

**Developing a Biomedical R&D and Innovation Landscape for India:
A Scoping Study**

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PREFACE

In May 2013, the WHO Member States requested the WHO to establish a Global Observatory on Health Research and Development (R&D) as part of a strategic work-plan to promote innovation, build capacity, improve access, and mobilize resources to address diseases that disproportionately affect the world's poorest countries. Continuing with the efforts, the WHO SEARO made a recommendation for the development of norms and standards for classification of health R&D and for the setting up of R&D observatories at the national level. In India, the WHO Regional Office for South-East Asia (SEARO) seeks to take this idea to its logical end.

In this scoping study the idea of observatory for developing the biomedical R&D and innovation landscape for India is evaluated. This study assesses the strengths and weaknesses of currently deployed ways of tracking the actors (funding agencies) in respect of collecting the required information on the emerging biomedical R&D and innovation landscape. It suggests that there exist some formidable barriers that the present system of biomedical R&D and innovation faces in respect of the collection and analysis of information. These barriers need to be removed by making changes in the system of steering and coordination.

The report brings out that the most critical steps concern the establishment of institutional mechanisms and giving incentives to the stakeholders for providing, as a matter of routine, relevant data to the national observatory. Funding agencies can very easily motivate stakeholders by fulfilling the obligation of access to information concerning the current status of programmes and activities; however, it should be specified as a precondition for availing funds in future from the central government departments. Those who are willing to cooperate in the implementation of the gaps and needs analysis and provide information to the expert panels for the purpose of better planning of biomedical R&D and innovation effort can be offered additional funding support in the form of gap funding, viability funding and bridge funding.

The report observes that the task of building the national observatory cannot be accomplished without strong cooperation from and between the concerned entities, that is, the funding agencies and the stakeholders. While the steps involved in creating the national level observatory have already been listed, this report is a critical assessment of the strengths and weaknesses of currently deployed ways of tracking the actors in respect of gathering required information on the emerging biomedical R&D and innovation landscape. It also focuses on the steps to be taken by funding agencies to enable the stakeholders to contribute to the processes of data collection for the purposes of planning, monitoring and evaluation. Nevertheless, it is important to note that the feasibility of the establishment of national observatory to be constituted as an independent entity under the Ministry of Science and Technology is confirmed.

We hope the idea of establishment of a national observatory for biomedical R&D and innovation will be pursued to its logical end and the institutional changes sought in the system of collection and analysis of information would come through soon.

Finally, we would like to acknowledge the support of the collaborating team created within the Institute for Studies in Industrial development to enable the contributors to complete this report. We are also thankful to the individuals who spared time to cooperate with us in the evaluation of sources of data and the completion of survey of the TB R&D and innovation landscape.

Acronyms and Abbreviations

AICTE	All India Council for Technical Education
CEWG	Consultative Expert Working Group on Research and Development: Financing and Coordination
CNPq	Conselho Nacional de Desenvolvimento Científico e Tecnológico (National Council for Scientific and Technological Development)
CPC	Cooperative Patent Classification
CSIR	Council for Scientific and Industrial Research
DBT	Department of Biotechnology
DHR	Department of Health Research
DOP	Department of Planning
DRDO	Defence Research and Development Organization
DSIR	Department of Scientific and Industrial Research
DST	Department of Science and Technology
GFHR	Global Forum for Health Research
G-FINDER	Genome Functional Integrated Discoverer
HRDG	Human Resource Development Group
ICD	International Classification of Diseases
ICER	International Center for Excellence in Research
ICMR	Indian Council of Medical Research
ISRO	Indian Space Research Organization
IRB	Institutional Review Board
LOD	Linked Open Data
MeSH	Medical Subject Headings
NIAID	National Institute of Allergy and Infectious Diseases

NHR	National Health Research
NHRMF	National Health Research Management Forum
NIH	National Institutes of Health
NMITLI	New Millennium Indian Technology Leadership Initiative
NLM	National Library of Medicine
NSTMIS	National Science and Technology Management Information System
NTDs	Neglected Tropical Diseases
OECD	Organisation for Economic Co-operation and Development
OSTP	Office of Science and Technology Policy
PI	Principal Investigator
R&D	Research and Development
RNTCP	Revised National TB Control Programme
SAIF	Sophisticated Analytical Instrument Facilities
SEARO	South-East Asia Regional Office
SERB	Science and Engineering Research Board
S&T	Science and Technology
UGC	University Grants Commission
UMLS	Unified Medical Language System
WHO	World Health Organization
XML	Extensible Markup Language

Executive Summary

WHO SEARO has sought to fulfill its vision of building a national level biomedical R&D and innovation observatory. In this report we have focused on the feasibility of establishing a national observatory in India by carrying out an evaluation of the existing data sources and suggesting steps for filling in the gaps. Recommendations with regard to governance have been made and the next set of steps been proposed for the setting up of the observatory.

Evaluation of Current Data Sources

The evaluation has revealed that gathering data for the R&D biomedical observatory from existing resources is going to be a laborious task and that the analysis will still be incomplete with the publicly available dataset. This is mainly owing to the lack of transparency in the processes, lack of systematic reporting by organizations and institutions, and not viewing the reporting of inputs and outputs as a critical component that would play a decisive role in policymaking and implementation. The data available is rather sparse, difficult to access with no uniformity with respect to data structure and details across different agencies and, in general, not frequently updated for intramural R&D funding. While existing resources and databases can be utilized to a certain extent for extramural funding, it is imperative that systematic reporting of data in a common format that can be automated and updated in real-time be implemented if the R&D observatory is to become a reality. These limitations are going to pose huge challenges for the national observatory. Therefore, it is recommended that many of the gaps in data collection and its analysis can be addressed by designing, testing and administering an appropriate instrument, for example, researcher and end user surveys.

Survey Instruments and a Short Pilot Project

As suggested above, in order to fill in the existing gaps in the currently available data, survey instruments have been developed.

- The first one is a gaps and needs survey questionnaire for researchers or principal investigators (PI). It seeks information at laboratory level, across all research projects of PIs.
- The second questionnaire seeks information from the PI at project level and is, therefore, more detailed.

An exhaustive list of researchers with names and contact details can be processed manually from secondary data sources. However, as indicated earlier, data technology tools are necessary to expedite the processing and analysis of extracted secondary data based on different database structures. A short, yet representative list of researchers based on type of research, from basic research to clinicians, was drawn up and a survey was conducted on a pilot scale. To gauge its effectiveness, few surveys were executed personally and others executed through email communication. Both methods have had partial success.

It is found that the response of PIs to the gaps and needs questionnaire is positive, around forty per cent. The response rate can possibly be increased by understanding what could be the takeaways for the researchers themselves from the observatory and by instituting appropriate incentives to enlist their cooperation. This will boost survey participation and in turn help gain insights from the researchers themselves and to prepare systematic analyses based on the data collected.

The project performance questionnaire has had zero response. It indicates that providing project performance data is possible but time consuming, and, worth filling in only if it is necessary for the funding agency and the reporting of performance is stipulated as an eligibility condition for the sanction of grant in the future. The project-based data will gauge research effectiveness as well as analyze its economic impact; therefore, it is important.

Recommendations to Enable Data Collection

Availability of data on inputs in the form of funding, resources, expertise and outputs such as products, technologies, patents and publications is one of the main foundations on which the observatory is going to be built. In order that the observatory fulfills its mandate, it is critical that data collection be robust, real-time and in an easily searchable format that can be analyzed by different end users. In order to ensure a two-pronged strategy:

- Set up the institutional mechanisms for the stakeholders to provide the relevant data to the observatory. Providing information to Observatory by recipients of grants can be made a mandatory requirement by funding agencies.
- Incentives of additional funding support in the form of gap funding, viability funding and bridge funding as a mechanism to promote cooperation with the national observatory.

These steps are only indicative and will have to be specified in the course of setting up of the observatory.

Scope and Governance of the Observatory

The observatory will have to prove to be of value to the relevant stakeholders such as the funding agencies of Central government, research performers and innovation making entities. The observatory will be required to enable planning, monitoring and evaluation of biomedical R&D and innovation landscape in the country on various parameters. It will have to help ensure increased yields in research productivity in a resource-constrained environment as well as in meeting the broader goals of health research for development and equity. Further it may enable monitoring of the timeliness of research being conducted in the national health research system. The data collected should be publicly available to all through a database driven web-service across platforms, with relevant search facilities. Further, the observatory should not be just a repository of information, but enable analysis to augment R&D planning and performance. In general, the observatory will follow the principles of Open Access in respect of data gathered by it, except in cases of confidential information. Also, the analyses and reports will be made available through open access journals.

It is recommended that the observatory be established as an autonomous agency under the administrative charge of the Ministry of Science and Technology but collectively governed by the relevant stakeholders. Governing Board members of the proposed body must comprise representatives of funding agencies, research performers and innovation making community.

This report proposes a roadmap as a two-step process for the implementation of the idea of the observatory for biomedical R&D and innovation.

1. As a first step, a National Level Consultation by WHO SEARO is proposed to bring together all central government departments and relevant stakeholders on board in order to initiate the development of the observatory.
2. The next step is to set up the observatory as a pilot project in order to be part of the global efforts being undertaken in the countries of Latin America, Southeast Asia and Africa. It proposes that the pilot project needs to be set up as a real-world experiment with few selected disease areas, with all stakeholders contributing to its development.

The report identifies two possible options in setting up the pilot study towards the establishment of the national observatory.

Option 1: A National Observatory with immediate and full participation from various government departments

This option suggests the establishment of a National Biomedical Observatory as an autonomous body under the Ministry of Science and Technology. The collaboration of different government agencies involved in funding is essential for successful operation of the observatory. This will include DSIR, CSIR, DBT, DST, all under the Ministry of Science and Technology, DHR, ICMR and various medical education institutions under the Ministry of Health, UGC and AICTE under the Ministry of Human Resources Development, DRDO under the Ministry of Defence, ISRO and Department of Atomic research. These organizations will have to agree to provide data in a uniform structure and require grantee institutions and researchers to provide details of the output and other particulars. The evaluation of existing data sources has revealed that the analysis will be incomplete with the publicly available datasets published by these organizations. This is mainly owing to the lack of systematic reporting by organizations and institutions. It is imperative that these organizations adopt a systematic reporting of data in a common format that is updated in real-time so that an automated R&D observatory can become a reality.

Despite the collaboration within government departments, a lot of other information is only known to the researchers. This will have to be obtained through surveys, which an essential component of gap and needs analysis. Such data will be obtained based on disease specific surveys.

Once data is obtained and uploaded, the observatory will carry out a gap and needs analysis of selected disease areas, every year. For this purpose it will engage expert panels and produce reports that have peer acceptance.

Option II: A Standalone Observatory

It is possible to create a standalone observatory, which may function independently of government departments. It can also be created within a government department, while a consensus is being built on the active collaboration of all funding agencies in changing their internal accounting and reporting procedures. There will be a limitation to this exercise—that it will be dependent on the public domain information and surveys to be conducted by the observatory. Though it may not be obligatory for researchers or institutions to share information, it might incentivize the sharing of information by providing latest data on their research in an internationally accepted portal like an observatory. Such models are currently in place, for example, the G-Finder.

The major limitation in this exercise is that the intramural funding data will be difficult to obtain. In India, the CSIR is the central scientific organization that provides intramural funding, while other departments provide intramural funding on a much smaller scale. Thus, it may be possible

to set up the observatory under the CSIR, though in collaboration with other government departments.

Like Option I, Option II will also conduct a gap and needs analysis and for this purpose, surveys will form an essential component. Experts shall be asked to carry out the gap and needs analysis that will have peer acceptance.

Prototype of Observatory

To realistically assess the challenges in creating the observatory, it is proposed to conduct a pilot project that will draw up a biomedical R&D landscape of a select set of priority disease areas. The rationale for starting with the pilot project is that the component systems of biomedical R&D and innovation are diverse in terms of their origin, mandates, financing, organizational structure and strategy. While few efforts have already been initiated at the global level, it is imperative to learn and adapt to India-specific requirements. Implementation of the pilot project will allow the country to participate in the global efforts and sustain the momentum as well as to learn from its own experience and from that of the others.

The proposed pilot project should involve all stakeholders in the design and implementation. The project will provide a realistic assessment of the challenges in gathering data with the available infrastructure, and of the costs and the human resources required for the establishment of the observatory. Further, it will provide an insight into the barriers that must be removed in order to ensure the smooth and sustained operation of the national observatory in India.

The pilot project will require a strong team, comprising stakeholders who shall actively contribute to the project and in a systematic way. It is critical that the scope and functions of the pilot project be defined through further dialogue between all relevant stakeholders. The diseases to be chosen for the real-world experiment should be of national importance and should be funded on a reasonable scale within the national system. Towards the establishment of the biomedical R&D and innovation observatory, it is recommended that priority diseases like TB and Cancer be a part of the pilot project.

Currently, data will have to be manually gathered and fed into the system. However, with further advances in technology, some of the relevant data may automatically get updated on the portal through the use of search engines/web crawlers that will allow the observatory to pick up data from appropriate databases. For improved analysis of the information so made available, the relevant stakeholders need to tackle the challenge of development of the tools of health informatics.

The Study recommends that considering the complexities involved in setting up a national observatory in India, it is necessary to conduct a pilot real-world experiment to arrive at the real challenges in setting up a real observatory. The pilot can be implemented with the following four objectives:

- 1) Implementation of a survey of stakeholders' needs and objectives, researchers' understanding of the impact, and end users' feedback and response for the objective of setting up of prototype observatory.
- 2) Development of a report of the R&D and innovation landscape (2010-15) for TB and cancer with the aim to understand, in practice, the challenges facing the decision makers with regard to the development of comprehensive database to provide for information on research capacity, research capability and researchers.
- 3) Establishment of a searchable online information system capable of mapping the capabilities and competencies, financial flows on specific areas and the output so far in these research sectors. The system should also provide information to inform policymakers and help researchers to identify possible collaborators.
- 4) Creation of a framework for the implementation of Gap Analysis of research capability and in funding of specific sectors of biomedical research to support policy decisions in building capacity and innovation in the following identified areas of priority.

Deliverables, Timelines, Human Resources and Budget for Pilot Project

- The deliverables from the pilot will be R&D and innovation landscape for TB and cancer. The outputs will include an online searchable database, and systematic analyses.
- The time period envisaged for setting up this prototype observatory is two years.
- The team is expected to have two full time professionals – a programme director and an IT manager, and six researchers. Associates, namely, scientists, data scientists and programme management specialists will complement the team. The team will rely on two expert panels, about five for each disease.
- The approximate budget for this initiative is INR 193 lakhs.

These estimates are indicative of the nature and scale of the study to be conducted and could be customized to align with the priorities and resources available.

