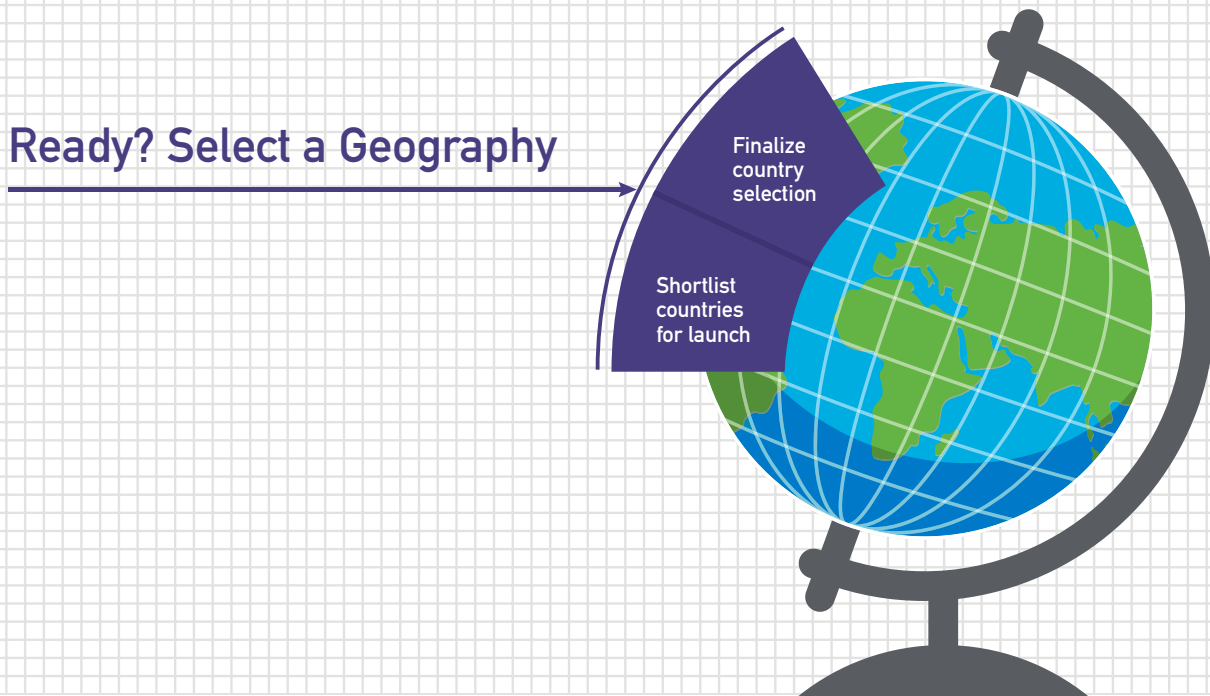


FROM LAB TO LAUNCH:

A Case Study on Country Prioritization

Ready? Select a Geography



IN PARTNERSHIP WITH:

CENTER FOR INNOVATION AND IMPACT

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USAID's **Center for Innovation and Impact** (CII) in the Bureau for Global Health encourages business-minded approaches and accelerates impact against some of the world's most important health issues. CII invests seed capital in the most promising ideas and applies a rigorous, market-oriented approach to cut the time it takes to transform discoveries in the lab to impact on the ground.



Monash University, located in Melbourne, is the largest university in Australia and a world leader for education and research. The university delivers

impactful and cutting-edge research to address the most significant global challenges, from climate change to antibiotic resistance. A research team at Monash, in partnership with GlaxoSmithKline, has been developing a novel, heat stable form of oxytocin to prevent life-threatening maternal bleeding — postpartum hemorrhage. This form of oxytocin can be inhaled by patients from a simple, disposable aerosol device immediately after childbirth.

CII would like to thank the team at Monash University for co-authoring this case study and sharing their experience with other innovators and partners. For contact information and to download the latest version of this report, please visit www.usaid.gov/cii.

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Photo: USAID

EXECUTIVE SUMMARY

Through an award from Saving Lives at Birth: A Grand Challenge for Development, a team of scientists at Monash University in Melbourne, Australia, received support to conduct an in-depth market analysis to identify countries best suited for first launch of its new product — an inhaled form of oxytocin to prevent or treat postpartum hemorrhage. The following case study summarizes the steps that the Monash team took to adapt the framework from *Ready, Set, Launch: A Country-Level Launch Planning Guide for Global Health Innovations* and apply it to its country prioritization exercise in two steps: (i) shortlisting countries for launch and (ii) finalizing country selection.¹

Country prioritization is an important step for innovators who are looking to introduce and scale their products or services. The case study and tools that the Monash team built, and resources listed in the appendix, can serve as a guide for innovators on how they might approach a similar country prioritization process. This case study is not a comprehensive description of the team's process; instead, it details insights, major steps, and lessons learned. These steps include developing a vision for success and impact pathway, shortlisting potential launch countries, and then finalizing country selection using quantitative and qualitative analyses. One key point to remember is that the process is iterative and must be revisited often in the lead up to product launch.

¹ To download *Ready, Set, Launch: A Country-Level Launch Planning Guide for Global Health Innovations* and its supplemental toolkit, please visit <https://www.usaid.gov/cii/ready-set-launch>.

Saving Lives at Birth: A Grand Challenge for Development: Every two minutes, a woman dies in childbirth. The onset of labor marks the start of a high-risk period for both mother and baby that does not ease until at least 48 hours after birth. Almost all the deaths during this high-risk period occur in low- and middle-income countries. Saving Lives at Birth: A Grand Challenge for Development calls on the brightest minds across the globe to identify and scale groundbreaking approaches to save the lives of mothers and newborns in poor, hard-to-reach communities around the time of birth. The Saving Lives at Birth partners — USAID, the Government of Norway, the Bill & Melinda Gates Foundation, Grand Challenges Canada, UK's Department for International Development, and the Korea International Cooperation Agency — have committed nearly \$100 million to support the scale up of innovative tools and approaches to improve the lives of mothers and newborns during their most vulnerable hours.

OUR JOURNEY AT MONASH UNIVERSITY

As innovators of a new drug, we at Monash University understand our technology well, its potential impact, and what we need to do to transform it from an idea into a usable product. However, as we have progressed along our product development journey, we have become acutely aware that technical achievements in product development are not enough to deliver the impact that we hope to achieve. Introducing an innovation into low resource settings is complex and requires strategic planning early on in the innovation journey.

A key step towards product introduction that requires careful consideration and early planning is selection of first launch countries. At Monash University, we wanted to be purposeful in selecting our first launch countries. We recognized that our first country launches needed to be in markets that would offer the greatest potential to generate evidence of impact, helping spark adoption and greater uptake in countries that followed.

The Innovation: Addressing Postpartum Hemorrhage with Novel Formulation of Oxytocin

Postpartum Hemorrhage (“PPH”) is a condition of excessive blood loss after childbirth and is a leading cause of death in women around the world. PPH can be effectively prevented or treated with oxytocin, which is currently available as an injection. However, access to injectable oxytocin requires a cold chain to maintain quality and trained medical personnel to administer the drug. Seeing these barriers to injectable oxytocin in certain use cases, a team of researchers at Monash University, in partnership with GlaxoSmithKline, developed a novel aerosol delivery system for oxytocin that can be inhaled by patients from a simple, disposable device immediately after childbirth — overcoming some of the most significant barriers to preventing and treating PPH.

In parallel with product development in 2017, we commenced our journey towards prioritizing early launch countries for the inhaled oxytocin product. Using *Ready, Set, Launch: A Country-Level Launch Planning Guide for Global Health Innovations* (“*Ready, Set, Launch*”), and with funding and acceleration support from the Saving Lives at Birth Grand Challenge, we sought to understand the opportunities and challenges in each country to identify those that were most likely to demonstrate early success.

The analytical tools adapted from *Ready, Set, Launch* and presented in this case study helped us better shape our own strategy, with the aim of accelerating the time to market to ultimately reach more of those in need. We hope that this tool, and lessons learned along our journey, will help in your efforts to develop a market strategy and bring your interventions into the hands of those that need them most.



Note to readers: The approach we at Monash University took to the country prioritization exercise is intensive. It was an exercise that lasted nearly two years, with significant resources allocated to the task. We acknowledge that it may not be possible, or even optimal, for all innovators to direct the same time or resources to this analysis. However, we hope that this case study will serve as a useful resource by demonstrating how we adapted the tools of *Ready, Set, Launch* to suit our product and implementation goals.

While we have developed a data-driven tool that applies a systematic approach to prioritization of early launch countries, the process is both art and science. There are several different factors that should be considered when deciding where to introduce your product first, and thus multiple ways to make the final selection. The breadth and depth by which countries are assessed with this tool allowed us not only to understand where to go, but more importantly why to go there.

Please refer to the call out boxes throughout this document denoted with the  icon for tips to apply this approach to your country selection process.

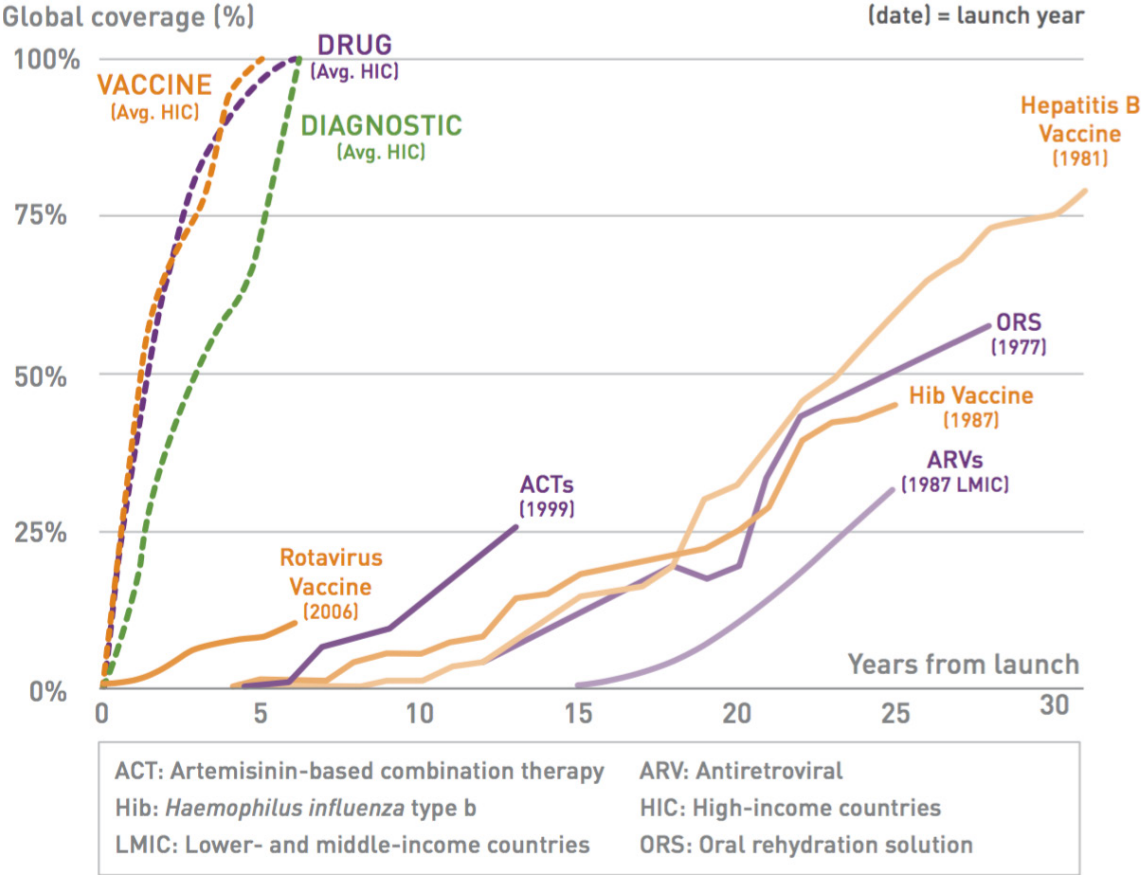
INTRODUCTION

Global health practitioners know that introducing and scaling new innovations, be it products or services or approaches, is a complex process. There is no shortage of activities to consider when developing a product or service and delivering it to the world's hardest to reach populations — 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.



Figure 1: Years to scale-up



Source: Bill & Melinda Gates Foundation, Dalberg Global Development Advisors, Boston Consulting Group

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. USAID's Center for Innovation and Impact (CII) developed the IDEA to IMPACT series to share guidance for scaling global health innovations to help practitioners accelerate impact through better coordination and earlier planning. The first publication in the series, *Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations* ("Idea to Impact"), outlines priority delivery-related activities through the product development process.² Its 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 launch country selection and operational launch planning.

Ready, Set, Launch is organized across a three-step framework, depicted in Figure 2.

Step 1 – Ready? Select a Geography

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

Step 2 - Set...Build a Strategy

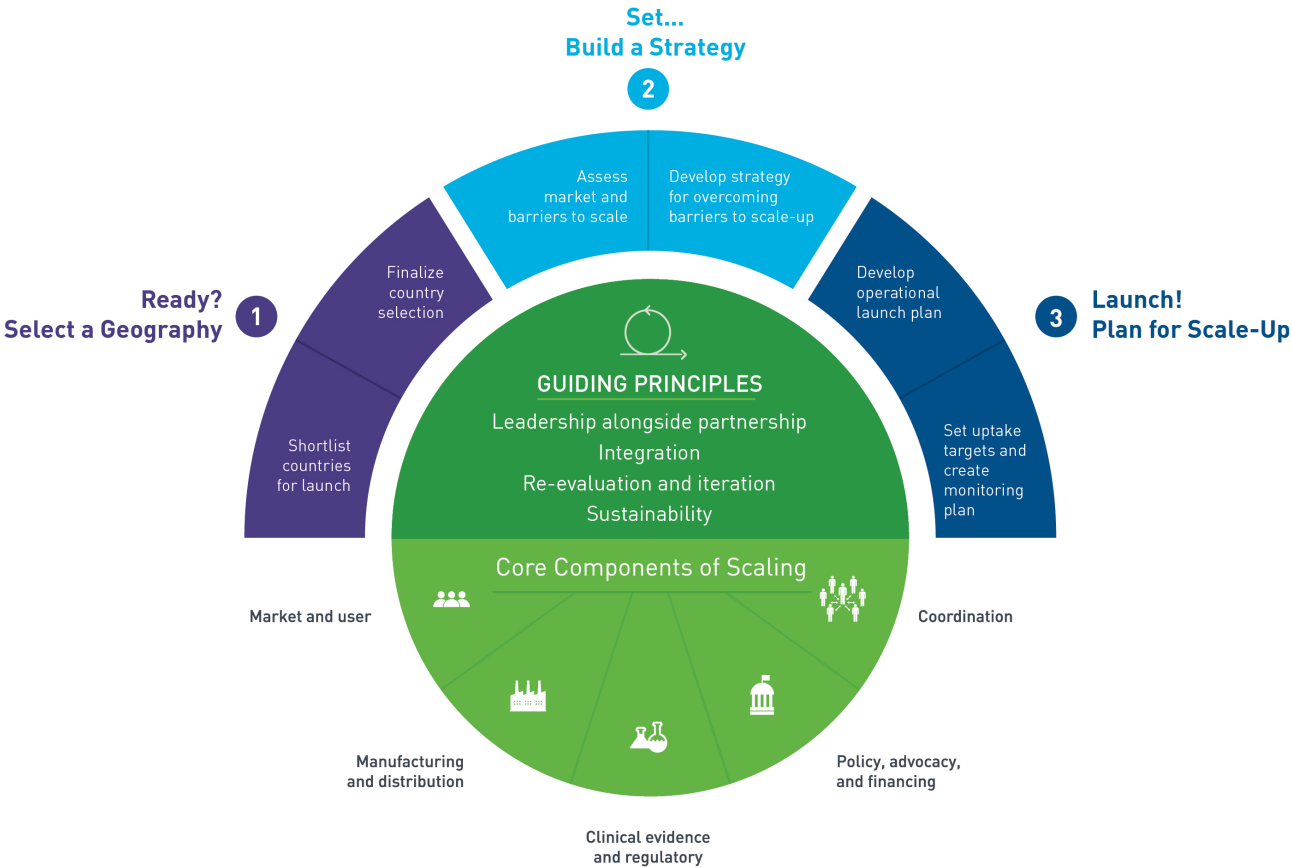
assesses the chosen market in depth in an effort to identify barriers to scale and address those barriers with thoughtfully designed interventions.

Step 3 - Launch! Plan for Scale-Up

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

² To download *Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations* and its supplemental toolkit, please visit <https://www.usaid.gov/cii/guide-introduction-and-scale>.

Figure 2: Ready, Set, Launch Three-Step Framework



Source: Ready, Set, Launch: A Country-Level Launch Planning Guide for Global Health Innovation



Photo: Karen Kasmauski / USAID
E U 2013

Before introducing and scaling an innovation, global health practitioners should have demonstrated cost-effectiveness of the product or service, validated clinical efficacy, and developed a global situation assessment as per guidance outlined in Stages 1 and 2 of *Idea to Impact*³ — for example defining the product’s global vision and value proposition, ensuring that the product meets WHO and other global guidelines and standards, etc. However, planning for country-level launch can — and should — occur in parallel of the first two stages of *Idea to Impact*. For example, the inhaled oxytocin product development team was in the process of conducting clinical trials for the product when they sought and received funding from the Saving Lives at Birth Grand Challenge to conduct analysis to prioritize countries for introduction.

While all steps of the *Ready, Set, Launch* framework are critical, this case study focuses on **Step 1 — Select a Geography**. Statistics abound on the importance of getting launches right from the beginning, which includes country selection. For example, in its white paper, *Launch Excellence IV: A New Launch Environment*, *IMS Health* describes a “six-month window” in which successful launches need to take shape. After this six-month window, only a few launches (~20 percent) were able to recover and achieve scale.⁴ Based on the literature and experience, Monash University knew that country selection was critical to its success in launching inhaled oxytocin.

³ Stages 1 and 2 of *Idea to Impact* are (i) identifying needs and design and (ii) beginning research and development.

⁴ *IMS Health*

THE APPROACH: COUNTRY PRIORITIZATION FOR INHALED OXYTOCIN

Selecting the appropriate geography is a critical first step towards country-level launch planning for a product or service. Building on Step 1 of the *Ready, Set, Launch* framework, the Monash team prioritized the countries best suited for introduction of inhaled oxytocin through two steps: (i) shortlisting countries for launch and (ii) finalizing country selection through in-depth quantitative and qualitative analyses.

Before beginning the prioritization process, Monash University developed a starting list of countries based on two key criteria: (i) burden of disease, measured by maternal mortality ratio and number of deaths due to PPH, and (ii) opportunities for implementation support or partnership, for example USAID focus countries or Global Financing Facility front runner countries. By considering these criteria, the team generated a list comprised of 41 countries, which served as a starting point that could be further narrowed down in Sub-Step 1.



Photo: Karen Kasmausk USAID

Sub-Step 1.1: Shortlist countries for launch

The purpose of this sub-step is to develop a shortlist of countries that could serve as 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 for future launches or if country selection needs to be reconsidered. This step relies on rapid analysis to eliminate countries that do not meet specific inclusion criteria, such as **market size** or **feasibility** of entry.



Overview: The aim of this step is to narrow what could potentially be a long list of countries to a subset which are most likely to be well suited for first launch. **Begin the process with a clear understanding of the basis on which you are shortlisting** — define the selection criteria, or characteristics, you are looking for in your first launch countries. Next, establish indicators to evaluate countries across these criteria in a rapid and pragmatic way to eliminate those that would not be suitable for initial launch.

The Monash team began by considering the key criteria or attributes that they were looking for in initial launch countries. This was highly linked to what the project team was seeking to achieve with first launches, which was to generate evidence of the impact of the product thereby inspiring uptake in other locations. With this aim in mind, the team developed a set of six criteria or characteristics that were desirable in initial launch countries (Box 1). The Monash team then evaluated the 41 countries under consideration based on these criteria, adapting the “Country Prioritization Matrix Tool” available in *Ready, Set, Launch* to visually compare countries across six selection criteria: **need, feasibility, market size, lead propensity, contexts, and synergies**.



Box 1: Criteria used for prioritization of early launch countries

SELECTION CRITERIA



NEED

Countries should have a high need for inhaled oxytocin in order for the product to demonstrate an improvement in health outcomes. Need is represented by current barriers to quality care that can be addressed by the product.



LEAD PROPENSITY

Countries which have a demonstrated capacity to serve as 'trail-blazers' or influencers of practice and policy in other countries are sought such that the evidence from early launch could be used to catalyze adoption in other locations.



FEASIBILITY

The ability of the product to reach end-users and deliver intended benefits will depend on a relatively well functioning health system. In other words, it must be feasible for the product to be introduced and incorporated into the local health system.



CONTEXTS

Countries with opportunities for product use in unique settings (community settings) or sectors (private) should be included in the shortlist such that evidence of product use in a variety of settings can be demonstrated.



MARKET SIZE

Reaching a significant number of women will be critical in order to demonstrate considerable impact and drive annual demand numbers sufficiently to enable sustainable manufacture at an affordable cost of goods.



SYNERGIES

Opportunities for effective information sharing will identify countries which provide greatest access to these channels and recognise countries which may serve as 'fast-followers' to first launch countries.

Market size helps practitioners understand the addressable market that they could realistically expect to capture for their product. Indicators that help practitioners assess addressable market size include ability to pay or willingness to pay (e.g., health expenditure per capita of a specific market segment), accessible channels of distribution (e.g., where can the product be sold), levels of care-seeking, and who is willing to procure.

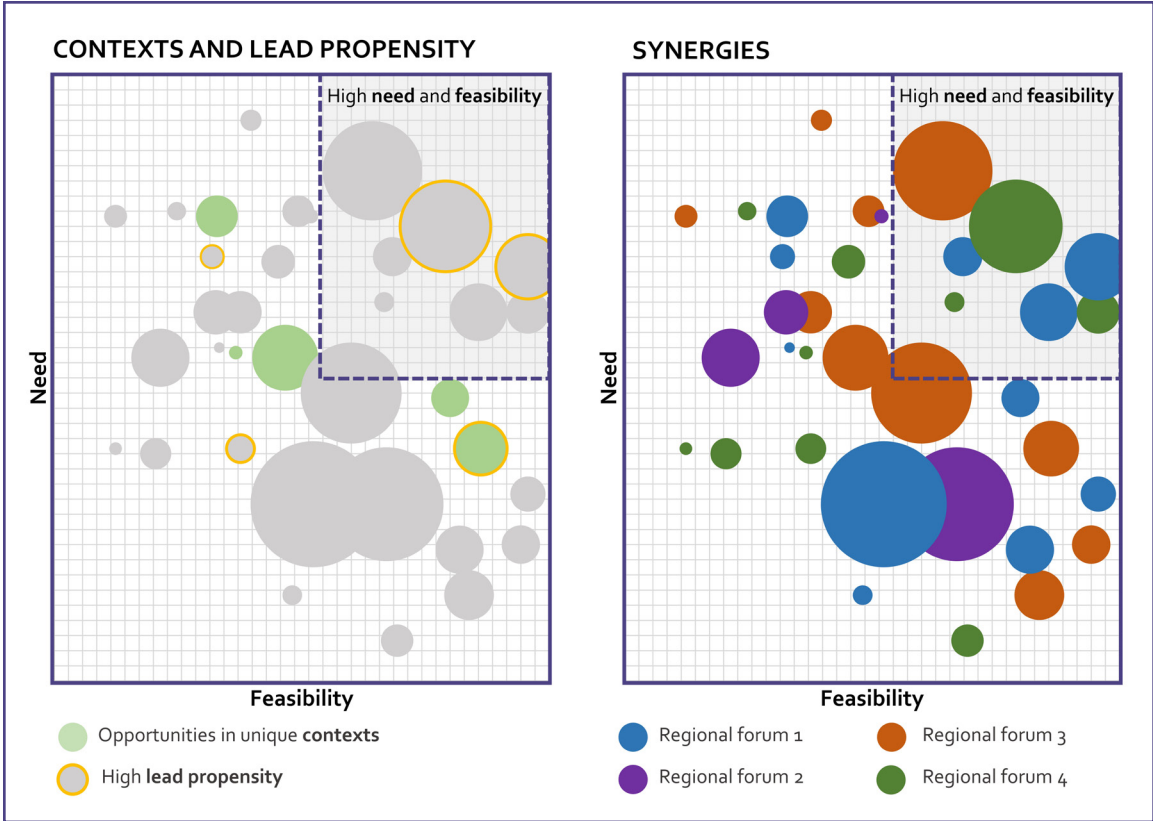
One of the biggest mistakes with country selection is overestimating potential demand — demand is not need, and total market size does not equal demand.



To evaluate of countries, the Monash team developed an analytical tool in which selection criteria were broken down into a set of indicators that, collectively, represent each criterion. For example, the **feasibility** selection criterion was composed of indicators such as “political will”, “regulatory efficiency”, and “supply chain reliability”. A scoring system was applied to the indicators, where scores would ultimately be aggregated to give each country an overall score for each selection criterion. See Annex 2 for more detail on how indicators can be defined, weighted, and scored to give a quantitative assessment of how well a country meets a selection criterion of interest.

The outputs of the analytical tool allows for countries to be plotted in the Country Prioritization Matrix Tool as shown in Figure 3. In both matrices, countries are plotted on according to their scores for **need** (vertical axis) and **feasibility** (horizontal axis), where the size of each ball represents a country’s **market size**. The matrix on the left-hand side shows the results of the assessment of the **context** and **lead propensity** selection criteria. Countries deemed to have opportunities for product use in unique contexts, such as community-based settings, are colored in green. Countries considered to act as trail-blazers (**lead propensity**) are given a gold outline. The matrix on the right shows the results of the assessment of the **synergies** selection criterion, where countries have been color coded according to the major health-focused regional forums.

Figure 3: Country Prioritization Matrix arising from Sub-Step 1



Visualizing countries in this way facilitates shortlisting of potential launch locations. Those countries classified as both high **need** and high **feasibility**, or those depicted in the top right quadrant of the matrix, were first to be shortlisted.







Other countries were added to the shortlist based on the other selection criteria in Box 1. This led to the inclusion of some countries that lay outside of the high need and high feasibility quadrant, but may still be promising launch sites due to favorable scores on other selection criteria, such as lead propensity or market size.

After filtering the countries by these criteria, the Monash team had a shortlist comprised of 14 countries as potential options for initial launch (see Table 1).



Audience Tip: A more rapid approach is to first eliminate any country that does not meet a priority selection criteria, such as product applicability within the country context, market size, or donor priorities (if applicable). The countries that pass through this first filter can then be compared against one another using a wider range of criteria that are most relevant to the product and most important to the practitioner. In most cases, two common criteria are market size and feasibility of entry. Publicly available quantitative data can be used to assess each country's performance against these key criteria. While this approach facilitates rapid shortlisting, there is a risk that promising launch sites are missed if a single selection criteria is used to deprioritize countries. For example, 'trail-blazer' countries that are small but have a high propensity to stimulate product uptake across several territories may be missed if market size alone is used as a first filter for shortlisting.

Table 1: Summary of countries that were shortlisted at Sub-Step 1

| |   NEED AND FEASIBILITY |  CONTEXTS |  LEAD PROPENSITY |  MARKET SIZE |  SYNERGIES | | | | |
|------------|---|---|--|--|--|------|-------|-------|------|
| | | | | | WAHO | ECSA | SAARC | ASEAN | PAHO |
| DRC | ✓ | | | H | | | | | |
| Bangladesh | | ✓ | | H | | | ✓ | | |
| Ethiopia | ✓ | ✓ | ✓ | M | | | | | |
| Ghana | ✓ | ✓ | ✓ | M | ✓ | | | | |
| Guatemala | | | ✓ | L | | | | | ✓ |
| Kenya | ✓ | ✓ | ✓ | M | | ✓ | | | |
| Malawi | ✓ | | ✓ | M | | ✓ | | | |
| Myanmar | | ✓ | | M | | | | ✓ | |
| Nepal | | ✓ | | L | | | ✓ | | |
| Rwanda | ✓ | | ✓ | L | | | | | |
| Senegal | ✓ | ✓ | | L | ✓ | | | | |
| Tanzania | ✓ | | ✓ | M | | ✓ | | | |
| Uganda | ✓ | | ✓ | M | | ✓ | | | |
| Zambia | | | ✓ | M | | ✓ | | | |

WAHO: The West African Health Organization

ECSA: The East, Central and Southern African Health Community

SAARC: South Asian Association for Regional Cooperation

PAHO: Pan American Health Organization



Lessons Learned:

In this step, analysis of countries must be very pragmatic — a large number of countries must be evaluated for criteria that are not easy to define. For example, how can you rapidly evaluate the feasibility of introducing your product into a country when this process is dependent on a multitude of interlinked processes with potential barriers that are not easy to anticipate? Thus, it is important to find one or two of the most important indicators you are trying to evaluate and ensure there are data readily available, particularly because data quality issues are a routine challenge in LMICs.

It can be useful at this stage to cast a wide net when shortlisting and include countries even if they do not score well across all selection criteria. For example, Monash shortlisted countries evaluated as having a high **lead propensity**, even though they did not score well on the **need** or **feasibility** selection criteria. The countries shortlisted at this stage are subjected to a more in-depth assessment in the next sub-step, which will give a clearer picture of their characteristics and how well suited they really are for initial launch.



Sub-Step 1.2: Finalize country selection

The purpose of this sub-step is to determine the intersection of where the product will have the greatest impact, the highest likelihood of success, and serve as a catalyst and inspiration for future country launches. It involves critically evaluating the countries shortlisted in Sub-Step 1.1 to finalize your selection of initial launch countries.



Overview: This step will require you to analyze a range of countries already shortlisted as having potential and identify those that are best suited for first launch. **Thus, you will need to determine additional indicators that will help you evaluate suitability in a more detailed and nuanced way than the first sub-step.** While the specific indicators used to evaluate countries will depend on the product and implementation goals, the overall finalization selection criteria should fit with the objective of the first wave launch.

Exercise 1 of 2

In this sub-step, the Monash team expanded the depth and breadth of the analytical tool developed in Sub-Step 1.1 by including a greater number of more nuanced indicators for each selection criterion in order to evaluate the shortlisted countries in more detail. Once countries were evaluated and scored, the 14 countries shortlisted in Sub-Step 1.1 were again plotted on the Country Prioritization Matrix Tool as shown in Figure 4.

First launch countries can be selected by focusing on the top right quadrant of this matrix (representing countries with highest **need** and **feasibility** of introduction) and identifying those that address the other selection criteria. For example, Bangladesh might be selected because it has a large **market size** and offers the opportunity for the product to be used in a unique **context** of interest (community-based settings). Kenya might be selected because it has a high **lead propensity** and offers the opportunity for the product to be introduced into the private sector (another **context** of interest). The **synergies** selection criteria could lead to the shortlisting of Ghana, which offers the opportunity for evidence and learnings of

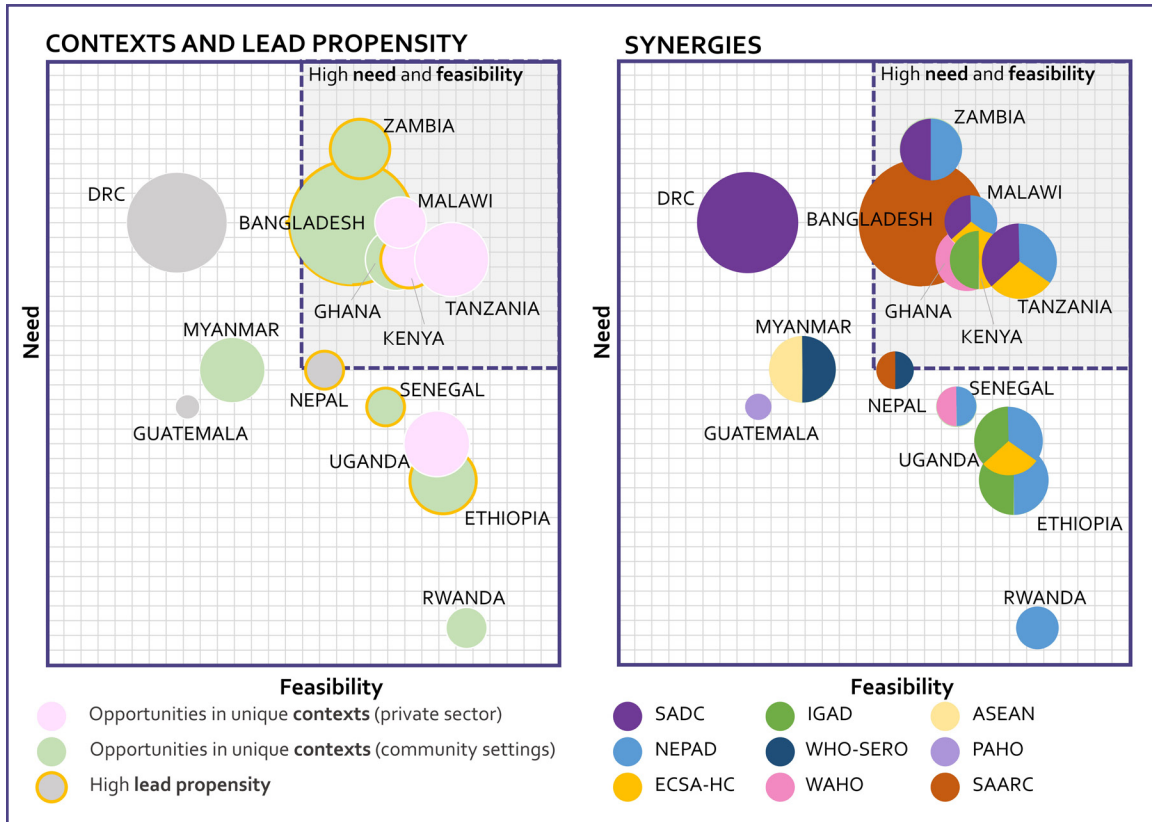
product uptake to be shared amongst the West African Health Organization.

As previously described, the process of shortlisting is not an exact science, and there is no one way to use the information from your evaluation to finalize the prioritized list. However, the depth of analysis not only enables an informed selection of the most ideal first

launch countries but also generates a package of information on a range of other potential candidates. See Annex 3 for an example of how information can be summarized into a Country Profile, serving as a quick reference card that can be drawn upon to either identify potential second wave launch countries or reassess first launch countries.



Figure 4: Country Prioritization Matrix arising from Sub-Step 1.2



ASEAN: Association of Southeast Asian Nations; ECSA-HC: The East, Central and Southern African Health Community; IGAD: InterGov Agency for Development; NEPAD: New Partnership for African Development; PAHO: Pan American Health Organization; SAARC: South Asian Association for Regional Cooperation; SADC: The Southern African Development Community; WAHO: The West African Health Organization; WHO SEARO: World Health Organization, South-East Asia Regional Office.



Audience Tip: A less thorough process to narrow the list to finalist countries is acceptable too! Instead of evaluating all countries for all selection criteria, innovators and organizations may want to tackle this process one country at a time. For example select one or two countries and evaluate whether it meets what is deemed as 'acceptable' for the desired selection criteria. Only move to evaluating another country if the first one or two is found to be 'unsuitable'. This process can also be adapted to allow for a small number of country candidates to be compared across prioritized selection criteria.





Lessons Learned:

The process of defining indicators for each of the selection criteria of interest is iterative. It is important to **draft the indicators and then take some time away**. Return with a fresh mind to critique and refine the indicators. Workshop what you've done with colleagues, especially those from different sectors or backgrounds. Fresh perspectives help the team think critically and differently about how to evaluate different features.





The number of indicators you include in your tool will be a balancing act. Too few indicators will lack depth of analysis and lead to an incomplete understanding of the countries under consideration and how well they meet your selection criteria. However too many indicators is overly complex, time demanding, and dilutes the impact of all markers. **Critically consider the time and resources you have available to direct to this activity and make a judgment call as to how detailed you will make your analysis.**



MAKING GO/NO-GO DECISIONS

Exercise 2 of 2

Ready, Set, Launch's, Exercise 2 of Sub-Step 1.2, or the Go/No-Go Checklist Tool, guides global health practitioners on making a final decision on whether or not to go ahead with the country selection, or to reconsider country selection based on the presence of no-go signals. Once the Monash team has determined the top one or more launch countries, this go/no-go exercise allows 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 across the core components of scale-up. During this process, global health practitioners such as the team at Monash, can continue to conduct research through literature review, analytics, and stakeholder interviews to evaluate those countries that rose to the top in the prior steps.

| 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, <i>signal to reconsider</i> |
| | 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, <i>signal to reconsider</i> |
|  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), <i>signal to reconsider</i> |
| | 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, <i>strong signal to reconsider</i> |
|  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, <i>signal to reconsider</i> |
|  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, <i>strong signal to reconsider</i> |

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.



Audience Tip: Consider using or adapting the “Go/No-Go Checklist Tool” to the chosen country or set of countries. Go/no-go signals should be evaluated even when entering Steps 2 and 3 of Ready, Set, Launch (which are not the focus of this case study).

As more time is spent gathering data and meeting stakeholders within a country, practitioners will learn additional facts and criteria that could impact country selection. During this process, country selection can be reassessed— in order to limit the potential of spending resources on a misguided decision. 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.



CONCLUSION

Prioritizing countries for introduction and scale is critical to accelerate time to market and increase potential for impact and sustainability of an innovation. Not all innovation ecosystems are the same, and it is important to understand the headwinds and tailwinds that will enable an innovation to be taken up into the system and championed by local voices.

The first launch of a product will generate evidence and provide a model for adoption in other contexts. To that end, it is important to apply a data-driven and strategic approach to identify locations that can give the greatest chance of success.

Prior to starting this process, the innovator should have a clear understanding of their

vision of success — what does scale look like and how can initial launch countries be selected to facilitate a more efficient pathway to get there? This will be the foundation underlying how first launch countries should be strategically selected. From that point, selection can be driven by an understanding of the situation on the ground that is as accurate and reliable as possible. Research literature and consult with a range of stakeholders who can share relevant insights to enable identification of locations that have the characteristics required to support the initial launch strategy. Finally, it is important to note that this process is iterative and should be continually revisited as the innovation is further developed and validated.



Photo: Morgana Wingard / USAID

ANNEX 1 — Resources

Resources to support decisions about selection criteria and indicators that will be used to prioritize countries

Yamey, G., Scaling up global health interventions: a proposed framework for success. PLoS Med, 2011. 8(6): p. e1001049.

Smith, J.M., et al., Scaling up high-impact interventions: how is it done? Int J Gynaecol Obstet, 2015. 130 Suppl 2: p. S4-10.

Brooks, A., et al., Implementing new health interventions in developing countries: why do we lose a decade or more? BMC Public Health, 2012. 12: p. 683.

Barker, P.M., A. Reid, and M.W. Schall, A framework for scaling up health interventions: lessons from large-scale improvement initiatives in Africa. Implement Sci, 2016. 11: p. 12.

World Health Organization, Beginning with the end in mind: planning pilot projects and other programmatic research for successful scaling up. 2011, WHO: Geneva.

World Health Organization and ExpandNet, Nine steps for developing a scaling-up strategy. 2010, WHO: Geneva.

Frost, L.J. and M.R. Reich, ACCESS: How do good health technologies get to poor people in poor countries? Harvard Series on Population and International Health. 2008, Cambridge, Massachusetts: Harvard Center for Population and Development Studies.

Ranson MK, Hanson K, Oliveira-Cruz V, Mills A. Constraints to expanding access to health interventions: an empirical analysis and country typology. Journal of International Development. 2003;15:15-39.

USAID Center for Accelerating Innovation and Impact, Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations. 2015: Washington DC, USA.

USAID Center for Accelerating Innovation and Impact, Ready, Set, Launch: A Country-Level Launch Planning Guide for Global Health Innovation. Washington DC, USA.

Sources of country-specific information to evaluate countries against selection criteria

- WHO global health observatory (GHO) database (<https://www.who.int/gho/en/>)
- UNStats (<https://unstats.un.org/home/>)
- World Health Report (<https://www.who.int/whr/en/>)
- Demographic and health surveys (DHS)
(<https://dhsprogram.com/Publications/Publications-by-Country.cfm>; <https://www.statcompiler.com/en/>)
- Health information system (HIS) data and reports
- Health facility readiness surveys
- I/NGO program reports
- Ministry of Health websites for strategic plans and annual reports

ANNEX 2 — Monash analytical tool for country prioritization

As an illustrative example of how the analytical tool is used to evaluate countries for selection criteria of interest, the table below gives an outline of individual indicators that were defined by the Monash team for the selection criterion of feasibility.

A country of interest is given a score of 1, 2, or 3 for each indicator based on how favorable the situation is for introduction of the product (1 reflecting the least favorable situation and 3 reflecting the most). For example, for 'supply chain reliability,' a score of 1 might be given if current availability of the oxytocin injection is low or inconsistent at health facilities across the country (indicating that existing supply chains are not functioning well enough to assure consistent supply), whereas if oxytocin is currently consistently and widely available (e.g. available at >90% of facilities) a score of 3 may be given.

In recognition that some indicators are more critical to overall feasibility, a weighting system was applied such that scores from highly weighted indicators contributed more

to the overall feasibility score. For example 'political will' was given a relatively high weighting (20%) because having strong political support impacts all elements of product introduction and thus contributes significantly to the feasibility of introduction. In contrast, the indicator of 'training mechanisms' was weighted comparatively lower (5%) because the simplicity of the inhaled oxytocin device may reduce the requirement for extensive training programs and thus lessen the impact of training mechanisms on overall feasibility of introduction.

Scores for each marker are weighted and then aggregated to give an overall score for the selection criterion of feasibility. A similar system was applied to the other selection criteria and ultimately allowed for countries to be plotted on the Country Prioritization Matrix according to the scores calculated for each selection criterion.

The selection of indicators and their weighting was made on the basis of desk-based research of key barriers and enablers to the introduction of other programs and technologies, particularly

those with similar characteristics or positioning to the inhaled oxytocin product. In addition, feedback was sought from key informants from other research groups and organizations with experience in product introduction.

It should be noted that, while some indicators are universally applicable, others will be specific to a given product or implementation strategy. Innovators wanting to develop a similar analytical tool to support country prioritization should define indicators (and even selection criteria) that reflect their product or program and are relevant to their implementation strategy.

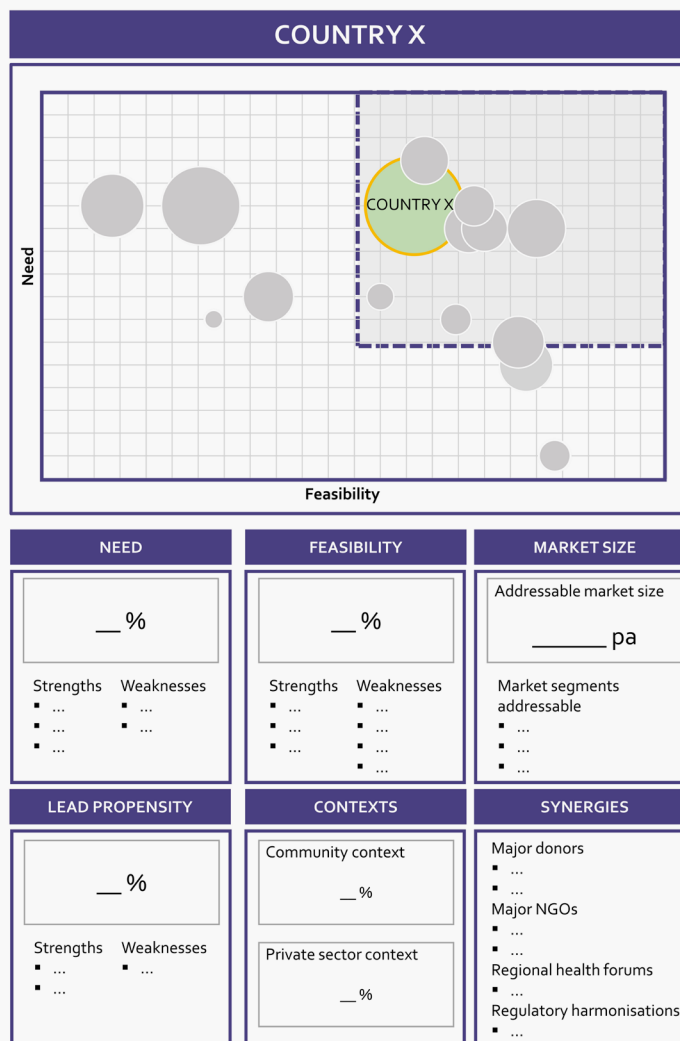
| SELECTION CRITERIA: Feasibility | Indicator | Score | Weight |
|---|--|---------|--------|
| | Partnerships opportunities: Reputable partners to facilitate launch are present in country | 1, 2, 3 | 10% |
| | Political will: Government is stable and motivated to adopt the innovation | 1, 2, 3 | 20% |
| | Uptake/scale efficiency: Policy systems are efficient and effective at implementing novel health technologies | 1, 2, 3 | 20% |
| | Willingness and ability to pay: Funding is available for introduction and ongoing commodity purchase | 1, 2, 3 | 15% |
| | Training mechanisms: Existing structures are in place to effectively train users | 1, 2, 3 | 5% |
| | Regulatory efficiency: Registration timelines are efficient and data requirements are feasible | 1, 2, 3 | 10% |
| | Supply chain reliability: Procurement and distribution chains will enable reliable supply of product | 1, 2, 3 | 10% |
| | Research capacity: Implementation research can be carried out to a high standard | 1, 2, 3 | 5% |
| User receptivity: Providers will be willing to adopt the product and product misuse/abuse is unlikely. | 1, 2, 3 | 5% | |

Overall feasibility score

__%

ANNEX 3 — Illustrative example of Country Profile

The figure shows a blank Country Profile template. Based on the results of research conducted in Sub-Step 1.2, this template can be populated to summarize the strengths and weaknesses of a country with respect to each of the selection criteria. This allows innovators to gain the full value of the extensive research conducted during the shortlisting process by generating an output that is more than a list of initial launch sites and provides information as to why certain countries are prioritized (or deprioritized).







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