READY, SET, LAUNCH

A Country-Level Launch Planning Guide
for Global Health Innovations

READY

SET

LAUNCH

From CII's IDEA to IMPACT Series

Foreword

USAID's Center for Accelerating Innovation and Impact (CII) was founded to both catalyze new global health innovations and address the roadblocks to rapidly developing and scaling them up. To address these challenges, we not only apply cutting-edge practices to our own work but also collect and share these best practices with the broader global health community.

We began sharing guidance and tools for scaling global health innovations a few years ago through our publication, *Idea to Impact*. This work brought together delivery-focused priority activities and practical tools at each stage of the product development process to ensure successful launch and scale. Our second companion piece in this *Idea to Impact* series, *Pathways to Scale*, provided early-stage innovators with a framework and tools to support business model design and partnership evaluation at critical points along their scaling journey. We have been thrilled with the response, especially the examples of how this work has been put into practice.

Now, with *Ready, Set, Launch: A Country-Level Launch Planning Guide for Global Health Innovations*, we look to complement the existing library of planning support with a companion piece targeted towards country-level launch planning. This work focuses on the critical pivot as you move from early user testing, product design, and building out your organization to actual country selection and planning for launch.

Whether you are asking "what is the right set of countries for my team and product to launch in next?" or "how do I assess and prioritize the highest value country-level interventions to achieve the greatest level of impact and scale?"—there is no shortage of considerations as you move toward implementation. This Guide addresses the complexity of product introduction by providing a simple framework and practical tools to support innovators and practitioners in 1) prioritizing countries for launch, 2) developing a country-specific strategy, and 3) converting this strategy into an operational launch plan—one that creates accountability, sets targets, is actionable, and is carefully budgeted.

With this latest addition to our *Idea to Impact* series, we're proud to continue offering demand-driven public goods to help entrepreneurs, implementing partners, and even donors accelerate impact by improving how they plan for the introduction of health innovations. As with all our work, we encourage you to put this Guide to the test and give us feedback so we can continue building, adapting, and sharing our collective learning.

We look forward to hearing from you.

Wendy Taylor
Director, Center for Accelerating Innovation and Impact
Global Health Bureau/USAID

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Global health practitioners know that introducing and scaling new innovations is a complex process. There is no shortage of factors to consider when developing a product and delivering it to the world's hardest to reach populations—from defining the problem and product requirements to evaluating market feasibility to developing and executing an operational launch plan. As a result, global health innovations often take decades to reach intended users at scale; at times, the innovation never reaches anywhere near global coverage targets (Figure 1). This is in contrast to "typical" launches in the United States and other high-income countries, which often reach their full coverage targets in less than five years.

To accelerate the impact and scale of global health innovations, lessons can be learned from the principles that pharmaceutical and medical technology companies use to coordinate and plan for market introduction and expansion. CII developed the predecessor to this document, *Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations*, with these principles of pharmaceutical and medical technology companies in mind. To support the product development process, *Idea to Impact* provides structure and practical tools from early product design through launch for those planning to reach global scale. Early-stage entrepreneurs, pharmaceutical and medical device companies, graduate students,

Figure 1. Years to scale-up
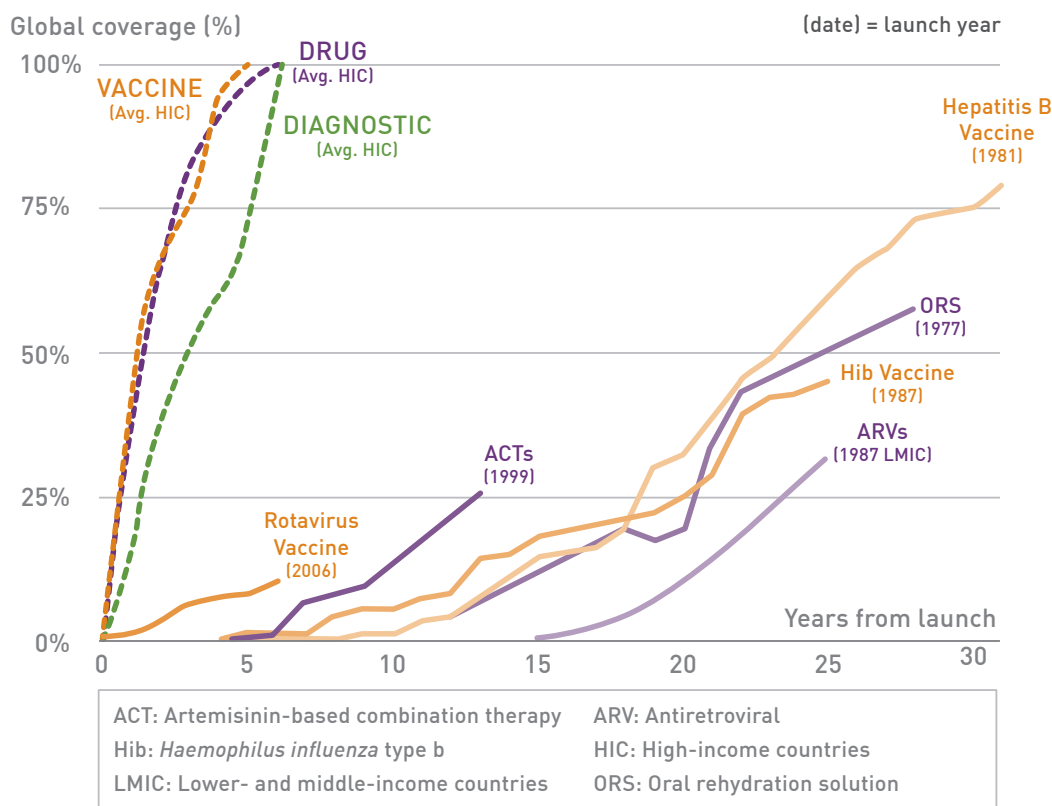
Source: Bill & Melinda Gates Foundation

This complementary Guide, *Ready, Set, Launch: A Country-Level Launch Planning Guide for Global Health Innovations* brings a sharp focus to the critical pivot from global product development to targeted country selection and launch planning.

NGOs, donors, implementing partners, and ministries of health alike have all seen the role that more deliberate and earlier delivery planning can play in accelerating the impact of life-saving innovations.

Achieving sustainable impact and scale, however, requires practitioners who think globally to act locally. This includes understanding and addressing the many country-level factors, including existing user behaviors, local regulatory requirements, supply chains, key opinion leaders, and local religious and cultural norms that can vary within a country, state, county, or village. This complementary Guide, *Ready, Set, Launch: A Country-Level Launch Planning Guide for Global Health Innovations*

brings a sharp focus to the critical pivot from global product development to targeted country selection and launch planning.

With input from a diverse set of practitioners and lessons gathered from both successful and not-so-successful launches, *Ready, Set, Launch* brings together guidance, tools, and case studies to support country prioritization and the development of a comprehensive scale-up strategy and launch plan. While there is no simple formula or one-size-fits-all solution, this Guide aims to provide practitioners with a set of key questions and a more systematic approach to launch and scale-up.

Ready, Set, Launch does...

- Help practitioners **select a country for product launch** and/or **determine whether they should scale a product in a specific country**

- Develop a **plan for country-level scale-up of products**

- **Tailor launch approaches to specific countries and products**

- Learn from **practical examples** and **apply tools**

Ready, Set, Launch does not...

- Help practitioners **develop new global health products**

- **Test new products** without any existing data from clinical trials and/or proof of concept

- Gather information **specific to one country or geography** or **specific to one product or type of products**

- Access a **ready-made scale-up strategy**

When to use this Guide

Ready, Set, Launch takes a deeper dive into many of the activities outlined in Stage 3 of *Idea to Impact*—with a sharp focus on country-level launch planning. This Guide assumes that practitioners have spent significant time (sometimes years) addressing the many related product development and delivery activities completed before Stage 3. For this Guide to be useful, practitioners should have a product that is cost-effective, has demonstrated clinical efficacy (although local clinical evidence or product modifications may be necessary) and have already developed a global situation assessment as per Stages 1 and 2 of *Idea to Impact*—for example, by defining the product's global vision and value proposition, understanding the global market feasibility and opportunity, ensuring that the product meets WHO and other global guidelines and standards, etc. However, planning for country-level launch can occur in parallel with some of the above activities, especially for those that take time (e.g., updating guidelines, obtaining clinical evidence).

Lessons learned from using this Guide can—and should—inform the overall development and delivery planning processes by providing new insights that can help shape both the global strategy and the country-level launch planning.

You can also read *Ready, Set, Launch* along with its companion Guide, *Pathways to Scale*, which supports global health innovators in the early stages of product development as they consider their particular business model and partnership options. An innovator with a technically viable product could be following *Ready, Set, Launch* to develop plans for country launch and scale-up, while at the same time, using *Pathways to Scale* to weigh short and long-term strategic options for business model and partnership decisions.

Figure 2 provides guidance on the primary focus of each publication, its target audience, and the ideal point in product development cycle for a practitioner to consult it.

> ❝ *An overarching global vision for the product should always remain top of mind. It drives purpose and alignment with necessary country-specific strategies.*
>
> **Jeffrey Jacobs, Merck for Mothers**

> ❝ *Some of the first questions I ask about a global health innovation is if there is an evidence-base for its health impact and if the innovation fits with global strategy. These questions are important for generating buy-in at the global level—with organizations such as the WHO—but also at the country level.*
>
> **Lily Kak, USAID, Maternal and Child Health**

Figure 2. The IDEA to IMPACT Series

IDEA TO IMPACT

Purpose: Identifies **priority activities and provides project management oversight** across four stages of the product development continuum to help practitioners think through, plan, and execute on delivery-related activities

Target Audience: Social entrepreneurs, innovators, implementers, and funders who are developing a global health innovation

PATHWAYS TO SCALE

Purpose: Provides organizational guidance for innovators in selecting **the most relevant business model and partnership options** to be able to scale

Target Audience: Social entrepreneurs and innovators building an organization and/or partnering in preparation for launch and scale

READY, SET, LAUNCH

Purpose: Supports practitioners in selecting **initial launch country(ies) and creating a comprehensive strategy and operational launch plan** to achieve scale

Target Audience: Social entrepreneurs, innovators, implementers, and funders ready to pivot from product development to actual introduction into a given geography

USAID's Center for Accelerating Innovation and Impact (CII's) IDEA to IMPACT series shares guidance for scaling global health innovations. Through case studies and tools, this series outlines delivery-focused priority activities at each stage of the product development process, provides a framework and tools to support business model design and partnership evaluation, and supports country-level planning for launch.

Who can use this Guide

Three audiences stand to benefit most directly from *Ready, Set, Launch*:

Innovators

Innovators, broadly defined, are organizations—either non-profit or for-profit—that have successfully developed and tested a product and are now looking to scale. Innovators are often resource constrained, and their expertise is generally concentrated in technical product development rather than in understanding and influencing markets. In many cases, innovators are trying to balance their desire for health impact with concerns around financial sustainability. They want to drive impact and sales—fast.

Implementers

Implementers include both public sector agencies and large non-profits that specialize in healthcare delivery and house significant global health expertise. These actors often have an established presence in countries of interest and their primary focus is impact and long-term uptake. Non-profit implementers often work on project-specific cycles that support multiple products at once. Implementers generally have strong relationships with local stakeholders, importantly governments, as a result of years of work in a given country.

Donors

Donors are development agencies, public and private financial institutions, and philanthropic entities that fund the activities of innovators and implementers. Donors are especially concerned with tracking the impact of their dollars. As such, they may want to use this Guide to ensure that grantees have a plan in place to achieve scale, and then monitor the scale-up efforts of their grantees to ensure that steps are taken toward achieving impact at scale.

- Depending on whether a practitioner is an innovator, implementer, donor, or other global health practitioner, the activities described here may prove easier or harder to take on. For example, innovators worried about sustaining their venture through scale-up will likely find challenges related to creating sustainable business models or generating funding much more salient than implementers who are adopting an innovation or donors who are funding one.

- In addition, different practitioners will face their own internal challenges depending on their skills, resources, and networks within a country; it is important to take these unique limitations into account when moving through this Guide. More importantly, focusing on the areas where these limitations exist is critical, even if these limitations are more difficult to address. A comprehensive launch and scale-up strategy needs to account for such limitations rather than ignore or overlook them and risk allowing important tasks to slip through the cracks.

Apart from these three audiences, *Ready, Set, Launch* can also inform other global health practitioners, including **research institutions and laboratories** that develop new products, **civil society organizations** that support healthcare delivery, and **large for-profits (e.g., pharmaceutical and medical technology companies)** interested in expanding product reach into emerging markets. This Guide can also be used as a teaching tool for **academic institutions** informing future global health and business leaders how to approach introduction and scale.

Ready, Set, Launch is primarily geared toward **drugs, devices, and diagnostics**. However, the principles discussed and the activities and tools included can be applied to other global health innovations as well, including vaccines, health behaviors, direct-to-consumer products, service delivery systems, and health equipment/infrastructure.

How this Guide fits together

This Guide is made up of two parts:

(1) **Ready, Set, Launch**
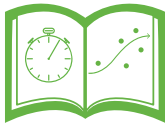
Ready, Set, Launch provides high-level guidance through three steps: 1) country prioritization, 2) strategy development, and 3) implementation planning. For each of these three steps, the Guide outlines key questions to consider, provides exercises (with approximate estimates of the time to complete), and suggests tools to help answer those key questions. It offers real-world examples through both short vignettes and more comprehensive case studies that highlight lessons relevant to the launch planning process.

(2) **Supplemental Toolkit**

The Supplemental Toolkit, available on CII's website, is a collection of tools and templates highlighted in the Guide that can provide structure, inspiration, and practical guidance for the launch planning process. To help see how these tools might be used in practice, this Guide contains illustrative, pre-populated tools based on the development of an operational launch plan for chlorhexidine (CHX) in Nigeria. See page 51 for more details.

We have also included a fold-out "Country Launch Canvas" which provides a composite of all of the key elements of a scaling strategy in one place. It can serve as a brainstorming tool to help practitioners think through many of the principles described in this Guide and to highlight key learnings and activities of a given launch plan. For those downloading this Guide, the Country Launch Canvas can be found in the Supplemental Toolkit. See page 68 in the appendix for more details on the Country Launch Canvas.

It should be noted that activities described are suggested steps for those who want to follow a "play book." They are only one way of doing things, but not the only way. It is more important to strive to answer the key questions posed in the Guide rather than to strictly follow the sequence of activities.

As this Guide will be continually updated with new thinking, case studies, and tools, we encourage input or suggestions. Contact information along with the latest version of the Guide and toolkit can be found at **www.usaid.gov/cii.**

Set...
Build a Strategy
2

Assess market and barriers to scale

Develop strategy for overcoming barriers to scale-up

Finalize country selection

Develop operational launch plan

Ready?
Select a Geography
1

Launch!
Plan for Scale-Up
3

Shortlist countries for launch

GUIDING PRINCIPLES
Leadership alongside partnership
Integration
Re-evaluation and iteration
Sustainability

Set uptake targets and create monitoring plan

Core Components of Scaling

Market and user

Coordination

Manufacturing and distribution

Policy, advocacy, and financing

Clinical evidence and regulatory

1 # Ready? Select a Geography

Prioritize an appropriate country (or set of countries) for scale-up, based on the vision for the product and market realities at hand.

2 # Set... Build a Strategy

Assess the chosen market in depth in an effort to identify barriers to scale and address those barriers with thoughtfully designed interventions.

3 # Launch! Plan for Scale-Up

Develop a detailed operational launch plan to guide day-to-day activities, set realistic uptake targets, and create a plan to monitor progress.

Guiding principles

Four key principles should guide country-level launch planning in order to ensure that resources dedicated to scale-up are used wisely and that the process stays on track.

- ## Leadership alongside partnership
  Successful launch planning requires a leader—a single entity responsible for coordinating scale-up of the product every step of the way. At the same time, a launch cannot succeed without partners—particularly those within the government and local ministry of health—supporting specific aspects of the process and advocating for the resources needed to push scale-up along.

- ## Integration
  Any scale-up strategy should seek to support a country's stated health priorities and to integrate into ongoing health systems (potentially both public and private, depending on the relevant channels in the country and of the product) in order to leverage existing infrastructure and avoid creating parallel programs. Ensuring that the product is integrated into existing health priorities and systems will increase the likelihood of a successful launch.

- ## Re-evaluation and iteration
  As they learn more, practitioners should continuously revisit both the decision to scale and the activities associated with scaling. Scale-up is far from a linear process with clear milestones—there are bound to be failures that will require backtracking, changing plans, and trying again. Practitioners can use what they learn from these experiences to pivot the product, strategy, and operational launch plan.

- ## Sustainability
  A country-level scale-up strategy should fit into an already established global pathway to scale for the product—whether that strategy is to grow through partnerships, a multi-stakeholder partnership, or a licensing deal. The launch plan should include a clear understanding of how the product will be financed (public market) or generate revenue (public and/or private market) over the long-term.

Core components of scale-up

During product introduction, there are five inter-connected **core components** of scale-up that require continuous evaluation and action on the part of practitioners. A failure to address an urgent need within one core component could put the entire scale-up effort at risk. During the country-level launch planning process, the questions below can serve as a reference to better understand the market and ensure launch planning is on track. **Note also** that for each core component of scale-up, a summary of product-specific scale-up barriers for drugs, devices, and diagnostics can be found in the appendix.

Core Components	1. Ready? Select a Geography
MARKET AND USER	• What signs can provide information about user demand (e.g., extremely low willingness to pay, market saturated with high-quality alternatives)?
MANUFACTURING AND DISTRIBUTION	• Are production/pricing economics viable for the market? • Is intellectual property protected?
CLINICAL EVIDENCE AND REGULATORY	• What is the length and cost associated with the regulatory approval process?
POLICY, ADVOCACY, AND FINANCING	• How do key decision makers and/or key opinion leaders feel about the product?
COORDINATION	• Who can support launch, either via a dedicated resource within the practitioner organization or a potential uptake coordinator in the country?

The guiding principles on the previous page, and the core components outlined here, sit at the center of the launch planning process. We will revisit them at each step of this Guide.

2. Set... Build a strategy	3. Launch! Plan for scale-up
• Who is the target user? • Who influences the target user? • What is the point of care/point of access that is most relevant? • What competing products exist?	• What specific activities can be carried out to generate demand with the target user? • Who are the initial sales targets? Secondary?
• Will the product be supplied via local and/or global manufacturing? • What are the target delivery channels to reach target users (e.g., public, private)? • Are production economics in line with ability and willingness to pay?	• Who should the distribution partners be? • How will sales and marketing responsibilities be split between these partners?
• What additional clinical evidence is needed? • What does the regulatory approval process require? How long does the process take?	• How can clinical evidence be used to rally support for the product?
• Who is the target payer? What is their ability to pay? Willingness to pay? • What organizations have been involved in or provided resources for scale-up activities for similar activities in the past? • What is the process for including the product in appropriate protocols/lists (e.g., essential medicines list, national protocol)	• How do key stakeholders continue to be engaged? • Which stakeholders should be involved vs. consulted vs. informed?
• Who are ideal candidates to lead the launch and scale-up and/or serve the uptake coordinator role?	• What will the lead/uptake coordinator do on a day-to-day basis to keep scale-up partners in alignment?

Ready? Select a Geography

Set...
Build a Strategy
2

Assess market and barriers to scale

Develop strategy for overcoming barriers to scale-up

Develop operational launch plan

Launch!
Plan for Scale-Up
3

Finalize country selection

Set uptake targets and create monitoring plan

GUIDING PRINCIPLES
Leadership alongside partnership
Integration
Re-evaluation and iteration
Sustainability

Shortlist countries for launch

Core Components of Scaling

Market and user

Coordination

Manufacturing and distribution

Policy, advocacy, and financing

Clinical evidence and regulatory

Why is this step important?

Too often, practitioners are not proactive in selecting where to focus their initial launch. They rely instead on tenuous connections ("A distributor in Country X expressed interest a few months ago...") or fall back on that which is most convenient ("We should launch in Country Y since our clinical trials took place there..."). This kind of thinking can lead practitioners to devote valuable time and resources to launch in a market that may not be the best fit for the product. Step 1 demonstrates how to choose launch countries in a purposeful, iterative, and strategic way that increases the chance of a successful scale-up. Selecting the right set of early adopter countries can also build evidence and inspire introduction and scale-up in other countries in the medium and long-term.

What does this step entail?

Practitioners should select criteria that are most relevant to them in determining where the product should launch (e.g., market size, market feasibility, etc.). Using these criteria, the practitioner will develop a shortlist of countries for launch and eventually choose one country or a subset of countries in which to focus launch planning.

What are the key outputs of this step?

- A shortlist of country(ies) for introduction and scale of the product
- A final choice for the country(ies) that is/are best suited for initial scale-up exploration and focus

Note that practitioners may approach this step differently, depending on how much they have thought about country selection to date. Consider the following scenarios:

- **Country selection has not been considered at all**
  This may apply to products that have been developed in an academic setting or with a developed market in mind. These products would benefit from completing this entire step to fully consider country selection.

- **One or more target countries have been identified for scale-up**
  This may apply to products that already have a shortlist of potential launch countries and could skip to Step 1.2. However, a quick vetting of the shortlist is always useful as it may raise additional considerations.

- **Target country has already been selected**
  Donors and implementers are the most likely practitioners in this scenario, particularly if they are supporting a product later in its scale-up efforts or have pre-determined priority countries. A quick revisit of the principles of Step 1 could be useful for vetting the existing rationale before moving forward—though the practitioner could also move directly to Step 2.

While Step 1 involves explicit country selection decisions, the ultimate decision to scale in a particular country should be continually revisited throughout the launch planning process based on new findings and early results—as per the guiding principle of re-evaluation and iteration. The situation on the ground will likely change (politically, economically, etc.), and new opportunities or barriers may emerge.

Step 1.1: **Shortlist countries for launch**

The purpose of this sub-step is to develop a shortlist of countries that could make for high-potential launch locations. The value in creating a shortlist, rather than immediately honing in on a single country, lies in having a menu of countries to choose from—both for future country launches and in case the need arises to reconsider the choice of a launch country later on in the process.

?

Key questions this sub-step will answer include:

- **What criteria (both quantitative and qualitative) are most important to consider** when shortlisting countries for launch for a given product?
- **What information do we need** in order to assess potential countries against these criteria, and **how can we obtain these data?**
- **What countries can be immediately eliminated from consideration** based on softer considerations (e.g., global strategy, donor strategy, etc.) or organizational-specific considerations (e.g., need for a market of a certain size, funding for specific geographies, regional ties)?

Exercise 1: Create a shortlist of countries via rapid analysis (One week)

To begin, eliminate any country that does not meet specific inclusion criteria, such as market size or donor priorities (if applicable). The countries that pass through this first filter can then be compared against one another using the criteria that are most relevant to the product and most important to the practitioner in question. In most cases, two common criteria are market size and feasibility of entry.

- **Market size** helps practitioners understand the addressable market for their product. Indicators that help practitioners assess market size include demand (e.g., the *actual* quantities of a product or service that would be purchased and/or used over a certain timeframe) and ability to pay or willingness to pay

(e.g., health expenditure per capita of a specific market segment), and accessible channels of distribution (e.g., where can the product be sold).

- **Feasibility of entry** allows practitioners to understand the ease of implementation and how quickly they can reach scale in a country. Indicators that help practitioners assess feasibility of entry include average length of regulatory approval process, security and political risk, ease of trading across borders, and tariff/VAT rates, among others.

You can use publicly available quantitative data to assess each country's performance against these key criteria.

> *Things change—we've changed priority countries before. So having a 'menu' of countries to choose from is important.*
>
> **Markus Steiner, FHI 360**

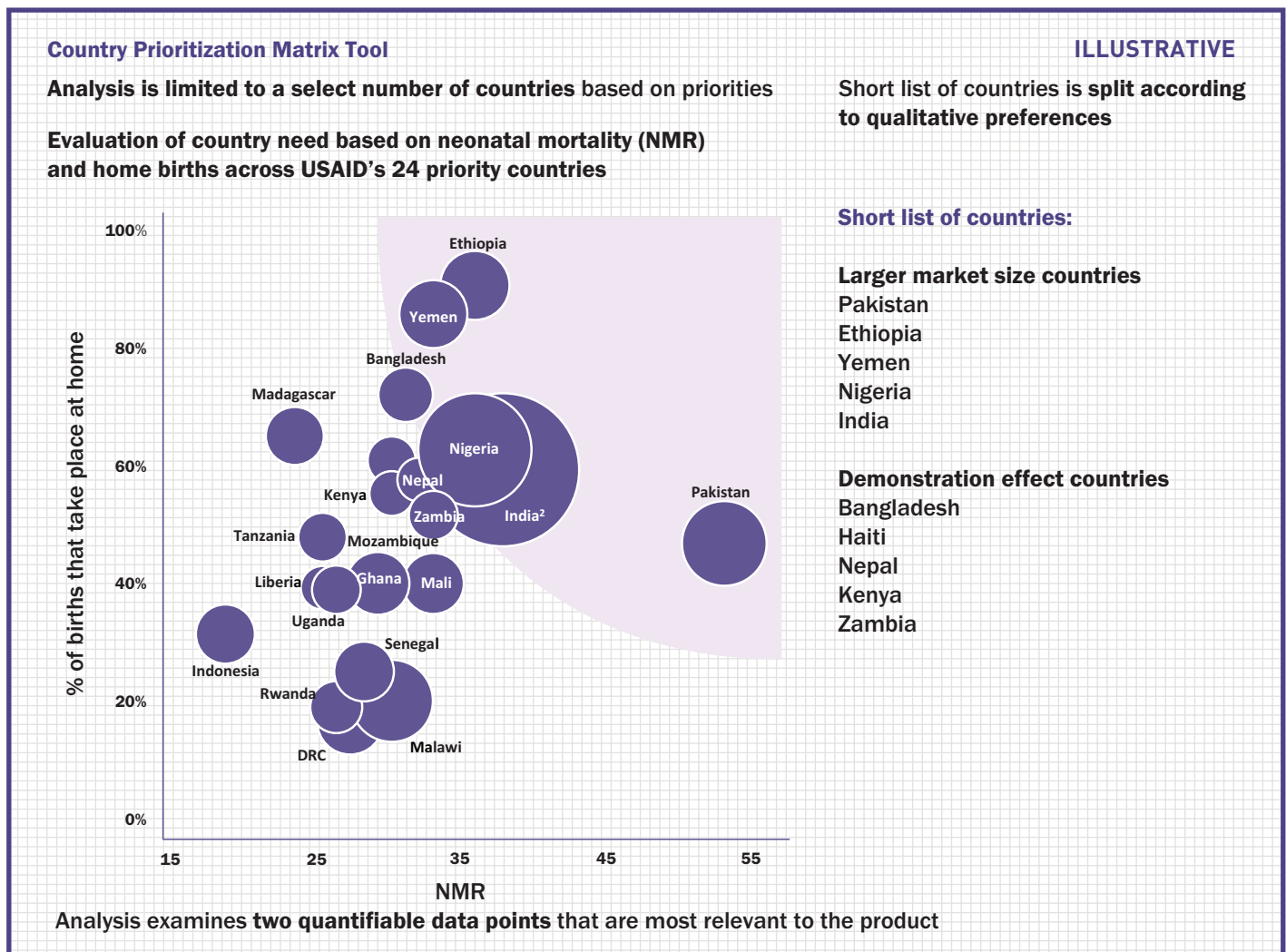> *Casting a wide net is important when choosing where to scale—one almost has to go on a roadshow in 25 countries and develop a shortlist accordingly. In planning for the introduction of our HIV diagnostic test, we needed to shortlist countries with a clear tender process and quality local distributors. Those were the critical selection criteria for us.*
>
> **Kara Palamountain, Kellogg School of Management**

The Country Prioritization Matrix Tool allows the practitioner to visually compare countries under consideration for launch by measuring their performance on market size and feasibility of entry in a basic 2x2 matrix. The simplest way to build such a matrix is to select two quantifiable data points that are most relevant to the product and that best represent market size and feasibility of entry. However, if practitioners wish to make the shortlisting process more nuanced, they can build two composite variables made up of several quantifiable data points that correspond to market size and feasibility of entry (see the Country Prioritization Excel Tool in the Supplemental Toolkit for an example of how composite variables can be created).

After completing this quantitative analysis, any outstanding qualitative preferences can then be applied to the shortlist—further narrowing the list down to a smaller selection of high-potential countries. One example of a qualitative criterion is the strength of the partnership landscape in a given country.

Country Prioritization Matrix Tool   **ILLUSTRATIVE**

Analysis is limited to a select number of countries based on priorities

Evaluation of country need based on neonatal mortality (NMR) and home births across USAID's 24 priority countries

Short list of countries is **split according to qualitative preferences**

Short list of countries:

Larger market size countries
Pakistan
Ethiopia
Yemen
Nigeria
India

Demonstration effect countries
Bangladesh
Haiti
Nepal
Kenya
Zambia

(Bubble chart: % of births that take place at home (y-axis, 0%–100%) vs NMR (x-axis, 15–55). Countries plotted: Ethiopia, Yemen, Bangladesh, Madagascar, Nigeria, Nepal, Kenya, Zambia, India², Pakistan, Tanzania, Mozambique, Liberia, Ghana, Mali, Uganda, Senegal, Indonesia, Rwanda, DRC, Malawi)

Analysis examines two quantifiable data points that are most relevant to the product

Source: DHS data. Analysis adapted by Center for Accelerating Innovation and Impact (CII) across 24 priority countries (Afghanistan and S.Sudan not shown)

> *One of the biggest mistakes with country selection is overestimating potential demand. Demand is not need—demand also depends on who is willing to procure and levels of care-seeking.*
>
> **Kate Schroder, Clinton Health Access Initiative, Inc.**

Step 1.2: **Finalize country selection**

The purpose of this sub-step is to determine where the product will have the greatest impact, the highest likelihood of success, and serve as a catalyst and inspiration for future country launches and global scale.

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Key questions this sub-step will answer include:

- What was the **experience of others that tried to scale** in the shortlisted countries?
- Which shortlisted countries **have developed/are developing an enabling environment** that will allow the product to achieve the greatest impact and scale?
- Which shortlisted countries **have the most significant barriers/challenging environments** to overcome?
- Are there **other important considerations in selecting a country** (e.g., demonstration effect, regional influence)?

Photo © Dominic Chavez/World Bank

Exercise 1: Finalize country selection via further assessment

(One–two weeks)

The objective of this exercise is to finalize the country(ies) for product launch and scale-up. In Step 1.1, a shortlist of countries based on the market size and feasibility of entry was created using publicly available data. Now, stakeholders deeply familiar with the public and private health landscape in a given country should validate this work. It is helpful to create a list of high-priority questions and circulate them with experts—including global health experts, distributors (distributors often hold a wealth of information about the market), and partners in facilities/communities.

Lessons learned in this fact-finding exercise can be entered into the **Country Prioritization Table Tool**.

This table serves as a framework for examining shortlisted countries in more detail. It highlights many different dimensions that make up the market size and feasibility of entry for shortlisted countries, allowing the practitioner to determine the relevance of individual indicators to the product—and weights them accordingly.

Country Prioritization Table Tool   **ILLUSTRATIVE**

Market size will apply a limiting factor to the total population impacted by the disease/health issue to estimate **the addressable market**

Measures of feasibility **blend qualitative and quantitative information**

Track feasibility vs. market size in a scorecard to populate underlying data for bubble chart

	Market size		Feasibility [1]						
Country	Burden	Addressable market size[3]	Uptake of similar products	Existing substitutes	Product registered	Product on EML or related list	Align with national priorities	In-country relationships	Overall feasibility[2,3] (1-10)
Uganda	10m	2m	◐	○	●	●	●	◐	7
Bangladesh	3m	1m	◔	◐	○	○	◐	◐	4

● ◕ ◐ ◔ ○ Harvey Balls are visually easier to absorb but **each rating can point back to a specific number**

*Overall feasibility = (distribution mechanism) + (2*players) - (other products) + (.5*substitutes) Overall **feasibility formula will use simple math and favorably weight inputs** that are more credible or that are better indicators of success

Note: (1) Use Harvey Balls to track feasibility variables with the exception of 'overall feasibility.' Other variables can be used as identified; (2) Roll up individual countries' feasibility variables to score overall on a scale of 1 (lowest feasibility) to 10 (highest feasibility); (3) Create bubble chart based on these two metrics.

Download this template at www.usaid.gov/cii

> " *There is a big gap between initial country selection and eventual scale-up. Innovators need to have enough experience in a market before making the decision to scale there. They need to build deep trust, create an extensive network, and fully understand the ecosystem.*

Laura Sampath, VentureWell

AUDIENCE TIP: Practitioners new to the selected country should consider reaching out to local NGOs knowledgeable about the country's health sector. These organizations could make great partners and often have valuable connections to other stakeholders.

AUDIENCE TIP: Indicators of feasibility may be more important to innovators pressing for immediate sales. For donors and implementers willing to invest significant resources and seek long-term impact, metrics of market size could be more important. The weight given to different criteria will vary according to what each practitioner deems most important.

CAVEAT: Country selection is not a cut-and-dried process. Sometimes, proactive market research (as described in this Guide) drives the decision making; in other circumstances, choosing a country is more reactive—a result of securing funding tied to a certain country or the advent of a not-to-be-missed opportunity. In many cases, it will make sense to focus on countries where there is clinical evidence, but that should not be the deciding factor. There is space for multiple approaches.

> *What we've learned in developing the BD Odon Device is that certain activities are fairly consistent across a broad range of markets. Such activities can be driven at the global level with some regional inputs. As you get closer to launch, though, a shift from global to local activities becomes necessary.*

Kaitlin Davis, Becton, Dickinson & Co.

> *In global health—perhaps more than in any other field— it's important to build a coalition before, during, and after launch of a product. To be successful, you constantly need to loop in stakeholders—most importantly, the ministry of health. This not only builds consensus and encourages alignment but also ensures that you understand the country context to the fullest extent possible. It can't be done alone.*

Steve Brooke, PATH

Finally, a **Go/No-Go Checklist Tool** can be applied to the chosen country or set of countries. This will allow the practitioner to make a final decision on whether or not to go ahead with the country selection or to reconsider country selection due to the presence of no-go signals in any of the five core component areas.

Go/no-go signals should be evaluated even when entering Steps 2 and 3. As they spend more time gathering data and meeting stakeholders within a country, practitioners will learn facts that can impact country selection. During this process, country selection can be reassessed—in order to limit resources spent on a potentially misguided decision. Unfortunately, practitioners often ignore warning signs and instead intensify investment in hopes of improving results. While there is admittedly a cost to changing direction midway through the launch planning effort, in cases where no-go signals appear, changing direction can often be the wisest course of action.

Go/No-Go Checklist Tool

Core Component	Relevant no-go signals and principles	Example	Guidance on how to interpret signal
MARKET AND USER	**Challenging market dynamics Limited product differentiation**	Product **substitutes are lower price and/or are more effective**	If a substitute product is firmly entrenched, priced lower, and offers a similar value proposition, *signal to reconsider*
	Signals of low demand	**Poor uptake on similar products** previously introduced in-country	If similar products have had poor uptake due to market/non-market factors that would similarly affect product, *signal to reconsider*
MANUFACTURING AND DISTRIBUTION	**Mismatch between production economics and pricing potential**	**Price/production economics are higher** than APT/WPT and economics cannot be improved	If production economics cannot be improved and product necessitates end user purchase (as opposed to donor funding), *signal to reconsider*
	Lack of infrastructure to accommodate product needs	**Product requirements cannot be met** at point of delivery	If distribution and handling requirement (e.g. cold chain, nurse administration, etc.) cannot be met, *strong signal to reconsider*
CLINICAL EVIDENCE AND REGULATORY	**Significant delays in country approval process**	Regulatory signals **suggest low likelihood of approval**	If regulators pose skeptical questions in meetings, express doubt and present no solutions, *signal to reconsider*
POLICY, ADVOCACY, AND FINANCING	**Strong opposition to product entry from key decision makers**	A **key stakeholder wishes to block scale-up**	If a senior government official or KOL has expressed a strong objection to scale-up in their country, *strong signal to reconsider*

If research during country selection identified any of these negative scenarios, evaluate the relative impact of the finding and reconsider scale-up and/or return to country selection to consider alternative countries.

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> ❝ *Country selection isn't only about sizing the need. You also need to gauge and understand relationships in country—ultimately, it's people on the ground who make product introduction and scale happen.*
>
> Tabitha Sripipatana, USAID, Family Planning and Reproductive Health

Strategic country selection

Lessons from Medicines360 & the LNG-IUS

SITUATION

Medicines360 is a global non-profit women's health pharmaceutical company with the mission of expanding access to medicines regardless of socioeconomic status, insurance coverage, or geographic location. Its first product was a hormonal IUD; recently, the organization needed to determine which countries to focus on for product introduction.

ACTIONS TAKEN

Medicines360 initially used unmet need for contraception, enabling environment, and opportunity (e.g., actual and predicted rates of increase of IUD use) as key criteria for country selection. This led to countries being ranked in four tiers: priority countries (Tier 1), countries to pursue opportunistically (Tier 2), countries that should be tagged for a second phase of rollout (Tier 3), and active conflict areas or countries with very small populations (Tier 4). Medicines360 also knew that strong partners skilled in service delivery, distribution, and training would be critical to rollout, so deprioritized countries in which potential partners were not focusing their efforts.

RESULTS

Medicines360 landed on a set of Tier 1 and 2 countries to work in, including Kenya and Madagascar, based on the fact that its potential partners in those countries had champions on staff or funding to support product introduction.
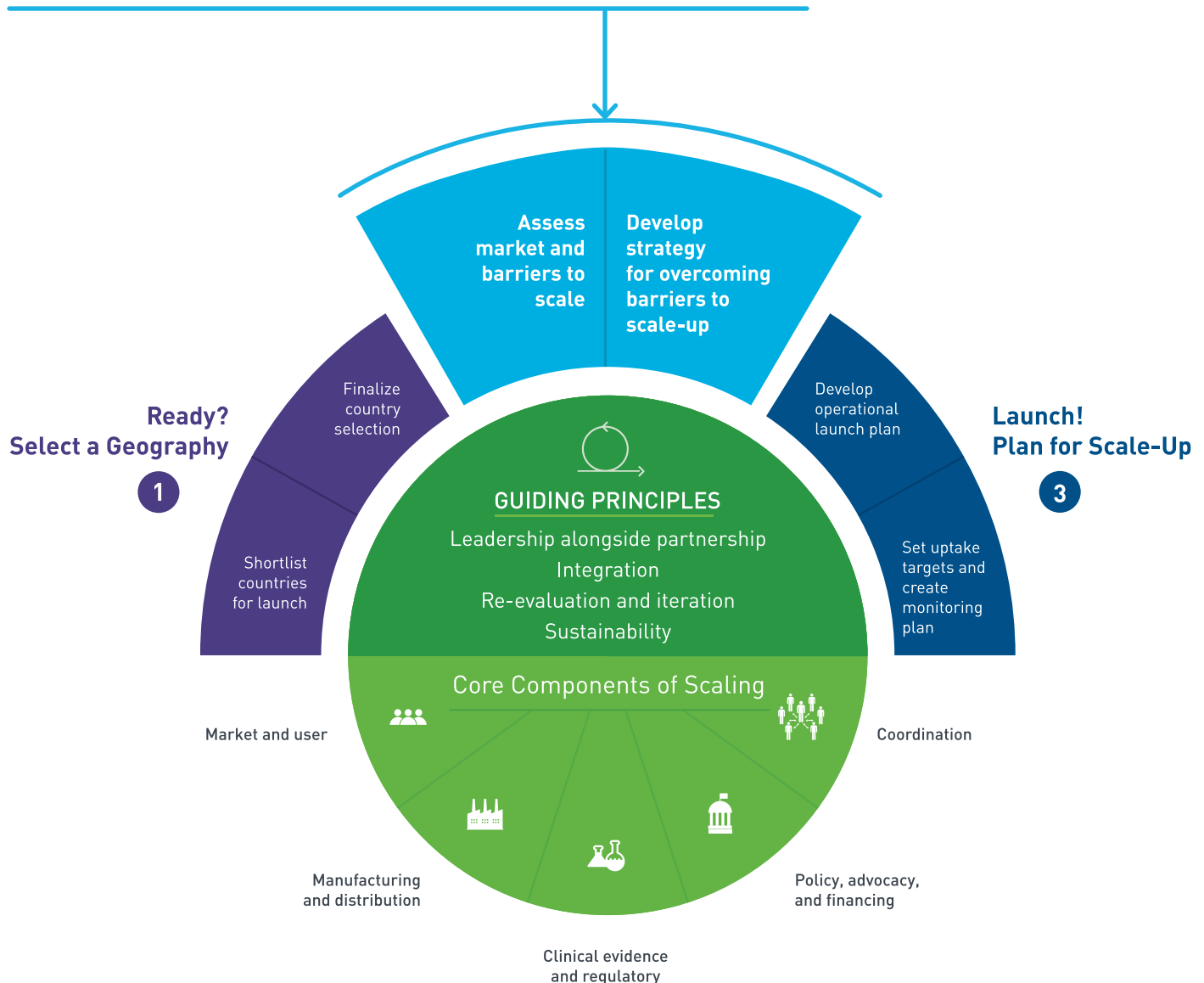
Photo © Liletta, Medicine360

LESSONS LEARNED

- **Practitioners should choose a small set of criteria (sometimes 1–2) that matter most to them, and let those criteria guide country selection:** For Medicines360, a strong partner was a critical ingredient for scale-up. Eliminating countries in which these partners could not or would not work was a wise choice.

- **Recognize that practical realities sometimes trump strategic analysis:** While Medicines360 might have chosen countries that made the most strategic sense in terms of unmet need, enabling environment, and opportunity, the company ultimately made the practical choice to launch its product in countries where its partners were receiving funding or had local buy-in.

- **Nothing succeeds like success:** Often times, selecting early adopter countries with a higher feasibility of entry can improve chances of success, even if at smaller scale initially. These early examples of success can be catalytic—building evidence and inspiration for greater impact at scale in larger markets to come.

- **Prioritize a set of countries rather than a single country:** Tiering countries into different categories of attractiveness, rather than eliminating countries until a single choice remains, will save time in case country selection needs to be revisited.

Medicines360 understands that aligning on strategy with key stakeholders is crucial to achieving its goal of expanding access to highly effective and affordable contraception.

Set...Build a Strategy

Assess market and barriers to scale

Develop strategy for overcoming barriers to scale-up

Finalize country selection

Develop operational launch plan

**Ready?
Select a Geography**

1

**Launch!
Plan for Scale-Up**

3

Shortlist countries for launch

Set uptake targets and create monitoring plan

GUIDING PRINCIPLES

Leadership alongside partnership
Integration
Re-evaluation and iteration
Sustainability

Core Components of Scaling

Market and user

Coordination

Manufacturing and distribution

Policy, advocacy, and financing

Clinical evidence and regulatory

Why is this step important?

A clear understanding of the chosen target market(s), key opportunities and barriers to scale, and interventions needed to overcome these barriers is critical to scale-up. Without such strategic thought, scaling efforts risk becoming unfocused and uncoordinated or may overlook critical barriers (e.g., prioritizing distribution, but not generating sufficient demand). An in-depth, country-specific strategy will test assumptions about what opportunities and barriers to scale exist and how to best address them.

What does this step entail?

Step 2 helps practitioners identify opportunities and barriers to scale across the five core components of scale-up through an in-depth market assessment. Potential **barriers** can include anything from low willingness to pay for the product to a fragmented supply chain to an opaque regulatory approval process.

Once barriers are uncovered, a strategy can be developed that identifies **interventions** that best leverage opportunities and address the most pressing barriers. The strategy should include only the highest-priority interventions—rather than a laundry list of every possible intervention that could be undertaken to support scale-up—in order to ensure focused and resource-efficient efforts.

Ready, Set, Launch definitions

BARRIER: A circumstance that puts scale-up at risk—e.g., doctors do not know how to use the product.

INTERVENTION: A broad action that needs to be taken to address the barrier—e.g., training healthcare professionals in how to use the product.

ACTIVITY: Specific tasks that make up the intervention—e.g., hold continuing medical education (CME) courses once a month at the three largest hospitals in the country, in which doctors are trained in how to use the product within established protocols—and are timed, costed, and assigned to a responsible party for execution. See more in Step 3.1

Continued stakeholder engagement, particularly with government actors, is essential during this step. Involving stakeholders will help practitioners build a comprehensive market assessment that is grounded in local insight, and will pave the way for strong coordination of essential in-country partners moving forward.

> *When thinking about stakeholder engagement, look to existing coordination mechanisms. All stakeholders need to talk to each other and feel ownership of the strategy. It is crucial to identify and involve major stakeholders early so one partner isn't driving scale-up alone.*

Joseph Monehin, USAID/Nigeria

What are the key outputs of this step?

- A stakeholder map identifying actors that can aid with scale-up efforts (both positively and negatively)
- A market assessment outlining the potential effects of the local context on product scale-up, as well as identifying target market segments, users, and channels for the product
- A barrier assessment identifying barriers to scale and categorizing by level of urgency
- An outline of potential high-priority interventions for addressing opportunities and critical barriers to scale

Step 2.1: **Assess market and barriers to scale**

The purpose of this sub-step is to develop a deeper understanding of the market through an assessment that determines the key opportunities and barriers to scale. Building on Step 1, this sub-step also helps to map out critical stakeholders at both the global level (e.g., WHO) and the country level (e.g., federal ministries of health, sub-national ministries of health, local policy makers, professional associations, faith-based organizations) in order to understand their priorities and incentives and to ensure buy-in throughout the scaling process. It is equally important to understand which stakeholders, if any, are against product scale-up—and why—as this can greatly influence potential success.

> *Understanding the target user is critical. During the development of the non-pneumatic anti-shock garment (NASG), a key clinical leader initially thought that nurses and midwives would be critical, early users. However, through a market assessment, we learned that in some settings ambulance drivers might also be users—as he/she would have the garment in the ambulance and apply it. This had implications for the device— we couldn't assume that a driver would understand pregnant anatomy, so we included application graphics on the device, so anyone, with medical background or not, could easily use it. Innovators need to be ready to change or shift the target user as market knowledge deepens.*
>
> **Robert Miros, 3rd Stone Design**

? Key questions this sub-step will help answer include:

- What are the most **significant barriers to introduction and scale-up that will require attention and effort** to overcome?
- Who are the **key stakeholders (decision makers and influencers)** that can potentially affect product scale-up at both the global and country level?
- Which stakeholders could be potential partners, and what are their **capabilities, interests, and potential roles** in product scale-up?
- Which stakeholders might block scale-up? What would be their **rationale**?
- What interventions could be used to **address significant barriers to scale?**

Photo © David Milestone, CII, USAID
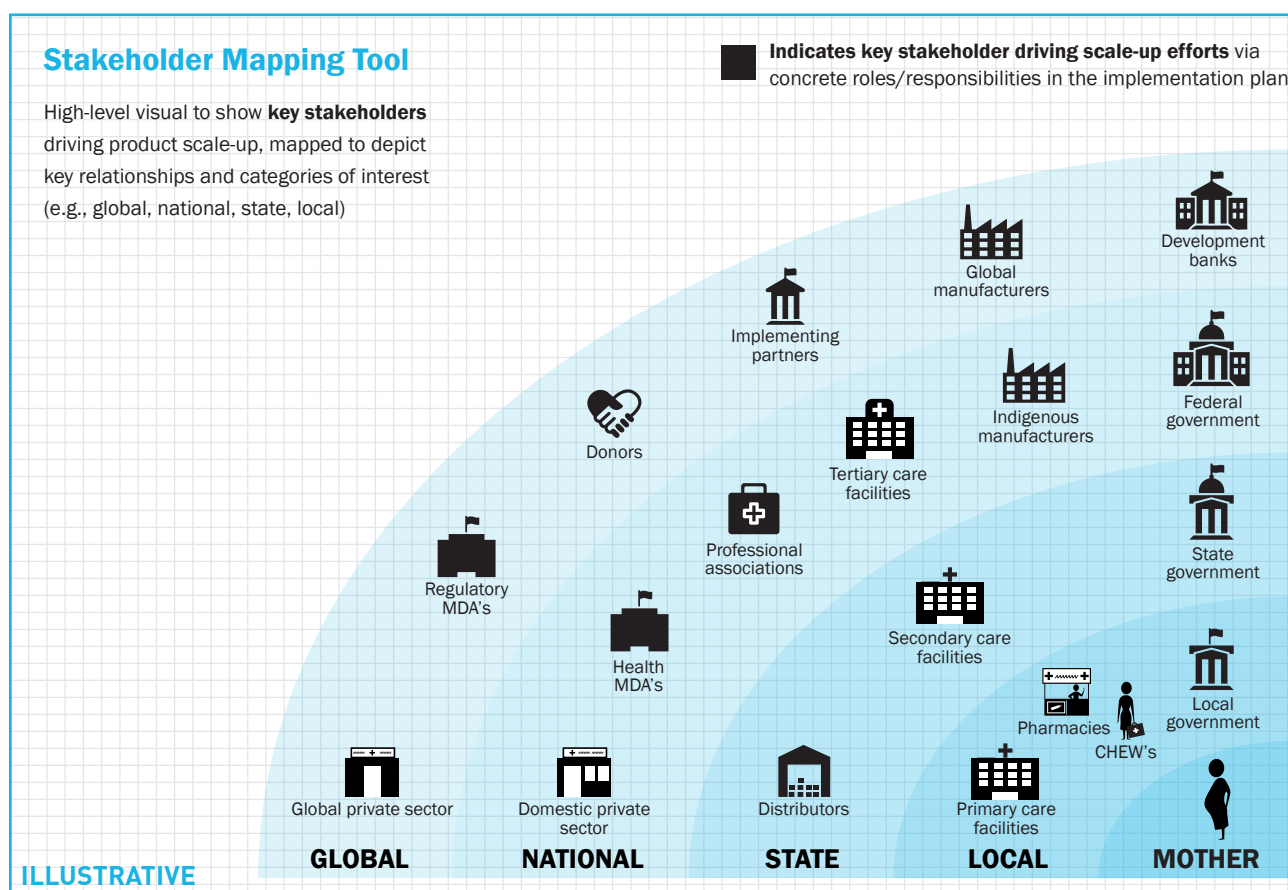
Exercise 1: Map and engage stakeholders

(Two weeks for initial mapping; ongoing process thereafter)

Ideally, mapping and engaging stakeholders starts early—during the country selection process, if possible—and continues throughout the entire launch planning and scaling process. While stakeholder engagement is an ongoing task, it is important to elevate it as a key activity here in Step 2 because of the critical role that stakeholders play in both uncovering and addressing potential barriers to scale.

To engage stakeholders successfully, identify important actors at every level (global, regional, national, and local), define their roles as a decision maker or influencer, and assess their relative importance to the scale-up process. Engagement with government stakeholders, and influential associations in particular, is often crucial, as their support or opposition to product introduction can make or break the scale-up effort. Likewise, pay close attention to stakeholders with existing programs in order to evaluate the potential for integration.

> *Understanding the concerns of key stakeholders is very important throughout product introduction and scale-up. New products can make prior products or practices obsolete. For example, training keepers of private pharmacies on how to perform rapid diagnostic tests may create a fear of losing clients among owners of private laboratories.*

Martin Alilio, USAID, President's Malaria Initiative

Stakeholder Mapping Tool

High-level visual to show **key stakeholders** driving product scale-up, mapped to depict key relationships and categories of interest (e.g., global, national, state, local)

■ **Indicates key stakeholder driving scale-up efforts** via concrete roles/responsibilities in the implementation plan

Development banks

Global manufacturers

Implementing partners

Federal government

Indigenous manufacturers

Donors

Tertiary care facilities

State government

Professional associations

Regulatory MDA's

Secondary care facilities

Local government

Health MDA's

Pharmacies

CHEW's

Global private sector

Domestic private sector

Distributors

Primary care facilities

GLOBAL   **NATIONAL**   **STATE**   **LOCAL**   **MOTHER**

ILLUSTRATIVE

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Following stakeholder mapping, create an engagement plan for the most important stakeholders (e.g., at what frequency and through what medium should updates be delivered?). Finally, consider establishing a formal working group or informal advisory group composed of the most influential stakeholders to facilitate widespread uptake of the product.

The Stakeholder Mapping Tool can help practitioners think critically about who is included in the landscape of stakeholders that could affect uptake, which stakeholders are most important to engage, and what the roles, responsibilities, and accountability of various stakeholders should be during the scale-up process.

> *We try to identify partners who have strengths and capabilities outside of our own. Smaller organizations who have run focused and localized programs can be successful in partnering with large organizations— we want to see that you have achieved success in your work to date.*
>
> **Anthony Gitau, Novartis Kenya**

Additional detail on capabilities, interests, and potential roles of key stakeholders

Group	Importance	Typical roles and responsibilities in scale-up	Examples of stakeholders included
Federal government	Government sets policy and oversees health programs and systems at the national level	Lead/coordinate efforts, set policy, conduct advocacy, provide funding	Department of Family Health, Department of Food and Drug Services
State government	Government sets policy and oversees health programs and systems at the state level	Oversee implementation of scale-up activities at the state level, including procurement and distribution of product	State ministries of health
[Other stakeholders]	*[Continue for other stakeholders]*	*[Continue for other stakeholders]*	*[Continue for other stakeholders]*

Exercise 2: Assess the market in-depth (Two-four weeks)

A market assessment will help the practitioner better understand the potential effects of the local context on product scale-up, as well as identify target market segments, users, and channels for the product. During the market assessment, it is important to note existing programs or interventions that can be used as a platform for potential integration. Common ways to conduct a market assessment include desk research, speaking with local experts, and (if located remotely) visiting the country for on-the-ground fact-finding.

The **Market Assessment Tool**, which highlights the main questions to be considered during desk research and expert interviews, can help facilitate this process. The stakeholder map referenced earlier can help identify which stakeholders should be engaged throughout this exercise.

Market Assessment Tool

Core Component	Key questions to ask as part of a market assessment
MARKET AND USER	• Who is the target user? • Who influences the target user? • What is the point of care/point of access that is most relevant? • What competing products exist?
MANUFACTURING AND DISTRIBUTION	• Will the product be supplied via local and/or global manufacturing? • What are the target delivery channels to reach target users (e.g., public, private)? • Are production economics in line with ability and willingness to pay?
CLINICAL EVIDENCE AND REGULATORY	• What additional clinical evidence is needed? • What does the regulatory approval process require? How long does the process take?
POLICY, ADVOCACY, AND FINANCING	• Who is the target payer? What is their ability to pay? Willingness to pay? • What organizations have been involved in or provided resources for scale-up activities for similar activities in the past? • How much have scale-up interventions in the past cost? • What is the process for including the product in appropriate protocols/lists (e.g., essential medicines list, national protocol)?
COORDINATION	• Who are ideal candidates to lead the launch and scale-up and/or serve the uptake coordinator role? • What entities have owned/managed interventions in the past? How long did these efforts take to carry out?

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> 66 *Securing financing is critical to successful product introduction and scale-up. Financing is needed to implement activities across all core components of scale-up. Without funding, nothing can be achieved.*

Lisa Bonadonna, GSK

Exercise 3: Determine opportunities and barriers to scale (One week)

With the help of a market assessment, it is possible to identify the most critical opportunities and barriers to scale across the five core components of scale-up. The **Barrier Assessment Tool** gives practitioners a framework to quickly assess visually the greatest opportunities and barriers for scale-up. Details on how to rate various activities (red, yellow, green) for addressing potential opportunities and barriers are included in the Supplemental Toolkit. By using the Barrier Assessment Tool, practitioners can zero in on what opportunities can be leveraged to save human, financial, and time resources. The Barrier Assessment Tool also uncovers the most critical barriers to a successful introduction and scale of the product—allowing practitioners to prioritize barriers accordingly when developing the strategy and operational launch plan in Steps 2.2 and 3.1. It is important to revisit the Barrier Assessment Tool during product launch and scale-up as certain barriers are addressed and others arise as the market evolves.

> *Determining priority needs is very important in launching a product. When introducing chlorhexidine in Nepal, there were a multitude of activities that needed to occur, so we had to prioritize them. We first focused on intensive stakeholder engagement through developing a list of key 'champions' and visiting each individually until we received their commitment.*
>
> **Leela Khanal, JSI Nepal**

> *Scale-up efforts should initially consider public, private, and community channels. A focus on just one could significantly limit the potential reach of any product.*
>
> **Jean Pierre Nyemazi, Permanent Secretary, Ministry of Health, Rwanda**

OTHER HELPFUL TOOLS FOR ASSESSING THE MARKET AND BARRIERS TO SCALE:

- Market Segmentation Analysis Tool
- Patient Journey Mapping Tool
- Manufacturing Analysis Tool
- Delivery Channel Analysis Tool
- Clinical Trial Analysis Tool

CII's Market Shaping Primer can also be a useful resource to refer to while conducting a market assessment. All of these tools can be found in the Supplemental Toolkit at **www.usaid.gov/cii**

Barrier Assessment Tool

Evaluate target users' current awareness of and demand for the product

Provide details and cite how you determined the level of need and relevant implications for scale-up

👥 MARKET AND USER

Barrier (Identified in market assessment)	Desired outcome	How to determine level of urgency	Barrier color (red, yellow or green)	Key considerations
Target users **do not see a need** for the product	Target users **understand the need** for the product and, therefore, are **more likely to seek out the product**	• Is the need for **treatment known and/or are flaws of current treatment options recognized** by the target user? *If no, then red.*		How have other sub-optimal health behaviors been improved?
Target users **are not aware of the value** of the product	Target users **know about the product's benefits** and are motivated to access it	• Do target users know **about the product and want to access it**? *If no, then red.*		How have other new products generated demand?
Target users **do not know how to use** the product	Target users **know how and when to use the product,** resulting in greater uptake of the product in the right circumstances	• Do target users know **how and when to use the product?** *If no, then red.* • Can the target user **easily access and understand instructions for use**? *If no, then red.*		How have target users been trained for other products?
It is **difficult to predict how much product** is demanded	Accurate **projections of market demand will aid in planning** for sufficient supply and scale-up activities	• Are there well informed **calculations that link coverage rates to total market demand** for the product? *If no, then red.*		How quickly could consumer demand change in-country?
It is **difficult to know where to set the price** of the product	Product is **priced appropriately** based on target user affordability and business needs/costs	• Is the product **affordable to target users**? *If no, then red.* • Does the price **provide a reasonable margin** for manufacturers and other actors in the supply chain? *If no, then red.*		What portion of target users are currently priced-out?
The **product and packaging design** is confusing/unclear to users or gate-keepers	Product and packaging design **reflects user-centered research to improve appeal and prevent improper usage**	• Is the product **differentiated and attractive to targets**? *If no, then red.* • Does **packaging design lend itself to product misuse**? *If yes, then red.*		Have there been reported cases of misuse? Does the product design resemble others, potentially creating confusion?

Note that the barriers listed here are a starting point and not a comprehensive list of all barriers in a market

High barrier	Medium barrier	Low barrier	Ratings are meant primarily to indicate relative barrier, and are more art than science

Barrier Assessment Tool

Evaluate how to optimize the supply chain and which delivery channels to prioritize

🏭 MANUFACTURING AND DISTRIBUTION

Barrier (Identified in market assessment)	Desired outcome	How to determine level of urgency	Barrier color (red, yellow or green)	Key considerations
There are not clear/functional **delivery channels**	Functional procurement and distribution systems **will link product supply to all points of access/target user**	• Can the product be placed into the target delivery channels and **assume it will flow seamlessly to target users?** *If no, then red.*		How have similar products optimized delivery channels previously?
There are not **incentives to integrate the product into existing delivery channels**	Public and private sector channels **incentivize affordable, fast, and reliable delivery of the product** to target users	• Are there large **bottlenecks in the delivery channels that will hinder the product's movement** to target users? *If yes, then red.*		What incentives have worked in moving global health product inventory in past scale-ups?
There are not **local and/or global manufacturers** willing or able to manufacture the product	**Production strategy** (including high-potential manufacturers) **exists,** and can meet scale-up needs	• Is there a **local manufacturer** that is already producing or ready to immediately produce **or a global manufacturer ready** to export to the country? *If no, then red.*		What other products has this local or global manufacturer brought to market?
Supply for the product **does not meet demand forecasts**	Production strategy includes a **clear plan to support anticipated demand**	• Do both demand and supply **forecasts exist and is supply sufficient to cover demand?** *If no, then red.*		What are future key points of inflection for manufacturing capacity?
Production economics **do not favor necessary margin requirements**	**Economics** (e.g., pricing, COGS) **are favorable** to manufacturers and distributors in order **to incentivize production and distribution** of the product	• Are the **manufacturers able to make an attractive margin** on the product? *If no, then red.*		Are there ways to lower COGS or increase price to make production economics more attractive?

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High barrier	Medium barrier	Low barrier	Ratings are meant primarily to indicate relative barrier, and are more art than science

Barrier Assessment Tool

Identify clinical data needed or any potential impact that new clinical data could have on scale-up

🧪 CLINICAL EVIDENCE AND REGULATORY

Barrier (Identified in market assessment)	Desired outcome	How to determine level of urgency	Barrier color (red, yellow or green)	Key considerations
There are signals that **additional clinical evidence** is needed and/or would accelerate scale-up	Presenting additional clinical evidence from local trials or new data **can expedite the approval process** or **expand the product's approved uses**	• **Is regulatory approval contingent** on additional clinical evidence? *If yes, then red.*		Have other products in country benefited from additional or updated clinical data?
Clinical studies/ evidence are ongoing in target country and/or other countries	Additional **evidence should be monitored** to determine if the strategy should be adapted	• Are there **active trials set to report data that could impact** the current product registration or regulatory process? *If yes, then red.*		Would outcomes of active trials impact government acceptance of product?

Establish an enabling environment for scale-up

🏛 POLICY, ADVOCACY, AND FINANCING

Barrier (Identified in market assessment)	Desired outcome	How to determine level of urgency	Barrier color (red, yellow or green)	Key considerations
There is not sufficient **commitment from KOLs**	KOL buy-in can **aid in policy makers and clinicians hearing about the benefits** of the product	• Have **policy makers spoken about the need** for the product publicly? *If no, then red.* • Do most **practitioners know about the clinical benefits** of the product? *If no, then red.*		What professional associations are key to clinical adoption of the product?
The product does not have **placement on EML or other relevant lists,** as needed	Inclusion in clinical lists **elevates the product as a standard of care** and ensures long-term utilization at health facilities	• Are there clinical lists or purchasing ledgers that **list a competing product/ treatment** as opposed to the product in question? *If yes, then red.*		What lists are currently used at the point of access?
There is **no clear buyer/payer** for the product (if the user is not the buyer)	Establishing funding beyond early activities **certifies that momentum in scale-up can be maintained**	• Are there buyers/payers who have **committed funds for short, medium, and long-term activities?** *If no, then red.*		Will medium and long-term funding for scale-up require a shift in payers?

High barrier	Medium barrier	Low barrier	Ratings are meant primarily to indicate relative barrier, and are more art than science

Barrier Assessment Tool

Ensure appropriate ownership and execution of strategy over time

👥 COORDINATION				
Barrier (Identified in market assessment)	**Desired outcome**	**How to determine level of urgency**	**Barrier color** (red, yellow or green	**Key considerations**
There **are not phasing plans** in place	Optimize limited resources for specific regions or channels so that 'early wins' provide demand and test interventions	• Are **resources limited** relative to the human and financial capital required for interventions and coordination? *If yes, then red.*		How have similar scale-up efforts phased resources?
There are not clear **roles and responsibilities** for launch and scale of the product (depending on stage of scale-up process)	Clear delineation of roles and responsibilities **encourages follow through** on implementation	• Are there a large **number of activities and actors,** and very little precedent for coordination during scale-up? *If yes, then red.*		Do key actors have geographic or functional preferences or strengths that can aid in assigning roles?
Supply and demand forecasts, and timing of supply and demand, **are not defined or matched**	Identify any **potential volume imbalances** between supply and demand today and in the future	• Do both demand and supply **forecasts exist, and is supply sufficient to cover demand?** *If no, then red.*		What is estimated supply capacity? Is it sufficient to cover demand?
There is not a clear, defined **M&E dashboard**	**Track progress** against key milestones & optimize	• Have **key metrics** been identified? *If no, then red.* • Are all **stakeholders aligned?** *If no, then red.*		How have similar scale-up efforts created dashboards? How can the metrics be kept lean?
There are signs of an **unhealthy market**	Identify any **market trends that could undermine the long-term sustainability** of the market	• Will **manufacturers continue to make an attractive margin on the product?** *If no, then red.* • In smaller 'test markets,' did a **steady state level of demand** remain? *If no, then red.*		How would the market react to a sudden change in supply or demand?

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High barrier	Medium barrier	Low barrier	Ratings are meant primarily to indicate relative barrier, and are more art than science

The importance of early and frequent stakeholder engagement

Lessons from the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)

SITUATION

EGPAF's Uganda office recently began efforts to scale a new type of packaging—the Pratt Pouch—that makes it easy for mothers to provide pre-measured, single doses of the HIV prophylaxis Nevirapine (NVP) to their babies. EGPAF's goal is to bring the Pratt Pouch to 40,000 Ugandan infants in three years.

ACTIONS TAKEN

Established as a reputable implementing partner in the country for 16 years, EGPAF Uganda knew how important stakeholder engagement was to the scale-up effort. "We mapped out the entire landscape at a very early stage—even before we'd acquired funding for the project," says Dr. Edward Bitarakwate, EGPAF Uganda's Country Director. "We brought stakeholders on board by capturing their ideas and allowing them to contribute to the process. When the project was finally funded, it was much easier to go to them—because they already felt as though they were part of something successful."

EGPAF Uganda also noted the importance of seeking buy-in from stakeholders that it was less familiar with. The foundation was used to working with the government on program implementation, but for the Pratt Pouch, it needed to take a more market-oriented view. By mapping out the value chain of the Pouch, the team was able to identify "missing" stakeholders—like manufacturing and distribution partners—and engage them accordingly. "My advice to others would be to really take a look at the entire landscape of stakeholders—not just the ones that come to mind immediately," says Dr. Bitarakwate.

The country office also made sure to re-engage with stakeholders at least once a month, whether by phone, e-mail, or dropping in person. "Keeping in contact was important to stay on top of potential donors and to keep people excited about the product," Dr. Bitarakwate adds.

Photo © Marc-Gregor Photography

LESSONS LEARNED:

- **Think of early stakeholder engagement as an investment:** Engaging early will provide more accurate knowledge of opportunities and barriers to scale. You will learn the realities of the market from people that have been working in the country for years.

- **Remember non-obvious stakeholders:** Too often, organizations assume that the ministry of health is the only important stakeholder to get on board. While it is incredibly important, there are many others to also consider, from hospital procurement officers to professional associations.

- **Treat stakeholder engagement as a continuous task—not a one-time, discrete step:** Important stakeholders should be continually engaged and updated to keep them excited about the product during preparations for launch.

RESULT

The team is now forming a working group for scaling the Pratt Pouch in Uganda, a process made much easier by the fact that so many important stakeholders are already on board. "Our early engagement—particularly with the government—helped us achieve buy-in tremendously," Dr. Bitarakwate says. "Without it, we would have a lot more barriers to deal with now."

"

Keeping in contact was important to stay on top of potential donors and to keep people excited about the product.

Dr. Edward Bitarakwate, EGPAF Uganda

Step 2.2: **Develop strategy for overcoming barriers to scale-up**

The purpose of this sub-step is to outline potential interventions to overcome the most critical barriers to scale. Using the barrier analysis as a starting point, the strategy should identify interventions to address each high and medium-priority barrier. To be most effective, the strategy should also incorporate lessons learned and best practices from other product scale-up efforts—both at the country level and at the global level. As with prior steps, continued engagement with stakeholders is critical, especially ministries of health for products considering public sector launch and scale. Engagement with ministries of health can be critical in implementing a range of interventions (e.g., updating national training curricula, updating guidelines and EMLs, etc.).

?

Key questions this sub-step will answer include:

- What can we learn from **past product successes/failures** in addressing similar barriers to scale, and what have stakeholders recommended to overcome this barrier?
- Are there any **existing programs** that can serve as a potential platform for integration?
- What are the **largest or highest-priority barriers** to scale? What are the **highest-priority interventions** for these barriers to scale? Which of these interventions are feasible given the present environment and available resources?
- Where should **launch or scale-up begin** in the country? What are **the phasing plans** thereafter?

" *Almost every product I've seen launched has been—or should have been—re-launched. Designers rarely get everything right with the first generation of a product because you can't predict entirely how a product, particularly an innovative one, will be used. The next generation of the product should be driven by talking to users and customers, observing how they use—and don't use—your product. There is always space to iterate and improve on the product so that it better fits into the market and can better have impact. This iteration is— and should be—a normal part of product development.*

Krista Donaldson, D-Rev

Exercise 1: Study comparable products (One-two weeks)

Examining the experiences of products that have faced similar barriers to scale can help practitioners evaluate a full list of interventions used by others to overcome specific barriers. An understanding of which interventions have proved most and least successful can guide practitioners in improving or tailoring existing interventions to their product contexts. As with much of the analysis outlined in this Guide, while this work can be done with publicly available data, the best insights will come from subject matter experts. As such, it is essential to inform and validate this work with people deeply familiar with the public and private health landscape in any given country and/or analogous product launches.

When completing the **Comparable Product Analysis Tool,** it is also useful to ask questions about the cost of comparable interventions, as well as their owners and timeframes. While specific activities will be fleshed out later in the Guide, having this information on-hand can greatly streamline the process down the line and reduce the need to return to stakeholders for this information.

The Comparable Product Analysis Tool can be used to identify interventions undertaken as part of other analogous scale-up efforts.

Comparable Product Analysis Tool

Organize relevant information according to the key activities required

Select comparable products that have similar target users, delivery channels, and price to ensure relevant insights

Use these interventions as starting points for a long list of interventions that are most relevant to the target product

	Activity	Comparable products			
		ORS/zinc	**Estimated cost**	**Misoprostol**	**Estimated cost**
MARKET AND USER	**Demand generation**	Because of the large target user base, a national marketing plan was disseminated through radio and print	$50,000	Key intervention was sensitized with community leaders Bundled other maternal and child health products with misoprostol to drive demand	$10,000
	Creating awareness	Care-seeking behavior for diarrhea was fragmented so awareness was driven through clinicians and retailers	$15,000	Introduced expecting mothers to product at ANC visits	$1,000
	Training and education	Training was conducted in communities, clinics, and PPMVs so that care seekers had ORS/zinc reinforced through all three points of care	$10,000	Focused training on community midwives and community-based health volunteers	$10,000
MANUFACTURING AND DISTRIBUTION	**Delivery channel incentives**	Used training and detailing at points of retail to encourage shop owners to improve stocking practices and increase inventory turns	$5,000	Community sensitization required meeting with community and religious leaders	$2,000
	Production economics	Encouraged manufacturers to enter the market and then provided a COGS analysis to manufacturers who were committed to decreasing price	$3,000	Affordable imported product; >50 branded and non-branded versions available globally	N/A
Additional core components	*Additional activity*	*Description of intervention used*	*cost*	*Description of intervention used*	*cost*
	Additional activity	*Description of intervention used*	*cost*	*Description of intervention used*	*cost*

ILLUSTRATIVE

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Exercise 2: Create a strategy for addressing barriers (One week)

With a strong understanding of what has worked in the past, practitioners can develop a plan of attack—or intervention—for each barrier, beginning with the most urgent. The **Intervention Design Tool** can be used to highlight what these interventions are and how they address the barriers to scale.

Intervention Design Tool

Interventions should provide as much detail on **where, what, and when** the activities should be carried out

If multiple activities are tied to the barrier they should **map back to specific roles** and identify if roles are national or sub-national

	Barrier		Recommended interventions and associated activities	Potential stakeholder responsible
MARKET AND USER	Low awareness at points of access for target users	Facilities	• **Conduct clinical mentoring and training activities at public and private facilities,** leveraging professional associations for many of the private sector visits and state ministries of health (SMoHs) at select public and private facilities to demonstrate commitment and secure buy-in	• **Manufacturers, implementers, SMoHs, facility directors, professional associations**
		Pharmacies	• **Conduct training activities at private pharmacies and public pharmacies at PHCs,** leveraging professional associations for many of the private sector visits and SMoHs at select public and private pharmacies to demonstrate commitment and secure buy-in; consider clinical mentoring at primary health centers	• **Manufacturers, implementers, SMoHs, PHC directors, professional associations**
		Direct	• **Conduct training activities for donors and private companies** currently distributing delivery/Mama kits or considering this work in the future	• **Implementers, SMoHs**
	Lack of aggregated demand forecasts		• **Support states** with their forecasts • **Compile state projections for demand into a forecast** and check against scale-up plan targets as well as realistic limitations (e.g., available funding) • **Update forecast annually**	• **Uptake coordinator** for national forecasts and aggregating state forecasts • **States/implementers** for state forecasts, with support of uptake coordinator, as needed
MANUFACTURING AND DISTRIBUTION	*List appropriate barrier here*		*Think through detailed intervention...*	*Determine responsible party...*
CLINICAL EVIDENCE AND REGULATORY	*List appropriate barrier here*		*Think through detailed intervention...*	*Determine responsible party...*
POLICY, ADVOCACY, FINANCING	*List appropriate barrier here*		*Think through detailed intervention...*	*Determine responsible party...*

ILLUSTRATIVE

Identifying and breaking down barriers to scale

Lessons from Novartis Access

SITUATION

Novartis Access is a portfolio of fifteen medicines to treat chronic diseases in low-income countries, launched by Switzerland-based pharmaceutical company Novartis. Novartis Access selected Kenya as their first country, with the official launch taking place in October of 2015. While the Kenyan government launched a strategy for the prevention, control, and management of non-communicable diseases (NCDs) in July 2015, at the time of Novartis Access' launch, there were still very few programs, policies, or resources focused on NCDs.

ACTIONS TAKEN

Novartis Access' Kenya team took a highly strategic approach to assessing and addressing barriers to scale. The team spent significant time working with stakeholders to understand the key challenges to accelerated introduction. This analysis highlighted registration as a significant bottleneck. In parallel, the team was also developing a strong relationship with the Kenyan authorities and ultimately developed a memorandum of understanding (MoU) with the government. As part of this MoU, the team worked with the government to fast-track registration of the drugs in the portfolio and consider adding the medicines to the Essential Medicines List.

Novartis also recognized that their core competency is in manufacturing and distributing the product. They had less of an idea of how to appeal to the market and user and raise demand in the public sector. To address this, Novartis sought out well-respected partners such as the Mission for Essential Drugs and Supplies, the Kenya Red Cross, the Christian Health Association of Kenya, and the Kenya Conference of Catholic Bishops, who have strong relationships on the ground and are able to provide training to facilities on how and when to administer drugs in the portfolio.

LESSONS LEARNED:

- **It is possible to work around barriers:** There are ways to address long regulatory approval processes. At the minimum, regulatory processes should play a role in country selection and prioritization. Also, there's much to learn from past success stories in country. Find those examples and reach out to those who have made it happen. Finally, work with governments to understand where some of these regulatory processes can be done in parallel to save time.

- **Partners are invaluable in breaking down barriers:** Many barriers to scale exist because the scaling organization simply lacks the skills or resources to overcome them. In these cases, the best way to break down barriers to scale is to bring on partners. Strong stakeholder management doesn't mean only people to engage, but also potential partners on the path to scale.

RESULTS

By working closely with the government, Novartis Access' Kenya team was able to fast-track the registration of medicines within the portfolio. A process that would have normally taken 12 to 14 months lasted only three. They were also able to address barriers related to demand-building by working through partners with a strong local footprint and network.

"

When thinking about partners, we want to find those organizations that complement our core strengths. For example, we provide medicines, but we need partners with core competencies in service delivery and training.

Anthony Gitau, Novartis Kenya

Launch! Plan for Scale-Up

Set...
Build a Strategy
2

Assess market and barriers to scale

Develop strategy for overcoming barriers to scale-up

Ready?
Select a Geography
1

Finalize country selection

Shortlist countries for launch

Develop operational launch plan

Set uptake targets and create monitoring plan

GUIDING PRINCIPLES
Leadership alongside partnership
Integration
Re-evaluation and iteration
Sustainability

Core Components of Scaling

Market and user

Coordination

Manufacturing and distribution

Policy, advocacy, and financing

Clinical evidence and regulatory

Why is this step important?

With an understanding of the biggest opportunities and interventions needed to address barriers to scale, the focus now shifts to developing an operational launch plan. This operational launch plan turns the strategy into action—serving as a work plan for product introduction and scale-up—outlining the what, when, and how—as well as serving as a critical advocacy tool for rallying and engaging stakeholders to collaborate and support scale-up. Without going through Step 3, practitioners risk a lack of accountability in terms of roles and responsibilities, poor coordination between key stakeholders, and a lack of articulation of resources needed to implement scale-up.

What does this step entail?

In this step, interventions outlined in Step 2 are translated into concrete activities with assigned owners, costs, and timeframes. As with other steps, the development of the operational launch plan requires continued stakeholder engagement to understand which actors are interested in and best suited to playing specific roles in scale-up.

The operational launch plan also requires the development of quantifiable goals and targets related to product uptake. These targets are necessary for calculating the cost of the strategy, tracking progress of scale-up, and supporting continuous improvement and course-correction. Quantification of targets can be based on estimates of current product uptake, the observed rate of uptake from comparable products, and hypotheses about the shape of the uptake curve. These targets, along with indicators crucial in achieving the targets, can be converted into a simple country dashboard.

What are the outputs of this step?

- An operational launch plan that includes a concrete list of activities—with owners, costs, and timeframes—and quantifiable uptake targets over the scale-up period
- A country dashboard that includes a list of prioritized indicators that are most critical to monitor and evaluate in product scale-up

A strong operational launch plan will include the following for each intervention:

OWNER: What single individual/entity will be accountable for a specific activity? Who will wake up every day thinking about getting this activity done?

COST: What estimated resources are required to successfully complete this activity?

TIMEFRAME: When should this activity start and end?

In addition, it should include **uptake targets** that are realistic but ambitious, as these will serve as the goal that all stakeholders work towards.

In developing an operational launch plan, it's important to focus on the long-term product vision and goals. When thinking only in the short term, decisions are made which may sacrifice larger-scale, long-term impact in favor of short-term results.

Jim Ricca, Jhpiego, Maternal and Child Survival Program (MCSP)

Step 3.1: **Develop operational launch plan**

The purpose of this sub-step is to develop an operational launch plan that guides country scale-up activities and coordination. To be complete, an operational launch plan should include a list of detailed activities across the five core components of scale-up with clear owners, timeframe, and cost breakdowns assigned on an activity-level basis. There should be quantifiable uptake targets, a demonstration of resource needs, and a plan to sustain scale-up efforts. The operational launch plan should also address the question of who will own implementation and coordinate the myriad activities and stakeholders involved. It is important to remember that the operational launch plan should be re-evaluated both during product launch and scale-up as certain barriers are addressed and others arise.

> *There are many products, services, and stakeholders working in Nigeria. To have a document outlining the activities related to implementation—as well as the timing and who is responsible—helps us in the ministry of health ensure accountability and track progress. We need to know what is happening in our country.*
>
> **Dr. Bose Adeniran, Federal Ministry of Health, Nigeria**

> *Pilots aren't only for establishing clinical evidence. They can also be used as an important advocacy tool for governments and partners to try something new on a limited scale. Caution should be used, however, in determining whether the approach is something new enough to warrant a pilot, or whether it is just implementation on a small scale being called a pilot.*
>
> **Kerry Ross, USAID, Maternal and Child Health**

? Key questions this sub-step will answer include:

- Across each of the core scale-up components, what **specific, actionable activities are needed to carry out the recommended interventions**?
- On an activity-level basis, **when should each activity start, and how long does each activity last**?
- Which stakeholder(s) is best-positioned to carry out each activity **given interest, core capability, and timing and duration of the activity**?
- How much will each activity **cost**? How can each activity's cost be mapped to a **specific source of financing**?

Exercise 1: Create an operational launch plan (Six-eight weeks)

In Step 2, prioritized interventions are outlined that address the greatest opportunities and the most acute barriers to launch and scale. In Step 3, the interventions can now be translated into concrete, specific, and actionable activities with specific owners, timeframe for implementation, and costing estimates for each activity. Overall costs of implementing the operational launch plan should then be aggregated by year and by core component of scale-up. Input from experts can provide reference points from comparable operational plans as well as validation and buy-in.

The **Operational Launch Plan Tool**, below, is designed to help create an operational launch plan. It includes two components: (i) a table enumerating all planned activities with a clear owner, cost, and timeframe assigned, and (ii) a high-level timeline demonstrating the overall sequencing of activities across the five core components of scale-up. To be effective, uptake targets need to be set in parallel with the creation of the operational launch plan, as targets tie into the overall business and/or costing model (e.g., revenue from units sold, cost of goods sold, training scaled by number of units). See the **Monitoring and Evaluation Tool** in Step 3.2 for guidance on creating uptake targets.

Operational Launch Plan Tool — ILLUSTRATIVE

Timeline to show overall sequencing of **activities** for strategic interventions across the five core components of scale-up

	MONTHS AFTER LAUNCH			
	0–3	**3–6**	**6–12**	**12–24**
MARKET AND USER	Release messaging materials	Complete national and state demand forecasts		
MANUFACTURING AND DISTRIBUTION	Create fund to subsidize 75% commodity cost	Start disbursing funds to states	Oversee efforts to subsidize 75% commodity costs for states launching programs	
			Expand private sector delivery channels	
CLINICAL EVIDENCE AND REGULATORY	Monitor evidence from future studies			
POLICY, ADVOCACY, AND FINANCING	Close funding gap for scale-up plan	Conduct in-person advocacy visits to hospitals		
		Send representative to promote product at all relevant professional association conferences		
		Add product to EML/relevant lists		
COORDINATION	Finalize M&E system	Conduct M&E activities		
	Formalize coordinating mechanism	Host coordination meetings (monthly for the first year, quarterly thereafter)		
		Update phasing strategy each quarter		

Table to enumerate all activities with clear owner, cost, and timeframe; if helpful, table can also include sub-activities

Owner	Strategy	Activity	Cost (USD	Timeframe
Donors	1. Market and user	Improve packaging and branding for product	200,000	6–12 months
MoH	1. Market and user	Release messaging materials	*Covered by existing staff*	0–3 months
MoH	1. Market and user	Update and disseminate training materials	10,000	0–3 months
MoH	2. Manufacturing and distribution	Create fund to subsidize 75% commodity cost	580,000	0–3 months
MoH	2. Manufacturing and distribution	Start disbursing funds to states	*Covered by existing staff*	3–6 months

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OTHER HELPFUL TOOLS FOR CREATING AN OPERATIONAL LAUNCH PLAN:
- Cost Estimate Tool

Integrating a new product into a community health system

Lessons from Medicines for Malaria Venture (MMV)

SITUATION

Since the publication of its first Standard Treatment Guidelines in 2006, WHO recommended the use of rectal artesunate suppositories (RAS) for the pre-referral management of children suspected to have severe malaria. However, when WHO first made this recommendation, no quality-assured product was available to meet this need. MMV—a product development partnership created to discover, develop, and deliver high quality, affordable antimalarial drugs—began working in 2014 with pharmaceutical partners to address this lack of quality RAS. MMV's collaboration with two companies is close to yielding success, with quality-approved RAS expected to become available in late 2016. Among other countries, MMV—along with partners—prioritized the Democratic Republic of the Congo (DRC) for introduction of RAS.

"

For its products, MMV has roadmaps with activities and sub-activities to coordinate with stakeholders and ensure implementation is on track.

Pierre Hugo, MMV

ACTIONS TAKEN

MMV recognized that to ensure the correct introduction of RAS, a well-functioning community health system was critical for diagnosing cases of likely severe malaria and then effectively referring patients to facilities. "Front-line and community health workers (CHWs) are critical players in combatting malaria before and after the 'last mile,' typically in far-flung rural settings. Helping health workers to diagnose and treat uncomplicated malaria—and worst case, to provide pre-referral treatment for severely ill children whose malaria wasn't detected early enough—is a key part of improving access to quality care where patients are most vulnerable" says George Jagoe, Executive Vice President on MMV's Access team.

MMV designed a series of activities to facilitate RAS use in community health delivery. First, MMV partnered with key organizations focused on the delivery of Integrated Community Case Management (ICCM) to ensure that the addition of RAS did not present major challenges to community acceptance, health worker training, and skills upgrading. Working hand-in-hand with the government and in-country partners, MMV created materials focused on the training of CHWs and health facility staff in diagnosing, pre-referring, and treating severe malaria. Through these efforts, MMV and partners are working to ensure that children with severe malaria are referred to treatment centers following administration of RAS—and that the introduction of RAS does not affect that linkage. Behavior change communication is also a priority so caregivers will recognize the signs and symptoms of malaria, understand the importance of care-seeking and referral, and sensitize communities to RAS. With partners, MMV is considering a variety of communication channels via traditional leaders, political structures, religious institutions, and media.

MMV has also designed an M&E framework not only to track uptake of RAS but also to develop and test innovative approaches to access and create demand for health services at the community level. MMV intends to re-evaluate its operational launch plan and refine its subsequent activities based on lessons learned along the way. "For its products, MMV has roadmaps with activities and sub-activities to coordinate with stakeholders and ensure implementation is on track," says Pierre Hugo, Senior Director–Access & Product Management at MMV.

RESULTS

With quality-approved RAS expected to become available in late 2016, MMV and partners have laid the groundwork to introduce and scale the product not only in DRC but also in other countries. The estimated demand for WHO prequalified RAS treatments in 2018 is 3–3.6 million.

> MMV and partners understood the importance of fitting RAS into the community health delivery system. Its operational launch plan emphasized integration as a means to sustainability.

LESSONS LEARNED

- **Plan for market introduction—even years in advance:** While quality-approved RAS is expected to become available in late 2016, MMV and partners have been planning for its introduction at the global level since 2014. Country-level introduction planning—such as country selection, assessing barriers, and designing activities to address these barriers—can occur well in advance of a product being "ready."

- **Think outside the box in terms of partners:** Given the barriers it faced, MMV relied more on organizations with expertise in community delivery (e.g., Save the Children International, IFRC, and UNICEF), as opposed to those solely with expertise in malaria.

- **Build the right team:** When developing and implementing an operational launch plan, it is important to build an effective team. This not only means having the right skill sets represented but also the right personalities at the table.

- **Ensure there is funding for spillover effects:** MMV's proposed approach for expanding access to RAS is to tap into co-funding from various partners. Some funders are more likely to support the introduction of a new commodity in the tool kit of community health workers, while other funders have historically aimed to fund the basic requirements of community health workers.

Step 3.2: **Set uptake targets and create monitoring plan**

The purpose of this sub-step is to set appropriate uptake targets and develop a monitoring and evaluation framework. In order to develop the framework, organizations need to identify the activities most critical in achieving impact and uptake, as well as an indicator demonstrating overall health impact. In addition to tracking uptake, monitoring and evaluation (M&E) allows for refinement and optimization of scale-up activities on a real-time basis. By pinpointing which activities are most and least effective, practitioners can refine their programming, saving financial and human resources as well as time.

?

Key questions this sub-step will answer include:

- What are **reasonable benchmarks for uptake** based on targets of comparable products?
- How might the **uptake curve differ based on characteristics** unique to the product or country?
- How will the **rate of uptake change** over time (e.g., no change over time, increase over time, decrease over time)?
- What **indicators should be tracked to measure the impact of the product** (e.g., indicators measuring health impact, geographic reach, usage among target demographics)?
- What **existing data sources can be leveraged** to collect data on these indicators? Do any **new data systems need to be established**, and if so, **is it realistic** to establish these systems?

Exercise 1: Develop the monitoring and evaluation framework

(One week)

To develop the M&E framework, practitioners should design indicators that track the desired health impact and the most critical activities needed to achieve successful product launch and scale. It is highly preferable to collect high-quality data on a smaller set of "must have" metrics as opposed to low-quality data on a larger set of indicators. Some practitioners may find it useful to revisit their theories of change when developing the framework, while others may rely only on the operational launch plan.

The definition of each indicator should be precise with the numerator and denominator clearly defined (where applicable) to ensure that all stakeholders collect and enter data consistently—otherwise, data will not be comparable once aggregated. Alignment and buy-in from all stakeholders around the prioritized metrics—especially with ministries of health if integrating into existing national surveys—is crucial to the success of monitoring and evaluation efforts.

The **Monitoring and Evaluation Tool**, on the following page, provides a dashboard for practitioners to outline the monitoring and evaluation framework. In addition to specific, precise definitions for each indicator, the frequency of data collection, stakeholder responsible for collecting and entering data related to the indicator, and at what level the data should be collected (e.g., facility, community) should be specified.

Monitoring and Evaluation Tool ILLUSTRATIVE

Identify the epidemiological impact(s) your product will have

IMPACT	NMR

Pick outcome metrics that are closely correlated to your desired impact

	MARKET AND USER	MANUFACTURING AND DISTRIBUTION	CLINICAL AND REGULATORY	POLICY, ADVOCACY, AND FINANCING	COORDINATION
OUTCOMES	**Target users correctly apply CHX** % of newborns (live births) that received first application of CHX gel to the umbilical cord at birth (home and facility births) % of women with a live birth in the last 2/5 years who reported applying no substance other than CHX gel on the umbilical cord % of health providers who recommended the use of CHX gel % of skilled birth attendants having comprehensive knowledge and correct skills on CHX gel use and application	**CHX is available to all target users** % of health facilities that provide maternity services with CHX gel stock-out in the last 3 months % of PCN registered retail outlets (PPMVs and community/private pharmacists) with CHX gel stock-out in the last 3 months	**CHX use follows latest clinical evidence and regulatory guidelines** % of health facilities that have copies of updated national protocols (STG, SOPs, standing order) No. of published in-country studies on CHX	**Policies, KOLs, and financing increase use of CHX** No. of states with budget line for CHX gel No. of states with at least one development partner supporting CHX scale-up CHX gel incorporated in published national EML (Y/N) CHX gel incorporated in published national STG (Y/N) No. of states with CHX gel on state EML No. of states that procured and distributed CHX gel	CHX included as agenda item in national child health working group (Y/N)

Pick outcome metrics that provide effective ways to monitor that your scale-up efforts are on track

	MARKET AND USER	MANUFACTURING AND DISTRIBUTION	CLINICAL AND REGULATORY	POLICY, ADVOCACY, AND FINANCING	COORDINATION
OUTPUT	**Providers are trained to use CHX correctly** No. of people trained on use and application CHX gel **CHX is widely promoted** No. of community mobilization activities held to promote CHX gel use No. of slots for CHX adverts aired	**Production and distribution of CHX is sufficient to meet demand** No. of CHX gel tubes produced No. of CHX gel tubes distributed			Bi-annual CHX coordination stakeholder meetings occurred (Y/N)

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OTHER HELPFUL TOOLS FOR SETTING UPTAKE TARGETS AND MONITORING PROGRESS INCLUDE:

- Goals and Targets Tool
- Country Dashboard
- Monitoring & Evaluation Framework Dictionary
- Download at **www.usaid.gov/cii**

The importance of prioritizing interventions in an operational launch plan

Lessons from the Strengthening Health Outcomes through the Private Sector (SHOPS) Ghana Project

SITUATION

In 2004, the WHO and UNICEF recommended the inclusion of zinc—in addition to oral rehydration salts (ORS)—for the treatment of diarrhea. While ORS treats dehydration from diarrhea, adding zinc reduces the duration and severity of a diarrhea episode, as well as the risk of further episodes in the ensuing months. However, many countries struggled with integrating zinc into existing programs aimed at improving caregiver and healthcare provider behaviors. In Ghana, SHOPS worked with the ministry of health (MoH) and other partners to address existing regulatory, supply-side, and demand-side barriers to develop a national scale-up strategy.

ACTIONS TAKEN

Based on a market assessment, the operational launch plan was developed and prioritized stakeholder coordination, training, demand generation, and local production.

SHOPS Ghana first focused on creating an enabling environment to support the implementation of the operational launch plan. Critical to establishing that enabling environment was government leadership. "We recognized that government leadership was the most important factor in scale-up. The Ministry of Health and

Photo © SHOPS Ghana

its service delivery arm, Ghana Health Service, needed to be in the driver's seat—in particular, its involvement in adding zinc and ORS to the Essential Medicines List and reclassifying the commodity into an over-the-counter drug was crucial," says Joseph Addo-Yobo, SHOPS Ghana Country Representative. To advocate to the Ghana MoH, data around public health impact, economic impact (e.g., reduced disease burden, higher employment due to local manufacturing, and higher taxes due to increased manufacturing profitability), and other countries' progress with scale-up of zinc were shared.

As zinc was a new commodity for diarrhea treatment—and many caregivers first seek treatment in the private sector (e.g., pharmacies and over-the-counter medicine sellers/drug shops)—it was also important to train healthcare providers in both the public and private sectors so that messaging would be consistent and mutually reinforced. Partners coordinated these training efforts with SHOPS Ghana leading private sector training and Ghana Health Service and UNICEF leading public sector training. Demand generation activities ranged from mass media to interpersonal communication (e.g., clinic activation and community activation) to raise awareness of zinc and ORS.

Monitoring and Evaluation (M&E) was included in the operational launch plan from the outset. "We wanted a strong M&E plan right from the beginning so that we could understand what was working and what wasn't working. We then adjusted accordingly," says Joseph Addo-Yobo. Metrics tracked the total amount of product distributed on a monthly basis, product availability in targeted outlets, and the quality and impact of training on providers.

RESULT

The implementation of the operational launch plan led to impressive gains in zinc uptake. In 2014, a SHOPS survey of three USAID target regions demonstrated that ~31% of children under five were treated with zinc—compared to 1% in 2012. Use of ORS increased from ~38% to 60% over the same period and in the same geographic regions. Furthermore, incorrect antibiotic use decreased from ~66% to 38%.

LESSONS LEARNED:

- **Leadership of the ministry of health and its service delivery arm is critical:** This involvement was key in creating the necessary enabling environment and ensuring effective coordination

- **Both public and private channels are important:** If healthcare providers across the public and private channels are messaging treatment differently, any demand generation efforts may be undermined.

- **Consumer education is key:** It is important to signal that there is a consumer desire for a new product - especially in a market with an active private sector.

- **M&E should be built into the program from the beginning:** It is important to be realistic as tracking data is expensive - both in terms of financial and human resources. Prioritize data to track and ensure it can be tracked with resources available.

The federal ministry of health needed to be in the driver's seat—in particular, its involvement in adding zinc and ORS to the Essential Medicines List and reclassifying the commodity into an over-the-counter drug was crucial.

In addition to the vignettes found throughout the Guide, the following Case Studies are more comprehensive, reflecting lessons across all three steps of the *Ready, Set, Launch* Framework.

SITUATION

In 2012, chlorhexidine (CHX) for umbilical cord care was introduced in two Nigerian states—Bauchi and Sokoto—through the USAID-funded Targeted States High Impact Project (TSHIP) implemented by JSI. This introduction was based on clinical studies that demonstrated chlorhexidine—an antiseptic applied to the umbilical cord—led to a 23–40% reduction in neonatal mortality in high-risk settings. Following this evidence, scaling efforts of chlorhexidine were occurring at the global level, with early adopter countries such as Nepal leading the way.

This clinical evidence also encouraged the WHO to add chlorhexidine for umbilical cord to its Model List of Essential Medicines in 2013. The following year, the WHO issued an updated recommendation of "daily chlorhexidine (7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% chlorhexidine) application to the umbilical cord stump during the first week of life ... for newborns who are born at home in settings with high neonatal mortality (30 or more neonatal deaths per 1000 live births)."

However, with TSHIP programming concluding in 2015, the future of chlorhexidine in Nigeria was uncertain. While Nigeria had introduced chlorhexidine in at least eight states, scale-up efforts remained fragmented. To build on, and accelerate, the momentum and local evidence created from TSHIP's initial successes, the federal ministry of health was determined to create an actionable, cohesive operational launch plan that outlined activities, roles and responsibilities, and resources needed to scale-up chlorhexidine at the national level.

> The introduction of CHX in two states in Nigeria prior to national scale-up was critical both to generate political will and momentum for CHX scale-up and to reveal important lessons on how best to scale nationally.

ACTIONS TAKEN:

Ready: Since chlorhexidine's introduction in Bauchi and Sokoto states, the federal ministry of health and partners collaborated to create an enabling environment and prepare for national scale-up—taking actions such as articulating the specifications for chlorhexidine, obtaining regulatory approval for local manufacturers, adding chlorhexidine to the Essential Medicines List, and conducting market-shaping efforts around pricing.

In addition to the federal ministry of health, partners at both the local and global levels had prioritized Nigeria for chlorhexidine scale-up due to its high neonatal mortality rates, demonstrated government interest, and potential for integration into existing programming. In particular, Nigerian manufacturers—who viewed demand generation as a barrier to scale-up—were eager to participate in the development of a national operational launch plan given their investment into chlorhexidine manufacturing. Global partners, including the Chlorhexidine Working Group (an international collaboration of organizations, led by PATH, committed to advancing the use of chlorhexidine), the Clinton Health Access Initiative, Inc. (CHAI), the Maternal and Child Survival Program (MCSP), and U.S. Agency for International Development (USAID), likewise committed to supporting Nigerian scale-up efforts. USAID—working in tandem with the Chlorhexidine Working Group—had prioritized Nigeria for chlorhexidine scale-up based on its global scaling vision which included a comparative analysis accounting for neonatal mortality, percentage of home births, and country readiness.

The size and diversity of Nigeria presented opportunities and challenges in developing a national plan for the scale-up of chlorhexidine. While the federal ministry of health desired a national plan, it also recognized the need for the plan to offer flexibility to the diverse states and stakeholders working in them, as well as state ownership of implementation.

To meet these objectives, the federal ministry of health—with support from partners—convened a stakeholder meeting in September of 2015. The stakeholder meeting brought together over 50 individuals from the federal ministry of health, state ministries of health, professional associations, local non-governmental organizations, manufacturers, and development partners such as the Chlorhexidine Working Group.

Set: The stakeholder's meeting provided a launching pad for the development of the national operational launch plan and a forum for organizations to provide early input into interventions that could address identified barriers to scale. Over the ensuing three months, a team conducted individual stakeholder interviews with both meeting participants and other priority organizations to more deeply examine and prioritize barriers to scale. Interviews also focused on mapping stakeholders, understanding the launch and introduction of comparable products in Nigeria, quantifying realistic uptake targets of chlorhexidine, and estimating resources needed (both financial and human). Following these interviews, a list of prioritized barriers to scale was developed. The team developed a strategy with interventions to address each prioritized barrier to scale.

Launch: The federal ministry of health wanted to convert the strategy into an operational launch plan clearly outlining the specific activities needed, as well as their responsible parties, timeframes, and estimated costs. Activities centered around demand generation, establishing and strengthening coordination, leveraging existing public and private distribution channels, seeking commitment from key opinion leaders, and mobilizing resources for scale-up. A comprehensive monitoring and evaluation plan was developed by reviewing chlorhexidine M&E plans in other countries and by reviewing comparable product M&E plans for other global health products introduced in Nigeria. Finally, an uptake coordinator, responsible for overseeing the implementation of the operational launch plan, was recruited to support the federal ministry of health.

Photo © Dalberg Design

RESULTS

Through this process, the federal ministry of health and partners created an operational launch plan that outlined the activities, roles and responsibilities, targets, and estimated costs. As partners were involved in the development of the strategy and operational launch, buy-in and alignment were ensured from the beginning. The operational launch plan also served as an important tool for the federal ministry of health to use for advocacy in meetings with development partners and state ministries of health.

There are often important lessons that can be learned across scale-up plans for the same product in different countries. For example, Nigeria learned about different approaches to scaling CHX from Nepal, where CHX had already begun to scale successfully. The Nigerian CHX scale-up strategy is already being used as an additional input as other countries seek to scale CHX as well.

LESSONS LEARNED:

- **Government leadership is key:** While a multitude of partners at the global and local level were interested in the launch and scale-up of chlorhexidine, government leadership and ownership of the operational launch plan was key—especially as the time came to implement the activities in the plan.

- **Collaboration with local and global partners aids alignment early on:** Throughout the development of the operational launch plan, a multitude of partners took part. Through this engagement, partners provided valuable feedback into the development of the strategy and could consider integrating chlorhexidine into ongoing programming.

- **Even if there is global evidence of clinical efficacy, local pilots/trials can be useful:** TSHIP's work in Bauchi and Sokoto provided a launching pad for introduction of chlorhexidine at the national level in Nigeria. Pilots/trials can be effective for reasons other than demonstrating clinical efficacy—such as serving as an advocacy tool, building credibility, and refining activities related to scale-up.

SITUATION

While the number of deaths attributed to tuberculosis (TB) has decreased by roughly 50% since 1990, in 2015, TB became the number one infectious disease killer in the world. To continue and accelerate progress in reducing the TB burden, global priorities have focused on earlier and improved case detection, especially in children and HIV-positive individuals, and improving capacity to diagnose multi-drug-resistant tuberculosis (MDR-TB).

The sputum smear microscopy test—developed 125 years ago—is the most widely used method to diagnose TB. This test has a number of drawbacks, including a low sensitivity to detect the causative agent of TB—especially in children and HIV-positive individuals—and an inability to determine drug-resistance.

To that end, a rapid diagnostic with a higher sensitivity for diagnosing TB and MDR-TB in all individuals with signs and symptoms of TB was developed. A partnership between the Foundation for Innovative New Diagnostics (FIND), Cepheid Inc., and the University of Medicine and Dentistry of New Jersey—with support from the United States National Institutes of Health and the Bill & Melinda Gates Foundation created this product, named Xpert MTB/RIF.

In 2009, demonstration studies for the diagnostic were underway—yet there had been little involvement from the larger TB community, including country governments, donors, and technical partners.

ACTIONS TAKEN:

Ready: In 2010, the WHO convened a global expert group—consisting of representatives from the WHO, National Tuberculosis Programs, donors, researchers, clinicians, and community representatives—to assess the evidence and cost-effectiveness of Xpert MTB/RIF. Based on the review of the evidence, in 2011, the WHO (i) strongly recommended the use of Xpert MTB/RIF as the initial diagnostic test for individuals suspected of MDR-TB or HIV-associated TB and (ii) conditionally recommended its use as a follow-on test in settings where MDR-TB and/or HIV is a lesser concern.

Simultaneous to this global evidence review, FIND negotiated with Cepheid to reduce prices for the diagnostic in the public sector of 145 high TB burden and developing countries. Reducing prices at the global level was crucial to demonstrate overall cost-effectiveness as well as make the diagnostic more affordable.

USAID—in line with initial WHO guidance—used criteria such as high rates of MDR-TB and HIV, as well as overall TB case detection gaps, available resources, active national tuberculosis programs and technical partners, and feasibility for implementation to guide country-level introduction. This led to an initial focus on Indonesia, in addition to three other countries. Even though USAID had prioritized four countries for introduction, a phasing plan outlining timing of introduction in other countries was also created.

Set: To kick-start the development of the strategy and operational launch plan in Indonesia, the country's National Tuberculosis Control Program (NTP) convened a meeting to appoint a multi-stakeholder team comprised of representatives from government, implementing partners, donors, policy makers, and local service providers. The team developed an operational launch for Xpert MTB/RIF introduction.

During the barrier analysis, the team focused on the need for local evidence, understanding the operational implications of introduction, and examining acceptance among patients, laboratory technicians, and clinicians. The main challenges to launch and scale were identified as cost (diagnostics and consumables), quality assurance of the diagnostic, capacity to treat patients diagnosed with MDR-TB, and behavior change among clinicians and laboratories to use the new diagnostic.

The team also signed a memorandum of understanding with the ministry of health to formalize site selection for Xpert MTB/RIF introduction in Indonesia. Criteria included sites already providing testing for TB, sites with increased prevalence of suspected MDR-TB and HIV-associated cases, and sites capable of evaluating performance and impact.

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Launch: The team developed an operational launch plan for 2011-12 that outlined specific activities including:

- **Procurement:** Funding needed to be identified so that Indonesia could purchase the diagnostics and cartridges. Through the Global Fund budget, the NTP was able to buy the diagnostics and cartridges—with partners on hand to step in if issues arose.

- **Training:** The plan placed a heavy emphasis on training clinicians and technicians. To do so, training materials and curricula were developed for both trainers and end users. Training played a key role in behavior change, as many technicians and clinicians had used the sputum smear microscopy test throughout their entire careers.

- **Supervision and monitoring:** Regular supervision and monitoring at operating sites were used to encourage and ensure proper use of the diagnostic among laboratory technicians and clinicians, as well as understand maintenance requirements and update training materials as needed.

- **Quality assurance:** To confirm results from Xpert MTB/RIF, additional quality-assured laboratories were needed. As such, the operational launch plan prioritized expanding access to these laboratories.

- **Expanding the number of MDR-TB treatment centers:** Due to Xpert MTB/RIF's ability to diagnose MDR-TB, the number of treatment centers for MDR-TB was increased to improve access to quality treatment regimens upon diagnosis.

The team also signed a memorandum of understanding with the ministry of health to formalize site selection for Xpert MTB/RIF introduction in Indonesia. Criteria included sites already providing testing for TB, sites with increased prevalence of suspected MDR-TB and HIV-associated cases, and sites capable of evaluating performance and impact.

RESULTS

As of 2015, there were 41 functional Xpert MTB/RIF machines in Indonesia. This diagnostic significantly increased the number of MDR-TB cases diagnosed in Indonesia—rising from 216 in 2010 to 1,414 in 2014. Furthermore, the average time between registration of suspected MDR-TB cases and second-line treatment initiation decreased from 81 to 15 days.

The Roadmap to Successful Xpert Implementation outlines the activities and expected outcomes that guide Xpert MTB/RIF introduction in-country. This can be found in the Supplemental Toolkit.

LESSONS LEARNED

- **Begin advocacy and communication early:** Instead of waiting until after the demonstration studies were completed, a communication and dissemination plan could have begun earlier to sensitize and integrate with the larger global health community. This may have accelerated introduction planning. It could have occurred in parallel with demonstration studies and WHO guidance.

- **Establishing an evidence base is crucial:** Due to a lack of evidence, the WHO was not able to strongly recommend the use of Xpert MTB/RIF for all individuals with TB symptoms—instead issuing a recommendation only in suspected MDR-TB and HIV-associated cases. This trickled down to country-level policy as well—limiting overall uptake of Xpert MTB/RIF.

- **Linkage from test to care:** With the introduction of Xpert MTB/RIF, the rate of diagnosis of HIV-associated TB and MDR-TB cases increased. However, pre-existing problems in linking diagnosis and care, as well as connecting the HIV and TB communities, meant that not all potential medical benefits of Xpert MTB/RIF were immediately realized.

SITUATION

The Universal Anesthesia Machine (UAM)—conceived in Malawi—allows doctors to deliver anesthesia in hospitals plagued by power outages and shortages of compressed medical gases. Gradian Health Systems launched in 2010, with a mission to scale the UAM across the globe— primarily by working with country-level distribution partners.

ACTIONS TAKEN:

Ready: The Gradian team began conducting desk research and interviews with anesthetists and knowledgeable NGOs in LMICs to understand which countries would be strong candidates for the UAM. The team honed in on five criteria to determine whether they should pursue business proactively in a given country:

- **Need:** Gradian wanted to sell UAM in geographies that needed it—places where conventional machines were failing due to the infrastructure challenges of unreliable electricity and oxygen supplies.

- **Demand:** The team knew that demand was very different than need, and sought out a country where hospitals and supporting organizations would both see the value of the UAM and be willing to pay for it.

- **Procurement:** The team knew that a product like the UAM (e.g., a large piece of capital equipment) would have a drastically different procurement process as compared to drugs, diagnostics, and even smaller medical devices. It was important to choose a country that had delivery channels and willingness and ability to pay for products like the UAM, which required an understanding of national health budgets and NGO/ donor presence in-country.

- **Competition:** The competition in these markets often came from traditional machines and donated or refurbished equipment that was inoperable and also lacked a service infrastructure. The team knew that the UAM would be well suited for the setting, but an ecosystem that provided adequate service and training with the machine would be critical to ensure reliable use and scale.

Uganda was one country that performed well against all of these criteria. In particular, conversations with a Ugandan anesthetist and potential distribution partners in the country showed the team that both the need and the likely demand for UAM in Uganda were high.

Set: The Gradian team uncovered several barriers to scale early on. The first barrier they encountered was learning that a tender for anesthesia machines had recently closed in Uganda. Given that Uganda is a relatively small country, this tender seemed to be a major barrier to entry. Its existence indicated two things: first, the market was already saturated with competitors and second, any potential customers had just purchased machines— meaning that they would not do so again for at least three to four years.

While this was a discouraging discovery, the Gradian team did not immediately abandon the possibility of scale in Uganda. Instead, while conducting a deep-dive market assessment, the team happened to meet with a distributor who focused largely on faith-based hospitals. The team learned that faith-based hospitals provide 45 percent of medical care in Uganda. These hospitals were not included in the tender, and represented a market that was in need of a working anesthesia equipment option. Additionally, it turned out that the large procurement went to the wrong facilities that could not use it, and the UAM was often sought as a replacement

Furthermore, ether, a highly primitive form of anesthesia, was still widely used across Uganda. Timing was on Gradian's side—there was an ongoing campaign to ban ether, and the WHO had just removed it from their Essential Medicines List as well. This was a clear signal to the distributor that ether and ether-based machines were obsolete, and that it was time to look for alternatives-like the Universal Anaesthesia Machine. Importantly, this distributor also understood Gradian's business and was committed to selling a high-quality product.

A second major barrier to scale that Gradian faced was low ability to pay. Gradian worked with their distributor to address this barrier. While some hospitals were able to pay full price upfront, Gradian and its distribution partner set up a payment plan for others who could only afford to pay in installments. Additionally, a donor came in and subsidized purchases of the UAM for hospitals willing to apply for a grant and contribute USD 5000 of their own funds. This financing scheme was a huge success, as it allowed Gradian to continue selling the product at its regular price, while also reaching hospitals that needed the UAM but had low ability but high willingness to pay. The hospitals were also incentivized to use the product and call for maintenance and repairs since they had made an investment along with the donor. Overall, Gradian was able to address barriers related to ability to pay (ATP) and willingness to pay (WTP) without ever having to lower the price of the UAM in Uganda.

Gradian continues to face certain barriers to scale in Uganda but is steadily making progress against its goal of bringing safe anesthesia to more hospitals. One challenge, for instance, is government tenders in the public sector—the specifications outlined in tenders are often vague and do not account for infrastructure challenges and new developments in anesthesia technology. Gradian is continuing to chip away at this barrier by selling to government hospitals on a one-off basis when possible to raise awareness of the product in the public sector.

Launch: With a team of only four people at Gradian, it was difficult to develop a detailed operational plan and set long-term targets, so they opted for strategic trial and error. The team focused on the driving principles of good launch planning. They made sure, on a daily basis, that all involved stakeholders were incentivized to support the introduction of the UAM in Uganda.

Rather than focusing on long-term sales targets, Gradian's launch planning prioritized building up the infrastructure needed to make UAM work. This infrastructure included an effective clinical and technical product training upon installation and ongoing service and maintenance of the machines by local distribution partners. There was a significant amount of hand-holding with the distributor early on, in order to help them drum up sales and respond to service needs. This time investment proved to be a good one in the long-term; after around two years, Gradian's distribution partner was able to fully manage sales, distribution, training, and service of the UAM.

> Rather than focusing on long-term sales targets, Gradian's launch planning prioritized building up the infrastructure needed to make UAM work.

> Gradian's work in Uganda has given the company a starting point to begin broader operations with medical equipment distribution throughout the region, in countries such as South Sudan and the Democratic Republic of the Congo.

RESULTS

As of October 2016, the UAM has brought safer anesthetic care to approximately 15,000 patients in 40 operating theaters across Uganda. Gradian's distribution partner is now able to handle all aspects of selling the UAM—from marketing and sales to maintenance and repair. They also hold a local spare parts and inventory depot in Kampala to quickly support customer needs and additional scale-up.

LESSONS LEARNED:

- **Trial and error and constant iteration is part of the strategy process:** The Gradian team learned that talking through a strategy for scale-up is useful, but the most relevant challenges and opportunities become evident during implementation. Trial and error is critical in these markets, and failing once is not always a signal that you should give up. "We tried a lot of things that didn't work—and then we found a model that did work," says Lina Sayed, Vice President of Market Strategy at Gradian.

- **If your desired target market for entry seems out of reach, do not lose hope—another one might be a better fit:** Gradian's initial reaction to Uganda was that it would be difficult to scale there due to a government tender for anesthesia machines. However, by focusing efforts on faith-based hospitals that did not participate in the tender process, they were able to capture a new (and large) market.

- **Distributors are invaluable sources of information—and it is important to choose the one that is right for you:** Distributors often have a bad reputation due to the margins they demand, but they also hold a wealth of information about the market. Engage with them early and often to learn about the barriers to scale that you are likely to face. And, when it comes to choosing a distribution partner to work with—shy away from those that do not have the capabilities you seek or the excitement you want in a partner. It is worth the time and effort to engage in "distributor speed dating"—vetting several distributors and seeing which shares your values and best understands your product and company.

Acknowledgments
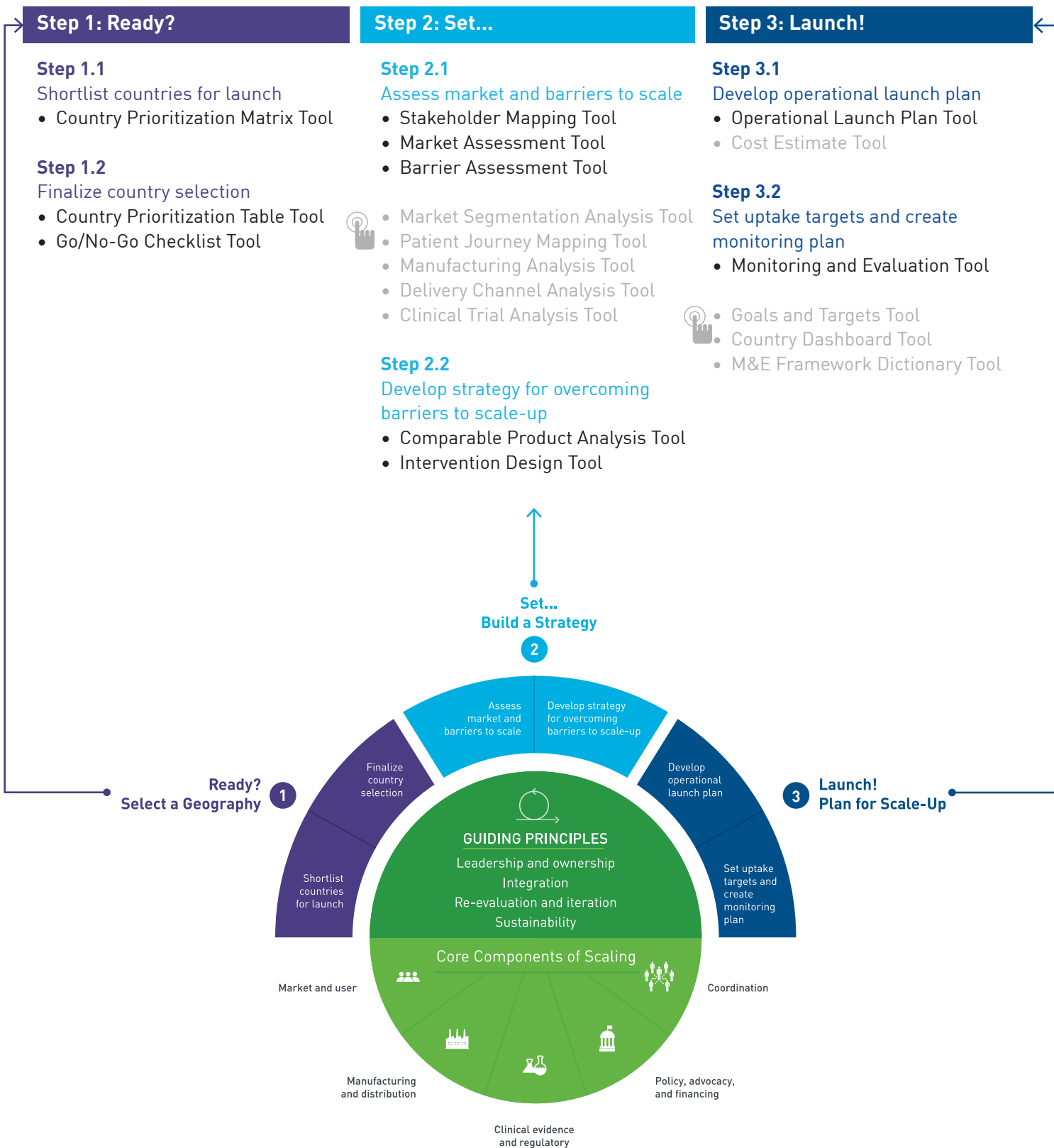
Summary of tools in Ready, Set, Launch

Step 1: Ready?

Step 1.1
Shortlist countries for launch
- Country Prioritization Matrix Tool

Step 1.2
Finalize country selection
- Country Prioritization Table Tool
- Go/No-Go Checklist Tool

Step 2: Set...

Step 2.1
Assess market and barriers to scale
- Stakeholder Mapping Tool
- Market Assessment Tool
- Barrier Assessment Tool

- Market Segmentation Analysis Tool
- Patient Journey Mapping Tool
- Manufacturing Analysis Tool
- Delivery Channel Analysis Tool
- Clinical Trial Analysis Tool

Step 2.2
Develop strategy for overcoming barriers to scale-up
- Comparable Product Analysis Tool
- Intervention Design Tool

Step 3: Launch!

Step 3.1
Develop operational launch plan
- Operational Launch Plan Tool
- Cost Estimate Tool

Step 3.2
Set uptake targets and create monitoring plan
- Monitoring and Evaluation Tool

- Goals and Targets Tool
- Country Dashboard Tool
- M&E Framework Dictionary Tool

Set...
Build a Strategy

2

Assess market and barriers to scale

Develop strategy for overcoming barriers to scale-up

Finalize country selection

Develop operational launch plan

Ready?
Select a Geography

1

Launch!
Plan for Scale-Up

3

Shortlist countries for launch

Set uptake targets and create monitoring plan

GUIDING PRINCIPLES
Leadership and ownership
Integration
Re-evaluation and iteration
Sustainability

Core Components of Scaling

Market and user

Coordination

Manufacturing and distribution

Policy, advocacy, and financing

Clinical evidence and regulatory

Product-specific scale-up challenges

This Guide is designed to be relatively product-agnostic in order to be applicable to a variety of global health innovations. However, opportunities and barriers to scale are bound to differ based on the type of product. The table below highlights some potential areas where these differences are most likely to manifest, specifically for the three types of products that are the focus of this Guide: drugs, devices, and diagnostics (grouped below as pharmaceuticals and non-pharmaceuticals).

Core Components	Pharmaceuticals (drugs)
MARKET AND USER	• While the challenge of building demand for drugs should not be underestimated, it can (sometimes) be simpler than doing so for non-pharmaceuticals. A rule of thumb in global health is that "drugs are expensive to make and cheap to sell; devices are the opposite." • Drugs that constitute a new category or require behavior change may take additional demand-building effort. • Drugs that are focused on prevention (rather than treatment) can also be harder to sell in places without a strong infrastructure and culture of prevention.
CLINICAL EVIDENCE AND REGULATORY	• The regulatory approval process is more rigorous and lengthier; on the plus side, requirements are also relatively clear.
MANUFACTURING AND DISTRIBUTION	• Drug manufacturing requires technical know-how; there are limited developing countries with local manufacturing capabilities (if desired) offering high quality. • In countries that do have quality manufacturing capabilities (e.g., India, Nigeria), tradeoffs around local manufacturing should be carefully considered. For example, economic impact (increased employment, increased tax revenues) can be a powerful advocacy tool with local governments, but local manufacturing can also require greater investment in manufacturer capacity, quality, etc.
POLICY, ADVOCACY, AND FINANCING	• Drugs typically receive more financing from governments compared to devices or diagnostics, since they are often used in treatment regimens (rather than for prevention). • Essential Medicines Lists (EMLs) exist in most low and middle-income countries (LMICs) to help healthcare systems prioritize which drugs to procure.

Non-pharmaceuticals (devices and diagnostics)

- The need for behavior change (especially in instances where health professionals have been operating without diagnostics) and training (especially for devices) can make generating demand more challenging.
- Proving the need for devices and diagnostics can be more difficult than proving the need for drugs, as the former improve healthcare in a less direct way.
- The payer and user can be different (and at times different from the patient), making demand generation more complicated.

- The regulatory approval process may be shorter (if it exists at all) but typically is more opaque and/or vague.
- For devices that enter the body (e.g., IUDs), the process is likely to be longer, so understanding which class a device falls into is critical.

- Complex device manufacturing may be even more difficult locally given the scarcity of required parts, so ease of trading across borders and import taxes become important metrics to consider during country selection.
- Distribution of devices is often more difficult at volume, particularly if there are no consumables (e.g., parts that require frequent repeat purchases) associated with the device, so locating a distribution partner may be more difficult.
- Devices also require preventative maintenance and repairs, which can be hard to provide in resource-limited settings.

- It is relatively more difficult to acquire financing for devices and diagnostics, for the same reason that it is difficult to convince the market of need—these products elevate quality of care, but do so indirectly.
- The equivalent of an EML for non-pharmaceuticals is still in development in many countries.

Additional resources and references

While creating *Ready, Set, Launch*, we were pointed to other publications for inspiration and reference. While they vary in relevance to the country launch planning process, the curated list below may be useful to review as complementary lessons/case studies and higher-level frameworks and tools. These can all be found in the Supplemental Toolkit.

FRAMEWORKS:

USAID's Center for Accelerating Innovation and Impact (CII)

- **Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations:** Identifies priority activities and provides project management oversight across four stages of the product development continuum to help practitioners think through, plan, and execute on delivery-related activities.

- **Pathways to Scale: A Guide for Early Stage Global Health Innovators on Business Models and Partnership Approaches to Scale-Up**: Provides organizational guidance for innovators in selecting the most relevant business model and partnership options to be able to scale.

Clinton Health Access Initiative (CHAI)

- **Knowledge Brief: Driving Uptake of New Products:** Provides a strategy framework for new product roll-out and shares best practices in accelerating uptake of new products through describing three critical success factors for rapid uptake: (1) strategic planning and operational coordination among stakeholders; (2) supply chain coordination; and, (3) effective communication with all stakeholders.

D-Rev

- **Impact Innovation for Medical Devices: A Decision-Making Framework:** A product development framework to equip entrepreneurs with the technical, design, and business tools and knowledge to address market introduction hurdles.

World Health Organization (WHO)

- **ExpandNet: Beginning with the end in mind: Planning pilot projects and other programmatic research for successful scaling up:** Provides 12 recommendations and a checklist to help build scale-up considerations into projects from the outset, allowing users to plan ahead for eventual scale up from the earliest stages of pilot design.

- **ExpandNet: Nine-Step Guide for Developing a Scaling-up Strategy:** A nine-step guide to assist program managers, technical assistance personnel, researchers, and policy makers with the process of developing a scaling-up strategy.

- **ExpandNet: Practical Guidance for Scaling-Up Health Service Innovations:** Provides a more comprehensive examination of scaling than the Nine-Step guide. It focuses not only on how to scale-up innovations but also suggests ways to strategically plan and manage scale-up.

CASE STUDIES

Clinton Health Access Initiative (CHAI)

- **Progress over a Decade of Zinc and ORS Scale-up: Best Practices and Lessons Learned:** This report highlights specific lessons that have led to successful outcomes across four key objectives: 1) facilitating a strong enabling environment; 2) improving availability of high-quality and affordable supply; 3) improving knowledge and skills of health providers; and, 4) generating demand among caregivers.

Federal Government of Nigeria

- **National Strategy and Implementation Plan for Scale-up of chlorhexidine in Nigeria:** A real-world country scale-up strategy and implementation plan leveraging the Ready, Set, Launch framework.

USAID's Maternal and Child Survival Program (MCSP), formerly known as MCHIP

- **Lessons Learned from a Preliminary Analysis of the Scale-Up Experience of Six High-Impact Reproductive, Maternal, Newborn, and Child Health (RMNCH) Interventions:** Lessons learned based on 18 case studies of six high-impact RMNCH interventions in 14 countries. The review analyzes the elements and strategies of the country scale-up experience and draws conclusions on lessons learned that could be applicable to other programs

Country Launch Canvas

The Country Launch Canvas is a template intended to help capture the most important learnings while working through the *Ready, Set, Launch* framework, as well as linking these learnings into a market assessment, the key activities necessary for launch, and targets to track progress of launch. The canvas is a visual chart that can:

● **Recap the product vision and country selection from Step 1 of Ready, Set, Launch, then**

● **outline key aspects of the target user, market, key stakeholders, barriers, and activities that are uncovered during Step 2 of Ready, Set, Launch, and**

● **develop activities for the operational launch plan, as well as the intended targets and indicators by which success will be measured during Step 3 of Ready, Set, Launch.**

READY, SET, LAUNCH

COUNTRY LAUNCH CANVAS

Recap of the product vision and country selection:

For _____ *(product name)* _____ , _____ *(country name)* _____ prioritized based on _____

(product vision and rationale for country)

Target user

Market size

See page 27, Market Assessment Tool, RSL

Key stakeholders

USER

LOCAL

STATE

NATIONAL

GLOBAL

See page 25, Stakeholder Mapping Tool, RSL

Key barriers to scale

See page 28, Barrier Assessment Tool, RSL

Potential interventions to overcome these barriers

See page 37, Intervention Design Tool, RSL

Key launch activities across the five core components of scale-up

MARKET AND USER

MANUFACTURING AND DISTRIBUTION

CLINICAL AND REGULATORY

POLICY, ADVOCACY, AND FINANCING

COORDINATION

See page 42, Operational Launch Plan Tool, RSL

Scale-up targets

See page 46, Monitoring and Evaluation Tool, RSL

Key indicators

■ Answers can be worked out from *Step 1* of Ready, Set, Launch
■ Answers can be worked out from *Step 2* of Ready, Set, Launch
■ Answers can be worked out from *Step 3* of Ready, Set, Launch

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Practitioners should use this canvas as a living document to collect notes and learnings at each stage of Ready, Set, Launch. The Canvas can be continually revisited and updated to ensure all pieces of the plan align at all stages so it provides an ongoing snapshot of the launch and scale-up planning process. However, the canvas is not intended to replace more detailed launch planning documents, such as the Stakeholder Mapping Tool, Barrier Assessment Tool, or Operational Launch Plan Tool.

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Cover photos: Dalberg Design