



**FIND** ➡➡➡  
Diagnosis for all

**TESTING FOR  
HEALTHY AND  
SAFE LIVES**

FIND STRATEGY  
2021





## OUR MISSION

FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis around the world.

◆ We connect countries and communities, funders, decision-makers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems.

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# FOREWORD

Since its emergence, COVID-19 has dominated international governmental attention and generated unprecedented mobilization of the funds and resources needed to support healthcare responses and economic interventions. Governments worldwide have been willing both to intervene and rapidly build capacity in their efforts to get the virus under control and protect their people. The pandemic has also reminded many of the interdependency of all countries in a health emergency, and the need for multinational and multisectoral cooperation.

This may not be new to those countries that continue to wrestle with the challenges such as Ebola and SARS, but it was clearly more unexpected for the highly industrialized countries of Europe and North America, whose populations have not faced comparable health challenges since the Spanish flu a century ago.

That testing surfaced as an Achilles’ heel in so many health systems around the world is not a surprise to those of us who have been advocating for diagnostics for years. We have known for some time that testing is the weakest link in the care cascade – preventing individuals from accessing the care they need, and also depriving decision-makers of the data that could enhance efficiency and effectiveness of healthcare delivery.

This new FIND strategy comes at the right time. After a year of battling COVID-19, governments must now see the value in systematically investing in testing, in prioritizing testing in national health strategies, in supporting local manufacturing, and in ensuring effective, real-time disease surveillance systems are in place. The virtuous cycle of innovation in both technology and access is key to strengthening our health systems so that they are both resilient and sustainable.

When the pandemic hit, low- and middle-income countries were already fighting not only deadly infectious diseases like tuberculosis, malaria and hepatitis, but also growing emergencies such as diabetes. Antimicrobial resistance is claiming lives at such a rate that it is on track to eclipse the losses due to COVID-19. Defeating these killers, making universal health coverage a reality, and ensuring that we have the early warning and response mechanisms in place to prevent another global pandemic, requires urgent and effective action. I believe FIND, working with partners as a global alliance for diagnostics, has the proven expertise and experience needed to transform testing so that everyone who needs a test can get one.

Health is a human right. With testing at the heart of our work, together we can rebuild a fairer, safer world.

**H.E. AMINATA TOURÉ,  
FORMER PRIME MINISTER OF SENEGAL  
AND FIND GOODWILL AMBASSADOR**





# EXECUTIVE SUMMARY

## DIAGNOSIS IS THE WEAKEST LINK IN THE CARE CASCADE

Quality, timely diagnosis is an essential enabler of health for all. Early diagnosis has been consistently linked to improved health outcomes and reduced out-of-pocket spending, and disease surveillance provides critical data to inform public health action. However, diagnosis is the weakest link in the care cascade, with basic diagnostic capacity available in just 1% of primary care clinics in low- and middle-income countries (LMICs).

No diagnostic tests exist for 60% of the “Blueprint” pathogens, which have been identified by the World Health Organization (WHO) as having the greatest outbreak potential. There is no appropriate test for 50% of the top 20 diseases responsible for the most lives lost. This lack of availability and access to quality, reliable tests threatens our ability to respond to health emergencies, and jeopardizes the achievement of universal health coverage (UHC).

Since 2003, FIND has been working to bridge product development gaps for essential diagnostics in collaboration with the international research community, the public sector, and industry. We have learned valuable lessons along the way, building on strengths across the diagnostics value chain from product development to delivery, identifying opportunities to better serve patients and their communities.

## THIS IS A UNIQUE MOMENT IN TIME FOR TESTING

In 2020, testing took centre stage, as the COVID-19 pandemic swept the world. Years of sustained neglect of diagnostics meant high- and low-income countries alike found themselves without the capacity to contain the spread of the virus, and fragile supply chains and nationalism sparked fierce competition for the procurement of the few tests available early on. Disruptions to essential health services had dire consequences for both infectious and non-communicable diseases (NCDs).

Against this bleak backdrop, unprecedented opportunities continue to emerge. Strong regional and country leadership led to rapid strengthening of testing and surveillance capacity. New digital technologies are improving diagnostics and testing, such as artificial intelligence algorithms that can enable computerized cough analysis to differentiate between COVID-19 and tuberculosis (TB). Connectivity paves the way for healthcare services to be accessed through mobile and digital apps, and the rise in wearables and at-home tests has the potential to transform self-monitoring and self-testing approaches.

## AN END-TO-END ALLIANCE MODEL TO ACCELERATE GLOBAL EFFORTS TOWARDS UHC AND HEALTH EMERGENCY RESPONSE

FIND has been at the forefront of the global pandemic response, co-leading the Diagnostics Pillar of the Access to COVID-19 Tools (ACT) Accelerator – a ground-breaking collaboration of many of the world’s international health organizations – alongside the Global Fund and WHO.

Our new strategy seeks to harness the momentum around testing for COVID-19, exploiting emerging digital innovations, and building on our organization’s 20-year experience as a product development partnership focused on diagnosis of TB, malaria and fever management, hepatitis C, and neglected tropical diseases (NTDs).

Our end-to-end alliance model builds on the ACT-Accelerator framework to maximize impact, from innovation to implementation.

In support of UHC, our goal is to expand primary care testing to combat diseases that disproportionately affect vulnerable populations. Reducing the huge diagnostic gaps in TB, hepatitis, antenatal screening for both communicable diseases and NCDs, fever, pneumonia and NTDs will save lives and livelihoods, save health systems money, and contribute to global and national disease elimination targets.

To mitigate health emergencies, our goal is to strengthen diagnostic surveillance and response systems to contain outbreaks and improve pandemic preparedness, aligned with a

One Health approach. Testing is the first line of defence against outbreaks that are becoming increasingly severe and complex. We are working to address not only recognized epidemic-prone pathogens such as SARS-CoV-2 and Ebola virus, but also the “silent pandemic” of AMR by improving access to AMR testing and surveillance to safeguard drugs and reduce mortality. Our fight against COVID-19 is far from over, and requires intensified efforts to realize mass testing for test-trace-isolate implementation and sequencing-based surveillance – so that viral evolution does not jeopardize progress.

Alongside our efforts to serve diseases and populations, we are working to strengthen the diagnostic ecosystem. This includes sequencing to improve surveillance and diagnosis, fostering an integrated biobank network to facilitate diagnostic development and implementation across diseases, and diagnostic network design and optimization so that data can be maximized to deliver context-specific testing strategies.

To enable accountability from all parties, we aim to cement the essential place of diagnostic testing within health systems through political commitments at the highest levels.

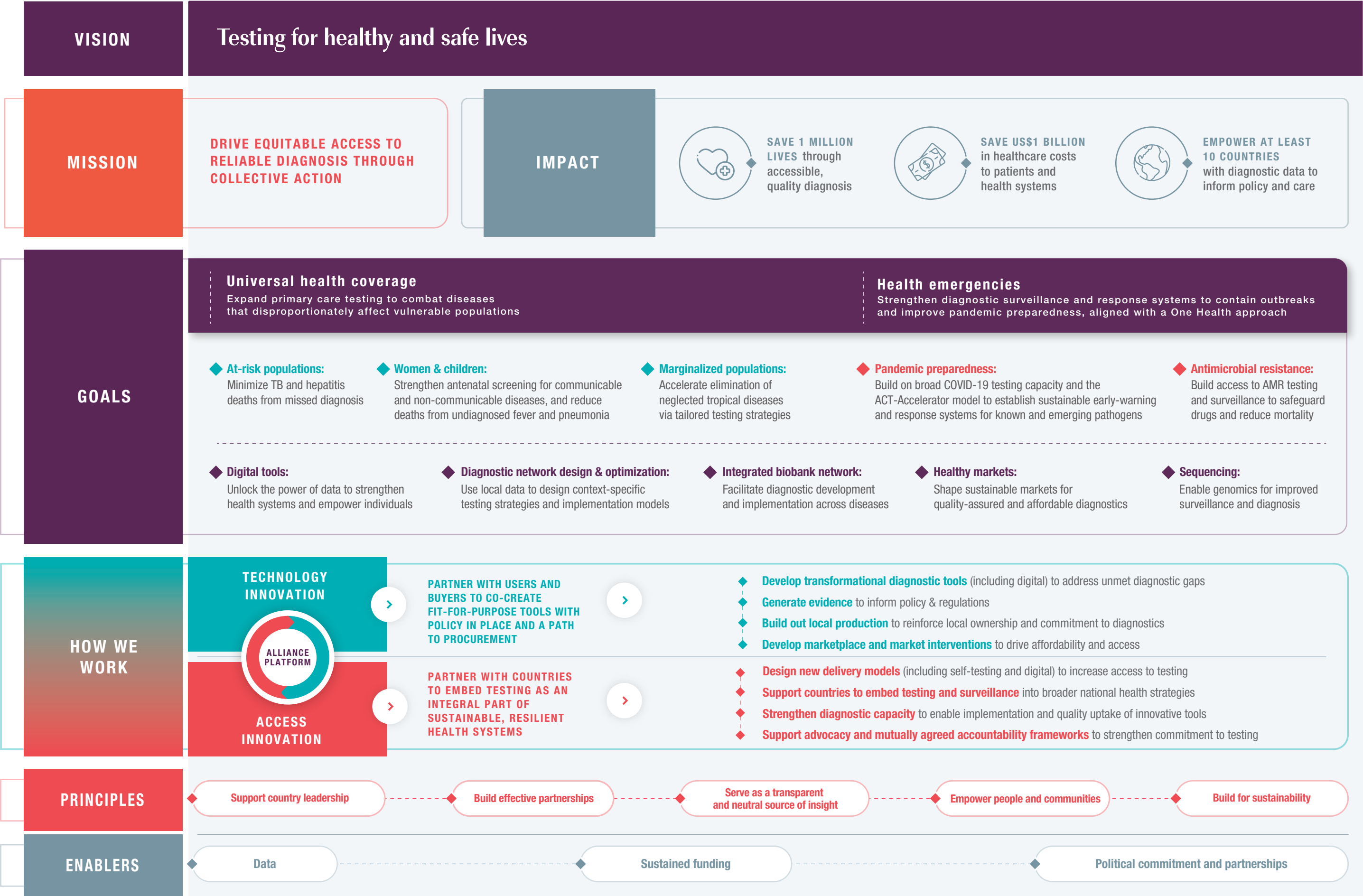
This end-to-end scope requires a robust, transparent business model built for diagnostic sustainability, designed to harness collective action and create a virtuous cycle of technology innovation (supply of new or improved tools) and access innovation (demand from countries).



**Harnessing partners’ strengths as part of an alliance will enable us to bring cutting-edge diagnostics to market faster and at scale, and increase the priority of essential diagnostics in national health programmes. Delivery of this ambitious plan will take US\$100–120 million per year. But with at least 1 million lives being saved over the 3-year period, US\$1 billion in savings to health systems and patients and at least 10 countries empowered with diagnostic data to inform policy and care, the return on investment is clear.**

**TOGETHER, WE CAN ENSURE THAT EVERYONE WHO NEEDS A TEST CAN GET ONE.**

# FIND, THE GLOBAL ALLIANCE FOR DIAGNOSTICS: 2021 STRATEGY AT A GLANCE







THE TIME FOR  
ACTION IS NOW

COVID-19 thrust diagnostics and testing into the spotlight, highlighting years of under-investment and neglect. Yet unprecedented opportunities also emerged, with effective regional leadership rapidly ramping up testing capacity, and new digital technologies paving the way for mobile and at-home testing.

Quality, timely diagnosis is an essential enabler of health for all. Early diagnosis has been consistently linked to improved health outcomes and reduced out-of-pocket spending, and disease surveillance is key to identifying, responding to and containing new outbreaks. However, compared with vaccines and treatments, the value of diagnostics has historically been overlooked by policy makers, healthcare workers and patients alike. As a result, no diagnostic tests exist for 60% of the “Blueprint” pathogens, which have been identified by the World Health Organization (WHO) as having the greatest outbreak potential.<sup>1</sup> Similarly, there is no appropriate test for 50% of the top 20 diseases responsible for the most lives lost.<sup>2</sup>

Despite the introduction of the WHO Essential Diagnostics List in 2018, testing remains (now very conspicuously) absent from national health strategic plans, without a dedicated budget line:<sup>3</sup> basic diagnostic capacity exists in just 1% of primary care clinics and 14% of hospitals in low- and middle-income countries (LMICs).<sup>4</sup> Without tools available to diagnose common causes of fever or cough, how can we expect early detection of potential disease outbreaks? In addition to being disproportionately affected by life-threatening diseases, vulnerable populations are often invisible to policy makers and can thus find themselves excluded from conventional healthcare services.<sup>5</sup>

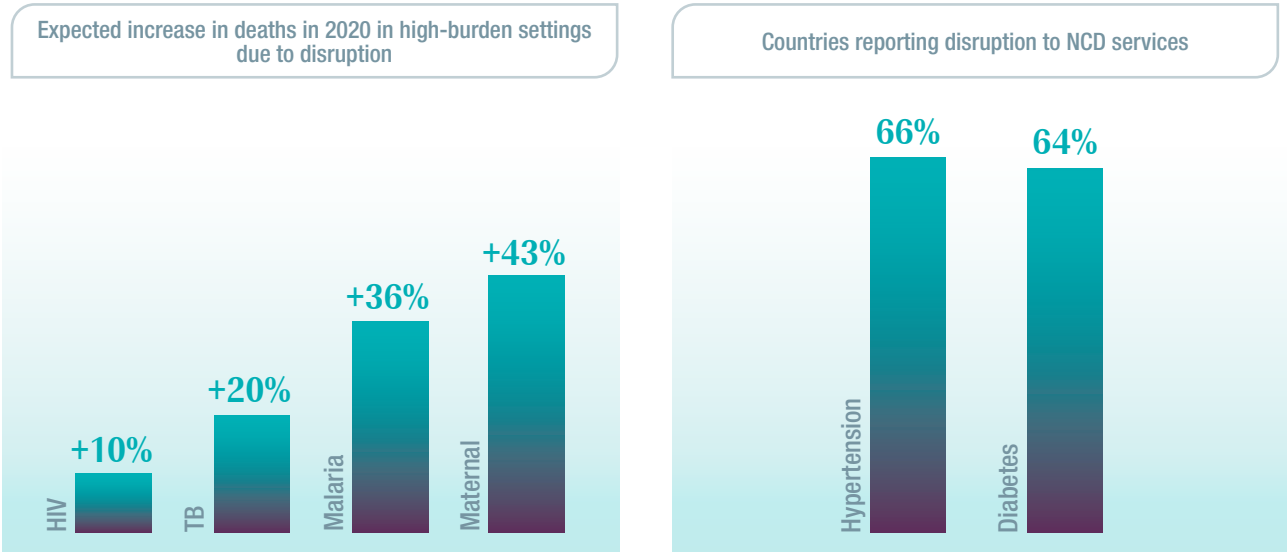
For every patient in the world who is diagnosed with a disease, a second goes undetected.<sup>6</sup> One in three cases of tuberculosis (TB) – the leading infectious disease killer in the world, claiming 1.5 million lives each year – is not diagnosed or reported;<sup>7</sup> one in three people with diabetes in LMICs have never had their blood glucose measured.<sup>8</sup>

Misdiagnosis is just as consequential. Two in five maternal deaths may have been preventable with a correct diagnosis, according to a study in Mozambique.<sup>9</sup> A study in Tanzania found that just 45% of patients treated for malaria actually had the disease.<sup>10</sup> The result is a patient deprived of the care or treatment that they really need, and over-prescription of antibiotics that fuels the deadly rise of antimicrobial resistance (AMR). Lack of access to quality, reliable tests threatens our global health security and jeopardizes the achievement of universal health coverage (UHC).

In 2020, testing took centre stage, as COVID-19 swept the world. Years of sustained diagnostic neglect meant high- and low-income countries alike found themselves without the capacity to contain the spread of the virus, and fragile supply chains and nationalism sparked fierce competition for the procurement of the few available tests early on. With the pandemic throwing millions of people into extreme poverty,<sup>11</sup> disparities are widening and vulnerable populations are growing. A year after the virus first emerged, testing rates in LMICs were 10 times lower than in high-income countries.<sup>12</sup>

A WHO survey of 105 countries found that almost every one of them also experienced disruptions to essential health services as a result of COVID-19, with LMICs reporting the greatest difficulties.<sup>13</sup> Challenges spanned non-communicable diseases (NCDs) and infectious diseases, as people encountered new obstacles to accessing health services for reasons including fear of contracting COVID-19, lack of transport options during lockdown periods, and worries about paying for medical care in the face of employment uncertainties.

COVID-19 HAS DISRUPTED ESSENTIAL HEALTH SERVICES FOR BOTH INFECTIOUS AND NON-COMMUNICABLE DISEASES <sup>14-16</sup>





Against this bleak backdrop, however, unprecedented opportunities also emerged. Strong regional and country leadership, such as the African Union Commission and the Africa Centres for Disease Control and Prevention (Africa CDC) Partnership to Accelerate COVID-19 Testing (PACT) initiative, led to rapid strengthening of testing and surveillance capacity. New digital technologies are providing immense opportunities to improve diagnostics and testing, such as artificial intelligence algorithms that can enable computerized cough analysis to differentiate between COVID-19 and TB.<sup>17</sup> The focus on connectivity paves the way for healthcare services to be accessed through mobile and digital apps, and the rise in wearables<sup>18</sup> and at-home tests<sup>19</sup> has the potential to transform self-monitoring and self-testing approaches.

COVID-19 HAS ACCELERATED GAME-CHANGING TECHNOLOGY ADVANCES



- **ARTIFICIAL INTELLIGENCE & MACHINE LEARNING**  
Quality diagnosis in areas without specialist healthcare workers
- **MOBILE DEVICES & CONNECTIVITY**  
Reach the hard-to-reach; enable real-time monitoring of health status
- **NEXT GENERATION TECHNOLOGIES (GENOMICS, CRISPR)**  
Sequencing for disease surveillance and rapid response
- **WEARABLES & HOME-USE-TOOLS**  
Self-monitoring, early detection and ambulatory management
- **SUSTAINABILITY**  
Minimize environmental impact of single-use tests



Crucially, the value of the actionable data that testing provides at every stage of a pandemic has become self-evident, with countless lives being saved from COVID-19 through effective test-trace-isolate strategies. Vaccines are critical, but the emergence of COVID-19 variants shows that there is no magic bullet – testing remains as crucial as ever to monitor and control disease spread. Now is the moment to address gaps across the whole diagnostic value chain that have been quietly claiming the lives of people with treatable diseases for decades. The Access to COVID-19 Tools (ACT) Accelerator was formed to ensure equitable access to tests, treatments and vaccines, in recognition that all three are interdependent and equally important for safeguarding health. The Diagnostics Pillar of the ACT-Accelerator, co-convened by FIND and the Global Fund, brought together over 30 international partners and provides valuable experience and insights that lay the groundwork for the formation of a global alliance for diagnostics that can live on beyond the pandemic.

For every single percentage point by which we can reduce the overall diagnostic gap, 25,000 lives could be saved.<sup>20</sup> Closing it completely will require transformative, scalable approaches that are backed by both political will and funding (including domestic resources). Unified, collective action is vital, as progress towards the UN Sustainable Development Goals is receding in the face of the pandemic, global health security remains a major risk, and the achievement of UHC by 2030 is in jeopardy. The time to act is now.



◆ THE RIGHT TO HEALTH DEPENDS ON  
EQUITABLE ACCESS TO QUALITY DIAGNOSIS

Improving equitable access to testing is at the core of our work: everyone who needs a test should be able to access one, when and where they need it, without financial hardship, stigma or discrimination. Primary healthcare and community-based organizations have a unique role to play in realizing this vision, not just in ensuring appropriate care and health monitoring for individuals in their communities, but also being on the front-lines against global threats including disease outbreaks and AMR.

WHO and UNICEF define primary care as a key process in the health system that supports first-contact, accessible, continued, comprehensive and coordinated patient-focused care.<sup>21</sup> In November 2018, UN Member States affirmed their commitment to UHC in the Astana Declaration, describing primary care as a “cornerstone of a sustainable health system for UHC and health-related Sustainable Development Goals”. This vision of equitable access to quality diagnosis is the driving force behind our work, and unlocking the value of diagnostics in primary care requires the availability of rapid, easy-to-use and affordable diagnostic tools (including self-tests and point-of-care tests) as part of an integrated health system that links diagnosis to care.

Vulnerable populations

Vulnerable populations can be excluded from accessing health services because of their age, gender, ethnicity, disability, or sexual orientation or because of their socio-economic status, geographic location, or the impact of humanitarian crises. The testing needs of vulnerable populations can hold the key to democratizing testing for all. The success of this strategy will be determined by our ability to reach:

- › Pregnant women and children
- › Urban poor
- › Hard-to-reach rural populations
- › Prisoners
- › People who inject drugs
- › People living with HIV
- › Migrants and refugees
- › Indigenous populations
- › Sex workers
- › Men who have sex with men



◆ A FOCUS ON GENDER AND EMPOWERING WOMEN CAN  
INCREASE ACCESS TO TESTING FOR EVERYONE

Sex and gender play an often-underestimated and ill-understood role throughout the research, development, and implementation process for all health technologies. For diagnostics and testing, gender norms and roles are critical determining factors to ensure the first step – diagnosis – is not missed in the cascade of care. Everyone, regardless of gender, will need a diagnostic test at some time in their lives, yet gender roles can exacerbate specific access barriers. In a study of pregnant women in South West Nigeria, 97% reported relying on their husbands for money to access antenatal testing and care; in Myanmar, only 40% of female factory workers in Myanmar sought testing for TB symptoms because they were not allowed to take time off work.<sup>22</sup> In some cases, the testing gap is more significant among men because social norms lead to increased health risks and insufficient focus on prevention. In addition to needing tests for conditions and diseases common to all, including HIV/AIDS, TB, and COVID-19, women additionally require tests unique to their reproductive systems, such as antenatal tests related to pregnancy.

In healthcare delivery, women themselves have a crucial role to play. UHC, including essential diagnostic testing, will be primarily delivered by women, as they form the vast majority of the health and social care workforce. On the policy front, women political leaders have shown their formidable influence in prioritizing health issues. At the community level, women are critical health influencers in families and communities. Testing empowers people by providing crucial information that improves lives and increases prosperity for all. But without a specific focus, we may fail to address the gender-related barriers to testing.

For example:

- ◆ The tests that women need are often not available in health systems
- ◆ Gender inequality creates information, financial, and cultural barriers for women to access testing
- ◆ Women lack trust in testing services, and may fear procedures, diagnosis, and stigma
- ◆ Barriers to testing are compounded for marginalized women, especially in humanitarian contexts
- ◆ Female health workers can scale up testing for everyone, if enabled with training, resources, and decent work
- ◆ Taking testing to women at home and work, and self-testing, can expand testing to more women and more people in communities







**FIND LEADERSHIP  
IN COVID-19  
GLOBAL RESPONSE  
BUILDS ON 20 YEARS  
OF SUCCESSFULLY  
DRIVING INNOVATION  
& DELIVERY  
OF DIAGNOSTICS**

FIND was founded in 2003 to bridge existing product development gaps for essential diagnostics by initiating and coordinating research and development (R&D) projects in collaboration with the international research community, the public sector, and the *in vitro* diagnostics industry.

Our previous strategy, spanning the period 2015–2020, expanded an alliance of partners to focus on translating the technical world of product development into access to diagnostic solutions that meet patient needs in low-resource settings.

Over the last 5 years, we have solidified FIND’s position as a nimble, specialist organization, with strengths across the diagnostics value chain from R&D to delivery, able to rapidly adapt to a changing global environment. We have learned valuable lessons along the way, identifying opportunities to build or shift our approach and better serve patients and their communities.

**FIND 2015–2020 STRATEGY IN NUMBERS**





◆ **BRINGING LOCAL INNOVATION TO SCALE**

In partnership with the Indian government, we expanded the molecular testing market with the approval of the first point-of-care molecular platform from an Indian manufacturer (Truenat™), now available in more than 50 countries. WHO endorsed Truenat tests for initial diagnosis of TB and detection of rifampicin resistance in July 2020, and a total of 6 million TB tests were tendered by the Indian national TB programme the same year. With tests currently available on the Truenat platform for over 14 global health priority diseases including malaria, HIV, hepatitis and gonorrhoea, the expanding instrument base was also used to conduct 5 million COVID-19 tests in 2020.



◆ **OPTIMIZING DIAGNOSTIC SYSTEMS AS AN INTEGRAL PART OF HEALTHCARE**

Through optimization of diagnostic networks to identify the most appropriate locations in which tools should be placed, defining the optimal device mix, and/or designing efficient referral network linkages, we have generated financial savings, integrated testing and informed country diagnostic strategies. In partnership with Ministries of Health in Kenya, Lesotho, Philippines and India, this approach was taken for scale up of molecular testing to find “missing” TB cases, improve detection of drug resistance and reach TB targets. In the Philippines, analysis indicated that implementing recommendations from the process could enable savings of US\$28 million in device procurement costs. In Kenya, 15 counties have already used this approach to create operational plans and strengthen their referral systems, and the process is underway in 11 additional counties.



◆ **TAMING THE DIAGNOSTIC “WILD WEST”**

FIND and WHO coordinated an independent global quality assurance programme for malaria rapid diagnostic tests (RDTs) for a decade, resulting in a 77% reduction in non-compliant or poor-quality tests, with 90% of malaria RDTs sold globally now complying with WHO criteria. The programme tested over 5,000 RDT lots – over 900 million RDTs – destined for more than 70 endemic countries. Lot testing was supported by donors and conducted free of charge for health ministries, malaria control programmes, RDT procurers, implementing organizations and RDT manufacturers. Since 2011, lot testing has been mandatory for all Global Fund grant recipients and has been adopted by all other major RDT procurers. Following successful completion of the programme, the project transitioned to WHO at the end of 2018.



◆ **ENABLING HEPATITIS C TESTING AND TREATMENT IN COMMUNITY SETTINGS FOR VULNERABLE POPULATIONS**

Making hepatitis C virus (HCV) screening, confirmation and care available at primary care level, including HIV community clinics, through the introduction of RDTs has increased linkage to care from less than 50% to over 99% – and the higher levels of test use has driven down prices. For example, our work to introduce HCV RDTs into the Malaysian public health system in a decentralized screening model resulted in over 8000 life-years saved. Switching to risk-based screening from general screening was found to reduce the cost of finding one positive case from more than US\$40 to US\$10, with overall cost savings to the Malaysian health system of US\$1.3 million. Data such as these have led to HCV policy changes in Malaysia, India and Myanmar.



◆ **ACCELERATING INNOVATION AND ACCESS TO COVID-19 TESTS, WITH A LEADING ROLE IN THE GLOBAL PANDEMIC RESPONSE**

As a result of our experience in diagnostics for global health and a track-record in successful partnerships, FIND was nominated to co-convene the Diagnostics Pillar of the Access to COVID-19 Tools (ACT) Accelerator – a ground-breaking collaboration of many of the world’s international health organizations – alongside the Global Fund and WHO. Together we were able to condense development timelines for antigen rapid tests into just 8 months (compared with 5 years for HIV rapid tests), and secure access to 120 million tests for LMICs through volume guarantees. We quantified the value of diagnostics, with analysis demonstrating that the life of a hospital worker is saved for every 1,042 tests conducted, and provided data and use case guidance that informed public policy and generated evidence for governments to make decisions on lockdowns and other interventions.

**ACTaccelerator**  
ACCESS TO COVID-19 TOOLS





# A SHIFT IN APPROACH THAT LEVERAGES LEARNINGS AND HARNESSES OPPORTUNITIES

	LESSONS LEARNED	STRENGTHS	POST-COVID-19 OPPORTUNITIES	SHIFT FOR 2021 STRATEGY
RESEARCH & PRODUCT DEVELOPMENT	<ul style="list-style-type: none"> <li>For diagnostic tools to have transformational impact, novel business approaches are required, such as co-creation with users and buyers to ensure new tests meet their needs. Otherwise, there will be limited demand (i.e. lack of market “pull”).</li> <li>The diagnostic “wild west” (i.e. many low-quality products that are not fit-for-purpose) harms global health systems and patients. Independent evaluation and a transparent marketplace are required by procurers and policy makers.</li> <li>A lack of common data systems and standards around diagnostic data collection and reporting impacts the quality and timeliness of decision making.</li> <li>Co-funding via innovative financing mechanisms is a viable approach, e.g. loans versus grants for diseases less impacted by market failures.</li> </ul>	<ul style="list-style-type: none"> <li>FIND benefits from significant end-to-end product development experience, including building in-country production capacity, and a robust understanding of technology R&amp;D pipelines for <i>in vitro</i> and digital diagnostics, across diseases.</li> <li>FIND has trusted relationships across a range of test developers, end users and evaluators, and has extensive clinical trial expertise for rapid regulatory and policy change in multiple diseases, across Phases I to IV, including sample collection and sharing to support development and validation of new tests.</li> <li>FIND has market-shaping know-how that can improve equitable access (via both “push” and “pull” mechanisms).</li> </ul>	<ul style="list-style-type: none"> <li>Diversified manufacturing capacity has emerged that can be harnessed to build sustainable supply, affordability and local ownership.</li> <li>Technology advances can be applied to broader global health needs and expanded use cases beyond formal healthcare settings (e.g. self-testing platforms, easy-to-use rapid tests, digital tools).</li> <li>Collection of high-quality samples has been expedited, with sequencing for surveillance.</li> <li>Active market-shaping initiatives can lower prices and nudge local procurement towards higher quality tests (e.g. access to trade finance mechanisms can be provided to support non-traditional donor-funded procurement, such as pharmacies and other private sector channels).</li> </ul>	<ul style="list-style-type: none"> <li>Strengthened focus on new products for surveillance as well as point-of-care tests for primary care, including rapid and self tests.</li> <li>Market “pull” mechanisms and active market shaping initiatives are being elevated as central elements to drive R&amp;D and improve uptake.</li> <li>Regional innovation and manufacturing hubs are being built out or strengthened.</li> <li>Marketplace and evidence platforms are being broadened to enable policy makers and procurers to make data-driven decisions.</li> </ul>
ACCESS	<ul style="list-style-type: none"> <li>COVID-19 has exposed massive gaps in diagnostic systems and capacity (i.e. testing limited to central laboratories, lack of diagnostic literacy among policy makers), as well as important data gaps.</li> <li>Adoption of and demand for essential diagnostics require funded national strategies and capacity to be built at all levels – from leadership to those conducting tests – alongside improved data systems and building proficiency for data-driven planning, and monitoring of progress and impact.</li> </ul>	<ul style="list-style-type: none"> <li>FIND has experience in facilitating translation of global policy into national action plans tailored to local needs, in partnership with countries, supporting expanded testing capacity and quality of testing services.</li> <li>FIND has established relationships with Ministries of Health and communities to understand needs and local context, and ensure successful implementation of innovative delivery models, including the use of digital data for better service delivery, health system efficiency, surveillance, and to support policy decisions.</li> </ul>	<ul style="list-style-type: none"> <li>Testing should move beyond formal healthcare settings only, and linkage to care can be provided through digital tools.</li> <li>Integrated, patient-centric care delivery can be improved by breaking testing silos and harnessing existing health infrastructure.</li> <li>There is appetite among key stakeholders for strengthening surveillance networks that can service multiple diseases for sustainability.</li> </ul>	<ul style="list-style-type: none"> <li>Support to countries is being deepened, for data-driven diagnostics systems planning, leveraging digital data to improve service delivery and cost-effectiveness, and to monitor impact, as well as to sustainably build diagnostics capacity at all levels.</li> <li>We are evaluating innovative delivery models to build implementation blueprints with multisectoral engagement.</li> <li>We are strengthening the voice of communities in design and delivery of people-centred, integrated screening and testing strategies, and implementation models.</li> </ul>
PARTNERSHIP	<ul style="list-style-type: none"> <li>The ACT-Accelerator has enabled political engagement at the highest levels, as well as the engagement of a diverse, broad stakeholder group (including buyers, WHO, local policy makers and communities) from the beginning; leveraging partner strengths along the value chain accelerates product development, policy and uptake, while adapting rapidly to evolving needs.</li> <li>There is no single strong partner to support LMIC capacity development and early and improved country engagement – which means this relies on a well-coordinated partner network in countries.</li> </ul>	<ul style="list-style-type: none"> <li>FIND has a substantial history of working through collaborations that leverage partner strengths across the value chain, to deliver on objectives.</li> <li>In addition to its headquarters in Geneva, FIND has established offices in India, Kenya, South Africa and Viet Nam, complemented by a flexible country operations model (currently in 20 LMICs) that builds on local partnerships to ensure that it can have broad health systems impact.</li> </ul>	<ul style="list-style-type: none"> <li>Increased political will and effective regional leadership have emerged for investment and prioritization of diagnostics due to a heightened awareness of the need for robust testing systems.</li> <li>The ACT-Accelerator offers a springboard for accelerated diagnostic innovation and implementation.</li> </ul>	<ul style="list-style-type: none"> <li>We are building on the ACT-Accelerator model to form an alliance of partners, coordinate local networks and give procurers and countries a seat at the table early in the product development process.</li> <li>Pathfinder countries are being supported to demonstrate the impact of strong diagnostic systems and demand aggregation.</li> </ul>



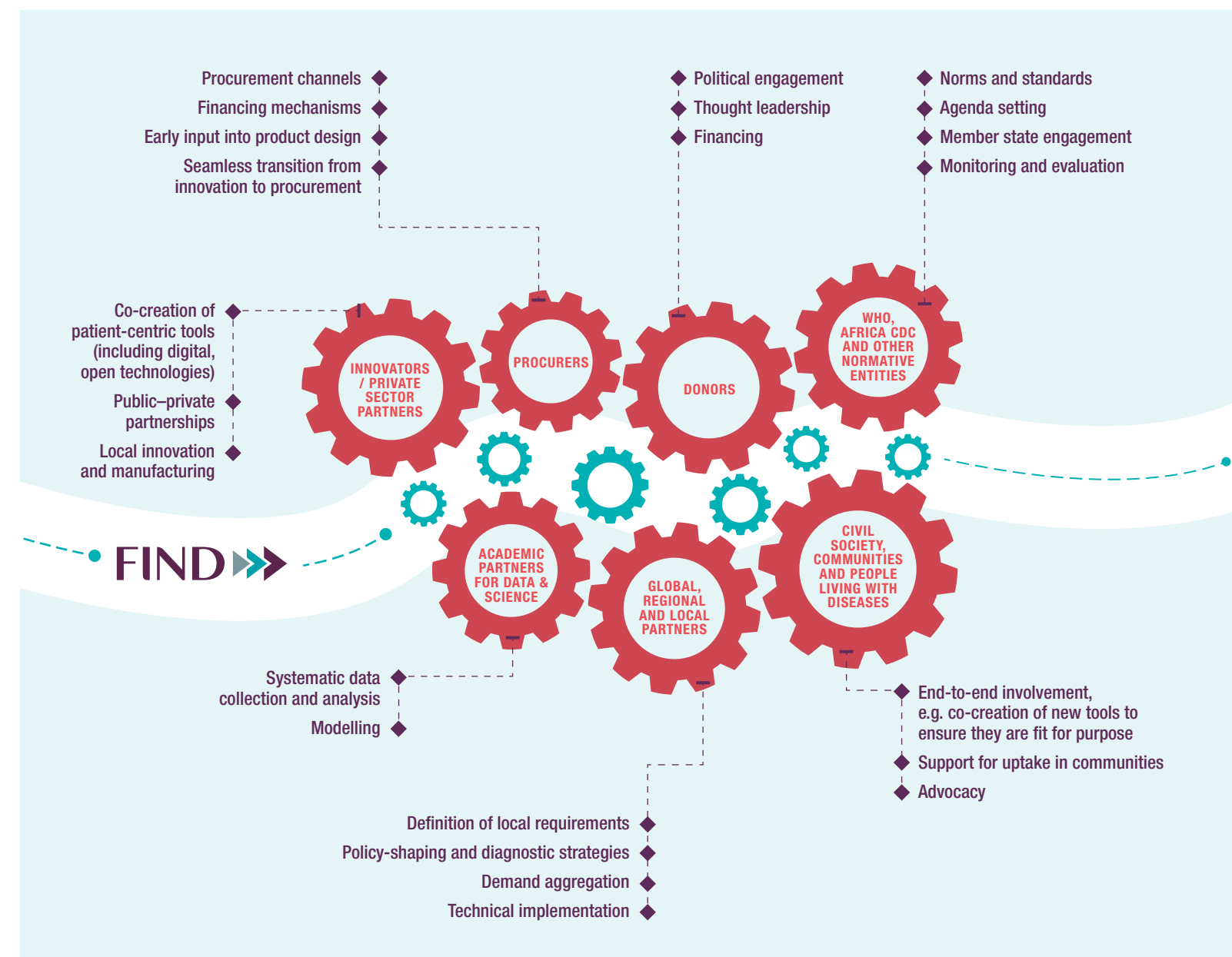


# TESTING FOR HEALTHY AND SAFE LIVES

AN ALLIANCE TO ADVANCE  
THE GLOBAL AGENDA

FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis around the world. We connect countries and communities, funders, decision-makers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems.

## OUR OPERATING MODEL HARNESSES THE STRENGTHS OF AN ALLIANCE OF PARTNERS, BUILDING ON THE COVID-19 TESTING MOMENTUM AND OUR PRE-PANDEMIC SUCCESSSES





# ACCELERATING GLOBAL EFFORTS TOWARDS UHC AND HEALTH EMERGENCY RESPONSE

Strong, universally accessible health systems are essential for both day-to-day patient care and to mitigate health emergencies – UHC and global health security have been described by Dr Tedros Adhanom Ghebreyesus, Director General of WHO, as “two sides of the same coin.”<sup>23</sup>

## FIND 2021 STRATEGY LAYS THE GROUNDWORK TO ACCELERATE GLOBAL EFFORTS TOWARDS UNIVERSAL HEALTH COVERAGE AND HEALTH EMERGENCY RESPONSE

### Universal health coverage

Expand primary care testing to combat diseases that disproportionately affect vulnerable populations

### Health emergencies

Strengthen diagnostic surveillance and response systems to contain outbreaks and improve pandemic preparedness, aligned with a One Health approach

◆ **At-risk populations:**

Minimize TB and hepatitis deaths from missed diagnosis

◆ **Women & children:**

Strengthen antenatal screening for communicable and non-communicable diseases, and reduce deaths from undiagnosed fever and pneumonia

◆ **Marginalized populations:**

Accelerate elimination of neglected tropical diseases via tailored testing strategies

◆ **Digital tools:**

Unlock the power of data to strengthen health systems and empower individuals

◆ **Diagnostic network design & optimization:**

Use local data to design context-specific testing strategies and implementation models

◆ **Integrated biobank network:**

Facilitate diagnostic development and implementation across diseases

◆ **Pandemic preparedness:**

Build on broad COVID-19 testing capacity and the ACT-Accelerator model to establish sustainable early-warning and response systems for known and emerging pathogens

◆ **Antimicrobial resistance:**

Build access to AMR testing and surveillance to safeguard drugs and reduce mortality

◆ **Healthy markets:**

Shape sustainable markets for quality-assured and affordable diagnostics

◆ **Sequencing:**

Enable genomics for improved surveillance and diagnosis

**In support of UHC, our goal is to expand primary care testing to combat diseases that disproportionately affect vulnerable populations.** Reducing the huge diagnostic gaps in TB, hepatitis, antenatal screening for both communicable diseases and NCDs, fever, pneumonia and neglected tropical diseases (NTDs) will save lives and livelihoods, save health systems money, and contribute to global and national disease elimination targets. Wherever possible, we are looking to decentralize testing so that services can be made available closer to patients, within health systems as well as outside of formal healthcare settings.

To achieve this, we are supporting R&D for products that can address WHO Essential Diagnostic List priorities, including commoditized tests (i.e. low cost, long shelf life, easy to use, mass distributed) and digital solutions, produced through regional manufacturing hubs. This includes self-tests that are co-created with users and procurers to optimally meet patient needs, as well as multi-pathogen platforms and multiplex tests to support the move towards an evidence-based, integrated approach to testing. We are also striving to improve the usability of existing tests, for example by supporting targeted redesign that can make them more

suitable for community-based use. Complementary digital tools will enable diagnostic data to be captured and fed into health information systems, to inform policy and planning.

We are pursuing active market sustainability initiatives to increase the availability and affordability of new tests. To ensure that stakeholders can access verified information on diagnostic tools, we are building a digital marketplace that is being paired with targeted investments and technology transfers, to build local manufacturing capacity in LMICs. We are working with local partners to demonstrate the impact of innovative delivery models, notably through communities and in non-formal health settings. We are also supporting countries to introduce policy changes that can improve access to testing, such as embedding self-testing into national health strategies and insurance schemes, and to expand procurement channels to non-donor channels (such as the private sector).

**To mitigate health emergencies, our goal is to strengthen diagnostic surveillance and response systems to contain outbreaks and improve pandemic preparedness, aligned with a One Health approach.** Testing is the first line of defence against outbreaks that are becoming increasingly severe and complex.

We are working to address not only recognized epidemic-prone pathogens such as SARS-CoV-2 and Ebola virus, but also the “silent pandemic” of AMR by improving access to AMR testing and surveillance to safeguard drugs and reduce mortality. Our fight against COVID-19 is far from over, and requires intensified efforts to realize mass testing for test-trace-isolate implementation and sequencing-based surveillance – so that viral evolution does not jeopardize progress.

We are striving to leverage ACT-Accelerator partnerships to protect the gains being made during the pandemic and build a more permanent structure that can deliver sustained supply and predictable demand of WHO Blueprint pathogen tests, as well as providing permanent early-warning and response systems. We are working to support development of broad menu, flexible tests – which can build from existing networks such as the WHO GISRS (Global Influenza Surveillance and Response System) and PIP (Pandemic Influenza Preparedness), or the International Atomic Energy Agency’s ZODIAC (Zoonotic Disease Integrated Action). Fast development of new tests depends on transparent evidence and sample sharing, and data integration is needed to support One Health initiatives. These all go hand-in-hand with

capacity in countries for both centralized and decentralized real-time surveillance and mechanisms for scale-up of outbreak pathogen testing.

Alongside our efforts to serve **diseases and populations**, we are working to strengthen health systems and transform the **diagnostic ecosystem** by redoubling our efforts in key disease-agnostic activities. These include sequencing to improve surveillance and diagnosis, fostering an integrated biobank network to facilitate diagnostic development and implementation across diseases, and diagnostic network design and optimization so that data can be maximized to deliver context-specific testing strategies.

To enable accountability from all parties, we aim to cement the essential place of diagnostic testing within health systems through political commitments at the highest levels.

This end-to-end scope requires a robust, transparent business model built for diagnostic sustainability, designed to harness collective action and create a virtuous cycle of **technology innovation** (supply of new or improved tools) and **access innovation** (demand from countries).



COLLECTIVE ACTION, FROM INNOVATION TO IMPLEMENTATION



OBJECTIVES								
◆ Develop transformational diagnostic tools	◆ Generate evidence	◆ Build out local production	◆ Develop marketplace and market interventions		◆ Design new delivery models (including self-testing and digital)	◆ Support countries to embed testing and surveillance into health strategies	◆ Strengthen diagnostic capacity	◆ Support advocacy and mutually agreed accountability frameworks
✔ Co-creation of new tools	✔ Trial sites	✔ Technology transfer Manufacturing capacity		Direct funding	✔ Catalytic introduction		✔ Diagnostic capacity Training	
✔ Shaping R&D agenda Open-access resources	✔ Trial design and coordination	✔ Matchmaking	✔ Market intelligence	Lead	✔ Evidence generation for policy		✔ Training material Technical assistance	✔ Advocacy agenda
✔ R&D portfolio management and RFPs (inc multi-source funding) Customization of digital solutions			✔ Market shaping	Coordination / support		✔ Global guidance tailored to local context		✔ Monitoring and evaluation



# ROADMAPS FOR ACTION

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ROADMAPS FOR ACTION  
DIAGNOSTIC  
ECOSYSTEM



◆ **DIGITAL TOOLS: UNLOCK THE POWER OF DATA TO STRENGTHEN HEALTH SYSTEMS AND EMPOWER INDIVIDUALS**

Digital technologies have a vital role to play in diagnosis across the healthcare cascade – from supporting screening and ensuring accurate diagnosis to providing treatment monitoring information. With trained healthcare personnel often in short supply at all levels, expanding access to diagnosis for people in remote and rural areas of LMICs can be especially challenging. Connected diagnostics can be deployed widely and used in community settings, reducing the need for people to travel to centralized laboratories for a test, while ensuring that population-level data are collected for diagnostic surveillance that can help decision makers optimize the allocation of resources and develop policy.

To drive demand for screening and diagnosis, focus is needed early in the patient pathway to empower patients and their influencers to build health knowledge, develop agency and engage in more efficient care-seeking. Digital health solutions that provide clinical decision support to healthcare workers (in the community, in primary care and in the local private sector) can help them work with greater efficiency and improve the quality of care. To enable effective use of diagnostic data for surveillance, as well as electronic health records and supply chain management, interoperability is critical between various diagnostic devices, systems and applications.

**Our focus** is on collaboration with Ministries of Health, technology companies, device manufacturers and implementation partners to support the development and scale up of fit-for-purpose digital solutions that can be integrated into existing workflows, address users’ pain points, and that are suitable for healthcare workers’ digital literacy levels and local digital infrastructure.

**WORKSTREAMS**

- 1 Support the development of solutions that are supplementary to existing tests as well as novel digital diagnostics, to bring testing closer to patients and detect complications early
- 2 Support, along with key partners such as WHO, the development of frameworks and implementation guidance for a user-centred evaluation platform for digital diagnostic technologies, including artificial intelligence-based diagnostic technologies for LMICs

◆ **INDICATIVE DELIVERABLES**

- ◆ Digital toolkit aimed at reducing care-seeking delay and linking patients to care early
- ◆ At least 3 digital tools for enabling data capture and use for near-patient, community-level diagnostics and surveillance
- ◆ Evaluation platform for generating evidence on – and informing adoption of – digital diagnostics in LMICs



MORE DETAILS ON THIS ROADMAP: [www.finddx.org/digital](http://www.finddx.org/digital)

◆ **DIAGNOSTIC NETWORK DESIGN & OPTIMIZATION: USE LOCAL DATA TO DESIGN CONTEXT-SPECIFIC TESTING STRATEGIES AND IMPLEMENTATION MODELS**

Designing optimal diagnostic systems is complex and highly context-dependent, relying on multiple data inputs and assumptions. Important variations in epidemiology, geography and health systems – often within the same country – must also be accounted for, as well as budgetary considerations.

Diagnostic network optimization takes a geospatial network analytics approach, used in many manufacturing industries, to improve patient access to services in the most cost-efficient way. Using data to inform instrument placement, sample transportation, referral mechanisms, staffing, and geographical prioritization, diagnostic access can be increased for those most in need, while also ensuring cost efficiency and feasibility. Data can also inform integration of diagnostic tools and services (such as testing for COVID-19 using molecular diagnostics already in place for TB), to provide patient-centred services and resource allocation across health sectors and programmes.

Together with other approaches to support countries to identify gaps and develop tailored interventions, such as patient pathway analysis and structured assessments, diagnostic network optimization can help target the right mix of diagnostic solutions to where they are needed most, at costs sustainable for health systems, and is able to rapidly adapt to emerging threats.

**Our focus** is on helping countries to build and maintain comprehensive, integrated digital network models that are coordinated and owned by Ministries of Health and used by all partners, with common standards for data collection, reporting and data management.

**WORKSTREAMS**

- 1 Optimize use of current diagnostics through diagnostic network optimization that can inform countries’ strategic plans, as a routine element of health systems and supported by sustainable funding mechanisms
- 2 Inform introduction of new diagnostics by using diagnostic network optimization to compare cost-effectiveness of different implementation models and understand decision drivers for use of new tests in different settings
- 3 Expedite testing strategies for new/emerging diseases by ensuring they are informed by rapid deployment of diagnostic network optimization analysis, using pre-existing network models

◆ **INDICATIVE DELIVERABLES**

- ◆ Pilot in 4 countries and launch OptiDx, an open-access software for conducting diagnostic network optimization across diseases in LMICs
- ◆ Scale up use of OptiDx and establish diagnostic network optimization as a key element in country strategic planning and investment decisions for at least 2 donors in laboratory systems strengthening
- ◆ Enable at least 20 countries to optimize multi-disease molecular testing networks to improve access and deliver efficient and sustainable services
- ◆ Inform design and optimization of surveillance networks for at least 2 diseases in at least 1 region



MORE DETAILS ON THIS ROADMAP: [www.finddx.org/dno](http://www.finddx.org/dno)



◆ **INTEGRATED BIOBANK NETWORK: FACILITATE DIAGNOSTIC DEVELOPMENT AND IMPLEMENTATION ACROSS DISEASES**

Biobanks – also known as specimen or sample banks – are repositories of pathogen samples (such as blood or sputum) that have been collected from people with specific diseases. Well-characterized samples are vital to commercial and academic researchers for the development, validation, evaluation and quality assessment of new and existing diagnostic tools.

Samples collected regularly from key strategic sites can also enable genetic sequencing that underpins comprehensive disease surveillance programmes.

With development needs constantly shifting as new scientific avenues are explored, there is often a mismatch between the samples needed and those available, which can hamper product development. With no standardized global process for sample collection, sample quality can vary greatly, and access to them can be limited. Import and export restrictions on biological material inhibits transport of specimens between high-burden countries where samples are usually collected, to developers’ laboratories, which are often located elsewhere. Building specimen bank capacity in countries provides local ownership of data and research.

Ethical considerations are also key. Countries – and individuals – should be involved in decisions on how samples are used, as well as receiving some benefit from having provided them.

**Our focus** is on fostering inclusive, ethical collection and use of fit-for-purpose, high-quality samples, when and where they are needed, to streamline the whole diagnostic development process.

**WORKSTREAMS**

- 1 Develop a network of integrated, disease-agnostic biobanks in strategic locations, with harmonized procedures, that are adapted to industry needs and support in-country research
- 2 Build on existing work to implement a virtual biobank directory that provides an open-access, global view of sample availability, with guidance on sample use

◆ **INDICATIVE DELIVERABLES**

- ◆ At least four sites in LMICs supported with capacity building to enable membership of the integrated biobank network, with standardized procedures and collections established
- ◆ Operationalize virtual biobank directory prototype for at least 10 diseases, by adding collections and facilitating access to samples



MORE DETAILS ON THIS ROADMAP: [www.finddx.org/biobank](http://www.finddx.org/biobank)

◆ **HEALTHY MARKETS: SHAPE SUSTAINABLE MARKETS FOR QUALITY-ASSURED AND AFFORDABLE DIAGNOSTICS**

New diagnostic tests must overcome multiple “valleys of death” on the road from R&D to delivery, any one of which can prevent them from becoming viable products ready for use by those who need them.

If test developers do not see the need for a new diagnostic or do not have an indication of the potential return on their investment, R&D may never get started. Similarly, if manufacturers do not see a viable market, then investment in manufacturing is at risk – especially investment in the high costs of automation, which can often be how a product becomes affordable to the end user. Policy makers depend on reliable evidence to be able to support new innovations, which is generated from robust clinical trials that also need investment. The complex, multi-faceted process of procurement across the public and private sectors involves registration, forecasting, supply chain management and health systems strengthening to support delivery. Distributors often need to assume significant risks, such as payment delays from buyers and foreign exchange rates, as well as the high cost of capital, which can lead to significant mark-ups that render a test unaffordable. Engaging suitable delivery channels across public and private sector hospitals, laboratories and pharmacies can result in long lead times in development of standard procedures, and supportive policy frameworks.

**Our focus** is on identifying opportunities to engage stakeholders and find solutions to unblock bottlenecks along this continuum and create a viable, efficient and sustainable market environment, so that new innovations can reach those who need them without delays.

**WORKSTREAMS**

- 1 Provide market intelligence that improves data and information transparency for both supply and demand, and meets the needs of buyers and sellers
- 2 Work with partners to devise and implement tailored market interventions across the continuum



◆ **INDICATIVE DELIVERABLES**

- ◆ Functional market intelligence data and reports to inform appropriate interventions on both demand and supply (targeting 1 per test identified in the R&D portfolio)
- ◆ Access to capital (grants or forgivable loans) facilitated for assay developers, manufacturers and distributors to support the business case and ensure affordability for a new diagnostic with at least 1 “exemplar” arrangement coordinated
- ◆ Volume commitment-linked access terms, negotiated for at least 1 new diagnostic (e.g. volume guarantee, advanced market commitment)
- ◆ Evidence from at least 7 countries for 3–4 innovative delivery channels engaged in the public health response, while decentralizing access to new diagnostics
- ◆ Digital marketplace to connect buyers (including workplaces, industry or private sector healthcare providers without access to existing procurement portals, such as Wambo) and suppliers to facilitate and aggregate procurement

MORE DETAILS ON THIS ROADMAP: [www.finddx.org/healthy-markets](http://www.finddx.org/healthy-markets)



◆ **SEQUENCING: ENABLE GENOMICS FOR IMPROVED SURVEILLANCE AND DIAGNOSIS**

Sequencing is a process used to understand the genetic makeup of a biological organism; next-generation sequencing (NGS) collectively describes various high-throughput, rapid, and scalable sequencing technologies that are used to determine the DNA or RNA sequence of the complete genome or part of a genome. NGS enables rapid identification of unknown pathogens, discovery of novel genetic variations, and improved understanding of disease-causing pathogens, to inform the development and utility of tests, treatments, and vaccines. An increasingly critical application of sequencing is genomic surveillance, which uses sequencing data to identify outbreaks of existing or novel pathogens, and to understand how pathogens are introduced and spread through a population.

The goal of our sequencing programme is to establish the use of NGS technologies for the diagnosis of drug-resistant TB, and genomic surveillance of COVID-19, TB, AMR, and other outbreak-prone diseases. Our anchor project is designed to generate evidence and boost in-country capacity to support the global adoption of targeted NGS for affordable, scalable, and rapid TB drug-susceptibility testing. Bringing the power of sequencing closer to communities with a high burden of drug-resistant TB will enable rapid diagnosis and comprehensive treatment guidance and catalyse an eventual decrease in its transmission.

As part of the ACT-Accelerator Diagnostics Pillar Genomic Surveillance Working Group, we are strengthening genomic surveillance capacity in LMICs as part of the COVID-19 response. We are also working on sequencing for AMR surveillance and viral haemorrhagic fevers.

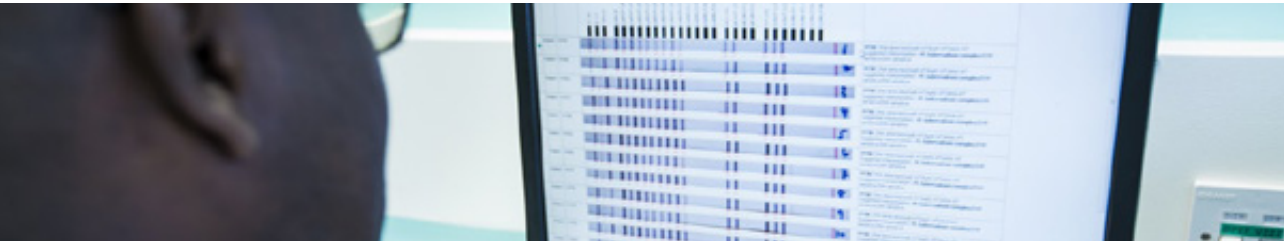
**Our focus** is on enabling end-to-end sequencing solutions – from sample processing to bioinformatics and interpretation – for disease surveillance and diagnostics in LMICs.

**WORKSTREAMS**

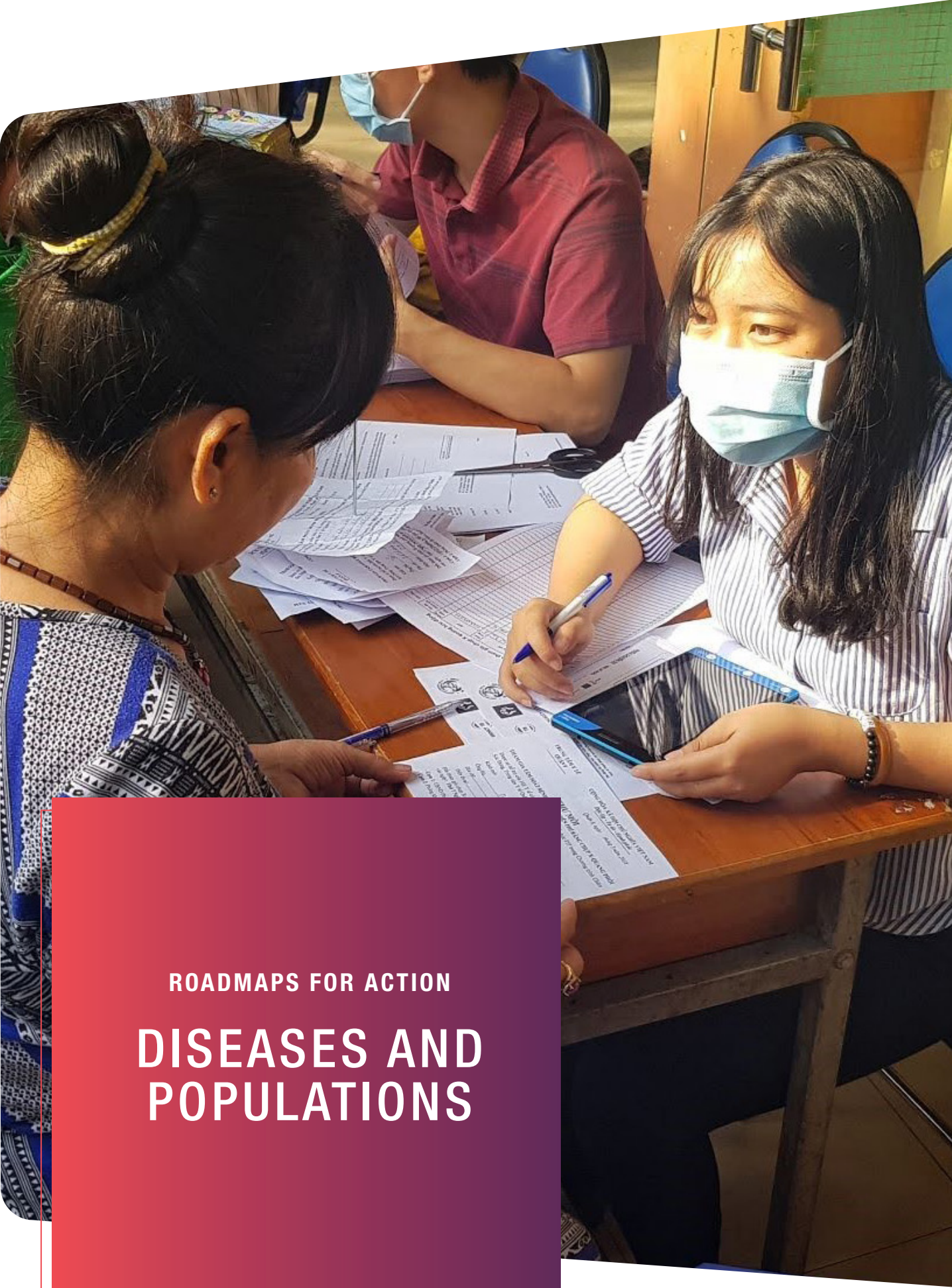
- 1 Generate clinical evidence to support WHO global guidance and policy on the use of targeted NGS for drug-resistant TB diagnosis, so that patients can be linked to the most appropriate care as fast as possible
- 2 Enable tools for analysis and interpretation of sequencing data to inform action, including variant identification and prediction of drug resistance
- 3 Provide technical and operational guidance for country capacity building and implementation of sequencing-based surveillance and diagnosis
- 4 Inform industry and donors on technology and access gaps via landscapes, target product profiles, capacity mapping and needs assessments

◆ **INDICATIVE DELIVERABLES**

- ◆ First WHO-endorsed global TB mutations catalogue to predict drug resistance from genetic data generated by molecular and sequencing-based tests
- ◆ Implementation guide and roadmap for country planning and adoption of sequencing for infectious disease surveillance in LMICs, with an initial focus on drug-resistant TB
- ◆ Global capacity mapping framework to support implementation of genomic surveillance, resource allocation, and country prioritization for COVID-19 and beyond
- ◆ Operational roadmap to inform investment case to strengthen sequencing and bioinformatics capacity in LMICs for surveillance, as part of the ACT-Accelerator Diagnostic Pillar Genomic Surveillance Working Group



MORE DETAILS ON THIS ROADMAP: [www.finddx.org/sequencing](http://www.finddx.org/sequencing)



**ROADMAPS FOR ACTION**  
**DISEASES AND POPULATIONS**



## AT-RISK POPULATIONS: MINIMIZE TB AND HEPATITIS DEATHS FROM MISSED DIAGNOSIS

Finding the missing millions of people with TB or hepatitis who are not diagnosed or reported to health systems has remained an elusive goal, despite the existence of tests and effective treatments for both diseases. Our TB and hepatitis strategy focuses on approaches to reduce the diagnostic gap through the development of new tests, especially those that can be used closer to the point of care, and innovation in delivery models. Diagnosis of both diseases requires a decentralized approach to testing programmes, with more tests suitable for community and self-testing, supported by digital tools that can ensure linkage to care. Easy-to-use, high-quality tests must be accompanied by innovation in the delivery of testing programmes and a switch to active case-finding, particularly to reach at-risk populations who are disproportionately affected.

### TUBERCULOSIS

In 2019, 10 million people fell ill with TB and 1.5 million people died from the disease. One in 10 people with TB were believed to be co-infected with HIV, and close to half a million people developed drug-resistant TB. More people received life-saving treatment than ever before, largely due to improved detection and diagnosis, but a staggering 2.9 million people remain undiagnosed or unnotified every year.<sup>7</sup> Most TB cases are found among the urban poor, and improving access to diagnosis remains a key priority to meet the WHO End TB strategy of 90% reduction in the annual TB deaths by 2030.<sup>7,24</sup>

COVID-19 has negatively impacted services in most high-burden countries, and is threatening to reverse global progress against TB. TB case notifications declined by a third in 2020,<sup>7</sup> and it is projected that there will be an additional 4.7 million cases of TB between 2021 and 2025<sup>25</sup> due to disruptions related to the pandemic.

**Our focus is on strengthening community-based testing and enabling integrated testing strategies for respiratory symptoms to find the millions of missed cases.**

#### WORKSTREAMS

- 1 Expand portfolio of sampling methods (including non-sputum-based), platforms and digital tools for TB and integrated testing, including bi-directional testing for TB and COVID-19
- 2 Generate evidence for policy to enable active case-finding for TB by bringing testing closer to patients through community and self-testing
- 3 Support new delivery models to increase access to testing, in particular for drug-resistant TB, and strengthen sequencing capabilities for surveillance

#### INDICATIVE DELIVERABLES

- ◆ An expanded portfolio of open-access resources for developers of TB diagnostics and implementing countries, including an expanded validation platform for ongoing computer-aided detection (CAD) development and implementation planning
- ◆ Evidence dossiers to support policy evaluation of 5 new TB tests
- ◆ 5 new CE-marked tools for detection of TB and integrated testing strategies, including at least 1 digital diagnostic solution
- ◆ Expanded use of molecular testing for TB through the uptake of new sampling strategies, notably through private sector channels
- ◆ Market interventions for 3 new TB and associated tests to increase affordability
- ◆ Ten demonstration studies on community, self-sampling and bi-directional screening approaches
- ◆ Technical guidance and best practice materials to support countries and partners in prioritizing decisions

MORE DETAILS ON THIS ROADMAP: [www.finddx.org/at-risk-populations](http://www.finddx.org/at-risk-populations)



### HEPATITIS C

Despite a ground-breaking cure for HCV completing development in 2014, there has been limited progress towards reaching the WHO goal of hepatitis elimination by 2030. Over 400,000 people die annually due HCV, and 71 million people globally are living with HCV.<sup>26,27</sup> Almost 80% of people living with HCV are in LMICs, and of those, less than 10% are estimated to have been diagnosed.<sup>27</sup>

While the HCV cure is already widely available in LMICs, usually at affordable prices, the challenge again remains finding the missing millions, as fewer than one in five of those living with HCV have been diagnosed. There is a great lack of simplified, decentralized diagnostics that can be integrated into existing healthcare models, and few countries are willing to embark on HCV elimination as “pathfinders” for others.

Over 50 million people living with HCV will need to be diagnosed and linked to treatment in the next 10 years to reach the elimination targets. Elimination depends on continued development of simplified point-of-care diagnostics, alongside partnership with countries to catalyse and prioritize HCV.

**Our focus is on increasing access to HCV testing, and enabling test-and-treat strategies.**

#### WORKSTREAMS

- 1 Expand active case-finding through the creation of targeted community screening packages, using multiplex tests and deployment of fit-for-purpose self-testing strategies
- 2 Support decentralized, simplified, integrated services through true point-of-care confirmatory testing and liver staging, to allow same day test-and-treat

#### INDICATIVE DELIVERABLES

- ◆ Toolkits to facilitate the introduction of cost-effective national screening programmes
- ◆ A true point-of-care core antigen (cAg) RDT
- ◆ Evidence on combination RDTs
- ◆ WHO-approved HCV self-tests available for use, including a supporting digital patient-centred toolkit
- ◆ Testing packages for best use and scale up of self-testing

MORE DETAILS ON THIS ROADMAP: [www.finddx.org/at-risk-populations](http://www.finddx.org/at-risk-populations)



◆ **WOMEN & CHILDREN: STRENGTHEN ANTENATAL SCREENING FOR COMMUNICABLE AND NON-COMMUNICABLE DISEASES, AND REDUCE DEATHS FROM UNDIAGNOSED FEVER AND PNEUMONIA**

Primary healthcare facilities play a critical role in supporting a healthy pregnancy and childhood, as they are the first port of call for antenatal screening and care for childhood illnesses. Accurate diagnosis at a primary care facility determines whether a patient can be treated then and there, or if they need to be referred to higher levels of care – yet only 1% of primary care facilities in LMICs have the basic diagnostic capacity to do this.<sup>4</sup> Access to essential diagnostic tests in primary care settings must be improved, to strengthen antenatal screening for communicable diseases and NCDs, and support differential diagnosis of patients presenting with fever and pneumonia.

**IMPROVE ANTENATAL CARE SCREENING FOR NON-COMMUNICABLE AND INFECTIOUS DISEASES**

Hypertensive disorders of pregnancy and gestational diabetes contribute extensively to over 2.7 million infant deaths, 2.6 million stillbirths, 303,000 maternal deaths, and preventable maternal and infant morbidity annually.<sup>28</sup> Globally, cardiovascular diseases and diabetes are responsible for almost 20 million deaths every year, occurring at a disproportional rate in LMICs (85% of all premature deaths occur in these countries).<sup>29</sup> Despite evidence demonstrating the health, economic and development value of screening and detection of NCDs, particularly in women of childbearing age, many still lack access to the testing interventions necessary to achieve UHC.

**Our focus** is on combining our efforts in infectious disease diagnostics to screen pregnant women for HIV, syphilis, hepatitis B, and malaria, with strengthened NCD screening globally, contributing towards the WHO target of 80% availability of affordable basic NCD technologies.<sup>30</sup>

**WORKSTREAMS**

- 1 Strengthen antenatal NCD testing through better access to NCD testing overall
- 2 Increase access to infectious disease testing for women, targeting HIV, syphilis and hepatitis B testing in antenatal care

◆ **INDICATIVE DELIVERABLES**

- ◆ Optimized multi-parameter cardiometabolic point-of-care device
- ◆ Technology innovation for self-monitoring of blood glucose for diabetes
- ◆ Up to 5 affordable existing NCD tools available to countries (including blood glucose test strips and HbA1c tests)
- ◆ Community and patient engagement models developed for holistic, integrated chronic disease management
- ◆ HIV/syphilis/hepatitis B combination RDT with digital decision tool and impact use cases



**IMPROVE THE SURVIVAL AND WELL-BEING OF CHILDREN AFFECTED BY FEVER AND PNEUMONIA**

In 2019, 5.2 million children died before they reached 5 years of age.<sup>31</sup> Nearly half (45%) of early childhood deaths were due to infectious diseases that present with fever and other symptoms, for example a cough in the case of bacterial or viral pneumonia.<sup>32</sup> Malaria and pneumonia are among the main contributors to those deaths resulting from inappropriate care or triage at the first point of contact with health providers. A lack of tools to support referral and treatment decisions contributes to the high mortality of children even when they reach the health system. Alongside this first triage decision, healthcare teams also need to assess the appropriate course of treatment for malaria and other illnesses.

The already challenging work of frontline healthcare workers has further been exacerbated by COVID-19. It was estimated at the beginning of the pandemic that an additional 1 million children will die due to health system disruptions,<sup>33</sup> including a lack of appropriate triage tools.

Additional innovations at point-of-care and community levels are needed to tackle child mortality and morbidity by ensuring every child who needs medical attention is triaged, and patients with febrile illnesses and pneumonia are identified, monitored, and cared for at the appropriate health system level. These innovations will be key to supporting syndromic surveillance activities, and to helping countries stay on track to achieve the SDG targets of reducing under-5 mortality to at least as low as 25 deaths per 1,000 live births, and ending the malaria epidemic, by 2030.

**Our focus** is on on improving triage and differential diagnosis at the lowest levels of the health system.

**WORKSTREAMS**

- 1 Improve triage of children at the point of care for timely referral of severe infections and differential diagnosis between typhoid, dengue, malaria and COVID-19, to inform appropriate treatment
- 2 Support global malaria elimination with improved tools for *Plasmodium vivax* and other threats to effective diagnosis
- 3 Support the uptake of integrated fever management approaches

◆ **INDICATIVE DELIVERABLES**

- ◆ Expanded use of at least 2 next generation electronic clinical decision aid tools
- ◆ At least 2 next-generation triage tools to support the assessment and monitoring of patients
- ◆ Bundle of point-of-care tests for fever / pneumonia management (including typhoid, dengue, malaria and COVID-19)
- ◆ At least 2 next-generation malaria tests to improve *P. falciparum* and *P. vivax* management
- ◆ Targeted country roadmaps to help advance integrated diagnostic algorithms for malaria and other febrile illnesses



◆ **MARGINALIZED POPULATIONS: ACCELERATE ELIMINATION OF NEGLECTED TROPICAL DISEASES VIA TAILORED TESTING STRATEGIES**

NTDs are a diverse group of 20 diseases that prevail in tropical and subtropical climates.<sup>34</sup> These diseases disproportionately affect the poorest and the most marginalized communities, primarily women and children, and as a result they are important tracers for identifying disparities in progress towards UHC and equitable access to quality health services. NTDs are responsible for the loss of 17 million healthy years globally, with a high proportion being lost in sub-Saharan Africa.<sup>35</sup>

For the past two decades, stakeholder commitments and action spurred by the WHO 2012–2020 NTD roadmap have resulted in significant achievements in the control and elimination of NTDs. Today, 500 million fewer people need treatment for NTDs than in 2010, and 40 countries or areas have eliminated at least one NTD.<sup>36</sup> Nonetheless, over 1 billion people worldwide still require interventions.<sup>36</sup>

Less than 5% of the limited research and development funding made available to NTDs has been invested in diagnostics.<sup>36</sup> There is a lack of coordination of R&D needs and, for many NTDs, poor return on investment, lack of data and inadequate forecasting mechanisms have led to low levels of investment. The focus on NTDs has been further diminished during the COVID-19 pandemic, with WHO advising that NTD surveys, active case-detection activities and mass drug administration campaigns should be postponed.<sup>37</sup> As a result, there is an urgent need for redoubled efforts as countries recover from the pandemic. The WHO 2021–2030 NTD roadmap identifies diagnostics as central to accelerating progress and making up lost ground.<sup>36</sup>

**Our focus** is on addressing key diagnostic gaps that must be filled to achieve the respective disease targets.

**WORKSTREAMS**

- 1 Develop a diagnostic pipeline aligned with the needs identified in the WHO NTD 2021–2030 roadmap and support advocacy to address critical product and funding gaps
- 2 Improve diagnosis and surveillance for NTDs with particularly significant diagnostic unmet needs: Buruli ulcer, Chagas disease, sleeping sickness (HAT), leishmaniasis, lymphatic filariasis, onchocerciasis and schistosomiasis

◆ **INDICATIVE DELIVERABLES**

- ◆ 1 novel RDT for an NTD
- ◆ Support for local production of 1 RDT for an NTD
- ◆ Evaluations of new diagnostic tests for leishmaniasis and schistosomiasis
- ◆ Specimen banks to support the development of new diagnostics for NTDs
- ◆ Strengthened country capacity for sleeping sickness (HAT) testing in 6 endemic countries and leishmaniasis testing in 1 endemic country



MORE DETAILS ON THIS ROADMAP: [www.finddx.org/marginalized-populations](http://www.finddx.org/marginalized-populations)

◆ **PANDEMIC PREPAREDNESS: BUILD ON BROAD COVID-19 TESTING CAPACITY AND THE ACT-ACCELERATOR MODEL TO ESTABLISH SUSTAINABLE EARLY-WARNING AND RESPONSE SYSTEMS FOR KNOWN AND EMERGING PATHOGENS**

The COVID-19 pandemic has had devastating health and economic impacts, with over 3 million deaths to date<sup>38</sup> and an expected total cost of between US\$8.1 and US\$15.8 trillion globally.<sup>39</sup> The pandemic has focused global attention on the importance of diagnostics and testing data to drive public health decision-making: the use of ongoing testing and surveillance to guide targeted lockdowns rather than broad restrictive measures, for example, could lower the economic burden 5-fold.<sup>40</sup>

Although the threat of a global pandemic due to a rapidly spreading, lethal respiratory pathogen had been documented,<sup>41</sup> prior to COVID-19, global funding for pandemic preparedness had been reactionary and not well sustained.<sup>42</sup> Diagnostics have always been the cornerstone for early warning, response and containment, yet they remain chronically inappropriate for global needs: significant diagnostic gaps remain for six of the ten WHO R&D Blueprint priority diseases, including an as-yet-unidentified disease X.<sup>41</sup>

The global response to COVID-19 has created a tremendous opportunity to bolster overall pandemic preparedness and response. It has demonstrated the importance of sequencing capacity for rapid pathogen and variant identification, and the benefit of open sharing of information between pathogen-specific experts and the global community, including genomic data, to track pathogen evolution and spur rapid test development. The need for fit-for-purpose testing networks to enable sustained, rapid differential diagnosis integrated across care networks from the community to tertiary level has also been highlighted.

**Our focus** is on leveraging our COVID-19 response activities, including experience from the ACT-Accelerator, to break the cycle of “panic then forget” for testing and surveillance for outbreak-prone pathogens.

**WORKSTREAMS**

- 1 Develop and deploy diagnostic tools to enable containment and clinical management of COVID-19 and other outbreak-prone pathogens, in support of acute outbreak responses
- 2 Enable testing strategies and systems for mass screening for COVID-19, particularly outside of healthcare settings, in support of a return to normality
- 3 Create a permanent early-warning and response system through a global network to build resiliency

◆ **INDICATIVE DELIVERABLES**

- ◆ 3 novel RDTs to enable triage for Blueprint pathogens
- ◆ Low-cost, decentralizable, multi-pathogen testing platform with expanded menu for outbreak-prone pathogens
- ◆ COVID-19 RDT price driven below US\$1 (ex-works) through active market-shaping
- ◆ Increased access to COVID-19 antigen RDTs through non-donor channels (including private sector)
- ◆ Evidence for non-clinical use cases (including self-testing) generated in at least 5 countries
- ◆ Catalytic engagement with 30–40 countries to support inclusion of COVID-19 testing in existing health strategies and capacity building (including training)
- ◆ Online sample repository and specimen bank to support the development of new diagnostics for COVID-19 and other outbreak-prone pathogens
- ◆ Technology transfers facilitated to build out regional manufacturing hubs in at least 3 locations
- ◆ At least 2 countries supported in the rollout of open-source digital tools for surveillance

MORE DETAILS ON THIS ROADMAP: [www.finddx.org/pandemics](http://www.finddx.org/pandemics)



◆ **ANTIMICROBIAL RESISTANCE: BUILD ACCESS TO AMR TESTING AND SURVEILLANCE TO SAFEGUARD DRUGS AND REDUCE MORTALITY**

Increased AMR is one of the top ten threats to public health according to WHO; it is the cause of severe infections, disease complications, longer hospital stays and increased mortality.<sup>43</sup> There are currently 700,000 deaths every year due to drug-resistant strains of common bacterial infections, and it is estimated that this will increase to 10 million deaths per year by 2050 – with LMICs being the most affected.<sup>44</sup> Testing plays a key role in reducing AMR by improving diagnosis of infections to prevent unwarranted use of antibiotics, and to rapidly detect and contain resistant infections.<sup>45</sup>

The COVID-19 pandemic is causing significant setbacks in the fight against AMR. There is growing concern that many people with COVID-19 are being prescribed inappropriate antibiotics, which may be fuelling an increase in drug resistant infections, particularly in countries lacking antimicrobial stewardship (AMS) programmes and with limited access to diagnostic tools.<sup>46</sup>

The growth of AMR is expected to result in a 25% increase in healthcare costs in low-income countries and a 6% increase in high-income countries by 2050.<sup>47</sup> AMS programmes are rudimentary or do not exist at all in most LMICs,<sup>48</sup> and there is an acute need for accessible diagnostics for blood stream infections, especially those associated with neonatal sepsis as well as severe hospital-acquired infections.<sup>49</sup> Data are critical for better patient management and the development of clinical guidelines, but there is currently a lack of both global and local AMR data.

**Our focus** is on preventing AMR development and mortality through developing and improving diagnostic systems.

**WORKSTREAMS**

- 1 Preserve existing and new antibiotics by supporting the development and enabling the use of point-of-care tests for gonorrhoea and chlamydia (NG/CT), and other sexually transmitted infections at primary care level
- 2 Implement innovative AMR packages (diagnostic technologies, digital solutions, AMR data) to reduce the mortality rate in patients with severe infections in hospitals (including neonatal sepsis)
- 3 Empower on-the-ground decentralized AMR surveillance efforts (including sequencing) to strengthen the One Health approach and improve use of local data

◆ **INDICATIVE DELIVERABLES**

- ◆ 1–2 affordable point-of-care tests for NG/CT
- ◆ 1–2 field evaluation studies to inform WHO Prequalification on NG/CT point-of-care tests
- ◆ Demonstration studies for NG/CT point-of-care tests
- ◆ Digital decision support and data collection tools to support AMS programmes
- ◆ A simplified blood culture system adapted for LMICs to enable the use of point-of-care tests for AMR detection or price reduction for existing automated systems
- ◆ Demonstration studies on cost-effectiveness of bundled AMR diagnostic solutions for level two of the healthcare system, including digital solutions
- ◆ Support for the development of decentralized surveillance systems in 2 countries



MORE DETAILS ON THIS ROADMAP: [www.finddx.org/amr](http://www.finddx.org/amr)





**IMPACT**  
EQUITABLE ACCESS TO  
INNOVATIVE TESTS FOR  
1 BILLION PEOPLE IN LMICS,  
1 MILLION LIVES SAVED

Harnessing partners’ strengths as part of an alliance platform will enable us to bring cutting-edge diagnostics to market faster and at scale, and increase the priority of essential diagnostics in national health programmes.

Delivery of this ambitious plan will take US\$100–120 million per year. But with at least 1 million lives being saved over the 3-year period, US\$1 billion in savings to health systems and patients, and at least 10 countries empowered with diagnostic data to inform policy and care, the return on investment is clear.

**ENABLING EQUITABLE ACCESS TO INNOVATIVE TESTS FOR 1 BILLION PEOPLE IN LMICs AND SAVING 1 MILLION LIVES: FIND TARGETS 2021–2023**

**DELIVERABLES**

- ◆ 10 transformational & affordable new primary care tests co-created with buyers and users
- ◆ 3 regional manufacturing hubs established, addressing 10 local priorities
- ◆ 10 market-shaping interventions designed and implemented to improve availability and affordability of tests
- ◆ 10 exemplar countries supported to embed testing and surveillance into national health strategies
- ◆ Diagnostic capacity strengthened across LMICs (100,000 health workers trained, 1,000 laboratories strengthened, diagnostic networks optimized in 10 countries)
- ◆ Annual diagnostic purchasing power of US\$1 billion achieved through alliance partnerships

**OUTCOMES**

- Diagnostic gap reduced by at least 10% in key populations
- 1 billion tests available for procurement on global access terms
- 10+ countries with national health strategies that include funded diagnostic components, supported by Essential Diagnostics Lists
- 100 laboratories contributing quality data to global surveillance network

**IMPACT**

- ◆  **SAVE 1 MILLION LIVES**  
through accessible, quality diagnosis
- ◆  **SAVE US\$1 BILLION**  
in healthcare costs to patients and health systems
- ◆  **EMPOWER AT LEAST 10 COUNTRIES**  
with diagnostic data to inform policy and care

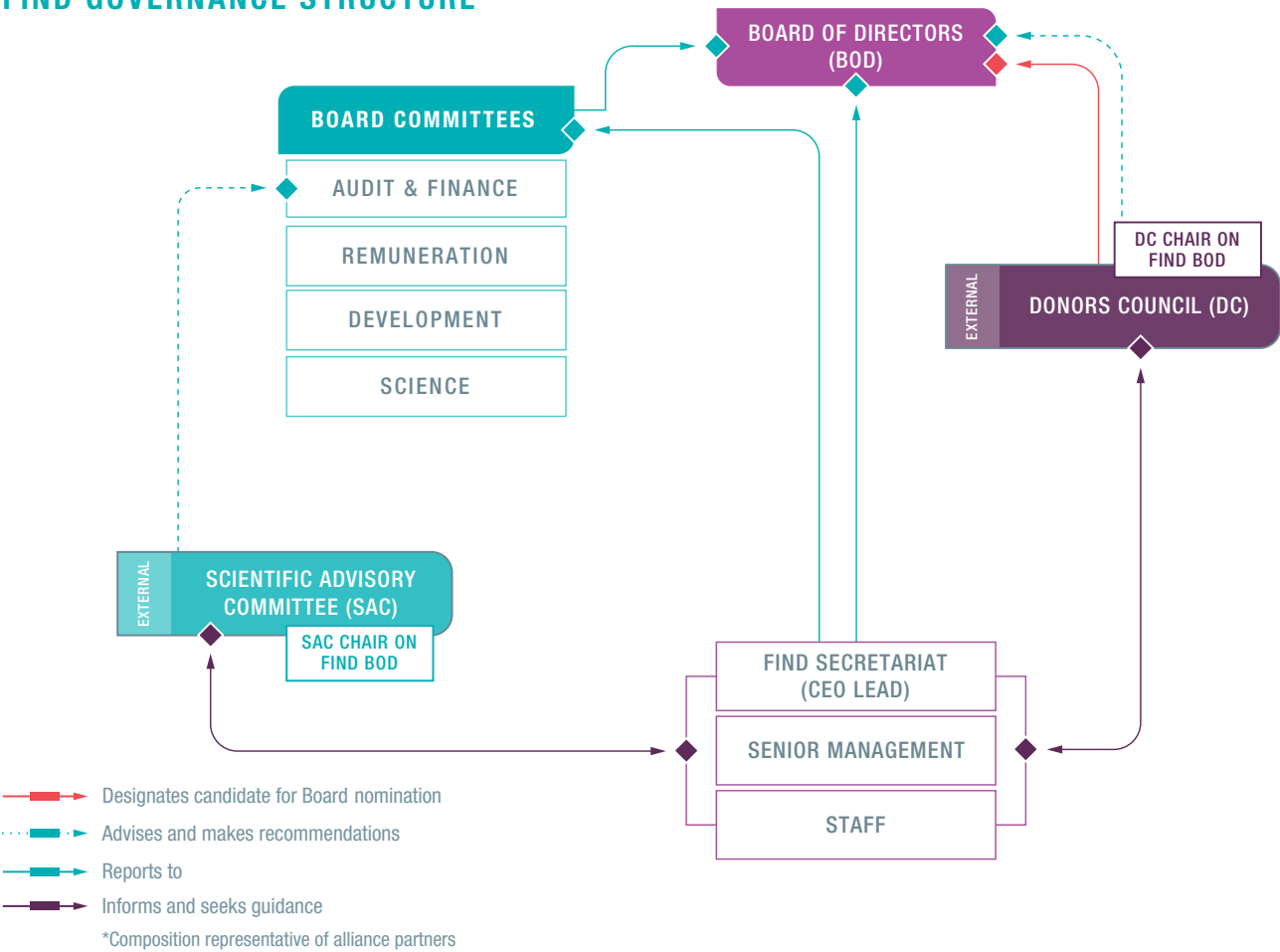




SET UP FOR  
SUCCESS

With 160 core staff across four country offices and our Geneva-based headquarters, our agile partnering model amplifies our reach in the countries in which we work. FIND continues to be an official WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation. Our work is underpinned by three key enablers: data, sustained funding, and political commitment and partnerships, as well as five operating principles. Our global access policy drives equitable access to testing, and our robust governance structure ensures accountability as well as expert input.

FIND GOVERNANCE STRUCTURE



TRANSPARENT, IMPARTIAL PROCESSES ACROSS ALL OUR WORK

We have in place a robust approach to mitigate conflicts of interest when working with a broad range of upstream and downstream partners. We issue open requests for proposals to determine where to invest, relying on independent experts to ensure requirements are objectively defined and decision-making is impartial. We ensure criteria at all stages are transparent and publicly accessible.

FIND retains no financial interest in any product we support, including no intellectual property rights and no royalties. We are not a regulatory body and do not recommend products; rather, we work to generate high-quality data that can enable others to make informed decisions.

Once a product is marketed and has secured all the required approvals, it is made available through eligible procurement channels. The eventual product selection and procurement decision lies solely with the procurer.

This end-to-end approach was successfully pressure-tested by the ACT-Accelerator Diagnostics Pillar with the development, scale up and roll out of antigen rapid tests for COVID-19.

More information can be found on our website here: [www.finddx.org/governance](http://www.finddx.org/governance)



FIND OPERATING PRINCIPLES

SUPPORT  
COUNTRY LEADERSHIP

Foster **country-led innovation** and commitment to diagnosis

FOSTER  
EFFECTIVE PARTNERSHIPS

Build **agile end-to-end alliance** to coordinate, accelerate and maximize impact of diagnostic investments

EMPOWER  
PEOPLE AND COMMUNITIES

Strengthen **pivotal role of communities and individuals** in the prioritization of needs, uptake and innovative delivery of tests

SERVE AS A TRANSPARENT  
AND NEUTRAL SOURCE OF INSIGHT

Provide **open resources and data** to enable innovation and evidence-based, transparent decision making

BUILD  
FOR SUSTAINABILITY

Build sustainable, scalable diagnostic systems mindful of the **financial and environmental impact of testing programmes**

OUR GLOBAL ACCESS POLICY DRIVES  
EQUITABLE ACCESS TO TESTING

Focus development and trials for regulatory clearance on transformative **DIAGNOSTIC TECHNOLOGIES** APPROPRIATE FOR LMICs


STRENGTHEN LOCAL PRODUCTION AND DIVERSIFY SUPPLY CHAINS  
through technology transfer and knowledge sharing with LMICs

NEGOTIATE ACCESS TERMS with innovators and manufacturers (fair pricing, intellectual property rights, non-exclusive licensing agreements registration in LMICs, supply and service commitments...)


BUILD ON EXISTING ALLOCATION MECHANISMS for equitable supply of tools to LMICs

Support inclusion of diagnostics in **NATIONAL STRATEGIES AND BUILD CAPACITY** to facilitate adoption of sustained testing


ENABLERS THAT ARE FUNDAMENTAL TO OUR SUCCESS



DATA  
CENTRES OF EXCELLENCE,  
DATA-SHARING AGREEMENTS



SUSTAINED FUNDING  
US\$100–120 MILLION  
PER YEAR



POLITICAL COMMITMENT  
AND PARTNERSHIPS  
GOODWILL AMBASSADORS, POLITICAL  
CHAMPIONS, CIVIL SOCIETY, GLOBAL,  
REGIONAL AND LOCAL PARTNERS

WE ACHIEVE A BROAD GEOGRAPHIC FOOTPRINT THROUGH  
A DIVERSE ENGAGEMENT MODEL

NIMBLE AND  
EFFICIENT  
ENGAGEMENT

COUNTRY OFFICES  
Provide permanent regional base with limited core staff to coordinate regional activities

IN-COUNTRY CONSULTANTS  
Hire local, in-country consultants with deep understanding of country needs and context

SECONDMENTS  
Support secondments into Ministries of Health to build technical capabilities at ministerial level

GLOBAL, REGIONAL AND LOCAL PARTNERSHIPS  
Build working relationships with implementation partners to support their diagnostics work and coordinate efforts across partners

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