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Development of Molecular Diagnostic Innovation System in India: Role of Scientific Institutions

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Abstract The study attempts to examine the system-building activities of scientific institutions in developing the Molecular Diagnostic (MDs) Innovation System in India. Scientific Institutions are the precursor of any technological development with their capabilities in generating new ideas. MDs are advanced and accurate diagnostic technology with considerable scope to serve the diagnostic needs and requirements of the healthcare system. We adopted a System framework and analyzed the development of MDs in terms of the Technological Innovation System (TIS) functions, and the systematic challenges are assessed through the System Failure Framework (SFF). Based on the secondary and primary survey of prominent science base actors, the study finds that the role of government is crucial for facilitating technological development within a science base through the mobilization of resources. In India, the MDs technological development gained significant momentum over the last decade with the development of specialized human resources and dedicated research institutes. However, we do find that the innovative capabilities in attaining need-based TIS are sub-optimal owning to the specific diagnostic needs of highly burdened diseases in the society. The system analysis reveals that the TIS functions are underperforming because of the absence of a well-defined funding mechanism and goal-oriented targeted policy regime of the government. Since MDs have a transformative effect on the present healthcare system, we argue that the government has to address the system-based challenges and issues for developing a need-based technological innovation system for MDs in the country.

Keywords MDs Innovation system, Science Base actors, Technological Innovation System, Need-based Innovations, Knowledge production

I. Introduction

The primary purpose of the present study is to examine the significance of scientific institutions in building the Molecular Diagnostics (MDs)[1] innovation

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1 "Molecular diagnostics" is a broad term describing a class of diagnostic tests that assess a

system in India. MDs are the advanced diagnostic technology, which is fast, accurate, and highly effective in detecting both infectious and lifestyle diseases (AdvaMedDx & DxInsights, 2013). During the recent episode of the COVID-19 pandemic, WHO has declared MDs a standard gold test to confirm the presence of the SARS-COV-2 virus in the patients (Guglielmi, 2020). Similarly, the Indian Council of Medical Research (ICMR), the leading Indian government agency for the management of the COVID-19 pandemic, has followed the WHO declaration and formed the country's advisory in which RT-PCR has been approved as a gold standard for COVID-19 detection in the population (ICMR Advisory: Newer Additional Strategies for COVID-19 Testing, 2020).

The technological feature of MDs is relatively more accurate and sensitive than any other contemporary diagnostic technology as the diagnostic principle in MDs is based on the detection of a genetic marker in the genome or proteome through Reverse Transcriptase Polymerase Chain Reaction (RT-PCR). Hence, it has emerged as one of the most dynamic and transformative areas of diagnostics technology that has led to advances in research and revolutionized healthcare across many diseases and health conditions (Poste, 2001).

The role of scientific institutions is crucial for producing the knowledge that serves as a direct source of idea generation for any technological development in society (Kennedy, 1994). The knowledge base developed within the scientific community can effectively enable applied research strategies to develop and diffuse the technology within the system. The scientific institutions are mainly constituted by government-supported universities and research institutes, leading to technological discovery and facilitating new knowledge production that serves as the foundation for any technological innovation (OECD, 1997). The new knowledge creation for technology development, especially concerning human health, is a complex task requiring dedication and demands time (Garcia, 2000). In such a scenario, the role of the government to support scientific institutions and their system-building activities becomes important in the following two steps: (i) facilitating funding for the development of human resources & new idea generation and (ii) maintaining the continuity of financial support till the desired outcome is received.

At present, the MDs innovation system in India is 70-80per cent import dependent (Singh & Abrol, 2017) which is characterized by the two major context-specific issues i) Unaffordability, as imported technologies are highly-priced, ii) inaccessibility due to unsuitability of imported technologies for resource-poor healthcare settings. Concerning the context-specific issues and recent episodes of the covid-19 pandemic, the expectations for developing the

person's health at a molecular level, detecting and measuring specific genetic sequences in deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) or the proteins they express (Constance, 2010).

MDs innovation system in India are enormous. On the one hand, technology has to deal with the detection challenges associated with the increasing incidences of coronavirus and already existing highly burdened infectious and lifestyle diseases like TB, Malaria, cancer, diabetes, etc. On the other hand, the technology has to deal with the context-specific issues of availability, affordability and accessibility. In such a scenario, the argument of the present study drives toward the development of a need-based technological innovation system for MDs development.

The study is organized as follows: Section II provides the research questions; Section III provides the analytical framework and methodology; Section IV includes landscape analysis of the performance of system-building activities of the Indian science base for MDs development. Section V provides the analysis of system weaknesses and the challenges encountered in MDs development in India. Section VI contains the discussion and conclusion of the study.

II. Research Questions

The study argues that the role of scientific institutions is significant for the development of the MDs innovation system and continuous funding support from the government is critical in the facilitation of the system-building[2] activities of these institutions. Based on these arguments, the following research questions are addressed in this study.

(i) What are the roles and conducts of science base actors in the development of MDs innovation system
(ii) What is the role of the government in mobilizing the science base actors; and
(iii) What are the factors that are hindering the pathways of development?

III. Analytical Framework and Methodology

1. Analytical Framework

The study examines the contributions of scientific institutions in developing the MDs innovation system and argues that the pathways required for the

2 "System-building" is "the deliberate creation or modification of broader institutional or organizational structures in a technological innovation system carried out by innovative actors (Musiolik et al., 2012).

development of the MDs innovation system need to be context-specific. Therefore, to analyze MD's innovation system development, the study combines two frameworks of innovation Systems (IS). **First**, it uses the Technological Innovation System (TIS)[3] framework to identify the innovation actors, institutions, and their functions (system-building activities) involved in developing MDs. The TIS functions used in the study to analyze the role of scientific institutions in building MDs innovation system in India are: *(i) Guidance and direction of search ii) Resource Mobilization iii) Knowledge Creation and Development.* **Second**, the study uses the System Failure framework (SFF)[4] to identify the constraints and challenges experienced in the pathways of the development.

The primary motive of combining these two frameworks of the Innovation System is to study the context-specific steps undertaken for MDs development and to track the challenges encountered that can be addressed at the level of policymaking, institution building & system development to attain need-based MDs Innovation systems in India.

2. Methodology and Data Sources

The study employs quantitative and qualitative information and follows a multi-dimensional design methodology (i.e., mixed method). It uses multiple data sources to provide a comprehensive account of MDs' development in India. The approach consists of retrieving a wide range of functional activities using various sources related to the development of MDs innovation system. The study collected archival data from multiple sources to identify the functional activities. These are listed as follows:

(i) Research Publications

The academic publications related to MDs in India were extracted from the Thomson Reuters' Web of Science database. Publications related to MDs between 1990 and 2018 were retrieved using the following strategies: Topic = (molecular diagnos*) AND Title = (molecular diagnos*) AND Address = (India)[5].

3 TIS is defined as a "network of agents interacting in a specific economic/industrial area under a particular institutional infrastructure or set of infrastructures and involved in the generation, diffusion, and utilization of emerging technology" (Carlsson & Stankiewicz, 1991; Bergek et al., 2008). The focus is on the working of technological functions of particular economic system.

4 The framework was initially developed by Woolthuis et al., (2005); Mierlo et al., (2010).

5 In the query, the asterisk (*) represents any group of characters or no character and the literature type was limited in "Article".

(ii) Extramural Research Projects (EMR)

Information on EMR is collected from the Department of National Science and Technology Management Information System (NSTMIS) database for 2000 to 2018 available at the Department of Science and Technology (DST), Government of India.

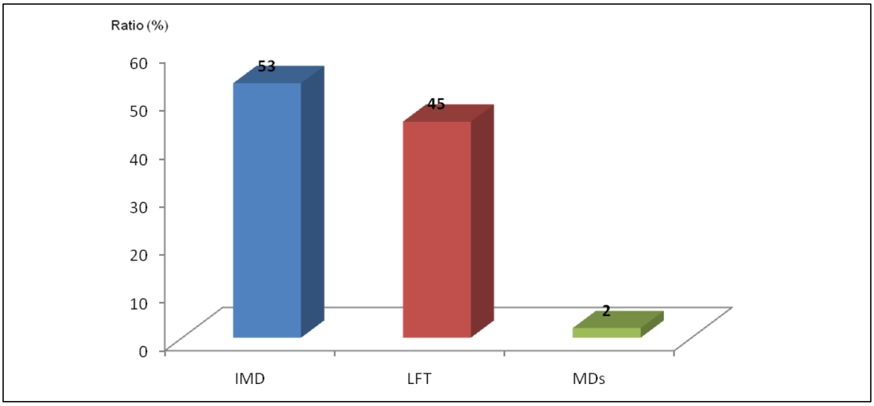
(iii) Primary Survey

We conducted in-person interviews by visiting 6 senior scientists from prominent science base institutes of India like the Indian Institute of Science (IISc) Bangalore, Centre for Cell and Molecular Biology (CCMB) Hyderabad, Centre for Diagnostics and DNA Fingerprinting (CDFD) Hyderabad, All India Institute of Medical Sciences (AIIMs) New Delhi, Jawaharlal Nehru University (JNU)New Delhi and Indian Institute of Technology (IIT) Delhi. This will help in understanding the system weaknesses that are hindering the pathways for the development of system-building activities.

IV. System-Building Activities for MDs Development within Indian Science Base: Analysis of Innovation System Functions

1. Guidance and Direction of Search and Resource Mobilization

The development of MDs in India started with "*guidance and direction of search" and "resource mobilisation"* system functions that are mainly carried out by the government. During the late 1980s and early 1990s, the Department of Biotechnology (DBT), Govt. of India has set a goal to foster R&D in diagnostics, realizing the importance of early diagnosis in disease management. This task was preceded under the "Mission Mode" initiative in coordination with public sector science-based institutions such as the Indian Council of Medical Research (ICMR), Council of Scientific and Industrial Research (CSIR), and All India Institute of Medical Sciences (AIIMS), etc. During the initial phase (in the late 1980s and early 1990s) of the program, DBT surveyed the status of the development of diagnostic kits in various research laboratories in the country, which led to the formulation of an expert group to provide funds for the development of workforce and infrastructure. Moreover, the government-funded several projects in R&D laboratories to develop diagnostic tools and transfer them to the domestic industry. In cases where the technologies were in an advanced stage of development, efforts were made to foster industry-institution collaboration to foster the transfer of technologies. A pilot plant was developed at the National Institute of Immunology in1991 to facilitate the diagnostic development on a commercial scale. DBT conducted a continuous evaluation of the performance of developed diagnostic kits by various experts and pathologists in the country. All these efforts of the DBT resulted in the development of various medical diagnostic technologies including Immunodiagnostics (IMD), Lateral Flow Tests (LFT) and MDs for the detection of various infectious and non-infectious diseases. However, in terms of the number of publication activities, the relative development of MDs during this phase was insignificant (see Figure 1).

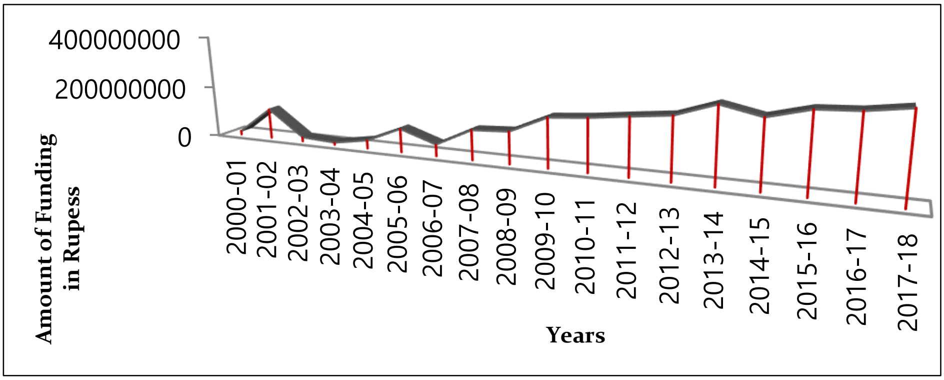


Source: Author's calculation based on the data collected from the Web of Science database
Note: IMD= immunodiagnostics, LFT= Lateral Flow Tests, MDs= Molecular Diagnostics

Figure 1 Development of Medical Diagnostics in India during the 1990s-2000s: By Cumulative Publication Activities

The foundation for the development of MDs took significant momentum during the 2000s due to the increasing burden of infectious and lifestyle diseases that created a situation to foster quality R&D in the area of biomedical technologies. As a result, DBT adopted a holistic approach to accelerating the pace of progress of the medical biotechnology program. The main thrust was on research support on long-and short-term basis leading towards scientific excellence, development of new products or processes, large-scale demonstrations, validation of R&D leads, involvement of user agencies and industries, technology development and transfer, and innovations for patenting purposes. Emphasis was also given to establishing new centers of excellence, infrastructural facilities, program support in priority areas, expansion of bioinformatics network and human resource development. In addition, DBT initiated several vital programs relevant to national medical needs and priorities. R&D for sensitive and accurate diagnostic technologies has become an important area to overcome the country's medical challenges. Not surprisingly, the funding for MDs R&D has increased substantially during this period (See

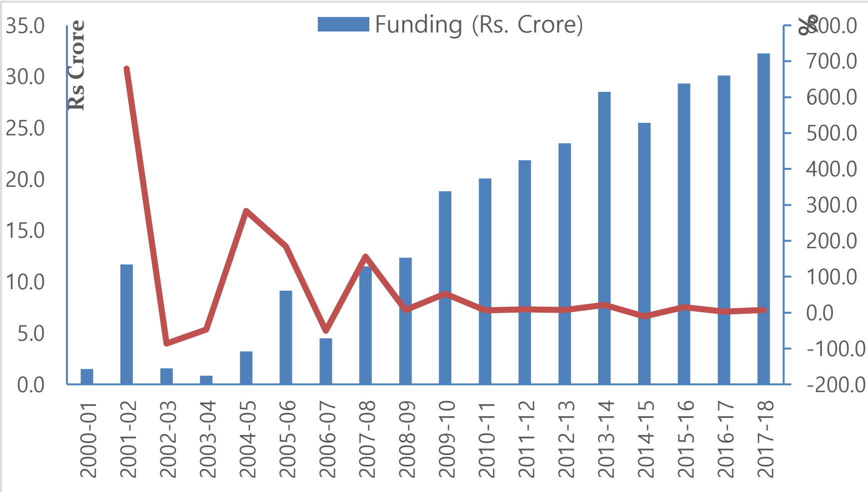
Figure 2). The distribution of Extra-Mural Research (EMR) for the period (2000-2018) indicates that the financing of diagnostic R&D has increased over the period, mainly in 2006-07 (See Figure 2), which roughly corresponds to the 11th and 12th five-year plan of the Government.[6] In terms of simple average growth rates, the EMR sanctioned for MDs R&D increased from 8 percent in 2000-2008 to 41 percent in 2009-2018 (See Figure 3).



Source: Author's calculation based on the data collected from the NSTMIS database

Figure 2 EMR Funding Expended for Medical Diagnostic Research (2000-2016)

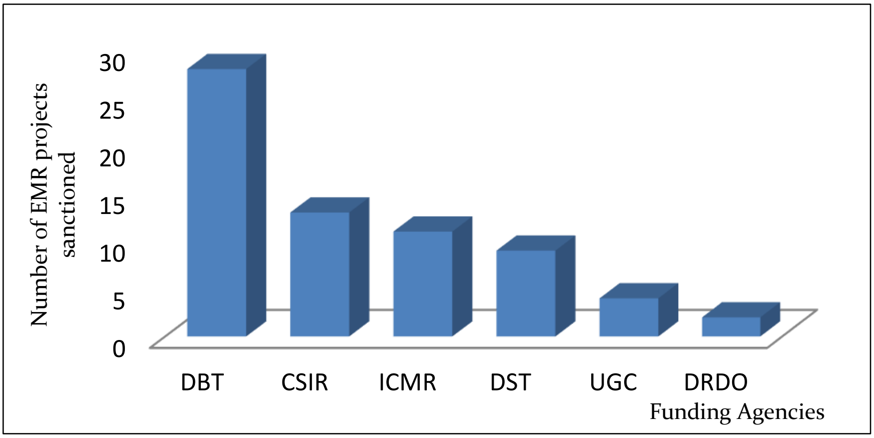
6 One of the main objectives of the 11th and 12th five-year plan was to meet the healthcare challenges of the country. Therefore, the government funding for the development of healthcare technologies has witnessed a considerable increase during this phase.



Source: Author's calculation based on the data collected from the NSTMIS database
Notes: The rate of growth is simple annual rates in percentages.

Figure 3 Total Number of EMR Projects Sanctioned for MDs development (2000-2018)

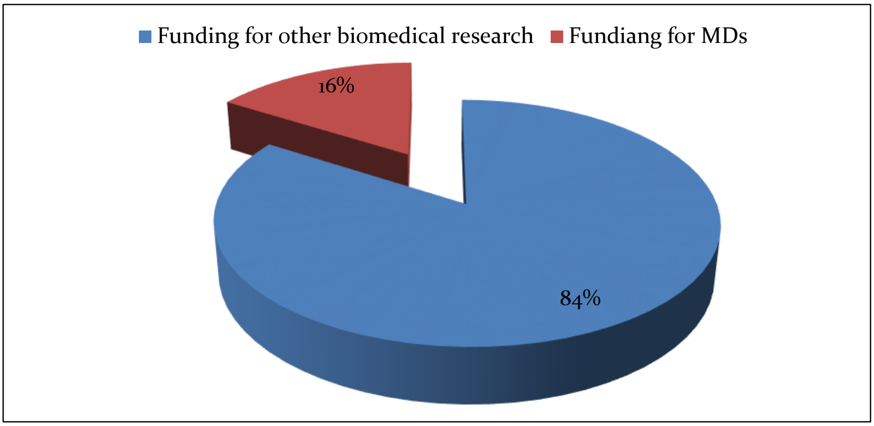
In Figure 4, the distribution of projects funded in the area of MDs is given. The study can see that in terms of the number of projects funded, DBT is the leading funding agency, followed by ICMR, CSIR and DST. The study found that DBT targeted MDs research in its affiliated institutions such as the Centre for DNA Fingerprinting and Diagnostics (CDFD), Rajiv Gandhi Centre for Biotechnology (RGCB) and also established the Translational Health Science and Technology Institute (THSTI), under which the National Biodesign Alliance (NBA) is developed to foster translational research in the area of modern medical biotechnology focusing on advanced diagnostic technologies like MDs.



Source: Author's calculation based on the Data collected from the NSTMIS database

Figure 4Cumulative Distribution of Projects Sanctioned by Funding Agencies (2000-2018)

The analysis of the distribution pattern of EMR funding to different biomedical research area indicates that even though the financing of MDs R&D has increased from 2000 to 2018 but compared to other biomedical research areas like drugs, vaccine and others, MDs has only received a small proportion out of the total amount of funding which is quite discouraging for MDs system development (see Figure 5).



Source: Author's calculation based on the data collected from the NSTMIS database

Figure 5Total EMR funding sanctioned for biomedical research (2000-2018)

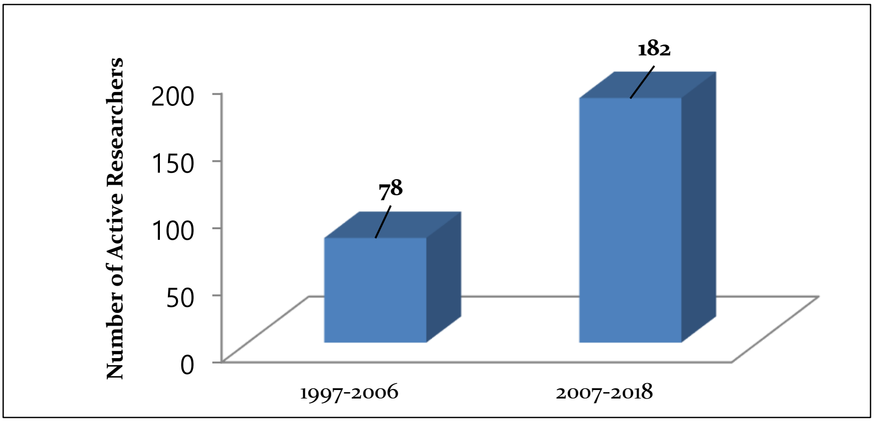
To sum up, the study sees clearly that the innovation system functions, *Guidance and Direction of Search and Resource Mobilization* are the precursors for the development of MDs innovation systems, and the system-building activities have majorly come from the government. The analysis revealed that various efforts had been put in by the government, beginning with the early 1990s and especially since the mid-2000, for the innovation of MDs technology. However, considerable efforts are introduced, relatively the MDs innovation system is rather small compared to several other biomedical researchers in India. This suggests that the government has to pay more attention to the promotion and development of R&D activities to enhance the capabilities for developing this diagnostic technology.

2. Knowledge Creation and Development

2.1 The Development of Human Capital

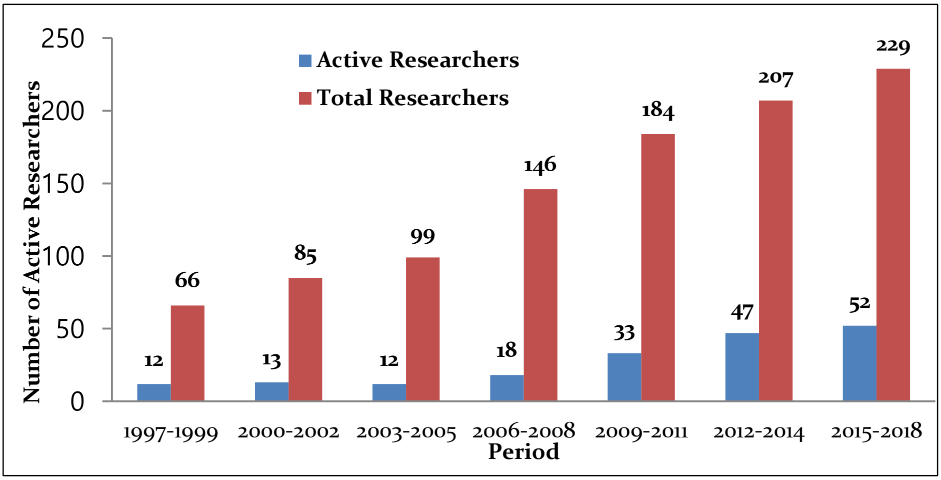
Human resources development is crucial for facilitating the innovation system function "Knowledge Creation and Development," and the public sector institutes are the primary supplier of human resources for R&D in India. Presently, the information on the total extant workforce involved in health research in India is scanty and fragmented. The study analyses the changing pattern of involvement of public sector researchers based on an inventory prepared of all researchers working in MDs R&D in research laboratories and institutes. This is carried out using the typology of researchers based on their contribution in terms of their number of publications in the area of MDs in the past 20 years (i.e., 1997-2018). The analysis reveals that 2007-2018 has witnessed a significant increase in the number of *Active Researchers (AR)*[7] in MDs research in India (see Figure 6). The substantial increase in the number of ARs in the last decade is an encouraging sign for MDs system development. However, the comparison of ARs with the total number of researchers in biomedical research who have published for each year from 1997 to 2018 reveals that it is exceptionally small (see Figure 7).

7 AR is defined as that group that has published at least one paper each year from 1991-2016.



Source: Author's calculation based on the data collected from the Web of Science database

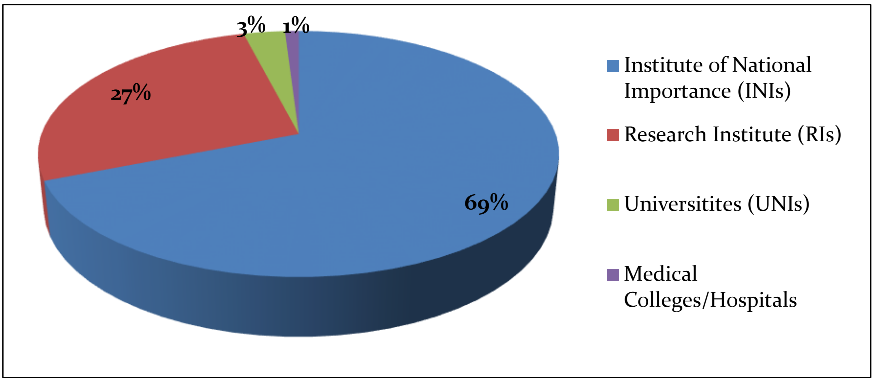
Figure 6 Number of Active researchers involved in MDs development: Decade wise (1997-2018)



Source: Author's calculation based on the data collected from the Web of Science database

Figure 7 Comparison of MDs Active Researchers with Total Researchers in biomedical research (1997-2018)

The location-wise analysis reveals that Active Researchers in MDs are concentrated in the Institutes of National Importance (INIs) followed by public sector Research Institutes (RIs). The study sees a lack of involvement of researchers from Universities and Medical Colleges/Hospitals (See Figure 8). Thus, the empirical analysis reveals that ARs for MDs are increasing. However, at present, they are relatively small in number, which we expect to grow so that more involvement of the researchers is directed into this diagnostic technology.



Source: Author's calculation based on the data collected from the Web of Science database

Figure 8 Location-Wise Distribution of Star and Active researchers (2007-2018)

So far, the analysis shows that the size of human resource MDs is extremely small. The current stock of workforce resources is not sufficient to meet the requirement of system-building activities needed to build the MDs innovation system of the country. Nevertheless, to create a robust system for MDs development, it is essential to invest in human resources. In the recent past, DBT has introduced various initiatives in this regard. The earliest program of the National Biotechnology Board, the predecessor of the DBT, is the Master in Sciences (MSc) biotechnology-teaching program started in five Universities[8] in 1985, based on their teaching capabilities and available infrastructure. More than 70 institutions and 150 companies are currently participating in building resources. The increased funding for Human Resource Development (HRD) over the period by DBT has significantly contributed to building the ecosystem for innovation.

Human capital is an important economic asset for a developing nation with limited financial resources. In this regard, DBT has helped to nourish many talents that are appreciated globally as some of the most brilliant minds. Recently, it has implemented an Integrated Human Resource Development Programme (IHRDP) in multidisciplinary areas of biotechnology, including multi-discipline training of researchers towards successful scientific careers

8 These universities are the following: Jawaharlal Nehru University (New Delhi), Madurai Kamaraj University (Madurai), Banaras Hindu University (Varanasi), M.S. University (Baroda), and Pune University (Pune).

within the field of diagnostic technologies under the planned educational program with Finland.

To promote HRD in MDs development, DBT and Translational Health Sciences and Technology Institute (THSTI) has constituted the National Biodesign Alliance (NBA). It is a multi-institutional partnership program that includes a network of biologists, engineers, clinicians and medical technology experts to promote an effective route for translation of essential findings into routine applications of paramount clinical importance using a multidisciplinary approach (See Table 1). This is done by combining new biomarkers, novel technological concepts and clinical expertise. The NBA and the University of Turku (UT) established a program for collaborating in research, innovation, higher education, training and capacity building for MDs development.

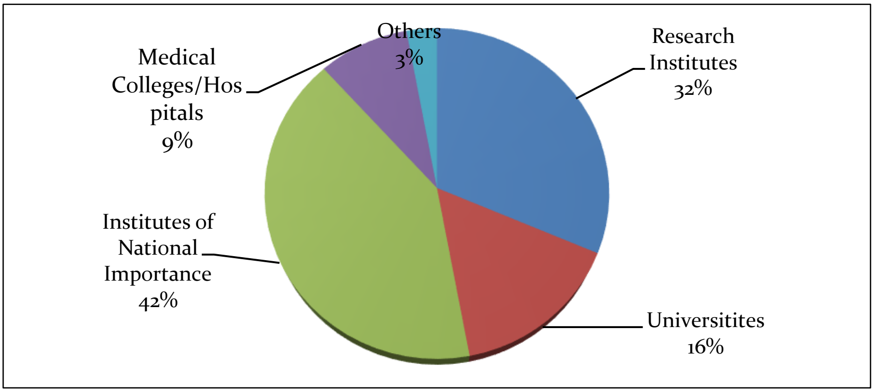
Table 1 List of Initiatives Undertaken by NBA for Promoting Diagnostic Research

Initiatives	Objectives
Indo-Finn Post-doctoral fellowships	To create a sizable pool of researchers who specialize in the development of diagnostics in India, the Department of Biotechnology has instituted five postdoctoral fellowships for training in various Finnish Institutes for two years
Indo-Finnish Diagnostic Research Centre	The goal of the Indo-Finnish Diagnostic Research Centre (IFDRC) is to complement and enhance the research capabilities of Indian and Finnish scientific networks from academia and industry in the area of diagnostics. The IFDRC intends to stimulate the exchange of junior and advanced students and researchers between the countries around everyday collaborative endeavors and research topics.
Sandwich PhD program between the NBA and University of Turku	The PhD students of the Indian partner institutions of the NBA will have an option for training at the University of Turku for a period not exceeding three months. Similar activity will also be made available for Finnish students working on Indo-Finnish projects in India for an equal duration. This exchange will initiate a relationship between the “diagnostics community” of the two countries to understand further each other’s needs, processes, and expertise.

Source: Author’s compilation from the data collected from the Centre for Biodesign & Diagnostics websites

2.2 Pattern of Knowledge Production

As shown in section 4.1, the resource mobilization for MDs development is majorly through EMR funding in India. The analysis of allocations of EMR funding made to different types of knowledge-producing institutes shows that the Institute of National Importance (INIs) and Research Institutes (RIs) received the more significant proportion of the funding, whereas Universities (UNIs) and medical colleges/hospitals lagged in receiving EMR funding (see Figure 9). This shows that knowledge production for MDs is evolving in a particular set of institutional cultures, i.e., both RIs and INIs produce knowledge that facilitates basic and applied research, which is very significant for technological development. However, the lack of involvement of UNIs and medical colleges /hospitals shows that funding for knowledge production has not been given much importance for UNIs-oriented basic research and medical colleges/hospital trained clinical research. Knowledge production for MDs innovation system development requires equal contributions from UNIs, Medical Colleges/Hospitals, RIs and INIs as the technology is dynamic.



Source: Author's calculation based on the data collected from NSTMIS Database
Note: The study selected the type of Institutions where the science base for MDs is located

Figure 9 Distribution of EMR funding to Types of Institutes (2000-2018)

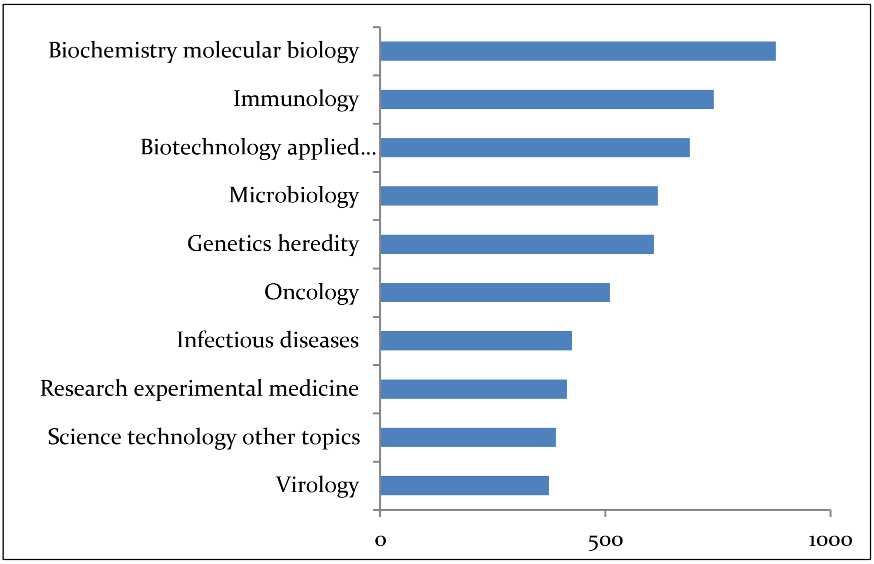
Further, the analysis of the pattern of knowledge production in terms of need-based, as such the trend of the publication activities along with disease wise from 1990 to 2016 is given in Table 2. The analysis shows that the publication trend of MDs targeting different conditions was the main focus area during the early 1990s, the communicable/ infectious diseases segment (CDs/IDs). Incidentally, this period also corresponds to a phase when biotechnology was emerging as a science stream with great potential to address the healthcare challenges of India (Ghosh *et al.*, 1997). Furthermore, DBT initiated a mission mode project called "*JaiVigyan*" in 2000. The development of potential diagnostics for CD/IDs was set as the main target to reduce the increasing burden of diseases. Since then, during the 2000s, the publication activities on MDs focusing on non-communicable lifestyle diseases (NCDs) have taken momentum because of the devolution of several national funding.

Table 2 Disease wise Cumulative Number of Publication Activities in MDs (1991-2018)

Type of Diseases	1991-1994	1995-1998	1999-2002	2003-2006	2007-2010	2011-2018	Total
Communicable Segments							
TB	13	19	36	67	132	408	675
Malaria	1	6	8	15	61	128	219
Leishmania	3	8	10	15	13	29	78
HIV	3	4	13	20	77	174	291
Hepatitis	14	13	27	24	17	28	123
Filaria	3	2	5	5	28	31	74
Cholera/Diarrhoea	3	6	15	17	27	37	105
Leprosy	1	8	5	4	10	19	47
Respiratory disease			1	3	11	62	77
Dengue/Chikungunya			1	13	22	60	96
Other Infectious diseases	13	26	47	117	254	590	1047
Total	54	92	168	300	652	1566	2832
Non-Communicable Segment							
Cancer	15	25	65	150	331	698	1284
Diabetes	3	18	76	118	214	298	727
Metabolic disorders			1	8	21	53	83
Chromosomal disorder			5	19	34	138	196
Cardiovascular diseases		1	4	8	19	26	58
Genetic Diseases	10	28	27	36	61	174	336
Bone Diseases/disorders		2	1	5	7	23	38
Autoimmune diseases		2	13	21	22	36	94
Eye diseases		1	13	8	14	26	62
Nervous disorder/Neurological disorder		5	8	15	33	78	139
Other non-communicable diseases		1	5	26	21	55	108
Total	28	83	218	414	777	1605	3125
Publications not specific to one disease (platform technologies)	25	20	61	107	211	354	778
Grand Total	107	195	447	821	1640	3525	6735

Source: Author's calculation based on the data collected from the Web of Science database

Also, the analysis of publication activities according to discipline wise from 1990 to 2018 found that most of the publications are concentrated around biochemistry, microbiology, genetics, infectious disease biology, pathology and parasitological disciplines, which covers around 93 percent of the total publication activities (i.e., 6315 out 6755 of total publications). Currently, the required solution to address the diagnostics challenges in India is to develop more advanced, sensitive, easy to use, cost-effective technologies. This would need R&D in the area of advanced disciplines of science and technology such as nanotechnology, biosensors, biomedical engineering, clinical research, etc. However, at present, the publication activities for MDs belonging to these disciplines is somewhat limited, i.e., only 7 percent of the total publication activities (See Figure 10).



Source: Author's calculation based on the data collected from the Web of Science database

Figure 10 The pattern of Publications Activities: By Discipline Wise (1990-2018)

The section has dealt with the analysis of the performance of TIS functions by the innovation actors involved in the development of MDs innovation system. The study finds that the system-building activities are in evolving stage at present. Although DBT, since the early 1990s, has begun several support initiatives, it is not seen to be adequate as more effort is required in resource mobilization for guiding the directions of research and development to produce the required knowledge. The empirical analysis of the performances of the innovation actors indicates some weakness in the system that restricts the performances of the innovation actors. The next section analyses the system weaknesses and will help highlight the factors responsible for the underperformance of innovation actors.

V. Analysis of System weaknesses and System Failures in Science Base

The analysis of TIS functions revealed that the government mainly supports the system functions for innovation activities within the science base through the established body like DBT. The operational activities of DBT have facilitated and paved the way for innovation in this field through the *direction of knowledge search* and *financial resource mobilization* that has helped build considerable scientific knowledge creation capabilities and development over the period. However, the TIS functional activities are not optimal for attaining the need-based MDs innovation system, which shows that weaknesses persist that hinder the development pathways. These system weaknesses that emerged through the functional analysis are mentioned below.

1. Mobilization and Fund Direction for Competence Building

It is to be noted that even though DBT has increased MDs research funding during the past ten years, compared to other biomedical areas, there is a lack of funding for exploratory learning. Moreover, the distribution of EMR funding is heavily concentrated towards selected organizations (INIs and RIs) at the expense of universities and national research laboratories to strengthen the science base. At present various scientific institutes lack infrastructure for MDs development.

2. Lack of Specialized Human Resources

As far as the specialized workforce is concerned in MDs research, it has a very grim picture despite continued support by DBT for human resource development. The same is replicated in intra-discipline catch-up, having fewer active researchers dedicated to MDs research. This is mainly because of the scant involvement from medical colleges and hospitals.

3. Lack of Scientific Capabilities to Meet Country-Specific Health Challenges

The funding pattern of EMR has shifted from communicable to non-communicable diseases, which reflects a lack of priority setting for targeted research. Since the development of MDs requires convergence and co-dependencies of various disciplines like molecular biology, biotechnology, clinical biology and biochemistry, the lack of coordination and interaction between the different scientific actors hinders socially responsible scientific knowledge creation and diffusion. Most of the knowledge produced from exploratory learning is restricted to basic research, and therefore, the knowledge production for applied research is fragile.

Overall, the presence of these *System Challenges* from the framework of TIS functional analysis reveals that the science base for MDs innovation system lacks problem-solving goal orientation in its research outlook. System-building for translating research into product development is still missing in the Indian science base. System-building lacks serious direction towards meeting the diagnostic specific needs, and as a result, there are still various gaps in research for priority/highly burdened diseases of the country. The weaknesses observed in the technology innovation process of system-building activities for science base in MDs system in the country indicate the persistence of several *System Failures* that hamper the effective creation and transfer of knowledge required for a need-based innovation system in India. The next section will highlight these ‘System Failures’ that have emerged from the primary survey based on in-person interviews with some of the leading science base actors in the country.

4. MDs Innovation System Failures of the Indian Science Base: Analysis based on Primary Survey

This section highlights the factors responsible for system weaknesses that lead to ‘System Failures’ as a whole. In-personal interviews with 6senior scientists working in the six leading science-based institutes that are involved in MDs have been conducted. This included the Indian Institute of Science (IISc) Bangalore, Centre for Cell and Molecular Biology (CCMB), Hyderabad, Centre for Diagnostics and DNA Fingerprinting (CDFD), Hyderabad, All India Institute of Medical Sciences (AIIMs) New Delhi, Jawaharlal Nehru University (JNU), New Delhi and Indian Institute of Technology (IIT) Delhi. Insights of interviews helped in bringing out the specific structural &functional challenges encountered in the development of system-building activities described in the following paragraphs.

The major challenges of innovation system-building that have been pointed out by the scientists are lack of infrastructure, rigid organizational structure, the culture of institutional setup and inadequate knowledge within the MDs domain. Hence, these complexities require a detailed assessment of the nature of the system challenges so that proper policy prescriptions can be prepared to address these issues. Hence this subsection brings out the detailed analysis of *System Failures* obtained through the interviews are discussed in this subsection of the study for analytical purposes, the list of system failures is categorized across three heads: Market-Based Failures, System Component Failures, and

Transformational System Failures given in Table 3.

Table 3System Failures in MDs Science Base

Categories of Failures	Types of Failure (Failure Mechanism)
Market Failures	The problem of Information Asymmetry and Market Distortions (Lack of incentive for research laboratories to undertake MDs research due to inadequate utilization of research) Issue of knowledge externality (Severe sub-optimal/ underinvestment in knowledge as the rewards and recognitions for scientists to undertake diagnostic research are meager in India, Concentration of Basic Research) Failure to meet Social-based Calculations (Inclination of research towards the diseases which are not very specific to the Indian population, lack of applied research)
Structural System Failures	Infrastructure Failure (Lack of Infrastructure facilities for highly sophisticated research like fabrication facilities for Microfluidics development, BSL3, etc.) Capability Failure (Lack of indigenous innovation for the development of reagents, enzymes, and vectors for which country is heavily dependent on imports, the poor conversion rate from Basic research to Applied Research) Interaction/Network Failure (Lack of convergence and coordination between different minds and ideas, Absence of proper validation process (rules) for MDs technologies)
Transformational System Failures	Directionality Failure (Lack of targeted goal-oriented research to prioritize the needs of the country Demand Articulation Failure (Absence of monitoring system to help the improvement of the quality of public expenditures and R&D for improved implementation of technology Policy coordination Failure (Inability of the science base institutes to integrate the country-specific diagnostic problems into their healthcare research system) Reflexivity Failure (Problem in swift adaptation to scientific knowledge changes, Lack of research and investment for CDs/NCDs which constitutes the high burden and for advanced technologies like biosensors, biomarkers, etc. shows the failure of demand articulation)

Source: Author's compilation based on the interviews conducted with the scientists through a primary survey

It can be observed that the system-building activities for exploratory learning are primarily driven by market-oriented economic calculation. The knowledge accumulation through the interaction of market forces in the science base organization faces the problem of information asymmetry, negative spillover of knowledge externality and failure to meet society's vital health issues. Some of the major factors behind these serious market drawbacks are the presence of considerable uncertainty, rewards and sound recognition for scientists, the poor conversion rate from basic research to applied research and misdirection of research effort toward diseases that are not relevant to the majority of the Indian population. Priority given towards market-oriented study led to diverging incentives and rewards away from undertaking scientific MDs innovative research towards the country's local needs.

In the existing innovation system component, the scientific community has an apparent absence of exploratory learning efforts due to a lack of appropriate infrastructure facilities, capability improvement deficiencies, failure to establish the network, and frequent interactions among researchers. The absence of well-developed scientific research facilities and labs prevents scientific development. Prevention in knowledge up-gradation further aggravates the lack of indigenous product capability development of reagents, enzymes, and vectors currently sourced from abroad. Since technology interaction among various organizational heads is critical, the institutional level failure indicates the absence of interactive learning, coordination between different agents' ideas, lack of validation process, and insufficient regulatory policies provide the emerging demand of the health sector in the country.

Apart from the structural weaknesses that prevent optimum creation and diffusion of scientific knowledge and innovative efforts, the science base actors face additional multi-level challenges. This brings us to the issue of dealing with Transformational system failures in terms of lack of vision and directions to prioritize scientific research, absence of reflexivity for the development of monitoring system to evaluate the performances of the innovation actors, lack of policy coordination and demand articulation due to insufficient conducts of system-building activities to meet the social demand. In general terms, it can be said that the system-building actions of the Indian science base are currently immature to develop a need-based innovation system for MDs. Need-based system development requires coherent policy vision and directions to induce exploratory learning toward social-based calculations

VI. Discussion and conclusion

The study analyses the system-building activities of Indian science base institutes involved in building up the ecosystem to develop MDs innovation systems. The analysis is carried out using the TIS approach, and the functional activities identified were *Guidance and direction of search, Resource*

Mobilization, Knowledge Creation and Development. The innovation indicators used to analyse the structure system functions are based on primary and secondary research.

The study finds that the system-building activities of the science base for the development of MDs innovation system are at an emerging stage in the country. Knowledge production is mainly attributed to the proactive effort by the government, primarily through the DBT. DBT has been instrumental in the system-building activities involving guiding and directing research and mobilizing financial resources for the technological development in various science base institutes of the country. However, the efforts from several other government agencies like CSIR, ICMR, and DST are insignificant.

The DBT has initiated various push and pull schemes to foster the technological development in MDs, including the development of human resources in the advanced biomedical area, infrastructure development, initiation of EMR funding, development of various bilateral programs to receive foreign funding, etc. EMR Funding is the primary driver for fostering system-building activities and has shown an increasing trend over the period. However, the allocation of EMR funding has been uneven as the maximum proportion is concentrated in INIs and RIs while the Universities' share is considerably lower. This is a significant loophole in the performance of the innovation system function as the primary research in universities is essential for knowledge production in technology development.

In addition, the study finds lesser EMR funding for the promotion of research activities in Medical colleges/Hospitals, which will be detrimental to the technological development for which clinical research is equally important. These two loopholes present a significant challenge for the system-building activities required for exploratory learning to develop emerging MDs innovation systems.

In terms of Knowledge Creation and Development, the recent past has shown significant progress as the participation of institutes, especially INI and RIs, in the system-building activities has increased in terms of publication activities. The increased knowledge production is characterized by the high amount of research articles in high-quality scientific journals and across various disciplines, which shows the increase in knowledge quality competence for technological development. Despite these encouraging trends, the knowledge output is significantly less than the system-building undertaken by other biomedical research fields.

The study finds a lack of contribution of the research publications from universities and medical colleges/hospitals. At present, the system-building lacks meeting the specific diagnostic needs, as there are several gaps in the country's scientific research for highly burdened diseases. For instance, the publication trend of infectious illnesses is decreasing. The research output in highly advanced MDs technologies required to meet specific needs like easy-to-use diagnostics, cost-effective technologies, and point of care testing is very less in number. The overall assessment shows that Knowledge creation and development at the moment lack in undertaking the country-specific system-building activities for need-based innovations.

The analysis of system failures through a primary survey pointed out several loopholes, gaps and shortcomings in the system that are needed to be addressed to obtain a need-based technological innovation system. The significant challenges pointed out by the scientists during the interviews are i) shortage of funding, ii) lack of coordination between researchers, iii) lack of infrastructure for the advanced technologies like biosensors, microfluidics, etc., and iv) lack of interest in the conversion of basic research to applications.

To sum up, the study finds that the existing science base for developing the MDs innovation system in India is emerging and the system-building activities are found to be sub-optimal. The role of DBT has been critical in shaping the system-building activities for innovation. However, the system faces various challenges due to perceived lacunae that hinder the development pathways. The challenge persisting in the system is the lack of problem-solving goal-oriented research for the diagnostic needs of the country. The government must play an essential role in addressing system weaknesses by mobilizing the financial resources more significantly towards targeted research to meet the country's specific healthcare diagnostic needs. The recent COVID-19 pandemic has set a successful story where ICMR, a government agency, played an important role in the development MDs based testing platforms. ICMR from the beginning of the pandemic has supported science-based institutes like the National Institute of Virology (NIV) and others for augmenting and diversifying their capabilities in the development of the MDs technologies that can meet the country-specific requirements. As a result, at present, there are around 2577[9] molecular-based diagnostic testing platforms for COVID-19 testing in India (ICMR, 2021).

9 1518 Real-Time RT-PCR, 920 TrueNat, 132 CBNAAT, and 7 other Molecular-Nucleic Acid (M-NA) Testing.

References

AdvaMedDx & DxInsights. (2013). Introduction to Molecular Diagnostics: The Essentials of Diagnostics Series, https://dx.advamed.org.

Bergek, Jacobsson, and Sandén. (2008). Legitimation and Development of Positive Externalities: Two key Processes in the Formation Phase of Technological Innovation Systems, Technology Analysis & Strategic Management, 20 (5), 575-592.

Kennedy. (1994). The relationship between Science and Technology. Research Policy, 23, 477-486.

Carlsson and Stankiewicz. (1991). On the Nature, Function and Composition of Technological Systems, Journal of Evolutionary Economics, 1 (2), 93-118.

Constance. (2010). The future of Molecular Diagnostics; Innovative Technologies Driving Market Opportunities in Personalized Medicine, Business Insights Ltd.

Garcia. (2000). Science and Technology and their role in Human Health in Developing Countries, Mem Inst Oswaldo Cruz, Rio de Janeiro,95 (1), 5-7.

Ghosh *et al.* (1997). Business Opportunities in Medical Diagnostics in India: A market report. Biotech Consortium India Limited.

Guglielmi. (2020). Researchers are scrambling to find new ways to diagnose the coronavirus and churn out millions of tests a week — a key step in returning to relative normality, Nature, 583, 506-509.

Mierlo, Arkesteijn, and Leeuwis. (2010). Enhancing the Reflexivity of System Innovation Projects with System Analyses, American Journal of Evaluation, 31(2), 143-161.

Musiolik et al. (2012). Networks and Network Resources in Technological Innovation Systems: Towards a Conceptual Framework for system building,Technological Forecasting and Social Change, 79(6), 1032-1048.

OECD. (1997). National Innovation Systems, Paris.

Poste. (2001). Molecular Diagnostics: A Powerful New Component of the Healthcare Value Chain, Expert Rev. Mol. Diag, 1 (1).

Singh and Abrol. (2017). In-Vitro Diagnostics (IVDs) Innovations for Resource-Poor Settings: The Indian Experience, African Journal of Science Technology Innovation and Development, 9 (5), 617-636.

Woolthuis et al. (2005). A System Failure Framework for Innovation Policy Design, Technovation, 25 (6), 609-619.

ICMR. (2020). Advisory: Newer Additional Strategies for COVID-19 Testing, 2020. https://www.icmr.gov.in/pdf/covid/strategy/New_additional_Advisory_23062020_3.pdf

ICMR. (2021) Role of evidence-based &well-researched guidance is vital in defeating the pandemic, e-Samvaad. https://www.icmr.gov.in/pdf/press_realease_files/Newsletter_English_May_2021.pdf.