

Technical Assistance Support for Health Innovations in Low- and Middle-Income Countries

A WHITE PAPER

Deepika Devadas, Annie Thériault, *Every Woman Every Child* Innovation Marketplace, Grand Challenges Canada Sweta Govani, Global Innovation Exchange, Results for Development









A white paper by the *Every Woman Every Child* Innovation Marketplace at Grand Challenges Canada in partnership with Global Innovation Exchange at Results for Development



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.



<u>Results for Development</u> (R4D) is a leading non-profit global development partner. R4D collaborates with change agents around the world — governments, civil society and innovators — to create strong systems that support healthy, educated people. R4D combines global expertise in health, education and nutrition with analytic rigor, practical support for decision-making and implementation, and access to peer problem-solving networks. This paper was developed in partnership with <u>Global Innovation Exchange</u> (GIE) which is part of <u>R4D's Innovation Practice</u> and supports the scale-up of innovations.



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Key barriers, best practices for success and a breakdown of support types available when scaling innovations in LMICs

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The 'valley of death' has become a well-used term in the sector of innovation, regardless of the international development context¹. The term refers to the funding gap that often occurs near the mid-point in the development cycle of an innovation, and is a feature of innovation and entrepreneurship; it is contrasted against the relative ease of obtaining funding and support at the outset and later in development. It is further accentuated in the sector of global health and impact. To traverse this valley of death (typically at the transition-to-scale stage²), innovators require support from the sector, with the aim of protecting the impact at stake and the entrepreneurial spirit itself. This support is often framed as 'technical assistance' and is usually provided to address common barriers to scaling faced by innovators.

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. That expertise was combined with the latest research^{1#} conducted by the Global Innovation Exchange (GIE) team part of Results for Development's Innovation Practice, which explored various barriers to scale faced by development innovations across geographies and sectors as well as the appropriate type of support to address those barriers. The points that we make should be interpreted as scholarly observations, rather than as an agenda endorsed by the partners of the EWEC Innovation Marketplace or Global Innovation Exchange.

1. BARRIERS TO SCALING

As the global health and development sector matured, there has been a continually evolving understanding of the barriers faced by innovators in a changing political, funding and health landscape.

- a. Financing
- b. Product Development
- c. No/poor Scaling Plan and Business Model
- d. Market Awareness
- e. Public Sector Adoption
- f. Impact Measurement
- g. Communication and Presentation
- h. Talent
- i. Operational Management
- j. Human Rights, Environment and Gender Perspectives
- **k.** Partnerships



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A. FINANCING

This barrier to scale is probably the most significant and obvious one. Lack of financing is often tied to the barriers described hereafter. It is commonly observed that, while innovators may list the lack of financing as the main barrier, deeper analysis often exposes other barriers, such as lack of impact evidence or networks to accessing funding. To tackle the financing gap itself, we have presented a navigational guide for innovators seeking various types of capital (along with characteristics, expectations and sources) in a separate white paper in this series³.

B. PRODUCT DEVELOPMENT

While early prototypes often demonstrate the promise and viability of an innovation, continued product development (especially for devices, diagnostics, therapeutics and digital platforms) is an ongoing priority, particularly in response to early market feedback, pilots and demonstration studies. Product development may include design, research and development (R&D) or refinements to increase efficacy, lower the cost of goods sold (COGS), expand use cases, improve local contextualization, provide language translation, ensure continued relevance and improve efficiency. Barriers to adoption must be identified and addressed quickly, especially at the early stages. Rewarding product development, both from a business and impact perspective, is linked to a strong awareness and understanding of the markets served.

C. NO/POOR SCALING PLAN AND BUSINESS MODEL

A significant number of early innovators develop promising and innovative products and services, but have no clear plan or strategy to bring it to the markets of interest. While support may be available to help craft strategy outlines, the strength of the team is closely tied to scaling impact, as they must ultimately judge the strategy's appropriateness, proficiently execute it, and be able to pivot and refine as the landscape evolves. Depending on the type of innovation, a variety of business or scaling models may be feasible. For example, we have highlighted the range of business models appropriate today to scale medical technologies in our third white paper of this series⁴. A viable business model is key to the long-term sustainability of any innovation.

D. MARKET AWARENESS

Global development focus implies the need to scale into markets that may be immature and rife with political, business and infrastructure barriers. A comprehensive market understanding of demand, product feasibility and strategy regarding segments, pricing and channels is critical for a successful business strategy. This is often a challenge, especially for teams not primarily based in these markets. Market data and insights are often not available or up-to-date for these contexts. Innovators that haven't consulted users or customers sufficiently regarding a product's or service's ease-of-use, accessibility or affordability will find it hard to form a thorough understanding of the market demand and appropriate strategy. User design often overlooks that health or impact need does not necessarily equate to market demand - a key to traction and scaling. Local co-creation methodologies partnerships, (especially where public sector adoption is required), human-centered design features, appropriate feasibility studies and customer engagement are critical to navigate these barriers.

E. PUBLIC SECTOR ADOPTION

Governments often play the predominant role in providing healthcare in low- and middle-income countries (especially for the LMIC populations that will drive impact) and increasingly so as Universal Health Coverage gains momentum. A lack of bandwidth from the public sector, lack of expertise to evaluate innovations, unclear processes, political risks, bureaucracy and high competition for small budgets all serve as tough barriers to navigate for an innovator with a solution. Identifying the right local stakeholders that can inform creation of and champion the solution, continue engagement and share data from customer demand and cost effectiveness are strategies of successful public sector adoption models. A notable tool that helps different stakeholders, innovators, funders and government themselves navigate this pathway is Village Reach's Journey to Scale with Government⁵. A positive example of innovation that has worked well in the public sector is Praekelt's MomConnect digital platform in South Africa, adopted by the National Department of Health, which already serves more than one million pregnant moms.

F. IMPACT MEASUREMENT

Given that achieving impact is the overarching goal of scaling innovative solutions for global health and development, robust measurement is the only tool at one's disposal to measure, inform and act upon the progress achieved. It is also a key performance indicator that is required to attract financing from impact funders, as well as supporting public sector adoption and other types of partnership and support. Many entrepreneurs lack expertise within their teams to develop measurement tools and require support to differentiate between user adoption and impact on health and lives, and between implied impact and quantifiable evidence, in order to create systems that are suited to measure impact and to present such data appropriately to different stakeholders. There is also a need for financing in the sector to support the collection of this evidence, as the cost of data collection is not inexpensive.

G. COMMUNICATION AND PRESENTATION

Even with appropriate solutions and strategies, communication and marketing of the innovation is critical to both financing and partnerships. Stakeholders may find alignment with slightly different aspects of the solution, and it is important that material be provided in the formats preferred by each sector to enable successful outcomes and transactions. For example, typical investor pitch decks capture succinct information on the market size, intellectual property, team and strategy in the form of PowerPoint slides, but donors may require detailed proposals capturing technical details of the solution, evidence to date, impact to date and partnerships, while still other stakeholders may prefer summary concept notes or one-pagers. Building such communications material can be an asset to the scaling of any innovation. It is important to note that these barriers can be especially pronounced for local innovators, not only because a majority of funding is in high-income countries that are not always a part of local innovator networks, but also because the above frameworks all have roots in Western society – together, these aspects often contribute to selection bias among innovators, which few funders are willing to address.

H. TALENT

The strength of teams can make or break the success of any venture or entity. Appropriate expertise for the stage of growth is imperative often a particular challenge in the early stages, when teams are typically very lean. Additionally, sourcing talent (especially in low- and middlemarkets where income entrepreneurial ecosystems are less developed) can become a serious barrier to the success of an entity and often requires support. There is a systemic need for capacity building and centralized mechanisms to find appropriate skills in these contexts that would apply beyond a single innovation.

I. OPERATIONAL MANAGEMENT

Efficient financial and operational management is an ongoing concern for entities, especially while transitioning to scale. They must have robust internal operations that are structured, organized and cost-effective, to effectively execute on growth and scaling plans, forecast growth and capital needs and manage supply chains and logistics.

J. HUMAN RIGHTS, ENVIRONMENT AND GENDER PERSPECTIVES

Concurrent with impact measurement support, innovators may also require support to challenge their own perspectives, share and learn from peers and identify practical solutions to implementing frameworks, to protect human rights and protect the environment during the activities they undertake and to drive gender equality. Emphasis on ESG (Environmental, Social and Governance) values of an entity has drawn attention to the specifics of how an innovation or an organization embeds culture, policy and goals around ensuring environmental protection, social inclusion and impact, along with governance issues related to diversity, decision-making and accountability.

K. PARTNERSHIPS

Partnerships can be pivotal to enabling faster scaling within a complex environment with elements of health, business, market access, finance and impact. These entities – whether local or global - can range from governments, civil society organizations, NGOs, academics, multilaterals, manufacturers, distributors and the wider private sector. Innovators typically require support to access networks of such stakeholders and facilitate the building of partnerships. While needs do overlap, research reveals that local innovators require access to global networks, mainly for funding, while high-income country (HIC) innovators additionally desire the networks to drive local partnerships that are required to scale their innovation. This access can be facilitated through provision of a platform for exposure and advocacy.

2. BEST PRACTICES AND COMMON ISSUES

There are many barriers to scaling a global health venture. To complicate matters, these are not consistent through time, nor are they equally important at all stages. The following are commonly seen as best practices.



Innovators can benefit most through early participation in one or more Technical Assistance (TA) programs to identify elements that uniquely work for their vison and to build their networks in the sector early.



Participation should become more selective and targeted to solve for more specific gaps or take advantage of benefits over time. Specifically, a comprehensive analysis of barriers (done internally or with the help of advisors) can identify both gaps and strengths. It is important that lean organizations not waste the limited resource of time on programs not suited to fulfil their gaps.



This is a foremost priority, especially within the goal of financing the scale-up. At all stages, irrespective of the organizational type, innovators must be able to realistically distinguish between optimistic and conservative plans, and to inspect over-achievements and under-achievements in the plan to inform what the average looks like in forecasts. Specific plan evolutions, or pivots, may be necessary and must ideally be undertaken after incorporating the advice from similar pivots. Additionally, presenting information on the scaling plan in a format that is suitable to the capital type being pursued can lead to better success. See our white paper on financing instruments³.

Set up a board

Building a strong formal board (or, at a minimum, an informal advisory board) that is appropriate to the stage is key. While a comprehensive discussion of board composition is beyond the scope of this review, directors/advisors must be sought out relevant to the stage who can speak to the various facets of the innovation and growth plan (e.g., angel investors, technical experts in health, technology or regulation, expertise in commercialization, fundraising or working with the public sector, etc.). Ensuring diversity of sector, perspective, gender, race and markets can enable the long-term growth of an entity.

Continuously identify areas of improvement

Innovators must leverage the skills and expertise of teams, boards and diverse advisors to actively identify areas of weakness for improvement. These will typically evolve as well as cycle through common challenges, such as markets, talents and operational management.



Understand the nuances

Various TA platforms are available. While a full review of that universe is beyond the scope of this review, a brief breakdown of the various types and their **of TA support** expectations are identified below.

i.) Accelerators

Accelerators are programs designed for early-stage businesses, to develop and validate their business and market strategies by providing education, mentorship and potentially small investments. Well-known examples include Y Combinator and TechStars; the global health and impact space have numerous programs led by or partnering with various funders (e.g., the World Food Programme Accelerator). Innovators typically engage with an intensive program for several weeks that provides helpful support for early-stage entities.

ii.) Incubators

Incubators are different from accelerators in that they may help innovators develop their ideas further, to a minimum viable product, as opposed to accelerating a business with an effective growth strategy. Incubators are also less structured and longer term, and can focus on providing product development, design support, coworking space, lab space, etc. A good example is the Stanford BioDesign program that fuels the conversion of ideas into feasible concepts. In the context of development and impact, numerous local accelerators have successfully emerged⁶. Satisfaction for support received is reported to be high, as these entities are better able to understand local infrastructure, market and positioning. On the other hand, global accelerators may provide better exposure to funding opportunities. A key finding has been that, due to the differences between geographies (Asia versus Africa), products (devices versus digital platforms), entities (non-profits versus businesses) and scaling pathways (public sector versus private sector), there may be limitations for accelerators with mandates that are too broad.

iii.) Individual Experts

Innovators can also often benefit from one-on-one support of trusted mentors and advisors with sectoral expertise in different areas ranging from commercialization, impact, procurement, public sector, finance, gender, health sector and markets. Mentors and advisors, whether from current investors or external, can be critical in growing the networks of an innovator. Accelerators that offer mentorship can benefit from providing a diverse list of mentors from various backgrounds, combined with platforms that provide better matchmaking. While expertise lent may be short-term or pro-bono, it can also be long-term in the form of a hired consultant, often filling expertise gaps in lean teams.

iv.) Peer-to-Peer

Challenges within each sub-sector can be quite unique and many innovators appreciate the efforts of platforms that allow peers to connect and learn from each other. For larger funders that support a portfolio of innovations within a sector, there may be opportunities for cross-learning and partnerships, especially when these opportunities to connect may not arise organically (e.g., if innovators are from different geographies). This is more common for service innovations (where competition risk related to intellectual property is not typically high) and is a feature of accelerators that bring together similar peers as part of the same focus or common portfolios.

v.) Networking

Networking is often an important or even primary goal at events and conferences, where the focus may itself be a particular barrier to scaling that brings together innovators along with other stakeholders. These platforms can serve as the building ground for partnerships and networks that are closely aligned with a specific barrier an innovator may be grappling with.

vi.) Online Platforms

Online platforms, such as the Grand Challenges Africa Innovation Network, may speak to the educational aspect of data, insights and learning, or may take the form of tailored webinars innovators can register for. Platforms can also be useful places to track opportunities, such as the Global Innovation Exchange or Devex, as well as other targeted trackers that often surface, such as those recently shared that specifically speak to COVID-related opportunities.

Figure 1 Technical Assistance is needed for innovators to traverse the innovation "valley of death"





CONCLUSION

In summary, this white paper summarizes the various barriers in innovation scaling that Technical Assistance programs support innovators to overcome. Specifically for the goals of Universal Health Coverage (which ensure health access, including to LMIC and last-mile populations), scaling models can be particularly challenged if they do not have highly efficient management, diverse and collaborative partnerships, and blended finance instrument options, all of which require very different funders and investors to align. Technical Assistance therefore plays a crucial role for the sector in the success of models to scale innovations.

From an innovator's perspective, this universe can seem overwhelming, with so many choices, all of which appear helpful. This paper identifies the key barriers an innovator must continuously monitor, the best practices in the sector for success, the internal 'North Star' an innovator must have for themselves and a breakdown of support types that may be available. Regardless of the type of support, the criteria for successful engagement are dependent upon the compatibility and trust between the advisor and the innovator, the ability of the innovator to learn from advisors while also remaining in charge of their venture, and their ability to forge strong relationships and partnerships that lift their progress towards the achievement of key milestones.

TA programs must focus on their expertise, resisting the temptation to attempt to tackle all barriers as collaboration with programs specialized in these other barriers is usually a better approach. They must also measure success metrics that can be specifically attributable to the support they provide. Insights drawn from the portfolio of the EWEC Innovation Marketplace, which adopts a multi-year, hands-on support approach, have been informed through innovators' demand for a longer-term, one-on-one format of TA support, in addition to the tactical short-term support provided by typical TA programs, which they also need. Development funders must assess how similar longer-term support can be provided to grantees and investees to protect the impact in which they have invested.

REFERENCES

1. Ford, G.S. et al (2007). A Valley of Death in the Innovation Sequence: An Economic Investigation. *Research Evaluation* 18. 10.2139/ssrn.1093006

2. The International Development Innovation Alliance (IDIA) (June 2017). Good Practice Guides for Funders Scaling Innovation

3. Devadas. D, Thériault A, McGahan A. (2021). Financing Instruments for Innovators to Scale Health Innovations in Low- and Middle-Income Countries

4. Devadas. D, Thériault A, McGahan A. (2021). Models to Scale Healthcare Technologies for Low- and Middle-Income Countries

5. The Journey to Scale with Governmet. <u>Retrieved from https://www.villagereach.org/wp-content/uploads/2020/10/The-Journey-to-Scale-with-Government-Interactive-Tool Final-2.pdf</u>

6. Monitor Deloitte Report (February 2015). Accelerating Impact: Exploring Best Practices, Challenges, and Innovations in Impact Enterprise Acceleration. *Funded by The Rockefeller Foundation*

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Financing Instruments for Innovators to Scale Health Innovations in 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



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A guide for innovators seeking funding, and for funders seeking ways to attract complementary funding for their portfolio

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Health innovations addressing the development agenda in lowand middle-income countries (LMICs) are financed by both public and private funders and investors. The role of each source of funding in the implementation of innovation has not been comprehensively explored. More often, the emphasis in most prior research has been on the role of the public sector in scaling innovations through governmental adoption. Various development initiatives have underscored the potential and the need to mobilize private sector investment to accelerate the pathways to meeting the Sustainable Development Goals (SDGs)^{1,2}, particularly for the goals related to health (SDG3) and gender equality (SDG5) in resource-limited settings. Lack of financing is often one of the biggest barriers to the scaling of proven solutions.

This white paper presents a guide for innovators seeking funding from both public and private sources to scale innovations in health, as well as for funders that can map their financial offering onto such frameworks to seek complementary funding for their portfolio. Within these broad categories, providers of funding are themselves varied, with governments, donors, universities, multilaterals, foundations, individuals, corporations and angel investors broadly representing the spectrum of public and private investment sources. This paper will discuss the types of financing available from these sources – mainly classified as grant, debt and equity – and their individual characteristics, along with various market insights.

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.

1. GRANTS

As the most traditional form of development aid, grants dominate the landscape of financing for health innovations that are targeted at low-resource settings. Grant capital can take many forms, depending on the receiving entity, the stage of scaling and the use of funds. Entities behind innovations include non-profits, academia, social enterprises and for-profit companies. Grants are typically the sole source of funding for non-profit organizations and academic innovators, while still being accessible by others. In the context of scaling, grant funding can be catalytic in helping a social enterprise or product innovation achieve early testing and validation results before the innovation is sufficiently de-risked for different and larger types of financing.

Grants, provided by public funders and governments, necessitate a high degree of accountability and can therefore be restrictive in the types of activities they are allowed to fund, requiring highly detailed budgets and, in some cases, the financial agreements can be quite complex and may require a legal review prior to signing. Grants may also include rights to access the intellectual property (sometimes called global access rights) under specified circumstances in specific LMICs, which may or may not be negotiable for the recipient's unique circumstances. While designed to enable the access for public good, these rights are often permanently tied to the intellectual property, which can affect the commercial viability of the venture. Grants provided by private foundations or corporate social responsibility (CSR) groups of large corporations may be similar to those provided by the public sector and governments or they may be more flexible, depending on the funder's philosophy and approach to grant-making. Some private funders are able to allow for more built-in flexibility on the use of funds.

While most grants are not repayable, a recent evolution of this financial instrument is the Repayable Grant, which is technically a loan. These grants are, as the name suggests, repayable to the funder based on agreed-upon milestones, market conditions, and/or growth and impact achievements. Repayable grants are often offered in lieu of debt/loans and offer more flexible terms to the recipient, including no-interest payments on the loan. In some cases, the repayment feature acts as a punitive deterrent in the event the impact strategy funded by the grant-maker is no longer pursued by the recipient in the future.



A. TYPICAL CHARACTERISTICS - GRANTS

_	
BEST USED FOR	 Testing and validating proposed high-risk ideas Demonstration studies and market-building activities Non-profitable impactful activities, such as product refinements to better serve LMIC segments
VARIATIONS	• One-off, tranched, multi-year, repayable, forgivable
MAIN FUNDERS	 Governments, multilateral agencies, foundations, universities, research institutes or private corporations (often through their CSR arms or Corporate Foundations)
EXPECTATIONS	 Detailed budget Intellectual property (IP) rights, often called global access rights (for some granting organizations) Periodic reporting of milestone progress Ability to measure and translate impact of the innovation
ADVANTAGES	 Non-dilutive Limited or no impact on cash flows Incentivizes impact Limited consequences to project failure High risk tolerance Achieve faster growth Patient capital
CHALLENGES	 Grant reporting may not be proportional to the size of the grant or organization IP rights can limit ability to attract other forms of capital Narrow scope (specific project or activities) with little flexibility and often excluding overhead costs needed to build strong organizations Grant funding cycles may not align with the timetable for project implementation or business needs Projects that rely on grant funding for long periods can set a growth course and organizational structure that may not be attractive to other forms of capital Compelling robust impact evidence and expertise in grant writing needed to procure grants in perpetuity

B. INSIGHTS - GRANTS

Innovator Insights

Innovators often find the grant application process tedious and difficult to navigate, especially in understanding selection criteria, effects of intellectually property rights clauses, flexibility and reporting requirements. This is especially true for non-academic teams and/or local Innovators who regularly struggle with the format, impact/scientific jargon, expectations and presentation norms. Innovators frequently underestimate the time and bandwidth associated with the application process, negotiations and reporting.

Funder Insights

Funders expect a detailed, thorough and well-presented plan at the application stage itself, including the ability to generate detailed performance reports and itemized budgets prior to the start of the project. Many funders have various external, internal and programmatic limitations on flexibility. That being said, funders, including public funders and governments, increasingly recognize the benefits of flexibility in fueling innovation and creativity; the few funders that do have flexibility on grant terms often pass these on to innovators.





2. DEBT

Debt financing (also called "borrowing") occurs when lenders provide capital to finance a company, the borrower. Loans are usually justified by the borrower's ability to repay the loan in the future. Loans are repayable at a specified interest rate either at regular intervals during the term of the loan – the borrowing period – or at its end. A borrower's ability to service a loan is judged based on evidence of current or future expected stable cash flows, which are often uncertain for early-stage organizations. The interest rate charged by the lender to a borrower is greater when the lender's level of confidence that the borrower will have stable future cash flows is lower.

There are different types of debt products available in the market from banks and alternative lending companies. Examples discussed here include senior debt, mezzanine debt, revenue-based lending, assetbacked lending and convertible debt. There are numerous variations in the interest rates, payment schedules and other features, so long as the borrower and lender agree to the terms and such terms are legally permissible in the relevant geography.

While impact investors – in the sense defined by the Global Impact Investment Network – seek market rates of return and tend to offer products inline with commercial markets for high-impact organizations, mission-driven investors (such as foundations and government-related entities, with mandates to be catalytic) offer a plethora of potential loan structures, with modifications designed to incentivized impact. When these are offered at or below market terms for high-impact ventures, the loans are called 'concessionary debt'.

The following types of debt instruments are described herein:

- i. Senior Debt
- ii. Mezzanine Debt
- iii. Revenue-Based Financing
- iv. Asset-Backed Lending
- v. Convertible Note
- vi. Concessionary Debt

i. Senior Debt

Senior debt or conventional debt is typically secured by all of the assets of a company, and offered to organizations that are more mature and meet stringent financial requirements, such as having stable and growing revenues, margins, cash flows and profits. Borrowers often need to make specific commitments to a payment schedule and to financial covenants, which are commitments to maintaining specific metrics of financial performance above specified levels. In the event of a failure to pay back the debt or meet the financial covenants, the borrower may be forced to repay the loan on short notice by (i) refinancing under more strident terms with a new lender, (ii) forced liquidation of assets, or (iii) undergoing a bankruptcy process.

ii. Mezzanine Debt

Mezzanine debt is similar to senior debt but the rights of the lender are subordinated to the rights of one or more senior lenders, meaning that in the event of a bankruptcy or liquidation process, the mezzanine lender is repaid after senior lenders receive their capital and interest. For this reason, mezzanine loans have higher interest rates compared to senior debt. Compared to senior lenders, mezzanine lenders have a greater appetite for risk, fewer financial metric targets, and/or weaker or fewer financial covenants.

iii. Revenue-Based Financing

This type of debt instrument is repaid as a percentage of monthly, quarterly or annual revenues until the total accumulates to a contractually predetermined amount, which may be either capped or unlimited. Compared to senior and mezzanine debt, this type of financing has the advantage of aligning interests of the lender and company by allowing the borrower to pay more when organizational revenue is higher and less when revenue is lower. The approach is effective as long as the borrower's cash flows are aligned with revenues. Problems arise if the borrower's customers pay for products and services a long time after the borrower books the associated sales revenue, as is often required by standard accounting practices. Lenders in this space are often interested in the potential for higher returns if the company outperforms expectations.

iv. Asset-Backed Lending

Another related but important category of debt is asset-backed lending. Asset-backed loans are tied to a valuable piece of property or equipment that the lender can take from the borrower if the loan is not paid on schedule. There are a wide variety of assets that can be used by borrowers as collateral, including intellectual property, invoices, receivables, fixed assets, buildings, production equipment and inventory. The key differentiation between these loans and senior debt is that they tie to just one asset, as opposed to the entire asset base of the company. These loans vary greatly with regard to terms, interest rates and appropriateness of use.

v. Convertible Note

A convertible note or loan is a debt instrument that combines elements of both conventional debt and equity. This type of debt converts into equity in the company after a period of time, after certain milestones are achieved and/or at the discretion of the lender. This type of arrangement may be attractive for higher-growth companies requiring significant amounts of growth capital to achieve future milestones. The downside for the borrower is that the interest payments on the debt continue if milestones are not achieved and/or if the lender does not convert its position into equity. This can result in either greater outlay of capital to pay off the debt (if it is paid off) or greater dilution of ownership (if the debt is converted). On conversion to equity, these loans also dilute the ownership position of the borrower and result in some loss of company control, as this is expected by equity investors of a company. (See equity section, below.)

Convertible debt is typically used by investors who see the potential of a venture to produce high returns, but are not prepared initially to invest in equity because of uncertainty related to the potential growth and/or valuation of the business. Through convertible notes, investors avoid the complicated negotiations of setting a share price for an early stage company, but ensure they get a 'piece of the action' if all goes well³.

vi. Concessionary Debt

Concessionary loans are often provided in lieu of a grant to early-stage, for-profit social enterprises and companies. These types of loans are typically offered by mission-driven investors (such as foundations and development arms of governments) to provide catalytic financing, with the main or only goal being impact and development. They can be structured like any other form of loan mentioned above, although asset-based structures are less common. Their common feature is that the terms of the loan include some type of concession, such as belowmarket interest rates, relaxed financial covenants, relaxed milestones, impact-based milestones, longer-term and/or impact-based interest rate reductions. Additionally, should the borrower not succeed or experience unpredictable circumstances, some concessionary lenders may renegotiate the terms of the loan and/or forgive the loan to support the continued impact and sustainability of the entity. Mission-investors using the convertible note structure may also be open to renegotiating the conversion rates or converting early in downside scenarios where companies are unable to pay back the debt, both to ensure they do not end up owning too much of the entity and to see impact continue.

A. TYPICAL CHARACTERISTICS - DEBT

BEST USED FOR	 Growth and expansion financing by organizations that have current or expected predictable cash flows tied to these activities Working capital (usually to fund short-term cash imbalances created by delayed payments or inventory)
VARIATIONS	 Senior, mezzanine, asset-backed, convertible, revenue-based, concessionary
MAIN FUNDERS	• Foundations, Development Finance Institutions (DFIs), private debt funds and banks, equity investors (convertible notes)
EXPECTATIONS	• Ability to service debt via positive cash flows and profits, conversion to equity during a future equity round (convertible notes)
ADVANTAGES	 Non-dilutive (except convertible notes) Tax-efficient Typically no loss of control via active positions on boards (though observer positions can be requested; except for convertible notes) Can increase value for existing equity investors
CHALLENGES	 Often inaccessible or inappropriate for pre-revenue or early stages under commercial terms Can stunt the venture when diverting cash flows away from growth Available interest rates can be prohibitive Bankruptcy risk Refinance risk (risk of re-financing with a new loan or other form of capital, such as equity, under less favorable terms)



B. INSIGHTS - DEBT

Innovator Insights

The lending market is difficult to navigate for most innovators, regardless of background. However, non-profits and academics particularly lack the skills or expertise to fully understand lending products available in their market. As a result, favourable options (such as flexible concessionary notes, project financing or the arrangement of micro loans for customers) are often overlooked as an alternative to grant financing. On the other hand, social enterprises often borrow excessively because they are viewed as too profitable for grants but not at the profit level or potential to issue equity. Even when debt is used appropriately, innovators may struggle to negotiate terms that reflect the unique context of their businesses. They also may fail to renegotiate terms early enough with lenders when circumstances or priorities change. In many instances, innovators underestimate the cost of convertible debt (given its unique characteristic to become equity combined with the specialty features of such agreements) or ignore the opportunity that convertible debt may offer when used appropriately. Borrowers frequently choose too much repayable debt, which may stunt their growth by limiting the availability of cash to finance growth. Early stage companies may also be composed of teams that are lacking in financial management expertise and systems to forecast, analyze and articulate needs and ability to pay back debt effectively.

Lender Insights

Many lenders active in global health are able to offer flexible terms and have the ability to renegotiate terms to the benefit of the continued operation of the business, especially when the impact mandate of the borrower is strong. However, lenders do expect portfolio companies to lead the effort by bringing informed proposals, including detailed cash flow projections, to the table. The space benefits from significant activity from new entrants with fintech offerings, new non-bank lenders and micro lenders, as well as impact-motivated investors and guarantee facilities that enable local lenders to take on more credit risk. As part of the mission in achieving gender equality, there is also a nascent trend to provide debt capital to female entrepreneurs that female founders should tap into when raising capital.

3. EQUITY

In equity financing, the investor provides the company with funds in exchange for a share of ownership in the organization. This arrangement provides equity investors with a claim on the venture's upside value creation. "Because the potential for a large return exists, the equity investor is typically willing to invest in riskier ventures – those developing breakthrough products, working with emerging technologies, or operating with unproven but potentially transformative business models"³. Technology-based start-ups that typically lack early revenue, cash flows or profits, but hold the promise of significant future growth and value creation are characteristically financed by equity. For these organizations, venture capital (VC) is the predominant source of capital in the early stages.

VC funding for health and impact is available at the angel, seed, Series A and Series B stages and beyond, depending on the revenue growth, milestones and/or regulatory stage of the company⁴. Typically, the entrepreneur seeks investors to fill each round based on the company's valuation and financing needs. Equity investors participate in these rounds based on their risk/reward preferences (often dictated by their agreements with their own investors in their funds) and receive a percentage ownership in the company in exchange for their capital. They realize their returns during an "exit," which is a contractually specified event in which the company is sold to or merged with larger industry players or when shares are offered to the public through an initial public offering (IPO), typically on regulated public stock exchanges. Before the exit, investors actively participate and support the company's growth to increase its value. They exercise varying levels of control on the business, depending on the investor group and negotiated terms of the investment. While angel investors typically invest their own capital, it is important that innovators recognize that most VC funds have fiduciary responsibility to their own investors for the capital they invest and that the terms they can offer relate to the terms they negotiated with their own investors. VC funds also have time limits on their funds, which may drive their decisions.

Other key players that invest in private companies are strategic investors such as VC groups that operate from within a larger corporation in the same industry as the innovator. These groups often operate similarly to VC funds, although they may also often request terms specifically related to the strategic nature of the relationship with an investee company. These terms can both help and hurt the company's path toward generating returns for other investors. Another mechanism that can be used to raise capital is crowdfunding, which is a form of financing where companies can raise equity capital or sell their products directly to the public via specialized online platforms.

A. TYPICAL CHARACTERISTICS - EQUITY

BEST USED FOR	• Growth and expansion financing by companies that expect high future growth, with varying degrees of uncertainty based on stage of financing
VARIATIONS	• Venture capital, private equity, quasi equity (such as convertible debt)
MAIN FUNDERS	 VC funds, private equity (PE) funds, angel investors, public (publically traded or crowd-funded), larger companies (strategic investors), DFIs, certain banks
EXPECTATIONS	 Dedication to growing financial value of the company Percentage of ownership Control of the company's decisions, typically via board positions and shareholder rights documented in the shareholder agreement
ADVANTAGES	 No repayment obligation Large amount of capital to facilitate accelerated growth plans and value creation Access to expertise of the investor group and their networks Flexible capital approved based on high-level plans for the use of funds
CHALLENGES	 Dilutes ownership Commercial value creation is a higher priority than impact, even when investors are impact investors Exit pressures and timing Loss of control



B. INSIGHTS - EQUITY

Innovator Insights

In the health and impact sectors, most innovators require much longer to close each round of financing (typically 18-24 months) than companies outside these sectors (typically 6-9 months). First-time CEOs often struggle with pitching to investors and understanding the process. They often underestimate the time required and begin fundraising later than optimal, which can lead to short runways and poor negotiating positions. Another potential issue is that innovators in global health who access grants as early-stage financing to achieve proof-of-concept often contractually agree to make their products/services available for the public good (sometimes referred to as "global access"). These clauses can negatively impact their valuation or their ability to raise equity to scale their innovation, if not drafted with sufficient flexibility to enable the crowding in of more commercial investors in the future. Many funders recognize this and will craft reasonable terms at the outset of a grant or negotiate after the grant is in effect to support companies in their subsequent growth by creating win-win scenarios between investors and beneficiaries. This can often be achieved by simple mechanisms (such as the segmentation of rights for different jurisdictions or populations) to ensure the needs of each party are met. Another approach is to enter into distribution and/or pricing commitments (with enforceable consequences if not met), leaving the intellectual property unencumbered. A degree of customization is typically required to ensure the objectives of current and future stakeholders are aligned.

Many equity investors do insist that prior debt either be extended or converted before making their investment. Those companies that carry outstanding debt when equity is raised must confront a concern by prospective investors that lenders will not cooperate with the issuance of equity. Cooperation typically requires lenders to extend the payment timeline or convert alongside new investors.

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Investor Insights

Investors that value impact also expect competitive returns, as they must fulfill their fiduciary duty to generate returns on behalf of their own investors. Other forms of capital such as grants and debt are therefore often essential tools as companies and equity investors seek to create a total capital structure that yields returns for each stakeholder, including the underserved populations that are the focus of impact. Notably, while impact investing has gained increasing traction in the last few years, the sectors that are most often represented are agriculture, livelihoods and energy. Fewer equity investors in health are available, especially when the targeted populations are in lower-income countries. Within this sub-sector, fewer still are the investors interested in pre-revenue or early-revenue stages of health technologies and devices. Those that do invest appear to either be small (thus limiting their financing to initial stages) or very large (thus participating only in the financing of companies that are already scaling). A wide missing middle cohort of investors has left the health sector underfinanced. We note that a number of new efforts are underway to address this problem, but that they face significant hurdles in raising the necessary capital to launch due to the emerging nature of the sector. There are also new technical assistance facilities being raised to support the efforts of these future funds, combining clinical and health expertise, regulatory and IP knowledge, market and local knowledge and local talent (See our white paper on the barriers to scaling addressable by Technical Assistance.)





4. NEW MECHANISMS

A. OUTCOMES-BASED FINANCING

Outcomes-based financing approaches are also increasingly being tested in the development sector. Simply put, the mechanism is structured to involve an outcomes-based funder that agrees to pay an innovator to implement a project if pre-defined outcomes are achieved, based on independent, third party verification. The investors who initially finance the project receive a pre-agreed return, in addition to the capital invested, if the project is successful in achieving the defined outcomes. The investor therefore takes on the risk that the project will fail - a risk that an outcomes funder, typically a government, is not willing to bear, thereby aligning impact goals and risk/reward appetites. The model is gaining popularity, as it aligns impact goals, financial goals and risk tolerance. Examples include social success notes, conditional cash transfers, advance market commitments, guarantees and social/development impact bonds. An example is the Kangaroo Mother Care Development Impact Bond (DIB) in Cameroon, which is structured between:

- i. **Outcomes Funder** Ministry of Public Health of Cameroon (through the Global Financing Facility) and Nutrition International
- ii. Third-Party Verification Institute for Research and Behavioural Studies (IRESCO)
- iii. Innovator/Service Provider Fondation Kangorou Cameroon
- iv. Investor Grand Challenges Canada

The complex structuring required for its success was facilitated by Social Finance UK and the MaRS Centre for Impact Investing.

The key drawbacks of this financing mechanism are its complexity, high transaction costs related to legal, financial and technical services for customization, time requirements and the need for multiple parties from different sectors to agree to common terms. More data is needed to build structures that are replicable and/or restricting these instruments to certain focus areas or minimum funding sizes to achieve better cost efficiency⁵.



B. BLENDED FINANCE

In recent years, blended finance has become the 'North Star' in the fields of global health and, more generally, other impact sectors. Blended financing refers to the coordinated structuring process to align risk/reward characteristics of an investment opportunity (including financial and impact characteristics) with risk/reward preferences of various investor types, to include various sources and categories of financial instruments, including a concessionary layer. This is common for larger investment vehicles of \sim \$20 million or more and has the potential to significantly grow the sector.

At the EWEC Innovation Marketplace, the hands-on support provided to innovators has allowed companies to secure blended finance at the company level for \$1-\$5 million dollars in total capital raised. Because their growth plans encompass both impact and return, the companies supported are able to secure financing from investors and funders with varying risk/return appetites. This includes grants, unique loan structures, equity investment and, in some cases, guarantees and outcomes-based funding. In ideal scenarios, participants in the blended finance structure coordinate transparently to select the risk/reward structure that most closely matches their actual requirements and collaborate to reduce the reporting burden on the innovator. This type of process tends to work better when an advisor (formal or informal) is available to nudge collaboration among investors. More commonly, each investor comes into the structure around the same time with their own structure in an un-coordinated manner and agrees to the hierarchy of lender priority through inter-creditor agreements.

Innovators should be aware that blended financing requires thought, advice and planning to accomplish optimally, including an understanding of future financings required to achieve scale. Three key skillsets innovators should equip themselves with for such a journey include:

- i. Ability to measure and report on impact and outcomes
- ii. Ability to forecast, strategize and manage financials effectively
- iii. Ability to identify and negotiate the financial instruments for the growth strategy of an entity

In addition, innovators should seek out formal or informal advisors with a high degree of knowledge and expertise in all potential financing instruments, to assist their journey for the long-term.



5. LEVERAGING INSTRUMENTS TO SCALE

Hypothetical examples of potentially successful models are provided below.

a. Medical device or technology company

Initial prototyping and testing is conducted using grants from foundations and academia in combination with small angel investments. Clinical trial, regulatory and product development stages are funded through larger grants from foundations and seed stage investors. Early stage VC supports the preregulatory approval stage where manufacturing and distribution models are being developed. Global access agreements are developed or refined together with the innovator, grant providers and commercial investors. Funding from strategic investors enables the growth of new distribution channels and/or entry into new markets. Debt financing is leveraged to achieve further growth once the company reaches predictable revenues, with grants potentially available to bring solutions to last-mile or LMIC populations. Long-term agreements are struck between the company, local entrepreneurs/distributors and governments to embed a solution locally, ensuring the impact survives potential exits.

b. Operationally intensive service models

Such models include hospital chains, clinics and other primary care delivery mechanisms that access foundation grants and angel investments to pilot their model in communities, test market acceptability and pricing strategies, begin developing systems for financial management and monitoring & evaluation of impact. As is typical, the organization is revenue-positive earlier on and raises financing rounds composed of concessionary debt to fund working capital to deliver on government contracts and service expansion and raises equity to finance new facilities or new markets. Success usually attracts debt financing from later-stage lenders (such as DFIs and banks), as well as equity from late-stage private equity investors.

c. Programmatic service models

These are typically led by non-profit entities or partnerships with service providers. Grants serve as the main instrument for a large period of time, proving aspects of the model especially related to cost effectiveness, user adoption and impact. In the long term, public sector adoption may manifest as fee-for-service, cost-sharing or licensing-in. Debt in the form of working capital can reduce cash flow issues for the non-profit, created by delayed contract payments from large providers or governments. For large projects, outcomes-based financing may also be suitable in some cases in securing government or donor financing.

d. Product based companies

Examples include products focused on nutrition or menstrual health, and commodities that may grow through a combination of early grants followed by debt or equity investment based on their cash flows or equity-return potential. Intellectual property-rich companies are more likely to receive venture capital investment, while companies commercializing commodities are more likely to receive debt. Volume guarantees and advance market commitments may also be feasible for some promising products.



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CONCLUSION

To conclude, innovators can benefit from weighing the costs and benefits of applying different models of financing to determine their best path to growth. The wide range of sources and types of capital described in this note are complex, and must be carefully considered to yield an approach that is suited to the unique capabilities and aims of innovators. The relationships between various types of financing tools are important to the long-term growth of organizations, but are infrequently considered or understood by novice investees or their investors or funders who often operate in silos and use different jargon and language to refer to shared aspects. Companies seeking to achieve social impact have unique access to blended finance that attracts both private and public capital, but require assistance to navigate these complex waters. Because the populations served by global health and social sector innovators are vulnerable, the consequences of organizational failure are significant. Investors and funders must understand and embrace the consequences of the terms that they impose through financial instruments and legal requirements for these populations as well as for the future financeability of the investee organization, as innovators cannot scale impact if they cannot raise growth capital. When each stakeholder ensures all aspects of the organization that are financed are well-supported throughout scaling, including impact, revenue, growth and financial return (when investor capital is needed), the approach can indeed be the elusive winwin the sector needs.

REFERENCES

1. USAID Center for Innovation an/d Impact (2019). Unleashing Private Capital for Global Health Innovation: Innovator and Investor Support Opportunities

2. UN Global Compact, UNCTAD, UNEPFI, PRI (2015). Private Sector Investment and Sustainable Development

3. Bussgang, J. (2014). Raising startup capital. Harvard Business School Background Note 814-089

4. Bocken, N.M.P. (2015). Sustainable venture capital - catalyst for sustainable start-up success? *Journal of Cleaner Production, 108(A), 647-658*

5. Itagaki, W. (2016). Reducing Transaction Costs in Development Impact Bonds. *Center for Strategic & International Studies: Prosper*

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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



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.



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Models to Scale Healthcare Technologies for Lowand Middle-Income Countries



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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-valvemask - 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 techtransfer 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 startup 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, startups 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 startup. 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 sustainably. This is growing 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, highquality 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 model. Robust partnerships growth and diversified offerings are key to reaching greater scale, as these companies benefit from costsharing 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 multiproduct companies, they are expected to show

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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-ofconcept 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 bourgeoning networks of accelerators and venture capital firms in these economies that have arisen due to the significant investments

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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 bv 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 а 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 lowincome countries, tiered pricing commitments for middle-income countries (to account for incomelevel-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 nonprofits 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 marketbuilding 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.



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| EWEC INNOVATION MARKETPLACE

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*

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Dual-Market Scaling Strategies for Impact

A WHITE PAPER

Deepika Devadas, Annie Thériault, *Every Woman Every Chil*d Innovation Marketplace, Grand Challenges Canada Apita M. McCabap, University of Toropto, Botmap School of

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



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.



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Dual-Market Scaling Strategies for Impact



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A deep dive into the dual market approach and its potential to unlock financing for innovations scaling in LMICs

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Over the past few years, a new business model for scaling early stage innovations has arisen in the global health community called a 'dual-market strategy' in which innovators introduce a similar product or service in both high-income countries (HICs) as well as low- or middle-income countries (LMICs). The drivers behind the emergence of the dual-market strategy include the challenges faced by innovators to attract investment capital for scaling in LMICs and the ambitions of companies headquartered in HICs to become relevant in wider markets and to deliver their solutions to impact lives in LMICs. This white paper examines the dual-market strategy in greater detail to identify insights and issues. It discusses opportunities for donors and grant funders to collaborate with private investors by implementing blended finance approaches, and explores other considerations relating to this model to assist innovators.

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.

1. DEFINING THE DUAL-MARKET STRATEGY

A dual-market strategy is a business model in global health in which for-profit companies introduce the same or a similar product in both HIC markets and LMIC markets, and that the returns from high-income markets help to enable the operations in low-income markets. Whether the product originated for the purpose of solving problems in HICs or in LMICs, its introduction in HICs facilitates its distribution in LMICs in multiple ways. The product is priced differently in each market – higher in HICs and lower in LMICs. In some instances, the products marketed to LMICs are modified slightly from the HIC versions to make them easier to use, more affordable or contextualized for LMICs (e.g., with language translation or adapted to cultural contexts, health system workflows, skill level, etc.) In all cases, the products introduced in different markets draw from the same innovative concept and evidence base.

A dual-market strategy differs from other approaches to scaling health technologies in LMICs because the innovation is usually first introduced into HIC markets targeting relatively resource-rich customers, and is introduced to LMICs relatively soon after or even concurrently with commercialization in HIC markets. This approach is faster than the traditional approach that causes delays in LMIC impact, where companies first aim to dominate HIC markets before turning their attention to LMIC markets, usually after several years. While LMIC-only technologies may be significantly cheaper by design, their ability to lead to best potential outcomes for impact is limited, as these strategies are not sufficient to attract and mobilize the type and level of capital needed to scale today. We also include innovations defined as 'reverse innovations'¹ – the opposite of this approach – where products designed with a "frugal innovation"² lens for LMICs increase the potential for financing the scale up of the innovation by expanding their accessibility to a much wider market in HICs. Reverse innovations are likely to become more common in the coming decades as the pace of innovation in LMICs accelerates.

2. BENEFITS OF THE DUAL-MARKET STRATEGY

Dual-market strategies have three main benefits. First and importantly, as a result of the anticipation of profitability, they have the ability to attract and channel diverse sources of investment to scale up an innovation. Since sales in HICs potentially generate much higher returns, private investors may be attracted to the project even during early stages when the company's approach, including its technologies, is not fully proven. Private investors (such as individuals or venture capital firms, especially in HICs where the venture capital sector is more established) may take product development risk in exchange for the potential of earning a high return, even when commercialization is a few years away. Dual-market ventures are also attractive to a subset of early-stage public and philanthropic funders that consider the long-term financial viability of projects as integral to investing decisions. For these funders, the long-term profitability of the venture serves to demonstrate the potential for long-term self-sustainability and continuation of the innovation beyond their funding. All in all, a dual-market strategy makes the investment attractive to multiple funders in the critical early stages, some of which would not have the ability to invest without the promise of financial returns, and others who cannot fund innovations that cannot become self-sustaining.

Second, patients and other buyers in LMICs often prefer to access the same products as those sold in HICs so as to quell any concern, real or perceived, that solutions designed or marketed solely to LMICs tend to be of poorer quality. If executed with the right amount of contextualization and training, this mechanism has the potential to ensure that LMIC markets have access to the latest health innovations, in line with those offered in HIC markets. It also has the potential to not only create access to the initial product, but also to any potential subsequent improvements made in the future.

Lastly, and further justifying the strategy for HIC market investors, who may initially see this as a distraction from their main goal of earning high returns on their investments, there are cases – especially where the HIC market strategy involves direct sale to a patient/customer – where there could be brand benefits in HICs from this approach. In particular, millennial buyers consistently express a preference for brands with ethical aspirations and motivations that go beyond the benefit they may themselves receive for the product or service³.

3. TYPES OF DUAL-MARKET STRATEGIES

Under the umbrella of 'dual market strategy,' there are three main models: pure cross-subsidy, independent self-sustaining and synergistic.

A PURE CROSS-SUBSIDY MODEL

This business model is often called 'the Robin Hood strategy'. In this model, a product or service is first introduced into a HIC market and the profits garnered from the revenue generated from the sales of this product or service are used to subsidize the sales (or even donation) of the same product or service into an LMIC market. The product or service is then sold at a lower price in the LMIC than in the HIC – typically, a price that is lower than the product's total cost of production (including delivery and other costs). In some instances, the product or service offered in LMIC markets may even be offered free of charge to customers. Thus, the cross-subsidy model uses profits from HICs to support the offering in LMICs.

B INDEPENDENT SELF-SUSTAINING MODEL

In this model, the introduction and profits of the product or service into HIC and LMIC markets are kept independent, and the business model for the LMIC setting is designed to be self-sustaining, meaning that the product price in the LMIC covers its total costs (including cost of goods, delivery, sales and other costs, often termed 'variable costs') and may generate a profit, although significantly less than the comparable HIC market. As such, the model ensures that the profits accrued in the LMIC will continue to support the sales of the product or service in the LMIC and may even justify some level of investment by the private sector in that market – usually lenders, as opposed to equity investors. However, the profits are not usually sufficient to cover future research and development investment costs necessary for future product improvements or market-building activities.

In independent self-sustaining models, therefore, the product or service's introductions into HICs and LMICs are separate. At the same time, access to the product or service itself and access to any product improvements rely on the health of the HIC-based business and the support of the HIC-based management team for certain functions.

C SYNERGISTIC MODEL

The synergistic model seeks to draw mutual benefits from the introduction of a product or service in both resource-rich and low-resource markets at once. For instance, one challenge of scaling up health innovations is their long lead times for development, trials and certification before they are ready to go to market. Synergistic models may use the access to multiple markets to overcome challenges of this sort. For example, trials conducted in both LMICs and HICs can lead to more robust evidence and can contribute to multiple regulatory approvals, such as CE (Europe) and FDA (U.S.). Products (including diagnostics that rely on machine learning) may benefit from testing on diverse populations to develop a higher-quality product that is relevant to more patients and more markets, with both monetary and impact benefits. Thus, synergistic models ensure mutualism between HIC and LMIC markets, as the lower economics earned in LMIC markets are outweighed by these non-monetary benefits.

4. CHALLENGES OF DUAL-MARKET STRATEGIES

Dual-market strategies continue to face several challenges, including (1) the legitimacy of the practice, (2) the evolution of corporate priorities, (3) the difficulty of achieving true self-sustainability and synergies and (4) the appropriateness of differences in treatment for certain types of health conditions.

When products are sold in resource-rich HIC markets at higher prices, the payers are usually the government of the HIC or private health insurance providers. Given the universal push for lower pricing, these governments and insurance providers may prefer cost savings as opposed to subsidizing sales in LMICs, despite the humanitarian intention. The argument is against the use of taxpayer money or insurance policyholder funds to subsidize access for citizens of other countries. Uninsured patients who pay for these expenses out-of-pocket in HICs may also view the practice as unfair, especially when they have limited means themselves. Thus, questions in HICs about the legitimacy of dual-market strategy practices may arise, especially when the cross-subsidy model is utilized. Further, while variable costs of the product or service may be covered with the self-sustaining model and while there are long-term benefits to the strategy for the synergistic model, companies may require grant funding to mitigate questions of legitimacy. In line with this challenge, donors and funders for LMICs may be reluctant to provide non-dilutive funding to private companies, due to the limited number of known established successes, perceived dilution of impact strategy, the need to designate funds solely for LMIC activity or for other regulatory reasons.

Separately, the long-term priorities of corporations seeking to scale up products may shift over time with changes in management, or after a corporate transaction (such as raising capital from new investors, or a merger or acquisition transaction). Initially, a corporation may support the LMIC participation irrespective of other HIC market opportunities. However, particularly for the cross-subsidy approach, the corporation may eventually face pressures from shareholders, including investors, to pursue opportunities where higher profits can be earned. For example, pressure may arise to redirect the capital devoted to the LMIC strategy toward the development of new products targeting HIC markets. Stakeholders may even pressure the corporation to distribute excess funds to shareholders as dividends. The evolution of corporate priorities may thereby also challenge the longevity of dual-market strategies, even when management team members or a subset of shareholders support the strategy.

A further common challenge of dual-market strategies is effective management of self-sustainability or synergies. Even when self-sustaining, corporate activities in LMICs will require continued access to capital, companies new to the strategy may not be aware of the full suite of mission-driven or local financing options that could be available for this purpose and may feel that this approach limits the company's overall capacity to use this capital for more profitable purposes. Similarly, the pursuit of synergies may be impeded by many factors. For example, when a company runs simultaneous clinical trials in HICs and LMICs, the regulatory processes of the involved countries can require different clinical trial designs, leading to an escalation of regulatory costs that outweighs synergistic benefits.

Other challenges that may need to be mitigated or monitored include price arbitrage, market shaping through price monopoly or legal/regulatory limitations on price discriminations⁴. Further differences in contexts and the need to nurture entirely different networks of actors in each market may challenge the abilities of corporations, especially early stage or smaller companies that are pursuing dual-market strategies to achieve real synergies for mutual benefit of the countries and markets in question.

5. CHOOSING A TYPE OF DUAL-MARKET STRATEGY

Ideally, companies would all have an opportunity to choose the synergistic approach as it is optimal for all parties involved, including companies, populations in both HICs and LMICs and investors, and therefore least likely to suffer some of the criticisms of the strategy, given the scope of aligned interests. However, there are many instances where the choice of this strategy is unlikely or at least difficult to realize. In such cases, most funders favour the independent, self-sustaining model to the pure cross-subsidy model, as the latter is most likely to fail in the event of an economic downturn, change of management or in the face of HIC market stakeholder challenges.

That said, there are also instances when only a pure cross-subsidy model is possible. In these cases, it may be helpful to request a direct donation towards the LMIC strategy, potentially as part of a social responsibility strategy.

6. DUAL-MARKET STRATEGY – AN OPPORTUNITY FOR CAPITAL EXPANSION IN GLOBAL HEALTH

Dual-market strategies are particularly effective when they leverage low marginal costs and network effects. Technologies characterized by high initial technology development and demonstration costs, and subsequent low marginal costs for diffusion and operation (such as digital technologies and a subset of other healthcare products and technologies) are ideally suited for this scale-up approach. This approach limits risks of legitimacy, shareholder objections, and the draining of management capacity and resources.

Because there is the potential of a strong value proposition for both private sector investors and donors, these strategies offer an opportunity for collaboration between these two groups that has the potential to result in significantly more impact for the same level of investment for funders. Ultimately, the financing tools relevant for such innovations may include the entire suite of those discussed in our financing instruments white paper in this series⁵. If utilized more frequently, dual-market strategies leveraging blended finance could result in an increase in the types, sources and amount of capital available for scaling health technologies in LMICs – an outcome that is critically needed in light of the current poor progress toward the achievement of Sustainable Development Goal 3, a problem that has worsened with COVID-19. The concept is illustrated in figure 1 below at the company level.





The figure represents the case of a technology that has a high initial development and demonstration cost that must be financed irrespective of the target market. In this specific example, the LMIC market upside from the product is insufficient to justify private investment. As such, without a dual-market strategy, donors must fund the entire product development and demonstration costs, as well as the market entry cost in LMICs. Once the product is in the market, there is an opportunity for some financing, primarily from mission-driven lenders at low interest rates, but the organization may find it difficult to thrive as it cannot finance new product innovations without further grant capital, which may be elusive.

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When using a dual-market strategy to achieve scale in LMICs, we note that there is a significant value proposition for private investors created by the additional HIC focus. In such a case, participation by donors (shown in green) in the early and riskier stages of the project may encourage companies to make commitments to make a technology accessible in all or a subset of specific LMICs, often termed 'Global Access Commitments' or 'Intellectual Property Rights'. (Note that such rights would need to be designed in a manner that takes the interest of all stakeholders into account, including investors, donors, the company and patient beneficiaries.) As illustrated, the costs of market entry in LMICs may be reduced by market entry in HICs because some of the activities required are also needed for HIC markets, such that they are mostly borne by investors interested in the return potential of the venture.

In the most ideal scenarios, donors remain involved with the company as it scales, and enable the company to grow its impact in LMIC populations in multiple geographies via grants, to enter new markets and to contextualize new innovations that are developed by the company.

That said, we note that market entry costs in LMIC markets can be significant when technological adjustments are needed to contextualize products, when demonstration trials are needed, or to build capacity for distribution by bolstering the capabilities of local ecosystem partners. They also require access to local networks of collaborators that donors and technical assistance platforms are generally better positioned to provide relative to private sector investors, making collaboration a critical component of this strategy. In the illustration the synergies accrue to all involved, as the presence of donor capital also has a small positive effect on investors (reduced dilution early on), which justifies the company's ability to sustain the LMIC strategy. While some donors may view this as a negative, we argue that the small positive effect on the company enhances the chance of long-term success as it provides the CEOs of these companies with stronger arguments to convince their commercially-oriented investors to support the dual-market strategy.

This framework is applicable whether the innovation initially originates from an HIC or an LMIC, and irrespective of which market is targeted first. The only requirement for this framework to be applicable is relative economics of each component of the strategy.



7. DUAL-MARKET STRATEGY – FOCUS ON OVERLAPPING NEEDS FOR HIGH IMPACT

The heart of the opportunity behind a dual-market strategy arises from the overlap of health needs of patients in HIC and LMIC markets. Priorities such as preventing maternal postpartum hemorrhage, diagnosing and treating childhood pneumonia, preventing and managing newborn prematurity, facilitating access to diagnostics and treatments for sexually transmitted infections, providing access to menstrual hygiene products and addressing non-communicable diseases – among other common needs – are universal needs for women, children and adolescents.

A product may be an incremental innovation on health outcomes for a patient in a HIC through, for example, workflow or cost efficiency. At the same time, the product may carry the potential to be a revolutionary, disruptive innovation, given the current standard of care in an LMIC. Likewise, a solution designed for LMICs to leverage limited resources can create cost efficiencies that are equally valued in HICs, and also assist HICs in addressing their own inequalities related to race, gender and wealth. The early involvement of the global health donor community for financing in these approaches can enable these mutually beneficial and relevant solutions to scale.

8. EXAMPLES OF SUCCESSES

Recent successes in global health highlight the benefits, risks and costs of the dual-market strategy approach. For example, Babylon Health has successfully adopted the strategy in bringing their UK-based solution to Rwanda, in addition to expanding to the U.S. and other HICs nearly concurrently.

Babylon Health is a digital healthcare platform that provides patients with artificial intelligence (Al)powered remote consultations to doctors via messaging and video through its mobile application. Babylon Health is a UK-based company that started in 2013 as a subscription business model for private healthcare services. Supported by donors like the Bill & Melinda Gates Foundation, the company was able to bring their technology platform to Rwanda in a 10-year partnership with the national government, registering as **Babyl**, a subsidiary of Babylon. Babyl, the LMIC entity, solves issues of access in Rwanda by addressing the shortage of doctors and Rwanda's desire to leverage its limited healthcare workforce efficiently. Many opportunities worked in Babyl's favour: Rwanda's tax incentives, the structure of the healthcare system, growing broadband investment, relative political stability, political commitment and high coverage by national health insurance (93%). Many of these enabled Babyl to overcome challenges, such as building a non-smartphone USSD (Unstructured Supplementary Service Data) version to compensate for lack of smartphone coverage, building central call centres to overcome lack of widespread infrastructure and even altering the name to accommodate cultural perceptions. Today, Babyl offers 3,500 consultations per day, available in all districts, and enjoys higher daily volumes compared to weekly volumes in the UK. Concurrently, the main corporation has extended its reach to Canada, the U.S. and Saudi Arabia. It has reached unicorn status and is valued at \$2Bn after its latest \$550 million Series C round.

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There are also multiple multinationals with successes, including General Electric, which financed a \$13M Healthcare Skills and Training Institute in Kenya in 2016; the corporation has also achieved positive synergies with other non-health related aspects of the business.

Earlier-stage companies adopting these dual-market strategies with early signs of success include Mobile ODT and GestVision, each targeting a broad group of diverse LMICs based on their networks and LMIC market demand for their products.

Mobile ODT⁶ has created the EVA System based on AI and machine learning technology with an accuracy similar to that of leading experts. The device is a colposcope linked to a smartphone that screens for cervical cancer, uploading images to a secure online data management system for doctors to examine. Mobile ODT's system has provided accessible visual assessments for over 40,000 patients in over 27 countries. Their primary markets are the United States, Europe, India and African countries. Their financing comes from several private investment sources, including venture partners OrbiMed, DAI, TARA Health Foundation and the Laerdal Million Lives Fund; the company was recently awarded a prestigious Small Business Innovation Research Authority grant of US \$2.3 million by the United States National Cancer Institute (NCI) and also recently secured non-dilutive funding for a large-scale pilot project in Kenya, in collaboration with GE Healthcare. This technology had the high early cost to develop and demonstrate the technology, with low costs to diffuse the device and app that were highlighted as a good candidate for this strategy.

GestVision⁷ is a company developing the GestAssured© test, to aid in the diagnosis of preeclampsia. The test is based on the Congo Red Dot (CRD) technology licensed from Yale University. Given preeclampsia affects women in the United States as well as globally in low-income markets, the company envisioned a dual market strategy where the U.S. market can provide commercial sustainability to allow pursuit of markets in developing nations. GestVision has raised over US \$12 million in private capital in the last 5 years from investors that include Cooper Surgical. Irina Buhimschi, one of the inventors of CRD technology, has lead trials in LMICs and has demonstrated the potential of the test to aid in the diagnosis of preeclampsia. These studies were possible due to grant opportunities (such as those by the <u>Grand</u> <u>Challenges organizations</u>), demonstrating the various types of support needed for a successful dualmarket approach.



CONCLUSION

Dual-market business models introduce products or services at higher prices in HICs and lower prices in LMICs. Dual-market scaling approaches include pure cross-subsidy, independent self-sustaining and synergistic models, and may unlock collaboration among funders and investors towards significantly expanding the amount of capital available to increase the number of leading technologies scaling in LMICs. With SDG 3 (the Sustainable Development Goal dedicated to Good Health and Well-being) becoming even more difficult to address due to health system challenges like COVID-19. This form of collaboration – allowing investors, donors, company management teams and patients across the world to benefit has the potential to expand the total amount of capital available for global health purposes by bringing more players to the table⁸. Initial priorities must include participating and sharing success stories to convert new and experienced participants in the health sector towards greater collaboration, while maintaining their own true nature on the risk/reward/impact continuum.

REFERENCES

1. Govindarajan, V. & Trimble, C. (2012). Reverse innovation: create far from home, wine everywhere. *Boston: Harvard Business Press.*

2. Weyrauch, T. & Herstatt C. (2017). What is frugal innovation? Three defining criteria. *Journal of Frugal Innovation*

3. Chatzopoulou, E. & de Kiewiet, A. (2020). Millenials' evaluation of corporate social responsibility: The wants and needs of the largest and most ethical generation. *Journal of Consumer Behaviour*

4. Fisher W. W., Syed T. (2017). Stanford University Press. Infection: The Health Crisis in the Developing World and What We Should Do About It. Chapter 3: Differential Pricing

5. Devadas, D., Thériault, A., and McGahan, A.M. (2021). Financing Instruments for Innovators to Scale Health Innovations in Low- and Middle-Income Countries, *Every Woman Every Child Innovation Marketplace White Paper*

6. Mobile ODT. Retrieved on July 24, 2019, from https://www.mobileodt.com/

7. GestVision. Retrieved on July 24, 2019, from https://gestvision.com/

8. Mangham, L.J. & Hanson, K. (2010). Scaling up in international health: What are the key issues? *Health Policy Plan*, 25(2), 85-96

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