

JUNE 2022

Lessons from the Coronavirus Pandemic: Leveraging Biotechnology to Tackle Infectious Diseases in India

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Contents

Abbreviations	i
Summary	1
Introduction	3
Scope of Biotechnology in Improving Public Health in India	4
How Did India Leverage Biotechnology to Tackle the Coronavirus Pandemic?	5
Regulation of Diagnostics in India and Related Challenges	7
Regulation of Vaccines or Drugs in India	9
Challenges to Leveraging Biotechnology to Tackle Infectious Diseases in India	12
Strengthening India's Biotechnology Sector to Prevent Future Pandemics	15
Conclusion	19

About the Author	21
Appendix A: How Did Other Countries Expedite Their Approval Process During the Pandemic?	23
Appendix B: Closed-Door Discussions	27
Notes	31

Abbreviations

AIIMS	All India Institute of Medical Sciences
BIRAC	Biotechnology Industry Research Assistance Council
CAGR	compound annual growth rate
CBER	U.S. Center for Biologics Evaluation and Research
C-CAMP	Centre for Cellular and Molecular Platforms
CDSCO	Indian Central Drugs Standard Control Organization
CLA	central licensing authority
DBT	Indian Department of Biotechnology
DCGI	Drug Controller General of India
EMA	European Medicines Agency
EU	European Union
EUA	emergency use authorization
FDA	U.S. Food and Drug Administration
HSC	EU Health Security Committee
ICMR	Indian Council of Medical Research
MOHFW	Indian Ministry of Health and Family Welfare

NGO	nongovernmental organization
R&D	research and development
SMEs	small- and medium-size enterprises
TB	tuberculosis
WHO	World Health Organization

Summary

In India, the coronavirus pandemic encouraged partnerships between academia and industry, fostered collaboration among competitor companies, and stimulated cooperation within different government departments to leverage biotechnology to develop new test kits, protective equipment, vaccines, and respiratory devices.

Despite this collaborative ecosystem, a few stakeholders faced several challenges during different stages of product development including discovery, research and development (R&D), clinical trial, or commercialization of their products. Some of these challenges can be attributed to a lack of an ecosystem that encourages collaborative research in India, limited involvement of private funding entities, a gap between academia and industry where university researchers lack sufficient awareness of the imperatives of industry, and a lack of awareness regarding contemporary applications of biotechnology among the regulatory community.

The goal of this paper is to provide all stakeholders and the Indian public an overview of the role that advancements in biotechnology can play in strengthening India's public health capacity. While the pandemic offered significant opportunities to the scientific community and private players in India to develop medical countermeasures, this paper only illustrates examples that discuss strategies that were adopted to accelerate the development of diagnostics and vaccines in the country. It further elucidates the challenges, both regulatory and funding, that some stakeholders faced in introducing new diagnostics and vaccines into the market during the pandemic.

The paper argues that it is important for India to adopt a systematic approach to sustain the collaborative ecosystem that was cultivated during the pandemic. It further provides a brief

assessment of the policies that regulate vaccines and diagnostic kits in India and the scope of enhanced and better implementation in the future. The paper also suggests strategies to maintain a continuous flow of investment to sustain research, streamline the regulatory infrastructure to minimize ambiguities regarding product approvals, and foster multi-stakeholder collaboration to create a sustainable research and innovation ecosystem that can be leveraged during health emergencies in the future.

Major Recommendations

- **Invest** in focused research programs to develop vaccines, therapeutics, and diagnostics.
- **Set up** tech transfer offices, with a strong business development group, in all academic research institutions to ensure that the proprietary knowledge developed by research institutions is licensed and translated to develop products that can solve real-world problems.
- **Modify** the existing education curriculum to include translational courses that provide research and entrepreneurial training during graduate programs.
- **Break** the product development pipeline—in this case, the diagnostics and vaccine development pipeline—into different stages wherein different kinds of funders are invited to fund different stages to ensure completion of research and commercialization of products.
- **Increase and sustain** financial investment, both public and private, to enhance the scale of innovation in India. Cofunded models, where the government makes an equal contribution as the private fund does in the project, can be explored to sustain investment in this space.
- **Maintain** continuous dialogue between researchers, the private sector, funders, and the regulatory community, both at the state and national level, to ensure that civil servants in the regulatory systems are up to date with advancements in technology and that scientists, industry experts, and funders are aware of different regulatory compliances.
- **Expedite** the introduction of legislation to replace the archaic Drugs and Cosmetic Act of 1940 to promote the production of safe and effective products in a cost-effective manner.

Introduction

In India, the coronavirus pandemic has encouraged a great deal of collaboration among researchers, private sector, and the regulatory community to leverage biotechnology for public health applications such as new test kits, protective equipment, vaccines, and respiratory devices. More importantly, the coherent action of academic and industry experts along with support from the regulatory authorities to help bring new vaccines and diagnostics to the market, and to foster their successful acceptance has emboldened the vision and action of the sector.¹ More can and should be done.

Despite the long history of infectious diseases in India, focus on new biotechnology advancements to develop indigenous products and therapies to prevent and treat infections has been limited. Three main factors have caused this underperformance: a reliance on exports for medical devices, diagnostics, and other products; a lack of prioritization of infectious diseases by academia, industry, and policymakers; and insufficient funding for taking products or businesses to scale. These problems are partly due to India's inefficient regulatory processes, which lead to insufficient confidence among potential investors that new products will get access to the market.

This paper explores the current scope of biotechnology to improve public health in India, highlights the related challenges, both regulatory and funding, and suggests ways to strengthen the research ecosystem to be able to better leverage biotechnology for public health applications. Taking stock of the efforts observed during the coronavirus pandemic, the paper studies the collaborative efforts of scientists, regulators, funders, and industry to develop indigenous medical devices and vaccines and examines challenges faced in introducing new products in the market during this period. Next, the paper assesses

regulatory changes that were made during the pandemic to get products to the market and describes ways to foster innovation to establish a robust and sustainable research ecosystem. The final section examines how the Indian government can leverage its soft power by incentivizing biotech firms to develop low-cost healthcare products that cater to both local and global needs. This paper is based on interviews with scientists, academics, and private sector experts; insights derived from closed-door workshops; and an extensive literature review.

Scope of Biotechnology in Improving Public Health in India

Advancements in biotechnology provide the potential to diagnose, prevent, and treat infectious diseases. Scientists in India are working to understand the molecular structure and function of known pathogens to explore their mechanisms of infection, pathogenicity, virulence, host-pathogen interactions, and drug resistance. They are also leveraging advancements in biotechnology to develop indigenous, reliable, cost-effective, and easy-to-use diagnostics for rapid and sensitive detection of pathogens. Further, researchers in India are conducting experiments to understand immune responses to identify potential vaccine candidates for infectious diseases of national and global importance. Some of the ongoing experiments that leverage biotechnology to tackle infectious diseases include the following:

- (i) Given the high burden of tuberculosis (TB) in India, major emphasis is being given to leveraging technological innovation to develop diagnostics, vaccines, and therapeutics for TB.
- (ii) Scientists in India are also working toward understanding the evolution of drug-resistance mechanisms in bacterial pathogens to develop indigenous and cost-effective therapies against the growing concern of antimicrobial resistance in the country.
- (iii) Considering the huge burden of viral diseases in India, the government has a focused program that conducts and supports research to understand the molecular mechanism for pathogenesis as well as host-pathogen interactions of viral infections such as dengue, chikungunya, influenza, and hepatitis B and C. Such studies are important to develop diagnostic kits, vaccines, and other therapies.
- (iv) To support India's vector control program, scientists conduct studies that gain insights into the clinical syndromes associated with parasitic infections, such as malaria, leishmania, and so forth. Such experiments help scientists develop better diagnostic tools for the species-specific diagnosis of active parasitic infection.²

In addition to the examples described above, the coronavirus pandemic offered significant opportunities for the scientific community and private players in India, as elsewhere, to develop and manufacture indigenous diagnostics and vaccines, which will be elaborated in detail in the next section.

How Did India Leverage Biotechnology to Tackle the Coronavirus Pandemic?

India's response to the coronavirus pandemic highlighted the country's strengths as well as its weaknesses. Every facet of what a country needs to detect, diagnose, and respond to biological threats, like the coronavirus pandemic, requires scientific research and technical capacity to be mobilized at scale. To their credit, Indian researchers, innovators, and regulators have come together to introduce low-cost diagnostics, develop therapeutics, and conduct research to create safe and effective vaccines during the pandemic.

Production and Regulation of Diagnostics During the Coronavirus Pandemic

Soon after the pandemic broke out, InDx, a large-scale public-private partnership implemented by the Centre for Cellular and Molecular Platforms (C-CAMP) and funded by the Rockefeller Foundation, was tasked to ramp up the production of indigenous COVID-19 test kits in the country.³ Since most components necessary to produce test kits were imported, C-CAMP faced huge challenges to produce these components indigenously at the beginning of the pandemic. Later, with support from Tata Consultancy Services, C-CAMP partnered with Indian manufacturers of medical technologies to ramp up production of reagents and other necessary components needed to manufacture test kits locally. This public-private partnership helped more than 160 Indian companies to collectively manufacture more than a million test kits per day.⁴

The Department of Biotechnology (DBT), set up under the Indian Ministry of Science and Technology, also supported manufacturing of indigenous COVID-19 diagnostic kits, ramping up the production capacity to about 1,500,000 kits per day.⁵ The department, under its COVID-19 Research Consortium Call, supported multiple projects to indigenously develop COVID-19 diagnostics in India. It took multiple initiatives to support researchers and industries involved in developing and manufacturing indigenous diagnostics in the country.⁶ It also worked with the Central Drugs Standard Control Organization (CDSCO) to expedite regulatory approvals for the development of diagnostics for the virus.⁷

The CDSCO issued a public notice wherein the applicant can approach the CDSCO's Public Relations Office for guidance on an expedited regulatory pathway. This notice elaborated that data requirements for clinical performance evaluation will be decided on a

case-by-case basis, depending on the nature of the kit and the evidence of available data on its clinical performance evaluation. During the pandemic, the time line to approve new diagnostics, per the notice, was reduced to almost seven days from the usual 140 days.⁸

Commending India's efforts to scale up indigenous production of diagnostic kits, the director-general of the Indian Council of Medical Research (ICMR) in his book *Going Viral* noted that “the remarkable story of how India became fully self-reliant in its testing capabilities in such a short time begins and ends with the sheer commitment of dedicated teams from research institutions, medical colleges, testing labs, ministries, airlines, and postal services working together.”⁹

The collaborative ecosystem and the subsequent production of indigenous COVID-19 diagnostic kits now contributes around 20–25 percent of the revenues of the Indian diagnostic industry.¹⁰ The support to Indian companies to locally manufacture test kits can in the long run strengthen the country's capacity in surveillance and infection prevention and control for other diseases.¹¹

Production and Regulation of Vaccines During the Coronavirus Pandemic

Accelerated approvals were given to COVID-19 vaccines by the end of 2020 or beginning of 2021. This was possible because businesses risked their investments and regulatory agencies accelerated their processes to develop and market the COVID-19 vaccines to tackle the unprecedented situation. Moreover, the process for the development of vaccines was simultaneous and not sequential, thereby reducing the time frame to develop and market a new vaccine.

The initiatives to indigenously develop vaccines were again led by the DBT and its dedicated Mission Implementation Unit at Biotechnology Industry Research Assistance Council (BIRAC). BIRAC expanded the existing activities under the National Bio-Pharma Mission and Ind-CEPI Mission to support Mission COVID Suraksha—the Indian COVID-19 Vaccine Development Mission.¹² Announced as part of India's Atmanirbhar Bharat scheme, the mission aims to support academic and private institutions to accelerate vaccine development for the delivery of safe, efficacious, affordable, and accessible COVID-19 vaccines to the Indian citizens.¹³ The mission provides end-to-end support to facilitate preclinical and clinical development, aids manufacturing and regulatory processes for deployment, establishes clinical trial sites, and consolidates all available resources toward accelerated vaccine development.¹⁴

DBT's initiatives, under Mission COVID Suraksha, to increase investments in research and development (R&D) and manufacturing of COVID-19 vaccines supported Biological E's COVID-19 vaccine candidate from preclinical to phase III clinical trials.¹⁵ The department, along with ICMR, augmented Bharat Biotech's capacity by providing the required infrastructure and financial support to manufacture Covaxin, which is India's first indigenous COVID-19 vaccine.¹⁶

Apart from locally produced COVID-19 vaccines, some pharmaceutical and biotechnology companies in India signed collaborative agreements with foreign vaccine developers to either conduct clinical trials or large-scale manufacturing. To support accelerated approval, the DBT allowed entities to submit preclinical and clinical data generated outside the country for vaccine approval in India. The approval to conduct clinical trials in India is, however, based on no objection certificate from Review Committee on Genetic Manipulation after examination of preclinical data studies.¹⁷ The regulator also allowed different phases of clinical trials to run simultaneously in India, based on interim data, thereby reducing the overall timeline of vaccine approval in India. The rules provided relaxation for skipping phase III trials, if “remarkable efficacy” is achieved with a defined dose in the phase II clinical trial.¹⁸

Some scientists, however, argue that although “remarkable efficacy” of a drug can be proven after a phase II clinical trial, the efficacy of a vaccine cannot be shown after a phase II clinical trial.¹⁹ In case of “unmet medical needs of serious and life-threatening diseases in the country,” the 2019 New Drugs and Clinical Trial rules mention accelerated approval of vaccines based on phase II clinical trial data. It also mentions additional, post-licensure studies to validate the anticipated clinical benefit.²⁰ The final approval of the vaccine, however, rests with the CDSCO. After the clinical trials are completed with satisfactory results, the manufacturer needs to approach the CDSCO again to obtain a license to market the new drug.

This ecosystem, as noted by former secretary of the DBT, “can now be used for further vaccine developmental research. The knowledge, experience and capacity acquired are critical to accelerate the development of vaccines for priority diseases like the pan coronavirus, tuberculosis, HIV, malaria, chikungunya, Zika and many others.”²¹

Despite the collaborative efforts of academia and industry and support from the government, a few researchers and some smaller firms in India faced challenges in introducing indigenous diagnostics and vaccines in the market. This is because of unfavorable tax structure and absence of an overarching legislation. Instead, different frameworks and organizations under different ministries are set up to regulate research, approval, and commercialization of diagnostics and vaccines in India. This leads to a lack of clarity of process, irregularity in the approval process, poor awareness about regulatory protocols, bureaucratic delays due to multiplicity of organizations, and a lack of private involvement and funding, some of which will be discussed in the next section.²²

Regulation of Diagnostics in India and Related Challenges

A few reports note that the coronavirus pandemic in India can pave the way for greater investments in the medical devices sector—including diagnostics, masks, gloves, ventilators, and so forth—which in the coming years will observe significant growth.²³

The current conditions, however, suggest a less promising scenario. India, until last year, imported 80 percent of its medical devices, including diagnostic instruments, from China, Germany, the Netherlands, Singapore, and the United States.²⁴ Although close to 450 India-based companies were looped in to manufacture reverse transcription polymerase chain reaction (RT-PCR) kits for COVID-19 diagnosis, the diagnostic industry is plagued with major issues that should be addressed for it to observe sustainable growth.²⁵

First is the inverted tax structure for diagnostics, which means that the customs duty to import diagnostic instruments is 0 percent, while duty to import raw materials to manufacture diagnostics in India ranges from 7.5 to 15 percent.²⁶ This, according to a local manufacturer,

“is not conducive to local manufacturing. If this was to be corrected, the import duty on finished products should be 10 to 15 percent and that on the components, should be as low as 0 to 2.5 percent. This will lead to an increase in the cost of the finished product and lower the cost of the components.”

The correction for this inverted tax structure was, however, left unaddressed in the latest budget released by the Indian government.²⁷

Second was the absence of a separate law to regulate the import, manufacture, and distribution of diagnostics in India until 2017.²⁸ The Medical Devices Rules 2017, issued under the Drug and Cosmetic Act of 1940, intended to distinguish medical devices from pharmaceuticals. It empowered the Drug Controller General of India (DCGI) to introduce risk-based classification into four categories—from A to D, with high-risk devices placed under class D. The rules have distinct provisions to obtain approvals for the manufacturing and import of diagnostics in India. It clearly distinguishes the role of central and state licensing authorities, with the former being in charge of issuing manufacturing licenses for devices that fall in categories C and D along with the ones that do not have a similar device in the Indian market, and the latter responsible for licensing manufacturing of diagnostics that are placed in categories A and B. The import for all diagnostics, however, rests with the DCGI.²⁹ In February 2020, the Indian government issued the Medical Devices (Amendment) Rules, 2020 that mandate medical devices, including diagnostics, to be regulated on the same lines as drugs. This move was to ensure the safety and efficacy of all medical devices introduced by their respective manufacturers or importers.³⁰ Although the newly issued regulations have introduced better transparency in the approval system, concerns remain that manufacturers or importers might face delays given the dual role of the CDSCO to regulate both drugs and medical devices under the ambit of the Drugs and Cosmetic Act of 1940.

Various arms of the Indian government have put forward proposals to regulate medical devices independent of drugs. NITI Aayog, the Indian government's think tank, drafted a Medical Devices (Safety, Effectiveness, and Innovation) Bill in 2019 to provide users with access to safe, innovative devices and address concerns on patient safety. This bill opposes the view of the Indian Ministry of Health and Family Welfare (MOHFW) to regulate

medical devices as drugs and instead recommends setting up an autonomous Medical Devices Administration that has powers to conduct audits, give approvals, and enforce penalties. The health ministry and NITI Aayog finally reached consensus on the medical devices bill in 2020, which suggested that medical devices should be regulated by a separate division under the CDSCO, as opposed to NITI Aayog's proposition. Furthermore, the regulation of medical devices will be under a separate act and not the Drug and Cosmetics Act of 1954, as suggested by the health ministry.³¹ Despite the consensus between the two organizations, the status of the bill is currently unknown.

Instead, a high-level committee under the chairmanship of the DCGI has been constituted to frame a New Drugs, Cosmetics, and Medical Devices Act to harmonize the regulation of new drugs, medical devices, and vaccines in India. The eight-member panel, headed by the current DCGI, was expected to submit its first draft by February 2022, the status of which is also unknown.³² Moreover, the panel does not include manufacturers, medical device experts, venture capitalists, scientists, doctors, and patient groups, thereby limiting the multistakeholder discussions needed to draft a comprehensive legislation.

Another initiative was taken by the Ministry of Chemicals and Fertilizers to introduce two schemes to promote greater investments in the medical devices sector, which were approved by the Indian government in 2020. The first was centered on the promotion of medical device parks and the second focused on introducing production-linked incentives to encourage domestic manufacturing of medical devices.³³ Although these are steps in the right direction, inverted tax structures along with complicated regulatory infrastructure hinders domestic manufacturers from stepping into manufacturing medical devices indigenously.

It is therefore important for India to skip through its piecemeal reforms and work toward developing a systematic approach to address the challenges of the medical devices industry. Right from rationalizing the inverted tax structure all the way to ensuring a separate regulatory framework to govern the medical devices sector is imperative for India to become a medical devices manufacturing hub.

Regulation of Vaccines or Drugs in India

As with medical devices, the import, manufacture, sale, and distribution of new drugs (including vaccines, unless specified otherwise by the licensing authority) are also regulated under the Drugs and Cosmetic Act of 1940 and the rules made thereunder in 1945 and 2017.

Drug and vaccine approval in India is a multistep process, where the manufacturer or organization intending to develop a new drug in India needs to provide preclinical data to

justify the testing of drugs in humans. Once the licensing authority is satisfied with the results of the preclinical study, the drugs qualify for a four-phase clinical trial period to ensure the safety and efficacy of new drugs, a period that is regulated by the New Drugs and Clinical Trial Rules, 2019, as elaborated below:³⁴

- i. Any institution or organization that intends to develop, manufacture, and conduct clinical trials for drugs or vaccines in India needs to obtain permission from the DCGI, which functions as the central licensing authority (CLA).
- ii. The CLA, after scrutiny of documents and detailed review and inquiry, grants permission to conduct clinical trials. If the CLA comes across any deficiencies in the application, the authority informs the applicant, who is then asked to provide additional information within a period specified by the CLA.
- iii. If the applicant rectifies the deficiency, the CLA scrutinizes the application again and, based on its satisfaction, grants permission to conduct clinical trials. If the CLA is not satisfied, the authority rejects the application. The process of either approving or rejecting the application for drugs and vaccines that are developed in India usually takes thirty days from the day of application. In the case of rejected applications, the applicant can request the CLA to reconsider its application within a period of sixty days from the date of rejection along with an allocated fee.
- iv. In the case where no communication has been received by the CLA in the said period, the permission to conduct clinical trials will be deemed to have been granted and will be legally valid for all purposes.
- v. An applicant who is aggrieved by the decision of the CLA may file an appeal before the MOHFW within forty-five days of the receipt of such decision. The government may, after further inquiry and after giving the appellant an opportunity to be heard, dispose of the appeal within a period of sixty working days.
- vi. In the case where an applicant wants to conduct clinical trials for drugs or vaccines that have been approved or marketed outside India, the CLA will follow the same process of approval or rejection as described above within a period of ninety working days.
- vii. Once an approval by the CLA is obtained, the clinical trials will be initiated only after approval of the clinical trials protocol by the ethics committee, registered with the CLA. In cases where the clinical trial site does not have its own ethics committee, clinical trials will begin after inspection by an ethics committee of another trial site or an independent ethics committee.

- viii. The decision of approval or rejection by the ethics committee needs to be communicated to the CLA within a period of fifteen days of the decision. In the case of rejections, once the decision is communicated to the CLA, the applicant can seek approval from another ethics committee within the same city or within a fifty-kilometer radius from the clinical trials site.
- ix. Once all necessary approvals are obtained, which is valid for a period of three years from the date of issue, clinical trials should be registered under the Clinical Trials Registry of India maintained by the ICMR, a research body set up under the MOHFW.
- x. The status of enrollment of trial subjects and status reports of each clinical trial should be submitted to the CLA every six months via the SUGAM portal.³⁵
- xi. Any report of serious adverse event occurring during clinical trial to an enrolled subject, should, after due analysis, be forwarded to the CLA, the chairperson of the ethics committee, and the institute where the trial has been conducted within fourteen days of its occurrence.
- xii. Clinical trials of drugs that are already approved in other countries with mature regulatory setups (such as Australia, Canada, Switzerland, the United Kingdom, and the United States, among others) are fast-tracked in India with an approval that is issued within eight weeks, as opposed to sixteen to eighteen weeks, as is the case for other drugs that do not fall under this category.³⁶

Although India did develop a few COVID-19 vaccines indigenously, concerns still lie in ensuring the continued development of safe and effective vaccines for other infectious diseases. This is because of the classic, so-called panic then forget approach, where once an outbreak is under control, both government and donors tend to divert their attention to other pressing concerns.³⁷ This leads to the lack of a sustainable research ecosystem where researchers are continuously motivated toward focused research programs to develop vaccines for other infectious diseases, a lack that will be discussed in the next section.

Because of the limited research focus on developing vaccines indigenously, the gestation period to develop a new vaccine in India is long. This is partly because the regulatory infrastructure to approve vaccines in India does not keep pace with technological advancements. This leads to the involvement of multiple regulatory bodies to approve a single vaccine, which results in delays in the approval process, a lack of transparency in the functioning of a regulatory agency, and limited communication between government and vaccine manufacturers.

Challenges to Leveraging Biotechnology to Tackle Infectious Diseases in India

Although a great deal of collaboration was observed among researchers, industry, and regulators during the coronavirus pandemic, these communities faced several challenges during different stages including discovery, R&D, clinical trials, or commercialization of their products. Some of these challenges, highlighted by participants in discussions and interviews, include the lack of an ecosystem that encourages collaborative research and innovation; limited involvement of private funding entities compared to Western countries; a gap between academia and industry, where university researchers lack sufficient awareness of the imperatives of industry; and a lack of awareness regarding contemporary applications of biotechnology among the regulatory community.

Weaknesses in India's Research Ecosystem

According to a UNESCO estimate, India has 156 researchers involved in R&D per million inhabitants. Western countries, by comparison, have between 4,000 and 7,000.³⁸ To promote individual talent in India, the Indian government introduced programs such as the Prime Minister Research Fellowship to improve the quality of research in several higher education institutions.³⁹ Although such schemes might attract competent people into research, they do not automatically stimulate multidisciplinary collaborative projects, thereby leading to a lack of a collaborative research ecosystem across the country.

To address this concern, the DBT, created in 1986 under the Indian Ministry of Science and Technology, has been spearheading innovative solutions to facilitate collaborative projects across the country. The department has created a research ecosystem through its autonomous institutions and biotechnology parks and incubators. It has established sixteen theme-based autonomous institutions to pursue basic and translational research, institutions that were also looped in to understand the epidemiology of the novel coronavirus and to develop diagnostics and vaccines to address the challenges posed by the coronavirus pandemic. In addition to autonomous institutions, the DBT has set up BIRAC to promote public-private partnerships, encourage foreign direct investment, empower small- and medium-size enterprises (SMEs), and help states to develop biotechnology policies.

To enable translational research, the DBT has so far established nine biotechnology parks and incubators across the country to offer facilities to scientists, as well as SMEs for technology incubation, technology demonstration, and pilot plant studies for accelerated commercial development of biotechnology.

Realizing the demand of medical technologies in India, the DBT also introduced an interdisciplinary bio design program to foster collaborative R&D activities between medical and engineering institutions to create an ecosystem that supports the development of indigenous and affordable medical technology innovations and entrepreneurship in the country.⁴⁰

Although the DBT has been leading multiple research initiatives to make India globally competitive in biotechnology research, innovation, translation, and entrepreneurship, it does not have adequate innovation funds or risk-funding mechanisms to strengthen its capacity to scale up innovations in case of an emergency. Although a few scientists in India have begun to explore the potential of new technologies such as gene editing or synthetic biology to develop healthcare products, India does not have a conducive model that supports bold ideas in both academia and industry.

Further, most scientists in India end up working in silos, which limits their engagement in collaborative projects and leads to repetitive projects, thereby limiting the scope of research in India. India's regulatory infrastructure (both at the central and the state levels) further impedes progress insofar as it sometimes results in high compliance burdens for homegrown companies, making it difficult for them to either produce low-cost, globally competitive, quality products or access the market. This might be one of the primary reasons that the scientific community in India still relies on foreign reagents and equipment for their research.

Limited Financial Support for Late-Stage Biotechnology Research

Bio-incubators, as described above, harness the entrepreneurial potential of start-ups by mentoring and providing access to infrastructure. While incubators support the infrastructural and knowledge requirements of start-ups, a wide funding gap had existed for start-ups in the early phase of research. To plug this gap, the Indian Ministry of Science and Technology has several funding departments that provide funds to biotechnology institutes, nongovernmental organizations (NGOs), researchers, and professionals to promote biotechnology and its products or businesses. BIRAC has also set up the Sustainable Entrepreneurship and Enterprise Development Fund to provide capital assistance to start-ups to enable them to reach a position where they could seek loans from commercial banks, financial institutions, or other private entities.⁴¹

This initiative to support start-ups through public funds narrowed the financial gap in early stages of research, but investments are still minimal for late-stage biotechnology research. This is because the Indian government, according to the latest budget, spends close to 0.7 percent of its gross domestic product on R&D, with only a small proportion of funds dedicated to biotechnology research, as against the expectation of 2 percent by 2022.⁴² Moreover, the private strategic or venture capital market for biotechnology R&D exists but is also mostly constrained beyond proof-of-concept work. This means that many

early-stage start-ups have access to funds but lack resources when they are prepared to scale up. To take promising ideas to the next levels, including development, manufacturing, and market access, larger pools of capital are therefore needed. Here, India faces the challenge of confidence, conviction, and support: potential investors worry that enterprises will face bureaucratic delays related to government approvals for new products, thereby limiting products' access to the market, while enterprises worry they will have trouble accessing the funding.

The process of developing, testing, and bringing biotechnology products to market takes a long time and is fraught with uncertainty. Although the different arms of the government have promoted many programs, the diffused and scattered nature of such programs often confuses the industry, thereby inhibiting successful development and commercial outcomes for the industry. In the private sector, venture capital and other sources of innovation capital tend to operate on shorter time frames and smaller scales than those necessary to bring such biotechnology products or treatments to market. Therefore, there is a need for larger longer-term sources and different pockets of capital to build successful programs in this sector. Those sources, however, need encouragement and confidence through an enabling ecosystem of efficient and predictive regulation to enhance transparency in the approval process, structured and consolidated public resource deployment to streamline research expenditure, enabling market access support to introduce products to the market, and favorable private equity and capital market regulations to enable capital churn.⁴³

Gaps in the Approval Process

The coronavirus pandemic has exposed deep fault lines in India's regulatory infrastructure, which drives approval of new drugs, diagnostics, or vaccines in the country. The CDSCO, headed by the DCGI, is considered unreliable for approving new drugs or vaccines in the market. For example, the drug sold under the brand name Fabiflu was evaluated in limited clinical trials and approved for use by the DCGI in SARS-CoV2 infections. However, because the clinical trial data were so limited, it was later excluded from the Clinical Guidance for Management of Adult COVID-19 Patients formulated by the All India Institute of Medical Sciences (AIIMS)–ICMR COVID-19 National Task Force. For two arms of the same ministry to give different approvals or recommendations indicates the problematic difference in decisionmaking standards and processes.⁴⁴

Similarly, the regulator was questioned after it granted emergency use approvals to Bharat Biotech's Covaxin. This was because of limited phase III clinical trial data, which the manufacturer was still conducting. Moreover, the approval of Covaxin for "restricted use in clinical trial mode" came just a day after the Subject Experts Committee, constituted under CDSCO, requested more efficacy data from the manufacturer before it could grant approvals.⁴⁵

The opaque approval of drugs and vaccines attracted more criticism because the New Clinical Trial Rules of 2019 do not mention the terms “emergency use” and “restricted use” but have a different term, “accelerated approval,” where approval can be granted based on phase II clinical data if remarkable efficacy has been observed. But the clinical benefit of the drugs or vaccines then needs to be validated with post-marketing trials after approval.⁴⁶ Therefore, the use of such terms to grant approvals not only undermines the credibility of Indian scientists but also builds distrust among the Indian population, which can ultimately weaken prospects of India’s immunization program. Some experts therefore suggest that rather than skipping a clinical trial phase before granting approvals, India should follow a rolling data review process, like in the United Kingdom, where data from each phase of the clinical trial is updated to the regulator regularly for an accelerated review and not an accelerated or abbreviated trial.⁴⁷

To summarize, access to capital, the lack of a collaborative approach between scientists, limited partnerships between academia and industry, and a compliance burden because of irregular regulatory infrastructure are major hurdles to leveraging biotechnology to tackle infectious diseases.

Strengthening India’s Biotechnology Sector to Prevent Future Pandemics

To address some of the challenges discussed above, India should consider developing a national program with the right financial and policy structure that invests in training and that has the quality mindset for it to become a global innovator. This would require greater academia-industry collaboration, measures to facilitate access to the market, and continuous dialogue between multiple stakeholders to streamline the regulatory process. This section also highlights measures that can be taken to strengthen India’s domestic biotechnology sector to play an active, even leadership role in collaboration among Global South countries and the broader arena of global public health. Some of these measures are discussed below.

Cultivating a New Generation of Scientists and Entrepreneurs

Universities should invest in focused research programs to develop vaccines, therapeutics, and diagnostics. They should also introduce translational courses with hospitals and other medical institutes to provide technical training to be able to leverage biotechnology to develop new therapies.

To spur innovation and entrepreneurship in the public health sector, special training programs at the educational level can be introduced to ensure that students gain the requisite

skills, including an understanding of the legal and regulatory structures that determine the approval and use of new interventions. This will encourage them to diversify their job prospects by either working for a prospective employer or starting their own health-related venture.

Additionally, technology transfer offices, with strong business development focus groups, should be built in all academic research institutions to ensure that the proprietary knowledge developed by research institutions is licensed and translated to develop products that can solve real-world problems. This capability, complemented with incentives for both academia and industry, will encourage collaboration between the two parties for new seed innovations. This will facilitate the setting up of a research ecosystem that supports and invests in bold ideas to create a new generation of scientists and entrepreneurs who think about the public health applications of biotechnology.

Therefore, modifications to the existing education curriculum to provide research and entrepreneurial training during graduate programs would serve as an incubator for bold ideas and subsequently for public health innovation in India.

Facilitating Access to the Market

Measures should be taken to link innovators with investors to encourage entrepreneurs in the field. Exciting ideas should be supported early, while addressing how they can be commercialized at large scale.

Further, the development pathway should be broken down into different stages wherein different kinds of funders are invited to fund different stages to ensure the commercialization of products—an approach that implies a need for some coordination to ensure that all stages are covered. A larger R&D budget alone cannot secure a quantum leap for innovation in India unless efforts are also coordinated between government and industry to bolster confidence that products that meet established criteria will be allowed market access with predictable timetables and returns. Much can be accomplished, however, if start-ups, other industry segments, the venture capitalist community, and the government share data with one another to strengthen the research and innovation ecosystem in India. This would require a nodal institution that gathers all the data, maintains the requisite databases, and hires people who monitor developments and facilitate cooperation between different communities.

For consistent and long-term research output in the sphere of biotechnology, India should increase its financial investment, both public and private, to enhance the scale of its innovation capacity. Cofunded models, where the government makes an equal contribution as the private fund in a project, can also be explored to sustain investments in the space. Since states in India have their own policies to promote innovation in the biotechnology sector, the inflow of investments will depend on the conduciveness of each state policy to promote

business ventures, the incentives it offers for private capital deployed in research, and the motivation it provides to adopt biotechnology to develop new products.

In addition to promoting entrepreneurial activity and encouraging academia-industry partnerships at the state level, the policies should also enable products that are manufactured in India to find market in India. One of the ways to do this could be for the government to encourage the use of drugs developed locally in government-funded programs, such as procedures paid for by Ayushman Bharat, a national public health insurance fund that aims to provide free access to health insurance coverage for low-income earners in the country. In addition to expanding its domestic market, it is important that each state improves its export performance, thereby opening new markets and better entrepreneurial prospects.

Besides working on the supply side to encourage therapies or drugs to reach the Indian market, it is also important to shape the attitude of potential consumers to accept the advancements coming out of biotechnology research. This requires information and awareness campaigns to improve the social acceptance of the role of biotechnology in improving public health in India. This can be facilitated at the state level by engaging with either social leaders or NGOs who are trained to communicate the applications of biotechnology for public health. Scientists and researchers should also be trained in science communication to expand the outreach of their research.

Ensuring Multistakeholder Engagement

As described in the previous section, there are multiple authorities set up under different ministries that often work in silos, thereby complicating the approval of vaccines and diagnostics in India. Moreover, the regulatory system in India is often not fully conducive to support smaller firms to fast-track approval of potential candidates. Therefore, it is important for Indian researchers, industry, and government to assess the impediments to indigenous discoveries, production, and distribution and create a streamlined regulatory infrastructure through technology like a single-window clearance.

Continuous dialogue among stakeholders, both at the state and the national level, is also necessary to ensure that civil servants in the regulatory systems are up to date with advancements in technology and scientists and industry experts are aware of different regulatory compliances. It is also important to invest in regulators with scientific expertise who understand technology and new innovations. This can be set up either through lateral entries in the system or through external consultants who can advise the government, thereby resulting in timely approvals of new and innovative technology solutions.

India should also expedite the introduction of legislation to replace the archaic Drugs and Cosmetic Act of 1940 to promote the production of safe and effective products in a cost-effective manner. The Indian government has already constituted a panel, headed by the

DCGI, to frame new law for drugs, cosmetics, and medical devices. The panel was supposed to undergo prelegislative consultations, examine the present law, and submit a draft for a revised bill by November 30, but the status of the bill is currently unknown. Rather than the DCGI heading the panel to develop a policy that will affect its own function, a senior official from the Ministry of Law and Justice should be involved to oversee global standards and draft an appropriate legislation for India. Moreover, for comprehensive legislation, it would be beneficial to consult and involve stakeholders like manufacturers, scientists, doctors, and patient groups. This bill can therefore be based on experiences and challenges that each community in the Indian healthcare industry faces and serve as a template for the Global South, showcasing India's regulatory leadership. It is also important for India to seriously consider drafting separate legislations to regulate drugs and medical devices in the country, which in the long run can create a conducive environment for both local and foreign manufacturers to invest in this emerging sector.

India's Role in Global Health Security

India, due to its low manufacturing costs, is recognized as the generic pharmacy of the world. This status can make it an active player in health diplomacy, as was observed during the pandemic when the capacity of Indian companies to manufacture vaccines not only ensured protection of millions in India but also strengthened diplomatic ties with India's neighbors. It is therefore important for the country to draw on its manufacturing capacity to develop products that cater to its own population and that of its neighborhood. Apart from strengthening its manufacturing capacity to develop generics, it is imperative to create a workforce that is invested in R&D along with response and delivery during an emergency.

Further, if India addresses its own health priorities, such as TB or neglected tropical diseases, and strengthens its innovation in diagnostics, it has the potential to help the world. To strengthen its position globally, India should think about global health security as a long-term goal and should invest in an ecosystem that ensures global reliability of products being manufactured in India.

Apart from the traditional hard-line security considerations, health should be at the front and center of India's diplomatic agenda. For a country with thousands of years of investment in health and wellness, India has the potential to collaborate and exchange its experiences at global forums and share best practices in clinical care and management, emergency response, biotechnology, and clinical trial experimentation. India should therefore support its local organizations and pick the right allies for it to establish leadership at the diplomatic level. It should also leverage its regional connections to create a web of cross-learning that is open to sharing lessons learned locally to build scientific prospects for pandemic preparedness and response.

Conclusion

This paper highlights that the coronavirus pandemic has transitioned India's biotechnology sector into a new phase of growth, where new collaborations among different stakeholders is observed to develop indigenous diagnostic kits and vaccines in a short span of time. The paper argues that this collaboration needs to be sustained beyond the current pandemic to ensure that India is ready to prepare for and respond to pandemics in the future. The paper highlights a few challenges that the country faced during the pandemic due to uncertainty in regulations, minimal coordination between different government departments, lack of collaboration between industry and academia, and limited private funding to translate research into useful products.

The paper therefore proposes several steps to ensure a consistent flow of investment and a platform for technology transfer to strengthen India's innovative capacity. Some of them include changes in the regulatory structure to draft separate regulations for medical devices and drugs in India, introduce measures to create a collaborative research ecosystem, ensure availability of funds to facilitate access to the market, and facilitate continuous dialogue between innovators and regulators to minimize the approval times to get a product to market.

About the Author

Shruti Sharma is a senior research analyst with the Technology and Society Program at Carnegie India, where she is currently working on exploring the challenges and opportunities in leveraging biotechnology to improve public health capacity in India.

Acknowledgments

The author is extremely grateful to George Perkovich and Marjory Blumenthal for their input on the paper. The author would like to extend her gratitude to the project's interviewers and contributors for their insights, feedback, and suggestions. The author would also like to thank Anirudh Burman, Priyadarshini D., Konark Bhandari, Rudra Chaudhuri, Alok Kumar, and the Carnegie communications team for their help and input.

Appendix A: How Did Other Countries Expedite Their Approval Process During the Pandemic?

Expedited Approvals of Diagnostics in Other Countries During the Coronavirus Pandemic

Like India, the Food and Drug Administration (FDA) in the United States also announced key actions to expedite access to COVID-19 diagnostics. This included the development of a template on the data and information that the developers need to submit to facilitate the emergency use authorization (EUA) process. As the pandemic spread, the FDA further streamlined its regulatory processes to scale up diagnostic capacity. This included a weekly webinar to answer developers' questions, new and updated information on the website under the Frequently Asked Questions section, and expedited reviews by setting up informal conversations between the developers and the regulators. Such proactive steps enabled the FDA to grant an EUA to the molecular test developed by the Centers for Disease Control and Prevention within twenty-four hours of its submission.⁴⁸

In Europe, the directive 98/79/EC calls on member states to maintain a common and updated list of appropriate COVID-19 rapid antigen tests. This list is regularly reviewed by member states and, if necessary, is updated either with new results from independent validation studies that assess the efficacy of tests with respect to mutations of the SARS-CoV-2 or with any new tests that have been introduced in the market. To further streamline the process to update the list in a more structured and coherent manner, a

technical working group on COVID-19 Diagnostic Tests was set up under the Health Security Committee (HSC) to review the information submitted by member states and manufacturers. The technical working group assesses these proposals against the criteria established under Council Recommendation EU 2021/C 24/01 and additional criteria agreed by experts on September 21, 2021. In case the technical working group is convinced to update the European Union (EU) common list of rapid antigen tests, a proposal is presented to the HSC for a formal agreement. The HSC therefore acts as a platform where agreement between member states is reached for updates to the list. To update the list on a regular basis, the working group meets once every month and updates the list as soon as relevant data that show the safety and efficacy of the test are made available.⁴⁹

Accelerated Approval and Emergency Use Authorization for COVID-19 Vaccines in Other Countries and the World Health Organization

Unlike India, the agency in the United States does not support the request of an EUA without a phase III efficacy study. The FDA issued a guidance document for the industry that outlines nonbinding recommendations for an EUA for vaccines to prevent COVID-19. Any entity with an EUA request should contact the Center for Biologics Evaluation and Research's (CBER's) Office of Vaccine Research and Review as early in the development cycle as possible. In parallel, the entity is recommended to communicate with the CBER's Office of Compliance and Biologics Quality, Division of Manufacturing and Product Quality to discuss issues related to the facility manufacturing the vaccine. For a timely review of an EUA request, the FDA expects a detailed description of the manufacturing process and the controls in an appropriate format, as described in the document. The issuance of an EUA is discretionary and is determined on a case-by-case basis where the FDA is the final approval authority. Early interaction with the agency is, however, critical in the approval process. Vaccine developers who engage with the agency on an ongoing basis during the development and clinical trial program have the benefit of early review and feedback. The review process for an EUA includes a strict check of the manufacturing facility, stringent evaluation of the product quality, and assessment of the trial data. An EUA request for a COVID-19 vaccine includes safety data from phase I and II clinical trials and a median follow-up duration of at least two months from the ongoing phase III studies.⁵⁰

In the EU, the European Medicines Agency (EMA) plays a crucial role in enabling the development, scientific evaluation, approval, and monitoring of COVID-19 vaccines. Any company that wishes to develop a COVID-19 vaccine makes small batches of the vaccine that are first tested in the laboratory for their quality and ability to evoke an immune response. After the *in vitro* studies, potential vaccine candidates are subjected to a three-phase clinical trial, which is authorized and managed at national levels, to ensure their safety and efficacy. For an expedited approval, EMA and regulatory agencies in Europe are diverting their resources to speed up the evaluation and approval of COVID-19 vaccines. EMA also offers informal consultation to COVID-19 vaccine developers on the best methods and study designs to generate robust data. Once all preclinical and clinical studies are conducted

by the vaccine developers, the companies submit all testing data to EMA, which then carries out scientific evaluation of the vaccines. The European Commission then reviews EMA's scientific opinion and grants an EU-wide marketing authorization if the results are satisfactory. After marketing authorization, the national authorities decide on introduction of the newly approved vaccine and vaccination policies.⁵¹

The World Health Organization (WHO) as part of its Emergency Use Listing pathway also assesses data from late phase II and phase III clinical trials, in addition to substantial data on safety, efficacy, quality, and risk management, before approving the vaccines for medical purposes. Therefore, any company producing the vaccine needs to generate data to enable full licensure and WHO prequalification of the vaccine candidate for its market authorization. Sometimes the protocol also requires the WHO technical advisory group to visit the manufacturing facility to examine the manufacturing practices.⁵²

Appendix B: Closed-Door Discussions

Workshop on the Role of Biotechnology in India's Fight Against the Coronavirus Pandemic

Date: April 23, 2021

Objective: India's contribution toward the global fight in tackling the coronavirus pandemic has given the country an opportunity to evolve from being the pharmacy of the world to being at the center of cutting-edge research. The session discussed the impact of the pandemic on India's biotechnology industry and prospects for future growth.

List of Participants

1. Ms. Anu **Acharya**, Founder and CEO, Mapmygenome
2. Dr. Debojyoti **Chakraborty**, Senior Scientist, Institute of Genomics and Integrative Biology
3. Dr. Raman **Gangakhedkar**, former head of epidemiology and communicable diseases, Indian Council of Medical Research
4. Mr. Kamal **Gottimukkala**, Consultant, New and Emerging Strategic Technologies Division, Ministry of External Affairs
5. Mr. Sameer **Guduru**, Consultant, NEST, Ministry of External Affairs
6. Mr. Rohan **Kamat**, Head of Discovery, Immuneel Therapeutics
7. Dr. Gagandeep **Kang**, Professor, Christian Medical College

8. Dr. Nupur **Mehrotra**, Co-founder & Chief Operating Officer, Premas Biotech
9. Dr. Shambhavi **Naik**, Fellow, Takshashila Institution
10. Dr. Anu **Raghunathan**, Senior Principal Scientist, National Chemical Laboratory
11. Mr. Hasmukh **Rawal**, Managing Director, Mylab
12. Dr. Taslimarif **Saiyed**, Director and CEO, Centre for Cellular and Molecular Platforms
13. Dr. Krishna Ravi **Srinivas**, Consultant, Research and Information System for Developing Countries

Workshop on Strengthening India's Biotechnology Sector to Prevent Future Pandemics

Date: July 15, 2021

Objective: Given the long history of infectious diseases in India, the scientific community in the country has accumulated years of experience and knowledge to prevent and treat them. The session assessed the need to invest significantly in strengthening these capabilities to give a fresh impetus to research into infectious diseases.

List of Participants

1. Ms. Anu **Acharya**, Founder and CEO, Mapmygenome
2. Ms. Marjory **Blumenthal**, Director, Technology and International Affairs Program, Carnegie Endowment for International Peace
3. Mr Vishal **Gandhi**, Founder and CEO, BioRx Venture Advisors Private Limited
4. Mr. Kamal **Gottimukkala**, Consultant, NEST, Ministry of External Affairs
5. Dr. Neeraj **Jain**, Country Director, PATH India
6. Dr. Gagandeep **Kang**, Professor, Christian Medical College
7. Dr. Nupur **Mehrotra**, Co-founder and Chief Operating Officer, Premas Biotech
8. Dr. Shambhavi **Naik**, Fellow, Takshashila Institution
9. Dr. George **Perkovich**, Vice President for Studies, Carnegie Endowment for International Peace
10. Dr. Anu **Raghunathan**, Senior Principal Scientist, National Chemical Laboratory
11. Dr. Taslimarif **Saiyed**, Director and CEO, Centre for Cellular and Molecular Platforms
12. Mr. Abhishek **Sethi**, Co-founder, gradCapital

13. Dr. Krishna Ravi **Srinivas**, Consultant, Research and Information System for Developing Countries
14. Mr. Sunil **Thakur**, Partner, Quadria Capital

Workshop on India's Contribution to Global Health Security

Date: September 3, 2021

Objective: In addition to catering to local health needs, the products derived through India's biotechnology sector are slowly gaining ground in the global marketplace. The session examined how India can leverage its soft power by encouraging biotech firms to develop low-cost healthcare products relevant to both domestic and global needs.

List of Participants

1. Ms. Anu **Acharya**, Founder and CEO, Mapmygenome
2. Ms. Marjory **Blumenthal**, Senior Fellow and Director, Technology and International Affairs Program, Carnegie Endowment for International Peace
3. Mr. Vivek **Chandra**, Head of Global Business Development, Premas Biotech
4. Dr. Neeraj **Jain**, Country Director, PATH India
5. Dr. Gagandeep **Kang**, Professor, Christian Medical College
6. Dr. Kayla **Laserson**, Deputy Director, Infectious Diseases, the Bill and Melinda Gates Foundation
7. Dr. Dhvani **Mehta**, Co-founder and Lead, Health, Vidhi Centre for Legal Policy
8. Dr. Shambhavi **Naik**, Fellow, Takshashila Institution
9. Dr. Roderico H. **Ofrin**, WHO Representative to India
10. Ms. Sangita **Patel**, Director, Health Office, USAID/India
11. Ms. Priti **Patnaik**, Author, Geneva Health Files
12. Dr. Anu **Raghunathan**, Senior Principal Scientist, National Chemical Laboratory
13. Dr. Taslimarif **Saiyed**, Director and CEO, Centre for Cellular and Molecular Platforms
14. Dr. Krishna **Srinivas**, Consultant, Research and Information System for Developing Countries

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