to

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
	and Small Enterprises (CGTMSE)		INR 100 Lakhs per borrowing unit are being provided.
Performance & Credit Rating Scheme	National Small Industries Corporation (NSIC)	Sector-agnostic	The incentives are proportional to the turnover of the MSMEs.
Raw Material Assistance	National Small Industries Corporation (NSIC)	Sector-agnostic	MSMEs will be helped to avail economics of purchases like bulk purchase, cash discount, etc. Also, all the procedures, documentation and issue of letter of credit in case of imports will be taken care of.
Revamped Scheme of Fund for Regeneration of Traditional	Khadi and Village Industries Commission	Sector-agnostic	Funds limited to a maximum of INR 8 Cr to support soft, hard and thematic interventions are provided.
Single Point Registration Scheme (SPRS)	National Small Industries Corporation (NSIC)	Sector-agnostic	Micro and small enterprises will get exemption from payment of Earnest Money Deposit (EMD) and will be issued tender sets free of cost.
Aspire - Scheme for promotion of innovation, entrepreneurship and agro-industry	Steering Committee, Ministry of MSME	Agriculture, pets & animals, social impact, healthcare & life sciences	Based on nature of existence of the incubator
Infrastructure Development Scheme	National Small Industries Corporation (NSIC)	Sector-agnostic	For a deposit of six months refundable rent, an office space of 467 sq.ft. to 8,657

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
			sq.ft. is provided.
MSME Market Development Assistance	Office of the Development Commissioner (MSME)	Sector-agnostic	Provides air fare reimbursements based on category entrepreneur lies in (General, women, SC/ST/PwD). The total subsidy on air fare & space rental charges will be restricted to INR 1.25 Lakhs per unit.
National Awards (Individual MSEs)	Office of the Development Commissioner (MSME)	Sector-agnostic	The Selected National awardee is facilitated with a cash prize of INR 1 Lakh, INR 75K, INR 50K in order of ranking.
Coir Udyami Yojana	Coir Board	Agriculture	The amount of bank credit will be 55% of the total project cost after deducting 40% margin money (subsidy) and owner's contribution of 5% from beneficiaries.
International Cooperation (IC) Scheme	Office of the Development Commissioner (MSME)	Travel & tourism, human resources, events, advertising	The incentives vary as per the organisation category.
Credit Linked Capital Subsidy for Technology Upgradation	Office of the Development Commissioner (MSME)	Sector-agnostic	Ceiling on loans under the scheme has been raised from INR 40 Lakhs to INR 1 Cr while the rate of subsidy has been enhanced from 12% to 15%.
Bank Credit Facilitation Scheme	National Small Industries Corporation	Sector-agnostic	N/A

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
	(NSIC)		
Atal Incubation Centres (AIC)	Atal Innovation Mission (AIM)	Chemicals, technology hardware, healthcare & lifesciences, aeronautics/aerospace & defence, agriculture, AI, AR/VR (augmented + virtual reality), automotive, telecommunication & networking, computer vision, construction, design, non-renewable energy, renewable energy, green technology, fintech, Internet of Things, nanotechnology, social impact, food & beverages, pets & animals, textiles & apparel.	AIM will provide a grant-in-aid of INR 10 Cr to each AIC for a maximum of five years
Atal Tinkering Laboratories	Atal Innovation Mission	Chemicals, technology hardware, healthcare & lifesciences, aeronautics/aerospace & defence, agriculture, AI, AR/VR (augmented + virtual reality), automotive, telecommunication & networking, computer vision, construction, design, non-renewable energy, renewable energy, green technology, fintech, Internet of Things, nanotechnology,	AIM will provide grant-in-aid that includes a one-time establishment cost of INR 10 Lakhs and operational expenses of INR 10 Lakhs for a maximum period of five years to each ATL.

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
		social impact, food & Beverages, pets & animals, textiles & apparel. Eligibility: Schools (Grade VI – XII) managed by the Government, local body or private trusts/society can apply to set up an ATL.	
Scale-up Support to Establishing Incubation Centres	NITI Aayog	Chemicals, technology hardware, healthcare & lifesciences, aeronautics/aerospace & defence, agriculture, AI, AR/VR (augmented + virtual reality), automotive, telecommunication & networking, computer vision, construction, design, non-renewable energy, renewable energy, green technology, fintech, Internet of Things, nanotechnology, social impact, food & Beverages, pets & animals, textiles & apparel.	Grant-in-aid support of INR 10 Cr will be provided in two annual instalments of INR 5 Cr each.
Udaan Training Programme For Unemployed Youth Of J&K	National Skill Development Corporation (NSDC)	Education, human resources	INR 750 Cr has been earmarked for the implementation of the scheme over a period of five years
Enhancement of Competitiveness in the Indian Capital Goods Sector	Department of Heavy Industries (DHI)	Chemicals, technology hardware, healthcare & lifesciences, aeronautics/aerospac	One time grant up to 25% of the cost of the technology acquisition of each technology.

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
		e & defence, agriculture, automotive, construction, non-renewable energy, renewable energy, green technology, Internet of Things, nanotechnology, social impact, food & beverages, textiles & apparel.	Maximum amount given shall not exceed INR 10 Cr
National Clean Energy Fund (NCEF) Refinance	Indian Renewable Energy Development Agency (IREDA)	Renewable energy, clean energy, green energy plants.	REDA would provide funds received from NCEF by way of refinance to scheduled commercial banks and financial institutions (including IREDA). Maximum refinance amount INR 15 Cr per project.
IREDA Scheme For Discounting Energy Bills	Indian Renewable Energy Development Agency (IREDA)	Renewable energy, clean energy, green energy	Upto 75% of the invoice value pending for maximum six months from the date of application subject to a maximum bill discounting facility of INR 20 Cr. The minimum amount of transaction covering a set of bills shall not be less than INR 1 Cr.
Bridge Loan Against MNRE Capital Subsidy	Bridge Loan Against MNRE Capital Subsidy	Renewable energy, clean energy, green energy	The projects will get up to 80% of the existing pending eligible capital subsidy claim, as verified by the IREDA with a minimum loan assistance of INR 20

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
			Lakhs.
Bridge Loan Against Generation-Based Incentive (GBI) Claims	Indian Renewable Energy Development Agency (IREDA)	Renewable energy, clean energy, green energy	A minimum loan assistance of INR 20 Lakhs is provided under this scheme.
Loan for Rooftop Solar PV Power Projects	Indian Renewable Energy Development Agency (IREDA)	Renewable energy, clean energy, green energy	The quantum of loan from the IREDA shall be 70% of the project cost with minimum promoter's contribution of 30%. IREDA may extend the loan upto 75% of the project cost.
Credit Enhancement Guarantee Scheme	Indian Renewable Energy Development Agency (IREDA)	Renewable energy, clean energy, green energy	Provide credit enhancement by way of unconditional and irrevocable partial credit guarantee to enhance the credit rating of the proposed bond.
Dairy Entrepreneurship Development Scheme	National Bank for Agriculture and Rural Development (NABARD)	Agriculture, pets & animals, social impact, food & beverages.	The incentives differ with respect to the cost of the required equipment or establishment of the facilities
4E (End to End Energy Efficiency)	Small Industries Development Bank of India (SIDBI)	Sector-agnostic	Up to 90% of the project cost with minimum loan amount of INR 10 Lakhs and maximum loan amount not to exceed INR 150 Lakhs per eligible borrower can be granted. The MSME unit has to pay only INR 30,000 and applicable taxes and the balance fee will

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
			be paid by SIDBI to auditors.
Pradhan Mantri Mudra Yojana (PMMY)	Micro Units Development and Refinance Agency Ltd. (MUDRA)	Sector-agnostic	MUDRA offers incentives through these interventions: >Shishu: covering loans upto INR 50,000/- > Kishor: covering loans above INR 50,000/- and upto INR 5 Lakhs > Tarun: covering loans above INR 5 Lakhs and upto INR 10 Lakhs
Stand Up India	Small Industries Development Bank of India (SIDBI)	Sector-agnostic	Composite loan between INR 10 Lakhs and INR 1 Cr to cover 75% of the project cost can be taken up, inclusive of term loan and working capital.
Sustainable Finance Scheme	Small Industries Development Bank of India (SIDBI)	Green Energy, Non-renewable Energy, Technology Hardware, Renewable Energy	Suitable assistance by way of term loan / working capital to ESCOs implementing EE / CP / Renewable Energy project provided.
SIDBI Make in India Soft Loan Fund for Micro Small and Medium Enterprises (SMILE)	Small Industries Development Bank of India (SIDBI)	Sector-agnostic	The loan amount granted is based on category entrepreneur lies in. (General, women, SC/ST/PwD)
Startup assistance Scheme	Small Industries Development Bank of India (SIDBI)	Sector-agnostic	The financial assistance provided is need-based, subject to a maximum of INR 200 Lakhs and equity kicker

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
Growth Capital and Equity Assistance	Small Industries Development Bank of India (SIDBI)	Sector-agnostic	MSMEs are helped to leverage equity / sub debt assistance from SIDBI for raising higher debt funds.
Assistance to Professional Bodies & Seminars/Symposia	Science and Engineering Research Board (SERB)	Events, chemicals, technology hardware, healthcare & lifesciences, aeronautics/aerospace & defence, agriculture, AI, AR/VR (augmented + virtual reality), automotive, telecommunication & networking, computer vision, construction, design, non-renewable energy, renewable energy, green technology, fintech, Internet of Things, nanotechnology, social impact, food & beverages, pets & animals, textiles & apparel.	The incentives include nominal support for pre-operative expenses
Ayurvedic Biology Program	Science and Engineering Research Board (SERB)	Chemicals, healthcare & life sciences, nanotechnology, social impact.	Support is primarily given to encourage participation of young scientists and research professionals in such events along with nominal support for pre-operative expenses.
Industry Relevant R&D	Science and Engineering Research Board (SERB)	Sector-agnostic	The industry share should not be less than 50% of the total budget. Overhead is provided to the academic partner.

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
			The SERB share shall not exceed INR 50 Lakhs for a project.
High Risk-High Reward Research	Science and Engineering Research Board (SERB)	Chemicals, technology hardware, healthcare & lifesciences, aeronautics/aerospace & defence, agriculture, AI, AR/VR (augmented + virtual reality), automotive, telecommunication & networking, computer vision, construction, design, non-renewable energy, renewable energy, green technology, fintech, Internet of Things, nanotechnology, social impact, food & beverages, pets & animals, textiles & apparel.	The research grant covers equipment, consumables, contingency and travel apart from overhead grants. No budget limit is prescribed for these projects.
Technology Development Programme (TDP)	Science and Engineering Research Board (SERB)	Chemicals, technology hardware, healthcare & lifesciences, aeronautics/aerospace & defence, agriculture, AI, AR/VR (augmented + virtual reality), automotive, telecommunication & networking, computer vision, construction, design, non-renewable energy, renewable energy, green technology,	Provided support for project staff salaries, equipment, supplies and consumables, contingency expenditure, patent filing charges, outsourcing charges, etc.

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
		fintech, Internet of Things, nanotechnology, social impact, food & beverages, pets & animals, textiles & apparel.	
National Science & Technology Management Information System (NSTMIS)	Department of Science and Technology (DST)	Chemicals, technology hardware, healthcare & lifesciences, aeronautics/aerospace & defence, agriculture, AI, AR/VR (augmented + virtual reality), automotive, telecommunication & networking, computer vision, construction, design, non-renewable energy, renewable energy, green technology, fintech, Internet of Things, nanotechnology, social impact, food & beverages, pets & animals, textiles & apparel.	Grant-in-aid are provided for projects. Also, overheads on projects are provided at the rate of 10% of the total project cost for educational institutions and NGOs and 8% for laboratories & institutions under Central Government departments/agencies.
Biotechnology Industry Partnership Programme (BIPP)	Biotechnology Industry Research Assistance Council (BIRAC)	Healthcare & life sciences	Support is provided for high-risk, accelerated technology development especially in futuristic technologies.
Industry Innovation Programme on Medical Electronics (IIPME)	Biotechnology Industry Research Assistance Council (BIRAC)	Healthcare & life sciences	The loan and grant are provided according to the startup stage.
Extra Mural	Science and	Chemicals,	The research grant

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
Research Funding	Engineering Research Board (SERB)	technology hardware, healthcare & lifesciences, aeronautics/aerospace & defence, agriculture, AI, AR/VR (augmented + virtual reality), automotive, telecommunication & networking, computer vision, construction, design, non-renewable energy, renewable energy, green technology, fintech, Internet of Things, nanotechnology, social impact, food & beverages, pets & animals, textiles & apparel.	covers equipment, consumables, contingency and travel apart from overhead grants. No budget limit is prescribed.
SPARSH (Social Innovation programme for Products: Affordable & Relevant to Societal Health)	Biotechnology Industry Research Assistance Council (BIRAC)	Healthcare & life sciences	The loan and grant are provided according to the startup stage.
Promoting Innovations in Individuals, Startups and MSMEs (PRISM)	Council of Scientific & Industrial Research	Sector-agnostic	Support grant is provided under categories such as PRISM Phase I, PRISM Phase II and PRISM-R&D Proposals.
Science and Technology of Yoga and Meditation (SATYAM)	Department of Science and Technology (DST)	Healthcare & life sciences	Not specified.
Rapid Grant for Young Investigator (RGYI)	Department of Biotechnology (DBT)	Healthcare & Life sciences	RGYI provides startup grants to young investigators across the country

Name Of The Scheme	Headed By	Industry Applicable	Fiscal Incentive (*T&C applied)
			working in different settings such as central government funded institutions, state government-funded university departments, scientists at DSIR-approved private institutions etc.
Biotechnology Ignition Grant (BIG)	Biotechnology Industry Research Assistance Council (BIRAC)	Healthcare & life sciences	Up to INR 50 Lakhs for research projects with a commercialisation potential with duration of up to 18 months are provided.

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CO-SPONSORS OF WORKSHOP ON BIOTEHNOLOGY START-UP ECOSYSTEM IN INDIA

1.   **Aurigene Discovery Technologies Limited**

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3.   **IMGENEX India Pvt. Ltd.**

4.   **Ipca Laboratories Ltd.**

5.   **Lupin Limited**

6.   **Yashraj Biotechnology Limited**

Aurigene Discovery Technologies Limited

Aurigene is a Drug Discovery Services company committed to the vision of being the most respected and valued scientific collaborator in India.

Based in Bangalore, Hyderabad and Kuala Lumpur, Aurigene has fully integrated Drug Discovery infrastructure from Hit Generation to Pre-clinical development.

Aurigene has pioneered customized models of Drug Discovery collaborations with large-pharmaceutical, mid-pharmaceutical companies and Biotechs.

In over 17 years of working with Pharma, Biotech and Academic partners, in a variety of Therapeutic Areas, Biologies and Chemistries and over 75 integrated Drug Discovery projects, Aurigene has contributed to delivering over 15 small molecule and peptide drug candidates to its biotech and pharmaceutical partners.

In addition, Aurigene's stand-alone Services partnerships have contributed to many projects in areas of Medicinal Chemistry, Crystallography, ADME/ PK, Process Development and non-GMP Scale-up.

Aurigene is a profitable company that has continuously invested in its people resources, infrastructure and expertise over the years.

BiOZEEN

At BiOZEEN, we provide robust automated bioprocess technologies to enable the biopharmaceutical industry manufacture regulatory compliant and economically competitive vaccines and biologicals.

Our deep expertise and experience in Bioprocess Engineering, Plant Automation, Fabrication Technologies and User Philosophies allow us to synthesise customised bioprocess hardware and automation infrastructure for enhanced productivity and train the end users in all processes.

We are a technology focused, innovation driven (Bio) Pharmaceutical services company, that provides *Production Support, Process support* and *People support.*

Product Support - **Design and Build Solutions**: Manufactures bioprocess related equipment such as Bioreactors, Fermentors, Cleaning-in-Place System, Sterilization-in-Place System, Filtration Skids, Process vessels, Inactivation system and Crystallizer for the bio-pharmaceutical industry.

Process Support - **Value Added Integration Service:** Our philosophy is to integrate bioprocess, engineering, automation and compliance expertise to support each phase of the Biopharmaceutical and Biologics manufacturing life – cycle.

People Support - **Training:** Our Training modules prepares the academia and industry for the Biopharmaceutical Industry at our world class Bio-Pilot Laboratory. Built closely to replicate a modern biopharmaceutical plant with state of the art equipments, it consists of extensive upstream and downstream equipments to provide in-depth training in the areas of Upstream Processing, Downstream Processing, Bioprocess Engineering, Utility Management and Regulatory compliances specific to the Biopharmaceutical & Biologics production industry.

We partner with companies across Europe, Asia, Americas and Oceania to provide result driven production infrastructure for their bio-production needs. With commitment, conscience and award-winning processes, we believe that "*We are into the business of saving lives*"

IMGENEX India Pvt. Ltd.

IMGENEX INDIA Pvt. Ltd**.,** is one of the foremost biotechnology company in the Eastern region of India and was founded by Dr. Sujay Singh, Ph.D., in the year 2004 at Bhubaneswar. IMGENEX India has built a state-of-the-art R&D facility at the Infocity complex. The R&D unit of IMGENEX India was inaugurated in 2005 by Dr. APJ Abdul Kalam, the then Hon'ble President of India and is recognized by the Department of Science and Industrial Research (DSIR), Ministry of Science & Technology, Govt. of India. The R&D Unit of IMGENEX India R&D laboratories are well-equipped for molecular biology, recombinant protein production, cell culture, antibody development and other downstream processes.

The main goal of IMGENEX India is to provide affordable healthcare to less privileged patients. Over the years IMGENEX India has received several grants from the Department of Biotechnology (DBT) that includes SIBRI grant from to develop drugs for osteoporosis using nanotechnology-based drug delivery. It is in the early development phase. In addition to this with grants from BIRAC, Dept. of Biotechnolgy, Govt. of India and Technological Development Board, Govt. of India we are developing biosimilar Trastuzumab/Herceptin for treatment of breast cancer. Other biosimilars in the pipeline includes Adalimumab (humira) for rheumatoid arthritis, Bevacizumab (avastin) for colon cancer, Ustekinumab (stelara) for psoriasis, and Nivolumab (opdivo) for lung cancer.

IMGENEX India is also engaged in the advancement of biotechnology in India through providing training to aspiring young students from across the country in proteomics and genomics to expose them to modern biotechnology and to make them industry worthy. It is associated with Biotech Consortium of India Limited (BCIL) and train students under the Biotech Industrial Training Program (BITP) under the patronage of Department of Biotechnology (DBT), New Delhi. Imgenex India also strongly supports the collaboration between academia and industry. This organization is involved in different R&D projects in collaboration with some reputed organizations, such as, Institute of Life Sciences, Bhubaneswar; National Institute of Science Education and Research, Bhubaneswar, etc.

In collaboration with National Institute of Immunohematology, a division of Indian Council of Medical Research (ICMR), IMGENEX India is developing first indigenous

diagnostic kit for detection of beta thalassemia, which should be available soon through ICMR.

IMGENEX India had received awards as Emerging Company in the Asia-Pacific Region in the year 2011 by Singapore based Bio Spectrum magazine and Emerging Company of the Year 2015 in Bio industry sector in India by Bangalore Bio.

Ipca Laboratories Ltd.

Ipca is a fully-integrated pharmaceutical company, manufacturing over 350 formulations and 80 APIs for various therapeutic segments. cGMP (current Good Manufacturing Practices) & Safety is a way of life at Ipca.

Our Values are *Qualiti*, *Safeti*, *Integriti*, *Digniti* & *Responsibliti*, '*y*' has been replaced with '*i*' for self ownership. We communicate to one and all to reach excellence in all walks of life.

Active Pharmaceutical Ingredients (APIs)

We are one of the world's largest manufacturers and suppliers of numerous APIs. We are supplying our APIs to a range of customers encompassing multi-national and large pharma companies spread across the globe. We also cater to highly regulated markets like Europe, USA, Japan, etc. Our manufacturing facilities have been inspected by various drug regulatory authorities and are well equipped to manufacture majority of the APIs right from the basic stage.

Domestic – Formulations Business

We produce wide variety of dose forms, viz. oral solids and liquids, dry powders for suspension, ointments and injectables (liquid and dry). We have **three** of our branded formulations being ranked among the Top-300 Indian brands by ORG-IMS(Data: **Dec'18**).

We are therapy leaders for anti-malarials and in DMARDs (Disease Modifying Anti-Rheumatic Drugs) treatment for rheumatoid arthritis and Pain Management. We have **14** therapy focused marketing divisions building strong brands mostly in life style related disease segments.

International Formulations Business

We have a comprehensive product portfolio of formulations in Generic & Branded markets. We export our products nearly to 120 countries across the globe.

We promote our branded formulations in over 30 countries in Asia, CIS, Middle East, Africa and some Latin American countries. We have built a strong field force of around 500 people in these markets for building our brands, globally. We have overseas offices and wholly owned sunsidiaries.

Ipca has a very strong position in global institutional funded markets where we are leading suppliers of anti-malarial formulations. We export our Generic formulations to US, UK, Europe, Canada, Australia, New Zealand and South Africa.

Human Resources

We, Ipcaites are open to learning at every age and at every stage. We propagate lessons learnt and spread awareness encouraging team to learn, engage and transform into better than yesterday. At Ipca, we nurture, groom and develop talent, offer opportunities for growth and capability building. To enhance the bonding with the employees, various employee engagement programs are regularly conducted which promotes work-life balance. We publicize and motivate active participation towards social awareness, inviting new ideas on saving resources and reducing wastage etc. We actively take part in Society development through our CSR (Corporate Social Responsibility).

We are continuously evolving and our constant efforts are to give the best.

Lupin Limited

Lupin is a global pharmaceutical company offering Branded & Generic Formulations, Biosimilars and Active Pharmaceutical Ingredients (APIs). Founded nearly 50 years ago, Lupin today is a significant player in US generics, India and Japan and in multiple countries across APAC, EMEA and LatAm. Lupin also holds a global leadership position in the Anti-TB and Cephalosporins segments. Lupin offers high-quality yet affordable medicines for some of the most chronic diseases addressing the unmet medical needs across many parts of the world.

Yashraj Biotechnology Limited

Progress is not how we grow; it is about how we make a difference in lives of others!

This is our guiding principle at Yashraj Biotechnology Limited (YBL). Established in 1999 as a research focused Biotech Company with ISO certifications ISO 13485:2016 and ISO 9001:2015, YBL manufactures a wide range of high pure biomarkers in the form of Native and Recombinant Antigens that are used by the diagnostic industry as Controls, Calibrators and Immunogens. Our Antigens are purified as high pure and part pure and customized using our in-house developed methodology. For 20 years, our flagship products of CRP, Cancer Antigens and HBsAg-Ad, HBsAg-Ay, NGAL, rSLO and rProlactin have routinely passed quality audits of leading global diagnostic manufacturers. With an emphasis on long term stability and specificity, our Antigens are tested in multiple platforms for quality by Immunonephelometry, Immunoturbidimetry, Latex Agglutination, ECLIA and ELISA to ensure batch to batch consistency and by US-FDA approved CLIA and PCR for compliance and safety. Our project management teams have created a pan India network to access bio-medical fluid in order to ensure timely delivery of quality Antigens to our clients with added benefits of consistency, customization and quality. Allow us to understand your specific requirements of purity, buffer and stability to provide you with the best quality Antigens corroborated through customer audits as well as bulk reservation of approved batches.

Come and join us at Yashraj Biotechnology Limited in our quest to make diagnostics affordable and accessible!

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