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PATHWAYS TO SCALE

A guide for early-stage global health innovators on business models and partnership approaches to scale-up

USAID's **Center for Accelerating Innovation and Impact (CII)** takes a business-minded approach to fast-tracking the development, introduction, and scale-up of health interventions that address the world's most important health challenges. CII invests seed capital in the most promising ideas, using the most forward-looking business practices to cut the time to transform discoveries in the lab to impact on the ground.

CENTER FOR *ACCELERATING*
INNOVATION AND IMPACT
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Pathways to Scale aims to help early-stage innovators develop business models and partnership approaches that align with the development of their products, and envision potential pathways to bring products to scale.

It introduces the most commonly found models for scaling up global health innovations, and features case studies that highlight and explain pathways taken by innovations that have begun to scale-up. It also offers a toolkit with exercises, structured questions, key considerations, and curated resources that innovators can use to identify the most suitable scaling model(s) to forge their path.

Questions and comments are welcome and can be directed to cii@usaid.gov.

For contact information and to download the latest version of *Pathways to Scale*, please visit www.usaid.gov/cii.

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FOREWORD

Accelerating the introduction and scale of global health innovations has been one of the Center for Accelerating Innovation and Impact's (CII) core mandates since its inception. Over the past six years, we have funded over 135 global health innovations through Grand Challenge programs, and supported their development in multiple ways – from broad skills building through accelerators to direct technical support including partnering, product design, launch planning and connection to buyers. We also developed *Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations* to help innovators plan a product launch and scale.

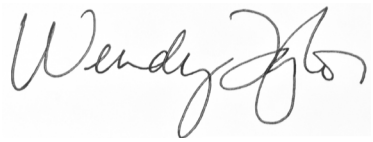
As we've worked with innovators, we've seen that many struggle identifying the right pathway to scale for their innovation and ask themselves the same questions. Should I spin out a company to take my innovation forward on my own, or are there better-suited entities with more resources and capabilities to take it to scale faster? Should I partner, license out the technology, or give it away for free so that others with a similar interest can replicate and introduce the innovation more broadly? What are the key tradeoffs and requirements I should consider, and when is the right time to make the change?

These questions highlight the variety of different business model choices innovators face along the scaling pathway. Determining the right path has as much to do with the profile of the product, and the resources and capabilities required for successful launch and scale, as it does the personalities and preferences of the entrepreneur. Understanding the possible options early on, and making a deliberate decision at the right times, can greatly enhance the chance of achieving the broadest impact down the road.

This guide is intended to help innovators do just that. We provide a framework for making scaling choices, case studies that bring various scaling pathways to life, and a set of exercises to guide the decision-making process. We also lay out key considerations for success once a pathway is chosen.

To build this guide, we drew on the experiences of the pharmaceutical and medical technology industries, experts in the innovation ecosystem, and global health innovators at various development stages. Treat this guide as a beta version and put it to the test. Tell us about your own choices of scaling pathways and the stories behind those choices. Share with us additional examples. Point out significant pathways that we may have missed. Together, we will enrich the learnings and make the pathways to scaling global health innovations a more strategic and successful endeavor.

We look forward to hearing from you.



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Introduction

This guide aims to help early-stage innovators develop business models and partnership approaches that align with the development of their product, and envision potential pathways for bringing products to scale. While many concepts and insights in this guide apply to all global health innovations, our focus is on medical devices and products, rather than drugs, commodities, or service-delivery models.

This guide touches upon, but does not directly address, topics related to R&D. It is not a comprehensive guide to planning for market introduction and scale-up. *"Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations"* and a forthcoming *"Country-Level Scaling Guide"* from CII will serve that purpose.

Photo: Getty Images

In the past decade, the global health innovation pipeline has significantly expanded products and technologies aimed at alleviating disease burdens and addressing unmet healthcare needs in under-resourced settings. However, few of these products have been commercialized, and even fewer have reached their intended users at scale.

Taking an innovation to full-scale[1] in target markets is complex, challenging and risky. The vast majority of innovators lack the internal capabilities and resources to achieve scale on their own. Even established medical device companies often rely on external partners to provide complementary capabilities, especially distribution and marketing expertise that is critical to penetrating emerging markets. Therefore, who you work with to access needed capabilities and resources, how you work with them, and when you enter into collaborative arrangements become make-or-break decisions on your way to scale.

As we emphasized in *"Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations"*, planning for scale with a focus on delivery must begin early, and continue throughout the development process. While concepts such as licensing, selling, and strategic partnerships are familiar to some global health innovators, most early-stage innovators need a deeper understanding of the models for taking a product to scale.

1 Maximizing the level of usage among target end-user segments in target countries in order to significantly improve health outcomes. While the precise threshold for 'scale' differs by country context, and depends on the business model, the magnitude of unmet need in resource-limited settings requires innovations to operate at a large scale to reach many thousands, preferably millions of people (concept borrowed from "Emerging Markets, Emerging Models" by Monitor Group, 2009)

We developed this guide as a supplement to *"Idea to Impact"*, and aim to help innovators still in the early stages of product development[2] to begin considering what their 'pathway to scale' might look like – the series of business model and partnership choices they must make to access the capabilities and resources to achieve scale.

This guide:

- Introduces a few of the most commonly found models for scaling up global health innovations, describes the feasibility requirements for each, and the implications for innovators.
- Features case studies that highlight and explain pathways taken by innovators that have begun to scale-up. Many of these pathways to scale are combinations of two or three scaling models.
- Offers a toolkit with exercises, structured questions and key considerations, along with curated resources that innovators can use to identify the most suitable scaling model(s) to forge the path for their innovations.

While some resources introduce related concepts and aim to help innovators navigate similar questions, few share this guide's focus on business models and partnerships, or address them systematically and in-depth. In Appendix A of this guide, we have included a curated list of these complementary resources.

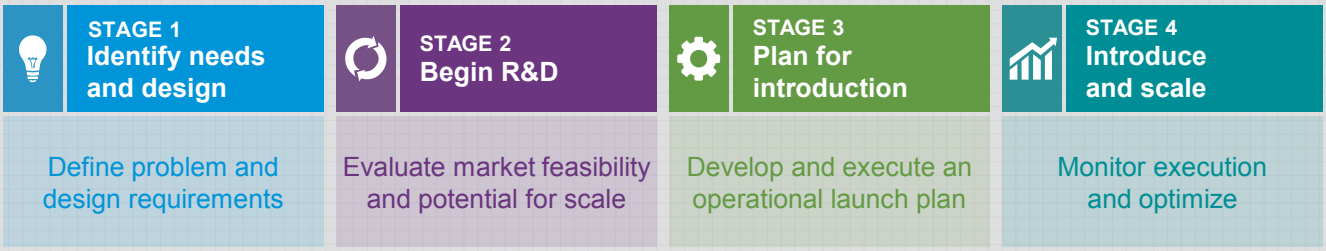
According to innovators who have successfully scaled innovations, it is important to frequently share ideas with mentors and advisors who can help guide decisions. In that spirit, as innovators work through the exercises in this guide, we recommend that they seek advisors to help pressure-test assumptions, explain unfamiliar concepts, and offer ideas for open questions. The experience and knowledge of real- life advisors can help generate more robust answers.

TARGET AUDIENCE

Who does this guide aim to serve?

We define the target audience using the same stages of the innovation continuum outlined in *"Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations"* (see image below). While this guide aims to help innovators at all stages, its primary audience is those at stage 2 of the *"Idea to Impact"* framework. During stage 2, innovators are deepening their market and user understanding, refining product design, and considering clinical/regulatory, manufacturing, and distribution requirements. These insights will inform the long-term vision for how an innovation could reach scale, and which business model and partnership approaches best align with the product, the innovator's aspiration, preferences and capabilities. This vision can, in turn, help inform near-term decisions and priorities.

Idea to Impact Framework



In addition, those at the earliest stage of development (stage 1) can use this guide to understand the major models for taking an innovation to scale, as well as how product design might imply different scale-up requirements down the road. Those who are planning a product launch and scale-up (stages 3 and 4) can use this guide to refine plans and to consider varying the scaling models for different products, countries, etc.

2 For this guide, we are focusing on global health products and technologies, including medical devices, diagnostics, delivery mechanisms (products) for vaccines, drugs, and nutrition, and information and communication technologies (ICT) for health

Five Scaling Models

Photo: Getty Images

While each innovation's pathway to scale is unique, we have observed five broad categories of scaling models across a wide range of innovations in global health -- five ways to access the capabilities and resources needed to take a product to scale. These capabilities and resources are outlined in Chapter 4 of this guide and more extensively introduced in *"Idea to Impact"*. While innovators at the early stages of product development might not be entering into any of these scaling models right away, it is important to start thinking about "how to scale" and understand what each scaling model might entail. Learnings from these early explorations can inform near-term decisions. For example, in considering model 1 (organic growth with selective out-sourcing), innovators could gain important insights into the cost and manufacturability of a product by talking to contract manufacturers without entering into any formal contractual agreements.

An innovator could pursue more than one of these models in sequence (e.g., set up an entity to drive scale-up first, then seek an acquisition), choose different models for different markets (e.g., licensing out in certain markets and organic growth in others), or pursue different models for different products (e.g., organic growth for one product, and licensing out for a different product). The case examples in Chapter 3 illustrate a few of these combination pathways to scale.

	Main feature	Details
1 Organic growth with selective out-sourcing	Scale-up led and coordinated by the innovator, selectively out-sourcing activities to partners. The innovator often creates a new entity to drive the scale-up	▪ Select functions are outsourced to partners, including any combination of the following: – Upstream partners to help facilitate clinical, regulatory and policy requirements – Contract manufacturers and suppliers – Partners to provide logistics/distribution and servicing capacities – Partners to help generate user demand and ensure user adoption (e.g., marketing, user training) – Partners to reach and acquire buyers (e.g., sales, tender response)
2 Multi-stakeholder partnership	Multiple partners (including the innovator) with common or complementary interests work together to drive scale-up. This often includes private sector partners and can be referred to as public-private partnerships	▪ Partnership provides partners with a platform to work together and pursue a common agenda, sometimes with formally outlined objectives, key policies and principles to guide actions ▪ A project manager (one individual or a team) could be chosen to coordinate activities among the partners. This role is also referred to as an "uptake coordinator" ▪ Innovator retains ownership and some decision-making power, and could handle selected scale-up functions
3 Licensing out	Licensing rights to parties to drive commercialization and generate a financial payback to the innovator	▪ Licensing can occur at all stages, from early product development to scale-up ▪ Rights that are licensed out could be limited by geography, market segment, and/or "field of use" (with the innovator retaining ownership of the IP) ▪ Innovator's degree of engagement and control can vary widely, based on the contract's terms
4 Open licensing	Replicating the product technology by setting up an open license that allows others to use the IP	▪ IP owner allows others to use the technology through an open license with few or no restrictions. Other organizations can build on the IP to enhance the product ▪ Innovator could choose to remain involved and provide ongoing support to replicators of the technology ▪ This model can be extended to include cases when an innovator does not create any license and simply allows others to freely use the technology (particularly relevant for hardware innovations, which could be more costly and burdensome to establish IP for than software innovations)
5 Getting acquired	Sale of innovation or business to a buyer	▪ Sale can occur at all stages, from early product development to scale-up ▪ Aspects being sold could be limited to intellectual property (through a full technology transfer, where the innovator loses ownership of the innovation), or include physical assets, part or all of the organization

Although they cover an extremely small portion of the innovation pipeline, multi-stakeholder partnerships are the predominant model for scaling up global health technologies and products today. Very few innovators have been able to license out or sell their technology to another party (e.g., limited commercial value, unable to reach the necessary milestones for licensing/selling), and many fail to drive scale-up themselves (e.g., lack of funding and capabilities, lack of suitable outsourcing partners). In addition, preferences of the innovators and their organizations are another major driver of the scaling model chosen. In the rest of this chapter, we outline the key considerations for each scaling model.

Are there archetypes of products that align with certain pathways to scale?

From the start, we sought to understand if different scaling models are more commonly aligned with certain categories of products (e.g., diagnostics versus therapeutic devices). We posed this question to industry experts and conducted our own landscape analysis. Thus far, we have found no apparent archetypes or patterns. For example, we investigated the pathways to scale of HIV rapid diagnostic tests (RDTs), and found that all scaling models, except open licensing, have been used by the innovators and makers of RDTs. The lack of archetypes is driven by two factors: (1) innovators' personal preferences and (2) the feasibility of taking global health innovation to scale. These two factors are not correlated to a product category, but are idiosyncratic and driven by a multitude of underlying factors.

Each of the five scaling models has a set of requirements that emphasize its feasibility.

Understanding what is truly important to make each model feasible is a critical consideration for an innovator when selecting a scale-up model. The exhibit below lays out a starting point for thinking through the feasibility requirements for pursuing each model.

Feasibility requirements of each scaling model (i.e., "must have's" in order to pursue model)

✓ Critical to success of scaling model

〰 Some importance to success of scaling model

	Strong in-house capabilities for driving scale-up	Existence of appropriate partners	Available funding sources and capability to fundraise	Evidence of a potentially sizable public health impact	Evidence of compelling commercial value
Organic growth with selective out-sourcing 1	✓	✓	✓		
Multi-stakeholder partnership 2	〰	✓		✓	〰
Licensing out 3		✓	〰		✓
Open licensing 4		〰		〰	
Getting acquired 5		✓	〰		✓

Certain themes emerge when viewing these requirements, including:

- **Model 1 (organic growth with selective out-sourcing)** is most feasible when the capabilities needed for scale-up can be developed in-house by the innovator and his/her team; this is more likely for products with lower complexity and easier market access. Pursuing Model 1 also requires significant access to capital throughout the scale-up journey. When revenue streams are insufficient to sustain growth, the innovator must be capable of raising funds from donors and investors.

- **Model 2 (multi-stakeholder partnership)** is most feasible when the innovation addresses a well-recognized global health priority (usually in an area with a large disease burden and the innovation could help a a large target population) that galvanizes the attention of a group of donors, governments, and other partners. The financial attractiveness of the innovation will further strengthen the value proposition for certain stakeholders to enter into the partnership, especially private sector companies seeking to unlock access to the innovation's target markets. Finally, this model is more feasible when each stakeholder has a clear domain to contribute to bringing the product to scale.
- **Models 3 (licensing out) and 5 (getting acquired)** are most feasible when there is a compelling commercial value, such as the potential size of the market, buyers' willingness and ability to pay for the product, and potential profit margins. These models require licensees or acquirers who are well positioned to commercialize the product and bring it to scale. In both cases, innovators may still need to raise capital in the shorter term to reach the product development milestones required to attract the licensee or acquirer.

Who are the appropriate partners?

The success of each of these five scaling models partially hinges on whether the innovation (and often also the innovator) can attract the appropriate partners and forge mutually-beneficial partnerships. To do so, an innovator must acquire a clear understanding of what he/she is looking for in potential scale-up partners and what potential partners might be looking for as well (the latter topic is addressed in the next Sidebar). There are at least three dimensions to consider when defining the traits of ideal partners:

- **Capabilities and resources:** *Can the potential partners help fill the capability gaps needed for scale-up? Will they provide or help attract appropriate sources of funding?* Answering these questions requires a clear understanding of the capabilities and resources needed for scale-up, and comparing them to the innovator's existing assets. Based on the gaps identified, innovators need to identify types of organizations that can address these gaps, and conduct due diligence on specific organizations to assess their capabilities and resources. A word of caution: While multi-national corporations (MNCs) typically have a physical presence in broad geographies, they do not necessarily have the right capabilities to access a new market segment. For instance, experience launching a premier product for an affluent population does not translate into the ability to generate demand for a mass product for BOP customers. Understanding the core competencies of partners and their transferability is essential.

- **Vision and value:** *Do the potential partners share the innovator's vision of success for the product? Will they use compatible values to guide strategy and operational decisions?* Global health innovators are often driven by social impact, instead of, or in addition to, financial return. The population they wish to target, and the price-point of their products are often not the most lucrative. Innovators cannot assume that potential partners will share these impact-driven goals. For example, the most profitable strategy for distributors and resellers could be selling to more affluent customer segments, at the expense of reaching those most in need. Understanding the values of potential partners is therefore critical for ensuring the integrity of a product's intended impact and preserving the longevity of the partnership.

- **Partnership approach and implications:** *Will the partner respect the roles innovators wish to play in the partnership? Will there be any "strings" attached by partnering? Would entering into a partnership impact the innovator's ability to reach near-term milestones?* Innovators with strong preferences for how they wish to participate in scale-up need to clearly understand how each potential partner is likely to operate in a partnership (e.g., willingness to involve the innovator in decision making, restrictions placed on IP, the extent to which internal corporate processes can delay product introduction, etc.).

- **Model 4 (open licensing)** is most feasible when there are actors who are interested in and able to use the open license for social impact. While the original innovator should be confident that such adopters exist when choosing Model 4, he/she does not need to know precisely who they might be. Open-licensing often draws an unpredictable number and range of replicators and contributors. These players are often motivated by the social value of the innovation, and the innovator needs to demonstrate evidence of the social impact. If the innovation requires substantial resources to complete development and those investments must be recouped through downstream profits or revenue, this model is less feasible. For this reason, open licensing typically works best for software innovations rather than for hardware innovations.

The scaling models have very different implications for the innovator

These implications include factors such as the degree of ownership, decision-making power, financial reward, and demand on time and capacity. The exhibit below is a reference point for innovators to consider how each model aligns with their goals and preferences.

Implications for innovators to pursue each scaling model

✓ High Degree

〰 Low Degree

	Legal ownership	Decision making power/control	Potential financial upside	Ability to "off load" risk	Ability to free up time and capacity
Organic growth with selective out-sourcing 1	✓	✓	✓		
Multi-stakeholder partnership 2	✓	〰	**Variable:** depends on the dynamics between profit margin (likely lower) and the volume (likely larger)	〰	✓
Licensing out 3	✓	**Variable:** depends on the contractual terms and the stage of innovation at the time of licensing	**Variable:** depends on the contractual terms and the licensee's ability to commercialize the product	〰	〰
Open licensing 4	〰	〰		✓	**Variable:** depends on the willingness of the innovator to support others in adopting the technology
Getting acquired 5			**Variable:** depends on the valuation and deal terms	✓	✓

Again, certain themes, though not hard-and-fast rules, emerge when viewing these implications:

- **Model 1 (organic growth with selective out-sourcing)** is often preferred by innovators who want to be a founder-CEO with full ownership and decision-making control. He/she is likely to have a high tolerance for risk and able to invest the time needed for success. If the product has a compelling commercial value, he/she wants to capture the full financial upside.

- **Model 2 (multi-stakeholder partnership)** is often preferred by innovators seeking to retain ownership, are willing to share scale-up decisions, and who want to free-up their time and capacity for other pursuits. This model also allows innovators to offload some, but not all risk, as he/she will continue to be involved in the scale-up journey, usually on a more prominent platform. Collaboration with donors and governments often leads to strong downward pressure on product pricing and profit margins. Even so, the total financial return could be more or less than the returns from other models, depending on the sales volume and market access for other products.

- **Model 3 (licensing out)** is for innovators willing to trade off some decision-making control (although the degree could vary significantly depending on the stage of the product at the time of licensing and the contractual agreements between the innovator and licensee) to free up time and capacity, and share risk with others. However, some innovators choose to be involved in scaling up their products after licensing out, continue to provide expertise and ensure the products are reaching intended beneficiaries while being commercialized.
- **Models 4 (open licensing) and 5 (getting acquired)** are for innovators interested in completely offloading scale-up risk. Model 4 is for those willing to sacrifice financial gains (and don't need to recoup development costs, which could be high for an innovation that involves hardware), but who wish to retain some ownership and decision-making control, and who continue to devote time and capacity to support others who adopt and scale-up the innovation. Model 5 is preferred by innovators who want to participate in the financial upside from the sale of the business, and fully exit from future involvement with the innovation and/or the business.

Innovators' choice of scaling model flows from two questions: "Which model is most feasible for me to pursue?" and "Which model is best aligned with my goals and preferences?" We developed a set of exercises to help innovators answer these two questions and identify the scaling model best suited to them. Chapter 4 overviews the exercises. The exercise worksheets and examples are available as a companion booklet and can be downloaded at www.usaid.gov/cii.

What are potential partners looking for?

A few of the most common factors partners look for include: technical viability, potential health and other social impact, user acceptance and demand, strategic relevance to the partner, and the commercial attractiveness of the business model. However, given the diversity of potential partners and their motivations, the relative importance of these factors and the criteria for assessing them can vary significantly. Potential partners for global health products and technologies span a wide range, including donors, governments, investors, medical device companies, manufacturers, distributors, global health NGOs. Their motivations are also highly diverse, even within one type of organization.

Take medical device multi-national corporations (MNCs) for example. Some MNCs are pursuing social impact and seek to partner with and support global health innovators through corporate social responsibility (CSR) efforts. Other MNCs are looking to address unmet needs for medical devices, alongside commercial opportunities in emerging markets, and have established regular business units to do so. While both groups of MNCs would certainly expect to see evidence of technical viability and user demand, the group with dual motivations would place a greater emphasis on strategic relevance and commercial attractiveness.

Strategic relevance includes considerations, such as if the innovation addresses a priority clinical focus area (e.g., an area that represents a significant disease burden and unmet needs among a large target-customer segment), if the innovation complements the existing portfolio of the company (e.g., the innovation facilitates market access for other products), and if the company can add value to accelerate the innovation's scale-up (e.g., the company's core competencies will fill the biggest capability/resource gaps for the innovator), and more.

Commercial attractiveness could include considerations, such as if there is a clearly identified buyer market (e.g., selling through large, public sector tenders, or selling to individual consumers), if the company and/or innovators will be able to penetrate the buyer market (e.g., if selling to government, having the ability to navigate government and donor procurement processes), and if the barriers to uptake have been mapped and solutions identified (e.g., if provider expertise is a barrier, developing an appropriate and scalable provider training model), and more.

Innovators can begin assessing these factors through research in the public domain and discussions with advisors. However, we encourage innovators to initiate frank discussions with potential partners and build an accurate and detailed understanding of their motivations and requirements.

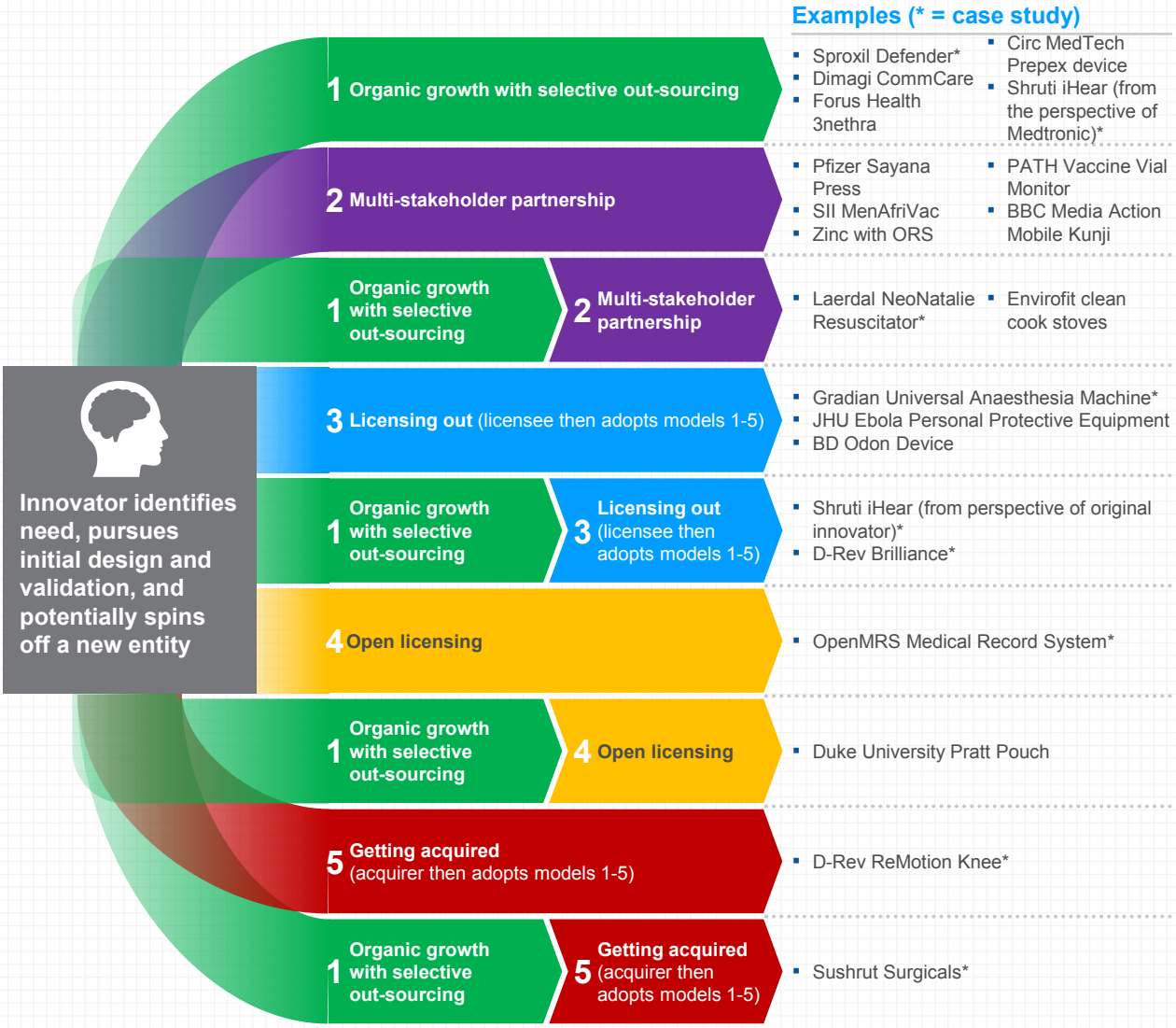
Case Studies

Are you an innovator? The global health innovation community becomes stronger through sharing collective experiences, lessons learned and best practices. We want to hear about your pathway to scale. Email us at cii@usaid.gov with your stories.

Photo: Getty Images

While we have identified five dominant models for taking innovations to scale, many successful global health innovations do not follow a single path, but often sequence a number of models. For example, ear screening device used in Medtronic's Shruti iHear program was originally developed by an Indian innovator who drove product development on his own before partnering with local industrial design firm Icarusnova, and eventually licensing out the technology to Icarusnova. The technology was then licensed in by Medtronic, which drove the design, implementation and scale-up of Shruti iHear in collaboration with a number of partners.

Innovators can also vary the scaling models used for the same product in different geographies, or pursue different models for different products in their portfolio. For example, D-Rev licensed out Brilliance to a major Indian medical device company with exclusive rights in the Indian market, but non-exclusive rights elsewhere, providing the company with the ability to adopt different models in other countries. For a different product, the ReMotion Knee, D-Rev is driving scale-up directly with select manufacturing and fulfillment partners. The image below illustrates a variety of pathways innovators have pursued on their journeys to take their products to scale and lists examples.[1]



In this section, we present eight case studies of innovations that have begun to scale, or in some cases, have already reached significant scale. Each case highlights the scaling model used, key decision points, and the rationale driving these choices. The case studies reflect a range of different pathways and demonstrate the evolving nature of these pathways, as many of the innovators profiled revisited their choices throughout their journeys.

1 Note that the examples shown are taken from the original innovator's perspective, unless otherwise noted. The name of the organization, however, may or may not reflect the original innovator's affiliation.

Photo: Sproxil

SPROXIL DEFENDER

SCALING MODELS HIGHLIGHTED

- Model 1: Organic growth with selective out-sourcing

OVERVIEW

Started by Ashifi Gogo, Sproxil's solution, Sproxil Defender™, allows consumers to text a unique code attached to a product to an in-country phone number, which validates the code to confirm the packaging authenticity of pharmaceuticals, consumer goods and many other products. Sproxil Defender is both novel and incredibly useful for people living in countries where counterfeiting is rampant. Similarly, Sproxil Defender helps companies battle counterfeiters who damage their brand and reduce their market penetration, as companies can access data[1] to locate hotspots for counterfeiting and work with the authorities to curtail illegal activities. Sproxil Defender is currently being used in six countries and through adoption of the solution, one client reported a 1,000% return on investment from increased sales.

PATHWAY TAKEN

Initial innovation

University innovator incorporated for-profit entity

Dartmouth student Ashifi Gogo founded an organization that developed a novel technology to combat counterfeit drugs in developing countries

Gogo saw compelling commercial value in the innovation, alongside the social impact, and incorporated Sproxil as a for-profit company in 2009

Organic growth with selective out-sourcing

Piloted innovation in Nigeria

Sproxil conducted its first market testing in Nigeria with support from the government, after a period of public outcry due to the adverse effects of counterfeit drugs. They worked together to apply the Sproxil solution on a diabetes medication and gained proof of concept. Within a few months, the partnering pharmaceutical company saw a 1000% return on their investment

Built internal capabilities to drive scale-up, including sales force for some countries

Sproxil has been able to manage most of the value chain in house, from sales to customer service

It has taken a country-specific approach to market access. In some countries, (e.g., Ghana, Nigeria, India and Pakistan), Sproxil has developed a small sales force to work with corporate customers

Partnering with "resellers" in some countries to access market

For some markets Sproxil has used resellers to reach the buyers, as these regions require deep knowledge of local business practices and would take years for Sproxil to develop in house capabilities

Continue to grow

Financing

Primarily founder seed capital

Impact equity ($1.79M from Acumen Fund) and impact debt

1 Sproxil complies with all applicable data privacy laws and regulations, as outlined in its Terms of Service

RATIONALE FOR DRIVING SCALE-UP WITH VERY LIMITED OUTSOURCING

- **Sproxil had the internal capacity for most scale-up activities:** As Gogo and partners at Sproxil began to think about scale-up, they recognized that the required capabilities could be developed internally. Their product did not require clinical trials and had a very low regulatory burden. Also, it did not have complex manufacturing requirements or servicing needs.

- **It was feasible for Sproxil to selectively outsource sales to partners in a few countries:** While Sproxil was capable of setting up marketing and sales operations in new markets, its start-up capital was insufficient for its scale-up goals. Moreover, over the coming years, its potential revenue from some countries was far below the start-up capital it needed. Therefore, while Sproxil prefers to interface directly with clients in all markets, there are some countries where working with a reseller is more effective.

- **Organic growth with selective out-sourcing aligned with Sproxil's organizational preference:** Gogo and its team prefer to maintain full control of the strategic direction of their business so they can maximize the social impact and capture any financial upside. Gogo was willing to take the risk of committing the time required to drive scale-up through Sproxil. As it grows, Sproxil will continue building its in-house capabilities, maximize margins and consolidate know-how by developing sales forces in countries currently using resellers.

> "There are some markets where the business opportunity is not big enough to set up on-the-ground operations. In order to scale, we are using a mix of distribution options. In some markets we partner and in others we build our own operations.
>
> *–Danielle Goldscheider*

Photo: Medtronic

SHRUTI IHEAR
PART A

SCALING MODELS HIGHLIGHTED

- Model 1: Organic growth with selective out-sourcing
- Model 3: Licensing out

OVERVIEW

Shruti iHear is a diagnostic program to identify hearing problems among low-income populations. In its base version, the ear screening kit used in Shruti iHear includes four components: a medically-approved otoscope to examine the eardrum and passage of the outer ear, a smart phone, a light source and a SIM card. Specially trained public health workers use this screening kit to administer diagnostic tests, identify unhealthy ears and damaged ear drums, and transmit photos to ENT surgeons who then call patients with complex problems to advise them if further consultations or surgery are needed. Approximately 200,000 people have been screened using the Shruti iHear system, and its reach continues to grow. Shruti iHear is driven by Medtronic and involves a wide range of partners, including the innovator of the otoscope, Jagdish Chaturvedi. Part A of this case study follows Jagdish's journey to invent the otoscope (which was originally intended for throat endoscopy, but can be used for ears as well). Part B of this case study follows Medtronic's journey to create the Shruti iHear program.

PART A: PATHWAYS TAKEN BY THE ORIGINAL INNOVATOR JAGDISH CHATURVEDI

Initial innovation

Innovator identified need in market for low cost endoscope

Jagdish Chaturvedi, an ENT trainee in India, noticed that many of his low income patients were coming into the hospital with advanced throat cancers, caused by the lack of equipment for healthcare providers in rural areas to detect small lesions and cancers in the throat

Built prototype

Encouraged by his mentors, Chaturvedi worked with an engineer to develop a portable prototype that paired a commercially available camera with a scope for ear, nose & throat endoscopy, although the primary use was for throat

Organic growth with selective out-sourcing

Incorporated company and filed for IP

In 2010, Chaturvedi filed for IP and incorporated as a company, after getting advice via participation in a business case competition

Partnered with Icarusnova on more advanced proto-type development

Realizing the need for more product development expertise, Chaturvedi partnered with Icarusnova, an Indian industrial design firm, to further develop the prototype. Driven by patient needs, the focus was on applying the technology to throat imaging

Licensing out

Licensed technology to Icarusnova

In 2013, running out of funding, Chaturvedi entered into a technology licensing deal with Icarusnova, and continued to remain involved in the clinical aspects of the product development

Sought licensing to a larger company

Chaturvedi realized that Icarusnova could only take the technology so far, due to lack of commercial experience, and began to look for large medical device and pharma companies that would be interested in licensing the solution from Icarusnova

To be continued in Shruti iHear Part B

Financing

Founder seed capital

Licensing fee

RATIONALE FOR THE PATHWAY CHOSEN

- **Chaturvedi's capability gaps included raising capital, medical device development expertise, and the commercial skills required to scale:** Soon after Chaturvedi developed the original technology for Shruti iHear, he realized he lacked many of the core capabilities required to scale the product. To create a more market-ready product, Chaturvedi needed greater design and medical device development expertise. He also needed manufacturing capabilities, and the know-how to oversee quality control for the product. Moreover, he lacked a distribution channel to reach those who would benefit from his device – the people working with the poor in India who could get his product into the hands of users – which required both a strong distribution network and service delivery capacity that he did not have.

- **Chaturvedi and Icarusnova preferred not to develop in-house commercialization capabilities to drive scale-up:** Neither Chaturvedi nor Icarusnova could develop significant in-house commercialization capabilities. Chaturvedi wanted to remain primarily an inventor and Icarusnova, an industrial design firm, did not have the experience to bring the product to market.

- **Given their preferences and capability gaps, Chaturvedi and Icarusnova decided to license the technology to an established medical device company:** Chaturvedi and Icarusnova were happy to license the innovation to Medtronic, because Medtronic engaged both Chaturvedi and Icarusnova to help it develop parts and contribute to the scaling process.

> "As a physician during my training, I took my innovation as far as I could. However, after the first prototype, I did not have the resources to continue developing it. That is when I licensed the technology to Icarusnova. For me, it was the best way to get the expertise needed to make progress toward scaling.
>
> *–Jagdish Chaturvedi*

Photo: Medtronic

SHRUTI IHEAR
PART B

SCALING MODELS HIGHLIGHTED

- Model 1: Organic growth with selective out-sourcing

PART B: PATHWAYS TAKEN BY MEDTRONIC

Following Shruti iHear Part A

Organic growth with selective out-sourcing

Continue to grow

Medtronic developed interest in BOP hearing diagnostic

Medtronic developed interest in building a program to address a significant disease burden affecting underserved populations in emerging markets. The Shruti program emerged to serve this purpose by bringing together technologies and an ecosystem of partners to care for patients

Medtronic identified ear-related illness, especially chronic ear infection, a significant cause of preventable hearing loss

Medtronic licensed technology from Icarusnova

Screening was an important component of the Shruti program, and Medtronic needed to find a solution that public health workers could use to diagnose ear problems

Among three potential solutions, Chatervedi's technology stood out as the most appropriate

Medtronic licensed the technology from Icarusnova and continued to engage Icarusnova for redesign the prototype for use by public health workers and for manufacturability

Medtronic partnered with ClickMedix for custom software

Realizing the need for a software platform to collect data, the Medtronic team partnered with ClickMedix, a mHealth social venture, to build a customized application

Medtronic partnered with multiple NGOs for implementation and scale-up

In 2013, with a strong prototype, Medtronic partnered with organizations with the network and experience to deliver products and services to low income communities, e.g. Dr. Shroff's Charity Eye Hospital and Health Management Research Institute. These partner organizations are driving scale-up in specific geographies, while gathering data and evidence that will allow Shruti to further partner with delivery organizations going forward

Financing

Shruti Program funded by Medtronic within the company's Transforming Healthcare program

RATIONALE FOR THE PATHWAY CHOSEN

- **While Medtronic had many of the capabilities needed to develop and scale up Shruti iHear, it needed external partners locally to develop a ground level innovation:** Once Medtronic licensed the technology from Chaturvedi, it was clear that this large company, will have to go beyond traditional product development capabilities (for Shruti program product) to innovate and to scale. Medtronic did have the capabilities and experience to complete product development and manufacture the otoscope, as well as the capital to finance the scaling process. However, it lacked start-up innovation culture to build the software component required for data collection. Additionally, the target users and beneficiaries of Shruti iHear are very different from Medtronic's typical customers, so the company needed to identify ground-up methods to develop the social business ecosystem.

- **Medtronic wanted to manage the ecosystem but limit on-the-ground presence:** For strategic reasons, Medtronic wanted to manage the ear care ecosystem for effective scaling up of Shruti iHear. However, it did not want to directly build up and manage a field workforce for the program.

- **Medtronic was able to find a range of partners to work with in scaling-up Shruti iHear, including service delivery organizations to reach beneficiaries:** Medtronic engaged with Icarusnova and Chaturvedi to develop a modified prototype best suited for use by public health workers and retained Icarusnova to help with design and oversee the manufacturing. It partnered with ClickMedix to develop Shruti's software platform. Medtronic continues to drive the scale-up strategy, but is working with numerous service delivery NGOs, such as Dr. Shroff's Charity Eye Hospital and Health Management Research Institute, to train health workers to use the technology and bring the service to low income communities.

Photo: Laerdal

LAERDAL NEONATALIE RESUSCITATOR

SCALING MODELS HIGHLIGHTED

- Model 1: Organic growth with selective out-sourcing
- Model 2: Multi-stakeholder partnership

OVERVIEW

Laerdal Global Health, an independent sister company of Laerdal Medical, is a not-for-profit company that develops products and programs aimed at helping save the lives of newborns and mothers in low-resource countries. Their innovations include devices and training programs that are designed to be durable, simple, culturally-adaptable and affordable.

Laerdal Global Health was formed after entering into a partnership with a USAID-supported Global Development Alliance called Helping Babies Breathe (HBB). The partners brought together a complementary mix of capabilities and interests: USAID and Save the Children had strong networks in low-resource settings and needed a strategy to address newborn asphyxiation. With support from the Laerdal Foundation, the American Academy of Pediatrics (AAP) and the National Institute of Child Health Development (NICHD) developed educational materials for newborn resuscitation that were appropriate for low-resource settings. Laerdal Medical also developed a low-cost neonatal resuscitator. Other partners, including Johnson & Johnson and Latter-day Saint Charities, had previously supported newborn resuscitation programs and wanted to expand their efforts. Additional partners came on board to support and help scale HBB as the program demonstrated early success.

As of March 2015, the HBB program has been used in 77 countries by over 300,000 specially-trained heath providers. Laerdal Global Health has provided 70,000 NeoNatalies and about 200,000 suction and resuscitation devices to support HBB. Through the program, trained health care providers successfully resuscitated 84% of the babies that were not breathing at birth, a marked increase.[1]

PATHWAY TAKEN

Organic growth with selective out-sourcing

Laerdal developed infant resuscitator device, and supported AAP to improve education of infant resuscitation

Laerdal developed and commercialized infant resuscitator device, not specifically aimed at low-resource settings.

Since 2006, American Academy of Pediatrics (AAP) worked with partners to develop an education program for neonatal resuscitation in low resource settings

Laerdal Foundation supported this work financially and provided technical expertise

Financing: *Laerdal Medical's investments in product development; Revenue from sales of infant resuscitator devices in developed markets*

Multi-stakeholder partnership

Laerdal joined USAID and partners to form Helping Babies Breathe (HBB)

In 2010, Laerdal Foundation joined USAID, AAP, Save the Children, and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) to form a Global Development Alliance to improve infant survival in the "golden moment" after birth

Laerdal supported healthcare training programs for health care personnel on use of resuscitation equipment

Financing from Laerdal Foundation (Laerdal Medical provided $30 million to Laerdal Global Health through 2017); Revenue from sales of devices at cost

Laerdal Global Health worked with HBB partnership to scale up

As provider training rolled out across countries, Laerdal began to supply its resuscitation equipment at cost to HBB partners that support the program, which involved redesign of existing devices to suit local needs

Laerdal also donated simulators and other equipment to enhance use and spark further demand

Laerdal Global Health continues to innovate, but will need to become fully sustainable

Laerdal Global Health is using feedback from HBB program and impact assessments to improve products, and is testing an improved resuscitator design

From 2018, Laerdal Global Health will need to be fully financially sustainable

The HBB program is broadening in scope under the Survive and Thrive partnership

Partnership funding will continue as HBB broadens its scope

Continue to grow

1 Helping Babies Breathe catalyzing Helping Babies Survive webinar presentation, June 2015

RATIONALE FOR ENTERING INTO MULTI-STAKEHOLDER PARTNERSHIP WITH HBB

- **Laerdal had strong in-house capabilities to develop and scale innovations, but needed support to understand, access and build demand in new markets:** Laerdal Medical is a leading provider of medical products and training programs for emergency medical care, with a focus on resuscitation. The company had developed the neonatal resuscitation device, and wanted to expand the market for the device to low-resource settings, where there was significant need. Prior to the formation of the HBB partnership, the Laerdal Foundation was already funding the AAP and others to develop a new, simplified neonatal resuscitation program appropriate for low-resource settings.

- **The HBB partnership, which was formed with the shared goal of scaling up neonatal resuscitation, provided Laerdal with numerous additional capabilities.** The HBB program provided additional financing, advocated including resuscitation equipment in the WHO and Interagency List of Essential Medical Devices, conducted impact assessments of the products and programs, and offered access to the networks and capabilities of USAID and numerous global health organizations. As a partner, Laerdal supplied HBB with resuscitation equipment at cost, and provided guidelines on purchasing and maintaining the equipment. To further build demand and contribute to the HBB program's success, Laerdal donated simulators and other equipment, and in select countries, Laerdal offered grants to support training.

- **Entering a multi-stakeholder partnership through HBB offered the most feasible pathway for Laerdal to achieve scale, given the need to build demand and address numerous barriers in the market:** Prior to the formation of HBB, an assessment of the neonatal resuscitation market in low-resource settings identified numerous challenges. For example, distribution channels were not well developed and barriers existed in shipping and customs; there were no consistent purchasing standards; national and sub-national programs lacked technical guidance and training; and the use of outdated or unsafe products was widespread. In addition to leveraging the strengths of partners to tackle these market challenges, the HBB partnership provided additional benefits to Laerdal and partners. The HBB partnership facilitated program introduction in countries, built credibility among health and medical networks, developed a platform to train health workers and validated the innovations and approach via impact evaluation and dissemination. Further, USAID served as the initiator, financial supporter and facilitator of the program, coordinating the various partners and activities. The distribution of activities and responsibilities among partners enabled Laerdal and others to focus on the key competencies each brought to the partnership.

- **Being part of HBB also offered Laerdal the opportunity to make its innovations widely available and to achieve a significant health impact:** Laerdal was committed to expanding the use of its neonatal resuscitation programs and products, and was investing in activities to scale before HBB was created. As a partner in HBB, Laerdal is improving the quality of its resuscitation equipment, lowering its costs, and developing efficient supply systems to deliver the equipment. Laerdal's investment in the HBB program resulted in the creation of Laerdal Global Health, which from 2018 will continue to innovate and supply products for women and children in low-resource settings on a sustainable basis (i.e., full cost-recovery).

Photo: D-Rev

D-REV BRILLIANCE

SCALING MODELS HIGHLIGHTED

- Model 1: Organic growth with selective out-sourcing
- Model 3: Licensing out

OVERVIEW

Brilliance is a line of low-cost, energy-efficient, durable, phototherapy devices for babies born with jaundice, a significant cause of infant mortality in low-income communities. D-Rev developed Brilliance after identifying functioning phototherapy units in health facilities as a significant unmet need. D-Rev's mission is to close the healthcare quality gap for people living in underserved communities by designing and delivering medical technologies for these populations. To date, close to 1,500 Brilliance units have been installed and have impacted the lives of over 120,000 infants.

PATHWAY TAKEN

Initial innovation

D-Rev identified need for innovation

D-Rev, a non-profit global health technology company, identified the lack of functioning phototherapy units in health facilitates as a significant cause of infant mortality in low-income countries

D-Rev conducted a detailed assessment of the phototherapy landscapes in India and Nigeria, and decided to design a technology to address this unmet need, leading to the development of Brilliance

Organic growth with selective out-sourcing

Built prototype and assessed capabilities for scaling

D-Rev built prototype and conducted the early tests with promising results on the technical performance of the unit

In thinking about how to take Brilliance to market and to scale, D-Rev evaluated its own capabilities and found gaps in multiple areas. To fill these gaps would require significant capital and involve high risks, especially to develop a local network for sales, distribution, and after-sale servicing

D-Rev believed that licensing to an established medical device company could be the best path to accelerating the market entry and scale-up of Brilliance

Licensing out

Licensed technology to Phoenix, took measures to ensure product reaches low-income communities

In 2012, D-Rev licensed Brilliance to Phoenix Medical Systems, the largest manufacturer of neonatal care equipment in India. Phoenix has rights to manufacture, distribute and sell exclusively throughout India and non-exclusively in much of the rest of the world.

D-Rev was very careful to select a licensing partner, conducting in-depth diligence on each candidate's manufacturing standards, after-sale service, and sales and distribution network. In addition, D-Rev chose Phoenix given aligned goals and compatible values

D-Rev structured the licensing agreement to incentivize sales to public hospitals in India and low-income countries by taking a lower royalty; it also agreed to cap selling price to ensure affordability

Continue to grow

Financing

Support for product development (~$1.1M) mainly from unrestricted funds provided by the Mulago Foundation and individual donors

D-Rev receives licensing fees and royalties Phoenix Medical Systems receives revenue from sales

RATIONALE FOR LICENSING OUT TO PHOENIX

- **Scaling up Brilliance required extensive sales, distribution and servicing capabilities that D-Rev could not easily develop in-house:** After developing Brilliance and conducting the initial testing, D-Rev realized that it would be difficult to take the innovation to scale using only internal capabilities. Although India's regulatory requirements are low, the product required a CE marking and ISO certified manufacturing to be marketed effectively to target customers, which was resource intensive for D-Rev to accomplish alone. Additionally, the buyer landscape - including hospitals, clinics and public health system procurers - is fragmented, necessitating a strong sales force and brand to penetrate. Many potential markets are also skewed by a strong presence of donated equipment. Finally, as is the case with many medical devices used repeatedly in hospitals, a locally-based servicing network is needed, which would be costly and inefficient for D-Rev to set up.

- **D-Rev recognized that serving the needs of poor families required extensive downstream support that would be inefficient to build in house:** D-Rev wants to focus on the design and development of new products, rather than commit significant energy and resources to sales and distribution. At the same time, D-Rev is committed to maximizing the social impact of its products, and requires partners who share the same incentives and goals. As a result, the preferred scaling model for Brilliance was to license to a mission-aligned company through an agreement that allows D-Rev to retain some degree of control over customers being served.

- **In the end, licensing was a feasible scaling model for D-Rev, as it found a licensee to help drive commercialization and scale-up:** D-Rev chose a licensee, Phoenix Medical Systems, the biggest neonatal equipment maker in India. Phoenix helped improve product design, drove the remaining clinical and regulatory approval activities, provided manufacturing capabilities at-scale, and brought the product to market through its network of distributors in India and beyond. Phoenix is a for-profit company with a mission-aligned CEO who was motivated to provide high-quality medical solutions in low-resource environments. In the licensing deal, Phoenix gained exclusive rights to manufacture and sell Brilliance in India, and non-exclusive rights in much of the rest of the world. The licensing agreement is unique in that it marked the first time that a US-based nonprofit received licensing fees and royalties from an Indian for-profit healthcare company. The royalties were structured to provide incentives for Phoenix to sell to public hospitals, and Phoenix agreed to cap the selling price of Brilliance. Today, D-Rev still contributes to the marketing of Brilliance in India and is driving the introduction and scale-up of Brilliance in other developing country markets.

> "Phoenix was the right licensing partner for us because their CEO shares our goals. Having an aligned outlook with the company you license your innovation to is essential for scaling.

–Vinesh Narayan

Photo: OpenMRS

OPENMRS MEDICAL RECORD SYSTEM

SCALING MODELS HIGHLIGHTED

- Model 4. Open licensing

OVERVIEW

OpenMRS is a large, flexible, technology platform that supports the delivery of healthcare in low-resource settings. Founded in 2004 by Paul Biondich, Burke Mamlin, Hamish Fraser and Chris Seebregts, OpenMRS started as a free and open-source medical records system for developing countries. A global network of volunteers and organizations now help the platform expand, and support the growing base of independent users of the software platform and reference application. Through 2015, OpenMRS was used in at least 1,100 locations across 27 countries and healthcare providers have used it to improve care for over 5 million patients[1]. Seven countries have pursued, or are pursuing, the national implementation of OpenMRS throughout their clinics and hospitals.

PATHWAY TAKEN

Founders met and realized a shared vision for an open MRS system

In 2006, Paul Biondich (Indiana University) visited western Kenya to support an HIV care program (MPATH) and saw the need for an electronic medical record system to improve healthcare quality

While designing the solution, Biondich and partner Burke Mamlin (Regenstrief Institute) met Hamish Fraser (Partners in Health) and Seebregts (South African Medical Research Council), who were addressing a similar problem. They decided to collaborate and write software together remotely, thus unintentially setting up OpenMRS as an open source project

The first OpenMRS platform was deployed in Kenya, Rwanda and South Africa in 2006

Founders remained at their home organizations to build support for the OpenMRS platform

Open licensing

From 2006 to 2010, OpenMRS existed with minimal organizational structure (a registered LLC to house the public license, 4-person management team to protect the license on behalf of the community)

A global "community of practice" formed and grew with volunteers contributing to programming, building the community (online forum, live events, technical support), surfacing needs and problems and then addressing them collectively. A new version of OpenMRS was released each year

New deployments of the platform were run by independent organizations, occasionally with technical support and training provided by the core team of OpenMRS developers

Grants given to partner organizations for implementation partially funded the development of new features (based on the needs of these partners)

Supporters and collaborators contribute to OpenMRS expansion

In 2010, as the community grew, the founders recognized the need to formalize coordination and support of the OpenMRS ecosystem, and registered a non-profit (501(c)3) to own all OpenMRS materials, maintain the public license, fundraise, and support training, certification and other activities

OpenMRS is being scaled-up by its partners (Partners in Health, South African Medical Research Council, Millennium Villages Project, IDRC), organizations that decide to implement the system for themselves, and a growing number of independent "distributor" organizations that modify and productize the system, and help others to implement

Continue to grow

Financing

In-kind and monetary support from the founder organizations

Grants and in-kind support from global health donors and partners (e.g. Rockefeller Foundation, US CDC, the World Health Organization) to fund implementation and new-features development

1 Due to the open source nature of OpenMRS, it is difficult to precisely track the number of countries and locations operating OpenMRS or OpenMRS-derived systems. According to the founder, Paul Biondich, OpenMRS has been implemented in over 50 countries.

RATIONALE FOR CHOOSING AND MAINTAINING OPEN LICENSING

- **Open licensing was a convenient choice for the founders to efficiently collaborate on software development remotely:** At the start, the founders of OpenMRS did not choose open licensing with the intention of establishing an open-source project and building a community around it. When the founders met each other, they were two groups of people working independently on software for which they shared a common goal: improving healthcare quality in resource-limited settings through an information system. Given limited capacity and resources, they decided to join forces and develop a common product. Not having a closed license was the most efficient way for them to collaborate remotely and write software together. Quickly, others learned about their efforts, wanted to contribute and the community of practice started to grow organically and unintentionally.

- **As OpenMRS evolved, open licensing continued to be the best way to expand its impact and tap into the capabilities and resources of like-minded supporters and contributors:** Even after joining forces, the founders and their organizations did not have all the resources and capabilities required to fully develop, implement, and scale-up their electronic medical record system. An open project allowed them to crowd-source volunteers and supporters at a time when a growing number of engineers, public health organizations, governments, and donors were interested in solving a common problem. Much of the software was developed by volunteer coders, and a host of organizations mobilized their resources (e.g., applying for grants) to implement OpenMRS for themselves, allowing the "core" of OpenMRS to remained lean. In addition, the open platform has encouraged financial support and in-kind contributions, such as license donations, from global health funders, technical organizations and software firms. These partners are evangelists of the system, enabling OpenMRS to spread through word-of-mouth, without advertising. While a nonprofit entity was registered in 2010 to formalize governance, expand the leadership team, and enable fundraising and other community-enhancing activities, the founders are committed to maintaining the open license and allowing others to freely use OpenMRS to improve healthcare quality around the world.

- **In addition to feasibility and efficiency, open licensing and the "community model" are aligned with the philosophy of the OpenMRS founders:** From the start, the founders shared the philosophy of supporting and empowering people to solve their own problems. While they realized their platform could potentially address an enormous need in health systems around the world, they wanted to achieve impact through the agency of local actors. The best pathway to reaching this objective was to build and support an open and flexible platform that many organizations could use and adapt with no strings attached, and provide support only when asked. Depending on the needs of its partners, the OpenMRS core team offers support through online sharing platforms, annual conferences, training, and on-the-ground implementation (funded through grants). In turn, these partners are invested in OpenMRS' success.

> “By making everything freely accessible, we empower local ecosystems to form and build their own solutions.
>
> *–Paul Biondich, OpenMRS*

Photo: D-Rev

D-REV REMOTION KNEE

SCALING MODELS HIGHLIGHTED

- Model 1: Organic growth with selective out-sourcing
- Model 5: Getting acquired

OVERVIEW

D-Rev's ReMotion knee is a prosthetic knee joint designed to be more durable and provide a better range of motion than standard prosthetics available to low-income people. Unlike Brilliance, D-Rev did not create ReMotion from scratch. The original innovators, three graduate students at Stanford, assigned the technology to D-Rev to further develop the prototype and eventually commercialize the product. ReMotion was launched in the market in 2015. To date, D-Rev and its clinical partners, including the JaipurFoot Organization, have reached over 7,000 users in India and around the world through ReMotion knee.

PATHWAY TAKEN

Initial innovation

University students designed knee joint, created new org

In 2008, As part of a design project for a class at Stanford University, graduate students developed the initial design of Jaipur Knee, a low-cost prosthetic knee joint, on behalf of the Jaipur Foot Organization

In 2010, three graduate students created a separate organization, ReMotion Designs, and designed a new knee with similar mechanism and conducted field trials in Ecuador

Getting acquired

ReMotion absorbed by D-Rev, which completed product development

The students saw that there was real potential for the innovation to reach those in need and chose to join forces with D-Rev, a non-profit technology incubator

In 2011, D-Rev worked with students to develop the prototype based on user feedback, conducted user testing in the field and began to build a scalable business model

Organic growth with selective out-sourcing

D-Rev outsourced to contract manufacturer

ReMotion Knee was launched in 2015. D-Rev outsourced mass production to a Chinese contract manufacturer who could produce at high volumes and bring down unit cost

D-Rev developed internal capabilities in sales and distribution

To date, D-Rev has built internal capacity to acquire customers and fulfill orders, and outsources warehousing and shipment to an external contractor

Continue to grow

Financing

Stanford University support

Acquisition by D-Rev

Support for product development (~$1.7M) from D-Rev's financial support and project-specific support from a broad mix of donors including the Wellcome Trust, IUSSTF, Focusing Philanthropy, Lemelson Foundation, and the Autodesk Foundation

RATIONALE FOR D-REV TO DRIVE SCALE-UP WITH SELECTIVE OUTSOURCING

- **Early on, D-Rev identified manufacturing and sales/distribution as capability gaps it needed to fill in order to bring ReMotion to scale:** D-Rev based this assessment on ReMotion's key product and market features , and the implications they have on the scale-up capabilities required. The overall market for prosthetics for above-knee amputees in low-income environments is still nascent and small, therefore centralized manufacturing is not only possible, but also necessary to reduce unit production costs and achieve economies of scale. Moreover, the purchasers of their product - clinics and hospitals - are fragmented, and locally-based sales and distribution will eventually be needed to serve such a market at scale. D-Rev is able to offer some capabilities in-house: clinical and regulatory (given that the product has low clinical and regulatory requirements), and after-sales servicing (easy to provide, as broken prosthetic knees can simply be replaced with new ones as long as they were within warranty).

- **D-Rev's desire to focus its energy on upstream innovation, while having the assurance that ReMotion would serve poor customers, led to licensing as the preferred scaling model:** D-Rev's organizational goals conflicted with the existing market in some ways. D-Rev wanted to remain a highly innovative organization that devotes most of its time and resources to its core competency – developing a portfolio of products that address the urgent health needs of the poor, rather than the downstream activities of commercialization and scale-up. At the same time, it wanted to retain sufficient control and decision-making power to ensure ReMotion reached as many people as possible. As a result, the preferred scaling model was to license to a mission-aligned company through an agreement that would allow D-Rev to retain some degree of control over customers being served, much in the same way it licensed Brilliance to Phoenix Medical Systems.

- **However, as there were no suitable potential licensees in the market, D-Rev followed an alternative path:** driving scale-up themselves and outsourcing production to a contract manufacturer. Thus far, D-Rev has not found an appropriate licensing partner in the market. However, as the market is still nascent, it is feasible for D-Rev to develop the needed sales and customer engagement capacity in-house. D-Rev has partnered with a central manufacturer in China and a third-party logistics company to warehouse and ship when needed. As the prosthetics market grows, sales and distribution will demand more time and resources from D-Rev. By putting these systems in place now, D-Rev hopes to demonstrate the viability of the product and attract long-term partners, including licensees, and eventually find value-aligned partners and/or licensees that enable it to stay true to its identity as an innovation organization.

> "It is critical to have a deep understanding of both the consumer and your market. We learned about product design through our field work but also learned about pricing, customer preferences, and distribution that have shaped the ReMotion Knee and have allowed us to scale.
>
> *–Vinesh Narayan*

Photo: Gradian Health Systems

GRADIAN UNIVERSAL ANAESTHESIA MACHINE

SCALING MODELS HIGHLIGHTED

- Model 1: Organic growth with selective out-sourcing
- Model 3: Licensing out

OVERVIEW

The Universal Anaesthesia Machine (UAM) is a general anesthesia machine that can work in any operating room, including those with unreliable access to electricity and/or compressed oxygen. Gradian Health Systems, the company currently in the scale-up phase with its UAM has the mission to strengthen access to safe surgery through technology, training and service. As of early 2016, Gradian has equipped over 150 operating rooms with UAMs in 24 countries in Africa, Asia, Europe and the Caribbean.

PATHWAY TAKEN

Initial innovation

Innovator identified need and developed prototype

Dr. Paul Fenton, a British anaesthesiologist with years of experience working in a hospital in Malawi saw an unmet need in his operating room for a machine that could supply anaesthesia in conditions of intermittent power and access to compressed oxygen

He designed the first prototype of the Universal Anaesthesia Machine (UAM) by 1999, and tested it in Malawi through 2001

Financing: *Self-funded*

Licensing out

Innovator licensed innovation idea to Nick Simons Foundation

Recognizing the market need for this kind of innovation, the Nick Simons Foundation provided seed funding to further develop and test the UAM, and eventually acquired the rights to the product

In 2010, GradianHealth Systems was created as a wholly-owned subsidiary of the Foundation to produce and commercialize the UAM around the world

Financing: *Grant funded by parent organization - Nick Simons Foundation*

Organic growth with selective out-sourcing

Gradian partnered with contract manufacturer

Gradian chose OES Medical, a single contract manufacturer with experience in anaesthesia located in the United Kingdom to provide the specific capabilities and skills needed to produce the machine

Financing: *Nick Simons Foundation*
OES Medical

Gradian working with multiple partners for sales, distribution and after-sale servicing

Gradian works with multiple partners to navigate a complex marketplace with interconnected stakeholders, distribute the product, and provide after-sales training and servicing

In addition, Gradian works closely with its in-country distributors to ensure appropriate training on the product and company mission; having these partners is critical, as building the capabilities in house to address numerous countries would be financially and logistically inefficient

Financing: *Product pricing to consumers covers cost, overhead paid by Nick Simons Foundation*

Continue to grow

RATIONALE FOR GRADIAN TO DRIVE SCALE-UP AND WORK WITH PARTNERS

- **Early on, Gradian realized it faced significant capability gaps in manufacturing and sales, distribution and servicing:** As the prototype for UAM was being refined, Gradian and OES Medical recognized product and market characteristics that would require capabilities they lacked. With funding from the Nick Simons Foundation (NSF), Gradian was able to finance the limited clinical and regulatory requirements, as well as the field testing that the technology required. Early on, NSF needed to find a manufacturing partner with expertise in manufacturing medical devices and experience with anaesthesia. Moreover, Gradian realized that sales, distribution and servicing would be a challenge. To sell their product, a major capital expenditure for most of Gradian's target customers, Gradian needed to forge strong relationships with customers, offer multi-day training and be able to reliably service the product for years.

- **Gradian preferred to work with select, trusted partners for distribution, sales and servicing, but wanted to retain strategic control of scaling:** Gradian wanted to retain direct control over the scale-up of its innovation, yet it also wanted to remain a small organization in terms of its core staff in the United States. Rather than growing a significant sales force, and opening country offices in each of its markets, Gradian sought partners that shared its vision of success, and that it could entrust with its brand.

- **Gradian identified distributors in each market for sales, distribution, training and servicing:** As Gradian did not want to staff up in-country sales and servicing capability, but did want to drive the strategy of the organization, it identified trusted distributors with strong footprints in target markets to handle servicing and distribution, as well as practicing anaesthesiologists in each country who could deliver clinical training on the UAM.

> "Having local partners with networks already on the ground and a strong understanding of how things work is critical for us. There is no substitute for people who have lived their lives in the community—they just know how to get things done.

–Stephen Rudy, Gradian Health

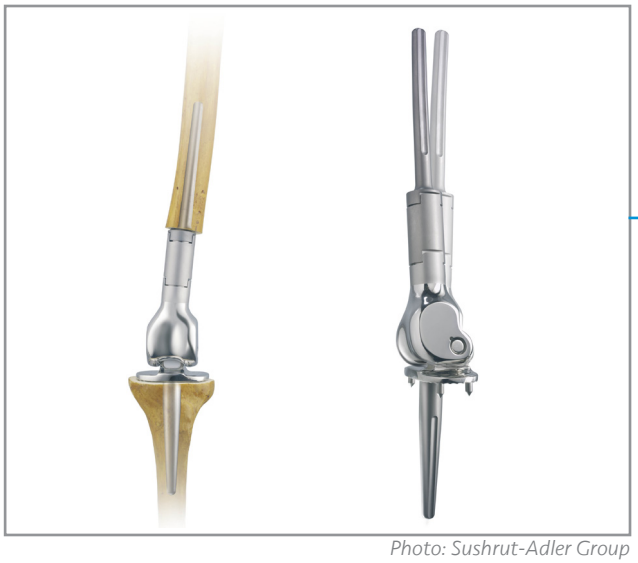


Photo: Sushrut-Adler Group

SUSHRUT SURGICALS

SCALING MODELS HIGHLIGHTED

- Model 1: Organic growth with selective out-sourcing
- Model 5: Getting acquired

OVERVIEW

Vimal Pitre started Sushrut Surgicals in 1973 to buy and resell imported surgical implants in India. Her husband, Vasant Pitre, joined the company in the early 1980s, and her son, Ajay Pitre joined the family business in 1984. The family grew the company to become a maker of high quality implants. Its product portfolio included a mix of generic, incrementally innovated and holistically innovative offerings. Today, Sushrut Surgicals and Adler Mediequip (the manufacturing company established by the family in 1992), under the ownership of Smith and Nephew, continues to design, manufacture and market high quality, affordable, surgical implants for India and emerging markets.

PATHWAY TAKEN

Organic growth with selective out-sourcing

Entrepreneur identified need for surgical implants in India

In 1973, Vimal Pitre was inspired by friends who were orthopedic surgeons to begin trading orthopedic implants, given the relative scarcity of the products in India

At the same time, she began to establish manufacturing facilities, beginning with reverse engineering and manufacturing generic implants

Established fundamental capabilities and began to scale-up

During 1980s, Mrs. Pitre's husband (Vasant Pitre) and son (Ajay Pitre) joined the company

Sushrut began to develop good reputation as a producer of high quality implants, and increased in scale and complexity of operations over time

Improved manufacturing and received regulatory approval

In 1992, the Pitre family started Adler Mediequip – a premier manufacturing company with high technical capabilities. They also pursued regulatory approvals, filing for the CE mark and ensuring they complied with ISO standards

Built trust with medical community through partnership and outreach

To gain acceptance in the medical community, the Pitre family opened a training facility to physicians on their products

The Pitre family also worked with renowned Indian medical centers, such as TATA Memorial in Mumbai, on product design, development, and user training on the products and diagnosis and treatment of related diseases

Developed network of distributors to access buyers

Sushrut developed a large network of distribution partners across India to engage and sell to customers

Sushrut also maintained a direct-to-customer sales channel that serves large clients

Acquired by Smith and Nephew

Getting acquired

Smith and Nephew approached Sushrut as an acquisition target to help them enter developing markets and in 2013 the Pitre family sold its manufacturing company Alder Mediequip and all brands and assets of Sushrut Surgicals

Financing

Self-funded (Sushrut Surgical / Adler Mediequip)

Acquisition by Smith and Nephew (along with Brazilian distribution business, deal totaled $70m)

RATIONALE FOR SUSHRUT'S PATH TO DRIVE SCALE-UP IN-HOUSE AND EVENTUALLY SELL TO SMITH AND NEPHEW

- **Sushrut developed most of the requirements for scaling in house, but needed partners to access missing capabilities:** Sushrut's path to scale was almost 40 years long. Through most of this journey, the company developed capabilities to scale-up in-house. Sushrut established its own high-quality manufacturing facilities in India (including the establishment of Adler Medieequip in 1992, a sophisticated medical device manufacturing company), growing in size and level of complexity over time. It gradually developed capabilities for product validation and innovation (starting with incremental innovations and moving to create its own IP), after developing the fundamental capabilities to manufacture generic implants. It also developed in-house expertise for gaining regulatory approvals. A key challenge that remained was to convince physicians and the medical community that their products were high quality and good substitutes for foreign products. However, sales and distribution were difficult as India's market for surgical implants is very fragmented and requires a strong sales force.

- **It was feasible for Sushrut to seek partners to fill capability gaps and help build in-house capabilities over time:** Sushrut was able to drive scale-up while outsourcing its capability gap functions to partners. For example, Sushrut worked with reputable medical facilities, such as TATA Memorial in Mumbai, to collaborate on product design, development, testing and even user training on the products and diagnosis and treatment of related diseases. This enhanced credibility, particularly when results were published in peer reviewed journals. It was also able to identify distribution partners with access to networks of physicians, and gradually develop an extensive distribution network of over 150 distributors, extending to 22 countries.

- **Sushrut was willing to drive scale-up internally, but was open to being acquired:** Sushrut's founders did not have a strong preferences for the type of scale-up model to pursue. The Pitres were the sole owners for 40 years, and drove the scaling process internally during this time, but they remained open to being acquired. After building a business with a proven and profitable commercial model, when a suitable buyer that shared its vision for the future of the company came along, the family sold the company. After the acquisition, Ajay resigned as managing director to give the Sushrut-Adler management team a clear field to identify new opportunities for growth.

> "Achieving wider adoption of innovation and building trust amongst users is a long journey – even more so as an Indian company. It took us decades of unflinching commitment to comprehensive quality and continual improvement to get there. Development of a capable organization & associating with right partners was key.
>
> *–Ajay Pitre*

Toolkit for Shaping a Pathway to Scale

We developed a set of exercises to help innovators assess the capabilities and resources needed for scale-up, identify the most suitable scaling model, and begin considering key questions for shaping a pathway to scale. The complete set of exercise worksheets and examples are available as a companion booklet and can be downloaded at www.usaid.gov/cii.

Photo: Getty Images

In this chapter, you will find three exercises to help innovators assess the capabilities and resources needed to scale-up their innovation, identify the scaling model most suited to them, and raise the right questions for shaping a pathway to scale. We recognize that given the ambiguities inherent in early-stage innovations, such as the exact location of the target market, or target users' precise needs, innovators cannot provide accurate answers to some components of these exercises. To address this challenge, we have provided examples where possible, such as completed worksheets using Brilliance from the perspective of D-Rev. We encourage innovators to seek a mentor with experience in a similar industry/market to go through the exercises with them, and to revisit the exercise when new information becomes available, or when they achieve a significant milestone.

Exercise 1: Assess the capabilities and resources you need to scale-up

- Based on the profile of your innovation and your understanding of the capabilities and resources needed to bring it to scale, identify your gaps.
- Your answer will inform your choices and considerations in Exercises 2 and 3.

Exercise 2: Select appropriate scaling model(s)

- Determine the "best fit" scaling model for you and your innovation, based on:
  - How feasible it would be for you to pursue and implement each of the five scaling models
  - Your preferences

Exercise 3: Understand the key considerations for the chosen scaling model(s)

- Explore key questions and considerations for your chosen scaling model (identified in Exercise 2)
- Answers could be used to create a blueprint for your pathway to scale

EXERCISE 1: ASSESS CAPABILITIES AND RESOURCES NEEDED FOR SCALE-UP

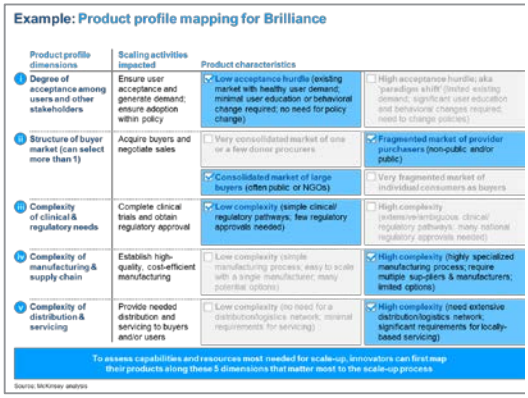
This toolkit begins with Exercise 1, aimed at helping innovators assess the scale-up capabilities and resources needed, given five dimensions of their product's profile, and identify gaps to meeting those needs on their own. This gap analysis helps inform the feasibility and preference considerations in Exercise 2 when innovators choose among potential scaling models, and also provides an important set of insights to help answer questions related to how innovators might pursue a chosen scaling model.

Exercise 1 has three sequential components: Part A, B and C. Each part builds on the previous piece and is explained below.

A

Identify where your product falls along five key dimensions that impact the capabilities and resources required for scale-up

Product profile mapping



Example: Product profile mapping for Brilliance

Product profile dimensions	Scaling activities impacted	Product characteristics	
I Degree of acceptance among users and other stakeholders	Ensure user acceptance and generate demand; ensure adoption within policy	☑ Low acceptance hurdle (existing market with healthy user demand; minimal user education or behavioral change required; no need for policy change)	☐ High acceptance hurdle; aka "paradigm shift" (limited existing demand; significant user education and behavioral changes required; need to change policies)
II Structure of buyer market (can select more than 1)	Acquire buyers and negotiate sales	☐ Very consolidated market of one or a few donor procurers	☑ Fragmented market of provider purchasers (non-public and/or public)
		☑ Consolidated market of large buyers (often public or NGOs)	☐ Very fragmented market of individual consumers as buyers
III Complexity of clinical & regulatory needs	Complete clinical trials and obtain regulatory approval	☑ Low complexity (simple clinical/ regulatory pathways; few regulatory approvals needed)	☐ High complexity (extensive/ambiguous clinical/ regulatory pathways; many national regulatory approvals needed)
IV Complexity of manufacturing & supply chain	Establish high-quality, cost-efficient manufacturing	☐ Low complexity (simple manufacturing process; easy to scale with a single manufacturer; many potential options)	☑ High complexity (highly specialized manufacturing process; require multiple sup-piers & manufacturers; limited options)
V Complexity of distribution & servicing	Provide needed distribution and servicing to buyers and/or users	☐ Low complexity (no need for a distribution/logistics network; minimal requirements for servicing)	☑ High complexity (need extensive distribution/logistics network; significant requirements for locally-based servicing)

To assess capabilities and resources most needed for scale-up, innovators can first map their products along these 5 dimensions that matter most to the scale-up process

Source: McKinsey analysis

In Part A, product profile mapping, the innovator identifies where his/her product falls along five key dimensions that impact the capabilities and resources required for scale-up. We identified these five dimensions as the most important drivers in deciding necessary capabilities for scale-up, and validated this framework with global health innovators, thought leaders, and other donors and investors.

The five dimensions are:

- **Degree of acceptance among users and other stakeholders:** A product with a high acceptance hurdle faces many challenges - its target users are not aware of the product, do not appreciate the benefits of the product, or might resist the product given current beliefs or routines. There could also be policy barriers that hinder user acceptance. For example, healthcare providers might not use a product unless it is included in the treatment guidelines for the illness it addresses. At the extreme, a product requires a "paradigm shift" from existing users' mindset and behaviors. Achieving this would require robust capabilities to generate evidence and craft messages tailored to key influencers, effective channels to convey the value proposition, sufficient capacity to educate or train end-user groups, and the ongoing ability to monitor and adjust the product and messaging.

- **Structure of buyer market:** Different buyer-market dynamics requires a different set of capabilities to acquire buyers and negotiate sales:

  - Very consolidated markets with only one or a few donor-funded agencies (e.g., the vast majority of contraceptives entering low-income country markets are procured by two donor-funded agencies) require the ability to navigate the specific procurement processes

- Consolidated markets with large public-sector or NGO buyers (e.g., essential surgical and delivery equipment are purchased through large government tenders) require the ability to respond to tenders and negotiate contracts that address a range of buyers' needs and requirements. In addition, it is often necessary to identify and cultivate funding sources, since governments might not be willing or able to pay for the product, especially when it is not part of the regular list of products they procure.

- A fragmented market of provider-buyers (e.g., many diagnostic tools are purchased by hospitals and clinics) requires the capability to respond to tenders and negotiate contracts with a very diverse set of buyers. In addition, to influence the decisions of buyers, healthcare providers and beneficiaries, it may be necessary to develop a sizable sales force and create a recognizable brand.

- Very fragmented markets where individual consumers are the buyers (e.g., nutritional products and sanitation products that are sold to families for household use) require robust and culturally-aligned marketing and sales capabilities for them to reach and convert customers.

- **Complexity of clinical and regulatory needs:** A product with high clinical and regulatory complexity may require extensive clinical trials and multiple, national regulatory approvals through arduous and/or ambiguous pathways. Managing a high degree of complexity requires the ability to respond to inquiries from an extensive network of clinical trial sites, to analyze data and ensure the efficacy of trials, to test for product safety and quality, to build relationships and develop a working knowledge of multiple local regulators and requirements, to complete and continuously respond to numerous regulatory filings in multiple regions, and to ensure coordination across all clinical and regulatory functions.

- **Complexity of manufacturing and supply chain:** Although nearly all innovators contract out manufacturing, a product with high manufacturing complexity often requires identifying highly specialized manufacturers and managing multiple manufacturers and suppliers. These innovators need personnel with the capabilities and expertise to handle extensive contracting and the diligence to identify high quality, cost-effective manufacturers and suppliers, to manage multiple manufacturers and suppliers, often in several countries, and to monitor and perform quality control of technical manufacturing process.

- **Complexity of distribution and servicing:** Products with high complexity are those that require direct distribution networks to bring them to end users, sophisticated logistic chains to reach remote areas, specialized storage equipment to maintain product integrity, and an on-the-ground presence to provide after-sales servicing. Capabilities and resources required to meet these needs can be extensive, and can pose a significant challenge to most innovators.

In the companion booklet and at www.usaid.gov/cii, innovators will find the template for mapping their innovations against these five dimensions. Many innovations will fall on the continuum between the two extremes of low and high complexity across each of the dimensions. As they move through this exercise, we recommend that innovators focus on the most defining characteristics of their product when placing it on the product profile map. We recognize that for many innovators, especially those in the early stages of development, this exercise can be difficult. Therefore, we strongly recommend engaging with mentors and advisors to pressure-test the placement. Below, we provide examples of a few of innovations from the earlier case studies:

D-Rev Brilliance

Product profile dimensions	Product characteristics	
i Acceptance among users	☑ Low acceptance hurdle	☐ High acceptance hurdle; aka "paradigm shift"
ii Structure of buyer market	☐ Very consolidated	☑ Large buyers
	☑ Fragmented provider purchasers	☐ Individual consumers as buyers
iii Clinical & regulatory	☑ Low complexity	☐ High complexity
iv Manufacturing & supply chain	☐ Low complexity	☑ High complexity
v Distribution & servicing	☐ Low complexity	☑ High complexity

Sproxil Defender

Product profile dimensions	Product characteristics	
i Acceptance among users	☐ Low acceptance hurdle	☑ High acceptance hurdle; aka "paradigm shift"
ii Structure of buyer market	☐ Very consolidated	☑ Large buyers
	☐ Fragmented provider purchasers	☐ Individual consumers as buyers
iii Clinical & regulatory	☑ Low complexity	☐ High complexity
iv Manufacturing & supply chain	☑ Low complexity	☐ High complexity
v Distribution & servicing	☑ Low complexity	☐ High complexity

Gradian Universal Anaesthesia Machine

Product profile dimensions	Product characteristics	
i Acceptance among users	☑ Low acceptance hurdle	☐ High acceptance hurdle; aka "paradigm shift"
ii Structure of buyer market	☐ Very consolidated	☑ Large buyers
	☑ Fragmented provider purchasers	☐ Individual consumers as buyers
iii Clinical & regulatory	☐ Low complexity	☑ High complexity
iv Manufacturing & supply chain	☐ Low complexity	☑ High complexity
v Distribution & servicing	☐ Low complexity	☑ High complexity

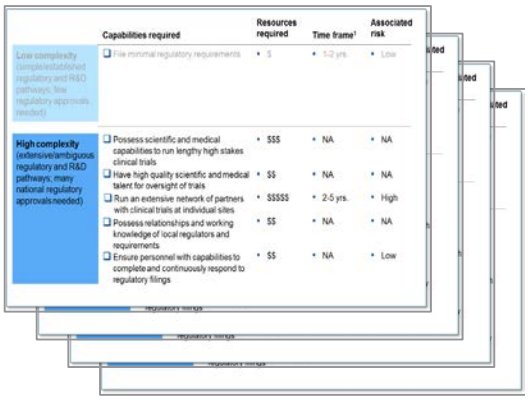
Shruti iHear ear screening kit

Product profile dimensions	Product characteristics	
i Acceptance among users	☐ Low acceptance hurdle	☑ High acceptance hurdle; aka "paradigm shift"
ii Structure of buyer market	☐ Very consolidated	☑ Large buyers
	☑ Fragmented provider purchasers	☐ Individual consumers as buyers
iii Clinical & regulatory	☑ Low complexity	☐ High complexity
iv Manufacturing & supply chain	☑ Low complexity	☐ High complexity
v Distribution & servicing	☐ Low complexity	☑ High complexity

B

Given your product profile and the corresponding capabilities and resources required for scale-up, assess your abilities to meet these scaling requirements alone

Scale-up requirements checklist



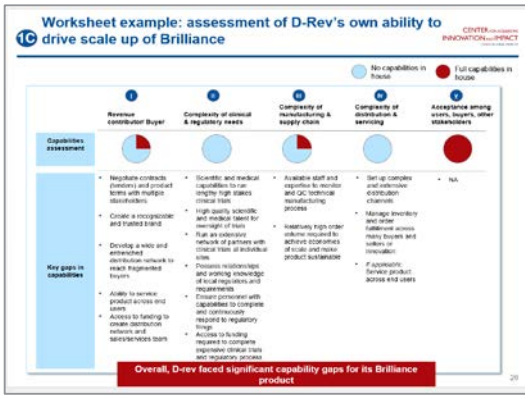
	Capabilities required	Resources required	Time frame[1]	Associated risk
Low complexity (complex/established regulatory and R&D pathways, few regulatory approvals needed)	❑ File minimal regulatory requirements	• $	• 1-2 yrs.	• Low
High complexity (extensive/ambiguous regulatory and R&D pathways, many national regulatory approvals needed)	❑ Possess scientific and medical capabilities to run lengthy high stakes clinical trials	• $$$	• NA	• NA
	❑ Have high quality scientific and medical talent for oversight of trials	• $$	• NA	• NA
	❑ Run an extensive network of partners with clinical trials at individual sites	• $$$$$	• 2-5 yrs.	• High
	❑ Possess relationships and working knowledge of local regulators and requirements	• $$	• NA	• NA
	❑ Ensure personnel with capabilities to complete and continuously respond to regulatory filings	• $$	• NA	• Low

As explained earlier, a product's characteristics along the five dimensions imply different capabilities and levels of funding needed for scale-up. In Part B, we developed a checklist of capability and resource requirements for each dimension. Using the product mapping results from Part A, innovators can use the checklist to assess their organization's ability to meet these scaling requirements alone. The checklists and the D-Rev Brilliance example are included in the toolkit.

C

Synthesize the results of Part B to identify need for accessing/convening capabilities and resources from outside parties to fill gaps

Assess the need for outside capabilities and resources



Worksheet example: assessment of D-Rev's own ability to drive scale up of Brilliance

No capabilities in house | Full capabilities in house

	Revenue contributor/ Buyer	Complexity of clinical & regulatory needs	Complexity of manufacturing & supply chain	Complexity of distribution & servicing	Acceptance among users, buyers, other stakeholders
Capabilities assessment					
Key gaps in capabilities	• Negotiate contracts (tenders) and product terms with multiple stakeholders • Create a recognizable and trusted brand • Develop a wide and entrenched distribution network to reach fragmented buyers • Ability to service product across end users • Access to funding to create distribution network and sales/services team	• Scientific and medical capabilities to run lengthy high stakes clinical trials • High quality scientific and medical talent for oversight of trials • Run an extensive network of partners with clinical trials at individual sites • Possess relationships and working knowledge of local regulators and requirements • Ensure personnel with capabilities to complete and continuously respond to regulatory filings • Access to funding required to complete expensive clinical trials and regulatory process	• Available staff and expertise to monitor and QC technical manufacturing process • Relatively high order volume required to achieve economies of scale and make product sustainable	• Set up complex and extensive distribution channels • Manage inventory and order fulfillment across many buyers and sellers or innovation • If applicable: Service product across end users	• NA

Overall, D-rev faced significant capability gaps for its Brilliance product

In Part C, the innovator will summarize the capability and resource gaps identified in Part B, and develop an assessment of the need to work with external actors on the scale-up journey. This 1-page worksheet is a synthesis of Exercise 1.

EXERCISE 2: SELECT APPROPRIATE SCALING MODEL(S)

As we mentioned in Chapter 2, the choice of scaling model(s) is determined by the answers to two questions: "Which model is feasible for me to pursue?" and "Which model is best aligned with my goals and preferences?" We designed this exercise to help innovators answer these two questions and identify the best-suited scaling model. As previously noted, this exercise should be revisited periodically as the determinants for either feasibility or preference may change along the innovator's journey.

This exercise also has three sequential components:

A

Assessing the feasibility of pursuing and implementing each scaling model

For each of the five models, the innovator is asked to rate the likelihood that their organization could execute the requirements introduced on page 6 successfully. Innovators and advisors who have successfully scaled innovations say this is a critical step. Many have noted that understanding how feasible a particular model was for their organization and product helped them narrow down the model choices for scale, and helped them identify what they needed to pursue a particular model type.

B

Assessing the preferences for each scaling model

The innovator should clearly define their goals and preferences and those of their organization, and rate their preference for each of the five models. The innovator must truly understand if a particular model aligns with these preferences. For example, as noted in the D-Rev Brilliance case study, the innovators wished to focus the organization on creating innovative new products, rather than build the capabilities to scale-up a product. Understanding this preference helped D-Rev choose licensing over other model types. When completing the worksheets, we encourage readers to refer to page 8, which lays out each model's impact on innovators' goals and preferences.

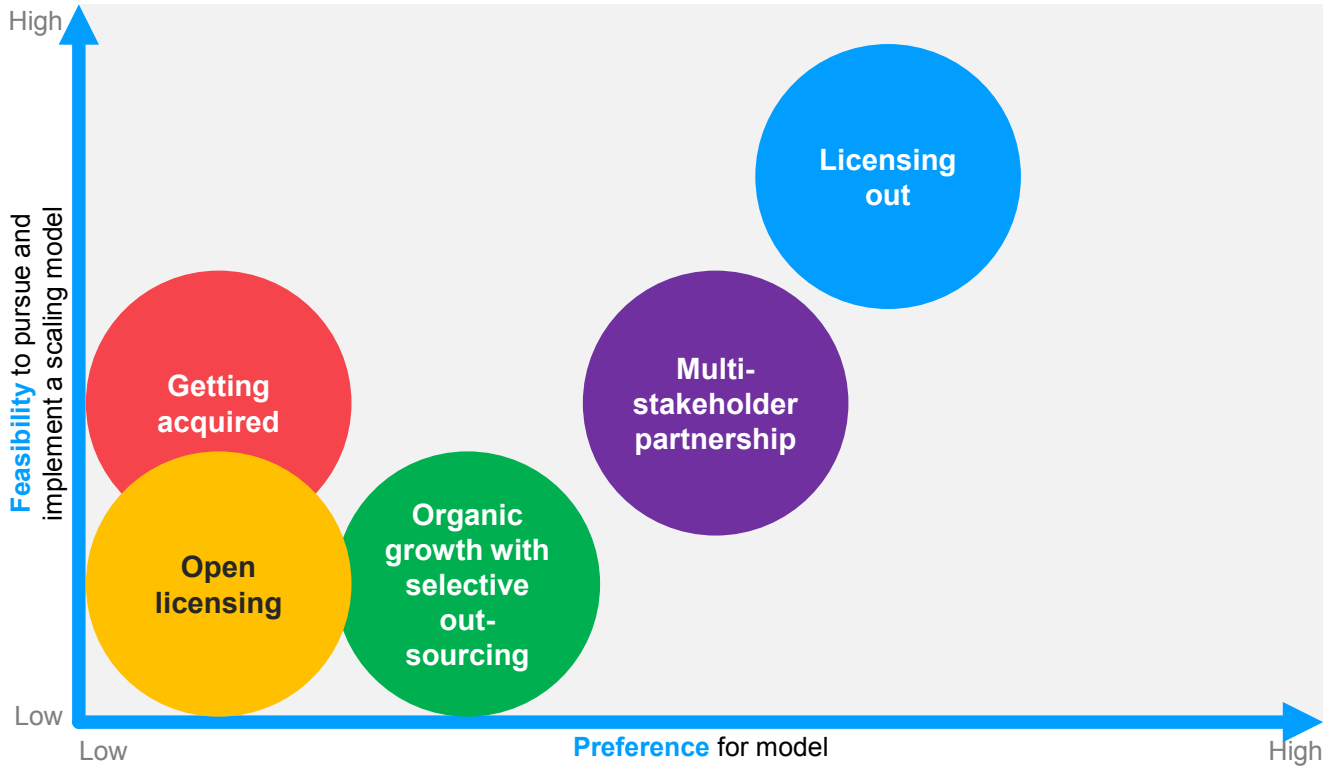
C

Prioritizing scale-up models

Using the ratings from Parts A and B of this exercise, the innovator can plot the five scaling models on a matrix with feasibility and preference as the two axes. D-Rev Brilliance's prioritization of the five scaling models is shown below. The model emerging on the top right quadrant is the "best fit" - for Brilliance, it was licensing out. If the top right quadrant is empty, the innovator should consider the most feasible models in the top left quadrant, even though they have a low preference rating. If these models are unappealing, the innovator should then decide whether to continue pursuing the innovation or to terminate or divest it.

Worksheet: Prioritization of scaling models based on feasibility and preference (Brilliance example)

Based on feasibility and preference for model types identified during Part A and B of this exercise, plot the five scaling models on this matrix



Licensing is the model that emerges as "best-fit" for Brilliance given feasibility and preference

EXERCISE 3: UNDERSTANDING THE KEY CONSIDERATIONS FOR THE CHOSEN SCALING MODEL(S)

Having a sense for which scaling model might be a good fit is akin to knowing the general direction of a journey. There is much to be done to sketch out and pursue a successful pathway to scale. An innovator needs to understand the important decision points, necessary milestones, and preferred timing along the journey. To help him or her do so, in this exercise, we present the most critical questions that an innovator must be able to answer when choosing a scaling model. For each scaling model, the questions fall into five categories:

What do I need the outside party to bring?

Which organizations are likely to meet my needs?

What values do I need to demonstrate to them?

What timing should I aim for?

What types of capital would I need, how much, and when?

Many of the questions require fact-gathering, analysis, reaching out to potential partners, and pressure-testing with mentors. If the innovation is still at a very early stage, the answers to some questions may not yet be available. Therefore, it may not be possible or practical to complete this exercise in one afternoon. Instead, we offer these questions as tools to help innovators structure their thought-process and prioritize activities as they chart a pathway to scale. To help innovators answer these questions, we have highlighted a few key considerations that stood out from our research and interviews while preparing this guide.

SCALING MODEL 1: ORGANIC GROWTH WITH SELECTIVE OUT-SOURCING

What do I need in a partner?

Which capability gaps must the partner be able to fill?

What other characteristics should an ideal partner have? E.g.:

- Size, maturity
- Brand and reputation
- Footprint in target geographies
- Experience with similar products and markets
- Ability to grow with me through the scaling process
- Relationships with key stakeholders
- Network and/or the ability to attract capital

What values does the partner need to have? Signs of value alignment:

- Vision of success for my product
- A customer base that aligns with my target users
- A willingness to let me influence strategy

Which partners are most likely to meet my needs?

Which types of organizations are best equipped to fill each of my capability gaps?

How do I create a short list of organizations that I should consider partnering with?

Which organizations on this list are most aligned with my criteria?

What value do I need to show potential partners?

Which of my preferred potential partners are interested in working with me? What motivates them? E.g.:

- Compelling social and/or commercial value
- Strategic alignment with existing markets
- Compatibility with existing product / project portfolio

What do I need to demonstrate to attract them? E.g.:

- Technical viability (through proof of concept or pilot trials)
- Potential Impact
- Strategic relevance to the partner, in terms of geographies, health issues, target markets, etc.
- User demand / existence of market
- Commercial sustainability and attractiveness (might not be needed)

What milestones must I reach to demonstrate success in these areas?

Do I need to make changes to my current legal structure (e.g. start a new entity that owns the IP) to reach these milestones?

What timing should I aim for?

Are there benefits to partnering early vs late for each area of partnership? Considerations include:

- Influence on other decisions (e.g. engaging a manufacturer early could affect product design)
- Potential financial return
- Bargaining power in contract negotiations
- Amount of time and resources I am willing to spend to reach each milestone

What types of funding do I need and when?

How much additional funding do I need at each stage to drive the scale-up of my product?

Given the stages at which I need funding, which types of capital should I seek?

- Friends and family money
- Competition and prize money
- Grants
- Program-related investments
- Impact capital
- Angel equity
- Equity investor
- Debt investor
- Revenue-based financing
- Convertible debt

What terms and restrictions would each type of capital entail?

- IP openness
- Growth strategy
- Payment timeline and schedule, interest rate (for debt)
- Valuation, voting rights (for equity)

Don't forget about value alignment: In defining the traits of an ideal partner and vetting potential candidates, it is important to confirm that their values are in alignment with yours, in addition to their capabilities and track record. Global health innovators are often driven by the pursuit of social impact, instead of, or in addition to, financial return. The population they wish to target and the price-point of their products are not usually financially optimal. Innovators cannot assume that potential partners will share these impact-driven goals. For example, the most profitable strategy for distributors and resellers could be selling to more affluent customer segments, at the expense of reaching those most in need. Doing thorough due diligence on the values of potential partners is, therefore, critical for ensuring the integrity of the product's intended impact and preserving the longevity of the partnership.

Understand what potential partners need from you: A healthy partnership is built on the foundation of trust, understanding, and mutual benefit. While it might be relatively straightforward for innovators to identify what they need from partners, it is much more difficult to know what their counterparts value. We encourage innovators to identify and begin engaging with potential partners early on. Understanding precisely what partners require could imply a change in strategic direction or product design, even in the early stages of an innovation.

> ***Anecdote:*** *The inventors of an Augmented Infant Resuscitator (AIR) from Mbarara University, Uganda and Boston realized early on that partnership with local distributors would be vital for taking their product to market and to scale. At the advice of their mentors, who understood medical devices, they learned that distributors in East Africa require products to be at a certain price-point to fit into their portfolios. The team asked market experts to explain the price-points needed to make their products marketable, and worked with manufacturers to gain an understanding of unit economics. By evaluating both end-user and distributor preferences and inputs, the AIR team was able to work with manufactures to bring the Cost of Goods down to a level that permitted performance at a price-point that will facilitate scale in the intended target settings. Without an early understanding of future distribution partners' needs, the innovators would have gone too far down the product development path (e.g., manufacturing processes and equipment locked in and costly to change) to easily course-correct.*

Typical things that partners look for could include:

- **Evidence of technical viability:** Unless you are simply paying for a contractor's services, most partners want to see proof of concept or pilot trials that demonstrate the technical viability of the innovation. As proof of concept can mean many things, it is important to talk to partners directly and ask them what they are looking for.

- **Evidence of impact:** NGO and mission-driven partners are likely to look for evidence of social impact. It is important to understand the degree of robustness in the evidence required by potential partners (e.g., clinical trials or field testing, results specific to certain geographies and/or user segments, sample size, confidence interval of the results, etc.).

- **Strategic relevance:** Socially-driven organizations usually have clear priorities across geographies, health issues, and user segments. Being able to relate the innovation to their specific areas of interest would make the partnership more feasible. Similarly, commercially-minded partners will seek strategic alignment between the innovation and their own businesses, whether it is to better serve their existing customers or to grow into a new market.

- **Commercial sustainability:** Partners with a vested interest in the long-term sustainability of a product require evidence of its commercial viability, including proven demand from end-users, the existence of buyers that are willing and able to pay, plausible revenue streams and/or other sources of capital. Again, it is important to understand how potential partners define commercial viability. Depending on their motivations, some might only require the ability to recover costs, while others look for a certain level of profitability.

SCALING MODEL 2: MULTI-STAKEHOLDER PARTNERSHIP

What do I need from a multi-stakeholder partnership?

Which capability gaps must the group of partners be able to fill?

What roles do the multi-stakeholder partnership need to perform?

How much decision-making control do I want to maintain in the multi-stakeholder partnership?

What other characteristics would an ideal set of partners have? E.g.:

- Size, maturity
- Brand and reputation
- Footprint in target geographies
- Experience with similar products and markets
- Ability to grow with me through the scaling process
- Relationships with key stakeholders
- Capital or the ability to attract capital

What values do the partners need to have? Signs of value alignment:

- Vision of success for my product
- A customer base that aligns with my target users
- The willingness to let me influence strategy

Which partners likely meet my needs?

Which types of organizations would likely meet my needs?

- Alliances/coalitions/public-private partnerships on a related issue
- Donors
- Governments
- Implementing NGOs
- Corporations

How should I develop a short list of specific organizations I should consider partnering with? What roles should they take on?

Which organizations from this list are most aligned with my criteria?

What value do I need to show potential partners?

Which of my preferred partners are interested in working with me? What motivates them? E.g.:

- Compelling social value
- Need for multi-stakeholder partnership to address barriers that a single entity cannot

What do I need to demonstrate to attract them? E.g.:

- Technical viability (through proof of concept or pilot trials)
- Potential Impact
- Strategic relevance to the partner, in terms of geographies, health issues, target markets, etc.
- User demand / existence of market
- Commercial sustainability and attractiveness (might not be needed)

What milestones do I need to reach to demonstrate evidence in these areas?

Do I need to make changes to my current legal structure (e.g. start a new entity that owns the IP) reach these milestones?

What timing should I aim for?

Are there benefits to entering into a partnership early vs late? Considerations include:

- Influence on other decisions (e.g. engaging a manufacturer early could affect product design)
- Level of decision-making power in the partnership

What types of funding do I need and when?

How much additional funding do I need to raise to reach the milestones required to enter into a multi-stakeholder partnership?

How much more funding would I need to raise after a multi-stakeholder partnership?

Given the stages at which I need funding, what are the potential types of capital?

- Friends and family money
- Competition and prize money
- Grants
- Program related investments
- Impact capital
- Angel equity
- Equity investor
- Debt investor
- Revenue-based financing
- Convertible debt

What terms and restrictions would each type of capital come with?

- IP openness
- Growth strategy
- Payment timeline and schedule, interest rate (for debt)
- Valuation, voting rights (for equity)

Look in unlikely places to "seed" a multi-stakeholder partnership: A multi-stakeholder partnership brings together the group of stakeholders required to address scale-up challenges that a single organization cannot do alone, often at the system-level. Sometimes, such a body already exists to help scale-up life-saving, health-promoting products. For example, today, a clean cookstove innovator would work with the Global Alliance for Clean Cookstoves to develop their business and scale-up. However, more often, a multi-stakeholder partnership is not readily found.

Innovators need to search for a partner with a shared interest and ability to galvanize other stakeholders to "seed" the multi-stakeholder partnership. This could include international agencies, donors, and large NGOs, as well as the less usual entities, such as governments at the national or sub-national level, academic institutions, physician alliances, and consumer groups.

> ***Anecdote:*** *In 2014, Medtronic sought to address the need for better management of traumatic brain injury in India but lacked any entry points to intervene on its own. It found a partner in the American Association of Physicians of Indian Origin. Together, they formed a public-private partnership model with the Indian state and central government to develop and implement national guidelines for managing traumatic brain injury patients.*

Be clear on the role of project manager: In *"Idea to Impact"*, we introduced the concept of an "uptake coordinator", also commonly referred to as a project manager. This role is vested with the responsibilities to convene stakeholders, delegate and coordinate work across them, share information, troubleshoot issues that arise, maintain a project timeline, and help prioritize decisions and activities. Such a role is integral to scaling up any innovation, and especially important to those being scaled up through a collaborative model involving multiple actors. The group of partners working together must clarify who is responsible for project management, or if a formal body should be created to serve that purpose. The designated project manager must be granted authority to lead, make decisions and hold all parties accountable. In exploring the model of scaling through a multi-stakeholder arrangement, we encourage innovators to raise these questions as early as possible with prospective partners. For more details on the concept of an "uptake coordinator", including case studies and lessons learned, please refer to page 59 of *"Idea to Impact"*.

SCALING MODEL 3: LICENSING OUT

What do I need in a licensee?

Which capability gaps must the licensee be able to fill?

How much decision making control do I want to retain, if any?

What other characteristics would an ideal licensee have? E.g.:

- Size, maturity
- Brand and reputation
- Financial health and available capital
- Footprint in target geographies
- Product portfolio
- Relationships with key stakeholders

What values does the licensee need to have? Signs of value alignment:

- Vision of success for my product
- A customer base that aligns with my target users
- The willingness to let me influence strategy

How do I want the licensee to use and not to use my IP? Common restrictions to state in a license:

- Degree of exclusivity
- Components of the technology
- Geography
- "Field of use", or use cases
- Pricing
- Rights over modifications or derivatives

Which licensees likely meet my needs?

What types of licensees would likely meet my needs? E.g.,

- Multi-national corporations
- Local manufacturers / distributors
- Innovation, R&D, design entities
- Global health organizations (e.g., PATH)

How do I create a short list of organizations I should consider as licensees?

Which organizations on the list are most aligned with my criteria?

What value do I need to show potential licensees?

Which of my preferred licensees are interested in working with me? What motivates them? E.g.:

- Compelling commercial value
- Strategic alignment with existing markets / customer base
- Compatibility with existing product portfolio

What do I need to demonstrate to potential licensees? E.g.:

- Technical viability (through proof of concept or pilot trials)
- Potential impact
- Strategic relevance to the licensee, in terms of geographies, health issues, target markets, etc.
- User demand / existence of market
- Commercial sustainability and attractiveness
- Pathway to regulatory approval
- Manufacturability

What milestones do I need to reach to demonstrate evidence in these areas?

Do I need to make changes to my current legal structure (e.g. start a new entity that owns the IP) to reach these milestones?

What timing should I aim for?

Are there benefits to licensing early vs late? Considerations include:

- The freedom to explore other scaling models
- Potential financial return
- Bargaining power in the license negotiations
- Amount of time and resources I am willing to spend to reach each milestone

What types of funding do I need and when?

How much additional funding do I need to raise to reach the milestone required for licensing?

How much more funding would I need to raise after a licensing deal, if any?

Given the stages at which I need funding, what sources of capital might I pursue?

- Friends and family money
- Competition and prize money
- Grants
- Program-related investments
- Impact capital
- Angel equity
- Equity investor
- Debt investor
- Revenue-based financing
- Convertible debt

What terms and restrictions would each type of capital come with?

- IP openness
- Growth strategy
- Payment timeline and schedule, interest rate (for debt)
- Valuation, voting rights (for equity)

Maximize your optionality: A license is a document granting permission for another entity (the "licensee") to use a technology in exchange for a payment to the owner (the "licenser"). It is possible for a license to contain any number of restrictions on how the technology can be used, including exclusive permission, geographic scope, field of use (i.e., use case), ability to make alterations and more. Depending on the goals of the innovator, it could be limiting to license out all rights to one partner exclusively. If the goal is to ensure that the innovation reaches the greatest number of target beneficiaries, an innovator might only license out rights to sell to market segments that the licensee is best-suited to serve, and retain the option of working with other partners in other markets. If the goal is to address many use-cases through the technology, an innovator might want to limit the field of use in the licensing agreement so he or she is free to develop alternate use cases (e.g., apply the technology to another therapeutic area) later on. When in doubt, negotiate the narrowest set of permissions for which the licensee can use the technology.

Use contract terms to achieve desired alignment with the licensee: The earlier discussion on ensuring value-alignment (page 41) is equally important to innovators seeking licensing partners. By structuring the licensing agreement, innovators can influence licensees to pursue strategies aligned with their values, using measures such as differentiating the levels of licensing fees or royalties, fixing the price range. For example, in their licensing agreement with Phoenix Medical Systems, D-Rev set a lower royalty for each unit of Brilliance sold to public and district hospitals to incentivize sales to institutions serving communities with the most unmet need. The licensing agreement also contained a price cap that Brilliance set to ensure intended users could afford the product. We encourage innovators considering licensing out to learn from others who have successfully licensed, and to seek guidance from legal experts working in their field (e.g., medical devices).

Find the optimal timing: Licensing could be arranged as early as proof-of-concept, or later, when a product is on the market. There are several tradeoffs for innovators to consider regarding the timing of licensing. An innovation still at an early stage of development has limited data on technical feasibility or commercial attractiveness, which would most likely lead to lower financial gains from the licensing deal. On the other hand, licensing early has at least three benefits: freeing time and resources that would otherwise go into reaching more advanced product development milestones, off-loading some risk to the licensee, and tapping into the licensee's complementary capabilities. Phoenix Medical Systems signed a licensing agreement with D-Rev when Brilliance was still in product development, and co-invested with D-Rev to complete product development, clinical testing, and regulatory affairs, which improved product design and accelerated its time to market.

SCALING MODEL 4: OPEN LICENSING

How do I want others to use my IP?

What goals do I want to achieve by opening up the IP? E.g.:

- Maximize the scale of impact beyond my own reach
- Building my brand
- Attract others to further innovate and improve the technology
- Allow the technology to be used with a different scope

In what ways do I want others to use the IP? Common restrictions to state in an open license to ensure proper use:

- Type of user (e.g., legal status of the organization)
- Components of the technology
- Geography
- "Field of use", or use cases
- Pricing
- Rights over modifications or derivatives

Who am I trying to attract?

What types of IP adopters are aligned with my goals? E.g.,

- Other innovators working to address a similar problem
- Target users/beneficiaries of the technologies
- Organizations that serve the target users/beneficiaries
- Players along the value chain looking to integrate upstream or downstream

Which organizations or individuals do I most want to attract?

What do I need to provide?

Which of my preferred IP adopters are interested in using it and/or contributing to it? What motivates them? E.g.:

- Compelling social and/or commercial value
- The technology addresses a specific need for them and/or their partners
- Their ability to implement the technology and/or contribute to its improvement

What do I need to provide to attract and support potential adopters? E.g.:

- Technical viability (through proof of concept or pilot trials)
- Potential Impact
- User demand / existence of market
- Documentation, and the resources to help others access the IP
- Support function to answer questions and help others adopt the IP
- Platform for further collaboration

What milestones do I need to reach to open up the IP in a way that is useful to potential adopters?

Do I need to make changes to my current legal structure (e.g. start a new entity that owns the IP) to reach these milestones?

What timing should I aim for?

Are there benefits to opening up the IP early vs late? Considerations include:

- Optionality to explore other scaling models that require a more restricted IP
- Feasibility for others to adopt and/or contribute to the technology
- Attractiveness of the technology for others to adopt and/or contribute to it
- Amount of time and resources I am willing to spend to reach each milestone

What types of funding do I need and when?

How much additional funding do I need to raise to reach the milestones required for an open IP?

How much more funding, if any, would I need to raise after opening up the IP?

Given the stages at which I need funding, which types of capital should I seek?

- Friends and family money
- Competitions and prize money
- Grants
- Program-related investments
- Impact capital
- Angel equity
- Equity investor
- Debt investor
- Revenue-based financing
- Convertible debt

What terms and restrictions would each type of capital come with?

- IP openness
- Growth strategy
- Payment timeline and schedule, interest rate (for debt)
- Valuation, voting rights (for equity)

Decide which permissions and restrictions you want to give: Innovators deciding to open up access to their intellectual property need an open license to do so.[1] Broadly speaking, an open license is one that grants permission to access, reuse and redistribute work with a few or no restrictions (definition from Opendefinition.org). Depending on the nature of the IP and the goals of the innovator, specific permissions and restrictions differ. As a result, many open licenses have been created to cater to different purposes.[2] For example, some licenses require modifications or derivative works be put under the same license as the original work (e.g., the GNU General Public License), while others do not (e.g., the Apache license). We encourage innovators interested in open licenses to seek out legal resources and counsel to help them choose a suitable existing open license to use as is, or adapt.

> ***Anecdote:*** *During the first five years, OpenMRS chose to adopt the Mozilla Public License Version 1 (MLP1}. Given the healthcare use case of OpenMRS, the founders added two additional clauses to MLP1 to protect from medical liability. In 2072, OpenMRS moved to Mozilla Public License Version 2, a standard and simpler license approved by the Open Source Initiative, with an addendum containing healthcare-related disclaimers. This open license allows additional modules developed outside the OpenMRS source code files to be assigned any license, which encourages innovation by a wider range of entities, including those interested in scaling up through commercialization.*

Understand and cultivate sources of support and learning: While open licensing requires no further involvement by the original creators, those aiming to accelerate adoption and maximize the impact of their innovations will need to invest time and effort in cultivating an open and collaborative community. An open project has the potential to attract crowds of supporters from expected and unexpected sources. For example, by participating in Google's "Summer of Code", OpenMRS tapped into a pool of talented volunteer engineers beyond the founders' expectation eager to contribute to the project. Over the years, several software firms made license donations to OpenMRS, which was also unanticipated at the start of the project. Innovators should proactively identify the full range of potential contributors and configure the community infrastructure to draw in, support and connect contributors with each other (e.g., provide peer-learning mechanisms for community members to share successes and failures, understand how local context affects the impact of the innovation, and catalyze further innovations).

Design an appropriate impact-tracking mechanism: With few restrictions contained in open licenses, the original creators cannot easily find out how and by whom the innovation is being used, other than count the times the files were downloaded. To collect more information on the use and impact of their technologies, innovators need to design tracking mechanisms and communication channels with potential users. These are best posted when the open content is published, and could be included in the open license agreement.

1 Without an explicit license, works are usually subject to the copyright laws of the jurisdiction they are published in by default. These laws typically give several exclusive rights to the copyright holder and prohibit unauthorized re-distribution and re-use by third parties. Open licenses enable creators to allow more freedom in what others can do with their works.

2 For a list of the most common open licenses, go to http://www.opendefinition.org/licenses

SCALING MODEL 5: GETTING ACQUIRED

What do I need in an acquirer?

How much do I want to stay involved post-sale?

What part of my organization do I want to sell? E.g.,

- The entire organization, including assets
- IP only

What characteristics would an ideal acquirer have? E.g.:

- An attractive financial offer
- Financial health
- Size, maturity
- Brand and reputation
- Potential to collaborate in the future
- Footprint in target geographies
- Product portfolio

What values does the acquirer need to have? Signs of value alignment:

- Vision of success for my product
- A customer base that aligns with my target users
- Willingness to let me influence strategy

Which acquirers likely meet my needs?

Which types of acquirers would likely meet my needs? E.g.,

- Multi-national corporations
- Local manufacturers/distributors
- Innovation, R&D, design entities
- Investor (e.g. private equity)

How do I create a short list of organizations I should consider selling to?

Which organizations on the list are most aligned with my criteria?

What value do I need to show potential acquirers?

Which of my preferred acquirers are interested in my technology/organization?

What motivates them? E.g.:

- Compelling commercial value
- Strategic alignment with existing markets / customer base
- Compatibility with existing product portfolio

What do I need to demonstrate to potential acquirers? E.g.:

- Technical viability (through proof of concept or pilot trials)
- Potential impact
- Strategic relevance to the acquirer, in terms of geographies, health issues, target markets, etc.
- User demand / existence of market
- Commercial sustainability and attractiveness
- Pathway to regulatory approval
- Manufacturability

What milestones do I need to reach to demonstrate evidence in these areas?

Do I need to make changes to my current legal structure (e.g. start a new entity that owns the IP) to reach these milestones?

What timing should I aim for?

Are there benefits to selling early vs late? Considerations include:

- Optionality to explore other scaling models
- Potential financial return
- Bargaining power in the negotiations
- The time and resources I am willing to spend to reach each milestone

What types of funding do I need and when?

Do I need to raise additional funding to reach the milestones required to sell my product?

Given the stages at which I need funding, which types of capital should I seek?

- Friends and family money
- Competitions and prize money
- Grants
- Program-related investments
- Impact capital
- Angel equity
- Equity investor
- Debt investor
- Revenue-based financing
- Convertible debt

What terms and restrictions would each type of capital come with?

- IP openness
- Growth strategy
- Payment timeline and schedule, interest rate (for debt)
- Valuation, voting rights (for equity)

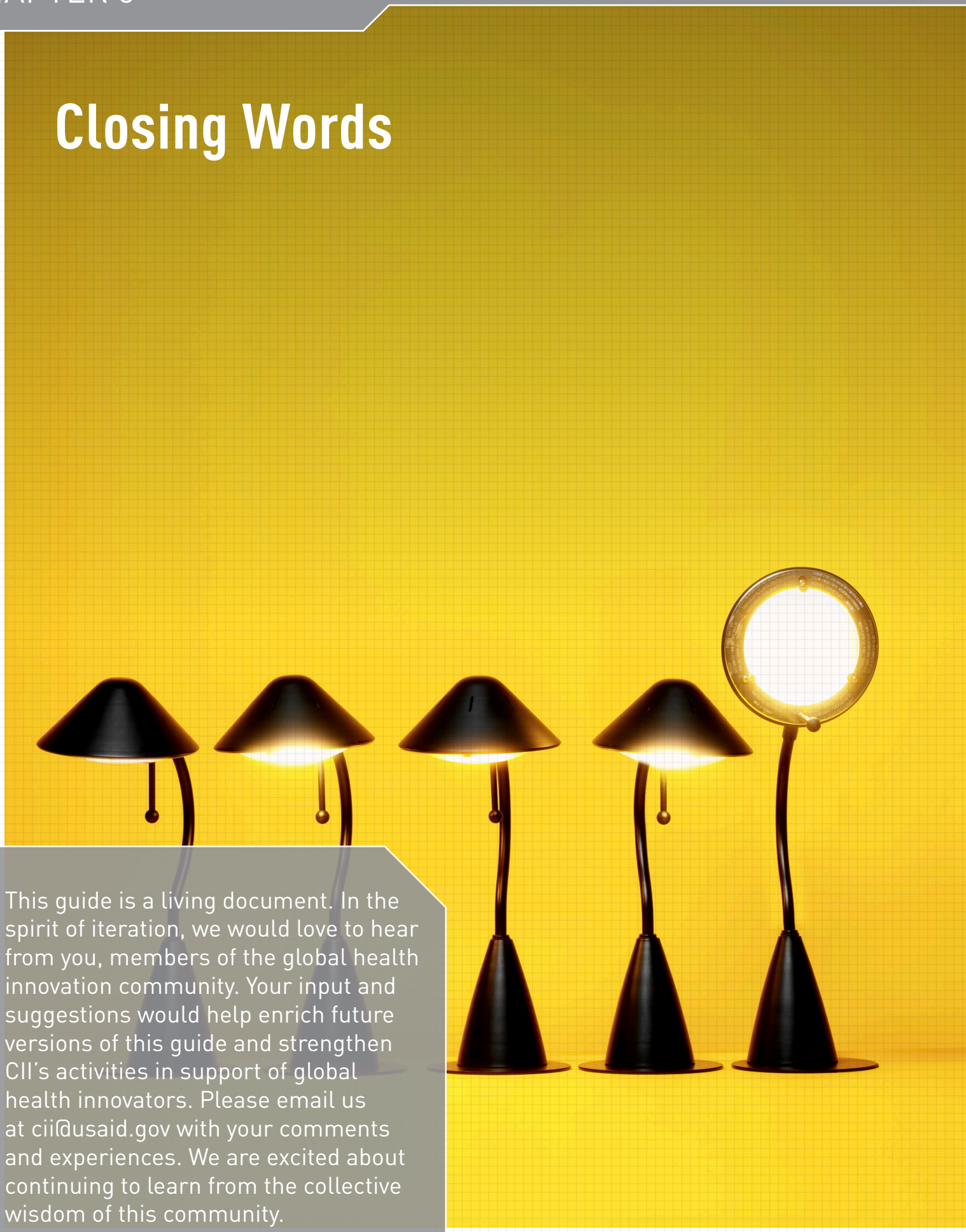
Determine which aspects of the organization to sell: An innovator seeking to be acquired needs to first determine what aspects of the organization to sell – intellectual properties (sold through a full technology transfer), physical assets, and/or the organization itself. The answer depends on the innovator's preferences and the interests of potential buyers. For example, if the innovator wants to retain the organization's core product development capabilities, he/she would choose to sell a specific IP to an individual buyer. If potential buyers value the talent and infrastructure built up to support an innovation, then they would be interested in buying the entire organization.

> ***Anecdote:*** *Sushrut sold its business "wholesale" to Smith and Nephew. Smith and Nephew was interested in entering the Indian market for surgical equipment, and wanted to buy the extensive sales and physician engagement infrastructure that Sushrut had built up over the years, in addition to its orthopedic implant products. After a brief post-sale transition period, the owners left the company, but all Sushrut employees remained to work as part of Smith and Nephew.*

Understand the investment criteria of acquirers and the implied milestones: As with other scaling models, innovators need to perform due diligence on prospective acquirers to understand why they are interested and what they are seeking. For corporations seeking commercial opportunities to consider a global health acquisition, the product or technology must support the corporate strategy and contribute to the company's financial performance and growth. This usually implies that the product or technology can fill a gap in the company's portfolio and give it access to new markets. Potential gains are weighed against risks and investments. For example, a potential acquirer may not have the distribution capabilities needed to scale-up the product or technology in target markets, and will need to make sizable investments to create such capabilities. To demonstrate strategic alignment, innovators need to show many types of evidence, including technical viability (i.e., that the product or technology works), IP ownership (i.e., the innovator has defendable ownership over the applicable IP for the product or technology), a value proposition for the relevant markets (i.e., the product or technology would bring a compelling and recognizable health impact and economic value to target users), a regulatory pathway (i.e., the product or technology will gain regulatory approval in target countries by following a set of well-understood pathways), and manufacturability (i.e., the product or technology can be made at commercial scale). Each of these dimensions could require the innovator to invest considerable time and resources, depending on the robustness of the evidence required. Innovators should ask prospective buyers to divulge their investment criteria early on so they can determine whether to pursue this pathway to scale, and if so, understand all the challenges it would entail.

Find the optimal timing: Similar to licensing, a company can be acquired early, when the products are still in proof-of-concept, or late, when the products are being sold on the market. The tradeoffs that innovators should consider when timing the sale of their innovations are similar to those for licensing (see page 45).

Closing Words



This guide is a living document. In the spirit of iteration, we would love to hear from you, members of the global health innovation community. Your input and suggestions would help enrich future versions of this guide and strengthen CII's activities in support of global health innovators. Please email us at cii@usaid.gov with your comments and experiences. We are excited about continuing to learn from the collective wisdom of this community.

Photo: Getty Images

In developing this guide, we consulted a number of global health innovators, medical technology industry experts, and leaders of organizations investing in and supporting this field. We asked them for advice to pass on to readers of this guide, and we have incorporated it into prior sections. As last words, we want to reiterate three simple, yet important messages, that were recurring themes in these conversations:

START EARLY

Planning for scale should happen as early as possible in the product development process. Knowing who your partners might be, how you are likely to work with them, and what would make these partnerships successful often has important implications for near-term decisions and milestones. Laerdal Foundation provided early support to health organizations to develop a newborn resuscitation training program, as they learned early on that a new program was needed for low-resource settings to complement their resuscitation device. Similarly, OpenMRS decided early on that its platform would remain a free and open source, which guided decision-making on how it expanded.

CONSULT WIDELY

While we hope this guide can help innovators consider their scaling model and pathway choices, these exercises and concepts will be more powerful when innovators discuss them with mentors and supporters, especially those with entrepreneurial experience scaling up products and demonstrating impact in similar markets. They would be able to provide reality checks to the answers innovators suggest for the exercise questions, offer more reference points to help innovators understand the capabilities and resources needed for scale-up, and suggest additional experts and resources for further investigation.

ITERATE OFTEN

As innovators develop their product or technology, new and better information will constantly arise that could be used to refine the assessments covered in this guide. For example, a realization that the regulatory pathway for a crucial market is much more complex than previously understood could change the innovator's decision from driving scale-up in-house to licensing out. Therefore, innovators should regularly iterate the choices made in this guide, especially when they reach a major milestone or receive feedback from customers, mentors, and other stakeholders.

APPENDIX A: CURATED RESOURCES

Framework, models, lessons, case studies on scaling up social innovations		
Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations USAID Center for Accelerating Innovation and Impact	https://www.usaid.gov/cii/guide-introduction-and-scale	Resource designed to support global health practitioners better coordinate and plan for developing, introducing and scaling global health solutions. Includes a reference guide that outlines the cadence of activities across a four stage model, case examples, a Microsoft® Excel-based project management tool and growing suite of supporting templates and tools.
From Blueprint to Scale: Case for Philanthropy in Impact Investing Monitor Group (now Deloitte) and Acumen Fund	http://acumen.org/content/uploads/2013/03/From-Blueprint-to-Scale-Case-for-Philanthropy-in-Impact-Investing_Full-report.pdf	Report offers an in-depth, demand-side understanding of the needs and challenges facing inclusive businesses and the role of "enterprise philanthropy" in bringing social impact to scale. The report uses Monitor's four-stage business lifecycle framework to track the development of inclusive businesses, uses case studies from the Acumen Fund portfolio to illustrate four themes of effective enterprise philanthropy practice and offers a playbook for interested funders.
Beyond the Pioneer: Getting Inclusive Industries to Scale Monitor Group (now Deloitte)	http://www.beyondthepioneer.org/	Report aims to identify the barriers to scaling market-based solutions, and to understand the factors that have helped solutions to scale successfully. The report describes four levels of scaling barriers, proposes an industry facilitator as a solution and offers recommendations for each major stakeholder group.
Hardware Pioneers: Harnessing the Impact Potential of Technology Pioneers FSG	http://www.fsg.org/publications/hardware-pioneers	Report outlines the challenges for hardware innovators in scaling their technologies in low-resource settings, due to the need for the right mix of both business and technology skills. It makes the case for networked approaches to scaling hardware technologies, including partnership, technology transfer, adoption and adaptation.
Local Markets for Global Health Technologies Lessons Learned from Advancing Six New Products	http://www.ghspjournal.org/content/2/2/152.full	Article reviews the experience of scaling six global health products, and identifies four key lessons learned: build supply and demand simultaneously; support a lead organization to drive the introduction process; plan for scale-up from the start; profitability for the private sector is an absolute.
Taking Innovations to Scale: Methods, Applications and Lessons Results for Development Institute and MSI	http://www.resultsfordevelopment.org/sites/resultsfordevelopment.org/files/Taking%20Innovations%20to%20Scale_0.pdf	Report aims to provide guidance on the practical implications of pursuing a systematic approach to scaling up, with insights on how two different approaches relate to each other and how they may best be applied.
Global Health Innovation Guidebook Stanford University	http://www.gsb.stanford.edu/sites/gsb/files/files-fpp/28721/globalhealthinnovationguidebook_2.pdf	Guide offers insights and lessons to help innovators navigate the process of taking a global health solution from idea to implementation. The guide compiles stories from global health stakeholders to offer global health-specific guidance to product identification, invention and implementation.

Framework, models, lessons, case studies on scaling up social innovations		
What's Your End Game? Dalberg Global Development Incubator, in Stanford Social Innovation Review	http://ssir.org/articles/entry/whats_your_endgame	Article makes the case for nonprofits to consider the long-term role in the solution they offer to address a social problem, rather than focus only on scaling up. It outlines six end game options: open source, replication, government adoption, commercial adoption, mission achievement and sustained service.
Marketing Innovative Devices for the Base of the Pyramid HYSTRA	http://hystra.com/marketing-devices	Report reviews analyses of 15 pioneer organizations selling devices to the Base of the Pyramid and offers 10 key lessons on how to design an appropriate value proposition, create effective marketing strategies, organize an efficient sales force and define the right level of overheads.
50 Breakthroughs LIGTT: Institute for Globally Transformative Technologies, Lawrence Berkeley National Lab	https://ligtt.org/50-breakthroughs	Report reviews the most critical development challenges and identifies 50 technology breakthroughs that are required to address them. It aims to focus attention on the most needed technologies, and provides technologists with context, needed parameters and insights on the market potential for each new technology.
Lean LaunchPad® video library and resources VentureWell	https://venturewell.org/i-corps/llpvideos/ https://venturewell.org/xcelerator/resources	Video library is designed to support the faculty of entrepreneurship programs in learning and teaching the Lean LaunchPad® methodology. The Lean LaunchPad® methodology teaches entrepreneurial skills via experiential learning as a way to engage students with real world entrepreneurship. The curated resources provide a range of articles, reports, case studies, videos and sites on key topics for global health innovators, including business model/planning, fundraising/pitching, commercialization and partnerships.
Principles for Digital Development Digital Principles	http://digitalprinciples.org/wp-content/uploads/2015/05/Principles-Overview.pdf	A streamlined list of principles to capture the most important lessons learned by the development community in the implementation of technology-enabled programs. Having evolved from a previous set of implementer precepts endorsed by over 300 organizations, these principles seek to serve as a set of living guidelines that are meant to inform, but not dictate, the design of technology-enabled development programs.
On Innovation and Pinballs: Five paths to scale in early-stage impact investing Omidyar Network and Accion Venture Lab, in Stanford Social Innovation Review	http://ssir.org/articles/entry/on_innovators_and_pinballs	Article describes five different routes for early-stage innovative firms to scale-up and spur social change. Two of these paths involve the initial firm delivering at scale (i.e. direct scale) - organic growth and acquisition/partnership. The other three are variations in the way an initial firm can cause or contribute to scale beyond the immediate sphere of its operations (i.e. indirect scale) - inspiring copycats, motivating competitive responses, as well as ecosystem effects around public goods availability and policy change. The authors argue that these indirect pathways are very powerful ways to creating and scaling impact, and investors need to consciously recognize them, value their impact, and find better ways to identify, measure and support them.

Tools for overall business planning, including scale-up		
Business Model Canvas Strategyzer	https://strategyzer.com/canvas	Strategic management tool that allows entrepreneurs to describe, design, challenge, invent, and pivot their business model. Tool is available via download and a web application.
Inventor to Entrepreneur Tool Miller Center for Social Entrepreneurship at Santa Clara University and NESsT	http://alexgmendoza.com/talent	Tools designed to help Entrepreneurs and Inventor-Entrepreneurs assess the core competencies that they need to develop in themselves or within their team in order to build their businesses for greater impact. Tools follow a two-stage process: 1) Self-discovery – use of a survey to assess talent and leadership skills compared to the complete set of competencies needed relative to the stage of enterprise; 2) Implementation – based on identified competency gaps, mentors and the inventor-entrepreneur work together on a talent development plan to respond to the enterprise needs of their business.
Social Enterprise Stage Assessment Tool Global Social Benefit Institute at Santa Clara University	http://static1.squarespace.com/static/55036eefe4b0fe6c8e833e4a/t/558dcadae4b02f92dcee377d/1435355866102/GSBI-Stage-Assessment-Tool+%281%29.pdf	Tool designed to guide the development of a social enterprise from conception to full-scale implementation. The tool allows users to design methodology and content for social enterprise accelerator programs, mentor social enterprises, benchmark social enterprises to track their progress and select social enterprises for awards and accelerator programs. Stages are based on the 2012 Monitor Group report, "From Blueprint to Scale: The Case for Philanthropy in Impact Investing."
Choose Your Business Structure US Small Business Administration	https://www.sba.gov/starting-business/choose-your-business-structure	Online reference guide that provides guidance on the legal and tax implications of various business structure options in the United States.
Business Planning for Enduring Social Impact Root Cause	http://socialenterprisefund.ca/uploads/Business%20Planning%20for%20Social%20Impact.pdf	Guide offers practical advice on defining organizational focus and strategy, establishing a road map, building a financially sustainable model and other aspects of business planning. Features a glossary of business planning terms, sample work plan and sample business plan.
A Business Planning Guide for Social Entreprises Social Ventures Australia	http://socialventures.com.au/assets/Business_Planning_Guide_for_Social_Enterprise.pdf	Guide offers step-by-step advice for new social entrepreneurs to think about, research, plan for, start and grow a social enterprise. Users can use the guide to create a business plan, obtain support and investment and monitor and evolve a social enterprise into the future.

Guidance on funding

Smart Impact Capital Center for the Advancement of Social Entrepreneurship (CASE) at Duke University's Fuqua School of Business	http://www.caseonlinelearning.com	Smart Impact Capital is a series of rigorous, highly-actionable online modules that address the needs and common pitfalls of impact entrepreneurs seeking to raise investment capital. The combination of short videos, diagnostic and financial tools, and "perspectives from the field" help entrepreneurs to communicate their ask, develop a strong fundraising strategy, and manage relationships with a broad array of investors with blends of goals around risk, return and impact. To find out more about pricing and access to the modules, please visit the website or email CASE@fuqua.duke.edu.
Fundraising for Global Health Social Enterprises, Lessons from the Field Duke CASE i3 and IPIHD	http://sites.duke.edu/casei3/files/2014/03/CASEi3_Fundraising_Report_.pdf	Report provides guidance to social entrepreneurs to effectively pitch to a potential investor, based on input from investors and successful global health social enterprises. Guidance includes determining the appropriate type of capital, how to screen potential funders or investors and how to craft an effective pitch.
Strengthening Health Systems in Developing Countries Through Private Investment Calvert Foundation	http://www.calvertfoundation.org/storage/documents/GHILP-Final-Deck-Publish-web.pdf	Report summarizes lessons from the Global Health Investment Landscaping Project and focuses on the landscape of global health investors in India and East Africa. The report offers a two-step framework in the last section that investors, and innovators, can use to assess market context using an ecosystem grid and then assess financing needs based on the current state of growth.
The Enterprise Development Toolkit: Supporting Clean Cooking Enterprises on their Journey to Scale (section 2) Global Alliance for Clean Cookstoves	https://cleancookstoves.org/binary-data/RESOURCE/file/000/000/336-1.pdf	The second section of this report on supporting clean cooking enterprises focuses on identifying the amount and types of financing companies need at each stage of development. The section offers a Financing Decision Tree tool, which helps entrepreneurs determine which financing instrument is most appropriate for their enterprise.

Guidance on building strategic partnerships

Evaluating and Selecting a Strategic Partner Donna Peek, SAS Institute, Inc. on Entrepreneurship.org	http://www.entrepreneurship.org/resource-center/evaluating-and-selecting-a-strategic-partner.aspx	Article offers eight steps to consider when selecting a strategic alliance partner, including developing partner selection criteria and preparing a "Partner Proposition Worksheet."

Guidance on licensing and IP		
Successful Technology Licensing World Intellectual Property Organization	http://www.wipo.int/edocs/pubdocs/en/licensing/903/wipo_pub_903.pdf	Manual offers user-friendly guidance on issues essential for understanding licensing, including the context for licensing, key terms of a licensing agreement, negotiation methods and how to prepare for and negotiate a win-win licensing contract.
Hacking the Patent System: a Guide to Alternative Patent Licensing for Innovators Stanford Law School	https://www.eff.org/files/2016/01/26/hacking_the_patent_system_belcher_and_casey_updated_january_2016.pdf	Paper argues that the current patent system is broken and offers guidance on alternative patent licensing options for small companies and startups to protect themselves. Alternative options described in the paper include defensive patent aggregators, patent pledges and patent troll insurance.
Licensing Page Office of Technology Transfer, National Institute of Health	http://www.ott.nih.gov/licensing	Website offers an overview of the intellectual property protection options used by the NIH Office of Technology Transfer on on NIH, CDC, and FDA inventions.
The Top Five Drivers of a Successful Out-licensing Process Ranan Lachman, Marc Samet, BioPharm International	http://www.biopharminternational.com/top-five-drivers-successful-out-licensing-process?id=&pageID=1&sk=&date=	Article offers insights into the five key challenges biotech companies face seeking a partner and managing the out-licensing process. Key challenges include identifying and selecting the right partner, developing relationships and preparing the offering material.
Open Source for Neglected Diseases: Magic Bullet or Mirage? Results for Development Institute	http://healthresearchpolicy.org/sites/healthresearchpolicy.org/files/assessments/files/Open%20source%20high%20res.pdf	Landscaping paper discusses open source approaches for R&D for neglected diseases and their potential to lower costs and R&D time frames, increase collaboration, and build a knowledge commons. The paper describes existing initiatives and ongoing debates and makes recommendations for how to better make use of open source approaches.

Guidance on selling technology or business to another party		
The Truth About Ben and Jerry's Antony Page, Robert A. Katz, Stanford Social Innovation Review	http://ssir.org/articles/entry/the_truth_about_ben_and_jerrys	Article reviews the history of the sale of Ben & Jerry's to Unilever, and dispels myths about this frequently-cited "cautionary tale." The article also offers lessons for social entrepreneurs in selling their business, including using the financial success of the enterprise to negotiate control mechanisms to maintain the social mission.
Selling Up Without Selling Out Dermot Egan, The Guardian	http://www.theguardian.com/social-enterprise-network/2011/may/10/selling-up-without-selling-out	Article reviews challenges in the sale of businesses with social missions, and presents the example of the White Dog Café, which used a "social contract" to license use of the brand to preserve its social mission.
4 Fundamental Principles to Getting Your Startup Acquired Dennis Hung, Tech.co	http://tech.co/principles-startup-acquired-2015-12	Article provides four principles for technology innovators who are looking to be acquired: market the enterprise effectively, have high-quality products or services, keep negotiations open with multiple buyers and make the vision for acquisition clear to buyers.
Building A Great Company May Not Be Enough To Get Acquired Tomio Geron, TechCrunch	http://techcrunch.com/2015/01/21/why-building-a-great-company-may-not-be-enough-to-get-acquired/	Article outlines key actions entrepreneurs can take to increase their chances of being successfully acquired. These include marketing yourself and your innovation within the field, building partnerships with companies that may later lead to an acquisition, and bringing in key talent with industry connections.
What Should A Healthcare Company Do With An Unsolicited Acquisition Offer? Dave Chase , Forbes	http://www.forbes.com/sites/davechase/2016/02/09/what-should-you-do-when-you-get-an-unsolicited-offer/#583f5f616f3f	Article offers key questions an entrepreneur should ask themselves and steps they should take if presented with an unsolicited offer for their enterprise, including: Are there other buyers? What does a process look like that would deliver choices for both a buyer and an equity sponsor?

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