

Received November 8, 2023, accepted December 1 2023, date of publication January 22, 2024

## A Landscape Study to Determine the Innovation Mortality Rate in Health Technology Innovations Across the Globe

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### ABSTRACT

**Introduction**: Health technology innovation encompasses many areas, such as medical devices, diagnostics, pharmaceuticals, digital health solutions, telemedicine, health informatics, and more. These innovations aim to enhance healthcare delivery, improve patient outcomes, increase access to services, reduce costs, and advance medical research.

**Methodology:** We have analyzed health technology innovations reported between January 2011 and December 2022. Regulatory approval for the innovative products was determined based solely on official open-access websites of health agencies, disregarding information from company websites or third-party sources. The search process utilized identified innovation agencies and sources like Primary Health Care (PHC) Tech Challenge, World Health Organization (WHO) compendium, Global Grand Challenges (GGC), and Biotechnology Industry Research Assistance Council (BIRAC). Innovations were thoroughly examined from these sources, focusing on health technologies, and success was gauged through regulatory approval.

**Results:** The WHO Compendium includes 200 health innovations primarily intended for low-resource settings, with the USA accounting for the highest number, followed by India, the only low- and middle-income country (LMIC) with significant innovations. However, 58% of the listed innovations did not obtain regulatory clearance. Medical devices dominated the listed innovations, while scalable assistive technologies were limited. Global innovation agencies, particularly Grand Challenges, supported many innovations, but the regulatory approval rate remained low. In India, BIRAC supported 92% of the mapped innovations, with a similar trend of low regulatory approval rates.

**Conclusion:** The study observed the highest number of innovations during 2015-2017, with medical devices being the most prominent category. However, most innovations from both global and domestic agencies were unapproved, raising concerns about regulatory clearance for these health technologies.

**Manuscript Highlights:** The manuscript presents several important highlights concerning health technology innovation and regulatory approval. It highlights the evaluation of health innovations from 2015 to 2022, focusing on their success rate based on health agency approval. It reveals an uneven distribution of innovations from different countries and emphasizes the need for critical interventions to improve the process. This study emphasizes the significance of innovations in achieving healthcare equity and sustainable development goals.

**Keywords** – Health technology innovation, Regulatory approval, Medical devices, WHO Compendium, BIRAC, Global innovation agencies.

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### **INTRODUCTION**

Innovation is fundamental to progress and development in various sectors, including business, healthcare, technology, and agriculture. It encompasses integrating fresh ideas, concepts, and creativity into tangible and usable products or services that cater to the needs of the public at large. Moreover, innovation is not limited to creating entirely new products; it also involves enhancing and improving existing offerings, resulting in better customer experiences and increased efficiency.<sup>1</sup>

Though various fields have distinct breakthroughs based on their domain, our analysis will be based on the product innovation of health technology innovation across different countries. Healthcare innovation can be as simple as changing a form to check out a patient five minutes faster or as complex as immunotherapy targeting specific cancer cell types. Simple or complex developments that lead to improvements in health outcomes and patient experiences are considered healthcare innovations. Health technology innovation refers to developing and implementing new and improved technologies in the healthcare sector.<sup>2</sup> It involves the application of scientific knowledge, engineering principles, and innovative ideas to create tools, devices, systems, and software that enhance the prevention, diagnosis, treatment, and management of diseases and improve overall healthcare delivery.<sup>3</sup>

In healthcare, innovation holds immense potential for revolutionizing patient care, disease prevention, diagnostics, treatment, and monitoring.<sup>4</sup> The healthcare sector thrives on innovations that can significantly improve health outcomes, enhance access to services, reduce costs, and contribute to advancements in medical research in the real world.<sup>5</sup> Innovations in medical devices, such as implantable devices, robotic surgery systems, prosthetics, and wearable sensors, have substantially impacted patient care and medical interventions. Similarly, diagnostic tools and techniques, like genetic testing, point-of-care diagnostics, imaging technologies, and lab-on-a-chip devices, have revolutionized early detection and accurate diagnosis of diseases, leading to better treatment outcomes.<sup>6</sup>

Despite the remarkable potential of health technology innovations, the innovation process can be arduous and challenging. Many innovators invest significant efforts into transforming their ideas into commercially viable products; however, many of these innovations eventually face failure. This failure could occur at any stage of the innovation process, and the reasons behind it can be multifaceted.<sup>5,7</sup>

It is laborious to think about a product from the initial seed of a concept through its commercialization. Even though many innovators need their innovations to complete this laborious procedure successfully, most fail after some period. Any stage of the invention process might fail.<sup>8,9</sup>

Start-up companies often confront a higher risk of failure, especially during their initial years of operation. The competitive landscape and rapidly evolving consumer needs and preferences can lead to shorter product life cycles, necessitating continuous innovation and adaptation for survival. As a result, organizations must constantly reinvent and improve their products or services to stay relevant in the dynamic market.<sup>10,11</sup>

Considering this, many start-up companies have a significant chance of failing, with many failing after a few years. This is attributed to intense competition and rapidly changing consumer needs, resulting in shorter product life cycles.<sup>12</sup> companies must continuously innovate and improve their products or introduce new ones to survive. Not all innovations are successful, and failing to commercialize them wastes important investments.<sup>5</sup> Acquiring company-level data on innovation failure is challenging. The study focuses on macro-level data at the country level to acquire insights into the information provided. Compared to well-established organizations, start-ups are more prone to failure, with a considerable proportion failing to survive beyond their first few years.<sup>13</sup> This is primarily due to their intense rivalry, exacerbated by the rapidly changing consumer needs. As a result, the market lifespan of items has been considerably reduced, necessitating ongoing innovation and adaptation.<sup>7</sup>

According to studies, the ratio of successfully commercialized discoveries to failed ones could be as low as 1:300.<sup>14</sup> This means that a significant amount of investment in innovation may be squandered. The financial expense of innovation adds another degree of complexity. Innovation activities are frequently expensive, involving research and development (R&D) costs, experimentation, and market testing. These costs can be enormous, and when combined with the risk of failure, they create a difficult environment for new businesses.<sup>15,16</sup> Innovation mortality refers to the rate at which new products or ideas fail to gain traction in the market or within an organization. It measures the failure rate of innovations or ideas and can be used to evaluate the success of an organization's innovation efforts.

While existing research has primarily focused on the positive impact of innovation on a company's survival, our study takes a different approach. It seeks to understand how innovation has attained the rate of mortality . Due to the numerous micro-level data regarding innovation, this research relies on macro-level data on specific agencies and organizations. By analyzing broader trends and patterns, the study aims to shed light on the relationship between innovation activities and the ultimate failure of health technology innovations.<sup>17,18</sup>

## **MATERIALS AND METHODS**

The methodology includes the mapping of health technology innovations across the various countries in the world. There were pre-defined criteria for including the health technologies. The inclusion criteria include any health technology innovations within a period of January 1, 2011, to December 31, 2022.

We depend on open access to official regulatory agency websites to determine health agency approval. We do not consider the information on the company website or any third-party websites, including newspapers.

The search includes list of already identified innovation agencies across the world, PHC (Primary Health Care) Tech Challenge, which is a search for innovations in a primary healthcare setting, WHO (World Health Organization) compendium of innovative health technologies for low-resource settings (2011 to 2020) and Global Grand Challenges, and Biotechnology Industry Research Assistance Council (BIRAC). Innovation agencies shall be of any entity, i.e., government, private, non-governmental organization, independent, a collaboration with UNDP (United Nations Development Program), charity organization, or any university collaborative agencies. We have selected five innovation agencies in total for this study. Among them, three were global, and two were from India. PHC Tech challenges was a special call for mapping innovations specific to primary health care. The rest are agencies aiming to find and support innovations from different areas.

We identified the website of each of the innovation agencies from a browser. We thoroughly investigated the English-language calls for proposals, grants, current initiatives, and services. We narrowed our search to just health innovations on the websites of individual innovation agencies based on the inclusion criteria. Irrespective of the agency's website, we also searched the health innovations from the "Global Grand Challenges," "WHO Compendium of innovations for low-resource settings," "PHC Tech Challenge," and "BIRAC."

Various innovations were found from the GGC, a family of initiatives fostering innovation to solve key global health and development problems, while the PHC Tech Challenge includes the compendium of health innovations for primary healthcare settings. These innovations are exclusively shown to bring promising health innovations across the globe to support PHC planning, management, and quality improvement. We also identified the health technology innovations from WHO Compendium of Innovative Health Technologies for low-resource settings from the year 2011 to 2020,<sup>19</sup> which consists of commercially available medical products and finally the BIRAC<sup>20</sup> and PHC Tech Challenge in India<sup>21</sup> in where the innovation and the company's name has been identified for the further collection of macro-level data.

The success of an innovation is decided based on the regulatory approval received from health agencies. All the health technology innovations mapped had been cross-verified to check the regulatory approval of the same products.

## **STATISTICAL ANALYSIS**

In this study, a descriptive assessment of the findings was conducted to summarize and present the results clearly and informally. The results of the analysis were represented in the form of summaries, tables, and figures. Descriptive graphs in bar charts, pie charts and histograms were used to provide visual insights into the data's patterns, trends, and distribution. Tables were also used to identify the trends and to provide comparisons. Bar charts were utilized to illustrate the frequency or distribution of categorical data. Pie charts were also used to present the proportion of each category within a whole to provide an understanding of relative components.

### **RESULTS**

The WHO Compendium represents the list of health technology innovations that are commercially available. The total number of commercially available products are 152 in number, and prototype products mentioned in the compendium are 48. Of 152 products, 114 received approvals from their respective countries of origin. The WHO Compendium identifies the manufacturer-reported information and the evaluation of innovation results. It focuses on health technologies that can potentially improve health outcomes and quality of life, or offer a solution to an unmet medical/health technology need. It acknowledges success stories and raises awareness of the pressing need for appropriate, affordable design solutions. It also promotes innovation in the field of health. This effort aims to promote interaction among ministries of health, procurement officers, donors, technology developers, manufacturers, clinicians, academics, and the public. Ultimately, it ensures greater investment in health technology towards universal access to essential health technologies. The table represents the date of commercialization of the product, country of origin of the product, and category of the product. All these innovations are at 8 to 9 technology readiness levels. This emphasizes that this has entered the regulatory approval pathway, got approved by their respective country's regulatory approval authority, and entered the commercial market. These innovations mentioned here are successful.

The innovations under PHC Tech Challenge are a platform that brings together promising MedTech, digital health, and cold chain innovations for strengthening primary healthcare. The PHC Tech Challenge document was published in 2018 where they mentioned the overall products as 22. It was rolled out to supply a platform that brings together promising MedTech, digital health, and cold chain innovations from across the globe to key stakeholders (government, health agencies, donors,

development partners, private sector companies and providers, etc.). PATH India with its partners embarked on a global search for innovators and entrepreneurs in the healthcare sector with the 'PHC Tech Challenge.' The success of a comprehensive PHC program by bringing together all the relevant stakeholders to advance efforts towards improving primary healthcare quality, access, and affordability and introducing transformative solutions/innovations that could be proven and scaled are found in this review.

A group of programs known as Grand Challenges promotes creativity to address significant global health and development issues. Every endeavor is a test of how to use difficulties to direct innovation towards having an effect. The Bill & Melinda Gates Foundation introduced Grand Challenges in Global Health in 2003. The first focus of this initiative was on 14 significant scientific problems that, if resolved, could make substantial progress in preventing, treating, and curing the illnesses and health conditions that contribute most to global health inequity. It was reintroduced in 2014 under the moniker Grand Challenges, reflecting its broadened focus to include problems with global development.<sup>22</sup>

We have considered 10 major Grand Challenges for identifying health innovations. The Majority were countryspecific, and few were exclusively for specific innovations (such as Grand Challenges for development).

The Department of Biotechnology (DBT), Government of India, established the BIRAC, a not-for-profit Section 8, Schedule B, Public Sector Enterprise, as an interface agency to support and enable the emerging biotech enterprise to engage in strategic research and innovation, addressing regionally pertinent product development needs. BIRAC, an industry-academia interface, conducts its mandate through a wide range of initiatives that have an impact, such as providing access to risk capital through targeted funding, technology transfer, IP management, and support programs that help biotech companies become more innovative and competitive on a global scale.<sup>20</sup> We have mapped a total of 253 innovations on medical devices from 2012 to 2021. The WHO Compendium included noticeable innovations in the healthcare arena, intending to seek more support and aid for the same.

Sl No	Innovation agency	Country
1	WHO (Innovation compendium)	Global
2	Grand Challenges Global	Global
3	Innovation Agencies	Global
4	PHC Tech Challenge	India
5	BIRAC	India

 TABLE 1. Innovation Agencies Considered for Mapping

All the innovations named by WHO, PHC Tech Challenges, were considered. However, innovations mapped from other agencies were included after considering technology readiness levels, scope, and novelty from a global perspective.

We have categorized our findings into three sections.

- 1. The WHO Compendium listed health innovations.
- 2. Health innovations supported through global innovation agencies.
- 3. Health innovations supported by India's major domestic innovation agencies and health innovation calls.

### The WHO Compendium listed health innovations

We have mapped a total of 200 health innovations from WHO innovation compendium. The compendium incorporates innovations intended for low-resource settings. The WHO Compendium lists manufacturer-reported data and WHO evaluation findings for health technologies that can enhance the quality of life or health outcomes or address an unmet medical or technological need. It clarifies the benefits and difficulties of using cutting-edge medical technology in low-resource environments. It may be utilized by non-governmental organizations, governments, and other stakeholders to support purchasing choices.

The USA accounts for more than a quarter of the innovations listed by the compendium. India is the only LMIC comprising many health innovations (18 of 200). Innovations from a total of 44 countries were considered for assessment. Of them, 37 countries accounted for less than 5% of health innovations.



**FIGURE 1.** Distribution of health innovations with respect to country of origin.

The health innovations from African countries were exceptionally low. The analysis finds that 58% of the health innovations did not obtain regulatory clearance.

Although Canada, China, and Switzerland found a high proportion of regulatory agency approved health innovations, the country-wise approval rate remains the same in absolute numbers.

Medical devices account for nearly three-fourths of the overall health innovations listed in the WHO Compendium (140 of 200). The innovations in scalable assistive technologies were very few (3 of 200). The absolute number of innovations categorized as medical devices was significantly high (86 of 140).

# Health innovations supported through global innovation agencies

Medical devices account for the maximum number of health innovations (32 of 67). E-health and assistive devices were the lowest (1 of 67). Regulatory agency approval for innovations mapped from global agencies was significantly low (6 of 67). The regulatory approval for GGC (1 of 43) was significantly low.







The 2015 to 2017 period showed the highest number of innovations supported by innovation agencies. Medical devices were the highest reported health innovation, followed by other technology and digital health. The analysis also found certain process innovations. Process innovations success rate cannot be determined based on health agency approval status.

## A deep dive into the health innovations supported by India's major domestic innovation agencies

We have analyzed innovations supported by the major innovation agencies BIRAC, the Ministry of Biotechnology, and the Government of India, and innovations supported through a grand challenge call for PHC Tech Challenge. We have mapped a total of 273 health innovations. BIRACsupported health innovations accounted for 92% of the total innovations mapped. Our analysis found that around 92% of the health innovations supported by domestic innovation agencies are not receiving regulatory clearance. The highest number of innovations were supported during 2015-2017. Although the reduction is insignificant, the COVID-19 pandemic could be accountable for the low support rate in the subsequent period. Medical devices accounted for the most supported medical innovations (58%). Other technology includes innovations in cold chain, infection control, etc.

The net regulatory agency approval was the lowest for the health innovations supported by global health innovation agencies. Innovations listed in the WHO Compendium, on the other hand, included many regulatory agencies' approved health innovations. Another noticeable finding was that the health innovations from low- and middleincome countries were significantly lower compared to high-income counterparts.

### DISCUSSION

The study mapped health innovations supported by six innovation agencies and used regulatory approval to measure success. Surprisingly, over one-third of the supported innovations failed to obtain regulatory clearance. Cross-verifying regulatory agency approval from respective countries was done. Still, some innovations developed in high-income countries for different populations could not be assessed due to a lack of regulatory data. The peak of innovation support was observed during 2016-2018. However, innovations beyond 2021 were not included in the study, except for pandemic-driven ones. While the focus was on medical devices, other categories like digital health and assistive devices were also considered if they played a crucial role in healthcare. Despite this, many innovations lacked supporting documents on regulatory approvals on open websites.

There is currently no widely acknowledged comprehensive definition of innovation, and many fields (such as economics, public health, geography, and sociology) use somewhat different definitions. One of the earliest economists to recognize the importance of innovations to all economic systems, from small businesses to entire countries and the global economy, was Schumpeter. He defined innovation as any modification to the way something is produced, the creation of new goods, the organization of businesses, the entry into a new market, and the "creative destruction" that drives all developments under a capitalist market framework.<sup>1</sup> According to Manuel García-Goñi, innovations in health care can be classified into objects, the relationship to the existing standard, the system affected, the extent of change, and the readiness level. The World Economic Forum, in its latest report, mapped five innovations that could change

Innovations Mapped from Global Agencies						
Category of Health Innovation	Approved by regulatory agencies		Not approved by regulatory agencies			
	Number	Percentage	Number	Percentage		
Medical device	5	16	27	84		
Digital health	Nil	Nil	15	100		
Other technologies	1	7	14	93		
Assistive device	Nil	Nil	1	100		
E-health	Nil	Nil	1	100		

#### TABLE 2. List of Health Innovations and Its Regulatory Agency Approval Status

Innovations Mapped from WHO Compendium						
Category of Health Innovation	Approved by regulatory agencies		Not approved by regulatory agencies			
	Number	Percentage	Number	Percentage		
Medical device	86	61	54	39		
E-health	13	37	22	63		
Other technology	2	13	14	88		
Digital health	2	33	4	67		
Assistive device	1	33	2	67		

Innovations Mapped from India (BIRAC & PHC Tech Challenge)						
Category of Health Innovation	Approved by regulatory agencies		Not approved by regulatory agencies			
	Number	Percentage	Number	Percentage		
Medical device	11	7	146	93		
Other technology	2	4	46	96		
Digital health	7	16	38	84		
Assistive device	2	11	17	89		

global health, which include artificial intelligence, 3-D printing, gene editing, virtual reality, and sensor development. Most of the health innovations mapped through the process were found to have some association with the forum-reported innovation domains.<sup>23</sup> David W. Feigal et

al., in their paper titled "Impact of the Regulatory Framework on Medical Device Development and Innovation" states that the rate of innovation for regulated items is a function of how quickly research and engineering are developed to make choices about regulations based on science. New scientific and public health concerns also have a life cycle, from conception to obsolescence, just as breakthrough medical products. Since the two are interwoven, delayed scientific advancement and a lack of a flexible, science-based regulatory decision-making process can hinder growth.<sup>24</sup> The author highlights that the slower the pace of regulatory agencies in approving the innovation, the more it affects the development of innovative medical devices. The World Trade Organization, in its Trade-Related Aspects of Intellectual Property Rights, is an international legal agreement between all the member nations of the World Trade Organization), states that the regulation of medical products has become difficult because of the globalization of product research, manufacturing, and supply as well as the rapid rate of technical and societal change in the setting of limited financial and human resources.<sup>25</sup> The Sixty-Seventh World Health Assembly approved resolution WHA 67.20, "Regulatory system strengthening for medical products," to recognize the value of strong regulatory frameworks. The resolution states that "effective regulatory systems are an essential component of strengthening the health system and contribute to better public health outcomes," "regulators are an essential part of the health workforce," and "inefficient regulatory systems themselves can be a barrier to access to safe, effective, and quality medical products."26 A study titled "Innovation and Death Rate of Enterprise" identified the mortality rate of companies, where it also aims to analyze how the influence of innovation activities measured through R&D expenditures and the number of resident patent applications on the death rate of companies in member countries of OECD.<sup>27,28</sup>

The evaluation of cutting-edge medical devices is where technological uncertainty is most evident because the regulator must comprehend the scientific principles underlying the operation of the device but fails to have a clear understanding of the information needed to be persuaded of the product's efficacy and safety before the product entered into the regulatory review the line.<sup>29</sup> Addressing the uncertainty over the structure and format of the data necessary for a given medical device's regulatory clearance. The lack of clear guidelines for the protocol for evaluating an innovative product causes content and format uncertainty, which affects how the applicant firm should present and how regulators should evaluate the findings of clinical studies and other tests (like biocompatibility and engineering tests). Without the creation of precise assessment criteria, this form of uncertainty, which always coexists with technological uncertainty for innovative products, may continue.<sup>30</sup> As there may be several reasons why innovation has failed at any stage where we are not accumulating information about the failure, the mortality of innovations is any health innovations that are not commercially available and did not pass through the regulatory authorized channels. A remarkably diverse range of goods fall under medical devices, including pacemakers, coronary stents, and silicone breast implants.<sup>31</sup> Obtaining regulatory approvals for innovations takes much longer than the average approval process of follow-on innovations. This could increase the cost of the approval process. There are many efforts from different parts of the globe to ensure appropriate implementation of the innovations. However, many such efforts fail to deliver the intended benefits to the end user. Government regulations can have dual effects when it comes to promoting health innovations. Ensuring a positive regulatory environment is important, and should consider regulation affects innovation as well as the consequences of technological development for their justification and regulatory design. The OECD report<sup>32</sup> on regulations and innovation states that regulatory reforms should be considered whenever needed to accommodate technological developments. Strict competition policy might restrict the rate of technological process. Competition policy may result in only the approval of innovations from large firms in concentrated industries. As they could finance themselves for the R&D.<sup>32,33</sup> According to the NHS UK, to innovate successfully in the health field, several major problems must be resolved. Budgetary considerations.<sup>33</sup> Hospitals have a notably sluggish adoption rate for technological advancements. One explanation is that their IT staff are already overworked with installing, upkeep, and improving electronic health record (EHR) systems. However, hospitals' unbalanced budgeting and incentive structures might be mainly held responsible.<sup>34,35</sup> Currently, challenges are hindering the progress and widespread adoption of medical innovations, which are crucial for addressing gaps in global healthcare provision. One major obstacle is the slowdown in productivity within healthcare R&D, leading to prolonged timelines for discovering new treatments

for emerging diseases.<sup>36</sup> Consequently, numerous acute and chronic conditions such as cancer, depression, and Alzheimer's still lack groundbreaking cures. Another challenge lies in the comparatively slower diffusion of healthcare innovations compared to other industries. Translating medical innovations from the research stage to practical implementation is often protracted, spanning several decades. This delay can be attributed to the intricate nature of the healthcare innovation ecosystem and the divergent motivations of various healthcare stakeholders involved. Overcoming these challenges is imperative to accelerate medical progress and ensure widespread access to innovative healthcare solutions.<sup>37</sup>

The study had some limitations that affected its scope and data collection. Examining various organizations was limited, potentially leaving out relevant health innovations. Innovations were identified using organization or company names when generic names were unavailable, which might have impacted data accuracy. Additionally, the study faced challenges in identifying health technology innovations and distinguishing between established businesses and start-ups. As a result, certain health innovations, including process innovations and non-medical product categories like digital health, e-health, cold chain, and prototypes, were not considered for health agency approval. Moreover, the study did not assess the outcome of patents granted as a measure of success for health innovations. Moving forward, qualitative research could shed light on factors contributing to the failure of regulatory approval for specific innovations, helping stakeholders address barriers to clearance. This knowledge would assist stakeholders in creating a more supportive environment for health innovation and encourage innovation agencies to provide appropriate assistance for regulatory clearance. Broader consideration of health innovations, including process innovations and non-medical product categories, could enhance our understanding of the health technology landscape's impact on healthcare. Future research should also explore the relationship between patenting and innovation success, recognizing the potential role of intellectual property protection in health technology development and commercialization.

### **CONCLUSION**

This review emphasizes the success of health innovations for the innovations mapped through our pre-defined inclusion criteria. We have considered health innovations mapped from 2015 to 2022 for this study. The distribution of health innovations as per the country of origin showed an uneven pattern and suggested that many innovations were incubated from high-income countries by the global agencies and WHO. The analysis also found specific innovations scaled up from high-income countries but intended for low and LMICs. The success of such innovations could not be determined only through health agency approval status. Health innovation support during the selected time duration showed an uneven pattern in supporting health innovations from the innovation agencies. Medical devices were the highest-mapped category of health innovation. Assessment of success for process innovations and e-health interventions could not be assessed for their success status as they do not require health agency approval. The report found that over three-fourths of health innovations fail to obtain regulatory clearance. This suggests the need for critical intervention interventions in health innovation facilitation by the innovation agencies. Innovations are paramount regarding healthcare equity and achieving the United Nation's sustainable development goals. However, meager support could result in redundant resource wastage. Hence, the global health agencies should streamline the process of innovation support.

### ACKNOWLEDGMENT

The authors thank Mr. Keerthan RM and Ms. Sesetti Harshitha for their valuable input on developing this paper.

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