



EVERY WOMAN
EVERY CHILD

FOR HEALTHY AND EMPOWERED WOMEN,
CHILDREN AND ADOLESCENTS
INNOVATION MARKETPLACE



Models to Scale Healthcare Technologies for Low- and Middle-Income Countries

A WHITE PAPER

Deepika Devadas, Annie Thériault, *Every Woman Every Child* Innovation Marketplace, Grand Challenges Canada

Anita M. McGahan, University of Toronto, Rotman School of Management



A white paper by the *Every Woman Every Child* Innovation Marketplace at Grand Challenges Canada and the University of Toronto, Rotman School of Management



**EVERY WOMAN
EVERY CHILD**
FOR HEALTHY AND EMPOWERED WOMEN,
CHILDREN AND ADOLESCENTS
INNOVATION MARKETPLACE

The [Every Woman Every Child \(EWEC\) Innovation Marketplace](#) is a strategic alliance of development organizations including Grand Challenges Canada, the Norwegian Agency for Development, the U.S. Agency for Development and the Bill & Melinda Gates Foundation. The EWEC Innovation Marketplace selects and supports the scaling of promising innovations that address high mortality and morbidity health conditions for women, children and adolescents in low- and middle-income countries.



**Rotman School of Management
UNIVERSITY OF TORONTO**

The [Rotman School](#) is part of the University of Toronto, a global centre of research and academic excellence at the heart of Canada's multicultural commercial capital. Rotman is a catalyst for transformative learning, insights and public engagement, bringing together diverse views and initiatives around a defining purpose: to create value for business and society.

Models to Scale Healthcare Technologies for Low- and Middle-Income Countries

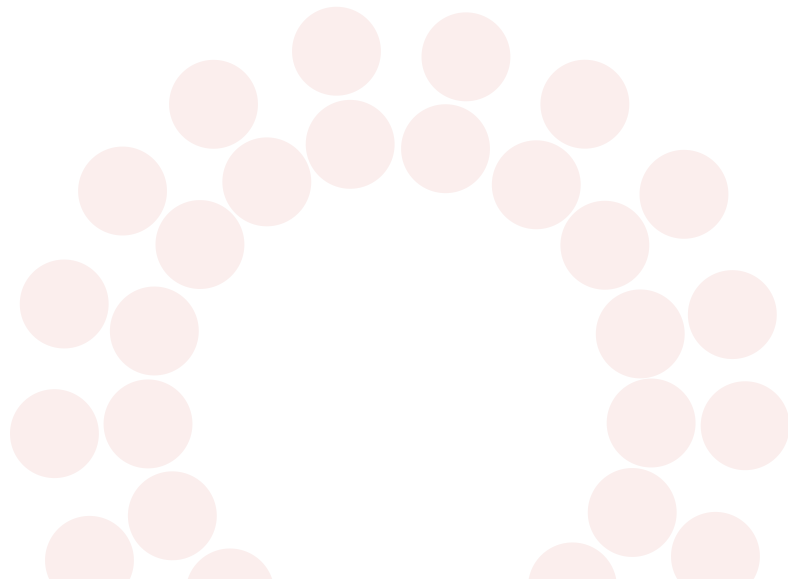


TABLE OF CONTENTS

Introduction.....	PG 5
The Starting Point Determines the Path.....	PG 6
a. Academic Institutions.....	PG 7
i. Third-Party Licensing Model.....	PG 7
ii. University Spin-Off Model.....	PG 8
b. For-Profit Companies.....	PG 9
i. LMIC Growth Model.....	PG 9
ii. Dual-Market Strategy.....	PG 11
iii. Intellectual Property Considerations for Public Good.....	PG 11
c. Non-Profit Organizations.....	PG 12
Conclusion.....	PG 14
References and Acknowledgments.....	PG 15



February 2021

INTRODUCTION

Technological innovations are a type of development innovation whose scaling strategies require special considerations in comparison to innovations in service delivery, community models or even consumer products. Complexities arise from regulatory requirements, clinical testing costs and duration, as well as safety and quality-related considerations. This white paper will examine models to scale this unique category of innovations in low- and middle-income countries (LMICs). For the purposes of this white paper, healthcare technologies will include devices, diagnostics and other digitally assisted tools.

Innovation in financing and market structures continue to diversify the type of strategies pursued. With Universal Health Care commitments being challenged by the slow pace of progress, the role of innovation must increase and leveraging approaches (such as those described below) toward achieving scale will be critical to amplify this impact and success.

The ideas expressed in this white paper evolved from expertise developed while studying scaling and in working with funders and innovators through the *Every Woman Every Child* (EWEC) Innovation Marketplace, a strategic alliance of development organizations consisting of Grand Challenges Canada, the Norwegian Agency for Development, the U.S. Agency for Development and the Bill & Melinda Gates Foundation – an initiative housed at Grand Challenges Canada. The points made should be interpreted as scholarly observations, rather than as an agenda endorsed by the EWEC Innovation Marketplace partners.



An overview of the
different pathways to
scale medical devices
and technologies in
LMICs

THE STARTING POINT DETERMINES THE PATH

We have observed that innovation and associated intellectual property (IP) for medical devices designed for LMICs mainly originate from the following types of organizations: academic institutions, for-profit companies or non-profit organizations. It is notable that where the innovation originates is often the primary driver of the scaling model, which also drives the types of financing instruments available to support that growth.

- a. **Academic Institutions**
- b. **For-Profit Companies**
- c. **Non-Profit Organizations**



A. ACADEMIC INSTITUTIONS

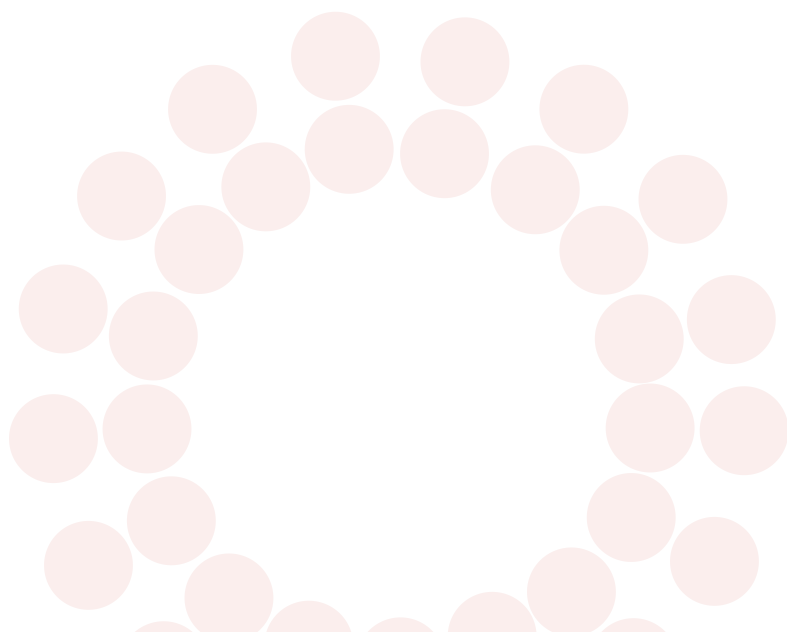
Innovation and associated IP are often developed by research programs and universities, which in turn protect the IP with patents that are owned by the institution. The two classical scaling pathways to scale up the technology involve either licensing the technology to a larger independent third party, such as a multi-national corporation (Third-Party Licensing Model) or licensing the technology into a for-profit start-up company, typically led by the inventor of the technology independently or together with a business partner or co-founder (University Spin-Off Model).

i. Third-Party Licensing Model

While the third-party licensing model has often been a successful pathway in life sciences and technology markets serving developed economies, the success stories in the global health sector are unfortunately few. A good example of one is the Augmented Infant Resuscitator¹ licensed by CAMTech (Consortium for Affordable Medical Technologies) and MGH (Massachusetts General Hospital) to Philips. This device innovatively provides real-time feedback on whether the resuscitation equipment – typically the bag-valve-mask – is properly positioned to ensure a sealed face-mask interface, thus preventing blocked airways, and providing the right ventilation frequency and efficient lung inflation, all resulting in an effective ventilation technique for newborn resuscitation in environments with low-skilled healthcare providers. Its potential to increase proper use of any bag-valve-mask allowed Philips to recognize the commercialization potential in this device.

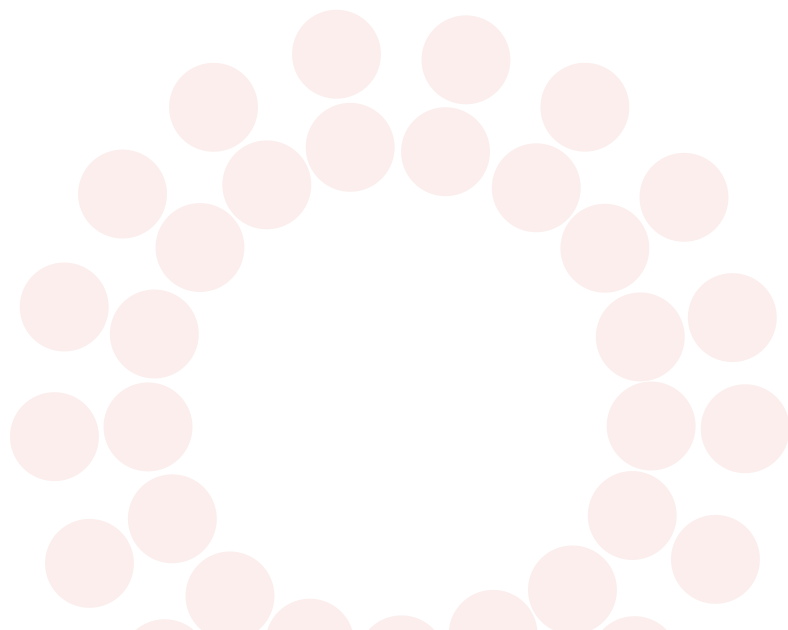
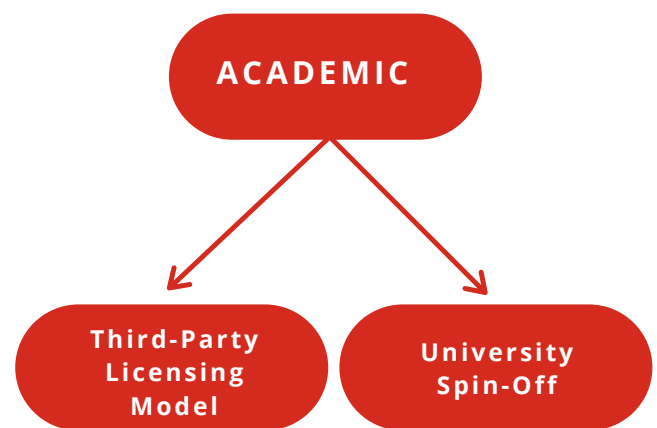
Among the challenges that have contributed to the wider poor track record of the third-party licensing model, whether the licensor be the public sector or a private sector entity, the most prominent is the lack of a clear value proposition for the third-party licensor, due to poor economics when the technology is only applicable to LMICs. While seemingly capital-rich, the

divisions of large corporations must compete with each other for capital to launch new products, and it is rarely the case that such a product can be selected over other more profitable products unless the corporation has a clear mandate to do so. Another commonly cited reason when such models fail is poor protection of IP by the institution initially patenting the concept, which is usually tied to limited IP budgets for most institutions. Innovators and university tech-transfer offices may also hamper the process as they can be reluctant to provide corporations with sufficient rights to the IP due to a desire to stay in control, often to ensure impact. Even when they are supportive, innovators and tech transfer offices also lack expertise in commercializing technologies, choosing partners and negotiating complex licensing agreements. They also have limited bandwidth for these tasks.



ii. University Spin-Off Model

The university spin-off model is one where a start-up is formed, usually by the academic founder or a university-related co-founder team. The start-up receives a license to the technology developed from the university for the purpose of commercializing the technology. The biggest barriers start-ups face in the early stages are also related to IP. When tech-transfer offices design the license agreements with terms that are unfavourable to the startup, investors may pass on the investment opportunity as this would lower the potential return they can ultimately earn on the investment. In order to be attractive to investors and therefore viable as a company, start-ups usually need to have exclusive long-term rights to the IP in relevant high-value markets. Licenses can have carve-outs for lower-value markets or milestone requirements related to continuing to work towards commercialization, but these need to be well-designed in order to ensure viability of the start-up. The most experienced tech-transfer offices typically recognize the benefits of having multiple successful spinoff start-ups from their research departments and have the expertise to design contracts that meet the needs of investors. In this case, the start-up can scale in the same way as discussed under the for-profit entity section below.



B. FOR-PROFIT COMPANIES

Technologies can also be developed by for-profit companies, which can either be larger, mature organizations or start-ups specifically formed for the development and growth of the innovation. While for-profit multinationals also play a role in the health and development sector, for the purposes of this discussion, we are focusing on start-up ventures. Critical parameters for success are team composition, quality of the underlying IP, a promising market size, a clear business strategy and access to capital, where the latter is driven by the first four characteristics. There are two key approaches used by for-profit companies to scale their technologies, namely the LMIC Growth Model and the Dual-Market Strategy.

i. LMIC Growth Model

In this model, an innovator seeks to scale their solution in the LMIC market(s) of interest via a financeable, long-term, sustainable and profitable business model. To be successful, the company must identify the demographic in need of the solution and then create a pricing strategy that both meets the demand and maintains a profitable margin for the company to continue growing sustainably. This is particularly challenging in the LMIC context because payers in this context typically seek to pay a price as close to cost as possible. This can fundamentally challenge the business value proposition if combined with expectations of low volumes. The company's success rests on securing the right local and international partnerships, including research, non-profit, community organizations, public and private sectors, for activities that include clinical trials, pilot product demonstrations for large buyers like governments, regulatory processes and cost-effective, high-quality manufacturing and distribution of the technology to target customer segments. Often the cost of many of these activities can add up; for example, each LMIC market may require its own regulatory process, sometimes in addition to internationally recognized FDA (U.S.) or CE mark (Europe) approvals. This is also typically concurrent with, or followed by, pilot demonstrations for various public sector buyers

that are not always able or willing to pay for these proof-points.

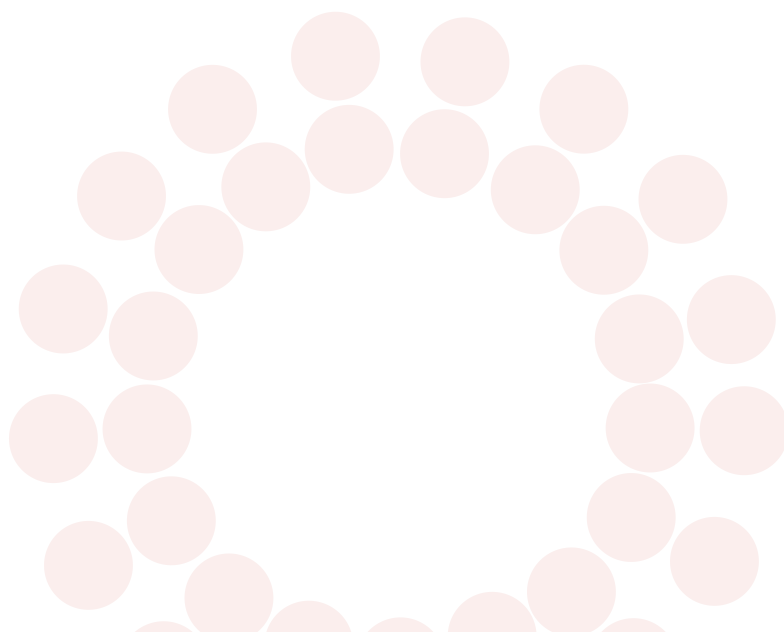
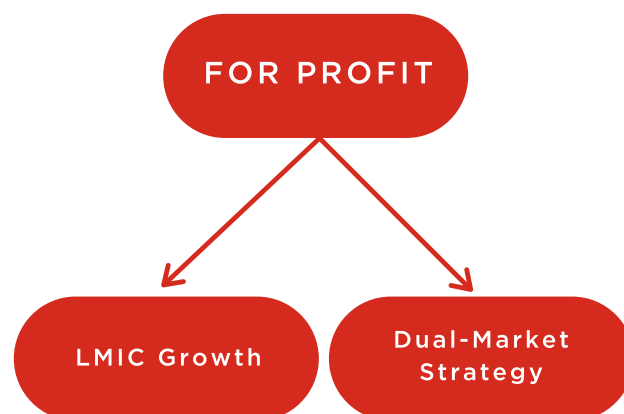
From a financial point of view, companies that focus on primarily middle-income markets that have multiple income level segments, such as India or South Africa, are often capable of sustaining such growth models once they reach a certain level of scale, usually via a slow-and-steady growth model. Robust partnerships and diversified offerings are key to reaching greater scale, as these companies benefit from cost-sharing among the offerings. Maintaining profitability at a sustainable pace for steady growth, combined with the relatively more developed financial markets, create opportunities for long-term success. The CEOs of these companies are typically highly resourceful, but nonetheless can struggle to attract the type of financing that can enable accelerated growth until they reach significant and consistent growth and profitability to access loans and revenue-based financing. Equity financing is usually elusive for companies focused on lower-income populations.

Single product medical device companies struggle more, especially when attempting to commercialize a bold new innovative device targeting lower-income populations. Like multi-product companies, they are expected to show

sustainable profitable growth before accessing loans and revenue-based financing products. In practice, what this means is that they are expected to complete product development and clinical trials for regulatory approvals, and begin early revenue before they can attract the first significant investment from investors. As such, even when these products could be profitable at scale – which is not often the case when they target LMIC populations via the public sector – companies struggle to raise sufficient capital to reach the commercial phase. While donors have been pivotal to bringing many of these products beyond the ideation phase, past the proof-of-concept phase and often even all the way through the regulatory process, there continues to be a high level of failures or stalling, as these companies require significantly larger amounts of capital to reach sustainable growth. Some examples of companies pursuing a multi-product strategy with early success are Sinapi Medical in South Africa and InnAccel Technologies in India.

Software companies fare much better, as they are not as capital-intensive early on and cheaper to scale, especially in countries that have significant and growing tech sectors, such as India, South Africa, Nigeria and Rwanda. These companies often benefit from their ability to bootstrap their businesses by securing early paying customers and servicing contract clients, due to their easy applicability and cost-competitiveness. Companies with disruptive models or offerings for the sector can also attract equity financing based on their potential to gain significant market share. The fact that LMIC markets often have no incumbent or legacy solution to displace, unlike high-income country (HIC) counterparts, bodes well for the potential of the sector. Of note is the fact that there are burgeoning networks of accelerators and venture capital firms in these economies that have arisen due to the significant investments

made by some governments^{2,3} and corporations⁴, combined with recent technology company exits^{5,6,7} in these markets, albeit more in the fintech and transport sectors (e.g., acquisition of Nigerian mobile transport directions app Hopstop by Apple for \$1Bn, and Kenya's mobility solutions Weza Tele by Ghana-based financial services AFB). Donors recognize the potential of technology in achieving Universal Health Coverage (UHC) and are also increasingly open to co-funding these opportunities. Innovators that can proposition the impact value and track impact data well are ideally suited or eligible for loans and grants provided by such impact-first investors. (See our white paper on financing instruments to explore the various options available to a company at these stages.)

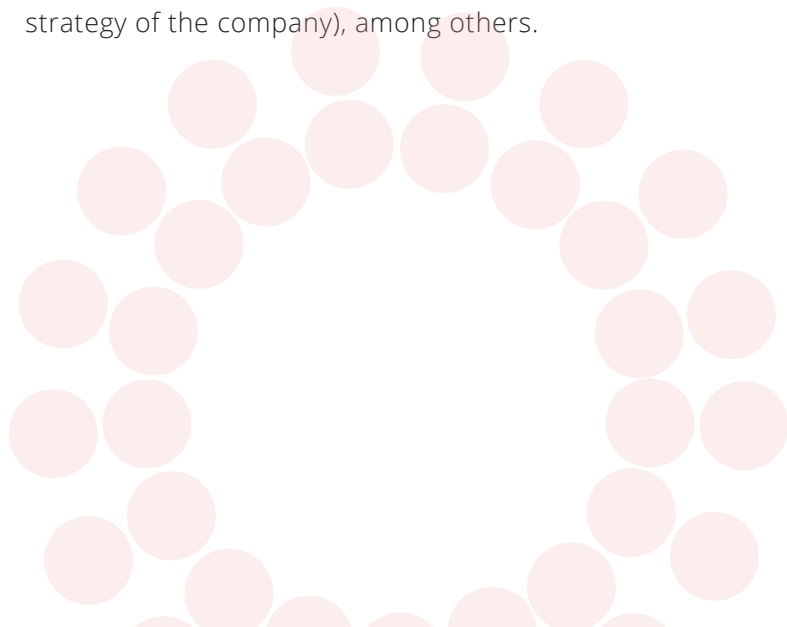


ii. Dual-Market Strategy

The dual-market strategy is an innovative growth strategy that has recently gained traction as a means to achieve scale in LMICs for technologies that require a significant upfront investment, such as medical devices, diagnostic tools and digital technologies leveraging models like machine learning and blockchain. A dual-market strategy, in this context, is designed or adapted to serve both LMIC and HIC settings. Of the various approaches to implementing the dual-market strategy described in a separate white paper in this series, the most financeable is the Synergistic Model, where the LMIC strategy succeeds in becoming moderately profitable and also provides at least some benefits for the growth of the HIC business, either financially or otherwise. This model can access the greatest number of types of capital available to support its growth, as the strategy enables the company to fulfill the criteria of multiple types of donors, funders and investors. Non-dilutive capital – grants and/or debt – may be available to pursue the development and impact strategy (e.g., LMIC product development and contextualization or pilot demos for potential public sector buyers). In addition, with investors often interested in HIC investment opportunities, this widens the pool of potential investors for growth plans. Strategic investors are also increasingly supportive of these approaches, as they seek to learn ways to enter or expand into LMIC markets to achieve their own goals of eventually having strong business drivers across all markets and market types. (See our white papers on financing instruments and dual-market scaling strategies for impact, for detailed discussions and examples of these concepts.^{8,9})

Intellectual Property Considerations for Public Good

Regardless of the pathway selected, the for-profit model can be undermined if the intellectual property (IP) is encumbered. This encumbrance can result from commitments made related to early-stage funders' rights (often called global access agreements). While these rights are designed to ensure the desired social purpose is met (i.e., that intended hardest to reach populations have access to the innovation), innovators and funders must consider the risk that such encumbrances may discourage investors from investing. Investors prefer companies with strong IP protection that are not hindered by license rights or other encumbrances; earning sufficient financial returns from investments in companies with weak IP is difficult because the acquirers of these companies would devalue these targets. While a comprehensive analysis of intellectual property rights is beyond the scope of this white paper, we consider the following forms of IP rights as the most benign for a company's ability to raise growth capital: non-exclusive licenses for low-income countries, tiered pricing commitments for middle-income countries (to account for income-level-related impact and revenue opportunities), or distribution rights with 1-10% net margin allowance (for LMICs not on the go-to-market strategy of the company), among others.



C. NON-PROFIT ORGANIZATIONS

Finally, the last type of entity in the business of medical technology innovations is the non-profit. For devices or portfolios of devices, these models typically function by either licensing in externally developed IP or developing the IP in-house with the potential option of licensing the IP out to a third-party manufacturer. While their financing options are limited to grant providers (like donors and foundations), the significant advantage to such models is the strong alignment between the organization and its impact mandate, which results in robust evidence demonstrating said impact, a high-level of understanding of local markets and typically strong embedding within local health systems.

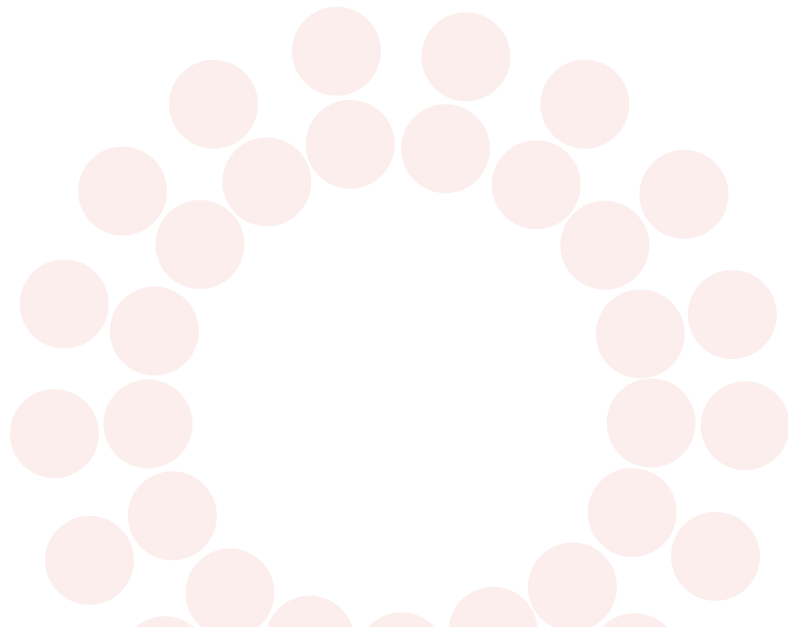
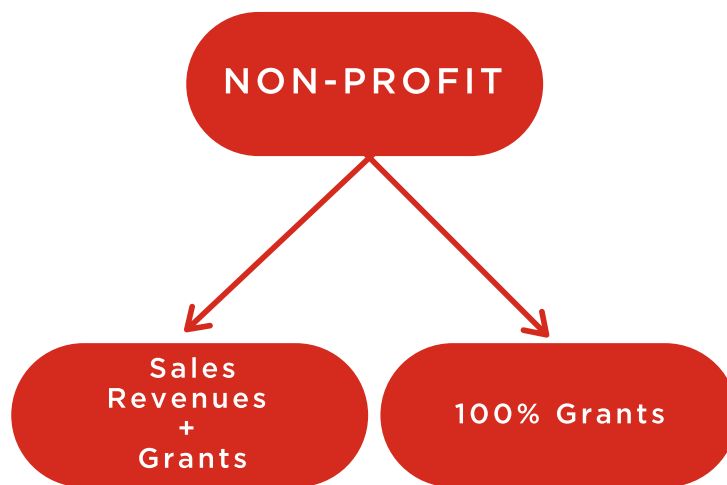
Successful models include Gradian Health and Equalize Health (formerly D-Rev), both of which are non-profits with revenues from sales to both the public and the private sector that contributes to the sustainability of the model, with sufficient donor interest to continue to innovate and perform market-building activities. Such models are able to bring appropriately priced, serviced and supported products into low-income countries, working closely with healthcare providers, local distributors and the public sector. These entities focus a significant part of their activities towards health systems strengthening, which is also an asset to receiving continued support from donors and funders.

The key challenge is that, while revenues enable access (because the pricing is appropriate (low) for the target markets), revenues sometimes do not exceed all the costs for such a model – costs associated with sales, maintenance and training, as well as necessary continued product improvements. Entities perpetually dependent on grant funding are especially vulnerable to changes in donor priorities, which can limit their ability to maintain as well as expand their operations to reach scale. It is also important to note that, while there are a growing number of investors and lenders in LMICs, the number of large donors able to continually provide funding to innovators does not appear to be increasing as quickly, thus putting pressure on innovators to consider self-sustainable approaches.

A noticeable subset includes non-profit digital organizations that also appear to be gaining traction, in large part due to the high current level of interest in the sector by donors, especially for open-source technologies. Innovators have to balance their commitments to enabling open access against ensuring that sufficient donor financing is available for maintenance and service of these platforms, in order to continually stay relevant with regard to digital infrastructure, security, privacy and impact. Examples of innovators scaling such models include MedicMobile, South Africa's HealthConnect, D-Tree and Project ECHO.

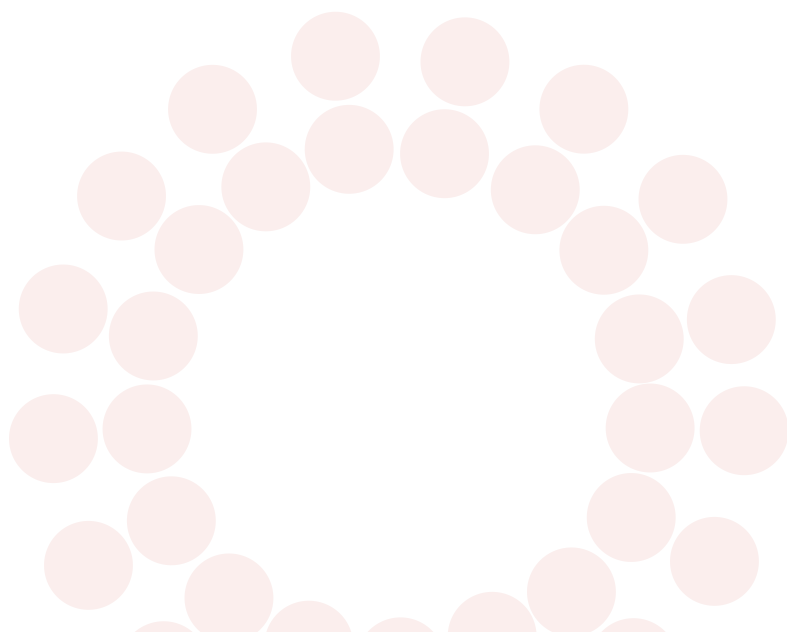


Alternative strategies in this realm could include companies that have entirely separate non-profit arms that are dedicated to the impact and development mission of the entity. This dual structure protects the primary aim of both the for-profit company and the non-profit entity, resulting in appropriate financing for each and strong synergy between the two. A successful example of this model is Jacaranda Health in Kenya, a non-profit providing nurse mentorship programs and scaling an SMS support platform to provide antenatal care and information to pregnant mothers. This entity works closely with its for-profit entity Jacaranda Maternity that was spun out of the non-profit. Jacaranda Maternity is able to attract investments to grow its network of hospitals that provides affordable but appropriately priced services for pregnancy and delivery.



CONCLUSION

This white paper has examined multiple pathways that medical devices and technologies use to scale in low-resource settings, largely determined by the type of entities. This includes academic entities that scale innovations through licensing pathways or start-ups, for-profit entities that can pursue a classical localized growth strategy or a dual-market strategy, and finally non-profits that scale through a combination of revenues and donations. Each pathway is unique in both the opportunities and challenges that innovators must bear in mind to secure the right type of financing, partnerships and teams to reduce the time needed to scale and increase the likelihood of success. Innovators should review these models carefully when launching a new venture, with particular attention to the financing tools available based on the model selected. The most successful scale-ups in global health often result from the innovators' unique ability to match their vision, business model, team composition and capabilities to the availability and expectations of funders in their space.



REFERENCES

1. Bennett D.J. et al. (2018). Evaluation of the Augmented Infant Resuscitator: A Monitoring Device for Neonatal Bag-Valve-Mask Resuscitation. *Anesth Analg*. 2018 Mar;126(3):947-955
2. Liquid Telecom News (October 26, 2020). CDC commits additional US \$40 million to Liquid Telecom supporting Africa's digital transformation
3. World Bank Feature Story (May 6, 2019). Achieving Africa's Digital Transformation is an Ambition that Requires Game-changing Cooperation
4. Orange Press Release (October 2020). Orange collaborates with Smart Africa and announces new investments in Africa to improve the quality of service and data security for end-users
5. The Guardian News (20 May 2015). Apple buys a Nigerian-owned ICT firm for \$1 billion
6. Disrupt Africa. Jackson, T. (May 15, 2015). Kenya's Weza Tele acquired by AFB for \$1.7M
7. Jumia Press Release (April 2019). Jumia announces pricing of Initial Public Offering
8. Devadas, D., Thériault, A., and McGahan, A.M. (2021). Financing Instruments for Innovators to Scale Health Innovations in Low- and Middle-Income Countries, *EWEC Innovation Marketplace White Paper*
9. Devadas, D., Thériault, A., and McGahan, A.M. (2021). Dual-Market Scaling Strategies for Impact, *EWEC Innovation Marketplace White Paper*

ACKNOWLEDGMENTS

The *Every Woman Every Child* Innovation Marketplace would like to thank the following individuals for their contribution to the development of this document.

- Jocelyn Mackie (Grand Challenges Canada)
- Karlee Silver (Grand Challenges Canada)
- Tasha Noronha (*Every Woman Every Child* Innovation Marketplace)



EVERY WOMAN
EVERY CHILD

FOR HEALTHY AND EMPOWERED WOMEN,
CHILDREN AND ADOLESCENTS
INNOVATION MARKETPLACE



Rotman School of Management
UNIVERSITY OF TORONTO

ewecinnovation.org
rotman.utoronto.ca

