

Biotech Startups in India -At the Cusp of Global Impact

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Contents

A VIBRANT ECOSYSTEM AND THE BOTTOM-UP REVOLUTION	1
ERA 1.0: LAYING A STRONG FOUNDATION FOR THE BIOTECH STARTUP ECOSYS	TEM 4
1.1 EXTRAMURAL GRANTS FOR VENTURES	4
1.2 INITIATIVES ADDRESSING STRUCTURAL GAPS:	5
1.3 CONTINUED PRIMING OF THE ECOSYSTEM WITH NEWER INITIATIVES	6
ERA 2.0: OVERVIEW OF THE CURRENT LANDSCAPE	10
2.1 GENESIS OF TECHNOLOGY & DNA OF ENTREPRENEURS	
2.2 EMERGENCE OF REGIONAL CLUSTERS & IMPROVED INFRASTRUCTURE	11
2.3 FUNDING	13
2.4 AREAS OF INNOVATION	15
ERA 3.0: RECOMMENDATIONS FOR TRIGGERING GLOBAL IMPACT	
3.1 FOSTERING MORE ROBUST PIPELINE OF DEEP SCIENCE DRIVEN STARTUPS	
3.2 Addressing Glaring Void in Scale-up Funding	21
3.3 CONTINUING INFRASTRUCTURE CHALLENGES AT SCALE-UP STAGE	24
3.4 CREATING REWARD FOR INNOVATION AND FOSTERING MARKET MATURITY	25
3.5 EASE OF DOING BUSINESS	27
ABBREVIATIONS	

A Vibrant Ecosystem and the Bottom-up Revolution

We are delighted to analyze state of biotechnology innovation in India with emphasis on early stage innovation and its acceleration. Over the last five years, Indian ecosystem for early stage biotech innovation and startups has gained significant momentum. Over 500 ventures have attempted to expand boundaries of science, pursue novel therapies, diagnostics, devices and industrial solutions, with surge in investment in early stage ventures. Robust clusters in Bengaluru, Pune, and Hyderabad etc. have converged biotech ventures and academic centers of excellence to co-create products and services, applying most cost-effective innovation frameworks. Since early stage ventures entail classic high-risk–high reward dichotomy, it is essential for Government to deploy significant level of risk funding to propel innovation. To a large extent, innovation investment support for pre-seed stage has witnessed significant surge due to Department of Biotechnology (DBT) and associated institutions committing early de-risking investments to hundreds of ventures.

Translational platforms such as the National Bio design Alliance (NBA), conceived, catalyzed and funded by DBT has evolved as a unique model of innovation convergence, transcending traditional boundaries of numerous research disciplines within the public research system. With demonstrated buy-in within IITs and national health research organizations, NBA has emerged as a pioneering and unique national alliance to address critical national needs in human health. Some of the ventures germinating from the NBA ecosystem are moving through progressive rounds of funding, thus duly establishing credentials of this model of convergent growth of start-ups around the academic eco-system.

However, there are number of areas that needs targeted focus, to enlarge and effectively sustain innovation in the start-up ecosystem. The thrust of the Prime Minister on "Make in India" is dependent on "Innovate in India". Life sciences provide the most promising opportunities for early stage innovation and for India to emerge at the forefront of the innovation pathway, we need to consider flow of resources intended for the "Innovate in India" imperative to percolate to the life sciences innovation ventures. The resources earmarked for Innovation acceleration through the fund of funds has hardly reached the peripherals of life sciences ventures and have gone into information technology and other sectors. The reason is partly the inability to perceive the risk of investing in the life science sector. We need to gain a large surge of investment for acceleration of these innovations. We need to see significantly larger investment in ecosystem enlargement, as startups converge at a rapid pace in bioclusters. We would like to see deeper convergence of the academic technologies into the private ventures with a policy framework that encourages academic spin-outs and technology flow to early stage innovators. Finally, we need public procurement to support and absorb these innovations with a policy that encourages affordable products to be taken to market without bureaucratic hurdle.

A Vibrant Ecosystem and the Bottom-up Revolution

Era 1.0 : Laying a Strong Foundation for the Biotech Startup Ecosystem

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The last decade has been transformational for the Indian biotech and medtech startup ecosystem. While several biotech ventures such as Biocon, Bharat Biotech, Biological E and Shanta Biotech among others, were seeded prior to that and have been nurtured into formidable industry players, biotech startups were not a widespread phenomenon. There were less than twenty scaled up success stories that charted unique paths primarily led by their founders' determination to navigate unpaved terrain. Early government innovation funding programs such as TDB and NMITLI provided thin lifelines in an otherwise nascent ecosystem. Role models were far and few for aspiring entrepreneurs, access to forgiving capital to shoulder technology risk was a challenge, equity capital to defray market risks was also hard to raise.

We now stand at a threshold of explosion with more than 500 ventures passionately advancing innovation to markets. This surge is not ephemeral because it is anchored in foundational changes led by design and supported by ecosystem tailwinds. The product IP regime introduced in 2005 in India was a major fillip for this wave of change. Pioneers such as Dr Mashelkar motivated several corners of the research system to go beyond publishing to patenting and thus, translational research. The institutional backbone was primed. Pioneered by DBT under Dr Bhan's vision, Government funding for ventures was geometrically expanded and extra-mural funding that can de-risk technology became a more tangible lifeline. BIRAC alone, through its several vectors has supported 617 projects that have filed closed to 150 patents as of September 2017.¹ Biotech innovation does not function in silos and convergence is critical for the symphony to function. The ecosystem lens was adopted, and collaboration platforms created to propel a culture of co-creation. Key elements of change that have contributed to the current fertile ground for biotech and medtech entrepreneurship include:

1.1 Extramural Grants for Ventures

Technology de-risking seed capital providing runway to take-off: Globally, public funding has been the most common starting point of biotech and medtech innovation, and has been instrumental in supporting initial proof of concept stages. This is especially true in ventures advancing innovations with deep rooted science. At this stage, technology risk is highest and probability of success is hard to determine. As progressive stages of proof of concept is established, technology risk reduces and equity capital becomes more accessible.

Significant component of public funding for research in India has traditionally been directed towards public research labs as intramural funding. The quantum leap in level of extramural funding programs such as SBIRI, BIPP and BIG has been one of the most significant stimulants for the entrepreneurship wave. It has empowered several aspirational entrepreneurs to pursue early proof of concept and embark on the startup journey. BIRAC alone has provided funding of close to INR 850 crores as of September 2017² and this stimulus has been pivotal in creating the base of the startup funnel. In addition to providing seed money, grants like BIG facilitate mentoring and monitoring through a diverse board of scientists and business veterans. Support in handholding for IP and technology management, capacity building, and stitching partnerships with other grant recipients allows ventures to expedite growth on the right tangents. This availability of grant funding has resulted in a cyclic effect with ventures being triggered and the resultant momentum leading to interest from other

^{1,2} BIRAC Innovations: Propelling the Bio-economy Report, 2017

philanthropic and science funders (The Bill and Melinda Gates Foundation, The Wellcome Trust to name a few) who have further expanded the pool of early stage non-dilutive funding.



1.2 Initiatives Addressing Structural Gaps:

Creating platforms for convergent innovation and seeding national pipeline: India has a strong institutional backbone at universities and national research networks such as CSIR, ICMR and ICAR. These academic institutions are at the base of the innovation pyramid and offer the most fertile platform for pursuit of research in multi-disciplinary areas such as medical

devices and diagnostics. However, translation of existing institutional strength into innovation pipeline with commercial potential has been restrained because of characterized silos. For instance, most leading US universities house high research strengths across engineering, biochemistry, microbiology, informatics and clinical delivery within one campus with several opportunities for identification of unmet needs and organic convergence of multi-disciplinary teams for creation of solutions. In the Indian context, same fluid innovation flow is not observed given the siloed presence of clinical pioneers, leading engineering colleges and basic science institutions. While forerunners such as SCTIMST in Trivandrum have developed complex Class III devices, such innovation engagement in medtech hasn't been a widespread phenomenon due to this structural issue in organization of research institutions.

Another foundational aspect in the last decade has been conceptualization and creation of translational platforms that have converged multi-disciplinary expertise to co-create nationally and globally relevant solutions. In addition to triggering a national pipeline of devices and diagnostics and demonstrating model of engagement in multi-disciplinary innovation advancement, these platforms have nurtured a deeper culture of convergent innovation across the ecosystem. A high impact example of such translational platforms is the National Biodesign Alliance created by the DBT that converged leading clinical and research institutions in thematic areas of focus (illustrated below). Programs within the platform have now resulted in multiple technologies being licensed and spun out into ventures and the models are now being emulated by other institutions.



National Biodesign Alliance

1.3 Continued Priming of the Ecosystem with Newer Initiatives

Startup momentum in the biotech and medtech segment is further strengthened by new initiatives that have the potential to expand opportunities and support value realization:

1.3.1 Start-Up India

The Start-Up India campaign launched in 2016, has been one of the most prominent steps taken towards promulgating culture of organized and rewarded innovation in India. It includes a fund of funds corpus of INR 10,000 crore, tax exemptions, rebates in patent filing and business self-certification. The program is gaining traction with number of registered companies increasing from 4536 registered companies in October-17 to 5350 in December-

17.³ Overall momentum in the entrepreneurial community has been enhanced, and if funneled strategically, funding and other benefits can bridge current gaps and support further evolution of this ecosystem.

1.3.2 Biotech parks with shared facilities

Bioincubation needs specialized infrastructure. Shared infrastructure platforms with wellstructured access models for critical equipment provide soft landing avenues for startups and significantly reduce initial investment. There has been substantial expansion in bioincubation

Incubators/infrastructure platforms: TDB funded 36 TBIs and STEP BIRAC funded 15 incubators with intent to create another 50 by 2020 (Source: TDB.gov.in; BIRAC Brochure, 2016)

space both in major hubs such as Bengaluru, Hyderabad, Delhi, Pune and emerging ones such as Coimbatore, Kanpur, Trivandrum. Ease of access to incubation space and equipment has been a key driver propelling momentum in ventures.

1.3.3 Corpus funds and incubation funding platforms

Incubators and accelerators provide more than brick and mortar to ventures. Services on legal and regulatory hurdles, shared tinkering & prototyping labs, and a collaborative knowledge network for fellow incubatees enable innovation creation and dissemination. A major initiative championing the movement has been funding for incubators from NITI Ayog under the Atal Innovation Mission, BIRAC under BioNest, DST under TDB and NIDHI PRAYAS. Additional fillip is anticipated from

Birac's i3 is a USD 250 million corpus created as part of Biopharma Mission to fund biotech startups and accelerate innovation in the areas of vaccines, bio-therapeutics and medical devices. With USD 125 million from the World Bank and an equal contribution from Government of India, the program will fund companies to advance assets and other capacity building efforts to address infrastructure and skill gaps.

BIRAC's \$250 million innovate in India (i3) programme that has been launched in collaboration with the World Bank.

1.3.4 Policy and regulatory thrust

There has been proactive engagement by policymakers with industry to address gaps, strengthen regulatory frameworks and simplify processes. Significant developments include introduction of the Medical Device Rules, new biosimilar guidelines, addressing inverse duty structure in certain medical device products. Continuing focus on ease of doing business and refinement of regulatory frameworks are promising for innovation ecosystem that is at the threshold of breaking into the next realm of growth.

³ Status Report on Startup India- www.startupindia.gov.in

Laying a Strong Foundation for the Biotech Startup Ecosystem

Era 2.0 : Substantial Momentum and Surge in Startup Activity

Era 2.0: Overview of the Current Landscape

The foundation laid by design has reaped substantial reward. The biotech and medtech entrepreneurship wave is a reality and there is a surge of ventures both in dominant geographic hubs and emerging ones. The current Era 2.0 presents a vibrant landscape where both socially relevant and globally opportune solutions are being passionately pursued. Even while being driven by a common motto, each venture can be traced to a different interplay of genesis, geography and trajectory:

2.1 Genesis of Technology & DNA of Entrepreneurs

There is no mantra that safeguards success of a venture, but ideas and people are two key components of the equation.



Reiterating the fact, today ventures can access non-dilutive grants more readily across stages of idea exploration, proof of concept and validation. which has enabled de-riskina. technology This continues to prompt the rise of first generation entrepreneurs, to step out of secure jobs and take the entrepreneurial plunge. There is no pecking order but there is now notable engagement in the ecosystem from industry veterans with several years of experience in R&D, expats either coming back to set up Indian ventures or founding ventures that have an Indian presence, recent graduates from leading Indian and global institutions

as well as faculty involved in institutional research. The accompanying graph indicates the equitable distribution of innovators from different backgrounds from three largest incubation centers in the country.

The number of spin-out ventures commercializing research with genesis in Indian institutions comprise a lower proportion of the overall startup landscape as compared to more mature innovation ecosystems. However, culture of collaboration is actively expanding, and ventures are increasingly leaning on institutions to leverage depth of scientific expertise. As translational focus expands and evolves, there is significant potential for institutions to emerge as a potent source of venture creation. An example of a spin-out from an academic institution with relatively deeper engagement in applied research is PathShodh Healthcare.

PathShodh Healthcare: Example of an Institutional Spinout

A spin out of IISc Bengaluru, PathShodh is focused on relatively more upstream R&D within PoC diagnostics. The startup co-founded by Navkanta Bhat, Vinay Chauhan and Gautam Sharma, has largely leveraged grants such as BIPP to advance to current stage of development. PathShodh Healthcare, has developed a patented biosensor device that monitors diabetes management and enables early detection of chronic kidney disease. The miniaturized patented device is targeted at clinics and hospitals in the rural and tier II cities with subsequent plans for home use.

2.2 Emergence of Regional Clusters & Improved Infrastructure

Biotechnology innovation is often a relay with several stakeholders steering innovation forward at various stages and a team game with co-creation often being invaluable. Consequently, it needs a co-evolving network of institutes, companies, universities, service providers and private capital to thrive. Prominent global hubs are living examples of organic clustering common in this segment and its impact on increased probability of success. Examples include startup and innovation clusters around San Francisco Bay Area supported by Silicon Valley, pioneering biotech companies such as Amgen and Genentech and abundant venture capital; Boston Biopharma cluster supported by presence of institutional backbone with Massachusetts Institute of Technology, Harvard, Massachusetts General Hospital, large pharma companies like Sanofi, Pfizer, Novartis, and the Minneapolis Medical devices hub led by giants like Medtronic.

Similar factors have led to concentration of technologies and innovation in and around certain regions in India, which have now emerged as megaclusters. Karnataka, for instance, has enjoyed strong applied science depth in institutions and the State Government's venture capital fund has provided additional boost for startups. Existence of larger biotech companies such as Biocon has also resulted in a vibrant research landscape and has seeded next generation of entrepreneurial scientists. Encouraging presence of global development centers of MNCs like GE and Philips in the state has also resulted in more experienced entrepreneurs emerging from these companies and adding to activity concentration and value enhancement in the cluster.

Therefore, congruous factors like large corporates, other successful ventures, incubation infrastructure and policy initiatives have contributed to geographical consolidation, creating three large biotech nuclei: Bengaluru, Hyderabad and Pune.



Percentage of BIG supported projects upto 8th Call (Source: BIRAC BIG Book 2016)

Bengaluru: Bengaluru has relatively higher number of startups, a notable concentration in diagnostics and medical devices and a higher (than national average) concentration of ventures founded by entrepreneurs with prior industry experience. Continuing momentum is fueled by abundant multi-disciplinary talent pool, active bio-entrepreneurship hubs such as BIRAC funded C-CAMP, and State Government initiatives such as the Bangalore Bioinnovation Center, a younger but active innovation hub in South Bengaluru, the Idea to PoC grant and venture capital funding from the KITVEN fund.

Delhi/NCR: Within Northern India, the Delhi-Faridabad-Gurgaon region is an active hub with significant innovation activity supported by stellar academic institutions including IIT Delhi, AIIMS, ICGEB, NII, THSTI, RCB and incubation anchors such as FITT, IIT Delhi.

Hyderabad: Concentration of large pharma and vaccine companies in the area and availability of incubation space has shaped Hyderabad into a leading biopharma cluster. T-Hub, IKP and academic institutes like IIT-H, University of Hyderabad, and LVPEI have provided a nurturing ground for curating new ideas and supporting entrepreneurs. While other clusters struggle with inadequacy of infrastructure for scale-up, availability of land for commercial scale-up (in Genome Valley) is an additional pull for the hub.

Pune: Research backbone of institutions such as NCL, NIV, NARI, NCCS, and IISER and active role played by the Venture Center (NCL) has provided fertile substrate for biotech ventures. Additionally, proximity to Mumbai venture constellation and strong presence of IT, agriculture and pharma advances ventures with multi-disciplinary focus.

There has been a recent emergence of newer incubation centers and significant innovation activity in locations such as Kanpur (UP), Trivandrum (Kerala), Bhubaneswar (Odisha). However, considering the strong interdependence and open alliances required for success within the biotechnology network, it is critical that concentration of engagement in emerging clusters is deepened with focused effort.

2.3 Funding

For any biotech or medtech venture, there is a much higher technology risk in initial phases, which transforms into higher market risk in subsequent phases. As technology risk is defrayed, equity becomes more accessible from both financial and strategic investors. In the initial stages, the entrepreneurial surge has been largely propelled by non-dilutive capital available from DBT and other Government sources as well as philanthropic sources where there is alignment of priorities. In recent years, bilateral and multilateral interaction has also given ground to newer funding schemes. Funding opportunities such as Indo-US VAP, Indo-Swiss and Indo-Finnish bilateral program have set a great precedence for collaboration, exposing Indian public research to otherwise unexplored collaborative opportunities and fostering programs with significant development.

As initial proof of concept is established, angel funding could serve as the critical next step with several angel networks now being active in the country. However, angel investments have been largely limited to diagnostics, devices and industrial biotechnology applications where path to markets are shorter and there has been very limited angel participation in drug discovery and development. As illustrated below, when ventures move towards the right on the continuum of path to markets and technology risk gradually reduces, equity funding becomes more tangible. In the Indian context, availability of equity funding has been easier for medical devices and diagnostics ventures and again drug discovery ventures have greater hardships finding first two rounds of equity capital with the appropriate risk profile. Substantial Momentum and Surge in Startup Activity



Indian Funding Landscape across Startup Lifecycle

Funding requirement varies across sub-segments for different phases of a start-up lifecycle. A large fraction of ventures have been able to get USD 100,000 from BIG grant and depending on the nature of the product, anywhere between USD 0.5 Million and USD 3.0 Million in following rounds. In the case of medtech ventures with relatively lower investment requirement, leading ventures have been able to raise up to USD 5.0 Million to USD 10.0 Million of equity capital for market launch and initial scale up. Conversely, the investment in core science remains elusive despite the glaring unmet needs in the field. One of the few examples of drug discovery startups that has raised rounds of venture capital funding is Vyome Biosciensces:

Vyome Biosciences: Funding Success

The Delhi based startup, Vyome Biosciences, was founded in 2010. The company has emerged from grassroots level as one of the promising startups in mainstream biotechnology arena, backed by an adroit clinical expert team. Beginning with SBIRI grant, followed by series A funding (USD 2.8 Mn) in 2012 and series B funding (USD 8 Mn) in 2014, the company touts a rich heritage of funding support. Enabled by strong funding, the venture has completed phase I and proof of concept studies for their lead product, which helps to cure moderate to serious acne. In 2016, Vyome secured series C funding (USD 14 Mn) towards phase 2 clinical studies for FDA approval of the product. The Company also boasts two patented novel platform technologies with a strong pipeline of drugs for antibiotic resistant acne and other opportunistic pathogens.

2.4 Areas of Innovation

Disruptive innovation has been the norm in several sectors but is only at the beginning of the curve in healthcare. We have witnessed incremental innovation as well as bottom-up technology creation across the biotech spectrum. The more pronounced areas of innovation that have emerged in the last ten years are discussed below:

2.4.1 Innovations addressing critical national needs

In out of pocket markets such as India with significant unmet needs and inefficiencies in healthcare, there is a rapid development of innovations catering to critical national needs across devices as well as biopharma. However, coordinated national effort is required to realize the potential and maximize public health impact.

Applied innovation in devices and diagnostics: To increase access and affordability of healthcare, there has been a constant focus on incremental innovation, platform and product innovation in medtech as well as diagnostics. This portfolio of innovation is expanding applications with existing science and combining synergistic and interdisciplinary approaches to address native public healthcare needs. Propelled by various philanthropic grant funding opportunities, there is a robust pipeline of maternal and child healthcare solutions and point of care diagnostics. There is also significant momentum around several ventures engaging in devices that provide connected care and diagnostics that leverage intelligence and information technology foundation to automate test interpretation, address skill-gaps, introduce efficiency in continuum of care and simplify healthcare delivery.

Sohum

The five year old venture developed under SIB, blends design innovation with auditory testing science BERA to bring an affordable and locally manufactured neonatal hearing screening device to diagnose congenital hearing loss in neonates for low resource settings.

SigTuple

Riding the digitization wave, SigTuple, founded in 2015 by experts in Big Data Analytics, has developed automated microscope. Built on AI platform with image analysis capability for various diagnostic applications, the product eliminates the need for skilled medical experts for accurate diagnosis.

Upstream drug discovery and development: India is burdened with high incidence of diseases such as antibiotic resistance, diabetes and respiratory. As problems more pronounced in developing countries such as India, these areas of drug discovery are not high priority areas for multinational pharma countries headquartered in US or Europe. Hence, it is critical that India nourishes its own pipeline of ventures seeking solutions to pressing needs in the country.

Despite the high need, there is a relatively lower level of startup engagement in upstream discovery and development of novel drugs and vaccines. Bugworks, Vitas Pharma and Tergene Biotech are examples of pioneer ventures engaged in areas of drug or vaccine development that has high level of relevance for India.

The high level of risk and investment involved, currently lower level of institutional spin-out creation, dearth of entrepreneurs experienced in global context of drug discovery and development and paucity of capital tend to be significant deterrents that need to be addressed.

Fergene

Bugworks

One of the very few startups exploring drug discovery and development, Bugworks, is developing novel class of antibiotics designed to treat multi-drug resistant infections. The asset in pre-clinical stage addresses an urgent global need in treating next-generation anti microbials for superbugs. With several innovation awards in the kitty it is the first Indian venture funded by CARB-X accelerator. In addition to BIG, the venture is also supported by Baxter Ventures, 3one4 capital and Biocon.

Tergene, a Hyderabad based innovation-led vaccine company is working on a novel multivalent Pneumococcal Conjugate Vaccine (PCV) that broadens the coverage of existing 13 valent vaccine and makes it more efficacious for the Asian subcontinent by identifying the predominantly existing strains for this region. Considering India has highest incidence of the disease with current 100% import dependence for the vaccine, Tergene's indigenous candidate has the potential to break affordability barriers and alleviate the national disease burden.

2.4.2 Innovations catering to global markets

In addition to addressing India specific problems, several innovative ventures have pursued solutions to globally relevant problems and are seeking global commercialization opportunities from the outset. These ventures have been able to leverage the relatively lower cost of development in India, build globally benchmarkable sophistication and move on the path of seeking regulatory approvals from USFDA or EMA or strategic partnership opportunities with US or European companies. Notable examples include medical device companies such as Perfint Healthcare that has developed USFDA cleared robotic devices for image guided interventional procedures, novel biomarker discovery companies such as Saarum Biosciences and Transcell and drug discovery companies such as Connexios, Curadev and Rhizen that have demonstrated merit of their program through global out-licensing deals.

Incozen Therapeutics: Example of venture catering to global market

Incozen is a clinical-stage biopharmaceutical company focused on discovery and development of innovative, small molecule drugs that target signal transduction networks and ion channels for the treatment of cancer, inflammation, autoimmune diseases and metabolic disorders. The company was founded by ex-R&D head of Glenmark and attracted strategic investment from Alembic. Their lead asset for oncology is currently in Phase 3, advanced by TG Therapeutics, USA while the immune therapeutic product is on-going Phase 1 clinical trial in partnership with Novartis.

2.4.3 Nextgen Innovations

Genomics: Genomics is the newest frontier in diagnostics and is scripting a required paradigm shift in providing targeted, predictive and preventive solutions. Role of genomics has

expanded from rare genetic disorders to common diseases namely cancer, diabetes & stroke and is emerging as a critical part of standard clinical workflow. There is an equal number of ventures catering to B2B as well as B2C markets. Ventures like Mapmygenome, The GeneBox and XCode are engaging in consumer focused genomic tests and products offering elective choices for genetically tailored solutions in fitness, nutrition, skincare etc. At the other end, ventures such as Strand Lifesciences and Mitra Biotech are pushing the envelope on clinical horizons and engaging in identifying and offering test panels with proprietary markers.

Regenerative Medicine: Globally, regenerative therapies are witnessing wider acceptance and escalating growth rates, with cell based products constituting the largest market share. This global trend is reflected in Indian startup landscape as well, across cell therapies, modified blood/tissue products, and gene therapy. Today, several autologous therapies are commercially being offered but scale-up models for startups in autologous therapies is still elusive. Therefore, many ventures are pursuing allogenic therapies as well due to ease of commercial scale up. Hospitals have been one of the drivers of research in autologous therapies. As illustrated below, despite gaps in regulatory framework and lack of clarity, there has been significant startup activity:

EyeStem Research

Ahmedabad based venture incubated at C-CAMP is developing breakthrough cell therapies for degenerative diseases of the eye through a combination of gene editing and stem cells. Their unique approaches are directed towards creating cells that can evade immune rejection, creating scalable allogenic therapies and also opening avenues for treatment of other degenerative therapies of the body.

Next Big Innovations Labs

With 3D printing expanding horizons of product development, NBIL is working at the nexus of engineering and biotechnology. The team has developed a 3D Bioprinter and in parallel working on novel tissue mimicking material composites to create 3D bioprinted scaffolds for both in-vivo and in-vitro uses. Their work will find application in preparing implants, training physicians for complex surgeries, drug discovery and others at an affordable price.

2.4.4 Artificial Intelligence & Machine Learning

Prominent innovation trends in the segment include

- Emerging use of 3D printing in medical applications across product development and commercial manufacturing;
- Increasing pursuit of drug device combinations for life cycle management and competitive advantage;
- Innovations in biomaterial expanding possibilities;
- Pervasive use of robotics, artificial intelligence and machine learning for developing smart devices and
- Leveraging Internet of Things (IoT) to progress towards a more connected continuum of care.

Substantial Momentum and Surge in Startup Activity

Era 3.0: Recommendations for Triggering Global Impact

Era 3.0: Recommendations for Triggering Global Impact

The last decade has been foundational for the biotech innovation ecosystem in India. A surge of startups has been commenced and entrepreneurs are motivated by availability of early proof-of-concept funding. Current policy initiatives such as Make-in-India and Startup India add to the momentum. As a country today, we have the invaluable opportunity of further shaping this innovation led era and making our mark on the world with drugs, devices and diagnostics invented and developed in India. However, as we chart Era 3.0, we need to acknowledge that the path to markets in the case of lifescience startups is longer, progressively more capital intensive, includes higher binary risk and is intrinsically more complex. While we have strategically pieced certain pieces of the maze, several other critical challenges stand it the way of realizing the true potential of biotech startups in India. It is critical that we appreciate our unique contextual challenges and urgently design catalytic solutions to foster a holistic and sustainable ecosystem for biotech startups and accomplish our Make-in-India and Startup India goals.



Addressing Continuing Challenges in Biotech Startup Ecosystem

3.1 Fostering More Robust Pipeline of Deep Science Driven Startups

3.1.1 Encouraging Greater Scientific Sophistication in Ventures:

India has distinctive specialism in frugal innovation and there has been great focus on rethinking affordable solutions. While price economics is a precursor to innovation adoption in the country, there is a simultaneous need to think beyond and pursue globally benchmarkable science. For the innovation ecosystem to evolve and gain global prominence, it is important we foster sophisticated and upstream scientific innovation, defensible IP portfolio, and

innovations with global market potential. There are a subset of ventures today that are pursuing high complexity areas of innovation such as novel drug discovery, next generation regenerative therapies, genomics and novel biomarker discovery, and novel medical devices. However, these represent a very small cross-section of the current startup landscape with majority focusing on incremental innovation. Having seeded initial momentum and an active entrepreneurial ecosystem in biotech, it is critical that we focus on strategically expanding the cohort of ventures pursuing deep-science led innovation pursuits. Raising the level of selectivity for non-dilutive funding, incentivizing higher level of global collaborations, nurturing scale-up funding avenues with greater risk appetite and celebrating a higher bar of science could help create more globally comparable startups.

3.1.2 Leapfrogging Institutional Engagement in Translational Research

Globally, most breakthrough biotech and medtech innovations have originated in academic labs and have been nurtured with non-dilutive government funding. When application potential is more evident, innovation is often spun out into ventures that either advance the innovation to markets or out-license to larger companies at later stages of development. The significance of academia and biotech startups has expanded multifold with large pharma and medtech

During 1996-2015, academic patents & subsequent licensing to industry bolstered US industry gross output by up to USD 1.33 trillion, GDP by up to USD 591 billion and supported up to 4,272,000 person years of employment.

The Economic Contribution of University/Non Profit Inventions in United States: 1996-2015 companies' increasing dependency on external research. However, in the Indian context, very few startups are spin-outs from academic research, and research institutions are yet to emerge as major drivers of upstream science with commercial potential. To nurture a holistic innovation ecosystem and a more evolved startup landscape, it is important that institutions are strategically engaged in this mission.

Several elements would need to be addressed to create a formidable backbone of institutional

research that serves as base of the innovation funnel. We need to enhance the level of institutional engagement in industry-relevant translational research. This will require reimagining delineated research construct from innovation lens and fostering multidisciplinary training across engineering, IT and basic sciences. Additionally, there is also great merit in strategic allocation of part of the intra-mural funding to identify areas of translational research where critical depth of engagement can be instated in concentrated institutional clusters. Platforms for industry-academia engagement need to be multiplied and global translational research collaborations need to be enhanced multi-fold. Finally, technology transfer capacity needs to be created across institutions and mechanisms formulated to reward inventors for IP creation, commercialization and monetization.

3.2 Addressing Glaring Void in Scale-up Funding

India today has a good foundation of seed and early proof of concept funding mechanisms under the broader umbrella of DBT and DST, complemented by international grants, philanthropic funding and state government resources. This has been highly empowering for entrepreneurial aspirants and provides initial risk capital in a non-dilutive form. In product segments with relatively shorter paths to market (such as certain medical devices and diagnostics), entrepreneurs have been able to leverage this early proof of concept funding to advance to a stage where equity has been more accessible for market entry and scale-up. However, more in capital intensive segments such as drug discovery and Class III medical devices. entrepreneurs have highlighted the insufficiency of the standard INR 50 lakhs seed grant and 18 months grant period. An alternative approach would be to complement the product and segment agnostic seed grants with more tailored seed grant programs for higher risk and more complex innovation pursuits.

Ease of access to capital ends at

Indicative global model - South Korea is a good global reference given the transformation from a domestically focused generics industry to a strong innovation force with USFDA and EMA approved drugs. Building blocks inducing such transformation include:

- KDDF- a USD 1.5 billion Government fund, providing grants to drug development companies with the aim of creating 10 blockbuster drugs by year 2020.
- NASDAQ like exchange where innovation led companies can list pre-revenue based on a technology assessment.
- Fiscal benefits for R&D pursuits as well as technology or corporate acquisitions.
- A VC ecosystem with flexibility to invest in international companies to create sustainability while domestic pipeline strengthens.

this early proof of concept stage and ventures thereafter step into a deep valley of death characterized with negligible level of early stage venture capital for high risk biotech innovation. New drugs and vaccines in particular can take between 8 to 10 years to develop and progressively need increasing amounts of capital as the asset is advanced through stages of pre-clinical and clinical validation. Even the stepping stone of angel networks that have

provided early risk capital for technology ventures have been relatively unforthcoming for biotech entrepreneurs. Even in the select cases where angel networks have invested in



horizon, lack of appreciation of product development pathway, and decision making challenges stemming from small tranche of investment being pooled from more than 20 angels. Based on the current pipeline in India and continued venture creation, we estimate that aggregate investment required for developing assets until stage of commercialization is USD 6.2 Billion. The illustration alongside depicts the approach for quantifying such capital requirement.

capital requirement This is almost completely unmet today, barring VC

appetite for lower risk devices and diagnostics. The Fund of Funds announced under Startup India served as a beacon of hope - it includes an allocation of INR 10,000 crores for Securities and Exchange Board of India (SEBI) registered Alternative Investment Funds (AIF). The corpus will be disbursed over two finance commission cycles, with the first allotment of INR

600 crore to 17 AIFs already in place. 75 Startups have received funding from these AIFs. Notably, most of these funds are concentrated in early stage technology investment, an area that already enjoys significant VC interest. Barring the Karnataka Government's KITVEN fund and agribusiness centric Omnivore, no other fund has a stated focus on early stage lifesciences. Even these are focused on smaller investments and no fund granted intends to participate in the gap area of \$5 Million to \$20 Million product development investment for biotech innovation in new drugs and vaccines. A welcome change was made in May 2017 when the definition of a startup was expanded from 5 years to 10 years for biotech startups. However, this change has not resulted in any significant increase in allotment of funds to VCs strategically focused on biotech. Inadequacy of scale-up funding is pushing cream of biotech ventures to re-domicile themselves in more evolved innovation hubs such as US, Singapore and Switzerland thereby shepherding innovation outside of India, drain of potential economic value or worse still, leading to venture mortality.



Funding Requirement across Startup Lifecycle

Need for catalytic Government investment in VC funds is most needed in areas where the void is deepest and has significant economic and social repercussions. Ideally, part of this Fund of Funds should be strategically allocated to biotech risk capital and should yield multiplier impact on private investments to urgently bridge this capital deficiency and avert venture mortality or fleet of high potential ventures from India.

Vitas Pharma:

Entrenched in the area of drug discovery and development, Vitas pharma is developing nextgeneration antibiotics to treat multidrug resistant hospital acquired infections, started as bootstrapped venture in 2011, the company was later supported by BIPP and BIG programs and received equity investment from IAN.

Co-founded by Radha Rangarajan and Rajinder Kumar, Vitas pharma is incubated at TBI at University of Hyderabad.

Innovator's Perspective

"The Indian biotech sector is characterized by incremental innovation, focused mainly on lowering the cost of products for the Indian consumer. Such product development has greatly benefited the Indian consumer but disproportionate investment in such product development leaves the country vulnerable to problems that are uniquely Indian or are low priority for MNCs.

A very small segment of the biotech sector is focused on innovative R&D, aimed at developing novel products. Unfortunately, this segment remains perennially under-capitalized. Many reasons are cited for this, including the risk appetite of the investors, quantum of capital required and product development timelines. Although successful products will deliver significant upside to the investor, the lack of such examples has discouraged investment. Thus the sector is trapped in a chicken-and-egg deadlock. A concerted effort bringing public and private investment sources is necessary to emerge from this impasse and give Indian entrepreneurs a chance to succeed."

Dr. Radha Rangarajan: Co-Founder, Vitas Pharma & Member, CII National Committee of Biotechnology

3.3 Continuing Infrastructure Challenges at Scale-up Stage

Biotech and medtech ventures require specialized infrastructure and incubation facilities. DBT and DST have both supported creation of several incubators with common infrastructure required for lab scale research. Most entrepreneurs have indicated a high level of satisfaction with availability of basic infrastructure. While there still remains a dearth of design, prototyping, fabrication and validation facilities for medical devices, these are being bridged with additional facilities currently being created across various cities.

However, ventures face significant infrastructure hurdles once they cross lab scale proof of concept and need to scale up to pilot scale. At this stage, most ventures require cGMP facilities to produce preclinical and clinical trial batches – an area where capacity in the country is close to non-existent. For example, several incubators have a 5 liter fermenter and lab scale facility where initial proof of concept can be generated, however biopharma products often need to be scaled up to about 100 liters at the next stage with cGMP compliance required for preclinical and clinical batches. Subsequently at a commercial scale, the molecules need to be further scaled up to a 200 liter to 3000 liter scale. Dearth of capital makes it close to impossible for

them to build their own facilities and outsourced services of the required quality are often unaffordable for cash strapped ventures to access. This converges with the valley of death stage when capital needs multiply as the program moves into preclinical and clinical validation. Akin to the capital access challenge, this infrastructure hurdle occurs at a time when significant value inflexion points are a few critical steps away but are elusive until preclinical and clinical milestones are accomplished. In addition to the ultimate threat of a mortality challenge, this infrastructure hurdle also leads to inordinate delays in program execution and erosion of value due to loss of contemporariness of the program. As India's biopharma pipeline is gradually maturing, more and more ventures are advancing to this critical stage and the need to address this infrastructure gap on an urgent basis is higher than ever.

Infrastructure and ecosystem gaps at the scale up stage are present in the medtech segment as well but ventures often address the problem by seeking service providers in US, Germany or China. Given the relatively lower capital needs in the medtech segment, infrastructure is a smaller threat to sustainability, but calls for early attention to ensure a stronger domestic ecosystem. Additionally, to cultivate engagement in more complex areas of medtech innovation, there is a need for specialized design, prototyping and validation infrastructure such as nanofabrication facilities, advanced 3D printing platforms, simulated validation centers for implants that could potentially be nurtured via international institutional partnerships that enjoy strength in these specific platforms. Creation of such infrastructure and technical platforms will be very important to steer the medtech innovation ecosystem into the next realm of complexity, sophistication and economic value creation. The BIRAC i3 program is a major step recently initiated to address this challenge and more such efforts are essential in the near future.

3.4 Creating Reward for Innovation and Fostering Market Maturity

At the end of the complex innovation continuum, realization of potential impact as well as creation of economic value finally depends on widespread innovation down streaming. Commercialization success is also fundamental for sustainability at both the venture and ecosystem level. To this end, two elements that need to be championed are market maturity and reward for innovation. While affordability and equitable access are of paramount importance for India, it is also essential that we pursue strategic models that also ensure reward for innovation.

In the case of drug discovery and development, level of investment is significant, lead time is long and risks are high. Drug pricing policy and market access for public healthcare needs to evolve to provide optimal incentive for innovators while ensuring healthcare access.

Medical devices and diagnostics startups, on the other hand, face the threat of very immature and fragmented markets where established scale-up pathways don't exist. It is noteworthy that the number of large Indian companies in the segment with revenues north of INR 100 crore are far and few with the exception of companies engaged in consumables or other low tech products. Mature channel partners and scale-up models that can be emulated do not exist.

Realizing optimal and sustainable price economics

As the Indian industry landscape grows beyond small molecule generics and low tech consumables in the case of medical devices with expanding innovation engagement, policymakers need to adjust the lens with which they view drug and device pricing. Pricing is a complex subject given the often-conflicted objectives of ensuing reward for industry and ensuring healthcare access. There has been widespread industry concerns around extensive use of price capping on drugs and now medical devices as well. It may be a justifiable approach for genericized and commoditized products but is inappropriate in the case of any innovative drug, device or diagnostics and can completely dampen the innovation momentum. While value based healthcare pricing approaches may be harder to implement in the Indian system with more than 70% out of pocket spending. alternative solutions such as cross-subsidization as exemplified by the Vaccine industry are great models to consider in the Indian context. Indian vaccine industry is a recognized manufacturing success story steered by high level of success in innovation absorption. In this case, affordable supply for Indian and global public immunization has been accomplished by concerned efforts at two critical ends substantial pooling of volumes in the public system driving volume based price economics, and flexibility to price in private markets allowing for cross-subsidization.

Facilitating rapid scale-up across market channels: Public Procurement

In addition to optimal pricing, pathways for rapid scale-up and innovation absorption is also critical for sustainability. The lack of transparency in public and private procurement channels is way more complex than it appears on the surface. The dampening effect is more brutal in the case of innovations for public healthcare problems where there is greater dependency on public procurement for market creation - case in point is at least handful of maternal and child health innovations and TB diagnostic products that haven't translated to commercial success as they still await public health attention and adoption. While NHSRC had rolled out a health technology assessment mechanism to support innovation adoption in public health, startups have indicated no tangible progress through the intended pathway. It is critical we create and effectively implement adoption and procurement mechanisms for innovation in public health. Even in the case of products already procured for public health, public markets continue to remain highly fragmented given the nature of de-centralized procurement, with even individual hospitals putting out tenders in several cases. There has also been a historical challenge of public tenders calling for CE marked and FDA cleared devices.

In the case of drugs, there is an incumbent advantage of several large companies with strong sales and marketing presence that could be potential partners for down streaming innovation. However, most of these are generics companies with low appetite currently to nurture innovative product portfolios. While a gradual shift is envisioned in innovation focus of larger companies, this change needs to be fostered in an accelerated way through appropriate policy mechanisms. This is important for nurturing a holistic innovation ecosystem where research institutions, startups and larger companies can work synergistically to develop innovations and deliver them to markets. While there has been R&D benefit on in-house R&D expenditure and there is now a lower tax rate for royalty revenue on Indian patents for the out-licensing entity, incentives for larger companies to absorb innovation through licensing or acquisition should also be provided. This will catalyze initial industry engagement and evolving market maturity will sustain the momentum.

In the case of medical device and diagnostics, market channels are underdeveloped for most product categories and more so for innovative ones. Private markets are highly fragmented and channel partners are distributors of sub-optimal size and reach, with no experience in concept selling. Several private hospitals have a preference for higher priced products as it allows them to increase their billing. There is a severe dearth of large domestic companies that can be commercialization partners. Transparency of pricing needs to be instigated across the supply chain and value based reward needs to be long term goal vs price capping of individual inputs. In the near term, the healthcare delivery ecosystem needs to be sensitized, incentivized to deliver high quality care and adopt innovation tools to that end. To create reward for innovation for medical devices, policy intervention needs to begin at level of healthcare delivery, especially given the greater focus on private sector involvement in the National Health Policy.

3.5 Ease of Doing Business

India this year jumped 30 notches to secure the 100th spot in World Bank's 'ease of doing business' ranking. There have been several positive developments that have benefited the biopharma and medtech segments including startups – notably, import of biomaterials for research use is now easier, there is greater regulatory clarity for biosimilars with introduction of the new guidelines, certain regulatory changes as requested by the industry has been initiated for vaccines and most importantly the medical device rules have been introduced. While the strategic focus and progress is very encouraging, there continue to remain concerns specific to biotech startups that are outlined below:

3.5.1 Enhancing clarity on policy and regulations

Bridging gaps in regulatory frameworks and simplifying processes: A significant continuing impediment is the regulatory headwinds and timeline in accessing raw materials, getting timely product approvals and penetrating markets. Although norms for import and export of human biological samples have been relaxed since 2016 with no license

scale-up across i market channels: a Private Markets

Facilitating rapid

requirement, there remains plenty that needs to be done. Specific issues that most affect startups in biotechnology and lifesciences include:

- **Continuing inverse duty structure for medical devices** while inverse duty structure problem has been addressed in certain medical device products, it continues to erode competitiveness of Indian product developers and manufacturers in several product categories where inputs and components have higher duty structure than final product.
- Regulatory lacuna in regenerative medicine and rare diseases, with poor regulatory awareness overall Within the subset of startups that are pursuing more complex and globally benchmarkable innovation, there are ventures engaged in therapeutics for rare diseases, next generation solutions such as gene therapy and emerging areas of regenerative medicine. While India does have a guideline for stem cell therapies, there is significant gap in the overall landscape of possibilities under regenerative medicine modified blood and tissue products, cell therapy (autologous and allogenic) as well as gene therapy. While there are therapy options now emerging in the global context, the price of these therapies (more than USD 500,000 per patient) make them prohibitive in the Indian context and it is extremely critical that we provide wings to domestic ventures pursuing breakthroughs in these areas. Additionally, most startups have poor awareness about regulatory implications and pathways for market access within and outside India, calling for multifold expansion in capacity building efforts in this area.
- Need to expand Access to regulators and formalize a time bound official response system – Given efforts made by DCGI, CDSCO, CDSA etc., there is greater accessibility of regulators now and several ventures have had the opportunity to interact with CDSCO officials at workshops or other events. Avenues for such access should continue to be created to further enhance this perception. Additionally, it is recommended that mechanisms are created for requesting formal meetings with regulators at various milestones of clinical development with a need for time-bound dispensation of such requests akin to possibilities with USFDA and EMA.
- Breaking the regulatory uncertainty and inactivity in agri-biotechnology Lastly, there have been several pioneering startups in India in the agri-biotechnology domain that either faced sustainability risks or have been forced to shift focus to less scientifically complex areas with no regulatory uncertainty. There is also a strong pipeline from Indian public research institutions with significant potential for economic impact. Biotechnology can help achieve India's goals for doubling farmers' income and with a robust regulatory pathway, can enhance competitiveness of several industries in the food and feed value chain. For instance, potential of poultry exports from India is attenuated as global counterparts with access to GM corn for feed enjoy significantly greater competitiveness. Startups in the agri-biotechnology segment have pursued globally benchmarkable science, and de-regulation will be critical for their resurrection.

3.5.2 Creating a pro-IP perception in the global context

India has also long battled global perception of poor IP policy & enforcement and often touted to be non-compliant with the minimum standards set by TRIPS. A couple of legal decisions pertaining to Section 3(d) of the Indian Patents Act, 1970 and compulsory licensing caused significant damage to the country's reputation. However, the perception is often harbored without awareness of details of either legal cases or circumstantial context. Section 3(d) is a debatable subject and the country's concerns on misuse for ever-greening needs to be appropriately articulated. While India's dominance in generics is widely known, there is limited

recognition of the evolving landscape of IP creation in the country. Similarly, there is also limited awareness of positive capacity enhancements augmented with changes in functioning of the Indian Patent Office.

While the poor IP and often negative IP perception is a challenge for the industry as a whole, it is a significantly larger problem for startups whose entire value rests on their innovation pursuits. This challenge impacts their prospects at several milestones and results in hardship in raising investments from international investors or pursuing global strategic partnerships for asset licensing or co-development. Despite such negative perception, startups that attract interest of global investors on the strength of their innovation program, are often asked to engage in IP inversion and re-domicile their IP assets in a different geography such as Switzerland, US, UK or Singapore based on investor preference. If innovation is to be nurtured in startups or larger companies and innovation led growth is to be pursued, India needs to urgently change the perception around unreliability and inadequacy of the IPR policy, and create awareness around the quality of innovation pipeline.

3.5.3 Making tax regime more globally competitive

To harbor a holistic innovation ecosystem, fiscal benefits need to evolve further to incentivize and reward continued momentum, and be globally comparable with successfully catalyzed innovation hubs such as South Korea and Switzerland. It is also important that such incentives apply to innovation pursuits through both pathways - in-house or in-licensed/acquired programs. Engagement in India needs to be strengthened across the continuum of lab to markets and there is merit in encouraging in-house discovery and development as well as optimal portfolio building through balance of in-house R&D and in-licensed programs. Lowering of tax incentive on in-house R&D expense was a disappointing development for the industry. While the lower tax rate on out-licensing revenue of Indian patents was a welcome development, it is restrictive due to applicability to only 'Indian patents' and only on royalty revenue from out-licensing.

Additionally, it is also vital to sync fiscal benefits with high thrust programs such as Startup India. A case in point is a challenge sighted by several biotech startups –DSIR registration is required for availing benefit of zero customs and excise duty on capital equipment purchased for research and being eligible for several Government funding programs. However, until the startup has been operational for at least 3 years, it doesn't qualify for DSIR registration. Hence, access to grants beyond INR 50 lakhs is a challenge for startups during the first three years and part of the funds accessed get further drained for payment of duties on R&D equipment.

We have come a long way from combating fundamental challenges like inadequate infrastructure, capital scarcity, suboptimal resources and brain drain to today boasting a rich domestic pipeline of biotech innovation. But there remains a huge potential that can be and needs to be harnessed. Strengthening core capacities in existing institutes, dedicated technology transfer cells, creating the right infrastructure for curating idea, providing funding across all stages of innovation lifecycle; and developing efficient reimbursement models for innovation absorption will be the key determining factors for accelerated growth of the industry. Transition from Era 2.0 to Era 3.0 heavily rests on synchronizing resources, plans, policies and priorities with a vision to build sustainable and structured model.

Recommendations for Triggering Global Impact

Abbreviations

Abbreviations

ACE Fund	Accelerating Entrepreneurs Fund	
ACR	Albumin Creatinine Ratio	
AIF	Alternative Investment Funds	
AIIMS	All India Institute of Medical Sciences	
BERA	Brainstem Evoked Response Audiometry	
BIG	Biotechnology Ignition Grant	
BIPP	Biotechnology Industry Partnership Programme	
BIRAC	Biotechnology Industry Research Assistance Council	
BISS	Bio-Incubator Support Scheme	
BMT Wing	Biomedical Technology Wing	
BRIC	BIRAC Regional Innovation Centre	
C-CAMP	Centre for Cellular and Molecular Platforms	
CDSA	Clinical Development Services Agency	
CDSCO	Central Drugs Standard Control Organization	
CEFIPRA	Indo-French Centre for the Promotion of Advanced Research	
CRS	Contract Research Scheme	
CSIR	Council of Scientific & Industrial Research	
CTCs	Circulating Tumor Cells	
DBT	Department of Biotechnology	
DCGI	Drug Controller General of India	
DPRP	Drugs and Pharmaceuticals Research Programme	
DSIR	Department of Scientific and Industrial Research	
DST	Department of Science & Technology	
EMA	European Medicines Agency	
FDA	Food and Drug Administration	
FITT	Foundation For Innovation And Technology Transfer	
GCI	Grand Challenges India	
GDP	Gross domestic product	
GITA	Global Innovation & Technology Alliance	
GLP	Good laboratory practice	
HITC	Healthcare Technology Innovation Centre	
HTIC	The Healthcare Technology Innovation Centre	
IAN	Indian Angel Network	
ICAR	Indian Council of Agricultural Research	
ICGEB	International Centre For Genetic Engineering And Biotechnology	
ICMR	Indian Council of Medical Research	
llSc	Indian Institute of Science	
IISER	Indian Institute of Science Education and Research	
IIT	Indian Institutes of Technology	
IITM	Indian Institutes of Technology Madras	
INR	Indian Rupee	
ΙοΤ	Internet of Things	
IP	Intellectual Property	

IPR	Intellectual property rights	
ITVUS	India Technology Venture Unit Scheme	
JNCASR	Jawaharlal Nehru Centre for Advanced Scientific Research	
KDDF	Korea Drug Development Fund	
KITVEN	Karnataka Information Technology Venture Capital	
KSIDC	Kerala State Industrial Development Corporation	
NARI	National AIDS Research Institute	
NBA	National Biodesign Alliance	
NCBS	National Centre for Biological Sciences	
NCCS	National Centre for Cell Science	
NCL	National Chemical Laboratory	
NHSRC	National Health Systems Resource Centre	
NIDHI	National Initiative for Developing and Harnessing Innovation	
NITI Aayog	National Institution for Transforming India Aayog	
NIV	National Institute of Virology	
NMITLI	New Millennium Indian Technology Leadership Initiative	
NSTDEB	National Science & Technology Entrepreneurship Development Board	
OSDD	Research on open source discovery of drugs	
PCV	Pneumococcal Conjugate Vaccine	
PoC	Point of Care	
PRAYAS	Pre-incubation initiative and a source of pipeline for incubators	
PRISM	Promoting Innovations in Individuals, Startups and MSMEs	
R & D	Research and development	
RCB	Regional Centre for Biotechnology	
SBIRI	Small Business Innovation Research Initiative	
SCTIMST	Sree Chitra Tirunal Institute for Medical Sciences and Technology	
SEBI	Securities and Exchange Board of India	
SEED Fund	Sustainable Entrepreneurship and Enterprise Development Fund	
SIB	Stanford-India Biodesign	
SMEs	Small and medium-sized enterprises	
SPARSH	Social Innovation Programme for Products Affordable & Relevant to Societal Health	
STEP	Science and Technology Entrepreneurs Parks	
TBI	Technology Business Incubators	
TDB	Technology Development Board	
THSTI	Translational Health Science & Technology	
TRIPS	Trade-Related Aspects of Intellectual Property Rights	
UAS	University of Agricultural Sciences	
UIC	University Innovation Cluster	
USD	United States Dollar	
VAP	Vaccine Action Programme	
VC	Venture Capital	
WHO	World Health Organization	



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Innovation Advisory Research strategy & portfolio optimization In/out-licensing, strategic partnerships Technology commercialization Technology scouting IP strategy & IP valuation Royalty audit	 Policy, Regulatory Advisory Product approval regulations Biosafety approvals Tax, FDI, corporate regulations Policy Advisory: regulatory frameworks, impact assessment, PPPs for translational research 	
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