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Strategic Linkages and Institutional Learning in India's STI Response to COVID-19: A Case Study of the Genome Valley Life Sciences Cluster

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The COVID-19 pandemic posed a new challenge for the world. While India, along with numerous other nations faced significant health and economic disruptions, a new opportunity emerged for Indian firms and research organisations to address the challenges and position themselves as key global players, particularly in vaccine development, diagnostic tools, and protective gear. This study is situated within this broader context. India, despite its structural limitations in its science, technology, and innovation (STI) ecosystem, responded in various ways to deal with the challenges created by this pandemic. The paper investigates India's pandemic response by highlighting key mitigation measures that had a major impact on pandemic containment. Further, it examines in depth the case of Genome Valley, focusing on the Indian firm Bharat Biotech, which developed the vaccine Covaxin. Using the analytical lens of the 'Triple Helix framework', the study highlights the importance of synergetic linkages among government, academia, and industry in enabling coordination, knowledge co-production, and innovation that led to successful innovations under these challenging conditions. The study also highlights the key role played by two specialised clusters, the Tiruppur textile cluster and the biopharma cluster Genome Valley, in meeting the pandemic challenges. Government emerges as a key facilitator in bridging funding gaps, addressing regulatory challenges, and fostering collaborative platforms. Key policy lessons that emerge from this study are the need to create and strengthen institutional mechanisms that can enable strong linkages among different stakeholders, including triple helix linkages for strengthening innovation ecosystems, building absorptive capacity, and ensure policy directionality.

Keywords: Covaxin, Innovation cluster, Open innovation, Triple helix model, University-industry linkage

Introduction

The world encountered an unparalleled global health emergency due to the COVID-19.[(1)] Although different actions like quarantine and lockdowns were implemented to contain the spread of COVID-19, cases of infection continued to surge considerably. This caused immense pressure on the health care infrastructure and unfavourable socio-economic effects globally, including in OECD nations. This situation needed a synchronised action globally to develop a drug/vaccine quickly with increased manufacturing capacity, and having a logistic network catering to global needs. It also called for synergising the efforts of each country for the effective containment of the pandemic, improving health care support systems, among others. One of the key challenges was to uncover the causes of this disease, how it targets the human body, and to draw leads from scientific research for drug/vaccine development. A 'new normal' emerged for resetting the timelines. The new vaccines came up within one and a half years or so, reducing the time period, which is, on average, 8–10 years for drugs and 10–15 years for vaccines. This was possible because of extensive global research, which has yielded new drug/vaccine candidates and novel partnerships across the research and innovation value chain.[2,3] Pharmaceutical companies collaborated with academia and R&D organisations, and connected with manufacturers so that the vaccine/drug could enter the market at the earliest. Robust multilateral initiatives, philanthropic backing, and collaborative public-private partnerships were instrumental in addressing research, innovation, manufacturing, and supply value chains.[4]

On the other hand, vulnerabilities in translating S&T infrastructure into more proficient public health solutions, the lack of focused research and innovation, and policy coordination were identified as key impediments to tackling the challenges created by the pandemic and preparing for future crises.[5,6] A significant asymmetry in global biomedical and health knowledge platforms, along with weak governance and poor coordination between STI and public health

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approaches, was observed. The development of viable strategies that would effectively exploit a country's capabilities was seen as a crucial enabler in countering the COVID-19 pandemic.[7] The restricted access of laboratory facilities due to lockdowns and interruption of research projects severely affected global S&T activities.[8] Concern was raised that the COVID-19 pandemic could inflict lasting harm on innovation systems precisely when the science, technology, and innovation were most crucial to address the climate crisis, achieving the SDGs, and drive digital transformation. This highlighted the need for measures to support innovation systems through stimulus and recovery packages.[5,6] Positive perspective also emerged, arguing that COVID-19 created opportunities for greater social inclusiveness within STI systems, enabling individuals, regardless of socioeconomic background, age, gender, ethnicity, religion, or place of residence, to contribute in research and innovation activities and to benefit from them. The pandemic highlighted the capacity of scientists, industries, and the public sector to take swift and coordinated action in addressing public health challenges.[9] Notably, there was active engagement from a wide range of stakeholders within the STI ecosystem, who contributed to developing innovative solutions, offering policy guidance, enhancing collaboration, and educating the public on scientific aspects to combat both the pandemic and misinformation.[6] These studies collectively demonstrated that the pandemic served as both a challenge and an opportunity for STI systems, stimulating innovation and creating new mechanisms for translating science into effective responses.

Like most countries, the COVID-19 pandemic spread rapidly across India, posing an unprecedented public health challenge for the world's most populous country. In its vast, densely populated regions, the virus affected millions and placed immense pressure on the healthcare system. The scale and diversity of India's population made containment, treatment, and vaccination particularly complex. This called for swift, innovative, and large-scale responses across policy, healthcare, and technology domains. India epitomises, to a large extent, the challenges of South-South countries. Thus, a close examination of India's response provides good learning lessons and prepares it further to address global challenges like this pandemic. The study is motivated by this.

Research Objectives

Various studies have drawn attention to how COVID-19 has widened inequalities between high- and low-income populations in terms of access and affordability of effective interventions. India is a crucial player in the world's generic drug market and among the largest producers of vaccines globally. It has, over the years, played a key role in addressing this imbalance of drug and vaccine access and affordability. India, however, does not have a robust STI ecosystem and a governance framework, and a disconnect is visible between the innovation system and the manufacturing and production sectors. The literature on India's innovation system has consistently identified these structural constraints. It has, among others, drawn attention to low R&D intensity, limited private sector participation, weak academia–industry linkages, and uneven regional distribution of innovation capabilities, which together constrain the translation of scientific knowledge into industrial and technological outcomes.[10,11] This is also reflected in policy analyses, which highlight that India's STI ecosystem and governance framework remain relatively underdeveloped.[12,13] A few studies have examined how crisis conditions reconfigured linkages within India's STI system.[14] Thus, within this context, how India responded to address the pandemic challenges can provide important insights and learning lessons, particularly for South Countries. Major research questions that the study explores:

- How did the COVID-19 pandemic reshape the innovation landscape in India, particularly within the life sciences and healthcare sectors?
- What role did India's innovation clusters, such as Genome Valley, play in mobilizing R&D and manufacturing capabilities?
- What lessons can be drawn from India's experience in responding to the COVID-19 pandemic?

Framework and Research Methodology

Analytical Framework

The conceptual and analytical framework of this study is based on the Triple Helix model, which focuses on the relations among university, industry, and government.[15] This framework highlights a structural shift towards a triadic and hybridized relationship among these three institutional spheres, observed behind many successful innovations.[16] The model emphasizes that such collaboration is not incidental but a systemic feature of knowledge economies, particularly reflected in innovations emerging from strong science–technology interfaces. The Triple Helix framework was adopted for this study because the nature of the COVID-19 pandemic demanded a coordinated and enabling ecosystem of university, industry and government working together in close partnership; calling for each of the entities to increasingly assume overlapping roles.[17]

Method

The study was multi-source qualitative inquiry. The key interventions for prevention and containment of the pandemic were uncovered based on analytical deconstruction from diverse secondary sources such as research papers, reports, including company reports, newspaper articles, clinical trials, and policy documents. Further, a case study was done for India's major life science cluster, Genome Valley, which played a key role in vaccine development.[18] Closer examination was undertaken of the firm Bharat Biotech International Limited (BBIL), located in Genome Valley, which contributed to the development of the indigenous vaccine Covaxin, by tracing and analyzing the paths taken to develop it, scaling, and production.[19] Additional insights were obtained from a structured brainstorming workshop with experts.

Data Sources

Information was collected from diverse sources to uncover the Indian actors involved in vaccine research and development, in developing various interventions, policy strategies, collaboration linkages, and other aspects that covered the mitigation efforts during the pandemic. Web of Science, Scopus, and Google Scholar databases were used to retrieve research papers from India that addressed the COVID-19 pandemic. This was supplemented by retrieving Clinical Trial information from the Clinical Trials Registry- India (CTRI).[20] Information was also collected from the life sciences firms' official websites and other sources, such as government reports and newspapers, regarding vaccine development, action plans initiated, among others. The Government of India websites, such as those of the Ministry of Health and Family Welfare[21], the Indian Council of Medical Research (ICMR)[22], and the Central Drugs Standard Control Organization (CDSCO)[23], were screened for guidelines and directives issued to govern and regulate changes implemented during COVID-19. The information collected was systematically analysed in line with the objectives of the study.

The authors also had interactions with some of the prominent actors in the network. This was facilitated by organising a brainstorming meeting titled 'Study of Life Sciences cluster in the context of COVID-19: A case study of Genome Valley' on 09 February 2023 at CSIR-NIScPR.[24] The experts in the brainstorming meeting were Prof. Suma Athreye, School of Public Policy, IIT Delhi; Dr. Taslimarif Saiyed, CEO and Director, Centre for Cellular and Molecular Platforms (C-CAMP), Bengaluru; Dr. Srikrishna S R, Advisor - Health Care Projects, IKP Knowledge Park; Dr. Kalaivani Ganesan, Scientist, Department of Biotechnology (DBT), New Delhi. Brainstorming was structured in a way to get the views of academia, cluster incubators, and government, representing the key actors of the Triple Helix, together. The brainstorming interaction served as an expert consultation to validate and contextualise the findings.

Results

Indian STI Ecosystem Response

The urgent challenge before the country was to overcome the scarcity of healthcare facilities and accelerate the R&D efforts for the development of diagnostic kits, face masks, Personal Protective Equipment (PPE) kits, development of effective vaccines, and therapeutic treatments. A governance mechanism was created as a first strategic step by the Government of India to tackle the unprecedented crisis that emerged due to the COVID-19 pandemic. It brought together on one platform several ministries and their departments, R&D institutions, reputed research organisations and universities, MSMEs, firms, etc. This was done to reduce the communication gaps, facilitate better coordination among the stakeholders, identify critical gaps, create novel programmes and funding mechanisms, and address various regulatory issues effectively.

The governance mechanism helped to create an enabling ecosystem that could address many of the challenges. A good example of this was the production of PPE kits during the pandemic. The pandemic had created an exponential requirement for these protective gears, but there was a great shortage globally.[25–27] In 2019, the global PPE market was \$52.7 billion and was estimated to be about \$92.5 billion by 2025.[28] India faced a severe shortage of PPE Kits. A key enabler for production of PPE kits was the partnership that was established between South India Textile Research Association (SITRA), an industry-sponsored institute supported by the Government of India, and the Defence Research & Development Establishment (DRDE), Government of India. This collaboration was instrumental in developing technical guidelines for PPE, standardizing testing and certification protocols, and establishing a national network of accredited testing laboratories.

With coordinated support from both the Government of India and the Tamil Nadu state government, the necessary infrastructure and incentives were provided to create a full-fledged production system for PPE Kits in Tiruppur, India's largest textile cluster. This created a lifeline and new opportunity for this cluster, estimated to have 28,000 manufacturing firms that include 3200 MSMEs that were facing severe economic challenges due to the ongoing pandemic. This exhibited a very structured pathway that brought together government, research institute, and industry in close partnership, a Triple Helix hybrid linkage. It created a standardised testing protocol, codification of quality standards, an accreditation mechanism, and a supply chain for production and scaling.

This also catalysed other SMES across India to manufacture face masks, including N95 variants and other PPE components, to meet surging domestic and global demand. This helped to address the critical gap in this in the country, and also led to India emerging as the second-largest producer of PPE kits globally, with nearly 30% of N95 masks exported.[29] The government's enabling role in policy coordination, creating the value chain, and addressing the demand gap can be seen as a key driver in addressing the critical gap for the first line of defence for containing and spreading the COVID-19 virus.

A severe shortage of life-saving medical equipment was required for critically ill patients, like oxygen concentrators, antigen testing kits, and ventilators, globally and in India.[30,31] Another critical requirement was for ventilators. India was dependent on importing ventilators from Europe and China. As of February 2020, ventilators were being manufactured by only eight firms in India. The Government of India created the needful facilitation to create partnerships to scale up ventilator manufacturing. Two useful partnerships were created, one with Bharat Electronics, a Government of India enterprise, and Skanray Technologies, and another between AgVa Healthcare and a major automobile company, Maruti Suzuki. This led to the manufacture of about 40,000 ventilators by the end of May 2020. Ventilator production increased from 2,500 (February 2020) to 5,500–5,750 (March 2020). By June 2020, about 1,000 ventilators were being manufactured daily.[32] The government and industry collaboration partnership was thus a driving factor in addressing this critical life-saving medical equipment, i.e., ventilators, to a large extent.

The Indian government also played a crucial role by making timely and appropriate regulatory frameworks and decisions, like the notification of CDSCO recommendations for drug and vaccine approval in the 2019 gazette, whereby emergency approval can be given based on Phase 2 results if the vaccine is developed using an established platform and whose safety has been proven.[33] DBT, Government of India came out with a Rapid Response Regulatory Framework for COVID-19 to deal with applications relating to developing vaccines, diagnostics, prophylactics and therapeutics in March 2020. It specified the time for fast-track response and regulatory approval. Guidance notes for the same were given in May 2020.

The government emerging as a key catalyst can be uncovered from various other effective interventions. The Government of India, Department of Science and Technology (DST), 'DST-SERB' (Science and Engineering Research Board) brought out special funding calls to accelerate the research efforts on priority. The DST-TDB (Technology Development Board) called project proposals from Indian companies and enterprises for making indigenous and affordable devices to cater to the safety and home-based respiratory intervention for COVID-19 patients.[34] NIDHI4COVID 2.0, an initiative by DST- NSTEDB (National Science & Technology Entrepreneurship Development Board), supported start-ups driven solutions and innovative products to combat the pandemic. NSTEDB supported R&D efforts and innovation in the areas of diagnostics, devices, informatics, and any intervention to contain COVID-19 and/or start-up ideas. The DST scouted and supported start-ups that showed promising interventions to address the pandemic challenge, helping them to rapidly scale their technologies and expedite deployment. Several digital initiatives were also launched by the Government of India. An integrated geospatial platform and analytic tool was developed by DST to guide decisions during the pandemic and help to develop the targeted interventions to combat the socio-economic impact throughout the recovery phase. The 'SAHYOG' mobile application along with a web portal were created to gather COVID-19-specific geospatial datasets via community participation enhancing the Government of India's efforts. Also, the

Government introduced 'AAROGYA SETU', mobile app to facilitate contact tracing, raise public awareness, and enable self-assessment. A web-based solution, 'Aarogyapath', for the healthcare supply chain was launched by CSIR that provides the real-time availability of critical healthcare supplies and connects the manufacturers, suppliers, and customers. The strategic and enabling role of the government during the pandemic is visible from these interventions.

The IDEA-V initiative supported by the Office of the Principal Scientific Adviser (PSA) to the Government of India, was a COVID-19 vaccine communication and community engagement programme aimed at addressing vaccine hesitancy and strengthening public awareness during the vaccination phase of the pandemic. The IDEA-V initiative also reflects elements of a Quadruple Helix configuration, where the STI response extended beyond university–industry–government linkages to include civil society through community engagement and vaccine communication efforts.

The various instances show the key role of the government in providing support in varied ways, and linkages among the stakeholders are instrumental in making a fast response possible. The coordinated responses showed the development of a Triple Helix configuration of academia-industry-government. The government played an active coordination role, moving from arm's length to a key player in the whole value chain. On the other hand, research institutions engaged more directly in translational activities, and firms actively partnered with government and research institutions in the whole value chain. These developments represent more than administrative facilitation. The creation of fast-track approval pathways, time-bound review mechanisms, and formal guidance notes reflects the development of new regulatory routines under crisis conditions. They indicate adaptive institutional learning within India's regulatory body, primarily policy and inter-organisational learning.[35] It also demonstrates an enhanced capacity for coordinated decision-making across ministries and regulatory bodies, signalling institutional learning at the level of governance restructuring. However, this can be seen as a quasi-arrangement driven by urgent emergency response due to the pandemic.

Brainstorming with some of the key factors involved in mitigating the pandemic provided further insights into the challenges, how they were addressed, and underscored some of the strategic linkages and institutional learning that happened. Prof. Suma Athreye provided valuable insights on clusters, their advantages, and how they help shape collaborations. She highlighted the various institutions that are visible in the top clusters globally in the whole value chain. She said that the pandemic showed many positive instances in India, and particularly in the life science cluster Genome Valley. This was instrumental in many successful outcomes, including the first indigenously developed vaccine, the Covaxin. She emphasized the need for quality control in drug and vaccine manufacturing facilities, which she felt was a matter of concern. Dr. Srikrishna drew attention to IKP Knowledge Park, which he highlighted is a key intermediary within the Genome Valley cluster. He underscored that IKP acts as a glue and plays an important role in facilitating coordination, incubation, and knowledge exchange among startups, research institutions, and industry actors in the Genome Valley. The role of IKP was significant in bridging many of the disparate activities together in Genome Valley and connecting to the STI and production ecosystem during the pandemic.

Dr. Taslimarif Saiyed drew attention to the important intermediary role played by C-CAMP, a DBT-supported life-science innovation hub, during the COVID-19 pandemic. Underscored several initiatives that it had taken to accelerate indigenous innovation and deployment of solutions. These included the COVID-19 Innovations Deployment Accelerator (C-CIDA), which screened more than 1,000 proposals and supported a select set of start-ups working on diagnostics, ventilators, and digital health solutions by facilitating regulatory navigation, pilot deployment, and manufacturing partnerships. In addition, the C-CAMP COVID Fund was created to provide catalytic financial support to promising pandemic-related technologies, while the IDEA-V initiative focused on strengthening vaccine awareness, training, and community engagement during the vaccination phase. Thus, C-CAMP became an important enabler, as a key intermediary linking start-ups, research organisations, industry partners, and government agencies, thereby facilitating the rapid translation of scientific knowledge into deployable solutions during the crisis. On the other hand, the experience during COVID-19 brought into focus the need to develop indigenous testing kits that meet global standards and are cost-effective during a pandemic in a short time frame.

Dr. Kalaivani Ganesan highlighted the Indian government's efforts to realize scientific potential to overcome COVID-19 and noted the coming together of various entities. Highlighted coordinated mechanisms and actions that could be taken very quickly, which were demanded by the COVID-19 pandemic. Firms were given various forms of support, including regulatory support. At the same time, it was seen that benchmarks were not diluted. Highlighted this in the context of testing kits that were developed, which showed initial promise, but during scaling up, did not perform accurately and hence were not promoted and were thus not in the market. Monitoring mechanisms were created to see that PPE kits produced were conforming to the standards that were developed through a strong partnership with the central and state governments and the public enterprise. From these experiences, one can draw indications that it strengthened institutional learning in various ways, particularly through the creation of mechanisms for technology scouting, rapid evaluation, regulatory coordination, and collaboration across different actors within the STI ecosystem, even if many of these arrangements emerged in response to the immediate crisis.

Drug Development

A 'new normal' emerged globally, urging to reduce the time period for drug development and vaccine development to less than a year as compared to earlier 8 to 10 years for drugs and 10 to 15 years for vaccines. This led to a strong policy push by different governments globally, developing strategic linkages in the global pharmaceutical/biopharmaceutical value chain.[36] Various novel instruments were developed, creating innovative funding arrangements, fast-tracking regulatory process, involving numerous agencies, and multilateral entities led by the WHO, striving to develop a global platform. Substantial funds from private financing entities, emergence of strategic connections throughout the research and innovation value chain—spanning firms, academia, research institutions, start-ups, and global partnerships—became evident. Indian firms and universities/research organisations were actively involved in the whole drug development and production value chain. These interventions were instrumental in developing important partnerships in the whole value chain, i.e., research-development-innovation and manufacturing.

India also had significant support from various global initiatives. Indian Institute of Science (IISc) received funding support from the Bill and Melinda Gates Foundation for research on characterisation and designing a number of spike protein derivatives. The Gates Foundation, along with GAVI Alliance (Global Alliance for Vaccines and Immunisation) helped in enhancing the production capacity of Serum Institute of India's (SII), the world's largest vaccine producer. Similarly, various partnerships developed between a public-funded research organisation, CSIR (Council of Scientific and Industrial Research, a chain of 37 laboratories), universities, and pharmaceutical firms. A good example of this was the partnership between CSIR-Indian Institute of Integrative Medicine (CSIR-IIIM), Jammu, and Cadila Pharmaceuticals, to test an immune modulator, Sepsivac. Sepsivac contributed to enhancing the innate immunity of the body, limiting the spread of the virus and recovery of critically ill patients.

Various partnerships were established by Indian firms with global drug companies and research institutes. Among them was the Serum Institute of India (SII)'s early stage partnership with AstraZeneca for undertaking production of the vaccine co-invented by the Oxford University and its spin-out company Vaccitech. Scaling up the production process to address the large demand of an effective COVID-19 vaccine in India and other countries was possible for AstraZeneca due to this partnership. It helped to address the critical gap for COVID-19 vaccine particularly in lower- and middle-income countries. SII also forged many strategic collaborations. It collaborated with Codagenix (American Biotech Company) for developing a live attenuated vaccine. It also developed a partnership with Novavax for the development of a recombinant nanoparticle protein-based COVID-19 vaccine. Emergency use authorization (EUA) of the recombinant nanoparticle protein-based COVID-19 vaccine, named COVAX, was given in India. The Philippines also procured 30 million doses from SII.

These developments reinforce the importance of the 'Triple Helix' configuration for successful innovation and translation. At the same time, the involvement of global philanthropic organisations and international partnerships draws attention to the increasingly transnational nature of the innovation process; domestic capabilities complemented by collaborations at global levels.

Case Study of Genome Valley

Genome Valley, a major life science cluster in India, played a key role in addressing the vaccine challenge.

It is India's first organized biosciences cluster and hosts over 200 pharma/drug firms, including major Indian vaccine manufacturers such as Shanta Sanofi, Bharat Biotech International Limited, Indian Immunologicals Limited, and Biological E. Limited.[37] Some major drug/pharma MNCs like Novartis, AMRI, DuPont, Aizant, and Daichi are also located in this cluster. Genome Valley contributes over 65% of India's domestic supply and exports worldwide. The Genome Valley also houses a unit of the US Pharmacopoeia, one of the first outside the US. Genome Valley has knowledge parks, special economic zones (SEZs), multi-tenanted laboratory, incubation hubs, office spaces, and a range of support services. It also has other specialised firms, such as contract research organisations like Sai Life Sciences, Synchron Research, Vimita Labs that offer preclinical, clinical trial, regulatory, and pharmacovigilance services, Contract Development & Manufacturing Organizations like Lonza, Laurus Labs, GVK Bio (now Aragen) that provide end-to-end drug development and production support.

To meet local and global needs, the cluster is highly dependent on entrepreneurial efforts that link with other knowledge actors and institutions.[38] Genome Valley also has six of the 10 major R&D firms and three of India's largest vaccine manufacturers (Fig. 1).

Vaccine development is a complex, risky, and time-intensive process. The different phases involved in the vaccine development include: i) Exploratory stage/Drug discovery, ii) Preclinical trials, iii) Clinical development (Clinical trials Phase I-III), iv) Regulatory approval, v) Pharmacovigilance (Clinical trial Phase IV). Normally, the time taken to develop a successful vaccine may take anywhere from 10 to 15 years or more, as it includes extensive research and regulatory approvals. A few companies invest in developing a novel vaccine/drug, as the uncertainty involved is high and may lead to failure at any of the phases.

One of the key responses to COVID-19 from India was the development of an indigenous vaccine, Covaxin, within a year by Bharat Biotech International Limited (BBIL), located in Genome Valley. This vaccine helped to significantly address the vaccine shortfall, was cost-effective, and was also exported to a large number of countries. The Indian government also created various mechanisms for easy availability and access at low cost to many South-South countries, also sometimes at no cost.

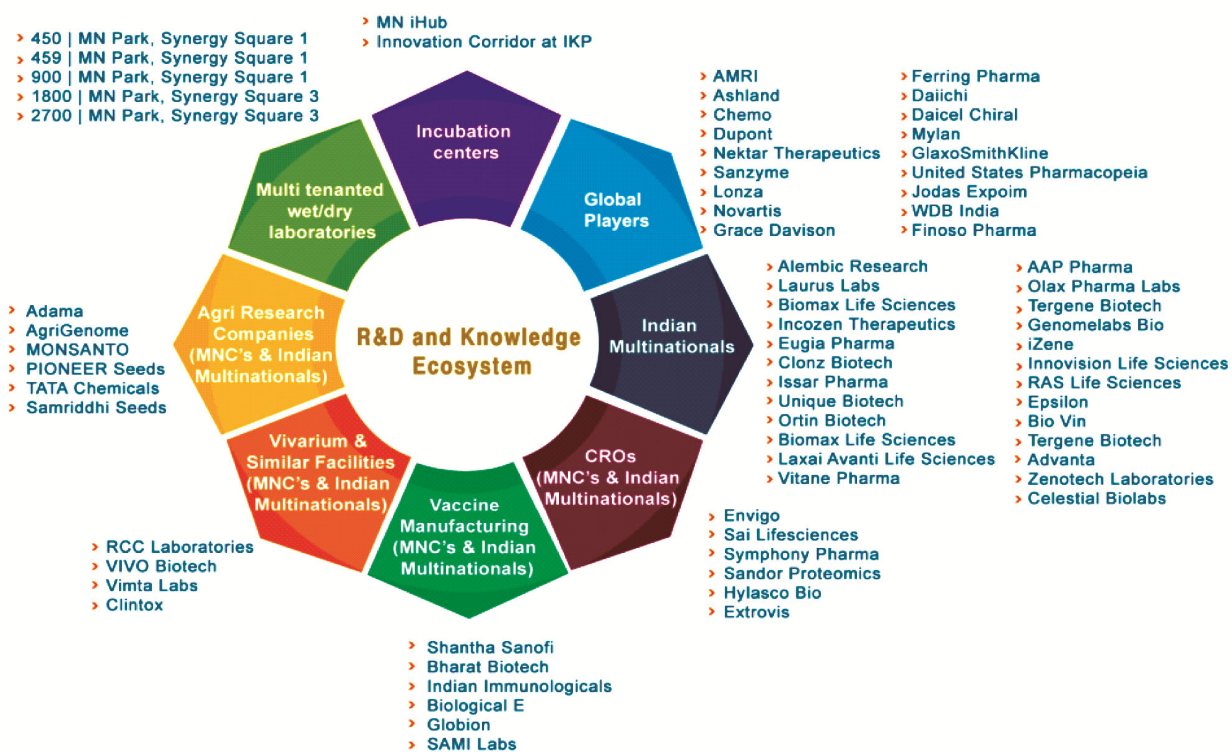

Fig. 1 — The global and national players in Genome Valley

Source: http://genomevalley.co/KeyOrganizations.html (assessed on 1st October, 2021)

Development of the vaccine was the result of many strategic collaborations and partnerships. The key enabler was the partnership with the Indian Council of Medical Research (ICMR). In March 2020, the vaccine strain was isolated by the National Institute of Virology (NIV), Pune, which has a Bio-Safety Level 4 lab. The vaccine has an adjuvant, Alhydroxiquim-II of ViroVax, USA. This adjuvant was developed with the funding support of the National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Health (NIH), part of the US Department of Health and Human Services. BBIL and Virovax entered into an agreement in 2019 after a meeting coordinated by NIAID under the aegis of Indo-US Vaccine Action Program for the use of the adjuvant for vaccine development. During the COVID-19 pandemic, this collaboration was extended for the use of Adjuvant in Covaxin. BBIL collaborated with the CSIR-Indian Institute of Chemical Technology (IICT), Hyderabad, which developed the synthetic route with indigenous chemicals for the agonist molecule that helped in scaling up the adjuvant production.[39] ICMR-NIV conducted the pre-clinical challenge studies in mice, hamsters, and *Rhesus Macaques*. BBIL and ICMR also undertook a study to check the vaccine efficacy against the UK strain, which was financially supported by the Ministry of Family Health and Welfare and ICMR. In January 2021, the Drugs Controller General of India (DGCI), Government of India granted restricted Emergency Use Authorization (EUA) for Covaxin. The clinical trials were conducted in India. In July 2020, the DCGI approved the vaccine candidate for human trials.

BBIL hired a Clinical Research Organisation (CRO) for trial monitoring, insurance, and laboratory testing during the Clinical Trials, and funded Phases I and II of the clinical trials. ICMR also funded the Phase III of the clinical trials. BBIL undertook the Phase 1 (sample 375) and Phase 2 (sample 380) clinical trials (CTRI/2020/07/026300) in 12 different hospitals and medical institutes spread across 11 states of India. The phase 3 clinical trial (CTRI/2020/11/028976) was completed with an enrolment of 25800 participants and involved 26 hospitals, universities, and government institutes. All the three trials were published in *The Lancet* and *The Lancet Infectious Diseases*[40–42] CROs in Genome Valley provided key support for the clinical trials. In May 2021, DCGI approved clinical trials in the age group of 2 to 18 years. Further, in June 2021, Bharat Biotech announced that it had started the Phase 4 clinical trials. The emergency use listing (EUL) for COVAXIN was issued by WHO on 3 November 2021, which certified that COVAXIN meets its standards for safety and efficacy, allowing for its use globally.

The whole value chain is a strong demonstration of the Triple Helix that enabled rapid vaccine development and deployment; the key actors being the industry (BBIL), public research institutions (ICMR, CSIR-IICT), and government agencies (DBT, MoHFW, DCGI). It also underscores the importance of strategic linkages in shaping and translating innovation. Adaptive coordination, emerging routines, and regulatory flexibility under crisis conditions show elements of institutional learning.

Various rapid decisions were taken by BBIL to increase capacity and scale during this period. BBIL acquired Chiron Behring Vaccines, located in Ankleshwar, from GlaxoSmithKline Asia in February 2019. The plant was manufacturing a WHO pre-qualified rabies vaccine based on inactivated Vero cell platform technology. In May 2021, BBIL announced that it would use the Ankleshwar plant to manufacture Covaxin, which is based on similar technology. To further enhance the manufacturing capacity, BBIL inked an agreement with Indian Immunologicals Limited, a public sector enterprise located within Genome Valley, in April 2021 to manufacture and supply the Covaxin drug substance to BBIL. To undertake this task, Indian Immunologicals Limited repurposed its BSL-2+ facility manufacturing anti-rabies vaccines to BSL-3 at Karakapatla in Genome Valley, and it commenced the delivery of the drug substance to BBIL in August 2021. Also in April 2021, the Government. of India, under the Mission 'COVID Suraksha', announced that BBIL will get about US$ 8.75 million approx. to repurpose its Bangalore facility to increase Covaxin production. This enabling support had a significant impact on scaling production.

In addition, three other public sector enterprises, namely Indian Immunologicals Limited, Haffkine Biopharmaceuticals Corporation Ltd, and Bharat Immunologicals and Biologicals Corporation Limited, were given grants by the Government of India of US$ 8.08 million, 8.75 million, and 4.04 million, respectively, to increase their vaccine manufacturing capacity for Covaxin production. To further enhance the Covaxin manufacturing capacity, the DBT, Government of India, assisted in the technology transfer of Covaxin production to three institutes in Gujarat, namely OmniBRx Biotechnologies Pvt. Ltd., Hester Biosciences, and Gujarat Biotechnology Research Centre, DST, Government of Gujarat. On a global level, Ocugen Inc., US, entered into an agreement with BBIL to co-develop and commercialize the Covaxin in the US in December 2020. Later in June 2021, this agreement was further extended, and Ocugen got exclusive rights to market Covaxin in Canada also. BBIL also received the Good Manufacturing Process (GMP) certificate from Hungary for Covaxin in August 2021. Thus, a clear pathway emerged that enabled significant scaling up of vaccine production, bringing together industry and government through coordinated interventions. This phase reflects the operational strengthening of strategic linkages and coordinated action within the innovation system, while also indicating emergent forms of capability alignment across institutions, without necessarily implying their long-term institutionalization.

Discussion

Within a short period of two months from the first COVID-19 case detected, the WHO had declared it a global pandemic. Due to its rapid transmission among humans, the emergence of different strains of the virus, and the fact that it was a new infectious disease, it posed a challenge to contain the pandemic. The virus was so contagious that it required healthcare workers to wear PPE kits and people to wear protective gear like masks and gloves. The pandemic compelled different countries to develop effective strategies for properly exploiting their resources for the containment of the disease and its prevention.

India also faced a severe challenge in containing the disease and preventing it. India epitomises to a large extent the challenges of South countries. In spite of a weak STI ecosystem in comparison with OECD countries, India has played a key role in developing generic drugs that have effectively been instrumental in providing a valuable support system for access to affordable vaccines and drugs globally. In many challenging crises, like combating the AIDS epidemic, India has played a very important role. It supplies nearly two-thirds of the world's antiretroviral drugs, making it a cornerstone in global HIV/AIDS treatment efforts. COVID-19 thus called for an effective response from India to address this global challenge of the pandemic. India responded in various ways that created a support system for India and many countries, especially South countries, for containing this pandemic.

The study draws attention to some of the important interventions done by India. Among them was the development and scaling up of the PPE Kits, ventilators, other life-saving equipment, the development of a vaccine, etc. Study highlights the innovation and partnerships developed between Indian firms and research organisations, with the government playing an enabling role. This could make a significant impact within a short time. Developing regulatory guidelines for PPE kits, facilitating SMEs, helped in producing huge volumes of PPE kits. The scarcity of PPE kits steered India to emerge as the second-largest producer of PPE kits globally. Similarly, the government helped forge partnerships between manufacturers for ventilator development, large-scale genome sequencing, and the development of testing kits.

Indian research organizations and universities helped to provide leads to Indian firms in terms of identifying drug and vaccine candidates, testing platforms for vaccine/drug development, developing testing kits, and adjuvants for increasing the efficiency of the vaccine, etc. Universities/research organisations are also showing increasing partnerships among themselves. Similarly, we observe competing firms coming together for clinical trials, joint manufacturing, and developing new leads. Cross-firm collaboration in clinical trials and manufacturing reflects relational institutional learning. It also showed a shift from a largely ‘closed innovation model’ that is observed in Indian pharmaceutical/biopharmaceutical firms towards an ‘Open innovation’ model in many instances. The crisis thus temporarily altered innovation routines, demonstrating adaptive learning at the firm and ecosystem levels. Firms created institutional mechanisms that help them to increase their absorptive capacity and learning from each other, as can be seen from the quick transitions that they are able to make. Another feature that is observed from the various instances is the strengthening of the academia-industry-government linkages. These types of linkages are especially important in science-based industries like the pharmaceutical/biopharmaceutical industry and are conceptualised within the framework of Triple Helix. The study highlighted the emergence of valuable partnerships between the university and industry during the pandemic, with the government acting as a key facilitator. Largely disjointed India's STI ecosystem and its weak linkages with the manufacturers showed a new resilience in confronting the challenges of the pandemic.

Entering a market, especially a global market, with a new vaccine is a difficult process. The regulation process is highly stringent and needs validation at different stages. Inspite of Covaxin demonstrating a high level of efficiency and vaccine doses being administered to a large Indian population, it was very difficult to get approval from the WHO. Meeting regulatory compliance was a key challenge. A multinational firm has these types of parameters integrated within its whole drug/vaccine development process, i.e., clinical data on each stage well validated as per international standards, making the data public, and publishing in respected peer-reviewed journals. Thus, a good learning from this is that along with technological capability, it becomes important to develop other capacities/capabilities also.

While the evidence demonstrates the emergence of new regulatory routines, collaborative practices, and coordination platforms during the crisis, the present study does not extend to a longitudinal post-pandemic evaluation of whether these arrangements became fully institutionalised. Institutional learning is therefore analysed here at the level of adaptive restructuring under crisis conditions rather than confirmed long-term consolidation. Crisis-driven adaptations do not automatically translate into institutional learning unless they are codified into enduring practices, policies, or organizational capabilities.[43,44] The learning among stakeholders and novel linkages that have been initiated also draw attention to the innovation systems framework, which calls for the need to build institutions that help actors to learn from each other.

Conclusions

The importance of developing strategic linkages for innovation and commercialisation is the key policy lesson from this study. One of the key institutions that helps create this type of strategic linkages, which the study showed, was the specialised clusters that provide an enabling environment. The production of PPE Kits, masks in Tiruppur and the knowledge life science cluster Genome Valley provided good empirical evidence of this. It also showed the changing role of the Government, to be present in the whole value chain. More importantly, the study highlighted the significance of developing a strong partnership between the university and industry. The government was the key enabler during the COVID-19 pandemic in creating a quasi-arrangement that helped to develop a strong university-industry partnership and also involved itself in the whole value chain. Many of the successful innovations that helped to address the challenges as highlighted in the study were due to these types of structures that were established. This provides an important learning lesson and a strong argument to focus policy attention on developing structures that can enhance partnerships between university-industry-government.

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