



## Entrepreneurship & Innovation in the New Health Economy

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# Entrepreneurship and Innovation in the New Health Economy

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## List of Abbreviations

<b>Abbreviation</b>	<b>Definition</b>
AI	Artificial Intelligence
APO	Asia Pacific Observatory on Health Systems and Policies
ASEAN	Association of Southeast Asian Nations
CHWs	Community Health Workers
CVD	Cardiovascular Disease
HER	Electronic health record
EMR	Electronic medical record
EPF	Entrepreneurship Policy Framework
GDP	Gross Domestic Product
GDPR	European Union's General Data Protection Regulation
ICTs	Information and Communication technologies
ILO	International Labour Organization
IPAs	Investment Promotion Agencies
ITU	International Tele-communication Union
LAC	Latin America and the Caribbean
LAVCA	Latin America Venture Capital Association
LMICs	Low- and middle-income countries
MSMEs	Micro, small and medium-sized enterprises
NCDs	Non-communicable diseases
NHE	New Health Economy
PAHO	Pan American Health Organization
PHC	Primary Health Care
PH	Personalized Healthcare
SMEs	Small and Medium-Sized Enterprises
UHC	Universal Health Coverage

## Glossary

<b>Term</b>	<b>Definition</b>
Digital health (digital healthcare)	Digital health is the field of knowledge and practice associated with the development and use of digital technologies to improve health. Digital health expands the concept of eHealth to include digital consumers, with a wider range of smart devices and connected equipment. The following areas are commonly understood as being part of, or related to, digital health: artificial intelligence, big data, blockchain, health data, health information systems, the infodemic, the Internet of Things, interoperability and telemedicine (WHO).
e-Health (e-Healthcare)	Umbrella term that includes all digital applications and technologies that are intended to improve or supplement patient care. It can be defined as the use of ICTs for health services and can include the use of email, text messaging, push notifications, web- and mobile-based applications. (Bernstein, 2021)
Health innovation (healthcare innovation)	Innovation can be defined as “the introduction of a new concept, idea, service, process, or product aimed at improving treatment, diagnosis, education, outreach, prevention and research, and with the long-term goals of improving quality, safety, outcomes, efficiency and costs (Omachonu & Einspruch, 2010)
Entrepreneurship in the health sector	Entrepreneurs are driving advancements in the health sector by improving the accessibility and affordability of healthcare solutions and technology through the development of market-specific solutions to pressing needs (Barto, 2022)
m-Health	Mobile Health, use of smartphones, tablets or smart watches for health purposes. Also includes medical apps (Bliestle, 2015)
New Health Economy (NHE)	The NHE is characterized by the delivery and innovation of healthcare solutions guided by consumer needs, with digital solution and data-driven models at the heart of the new health ecosystem (PwC, 2020)
Scalability and sustainability criteria	To be successful, innovations in the NHE must be scalable and sustainable. This relates to their scalability across regions and financial sustainability for entrepreneurs to bring an innovative approach to healthcare practice and delivery (Chowdury, 2012)
Tele-Health	Devices or sensors allow remote monitoring of the patient. Data is transmitted electronically to the doctor and the patient is informed of any abnormalities. (Tele-medicine is a sub-category) (NEJM, 2018)

## Executive summary

Healthcare sectors around the world require a major rethink and overhaul following weaknesses that surfaced during the COVID-19 pandemic and a changing healthcare landscape with regard to customer needs.

Entrepreneurs of small and medium-sized enterprises (SMEs) and start-ups can greatly contribute to health innovation and thereby improve productivity and customer experience and provide more affordable care. They can help advance the current trend toward networks of different value chain participants such as suppliers, platforms, service providers and customers, integrated through common commercial models and data.

As demand for healthcare rises, governments cannot cope alone, which is the reason why health systems are more and more turning to the private sector for solutions using data, digital technology, and artificial intelligence (AI). These are areas where innovation is fuelled by start-ups and SMEs.

This shift, characterized by the delivery of targeted healthcare solutions guided by consumer needs, with digital solutions and data-driven models, is generally referred to as the New Health Economy. Entrepreneurship is considered a vital component of that shift.

This publication analyzes the increasingly important role played by entrepreneurs of SMEs and start-ups in strengthening health systems in developing countries. It builds on three sessions of the World Investment Forum (WIF) that took place in 2021, focusing on entrepreneurship in the new health economy in Africa, Latin America and the Caribbean and Asia-Pacific.

The main findings are the following:

- **To promote innovation in the health sector, it is important to strike an appropriate regulatory balance.** While regulation is necessary to protect patients and to ensure that only safe and high-quality products and services enter the market, excessive regulation can stifle innovation. The innovation opportunity offered by the rise of data analytics, machine learning and AI, means that one of the primary challenges concerns privacy and data management. Clarity with regard to regulatory processes is equally important to avoid uncertainty for investors.
- **In the healthcare industry, regulation and access to finance are closely linked.** Access to finance is important for entrepreneurs in general, but even more so in health sectors. Longer timelines and higher levels of requirements to obtain funding are often an insurmountable obstacle for start-ups. Investors have to wait longer for a return on their investment than in other sectors. Additionally, banks and other traditional sources of finance are sometimes not familiar with the healthcare industry. There is a need for stronger linkages between funders and entrepreneurs, based on a good contextual knowledge of local market specificities.
- **Private sector innovation does not always integrate well in public health institutions.** In many countries there is a lack of trust towards innovation in health sectors. It can be difficult to inform and convince the different stakeholders in the healthcare value chain, and there are often contradictory incentives between stakeholders. This affects the link between product innovation and services innovation. It is also a major barrier to the scalability and sustainability of health innovation. Public institutions can play a role in building bridges between the different stakeholders.

## 1. Introduction

In the last decades healthcare landscapes around the world have changed dramatically due to demographic and epidemiological shifts, technological innovations and rising consumer expectations. Adding to this is the COVID-19 pandemic that brought to the surface overlooked weaknesses that call for a major rethink and overhaul of the healthcare sector.

A term that is often associated with the changing healthcare landscape is the New Health Economy (NHE), which refers to changes in the traditional dynamics of health economies by hastening innovation in both the practice and the delivery of health services, thus promoting entrepreneurial activities of small and medium-sized enterprises (SMEs) and start-ups to catalyze innovation within the health sector (Singhal, 2020, PwC 2020). In the health sector as well, new ventures have fueled a wave of innovation using big data, artificial intelligence (AI) and other technologies (Global Innovation Index, 2019).<sup>1</sup>

In this publication, the United Nations Conference on Trade and Development (UNCTAD) reflects on how entrepreneurs of SMEs and start-ups contribute to healthcare innovations and proposes policy options to enrich the debate on the topic. It brings forward the different types of health innovation, the obstacles to create a conducive business environment for entrepreneurs in healthcare innovation and provides an overview of global policy movements addressing innovation and entrepreneurship in the health sector.

Particular focus is given to the healthcare sectors of Africa, Latin America and the Caribbean and Asia-Pacific analyzed through the lens of a scalability and sustainability framework and supported by case studies. The report is a follow-up to sessions of the World Investment Forum (WIF) that took place in November 2021 where experts from the three regions discussed the future of healthcare.<sup>2</sup>

The emergence of increasingly complex health conditions necessitating access to specialists and treatments beyond standard practices of care, the ageing populations globally leading to an increased demand in health care, the rise in non-communicable disease (NCD) rates, as well as the lack of access to quality healthcare, particularly in low- and middle-income countries (LMICs), contribute to the high burden national public health systems must overcome. Most recently, the COVID-19 pandemic has accelerated these struggles due to even higher demand for primary health care and hospital services. As a result, the pandemic has strengthened the use of digital solutions in the practice and delivery of care for patients, transforming the existing health ecosystem even more profoundly. These shifts are likely to persist, underlining the need to foster innovation as the key to ensuring growth in a post-crisis recovery.

Consequently, based on the observation that the public sector cannot face the increasing healthcare needs of populations alone, governments in developing countries have more and more collaborated with the private sector and implemented market instruments to improve the quality and efficiency of their healthcare system. High performing health systems are typically characterized by a mixed delivery of services, with private providers playing an integral role. Indeed, many countries implement a public-private partnership model in which the public and the private sector provide health care infrastructures as well as delivery of health care services to patients (IFC, 2013). While the private sector can entail many different sectors of the economy, this paper focuses on SMEs and start-ups in health innovation, including digital innovation, which are considered to be one of the most important, upcoming sectors of any developed/developing economy (Purbasari et al., 2021). When building resilient and equitable health systems, it is therefore crucial to consider the private sector as a partner which complements the activities of the public sector (Kanneganti, 2021).

Additionally, the health-related Sustainable Development Goals (SDGs) call for innovative ways of thinking about health systems. There is a vital need for high-quality health systems

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<sup>1</sup> Global healthcare AI start-ups have raised US\$4.3 billion through 576 deals since 2013, for example (Global Innovation Index 2019).

<sup>2</sup> World Investment Forum <https://worldinvestmentforum.unctad.org/>



fostering a new dynamic in the traditional way of delivering medical care while optimizing healthcare globally. In this regard, investment in sectors relevant to SDG 3 on good health and well-being decreased in 2020, whereas the needs in the health sector were increasing, underlining the importance of investment promotion in health using different mechanisms, including Investment Promotion Agencies (IPAs) (UNCTAD, 2021). As a result, the development of mechanisms to ensure investment promotion in health has a direct impact not only on existing firms in the healthcare ecosystem, but most importantly on the development of entrepreneurship in health sectors allowing smaller actors, from start-ups to SMEs, to develop their ideas, thus unlocking innovation in health. Digital health, including telemedicine, can provide essential access to quality health services in remote areas directly targeting the core of the SDGs principle of “*leaving no one behind*”. It should however be mentioned that in countries where vulnerable groups still lack access to Information and Communication Technologies (ICT), the move towards digitalization of health care can also marginalize them even further.

Hence, a shift is seen towards the implementation of the NHE, which is characterized by the delivery and innovation of healthcare solutions guided by consumer needs, with digital solutions and data-driven models. Innovation in the NHE, including digital health innovation, must be scalable and sustainable. This relates to scalability across regions and financial sustainability for entrepreneurs to bring an innovative approach to healthcare practice and delivery (Chowdhury, 2012). In line with the increase in private sector participation in healthcare systems, entrepreneurship and innovation have become a vital component of economic growth and sustainable development. The urgent need for innovation in the health sectors has been recognized globally, as outlined in section two. At the same time, opportunities to innovate are being grasped by entrepreneurs in developed and developing countries. This increases the necessity to revise policy options that are currently available to help developing countries and countries in transition to stimulate inclusive and sustainable growth while facilitating entrepreneurship (UNCTAD, 2012).

The United Nations formally recognizes entrepreneurship as a key ingredient in development through a series of General Assembly resolutions on entrepreneurship for sustainable development since 2012. UNCTAD provides continued support to micro, small and medium-sized enterprises (MSMEs) and start-ups,<sup>3</sup> in line with the 2030 Agenda for Sustainable Development.

## **2. Global policy initiatives to promote entrepreneurship and innovation in healthcare sectors**

Innovation in health depends on quality health systems, in addition to appropriate environments for entrepreneurs to develop their ideas and implement these in practice. Hence, global initiatives by international organizations focus on improving the foundations of the healthcare ecosystem and on paving the way for governments to implement their own national policies to enable the continuous development of entrepreneurship and innovation in the health sector. Most recently, and in response to the pandemic, the focus of these global initiatives specifically targeted the promotion of telemedicine and e-health applications as well as training of human resource and manufacturing of medical equipment. An overview of some of the current and most relevant global health innovation and entrepreneurship initiatives and programmes are presented in table 1.

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<sup>3</sup> The Bridgetown Covenant, paragraph 127r, October 2021, United Nations Conference on Trade and Development. [https://unctad.org/system/files/official-document/td541add2\\_en.pdf](https://unctad.org/system/files/official-document/td541add2_en.pdf)

Table 1: Selected examples of global initiatives and programmes towards health innovation and entrepreneurship

Organization	Initiatives	Aim
Health Data Collaborative	<a href="#">Principles for Digital Development</a>	Implementation of interoperable systems able to 'speak' to one another and share information to avoid duplication of initiatives and increase impact through collaboration.
International Labour Organization (ILO)	<a href="#">Sustaining Competitive and Responsible Enterprises (SCORE)</a>	Improvement of productivity, sustainability and job quality in SMEs. Since the launch of the programme, over 3'100 SMEs received SCORE training in several countries of the three regions covered.
Program for Appropriate Technologies for Health (PATH)	<a href="#">The journey to scale: Moving together past digital health pilots</a>	Identification of the conditions of success required to establish and support digital health solutions. A framework was provided of investment in digital health solutions required to achieve success.
United Nations	<a href="#">Framework for immediate socio-economic response to COVID-19</a>	Provision of support to countries and societies in the face of the pandemic, including an economic response and recovery programmes with the purpose of protecting jobs, supporting SMEs, and informal sector workers.
UNCTAD	<a href="#">Global Initiative towards post-Covid-19 resurgence MSME (2020-2022)</a>	Ensure of the continuity of the EPF in place while integrating policy responses related to the resurgence of MSMEs post-pandemic.
World Health Organization (WHO)	<a href="#">Global Strategy on Digital Health (2020-2025)</a>	Proposal of a framework for regulating, benchmarking and certifying digital health services and devices to support countries in strengthening their health systems through the application of digital health technologies and ensure access to health for all.
WHO	<a href="#">MAPS Toolkit (mHealth Assessment and Planning for Scale)</a>	Strengthen the discussion on how digital health innovations, specifically mHealth, can be scaled up and find ways to maximize their impact on health outcomes.
WHO and International Tele-communication Union (ITU)	<a href="#">National eHealth Strategy Toolkit</a>	Preparation of the landscape to allow digital innovations to flourish while ensuring stakeholder involvement from early stages of the planning and implementation process for digital health.

The table of global initiatives and programmes provides an overview of relevant sources that can be used by entrepreneurs of SMEs and start-ups in the health care sector for governments to draft digital health innovation legislation, develop public-private partnerships, establish collaborations and find investments to plan and implement health innovation. To supplement and detail the global overview, the next sections will take a closer look at the type of innovations in health care, propose a framework to identify barriers to innovation and entrepreneurship in the sector, which are then used to analyze barriers to innovation and entrepreneurship in Africa, Latin America and the Caribbean (LAC) and Asia-Pacific.

### 3. Assessing barriers to entrepreneurship and innovation in healthcare sectors

The World Health Organisation (WHO) laid out in its 2020 global strategy on digital health overarching principles for health innovation, which included that “*digital health should be an integral part of health priorities and benefit people in a way that is ethical, safe, secure, reliable, equitable and sustainable. It should be developed with principles of transparency, accessibility, scalability, replicability, interoperability, privacy, security and confidentiality.*” (WHO, 2021a).

Over the last decades and accelerated by the COVID-19 pandemic, a substantial move towards innovation in healthcare emerged. It can be observed that nearly all areas along the care cascade - prevention, testing, diagnosis, treatment and follow-up care, are experiencing the adoption of different types of innovation.

Four types of innovation are usually identified. These are product, process, marketing and organizational innovation (OECD, 2010). The most relevant for this paper is the product innovation, defined as: “*A good or service that is new or significantly improved. This includes significant improvements in technical specifications, components and materials, software in the product, user friendliness or other functional characteristics.*” However, within the healthcare sector many different types of product innovation by many different types of entrepreneurs exist.



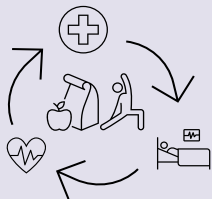
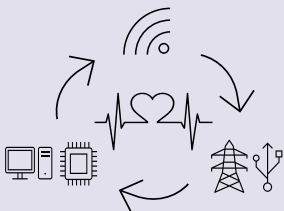
Table 2 provides a concise overview of the main categories of innovations for entrepreneurs of SMEs and start-ups and definitions of key terms in health innovation which are used throughout the paper. Further, the typology of innovation was used in the selection process of the case studies (key informant interviews with start-ups). Businesses were selected that represent all three types of innovation (see later sections on Africa, LAC and Asia-Pacific). This categorization might not be exhaustive but sufficient for the purpose of this paper. Specific terms such as m-Health, e-Health, tele-health and tele-medicine used in this overview are defined in the glossary at the beginning of the paper.

Table 2: Types of innovation in healthcare

	Product innovation	Digital health technology	Personalized medicine
Definition	Refers to product-specific health innovation to improve the care cascade.	Refers to tools and services that use ICTs to improve the care cascade. It encompasses e-health, as well as developing areas such as the use of advanced computer sciences (for example, in the fields of “big data”, genomics and artificial intelligence) (Bernstein, 2021).	Refers to the use of new methods of molecular analysis to better manage a patient’s disease or predisposition to disease and a no ‘one-size-fits-all’ medicine by adjusting diagnostic procedures, therapy or prevention programme specifically for one patient or a smaller group of patients (Personalized Medicine Coalition, 2017).
Examples	Refrigerated bag to transport vaccines and other sensitive medical products, robots that assist operations, wearable health devices.	e-Health services, tele-medicine, tele-health, MHealth (Mobile Health Apps), Electronic Medical Records (EMRs), Electronic Health Records (EHRs).	Targeted therapies to treat specific types of cancer cells, such as HER2-positive breast cancer cells, or using tumor marker testing to help diagnose and treat cancer.

Based on the above typology and other frameworks developed to assess scalability and sustainability of innovation (Labrique et al., 2018a and PATH & Vital Wave 2016), table 3 presents an overview of areas that should be considered when evaluating the implementation of innovation in healthcare. These span from the product innovation itself to the ecosystem of the innovation. To better understand what these areas are trying to assess, example questions are included that can be used to identify possible barriers to the implementation of the health innovation by entrepreneurs of SMEs and start-ups.

Table 3: Framework to assess scalability and sustainability of health innovation

Focus Area	Example Questions
<p><b>Human factors (workforce and end-users)</b></p> 	<ul style="list-style-type: none"> <li>- Was there sufficient human resource available to adopt the product/service or did it require capacity building?</li> <li>- Were the end-users sufficiently trained to fully embrace and to utilise digital health solutions or was training required?</li> </ul>
<p><b>Technical factors (standards &amp; interoperability)</b></p> 	<ul style="list-style-type: none"> <li>- How complex is the product/service (simple versus complex technology)?</li> <li>- Is the product interoperable with other systems/products?</li> </ul>
<p><b>Healthcare Ecosystem (legislation, policy &amp; compliance, leadership &amp; governance, strategy &amp; investment)</b></p> 	<ul style="list-style-type: none"> <li>- Is there financial support available to launch new innovations?</li> <li>- Are the regulatory standards and frameworks that ensure compliance with national health guidelines and strategies clear and easy to follow for start-ups? Are there specific legislation or laws in place to enhance the implementation of digital health?</li> <li>- Are there initiatives in place that support the collaboration between entrepreneurs and policy makers to help boost the emerging digital health sectors?</li> <li>- Is there a public-private sector partnership in place that supports the launch of new innovation?</li> </ul>
<p><b>Extrinsic Ecosystem</b></p> 	<ul style="list-style-type: none"> <li>- Is there reliability and a bandwidth of internet?</li> <li>- Is there electricity available to charge devices?</li> <li>- Is there high-quality hardware available?</li> </ul>

Source: adjusted from Labrique et al., 2018a and PATH & Vital Wave 2016

This framework was used to assess how entrepreneurship in health innovation in respectively Africa, LAC and Asia-Pacific can be increased. Based on country-specific examples, product-specific barriers, human and technical factors as well as factors linked to the healthcare and the extrinsic ecosystem were analyzed.

## 4. Health innovation and entrepreneurship in Africa

The African e-health entrepreneurial ecosystem is flourishing with the number of e-health start-ups operating in Africa having increased by more than 50% since 2017 (WIF Africa, 2021). According to Disrupt Africa (2020), there are currently 180 health-tech focused start-ups across the African continent. Hence, a strong potential exists for the development of digital solutions, particularly eHealth and mHealth that can contribute to the improvement of healthcare delivery systems to enable equitable and high-quality delivery of care.

In this regard, IPAs play a pivotal role as they are responsible for accessing funding of health investment by acting as intermediaries between governments and the private sector. IPAs create awareness of existing investment opportunities, attract investors that can foster health innovations and bolster entrepreneurship in health, as well as facilitate the scalability and sustainability of these innovations. In Africa, they offered support in the transformation or expansion of new sectors in response to the pandemic, for instance in the areas of manufacturing of ventilators, masks and hand sanitizers.

Nevertheless, challenges in terms of scalability and sustainability of health innovation are leading to the failure of yet very innovative ideas. Indeed, not all regions and entrepreneurs of SMEs or start-ups are benefitting from the flourishing e-health ecosystem. Consequently, it is essential to identify the main barriers to innovation preventing the latter to spread across countries within the region. While acknowledging the differences in economies, government structures and public health approaches across the countries of the African continent, a summary is presented of the most important challenges to health innovation and entrepreneurship. These include three main challenges (Oleribe et al., 2019):

*Human resource constraints.* The region faces the most severe shortage of health workers worldwide, which affects the delivery and quality of care and services in nearly all its countries (Haseeb, 2018). In addition, the existing workforce lacks data and tools needed to optimize its action and advocate for more resources (WHO, 2021b). The importance of Community Health Workers (CHWs) has been acknowledged in the African healthcare ecosystem as having the potential to deliver proven health and socioeconomic benefits and materialize health innovations in practice, enabling their use. Therefore, CHWs have the potential to serve as a “bridge” between communities and health systems (Gebremeskel et al., 2021).

*Funding constraints.* It is estimated that around 60% of healthcare financing in Africa is derived from private sources, with specific contributions and funding models varying according to the healthcare contexts in different countries (International Finance Corporation, 2008). Therefore, financing of public structures is easily set aside in favour of the mobilization of external funds, public or private, aimed at funding vertical programmes that are often disease-specific or project based. This leaves little room for innovation or flexibility in the innovation process. Consequently, the dependence on donor funding interlinked with the widespread vertical and silo funding impacts both political prioritization and health systems altogether (Gichaga et al., 2021). Thus, a strong reliance on external funding priorities for health tends to leave countries more susceptible to unpredictable and short-term inflows. However, governments consider health as a priority sector and are willing to attract more investment towards the health sector in their national strategies and economic recovery plans.<sup>4</sup>

*Health system constraints.* The pattern of aid dependency as considered earlier affects the ability of governments to use sustainable funding models to allocate more public funds to their health sector, which has an impact on their healthcare systems. This comes in line with the lack of political prioritization significantly influencing the allocation of resources where needed. Moreover, when considering the delivery, access and quality of healthcare, there are stark differences across the region, stressing the complexities of delivering healthcare in a

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<sup>4</sup> World Investment Forum. 3 sessions on entrepreneurship and innovation in the New Health Economy. <https://worldinvestmentforum.unctad.org/session/scaling-innovation-new-health-economy>  
<https://worldinvestmentforum.unctad.org/session/entrepreneurship-new-health-economy>  
<https://worldinvestmentforum.unctad.org/session/entrepreneurship-new-health-economy-0>



decentralized market (Ajisehiri et al., 2021). Overall, the sustainability and efficiency of the supply chain and the delivery of care cannot be achieved without considering all actors of the healthcare ecosystem. Thus, all stakeholders must be involved in the development and implementation of actions to improve health systems, including entrepreneurs as part of the solution.

In this regard, two global initiatives that support the African continent with its effort to implement health innovation and entrepreneurship can be mentioned:

1. UNCTAD’s investment into entrepreneurship training and policy. For instance, the EMPRETEC capacity-building programme for entrepreneurship development. Additionally, UNCTAD supported the governments of Angola, Cameroon, Ethiopia, South Africa, Tanzania, The Gambia and Uganda in the development of their entrepreneurship strategies.
2. UNCTAD’s Investment and Public Health Programme, to support the development of local production in health industry and capacity building in public health policy. The Programme achieved important results in Africa. A concrete example of its success relates to the WIF in 2016, during which Kenya, South Africa, the African Union, the Joint United Nations Programme on HIV/ AIDS and UNCTAD signed the [Nairobi Statement on Investment in Access to Medicines](#), with the aim to facilitate investment in pharmaceutical production in Africa and emphasizing the importance of coherence among African domestic policies related to health, investment, trade, intellectual property and the importance of integrating markets.

#### a) Case studies

Two case studies were analyzed to gain a deeper understanding of the challenges of entrepreneurs of SMEs or start-ups in health innovation in Africa.

The first one is Senegal based Laafi Monitor that manufactures a device that can collect any relevant information from vaccine transportation equipment and in doing so contributes to improving logistics and transport infrastructure which are considered weak across the continent and being the main causes of vaccine destruction (Nyantakyi & Munemo, 2021). The second case study was made on Elea Pad that produces reusable sanitary pads from biodegradable cotton, manufactured by women in Tanzania. The business contributes to the improvement of menstrual health and hygiene with a positive impact on education, gender equality and the national economy. Both products fall under the category of innovative health technology.

Table 4 presents the challenges to launching the product, solutions to the challenges and wider effects of the product.

Table 4: Overview of case studies in Africa

Case Study	Laafi Monitor	Elea Pads
<b>Aim</b>	Strengthen the provision of vaccines to rural and remote area.	Raise the quality of reproductive health and ensure no girl is missing school because of it.
<b>Product description</b>	The “Laafi Monitor” can be added to any existing transportation equipment and uses information to attest who received which vaccine at what time, while ensuring that the administrated vaccine has always remained in the right conservation range during the entire storage and transportation period.	“Elea Pads” are reusable sanitary pads from biodegradable cotton, manufactured by women in Tanzania.


Case Study	Laafi Monitor	Elea Pads
<b>Challenges to launching product</b>	<ul style="list-style-type: none"> <li>- Access to funding and strict security guarantees required, which were too onerous for a young start-up;</li> <li>- High degree of standards and strict regulatory environment;</li> <li>- Lack of trust in start-ups linked to the local environment (local stakeholders are not confident in using solutions produced at local level);</li> <li>- Lack of prototyping accelerator.</li> </ul>	<ul style="list-style-type: none"> <li>- Access to funding;</li> <li>- Availability and affordability of raw materials (especially during COVID-19: supply of raw material exclusively imported from China);</li> <li>- Lack of trust in local entrepreneurs;</li> <li>- Bureaucratic health system preventing private sector involvement in health such as scalability of private sector initiatives depends on governmental decisions.</li> </ul>
<b>Solutions to the challenges</b>	<ul style="list-style-type: none"> <li>- Adjusting the product: An alternative solution to the bag was found in the “Laafi Monitor” currently under experimentation;</li> <li>- Establishing partnerships: since August 2021, the Monitor is being tested in the field in collaboration with the Burkina Faso Ministry of Health and the United Nations Development Programme.</li> </ul>	<ul style="list-style-type: none"> <li>- Secured funding in 2017, allowing the company to scale-up, improve the product, focus on distribution and work with different organizations to distribute or sell the pads directly (e.g., provision of Elea Pads in refugees camps);</li> <li>- Establishing partnerships with various organizations involved in different area, for instance on water sanitation, girls’ education, to ensure capacity building.</li> </ul>
<b>Wider effects of product on health systems</b>	The “Laafi Monitor” has an attentive eye on the essential parameters of conservation of vaccines. It has the potential to be applied in other industries (e.g., health supplements for children suffering from malnutrition).	Direct link to SDG 5 on “Gender Equality” thus a strong element of social innovation. Elea pads offers training on menstrual hygiene management education, a task usually assumed by governments.


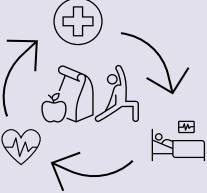
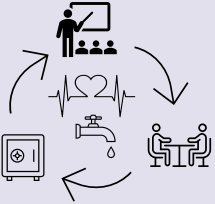
### b) Conclusions from context specificities and case studies

Despite a flourishing e-health entrepreneurship environment in the region, there are still fundamental gaps in the healthcare system which can be greatly improved through health innovation, including digital innovation. The pandemic offers an opportunity for this “great reset” (Kalenzi & Teklemariam, 2020).

Table 5 presents an overview of the health innovation environment based on the previously mentioned scalability and sustainability framework and to subsequently formulate policy options.

Table 5: Overview of barriers to entrepreneurship in healthcare in Africa and policy options

Focus Area	Limitation	Policy Options
<b>Human Factors</b> 	<ul style="list-style-type: none"> <li>- Lack of healthcare professionals;</li> <li>- Shortage of skilled health workforce.</li> </ul>	<ul style="list-style-type: none"> <li>- Promote health innovations as they have the potential to train more health workers and improve the effectiveness of CHWs by facilitating their work;</li> <li>- Foster the development of human resource for health (HRH) policy and strategic plans to facilitate the training</li> </ul>

		and exchange of health professionals across countries (Afriyie et al., 2019).
<b>Technical Factors</b> 	<ul style="list-style-type: none"> <li>- Lack of interoperability (WIF Africa, 2021)</li> </ul>	<ul style="list-style-type: none"> <li>- Promote data governance, standards and patient empowerment.</li> </ul>
<b>Healthcare Ecosystem</b> 	<ul style="list-style-type: none"> <li>- Regulatory approval is challenging and must often be repeated between countries such as differences in the regulation of medical devices, clinical studies being conducted in different countries for the same product;</li> <li>- Lack of partnerships. Young companies with technical expertise often require commercial expertise;</li> <li>- Challenges to access to funding in a highly regulated environment from R&amp;D all the way to product development;</li> <li>- Lack of trust in locally developed solutions.</li> </ul>	<ul style="list-style-type: none"> <li>- Regulatory harmonization across countries and at regional level, including strengthening regulatory agencies and focus on capacity building of regulatory bodies (African Medicines Agency (AMA, 2019), including certification, approval and monitoring bodies, establishing connections with partners in other countries;</li> <li>- Innovative financing solutions, for instance resource-based financing. Finance must be made flexible, long term and affordable;</li> <li>- Access to capital: securing funding from established financial institutions and improve the ability of local financial institutions to support healthcare enterprises;</li> <li>- Regional health financing hubs: innovative financing solutions in response to unique needs of the health sector;</li> <li>- Regional hubs for innovation: creation of cutting-edge technology hubs or networks of entrepreneurs.</li> </ul>
<b>Extrinsic Ecosystem</b> 	<ul style="list-style-type: none"> <li>- Uneven distribution of - often poor quality, health infrastructure, including major gaps in the coverage of rural areas;</li> <li>- Lack of supply of raw materials:</li> </ul>	<ul style="list-style-type: none"> <li>- Opportunities to develop advocacy with other social sectors to prioritize such as water sanitation, education, food security;</li> <li>- Partnerships between IPAs, development banks, and private equities can enable the creation of better health infrastructure;</li> <li>- Promote local sources of supply of equipment and raw materials, enabling the supply of locally available materials.</li> </ul>

In summary, some of the key determinants to attract new investments in the health sector in the African region include investment in skilled workers, establishment of clear regulatory structures and partnerships, creation of additional funding options and investment in health care structures. In terms of access to funding, there is a need to distinguish donor funding and funding for R&D. Regarding donor funding, it is suggested to place less reliance on private donors given the economic uncertainties and the fact that most tend to approach disease vertically (Azevedo, 2017). This comes in line with the position of the United Nations recommending that African countries focus on the development of horizontal health systems



that address a broad range of needs, along with vertical programmes that address specific diseases (United Nations, 2019). With regard to R&D funding a strong collaboration with the private sector is recommended.

## 5. Health innovation and entrepreneurship in Latin America and the Caribbean

Latin America and the Caribbean (LAC), like many other regions, hosts culturally and ethnically diverse populations and experience high variations in terms of economic development, rising political instability and changing epidemiological profiles - including a rise in chronic non-communicable diseases (NCDs). Overall, LAC exhibits deeply fragmented and segmented health systems, thus impacting the provision quality care, as well as overall equity levels in the region (Ruano et al., 2021).

Therefore, a common characteristic to all health systems in LAC is the lack of access to health care services and strong inequalities in health. Indeed, around 30% of the population does not have access to health care for economic reasons, and more than 20% do not seek care due to geographical barriers (García-Ramirez, 2016). In addition, LAC is faced with another particularity, that of indigenous populations impacted by a general marginalization from health systems. They are also one of the most excluded population groups in the region (Samuel et al., 2020; ECLAC and others, 2021). Consequently, LAC is faced with an additional challenge of integrating “intercultural medicine” to its health systems that respects the cultural, social, and economic realities of all communities (Sandes et al., 2018).

Across the region, there is a strong consensus that entrepreneurs, especially start-ups, play a vital role in ensuring access to innovation in healthcare, within and across countries (OECD, 2016). Consequently, ensuring the scalability of health innovation has the potential to address health inequalities, improve access to health care, especially in rural areas, and enhance equity across all populations while allowing to reduce or control healthcare costs. Moreover, the COVID-19 pandemic has accelerated the growth of the start-up ecosystem across LAC hastening the digital transformation of the region and its integration within the economy (The Economist, 2022). In this regard, 36 Health-tech start-ups in the region were surveyed by the Latin America Venture Capital Association (LAVCA) and IDB Labs regarding the impact of the pandemic on their businesses, adoption of healthcare technology and access to healthcare services. Half of these start-ups declared that the pandemic has had a positive effect on their activity growth and economic welfare (LAVCA, 2021). More specifically, LAC is experiencing an unprecedented growth in its tech ecosystem with a strong digitalization of healthcare systems (AS/COA, 2020).

Hence, there is a strong interest in digital health in this region, particularly telehealth technologies, allowing for more substantial access to primary healthcare. Indeed, considering that access to health care professionals is unevenly distributed, telemedicine is often presented as an effective solution to address challenges of access to care. On this matter, the Pan American Health Organization (PAHO) considers that telemedicine plays a role in providing solutions to the challenges posed by socioeconomic changes in health care systems, for example in increasing demand for healthcare, ageing populations and rise in NCDs, especially in economic and resource constraints environments (PAHO, 2016).

Nevertheless, although innovative companies are emerging and venture capital investments are rising, ensuring the establishment of innovation systems is an ongoing challenge in LAC. Three main challenges to health innovation and entrepreneurship can be identified in the region:

*Human resources constraints.* Geographical disparities apply concerning the distribution of human resources in health, leading to significant gaps in access to health care professionals, associated with insufficient training of the latter, especially in resource-constrained settings (Curioso, 2019).

*Funding constraints.* Health systems in LAC are based on disease not prevention, which is not deemed sustainable especially with regard to the changes in patterns of disease and rising ageing populations that are increasing the cost of health care (García-Ramirez, 2016).

Additionally, many countries within the region are witnessing the privatization of public health care, which is detrimental to public health care services for which capacities are already limited (Ruano et al., 2021). Furthermore, investments in LAC are heterogeneous between countries and public investments in health must be accelerated to achieve the PAHO recommendation of spending 6% of the gross domestic product (GDP) on public health expenditure to support the provision of universal healthcare, which has only been achieved by a few countries such as Costa Rica and (ECLAC & PAHO, 2020).

*Infrastructure constraints.* To ensure the scalability of telehealth innovations, reliable and adequate connectivity and technology infrastructure is essential. However, less than 50% of the population has fixed broadband connectivity (Drees-Gross & Zhang, 2021). Additionally, it has been estimated that 32% of the population does not have access to Internet services, excluding these individuals from the possibility of accessing services that can replace some activities that usually require physical contact (Katz et al., 2020). The lack of technological infrastructure is also a limiting factor and relates to the gap of access to digital trainings for healthcare workers. In this regard, frameworks on the use of telehealth, regulations and reimbursement policies have yet to be strengthened to match the needs of health innovation (Pierce et al., 2021).

A non-exhaustive list of examples of global and regional initiatives that support the efforts to implement health innovation and entrepreneurship in LAC is provided below.

1. UNCTAD's EMPRETEC capacity-building programme for entrepreneurship development was launched more than 30 years ago in Argentina. There is a strong presence of the network of Empretec centers hosted in national business development centres in the region through which entrepreneurship promotion and training are offered. Additionally, UNCTAD has supported the government of Costa Rica, Ecuador and El Salvador in the development of their entrepreneurship strategies.
2. In October 2019, the 57th Directing Council of the PAHO, through Resolution CD57/9, adopted the Plan of Action for Strengthening Information Systems for Health 2019-2023 to ensure better collection and management of data. The Plan also sets the objective of improving "human resource training in all aspects of information systems for health" (PAHO, 2019, Strategic Line of Action 4 – Objective 4.2).
3. Around 40% of the IPAs in LAC identified health-tech as a priority sector and most tend to demonstrate their support in this field (LAVCA, 2021). For instance, Costa Rica's IPA was awarded one of the three awards given to IPAs in excellence in promoting investments in health for its commitment to attract investments in health, including talents and specific economic incentives.

#### a) Case studies

The two case studies presented in table 6 analyze innovative products brought about by Artificial Intelligence (AI) and Telehealth. Arkangel Ai based in Argentina creates AI models for early disease detection while Guatemala's Doctor Online facilitates the use of telemedicine programmes by companies related to the health sector. Both businesses offer products that fall under the category of digital health technology.

AI applied to the healthcare sector has a revolutionary potential and will be used increasingly as a result of the complexity and growth of the data. In the region, it has been recognized as a game changer in, for instance, clinical radiology. Telemedicine techniques have been used more and more by social security and health care organizations in LAC, a trend that has been further accelerated during the pandemic. Across the continent, frameworks and models promoting telemedicine have been implemented between 2019 and 2020 with excellent results.<sup>5</sup> The export of telemedicine service is a major opportunity for countries in the region. There is a positive relationship between the use of international telemedicine and the productivity and efficiency of health

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<sup>5</sup> The International Social Security Association. <https://ww1.issa.int/analysis/telemedicina-buenas-practicas-en-america-latina>

professionals. The use of international telemedicine is also associated with better returns for national health systems (Rubiò et al. 2021).

Table 6: Overview of case studies in Latin America and the Caribbean

Case study	Arkangel Ai <sup>6</sup>	Doctor Online <sup>7</sup>
<b>Aim</b>	Transform medical data into AI models without code, for early disease detection and diagnosis to prevent avoidable deaths.	Facilitate the implementation of telemedicine programmes by companies in different countries, such as instance insurance, assistance companies and healthcare companies.
<b>Product description</b>	Started by building a chatbot, which ended up being used by more than 9,000 users in 22 countries over the course of one month, conversations came about with the users allowing for the identification of three main challenges in health systems worldwide that the business identified which are prevention, early disease detection and lack of access to health care of important parts of populations. AI is the solution to these challenges, to build a cost-effective algorithm to improve access to care and enable early disease diagnosis for any type of disease that is more prevalent in a specific area or country.	The first product was an SMS based system to access a health care professional using a mobile phone based on a medical assistance Q&A. Now, a platform and service are offered to consumers that can be tailored and personalized depending on the client (e.g., integration of the client's database, specific medical protocols). It is a B2B solution customizable to consumer needs. In most cases, patients are benefitting from the services offered via the platform through their insurance. The solution can also be used as a first level of care for employees in companies that have no in house doctors.
<b>Challenges to launching product</b>	<ul style="list-style-type: none"> <li>- Health ecosystem is unfamiliar with health technologies;</li> <li>- Lack of regulation in the area of health technologies;</li> <li>- Challenges in accessing data to feed the algorithms (e.g., clinical data: biopsy).</li> </ul>	<ul style="list-style-type: none"> <li>- Data interoperability in the ecosystem;</li> <li>- Uncertainty of the legislation and regulatory framework on telehealth;</li> <li>- Need to ensure scalability;</li> <li>- Access to funding (no funding from outside sources), especially challenging in smaller countries in LAC.</li> </ul>
<b>Solutions to the challenges</b>	<ul style="list-style-type: none"> <li>- Educate systems on the use and potential of health technologies;</li> <li>- Regulations are needed but there is a risk of being "over-regulated". Striking an appropriate balance in the regulation of new tech;</li> <li>- Building trust in the ecosystem;</li> <li>- Need for options for start-ups to "try", for example encouraging pilots, regulatory sandbox.</li> </ul>	<ul style="list-style-type: none"> <li>- Standardizing data across the system: including prescription, diagnostics, list of labs and exams. Need for harmonization of medical records and international standard ways of communicating data;</li> <li>- Legal and regulatory enhancements, for instance the release of a new legislation on telehealth in Mexico in 2022;</li> <li>- Funding is essential, there is a need to scale-up fast in bigger markets.</li> </ul>
<b>Wider effects of product on</b>	Prevention and early disease detection requires important infrastructures that most countries do	Digital health, here telemedicine, allows to provide 24/7 on demand health care with no previous appointment required,

<sup>6</sup> <https://www.arkangel.ai>

<sup>7</sup> <https://www.doctor-online.co/index.php>

Case study	Arkangel Ai <sup>6</sup>	Doctor Online <sup>7</sup>
<b>health systems</b>	not have access to AI has shown a growing impact in key categories of healthcare allowing to strengthen the innovation ecosystem, mainly involving the screening and the early detection of different health priorities (Tentori et al., 2020). The solution was extended to countries in other regions such as Spain, the United Kingdom and the United States.	improving access to care. The company is implemented in LAC and Greece. Future development will aim at integrating more services and integral care to the platform, including integrating the possibility of house visits, recommendations to healthcare professionals for F2F appointments, pharmacies.

## b) Conclusions from context specificities and case studies

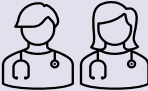
In summary, a new health system appears to emerge in LAC, where the service-oriented side of healthcare is becoming prominent, offering new opportunities for start-ups to enter the market. If properly framed and regulated, public and private sector partnerships and entrepreneurial ventures are going to be key in making healthcare services more affordable and more evenly distributed in the region. Telehealth is considered as a valuable way forward to overcome the historical weaknesses of health systems.


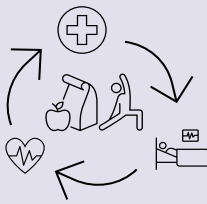
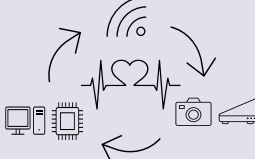
The scalability and sustainability of telehealth programmes and innovations would benefit from a “multinational research agenda”. It would foster collaboration in the testing of emerging telehealth innovation and allow for the rapid replication of best practices. (Dinesen et al., 2016). This has the potential to provide a uniform framework for identifying and rapidly replicating successful practices while simultaneously fostering global collaboration in the development and rigorous testing of new telehealth technologies.

Table 7 presents an overview of the health innovation environment based on the previously mentioned scalability and sustainability framework and to subsequently formulate policy options.

Overall, five commonly acknowledged barriers to telehealth innovations could be identified, ranging from regulatory, financial, technological, organizational, and human factors (LeRouge et al., 2019). Moving forward, some of the key determinants to attract new investments in the health sector include, among other areas, investment in telehealth, the establishment of clear partnerships, the creation of additional funding options and the investment in overall health care structures.

Table 7: Overview of the barriers to entrepreneurship in healthcare in Latin America and the Caribbean

Focus Area	Limitation	Policy Options
<b>Human Factors</b> 	Training and distribution of human resources in health; Unmet need for training and building the capacity of professionals in digital health (Curioso, 2019).	A workforce trained in digital health will be essential to well-functioning telehealth initiatives and will allow to strengthen health systems and ensure adequate service delivery (Curioso, 2019); Promote training programmes including in, for instance, intercultural and multilingual educational tools and solutions in line with local health needs that comprise economic, social, cultural and organizational factors; Programmes that is responsive to the needs of all relevant regional stakeholders including government agencies, non-governmental

		organizations, industry, academic or research entities and local communities).
<b>Technical Factors</b> 	Lack of interoperability; Concerns around data protection.	Promote data governance, standards, and patient empowerment, such as Brazil's General Data Protection Law to regulate the collection and use of personal data that came into effect in 2020 and was influenced by the European Union's General Data Protection Regulation (GDPR).
<b>Healthcare Ecosystem</b> 	Innovators can find partnering with the public sector to be difficult due to delays in repayments and lack of transparency in procedures, including tendering processes (Escobar et al., 2016) Regulatory barriers: lack of appropriate regulatory frameworks, data privacy regulations, taxation and compliance regulations (LAVCA, 2021). Lack of patient acceptance of new technologies. Heterogenous investments between and within countries and lack of appropriate funding for entrepreneurs.	Encourage public-private partnerships at all levels to promote innovation in health and ensure trust between stakeholders (OECD, 2016); Government partnerships can be beneficial to entrepreneurs as governments play a very large role in healthcare delivery and payment, especially for low-to middle-income populations (Escobar et al., 2016); Political commitment is key to realizing the full potential of health innovation. This comes in line with the need to work towards a multi-stakeholder environment in which one system's problem is not only one stakeholder's issue; Investment in the development of telemedicine (AS/COA, 2020); Need for specific ways to enable investment, such as matching funds from governments to attract investment in smaller regions.
<b>Extrinsic Ecosystem</b> 	Strong digital divide in the region; lack of digitalization system.	Ensure reliable and affordable access to the internet.

With regard to access to funding, the implementation of financing mechanisms that facilitate the creation of technology-based enterprises has the potential to promote digital entrepreneurship and encourage public sector innovation (ECLAC, 2021). In addition to their work towards improving the efficiency of health systems using existing resources, decision makers may need to consider options to raise additional resources to fund health services. Overall, governments have a role in channeling investments and funding towards the health sector, as well as finding alternative funding mechanisms that encourage prevention (AS/COA, 2020). Finally, prioritization should be addressed within the region and across countries as it will contribute to ensure the long-term sustainability of health systems and increase resilience against future challenges (OECD & World Bank, 2020).



## 6. Health innovation and entrepreneurship in Asia-Pacific

Asia-Pacific is the most populous region in the world (United Nations, 2019). Defined by a wide variety of populations, the region comprises a diverse group of countries in terms of their respective economic development, demographic and epidemiological profiles, political systems, historical background, and culture. Consequently, these diversities are also felt in their respective health systems (OECD, 2020). Indeed, the latter implies important health challenges, including a rapidly aging population in the region, larger prevalence of NCDs and chronic diseases, as well as health systems based on hospital-centric care, focusing on curative care at the expense of disease prevention (Yip, 2019).

Therefore, not all countries are impacted by health innovations to the same degree and at the same pace, which makes it essential to understand the different market dynamics in the region. Common challenges and opportunities to deliver scalable and sustainable innovations for Asia-Pacific are presented below.

*Human resources constraints.* Low quality and efficiency of care delivery due to an asymmetric health professional to patient ratio, as well as a strong shortage of specialists can be seen. Resources are unevenly distributed across and within countries in the region. Public health facilities suffer from human and infrastructures constraints notably due to the maldistribution of health workers in Asia-Pacific, leading to a shortage of the latter, especially in rural areas (Short et al., 2016). In addition, available evidence of effective primary health care (PHC) and research towards the organization of PHC services, especially in APAC's low- and middle-income countries, are strongly lacking (Palagyi et al., 2021).

*Funding constraints.* This is especially true considering the medical inflation in Asia-Pacific, consistent with low levels of price transparency and price discipline. In this regard, the Association of Southeast Asian Nations (ASEAN) acknowledges the importance of private investments in the healthcare sector. A significant involvement of the private sector and international private investors has been observed among developing regions from R&D to hospital services or medical equipment (ASEAN & UNCTAD, 2018). This confirms that healthcare goals in the region cannot be met solely on the basis of public investment. Considering that private investment in the development of digital health services has been much greater than that of governments and international funders, evidence suggests that government support needs to be based on partnerships with other stakeholders, beyond simply implementing changes to government health systems and funding of pilot projects (Bloom, 2019).

*Digital infrastructures constraints.* Although Asia-Pacific accounts for half of the world's internet users (Tonby et al., 2019), significant gaps in internet coverage remain in for instance Indonesia and Pakistan with the widest gap in Bangladesh where nearly two-thirds of the population had no access to mobile internet in 2020 (Statista, 2022).

Besides their contribution to digital innovation, entrepreneurs have the potential to contribute to the improvement of existing infrastructures such as advancing regional connectivity through cross-border solutions, local operations and investments. Indeed, healthcare start-ups are providing a wide range of health solutions, from technical to medical solutions, using inter alia telehealth, data analytics, as well as artificial intelligence. Moreover, evidence shows that entrepreneurship has the potential to address socio-economic problems in resource-poor settings including South Asia (Sharmelly, 2018).

Overall, entrepreneurs of SMEs and start-ups play an important role in strengthening the health ecosystem in the region. However, SMEs still face important barriers to entry that are often more challenging, including regulatory barriers, limited access to funding, and lack of support to innovate (ASEAN & UNCTAD, 2019).

The COVID-19 pandemic has accelerated the trend towards personalized healthcare (PH) in the region (ASEAN & UNCTAD, 2021). In this regard, it is acknowledged that Asia-Pacific has the potential to be a strong leader in PH, notwithstanding rising healthcare costs, as well as growing and aging populations (Das, 2021). According to the Asia Pacific Personalized Health

Index, the region – despite its significant regional differences in readiness for personalized healthcare, is successfully adopting an approach based on personalized diagnosis and treatment as well as enabling the use of digital innovations (FutureProofing Healthcare, 2021).

While low awareness towards personalized healthcare in society and lack of political support and financial investment are main barriers to this type of care, multi-stakeholder approaches and multi-country strategies have been identified as potential to leverage resources and expertise, increase reliance, and enable the adoption of solutions to it (Chong et al., 2018).

A non-exhaustive list of examples of regional initiatives that support the efforts to implement health innovation and entrepreneurship in the region is provided below.

1. UNCTAD's investment in entrepreneurship capacity building. For instance, the EMPRETEC capacity-building programme for entrepreneurship development.
2. The Asia Pacific Observatory on Health Systems and Policies (APO) is a collaborative partnership of interested governments, international agencies, foundations, and researchers that promotes evidence-informed health system policy regionally and in all countries in the Asia Pacific region.<sup>8</sup>
3. The ASEAN Digital Integration Framework, adopted in 2018, aims to strengthen digital integration and focuses on six priority areas: facilitate seamless trade, protect data while supporting digital trade and innovation, enable seamless digital payments, broaden the digital talent base, foster entrepreneurship and facilitate regional coordination efforts.<sup>9</sup> Encouraging digital cooperation led to other noteworthy regional initiatives. For instance, the ASEAN Data Management Framework (2021),<sup>10</sup> the ASEAN Framework on Personal Data Protection (2016)<sup>11</sup> and the ASEAN Model Contractual Clauses for Cross Border Data Flows (2021).<sup>12</sup>
4. In the Philippines, Regional Inclusive Innovation Centers are promoting inclusive growth and development.<sup>13</sup> They were implemented as platforms to link stakeholders from the government, academia and industry to address gaps in the innovation and entrepreneurship ecosystem (Aldaba, 2019). In practice, they bridge the gaps and forge linkages among innovators, entrepreneurs and enablers in the country's regional innovation and entrepreneurship ecosystems to support enterprises, especially MSMEs, in innovating products, processes and business models, and to address market gaps and societal needs.

#### a) Case studies

The two case studies presented in table 8 cover the challenges faced by entrepreneurs in Asia-Pacific falling under the category of innovative health technology and digital health companies. The first one is improving heart health. With 17.9 million deaths per year, cardiovascular diseases (CVDs) are the leading cause of death worldwide. Of these, more than 75% are attributable to low and middle-income countries.<sup>14</sup>

The second case study is Malaysia's digital health company DoctorOnCall that offers an online medical video-consultation platform combining advanced video and voice technologies with the medical knowledge and experience of the country's top doctors.

The digital health sector is emerging at unprecedented scale in across Asian countries. It affects more than one billion lives and will continue to grow, pushed by many factors such as aging population, lack of doctors, rising consumer expectations, technological

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<sup>8</sup> Asia Pacific Observatory on Health Systems and Policies, <https://apo.who.int>

<sup>9</sup> ASEAN Digital Integration framework, [Adopted-ASEAN-Digital-Integration-Framework.pdf](#)

<sup>10</sup> ASEAN Data Management Framework, 2021, [2-ASEAN-Data-Management-Framework\\_Final.pdf](#)

<sup>11</sup> ASEAN Framework on Personal Data Protection, 2016, [Microsoft Word - ASEAN Framework on PDP\\_final \(16 Nov 2016\)](#)

<sup>12</sup> ASEAN Model Contractual Clauses for Cross Border Data Flows, 2021, [3-ASEAN-Model-Contractual-Clauses-for-Cross-Border-Data-Flows\\_Final.pdf](#)

<sup>13</sup> Regional Inclusive Innovation Centers, [RIICs: Building Innovation Platforms and Networks in the Regions - innovate.dti.gov.ph](#)

<sup>14</sup> WHO. [https://www.who.int/health-topics/cardiovascular-diseases#tab=tab\\_1](https://www.who.int/health-topics/cardiovascular-diseases#tab=tab_1)

innovation and a growing financial burden (governments are the dominant payers in Asia, accounting for 64 percent of all health expenditures in 2018).

Table 8: Overview of case studies in the Asia-Pacific region

Case study	Imedrix <sup>15</sup>	DoctorOnCall <sup>16</sup>
<b>Aim</b>	The aim of iMedrix is to extend heart health beyond hospital to primary, community and home settings.	Provide fast, easy and cost-effective access to Malaysia's top doctors and other healthcare providers in the country. Patients can have medical video visits on their smartphone or computers at any time, anywhere.
<b>Product description</b>	KardioScreen, the flagship product of iMedrix is a scalable mobile ECG device that records real time cardiac impulses in clinical and out of hospital settings. It analyzes and transmits the data through cloud for a primary clinician or paramedic and further to an expert's interpretation.	A digital health platform offering three main lines of services, an e-pharmacy, with e-prescription and medication delivery, medical services with health screening and consultation by specialists and medical content in local language.
<b>Challenges to launching product</b>	<ul style="list-style-type: none"> <li>- Smaller medical practices are not used to new technology and new method of producing diagnostic. On the patient side, resistance to new technology is high as well. This results in a slow adoption of new technology, due to the strength of traditions;</li> <li>- Regulatory approval is long and cumbersome and too diverse from country to country in the same region;</li> <li>- Uncertainty related to the production, use and storage of medical data is too high.</li> </ul>	<ul style="list-style-type: none"> <li>- Uncertainty caused by the absence of any laws regulating digital health. A lot of pushbacks from authorities and associations of medical profession;</li> <li>- Lack of trust among the population and doctors due to the use of new technology;</li> <li>- Lack of funding as Malaysia is a smaller market than other countries in the region.</li> </ul>
<b>Solutions to the challenges</b>	<ul style="list-style-type: none"> <li>- Different go-to-market strategic alliances with different corporations (Siemens, Philips, Medtronic) allowing iMedrix to improve its market access and distribution channels, solve regulatory issues.</li> </ul>	<ul style="list-style-type: none"> <li>- Cooperation with regulatory authority to set up sandbox regulation based on the case of DoctorOnCall;</li> <li>- Production of medical content in local language to build trust of potential patients;</li> <li>- Use of the start-up founder network to raise capital through VC deals.</li> </ul>
<b>Wider effects of product on health systems</b>	People in the remote areas do not undergo this test regularly and the reasons are many, from access to awareness to affordability. As KardioScreen is a portable electrocardiogram machine that resembles a tablet, provides an ECG test result in 3-5 seconds and has data stored in cloud, it allows for an early diagnosis and reduces the cost	Radical disruption in the Malaysian market for healthcare in the area of quality and affordable healthcare for everyone, especially for population leaving in rural areas. The start-up has wider effect on the health system as it offers the Malaysian counterpart of "webmd" in local language, thereby reducing medical illiteracy.

<sup>15</sup> <https://www.imedrix.com/>

<sup>16</sup> <https://www.doctoroncall.com.my/>



Case study	Imedrix <sup>15</sup>	DoctorOnCall <sup>16</sup>
	burden for the patient. Finally, it paves the way for remote cardiac care.	



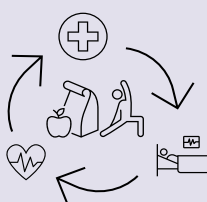
## b) Conclusions from context specificities and case studies

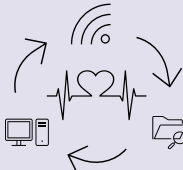
Asia-Pacific is witnessing a rising demand for health notably due to population growth, changing demographics and epidemiological profiles, aging populations, and an increase in NCDs and chronic diseases. Facing these challenges will require the involvement of the public and the private sector, which has a role to play in complementing public efforts to meet healthcare needs and support the development of a new innovative health ecosystem.

Such an ecosystem calls for a meaningful dialogue between stakeholders even though countries in the region are faced with different challenges and opportunities, thus necessitating the elaboration of solutions tailored to local needs. Indeed, it is once again fundamental to consider that there is no one-size-fits-all solution in this environment. Therefore, creating dynamic health ecosystems will require collaboration to avoid fragmented regulatory policies and legislations, as well as more policies to enable innovation and more cost-efficient solutions, including among others close collaboration with local governments.

Table 9 presents an overview of the health innovation environment based on the previously mentioned scalability and sustainability framework and to subsequently formulate policy options in the region.

Table 9: Overview of the barriers to entrepreneurship in healthcare in Asia-Pacific

Focus Area	Limitation	Policy Options
<b>Human Factors</b> 	<ul style="list-style-type: none"> <li>- Disparities in the distribution of health care professionals across and within countries.</li> </ul>	<ul style="list-style-type: none"> <li>- Consider the policy options proposed by the WHO Global strategy on human resources for health: workforce 2030 (WHO 2016).</li> </ul>
<b>Technical Factors</b> 	<ul style="list-style-type: none"> <li>- Lack of interoperability (WIF APAC, 2021).</li> </ul>	<ul style="list-style-type: none"> <li>- Promote data governance, standards and patient empowerment.</li> </ul>
<b>Healthcare Ecosystem</b> 	<ul style="list-style-type: none"> <li>- Funding;</li> <li>- Overregulated environments can be detrimental to innovation;</li> <li>- In a digital environment, there is a need to consider the issues of data ownership, residency, protection and security;</li> <li>- Lack of tangible, reproducible data.</li> </ul>	<ul style="list-style-type: none"> <li>- Foster a climate more conducive to private investment such as a combination of public and private funding;</li> <li>- Enable access to and use of “meaningful data”, including an increased data interoperability (Das, 2021);</li> <li>- Strike a balance between regulating and promoting innovation. This balance can also be found at the regional level (introduction mutual recognition of certain standards across between ASEAN countries);</li> </ul>

		<ul style="list-style-type: none"> <li>- Promote sustainable innovation to improve efficiency and quality of health care delivery (ASEAN &amp; UNCTAD, 2019);</li> <li>- Enforce transparency, including data transparency, and price discipline;</li> <li>- Ensure data interoperability and standards.</li> </ul>
<p><b>Extrinsic Ecosystem</b></p> 	<ul style="list-style-type: none"> <li>- Strong infrastructure disparities between countries and different states of readiness for innovations in health (WIF APAC, 2021).</li> </ul>	<ul style="list-style-type: none"> <li>- Promote the strengthening of infrastructures on different points including access to data, connectivity, use of Electronic Health Records (EHRs).</li> </ul>

Where appropriate, certain regulatory issues could be harmonized to facilitate cross-border decisions and investments in health innovation (ASEAN & UNCTAD, 2019). In this regard, establishing appropriate regulatory systems is essential to promote health innovation and improve access to quality care for all. This is particularly important in Asia-Pacific considering the growing prevalence of chronic diseases that comes in line with population aging as previously mentioned (Lim, 2018). Consequently, a multi-stakeholder approach needs to be the cornerstone of any initiative aimed at addressing the challenges faced by regulatory systems. Practical solutions can be found including innovative regulatory mechanisms in the form of regulatory sandboxes and allowing small-scale and live testing of innovations in a supervised environment. To conclude, new innovations, including the rise in personalized healthcare, offer new opportunities to prioritize decision-making directed to emerging changes in healthcare systems and build future healthcare systems that are fit for purpose.

## 7. Discussion

The pressure on health systems to meet the needs of populations in an efficient and economic manner has never been greater. The increase in health expenditure, aging populations, the rise in the prevalence of chronic diseases are, among other factors, intensify the challenges faced by health systems in all regions. The COVID-19 pandemic accelerated these pressures. As a result, innovative approaches to healthcare practice and delivery are increasingly needed. As mentioned throughout this paper, health innovation can materialize in different ways, from innovative health technologies to digital health technologies, all the way to personalized healthcare. Nevertheless, regardless of the type of innovation considered in a particular setting, common barriers remain and were identified across regions.

In this regard, innovation in health is largely driven by entrepreneurs, yet they are experiencing significant barriers in terms of scalability and sustainability of their innovation. These include contradictory incentives between stakeholders, lack of appropriate funding, as well as demanding accountability, which are well known challenges that were identified years ago but still relevant in 2022 and remain over time (Herzlinger, 2006).

In the context of the NHE, complex and fragmented health systems within regions, multi-stakeholder environments, as well as external factors are highly impacting the scalability of health innovations.

While it is acknowledged that there is no one-size-fits-all approach in this area, five options are proposed that can be applied and adapted in different settings. They are aligned with UNCTAD's Entrepreneurship Policy Framework (EPF) which comprises six key components

respectively formulating a national entrepreneurship strategy, optimizing the regulatory environment, enhancing entrepreneurship education and skills development, facilitating technology exchange and innovation, improving access to finance, and promoting awareness and networking.

The following proposed policy options are intended to encourage the creation of a “culture for innovation” that acknowledges, encourages and rewards new ideas, providing the right environment conducive to innovation (Kelly & Young, 2017). The first three options target the overall system, while the last two are aimed at the product or service itself.

- 1) **The regulatory environment.** The main challenge for governments is to strike an appropriate balance between an overregulated environment and a lack of regulation. Moreover, support from governments and policies that promote alignment between the characteristics of an innovation and local regulations can facilitate entrepreneurship and allow space for local adaptation without compromising the potential of the innovation (Côté-Boileau et al., 2019). Finally, policymakers may also benefit from the experience of successful local entrepreneurs to add to the discussion and create more efficient regulatory environments. This can be done by inviting the latter to workshops and discussions during the process of drafting legislation (Barto et al., 2022).
- 2) **Access to funding**, which in the healthcare industry is intimately linked to regulation was presented as an important challenge by entrepreneurs. Long timelines and stringent requirements to obtain funding are most often an insurmountable obstacle for start-ups. Therefore, early-stage support and funding opportunities for entrepreneurs can be provided by both the public and private sector, as well as support organizations, for example in the form of grants. There is a need for better communication between funders and entrepreneurs, including a good contextual knowledge of local market specificities and cultural differences (Barto et al., 2022). This comes in line with the necessity to implement more flexibility in the demonstration of the cost-effectiveness and long-term safety of an innovative product/service. In addition to innovative funding models, there is a recognized need for health systems to align reimbursement policies towards digital health solutions to increase their adoption (Schlieter et al., 2022). Additionally, access to capital can be improved by aligning the objectives of investors and entrepreneurs. Finally, incentive models for entrepreneurs to develop products aimed at supporting specific needs and solving targeted health system challenges can be explored.
- 3) **Foster an enabling environment for entrepreneurship by building long-term innovation capacity** (Barto et al., 2022); underlining the need to increase trust towards innovation in health while **increasing awareness and networking** among stakeholders. To guarantee the scalability and sustainability of health innovations, the involvement of all stakeholders is required. There is a need to consider the interconnectedness between product innovation and service innovation with regards to the environment in which these are implemented. Innovative solutions from private stakeholders should be integrated into public health systems. SMEs are mostly responsible for driving innovation in the field of digital health, yet these businesses face important barriers to entrance, particularly in public health systems. SMEs face substantial difficulties in attracting users and payers from the public system due to unfavorable economic incentives. Doctors are paid through in-person visits, but digital health solutions aim to keep patients out of clinics and hospitals (Kelley et al., 2020). On this matter, there is a need to “maximize” value in public-private partnerships (Shaw et al., 2018). This applies to all stakeholders involved in the health ecosystem via increased collaboration and dialogue and identify cross-cutting needs to the development of entrepreneurship in the health sector. Another solution is to create innovation hubs, which have the potential to support innovators in the development of their project by bringing entrepreneurs and stakeholders with expertise together, allowing to transform ideas into concrete innovations (iED, 2020). Innovation hubs can benefit from investments by a variety of funders including governments, mobile operators, private stakeholders, and venture capitalists.

- 4) **The engagement of stakeholders will be facilitated by** implementing training and capacity-building for different stakeholders, not only entrepreneurs and innovators. In this regard, evidence demonstrates the benefits of training local health professionals, including frontline workers and CHWs, to ensure the sustainability and continuity of specific initiatives through health workforce development (Long et al., 2018). Leveraging the capabilities of the local workforce has the potential to increase trust towards innovative solutions developed at local level. This of course requires sufficient training opportunities for those workers. These can be complemented by specific programmes to support entrepreneurs, notably in the market entry process such as support in meeting regulatory requirements, intellectual property rights, technical assistance among others. Moreover, another study revealed that entrepreneurs reported the lack of qualified mentors in the health sector (Barto et al., 2022). This underlines the need to prioritize mentorship and training of future health innovators and entrepreneurs, especially from local stakeholders with relevant experience, which has the potential to increase the sustainability of innovative initiatives (Suryavanshi et al., 2019).
- 5) **Addressing barriers to interoperability and implementing a pragmatic approach to information governance** (PwC, 2020). Indeed, interoperability is critical and directly aligned with component (4) of UNCTAD's EPF. While privacy is important, so too is data sharing (Kelly & Young, 2017). Without distinguishing between different components, layers or levels, interoperability can be defined as "the ability of two or more systems or components to exchange information and to use the information that has been exchanged" (Lehne et al., 2019, p.1). Innovations, particularly digital health innovations depend on interoperability. As recommended by the WHO on digital health, there is a need to promote standards for interoperability and data sharing, as well as to provide support for the implementation of digital solutions (WHO, 2021a). From AI to telehealth or mobile applications, digital medicine depends on interoperable and standardized data (Lehne et al., 2019).

Overall, there is a need to ensure the recognition and uptake of innovations in healthcare. The process of diffusion is social and interactive and therefore requires collaboration, communication, and knowledge exchange between all stakeholders involved in the health system (Kimble & Massoud, 2017). As underlined in the Principles for Digital Development<sup>17</sup> there is a need to ensure that health innovations are "contextually appropriate and valuable for all stakeholders, specifically end-users (e.g., local health workers) and policymakers, as well as investors".

To summarize, understanding the barriers to the implementation, scalability and sustainability of health innovations helps to better understand what is needed at the local level in order to bring about lasting and large-scale changes to improve the efficiency of health systems. "(Digital) health innovations are increasing accessibility, promoting transparency, and have the capacity to increase accountability — all necessary facets of lasting health systems strengthening" (Labrique et al., 2018b, p.S15).

Colombia can be cited as an example of a best practice of a national government that is in the process of establishing a favourable e-health environment for entrepreneurs of SMEs and start-ups by already implementing many of the above-mentioned policy options. To promote a dialogue among the different stakeholder in this field in an effort to strengthen the entrepreneurship ecosystem in the healthcare industry, iNNpulsa, the Agency for Entrepreneurship and Innovation of the Colombian National Government, organized a series of workshops, one of which was co-organized by UNCTAD. Colombia's process is valuable in terms of lessons learnt, which could inspire other countries.

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<sup>17</sup> Principals for Digital Development, [| Principles for Digital Development \(digitalprinciples.org\)](https://digitalprinciples.org)

Table 10: Colombia's new health economy

iNNpuls Colombia <sup>18</sup>	
<b>Aim</b>	<p><b>iNNpuls</b> provides a formal structure between the private sector (i.e., entrepreneurs and larger stakeholders) and the public sector including government entities and other relevant actors in the healthcare system with the aim to accelerate innovation and entrepreneurship, while addressing systemic challenges as addressed earlier. The CEmprende Program,<sup>19</sup> led by iNNpuls Colombia, facilitates connections between stakeholders including academia, private enterprises, governmental institutions, to strengthen and encourage the development of entrepreneurship and innovation, as well as to strengthen the health sector in the country. Overall, iNNpuls has been working on two main areas: cultivating a community among entrepreneurs and start-ups and promoting open innovation and collaboration between corporations/ larger organizations and start-ups.</p>
<b>Moving Forward: Best Practices and needs</b>	<p>The workshop led to overall policy options on how to move forward:</p> <p>Ensuring a dialogue on how policy reforms could maximize the role of start-ups in the health sector and the overall economy, including a more active participation of regulators, particularly the Ministry of Health in Colombia, and allowing to develop mechanisms to work collaboratively with start-ups to solve challenges to innovation.</p> <p><b>Overall, there is a need to adopt a systemic approach</b> at government level and ensure better inter-ministerial coordination:</p> <p><b>Ministry of Science Technology and Innovation:</b> plays a critical role in connecting the world of research and entrepreneurs) and providing economic support for prototyping and market access;</p> <p><b>Ministry of Commerce</b> (in which INNpuls is situated): plays a critical role in terms of access to funding. This includes the need to design tools for early-stage financing in the venture capital stage, to create guarantees;</p> <p><b>Ministry of Information and Communication Technologies:</b> is a key enabler of all digital initiatives, in charge of the connectivity agenda and the digitalization of the country, as well as the provision of connectivity services in remote areas;</p> <p>Multi-stakeholder dialogue and coordination should involve the <b>private sector</b> as much as possible. Leaders by the entrepreneurs also insure a certain degree of independence from the political restructuring.</p> <p>Solving regulatory challenges is one of the main barriers to overcome in addition to the promotion of innovation in health systems. For instance, opportunity to establish <b>regulatory sandboxes</b> for the Healthtech space can be considered.</p>

## 8. Conclusions

As discussed in this publication, the achievement of SDG 3 (“ensure healthy lives and well-being for all at all ages”) could greatly benefit from the involvement of start-ups and SMEs. They have an increasing role to play in the changing and fragmented landscape of the healthcare industry as drivers of innovation. Inadequate regulations, frequent lack of coordination and support can lead to services gaps and unsustainable solutions in the value

<sup>18</sup> iNNpuls, Colombia, <https://www.innpulsacolombia.com/>

<sup>19</sup> CEmprende Program, [Cemprende Colombia \(innpulsacolombia.com\)](http://CemprendeColombia.innpulsacolombia.com)

chain of healthcare. The COVID-19 pandemic created an opportunity for countries to re-define their approach towards innovation and entrepreneurship in the health sectors with a view of achieving SDG 3 which governments can seize.

To achieve this objective, understanding individual market dynamics and incentives and aligning investment in human resources for health with the current changing landscape of the health ecosystem of a country should be the cornerstone of any government's plan of action to create a dynamic ecosystem that provides access to talents, expertise and capital.

There is a necessity for government institutions to engage in dialogue and to participate in the elaboration of such ecosystems. Gathering the key stakeholders of the healthcare value chain will help create a culture for entrepreneurship and innovation and facilitate the adoption and the scaling up of solutions. International organizations such as UNCTAD can assist governments in this process.

Ultimately, policy options must be based on the consensus that there is no one-size-fits-all approach to solving the challenges of entrepreneurs in healthcare sectors. As demonstrated during the three World Investment Forum sessions that provided the basis for this publication, which focused on three different continents, policies must be tailored to the peculiarities of national and regional contexts.

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## Annex: Methodology

A pragmatic literature search was performed, undertaken between May and June 2022. Well-known search engines such as PubMed and Google Scholar were used with the following search terms: health innovation, entrepreneurship, digital health innovations, scalability and sustainability. Inclusion criteria included literature between 2016 – 2022. The aim of the literature search was to find evidence on different types of innovation, frameworks to assess barriers to health innovation and information on entrepreneurship in the three selected regions which are Africa, Latin America and the Caribbean and Asia-Pacific. In addition to the literature search, three sessions of the World Investment Forum (WIF) that took place in 2021 focusing on Entrepreneurship in The New Health Economy respectively in Africa ("Unlocking digital health innovation in Africa"), LAC ("The rise of MedTech in Latin America") and Asia-Pacific ("Scaling innovation in the NHE"), were analyzed to understand the environment and specificities in each region, the challenges faced by stakeholders and health systems overall, as well as the main policy options issued by panellists during the sessions.

The qualitative part of this research included key informant interviews. The interviewees were entrepreneurs from SMEs, who were selected mainly based on their experience in running a start-up business in health innovation in the selected regions. Prior to conducting the interviews, the research team developed a semi-structured interview guide based on literature. The interviews were conducted during May and August 2022 via Microsoft Teams and lasted for 60 minutes. As interviewees gave their consent, all interviews were recorded. The content of the interviews was analyzed against the prior identified assessment frameworks.