



LONGITUDE PRIZE

DEVELOPING A PRODUCT COMMERCIALISATION PLAN

Guidance for Longitude Prize applicants on the development of a product commercialisation plan for their In-Vitro Diagnostics

PURPOSE OF THIS DOCUMENT

All competitors who apply to the Longitude Prize (LP) are required to submit an overview of their product commercialisation plan (CP) as part of their application. This document is intended as a guide to the processes and thinking that should inform that plan. It is not intended to be exhaustive but identifies important issues that should be considered when devising this plan.

As candidate products submitted for the LP will be tested in their design-locked, manufacturable form when submitted, a diagnostics manufacturer with knowledge of ISO13485 and product regulatory requirements will normally already be in place.

In many cases, a manufacturer or commercialising entity will have their own established processes, and these will form the basis of the plan. The submission to the LP should include an overview demonstrating that the major risks and opportunities have been addressed and should include a completed CP risk analysis. The overview should refer to the major areas addressed in this guide, how they will be budgeted, and note risks to commercial success and the mitigation measures put in place to address these.

Since start-ups or small to mid-size enterprises (SME) may not have the capacity to directly market their product the LP strongly encourages collaboration with companies that can help finance and deploy international marketing and distribution.

Regulatory requirements for in-vitro diagnostics (IVD) are not discussed in this document. A collection of frequently asked questions on level of development required for LP submission are given [here](#), with discussion on the new EU regulatory requirements.

TARGET AUDIENCE

Applicants for the LP who may not have experience in the manufacturing and commercialisation of products for global point-of-care markets.

This guidance is intended for product developers planning to apply for the LP, to ensure that issues that impact the ability to reach markets such as the UK, other developed countries and lower and middle income countries (LMIC) countries are considered at an early stage, so that risks and costs can be more efficiently addressed.

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LONGITUDE PRIZE



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PART 1 INTRODUCTION

“The Longitude Prize will reward a competitor that can develop a transformative point-of-care diagnostic test that will conserve antibiotics for future generations and **revolutionise the delivery of global healthcare**. The test must be accurate, rapid, affordable, easy-to-use and **available to anyone, anywhere in the world**. It will identify when antibiotics are needed and, if they are, which ones to use.”, excerpt from the LP Prize Rules.

Product success, in terms of both health impact and financial return, can depend more on good planning and realism in the commercialisation process than on the underlying technology or the public health need. The best product can die in development due to unanticipated costs of trials and regulatory filings, or failure to appreciate the time taken to achieve sufficient market uptake.

As a result, it is important that the basis on which the commercialisation plan (CP) will be formulated should be considered at the proof-of-concept phase within the overall development plan (see example in **Figure 1**) rather than waiting until the development process is well established. Performance criteria, price and physical characteristics critical for commercial viability must be defined within the target product profile (TPP). While a CP is specific to the assay, commercialisation partner and markets, this document covers the major areas common to any diagnostic product aimed at a diverse global marketplace.

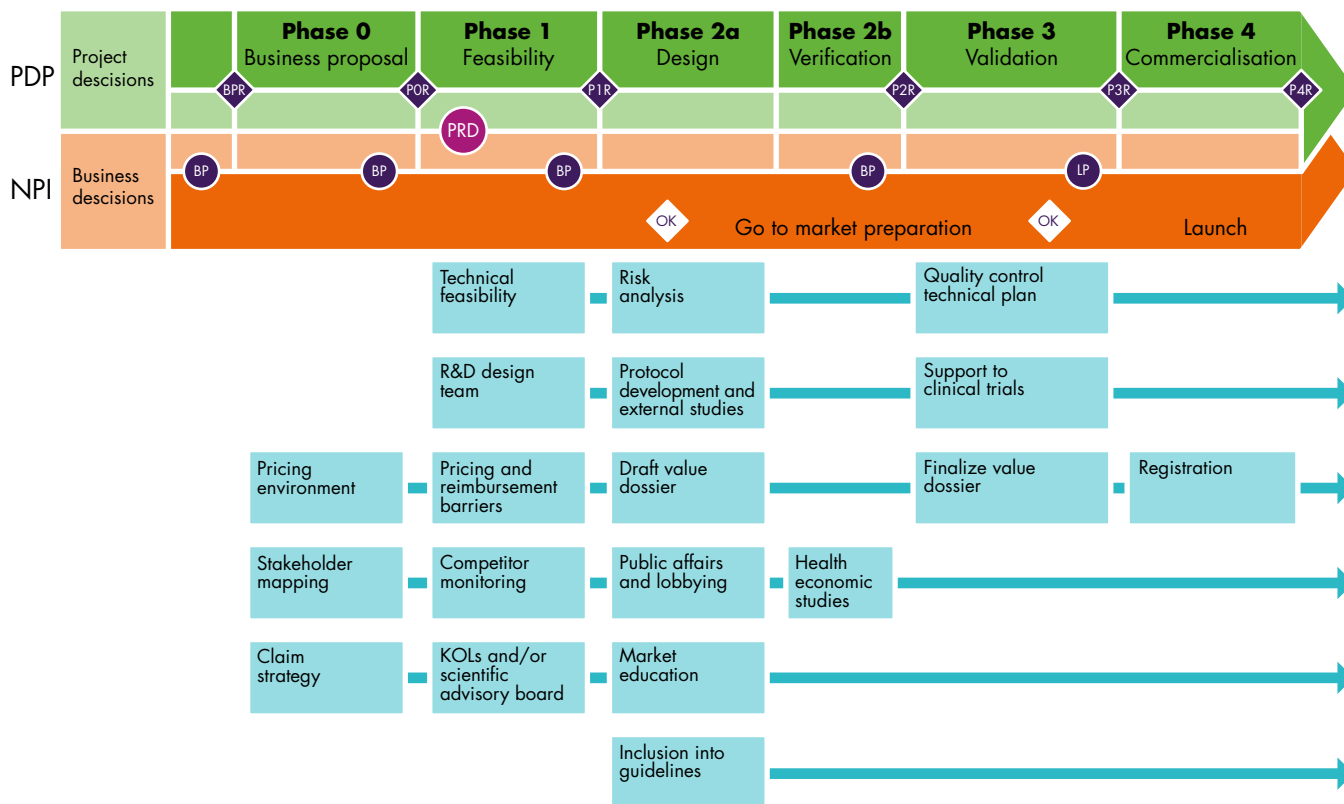


Figure 1: Major areas of work during product development of a diagnostic test that develop the basis for later commercialisation

(van Belkum A. et al. Developmental roadmap for antimicrobial susceptibility testing systems. Nat Rev Microbiol. 2019 Jan; 17(1):51-62). BP (Business Plan), BPR (Business Plan Review), POR (Phase 0 Review), PRD (Product Requirements Document), P1 (Phase 1 Review), P2R (Phase 2 Review), LP, P3R(Phase 3 Review), P4R(Phase 4 Review), PDP (Product Development Plan), NP1 (New Product Introduction)

PART 2

SELECTION OF A MANUFACTURING PARTNER

The costs of manufacturing and user access are critical to product success. Early involvement of manufacturers enables manufacturability to be built into product design and ensures that regulatory requirements are addressed during the development process.

At time of application for the Longitude Prize (LP) product development should be well advanced (design-locked, ready for regulatory submission) and therefore:

- ✓ A manufacturer will have already been engaged, and product hand-off would be well advanced;
- ✓ A UK partner and commercial release plan is in development;
- ✓ A CP covering product release in broader market, including a credible path to global impact, is well advanced.

Ideally, selection of the right partner(s) to manufacture and/or distribute the device should occur early in the product development process, to ensure that:

- ✓ Manufacturability is built early into design (to avoid having to re-design and re-test later);
- ✓ Quality control and documentation processes required for quality manufacturer and for regulatory submissions are in place.

Certain large markets (e.g. India) may prioritize locally manufactured or assembled products. Access from the manufacturing site to other important national markets may be eased by bilateral trade agreements. Such issues should influence manufacturing partner selection.

What type of manufacturing partner?

A manufacturer may produce the product under an original equipment manufacturer (OEM) agreement, providing the device but not be involved in branding and marketing, or may be integrally involved in late-stage trials and regulatory filings and managing product distribution and post-market support.

For a product intended to have global reach (as with LP applications), it may be necessary to engage with manufacture or post-manufacture distributors with specific familiarity and networks in various market segments.

High income country (HIC) market entry often requires very different approaches to those of LMIC public or private sector markets, as product formats may vary (due to differing bearable costs) and market dynamics can differ greatly. The process for selecting a manufacturing partner should consider:

- ✓ Experience with assay type;
- ✓ Distribution experience and network in the target markets;
- ✓ Quality manufacturing practice;
- ✓ Experience with relevant regulatory environments of target markets;
- ✓ Fit of product to manufacturer's internal priorities;
 - No internal competition that will restrict further development
 - Compatibility with company strategy – likely to be sustained
- ✓ Financial stability, ability to take product to market and manage risks;
- ✓ Ability to manufacture within the bearable costs for major target markets.

Characteristics of different markets are discussed later. The CP should detail plans for manufacture, provide evidence that the partner(s) engaged will be appropriate to address the range of target markets, or outline processes that will be undertaken to ensure this.

PART 3

INTELLECTUAL PROPERTY AND COMPETITOR LANDSCAPE

IP applicants should consider IP protection issues. An IP landscape can be undertaken to ensure freedom to operate and to identify potential rights held that may create licensing costs in some markets.

Securing IP throughout the development process is seen by some as a means to protect the investment and secure the market from potential competitors and enable sufficient market scale to be achieved to ensure cost reductions through economies of scale.

The Longitude Prize does not have a policy on how aggressive a developer should be in terms of producing its IP but there is a requirement outlined in the **Prize Rules** that states, *“The Longitude Prize winner will retain all intellectual property rights. However, if the competitor fails to develop and exploit their rights within five years of the award of the Prize, a license will be granted to InnovateUK or Nesta to develop and exploit the intellectual property rights.”*

PART 4

WHO WILL USE THE PRODUCT? – ENGAGING THE MARKET

The 'use-case' for a diagnostic product defines the intended context within which a product will be utilized, encompassing target population and user (provider) characteristics and the clinical situation that would trigger its use.

Understanding this use-case, and the corresponding factors that enable impact, is critical to product design and to the CP. The **Prize Rules** provide detail on the set of use-cases that the LP is designed to address. At a minimum, a candidate device must be targeted for use at point-of-care, address a globally relevant need, and provide information to guide improved targeting of antimicrobials by one or more of the following:

- ✓ Distinguish viral from bacterial infections;
- ✓ Identify pathogens more effectively to guide therapy;
- ✓ Define antimicrobial susceptibility.

This essentially defines the 'Total Addressable Market' (TAM) or population discussed later.

The corollary of the device being available and accessible for a global problem at point-of-care is that it must:

- ✓ Be affordable (in a wide range of markets);
- ✓ Be stable, to enable transport and storage to point-of-care;
- ✓ Require low maintenance (or be single use);
- ✓ Be sufficiently simple to use, with few procedural steps, so that clinicians or paramedical staff with limited specialist training and support can perform and interpret the test.

Matching the product to market

Marketing aims need to be changed over the course of development. Emerging performance and cost characteristics may require revision of the expected final product characteristics, and its ability to address the target use-case. Understanding the fit of the 'locked-down' product performance to the initial use-case and TPP and refining the use-case considering this performance is critical to developing a viable CP.

Such a review must be undertaken systematically when the expected performance data becomes available, with a clear understanding of the implications of any variance from TPP requirements. This review will define the market that can reasonably be expected to be achieved by the product, the time taken to reach commercially viable scale and the impact of various pricing structures on this.

PART 5

MARKET SIZE ESTIMATES

A viable CP depends on understanding the total potential market, the proportion (and/or defined segments) of that market that is appropriate for use of the product given its specific characteristics and fit to TPP and the proportion of these users that can realistically be expected to access the product. This is influenced by the level of competition, of resources allocated to market development, and other controllable or non-controllable variables. This market understanding is frequently defined along the following lines (Figure 2);

- ✓ **Total addressable market (TAM)**, or total available market, is the total market demand for a product or service, calculated in annual revenue or unit sales if 100% of available market is achieved. For the products targeted for the LP, the TAM may depend on variables such as population age structure and geographical variations in prevalence of infection. Seasonality and frequency of outbreaks (of targeted infectious diseases) may make the TAM somewhat time-dependent.
- ✓ **Serviceable available market (SAM)** is the portion of TAM targeted and served by a company's products or services, for which point of care testing is needed, and the product type can reasonably be expected to obtain clearances necessary for access.
- ✓ **Serviceable obtainable market (SOM)**, or share of market, is the percentage of SAM that can realistically be reached. The part of the SAM that is not expected to be taken by competitors, or for which certain other factors (e.g. cultural, geographic, social, financial, programmatic uptake) will prevent potential users from obtaining access. This will be time-dependent – the SOM may increase with improved product knowledge, with changing national regulatory environments, or by addressing cultural barriers etc.

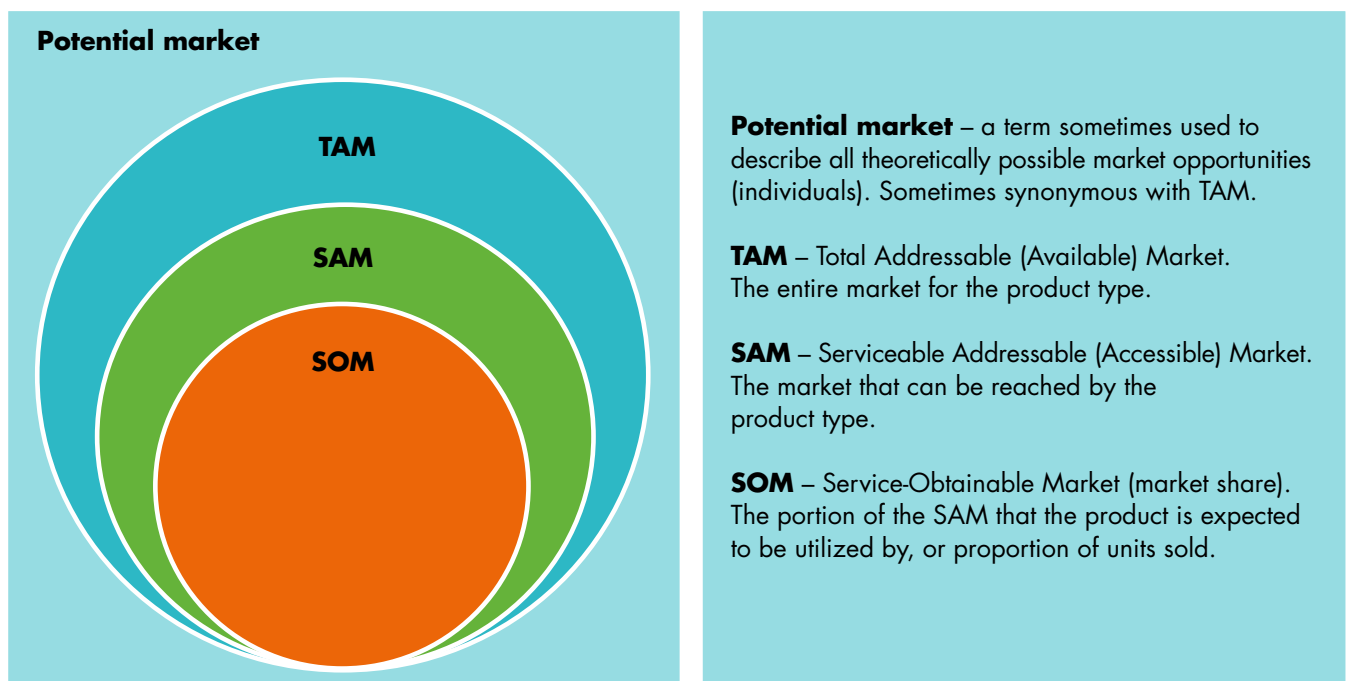


Figure 2. Market definitions for introduction of a new product. Variants of this segmentation approach can be found at a variety of sources

(e.g. REF: https://www.thebusinessplanshop.com/blog/en/entry/tam_sam_som Accessed 14/10/2019)

Much of the effort of commercialisation will be aimed at expanding the SOM. A positive feedback loop is likely to be involved to some extent in which cost-barriers are reduced with economies of scale as the SOM expands. The LP expects a clear, realistic plan to initially reach the SOM, and a credible plan for expanding this market over time to ensure broad, safe access.

Determinants of serviceable available market and serviceable obtainable market

The decision to use a diagnostic test usually depends primarily on a provider (clinician). In certain cases, such as self-testing, the patient may have sole discretion. It is assumed below that a clinician is involved in the process although this is not a requirement of the LP. A market plan for a self-testing kit will require greater detail on the characteristics of the target population in terms of influencers on decision-making.

Understanding the target population

Enumerating the target patient population on whom the test will be used on is important for determining the TAM and SAM. Understanding this population's characteristics in more detail is important to determine the SOM. The population's attitudes to use of a product and their ability to access it contributes to the receptiveness of the market and defines the associated work that will be involved in the commercialisation and marketing process. For example:

- ✓ **The perceived importance of medication to counter sickness. A test that restricts antimicrobial therapy may be unpopular.**
- ✓ **The ability and willingness to pay. This is relevant only if the user is expected to contribute to the cost of a test.**

The decision-making process underlying general health-seeking behavior (may be determined by cultural factors around gender and age).

Understanding the provider (clinician or technician)

Understanding the provider's characteristics, and the context in which the provider works, is critical to development of a CP as it is a major determinant of test uptake, and of long-term reputation of the test. The use of a POC test on a global scale assumes that many users of the test will be working in low-resourced health systems, have limited formal training, and often limited supervision and opportunity to seek immediate assistance (**Figure 3**).

Health system policy and the remoteness of the target population will determine the cadre of provider (e.g. community health worker, nurse-practitioner, doctor) who will be administering a test and making decisions on antimicrobial therapy.

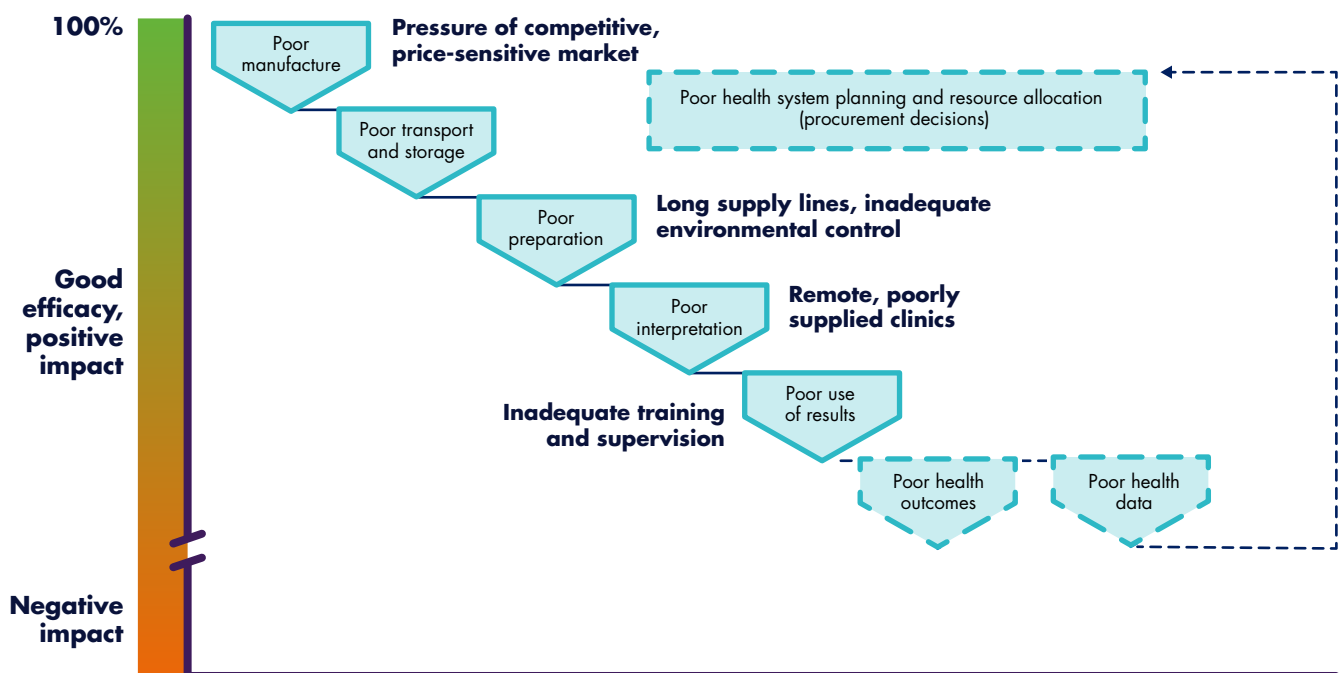


Figure 3. Potential contributors to loss of performance, and product impact, of a diagnostic test aimed for use at point of care

The LP does not expect detailed analyses, or derived plans for market entry, for a large number of countries. This would be unrealistic at time of submission. At a minimum, the applicant should have an outline for market entry into the first launch countries. We envisage that this would usually include their home country, plus the United Kingdom and several other countries.

Commonly, partners will be engaged to develop materials to support product release in a given market, or public health services will have processes in place to develop these, including development of guidance materials for users and the community with appropriate language and level of literacy, plans for action on basis of results, and maintenance plans. The LP will not expect to receive detail of such preparations, but a CP should provide an overview of how such engagement would occur in its first launch markets.

Understanding the clinical context

However well the concept of a diagnostic test is understood and accepted by clients and providers, it is unlikely to be used, and certainly will not achieve impact, if it is not possible to act on the results with appropriate management. From both a commercial and a health-impact perspective, it is essential to understand the availability, and cost, of such alternative management options. Although it is not be feasible in a LP application to detail this information for all markets, it would be helpful to see illustrations of the potential clinical impact of your test in the UK, some other developed country markets and selected LMICs, together with modeling for the total market. Information about clinical utility will be important to share.

PART 6

UNDERSTANDING THE HEALTH SYSTEM CONTEXT

Health systems operate in quite different ways between and within countries. Some systems will be more open to introduction and scaling of new technologies, and clearly support higher costs (Figure 4). The LP expects the CP to initially prioritize markets that will support sustainability of the product, and to demonstrate how the UK market will be included. Expansion to achieve a global reach must be shown to be potentially feasible – the CP may base this on selected country specific information combined with modeling and is not expected to provide detail beyond some initial target countries.

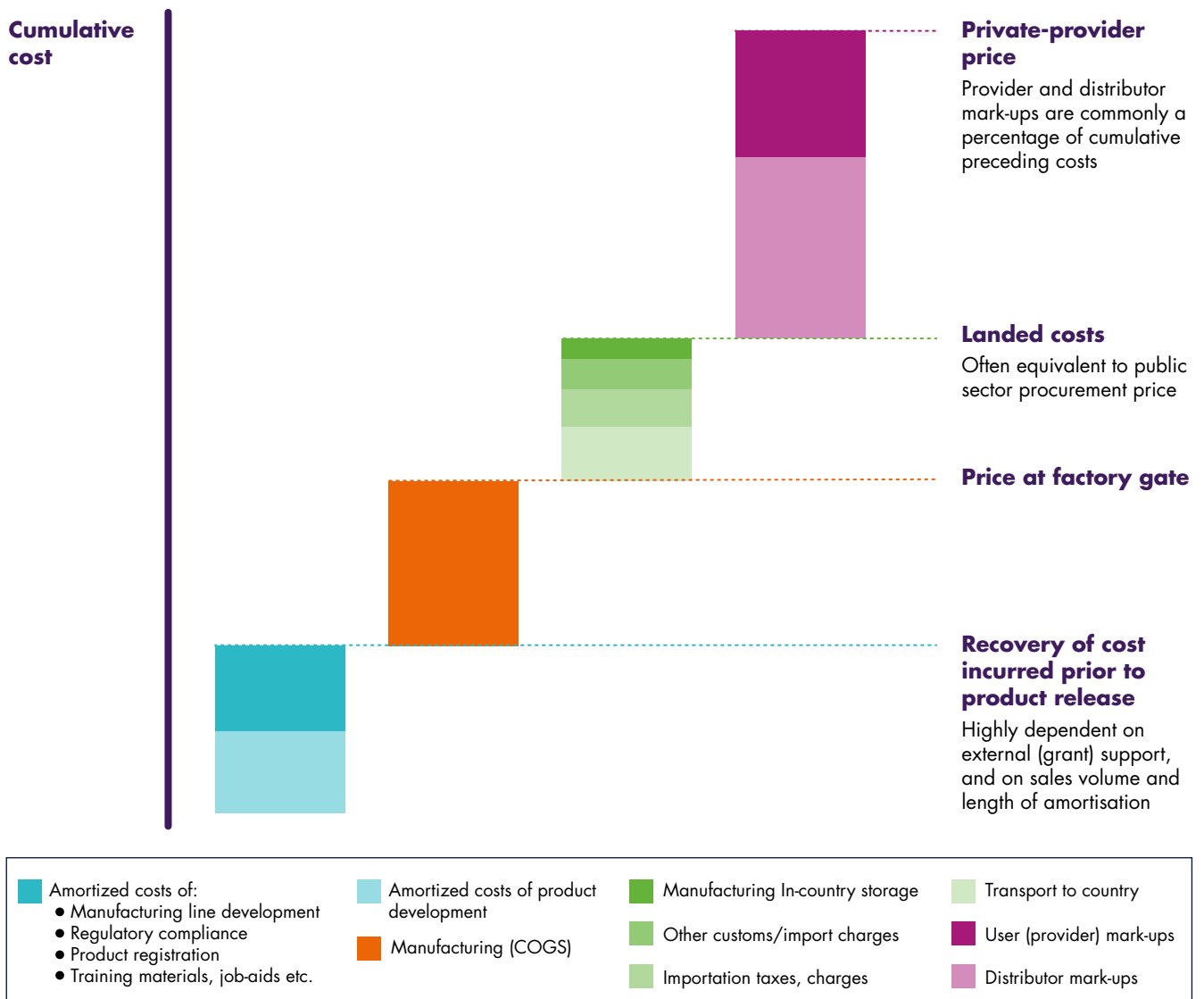


Figure 4. Potential contributors to the retail price of a point of care diagnostic test in the private sector

The potential for integration into existing health practices and systems will lower the bar for entry of a new product. These include compatibility with existing distribution networks and schedules, with existing storage practices, and data handling that is readily compatible with existing (or planned) data management systems.

Importation of health products can be subject to stringent import regulations and taxes. These processes usually need to be navigated by an in-country agent and can add considerably the final cost of the product and can increase required storage times and reduce available shelf-life at point of use. Such requirements must be also be understood as the CP is constructed, to ensure that market projections are realistic.

UK healthcare market

The healthcare market in the UK is dominated by the National Health Service (NHS), comprised of the public health services of England, Wales, Scotland and Northern Ireland; and NHS Improvement, which guides innovation and education within the components of the NHS. The system in England is somewhat decentralized, with local health authorities managing procurement for hospital-based and primary care medicine. The private sector is relatively small, and in order to gain significant impact in the UK formal health sector market, incorporation of new products into use within the NHS is essential.

Overall standards and policy for the health sector are set by the National Institute for Health and Care Excellence ([NICE](#)). NICE develops recommendations on the use of diagnostics and provides guidance on emerging healthcare priorities and on the evidence-base required by them to make decisions on procurement and use recommendations.

NICE diagnostic evaluation recommendations are prepared by an independent advisory committee called the Diagnostics Advisory Committee, drawn from the diagnostics industry, academia, the NHS and patient care organizations. Details on the requirements of the diagnostics assessment programme can be found [here](#). This includes a formal evaluation of evidence matched against identified public health priorities (of which antimicrobial resistance (AMR) is one) and recommendations are then formed regarding implementation within the NHS. This [process](#) should be understood in order to manage activities and timing within the CP prepared for the UK market.

Gathering data through product evaluations in the UK requires partnering with UK-based research institutions – academia, NHS-based and other organizations depending on the area of research. The National Institute of Health Research ([NIHR](#)), Medical Research Council ([MRC](#)), NHS Improvement and various other agencies support or undertake such research through specific timed calls for interest, or through direct application.

Other high-income markets

Healthcare markets in other high-income countries differ greatly in form, but AMR is a significant and rising priority in most. Most European markets follow EU regulatory processes (European Commission In-Vitro Diagnostic Medical Device Regulation - EC IVDR) requiring a CE mark, and have significant public sectors, financed by government-mandated public or private health insurance or within public sector government budgets. Most other developed economies have independent regulatory authorities (e.g. FDA in the United States and the Therapeutic Goods Administration - TGA in Australia), and widely varying models for funding. They may also require recommendations from institutions that provide evidence-based guidance (such as NICE in the UK).

These markets commonly need to be approached individually, and through existing public or private distributor networks. The LP does not expect to see detailed country-specific CP for these markets, but high-level examples of plans for market entry into high-income countries, navigating examples of these differing health systems, will strengthen evidence towards likely expansion to achieve broad impact.

Low and middle-income countries markets

Public sector:

'Public Sector' health delivery usually refers to that provided by a government, whether centrally or through a decentralized system. It may have no direct user fees at time of consultation or is provided at a heavily subsidized cost.

Characteristics necessary to ensure the product is sufficiently robust for use in low-resourced health systems are covered in the [Prize Rules](#).

Examples of countries with dominant public sector health services include Ethiopia, Rwanda and Vietnam. These illustrate strong centralized decision-making, with close consultation with Ministries of Health and/or their operational health programmes being essential for access. Many countries will expect evidence of widely recognized regulatory certification where this is available (e.g. WHO PQ and EC IVDR), and most countries impose their own regulatory processes for diagnostics. These can impact cost and time for market entry, requiring prior planning.

Many LMIC public sector health services are heavily donor dependent for provision of programmes for certain diseases and for broader health systems support.

Private sector:

Private not-for profit – e.g. NGO or faith-based:

This sector often operates analogously to the public health system and may be integrated into it with overlapping procurement and distribution channels. They commonly provide care at no or heavily subsidized cost, and may operate tiered pricing structures.

Private for-profit:

The private for-profit healthcare sector in LMIC ranges from individual primary care practitioners and providers to sophisticated facilities catering for wealthier segments of the population and is highly country specific. The level of regulation and training can vary widely between countries, ranging from formalized sector of medical and nurse practitioners, to an informal sector of providers including informal pharmacies and traditional healers.

PART 7

BRINGING IT ALL TOGETHER – PRIORITIZING COUNTRIES FOR MARKET ENTRY

Understanding the health system and the context in which the product will be used is essential not only for designing a CP for efficient and achievable market entry, but for developing a positive product reputation that will support scale-up.

A reputation for low impact or misleading data is hard to overcome, irrespective of the underlying cause of failure (Figure 3). A credible CP must recognize the complexity of the various market segments and risks and provide a credible approach to deal with these. This requires matching opportunity with cost, and will usually require a tiered approach, concentrating first on countries and market segments where uptake is likely to be:

1. Relatively rapid and with low preparatory costs, and
2. Sufficiently successful and transparent to provide impetus for product uptake elsewhere.

In addition, certain markets prioritize products with local manufacture, or have bilateral agreements that lower barriers to importation from certain countries – also important considerations when choosing a manufacturer.

While the LP is looking for products with potential for global impact, it also recognizes the necessity to establish early commercial viability in markets that provide sufficient margins, while scaling in markets that offer lower return may come later. Examples of aspects that strengthen market attractiveness include:

- ✓ Significant prevalence of the health issue that the test is intended to address.
- ✓ SOM size, and high likelihood of receptiveness of providers and their patients (see sections above).
- ✓ Receptive policy and health system environment – prioritization and support for the health issue the product is addressing.
- ✓ Ease of importation and low duties, or within-country manufacture.
- ✓ Predictable and affordable time and cost required to negotiate regulatory processes. It is frequently more efficient to prioritize large markets /countries where effort and expenditure will open far larger opportunities. Internationally recognized regulatory approvals can facilitate this process.
- ✓ Low and predictable costs and complications in importation and distribution - the ability to use pre-existing distribution and support networks will reduce the costs of introduction.
- ✓ Low costs and strong capacity for product support and monitoring – particularly important in early stages of roll-out.
- ✓ Understanding of the relative strength of public versus private sectors in health delivery. Either sector may prove more suitable for initial prioritization and product demonstration.

While not exhaustive, this list illustrates the type of considerations the LP will be examining in submitted CPs. The LP is not only interested in the technical strengths of a test but also in the companies' ability to successfully market the test to ensure impact.

PART 8

PRICE STRUCTURE AND PLANNING FOR SCALE-UP

The CP submitted with the LP is expected to outline a price structure for the end product based on a realistic balance between a number of somewhat competing factors:

- ✓ **Willingness to pay (of the procurer – an institution or provider/patient – the ‘consumer’)**
This requires the end price to be sufficiently low to achieve the scale of use necessary to achieve health - impact goals – and consistent with requirements regarding equity of access. In the case of LMICs there may be a need to subsidize purchase (with government or international funds).
- ✓ **Sufficient margin to ensure viability (profitability) of the manufacturer**
This is complex, and dependent on both the price paid by the consumer or health network, and any subsidies or buy-downs that are available to lower the price to the consumer and reduce requirements for amortization.

Cost variations through the development pipeline

High costs can be incurred late in the development/market readiness process (Figure 4, Figure 5). These must be anticipated early for budgeting purposes, and to enable mitigation strategies to be developed. A CP must address the lag in recovery of funds through sales and demonstrate that subsequent sales can credibly be expected to cover outstanding prior costs and encumbrances. Regulatory and market preparation costs are discussed elsewhere in this document.

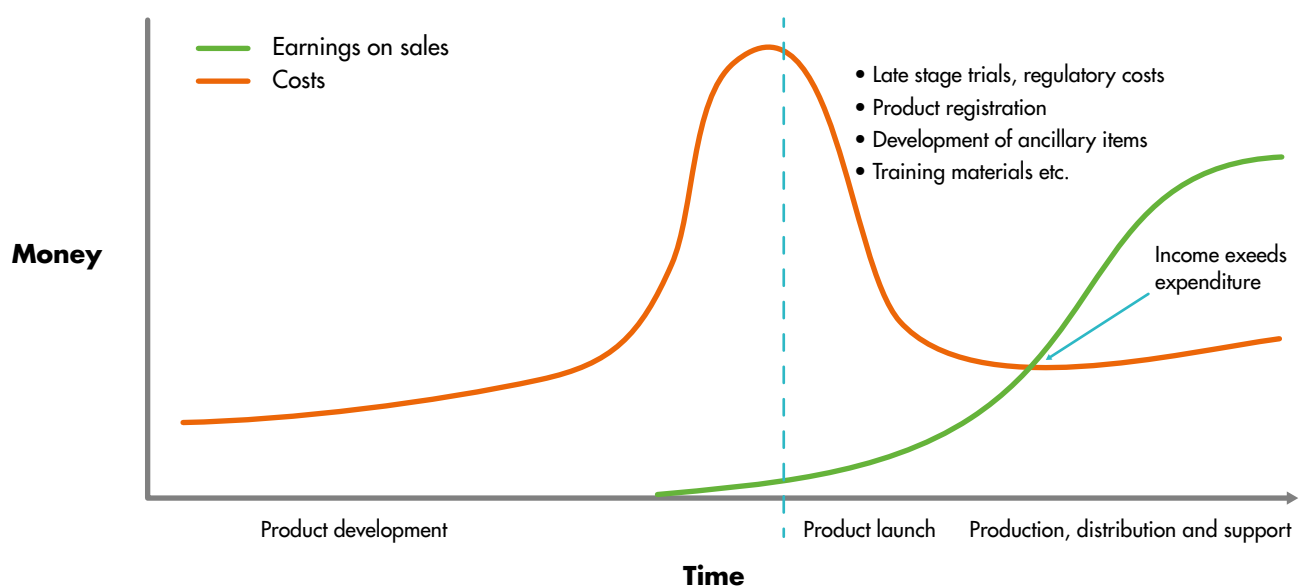


Figure 5. Product costs versus income through the product development process and early launch

Product pricing, and cost of manufacture and delivery

Critical to understanding commercialisation of a product is the concept of fixed and variable costs:

Fixed costs include costs unrelated to volume of manufacture, such as rent on an existing manufacturing plant, costs of core full-time staff, servicing of loans, and costs of obtaining and maintaining registration and distribution channels in target markets etc.

Variable costs change with the volume of product manufactured, including manufacturing costs (base materials, out-sourced components, over-time workforce charges), transport costs of distribution, taxes etc.

Variable costs increase with total production volume, linearly where the cost of producing each unit is constant (ignoring the fixed costs of the site), but more commonly with incremental (per unit) costs reducing as volume of production increases. In the manufacture of diagnostic tests, it is very common to achieve greatly reduced unit costs when production numbers are high, as costs can be saved through automation, through moving production (e.g. off-shore) to where wages are lower, and through supply agreements on of externally sourced components that include lower cost for higher volume. These 'costs of goods sold' (COGS) include the cost of products or raw materials including freight or shipping charges, the cost of storing products at the manufacturing site, the direct labour costs for workers who produce the products, and a proportion of factory overhead expenses.* COGS are commonly expressed in terms of production numbers: e.g. for 100,000, 1,000,000 and 10,000,000 units. These economies of scale can then become very substantial.

Competitors

When the LP was launched in 2014 there were few tests on the market that would compete with products that fit the Prize's eight criteria. This is still the case although any assay will encounter competition on market entry:

- ✓ **Competition from other products aimed at the same clinical picture (irrespective of the usefulness of the information they provide).**
- ✓ **Competition with other public health priorities that must be funded from finite domestic and external health resources.**
- ✓ **Competition with other health priorities of consumers and providers (that may be perceived as more important to the client or provide more income to the provider).**

The CP should include a landscape of competing products, both currently on the market and expected to become available. It should demonstrate the relative advantages of the applicant product, and why it is expected that procurers/consumers will prioritize it.

While a LP test may have no identical competitors, there may be alternative products aimed for use with the same clinical presentation, appropriately or otherwise. Where resources are limited, it is likely that these will compete. These competitors need to be highlighted and a credible strategy to replace or supplement them, demonstrating that this is affordable and safe for the client.

* Note: COGS can sometimes include amortization (of manufacturing line)

Summary - strategies for navigating scale-up

The CP submitted with the LP application should recognize the commercial realities of successful market entry. Pricing and targeting must address the goals of the LP but should demonstrate that this is done in a manner that supports long-term viability and accessibility. It must include a plan for scaling and affordability, while ensuring sufficient financial stability to support this.

Surviving the cost of introduction (Figure 5) is addressed through a number of mechanisms:

- ✓ **Tiered introduction , initially prioritizing high-return markets to obtain sufficient revenue flow. e.g.:**
 - High-resource markets where larger margins can be sustained.
 - Private sector where introduction may be faster and margins can be higher.
 - Large volume markets (i.e. large country public sector) where economies of scale in can be realized.
 - Differential pricing, with higher returns from populations with higher ability to pay (e.g. high-end private sector).

 - ✓ **Obtain grant funding (or equivalent) to buy-down costs of manufacturing scale-up**
 - Donor mechanisms have been used to reduce costs at introduction (e.g. for certain tuberculosis diagnostics). However, similar mechanisms for AMR are yet to be developed.

 - ✓ **Where there is financial capacity, absorb initial costs of broad scale-up on strong evidence of later return due to high assured volume, or external market support.**
-

PART 9

WHO WILL FINANCE?

At time of submission for the LP, applicants will have a design-locked prototype intended for regulatory approval, and so the bulk of product development will have been financed (although any remaining debt to be financed will be factored into the CP).

The CP submitted for the LP will be expected to provide a clear picture of how costs will be addressed across three major categories:

- ✓ **Cost of manufacture & scale-up.**
- ✓ **Market readiness, entry costs and distribution.**
- ✓ **Direct costs in accessing and using the product.**

Where some aspects, such as distribution, will not be the responsibility of the applicant, this should be stated and the alternative mechanisms (e.g. existing health service mechanisms) briefly noted.

ANNEX

DIAGNOSTIC PRODUCT SUPPORT AND MARKETING COSTS ENCOUNTERED IN LOWER AND MIDDLE INCOME COUNTRIES

In certain markets, the manufacturer may need to be involved in assisting the development of ancillary activities necessary to enable use and scaling of the product. In such cases, the commercialisation strategy may prioritize other markets where costs of entry are lower, or the CP may include an overview of costs and timescale to put such activities in place e.g.:

✓ **Logistics (getting tests to users)**

Identifying appropriate supply lines: Appropriate environmental management, replenishment frequency, and security.

✓ **Training, training materials and job-aids (ensuring tests are used correctly)**

Development of (where possible, adaption of existing) evidence-based training materials and job-aids. Testing of training materials and job-aids on a representative set of intended users – including translation and testing for different linguistic groups, can add significant cost. Examples exist that can form a basis for adaption and facilitate this process, e.g.: <https://www.finddx.org/implementation-resources/>

✓ **Educational and marketing materials**

Identification of key messages that will address knowledge gaps or beliefs in the population that could restrict access or interest in appropriate testing. This may require formal studies of health-seeking behavior and beliefs and is a specialist activity normally carried out by research institutions.

✓ **Data management and reporting**

Development of connectivity and compatibility with existing and anticipated data management systems. Easing the burden on the health provider of monitoring and planning may lower the threshold for market entry. Standards and guidance on this area, which is of increasing importance to new product integration, are being developed by WHO, e.g.: <https://apps.who.int/iris/bitstream/handle/10665/260480/WHO-RHR-18.06-eng.pdf?sequence=1>

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