Sustainable Business Models & Market-Shaping Strategies for Digital & AI-Enabled Healthcare Technologies in Low- and Low-Middle Income Countries (LMICs)



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Dedications

To the over 4.5 million children who, by 2030, due to cuts to global health funding, we may no longer share our earth with.

To all the community health workers, nurses, physicians, policymakers, and health administrators who, despite the challenge, will keep striving to do whatever they can for whoever they can reach.

To my supervisors, my partner, my family and my friends who continue to inspire me to seek truth, help others and live well.

Abstract

Although digital health and AI technologies hold promises for strengthening health systems in LMICs, numerous challenges remain in developing sustainable business models that balance long-term viability with significant health system benefits. Market-shaping as a practice aims to strengthen the alignment between public value and private-sector incentives in healthcare through targeted interventions that align business model sustainability with public health goals.

While significant market-shaping efforts have led to improvements in patient access to vaccines and essential medicines for diseases like tuberculosis, HIV/AIDS and malaria, fewer initiatives have been launched at a similar scale to improve access to cross-therapeutic digital health interventions. Given the funding constraints and the unique potential of digital technologies to extend workforce capabilities and address operational inefficiencies at scale, market-shaping for digital health technologies warrants investigation.

This research aims to advise key stakeholders on interventions vital for creating a sustainable environment for organisations offering advanced digital health solutions. It examines the challenges affecting the sustainability of digital health business models in LMICs and AI-enabled digital health business models in Kenya's public health sector and offers potential external market-shaping strategies.

The methodology combined two approaches: a critical interpretive synthesis of 21 articles focusing on business model challenges and potential interventions for digital health companies in LMICs, and empirical research using semi-structured interviews with 16

stakeholders involved in AI health initiatives in Kenya, analysed via the Framework Method.

Results led to a four-part conceptual framework encompassing internal entrepreneurial challenges (such as managing value creation within complex stakeholder networks), external market challenges (including financial uncertainty, regulatory ambiguity, and infrastructure issues, internal business strategies, and external market-shaping strategies. The empirical findings validated this framework, revealing additional AI-specific challenges like high costs for data infrastructure and model training, along with a new theme of systems-level trust, highlighting widespread skepticism regarding AI deployment speed and safety.

Both studies suggest that while market-shaping strategies could align private-sector sustainability with public health goals, significant barriers hinder implementation. The disconnect between stakeholder support and the actual capacity for effective market-shaping, given the limited regulatory, financial, and technical resources in most LMICs, raises questions about the realism of these interventions in AI-enabled digital health and the scale of investment, political will and systems-change that might be required to realise such ambitions.

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List of Abbreviations

AI = Artificial Intelligence

ML = Machine Learning

GenAI = Generative Artificial Intelligence

LLM = Large Language Model

Agentic AI = Agentic Artificial Intelligence

LMICs = Low- and Low- middle-Income Countries

NCDs = Non-communicable Diseases

CHW = Community Health Worker

EHR = Electronic Health Record

mHealth = Mobile Health

CDSS = Clinical Decision Support System

POC = Point-of-Care (for example, POC ultrasound)

ROI = Return on Investment

R&D = Research and Development

BMC = Business Model Canvas

CIS = Critical Interpretive Synthesis

B2B = Business-to-Business

B2C = Business-to-Consumer

USAID = United States Agency for International Development

Gavi = Global Alliance for Vaccines and Immunisation

WHO = World Health Organization

DPI = Digital Public Infrastructure

Key Definitions

Market-Shaping	Coordinated actions to align private-sector incentives with public health goals by altering business models to improve affordability, availability, awareness, assured quality, and appropriate design of public health interventions.
Value Proposition	The specific bundle of benefits a solution offers to its target users or customers.
Value Creation, Delivery & Capture	Process view of business models: co-creating value with stakeholders, delivering it efficiently, and sustaining operations via revenues through different pricing models.
Business Model Canvas	A nine-component schema for describing business models published by Alexander Osterwalder.
Critical Interpretive Synthesis	Iterative, inductive literature synthesis used to develop theories from complex, interdisciplinary research.
Telemedicine	Digital delivery of clinical services across distance, for example specialist support to rural providers.
mHealth	Mobile-based tools for patient engagement, monitoring, and behaviour change.
Clinical Decision Support System	Digital tools that support diagnosis and clinical decision-making.
Large Language Model	A GenAI model that generates text and supports natural-language tasks in health workflows.
Agentic AI	Goal-directed AI that is Autonomous or semi-autonomous AI and can function independently or operating within a team of other “agents”.

Post-Market Surveillance	Ongoing monitoring of deployed AI models for accuracy and safety in real-world use
Model Drift	Degradation of model performance over time as data distributions change.
Outcomes-Based Financing	Payments linked to verifiable performance metrics in patient outcomes or health-system efficiency.
Blended Finance	Combining concessional and commercial capital to de-risk private investment.
Mezzanine Finance	Hybrid financing that mixes debt and equity features for flexible capital.
Regulatory Sandbox	A controlled environment where innovators test solutions under relaxed rules with oversight.
Interoperability	The ability of systems to exchange and use data reliably across settings.
Digital Public Infrastructure	Infrastructure such as digital IDs, mobile payments and facility-level data exchange that enable health solutions.

Declaration & Publications

I hereby declare that this dissertation is my original work and has been written by me in its entirety. I have acknowledged all sources of information used in the dissertation. This dissertation has not been submitted for any other degree. The outputs of Chapter 2 and Chapter 3 (Critical Interpretive Synthesis) are expected to result in a future publication where I am the first author. I certify that for this work I led all aspects of research, including but not limited to: the drafting and editing of the manuscript, recruitment of the expert panel and data analysis.

Outline of the Dissertation

Introduction (Chapter One)

Chapter 1 (Introduction) presents the idea of “market-shaping,” strategic interventions undertaken by organisations to address “market failures” or misaligned incentives within private-sector business models that hinder or discourage organisations from actively addressing public health issues. Considering the successes of market-shaping in increasing access to many essential medicines and the unique difficulties of maintaining digital health initiatives, the introduction raises the question of whether market-shaping interventions could be effective in amplifying the impact of digital health tools for public health challenges.

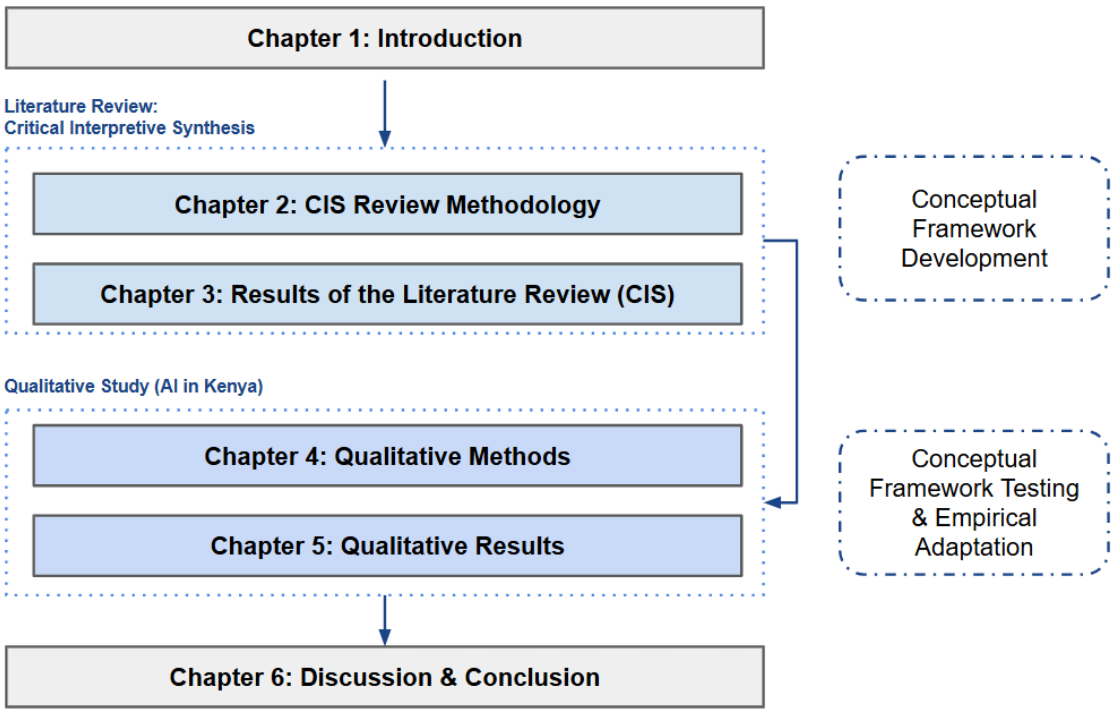


Figure 1: Visual Dissertation Outline

Literature Review: Critical Interpretive Synthesis (Chapters Two and Three)

Chapter 2 (Review Methodology) explains and justifies the choice of critical interpretive synthesis (CIS) as a methodology for developing a conceptual framework to understand the phenomenon through existing literature. Chapter 3 (Results of the Literature Review) presents the findings of the CIS, resulting in a conceptual framework that aims to provide a broadly applicable yet comprehensive process-oriented understanding of the challenges and strategies involved in sustaining business models and markets of digital health solutions for impact in LMICs.

Empirical Methods & Results (Chapters Four and Five)

To test this framework in a specific empirical context, Chapter 4 (Qualitative Methods) details how the 'Framework Method' enabled the CIS to serve as the basis for multi-stakeholder semi-structured interviews. These interviews focused on identifying barriers and facilitators for sustaining AI-enabled products and services for public health in Kenya. Chapter 5 (Qualitative Results) presents the thematically organised findings from the qualitative research, resulting in an updated conceptual framework and several country-specific insights into the barriers and facilitators of 'market-shaping' for AI in Public Health in Kenya.

Discussion & Conclusion

Chapter 6 (Discussion & Conclusion) concludes the dissertation by analysing the empirical results within the context of the broader literature and offering an evaluation of the strengths and limitations of the overall work.

Chapter 1: Introduction

A Primer on Global Health Market Failures & Market-Shaping

Market Failures in Global Health

The challenges of providing affordable healthcare in LMICs have continued to require the involvement of private-sector firms. Traditionally, many of these organisations in the global health market have consisted of entities focused on the development, manufacturing, distribution, and sometimes provision of health commodities like essential medicines and vaccines.[1,2] However, sometimes markets for global pharmaceutical and medical technologies fail to sustainably match the needs of low- and low-middle-income health systems with the incentives of private companies, resulting in what are called "market failures".[1] Given the high costs of research and development (R&D), product distribution, and other commercial activities, many healthcare companies might see greater barriers to entry in LMICs compared to high-income countries contexts.[1] Furthermore, relying solely on consumer demand may not encourage R&D investments, especially for diseases and conditions that mainly impact the poor. Recognising this lack of incentives for the private sector to engage in specific interventions, stakeholders in global health have increasingly turned to market-shaping initiatives.[1,2]

Market-Shaping for the 5 'A's' of Public Health Value

Market shaping is a method of developing markets that connect private-sector profit motivations with public health aims. [3] The goals of market-shaping often centre around the '5 A's': *the affordability, awareness, availability, assured quality and appropriate design of health products or services.*[1] By carefully examining the end-to-end business model of

potential healthcare suppliers, market-shapers have been able to identify parts of a business's 'value chain' that can be modified to incentivise a company or a collection of companies to address one or more of the '5 A's' in a specific LMIC healthcare setting context.[4,5] Several market-shaping levers exist to rebalance private-sector incentives, including: the reduction of transaction costs, the increase of market information and a balancing of supplier versus buyer risks. [1,6,7] The table below provides examples of market-shaping interventions for each lever.

(1) Reduce Transaction Costs	(2) Increase Market Information	(3) Balance Supplier & Buyer Risks
Pooled Procurement: Combining resources to purchase a higher volume of goods at a cheaper price	**Market Landscape Analysis:** Providing an up-to-date analysis of market participants and the underlying power dynamics underlying them	**Advance Market Commitments:** Offering to purchase a volume of product before an eligible product exists to spur early-stage R&D
Coordinated Ordering: Use of a third party to negotiate on behalf of individual purchasers	**Strategic Demand Forecasting:** Aggregating data to understand patient or country-level demand for a specific product	**Volume Guarantees:** Legal promise to purchase a specific volume of a pre-existing intervention or product
Simplified Product Registration: Clear and harmonised platforms for registering new products	**Price Information Exchange:** Reducing price variation by creating open forums for information exchange across buyers and suppliers	**Channel Subsidies:** Reducing prices by subsidising an expensive part of the distribution channel

Table 1: Three Key Types of Market-Shaping Interventions in Global Health

Suppose companies are supplying products, but governments lack the budget to buy them at large scale. In that case, organisations have used tools like pooled procurement to reduce prices by enabling collective bargaining across regions or countries. These mechanisms are widely used by groups like the Global Fund and the Clinton Health Access Initiative.[5] It's estimated that pooled procurement projects targeting paediatric anti-retroviral medications by the two organisations have led to a total of 210,000 deaths

averted.[1] Furthermore, the initiative delivered price reductions between 35% and 81%, representing both significant impact and value for money. [1]

However, companies may be willing to explore opportunities to supply underserved markets but lack the capabilities or networks to assess the demand for specific medications or interventions accurately. This information is typically necessary to build an initial business case to support upfront investments in new R&D or distribution channels. In such cases, market shapers have utilised tools like market landscape analysis and strategic demand forecasting.[4,6] These tools provide companies with nuanced insights into potential challenges, opportunities, and projected costs of supplying specific underserved markets.[4,6] Gavi, for example, has used such analyses to help suppliers recognise vaccine demand in underserved markets, providing the data necessary to justify investments in new capabilities to serve those markets over time.[1,6] Furthermore, such forecasts often act as initial due diligence to facilitate more complex forms of market shaping that demand substantial investments by market shapers themselves.

Lastly, for products yet to be created, interventions like advance market commitments (AMCs) can help de-risk early-stage investments in R&D and product development. For example, Gavi's COVAX AMC provided over half a billion US dollars in upfront funding to pharmaceutical manufacturers.[8] This funding supported the opening of new COVID-19 vaccine manufacturing and distribution capabilities, with a commitment to reserve half the supply exclusively for lower-income countries. This addressed a situation where these countries might otherwise have been unable to compete against higher-income countries for vaccine access.[8] Such market-shaping examples have yielded positive, sometimes

transformative results in several domains. However, leveraging these mechanisms beyond pharmaceuticals has proven challenging.[1,2]

Where has Market-Shaping yet to Impact?

Despite the importance of market-shaping in addressing health-system issues related to affordability, awareness, availability, assured quality, and appropriate design of essential medicines, market-shapers have struggled to adapt their models to a wide range of emerging issues.[1,2] These include addressing non-communicable diseases (NCDs), disseminating cross-therapeutic products such as digital health technologies, and serving markets characterised by fragmented purchasing patterns rather than nationalised purchasing.[1]

For example, while extensive focus has been placed on market-shaping for tuberculosis, HIV/AIDS, malaria, and vaccines, fewer mechanisms have been deployed at the same scale to provide access to medications treating NCDs – the emerging public health threat facing many LMICs globally.[9,10] Furthermore, given a philanthropic culture that favours vertical, disease-oriented initiatives, many cross-therapeutic interventions, such as comprehensive primary care provision and holistic maternal and child health programs, have received less attention despite their importance for health system strengthening.[1]

Within this culture, there may be a sense that the "low-hanging fruit", particularly supply-side interventions with clearer 'value-for-money', may be exhausted.[1,2] Furthermore, given that many health product markets are fragmented and sub-national, new opportunities may likely require a combination of micro-level market-shaping interventions alongside larger, holistic efforts, such as regulatory reform.[10] Thus, future

efforts to catalyse innovation for more complex, "high-hanging fruit" may require novel market-shaping approaches, including but not limited to, more iterative coordination and a focus on longitudinal impact measurement. [1,2,10,11]

Thus, as market-shapers look to tackle challenges of workforce shortages, organisational inefficiencies, and NCDs, new investments may need to be made in interventions that are more cross-cutting, longitudinal, and organised at sub-national or local levels.[1] Market-shaping initiatives for digital health technologies, which may be uniquely positioned to extend the capabilities of a limited workforce, address operational inefficiencies, and engage patients more cost-effectively at scale, stand out as a potential next step for market-shaping if done intentionally and iteratively with the aim of increasing public health value.[12–15]

Overview of the Literature on Digital Health Technologies in LMICs

Public health systems in LMICs face challenges in providing higher-quality services amid limited funding, workforce shortages, and disruptive infrastructural or geopolitical environments. Due to these limitations, digital health technologies have been tested as tools for health-system strengthening in a number of domains including for the provisioning of new modes of healthcare delivery (e.g., telemedicine) and the creation of new systems for supporting healthcare professionals with information support (e.g., AI-enabled clinical decision).[13,16–18]

However, the evidence on digital health interventions in LMICs reveals substantial geographic concentration as well as technological focus. An umbrella review of 88

reviews demonstrated that African countries dominated the literature, followed by South and Southeast Asia with other geographies trailing behind.[19] However, even with this geographical focus a focus on a particular modality of delivery remains. Telemedicine represents the overwhelmingly dominant intervention type, featured in 68% of all reviewed studies on digital health in LMICs.[19] Furthermore, a scoping review of DHIS for Non-Communicable disease management in primary care settings found that only 14 of 28 WHO digital health intervention categories were represented in the literature with a complete absence of evidence in a number of domains including referral coordination, health worker activity planning, human resource management, and supply chain management.[20]

Perhaps most critically, publication bias may likely skew the evidence base toward positive findings. Studies reporting null or negative results are notoriously difficult to publish, yet these "failed" interventions may offer the most valuable lessons for implementation in resource-constrained settings. The Craig et al. review candidly acknowledges that many DHIs have been "short lived, limited in scale, or contextually misaligned," yet the published literature most likely disproportionately features successful pilots rather than scaled implementations or failed programs.[19] This bias toward pilot studies and proof-of-concept research, means that policymakers attempting to make real-world decisions may need to navigate an evidence base that systematically overestimates effectiveness and underestimates implementation challenges if relying on traditional scoping and systematic evidence bases.

Furthermore, literature on the facilitators of DHIs success reveal a number of both universal and technology-specific patterns. Political commitment with supportive

regulation particularly emerges as the single most consistent factor across all types of DHIs.[21] India's telemedicine services provide illustrative examples of this. A scoping review of services from 200-2023 identified 115 unique telemedicine programs, with the most successful demonstrating "institutional anchoring", or the embedding digital innovations within stable, government-supported institutions rather than within more fragmented and individual donor-dependent.[22] For communication-based interventions like those reliant on SMS, mobile apps and telemedicine, the facilitators differed meaningfully from other forms of more complex DHIS requiring new devices or creating new health-system workflows.[14,21] These communication-based interventions succeeded when they leveraged more ubiquitous personal mobile phone ownership, thus requiring less additional infrastructure costs on both digital health implementers, users and other health-system personnel.[19,21] Of the published systematic, scoping and umbrella reviews focused on digital health in LMICs, the most consistently positive results tend to cluster around mHealth applications therapeutic areas like maternal health which may arguably be more politically salient to address by governments and more financially supported by traditional global health funders.[23–27]

However, more sophisticated DHIs, such as EHR systems and clinical decision support systems, required more or different facilitators to succeed. These interventions depended on reliable electricity, stable internet connectivity, hardware connectivity and digital literacy amongst health workers in addition to sustained technical and non-technical support for troubleshooting and maintenance.[28–31] Despite the apparent need for integration with existing health systems rather than creating parallel systems of care, the broader literature reveals that true integration remains low with most DHIs in LMICs

operating as vertical programs that add to rather than streamline pre-existing health worker responsibilities.[28–30] We examine a few more of these challenges in sustaining digital health markets as a whole below.

Key Challenges in Digital Health Markets

Despite the potential for digital health and AI-enabled technologies to strengthen health systems in LMICs, many challenges lie in creating sustainable operating or business models that balance sustainability with health system impact. Digital health technologies broadly face a few challenges in LMICs, including infrastructure gaps, financial uncertainty and regulatory ambiguity. Infrastructure gaps related to power, connectivity and the affordability of devices erode the usability of digital & AI health technologies.[32,33] Financially, challenges related to lack of funding, unreliable reimbursement and financing, and high transaction costs hinder digital health initiatives' ability to plan their resource allocation as they invest in new capabilities to scale impact.[33,34] Encompassing many of these issues is the challenge of regulatory compliance, where a lack of regulation or regulatory complexities risks both unsafe products entering the market and complicating the scale of safe, high-impact digital health interventions.[35]

However, at the centre of all these challenges are several inherent entrepreneurial challenges that make disseminating any technology in digital health difficult. Managing the creation of value in global healthcare, where stakeholders are dispersed but highly interconnected and sometimes have their incentives inherently difficult. As part of this experience, those looking to create sustainable digital health initiatives must carefully

identify feasible opportunities for impact, measure and communicate the value created across the stakeholder network while simultaneously integrating with health systems to drive scale and expand impact.[33,35,36]

Furthermore, cultural and social barriers receive inconsistent attention across DHI reviews, although these factors could prove as consequential as technical issues in determining the success or failure of a DHI intervention. For patients, for example, stigma surrounding certain health conditions can prevent patients from engaging with digital health tools that create visible traces of their health conditions, such as SMS reminders about clinic appointments for HIV treatment.[37–39] Furthermore, there has also lacked enough literature focused on challenges related to healthcare professionals leveraging DHIs for more advanced clinical or operational use-cases in LMICs.[18,21,40] Health worker resistance to DHIs in LMICs could stem from multiple sources: fears that digital systems threaten their professional identity and autonomy, anxiety about digital systems exposing poor performance or serving as management surveillance tools, and skepticism that externally imposed innovations might reflect donor or researcher priorities rather than local needs.[22,31,40–42] Lack of professional appraisal of the use of such systems in LMICs remains pervasive and may need to be addressed continually as studies that involve DHIs continue to be published in the open domain.[41]

AI in Health System Strengthening

Potential for AI in Health

Artificial intelligence (AI) can be broadly described as the capacity of machine systems to perform goal-oriented tasks typically associated with human intelligence.[43] Given the many challenges in healthcare delivery for LMICs, AI has been proposed by the World Health Organisation (WHO) and the United Nations (UN) as a potential force multiplier for improving healthcare systems.[44] By potentially automating routine tasks, optimising supply chains, and supplying new scalable means of expanding diagnostic capabilities and patient engagement, AI could one day potentially address crucial gaps in healthcare access, cost-effectiveness, quality, and patient experience.[18,45] For example, AI-enabled tools like AI-enabled point-of-care ultrasound devices have allowed lower-cadre health workers like community health workers to extend their clinical capabilities by triaging and diagnosing antenatal issues more accurately, tasks previously requiring more advanced skills training.[46] However, understanding how to realise the full promises of such AI-enabled technologies requires an in-depth understanding of its various components, classifications, current capabilities and challenges in order to effectively forecast it's future potential.

Key Challenges & Steps for AI Deployment in Healthcare

Deploying AI or AI-enabled technologies in healthcare requires a careful, staged approach.[47] Given the need for AI systems to be trained on real-world data (training on synthetic data has only recently emerged), the "problem to be solved" should be clearly defined to enable relevant stakeholders to understand the scope, scale, and quality of data to be included in training AI models.[47,48] A pre-emptive understanding of the

workflows in which the AI-enabled technology will be augmenting, as well as the environmental constraints of those workflows, can help ensure that the initial processes for model development are fit-for-purpose in new environments.[48]

1. *Data Creation and Acquisition*

Once such problems are identified, it becomes crucial to identify avenues for data acquisition. Without strategic partnerships with healthcare institutions that have pre-existing pipelines for data acquisition, initiatives aiming to train AI algorithms may need to invest in pre-processed data that accurately represents the population they intend to serve.[47,48] Measures should be taken carefully to ensure compliance with any relevant patient data requirements, protecting the privacy of individuals and health facilities involved in initial model development.[48] Unfortunately, for emerging technologies like AI, a lack of regulatory guidance in LMICs can create distrust across stakeholder groups and leave companies unsure how to engage with public health entities while remaining compliant.[49,50]

2. *Model Development*

Developers designing AI models for healthcare will need to understand both the scale and quality of the data at their disposal as well as the healthcare process they aim to augment. By understanding several of these factors, they can make better decisions on which algorithms to select based on their intent (eg, prediction versus diagnosis) and their constraints (eg, developing a small-language model versus a large-language model).

Furthermore, the applicability of AI output often depends on both the data leveraged for training and how it was captured. For example, AI models that leverage physical hardware

but don’t control their usage (i.e. mobile phone cameras) to input, transfer and compute data will need to be indiscriminate against the technologies available to a vast mass of users. For AI models that require specific hardware components, companies need to build specialised hardware alongside their AI models to host the higher-order capabilities, possibly increasing the cost and complexity of deployment.[51]

Lastly, challenges related to finding and retaining the necessary technical talent (i.e. data and machine learning engineers) towards conducting machine learning work can hinder local companies' ability to create and disseminate powerful models and algorithms for use in their local LMIC context.

3. *Model Evaluation*

However, even after such models have been created, ensuring their generalizability, let alone their efficacy against a straightforward clinical or operational task, can be a complex endeavor. For example, such measures for benchmarking simplistic AI models can include technical measures for accuracy, sensitivity and specificity.[52] For emerging AI technologies like GenAI and Agentic AI, such evaluation measures can include measures for creativity (i.e., temperature) and the scope of tokens leveraged (i.e., Top P)[53,54]. As these models are tested for scale, understanding their trustworthiness in the field, reducing operational friction, and leading to a return on investment for the buyer/funder becomes increasingly important. Such evaluation measures are increasingly important in Generative AI applications, as large language models have a propensity to “hallucinate” or generate false responses.[54,55]

4. *Model Deployment*

Once AI models are deployed, some may face an iterative journey of technical improvements, including the modulation or “fine-tuning” of the output to be more applicable to specific populations.[56]. An iterative approach to model development becomes necessary to ensure the AI algorithms remain accurate and trustworthy across different populations and use cases. During this longitudinal process of deployment, depending on the regulatory environment, some models may undergo post-market surveillance, a process of continuous monitoring and reporting of AI model accuracy. In contrast, others will be deployed without subsequent surveillance.[57] Post-market surveillance is important as gaps in model generalizability can contribute to a slow degradation in AI model outputs over time, known as ‘model drift’.[58,59]Such technical challenges can raise ethical questions when evaluating the merits of scaling these technologies across LMIC health systems.

Classifications of Artificial Intelligence with Example Applications

Although the term "AI" is colloquially used as blanket terminology, artificial intelligence encompasses several distinct but related concepts, with different practical applications and recent advances.

Type of AI	Description
Machine Learning (ML)	*Machine Learning (ML)* forms the foundational layer, defined as the development of algorithms that learn through “experience". ML approaches can be categorised as either supervised (learning through labelled data) or unsupervised (learning purely inductively through first principles).[60] Further advancements in machine learning, including deep learning, have uncovered new techniques for classifying and representing multi-dimensional data.
Deep Learning	*Deep Learning* represents a specialised subset of ML that leverages multi-layered neural networks to learn from more complex, hierarchical representations of data. Deep learning has, for example, enabled the analysis and classification of medical images based on their edges, textures, anatomical boundaries, and other higher-order data attributes.[61]
Generative AI (GenAI)	*Generative AI (GenAI)* encompasses AI systems capable of generating new content like text, speech or graphics using underlying data or knowledge graphs. These capabilities have enabled digital health organisations to craft responses to patients in natural language through the use of technologies like Large Language Models (LLMs), offering scalable and personalised advice to patients and supporting

	provider workflows through augmented patient-provider interactions.[62,63]
Retrieval Augmented Generation (RAG)	More advanced AI Techniques have also been developed to help integrate AI capabilities into more accurate or use-case-constrained workflows. Such advances include *Retrieval Augmented Generation (RAG),* which can restrict the outputs of GenAI methods, such as large language models (LLMs), to specific predefined corpora of documents and data sources, including clinical guidelines or patient charts.[64,65]
Agentic AI	Lastly, *Agentic AI* has recently emerged for complex workflows and use-cases where orchestrating multiple types of specialised AI algorithms would be advantageous. Agentic AI refers to autonomous or semi-autonomous AI-enabled digital agents that can combine various forms of AI or collaborate with other AI agents to achieve preset goals.[66]

Table 2: Overview of Potential Use-Cases of Machine Learning for Healthcare

Potential Use-Cases of AI in Healthcare

AI applications have the potential to address both clinical and operational challenges in healthcare, provided the necessary enabling technical, human, and financial infrastructure is available.[67] The following section extrapolates the little evidence in this domain into forward-looking statements for two key reasons. First, the pace and breadth of AI in Healthcare as an industry continues to move at an accelerated pace. But second, and most importantly, market-shaping activities are often focused on the re-engineering of the "status-quo" towards new market configurations that allow for what was previously un-evidenced to become practically relevant in application. Thus, I provide several potential use-cases for AI in Healthcare in LMICs, recognizing that the present successes generated can be highly variable across geographies and at different levels of scale both in the present and into the future.

1. *Prediction & Risk Stratification*

AI for clinical prediction and risk stratification leverages advanced machine learning models to analyse multi-modal patient or population datasets and detect patterns that could inform which patients might be at risk of a particular clinical outcome, like hospital readmission or disease onset. At scale, such capabilities could prove helpful in prioritising patients for triaged decision-making or for managing population health during public health emergencies, such as the COVID-19 pandemic.[68,69]

2. *Diagnostic Enhancement*

AI for diagnostic enhancement focuses on improving the accuracy, speed or confidence of diagnoses, primarily by healthcare providers. Such capabilities could include clinical

decision support at the point of care for a wide variety of acute or chronic conditions. Deep learning algorithms have already been deployed, particularly for conditions such as tuberculosis (TB) in countries like Zambia and Bangladesh.[70,71] Such algorithms have demonstrated performance in TB diagnosis that is comparable to that of radiologists, and sometimes even surpasses their diagnostic success rates.[70–72]

3. *Prognostic Modelling*

AI for prognostic modelling can help predict the likelihood of a future outcome or course of disease in a patient who has already been diagnosed with a condition. For example, such models could be used to tailor oncological treatment and medication plans or provide patients with more accurate information on their cancer progression. Although all forms of AI require advanced analytical talent and big data, making accurate predictions about disease prognosis requires a unique set of both broad and in-depth longitudinal patient-level data that can be difficult to procure in LMIC healthcare settings. [73] However, the availability of large-scale, peer-reviewed prognostic AI models in LMIC contexts remains limited.

Operationally, AI may also in the future help to manage complex healthcare processes by ingesting data from a wide range of human, financial, and capacity-focused systems to output strategic recommendations for optimising patient throughput, allocating supply chain resources, and managing pathways for care and referral.

4. *Patient Flow Prediction and Scheduling*

Since the demand for patients with various conditions, both acute and chronic, determines the required resources and personnel for a given facility or health system, managing, predicting, and planning for patient demand becomes one of the most crucial aspects of delivering efficient healthcare services. For example, by aggregating data from district health information systems in Southwest Ethiopia over 41 months, two machine learning models were able to model out-patient flow with high accuracies (0.83-0.85).[74] Such applications suggest that data-driven prediction tools may help support surge planning, reduce overcrowding in outpatient facilities like emergency departments, and potentially help optimise staffing levels.

5. *Supply Chain and Resource Allocation*

Given the resource-intensive nature of healthcare and its considerable reliance on single-use supplies, managing the supply distribution of essential medicines, diagnostics, and other medical technologies becomes crucial for both cost-effective and equitable health system reliability. AI systems for supply chains might ingest data related to inventory, facility demand, logistical options (transport and storage) and supply chain budgets to help optimise procurement, stock management and distribution across health facilities or clinics.[75,76]

6. *Care Coordination and Referral Pathways*

Quality healthcare often relies on ongoing patient engagement in both personal health monitoring and interaction with the healthcare system and its providers. Disjointed continuation of patient engagement can result in decreased adherence to treatment protocols and reduced opportunities to prevent healthcare issues from arising. Given the

scalability of software tools and the time limitations of healthcare workers, AI-enabled systems may prove beneficial in extending the scale and continuity of patient communication and health monitoring. For example, PROMPT, an SMS-based tele-triage and patient education platform, is widely used in Kenya to provide women in resource-poor settings with tailored, AI-generated maternal health advice. [77,78] Using a two-way AI-enabled system, PROMPTs is able to simultaneously provide basic medical advice in multiple dialects while also identifying and flagging high-risk mothers for immediate medical referral.[77,78] Such uses illustrate the capabilities AI may play in helping to engage and monitor patients where the capacity of human providers is already sparse and where conditions are either acute emergencies or stigmatised.

Study Justification

Opportunities: Rapidly advancing Technologies for Healthcare

The advent of AI-enabled technologies has created new conversations about the role digital health technologies could play in enabling LMICs to strengthen their health systems. Potential benefits range from leveraging AI-enabled devices to improve the efficiency of Community Health Workers to harnessing LLMs to more personally engage patients in self-managing NCDs. With access to mobile phones rapidly expanding across many LMIC contexts, especially in sub-Saharan Africa, an increasing number of patients, both rural and urban, now have some initial gateway into a digital system.[79] Furthermore, post-COVID pandemic, DHI's like telemedicine have seen increased adoption and have become more acceptable to patients and users. Since Digital Health & AI seem to be

continued priorities for international development, healthcare partners will need to ensure that aspiration is converted to safe action and equitable impact. This may be especially important given several unprecedented challenges affecting global health funding.

Challenges: A Shifting Funding Landscape in Global Health amidst the Challenges of Digital Health Implementation

Development assistance for health has experienced a dramatic 21% reduction in funding between 2024 and 2025.[80,81] While some private donors such as the Gates Foundations have stepped up to provide increased funds, governments like the United States, the United Kingdom and Germany have pulled back significantly. In 2023, The United States accounted for nearly a third of external health funding alone. In 2025, The United States has pulled more than 67% of its budget.[80,81] Such funding reductions have resulted in the shuttering of entire global health programs, reduced government budgets for healthcare spending and disrupted the provisioning of basic health goods like antiretroviral (ARVs) and vaccines.[82] Nigeria and Kenya have both seen reductions in their health budgets as high as $300-400 million USD.[80] Some countries, such as Malawi, Lesotho, and Mozambique, have seen reductions that total up to 16.5% of all nationwide health spending.[80]

Such challenges may require many LMICs to seek new ways of delivering their pre-existing healthcare services under the stresses of significantly tightened budgets. Will digital interventions for public health play a role in formalising new cost-effective ways of triage, diagnosis and management in response to these budget shocks? Given the

immense challenges related to implementing digital health at scale in LMICs, it remains unclear if digital health applications can rise to the promise, especially without strong external interventions.

Market-Shaping for Digital Health & AI

These intersecting opportunities and obstacles prompt critical questions about the role of digital health innovations (DHIs) in addressing public health crises. What unique contributions can DHIs offer when confronting these health system challenges? What mechanisms should LMIC health systems develop to directly motivate the private sector to create and operate cost-effective digital solutions that enable tangible health-system outcomes? And crucially, how can these programs maintain long-term sustainability as international health financing continues to contract? Understanding the barriers and facilitators of implementing market-shaping interventions for digital health in LMICS could help inform governments, NGOs and philanthropists on pathways for more effectively deploying private-sector innovation towards tackling the needs of their public health systems.

Research Aims & Objectives

Health systems in LMICs face several critical organisational, logistical, and human issues in providing equitable, cost-effective, high-quality care amidst a shifting geopolitical and funding landscape. The private sector (including both for-profit, social ventures, NGOs) may be better positioned to provide sustainable digital interventions to public health systems if specific incentives have been aligned to tie the sustainability and scale of their business models to the needs, outcomes and constraints of specific public health systems.

Aim

This research aims to inform governments, NGOs, and multilateral organisations on the types of interventions that may be crucial to developing a more sustainable environment for organisations providing advanced digital technologies for public health. Four key objectives were designed to inform this goal.

Objectives

1. ***Objective 1:*** Outline the business model challenges facing the sustainability of Digital Health companies in LMICs. ***(Chapter 3)***
2. ***Objective 2:*** Document potential business strategies and market-shaping interventions to improve the ability for Digital Health companies to sustain their impact. ***(Chapter 3)***
3. ***Objective 3:*** Determine the business model and market challenges of sustaining AI-enabled healthcare technologies in a more specific Kenyan health-system context. ***(Chapter 5)***

4. ***Objective 4:*** Investigate the barriers and facilitators to using market-shaping initiatives for AI-enabled healthcare technologies in the context of the Kenyan health system. ***(Chapter 5)***

Overview of Study Designs with Key Objectives

Literature Review (Chapter 3)

For the first two objectives, I undertook a critical interpretive synthesis to investigate the business model and market challenges facing Digital Health companies in LMICs and potential business strategies and market-shaping interventions. My research questions are staggered below under each of the initial objectives to be addressed:

Objective 1: Outline the business model challenges facing the sustainability of Digital Health companies in LMICs.

i. **RQ1:** What are the key challenges to the sustainability of digital health business models in LMICs?

Objective 2: Document potential business strategies and market-shaping interventions to improve the ability for Digital Health companies to sustain their impact.

ii. **RQ2:** Which internal entrepreneurial strategies could entrepreneurs in LMICs employ to overcome these challenges?

iii. **RQ3:** What external market-shaping strategies could government bodies and philanthropic organizations implement to support the sustained development and scaling of digital health innovations for public health systems?

The CIS was conducted with inputs from an expert panel including executives with experience operating or funding digital health companies in multiple LMICs. Panel feedback was purely advisory and helped to assess the relevance of the findings across different technologies and LMIC health-system contexts. From the CIS findings, I created a conceptual framework to outline the challenges and opportunities associated with sustaining business models, into the broader market context in global health. Externally led interventions under the umbrella of ‘market-shaping’ were identified as a crucial element for aligning private-sector technologies with public health goals, creating a subsequent focus for the empirical work.

Qualitative study with Kenyan Stakeholders (Chapter 5)

To test the conceptual framework, I conducted empirical qualitative research to assess the associated challenges and strategies related to sustaining AI-enabled healthcare technologies for public health in Kenya. By narrowing the scope to a more specific technology and country context, the empirical study facilitated an in-depth analysis of the technical, financial, political, and organisational realities associated with market-shaping AI and digital health technologies in a real-world context. My research questions are staggered below under each of the remaining objectives to be addressed:

Objective 3: Determine the business model and market challenges of sustaining AI-enabled healthcare technologies in a more specific Kenyan health-system context.

I. **RQ4:** Which challenges have impacted the sustainability of AI-enabled digital health business models in serving the public health sector in Kenya?

Objective 4: Investigate the barriers and facilitators to using market-shaping initiatives for AI-enabled healthcare technologies in the context of the Kenyan health system.

II. **RQ5:** What external market-shaping strategies seem most necessary, feasible and acceptable for the Kenyan Government (and other market-shapers) to implement to align private-AI companies to public health goals?

I used the Framework method to provide an initial deductive framing for the empirical work while remaining inductively flexible in response to unique themes or sub-themes that emerged. The qualitative study resulted in two deliverables. First, identifying evidence to inform practical, collaborative pathways for advancing and sustaining AI-enabled healthcare technologies in Kenya. Second, an updated conceptual framework

resulting from the empirical results could potentially provide value to future research in the AI for public health domain.

Epistemological Foundations

By understanding the phenomena from a constructivist and interpretive lens, I was able to take a pragmatic approach to my research objectives, focused on providing qualitative insights to inform solutions to real-world challenges that involve the dynamic interactions of entire groups of people with potentially different incentives, experiences and levels of power. There are several reasons for each approach.

First, 'markets' are often viewed as an iterative and frequently collaborative process constructed by actors whose decisions and reactions aggregate to form a dynamic 'ecosystem'.[83–85] A constructivist lens therefore makes sense because markets for digital health products, which involve funders, partners, government officials and entrepreneurs, would then be emergent phenomena that arise from human interpretation of social interactions, power dynamics, opportunities and threats. An objectivist epistemology could fail to account for the on-the-ground implications of stakeholder power dynamics, the context-dependent nature of health system strengthening and the fundamental challenge of markets which lack a material “existence”.

Furthermore, since these social interactions, man-made incentives, power dynamics and relationships underpin the make-up and direction of these markets, an interpretive lens becomes essential. I used an interpretive lens to ground people as the core of the study and examined how different stakeholders are interpreting signals from other stakeholders, how narratives are being constructed about the value of digital health and how others are responding to perceived threats and opportunities.

By combining these foundations and involving a broad group of stakeholders for my empirical work, I decided to leverage a research paradigm rooted in pragmatism focused on providing qualitative insights to inform solutions to a real-world problem.

However, since ‘market-shaping’ is not just a concept, but a practice area actively being adopted by global health funders, partners and governments, the understanding was that such insights may prove helpful in informing individuals looking to actively re-align the “market” towards “public value” or “public good”. Thus, for my empirical work, I focused my lines of inquiry to stakeholder participants around practical questions of the necessity, acceptability and feasibility of market-shaping interventions for AI-Health in Kenya.

Researcher Positionality

As a Rhodes Scholar and researcher from the Global North, educated at Oxford and Indiana University, with a background in digital health entrepreneurship, I approach this study on sustainable business models and markets for AI-enabled health in Kenya and other low- and low-middle-income countries (LMICs) with a critical awareness of my positionality. My upbringing in the United States and extensive experience in US-incorporated digital health companies inherently shape my perspective. This background may incline me towards market-based solutions and technological optimism, reflecting the environments where my expertise was formed.

My identity as the son of Rwandan immigrants, combined with my professional role on Zipline's (Medical Drone Delivery Company) Africa commercial team, provides contextual familiarity with some of the issues at hand. However, I consciously acknowledge that I lack embedded knowledge as a citizen or long-term researcher within the context of an LMIC. I remain acutely aware of the power imbalance inherent in my position. While I hold elements of connection that contribute to the willingness of participants and partners to collaborate on this topic, my primary education, birthplace, and professional trajectory fundamentally situate me as an outsider.

To actively mitigate these biases and power dynamics, I worked with experienced Kenya-based partners and an expert panel from across LMICs to gather their real-life context and understand where my cultural blind spots could affect the relevance of my work. This commitment is operationalised in my research design, notably using an expert panel of digital health executives in LMICs to inform the development of the conceptual framework

in Chapter 3. Throughout this work, I maintain a reflexivity journal to iteratively document and challenge my assumptions, biases, and evolving thought patterns with a particular focus on documentation as I conducted my qualitative work focused on Kenya in Chapter 5.

I acknowledge that my positionality inevitably influences how I conceptualise 'sustainability' and 'impact', and how I assess the risks of private-sector commercialisation, including the weighted potential for rent-seeking and regulatory capture. This ongoing reflexivity is central to the integrity of the research process and findings.

Chapter 2: Review Methodology

TITLE: Improving the Sustainability of Digital Health Markets & Business Models for Impact in Low-and Low-Middle Income Countries: A Conceptual Framework

Overview

Sustaining and scaling private-sector digital health innovations for global health impact remains a significant challenge in LMICs. To address this, I employ two interlocking approaches:

1. Critical Interpretive Synthesis (CIS):

Using an inductive and iterative approach to literature analysis, I investigate the following research questions:

I. **RQ1:** What are the key challenges to the sustainability of digital health business models in LMICs?

II. **RQ2:** Which internal entrepreneurial strategies could entrepreneurs in LMICs employ to overcome these challenges?

III. **RQ3:** What external market-shaping strategies could government bodies and philanthropic organisations implement to support the sustained development and scaling of digital health innovations for public health systems?

2. Expert Review:

Second, I collected feedback from a panel of experts with experience in commercialising, funding or consulting for digital health companies in LMICs across the globe. Their input helped to assess the relevance of findings across different technologies and health-system contexts, thus helping to refine the proposed market-shaping process to balance

broad applicability across LMICs with an acknowledgement of the need for local adaptation.

By addressing these questions, the study aims to provide actionable insights for a diverse range of stakeholders (entrepreneurs, governments, philanthropy, and strategic/implementing partners) to enhance the current and future sustainability and impact of digital health solutions in LMICs.

Study Design & Justification

A review was warranted because few studies have sought to create comprehensive cross-disciplinary understanding of how to enhance the financial sustainability of digital health initiatives in LMICs at a macro-level. Existing literature remains highly fragmented across disciplinary boundaries, with most studies situated within more narrowly defined domains such as implementation science or business management.[42,86,87] This has thus led to empirical work to date that has largely focused either on the micro-level, examining the internal dynamics of digital health enterprises to inform managerial or operational decision-making;[88] or on the meso-level, describing barriers and facilitators to implementing specific digital tools within very specific clinical settings.[21] The few studies that examine digital health enterprises in LMICs at a macro (market-level) tend to focus on tracking easily discoverable market trends, like the volume of new digital health startups in a particular country, rather than uncovering rich, descriptive evidence to understand the driving factors behind the financial sustainability or unsustainability of their business models.

This lack of synthesis as well as the absence of more integrative frameworks for digital health market-shaping that connect macro-economic, meso-public health system perspectives and mico-organizational perspectives may be a contributor to what I found was a lack of cross-disciplinary and cross-industry dialogue towards a shared goal. Lacking a shared "language" or context in this domain may contribute to constraints on policymakers, funders, and entrepreneurs who seek actionable insights for collaborating in the funding or design of scalable and sustainable digital health business models in LMICs that match financial viability with delivering tangible public value.

Thus, given the highly complex nature of the research phenomenon, which spans domains as disparate as public health, implementation science and entrepreneurial studies, I deemed Critical Interpretive Synthesis (CIS) a more appropriate tool for synthesis than a systematic or scoping review. The use of more iterative qualitative techniques like CIS can become increasingly important when analysing cross-disciplinary research, where the parameters of the initial research question may be inherently ill-defined.[89] CIS is also particularly well-suited to theoretical development within complex, interdisciplinary research as it focuses on an inductive approach to literature analysis, emphasising the iterative interpretation and refinement of core concepts and research questions as new insights emerge. [89] The key steps of the CIS methodology revolve around the initial formulation of a research question, literature search, sampling, a preliminary assessment of quality, data extraction, and the synthesis of final critical arguments. [89]

Search Strategy and Selection Criteria

I conducted a database search (Business Source Ultimate, PubMed, Web of Science, SCOPUS, Google Scholar) using a search string with 28 terms focused on both business models and digital health. (Supplementary Appendix: Search Strings & Databases). The search, limited to English articles published between 2014 and May 14th, 2024, identified 893 relevant titles and articles, of which 21 full-text articles were included in the final analysis. Inclusion and exclusion criteria were then applied during the abstract and full-text screening to assess relevance and quality. I then conducted the title, abstract and full-text screening, and a second reviewer (NA) conducted a quality check on a random sample of the article count (20% of the total). I then cross-compared the results to improve the clarity of the inclusion/exclusion criteria, and a discussion was held once more, which removed the disagreement of one article which took place in a high-income setting.

Table 1 below illustrates the inclusion and exclusion criteria for each stage of screening.

Abstract Screening	
Inclusion Criteria	***Exclusion Criteria***
Articles at the abstract-screening phase were required to answer one of three key research questions for inclusion: 1. Does the article explicitly discuss the ***attributes or components of a "business model***" in digital health? 2. Does the article implicitly or explicitly discuss challenges or strategies related to initiating or operating business models in digital health for financial sustainability or scalability?	Articles that ***are explicitly focused on only non-LMIC*** digital health companies or initiatives.
Full-text Screening	
Inclusion Criteria	***Exclusion Criteria***
Provide explicit appraisal or interpretation of a digital health business model, specifically addressing its construction or adaptation for ***sustainability and/or scalability.*** ***Case studies*** must include at least one explicit evaluation of a digital health company or project operating in an LMIC context.	1. Focused explicitly on digital health initiatives and case studies from ***high-income contexts*** 2. No appraisal of the sustainability of scalability is outlined. 3. Did not meet a *minimal threshold of methodological quality*. by **lacking a study design**

Table 3: Inclusion and Exclusion Criteria for the Critical Interpretive Synthesis

Quality Determination

The absence of a strict hierarchy of study designs for qualitative synthesis, combined with the inherent reflexivity of the CIS methodology, allowed me to prioritise articles based on their relevance to the research questions rather than apply strict inclusion and exclusion criteria. Given these factors, I used a low threshold for quality appraisal, and I excluded only two articles from the review because they lacked a study design. The five conditions

for quality appraisal (Supplementary Appendix Table 4) were adopted to facilitate this evaluative process.[89]

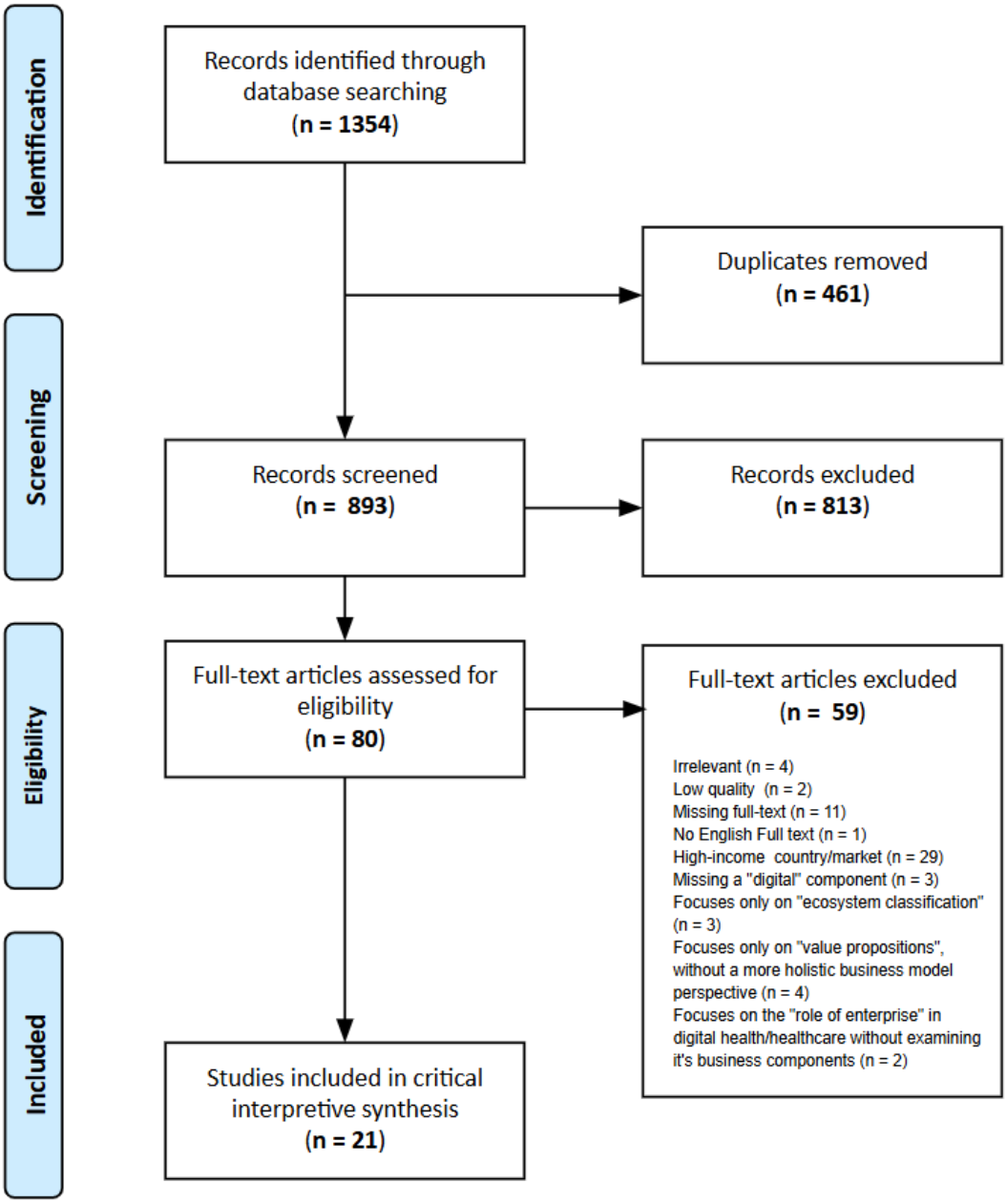


Figure 2: PRISMA Diagram for Included Studies in Critical Interpretive Synthesis

Data Extraction

Open Coding

I structured the evidence extraction into three iterative steps: open coding, axial coding, and selective coding. First, I conducted open coding on an initial set of articles to create a structured data extraction form, focusing on identifying a unified conceptualisation of a 'digital health business model' from the digital health literature.[34,90–99] The final conceptualisation combined the overarching structure of the 'CompBizMod' model (an evaluated business model framework for digital health) with the key sub-components of Dr. Alexander Osterwalder's 'Business Model Ontology' (a predominant business model ontology). [96,100]

This hybrid framework conceptualises digital health business models as a dynamic, four-component process of identifying value propositions[34–36,90,91,95,96,98,101–103], creating or co-creating value[34–36,90,95,96,96,98,102], delivering and communicating value[34,95,96,101,102], and lastly, capturing value[34,95,96,98,102]. These four components, illustrated alongside their associated sub-components in Table 2 below, provide a unified analytical lens for examining digital health business models across heterogeneous article types that focus on a diverse array of technologies, market structures and health-system contexts for implementation.

Key Business Model Components	Key Subcomponents
Value Proposition: The unique benefit or solution a product or service offers to meet the needs of one or more stakeholders in the health system.	***Customer Segments:*** The groups of people or organisations that your business can service. ***Customer Value Proposition:*** The core offering (product, service, feature) that solves a problem or fulfils a need for a specific customer segment.
Value Creation: The process of creating products or running services that improve the quality, access, cost or operational efficiency of care delivery.	***Key Activities:*** The essential actions a business performs to deliver the value proposition. ***Key Resources:*** The key assets (i.e people, funding, technology) required to create and offer the product or service. ***Key Partners:*** External implementers, organisations and stakeholders that help reduce risks or optimize operations
Value Communication & Delivery: The approach to both disseminating the product or service and demonstrating it's worth.	***Channels:*** The methods through which a value proposition is communicated and delivered to customers and key partners. ***Customer Relationships:*** The type of relationships established with your customers and/or key partners to improve satisfaction and retention.
Value Capture: The process of retaining a portion of the value created through profit or another strategic benefit necessary for the scalability of the company.	***Revenue Streams:*** How a company generates income from delivering value to each of its key customer segments. ***Cost Structure:*** The costs a company incurs in creating and delivering the value proposition. These costs can be either "variable", an expense proportional to how much a company sells or produces, or "fixed".

Table 4: Conceptual Components of a Business Model in Digital Health

However, given variation in the level of descriptive and longitudinal evidence encountered during open coding, it became necessary within the extraction form to distinguish between two key dimensions of business model evidence: (1) evidence pertaining to the initial design and selection of business models, capturing the range of strategic decisions available or made at the outset, and (2) evidence related to how these models evolved

and were sustained (or not sustained) over time, focusing on the ongoing management and adaptation of prior decisions in response to real-world challenges and opportunities. Thus, I extracted short quotes related to the four business model components from the 21 articles and further stratified them into either the first or second categories.

Axial Coding

During axial coding, I systematically grouped short quotes from the literature into sub-themes. Two key conceptual distinctions emerged: (1) themes identifying business model challenges and (2) themes concerning potential strategies to overcome these challenges. Additionally, these themes varied in relevance depending on the stage of business model maturity, whether at the pilot, scaling, or sustaining phase. The expert panel confirmed the practical salience of our challenge vs strategy split and encouraged indicating where themes vary by stage of maturity. My thematic labels were kept, and the reviewer comments were used to sharpen the labels. Panellists did not make inclusion decisions or code data. Their role was advisory, and feedback was incorporated when it improved clarity or semantic completeness. After three consecutive coding rounds (offering summaries of changes to my supervisors) without new codes or changes to theme relationships, I considered saturation achieved and recorded this in reflexive memos.

Selective Coding

In the final selective coding phase, the core concepts developed in the previous axial coding phase were consolidated into larger constructs and the relationships between the constructs were refined for both theoretical and semantic accuracy. More apparent distinctions were drawn between four key macro-constructs: (1) internal entrepreneurial

challenges, (2) internal business strategies, (3) external market challenges, (4) external market-shaping strategies.

Macro-Constructs	Sub-Constructs
Internal Business Challenges	Identifying Feasible Opportunities Measuring and Communicating Value Navigating System Integration & Expansion
External Market Challenges	Financial Uncertainty Regulatory Ambiguity Infrastructure Challenges
Internal Business Strategies	Strategies related to Value Propositions Strategies related to Value Creation Strategies related to Value Communication & Delivery Strategies related to Value Capture
External Market-Shaping Strategies	Support with Strategic Partnerships Fit-for-Purpose Regulatory Frameworks Enhanced Public Procurement Innovative Funding Mechanisms

Table 5: Key Conceptual Components Emerging from Selective Coding

The emphasis on the necessity for external market interventions, including concepts such as strategic partnerships, regulatory frameworks, public procurement, and innovative financing, directed subsequent purposive sampling of new articles and grey literature outside the initial article set. This revealed a significant and strongly correlated subset of mostly grey literature under the umbrella of *market-shaping*. Consequently, I intentionally incorporated evidence from relevant articles and grey literature pertaining to these four types of market-shaping interventions to supplement the findings.

Critical/Interpretive Elements & Development of a Synthesising Argument

Adopting both interpretive and critical practices became necessary as I synthesized the literature. Both elements were crucial as different study designs from different disciplines

often had distinct differences in semantics, biases and levels of analyses. For example, to address the question “What business model challenges are endemic to financial sustainability” I often had to examine business models from entrepreneurial perspectives that carefully highlighted technical, commercial and organisational challenges that might be addressed within an organisation at both the micro- (eg., management practices within a startup) and meso-levels (eg., strategies for digital implementation at a county-level). However, to address the question “What could be done in a global health context” it becomes necessary to also synthesise potential solutions from both meso- and new macro-domains as academically distinct as public policy or philanthropic finance. Without connecting the micro, meso and macro-perspectives, a study looking for pragmatic solutions for these research questions runs the risk of attempting to a modify an entire market without understanding the narratives and on-the-ground challenges faced by the business models that encompass ‘the market’. Furthermore, if one suggests solutions at the macro-level that rely only on market-level solutions from external organisations, they similarly run the risk of neglecting or under-estimating the contribution that entrepreneurs themselves may have on making management decisions that determine the financial and impact trajectories of their ventures. The ability to synthesise information across disciplines thus requires a dedication to both critical and interpretive analysis.

The interpretive element was operationalised through inductive, iterative analysis and constant comparison. I coded quotations and descriptive passages from the included studies, repeatedly re-coded new material against evolving constructs, and used theoretical sampling to seek literature that tested or extended emerging ideas. The critical element was enacted by treating the literature as an object of scrutiny rather than a

passive data source. This is important since pragmatic action can sometimes require unearthing and/or addressing disagreement across stakeholder perspectives. Concretely, as I examined each paper, I found it necessary to consciously reflect and record where and how sustainability, scalability and public value were mentioned, which stakeholders and outcomes were seemingly prioritised, and where technical, donor or investor semantics or framings could obscure the delivery of objective evidence. This process was undertaken with the aim of identifying where perspectives seemed to differ in the literature on digital health business model sustainability across crucial global health stakeholder groups. I flagged such instances for targeted re-reading and potential critical reflection and used those flags to guide purposive searches for contrasting evidence including within the grey literature. These critical interrogations informed sampling and selection decisions throughout the review rather than being applied only as a stage of exclusion. In this way the critique was dynamic, recursive and formative to theory generation, consistent with the best practices described by Dixon-Woods.[89]

The combined critical and interpretive procedures produced synthetic constructs and a synthesising argument that link internal organisational strategies (micro & meso) for value propositions, creation, communication and delivery and value capture with external market-shaping mechanisms (meso & macro) related to partnerships, regulation, procurement and financing. These outcomes are presented as a theoretical framework in Chapter 3.

Expert Panel & Researcher Positionality

Although my supervisory team has a background in digital health implementation in LMICs, reflexivity remains key during critical interpretive synthesis, as other individual biases and experiences can affect the interpretive process. These positions can bias researchers to underestimate the difficulties of private sector involvement in LMICs and to overlook cultural, political economy, and historical factors that shape implementation. Thus, I kept reflexive memos during coding and synthesis phases to document potential sources of personal bias for reflection with the authorial team. Such personal biases could include the Africa-focused leaning of my supervisory team's expertise, the graduate education received by myself in the global north and my entrepreneurial background.

At key points throughout this process, feedback from the review team, with expertise in digital global health technologies (FW, ME, CP, SN, BH, SH, NA, EI), international business strategy (BH, FW, EI) and complex market-creation (BH, FW, JH), was used to ensure multiple perspectives were incorporated into the longitudinal processes of categorization and synthesis. Furthermore, I invited feedback from seven expert panellists with experience of funding or operating digital health companies in LMICs to help provide necessary opportunities for sense-making of the results.

Reviewer	Professional Role	Description of Primary Organisation(s)	Focus Geographies
1	*Chief Executive Officer (Startup)*	Large Telemedicine Startup	Southeast Asia
2	*Chief Executive Officer (Startup)*	Small/Medium-Sized HealthIT Startup	Sub-Saharan Africa
3	*Chief Strategy Officer (Startup)*	Large Telemedicine Startup	Southeast Asia
4	*Chief Executive Officer (Funder & Implementing Partner)*	Large Development-Focused Startup Incubator	Several LMICs World-Wide
5	*Chief Executive Officer (Funder & Implementing Partner)*	Global Health NGO Focused on Market-Shaping	Several LMICs World-Wide
6	*Chief Executive Officer (Investor)*	Healthcare/Digital Health Venture Capital Firm	Sub-Saharan Africa
7	*PhD Candidate & Digital Health Consultant (10 yrs)*	Multiple Large Healthcare Firms	South Asia

Table 6: Professional Backgrounds of the CIS Expert Panel

During selective coding, four professionals suggested additional sources and five professionals highlighted potential context factors that could have been under-weighted for me to review back in the literature. Expert panel input at the selective coding stage helped provide a necessary sense-making step that contributed to my critical thought process. Below is a timeline of contributions (not presented in chronological order) provided by each of the seven expert panellists during the CIS.

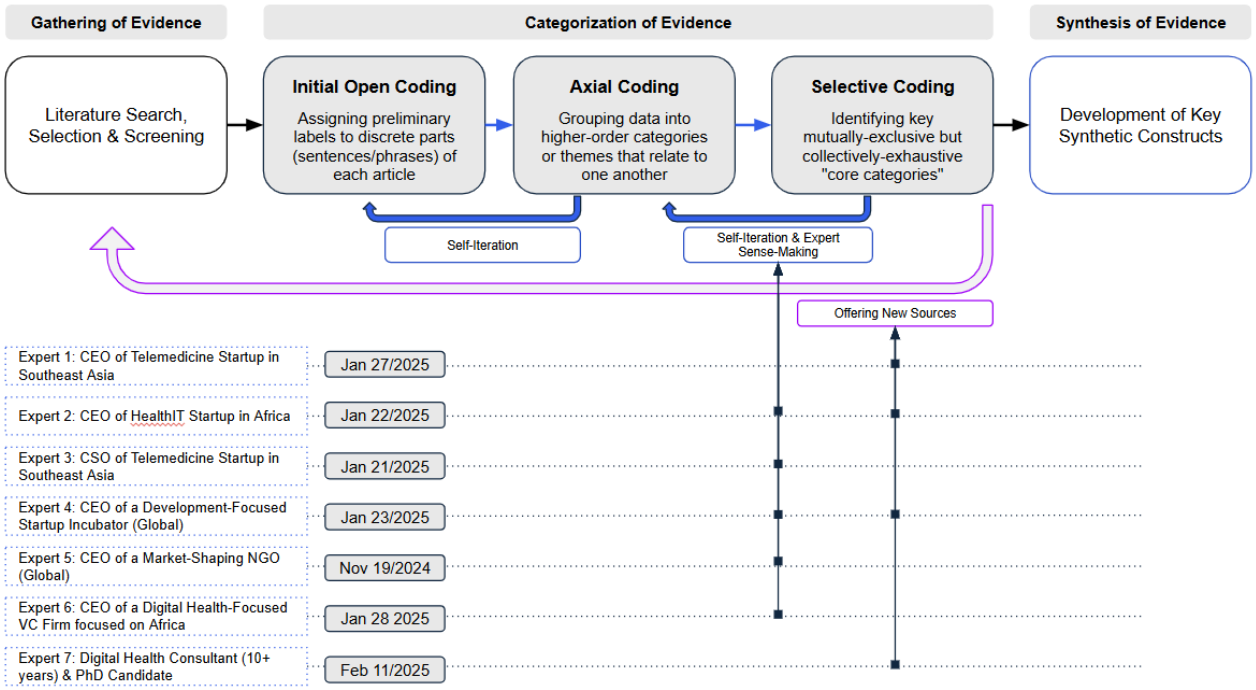


Table 7: Timeline of Interactions with Expert Panellists

Digital health implementation and financial sustainability have locally contextual elements that differentiate across regions; thus the goal of the CIS was to synthesize both a framework and critical commentary that remained broadly generalisable to a wide number of contexts. Although more time-consuming, use of the expert panelists revealed a palpable lack of variance between the overall commentary provided by the panelists and the depth of insights offered by the combination of the initial and purposive selection of literature indicating that the end-results had reached both theoretical saturation and a level of evidence-based practical, real-life applicability. I re-iterate once more that throughout this process the expert panel elaborated sub-themes as part of a sense-making process to reduce my personal biases as a researcher, but I along with my supervisors, retained complete control of screening, coding, and interpretation. Use of

this sense-making process remains a crucial element of developing research outputs that have legitimacy amongst the small number of individuals, groups and institutions that conduct this market-shaping work at a global level.

An overview of the results of the CIS is examined below in Chapter 3, including the conceptual framework.

Chapter 3: Results of the Literature Review

TITLE: IMPROVING THE SUSTAINABILITY OF DIGITAL HEALTH MARKETS & BUSINESS MODELS FOR IMPACT IN LOW-AND LOW-MIDDLE INCOME COUNTRIES: A CONCEPTUAL FRAMEWORK

Overview

Through the CIS, I establish an initial conceptual background to define "what a business model in digital health is", consolidating evidence that spans business management, healthcare implementation, and digital innovation. By systematically analysing various representations, schemas, and taxonomies found in the literature, I developed a unified methodological conception of a "digital health business model". The background below consists of three components derived from the CIS:

1. What is a Business Model?
2. What is a Business Model in Digital Health?
3. Business Models for AI in Digital Health

This initial work during the CIS informed the initial open coding and axial frameworks. In the final selective coding phase, a conceptual framework was developed consisting of four main macro-constructs related to sustaining business models in LMIC Digital Health. Each of these "macro-constructs" and their associated sub-themes is examined in depth, including short quotes from the literature:

1. Internal Entrepreneurial Challenges
2. External 'Market' Challenges
3. Internal Entrepreneurial Strategies
4. External 'Market-Shaping' Interventions

Lastly, to integrate these findings into an actionable structure, I propose a structured market-shaping process for governments and NGOs. This process seeks to strike a balance between the use of the evidence uncovered during CIS and the critical need for more specific empirical evidence to inform market-shaping interventions for geographies and technology types.

Results

Defining “Business Models” in Digital Health

Theoretical Foundations

Although many colloquial definitions and constructs of a “business model” exist, business models are highly significant for implementers as cognitive representations of the link between a company’s, nonprofit's, or social venture’s activities and its overall strategy for financial sustainability and growth.[92,104] Linguistically, the term “model” indicates the constructed nature of these schemas: simplified yet structured representations of reality made up of interconnected constructs that can be expanded or altered. These cognitive and linguistic schemas enable empirical classifications of real-world processes and strategies, providing opportunities for leadership to align decision-makers, internal teams, and external stakeholders around the question, “What is it that we do?”[92,104]

However, business models do more than just categorise an organisation’s current state; they also enable comprehensive mapping of potential new products and commercial opportunities throughout the venture’s life cycle. By comparing different configurations of

business models, executive leaders can identify the most effective pathways for long-term sustainability. This ongoing process then guides the organisation's strategic direction, communication, and alignment. We can compare a business model to an initial architectural diagram showing a building's intended appearance and function. As zoning requirements, climate risks, and material costs emerge, civil engineers refine the architect's plans to realise the original artistic vision while practically ensuring the structure's robustness and cost-effectiveness. For stakeholders outside a venture, such as customers, investors, or strategic partners, understanding an organisation's business model offers a mental taxonomy for benchmarking its activities against those of similar entities. This heuristic helps them gauge their willingness to participate in, purchase from, or invest in the organisation. Without a cohesive understanding of an organisation's business model, internal and external stakeholders may be unaware of how their interactions contribute to the ongoing operations of the systems and processes in place.

Business Models in Digital Health

In digital health, several generic frameworks have gained predominance for their usability during the ideation and evaluation process. Most articles reference Dr. Alexander Osterwalder's 'Business Model Ontology'[100] as a foundational tool, while some use it exclusively to analyse the structure, challenges, and opportunities of digital health companies.[94,101,105] The Business Model 'Ontology' or 'Canvas' consists of nine key components displayed below:

Key Partners	***Key Activities***	***Value Propositions***	***Customer Relationships***	***Customer Segments***
Identifies the network of suppliers and partners that help the business model work, such as joint ventures and strategic alliances.	Describes the most important actions a company must take to operate successfully. ***Key Resources*** Describes the most important assets required to make a business model work, including physical, intellectual, human, and financial resources.	Describes the bundle of products and services that create value for a specific Customer Segment.	Explains the types of relationships a company establishes with specific Customer Segments. ***Channels*** Outlines how your company communicates with and reaches its Customer Segments to deliver a Value Proposition.	Defines the different groups of people or organizations your business aims to reach and serve.
Cost Structure			***Revenue Streams***	
Describes all costs incurred to operate a business model, including fixed and variable costs.			Represents the cash a company generates from each Customer Segment, product or service.	

Table 8: Key Components of the Business Model 'Ontology' by Dr. Osterwalder [100]

Academics have sought to adapt the Business Model Canvas (BMC) for digital health through two primary approaches: by reorganising its nine components into broader categories (e.g., classifying them as business assets versus processes) or by modifying its visual representation to enhance strategic usability. These adaptations aim to balance theoretical rigour with practical clarity, ensuring frameworks remain both theoretically comprehensive and readily actionable for practitioners.

For instance, Gand et al. (2018) reorganised the BMC's nine components into three asset-focused macro-constructs for health information technology (HIT)[92]:

1. ***Value Architecture*** (key activities/resources)

2. ***Value Finance*** (cost structure/revenue streams), and
3. ***Value Network*** (partners, customer segments, relationships, channels)

However, this asset-based approach risks oversimplification by treating components as static elements rather than dynamic, interconnected processes.[90] This may be especially problematic within digital health since healthcare is an industry which often requires many collaborative and iterative human interactions. To address this limitation, some academics have proposed more process-based classifications that emphasise resource flows, stakeholder interactions, and value generation.[34,35,96] The CompBizMod Model illustrates this focus with the following components:

1. ***Value Proposition*** (overall proposition for healthcare impact)
2. ***Value Co-Creation*** (designing solutions aligned with stakeholder needs)
3. ***Value Delivery*** (efficiently distributing services/products), and
4. ***Value Capture*** (monetising outcomes sustainably)

Validated as the sole evaluated business model framework for digital health, the CompBizMod Model combines theoretical depth with intuitive visualisation.[103] Its process-oriented structure, beginning from value proposition to value capture, grounds business ideation in its process-oriented roots while also providing opportunities for comparative analysis by highlighting multiple areas for strategic choice within each domain of “value” (e.g., prenatal vs. postnatal care value propositions).[96]

Dimension	Parameter	Characteristic			
Value Proposition	Overall purpose	Prevention	Diagnosis	Therapy, curative	Therapy, palliative
	End consumer	Professional provider, physician (B2B)		Patient, relatives (B2C)	
	Partner network	A fixed set of other partners is involved	A flexible, competing set of partners is involved	No partners are involved, or if at all indirectly	
	Realization of benefits for the patient	By application		(if at all) indirectly	
Value Co-Creation	Portfolio role	One of several offerings in the same area	Complement offering	Singular, stand-alone offering	
	Contact with patient	Direct	Indirect	No	
	Domain-specific know-how	Not necessary	Necessary, provided by own employees / in-house	Necessary, requires cooperation with (external) domain experts	
	Required responsiveness	Immediate personal reaction	Automated immediate info forwarding, non-immediate personal reaction	Non-critical	
Value Communication & Transfer	Required means of communication*	No*	Platform (server, database)*	Measuring devices / wearables & platform*	
Value Capture	Type of revenue	Transaction-based	Transaction-independent	Mixed	
	Paying entity	Health insurance	Patient	Other stakeholder	Mixed
	Cost drivers	Personnel costs		Equipment	

Color scheme legend for each parameter: Only this characteristic | Also this characteristic | Not this characteristic

Comments: *Internet, telephone, mobile phone incl. mobile data are considered as given

Table 9: Example use of the CompBizMod Framework from Peters et al. 2015 to Map Potential Business Strategies[96]

Business Models for AI in Global Health

Emerging technologies, such as artificial intelligence (AI) and generative AI, are poised to transform traditional business models in digital health. As outlined by Garbuio et al. (2019), startups can integrate AI at three distinct levels of impact.[93] The first, assisted intelligence, enhances existing processes by automating simpler, repetitive, and rule-based tasks. The second, augmented intelligence, reimagines clinical pathways by embedding AI into higher-level clinical decision-making. The third, autonomous intelligence, enables AI systems to act independently toward predefined goals, potentially reshaping roles traditionally reliant on human expertise.

Changes in pricing models are an example of the type of changes that could take place as AI adoption increases. For example, given the difficulties of quantifying the impact of entirely new AI-native workflows in healthcare, startups may choose to align their pricing with direct “value creation” or customer-level ROI to incentivize buyers to purchase their products. This could represent a fundamental shift from flat subscription fees to more outcome-based reimbursement models.[93] Although challenging to implement, such approaches may prove critical in LMICs, where health systems are under immense budget pressures and may increasingly demand more apparent economic benefits, such as reduced errors or faster turnaround times, to foster large-scale investment from institutional funders.

As AI’s technical maturity grows alongside advancements in digital infrastructure and regulatory frameworks, novel business models will likely emerge.[93] These models must strike a balance between the pace of technical innovation and the financial and operational realities of healthcare systems in LMICs, ensuring that AI’s transformative potential is both scalable and sustainable in diverse global contexts.

Overview of the 4-Part Conceptual Framework

The critical interpretive synthesis, including both 21 article extractions (Supplementary Appendix Tables 1-2: Overview of Extracted Articles) and purposive selection of 'market-shaping' literature, resulted in the creation of a 4-part conceptual framework. This conceptual framework depicts four key challenges to the sustainability of digital health business models in LMICs, which the strategic deployment of both iterative internal business strategies and external market-shaping interventions could potentially reduce. The Conceptual Framework in Figure 2 below details these concepts.

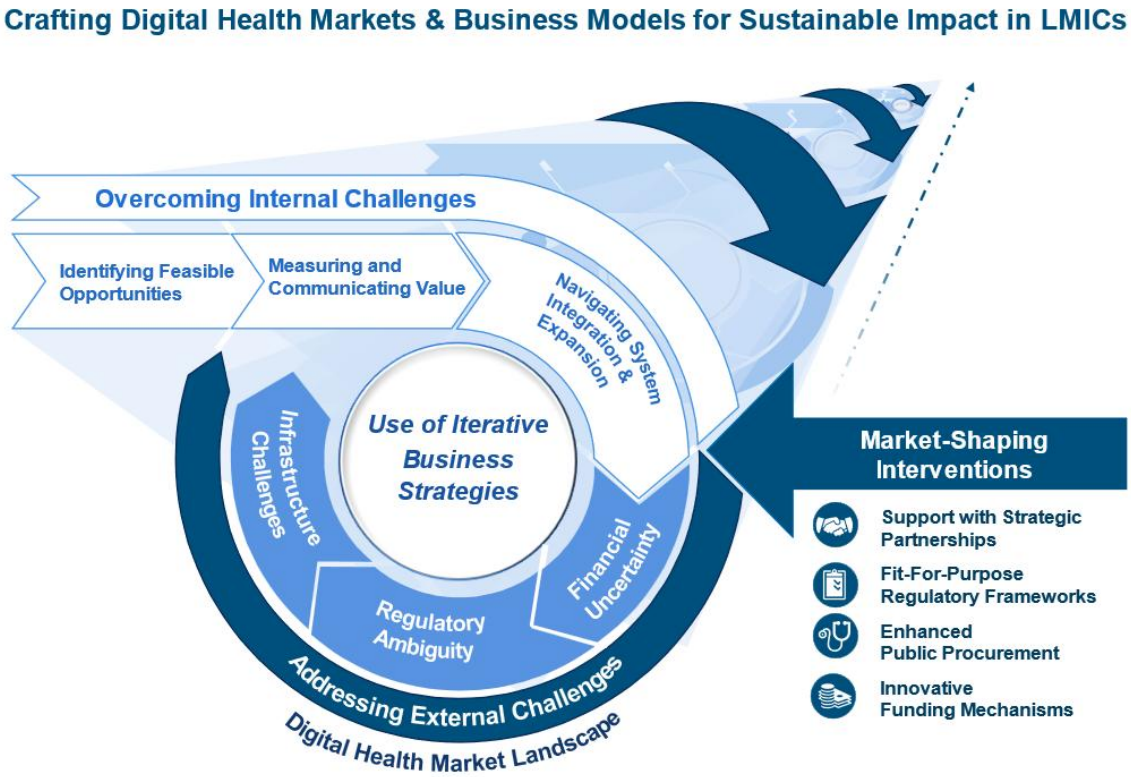


Figure 3: Conceptual Framework Derived from the CIS

Internal threats to sustainability consist of challenges related to managing value creation for complex stakeholder networks, including difficulties associated with identifying

feasible opportunities, measuring and communicating value, and navigating system integration and expansion. Externally, market challenges include financial uncertainties, infrastructure limitations, and regulatory ambiguity. These overarching challenges encompass additional sub-challenges that may vary in severity depending on the technology or country in question. Depending on the context, addressing these challenges may require both iterative business strategies which differ based off the stage of the company or digital health initiative as well as external market-shaping interventions which can be in the form of: strategic partnerships, fit-for-purpose regulatory frameworks, innovative funding mechanisms and enhanced public procurement. Each of the components of the conceptual framework is explored in further depth below. A full list of example short-quotes for each construct, theme and sub-theme are available in the Appendix (Supplementary Appendix Tables 5-8).

Internal Entrepreneurial Challenges

Digital health companies face several inherent challenges in running entrepreneurial organisations that have the dual responsibility of managing the complexities of rapid technological innovation, which can deliver value, alongside the slow and human-centric processes of healthcare. These challenges are further compounded by the difficulties of navigating the global health landscape, which is often characterised by a complex network of stakeholders across multiple regions with diverse agendas, priorities, and timelines for impact. Three key challenges underpin the core difficulty of creating value within these complex stakeholder networks. Below, I explore these challenges and include several brief quotes from the literature to illustrate these themes.

Identifying Feasible Opportunities

A value proposition in digital health describes a bundle of products or services that enables a company to deliver a tangible impact for its users. These propositions can be categorised into four core types: functional value (e.g., telemedicine platforms enabling remote consultations), emotional value (e.g., mental health apps providing emotional support), social value (e.g., community networks connecting patients to peer groups), and epistemic value (e.g., educational tools improving health) literacy).[95] Common themes include improving care coordination, personalized services, bridging infrastructure gaps, and reducing costs through operational efficiency gains.[35,102]

"It is imperative to assess what benefits are possible and thus what value a telemedicine service can offer to its entire network of stakeholders, the meaning of this value to each stakeholder, the need for stakeholders to be inspired to collaborate and co-create value for themselves and each

other and the significance to discover how this co-created value can be properly divided among the stakeholders" [34]

However, crafting value propositions in digital health can be complex. Digital health companies face significant hurdles in defining value propositions that balance impact with commercial viability. Early-stage ventures must co-create solutions that appeal to stakeholders with sometimes conflicting priorities: patients seeking affordability, providers prioritising workflow efficiency, and policymakers or funders who are often focused on systemic outcomes that can generate political gains. For example, a tool designed to streamline provider workflows may fail if it overlooks patients limited digital literacy or policymakers' regulatory concerns. Therefore, without context-specific information to identify and test areas for value creation, companies risk developing solutions that address isolated problems in pilot projects but lack the potential for scalability or sustainability across larger segments of the health sector system.[34,90,103] Lastly, differences in resource availability, timelines for impact, and power dynamics complicate efforts to translate stakeholder needs into clear product roadmaps.[36,90,106]

Measuring & Communicating Value

Multi-sided business models, which are common in digital health, can pose unique challenges to operating sustainability. For example, Aravind Eye Hospital in India uses a business-to-consumer (B2C) telemedicine model where rural doctors connect patients to remote ophthalmologists for diagnostic interpretation of eye scans. Therefore, the long-term sustainability of the model depends on aligning the incentives of both physician groups towards ongoing collaboration.

> *"The evaluation of costs and benefits in e-health and healthcare in general is a perennial problem involving a large number of different stakeholders and sometimes conflicting views on the value of a particular course of action."* [101]

For example, if urban ophthalmologists face higher opportunity costs due to uncompensated time or workflow disruptions when treating remote village patients versus urban in-person patients, they might eventually withdraw from providing these services. This mismatch highlights the "wrong pocket" problem in digital healthcare, where the main beneficiaries, such as patients gaining access to care, do not bear most of the costs. Meanwhile, the urban providers, like ophthalmologists, may see a reduced return on their efforts investment.[34,90,94,107] Even as startups scale, such misaligned metrics for success can undermine long-term engagement and thus the possibility of recouping the up-front investment costs put into the initial pilot.

Furthermore, for digital health startups seeking global health funding, such vague distributions of economic or financial impact can also hinder clear articulation of an intervention's value and its apparent success. Variability in data quality, interpretability, and interoperability can make outcome measurement even more difficult, creating inherent challenges in securing financial support for digital health initiatives. [101]

Navigating System Integration & Expansion

Business Models in digital health, especially those serving lower-income markets, are often constructed of complex, high-dependency value networks where the quality of a given service depends on several partners or stakeholders.[35] The need for the close integration of stakeholders in a healthcare ecosystem creates inherent challenges trying

to develop trust and cost-effectively scale early pilot success in new geographies that have different needs, power dynamics and external challenges. As digital health startups expand, many find challenges integrating with new processes, workflows and technical systems.

"Integrating innovative healthcare solutions with existing healthcare systems, workflows, and technologies can be challenging due to interoperability issues, data silos, and legacy infrastructure." [36]

Lastly, even if a digital health solution experiences continuous user growth or gains adoption within the public health system, long-term economic and health benefits may not be achievable if the health system lacks the capacity to fully capitalise on the tool's advantages. For instance, an mHealth tool used to triage mental health issues may see increased usage at the community health level – but if the tool fails to assist local clinics in managing the new demand or redirect patients to clinics with greater capacity, the expected downstream health benefits could be only marginally realised affected.[33] Thus, without continuously integrating digital health tools into trusted systems for care management, many digital health solutions may continue to only operate at discrete “points” in the health-system without possibility of scale.

External Market Challenges

Financial Uncertainties

Financial uncertainties, especially past pilot stages, continue to stifle the sustainability of digital health solutions in LMICs.[34,93,98,101,108] Three key issues exacerbate financial uncertainties: lack of funding, funding unreliability and high transaction costs.

As a former head of e-health for the Ministry of Health in a LMIC, reportedly explained:

> *"Many [mHealth] projects ... begin without an idea of who will fund them in the long run. Often, without continued funding from initial donors, high operating costs cause the eventual downfall of the project."* [33]

Culturally, the global health financing system, which often prioritises 'vertically-focused' interventions with clear 'value for money,' could have implicit difficulties funding 'horizontally-integrated' digital health interventions with less-proven business models or impact timelines.[1,94,109] Furthermore, the context-specific nature of digital health implementation, which often demands longer and more iterative approaches, may conflict with a philanthropic culture of short-term, milestone-driven grant cycles. [33,109]

> *"Often, without the continued funding from initial donors, high operating costs cause the eventual downfall of the [mHealth] project."* [33]

High transaction costs, referring to sales, marketing, and payment collection, are another key barrier.[110] Digital health tools often require frequent training and ongoing support, making it costly to reach and retain users across dispersed populations with infrastructure and language barriers.[33,94] Even when digital health companies demonstrate impact,

reimbursement inefficiencies can result in delayed payments leading to operational and financial tensions.[35,94,109]

> *"There are also delays and desynchronization of funding flows in public sector procurement." [94]*

When institutions, whether government or NGOs, fail to pay digital health companies for products and services rendered, such delays can prove catastrophic to the financial health of an organisation. Delays in reimbursement can reduce the on-hand cash stores to pay for ongoing operational costs related to personnel, technical infrastructure or user support.[35,94,109] Such delays may also reduce the willingness of funders and investors to invest in these technologies for deployment in LMICs in the future.

Infrastructure Challenges

Digital health technologies often require access to cellular or Wi-Fi networks to facilitate consultations or exchange health data. A lack of quality infrastructure, both digital (e.g., Wi-Fi, cellular, data exchange, digital payment, digital ID) and physical (e.g., power, devices), can hinder pilot success and scalability.[105] Chronic infrastructure challenges can degrade service reliability, eroding user trust and retention.

> *"MOTECH, an mHealth system in Ghana, attempted to store health information on employees' cell phones. However, limited memory capacities forced a significant business model change." [33]*

Even when connectivity is available, costs for connectivity are often several magnitudes higher in LMICs compared to other contexts[33]. This is problematic since many value propositions in digital health require high-volume data exchange as a foundation for quality user engagement.[33,111] Furthermore, as companies scale, operational costs for electricity and physical devices can also outpace financial sustainability, especially in LMIC's where such costs may be too high to pass onto other stakeholders.[33,98,102,103,106,111]

> *"With poor cell phone infrastructure, cell carriers charge extra for roaming and these costs can quickly add up with a high volume of text messaging."* [33]

In conclusion, digital health companies face tough decisions in managing these infrastructure costs. Whether building in-house systems, relying on third-party providers, or leveraging existing platforms, expenses in LMICs are high, with limited alternatives.[33,94,98] This reality can complicate balancing scalability with financial sustainability.

> *Living Goods, an mHealth venture based in Uganda, "found that the inability of both clients and employees to charge their cell phones limited their customer base."* [33]

Regulatory Ambiguity

I. Lack of Regulation

Lack of regulation can create challenges establishing trust with potential users, partners and even potential employees of digital health companies. Creating regulatory capacity to evaluate the impact and necessity of various digital health policies may be inherently challenging given the interdisciplinary nature of digital health technologies which combines medicine and computer science, two highly technical domains.

> *"Although several contributions exist, regulatory paths are often unclear or have not been defined yet, and more research is needed to understand how startups can cope with the challenges."* [103]

The absence of regulatory frameworks for digital health could lead to the proliferation of un-evaluated digital health products and hinder the market entry of products that have been deemed safe in other markets. [35,103,106]

II. Regulatory Complexity

Regulatory complexities can create internal challenges managing the compliance processes required to disseminate digital health technologies at multiple levels. [94,103] Within countries, poor harmonisation across counties or states can create challenges scaling digital health interventions, even when there is an expressed interest by potential users and customers to adopt such technologies. [35,103,106]

Given the interdisciplinary nature of digital health regulation which may span multiple government ministries (Health, Telecommunications, Standards etc.) but also various divisions of ministries (Medical devices, IT etc.), such challenges could remain systematic

without a clearly coordinated effort at the highest levels to coordinate cross-ministerial responsibilities for digital health evaluation, purchasing and adoption. [36,106,112] Thus, weak cross-coordination at multiple levels can delay compliance processes by forcing companies into lengthy, expensive and redundant processes for device certification and data privacy certifications. [36,106,112]

> *"Prior to the COVID-19 pandemic, the GOI had not published clear guidelines for services like teleconsultations and telemedicine ...The norms and protocols related to physician–patient relationship, issues of liability and negligence, evaluation, management and treatment, informed consent, medical records, privacy and security of patient records were ambiguous."* [105]

Lastly, the misapplication of regulations designed for other types of healthcare enterprises can limit the ability of digital health companies to reach the economies of scale necessary to become financially sustainable. For example, under laws that prohibit pharmaceutical companies from advertising medical drugs, telemedicine companies in India have reported facing fines and warnings for advertising remote consultations. [105,112] Such barriers can reduce the legitimacy and trustworthiness of digital health companies, even where best practices and clinical guidelines are being followed. [33]

Internal Business Strategies: Iterative and Fit-for-Purpose

Digital health companies face significant internal and external challenges when seeking to create value in low- and middle-income countries (LMICs). To address or mitigate these challenges, implementers of digital health technologies will need to adopt iterative business strategies that are tailored to their specific LMIC contexts. The table below offers a summary of these strategies stratified by where they emerge during the ‘life cycle’ of a digital health company. Below, I investigate these strategies more in-depth.

Overview of Potential Internal Business Strategies

Summary of Key Entrepreneurial Strategies for Digital Health Companies in LMICs

Stages of Startup Maturity

Business Model Component	*Pilot-stage*	*Scaling-up*	*Sustaining*
Value Proposition	**Map stakeholder interactions** and power dynamics. **Conduct discovery interviews** to identify and co-create valuable solutions. **Ensure integration** with broader healthcare processes and incentives.	**Continuously test and refine value propositions** based off feedback.	**Use feedback mechanisms to anticipate changes** and prevent quality control issues.
Value Creation	**Co-create metrics** and expected outcomes with funders, users & customers. **Incorporate regulatory compliance** into timelines and trade-offs for product development. **Use iterative business methodologies** like Lean Startup & Agile Development. **Conduct robust research**, monitoring and evaluations.	**Regularly align an interdisciplinary team around key performance indicators** (i.e. clinical, operational and financial metrics) to drive strategic decision-making. **Implement frugal technical approaches to enable cost-effective scale** (e.g., Store and Forward mechanisms).	Leverage brand reputation to **lower infrastructure and other costs through partnerships.** Engage in **cooperative competition** to institutionalise new industry standards.
Value Communication & Delivery	**Establish partnerships** to cost-effectively reach an initial group of users. **Engage regulators** with early outcomes data where regulation is lacking.	**Further empower local partners, users and other stakeholders** in promoting the product or service.	**Advocate for more effective public-sector procurement.**
Value Capture	**Identify stakeholders with motivation to become customers.** **Test pricing strategies** and conduct market research.	**Consider providing ancillary services** to cross-subsidize essential but less profitable services. **Offer hybrid pricing models to maximize revenue streams** and accommodate for variation in customer purchasing power.	**Advocate for more effective reimbursement mechanisms**

Table 10: Overview of Potential Internal Business Strategies

Piloting Business Models in Digital Health

Digital health companies should leverage public reports and interviews with local experts to map key stakeholder interactions and power dynamics in the health system, uncovering pilot opportunities for value creation.[36,93,94,106] Conducting discovery interviews can also help identify valuable local value propositions and generate insights into why pre-existing companies succeeded or failed.[36,91,94,96]

However, the depth of this initial work can vary greatly depending on if the proposed solution is meant to create value at a single discrete ‘point’ in a care or operational workflow or if it’s meant to augment an entire workflow end-to-end For digital health ‘point solutions’, products that target select segments of a healthcare workflow, extra consideration may be needed to ensure the product integrates well with broader health-system factors. [36,96] These interconnected factors, such as the capacity of the health system to absorb new patient demand, heavily influence the outcomes these technologies may look to tackle and thus their potential for long-term sustainability.

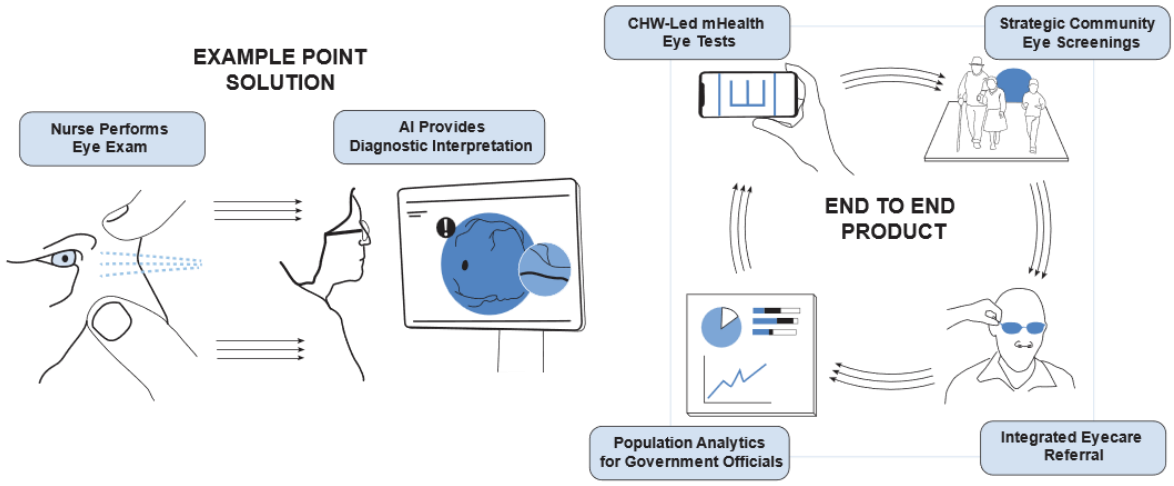


Figure 4: The Point solution on the left, an AI algorithm for assessing diabetic retinopathy from retinal images augments a specific section of a clinical providers workflow. The right however encompasses eye-care across a continuum of triage and treatment.

Once a digital health company has co-created metrics for a pilot project, it will need to ensure that it has the capacity to deliver and evaluate its impact cost-effectively.[36,96,98,106] Collaborating with academic institutions may help in addressing early gaps in scientific and research expertise.[35,103] Meanwhile, where regulation exists, understanding how a product's intended use will influence its regulatory classification will help ensure the challenges of regulatory compliance are accounted for in the long-term company strategy.[90,103] Where regulation is lacking, entrepreneurs should engage regulators with early outcomes data and follow international best practices (e.g., WHO Guidelines, GDPR, HIPAA).[36,94,106]

As digital health companies attempt to scale, they must carefully decide which value propositions to develop and when.[35,36,90] To do this cost-effectively, they should use iterative methods like Lean Startup and Agile Development methods.[13,113] By continuously testing and refining their offerings using customer and user feedback, companies can

ensure they're focused on maximising user-centric value as cost-efficiently as possible.[13,111,113]

Lastly, companies should identify stakeholders with the motivation to become customers and tailor their business models accordingly.[13] Testing pricing strategies, conducting market research with patients, providers, or partners and diversifying funding streams can help create financial models to inform strategy for ensuring long-term sustainability.[35,36,103,111]

Scaling-Up Business Models in Digital Health

Scaling digital health in LMICs requires continuous monitoring of clinical, operational, and financial metrics to assess impact, optimise cost-effectiveness, and identify new opportunities to deliver greater value at lower costs.[35,36,113] Aligning an interdisciplinary team around these insights will be critical for navigating complex strategic decisions and ensuring long-term success.[106]

As digital health companies expand, rising costs for cellular connectivity, data storage, electricity and physical devices can quickly become unsustainable.[33,35,36] 'Store and Forward' mechanisms, which balance use of local phone storage versus cellular networks based on cellular availability, are an example of an enabling frugal approach.[33] Such mechanisms may be particularly valuable for extending technologies to areas with inconsistent or expensive cellular networks or to workers who have limited memory capacity on their devices.

Beyond technology, empowering local workers and communities can provide a cost-effective way to scale the user base. By leveraging existing social networks, companies can spread awareness, recruit employees, and build community trust.[33,35,36,111] However, aligning partner and employee incentives is necessary to prevent malpractice, for example, if community-health workers began unintentionally overprescribing antibiotics due to volume-based sales incentives.[33,111]

Lastly, to ensure financial viability, many digital health companies may introduce ancillary services like e-pharmacy or lab testing to generate additional revenue and cross-subsidise essential but less profitable services, such as maternal health screenings.[36,111] Additionally, hybrid pricing models, for example, combining subscription fees with small pay-per-use charges, can help shift revenue streams to different stakeholders depending on their purchasing power.[13,34,111]

"Most firms used a combination of revenue streams in order to aim towards sustainability. These include subscription-based fees, pay-per-use charges, IT platform fees from doctors, e-pharmacy and diagnostic tests. "It was found by the authors that telemedicine firms in India generally used hybrid business models, providing options of pay-per-use model, subscription and freemium models." [105]

Sustaining Business Models in Digital Health

As digital health companies mature and continue to reach scale sustainably, they should continue to coalesce an interdisciplinary team around key metrics for clinical, operational and financial success. To proactively anticipate changes in user needs and value

propositions, digital health companies should empower partners, users, customers and local employees to provide regular feedback through established processes and systems.[35,36,99,113] Furthermore, to continue providing impact at scale, companies can also consider strategic partnerships as a pathway for further cost reductions related to marketing and infrastructure.[101,106]

For example, Telenor, a Norwegian telecommunications company seeking to expand in Bangladesh, a new, unfamiliar market, opted to partner with Grameenphone, a local Bangladeshi telecommunications company in which they had previously invested.

> *"Telenor [Health] used Grameenphone's go-to market structure to drive the new service's distribution and reach. Grameenphone customers who qualified as revenue customers and enrolled in the new service received a basic bundle of health services for free. This helped increase Grameenphone's market share and helped it attract revenue-generating customers."* [106]

Leveraging the go-to-market infrastructure of well-regarded partners or larger parent companies not only allows new digital health enterprises to scale their customer base more quickly and cost-effectively but also allows new companies to develop legitimacy by leveraging the brand name of their partners or parent companies.[101,106]

Lastly, engaging in cooperative competition (co-opetition) can unlock new avenues for private-sector coalitions to jointly contribute to advancing legislation related to patient safety, reimbursement or public sector procurement. [36,94] As advanced technologies like AI and Agentic AI begin to hold promise for healthcare transformation in LMICs, such

private-sector expertise could be crucial in enabling more proactive legislation that helps improve the business environment for future technological adoption.

External Market-Shaping Strategies: Developing an Enabling Business Environment

Given the external market challenges associated with commercialising digital health technologies in LMICs, external ‘market-shaping’ strategies emerged as enabling interventions to create an market environment that strategically aligns private-sector business models towards tackling public health priorities. The table below provides a summary of these strategies, segmented by the challenges they address.

Overview of Potential Market-Shaping Strategies for Digital Health Technologies

Summary of Market-Shaping Strategies for Enabling Digital Health Markets in LMICs Types of 'Market-Shaping' Interventions & Instruments				
	Support with Strategic Partnerships	***Fit-for-Purpose Regulatory Frameworks***	***Enhanced Public Procurement***	***Innovative Funding Mechanisms***
Addressing Internal Challenges				
Managing Value Creation for Complex Stakeholder Networks	Facilitate **stakeholder knowledge exchange and alignment** through incubators, accelerators, and networking events. Engage **academic institutions** to provide scientific expertise and evaluation capacity.	Establish **regulatory sandboxes** to collaboratively test innovations under relaxed requirements.	**Articulate key gaps and priorities** in the public health system Use of **transparent Procurement** Platforms and Processes Use **positive and negative incentives** to encourage digital health adoption in the public-sector.	
Addressing External Challenges				
Regulatory Ambiguity		Co-develop **locally relevant regulatory frameworks**. **Clearly articulate and enforce technical standards** for interoperability, privacy and data ownership. Enable **regional regulatory harmonisation** to support cross-border scaling.		
Financial Uncertainties			**Aggregate demand across regions** to negotiate lower costs and expand access. Commit to **longer-term contracts** to account for implementation challenges. **Disburse timely payments** for contracted products and services.	Introduce **outcomes or performance-based financing** linked to operational or clinical metrics. Deploy **blended and mezzanine financing models** to help bridge funding gaps.
Infrastructure Challenges	Build **cross-industry partnerships** (e.g., telecommunications, banking) to share infrastructure and expand reach.	Subsidise access **to public technology infrastructures** (e.g., satellite networks) for underserved populations.	**Focused investments in digital public infrastructure** (e.g., data ID, digital payment, data exchange). **Focused investments in technology infrastructure** for the most underserved health system users	

Table 11: Overview of Potential Market-Shaping Strategies for Digital Health Technologies

Support with Strategic Partnerships

Given the interdisciplinary skill-sets and resources required to deliver digital health solutions, facilitating strategic partnerships can enhance the cost-effectiveness and scalability of digital health initiatives through exchanges of knowledge, capabilities, social capital and infrastructure.[13,33,35,36,103] For instance, externally sponsored initiatives such as incubators, accelerators, and networking events can provide private-sector innovators with equitable opportunities to understand the on-the-ground realities of healthcare delivery.[36,103] These platforms can enable innovators to uncover shared pain points in the local health system, build connections across stakeholder networks, and promote the adoption of new products and services.[33]

Moreover, governments can further reduce the costs associated with infrastructure challenges by facilitating cross-industry partnerships with companies in industries like banking, insurance and telecommunications.[94,101] Such companies already have established digital infrastructure and larger customer bases that can help improve the scalability of smaller digital health initiatives.[106] Lastly, fostering proactive partnerships between digital health companies and academic institutions can provide access to the scientific expertise needed to effectively research, monitor, and evaluate the impact of complex digital health interventions.[35,36,103]

Fit-for-Purpose Regulatory Frameworks

Given the complex, fast-moving trajectory of digital health, LMIC governments should prioritise establishing or joining regulatory sandboxes. Regulatory sandboxes are controlled environments that allow policymakers to directly collaborate with the private

sector to assess how emerging technologies perform in their local environment and to develop fit-for-purpose regulatory frameworks that balance safety and equity with incentives for regional innovation.[13,36] This approach may be beneficial for interdisciplinary technologies like digital health, which may require the collaboration of multiple groups of authorities (i.e. telecommunications, health services, labour) to coordinate on interoperability requirements, technical standards and protocols for patient safety.

In the long term, regulatory sandboxes could also help enable regulatory harmonisation at regional, national or multinational levels. [114] By aligning digital standards and technical requirements across borders, governments can help simplify the expansion of high-impact digital health technologies, enabling digital health innovations to scale to new geographies more cost-effectively.[13,115] Such regulatory efforts should consider the government's capacity to manage new digital health evaluation and compliance efforts and seek to prevent regulatory capture by commercial interests.

Finally, regulatory mechanisms can also be used to broker access to digital public infrastructure (DPI).[115] The Indian Space Research Organisation has taken this approach by enabling select telemedicine solutions to leverage its satellite infrastructure for serving rural populations.[101] Such approaches can help dramatically lower the costs of scaling such technologies, especially in LMIC's with high costs of connectivity.

Enhanced Public Procurement

To drive public-sector demand for digital health technologies with complex implementation timelines, governments could consider carefully selected positive and/or negative financial or non-financial incentives.[116,117] For example, the Indian National Health Authority launched 'the Digital Health Incentives Scheme' (DHIS) to incentivise health facilities, labs, and digital health providers to register patients into their new national EHR registry.[118]

However, with an increase in the supply and demand for digital health solutions, there also runs the risk of accelerating a more fragmented and inequitable distribution of digital health in the public sector.[115,119] To prevent over-fragmentation, governments will need to continue to enforce interoperability of health records, services and claims while streamlining public-sector procurement through efficient but transparent platforms and processes.[13,115,120,121] To facilitate this, governments should consider focused investments and procurement into digital public infrastructure, including infrastructure for digital IDs, digital payments and data exchange.[94,122,123]

In addition, governments should consider focusing technology infrastructure investments for digital health adoption in areas of the highest need. Furthermore, governments can consider committing to longer-term contracts or aggregating demand from purchasers across multiple regions, counties, or even countries to negotiate lower costs and expand access to digital health technologies. [115]

Lastly, public entities must establish reliable mechanisms to ensure the timely reimbursement of public funds to digital health companies as per contractual agreements.

Persistent delays in payment can cripple companies' ability to pay employees, invest in scaling their solutions, and maintain operations, eroding investors' and funders confidence in private-sector digital health initiatives in LMICs.[109]

Innovative Funding Mechanisms

One of the most persistent and complex market issues in LMICs is the lack of funding for digital health companies. While public procurement is essential for supporting high-impact digital health markets, direct reforms in funding mechanisms are crucial. [103,124]

First, the context-specific nature of digital health means the timelines and costs of customer-specific implementation can be high. These challenges mean that digital health companies may require longer-term guarantees, which could conflict with a philanthropic culture of providing catalytic capital for pilots without subsequent funding to support companies' scaling efforts. [103,124] To de-risk long-term guarantees, philanthropists and governments should consider offering outcomes-based reimbursement, which involves variable payments to companies based on the achievement of specific clinical or operational outcomes. [36,115,125] Moreover, such performance-based incentives may also encourage digital health companies to shift from offering isolated point solutions that marginally improve systems to creating more comprehensive offerings with a higher economic impact. [13,109]

Second, given the perceived lower returns of ventures in LMICs, pure grant, equity or debt models may not be as effective for aligning the incentives of investors and entrepreneurs as more innovative forms of financing.[124,125] For example, traditional equity

financing, which dilutes control and future profits, has been shown to have a lower level of acceptability for digital health entrepreneurs in East Africa than more flexible financing options like blended finance and mezzanine financing, which combine equity (e.g., ownership stakes) and convertible or non-convertible debt (e.g., loans). [124,125]

Third, funders and government payers can consider prioritising high-impact entrepreneurs with a strong contextual knowledge of the local environment. Foreign teams or academic pilots without local experience should be encouraged to hire local talent to ensure productive, locally driven change.

Next Steps

The use of Critical Interpretive Synthesis reveals immense internal and external challenges facing digital health organisations from the literature. Most importantly, the evidence points towards external market-shaping interventions, if leveraged alongside fit-for-purpose entrepreneurial strategies, could have the potential to improve the alignment of financially sustainable digital health businesses towards addressing the needs of public health systems. However, the real-world implementation of such market-interventions has complexities that must be examined beyond literature. Thus, for practical application in the real-world, it becomes necessary to investigate a narrower scope of technologies within a more specific country-level context. Therefore, leveraging these theoretical findings, I used the conceptual framework to inform qualitative empirical work explicitly focused on AI-enabled digital health technologies in Kenya.

Chapter 4: Qualitative Methods

TITLE: What Are the Barriers and Facilitators To Deploying Market-Shaping Interventions for AI-Enabled Digital Health Solutions in Kenya's Public Health System?

Overview and Study Context

Significant gaps in the scale of the healthcare workforce and the availability of key resources for health facilities continue to create immense health-system challenges in Kenya.[126–128] Access barriers for patients, such as long travel distances, poverty and reliance on informal employment, mean that many patients, especially those who are poor or in rural areas, delay care until their condition has advanced.[127,129] Challenges, both clinical and operational, call into question the role that technology may be able to have in creating or facilitating healthcare service delivery in Kenya that is more equitable, high-quality or cost-effective.[130–132]

Several policies, including the Social Health Insurance Act, the Primary Health Care Act, the Facility Improvement Act, and the Digital Health Act, have initiated strategic transformations in public health delivery. These acts, passed in 2023, have laid the foundation for advances such as more accessible universal health insurance and decentralised hospital purchasing technologies.[133,134] Furthermore, they have aimed to establish a high-quality, interoperable nationwide digital infrastructure, or 'superhighway,' for healthcare data and have established a standalone Digital Health Agency to lead in several of these strategic efforts.[135]. These efforts point to a coordinated strategic effort to launch policy aimed at adopting digital health, creating a potential window in which state capacity may be more effectively allocated to market-shaping in digital health than in the past.

AI-Enabled Digital Health Initiatives in Kenya

Kenya has been an early adopter of digital health tools, but implementation remains fragmented. For example, A 2025 evaluation noted that 91% of surveyed facilities in one county used the KenyaEMR for HIV care. Still, the lack of interoperability, the absence of patient IDs and frequent infrastructure issues affecting application downtime have hampered data sharing and use.[136] Despite some of these challenges, both the private sector and the public sector have continued to attempt to disseminate DHIs at scale.

For example, organisations from Peek Vision (AI/Computer Vision for Eye-Care) to Jacaranda Health (AI-LLMs for Patient Triage) have offered AI-enabled services that have extended clinical triage and diagnostic capabilities to last-mile community health workers and patients. These efforts have resulted in new cost-effective preventative healthcare workflows that have improved treatment-seeking behaviours and patient outcomes through more automated and decentralised patient management.[137,138]

Furthermore, Penda Health in Nairobi, in collaboration with OpenAI, released an AI-enabled EMR in Kenya that represented one of the first real-world studies of LLM clinical decision support for primary care. Such efforts by Penda and OpenAI to implement AI for provider decision-support through an ambient warning system have resulted in increased guideline adherence and improved patient safety, albeit without yet proving a statistically significant increase in patient outcomes.[12] These efforts, both recent and longitudinal, draw attention to the role that private organisations have played in augmenting or potentially augmenting clinical practice in Kenya.

No academic or industry publications have examined market-shaping work explicitly focused on AI-enabled products and services in LMICs. Given the increase in large-scale AI applications in Kenya's public health system as well as the presence of new Kenyan regulations in the AI-Health space, the technology-context choice was deemed appropriate. Furthermore, qualitative methods were deemed appropriate for the empirical study, as they enable an in-depth exploration of stakeholder perspectives, contextual factors, and implementation processes surrounding AI adoption in Kenya's health system. Quantitative or Mixed-methods approaches like the use of a survey of would be premature at this stage, as key parameters, such as the maturity of the AI-Health market and the measurable outcomes of AI-enabled interventions, remain ill-defined and heterogeneous across use cases. Empirical testing of the framework derived from the CIS might improve the applicability of the framework for real-world contexts and thus enable quantitative or mixed methods approaches in the future.

Overview of the Methodology

1. Research Questions

I conducted 16 semi-structured interviews with multiple stakeholder groups involved in piloting, scaling and sustaining AI for the Kenyan public health system. Through these interactions, I gathered evidence to investigate the following research questions. Under each research question, I offer a direct linkage between the results of the CIS and the design of the empirical work to address each question.

I. **RQ3:** Which challenges have impacted the sustainability of AI-enabled digital health business models in serving the public health sector in Kenya?

The CIS emphasizes that market-shaping interventions are more effective when they strategically remove market barriers in exchange for better market alignment with public health value (5 A's of global health market-shaping from the introduction). Thus, I sought to generate a strong initial understanding of the specific challenges being faced by Health-AI companies serving Kenya's public health sector. The line of questioning around this research question directly assesses stakeholder attitudes regarding the challenges uncovered during the CIS: three of which were internal entrepreneurial challenges and three of which were external market challenges. Framework analysis later allowed for new themes to emerge outside of the initial deductive framework.

II. **RQ4:** What external market-shaping strategies seem most necessary, feasible and acceptable for the Kenyan Government (and other market-shapers) to implement to align private-AI companies to public health goals?

The CIS uncovered many potential market-shaping strategies that could be leveraged in digital health. However, the CIS also anticipated challenges regarding the applicability of these strategies in the global health domain where many stakeholders interact under their own incentives and thus have their own perspectives regarding the necessity, acceptability or acceptability of any specific market-shaping intervention. Thus, the CIS informed the need to include a wide range of stakeholders when examining potential market-shaping interventions for global digital health. Thus, I sought to include Health-AI Entrepreneurs/Executives, global health funders, government officials, global health implementing and strategic partners and clinical leaders in public health. Furthermore, the line of inquiry was directly shaped to assess the perceived necessity (do we need this), feasibility (would this work) and acceptability (would others accept this) of each of the four market-shaping interventions uncovered during the CIS. Use of the framework analysis enabled new semantic changes to occur to several key constructs as well as the emergence of sub-constructs unique to the specific technology-public health context under study.

2. Framework Analysis

Given the broad applicability of the four-part conceptual framework outlined in Chapter Three, I used the Framework Method as an initial guide for the empirical investigation. This approach was especially suitable because it allowed me to stay anchored in a broad yet specific analytical perspective derived from the CIS without being constrained by the strict theoretical limitations of a solely deductive approach (strictly using the CIS) or the practical difficulties of transparent collaboration through a fully inductive approach to data

extraction, analysis, and theoretical recombination. The framework was subsequently revised after conducting the empirical work. More detail on the practical application of the framework method is offered in this section.

Study Design

Methodological Approach and Justification

Given the research phenomena which cross professional domains from medicine and AI to public policy and philanthropy, the use of qualitative methods was necessary to generate rich, nuanced data necessary for describing key challenges to AI adoption and potential strategies for shaping the market of such products towards addressing public health goals. Furthermore, since AI in Healthcare is a rapidly evolving technical domain and Market-shaping as a concept has yet to have been systematically applied to the domain, use of a semi-structured interview tool allowed for insights and personal experiences to emerge around nuanced country-specific political trends or technical advances (e.g., the emergence of agentic AI) that may have been difficult to predict in advance of a participant interaction without being a full “insider”. In the absence of a framework for AI-Health market-shaping, use of the broad digital health market-shaping framework from the CIS as an initial deductive framing was most appropriate as the framework method later would allow for any key nuanced differences in the empirical work to emerge.

For qualitative analysis, the Framework Method can be beneficial as a qualitative tool for multi-disciplinary health research, offering both practical and conceptual benefits.[139] Practically, it allows for more straightforward collaboration across large volumes of

qualitative data as it leverages a pre-set structured set of constructed matrices for initial data categorisation. This transparent and systematic approach enables a more streamlined cross-comparison of emerging themes compared to an entirely inductive approach initiated from the start of the analysis.[139] This can also be particularly helpful for driving a more transparent audit trail if collaborators may have varying levels of technical expertise in different domains of the phenomena of interest.[139]

Sample Selection and Characteristics

Target Population & Inclusion/Exclusion Criteria

I initially identified three key groups of stakeholders involved in AI implementation and sustainability within Kenya's public health sector. These stakeholders included: (1) digital health companies implementing AI-enabled healthcare solutions in Kenya's public health system, (2) global health funders and partners involved in implementation and/or strategic planning, and (3) officials with experience in evaluating and/or purchasing digital health technologies for the public health system. Inclusion criteria required participants to have professional expertise with digital health technologies in LMIC environments, particularly those with direct experience within Kenya's public health system. For AI-enabled digital health companies, participants held senior or decision-making positions within organisations developing, deploying, or expanding AI-driven healthcare technologies aimed at enhancing direct clinical care through managing clinical pathways, patient triage, or decision support functions. The study included companies involved with either software or hardware products. Regarding public health officials, I targeted employees involved in

planning, purchasing, and/or implementing strategic Health-IT initiatives. Participant selection in this category focused on individuals from Tier 4 hospitals or higher, for practical reasons. However, no current public health officials were available or willing to participate in the study despite significant follow-up.

Sampling Strategy

I conducted purposive sampling of digital health CEOs, senior executives, as well as global health partners, funders and individuals involved in health-IT purchasing for public health. I identified participants with relevant expertise and experience with the research phenomena. The target sample size was informed by literature such as Hennick et al., which confirmed that qualitative studies can reach saturation at as few as 9-17 interviews. [140] Furthermore, sample size was also considered based on the principle of information power as studied by Malterud et al.2016.[141] Given the technical complexity and the specialised knowledge required to take part in AI implementation in healthcare, fewer participants with deep, relevant experience could provide rich insights compared to larger samples with limited exposure to the phenomena of interest. [141] At a total of 16 conducted interviews with highly experienced professionals in the Kenyan-AI ecosystem, both sample size recommendations were satisfied.

This initial purposive approach was supplemented by snowball sampling, where participants referred colleagues and contacts from their professional networks who could provide additional perspectives on AI implementation challenges and opportunities.

Recruitment and Informed Consent

I recruited participants in two stages: First, I contacted potential participants identified through a combination of professional networks, targeted outreach, and recommendations from colleagues and collaborators. Then, I sent each participant a personalised message inviting them to take part in the study, including a participant information sheet. Participants who agreed to participate, met the inclusion criteria, and consented, received an informed consent form via the encrypted legal document service (DocUSign). They were then invited to participate in an online semi-structured interview, scheduled at their convenience. Participants also had the option to indicate their interest or disinterest in being quoted anonymously through short quotes, and their consent was confirmed at the start of their interview.

Participant Backgrounds

Sixteen participants were interviewed for data collection. All had extensive experience as operators, funders, or partners of digital health initiatives serving Kenya's public health sector. The group included representatives from seven AI companies, three major global health funding organisations, and five global health partner organisations. Several participants had worked across multiple domains, and two had previously been healthcare providers within the public health system. Six of the sixteen held Chief Officer roles (such as CEO, CTO, or COO), while the rest held titles such as Senior Director, Director, or Senior Manager.

Data Collection and Management

Timeline

Ethical approval was granted by OxTREC REF # MS IDREC: 669176. Interviews were conducted between April - May 2025.

Data Handling & Security

This study collected and processed various data, including contact details, consent records, transcripts, and audio recordings obtained from semi-structured interviews. All tools employed in the study have been used by other principal investigators and researchers within the research group for similar qualitative research. All transcripts were pseudo-anonymised and coded to remove direct identifiers. Individual and organisational names within the transcripts were replaced with secure codes, and contact details were stored securely within Nexus 365 OneDrive for Business, with access restricted to authorised team members. Recordings were stored in a password-protected format, digitally stored in a dedicated, access-restricted, and encrypted folder using Microsoft OneDrive for Business. The identification keys were stored separately from the audio recordings and transcripts to enhance confidentiality and security. All devices used to store or process data were encrypted, and all digital documents were anonymised and password protected. All findings are presented in aggregate. Only participants who indicated their willingness to be quoted in full while remaining pseudo-anonymised have short quotes subsequently displayed in the results section.

In compliance with GDPR requirements, all participants are aware of the protocols for contacting institutional bodies and the research team in case of any issues. Furthermore,

recordings, identification codes, and contact details were deleted immediately after the study, following transcription and verification in accordance with GDPR guidelines. All consent records and de-identified transcripts that have been pseudo-anonymised will be retained for three years following the conclusion of the study and in compliance with these guidelines. The verification that these processes were followed was confirmed through the ethics approval procedure and via the informed consent form signed by both the participant and the primary researcher.

Interviews

I focused each interview not only on seeking to understand the participants' internal perceptions of the issues and solutions at hand but also on how they perceived the roles and motivations of other stakeholders in the system. This combination of internal and external inquiry was important for me to grasp the narratives and beliefs underpinning the market I was examining, and how those beliefs or narratives influenced economic activity or its absence. To understand these barriers and facilitators, I directed the line of inquiry during semi-structured interviews towards understanding stakeholder perspectives on three interrelated but distinct areas across each of the four types of market-shaping interventions (Support with Strategic Partnerships, Fit-for-Purpose Regulatory Frameworks, Innovative Financing, Enhanced Public Procurement).).

1. **What is the Necessity of Market-Shaping Interventions for Health-AI in the Public Health Sector?**

Market-Shaping Interventions, aligned with the public good, should broadly be considered where stakeholders involved in the ecosystem believe that specific interventions are

necessary to generate public health outcomes. At the core of this are questions that seek to understand the stakeholder perspectives on the current challenges of sustaining AI ventures/initiatives for public health and whether they believe non-intervention versus intervention is fundamentally warranted.

2. **What is the Acceptability of Market-Shaping Interventions for Health-AI in the Public Health Sector?**

Some Market-Shaping Interventions may require upfront or longitudinal changes in strategy or resource allocation by one or multiple groups of stakeholders. Even if interventions are deemed necessary, stakeholders could have varying levels of interest in pursuing them. Thus, I focused intently on understanding how different stakeholders perceived the willingness of the other external stakeholders to lead, participate, invest or comply with market-shaping interventions.

3. **What is the Feasibility of Market-Shaping Interventions for Health-AI in the Public Health Sector?**

Lastly, I focused my line of inquiry during semi-structured interviews on understanding the perspectives that stakeholders had on the practical feasibility of implementing different types of market-shaping interventions. Even if an intervention was deemed necessary and widely acceptable, there could be systemic factors at play that stakeholders might deem insurmountable. An example might be a need for governments to invest in digital public infrastructure, where political will from the governments to fund exists, but where

there a lack of access to private debt financing for the government to pursue such investments.

Examining perspectives across these three lines of inquiry offered me a holistic sense of the barriers and facilitators to implementing each of the four types of market-shaping interventions while revealing nuances specific to AI in Kenya. These perspectives also offered early insights into areas of stakeholder disagreement that might necessitate future research and stakeholder workshops.

Data Analysis

Procedure for Analysis

The conceptual framework developed in Chapter 3 was tested using the qualitative empirical study. A framework method for the study of qualitative data in multi-disciplinary health research consists of seven key steps.

I. Transcription

Transcriptions were processed using an integrated and secure third-party application (Otter.ai), which is also employed by other researchers in the research group for qualitative work. To secure an accurate verbatim transcript, each recording from each participant interview was reviewed manually alongside the auto-generated transcript, and edits were made accordingly. Transcripts were edited to retain the full content while omitting specific phrases (such as pauses or simultaneous talking) that lacked meaning and made the transcripts more challenging to read. Conversational openings (i.e., “How’s

the weather?" or "Is the family doing well?") were similarly omitted as expected to maintain relevance and participant privacy.

II. Familiarisation with the interview

Although transcription cleaning provided an upfront re-introduction to the evidence, key parts of the recording, especially those containing complex, rich quotes or industry-specific jargon, were re-reviewed to become accustomed to any unfamiliar terminology. While becoming familiar with the transcripts, I used a reflexive journal to record my initial thoughts and reflect on my own cognitive biases and positionality as a researcher.

III. Coding

To maximise the applicability of the framework method, I used an initial deductive framing while conducting open coding on several transcripts to test for newly emergent themes or sub-themes that may have been missed in the theoretical findings or deemed more specific to AI. The core constructs from Chapter 3 provided this initial deductive framing as I read the transcripts one line at a time in NVivo and each key emerging theme was coded for its macro-construct and associated sub-construct.

As an example of an inductive addition that was made, the importance of "systems-level trust" as an overarching concept that applies broadly to patients, providers, and administrators continued to emerge across the transcripts. Although aspects of trust could be included in other parts of the initial framework (i.e. challenges of system integration), its repeated inclusion in participant responses as an external challenge between stakeholders lent itself to its code within the 'external market challenges' construct. Other concepts that did not seem to fit naturally within the preconceived sub-constructs were

labelled “other” under the appropriate macro-construct until sufficient evidence emerged to necessitate a code during later rounds of coding.

IV. Developing a working analytical framework

After a group of transcripts had been coded, I organised the codes into a tree diagram and discussed in consultation with my researcher supervisors for initial feedback and transparency. These codes formed the basis of the analytical framework to be applied to all transcripts.

Macro-Constructs	Sub-Constructs
Internal Business Challenges	Identifying Feasible Opportunities Measuring and Communicating Value Navigating System Integration & Expansion ***Managing the Costs of AI Deployment (New)*** ***IBC-Other***
External Market Challenges	Financial Uncertainty Regulatory Ambiguity Infrastructure Challenges ***Systems-Level Trust (New)*** ***EMC-Other***
Internal Business Strategies	Strategies related to Value Propositions Strategies related to Value Creation Strategies related to Value Communication & Delivery Strategies related to Value Capture ***IBS-Other***
External Market-Shaping Strategies	Support with Strategic Partnerships Fit-for-Purpose Regulatory Frameworks Enhanced Public Procurement Innovative Funding Mechanisms ***EMSS-Other***

Table 12: Working analytical framework for Nvivo Coding

V. Applying the analytical framework

After receiving supervisory feedback, I converted the working analytical framework into a series of coded abbreviations to facilitate accurate but timely indexing of the remaining transcripts. NVivo was used to organise and classify the coded data.

VI. Charting data into the framework matrix

Efforts were made to select rich, contextual quotes that balanced “breadth” of information, with the need to reduce the data to retain the theoretical core of each of the participants responses while ensuring the “feel” of their responses was maintained. It was at this point that the need for continuous reflexivity became crucial. I leveraged journal entries throughout this process to interrogate research positionality and ensure selectivity bias of information was reduced where possible.

VII. Interpreting the data

Using NVivo, I examined each macro-construct in detail, and a separate computer file was created to record early impressions of the data, informing any emerging concepts, relationships, or dynamics. Quotes from the evidence were iteratively placed in context with one another in Word to thematically group and narrate the evidence in context of the emerging inductive sub-themes. All thematic groupings and classifications were maintained after this process except for one marginal semantic change. The external market challenge theme ‘Systems-Level Trust’ was retrospectively amended to ‘System-Wide Trust’ as the new semantic conceptualisation more appropriately captured and effectively described the underlying connection between its four sub-themes specifically: a lack of trust from health professionals, communities and patients, government and public health facilities and a larger societal concern with the pace of AI development.

Chapter 5: Qualitative Results

TITLE: What Are the Barriers and Facilitators To Deploying Market-Shaping Interventions for AI-Enabled Digital Health Solutions in Kenya's Public Health System?

Overview

Kenya offers a mix of factors that seemingly create conditions for market- shaping efforts to better align AI- healthcare companies with public health needs. Yet, the true potential for such alignment remains debated. Recent policies, such as the Digital Health Act and the creation of a dedicated Digital Health Agency, indicate policy momentum for tech integration. However, questions linger about implementation capacity and the political sustainability of these efforts. This regulatory drive, combined with Kenya' s technological ecosystem, offers a compelling but complex setting to assess whether market- shaping mechanisms can effectively close the gap between private AI innovation and public health priorities, or if structural mismatches are more resistant than policy optimism suggests.

To examine this, I recruited sixteen participants involved in implementing, funding, or operating Health- AI initiatives within Kenya' s public health sector. Through semi-structured interviews directly informed by the CIS, I gathered their views on the necessity, feasibility, and acceptability of market- shaping strategies for Health- AI, focusing on four key market-shaping intervention types from the framework developed in Chapter 3. Using brief quotes from participants, I highlight the main challenges and solutions faced by AI-Public Health companies in Kenya, emphasising (1) internal entrepreneurial challenges and (2) external market challenges to understand stakeholder perspectives on the need for market- shaping strategies. I then analyse the evidence related to (3) external market-shaping interventions.

Applying the Framework Method, I evaluated the relevance of the conceptual framework in the Kenyan context while conducting inductive thematic analysis to identify new challenges and solutions, with emerging themes or constructs. I conclude by presenting an updated conceptual framework based on the empirical findings and visual comparisons, providing deeper insights into the differences between observed evidence and the insights derived from CIS.

Results

Internal Entrepreneurial Challenges: Managing Value Creation for Complex Stakeholder Networks

At the heart of the internal entrepreneurial challenges faced by AI-enabled digital health companies in Kenya is the difficulty of managing long-term value creation within a complex network of global health stakeholders. This issue is characterised by three sub-issues found in both the theoretical and empirical results: challenges in identifying viable opportunities, difficulties in measuring and communicating value, and obstacles in navigating system integration and expansion. However, the empirical findings also highlight a distinct fourth sub-issue: specific internal challenges related to managing the costs of AI development. Below, we offer a more detailed analysis of these four challenges, drawing on multi-stakeholder perspectives to explore their impact on the sustainability of AI-enabled digital health technologies for public health.

Identifying Feasible Opportunities for AI

1. *Misaligned Stakeholder Demands*

Several leaders of AI-enabled healthcare companies emphasise a disconnect between donors and the needs of the Kenyan public health system, which results in conflicting expectations for various outcomes. Many or most perceive the system as inherently flawed, marked by increased bureaucracy, a lack of urgency in project funding, and the proliferation of poorly aligned projects that struggle to scale.

"I've counted 263 meetings with people at the UN… It's just that they are pushing the conversation around. There is no one who says, I'm going to make a decision… the system is designed to protect itself, but not protect the people it's meant to serve." (CEO AI Company 2)

However, more frustrations among global health partners and AI-enabled digital health companies over misalignments with donor priorities are often countered by stakeholder realisations that these companies must focus on tackling real-world public health problems in Kenya, rather than merely promoting advanced technologies without fully understanding local issues.

"So I haven't met a lot of founders who are truly, truly and genuinely and honestly looking to make an impact and looking to stay for 10 years and looking at addressing specific problems that are ailing the [Kenyan] healthcare system so they are using westernised problems a lot… You know, it's cool. It's cool. But I mean, what exactly have you solved?" (Manager Global Health Partner 3)

2. *Limited Customer Purchasing Power*

However, even when stakeholders successfully come together around a public health AI initiative, executives at AI-Health companies state difficulties establishing and maintaining a sustainable, long-term business model that ensures lasting public health impact.

"There is functionally little, if any, good evidence of what a scalable business model is in digital health. It gets even harder in AI for health when you're thinking about AI as a medical device." (Chief Officer Global Health Partner 2)

Considering the low willingness-to-pay and limited purchasing power of many end-users and public health systems in the country, participants from all stakeholder groups acknowledge that the affordability of the AI-enabled service is crucial for establishing a sustainable business model. However, despite widespread discussion among stakeholders about its importance, maintaining affordability remains a significant challenge, both at the beginning of a new programme and when scaling up.

"Many businesses are unable to answer..is there an addressable customer segment..what is the sustainability?" (Senior Manager Funder 2)

"What's the market-clearing price… willingness to pay is much lower than you want it or need it to be." (Chief Officer Global Health Partner 2)

"If the price keeps going up...we're not actually solving the number one problem… affordability." (Senior Manager AI Company 6)

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3. Balancing Impact and Commercial Viability

Digital Health executives found that manufacturing shared value across a complex network of public health and global health stakeholders is a complex human and political endeavour. Thus, executives at AI-enabled digital health companies continue to struggle balancing impact and financial sustainability while tackling public health goals given the pressures posed by potential financial instability and limited customer purchasing power.

If you have a feature phone, you don't have disposable income to spend anywhere else, yeah. So we've made the service free to the user (pregnant mothers) end to end, from the time they're pregnant through to one year post-delivery. So then we bear the costs, or have been

bearing the costs of the entire services, including technology costs" (Technology Lead AI Company 5)

Such challenges can also lead to entrepreneurial moral distress as one entrepreneur noted the motivational struggles of having to focus on profit in Western markets to support unprofitable operations in Kenya and other LMICs.

"But my, my problem is sometimes you just feel like giving up. You go, I tried, man, like, I really did try… Or when I'm feeling better about it I just go, right, lets get the money sorted somewhere else that can pay everyone's [employee's] bills and then you do this [work in Kenya] on the side. And this is kind of the passion project, which it shouldn't be. It should be the main thing." (CEO AI Company 2)

Managing the Costs of AI Deployment

1. Data Infrastructure and Storage Costs

Executives at AI-health companies in Kenya comment extensively on the substantial expenses required when building and operating data infrastructure for integrating and storing health data. As AI-health companies seek to scale, processes such as maintaining data warehouses and performing Extract-Transform-Load (ETL) operations on datasets can begin to force teams to choose between performance and affordability, especially when serving areas with limited or expensive connectivity, like rural villages. An executive running a large service focused on rural patient access commented on the issue below:

"It's really expensive to maintain a data warehouse and to move data and do all the ETL and things that one has to do… it was barely

affordable before, now it's just not affordable, wow." (CEO AI Company 1)

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2. AI Model Training and Inference

Technical leads and Chief Technology Officers comment significantly on the significant ongoing cloud and hardware costs that are generated by training and running models that require continuous connectivity (i.e Large Language Models) or supporting high-volume inference (ex. Computer Vision Systems for X-Ray Diagnosis). A technical lead noted the potential for costly mistakes during AI development can range end-to-end from the initial pre-training of the AI algorithm to the longitudinal process of model evaluation and post-market surveillance, especially as the service continues to scale to new users.

"When we were first developing it [the AI model], we didn't know how to do it, so we tried many different things. We went down a lot of dark paths that ended up nowhere, and all of that incurred costs" (Technology Lead AI Company 5)

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3. Talent Acquisition and Retention Costs

Executives comment that intense competition for technical talent in other private sector industries (ex. Banking or Insurance) has created challenges paying for and retaining the scale of technical staff necessary towards launching and scaling highly technical AI products in more “mission-driven” industries like public health. Given the scarcity of talent and the surge in AI adoption, these professionals have become some of the most in-demand professionals in both high-income countries and Kenya alike.

"The cost of an ETL engineer who can take a system like [Redacted Company Name] , transform it and stick it into the national data warehouse… those engineers are very sought after… they can get paid a lot in the private sector… it's a really hard skill set… it's getting more expensive." (CEO AI Company 1)"

Measuring and Communicating Value

AI-Health companies face significant difficulties quantifying and communicating the value of their AI-enabled products and services due to conflicting measurement standards across stakeholders and technical challenges aligning data and thus attributing outcomes across fragmented care pathways. Stakeholders point to two challenges:

1. Differing Standards for Outcome Measurement Across Stakeholders

Though the study designs and purported economic benefits of vaccine or pharmaceutical intervention in global health are often well recognised within the international health community, funders and global health partners acknowledge that digital health interventions often fail to provide the same depth or robustness of evidence expected by major global health funders.

"It's like the evidence around using data for decision making or collecting data faster, it's just not as compelling" (Senior Director Funder 1)

Funders and partners suggest that AI-Health companies, even those generating well-recognised positive outcomes for their end-users, may often need to conduct expensive

and large-scale studies to adhere to the scientific and academic culture of international global health donors with one partner stating:

"They'll let you do a pilot somewhere you can implement at your own cost, but if you need them to carve out a budget line in a national budget, the quality and quantity of evidence you need is often a big barrier for companies because they're staring at the cost of a phase three RCT trial going and they don't really want to do that" (Chief Officer Global Health Partner 2).

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2. Data Quality and Interoperability Challenges

Further adding to the challenges of value measurement and communication are technical and organisational challenges related to data quality and interoperability. Since care pathways and thus data systems for public health in Kenya can often be fragmented both longitudinally and between providers or vertically focused initiatives across a patient care journey, global health stakeholders comment extensively on issues collecting the depth, complexity and length of data necessary for outcomes attribution.

Most people are thinking about their HIV outcomes, their family planning outcomes. They're not thinking about the quality of a digital tool in the context of a system and whether things are interoperable. And so I think they notice, of course, when things aren't interoperable, or there's multiple tools, sort of things, but they're not, like, empowered, or, you know, mandate to do anything about that, right?" (Senior Director Funder 1)

Navigating System Integration and Expansion

Many entrepreneurial organisations need upfront investments in infrastructure, staff, and other overheads to develop an initial product or service. Since it takes time to establish a source of recurring revenue or funding, trying to “scale” or serve more users at a decreasing marginal cost can become essential to offset initial development expenses and reach a sustainable financial position. Failing to navigate scaling costs effectively within a health system can lead to the complete shutdown of a digital health firm, particularly without long-term donor support.

1. Challenges Aligning User Incentives

No digital Health company can attempt long-term integration without incentivising its users to adopt the product or service meaningfully. However, all stakeholder groups agree that digital health solutions often create efficiencies and benefits for some stakeholders while simultaneously imposing costs, revenue loss or operational burdens on others, making it challenging to secure buy-in for all necessary parties. An AI-Health Executive with experience as a physician in the Kenyan public health system spoke at length about the issue:

I don't know. I don't know the right answer, but digital adoption is still extremely poor among the people who are supposed to use these, these technologies, yeah, and maybe we need to innovate around it to make it easier for them to use these because at times, the truth is the digital one is, is it's more time consuming than what they are used to. (CMO AI Company 4)

Furthermore, all stakeholder groups agree that without aligning incentives across different parts of the healthcare delivery system, it may still be difficult to motivate key practitioners within the Kenyan public health sector to genuinely adopt AI technologies, especially if such systems remain primarily focused on data collection and advanced reporting without a demonstrable impact on the workflows of end-users. The same Chief Medical Officer commented further on the issue stating:

It's and it's not digitizing just to collect data, because that's what most people do at times, those doctors don't really care about the data, so because it at times, it never even comes back to them. Yeah. So I think it's looking at what is in it for them and and addressing that. (CMO AI Company 4)

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2. Challenges Managing Fragmentation Across Kenyan Counties and Partners

Stakeholders across participant groups point to the challenges of Kenya's decentralised governance structure which results in varying expectations and implementation capacities at the county level, thus requiring AI-Health companies to negotiate and adapt to unique circumstances, incentives and pathways for integration in each new geography.

And to think about you going not just at every hospital in Kenya, but every hospital in Sub Saharan Africa who sign individual contracts, explains why there is no health care AI digital health unicorn on the continent, right?" (Chief Officer Global Health Partner 2)

While this fragmentation may offer AI-Health companies more opportunities to reach decision-makers for early adoption, entrepreneurs believe it can also lead to duplicative

efforts, administrative delays, and cause resource strains for smaller ventures, especially when dealing with high levels of bureaucracy within each health system.

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bureaucracy is like the number one bottleneck, and then the other thing is, the other thing is, sometimes the people who like, who are in those discussions, they don't even want the change. They they just want things to remain the same. So you, you have to have people in those positions who are willing to bring the change, yeah, yeah." (Senior Manager AI Company 6)

External Market Challenges

AI-Health companies seeking to positively impact public health outcomes sustainably face numerous significant challenges in the broader "market" of stakeholders within which they must implement their offerings. Core to these challenges are three key domains that have been similarly identified by the Critical Interpretive Synthesis covered in Chapter 2, including Regulatory Challenges, Financial Challenges, and Infrastructure Challenges. However, given the nascent nature of AI-enabled healthcare solutions and the technical complexity underpinning their development and implementation, a fourth component relating to the concept of "Systems-Wide Trust" has emerged. Below, we leverage multiple stakeholder perspectives to examine the external challenges that underpin the complexity of the space in which AI-enabled digital health companies seek to create and capture value within.

Financial Uncertainty

1. Lack of Funding

A dramatic reduction in governmental and donor funding, particularly from USAID and EU sources, has led to an existential crisis for several executives at AI-health companies. Many digital health organisations face potential closure as traditional funding streams have either fully closed or begun to close at significant rates. Company leaders describe the situation in stark terms:

"An analogy I have been giving funders I've been talking with is, you know, us and everybody I mean, the money available for digital systems just shrank, possibly all the way to zero, but very dramatically. And I think nobody knows what the market's gonna look like going forward." (CEO AI Company 1)

"Grant funding has been shrinking across the US and also the EU. As the EU shifts focus to things like defense, we don't have the answers [when it comes to financial sustainability]." (Technology Lead AI Company 5)

One executive believed that the immediate casualties of the funding collapse may prove to be the large-scale implementations of digital health technologies, such as community health worker systems, which provided these AI-health companies with their initial reputations but continue to require more substantial long-term capital to scale.

"There's bigger implementations often are community health worker use cases, which are the predominant scenarios we are best known for… electronic Community Health Information Systems. However, we believe these are now significantly at risk regarding ongoing to keep going, how these systems will continue to be maintained and supported?" (CEO AI Company 1)

2. Funding Unreliability Due to Project-Based 'Short-Terminism'

Participants across all stakeholder groups mentioned how the current project-based funding model continues to create unsustainable environments for AI-Health companies, where such ventures cannot rely on ongoing funding regardless of how successful their implementations are. Many stakeholders agree that the drawbacks of the current system have led to perverse incentives, causing organisations to overpromise to secure short-

term financing without considering the long-term sustainability of their proposed programmes or solutions.

> *So the project based funding creates this incentive structure where everybody's incentivized to oversell the government. Means, if you're trying to create a model that is really sustainable, that you believe the government can really maintain and afford, you were previously at a massive disadvantage, somebody else was going to walk in right behind you and say, like, Oh no, I can promise you the moon, because I'm just worried about getting paid during this build phase, regardless of whether or not you can afford to maintain it, or regardless of whether or not I can afford to keep my company running. (CEO AI Company 1)*

Furthermore, most participants across stakeholder groups point to structural issues in digital health funding stemming from the fundamental disconnect between the iterative way technology companies operate and the methods by which funders allocate money.

> *"I think in the first instance, everyone's keen and it's easy to get project money, but it's hard to get ongoing money. So that's because they are all project based. So that's why it's quite challenging." (CEO AI Company 2)*

This project-based approach results in a business model that is inherently inconsistent and therefore unsustainable. In this status quo, success in one project, even if the outcomes are achieved, does not lead to future revenue streams and thus may not contribute to generating improved economies of scale to improve the financial sustainability of the overall offering. A former philanthropist, and now a major global health partner, offered significant self-criticism regarding the current culture of philanthropic grant-giving stating:

"The first thing, I was a professional philanthropist for [REDACTED] years, so I'm criticizing myself, right? It often takes you doing the bad thing to realize what it is, but the if you speak to any professional philanthropist, they will tell you that the party line is philanthropic, capitalist, catalytic capital. We are there to kick something off. We are not long term sustainable financing." (Chief Officer Global Health Partner 2)

This lack of long-term, sustainable donor funding, combined with the challenges of AI-health companies identifying their long-term end-customers, leads to what multiple funders called a “valley of death” for many digital health companies. Entrepreneurs also comment significantly on a perceived hypocrisy between funders looking for sustainable impact while simultaneously refusing to fund ongoing reimbursement.

Nobody's happy paying any of us profit. Like you guys are all saying we need to be sustainable but you're sick of funding the platforms. Where do you think we're magically coming up with margin right to make this model tie out? And so what I wanted academia and some of these honest broker type entities to do is be more forthright about that. (CEO AI Company 1)

3. Funding Fragmentation: Within & Across Global Health Funders

Funders and global health partners focused in on how the organizational structure of global health funding bodies has generated inefficiencies by dividing internal operations across vertically focused global health programmes. These stakeholders have found that such organizational structures have limited more holistic approaches to funding

improvements for end-to-end systems of care that are more longitudinal and disease cross-cutting with one senior funder in global health stating:

"With digital health, the approach was all about optimizing, because you just had all these vertical programs that weren't talking to each other. There wasn't really a focus on supporting the people in government who think about digital." (Senior Director Funder 1)

Furthermore, several funding stakeholders believed this fragmentation of coordination and funding has led to an oversaturated market in public health services in which healthcare providers are bombarded with competing digital health solutions from both NGOs and Digital Health Startups themselves. A Global Health Partner with expertise in both the public sector, private-sector and NGOs explains below:

"We've come, we have this program, we have this app, we have this partner. And then USAID is going to come, and then Save the Children is going to come. And then everyone has their own app, their own solutions, their own so the healthcare providers like having to do a lot of duplication of work." (Manager Global Health Partner 3)

However, challenges may remain regarding this consensus. Global health partners and funders acknowledge that there are trade-offs between jointly allocating funding to fewer organizations with the aim of improving the sustainability of any given venture and spreading funding thinner in hopes of spurring more rapid iteration and experimentation. The way forward remains unclear.

4. High Transaction Costs

Transaction costs encompass the expenses linked to sales, marketing, and payment collection. In Kenya, as in many LMICs, entrepreneurs state that the bureaucratic process of securing funding and contracts, particularly with multilateral organisations, government bodies, and county authorities, generates prohibitively high transaction costs that hinder market adoption and deplete the resources of smaller AI-Health ventures. Executives seeking global health funds spoke at length on the challenges of dedicating substantial resources to proposal writing and managing donor relationships, often with limited immediate returns, making it incredibly difficult to maintain financial sustainability. The CEO of an AI-enabled digital health company elaborates on the challenges of managing bureaucratic funder relationships:

"I have had 200 I've counted 263 meetings with people at the UN, and I've made a grand total of $30,000 right? Well, and, and the reason is, it's not that we have a good idea, and it's not that it wouldn't have the mission, and it's not it wouldn't solve it. It's just that they are pushing the conversation around. There is no one who says, I'm going to make a decision." (CEO AI Company 2)

Trying to procure large volumes of competitive but small grants is described by both entrepreneurs and funders as one of the hallmarks of an presently unproductive funding landscape that lacks the ability to incentivize the scale of long-term, iterative efforts needed for tangible digital improvements in public health service delivery.

"It's like, who's the Gates Foundation's favorite? Who's this organization's favorite? Who does Global Fund like, who does, you

know? And it's like, or they do open procurement calls and all these organizations, rather than focusing on building their platforms, are like spinning on all these proposals over and over and over and trying to get little tiny tranches of dollars." (Chief Officer Global Health Partner 2)

Infrastructure Challenges

1. Connectivity Constraints

Technical leaders at AI-Health companies point to the fact that limited and expensive internet connectivity, particularly in rural areas, have constrained the successful deployment of AI-Health solutions. Stated challenges include prohibitive data-costs and lack of connectivity that stifle SMS usage by both patients and community-based healthcare workers.

"When we started out, most of our users had feature phones, like the old Nokia burner phones. Right now it's slightly less than half, but most of our users still prefer to use SMS over things like WhatsApp, because WhatsApp incurs a data cost. Data here in Kenya is not that cheap." (Technology Lead AI Company 5)

Thus, the limitations of data connectivity in Kenya have often required executives at AI-enabled digital health companies to proactively plan to supply their partners and service providers with the reimbursement necessary to stay digitally connected.

"So I've got, I've got photos of me and doctors, like underneath trees trying to find, like, a 3g connection, right? But what's interesting, actually, is data is quite expensive. So like, you have to send people data bundles if you want them to do stuff." (CEO AI Company 2)

Technical leaders have found that failure to account for the costs of connectivity challenges the end-user so can result in ineffective data transfer which can threaten the reliability of service delivery, especially with regards to healthcare delivery.

"Users sometimes switch their phone on just once, or the data on once a day just to send and receive all the messages and then turn the data connection off again, which wouldn't be very effective for our service." (Technology Lead AI Company 5)

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2. Digital Health Infrastructure & Interoperability

All stakeholders point to the need for basic digital health infrastructure to enable more advanced forms of AI-enabled healthcare analytics and outcomes attribution.

"I mean, the digital health transformation is a prerequisite to adoption of AI. Like if our whole thing was, if you don't have your basic digital health architecture set up in your country, then AI is your it's too premature to think about how you respond to AI as it relates to health." (Senior Director Funder 1)

Global health partners acknowledge that the absence of standardized interoperability standards can often force companies to build custom solutions that are costly and vary across the facilities they are looking to serve. They've found that such challenges may disincentivize or dissuade innovators from integrating data from the wider system context into their digital systems.

"We are all collecting. The data is everywhere. It's sitting in different pockets. Nobody's looking at it, nobody's using it to make decisions or, you know, and a lot of it is because everybody is very guarded with their

own data. No one wants to share. So that's that's something that's missing in a very big way, because a lot of people are saying, Oh, it will take a lot of money for us to figure out, but we have everything. We have all the data sitting in very many different places, some manual, but a lot digital." (Manager Global Health Partner 3)

Several global health partners have also found that within the Kenyan system a lack of digital IDs or centralised health information exchanges has led to siloed data across vertical and disjointed care programs, stunting the full capacity of AI-enabled products and services and resulting in duplicated information sharing that can impact service reliability and user experience.

"So on people, the biggest challenge is we need to have a digital ID, so being able to identify each person uniquely, and currently, don't really have that in place." (Digital Infrastructure Lead Global Health Partner 5)

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3. Device Affordability and Accessibility

All participants groups commented on the significant portion of patients in Kenya that still lack affordable access to smartphones or reliable internet.

"There's a very large segment of the population that does not have access to smartphones yet or internet for that matter, right?" (Senior Manager Funder 2)

A challenge that has led to AI-health solutions to accommodate feature phones and provide free services. Stakeholders have found that this digital divide particularly affects rural and low-income populations who represent the primary beneficiaries of many health interventions funding by public health systems. This creates a challenging business

model dilemma for executives seeking to impact particularly vulnerable patient groups, like maternal or child health populations, who they say have the most challenges procuring advanced devices or connectivity. Such challenges have incentivized product leaders to find creative frugal approaches to service such users, such as deploying AI over SMS rather than WhatsApp or other bespoke apps often used on smartphones. One executive found following these frugal technical approaches as crucial for health equity:

"And I feel like a big use case [for AI is], any time that repetitive, straightforward information is needed to inform a patient's decision. I think there's a huge opportunity for that. So that's where, in particular, a majority of people who have feature phones that don't have access to the internet, that are not able to, you know, Google something for themselves." (Product Lead AI Company 5)

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4. Power Availability and Reliability

Lastly, although sparsely focused upon by many stakeholders, power reliability still emerged as a crucial and often overlooked component of enabling digital infrastructure for health with one global health partner stating below:

"A lot of the technologies we are talking about make basic assumptions about connectivity and power access, right? There's a very, very weak or we can't make very strong assumptions, because we know that not everyone has 24/7 access to reliable power, right?" Chief Officer Global Health Partner 2)

Stakeholders who commented on the challenges of power availability believed that such infrastructure factors remain crucial to examine, especially when evaluating the

sustainability of AI-enabled digital health companies serving rural areas, where access to power and connectivity may be limited and sporadic. Several technical leads found that interruptions to such power infrastructure can result in the financial unsustainability of AI-enabled services or even the underlying IT infrastructure like EHR records that often enable the services to begin with.

"You know, primarily overcome basic things like electronic medical records. A lot of health systems or facilities here are still paper based, so making or upgrading the health system to have basically electronic medical records for each user that can go that can be a significant like force multiplier when implementing programs like this but that requires things like stable power infrastructure and stable data infrastructure." (Technology Lead AI Company 5)

Regulatory Ambiguity

1. Lack of Policy Implementation of Pre-Existing Digital Health Acts Creates Challenges Scaling Compliance and Stakeholder Trust

Stakeholder groups widely recognize the presence of digital health legislation in Kenya but many express doubts over the effectiveness of these policies dissemination and implementation.

"Actually, for a lot of digital health companies, there's a lot of data flowing in. Right now, our data protection laws are starting to come up. There's been a lot of acts coming up in the last couple of years. They have not been fully, fully fully implemented, but because no one really knows when and where, everybody is very scared." (Manager Global Health Partner 3)

"I think we the policies are, are great. The problem is now implementation. We have really good policies on paper, but they are barely implemented. So when you look at it, you know, a policy was written in 2017 and you are like, Oh, it is on paper, but you've never seen it's being implemented anywhere." (Senior Manager AI Company 6)

However, given the fact that state capacity is necessary towards regulating such emerging technologies in healthcare, the government structures meant to oversee digital health and AI applications came into question. One stakeholder with deep experience in both philanthropy and AI implementation expressed doubt on whether the organizational set-up of the Kenyan Digital Health Agency has the capacity to deliver on its promises while falling under the Ministry of Health rather than resting across a more cross-functional government agency like a body of National Standards:

They've made a decision. It's just a bizarre decision. The regulation of clinical decision support systems, or the oversight of clinical decision support systems, including those that are AI based, falls under the digital health agency, which is an executive arm lands arm led body of the Ministry of Health, despite the fact that in every other country you would expect the national regulator to have this responsibility, the national regulator has been funded to think through software and AI as a medical device regulation. So you've got this weird devolution of power where a group of people that shouldn't be responsible is told they're responsible, and the people that should be responsible are currently trying to figure out if they are responsible or not, right? Well, as a product developer, why on earth do I want to get involved into a country where there is such a lack of regulatory clarity? I'm like, this is just liability. (Chief Officer Global Health Partner 2)

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2. <u>Lack of AI-Specific Regulatory Frameworks</u>

For AI-specific regulations, both entrepreneurs and global health partners commented on a regulatory landscape that is ever more uncertain, with frameworks still in development or seemingly non-existent:

"I think the most relevant one here in Kenya is the Data Protection Act, which is GDPR adjacent, so there are no AI regulations yet. I think there's some frameworks being developed, and of course, we'll see some in the next few years." (Technology Lead AI Company 5)

I think the policies around AI can be more robust, I think what I've seen is basic. CMO (AI Company 4)

Some companies find that the lack of AI regulation creates situations more challenging than over-regulation, as it provides no clear guidance for compliance but offers the potential for regulatory backlash.

"You scare them off when they go I have to figure out medical device regulation like I don't want to do that, and I don't have to pay hundreds of 1000s to have someone smart enough to figure that out for me." (Chief Officer Global Health Partner 2)

Lack of System-Wide Trust

1. Skepticism from Health Professionals

Executives at AI-Health companies with experience in implementation point to immense challenges convincing healthcare workers that AI-powered tools can enhance rather than replace their expertise. However, they found that this skepticism seemingly extends

beyond mere technological resistance to encompass deeper concerns about trust and behavioral change. A fundamental barrier encountered by all stakeholder groups was the unresolved ethical and legal question of liability and responsibility when AI systems are involved in clinical decision-making.

> *"There's also the issue that needs to be addressed, which is the issue, the issue of trust, like, who's going to be to take responsibility for the AI decisions that, let's say, if, like, it's a tool AI powered, and it can make certain decisions, like, who's going to take that responsibility of the decisions that are made by AI?" (Senior Manager AI Company 6)*

One global health partner has found that the resistance has been particularly pronounced among senior healthcare workers who have built their careers around manual systems and are approaching retirement:

> *"For example, by the what the more experienced people in the workplace. So we have people who are nearing retirement, who have used manual books registers all their professional for professional life. They become a bit hard to do digital systems, like at the tailing of their of their careers." (Digital Infrastructure Lead Global Health Partner 5)*

2. Community and Patient Trust

All stakeholders point to the challenge of building community-wide trust for AI-powered healthcare as representing one of the most significant barriers to scaling digital health solutions in Kenya. Several Kenya-born stakeholders believed that this trust deficit may be rooted in cultural preferences for personal relationships and community-based healthcare delivery.

A lot of these customers that you're looking to target are rural populations, bottom of the pyramid, and there is still a question of trust that that arises in the in this segment of the population, I don't think they feel comfortable yet to to, you know, rely on AI or on on a person on the phone right to receive health care services. Most of these communities go to their local centers who they've established relationships with, like, look at it in Kenya. How. I mean, you know, how close are we in terms of our community, and how important is our community to us? Senior Manager (Funder 2)

One stakeholder with experience delivering care in the public sector believed that local Kenyans may also be suspicious of potential corruption underpinning the adoption of solutions that are government-proposed or private-sector led.

"from a government perspective, now, it's been difficult to implement anything that doesn't look like, you know, corruption, like who who owns this app? You know, Kenyans, we are very like who owns it. We know it's one of you guys [from the government] who own it." (Manager Global Health Partner 3)

3. Government and Health Facility Mistrust

However, on the other hand several stakeholders also noted that government officials and institutions are also wary of external technology partners with concerns centering around data ownership and maintaining authority. Such stakeholders pointed to suspicion about foreign-owned solutions and fear of being circumvented or undermined by technological implementations. A stakeholder, who opted out of anonymous quoting, noted that startup founders coming from the outside of the Kenyan system often severely underappreciate the importance of government relationships. They insisted that building trust with

government institutions would continue to require a deep understanding of internal power dynamics and the decision to include government participation from the earliest stages of product development.

However, further trust issues may also extend to healthcare facilities themselves, where administrators worry about data ownership and maintaining direct relationships with their own patient populations. One global health partner pointed to this issue of facility-wide trust below:

I discussed digital health literacy from an adoption perspective, even for facilities, is how do I trust these guys who want to come in and do 123, right? Do they want my data? Are they going to steal my patients? Because a lot of a lot of these digital health startups have access to these patients. So there's that lack of trust. And this comes down to our culture in general. There's a lack of trust that if I have this partnership with you, that you're going to be able to help me rather than harm me. So a lot of people are choosing to just either stay away or build some of those solutions in house as much as they can, at least from to a very MVP level" (Manager Global Health Partner 3)

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4. Larger Societal Concerns with the pace of AI Development

One of the predominant feelings of almost all stakeholder participants is that the rapid deployment of AI in healthcare is happening universally without enough attention to safety. Most stakeholders, namely stakeholders not involved in private-sector activity, believed that such concerns seem to mirror broader society-wide concerns about the existential risks of AI deployed at scale that is shared by technologists, partners, funders and public health experts alike. They believe that underlying some of these worries from

stakeholders may be sentiments that AI development may be prioritizing speed over ongoing monitoring and adaptation.

"You cannot think of the implementation, especially of AI, as a one and done process, because we already know from other applications that there's data drift, there's demographic changes, there may be other reasons that cause degradation." (Senior Manager Funder 2)

Thus, several funders point to the need for more substantial advances in model evaluation and performance monitoring that take into consideration that challenges of data quality, interoperability and bias that could be prevalent when disseminating AI algorithms in LMICs like Kenya.

That's the wonder and like, the difficulty is they're [AI applicatons] coming up so quickly, and there's so many variations that I don't think it's going to be about your performance when you first benchmark it. I think it's going to be your ability to maintain performance that is going to kind of differentiate groups, and that's going to be a black box if you don't have measurement tools. Senior Manager (Funder 2)

External Market-Shaping Strategies: Developing an Enabling Business Environment

Overcoming the scale of internal entrepreneurial and external 'market' challenges that pervade the landscape of AI-Health implementation in Kenya requires active interventions by institutions like governments, global health funders and other bodies. In doing so, such institutions will need to undertake or continue to undertake efforts to align these interventions in a way that ensures that financial or operating sustainability is matched with serving the public good. The four overarching forms of market-shaping intervention continue to remain conceptually relevant in line with the evidence uncovered during the CIS. However, differences in their focus remain. Below offers evidence for each theme and sub-theme paired with short quotes from participants for each type of market-shaping intervention.

Support with Strategic Partnerships

1. Funder Coordination to Create Cross-Portfolio Synergies

Several funders and AI-Health executives emphasised that more intentional collaboration between funders could help avoid a hyper-proliferation of competing AI-enabled technologies that all have minimal financial runway. One way they suggested accomplishing this is by creating a stronger, more sustainable digital health infrastructure that can be leveraged across their portfolios.

"I really think that them coming together and saying, we want to make a big bet on a backbone that you can build on… right now it's let 1000

flowers bloom. And… they're all going to die and one might survive because it got lucky" (Chief Officer AI Company 7).

Funding stakeholder focused on the need for coordinated decision-making of this kind, focused on sharing and integrating joint assets ("digital public goods" or "global public goods"), to ensure that investments build upon one another rather than competing in the same limited space or forcing ventures to duplicate difficult technical or non-technical work. However, these same funders acknowledged such coordination may require difficult up-front commitments from funders towards sustaining these joint assets.

"There are so many software… global goods that these health… innovators don't know about… there's a lot of re-creation and duplication… supported by [REDACTED] and Gates and UNICEF… and there's no connectivity between them" (Senior Director Funder 1).

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2. Horizontal Partnerships Among Digital Health Innovators & Other Health-System Stakeholders

Stakeholders emphasised the need to broker partnerships that connect digital health innovators with other complimentary health-system actors such as government agencies, academic institutions, insurers, patient groups, and NGOs. Given the integrated nature of healthcare delivery, pooling data from diverse health-system stakeholders was seen across all stakeholder groups as a major untapped opportunity for improving service design.

"We have insurance guys… patient groups… research organizations… we're all sitting on different data that can… inform how we design our

care models… there's no patient journeys… for even the most obvious things" (Manager Global Health Partner 3).

Technology leads found that these relationships could help unlock complementary resources, knowledge, and datasets that few organisations could access independently helping organisations focus on the aspects of public health issues that they have the most capabilities and context to tackle.

"That's implementers, the government of course, educational institutions and other for-profit, nonprofit organizations that can come together and share knowledge, share ideas… which could then be accelerated by grant makers and donors" (Technology Lead AI Company 5).

However, funders and partners agreed that forming such cross-sector alliances can be hampered by bureaucracy, slow decision-making, and misaligned incentives. These stakeholders pushed for finding new ways of partnership governance, partnership cost-sharing and further ecosystem alignment to break down these organisational silos.

3. Vertical Partnerships with Technology & Digital Infrastructure Providers

Furthermore, stakeholders also found that partnerships with large technology companies and digital infrastructure have continued to help accelerate AI product development and deployment for Health-AI ventures in Kenya by enabling access to the engineering talent, technical infrastructure and financial resources of major technology firms. One partner commented on the success of a particular AI-Health technology company in Kenya stating:

"Why is [REDACTED PRODUCT] where it is today? It's very easy to make a best-in-class product when you have [MAJOR TECH COMPANY]'s engineers supporting you… [he] did [have] a competitive advantage because he… [had] very early [MAJOR TECH COMPANY] funding… with the support of some of the world's best AI engineers" (Chief Officer Global Health Partner 2).

However, the recipient of the technical support agreed with the partners assessment, stating that such support from a major technology company was complemented by the fact that the company was willing to move quickly to support their initiatives and were willing partners as they iterated to improve their product.

"Once they decide to move in a certain direction… they're able to mobilize resources fast… technical resources… that… have massively accelerated the development of our work" (Technology Lead AI Company 5).

Furthermore, the same technology lead stated that cloud credits and reduced-cost connectivity agreements from technology providers have also helped significantly lower cost barriers and accelerate their product delivery timelines. Telecommunications companies were also highlighted by several stakeholders as critical infrastructure partners, both for their reach and their ability to reduce recurring operational costs.

"We were… able to build thanks to… Cloud Credits. But if… costs had been a strong consideration, then our progress would have been much slower" (Technology Lead AI Company 5).

One of the largest cost drivers… is SMS… we're trying to work with mobile network operators to… significantly reduce the cost"
(Technology Lead AI Company 5).

Fit-for-Purpose Regulatory Frameworks

1. Build Regulatory Capacity Through Strategic Workforce Development

Stakeholders stressed that effective regulation of digital health and AI requires targeted investments in state capacity, both in technical expertise and in policy leadership. Limited state capacity, particularly in technology skills, was identified by several funding and partner stakeholders as a fundamental barrier to scaling and governing digital health solutions. These funding and partner stakeholders emphasised that this capacity building must extend beyond generic policy skills to include professionals with direct experience building and deploying technology.

"For the public sector… tech talent is very limited… you need tech people in the background… do we have the technical know-how?"
(Senior Manager Funder 2).

Stakeholders with experience embedding in the government believed that ultimately, workforce development for regulatory capacity must be strategic: combining technical and policy skills, embedding practical industry experience, and building the institutional readiness to adapt regulations as political priorities, market conditions, and technological capabilities evolve. Several believed that this expertise would strengthen the design of

regulatory sandboxes, environments where new technologies can be tested in concert with regulators, to ensure policy keeps pace with the rate of AI innovation.

"we need to be empowering leaders… who have to set policy, set regulatory frameworks, figure out how to engage with innovators… set the right incentives… not just to have… a saturated market" (Senior Director Funder 1).

One stakeholder even suggested that investing in regulatory capacity can also improve public safety while forming a sustainable revenue model for government agencies built around evaluations.

"If they can support innovators getting through a robust… regulatory framework… you… remove the stuff that is problematic… you end up making money for the regulator through evaluations and… you've only let the effective stuff onto the market" (Chief Officer Global Health Partner 2).

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2. Implement Mandatory Technical Standards to Enable Interoperability

Across stakeholder groups, all participants emphasised that clear technical standards are essential to unlocking innovation in digital health and AI. Without such standards, they found that companies are often left creating custom integrations for a wide range of stakeholders while taking on the financial and regulatory risk of having to navigate ambiguous or non-existent regulations around issues like data privacy. Interoperability was viewed by all stakeholders as a priority to ensure that systems can communicate seamlessly. This seems to be a strategic challenge actively being tackled by several partners within the Kenyan Public Health system with one stating the following:

> *"We have the client registry… facility registry… healthcare worker registry… we're using FHIR as the standard… all systems should be FHIR capable… so that… one point of care system… speaks to any other point of care system in the country" (Digital Infrastructure Lead Global Health Partner 5).*

However, given the fast speed at which AI-enabled healthcare is operating, several entrepreneurs believed that for the regulation to be effective over time, such technical standards should be robust and clear while also remaining broad enough to remain relevant as technology evolves. One technical lead commented on the issue:

> *"AI regulation has to be drafted carefully… with broad guidelines to protect the user without too specific details [that] will be out of date… long before [its] implemented" (Technology Lead AI Company 5).*

3. Deploy Continuous Performance Monitoring and Benchmarking Systems

Several funders stressed that the sustainability and effectiveness of AI-enabled health tools would soon depend on moving beyond one-off evaluations toward continuous performance monitoring and benchmarking. Without such systems, funders found that they'd be liable to significant risks if they were to rely on marketing claims or single-point validations rather than transparent, comparable evidence on an ongoing basis.

> *"You cannot think of the implementation, especially of AI, as a one and done process… there's data drift, there's demographic changes… if you don't build in a loop to collect outcomes… there's just going to be a continuing mess" (Senior Officer Funder 3).*

Funders suggested several ways forward including: First, they suggested establishing continuous benchmarking systems which would require structured, third-party validation processes that operate across geographies, user groups, and use cases. Second, they suggested building on-top of this data to enable more dynamic, outcome-based decision-making, allowing underperforming digital health tools to be replaced when superior alternatives became available or proved to be higher preforming.

> *"Until you build those product feedback loops, you really can't do… outcome-based solutions… you'll end up with entrenched players again, and not necessarily the best solutions" (Senior Officer Funder 3).*

By institutionalising performance tracking, funders commented on the overarching aim to improve the alignment of public health procurement decisions towards technologies with tangible evidence so that the landscape would be a competitive environment that rewards effectiveness and innovation rather than brand familiarity or sales influence.

Enhanced Public Investment & Procurement

1. Deploy Investments in Core Digital Public Infrastructure

Several entrepreneurs and partners emphasised that enabling sustainable digital health market eco-systems would require long-term, coordinated investment in public digital infrastructure. Such stated investments by these stakeholders included investments in both physical infrastructures, like data centres, as well as investments in technology enablers such as digital identification and digital payments.

"We have a lot of data, and the data needs a lot of storage. So initially we had the challenge of where will we be hosting this data? Then, of course, the data will need data centers and all those things… so passing it together" (Digital Infrastructure Lead Global Health Partner 5).

"For Kenya… we're very progressive in terms of digital payments… so our next step is to ensure that we have the digital ID… so at least we can uniquely identify each person… same as the Aadhaar system in India" (Digital Infrastructure Lead Global Health Partner 5)

This, they noted, would make the system "more robust and able to save costs and offer better services to the people" by reducing fraud and enabling health records to be reliably linked to individuals across facilities. Furthermore, several stakeholders advocated for increased allocation and coordination of funds towards digital infrastructure, arguing that such investments would trickle down to improvements in digital health sustainability.

"Rather than having every NGO come with their small funding… the same way we will allocate some [development aid] to roads and some of it to vaccines… some of it should also go into the digital infrastructure, because it affects everything. If you are spending money to strengthen healthcare supply chain, you can be more efficient with your supply chain by digitizing it" (CMO AI Company 4).

2. Strengthening Public Procurement Processes and State Capacity

Stakeholders across all groups noted that effective public procurement of digital health solutions will require not just financial resources but a level of technical and governance maturity to ensure that purchasers make value-based purchasing decisions. Several noted that current procurement processes suffer from misalignments in expectations

borne from unrealistic timelines, political pressures, and a lack of open dialogue. Several stated that this may lead to scenarios where AI companies are incentivised to over-promise and under-deliver to get government contracts and stave off competition from other ventures, which may be over-promising even more.

"You get into this dance where you're like, I'll ask you for 3x what I know you can do… everybody knows they're going to miss it… and it just creates such a bad dialogue between everybody" (CEO AI Company 1).

Another recurring issue uncovered by global health partners is that many procurement officials in LMICs have little to no training in evaluating complex digital health and AI tools. Without holistic guidance such as buyer's guides or evaluation frameworks, partners found that many officials may be left without the resources to weigh AI against other investments in healthcare delivery or infrastructure.

"Much like doctors… get no training [in management], people within public administration get senior enough and suddenly get given billion dollar budgets… but at no point are taught what an effective procurement looks like" (Chief Officer Global Health Partner 2).

Furthermore, AI technologies in healthcare may have variable impacts based on the context of the workflows they're implemented within. Global health partners and founders found that this variability introduced challenges measuring the potential return-on-investment of such technologies which complicated the confidence procurers had in adopting AI technologies.

"A malaria vaccine will work as well in Kenya as it will in Senegal… for AI most will not" (Chief Officer Global Health Partner 2).

Furthermore, several stakeholders with experience as public heath providers, cautioned against overwhelming the system with too many tools too quickly suggesting that AI products must be introduced in a stepwise fashion that matched the absorptive capacity of public health systems to ensure they are adopted and embedded into practice.

"It's genuinely exhausting… we have to be mindful of how much we're introducing into the system… we're not selling pizzas" (Manager Global Health Partner 3).

3. Build Market Demand Through Purchaser Education and Incentive Alignment

Several stakeholders emphasized that a critical barrier to adoption of AI in public health is the limited understanding among decision-makers of what AI is, what it can deliver, how to use it and its potential risks.

"I think everything starts with education at the public health sector. So bringing practitioners, health leaders, health system and county government leaders up to speed with what AI is, what it's capable of, what the risks are, what the benefits are. A lot of folks… hear AI, they're not really sure. They might be scared. They might think it's capable of more than what it actually is in practicality" (Technology Lead AI Company 5).

Without such training, even frontline providers may revert to old ways of working, leaving new tools underused. As one global health partner noted, "You are giving people apps… and there's no training. So guys

will always resort to what they know… and then, you know, nothing much to do with it" (Manager Global Health Partner 3).

However, beyond education, all stakeholder groups expressed the need for public health purchasers to be equipped to more actively signal their demand for the AI use-cases they find the most feasible, necessary and would be most willing to pay for.

"How do you equip teams on the ground to better express their demand signal?… You start with them, and you work backwards and build a pipeline from their needs, and you equip them to make some of those decisions" (Senior Officer Funder 3).

Lastly, entrepreneurs emphasized that the incentives of the purchaser matter as much as education in sustaining demand. For example, one CMO illustrated one example where clear financial benefits for technological adoption at the county level trumped the clinical rationale behind technology adoption stating:

"In Kenya… digitization has been a game changer in revenue enhancement for hospitals… the primary reason for enforcing EMRs was not even patient care but revenue collections… hospitals actually for this will… gladly pay for those EMRs" (CMO AI Company 4).

Understanding these incentives and re-aligning them at the county-level was seen as a critical action across the participant groups in order to drive more adoption of AI tools for public healthcare in Kenya.

Innovative Funding & Reimbursement Mechanisms

1. <u>Restructure Internal Funder Operations to Enable Horizontal Digital Health Investments</u>

Several funders strongly emphasized how a funders' internal budgeting and accountability structures often lock resources into disease-specific "verticals," making it difficult to finance cross-cutting digital infrastructure. A major funder explained the challenge they faced in supporting more "horizontal" digital health initiatives:

"the accountability structures are… tied back to that vertical program… much less focused on, is the digital health system optimized for the government?… Now we have an opportunity to… think about… supporting a system, as opposed to just a vertical program" (Senior Director Funder 1).

Several of these global health funders found that shifting to horizontal investment models would require the difficult job of aligning internal priorities, timelines, and reporting requirements across teams that were otherwise previously dedicated only to specific conditions. Stated changes might also require replacing some earmarked budgets with pooled resources that can support interoperable platforms, shared registries, and analytics layers that serve multiple health areas. They believed that such initiatives could potentially increase the amount of funding allocated to health-system challenges that cross traditional philanthropic vertical lines (i.e. chronic conditions).

2. <u>Deploy Financial Instruments That Align Outcomes with Reimbursement</u>

Stakeholders across all groups consistently stressed that shifting from short-term, project-based grants to ongoing, performance-linked payments could unlock more substantial incentives and market sustainability.

"It is about finding a way to pay people for the interesting products out there… the moment that you create a mechanism that allows someone to pay a product developer for demonstrated outcomes… all of the incentives… will align… The winners will win… generate enough capital to scale organically… and demonstrate enough of a value proposition to other investors" (Chief Officer Global Health Partner 2)

"Creating that transparency on ongoing performance… makes it easier to… think about… paying for population outcomes" (Senior Officer Funder 3)

Furthermore, entrepreneurs, funders and global health partners argued that recurring, outcome-based funding would correct the misaligned incentives of project grants and incentives, encouraging more competition and incentivizing cross-coordination and partnerships aimed at public health impact.

"Rather than paying me to do a three year project in Kenya, you're paying me… per CHW… using technology to create impact… If you are instead paid… for an outcome… that aligns so many more… incentives" (CEO AI Company 1).

However, they also acknowledged such shifts would significantly challenge current philanthropic practices, requiring an increase in the number of cost-effective evaluations of AI-enabled technologies in healthcare, but also investments in the infrastructure necessary towards collecting and analysing such real-world evidence in an ongoing manner.

"Outcomes-based reimbursement…. Requires monitoring and evaluation… at a much more detailed granular level… There are legal

contractual considerations… tied to measured outcomes" (Director Global Health Partner 1).

Furthermore, funders started how shifts towards outcome-based reimbursements may require higher levels of funder commitment and technical capacity to operationalize and scale.

"Outcomes-based mechanisms can be very complicated… you're actively tracking… actively managing the grant… a lot more commitment from grant providers" (Senior Manager Funder 2).

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3. Leverage Blended Financing to Support Early-Stage Investments

All stakeholders agreed that early-stage digital health ventures often face a "funding gap" between grant-supported prototyping and commercial viability. Several argued that philanthropic and donor capital should be deployed in more flexible, investment-oriented ways to bridge that gap, rather than perpetuating dependency on short-term grants. As one global health partner put it:

"Grants [are] seen as free money at the moment… you can build in mechanisms to make people more accountable… repayable grant structures… they become responsible for it… On the blended finance side… you could have… outcome-based financing… pool procurement… first loss capital… to facilitate private sector investments" (Senior Manager Funder 2).

Others described using blended finance structures like equity investments, milestone contracts, repayable grant structures, first-loss capital and outcome-based financing to make recipients more accountable.

"We need to stop giving these people grants… and start giving them things like convertible notes and start taking equity positions… This is a venture… either it will prove out and be effective… or it won't… philanthropy… prop[s] up… people that the market would otherwise have squashed… You don't let the winners win" (Chief Officer Global Health Partner 2).

One funder believed that such targeted investments can also help to ensure funders can more actively set the strategic direction of AI-venture product decisions in response to emerging challenges, providing their contextual knowledge and vision as the AI product undergoes development, rather than a more blind approach pending the final deliverable.

"The paradigm… that was very useful was combining equity investments with milestone driven contracts… you would get a seat at the table… be part of how the team is thinking… balancing their opportunities… [and] mix and match financial instruments with… on-the-ground connections and expertise… convening, connecting, [and] technical assistance alongside those awards" (Senior Officer Funder 3).

Summary & Updated Conceptual Framework

The empirical work revealed similar conceptual components in comparison to the original literature-based results. However, underpinning the challenges and potential market-shaping interventions were several notable conceptual additions and semantic changes to the three major constructs that were examined empirically.

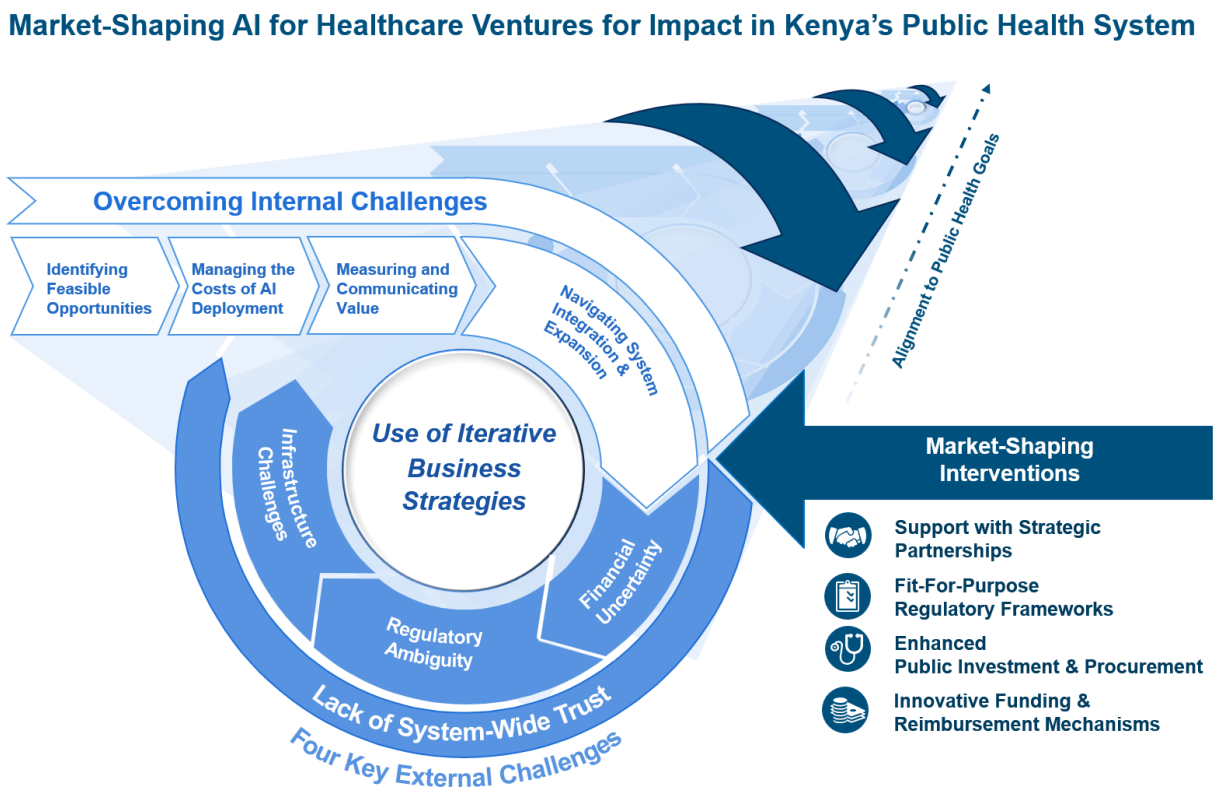


Figure 5: Updated Conceptual Framework Derived from the Qualitative Study

The' internal business challenges" concept was expanded to include the issue of managing AI deployment costs, which encompasses infrastructure, data storage, AI training, inference, and the expenses associated with acquiring and retaining technical talent. The' external market challenges' were further broadened to highlight a pervasive lack of system-wide trust in AI, characterised by skepticism from health professionals,

patients, communities, government, and health facilities. This distrust appears rooted in the concern that AI development's rapid pace and hype, both within and outside healthcare, may be outstripping efforts to address the human and regulatory risks of inaccurate AI. Furthermore, nuanced differences also surfaced, even within the core themes shared by both the CIS results and the qualitative study.

For each of the three constructs examined, there is a visual summary comparing literature-based conceptual components (left) with themes from empirical findings (right). The right panel highlights in bold dark blue either new themes or sub-themes (' Funder Coordination') that distinctly emerged from empirical work beneath existing or new themes. Conversely, bolded items on the left represent sub-themes from the CIS that did not appear in the empirical findings.

Qualitative Study Updates to “Internal Entrepreneurial Challenges”

The Qualitative study showed an increased emphasis on the challenges that limited customer purchasing power had on the sustainability of AI-enabled services. Since many AI tools are meant to augment pre-existing workflows, it may be increasingly challenging for customers to identify the economic value of the intervention compared to the status quo. Thus, individual patients may be unable or unwilling to pay for such services, leaving the costs to be passed onto governments and funders who are equally challenged in identifying what the appropriate amount might be to reimburse an AI-enabled product.

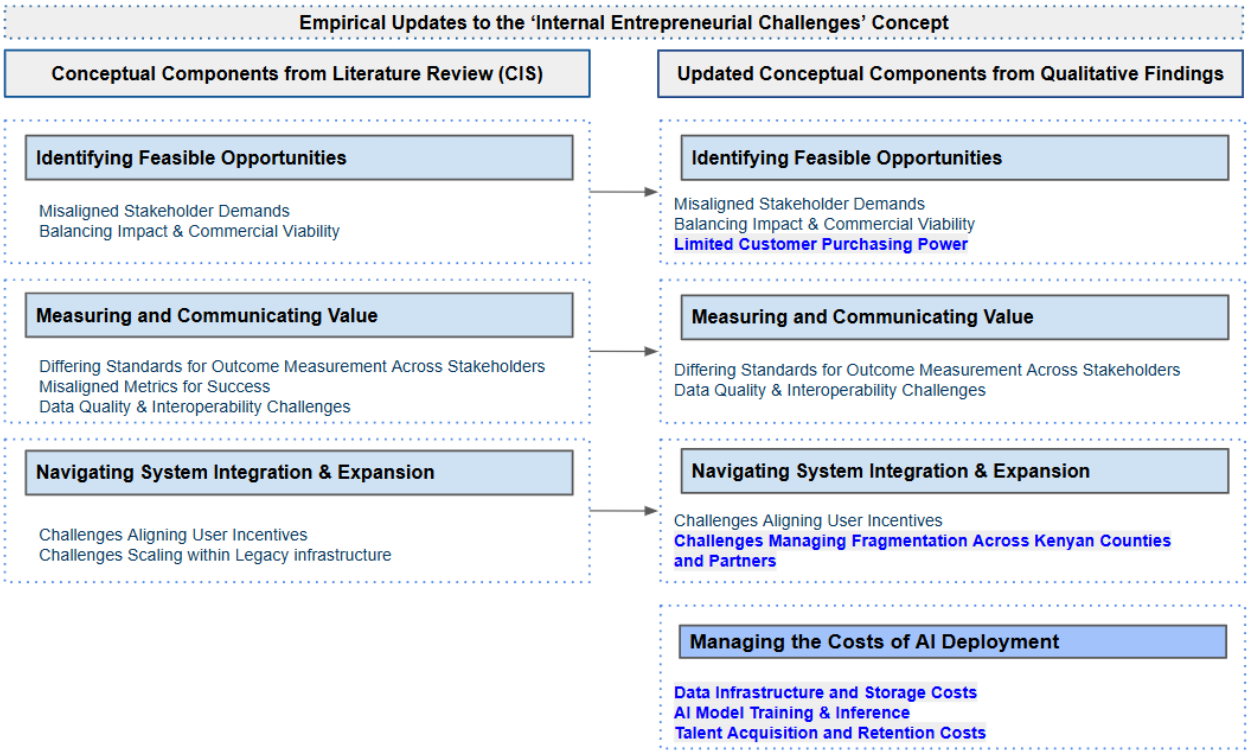


Figure 6: Empirical Updates to the 'Internal Entrepreneurial Challenges' Concept

Furthermore, Kenya’s decentralized purchasing environment was also uniquely highlighted as an internal entrepreneurial challenge. Managing AI implementation and building trust across counties and health facilities can be difficult in decentralized settings

as it requires scaling human support for new customers that could have varying levels of experience with digital health or IT adoption.

Qualitative Study Updates to “External Market Challenges”

Separate from the “Lack of System-Wide Trust” theme, the Qualitative study showed a high degree of alignment with the CIS. However, several additions to the empirical framework were developed considering new qualitative evidence.

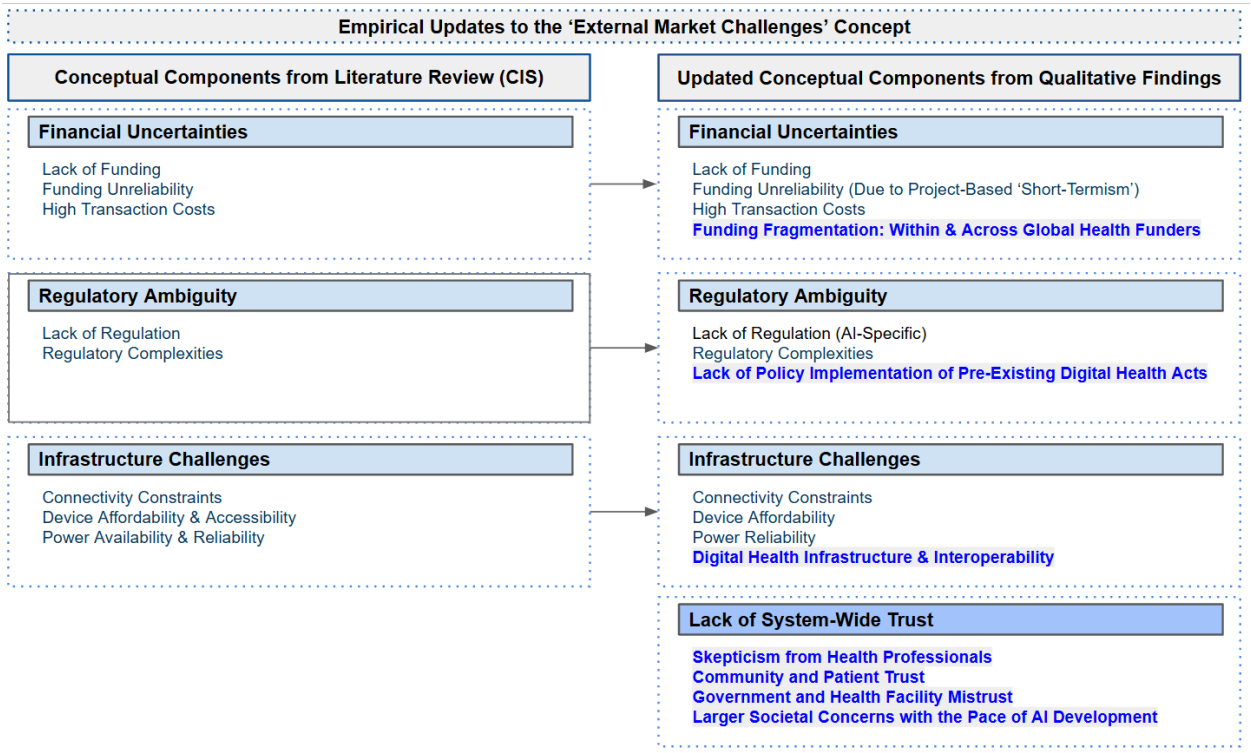


Figure 7: Empirical Updates to the 'External Market Challenges' Concept

The empirical work highlights an increased focus on the challenges that funding fragmentation creates for the sustainability of business models in Health-AI. Entrepreneurs find themselves needing to find, collect, and consolidate small pools of money across multiple departments within a large global health organisation rather than being able to access a more comprehensive digital health-specific fund. Challenges in

raising funds persist in a funding paradigm where “disease-specific” interventions attract more attention than more “holistic” or cross-cutting health system strengthening interventions. Regarding infrastructure, increased emphasis is explicitly placed on the importance of digital payments, digital patient IDS, and technical standards for interoperability, which are essential backbones for large-scale big data analytics and machine learning. Lastly, Kenyan stakeholders point to a lack of policy implementation of existing digital health and data privacy regulations, which may be complemented by further AI-specific regulation to improve regulatory clarity around challenges such as medical liability.

Qualitative Study Updates to “External Market-Shaping Interventions”

While the CIS provided an exhaustive list of market-shaping interventions, most of which were evidenced by the empirical work, several unique needs in the Kenyan context emerged for funders and governments to pursue potentially.

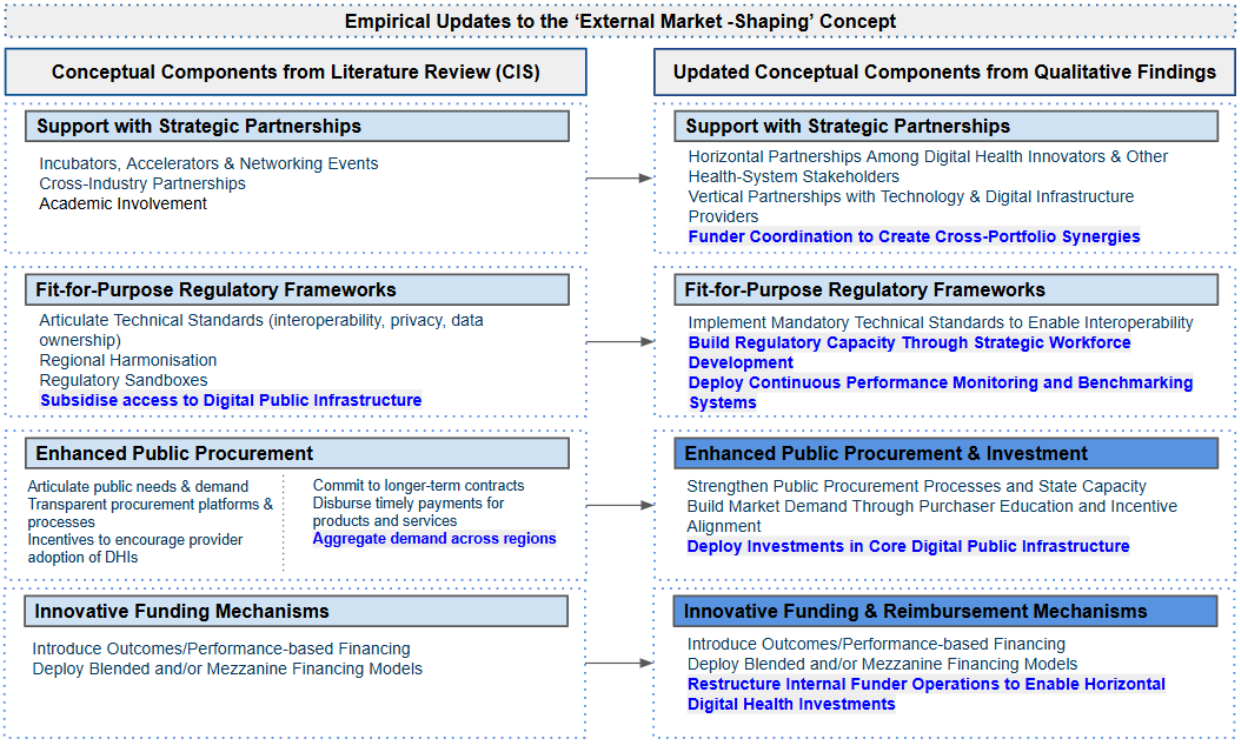


Figure 8: Empirical Updates to the 'External Market-Shaping' Concept

The need for funders to assess potential synergies across different funders' portfolios has become apparent, alongside the necessity for operational changes that would allow for increased funding towards holistic interventions that may cross traditional disease-focused funding lines. Nonetheless, government-led market-shaping interventions might encounter obstacles without additional investment and focus on regulatory capacity. Strategic workforce development, including improving public procurement and recruiting technical experts into leadership roles, will be essential to enable the 'digital health super-highway" the government seeks to implement. This "highway" could be a vital step towards creating a regulatory or technical platform for ongoing performance oversight of AI-enabled healthcare products. Continuous performance monitoring can help manage potential model drift and support more evidence- and outcomes-based purchasing decisions by benchmarking various AI-enabled products against competitors and patient

outcomes. The emphasis on long-term investment by both funders and governments is reflected in semantic updates to the framework.

Chapter 6: Discussion

Summary of Results

I conducted two complementary studies to understand the challenges to financial sustainability faced by digital health business models in LMICs with the aim of evaluating the potential of market-shaping interventions towards aligning financial sustainability with public value (5 A's: affordability, availability, appropriate design, assured quality, and awareness). Internal entrepreneurial challenges primarily involve managing value creation across complex stakeholder networks which manifests in several domains. First, companies struggle to identify viable opportunities that balance impact and commercial viability, especially given limited customer purchasing power. Second, companies find it difficult to measure and communicate value in multi-sided business models where beneficiaries cannot pay full costs. Third, system integration is challenging because digital health solutions depend on highly dependent but often bureaucratic partnerships, with service quality relying on multiple stakeholders.

However, external market challenges can also include financial uncertainties caused by unreliable project-based funding and high transaction costs, infrastructure issues related to connectivity and device accessibility, and regulatory ambiguity stemming from both absent and overly complex frameworks. In summary, the synthesis identified potential solutions via internal business strategies that evolve according to company maturity, as well as external market-shaping interventions such as strategic partnerships, regulatory reforms, public procurement updates, and innovative financing mechanisms.

However, the emergence of ‘market-shaping’ as a critical element for sustaining business models for digital health in LMICs prompted me to conduct an empirical study focusing on the feasibility, acceptability, and necessity of market-shaping interventions for AI-enabled products and services serving Kenya’s public health sector. Consequently, I interviewed 16 stakeholders involved in AI-enabled healthcare initiatives in Kenya, including entrepreneurs, funders, and global health partners. The empirical work validated the theoretical framework while also uncovering additional challenges specific to AI.

Internal challenges appeared more severe than indicated in existing literature. Beyond expected stakeholder alignment issues, AI companies face significant costs related to data infrastructure, model training, and attracting scarce technical talent. Limited customer purchasing power presents difficulties since AI tools usually complement rather than replace existing workflows, making it hard to demonstrate economic value. Kenya's decentralised governance necessitates separate negotiations with multiple county authorities.

External challenges highlighted a funding crisis following reductions in development aid. Several participants described existential threats, with one company compelled to shut down its Kenya operations entirely. Fragmentation of funding across disease-specific programmes hampers comprehensive investments. A new theme emerged regarding systems-wide trust, with widespread scepticism about the speed and safety of AI deployment among health professionals, patients, and government institutions.

Market-shaping interventions received unanimous support in principle but faced substantial feasibility challenges. Participants regarded regulatory frameworks as essential but questioned the capacity to implement them given limited state resources.

Enhancing strategic partnerships appeared bureaucratic although promising, especially in partnership with technology companies offering technical support or infrastructure. Public procurement reforms require extensive capacity building for technical evaluation. Innovative funding mechanisms attracted strong interest but would involve major organisational changes by funders.

Both studies indicate that while market-shaping interventions might promote alignment between private-sector financial sustainability and public health objectives (Five As), their implementation could encounter considerable obstacles. The gap between stakeholder support for these interventions and the actual capacity to implement them raises concerns about whether most LMICs possess the necessary regulatory, financial, and technical resources for effective market-shaping in AI-enabled digital health.

Discussion of Results in Relation to the Wider Literature

A mentor of mine once said ‘a good research question provides a contribution to a gap in the literature, but a great research question stretches it.”

The original critical interpretive synthesis (CIS) was leveraged as a means of synthesizing a wide corpus of interdisciplinary literature to contribute to an understanding of why business models in digital global health (specifically LMICs) failed and what could be done to more directly tie their financial sustainability with the creation of public health value (5 A’s: affordability, availability, appropriate design, assured quality, and awareness) rather than simply saturating a market with solutions. Through the CIS, 'Market-Shaping' emerged, not necessarily as a discrete research domain, but as practical active actor-driven processes that have been instrumental in shaping a small number of markets in healthcare towards addressing public health challenges in LMICs since the 1980s.[1,2] At face value, both the critical interpretive synthesis, which broadly focused on digital health market-shaping in LMICs, as well as the subsequent empirical study, which specifically focused specifically on Market-Shaping AI-Health in Kenya, contribute both to academic gaps in the literature on 'Market-Shaping' and to practical gaps in global health market-shaping implementation.

Academically, few academic papers have retroactively examined or evaluated formally organised market-shaping interventions, let alone extending the little academic evidence that exists on market-shaping to examine new approaches that could be used to address the opportunities and challenges of market-shaping technologies like digital health which require more local adaptation and iteration.[1] Practically, the need to address this gap has

continued to intensify as the small number of organisations who lead this work (ex. CHAI, R4D, PATH, GAVI) have continued to push their market-shaping efforts to address market failures in LMICs that have new and unfamiliar market dynamics including improving access to medical oxygen, assistive technologies and mental health.[4–6] PATH and Digital Square have released very nascent white papers assessing the challenges of market-shaping open-source and EHR-focused digital health technologies with similar conclusions regarding external market interventions that include financing, regulation, partnerships and public procurement.[142] However, even with the recent digital-health specific market-shaping work, a comprehensive framework connecting end-to-end solutions from entrepreneurs at the venture-level to external solutions that encompass large global health partners, funders and governments remains absent. Thus, the empirical work, by including senior executives at each of the largest organizations involved in global health market-shaping as well as the on-the-ground individuals involved in AI-Health in Kenya, embodies a collaborative approach to research in this domain that matches its practical origins.

However, this work also embodies several key developments happening in wider research disciplines at the intersection of international development and industrial innovation policy. Industrial policy, once a domain primarily concerned with stimulating manufacturing and export-led growth through targeted interventions in industries like automobiles, has been revitalized in recent years through the work of scholars such as Mariana Mazzucato.[143,144] Her concept of the entrepreneurial state reframes industrial (innovation) policy not as passive correction of free-market failures, but as an active process of “mission-oriented” market creation with directionality set towards tangible

public goals.[143,144] A paradigm where the state and aligned institutions (ex. market-shaping NGOs) shape market ecosystems (especially in rapidly advancing fields) towards innovation that helps in tackling societal challenges such as climate change, health inequities, and digital inclusion.[143,144] Within this renewed paradigm, the market-shaping lens that emerged from the CIS can be understood as a practical extension of this "mission-oriented" industrial innovation policy to international development within global health. Where older traditional industrial policies may have focused on protecting domestic manufacturing through import/export controls (ie., Electronics Industry amongst the East Asian 'Tigers'), market-shaping in digital global health may focus on generating public health value outcomes (the 5 A's) using tools like: aligning stakeholder incentives in healthcare, improving institutional processes for regulation and procurement, signaling public health needs, and upgrading shared public digital infrastructure.

This perspective could help to situate present and future work on digital health sustainability towards informing more practical experimentation in international development. However, integrating academia into this more "mission-oriented" proactive approach to public-private partnerships may require the wider academic community in global health to consider a few steps. First, researchers can consider incorporating management and finance perspectives into their implementation research rather than negating terminologies related to business, management or entrepreneurship or assuming blanket assumptions of ill-will by the private sector.[145] Second, those in academia may have to reckon with the potential ethics issues of launching their own pilot-digital health initiatives in LMICs if they have little incentive or institutional backing to attempt the incredibly difficult technical, commercial and personal challenge of scaling

their academic projects into sustainable operations over what can take five to ten years in LMIC contexts. Third, researchers can help contribute to gaps in government monitoring capacity by embedding themselves in real-time or retrospective monitoring and evaluating digital health interventions using, for example, the NASSS (Non-adoption, Abandonment, Scale-up, Spread, and Sustainability) Framework.

While both the frameworks from this research and the NASSS seek to address challenges of digital health implementation, they offer complementary analytical lenses for application at different levels. The NASSS framework was developed to predict the real-time success or failure of a particular digital health value proposition in the context of a pre-defined set of stakeholders within a wider health system.[145] In contrast, the four-part conceptual framework takes a more LMIC-centric policy-focused approach, examining how internal business model dynamics and external market forces can be identified and mapped onto strategic opportunities for government intervention and market shaping. Together, they could enable researchers and policymakers to move beyond documenting failure toward identifying actionable leverage points, whether at the organizational level (through NASSS-informed implementation strategies) or at the market level (through government policies that address systemic sustainability challenges).

Regulatory & Technical Challenges of Market-Shaping AI for Public Health

Market-shaping aims to realign private incentives with public health value; however, for AI, the institutional or state capacity requirements may be steeper than for healthcare commodities. Many LMICs may not have mature AI talent, clinical data infrastructure or

stable public procurement channels that can sustain multi-year AI contracts. Several indices regarding AI readiness place only a small number of LMICs in the high-capacity tier, with Kenya as a regional outlier.[146] Such challenges suggest that only a handful of LMICs may be well-positioned to execute on local market-shaping for Health-AI.

However, when it comes to the feasibility of launching such frameworks, there remains a cautious optimism for regulatory sandboxes to help develop a number of these frameworks in Kenya. Historically, Kenya has successfully experimented with regulatory sandboxes for Financial services, Information and Communications Technology (ICT), and has more recently sponsored Health-Tech Regulatory sandbox events through the Kenya Medical Research Institute (KEMRI).[147–149] Ensuring the Digital Health Agency has the capacity and agency to deliver on such goals will be crucial, especially given the potential cross-cutting nature of AI-enabled technologies across multiple agencies and the historical reliance on older and more established agencies like the Ministry of ICT & The Digital Economy, [147–149] to oversee regulatory innovation. Given the fast pace of AI development, there are several reasons why such regulatory capacity and action become crucial.

First, LLMs and other AI systems can produce confident but incorrect outputs. A 2025 multi-model analysis demonstrated that simple ‘attack patterns’ were able to induce model ‘hallucinations’ in LLMs involved in clinical decision support that resulted in false clinical details with tangible associated risks.[150] Thus, without significant technical and cybersecurity oversight, large centralised systems for AI deployment could prove to be dangerous fault lines for national security if patient data or other healthcare workflows were put at risk. However, even non-maliciously, there can also be significant issues

related to the transferability of AI developed in non-local contexts.[151–153] A 2024 Nature Communications study showed that models developed in the UK performed less effectively in Vietnamese hospitals until re-trained for local practices.[153] Furthermore, reviews have shown potentially dangerous sources of model bias that must be mitigated with technical measures like transfer learning, continuous post-deployment monitoring or non-technical measures like participatory design with local healthcare providers and patients [151,152]

Given these immense challenges to patient safety and provider liability, the successful adoption of AI-enabled products and services will require actions taken by both vendors and governments to build trust in the communities they work with.[154,155] Scoping reviews emphasise that provider trust depends on perceived usefulness around known pain-points, transparency about the limitations of the tool, integration into pre-existing workflows and clear boundaries for where AI augments rather than replaces clinical judgement.[155]

Furthermore, early data from the OpenAI and Penda Health Health-AI preprint suggest that AI-Copilots that are guideline-linked and embedded seamlessly with pre-existing technologies and workflows can improve clinical guideline adherence and improve patient safety.[12] Yet the lack of reported improvements in patient outcomes by the same study points to some of the challenges that AI-enabled products will face in measuring and communicating impact and thus receiving long-term reimbursement for deploying their solutions.[12]

Market-Shaping in the Context of the Deflated Global Health Funding Environment

Given these immense challenges, practical and ethical conversations on the fundamental availability of funding to conduct market-shaping are warranted. In January 2025, the United States administration defunded the United States Agency for International Development (USAID).[156] Freezing the world's largest source of developmental aid with the intent to cancel 86% of its programs.[157] Further cuts to global health funding by the United States were announced for organisations such as the Global Alliance for Vaccines and Immunisation (GAVI), the World Health Organisation (WHO), and UNICEF, some of the largest multilateral organisations dedicated to healthcare provision in many low- and low-middle-income countries (LMICs).[158] Such disruptions to the global developmental aid have already resulted in the complete dismantling of at least one of the participating AI companies' Kenya-based teams. The near-term response by academics has included new calls for pooled funding vehicles, stop-gap measures, outcomes-based contracts and innovative financing; however, without a strong convener amongst global health funders and a shared framework to think about outcomes measurement, funding may continue to fragment within organisations and across organisations.[159]

Given these challenges, it becomes pertinent to consider whether LMICs would benefit materially from allowing high-income countries with larger markets, more purchasing power and higher levels of access to technical talent to bear the costs, and thus the unforeseen risks of AI experimentation in these nascent stages of development.

Strengths & Limitations of the Research

This study aimed to comprehend and address a complex phenomenon spanning multiple professional disciplines, including industrial public policy, entrepreneurship studies, global health, and digital health. A key challenge was developing a shared language that remained accessible and actionable for diverse readers while faithfully representing the core evidence.

A significant strength of this work was leveraging my existing literature-based foundation to establish an initial theoretical framework that guided my empirical research. By simplifying the complexity of the phenomenon into a fundamental set of concepts—such as “What is a business model? In Digital Health?”—and progressing towards more advanced ideas, I was able to streamline the initial coding process for the empirical data without becoming rigid in my initial categorizations. I believe this contributed to more trustworthy, transparent, and actionable outcomes. It also enabled me to focus more closely on capturing the depth of stakeholder quotes, reflecting perspectives and experiences that were often nuanced, multi-dimensional, and personal in nature. Additionally, involving an expert panel during critical interpretive synthesis to inform mid-stage outputs enhanced my reflexivity and helped consolidate learnings from LMICs beyond the knowledge of my supervisory team and myself.

A key limitation of my research was the limited participation from current government stakeholders, such as administrators from the Digital Health Agency or clinical executives from major public hospitals in Kenya. Despite concerted efforts through cold messaging and leveraging personal and mutual networks, few were willing to respond, and those

who did were hesitant to participate at this stage. Greater involvement from such stakeholders could provide valuable insights into the politics of digital health adoption in public health settings, which is crucial for understanding the feasibility of market-shaping initiatives from the perspective of regulators or health-system purchasers. Moreover, the absence of input from patients experienced in using AI tools to access public health services was also a limitation. Patient participation can reveal important nuances related to trust and usability, as well as shed light on patients' willingness to pay for various types of services.

Future Research

Future research could move in several directions. The most compelling direction would be to conduct focus groups or participant workshops that include more stakeholders from government and public health facilities, including both small and large facilities. Furthermore, workshops with a wide range of global health funders could help determine new strategic options for pooling resources, creating cross-portfolio synergies or assessing the potential for outcomes-based reimbursement. Both could be particularly helpful in exploring the feasibility of specific market-shaping interventions that had been deemed necessary but infeasible due to perceived mal-incentives in the ecosystem. Research approaches that champion collaboration and stakeholder engagement will continue to be key in advancing research in this space.

Conclusion

Companies in digital health within LMICs encounter numerous challenges that restrict their capacity to sustain financial viability while achieving impactful outcomes. In response to these challenges, market-shaping interventions designed to align private-sector sustainability with targeted public health objectives may serve as a valuable instrument in LMICs, particularly where there exists political willingness to enhance regulatory capacity. To address these issues, policymakers and market-shapers should consider implementing fit-for-purpose regulation, strategic partnerships, innovative financing and reimbursement mechanisms, as well as public investments in procurement and infrastructure. Market-shaping AI-enabled products and services tailored to the Kenyan context must confront new challenges, including internal obstacles related to cost-effective AI deployment and external hurdles in disseminating systems-level trust amid the rapid evolution of AI technology. Effectively managing change within such interventions will require strong political leadership to foster investments in regulatory capacity for AI-Health procurement and evaluation, potentially necessitating the coordination of a complex network of global health funders around new visions of collaborative funding that draw inspiration from contemporary debates on “mission-oriented” industrial innovation policy.

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Supplementary Appendix

Overview of Appendix Items

1. Table 1: Overview of Extracted Articles (Article Background & Study Designs)
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Appendix Items for the Literature Review (Chapters 2 and 3)

Supplementary Table 1: Overview of Extracted Articles (Article Background & Study Designs)

Key Background Information					
Title	**Author(s) and Date of Publication**	**Specific DH Technology Focus?**	**Explicitly LMIC focus or General applicability?**	**Study design**	**Business Model Construct/Framework Used or Created**
Business Models for Telemedicine Services: A Literature Review	*Acheampong and Vimarlund, 2015 [31]*	Telehealth	Multiple LMICs	Literature Review	Modified Business Model Canvas
Why classic Business Modelling doesn't work for collaborative contexts	*Albert and Van der Auwermeulen, 2017[21]*	No – General DH Technologies	General applicability	Interviews & Workshops	Unique Construct
Business model innovation in healthcare: A theoretical perspective	*Babatunde, 2024 [11]*	No – General DH Technologies	General applicability	Systematic Review	Unique Construct
Indian Telemedicine Industry: Evolving Nature of Business Models and Customer Interactions	Bhattacharyya et al. 2021 [38]	Telehealth	India	Multiple Case Studies	NA
Designing sustainable revenue models for CHW-centric entrepreneurial ventures	*Callan et al., 2014 [9]*	No – General DH Technologies	LMICs	Systematic Review & Expert Opinion	Business Model Canvas
Investigating on Requirements for Business Model	*Gand et al., 2017 [23]*	No – General DH Technologies	General applicability	Literature Review &	Unique Construct

Representations in the Health IT domain				Design Approach	
Towards conceptual enhancements of the Business Model Canvas for the design of Health IT solutions	*Gand et al., 2018 [22]*	No – General DH Technologies	General applicability	Literature Review & Design Approach	Modified Business Model Canvas
Artificial Intelligence as a Growth Engine for Healthcare Startups	*Garbuio and Lin , 2019 [24]*	AI-Technologies	General applicability	Multiple Case Studies & Expert Opinion	Unique Construct
Care coordination in a business-to-business and a business-to-consumer telemonitoring case	*Grustam et al., 2017 [37]*	Remote Patient Monitoring	General applicability	Literature Review	Unique Construct
Exploring business models for managing uncertainty of new products in medical device and biotechnology firms	*Javanmardi et al., 2024 [33]*	No – General DH Technologies	General applicability	Systematic Literature Review	Modified Business Model Canvas
Business approach for IoT based health solutions	*Jog et al., 2015 [30]*	No – General DH Technologies	General applicability	Multiple Case study	Business Model Canvas
Business Models for E-Health: Evidence from Ten Case Studies	*Kimble et al., 2015 [34]*	No – General DH Technologies	Mix	Multiple Case Studies	Business Model Canvas
Challenges and Success Factors of Business Models in Digital Health:	*Luur, 2023 [25]*	No – General DH Technologies	General applicability	Narrative Literature Review	Business Model Canvas

A Narrative Literature Review					
mHealth Business Model Framework for the Maternal and Baby Segment: A Design Science Research Approach	*Mueller et al., 2019 [26]*	mHealth	General applicability	Design Approach	Unique Construct
Business Models in Digital Health: Bibliometric Analysis and Systematic Literature Review	*Pascarelli et al., 2023 [35]*	No – General DH Technologies	General applicability	Systematic Literature Review	Modified Business Model Canvas & Ojala Framework
Anatomy of Successful Business Models for Complex Services: Insights from the Telemedicine Field	*Peters et al., 2015 [27]*	Telehealth	General applicability	Design Approach	CompBizMod Framework
Developing Sustainable Business Models: A Micro foundational Perspective on the Role of Individuals	*Ringvold et al., 2023 [10]*	Telehealth	Bangladesh	Case Study	NA
On the utility of e-health business model design patterns	*Sprenger and Mettler, 2018 [28]*	No – General DH Technologies	General applicability	Design Approach & Focus Groups	Unique Construct
Why do entrepreneurial mHealth ventures in the developing world fail to scale?	*Sundin et al., 2016 [5]*	mHealth	LMICs	Literature Review & Multiple Case Studies	NA
The 4P telehealth business framework for Iran	*Velayati et al., 2022 [29]*	Telehealth	Iran	Literature Review & Delphi Workshop	Unique Construct (4P Framework)

Conceptualizing the landscape of digital health entrepreneurship	*Weimar et al., 2024 [36]*	No – General DH Technologies	General applicability	Systematic Literature Review	Unique Construct

Supplementary Table 2: Overview of Extracted Articles (Findings Addressed)

Key Background Information					
Title	**Author(s) and Date of Publication**	**(1) Internal Entrepreneurial Challenges**	**(2) External Market Challenges**	**(3) Potential Internal Business Strategies**	**(4) Potential External Market-Shaping Strategies**
Business Models for Telemedicine Services: A Literature Review	*Acheampong and Vimarlund, 2015 [31]*	YES	YES	YES	NA
Why classic Business Modelling doesn't work for collaborative contexts	*Albert and Van der Auwermeulen, 2017[21]*	YES	YES	YES	NA
Business model innovation in healthcare: A theoretical perspective	*Babatunde, 2024 [11]*	YES	YES	YES	YES
Indian Telemedicine Industry: Evolving Nature of Business Models and Customer Interactions	Bhattacharyya et al. 2021 [38]	YES	YES	YES	NA
Designing sustainable revenue models for CHW-centric entrepreneurial ventures	*Callan et al., 2014 [9]*	YES	YES	YES	NA
Investigating on Requirements for Business Model Representations in the Health IT domain	*Gand et al., 2017 [23]*	YES	YES	YES	NA
Towards conceptual enhancements of the Business Model Canvas for the design of Health IT solutions	*Gand et al., 2018 [22]*	YES	YES	YES	NA
Artificial Intelligence as a Growth Engine for Healthcare Startups	*Garbuio and Lin , 2019 [24]*	YES	YES	YES	NA
Care coordination in a business-to-business and a business-to-consumer telemonitoring case	*Grustam et al., 2017 [37]*	YES	YES	NA	NA
Exploring business models for managing uncertainty of new products in medical	*Javanmardi et al., 2024 [33]*	YES	YES	YES	YES

device and biotechnology firms					
Business approach for IoT based health solutions	*Jog et al., 2015 [30]*	YES	NA	YES	YES
Business Models for E-Health: Evidence from Ten Case Studies	*Kimble et al., 2015 [34]*	YES	NA	YES	YES
Challenges and Success Factors of Business Models in Digital Health: A Narrative Literature Review	*Luur, 2023 [25]*	YES	YES	YES	YES
mHealth Business Model Framework for the Maternal and Baby Segment: A Design Science Research Approach	*Mueller et al., 2019 [26]*	YES	YES	NA	NA
Business Models in Digital Health: Bibliometric Analysis and Systematic Literature Review	*Pascarelli et al., 2023 [35]*	YES	NA	YES	NA
Anatomy of Successful Business Models for Complex Services: Insights from the Telemedicine Field	*Peters et al., 2015 [27]*	YES	YES	YES	NA
Developing Sustainable Business Models: A Micro foundational Perspective on the Role of Individuals	*Ringvold et al., 2023 [10]*	YES	YES	YES	YES
On the utility of e-health business model design patterns	*Sprenger and Mettler, 2018 [28]*	YES	NA	NA	NA
Why do entrepreneurial mHealth ventures in the developing world fail to scale?	*Sundin et al., 2016 [5]*	YES	YES	YES	YES
The 4P telehealth business framework for Iran	*Velayati et al., 2022 [29]*	YES	YES	YES	NA
Conceptualizing the landscape of digital health entrepreneurship	*Weimar et al., 2024 [36]*	YES	YES	YES	YES

Supplementary Table 3: Search Strings & Databases

5 databases: Full Text Available/English

Database (& date of search)	Search String	Number of articles
Business Source Ultimate All Fields Dates published: 2014-5/14/2024	(“business model*” OR “business model framework” OR “business model innovation” OR “business strategy*”) AND (“digital health” OR “ehealth” OR “electronic health” OR “e-health” OR “health informatics” OR “medical informatics” OR “mHealth” OR “mobile health” OR “electronic health record” OR “healthcare management system” OR “health financing” OR “health IT” OR “healthcare IT” OR “health information technology” OR “health-tech” OR ”health tech” OR “tele-health” OR “telemedicine” OR “tele-medicine” OR “digital diagnostics” OR “healthcare AI” OR “healthcare artificial intelligence” OR “Software as a Medical Device” OR “SaMD”)	112
Pubmed All fields Dates published: 2014-5/14/2024	Search((“business model*” OR “business model framework” OR “business model innovation” OR “business strategy*”)) AND (“digital health” OR “ehealth” OR “electronic health” OR “e-health” OR “health informatics” OR “medical informatics” OR “mHealth” OR “mobile health” OR “electronic health record” OR “healthcare management system” OR “health financing” OR “health IT” OR “healthcare IT” OR “health information technology” OR “health-tech” OR ”health tech” OR “tele-health” OR “telemedicine” OR “tele-medicine” OR “digital diagnostics” OR “healthcare AI” OR “healthcare artificial intelligence” OR “Software as a Medical Device” OR “SaMD”) Sort by: Best Match	162
Web of Science Topic search NOT Database:Preprint Citation Index Dates published: 2014-5/14/2024	TOPIC: (“business model*” OR “business model framework” OR “business model innovation” OR “business strategy*”) AND TOPIC: (“digital health” OR “ehealth” OR “electronic health” OR “e-health” OR “health informatics” OR “medical informatics” OR “mHealth” OR “mobile health” OR “electronic health record” OR “healthcare management system” OR “health financing” OR “health IT” OR “healthcare IT” OR “health information technology” OR “health-tech” OR ”health tech” OR “tele-health” OR “telemedicine” OR “tele-medicine” OR “digital diagnostics” OR “healthcare AI” OR “healthcare artificial intelligence” OR “Software as a Medical Device” OR “SaMD”)	408
SCOPUS Title/Abs/Key Dates published: 2014-5/14/2024	(TITLE-ABS-KEY (“business model*” OR “business model framework” OR “business model innovation” OR “business strategy*”) AND TITLE-ABS-KEY (“digital health” OR “ehealth” OR “electronic health” OR “e-health” OR “health informatics” OR “medical informatics” OR “mHealth” OR “mobile health” OR “electronic health record” OR “healthcare management system” OR “health financing” OR “health IT” OR “healthcare IT” OR “health information technology” OR “health-tech” OR ”health tech” OR “tele-health” OR “telemedicine” OR “tele-medicine” OR “digital diagnostics” OR “healthcare AI” OR “healthcare artificial intelligence” OR “Software as a Medical Device” OR “SaMD”))	472

Google Scholar Dates published: 2014-5/14/2024	("business model") AND ("digital health") AND ("global health")	First 200

Supplementary Table 4: Five Conditions for Quality Appraisal

Appraisal prompts for informing judgements about quality of papers (Dixon-Woods et al. 2006)
1. Are the aims and objectives of the research clearly stated?
2. Is the research design clearly specified and appropriate for the aims and objectives of the research?
3. Do the researchers provide a clear account of the process by which their findings were reproduced?
4. Do the researchers display enough data to support their interpretations and conclusions?
5. Is the method of analysis appropriate and adequately explicated?

Supplementary Tables 5-8: Overview of Macro-Theoretical Constructs, Themes, Sub-themes & Examples

Macro-Construct #1: Understanding Internal Entrepreneurial Challenges

Core Theme	*Subthemes*	*Example Articles*	*Example Quote*
Managing Value Creation for Complex Stakeholder Networks	**Challenges Identifying Feasible Opportunities**	*Albert and Van der Auwermeulen, 2017; Garbuio and Lin, 2019; Babatunde, 2024;*	Garbuio and Lin, 2019 - ***"For a new business, we recommend looking at low-hanging fruit, such as improvements in operational effectiveness and solving inefficiencies. It is exciting to solve big problems, such as optimizing patient treatments, but they also carry important regulatory hurdles, difficulty in acquiring patient data, and data cleaning."***
	Challenges Measuring & Communicating Value	*Acheampong and Vimarlund, 2015; Kimble, 2015; Luur, 2023*	Kimble, 2015 - ***"The evaluation of costs and benefits in e-heath and healthcare in general is a perennial problem involving a large number of different stakeholders and sometimes conflicting views on the value of a particular course of action."***
	Challenges Navigating System Integration & Expansion	*Sundin et al.,2016; Gand, 2018; Babatunde, 2024;*	Babatunde, 2024 - ***"Integrating innovative healthcare solutions with existing healthcare systems, workflows, and technologies can be challenging due to interoperability issues, data silos, and legacy infrastructure."***

Macro-Construct #2: Understanding External Market Challenges

Core Themes	*Subthemes*	*Example Articles*	*Example Quote*
Financial Uncertainty	**Lack of Funding**	*Sundin et al.,2016; Velayati et al., 2022; Luur, 2023;*	Velayati et al., 2022 - ***"For example, in Iran, the commercialization of telehealth technology has been hindered by several factors such as physician resistance and insufficient funding to develop and support telehealth systems."***
	Funding Unreliability	*Sundin et al.,2016; Luur et al. 2023; Weimar et al., 2024;*	Sundin et al., 2016 - ***"Often, without the continued funding from initial donors, high operating costs cause the eventual downfall of the [mHealth] project."***

	High Transaction Costs	*Grustam et al., 2017; Luur, 2023; Javanmardi et al., 2024;*	Luur, 2023 - ***"There are also delays and desynchronization of funding flows in public sector procurement."***
Infrastructure Challenges	**Connectivity Constraints**	*Callan et al., 2014; Sundin et al. ,2016; Bhattacharyya et al., 2021;*	Sundin et al., 2016 - ***"With poor cell phone infrastructure, cell carriers charge extra for roaming and these costs can quickly add up with a high volume of text messaging."***
	Device Affordability/Accessibility	*Callan et al., 2014; Sundin et al. ,2016; Bhattacharyya et al., 2021;*	Callan et al., 2014 - ***"As organizations move to monetize services, the feasibility of device acquisition and maintenance becomes a pressing concern."***
	Power Availability/Reliability	*Callan et al., 2014; Sundin et al. ,2016; Velayati et al., 2022;*	Sundin et al., 2016 - ***Living Goods, an mHealth venture based in Uganda, "found that the inability of both clients and employees to charge their cell phones limited their customer base."***
Regulatory Ambiguity	**Lack of Regulation**	*Velayati et al., 2022; Luur, 2023; Weimar et al., 2024;*	Weimar et al., 2024 - ***"Although several contributions exist, regulatory paths are often unclear or have not been defined yet (Rassi-Cruz et al. 2022), and more research is needed to understand how startups can cope with the challenges."***
	Regulatory Complexity	*Bhattacharyya et al. 2021; Luur, 2023; Weimar et al., 2024;*	Bhattacharyya et al., 2021 - ***"Prior to the COVID-19 pandemic, the GOI had not published clear guidelines for services like teleconsultations and telemedicine ...The norms and protocols related to physician–patient relationship, issues of liability and negligence, evaluation, management and treatment, informed consent, medical records, privacy and security of patient records were ambiguous."***

<u>Macro-Construct #3:</u> Potential Internal Business Strategies

Core Themes	***Subthemes***	***Example Articles***	***Example Quote***
Value Propositions	**Map stakeholder interactions and power dynamics. (Pilot stage)**	Albert and Van der Auwermeulen, 2017; Javanmardi et al.,	Albert and Van der Auwermeulen, 2017 - ***"Clarity regarding how these stakeholders make decisions and how potential***

		2024; Weimar et al., 2024;	***incentives for them would look like was prioritized by all encountered companies."***
	Conduct discovery work/interviews to identify and co-create valuable solutions. (Pilot stage)	Albert and Van der Auwermeulen, 2017; Babatunde, 2024; Weimar et al., 2024;	Weimar et al., 2024 - ***"Research has shown that it is essential for health startups to engage with stakeholders early in the development process (Barlow et al. 2006; Nilsen et al. 2020), as failing to do so can lead to conflicting perspectives and interests (Lyles et al. 2021)."***
	Ensure integration with broader healthcare processes and incentives. (Pilot stage)	Peters et al., 2015; Albert and Van der Auwermeulen, 2017; Gand, 2017;	Gand, 2017 - ***"The HIT implementation has to fit in the existing care structures and possibly result in innovative care modes. Hence, the development of HIT solutions goes beyond solely technical design. It also has to include strategic aspects to ensure solutions that are embedded in the respective care setting."***
	Continuously test and refine value propositions based off feedback. (Scaling Up)	Ringvold, 2023; Babatunde, 2024; Weimar et al., 2024;	Ringvold et al. 2023 - ***"Testing of ideas are an important part of the "searching for SBM [Sustainable Business Models] solutions" phase. These processes contribute to in-depth problem understanding to further develop the product or service and to be able to deliver the service in a manner that brings value to the customer."***
	Use feedback mechanisms to anticipate changes and prevent quality control issues. (Sustaining)	Luur, 2023; Ringvold, 2023; Babatunde, 2024;	Ringvold et al. 2023 - ***"Soliciting feedback from patients and caregivers, and using it to drive continuous improvement and innovation, is essential for delivering patient-centered care. Entrepreneurs can leverage patient feedback mechanisms, such as surveys, focus groups, and patient advisory councils, to identify areas for improvement, prioritize initiatives, and measure outcomes."***
Value Creation	**Co-create metrics and expected outcomes with funders, users & customers. (Pilot stage)**	Callan et al., 2014; Babatunde, 2024; Weimar et al., 2024;	Callan et al., 2014 - **"*When money is tied to a particular outcome, there should be validation that the venture's products will not only be financially sustainable but will also make a positive social impact as well. If a venture can effectively demonstrate the feasibility and social impact of their products, then acquiring start-up capital should be easier. The measurement of such metrics should***

		be an integral part of the operations of the venture."
Incorporate regulatory compliance into timelines and trade-offs for product development. (Pilot stage)	Luur, 2023; Javanmardi et al. 2024; Weimar et al., 2024;	Javanmardi et al. 2024 - ***"The important issue is that the fields of healthcare and medical equipment require a very long time for technology development, clinical tests, issuance of permits, insurance registration, and distribution to be finally commercialized, and because of this situation they need a sustainable [product] strategy."***
Conduct robust research, monitoring and evaluations. (Pilot stage)	Luur, 2023; Babatunde, 2024; Weimar et al., 2024;	Weimar et al., 2024 - ***"It may be advisable for healthcare startups to invest in clinical validation efforts to increase trust in their products, as relying solely on internal data may not be sufficient to establish their validity (Cristea et al. 2019)."***
Use iterative business methodologies like Lean Startup & Agile Development. (Pilot stage)	Eppley et al., 2021; Ringvold, 2023; Weimar et al., 2024	Weimar et al., 2024 - ***"Recently, there has been a shift towards methods that guide entrepreneurs in designing digital health solutions. This marks the transition from classical product development as conducted in hardware-heavy medical technology companies (waterfall method) towards agile methods needed to develop digital solutions."***
Regularly align an interdisciplinary team around key performance indicators. (Scaling Up)	Velayati et al., 2022; Ringvold, 2023; Babatunde, 2024;	Babatunde, 2024 - ***"Forecasting revenue projections and monitoring key performance indicators, such as customer acquisition costs, lifetime value, and churn rates, is essential for revenue model optimization (Gupta et al., 2006). Entrepreneurs should continuously evaluate and refine their revenue model based on market feedback, competitive dynamics, and business performance to maximize revenue growth and profitability over time"***
Implement frugal technical approaches to enable cost-effective scale. (Scaling Up)	Sundin et al. ,2016; Gand, 2017; Javanmardi et al., 2024;	Javanmardi et al., 2024 - ***"More specifically, to successfully compete in the segments of emerging markets, companies must come up with resource-constrained innovations and BMs [Business Models] that can create a high value against low costs."***
Leverage brand reputation to lower infrastructure and	Sundin et al. ,2016; Luur, 2023; Babatunde, 2024;	Sundin et al., 2016 - ***"The health venture Securing Ugandans Right to Essential Medicines (SURE) teamed with Makerere University to conduct their***

	other costs through partnerships. (Sustaining)		***MMS (Multimedia Messaging Service) training workshops. With this partnership, SURE was able to train 113 people in one year, a feat that was only achievable by partnering with Makerere University."***
	Engage in cooperative competition. (Sustaining)	Sundin et al. ,2016; Babatunde, 2024; Javanmardi et al., 2024;	Javanmardi et al., 2014 - ***"In open innovation BMs... companies active in one industry, those active in several completely different industries, and even competitors may have cooperation with each other. Collaborating companies in such BMs contribute to the development of research and innovation projects, by collectively providing the resources."***
	Establish partnerships to cost-effectively reach an initial group of users. (Pilot stage)	Callan et al., 2014; Ringvold et al., 2023; Luur, 2023;	Ringvold et al. 2023 - ***"Telenor [Digital Health Company] used Grameenphone's [Tele-Com Company] go-to market structure to drive the new service's distribution and reach. Grameenphone customers who qualified as revenue customers and enrolled in the new service received a basic bundle of health services for free."***
	Engage regulators in co-creation and data-sharing with regulators. (Pilot stage)	Luur, 2023; Ringvold et al. 2023; World Bank (Regulatory Sandboxes for Digital Health);	World Bank (Regulatory Sandboxes for Digital Health) - ***"Innovators and entrepreneurs may also contribute to the development of new regulations and to the revision of existing regulations through participation in sandboxes."***
Value Communication & Delivery	**Further empower local partners, users and other stakeholders in promoting the product or service. (Scaling Up)**	Callan et al., 2014; Sundin et al., 2016; Ringvold et al., 2023;	Sundin et al., 2016 - ***"By establishing a connection between customers and the surrounding communities, telemedicine systems can better market themselves as both a health service and as a community resource that people can leverage for a variety of different needs."***
	Advocate for more effective public-sector procurement/collaboration. (Sustaining)	Velayati et al., 2022; Luur, 2023; Javanmardi et al., 2024;	Javanmardi et al., 2014 - ***"Companies in the medical device, biotechnology, and healthcare sectors may draw on governmental subsidiaries or financial aids, tax advantages, science and technology parks, and governmental research grants. Public or governmental budgets for R&D can reduce private costs and potentially turn non-profitable projects into profitable ones."***

	Identify stakeholders with motivation to become customers. (Pilot stage)	Albert and Van der Auwermeulen, 2017; Babatunde, 2024; Javanmardi et al., 2024;	Babatunde, 2024 - ***"Understanding the needs, preferences, and pain points of target customers is essential for designing a compelling value proposition."***
	Test pricing strategies and conduct market research. (Pilot stage)	Callan et al., 2014; Jog et al., 2015; Sundin et al., 2016;;	Sundin et al., 2016 - ***"The price points must be determined by pilot tests with paying customers rather than relying on conducting surveys or assuming appropriate costs. CycleTel, a telemedicine system based in India, initially offered its services for free. After market tests with customers, the venture eventually found that INR 30 (USD 0.50) was an appropriate price to charge for the service."***
Value Capture	**Consider providing ancillary services to cross-subsidize essential but less profitable services. (Scaling Up)**	Acheampong and Vimarlund, 2015; Jog et al., 2015; Bhattacharyya et al., 2021;	Bhattacharyya et al., 2021 - ***"The telemedicine firms also operate e-pharmacies and provide options for booking diagnostic tests to earn additional revenue."***
	Offer hybrid pricing models to maximize revenue streams and accommodate for variation in customer purchasing power. (Scaling Up)	"Acheampong and Vimarlund, 2015; Jog et al., 2015; Bhattacharyya et al., 2021;"	Bhattacharyya et al., 2021 - ***"It was found by the authors that telemedicine firms in India generally used hybrid business models, providing options of pay-per-use model, subscription and freemium models."***
	Advocate for more effective reimbursement or financing/funding mechanisms. (Scaling Up)	Velayati et al., 2022; Luur, 2023; Javanmardi et al., 2024;"	Luur, 2023 - ***"Financing is a key challenge for digital healthcare platforms. Since these platforms often operate driven by a 'social purpose,' their scaling can be slower and less attractive to private [versus public] investors"***

<u>Macro-Construct #4:</u> Potential Market-Shaping Strategies

Core Themes	***Subthemes***	***Example Articles***	***Example Quote***

Support with Strategic Partnerships	**Facilitate Knowledge Exchange via Incubators, accelerators etc.**	Babatunde, 2024; Weimar et al., 2024; McKinsey & Company (How Digital Tools could boost efficiency in African health Systems);	Weimar et al., 2024 - ***"Njoku et al. (2023) found that accelerator programmes play a significant role in supporting the adoption of digital health technologies by small- and medium-sized enterprises."***
	Broker Academic Partnerships	Weimar et al., 2024; McKinsey & Company (How Digital Tools could boost efficiency in African health Systems); World Bank (Digital-in-Health Unlocking the Value for Everyone) ;	Weimar et al., 2024 - ***"Alliances between startups and other organizations, particularly academia-industry alliances, contribute to the success of digital health products (Kikuchi et al. 2021; Capponi and Corrocher 2022) and can even be a basis for receiving grants or support (Ford et al. 2019, 2021)."***
	Broker Cross-Industry Partnerships (ie. telecom/banking)	Sundin et al. ,2016; Javanmardi et al., 2024; World Bank (Digital-in-Health Unlocking the Value for Everyone) ;	World Bank (Digital-in-Health Unlocking the Value for Everyone) - ***"Productive partnerships will be essential to success. This includes new types of working arrangements and partnerships with and among private sector partners, as well as with stakeholders supporting wider digital transformation efforts outside the health sector."***
Fit-for-Purpose Regulatory Frameworks	**Organise Regulatory Sandboxes**	Babatunde, 2024; World Bank (Regulatory Sandboxes for Digital Health); World Bank (Digital-in-Health Unlocking the Value for Everyone) ;	Babatunde, 2024 - ***"Policymakers can establish regulatory sandboxes or innovation hubs to provide a safe and flexible environment for testing and scaling innovative healthcare solutions (Omaghomi et al., 2024). Regulatory sandboxes allow startups to experiment with new business models, technologies, and care delivery models under regulatory supervision, fostering innovation while ensuring patient safety and quality of care."***
	Create Fit-for-Purpose Technical & Non-technical Standards	Babatunde, 2024; McKinsey & Company (Building inclusive digitally-enabled health systems in LMICs); Arthur D. Little (Catalyzing digital health India 2024);	Babatunde, 2024 - ***"Establishing interoperability standards, data exchange protocols, and privacy frameworks can facilitate seamless integration of digital health solutions, improve care coordination, and enhance patient outcomes while protecting patient privacy and security (Ogugua et al., 2024)."***
	Engage in Regional Regulatory Harmonization	World Bank (Digital-in-Health Unlocking the Value for Everyone) ; Digital Square (Digital Public Infrastructure for Health); McKinsey & Company (Building inclusive	World Bank (Digital-in-Health Unlocking the Value for Everyone) - ***"Regulatory improvements at national and international levels that enable personal data transfers across borders with data protection and security safeguards are***

		digitally-enabled health systems in LMICs);	***critical to harnessing the potential of crossborder digital health innovations."***
	Share Public Technology Infrastructures (e.g., satellite networks)	Digital Square (Digital Public Infrastructure for Health); World Bank (Digital-in-Health Unlocking the Value for Everyone) ; McKinsey & Company (Building inclusive digitally-enabled health systems in LMICs);	McKinsey & Company (Building inclusive digitally-enabled health systems in LMICs) - ***"Governments and other stakeholders can capitalize on the rapid growth of mobile and internet penetration in LMICs by leveraging existing digital infrastructure, including mobile networks, digital payment systems, and digital identity solutions."***
Enhanced Public Procurement	**Drive Efficiencies in Contracting & Public Procurement**	World Bank (Digital-in-Health Unlocking the Value for Everyone) ; Digital Square (Digital Public Infrastructure for Health); McKinsey & Company (Building inclusive digitally-enabled health systems in LMICs);	World Bank (Digital-in-Health Unlocking the Value for Everyone) - ***"Traditional procurement can be limited by short timeframes and a lack of focus on outcome measurement and benefit realization, which are crucial for digital health initiatives. One-year contracts, for example, do not align with the rollout of digital health solutions."***
	Create Incentives for Public-Sector Digital Health Adoption	Luur, 2023; Arthur D. Little (Catalyzing digital health India 2024); World Bank (Digital-in-Health Unlocking the Value for Everyone);	Arthur D. Little (Catalyzing digital health India 2024) - ***"India's government has designed and implemented several initiatives to push digitalization through ABDM [Ayushman Bharat Digital Mission]. Simultaneously, the Digital Health Incentives Scheme (DHIS) aims to reward users of ABDM through financial incentives for crossing certain established thresholds of health record linking with ABHA."***
	Deploy Investments in Technology Infrastructure	"Digital Square (Digital Public Infrastructure for Health); World Bank (Digital-in-Health Unlocking the Value for Everyone); McKinsey & Company (How Digital Tools could boost efficiency in African health Systems);"	"Digital Square (Digital Public Infrastructure for Health) - ***"Connectivity, access to mobile network infrastructure for basic mobile messaging capability, and, for analytics use cases, cloud computing infrastructure similarly will need to be part of national DPI to support DPI-H at scale."***

Innovative Funding Mechanisms	**Consider Outcomes or Performance-based Payment/Funding Models**	Babatunde, 2024; World Bank (Digital-in-Health Unlocking the Value for Everyone); Sattva Knowledge Institute (Digital Health Financing for Health Equity);	Babatunde, 2024 - ***"Policymakers should consider reforms to reimbursement models and payment mechanisms to incentivize value-based care, preventive interventions, and innovative healthcare solutions (Ehimuan et al., 2024). Aligning reimbursement with quality outcomes, patient satisfaction, and cost containment can encourage healthcare organizations to invest in innovation and adopt more efficient and effective care delivery models."***
	Utilise or Test Innovative Financing (e.g. Blended, Mezzanine instruments) by Digital Health Investors	Sattva Knowledge Institute (Digital Health Financing to Accelerate Health Equity) Stanford BioDesign (HealthTech in East Africa: An Ecosystem Overview); Rethink Priorities Ltd (An Overview of Market-Shaping in Global Heath);	Sattva Knowledge Institute (Digital Health Financing for Health Equity) - ***"On the supply side, different financing instruments can make digital health solutions available to the underserved by providing upfront capital, supporting providers with risk capital during the trial phase, and returnable grants or result-based financing to demonstrate the value of such solutions. Low-cost or concessional debts can enable the digitisation of low-cost private healthcare facilities, while citizen demand can be accelerated through social or development impact bonds."***

Appendix Items for the Qualitative Study (Chapters 4 and 5)

Document 1: Ethics Approval

Medical Sciences Interdivisional Research Ethics Committee (MS IDREC)
Research Governance, Ethics & Assurance, Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB

Applicant: Elvin Irihamye
Principal Investigator: Dr. Mike English
Department: Nuffield Department of Clinical Medicine Experimental Medicine Division

Study title: What is the Perceived Necessity, Feasibility & Acceptability of Applying Market-Shaping Interventions for AI-Enabled Digital Health Solutions in Kenya's Public Health System?
(Version: 1.0)

Ethics reference: Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) **-** 669176

Dear Dr. Mike English,

On behalf of the Committee, I confirm that the above research study described in the application and other supporting documentation submitted to the committee has been carefully considered on behalf of the Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) in accordance with the University's regulations and policy for ethics approval of research involving human participants, human tissue and/or personal data. The opinion is as follows:

Opinion of Research Ethics Committee: Favourable Opinion

Subject to the following conditions: N/A

Decision Date: 3 Apr 2025, 11:01

Opinion End Date: 2 Oct 2026

If favourable, insurance-provided indemnity arrangements will be in place between the decision date and opinion end date and you may now commence your study activities. Should you plan to continue the research beyond the end date above, it is your responsibility to ensure that you request, and receive, an extension (via amendment) from the committee for indemnity to remain in place. You may be required to provide a justification.

Please note the following:

Amendments: Should there be any subsequent changes to the reviewed study, applications for amendments can be made via the Oxford Ethics Application System (Worktribe Ethics).

Reports: Studies considered by OxTREC are expected to submit an *annual progress report* on each anniversary of study approval, until the study is completed. An end of study report is also required.

Audit: This study may be selected for audit at the discretion of the Research Governance, Ethics and Assurance Team.

Data safety: It is the responsibility of the PI to ensure that all data collected during the course of the study is stored and transferred safely and securely in accordance with University requirements. Further

guidance and advice are available from the Research Data Team. Additional information is available at https://researchsupport.web.ox.ac.uk/governance/ethics

Yours Sincerely

Dr Helen Barnby-Porritt
Research Ethics Manager

MS IDREC Ethics Officer

Email/Linkedin Recruitment Template

Email Template for the Study “Exploring Market-Shaping Approaches to Support AI-Enabled Digital Health Products and Services in Kenya”

Central University Research Ethics Committee (CUREC) approval reference: [MS IDREC: 669176]

Subject: Quick Introduction to my Research on "AI-Enabled Digital Health in Kenya"

Dear [Participant's Name],

I hope this email finds you well.

My name is Elvin Irihamye, I’m a Rhodes Scholar and MSc Candidate at The University of Oxford– Centre for Tropical Medicine & Global Health, and I would like to invite you to participate in a graduate research study titled *“Exploring Market-Shaping Approaches to Support AI-Enabled Digital Health Products and Services in Kenya.”*

The purpose of this study is to understand the challenges and opportunities of providing AI-enabled digital health solutions for the public sector in Kenya. Your unique perspective, as someone actively involved in shaping or supporting Kenya’s digital health ecosystem, is crucial to providing valuable insights for this research.

If you are interested in participating, please review the more detailed participant information sheet and the attached Informed Consent Form (ICF) and let me know of your interest. The ICF outlines the study's objectives, the nature of your participation, your rights, and the measures we take to ensure confidentiality. Participation is entirely voluntary, and you may withdraw at any time without providing a reason.

I will then coordinate the time that works for you to finalize the consent process and schedule an online focus group or interview.

Should you have any questions or require further clarification, please don’t hesitate to reach out!

Thank you for considering this invitation.

Best regards,
Elvin Irihamye, MSc, Rhodes Scholar
Global Health Markets Researcher
University of Oxford – Centre for Tropical Medicine & Global Health

Attachments: Participant Information Sheet, Informed Consent Form

Document 3: Participant Information Sheet

“Exploring Market-Shaping Approaches to Support AI-Enabled Digital Health Products and Services in Kenya”

PARTICIPANT INFORMATION SHEET

Central University Research Ethics Committee Approval Reference: [MS IDREC 669176]

You are being invited to take part in a research project to understand the role market-strengthening could play in supporting AI-enabled digital health solutions in Kenya. Before you decide, please take a moment to understand why the research is being conducted and what your participation will involve. Feel free to ask any questions or discuss this with others before making your decision.

1. Why is this research being conducted?

The purpose of this project is to understand the challenges and opportunities of sustaining and scaling AI-enabled digital health products and services for Kenya’s public healthcare system. By engaging key stakeholders—including AI-enabled digital health companies, global health funders, and public sector purchasers of digital health products and services—the study aims to identify potential market-based strategies that could improve the health and efficacy of AI-enabled healthcare products & services in Kenya.

2. Why have I been invited to take part?

You have been invited to participate in this study because of your expertise and involvement in Kenya’s digital health sector. We are seeking insights from key stakeholders, including digital health companies, public sector purchasers, global health funders, and implementing partners. This research will engage approximately 20 participants to gain a well-rounded understanding of the potential for applying market-shaping approaches for AI-enabled digital health innovations.

3. Do I have to take part?

No, participation is entirely voluntary. If you choose to take part, you may withdraw at any time without providing a reason and without any consequences. You can also request that your data be removed from the study before May 15th, 2025. Any data related to your participation that was collected before your withdrawal will be securely deleted where possible.

4. What will happen to me if I take part in the research?

If you agree to participate, you will take part in either a one-time interview or small group discussion lasting approximately 45-60 minutes via an online platform (Zoom).

Consent Process: Before the online session begins, you will be asked to provide informed consent.

Interview Process: Depending on your professional background, the discussion will focus on topics related to the funding, creation, purchasing, implementation, financial sustainability and

regulation of digital health and AI-enabled digital health products and services. Questions will be open-ended to allow you to share your perspectives freely.

Recording and Transcription: With your consent, the conversation will be audio-recorded to ensure accuracy. All recordings will be transcribed and pseudo-anonymized, meaning that your name and organization name will be replaced with non-identifiable “identification codes” to obscure all personally identifiable information from transcripts and results. Recording and transcription will ensure your input is accurately analyzed after the session is concluded.

Data Use: The findings will be used solely for academic and policy purposes. No direct mention of your name or company will be made in any publications or reports.

Follow-up: There will be no required follow-up interviews unless you express interest in contributing additional insights.

You may request to pause or stop individual interviews or withdraw from small group discussions at any time.

5. What are the possible disadvantages and risks in taking part?

There are no significant risks associated with taking part in this study. However, discussions about funding, procurement, implementation, financial sustainability, and regulation of digital health may involve sensitive topics. Please note that because some sessions involve group discussions, there is a risk that other participants might share information discussed during the sessions outside of the study. While we take every measure to protect your confidentiality by replacing any identifying information with un-identifiable “identification codes,” we cannot control what others choose to do with what they hear. You have the right to withdraw your data up until the point where the data has been fully incorporated into the final master’s dissertation on May 15th, 2025.

6. Are there any benefits in taking part?

There will be no direct or personal benefit to you from taking part in this research. However, your insights may contribute to a better understanding of the potential of market-shaping strategies in supporting the sustainability of AI-enabled digital health innovations in Kenya’s public health system.

7. What information will be collected and why is the collection of this information relevant for achieving the research objectives?

This study will collect your contact details, consent forms, interview transcripts, and digital recordings from interviews or group discussions. We need your contact details to schedule sessions and your consent forms to show that you agree to take part. The recordings and transcripts capture your views on the challenges and opportunities of using market-shaping strategies to support AI-enabled digital health innovations in Kenya. This information helps us understand the issues and possible solutions from the perspectives of digital health companies, public procurement officials, and global health funders.

All data will be securely stored in encrypted, password-protected folders within Nexus 365 OneDrive for Business. Contact details will be deleted immediately after the study ends to ensure confidentiality. Digital recordings will be stored in a dedicated, secure folder and deleted immediately post-study closure following transcription and verification. The transcripts, once your name and personal details are removed and replaced with a unique code, and the consent forms will be kept for three years after the study ends, following GDPR and our institutional policies. Only authorized members of the research team, including supervisors and the principal investigator, will have access to this data.

8. Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research will be written up as a master's thesis/ dissertation and may be further published in a peer-reviewed journal or used for a conference presentation. Participants will not be identifiable from the outputs but can also request that your data be removed from the study before May 15th, 2025. Any data related to your participation that was collected before your withdrawal will be securely deleted where possible.

I would like your permission to use direct quotations without identifying you (de-identified) in the research outputs.

A copy of a written Master's thesis/ dissertation will be deposited online in the Oxford University Research Archive where it will be publicly available for reference in future research.

9. Data Protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the research. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available from the University's Information Compliance website at https://compliance.admin.ox.ac.uk/individual-rights.

10. Who has reviewed this research?

This research has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee. (Ethics reference: MS IDREC 669176).

11. Who do I contact if I have a concern about the research or I wish to complain?

If you have a concern about any aspect of this research, please contact Elvin Irihamye at elvin.irihamye@ndm.ox.ac.uk or Dr. Mike English at mike.english@ndm.ox.ac.uk, and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) team at rgea.complaints@admin.ox.ac.uk or on +44 (0)1865 616480.

12. Further Information and Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Elvin Irihamye, MSc by Research Candidate (Global Health)

Nuffield Department of Clinical Medicine, Centre for Tropical Medicine & Global Health

University E-mail: elvin.irihamye@ndm.ox.ac.uk

Centre for Tropical Medicine and Global Health

The Peter Medawar Building for Pathogen Research, Level 05

University of Oxford, South Parks Road

Oxford OX1 3SY, UK

Document 4: Electronic Informed Consent Form

Consent to take part in "Exploring Market-Shaping Approaches to Support AI-Enabled Digital Health Products and Services in Kenya"

Central University Research Ethics Committee (CUREC) approval reference: [MS IDREC: 669176]

Purpose of Study: The purpose of this study is to examine how and if market-based interventions can support the long-term sustainability and scalability of AI-enabled digital health solutions in Kenya's public health system by assessing their perceived necessity, feasibility, and acceptability across key stakeholders.

	Please initial each box if you agree with the statement
I confirm that I have read and understand the information sheet (Version 2 dated 20th March 2025) for the above research. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
I understand that my participation is voluntary and that I am free to withdraw at any point until May 15th, 2025 (expected date of dissertation completion), without giving any reason.	☐
I understand who will have access to personal data provided, how the data will be stored and what will happen to the data at the end of the project.	☐
I understand that I will not be identifiable from any publications, presentations or reports.	☐
I consent to being audio recorded for transcription.	☐

I understand how audio recordings will be used in research outputs & analysis.	☐
Use of quotations: Please indicate your preference (select *one* option):	☐
a)I do not wish to be quoted. **or** b)I agree to the use of quotations in research outputs if I am not identifiable. **or**	☐
I give permission for you to contact me again to clarify information.	☐
I understand how to raise a concern or make a complaint.	☐
I agree to take part.[1]	☐

_____	dd / mm / yyyy	_____
Name of participant	Date	Signature
_ Elvin Irihamye ___	dd / mm / yyyy	__ **Elvin Irihamye**___
Name of person taking consent	Date	Signature

_____

Documents 5-7 : Interview Guides

Interview Guides for the Study "Exploring Market-Shaping Approaches to Support AI-Enabled Digital Health Products and Services in Kenya"

Central University Research Ethics Committee (CUREC) approval reference: [MS IDREC: 669176]

Overview: Participant Groups

The interviews will be organized around groups of stakeholders based on their roles, experiences, and contributions to Kenya's digital health ecosystem. This structure enables the research team to gather a diverse set of insights that directly address the research objectives and provide actionable recommendations for exploring the potential of market-based interventions in improving the sustainability of AI-enabled digital health solutions. The participant groups are as follows:

1. **Private Sector Digital Health Companies**
   This group includes founders, executives, and senior managers of small-to-medium enterprises (SMEs) actively involved in developing and deploying AI-enabled digital health solutions for use in Kenya's public health system.
   - ***Purpose:*** First, their insights will illuminate the challenges of building, sustaining and scaling viable digital health business models (value proposition, value creation, value communication and delivery, value capture) in Kenya. Second, their insights will offer insight into the perceived impact of market-shaping approaches (Partnership support, Public procurement, Regulation, Financial tools) that have already been deployed or could be deployed in the future.
2. **Public Health Stakeholders Involved in Technology Purchasing & Procurement**
   This group includes individuals involved in purchasing and procuring technologies for public health systems in Kenya with a particular focus on engaging individuals who have purchased AI solutions for care delivery in a public healthcare setting. Given the technical complexities regarding AI, we expect the majority of participants to come from larger county, regional, national and specialised hospitals (Tier 3-6).

- ***Purpose*:** Their perspectives will help us understand the perceived systemic challenges and opportunities within public-sector adoption pathways, regulatory frameworks, procurement mechanisms and payment models for AI-enabled digital health solutions.

3. **Global Health Funders and Implementing Partners**
   This group consists of representatives from donor organizations, venture capital firms, NGOs, and implementation agencies who fund or support digital health initiatives. We aim to host grant officers, program managers, and venture capitalists.
   - ***Purpose*:** Their perspectives will help us understand if & how funding priorities and partnership models can support the sustainability of AI-enabled digital health solutions, and the role of market-shaping interventions (e.g.partnership support and financial tools) in driving long-term viability.

Interview Template: Private Sector Digital Health Companies

Date: *Time Start:*

Observer:

Interview ID: *Time End:*

Team members present (note down initials of the participant):

Engagement/Warm-Up Questions

1. What excites you most about working in Kenya's digital health ecosystem?

Exploration Questions

Business Model Challenges

Base Questions	***Possible Probing Questions***
2. How do you think your product or service helps improve healthcare in Kenya?	*Have you encountered skepticism or resistance from stakeholders when explaining your product's value? Which ones & how do you address that?* *How do you measure the impact of your product or service on healthcare delivery?* *Do you see your product addressing gaps that other solutions haven't tackled?* *Could you share specific examples of how your solution has benefited patients or healthcare providers?*
3. What have been the most difficult technical & commercial challenges of growing your business?	*Are there specific systemic barriers in Kenya's healthcare system that have been particularly challenging?* *How do issues like infrastructure, connectivity, or funding availability affect your ability to scale?*

	Are there challenges unique to AI-enabled solutions that make scaling harder? *What role do partnerships play in overcoming these challenges?*
4. How do you typically reach the people or organizations that use your product?	*What strategies have worked best for engaging healthcare providers, patients, or public sector buyers?* *Do you primarily work through partnerships, or do you engage directly with end-users? Why?* *How do you adapt your messaging for different stakeholders (e.g., government, providers, patients)?* *Have you found any specific channels or outreach methods to be more effective than others in Kenya's context?*
5. What has been your approach to making your business financially sustainable?	*How do you determine pricing for your solution, and has affordability been a barrier?* *Do you rely on a particular revenue model (e.g., subscriptions, pay-per-use, grants)? Why did you choose this model?* *Have you explored alternative revenue streams, like offering ancillary services or expanding to new markets?* *What role does private or public funding play in keeping your business operational, and how stable is that support?*

Market Intervention Questions

Base Questions	***Possible Probing Questions***
6. Have you ever worked with public healthcare systems or tried selling to them?	*How do you approach procurement processes, and what challenges have you encountered?* *Have government partnerships helped you scale your solution or expand your reach?* *What barriers, if any, make it difficult to collaborate with government institutions?* *How would you compare working with the government to working with private or non-profit organizations?*
7. What do you think about current policies or regulations in digital health?	*Do you feel the existing policies are supportive of businesses like yours, or are there areas where they fall short?* *Have you had to make changes to your product or processes to comply with regulations? If so, how challenging was that?* *Are there specific policies or regulations you believe could make it easier for digital health companies to succeed?* *Do you think the government is doing enough to encourage innovation in AI and digital health? Why or why not?*
8. How has funding or financial support influenced the way you run your business?	*What strategies have worked best for engaging healthcare providers, patients, or public sector buyers?* *Do you primarily work through partnerships, or do you engage directly with end-users? Why?* *How do you adapt your messaging for different stakeholders (e.g., government, providers, patients)?*

	Have you found any specific channels or outreach methods to be more effective than others in Kenya's context?
9. Have partnerships contributed to your efforts in any meaningful way, or have their benefits been more limited so far?	*What are some challenges you've faced in building or maintaining partnerships, and how have you addressed them?* *Are there specific types of partners (e.g., funders, regulators, healthcare providers) that you feel are most critical to your success? Why?* *How do you ensure that partnerships are mutually beneficial and sustainable over time?* *If you haven't had the opportunity to collaborate with certain stakeholders (e.g., government agencies), what barriers have prevented this, and how could they be addressed?*

Exit Question: Looking ahead, what do you think is the most urgent policy or market change needed to support the growth and sustainability of AI in Kenya's digital health ecosystem?

Interview Template: Public Health Stakeholders Involved in Technology Purchasing & Procurement

Date: *Time Start:*

Observer:

Interview ID: *Time End:*

Team members present (note down initials of the participant):

Engagement/Warm-Up Questions

1. How has the environment for purchasing Digital health tools changed in the last few years?

Exploration Questions

Business Model Challenges

Base Questions	***Possible Probing Questions***
2. What potential do you see for digital health technologies to improve healthcare in Kenya?	*What healthcare challenges in your hospital do you think digital health or AI technologies could address?* *When you're considering a digital health solution, what's most important to you? (e.g., cost, ease of*

	use, benefits to patients or staff). *Are there specific areas (e.g., diagnostics, patient records, or communication) where you feel these tools could make the biggest impact and*
3. When companies present their products, do you feel the value and benefits are clear?	*What kind of information or evidence do you need to see from these companies to feel confident about AI tools?* *Have you noticed challenges in how digital health companies explain the value of their products to you or others who purchase technologies?* *How can companies make their AI solutions more understandable to people without a technical background?*
4. What support do you need from digital health companies to ensure their tools work well in your hospital?	*How easy or difficult has it been to integrate new technologies into your hospital's existing workflows?* *Have you seen examples where digital health or AI technologies improved the quality of care or made processes more efficient?* *Are there areas where these tools haven't worked as expected or created challenges?*
5. How do you decide if a digital health solution is worth the investment?	*Are there challenges with the pricing or payment models offered by these companies?* *What payment mechanisms would work best for your facility - given the resources at your disposal?*

Market Intervention Questions

Base Questions	***Possible Probing Questions***

6. How easy or difficult is it for hospitals like yours to buy new digital health or AI tools?	*What changes would make it easier to purchase these technologies quickly and efficiently?* *Improving Procurement Policies* *Are there any policies or rules that make it harder for smaller companies to sell their tools to hospitals?* *What do you think should be done to make procurement more flexible for new and innovative solutions?*
7. Have recent laws or policies changed how you think about procuring digital health technologies?	*Do current rules and regulations keep up with how quickly AI technologies are being developed?* *What would help you feel confident that a new AI tool has been properly tested and approved?* *What changes could make it easier for innovative tools to meet regulatory requirements and enter the market?*
8. What kinds of partnerships do you think work best for introducing AI technologies in healthcare?	*Have you seen partnerships between hospitals, companies, or other groups (e.g., NGOs) help bring in new health technologies?* *If you haven't had the opportunity to collaborate with certain stakeholders (e.g., government agencies), what barriers have prevented this, and how could they be addressed?* *How can hospitals and health facilities like yours be better supported by partnerships when adopting new technologies?*

Exit Question: Looking ahead, what are the most critical policy changes or regulatory reforms that would accelerate the adoption of AI in Kenya's digital health ecosystem?

Focus Group/Interview Template: Global Health Funders and Implementing Partners

Date: *Time Start:*

Observer:

Interview ID: *Time End:*

Team members present (note down initials of the participant):

Engagement/Warm-Up Questions

1. Can you briefly describe your organization's role in supporting digital health initiatives in settings like Kenya?

Exploration Questions

Business Model Challenges Questions

Base Questions	***Possible Probing Questions***
2. How does your organisation think about financing AI in digital health?	*What factors influence whether an AI solution is financially viable in Kenya's public health system?* *How does the funding process for AI-enabled solutions differ from more traditional health technologies?* *What role do investors play in shaping AI health solutions in Kenya?*
3. What are the key factors you consider when evaluating the sustainability of AI-enabled digital health solutions in Kenya?	*How do you measure the long-term impact of these solutions on healthcare delivery?* *What specific outcomes or metrics help you assess whether an AI solution will be sustainable?* *How do you weigh financial sustainability versus social or healthcare impact in your evaluations?*
4. From a funding perspective, what are the main challenges facing digital health companies in scaling AI solutions within Kenya's public health system?	*What funding models seem to work best for scaling these solutions?* *Do you see specific barriers for local companies compared to international ones in securing funding?* *How important is government or donor funding in overcoming these challenges?*
5. Has local partnerships (e.g., with government, healthcare providers, NGOs) played a role in ensuring the success of AI initiatives?	*Can you give examples?* *What makes these collaborations effective or challenging?* *How can these partnerships help address issues like infrastructure or trust in AI technologies?*
6. Are there any challenges related to cost-effective delivery of these services?	*How do you see the trade-off between cutting-edge AI technology and the need for affordability*

	in the local context? *What role does price play in the adoption of AI solutions, especially among lower-income populations?* *Are there any examples of affordable AI solutions that you think should be scaled?*

Market Intervention Questions

Base Questions	***Possible Probing Questions***
7. How do you perceive the role of public procurement policies in supporting or hindering the scalability of AI-enabled digital health solutions in Kenya?	*How do you approach procurement processes, and what challenges have you encountered?* *Have government partnerships helped you scale your solution or expand your reach?* *What barriers, if any, make it difficult to collaborate with government institutions?* *How would you compare working with the government to working with private or non-profit organizations?*
8. How do regulations affect the development or implementation of AI solutions?	*What are your views on the current regulatory landscape (e.g., Digital Health Act, data protection laws) and its impact on the ability of AI-enabled solutions in Kenya?* *What specific regulations seem to be an obstacle or enabler for AI in healthcare?* *How do you see data privacy laws influencing the scaling of AI solutions in health?*
9. How do financial tools (e.g., grants, loans, impact investing) influence the viability and	*Which financial tools do you think provide the*

sustainability of AI in Kenya's health sector? Are there specific financial tools that have been particularly effective or ineffective?	*most support to AI-driven digital health initiatives?* *Are there gaps in funding that make it harder for AI projects to reach scale?* *What financial mechanisms would improve the long-term sustainability of AI solutions?*
10. What are some of the most significant market-shaping interventions (such as policy changes, financial incentives, or procurement reforms) that you believe could improve the sustainability of AI-enabled digital health solutions in Kenya?	*In your opinion, which interventions have been the most successful in other countries or regions?* *How could these interventions be adapted to the Kenyan context?* *What role do you think the government should play in shaping these interventions?*

Exit Questions

11. Looking ahead, what are the most pressing policy or market changes needed to accelerate the adoption and scaling of AI in Kenya's digital health ecosystem?