ALIGN
CONSORTIUM

Strengthening health innovation introduction

Policy, financing, and advocacy enablers of effective, efficient innovation introduction

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The ALIGN Consortium aims to improve health outcomes by strengthening the critical decision-making systems that determine how health product innovations are prioritized and introduced in countries, to make those systems more effective and efficient. Comprised of the Duke Global Health Innovation Center, the South African Medical Research Council (SAMRC), Keprecon, and ENDA Santé, the ALIGN Consortium supports national governments in Kenya, Senegal, and South Africa to enhance innovation introduction looking at four focus areas: whole-of-government coordination and capacity, data-driven decision making, whole-of-market engagement (including national, regional, and global engagement), and portfolio-based planning. The goal is to create more accountable, resilient health systems that deliver better health outcomes faster for all, and to generate insights, tools, and resources that can be used by stakeholders around the world.

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Learn more about the ALIGN Consortium.

Executive summary

Policy, financing, and advocacy enablers of strong health innovation introduction

Health innovation is advancing rapidly. Yet many promising technologies—demanded by and with the potential to improve wellbeing in low- and middle-income countries (LMICs)—fail to be delivered at scale, fairly, and sustainably to those who need them most. Country-level innovation prioritization and introduction is the inflection point—and too often, the bottleneck—between pipeline progress and real-world impact. High-quality decision-making is needed at this moment.

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Amid worsening fiscal pressures, country leaders face mounting imperatives to optimize decisions about which health innovations to prioritize, how to finance them, and how to prepare systems for safe, sustained rollout and use. Too often, they cannot. Without ready access to trusted, quality, and relevant data or mature systems to guide decision-making, these prioritization decisions are fragmented, duplicative, or poorly aligned with delivery capacity and public demand.

In this paper—and the initiative (**ALIGN Consortium**) it informs—we focus on the policy, financing, and advocacy enablers for effective, efficient innovation prioritization and introduction. These enablers are reinforced by strong functioning of four core, system-enhancing pillars: market data for decision-making, portfolio-based logic, whole-of-government coordination and capacity, and whole-of-market engagement. These determine whether and how innovations are prioritized, adequately resourced, and successfully optimized for health system integration.

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Strengthening these pillars can improve how decisions are made: by whom, with what information and input, and on what timeline. It will require reinforcing system pillars that already exist, then drawing on promising practices across many countries to make innovation introduction decisions more strategic, system-aligned, and accountable. In turn, the decisions can ensure strategic, speedy, and safe introduction processes that serve overall country goals, such as universal health coverage, contributing to thriving health and economic wellbeing.

The challenge: fragmented pillars weaken policy, financing, and advocacy enablers of innovation introduction

Despite robust pipelines, access to innovation remains slow, uneven, and too often shaped by donor and Global North-driven initiatives rather than country-set health policy priorities and population demand. Gaps between introduction timelines in the Global North and Global South are not merely technical. They reflect deeper challenges in how innovations are assessed, prioritized, financed, and introduced.

National systems sit at the front line of innovation decision-making—but many remain fragmented and under-resourced. Rising debt, shrinking multilateralism, and reduced external financing have only intensified the challenge. Even where promising practices exist, countries struggle to manage the growing volume and complexity of innovation opportunities. The result is duplication, delay, and misaligned investments. The ultimate cost is high: lost lives, eroded trust, and delayed progress toward more resilient systems.

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Four interdependent, system-enhancing pillars for strategic innovation introduction

Drawing on published evidence and implementation experience, we have identified four interdependent pillars that individually and jointly may strengthen the policy, financing, and advocacy enablers of strategic innovation introduction decisions:

Whole-of-government coordination and capacity

Mechanisms that align decision-making across ministries, departments, and levels of government, ensuring that approvals, budgeting, procurement, and implementation are sequenced, coordinated, coherent, and well-governed.

Portfolio-based logic

Processes that leverage shared characteristics across innovations (e.g., delivery platform, population served, point in care continuum) to support strategic prioritization and/or efficient implementation planning, improving integration of new and existing products and services.

Market data for decision-making

Systems that integrate timely, trusted, forward-looking supply and demand data, supporting transparent comparative analysis and trade-off assessment.

Whole-of-market engagement

Structured multi-sector engagement, including public sector, civil society, industry, professional associations, private providers, and funders, in shaping prioritization and introduction plans, surfacing constraints, and improving accountability.

When these pillars are weak, introduction falters. When they are reinforced together, countries can make more timely, transparent, and system-aligned decisions, leading to greater effectiveness (fitting innovations to meet population demand, delivery realities, and considerations of quality and fairness) and improved efficiency (reducing delays, duplication, and waste).

The opportunity: Learning from a practical, country-driven approach

Over the next two and a half years, the ALIGN Consortium will work with national and subnational stakeholders in Kenya, Senegal, and South Africa to support governments in tailoring and implementing these system-strengthening pillars, in turn strengthening policy, financing, and advocacy enablers of high-quality innovation prioritization and introduction decisions. This will support more effective, efficient innovation introduction.

This initiative does not measure success by the number of products introduced. Instead, it tracks whether health innovation prioritization and introduction decisions become more deliberate, data-informed, and aligned with system realities, including financing, delivery, and regulatory processes.

We expect to see early shifts in how countries:

- Compare innovations side-by-side using shared criteria and frameworks
- Coordinate budgeting, procurement, and rollout more seamlessly
- Engage actors across sectors earlier and more consistently
- Use improved data for decision-making and real-time learning to adapt introduction strategies

In this paper, we synthesize evidence through a purposive review of published evidence and experience. Our aim is to generate a practical synthesis to inform the first steps in our program design and strategy development.

Why it matters—and why now

The innovation landscape is changing fast but so are the stakes for choosing within that landscape, with implications for population health and economic outcomes, equitable access to high-quality biomedical and care delivery innovations, and public trust in health systems and government decision-making more broadly. Without more effective and efficient country-led systems for innovation introduction, the best-fit tools will arrive late—or not at all—and fail to be sustainably scaled to the front lines. This moment demands urgent action to strengthen the systems that determine what gets introduced, when, how quickly, and how well. Done right, this work offers an accelerated pathway to more accountable, resilient health systems, and to better health and economic outcomes, faster, for the people who stand to benefit most.

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Résumé exécutif

Politiques, financement et plaidoyer: les leviers pour une introduction solide, efficace et efficiente de l'innovation en santé

L'innovation en santé progresse rapidement, mais de nombreuses technologies prometteuses, susceptibles d'améliorer le bien-être dans les pays à revenu faible et intermédiaire (PRFI), ne parviennent pas à être déployées à grande échelle, de manière équitable et durable auprès de ceux qui en ont le plus besoin. Une prise de décision de qualité est aujourd'hui indispensable.

Dans un contexte de resserrement des marges de manœuvre budgétaires, les acteurs nationaux doivent prendre des décisions opportunes et cohérentes quant aux innovations à privilégier, à leur financement et à la préparation des systèmes à leur déploiement. Trop souvent, ils n'y parviennent pas. Sans accès facile à des données fiables et pertinentes ou à des systèmes matures pour guider la prise de décision, les processus de priorisation sont fragmentées, redondantes ou mal adaptées aux capacités de mise en œuvre et à la demande publique.

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Dans ce document, et l'initiative qu'il sous-tend à travers le consortium **ALIGN**, nous nous concentrons sur les leviers politiques, financiers et de plaidoyer pour une priorisation et une introduction efficaces et efficientes de l'innovation . Ces leviers sont renforcés par quatre piliers fondamentaux qui améliorent le système : les données de marché pour la prise de décision, la logique de portefeuille, la coordination et les capacités pangouvernementales, et l'engagement de l'ensemble du marché, qui déterminent si et comment les innovations sont priorisées, dotées de ressources adéquates et optimisées pour l'intégration du système de santé.

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Le renforcement de ces leviers ne nécessite pas la création de nouvelles institutions. Il s'agit d'améliorer les modalités de prise de décision : par qui, avec quelles informations et contributions, et dans quels délais. Il s'agit également de renforcer les fonctions systémiques existantes, en s'inspirant des pratiques prometteuses de nombreux pays, afin de rendre l'introduction de l'innovation plus stratégique, plus cohérente et plus responsable. En retour, des processus d'introduction stratégiques, rapides et sûrs peuvent servir les objectifs généraux du pays, tels que la couverture sanitaire universelle, contribuant ainsi à l'amélioration de la santé et lebien-être des populations.

Le problème: la faiblesse des politiques, du financement et des mécanismes de plaidoyer compromet l'introduction de l'innovation.

Malgré des filières solides, l'accès à l'innovation reste lent, inégal et trop souvent influencé par les initiatives des donateurs et des pays du Nord plutôt que par les priorités nationales en matière de politique de santé et la demande des populations. Une analyse rétrospective portant sur 59 produits de santé mondiaux a révélé que le délai médian entre l'idée et son adoption à 20 % dans les pays à revenu faible ou intermédiaire était de 13,5 ans, soit plus de deux fois plus long que dans les pays à revenu élevé. Ces retards ne sont pas seulement techniques. Ils reflètent des défis plus profonds dans l'évaluation, le financement et le lancement des innovations.

Les systèmes nationaux sont en première ligne des décisions en matière d'innovation, mais nombre d'entre eux restent fragmentés et manquent de ressources. L'augmentation de la dette, le recul du multilatéralisme et la réduction des financements extérieurs n'ont fait qu'aggraver la situation. Même lorsque des pratiques prometteuses existent, les pays peinent à gérer le volume et la complexité croissants des opportunités d'innovation. Il en résulte des doublons, des retards et des investissements inadaptés. Le coût final est élevé : pertes en vies humaines, une détérioration du capital de confiance et retard dans la progression vers des systèmes plus résilients.

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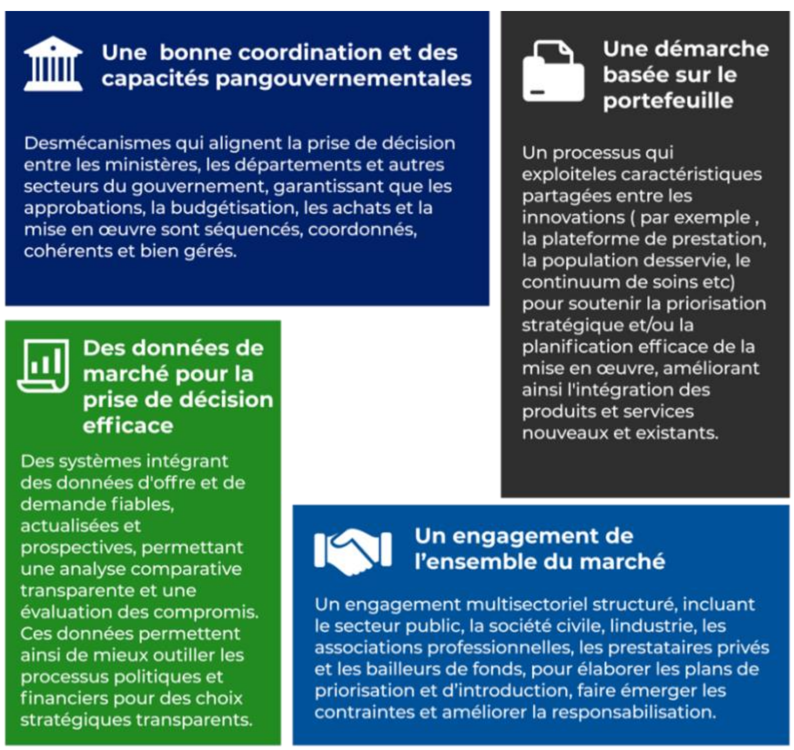
Quatre piliers interdépendants et qui peuvent améliorer le système pour une introduction à l'innovation stratégique

En nous appuyant sur des données publiées et sur l'expérience de mise en œuvre, nous avons identifié quatre piliers interdépendants qui, individuellement et conjointement, peuvent renforcer les facteurs politiques, financiers et de plaidoyer des décisions stratégiques d'introduction de l'innovation:



Lorsque ces piliers sont faibles, l'introduction est compromise. En les renforçant ensemble, les pays peuvent prendre des décisions plus rapides, transparentes et alignées sur le système, ce qui conduit à une plus grande efficacité (adaptation des innovations à la demande de la population, aux réalités de la prestation et aux considérations de qualité et d'équité) et à une meilleure efficience (réduction des retards, des doublons et du gaspillage).

Une opportunité à saisir: tirer partie d'une approache pratique pilotée par les pays.

Au cours des deux ans et demi à venir, le Consortium ALIGN collaborera avec les acteurs nationaux et infranationaux du Kenya, du Sénégal et d'Afrique du Sud pour aider les gouvernements à adapter et à mettre en œuvre ces outils de renforcement des systèmes, renforçant ainsi les leviers politiques, financiers et de plaidoyer pour une priorisation et une introduction de l'innovation de qualité. Cela favorisera une introduction plus efficace et efficiente de l'innovation.

Cette initiative ne mesure pas le succès au nombre de produits lancés. Elle évalue plutôt si les décisions d'innovation deviennent plus réfléchies, fondées sur des données et alignées sur les réalités du système, notamment en matière de financement, de mise en œuvre et de réglementation.

Nous prévoyons des changements rapides dans la manière dont les pays:

- Comparent les innovations en paralelle en utilisant des critères et des cadres partagés;
- Coordonnent la budgétisation, l'approvisionnement et le déploiement de manière plus transparente;
- Impliquent les acteurs de tous les secteurs plus tôt et de manière plus cohérente;
- Utilisent des données probantes pour la prise de décision et l'apprentissage en temps réel pour adapter les stratégies d'introduction.

Dans cet article, nous synthétisons les données probantes issues d'une revue ciblée des données publiées et de l'expérience. Notre objectif est de générer une synthèse pratique pour éclairer les premières étapes de la conception de notre programme et de l'élaboration de notre stratégie.

Justification stratégique

Pertinence et urgence de l'action Le paysage de l'innovation évolue rapidement, tout comme les enjeux des choix qui s'y font, avec des conséquences sur la santé des populations et les résultats économiques, l'accès équitable à des innovations biomédicales et de soins de haute qualité, et la confiance du public dans les systèmes de santé et, plus généralement, dans les décisions gouvernementales. Sans systèmes nationaux plus efficaces et efficients pour l'introduction de l'innovation , les outils les plus adaptés arriveront tardivement, voire pas du tout, et ne seront pas déployés durablement en première ligne. Il est urgent d'agir pour renforcer les systèmes qui déterminent ce qui est introduit, quand, à quelle vitesse et avec quelle efficacité.

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Bien mené, ce travail offre une voie accélérée vers des systèmes de santé plus responsables et plus résilients, et vers de meilleurs résultats sanitaires et économiques, plus rapidement, pour les personnes qui en bénéficieront le plus.

INTRODUCTION AND RATIONALE

Focusing on policy, financing, and advocacy enablers of effective, efficient innovation introduction amid global challenges

In this paper, we examine why the most strategic health innovations fail to reach the people who need them most—and what it would take to change that. We focus on a crucial but often overlooked part of the puzzle: the policy, financing, and advocacy enablers of effective, efficient innovation introduction. Our synthesis draws on published evidence as well as experience across countries, with selected citations from our consortium's work emboldened.

Figure 1: Innovation introduction as the inflection point between innovation pipelines and scaled, sustained delivery

Strong policy, financing, and advocacy enablers of high-quality innovation introduction decisions connect global and domestic R&D pipelines with national planning and delivery systems.

Introduction decisions—technical and political—are the inflection point at which global R&D and innovation readiness can translate into on-the-ground, scaled, and sustained delivery to save and improve lives (see Figure 1). Regional, national, and subnational governments—across ministries and departments within them—are expected to make timely, coherent decisions about what to introduce, how to finance it, and how to deliver innovations into health systems. Yet too often they cannot. These decisions are frequently made without market-wide data, with duplicative or misaligned processes across departments, and with limited ability to shape or sequence donor-driven priorities. The effects ripple outward: program planners lack information about delivery capacity or community demand; private sector actors lack visibility into innovation priorities or financing plans; and civil society is left without the information needed to hold systems accountable. The current system for innovation introduction is not just ineffective or inefficient—it is disempowering. It is a whole-system problem, requiring a whole-system solution (Deming 1982; **Goldmann et al 2024**).

In this paper, we assess how and why introduction decisions break down—and what can be done to strengthen its core policy, financing, and advocacy enablers. Drawing on published research and global implementation experience, we highlight specific prioritization and planning challenges that arise during product introduction. We then surface partial solutions that have worked in some settings and propose a testable, adaptable model built around four core pillars: portfolio-based logic, market data for decision-making, whole-of-government coordination and capacity, and whole-of-market engagement across sectors and the value chain.

This paper serves as a foundation for our work over the next 2.5 years. While our initial focus emphasizes biomedical products due to their regulatory complexity and resource intensity, the enablers and pillars we describe apply broadly to health system innovations and digital health tools. We concentrate on four interdependent pillars—market data for decision-making, portfolio-based logic, whole-of-government coordination and capacity, and whole-of-market engagement—that individually and jointly may strengthen the policy, financing, and advocacy enablers of more effective and efficient innovation introduction.

This paper serves as a foundation for our work over the next 2.5 years.

The ALIGN Consortium, working across the three pathfinder countries of Kenya, Senegal, and South Africa, will support governments and other stakeholders in co-developing and iteratively refining how to strengthen key enablers of innovation introduction. By learning within and across contexts, we will produce transferable insights about the technical, organizational and political pillars required to make introduction decisions that are more deliberate, data-informed, and aligned with national priorities.

Innovations can improve lives and economies—if introduced and, in turn, accessible at scale

Health innovations hold enormous potential to improve population well-being and economic resilience in low- and middle-income countries (LMICs). These innovations include not only biomedical tools and pharmacologic agents but also digital platforms, service delivery models, and system-level approaches that expand access and use. Even focusing narrowly on biomedical and pharmacologic tools, the global pipeline is more robust than ever, with technologies such as mRNA vaccines, long-acting injectables, and monoclonal antibodies poised to address a wide range of health challenges (Yamey *et al*. 2024). Strategic investments in health innovation—from essential services to frontier technologies—consistently demonstrate substantial health and economic returns (Jamison *et al*. 2013; WHO 2023).

Despite this momentum, many innovations still fail to reach the people and places that need them most—quickly, at scale, or in meaningful ways. Access remains slow, uneven, and too often shaped by novelty or donor interest rather than population demand (Spicer *et al*. 2020; Gautier & Ridde 2017). Recent commentary on newly approved long-acting injectable lenacapavir for HIV prevention underscores this disconnect—showing that even high-impact innovations may stall without coordinated planning, aligned platforms, and delivery system readiness (Lynch *et al.* 2025). The data reflect this challenge: a retrospective analysis of 59 global health interventions found that the median time from ideation to 20% uptake in LMICs was 13.5 years—more than twice as long as in high-income countries (**Mao *et al*. 2025**). These delays are not just technical or financial—they are systemic, rooted in how introduction decisions are made, who is empowered to make them, and how they are equipped.

These divergent timelines are likely to persist—if not worsen—as more complex, cross-sectoral, and resource-intensive innovations move toward introduction. Without stronger innovation introduction systems, countries may continue to face fragmented or duplicative decisions, delays, and opaque or poorly coordinated processes (Hendricks *et al*. 2022). Ministries may approve new products without securing budget lines; donor procurement may advance before national guidelines are updated; and providers may be expected to deliver new tools before training or system readiness is in place (Gatome-Munyua *et al*. 2022).

These disconnects do more than delay rollout or divert resources to less-strategic innovations —they reflect deeper dysfunctions in policy, financing, and system readiness that undermine trust, diminish the return on innovation investment, and delay urgently needed health gains. When decisions about what to introduce are made in isolation—from budget realities, from delivery system capacities, or from population preferences—the result is friction at every stage of the pathway from approval to access. These breakdowns not only waste time and resources but also reinforce health disparities.

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Today, the mortality rate from communicable, maternal, neonatal, and nutritional diseases in LMICs remains 2.7 times higher than the global average—and 7.5 times higher than in high-income countries (IHME 2023). At the same time, noncommunicable diseases (NCDs) now account for 71% of global deaths, 73% of which occur in LMICs (WHO 2022). The cost of weak enablers is therefore measured not only in inefficiency or ineffectiveness, but also in lives lost, resources misdirected, and delayed progress toward more resilient, responsive, and sustainable systems. Without stronger coordination across the policy, financing, and delivery ecosystem, proven tools will continue to underperform, arrive late, or fail to reach the people who need them most.

Globally, innovation introduction is fragmented and weakening

Globally, innovation introduction is under mounting pressure. A convergence of systemic forces—rising populism, shifting development priorities, aspirations for sovereignty and self-reliance, geopolitical fragmentation, and shrinking multilateralism—has eroded trust and weakened cooperation. Fiscal tightening has further redirected donor and investor priorities inward. As a result, health systems are expected to do more, faster, fairer—with fewer resources. This fragmented global backdrop is beyond the scope of the ALIGN Consortium's direct work, but it raises the stakes for national and regional systems. Now more than ever, innovation introduction must be effective and efficient in setting priorities and policy, aligning financing, supporting advocacy, and coordinating decisions.

Even before COVID-19, global-to-national innovation pathways were fractured, compounded by regulatory bottlenecks, limited local manufacturing, and insufficient mechanisms for joint market authorization across countries (Ahonkhai *et al*. 2016; Sillo *et al*. 2021). During the pandemic, these cracks were fully exposed: vaccine inequities and the delayed global rollout of oral therapeutics like nirmatrelvir/ritonavir revealed how fragile and donor-centric access systems remain (COVID-GAP 2023; Moon *et al*. 2022). Generic versions of nirmatrelvir/ritonavir reached LMICs more than 20 months after U.S. approval—despite high demand and a well-established safety profile—fueling mistrust and undermining solidarity (COVID-GAP 2023).

In the years since COVID-19, inequities have persisted. Voluntary licensing deals—including through the Medicines Patent Pool (MPP)—were intended to accelerate access but proved insufficient without aligned procurement, financing, and regulatory mechanisms (MPP 2023). The mpox vaccine response reinforced these weaknesses: despite existing tools, access was delayed or uncertain, particularly in Africa, reigniting concerns about exclusion, waning solidarity, donor control, and the absence of clear national mechanisms for prioritizing and financing introduction (WHO Africa 2023; MSF 2024).

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These challenges are not limited to emergencies or vaccines. Innovations for noncommunicable diseases—including WHO-endorsed hypertension screening tools and affordable insulin formulations—have also struggled to reach scale. Here, delays are less about technical uncertainty and more about systemic barriers such as procurement lags, unclear cost-recovery models, and workforce bottlenecks (Abbott & Sampath 2022). These recurring breakdowns highlight a broader reality: innovation introduction systems are neither resilient in crises nor effective and efficient under normal conditions.

These dynamics are now compounded by a contracting fiscal environment. Even before the pandemic, LMICs faced limited fiscal space due to rising debt burdens and domestic financing shortfalls (World Bank 2021). The COVID-19 response further strained budgets and eroded trust, and today projections point to a US$70 billion global aid shortfall by 2025 (Georgieva 2024). Major bilateral donors have already scaled back: the UK cut health ODA by 30% between 2020 and 2022 (UK FCDO, 2024) , while analyses suggest that roughly one-third to one-half of all USAID awards have been canceled, with wide-reaching implications for country-level investment and partnership (Sandefur and Kenny 2025).

The Africa CDC underscores the growing mismatch between regional health needs and available financing—showing that even sustained external funding will be insufficient to meet future innovation and system demands (Africa CDC 2025). As the innovation pipeline expands and fiscal constraints tighten, the imperative is clear: countries must be equipped to set their own priorities, align financing, and coordinate decisions around innovation introduction. The challenge is not only a fraying global resource environment but also an urgent need to sustainably strengthen national introduction systems.

Definitions and roadmap

The inflection point between R&D and scaled access: effective, efficient innovation introduction

To achieve access to strategic innovations, countries first need effective and efficient innovation introduction—bridging global or domestic innovation R&D with local delivery and scale. Innovation introduction is the point at which stakeholders must make three crucial decisions (see Box 1).

Box 1: Innovation introduction as the inflection point between innovation pipelines and scaled, sustained delivery

In this box, we list three core decisions that determine whether innovation introduction is effective and efficient. Each can be strengthened by policy, financing, and/or advocacy enablers.

Which, and in which sequence, of innovations **to prioritize** relative to existing, approved offerings and others on the horizon	**How to finance** prioritized innovations for scaled, sustained, and fair access	**How to prepare** rollout-ready systems for speedy, safe, sustained rollout

Yet these decisions are often fragmented, underfunded, or disconnected from country priorities and system realities. Strengthening innovation introduction requires anticipating delivery and scale from the outset—not retrofitting them later. We hypothesize that reinforcing policy, financing, and advocacy enablers will lead to more effective and efficient innovation introduction and, in turn, improved delivery, access, and use. Doing so requires both technical and political effort. Analyses of health reform emphasize that decisions about adopting new products are shaped not only by technical evidence but also by political-economic dynamics—incentives, interests, influence, and ideas—underscoring the importance of transparent, nationally anchored processes (Reich 1995).

In this paper, we lay out the foundation of an approach for improving coordination, capacity, evidence use, and accountability in innovation introduction—helping countries move from fragmented decisions toward more strategic, system-aligned choices.

Box 2: Key definitions for understanding innovation introduction

In this box, we define core terms used throughout the paper—innovation introduction, enablers, effectiveness, and efficiency—drawing on current literature and consortium consensus.

Innovation: We take a broad view of innovation, including products and services as well as models of delivery, workforce, and financing that (1) are novel or newly adapted to a context and (2) have proven or potential impact. For the purposes of this paper, however, we focus more narrowly on biomedical products with evidence of health impact.

Innovation introduction: The coordinated set of national and subnational processes through which new health innovations are assessed, adopted, financed, and prepared for sustained, scaled access. These processes include prioritization and a variety of rollout readiness activities (financing, policy development, regulatory review, procurement, and operational planning for rollout, including guideline and training revision)—but exclude both R&D and rollout.

Effective: Prioritization and introduction decisions that are evidence-informed, fair, and safe, reflecting country-set priorities, goals, and population demand while aligning with system capacity. They also support system legitimacy, trust, and sustainability.

Efficient: Prioritization and introduction decisions that optimize value (health, trust, economic) for resources allocated (time, funding, coordination effort) including by minimizing delays, duplication, and fragmentation.

Policy, financing, and advocacy enablers: The institutional relationships, governance processes and incentives, and system capabilities that determine whether, which, and when innovations are prioritized, funded, and introduced into health systems (*e.g.*, WHO WPRO 2023).

Portfolio-based logic: A mindset and method for the coordinated consideration of multiple innovations simultaneously for prioritization, regulatory review, and/or rollout planning, leveraging commonalities and complementarities across product type, population targeted, and/or point of care. This logic improves effectiveness by harnessing complementarities and synergies, and efficiency by reducing duplication and supporting more strategic, system-aligned introduction (PATH 2022; Gordon *et al.* 2012; Gavi 2021; Kovach 2022; WHO WPRO 2023).

Market data for decision-making: Decision tools, underlying data, and supporting decision-relevant analyses that allow evidence-informed innovation introduction decisions by bringing together information on supply (*e.g.*, pipeline visibility, product availability), system capacity (*e.g.*, supply chain and workforce readiness), and demand (*e.g.*, disease burden, population preferences). Market intelligence enables comparative assessment of innovations, clarifies trade-offs, and supports more transparent, timely, and system-aligned prioritization (Nutley & Reynolds 2013; **Taylor *et al*. 2022**; WHO WPRO 2023).

Whole-of-government coordination and capacity: The deliberate alignment of public authorities across ministries, departments, and levels of government to prioritize, finance, and prepare for innovation introduction. Through formal and informal mechanisms, governments coordinate timelines, budgets, regulatory approvals, and implementation plans to achieve shared goals and coherent responses to cross-cutting challenges. Strengthening this pillar improves effectiveness by ensuring decisions reflect country priorities and delivery realities, and efficiency by reducing duplication, delays, and fragmentation (UK Cabinet Office 1999; Management Advisory Committee 2004; OECD 2008; United Nations 2015).

Whole-of-market engagement: The structured engagement of government with actors beyond government—including civil society, industry, professional associations, private providers, and funders—in innovation introduction. Convening these stakeholders early and predictably provides a key pillar, allowing governments to surface and address constraints, align decisions with delivery realities, expand co-financing potential, and strengthen accountability for commitments. Whole-of-market engagement goes beyond *ad hoc* consultation toward routine, transparent mechanisms that make introduction more coherent, inclusive, and legitimate (Wale *et al*. 2023; Surgey et al. 2022; WHO QoC Network 2023; PATH 2022; WHO WPRO 2023).

We organize the rest of the paper in two parts.

First, we **examine four persistent gaps** in the policy, financing, and advocacy enablers that undermine effective and efficient innovation introduction—alongside emerging evidence on how countries are addressing these challenges.

Second, we **propose a country-driven approach** for testing, refining, and scaling practical strategies that reinforce these pillars and drive system change.

To consider emerging evidence, we synthesized findings from a purposive review of peer-reviewed and high-quality gray literature. We focused on policy, financing, and advocacy enablers of health product introduction, including prioritization, sequencing, and rollout planning, especially in LMICs and especially from 2018 onward. Our search—supported by ChatGPT's Deep Research for initial scanning, then hand-reviewed—was guided by the four core pillars of strong introduction: (1) market data for decision-making (*e.g.*, decision-support tools, prioritization frameworks, market intelligence); (2) portfolio-based logic (*e.g.*, bundled, simultaneous, or sequenced introductions; shared HTA and training processes); (3) whole-of-government coordination and capacity (*e.g.*, cross-ministerial planning, budg*et al*ignment, public financial management); and (4) whole-of-market engagement (*e.g.*, multi-stakeholder or total market approaches, civil society platforms, scorecards). Country examples were purposively selected to illustrate recurring patterns and emerging practices, with emphasis on Kenya, Senegal, and South Africa as pathfinder countries for the ALIGN Consortium, complemented by lessons from other LMICs. This was not a systematic review; limitations include possible omission of less-documented experiences and reliance on secondary reporting. Our aim was to generate a practical synthesis of evidence-informed enablers of health product introduction to inform research and strategy in Kenya, Senegal, and South Africa.

Key effectiveness and efficiency gaps innovation introduction: Evidence and implications

We propose that innovation introduction decisions can be made more effective and efficient by leveraging policy, financing, and advocacy enablers. In turn, these enablers are supported by four key, interdependent pillars. Two are anchored in relationships and skills: whole-of-government coordination and capacity, and whole-of-market engagement—both of which can support, synchronize, and streamline decision-making. The other two are anchored in approach and information: portfolio-based logic and market data for decision-making, which can inform more strategic and coherent choices.

Each of these pillars addresses a specific gap that can undermine timely, coherent, and well-sequenced innovation introduction. When one or more pillars are weak or missing, countries are more likely to experience duplicative efforts, poorly aligned investments, and missed opportunities to optimize impact.

- When market data for decision-making are fragmented or underused, or even absent, trade-offs remain unexamined, comparative value is unclear, and decisions are disconnected from both population needs and system readiness.

- Without portfolio-based logic, countries make decisions one innovation at a time, resulting in duplication, overload, short-sightedness, and poor alignment between innovations and delivery capacity.
- Without whole-of-government coordination and capacity, decision-making falters as priorities compete across health verticals and different ministries, planning remains siloed, and regulatory, financing, and implementation timelines fall out of sync.
- Without structured whole-of-market engagement, introduction excludes key actors—private sector suppliers and implementers, civil society advocates, and delivery partners—who are essential for operational alignment and accountability.

Despite committed efforts, many LMICs still face significant challenges in making coherent, timely, and well-sequenced innovation introduction decisions. Too often, choices about whether to adopt, delay, or decline new products are fragmented, slow, or misaligned with priorities, capacity, and scale potential. These outcomes are not inevitable. They reflect persistent but addressable weaknesses in the pillars that underpin the policy, financing, and advocacy enablers of effective and efficient introduction decisions. Importantly, strong introduction systems help countries decide not only when to say yes but also when to say no—or not yet. In Table 1, we summarize each pillar-related challenge and its consequences.

Table 1: Four core challenges with innovation introduction pillars and their consequences for decision-making quality

In this table, we summarize the four recurring breakdowns that limit effective and efficient innovation introduction. For each, we outline the underlying system gaps and the resulting implications for prioritization and introduction decisions.

Challenge area	Key gaps identified	Consequences for innovation introduction
1. Compartmentalized data, compromised decision-making	• Data systems siloed by program or funding stream • Fragmented market intelligence across supply and demand, public and private • Data tools misaligned with planning and budgeting cycles • Limited capability to analyze trade-offs across innovations leveraging aggregated market data	• Innovation decisions disconnected from need and system readiness • Innovation decisions connected from near-future pipeline of opportunities • Inability to compare trade-offs between innovations • Weak prioritization based on evidence **Result**: Ineffective introduction decisions

2. **Innovation-by-innovation processes impede strategic prioritization and introduction**	• No framework for grouping or sequencing innovations based on commonalities or complementarities • Reactive prioritization driven by donor timelines or external factors • Disconnected planning across innovations using the same platforms/resources • Duplicative investments that fail to leverage shared characteristics	• System overload with duplicative introduction processes • Missed opportunities to bundle complementary innovations • Poor sequencing of innovations with similar characteristics • Inefficient use of limited training and system resources, duplicating across innovations with shared characteristics • Inability to assess opportunity costs across innovations **Result**: Ineffective and inefficient introduction decisions
3. **Misaligned priorities and processes across whole-of-government impede introduction**	• Horizontal fragmentation across ministries and departments • Hierarchical fragmentation between national and subnational levels • Cross-sector coordination challenges (health, treasury, ICT) • Siloed capabilities and limited cross-government learning • Regulatory approvals disconnected from financing and implementation planning	• Delayed or stalled introduction processes • Misaligned regulatory, financing, and implementation timelines • Duplicative efforts across government entities • Disconnects between national policy and subnational preparation introduction **Result**: Inefficient introduction decisions
4. **Weak alignment and accountability across whole-of-market stakeholders hinders innovation introduction**	• Private sector providers excluded from introduction planning • Civil society engaged too late to influence key decisions • Implementing partners lack visibility into pipeline and planning • Limited transparency about introduction processes and timelines • Few mechanisms for non-governmental accountability	• Introduction decisions misaligned with delivery realities • Reduced accountability for follow-through on commitments • Limited trust and buy-in from key implementation partners • Missed opportunities for co-financing and operational synergy **Result**: Ineffective and inefficient introduction decisions

These gaps, while distinct, are deeply interconnected. For example, without comparative market data, portfolio planning becomes guesswork. Without whole-of-government coordination, even the best engagement platforms struggle to align timelines and responsibilities. Addressing each pillar in isolation may bring incremental improvements—but unlocking catalytic change requires strengthening and leveraging them together.

In the following sub-sections, we examine four challenges that correspond directly to the core pillars underpinning stronger policy, financing, and advocacy enablers. For each pillar, we analyze what breaks down when it is weak, why this matters for introduction decisions, and emerging evidence on how countries are addressing these challenges in practice.

CHALLENGE 1:

Compartmentalized data, compromised decision-making

Why this pillar matters

Timely, trusted, and aggregated market data are foundational to effective and efficient innovation introduction. Without visibility into both the supply pipeline and population demand, countries struggle to assess trade-offs, align timelines and capacity, or plan for system readiness. This is not merely an information gap—it is a structural vulnerability. When market intelligence is fragmented or inaccessible, countries may prioritize based on donor signals rather than comparative value, introduce products without budgeting for them, or miss opportunities to sequence rollouts coherently. The result is wasted effort, distorted priorities, and eroded legitimacy.

Evidence: what breaks down

In many LMICs, market data systems remain fragmented—by program, funding stream, or ownership. Common breakdowns include:

- **Vertical silos**: In Kenya, dozens of parallel systems track service delivery, financing, and planning—often with misaligned indicators and limited interoperability (Nyangena et al, 2021). In Nigeria, vertical programs maintain independent data flows, complicating cross-innovation comparisons and reinforcing disease-specific fragmentation (PATH 2022).
- **Public–private disconnects**: In South Africa, data from private providers—who deliver a large share of health services—remain largely disconnected from national platforms, despite major investments in digital systems (Appleford *et al*. 2023).
- **Utilization and timing gaps**: In Senegal, outdated dashboards slowed COVID-19 targeting decisions (Ba et al. 2022). In Malawi, scorecards intended to track availability and accessibility of RMNCH commodities were perceived primarily as donor tools—limiting their use in national decision-making and planning (Nemser *et al*. 2018). When tools are not aligned to national decision cycles, even strong data fail to inform introduction.

➡ **These examples show that it is not just whether data exist**—it is whether systems are designed to own, integrate, and apply that data at critical moments, such as budgeting, procurement, and rollout planning.

Evidence: what countries and partners are doing

Despite these challenges, several countries have made progress aligning data systems with innovation planning:

- **Kenya**: RMNCAH scorecards are used by counties for structured budget planning and investment tracking (UNICEF 2017). Their success depends not only on the tool itself but on its alignment with real planning cycles and decision forums.
- **Malawi**: District dashboards guide decisions under reproductive health trust funds, linking real-time insights with subnational resource allocation (Nemser *et al*. 2018).
- **Rwanda**: The COVID-19 Data Analytics System integrated clinical and vaccination data to support planning for new interventions—providing a model for linking operational data with strategy (Mugabo *et al*. 2024).
- **India**: National innovation review committees use pilot data to assess performance, feasibility, and equity before advancing new products for public financing (MoHFW & NHSRC 2022).
- **Global**: WHO's Market Information for Access (MI4A) platform provides comparative data on vaccine prices and procurement volumes, improving countries' ability to negotiate, plan financially, and make evidence-informed introduction decisions (WHO 2023).

Global platforms like Unitaid's ACTwatch (for malaria commodities) and the Launch and Scale Speedometer (for COVID-19 vaccines) have also expanded access to timely pipeline and pricing data (Unitaid 2016; **Taylor *et al.* 2022**). But many of these tools were designed primarily for donor audiences, rather than to support national prioritization cycles or cross-innovation comparisons.

Takeaway

Effective data systems are not just technical—they are political and strategic. Countries need tools that:

- Integrate pipeline, readiness, and demand data across silos
- Support side-by-side comparisons and trade-off analysis
- Are seen as legitimate and are used in real decision-making spaces

Without this alignment, even the best data fails to shift introduction decisions. But when systems are adapted to decision timelines and backed by institutional authority, even simple tools—like scorecards or prioritization matrices—can reshape planning and accountability.

CHALLENGE 2:

Innovation-by-innovation processes impede strategic prioritization and introduction

Why this pillar matters

In many countries, innovations are considered and, if prioritized, introduced one at a time—through siloed processes often triggered by donor timelines or product readiness rather than system readiness. This innovation-by-innovation logic fragments planning, duplicates effort, and impedes strategic alignment. Both effectiveness and efficiency are undermined.

When products are prioritized based on donor momentum, historical precedent, or institutional preference—rather than on deliberate assessments of system fit or comparative value—countries risk making decisions that overload delivery systems or duplicate investments. Across verticals and levels of government, repeated trainings, parallel procurement chains, and redundant guideline updates consume scarce resources. Lessons from one introduction are rarely applied to the next. Over time, this drains system responsiveness and makes it harder to introduce high-value innovations at scale or in sequence.

Evidence: what breaks down

Innovation-by-innovation introduction processes create fragmentation across multiple decision points:

- **Reactive prioritization:** Innovations are often selected based on donor momentum, regulatory readiness, or historical precedent—not through deliberate comparisons of system fit or relative value.
- **Duplicated preparation:** When each innovation is introduced in isolation, countries conduct separate trainings, revise guidelines multiple times, and plan distinct supply and financing chains—even when innovations target similar products, platforms, or populations.
- **Fragmented learning:** Lessons from one product introduction are rarely applied to others. Each rollout resets the learning curve, requiring new coordination efforts, new systems investments, and new cycles of readiness.

As a result, ministries may support competing innovations that stretch delivery capacity; funders may advance products that overwhelm limited procurement or regulatory teams; and frontline workers may face multiple, uncoordinated demands.

For example:

- Independent assessments have documented that vertical, donor-funded health programmes frequently operate with separate financing, supply chain, data, and governance systems — even when they draw on the same first-line PHC infrastructure (Chaitkin et al. 2019). That fragmentation poses a structural risk: each new innovation adds another parallel system, stretching capacity, undermining efficiency, and threatening sustainability (Chaitkin et al. 2019).

- Digital health tools are frequently introduced one by one, each with separate infrastructure, user training, and reporting demands—undermining the system efficiencies they promise to deliver (Appleford *et al*. 2023).

These examples reflect growing recognition that introduction decisions cannot be made in isolation. Without leveraging commonalities and complementarities across innovations using portfolio-based logic, the process itself creates discordant investments and duplicative effort. Even simple tools—such as matrices that align innovations by delivery platform, cost, and readiness—can help countries surface trade-offs, improve stakeholder alignment, and coordinate phased rollout. Without such tools, countries may struggle to say "no" or "not yet" to donor-driven innovations that are promising but poorly matched to current system capacity.

At the same time, approaches leveraging portfolio-based logic require careful design. Gavi's experience shows that as portfolio complexity increases, decision timelines can lengthen and coordination demands rise (Gavi 2021). PATH found that while bundling improved efficiency, it also raised the technical burden on ministries—particularly where analytic or coordination capacity was limited (Gordon *et al*. 2012).

To be effective, portfolio approaches must be flexible, context-specific, and reviewed regularly to avoid introducing new bottlenecks. When implemented well, they enable systems to make more coherent, transparent, and forward-looking decisions about innovation introduction—even in the face of external pressure or competing priorities. Portfolios might be bound by multiple commonality and complementarity 'threads,' with the goal of improving effectiveness (better inputs into prioritization) and/or efficiency (reducing duplicative processes and lesson-learning). These threads might include product features, populations served, platforms for delivery, or point of care in the continuum of care.

Evidence: what countries and partners are doing

Several countries and global partners are beginning to adopt portfolio-based planning logic—assessing multiple innovations together, identifying shared delivery needs, and sequencing them more strategically:

- **Gavi:** The Vaccine Investment Strategy (VIS) evaluates candidates side-by-side using multi-criteria decision frameworks—including health impact, equity, cost, and system fit (Gavi 2021). Many countries apply this approach by bundling campaigns or targeting multiple age groups in one rollout to reduce strain on delivery systems.
- **PATH:** Analysis of simultaneous vaccine introductions found that bundling reduced training time, cold chain redundancy, and guideline complexity—but only when system readiness was assessed and aligned early (Gordon *et al*. 2012).
- **India and Ethiopia:** National innovation review committees compare multiple product candidates by cost, expected impact, delivery feasibility, and readiness, helping governments prioritize and sequence introductions more coherently (MoHFW & NHSRC 2022).
- **Ethiopia and Indonesia:** Stakeholders have piloted decision-support tools such as the CAPACITI framework, which combines pipeline supply data, local evidence, and stakeholder input to guide transparent prioritization (Jansen *et al*. 2024).

- **Unitaid and the UN Commission on Life-Saving Commodities:** Both have promoted portfolio approaches in maternal, newborn, and child health by encouraging coordinated introduction timelines and harmonized procurement strategies for multiple products that rely on the same delivery platforms.

Takeaway

Portfolio-based approaches can make innovation introduction more coherent, deliberate, and system-aligned. When used well, they:

- Encourage side-by-side comparison of innovations
- Help identify bundling or sequencing opportunities
- Reduce duplication across regulatory, training, or financing processes
- Enable more transparent and accountable prioritization

But design matters. Gavi's experience shows that as portfolio complexity increases, timelines can slow and governance demands rise (Gavi 2021). PATH similarly found that portfolio approaches can raise the technical burden on ministries—especially where coordination capacity is limited (Gordon *et al*. 2012).

To succeed, portfolio approaches must remain flexible, context-appropriate, and regularly reviewed. They should support—not constrain—decision-making, and they work best when integrated with market data and delivery readiness assessments. Done well, they help countries shift from reactive to strategic introduction—making better use of resources while improving delivery outcomes.

CHALLENGE 3:

Misaligned priorities and processes across whole-of-government impede introduction

Why this pillar matters

Introducing health innovations requires coordinated action across multiple government entities—regulators, budget authorities, procurement agencies, technical programs, and implementers across ministries and levels of government. When these actors operate with misaligned timelines, competing priorities, unclear mandates, or fragmented technical capacity, even high-priority innovations can stall. The result is fragmented prioritization, duplicative introduction efforts (such as regulatory review, guideline development, or pharmacovigilance planning), delayed rollout, or incomplete implementation—even after formal approval or financing.

These disconnects are costly. Products may be approved before budget lines are secured; procurement may proceed without updated guidelines; or national priorities may fail to align with subnational delivery timelines. Over time, such misalignments weaken trust and reduce the system's ability to respond to emerging needs. Coordination challenges are especially acute in decentralized systems, where responsibilities may be shared but capacity and decision rights are uneven.

Evidence: what breaks down

Coordination breakdowns typically take two forms:

- **Horizontal fragmentation:** Ministries, departments, and agencies at the national level operate in parallel on innovation-related decisions, with little structured coordination around timelines, data, or responsibilities.
- **Vertical fragmentation:** National and subnational actors operate on different planning, budgeting, or regulatory cycles. Subnational implementers are often responsible for delivery without adequate authority, resources, or input into upstream decisions.

Examples include:

- In **South Africa**, procurement, workforce planning, and clinical guideline development often occur in silos—even within the Ministry of Health—resulting in misaligned rollout of innovations (Kredo *et al*. 2018; Appleford *et al*. 2023).
- In **Kenya**, national regulatory approvals sometimes outpace procurement or county-level budget cycles, leaving approved products stranded without resources for scale-up (PATH 2022; Barasa *et al*. 2023).
- In **Senegal**, essential medicines such as artemisinin-based combination therapies have faced rollout delays when national decisions were not matched by coordinated subnational planning or logistics capacity (WHO 2024).

Together, these examples show that coherence and coordination require both institutional mechanisms and political commitment. Through HTA and structured prioritization, cross-ministerial planning, and embedded learning loops, progress depends on aligning mandates, incentives, timing, and accountability both horizontally and vertically across government.

Cross-sector innovations compound these challenges. Digital health tools, for instance, often require coordination between ministries of health, information and communication technology, and finance. In Kenya, Senegal, and South Africa, responsibility for digital innovations has been fragmented across agencies with insufficient mandate or technical capacity for coordination (MoH Senegal 2025; RSA NDoH 2019; Tsofa *et al*. 2017).

Finally, learning is often siloed. In Kenya, county officials report responsibility for rollout without having access to the data or decision authority needed to adapt. This replicates earlier mhealth innovations, in which hundreds of pilot projects generated valuable operational lessons that were rarely synthesized or applied to national scale-up, resulting in duplicated efforts, unrealistic expectations, and delays in implementation (Tomlinson et al. 2013).

Evidence: what countries and partners are doing

Some governments are strengthening coordination platforms and building shared capacity across institutions and levels. Strengthening public financial management systems—the rules and processes by which governments budget, allocate, and disburse funds—is increasingly recognized as a prerequisite for product introduction, ensuring that new technologies are not only prioritized but also financed and implemented on time (Adjagba *et al*. 2025; Barroy *et al*. 2024). Building such coordination and financing mechanisms also responds to broader analyses of universal health coverage reforms, which highlight institutional and political dimensions as critical enablers of sustained product introduction (Reich and Campos 2024). Health Technology Assessments (HTA) and Health Benefits Packages (HBP) may serve as a bridge and coordination function to make universal health coverage aspirations a reality (Norheim et al. 2023).

More broadly, reviews of LMIC experience suggest that institutionalizing HTA can enhance analytic legitimacy and structured priority-setting, but remains vulnerable without clear mandates, sustainable financing, and stakeholder buy-in (Baltussen et al. 2016; Chalkidou et al. 2017). In Kenya, multiple efforts have sought to institutionalize HTA, including establishing governance structures and advisory panels, enacting policy frameworks, and building awareness through training and advocacy (Mbau et al 2023). At the same time, progress has been shaped by political commitment, financing, data systems, and stakeholder incentives, highlighting both opportunities and fragilities in embedding HTA into national decision-making (Mbau *et al*. 2023).

In Ghana the HTA agenda illustrates this wider regional trend, where ministries and partners are working to formalize processes that connect technical assessments to policy and budgetary decisions. With development partner support, the Ghanaian MoH used summits and existing bureaucratic structures to create HTA technical and steering committees, embed HTA into policy planning, and pursue capacity-building—despite constraints in funding and local expertise (erkuuah *et al*. 2023). Experience from Ethiopia shows that while investments in HTA training and analytic capacity are strengthening the technical foundation for priority-setting, institutionalization remains fragile without sustained political commitment, formal mandates, and government stewardship (Erku et al. 2023; Zegeye et al. 2018).

Alongside HTA, some countries have also piloted joint planning mechanisms that bring together ministries of health, finance, and implementing partners to align procurement, budgeting, and rollout timelines, showing how deliberate joint planning can reduce duplication and improve sequencing of introduction decisions (Gatome-Munyua *et al*. 2022).

These bodies are most effective when they are embedded in decision timelines (*e.g.*, budget submission windows) and linked to real accountability mechanisms (UNICEF 2017; Barasa *et al.* 2023). During COVID-19, Kenya also tested embedded learning models, placing academic teams within county health departments to support real-time adaptation. These partnerships helped align implementation with local capacity and surfaced delivery bottlenecks before national guidelines were finalized (Peters *et al*. 2023).

Yet challenges remain, especially when platforms are underutilized or disconnected from planning and financing. For example, a study of fixed-dose combination hypertension drugs found that fragmented financing, lack of planning alignment, and unclear coordination mandates continue to hinder NCD innovation introduction in Kenya—underscoring the need to translate platform presence into practice (Murphy *et al*. 2025).

Beyond formal coordination bodies, several LMICs have piloted joint planning mechanisms that bring together ministries of health, finance, and implementing partners to align procurement, budgeting, and rollout timelines. While often *ad hoc*, these mechanisms have shown that deliberate joint planning can reduce duplication and better sequence introduction decisions (Gatome-Munyua *et al*. 2022).

Some high- and middle-income countries also offer potential models. In Israel, the national "basket" process functions as a formal mechanism to prioritize and fund new health technologies. It brings together stakeholders from across government, finance, and medicine, operating within a politically stable consensus about fiscal discipline and universal health coverage. The legitimacy of the process rests on its transparency, independence, and its connection to annual budget negotiations (Myers *et al*. 2023). In Thailand, the Health Intervention and Technology Assessment Program (HITAP) links technical review with benefit package design and budgeting decisions. HITAP has influence not only because of its analytic rigor, but because it is embedded in the broader policy process and enjoys sustained political support (Leelahavarong *et al*. 2019).

Takeaway

Technical coordination and capacity are not enough. Platforms gain power and traction when they are:

- Aligned with real decision cycles (*e.g.*, budget planning),
- Supported by clear mandates and accountability structures,
- And situated within broader political settlements that reinforce shared goals and values.

Effective innovation introduction requires structured, routinized coordination—not just convenings or consultations. As innovation pipelines grow more complex, systems must clarify:

- Who has authority to make which decisions,
- How those decisions connect across ministries and levels of government,
- And when coordination must occur to align policy, financing, and rollout.

Where formal platforms exist, they must be assessed and adapted to meet this purpose—not layered on top of existing fragmentation. In countries like Kenya, Ethiopia, and Ghana, the most promising efforts combine coordinated planning, learning loops, and decision-aligned timing. Meanwhile, Israel and Thailand remind us that the most promising mechanisms for coordinated introduction are those that are: institutionalized, politically legitimate, and functionally linked to resource allocation. Systems that embed coordination into the structure of decision-making—not just its rhetoric—are far more likely to introduce innovations effectively and efficiently.

CHALLENGE 4:

Weak alignment and accountability across whole-of-market stakeholders hinders innovation introduction

Why this pillar matters

Innovation introduction rarely succeeds through government action, however well-coordinated, alone. Civil society, industry, professional associations, private providers, and funders from the public, private, and philanthropic sectors: synchronizing with government priorities, stewarding investment, supporting delivery, shaping demand, sustaining impact, and ensuring accountability. Yet across many systems, these whole-of-market actors, both national and global, are engaged late—or not at all—during innovation planning and prioritization. Co-creation is often absent.

This lack of engagement creates two major risks:

- **Operational misalignment:** Innovations are introduced without input from those responsible for delivery, financing, or public engagement, and without synchronization with government priorities. The result is bottlenecks, duplication, limited financing, or limited uptake.
- **Transparency and accountability deficits:** When innovation decisions are opaque or exclusionary, civil society cannot track commitments or advocate for system responsiveness. This weakens trust and reduces follow-through.

These problems are especially acute when products are introduced through vertical programs, temporary platforms, or donor-driven channels—leaving national actors without durable systems for consultation, feedback, or shared planning.

Together, these examples highlight that engagement must be structured, consistent, and linked to real decisions to have an impact. When diverse actors—public, private, philanthropic, and civil society—are involved early and predictably, alignment improves, accountability deepens, and introduction becomes more feasible and sustainable.

Evidence: what breaks down

In many settings, whole-of-market engagement for innovation introduction is *ad hoc*, donor-led, or symbolic, creating several barriers to effective introduction:

- **In Kenya**, long-acting PrEP was introduced in public clinics, but private pharmacies, where many adolescent girls and young women prefer to seek care, were not included in planning. This limited early access and delayed uptake.
- **In Malawi**, community scorecard data have been used to improve maternal health programming. But few formal mechanisms exist to connect these insights back to national innovation planning, limiting their potential to shape introduction decisions (WHO QoC Network 2023; van Pinxteren *et al.* 2022).

Even when donor platforms solicit feedback, they rarely create sustained national mechanisms for transparency or responsiveness. Civil society actors often report uncertainty around what is being introduced, on what timeline, and with what financing—limiting their ability to coordinate, advocate, or hold governments accountable.

Evidence: what countries and partners are doing

Several countries have begun building more structured whole-of-market engagement platforms that improve both alignment and accountability, including through co-production. The total market approach, long applied in family planning, is increasingly used in other health areas to segment demand and coordinate public, private, and donor roles, ensuring introduction strategies are sustainable across the whole market (Global Health eLearning Center 2023).

- **Kenya**: RMNCAH (reproductive, maternal, newborn, child, and adolescent health) stakeholder platforms convene government actors, private sector representatives, donors, and civil society to align introduction priorities, budgets, and timelines (UNICEF 2017; Gatome-Munyua *et al*. 2022). Building on these experiences, other countries have likewise developed multi-stakeholder engagement platforms to convene civil society, providers, and funders around shared innovation priorities (Wale *et al*. 2023). These platforms can improve transparency and accountability, though their influence depends on being embedded in actual decision cycles rather than operating as stand-alone consultations.
- **Tanzania**: Through a formally structured Health Technology Assessment (HTA) Committee, Tanzania created pathways for private provider and supplier input during diagnostic introduction. This collaboration enhanced alignment between private market realities, local manufacturing capacity, and public sector diagnostic choices—reflecting whole-of-market engagement in action (Surgey et al 2022).

Together, these examples show that institutionalizing HTA and piloting joint planning mechanisms can strengthen analytic legitimacy, reduce duplication, and improve sequencing of introduction decisions—especially when embedded in formal timelines and accountability structures.

Global mechanisms like Unitaid's market-shaping projects offer models for engaging suppliers, civil society organizations, and governments around shared introduction planning. Other global intermediaries, such as the Medicines Patent Pool, also shape which innovations become available and on what terms, underscoring the need for governments to engage them as part of broader market planning. These efforts demonstrate that whole-of-market engagement is feasible, but often fragile when driven by external funders or focused on single products. A systematic review of global market shaping interventions found that many efforts failed to adequately engage country stakeholders, consider system readiness, or connect to national introduction planning processes (**Mao *et al*. 2025**).

Takeaway

Experience across countries and global initiatives shows that whole-of-market engagement can strengthen both alignment and accountability but only when it is structured as a system function, not treated as *ad hoc* consultation. To be effective, engagement platforms must be embedded in national introduction processes, linked to real decision points (*e.g.*, budget submissions, regulatory reviews, guideline development), and resourced for continuity.

Whole-of-market engagement is not a communication or convening exercise, it is an infrastructure problem. To be effective, engagement must:

- Start early: at the prioritization stage, not just rollout
- Be tied to specific decisions: budgeting, guideline development, procurement planning
- Include actors with real implementation or accountability roles
- Share timely, transparent information on what is being introduced, when, and how

When this kind of engagement is routine, it can surface delivery constraints early, improve operational planning, and build trust across sectors. It also creates channels for civil society to monitor commitments and advocate for alignment with population needs. Countries like Kenya, Senegal, and Tanzania show that even in resource-constrained settings, engagement platforms can function when linked to decision processes. But sustainability requires more than goodwill: it requires mandates, resources, and structured opportunities to shape, not just receive, decisions.

Structured whole-of-market engagement completes the four pillars that support policy, financing, and advocacy actions to ensure that prioritization and introduction decisions are not only technically sound and coordinated within government but also aligned with market realities and population demand but also subject to appropriate public accountability.

Summary of four challenges to effective, efficient innovation introduction decisions

The four challenges outlined above—**fragmented data, innovation-by-innovation decision-making, misaligned government processes, and weak whole-of-market engagement**—represent distinct breakdowns. But in practice, they often compound one another:

- Without comparative data, portfolio planning becomes reactive.
- Without portfolio logic, coordination platforms are overloaded by one-off decisions.
- Without structured coordination, stakeholder engagement becomes episodic and performative.

Without whole-of-market input, even the best technical plans may falter during rollout.

As we show in Table 2, promising practices already exist for each pillar. Yet many remain isolated, inconsistently applied, or disconnected from other pillars, limiting their ability to reinforce one another and generate broader system gains.

Table 2: Promising practices for strengthening each of four interdependent pillars for effective, efficient innovation introduction decisions

In this table, we link the four key challenge areas to the corresponding pillar of strong innovation introduction. For each, we highlight selected examples of promising practices from countries or partners working to improve innovation introduction.

Challenge identified	Pillar to strengthen	Promising practices
Compartmentalized data, compromised decision-making	**Market data for decision-making**	• Kenya: RMNCAH scorecards • Rwanda: COVID-19 Data Analytics System • India: innovation review committees • Unitaid: ACTwatch platform
Innovation-by-innovation processes impede strategic prioritization	**Portfolio-based logic**	• Gavi: Vaccine Investment Strategy, • National Expanded Programme for Immunization (EPI): Bundled campaigns for immunization • Unitaid: Portfolio approaches to reproductive health • India and Ethiopia: Innovation review committees
Misaligned priorities and processes across whole-of-government	**Whole-of-government coordination and capacity**	• Kenya: Inter-Agency Coordinating Committees (with TWGs under them) • Thailand: Institutionalized HTA process • Israel: 'Basket' process • Ethiopia: Cross-departmental learning platforms
Weak alignment and accountability across whole-of-market stakeholders	**Whole-of-market engagement**	• Kenya: RMNCAH stakeholder platforms • Senegal: Municipal planning platforms • Malawi: Community scorecard integration

The task ahead is to connect and strengthen the functionality of these four core pillars—not to build new structures from scratch. By embedding smarter data use, cross-cutting planning, consistent coordination, and transparent engagement into everyday processes, countries can reduce friction, improve coherence, and introduce innovations more effectively and efficiently. In addition, stronger pillars can help countries navigate the influence of global actors—through donor priorities, procurement decisions, or supplier lobbying—by equipping governments to align external contributions with national priorities, sequencing, and system readiness.

In the next section, we outline a practical roadmap for connecting and strengthening these pillars—building on what already exists to move from isolated promising practices toward a more coherent, strategic, and system-aligned approach to innovation introduction.

Putting the pieces together: a roadmap towards strong innovation introduction

Countries may already have many of the ingredients for a strong innovation introduction: planning platforms, stakeholder groups, scorecards, and review forums. But implementation of these ingredients, including in the face of donor pressure, is not guaranteed. Further, few of these components are structured to work together as an effective, efficient system for innovation introduction, nor designed to evolve with growing innovation pipelines and changing system needs. When these enablers are strengthened, they can enhance system coherence and responsiveness—without requiring new institutions or major structural reform. We reflect this in our 'core hypothesis.'

Box 3: Core hypothesis of what strong policy, financing, and advocacy enablers can achieve

In this box, we articulate the testable hypothesis underpinning this work: strengthening and leveraging four core pillar will reinforce policy, financing, and advocacy enablers, resulting in more timely, transparent, and coherent innovation prioritization and introduction decisions.

- **If** national stakeholders strengthen when and how they use market data, organize innovations into portfolios, coordinate across government, and engage stakeholders across innovation introduction,
- **Then** innovation introduction decisions will become more timely, evidence-informed, and aligned with national priorities.
- **As a result**, innovation introduction will become more effective—better reflecting population demands, system capacities, and safety needs—and more efficient—reducing duplication, delays, and wasted resources.

In this section, we draw on the evidence presented above to outline a functional (rather than structural) approach to help countries connect and reinforce the four core pillars that strengthen policy, financing, and advocacy enablers of innovation introduction.

Strengthening four interdependent pillars for effective, efficient innovation introduction

Strategic health innovation introduction depends on four mutually reinforcing pillars, market data for decision-making, portfolio-based logic, whole-of-government coordination and capacity, and whole-of-market engagement (Figure 2). Stakeholders can leverage these pillars to strengthen policy, financing, and advocacy enablers, making prioritization and introduction decisions more effective and efficient.

Figure 2:

Together, these four pillars provide a functional foundation for strengthening the policy, financing, and advocacy enablers of innovation introduction. Improvements in any single pillar can be meaningful. But when the pillars are strengthened and leveraged in concert, countries are more likely to make prioritization and introduction decisions that are timely, transparent, and system-aligned. This, in turn, enhances effectiveness—by ensuring decisions reflect population needs, delivery capacities, and standards of safety and fairness—and improves efficiency—by reducing duplication, accelerating timelines, and optimizing resource allocation.

Portfolio-based logic provides a structured framework for prioritizing innovations, clarifying trade-offs, and identifying shared delivery requirements. Strengthening this pillar requires—and, in turn, reinforces—better use of market data, clearer coordination across government ministries and levels, and earlier engagement with whole-of-market actors.

When strengthened and leveraged together, these four pillars may help countries move from fragmented, one-off prioritization and introduction processes to more transparent, coherent, and system-aligned decisions. Each pillar provides the infrastructure that allows policy, financing, and advocacy enablers to function:

Market data for decision-making	Portfolio-based logic	Whole-of-government coordination and capacity	Whole-of-market engagement
when systems bring together supply, demand, and system capacity data in accessible, trusted ways, policymakers and financiers are better equipped to weigh trade-offs and set priorities and policies more transparently and strategically.	when innovations are considered as part of portfolios, rather than one by one, policy and policy and financing enablers can reduce duplication, plan sequencing, and allocate resources more strategically.	when mechanisms align ministries, departments, and levels of government, policy and financing enablers can work in sync, ensuring that approvals, budgets, and implementation plans are coherent.	when civil society, professional associations, industry, implementing partners, and funders are engaged early and predictably, advocacy enablers can amplify population needs, reinforce accountability, and ensure alignment with delivery realities while financing enablers can be well-coordinated.

Together, these pillars provides the backbone that enables policy, financing, and advocacy functions to deliver more effective (responsive, fair, safe) and efficient (timely, streamlined, resource-conscious) innovation introduction decisions.

We summarize this logic in Box 4, offering a concise view of how each pillar can contribute to a more effective and efficient innovation introduction.

Box 4: Four core pillars that strengthen policy, financing, and advocacy enablers of effective, efficient innovation introduction

In this box, we provide a detailed overview of four interdependent pillars —market data, portfolio-based logic, whole-of-government coordination and capacity, and whole-of-market engagement—highlighting what each entails and how, by strengthening policy, financing, and advocacy enabling functions, they may contribute to more effective and efficient innovation introduction.
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When strengthened and leveraged together, these four pillars may help countries move from fragmented, one-off prioritization and introduction processes to more transparent, coherent, and system-aligned decisions. Each pillar provides the infrastructure that allows policy, financing, and advocacy functions to operate optimally.

Market data for decision-making: When systems bring together supply, demand, and system capacity data in accessible, trusted ways, stakeholders can make policy and financing choices transparently and strategically by weighing trade-offs. In turn, this transparency can anchor advocacy actions.

Portfolio-based logic: When innovations are considered as part of portfolios rather than one by one, policy and financing functions can plan sequencing, reduce duplication, and allocate resources more coherently. Clear portfolio rationales also create an advocacy platform for explaining why some innovations are prioritized while others are delayed or declined.

Whole-of-government coordination and capacity: When mechanisms align ministries, departments, and levels of government, policy and financing processes are synchronized—ensuring that approvals, budgets, and rollout plans reinforce one another. Such coherence creates clearer entry points for advocacy, as stakeholders can track and respond to decisions across the system.

Whole-of-market engagement: When civil society, professional associations, industry, implementing partners, and funders are engaged early and predictably, financing choices are better aligned with delivery realities, and policy decisions are more feasible to implement. Engagement also strengthens advocacy by creating channels for population needs and accountability demands to shape introduction decisions.

Together, these pillars provide the backbone for policy, financing, and advocacy functions to deliver innovation introduction decisions that are more effective (data-driven, fair, safe) and more efficient (timely, streamlined, resource-optimizing).

To test this approach, the three pathfinder countries—Kenya, Senegal, and South Africa—will apply these principles to strengthen the environments for health innovation introduction. One possible area for initial exploration, if consistent with country priorities, is long-acting injectables (LAIs). LAIs represent a diverse portfolio with applications across HIV prevention and treatment, family planning, malaria prevention, and chronic disease management. This diversity makes them a useful example for examining whether cross-product, coordinated, and data-informed prioritization can improve innovation introduction—while recognizing that countries will ultimately determine which innovation areas best align with their national strategies and priorities.

Where national stakeholders can start

What is needed next is not a new structure, but a shift in how existing systems function and in how they draw on, strengthen, and connect available pillars. Many countries already have planning platforms, dashboards, review groups, or coordination bodies in place—at least on paper. The opportunity is to adapt and leverage these pillars so that they reinforce policy, financing, and advocacy actions that ensure effective, efficient innovation introduction.

We start this section by outlining near-term starting points for strengthening and connecting each pillar. While progress on any one pillar may add value independently, the greatest impact is likely when they are strengthened together. We emphasize adapting and activating pillars rather than prescribing new structures or forms, recognizing that countries will, and should, tailor approaches to fit their contexts, build on existing capacities, and respond to political-economic realities.

In Table 3, we summarize early opportunities, first steps, and expected system gains for each pillar. The remainder of this section then describes practical entry points and examples in more detail, one pillar at a time.

Table 3: Starting points and near-term actions for strengthening pillars that support strong innovation introduction

In this table, we provide practical entry points and immediate actions national stakeholders can take to strengthen each of the four pillars. We also outline near-term shifts and potential system gains that, by reinforcing policy, financing, and advocacy functions, contribute to more strategic and efficient innovation introduction.

Pillar	Existing opportunities to build on	Near-term entry points / actions	How the pillar strengthens enablers	Early shifts in practice	System gains over time	Contribution to introduction decisions
Market data for decision-making	• Existing dashboards, scorecards, pipeline trackers • Routine data platforms tied to programs or funders • Emerging health technology management systems	• Map available data sources and decision moments (budgeting, procurement, guideline updates) • Identify information gaps, timing misalignments, and capacity needs • Engage decision-makers in co-design of comparative prioritization and planning tools • Pilot simple matrices linking pipeline, demand, and system readiness	• Makes policy and financing processes more evidence-informed, enabling trade-off analysis and comparative prioritization • Anchors advocacy in transparent, trusted information flows	• Comparative tools introduced to clarify trade-offs and align budgets • Data linked more explicitly to prioritization and financing discussions • Greater user demand for credible, decision-relevant data	• Comparative planning tools reused across cycles and portfolios • Data seen as legitimate and embedded in national decision platforms • Routine integration of private sector and subnational data	• Prioritization and rollout-readiness decisions become more transparent and strategic • Resources allocated in ways that reflect supply, demand, delivery capacity, and trade-offs • Greater ability to say "no" or "not yet" when data show misalignment
Portfolio-based logic for prioritization and planning	• Existing planning platforms, investment cases, or program-specific scorecards • *Ad hoc* and pilot bundling efforts (*e.g.*, joint vaccine campaigns) • Innovation review committees in some settings	• Scan pipeline to identify innovations, delivery platforms, target populations, and system requirements • Map overlaps, duplications, or conflicts across current introduction processes • Co-develop principles for grouping, sequencing, or bundling innovations • Pilot matrices that align products by platform, cost, or readiness	• Makes policy and financing processes more coherent by structuring side-by-side comparisons • Improves sequencing of approvals, financing, and rollout • Creates clearer advocacy narratives to explain why some innovations are prioritized while others are delayed or declined	• Side-by-side comparisons introduced into prioritization discussions Rollout readiness • Coordinated planning across procurement, delivery chain, training, and rollout timelines	• Shared portfolio logic applied across ministries and levels of government • Portfolio reviews routinized as part of prioritization cycles • Growing political legitimacy for structured trade-off analysis	• Introduction decisions become more strategic, system-aligned, and transparent • Duplication reduced across financing, training, and delivery planning processes • Countries better able to plan phased rollouts and say "no" or "not yet" when innovations exceed current capacity or offer insufficient improvement over status quo

Whole-of-government coordination and capacity	• Existing coordination platforms (*e.g.*, Inter-Agency Coordinating Committees, Health Sector Working Groups, delivery units) • Budgeting and planning forums across ministries • Emerging HTA structures and advisory panels	• Map formal and informal coordination processes across ministries and levels of government • Identify mandate, timing, incentive, and participation gaps • Test coordination mechanisms around a shared innovation portfolio • Clarify roles and responsibilities in decentralized systems	• Aligns policy and financing processes by sequencing approvals, budgets, and rollout planning • Reduces fragmentation across ministries and levels of government • Strengthens advocacy by creating clearer accountability mechanisms	• Shared roadmaps and timelines across ministries and verticals • Fewer breakdowns between regulatory approval, budget *al*location, and procurement • Greater clarity of roles across levels of government	• Coordination routinized with clear mandates, defined decision rights, and shared review points • Platforms embedded in budget and planning cycles • Enhanced legitimacy and responsiveness of decision processes	• More coherent introduction decisions across disease areas and populations • Better alignment between national approvals, financing flows, and subnational implementation • Reduced duplication, delays, and misaligned priorities
Whole-of-market engagement	• Existing stakeholder platforms, technical working groups, and partner coordination forums • Informal networks with influence on delivery, advocacy, or procurement • Community scorecard and accountability processes in some countries	• Map stakeholder roles, incentives, interests, influence, and engagement points • Identify actors responsible for delivery, financing, and shaping expectations • Clarify which engagement mechanisms are already functioning and where gaps remain • Link engagement opportunities to real decision cycles (budgeting, guideline development, rollout planning)	• Makes policy, financing, and advocacy actions more transparent and accountable • Improves alignment of decisions with delivery realities and community demand • Strengthens advocacy by embedding diverse voices earlier in decision processes	• Stakeholders engaged earlier and more predictably • Input shapes rollout plans, not just communication • Improved trust, transparency, and cross-sector alignment	• Engagement routinized and tied to accountability processes • Civil society and private sector roles formalized in introduction planning for alignment • Transparent dashboards or mechanisms track commitments and follow-through	• Introduction decisions better reflect delivery capacity and population needs • Uptake improved through earlier problem-solving with implementers • Accountability for follow-through strengthened across government and partners

Market data for decision-making

Portfolio-based logic and evidence-informed decision-making is only as strong as the information that supports it. To prioritize and sequence innovations effectively, countries need data systems that inform real-time decision-making, not just post-hoc monitoring. Strengthening this pillar means ensuring that market data are timely, trusted, and structured in ways that allow comparative analysis and alignment with budgeting, procurement, and rollout-readiness decisions.

Strengthening this pillar begins with mapping what data already exist, where they sit, and how they are—or are not—used. Most countries have some combination of supply-side data (*e.g.*, pipeline visibility, product registration, procurement flows) and demand-side data (*e.g.*, disease burden, service use, population preferences). Yet these data often remain fragmented by program, donor, or system function.

Early actions include identifying decision moments—such as budgeting, procurement, or guideline updates—and assessing whether available data are accessible, current, and structured to support cross-innovation comparison. In many cases, the challenge is not a lack of data, but a lack of alignment between data systems and decision processes.

Market data systems become decision-relevant when they help answer practical questions such as:

- Which innovations are likely to enter the pipeline soon?
- Which populations would benefit most?
- At what point in the continuum of care is this innovation relevant?
- What delivery requirements must be addressed?
- How does the cost or expected impact of one innovation compare with others under consideration and with those already approved and in use?

Governments can work with planners and analysts to determine which data tools are most useful and legitimate for informing innovation decisions. Even simple dashboards or planning matrices—when co-designed with end users and aligned to real decision cycles—can unlock more strategic use of existing information.

Some countries are already advancing this agenda. In India, innovation review committees incorporate pilot data on performance, feasibility, and equity to inform public financing decisions (MoHFW & NHSRC 2022). In Malawi and Kenya, RMNCAH scorecards have been adapted to guide budget planning and investment prioritization. These efforts show that when market data are linked to actual processes—and perceived as credible—they can reshape how decisions are made. In Zambia, the Ministry of Health used insights from its health technology management system to identify which oxygen concentrator models were feasible to scale given power and maintenance constraints. This avoided procurement mismatches and supported more appropriate scale-up strategies in response to oxygen needs (Clinton Health Access Initiative 2023).

> *Ultimately, strengthening this pillar is not about collecting more data. It is about designing systems that integrate relevant data sources, align with decision cycles, and support comparative, forward-looking prioritization and planning.*

Portfolio-based logic

Portfolio-based logic is a possible and practical entry point for moving from reactive, one-by-one decisions to more strategic, system-aligned innovation introduction. Many countries already have planning platforms or scorecards—focused on single programs or products—that may provide initial guides for portfolio thinking as a systematic pillar. Strengthening this pillar may not require new institutions; early progress is often possible by repurposing and reorienting existing tools and processes.

Governments and their partners can begin by scanning the pipeline of innovation—identifying product features, delivery platforms, target populations, points of care, and system requirements. This horizon-scanning exercise can highlight where evaluation, financing, and deployment processes are duplicated or poorly sequenced, while also clarifying a grouping logic that reflects delivery capacity and system realities.

From there, countries can co-develop shared principles for prioritization and sequencing, building on existing processes and frameworks. These may include bundling products that use similar supply chains, staggering introductions to reduce provider training burdens, or coordinating timelines across disease areas. Even simple matrices—categorizing innovations by platform, cost, or readiness—can make trade-offs visible and support phased rollout planning.

Some countries have already begun moving in this direction. India and Ethiopia, for example, use national innovation review committees to assess multiple product candidates side by side. These bodies weigh cost, feasibility, equity, and system readiness—helping ministries align innovation choices with implementation capacity and broader health goals (MoHFW & NHSRC 2022).

> *The shift to portfolio-based logic requires a change in mindset, from responding to innovation opportunities as they arise to managing them as a coordinated pipeline. Done well, this approach enables countries to use limited resources more strategically, reduce duplication, and prepare systems for sustained introduction over time.*

Whole-of-government coordination and capacity

Introducing health innovations depends on coordinated action across government—linking regulators, budget authorities, procurement officials, technical experts, and operational managers. When these actors work in silos, even high-priority innovations can stall. Strengthening this pillar does not require creating new institutions, but rather clarifying roles and incentives, aligning timelines and planning processes, and making better use of existing coordination platforms.

A practical starting point is to map how coordination currently happens—formally and informally—across ministries and levels of government. This includes identifying:

- Which platforms (*e.g.*, inter-agency committees, health sector working groups) already exist
- What types of decisions they should (by mandate)—and do—influence
- How those platforms connect to budgeting, planning, and procurement cycles
- Where coordination tends to break down

In Ethiopia, the Ministry of Health has convened cross-departmental learning sessions and embedded research partnerships to link strategic planning with operational realities. In Senegal, municipal reforms have improved alignment between national policy decisions and subnational execution, helping to synchronize priorities and rollout timelines. In Kenya, embedded implementation research during COVID-19 placed academic teams within county health departments to adapt national guidance in real time—surfacing bottlenecks and testing operational solutions before rollout. This approach reduced friction between levels of government and has since been extended to neonatal infection management, showing how embedded learning can strengthen coordination under both crisis and routine conditions (Peters *et al*. 2023).

> *Decentralized systems often face vertical fragmentation, where national priorities are disconnected from local delivery capacity or authority. Clarifying who is responsible for what—and when—can reduce duplication, strengthen accountability, and enhance the legitimacy of introduction decisions.*

The goal is not to add new bureaucratic layers nor to create new verticals, but to catalyze structured, routinized collaboration that aligns regulatory approval, budgeting, procurement, and system preparation and capacities. Coordination platforms that operate with clear mandates, defined decision rights, and timing aligned to key processes—especially when tested on a concrete innovation portfolio—are more likely to generate durable system gains.

Whole-of-market engagement

Innovation introduction succeeds not only when governments are prepared, but also when implementers, providers, civil society, and private sector actors are informed, engaged, and aligned. Strengthening this pillar means treating engagement not as a one-off consultation or communication exercise, but as a system function with defined tools, timing, and structures.

When whole-of-market engagement is weak, decisions risk being misaligned with delivery realities, financial flows, or population priorities. When it is strong, it helps ensure that financing, policy, and advocacy actions are better coordinated, more transparent, and more accountable.

A practical starting point is to identify:

- Who needs to be at the table (*e.g.*, civil society, industry, professional associations, implementers, providers, local leaders)
- What decisions they are being asked to inform (*e.g.*, prioritization, product choice, capacity strengthening)
- When and how they can engage meaningfully (*e.g.*, before budget finalization, during adaptation of guidelines or tools)

In Kenya, multi-stakeholder platforms for reproductive, maternal, newborn, child, and adolescent health (RMNCAH) have become trusted forums for aligning government, donors, civil society, and private providers around shared priorities and rollout plans (UNICEF 2017; Gatome-Munyua *et al.* 2022). Their credibility rests on recurring engagement, data sharing, and visible responsiveness to partner input.

In Malawi, scorecard processes have enabled local actors and civil society to review service data and hold implementers accountable. Yet these insights are rarely connected back to national innovation planning—limiting their influence on product choice, financing, or rollout design (van Pinxteren *et al.* 2022; WHO QoC Network 2023).

Globally supported platforms often focus on advocacy or coordination without establishing mechanisms for feedback, revision, or accountability. For engagement to improve outcomes, it must be tied to real decisions—such as budgeting, procurement timelines, or guideline finalization.

> *Governments can take practical steps to embed this function: ensuring diverse participation in review processes, publishing draft rollout plans with opportunities for comment, using implementation data to trigger feedback loops, and co-designing training or communication tools with frontline actors. Ultimately, whole-of-market engagement is not about consensus, it is about coherence and accountability, with stakeholders understanding the rationale, shaping the approach, and trusting the process.*

In some settings, national comparator tools—such as regulatory benchmarking frameworks or innovation system scorecards—have helped bring visibility to system readiness and strengthen accountability across stakeholders. The WHO Global Benchmarking Tool, for example, enables regulators and partners to assess regulatory maturity and identify system gaps, creating a shared basis for investment and reform (WHO 2021). Similarly, RMNCAH/RMNCH scorecards used in countries like Kenya and Malawi have empowered civil society and subnational implementers to surface bottlenecks and track progress—mobilizing co-responsibility for performance improvement (Nemser *et al*. 2018; WHO 2023). When referenced by civil society, implementers, or funders, these tools can reveal coordination challenges, improve transparency, and establish shared expectations for innovation readiness and follow-through.

What may shift next

Taking initial steps to strengthen these pillars does not guarantee better innovation decisions, but it increases the likelihood that choices will be more timely, transparent, and aligned with national priorities and system realities. Early signs of change may include:

- **More deliberate prioritization processes**, with innovations compared side by side using structured criteria and informed by both market data and system readiness
- **Improved coherence across decision types**, with clearer alignment between regulatory approvals, budgeting, procurement, and rollout planning
- **More strategic sequencing and bundling of innovations**, reducing duplication in training, financing, and supply chain efforts
- **Greater ability to say "no" or "not yet"** to promising innovations when system capacity is insufficient or a good enough option is available
- **Earlier and more consistent engagement with whole-of-market actors**, including civil society, private providers, and implementing partners
- **More transparent adaptation of rollout strategies** based on subnational feedback or early implementation learning
- **Stronger coordination across government units and levels**, reducing policy–practice gaps and misaligned timelines

As these shifts take hold, countries may become better equipped not only to respond to external innovation opportunities, but also to shape, pace, and align them with national goals. When processes are more transparent and decisions more systematic, innovation introduction can become governable, repeatable, and trustworthy.

Box 5: Initiative goals and definition of success

In this box, we describe the overarching goal of the ALIGN Consortium's work: to test whether and how countries can strengthen key pillars that reinforce policy, financing, and advocacy enablers of effective, efficient innovation introduction in practical, context-specific ways. It defines success in terms of decision quality, participation, and learning—not product counts.
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The overarching goal of this initiative is to test whether and how countries can strengthen key pillars that, in turn, reinforce policy, financing, and advocacy enablers of effective, efficient innovation introduction.

Success is defined not by the number of products introduced, but by improvements in how decisions are made and sustained.

Over the next 2.5 years, we will demonstrate success when:

- Prioritization, financing, and rollout-readiness decisions are more timely, transparent, and aligned with national priorities
- Decision-making processes are more deliberate, data-informed, structured, and coherent across government levels and sectors
- Civil society, industry, professional associations, private providers, and other stakeholders participate earlier and more consistently in shaping and monitoring introduction decisions
- Systems demonstrate capacity for learning, adaptation, and accountability in real time

Ultimately, success means stronger country systems for innovation introduction—systems that are more effective (system-aligned, fair, safe) and more efficient (timely, streamlined, resource-optimizing).

Why these shifts matter

The early shifts described above—clearer timelines, more deliberate trade-offs, and earlier engagement—are meaningful achievements on their own. They also signal a deeper transition: from fragmented, reactive decision-making to stronger policy, financing, and advocacy functions supported by core pillars.

These shifts matter because they strengthen the systems that determine how innovations are prioritized, how resources are aligned, and how rollout-readiness decisions are made. Shared timelines, bundled planning, and sequenced review processes become repeatable templates in a toolkit that reduces friction, clarifies trade-offs, and improves coherence. Even modest improvements in market data use, coordination platforms, or stakeholder engagement can lead to more timely, evidence-informed, and systematic choices, making better use of limited resources. A recent scoping review of vaccine introduction decisions in LMICs confirms that disease burden, cost, financing, and communication factors consistently shape policymakers' choices, underscoring the need for structured, transparent processes (Guillaume *et al*. 2023).

These shifts also lay the groundwork for broader system change. While rollout and uptake are beyond the direct scope of this initiative from the ALIGN Consortium, stronger pillars and enablers increase the likelihood that downstream processes unfold more smoothly. When budgeting and procurement are coordinated, financing gaps shrink. When civil society and industry are engaged earlier, introduction plans are more realistic. And when comparative tools are applied to assess innovations, systems are better positioned to allocate resources where they will have the greatest impact.

Evidence from prior reforms supports this logic. Countries that have institutionalized tools such as scorecards, investment planning frameworks, or cross-sector coordination platforms—like Kenya, Malawi, and Thailand—have documented gains in planning alignment, budget efficiency, and stakeholder trust. These are not access outcomes in themselves, but they reduce the structural friction that delays and distorts introduction. More broadly, systems governance research suggests that even incremental improvements to coordination, decision rights, and data use can strengthen responsiveness, legitimacy, and long-term adaptability (OECD 2018; UNDP 2023; Kovach 2022).

➡ Most importantly, these shifts help make innovation introduction more routine and strategic. When prioritization is structured, coordination is predictable, and decisions are transparent, introduction becomes governable—not reliant on individual champions or external pressure but embedded in system functions. The result is both greater effectiveness—decisions that better reflect country priorities, capacities, and values—and improved efficiency—reducing duplication, delay, and waste during the critical introduction phase.

What comes after

Some of the most meaningful outcomes of this initiative will take shape beyond the initial 2.5-year project window. If the early shifts described above—clearer prioritization, better coordination, more predictable engagement, and more systematic decision-making—take hold, they can lay the foundation for a more strategic and sustainable approach to innovation introduction.

Over time, we expect to see stronger alignment between national strategies and the innovation pipeline. Prioritization processes may evolve from one-off choices to structured cycles that integrate market data, delivery realities, and cross-sector input. Budgeting and planning may become more synchronized, reducing the gaps between approvals and implementation. Coordination platforms may gain clearer mandates, enabling policy and financing enablers to align not just actors but also timelines and decisions.

As systems mature, they may also shift how success is defined. Instead of focusing narrowly on the number or speed of introductions, countries may ask how well innovations fit population needs, align with system readiness, and contribute to broader goals such as resilience, financial protection, and fairness.

Portfolio-based logic can support this transition by helping governments plan across products, platforms, and constraints. But portfolios must remain tools—not straitjackets. Experience from Gavi, PATH, and others suggests that overly rigid frameworks can slow decisions or exclude high-value innovations that do not fit neatly into predefined categories. For portfolio logic to be useful, it must support—not constrain—deliberate, adaptable planning.

The integration of market data may also become more sophisticated. Countries may begin combining global pipeline insights with local needs assessments and readiness indicators, creating systems that enable more proactive preparation for upcoming innovations.

Whole-of-government coordination mechanisms may evolve from periodic meetings into institutionalized processes where approvals, budgets, and implementation planning are synchronized by design.

Likewise, **whole-of-market engagement** may shift from consultative to collaborative—giving civil society, private providers, and implementing partners defined roles in shaping strategies and monitoring follow-through.

Ultimately, innovation introduction may become a governable, repeatable system function, not reliant on global attention or individual champions, but embedded in how countries prioritize, plan, and act. Change will not be uniform nor linear, but even incremental improvements in how pillar are strengthened and enablers reinforced can reshape systems for introduction, making decisions more effective (priority-aligned, system-responsive, fair, safe) and efficient (timely, streamlined, resource-conscious).

Box 6: Core activities of the ALIGN Consortium

In this box, we outline the approach the ALIGN Consortium will take and test be in Kenya, Senegal, and South Africa to support government-led change. We emphasize adaptation of existing structures, a focus on real decision points, and a commitment to co-developing tools and processes that improve coherence, effectiveness, and efficiency.

This initiative is designed to strengthen key pillars that underpin policy, financing, and advocacy enablers of effective, efficient innovation introduction. Activities focus on supporting governments in practical, context-specific ways—adapting what already exists, targeting real decision points, and embedding cycles of learning and accountability. What is being tested is not a new structure, but a new way of working: one that makes innovation introduction more coherent, effective, and efficient.

Core ALIGN Consortium activities include:

- **Aggregate, adapt, and deploy market intelligence and insights:** Develop and strengthen hubs and tools that integrate supply, demand, and system capacity data; support governments in using them for proactive prioritization and planning.

- **Provide technical tools, training, and assistance:** Deliver frameworks, scorecards, capacity-strengthening, and practical toolkits on technical topics, policy options, portfolio logic, and advocacy skills (*e.g.*, framing trade-offs, communicating decisions).

- **Facilitate whole-of-government coordination:** Strengthen and align existing platforms that connect ministries and levels of government, ensuring priorities, financing, and timelines are coherent and mutually reinforcing.

- **Facilitate whole-of-market engagement:** Strengthen and align existing platforms that connect government, civil society, industry, professional associations, private providers, and funders early and predictably so that introduction decisions reflect delivery realities, population needs, and accountability requirements.

- **Embed learning and adaptation:** Establish regular cycles of evidence capture, reflection, cross-country exchange, and improvement; co-develop toolkits and guides that sustain capacity and change beyond ALIGN's direct support.

In these activities, we are guided by core principles as we pursue clarity in decision making, coherence in rollout planning, and consistency in learning and adaptation:

- **Build on and mobilize what already exists** (dashboards, review forums, coordination bodies, stakeholder platforms)

- **Focus on real government decision points** (budget windows, planning timelines, prioritization cycles)

- Treat **data and portfolio-based approaches** as cross-cutting enablers, not standalone tools
- Approach **coordination and engagement** as practical mechanisms, not abstract ideals
- **Define success** by how decisions are made, who participates, and whether processes become more transparent, timely, and strategic

While this investment focuses on three pathfinder countries, it is designed to generate actionable insights and adaptable tools. These can be applied to additional innovation portfolios within those countries and, potentially, scaled across other geographies—supporting parallel shifts in regional and global processes that shape how innovation priorities are set and supported.

Conclusion

Health innovation is advancing faster than ever, but decision-makers in low- and middle-income countries face a growing dilemma: how to decide among more innovations, more quickly, with fewer resources and greater public ownership. Ministers and senior officials are under pressure to do more with less—to prioritize innovations wisely, finance them sustainably, and ensure rollout-readiness—all while maintaining legitimacy, trust, and fairness. Too often, they are asked to make these choices without the data, coordination, or engagement needed to act decisively and coherently. The result is duplication, delay, and misalignment, measured not only in wasted resources but also in lives lost and trust eroded.

In this paper, we have laid the foundation for addressing that dilemma. We argue that effective, efficient innovation introduction depends on four mutually reinforcing pillars: market data for decision-making, portfolio-based logic, whole-of-government coordination and capacity, and whole-of-market engagement. These pillars strengthen the policy, financing, and advocacy enablers that shape whether and how decisions are made. Together, they provide the means for countries to move from fragmented, one-off choices to more transparent, timely, and strategic decisions about which innovations to adopt, defer, or decline.

The ALIGN Consortium's role is to support governments in meeting this decision-making challenge. We do not propose new structures, but instead adaptation and activation of what already exists—planning platforms, coordination bodies, and stakeholder forums—so they function more effectively under pressure. Our activities include aggregating and adapting market intelligence, providing technical tools, training, and assistance, facilitating whole-of-government and whole-of-market coordination, and embedding cycles of learning and adaptation. Guided by core principles, we emphasize focusing on real decision points, treating data and portfolio approaches as cross-cutting enablers, and defining success by the quality, transparency, and inclusiveness of decisions.

Over the next 2.5 years, progress will not be judged by the number of products introduced, but by whether countries demonstrate stronger pillars and enablers: decisions that are deliberate, data-informed, and coherent across levels of government and sectors; civil society and private actors engaged earlier and more consistently; and systems that show capacity to learn and adapt in real time. Even incremental shifts will signal progress toward resolving the decision-maker dilemma—reducing the gap between what is possible in the pipeline and what is delivered at the front line.

With urgency, humility, and a commitment to learning, we aim to help governments build systems that can manage the demands of doing more with less. Strengthening pillars and enablers for innovation introduction can make decisions more effective (aligned with needs, safe, fair) and more efficient (timely, streamlined, resource-conscious). Done well, this work will shorten the distance between promising innovations and the populations they are meant to protect, ensuring that every introduction decision maximizes health value.

Glossary

Acronym	Expansion
CSO(s)	Civil Society Organization(s)
EPI	Expanded Programme on Immunization
Gavi	Gavi, the Vaccine Alliance
HTA	Health Technology Assessment
ICT	Information and Communications Technology
LAI(s)	Long-Acting Injectable(s)
LMIC(s)	Low- and Middle-Income Country(ies)
NCD(s)	Noncommunicable Disease(s)
PATH	PATH (formerly Program for Appropriate Technology in Health)
R&D	Research and Development
RMNCAH	Reproductive, Maternal, Newborn, Child, and Adolescent Health
UNFPA	United Nations Population Fund
UNICEF	United Nations Children’s Fund
USAID	United States Agency for International Development
WHO	World Health Organization

References

Abbott FM, Sampath PG. A competition law approach to accessing insulin: a working paper. New York: United Nations Development Programme; 2022. Available from: https://uniatf.who.int/docs/librariesprovider22/default-document-library/undp-a-competition-law-approach-to-accessing-insuling-a-working-paper.pdf

Adebisi YA, *et al*. The African Medicines Agency and medicines regulation: progress, challenges, and recommendations. Front Med. 2023;10:1176349.

Adjagba, A.O., Oguta, J.O., Akoth, C. et al. Sustainability starts with spending: public financial management lessons from Kenya's universal health care pilot. BMC Health Serv Res 25, 1029 (2025). https://doi.org/10.1186/s12913-025-13194-7

Africa Centres for Disease Control and Prevention. Africa's health financing in a new era. Addis Ababa: Africa CDC; 2025.

Africa Centres for Disease Control and Prevention (Africa CDC). Digital transformation strategy 2023–2030. Addis Ababa: Africa CDC; 2023.

African Union Development Agency – NEPAD. Call for industry applications of mpox candidate medicinal products for expedited evaluation by the evaluation of medicinal products technical committee. 2024. Available from: https://www.nepad.org/publication/call-industry-applications-mpox-candidate-medicinal-products-expedited-evaluation

Ahonkhai V, Martins SF, Portet A, Lumpkin M, Hartman D. Speeding access to vaccines and medicines in low- and middle-income countries: a case for change and a framework for optimized product market authorization. PLoS One. 2016;11(11):e0166515.

Appleford G, Cocozza A, Nabyonga-Orem J, Clarke D. How to better engage the private sector in health service delivery in Africa. BMJ Glob Health. 2023 Dec 16;8(Suppl 5):e013046. doi: 10.1136/bmjgh-2023-013046. PMID: 38103893; PMCID: PMC10729254.

AUDA-NEPAD. African medicines regulatory harmonization initiative. 2024.

Ba, A., Loko Roka, J., Ndiaye, M. et al. Evaluating Senegal's COVID-19 surveillance system for early detection and response: lessons from the Keur Massar district, March 03, 2020 to May 31, 2022. BMC Public Health 24, 3246 (2024). https://doi.org/10.1186/s12889-024-20692-6

Barasa E, *et al*. Examining the influence of health sector coordination on the efficiency of county health systems in Kenya. BMC Health Serv Res. 2023;23(1):1160.

Barasa E, Nyawira L, Musiega A, *et al*. The autonomy of public health facilities in decentralised contexts: insights from applying a complexity lens in Kenya. *Health Policy Plan*. 2023; 38(5): 631–647. doi:10.1093/heapol/czad021

Barasa E, Mbau R, Gilson L. Examining the influence of health sector coordination on the implementation of universal health coverage in Kenya. BMC Health Serv Res. 2018;18(1):1-11.

Barroy H, Yameogo P, Blecher M, Sabignoso M, Piatti M, Kutzin J. Public financial management: a pathway to universal health coverage in low- and middle-income countries. *Health Syst Reform.* 2024;10(3):2368051. doi:10.1080/23288604.2024.2368051.

Baltussen, R., Jansen, M. P., Mikkelsen, E., Tromp, N., Hontelez, J., Bijlmakers, L., & Van der Wilt, G. J. (2016). Priority Setting for Universal Health Coverage: We Need Evidence-Informed Deliberative Processes, Not Just More Evidence on Cost-Effectiveness. *International journal of health policy and management*, *5*(11), 615–618. https://doi.org/10.15171/ijhpm.2016.83

Bossert TJ. Analyzing the decentralization of health systems in developing countries: decision space, innovation and performance. Soc Sci Med. 1998;47(10):1513-27.

Chaitkin, Michael, Nathan Blanchet, Yanfang Su, Rebecca Husband, Pierre Moon, Andrea Rowan, Steve Gesuale, Candice Hwang, Paul Wilson, and Kim Longfield. Integrating Vertical Programs into Primary Health Care: A Decision-Making Approach for Policymakers. Washington, DC: Results for Development, 2019.

Chalkidou, K., Li, R., Culyer, A. J., Glassman, A., Hofman, K. J., & Teerawattananon, Y. (2016). Health technology assessment: Global advocacy and local realities: comment on" priority setting for universal health coverage: We need evidence-informed deliberative processes, not just more evidence on cost-effectiveness". *International Journal of Health Policy and Management*, *6*(4), 233.

Clinton Health Access Initiative. https://www.clintonhealthaccess.org/wp-content/uploads/2024/11/CHAI-Annual-Report-2023-English.pdf.

COVID Global Accountability Platform (COVID-GAP). Pills to people: accelerating equitable global access to oral therapeutics for COVID-19. Duke Global Health Innovation Center; 2023.

Daniels N, Sabin J. *Setting Limits Fairly: Learning to Share Resources for Health.* 2nd ed. New York: Oxford University Press; 2008.

Deming WE. Out of the crisis. Cambridge (MA): MIT Press; 1982. Reissued 2018.

Erku, D., Walker, D., Caruso, A. A., Wubishet, B., Assefa, Y., Abera, S., Hailu, A., & Scuffham, P. (2023). Institutionalizing health technology assessment in Ethiopia: seizing the window of opportunity. *International journal of technology assessment in health care*, *39*(1), e49. https://doi.org/10.1017/S0266462323000454

Federal Ministry of Health (FMOH). Health sector transformation plan II: 2020/21–2024/25. Addis Ababa: FMOH; 2021.

FHI 360. Evaluation of HSS pilot in Senegal: final report. Washington, DC: FHI 360; 2023.

Frazer H, *et al*. Municipal engagement in health planning in Senegal. J Public Health Policy. 2021.

Gatome-Munyua A, *et al*. Applying the strategic health purchasing progress tracking framework: lessons from nine African countries. Health Syst Reform. 2022;8(2):e2051796.

Gautier L, Ridde V. Health financing policies in sub-Saharan Africa: government ownership or donors' influence? A scoping review of policymaking processes. Glob Health Res Policy. 2017;2(1):23.

Gavi, the Vaccine Alliance. Vaccine investment strategy 2021–2025: white paper. Geneva: Gavi; 2021.

Georgieva K. Strengthening global solidarity for development financing. Statement by the Managing Director of the IMF; 2024.

Ghaffar A, *et al*. Reflections on the African Health Initiative: the role of embedded implementation research. Glob Health Sci Pract. 2022;10(Suppl 1):S144-S153.

GHTC. Addressing regulatory challenges through the product development process. Global Health Technologies Coalition; 2023.

Gill T, King L, Webb G. Obesity prevention: necessary and possible—a structured approach for effective planning. Proc Nutr Soc. 2005;64(1):123-130.

Global Health eLearning Center. Total Market Approach: a primer. Washington, DC: USAID; 2023. Available from: https://www.globalhealthlearning.org/course/total-market-approach

Goldmann, D., Rajan, S., & Udayakumar, K. (2024). Preventing and controlling global antimicrobial resistance—Implementing a whole-system approach. New England Journal of Medicine, 391(8), 681-685.

Gordon WS, Jones A, Madan K, Seward JF, Chunsuttiwat S, Zipursky S, *et al*. Introducing multiple vaccines in low- and lower-middle-income countries: issues, opportunities and challenges. Health Policy Plan. 2012;27(suppl_2):ii1-ii14.

Guillaume D, Burchett H, Griffiths U, Phillips M, Mumba N, Dawa J, *et al*. Factors influencing the prioritization of vaccines by policymakers in low- and middle-income countries: a scoping review. *Health Policy Plan.* 2023;38(3):363-76. doi:10.1093/heapol/czad002.

Hendricks CL, Alessandrini M, Pepper MS. Equitable access to cell and gene therapies in South Africa: opportunities and hurdles. Gene Ther. 2023;30:180-186. https://doi.org/10.1038/s41434-021-00309-y

IFPMA. Collaboration, convergence, and regulatory reliance. 2023.

IHME. GBD results tool (global burden of disease data for 2020). Seattle, WA: Institute for Health Metrics and Evaluation; 2023.

Ittaquera R, Ouedraogo N, Shayo E, *et al*. Conceptualization and practices in digital health: voices from Africa. J Health Inform Afr. 2022;9(Suppl):S65-S72.

Jamison DT, Summers LH, Alleyne G, *et al*. Global health 2035: a world converging within a generation. Lancet. 2013;382(9908):1898-1955.

Jansen, M., Spasenoska, D., Nadjib, M., Ararso, D., Hutubessy, R., Kahn, A. L., & Lambach, P. (2024). National Immunization Program Decision Making Using the CAPACITI Decision-Support Tool: User Feedback from Indonesia and Ethiopia. Vaccines, 12(3), 337. https://doi.org/10.3390/vaccines12030337

Koduah A, Boadi JA, Azeez JNK, Asare BA, Yevutsey S, Gyansa-Lutterodt M, Nonvignon J. Institutionalizing health technology assessment in Ghana: enablers, constraints, and lessons. Health Syst Reform. 2023;9(3):2314519. doi:10.1080/23288604.2024.2314519.

Kovach KA. A portfolio approach for innovation in public health: introducing the innovation for equity matrix. J Public Health Manag Pract Direct. 2022 Aug 2.

Kredo T, Cooper S, Abrams A, Daniels K, Volmink J, Atkins S. National stakeholders' perceptions of the processes that inform the development of national clinical practice guidelines for primary healthcare in South Africa. Health Res Policy Syst. 2018;16(1):68.

Surgey G, Mori AT, Baltussen R. Health Technology Assessment in Tanzania: Capacity and experience of HTA committee members. Journal of Global Health Economics and Policy. 2022;2:e2022004. doi:10.52872/001c.33116

Lal A, *et al*. Fragmented health systems in COVID-19: rectifying the misalignment between global health security and universal health coverage. Lancet. 2021;397(10268):61-67.

Leelahavarong P, Doungthipsirikul S, Kumluang S, Poonchai A, Kittiratchakool N, Chinnacom D, Suchonwanich N, Tantivess S. Health technology assessment in Thailand: institutionalization and contribution to healthcare decision making: review of literature. *International Journal of Technology Assessment in Health Care*. 2019; 35(6): 467–473. doi:10.1017/S0266462319000321

Lynch, S., Cohen, R. M., Kavanagh, M., Sharma, A., Raphael, Y., Pillay, Y., & Bekker, L. G. (2025). Lessons for long-acting lenacapavir: catalysing equitable PrEP access in low-income and middle-income countries. The lancet. HIV, 12(10), e722–e731. https://doi.org/10.1016/S2352-3018(25)00161-4

Makenga G, Mugambi ML, Saito S, *et al*. Accelerating regulatory harmonization in the East African Community: progress and lessons from joint assessment procedures. BMJ Glob Health. 2024;9:e013456. doi:10.1136/bmjgh-2023-013456

Management Advisory Committee. *Connecting Government: Whole-of-Government Responses to Australia's Priority Challenges.* Canberra: Australian Public Service Commission; 2004. https://catalogue.nla.gov.au/catalog/3107904

Mbuthia, D., Willis, R., Gichagua, M., Nzinga, J., Mugo, P., & Murphy, A. (2025). Acceptability of fixed-dose combination treatments for hypertension in Kenya: A qualitative study using the Theoretical Framework of Acceptability. PLOS global public health, 5(3), e0003012. https://doi.org/10.1371/journal.pgph.0003012

Mao W, Cooke R, Silimperi D, Hodges EU, Ortiz E, Udayakumar K. Scaling malaria interventions: bottlenecks to malaria elimination. BMJ Glob Health. 2023;8:e013378. doi:10.1136/bmjgh-2023-013378

Mao W, Urli Hodges E, Zimmerman A, Ortiz EJ, Kilburn K, Silimperi D, Udayakumar K. Development, launch, and scale-up of health products in low-income and middle-income countries: a retrospective analysis on 59 health products. Lancet Glob Health. 2025 Jun;13(6):e1132-e1139.

Mao W, Olson K, Urli Hodges E, Udayakumar K. Progress, impacts and lessons from market shaping in the past decade: a systematic review. Frontiers in Public Health. 2025 Aug 21;13:1614471

Mbau R, Vassall A, Gilson L, Barasa E. Factors influencing institutionalization of health technology assessment in Kenya: a case study. BMC Health Serv Res. 2023;23:681. doi:10.1186/s12913-023-09673-4.

McAdams D, Raju E. Challenges in international health financing and implications for the Pandemic Fund. Health Policy Plan. 2024;39(1):12-18.

Medicines Patent Pool. Annual report 2022: expanding access through voluntary licensing. Geneva: MPP; 2023. Available from: https://medicinespatentpool.org/news-publications/resources/annual-report-2022

Ministry of Health and Family Welfare (MoHFW), National Health Systems Resource Centre (NHSRC). Innovation portal: health innovations under National Health Mission. New Delhi: MoHFW; 2022. Available from: https://nhsrcindia.org/health-innovation-portal

Ministère de la Santé et de l'Action Sociale du Sénégal (MoH Senegal). Politique nationale de santé numérique 2025. Dakar: République du Sénégal; 2025.

Moon S, Armstrong J, Hutler B, Upshur R, Katz R. Governing the Access to COVID-19 Tools Accelerator: towards greater participation, transparency, and accountability. Lancet. 2022;399(10322):179-181.

Mugabo H, *et al*. Assessing the adoption and utilization of the Rwanda COVID-19 Data Analytics System (RCAS): a mixed methods study. Oxf Open Digit Health. 2024;2(2):oqad034.

Muhoza P, Saleem H, Faye A, Diop I, Njai R, Mboup S, *et al*. Key informant perspectives on the challenges and opportunities for using routine health data for decision-making in Senegal. Gates Open Res. 2021;5:9.

Mulder M. South African medical device landscape analysis: strengthening innovation readiness and regulatory capacity. Pretoria: South African Medical Research Council; 2022.

Myers V, *et al*. Priority setting for health technology adoption at the national level: lessons from 25 years in Israel. Health Res Policy Syst. 2023;21(1):91.

Médecins Sans Frontières. Access (or not) to vaccines for mpox in Africa: a sense of déjà vu? 2024.

National Health Systems Resource Centre. Terms of reference for assessment committees on program and product innovations. New Delhi: NHSRC; 2023.

Nemser B, *et al*. Data-informed decision-making for life-saving commodities investments in Malawi: a qualitative case study. Malawi Med J. 2018;30(1):30-37.

Nyangena, J., Rajgopal, R., Ombech, E. A., Oloo, E., Luchetu, H., Wambugu, S., Kamau, O., Nzioka, C., Gwer, S., & Ndiritu Ndirangu, M. (2021). Maturity assessment of Kenya's health information system interoperability readiness. BMJ health & care informatics, 28(1), e100241. https://doi.org/10.1136/bmjhci-2020-100241

Nutley T, Reynolds HW. Improving the use of health data for health system strengthening. Glob Health Action. 2013;6(1):20001.

OECD. System approaches to public sector challenges: working with change. Paris: OECD Publishing; 2018. https://doi.org/10.1787/9789264279865-en

OECD. *Whole-of-Government Approaches to Fragile States. OECD Journal on Development.* 2008;8(3):179-228.

Oh E, *et al*. Strategies to promote the use of evidence in policymaking in LMICs: a scoping review. Health Res Policy Syst. 2022;20(1):26.

PATH. Research and development for health in Kenya. PATH; 2016.

PATH. How portfolio-based product development can accelerate progress in global health. Seattle: PATH; 2022.

PATH. Harmonized Africa health manufacturing platform meeting summary. Nairobi: PATH; 2023.

Peters MA, *et al*. Embedding implementation research to cross the quality chasm during COVID-19. BMJ. 2023;383:e076331.

Regional health innovation strategy for the Western Pacific. Manila: World Health Organization Regional Office for the Western Pacific; 2024. Licence: CC BY-NC-SA 3.0 IGO

Reich MR. The politics of health sector reform in developing countries: three cases of pharmaceutical policy. Health Policy. 1995;32(1-3):47-77

Reich MR, Yazbeck AS. *Politics and Health Sector Reform: The Political Dimensions of Health Reform.* World Bank; 2003.

Reich MR, Campos PA. "Applied Political Analysis for Health System Reform." Health Systems & Reform 10(3), 2024

Republic of South Africa, National Department of Health. National digital health strategy for South Africa 2019–2024. Pretoria: RSA NdoH; 2019.

Sandefur J, Kenny C. USAID cuts: new estimates at the country level. Washington (DC): Center for Global Development; 2025 Mar 26.

Seydi M. COVID-19 outbreak, Senegal, 2020. Emerg Infect Dis. 2020;26(11):2772-4.

Sillo H, Ambali A, Azatyan S, Chamdimba C, Kaale E, Kabatende J, *et al*. Coming together to improve access to medicines: the genesis of the East African Community’s medicines regulatory harmonization initiative. *PLOS Medicine*. 2020; 17(8): e1003133. doi:10.1371/journal.pmed.1003133

Spicer N, Agyepong IA, Ottersen T, *et al*. "It's far too complicated": why fragmentation persists in global health. Global Health. 2020;16(1):60.

Taylor A, Biru B, Udayakumar K. Creating an evidence engine to drive impact: lessons learned from real-time analysis for COVID-19 global response. Durham (NC): Duke Global Health Innovation Center; 2022

Tomlinson, M., Rotheram-Borus, M. J., Swartz, L., & Tsai, A. C. (2013). Scaling up mHealth: where is the evidence?. PLoS medicine, 10(2), e1001382.

Tsofa B, Molyneux S, Gilson L, Goodman C. How does decentralisation affect health sector planning and financial management? A case study of early effects of devolution in Kilifi County, Kenya. Int J Equity Health. 2017;16(1):151.

UK Foreign, Commonwealth & Development Office (UK FCDO). Statistics on international development: final UK aid spend 2022. London: FCDO; 2024.

UNDP. Strategic innovation portfolio playbook. United Nations Development Programme; 2023.

UNFPA. UNFPA supplies partnership: annual impact report 2023. New York: United Nations Population Fund; 2023. Available from: https://www.unfpa.org/sites/default/files/pub-pdf/Web_UNFPA%20Supplies%20Impact%20Report%202023.pdf

UNICEF. Use of the RMNCAH scorecard to strengthen data-driven service delivery in Kenya: progress report. Nairobi: UNICEF Kenya; 2017.

Unitaid. ACTwatch project summary: generating market intelligence for malaria diagnosis and treatment. Geneva: Unitaid; 2016.

Unitaid. Strategy 2023–2027: driving equitable access to innovation. Geneva: Unitaid; 2022.

UK Cabinet Office. *Modernising Government White Paper.* London: Her Majesty's Stationery Office; 1999.

United Nations Commission on Life-Saving Commodities for Women and Children. Commissioners' report. New York: United Nations; 2012.

United Nations General Assembly. *Transforming Our World: The 2030 Agenda for Sustainable Development.* Resolution adopted by the General Assembly on 25 September 2015, A/RES/70/1. New York: United Nations; 2015.

University of Gondar, WHO Alliance for Health Policy and Systems Research. Embedding implementation research to improve immunization systems in Ethiopia: learning from partnership and practice. Geneva: WHO AHPSR; 2023.

van Pinxteren M, *et al*. Using health information for community activism: Movement for Change and Social Justice (MCSJ) in South Africa. PLOS Glob Public Health. 2022;2(12):e0001293.

Verguet S, Neumann PJ, Nugent R, *et al*. Prioritising and financing health services in low-income and middle-income countries using modular cost-effectiveness analysis: a Lancet Commission. Lancet. 2024;403(10436):1311-1348.

Wafula FN, Goodman CA. Drug regulation in Kenya: the dilemma of public–private policy implementation. Health Policy Plan. 2010;25(5):357-365.

Wale JL, *et al*. Civil society and medical product access in Africa: lessons from COVID-19. Front Med Technol. 2023;5:1149841.

Waweru E, Goodman C, Odero W, Oortwijn W, Chalkidou K, Suleman F, *et al*. Institutionalising health technology assessment in Kenya: building the foundations for priority setting and resource allocation. BMC Health Serv Res. 2023;23:1255. doi:10.1186/s12913-023-09673-4.

WHO. Market Information for Access to Vaccines (MI4A): global vaccine market database. Geneva: WHO; 2023. Available from: https://www.who.int/teams/immunization-vaccines-and-biologicals/market-information

WHO. WHO network for improving quality of care for maternal, newborn and child health. Case study: Malawi—institutionalizing learning to improve quality of care. Geneva: World Health Organization; 2023.

WHO Council on the Economics of Health for All. Health for all: transforming economies to deliver what matters - Final report. Geneva: World Health Organization; 2023

WHO. WHO global benchmarking tool (GBT) for evaluation of national regulatory systems. Geneva: World Health Organization; 2021. Available from: https://iris.who.int/handle/10665/341243

WHO, Regional Office for Africa. Progress report on the framework for implementing the global strategy on digital health in the WHO African Region. Brazzaville: WHO AFRO; 2024.

World Bank. From double shock to double recovery: health financing in the time of COVID-19. Washington, DC: World Bank; 2021.

WHO. ACT-Accelerator strategic review: executive summary. Geneva: WHO; 2021.

WHO. Noncommunicable diseases: key facts. Geneva: WHO; 2022.

WHO. Investment case for health: every $1 spent on health yields $9 in benefits. Geneva: WHO; 2023.

WHO. World malaria report 2024. Geneva: WHO; 2024.

WHO. Decentralization and health systems in Africa. 2024.

WHO Western Pacific Regional Office. Regional strategy for health innovation for the Western Pacific (2023–2030). Manila: WHO WPRO; 2023.

Yamey G, Machinaizdze S, Ogbuoji O. Accelerating the discovery and development of new health technologies. Washington (DC): Brookings Institution, Future Development Blog; 2024 Jul 22. Available from: https://www.brookings.edu/articles/accelerating-the-discovery-and-development-of-new-health-technologies/

Zegeye, E. A., Reshad, A., Bekele, E. A., Aurgessa, B., & Gella, Z. (2018). The state of health technology assessment in the Ethiopian health sector: learning from recent policy initiatives. *Value in Health Regional Issues*, *16*, 61-65.