BROOKINGS

Report

Advancing precision medicine through agile governance

Bridging innovation and regulation for the greater good

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Summary

The convergence of Fourth Industrial Revolution technologies, including genome editing and artificial intelligence, are revolutionizing modern medicine. At the nexus of these tools sits the emerging field of precision medicine, an area of immense potential which is increasingly attracting attention. Precision medicine uses personal information, such as DNA sequences, to prevent, diagnose, or treat disease. From targeting late-stage cancers to curing rare genetic diseases, precision medicine is poised to impact millions of people within the next decade. Despite such promise, this form of healthcare is not without unique challenges. Data storage and tracking, inefficient regulatory processes, and complex supply-chains all create barriers and bottlenecks that hamper the equitable delivery of precision medicine to society. Governments aiming to integrate precision medicine into their healthcare systems must find a way of overcoming technological, ethical, and legal challenges. Fortunately, an agile governance approach offers essential tools and processes capable of promoting technology innovation while safeguarding the public from unintended consequences.

This report builds on the "A blueprint for technology governance in the post-pandemic world" by Landry Signé and Steven Almond and on governance work from the World Economic Forum.[1] We describe the process of precision medicine, from basic research to patient care, highlighting key challenges along the way, and describe the role agile governance can play in overcoming these challenges. Next, we provide global case studies highlighting how governments, companies, and other stakeholders are using agile governance processes to prepare their countries and industries for precision medicine.

Introduction

Unmet medical needs and inefficiencies drive healthcare innovation with the goal of protecting and promoting health for individuals and society at large. Leveraging the latest technologies to improve treatment regimens, store patient data, and track outcomes is essential for a country to reach their healthcare goals amidst changing environmental, economic, and social conditions. While traditional governance and oversight mechanisms, like federal health agencies and clinical trial testing, can successfully regulate and monitor advancements in healthcare, additional processes, collectively referred to as "agile governance," play a vital role in helping governments keep pace with emerging technologies while serving the greater good. Agile governance, as defined by the World Economic Forum, "calls for a multistakeholder effort, in which the public and private sectors collaborate to develop forward-thinking solutions to encourage industry growth, while addressing the concerns of a fast-paced digital world."[2] Agile governance also ensures accountability through human-centric processes designed for the benefit of citizens.[3]

Precision medicine is an approach to healthcare that uses personal information, including genetic, environmental, and lifestyle data, to improve the prevention, diagnosis, and treatment of disease. Alongside the positive

potential of precision medicine exists concerns of data-sharing, patient privacy, and equitable access to treatments. The enormous potential and rapid pace of innovation, paired with anticipated risks and unintended consequences, makes precision medicine an ideal technology area for agile governance.

The COVID-19 pandemic demonstrated the necessity for governments to coordinate and adapt quickly, using all available technologies to protect the health and well-being of citizens. The rapid design, testing, and manufacturing of mRNA vaccines showcased the incredible impact of biotech innovation, while coincidingly revealing the unfortunate reality of slow international coordination and poor global distribution.[4] [5] To address these problems, cross-jurisdictional partnerships, such as those formed between local health departments for COVID-19 contact tracing, and public-private partnerships, which are actively forming to accelerate the production and distribution of vaccines in low- and middle-income countries, are two ways governments can improve coordination and accelerate pandemic responses.[6] [7]

The COVID-19 pandemic exemplified the tensions and difficulties that arise when developing and disseminating technologies designed to address issues in human health – learnings that can be applied to precision medicine. Precision medicine would benefit from agile governance processes to improve government coordination, leverage public-private partnerships, and actualize the potential of personalized healthcare without further exacerbating health inequity.

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This analysis is the first of its kind and aims to address the role that agile governance can play in advancing the opportunities presented by precision medicine. It will start by defining agile governance, its role as part of the Fourth Industrial Revolution, and the seven pillars on which it can provide a blueprint for regulators. Next, it will identify the unique value gains and critical technological, ethical, and policy challenges of precision medicine. Then it will present global case studies to show how governments, companies, and other stakeholders are capitalizing on agile governance processes related to healthcare with implications for precision medicine. The report will conclude with implementation measures that can help to turn learnings into practices.

The Role of Agile Governance

The disruptive nature of the Fourth Industrial Revolution has accelerated the necessity of agile governance in policy-making. In 2001, 17 software developers drafted an Agile Manifesto in Silicon Valley, systematizing evolving practices of the 1990s and conceptualizing the notion of agility between sponsors, developers, and users.[8] The notion of Agile Governance has since been adapted for the public sector and policy-making processes by the World Economic Forum.[9] [10] Policy-makers and governments have the opportunity

to capitalize on the expertise of the private sector and academia, to work alongside technology researchers and developers. Single jurisdictions are becoming a thing of the past as new standards, norms, and policies defy borders. For example, the recent Agile Nations agreement between Canada, Denmark, Italy, Japan, Singapore, UAR, and U.K. aims to foster multi-jurisdictional cooperation by "helping innovators navigate each country's rules, test new ideas with regulators and scale them across the seven markets."[11] Similarly, the Global Financial Innovation Network (GFIN), composed of over 60 organizations, was established to help firms "test innovative products, services or business models across more than one jurisdiction."[12]

According to Signé and Almond (2021), agile governance is enhancing how regulators respond to the emergence of new technologies, helping to address the fast pace of technology development and discoordination between regulators.[13] Put simply, the World Economic Forum defines agile governance as "*adaptive, human-centered, inclusive and sustainable policy-making*, which acknowledges that policy development is no longer limited to governments but rather is an increasingly multistakeholder effort. It is the continual readiness to rapidly navigate change, proactively or reactively embrace change and learn from change, while contributing to actual or perceived end-user value."[14] Governments are using agile governance processes across many technology sectors. For example, Sweden created opportunities for companies to test autonomous vehicles without requesting any changes to national or EU laws.[15] The U.K. government launched Project Innovate to support financial technologies by facilitating testing with real consumers and improving communication with regulators.[16]

In "A blueprint for technology governance in the post-pandemic world," Landry Signé and Steven Almond provide seven pillars (processes) constituting a blueprint for regulators seeking to respond effectively and efficiently to

technological innovation worldwide (see Table 1 below).[17] They explicitly address how an adaptive, collaborative approach to governance is required in the era of the Fourth Industrial Revolution.[18]

1. **Anticipate innovation and its implications.** Regulators who can employ foresight mechanisms will be better able to capitalize on opportunities that new technologies create while mitigating the risks. The goal is to recognize new opportunities or threats while enabling regulators the requisite time to take action and address them. The aim is not to stifle innovation but to be prepared for what the future may look like through gathered insights.
2. **Focus regulations on outcomes.** Governments, including Denmark, Japan, and the U.K., focus on prescriptive processes to hone in on achieved results. This promotes innovation by allowing businesses to achieve regulatory goals in the most efficient ways, while still complying to guidelines. Flexibility is vital, and regulatory guidance can be used as a means to promote innovation.
3. **Create space to experiment.** The idea behind this pillar is that regulation should not be written in isolation but instead developed in conjunction with the technology it ultimately seeks to regulate. The goal, therefore, is to endure better outcomes with the proper mechanisms in place.
4. **Use data to target interventions.** Currently, data can be gathered and analyzed in countless ways. This allows for more finely targeted regulatory interventions that grant businesses greater flexibility to innovate, as regulators can rapidly intervene through data-driven technologies.
5. **Leverage the role of business.** Regulators need to harness the role that the private sector can play in the governance of innovation. Industry-led governance mechanisms can convey policy objectives faster and can manage risks from technological innovation more efficiently.

6. **Work across institutional boundaries.** New technological innovations often stretch across sectors and institutions, making it hard for businesses to innovate. Therefore, a more localized "one-stop-shop" is being introduced by governments to help companies to engage more directly with national regulators.[19]
7. **Collaborate internationally.** Cooperating across borders allows regulators to address shared challenges, share foresight, experiment jointly, and facilitate trade and investment more efficiently. This type of collaboration can create plurilateral alliances that have already emerged in fintech.

Creating a more agile system of governance requires the ability to work around existing governance structures, change the policy-making system itself, reform institutions, and change how decisions are made and who makes them. Fortunately, governments have a suite of tools designed to address these obstacles, which can be individually deployed or used in combination (see Table 2 below).[20] The first tool is policy labs, which offer an approach that can aid in the adoption of new policy techniques catered to government bodies through the use of data analytics and digital tools. Regulatory sandboxes can be used to foster safe spaces for businesses to innovate outside the realm of typical regulatory hurdles. Increasing agility through technology, which can generate agile, distributed, and transparent processes (examples including Sweden and autonomous vehicles, Bahrain and financial technologies, and energy innovation[21]). Promoting governance innovation can help make innovation manageable among different government institutions. Crowdsourced policy-making can increase trust among governments and citizens to engage people, improve policies, and foster transparency. Promoting collaboration between regulators and innovators aims to decrease the time between the idea stage and getting the innovation to market. Public-private data sharing can help to create more accurate and rapid systems for governance decision-making. Direct representation in governance fosters public communication and participation in technological innovations. The

expansion of governance beyond the realm of just the government will also play a vital role in the successful implementation of a more agile governance model.

Applying agile governance processes can follow two unique methods designed to achieve a more adaptive and coordinated approach to regulation in healthcare.[22] A "design method" can identify and address problems as they arise- for example, adjusting clinical trial design during a global pandemic. In contrast, a "system method" takes into account the whole system and addresses foundational problems. It can create robust frameworks that can solve multiple issues – for example, establishing cross-national systems between regulatory bodies to more quickly and efficiently approve personalized therapies.

Countries looking to leverage agile governance process to help integrate precision medicine in their healthcare systems must begin by understanding the unique challenges posed by genomics-based medicine. The next section will cover the precision medicine "pipeline," from population-level genome sequencing to personalized therapeutic delivery, and the related technical, ethical, and policy challenges along the way.

Precision Medicine and Its Unique Challenges

Global incidences of cancer, neurodegenerative diseases, and cardiovascular diseases are on the rise. By 2040, the global cancer burden is expected to reach 28.4 million, a 47% increase from 2020.[23] In 2017, the estimated economic burden of cancer in the U.S. was almost $350 billion (in U.S. dollars).[24] As populations continue to age, the prevalence of neurological disorders sharply increases, while cardiovascular disease incidence has risen to account for one third (over 18 million) of all deaths globally in 2019.[25] [26] These trends are

prompting governments, including the U.S., China, and EU to look to precision medicine as a promising approach for addressing these pressing public health challenges.[27] [28] [29]

Precision medicine uses a combination of genetic, environmental, and lifestyle information to prevent, diagnose, or treat disease. This approach to healthcare is a shift from the current one-size-fits-all medical model, which focuses on the "average" patient rather than selecting or creating a treatment based on the individual. For example, analyzing the DNA of a cancer patient's tumor cells can guide a doctor towards the most effective treatment option, while avoiding drugs or surgeries that would waste time and resources.[30] The potential of precision medicine is forcing countries to evaluate the future of their healthcare systems and better position themselves to support this type of innovation.

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Over the last decade, at least 14 countries have voluntarily and independently launched national genomic-medicine initiatives, collectively investing billions of U.S. dollars across government, academic, and private research and infrastructure development (see Table 3 below).[31] These large-scale programs, which use different data use policies and participant enrollment plans, aim to gather personal genetic and demographic information from thousands or even millions of citizens.[32] [33] [34] If successful, these initiatives will help improve

the integration of genomics into healthcare systems, yet it remain to be seen whether these large nation-wide projects will lead to significant industry-shifting outputs, particularly for precision medicine.

Precision medicine is not yet a common route for disease diagnosis and treatment, an unfortunate reality for those confronted with cancer, rare genetic disorders, or neurodegenerative diseases.[35] [36] [37] Addressing the hurdles preventing precision medicine from entering the clinic requires a critical examination of the precision medicine "pipeline" (see Table 4 below). Roughly segmenting this pipeline into four stages helps expose unique challenges that may impair a country's ability to ethically innovate and equitably deploy precision medicine. These stages were created for the purpose of this report, as a means to critically examine the full spectrum of activities that constitute precision medicine.

- Data acquisition and storage
- Information access and research
- Clinical trials and commercialization
- Societal benefit

Not all stages may be relevant to every country due to limited medical infrastructure, healthcare policy, and private sector activity. Regardless, countries should consider aspects of each stage as they aspire to integrate precision medicine into their healthcare systems. Overcoming precision medicine's unique challenges and successfully delivering on its promise will require agile governance and processes that promote scientific innovation while improving enhanced healthcare delivery. This report covers the benefits and tools of agile governance, but before suggesting a solution we must further examine the problem.

Data acquisition and storage

Big data forms the foundation of precision medicine. Deciphering the root causes of complex or rare diseases requires large amounts of genetic, demographic, and other personal information. This data may be voluntarily given to private companies or collected for a clinical trial or by a regulator like a federal government. Obtaining this information from diverse cohorts, including underrepresented minority groups, raises concerns of data ownership and privacy.[38] For example, the All of Us research program, led by the U.S.'s National Institutes of Health, aims to sequence the genomes of 1 million citizens to advance the country's precision medicine goals. To date, over 770 verified and approved researchers have gained access to de-identified participant data, and over 570 research projects have been launched.[39] Concerns by indigenous communities over participant consent and data acquisition prompted a two-year consultation process with tribal leaders, leading to a list of NIH commitments, including respect for tribal sovereignty and commitments to data protection.[40] [41]

Once acquired, DNA sequencing data is stored in a wide variety of formats across thousands of online repositories, ranging from small academic databases to large repositories controlled by companies like 23&Me. Policy differences and legal constraints can inhibit movement and storage of data across jurisdictions. Additionally, variability in formatting and nomenclature can make it difficult to merge data across repositories and integrate files with electronic health records (EHR).[42] Storing genomic information and merging that data to a patient's EHR requires infrastructure and expertise, investments that have been shown to deter healthcare providers in the U.S. from adopting precision medicine technologies and programs.[43]

Information access and research

Access to the aforementioned personal data by researchers helps drives innovation and supports ambitious corporate and public projects. While some repositories make their data freely available, others are restrictive, like

Genomics England in London, limiting access to select institutions.[44] [45] Determining who, how, and when someone can access data significantly impacts health innovation, but maintaining a level of oversight and protection is necessary to ensure privacy, appropriate use, and security.[46] For example, the Global Alliance for Genomics and Health is developing frameworks for the responsible sharing of genomic and clinical data internationally to improve precision medicine and cancer research.[47] Appropriate use and authorization of biological specimens and health data is not always made clear to donors or explicit under legal codes. For example, newborn screening (or "Guthrie") cards provide early identification of genetic disorders, but controversies within the EU, U.S., and Australia revealed ambiguity over ownership and secondary uses of these cards.[48]

Precision medicine research can take on many forms, including DNA sequencing to identify new disease-causing mutations or testing drug efficacy based on a person's genetic makeup. This research may occur in academic labs or for-profit industry settings, a line that can sometimes blur, complicating the use, transfer, and ownership of data.[49] Data regulations and research review processes vary across healthcare organizations, direct-to-consumer (DTC) companies and other entities collecting human health data, creating incongruence when data is shared for research purposes and may not be transparent to individuals providing their personal information. For example, in a 2016 survey, 67% of DTC genetic testing companies provided insufficient information about how a customer's genomic data would be used.[50]

Clinical trials and commercialization

While most clinical trials involving precision medicine treatments follow conventional safety and efficacy testing, some precision medicine treatments, specifically for rare diseases, present unique difficulties for regulatory agencies. Precision medicine treatments pose considerable promise for patients with rare diseases, like sickle cell disease or muscular dystrophy, due

to an ability to make targeted changes to a person's genome.[51] [52] For certain rare diseases, conventional large-scale, placebo-based clinical trials do not work on small patient populations, requiring a new approach to evaluating short- and long-term safety, efficacy, durability of precision medicine treatments.[53] For example, a promising precision medicine cure for patients with progeria, a rare genetic disease impacting 400 people worldwide, is leading researchers and regulators to design a clinical trial that can evaluate the long-term efficacy of this treatment using only a small patient sample size.[54] Groups like the International Rare Diseases Research Consortium (IRDiRC) and the Privacy-Preserving Record Linkage (PPRL) Task Force are creating standards and processes to improve international data sharing and enable global harmonization of data sharing to facilitate research from diverse clinical sites.[55]

Once precision medicine therapies make their way through regulatory approval, processes which can vary across countries, companies must find ways to bring their products into the market. The individualized nature of precision medicine products, such as cell and gene therapies, creates unique commercialization hurdles, particularly in the supply chain pipeline.[56] Scaling the production of complex biological molecules, managing the transportation of living cells, and standardizing manufacturing across different facilities present challenges for introducing precision medicine into the clinic.[57] Companies and regulators are exploring ways to "decentralize" manufacturing of cell and gene therapies to streamline and safeguard the production and movement of custom molecules and human cells.[58]

Societal benefit

Patients are at the center of precision medicine innovation, but sometimes the end product does not make its way to those who could most benefit. For example, cell and gene therapies are some of the most expensive treatments in

the world, costing millions of dollars.[59] Zolgensma, a gene therapy for a rare nerve disease, costs $2.1 million for a single dose.[60] The high cost of these life-saving treatments are forcing insurers, hospitals, manufacturers, and governments to experiment with payment models.[61]

The complexity and potential risk of precision medicine therapies means that a limited number of hospitals have the necessary equipment and trained personnel to carry out these procedures Often times these are academic medical centers or top-tier hospitals in metropolitan areas.[62] Expanding the benefits of precision medicine beyond major health centers in and into lower-resourced areas means training a new workforce and investing in healthcare infrastructure. Achieving "equitable" access to precision medicine means that insurance coverage, geographic location, and other factors don't inhibit an individual's ability to receive a diagnosis or treatment. Efforts like those of the Bill and Melinda Gates Foundation, U.S.'s National Institute of Health, and pharmaceutical company Novartis to bring precision medicine treatments for HIV and sickle cell disease to Africa countries are examples of equitably delivering the benefits of precision medicine to patients with unmet medical needs.[63] [64]

Agile Processes for Precision Medicine

Critical examination of the precision medicine pipeline, from data acquisition to therapeutic delivery, exposes bottlenecks and hurdles that may limit or prevent a country's capacity to develop and deploy precision medicine within their healthcare system. While conventional governance frameworks, such as the EU's General Data Protection Regulation, may be sufficient to safely guide precision medicine advancements, agile governance processes offer additional ways to approach regulation that simultaneously protects citizens while also promoting technological innovation.[65]

The following section covers the seven pillars of agile governance, describing how they apply to various stages of the precision medicine pipeline. Examples of current initiatives and programs, covering different regions of the world, are then provided to highlight ways in which governments and innovators are leveraging agile governance processes to advance precision medicine for the public good. Many of these examples are not solely constrained to precision medicine, but may also apply to other facets of healthcare.

Anticipate innovation and its implications

Although precision medicine holds considerable promise for treating previously incurable diseases, governments must consider its full spectrum of uses and implications to maximize benefits while minimizing undue risk. Strategic foresight and Horizon Scanning helps regulators proactively set policy that promotes innovation while safeguarding society from unintended consequences by identifying new opportunities and challenges, and stress-testing existing or proposed strategies.[66] [67] The impact of precision medicine, from entire healthcare systems to individual data privacy, is uncertain, especially as this area continues to combine multiple emerging technologies, including AI. Given this uncertainty, governments are using anticipatory governance processes to consider both the short- and long-term implications of precision medicine on individual and society-levels.

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The high costs of select precision medicine treatments, including cell and gene therapies, are forcing countries to critically examine the potential impact these breakthrough treatments will have on their healthcare systems. To this end, Singapore's Ministry of Health setup the Agency for Care Effectiveness, which launched a horizon scanning system (HSS) in 2019 to identify emerging technologies and predict their impact on patient health and costs to society and Singapore's healthcare system.[68] The first application of Singapore's HSS was on cell and gene therapies, helping to inform advanced planning, allocation of resources, and funding policies. Horizon scanning for healthcare decision making has evolved into a useful tool used by other countries, including Australia, United States, Brazil, Canada, South Korea, and the United Kingdom.[69]

Compared to the relatively short- to mid-term forecasting of Singapore's HSS, the U.K.'s Human Fertilisation & Embryology Authority is anticipating the long-term use of precision medicine technology in human reproduction.[70] Their Horizon Scanning Meetings bring together international experts and regulatory bodies to discuss advancements in genome editing and other technologies that may one day find their way into fertility clinics. For example, foresight exercises would help the U.K. examine how embryo engineering in China may impact global trends in reproductive technology.[71] Staying ahead of the technological innovation gives the U.K. government time to consider the legal, ethical, and scientific implications of an application of precision medicine with broader societal-level implications.

Focus regulations on outcomes

The COVID-19 pandemic provided a global case study in regulatory agility, demonstrating the need for reflexive processes that focus on outcomes. Countries reacted to the urgency of the pandemic by accelerating the testing and emergency use authorization of COVID-19 vaccines and therapeutics through approaches collaboratively designed by regulators, scientists, and

industry members. For example, the FDA established the Coronavirus Treatment Acceleration Program (CTAP) designed to speed up the testing, approval, and delivery of effective therapies to patients.[72] The vaccines were given "emergency use authorization," eventually requiring more data before receiving full approval. The EU fast-tracked vaccine development by temporarily suspending certain clinical trial restrictions, recognizing the need to adapt rules in favor of essential outcomes.[73] Within these agile processes, vaccines were still appropriately tested for safety and efficacy.

Lessons learned during COVID-19 can feed into the post-pandemic world of precision medicine. The pandemic disrupted the regulatory approval personalized therapeutics, including cell and gene therapies. Normally, regulatory agencies perform surveillance and preapproval inspections of biopharmaceutical facilities, evaluating manufacturing and other critical processes, but the pandemic hindered regulators' ability to perform in-person inspections. With a focus on outcomes over processes, the FDA is considering virtual inspections, which would minimize delays of future approvals and allow simultaneous inspections by multiple agencies at once.[74]

Create space to experiment

Creating spaces and opportunities for experimentation in business, finance, and law will help countries as they begin integrating precision medicine into their unique healthcare systems. Given the variability of these systems across jurisdictions, countries must test solutions that fit their legal, political, and cultural context. Two primary areas of experimentation include regulation and payment models.

Once therapies make their through regulatory approval and reach market, payers and providers must negotiate how to bring these treatments to patients. Rather than paying for volume, healthcare systems are looking to pay for value, which requires new payment and financing models. The U.S.'s Center for Medicare and Medicaid Innovation (CMMI) Center tests innovative

healthcare payment and service delivery models across different states, recognizing that each community may require a different solution.[75] One example is their State Innovation Models Initiative, which partners with states, providing hundreds of millions of dollars, to develop and implement innovative healthcare payment and delivery models. The federal government provides the funding, learning tools, and expert technical assistance, while the states "utilize policy and regulatory levers to accelerate health system transformation."[76]

Use data to target interventions

Data does not only form the foundation of precision medicine; it can also be used to improve regulation. Big data helps governments become more agile by providing a holistic perspective that no single individual or agency can capture. A broader perspective is particularly useful in healthcare, especially when a country's medical system is overseen by several different agencies, regulated under multiple frameworks, and decentralized across cities and states. Gleaning insight from data can improve cooperation across institutions, reducing redundancy and streamlining processes.

Research and development programs are fragmented across 14 different ministries within the Korean government. This decentralization leads to uncoordinated technology development and unproductive bureaucratic procedures. To address this issue, the Korean government created the Korean Research and Development Platform for Investment and Evaluation (R&D PIE),[77] which uses big data analytics and machine learning to identify overlaps and potential opportunities across Korean ministries. With precision medicine as a core focus area, they hope to align inter-agency efforts and promote cross-sector innovation. They plan to accomplish this by analyzing data from patents, scientific publications, and budgets, leading to evidence-based policy-making.

In addition to intragovernmental insight, data can provide a valuable perspective across countries. The FutureProofing Healthcare initiative monitors and quantifies the sustainability of healthcare systems across the EU, Africa, and Asia Pacific regions. The initiative's Asia Pacific (APAC) Personalized Health Index measures how countries are progressing towards more personalized, integrated, and digital health systems.[78] Measurements are based off of data from the World Health Organization, World Bank, United Nations Children's Fund (UNICEF), academic institutions, and other nonprofits. By identifying which countries are equipped to deliver precision medicine, governments in the region can learn from their neighbors.

Leverage the role of business

Strict regulatory frameworks do not always cover the actions of precision medicine companies, leading to unique governance challenges. These circumstances present an opportunity for responsible industry-led governance, which can help improve accountably through a network of similar companies.

The market for direct-to-consumer genetic testing offered the public a new way to explore personal health, yet despite the reach of consumer genetics companies this sector suffers from a lack of regulation.[79] The Future of Privacy Forum, a nonprofit promoting data privacy, partnered with consumer genetics companies to announce best practices for protecting consumer genetic data privacy.[80] One key area of transparency is how companies share personal data with governments and how these interactions are reported.

Industry leaders can act as conveners to move forward innovation in step with policy-makers and other stakeholders. One example of coalition movement is the Decentralized Trials Research Alliance (DTRA), which unites healthcare companies, regulators, and patient groups across jurisdictions to improve clinical trial participation, through identifying best practices, resolving regulatory gaps, and building a data and knowledge repository.[81] DTRA's

industry-led movement could have significant repercussions for the field of precision medicine. The testing of personalized therapeutics is often characterized by small patient populations; thus, decentralized clinical trials would help recruit the requisite cohorts, particularly those who may not be able to travel due to their specific diseases.

Work across institutional boundaries

Companies innovating in precision medicine, like Novartis, Roche, and Editas Medicine, are reimagining the future of healthcare, aspirations driven by clear end goals but sometimes encumbered by regulatory and market approval processes. Establishing one-stop points of guidance, where companies can receive feedback on product plans, helps streamline approval processes and promotes innovation. Setting up these central points of contact involves networking between regulatory institutions, opening up lines of communication.

The U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) established an Innovation Office that fosters dialogue across institutional boundaries, providing advice on how to navigate U.K.'s regulatory landscape. [82] The Innovation Office offers advice that can save precision medicine companies significant time and money. For example, the office reviews manufacturing processes involving novel materials. As precision medicine companies manufacture complex biological material for personalized therapeutics, they can work with the Innovation Office to ensure that their methods and products meet regulatory requirements.

Collaborate internationally

The benefits of healthcare innovation should cross borders, a goal that can be facilitated through an alignment of regulations and ongoing communication between stakeholders. When bringing precision medicine to international markets, companies must navigate complex networks of policies, standards,

and approvals. International coordination between regulators and in consultation with companies can accelerate innovation and improve patient access, while simultaneously preserving safety standards.

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A model example of international coordination is the Access Consortium, a coalition of regulatory authorities from Australia, Canada, Singapore, Switzerland, and the United Kingdom.[83] Similar to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), which was founded in 1990, the Access Consortium forges international cooperation through information and work sharing, reducing duplicative efforts and increasing each agency’s functional capacity. The five members of the Access Consortium “are all like-minded medium-sized regulatory authorities facing similar challenges like an increasing workload, intensifying complexity, as well as growing resource constraints.”[84] This group recognizes that the globalization of the pharmaceuticals industry and the emergence of 4IR technologies necessitates the coordination of shared technical expertise for assessing the value and risks of modern medicine, including personalized therapeutics.

The European Medicines Agency (EMA) and the U.S.’s FDA support a parallel advice program in which companies can engage with both regulatory agencies early on or prior to product development.[85] Creating opportunities for structured, international engagement avoids unnecessary redundancy for

companies as they seek to bring medical products to multiple markets. The parallel advice program is also an example of working across institutional boundaries, mapped onto a global scale.

Using "Reliance-based regulatory pathways," in which government agencies use another agency's work product (scientific assessment report, inspection report, etc.) to inform its own decision making, will be essential for lower- and middle-income countries who lack updated regulatory policies or are resource constrained.[86] Sharing best practices and lessons learned across governments will help countries like Brazil, India, and South Africa as they look to build their capacity to test, manufacture, and deliver precision medicine therapies.

Conclusion

Precision medicine offers unique potential for the future of healthcare. Technological innovation in this area is improving the efficacy and feasibility of personalized approaches to disease prevention, diagnosis, and treatment, raising the prospect of addressing previously untenable conditions. Despite its potential, precision medicine has not broadly integrated into healthcare systems as quickly as many people had hoped. While innovators across genomics, data science, and AI aim to overcome technological hurdles limiting the impact and deployment of precision medicine, policy-makers and regulators must update systems in a way that promotes innovation while ethically and equitably protecting society. In order to strike this balance, policy-makers and regulators should look to the seven pillars of agile governance as a blueprint and a guiding structure. These agile governance processes can be applied to each stage of the precision medicine pipeline, recognizing that precision medicine encompasses a wide range of activities from basic research to care delivery. By using agile governance to foster a more coordinated and reflexive relationship between regulators and innovators, precision medicine is more likely to deliver on its potential and improve patient care globally.

Appendix: Tables

Table 1: The Seven Pillars of Agile Governance

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Agile governance processes	Intended purposes
Anticipate innovation and its implications	Give regulators time to work with stakeholders and iterate policy through the use of foresight mechanisms intended to recognize new opportunities or threats, while providing the requisite time to take action.
Focus regulations on outcomes	Shift focus to long-term policy goals, providing businesses with space and flexibility to effectively meet those goals while still complying with regulations.
Create space to experiment	Establish oversight environments for innovators to test technologies under regulatory supervision and/or provide opportunities for innovators to receive advice on the implications of their ideas.
Use data to target interventions	Effectively target regulatory interventions using data-driven technologies, offering businesses greater flexibility to innovate.
Leverage the role of business	Harness the private sector through compliment outcomes-based policy using “soft governance” (i.e. industry-led codes of conduct and voluntary standards), which can help convey policy objectives faster and manage risks from technological innovation more efficiently.
Work across institutional boundaries	Foster bidirectional communication within governments and with industry to reduce redundancy and confusion in order to accelerate innovation.
Collaborate internationally	Share learnings and combine regulatory efforts to address common challenges, experiment jointly, and facilitate trade and investment more efficiently.

Table 2: Tools for Agile Governance

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Agile governance tools	Intended purposes
Policy labs	Aid the adoption of new policy techniques catered to government bodies through the use of data analytics and digital tools designed to enhance policy creation.
Regulatory sandboxes	Foster safe spaces for businesses to innovate outside the realm of typical regulatory hurdles
Increasing agility through technology	Generate agile, distributed, and transparent processes; for example, using blockchain for voter identification to increase citizen participation in governance.
Promoting governance innovation	Make innovation manageable among different government institutions, through the use of guidebooks, templates, and other mechanisms.
Crowdsourced policy-making	Increase trust among governments and citizens by engaging people, improving policies, and fostering transparency.
Promoting collaboration between regulators and innovators	Decrease the time between the initial idea stage of innovation and getting technologies to market.
Public-private data sharing	Create more accurate and rapid systems for governance decision-making through data sharing platforms.
Direct representation in governance	Foster public communication and participation in technological development, assessment, commercialization, and regulation.
Expansion of governance beyond government	Improve the speed of rule-making, monitoring, enforcement, and remediation processes through private sector self-regulation, including codes of conduct and industry standards.

Table 3: Government-Funded National Genomic-Medicine Initiatives

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Country	Initiative(s)	Cost	Year launched
Australia	Australian Genomics	AUD $125M (USD $95M)	2014
	Genomics Health Futures Mission	AUD $500M (USD $372M)	2018
Brazil	Brazil Initiative on Precision Medicine	–	2015
China	China Precision Medicine Initiative	CNY 60 billion (USD $9.2 billion)	2016
Denmark	Genome Denmark	DK 10M (USD $13.5M)	2012
	FarGen Project	DK 10M (USD $1.6M)	2011
Estonia	Estonian Genome Project	2017: €5M for 100,000 individuals	2000
Finland	National Genome Strategy	€50M (USD $59M)	2015
France	Genomic Medicine Plan	USD $799M	2016
Japan	Japan Genomics Medicine Program	JPY 10.2B (USD $90.05M)	2015
Netherlands	RADICON-NL	–	2016
Qatar	Qatar Genome	–	2015
Switzerland	Swiss Personalized Health Network	CHF68M (USD $69M)	2017
Saudi Arabia	Saudi Human Genome Program	SAR 300M (USD $80M)	2013
Turkey	Turkish Genome Project	–	2017
United Kingdom	Genomics England	£350M (USD $485M)	2013
	Scottish Genomes	£6M (USD $8M)	2015
	Northern Ireland Genomics Medicine Centre	£3.3M (USD $4.6M)	2017

Country	Initiative(s)	Cost	Year launched
	Welsh Genomics for Precision Medicine	£6.8M (USD $9M)	2017
United States of America	National Human Genome Research Institute	USD $427M	2007
	All of Us	USD $500M (first two years)	2016

Table 4: The Unique Challenges and Societal Benefits of Precision Medicine

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Precision medicine stage	Challenges	Payoff
Data acquisition and storage	Data ownership and privacy; disparate data repositories; non-standardized formatting and nomenclature	Broad societal representation; benefit-sharing agreements; data compatibility
Information access and research	Variability in data access; blurring line between academia and industry	Responsible data oversight; transparent industry practices; Innovative diagnostics and therapies
Clinical trials and commercialization	Unique clinical trial hurdles (i.e. small patient populations); conflicting international regulatory frameworks; Complex manufacturing and supply chain logistics	Creative use of 4IR technologies in clinical trials; Improved regulatory coordination across intergovernmental agencies
Societal benefit	Limited access due to treatment center locations; novel payment and reimbursement plans	Reach all patients with unmet medical needs; update healthcare systems to integrate precision medicine

Precision medicine stage	Challenges	Payoff
Cross-cutting considerations	Engaging patients throughout the precision medicine pipeline; Funding mechanisms that maximize societal benefits	Align precision medicine with patient needs; Leverage multiple funding mechanisms to improve equitable diagnostic and therapeutic access

Footnotes

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