



**Financing and
Implementing Innovation
in Healthcare Systems:**
A Component of the
Precision Medicine
Readiness Principles

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Foreword

This white paper highlights the need to bridge existing gaps in investment approaches.



Genya Dana
Head of Healthcare
Transformation,
World Economic Forum



Elissa Prichep
Lead, Shaping the Future
of Health and Healthcare,
World Economic Forum

The ability to design and implement targeted and personalized approaches to screening, preventing, diagnosing and treating diseases continues to improve. There is great promise in precision medicine, with improved outcomes and more efficient use of scarce resources.

As precision medicine approaches continue to make their way into more care systems, we are still woefully lopsided in terms of who has access to the necessary research, technologies, treatments and skill sets. Trust in healthcare systems' ability to deliver care in equitable and agile ways continues to be tested and found wanting during the COVID-19 pandemic.

Many healthcare systems, clinicians and policy-makers who want to harness the power of precision medicine approaches find themselves faced with the daunting task of determining where to begin. This is especially true in places that are under-resourced or making a transition from prioritizing basic primary care and infectious disease treatment to treating diseases such as cancer and rare diseases. Investments must be made across many areas, including workforce, infrastructure, technology and strategic planning, in ways that are complementary and responsive to the

circumstances of the geographic location, patient population, economic situation and political realities.

The World Economic Forum wishes to aid policy-makers, funders, investors, clinicians and others who are preparing their healthcare systems for a future state that includes precision medicine approaches. We are pleased to present this instalment in the Precision Medicine Readiness Principles, which identifies capabilities stakeholders can use to benchmark progress in nurturing a system that is ready for precision medicine approaches.

This white paper on the financing and implementation of precision medicine approaches explores the necessary components to build and sustain advanced healthcare innovation ecosystems. While the focus of this paper is on the mechanisms that can be used today, as well as case studies describing how different countries have implemented such initiatives, the work also highlights the need to bridge existing gaps in investment approaches. The white paper offers both a path to innovation in healthcare ecosystems and a call for continued investment in delivering the highest standards of health and healthcare to people around the globe.



Executive summary

In 2016, the National Academy of Medicine published a discussion paper, [Realizing the Full Potential of Precision Medicine in Health and Healthcare](#), that would respond to the growing interest in supporting precision medicine through US health policy by proposing a framework that leaders in policy, business and healthcare could reference for the development and integration of precision medicine. Informed by this work and developed through desk research, interviews and a multistakeholder workshop at the 2019 World Health Assembly, the World Economic Forum's Platform for Shaping the Future of Health and Healthcare developed a framework for the **Precision Medicine Readiness Principles**: a global roadmap that identifies precision medicine capabilities from which policy-makers and others looking to advance precision medicine in their countries can find benchmarks for readiness.

Under the broader faculty of the **Precision Medicine Readiness Principles**, the innovation ecosystem topic aims to address the processes that enable the creation and expansion of a precision medicine marketplace. Specifically, this paper discusses the necessary functions of business producers, resource funders and regulatory governors to encourage, establish and build a continuously growing economic marketplace for precision medicine technologies. To this end, the paper presents: (1) a framework for the capabilities of the precision medicine innovation ecosystem; (2) benchmarks to assess the stage of readiness across these capabilities; and (3) outstanding gaps in the investment approaches needed to drive precision medicine implementation.

Policy-makers and others looking to advance precision medicine in their countries are invited to use this guidance document to gauge the maturity of the various capabilities that build and sustain a

precision medicine innovation ecosystem. Case studies from developed and emerging economy countries are used to illustrate the implementation of such capabilities by countries at any (early, intermediate, advanced) stage of precision medicine readiness. Developed under the **Leapfrogging with Precision Medicine** project, this paper also calls attention to tools and case studies that can help address inequities in the application of innovation drivers and the accessibility of precision medicine approaches globally.

Go-to-market strategies for precision medicine innovations remain challenging given the incentive gaps for technology producers, funders and service provider adopters and payors alike. Forming the necessary enablers and conditions for the innovation ecosystem requires novel policy instruments, financing approaches, collaboration models and economic development as explored in this white paper.

Figure 1 below summarizes the core discussion areas explored in this work – the exemplary capabilities and implementation milestones across four main categories: innovation governance; innovation financing; community and partnerships; and workforce and infrastructure. These benchmarks are further positioned along the readiness axis to inform the criteria for progress and capability maturity. “Exploring” health systems are early in their adoption of precision medicine approaches, potentially conducting some research studies or piloting programmes, but will generally not have precision medicine approaches accessible to members of the population. “Activating” health systems have some clinical use of precision medicine approaches with limited accessibility, while “implementing” systems have several precision medicine approaches accessible to a large number of people.

Insights from this work include the importance of:

Establishing national innovation policy instruments:

The innovation policy mix consists of the initiatives – e.g. intellectual property legislation, cluster initiatives, market review processes, federal budgets – that build the early national public confidence and market demand for precision medicine approaches that private entities cannot build alone.

Developing novel financing approaches that capture value:

Novel financing models for precision medicine technologies that capture value and promote equity and access are encouraged to spur private investment activity.

Public funding and philanthropy dollars may be insufficient or unavailable in the longer term for low- and middle-income countries (LMICs) seeking to develop their precision medicine capabilities. Cross-cutting diagonal funding approaches that support health-system strengthening are particularly encouraged to close this financing gap.

Actualizing value-based care: Coverage and reimbursement gaps persist globally, in part because of insufficient data on precision medicine value-add and payment uncertainty. Emerging

value-based care approaches – e.g. evidence-based modelling studies, performance-based contracts – may align stakeholder incentives and invite consensus on precision medicine’s value.

Expanding collaboration and operating models:

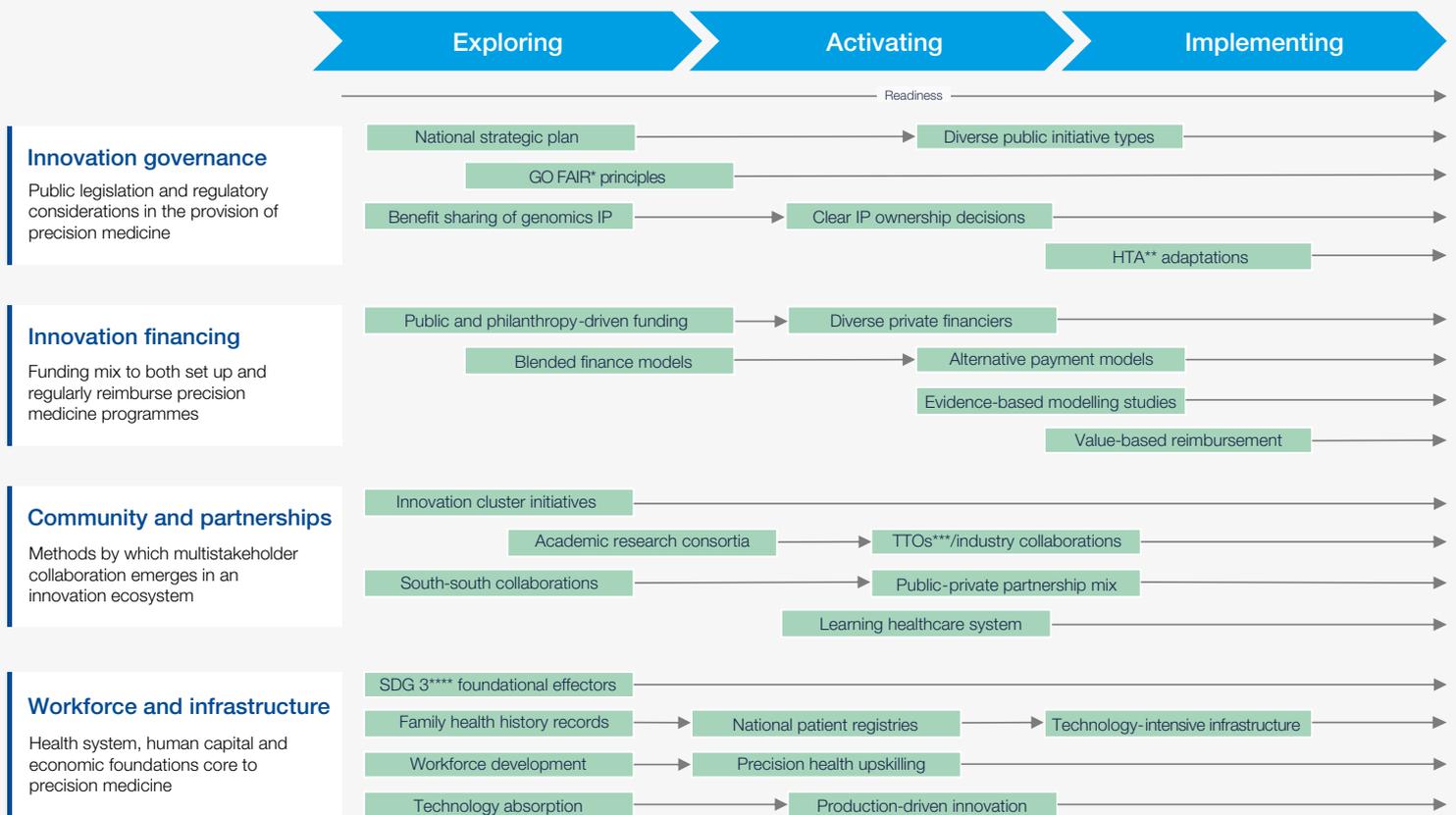
Various multistakeholder partnership models have emerged across the value chain to advance precision medicine research and development (R&D) and commercialization. Further collaborations between both public and private parties are encouraged to explore novel operating models such as the learning healthcare system and open science for genomics.

Nurturing incremental innovation and sustainable adoption:

Incremental innovation in precision medicine remains the most prevalent form of development. Early initiatives such as systems for collecting family health history or national disease surveillance registries may be initial steps towards precision medicine adoption.

While this work represents only one part of the **Precision Medicine Readiness Principles**, it is the hope of the authors that the readiness principles are used by policy and healthcare leaders as central points of departure from which to build robust precision medicine capabilities into their health systems.

FIGURE 1 Precision Medicine Readiness Principles for the innovation ecosystem topic



*Findability, Accessibility, Interoperability and Reuse of digital assets, **Health technology assessment, ***Technology transfer organization, ****United Nations Sustainable Development Goals



Introduction

Leaders in policy, business and healthcare, while receptive to the potential of precision medicine applications, do not have the benefit of a consistent and standardized framework to both evaluate their health system's current readiness for the practical implementation and integration of precision medicine and elucidate the capabilities needed to drive future growth. Stakeholders in emerging economies, in particular, indicated that they would value a guidance document that includes case studies and access to partner communities as they think about how to strategically grow the precision medicine capabilities of their healthcare ecosystems.

In alignment with this need, the World Economic Forum's Platform for Shaping the Future of Health and Healthcare is developing the **Precision Medicine Readiness Principles**: a thought leadership project, inspired by a [National Academy of Medicine discussion paper](#), that includes developing a living document from which those aiming to advance precision medicine in their countries can find benchmarks for readiness. Precision medicine offers a more personalized and targeted approach to preventing and addressing disease through screening, diagnosing and treating patients by considering their genetic and biological make-up, surrounding environmental factors and lifestyle behaviours.

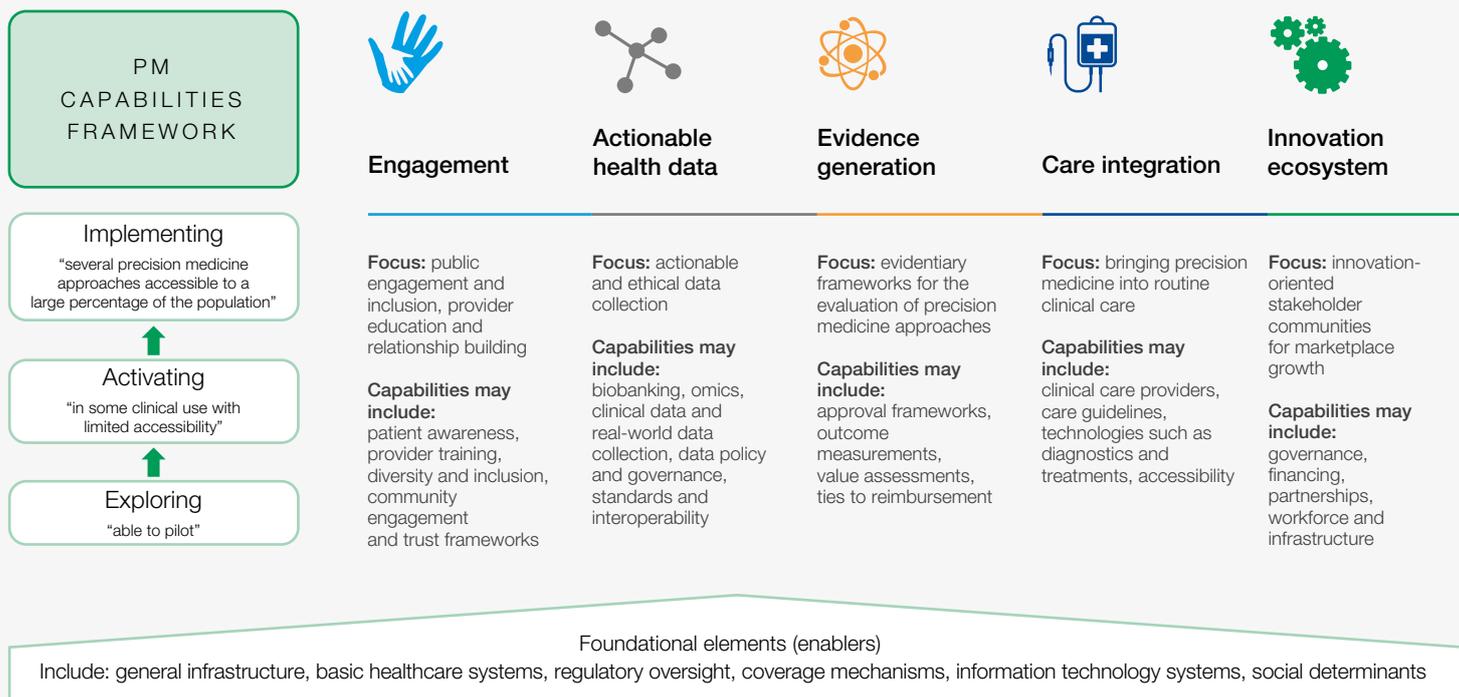
By identifying best practices and strategic opportunities for precision medicine adoption in a healthcare setting, the Precision Medicine Readiness Principles serve as a gauge that policy-makers and others looking to advance precision medicine in their countries can use to: (1) find maturity assessment benchmarks for readiness; and (2) identify potential steps forward to implementation. These benchmarks are illustrated

in the form of "capabilities", defined as the working set of key elements employed to drive development of precision medicine approaches within healthcare ecosystems. These capabilities are neither an exhaustive list nor mandatory criteria, but represent a distillation of critical drivers in developing a precision medicine environment within a country.

This white paper focuses on one pillar of the Precision Medicine Readiness Principles: the **innovation ecosystem**. Hence, the capabilities described in this paper should be considered in the context provided by the foundational elements and other categories captured in the Precision Medicine Readiness Principles.



FIGURE 2 Precision Medicine Readiness Principles framework. This framework comprises five core topics that establish criteria that countries or stakeholders can use to evaluate their progress towards precision medicine



Innovation ecosystem overview

What are the capabilities that build and sustain a precision medicine marketplace?



A Defining the innovation ecosystem

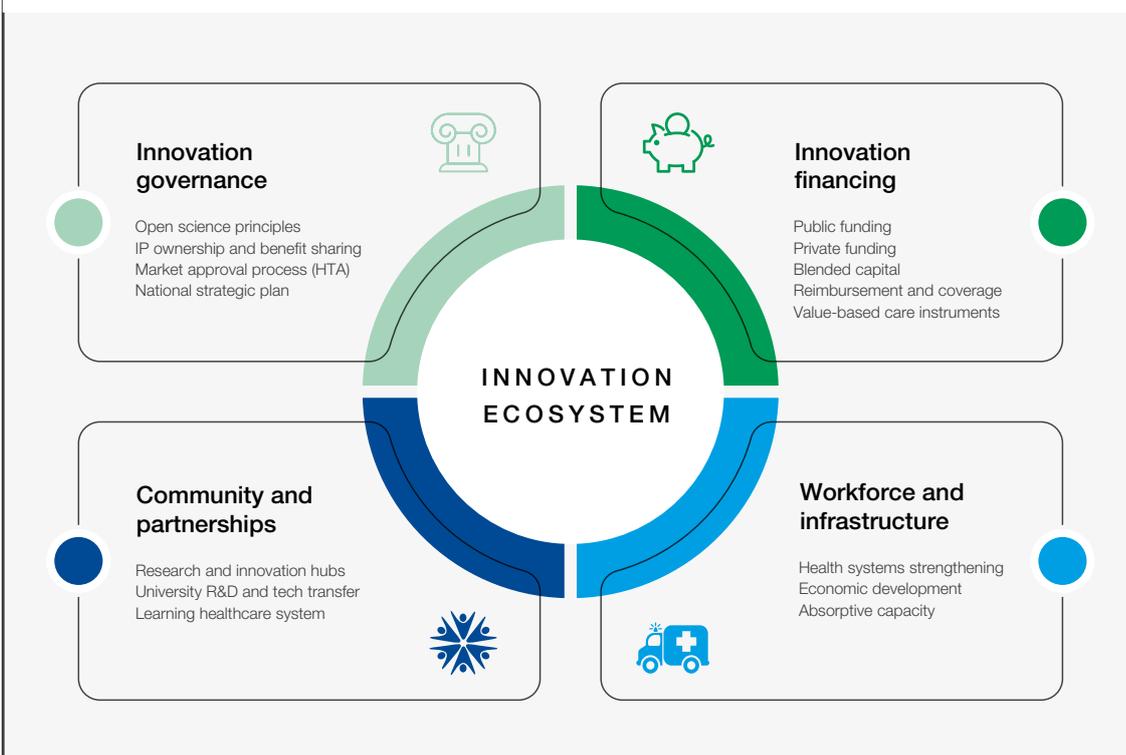
The innovation ecosystem topic aims to address the processes that pave the way for the creation and expansion of a precision medicine marketplace and its enabling conditions. Specifically, the white paper discusses the necessary functions of business producers, resource funders and regulatory governors to encourage, establish and build a continuously growing economic marketplace for precision medicine technologies. The guiding research question for this topic can be framed as “What are the capabilities that build and sustain a precision medicine marketplace?”

Under the broader umbrella of precision medicine implementation, the innovation ecosystem refers

to the various forms of novel developments in precision medicine and includes new products, firms, technology, business models, behavioural changes and policies. Such forms of precision medicine “innovation” manifest differently in a global context; innovation may range from the preferential introduction of incremental, marginal improvements in process to significant technological adoption or novel product development. Hence, while this white paper provides capabilities that may serve as a preparatory model for the implementation of a precision medicine innovation ecosystem, it excludes specific, prescriptive guidelines as programmes almost always require modifications and adaptations to fit local contexts.

B Innovation ecosystem components

FIGURE 3 Innovation ecosystem framework. This topic area in the Precision Medicine Readiness Principles covers four foundational areas: innovation governance, innovation financing, community and partnerships, and workforce and infrastructure



The innovation ecosystem white paper was developed through a multistakeholder workshop on the sidelines of the 2019 World Health Assembly, desk research, the compilation of a [Precision Medicine Readiness Principles: Innovation Loop Resource Guide](#) and individual consultations with approximately 40 professionals across international health systems representing a range of industries, organizations and governments. This research pointed to the four foundational areas outlined in Figure 3: (1) innovation governance; (2) innovation

financing; (3) community and partnerships; (4) workforce and infrastructure. For the purposes of this paper, these areas and their corresponding capabilities are defined below.

Innovation governance refers to public legislation and regulatory considerations in the provision of precision medicine. These include mandates set forth by ministries of health, market-review processes and policy-driven initiatives enabled by the country’s governing bodies.

Innovation financing refers to the funding mix to both set up and regularly reimburse precision medicine programmes. This may range from stand-alone public or private financiers, public-private funding partnerships and specific financing mechanisms for precision medicine.

Community and partnerships refers to the methods by which multistakeholder collaboration emerges in an innovation ecosystem. In the precision medicine context, this area explores the changing role of various stakeholders and the conditions needed to enable innovation.

Workforce and infrastructure describes the broader health system, human capital and economic considerations necessary to support a precision medicine marketplace. Such foundational elements are necessary to power the discovery and economic sustainability of precision medicine innovations.

The following sections will explore these four areas and their attendant capabilities. The discussion of each area will reflect how capabilities mature as health ecosystems adopt and incorporate more precision medicine approaches overall. Each area is supported by illustrative ongoing case studies.



1

Innovation governance

The public legislation and regulatory considerations in the provision of precision medicine.



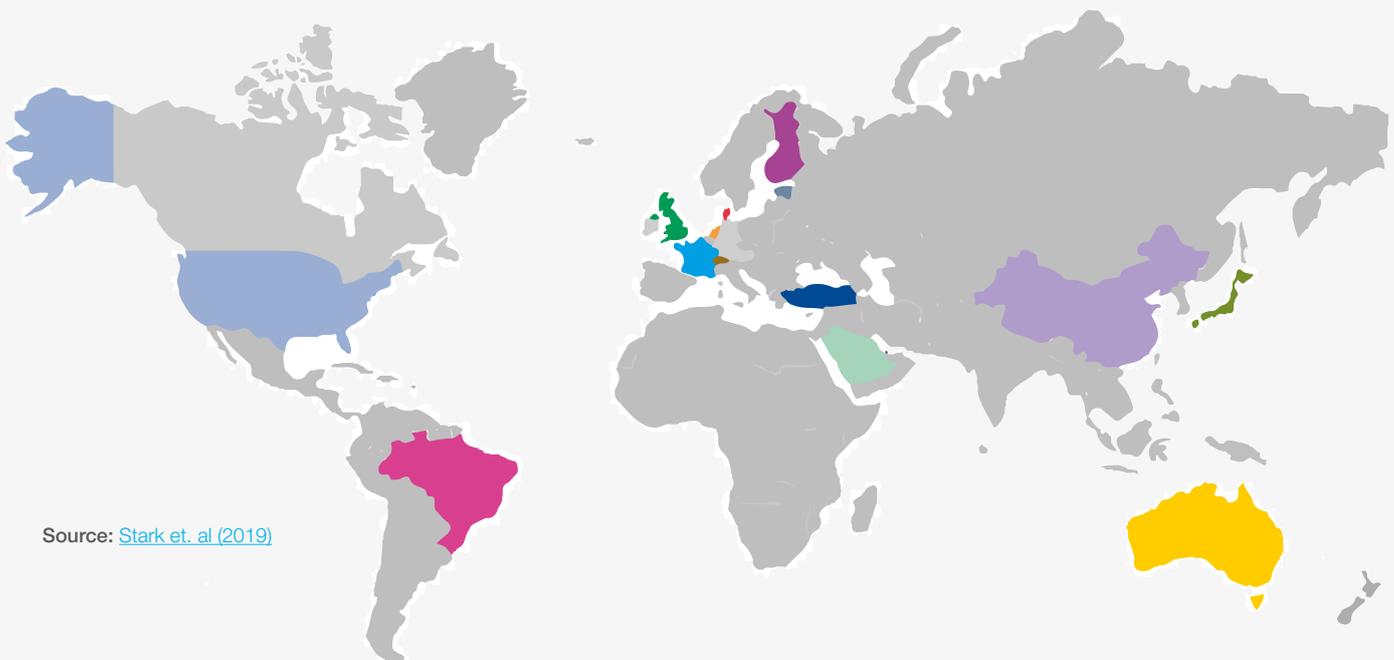
1.1 Precision medicine implementation roadmap from national strategic plans

Summary: Some level of government-driven implementation builds the national public confidence and market demand for precision medicine approaches that private entities cannot build alone. The national strategic plan is created based on country-specific population health burdens and a shift to preventative care.

A precision medicine national strategy consists of both: (1) the aspirational metrics of the ministry of health (or equivalent government decision-making agencies) to incorporate precision medicine approaches into care; and (2) the steps and partnerships outlined to achieve such targets within a certain time frame. Top-down policy entrepreneurship from key government leaders inspires the early activity of the precision medicine innovation ecosystem through large-scale national initiatives, barring specific cases in which precision medicine approaches are

first adopted at the private health provider level. Even in this latter scenario, performance evaluation of such private activity may provide compelling cases for national precision medicine programmes. These national initiatives have taken a variety of approaches: rare diseases, oncology, population health surveillance and infrastructure development are among the many focus areas of the 36-plus formal national or international strategies for precision medicine developed as of 2019. A snapshot is captured in Figure 4 below.

FIGURE 4 Ongoing government-funded national genomic-medicine initiatives



Source: Stark et. al (2019)

<p>United Kingdom</p> <p>Genomics England 2012 – 100,000 genomes: rare disease, cancer £350M (\$485M) Scottish genomes: £6M (\$8M) Welsh Genomics for Precision Medicine: £6.8M (\$9M) Northern Ireland Genomic Medicine Centre: £3.3M (\$4.6M)</p>	<p>France</p> <p>Genomic Medicine Plan 2016-2025 – Rare disease, cancer, diabetes €670M (\$799M)</p>	<p>United States of America</p> <p>National Human Genome Research Institute 2007 – Infrastructure and clinical cohorts \$427M All of Us 2016-2025 – Population cohort \$500M (first two years)</p>	<p>Qatar</p> <p>Qatar Genome 2015 – Infrastructure, population cohort</p>
<p>Netherlands</p> <p>RADICON-NL 2016-2025 – Rare disease Health Research Infrastructure</p>	<p>Switzerland</p> <p>Swiss personalized health network 2017-2020 – Infrastructure CHF68M (\$69M)</p>	<p>Brazil</p> <p>Brazil 2015 – Brazil Initiative on Precision Medicine Infrastructure, disease and population cohorts</p>	<p>Japan</p> <p>Japan Genomic Medicine Program 2015 – Infrastructure, clinical and population-based cohorts, drug discovery JPY10.2B (\$90.05M)</p>
<p>Denmark</p> <p>Genome Denmark 2012 – DK86M (\$13.5M) FarGen 2011-2017: DK10M (\$1.6M) Infrastructure, population-based cohort, pathogen project</p>	<p>Estonia</p> <p>Estonian Genome Project 2000 – Infrastructure and population-based cohort 2017: €5M for 100,000 individuals</p>	<p>Saudi Arabia</p> <p>Saudi Human Genome Program 2013 – Infrastructure, clinical cohorts and population-based cohorts SAR300M (\$80M)</p>	<p>China</p> <p>Precision Medicine Initiative – 1,000,000 genomes CNY60B (\$9.2B)</p>
	<p>Finland</p> <p>National Genome Strategy 2015-2020 – Infrastructure €50M (\$59M)</p>	<p>Turkey</p> <p>Turkish Genome Project 2017-2023 – Infrastructure, clinical and population-based cohorts</p>	<p>Australia</p> <p>Australian Genomics 2016-2021 – Infrastructure, rare disease and cancer AUD\$125M (\$95M) Genomics Health Futures Mission 2018-2028 – AUD\$500M (\$372M)</p>

“ Initial use cases may be prioritized based on: (1) disease burden; (2) applicability to population health surveillance; and (3) a shift to preventative care, particularly for non-communicable diseases, and provision of information to the government.

The readiness of a national strategic plan will rest heavily on the government’s prioritization of precision medicine in its health system. In countries where precision medicine implementation is low – typically in LMICs – the ministry of health (or equivalent) will likely have existing strategic programmes for other disease areas such as infectious or neglected tropical diseases, given other national health priorities. If precision medicine is included in the national strategy, however, initial use cases may be prioritized based on: (1) disease burden; (2) applicability to population health surveillance; and (3) a shift to preventative care, particularly for non-communicable diseases, and provision of information to the government

as to the value of such initiatives. In countries where precision medicine is further embedded in clinical care – more commonly occurring in high-income countries – there is greater opportunity to implement public-driven initiatives given the increased resourcing and established foundation. As markets develop and more research and funding are able to drive discovery, the national strategy may include additional initiative types or enter other disease areas. A table of illustrative initiative types are presented in Table 1, referenced from the Global Alliance for Genomics and Health (GA4GH). Greater private-sector participation is also observed alongside maturing markets, which is further discussed in the innovation financing section.

TABLE 1 Selected precision medicine innovation types drawn from the 221 initiatives categorized by the [Global Alliance for Genomics and Health \(GA4GH\) Catalogue](#)

Initiative type	Description
Biobank/repository	Biological material repositories that collect and store biospecimens for medical research
Consortium/collaborative network	Operational or infrastructure collaborations with multiple partner organizations
Database	Storage of organized health and genomic-relevant information, often for catalogue and research use
Industry	Collaborative partnerships with industry stakeholders such as health providers, payers, pharmaceutical companies or diagnostic/sequencing companies
Ontology or nomenclature tool	Standardized vocabularies and terminology of biological or clinical information
Research network/project	Knowledge-generating and sharing initiatives, often through academic-driven partnerships
Standards	Common, shared-information frameworks
Tool	Other frameworks, platforms, architecture or programmes relevant to precision medicine

Case study – [Nigeria’s Cancer Control Plan](#) by the Ministry of Health formalizing support of precision medicine implementation: In 2015, the Nigerian Ministry of Health announced its new Cancer Control Plan (CCP), which lends formalized support for country-wide implementation of approaches such as DNA-based cancer testing. Supported by the Clinton Health Access Initiative, the American Cancer Society and the US National Cancer Institute, the CCP established updated

guidelines for cancer management from the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology, which is now taught in Nigeria’s medical training curriculums. The CCP outlines measures to support the Nigerian government’s screening programme, with the goal of screening half the eligible Nigerian population by 2022. Over the long term, the Ministry of Health aims to incorporate routine screening of eligible cancers into existing clinical programmes.

Case study – US NIH All of Us initiative: In 2018, the US National Institutes of Health (NIH) launched the All of Us initiative (formerly known as the Precision Medicine Initiative Cohort Program) with the objective of collecting genomic and health data on a longitudinal basis from 1 million volunteers in the United States. The initiative acts as a consortium with 100-plus programme partners

that include data and research centres (DRCs), biobanks, patient participant centres, healthcare provider organizations and community engagement partnerships. Specific steps exist through the data collection process (consent forms, survey modules, partner protocols) and particular attention is paid to strategic enrolment of demographics under-represented in biomedical research.

1.2 Open science principles

Summary: Policy applications of open science can inspire data-driven research and development (R&D) of precision medicine innovations. The guiding principles are described by the international GO FAIR initiative, and should be considered alongside relevant biodata standards.

In contrast to the more proprietary intellectual property ownership models based on trade secrecy and competition, open science – as defined by the Organisation for Economic Co-operation and Development (OECD)'s [Making Open Science a Reality](#) paper – is a movement enabled by information and communication technologies towards transparent data sharing, rapid knowledge dissemination and broad research accessibility. Emerging policy applications of open science have particular relevance in the field of precision medicine as they are: (1) changing how genomics-related research is conducted and disseminated; and (2) reducing the otherwise high costs and uncertainty risk of precision medicine if actors were to invest resources in R&D as stand-alone initiatives. Importantly, the access to higher volumes of data as a result of open science principles can improve both the granularity of information for stratified care delivery and the applicability of clinical research discoveries to increased patient populations.

Open science for precision medicine research may manifest in various initiatives – e.g. international multistakeholder genome research consortia, centrally accessible databases for research and clinical use or collaborative efforts that avoid duplicated work. In moving towards implementation, various [open science guiding principles described by the international GO FAIR initiative](#) enable researchers to find, access, interoperate and reuse each other's research objects. These are described in Figure 5 below. Readiness benchmarks for innovation can be found in: (1) the extent to which countries follow the FAIR principles; (2) the agreed-upon standards for exchanging genomic, phenotypic and clinical data attributes; (3) the recognition of participant consent and privacy; and (4) the extent to which open science principles are implemented alongside proper intellectual property (IP) ownership regulations.

FIGURE 5 The FAIR Guiding Principles

To be Findable:

- F1. (meta)data are assigned a globally unique and persistent identifier
- F2. data are described with rich metadata (defined by R1 below)
- F3. metadata clearly and explicitly include the identifier of the data it describes
- F4. (meta)data are registered or indexed in a searchable resource

To be Accessible:

- A1. (meta)data are retrievable by their identifier using a standardized communications protocol
 - A1.1 the protocol is open, free and universally implementable
 - A1.2 the protocol allows for an authentication and authorization procedure, where necessary
- A2. metadata are accessible, even when the data are no longer available

To be Interoperable:

- I1. (meta)data use a formal, accessible, shared and broadly applicable language for knowledge representation.
- I2. (meta)data use vocabularies that follow FAIR principles
- I3. (meta)data include qualified references to other (meta)data

To be Reusable:

- R1. meta(data) are richly described with a plurality of accurate and relevant attributes
 - R1.1. (meta)data are released with a clear and accessible data usage licence
 - R1.2. (meta)data are associated with detailed provenance
 - R1.3. (meta)data meet domain-relevant community standards

Source: [Wilkinson et. al \(2016\)](#)

Early collaboration with large-scale research groups and involvement in international human genomics initiatives may accelerate the formation of a country's precision medicine innovation ecosystem. To start this process, policy-makers have a greater opportunity to design early opt-in incentives for institutionalizing open science and set a precedent for national, centralized biorepositories with interoperability and collective contribution requirements. Such early attention to open-science principles can prevent the emergence of the potentially ad hoc or isolated genomic research programmes more common in existing precision medicine programmes. In this latter

environment, policy-makers may note inefficiencies, with current access restrictions to scientific and research data (e.g. isolated research groups/health systems, data-sharing restrictions across country borders), which limits the potential for holistic precision medicine R&D advancement for all involved participants. The Canadian government's [Roadmap for Open Science](#) provides an excellent model to move beyond such restrictions. The Canadian roadmap outlines the steps they took to make federal science open to all, while respecting privacy, security, ethical considerations and appropriate intellectual property protection.

Case study – [Structural Genomics Consortium \(SGC\)](#): A charitable open science public-private partnership, the SGC was started in 2003 with the core mandate of determining 3D structures of human proteins and parasite proteins that are of biomedical importance (e.g. potential drug targets). It is recognized as one of the earliest and largest pioneers of open science and releases structural genomics data into the public domain through the Protein Data Bank annually. The

precompetitive principles adopted by the SGC translate into other open science conditions imposed on its researchers and collaborators via a trust agreement that prohibits the patenting of research outputs using SGC data and stipulates fast dissemination and prepublication sharing of its structural and chemical biology outputs. The current collaborators with SGC include pharmaceutical companies, governments, academic institutions and NGOs.

Case study – [Estonian Genome Center of the University of Tartu \(EGCUT\) Biobank](#): Estonia's biobank initiative, the EGCUT Biobank, has been funded by the Estonian government since 2000 and includes a collection of health and genetics data from 5% of Estonia's adult population. The EGCUT actively collaborates with many universities, research institutions and consortia given its membership in various international networks such

as the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI), the European Research Infrastructure Consortium (BBMRI-ERIC) and the Public Population Project in Genomics (P3G). The EGCUT maintains a data-sharing policy in which collaborators accessing EGCUT resources must send any scientific results obtained from the research project using EGCUT data or samples back to EGCUT for addition to the Estonian Biobank.

1.3 Precision medicine IP policy and benefit sharing

Summary: Clear intellectual property (IP) policy for precision medicine technologies acts as a market incentive for precision medicine innovators. These policies may not be so effective in all locations, particularly those with little precision medicine infrastructure, and require other push-and-pull measures. Benefit-sharing models aim to close the gap regarding equitable distribution of value from international precision medicine projects.

“ Policy-makers must assess the strength of this ‘pull’ incentive on private-sector engagement relative to the benefits of open innovation principles that aim to collectively advance precision medicine in the long term.

The core question to be addressed by policy-makers for precision medicine IP can be summarized as: “Do current national patent regimes promote R&D and innovation in precision medicine while also benefitting the collective interest of public health?” While IP protections are critical incentives for precision medicine innovators, policy-makers must assess the strength of this “pull” incentive on private-sector engagement relative to the benefits of open innovation principles that aim to collectively advance precision medicine in the long term.

A recommended benchmark for readiness is the clear articulation of IP policies for precision medicine innovations. Clearly defined rules provide researchers and technology producers with an

awareness of the risks and rewards associated with an innovation, such as when conducting freedom-to-operate searches. Likewise, it may offer similar risk-and-reward insight to public-sector organizations considering opening their databases to commercial parties.

However, the incentive effects of IP policies may be limited or non-existent for precision medicine innovations addressing health problems mainly affecting LMICs due to the small and uncertain market demand for such innovations. [The World Health Organization states that there is a need for other governance responsibilities, financial mechanisms and multistakeholder partnership models to fill the IP incentive gap.](#)

IP incentive gaps are also observed among LMIC-based researchers participating in international open genome projects; while data is contributed by and accessible to all involved countries, wealthier nations are more likely to patent innovations from such projects. The MalariaGEN case study illustrates an early use of benefit-sharing models to close this gap in its international open science initiative. Under this model, the IP owner can: (1) provide differential access or pricing for innovations

used by LMICs; or (2) arrange country-specific socially responsible licensing via negotiations with respective government agencies if their citizens provided data. To be sure, this does not address mechanisms to overcome the lack of representation of LMIC populations in large genomic datasets. More work on equitable collaboration models is encouraged, particularly for genomics IP and locally relevant data. This topic is further discussed in the “workforce and infrastructure” section.

Case study – [Malaria Genomic Epidemiology Network’s \(MalariaGEN\) data release policy](#):

MalariaGEN is an international open science project to identify the specific genetic underpinnings of malaria funded by the Grand Challenges in Global Health Initiative through the Bill & Melinda Gates Foundation and the Wellcome Trust. Thirty-nine countries currently participate in the MalariaGEN research consortium, sharing and integrating data

types (including genetic data) across collaborators. Under its online data release policy, the website states that “the owner of the IP agrees to license it on a reasonable basis for use in the developing world and on a preferential basis to the countries whose citizens are the subject of the database”. This acts as a benefit-sharing mechanism for LMICs that can more equitably gain from participating in MGEN’s open data project in the event of royalty flow from IP.

1.4 Adapted health technology assessment processes for precision medicine technologies

Summary: The integration of precision medicine technologies into standard market-review processes remains a gap in both high- and low-income countries. If traditional health technology assessment methods are unable to properly evaluate precision medicine, novel refinements must be adopted by pharmacoeconomic groups globally.

“The inclusion of precision medicine in clinical practice has been recognized to ‘impact each stage of the Health Technology Assessment (HTA) process, from scoping and modelling through to decision-making and review’.

Novel precision medicine technologies may not fit traditional evaluation and market approval processes for biotechnologies. While conventional HTA aims to evaluate the social, economic, organizational and ethical issues of a health intervention, its systematic evaluation varies from country to country and often does not cover novel scenarios posed by precision medicine technologies. The inclusion of precision medicine in clinical practice has been recognized to “[impact each stage of the Health Technology Assessment \(HTA\) process, from scoping and modelling through to decision-making and review](#)”. For instance, pharmacogenomic tests (PGx) that assess the adverse event (AE) risks of certain therapeutics may not fit into traditional assessment models given their indirect effect on patient outcomes if the resulting information gain from the PGx diagnostic changes the course of care. This variability in the patient pathway may be more difficult to capture in standard HTA analyses.

Refinements to various components of HTA are encouraged, so as to adapt to the influx of precision medicine algorithms, digital health applications and “omics”-based tests. This may manifest in various

ways through the approval process and may include, but is not limited to, faster regulatory review timelines, clear pricing standards and relevant medical feedback. However, in creating robust frameworks to formally evaluate precision medicine technologies, HTA bodies may struggle to keep pace or may attempt some level of ad hoc review processes on such technologies. Nonetheless, these traditional review processes may not fully account for accurate end points that capture the value-add of a precision medicine innovation.

To date, only a few HTA bodies internationally accommodate specific considerations or traditional evaluation methods for precision medicine – e.g. the Diagnostic Assessment Programme at the National Institute for Health and Care Excellence (NICE) in the UK, the Health Interventions and Technology Assessment Program (HITAP) in Thailand and the HTA Access Point in Australia. Australia’s entry point for companion diagnostics (CDx) is illustrated as a case study below. The conduct of enabling studies to collect the necessary data for HTA processes is further discussed in the “reimbursement conditions and coverage models” section under innovation financing.

Case study – [Australia's HTA Access Point for Co-dependent Diagnostic Technologies](#): The Australian government's Department of Health established a "single entry point", the HTA Access Point (HTAAP), that assists specific applicants for HTA and reimbursement if they are uncertain about the funding programme for which their technology may be eligible, or where their technology may need

to be assessed by more than one expert advisory committee. The latter is particularly relevant for designated "co-dependent technologies" such as targeted therapies that require companion diagnostic technology, in which HTAAP will work with the applicant to form a tailored assessment methodology for the eligible technology in the hope that assessment timelines may be reduced.



2 Innovation financing

The funding mix to both set up and regularly reimburse precision medicine programmes.



2.1 Public funding and fiscal space usage

Summary: Government spending on precision medicine programmes demonstrates national support and encourages private-sector funding for the innovation ecosystem. LMIC settings with constrained fiscal space may seek to prioritize precision medicine initiatives when relevant to other national health priorities. Expansion of targeted budgetary allocations over time remains necessary for sustainable public funding of precision medicine.

Public funding is often vital in spurring precision medicine programmes and such investment will depend on the fiscal space – defined as the budgetary allocation for a targeted investment area – available from the ministry of finance or respective treasury agency. While constrained by limited resources, especially relative to private funding, public spend can either fully establish or partially underwrite early innovation programmes via an initial mix of grant-based and/or loan financing. Additionally, public grants are often used to finance research initiatives in both academic institutions and relevant private projects. These government investments often take the form of milestone-based tranche payments or upfront disbursements but will depend on the project arrangement.

While national precision medicine programmes may ultimately be financed by a variety of public- and private-funding sources, the readiness criteria for public funding are defined by: (1) the fiscal space allocation to precision medicine from existing budgets or new funding channels; and (2) the diversity of investment partners supporting the project portfolio. The former is based on the ability of a government's budgetary leadership to audit the return on investment (ROI) of potential precision medicine efforts, measure the national priority level and understand the value from precision medicine approaches. As the innovation ecosystem matures, a greater evidence base of early precision medicine initiatives can provide traction for further public funding. Similarly self-perpetuating, the latter benchmark highlights the diversity within types of precision medicine innovation and the growing co-

financing involvement from private innovators as the precision medicine market matures. This funding shift from top-down public spending to greater private investment activity is commonly observed as the innovation ecosystem supports further translation of R&D.

While LMICs may not have the available fiscal space for precision medicine due to the focus on other national health priorities (e.g. infectious disease or neglected tropical diseases), public funding is crucial in the early stages of the innovation ecosystem. In such scenarios where precision medicine is a national investment interest, precision medicine programmes may be incorporated into related health initiatives of national focus with already ongoing fiscal spending (e.g. infectious disease surveillance or genomic studies of rare disease prevalent in the country). For emerging and more developed economies able to consider greater public investment, the fiscal space remains particularly important to de-risk a reliance on private aid. The World Health Organization (WHO) notes that creating [fiscal space expansions, often driven by macroeconomic growth, budget reprioritization and efficiency improvements, enables the long-term financial sustainability of precision medicine approaches](#). The government of Thailand case study below demonstrates the effective use of public funding for precision medicine approaches as an upper-middle-income country, first within Stevens-Johnson syndrome and toxic epidermal necrolysis (TEN) in 2004, now into larger-scale five-year genome catalogue initiatives (2019).

Case study – public financing of the [Genomics Thailand Initiative](#) and pharmacogenomics (PGx) studies:

In early 2019, the Thai government approved a \$150 million five-year initiative to catalogue the genomes of 50,000 citizens. This project, named the Genomics Thailand Initiative, aims to expand the understanding of South-East Asia's under-represented genomic composition and advance Thailand's genomics capabilities in personalized diagnostics, drug selection and treatment in various disease areas. Thailand pursued precision medicine research as early as 2004 through the Thai PGx Project for Stevens-Johnson

syndrome (SJS) and toxic epidermal necrolysis (TEN) screening, with investments from the Thai Ministry of Science and Technology. The project used genetic testing to identify epilepsy patients at risk of developing these severe responses to a widely prescribed generic medication, and ultimately reduced such cases by 80% in 2018. Continuing its precision medicine efforts, the most recent Genomics Thailand Initiative falls under the broader remit of the Thailand 4.0 government campaign to close the middle-income country gap towards an innovation-driven economy, starting with a competitive genomic medicine industry.

2.2 Private-sector financial backing

Summary: Private funding provides the funding scale and expertise to support precision medicine initiatives. Engagement by different types of financiers (innovation producers, investors, aid donors and service providers) may shift as the innovation ecosystem grows. Private financing of precision medicine is scarce in LMICs, even from development assistance for health (DAH) groups.

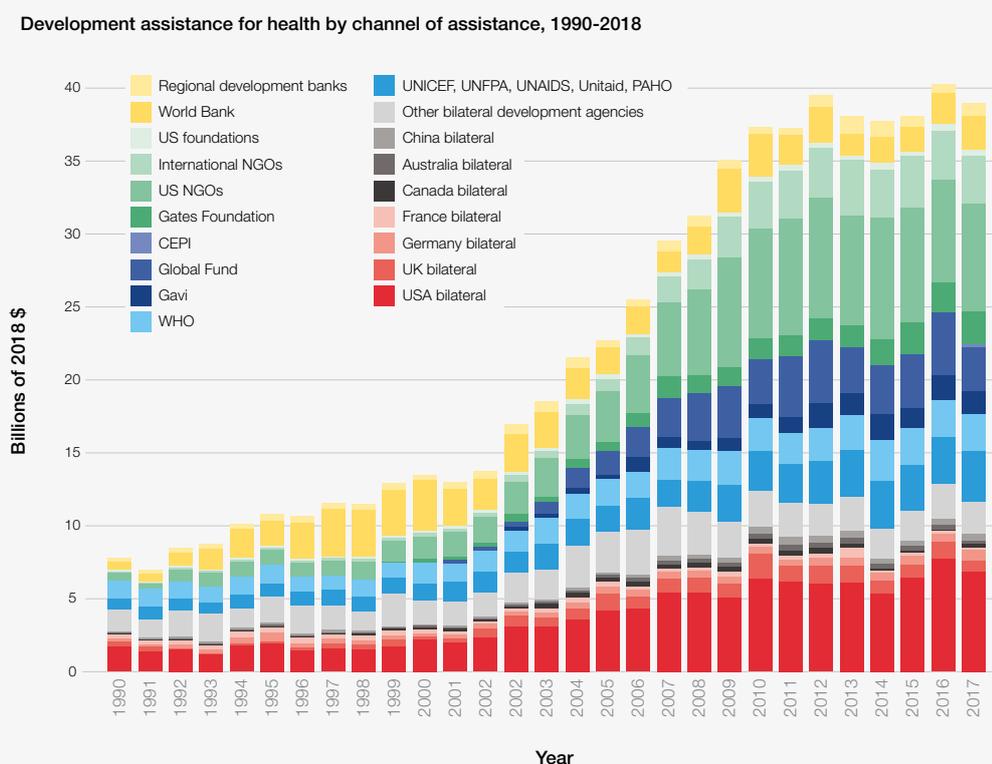
In tandem with the public fiscal space, private funding provides the funding scale and expertise to support the continuous development of the precision medicine innovation ecosystem. These private-sector financiers range in funding size and involvement – examples may include development aid agencies, global health philanthropies, biopharmaceutical companies, technology manufacturers and impact investing groups among various other NGO and corporate investors. The expansion of the precision medicine marketplace is often supported by increased public-private co-financing partnerships and individual private-sector activity (further discussed as a readiness benchmark under the “public funding” section above).

Readiness benchmarks for private-sector financing activity can be viewed as the extent to which private stakeholders are able to participate in and fund projects in the innovation ecosystem. Policy-makers are encouraged to conduct a stakeholder analysis of relevant private actors in order to map potential collaboration opportunities and current funding gaps in the precision medicine marketplace. Private funders for precision medicine can be broadly categorized into: (1) innovation producers; (2) investors; (3) aid donors; and (4) service providers. Importantly, the mix of stakeholders shifts depending on the maturity of the innovation ecosystem. For instance, countries in the early stages of private financing activity primarily attract aid donors in the form of disease-

specific funds and development assistance for health (DAH) groups (e.g. foundations, family offices or high-net-worth individuals [HNWIs]). As the marketplace develops, producers – ranging from biopharmaceutical to diagnostic/sequencing companies (and investors), including private equity and venture capital (PEVC) groups – actively deploy financial and in-kind advisory/expertise resources for precision medicine projects. Such private-sector stakeholders enter as the innovation ecosystem grows to provide lower-risk operating environments and tenable investment exit opportunities. At advanced stages of readiness, service providers such as private provider systems are able to self-finance precision medicine approaches within their clinical practices.

Private financing of precision medicine technologies in the LMIC context remains scarce. Attention from DAH groups and global innovative financing mechanisms (IFIs), including The Global Fund, Gavi, the Vaccine Alliance and Unitaid, [have historically focused on preventing and treating infectious diseases such as HIV/AIDs, tuberculosis and malaria](#). As such, non-communicable diseases (NCDs) including cancers and cardiovascular disease – areas in which precision medicine approaches are currently most applicable – [remain underfunded through traditional global health DAH and IFI channels](#). This remains a notable gap that is further highlighted in the DAH financing disease area breakdown in Figure 6.

FIGURE 6 Development assistance for health (DAH) by financing channels



Source: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(19\)30841-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30841-4/fulltext)

Case study – series [A financing of 54Gene by Adjuvant Capital](#): Founded in 2019, 54Gene is an African genomics research, services and development company established with the aim of including under-represented African genomic data in health research and drug development. In April 2020, the US- and Nigeria-based genomics company 54Gene announced a \$15 million series A financing round led by Adjuvant Capital, a global health-focused investment fund for life science technologies backed by the Bill & Melinda Gates Foundation, Novartis and the International Finance Corporation (IFC). 54Gene

has predominantly taken a private-financing approach to grow its capabilities and positioning in the wider precision medicine marketplace, with a total of \$21.5 million raised venture capital funding stimulated by initial participation in accelerators (Y Combinator and Google Developers Launchpad). While servicing more than 100,000 participants in its biobank to expand African representation in population genetics as of 2021, 54Gene has also been able to build up infrastructural gaps on the African continent by both upskilling the workforce and strengthening genomics R&D capabilities.

Case study – [private equity financing of largest precision medicine provider in Morocco by Alta Semper](#): Frontier markets private equity firm Alta Semper has invested in Morocco's largest oncology, radiology and diagnostics services platform, Oncologie Diagnostic du Maroc (ODM). The provider owns and operates five facilities for

oncology treatments alongside an array of imaging and genomic diagnostic services. In addition to financial capital, Alta Semper aims to help ODM's expansion strategy by providing operating expertise across north and sub-Saharan Africa, alongside access to its existing healthcare holdings in Morocco.

Case study – [UBS \\$500 million Oncology Impact Fund](#): Swiss multinational bank UBS Group raised ~\$500 million from HNWI's for investment by MPM, a healthcare venture capital firm with oncology expertise. The fund serves as an impact investment initiative that invests in early-stage cancer treatments and, in turn, manages the royalties and performance fees from successful drug sales of such investments for impact-based key performance indicators (KPIs). The UBS Optimus

Foundation will manage any such generated capital from initial early-stage oncology investments and specifically direct this flow to: (1) academic grants to promising oncology-related research; and (2) health access initiatives in developing countries. This combination of HNWI impact investors (scale) and VC expertise (domain knowledge and experience) presents a potential replicable financing model for private-driven impact investing in precision medicine technologies.



2.3 Blended finance and the diagonal approach

Summary: Precision medicine approaches are unproductive without accompanied achievable decision-making steps (“effectors”). Cross-cutting diagonal approaches reinforce precision medicine investments alongside health system strengthening. Blended finance may be a particularly relevant financing model for precision medicine to encourage long-term economic growth.

“The diagonal approach to financing health system strengthening ‘overcomes the barriers between vertical (disease-specific) and horizontal (systemic) approaches by making full use of potential synergies between disease programmes and health functions’.

Any patient population stratification method or targeted approach to care delivery is unproductive without accompanying achievable decision-making steps (“effectors”). Countries may lack foundational effectors such as having sufficient targeted therapy drug supplies or a workforce with proper technical knowledge to interpret genomic risk profiles. The [diagonal approach to financing health system strengthening, addressed in literature on universal health coverage](#), “overcomes the barriers between vertical (disease-specific) and horizontal (systemic) approaches by making full use of potential synergies between disease programmes and health functions”. Instead of financing precision medicine technologies specific to each disease, this cross-cutting framework emphasizes: (1) early financing of precision medicine approaches spanning multiple disease areas; and (2) reinforcing foundational health and economic effectors critical to any precision medicine intervention.

Blended finance serves as one such “diagonal approach” linking macroeconomic development

and specific investment in precision medicine programmes. Specifically, blended finance uses various risk-adjusting financing structures to mobilize private capital alongside development and philanthropic funding towards economic development objectives in emerging markets. An overview is illustrated in Figure 7. Blended finance approaches often converge in their ability to attract private investment to public-driven development initiatives that encourage overall economic growth. Such development initiatives can strengthen the precision medicine innovation ecosystem in which infrastructure growth enables further job creation, knowledge transfer and improved overall health outcomes. The [Blended Finance Toolkit](#) from the joint ReDesigning Development Finance Initiative (RDFI) of the World Economic Forum and the OECD provides more specific recommendations for adopting this investment approach in emerging and frontier markets. Further detail on overall health system strengthening and economic development is discussed in the “workforce and infrastructure” topic.

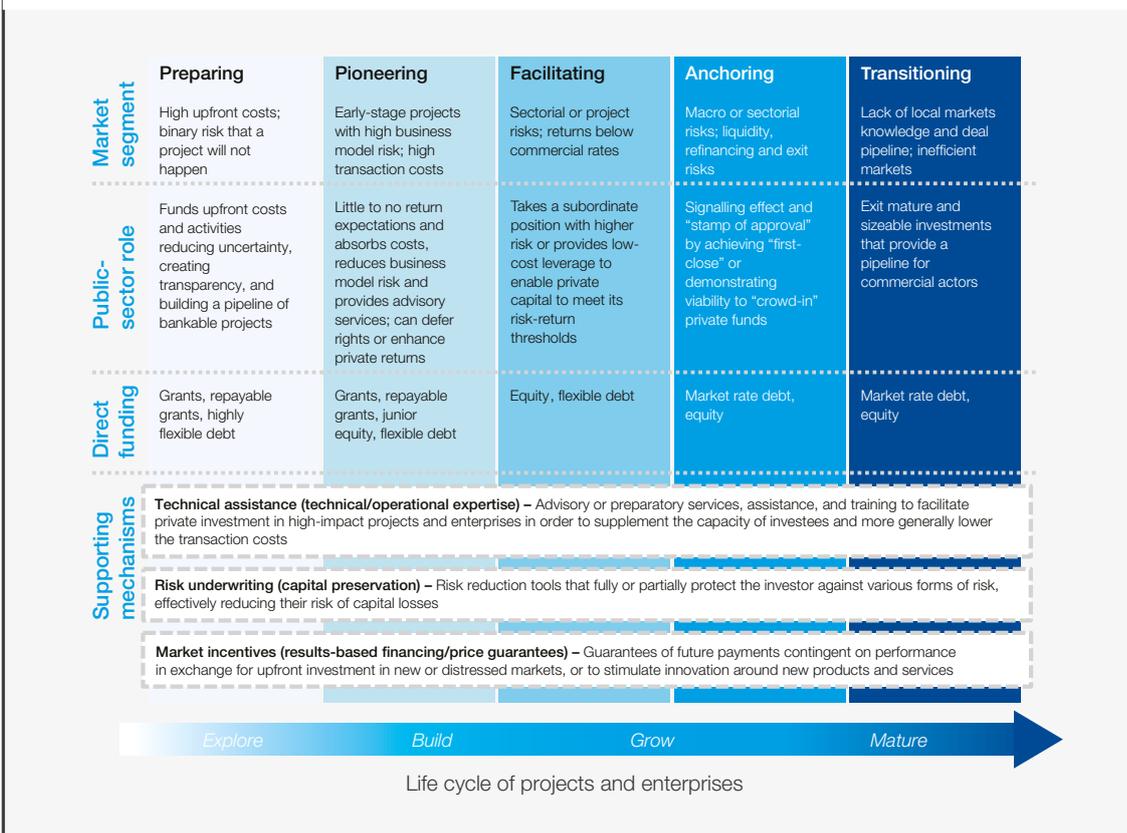


Case study – [Chile and Pfizer Center of Excellence in Precision Medicine \(CEPM\)](#):

The Chilean Economic Development Agency (CORFO) has provided co-financing of \$7 million over a period of four years since 2015, to create the Santiago-headquartered Center of Excellence in Precision Medicine (CEPM). The result of a joint effort between the Chilean government and the pharmaceutical company Pfizer, CEPM was formed to promote Chile as a hub for research, development and innovation in Latin America. CORFO acts under the Chilean government mandate of promoting economic growth and has done so through various initiatives, including its programme to create international “centres of excellence”. CEPM acts as one such international programme partnership, bolstering Chile’s objective

to diversify from a commodity-driven to knowledge-based economy attracting global R&D research. The centre has focused its initial efforts on non-small cell lung cancer (NSCLC) next-generation sequencing through its technology partner, Thermo Fisher, which invested \$3 million in the collaborative project. NSCLC has a high incidence in the region (~2,000 cases annually) and its treatment is currently associated with a companion diagnostic to identify eligible patients for medication based on an ALK gene mutation. Since its inception, CEPM has published more than 140 articles and improved its technology transfer system, all while simultaneously strengthening the regional economy through job creation and knowledge transfer from Pfizer’s R&D techniques and collaborations with its other R&D centres globally.

FIGURE 7 Blended finance approaches



2.4 Reimbursement conditions and coverage models

Summary: The gap between coverage and reimbursement of precision medicine technologies remains. The shift from out-of-pocket models and growing incentive alignment between providers and payers indicates progress towards precision medicine readiness. The emergence of novel alternative payment models, while currently limited to high-income environments, may help close the reimbursement gap.

Measuring coverage and reimbursement readiness for precision medicine can be benchmarked by: (1) the shift from out-of-pocket payment models towards accessibility and coverage within available insurance schemes; and (2) sustainable contracts between health providers and respective public or private payers on primary coverage conditions and treatment value.

The effective financing of precision medicine innovations is closely tied to its coverage and reimbursement, which remains one of the largest hurdles of successful implementation and marketplace growth. Clear coverage and reimbursement standards enable innovators and adopters to recognize the financial ROI payoff and usage costs of precision medicine technologies, respectively. Policy-makers can support coverage and reimbursement by formalizing: (1) the payer stakeholder(s) responsible for reimbursement; (2) the circumstances and conditions on which and how precision medicine interventions are covered; and (3) the review process for reimbursement decisions based on health technology assessments (HTA). Such steps may often involve collaborations with payers, industry producers and medical societies, especially when setting conditions for coverage and standards of care. As regulators and payers increasingly look towards real-world evidence (RWE) assessments for coverage decisions, additional emphasis is placed on evidence generation via formalized processes for data collection and indicators for performance

review. This discussion is closely linked to the “adapted HTA processes for precision medicine technologies” section under innovation governance.

Measuring coverage and reimbursement readiness for precision medicine can be benchmarked by: (1) the shift from out-of-pocket payment models towards accessibility and coverage within available insurance schemes; and (2) sustainable contracts between health providers and respective public or private payers on primary coverage conditions and treatment value. The first indicator contrasts the interim coverage programmes adopted by countries, often patient out-of-pocket or direct fee-for-service payment models, that may discourage the use of precision medicine approaches through inadequate patient accessibility or misaligned incentives. These challenges are magnified in underinsured patient populations, where the payment burden of poorly covered techniques on both the provider and patient discourages the use of precision medicine technologies. While coverage models and payer systems vary greatly across countries, reimbursement models that replace out-of-pocket expenditure

for precision medicine approaches support the equitable growth of an emerging marketplace for precision medicine. As alignment with this readiness benchmark matures, a country may observe greater coverage of various precision medicine approaches, such as population-level screening for certain diseases or widespread adoption of precision therapeutics to treat certain diseases.

The second benchmark gauges the extent of favourable adoption conditions and payer-provider incentive alignment. Importantly, a coverage decision dilemma arises in which: (1) providers will not adopt novel precision medicine technologies unless they are financially covered by payers; and

(2) payers are unwilling to cover innovations due to their uncertain value-add relative to coverage costs. Various value-based reimbursement contracts and alternative payment models (APM) have emerged as potential solutions – one such case study below from genomics tool producer Illumina and private insurer Harvard Pilgrim Health Care highlights an APM in which producers share the financial risk with the insurer to cover precision medicine technologies under a fees-at-risk model.

Further readiness metrics on the progression towards value-based care is discussed in the following section on “experimentation with value-based care instruments”.

Case study – [Illumina and Harvard Pilgrim value-based contract for non-invasive prenatal genetic testing](#): In February 2018, US-based private payer Harvard Pilgrim Health Care entered into its first next-generation sequencing (NGS) contract with the genomics tool producer Illumina to broaden the eligibility of non-invasive genetic testing to younger women, under the age of 35, with average-risk pregnancies to screen for prenatal genetic abnormalities. While Harvard Pilgrim already anticipated the cost of this test to be

offset by reduced expenditures on other screening modalities, Illumina agreed to further de-risk the investment by covering any potential increased costs. The collaboration also includes a two-year study on Harvard Pilgrim’s patient population to explore the clinical outcomes relative to the total costs of this expanded genetic testing intervention, grounding an experiment of clinical value-add to real-world evidence that demonstrates further proof of concept for precision medicine technologies.

2.5 Experimentation with value-based care instruments

Summary: Value-based care models that create incentives for prevention and proactive care are foundational to any serious adoption of precision medicine. Emergent value-based approaches include evidence-based modelling studies and various types of managed entry agreements. Gaps remain in creating value-based models due to a lack of available data on precision medicine approaches needed to calculate its value-add relative to other options.

⚙️ The experimental techniques discussed are a step forward, but more work is required to generate the evidence base needed to transition effectively to value-based care and reimbursement.

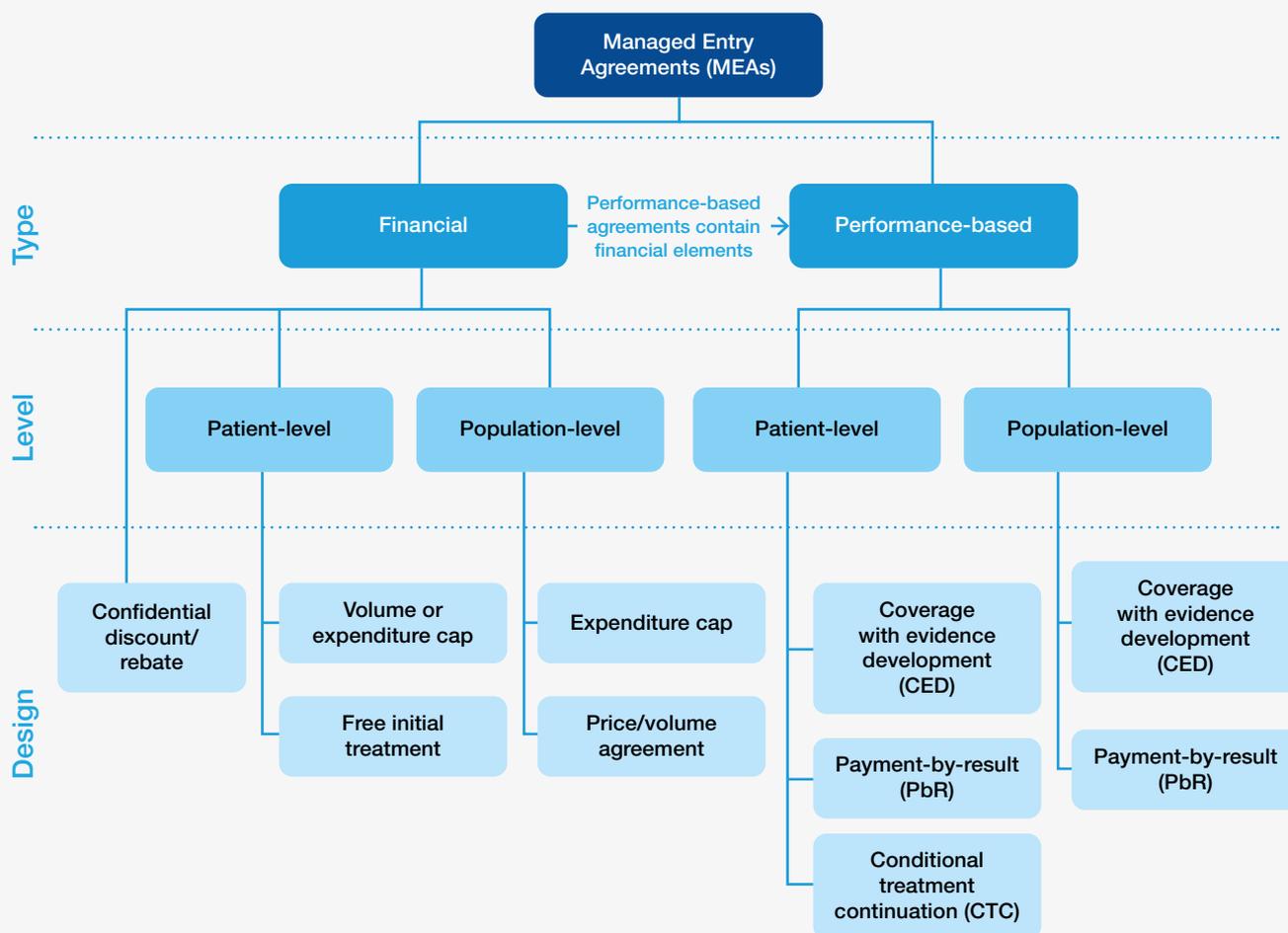
Clinicians and policy-makers alike continue to focus on the value of care, driven by the growing imperative to measure outcomes relative to healthcare costs. This shift away from traditional fee-for-service models to approaches that focus on added value is particularly relevant for precision medicine innovations that are promoted for their ability to deliver compelling ROI to patients, health systems and society. Under value-based care approaches, reimbursement is closely linked to the potential for cost-effective outcomes derived from the use of a precision medicine intervention.

While countries vary widely in their progress towards value-based healthcare, several experimental value-based approaches for precision medicine have emerged in the past decade. Two common approaches are: (1) evidence-based modelling studies; and (2) managed entry agreements (MEAs). For the former, modelling studies aim to demonstrate the proven cost-effectiveness of an intervention through pharmacoeconomic metrics such as quality-adjusted life years. These studies most optimally run in partnership with a payer stakeholder involved in the model design and critique, and use real-

world evidence to inform the compelling ROI of a precision medicine intervention. On the latter, MEAs consist of a wide class of innovative reimbursement approaches, such as performance-based risk-sharing agreements (PBRsAs) or coverage with evidence development (CED) broken down by the OECD in Figure 8. Payers internationally are exploring these novel coverage approaches for early patient access while managing financial and performance uncertainty, and several of them may emerge as potential paths forward to reimburse precision medicine technologies that may not fall under traditional coverage paradigms.

While precision medicine readiness can be observed based on the country’s experimentation with performance-based approaches such as those discussed above, this capability remains a gap in many countries, irrespective of income level, due to a lack of data on the value-add of precision medicine approaches and the unaffordable prices of some such innovations. The experimental techniques discussed above are a step forward, but more work is required to generate the evidence base needed to transition effectively to value-based care and reimbursement.

FIGURE 8 | OECD Breakdown of Managed Entry Agreements



Source: OECD, "Performance-based managed entry agreements for new medicines", <https://www.oecd.org/health/health-systems/pharma-managed-entryagreements.htm> (accessed 7 September 2020)



3

Community and partnerships

The public and private multistakeholder collaborations enabling precision medicine innovation.



3.1 Entrepreneurship, research and innovation hubs

Summary: Biotechnology clusters, incubators and accelerators are natural drivers of the precision medicine innovation ecosystem. They form collaborative knowledge-generating environments conducive to R&D collaboration and entrepreneurial activity, particularly relevant to encourage genomics-based partnership models and project commercialization.

The emergence of precision medicine R&D activity may arise in co-located geographic areas, often as part of existing biotechnology cluster initiatives (CIs) or stand-alone research and innovation hubs. Such regions serve a vital role in the innovation ecosystem as: (1) a collaborative knowledge-generating environment linked closely to entrepreneurial activity; and (2) a connected ecosystem that bridges burgeoning projects with financial and in-kind resources to achieve market access and scale.

Specific to precision medicine, these innovation environments encourage the expansion of novel partnership models, including various forms of public-private partnerships (PPPs). Especially noticeable in CIs where many active stakeholders co-locate, cross-collaboration among pharmaceutical and biotechnology companies, diagnostic/sequencing tool producers, academic research and provider systems may naturally occur. [Policy instruments can support these frontier technology developments through levied programmes](#) such as tax incentives for R&D, market-access support and grant provisions or loan guarantees with accompanying firm-level capacity building and advisory programmes. Other formal innovation policy initiatives may support independent entrepreneurial development programmes such as incubators and/or accelerators.

Readiness can be benchmarked by: (1) the existing productivity and natural fit of precision medicine initiatives within such innovation centres; and (2) the role of technology absorption within the country's innovation ecosystem. On the former, it is sensible to promote precision medicine within biotechnology CIs when such clusters have available capacity and stakeholders to drive such initiatives. The cluster's readiness for precision medicine initiatives may manifest in the form of signals such as a growing research base and commercialization activity in fields relevant to precision medicine such as genomics, rare disease or population health.

On the latter benchmark, it is important to preface that the development of innovation hubs may be constrained by resource availability; countries may instead drive their innovation efforts primarily through technology absorption. This is observed in some LMICs where greater attention is placed on addressing present infrastructure and human capital gaps, as opposed to investing in large-scale innovation hubs. There are, however, growing exceptions to this observation as support for LMIC innovation ecosystems emerge – complementary economic factors such as the growth of small- and medium-sized enterprises (SMEs), the availability of financing, and efficient industry activity continuing to develop gradually. There is further discussion on economic and infrastructure capabilities in the “workforce and infrastructure” topic.

Case study – [Precision Medicine Scotland Innovation Centre \(PMS-IC\) Precision Medicine Ecosystem](#): The PMS-IC is Scotland's national initiative towards creating the Scottish Precision Medicine Ecosystem (PME) to enable broader academic, industrial and NHS participation throughout the country. Built from investment funding totalling ~£12 million (\$16.7 million) through 2016 from the Scottish Funding Council and other various donors, PMS-IC acts as an

industry/academic consortium consisting of various partners from the NHS health boards, Scottish universities and industrial genomics partners. PMS-IC coordinates various existing precision medicine academic research and business development initiatives throughout Scotland, providing: (1) an environment to facilitate innovation through academic/industry partnerships; and (2) a path to commercial market entry for large genomic service providers and SMEs alike.

Case study – [Genomics Institute of Singapore \(GIS\) within the Biopolis Research Cluster](#): Singapore's national flagship genomics programme, the Genome Institute of Singapore (GIS), was started in 2000 within the larger Biopolis research hub for biomedical sciences. Biopolis itself acts as Singapore's research cluster, hosting myriad public and private biotechnology research organizations. It further serves as an incubator and accelerator

providing co-innovation spaces, life sciences facilities with diverse equipment and proximity benefits promoting idea exchange and joint projects. Over the decades, the Biopolis cluster and GIS have initiated various genomics-based projects in conjunction with neighbouring research institutions and industry partnerships with co-located large pharmaceutical companies that have established offices within the cluster (e.g. Novartis, Procter & Gamble, GSK).

3.2 University-industry collaboration

Summary: Universities are encouraged to promote internal environments that support precision medicine R&D and commercialization through initiatives such as industry collaboration policies and technology transfer offices. Developing various academic consortia/partnership models and industry-minded researchers may be early steps in growing the precision medicine innovation ecosystem.

🗨️ **Promoting precision medicine innovation through academic institutions and industry partners aims to reduce friction in the path from research and development to evaluation and use.**

Promoting precision medicine innovation through academic institutions and industry partners aims to reduce friction in the path from research and development to evaluation and use. Illustrative policy instruments may include grant proposal requests providing project prototyping, testing and technical assistance ultimately to support commercialization, or advocating for academic consortia models that expand collaboration networks with industry partners in formal PPP programmes. These services may also be formally set up within academic institutions through technology transfer offices (TTOs), established centres within universities that are responsible for the translation and commercialization of local research. Irrespective of the policy instrument, there is a need for universities to promote internal environments that support and motivate participation in the innovation ecosystem.

Readiness indicators can be measured by: (1) the extent to which translation research lags behind or acts in parallel to basic science; and (2) the volume and quality of university-industry collaborations for research translation. In the former, a common challenge experienced by academic institutions globally is the lack of translational initiatives relative to basic research progress. These clinical implementation projects may fall short of conventional grant funding because they are deemed not to fit its criteria, which are often focused instead on basic research. Instead, a greater shift towards implementation science (the scientific study of methods and strategies

to increase the use of evidence-based research and practices) may encourage industry-minded researchers and clinical institutions open to entrepreneurial initiatives. On the latter benchmark, robust university-industry collaborations drive innovative joint R&D and alignment with the technology pull principle. Under such models, universities may develop tools, tests or practices based on industry and community needs as opposed to in potential academic isolation.

The initial steps in closing academic innovation gaps between LMICs and more developed countries may centre on building infrastructure and R&D capabilities. Limitations in the available clinical settings and academic research institutions with genomics-based infrastructure, in addition to funding gaps, will likely constrain the number of studies, scale of research initiatives and translation necessary for precision medicine initiatives. The H3Africa consortium serves as an exemplary organization addressing this gap through capacity building. The case study below highlights how LMICs have a particular opportunity to develop south-south collaborations that support representative research while simultaneously strengthening overall precision medicine infrastructure. As the precision medicine innovation ecosystem matures, more publicly available funding (e.g. competitive research grants), coupled with the growth of supporting infrastructure, will enable universities to develop precision medicine R&D initiatives and commercialization programmes, either in formal university TTOs or one-off project spin-offs into commercial ventures.

Case study – [Human Heredity and Health in Africa \(H3Africa\) Consortium](#): The H3Africa initiative is a partnership between the US NIH, the African Society of Human Genetics, the African Academy of Sciences and the Wellcome Trust. It was formed in 2010 to facilitate modern research approaches into diseases on the African continent with the goal of improving the health of African populations. Led by African scientists,

the H3Africa Consortium currently consists of 51 research projects in 30 African countries to study the population-based genomics of NCDs (e.g. heart and renal disease) and infectious disease (e.g. tuberculosis). In addition to research coordination and funding, the programme also develops infrastructure, resources, training and ethical guidelines to support a sustainable African research enterprise.



3.3 Learning healthcare system

Summary: The learning healthcare system concept promotes ongoing system improvement across collaborator networks to reinforce targeted care delivery. It captures data at the clinical encounter for later holistic use to inform future practice and research. This ability to “learn” enables the development of focused precision medicine at lower costs, which is particularly beneficial for economically strapped counties.

“ Health systems have the opportunity to sidestep existing complexities, data interpretation challenges and other quality barriers in an ongoing system improvement model that: (1) captures data at the clinical encounter across participating sites; and (2) uses that data to inform ongoing clinical and community practice.

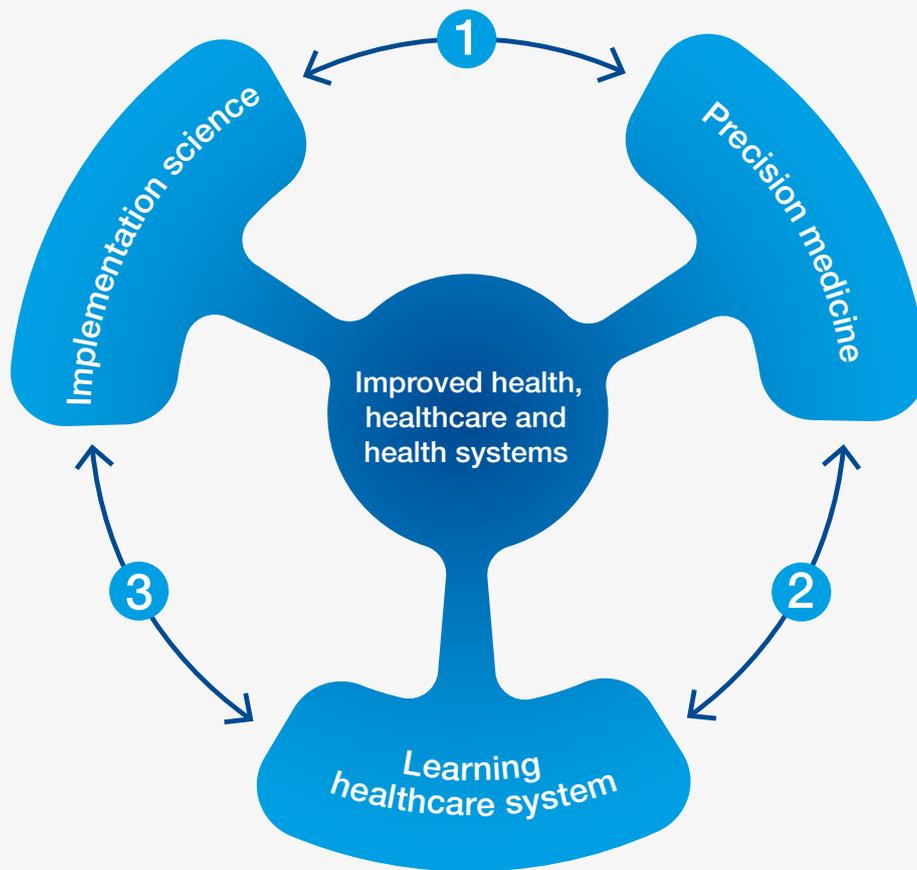
The learning healthcare system (LHS) concept was developed as a means of averting the traditional model of health innovation: intervention development, then efficacy and effectiveness studies, followed by health technology implementation. The learning healthcare system instead aims to provide more efficient and lower-cost means of healthcare delivery improvement via a method that gathers knowledge from many care delivery experiences across diverse medical practices and is engineered to promote continuous improvement. Here, health systems have the opportunity to sidestep existing complexities, data interpretation challenges and other quality barriers in an ongoing system improvement model that: (1) captures data at the clinical encounter across participating sites; and (2) uses that data to inform ongoing clinical and community practice.

In practice, this often manifests as a system linked by a common electronic health record (EHR) and shared databases, in which near real-time findings of precision medicine initiatives can be applied in clinical practice. Implementation science supports this system by providing evidence-based strategies (e.g. system-change interventions, training, supervision, quality-monitoring tools) for the purpose of integrating genomics and other precision medicine interventions into system practice. This complementarity of the LHS, implementation science and precision medicine is illustrated in Figure 9 below. The learning healthcare system concept is particularly beneficial for low-resource or financially constrained health systems, given that the ability to learn is less constrained by available fiscal space – notably, the combination of learning healthcare systems with open innovation may enable early stratified care delivery in disease areas traditionally requiring higher investment.

Case study – [American Society of Clinical Oncology \(ASCO\) CancerlinQ Database](#): The only non-profit, physician-led big data analytics platform for oncology in the United States, the CancerlinQ platform formalizes the learning healthcare system across its member network, spanning more than 100 oncology practices, by aggregating the ~1.5 million patient records from contributing member EHR into the de-identified CancerlinQ database. CancerlinQ then acts as both an academic and

research database in which participating physicians can use the data to inform clinical decisions and conduct further research. The CancerlinQ network consists of providers across the cancer care continuum (such as large institutions, community practices and academic medical centres) and enables members to both: (1) use insights from one of the largest oncology database for targeted care delivery; and (2) contribute to this larger pool of knowledge with data from their local EHR system.

FIGURE 9 | Contributions of implementation science, the learning healthcare system and precision medicine



Implementation science

Optimal integration of effective diagnosis, prevention, and treatment
 Understanding of multilevel context
 Theories and strategies to drive healthcare improvement

Precision medicine

Optimal use of genomics and behavioural data to drive clinical and patient decision-making
 Ongoing development of genomics evidence base
 Personalized and population impact

Learning healthcare systems

Use of ongoing data to drive health system improvement
 Focus on iterative and ongoing learning
 All stakeholders participate

Key areas of synergy

1

Evolution of evidence base for precision medicine and implementation science
 Recognition of underuse and overuse of interventions
 Management of abundance of data

2

Refresh cycle of evidence base
 Determination of degree of achievable personalization of care

3

Support for implementation of effective practices
 Contextually sensitive improvement of practices

Source: Adapted from data provided in Chambers, D.A., et al., "Convergence of Implementation Science, Precision Medicine, and the Learning Health Care System", *Journal of the American Medical Association*, 2016

4 Workforce and infrastructure

The broader health system, human capital and economic considerations necessary to support a precision medicine marketplace.



4.1 Foundational health systems strengthening

Summary: Aligned with the United Nations Sustainable Development Goal 3 (SDG3), overall health systems strengthening and the accompanied development of achievable decision-making steps (“effectors”) are critical to productive precision medicine. Policy-makers are encouraged to consider appropriate innovations relative to the available resources – basic family health history or cascade screening may be first steps for precision medicine.

“ Early adoption of precision medicine innovations may come from health systems strengthening and fundamental population health use cases.

The discussion of precision medicine innovation must take into broader consideration a country’s overall health system development. It must be restated that many precision medicine approaches are unproductive without accompanying achievable decision-making steps (“effectors”). These effectors enable the follow-through of precision approaches and can be illustrated through foundational health system factors such as having sufficient targeted therapy drug supplies or providers with proper technical education to interpret genomic risk profiles. Progress in general health systems strengthening is necessary for the continued and productive use of precision medicine tools as they advance.

Readiness for precision medicine innovation may vary greatly across a country’s range of health systems and is often linked to the foundational strength of such systems. Hence a further suggested benchmark is alignment with progress towards [the United Nations’ SDG3: Good Health and Well-being](#). The UN has defined 28 indicators as metrics for the 13 targets of SDG3, many of which are critical for precision medicine innovation. Notably, some of these indicators include “health

worker density”, “coverage of essential health services”, “development assistance to medical research and basic healthcare” and “availability of essential medicines”.

Early adoption of precision medicine innovations may come from health systems strengthening and fundamental population health use cases (often termed “precision public health”). These activities may include family health history considerations, cascade screening techniques and national health surveillance programmes in the form of patient registries. There is a need for governments to support locally relevant initiatives – e.g. understanding population-relevant genomic data – that present early steps for precision medicine alongside complementary health systems growth and resourcing. Financing health systems strengthening for precision medicine is further discussed in the “blended finance and the diagonal approach” section under the innovation financing topic. It is only as health systems establish the foundational “effectors” that further technology- or resource-dependent precision medicine use cases emerge in standard of care.

Case study – [Genome India Project \(GIP\)](#): In early 2020, the Indian Department of Biotechnology (DBT) launched the Genome India Project (GIP) with the goal of building an “Indian reference genome” through sequencing 10,000 citizens across India. With a budget of INR 23.8 billion (\$325,000), the DBT coordinates between the Centre for Brain Research at the Bengaluru-based Indian Institute of Science and 20 institutions that each collect patient samples and conduct their own research.

In clinical settings, the DBT has further started to establish diagnostic laboratories for genetic testing (subsequently added to coordinated biobanking efforts) and training programmes for personnel to set up more such laboratories. Through GIP, the DBT aims to unearth India’s genetic diversity across its various subpopulations while searching for novel genomic biomarkers predictive of priority diseases for clinical application.

4.2 Economic development

Summary: Policy instruments that reinforce economic growth and stability in the form of management, organizational and production capabilities support the precision medicine innovation ecosystem. Incipient innovation systems in LMICs may particularly benefit from capacity-building, personnel development and south-south collaboration initiatives.

The policy mix that governments adopt to support precision medicine approaches should aim to establish systems stability. These foundational instruments reinforce the management, organizational and production capabilities of an economy and strengthen the complementary public goods and services necessary for an innovation ecosystem.

While this section focuses on foundational economic development more applicable to LMIC settings, persistent market failures of precision medicine in higher-income countries also warrant novel policy considerations. The growth of common policy needs for an innovation ecosystem as a country’s development matures is illustrated in Figure 10.

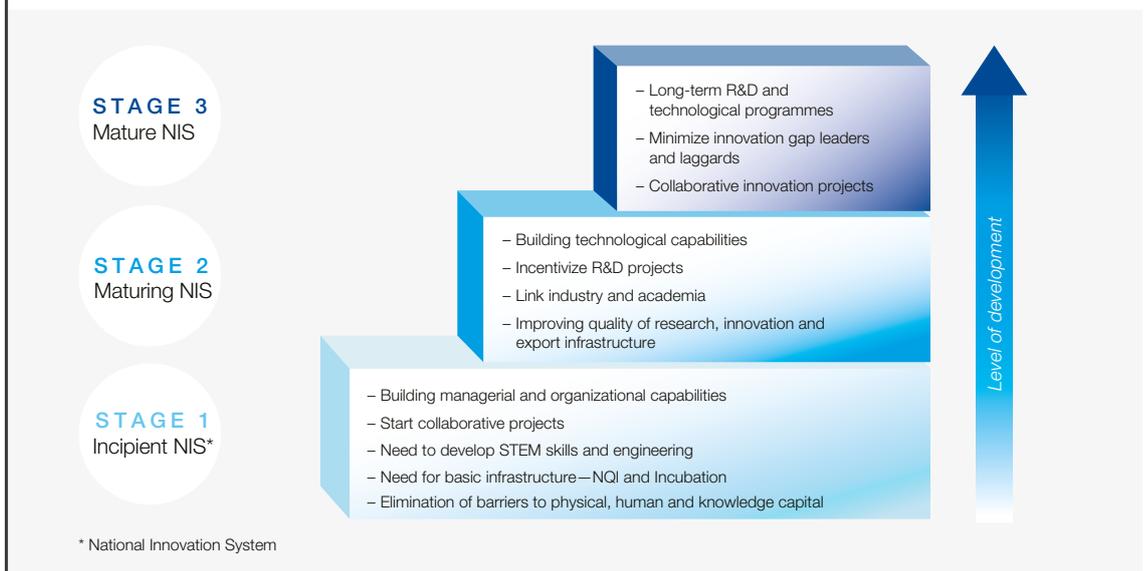
“ LMICs, which often have greenfield policy spaces, have a unique opportunity to create advanced initiatives customized to country needs, building on techniques and lessons learned from other countries implementing precision medicine.

One approach to benchmarking readiness is via progression on existing indices (e.g. the ease of doing business index or the corruption perceptions index) that measure broader sociopolitical and business environments. This may complement specific economic development considerations for precision medicine: (1) capacity building; (2) highly qualified personnel (HQP); and (3) south-south collaborations. The first metric pertains to the investment in innovation infrastructure (e.g. biobank facilities, laboratories and research equipment) and advisory services (e.g. knowledge transfer groups, precision medicine policy boards governing ethical, legal and social implications [ELSI]). On the second, there remains a shortage of HQP trained in precision medicine techniques and the use of genomic technologies. Workforce training – e.g. researchers, engineers, policy-makers and entrepreneurs – remains one of the largest gaps in LMICs. Human resource development plans and policies may spur precision medicine adoption:

[Health Education England \(HEE\)](#) provides a case study of how the National Health Service (NHS) accommodated precision medicine techniques via developing a genomics education and training programme for NHS professionals. Lastly, as the majority of precision medicine partnerships are in developed countries, promoting south-south collaborations (e.g. H3Africa) has strong potential to promote locally relevant and equitable developments in precision medicine.

LMICs, which often have greenfield policy spaces, have a unique opportunity to create advanced initiatives customized to country needs, building on techniques and lessons learned from other countries implementing precision medicine. Proactive policy development in important areas such as genomic data sharing or workforce training strategies are highly relevant, and should be considered in tandem with economic growth for maximum impact.

FIGURE 10 The Capabilities Escalator



Source: [The Innovation Paradox \(2017\)](#), p. 148.

4.3 Absorptive capacity

Summary: Incremental innovation remains the most prevalent form of precision medicine development – radical advances in this field remain isolated. Health ecosystems that are beginning to adopt precision medicine approaches may benefit by prioritizing absorptive capacity and shift to production-driven innovation as health systems and economic capabilities mature.

Precision medicine innovation often occurs incrementally, with radical technological advances being the exception. Incremental advances are characterized by a growing maturity of health systems care delivery and the long-term growth of R&D innovation projects. As such, the absorptive capacity of a country’s precision medicine ecosystem – its ability to transfer and adapt external knowledge, research or practice for use in a local context – aligns with this incremental approach to innovation. Global cooperation and net trade activity aim to support innovation in low- and high-resourced countries alike.

Given their characterization as net importers of such innovation, LMICs that do not have much experience with precision medicine may find challenges in attempting to immediately build a precision medicine innovation ecosystem. Many of the steps needed to address this gap are similar to those posited for overall economic development (e.g. building innovation infrastructure or knowledge transfer groups). By prioritizing absorptive capacity, LMICs are able to capture the benefits of net innovation imports of precision medicine technology while building internal country

capacity in knowledge transfer, skills development and genomics education training. In tandem with building foundational elements of economic activity, strengthening the absorptive capacity of firms acts to establish the incipient precision medicine innovation ecosystem in LMICs.

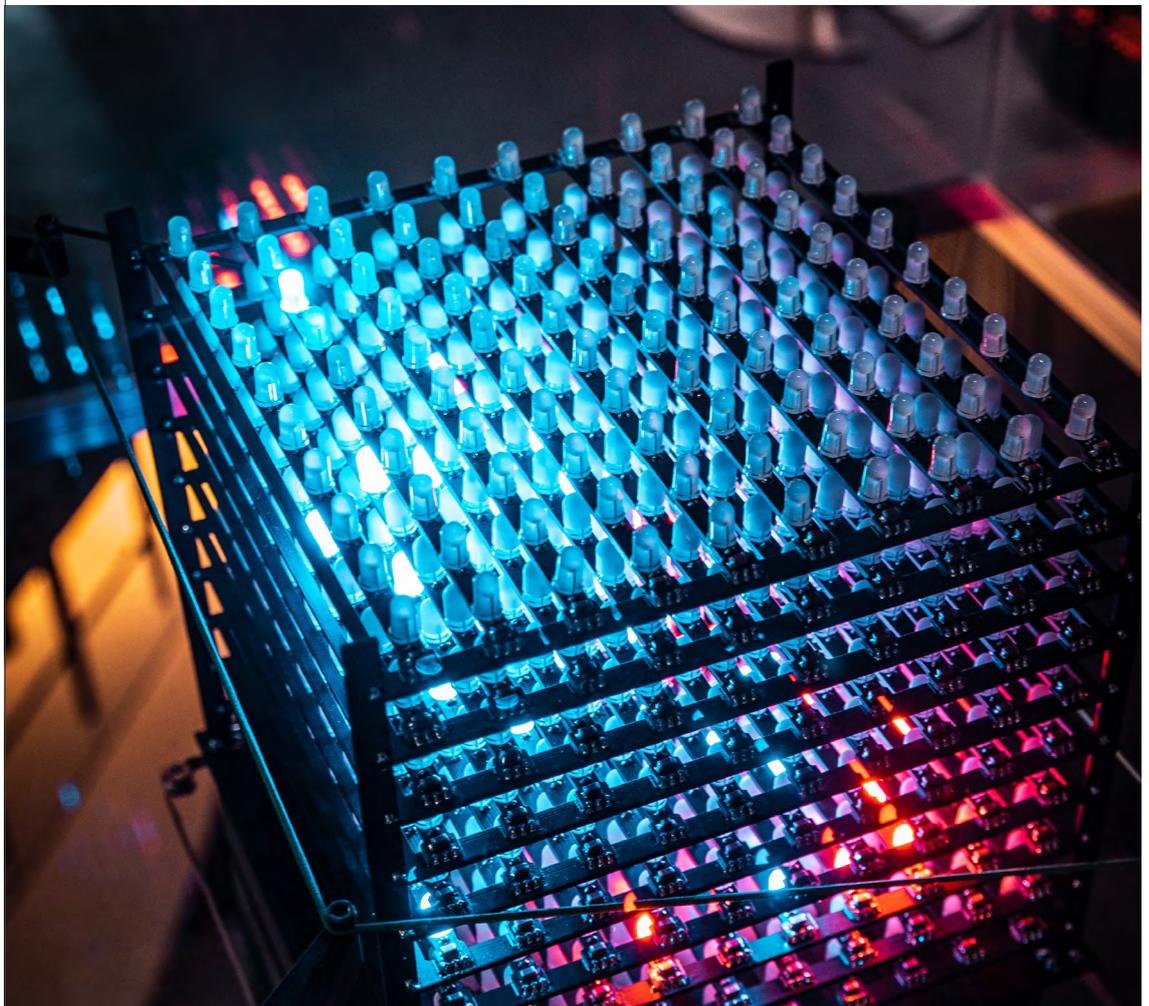
Countries with more developed precision medicine ecosystems may present a shift in their innovation ecosystem from absorption- to production-driven. When technological infrastructure and higher

research quality are more available alongside the corresponding growth in a trained workforce, countries can also begin to shift roles from a primary net importer of innovation to an export participant. By investing further in R&D capabilities and other innovation areas described in this white paper, such countries are likely to observe increasing numbers of partnership models, financing capabilities and governance frameworks that enable growing sophistication of their innovation ecosystem.



Gaps and future research areas

Traditional models leave gaps and barriers in terms of inspiring a more robust, equitable and beneficial innovation ecosystem.



While this white paper has identified many existing capabilities and benchmarks to drive innovation in precision medicine, new approaches are also required. Traditional models leave gaps and barriers in terms of inspiring a more robust, equitable and beneficial innovation ecosystem.

A selection of those are highlighted in the four categories below. Policy-makers, business leaders and others are encouraged to address these through creating “sandboxes” in which to test new approaches, iterating upon results and then scaling more broadly.

New financial and market incentive models

Encouraging private financing activity: Market incentive gaps in precision medicine pose high investment risks for private-sector actors. The current reliance on public funding and philanthropy dollars, with limited private capital, may slow or limit progress in the initial phases of precision medicine deployment, and may also contribute to funding gaps that hinder the scaling of precision medicine within a country. LMICs are most affected by the need for new market models to drive private financing.

Expanding beyond IP policy: Clear IP policy acts as a market incentive for innovators, but these policies alone may be insufficient in LMICs. There is a need for novel pull incentives from government and financiers alike to fill the IP incentive gap. Research is encouraged to explore other governance responsibilities, financial mechanisms and multistakeholder partnerships that may encourage market activity for precision medicine innovators.

Value assessment of innovations

Developing value-based care partnership models: The coverage and reimbursement gap persists globally, given the insufficient data on precision medicine value-add and payment uncertainty. Further incentive alignment is encouraged between payer, provider, patient and producer stakeholders to form appropriate partnerships that share risk and recognize the value of precision medicine.

Measuring and pricing innovation: Gaps in monitoring and evaluation lead to a lack of data on precision medicine value-add in relation to the current standard of care approaches, and existing value-oriented pricing models may have connotations of unaffordability, particularly in less resourced health systems. Research is encouraged to understand the role of novel innovations such as payer-guided modelling studies or managed entry agreements in value-based contracts.

Global collaboration

Strengthening south-south collaborations: Further research is needed on the potential of regional innovation hubs and large-scale collaborations in LMICs. Greater understanding of the scalability and replicability of existing partnerships (e.g. H3Africa) may inform relevant leapfrogging efforts in LMICs previously uncertain of precision medicine adoption.

Establishing optimal partnership structures: Developed and emerging economies alike may benefit from established groundwork on the assets and liabilities of various collaboration models between north and south countries. Further investigation is encouraged to establish optimal alliance structures between laboratories, funding agencies and other respective stakeholders.

Implementation research

Understanding the precision medicine theory of change: Research is encouraged to understand how thought leadership consensus is built for novel precision medicine innovations, and how it is subsequently promulgated across professionals throughout the health system and wider country for adoption. Additionally, as some novel operating and behavioural innovation models for precision medicine are currently limited to developed countries, further research is encouraged on how the absorptive capacity of LMIC health systems may translate similar innovations.

Studying how precision medicine affects the patient journey: The patient journey through presentation to diagnosis and treatment to follow-up care differs widely from provider to provider within one country and culture, and even more so across different countries and cultures. Mapping out how the patient journey is changed or improved by precision medicine and establishing standards to guide providers in adjusting the patient journey would be valuable both as research and guidance.

Conclusion

This white paper has explored the methods and capabilities by which countries can address the sustainable financing, market structure and strategic partnerships needed to build a precision medicine innovation ecosystem. Applying the approaches described, adapted to the needs of individual health ecosystems, can spur the innovation and investment necessary to grow and sustain precision medicine in a variety of health ecosystems. It must be remembered, however, that this is a pillar of

the Precision Medicine Readiness Principles, and building an innovation ecosystem must be pursued in the context of the other pillars. It is hoped that this white paper, and the projects or initiatives inspired by it, informs the development of guidelines, partnerships and new approaches to investment in precision medicine and, ultimately, supports healthcare systems to adopt the most scientifically and technologically appropriate approaches to precision medicine.



Appendix

TABLE 2 Innovation ecosystem quick reference

Policy-makers and others looking to advance precision medicine in their countries can: (1) find maturity assessment benchmarks for readiness; and (2) identify potential steps forward to implementation. Policy-makers can ask themselves the questions under the Benchmark/capabilities column to quickly identify their state of readiness for that particular capability.

Innovation ecosystem topic	Benchmark/capabilities	Steps for implementation
Innovation governance		
National strategic plan	<ul style="list-style-type: none"> – Does a national strategic plan exist? – Are public entities aware of or involved in precision medicine initiatives? – Is there a focus on preventative care, particularly for NCDs? 	<ul style="list-style-type: none"> – Prioritize precision medicine approaches addressing relevant local disease burden – Identify prime implementation metrics and priority areas for innovation Ensure public backing from ministry of health
Open science principles	<ul style="list-style-type: none"> – To what extent are the GO FAIR principles followed? – What data exchange standards exist? – Are there consent and privacy processes? – How are open science principles balanced with IP ownership regulations? 	<ul style="list-style-type: none"> – Design opt-in incentives to participate in open science – Set a precedent for centralized biorepositories – Establish ethics committee to govern data sharing and use policy
IP ownership and benefit sharing	<ul style="list-style-type: none"> – Are there clear patent law decisions regarding precision medicine technologies? – Is there equitable participation in international genomic projects? 	<ul style="list-style-type: none"> – Identify the strength of IP protection to encourage innovation – Consider other capabilities to fill the potential IP pull incentive gap
Market approval process HTA	<ul style="list-style-type: none"> – Do health technology assessment (HTA) groups recognize how to appropriately appraise precision medicine technologies? 	<ul style="list-style-type: none"> – Refine relevant components of HTA to account for complexities in accurately evaluating precision medicine innovations



Innovation financing		
Public funding/fiscal space usage	<ul style="list-style-type: none"> – Is there a volume of public budgetary allocation available for precision medicine initiatives? – Are there a diverse set of investment partners? – Is there a relative mix of public and private funders for precision medicine? 	<ul style="list-style-type: none"> – Ensure long-term focus on macroeconomic growth, budget reprioritization and efficiency improvements, which may expand fiscal space
Private-sector financial backing	<ul style="list-style-type: none"> – Can private stakeholders participate and fund projects? 	<ul style="list-style-type: none"> – Conduct a stakeholder analysis of relevant private actors in order to map potential collaboration opportunities and current funding gaps in the precision medicine marketplace
Blended finance and the diagonal approach	<ul style="list-style-type: none"> – Are foundational health system effectors in place for precision medicine approaches to be useful? 	<ul style="list-style-type: none"> – Ensure diagonal approach to finance overall health system strengthening alongside precision medicine – Consider blended finance instruments
Reimbursement conditions and coverage models	<ul style="list-style-type: none"> – Are we shifting away from out-of-pocket payment models? – Are we using sustainable contracts? 	<ul style="list-style-type: none"> – Aim for risk-sharing partnerships among stakeholders – Consider value-based reimbursement contracts and alternative payment models (APMs)
Value-based care instruments	<ul style="list-style-type: none"> – Is there experimentation and wider use of value-based care approaches? – Is real-world evidence used in analysing the benefits of precision medicine? 	<ul style="list-style-type: none"> – Set up evidence-based modelling studies in partnership with payer stakeholders – Consider managed entry agreements such as performance-based risk-sharing agreements or coverage with evidence development

Community and partnerships		
University-industry collaboration	<ul style="list-style-type: none"> – Is translation research keeping up with basic science? – What is the volume and quality of university-industry collaborations for translation? 	<ul style="list-style-type: none"> – Promote internal environments that support precision medicine R&D and commercialization – Establish industry collaboration policies and technology transfer offices
Entrepreneurship, research and innovation hubs	<ul style="list-style-type: none"> – Are our existing innovation centres productive? – Does precision medicine have a spot in ongoing R&D activities? 	<ul style="list-style-type: none"> – Encourage policy instruments that support cluster initiative operations and entrepreneurial development programmes, such as incubators and accelerators
Learning healthcare system	<ul style="list-style-type: none"> – Are our electronic health records linked to research databases? – Are there opportunities to participate in shared health system projects and learn iteratively from care data? 	<ul style="list-style-type: none"> – Ensure implementation science initiatives

Workforce and infrastructure		
Foundational health systems strengthening	<ul style="list-style-type: none"> - Are we making progress on SDG 3? - Are we implementing precision public health? 	<ul style="list-style-type: none"> - Take into account basic family health history considerations - Conduct cascade screening - Compile patient registries as part of health surveillance programmes
Economic development	<ul style="list-style-type: none"> - Are there existing indices on the sociopolitical and business environment? - What is the number of highly qualified personnel trained in precision medicine? - What is the extent of relevant innovation infrastructure? 	<ul style="list-style-type: none"> - Ensure policy instruments that reinforce economic growth and stability (e.g. management, organizational and production capabilities) - Promote south-south collaborations - Develop human resource development plants
Absorptive capacity	<ul style="list-style-type: none"> - Is there a relative prioritization of absorption-driven and productive-driven innovation? 	<ul style="list-style-type: none"> - Identify existing capabilities and prioritize relevant methods of innovation

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Contributors

Lead Author

Hoyt Gong

The Roy and Diana Vagelos Program in Life Sciences & Management, The Wharton School, University of Pennsylvania, USA; Research Fellow, World Economic Forum

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Delali Attiogbe Attipoe

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President and Chief Executive Officer, BIO Ventures for Global Health

Katherine Dunn

Associate Advisor, Intermountain Healthcare

Joseph Hargan-Calvopiña

Associate Director, BIO Ventures for Global Health

Chandresh Harjivan

Partner and Managing Director, Boston Consulting Group

Ragan Hart

Director of Operations and Business Development, MDisrupt; Founding Partner, Evergreen Value Advisory

Amy Israel

Vice-President and Global Head of Oncology Policy and Healthcare Systems, Novartis

Oliver Keown

Director, Intuitive Ventures

Catalina Lopez-Correa

Executive Director, Canadian COVID Genomics Network (CanCOGeN) with Genome Canada

Gillian Marcelle

Managing Member, Resilience Capital Ventures

Surakameth Mahasirimongkol

Director, Genomic Medicine and Innovation Support Division, Department of Medical Sciences, Thailand Ministry of Public Health

Lisa Ooi

Vice-President, Singapore Economic Development Board

Laura K. Povlich

Program Officer, Fogarty International Center, National Institutes of Health

Elissa Pritchep

Lead, Shaping the Future of Health and Healthcare, World Economic Forum

Daryl Pritchard

Senior Vice-President, Science Policy, Personalized Medicine Coalition

Stephen Sammut

Lecturer, The Wharton School; Chair, Industry Advisory Board of Alta Semper Capital

Sheri Schully

Acting Chief Medical Officer, All of Us Initiative, National Institutes of Health

Bartholomew (B.A.) Sillah

Managing Partner, Kola Global Advisors

Casimir Starsiak III

General Manager, Project Baseline, Verily Life Sciences

Patrick Tan

Executive Director, Precision Health Research, Singapore (PRECISE)

Andrew Trister

Deputy Director, Digital Health and Innovation, Bill & Melinda Gates Foundation

Meredith Van Natta

Assistant Professor of Sociology, University of California Merced

Luis Wyss

Graduate student in Bioinformatics, ETH Zürich

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World Economic Forum
91–93 route de la Capite
CH-1223 Cologny/Geneva
Switzerland

Tel.: +41 (0) 22 869 1212
Fax: +41 (0) 22 786 2744
contact@weforum.org
www.weforum.org