

The Future of Diagnostics

Financing the Continuum from Innovation to Scale

A report from the Executive Roundtable convened by
PATH · Wellcome · Unitaid · MedAccess

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FOREWORD



Diagnostics are central to effective treatment, disease surveillance, antimicrobial stewardship, and health security. They are the basis on which clinical decisions are made, constitute a critical pillar informing health systems resource allocation, and can transform how populations react to emerging threats. Yet diagnostics have been consistently sidelined in global health financing, receiving a fraction of the attention and investment afforded to vaccines and therapeutics.

This imbalance has consequences. Products with demonstrated value stall between development and delivery. Promising markets remain unattractive to investors. Countries transitioning to domestic financing face procurement systems that are neither designed for nor resourced to sustain diagnostic services at scale. The cost of inaction is measured not only in delayed diagnoses and preventable deaths, but in the erosion of the broader infrastructure on which effective health systems depend.

The financing landscape is at an inflection point. Traditional donor funding is under pressure, but new sources of capital are engaging in global health. Development finance institutions are expanding their health portfolios. Innovative financing instruments are demonstrating that diagnostics markets can be shaped. Political frameworks, from the 2023 World Health Assembly diagnostics resolution to the African Union's manufacturing commitments and ten-year strategy, have created openings that did not exist five years ago. The question is whether the diagnostics sector can mobilise the analytical foundation and institutional coordination required to act on them.

On 19 March 2026, PATH, Wellcome, Unitaid, and MedAccess convened senior representatives from over 30 organisations, such as development finance institutions, multilateral development banks, philanthropic and bilateral funders, regional organisations, impact investors, procurement agencies, and technical partners, to examine this question directly. Organisations were invited to provide brief statements in response to a set of theme-based questions. The objective was to highlight the diversity of funding opportunities, improve understanding of existing constraints, and identify gaps in both funding and coordination. This report captures the priority findings and opportunities for action that emerged from that session. It is intended as a resource for participants and the wider financing ecosystem, and as a foundation for the sustained engagement that will follow.

Dr Melanie Saville

On behalf of PATH, Wellcome, Unitaid, and MedAccess

Executive Summary

Diagnostics remain among the most underfunded areas of global health relative to their impact. They receive a fraction (2%–3%) of total investment directed toward research and development (R&D) across diagnostics, vaccines, and therapeutics, despite underpinning every credible strategy for antimicrobial resistance, pandemic preparedness, and equitable access to care. Closing the diagnostic gap for just six tracer conditions could avert over one million premature deaths annually in low- and middle-income countries, with benefit-cost ratios ranging from 1.4:1 to 24:1.¹

The financing landscape is shifting. Traditional donor funding is under pressure. Development finance institutions are expanding their health portfolios. Innovative instruments are demonstrating that diagnostics markets can be shaped. But these developments remain fragmented, and the sector lacks the analytical foundation and institutional architecture to connect them.

This roundtable convened senior representatives from over 30 organisations to examine how financing flows across the diagnostics value chain and where new partnerships could unlock progress. Six findings emerged:

- **The health economic argument of diagnostics can be better articulated**, in context of interventions and positive behaviours they enable. There is opportunity to improve how the value proposition for diagnostics is assessed and communicated.
- **The investment case for diagnostics exists but has not been translated** into the risk-return frameworks used by investment committees, bilateral funding decisions, or ministry of finance budget processes. The health economic value is compelling, but the evidence has not been assembled in a form that moves funding.
- **The evidence base on the true cost of developing and manufacturing diagnostics** for low- and middle-income markets is inadequate, limiting the ability of funders and investors to assess risk accurately. This may translate into insufficient upstream funding and willingness to invest in products designed for low-resource settings, alongside an underestimation of the costs required for scale-up.
- **A persistent gap between grant-funded research and commercially viable products at scale** remains the most consequential point of failure. This reflects a lack of coordination among donors in their investment strategies and a missing, clearly defined pathway to scale from the outset.
- **Financing instruments that address parts of the value chain exist and are working**, but they operate in isolation. The absence of coordinating architecture across them compounds their individual limitations.
- **Development finance institutions and impact investors face specific structural barriers to entry**, including deal sizes, return profiles, and demand uncertainty, that are addressable through targeted intervention.

The discussion identified concrete areas where coordinated action in the next 12 to 24 months could shift the trajectory, including the development of a diagnostics investment thesis for development finance, the assembly of credible cost evidence, and deliberate mechanisms to connect upstream and downstream financing across the value chain. Figure 1 maps these findings to corresponding opportunities for action, illustrating how specific challenges translate into targeted responses and highlighting the foundational role of a clear investment thesis and robust cost evidence across all areas.

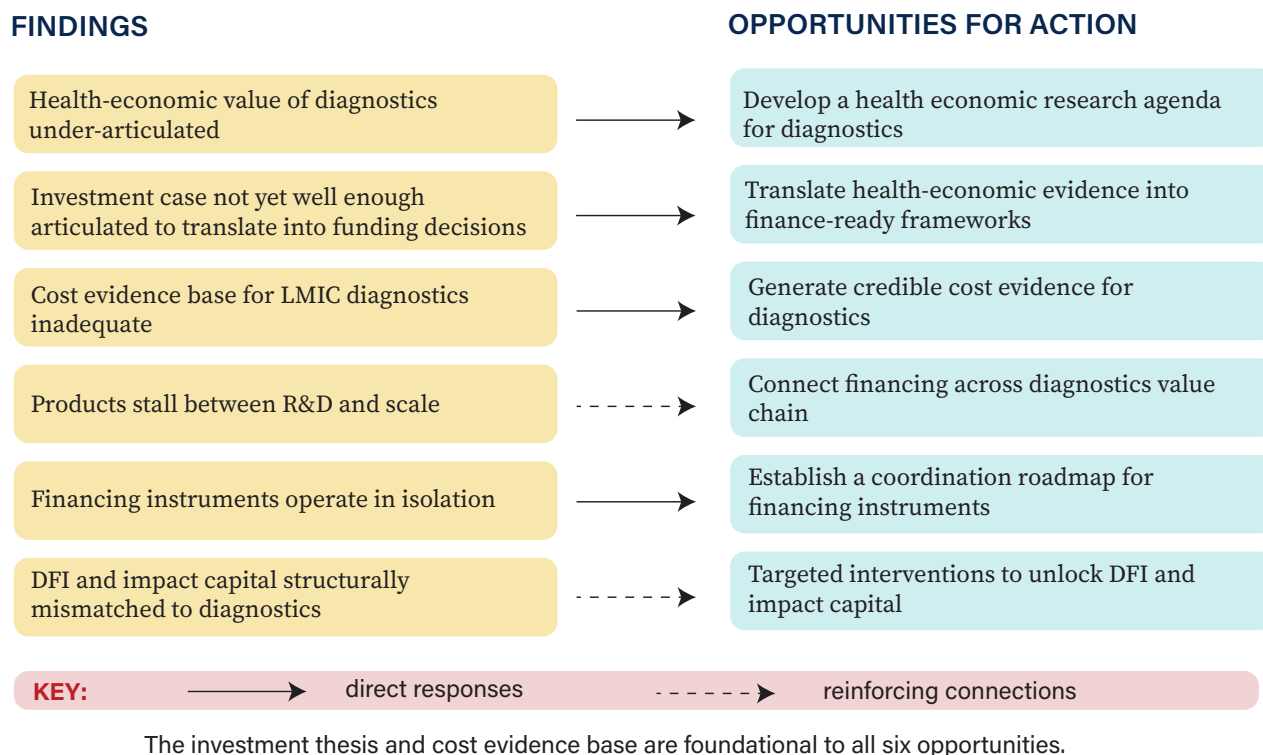


FIGURE 1: Mapping findings to opportunities for action

The Financing Landscape

The global diagnostics sector remains chronically underfunded relative to its value. R&D funding for diagnostics in neglected diseases has declined to 60% of its long-term average, driven in part by the withdrawal of key bilateral funders.² The decline in aid for product procurement poses a significant threat to the entire diagnostics value chain. The sector's reliance on a narrow base of public funders creates acute vulnerability at a time when official development assistance is contracting across major donor countries.³ The financing environment that built the current diagnostics infrastructure is changing on multiple fronts. Major pooled procurement mechanisms are evolving as countries move toward domestic financing under accelerated transition timelines, fragmenting demand that was previously aggregated.⁴ At the same time, development finance

institutions are expanding their health portfolios, innovative instruments such as volume guarantees are demonstrating that diagnostics markets can be shaped, and regional manufacturing commitments in Africa and Asia are generating new demand for investment. The political architecture has also shifted: the World Health Assembly diagnostics resolution, the African Union's manufacturing targets, and the pandemic agreement's provisions for diagnostics each provide frameworks that did not exist five years ago.

The G20 MDB Capital Adequacy Review has identified measures that could unlock up to \$357 billion in additional multilateral lending headroom over the next decade.⁵ Whether the diagnostics sector can position itself within that expanded capacity depends on having the analytical foundation to make the case.

Yet financing across the diagnostics value chain remains structurally disconnected. Grant funders support early-stage research and product development. Downstream actors, including procurement agencies, development banks, and commercial investors, operate on a fundamentally different logic: market viability, return on capital, and demand certainty. Between the two sits a gap where products developed with public funding cannot reliably access the investment and market structures needed to reach populations at scale. Different product categories also face distinct market dynamics: products needed only during outbreaks, lower-margin, high volume endemic products, and dual-market products with both routine and surge demand each require separate financing approaches.⁶ Market signals from procurement systems do not reach developers and investors early enough to shape product design, regulatory strategy, or production planning.

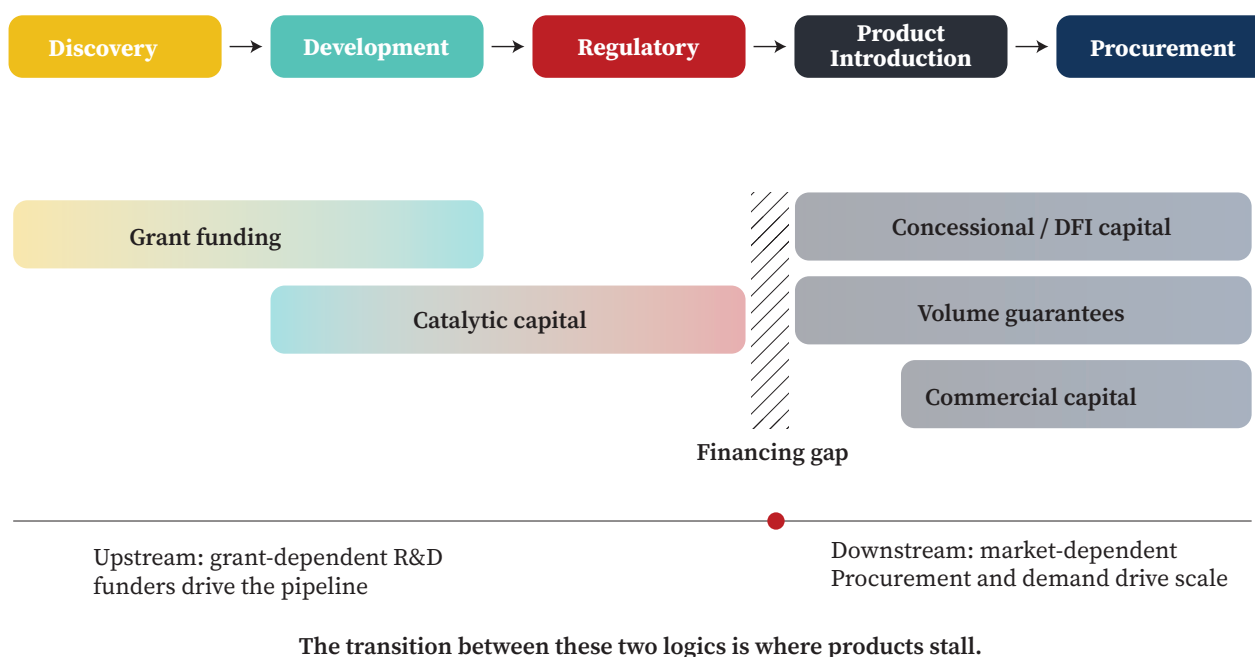


FIGURE 2: Financing instruments across the diagnostics value chain. DFI, development finance institution.

Findings

The investment case exists but has not been made in the language that moves capital

The health economic evidence for diagnostics is compelling. The downstream value, in reduced antimicrobial resistance, avoided hospitalisations, earlier treatment, and more efficient health systems, is substantial and increasingly well documented. But this evidence has not been assembled in a form that would move an investment committee, a bilateral funding decision, or a ministry of finance budget allocation.

Development finance institutions assess opportunities using risk-return frameworks, time horizons, and due diligence processes that the diagnostics community has not yet engaged with systematically. Bilateral donors need evidence they can use to justify continued investment to domestic constituencies in an environment of shrinking overseas development assistance. Ministries of health need to make the case to ministries of finance that diagnostics lower overall system costs, enabling governments to reinvest into the health system to address broader health challenges. In each case, the evidence requirements are specific, and the diagnostics sector has not met them.

Critically, the investment case for diagnostics should not be made in isolation. Diagnostics are only as valuable as the clinical decisions, treatment pathways, and the behaviours they enable. The case is strongest when diagnostics are positioned as an integral component of broader health interventions, including vaccine deployment, antimicrobial stewardship, and pandemic preparedness, rather than as a standalone product category. This reframing also opens the door to co-investment structures that the sector rarely explores.

The cost evidence base is inadequate

The sector lacks fit-for-purpose data on what it truly costs to develop, manufacture, and sustain diagnostics for low- and middle-income markets. Without this evidence, funders cannot accurately assess risk, investors cannot benchmark expected returns, and the sector cannot credibly articulate the scale of investment required.

This gap is particularly acute for regional manufacturers, where production costs, regulatory compliance costs, and working capital requirements are poorly documented and poorly understood by the investment community. It extends to the full cost of end-to-end service delivery: infrastructure, training, quality assurance, maintenance, and the ecosystem of support that turns a diagnostic product into a diagnostic service. These costs are frequently not forecasted when innovation funding is allocated, and they fall outside the scope of most current financing instruments.

Credible, independent evidence on these costs would serve multiple purposes: informing funder strategies, supporting investment cases, enabling more accurate risk assessment, and grounding the broader investment thesis in data rather than assumption.

Validated products are failing to reach patients at scale

The transition from grant-funded development to commercially viable products at scale is often where progress stalls. This reflects a dual pattern of underinvestment.

On the upstream side, products developed for high-income laboratory settings are frequently unsuitable for low- and middle-income country infrastructure. Fit-for-purpose development, designing for the edge of the health system from the outset, demands simultaneous achievement of multiple exacting criteria: ease of use by non-laboratory staff, climate resilience beyond standard industry thresholds, demanding stability profiles, accuracy, and affordability. There is a persistent and incorrect assumption that developing for low-resource settings should require less investment than developing for high-income markets. The opposite may be true, particularly as regulatory environments become more rigorous. Without adequate investment in fit-for-purpose development, countries end up with technologies they cannot sustain.

On the downstream side, products that have been validated and for which demand has been demonstrated still struggle to navigate the financing and market structures needed to reach procurement systems and patients. The market conditions that characterise diagnostics in low- and middle-income settings, including small and fragmented volumes, multiple procurement channels, low willingness to pay, and demand uncertainty, create an environment that deters conventional investors and challenges even catalytic instruments.

Instruments exist but lack coordinating architecture

Volume guarantees, catalytic capital, concessional lending, pooled procurement, and grant-based market shaping have each demonstrated value in specific parts of the value chain. Catalytic funding has been effective at de-risking late-stage innovation where the commercial case is weak but the public health case is strong. Volume guarantees have driven significant price reductions and demand certainty for specific products. Pooled procurement through multilateral mechanisms remains a critical lever for aggregating demand.

But these instruments operate largely independently. Grant capital, concessional finance, and commercial investment do not flow in sequence across the value chain; they pool at either end, leaving the transitions between them unfinanced. The consistent finding from the discussion was that individual instruments are each underperforming relative to need, and the absence of a coordinating architecture across them compounds the shortfall.

What is missing is deliberate connective tissue: structured handoff points between grant funders and concessional lenders, co-investment frameworks that bridge the translational gap, and procurement signals that reach manufacturers and investors early enough to inform production planning and capital allocation. The financing ecosystem has the instruments. Building the architecture to connect them is the central challenge.

Development finance is available but structurally mismatched

Development finance institutions and impact investors expressed clear willingness to engage with the diagnostics sector but identified specific and recurring barriers. Deal sizes for diagnostics companies frequently fall below institutional investment thresholds. Return profiles do not align with conventional frameworks, in part because the value of diagnostics is captured across the health system rather than accruing to a single investable entity. Demand uncertainty, driven by fragmented and unpredictable procurement, undermines the business case for manufacturing investment. And the absence of clear exit pathways means that even investors with appetite for concessional returns struggle to construct viable propositions.

These barriers are real but not immovable. The discussion surfaced several emerging approaches. Profit-sharing structures that link repayment to business performance rather than fixed schedules may be better suited to the cash flow profiles of diagnostics companies, particularly at early growth stages. Long-term patient capital, deployed over five to ten years with milestone-based structures, can bridge the gap between regulatory approval and commercial traction. Pre-investment technical assistance that strengthens

business fundamentals, investment readiness, and financial management directly reduces the due diligence burden and de-risks at the company level.

The discussion also highlighted persistent funding gaps—particularly in regional manufacturing—that require capital expenditure, working capital, and long-term investment beyond the scope of grants alone. While private investors and commercial banks are ultimately needed, the perceived risk often remains too high. Blended finance and risk-sharing approaches, combining grant-funded technical assistance with seed funding, were cited as a practical way to de-risk investments and crowd in private or development finance.

And private sector delivery models, including laboratory chains operating at scale, offer a pathway to cost-effective, high-volume diagnostics that inherently bring sustainability, workforce development, and capacity building.

The broader insight is that diagnostics need to become legible to investors as an asset class. This requires both demand-side interventions, including volume guarantees, advance purchase commitments, and pooled procurement with longer-term contracts, that create revenue visibility, and supply-side support that makes diagnostics companies investable. When the cost of capital is manageable and revenue visibility exists, diagnostics is an investable space. The task is to create the conditions that make this true at the scale the sector needs.

Opportunities for Action

The discussion identified areas where conditions are emerging for meaningful progress in the next 12 to 24 months. These reflect convergence between need, institutional appetite, and political momentum.

A research agenda to develop robust health economic arguments for the value proposition of diagnostics

Health economic assessment of diagnostics is not as robust as for vaccines or therapeutics, undermining the ability to clearly articulate the health benefits and value proposition of diagnostics. There is a need to clearly articulate how diagnostics could warrant a higher priority within constrained health budgets by demonstrating their potential to generate downstream cost savings recognising that cost savings will look differently across the different use cases for diagnostic tools. A research agenda to strengthen this evidence base, including adapting evaluation frameworks to account for the benefits of diagnostics, would enable more confident articulation of the value proposition of diagnostics.

A diagnostics investment thesis for development finance

There is appetite among both health funders and financial institutions for a structured analysis that maps the barriers to private and concessional capital in diagnostics, articulates the return proposition in language that investment committees can act on, and proposes targeted de-risking instruments. This is particularly the case for diagnostics, where procurement is particularly fragmented in comparison to vaccines for example. Crucially, this work should place greater emphasis on defining and

demonstrating an addressable market upfront, linking health needs to viable demand and revenue pathways. This work would need to be developed in partnership with the financial institutions and development banks it is intended to serve.

Credible cost evidence

Independent, rigorous evidence on the true costs of diagnostics development and manufacturing in low- and middle-income settings would address a foundational gap. This could be commissioned as a standalone exercise or integrated into ongoing portfolio analysis by organisations already operating in this space.

Connecting financing across the value chain

The discussion pointed clearly toward the need for mechanisms that deliberately link upstream and downstream financing. This could include structured handoff frameworks between grant funders and concessional lenders, coordinated procurement signals that reach manufacturers early enough to inform investment decisions, co-investment vehicles that bridge the translational gap, and alignment of diagnostic deployment with vaccine and therapeutic introductions for the same disease areas.

A coordination roadmap

A coordination roadmap would serve as the planning and reference tool through which these connected financing approaches are designed, sequenced, and implemented. Multiple participants identified the need for such a joint roadmap that maps the process from technology development to procurement, defines where each category of funder operates, and makes visible the gaps and overlaps. As a shared planning and reference tool, this roadmap would enable alignment across stakeholders and provide a foundation for more deliberate financing design.

Sustained dialogue

This roundtable was the first in a planned series of convenings. There is clear interest in maintaining the conversation through subsequent sessions at key moments across the year, deepening the technical work on specific themes, and building a sustained working relationship among the funders and institutions represented. The aim is to move from shared diagnosis toward coordinated action.

Participating Organisations

The following organisations were represented at the roundtable:

Africa CDC

Asian Development Bank

Asian Infrastructure Investment Bank

ASLM

British International Investment

CARB-X

CEPI

Children's Investment Fund Foundation

DFAT

DG HERA (European Commission)

Fleming Initiative

Gates Foundation

(continued)

GHIT Fund	Novo Nordisk Foundation
GiveWell	Open Capital
Global Health EDCTP3	PATH
Global Health Investment Cooperation	PDP Funders Group
Global Innovation Fund	RIGHT Foundation
IPPS	The Global Fund
LifeArc	Unitaid
Lion's Head Global Partners	Wellcome
MedAccess	WHO
Netherlands Ministry of Foreign Affairs	

NOTES

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3. Munich Security Conference. *Too Big to Fill? Reducing Gaps in Development Finance Post-USAID*. 2025; UK Government ODA spending announcement, March 2025.
4. The Global Fund. *Seventh Replenishment and GC8 Transition Framework Documentation*. The Global Fund; 2022.
5. G20 Independent Review of Multilateral Development Banks' Capital Adequacy Frameworks. 2022; G20 CAF Progress Reports. 2024; World Bank, Heads of Multilateral Development Banks Commit to Strong Joint Action, June 2025.
6. IPPS, Brown University Pandemic Center, FIND. *Advancing the 100 Days Mission for Diagnostics: 2025 Global Gap Assessment*. IPPS, Brown University Pandemic Center, FIND; 2025.

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