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Asian Biotechnology and Development Review
Vol. 27, No. 1, pp 1-2

Editorial Introduction

Krishna Ravi Srinivas*

Welcome to the first issue of Volume 27 of the Asian Biotechnology Development Review! We express our sincere gratitude to all the contributors and all members of the International Editorial Advisory Board. The response to the last issue was excellent.

The current issue features three articles and a perspective. All the three articles featured in this issue pertain to the linkages between biotechnology, innovation system, development and affordable healthcare in India's context. The perspective piece captures the issues related to Biosimilars in India.

The first article by Nidhi Singh and Geetika Patel examines the challenges of building an innovation ecosystem for Emerging Medical Diagnostics (EMDs) in India, focusing on advanced biomedical technologies such as molecular biology, gene editing, and synthetic biology, which could address India's context-specific diagnostic needs. The article highlights systemic weaknesses that hinder system-building activities of key innovation actors using the Transformational System Failure (TSF) framework.

The second article by Yamini Parashar and Vikas Kumar analyses the critical role of women entrepreneurs and startups in India's biotechnology sector, focusing on their efforts to create affordable health innovations under financial constraints. It also deals with the impact of government initiatives, funding programs, and incubation support in fostering an enabling ecosystem for these ventures. Further, India's biotechnology sector has emerged as a transformative force in addressing public health challenges, offering innovative, scalable solutions to bridge critical healthcare gaps. With this context, bio-entrepreneurs play a pivotal role in transforming scientific discoveries into scalable solutions with public health relevance in India.

The third article by Manjunathareddy G R and Raveesha H R deals with the biotechnology's role in socio-economic development in developing

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countries; highlighting the challenges, opportunities, and strategic approaches.

Finally, the perspective article by Chetali Rao and K M Gopakumar analyses the issue of advancing affordable access to Biosimilars in India and argue for the Need for a science and evidence-based regulatory framework in the latest Indian Draft Guidelines.

Your comments, responses and ideas are welcomed.

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Asian Biotechnology and Development Review
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Emerging Medical Diagnostics (EMDs) Innovation System in India: Challenges to Deal with Context-Specific Needs

Nidhi Singh* and Geetika Patel**

Abstract: This study examines the challenges of building an innovation ecosystem for Emerging Medical Diagnostics (EMDs) in India, focusing on advanced biomedical technologies such as molecular biology, gene editing, and synthetic biology, which could address India's context-specific diagnostic needs. Using the Transformational System Failure (TSF) framework, the study highlights systemic weaknesses that hinder system-building activities of key innovation actors. Four components of TSF- Directionality, Demand Articulation, Policy Coordination, and Reflexivity are used to analyse barriers to socio-technical transitions.

The analysis has been done using mixed-method approach, combining quantitative and qualitative data, draws on multiple sources including SCOPUS, Web of Science, Patent Scope, National Science & Technology Management Information System (NSTMIS), and annual reports of major stakeholders. The findings reveal that India's EMD innovation ecosystem remains in a formative stage. Among government bodies, the Department of Biotechnology (DBT) emerges as the most proactive, supporting the sector through grants, exchange programs, training, and startup aid, while contributions from Indian Council of Medical Research (ICMR), Council of Scientific and Industrial Research (CSIR), and Department of Science and Technology (DST) are comparatively limited.

Further, the analysis shows only a sparse presence of domestic startups, largely at early stages of development. Major barriers include inadequate hands-on training, weak collaboration among a small researcher pool, and the absence of dedicated canters of excellence. The study calls for a well-defined policy framework, targeted government interventions, and tailored policy instruments drawing on lessons from the U.S. and China to strengthen India's EMDs innovation ecosystem.
Keywords: Emerging Medical Diagnostics, Innovation System, Transformational System Failure, Socio-Technical Transition, Context Specific Needs, Challenge-Led Innovation Policies

Introduction

Medical diagnostics have become the critical component of healthcare system in the current era of evidence-based treatment approach where reliable and accurate diagnostic investigations play an important role

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in healthcare decisions, choice of treatment, and achievable survival (Sharma, et al., 2015). The advancement in biotechnological research in recent decades, including the completion of Human Genome Project Project (International Human Genome Sequencing Consortium, 2004), developments in Molecular biologyand CRISPR research (Jinek et al., 2012), Synthetic Biology (Courbet et al., 2016), Nanotechnology (Jain, 2005) have rapidly advanced the biomedical sector and led to the emergence of new and effective medical diagnostics technologies known as Emerging Medical Diagnostics (EMDs). These technologies are transforming the practice of diagnosis and shifting the healthcare sector towards sustainable management. These EMDs, however, are in various stages of maturity and commercialization. In contrast, molecular diagnostics including PCR-based assays and next-generation sequencing (NGS) platforms are already well commercialized products widely adopted within routine healthcare settings (Mardis, 2013), while CRISPR-based diagnostics are still in the translational and early-market stages (Kellner et al., 2019); (Joung et al., 2020) with other subtypes such as nanotechnology-based diagnostics (Choi & Yoon, 2023) largely confined to the laboratory or pilot stage. This article primarily focuses on molecular diagnostics, including CRISPR-based platforms, and point-of-care diagnostic tools relevant to resource-limited settings in India, with an emphasis on their innovation system dynamics and the challenges to address the context-specific healthcare needs.

EMDs offer potential technological advantages over conventional diagnostics, including early detection with high sensitivity and specificity, and also opened the door to new tools that offers cost effective, portable and point of care diagnostics (Patrinos, et.al., 2017; Geraldi and Rachman., 2018; Serra, et al., 2022). This is turn provides solutions to deal with the grand healthcare challenges of un-affordability, inaccessibility and unavailability. However, successfully addressing these grand healthcare challenges require the capabilities to build new paradigms of ‘Transformative’ or ‘Mission-Oriented’ innovation policy for setting or shaping the directions of socio technical transitions (Bergek, et.al., 2023).

Table 1: Context Specific Diagnostic Challenges and Potential Use of EMDs in India

Diseases	Diagnostic challenges	Potential use of EMDs
Malaria	Increasing incidence of drug resistance in the malarial parasite.	Identification of drug resistance requires molecular characterisation of malarial parasite

Continued...

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HIV/AIDS	Immunodiagnostics fails to detect the pathogen during the window period (the first three months of infection)	EMDs are more sensitive and are able to detect the presence of the virus in the blood during the window period.
Tuberculosis	Conventional diagnosis methods and immunodiagnostics of TB have limited sensitivity and specificity and take a longer time period to provide the results. These tests also fail to detect drug resistance in patient.	EMDs are more sensitive and can detect Mycobacterium in extra pulmonary TB drug resistance in M. tuberculosis and for quantitative measurement for monitoring the disease's response to treatment
Cancer	India has developed MDs for detection of different types of cancer. But the major constraint is the difficulty in obtaining monoclonal antibodies against new markers.	Combining the Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR/Cas9) system with next-generation sequencing (NGS) has the potential to speed up the identification, validation, and targeting of high-value targets.
Diabetes	Identification of the genetic factors has been a challenge in Type 2 Diabetes	A holistic systems biology approach is required to detect how genetic variation leads to diabetes.
Cardiovascular Diseases (CVDs)	Underreporting of CVD events resulting from poor access to diagnostic facilities in India.	Points of care molecular diagnostics are required for the continuous monitoring.
Neurological Disorder	Neurological conditions can be difficult to diagnose because symptoms of one condition can be similar to another	NGS (next-generation sequencing)-based testing is comprehensive and can detect all types of variants including structural variants.

Source: Adapted from TIFAC Report., (2009); Selvakumar, et.al., (2022); Prasad and Groop., (2015); Prabhakaran, et.al., (2016); Ganapathy, et.al., (2019)

In India, the development of EMDs is abounded with the expectations to deal context-specific diagnostics challenges that contribute to grand societal challenges and continuously compromise the healthcare system of the country. The Technology Information, Forecasting and Assessment Council (TIFAC) report from 2009 and some scientific studies have identified the diagnostics challenges associated with highly burdened communicable diseases such as malaria, tuberculosis, HIV/AIDS, as well as non-communicable diseases like cancer, diabetes, CVD, neurological disorder in India. The potential uses of EMDs in dealing with these challenges are highlighted in Table 1.

The failure of the healthcare system to address these diagnostic challenges is evident from the high prevalence of deaths due to communicable and non-communicable diseases as well as maternal, prenatal, and nutritional conditions in recent periods, as shown in Table 2. For instance, the incidence of death due to non-communicable diseases and maternal, prenatal and nutrition conditions has increased from 46 percent to 66 percent during the period of 2000-18. In effect, both types of diseases correspond to around 90 percent of total incidence of death during this period. Due to the increased disease burden, the out-of-pocket expenditure, as percentage of the total health expenditure, has also been very high, reaching around 55 percent in 2018. Despite public health being one of the major priorities of the government, the persisting low levels of public expenditure on health, which is less than 5 percent of the total expenditure, indicate the lack of coherent policy priorities and thrust by the policy makers, as detailed in Table 2.

The present study argues that in order to effectively deal with context-specific diagnostic needs and sustainable societal development, challenge led innovation strategies are required for the development of EMDs. Against this background, the study argues that a more detailed approach is needed to better understand the 'challenges of socio technical transition' that can help the policymakers in strategizing the EMDs development in a sustainable manner. The primary intention in identifying these challenges is to build sustainable ecosystem for EMDs development and to address the grand diagnostics challenges through sufficient investments for the development of EMDs technologies. This, in turn, can contribute to reducing the issues of unavailability, inaccessibility and unaffordability that can effectively reduce the increasing incidence of highly burdened diseases, and result to lower out-of-pocket expenditure.

Further, the paper is divided in five sections, Section II provides the analytical framework and data sources used in the study; Section III provides the glimpse of global perspective on the emergence of EMDs innovation ecosystem; Section IV provides the literature review on the features of existing innovation ecosystem for EMDs development; Section V provides the analysis of 'Transformational Failure' that reflects on the challenges to deal context specific needs; Section VI provides conclusion.

Table 2: Causes of Death and Health Spending Patterns in India: Select Indicators (1995-2018) %

Indicators	1995	2000	2010	2014	2018
Cause of death by communicable diseases (% of total)		43.7	33.4	28.1	24.16
Cause of death, by non-communicable diseases and maternal, prenatal and nutrition conditions (% of total)		46.1	55.7	60.8	65.9
Cause of death, by injury (% of total)		9.27	10.1	9.69	9.9
Health expenditure, total (% of GDP)	4.0	4.3	3.2	3.6	2.9
Out-of-pocket health expenditure (% of total expenditure on health)	67.5	67.9	65.1	67.0	55.3
Health expenditure, private (% of GDP)	3.0	3.2	3.1	3.3	3.3
Health expenditure, public (% of GDP)	1.1	1.1	1.2	1.4	1.6
Health expenditure, public (% of government expenditure)	4.5	4.4	4.3	5.0	5.0

Source: Author compilation from the World Development Indicators (WDI), online database

Analytical Framework and Data Sources

The study involves tracking the processes of emergence of EMDs innovation system building in a wider framework that identifies the deficiencies or improper systematic dimensions of system activities. The analytical framework, therefore, is seek to identify 'System-Challenges' to accentuate on the structural rigidities and institutional voids capable of preventing the system to focus on the societal challenges and impede the developmental of sustainable pathways. To identify these challenges of EMDs innovation system in dealing with country-specific needs, the present study uses 'Transformational System Failure' approach of Weber and Rohracher in 2012. This approach builds on the previous rationales of 'market failures' and 'structural system failures', but introduces the notion of 'transformational system failures' to consider a broader transition perspective on innovation for sustainable development. The approach combines the technological innovation systems approach with the multi-level perspective on sustainability transitions. Hence, the Transformational System Failure provides a useful starting point for legitimizing interventions for technological development in the context of grand societal challenges. Weber and Rohracher (2012) distinguish four types of 'transformational system failures', which are detailed in Table 3.

Table 3: Transformational System Failures

Categories of Failures	Types of Failure
Directionality failure	Refer to the observation that in the context of grand societal challenges, there is a need to consider the direction of innovation in such a way that innovation contributes to those societal challenges. Technological innovation systems may fail to develop endogenously into the desired direction (because those directionality requirements emerge outside of the TIS, e.g., in policy arenas or through societal debates), which legitimises additional policy intervention.
Demand articulation failure	Refer to the observation that in the context of grand societal challenges, markets for new technologies may not exist 'out there', resulting in a lack of articulation of what markets requirements are or what user preferences are, and therefore 'a deficit in anticipating and learning about user needs.
Policy coordination failure	Refer to the observation that in the context of grand societal challenges, policies and public institutions may need to transform in response to those challenges as well as develop innovations to address those challenges. Policy coordination failures can occur between different policy levels (vertical policy coordination failures) or between different sectors (horizontal policy coordination failures)
Reflexivity failure	Refer to the observation that in the context of grand societal challenges, there is a need for continuous monitoring of TIS development with respect to the progress towards the broader transformation goals and the development of adaptation strategies.

Source: Adapted from Weber and Rohracher (2012)

This study uses a mixed method approach, employing both quantitative and qualitative information and follows a multi-dimensional design methodology. The study uses multiple data sources to analyse the Transformational System Failure in the formation of the EMDs innovation system. The study uses various databases and timeframe, which are outlined as follows:

a) Research Publications in EMDs were extracted from Elsevier's abstract and citation database called 'SCOPUS'. Publications related to EMDs research between 2000 and 2020 were retrieved using the following strategies:
   Topic = (Molecular Diagnostics*), (CRISPR and Diagnostics*),

(Synthetic Biology and Diagnostics), (Nanotechnology and Diagnostics*)

AND Title = (Molecular Diagnostics*), (CRISPR and Diagnostics*), (Synthetic Biology and Diagnostics), (Nanotechnology and Diagnostics*)

AND Address = (India).

b) Projects supported through Extramural Research Projects (EMR) Funding is collected from the National Science and Technology Management Information System (NSTMIS) database for 2000 to 2019, made available by the Department of Science and Technology (DST), Government of India. The 'Extramural R&D Projects' database on NSTMIS website was analyzed with the filter for the Directory of Extramural R&D projects set to 'Subject'. Medical Sciences as sub-area was selected for analysis to retrieve the details on 'Project Title', 'Funding Agency', 'Investigator name', 'Institution Name', 'Address'.

c) The datasets on patents were obtained by using Patents cope search tool. World Intellectual Property Organization (WIPO) database was used to get an overview of the Indian Patent landscape around EMDs technologies. Also, the search engine http://www.ipindia.nic.in/, has been used that is supported by Department of Industrial Policy and Promotion (DIPP), Ministry of Commerce and Industry, Government of India. The data on patents was collected from 2000-2020.

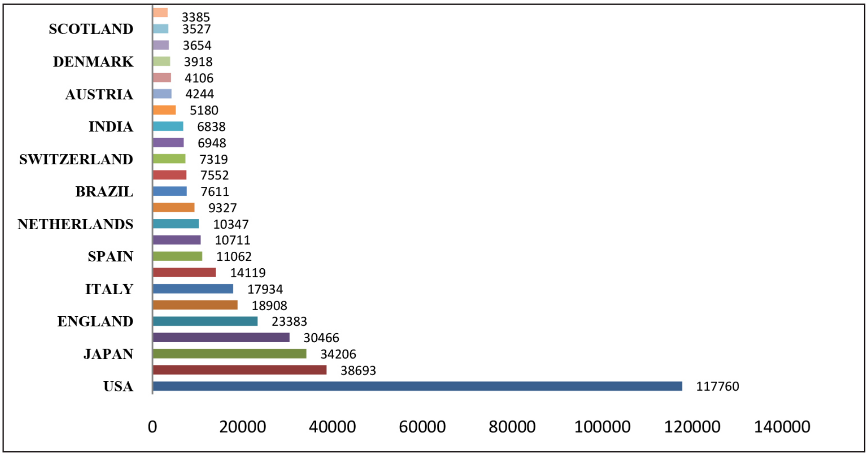
d) The trade statistics for India are based on the Harmonised System (HS) classification of Indian foreign trade, which was obtained from the United Nations Commodity Trade (UN Comtrade) database through the World Integrated Trade Solution (WITS). The data was taken for the period from 1990 to 2020.

e) Further, the websites search and study of annual reports of Industries, research institutes, universities and departments of government have been done for the period from 2000-2020.

Emergence of EMDs Innovation System: Global Perspective

The United States is the dominant country in the research and development of EMDs innovation system at global level (see Figure: 1). It is evident that the number of publications on EMDs by the US (29 percent) far surpasses those of the other developed countries like Japan (9 percent), Germany (8 percent), the UK (6 percent). However, the performance of China (10 percent) from an emerging economy is quite significant as it stands next to US and positioned itself as the second largest leader globally. The performance of India (2 percent) needs to be improved to touch global levels.

Figure 1: Country-wise List of Research Publication Activities on EMDs (2000-2020)



Source: Author calculation based on SCOPUS database

The EMDs innovation system in the US is derived by the adoption of evidence-based treatment approach (Constance, 2010), and contains 'strong system' features that makes them the global leader Firstly, the US has a robust scientific base that is supported by massive state interventions and continuous funding support, especially through National Institute of Health (NIH) since the 1950s. The NIH funding has led to critical discoveries such as Watson-Crick DNA model (1953), Polymerase Chain Reaction (1985), Establishment of the first human genome project (HGP) (1987), that have rrevolutionized the process of diagnosis worldwide by introducing the more accurate and sensitive EMDs technologies. The introduction of the Bayh-Dole Act in 1980 (Bera, 2009), which has hugely supported the universities-based research, have also facilitated the discovery of New Biotechnology Firms (NBFs) around the nucleus of academic institutions to gain from basic research and to convert them into commercial products (Perkmann, et al., 2013).

Secondly, the US has developed a strong industrial base with active government interventions like (1) timely and sufficient supply of bio chemicals, (2) Infrastructure development for new or modified instrumentation such as DNA and peptide synthesizers as well as large-scale purification instruments such as HPLCs, (3) the design of new substance for research and production, and (4) a continuous exchange of information between suppliers and companies using biotechnology resulted in the creation of new products and constant improvement in existing instrumentation equipment and software use in biotechnology R&D (United States Congress office of Technology Assessment,1984). This has resulted in the emergence of NBFs and helped large established firms to focus on production and marketing once technology has matured. The unique dynamism and complementarily between NBFs and established firms made the US industrial sector the biggest manufacturing producer of EMDs technologies, leading to the emergence of firms like Roche Diagnostics, bioMérieux, Becton, Dickinson and Company; Abbott Molecular; and Gen-Probe.

Thirdly, the US has evolved policies and institutional arrangements that have guided technological regulations, intellectual property rights (IPR) and stringent reimbursement system for EMDs development. The FDA regulations on labeling requirements & procedures for standards for diagnostics in 1973, IVD Device Evaluation and Safety (OIVD) to consolidate regulatory oversight of diagnostics in 2002, FDA guidance for Pharmacogenomics data submissions in 2003 and Genetic Information Nondiscrimination Act of 2005 have helped in developing a stringent regulatory system for EMDs. Similarly, the United States Patent and Trademark Office (USPTO) has developed guidelines on "utility" and "written description" specifically for examining EMDs based on molecular methods, and the NNIH developed guidelines for Best Practices for the Licensing of Genomic based EMDs. The Center for Medicare and Medicaid Services (CMS) has also streamlined the reimbursement procedures by announcing new test-specific Current Procedural Terminology (CPT) codes in 2013 (Constance, 2010). Thus, the US National Innovation System holistic features have created a vigorous ecosystem for EMDs development.

Since the early 2000, China has apparently emerged as a major knowledge producer, which can be attributed to the deliberate strategy adopted by the Chinese government to mobilize public funds for targeted research to promote inclusive innovation (Wang, 2007). The key funding agencies, such as the National Natural Science Foundation of China (NSFC), Ministry of Education (MOE) and the National Social Science Foundation of China (SSFC), have played a major role in supporting science base for EMDs development. For example, around 200 million RMB of government funding was granted to support the biology, medical, and health engineering departments in Shenzhen Institute of Advanced Technology (SIAT) for research on affordable medical technologies (Liu, et al., 2015).

The Chinese government has established initiatives to foster the collaboration between firms and research laboratories of universities to promote production and commercialization of innovations to establish a strong local innovation and production system (Liu, et al., 2015). Similarly, the government support has also been extended to the industrial base in China, enabling the establishment of manufacturing capabilities and market generation. Notably, the major support provided by the government to industry came through the establishment of EMDs dedicated institutions like the Suzhou Institute of Biomedical Engineering and Technology (SIBET) and the Chinese Academy of Sciences (Liu, et.al, 2015). These institutes carry out research on medical devices, medical materials and biological reagents to quicken the pace of restructuring and upgrading the industries. In 2012, the Ministry of Health in China has strategically proposed to spent 100 billion Chinese Yuan on medical care equipment for hospitals for the period 2012-2020, under the strategy of inclusive innovation (Strategy Report on Health China 2012). Consequently, the industrial base in China has emerged with outstanding manufacturing capabilities with a solid base for businesses to pursue the growth of low-cost affordable healthcare technologies. Hence, the continuous efforts of Chinese government to support its science base and industrial base under the inclusive innovation strategy have created a robust ecosystem for EMDs development.

The experiences from US and China in EMDs development reveals two distinguish innovation scenarios. US being a developed economy has put a continuous effort through mobilizing its resources to develop knowledge base for EMDs development. The target-based development strategy of US to channelize the knowledge development within science and industrial base of the country has enabled them to achieve the status of a global leader. In the case of China, the successful catchup strategy is mainly attributed to the strategic policy intervention of the state that favor developing learning and innovation capabilities in the short span of time to foster the rapid development of EMDs. Drawing from the experiences of these two separate innovation strategies, the present study aims to review the literature on existing innovation ecosystem in India for the development of EMDs technologies. This is attempted in the following section.

Review of the Existing Ecosystem for EMDs development in India

Currently, the performance of India for EMDs development is not optimal on a global level, as shown in figure 1, indicating the presence of 'system lacunae' that hamper performances. At present, the innovation system for EMDs technologies is embedded in the capabilities of systems being developed for healthcare, biotechnologies, in-vitro diagnostics and pharmaceuticals. The biomedical sector builds on the technologies and social/human capacities already established by the pharmaceutical and biotechnology sectors that traditionally focus on a process engineering model for innovations (Lander and Thorsteinsdóttir, 2011). Despite the development of capabilities in the pharmaceutical and biotechnology sector since the beginning of the reform period, India lacks innovation capabilities for modern emerging biomedical innovations (Chaturvedi, 2007). The technological transition is hindered by the path dependent model of learning (reverse engineering) adopted by firms with process innovations to undertake low-cost manufacturing (Lander and Thorsteinsdóttir, 2011). To meet the increasing specific needs and demands of emerging biomedical technologies, innovation policies need to be restructured according to sectoral requirements by encouraging targeted research and generating enabling conditions at the firm and institutional levels (Chaturvedi, 2007).

Historically, the efforts for EMDs development in India dates back to the establishment of the Department of Biotechnology (DBT) in 1985, which provided a new structure for biotechnological research in the country. During the 1990s, DBT established various specialized biotechnological research institutes and facilitated diagnostic research in laboratories such as the National Institute of Immunology, Centre for DNA Finger Printing and Diagnostics, and the Rajiv Gandhi Centre for Biotechnology and facilitated diagnostics research. During that period DBT set up the "Mission Mode" initiative in coordination with the Indian council of Medical Research (ICMR), Council of Scientific and Industrial Research (CSIR), and All India Institute of Medical Sciences (AIIMS), targeting highly prevalent infectious diseases such as tuberculosis, leprosy, malaria, leishmaniasis, filariasis, typhoid, hepatitis, diarrheal diseases, amoebiasis, streptococcal infections, schistosomiasis and sexually transmitted diseases, and later expanded to cover screening tests for non-communicable diseases like cancer markers, detection of physiological status of the body and blood grouping sera.

Based on the survey of the status of development of medical diagnostics in various research laboratories and the recommendations of the expert committees, mobilization of the resources have been directed towards the creation of manpower, infrastructure development and to support diagnostics research projects in laboratories in the country. In 2007, the Translational Health Science and Technology Institute, Faridabad (THSTI), was established by DBT to support translational research in the area of biotechnology. THSTI set up a dedicated centre called Centre for Bio-design (CBD)for diagnostics research and development. So far it has promoted strategic basic research and an effective translational route of science into development of novel diagnostics technology platforms and supported multidisciplinary approach for combining novel technological concepts and clinical expertise (http://www.thsti.res.in). CBD has successfully implemented the Biodesign programme, a med-tech innovation flagship programme jointly with AIIMS, New Delhi and IIT-Delhi in collaboration with the Stanford University, USA and other international partners, aimed at training researchers in the area of advanced medical technology. This programme has been successful in encouraging medical device innovation, promoting entrepreneurship in medical device sector by formation of startups, indigenous manufacturing of medical devices and dissemination of innovations at national and global level. The Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking by

DBT, was established in 2012, to support industry for product development, commercialization and patenting. BIRAC has been continuously supporting start-up ecosystem and promoting industry-academia collaborations in the area of EMDs innovation research through its financing mechanism.

Despite the above-mentioned efforts, the national health-industry-research system in India faces the challenge of developing a suitable, need-specific EMDs innovation system . Past studies have highlighted various challenges that confirms the presence of 'system lacunae'. In comparison to other biotechnological developments, the efforts of DBT for In-vitro Diagnostics (IVDs) developments has been limited over the past 30 years. The formation of innovation system is primarily guided by market-based calculations rather than social based calculations (Singh and Abrol, 2017). The Science Base for Molecular Diagnostics (MDs) development lacks optimal funding support from the government and fails to undertake research on Indian specific diagnostics problem. Similarly, the Industrial Base for MDs development is dominated by foreign players, leading to issues such as unaffordability from rising cost of imported medical diagnostics and inaccessibility because of (unsuitability of imported products in resource poor settings of the country (Singh, 2021; 2022). During the early nineties, non-availability of ELISA plates and various raw materials from an indigenous source was a key challenge for the development and diffusion of indigenous immunodiagnostics and system wide factors hindered the commercialization of indigenous innovations (Visalakshi,1993; Ramani and Visalakshi, 2001). The innovation process of advanced emerging biomedical technologies like regenerative medicines, stem cell research and RNA interference etc. were hampered by the path dependence model of learning, lack of collaborative efforts and target-based research (Tiwari and Desai, 2011).

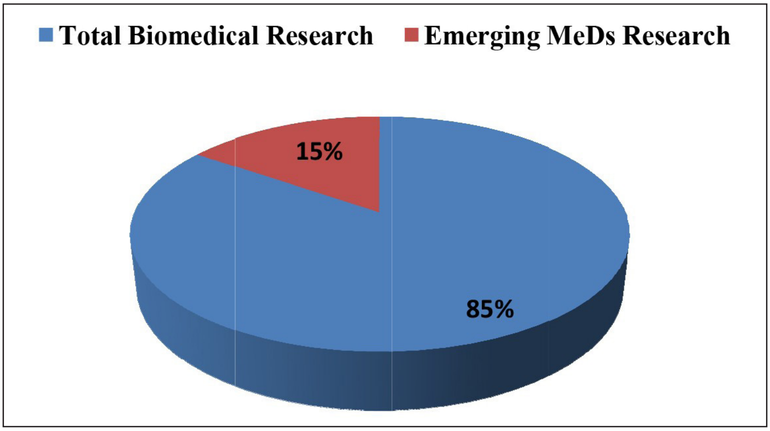
The studies cited in the section have reflected various factors that impede the pathways of the development of EMDs and contribute to the existing 'system-lacunae' in the innovation ecosystem. Building on this, the following section provides a comprehensive analysis of the 'Transformational System-Failures' that are currently overseeing the system-building efforts and preventing them from effectively addressing the context specific needs in India.

Analysis of Transformational System-Failure: Challenges to deal Context-Specific Needs

1 **Directionality Failure:** The section analyses the efforts being made to build knowledge base for an EMDs innovation system and examines whether the directions of system-building activities are optimal to deal the country's specific diagnostic needs. The analysis

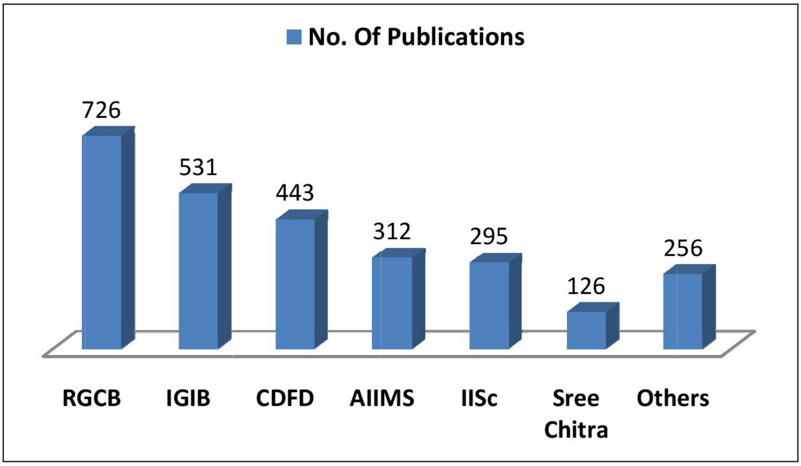
of publication activities (2000-2020) indicates that the efforts for knowledge creation in the area of EMDs are still in their early stages in comparison to total publication activities for biomedical research (see Figure 2). Currently, only a few research institute such as the Institute of Genomics and Integrative Biology (IGIB), Rajiv Gandhi Centre for Biotechnology (RGCB), the Centre for DNA Fingerprinting and Diagnostics (CDFD), the All India Institute of Medical Sciences (AIIMS), the Indian Institute of Science (IISc), and Sree Chitra Tirunal Institute for Medical Sciences & Technology are actively contributing towards the knowledge creation for EMDs development, as shown in Figure 3.Notable among them are the establishment of Laboratory Medicine and Molecular diagnostic (LMMD) at RGCB, the development of 'Feluda' test by IGIB, the state-of-art facilities at CDFD to provide high quality forensic DNA fingerprinting services. The limited participation of Indian scientists in EMDs publication activities raises concerns about the lack of scientific capabilities to perform EMDs research and the absence of instruments and mechanisms to incentivize researchers to undertake EMDs research and development. Therefore, an analysis of EMR funding (2000-2020) is very critical as it is the primary funding mechanism currently to supporting and facilitating the knowledge production for emerging EMDs development.

Figure 2: Research Publication Activities (2000-2020): Total Biomedical Research v/s EMDs Research



Source: Authors calculation based on Scopus Database

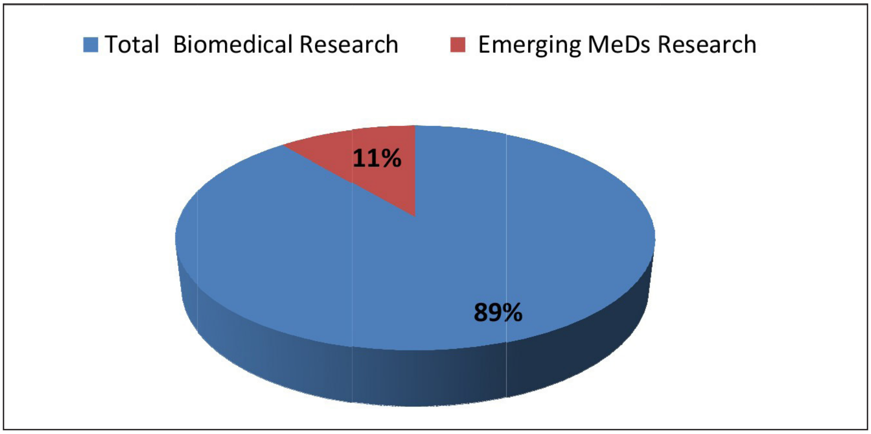
Figure 3: Research Publication Activities (2000-2020): Active Institutes in EMDs Research



Source: Authors calculation based on Scopus Database.

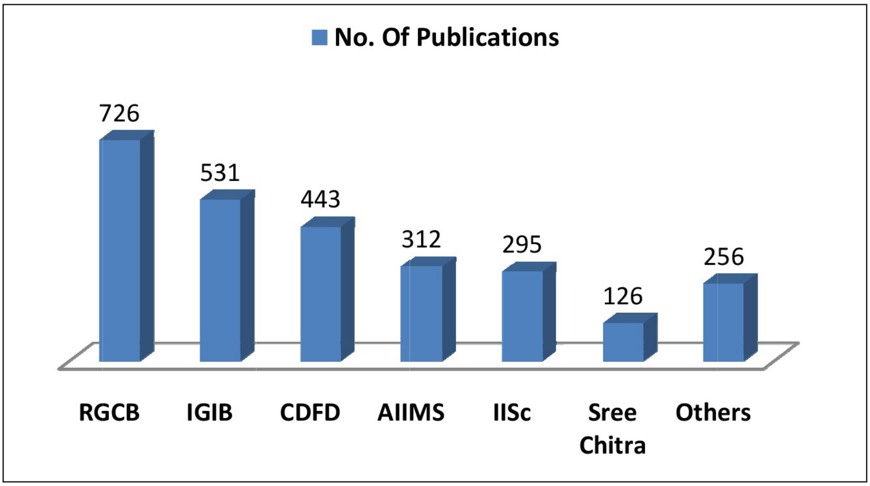
The analysis reveals that contribution of EMR funding allocated to support knowledge creation for EMDs development is insufficient in comparison to another biomedical research (see Figure 4). This suggests that there is lack of dedicated calls for proposals or projects from funding agencies in the area of EMDs. Among the leading funding agencies, DBT has been the major contributor towards system building activities for knowledge creation. The DBT in the last one decade has devoted continuous efforts to guide and direct research and resources to foster system building activities in the area of EMDs (see Figure 5). Efforts have been made to encourage several R&D programs for the creation and development of knowledge base for emerging genome engineering technologies and their applications through focused calls for proposals. However, the efforts from other leading funding agenesis like CSIR, ICMR, and DST, have started taking shape a bit later and now initiatives of ICMR like Medical Devise and Diagnostic Mission Secretariat (MDMS) and MedTech Mitra in partnership with CDSCO and NITI Aayog may be the game changer.

Figure 4: Research Publication Activities (2000-2020): Active Institutes in EMDs Research



Source: Authors calculation based on NSTMIS Database

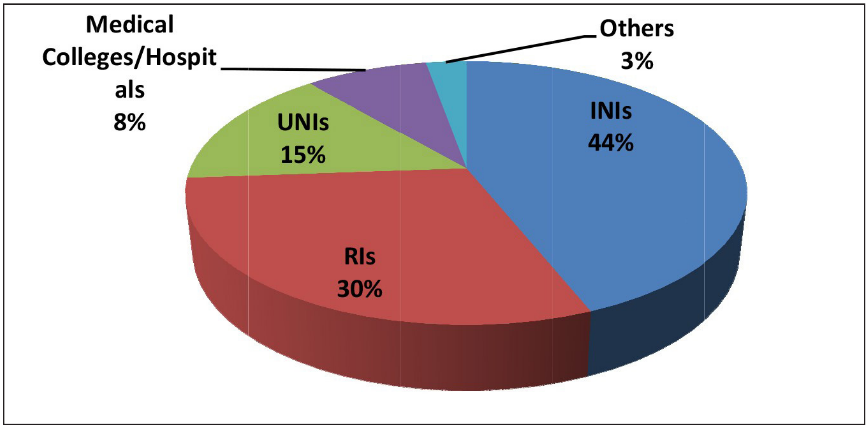
Figure 5: Extramural Research (EMR) Funding (2000-2019): Number of Research Projects on EMDs Supported by Different Funding Agencies



Source: Authors calculation based on NSTMIS Database

Further analysis reveals EMR funding distribution is unevenly skewed towards Research Institutes (RIs) and Institute of National Importance (INIs), while Universities (UNIs) based basic research which is crucial for building knowledge base for an emerging technology, have not received substantial funding (see Figure 6).

Figure 6: Extramural Research (EMR) Funding (2000-2019): Allocation of Funds to Different Type of Institutes to Support EMDs Research



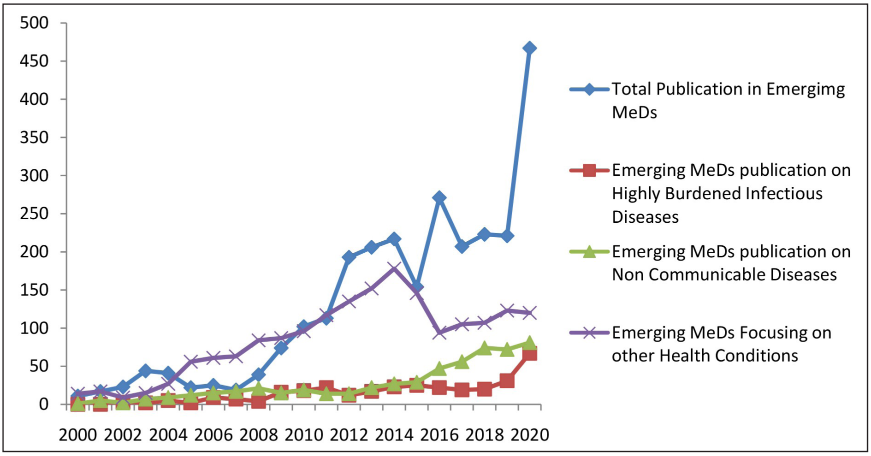
Source: Author calculation based on NSTMIS Database

The analysis of directionality failure reveals that the current system building activities for EMDs innovation system are inadequate and also being deviated from the path of building a substantive knowledge base for EMDs development. Additionally, the system building activities lack priority setting and mission orientation to deal the grand societal challenges through the formation of need-based innovations.

2 **Demand Articulation Failure:** In the earlier section, it was noticed that the system building activities lacked mechanisms to stimulate the EMDs development in the direction of achieving the required goals and objectives. Therefore, this section will examine how the deficiencies in the directionality have impacted the articulation of diagnostics solutions to meet the context specific societal challenges. An analysis of research publications from 2000 to 2020 based on thematic area revealed that while the research activities in the area of EMDs gained momentum in 2007, the efforts to develop knowledge to deal the diagnostics needs for both communicable/infectious and non-communicable diseases were insignificant compared to those made for other health concerns such as genetic disorders that contribute to a relatively less disease burden (see Figure 7). Similarly, an analysis of research project supported through EMR Funding during the period from 2000 to2019 revealed an unequal distribution of funds. Projects based on non-communicable disease related EMDs diagnostics were more successful in attracting the funding, while support for EMDs projects related to infectious or communicable was limited, despite the

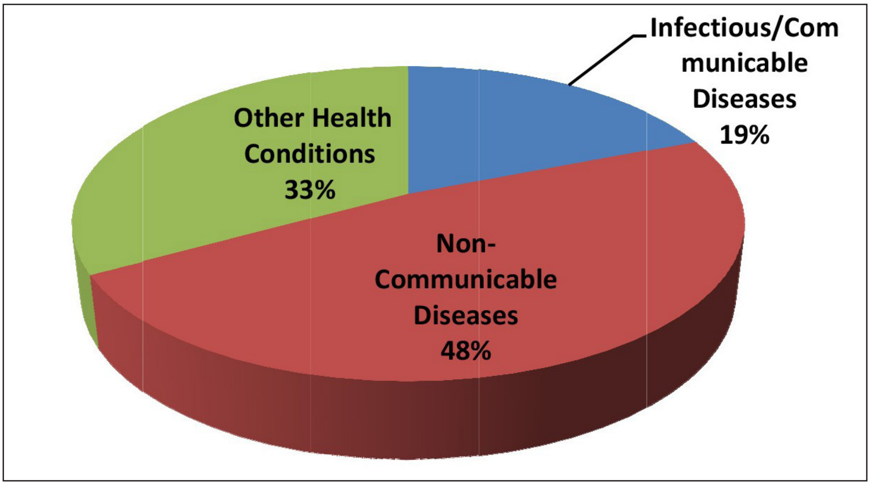
fact that these diseases are more prevalent in resource-poor-settings and are major contributors to grand societal challenges (see Figure 8).

Figure 7: Number of Research Publications (2000-2020): Total EMDs Publications v/s EMDs Publications for Different Categories of Diseases



Source: Author calculation based on Scopus Database

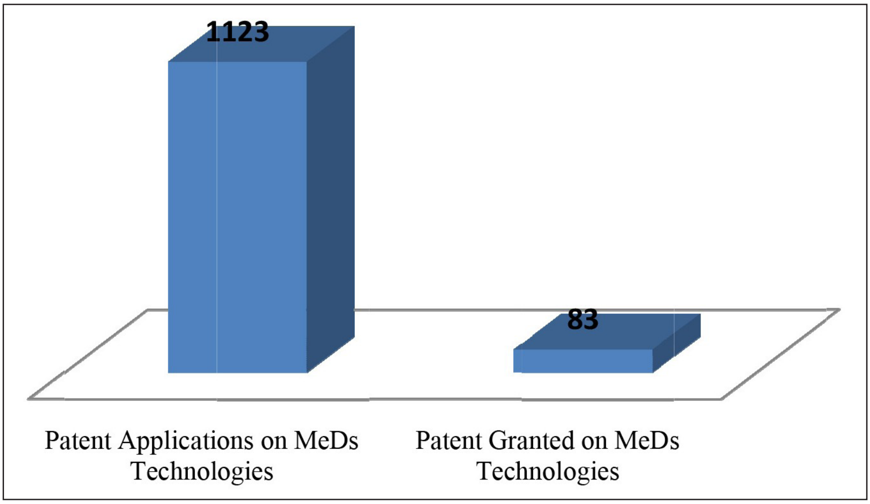
Figure 8: Extramural Research (EMR) Funding (2000-2019): Ratio of EMDs Research Projects Supported for Different Categories of Diseases



Source: Author calculation based on NSTMIS Database.

Moreover, the analysis of patents during 2000-2020 as an indicator of technological progress in the form of novel process or products and their significance for market formation for an emerging technology and in meeting the demands was conducted. The analysis showed that out of 1123 patents applications filed by Indian innovators in the area of EMDs in the last two decades, only 83 patents were granted (see Figure 9), reflecting a grant rate of merely 7.4 per cent. By comparison, India's overall patent grant rate in the fiscal year 2019–20 was approximately 44.3 per cent, with 24,936 grants out of 56,267 applications (Intellectual Property India Annual Report, 2019–20). This stark disparity suggests that patent applications in the EMDs sector face significant challenges related to novelty, inventive step, and alignment with emerging technological requirements. The findings highlight an urgent need to strengthen innovation pathways and enhance support frameworks tailored to EMD development in India.

Figure 9: Number of EMDs Patents Applications v/s EMDs Granted Patents (2000-2020)

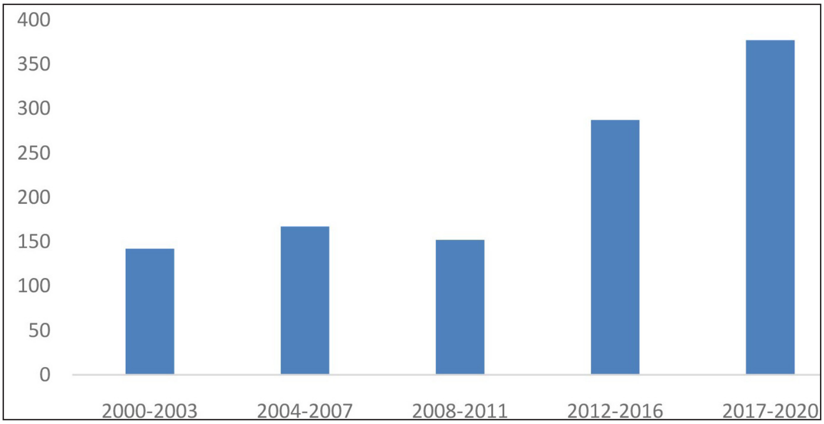


Source: Author calculation based on USPTO database.

The demand articulation failure reveals that the efforts being made to build EMDs innovation system are ineffective in delivering the potential solutions in terms of research publications, project support through EMR funding and granted patents to resolve the diagnostic needs for the highly burdened diseases. The knowledge generated to build the system for EMDs development is inadequate in aligning with the specific needs and ineffective in articulating the context specific demands. This is evident from the lack of research publications, inadequate project support through EMR funding, and a low number of granted patents in the field of EMDs development.

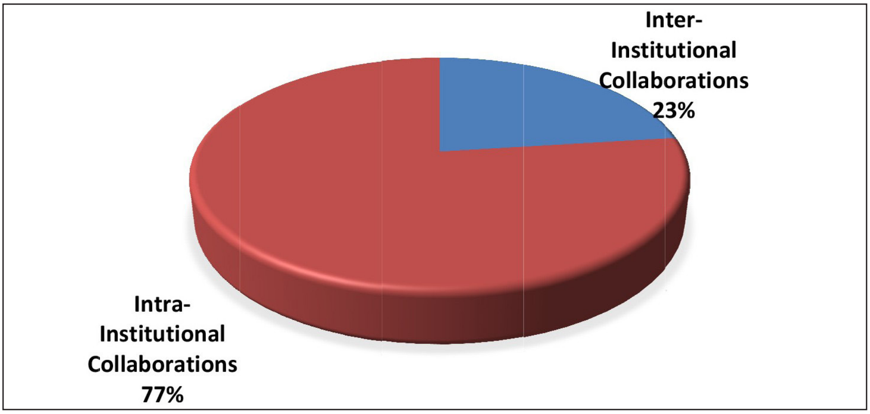
3 **Policy Coordination Failure:** This section reflects upon the mechanisms and instruments responsible for coordination failures in the complex policy setting of EMDs innovation system, where multiple instruments from different domains, levels and actors coexist. Our analysis of the amount of interactive learning or collaborative research undertaken in the knowledge creation for the development of EMDs through publication activities illustrates that collaborative research have increased in the R&D activities of EMDs over time (see Figure 10). However, a detailed assessment of the pattern of collaboration (see Figure 11&12) does not seem to be encouraging as the collaboration between industry-academia and academia-medical colleges/hospitals are comparatively low, even though these collaborations are critical for the creation of knowledge base for EMDs technology. The translation of basic ideas into products requires industry-academia interactions, while the interactions between academia-medical colleges/hospitals facilitate the understanding of researchers about the clinical aspects of the diseases and the role of technology in disease detections by clinicians. Hence, the emerging interactions among various innovation actors lack knowledge sharing and coordination, which negatively impact the creation of a strong and vibrant knowledge base for EMDs.

Figure 10: Cumulative Collaborative Research Publications in EMDs: By Selected Periods (2000-2020)



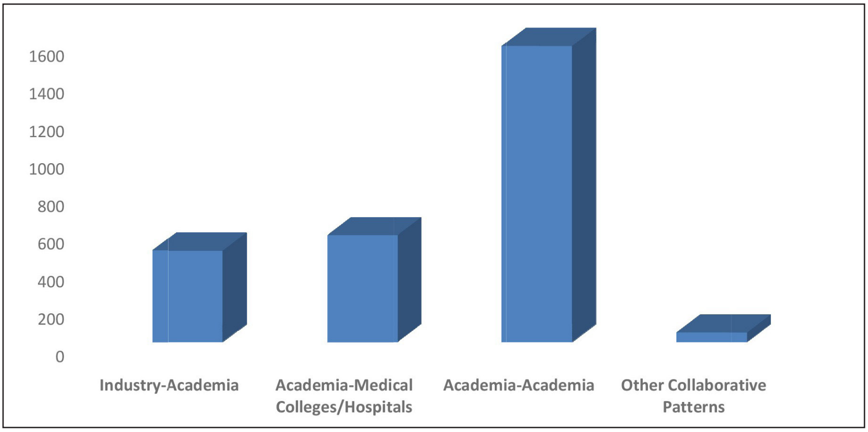
Source: Author calculation based on Scopus Database

Figure 11: Ratio of Intra and Inter Institutional Collaborations in EMDs (2000-2020)



Source: Author calculation based on Scopus Database

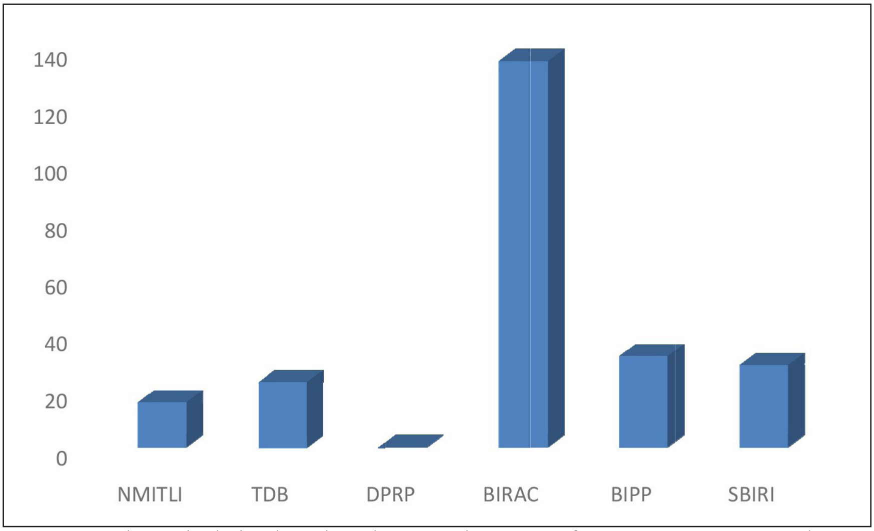
Figure 12: Number of EMDs Publications Showing Intra and Inter Institutional Pattern of Collaborations (2000-2020)



Source: Author calculation based on Scopus Database

In last few years, the government has taken steps to strengthen the coordination mechanism between academia and industry by facilitating the public-private partnerships (PPPs) to build a robust ecosystem for technological developments. This is done through the introduction of various promotional schemes and through setting up of the institutional mechanisms including the Council of Scientific and Industrial Research (CSIR), Drugs and Pharmaceuticals Research Programme (DPRP) and Technology Development Board (TDB) of Department of Science and Technology (DST), Biotechnology Industry Partnership Programme (BIPP) Small Business Innovation Research Initiative (SBIRI) and Biotechnology Industry Research Assistance Council (BIRAC) of Department of Biotechnology. The total numbers of projects funded for EMDs R&D under these schemes are shown in Figure 13a. It is evident that DBT's BIRAC is the leading agency for funding and promoting EMDs research.

Figure 13a: Number of Public Private Partnerships (PPPs) Based EMDs Projects Supported Under Various Funding Schemes (2010-2020)



Source: Author calculation based on the Annual Reports of DBT, BIRAC, DST and CSIR

Since its inception in 2012, BIRAC has been in the process of funding emerging biotechnologies with translation potential to promote the start-up ecosystem with the goals of "Make in India" and "start-up" India. BIRAC has been supporting innovation through schemes such as Biotechnology Ignition Grant (BIG), Small Business Innovation Research Initiative (SBIRI), Biotechnology Industry Partnership Programme (BIPP), Contract Research and Services Scheme (CRS) and Social Innovation programme for Products: Affordable and Relevant to Societal Health (SPARSH) and Industry Innovation Programme on Medical Electronics (IIPME). A comprehensive analysis of the system building activities contributing to EMDs development have shown that the ratio of EMDs projects funded by BIRAC is comparatively lower than the fund allocated for other diagnostics and biotechnological projects (see Table 4).

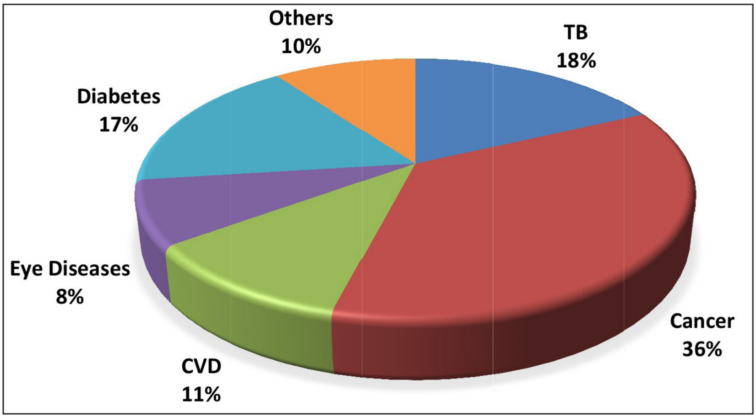
Table 4: Projects Supported Under Different Areas by BIRAC Through its Various Schemes (2012-2020)

BIRAC Schemes	Project supported in different Biotechnological Area (%)	Project supported in other diagnostics area (%)	Project supported in EMDs area (%)
BIG	56	30	14
SBIRI	78	15	7
BIPP	81.5	12	6.5
CRS	87	10	3
SPARSH	91	7	2
IIPME	37	37	26

Source: Author computation from BIRAC Annual Reports (2012-2020).

The analysis of funding allocation per disease area showed that eye care, cancer, cardiovascular diseases, tuberculosis and diabetes are the top five disease areas that have attracted funding for EMDs (see Figure 13b). While system building activities in these five disease areas are encouraging, the heavy concentration of funds among five disease areas for EMDs indicates an unequal distribution of funds. This suggest that there is a need to foster system building for other highly burdened diseases such as malaria, HIV/AIDS and neurological disorders. As a leading agency for supporting emerging technological development and creating a start-up ecosystem, BIRAC is expected to make more commitments towards strengthening the ecosystem for EMDs development.

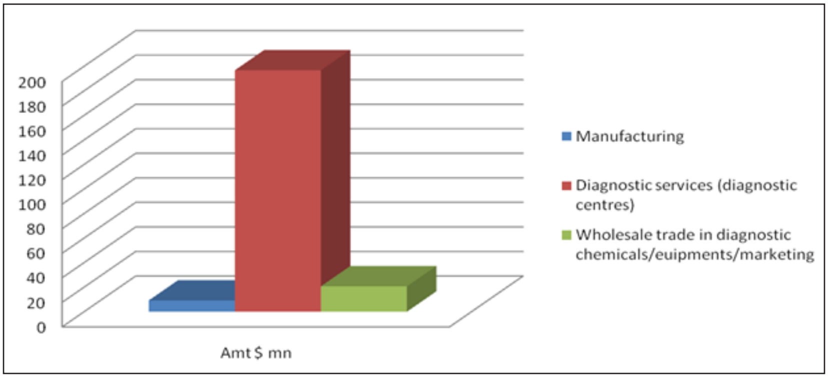
Figure 13b: Ratio of EMDs Projects Supported Under Different Disease Areas by BIRAC (2012-2020)



Source: Author calculation based on Scopus Database.

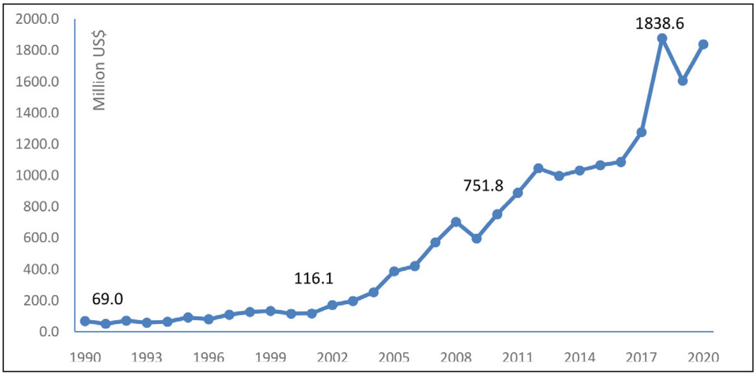
Further, the direction of FDI inflow more towards service sector and heavy import dependency (see Figures:14 &15) has created the unfavourable conditions for domestic medical device firms, leading to concerns about affordability and accessibility. This reflects the absence of proper synchronisation between different departmental policies, such as IPR policy, trade and investment policy, innovation policy and manufacturing policy. However, there is hope with the announcement of recent Draft on Medical Device Policy 2022, which aims to promote the growth of the sector by addressing issues of accessibility, affordability, safety & quality, while ensuring self-sustainability and innovation.

Figure 14: FDI Inflow in Diagnostic Sector in India (2000-2020)



Source: Author computation from Department of Industrial Policy and Promotion (DIPP) website

Figure 15: Trends in India's Import of MDs Products (Million US$) 1990-2020



Source: Author computation from the UN comtrade database, accessed from WITS

The analysis of 'Policy co-ordination failure' highlights the underperformance of instruments and mechanisms established to coordinate among innovations actors. Currently, the system building activities lacks optimal amount of interactive learning to build the knowledge base for EMDs. Similarly, the efforts of BIRAC need to be facilitated more towards targeted base funding to meet unmet needs. Furthermore, the improper co-ordination between ministries and departments hinders the effective implementation of policies for addressing social needs.

4 **Reflexivity Failure:** The analysis of three failure experiences in 'Directionality', 'Demand articulation' and 'Policy Coordination', collectively contribute to the 'Reflexivity Failure' in the development of EMDs innovation system. The presence of incompetency in developing sufficient knowledge capabilities, lack of sound network or interaction among innovation actors various and inadequate institutional apparatus reflect the absence of a reflexive system for a technological development.

The major factor responsible for reflexivity failure in building EMDs innovation system is the lack of proper governance mechanism. Firstly, the failure to undertake mission-oriented research and inadequate fund mobilisation hampers knowledge creation, and absence of defined goals lead to a lack of specificity. Secondly, current deregulation policy regime of the government has resulted in large import of finished MDs products that are maladapted to resource poor settings in India. Country lacks effective analytical and clinical validation process, which involve accreditation from a clinical laboratory performing diagnostic tests to get certificate from regulatory body (NABL, CLIA and CAP). Thirdly, the regulatory mechanisms for EMDs are poorly developed, as only less than 10 percent of clinical laboratories are currently accredited. The burden of cost for the implementation of quality control programme and a general lack of awareness are leads to a lack of pressure for appropriate innovation . Although the government has taken several steps to develop a reflexive mechanism for the medical diagnostic sector, as shown in Table 5, the institutionalization and legitimation system building functions involving reflexive apparatus is currently lacking in EMDs due to absence of effective monitoring mechanism required to address the uncertainty surrounding technological innovations and change in the transformative process.

Table 5: Efforts of DBT Towards Creation of Reflexive Technological Development

Policy Initiatives	Aims and Objectives
Focus on Translational Research	Main focus of this initiative is to focus on translational research that would address affordable solutions in the area of healthcare. DBT adopted Grand Challenge Programs which is supported by the Bill & Melinda Gates Foundation, the US National Institutes of Health, the UK Welcome Trust and the Canadian Institute of Health and Research THSTI has been set up in 2009 to create an institutional environment for multidisciplinary research to translate technological advancement into medical innovations for affordable healthcare solutions.
Facilitating technology access through global consortia	Main aim of this initiative is to span global partnerships for Indian researchers to collaboratively learn to adopt best practices in technology generation, translation and commercialization. The selected global collaborations are: 1 The Indo-Swiss Collaboration in Biotechnology (ISCB) is DBT's longest established bilateral R&D program, jointly funded and steered with SDC (Swiss Agency for Development and Cooperation). 2 Wellcome Trust, UK. The Wellcome Trust-DBT India Alliance is a biomedical fellowship program across the full spectrum of biomedical sciences. Under it a initiative called 'R&D for Affordable Healthcare' was launched specifically to support translational research projects that deliver safe and effective healthcare products at affordable costs for India. 3 Indo-US Vaccine Action Program (VAP). Was initiated in 1987 for five years, and is continuing till now. Its main aim was the development of joint R&D projects for new and better vaccines against major communicable diseases of importance to India.

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Supporting innovations for affordable technology development through Public Private Partnerships (PPPs)	Under this initiative DBT has developed two funding initiatives: Small Business Innovation Research Initiative (SBIRI) and Biotechnology Industry Partnership Programme (BIPP) in order to create affordable solutions in the area of health. For the 12th five-year planning process (2012-2017), DBT proposed 30 percent of its anticipated augmented total budget flow to the private sector to engage in collaborative research, adaptation and validation for accelerated commercialization, including through scaled-up SBIRI and BIPP funding.
Strengthening diversified skills development	Main aim is to re-skill existing professional scientists to engage in a more diverse arena of research and to create new talent in young scientists to engage in inter-related multidisciplinary research. For this various fellowship programmes have been established like DBT-Wellcome Trust biomedical research fellowship program, Ramalingaswamy Re-entry Fellowship program, The TATA Innovation Fellowship program, The Stanford-India Biodesign (SIB) fellowship program, The partnership between DBT and the not-for profit Association of Biotechnology Led Enterprises (ABLE) to provide exposure to graduating students in bio-entrepreneurship and creation of the Society for Technology Management (STEM) for enhancement of technology management skills across multi-disciplinary functional competencies.
Establishing required regulations.	Under this initiative DBT has proposed the Biotechnology Regulatory Authority Bill 2009 to establish an independent, autonomous, statutory agency to regulate the research, transport, import, manufacture and use of organisms and products of biotechnology. Creating a reward mechanism for technology transfer and providing a legal mandate for technology generating agencies to license them to enterprises.

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Creating institutional mechanisms for effective governance.	A project management entity was conceived for each of the initiatives to ensure efficiency, speed and transparency in governance and administration. Institutional frameworks were conceived and developed to suit the rules of engagement in mid-level research focused on the generation of affordable goods and services.

Source: Author own compilation from the DBT website.

Concluding Remarks

The study contributes in identifying the 'Transformation System Failures' that need to be considered while formulating a system-building activities for EMDs development in India. The empirical analysis revealed that the current efforts involved in EMDs innovation making are not sufficiently dealing the requirements of 'socio-technical transition' in order to deal with context specific diagnostics needs of the country. The current system lacks in establishment of policy instruments and research mechanisms to foster 'goal-oriented' knowledge creation within the participating innovation actors. Instead, we identified the lack of 'vision' and 'mission' in directing the pathways of knowledge creation towards sustainability that are contributing towards suboptimal demand articulation. Moreover, the lack of coordination between different ministries and departments is leading to misalignments and goal conflicts, which in turn is hindering the effective governance and proper implementation of relevant policies. Thus, the transformation System Failures include a lack of policy instruments and research mechanisms to promote goal-oriented knowledge creation, a lack of vision and mission to direct knowledge creation towards sustainability, and improper coordination between different departments and ministries.
The study recommends adopting a challenge-led innovation strategies that prioritise 'transformative' or 'mission-oriented' innovation policy that can address the need-based challenges and set the directions of sustainable socio-technical transitions. This requires the deflection of the pathways from routine 'comfort zone' of innovation making to the new paradigm of transformative approach where participating stakeholders have to strengthen their capabilities and capacities to understand the prerequisites for transition of the involved regimes, sectors, and innovation systems of technological development. Further, the study hope to inspire future research on the implementation of transformative innovation policy and the development of sound policy strategies to address the identified failures in the transformational system.

The experience of US and China in EMDs development offer valuable policy insights. The emergence of the US as the global leader in EMDs with robust scientific base is supported by massive State interventions and continuous funding support. The development of a strong industrial base was also achieved with active State support in the form of timely and sufficient supply of biochemicals, infrastructure development for new or modified instrumentation and the design of new substances for research and production. In the Chinese case, the State was active in mobilizing public funds for targeted research to promote inclusive innovation. The Chinese recognised the relevance of policy coordination and established initiatives to foster collaboration between firms and research laboratories of universities to promote development and commercialisation of innovations. Learning from these experiences, the Indian government can reorient their policy instruments for establishing EMDs institutions to foster affordable and accessible medical technologies for the society.

Endnotes

1 In Figure 1, the figures in percentages are based on the total number of publications on EMDs. The percentage distribution is derived from the number of publications by individual country in the total number of publications by the selected 24 countries in the sample.

2 Diagnostics which are suitable for resource constraint settings.

3 offers advanced diagnosis based on EMDs over 69 different viral disease tests, all bacterial infection testing inclusive of genetic analysis for antibiotic resistance, early prediction of lifestyle diseases, disease progression, and survival analysis using sequencing in diseases like cancer & cardiovascular diseases, and pharmacogenomic analysis for personalized medical care.

4 is the significant achievement for Indian scientific community. “FELUDA” is the world’s first diagnostic test to deploy a specially adapted Cas9 protein to successfully detect the virus causing Covid-19

5 BIRAC, a not for-profit, public-sector enterprise has been set up in 2012 by DBT, Govt. of India. The mandate of BIRAC is to act an interface agency to strengthen and empower the emerging Biotech enterprises to undertake strategic research & innovation, translating knowledge into technology led affordable and globally competent product development, addressing unmet needs.

6 Among all the laboratories participating in quality control programme, 75 percent exist in only five states, accounting for thirty per cent of the population. Since most of these laboratories are private, the population residing in rural areas not only lacks access to private labs, but also is more likely to undergo maladapted and substandard testing which is subject to inadequate safety protection.

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RIS
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Women-Led Biotech Startups in India: Catalyzing Inclusive and Affordable Health Innovation

Yamini Parashar* and Vikas Kumar**

Abstract: This paper attempts to scrutinize the critical role of women entrepreneurs and startups in India's biotechnology sector, focusing on their efforts to create affordable health innovations under financial constraints. It also deals with the impact of government initiatives, funding programs, and incubation support in fostering an enabling ecosystem for these ventures. Further, India's biotechnology sector has emerged as a transformative force in addressing public health challenges, offering innovative, scalable solutions to bridge critical healthcare gaps. With this context, bio-entrepreneurs play a pivotal role in transforming scientific discoveries into scalable solutions with public health relevance in India. They operate in areas such as affordable diagnostics, vaccine development, molecular medicine, and digital health platforms. The study is based on the secondary data.

Keywords: Biotechnology, Women entrepreneurs, Startups, innovation, Startup ecosystem

Introduction

India's biotechnology sector has emerged as a transformative force in addressing public health challenges, offering innovative, scalable solutions to bridge critical healthcare gaps. Biotechnology, as defined by the United Nations Convention on Biological Diversity, is "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use" (CBD, 1992). In the Indian context, biotechnology has evolved as a critical sector driving healthcare innovation, sustainable agriculture, industrial processes, and environmental solutions. As per the Department of Biotechnology (DBT), Ministry of Science and Technology, India's biotech industry was valued at USD 80.12 billion in 2022 and is expected to reach USD 150 billion by 2025, making it one of the fastest-growing sectors in the country (DBT, 2022). Entrepreneurship, according to the (OECD, 2023), is the capacity and willingness to develop, organize, and manage a business venture along with any of its risks to make a profit. In the biotechnology sector, this process is deeply intertwined with research, innovation, intellectual property, and navigating complex regulatory systems. Bio-entrepreneurship, therefore, refers to the creation and management of business ventures

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within the domain of biotechnology a multidisciplinary and innovation-driven ecosystem involving scientists, technologists, business experts, and healthcare professionals working together to translate life sciences research into commercially viable solutions.

In India, bio-entrepreneurs play a pivotal role in transforming scientific discoveries into scalable solutions with public health relevance. They operate in areas such as affordable diagnostics, vaccine development, molecular medicine, and digital health platforms. The Biotechnology Industry Research Assistance Council (BIRAC), an initiative of the DBT, has supported over 1,500 biotech startups and small enterprises since its inception in 2012, many of which focus on cost-effective, accessible healthcare technologies (BIRAC Annual Report, 2023). Women entrepreneurs, as defined by the Government of India's MSME Ministry, are those women who own and control at least 51per cent of the business enterprise and are involved in the decision-making process (MSME Policy Guidelines, 2022). In India's innovation ecosystem, women entrepreneurs are underrepresented, particularly in STEM-intensive domains like biotechnology. Despite policy initiatives such as the Women Entrepreneurship Platform (NITI Aayog) and BIRAC's LEAP fund, the proportion of women-led startups in India remains significantly low estimated at around 14 per cent across all sectors and even lower in deep-tech domains (Startup India, 2023). An emerging trend signals a promising shift: a growing number of women scientists, researchers, and innovators are launching biotech startups aimed at solving real-world problems, especially those related to public health, maternal care, and rural diagnostics. These ventures often operate under severe resource constraints, leading to the rise of a new paradigm "biotech on a budget" wherein frugal innovation, local relevance, and community-oriented solutions take precedence. Unlike traditional biomedical enterprises backed by heavy funding and global R&D networks, these women-led ventures leverage incubator support, grassroots needs assessments, and low-cost engineering to create impactful solutions. This shift is especially crucial in India, where over 60 per cent of the population resides in rural areas with limited access to quality healthcare. Women entrepreneurs, in many cases, have shown a unique ability to contextualize innovation designing products that are culturally appropriate, economically accessible, and environmentally sustainable. Examples include affordable point-of-care diagnostic kits, AI-enabled screening devices, and home-based health monitoring tools, many of which are incubated under programs like DBT-BIRAC's BIG Scheme, Biotech Ignition Grant, and Social Innovation Fellowships. These entrepreneurs face a triple burden: navigating the high-risk biotechnology sector, contending with financial and institutional barriers, and breaking gender norms that limit women's participation in leadership and science entrepreneurship. Research indicates that access to funding, mentorship, and gender-inclusive incubator networks remain a critical barrier (World Bank, 2022).

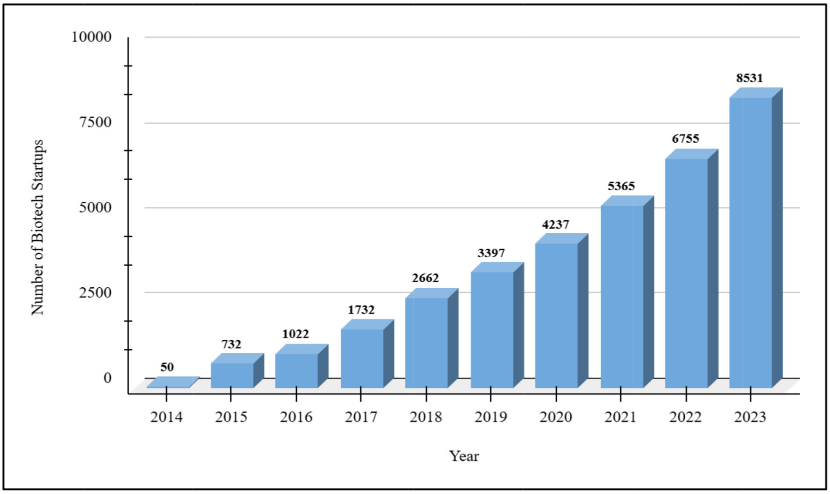
Furthermore, the socio-cultural expectations of women in India often constrain their time, mobility, and risk appetite further widening the gender gap in high-growth entrepreneurship. This paper, therefore, seeks to critically examine the experiences, innovations, and challenges of women biotechnology entrepreneurs in India who are developing low-cost health technologies. It also evaluates the effectiveness of public policy, incubation models, and international collaborations in supporting these ventures. It also analyzing case studies, policy frameworks, and secondary data, this research contributes to the broader discourse on inclusive innovation, gender equity in STEM, and sustainable entrepreneurship in the Global South. And also, this study underscores the need to recognize and support women-led innovation as a vital component of India's bioeconomy. It calls for reimagining biotech policy frameworks that go beyond financial assistance and address deeper issues of gender inclusivity, representation, and equitable access to entrepreneurial resources. This research paper focuses on examining the role of women entrepreneurs in India's biotechnology sector who are driving affordable and context-specific health innovations under financial constraints. Through a gendered lens on inclusive innovation and entrepreneurial resilience, the study is structured around the following three objectives:

- To examine the critical role and contributions of women entrepreneurs in India's biotechnology sector,
- To assess the impact and effectiveness of government initiatives, funding programs, and incubation support
- To analyse the strategies and innovative practices adopted by women entrepreneurs
- To discuss the case study of women entrepreneurship in Biotechnology Sector India

Understanding the Growth of Biotechnology Startups in India

The section presents a detailed analysis of the evolving landscape of biotechnology entrepreneurship in India. The data also reflects how state-wise efforts and regional ecosystems have played a major role in shaping the startup environment. Sectoral diversity is examined to understand which areas are gaining prominence and why. Special attention is given to women-led initiatives in the health biotech domain, including inspiring journeys of key female entrepreneurs. In addition, government schemes supporting innovation and inclusion in the biotech space are reviewed.

Figure 1: Growth of Biotechnology Startups in India



Source: Authors compilation from India Bioeconomy Report (IBER) Report 2024.

The figure.1 illustrates a remarkable growth trajectory in the number of biotechnology startups in India over the past decade. In 2014, the sector was at a nascent stage with only 50 startups. However, by 2015, this number had grown more than fourteenfold to 732, indicating a strong early interest driven likely by the government's initiatives like Startup India and increased focus on biotechnology through the National Biotechnology Development Strategy (NBDS).

This momentum continued steadily: by 2016, the number had crossed 1,000, and by 2017, it had increased to 1,732. Notably, 2018 witnessed a sharp rise to 2,662 startups an indication of maturing entrepreneurial ecosystems, increased availability of incubators and bio-clusters, and greater access to early-stage funding. The sector's growth gained further traction post-2019. Between 2019 and 2023, the number of startups more than doubled from 3,397 to 8,531. This period coincides with India's COVID-19 response, which spurred innovation in vaccine research, diagnostics, and bio-services. Government support, policy reforms, and rising health-tech demand accelerated the formation of biotech startups during this time.

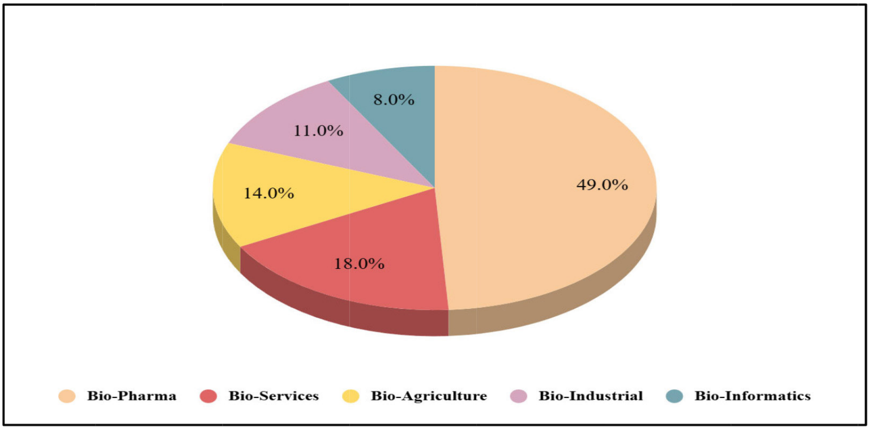
The most rapid growth occurred between 2021 and 2023, with over 3,000 startups added in just two years. This trend reflects both increased entrepreneurial activity and investor confidence in India's biotechnology sector. It also underscores the strategic importance of biotech in the country's health, agriculture, and industrial innovation ecosystems.

Table 1: Sectoral Distribution of Biotechnology Startups in India

Biotechnology Sector	Number of startups	Description
Bio-Pharma	49%	Includes biopharmaceuticals, vaccines, and therapeutic products.
Bio-Services	18%	Covers contract research, clinical trials, and testing services.
Bio-Agriculture	14%	Focuses on bio-fertilizers, GM crops, and agri-biotech solutions.
Bio-Industrial	11%	Involves biofuels, industrial enzymes, and green chemicals.
Bio-Informatics	8%	Encompasses genomics, data analytics, and computational biology.

Sources: Author compilation from (ABLE, 2020), (DOB, 2024), (Invest India, 2025).

Figure 2: Sectoral Distribution of Biotechnology Startups in India



Sources: Author compilation from GOI (DOB, 2024).

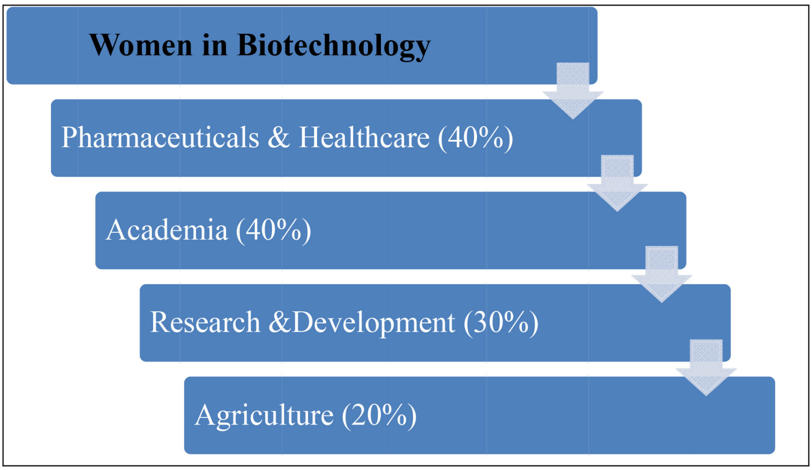
The table 1 and figure 2 describes about the India's biotechnology sector demonstrates a diversified ecosystem, with each sub-sector contributing uniquely to the country's innovation-driven bioeconomy. As per the Department of Biotechnology, the Bio-Pharma sector dominates, accounting for approximately 49 per cent of all biotechnology startups. This strong presence is reflective of India's global position as a major supplier of vaccines and generic medicines, bolstered by robust R&D capabilities and government support for affordable healthcare solutions. The prominence of Bio-Pharma also aligns with the increasing focus on indigenous vaccine development, biotherapeutics, and diagnostic tools, particularly in the post-COVID-19 era. The Bio-Services segment holds the second-largest share at 18 per cent, signifying the country's emerging strength in clinical research, contract manufacturing, and diagnostic testing services. India's cost-effective infrastructure, combined with a skilled workforce, has made it a favoured destination for contract research organizations (CROs), especially in the pharmaceutical and life sciences industries. Following this, Bio-Agriculture contributes 14 per cent to the sector. This includes startups working on genetically modified crops, bio-fertilizers, and sustainable agri-biotech solutions aimed at improving productivity and climate resilience in Indian agriculture. As climate change and food security become critical challenges, bio-agriculture startups are increasingly vital in creating sustainable farming ecosystems. The Bio-Industrial segment, comprising 11 per cent of biotech startups, is gaining traction with innovations in biofuels, industrial enzymes, and green manufacturing processes. This sub-sector plays a key role in India's transition towards cleaner and more sustainable industrial practices. Lastly, Bio-Informatics, though currently the smallest segment at 8 per cent, is rapidly growing. This field combines genomics, AI, machine learning, and big data analytics to facilitate personalized medicine, drug discovery, and precision agriculture.

Women Entrepreneur in Biotechnology

With the digital transformation of healthcare and the increasing need for data-driven decision-making, bioinformatics is expected to be one of the most dynamic sectors in the coming years. These five sub-sectors paint a picture of a resilient, multifaceted biotechnology ecosystem, where startups are addressing a wide range of societal needs health, agriculture, industry, and information. The balanced yet health-centric distribution also suggests a strategic national focus on public health innovation, while nurturing other emerging bio-industries for long-term sustainability. The figure given below depicts about the sector-wise distribution of women entrepreneurs and professionals in biotechnology in India reveals a dynamic yet uneven pattern.

The sector-wise distribution of women entrepreneurs and professionals in biotechnology in India reveals a dynamic yet uneven pattern. Overall, women constitute approximately 30 per cent of the biotechnology workforce, aligning with the global average for women in STEM fields (UNESCO Institute for Statistics, 2020). Within the sector, female representation is relatively balanced in Research & Development and Agriculture & Environment, both at around 30 per cent. The figures above suggest that while women are actively participating in foundational scientific research and environmental applications, there is still room for improvement in ensuring equitable participation in these domains. Conversely, women have a stronger presence in Pharmaceuticals & Healthcare and Academia & Education, each with approximately 40 per cent representation (Association of Biotechnology Led Enterprises, 2020). This trend indicates that women are finding greater opportunities and support in health-focused and knowledge-driven areas of biotechnology, possibly reflecting targeted initiatives and institutional support. But the sectoral imbalance underscores the need for comprehensive policies and programs that promote women's active involvement across all biotech domains, including the traditionally male-dominated agricultural biotechnology sector. Addressing these disparities can help leverage the full potential of women's contributions to India's vibrant and growing biotech ecosystem.

Figure 3: Distribution of Women in Biotechnology



Sources: Authors compilation from (ABLE, 2024) report.

Table 2: Government Schemes Supporting Biotechnology & Women Entrepreneurs in India (Health Sector)

Name of Scheme/ Policy	Launched By	Objective/Support	Relevance to Women in Health Biotech
Biotechnology Ignition Grant (BIG)	Biotechnology Industry Research Assistance Council (BIRAC), DBT	Provides early-stage funding (up to ₹50 lakhs) for biotech startups and entrepreneurs.	Women-led startups in health-tech receive funding for product development, diagnostics, and PoC devices

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Stand-Up India Scheme	Ministry of Finance, Govt. of India	Offers bank loans (₹10 lakh–₹1 crore) to SC/ ST and women entrepreneurs.	Women biotech entrepreneurs in healthcare can avail capital support to start ventures
Biotech Start-up Policy (e.g., Telangana, Karnataka)	Various State Governments	Provides incubation, funding, and mentorship to biotech startups	Special incentives and reserved seats in biotech incubators for women-led health tech ventures
Women Entrepreneurship and Empowerment (WEE) Program	Department of Science & Technology (DST), India	Training and mentoring support for women in STEM entrepreneurship	Encourages women to launch science-based health solutions,
Biotechnology Industry Partnership Programme (BIPP)	BIRAC, Department of Biotechnology	High-risk, high-reward biotech innovation funding	Supports scalable biotech innovations in health, including proposals from women entrepreneurs
National Biopharma Mission	BIRAC-DBT with World Bank support	Strengthens the biopharmaceutical industry by supporting product development and translational research	Women-led startups in affordable therapeutics, diagnostics, and vaccines receive funding and mentoring support
Support for International Patent Protection in Electronics & IT (SIP-EIT)	Ministry of Electronics and IT	Financial support for patent filing in foreign countries	Women-led biotech startups in diagnostics and med-tech can seek IP protection for innovations
TIDE 2.0 Scheme	Ministry of Electronics and IT (MeitY)	Technology Incubation and Development of Entrepreneurs (TIDE) funding and incubation in health tech innovation	Women entrepreneurs in digital health, wearable biotech, and mobile diagnostics get seed funding and incubation

Continued...

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Start-up India Initiative	Department for Promotion of Industry and Internal Trade (DPIIT)	Offers tax benefits, funding access, and innovation support	Recognizes women-led biotech startups under DPIIT and connects them with BIRAC and SIDBI for capital support

Sources: Authors compilation from official government websites and policy documents (BIRAC, DBT, MeitY, DST, DPIIT, Ministry of Finance, 2024).

The table 2. highlights a range of national and state-level schemes that collectively create a comprehensive support ecosystem for women entrepreneurs in health biotech. These initiatives such as the Biotechnology Ignition Grant (BIG), Stand-Up India, state-specific Biotech Start-up Policies, Women Entrepreneurship and Empowerment (WEE) Program, Biotechnology Industry Partnership Programme (BIPP), National Biopharma Mission, SIP-EIT, TIDE 2.0, and the Start-up India Initiative—are crucial in addressing the financial, technical, and structural barriers that women-led health-biotech ventures often face. The BIG scheme, with its early-stage funding for product development and proof-of-concept, is particularly impactful, helping women-led health-tech startups move from idea to innovation. Similarly, Stand-Up India provides vital credit access, while state policies offer regional incubation and funding opportunities that often include incentives for women founders.

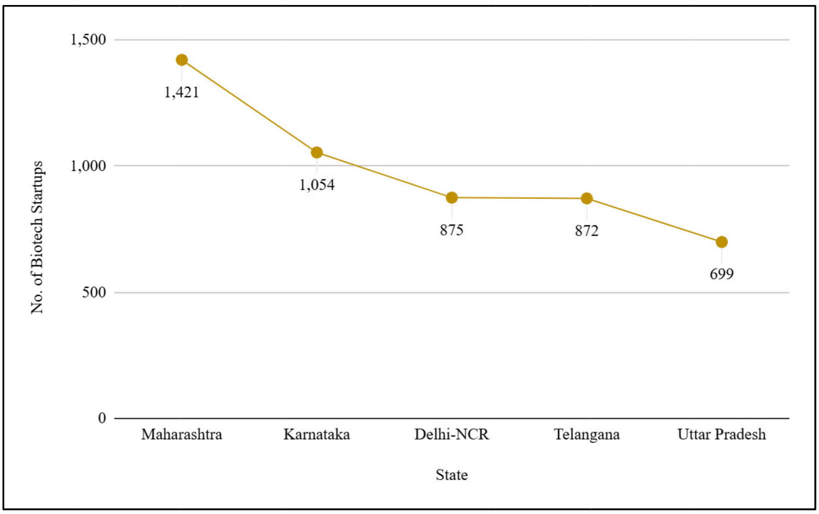
The WEE Program stands out as a gender-focused initiative, directly supporting women in STEM entrepreneurship through mentorship and training. BIPP and the National Biopharma Mission address high-risk health-biotech innovations, offering substantial funding and translational support that can be game-changing for women working on scalable diagnostics, therapeutics, or vaccines. SIP-EIT ensures that women's innovations are protected through international IP filing support, and TIDE 2.0 backs health-tech and digital health innovations with incubation and seed funding. The Start-up India Initiative further integrates women entrepreneurs into India's startup ecosystem by offering tax benefits, market linkages, and connections to funding agencies like SIDBI. However, while WEE and Stand-Up India are explicitly gender-specific, most programs are gender-neutral, underscoring the need for targeted outreach and facilitation to ensure equitable participation by women. Overall, these programs form a strong pipeline that empowers women to launch, grow, and scale health-biotech ventures fostering inclusive growth, driving health-tech innovation, and addressing critical healthcare needs in India.

Table 3: State-wise Distribution of Biotech Startups

State/Region	No. of Biotech Startups	Key Highlights
Maharashtra	1,421	Leading state in biotech; strong presence in Mumbai–Pune corridor.
Karnataka	1,054	Bengaluru hosts India's largest biocluster; major biotech investments.
Delhi-NCR	875	A key hub for startups in bio-pharma and bio-informatics.
Telangana	872	Genome Valley is a biotech hotspot; state policies support innovation.
Uttar Pradesh	699	Emerging region; growing number of biotech startups supported by state innovation programs.

Sources: Author compilation from different Bio-economy report (2025).

Figure 4: Graphical representation for State-wise Distribution of Biotech Startups

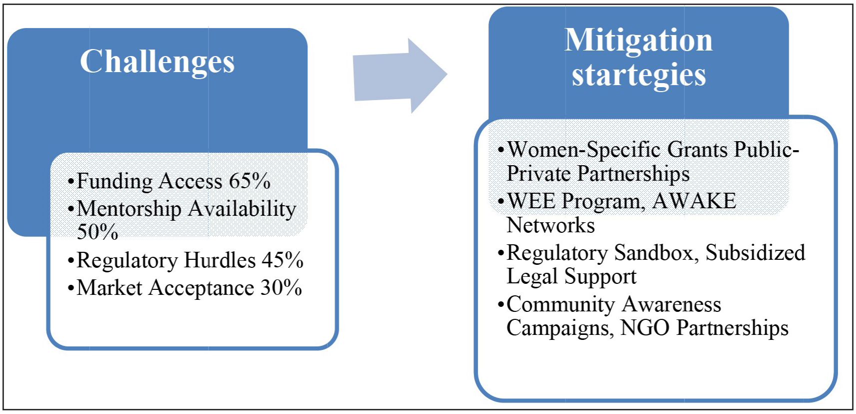


Sources: Author compilation from different Bio-economy report (2025).

The graph and table illustrate the state-wise distribution of biotech startups in India, showcasing the dynamic landscape of the country's biotechnology sector. Maharashtra emerges as the leading state with 1,421 biotech startups, cementing its position as a powerhouse in the field. This dominance is primarily attributed to the thriving Mumbai–Pune corridor, a vibrant ecosystem that fosters research, innovation, and partnerships between academia and industry. Karnataka ranks second with 1,054 biotech startups, largely driven by Bengaluru's status as India's largest biocluster and a globally recognized center for biotech innovation. The city's robust academic ecosystem, presence of global companies, and supportive policies have created a fertile ground for biotechnology entrepreneurship. Delhi-NCR, hosting 875 biotech startups, stands out as a key hub for bio-pharma and bio-informatics ventures, leveraging its strategic location and the proximity to national research institutes and regulatory bodies. Telangana follows closely with 872 startups, highlighting the state's proactive approach to biotechnology development through initiatives like Genome Valley, which provides cutting-edge infrastructure and policy support for startups.

In addition to this, Uttar Pradesh, while traditionally not associated with biotechnology leadership, has shown impressive growth with 699 biotech startups, driven by state-level innovation programs and a rapidly evolving ecosystem that encourages entrepreneurs to establish and scale their ventures. Collectively, these figures underscore the regional diversity and vibrancy of India's biotechnology sector. Established centers like Maharashtra and Karnataka continue to lead with their mature ecosystems, while emerging regions such as Uttar Pradesh signal a promising future for a more decentralized and inclusive biotechnology landscape. This state-wise distribution offers a comprehensive view of how India's biotech ecosystem is evolving, adapting to regional strengths, and fostering innovation across a range of scientific and industrial domains.

Figure 5: Challenges and Mitigation Strategies for Women Biotech Entrepreneurs in India



Sources: Authors compilation from various government reports world economic forum (2024).

The figure 4 demonstrate overview of the primary obstacles faced by women in entrepreneurship and the proposed solutions to address these issues, reflecting systemic barriers and actionable interventions. On the challenges side, funding access stands out as the most significant hurdle, with 65 per cent of respondents identifying it as a barrier, indicating that a majority of women entrepreneurs struggle to secure the financial resources necessary to start or scale their ventures. This is followed by mentorship availability at 50 per cent, highlighting a critical gap in access to guidance and support from experienced professionals, which is often essential for navigating the complexities of business ownership. Regulatory hurdles, cited by 45 per cent of respondents, point to the difficulties women face in dealing with bureaucratic processes, compliance requirements, and legal frameworks that may disproportionately affect them due to limited resources or networks. Lastly, market acceptance, noted by 30 per cent, underscores the challenge of gaining traction and credibility in competitive markets, where biases or stereotypes about women-led businesses may persist.

On the other hand, to mitigate these challenges, the chart proposes several strategies aimed at creating a more supportive ecosystem for women entrepreneurs. These include women-specific grants through public-private partnerships, which directly address the funding gap by providing targeted financial support, and participation in programs like WEE (Women's Economic Empowerment) and AWAKE (Association of Women Entrepreneurs of Karnataka) networks, which offer mentorship, networking opportunities, and resources tailored to women's needs. Additionally, the introduction of regulatory sandboxes and subsidized legal support aims to ease the burden of compliance and legal challenges by providing a testing ground for innovations and affordable access to legal services.

Finally, community awareness initiatives through NGO partnerships seek to tackle market acceptance issues by raising awareness and reducing biases, fostering a more inclusive environment for women-led businesses. This analysis suggests that while significant barriers persist for women entrepreneurs, a multifaceted approach combining financial, regulatory, and social support could pave the way for greater equity and success in the entrepreneurial landscape. Further research into the effectiveness of these mitigation strategies across different regions and industries could provide deeper insights into their impact and scalability.

The funding support landscape for women-led biotech startups in India is multi-layered, encompassing early-stage grants, credit facilities, equity funding, intellectual property (IP) support, and mentorship programs. At the early-stage level, schemes like the Biotechnology Ignition Grant (BIG), which offers up to ₹50 lakh, the BIRAC-TiE WInER providing ₹5–25 lakh, and the Startup India Seed Fund Scheme (SISFS) with ₹227.12 crore distributed across 1,278 startups, play a vital role in enabling women entrepreneurs to develop proof-of-concept and prototype models. These early-stage grants, provided by government bodies like the Biotechnology Industry Research Assistance Council (BIRAC) and Startup India, are essential in bridging the funding gap faced by women at the initial stages of their biotech ventures (BIRAC, 2024). Beyond early development, debt and credit support are crucial to ensure scalability and sustainability. Programs such as Stand-Up India, offering ₹10 lakh to ₹1 crore, and the Credit Guarantee Scheme for Startups, with ₹24.6 crore guaranteed, provide collateral-free loans to overcome gender-based barriers to accessing bank finance. Similarly, private initiatives like Kinara Capital's HerVikas, with an allocation of ₹100 crore, fill critical gaps in institutional financing, ensuring that women-led biotech startups can secure working capital and manage cash flow constraints effectively (Stand-Up Mitra, 2025).

Figure 6: Funding Support for Women Entrepreneurs in Biotechnology in India

•Early-stage Grants & Seed Funding

□Biotechnology Ignition Grant (BIG) – ₹50 lakh
□BIRAC-TiE WInER – ₹5 lakh to ₹25 lakh
□Startup India Seed Fund Scheme – ₹227.12 crore across 1,278 startups

•Debt / Credit Support

□Stand-Up India – ₹10 lakh to ₹1 crore
□Credit Guarantee Scheme for Startups – ₹24.6 crore guaranteed
□Kinara Capital HerVikas – ₹100 crore

•Equity / Investment Funds

□Alternative Investment Funds – ₹3,107.11 crore
□Fund of Funds for Startups – 10% of ₹10,000 crore corpus
□BIRAC AcE Fund – ₹149.5 crore allocated, ₹1,172 crore invested

IP Protection / Support

□SIP-EIT – Up to ₹15 lakh for international patents

•Capacity-building / Mentorship

□Women Scientist Scheme (WOS) – DST
□Women Entrepreneurship and Empowerment (WEE) – D

Source: Author compilation based on data from BIRAC (2024), Startup India (2025).

Equity and investment funds play a pivotal role in fostering mid- and growth-stage development of women-led biotech startups. Notably, Alternative Investment Funds (AIFs) have invested ₹3,107.11 crore in these ventures, while the Fund of Funds for Startups (FFS) reserves 10 per cent of its ₹10,000 crore corpus for women-led enterprises, reflecting a significant commitment to gender inclusivity in India's startup ecosystem. The BIRAC AcE Fund further bolsters this ecosystem with ₹149.5 crore allocated and ₹1,172 crore already invested in biotech innovation. These equity investments enable women entrepreneurs to scale up operations, enter new markets, and pursue advanced R&D, which are critical for long-term competitiveness and sustainability (BIRAC, 2025). Securing intellectual property (IP) is another essential dimension, especially in the biotech sector, where innovation protection is paramount. The SIP-EIT scheme, providing up to ₹15 lakh for international patent filing, empowers women-led biotech startups to safeguard their innovations and build global competitiveness, which is crucial for attracting further investment and forging strategic partnerships (Ministry of Electronics & IT (MeitY, 2024).

Finally, capacity-building and mentorship programs such as the Women Scientist Scheme (WOS) and the Women Entrepreneurship and Empowerment (WEE) initiative, both supported by the Department of Science and Technology (DST), aim to cultivate a pipeline of skilled women entrepreneurs in the biotech sector. These initiatives focus on bridging gender gaps in STEM leadership, supporting re-entry of women scientists into active research and entrepreneurship, and providing mentorship to navigate the complex challenges of commercializing biotech innovations (DST, 2024).

Women Entrepreneurs in Biotechnology: Few Examples

The women entrepreneurs in India's biotechnology and healthcare sectors showcase their extraordinary resilience, innovation, and transformative impact on addressing pressing societal challenges through science and business.

Case Study 1: Kiran Mazumdar-Shaw founded Biocon Limited in 1978 in Bangalore with a modest capital of Rs. 10,000, initially focusing on producing enzymes; trained as a brewmaster, she pivoted to biotechnology, facing significant gender bias and skepticism in a male-dominated industry, but overcame funding and credibility challenges to build Biocon into a $7 billion biopharma giant, pioneering affordable therapies for diabetes and cancer, making India a global biotech hub, and earning recognition as a leading woman entrepreneur, with her journey underscoring how resilience and innovation can transform challenges into global leadership, inspiring women in STEM.

Case Study 2: Anuradha Acharya founded Ocimum Bio Solutions in 2000, focusing on life science informatics, and later established Mapmygenome in 2013 for personal genomics in Hyderabad, overcoming gender assumptions and funding barriers while educating the Indian market on the importance of genomics for preventive healthcare; her ventures, Mapmygenome and Ocimum, promote proactive health through genetic testing and support global biotech research, respectively, with Acharya also serving on the

IvyCap board, demonstrating how bridging science and business can advance preventive care despite biases and market challenges.

Case Study 3: Suchitra Ella co-founded Bharat Biotech in 1996 with her husband Krishna Ella, focusing on vaccines for neglected diseases, navigating limited biotech infrastructure and societal expectations as a woman to scale operations and compete globally; Bharat Biotech developed Covaxin, India's first COVID-19 vaccine, alongside vaccines for polio and cholera, saving millions of lives, with Ella's strategic leadership making the company a global vaccine leader, highlighting the power of perseverance in addressing critical health needs.

Case Study 4: Dr. Geetha Manjunath, with a Ph.D. in Artificial Intelligence from the Indian Institute of Science (IISc), founded NIRAMAI Health Analytix in 2016 after transitioning from roles at C-DAC, HP Labs, and Xerox Research to address limitations in traditional breast cancer screening methods; NIRAMAI developed "Thermalytix," an AI-based, non-invasive, radiation-free screening tool for early breast cancer detection, especially beneficial for women under 45, earning global recognition and support from the Bill & Melinda Gates Foundation, exemplifying how technology can revolutionize early disease detection and make healthcare more accessible and affordable.

Case Study 5: Dr. Vanita Prasad with a Ph.D. in Environmental Biotechnology and over 28 years of experience, founded REVY Environmental Solutions in 2017 to tackle waste management challenges through anaerobic digestion and bio-cultures, developing customized microbial solutions for waste treatment; her innovations, backed by grants from DBT-BIRAC and multiple patents, have provided sustainable, low-energy solutions for waste and wastewater treatment, contributing to cleaner environments and renewable energy generation, underscoring the critical role of biotechnology in environmental sustainability and the impact of women-led initiatives in this domain.

Case Study 6: Dr. Anusuya Roy an alumnus of IIT Delhi, established Nanosafe Solutions Pvt. Ltd. as a spin-off to commercialize her research in antimicrobial nanotechnology, developing copper-based antimicrobial products like NSafe masks and AqCure water bottles to address public health needs; her innovations proved pivotal during health crises, offering effective protection against pathogens, with the company receiving accolades like the Women Entrepreneurship Award by the Delhi Management Association, highlighting the potential of research-driven innovations in solving real-world health challenges.

Case Study 7: Dr. Praapti Jayaswal and Dr. Avlokita Tiwari both scientists with a focus on infectious diseases, co-founded AarogyaAI in 2019 to combat antimicrobial resistance by developing a SaaS platform using machine learning to analyze bacterial DNA, enabling rapid diagnosis of drug-resistant infections; their technology facilitates personalized antibiotic treatments, reduces treatment durations, improves patient outcomes, and has garnered support from industry leaders with plans for global expansion, exemplifying how AI and genomics can transform infectious disease management and the vital role of women in tech-driven healthcare solutions.

Case Study 8: Dr. Sudeshna Adak with a background in cancer research from Harvard School of Public Health, returned to India to found OmiX Laboratories, focusing on rapid diagnostic tools for diseases like tuberculosis; her innovations have significantly reduced the time to detect patient responses to TB treatments, enhancing disease management and patient care, showcasing the impact of dedicated research in strengthening public health infrastructure.

Case Study 9: Dr. Maroudam Veerasami founded CisGEN Biotech Discoveries in 2017, concentrating on animal health and zoonotic diseases by developing diagnostic kits for bovine tuberculosis, a significant public health concern due to its potential transmission to humans; her work has improved disease detection in livestock, aiding in controlling zoonotic diseases and ensuring food safety, highlighting the importance of veterinary biotechnology in safeguarding public health.

Case Study 10: Romita Ghosh a cancer survivor who pursued biotechnology and later an MBA from IIM Udaipur, channelled her experiences into founding Medi Samaan, an online marketplace providing affordable medical equipment to hospitals; her platform has streamlined the procurement of medical supplies, reducing costs and improving healthcare delivery in underserved areas, illustrating how personal experiences can drive impactful solutions in the healthcare sector.

Case Study 11: Meena Ganesh with a background in physics and extensive corporate experience, co-founded Portea Medical to offer in-home healthcare services, including post-operative care and chronic disease management, expanding healthcare access for the elderly and those with mobility challenges across multiple Indian cities; her work underscores the potential of combining technology and personalized care to revolutionize healthcare delivery. These women collectively demonstrate how resilience, scientific expertise, and entrepreneurial vision can address global challenges in health, environment, and sustainability, paving the way for future generations of women in STEM and entrepreneurship to innovate and lead with impact.

Conclusion

This research underscores the transformative role that women entrepreneurs play in India's biotechnology sector, particularly in addressing the urgent need for affordable and inclusive health solutions. Despite systemic barriers such as limited access to capital, gendered expectations, and underrepresentation in STEM-intensive domains, women-led biotech startups have emerged as key drivers of innovation and equitable healthcare access (World Bank, 2022; UNESCO Institute for Statistics, 2020). The resilience and creativity demonstrated by these women are evident in their ability to develop affordable and locally relevant solutions that address critical health needs across underserved and marginalized populations. Through in-depth case studies of pioneering women like Dr. Geetha Manjunath of NIRAMAI, Romita Ghosh of Medi Samaan, and Dr. Vanita Prasad of REVY Environmental Solutions, this research highlights how women entrepreneurs in biotechnology are translating cutting-edge research and technology into scalable products and services (viestories.com; entrepreneur.com). Their innovative solutions—ranging from AI-driven breast cancer screening tools to eco-friendly waste management systems—are examples of how frugal innovation and community-oriented design can overcome the limitations of traditional, capital-intensive biomedical models (Invest India, 2025).

Government schemes and policy frameworks such as the Biotechnology Ignition Grant (BIG), Stand-Up India Scheme, Women Entrepreneurship and Empowerment (WEE) Program, and National Biopharma Mission have played a crucial role in supporting these ventures (BIRAC, 2024; DST, 2025; Ministry of Finance, 2024). These programs not only provide essential funding and mentorship but also signal a growing recognition of the need for gender-sensitive support structures. However, the majority of these initiatives remain gender-neutral, highlighting the need for more targeted and sustained efforts to close the gender gap in biotechnology entrepreneurship (DBT, 2022; ABLE, 2020). The state-wise distribution of biotech startups, with Maharashtra, Karnataka, and Delhi-NCR leading in numbers, further illustrates the importance of regional ecosystems in fostering innovation (India Bioeconomy Report, 2024). While these hubs provide fertile ground for entrepreneurial activity, this research suggests that equitable participation requires more than just policy incentives—it demands a cultural shift that recognizes and values the unique contributions of women entrepreneurs. Women constitute about 30 per cent of the biotechnology workforce in India, yet their presence in leadership and ownership roles remains disproportionately low (ABLE, 2020; UNESCO Institute for Statistics, 2020). Addressing these disparities is crucial for harnessing the full potential of India's bioeconomy and ensuring that health innovations reach the communities that need them most. This research contributes to the growing discourse on inclusive innovation, gender equity, and entrepreneurial ecosystems in India. It calls for a reimagined approach to biotechnology policy—one that not only provides financial support but also tackles structural and socio-cultural barriers faced by women entrepreneurs. Recognizing and investing in women's leadership is not just an issue of equity it is a strategic imperative for achieving India's health and development goals. Further creating more inclusive and supportive ecosystems, India can unlock the immense potential of women-led biotech enterprises to drive affordable, sustainable health innovations that benefit all.

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RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

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Biotechnology's Role in Socio-Economic Development in Developing Countries: Challenges, Opportunities, and Strategic Approaches

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***Abstract*:** Biotechnology is increasingly critical in addressing the complex socio-economic issues developing countries face, such as food insecurity, public health crises, and environmental degradation. This review explores the potential of biotechnology to drive sustainable development in these regions, focusing on its applications in agriculture, healthcare, and environmental management. By evaluating both the benefits and the challenges, the article provides an overview of the factors affecting the adoption of biotechnological innovations, including regulatory frameworks, technical capacity, infrastructure, and cultural attitudes. The review emphasizes the importance of ethical considerations, international collaboration, and the creation of inclusive policies to ensure that biotechnology contributes equitably to the socio-economic progress of developing countries.

***Keywords*:** Agriculture, Biotechnology, Environmental Sustainability, Healthcare, Innovation,

Introduction

Overview of Biotechnology's Role in Socio-Economic Development

Biotechnology, a field that encompasses the use of biological organisms or systems to develop products and technologies, has emerged as a vital component in addressing the socio-economic challenges developing nations face. As a transformative tool, biotechnology offers the potential to improve critical sectors such as agriculture, healthcare, and environmental management Lokko *et al*., (2018). By harnessing the power of genetic engineering, microbial fermentation, and other biotechnological innovations, developing countries can unlock new solutions to long-standing problems, as noted by Haque *et al*. (2024). Whether it is the development of genetically modified (GM) crops to boost food production or using biotechnology to manufacture life-saving medicines, this field can foster long-term economic growth, alleviate poverty, and enhance the quality of life (Roberts and Naimy, 2023).

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The ability of biotechnology to enable agricultural productivity, combat diseases, and reduce environmental impact is particularly crucial for developing countries, where such challenges often hinder economic advancement and sustainable development. In this context, biotechnology represents a means of overcoming immediate hurdles and an opportunity for these countries to position themselves as leaders in sustainable agriculture, affordable healthcare, and renewable energy, as highlighted by Kumar et al. (2024).

Significance of Biotechnology in Developing Countries

In many parts of the developing world, countries face many issues, such as food insecurity, insufficient healthcare systems, and environmental degradation, which are compounded by poverty, inadequate infrastructure, and limited access to technology, as discussed by Woodhill et al. (2022). Biotechnology offers a promising solution to these challenges, providing tools that can help improve agricultural yields, facilitate affordable healthcare solutions, and enhance environmental sustainability (Gamage et al., 2024).

For example, biotechnology can develop crops resistant to pests, diseases, and extreme weather conditions in agricultural regions prone to droughts or floods (Ngongolo et al., 2024). In healthcare, biotechnological advancements can lead to the creation of affordable diagnostic tools and vaccines and provide new methods for treating diseases that disproportionately affect the global South, such as malaria, HIV/AIDS, and tuberculosis (Behera et al., 2023). Additionally, biotechnology is increasingly important in addressing environmental issues by enabling sustainable practices in waste management, renewable energy production, and climate change mitigation (Nath, 2024).

However, despite its potential, biotechnology's widespread adoption in developing countries is often impeded by a combination of factors. Limited infrastructure, inadequate regulatory frameworks, insufficient funding, and lack of public awareness present significant barriers to the successful integration of biotechnology into national development strategies (Jimenez et al., 2022). Socio-cultural resistance to new technologies, particularly GMOs, further complicates efforts to realize the full benefits of biotechnological advancements.

Objectives and Scope of the Review

This review seeks to provide a comprehensive and in-depth analysis of the role of biotechnology in promoting socio-economic development in developing countries. It will explore how biotechnological innovations address critical challenges in agriculture, healthcare, and environmental sustainability and examine the factors influencing their adoption and success.

The primary objective of the review is to identify and analyze the opportunities biotechnology offers for enhancing food security, improving public health outcomes, and advancing environmental sustainability in the context of developing countries. It will also focus on the barriers that hinder the effective implementation of biotechnological innovations, such as regulatory obstacles, infrastructure deficiencies, limited access to resources, and cultural or societal resistance.

The review will explore strategies for overcoming these barriers and ensuring biotechnology's successful integration into developing nations' development frameworks. These strategies will include recommendations for strengthening policy frameworks, promoting international cooperation, improving public engagement, and enhancing local technical capacity. Finally, the scope of the review will extend to ethical considerations, addressing concerns related to biotechnology's potential risks and challenges and proposing solutions for aligning technological advancements with societal values and sustainable development goals (SDGs).

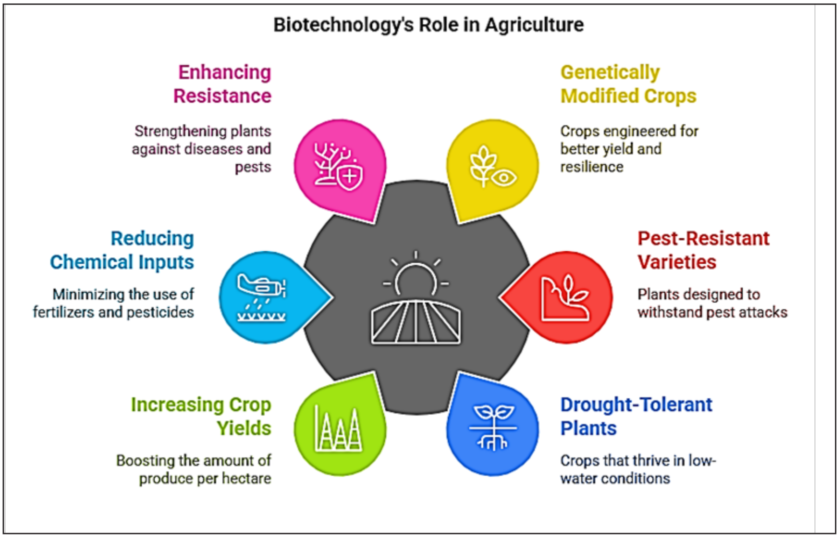
Biotechnology in Agriculture

Importance of Biotechnology in Enhancing Agricultural Productivity

Agriculture is a fundamental pillar of many developing nations, serving as a key driver of economic growth and food security (Akpabio et al., 2025). With the global population steadily rising and climate change intensifying, biotechnology has emerged as a vital tool to address the agricultural sector's challenges (Baraj et al., 2024). Through innovations such as GM crops, pest-resistant varieties, and drought-tolerant plants, biotechnology offers solutions that can significantly boost agricultural productivity, improve food security, and promote sustainable farming practices in regions that are especially vulnerable to environmental stressors like droughts, floods, and soil degradation (Hamdan & Tan., 2024).

Biotechnology's potential to increase crop yields, reduce dependency on chemical inputs, and enhance resistance to pests and diseases holds particular promise for developing countries, where the agricultural sector is often central to livelihoods and national economies (Ndudzo et al., 2024). By enabling the cultivation of more resilient crops adaptable to changing environmental conditions, biotechnology can help farmers in these regions increase their productivity while reducing losses due to factors beyond their control.

Figure 1: The Role of Biotechnologies in Enhancing Agricultural Productivity and Sustainability



Sources: Authors compilation.

Key Applications: GM Crops, Pest Resistance, and Drought Tolerance

One of the most well-known and widely used biotechnology applications in agriculture is developing GM crops. These crops must possess specific traits that improve yield, pest resistance, and tolerance to environmental stresses (Fig. 1). For instance, GM cotton, such as Bt cotton, has been developed to resist pests like the cotton bollworm, significantly reducing the need for chemical pesticide applications minimizes the environmental impact associated with pesticide use (Hamdan & Tan., 2024).

In addition to pest resistance, biotechnology has made crops more resilient to drought, a particularly pressing issue in regions that suffer from water scarcity. Drought-tolerant crops maintain higher yields under limited water availability, allowing farmers in arid and semi-arid areas to grow food despite unpredictable rainfall patterns (Tarolli et al., 2024). These drought-resistant crops can help stabilize food production in regions facing water shortages, ultimately improving food security and reducing the vulnerability of local populations to hunger and malnutrition.

Case Studies: Success Stories from India, China, and Africa

The adoption of biotechnology in agriculture has already led to notable success stories in several developing countries. For example, the introduction of Bt cotton has had a transformative impact on cotton farmers in India. By reducing the need for chemical pesticides and improving yield consistency, Bt cotton has boosted the income of millions of smallholder farmers. The reduction in pesticide use has also contributed to a safer environment for farmers and their communities while increasing cotton production to meet the demands of both domestic and international markets, as noted by Nagaraj et al. (2024). China has also seen substantial gains from using GM crops, particularly in the form of pest-resistant varieties of rice and cotton. These crops have allowed Chinese farmers to reduce pesticide use, lower production costs, and increase yields (Zhang & Dong., 2024). In some parts of Africa, biotechnology has been instrumental in developing drought-tolerant maize varieties, helping to secure food supplies in countries such as Kenya and South Africa. In these areas, genetically engineered maize has alleviated the food insecurity caused by unpredictable rainfall and prolonged dry spells (Adegbaju et al., 2024).

Despite the proven benefits, the adoption of biotechnology in agriculture has been uneven across developing countries. While these successes demonstrate the potential to transform agriculture, many nations face significant challenges in overcoming skepticism surrounding GM crops and the logistical and regulatory barriers that hinder the widespread adoption of these technologies.

Biotechnology in Healthcare

Biotechnology's Contribution to Public Health: Vaccines, Diagnostics, and Treatments

Biotechnology has emerged as a transformative tool in healthcare, offering the potential to provide more affordable, accessible, and effective solutions for disease prevention, diagnosis, and treatment (Alowais et al., 2023). One of the most significant contributions of biotechnology has been the development of vaccines, which have been instrumental in reducing the prevalence and mortality rates of several infectious diseases. Vaccines for diseases like hepatitis B, tuberculosis, and polio, developed using biotechnological techniques, have proven successful in many low-income regions, significantly improving public health outcomes.

Biotechnology also plays a crucial role in developing diagnostic tools that enable timely detection and monitoring of diseases. For example, rapid diagnostic tests (RDTs) for diseases like malaria, HIV, and other infectious conditions are helping healthcare providers deliver quicker and more accurate diagnoses, improving patient outcomes and reducing the burden on overstretched healthcare systems in developing countries (Moore et al., 2023). These innovations not only make healthcare more accessible but also provide the means to track and respond to disease outbreaks efficiently.

Advances in Biotechnology for Infectious Disease Control

Infectious diseases continue to pose major public health challenges in developing countries, where limited resources and healthcare infrastructure exacerbate the impact of diseases like malaria, HIV/AIDS, and tuberculosis. Biotechnology has provided new, more effective treatments for these diseases. For instance, the development of antiretroviral (ARV) drugs for HIV has transformed the management of the disease, allowing millions of individuals to live longer, healthier lives (Nayan et al., 2023). These treatments, which include a combination of drugs to suppress the virus and prevent transmission, have been made more accessible through biotechnology, helping to curb the global HIV/AIDS epidemic, particularly in sub-Saharan Africa.

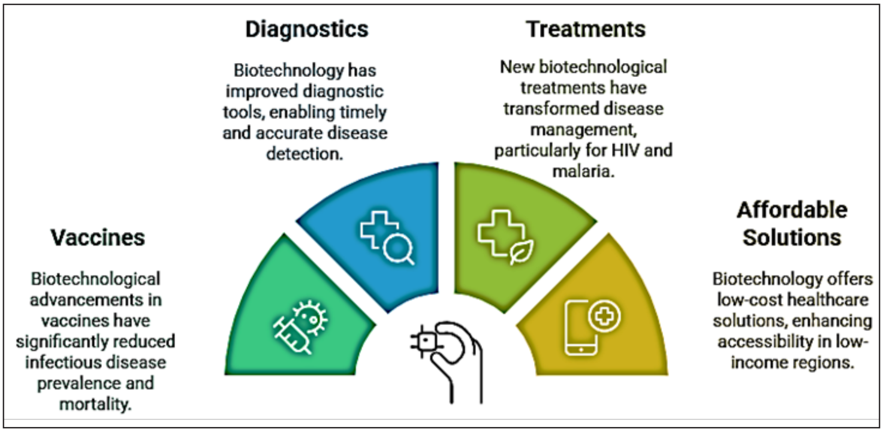
Similarly, biotechnology has enabled the development of artemisinin-based combination therapies (ACTs) for malaria, a disease that remains a leading cause of morbidity and mortality in many tropical regions, as noted by Nguyen et al. (2023). ACTs have become the standard treatment for malaria, significantly improving recovery rates and reducing mortality. Biotechnology-based vaccines, such as the rotavirus vaccine, are also making strides in preventing diseases that disproportionately affect children in low-income regions. These vaccines help reduce the incidence of life-threatening diseases like diarrheal diseases, major contributors to child mortality (Fig. 2).

Affordable Healthcare Solutions: Biotechnology for Low-Income Populations

One of the most promising aspects of biotechnology is its ability to make healthcare more affordable and accessible to low-income populations. The development of low-cost biosensors and diagnostic devices has revolutionized healthcare delivery in resource-poor settings, providing the means to monitor diseases and track health metrics without requiring expensive, centralized laboratory facilities (Fig 2). These innovations are particularly crucial in rural and remote areas, where healthcare access is often limited.

Mobile health (mHealth) technologies, powered by biotechnology, are another avenue for improving healthcare accessibility. By leveraging mobile phones and other digital technologies, healthcare providers can offer remote consultations, diagnostic services, and health monitoring, overcoming geographical distance barriers and healthcare infrastructure barriers (Sharma et al., 2022). These technologies are helping to bridge the healthcare gap in underserved populations, ensuring that individuals in rural and isolated areas can receive timely and effective care.

Figure 2: Transformative Impact of Biotechnology on Global Healthcare Access



Sources: Authors compilation.

Case Studies: Role of Biotechnology in Combating HIV/AIDS, Malaria, and Tuberculosis

Biotechnology has made significant strides in combating some of the most pressing infectious diseases in developing countries. In sub-Saharan Africa, where HIV/AIDS has devastated communities for decades, the availability of affordable antiretroviral drugs (ARVs) has been a game-changer. These drugs, which use biotechnological processes, have made treatment more accessible, providing hope and improving the quality of life for millions of people living with HIV/AIDS.

In regions heavily affected by malaria, particularly in Asia and Africa, biotechnology has improved diagnostic capabilities and facilitated the development of effective treatments. Rapid diagnostic tests (RDTs) have become a crucial tool for diagnosing malaria at the point of care, enabling healthcare providers to administer treatment quickly and reduce the spread of the disease (Abdul-Rahman et al., 2025). Moreover, the use of biotechnology in developing artemisinin-based combination therapies has significantly improved malaria treatment outcomes, contributing to a decline in malaria-related deaths.

Similarly, biotechnology-based diagnostics for tuberculosis (TB) have allowed for earlier disease detection, ensuring timely and effective treatment. Early diagnosis and treatment of TB are essential in preventing the spread of the disease and reducing mortality rates, particularly in developing countries where TB remains a major public health threat (Bartolomeu-Gonçalves et al., 2024).

Biotechnology for Environmental Management and Sustainability

Biotechnology in Waste Management: Bioremediation and Biodegradation

Environmental sustainability is a growing concern for many developing countries, where industrialization, urbanization, and population growth have led to rising levels of pollution and waste. Traditional waste management methods, such as landfilling and incineration, are often costly, inefficient, and environmentally harmful. Biotechnology, however, offers sustainable and cost-effective alternatives, particularly through processes like bioremediation and biodegradation.

Bioremediation involves using microorganisms, fungi, or plants to break down or neutralize soil, water, and air pollutants. This biotechnological process can address various environmental pollutants, including heavy metals, petroleum products, and agricultural chemicals (Dinakarkumar et al., 2024). By utilizing the natural capabilities of microorganisms to digest contaminants, bioremediation offers an environmentally friendly solution to pollution control. Bioremediation is often less expensive than conventional remediation methods, making it especially attractive for low-resource settings.

Similarly, biodegradation leverages microorganisms' natural breakdown of organic waste, converting harmful waste into harmless by-products like carbon dioxide, water, and biomass. This process is commonly used to treat organic waste in landfills, composting facilities, and wastewater treatment plants, helping reduce the environmental impact of waste disposal in developing countries (Kuppan et al., 2024).

Use of Biotechnology in Renewable Energy: Biofuels and Bioenergy

As the demand for renewable energy sources rises globally, biotechnology has an important role in developing biofuels and bioenergy. Biofuels, such as ethanol and biodiesel, are produced from biomass—organic materials like crops, algae, and agricultural waste. In developing countries, where access to conventional fossil fuels may be limited or costly, biofuels offer a viable alternative to reduce dependence on imported energy sources.

Biotechnology improves the efficiency of biofuel production by developing genetically engineered organisms that can break down biomass more effectively or produce higher yields of biofuel. For example, algae-based biofuels have gained attention as a promising alternative, as algae can produce oil that can turn into biodiesel. Biotechnology has also facilitated the production of second-generation biofuels from non-food crops and agricultural waste, addressing concerns over food security and land use associated with traditional biofuel production (Singh et al., 2022).

Biotechnology in bioenergy production extends beyond biofuels to include biogas through the anaerobic digestion of organic materials. Biogas can be used for electricity generation, heating, and cooking, providing an affordable and renewable energy source for rural and off-grid communities. By improving the efficiency and scalability of bioenergy technologies, biotechnology is helping developing countries tap into sustainable energy sources that contribute to both environmental sustainability and economic development (Ngabala & Kamuhabwa, 2024).

Biotechnology's Role in Climate Change Mitigation and Adaptation

As the impacts of climate change become increasingly evident, biotechnology offers solutions to mitigate greenhouse gas emissions and help communities adapt to changing environmental conditions. One of the most promising areas of biotechnological innovation in mitigation is carbon capture and storage (CCS). Biotechnology-based approaches for capturing and storing carbon dioxide are potential solutions to help lower atmospheric CO2 concentrations. These technologies hold the potential to play a critical role in addressing climate change by reducing the carbon footprint of industries and power generation (Schweitzer et al., 2021).

Biotechnology can also contribute to climate change adaptation by developing crops resilient to extreme weather events such as droughts, floods, and heat waves. GM crops designed to withstand these conditions can help farmers maintain productivity in regions where climate variability is becoming more severe. For example, drought-resistant crops, such as drought-tolerant maize, can help farmers cope with water scarcity, and flood-resistant rice varieties can support agricultural production in areas prone to flooding (Benitez-Alfonso et al., 2023).

Beyond agriculture, biotechnology also has the potential to enhance ecosystems' resilience to climate change. Using biotechnological approaches to restore degraded soils, improve water management, and promote biodiversity conservation can help ecosystems recover from the impacts of climate change and provide vital ecosystem services to local communities.

Policy and Regulatory Frameworks

Role of Government Policy in Facilitating or Hindering Biotechnology Adoption

Government policy plays a crucial role in fostering biotechnology adoption in developing countries. Supportive policies promoting innovation, research, and integrating biotechnological solutions are key to addressing challenges like food security, healthcare, and environmental sustainability. For instance, policies incentivizing biotechnology R&D can attract local and international investment. Clear and efficient regulatory frameworks are also essential to expedite the approval process for new biotechnological products, ensuring timely access to beneficial technologies.

However, many developing countries face weak or inconsistent regulatory frameworks, which can hinder biotechnology adoption. Bureaucratic delays, unclear legislation, and slow approval processes often stall the introduction of vital innovations. A lack of government support or vision can create uncertainty, deterring investment. To foster biotechnology growth, governments must prioritize creating a balanced policy environment that encourages innovation while ensuring safety and sustainability.

Regulatory Standards for Biotechnology: A Global Perspective

Biotechnology regulations vary significantly across countries. High-income nations like the United States, European Union countries, and Japan have robust regulatory frameworks that ensure biotechnology's safety, efficacy, and ethical standards. These regulations involve stringent testing and approval processes for GMOs, pharmaceuticals, medical devices, environmental biotechnology products, and continuous post-market monitoring.

In contrast, many developing countries lack comprehensive regulatory standards for biotechnology, creating uncertainty for businesses, researchers, and policymakers. The absence of clear, science-based regulations leads to slow, opaque approval processes, delaying the implementation of biotechnological innovations in agriculture, healthcare, and environmental management. Developing countries must create adaptable, science-driven regulatory frameworks prioritizing safety, efficacy, and sustainability while responsive to emerging biotechnological advances.

Developing Countries' Approaches to Biotechnology Regulation

In many developing countries, the regulatory landscape for biotechnology is still in its infancy or evolving as governments work to balance innovation with safety, ethics, and public perception concerns. Some countries, like

Brazil and India, have progressively established regulations for developing, approving, and commercializing GMOs (Jones et al., 2022). For instance, Brazil has created a regulatory body, the National Technical Commission on Biosafety (CTNBio), to oversee GMO safety, and India has implemented policies such as the Biotechnology Regulatory Authority of India (BRAI) to ensure that GMOs are subject to rigorous scrutiny before release.

Despite these advances, many developing nations remain cautious or resist adopting certain biotechnological products, particularly GMOs. Regulatory policies in these countries may reflect a broader apprehension about biotechnology's long-term ecological, health, and socio-economic effects. Furthermore, political considerations, lack of technical expertise, and limited public awareness about biotechnology can contribute to resistance, delaying or hindering the development of an enabling regulatory environment.

Importance of Science-based Decision-Making and Public Engagement

Science-based decision-making is crucial for effective biotechnology regulation. Clear, evidence-driven frameworks allow regulators to assess biotechnological innovations' safety, effectiveness, and risks. Governments should prioritize transparency, making scientific data and findings available to the public and stakeholders, which helps build trust with researchers, industry professionals, and the broader community.

Public engagement is also key. Misconceptions and fears about biotechnology can lead to resistance. Governments must invest in educational initiatives to help the public understand biotechnology's benefits and safety measures. Public consultations and open dialogues with stakeholders like farmers, consumers, and environmental groups can help create inclusive policies. Engaging the public ensures concerns and informed decision-making that benefits everyone.

Balancing Innovation with Safety: The Case of GMOs

GMOs are a contentious issue in biotechnology regulation, particularly in developing countries. While GMOs can address agricultural challenges like pest resistance, drought tolerance, and disease resistance, concerns about their safety, environmental impact, and ethical implications persist.

In developing countries, GMOs offer the potential to tackle food insecurity in regions struggling with pests, droughts, or diseases. However, there are concerns about unintended environmental consequences, such as gene flow to wild crops, biodiversity risks, and long-term health impacts on humans and animals.

Regulators must balance these potential benefits with safety and sustainability. Science-based risk assessments, clear guidelines for testing and monitoring GMOs, and consideration of local agricultural practices and needs are essential. Sometimes, a precautionary approach, like temporary bans or moratoriums, may help mitigate uncertainty and allow for further scientific evaluation.

Ethical and Cultural Considerations in Biotechnology

Ethical Issues: Genetic Engineering, Biopiracy, and Access to Genetic Resources

Biotechnology offers immense promise for addressing global challenges but raises ethical concerns, especially in developing countries. Genetic engineering can help solve issues like hunger and disease but also carries risks, including potential harm to biodiversity, human health, and ecosystems.

Another ethical challenge is biopiracy, where companies from wealthier nations exploit the genetic resources of developing countries without providing fair compensation. These countries often hold valuable biodiversity and indigenous knowledge yet receive little recognition or financial benefit. This undermines the principle of fair benefit-sharing, which is vital for ethical biotechnology development.

Access to genetic resources also remains a contentious issue. As biotechnology advances, these resources become increasingly valuable. For developing countries, securing control over their genetic assets is essential to ensure that local communities benefit. The ongoing debate over whether genetic materials should be treated as intellectual property or remain in the public domain further complicates the matter.

Cultural Acceptance of Biotechnology: Regional Perspectives and Public Opinion

Cultural acceptance plays a key role in the success and integration of biotechnology, especially in developing countries. While some regions may embrace biotechnology in agriculture, healthcare, and environmental practices, others may resist it due to concerns about genetic modification, cloning, or biotech in food production. Religious beliefs, traditional practices, and social values shape public opinion on biotechnology. In certain cultures, altering the genetic makeup of plants or animals may conflict with spiritual or ethical beliefs, while mistrust of foreign biotech companies may stem from historical exploitation. Thus, biotechnology's success in developing countries depends on its cultural compatibility, making it essential to consider local values and perspectives.

Role of Education and Community Engagement in Shaping Biotechnology Perceptions

Education and community engagement are vital in shaping public perception of biotechnology, especially in overcoming misinformation and fear. Governments, organizations, and local communities should collaborate to create educational programs that explain biotechnology's benefits and risks. Public discussions and awareness campaigns can simplify complex biotech concepts, such as the advantages of GM crops—like higher yields, pest resistance, and improved nutrition—while addressing safety concerns. Involving local communities in decision-making helps build trust, as stakeholders can voice their concerns and feel more confident about the technology. Educators, community leaders, and local media play crucial roles in promoting balanced and informed views of biotechnology.

Ethical Frameworks for Biotechnology: Aligning Innovation with Societal Values

For biotechnology to succeed and gain acceptance, it must be developed within an ethical framework that aligns with societal values, prioritizing the well-being of individuals, communities, and the environment. This framework should respect cultural and ethical boundaries, avoiding technologies that conflict with deeply held beliefs.

Such a framework requires input from diverse stakeholders, including scientists, policymakers, ethicists, local communities, and civil society organizations. A participatory approach helps identify shared values and ethical principles that guide biotechnology in ways that uphold human rights, environmental sustainability, and social justice.

The framework must be flexible to account for the unique contexts of developing countries. While fairness, transparency, and cultural respect are universal, their application should be to local needs, such as considering the impact on smallholder farmers and traditional practices.

Ultimately, an ethical biotechnology framework should ensure that advancements are scientifically sound, socially responsible, culturally sensitive, and aligned with sustainable development goals. This framework should help mitigate risks and maximize biotechnology's potential in addressing critical challenges.

International Collaboration and Funding

Role of International Organizations and Partnerships in Advancing Biotechnology

International collaboration is crucial for advancing biotechnology in developing countries, as it combines diverse expertise, resources, and technological innovations. Global organizations like the World Health Organization (WHO), the World Bank, and the United Nations play key roles in supporting biotechnological development by shaping policies, providing technical assistance, and fostering international cooperation. These organizations help coordinate research, set regulatory standards, and fund initiatives, ensuring that biotechnology reaches.

In addition to intergovernmental bodies, partnerships between governments, universities, private companies, and non-governmental organizations (NGOs) are also essential. These collaborations pool resources and expertise, driving innovation while addressing local challenges. They also facilitate technology transfer, providing access to advanced biotechnological solutions that countries may be unable to develop independently.

Joint initiatives highlight the power of international collaboration in biotechnology, particularly in areas like sustainable agriculture, public health, and climate change. By working together, countries can combine their strengths, avoid redundant efforts, and tackle global issues that impact multiple regions.

Collaborative Research: Public-Private Partnerships in Biotechnology Innovation

Public-private partnerships (PPPs) are a powerful way to drive biotechnology innovation in developing countries with limited resources. These collaborations combine financial support, technical expertise, and infrastructure to speed up the development of biotech solutions. Public research institutions contribute scientific knowledge, while private companies provide technological capabilities and commercialization expertise.

In agriculture, PPPs have helped create GM crops to boost food security, and in healthcare, they have accelerated the development of vaccines and treatments for diseases like malaria, HIV, and tuberculosis. By involving international organizations, private companies, and local governments, PPPs ensure biotech innovations meet the specific needs of the regions they serve.

A notable example is the partnership between the International Food Policy Research Institute (IFPRI) and the Bill and Melinda Gates

Foundation, which developed drought-resistant crops for sub-Saharan Africa. This collaboration shows how combining strengths from different sectors can bring vital biotechnological solutions to market, benefiting communities in need.

Funding Mechanisms for Biotechnology in Developing Countries

Access to sustainable funding is one of the biggest challenges developing countries face in adopting biotechnology. Many lack the financial resources to build infrastructure, invest in research, or scale up biotechnological solutions. To address this, effective funding mechanisms are crucial for ensuring biotechnology's success in these regions.

Collaboration between governments, international organizations, and private investors is essential to create funding solutions supporting basic and applied biotechnology research. These could include grants, loans, equity investments, and public funding for R&D. Global programs like those from the United Nations Development Programme (UNDP), the World Bank, and the Global Fund, which are vital in providing financial backing for health, food security, and sustainability initiatives.

Additionally, exploring innovative funding options such as crowdfunding, venture capital, and impact investing can help mobilize the resources needed for biotech development. By diversifying funding sources, developing countries can overcome financial barriers and improve their chances of success in biotechnology ventures.

Role of Development Aid and Foreign Investment in Biotechnology Adoption

Development aid and foreign investment are key drivers in enabling biotechnology adoption in developing countries. Financial support from international development agencies, bilateral aid organizations, and foreign investors helps build the infrastructure needed for biotechnology, such as research labs, agricultural production facilities, and healthcare centers. It also enhances the technical and human capacity to operate and maintain biotechnology systems.

Additionally, development aid can fund training programs for local scientists, researchers, and healthcare professionals, ensuring they have the skills to manage and implement biotechnological innovations. Beyond funding, R&D, aid, and investment can assist in commercializing biotechnology products, making them more accessible to low-income populations otherwise excluded from these advancements.

However, the influx of foreign investment and development aid must align with the long-term goals of the recipient countries. Biotechnology initiatives should prioritize local needs and goals, not just the interests of external stakeholders. Developing countries must also ensure that their regulatory frameworks and governance structures are strong enough to manage foreign investment responsibly, promoting sustainability, equity, and fairness.

Case Study: Successful International Collaborations in Agricultural Biotechnology

A successful example of international collaboration in agricultural biotechnology is the partnership between the International Food Policy Research Institute (IFPRI) and the Bill and Melinda Gates Foundation. This collaboration has made significant strides in developing drought-resistant crops, like drought-tolerant maize, which can improve food security in sub-Saharan Africa.

The IFPRI-Gates Foundation partnership focuses on biotechnology development and ensures these innovations are accessible to smallholder farmers, which is vital to the region's food production. This collaboration has helped create a sustainable agricultural model that improves food security, strengthens local economies, and reduces vulnerability to climate change.

This case study underscores the power of international cooperation in advancing biotechnology. It shows how combining resources, expertise, and technology can lead to meaningful changes that positively affect millions of lives. It models future global partnerships to tackle hunger, poverty, and environmental degradation.

Challenges to Biotechnology Integration in Developing Countries

Infrastructure and Technological Gaps: Bridging the Divide

A major challenge to biotechnology integration in developing countries is the lack of adequate infrastructure. Many regions lack access to modern research labs, biotech hubs, and advanced equipment necessary for high-quality research and development. Without these resources, progressing in biotechnology becomes difficult.

Significant infrastructure investments are needed to overcome this. Governments, international organizations, and the private sector should collaborate to build and upgrade research facilities, universities, and biotech labs. Additionally, establishing reliable communication networks, electricity, and water systems is crucial for supporting biotech work. Modernizing technology and equipment will also drive innovation and improve the efficiency of biotechnology research in these regions.

Technical Expertise: Building Local Capacity in Biotechnology

A key challenge in biotechnology adoption is the shortage of specialized technical expertise. Biotechnology requires skilled professionals in genetics, molecular biology, and bioinformatics, and many developing countries lack such trained experts.

Local capacity should be built through education and training programs to address this. Governments and institutions should invest in biotechnology programs at universities and technical institutes, offering undergraduate and postgraduate degrees and hands-on training. Promoting knowledge transfer from developed countries through exchange programs and collaborations will also help. This approach workforce is capable of driving innovation and solving local challenges.

Access to Resources: Intellectual Property, Equipment, and Funding

Access to essential resources, such as intellectual property (IP) rights, research equipment, and funding, is a major barrier to biotechnology adoption in developing countries. Restrictive IP laws and limited financial resources make it difficult for local researchers and institutions to access key technologies and equipment.

A multifaceted approach is needed to overcome these challenges. Governments, international organizations, and the private sector should collaborate to create funding mechanisms for research institutions and startups, such as grants and affordable loans. IP frameworks should promote knowledge sharing and technology transfer, allowing local innovators to access the necessary tools. Lastly, developing countries should prioritize investments in high-quality research equipment, possibly through partnerships with international organizations for funding and expertise.

Socio-Economic Constraints: Poverty, Education, and Inequality

Poverty, limited education, and inequality are major barriers to biotechnology integration in developing countries, limiting access to its benefits, especially in healthcare, agriculture, and environmental sustainability. For instance, impoverished individuals may struggle to afford GM crops or biotechnology-based healthcare treatments, and poor infrastructure can hinder access to these innovations. Addressing these issues requires a holistic approach focused on reducing poverty, promoting equity, and improving education.

Governments should prioritize social programs to tackle inequality and increase access to essential services. Ensuring biotechnology benefits marginalized communities will require targeted initiatives promoting social inclusion and addressing income disparities in underserved areas.

Addressing Public Resistance: Overcoming Misinformation and Cultural Barriers

Public resistance to biotechnology in developing countries often stems from skepticism, misinformation, and cultural or religious beliefs. A strategic communication approach is needed to overcome this, including public education campaigns that address safety, risks, and benefits. These campaigns should be culturally sensitive and tailored to local communities. Engaging the public through discussions, town hall meetings, and participatory policy development helps build trust. Collaboration among scientists, policymakers, NGOs, and local communities is crucial to dispel myths and promote informed decision-making, facilitating wider adoption of biotechnology.

Strategies for Effective Biotechnology Integration

Tailoring Biotechnology Solutions to Local Needs and Conditions

The success of biotechnology in developing countries depends on how well it addresses local needs and challenges. Innovations must fit each region's specific agricultural practices, healthcare systems, environmental conditions, and cultural contexts. This ensures that solutions are feasible, socially accepted, and effective.

For instance, drought-resistant crops are crucial in areas with water scarcity, while healthcare solutions should focus on prevalent diseases and local medical infrastructure. By focusing on context-specific solutions, biotechnology can have a lasting, positive impact, improving the lives of communities in developing countries.

Fostering National and Regional Biotech Clusters

Biotechnology clusters combine companies, research institutions, and universities in one area and are crucial for driving innovation, knowledge sharing, and collaboration. These clusters promote partnerships between the public and private sectors and local and international entities, creating a thriving R&D ecosystem.

Governments can foster biotech clusters by offering funding, tax incentives, and infrastructure support. Public-private partnerships

(PPPs) help companies have the resources to innovate and bring biotechnological products to market. Additionally, regional collaborations between neighboring countries with shared challenges can strengthen the biotechnology sector and boost collective innovation.

Strengthening Research and Development Capacity

Investing in R&D is essential for the long-term success of biotechnology in developing countries. A strong R&D foundation enables countries to drive innovations and reduce reliance on foreign technologies. Governments, universities, and private companies must collaborate to boost local research capabilities, fund scientific studies, and promote a culture of innovation.

An effective strategy is establishing dedicated biotech research institutions focusing on basic and applied research. These centers should be equipped with advanced labs and staffed by skilled researchers. R&D should be targeted at addressing local issues, such as disease prevention, crop improvement, and environmental sustainability, ensuring biotechnology is relevant and impactful for the local population.

Developing Inclusive Policies for Technology Transfer and Knowledge Sharing

Inclusive policies, technology transfer, and knowledge sharing between developed and developing countries. Technology transfer allows recipient countries to benefit from advancements without duplicating research efforts, which is especially important in biotechnology, where many developing countries lack the infrastructure to conduct cutting-edge research independently.

Governments should create policies encouraging collaboration with international research institutions, universities, and biotech companies. These policies can support technology sharing, joint development of new technologies, and adaptation of innovations to local contexts. Knowledge-sharing platforms, conferences, and workshops can also help bridge the gap between global scientific communities. We can build a more inclusive biotechnology landscape that benefits developed and developing nations.

Addressing Equity Issues: Ensuring Access to Biotechnological Benefits for Marginalized Populations

One of the biggest challenges in adopting biotechnology is ensuring that its benefits reach marginalized and underserved populations. In many developing countries, rural and low-income communities face barriers to healthcare, education, and access to new technologies. Creating policies that ensure equitable access to biotechnology is essential for making these innovations accessible to those who need them the most.

Government and institutional policies should focus on developing affordable biotechnology solutions for disadvantaged groups. For instance, biotechnology-based healthcare treatments should be available to low-income populations, and agricultural biotechnologies should assist smallholder farmers who may not have access to costly inputs or advanced technologies. Public awareness campaigns and community engagement efforts can help these groups understand and embrace biotechnology.

Targeted initiatives, such as subsidies, microloans, or affordable biotechnological products, can improve equity in biotechnology access. Ongoing consultation with local groups, stakeholders, and advocacy organizations is essential to address their concerns and ensure inclusivity.

Conclusion

Summary of Key Findings: Opportunities, Challenges, and Solutions

Biotechnology holds great potential for socio-economic development in developing countries, offering solutions to pressing issues like food insecurity, poor healthcare, and environmental degradation. Agriculture, healthcare, and environmental management applications have already shown positive outcomes, improving productivity, disease control, and sustainability. However, challenges like inadequate infrastructure, limited technical expertise, regulatory hurdles, and varying public perceptions must be met for biotechnology to enter these regions. Overcoming these obstacles requires targeted investments in education, infrastructure, policy reforms, and public engagement to ensure biotechnology can fully realize its potential.

Future of Biotechnology in Developing Countries

The future of biotechnology in developing countries looks promising, especially with the right policies. International partnerships will facilitate knowledge transfer, resource sharing, and collaborative research. Ongoing investments in education, infrastructure, and local R&D will empower these countries to tap into biotechnology's potential fully. With a global focus on sustainable development, biotechnology can be vital in tackling urgent challenges—especially if its benefits are accessible to everyone.

Recommendations for Policymakers, Researchers, and Industry Stakeholders

Policymakers should create clear, flexible regulations that promote innovation while ensuring safety. Strengthening regulatory bodies through training, harmonizing standards with international bodies, and engaging stakeholders can help. Supporting pilot programs, facilitating technology transfer, and fostering public-private partnerships will also be crucial. Raising public awareness and addressing misinformation will help build trust and acceptance of biotechnology.

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Perspective

Advancing Affordable Access to Biosimilars in India: Need for a Science & Evidence Based Regulatory Framework in the New Indian Draft Guidelines

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Introduction

Bio-therapeutics (biologics) represent a significant leap forward in medical treatment, offering therapies for a number of disease segments. Unlike small molecules which offer a one size fit all approach, biologics are derived from living cells and many biologics offer a very targeted approach by interacting with specific biological pathways. These transformative therapies have altered the treatment landscape for multiple diseases including cancer. Monoclonal antibodies have become a cornerstone of cancer therapy, offering precise, targeted treatment that significantly improves outcome for patients battling various forms of the disease. With traditional antibodies now a passe, next-generation antibodies such a bispecific-monoclonal antibodies, antibody fragments, radio-immunotherapies, and antibody-drug conjugates have now taken the centre stage. Apart from the tremendous impact biologics have demonstrated in the field of oncology, they have also penetrated innumerable diseases offering hopes to patients where previously, treatment options were unsatisfactory. These include drugs for the treatment of Crohn's disease, ulcerative colitis, rheumatoid arthritis, and other autoimmune diseases. In addition to these, biologics have also touched the lives of numerous patients suffering from untreatable genetic disorders including many rare diseases for which no treatment was available.

Biologics continue to register tremendous growth in the market segment. The global biologics market size is valued at USD 511.04 billion in 2024 and is projected to reach USD 1,374.51 billion by 2033, growing at a CAGR of 10.4 per cent during the forecast period 2024 to 2033 (Nova 2025). In 2024, eight of the top ten selling drugs were biologics (Manalac,

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T. 2025). Increasing burden of cancer, genetic diseases and autoimmune diseases and the approval of novel biologic drugs such as gene therapy, and antibody-drug conjugates have fuelled the biologics market. In addition to the already marketed biologics and gene therapies that are already present in the market, a strong pipeline of new biologic drugs is expected to fuel the market. Despite the extensive benefits biologics offer both for health care providers and patients, exorbitant cost continue to plague the biological landscape, thus making these innovative therapies out of reach of many patients especially those living in developing countries.

As patents on biologics expire, it provides opportunities for generic version of biologics known as "biosimilars" or "similar biologic product" to be launched in the market. Unlike generics which are chemically synthesized and hence are exact copies of the originator, biologics are produced in living organisms and hence are not exact copies but similar to the innovator product (known as reference product). The availability of biosimilars in the market have ensured lower healthcare costs and increased accessibility for patients. However in comparison to generics which are available at almost 90 per cent lower costs as compared to innovator molecules, upon patent expiration, biosimilars do not exhibit a similar price erosion. There are several reasons for the underperformance of biosimilars in comparison to their generic counterparts.

High costs of biosimilars stems from lack of competition in the biosimilar market largely driven by questionable and predatory patent practices and stringent regulatory barriers. Because of the lucrative revenues offered by these drugs they are fiercely protected by multiple patents many of which are secondary in nature. Unlike small molecules where a single composition of matter (covering the active ingredient) can often secure a strong and comprehensive patent protection, biologics usually require a portfolio of patents (patent thickets) to comprehensively safeguard the product. Additionally, stringent regulatory requirement for biosimilars as compared to small molecules further inflates the development costs. The development of biosimilars is expensive and a typical biosimilar can cost as much as US $100 to $300 million and may take up to 9 years from analytical characterization to approval (Makurvet, F. D. 2021). The main factors for high development cost includes establishing manufacturing facilities, conducting animal studies and extensive clinical trials which includes significant expenses associated with sourcing the reference product and a large patient sample size to prove clinical equivalence. It is estimated that clinical efficacy trials constitute more than 50 per cent of the cost of developing biosimilars (McKinsey & Company. 2022). These high development costs are often passed on to patients or healthcare systems, making these therapies less accessible, particularly in developing countries.

These high development cost deter biosimilar and act as a formidable barrier to manufacturers especially from developing countries and also constraints the ability of the current manufacturers from producing low cost biosimilars. Driven by the growing imperatives to increase affordable biosimilars and reinforced by significant scientific advancement – the global landscape of regulatory approval pathways has undergone notable evolutions. This paper aims to examine the changes introduced in the recently released draft guidelines by India's Regulatory body – the Central Drugs Standard Control Organisation (CDSCO), and highlight the existing ambiguities with these current draft guidelines. It further contends that an urgent revision of these guidelines, grounded in rigorous scientific evidence, is essential to enhance access to this critically important class of drugs.

Regulatory Challenges Associated With Biosimilar Development

India has been a pioneer in biosimilar development and was the first country to formulate the biosimilar regulatory guidelines. In India the first biosimilar - epoetin alpha was launched in 2001, making India one of the first countries to launch a biosimilar, much ahead any developed country In EU the first biosimilar, Omnitrope was launched in 2006, while the US approved the first biosimilar filgrastim in 2015 - almost a decade after EU.

The regulatory guidelines for biosimilars were drafted when the technology for production was in the nascent stage and there were many uncertainties. There were challenges in characterizing the products and it was thought that even minor variations in manufacturing processes could result in differences in product quality. The initial guidelines from both EU and US regulatory bodies were conservative in nature and were based on a stepwise approach. Since then, the developmental framework for biosimilars has been firmly established and validated for almost over two decades now.

In light of the significant technological and scientific advancements, regulatory pathways globally have undergone a paradigm shift. The WHO first issued its guidelines on Similar Biologic Products in 2009, and subsequently revised it in 2022 to reflect the advancements in scientific understanding and regulatory practices. Many leading jurisdictions such as European Medicine Agency (EMA), United States Food and Drug Administration (US FDA), United Kingdom Medicines and Healthcare Products Regulatory Agency (UK MHRA) and Health Canada have either revised their guidelines or are actively engaged in the process of updating them to reflect recent scientific advancements. Aligning itself with the growing demands from the scientific community and following the shifts globally, CDSCO also recently released a draft biosimilar guidelines (CDSCO & DGHS, MoH&FW 2025). These changes embody a science-driven regulatory approach, that not only fosters innovation but also aligns with international movements towards increased focus on data and advanced analytical techniques in biosimilar development. Notable regulatory improvements include increased focus on analytical and structural characterization, streamlining the approval process, in-vitro comparability, following the 3R principle (Replace, Reduce, and Refine) for animal studies, and allowing conditional waivers for clinical efficacy trials. These guidelines are poised to reduce the development burden for biosimilar manufacturers. Nonetheless, certain ambiguities in the language related to animal studies and clinical efficacy studies waivers persist.

Redundancy Of Animal Testing

The push for removing animal studies for biosimilars approval stems from the mounting scientific evidence questioning the reliability of the animal models to predict biosimilarity. One of the most important issues regarding animal testing for biosimilars is that many animal studies use species lacking critical drug binding receptors present in humans. In the absence of clear guidelines based on scientific evidence, biosimilar manufacturers conduct redundant toxicology studies in non-responsive species. These tests yield minimally relevant results into human safety, creating unnecessary costs and delays (Niazi, S. K. 2021). Most of the advanced regulatory bodies like the US FDA, UK MHRA, Health Canada and the EMA have moved away from animal studies as part of biosimilar approval process. The UK MHRA shifted its regulatory perspective and came out with clear recommendations on removing the need for animal studies for biosimilar approval. According to the MHRA Guidelines, "No in vivo studies from animals are requested as these are not relevant for showing comparability between a biosimilar candidate and its RP: this includes pharmacodynamic studies, kinetic studies and toxicity studies" (UK MHRA 2021). Similarly, Health Canada states that in vivo toxicology studies (animal studies) are generally not needed (Health Canada 2010).

The EMA has also progressively moved away from requiring animal studies in biosimilar development, emphasizing in turn on the use of advanced in vitro assays and analytical methods for establishing biosimilarity. The US FDA Modernization Act 2.0 now authorize the use of human biology-based test methods, such as cell-based assays and computer models to determine the safety and efficacy of drugs (U.S. Congress 2022). In a major advancement towards public health, in April this year, the US FDA announced that it planned to phase out animal testing requirement for monoclonal antibodies and other drugs. The FDA planned to reduce, refine, or potentially replace animal testing using a range of approaches, including AI-based computational models of toxicity and cell lines and organoid toxicity testing in a laboratory setting (so-called New Approach Methodologies or NAMs data) (US FDA 2025).

Nevertheless, the Indian draft guidelines still permit animal studies under certain circumstances, leaving significant discretion to the licensing authorities. It states: "On the basis of the totality of quality and nonclinical in vitro data available and the extent to which there is residual uncertainty about the similarity of a similar biologic and its RBP, it is at the discretion of Licensing Authority to waive or not to waive a requirement for additional nonclinical in vivo animal studies." This conditional waiver creates ambiguity and uncertainty in the regulatory landscape for Indian manufactures. The continued recommendation of animal studies appears inconsistent with the evolving scientific consensus and regulatory advancements internationally – which increasingly advocate for the elimination of animal testing in biosimilar development. Aligning India's guidelines with these contemporary standards would not only enhance the regulatory coherence but also support more efficient and affordable access to biologics.

Reevaluating The Role Of Comparative Efficacy Studies (CES)

Comparative efficacy (and safety) studies (CES) have traditionally been considered to be a gold standard for establishing the safety and efficacy of a drug, when its clinical outcomes are unknown. However, in case of biologics drugs - where efficacy has already been established and demonstrated - conducting CES studies is increasingly being viewed as controversial with limited incremental value (Pekka Kurki. 2025). In the context of biosimilars – the principle that "the product is the process" holds true - meaning that if two product demonstrate molecular similarity through rigorous analytical and characterization studies, they are expected to exhibit comparable pharmacological properties and clinical efficacy. Under such circumstances, conducting CES offers little or no additional value in confirming the safety and efficacy of biosimilars.

In a study - it was concluded that physicochemical and functional data package serve as reliable predictors for the authorization of complex biosimilars (Stefan, *et al*. 2023). The paper authored by scientific experts and the representatives of multiple regulatory agencies across the EU (including EMA), clearly supported the argument that if sufficient evidence for biosimilarity can be obtained from a combination of analytical and functional testing and pharmacokinetic studies (PK), then the usefulness of CES in regulatory decision-making for the approval of biosimilar monoclonal antibodies and fusion proteins is highly questionable. There were no instances where the evaluation of the quality dossiers conflicted with the outcome of the marketing authorization process. CES did not play a decisive role in the final regulatory approval process. Furthermore, CES were unable to resolve uncertainties regarding physiochemical and functional comparability between a biosimilar and reference product.

Based on the evolving scientific evidence, in a Reflection paper released in April this year, EMA has proposed to waive CES for the marketing approval of biosimilars in most cases (EMA 2025). It states: "…biosimilars may be approved without providing CES or even PD data if similar clinical efficacy and safety pharmacology can be inferred from a sufficiently stringent evaluation of analytical comparability, in vitro pharmacology, and a comparative clinical PK trial. Whether a development programme without a CES could be envisaged depends on the ability to extensively characterise the structure and function of the RMP, and understanding whether the differences in particular QAs have a meaningful impact on clinical outcomes". EMA's Reflection Paper follows a science-driven approach where in most cases, the combination of a robust package of physicochemical and functional testing, with appropriately designed pharmacokinetic studies provides sufficient evidence to establish biosimilarity. Similarly, the UK MHRA in its guidelines has also made CES an exception rather than a rule. Both UK MHRA and EMA Reflection Paper explicitly stipulate that in most CES may not be required, except under certain circumstances. These include situations like - when there is an incomplete understanding of the biologics with an unknown or poorly characterized mechanism of action or products with high intrinsic heterogeneity or insufficient characterization or situations where PK studies are not relevant.

Health Canada draft guidelines have also showed a progressive shift by placing greater responsibility on the clinical trial sponsors i.e. the biosimilar manufacturers, to justify the necessity of the clinical trials (Health Canada 2025). The guidelines state "If a comparative clinical efficacy and safety trial is deemed necessary, sponsors should provide a rationale to explain the purpose of the trial in the context of the biosimilar submission." This shifts provides a rigorous and science based approach requiring the manufacturer to present a compelling evidence for conducting CES rather than automatically mandating it. By doing this the draft guidelines provide a more efficient development process, allowing for CES to be conducted only when they are truly needed. The shift in the stand of developed regulatory agencies has the potential to reduce the entry barriers of biosimilar by doing away with the current mandatory requirement of CES. This science-driven approach would lower development expenses while accelerating the timeline for biosimilar production.

In contrast to the previous framework, India's draft guidelines mark a significant shift by proposing CES as an exception rather than a standard requirement. Under the 2016 Guidelines, CES (Phase 3 trials) were mandatory to establish the safety and efficacy of the product unless there was “no residual uncertainty”. The new draft guidelines adapt a more flexible approach suggesting that “a comparative efficacy trial may not be necessary if evidence of biosimilarity can be inferred from parts of the comparability exercise”. While this statement reflects a progressive intent to reduce the reliance on clinical trials, it lacks a clear objective criterion for when such studies are required or can be waived. It is important that the guidelines need to specify the exceptional cases where CES is required. For instance, the UK MHRA Guidelines state: “ Exceptionally, additional clinical safety data may be required where safety uncertainties cannot be resolved without patient exposure pre-licensing. For example, where serious ADRs to the RMP have unpredictable root causes (for example, pure red cell aplasia with epoetin), exposure of a significant patient cohort to the biosimilar candidate is considered the most appropriate approach to resolve any residual uncertainty around safety and immunogenicity.” Similarly, the EU reflection paper states: “ CES, however, may still be important in cases where a biological is not well-characterisable and/or has an unknown or poorly understood MoA, structure function relationship, or if the impact of observed differences on clinical outcomes is unclear. In such cases, it would be challenging to fully rely on comparative analytical data for the demonstration of similar efficacy and safety.”

The ambiguity in the Indian draft guidelines delegates substantial discretion to the regulatory authority, thereby introducing a notable degree of uncertainty in the biosimilar approval process. In the absence of an explicit transparent guidance, subjective decision making could introduce uncertainty and inconsistent regulatory outcomes and potentially hinder harmonization towards global regulatory frameworks.

Conclusion

India is one of the few countries which has the leading number of biosimilar manufacturers among developing countries. However the economic viability of biosimilar development needs a reassessment in the light a recent IQVIA report (IQVIA Institute 2025). The report clearly indicates a critical mismatch between patent expirations and active biosimilar pipelines. The analysis projects that of 118 biologics losing patent protection in US by 2028, 90 per cent currently lack any biosimilar candidates in clinical development phases.

Biologics represent one of the most expensive categories of medicines and biosimilars offer a critical pathway to improving access and affordability. Biosimilars offer cheaper, safe and efficacious alternatives specially for non-communicable diseases and rare diseases offer. For the system to work efficiently and at the same time serve the public health interest, it is important that we must focus on streamlining regulatory requirements – avoiding redundant or "commonly" used animal studies and CES - and create an environment which enables timely and competitive entry of biosimilars into the market.

Recent scientific and technological advancement provide a very pivotal opportunity to reform the regulatory guidelines, enabling the removal of unnecessary entry barriers without compromising the safety and efficacy. The new draft guidelines represent an important progress towards this goal, but they fall short in delivering unequivocal direction regarding animal studies and CES. It is now a well-established practice among leading regulatory authorities in Canada, EU, UK and US to not require animal studies as a part of biosimilar approval process. Additionally, authorities like UK MHRA and both Canada and EMA (in their respective drafts) have moved away from mandating CES, focusing instead on robust analytical and in-vitro evidence. However, the proposed changes in the Indian draft guidelines lack sufficient clarity and confer a lot of discretion to the regulatory authorities, potentially introducing ambiguities in the approval process. Such ambiguities could discourage innovation and hinder the development of biosimilars. It is therefore imperative for the guidelines to provide explicit, science and evidence-based criterions. Clear guidance in these areas would not only lower entry barriers for manufactures but would also promote broader patient centred access to biologics.

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