Strengthening Medical Technology Innovation Ecosystems

to address Non-communicable Diseases in Least Developed Countries

WIPO

In cooperation with our partners

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to address Non-communicable Diseases in Least Developed Countries

WIPO
WORLD INTELLECTUAL PROPERTY ORGANIZATION

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Contents

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Executive summary

The World Health Organization (WHO) defines health technologies as including medicines, medical devices, assistive technologies, techniques and procedures developed to solve health problems and improve the quality of life.[1] The COVID-19 pandemic highlighted the critical roles of all types of health technologies in enhancing and protecting human health.

Within this expansive field of health technologies, medical devices represent a key subset. The term "medical devices" serves as an umbrella term, encompassing a wide range of instruments, apparatuses, machines and articles used for the prevention, diagnosis and treatment of diseases or conditions.[2] Medical devices include in-vitro diagnostics (IVDs), imaging equipment, surgical instruments, life support equipment, assistive devices, dental tools and vision aids. These devices can vary greatly in complexity. Some, like bandages, thermometers, stethoscopes, scalpels, forceps and alcohol swabs are simple in both design and function. Others, like pacemakers, dialysis machines, magnetic resonance imaging (MRI) scanners, prosthetics, insulin pumps, laser surgery equipment and hearing aids, are far more advanced, incorporating sophisticated technologies. Despite their prominent roles in healthcare systems, medical devices have received little attention compared to other categories of health technologies such as pharmaceuticals and vaccines.

Advanced medical devices often contain highly engineered components with intricate specifications. The development and manufacture of these devices pose unique challenges. These include the need for specialized manufacturing capabilities; alignment with rapid technological advancements; and the continuous demand for improvement, optimization and innovation. They are also vulnerable to global supply chain disruptions.

Focus on advanced medical devices

This study focuses specifically on advanced medical devices, henceforth referred to as "MedTech." It explores the intellectual property (IP) and innovation ecosystem required to support the growth of, and access to, the MedTech sector in least developed countries (LDCs).

Systematic analyses show that there is a higher prevalence of certain noncommunicable diseases (NCDs) (e.g., hypertension, diabetes, cardiovascular diseases, cancer and chronic respiratory diseases) in LDCs than in developing and developed countries, and simultaneously less awareness and management of these diseases due to limited detection and treatment options. NCDs are often managed with MedTech, including complex devices (e.g., insulin pumps for diabetes or pacemakers for cardiovascular diseases) or devices that require complex infrastructure (e.g., computed tomography [CT] scanners and MRI scanners for stroke diagnosis, or interventional cardiology labs for minimally invasive stent placement).[3]

1 World Health Organization (2023). *Health Technologies*; available at: https://www.who.int/europe/news-room/fact-sheets/item/health-technologies.
2 Ibid.
3 World Health Organization (2017). *Least developed countries: health and WHO: country presence profile*; available at: https://iris.who.int/handle/10665/255802.

MedTech solutions scarce in LDCs

Unlike their counterparts in higher-resource settings,[4] people living in LDCs often do not have access to MedTech solutions. In order to ensure that patients in LDCs receive the care they need, it is crucial to identify and overcome challenges currently limiting MedTech innovation and access in these countries.

The so-called triple helix model of innovation posits that both the public and private sectors drive innovation. The public sector defines and incentivizes the direction of innovation and the private sector benefits from public sector programs to make quick progress in new fields. This report analyzes both the public and private sectors and identifies enablers and barriers to MedTech innovation in LDCs. It studies multiple aspects of the MedTech ecosystem, including the MedTech innovation culture and capacity, IP system, regulatory systems, financing opportunities and policies that can promote innovation and access.

Lessons learned

This report further examines the current state of MedTech innovation and access to technologies in this sector in LDCs. It uses Bangladesh and Rwanda as case study countries to provide specific examples of ground-level realities and to extract lessons learned from their challenges and successes. It identifies opportunities to support the development of and access to MedTech products in LDCs.

This study identifies several enablers and barriers to MedTech innovation and access in LDCs in multiple areas of MedTech development:

Intellectual property

As part of their overall growth strategy, many LDCs are developing their IP systems by enacting industrial property and copyright laws, establishing IP offices and signing IP treaties. Generally, LDCs are perceived as lacking the resources necessary to manage, review, and process IP filings and to facilitate the enforcement of IP rights. As a result, they are often overlooked as IP filing destinations by global MedTech companies. Furthermore, there is often a lack of IP awareness amongst local innovators, who are often not aware of how to utilize the IP ecosystem. To address this, WIPO and government agencies in LDCs can collaborate to strengthen their efforts in training innovators, examiners from local IP offices, judges, and law enforcement officers on leveraging national IP protection to boost innovation and enhance enforcement mechanisms.

Regulatory systems

Regulatory systems in LDCs may be less mature than those in developing and developed countries, complicating the process of registering a MedTech product for in-country approval. This risks disincentivizing both local and international medical device developers from registering for in-country regulatory approval. Even if the innovators apply for approval, there is often a delay in processing applications, constituting a barrier to MedTech innovation and access in the country. Regulatory harmonization, which coordinates regulatory approval application requirements among countries, could help address this challenge. Regulatory reliance (expediting regulatory approvals in one jurisdiction based on previous approval in other countries) can also help to decrease the burden on innovators and regulatory application reviewers while local regulatory frameworks are still under development, continuing to ensure the quality and safety of devices. It is also important to recognize the differences between drugs and medical devices, which may require pursuing different regulatory pathways.

4 A.S. Sarvestani and K.H. Sienko (2018). *Medical Device Landscape for Communicable and Noncommunicable Diseases in Low-Income Countries.* Globalization and Health. We rely on a recent Low-Income Countries (LICs) report to reflect the situation in LDCs. We acknowledge that while the two groups are defined using different criteria, income for LICs and broader development metrics for LDCs, most LDCs are included within the LIC category. Given the absence of recent LDC specific data, this report offers the closest available proxy for understanding relevant trends.

Financing

Local innovators often struggle to access sufficient funds to support early-stage development of high-end medical devices. Investors may be hesitant to engage with an underdeveloped MedTech ecosystem, seeing it as high risk, or may perceive the amount of equity requested in exchange for investment as too high. International innovators may be reluctant to enter LDC markets due to the cost of entering the market surpassing expected profits. To address these challenges, countries can design strategies to support the development of the MedTech ecosystem as a whole, including programs to attract investors and examining ways that the local government can provide incentives to encourage and support local early-stage technology development. In addition, international companies can utilize creative market strategies to facilitate more sustainable market entry.

Training and skills development

The delivery and proper use of MedTech relies on the availability not just of skilled engineers and technicians, but also of medical practitioners. Medical practitioners not only diagnose the need for the technology, but also innovate and improve existing technologies, correctly deploying them and providing appropriate follow-up, monitoring and maintenance. This is often challenging in LDC settings where the necessary human resources, including healthcare providers as well as engineers and technicians, may not be in place. This hinders both local innovation and technology adoption. To address this, governments can invest in the development of both medical and technical/engineering schools to support their countries' changing needs. Multinational companies for their part can provide trainings for healthcare providers to increase their awareness and comfort in adopting new technologies. Additionally, infrastructure challenges can make the local manufacture of medical devices challenging. To resolve these issues, countries must improve their infrastructure and companies should consider LDC-specific needs when developing products for these markets.

Introduction

The report applies the triple helix model to assess MedTech innovation enablers and barriers in least developed countries, using literature, stakeholder interviews, and case studies in Bangladesh and Rwanda, coordinated by WIPO, the UN Technology Bank, and Medtronic.

Objectives

This study is a collaboration among the World Intellectual Property Organization (WIPO), the United Nations Technology Bank for the Least Developed Countries (UN Technology Bank) and Medtronic, a multinational company that is the largest global manufacturer of MedTech. These organizations came together to leverage their respective areas of expertise in an exploration of the challenges and opportunities for the growth of MedTech innovation and access in LDCs.

The United Nations (UN) determines LDC status using three criteria: per capita income, human assets (under-five mortality, maternal mortality, adult literacy rates and gender parity for secondary school enrollment) and economic and environmental vulnerability. LDCs have an average per capita income below $1,018, a low score on the Human Assets Index and a high score on the Economic and Environmental Vulnerability Index. LDCs make up 1.1 billion of the approximately eight billion people on the planet, or about 14 percent of the total population. While the population in more developed countries is decreasing at an annual rate of -0.2 percent, the population in LDCs is growing at 2.4 percent per year.[1] By 2031, more people will be living in LDCs than in more developed countries, yet they have access to significantly fewer medical treatment options. Some of the reasons for this include the lack of availability of medical products; lack of training in how to operate, maintain and repair equipment; and lack of support to innovators seeking to bring new products to market. These issues are caused by multiple factors which will be discussed throughout the report.

Understanding the MedTech sector

To understand why MedTech innovation and access to that innovation is important in LDCs, it is imperative to first understand the MedTech sector itself and the major causes of mortality and morbidity among populations in LDCs. The top causes of death in LDCs are maternal conditions (such as preeclampsia, eclampsia and postpartum hemorrhage) and neonatal conditions (such as neonatal jaundice and respiratory distress syndrome), communicable diseases and malnutrition.[2] All these conditions require MedTech to properly diagnose, treat and monitor patients.

This report defines MedTech as medical devices and diagnostics that require advanced training and infrastructure to utilize (e.g., insulin pumps, pacemakers, X-ray machines, stents). This study explores the current enablers of, and barriers to, MedTech innovation ecosystems in LDCs and

1 Population Reference Bureau (2023). *World Population Data Sheet*; available at: 2024 World Population Data Sheet.
2 World Health Organization (2017). *Least developed countries: health and WHO: country presence profile*; available at: https://iris.who.int/handle/10665/255802.

identifies lessons learned and opportunities for continuing to develop MedTech innovation and access across the developing world, with a focus on LDCs.

To provide insights into the current situation of LDCs in Asia and Africa, the study uses Bangladesh and Rwanda as case studies. Both countries have developed significantly in the past few decades, with Bangladesh making so much progress that it is scheduled to graduate from LDC status in 2026.[3]

Definitions

This report includes imported MedTech products manufactured by multinational companies as well as local MedTech innovation. Throughout this report, the term "innovation" refers to the local development of MedTech within LDCs for domestic use. The term "access" refers to making MedTech that was developed in other countries available and affordable in the target countries.

When discussing life science innovation and access, it is important to consider the differences among the various sectors within the industry. The pharmaceutical, biotechnology and MedTech sectors contribute to improving quality of healthcare but are distinguished by the types of products developed and the infrastructure and skill set required to develop those products. This study focuses exclusively on the MedTech sector.

Demographic and epidemiological context of MedTech in LDCs

More than 75 percent of the people in LDCs live in poverty.[4] The median age in LDCs is 19.2 years,[5] and the life expectancy at birth is around 65 years.[6] In LDCs, there are 0.3 physicians per 1,000 people. In comparison, Brazil, a developing country, has 2.1 physicians per 1,000 people and the United States of America, a developed country, has 3.6 physicians per 1,000 people.[7]

On average, LDCs spend about 4 percent of their GDP on healthcare, while more developed countries spend about 13 percent of their GDP on healthcare.[8] Furthermore, most of the people in LDCs live in rural areas,[9] where health systems tend to be weaker.[10]

Currently, the top causes of death in LDCs are a mix of communicable diseases and NCDs.[11] However, the disease pattern in LDCs is increasingly shifting toward NCDs. NCDs were responsible for 26 percent of fatalities in LDCs in 2000; 31 percent of fatalities by 2010; and 41 percent of fatalities by 2019.[12]

Methodology

Triple helix model of innovation

This report considers the so-called triple helix model, which describes the interplay of university-industry-government relations as a major enabler of innovation. This model argues

3 United Nations (n.d.). *Bangladesh Graduation Status | LDC Portal - International Support Measures for Least Developed Countries*. available at: https://www.un.org/ldcportal/content/bangladesh-graduation-status.
4 Ibid.
5 United Nations, Department of Economic and Social Affairs, Population Division (2022). *World Population Prospects: The 2022 Revision*; available at: https://population.un.org/wpp/.
6 World Bank Group (2024). *Life expectancy at birth, total (years) - Least developed countries: UN classification | Data*. available at: https://data.worldbank.org/indicator/SP.DYN.LE00.IN?locations=XL.
7 World Bank Group (2022). *Physicians (per 1,000 people)*; available at: https://data.worldbank.org/indicator/SH.MED.PHYS.ZS.
8 World Bank Group (2025). *Current Health Expenditure (% of GDP).* available at: https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS.
9 United Nations Trade and Development (2015). *Least Developed Countries Report*. available at: https://unctad.org/news/least-developed-countries-report-2015#:~:text=More%20than%20two%20thirds%20of,on%20the%20fight%20against%20poverty.
10 World Health Organization (2021).*Addressing Health Inequities Among People Living in Rural and Remote Areas.* available at: https://iris.who.int/bitstream/handle/10665/341139/9789240024229-eng.pdf.
11 World Health Organization (2020). *The top 10 causes of death*. available at: https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death.
12 Institute for Health Metrics and Evaluation (IHME). (2021). *Global Burden of Diseases (GBD) Results*. available at https://vizhub.healthdata.org/gbd-results/.

that governments, universities and businesses interact dynamically to promote innovation.[13] For example, government defines the IP framework, which helps businesses create new products by licensing the use of technologies developed in universities.

Some important points from this model of innovation include:

- The evolving role of government throughout the innovation cycle: at some stages in the innovation cycle, the government's role is central (e.g., while developing the initial IP and regulatory ecosystem, or providing adequate incentives to de-risk innovation), while in other stages, involvement that promotes direct interaction among academic/medical institutions and industry (e.g., when determining which inventions and discoveries should be transferred out of theoretical research in medicine/academia and commercialized) will be beneficial.
- Different countries have different strengths. Each country has a different mix of human capital with unique skills, knowledge and medical needs. This contributes to the variation seen across different national economies. By leaning into their countries' natural strengths and encouraging specialization in these fields, governments can increase the likelihood of successful economic and industrial development. Therefore, strategies for innovation and economic growth need to be tailored to the unique needs and strengths of each LDC. For innovation to flourish, academics and businesses need to recognize what drives the other and what information is important to share with each other to encourage a successful relationship and build trust. Further, and perhaps most importantly, they need to recognize areas of common ground and the end goal. The establishment of intermediary institutions can help them bridge the divide and translate scientific advances into viable products. A functional and well-coordinated institutional setup is essential for translating the theoretical framework of the triple helix, government, academia and industry collaboration, into tangible innovation outcomes. In LDCs, where innovation ecosystems are typically nascent, the absence of strong intermediary institutions often hinders the alignment of actors.

To understand the roles of governments, businesses and academic institutions in promoting MedTech innovation and access, it is imperative to keep these points in mind throughout the rest of this publication.

This study began with a literature review that looked into enablers of, and barriers to, MedTech innovation and access. The literature was collected from a variety of sources including but not limited to academic journals, patent landscape reports and government reports. It encompassed topics that included innovation ecosystem frameworks, the role of IP in MedTech development, and information on the status of IP, regulatory systems, infrastructure, workforce and manufacturing capacity in LDCs in general. It also examined national health, industrial, IP, innovation and regulatory policies.

Translating lessons learned from case studies

To provide a more comprehensive and practical understanding of the enablers of and barriers to MedTech innovation and access, it was essential to select specific countries as case studies. The case study countries were chosen based on several criteria, including their location in regions with a high concentration of LDCs so that lessons learned could be more easily transferrable and applicable to neighboring LDCs. Most LDCs are in Africa (32 of 44) and Asia (8 of 44).[14] Selected countries also needed to commit to developing their healthcare innovation and access ecosystems and to already have some existing MedTech industry present. Based on these criteria, we selected Bangladesh and Rwanda.

Rwanda has emerged as one of Africa's most innovative economies. It has prioritized its population's healthcare needs over the last few decades and has been a leading country in Sub-Saharan Africa in tracking NCDs and developing programs to tackle the challenges they pose. Rwanda hosts the headquarters of the African Medicines Agency, a specialized agency of

13 L. Leydesdorff and H. Etzkowitz (1996). *Emergence of a triple helix of University—Industry—government relations*. Science and Public Policy, available at: https://doi.org/10.1093/spp/23.5.279.
14 UN Trade and Development. (2024). *UN List of Least Developed Countries*. Available at: https://unctad.org/topic/least-developed-countries/list.

the African Union,[15] which acts as the leading medical regulatory body for the African continent. Home to a growing MedTech innovation ecosystem, which contains initiatives like the East Africa Biodesign program,[16] it is paving the way for new medical technologies to be developed and made available.

Bangladesh was selected due to its status as a graduating LDC in 2026[17] and the progress it has made over the past few decades in advancing healthcare innovation and improving healthcare access for its population. For example, the Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine and Metabolic Disorders (BIRDEM) has the largest diabetic outpatient turnover (i.e., the rate at which diabetic patients are seen and discharged from a facility) in the world in a single physical space and is a leading research center worldwide.[18]

WIPO, the UN Technology Bank and Medtronic contributed to the study in the following ways:

- WIPO: Program managers – coordinated activities across the three organizations and led research and report writing activities.
- UN Technology Bank for the Least Developed Countries: Public sector specialists – supported local research activities in Rwanda and Bangladesh and provided resources to assess the technology needs of LDCs.
- Medtronic: Private sector specialists (largest MedTech company in the world[19]) – connected investigators to subject matter experts who support or come from the private sector and share insights.

PatentSight, the African Regional Intellectual Property Organization (ARIPO) patent database, and the Bangladesh and Rwanda national IP databases were consulted. The WIPO country profiles for Bangladesh and Rwanda were also referenced, as were the UN Technology Bank's Technology Needs Assessments for Bangladesh and Rwanda.

Once the literature review and background research relevant to the national IP systems were completed, semi-structured, open-ended interviews were conducted with subject-matter experts to complement the secondary data. The interviews were conducted to collect direct feedback on the current state and aspirations of MedTech stakeholders in each country and internationally. The UN Technology Bank supervised local MedTech consultants in Bangladesh and Rwanda to conduct in-country interviews. These interviews captured the constraints and aspirations of relevant, local MedTech stakeholders in each country, including health ministries, science and technology ministries, IP offices, local industry, innovators, investors, donors, NGOs and academic institutions.

The study partners collaborated to generate a questionnaire to drive uniformity across all open-ended interviews in Bangladesh, Rwanda and internationally. The interviewers used this questionnaire to structure their conversations with the interviewees, giving them the opportunity to dive deeply into specific topics where relevant. This questionnaire, which can be found in Annex 1, gathered holistic information about the innovation ecosystem and explored topics related to MedTech IP, regulatory, financing and infrastructure/capacity. The questionnaire was used to interview a broad range of stakeholders including but not limited to executives of international corporations, government ministry representatives, multilateral development banks, regulatory experts, IP experts, local innovators, professional societies, etc. A total of 68 interviews were conducted for this project over six months. More information on the types of stakeholders interviewed can be found in Annex 2.

15 African Medicines Agency (AMA). (n.d.). available at: https://amrh.nepad.org/african-medicines-agency-ama; AUDA-NEPAD African Union Development Agency. (2022). *List of Countries that have ratified AMA treaty*; available at: https://www.nepad.org/content/list-of-countries-have-ratified-ama-treaty.

16 Stanford Mussallem Center for Biodesign. (n.d.). *East Africa Biodesign*; available at: https://biodesign.stanford.edu/programs/global-initiatives/east-africa-biodesign.html.

17 United Nations: LDC Portal - International Support Measures for Least Developed Countries. *Bangladesh Graduation Status*; available at: https://www.un.org/ldcportal/content/bangladesh-graduation-status?&&&&node_field_publication_date_value%5Bmax%5D&node_field_publication_date_value%5Bmin%5D&node_field_publication_date_value%5Bvalue%5D&node_field_uw_document_is_archived=All&&search_api_views_fulltext=Bangladesh&page=1.

18 Sunman- Birdem Pharma (2024). *About Us*; available at: https://www.sunmanbirdem.com/about-us/#:~:text=BIRDEM%20(Bangladesh%20Institute%20of%20Research.

19 H. Burke. *Who are the top 10 medical device companies in the world in 2024?* Proclinical; available at: https://www.proclinical.com/blogs/2024-10/top-10-medical-device-companies-in-the-world-in-2024.

Main challenges and enablers in the MedTech sector in LDCs

This section examines challenges and enablers in areas of IP, regulation, finance, and capacity in LDCs from public and private sectors. It highlights that governments, academic institutions and private companies influence MedTech innovation through policy, funding, and the triple helix model.

The MedTech sector in LDCs is affected by several challenges and enablers. The challenges make it more difficult for the MedTech sector to flourish and the enablers increase the likelihood of the sector succeeding. These challenges and enablers come from both the public and private sectors. Governments can pursue policies that have beneficial or detrimental effects on MedTech developments. They can encourage research and development (R&D) by providing sources of funding for entrepreneurs or by pursuing the triple helix model of innovation to promote development in specific fields that are best suited to their local contexts.

Similarly, academic institutions and private companies can encourage development by engaging with public sector institutions to foster improved capacity and more efficient performance. The study has divided the main challenges and enablers into four categories: IP, regulatory systems, financial incentives and capacity.

Intellectual property's role

IP plays an important role in stimulating innovation to develop new medical products to address global health challenges. IP contributes not only to fostering innovation but also to the manufacture of MedTech products by providing incentives to attract investment; offset the risks of failures; and support the transfer of technologies and know-how. Appropriate IP protection fosters innovation, including domestic innovation, and technological development by incentivizing entrepreneurs and businesses, whereas its absence can hinder progress.[1]

MedTech products can be protected by various categories of IP, including patents, utility models, trademarks, trade secrets, copyright and industrial designs.[2]

Patents for innovation

A patent is an exclusive right granted for an invention that introduces a new way of doing something or offers a new technical solution to a problem.[3] To obtain a patent, an inventor, among other conditions, must clearly disclose the technical details of the invention in the patent application, enabling a person skilled in the relevant technical field to replicate it.[4] The details of

1 Commonwealth Secretariat and the UN Trade and Development. (2024). *Harnessing Intellectual Property Rights for Innovation, Development and Economic Transformation in Least Developed Countries;* available at: https://unctad.org/system/files/official-document/comsec2024d1_en.pdf.
2 T. Aplin and J. Liddicoat. *Discussion Paper on The Interplay Between Patents and Trade Secrets in Medical Technologies.* SSRN Electronic Journal' available at: https://doi.org/10.2139/ssrn.4606923.
3 World Intellectual Property Organization. (n.d.). *Patents: What is a Patent?*; available at: https://www.wipo.int/en/web/patents.
4 Ibid.

the invention are then published and made available to the public at large, thereby contributing to knowledge dissemination through technology disclosure and accelerating progress by encouraging innovative and novel product development. The patent owner has the right to stop others from using the patented invention for commercial purposes without the patent owner's authorization.[5] By providing such exclusive rights for a limited time (in most cases 20 years), patents enable inventors to recoup their investments while contributing to the broader scientific community's knowledge.[6] Information contained in patent documents can be very useful to researchers, entrepreneurs and many others.

For example, it allows freedom to operate analyses (i.e., ensuring that the commercial production, marketing and use of a new product or process does not infringe the patent rights of others). These analyses enhance the innovation ecosystem by guiding innovators in identifying opportunities and eschewing infringement, thereby better directing research and development efforts.[7]

Further, innovators use patent information to build on existing patents, evaluate the patentability of their own innovations, identify licensing and partnership opportunities, and stay informed about industry developments.[8]

Patents vs. trade secrets

In contrast, trade secrets protect confidential information. Trade secrets can have significant value and may be licensed, while not being subject to public disclosure.[9] Trade secrets are safeguarded through various measures, such as non-disclosure agreements with employees, business partners, consultants and agents, as well as security infrastructures, offering a cost-effective way to prevent misuse of proprietary information.[10] Trade secrets can be transferred through licenses.[11] Trade secrets can either supplement patents or serve as an alternative, providing flexibility in the way MedTech innovations are protected.[12]

Trade secrets, however, do not stop other innovators from re-inventing or reverse engineering a technology, making such protection relatively limited.[13] When an invention is likely to qualify for patent protection, the decision about whether to use a patent or to keep information as a trade secret should be made on a case-by-case basis. Patents are typically preferred for protecting product innovations, while trade secrets are often better suited for safeguarding process innovations.[14] Moreover, trade secret protection should be considered in cases where the subject matter is not patentable, or where secrecy can be maintained for a considerable period of time (longer than the maximum term of patents).[15]

Trade secrets protection is generally useful to protect an innovation until the innovator has decided on a clear patent strategy.[16]

Utility models

Similar to patents, utility models protect minor improvements to existing products that may not meet the requirements for patentability but can still play a significant role in local innovation.[17] Utility models protect the exclusive right to commercial use of the protected invention.[18] Utility

5 Ibid.
6 World Intellectual Property Organization (n.d.). *Frequently Asked Questions: Patents*. available at: https://www.wipo.int/web/patents/faq_patents.
7 Commonwealth and UNCTAD; op. cit.
8 World Intellectual Property Organization (n.d.). *Patent and Technology Information*; available at: https://webcms.wipo.int/en/web/patents/patent-information.
9 World Intellectual Property Organization (n.d.). *Trade Secrets: What is a Trade Secret?; available at:* https://www.wipo.int/tradesecrets/en/.
10 Ibid; United Kingdom Intellectual Property Office (2021). *The economic and innovation impacts of trade secrets;* available at: https://www.gov.uk/government/publications/economic-and-innovation-impacts-of-trade-secrets/the-economic-and-innovation-impacts-of-trade-secrets.
11 Ibid.
12 Ibid.
13 See Aplin and Liddicoat, op. cit.
14 See United Kingdom Intellectual Property Office, op. cit.
15 See WIPO, op. cit.
16 See WIPO, op. cit.
17 World Intellectual Property Organization (n.d.). *Utility models;* available at: https://www.wipo.int/web/patents/topics/utility_models.
18 Ibid.

models are recognized and protected in the IP laws of relatively few countries.[19] LDCs such as the Lao People's Democratic Republic, Mozambique, Rwanda, Uganda and the United Republic of Tanzania provide protection for utility models.[20] Utility models can enable LDCs to convert minor inventions to wealth and social benefits.[21]

Trademarks, copyright and industrial designs

Trademarks and copyright can be used to help distinguish MedTech products, inform consumers and fight piracy, counterfeiting and unfair competition in the MedTech industry.[22] A trademark is a sign that distinguishes the goods or services of one enterprise from those of other enterprises.[23] A trademark can be a word or a combination of words, letters, numerals, drawings, symbols and three-dimensional features, such as the shape and packaging of goods.[24] Copyright covers rights of creators over their literary and artistic works and, in the case of MedTech products, it protects the contents on their packaging, such as the brand name, logo, color scheme, product information and other elements comprising the overall look and feel.[25] In some cases, they may protect the unique aesthetic features of the product inside the packaging that signify its origin, such as its shape and patterns.

Industrial designs may consist of three-dimensional features, such as the shape of an article, or two-dimensional features, such as patterns, lines or color and the ornamental aspects of a MedTech product that enhance patient experience. These could serve to build brand value and consumer recall, thereby contributing to the commercial success of a MedTech product.[26]

International IP law and special treatment for LDCs

WIPO administers 28 treaties that cover different areas of IP, setting basic standards, global protection systems and classification rules for various products, services and other subject matters.[27] For example, the Paris Convention[28] applies in the widest sense to industrial property, including patents, trademarks and industrial designs, and lays down substantive provisions governing their registration. In contrast, the Berne Convention[29] sets out minimum standards for copyright protection for literary and artistic works. Another key treaty is the Patent Cooperation Treaty, which allows inventors to seek patent protection in almost 160 countries with a single international application.[30]

In addition to the treaties administered by WIPO, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) is a comprehensive multilateral treaty covering all key areas of IP, including patent, undisclosed information, trademark, geographical indication, industrial design and copyright. It sets out minimum international standards for the protection of various forms of IP rights; establishes general principles on domestic enforcement mechanisms; and addresses disputes between members.

Both the TRIPS Agreement and the Paris Convention also provide certain mechanisms that countries use to meet their public health objectives.

LDCs receive special treatment under the TRIPS Agreement due to their unique needs, financial constraints and the necessity for flexibility to establish a strong technological foundation.[31]

19 See Commonwealth and UNCTAD, op. cit.
20 See Commonwealth and UNCTAD, op. cit.
21 See Commonwealth and UNCTAD, op. cit.
22 WHO-WIPO-WTO (2012). *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade;* available at: https://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf.
23 World Intellectual Property Organization (n.d.).*Trademarks: What is a trademark?;* available at: https://www.wipo.int/trademarks/en/
24 Ibid.
25 World Intellectual Property Organization (n.d.).*Copyright: What is copyright?; available at:* https://www.wipo.int/copyright/en/.
26 World Intellectual Property Organization (n.d.). *Industrial Designs: What is an Industrial Design?*; available at: https://www.wipo.int/designs/en/.
27 World Intellectual Property Organization (n.d.). *WIPO-Administered Treaties*; available at: https://www.wipo.int/treaties/en/.
28 Paris Convention for the Protection of Industrial Property (1883).
29 Berne Convention for the Protection of Literary and Artistic Works (1886).
30 Patent Cooperation Treaty (PCT) (1970).
31 United Nations. (2022). *A Guide to Least Developed Country Graduation;* available at: https://www.un.org/ohrlls/sites/www.un.org.ohrlls/files/graduation_booklet_2022_en.pdf

In this respect, LDCs are exempt from applying the provisions of the agreement until 1 July, 2034, or before the date of their graduation from LDC status, whichever is earlier, according to the decision of the WTO.[32] However, the majority of LDCs have enacted laws and put in place mechanisms to provide protection for these IP rights through national or regional offices.

In Africa, several LDCs are leveraging regional cooperation to create capacity for processing IP filings and administering the rights registered or granted through two regional IP offices: the African Intellectual Property Organization (OAPI) and ARIPO.

OAPI serves as the IP office for industrial property for 17 member states in Africa and provides unitary protection for the territory of its entire membership.[33] OAPI was established under the Bangui Agreement adopted in 1977, which aims to enhance development in member states by promoting technological innovation, technology transfer and creativity and by providing uniform and effective protection and education in IP rights.[34] LDCs that are member states of OAPI are Benin, Burkina Faso, Central African Republic, Chad, Comoros, Guinea, Guinea-Bissau, Mali, Mauritania, Niger, Senegal and Togo.[35]

ARIPO was established under the Lusaka Agreement adopted in 1976 as a designation system to pool the resources of its member states in IP matters and to thereby prevent duplication of financial and human resources. The Lusaka Agreement's preamble highlights the benefits of effective and continuous information exchange, as well as the harmonization and coordination of laws and activities in IP matters among member states. LDCs that have signed on to the ARIPO system are Gambia, Lesotho, Liberia, Malawi, Mozambique, Rwanda, Sierra Leone, Somalia, Sudan, United Republic of Tanzania, Uganda and Zambia.[36]

While there is no regional IP office in Asia, the Association of Southeast Asian Nations (ASEAN) is working to harmonize standards to guide the practices of IP offices in member states. Additionally, ASEAN provides several services and programs for businesses, such as IP training platforms for small and medium-sized enterprises (SMEs), databases of case laws and case studies, IP action plans and IP statistics. It also provides a patent work-sharing program among IP offices of nine member states, including two LDCs, Cambodia and Lao People's Democratic Republic. The goal is to share search and examination results among the participating offices, enabling applicants to obtain corresponding patents more quickly and efficiently.[37]

LDCs often overlooked

During the interviews conducted for this study with IP experts from MedTech companies, national IP offices and law firms, it became evident that global MedTech companies often overlook LDCs and do not prefer them as IP filing destinations. The stakeholder interviews in the study suggested that they perceive LDCs as having weak IP administration and enforcement capacities, which deters companies from filing there. They acknowledged the importance of having a strong IP protection and enforcement system in place to encourage foreign investment. Some experts highlighted a lack of trust in IP systems in LDCs, mentioning that both local innovators and global MedTech companies often prefer to file for their IP in more developed markets. This preference is driven by the higher sense of certainty that their applications will be reviewed promptly and that their IP rights can be effectively enforced by customs or judicial authorities in those countries. In LDCs, applications filed for industrial property account for only a fraction of those filed globally.[38] Specifically, applications for patents, utility models and industrial designs in LDCs represent just 0.04 percent, 0.01 percent

32 World Trade Organization. (2021). *WTO members agree to extend TRIPS transition period for LDCs until 1 July 2034*; available at: https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm; World Trade Organization. (1994). *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*. Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299; available at: https://www.wto.org/english/docs_e/legal_e/27-trips.pdf; LDCs are however not exempt from applying Articles 3, 4 and 5 of TRIPS.
33 OAPI, African Intellectual Property Organization; available at: https://www.oapi.int/wp-content/uploads/2023/11/anglais.pdf; Bangui Agreement Relating to the Creation of an African Intellectual Property Organization. (1977).
34 Ibid.
35 Ibid. See also World Intellectual Property Organization. *African Intellectual Property Organization (OAPI): Member States;* available at: https://www.wipo.int/wipolex/en/members/profile/OAPI
36 World Intellectual Property Organization. *IP Treaties Collection: Lusaka Agreement (ARIPO) (Total Members: 22)*; available at: https://www.wipo.int/wipolex/en/treaties/parties/202.
37 ASEAN Intellectual Property Portal. *What is ASPEC?*; available at: https://www.aseanip.org/services/asean-patent-examination-co-operation-(aspec)/what-is-aspec.
38 Commonwealth and UNCTAD, op. cit.

and 0.25 percent of the global total, respectively. Even trademarks, which are the most-used form of IP in LDCs and globally, filings in LDCs account for only 1.52 percent of global filings.[39] Reasons behind lower IP filings in LDCs include poor awareness, limited use of information and communication technology, high filing fees, inadequate legal frameworks, lack of specialized skills and insufficient enforcement mechanisms.[40]

However, the number of applications has generally increased in recent years.[41] Particularly for patents, several LDCs show higher filings in the MedTech sector as compared to other sectors, indicating a growing presence of MedTech innovations. WIPO's country-specific IP statistics for 2023 show that MedTech was one of the top technical fields for patent filings through the Patent Cooperation Treaty system in the Democratic Republic of the Congo, Ethiopia, Nepal, Niger and United Republic of Tanzania.[42]

Effectively navigating the path to graduation from LDC status would be facilitated by concerted efforts from countries to strengthen their innovation capacities and IP ecosystems. This would require a context-specific approach aligned with their development goals.[43] The following sections of the report on the case studies of Bangladesh and Rwanda will demonstrate this.

Technology transfer

WHO's Local Production and Technology Transfer to Increase Access to Medical Devices Report defines technology transfer as "the transfer of technical information, tacit know-how, performance skills, technical material or equipment, jointly or as individual elements, with the intent of enabling the technological or manufacturing capacity of the recipients." Particularly for medical devices, technology transfer entails sharing resources and know-how to manufacture the medical devices needed to address public health needs.[44]

Technology transfer in LDCs, particularly in the MedTech sector, is essential but faces numerous challenges, as many of these countries may not have the optimal technical expertise, absorptive capacity, infrastructure and resources available to fully benefit from technology transfer processes. While technology transfer occurs through various channels, such as foreign direct investment, joint ventures, licensing agreements, public-private partnerships and research collaborations, its presence in LDCs' MedTech sector is limited.

In LDCs, examples of successful technology transfer are more prevalent in other industries. For example, the garment sector benefits from joint ventures with foreign firms; the pharmaceutical sector frequently engages in licensing agreements to produce generic drugs; and academic exchanges facilitate agricultural research advancements through collaborations between universities and international institutions.

The challenges hindering technology transfer in the MedTech sector include regulatory and policy barriers, such as inconsistent enforcement of IP rights. This inconsistency can deter foreign companies from transferring technology, as they may perceive risks associated with inadequate IP protection. Additionally, lack of infrastructure, insufficient local expertise and limited financial resources can further impede the development and implementation of effective technology transfer mechanisms. Despite these challenges, technology transfer in

39 Commonwealth and UNCTAD, op. cit.
40 Commonwealth and UNCTAD, op. cit.
41 Commonwealth and UNCTAD, op. cit.
42 World Intellectual Property Organization. (2023). WIPO Intellectual Property Statistical Country Profile: Democratic Republic of Congo; available at: https://www.wipo.int/edocs/statistics-country-profile/en/cd.pdf; World Intellectual Property Organization. (2023). WIPO Intellectual Property Statistical Country Profile: Ethiopia; available at: https://www.wipo.int/edocs/statistics-country-profile/en/et.pdf; World Intellectual Property Organization. (2023). WIPO Intellectual Property Statistical Country Profile: Nepal; available at: https://www.wipo.int/edocs/statistics-country-profile/en/np.pdf; World Intellectual Property Organization. (2023). WIPO Intellectual Property Statistical Country Profile: Niger; available at:https://www.wipo.int/edocs/statistics-country-profile/en/ne.pdf; World Intellectual Property Organization. (2023). WIPO Intellectual Property Statistical Country Profile: United Republic of Tanzania; available at: https://www.wipo.int/edocs/statistics-country-profile/en/tz.pdf.
43 T. Pengelly. (2024). *International Trade Working Paper: Graduating with Momentum: Intellectual Property Issues, Challenges and Opportunities for Least Developed Countries.* The Commonwealth Secretariat; available at: https://www.thecommonwealth-ilibrary.org/index.php/comsec/catalog/download/1128/1226/9803?inline=1.
44 World Health Organization. (2012). *Local Production and Technology Transfer to Increase Access to Medical Devices – Addressing the barriers and challenges in LMIC*; available at: https://www.who.int/publications/i/item/9789241504546.

LDCs has recently started to gain more traction in the life sciences sector.[45] A WHO literature review study identified health information technology, medical products and health service delivery as key areas in which LDCs could greatly benefit from technology transfer.[46] As an enabler, technology transfer can facilitate the increase of local manufacturing and supply capacity by reducing dependency on international supply chains and mitigating the risk of supply chain disruptions. This can delay the availability of critical MedTech products, especially during emergencies like pandemics or natural disasters. This issue was exposed during the COVID-19 pandemic, when the absence of local manufacturing capability and capacity hindered the ability of some countries to rapidly deploy necessary medical countermeasures.

Technology transfer for MedTech during COVID-19

During the pandemic, some innovator companies entered into voluntary licensing agreements with local generic manufacturers to produce certain MedTech products. Others waived their IP rights for the duration of the pandemic to facilitate early access to their products. For example, a leading global MedTech company has worked to improve local capacity via technology transfer and, in doing so, gained firsthand experience of technology transfer enablers and barriers in LDCs as a result (see Box 1).

Box 1. Case study of ventilator technology transfer during COVID-19

At the start of COVID-19 in early 2020, patients and health systems around the world struggled to access technologies that addressed respiratory failure and provided mechanical ventilation support.

At the time, a leading global MedTech company ("the company") manufactured multiple types of ventilators, but it was unable to meet international demand due to operational and supply chain challenges affecting production. To help address these challenges and improve access to care for patients around the world, the company decided to pursue technology transfer to support regional ventilator manufacturing capacity and help increase access for patients.

To make this possible, the company had to decide which ventilator to select for the technology transfer. It decided to go with a simple, compact and versatile model.[47] To decide which ventilator specifications to make available, the company analyzed multiple factors, including the target population (adults vs. children), the number of subcomponents and overall supply requirements of the ventilator parts, and any expected challenges that new MedTech manufacturers could face. The company decided to share the technical details of the ventilator that was effective for adults as it met a mix of criteria, including effective treatment of the affected population (adults) and availability of supply chain and support.

Then, company officials had to decide how to transfer the technology. They considered licensing directly with specific parties; posting all information about the ventilator on the internet; or making it open source. Direct licensing would have limited the number of partners that the company would be able to work with to transfer the technologies. Standard, open-source licenses would not have been focused on support for the pandemic.

Company officials decided to share online all design files about their selected ventilator and to provide a permissive license to all associated IP. The license granted rights to use all the design files during the COVID-19 pandemic. Design files that were shared included manufacturing instructions, bills of material, computer-aided design files and software. As users accepted the license and downloaded the design files, multiple organizations asked the company for technical clarifications and support in manufacturing. These interactions gave the company

45 U. Murad and M. Ahsan. (2019). *Critical success factors of technology transfer: an investigation into the health sector of Bangladesh*. University of Technology; available at: https://www.researchgate.net/publication/345701215_Critical_success_factors_of_technology_transfer_an_investigation_into_the_health_sector_of_Bangladesh.

46 S.B. Syed, *et al.*. (2012). *Developed-developing country partnerships: Benefits to developed countries?.* Globalization and Health; available at: https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-8-17#citeas.

47 Medtronic. *Puritan Bennett™ 560 Ventilator*; available at: https://www.medtronic.com/covidien/en-ca/products/mechanical-ventilation/puritan-bennett-560-ventilator.html.

confidence in a number of these organizations' institutional knowledge and capacity to manufacture ventilators.

During these discussions, the company identified partners with whom they went on to build stronger relationships, generally via strategic partnerships or assembly agreements. The representatives of these closer strategic partners entered into no-cost collaboration agreements, which included liability and IP confidentiality terms exchanged from either side.

This initiative enabled the company to educate the global community on how to build a ventilator, regardless of whether they chose to manufacture the specific model provided under the company's permissive license. The shared design and manufacturing files highlighted the complexity involved in designing, testing, validating, assessing risks, documenting, auditing, obtaining regulatory clearance for, manufacturing, distributing, training users and servicing a ventilator.

This kind of knowledge sharing equips stakeholders, including innovators, regulators, manufacturers and others, with critical insights to better inform their emergency-response efforts.

In this case, it served as a valuable form of know-how transfer that enabled others to learn from the company's practical experience.

In selecting local partners, the company considered multiple factors, including but not limited to their technical capabilities and the availability of existing manufacturing facilities.

Strategic partnerships

The company entered strategic partnerships with manufacturers in Canada and the Socialist Republic of Viet Nam, which had high levels of existing knowledge and capacity. The company dedicated time and engineering resources to consulting with the partners about the ventilator technology and helping them troubleshoot and refine their manufacturing processes so that they were appropriate for the local context. These partners were solely responsible for the complete manufacturing process of the ventilators as well as for the quality control of the completed devices. Ventilators manufactured pursuant to these relationships were distributed under the local manufacturers' brand.

Assembly agreements

For local manufacturers in several countries, including in Bangladesh, the company entered into assembly agreements to allow for broader access to ventilators in those countries. In these arrangements, these manufacturers had to meet certain quality requirements and sign quality agreements with the company. After passing the necessary initial quality requirements, these manufacturers could obtain from the company partially assembled ventilators and additional subcomponents and then complete final assembly in-country. The goal of this process was to increase local access to ventilators necessary to address the demand related to COVID-19.

In Bangladesh, the demand for ventilators was greatly reduced prior to the end of the COVID-19 pandemic and this initiative was paused in late 2021.

The handover of know-how and skills that inherently comes with technology transfer can aid in bridging the manufacturing capacity gap that hinders local production of medical technologies in many LDCs.

Factors contributing to successful technology transfer

Broadly speaking, evidence-based studies on successful technology transfer in the MedTech sector are limited; this is even more evident when looking at examples in LDCs.[48] However, a recent study on the transfer of technology related to the health sector in developing countries and LDCs found that factors like top management support, political support for adopting standardized project management practices, financial support and availability of technology infrastructure are critical to the success of a technology transfer process.[49]

These findings are supported by the ventilator case study on technology transfer during COVID-19, which illustrates how openly sharing technical knowledge, when combined with strong organizational and infrastructure support, can effectively facilitate such a transfer.

For Bangladesh, the study highlighted 15 critical success factors for technology transfer (see Box 2). The data highlight that risk management, communication and IT infrastructure are most frequently cited. Capacity-related factors – such as employee training, skilled human resources and the receiver's absorptive capacity – also emerge as critical enablers of successful technology transfer in the health sector.

Box 2. Critical success factors for technology transfer in the health sector

Factor	Number of sources identifying the factor as a critical success factor
Associated risk	44
Effective communication	43
IT infrastructure	42
Top management support	41
Suitability of technology	31
Employee training	30
Receiver's capacity	29
Cost of technology	24
Skilled human resource	23

Source: Critical success factors of technology transfer: an investigation into the health sector of Bangladesh by Uddin Murad, Md Ahsan, 2019.

The complexity of implementing a successful technology transfer in the MedTech sector can be inferred from the factors mentioned above. Moreover, during the interviews conducted with stakeholders, many indicated having encountered challenges in addition to those mentioned above. They included lack of infrastructure for advanced manufacturing, supply chain complexities, shortage of skilled workers, lack of regulatory frameworks, inadequate IP protection, and ensuring the technology was maintained.

To tackle the complex challenges of technology transfer, coordinated efforts and strategic alliances are key. Collaborative partnerships in the life science sector harness the collective strengths of multiple stakeholders and have proven useful to efficiently utilize resources and mitigate risks.

48 A. Vexler and J. Yu. (2018). Empirical Likelihood Methods in Biomedicine and Health. Chapman and Hall/CRC.
49 U. Murad, *et al.* (2021). *Critical Success Factors of Technology Transfer: An Investigation into the Health Sector of Bangladesh Using ISM-DEMATEL Approach.* Technology Management and Leadership in Digital Transformation" PICMET '21 Conference; DOI: 10.23919/PICMET59654.2023.10216839.

Patent pooling for technology transfer

Another way to facilitate technology transfer in LDCs is patent pooling – an agreement among two or more patent owners to license one or more of their patents to one another or to third parties. This mechanism can substantially facilitate technology transfer in LDCs by leveraging shared resources, reducing costs and enhancing access to technologies.

The Medicines Patent Pool (MPP) was the first patent pool organization with a specific mandate to negotiate licenses driven by public health with innovator pharmaceutical companies and then sublicense to generic producers, with the aim of increasing access to life-saving therapies in developing countries and LDCs. Since its establishment in 2010[50], most of the licenses negotiated by MPP have targeted medicines. Nonetheless, in early 2024, MPP signed a license agreement with an in-vitro diagnostics company. In that instance, the license agreement was signed with SD Biosensor, Inc., to provide the know-how to manufacture rapid diagnostic testing technology (see Box 3).

Box 3. Technology transfer for rapid diagnostic testing (RDT) technology

In January 2024, WHO and MPP signed a license agreement with an in-vitro diagnostics company, SD Biosensor, Inc. (SDB), to provide sublicensees with the rights, know-how and material to manufacture SDB's rapid diagnostic testing (RDT) technology.[51] This agreement will enable the manufacture of diagnostics for diseases like malaria, syphilis and HIV, as well as for COVID-19.

The technology transfer plan foreseen under this agreement aims to develop the manufacturing capacity of less developed and developing countries' manufacturers.[52] Through the use of phased technology-transfer plans, these countries will incorporate special provisions to support technology transfer into their sublicense agreements with manufacturers.

Both Bangladesh and Rwanda are among the eligible countries that can take advantage of the license to increase local and regional manufacturing of RDTs. A call for manufacturers to express their interest has been published.

Regulatory systems for MedTech

MedTech products are fundamental in the prevention, diagnosis and treatment of various medical conditions and it is essential that these devices are safe and quality assured. To ensure these devices are effective, safe and used as instructed, governments entrust regulatory authorities to provide oversight on access to these medical products.[53]

Some of the main functions for which regulatory authorities are responsible include licensing of the manufacture, import, export and distribution of medical products; issuance of market authorization; assessment of the safety and efficacy of medical devices; inspection of manufacturers and distributors; and control and monitoring of the quality of medical devices.[54]

50 Medicines Patent Pool. *Who We Are*. Available at: Who We Are - About MPP.
51 Medicines Patent Pool. (2024). *Rapid Diagnostic Testing (RDT) Technology*; available at: https://medicinespatentpool.org/licence-post/rapid-diagnostic-testing-rdt-technology#:~:text=In%20January%202024%2C%20WHO%20and,diagnostic%20testing%20(RDT)%20technology.
52 Medicines Patent Pool. (2024). *WHO and MPP announce technology transfer license to enable greater patient access to multiple essential diagnostics*; available at: https://medicinespatentpool.org/news-publications-post/who-and-mpp-announce-technology-transfer-license-to-enable-greater-patient-access-to-multiple-essential-diagnostics.
53 World Health Organization (n.d.).*Regulation and Prequalification*, available at: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/rss/programme.
54 L. Rägo and B. Santoso. (2008). *Drug Regulation: History, Present and Future.* Drug Benefits and Risks: International Textbook Of Clinical Pharmacology. IOS Press.

LDCs often lag behind developed countries when it comes to robust regulatory systems for medical devices. In more developed settings, like North America and the European Union, countries have strict and specific regulations that govern medical devices, providing patients with assurance of safe and effective devices.[55] In LDCs, this level of assurance is still evolving. Weak regulatory systems may go hand-in-hand with fragmented regulatory functions in a country as well as lack of medical device-specific regulations and explicit regulatory guidance for new and emerging medical technologies, like healthcare solutions driven by artificial intelligence (AI).

To be able to implement the above-mentioned functions, regulatory authorities must have a legal mandate to function. In practice, this mandate would be rooted in a legal or regulatory framework that allows them to control the efficacy and safety of medical devices being imported into or manufactured in their country. In Africa, the regulation of medical devices differs from country to country. In some countries, a separate regulatory body regulates medical devices; in others, it is the ministry of health or ministry of trade.

Simplify by streamlining regulatory process

A streamlined regulatory process across African countries could simplify the process of introducing medical technologies into the market. However, while the African Union has created a regulatory framework model for medical devices, it has not been widely implemented.[56]

Only a handful of countries in Africa have established regulatory systems.[57] A 2017 report by WHO indicated that 40 percent of countries in the African region had no regulations for medical devices, 32 percent had some regulations and, for the remaining 28 percent, there were no available data.[58] Many countries lack the financial resources and technical expertise (which includes trained reviewers with the right technical backgrounds) to strengthen their regulatory systems.

To better understand the state of medical device regulations in Africa, experts in 14 countries from East, Central and Southern Africa surveyed the medical device regulation landscape and found that half had no formal regulatory process for evaluating medical devices.[59] The experts also found that two factors were closely linked to the level of medical device regulation: the country's GDP and how long the country had been independent from any colonial power.

A comparative study of medical device regulation among countries based on their economies found that developed countries have strict regulatory frameworks for medical devices.[60] On the other hand, in Africa, regulations around medical devices are complex and lack clarity among regulatory organizations in the region. However, despite this, the demand for medical devices is on the rise on the continent, highlighting the need for efficient and harmonized medical device regulation.[61] Cognizant of the importance of regulatory control, leaders of several African countries are developing regulations by adopting or harmonizing provisions.

MedTech regulatory guidance needed

Another challenge many LDCs encounter in their regulations is the lack of specific regulatory guidance for new and emerging medical technologies, including those that incorporate the use of AI in medical devices. This gap in the regulatory framework can create significant uncertainty for companies trying to bring innovative products to market, as they may struggle to understand the requirements and navigate the approval process effectively. To address this,

55 B. Chettri and R. Ravi. (2024). *A comparative study of medical device regulation between countries based on their economies,* Expert Review of Medical Devices; available at: https://pubmed.ncbi.nlm.nih.gov/38832832/.
56 Chettri and Ravi. (2024); op. cit.
57 S. Hubner, *et.al.* (2021). *The evolving landscape of medical device regulation in East, Central and Southern Africa*. Global Health: Science and Practice; available from: The Evolving Landscape of Medical Device Regulation in East, Central, and Southern Africa - PubMed.
58 World Health Organization. (2017). *WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices.* WHO Medical Device Technical Series; available at: https://www.who.int/publications/i/item/9789241512350.
59 See Hubner, *et al.*; op. cit.
60 Chhetri and Ravi; op. cit.
61 C. De Maria, *et al.*. (2018). *Safe innovation: On medical device legislation in Europe and Africa*. Health Policy and Technology; available at: https://www.sciencedirect.com/science/article/pii/S2211883718300303.

both the United States and the European Union have released action plans on the use of AI in medical devices and are continuously working on aligning their regulations to ensure safe use of AI in medical devices.

Effective regulatory systems are essential to strengthening health systems and improving public health outcomes. An inefficient regulatory systems can serve as a barrier to MedTech access[62] by limiting a country's ability to regulate products and disincentivizing local innovation and manufacturing and foreign investment. Globally, more than 70 percent of countries have weak national regulatory systems.[63]

Many of these systems are designed primarily with a pharmaceutical lens, with regulators trying to fit MedTech into pharmaceutical-compliant regulatory systems. The inability to fully differentiate between MedTech and pharma can negatively affect public health insofar as access to health technologies is concerned. Without regulatory frameworks that are appropriate for the MedTech space, it can take much longer to move innovative devices from concept to market.

Policymakers and regulators may not understand the fundamental differences among different types of health technologies (vaccines, drugs, medical devices and diagnostics). In some LDCs, medical devices and drugs fall under the same regulations, which can lead to operational challenges and delays in approvals. That is because each type of health technology is unique and may require a different regulatory pathway.

Regulatory reliance

One way to continue to encourage MedTech innovation and access while the national regulatory system is developing is to pursue regulatory reliance. Regulatory reliance occurs when one country's national regulatory authority (NRA) considers the assessment performed by another country's NRA in reaching its own decision.[64] This approach helps health authorities expedite the approval process by leveraging assessments of trusted regulatory bodies, thereby avoiding the need to duplicate resource-intensive evaluation. Through this practice, MedTech products can reach the market faster, enhancing timely access to critical innovations.

There are several ways to practice regulatory reliance, including work-sharing, abridged pathways and unilateral or mutual recognition. Work-sharing happens when NRAs of two or more jurisdictions share the workload to accomplish regulatory approvals. In contrast, abridged pathways take place through procedures where regulatory decisions are based on the application of reliance, and lastly, reliance through recognition often entails the acceptance of a regulatory decision that has been issued by another NRA or institution.

To strengthen countries' regulatory cooperation and convergence and to speed access to medical technologies, WHO has issued the good regulatory practices (GRP) and the good reliance practices (GRelP) documents. Published in 2021, these documents aim to support countries in their efforts to improve regulation and oversight of medical products.[65] Additionally, WHO's Global Model Regulatory Framework provides comprehensive guidelines for countries to develop and enhance their regulatory systems, promoting convergence toward international best practices. The framework offers a stepwise approach to regulating medical devices, acknowledging countries' varying levels of development and prioritizing regulatory responsibilities accordingly.[66]

62 World Health Organization. (2014). Resolutions and Decisions. Sixty-Seventh World Health Assembly. Geneva; available at: apps.who.int/gb/ebwha/pdf_files/WHA67-REC1/A67_2014_REC1-en.pdf.

63 S. Azatyan. (2023).*Technical Briefing Seminar (TBS) on Medicines and Health Products*, World Health Organization; presentation available at: cdn.who.int/media/docs/default-source/health-products-policy-and-standards/7_who-guidelines-on-good-reliance-practices–applicability-and-prospects-for-implementation_samuel-azatyan.pdf?sfvrsn=2e31f8ca_1.

64 World Health Organization. (2021). *WHO Publishes new guidance to promote Strong, Efficient and Sustainable Regulatory Systems*; available at: https://www.who.int/news/item/29-04-2021-who-publishes-new-guidance-to-promote-strong-efficient-and-sustainable-regulatory-systems.

65 World Health Organization. (2021). *TRS 1033 - Annex 11: Good regulatory practices in the regulation of medical products*; Annex 11, WHO Technical Report Series; available at: https://www.who.int/publications/m/item/annex-11-trs-1033; World Health Organization. (2021). *TRS 1033 - Annex 10: Good reliance practices in the regulation of medical products: high level principles and considerations*; available at: https://www.who.int/publications/m/item/annex-10-trs-1033.

66 See WHO GMRF; op. cit.

Harmonization creates uniform standards

Another way to encourage MedTech innovation and access is through regulatory harmonization, defined as "a process whereby the technical guidelines of participating authorities in several countries are made uniform." Harmonization can simplify the regulatory process for companies seeking approval across multiple countries by standardizing requirements, thereby reducing the complexity and duration of the approval process. Discrepancies in dossier requirements across countries can complicate and prolong the submission process, creating significant challenges for companies trying to meet diverse regulatory demands.

It is important to note that, while harmonization facilitates regulatory reliance by creating uniform standards across jurisdictions, the absence of harmonization does not preclude the practice of reliance. Regulatory authorities can still rely on the assessments of trusted partners, even if complete harmonization is not achieved. In March 2024, the 25th Management Committee Meeting of the International Medical Device Regulators Forum highlighted reliance as a cornerstone of collaboration and harmonization in regulatory frameworks for medical devices.[67] Immediately after this session, Kenya's Pharmacy and Poisons Board formalized a strategic partnership with the FDA and committed to pursue reliance and harmonization.[68]

Regional and international initiatives have facilitated the use of regulatory reliance and good regulatory practices for LDCs. WHO's Prequalification of Medical Products, for example, assesses the quality, efficacy and safety of medical products and provides many LDCs with a trusted reference.[69] In 2010, WHO launched the prequalification of IVD, which provides regulatory support for NRAs in LDCs where medical device regulation is still evolving.

Some interviewees reported potential areas for improvement to the prequalification process, particularly regarding its duration, which can extend to several years. Suggested improvements included adopting internationally recognized standards, as recommended in the framework. This alignment could eliminate the need for extensive performance evaluations by enabling WHO to rely more effectively on assessments already conducted by trusted regulators. Such changes would significantly shorten the prequalification process, making the approval pathway for medical devices and IVDs more similar to the streamlined, efficient processes applied to vaccines and medicines, which do not require separate performance evaluations.

The Medical Device Single Audit Program allows an auditing organization recognized by the program to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of participating regulatory authorities.[70] Participating members, including Australia, Brazil, Canada, Japan and the United States, share a standardized dossier that companies can use to meet the regulatory requirements in multiple countries simultaneously.

Despite these efforts, LDCs still face several challenges in fully implementing regulatory reliance and good regulatory practices.

Resources for LDCs are limited, as evidenced by the input gathered during interviews with stakeholders. LDCs often lack adequate infrastructure to support regulatory activities and to ensure regulatory authorities can effectively rely on and use international regulatory decisions.

A regulatory expert at a global medical device company who is also a former regulator explained that, on average, it takes about 18 months for a medical device company to obtain market authorization in primary markets. The length of time varies, depending on the primary market involved, the device's risk classification, readiness of the regulatory dossier, maturity of the technology, robustness of the technology's testing and strength of the clinical evidence. It takes companies another two to five years to obtain market authorization for use of their products

67 Pharmacy and Poisons Board, Republic of Kenya. (2024). *Kenya's PPB and US FDA Form Strategic Alliance to Advance Regulatory Standards*; available at: https://web.pharmacyboardkenya.org/Pharmacy-and-Poiso-6/.
68 Ibid.
69 World Health Organization. (2013). *Prequalification of medicines by WHO*; available at: https://www.who.int/news-room/fact-sheets/detail/prequalification-of-medicines-by-who.
70 US Food and Drug Administration. *Medical Device Single Audit Program (MDSAP)*; available at: www.fda.gov/medical-devices/cdrh-international-affairs/medical-device-single-audit-program-mdsap.

in additional countries that are not aligned with international standards and do not practice regulatory reliance.

Some countries impose jurisdiction-specific requirements, such as unique registration requirements, in-country clinical trials, in-country lot testing, country-specific labeling requirements and prior approval in the country of origin or manufacture. These requirements can significantly delay approval.

While it may be appropriate to have jurisdiction-specific requirements, such requirements should be supported by objective scientific evidence that this practice improves safety and performance.

The added cost and time required to gather additional regulatory evidence, assemble dossiers and, in some cases, redesign the device for non-harmonized markets, sometimes disincentivizes companies from entering these markets.

The regulatory expert said that use of reliance practices can shorten the timeline needed to obtain market authorization to around 30 to 60 days, compared with two to five years for non-harmonized and non-reliance markets. Countries that pursue regulatory harmonization and/or reliance are more likely to gain access to new medical technologies.

In many instances, countries that practice regulatory reliance and harmonization have found that the average approval time has been shortened considerably.[71] Equally, the same measures could encourage local innovators in the target country to develop new medical devices for their own market and regional/global markets.

LDCs often face challenges related to harmonization of their regulatory frameworks, particularly in the medical and pharmaceutical sectors.[72] Ineffective product registration systems, poor inspection practices and inadequate access to quality control laboratories are some of the challenges faced by regulatory systems in LDCs. In addition, regulatory agencies in LDCs responsible for medical technology may struggle to identify and retain specific engineering and technical expertise to appropriately evaluate medical technology safety and efficacy.

To address these challenges and to increase the capacity of these countries to regulate medical products and to encourage harmonization, many regional harmonization strategies have been created. Some of these initiatives include the following:

- Asia Pacific Economic Cooperation Life Sciences Innovation Forum Regulatory Harmonization Steering Committee: Established by Asia-Pacific economic cooperation leaders, under this forum, the Regulatory Harmonization Steering Committee promotes regulatory harmonization by engaging with regulatory authorities. One of the priority work areas of this committee is the medical devices sector. Under this work area, the committee is looking into conducting training on regulatory revision and convergence.[73]
- Pan American Health Organization (PAHO): To support the process of pharmaceutical regulatory harmonization in the region, PAHO and local regulatory authorities in the Americas created the Pan American Network for Drug Regulatory Harmonization.[74]
- African Medicines Regulatory Harmonization (AMRH): Aims to strengthen regulatory capacity and encourage harmonization of regulatory requirements in the African Union. Moreover, its Medical Devices Technical Committee aims to establish a harmonized medical devices framework for regulation in Africa.[75]

71 Xu M, *et al.* (2022). *Regulatory reliance for convergence and harmonisation in the medical device space in Asia-Pacific*. BMJ Global Health; available at: https://pubmed.ncbi.nlm.nih.gov/35985696/.
72 T. Sithole, *et al.* (2021). *Evaluation of the Review Models and Approval Timelines of Countries Participating in the Southern African Development Community: Alignment and Strategies for Moving Forward*. Frontiers in Medicine; available at: https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2021.742200/full.
73 Asia-Pacific Economic Cooperation. (n.d.). *About Us*; available at: https://www.apec.org/rhsc/about-us.
74 Pan American Health Organization. (n.d.). *The Pan American Network for Drug Regulatory Harmonization (PANDRH)*; available at: https://www.paho.org/en/pan-american-network-drug-regulatory-harmonization-pandrh.
75 African Medicines Regulatory Harmonization. *Who We Are*; available at: https://amrh.nepad.org/amrh-microsite/who-we-are.

These initiatives have yielded positive results in several LDCs and developing countries. For instance, as part of the AMRH initiative, the East African Community went from an average registration process length of a few years to less than 10 months – a substantial improvement.[76] [77] Covering 85 percent of countries in Sub-Saharan Africa, the initiative has been implemented in the Economic Community of Central African States and the Economic Community of West African States.[78]

Financial incentives

Financing is one of the most critical factors in driving MedTech innovation worldwide. As high-end MedTech is capital intensive and investors may view LDCs as risky, financing presents a major challenge for development and innovation in LDCs.

While the development of MedTech holds immense potential to address healthcare needs, the process is often financially demanding and involves long timelines, high R&D costs, lengthy and complicated regulatory processes and a substantial risk of failure. Innovators can face several barriers, such as securing initial capital, navigating regulatory approvals and obtaining market access. These challenges are significant across the globe but are particularly pronounced in LDCs, where financing options tend to be limited, and the innovation ecosystem lacks the support and incentives typically available in more developed markets.

In LDCs, the lack of financing has been identified as a major challenge and is even identified as a bottleneck that precludes some medical innovators, usually physicians, from becoming entrepreneurs.[79] This financial gap also hinders progress toward achieving Sustainable Development Goal 3, which focuses on ensuring healthy lives and promoting well-being for all. By improving access to financial incentives for MedTech startups, LDCs can empower local innovators to develop local solutions that address urgent healthcare needs, ultimately contributing to achieving the broader agenda of universal health coverage, improved healthcare systems and equitable access to MedTech.

Long timelines may dissuade investors

Many investors may perceive innovations from LDCs as too risky and may be dissuaded from bringing new ideas to market by long timelines (which can extend up to 20 years) and a high chance of failure.[80] While established firms typically have access to large funds and startups typically have access to various types of early-stage funding, including seed capital, angel investors and small grants that are tied to specific activities, smaller firms may find it significantly more difficult to secure the financing that is needed for scaling up and commercialization.

The venture capital market's potential in LDCs also remains relatively unexplored.[81] This missing middle in funding – where entrepreneurs are beyond the seed stage but not large enough to attract major investments – poses a substantial barrier.[82] As a result, many promising innovations struggle to reach the market, further exacerbating the challenges faced by innovators in LDCs. Without access to sufficient medium-term financing, innovators find that it is increasingly difficult to develop and commercialize impactful MedTech on a broad scale.

76 J.M. Mwangi. (2016). *Towards African Medicines Regulatory Harmonization: The case of the East African Community*. Pharmaceuticals Policy and Law; available at: https://ifpma.org/wp-content/uploads/2023/01/i2023_9.-African-Medicines-Regulatory-Harmonization-AMRH-EAC.pdf.
77 M. Ndomondo-Sigonda and A. Ambali. (2011). *The African medicines regulatory harmonization initiative: rationale and benefits*. Clinical Pharmacology & Therapeutics; available at: https://pubmed.ncbi.nlm.nih.gov/21252936/.
78 M. Ndomondo-Sigonda, *et al.* (2021). *Harmonization of Medical Products Regulation: A Key Factor for Improving Regulatory Capacity in The East African Community*. BMC Public Health; available eat: https://doi.org/10.1186/s12889-021-10169-1.
79 H. Thorsteinsdottir, *et al.* (2021). *Cultivating Small and Medium-Sized Firms: Entrepreneurship Development, Gender, and Technology in Bangladesh, Cambodia, Ethiopia and Senegal*. United Nations Technology Bank for the Least Developed Countries, International Development Research Centre; available at: https://www.un.org/technologybank/sites/www.un.org.technologybank/files/cultivating_smes_report_2021.pdf.
80 East Africa Biodesign. (2024). *Health Tech in East Africa: An Ecosystem Overview*.
81 United Nations. (2022). *LDC Insight #5: Four current trends in the African least developed countries' startup world*; available at: https://www.un.org/technologybank/fr/node/1192.
82 See Thorsteinsdottir, *et al*..; op. cit.

There are three main types of project funding that are most often leveraged in the MedTech innovation process:

- Grants, prizes and any other sources of funding that are given to projects without an expectation of ownership being given to the funder in return, for example national innovation funds.
- Debt financing; and
- Equity-dilutive funding, including venture-capital investments and similar funding methods that provide financial support in exchange for partial ownership of the project.

Several of the stakeholders interviewed for this study highlighted the financial challenges faced by local entrepreneurs. They noted that the practice of offering grants to innovators is not as culturally embedded in LDCs as it is in other regions, and systematic efforts to provide funding remain limited.

While the long development timelines for MedTech are a contributing factor, stakeholders interviewed pointed out other, broader issues within the innovation ecosystem. The demand from hospitals for new technologies, limited commercialization efforts by innovators and insufficient incentives for early-stage public funding all contribute to the scarcity of grants.

In developed countries with robust innovation ecosystems, it can take three to eight years to bring a new medical device to market, potentially longer for more complex devices.[83] The stakeholders interviewed proposed that this timeline would be even further extended in LDC environments where innovation ecosystems may be less developed and infrastructure/capacity-based delays in certain activities may occur (e.g., IP/regulatory submission review). In addition to the lack of public funding and limited capacity to undertake R&D projects, these extended timelines may discourage private funders who want to see the impact of their grants quickly.

Regardless of the reason for the dearth of grant funding, the outcome is that most sources of project funding in LDCs are loans or dilutive investments (funds provided in exchange for equity).

The stakeholders interviewed mentioned that dilutive investments are typically more challenging for entrepreneurs in LDCs compared to entrepreneurs in developing and developed countries. In LDCs, it is less common for prospective investors to take IP into account when determining a company's value. This risk-focused and conservative valuation of intangible aspects of the business model can lead to a lower valuation of assets. That, in turn, can lead to companies in LDCs being less valued by investors. The result can be that investments in LDCs can command more equity than they would be able to command in developing or developed countries, where IP assets are more often taken into account.

Loss of operational control is a risk

This results in innovators in intangible asset-intensive industries needing to dilute their ownership of the company to raise funds to the point that they may lose operational control. This diluted ownership may discourage entrepreneurs from pursuing innovation, as it reduces the potential rewards for the risks they take.

The commercialization experts we interviewed mentioned that, in certain geographies, IP can be used as collateral for bank loans, allowing entrepreneurs to obtain funds without diluting their equity. However, they also said that this is not a common practice in LDCs. A key reason may be that few innovators secure IP in these geographies and, as a result, the stakeholders typically have limited experience in their enforcement. Another reason may be that infrastructure needed to develop IP commercialization strategies is limited. We interviewed some experts who provide loans and grants in LDCs. These experts said that, while they do not

83 A. Lasso, (n.d.). *3 Ways to Speed Up the Medical Device Development Timeline.* Jabil Healthcare; available at: https://www.jabil.com/blog/healthcare-product-development-cycle.html#:~:text=Historically%2C%20the%20medical%20device%20development,shaking%20up%20the%20status%20quo.

accept IP as collateral for loans, they do evaluate the status of the company's IP portfolio and the country's IP ecosystem when deciding whether to invest in a project.

Financing is also an issue for MedTech innovation and access to business models in LDCs, where the high cost of imported MedTech products can act as a market barrier.[84] A number of experts interviewed for this study said that, for a project to be financially sustainable and attractive for global companies, the market must be large enough to justify the costs of entering it. This is sometimes challenging in LDCs, where the population may be relatively small, and infrastructure may be sub-optimal when it comes to access to medical services as well as to services and public utilities more broadly.

In addition, poor reimbursement systems may not support the financing of medical technology in the public and/or private sectors. This can be exacerbated for countries that do not practice regulatory reliance and harmonization, or for those that add unique requirements to enter the market. One way to address this is to evaluate a group of countries as a "regional market" to generate sustainable demand.

Donors have begun to support pooled procurement initiatives in Africa to make a strong business case and generate economies of scale. This method presupposes a degree of trade and regulatory harmonization among the countries. Some entities that pursue pooled procurement initiatives include the United Nations Children's Fund (UNICEF);[85] Gavi, the Vaccine Alliance;[86] and the Global Fund[87].

Experts from multinational MedTech companies stressed the importance of considering specialized market-access strategies to be able to expand access. For example, laboratory equipment has historically been more accessible than medical devices because MedTech companies utilize innovative market entry strategies to make solutions more accessible and affordable.

Placement contracts and phased market entry in LDCs

One example is the placement contracts model, which provides equipment to a medical facility at no cost in exchange for the company being the exclusive supplier of other consumables to that same facility. Placement contracts usually have a three- to five-year duration, which is typically long enough for the medical facility to pay for the equipment in multiple tranches over time, rather than paying the full amount up-front.[88] This system could work well for larger or more specialized capital equipment that might not otherwise be affordable to hospitals in LDCs.

One stakeholder said that affordability and lack of reimbursement represent the main access challenges in emerging markets. The funding level of national healthcare systems also presents a constraint, with a majority of the population in LDCs paying out of pocket for a high percentage of their medical services and use of technologies.

On average, out-of-pocket expenses account for about 48 percent of the current health expenditure in LDCs, and only around 13 percent of current health expenditure in high-income countries.[89] In certain instances, this reliance on out-of-pocket payments can negatively affect access to medical care.[90]

84 M. Razworthy, *et al.* (2022). *Biomedical Engineering as a Driver for Healthcare Improvements in East Africa*. University of Leeds; available at: https://eprints.whiterose.ac.uk/id/eprint/196342/7/BME-Driver_Report_Final_Digital.pdf.
85 Immunization Economics. *Pooled Procurement*. (n.d.); available at: https://immunizationeconomics.org/wp-content/uploads/2017/12/BRIEF12.pdf.
86 Gavi. (2024). *Gavi's approach to engaging with middle-income countries*; available at: www.gavi.org. https://www.gavi.org/types-support/sustainability/gavi-mics-approach.
87 The Global Fund. (2023). *Operational Policy Note: Pooled Procurement Mechanism Process Objective*; available at: https://www.theglobalfund.org/media/13720/gmd_pooled-procurement-mechanism_opn_en.pdf.
88 M. Zander. (2021). *Medical and Laboratory Equipment Landscape in East Africa.* Africon; available at: https://www.spectaris.de/fileadmin/Infothek/Verband/Au%C3%9Fenwirtschaft/Internationale-Zusammenarbeit/2021-10-31_Medical_and_laboratory_equipment_landscape_in_East_Africa_-PPT.pdf.
89 World Bank Group. (2024). *Out-of-pocket expenditure (% of current health expenditure) – Least developed countries: UN classification, High income*; available at: https://data.worldbank.org/indicator/SH.XPD.OOPC.CH.ZS?locations=XL-XD.
90 M. Jakovljevic, *et al.* (2021). *Editorial: Health Financing and Spending in Low- and Middle-Income Countries*. Frontiers in Public Health; available at: https://doi.org/10.3389/fpubh.2021.800333.

Another stakeholder mentioned entering a new market in multiple stages. In the first stage, the company focused on addressing the needs of the most accessible patients (patients in urban settings with private insurance). During this stage, the goal was to become established within the country's reimbursement system; to increase awareness of the specific MedTech product; and to provide trainings to healthcare providers on how to use the new technology. Once these baseline requirements were met, adoption and demand gained traction/reached critical mass as more patients learned about the product and healthcare providers became more comfortable with using it to provide improved healthcare.

At this stage, the company could more easily work with the local government to make its solution accessible to as many patients as possible and was able to reach far more patients than it would have had it tried initially to reach every hospital and health clinic.

Product-market fit of MedTech in LDCs

Product-market fit in MedTech means developing a solution that effectively addresses the needs of patients while also aligning with the expectations of healthcare providers, payers and regulatory bodies. There are ten main types of issues that affect the product-market fit of MedTech in LDCs: availability, appropriateness, functionality, affordability, spare parts, personnel, infrastructure, medical training, management/public policy and culture.[91]

Availability

Availability relates to how obtainable a device or its components may be and affects both the product-market fit of the device in a healthcare setting and the capacity to manufacture MedTech within certain regions. For example, single-use, plastic speculums are more cost-effective and carry a lower risk of contamination than reusable metal ones.[92] However, in clinics located in areas with poor transportation infrastructure, it can be difficult to restock these single-use items, making their use impractical in such settings. Single-use devices, devices with consumable components and products that require cooling during transportation are all less suitable for these environments than are products that are reusable and temperature stable.

As another example, if country officials want to improve their local manufacturing capacity but do not have reliable access to subcomponents, they will not be able to consistently produce high-quality MedTech products.

Appropriateness

Appropriateness has to do with the suitability of the device in the physical or cultural environment where it would be used. For instance, in areas with frequent power outages, battery-operated devices are more practical than are those that require a constant external power supply.

Similarly, cultural norms of modesty in some communities can make women uncomfortable interacting with male providers or undergoing invasive procedures like mammograms or Pap smears. In such cases, it is imperative to adjust the care provided to meet their needs.[93] [94] [95]

91 A. Gauthier, *et al.*. (2013). *Design factors for medical device functionality in developing countries*. IISE Annual Conference Proceedings. pp. 2227-2236.
92 GD Medical. (n.d.). *Vaginal Specula: Single-Use vs. Reusable*; available at: https://gdmedical-live-c3e9de9e28d24f19bbce309-e76bdbf.aldryn-media.com/filer_public/14/32/143216cc-673c-446b-9368-edc47a8d059e/obp_vaginal_specula_single_use_vs_reusable_10818.pdf.
93 C. Andrews. (2006). Modesty and healthcare for women: understanding cultural sensitivities. *Community Oncology*, 3(7), 443–446.
94 Cardiovascular Medicine. (n.d.). *The ECG leads: electrodes, limb leads, chest (precordial) leads, 12-Lead ECG (EKG)*; available at: https://ecgwaves.com/topic/ekg-ecg-leads-electrodes-systems-limb-chest-precordial/.
95 J. Madias. (2003). *A comparison of 2-lead, 6-lead and 12-lead ECGs in patients with changing edematous states: implications for the employment of quantitative electrocardiography in research and clinical applications.* Chest; available at: https://pubmed.ncbi.nlm.nih.gov/14665478/.

Functionality and affordability

Functionality relates to whether a device works properly. For example, LDC patients with above-the-knee leg amputations often find state-of-the-art prosthetics cost prohibitive but may experience poor quality and unreliable performance with low-cost devices. The makers of these prosthetics cut costs by reducing functionality. They often use a single-axis knee joint design, which is less stable and provides less toe clearance when walking compared to a normal knee. The low-cost ReMotion JaipurKnee is a polycentric prosthetic knee – it works like a human knee and performs like devices in high-income countries. The JaipurKnee has seen success in low-income areas, with 79 percent of patients continuing to use the prosthetic six months after fitting and 95 percent of patients reporting good performance with no failures.[96] Therefore, multiple technologies often support the same function, but differ in cost, durability and user experience. Choosing the right technology involves balancing these factors while ensuring the core functionality meets patient needs.

Spare parts

Spare parts refer to the cost and effort needed to maintain and repair equipment. Factors that exacerbate the use and maintenance of a device in an LDC setting include using custom parts instead of off-the-shelf components and requiring a high level of skill to maintain and repair the equipment.

Personnel, infrastructure and medical training

References to personnel denote both the level of training needed to operate or implant the MedTech product as well as the number of personnel required to facilitate its usability in an LDC setting. If a MedTech product requires multiple trained personnel but the hospital is routinely understaffed, the product is less likely to be used even if it is available. This underscores the impact of human resources on the product-market fit of MedTech.

Management/public policy

Management/public policy reflects the triple helix model of innovation in discussing the extent to which the local government regulates the use of a device. This can be a barrier if there is either not enough or too much regulation on MedTech. Under regulation reduces reliability in the quality of products on the market. Overregulation can stifle innovation, making it difficult for new products to enter the market. Government officials who know how to properly regulate the technology greatly enable the MedTech sector to thrive.

Culture

Finally, culture refers to the differences in mindsets/approaches to treatment between the setting in which the technology was developed and the setting in which it will be used. Populations that tend to go to traditional healers for specific treatments may not pursue care in a hospital or clinic even if the needed devices and staff trained to operate these devices are available there. For example, in Ethiopia, cervical cancer patients tend to prefer traditional remedies and to perceive modern treatments as having few benefits, often causing delays in access to modern care.[97]

The ten factors discussed above affect the product-market fit of MedTech in LDCs by contributing to barriers in workforce training, local uptake and use of products and local manufacturing capacity. Anticipating and addressing these factors is an important part of increasing capacity for MedTech innovation and access in LDCs.

96 S. Hamner, *et al.*. (2015). *ReMotion Knee: Scaling of an Affordable Prosthetic Knee for Developing Countries.* Technologies for Development. pp. 137–151; available at: https://doi.org/10.1007/978-3-319-16247-8_14.
97 Z. Birhanu, *et al.* (2012). *Health seeking behavior for cervical cancer in Ethiopia: a qualitative study.* International Journal for Equity in Health; available at: https://doi.org/10.1186/1475-9276-11-83.

Workforce training

Unlike most pharmaceutical-based solutions, MedTech solutions often evolve rapidly and require up-to-date skills and training. Frontline healthcare providers, including doctors, nurses and technicians, play a pivotal role in MedTech innovation, not only as inventors themselves, but also as essential stakeholders throughout the entire development process. Their frontline experience allows them to identify unmet clinical needs, ideate practical solutions and assess the appropriateness and feasibility of new technologies. Importantly, they work closely with biodesign engineers, combining clinical insight with technical expertise to co-develop effective, user-friendly MedTech. They are also instrumental in deploying and administering MedTech and providing ongoing feedback, ensuring that innovations are both safe and impactful in real-world healthcare settings. Lack of trained doctors, surgeons, technicians and nurses is one of the biggest barriers to the adoption and use of MedTech in LDCs.

Furthermore, limited awareness, lack of screening opportunities, and limited diagnosis and treatment options remain key barriers to the detection and management of NCDs. LDCs may lack trained cardiologists and endocrinologists to diagnose and treat heart disease and diabetes, for example. In settings like this, the capacity to both innovate and appropriately use MedTech solutions will be correspondingly low.

In addition, healthcare providers who do not have sufficient training on how to use equipment properly will not adopt technologies that could dramatically increase the quality of care for their patients. Even in Ghana, a developing country, lack of medical training resulted in 18 percent of hospitals not stocking pediatric chest tubes in their facilities.[98] When training opportunities are provided, the MedTech access gap is addressed and the adoption of medical technologies increases. In Ethiopia, an LDC, training healthcare providers in the use of surgical devices led to a 50 percent increase in surgical services provided and reduced surgical mortality by 33 percent over a seven-year span.[99]

There are unique considerations for the local manufacturing of advanced MedTech, such as the need for specialized talent, scalability, market demand and high-capital investments. WHO estimates that in some developing countries about 80 percent of all medical devices are donated or funded by donations.[100] However, only 10 to 30 percent of donated equipment becomes operational in the recipient country,[101] and less than 50 percent of all laboratory and medical technology (regardless of origin of procurement) is usable.[102] Often, this is due to lack of user training and lack of knowledge on how to repair and maintain devices.[103]

In some instances, MedTech is not usable due to a lack of local technicians with adequate skills to repair broken equipment.[104] One study found that 72 percent of the capital equipment classified as "failed" in resource-poor settings could have been repaired and placed back into service without needing to import any parts.[105] Often, the main issue obstructing use of the device was lack of proper installation or user training.[106] In 66 percent of cases, the equipment could have been repaired with "far less knowledge than that required of a biomedical engineer or biomedical engineering technician," suggesting that providing training equivalent to the skillset of a biomedical technician's assistant could return into service two-thirds of out-of-service MedTech products,[107] and increase the total amount of MedTech in service from less than 50 percent to around 80 percent. This underscores the vital role played by frontline healthcare providers, not just as users of technology, but as key contributors to the innovation

98 J. Ankimah, (2015*). Strategic Assessment of the Availability of Pediatric Trauma Care Equipment, Technology and Supplies in Ghana*. Journal of Pediatric Surgery; available at: https://pubmed.ncbi.nlm.nih.gov/25841284/.
99 Safe Surgery 2020. (n.d.). *Overview*; available at: https://www.pgssc.org/safe-surgery-2020.
100 World Health Organization. (2024). *Medical device donations: Consideration for Solicitation and Provision*. WHO Medical Device Technical Series; available at: https://www.who.int/publications/i/item/9789240093621.
101 World Health Organization. ([2010])*. Barriers to Innovation in the Field of Medical Devices: Background Paper 6*. World Health Organization. https://iris.who.int/handle/10665/70457.
102 World Health Organization (2024); op. cit.
103 World Health Organization (2024); op. cit.
104 R. Malkin. (2007). *Barriers for Medical Devices for the Developing World*. Expert Review of Medical Devices; available at: https://pubmed.ncbi.nlm.nih.gov/18035940/.
105 R. Malkin and A. Keane. (2010). *Evidence-based approach to the maintenance of laboratory and medical technology in resource-poor settings.* Medical & Biological Engineering & Computing; available at: https://doi.org/10.1007/s11517-010-0630-1.
106 Ibid.
107 Ibid.

ecosystem who can identify recurring challenges, inform design improvements and help ensure technologies are context-appropriate and sustainable.

MedTech companies know more about their own products than anyone else and therefore have an ideal opportunity to address access issues and increase the adoption of MedTech through training and education programs. Most large MedTech companies already provide training and education services to healthcare providers, empowering them to harness MedTech innovations and improve health access. For example, in the years 2020 and 2023, Medtronic trained 993,000 healthcare providers.[108] These training courses can drive significant improvements in care around the world (see Box 4).

Box 4. Case study on training and education (T&E) for MedTech access in the Philippines

Micra pacemaker market adoption before the T&E initiative

Micra, the smallest pacemaker available, is less than tenth the size of conventional pacemakers, roughly the size of a large vitamin capsule. This innovative, leadless device requires no chest incision, eliminating the need for an incision that would result in a scar or an insertion that would result in a bump under the skin. Additionally, Micra's design is associated with 63 percent fewer medical complications and fewer cases of post-implant activity restrictions in patients. It was launched in 2018 in the Philippines, a developing country that was experiencing steady growth until 2020, when the pandemic took hold, stunting its expansion through most of 2022. During this period, the Philippines saw only about 10 Micra implants per year, all performed by electrophysiologists, and only 30 percent of trained implanters were performing Micra implants.

In five years, 11 implanters were formally trained in Micra implantation, with three becoming active implanters. Training involved costly overseas programs and lengthy proctorship periods. The key issue identified was the difficulty in translating training into actual clinical practice. Given these training challenges, many implanters felt demotivated to train and adopt the Micra pacemaker over to conventional pacemakers.

The launch in late 2022 of Micra AV, a follow-on to the Micra pacemaker, indicated a need to re-strategize for better patient reach.

Identification of opportunity

To address the care capacity gap in the Philippines, Medtronic, the manufacturer of this pacemaker, sought to better train physicians to provide care. It identified interventional cardiologists (ICs) as potential implanters due to their existing catheter skills matching the requirements for Micra implantation and started refining their training and education to address the needs of these physicians. The aim was to create awareness and teach the implantation procedure to ICs, reducing apprehensions about the steep learning curve and high training costs associated with Micra implantation.

Deciding on the T&E initiative

To reinforce training and address the issue of costly and inaccessible overseas training, Medtronic proposed the idea of using Extended Reality (XR). XR training modules provide a step-by-step guide to Micra implantation, offering a refresher for trained electrophysiologists and a tool to engage potential IC implanters. This tool was envisioned for educational visits in hospitals and as a feature at major IC society conventions.

108 G. Martha. (2023, September 25). *Strengthening Healthcare Resilience Through Education and Training* [Post]. LinkedIn. https://www.linkedin.com/pulse/strengthening-healthcare-resilience-through-education-geoff-martha/.

Coordinating and running the initiative

The goal was to increase the number of Micra implants by at least 80 percent the following year. Specific hospitals with interested ICs were identified and a prime "learning lab" spot was secured at the Philippine Society of Cardiovascular Catheterization and Interventions (PSCCI) 2023 Convention. At and after this convention, Medtronic used XR training to familiarize ICs and electrophysiologists with the procedure.

Micra market adoption after the T&E initiative

The XR initiative helped increase the number of trained healthcare providers who were able to implant Micra pacemakers and thereby increased care capacity in the Philippines.

A year after the XR initiative was implemented, implantations had increased by 104 percent, with about 35 percent performed by ICs. Four ICs underwent formal training, while three were comfortable enough with the XT training that they opted to pursue direct proctorship with an expert without undergoing formal overseas training.

Applicability for LDC contexts

Creative training and education initiatives like this XR activity can increase training opportunities and care capacity for physicians who otherwise would not be able to afford to travel from rural to urban settings or from LDCs to other countries to receive training. By providing training and educational activities such as this one, companies can support mutually beneficial increases in the adoption of new MedTech in LDCs.

Government and company investment in the education and training of physicians, engineers and technicians can help healthcare systems to become more resilient; improve quality of care; and increase MedTech innovation and access.

Local manufacturing challenges and use

The majority of MedTech products are imported into LDCs from innovator companies in the United States and Europe. Currently, there is limited capacity in LDCs to manufacture advanced medical technologies. While low-cost MedTech products are produced locally, over 70 percent of stents and MRI machines are imported by LDCs. Unlike drugs, these products cannot be produced locally through reverse engineering. While some governments are keen to encourage local production in the MedTech sector, several obstacles remain. In LDCs, these obstacles often include security, climate, communications, power supply and transport issues; they make it more challenging both for international entities to set up local operations and for local startups to deliver their products to patients.[109]

During interviews, several stakeholders cited challenges associated with setting up local manufacturing. A few stakeholders said that global MedTech companies have well-established manufacturing sites with high-quality control standards and that it would take exceptional circumstances to set up new facilities in a country that doesn't already have existing facilities. They said that it takes 18 to 24 months to evaluate new locations for manufacturing and another 24 months to build the site. Additionally, they are subject to high regulatory scrutiny to qualify as suppliers, which takes an additional nine to 18 months to complete. Interviewees said that this investment of time and resources does not necessarily improve access. While some vaccine manufacturing supply chains are simple and short, MedTech products often comprise hundreds of subcomponents made of thousands of materials. Setting up a completely new MedTech supply chain in a new country can be challenging because it requires access to a reliable supply of hundreds of high-quality subcomponents. One company said that each of its ventilators contains 1,500 parts from 100 manufacturers in 14 countries.

109 Zander (2021), op. cit.

Regionalizing manufacturing is inefficient

Stakeholders across different companies also mentioned that, while vaccines are manufactured in high volumes because they need to reach entire populations, MedTech products need to reach a very specific group of patients. One interviewee presented the example that imaging products (CT scanners, MRIs, X-ray machines, etc.) are manufactured in quantities of a few thousand units per year and are made to order for specific clients. Due to the low production volumes, regionalizing manufacturing to meet local demand is inefficient; instead, these products are sold globally, making "the whole world our market," the interviewee said.

Some of the stakeholders interviewed said that their organizations had reduced their presence in LDCs due to issues with payments, agreements and manufacturing capabilities that did not allow for sufficient scaling. They also cited concerns over high staff turnover in LDCs that made it difficult to retain institutional knowledge about complex devices and therefore challenging to manufacture these devices successfully.

Additionally, interviewees said it was sometimes hard to confirm that local companies can meet the necessary quality and safety standards, such as sterilization capacity, because local facilities may not have certification from the International Organization for Standardization. Experts recommended that if a country would like to increase its regional manufacturing capacity, it should focus first on building expertise and a reputation as a reliable manufacturer of subcomponents. This would allow the country to increase its technical capacity and business capacity, which would allow local manufacturers to evolve into developers of more complex technologies.

Bangladesh case study

This case study captures national laws and policies, institutional and academic research, and stakeholder insights from government agencies, hospitals, the Medtech industry, academia, and IP and innovation experts to identify Bangladesh-specific opportunities and recommendations.

Healthcare overview

Bangladesh is the eighth-most populous country in the world,[1] with a population of 175 million people and a population growth rate of 1.1 percent per year.[2] The life expectancy at birth is around 74 years.[3]

In Bangladesh, there are 0.7 physicians per 1,000 people.[4] There is a severe shortage of healthcare professionals, with a doctor: nurses:technologists ratio of 1:0.4:0.24, against the WHO recommended ratio of 1:3:5. [5] Only about 23 percent of all health professionals serve in rural areas, which is where roughly 60 percent of the population resides.[6] [7]

Each year, Bangladesh spends about 2 percent of its GDP, or around USD 10 billion, on healthcare.[8] In 2023, the country's Human Development Index, which measures average achievement in the three key dimensions of human development – long and healthy life, knowledge, and a decent standard of living – was 0.685, placing it in the medium human development category.[9]

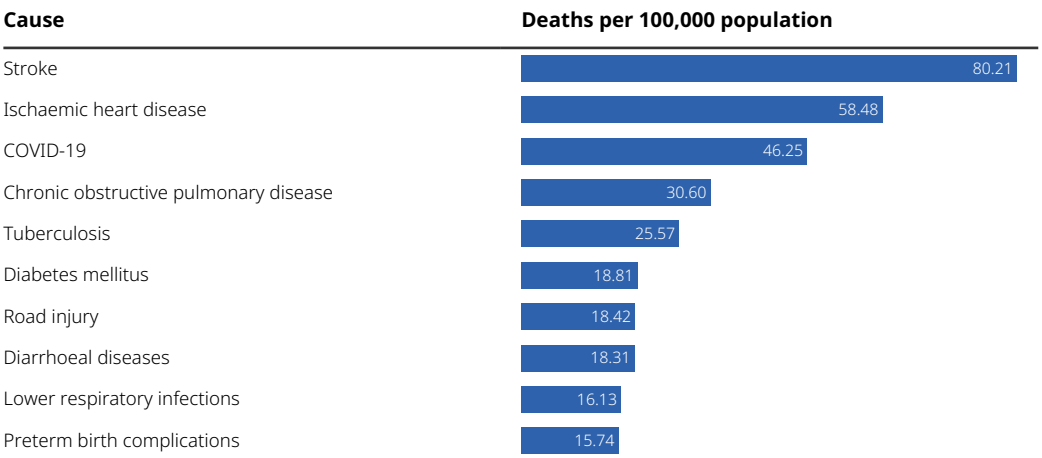
About one fifth of the population lives below the poverty line.[10] The public health sector provides basic services to all citizens, but relies predominantly on out-of-pocket household

1 World Population Review. (2025). *Population of Bangladesh*; available at: https://worldpopulationreview.com/countries/bangladesh.
2 Ibid.
3 Ibid.
4 World Bank Group. *Physicians (per 1,000 people)*; available at: https://data.worldbank.org/indicator/SH.MED.PHYS.ZS.
5 A. Begum and R. A. Mahmood. (n.d.). *Labor Market and Skills Gap Analyses Healthcare: Nursing and Care*. Skills for Employment Investment Program (SEIP), Ministry of Finance, Bangladesh; available at: https://seip-fd.gov.bd/wp-content/uploads/2023/06/7.-Labor-Market-and-Skills-Gap-Analyses-on-Healthcare-Nursing-and-Caregiving.pdf.
6 World Health Organization and UKaid. (2021). *Assessment of Healthcare Providers in Bangladesh*; available at: https://cdn.who.int/media/docs/default-source/searo/bangladesh/assessment-of-healthcare-providers-in-bangladesh-2021.pdf.
7 Statista. (2024). *Share of rural population in Bangladesh from 2013 to 2022*; available at: https://www.statista.com/statistics/760934/bangladesh-share-of-rural-population/.
8 World Health Organization (2024). *Bangladesh: Health data overview for the People's Republic of Bangladesh*; available at: https://data.who.int/countries/050; World Bank Group. (2023). GDP (current US$) –; Bangladesh; available at: https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?locations=BD.
9 United Nations Development Programme. (2024). *Data Futures Exchange. Bangladesh;* available at: https://data.undp.org/countries-and-territories/BGD#:~:text=Bangladesh's%20Human%20Development%20Index%20value,of%20204%20countries%20and%20territories.
10 Aljazeera. (2020). *Bangladesh: One in five people live below poverty line* 2020; available at: https://www.aljazeera.com/videos/2020/1/26/bangladesh-one-in-five-people-live-below-poverty-line.

expenditure,[11] with lower government funding compared to private-sector funding.[12] The country's universal health coverage (UHC) index, i.e., the average percentage of health services needed that are being received by patients from public or private sources on a scale of 1-100, is 52.[13] This indicates that just over half of the population is receiving the essential health services they need, while a significant portion remains underserved or is compelled to pay out-of-pocket for essential healthcare. In 2022, out-of-pocket spending accounted for about 72.53 percent of healthcare spending in the country, one of the highest in the world.[14]

Bangladesh's national health policies have focused on addressing the high burden of maternal and child deaths, malnutrition, communicable diseases and the recent rise in NCDs. The top causes of death in Bangladesh currently are stroke, ischemic heart disease, chronic obstructive pulmonary disease, neonatal conditions and tuberculosis.[15] These conditions could benefit from MedTech solutions, for example, in interventional cardiology capacity, imaging equipment and incubators.

Figure 1. Top 10 causes of death in Bangladesh in 2021



Source: WHO, 2021. Global Health Estimates: Leading Causes of Death. Available at http://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates/ghe-leading-causes-of-death.

The disease pattern in Bangladesh is swiftly transitioning from communicable diseases toward NCDs like cancer, diabetes and heart disease. NCDs were responsible for 43 percent of all deaths in the country in 2000 but accounted for 59 percent of deaths by 2010 and 70 percent by 2019.[16] The management of NCDs often necessitates long-term treatment and medication regimens.

Efforts to increase health insurance coverage, which can affect the ability to access health technologies, are underway in Bangladesh, driven by rising healthcare costs and the need for financial protection against medical expenses. Bangladesh is committed to achieving universal

11 World Health Organization. (n.d.). *Households with out-of-pocket payments greater than 40% of capacity to pay for health care (food, housing and utilities approach - developed by WHO/Europe)*; available at: https://www.who.int/data/gho/indicator-metadata-registry/imr-details/4989. According to the International Classification for Health Accounts, out-of-pocket expenditure is defined as formal and informal payments made at the time of using any health care good or service provided by any type of provider; including user charges (co-payments) for covered services and direct payments for non-covered services; and excluding any pre-payment in the form of taxes, contributions or insurance premiums and any reimbursement by a third party such as the government, a health insurance fund or a private insurance company.

12 World Health Organization, Foreign, Commonwealth and Development Office and Sweden Sverige. (2023). *Review of Bangladesh's Healthcare Financing Strategy*, available at: https://heu.portal.gov.bd/sites/default/files/files/heu.portal.gov.bd/page/c1d65061_f61c_4df2_bd96_cd2e06a4d7f9/2024-04-22-09-54-6a997da367a434169e7da35af5dc7d4b.pdf.

13 World Health Organization. (2023). *UHC service coverage index –; Bangladesh*; available at: who.int/data/gho/data/themes/topics/service-coverage.

14 World Bank. (2024). *Out-of-pocket expenditure (% of current health expenditure)*; available at: https://data.worldbank.org/indicator/SH.XPD.OOPC.CH.ZS.

15 World Health Organization. (2021). *Global Health Estimates: Leading Causes of Death*; available at: http://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates/ghe-leading-causes-of-death.

16 World Bank Group. (2020). *Cause of death, by non-communication diseases (% of total) –; Bangladesh*. Global Health Estimates. World Health Organization; available at: https://data.worldbank.org/indicator/SH.DTH.NCOM.ZS?end=2019&locations=BD&start=2000&view=chart.

health coverage by 2032 and is actively preparing to expand access and enhance the quality of medical services.[17]

Despite challenges, Bangladesh's healthcare industry has made significant strides in recent years. Growing at a compound annual rate of 10.3 percent since 2010, the healthcare industry in Bangladesh has expanded substantially. In 2012, Bangladesh launched the Bangladesh Healthcare Financing Strategy.[18]

In addition to the formal public and private healthcare sectors, traditional medicine is still widely practiced and alternative care options are often pursued. Around 700,000 Bangladeshi citizens travel abroad for medical care each year, accounting for over half of India's medical tourism.[19] Bangladeshi citizens are spending approximately USD 3.5 billion on medical treatments abroad requiring the use of high-end MedTech, predominantly in countries such as India, Malaysia, Singapore and Thailand.[20]

Industrial policy

The 2023 National Industrial Policy of Bangladesh has as its main objective "to economically enrich Bangladesh, increase sector-wise productivity and achieve excellence in the quality of manufactured products by embracing technology advantages.[21] Furthermore, to successfully implement the national industrial policy, the government intends to facilitate an investment-friendly environment to accelerate investment in the private sector.[22]

Bangladesh's national industrial policy highlights the progress achieved in the pharmaceutical industry. Bangladesh currently manufactures 98 percent of the medicines needed to meet domestic demand. This advancement in manufacturing has made medicines more accessible because domestically made medicines are cheaper than imported ones[23] and has transformed the country into an exporter of medicines. This is a robust example of the triple helix model of innovation in action –; through purposeful policy approaches and financial incentives, the government enabled the domestic pharmaceutical industry to expand rapidly. As a result of the government support provided to the industry, Bangladesh now exports medicines to more than 150 countries.[24]

Bangladesh's national industrial policy does not currently include specific provisions on medical technologies. In contrast to the pharmaceutical sector, the medical device industry in Bangladesh remains less developed. Insights gathered from the interviews conducted with MedTech stakeholders in the country underscore the potential to incorporate a strategic focus on MedTech into Bangladesh's national industrial policy in the same "triple helix" way that the government encouraged the pharmaceutical industry.

Many of the interviewed stakeholders indicated that this could bring substantial benefits by enhancing healthcare infrastructure, fostering economic growth, leveraging existing strengths, promoting innovation and addressing public health needs. Achieving these benefits would ultimately position Bangladesh as a significant player in the global MedTech industry.

17 S. El-Saharty, *et. al.* (2015). *The Path to Universal Health Coverage in Bangladesh,* World Bank Group; available at: https://www.exemplars.health/-/media/files/egh/resources/community-health-workers/partner-content/the-path-to-universal-health-coverage-in-bangladesh-bridging-the-gap-of-human-resources-for-health.pdf.
18 Health Economics Unit, Ministry of Health and Family Welfare. Government of the People's Republic of Bangladesh. (2012). *Health Care Financing Strategy 2012-32*; available at: http://oldweb.heu.gov.bd/pdf/Health%20Care%20Financing%20Strategy%202012-2032.pdf.
19 M. Zakaria. (2023). *Determinants of Bangladeshi patients' decision-making process and satisfaction toward medical tourism in India*. Frontiers in Public Health.
20 Ibid.
21 Government of Bangladesh. (2023). *Bangladesh Economic Review, Chapter 8: Industry*. Available at: https://mof.portal.gov.bd/site/page/28ba57f5-59ff-4426-970a-bf014242179e/Bangladesh-Economic-Review-2023.
22 Ibid.
23 International Trade Administration, United States Department of Commerce (2020). *Healthcare and Pharmaceuticals*, Available at: https://www.trade.gov/country-commercial-guides/bangladesh-healthcare-and-pharmaceuticals.
24 Bangladesh Association of Pharmaceutical Industries. *Overview;* available at: http://www.bapi-bd.com/bangladesh-pharma-industry/overview.html.

MedTech imports/exports

About 85 percent of medical devices in Bangladesh are imported.[25] Around USD 416 million worth of medical equipment/devices were imported in FY2019-20, with a consistent 10.2 percent compound annual growth rate over five years.[26] Diagnostic imaging devices,[27] such as MRIs, CT scanners and ultrasound scanners,[28] represent the largest category of imported devices. Imports also include physical and chemical analysis equipment and catheters. Notable increases were seen in intravenous cannulation (IV equipment), optical instruments (e.g., microscopes, cameras or lenses), therapeutic respiration apparatus (e.g., oxygen masks, ventilators), ionizing radiation detection devices (e.g., X-rays), blood lancets (finger-stick blood samplers) and various syringe types.[29]

The MedTech manufacturing sector in Bangladesh comprises several homegrown companies, such as Bi-Beat Ltd, CMED Health and joint ventures between local and multinational companies such as Nipro JMI Pharma Ltd.[30]

Bi-Beat Ltd., a technology company focusing on health and well-being, manufactures various kinds of equipment, such as electrocardiogram (ECG) circuit trainers (educational or training devices used to simulate, analyze and understand ECG signals and circuits) and muscle and nerve stimulators, on a smaller scale. CMED Health Ltd., an AI and Internet of Things-based MedTech company, aims to transform healthcare in Bangladesh with its end-to-end, multi-layered, scalable, smart-health platform Susastho, to reduce health risks, costs and time and contribute to achieving UHC.

Addressing the lack of access

Leveraging the Fourth Industrial Revolution technologies, as represented by the fusion of digital, physical and biological systems, CMED addresses the lack of access to health services in Bangladesh. It does so by providing affordable, quality healthcare through its digital healthcare platform, which connects patients with health services such as diagnoses and referrals for interventions.

Over the past decade, new companies like Getwell Ltd. and ANC Medical Device Bd. Ltd. have entered the market for consumables (disposables and surgical equipment), while others are focusing on radiological, electromedical, orthopedic and diagnostic devices.

Bangladesh reported modest manufacturing figures of less than USD100 million in FY 2020-21 for medical equipment and devices, with over 70 percent comprising medical disposables (e.g., syringes and needles).

Bangladesh has also begun to export medical devices, with FY2020-21 seeing exports worth USD 48.8 million, including ophthalmic and orthopedic devices, consumables and respiratory instruments.[31] Around two-thirds of orthopedic products used in Bangladesh are produced locally and around 90 percent of devices used in the treatment of soft-tissue injuries and fractures (fixation devices) are manufactured in-country.

Bangladesh also exports orthopedics, prosthetics and other medical devices (wheelchairs, etc.), primarily to the United States and the Republic of Türkiye.[32] Exporters of MedTech enjoy incentives such as a 50 percent tax exemption on export income, no value-added tax (VAT) on exported goods and a 10 percent cash incentive based on export value.[33]

25 Bangladesh Investment Development Authority. (n.d.). *Medical Device*; available at: https://www.bida.gov.bd/investment-sector/medical-device.
26 Ibid.
27 Ibid.
28 Ibid.
29 Ibid.
30 Ibid. Nipro JMI is the largest manufacturer of consumables.
31 Ibid.
32 Ibid.
33 BIDA (n.d.), op. cit.

Foreign companies wishing to operate in Bangladesh must establish a liaison or representative office, a branch office, a joint venture company, or a fully foreign-owned company under the Companies Act of Bangladesh.[34] A foreign company can conduct only commercial activities or earn revenue through a branch office, joint venture or fully foreign-owned distributor or agent, and must manufacture through a Bangladesh subcontractor, a joint venture or fully foreign-owned company.[35]

Certain drugs and medical devices are exempt from import tariffs and the maximum most-favored-nation applied tariff rate is 25 percent.[36]

MedTech challenges and enablers in Bangladesh

According to interviewees, MedTech imports and exports in Bangladesh face several challenges, such as customs clearance delays and rising shipping costs, which are exacerbated by challenges regarding utilities and logistics. Skills shortages and challenges in the R&D space can further hinder innovation, while the lack of local repair options for imported MedTech leads to underutilization. The absence of dedicated testing labs and supporting industries, such as mold and die manufacturers, along with restricted access to finance, further complicate the development of a strong MedTech innovation ecosystem.[37]

Intellectual property

Bangladesh, a founding member of the WTO, has a long history of protecting IP. The country has been gradually liberalizing the protection of IP since it gained independence from Pakistan in 1971,[38] and over the past two decades, it has significantly developed its IP system, enacting key legislation for the protection of copyright, trademarks, industrial designs and patents.[39]

The Department of Patents, Designs and Trademarks (DPDT) is the central office that administers laws related to industrial property in Bangladesh. It accepts and processes applications for the protection of industrial property, including patents, trademarks and industrial designs. Bangladesh has more IP filings than other LDCs, significantly driving the average filings for the group, indicating that it is performing better than other LDCs.[40]

34 Switzerland Global Enterprise. (2021). *Bangladesh: Business Guide.*
35 Ibid.
36 International Trade Administration. (2022). *Bangladesh –; Country Commercial Guide;* available at: https://www.trade.gov/country-commercial-guides/bangladesh-import-tariffs.
37 BIDA (2022). op. cit.
38 Khondker A. Mamun. (2024). *Investigating Barriers and Enablers to MedTech Innovation and access in LDCs Bangladesh.* (on file with WIPO).
39 Copyright Act of 2000. Act No. 34 of 2023. (Bangladesh); Trademarks Act of 2009. Act No. XIX of 2009. (Bangladesh); Patents Act, 2023. Act No. 53 of 2023. (Bangladesh); Industrial Designs Act of 2023. Law No. 22 of 2023. (Bangladesh).
40 Commonwealth and UNCTAD, op. cit.

Table 1. Industrial property filing in Bangladesh in 2013

National IP Office (DPDT) applications			Applications per examiner	Pendency
Patents	Resident applications	67	53.2	6 months
	Non-resident applications	252		
	Total	319		
Trademarks	Resident applications	8,814	2589.6	10 days
	Non-resident applications	4,134		
	Total	12,948		
Industrial designs	Resident applications	999	550.5	270 days
	Non-resident applications	102		
	Total	1,101		

Source: World Intellectual Property Organization. (2023). Intellectual Property Statistical Country Profile 2023: Bangladesh. Available athttps://www.wipo.int/edocs/statistics-country-profile/en/bd.pdf.

Table 1 shows that the number of filings in Bangladesh is low, and processing times are short. MedTech is not one of the top technical fields for patent applications in Bangladesh. However, a review of patent applications published by the DPDT in 2023 and 2024 indicates that some MedTech innovations have been translated into patent filings. Examples include patent applications for a device for collecting human excreta through a stoma (an opening in the body),[41] a device for applying fluids on the body,[42] a device for cancer screening[43] and an electrocardiogram device.[44]

Bangladesh protects trade secrets through contract law, antitrust law, criminal law and tort law.[45] A proposal for Protection of Undisclosed Information Law appears to be underway in Bangladesh.[46]

IP seen as key to advancement

Bangladesh's National Innovation and Intellectual Property Policy, 2018[47] ("IP policy"), has recognized IP as being key to the country's graduation from LDC status, setting out the country's goals and strategies, including the following:

41 M.K. Khan. *Two-piece device for collecting human excreta through stoma in ostomy patients*. BD/P/2023/186. Department of Patent, Designs and Trademarks, Bangladesh. (filed on 16 Jul. 2023).
42 L.E. Matías. *Device for applying fluids on the body*. BD/P/2022/64. Department of Patent, Designs and Trademarks, Bangladesh. (filed on 24 Feb. 2022).
43 A.M. Shamsuddin and K. Vanderlinden. *Method, device, and kit for population screening for cancer, cancer recurrence and precancerous conditions in symptom free individuals*. BD/P/2022/164. Department of Patent, Designs and Trademarks, Bangladesh. (filed on 8 May. 2022).
44 A. Luigi, *et al. Electrocardiogram analysis*. BD/P/2021/116. Department of Patent, Designs and Trademarks, Bangladesh. (filed on 4 Apr. 2021).
45 The Contract Act of 1872, Act No. IX (1872). § 73; available at: http://bdlaws.minlaw.gov.bd/act-26.html; The Competition Act of 2012, Act No. 23 (2012). Preamble; The Penal Code, Act. No. XLV (1860). § 405 and 406.
46 B.H. Khondker and S. Nowshin. (2013). *Developing National Intellectual Property Policy for Bangladesh*. World Intellectual Property Organization.
47 Ministry of Industries, Government of The People's Republic of Bangladesh. (2018). *The National Innovation and Intellectual Property Policy*; available at: https://moind.portal.gov.bd/sites/default/files/files/moind.portal.gov.bd/policies/b1cfda28_fad3_4c4a_a63b_b69691056a42/National%20Innovation%20and%20Intellectual%20Property%20Policy%202018-%20English.pdf.

- Establishment of mechanisms through IP offices and institutions to coordinate innovation, creativity, commercialization and valuation of IP in different public sector research facilities, inter alia, those focused on health.
- Establishment of technology transfer organizations (TTO), technology and innovation support centers, research and development centers, innovation hubs, labs.
- Supporting startups and individual innovators to enable them to leverage intellectual property rights and provide access to financial assistance for the same.
- Establishment of a national innovation fund for promotion, protection, preservation and commercialization of home-grown innovators.
- Allocating adequate funds in the national budget to promote science and technology, innovation, creativity and overall development of a national innovation ecosystem in the country.
- Launching educational and awareness programs on intellectual property for schools, colleges, universities and other relevant stakeholders, organizations and institutions.
- Revitalizing and strengthening Bangladesh's Anti-Piracy Task Force to address the violation of patents, designs and trademarks.
- The IP policy outlines a 10-year implementation timeline, marking a decade dedicated to innovation. The IP policy lays the groundwork for supporting the development of the country's MedTech sector, among others. A significant advancement in implementing the IP policy was the enactment of the Patent Act of 2023 in Bangladesh, which replaced the Patent Act of 2022.

Box 5. What is new in Bangladesh's Patent Act, 2023?

Bangladesh passed the Patent Act, 2022, repealing the earlier Patents and Designs Act, 1911, to make its IPR protections compliant with the TRIPS Agreement. The Patent Act, 2022, was replaced by the Patent Act, 2023[48], which further delineated the provisions.[49] The Patent Act, 2023, aims, inter alia, to align Bangladesh's public health objectives with its patent ecosystem. The following are the key changes in the law:

- It offers clearer definitions of invention and patentability criteria to enable a more comprehensive patent examination.[50]
- It provides that the patent claims must be clearly and fully described to allow evaluation and implementation by someone skilled in the relevant field.[51]
- It sets a three-year deadline for filing divisional applications, which are used to separate claims from an earlier application covering multiple inventions, and limits these to three per original application. This change is expected to improve clarity and certainty regarding patent coverage and processing times, enabling competitors to conduct more accurate freedom-to-operate analyses.[52]

The Patent Act, 2023, advances Bangladesh's goal of building a stronger innovation ecosystem and could benefit the MedTech sector by offering clearer patentability criteria and streamlined processes.

Bangladesh also has a strong IP enforcement framework. An aggrieved person can initiate civil action for IP infringement in Bangladesh in the appropriate civil court under the relevant statute or common law. Additionally, the owner of a registered IP right can apply for the right to be recorded with the customs authority. The customs authority is empowered to suspend the release of goods if it suspects that they are infringing a registered IP right recorded with them.[53]

48 Law No. 53 of 2023, Patent Act, 2023. (Bangladesh).
49 N. Syam. (2024). *Bangladesh adopts new patent law to make use of TRIPS flexibilities for public health*. South Centre; available at: https://us5.campaign-archive.com/?u=fa9cf38799136b5660f367ba6&id=acb2ce663e.
50 Patent Act, 2023. Law No. 53 of 2023. (Bangladesh). Section 2, 4 and 6.
51 Patent Act, 2023. Law No. 53 of 2023. (Bangladesh). Section 8 (6).
52 Patent Act, 2023. Law No. 53 of 2023. (Bangladesh). Section 14.
53 The Intellectual Property Enforcement (Imports and Exports) Rules, 2019. (Bangladesh).

However, MedTech stakeholders in Bangladesh are underutilizing civil and criminal remedies for IP enforcement due to several challenges, including lack of awareness and limited financial and human resources.[54]

The statutes also provide options for initiating administrative proceedings to pursue pre-grant and post-grant challenges for industrial property before the DPDT.

Progress to date and suggested measures

A number of stakeholders who were interviewed said they believe that significant progress has been made with the introduction of new IP laws and enforcement rules, while others suggested additional measures be taken to build a stronger innovation culture.

Specifically, interviewed stakeholders in Bangladesh have highlighted the following additional opportunities for improvement:

- TTOs and research centers in universities have the potential to drive innovation. Stakeholders indicated that there are some innovations coming out of universities in Bangladesh, such as a continuous positive airway pressure (CPAP) machine (a device prescribed to treat sleep apnea) from a team at Bangladesh University of Engineering and Technology under the trademark OxyJet.[55] Strengthening TTOs and research centers through government as well as private-sector support will create an environment conducive to innovators and can thereby help bring new technologies to market. Mechanisms and policies for IP financing can serve as powerful catalysts for innovation. Additionally, there is a need to invest further in research facilities in Bangladesh, such as:
  - The Research and Innovation Centre for Science and Engineering in Bangladesh University of Engineering and Technology
  - The Institute of Research, Innovation, Incubation & Commercialization in United International University
  - Hi-Tech Park Authority
- Investment is needed to develop a more user-friendly IP database and comprehensive guidance for patent filing in universities, incubation centers and startups. For instance, search tools for patents, designs and trademarks are not available on the DPDT website. Additionally, most information is provided only in Bengali, making it difficult for non-Bengali speakers to access fundamental information and forms. For comprehensive searches, MedTech innovators typically have to rely on local law firms specializing in such services.

Lastly, raising awareness about IP is a must among innovators, judges and government officials for overall improvement of the IP ecosystem in Bangladesh.

Regulatory systems

In Bangladesh, the Directorate General of Drug Administration (DGDA) regulates the registration, manufacturing, importation, distribution, quality, pricing and safety of pharmaceuticals and medical devices. The DGDA practices regulatory reliance with Australia, France, Germany, Japan, Switzerland, the United Kingdom and the United States,[56] for antimicrobial/pharmaceutical products. The DGDA also practices harmonization for pharmaceuticals by utilizing a common technical document to submit regulatory approval applications. [57] The common technical document is an internationally recognized standard used to submit applications to NRAs for the registration of pharmaceuticals. This standardization makes it easier for NRAs across different regions to review and assess applications in a consistent manner.

54 Mamun (2024), op. cit.
55 BUET. (2021). *OxyJet: A Low-cost CPAP system*; available at: https://bme.buet.ac.bd/project/oxyjet-a-low-cost-cpap-system/.
56 E.S.F. Orubu, *et al.* (2021). *The Integrity of the Antimicrobial Supply Chain in Bangladesh: Assessing the Regulatory Environment and Contextual Challenges*. medRxiv; available at: https://doi.org/10.1101/2021.10.28.21265605.
57 Ministry of Health & Family Welfare, Directorate General of Drug Administration, Bangladesh. (2015). *Guidelines for the Submission of Bangladesh Common Technical Document: General Guidelines and Module 1*,

There are different routes of approval for new drugs and medical devices in Bangladesh. Not all regulatory pathways require the same level of review or follow the same timelines. As noted above, Bangladesh applies regulatory reliance and harmonization approaches for pharmaceuticals. The traditional pathway (see Box 6) is laid out in the Drug and Cosmetics Act of Bangladesh[58] (the DC Act), which was updated in 2023 (the amended DC Act). This act regulates the manufacture, sale, distribution, storage, import and export of drugs and medical devices. Since the DC Act was amended to incorporate medical devices, there have been notable developments in the regulatory landscape. The amended DC Act has introduced a comprehensive framework aimed at enhancing the safety, efficacy and quality of medical devices, alongside drugs, vaccines and cosmetics. Key improvements include stringent requirements for clinical trials, adherence to good clinical practice guidelines and robust pharmacovigilance to monitor and report adverse reactions.

The inclusion of medical devices in the amended DC Act means that regulatory scrutiny now extends to diagnostic tools, treatment and monitoring equipment, setting rigorous standards for their approval and use.

The amended DCA Act also outlines detailed regulations for vaccine release, including provisions for accelerated approval processes during public health emergencies, ensuring that critical medical supplies can be deployed quickly when needed.

Despite these significant improvements, the concrete impact of the amended DC Act on the MedTech sector is still emerging. The regulatory framework has undoubtedly established higher standards for product safety and quality control that should, in theory at least, lead to improvements in the quality and safety of MedTech products. However, the industry is in the process of adapting to these new requirements and it will take time to fully gauge the effectiveness of these changes.

To determine the true impact of the amended DC Act, it will be essential to monitor how well these new regulations are being implemented and enforced, including whether the increased regulatory rigor translates into tangible improvements in product quality and safety. Additionally, ongoing feedback from industry stakeholders, including manufacturers, healthcare providers and regulatory authorities, will be crucial in assessing the practical benefits of the amended DC Act and identifying areas for further refinement.

Box 6. Regulatory pathway for the registration and approval of drugs and medical devices in Bangladesh

On 18 September 2023, the amended DC Act entered into force. It formalizes the requirements for, among other things, in-vitro diagnostics, reagents and medical devices. In the amended DC Act, the term "software' was included under the definition of medical devices.[59] More broadly, the definition of "drug" under this act includes medical devices and in-vitro diagnostics.

Production of medical devices under license agreements, loan licenses and contract manufacturing

Subject to public health protection conditions, the licensing authority may grant permission to any foreign establishments to manufacture medical devices within Bangladesh under a license agreement with any pharmaceutical manufacturing establishment of Bangladesh.

Under a written agreement, a medical device manufacturing company in Bangladesh can be granted authorization to manufacture medical devices with a medical device manufacturing company of the same type.

58 The Drug and Cosmetics Act 2023. Act No. 29 of 2023. (Bangladesh); available at: Bangladesh-Drug-and-Cosmetics-Act-2023-English.pdf (asiaactual.com).
59 Ibid.

For the purposes of export only and under contract manufacturing[60] or loan license,[61] a foreign company that does not have a pharmaceutical manufacturing plant in Bangladesh can manufacture all recognized drugs.

In an effort to standardize and harmonize the regulatory system of medical devices in Bangladesh, the Directorate General of Drug Administration introduced, in 2015, the registration guidelines for medical devices. The guidelines apply to all medical devices, as decided by the government, and provide instructions for registration of medical devices for manufacture and import into Bangladesh and classification rules for medical devices and in vitro diagnostics. The guidelines follow a regimen that classifies devices into four categories (A, B, C, D) based on risk level, with Class A being lowest risk and Class D highest risk, requiring registration for higher-risk categories (B, C, D) before importation or manufacturing. The registration process involves detailed application submissions, including product details, manufacturing processes and plans for marketing and after-service, along with DGDA inspections to ensure product safety and efficacy.

Since the introduction of the above-mentioned guidelines a decade ago, the MedTech sector in Bangladesh has experienced both benefits and challenges. On the positive side, the guidelines have brought much-needed regulatory clarity, standardized medical device approvals and improvement in the quality of devices in the market. This has boosted confidence among healthcare providers, patients and international companies; facilitated better healthcare outcomes; and attracted foreign investment.

However, according to experts interviewed for this study, the sector has also faced significant challenges. The registration process can be lengthy and cumbersome, with complex documentation requirements that can be particularly burdensome for local manufacturers. Additionally, there can be delays in processing applications and challenges in compliance monitoring. The current capacity for regular inspections and post-market surveillance presents opportunities for enhancement within the regulatory framework, particularly in ensuring ongoing device safety and quality. With additional focus and resources in these areas, the effectiveness of the system could be further strengthened to better support the MedTech sector's growth and innovation.

Regulatory challenges

Regulatory authorities are vital for the effective implementation of health policies and regulations.[62] Nevertheless, enforcement of health regulations can be a highly resource-intensive task, one that is often complex for LDCs to execute.[63] When asked about engagement with the regulatory system, most interviewees said they consider the existing regulatory policies generally adequate. However, common challenges identified include the lack of a dedicated regulatory body within the DGDA to provide the necessary oversight and encouragement, and lack of capacity to innovate within the local sector to further grow the ecosystem. Regarding the latter, many industry stakeholders said that, while existing regulations might be adequate, the local ecosystem struggles with developing and implementing new ideas, technologies and business models. As a result, this could hinder overall growth and fail to push the regulatory framework to evolve and improve.

60 Ibid. Contract manufacturing refers to production contracts executed between foreign companies that do not have pharmaceutical factories in Bangladesh and pharmaceutical manufacturing companies of Bangladesh that have such units and establishments in Bangladesh for manufacturing approved drugs only for export purposes.
61 Ibid. Loan license refers to a license issued by the Licensing Authority in favor of any person or establishment that has neither its own facilities nor facilities for the manufacture of drugs but is owned by another licensee for the manufacture of drugs.
62 L. O. Gostin. (2008). Public Health Law: Power, Duty, Restraint. Berkeley. University of California Press.
63 L.O. Gostin *et. al*. (2010). *Implementing Public Health Regulations in Developing Countries: Lessons from the OECD Countries*. Journal of Law, Medicine and Ethics; available at: SSRN: https://ssrn.com/abstract=1703456.

Financial incentives

A recurring theme in the interviews was the pressing need for financing for research and development; production of raw materials; and a reduction of Bangladesh's dependency on imports. The Bangladesh government has introduced several incentives to promote growth in the healthcare sector. Hospitals outside major cities like Dhaka, Narayanganj, Gazipur and Chittagong are granted 10-year corporate tax exemptions, subject to conditions (SRO 169/Law/Income tax/2021). Institutes providing technical training for healthcare-related skills development receive similar tax exemptions (SRO 168/Law/Income Tax/2021). MedTech manufacturers benefit from concessional import duties on raw materials, including those used for items related to COVID-19. Exporters of MedTech enjoy incentives such as a 50 percent tax exemption on export income, no VAT on exported goods and a 10 percent cash incentive based on export value.[64]

Experts interviewed for this study said that most consumer insurance, public or private, does not cover medical devices. Without insurance coverage, patients must bear the entire cost of medical devices, which leads to high out-of-pocket expenses. This financial burden could deter consumers from purchasing the devices they need, reducing overall market demand. The government has committed to implement a national health insurance scheme covering the entire population by 2032. It will be important to give due consideration to medical devices and diagnostics in this scheme.

To further develop the country's high-tech industries, the Bangladesh Hi-Tech Park Authority Act of 2010 was introduced with the objective of developing an investment-friendly environment. Since then, several Hi-Tech parks have been set up. These parks act as incubators for startups and other companies and help foster a robust ecosystem in industries, including engineering, electronics, telecommunications and biotechnology.

The government is also working on a 10-year plan to build in Dhaka a "health city" that would include three educational institutions and two hospitals.[65]

The government also has backed the creation of the Innovation Design and Entrepreneurship Academy, an accelerator providing tech startups with an ecosystem of entrepreneurs, investors, mentors and advisors. The academy has already supported multiple MedTech startups as part of its "Corona Initiative."[66]

In 2020, the government-backed venture capital fund Startup Bangladesh was founded. This fund provides support to technology-based innovations, specifically by providing investments to seed-stage and growth-stage startups.[67]

Local MedTech industry capacity

Bangladesh domestically manufactures roughly five to seven percent of the medical devices used in-country.[68] Locally produced items consist primarily of consumables like disposable/precision safety syringes, needles, blood bags, blood transfusion sets, cannulas (thin tubes often used for delivery or removal of fluids) and blood-collection tubes. These consumables hold a significant portion of the market, estimated at USD 55 million to USD 60 million annually in the country.[69]

In Bangladesh, managing MedTech and ensuring after-sale service presents significant challenges due, for example, to resource constraints and import delays, affecting the already complex healthcare landscape. Interviewees referred to the scarcity of medical parts, delays in importation, limited access to repair services and shortages of skilled technicians. Suboptimal infrastructure and management challenges also contribute to disruptions in device maintenance and repair services, which in turn affect patient care.

64 BIDA (n.d.), op. cit.
65 Ibid.
66 Innovation Design and Entrepreneurship Academy, iDEA. Available at: idea.gov.bd/covid19.
67 Startup Bangladesh Limited. What we do? available at: https://www.startupbangladesh.vc/about/about-what-we-do/
68 BIDA (n.d.), op. cit.
69 BIDA (n.d.), op. cit.

From a regulatory standpoint, interviewees said that the medical technology industry in Bangladesh would benefit by addressing current challenges in a number of areas, including streamlining the product registration process and examining pricing regulations.

VAT disparities and high import duties hinder local manufacturing competitiveness. Customs clearance delays and rising shipping costs add strain, exacerbated by challenges in the area of reliable utilities and logistics. Skill shortages and the lack of local repair options for devices can also lead to underutilization.

Ending the "brain drain"

Interviewees noted that, while Bangladesh recognizes the importance of, and invests in, medical education, it has not held a forward-looking focus on MedTech as a subject. Both physicians and entrepreneurs alike may find it difficult to identify unmet needs and work with the ecosystem to develop solutions to address these needs.

Although some universities in the country have biomedical engineering technology departments, these are relatively new and require more support to focus on research and innovation. Academics can play a crucial role in developing the curricula, encouraging students to pursue research and ultimately contributing to the local capacity for innovation in the MedTech industry. This would help students understand the opportunities in the sector and enable them to utilize their research and innovation skills to support the development of this sector in Bangladesh.

A number of stakeholders recommended increasing the number of biomedical technology departments in universities and creating incentives to address talent loss, commonly referred to as "brain drain."

The absence of dedicated testing labs and supporting industries further complicates matters, along with restricted access to finance, constraining industry growth and development.[70]

Potential to expand MedTech manufacture

Many interviewees said they felt that the potential to expand the manufacture of medical devices and equipment in Bangladesh is immense. Demand-side dynamics present a significant opportunity, with the market size projected to exceed USD 800 million by the end of 2025.[71] Rising awareness about the importance of early detection of disease, coupled with the increasing prevalence of chronic illnesses requiring long-term treatment plans, is expected to further drive the demand for healthcare services in the country.[72]

It is clear that Bangladesh is on the path to promoting MedTech innovation and developing the MedTech ecosystem domestically. The country has laid important foundations, such as building major hospitals in Dhaka and Chittagong, increasing local production of basic medical supplies, and establishing government initiatives like the Digital Bangladesh program, which seeks to integrate technology into the healthcare system. Private hospitals and health-tech startups are increasingly contributing to the sector and events like the International Conference on Medical Engineering, Health Informatics and Technology, held in 2016, have helped to foster the exchange of ideas and collaboration, harnessing the multiple disciplines that contribute to the MedTech industry.

Despite these promising steps, several critical elements still need to be developed, including dedicated R&D facilities, funding for innovation and MedTech-focused incubators and accelerators.

70 BIDA (2022), op. cit.
71 BIDA (2022), op. cit.
72 BIDA (2022), op. cit.

Establishing dedicated R&D facilities and funding for innovation, and MedTech-focused incubators and accelerators is essential to supporting the entire innovation lifecycle, from idea generation to prototype development, clinical trials and commercialization.

In Bangladesh, the lack of clinical trial infrastructure for MedTech poses a significant challenge. Setting up these facilities would not only ensure the safety and efficacy of locally produced technologies, but would also accelerate their market entry.

Strengthening collaboration between academia and industry, streamlining regulatory processes, and increasing the availability of venture capital will further enhance the sector's growth and development.

Rwanda case study

This case study captures national and regional laws and policies, institutional and academic research, and stakeholder insights from government agencies, hospitals, innovation hubs, advocacy groups, digital health firms, MedTech companies, and IP and innovation experts to identify Rwanda-specific MedTech opportunities and recommendations.

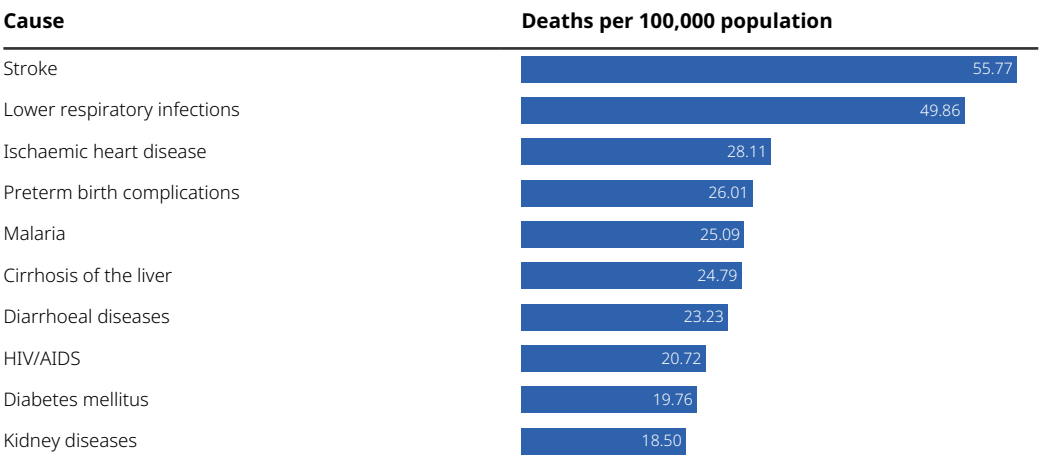
Healthcare overview

As of 2023, Rwanda had a population of about 14 million people and a population growth rate of 2.2 percent per year.[1] In Rwanda, according to data available from 2019, there are 0.1 physicians per 1,000 people. That rate contrasts sharply with data from developed countries such as Australia, Austria, Denmark, Germany, Spain, Sweden and Switzerland. In recent years, the rate of physicians to the general population in each of those countries has been more than 40 times (4.0 vs. 0.1) the rate in Rwanda.[2]

In 2023, Rwanda's human development index was 0.578, placing it in the medium human development category.[3] However, in 2022, 9.5 percent of its general government expenditure was allocated to health.[4] This indicates that the country is prioritizing health.

The top causes of death in Rwanda are stroke, respiratory infections such as influenza and pneumonia, preterm birth complications, ischemic heart disease and malaria.[5]

Figure 2. Top 10 causes of death in Rwanda in 2021



Source: WHO, 2021. Global Health Estimates: Leading Causes of Death. Available at: http://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates/ghe-leading-causes-of-death.

1 World Bank Group. *Rwanda.* World Bank Open Data; available at: https://data.worldbank.org/country/rwanda.
2 World Bank Group, op. cit.
3 United Nations Development Programme. (2024). *Human Development Reports: Rwanda*; available at: https://hdr.undp.org/data-center/specific-country-data#/countries/RWA.
4 World Health Organization. (2022). *Health Expenditure Profile: Rwanda*; available at: https://apps.who.int/nha/database/country_profile/Index/en.
5 World Health Organization. (2021), op. cit.

The disease pattern in Rwanda is swiftly transitioning toward NCDs. They were responsible for 30 percent of all fatalities in 2000, 39 percent by 2010 and 50 percent by 2019.[6]

In 1999, the country introduced a community-based health insurance (CBHI/"Mutuelles de santé") system in three health districts (Byumba, Kabgayi and Kabutare) as a pilot project.[7]

In 2004, the government approved the policy and, in 2008, it became obligatory for all citizens.[8] Originally, citizens paid USD 2 per family member per annum to receive coverage, but in 2011 the system was updated to reflect a variable fee based on individuals' economic status.[9]

CBHI divides households into three groups based on their economic status and has developed a tiered pricing model to co-finance the UHC scheme. Group 1 comprises the lowest-income residents (26 percent of the population); their coverage is free. Group 2 comprises 58 percent of the population; their premium is 3,000 Rwandan Francs (about USD 2) per person per year. Group 3 covers the wealthiest households (16 percent of the population) for 7,000 Rwandan Francs (about USD 5) per person per year.[10] [11]

According to 2019-20 Rwanda Demographic and Health Survey, about 77 percent of women and 78 percent of men between the age of 15 and 49 are covered by this insurance.[12] The premium covers 55 percent of the cost of CBHI. An additional 21 percent of the cost is covered by the Rwandan government; 11 percent is covered by donors; and other system fees make up the remainder.[13] Additionally, out-of-pocket expenditure is relatively low at around 10 percent of total health spending.[14]

Quadrupling the healthcare workforce

In July of 2023, the government of Rwanda approved the "4x4 Reform," a strategy aimed at quadrupling the number of healthcare workers in the country within the next four years. This reform is based on WHO's recommendation of at least four healthcare professionals per 1,000 population density.[15] Stakeholders who were interviewed lauded this reform as a promising step toward bolstering healthcare access and availability in Rwanda. The government has given special attention, including a dedicated cadre of frontline health workers, to addressing NCDs.

Interviewees highlighted several developments that have recently further improved access to affordable healthcare in the country. These include the introduction of drone delivery systems like Zipline (that are currently being used to deliver blood to patients in remote areas),[16] digitization of health data, unique patient identification, introduction of digital payment applications such as Flutterwave,[17] increased capacity of health centers and community health workers, and the use of AI, digital health and telemedicine.

Specifically, drone delivery systems and telemedicine have proved to be excellent mechanisms to deliver last-mile healthcare. Continued support from bilateral initiatives, international organizations, public-private partnerships and non-profits has also played a crucial role.

6 World Bank Group (2020), op. cit.
7 A. Woldemichaelandinet, *et al.* (2019). *The impact of community based health insurance schemes on out-of-pocket healthcare spending: Evidence from Rwanda.* IMF Working Papers; available at: https://doi.org/10.5089/9781484398074.001.
8 A. Twahirwa, (2008). *Sharing the burden of sickness: mutual health insurance in Rwanda*. Bulletin of the World Health Organization; available at: doi:10.2471/blt.08.021108.
9 Ibid; M.A. Achaw *et al.* (2025). *Determinants of willingness and ability to pay for an improved community-based health insurance in Rwanda*. SSM –; Health Systems; available at: https://www.sciencedirect.com/science/article/pii/S2949856225000212.
10 Rwanda Social Security Board. *CBHI Scheme*; available at: www.rssb.rw/scheme/cbhi-scheme.
11 Ministry of Health, Rwanda. (2010). *Rwanda Community Based Health Insurance Policy*; available at: https://rbc.gov.rw/fileadmin/user_upload/Rwanda_Community_Based_Health_Insurance_Policy.pdf.
12 National Institute of Statistics of Rwanda (NISR), Ministry of Health (MOH) [Rwanda], & ICF. (2021). *Rwanda Demographic and Health Survey 2019–20: Final report*. NISR and ICF; available at: https://dhsprogram.com/pubs/pdf/FR370/FR370.pdf.
13 Ibid.
14 World Bank. (2024). op. cit.
15 Ministry of Health (Rwanda). (2023). *The 4X4 Reform: A Path to Quality Health Care in Rwanda*; available at: https://www.moh.gov.rw/news-detail/the-4x4-reform-a-path-to-quality-health-care-in-rwanda#:~:text=In%20July%20of%202023%2C%20the,professionals%20per%201%2C000%20population%20density.
16 Ministry of ICT and Innovation (Rwanda). (n.d.). Rwanda signs agreement with Zipline to use drones for delivery of essential medical products; available at: https://www.minict.gov.rw/news-detail/rwanda-signs-agreement-with-zipline-to-use-drones-for-delivery-of-essential-medical-products.
17 Flutterwave. (2023). *Muraho Rwanda, Flutterwave is Back!*; available at: https://www.flutterwave.com/tz/blog/muraho-rwanda-flutterwave-is-back.

Industrial policy

Rwanda's National Industrial Policy is based on two main economic pillars: domestic production and export competitiveness.[18] These two pillars aim to support the country's economic growth and its structural transformation to create an enabling environment for industrialization.[19]

In 2011, Rwanda introduced policy actions aimed at facilitating technology transfer through the restructuring of the Industrial Research and Development Agency (IRDA) in support of the transfer of innovative technologies. This led to the development of the National Industrial Research and Development Agency, which seeks to support local innovators to become competitive through technology monitoring, acquisition, development, transfer and applied research.

Subsequently, and in line with Rwanda's National Strategy for Transformation 2017-2024,[20] the country's industrial policy incorporated a manufacturing-centric focus through the prioritization of development, economic growth and job creation led by the private sector.[21]

Notably, this strategy also includes the promotion of pharmaceuticals and medical devices manufacturing. To further this, the strategy proposes to create sector-specific incentives, investment in capacity building of priority sectors and to support technology acquisition. Policies such as these can play important roles in developing the IP and innovation ecosystem required to support the development of the local MedTech sector.

Lastly, the strategy acknowledges Rwanda's reliance on imports and recommends further industrialization to support a structural shift in its export base. For this purpose, the strategy looks to promote local manufacturing and its "Made in Rwanda" policy, which includes, among other things, the creation of a pharmaceutical production plant.

MedTech imports/exports

On average, from 2011 to 2021, total trade (imports and exports) contributed 54.2 percent to Rwanda's GDP each year.[22] The East African region relies primarily on imports to support its medical device needs and has the same top two MedTech supplier countries (China and Germany) as Bangladesh, with India in third place.[23]

Rwanda imports nearly all of its medical devices and laboratory equipment.[24] Different types of equipment come from multiple countries. For example, optical equipment at the Rwanda Charity Eye Hospital comes from countries that include China, Dubai, Germany, India, Korea, Lithuania, Sweden and Switzerland. The differing standards, compatibility issues and specialized training needs from multiple suppliers[25] complicate procurement, assembly and maintenance of products. They can potentially cause delays and, in some cases, high costs.

Rwanda is also a global exporter of instruments and appliances for medical use, predominantly in Africa; key markets include the Democratic Republic of the Congo, Ethiopia, Ghana, Kenya, the Kingdom of the Netherlands, South Sudan, United Republic of Tanzania, Uganda, and the United

18 Ministry of Trade and Industry (Rwanda). (2011). *National Industrial Policy of* Rwanda; available at: https://climatechange.gov.rw/fileadmin/user_upload/Documents/Policy/RwandaIndustrialPolicy.pdf.
19 Ibid.
20 Government of Rwanda. *7 years of Government Programme: National Strategy for Transformation (NST 1) 2017-2024*; available at: https://faolex.fao.org/docs/pdf/rwa206814.pdf.
21 Rwanda Development Board. *Investment Opportunities in Manufacturing*; available at: https://rdb.rw/investment-opportunities/manufacturing/#:~:text=Contact%20Us-,Overview,knowledge%2Dbased%20services%20and%20ICT.
22 Sherillyn Raga. (2023). *Rwanda: Macroeconomic and Trade Profile, ODI–;GIZ AfCFTA Policy Brief Series*; available at: http://cdn-odi-production.s3-website-eu-west-1.amazonaws.com/media/documents/Rwanda_macroeconomic_and_trade_profile_.pdf.
23 Zander, Marcand Harrison Mwaura. (2021). Medical and Laboratory Equipment Landscape in East Africa." 2021, Bremen, Germany.
24 UNAIDS and CCCM HPIE. (n.d.). *21 Country Profiles: An Introduction to Local Pharmaceutical Production Opportunities in Africa*, available at: https://developmentreimagined.com/wp-content/uploads/2019/01/unaids-report-new_english_webversion.pdf.
25 Jeremy Holmes Consulting Ltd. (2024). *Healing the Great Rift: Investing in the East African Pharmaceutical Sector to close the Medicines Supply Gap*; available at: https://www.abhi.org.uk/media/nfhbi1jr/healing-the-great-rift_25-jan-2024.pdf.

Arab Emirates.[26] However, the available data on import and export of medical devices to and from Rwanda often do not separately identify the data for MedTech, highlighting the need for studies and research specific to MedTech.

Rwanda has made significant strides in reducing trade and taxation barriers for medical imports and exports through regional economic free trade agreements and its domestic policies and regulations. It is a member of the East African Community, the Common Market for Eastern and Southern Africa and the African Continental Free Trade Area. It benefits from the customs union within these regional economic blocs, which serve as regional integration mechanisms. These unions facilitate the free trade of goods and services with zero duty and implement a common external tariff for imports. Additionally, they apply uniform, harmonized rules for both imports and exports.

No common external tariff rate is applied under these regional integration systems for some MedTech products, such as cameras for medical or surgical examination of internal organs, ECG machines, ultrasound machines, MRI apparatuses, X-ray machines and orthopedic and assistive care devices, such as hearing aids and wheelchairs.[27] Furthermore, goods and services exported from Rwanda are not subject to a VAT.[28]

The country has recently announced regulations related to licensing and authorization of imports and exports of medical devices and issued supporting guidelines.[29] Furthermore, the Rwanda Trade Portal sets out a detailed procedure for import of medical equipment, including information on permits, clearance, costs and required documents.[30]

Rwanda is establishing itself as a model by implementing strong policies, regulations and guidance to facilitate the import and export of medical devices. However, due to limited data on trade in the MedTech sector, it is challenging to fully assess the opportunities and scope for improvement in MedTech imports and exports.

Intellectual property

Rwanda stands out as an African nation that has made significant and proactive efforts to leverage IP for its economic growth. The country passed its first IP law in 1963, establishing a basic framework for IP protection.[31] This law was significantly updated and replaced in 2009 to align with international standards and the country's development goals.[32] That same year, the country also introduced its first national IP policy, which aimed to leverage IP to encourage technology transfer, focusing on knowledge creation, acquisition and transfer.[33]

26 World Integrated Trade Solution (WITS). (2022). *Rwanda Instruments and appliances used in medical or v exports by country in 2022*; available at: https://wits.worldbank.org/trade/comtrade/en/country/RWA/year/2022/tradeflow/Exports/partner/ALL/product/901890; World Integrated Trade Solution (WITS). (2022). *Rwanda Medical or surgical furniture (940290) exports by country in 2018*; available at: https://wits.worldbank.org/trade/comtrade/en/country/RWA/year/2018/tradeflow/Exports/partner/ALL/nomen/h5/product/940290.

27 EAC Customs Union, *Common External Tariff: 2022 Version*; available at: https://www.eac.int/documents/category/eac-common-external-tariff.

28 PricewaterhouseCoopers. *Rwanda: Corporate –; Other Taxes*; available at: https://taxsummaries.pwc.com/rwanda/corporate/other-taxes.

29 Rwanda FDA. (2022). Regulations Governing Control and Importation and Exportation of Pharmaceutical Products and Medical Devices. Law No. 003.2018 of 09/02/2018. Article 9; available at: https://images.chemycal.com/Media/Files/TBT/23_1251_00_e.pdf; Rwanda FDA. (2022). Guidelines for Importation and Exportation of Pharmaceutical Products and Medical Devices; available at: https://images.chemycal.com/Media/Files/TBT/23_1251_01_e.pdf.

30 Rwanda Trade Portal. *Import of Medical Equipment*; available at: https://rwandatrade.rw/objective/search?l=en&embed=&includeSearch=true&filter_tab=1&flt_1=2&flt_2=103&flt_4=.

31 Law on Patents, Designs, 1963; available at: https://www.wipo.int/wipolex/en/legislation/details/9136; World Trade Organization. (2004). *Trade Policy Review*, WT/TPR/S/129.

32 Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual Property.

33 M. Banda. (2019). *WTO TRIPS Agreement: A Hindrance to the Economic Development of Least Developed Countries? The Case of Malawi and Rwanda*. World Trade Organization; available at: https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2019/chapter_9_2019_e.pdf.

In 2018, Rwanda revised its IP policy to enhance the protection of IP rights and strengthen the institutional framework. The updated policy aims to create an environment that supports the economic use of IP rights by innovators and businesses. It sets the following goals to encourage innovation:

- Intensify awareness among IP users and potential users (including creators, innovators, potential investors, research centers and universities, small and medium enterprises and relevant government officials) of the policy and legal framework related to protection of IP rights in Rwanda;
- Create a suitable environment for the advancement of scientific and technological skills that in turn would increase innovation capacity in the country;
- Facilitate the development and economic exploitation of innovative and creative projects by creators, inventors, innovators and SMEs;
- Comply with international treaties on IP

To accelerate industrialization and attract manufacturers and innovators, the policy suggests that Rwanda strengthen its IP framework. In the policy, Rwanda also expresses its commitment to strengthening regional and international cooperation in IP rights, aiming to reduce filing costs and increase efficiency. The country actively participates in the TRIPS Council at the WTO and seeks more engagement in WIPO, ARIPO and other UN agencies related to IP policymaking, guided by the WIPO Development Agenda and the WHO Global Strategy and Plan of Action on Public Health.[34]

The IP Office within the Rwanda Development Board (RDB) administers registration of IP in Rwanda and related contentious (disputes such as oppositions) and non-contentious (routine registrations and administrative matters) proceedings.[35] It also conducts training and awareness-raising programs targeted at innovators and students.[36]

Commitment to support innovation

The most recent update in Rwandan IP law occurred in July 2024, when the country replaced the 2009 law with a new law that represents a significant evolution. This reflects Rwanda's ongoing commitment to strengthening its IP regime to support innovation and economic growth.[37] Like the 2009 law, the 2024 law creates the framework for protection of IP rights (including patents, utility models, industrial designs, trademarks and copyright) and enables their transfer.[38] It also provides statutory protection for trade secrets, recognizing unauthorized use of technical know-how, industrial and commercial espionage, breach of confidential contracts and acquisition of secret information as acts of unfair competition, with remedies available through civil action.[39]

Box 7. What is new in Rwanda's 2024 IP law?

The 2024 IP law substantially updates and broadens the scope of the 2009 law in Rwanda and provides clearer guidance on protection and enforcement. The key highlights of the law that indicate Rwanda's commitment to strengthening its health sector through the strategic and appropriate use of IP are as follows:

- There are no changes to MedTech patentability requirements, but a key update now limits the exclusion of pharmaceutical products in the 2009 law to those specified by executive order.[40]

34 Ministry of Trade and Industry, Rwanda. *Revised Policy on Intellectual Property in Rwanda.* (2018); available at: https://org.rdb.rw/wp-content/uploads/2020/09/Rwanda_Revised_Policy_on_Intellectual_Property_2018.pdf.
35 Ibid.; Rwanda Development Board. *Intellectual Property Rights*; available at: https://rdb.rw/neworg1/intellectual-property-rights/; Rwanda Development Board. (2019). *RDB concludes nationwide Intellectual Property awareness campaign*; available at: https://rdb.rw/rdb-concludes-nationwide-intellectual-property-awareness-campaign/; Rwanda Development Board. (2019). *RDB in nationwide Intellectual Property awareness* campaign; available at: https://rdb.rw/rdb-in-nationwide-intellectual-property-awareness-campaign/.
36 Ibid.
37 Law No. 55/2024 of 20/06/2024 on the Protection of Intellectual Property.
38 Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual Property.
39 Art. 275-277, Law No. 55/2024 of 20/06/2024 on the Protection of Intellectual Property.
40 Art. 23, Law No. 55/2024 of 20/06/2024 on the Protection of Intellectual Property.

So far, no such order has been issued. This shift signals Rwanda's evolving public health policies and a growing focus on encouraging medical innovations.

- Rwanda now provides a mechanism for filing pre-grant oppositions against a published patent application by any interested person, as well as for appeal against the order passed in such proceedings.[41] The 2009 law had no provision for pre-grant challenge. This signifies Rwanda's commitment to ensuring both the quality and validity of patents.
- The law reaffirms "distinctiveness" as a requirement for registration of trademark, while also clarifying that distinctiveness, in addition to inherent distinctiveness, should also mean distinctiveness acquired through continuous use.[42] This enhances trademark protection in Rwanda, which is critical to reduce consumer confusion, build loyalty and fight against counterfeiting, especially in cases involving health technologies.
- The law strengthens innovators' rights by clarifying the "effect of publication" for patent application, utility model applications, industrial designs and trademark applications (Art. 28, Art. 87, Art. 114 and Art. 197).[43] It grants applicants the same rights and privileges as if their IP were registered during the publication stage, unless a pre-grant opposition is filed. This further strengthens IP protection provided in Rwanda, making it easier for rights holders to protect and enforce their rights.

These changes demonstrate Rwanda's commitment to advancing the goals of its 2018 IP policy, particularly in promoting scientific and technological innovations and their commercialization. They are expected to strengthen Rwanda's IP ecosystem and create a more supportive environment for innovators.

Like the 2009 law, the 2024 law allows rights holders to pursue civil remedies for infringement and unfair competition by filing lawsuits.[44] The Commercial Court, which was established in

May 2008 as part of the High Court of Rwanda, continues to handle IP cases. Its rulings can be appealed as per Rwandan law.[45] Feedback from Rwandan IP law experts highlights that judges often summon officers from RDB during civil suits when necessary, ensuring comprehensive adjudication of IP disputes.

Criminal action in Rwanda addresses trademark and copyright infringements with penalties. Additionally, the IP law empowers customs authorities to suspend the clearance of counterfeit goods, a mechanism praised by IP law experts as both effective and popular. This multifaceted approach to IP enforcement demonstrates Rwanda's commitment to safeguarding IP through diverse and robust strategies.

While the IP law experts interviewed for this study provided detailed accounts of the judicial and administrative remedies for IP matters in Rwanda, they noted there are no noteworthy examples of IP disputes or case laws in the MedTech sector, indicating minimal use of these remedies for MedTech.

Rwanda, as an ARIPO member, benefits from technical expertise and guidance, including support for IP registration, capacity building and regional collaboration on IP matters. WIPO's statistics on IP filings in Rwanda (see Table 2) from 2023 show that RDB's IP office is less burdened and has fewer filings, with the exception of trademark filings, compared to ARIPO.

41 Art. 29 and 30, Law No. 55/2024 of 20/06/2024 on the Protection of Intellectual Property.
42 Art. 184, Law No. 55/2024 of 20/06/2024 on the Protection of Intellectual Property.
43 Art. 28, Art. 87, Art. 114 and Art. 197, Law No. 55/2024 of 20/06/2024 on the Protection of Intellectual Property.
44 Art. 37, Art. 99, Art. 125, Art. 160, Art. 203 and Art. 277, Law No. 55/2024 of 20/06/2024 on the Protection of Intellectual Property.
45 Law No. 51/2008 of 09/09/2008 Determining the Organization, Functioning and Jurisdiction of Courts, Art. 36; Organic Law 6 of 2012 Determining the Organization, Functioning and Jurisdiction go Commercial Courts, Art. 2. 10°.

Table 2. Industrial property filing in Rwanda in 2023

National IP Office applications			Applications per examiner	Pendency
Patents	Resident applications	12	7.5	Data not available
	Non-resident applications	3		
	Total	15		
Trademarks	Resident applications	1,400	1953.5	20 days
	Non-resident applications	2,507		
	Total	3,907		
Industrial designs	Resident applications	8	44.5	Data not available
	Non-resident applications	81		
	Total	89		

Source: World Intellectual Property Organization. (2023). Intellectual Property Statistical Country Profile 2023: Rwanda. Available at: https://www.wipo.int/edocs/statistics-country-profile/en/rw.pdf.

Rwanda receives patent applications through its national IP office or ARIPO. Due to a lack of domestic technical expertise, Rwanda relies on ARIPO's expertise for examination before granting patents.

In an interview with a leading Rwandan technology company, it was revealed that its leadership was unaware of ARIPO's filing and designation system. The representative recommended raising awareness of regional filing systems in LDCs.

Feedback from IP experts from Rwanda highlighted a lack of technical capacity for drafting patent specifications and claims, and handling administrative steps for registration applicants and their agents. Although the processing time for a patent application can be as short as a year,[46] significant delays often occur due to the time required to draft and finalize applications and respond to questions or requests from the IP office reviewing their application.

A review published by ARIPO showed that most of the patents filed for MedTech have either lapsed or been withdrawn.[47] However, there are a few patents in force in the MedTech field, including a patent for a handheld device that uses polymerase chain reaction with diagnostic applications;[48] a device for automatic injection of drug doses;[49] and an inhaler device.[50]

Rwanda's IP policy places a strong emphasis on advancing the health sector. Further, while there have been advancements in information and communication technologies that support healthcare services,[51] there are no notable examples of homegrown MedTech products from Rwanda.

Feedback from stakeholder interviews highlighted the need for a deeper understanding of the MedTech ecosystem and the various forms of IP applicable to different products and their components.

46 Rwanda Development Board. *Business Procedures: Register a Patent*; available at: https://businessprocedures.rdb.rw/procedure/32/32/step/132.
47 Extracted from ARIPO Database.
48 BigTec Private Limited. (2023). *Device for automatic injection of drug doses*, P/2014/007489. ARIPO.
49 Philip Jerome Driver, et al. (2023). *Device for automatic injection of drug doses*. P/2014/007489. ARIPO.
50 Frank Pieters and Xerxes Rao, (2023). *Inhaler Device.* P/2016/009515. ARIPO.
51 Such as innovative software solutions brough by Ishyiga Software. Ishyiga Software; available at: https://www.ishyiga.net/web/.

Embracing innovation

Stakeholder feedback indicates that Rwanda's proactive government attitude toward innovation and rapid policy reforms fosters an environment conducive to all types of innovations, including MedTech. The country's policies attract foreign talent and facilitate the exchange of ideas, making it a regional hub for innovation. Centers of excellence and robust infrastructure, including widespread internet access and reliable electricity, further bolster Rwanda's innovation capabilities.

Rwanda's National Industrial Research and Development Agency ("NIRDA") plays a significant role in supporting SMEs through various initiatives. These include assistance in product development and provision of training in several areas, particularly IP.[52] NIRDA's IP training focuses on trademarks and branding and teaching participants how to conduct trademark searches using keywords and trademark classification. Additionally, NIRDA helps innovators complete trademark registration forms and follows up on their IP applications until completion. The organization also hosts open calls to select innovators for training and incubation, with funding provided by NIRDA. Stakeholder feedback indicated that NIRDA may not necessarily have the technical expertise to extend this support to include patents.

Filling the gaps

While Rwanda's policy and legal framework for IP and innovation is promising, gaps remain between policy goals and on-the-ground practice, according to interviewees. Key areas for implementation include training and awareness programs across all facets of administration and enforcement; capacity building for IP experts; and a reassessment of fees to ensure they are not unintentionally discouraging filing. Stakeholders have highlighted WIPO's role in training and teaching assistance in Rwanda and have recommended increased, continuous and consistent collaborations in the future.

Stakeholders interviewed for this study identified several areas for improvement to strengthen the IP and innovation ecosystem in the country. The key findings are summarized as follows:

- Based on discussions with IP law practitioners in Rwanda, it has become apparent that the focus tends to be only on filing for and enforcing trademark rights, even within the MedTech industry. This trend indicates that innovators and entrepreneurs are investing neither time nor resources in developing a comprehensive IP portfolio that includes other forms of IPs, particularly patents. Furthermore, multinational MedTech companies and innovators often overlook Rwanda as a preferred jurisdiction for patent registration due to concerns about the functionality of its IP offices and enforcement mechanisms. In settings without robust IP enforcement, innovations may be vulnerable to infringement, which can deter companies from establishing operations in, or transferring technology to, these settings. It was the view of the IP practitioners who were interviewed that the full potential of IP in Rwanda remains untapped, and constraints via-à-vis technical capacity may hinder technology transfer and local manufacturing efforts.
- Interviewees said that there is a general lack of IP awareness among all stakeholders in the country, including personnel in IP and regulatory offices, law enforcement agencies (who are often unaware of criminal provisions for IP enforcement), judges (who might struggle with understanding technical aspects of IP disputes), entrepreneurs and innovators. Consequently, a recurring recommendation that emerged from most of the interviews was to intensify IP training initiatives in Rwanda and maintain the collaborative efforts between WIPO and NIRDA in the following areas:

    - Judges presiding over general commercial courts handle civil IP cases, and there is room for enhancing their specialized technical expertise for healthcare-related filings.
    - There is a scarcity of patent attorneys in Rwanda, which results in a significant lack of technical expertise for patent drafting, filing, prosecution and litigation.
    - The IP filing and prosecution fees can be prohibitively expensive for individual applicants, startups and SMEs.

52 National Industrial Research and Development Agency. *Overview* available at: https://www.nirda.gov.rw/.

- Awareness programs should start at the ground level. The lack of IP education in technical institutions highlights the need for schools to teach and equip students with theoretical knowledge of IP and practical skills.
- IP policies should help to address certain health challenges. For example, the escalating challenge of counterfeit health technologies that can be purchased online necessitates the formulation of robust policies and legislation.

Regulatory systems

The country's registering authority is the Rwanda Food and Drug Authority. The Rwanda FDA practices reliance, and foreign manufacturers can leverage their existing approvals in recognized markets (Australia, Canada, European Union countries, Japan and the United States) to receive expedited regulatory reviews and shorten their timelines.[53]

Rwanda practices pharmaceutical regulatory harmonization through its membership in the East African Community Medicines Regulatory Harmonization Program;[54] on August 2, 2021, the Rwanda FDA also signed a harmonization agreement with the United Republic of Tanzania Medicines and Medical Devices Authority.[55]

In April 2020, the Regulations Governing Registration of Medical Devices including in vitro diagnostics came into effect. These regulations, which can be cited as Rwanda FDA regulations, include the registration procedures (see Box 9) applicable to all regulated human and veterinary medical devices, such as in vitro diagnostic dossiers submitted for market authorization.[56]

Box 9. Regulatory pathway for the registration of medical devices, including in vitro diagnostics, in Rwanda

On April 20, 2020, the Rwanda FDA adopted the provisions of the Regulations Governing Registration of Medical Devices.

The regulations were amended in 2021 to allow the regulatory authority to issue emergency use authorization when a national public health emergency has been declared or if the medical device meets certain requirements, such as being prequalified by WHO or previously registered or granted authorization for emergency use by countries that have collaborative agreements with Rwanda, among others.[57]

In 2022, these guidelines were further revised to include in vitro diagnostics as products covered under this regulation.

To complement the technical regulations, Rwanda FDA has also issued Guidelines on Submission of Documentation for Registration of Medical Devices. The purpose of these guidelines is "to provide guidance to medical devices importers, manufacturers and distributors intending to market their products in Rwanda on the documentation requirements."

53 Zander (2011). op. cit.
54 East African Community (EAC), MRH Programme. *EAC-MRH Programme Contacts*; available at: https://www.eac.int/contact-us.
55 Rwanda FDA. (2021). *Cooperation in the Regulation of Medical Products*; available at: rwandafda.prod.risa.rw/news-details/agreement-mou-was-signed-between-rwanda-and-tanzania-governments-for-collaboration-between-the-nras-of-the-2-countries-rwanda-fda-and-tmda.
56 Rwanda FDA. (2022). *Revised Regulations Governing Registration of Medical Devices including In Vitro Diagnostics*; available at: https://rwandafda.gov.rw/wp-content/uploads/2022/11/REGULA1-9.pdf.
57 Ibid. Article 15.

Financial incentives

In 2018, the government launched the Rwanda Innovation Fund (RIF), which supports tech-enabled SMEs. This initiative is managed by the Rwanda National Council for Science and Technology and includes mentoring, incubation and funding. The council harnesses the RIF and mobilizes other top funders, like the Bill and Melinda Gates Foundation, to assist projects that address health-related needs. Interviewed stakeholders said that these initiatives supported multiple projects, which facilitated their progress toward commercialization. Projects supported by this initiative include the use of smartphone technology to self-manage NCDs like diabetes. See Box 10.

Box 10. Case study on MedTech in Rwanda - the use of smartphone technology in the self-management of type 2 diabetes

This case study explores a pioneering MedTech solution that leverages smartphone technology to empower patients in the self-management of diabetes. By providing accessible, cost-effective tools for daily health monitoring, the project aims to bridge healthcare gaps and improve the quality of life for patients, while laying the foundation for scalable digital health solutions in Rwanda.

The challenge

Type 2 diabetes is one of the most prevalent NCDs, accounting for over 90 percent of all cases of diabetes mellitus. It is linked to serious complications and other major NCDs, such as cardiovascular disease, hypertension, obesity and cancer. Once diagnosed, diabetes is a lifelong condition that significantly affects quality of life and requires costly long-term management.

The innovation and how it works

To address this challenge, the project leverages smartphone technology via a tele-genetics platform to help patients with type 2 diabetes self-manage their condition. The innovation consists of smartphone applications that support key self-management activities such as blood glucose monitoring, exercising, healthy eating, taking medications, and monitoring complications. The use of mobile health technology helps bridge gaps in primary care, especially where healthcare resources or patient access to care are limited. This approach requires minimal infrastructure and provides educational and motivational support to patients, reducing both health risks and costs.

Progress to date

Thus far, the project has received funding of 150 million Rwandan Francs (approximately USD 100,000), allowing the implementing team to deliver on key project activities. In addition to providing financial support, the National Council for Science and Technology has provided technical assistance, IP guidance and administrative support through monitoring and evaluation processes. The research team has engaged stakeholders, including the Rwanda Biomedical Center and the Ministry of Health, to explore the integration of the platform into the national healthcare system. Initial pilot tests with type 2 diabetes patients have yielded positive feedback, with users reporting improvements in their health since adopting the system.

IP strategy

The research team secured copyright protection for the system's software through the RDB and registered a trademark for the associated online clinic. Looking ahead, they plan to formally register the clinic to establish its legal standing and expand access to digital diabetes management services. This IP strategy not only safeguards the technology but also lays the groundwork for future commercialization.

Lessons learned: enablers and challenges

The project benefited financially and technically from strong government support through the National Council for Science and Technology, which provided crucial guidance on IP registration and monitoring and evaluation processes. These enablers helped the team innovate and gain initial traction. However, the team faced significant challenges related to IP ownership. There was a lack of clarity from the outset regarding IP rights, as expectations from university and industry partners differed. These differences created complications over who would retain the IP, highlighting the need for clearer agreements when academic institutions and private sector partners collaborate on projects.

A major lesson learned is the importance of establishing clear IP ownership and collaboration frameworks from the beginning, especially when working with multiple stakeholders. This ensures smoother innovation processes and commercialization. Moreover, strengthening policies that foster collaboration between research institutions and the private sector is essential for sustainable innovation.

Source: Jean Pierre Hakizimana, National Consultant

In August 2020, the Rwanda Ministry of ICT (Information and Communications Technology) & Innovation held the first of three meetings to discuss the development of Rwanda's Startup Act intended to build a stronger entrepreneurial ecosystem.[58] This act aims to provide innovators with a variety of resources, including IP support, tax incentives, seed funding and immigration incentives to draw talent.[59]

As shared by stakeholders during interviews, the private sector, driven largely by external funding, plays a pivotal role in Rwanda's innovation landscape. The government of Rwanda is a major buyer of healthcare technologies and, as such, a balance between market-driven solutions and public sector support remains critical.

Local MedTech industry capacity

Rwanda is the host of the regional Center of Excellence in eHealth and Biomedical Engineering and the African Medicines Agency, i.e., Africa's medical regulatory body. In the past two decades, Rwanda has added several educational programs aimed at increasing the capacity of the country to innovate in the medical sector. For example, in 2010, Rwanda added a biomedical engineering curriculum to the Integrated Polytechnic Regional Center.[60] In October, 2023, the Institut de Recherche contre les Cancers de l'Appareil Digestif (IRCAD), Afrique or the Research Institute Against Digestive Cancer, Africa, was launched in Kigali, marking the inauguration of the first center of excellence for minimally invasive surgery on the African continent. January 2024, brought the launch of the East Africa Biodesign Program. Both initiatives aim to develop local institutional capacity to address NCDs like cancer and diabetes using medical technology.

The Kigali-based East Africa Biodesign Program is a 10-month fellowship program focused on biomedical innovation on the continent. It is a collaboration among the University of Global Health Equity (UGHE), the University of Rwanda, Kenyatta University and the Stanford Byers Center for Biodesign.[61] Hosting centers of excellence, innovation hubs and regional regulatory bodies makes Rwanda a highly influential center of medical device innovation on the continent. The case study below illustrates how universities like UGHE are working with local governments to support institutional capacity and local innovators to develop MedTech solutions.

58 Ministry of ICT and Innovation, Rwanda. (2022). *MINICT Held a Consultative Meeting on the Development of Rwanda Startup Act*; available at: minict.prod.risa.rw/news-detail/minict-held-a-consultative-meeting-on-the-development-of-rwanda-startup-act.
59 A. Edwin. (2023). *Nine Major Incentives in Rwanda's Proposed Startup Act*. The New Times; available at: www.newtimes.co.rw/article/11041/news/technology/nine-major-incentives-in-rwandas-proposed-startup-act.
60 M. Raxworthy, *et al.*, (2022). *Biomedical Engineering as a Driver for Healthcare Improvements in East Africa*. Biomedical Engineering; available at: https://www.researchgate.net/publication/369172042_Biomedical_Engineering_as_a_Driver_for_Healthcare_Improvements_in_East_Africa.
61 University of Global Health Equity. (n.d.). *East Africa Biodesign Fellowship: About EAC*; available at: https://ughe.org/east-africa-biodesign-fellowship/.

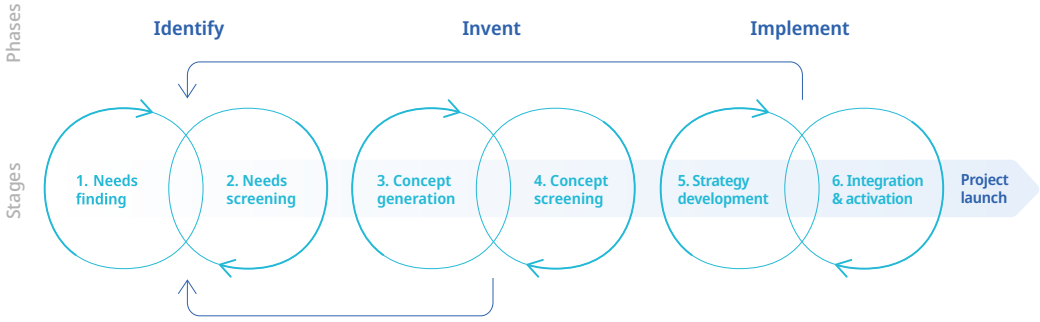
Box 11. Case study: Stanford-Biodesign Program to nurture local innovation ecosystems

The local production of MedTech in LDCs is a complex opportunity. Governments can support the innovation ecosystem to nurture local product development. As knowledge producers, academic institutions play a fundamental role in the development of local innovation ecosystems.[62] Not only do they generate and transfer specialized knowledge, but they are also a source of talent with technical expertise.

The Stanford Biodesign Fellowship Program was launched in 2000 offering medical technology postgraduate training to physicians and engineers wishing to translate clinical insights into new technologies.

Since its inception, the program's curriculum has followed a three-phase process: identification, invention and implementation.

Figure 3. Biodesign process overview



Source: https://www.researchgate.net/figure/The-3-Phases-of-the-Stanford-Biodesign-Process

Over the course of the 12-month program, fellows can leverage the expertise of local MedTech experts, venture capitalists, regulatory experts, coaches and mentors who guide them at every stage of the biodesign process.

During the first five years of the program, over 200 fellows and graduate students were trained and nine companies were formed based on products developed by the fellows. The success of the program prompted Stanford officials to consider broadening the project's scope to train leaders from around the world in biomedical technology innovation. They set up local biodesign programs in several countries, including India, Ireland, Japan and Singapore. Adapting lessons learned from these centers, the Stanford Biodesign Program was recently launched in Rwanda.

East Africa Biodesign is a global collaboration among the UGHE, the University of Rwanda, Kenyatta University and Stanford Biodesign. The program aims to enhance health outcomes and equity for underserved populations in East Africa by training local innovators to develop appropriate, accessible and sustainable health innovations.

Rwanda can leverage the lessons from other countries to build up its MedTech innovation ecosystem with the technical support of the Biodesign Program. For example, political leadership and local champions are important to build up local institutional capacity. In India, the biotechnology secretary championed the Biodesign Program and provided necessary infrastructure and support, such as research laboratories and hospital immersions. This was accompanied by identifying technical experts and institutions to oversee the program's

62 G. Schiuma and D. Carlucci. (2018). *Managing Strategic Partnerships with Universities in Innovation Ecosystems: A Research Agenda*, Journal of Open Innovation: Technology. Market and Complexity. Volume 4. Issue 3. ISSN 2199-8531; available at: https://www.sciencedirect.com/science/article/pii/S2199853122002803. .

operations. The Indian Institutes of Technology housed the program with an engineering faculty to provide expertise and guidance to the students. Simultaneously, a leading cardiologist from the government provided medical expertise and access to hospitals to support clinical immersions.

Based on the existing Biodesign Program, a new curriculum was developed, and the Stanford-India Biodesign Program was launched with the goal of training Indian MedTech innovators who would support the country's then-nascent MedTech industry to address local needs.

Programming biodesign to meet each country's needs

The Stanford Biodesign Program is adaptable to each country's unique needs. For example, India offered a slightly different approach than the one offered in the original Stanford Biodesign Program. For starters, it was designed to be a two-year, team-based fellowship instead of a one-year program. There are 11 affiliated biodesign centers across India today that provide end-to-end support to help students identify clinical needs, develop and test their prototype solutions and take their products to market. This includes incubation support, IP protection, valuation and commercialization. As a result of the program, a number of innovators have filed for patents.

The Biodesign Program also forges strong partnerships among universities, innovators and industry to facilitate the commercialization process. In India, a number of partnerships were established for product development, licensing and technology transfer to scale up local manufacturing and distribution of MedTech.

The biodesign process is transferable and applicable to LDCs in Africa, Asia and Latin America. But this requires investing in the development of well-trained engineers and clinicians to support local R&D efforts. Several leading universities across the continent are developing strong medical and engineering faculties to lead the way. Strong partnerships between local and global universities can help to build up local research and development capabilities in the MedTech sector. This will take time to develop, and once it does, it will be important to retain that operational experience and expertise in the country.

The program's multidisciplinary approach, focus on local needs and hands-on training, coupled with the strong mentorship and networking opportunities for the fellows, have made these programs sustainable, scalable and impactful.

East Africa, in general, has found academic partnerships with training institutions in Africa and in the global north to be great for developing human resources and building capacity, finding that "70% of science and technology publications from East Africa – and probably a greater proportion for MedTech – involve international collaborations."[63]

Feedback from stakeholders highlights good practices in academic programs to support innovations in Rwanda, for example:

- Universities engage in research on how to implement innovations, i.e., investigating whether published research translates into practical applications on the ground.
- In many cases, universities have their own IP policies (which typically include guidance on licensing and technology transfer) and provide assistance to innovators to file their IP.
- There is increased support from the government for innovation projects

However, feedback also highlights certain challenges. For example:

- Limited resources and prototyping spaces (dedicated spaces equipped with relevant tools and resources to facilitate creation and testing of prototypes)in Rwanda necessitate collaborations with other countries such as India and China, complicating back-and-forth

63 Ibid.

logistics. The country faces deficiencies in manufacturing capacities and resources for conducting clinical trials, which are crucial for healthcare technologies.
- There is a need not only to train doctors and biomedical engineers, but also to educate and employ health professionals, such as technicians and pathologists.
- There are limited opportunities to foster meaningful collaboration among multidisciplinary teams, including medical professionals, scientists, technologists and engineers.

Most stakeholders praised Rwanda's private and public sector actors for enhancing essential infrastructure, including electricity, roads and internet. Additionally, they acknowledged the expansion of healthcare access through investments in related sectors like drone technology and digital payment applications, such as Flutterwave,[64] which have simplified payment processes for healthcare providers and migrant patients.

64 Flutterwave. *Payment Solutions*; available at:https://flutterwave.com/us/.

Lessons learned: applicable to all LDCs

Intellectual property

Public sector:

- There is a general lack of awareness about different forms of IP protection, filings and enforcement systems.
- Investing in the hiring and training of sufficient administrative staff and examiners is critical to building a robust IP ecosystem.
- It is crucial for countries to build trust in their enforcement and efficient management of IP processes so that the private sector will increase their utilization of the system.

Private sector:

- A country's IP system can become more efficient and effective only if it is utilized. The more companies engage with the IP ecosystem, the stronger it becomes, incentivizing innovation and entrepreneurship and reducing the likelihood of infringement and counterfeiting.
- Local manufacturers should explore the possibility of in-licensing MedTech from other local and overseas providers.
- It is important to support the development of TTOs and policies in universities to bridge the gap between the private sector and academia.

Regulatory systems

Public sector:

- Countries that adhere to international standards and best practices benefit from faster access to MedTech. This is because global MedTech companies can leverage existing regulatory dossiers.
- Lack of differentiation between pharmaceutical and MedTech regulation can slow down innovation by applying overly rigid or inappropriate requirements to MedTech. MedTech products often have shorter development cycles, different risk profiles and distinct testing needs compared to pharmaceuticals.
- Without a tailored, regulatory pathway, MedTech innovators face delays and barriers that hinder the development, adaptation and timely market entry of new health solutions.
- Regulatory harmonization and reliance are not only effective ways to streamline approvals but also represent opportunities to build and enhance local authorities' regulatory skills and capacity. This is particularly beneficial in environments where the regulatory ecosystem is still maturing, as it allows for the adoption of best practices and standards without the need for extensive local resources.
- Imposing unique, country-specific requirements to enter a given market (e.g., requiring country-specific inspections instead of utilizing recognized Quality Management System evidence such as Medical Device Single Audit Program audit reports or ISO 13485 certification to ensure medical devices manufacturers adhere to the relevant international standards) can make it more challenging to attract global MedTech companies. This regulatory burden is especially difficult for domestic innovators, who often lack the resources to navigate complex approval pathways.

Private sector:

- Stakeholders in the private sector should determine which LDCs practice regulatory harmonization and reliance, because it will be easier to provide services to these countries by streamlining or decreasing the time it takes to prepare regulatory dossiers.
- Stakeholders should engage in ongoing dialogues with governments of LDCs to highlight the challenges posed by non-harmonized regulatory environments and to illustrate how unique regulatory requirements affect MedTech access and reduce the attractiveness of different markets to companies.
- Stakeholders should actively participate in government-led policy dialogues to ensure that, prior to policy formulation, the private sector is heard and considered.

Financing

Public sector:

- The gap in mid-sized, unrestricted funding opportunities for local entrepreneurs is making it more challenging for innovators to succeed.
- Tax incentives like the ones established in Rwanda and Bangladesh can help promote MedTech access by facilitating device imports.
- Government funding through industrial policy grants, innovation centers and interest-free loans can support young innovators to access capital in the MedTech sector.

Private sector:

- When officials who manage funds and banks consider intangible assets like IP in company valuations and loan collateral agreements, innovators are more easily able to access necessary funding to achieve their project goals.
- Venture capital plays a crucial role in supporting MedTech innovation in LDCs by providing the funding and resources they need to grow and scale their solutions. Global MedTech companies may benefit from utilizing creative business models to help widen access to their products.
- Public-private partnerships can pool financial, human and technical resources to support the growth of the local MedTech sector.

Capacity

Public sector:

- It is important to invest in training programs for all stakeholders (e.g., surgeons, doctors, nurses, regulators and policy makers) in MedTech development, regulation, utilization and deployment.
- Identifying and addressing causes of brain drain and employee turnover can support the development of the local innovation ecosystem; encourage local innovation led by doctors and engineers; and make countries more attractive to global MedTech companies seeking to set up operations.
- Technology transfer projects can be tools to develop local manufacturing capacity

Private sector:

- Companies can exert a dramatic impact on MedTech access by building partnerships with local organizations to provide training and education opportunities for healthcare providers.
- Engaging in technology transfer projects with local partners can be useful in providing value for patients in situations where the company would not otherwise have been able to meet patient needs on its own.
- Products and product support systems (e.g., maintenance technician training) that are designed with the country's ecosystem in mind are more likely to succeed.

Country-specific opportunities and recommendations

Bangladesh

Intellectual property

Public sector

- To support a smooth transition toward graduation from LDC status, ensure that national IP laws are aligned with international standards and strengthen IP protection and enforcement mechanisms.
- Continue providing financial and infrastructure support (including incentives and subsidies) for companies investing in research and development.
- Develop robust national IP policies and enforcement mechanisms to garner national and international trust and investor confidence in the national IP system.
- Establish, support and promote research centers in universities, TTOs and other institutions working in MedTech innovation.
- Provide education and training to healthcare stakeholders on the different aspects of IP, including conducting patent searches, filing patent applications, IP valuation, and IP commercialization support. This will help local inventors access funding and scale up their innovations in the MedTech sector.

Private sector

- Officials at private universities, innovation hubs and incubators should consider offering guidance on patent filing to support first-time innovators engaging with the system.
- Companies should prioritize partnerships with academic institutions, research organizations and startups to leverage combined expertise and resources to develop patentable MedTech products.
- Incubators should consider providing funding or grants specifically aimed at covering IP-related costs.

Regulatory systems

Public sector

- Consider the merits of introducing a dedicated regulatory body for medical devices, within the Directorate General of Drug Administration, to provide necessary oversight to address the gap in technical expertise. There would be benefits to this body operating based on internationally recognized standards and best practices to ensure global convergence and regulatory reliance. This would enable Bangladesh to serve as a model for other LDCs.
- Encourage regulatory enforcement and seek technical assistance from international organizations to ensure regulatory bodies have the necessary resources and expertise. This could include adopting reliance practices that allow leveraging assessment from mature regulatory authorities.
- Develop mechanisms that allow regulatory bodies to support responsible innovation while maintaining high standards for safety and effectiveness.

Private sector

- Invest in appropriate capacity-building initiatives in partnership with government and relevant international organizations for regulatory officers to improve their knowledge of MedTech regulation. Training should focus on international best practices, convergence and reliance principles to ensure alignment with global regulatory standards.
- Support regulatory science and research that can serve as a scientific basis for developing regulations and standards. Encourage collaboration between industry and regulatory bodies to foster innovation and create a robust regulatory framework grounded in evidence-based practices.

Financing

Public sector

- Further support government initiatives like the Hi-Tech Park that provide incentives and attract foreign investment into the technology industry.
- Further promote and replicate the success of initiatives like Startup Bangladesh Limited and the Innovation Design and Entrepreneurship Academy, which provide funding to technology-based innovations.

Private sector

- Allocate grants to incubators and technology parks working on health technologies.
- Local innovators should take advantage of government-backed initiatives like StartUp Bangladesh Limited to obtain funding for their projects.

Capacity

Public sector

- Continue developing initiatives such as the High-Tech Park to support entrepreneurs and help develop a MedTech ecosystem in collaboration with the Ministry of Health and Family Welfare.

Private sector

- Nurture the innovation ecosystem by developing networking platforms where local entrepreneurs, investors and experts in the MedTech field can connect and collaborate.

Rwanda

Intellectual property

Public sector

- Consider creating training programs tailored to increasing awareness of IP for non-IP professionals in different government agencies affecting the MedTech sector, including health, commerce, science and information and communications technology ministries.
- Continue providing assistance/education on IP to personnel in law enforcement agencies, IP and regulatory offices, students in STEM, innovators and entrepreneurs.
- To address the issue of fewer patent filings and limited capacity:
    - Investigate the underlying causes by identifying gaps in existing training programs; assessing the availability of resources and expertise; and understanding challenges faced by innovators and IP professionals in this area.
    - Develop effective solutions to train innovators and lawyers in patent drafting through specialized workshops, mentorship programs, online courses, or partnerships with experienced patent professionals.

Private sector

- Local innovators and entrepreneurs should explore the benefits of patents, utility models and industrial designs in addition to trademarks in order to fully leverage the potential of IP.
- By diversifying their IP portfolio, innovators can better protect their innovations, secure a competitive advantage, potentially generate additional revenue streams and contribute to the fight against infringement and counterfeiting.
- Local innovators and entrepreneurs should consider how they can benefit from IP training and assistance provided by NIRDA and WIPO to enhance their understanding of IP and become more confident in engaging with IP-related matters.

Regulatory systems

Public sector

- Continue creating distinct regulatory procedures for devices and diagnostics to ensure that the unique requirements and challenges of devices and diagnostics are adequately addressed.
- Continue practicing harmonization with international standards and best practices and enhance regulatory reliance, including increased use of reliance for multinational companies entering the country, particularly for devices that have undergone stringent regulatory assessment (e.g., by Management Committee members of the International Medical Device Regulators Forum).

Private sector

- Take advantage of the Rwanda FDA's regulatory reliance framework to facilitate dossier submissions and expedite access to essential MedTech for the local population.

Financing

Public sector

- Recognize IP as an important asset:
  - to create avenues for financing;
  - to introduce fee concessions for individual applicants and SMEs;
  - to create institutional frameworks enabling IP owners to leverage their IP as assets
- Continue to engage with global partners, including international organizations, government agencies and philanthropic organizations to further advance Rwanda's health policy objectives by leveraging financing instruments.

Private sector

- Funders, donors and investors should consider maintaining continuous support for projects in the MedTech sector as they play a vital role in driving innovation and long-term progress.
- Innovators and entrepreneurs should make active efforts to meaningfully collaborate with the public sector and funders to communicate their needs and suggestions.

Capacity

Public sector

- Initiatives by NIRDA (such as investing in STEM laboratories[1]) are vital to increasing innovation capacity and capacity for domestic prototyping capabilities rather than relying on prototyping facilities outside of the country.
- Consider adopting a more practical and hands-on approach to training, so that entrepreneurs are equipped with the mental framework for how to approach innovation.
- Promote research into the most important health areas following the triple helix model of innovation.

Private sector

- Focus investment and reform efforts to address infrastructure challenges that can inflate production costs (such as high cost of water) and build facilities to enable prototyping and local manufacturing.
- Invest in and prioritize innovations for alternative infrastructure support projects, such as Zipline and Flutterwave. Note that telemedicine programs can also help to overcome some of the traditional infrastructure challenges and increase geographical access to health innovations.

1 NIRDA. (n.d.). *NIRDA to Invest $82M in STEM Lab*; available at: https://www.nirda.gov.rw/home/news-detail?tx_news_pi1%5Baction%5D=detail&tx_news_pi1%5Bcontroller%5D=News&tx_news_pi1%5Bnews%5D=42657&cHash=37580c201e470dbfe0eba59f9d15487b.

Study limitations and areas for further research

This is a first-of-its-kind report running a multifactorial analysis of the current state of MedTech in LDCs based on two country case studies and making recommendations accordingly. There is always room for additional analysis and more specific recommendations, and we encourage further research. However, it offers valuable lessons for many other LDCs as they ponder, deliberate and strategize about MedTech's role in their health systems and economies.

The authors of this study faced challenges in accessing information on insurance programs in LDCs, particularly regarding coverage of MedTech and NCD-related products under national schemes. Additionally, they found that there was a lack of research and data comparing staffing levels, funding and capacity between public and private hospitals in LDCs.

In both case study countries, it was challenging to access legislative and policy documents that offered detailed research and analysis of policy objectives. Many of the IP policies had only recently been enacted and it was therefore too early to evaluate their practical impact. In Bangladesh, the lack of official English translations made it particularly difficult to review updates to IP laws.

Gathering reliable data on IP enforcement mechanisms in both countries also proved challenging. Lastly, the authors found very few documented examples of technology transfer involving MedTech in LDCs.

The authors recommend that future researchers collect and publish detailed, country-specific information for each LDC to support more targeted analysis and the development of tailored recommendations for the MedTech sector.

This study, while providing a valuable starting point by focusing on Bangladesh and Rwanda, does acknowledge its limitations. Specifically, it does not fully explore the unique challenges faced by other LDCs, such as those in Small Island Developing States, with their connectivity and scale issues, or those in conflict zones, where instability and security concerns create additional hurdles. Despite these gaps, this study serves as an important initial step in understanding and supporting the MedTech environment across diverse LDC contexts, laying the groundwork for future research and solutions tailored to these specific challenges.

Annex 1. Open-ended interview questions

1. What are the current IP initiatives and challenges in your country? What resources are you aware of to support IP development?

2. What role can licensing and technology transfer (research institute-Industry vs. industry-industry) play in encouraging a boost of MedTech in Rwanda and Bangladesh? Is there any sort of technical support for spinouts (e.g. incubators that support business model development, government entities that give advice, promotions of hospital collaborations with smaller companies, etc.)?

3. What local innovations are happening in MedTech? How are patents/trademarks/copyrights/ trade secrets being used to stimulate the MedTech sector in your country?

4. What are the current regulatory initiatives/policies and challenges in your country? How has policy development favored/encouraged MedTech innovation in your country? Based on your experience, what are the necessary actions to be taken to overcome these challenges?

5. What are the current financing initiatives and challenges in your country? Are medical technologies covered by insurance? How inclusive are the financing initiatives for new and emerging MedTech initiatives? Based on your experience, what are the necessary actions to be taken to overcome these challenges?

6. What are the current infrastructure initiatives and challenges in your country? Based on your experience, what are the necessary actions to be taken to overcome these challenges?

7. What is the current status of local capacity on MedTech Innovation and technology? Do you see any challenges or barriers about local capacity? If so, what action needs to be taken for the improvement?

8. What MedTech innovation and access barriers have you encountered and how have organizations tried to address them? What is the top barrier for [each country]?

9. What MedTech innovation and access enablers have you encountered how have organizations tried to capitalize on them? What is the top enabler for [each country]?

10. What do you wish that MedTech innovation and access advocates in the [other: public/ private] sector would understand about [your: public/private] sector?

11. What ecosystem needs to exist to promote MedTech Innovation and access in [each country]? What are the low-hanging-fruits for [each country]?

12. Do you have any suggestions for to promote MedTech in Rwanda/Bangladesh?

Annex 2. Interviewee profiles

Bangladesh interviews (total: 21)	*Rwanda interviews (total: 21)*	*Global interviews (total: 26)*
10 government organizations	*9 government organizations*	*1 health research institute*
2 hospitals	*1 hospital*	*2 international bank*
2 MedTech industry association	*2 innovation hub*	*3 interviews across 2 trade and development agencies*
1 local IP law firm	*2 health advocacy civil societies*	*1 MedTech innovation incubator*
3 local MedTech companies	*1 healthcare provider society*	*1 IP office of a developed country*
1 academic institution	*2 local IP law firms*	*1 panel of IP and trade experts*
1 international cooperation agency	*2 local MedTech companies*	*1 innovation commercialization expert*
1 local office of a foreign pharmaceutical company	*1 local pharmaceutical company*	*1 IP analytics expert*
	1 local digital health company	*1 tech and innovation expert*
		13 interviews across 3 multinational MedTech companies
		- 1 former CEO
		- 1 international affairs
		- 2 intellectual property
		- 1 regulatory
		- 4 training and education
		- 2 manufacturing
		- 2 country-specific multidisciplinary panels (including a variety of experts)
		- 1 president of a corporate-funded healthcare access non-profit

A collaborative study by the UN Technology Bank, Medtronic and WIPO examines how the MedTech sector can tackle the rising burden of non-communicable diseases, which account for over 70% of global deaths.

Through fieldwork in Bangladesh and Rwanda, researchers analyzed innovation culture, intellectual property systems, regulations, financing and policies to identify barriers and enablers of MedTech development in least developed countries (LDCs).

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