

Diagnosics for Better Health: Considerations for Global Implementation

INSIGHT REPORT

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Executive summary

Diagnostics function as a compass in healthcare. They help determine the cause of a person's condition, thus steering the healthcare provider towards the appropriate treatment or care pathway to address a disease and determine whether the approach is working.

Despite their value in the healthcare delivery system, innovation, implementation, reimbursement and accessibility include barriers that constrain the use of diagnostics, particularly in low- and middle-income countries (LMICs), where increased availability could lower healthcare costs while saving lives.

As the pace of diagnostic innovations quickens – informed by genomic sequencing, artificial intelligence and machine learning as well as wearable, implantable and point-of-care technologies – people with access to these advances will benefit from more individualized or customized care.

Given this situation, how can leaders increase affordable access to essential diagnostics globally? How can diagnostic advances be supported without contributing to growing disparities across the globe?

This report seeks to address these questions through a landscape review of the global diagnostic ecosystem – including identifying key stakeholders, barriers and enablers along the product life cycle and the effectiveness of diagnostics – while highlighting the various challenges, opportunities and potential solutions across high-income countries and LMICs.

Key insights from this review include, among others, the need to:

- Explore innovative and collaborative research and development (R&D) and business models that enhance incentives to engage in LMICs
- Support the continued harmonization of regulatory requirements across high-income countries and LMICs, while ensuring products are still fit for purpose in target markets
- Improve diagnostic performance in markets by better understanding user input, contextual awareness, cultural and social concerns and the applicability of reference data
- Attend to the urgent gaps raised by the increased use of human health, clinical and genomic data in developing diagnostics, including policy issues pertaining to consent, data privacy, data access and benefit sharing as well as practical issues with regard to, for instance, ensuring diagnostics are developed with reference data aligned to that of the population using the tests.

The assessment of the global diagnostic landscape and discussions of its main insights by the World Economic Forum Global Future Council on Biotechnology (2019-2020), several members of which authored this report, led the Council to recommend strengthening current initiatives to improve access to diagnostics and establishing a global alliance for affordable diagnostics. The Council hopes this document contributes to the critical work under way and will bolster initiatives to drive improvements in individual patient care and overall global human health.



Introduction

Diagnostics¹ are an essential component of the healthcare system and the cornerstone of precision medicine, enabling the customization of medical decisions and treatments for patients. They predict susceptibility to disease, provide diagnoses and determine responsiveness to therapy. High-quality diagnostic technologies are available for major disease burden areas in most developed countries, but they are not accessible, affordable or designed for application in many low- and middle-income countries (LMICs). In LMIC populations, inaccurate diagnostics can be among the most expensive and logistically difficult barriers to accessing quality healthcare. Despite efforts by such global non-profit agencies as the Foundation for Innovative New Diagnostics (FINN), investment in diagnostics for use in LMICs is unable to meet increasing demand.

To change this scenario, building capacity for high-quality diagnostics in LMICs is necessary, by promoting innovation and creating new models for technology transfers that include manufacturing and system-wide planning at a local level.

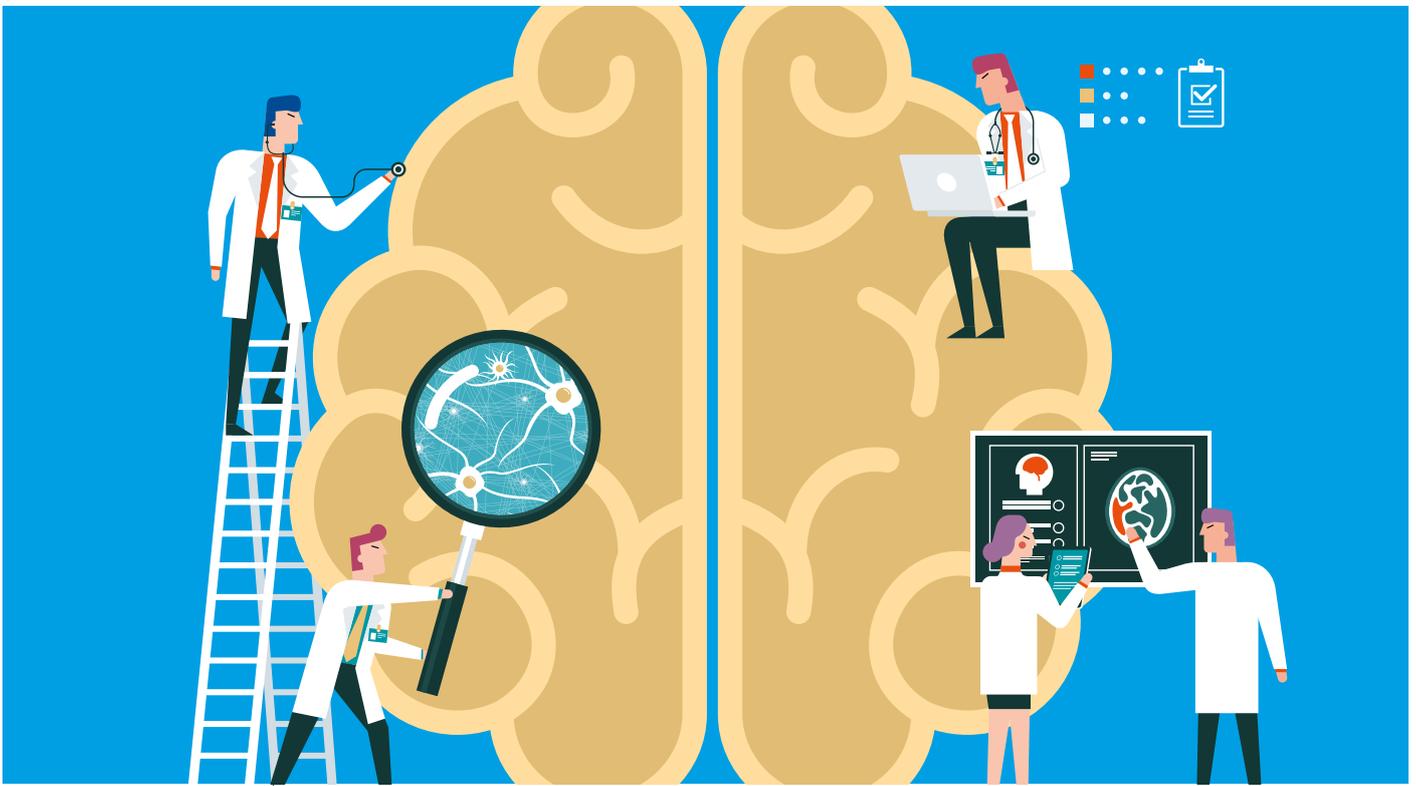
In both industrialized and emerging economies, innovation and new technology transfer models are important. These approaches, if applied with the goal of expanded access, will increase the adoption of diagnostics, reduce implementation barriers and broadly make diagnostics more accessible and affordable, particularly so in LMICs. Despite some commonalities, LMICs face different sets of challenges related to the scaling of advanced technologies, regulatory hurdles, reimbursement challenges, social and cultural differences, and

accessibility issues in remote and rural areas.

As recently as 2018, the importance of diagnostics for health was reiterated by the World Health Organization (WHO) through its essential diagnostics list² and by FINN,³ leading to a formalized collaboration to ensure more equitable access to diagnostic technologies.⁴ The importance of diagnostics has also been emphasized by their need as part of the global COVID-19 response.

This report explores the diagnostic ecosystem and identifies key stakeholders. It considers the barriers and enablers of the implementation, adoption and effectiveness of diagnostics; presents the current diagnostics landscape with its challenges and opportunities; and offers possible solutions for application in both industrialized countries and LMICs. It further outlines the issues associated with the adoption of diagnostics in various economies, while noting that diagnostics development and deployment during emergencies differs. The report aims to serve as an inspiration and educational tool for professionals in the industry, as well as for entrepreneurs, policy-makers and the general public, on the ways in which diagnostics and their practices can be leveraged for better global human health.

With new technological developments, precision medicine investments in both industrialized economies and LMICs, and an ever-deepening understanding of biology, the diagnostics industry is poised to revolutionize the way societies manage and prevent disease.



1 Current landscape

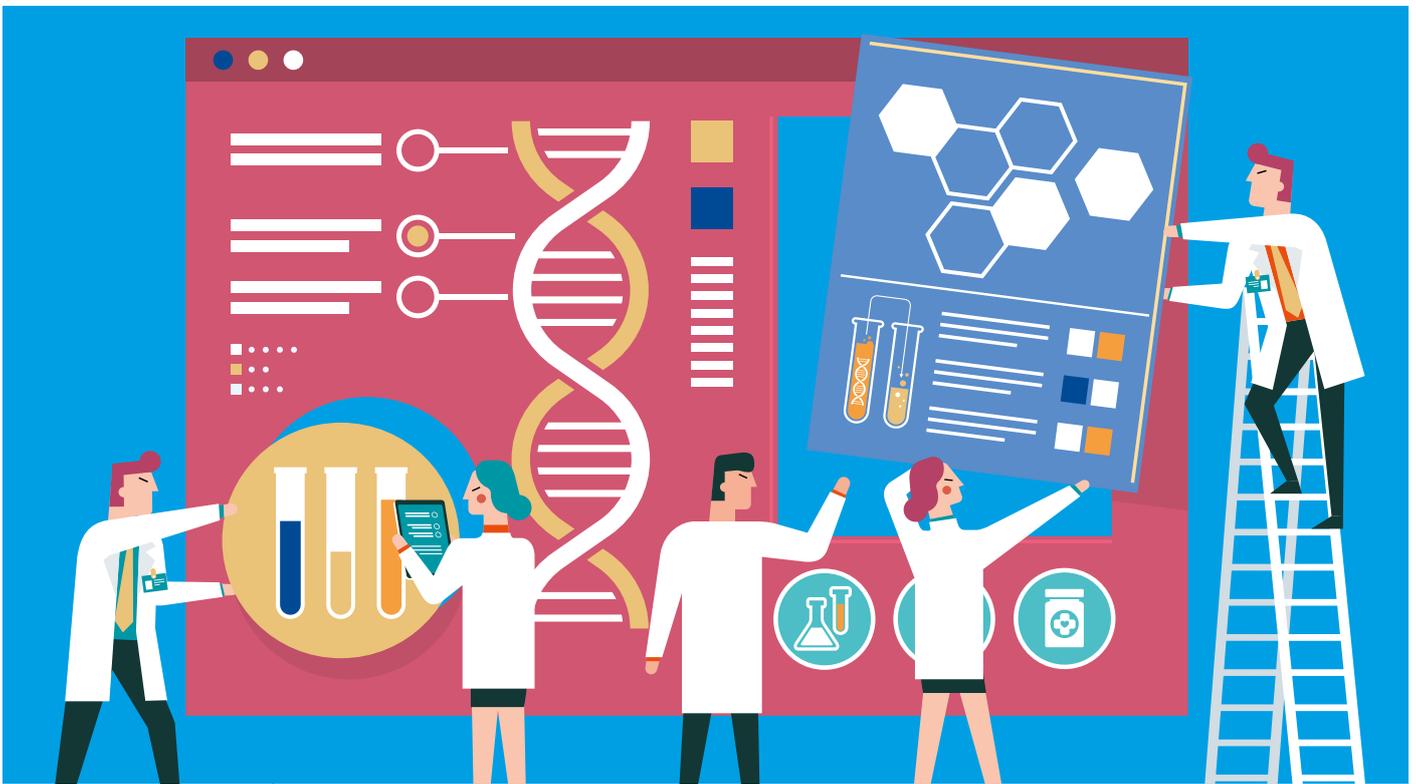
The history of laboratory testing is the story of medicine’s evolution from empirical to experimental and confirmatory techniques, showcasing the laboratory as a critical element of medical decision-making. Conventional diagnostic methods rely on imaging (magnetic resonance imaging (MRI), computerized axial tomography (CAT) scan, X-ray), cell-based fluids testing (lipids, white and red blood cells, glucose, etc.) and, more recently, moving beyond the laboratory to the individual, on wearables (to measure heart rate, gait, sleep patterns, glucose levels, etc.). With the explosion of “omic” technologies, diagnostics have expanded to include genomic, proteomic, metabolomic and post-translational modification characterizations that not only support more accurate disease treatment but also expand the understanding of disease mechanisms. At the same time, economies in LMICs have begun seeking ways to leapfrog stages in their healthcare ecosystems by using these developing technologies in their populations, leading to the need to rethink issues of cost, privacy and equality across geographies and cultures.

Not only have diagnostics become more specific to individuals but their use has expanded to cover many stages of one’s experience of a disease:

Screening applications are used prior to the onset of disease symptoms. For instance, in the United

States, screening has been approved by the Food and Drug Administration (FDA) for carrier screening/germline testing, Lynch syndrome, BRCA1/2 and familial hypercholesterolemia. Several other countries (particularly those with government-sponsored healthcare) are pursuing population-scale testing for oncologic and viral disease while balancing careful cost and privacy considerations. Once a disease has manifested, **diagnostic** applications are appropriate. Since clinical evidence requires less investment than screening, many diagnostics have already been approved for this application in industrialized countries. During the **treatment** phase, diagnostics include targeted therapy selection, companion diagnostics for specific drugs and dosing/pharmacogenomics. Finally, once treatment has concluded, **monitoring and surveillance** diagnostic tests watch for the emergence of both the treated disease and ancillary disease.

At each step in a patient’s journey through a disease, screening and diagnostics play critical roles to ensure that the disease is identified and treated in the most efficient way. In all economic and health sectors and geographies, these stages present a diverse set of challenges and will be experienced differently. Understanding what is unique in each setting will ensure that any differences are dealt with in ways that respond to the needs of the populations and the capabilities of their economies.



2 Diagnostic product development

Diagnostics make up a broad and diverse product category. A wide range of technologies and applications address every disease area, including products as diverse as at-home testing for diabetes management, to imaging on-site at hospitals for cancer detection, to sophisticated assays run in highly controlled laboratory settings for neurologic disease. Diagnostic stakeholders are also diverse,

including patients, healthcare providers, governments and other payers that assess the value of the test, and regulators who ensure patient safety. This complexity must be navigated throughout the process of delivering a technology from R&D to the market, with attention paid not only to the performance of the technology but also to its acceptability, utility and expected use by all stakeholders.

2.1 Technology

Conventional diagnostic technologies have been developed and used over the course of the past several decades, leading to bodies of clinical evidence that are, for the most part, well-understood. With the advent of Sanger and genomic sequencing, artificial intelligence (AI), wearable technologies and other innovations, advanced diagnostics now hold the promise of enabling fit-for-individual customized treatments. The pace of diagnostic innovation in industrialized societies is accelerating, fuelled by the software

technology sector's talent, venture capital investment and a desire to reduce the burden of healthcare costs.

While this is occurring, many LMICs continue to face challenges related to the deployment of traditional testing. Referred to as the "10/90 gap", 90% of the investment in research money in genomics and related biotechnologies addresses the needs of only 10% of the world's population.⁵ The centralization of these innovations to specific

economies and geographies can result in diagnostic products that miss key LMIC requirements. At the same time, LMICs lack the investment and infrastructure required to develop their own products, leading some LMIC governments to explore ways to leapfrog traditional diagnostics and focus investment in key, impactful advanced diagnostics that are specifically designed to match their population and environmental needs.

In bringing a technology to patients in a resource-limited setting, the WHO, as part of the Sexually Transmitted Diseases Diagnostics Initiative (SDI), has defined the ideal characteristics (or requirements) of a diagnostic test.⁶ The “ASSURED” characteristics are challenging but set criteria for diagnostic products if new innovations are to meet the needs of both industrialized country and LMIC populations:

Affordable by those at risk of infection

Sensitive (few false negatives)

Specific (few false positives)

User-friendly, simple to perform with minimal training

Rapid results and robust (for example, without refrigerated storage)

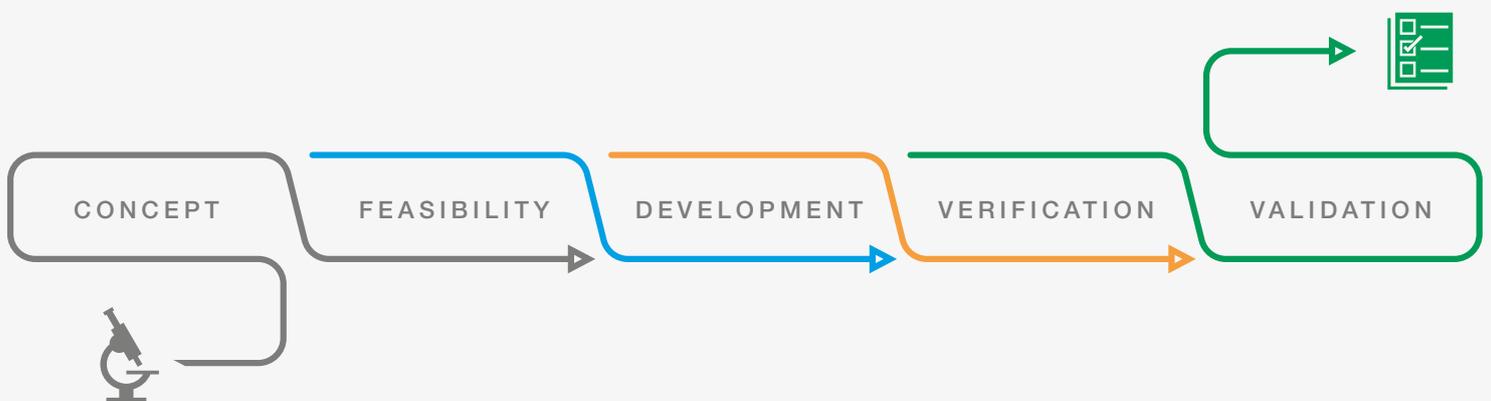
Equipment free

Delivered to those who need it

2.2 The path from R&D to patient

To ensure that stakeholder requirements will be met by a new technology, new products must go through key stages and hurdles to prove safety, efficacy and usefulness to the practice of healthcare. These stages also demonstrate that a product is consistent as it scales up from point of

use at the lab bench to high-volume use in multiple geographies. While these stages are the ideal path for technology to follow, cases exist in which a technology may skip stages or have different criteria to meet at each distinct stage in order to address emerging patient, physician and regulatory needs.



The stages in the pathway start with the **concept** stage, which defines the potential for the technology and develops a hypothesis for the kind of patient use case that will drive the most health system value. If the potential performance of the technology can address an unmet need in the market, the technology will move on to the **feasibility** stage, in which the technology is tested further and the commercialization strategy is developed. From

there, the technology moves into **development**. In this stage, the specific requirements of each stakeholder (patient, healthcare provider, payer, compliance officer) are defined and mapped against the technical requirements of the technology. Once the diagnostic technology is built to address those requirements, it then moves to the testing stages, called **verification** and **validation**, to prove consistency and reliability in performance.

2.3 Test validation

The validation stage typically consists of two types of validation: analytical validation, which proves that the test can be run in an environment with consistent performance, and clinical validation, which proves that the test performs consistently on humans. Most regulatory bodies require both validations before they will approve a test for use commercially (see the “Regulatory” section).

Analytical validation involves evidence that the test results are accurate, repeatable and reproducible, specific and sensitive. For tests run in a lab, additional requirements are needed to establish lab performance, including verification of test accuracy and the stability of materials used in the lab process, and documentation on the confidence in the reportable range of results.

Clinical validation is the predictive value of a test for indicating an association between an analytic endpoint and a clinical outcome and is typically proven through a clinical study, controlled by an investigational protocol. The burden and investment required for clinical validation vary drastically between the reviewing body, the clinical application (e.g. population screening versus therapy selection tests) and the disease (e.g. it is typically faster to complete a trial for fast-developing, common diseases than for slower-developing and rare diseases).

In some scenarios, as the following example cases from the US show, inconsistent clinical validation requirements are proving to be a challenge; with the accelerating pace of innovation, some companies choose to default to “lighter” clinical validations to accelerate commercialization. In response, the FDA has exercised oversight of these technologies in order to maintain patient safety, such as in 2010 when it required 23andMe to stop reporting health information from its genomic test due to a lack of both analytical and clinical validation evidence. In another example, in 2015, the FDA stopped Pathway Genomics from selling a test directly to individuals to detect cancer without a physician’s oversight, because of the lack of clinical validation evidence.⁷

In LMIC populations, additional and different concerns may prevail. The cost of enrolling patients in a clinical trial may be lower, but the required infrastructure is a challenge. And ensuring tight environmental controls, established study sites, ethical legal systems, consistent skills training for investigators and reliable tools to monitor outcomes can be challenging in the pursuit of developing a robust body of evidence for clinical validation. Even with clinical validity data, regulatory reviews in most countries vary and are lengthy, requiring long periods of investment before a company can expect approvals.

2.4 Clinical utility

Clinical utility is the ability of an intervention to meaningfully improve patient health outcomes, when used to inform and support clinical decisions, compared to decisions made without test results. Clinical utility establishes the value the diagnostic can bring to the healthcare system – that the test or intervention will provide a better outcome than the incumbent diagnostic practice.

Those who pay for the new test, whether a government, a private insurance company, a clinical service or an individual, will want assurance that

the test will have a positive effect, driving improved clinical actions. Proof will be provided through health economic studies that establish value and, therefore, price. It is important to note that in some countries, analytical validation, clinical validation and clinical utility are not always assessed together. Often, a regulator reviews the analytical and clinical validation of a diagnostic for approval to make it legally acceptable to market the test. The utility of the test is often evaluated by separate stakeholders, such as payers or government agencies, which drive the reimbursement and pricing.

2.5 Epidemiological considerations

**Target
population
characteristics
must be
understood**

For the diagnostic path from test to patient to be successful, external factors must be considered and accounted for. Potential differences in disease patterns in communities both within and across countries are an area of concern. When developing a new test, the local epidemiology and characteristics of the target population must be well understood. A complex combination of factors will be at play in the uptake of a diagnostic technology or approach. These include language (scientific/medical vs lay), experience and classification of the urgency of the medical issue, resources and the proximity of people to healthcare facilities, and other competing demands on people's lives.^{8,9}

As populations from different geographies can present different biological responses to a disease, understanding how that disease manifests and progresses in diverse environments supports the tailoring of the diagnostic for the intended use population and can maximize the conditions that increase and support the adherence to and effectiveness of the product. Test design, for instance, must accommodate evolutionary

differences in pathogens that lead to geographic variation in antigen presentation or nucleic acid signals. Confounding environmental conditions can alter test performance, including sensitivity and specificity.¹⁰ Researchers and organizations assessing utility need to consider local clinical guidelines for pharmacology/dosing and the willingness of stakeholders to adopt new methods and interventions.

Epidemiological evidence therefore relies on knowing population trends and local characteristics for disease, and being able to track and document disease occurrence with adequate frequency to make decisions on diagnostics more easily and accurately. This means understanding the contexts in which tracking and population surveillance occur for the future safety and efficacy of a diagnostic. Irrespective of a country's level of industrialization, the circumstances and environments under which diagnostic pathways are created, executed and experienced are not universal and can alter epidemiological results.

2.6 Emerging R&D and product development models

The current pace of innovation is inspiring. Traditionally, large multinational corporations have led R&D initiatives because of the high level of investment required. This has led to a bias towards profit optimization that leaves behind poorer populations, niche applications or risky technologies. In recognition of this traditional bias, three R&D models have emerged to expand and understand LMIC requirements:

- Government sponsored research
- Academic collaborations
- Venture-backed technology company investment.

To increase the reach of these innovations, both governments from industrialized countries and from LMICs are thinking creatively about models that can take a broader set of requirements into account and can accelerate adoption in underserved populations.



3 Regulatory

The availability of safe, effective diagnostics benefits developers and manufacturers, policy-makers and the public alike. The regulatory environment must be sufficiently stringent to ensure patient safety through reviews of appropriate analytical and clinical validation evidence, while not stifling innovation and development.¹¹ At the same time, the speed of diagnostic evolution risks outpacing regulation; determining the adequacy of evidence for a diagnostic may be situation-dependent and needs to be weighed against the impact of the test and the urgency of the clinical need. Expedited approval of a diagnostic with less evidence may be deemed appropriate, particularly when the demand for diagnostics serves to meet health crises, as evidenced by the COVID-19 pandemic.

The diagnostic market is overwhelmingly focused on high-resource settings. Four-fifths (80%) of global medical devices are sold in the Americas and Europe, and two-thirds of the top companies in this sphere are based in the United States.¹² In the United States, the Department of Health and Human Services has overarching responsibility for the efficacy and safety of diagnostics; regulatory oversight over implementing the Clinical Laboratory Improvement Amendments (CLIA) is shared between the Centers for Medicare & Medicaid Services and the FDA.¹³ Although Europe traditionally had the reputation of having a relatively “light touch” towards diagnostic regulation, the formation of the European Union led to considerable regulatory reform in the area.

Momentum towards the harmonization of regulatory processes internationally has grown over the past two decades, to improve efficiencies and mitigate administrative barriers that extend diagnostics’ time to market and time to patient:

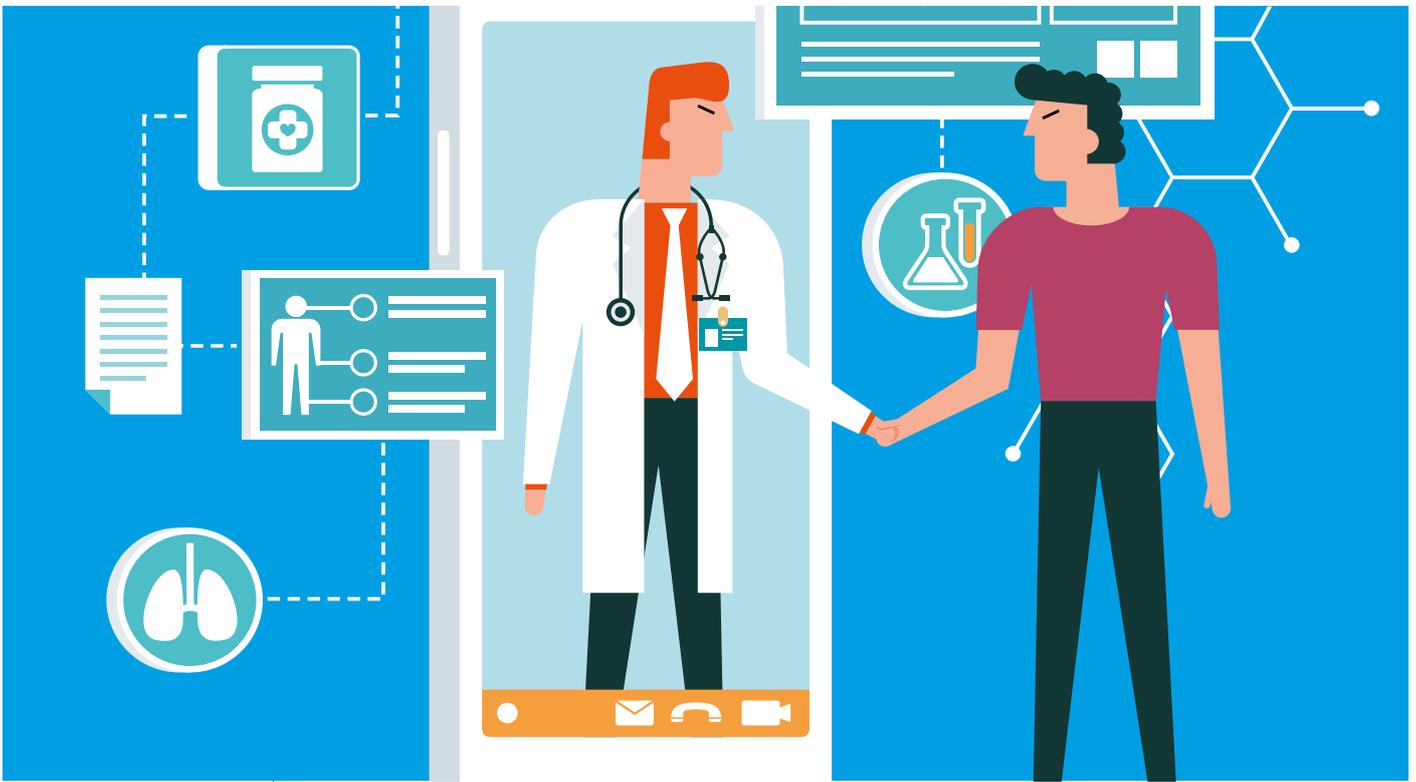
- The Global Harmonization Task Force of regulators and industry representatives was superseded in 2011 by the International Medical Device Regulators Forum, which includes broader representation from emerging economies, but excludes industry. The WHO has worked to converge international regulatory processes for devices and diagnostics. Its 2001 report, [A Model Regulatory Programme for Medical Devices: An International Guide](#), was designed to provide guidance to countries yet to have mature regulatory frameworks for diagnostic interventions.
- National regulatory authorities are further supported by the WHO Regulatory Systems Strengthening programme, which provides standardized frameworks to benchmark national regulatory frameworks to international standards.
- The WHO Prequalification of In Vitro Diagnostics programme aims to overcome challenges related to complex regulatory pathways in LMICs, expediting products approved by stringent regulatory authorities.



While these initiatives may accelerate the adoption of diagnostics in LMIC settings, local regulators need to ensure the product is fit for purpose in the target market. The implications of differences in the clinical evidence (population, genotype, immunosuppression); in the analytical evidence, including in the environment (temperature, dust); in infrastructure (the reliability of power supply, reliance on laboratories); and in implementation (the need for a trained workforce for diagnostic delivery or interpretation) will all need to be considered and managed locally. Both developers of diagnostics targeted to a LMIC setting and the local regulators must also consider the features of the diagnostic in the local context; a less-sensitive test that is broadly available for use at the point of care may be more appropriate than a highly sensitive, resource-intensive laboratory-based diagnostic.¹⁴

The post-launch surveillance of a diagnostic's performance and use is critical to the long-term utility, safety and sustainability of a product. The [WHO Safety and Vigilance programme](#) records domestic product failures and notifies other regulatory agencies, but the use of this database suggests that two-thirds of countries lack a functional post-marketing surveillance system.

As a consequence, despite prior stringent regulatory assessment, local product registration is still critical to ensure the safety and efficacy of a diagnostic, which can be a disincentive for production in some LMIC markets.¹⁵ However, the market size may reignite the interest of diagnostic developers. A review by Brooks, Smith, de Savigny and Lengeler reported that due to the disease burden in LMIC settings, rapid diagnostic tests were implemented in a greater proportion there than in high-income countries, but they note the uptake was very slow: 10 years after regulatory approval, only one-third of LMICs had begun to use the interventions,¹⁶ suggesting regulatory barriers are not the only impediments to diagnostic implementation in low-resource settings. Fundamentally, too, there are ethical challenges to imposing regulatory frameworks in different parts of the world. Current global efforts towards regulatory convergence increasingly cite strategies for the culturally appropriate development of regulation to support a diagnostic industry that is responsive to, and respectful of, populations in both low- and high-resource environments.



4 Implementation

Achieving validation and appropriate regulatory approvals are only first steps in delivering impact to patients. The next challenges for the diagnostic developer are to distribute the product, train and educate patients and healthcare providers, and

collect evidence to pay for the test and further improve the performance. Layered into each are cultural differences and privacy concerns that must be thoughtfully navigated.

4.1 Distribution models

Diagnostics have a wide range of distribution methods, determined by the complexity of the technology, test robustness and ease of use. Ideally, testing should be performed as close to the patient as possible to reduce the time to results, decrease the risk of sample contamination and control patient information, but often this is not possible. Several distribution models have emerged to address both the characteristics of the test and the needs of the healthcare ecosystem:

- At-home diagnosis
- Point-of-care testing
- Laboratory developed tests (at a single lab)
- Distributed lab testing (at several labs)
- Direct-to-consumer testing.

At-home diagnosis (sometimes called point of care outside a healthcare setting) is the processing of a test in an individual's home, with immediate results, without the intervention of a healthcare provider. This is the most user-friendly option but requires significant robustness, ease of sample collection and simple instructions for use. Requiring regulatory oversight and approval, typically these diagnostics are more mature, with large bodies of evidence. Examples include pregnancy testing, blood glucose monitoring and urinary tract infection detection.

Point-of-care testing within a healthcare setting has the benefit of returning results to a patient as close as possible to the point-of-treatment delivery. These diagnostics are performed at a healthcare provider's request and require the provider to participate in communicating the results back to the patient. Diagnostic devices and tests within a healthcare setting include imaging, blood tests and electrocardiograms.

Distribution
models
must be fit
for purpose

Laboratory developed tests (LDTs) are in vitro diagnostic tests that are designed, manufactured and run in a single lab site. With the increase in precision medicine testing and the rate of complex innovation, this path is frequently pursued for diagnostics companies to commercialize their product. This model in the United States is governed by the College of American Pathologists and requires a CLIA licence. The FDA also provides oversight and can intervene in the distribution of the diagnostic if it deems that the level of analytical and/or clinical validation evidence is insufficient to ensure patient safety. Typically, these tests require specialized equipment, complicated sample preparation and/or special environments to ensure accurate test results. Examples of LDTs are blood-based cancer detection, chemistry tests on fluids other than blood and drug testing requiring a mass spectrometer. In the United States, LDTs fall under FDA oversight and may require additional applications such as a 510(k) or Premarket Approval, depending on the risks involved in the clinical use of the test.

Distributed lab testing is often an evolution of LDTs. By developing more rigorous evidence of the consistent processing of samples through multisite validations, companies are able to meet regulatory hurdles for distributed testing. This frees the company from a single site for sample processing and allows the testing to be located closer to the point of care, often decreasing the time to return the results to patients and potentially decreasing the cost of the test. The diagnostics company can achieve multisite testing in two ways, each with regulatory and cost considerations:

- Create “kits” of the necessary components to run the test, so other lab companies or institutions can process samples on their own equipment
- Do “technology transfers” of the entire ecosystem of equipment, software and reagents required to process samples.

With more recent, complex technologies, the diagnostics company will allow the distributed labs to process the samples, but require that the data from the sample be sent to the diagnostics company for analysis and results. This is especially the case with recent genomic diagnostics, where the analysis of genomic data to return a result often requires a proprietary and specialized skill set.

Direct-to-consumer (DtC) testing has increased exponentially in genomics testing in recent years. These tests carry risk because they are marketed directly to individuals, without the oversight of a healthcare provider. In general, DtC tests for non-medical, recreational genomics or low-risk medical purposes are not reviewed by the FDA before they are offered. If the test makes medical claims or can lead to medical care decisions, the FDA will exercise authority over it, requiring analytical and clinical evidence to support claims. Examples of DtC tests with FDA marketing authorization are rare, but include 23andMe’s genetic health risk report for breast cancer types 1 and 2 (BRCA1/BRCA2).

Within the LMICs, distribution models may take unique forms that depend on the needs of the population, the traits of the disease and the resource capacities and preparedness of health infrastructures. For example, the urgency of diagnosing and tracking Ebola outbreaks was enabled by mobile technologies that were not validated to traditional LDTs or in vitro diagnostic requirements. Instead, governments established procedures that guided the risk assessment, balancing speed and impact over instances of minimal evidence or lack thereof. A time-sensitive and needs-driven approach using mobile tracking devices, hubs for data collection and empowered personnel in the field helped to overcome issues related to the transportation and infrastructure of data and samples that would have normally slowed responses in traditional settings.

4.2 Training and education

Education on diagnostics, including proper training on when and how to use them, is critical to ensuring both accurate test results and patient safety. The approach to training often begins internally, with the diagnostic manufacturer training employees, who will then train and educate care providers, lab technicians and other healthcare professionals.

Employee training covers two main categories: legal and regulatory policy, and diagnostic labelling and use. Training in legal and regulatory policy ensures that company representatives are aware of and comply with rules intended to protect patient safety, limit the unnecessary use of diagnostics

and prevent fraudulent billing. Training on the product label approved by the regulatory authority includes the product name and other identifying information, technical description, intended purpose, instructions for use, relevant data and warnings or precautions.

Once internal training is completed, approved company representatives are then able to educate the diagnostic users, which include doctors, nurses or technicians, on appropriate use. For diagnostics in the evolving field of precision medicine, an additional educational focus on when to test for certain biomarkers, genetic material or other precise

indicators that can help inform disease diagnosis and appropriate treatment will likely be needed. Furthermore, instruction on proper sample collection and handling is critical as damage to the sample can lead to inaccurate or inconclusive test results.

In the less common circumstances when patients engage in their own diagnostic tests, they will often receive education from their care provider and non-personalized materials from the diagnostic manufacturers. Recent examples include saliva sample genetic tests, colorectal cancer screenings

and infectious disease screenings. Lessons from consumer responses to these approaches can be applied elsewhere to overcome critical healthcare needs. For example, a consortium of organizations that includes the WHO is advocating [self-sampling for human papillomavirus \(HPV\)](#), a virus that causes cervical cancer. Cervical cancer is the leading cause of cancer deaths in LMICs, but it is highly treatable if caught early. Enabling women to self-sample may increase HPV screening and encourage those with positive test results to seek treatment, ultimately saving lives.

4.3 Ongoing evidence and performance data collection

The design of a diagnostic tool requires continuous improvements based on many inputs to ensure that it still performs the task it was meant to do and, above all, that it is safe and accurate:

- User feedback will give manufacturers critical design information to ensure ongoing improvement in usability to meet each population’s needs.
- The data, chemical and engineering components that are used to build diagnostic technologies need constant quality checks to ensure the safety of that technology.
- Diagnostics must adhere to changing industry standards to ensure that their safety and utility are monitored in a systematic and transparent manner.

While various industry standards exist for the purpose of quality control, occasionally there are no equal standards for the data that is used. As such, monitoring the performance of the diagnostic is vital to cross-check results. This includes validation with other clinical symptoms, triangulating with related tests and ensuring, above all, that the data sets are not biased towards sections of society, or against certain members of society. If technologies are built to diagnose disease, the different possible adjustments must be made to make those results meaningful to a population. For instance, using genetic tests to diagnose a cardiac condition must consider the comparative base of genetics

knowledge, which so far results in many individuals receiving inaccurate results. The development of technologies must therefore always consider the data that is used to create the parameters of normality or abnormality and pay particular heed to whether the reference data is sufficiently broad to cover all populations or is based on specific sections of the population only. This would attend to the test’s utility and clinical validation, explained in the earlier section on product development.

User feedback itself is a vital component in the diagnostic ecosystem to guard against unintended harms that may result from incorrect results. Technological design can affect the ease of use of a diagnostic technology, or its acceptance by the target population. Although, ideally, diagnostics should be as minimally invasive and disruptive as possible, the environments in which they are used is also important. For instance, point-of-care tests might be better employed in areas where travel to medical institutions is difficult or expensive. Users would thus provide the necessary knowledge and information about their disease, which those conducting home-based diagnostic tests might not need to furnish. Additionally, some sections of the community may sometimes prefer self-administered tests, which may offer a sense of autonomy or independence in the management and diagnosis of a disease. Also important is knowledge of and attendance to any additional cultural concerns that can accompany a diagnostic technology, or even the diagnosis itself.



5 Data

Data is the foundational unit driving diagnostic development and implementation: at every level, different types of data serve different purposes.

The collection, analysis and storage of this data from the development and application of

diagnostics are critical. While consent and privacy considerations must underpin these data activities, thinking about data in a diagnostic ecosystem involves a range of issues.

5.1 Data generation, collection and storage

Effectively deploying diagnostics requires the technology and infrastructure to capture test result data and marry it with other demographic or health data to inform healthcare decisions. This requires collaboration among multiple organizations. Health systems and commercial providers are currently developing connectivity solutions to enhance health data discoverability and access partnerships between technology companies and diagnostics companies. Additionally, institutions that collect and use diagnostic data, in partnership with public health authorities, will need to incentivize the development of low-cost or open source technology, data governance frameworks and standards, as well as training materials for diagnostics with next-generation data capture capabilities. These would need to be developed with LMIC considerations fully embedded in them.

In addition, the breadth of data points of interest adds complexity to the scope and storage of data. Emerging diagnostic technologies, such as genomics, also generate large volumes of data of a potentially reidentifiable, highly sensitive nature: sequencing one human genome generates about 250 gigabytes (GB) of data with 3 billion base pairs and 5 million genetic changes per patient.

Because of the sensitivity of these growing data sets, the requirements for their secure storage and protection are in tension with the imperative of sharing clinical, research and development applications to enrich scientific knowledge and ongoing diagnostic improvement. Both legal and non-legal barriers impose restrictions on health data sharing – within nations and internationally – and data custodians are systemically risk-averse.¹⁷

As a consequence, health data is usually siloed, exacerbating the challenges of data access and aggregation for diagnostic development and use, even in high-resource settings. Cloud storage and federated access models have partially addressed this challenge, and the Global Alliance for Genomics & Health's [Framework for Responsible Sharing of Genomic and Health-Related Data](#) has provided international guidance on data governance standards. Compounding the challenges of data storage and access, the data used to drive diagnostics must be current, which is reliant on health system infrastructure that is often lacking in both high- and low-resource settings.

Engagement with different communities regarding data generation, collection and storage will require culturally appropriate recognition that the population may hold wide-ranging beliefs about the significance or sensitivity of data and health information. Those who manage the data should be cognizant of these local beliefs, such as data and sample repatriation.¹⁸ When engaging local communities, the communication about the data associated with the design and use of a diagnostic must be clear and well documented. The identification of, and respect for, local information

management practices can provide opportunities for local partnership and involvement – and novel insights into LMIC use cases and market needs that can align local interests with diagnostic design and market identification.¹⁹

The relationship that different indigenous peoples have with their personal health data cannot be assumed in diagnostic development and application. A number of initiatives globally are developing policy frameworks and standards to guide research and development activities to ensure the culturally appropriate management of data under the [Care Principles for Indigenous Data Governance](#). In addition to these frameworks and standards, data collection strategies for a particular diagnostic product cycle must also consider the cost of longitudinal data collection, the risks associated with the diagnostic, the likelihood of long-term impacts and product evolution, the time to cease data collection and the cultural implications of each aspect. An ethical market exit strategy should also consider the population's reliance on the product and the possibility of an alternative diagnostic available to meet the society's need, and should not be driven by commercial imperatives alone.

5.2 Advanced and predictive analytics (artificial intelligence and machine learning)

Advanced analytics is the examination of data using a suite of interrelated and highly developed techniques and tools, including big data, data mining, predictive analytics, machine learning and AI. These methods hold considerable promise to reduce workloads and improve accuracy in the analysis of large diagnostic data sets. For example, AI-based diagnostics are being applied in image analysis, and will be fundamental to the success of precision medicine. This promise has stimulated the interest of software companies globally,²⁰ but adequate regulatory oversight in the broad clinical use of these algorithms will need to balance the potential of advanced analytics with patient safety.²¹ As regulatory agencies race to keep up with the pace of innovation in this area, they look to develop minimization principles where data collected and accessed is ethically collected and limited to that required for the analytic task/diagnostic. For instance, Chapter II, Article 9 of the General Data Protection Regulation (“Processing of special categories of personal data”) begins by explicitly prohibiting the processing of genetic data before

listing caveats where such analysis is allowed.²² This poses broadscale implications for the application of advanced analytics in diagnostics, but emerging data technologies, such as blockchain encryption technology, may address privacy expectations as the linkage of multiple sources of data becomes more common.

Algorithms require “training” to know what to look for when they draw conclusions. These algorithms rely on access to high-quality training data sets, which can be difficult and costly to access in high-resource settings and unavailable in many LMICs. The resultant bias in AI learning data means ethnic and racial minorities, rural and socio-economically disadvantaged populations may be excluded from the benefits of AI-powered diagnostics – with the risk of advanced analytics actually widening a health disparity, rather than reducing it. Broadening the reach of data in LMICs and other underserved populations will improve the quality and representativeness of data, AI learning outcomes and the potential global impact of a diagnostic.^{23,24}

5.3 Technological governance

For diagnostic interventions to maximize their impact and benefit, they have to be both meaningful to their audience and responsive to the ever-changing contexts in which they are deployed. This means that those who create or deploy diagnostics must continuously evaluate their positions in relation to their aims and goals and the needs of their populations. Technological governance is useful to inform those evaluations, providing clarity and transparency on stakeholders' positions and articulating the factors influencing different behaviours. According to the Organisation for Economic Co-operation and Development (OECD), technological governance is defined as "the process of exercising political, economic and administrative authority in the development, diffusion and operation of technology in societies".²⁵ Broadly speaking, for this report, technological governance relates to responsibilities towards others that can be realized at different stages of a product's life cycle. No single activity related to the development or deployment of diagnostics

can be defined as good governance: several factors must be engaged simultaneously for good governance to be achieved. The interventions and their implementation should uphold the safety and concerns of patients or members of the public.

How technological governance is implemented should align with regulatory considerations but should go beyond regulation by securing ethical compliance as well as adherence to strict standards. The governance of diagnostics must be adaptable to a range of socio-economic and political contexts, so they benefit human health globally. Moreover, general governance principles that have been previously discussed in literature and beyond can guide a range of diagnostic activities,^{26,27,28,29} but they must also be refined according to the type of product and market being considered. This will enable a more context-driven response to diverse levels of health, societal and political contexts in which products are implemented rather than their assuming universality in need.

5.4 Consent, privacy and social engagement

The implications of informed consent, privacy and social engagement should be paramount in the design, development and application of diagnostics in both high-income and LMIC settings, but the means to achieve and demonstrate the attainment of these metrics may differ markedly in various resource environments and cultures. One challenge to be acknowledged regarding consent is that the fast pace at which technology is developing means companies and individuals may not fully realize the extent of what they are committing to. As far as possible, however, consent must still be sought in a meaningful way that enables people to reconsider their choices if they wish.

Understanding the potential for the diagnostic's application to result in inadvertent social implications needs to be evaluated and mitigated. Examples include stigmatization by practices, for example conducting HIV testing in dedicated centres, criminal familial association through genetic data or loss of privacy through medical information sharing.

Obtaining consent, both in the application of a diagnostic and in related data practices, should be strategically and ethically managed, to align with expectations of consent in different communities,³⁰ and an analysis of the target market may reveal power dynamics that undermine the delivery of freely given consent. Various models of consent, including for LMICs, can be particularly useful to ensure the socially responsible deployment,

surveillance and use of diagnostic interventions and the data they generate or require.^{31,32} Any models of intervention and consent must continue to be evaluated as new information about a diagnostic emerges and consultations are made with the affected communities, to ensure the previously collected diagnostic practices remain acceptable.

Collective benefit from the use of data requires the design and function of data ecosystems to enable the local community to gain advantage: inclusive development, innovation, improved governance and equitable outcomes.³³ This should be a core principle of engagement with a target LMIC market for a diagnostic, and may be manifest as capacity building or workforce development, or a recognition of the rights of countries to retain sovereignty over intellectual property (e.g. genetic resources and data).³⁴

Ensuring that stakeholders are aligned with the use of these tools is imperative, given historical concerns by multiple stakeholders about the improper use of certain diagnostic technologies, such as genomic information and testing.^{35,36} While diagnostics can greatly benefit healthcare, in general, these tools remain unequally distributed globally. Given the public's concerns about the potential loss of privacy and other harms in diagnostics,³⁷ ethics and governance must ensure that activities related to their design, implementation and monitoring are driven by populations' needs rather than by an assumption

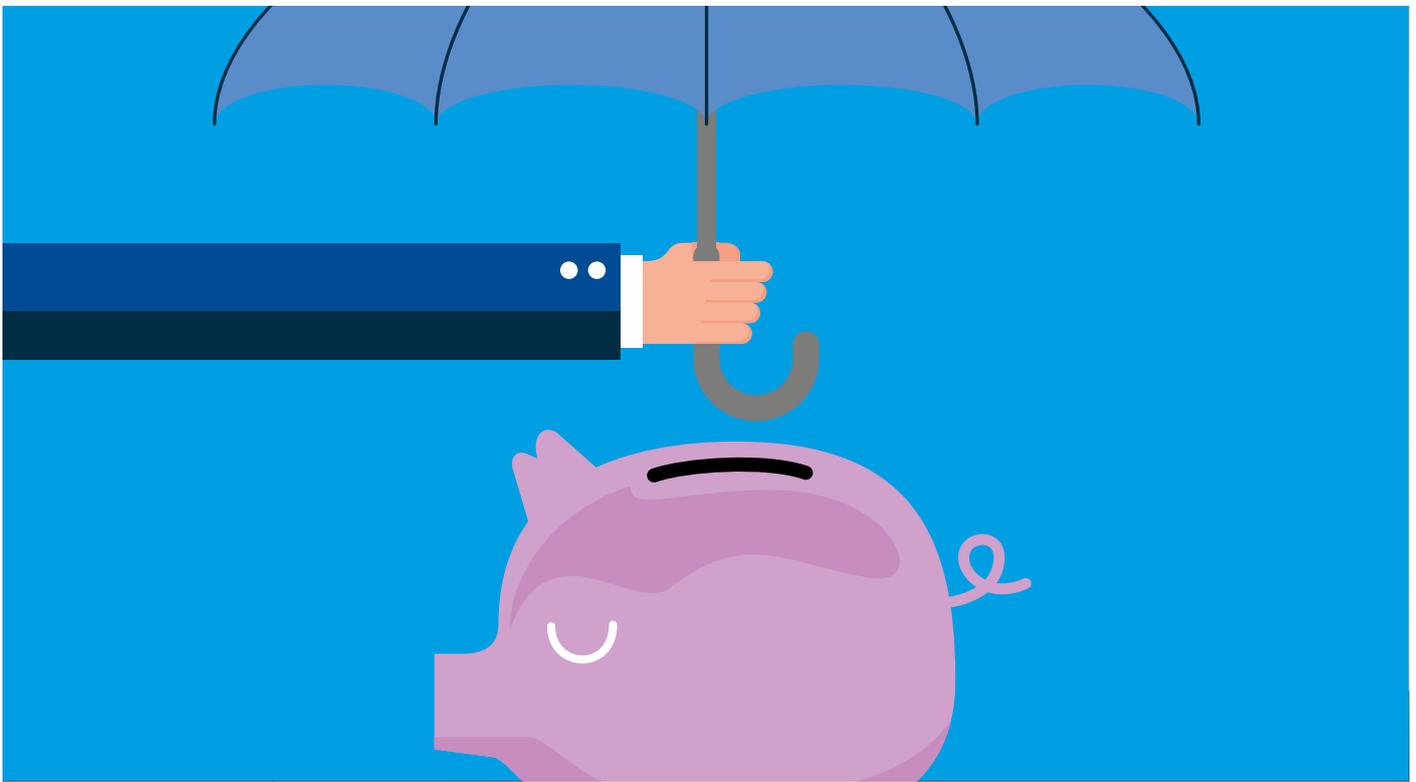
of knowledge and need that responds to certain sections of society and not to whole populations. That is the aim of such collaborations as the [Global Alliance for Genomics & Health](#), which provides support to develop policy frameworks and standards to guide genomics-based activity, and [FIND](#), which strives to ensure that diagnostic technologies are validated within the industry and that those who implement these technologies consider the contexts in which the technologies will be used. Adhering to these standards and tools brings the various professional stakeholders a step closer not only to complying with regulations but to developing a more ethical framework to undertake their diagnostic-related activities.

Safety and efficacy must always precede implementation, and surveillance measures must be in accordance with methods that promote community security while maintaining individuals' rights to decision-making and bodily autonomy. Cooperation and communication

between stakeholders will create and foster trust and transparency, which will influence peoples' likelihood of accepting diagnostic technologies. In this way, technological innovation and governance are attuned not only to industry, clinical or research compliance but also to the social and medical needs of the population³⁸ while respecting people and their agency and choice.^{39,40,41}

Designs, technologies, implementation and analyses that impose certain top-down, rigid approaches of political and charitable bodies, particularly from high-income to emerging communities, are unethical. Even in urgent or crisis situations, technological designs and their use must be executed in ways that do not harm participants, patients or communities; all clinical or research trials must undergo rigorous ethical scrutiny, even if that scrutiny is fast-tracked. Developing standards against such a backdrop will enable regulations, standards and ethics to co-exist and benefit all stakeholders.





6 Access and affordability

6.1 Scope of the problem

Access to affordable and accurate diagnostics is a cornerstone of personal and public health, serving as the entry point to disease management for individuals and populations. Unfortunately, diagnosis is often the weakest link in the overall spectrum of care. Large gaps exist in the diagnosis of both inherited and acquired diseases, leaving millions underdiagnosed in both industrialized and LMIC populations worldwide.

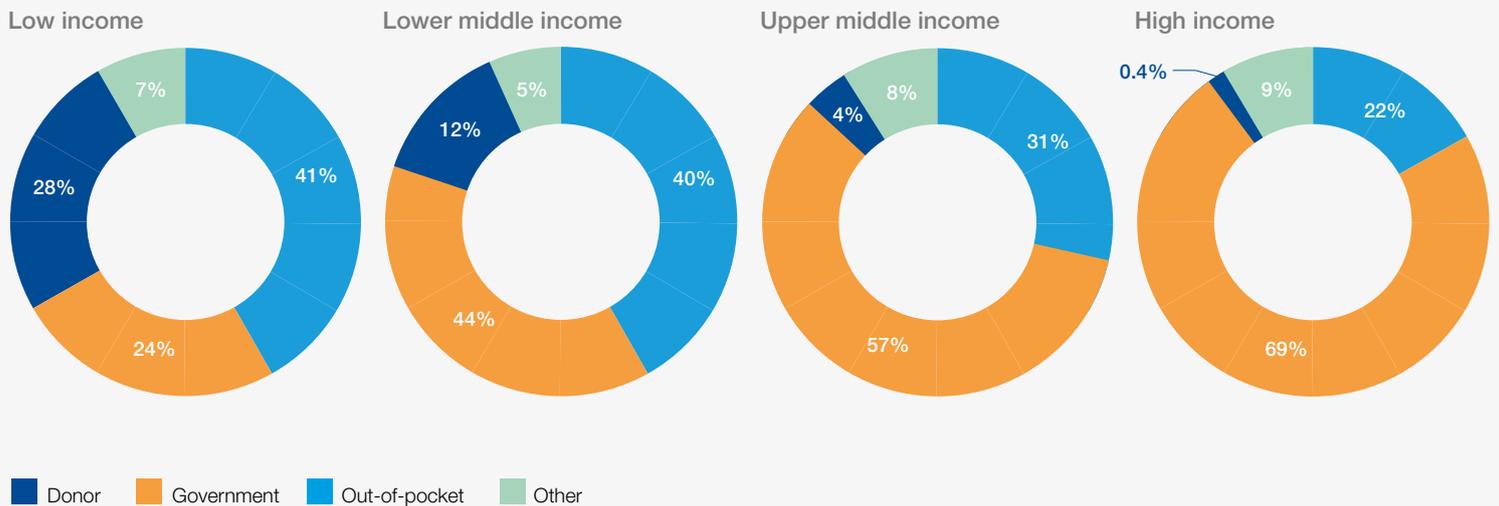
The lack of access to diagnostics is directly tied to loss of life and higher healthcare cost. In 2020, of the 20 diseases responsible for the most years of life lost in LMICs, over 90% require a laboratory diagnostic assessment.⁴² Yet in LMICs, the WHO estimates that only 1% of primary care clinics have basic diagnostic capacity.⁴³ For example, despite the importance of pathology in cancer care, countries in Sub-Saharan Africa have about one-tenth the pathology coverage of industrialized countries.⁴⁴ As a result, most clinicians in many LMICs cannot detect diseases early enough to provide timely intervention and treatment. The costs associated with missed prevention and therapeutic opportunities dwarf direct diagnostic costs.

Reducing the global disease burden will require effective screening, diagnosis and treatment, and thus increased investment across the diagnostic ecosystem (research, infrastructure, training, distribution), especially in LMICs. In recent years, healthcare spending as a share of GDP has grown consistently in LMICs and upper-middle-income countries,⁴⁵ but large inequalities remain. In 2017, per capita health spending in high-income countries was more than 70 times greater than in low-income countries (\$2,937 vs \$41, respectively).⁴⁶ Part of this discrepancy is due to differences in disposable income, and LMICs often rely heavily on donor funding to supplement healthcare spending. In these countries, investment in laboratory infrastructure must compete for resources with more fundamental needs. This may leave these services underfunded, with little support for implementation, procurement, supply or reimbursement. The consequences of this underinvestment include lower-quality disease management for individuals and a weak foundation for expanding services in times of public health crises (see the COVID-19 case study).

High-quality, cost effective healthcare begins with a timely, accurate diagnosis, which leads to appropriate therapy. Even in high-resource settings, policies and reimbursement models that incentivize investment in therapeutics have directed resources away from diagnostic development. As the treatment of most acute or chronic diseases

is more expensive as the disease progresses, the importance of shifting intervention earlier in the disease curve is a central component of effective disease management. Healthcare expenditures can be reduced by increasing LIMCs' access to affordable and rapid diagnostic tests that are commonplace in the developed world.

FIGURE 1 Shares of health spending by country income, 2017



Source: World Health Organization, "Global Spending on Health: A World in Transition", 2019, p. 9.

The WHO's recognition of diagnostics as an essential component of an effective healthcare delivery system is a major step towards promoting public and private investments in the diagnostics field.

6.2 Moving forward

Globally, diagnostics must be acknowledged and committed to as a critical component of health. The WHO released the first "Essential Medicines List" in 1977, but it was not until 2018 that it released its first "World Health Organization Model List of Essential In Vitro Diagnostics".⁴⁷ The latest edition of this list, released in 2019, includes 122 test categories.⁴⁸ These test categories were designed to advance the three strategic priorities of the WHO's "Thirteenth General Programme of Work, 2019-2023" – achieving universal health coverage, addressing health emergencies and promoting healthier populations.⁴⁹ According to the WHO, the "Model List of Essential In Vitro Diagnostics" will be updated regularly and will expand to include diagnostics to screen for microbial resistance, neglected tropical diseases, emerging pathogens, and other non-communicable diseases. This is

a major step forward to raise awareness of the need for diagnostics. However, to turn this call for increased access into a reality, it must be met with increased funding and innovation.

A coordinated commitment from government and the private sector to fund the development and implementation of diagnostics is essential. Government financing needs to support equitable access, R&D and regulatory oversight in diagnostics. Financing systems need to be sustainable and sufficiently flexible to adapt to changes in disease prevalence, microbial resistance patterns, emerging diagnostic technologies and new forms of treatment. These efforts also need to include improved access to data and harmonized regulatory processes across regions and jurisdictions, which may encourage entrepreneurial

ventures and the introduction of new products in LMICs. Programmes that provide public funding and collaboration with private entities can also incentivize investment in sustainable and scalable diagnostics. Egypt's "100 Million Healthy Lives" campaign⁵⁰ to detect and eradicate hepatitis C is an example of how governments in LMICs and industry in upper-middle-income countries can partner in a leadership role. These public-private partnerships have the potential to provide the most efficient path to deliver high-quality diagnostics and capacity in a cost-effective manner. To bring affordable diagnostics to populations, multi-tier payment models and incentives that serve populations of different socio-economic levels will need to be established.

Suggestions to address these and other major gaps in the access to diagnostics include:

- Investment in affordable technologies that can reduce R&D and manufacturing costs (e.g. additive manufacturing)

- Public-private partnerships to leverage knowledge and technology transfers
- Multi-tiered, connected, integrated laboratory networks (central labs and point-of-care testing)
- Procurement of high-quality diagnostics, instruments and consumables
- Effective supply chain management
- Training of laboratory professionals to administer tests and analyse results
- Regulatory and quality assurance systems
- Disease surveillance and monitoring technologies
- Information technology capabilities that emphasize point-of-care delivery, connectivity and AI analytics that promote data aggregation, integration and population management.

FIGURE 2 Multi-tier model for affordable diagnostics



Source:
World Economic Forum

Over the past 40 years, global challenges, such as HIV/AIDS, malaria, tuberculosis, influenza, Ebola, MERS, SARS-CoV and the recent COVID-19 pandemic, have demonstrated the interconnectedness of global healthcare systems

and the risks (health and financial) to governments and industry of deferring investment in diagnostic infrastructure. There is a real opportunity, now, to leverage the use of diagnostics to better support healthcare systems around the world.



7

COVID-19 case study

On 30 January 2020, the WHO declared the outbreak of a respiratory disease caused by a novel coronavirus in a declaration of a public health emergency of international concern.

On 11 February 2020, the WHO named the virus “SARS-CoV-2” that causes coronavirus disease 2019, or “COVID-19”. Within six months of this declaration, the global number of cases had surged into tens of millions, with hundreds of thousands of deaths. Despite preventive measures, the pandemic

continues to expand throughout the world. The COVID-19 response exemplifies issues concerning the design and deployment of diagnostic technologies.

The COVID-19 case study explores the role of diagnostic technologies in pandemics and how scientific, policy and social practices related to these technologies enhance or diminish efforts to contain a growing public health crisis.

Epidemiology

Coronaviruses are a large family of viruses that are known to circulate in many species of animals. COVID-19 is an infectious disease caused by a newly discovered coronavirus. It has relatively high

transmissibility and low lethality rates. To date, no region of the world has been spared from the virus; even where infection rates have been considered low, social and economic effects remain.

FIGURE 3 | Global map of COVID-19 infections, February 2021



Source: Johns Hopkins University & Medicine⁵¹

Attempts to contain the spread of the virus in the pre-vaccine period rely on minimizing transmission and on the accurate and timely diagnosis of infections. At various levels of implementation, enforcement and controversy, the measures have included:

- Stopping all but essential travel, both locally and internationally
- Confining people to their homes

- Requiring people to wear a mask
- Closing schools and non-essential industries
- Launching public health campaigns for handwashing and physical distancing.

While rapid diagnosis and accurate detection are crucial for the prevention and control of further outbreaks, the ways in which diagnostic technologies for COVID-19 have been designed and deployed have been contentious.

Diagnostic and public health concerns

COVID-19 has had a catastrophic impact on governments, economies, medical systems and society. Unprepared to handle a pandemic, nations have implemented a range of responses with varying success. While the effects of inadequate medical and surveillance systems have been highlighted in LMICs in particular, structural inequalities and the chronic underfunding of research and healthcare have also impeded COVID-19 responses in industrialized nations.

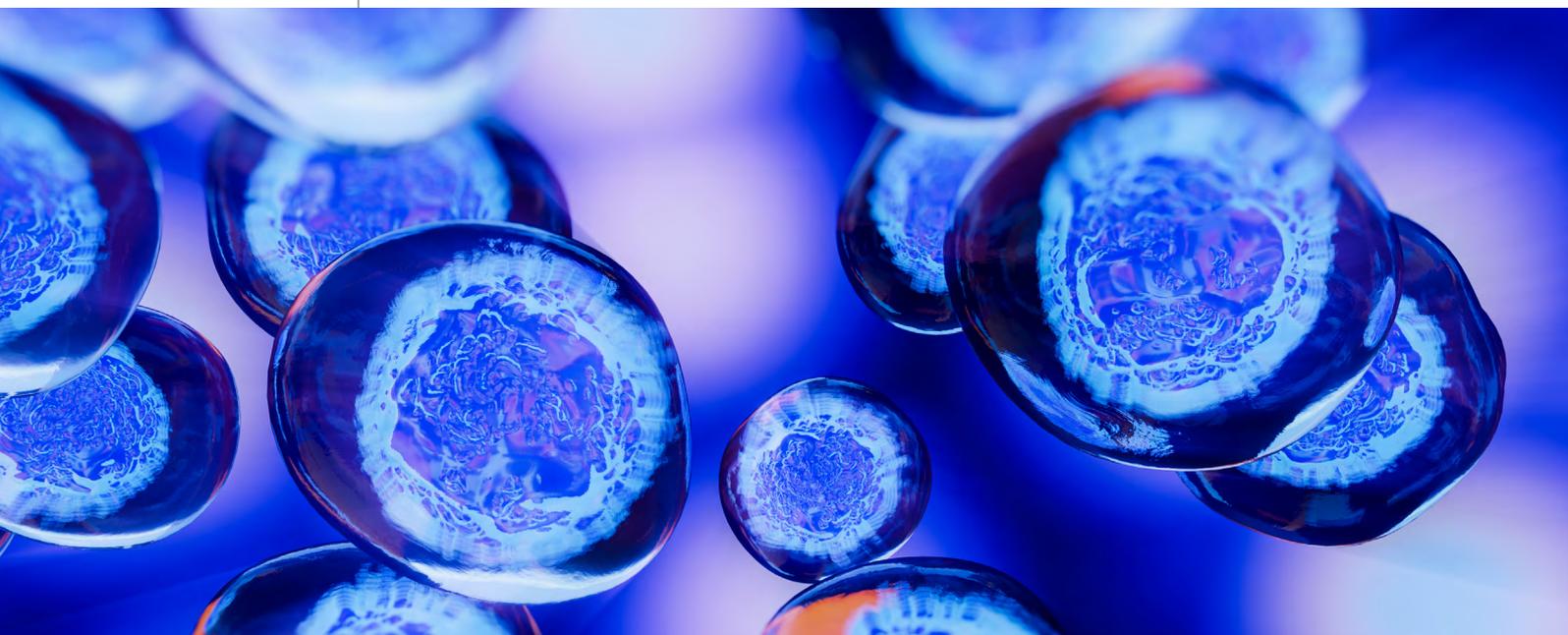
As mentioned, advances in diagnostic technologies are usually gradual – reliant upon interdependencies between investment, scientific advancement, validation, regulation and implementation. These processes have had to accelerate during the COVID-19 pandemic, but the acceleration has been inconsistent, both in the effectiveness of the diagnostics themselves and in their distribution and adoption across geographic boundaries. Many nations have encountered supply challenges and

insufficient capacity to implement certain diagnostic tools at the required volume. Where the supply of COVID-19 diagnostics has been unable to meet the demand, authorities have resorted to alternative means of detection, through symptom checking and contact tracing. However, when asymptomatic infection was confirmed, both civil measures and diagnostic implementation had to be revised.

In LMICs, the reliance has been on donations or support from charitable and philanthropic organizations, agencies and governments. However, the lack of acknowledgement of local testing and storage conditions has resulted in diagnostic equipment failure in different climates, and incompatibility with local infrastructure has caused testing kits to be returned. Many small-scale responses have been insufficient to counter the large-scale public needs, against the backdrop of chronic underinvestment in healthcare and capacity building in many LMICs.

Health crisis emergencies can also cause ethical considerations, such as those that follow, to be minimized:

- COVID-19 diagnostics involving genetic analysis of both viral strains and of human risk, amplifying historical injustices for those who are already marginalized in society
- Information collection pertaining to contact tracing, raising concerns about personal agency and compounding the level of public anxiety
- The dramatic increase in demand for personal protective equipment and the imbalanced distribution of medical resources, with some countries' lack of solidarity and the politicization of supply, undermining equipment distribution
- Policy decisions meant to assess COVID-19 transmission and public safety, negatively impacting the economic sustainability of a nation.



Responses and measures

Progress is being made despite the challenges of the global response to the COVID-19 pandemic. Authorized assays for SARS-CoV-2 testing include viral tests that detect nucleic acid or antigens. Robust standards have been introduced to support technological equivalency, so tests in one area mean the same as tests in another area, which is crucial to create a global understanding of the virus.⁵² Further, COVID-19 diagnostics are increasingly specific, which is critical for public healthcare delivery and to maintain public trust in the response to the pandemic.

The urgency of the pandemic has put pressure on innovation and created new models that have disrupted prior protocols for diagnostic practice, for

example the implementation of point-of-care, rapid turnaround tests that do not require delivery at a medical facility. This model reduces the need for human contact, mitigates the risk of transmission and avoids the overwhelming of health system capacities.

Considering the large-scale infection rate and strong transmissibility of COVID-19, high throughput sequencing tools and automatic lab capacity have become key factors of rapid diagnosis. And public health and private partnerships and responses have been vital; diagnostic testing and laboratory companies have come together to assist public health responses to the pandemic, and opening up data for testing and creating new diagnostic technologies have been transformative.

Recommendations

Experiences gained from the COVID-19 pandemic can inform recommendations for evaluating diagnostic development and access. Both developing and developed countries must evaluate their COVID-19 response and consider future intervention and management, asking themselves whether diagnostic capacity did and can meet demand, and whether ongoing R&D is sustainable.

New models of effective healthcare should be explored via public-private collaboration. While the balance between commercialization and the provision of public goods is ethically and operationally complex, it will rely upon clear strategies.

These elements of the diagnostic ecosystem will be vital to contain COVID-19 and to respond to future pandemics.

Countries with established scientific infrastructure and credentials have considerable advantage in the global response to COVID-19; capitalizing on large production capacity, researchers pivot to develop diagnostics and vaccines in a regulatory environment amenable to R&D. However, these opportunities may be lost to LMICs. Internal health system capacity must be built to facilitate an efficient local response, and standards should be regulated and set through international collaboration.

COVID-19 has emphasized that health threats must be faced collectively, independent of nation or community. Collaboration across countries and interdisciplinary cooperation are critical for collective success. Sharing information and data, lessons and experiences; distributing diagnostics, equipment and personal protective equipment across borders; and, importantly, sharing the financial burdens of diagnostics will all be useful for a global response to the pandemic.

No one country can win the battle against the virus until all countries are able to respond to it in a concerted way.

The diagnostic ecosystem – people and technology, public and private institutions, and R&D – has a critical role to play in responding to pandemics. This ecosystem should be a global framework that is improved systematically, to better not only people's health but to ensure greater capacity, ability and confidence to confront the unpredictable future.





Recommendation and conclusion

Diagnostics are a major component of healthcare provision in any health system. For diagnostics to be effective and efficient across different settings, health ecosystems must account for a wide range of issues from the laboratory to the patient. This report highlights that the broad use of diagnostics must recognize that the pathway from the lab to the patient differs according to geographies and available capacities in countries. To address these and other gaps, investment in affordable technologies and the creation of innovative funding approaches for diverse markets are needed. Additionally, the relevant high-quality resources required to realize global diagnostics must be brought together with effective supply chain management and the training of laboratory and clinical professionals to administer and analyse diagnostic tests and results.

One size does not fit all. Disease surveillance, diagnostic use monitoring, uptake and safety, data analytics and point-of-care practices must be both ethical and suitable for the resource and cultural setting. As explored in this report, diagnostics can be more effectively deployed in diverse settings and still provide the intended outcomes per population, if stakeholders align their diagnostic capabilities to a global health agenda. Next steps include moving this diagnostics agenda forward by increasing support for current global initiatives, and increasing efforts through the establishment of a coordinated *global alliance for affordable diagnostics*. This proposed alliance would learn from the successful models of other global public health initiatives that create long-term, sustainable markets for diverse healthcare necessities, such as vaccines. It would adapt those approaches to expand the availability of essential diagnostics, fostering their “fit for purpose” development relative to markets, and would explore mechanisms that support access to advanced diagnostics.

Contributors

Tiffany Boughtwood

Managing Director, Australian Genomics, Murdoch Children's Research Institute
Australia

Jenn Buechel

Chief Operating Officer, Delfi Diagnostics
USA

Mavis Machirori

Research Fellow, Schools of Social and Political Sciences, University of Glasgow; Visiting Researcher, Policy Ethics and Life Sciences, Newcastle University
United Kingdom

Elizabeth O'Day

Chief Executive Officer and Founder, Olaris Inc.
USA

Elissa Prichep

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

Pam Randhawa

Chief Executive Officer and Founder, Empiriko Corporation
USA

Xu Xun

Chief Executive Officer, BGI Group
People's Republic of China

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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