ADVANCING THE 100 DAYS MISSION FOR DIAGNOSTICS:

2025 GLOBAL GAP ASSESSMENT

An independent report by the Brown University Pandemic Center, International Pandemic Preparedness Secretariat and FIND

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FIND Diagnosis for all

Executive Summary

Diagnostics are a cornerstone of the 100 Days Mission (100DM), yet the field continues to suffer from chronic underfunding, fragmented coordination, and misaligned incentives that threaten global pandemic readiness. The 100DM for Diagnostics seeks to ensure that safe, effective, and affordable diagnostic tools are authorized (e.g., Emergency Use Listing) and ready for scaled production within 100 days of a declared Public Health Emergency of International Concern (PHEIC). This timeline is critical; early diagnostic availability defines whether outbreaks are contained or escalate into pandemics.

Drawing on structured interviews with over 30 global stakeholders, this gap assessment identifies the most urgent and systemic barriers that must be addressed to enable diagnostic readiness within 100 days of a PHEIC declaration. It also proposes concrete recommendations to unlock faster innovation, stronger coordination, and more resilient diagnostic capabilities.

Our analysis reveals interdependent barriers spanning the full diagnostics value chain, including sample access, regulatory harmonization, regional manufacturing, and sustainable financing, with specific manifestations across different pathogen market archetypes, geographies, and stakeholder types. Through case study analysis of Ebola, Dengue, and H5N1 influenza, we identify both universal challenges and archetype-specific solutions.

The most critical barriers that consistently emerged include:

- **R&D acceleration failure** – Chronic underinvestment in diagnostics R&D; lack of actionable Target Product Profiles (TPPs); unsustainable single-pathogen business models; and delayed access to pathogen sequence data, slowing assay and test development.
- **Sample access bottlenecks** – Scarcity of well-characterized specimens, insufficient reference standards, and fragmented validation systems, especially for high-containment pathogens and novel or geographically restricted diseases.
- **Regulatory fragmentation** – Lack of harmonized regulatory frameworks, standards, and evidence requirements; insufficient regulatory agency capacity to evaluate emerging technologies; paper-based processes; and unpredictable emergency use authorization requirements that disproportionately burden LMIC-focused or small-scale developers, slowing patient access.
- **Manufacturing and supply chain vulnerabilities** – Over-concentration of production in a few countries and companies, underinvestment in regional infrastructure and skilled workforce, raw material bottlenecks, and limited technology transfer mechanisms that leave LMICs behind during emergencies.
- **Broken financing architecture** – Zero-market dynamics for emerging threats like Ebola; fragmented procurement for endemic diseases like dengue; dual-market global access challenges for H5N1-like pathogens; inadequate coordination of surge financing for scale-up during outbreaks; and no tailored financing models for disease-agnostic platforms or Disease X diagnostics with inter-epidemic sustainability.
- **Cross-cutting structural weaknesses** – Coordination failures, limited clinical adoption, weak integration with vaccine and therapeutic development pathways, and fragmented surveillance and digital infrastructure.

Summary of priority recommendations with comprehensive suggestions for implementation in Table 1:

- **Accelerate diagnostics R&D capabilities** – Developers, WHO, and regulators should co-develop practical Target Product Profiles tied to use case and outbreak phase; funders and procurement agencies should incentivize multiplex panels and modular platform technologies; and public health agencies should strengthen pathogen sequence data sharing systems with standardized governance to enable rapid assay development.
- **Secure sample access and validation infrastructure** – The WHO Intergovernmental Working Group (IGWG) should consult with technical experts, including industry stakeholders, to finalize the Pathogen Access and Benefit sharing (PABS) annex under the Pandemic Agreement with practical equitable access terms; governments, multilateral funders, and industry should establish regional evaluation hubs organized by pathogen family or biosafety requirements; with the standards community (comprising reference laboratories, material providers, metrologists and regulators) supporting the timely development and characterization of appropriate analyte control materials and samples for validation.
- **Advance regulatory harmonization and modernization –** WHO, IMDRF, regional bodies (e.g. EMA, AMA), and national regulators should adopt international best practices (including the WHO Global Model Regulatory Framework and IMDRF standards) to build risk-based, fit-for-purpose oversight. Priorities include common dossier templates, standardized evidence requirements, an Emergency Use Table of Contents, and digital modernization (e-dossiers, labeling, and signatures) to enable reliance and near real-time regulatory review, particularly benefiting LMIC-based and smaller manufacturers.
- **Build geo-diversified manufacturing resilience** – International finance institutions (IFIs) should prioritize investments in regional diagnostic manufacturing certified to the international Quality Management Standard, ISO 13485, 16766, or Medical Device Single Audit Program (MDSAP), for the manufacturing of diagnostics for pandemic pathogens like influenza and local epidemic threats through coordinated investment; WHO, development finance institutions (DFIs), and global and regional developers should establish technology transfer partnership platforms where appropriate and when international Quality Management Standards can be met; and regional manufacturers and governments should invest in supply chain diversification and local reagent manufacturing in LMICs to prevent disruption during emergencies.
- **Deploy fit-for-purpose financing mechanisms** – DFIs, International Finance Corporation (IFC) working capital fund, governments, procurement agencies, and private and philanthropic funders should coordinate to deploy tailored market-specific incentives including advanced market commitments, volume guarantees, and stockpiles; shift toward investing in multi-pathogen syndromic panels and portfolio approaches that support both pandemic response and inter-epidemic viability of platform technologies; and establish surge financing mechanisms for rapid scale-up during outbreaks.
- **Strengthen diagnostic ecosystem coordination** – WHO should operationalize the Global Diagnostics Coalition with a dedicated pandemic preparedness working group; developers and funders should integrate diagnostic development with vaccine and therapeutic pathways where appropriate; and developers, clinicians, economists and other end users should generate health economic evidence to drive adoption and policy prioritization; and governments and partners should build integrated surveillance networks anchored in strong laboratory systems and real-time data sharing to enable timely alerts and responses.

This gap assessment offers an actionable roadmap to unlock faster, more equitable diagnostic readiness for future outbreaks. Without immediate and coordinated action, diagnostics will remain the weakest pillar in the global medical countermeasure arsenal, slowing response, hampering containment, and leaving the world vulnerable. The 100 Days Mission for diagnostics is not aspirational; it is achievable, but only if stakeholders move decisively from recognizing challenges to delivering coordinated, time-bound solutions that match the urgency of the next threat.

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1. Introduction

The 100 Days Mission (100DM) sets a bold but necessary objective: to ensure that safe, effective, and affordable diagnostics, therapeutics, and vaccines are authorized (e.g., Emergency Use Listing) and ready for scaled production within 100 days of a Public Health Emergency of International Concern (PHEIC) declaration. This timeline reflects the critical window in which public health interventions can shift the trajectory of an outbreak from uncontrolled spread to containment.

Diagnostics are the foundation of that window. They determine infection or immune status from human samples and may be laboratory-based, requiring accredited facilities, quality systems, and trained personnel, or point-of-care (POC), which can be administered in the field, at the bedside, or at home for rapid results. Effective outbreak response requires complementary test modalities to be available in the right place, at the right time. While approved laboratory-based diagnostics exist for several priority pathogens with high pandemic potential, significant gaps persist in rapid POC tests (100DM Scorecard 2.0). The Lancet Commission on diagnostics highlighted that almost half of the global population has little or no access to essential diagnostics, with the gap particularly severe in low- and middle-income countries (LMICs), where only 19% of patients have access to essential tests at the primary care level. Without timely and accurate diagnostic testing, targeted deployment of vaccines and therapeutics becomes challenging, surveillance systems cannot track transmission patterns, and public health measures fail to adapt to evolving pathogens.

Yet today, diagnostic development and deployment timelines routinely miss the 100-day mark. While speed of development is critical, maintaining quality and trust in test performance remains paramount for public acceptance and effective outbreak response. Diagnostic tests are generally regulated as in vitro diagnostic devices (IVDs) within risk-based medical device frameworks. During COVID-19, it took over five months from the first reported case for a commercial rapid test to receive Emergency Use Authorization (EUA) in the United States, and far longer for those tools to reach LMICs. The ongoing mpox outbreak has similarly exposed continued gaps in rapid POC testing, especially in clade-specific detection and decentralized availability.

These delays reflect structural barriers across the diagnostics ecosystem. Research and development (R&D), regulatory review, manufacturing, procurement, and adoption are each hampered by systemic constraints that compound to create critical delays. These interconnected barriers manifest differently across region, pathogen, and market context, but they share a common outcome: diagnostics arrive too late and are inequitably distributed.

Achieving the 100DM for diagnostics requires tailored solutions to strengthen the ecosystem to be faster, more coordinated, regionally distributed, and capable of pivoting quickly from routine use to outbreak response.

This global gap assessment identifies the core constraints that prevent diagnostic tools from reaching readiness by Day 100. Through a mixed-methods approach, combining over 30 structured stakeholder interviews, thematic analysis, and desk research, we identify evidence-based obstacles and generate actionable recommendations.

Through targeted analysis of three priority pathogens—Ebola virus, dengue virus, and H5N1 influenza virus—representing distinct epidemiological characteristics, geographic distributions, market archetypes, and deployment needs, this assessment offers nuanced strategies to accelerate time-to-impact and strengthen global pandemic preparedness capabilities (systematic analysis in *Section 3*).

Achieving the 100DM requires more than new technologies, it demands new coordination models, dedicated, regionally-relevant and smarter financing mechanisms, harmonized regulatory pathways, and sustained commitment to equity and speed. This assessment offers a blueprint to act, and a warning of the cost of inaction.

A consolidated table of all identified barriers and recommended actions is provided at the end of the report to support implementation planning and stakeholder alignment.

2. Scope and Methodology

2.1 Scope

This assessment focuses on the diagnostic tests, platforms and systems most critical to achieving the 100 Days Mission: those that enable early detection, guide public health response, and scale rapidly at or near the POC.

Specifically, it centers on diagnostic technologies deployable within the first 100 days following a PHEIC declaration, including rapid antigen tests, isothermal nucleic acid amplification tests, and simplified PCR-based platforms operable in decentralized or basic laboratory settings. High-complexity technologies, such as next-generation sequencing or advanced genomic surveillance systems, fall outside this report's primary scope, though their integration into diagnostic strategies is acknowledged where relevant.

This analysis evaluates the barriers and enabling conditions across several core and interconnected domains of the diagnostic ecosystem: research and development (R&D), regulatory pathways, manufacturing and supply chains, and financing mechanisms. It emphasizes challenges that most directly impact 100DM timelines, while also identifying systemic reforms needed to sustain readiness between outbreaks.

We selected three priority pathogens as case studies to illustrate distinct market archetypes, each requiring differentiated approaches to achieve 100DM goals. These archetypes are defined by their demand patterns, commercial viability, and target markets:

- **Ebola virus represents emerging/re-emerging diseases** (including Marburg, Nipah, and Oropouche) characterized by sporadic, unpredictable outbreaks with outbreak-driven development cycles, near-zero commercial markets, and often high biosafety requirements.
- **Dengue virus represents high-burden endemic diseases concentrated in LMICs** (including mpox, malaria, and tuberculosis), where diagnostic demand is high but fragmented, and commercial returns are low.
- **H5N1 influenza virus represents dual-market pathogens with pandemic potential or global spread** (including seasonal influenza, SARS-CoV-2, HIV and RSV) requiring products that can serve both routine surveillance and emergency surge needs across high-income and LMIC contexts.

The case study pathogens were selected based on their inclusion in WHO's viral family prioritization framework, FIND's Pathogen Diagnostics Readiness Index, and alignment with other key funders and product development coalitions, including Gavi, CEPI, and the Therapeutics Development Coalition. Together, they offer a lens to examine both shared and context-specific diagnostic system gaps. This provides a pragmatic, implementation-oriented foundation for improving readiness. Additional information for each case study pathogen is provided in the Annex.

2.2 Methodology

The assessment employed a mixed-methods approach combining structured stakeholder interviews, thematic analysis, and desk research to identify high-priority barriers and actionable recommendations across the global diagnostics ecosystem.

We conducted 60-minute structured interviews with more than 30 stakeholders across the diagnostic value chain, including diagnostic developers, regulators, procurement agencies, investors, and global health institutions (see full list in Annex). Participants were selected to ensure diverse perspectives across LMIC and high-income country (HIC) settings, organizational type and size, and diagnostic technology platforms.

Interviews followed standardized templates tailored to stakeholder type and pathogen context. Core themes explored barriers across the end-to-end diagnostics lifecycle (R&D, regulatory pathways, manufacturing, financing and surge capacity), and stakeholder-specific challenges and potential solutions. Interviews were recorded with participant consent and transcribed for analysis.

We employed a structured thematic analysis using predefined codes derived from the 100DM Diagnostic Framework to systematically identify barriers and recommendations across different pathogen contexts and stakeholder perspectives. Computational analysis with structured analytical prompts helped extract key insights from interview transcripts, with all outputs manually reviewed and validated by experienced researchers to ensure accuracy and contextual relevance. We conducted frequency analysis to identify recurring themes.

We supplemented interviews with desk research from academic literature, policy documents, FIND's Pathogen Diagnostics Readiness Index and DxConnect database, industry reports, and diagnostic manufacturing landscape analyses to provide comprehensive evidence for recommendations.

Priority recommendations were developed based on frequency, convergence across stakeholders, and feasibility of action. Where appropriate, we disaggregated recommendations by pathogen archetype, region or stakeholder type to support targeted implementation.

Limitations

This assessment offers directional insights that establish a foundation for immediate action rather than definitive conclusions applicable to every context. The analysis is based on research conducted over a four-month period (March–June 2025), during which stakeholder engagement was shaped by availability and outreach constraints.

While we sought a balanced mix of diverse perspectives, certain key actors, such as national ministries of health, civil society organizations, and frontline health implementers, were underrepresented in the stakeholder sample. Their inclusion in future assessments will be essential to ensure ground-level feasibility and community alignment.

The focus on three case study pathogens provides important nuance and depth but may not capture all relevant dynamics across the full spectrum of outbreak-prone diseases. However, the study provides valuable evidence to guide strategic investments and policy interventions while identifying priority areas for more comprehensive future evaluations. We also acknowledge that in some areas, detailed economic costings will be required to support implementation of specific recommendations, but this was outside the scope of this report.

3. Comprehensive barrier analysis across end-to-end development

3.1 R&D Acceleration Barriers

Diagnostics R&D encompasses the complete process of developing new diagnostic testing solutions, from initial concept and design through prototype development and analytical validation. This foundational stage is critical for ensuring appropriate tests are available when outbreaks occur.

However, diagnostics R&D suffers from high uncertainty and chronic underinvestment from both public and private sectors (see 100DM Scorecard 2.0 and Annex), with governments allocating minimal research funding and companies struggling with limited to zero returns on investments for outbreak-specific diagnostics (*Section 3.5*) . Industry stakeholders raised the importance of Target Product Profiles (TPPs) and defined use cases to guide diagnostic R&D. For pathogens like H5N1, this translates to clarity on whether broad influenza A detection suffices or if H5N1-specific subtyping is required based on clinical and public health management needs.

Industry stakeholders also highlighted that limited access to pathogen sequence data creates delays in obtaining essential genomic information needed for rapid assay development (Section 3.6). Moreover, industry stakeholders and funders emphasized that while single-pathogen tests remain viable for high-volume diseases or novel pathogens requiring immediate response, developing individual diagnostics for the full spectrum of potential pandemic threats is neither financially nor operationally viable at scale. This necessitates a fundamental shift toward modular, multiplex or disease-agnostic platforms serving primary healthcare while maintaining outbreak response capabilities.

These interconnected R&D barriers, together with regulatory hurdles, chronic underinvestment, and unsustainable development models, form a critical bottleneck that must be addressed to accelerate diagnostic readiness within the 100-day window.

Priority recommendations to accelerate R&D include:

1. **Develop practical TPPs differentiated by intended use case and outbreak phase.** Multiple industry stakeholders emphasized the need for practical TPPs that are grounded in operational realities, including specific needs of different outbreak phases, ranging from early detection and triage to confirmatory diagnosis and test-to-treat integration. To achieve this, developers should engage with public health agencies, WHO, and regulatory bodies to co-develop consensus TPPs that are built upon existing standards and include practical specifications aligned with manufacturing capabilities and evidence requirements for emergency use pathways. WHO's Collaborative Open Research Consortium (CORCs) should support TPP development at the viral family level to foster standardization across related pathogens and promote reuse of platform infrastructure. Additionally, developers should work with metrology institutes and standards organizations to ensure that TPPs also embed reference measurement systems early in development, supporting consistent analytical validation and underpinning accuracy. This engagement should also include WHO, reference laboratories, IVD developers, regulators and regional evaluation hubs (Box 1) in development activities to embed metrological practices throughout the development process.

2. **Prioritize development of multiplex panels combining endemic and emerging pathogen detection, as well as modular platform technologies**. Public and philanthropic funders should prioritize the development of multimodal tests and multiplex panels tailored to routine clinical use in high-burden settings, addressing common clinical presentations such as respiratory illness or febrile syndromes. Examples include respiratory panels capable of detecting influenza A/B, SARS-CoV-2, and RSV, or arbovirus panels that distinguish dengue, Zika, and chikungunya. These tools can provide immediate clinical value while also enabling rapid pivot during outbreaks. In parallel, to the extent that technologies can meet IVD and cross cutting regulation such as cybersecurity, electrical and environmental requirements, funders should support modular platform technologies with scalable, plug-and-play components, such as open-source PCR modules, cartridge-based assay systems, and isothermal amplification methods compatible with lateral flow formats. These platforms allow developers to validate and test updated diagnostic capabilities, navigate appropriate regulatory processes, and rapidly adapt existing infrastructure to new or evolving threats, while maintaining safety and effectiveness standards. To ensure sustainability and accessibility, Ministries of Health and donor-supported procurement agencies should partner with developers to integrate these platforms into routine diagnostic programs for diseases such as HIV, TB, and malaria. Maintaining operational use between outbreaks will be essential to preserving the infrastructure, manufacturing capacity, and workforce needed to respond during emergencies.

3. **Expand and strengthen systems for sharing timely and secure pathogen sequence data.** Rapid access to accurate and annotated pathogen sequence data is essential to enable early assay design, particularly for molecular diagnostics. Philanthropic funders and public health agencies should prioritize investments in platforms that demonstrate strong governance frameworks, transparent operations, and robust infrastructure security in alignment with WHO's attributes and principles for pathogen genomic data-sharing platforms (PGDSPs). These platforms should support real-time sequence sharing with standardized metadata, maintain rigorous data curation standards with auditable data provenance trails, provide integrated search and analytical capabilities, provide equitable access policies with clear data use licenses and benefits-sharing frameworks that ensure data contributors receive fair recognition and value from their contributions.

These platforms should also support One Health approaches by accommodating pathogen data from human, animal, and environmental sources. These PGDSPs could build on existing platforms like NCBI Virus, GISAID, and Pathoplexus. Major sequence databases, national public health institutes, and international organizations must collaborate to implement common data standards and develop interconnected yet independently governed repositories.

Recognizing that effective sequence sharing systems are prerequisite to a functional Pathogen Access and Benefit-Sharing (PABS) annex under the Pandemic Agreement (*Section 3.2*) , technical expertise in these negotiations is essential to balance rapid access with equitable distribution of benefits from resulting innovations.

3.2 Clinical Sample Access, Reference Standards, and Test Validation Infrastructure Barriers

Access to clinical samples, reference materials, and appropriate validation infrastructure emerged as one the most consistent and acute bottlenecks in diagnostic development, with over 90% of stakeholders identifying this as a critical constraint to achieving the 100 Days Mission. These barriers delay every stage of the diagnostic lifecycle, from assay design and analytical validation to regulatory submission and post-market implementation, including External Quality Assessment (EQA), especially for novel, geographically restricted, or high-containment pathogens.

The availability of well-characterized clinical samples is highly variable across pathogens and regions. For high-consequence pathogens like Ebola, biosafety level 4 (BSL-4) requirements severely restrict the number of facilities able to handle specimens, limiting where validation can occur. Conversely, for endemic pathogens like dengue, access to relevant samples may be difficult in non-endemic regions where many diagnostics are developed or regulated, hindering validation and performance evaluation. Further complexity arises from pathogens with overlapping clinical presentations, such as Zika and dengue, where serological cross-reactivity, co-infections, and strain variation present unique challenges for assessing test accuracy and specificity across geographies.

Across all contexts, stakeholders described difficulty navigating import/export controls and international regulations such as the Nagoya Protocol, which disproportionately burden smaller manufacturers and LMIC-based developers without global networks or legal infrastructure. Biobank initiatives such as the WHO BioHub have demonstrated potential to address some of these barriers through coordinated pathogen sharing mechanisms.

In addition to uneven access to samples, the field suffers from lack of internationally recognized standards and limited infrastructure for conducting validation studies aligned to regulatory expectations. Indeed, while some validation challenges may reflect genuine epidemiological differences across regions, inconsistent global access to certified reference materials represent the primary barrier to consistent results across developers and regions. These gaps delay regulatory approval, complicate procurement decisions, and erode trust in test performance during emergencies.

Priority recommendations to overcome sample access and validation barriers include:

1. **Establish regional evaluation hubs organized by pathogen family and biosafety containment requirements.** Stakeholders strongly supported the creation of a globally coordinated network of regionally distributed validation facilities capable of supporting diagnostics developers with access to clinical samples, reference panels, and regulatory-aligned evaluation services for both development-phase validation and ongoing post-market quality assurance. These hubs should be organized around pathogen families (e.g., viral haemorrhagic fevers, respiratory viruses, arboviruses) and biosafety containment levels to ensure that validation activities are appropriately structured and context-specific. These facilities will be particularly valuable for supporting small and medium-sized manufacturers who may lack the resources and infrastructure to conduct comprehensive validation studies independently. Implementation should build on successful models such as the NIH RADx Tech Innovation Funnel and Independent Test Assessment Program (ITAP), which accelerated COVID-19 diagnostic development in the U.S. through centralized validation laboratories and wraparound regulatory services, the UKHSA Diagnostics Accelerator, and CEPI's laboratory network model (which offers relevant approaches for distributed validation capacity), but adapt them to serve both outbreak and routine use cases. These hubs should build on WHO's established diagnostic evaluation protocols, including the First Few X cases and contacts framework and the forthcoming antigen RDT protocol, to ensure consistent validation approaches across pathogens and regions. Additionally, they should leverage existing expertise from External Quality Assessment providers and coordinate with initiatives such as the Pandemic EQA Providers (PEQAP) to address shared challenges in sample access and alternative material development.

2. **Complete the Pathogen Access and Benefit-Sharing (PABS) system with practical equitable access terms.** The development of a functional PABS annex under Article 12 of the WHO Pandemic Agreement is an essential opportunity to enable timely and equitable access to clinical specimens and digital sequence information for R&D. To succeed, the annex must avoid creating new bottlenecks or disincentives for rapid diagnostic development. The IGWG should actively engage technical experts, including developers, biobank managers, researchers, and civil society representatives, to ensure the final framework reflects operational realities and supports rapid mobilization of specimens during emergencies.

   In parallel, CEPI and PATH's Biospecimen Sourcing Initiative is developing harmonized global guidance to support rapid and secure collection of survivor samples during outbreaks. Mapping and linking biobanks (e.g., WHO Biohub, European Virus Archive, FIND's Biobank services) through this initiative could support operationalising the PABS framework.

Box 1: Regional Evaluation Hubs Implementation Approach

A global consortium of regional hubs could be jointly financed by multilateral donors, governments, and industry, with a hybrid model that combines the public investment with developer participation fees. Tiered pricing structures could promote sustainability while ensuring accessibility for smaller organizations. These facilities should be linked with procurement-aligned quality benchmarks and integrate with broader efforts on regulatory harmonization and technology transfer platforms to provide end-to-end technical and regulatory support. This adaptable model could enable facilities to maintain operational capacity through routine validation work, allowing rapid pivot to emerging pathogen evaluation during outbreaks.

Cross-cutting Integration Elements	Section
Sample Access: Regional hubs could be organized by pathogen families and biosafety containment requirements, equipped to serve multiple developers with clinical specimens, standardized reference panels, and independent evaluation services.	3.2
Regulatory: Regional hubs could offer regulatory-aligned evaluation services and serve as centralized access points for developers, especially smaller manufacturers without in-house regulatory expertise, to obtain support including for usability testing, evidence package preparation, and pathway guidance. Formal coordination mechanisms between global health stakeholders, such as FIND and PATH, and regulatory authorities would help ensure independent evaluations meaningfully inform regulatory decision-making.	3.3
Manufacturing Coordination: Regional hubs could provide regulatory compliance support to regional manufacturing facilities and technology transfer partnerships, and quality validation of locally produced diagnostics.	3.4
Procurement & Financing: Regional hubs should align with international quality benchmarks and validation standards (e.g., ISO, IEC) to support evidence-based procurement. By consolidating services such as sample access, regulatory support, and quality validation, they enable efficient, de-risked investment, reducing duplication and maximizing impact.	3.5

3. **Expand development and regulatory acceptance of synthetic and contrived controls and alternative validation methods and materials.** In the absence of clinical samples, particularly early in outbreaks or for pathogens requiring high containment like Ebola, synthetic or contrived materials characterized using appropriate methods can provide critical support for assay development and regulatory submission. DNA and RNA constructs, pseudoviruses, and recombinant antigens may offer flexible tools for preliminary analytical validation. To maximize their utility, developers, metrology institutes, and regulators should collaborate to establish routes to rapidly develop synthetic reference materials (and reference methods) along with clear guidance on acceptable use cases that clearly detail associated benefits and limitations.

   This will require bridging studies to demonstrate that synthetic controls or samples accurately reflect real-world test performance across geographies and epidemiological contexts. For rapidly evolving pathogens, such as influenza, synthetic controls and samples may also support rapid re-validation of test performance as new clades or strains emerge. While maintaining agility, regulatory bodies should integrate guidance on synthetic validation into emergency use frameworks to streamline test approval timelines.

3.3 Regulatory Capacity, Harmonization, and Complexity Barriers

Regulatory complexity is a core constraint to achieving the 100 Days Mission. Over 80% of stakeholders identified fragmented regulatory frameworks, limited capacity, and lack of harmonized processes as fundamental barriers to the timely development, approval, and deployment of diagnostic tools. These challenges manifest at multiple levels, including jurisdictional, institutional, and procedural, all leading to delays, duplication, and uncertainty, particularly for developers without in-house regulatory expertise or global reach. Stakeholders emphasized the tension between speed and compliance, highlighting the need to embed internationally recognized quality standards and technical specifications into accelerated pathways so that safety, quality, effectiveness, and public trust are not compromised.

Unlike therapeutics and vaccines, diagnostics did not benefit from the international regulatory coordination seen during COVID-19, where mechanisms such as the International Coalition of Medicines Regulatory Authorities (ICMRA) enabled rapid harmonization of criteria, study designs, and mutual reliance (e.g EMA approvals served as a basis for LMIC reliance). Diagnostic devices also span a much wider range of technologies and risk classifications, creating variable oversight requirements and fragmented evidence expectations across markets. During health emergencies, as with COVID, devices were classified differently in some jurisdictions creating higher evidence requirements. This caused significant delays to access to products already available in other countries. For emerging diseases, such as Ebola or H5N1, regulatory pathways may be undefined or inconsistent across regions, requiring developers to engage in lengthy, redundant development, testing, and approval processes.

Regulatory convergence in non-emergency times is essential for effective cross-border collaboration during public health emergencies. However, even when emergency use mechanisms exist, they are often slow to activate, lack pre-defined evidence requirements, and vary significantly in terms of transparency and speed. Smaller manufacturers, particularly those based in LMICs, face significant disadvantages in navigating these fragmented systems due to limited technical assistance, multilingual guidance, and regulatory engagement infrastructure. In many LMICs, regulators also lack the capacity to evaluate new or unfamiliar diagnostic platforms, particularly those incorporating novel technologies such as AI-enabled interpretation or multiplexed formats.

These constraints not only delay product availability during emergencies but also weaken developer incentives to invest in outbreak-prone pathogens. Stakeholders also noted that alignment with international standards enables local manufacturers to export and access new markets, fostering the growth of regional industries and strengthening resilience. Without predictable, rapid, and aligned regulatory pathways, diagnostics developers face significant disincentives to prioritize products for time-sensitive deployment, directly undermining the goals of the 100 Days Mission.

Priority recommendations to overcome regulatory barriers include:

1. **Improve pre-negotiated emergency use authorization frameworks.** Stakeholders strongly supported the development of clearer, faster, and more predictable emergency regulatory pathways. National and regional regulators should build on successful models such as the FDA EUA and complementary WHO mechanisms, including the ~~Prequalification (PQ)~~ process, which provides quality assurance to support global procurement; the Emergency Use Listing (EUL), activated during PHEICs and most recently applied for COVID-19 and mpox; and the Expert Review Panel for Diagnostics (ERPD), which recommended seven dengue diagnostics for procurement in 2025. Regulators should establish standardized dossier templates, transparent evidence requirements, and pre-defined timelines for review. A first step in harmonization is developing a comprehensive shared understanding of both divergences and areas of convergence across international emergency use procedures. These frameworks should be pre-negotiated with key regulators and include scenario-based triggers for activation during outbreaks. Implementation must also address current operational challenges, including surge review capacity, inconsistent documentation formats, and lack of mechanisms to transition from emergency use to full regulatory approval. Where possible, emergency use pathways should incorporate fast-track mechanisms for test adaptation in response to evolving strains, clades, or variants.
2. **Expand regional and global regulatory harmonization and reliance mechanisms.** Developers consistently called for greater standards and regulatory alignment and the implementation of recognition and reliance across regulatory agencies, the WHO and regional initiatives. WHO Prequalification (PQ) programs, International Medical Device Regulators Forum (IMDRF), regional regulatory bodies such as the European Medicines Agency (EMA) and the African Medicines Agency (AMA), and national regulators should collaborate to develop practical harmonization workplans for diagnostics relevant to pathogens with pandemic potential. This should build on IMDRF's relevant documents including: Essential Principles of Safety and Performance for Medical Devices and IVDs; In Vitro Diagnostic Device Regulatory Submission Table of Contents (IVD ToC); IMDRF terminologies for categorized Adverse Event Reporting (AER); and the Playbook for Medical Device Regulatory Reliance Programs (final version expected in 2026). IMDRF and WHO should jointly develop an Emergency Use Authorization Table of Contents to standardize emergency dossiers globally, giving developers a clear target for product design and enabling faster access across all regions. Stakeholders also cautioned that harmonization should not inadvertently create barriers by imposing standards that are ill-suited to different health system contexts; regulatory pathways must remain flexible enough to support affordable, appropriate solutions across regions.

   Prioritized implementation should include recognition or abridged assessments, evidence requirements in line with international best practice, and secure information-sharing platforms to reduce redundant review processes. For example, the African Medicines Regulatory Harmonization (AMRH) continental documents have been designed to ensure that continental work aligns with IMDRF global harmonization efforts. The Global Benchmarking Tool+ should be leveraged to enhance the existing list of suitable Reference Agencies recognized for their oversight of IVDs (original GHTF founding members; US, EU, Canada, Australia and Japan), enabling increased reliance and downstream approval in multiple markets. Where a conformity assessment procedure has already been completed by a designated Reference Agency, regulators should practice reliance, including recognition where appropriate, to avoid duplicative evaluations.

Where needed, additional in-country testing should only be required when scientifically justified, for example to address unique epidemiological characteristics, and could be streamlined through abridged approaches and use of real-world evidence. This enhanced regulatory capacity and harmonization is critical as major procurement agencies often require stringent regulatory authority approvals or WHO PQ, creating delays when local capacity is insufficient during outbreaks. IPPS, in collaboration with global (e.g., IMDRF) or regional regulatory bodies, could initially serve as a convening platform for regulator-regulator and regulator-industry collaboration to support convergence on dossier standards, especially for platform and syndromic technologies.

3. **Strengthen regulatory support systems, particularly for small and LMIC-based manufacturers.** Regulatory fragmentation and complexity disproportionately affect small and LMIC-based developers. Stakeholders emphasized the need for enhanced pre-submission support, including clearer technical guidance, multilingual documentation templates, and access to technical assistance. National and regional regulatory authorities, supported by multilateral organizations, should establish training hubs and advisory services modeled on successful initiatives such as the Asia-Pacific Economic Cooperation (APEC) Training Centers of Excellence and AUDA-NEPAD's training tools for smaller manufacturers and LMIC regulators with a particular focus on developing IVD-specific regulatory expertise and auditor capacity. International Finance Institutions (IFIs) and Development Finance Institutions (DFIs) should provide blended finance mechanisms and grant support to help regional and local manufacturers access regulatory expertise. These regulatory capacity building initiatives could be integrated with regional evaluation hubs (*Section 3.2*) and technology transfer platforms (*Section 3.4*), creating a coordinated system of support that accelerates time-to-submission and reduces the regulatory burden on developers without large regulatory teams.

4. **Establish internationally aligned post-market surveillance systems for ongoing diagnostic effectiveness.** Stakeholders emphasized that emergency approval must be matched by robust mechanisms to monitor diagnostic performance in the field. Regulators and public health agencies should collaborate to establish enhanced pathogen surveillance systems linked to post-market test performance monitoring. These systems should incorporate variant tracking, real-world effectiveness and safety data, and mechanisms for adaptive response to enable rapid test modifications or updated interpretation algorithms without requiring full re-approval processes. Where appropriate, regulators should establish conditional approval mechanisms that allow for time-limited authorizations pending confirmatory data, with pre-established protocols for modification or withdrawal in response to pathogen evolution or performance shifts. These systems will be especially critical for diagnostics targeting rapidly mutating pathogens or those deployed in diverse epidemiological settings. Regulators should complement adverse incident reporting with stage-gated guidelines that require proactive post-market monitoring by both manufacturers and authorities to ensure ongoing diagnostic effectiveness.

5. **Build capacity and adaptive frameworks to ensure regulation of breakthrough technologies.** Novel diagnostic technologies, such as AI-assisted interpretation tools, CRISPR-based assays, and modular platform diagnostics, often fall outside conventional regulatory classifications, creating delays and uncertainty for developers. These emerging technologies challenge traditional models of risk classification, performance evaluation, and software validation, and require tailored regulatory approaches that accommodate their flexible, multi-pathogen capabilities. Global capacity building is needed to help regulators understand how innovative diagnostics fit within existing regulatory classifications, while interim reliance on approvals from Reference Agencies or WHO can ensure timely access as that capacity develops.

Regulatory agencies should establish frameworks that provide clear guidance for platform technologies capable of being rapidly reconfigured for emerging threats. These frameworks should include validation protocols for integrated software components, update pathways for modular assay cartridges, and transparent change management systems that allow for timely modifications in response to evolving epidemiological needs.

Building on models such as the UK Medicines and Healthcare products Regulatory Agency (MHRA) Innovative Devices Access Pathway (IDAP), regulators should also consider establishing "sandbox" environments for controlled real-world testing of novel diagnostics, especially in LMIC settings where performance data are often limited. These mechanisms can support both regulatory confidence and innovation by enabling early engagement and iterative feedback between developers and regulators during the development process.

6. **Modernize regulatory processes, including electronic dossiers, electronic labeling, and signatures.** Regulators should accelerate approvals by adopting fully electronic dossier submission, review, labeling, and signatures, as COVID-19 showed that reliance on paper-based processes delayed market authorization for some tests. Funders should support the implementation of the IMDRF/WHO developed dossier Table of Contents for emergency use such that one dossier can be submitted to a common electronic location, reviewed by the Reference Agencies and immediately adopted by many countries for use.

By modernizing regulatory frameworks and building capacity for accelerated, harmonized decision-making, stakeholders can dramatically reduce the time required to bring high-quality diagnostics to market during public health emergencies. Without such reforms, diagnostic innovation will continue to outpace regulatory systems, leaving critical tools stranded in development pipelines while outbreaks grow. Addressing regulatory bottlenecks is not only essential for achieving the 100 Days Mission – it is a prerequisite for equitable, timely access to diagnostics in future pandemics.

3.4 Manufacturing Capacity, Supply Chain Resilience, and Technology Transfer Barriers

The global diagnostics manufacturing landscape remains highly concentrated and vulnerable to disruption. Over 80% of stakeholders identified manufacturing capacity limitations and supply chain fragility as core barriers to rapid and equitable diagnostic availability during health emergencies. These challenges include inadequate regional production infrastructure, limited technology transfer mechanisms, and dependency on constrained global supply chains for critical components and raw materials.

Global manufacturing is dominated by a small number of companies headquartered in high-income countries, often producing diagnostics at centralized facilities in Asia, North America, or Europe. During health emergencies, global manufacturers face overwhelming demand, export restrictions, and raw material shortages leaving even capable importing regions vulnerable to supply chain breakdowns, and LMICs facing even greater challenges accessing essential tools in a timely manner. Local and regional manufacturers, particularly in Africa, Latin America, and Southeast Asia, struggle with limited supplier diversification options and frequently lack access to validated technologies, skilled labor, and quality control systems necessary to contribute meaningfully during crises.

These vulnerabilities are compounded by the absence of structured technology transfer platforms that could enable rapid expansion of production capacity across regions. Many developers lack the legal, financial, or technical infrastructure to enter into equitable manufacturing partnerships, and current systems require ad hoc negotiations that are too slow to activate within the 100DM window.

Priority recommendations to overcome manufacturing capacity and supply chain barriers include:

1. **Develop innovative and quality-compliant regional diagnostic manufacturing capabilities through coordinated investment, sustained technical assistance, and skilled workforce development.** Stakeholders emphasized the need to reduce dependency on concentrated global production by establishing geo-diversified manufacturing capacity in multiple regions, particularly in LMIC settings including Africa, Southeast Asia and Latin America, where diagnostic needs are high, but production capabilities are limited. Expanding geographically distributed manufacturing certified to the international Quality Management Standard, ISO 13485, 16766,or MDSAP, is essential to reduce reliance on a small number of global producers and ensure timely availability of diagnostics during emergencies. Regional development banks and national governments, supported by development finance institutions and multilateral funders, should coordinate investments to establish regional manufacturing hubs in strategically located LMICs with high diagnostic demand and workforce potential, ensuring financing is linked to regional priorities.

    - This requires both physical infrastructure investment, comprehensive technical assistance and human resource development. Development finance institutions should coordinate with governments and private manufacturers to identify priority regions and establish production facilities with flexible manufacturing systems capable of producing platform diagnostics for priority pandemic pathogens like influenza and local epidemic threats. This manufacturing financing coordination should leverage and expand on the IFC working capital financing mechanisms and include establishing a secretariat or platform among DFIs to share technical capacities, align grant financing mechanisms, and provide coordinated assistance with regulatory pre-qualification processes. Infrastructure investment must be matched by comprehensive technical assistance, including support for production process optimization, quality assurance systems, regulatory compliance, and supply chain management. Sustained investment in skilled workforce development is similarly essential, including training programs for quality control technicians, production engineers, regulatory affairs specialists, equipment maintenance personnel, and other critical roles to ensure facilities can operate at international standards. These facilities should be designed for flexibility, capable of producing a range of diagnostic modalities (e.g., lateral flow assays, molecular platforms), and integrated with local regulatory and evaluation infrastructure (*Section 3.2*). Models such as the IFC's African Medical Equipment Facility and FIND's Regional Manufacturing Programme offer relevant examples that could be scaled and adapted.

2. **Establish technology transfer partnership platforms for diagnostic development.** Equitable and pre-negotiated technology transfer mechanisms are critical to enable rapid scale-up of validated diagnostics during emergencies. Stakeholders emphasized the need for structured platforms that facilitate partnerships between diagnostic developers and regional manufacturers. These platforms should provide standardized legal templates, intellectual property licensing models, and technical documentation packages to streamline collaboration. Examples such as the Bioaster-GADx-Diatropix partnership for Ebola diagnostics and the SD Biosensor-Codix Bio partnership for HIV diagnostics illustrate successful models of global north-south and south-south manufacturing partnerships. These platforms should be established through government, philanthropic, and private sector funding, with coordinated implementation through WHO Health Technology Access Programme (HTAP), FIND, PATH, MPP, and other multilateral partners. Building on these models, WHO HTAP and similar programs should expand partnership platforms that match organizations with complementary capabilities while addressing competitive concerns through structured agreements. Additionally, platforms should integrate with regional evaluation hubs (*Section 3.2*) to provide developers with clinical specimens, standardized reference panels, and regulatory-aligned evaluation services. These regional hubs can also provide regulatory compliance support to local and regional manufacturing facilities, including quality validation services for locally produced diagnostics and technical assistance with international quality standards.

3. **Build regional supply chain resilience to prevent LMIC supply disruption during emergencies.**

   Stakeholders highlighted how HIC markets often consume available supplies during health crises, leaving LMIC regions with extended wait times and reduced access to essential tools and materials. Regional manufacturers should be supported to pursue vertical integration strategies where feasible, while national governments and regional blocs should invest in reagent manufacturing, raw materials production, cold chain infrastructure, and warehousing capabilities. Additionally, cross-border collaboration remains essential for accessing specialized equipment, sharing technical expertise, and coordinating emergency responses. Governments should implement more agile export control reforms that facilitate cross-border collaboration during health emergencies. The Interim Medical Countermeasures Network (i-MCM-Net), international organizations, and regional development banks should support regional reagent production facilities and implement emergency allocation frameworks to facilitate equitable access during crises. Additionally, coordination or pooling mechanisms for critical raw materials and components should be developed by regional manufacturing associations and industry consortiums with development bank support, leveraging successful pooled procurement models like Africa Medical Supplies Platform (AMSP), to help smaller manufacturers overcome supply chain barriers.

4. **Establish capacity assessment systems to enable rapid emergency response coordination.** The absence of comprehensive data on global and regional diagnostic manufacturing capabilities hinders timely coordination during outbreaks. Stakeholders emphasized the need for real-time capacity mapping systems that track diagnostic production infrastructure, technical capabilities, raw material inventories, and available surge capacity during health emergencies. Governments and regional organizations should collaborate to create comprehensive databases of manufacturing capacity, equipment inventories, and stakeholder networks that can be rapidly accessed during crises. Data should include facility-level information disaggregated by technology type (e.g., molecular, antigen, multiplex), regulatory status, and potential for rapid conversion to outbreak-relevant production.

Initiatives such as PATH's interactive dashboard mapping diagnostics companies with manufacturing presence in Africa, Latin America, and Southeast Asia and PATH's convening on diagnostic needs for Africa and opportunities for development finance institutions provide a useful starting point. These systems should be expanded into dynamic, interoperable databases that integrate with regional manufacturing hubs, regional evaluation centers (*Section 3.2*) and technology transfer platforms to provide coordinated emergency response capabilities that leverage existing infrastructure for maximum efficiency during health crises.

Without regionalized manufacturing capacity, agile technology transfer, and resilient supply chains, diagnostics will continue to lag behind vaccines in pandemic response. Investing in these capabilities not only strengthens preparedness and global health security for the next emergency; it builds long-term industrial capacity, supports equitable access, and anchors sustainable diagnostics ecosystems globally.

3.5 Market Viability, End-to-End Financing, and Investment Ecosystem Barriers

Market failure is one of the most entrenched and universal barriers to sustainable diagnostic development and deployment. Over 90% of stakeholders identified financing barriers, ranging from poor market visibility, uncertain or zero-market size for outbreak-prone pathogens, and limited commercial returns to fragmented investment pathways and insufficient surge capital, as a core constraint across the diagnostics value chain. Moreover, traditional financing models inadequately support platform technologies and breakthrough innovations, which require extended development timelines and higher upfront investments than conventional single-disease diagnostics. These challenges vary substantially by pathogen archetype and market setting, but their cumulative effect is to disincentivize private sector engagement, undermine public investment, and prevent scale-up at the speed required to meet the 100 Days Mission. To address these barriers, our recommendations focus on three areas: establishing surge financing for rapid outbreak response, implementing market shaping tools tailored to specific pathogen types, and creating specialized incentives for platform technologies and breakthrough innovations.

Priority recommendations to overcome financing barriers include:

I. Establish Coordinated Surge Financing for Diagnostics Manufacturers

Stakeholders identified the absence of diagnostic-specific investment tools that span the R&D-to-deployment continuum as a critical gap. Existing models often prioritize therapeutic or vaccine development, with few tailored mechanisms that reflect the capital requirements, pricing constraints, and regulatory challenges unique to diagnostics.

1. **Establish a new, dedicated platform to coordinate concrete financing mechanisms for epidemic and pandemic-relevant diagnostics.** Donors, governments, and development agencies currently fund diagnostic development, manufacturing, and deployment through fragmented mechanisms that create gaps in support, including post-epidemic funding drop-offs that stall promising projects. Funding opportunities should be better aligned with R&D timelines to maintain momentum and prevent project stagnation. These stakeholders must establish coordinated funding approaches that support diagnostics from R&D through manufacturing to deployment, ensuring sustained investment across all lifecycle stages. To address this issue, several stakeholders proposed a coordinated effort to design and pilot diagnostic-specific financing tools. Funders could draw lessons from successful models such as CARB-X for antimicrobial resistance.

- Philanthropic and private sector financiers should establish a dedicated initiative to design and pilot financing tools specifically for epidemic and pandemic-relevant diagnostics. The initiative should create flexible frameworks that rapidly deploy appropriate push mechanisms (R&D grants, capacity building) and pull mechanisms (advance market commitments, volume guarantees) based on outbreak scale, pathogen characteristics, and manufacturer capacity. The initiative should include technical assistance in the form of grants to improve manufacturers' capacity to meet international standards, regulatory assistance, and assistance with pre-approvals for commercial loans. This effort should prioritize real-world piloting to enable rapid iteration and refinement based on actual outbreak response experience.
- The diagnostics surge financing initiative could be paired with a larger effort focused on financing coordination for a broader range of epidemic and pandemic MCMs (e.g., vaccines, treatments, and PPE) and could include stress testing of facilities, market analysis, and market shaping mechanisms, such as those recommended below.

2. **Establish surge financing mechanisms for rapid scale-up during outbreaks.**

Manufacturers frequently cannot access the working capital needed to expand production quickly during emergencies, creating critical supply bottlenecks when diagnostics are most urgently needed. This gap is especially acute for small and regional developers, who may lack collateral or procurement certainty to justify major capacity expansion.

- Development Finance Institutions and other relevant international financing institutions should establish, fund, and coordinate rapid-activation financing mechanisms to enable scale-up from routine to pandemic-level. These mechanisms should combine technical assistance, use blended finance, and provide concessional first-loss funding, where public or philanthropic investors absorb initial losses to reduce risk for commercial funders. Consistent with this recommendation, the G7 Development Finance Institutions and World Bank International Finance Corporation should accelerate their planned pilot program and develop standardized surge financing products that combine technical assistance, grants, and loans to enable regionally based manufacturers to overcome working capital constraints and rapidly scale production in response to outbreak demand. Accelerating this working capital facility, and complementing it with a dedicated, philanthropically supported technical assistance entity for market assessment, targeted market shaping, and regulatory support, should be a high priority.
- Current procurement rules typically require WHO prequalification or approval by stringent regulatory authorities before financing can be deployed, creating delays that undermine outbreak response. The World Bank and other multilateral development banks should establish at-risk financing mechanisms that allow LMICs to secure diagnostic procurement for products undergoing emergency use authorization as well as those progressing toward full approval. This approach would provide demand certainty to manufacturers and incentivize earlier production scale-up, ensuring adequate supply is available for rapid deployment once products receive full approval.

II. Deploy Market-Specific Financing Tools and Enhanced Forecasting

Emerging diseases like Ebola often present zero-market scenarios during inter-epidemic periods, with development driven by philanthropic or public sector push funding rather than sustainable demand. In contrast, high-burden endemic diseases such as dengue exhibit substantial clinical need but face fragmented purchasing power across LMICs and minimal interest from high-income markets, resulting in poor price-volume signals. Even dual-market threats like H5N1, which pose global pandemic risk, require innovative pricing and procurement models to align commercial incentives with equitable access, particularly during non-outbreak periods when demand is uncertain.

3. **Implement innovative financing tools tailored to market archetypes.** International development agencies, multilateral organizations, philanthropic funders, and national health ministries should deploy advance market commitments (AMCs) and volume guarantees to address different aspects of market uncertainty. AMCs are legally binding agreements where buyers commit to purchase specified quantities of not-yet-developed diagnostics at predetermined prices to incentivize R&D investment, contingent on achieving specific product targets, while volume guarantees are commitments to buy minimum quantities of existing or near-market diagnostic products to secure better pricing and provide contractual assurance of minimum demand levels.

   Approaches where a volume guarantee covers a bundle of products, leveraging demand for a high-volume assay to secure uptake of additional tests on the same platform, can further improve pricing transparency and incentivize programs to maximize use of existing diagnostic systems. Public and philanthropic investments should include binding access provisions, including affordability clauses, allocation frameworks, and equitable distribution guarantees to ensure that financing serves both innovation and equity. To address specific market failures, financing tools must be designed around the commercial realities of each pathogen archetype:

   - **For diseases with zero-market scenarios (e.g., Ebola),** WHO and regional health organizations should establish regional stockpiling strategies to ensure rapid availability during outbreaks. Physical stockpiles, backed by maintenance contracts and blended finance models that combine grant funding with milestone-based payments, can provide immediate access but risk expiry and wastage, while virtual stockpiles, where financing commitments are made in advance and manufacturers are obligated to deliver agreed volumes on demand, reduce these risks but require strong agreements and reliable funding. Governments, philanthropic funders, and development institutions should deploy minimum volume guarantees backed by substantial grant subsidies to address the absence of routine commercial demand.

   - **For high-burden endemic diseases in LMICs (e.g. dengue),** pooled procurement mechanisms such as the Global Fund, PAHO Strategic Fund, or the AMSP should aggregate demand and deploy volume guarantees to improve pricing and reduce market uncertainty. All such mechanisms must be underpinned by strong quality standards to prevent proliferation of low-performing products.

   - **For dual-market pathogens (e.g. H5N1 influenza),** international organizations and finance institutions should deploy minimum volume guarantees, and rapid-activation financing mechanisms to enable tiered pricing structures for diagnostic products. That is, higher margins in high-income markets support affordable access in LMIC settings. These structures must be pre-negotiated to ensure rapid scale-up when outbreaks emerge.

- **For Disease X scenarios,** international agencies and government should deploy "capacity insurance" models, where manufacturers are paid to maintain idle production capacity or pre-approved product configurations during non-emergency periods, with automatic triggers for surge production when outbreaks occur.

  The diagnostics surge financing initiative recommended above should stress test and pilot advance market commitments and volume guarantees for different priority pathogens to identify effective approaches.

4. **Develop improved market intelligence and forecasting systems.** Transparent, dynamic forecasting is essential for effective procurement planning, volume guarantee design, and investment mobilization. Currently, diagnostics demand forecasting remains ad hoc, siloed, and under-resourced. International agencies, procurement organizations, and manufacturers should establish formalized forecasting systems for supply planning and investment decisions that incorporate not only epidemiological trends and surveillance data, but also climate and seasonal factors, cross-border procurement pipelines, and evolving product landscapes.

   - Regional procurement mechanisms, including the Global Fund, PAHO's Strategic Fund, UNICEF, and AMSP, should embed dedicated forecasting functions within their operations and strengthen partnerships with manufacturers and technical partners to integrate demand forecasting processes. These enhanced forecasting capabilities should be supported by comprehensive market intelligence systems that WHO and regional health organizations establish to provide visibility into diagnostic performance characteristics, regulatory status, potential use cases, and buyer preferences, providing early-stage developers and investors with the information needed to model market entry, scale, and return on investment. Publicly available annual forecasts, particularly for neglected tropical diseases and outbreak-prone pathogens, will enable manufacturers to optimize production planning, consolidate manufacturing runs, and maintain strategic inventory for rapid outbreak response.

III. Create Financing Incentives for Platform Technologies and Innovation

Single-pathogen diagnostics often fail to achieve commercial viability, even with modest procurement volumes. Platform technologies serving multiple diseases and breakthrough innovations require fundamentally different financing approaches than traditional single-disease diagnostics due to their longer development timelines, higher upfront costs, and different risk profiles (*Section 4*). Stakeholders emphasized the need for tailored investment instruments that reflect the broader public health value of adaptability, rapid reconfigurability, and inter-epidemic usability.

5. **Provide financing incentives for multiplexed tests, platform technologies, and breakthrough innovations.** Development finance institutions and research funding agencies should establish specialized financing mechanisms that address these unique characteristics. These mechanisms should provide extended funding timelines that accommodate the complex development periods required for breakthrough innovations and offer pathway-specific incentives for technologies that can simultaneously address multiple barriers such as cost, accessibility, and regulatory requirements. Public and philanthropic funders should support milestone-based grant structures, risk-sharing agreements, and pooled R&D mechanisms that reward development of modular systems with embedded manufacturing resilience and regulatory alignment.

In addition to financing new technologies, incentives should also consider how existing diagnostic platforms and infrastructure already available in countries can be leveraged for pandemic preparedness and response, linking to capacity mapping initiatives (*Section 3.4*). Investment should be structured to support both initial development and long-term sustainability, including provisions for staff retention, revalidation, and readiness between outbreaks.

6. **Implement portfolio-based manufacturing and distribution strategies that cross-subsidize diagnostic development**. Manufacturers and development agencies should bundle diagnostics for diseases with diverse market profiles into unified manufacturing and distribution portfolios. For example, pairing diagnostics for emerging pathogens with those used in routine testing (e.g., TB, HIV, diabetes). This approach enables commercially viable business models for niche or low-volume diagnostics by cross-subsidizing production costs and leveraging combined volumes to achieve economies of scale. These models are particularly relevant in LMIC contexts, but they must be structured carefully so that additional costs do not disproportionately disadvantage manufacturers already operating with low margins. Public-private partnerships, social enterprises, and mission-aligned development consortia should design and execute these models to align commercial incentives with public health outcomes.
7. **Invest in shared materials and infrastructure to reduce development costs.** Public and philanthropic funders should invest in public infrastructure, such as open-access reagent libraries, standard reference panels, and platform-agnostic protocols, that can reduce development costs and de-risk innovation for smaller developers.

Financing remains the invisible infrastructure of diagnostic preparedness. Without predictable, fit-for-purpose investment tools, developers will continue to prioritize higher-margin technologies, and LMICs will remain underserved. Achieving the 100 Days Mission requires nothing less than a new financial architecture for diagnostics; one that is dynamic, diversified, and designed to deliver both speed and equity.

3.6 Cross-cutting Barriers

Beyond the specific constraints in R&D, test evaluation, regulation, manufacturing, and financing, we identified a set of structural challenges that undermine the end-to-end diagnostics ecosystem. These cross-cutting barriers include fragmented coordination, weak clinical adoption, and inadequate surveillance infrastructure. Together, they create persistent system-level vulnerabilities that delay time-to-impact, reduce developer incentives, and limit the operational value of diagnostics in both routine care and emergency response.

Without mechanisms to align actors, embed diagnostics into care pathways, and generate actionable data for decision-making, even high-performing technologies risk failing to reach scale or influence the trajectory of an outbreak. These interconnected and foundational challenges require coordinated solutions that address system-wide inefficiencies affecting all diagnostic development efforts, regardless of pathogen type or market context.

I. Diagnostic Ecosystem Coordination and Partnership Fragmentation

The diagnostics ecosystem remains highly fragmented compared to the vaccine and therapeutics sectors. It exhibits greater complexity than other medical countermeasure areas, with more diverse stakeholders, product types, and use cases, leading to significant coordination challenges. The 2021 Lancet Commission and over 70% of interviewed stakeholders highlighted the absence of a global forum or unifying mechanism to coordinate across diverse actors, including diagnostic developers, public health agencies, regulators, procurement platforms, funders, and implementing partners. This fragmentation leads to effort duplication, critical gaps in information sharing, unclear roles, and inefficient response activation during emergencies.

The launch of the WHO Global Diagnostics Coalition in May 2025 provides a critical opportunity to establish a platform for global coordination, aligned with the WHA76.5 resolution on strengthening diagnostics capacity. However, operationalizing the Coalition will require dedicated focus on pandemic preparedness and response, including clear mandates, sustainable resourcing, and mechanisms for integrating private sector innovation and regional leadership.

1. **Operationalize the Global Diagnostics Coalition with an epidemic and pandemic preparedness working group.**

   The Coalition should establish a dedicated working group focused on diagnostics for outbreak-prone pathogens. This group should support coordination from R&D through procurement and implementation, building on ACT-A's coordination model and integrating with existing efforts such as the Interim Medical Countermeasures Network (i-MCM-net). Implementation priorities include mapping capabilities and roles across stakeholders, developing technical working groups aligned to viral families (e.g., WHO CORCs) or diagnostic modalities, and facilitating communication across regulatory, manufacturing, and procurement efforts. The Coalition should also connect diagnostic coordination efforts to global financing mechanisms, helping translate coordinated strategies into funded initiatives and amplifying the voice of diagnostics within multilateral health security discussions.

Time-limited entities like IPPS can support this coordination by building stronger evidence bases for critical diagnostics bottlenecks, catalyzing stakeholder alignment around pressing gaps, ensuring actionable priorities are developed for implementation by organizations best positioned to deliver solutions, and identifying and leveraging potential synergies across medical countermeasures (e.g., the Therapeutics Development Coalition). Product development partnerships like FIND support coordination through development of tools such as the Pathogen Diagnostics Readiness Index and DxConnect test directory, providing critical readiness assessments that enable evidence-based priority setting.

II. Clinical Adoption and Policy Integration

Many diagnostics fail not due to technical shortcomings but because they are not adopted by health systems. The absence of robust cost-effectiveness data, implementation science, and clinician engagement was highlighted as a barrier to adoption and sustained use. This disconnect between diagnostics developers and end users, undermines both commercial viability and public health impact. In some cases, diagnostics are met with resistance due to stigma, perceived lack of utility, or misalignment with care workflows. In others, there is no mechanism to integrate diagnostics into policy, procurement, or clinical guidelines, even when tests are available.

2. **Develop health-economic evidence and value demonstration initiatives.** Funders and research institutions should support clinical trials and implementation studies that quantify the added value of diagnostic to health systems. These can be measured in terms of improved patient outcomes, cost savings, or reduced time-to-treatment. A multi-stakeholder consortium, similar to the VALUE-Dx initiative for antimicrobial resistance, could coordinate across clinicians, economists, public health experts, and industry to generate evidence packages that support product adoption and policy inclusion.

3. **Develop community engagement and social acceptance initiatives**.

   Developers and implementers should engage civil society organizations and community-based groups in co-creating testing strategies. This would be especially useful for high-consequence pathogens associated with quarantine, stigma, or economic disruption (e.g., mpox). Early engagement with affected communities can reduce barriers to uptake and ensure diagnostic interventions are designed with user perspectives in mind.

4. **Integrate diagnostic development with other critical medical countermeasure pathways**.

   Diagnostics should be embedded into vaccine and therapeutic development strategies from the outset where appropriate. This includes companion diagnostics for vaccine trial enrollment, tools for assessing correlates of protection, and test-to-treat platforms that enable targeted antiviral deployment. Institutions and international consortia such as CEPI, the Therapeutics Development Coalition, WHO CORCs and relevant clinical trial networks should promote, coordinate and invest in diagnostics as enabling technologies, not just standalone tools, to maximize synergies and resource efficiency across pandemic countermeasure development. Government and international procurers should provide demand signals for joint packages of tests and treatments to be developed and delivered.

III. Surveillance and Data Infrastructure

Effective diagnostics are most valuable if they generate actionable information for outbreak detection, response coordination, and health system decision-making. However, inadequate digital infrastructure, siloed data systems, and limited integration between diagnostic tools and public health surveillance networks weaken early warning capabilities, and delay the deployment of targeted interventions which, in turn, undermine the goals of the 100 Days Mission.

In many LMICs, diagnostic data do not flow into real-time surveillance systems due to inadequate connectivity, incompatible data standards, and fragmented governance structures. Diagnostic test results from clinics, laboratories, and point-of-care settings are often recorded manually and/or stored locally, with limited transmission to national and regional databases. In parallel, human, animal, and environmental surveillance systems remain poorly integrated, impeding early detection of zoonotic threats. These gaps are compounded by inconsistent case definitions across jurisdictions and a lack of standardization in data formats and indicators, limiting cross-border analysis and global risk assessment.

Improving data systems is also important for monitoring diagnostic performance over time, detecting declines in test sensitivity due to viral evolution, and informing decisions about test deployment, withdrawal, or adaptation (*Section 3.3*).

5. **Establish integrated collaborative surveillance networks connecting diagnostic testing with public health systems.** National and regional health authorities should invest in the development of laboratory and hospital networks and digital platforms that enable secure, real-time data exchange between diagnostic sites and public health institutions. These networks should prioritize interoperability, user-friendly data capture tools, and integration with existing national health information systems. Investments should be made in both software and connectivity infrastructure to ensure that POC tests and decentralized facilities are fully included in surveillance networks.

   Public and private partnerships should adopt a One Health approach, linking human, animal, and environmental health data systems to enable early detection of zoonotic spillovers. Coordinated sampling strategies across sectors can improve pathogen discovery and inform both preparedness and response activities. Existing models, including the BRIDGE Alliance and Africa CDC's Pathogen Genomics Initiative 2.0, offer promising platforms for expanding genomic surveillance, harmonizing protocols, and fostering cross-border collaboration. These initiatives should be scaled and linked to diagnostics deployment strategies to enable integrated outbreak response.

   Robust coordination, widespread clinical adoption, and integrated surveillance systems are the essential infrastructure that determines whether diagnostics reach patients quickly, generate actionable data, and meaningfully alter outbreak trajectories. Without these foundational systems in place, the 100 Days Mission cannot be realized, regardless of how quickly tests are developed or approved. Building a responsive and equitable diagnostic ecosystem requires deliberate, sustained investment in these structural enablers.

4. Emerging Breakthrough Technologies

While this diagnostic gap assessment is grounded in current technologies and infrastructure, achieving the 100 Days Mission will require bold investments in emerging diagnostic innovations. Recent technical advances have the potential to reduce infrastructure dependencies, compress development timelines, and enhance test adaptability for rapidly evolving or unknown pathogens. However, without intentional system adaptation, including regulatory reform, financing innovation, and manufacturing readiness, breakthrough tools will remain trapped in pilot phases or sidelined during emergencies.

Next-generation diagnostic technologies that are advancing rapidly can reduce infrastructure requirements and facilitate decentralized deployment compared to current platforms. Rapid diagnostic tests using novel nanomaterial labels, including quantum dots, enzymatic nanoparticles, and nanodiamonds, may improve sensitivity and specificity while maintaining low cost and rapid turnaround times. Paper-based molecular diagnostics incorporating microfluidics, synthetic biology circuits, or CRISPR-based detection modules can enable nucleic acid testing in settings with limited laboratory infrastructure. Computational prediction and optimization methods for antibody and antigen design can dramatically compress lateral flow test development by eliminating the time-intensive animal immunization and antibody screening processes. Many of these technologies and methods could enable accurate nucleic acid or antigen detection in decentralized settings, expanding testing access in health systems with limited laboratory capacity.

In parallel, modular diagnostic platforms are gaining traction. These systems are designed to support multiple assays using a single base instrument or cartridge system, allowing users to switch between tests for different pathogens based on need, all while remaining portable and close to patient. Such platforms are ideal for both routine care and emergency response, with the flexibility to scale or pivot during outbreaks. When paired with pathogen-specific reagents or software updates, modular systems could dramatically accelerate response timelines by reducing the need for new device distribution or user retraining.

Innovative sampling and detection methods, such as breath-based diagnostics, or non-invasive wearables, are also emerging as tools to improve patient acceptance, reduce biosafety risks, and increase compliance. These modalities may be especially valuable for pediatric populations, community-based screening, or surveillance in hard-to-reach areas.

Artificial Intelligence (AI) is increasingly being integrated into diagnostics workflows. Smartphone-connected lateral flow readers with embedded AI algorithms can standardize test interpretation across users and formats while automatically uploading results to surveillance systems and linking to treatment protocols. Such tools may be especially valuable in under-resourced or high-volume testing environments, where operator variability and delayed data entry have historically undermined diagnostic accuracy and utility.

However, despite these advances, breakthrough technologies face several systemic obstacles to deployment:

- Regulatory frameworks remain poorly adapted to evaluate AI-enabled tools, modular and combination devices, and synthetic biology-based platforms. Many of these innovations fall outside existing risk classifications or evidence requirements.
- Manufacturing capacity for advanced materials and microfluidic components remains limited in many LMIC regions, creating potential bottlenecks in supply during scale-up.
- Financing mechanisms typically do not support long development timelines, complex validation processes, or the high initial capital costs associated with novel platforms.
- Clinical adoption can be slow and integration with care pathways is often overlooked, leaving even promising technologies misaligned with clinical workflows or underutilized by health workers.

To fully realize the potential of breakthrough diagnostics, stakeholders must take coordinated action across multiple domains:

- **Regulatory agencies** should establish dedicated frameworks for adaptive and platform-based technologies, including clear protocols for software validation, modular assay updates, and real-world performance monitoring (*Section 3.3*) . Regulatory environments must evolve to support AI-enabled diagnostics, reconfigurable platforms, and synthetic biology approaches that do not fit neatly within traditional device categories. Flexible approval pathways, with sandbox testing models and conditional authorization linked to post-market data, can accelerate safe deployment of these tools during emergencies.

- **Manufacturers and technology developers** should begin investing in the production capabilities required to scale modular platform components (*Section 3.4*). Building regional manufacturing capacity for these components, especially in LMICs, can reduce supply chain bottlenecks and ensure that innovations reach the intended use settings. The success of these efforts will depend on effective regional coordination, supply chain strengthening and appropriate mapping of required raw materials and inputs. Open-source design standards and collaborative engineering platforms may further support distributed manufacturing and local adaptation.

- **Funders** must design targeted financing mechanisms that reflect the distinct needs of breakthrough technologies (*Section 3.5*) . These include longer development timelines, higher early-stage costs, and broader uncertainty around product-market fit.
  Innovative models such as milestone-based grants, pooled innovation funds, and dual-purpose procurement agreements should prioritize adaptability, inter-epidemic utility, and equitable access. Investments should explicitly reward platform designs that address multiple pathogen families and pivot quickly during outbreaks.

- **Global coalitions, procurement agencies, and public health implementers** must ensure that breakthrough diagnostics are integrated into the full cascade of response; from surveillance and triage to clinical care and test-to-treat strategies (*Section 3.6*). This includes articulating demand, incorporating novel tools into procurement frameworks and training curricula, and creating pathways for rapid scale-up and adoption when new threats emerge.

Emerging technologies will not replace the need for foundational system reforms, but they can dramatically reduce the barriers to speed, scale, and access tests if the broader ecosystem is ready to support them.

By investing now in regulatory adaptation, flexible financing, regionalized manufacturing, and systems integration, stakeholders can ensure that the most advanced diagnostic tools do not sit on the sidelines, but instead serve as frontline accelerators of pandemic response. The 100 Days Mission will only be achieved if the future of diagnostics is both developed and implemented.

5. Conclusion

The 100 Days Mission for diagnostics—ensuring that safe, effective, and affordable diagnostic tools are authorized (e.g., EUL) and ready for scaled production within 100 days of a declared PHEIC—is not a distant aspiration, but an urgent, achievable goal. Reaching it will require confronting the diagnostic ecosystem's most persistent barriers with speed, coordination, and political will.

This global diagnostic gap assessment, grounded in over 30 structured stakeholder interviews and targeted analysis across three priority pathogens, identifies six interlocking domains that consistently constrain diagnostic readiness: R&D acceleration, sample and data access, regulatory fragmentation, manufacturing vulnerabilities, financing gaps, and cross-cutting systemic weaknesses in coordination, adoption, and surveillance. While these barriers emerged across our analysis of Ebola, dengue, and H5N1, they manifest with important nuances across both market archetypes and stakeholder attributes, with different challenges facing large versus small organizations, HIC versus LMIC manufacturers, and various stakeholder types.

Addressing these gaps requires coordinated action across global and regional actors. The diagnostic ecosystem must:

- **Accelerate R&D** through disease-agnostic platforms, multiplex syndromic panels, and practical Target Product Profiles.
- **Secure sample access and validation capacity** via regional evaluation hubs and finalizing the PABS framework with practical equitable access provisions.
- **Streamline and harmonize regulatory processes** with common dossier templates, faster emergency use pathways, and adaptive frameworks for breakthrough technologies.
- **Strengthen regional manufacturing and supply chains** through equitable technology transfer and real-time capacity mapping.
- **Transform financing architecture** with incentives tailored for each market archetype, investments in modular platforms and breakthrough technologies, and surge financing mechanisms for emergency response.
- **Fix system-level fragmentation** by operationalizing the Global Diagnostics Coalition with a dedicated pandemic focused working group to support coordination.

Each of these pillars is addressed in this report with actionable, stakeholder-informed recommendations and implementation strategies. Collectively, they form an evidence-based roadmap for end-to-end diagnostic readiness. But without implementation, this roadmap remains merely theoretical. The 100DM window is a real constraint. Every delay in addressing these system weaknesses costs lives, increases transmission, and diminishes global trust in outbreak response.

Ultimately, what is required is not just progress within individual domains but diagnostic systems that bring these elements together into an integrated framework capable of serving both routine health needs and emergency response. Developing and implementing such systems will require countries to adopt national diagnostic strategies that link R&D, regulation, manufacturing, financing, and surveillance into resilient health infrastructures. These strategies must span from community to national levels while connecting through regional and global mechanisms to ensure coordination, equity, and speed during outbreaks.

This report also serves as a strategic tool for funders, ministries, implementing partners, and developers. It identifies practical interventions that can be piloted, financed, and scaled now. The benefits of building diagnostic capacity extend far beyond pandemic threats. Strengthened diagnostic systems will also support antimicrobial resistance control, precision medicine deployment, biosurveillance, and global manufacturing equity.

Crucial opportunities are on the horizon to advance these recommendations through multilateral action. The G20 Joint Finance and Health Task Force and recommendations from the High Level Independent Panel on health security financing provides a platform for developing diagnostic-specific financing mechanisms. France's 2026 G7 presidency offers momentum for regulatory harmonization and manufacturing resilience initiatives. And the 2026 UN High-Level Meeting on Pandemic Prevention, Preparedness and Response presents a global forum for committing to specific diagnostic capability targets.

The time for coordination and investment has arrived. Diagnostics can no longer remain the under-resourced pillar of pandemic preparedness. The 100 Days Mission is within reach but requires stakeholders to move beyond recognition of challenges to coordinated implementation of solutions. The time for action is now.

Acknowledgements

We would like to acknowledge all those who participated in the interviews and roundtable discussions (see full list in Annex), whose insights and recommendations formed the foundation of this report.

Disclaimer

This report references various companies, diagnostic products, and organizations to illustrate current market capabilities, technological approaches, and partnership models within the diagnostics ecosystem. These references are included solely for analytical purposes and do not constitute endorsements or quality assessments of any products or services. Similarly, the absence of any company or product should not be interpreted as a negative evaluation of their capabilities.

6. Summary of recommendations

Table 1. Critical barriers and actionable recommendations with suggestions for implementation

See Table 2 for priority recommendations grouped by stakeholder type.

Dx pillar	Barrier	Recommendations	Suggestions for implementation
R&D	R&D Process and Gaps and Guidance	Develop practical Target Product Profiles differentiated by intended use case and outbreak phase	**Developers** should engage with **public health agencies, WHO, and regulators** in consensus TPP development to align specifications with technical feasibility, manufacturing capabilities, and emergency use requirements, with WHO CORCs coordinating at the viral family level. **WHO, developers, and regulators** should work with national metrology institutes and standards organizations to embed reference measurement systems early in development, particularly for novel or rapidly mutating pathogens.

R&D		Expand and strengthen pathogen sequence data sharing systems	**Developers, academic researchers, and public health agencies** should support federated, independently governed data repositories like GISAID with global access standards and biosafety protections to ensure both rapid sharing and responsible stewardship of critical pathogen data.
	Siloed, single-pathogen test development	Incentivize development of multiplex panels combining endemic and emerging pathogen detection, as well as modular platform technologies.	**Funders** should prioritize syndromic panels for routine clinical use in high-burden settings and modular platforms capable of pivoting during outbreaks. **Platform developers** should design adaptable technologies with scalable plug-and-play components for rapid response to emerging threats and Disease X scenarios. **Ministries of Health and donor-funded procurement** should partner with **developers** to ensure platform accessibility in resource-limited settings and maintain platform operations between outbreaks through routine testing.
	Limited access to pathogen sequence data	Expand and strengthen systems for sharing timely and secure pathogen sequence data	Philanthropic funders and public health agencies should prioritise investments in near-real-time and standardized genomic data-sharing platforms with strong governance frameworks, transparent operations and robust infrastructure security aligned with WHO's attributes and principles for pathogen genomic data-sharing platforms (PGDSPs).

Sample Access	Limited access to Clinical Samples, Reference Materials, Standards, and Test Validation Infrastructure	Establish regional evalauation hubs organised by pathogen family and biosafety containment requirements	Governments, multilateral donors, and industry partners should jointly establish a network of regionally distributed validation facilities. These hubs would provide developers with clinical sample access, independent regulatory-aligned validation services, and regulatory support while maintaining operational capacity through routine work and enabling rapid pivot during outbreaks. A hybrid financing model that combines public investment with developer participation fees should be used, with tiered pricing structures adopted to ensure both financial sustainability and accessibility for smaller organizations. Hubs should align with quality benchmarks to support evidence-based procurement, creating market incentives that de-risk investment while ensuring equitable access to validation infrastructure.

		Expand development and regulatory acceptance of synthetic controls and alternative validation materials.	**Metrologists, developers, and regulators** should collaborate to develop high-quality synthetic controls (DNA/RNA constructs) and establish clear regulatory guidance on acceptable use cases, particularly for high-containment pathogens like Ebola and rapidly evolving pathogens. Regulatory bodies should integrate guidance on synthetic validation into emergency use frameworks to streamline test approval timelines.
		Complete the Pathogen Access Benefit-Sharing (PABS) companies, system with practical equitable access terms.	**IGWG should engage with technical experts** from research facilities, companies, and civil society representatives from all regions to finalise PABS annex.
Regulation	Regulatory Capacity, Harmonization, and Complexity	Improve pre-negotiated emergency use authorization frameworks	**National and regional regulators** should build on successful elements of existing (FDA EUA, WHO PQ, EUL, ERPD) to establish standardized dossier templates, transparent evidence requirements, and pre-defined timelines for review. Where possible, emergency use pathways should incorporate fast-track mechanisms for test adaptation in response to evolving strains, clades, or variants. Developing a shared understanding of divergences and convergence across international EUA procedures is a critical first step.

		Expand regional and global regulatory harmonization and reliance mechanisms.	**WHO, IMDRF, regional regulatory bodies (EMA, African Medicines Agency), and national regulators** should develop practical workplans for pandemic pathogens based on internationally recognized standards building on existing IMDRF frameworks and WHO mechanisms. Priorities include mutual recognition, standardized guidelines, and secure information sharing platforms. **IMDRF and WHO** should jointly develop an Emergency Use Table of Contents to provide a global baseline for emergency dossiers. **IPPS**, in collaboration with global (e.g., IMDRF) or regional regulatory bodies, could initially serve as a convening platform for regulator-regulator and regulator-industry collaboration to support convergence on dossier standards, especially for platform and syndromic technologies. **Regulators and WHO** should collaborate through the Global Benchmarking tool to support regulators becoming WHO Listed Authorities (WLAs) for medical devices.
		Strengthen regulatory capacity building and support systems, particulalry for small	Regulators should develop enhanced pre-submission processes with clear technical requirements, multilingual support, and technical assistance

		and LMIC-based developers.	programs, particularly for small and LMIC-based developers. **Multilateral organizations and regulatory bodies** should establish training networks (e.g., APEC Training Centers of Excellence, AUDA-NEPAD training tools), with tailored support for LMIC manufacturers, including the development of IVD-specific regulatory expertise and auditor capacity. These initiatives could be integrated with regional evaluation hubs to provide coordinated technical and regulatory support. **International Finance Institutions (IFIs) and Development Finance Institutions (DFIs)** should provide blended finance mechanisms and grant support to help regional and local manufacturers access regulatory expertise.
		Establish internationally aligned post-market surveillance systems for ongoing diagnostic effectiveness.	**Regulators and public health agencies** should establish internationally aligned PMS systems that link pathogen surveillance with test performance monitoring. These systems should incorporate variant tracking, real-world effectiveness data, and mechanisms for adaptive response to enable rapid test modifications or updated interpretation algorithms without requiring full re-approval processes.

	Lack of frameworks for breakthrough technologies	Build capacity to ensure regulation of breakthrough technologies	**Regulatory agencies** should build capacity and establish adaptive frameworks for emerging technologies including AI-enabled diagnostics, multiplex platforms, and novel detection methods, building on initiatives like MHRA's Innovative Devices Access Pathway (IDAP). Frameworks should include software validation protocols and sandbox environments for testing innovative approaches.
	Lack of electronic processes	Modernize regulatory processes, including electronic dossiers, electronic labeling, and signatures.	**Funders and regulators** should modernize processes with electronic dossiers, using the IMDRF/WHO Table of Contents to enable single electronic submissions adopted across multiple countries.
Manufacturing & Supply Chain	Concentrated global production and inadequate regional manufacturing infrastructure	Develop innovative and quality-compliant regional diagnostic manufacturing capabilities through coordinated investment, sustained technical assistance, and skilled workforce development.	**Development finance institutions** should prioritize investments in regional manufacturing hubs for pandemic pathogens like influenza and local epidemic threats through coordinated investment.

	Limited technology transfer partnerships and knowledge sharing mechanisms	Establish technology transfer partnership platforms for diagnostic development	**WHO, development finance institutions (DFIs), private sector and philanthropic donors, global and regional developers, and multilateral partners (e.g., FIND, PATH, MPP)** should establish technology transfer partnership platforms. **WHO HTAP** and **similar programs** should expand partnership platforms with standardized legal templates, intellectual property licensing models, and technical documentation packages. Platforms should integrate with regional evaluation hubs to provide clinical specimens, reference panels, and regulatory-aligned evaluation services.
	Supply chain vulnerabilities	Build regional supply chain resilience to prevent LMIC supply disruption during emergencies	**National governments and regional blocs** should invest in supply chain diversification, local reagent manufacturing, cold chain infrastructure, and warehousing capabilities. Where possible, **manufacturers** should facilitate company-level vertical integration to bring critical component production in-house. **i-MCM-Net, international organizations, and regional development banks** should support regional reagent production facilities and implement emergency allocation frameworks.

			Governments should implement more agile export control reforms that facilitate cross-border collaboration for accessing specialized equipment and sharing technical expertise during health emergencies. **Regional manufacturing associations and industry consortiums with development bank support**, should develop coordination and pooling mechanisms for raw materials and products, leveraging successful pooled procurement models like AMSP, to help smaller manufacturers overcome supply chain barriers.
	Insufficient capacity mapping for emergency response coordination	Establish capacity assessment systems to enable rapid emergency response coordination	**Governments and regional organizations** should create real-time databases tracking diagnostic production infrastructure, technical capabilities, raw material inventories, and available surge capacity. Systems should integrate with regional manufacturing hubs, evaluation centres, and technology transfer platforms.
Financing	Lack of diagnostic specific financing mechanisms and tools	Establish coordinated financing for diagnostics	**Philanthropic and private sector financiers** should establish a dedicated initiative to design and pilot financing tools for epidemic and pandemic-relevant diagnostics, aligned with the **G20 High Level Independent Panel,** creating flexible frameworks for push mechanisms

				(R&D grants, capacity building) and pull mechanisms (AMCs, volume guarantees).
	Limited access to working capital for emergency scale-up		Deploy surge financing mechanisms for rapid scale-up during outbreaks	**Development Finance Institutions and other relevant international financing institutions** should establish rapid-activation financing mechanisms combining technical assistance, blended finance, and concessional first-loss funding. **G7 DFIs and World Bank IFC** should accelerate their planned pilot program. **The World Bank and other multilateral development banks** should establish at-risk financing mechanisms allowing LMICs to secure diagnostic procurement before full regulatory approval, providing demand certainty to manufacturers.
	Lacking innovative financing tools tailored to market archetypes.	**Emerging/re-emerging diseases market failure (e.g., Ebola):** Unpredictable demand, zero-market scenarios, outbreak-driven development	Implement national or regional stockpiling strategies with maintenance contracts and blended finance models	**WHO and regional health organizations** should establish regional stockpiling strategies (physical or virtual) backed by maintenance contracts and blended finance models combining grant funding with milestone-based payments. **Governments, philanthropic funders, and development institutions** should deploy minimum volume guarantees backed by significant grant subsidies to address the absence of routine commercial demand.

		High-burden LMIC diseases archetype (e.g., Dengue): Fragmented purchasing power despite high disease burden, limited commercial markets in HICs	Deploy volume guarantees paired with regional pooled procurement	**Pooled procurement mechanisms** (Global Fund, PAHO Strategic Fund, Africa Medical Supplies Platform) should aggregate demand across multiple countries and deploy volume guarantees to improve pricing and reduce market uncertainty. All mechanisms must be underpinned by strong quality standards to prevent proliferation of low-performing products.
		Dual-market archetype (e.g., H5N1): Serving both HIC and LMIC settings equitably, limited LMIC affordability during pandemics	Implement tiered pricing combined with volume guarantees and rapid-activation financing	**International organizations and finance institutions** should deploy minimum volume guarantees and rapid-activation financing mechanisms to enable tiered pricing structures where higher margins in high-income markets support affordable access in LMIC settings. These structures must be pre-negotiated to ensure rapid scale-up when outbreaks emerge.
		Disease X	Establish government-supported insurance-like models	**International agencies and governments** should deploy "capacity insurance" models where manufacturers are paid to maintain idle production capacity or pre-approved product configurations during non-emergency periods, with automatic triggers for surge production when outbreaks occur.

	Inadequate market intelligence and demand forecasting	Develop improved market intelligence and forecasting systems	**Regional procurement mechanisms (Global Fund, PAHO Strategic Fund, UNICEF, AMSP)** should embed dedicated forecasting functions. **WHO and regional health organizations** should establish market intelligence systems providing visibility into performance characteristics, regulatory status, and buyer preferences.
	Platform technologies don't fit traditional financing models	Provide financing incentives for multiplexed tests, platform technologies, and breakthrough innovations	**Development finance institutions and research funding agencies** should establish specialized mechanisms for innovative diagnostic technologies with extended funding timelines, milestone-based grants, risk-sharing agreements, and pooled R&D mechanisms rewarding modular systems.
	Commercially unviable business models for niche/low-volume diagnostics	Implement portfolio-based manufacturing and distribution strategies	**Manufacturers and development agencies** should bundle production of diagnostics with diverse market profiles supported by **public-private partnerships, social enterprises, and mission-aligned consortia**.
	Duplicated efforts and inefficiencies in product development	Invest in shared materials and infrastructure to reduce development costs	**Public and philanthropic funders** should invest in public infrastructure like open-access reagent libraries.

Cross-cutting	Diagnostic ecosystem coordination and partnership fragmentation	Operationalize the Global Diagnostics Coalition with an epidemic and pandemic preparedness working group.	**WHO Global Diagnostics Coalition** should establish a dedicated epidemic and pandemic preparedness working group to coordinate R&D through procurement and implementation activities for outbreak-prone pathogens. The Coalition should facilitate communication across existing efforts (i-MCM-net), reduce duplication through clear role delineation, and map stakeholder roles and capacities during peacetime to enable faster crisis response. Priority areas should include R&D for point-of-care tests across pandemic-prone viral families and engaging fora like IMDRF to advance regulatory harmonization, supported by international organizations like IPPS and FIND.
	Clinical adoption failures and policy integration gaps	Develop health economic evidence and value demonstration initiatives	**Funders and research institutions** should support clinical trials and implementation studies that quantify the health system value of diagnostics. Multidisciplinary consortium similar to VALUE-Dx for antimicrobial resistance should coordinate **clinicians, health economists, and industry representatives** to generate evidence packages that support product adoption and policy inclusion.

		Develop community engagement and social acceptance initiatives	**Developers** and **implementers** should engage **civil society organizations and community-based groups** in co-creating testing strategies.
		Integrate diagnostic development with other critical medical countermeasure	**Diagnostic developers** should coordinate with **clinical trial networks** and **CEPI** to develop rapid tests that accelerate vaccine trials and support correlates of protection, and with the **Therapeutics Development Coalition** to enable test-to-treat strategies for priority pathogens. **Government and international procurers** should provide demand signals for joint packages of tests and treatments to be developed and delivered.
	Inadequate surveillance and data infrastructure for outbreak detection and response coordination	Establish integrated collaborative surveillance networks connecting diagnostic testing with public health systems	**National and regional health authorities** should invest in laboratory networks and digital infrastructure that enable secure, real-time data exchange between diagnostic sites, public health institutions, and patient care systems. These systems should support integration with surveillance platforms and geospatial tools across both laboratory and decentralized testing sites, including at the primary and community care levels. **Public and private partners** should adopt a One Health approach through coordinated sampling strategies across human, animal and environmental health.

Table 2. Stakeholder-specific actionable recommendations with suggestions for implementation

Stakeholder groups	Priority recommendations with suggestions for implementation
Industry, developers, manufacturers	**R&D:** - Co-develop practical TPPs with WHO CORCs, metrology institutes, and regulators. **Samples & validation:** - Provide technical input into PABS annex. - Participate in regional evaluation hubs for sample access, validation, and regulatory support (co-finance through participation fees). **Manufacturing & supply chain:** - Establish technology transfer partnerships where appropriate and when international Quality Management Standards can be met. - Share capacity data for rapid surge coordination. **Cross cutting:** - Engage civil society organizations and community groups in co-creating testing strategies. - Integrate diagnostic development with vaccine and therapeutic pathways where appropriate.
Funders (DFIs/IFIs, philanthropy, private, procurement agencies)	**R&D:** - Prioritize investments in syndromic panels for routine clinical use in high-burden settings and modular platforms able to pivot in outbreaks. **Samples & validation:** - Co-finance regional evaluation hubs. - Fund high-quality reference panels and development of synthetic controls. **Regulation:** - Finance regulatory capacity-building networks and digital modernization (e.g., e-dossiers, e-signatures).

	Manufacturing & supply chain: - Invest in geo-diversified manufacturing facilities certified to the international Quality Management Standard, technical assistance and workforce development - Stand up tech-transfer platforms where appropriate and when international Quality Management Standards can be met. - Back regional reagent and raw-material production. **Finance/market shaping (including procurers):** - Design and pilot diagnostics-specific tools (rapid-activation surge financing; at-risk mechanisms for LMIC procurement) - Coordinate with other funders to deploy tailored market-specific mechanisms including regional stockpiling strategies, advanced market commitments, volume guarantees, pooled procurement to aggregate demand, and tiered pricing structures; explore capacity-insurance models and build demand forecasting and market-intelligence functions. - Establish specialized mechanisms for innovative diagnostic technologies with extended funding timelines, milestone-based grants, and risk-sharing. **Cross cutting:** - Resource diagnostics ecosystem coordination efforts (e.g., Global Diagnostics Coalition). - Support clinical trials and implementation studies that quantify the health system value of diagnostics.
Regulators (national, regional, WHO, IMDRF)	**R&D:** - Integrate guidance on synthetic/contrived validation materials into emergency frameworks. **Regulation:** - Adopt international best practices (including the WHO Global Model Regulatory Framework and IMDRF standards) with pre-negotiated emergency pathways, common dossier

	templates, transparent evidence requirements and timelines, expand reliance and recognition. - IMDRF, WHO and partners to develop an Emergency Use Table of Contents to provide a global baseline for emergency dossiers. - Enhance pre-submission support with technical assistance programs, particularly for small and LMIC-based developers. - Establish internationally aligned PMS linking surveillance with test-performance monitoring. - Build adaptive frameworks for AI-enabled, multiplex, and novel methods. - Adopt electronic submissions/labels/signatures. **Cross cutting:** - Engage in WHO CORCs and the Global Diagnostics Coalition to align with broader MCM strategies where relevant.
International and multilateral organizations (e.g., WHO, i-MCM net, IPPS)	**R&D:** - WHO CORCs coordinate viral-family TPPs and DTV synergies. **Samples & validation:** - Finalize the PABS annex with technical input and practical equitable access terms. **Regulation:** - WHO PQ/EUL and IMDRF develop Emergency Use Table of contents and promote WLA and reliance mechanisms. - IPPS to initially convene regulator-regulator and regulator-industry collaboration to support convergence on dossier standards, especially for platform and syndromic technologies. **Manufacturing & supply chain:** - Support and enable technology transfer platforms (e.g., WHO HTAP). - i-MCM-Net and regional bodies coordinate emergency allocation. **Finance/market shaping:** - Build shared market-intelligence/forecasting with procurers and regions.

	Cross-cutting: - Operationalize the Global Diagnostics Coalition with a pandemic preparedness working group to facilitate coordination, match country needs with funder capabilities, and reduce duplication. - Generate health economic evidence to drive adoption and policy prioritization.
Governments	**R&D:** - Invest in multiplex syndromic panels and modular platform technologies. - Strengthen secure pathogen sequence data sharing systems. **Samples & validation:** - Co-establish, finance, and host regional evaluation hubs that provide developers with clinical sample access, independent validation, and regulatory support. **Manufacturing:** - Invest in regional production and diversified supply chains, including local reagent/raw-materials. - Implement more agile export control reforms that facilitate cross-border collaboration. - Support building a skilled workforce. - Maintain real-time databases tracking diagnostic production infrastructure, technical capabilities, raw material inventories, and available surge capacity. **Finance & procurement:** - Design and pilot diagnostics-specific financing tools (rapid-activation surge financing) - Deploy market-tailored financing mechanisms: Develop national and regional stockpiling strategies; pooled procurement to aggregate demand; deploy volume guarantees to enable tiered pricing; deploy "capacity insurance" models. **Cross-cutting:** - Invest in laboratory systems and integrated surveillance networks with real-time data sharing to enable timely alerts and responses. - Provide demand signals for joint test-and-treat packages. - Adopt a One Health approach across human–animal–environment surveillance.

Non-profit, Research (PDPs, academia)	**R&D:** - Co-lead practical TPPs with WHO CORCs, industry, and regulators. - Contribute to federated sequence/data repositories. - Design adaptable technologies with scalable plug-and-play components for rapid response to emerging threats and Disease X scenarios. **Samples & validation:** - Develop high-quality synthetic controls/contrived materials; - Contribute to regional evaluation hubs with regulatory-aligned protocols. **Cross-cutting:** - Generate health-economic and implementation evidence to drive adoption.

Annex

Interviewee participants & expert feedback

Africa Medical Supplies Platform (AMSP), Altona Diagnostics, ANRS, Bioaster, Bioclin, bioMérieux, Brown University Pandemic Center, CEPI, Cepheid, Diatropix, European Medicines Agency, Fiocruz, Gates Foundation, Ghana FDA, Global Access Diagnostics, Global Health Investment Corp, Health Canada, HERA, IDEXX, International Finance Corporation, International Medical Device Regulators Forum, Lancet Commission on Diagnostics, MedAccess, MHRA, Molbio Diagnostics, PATH, RIGHT Foundation, Roche, SD Biosensor, ThermoFisher, UK National Measurement Laboratory (NML) at LGC, Unitaid, UNICEF, WHO (Health Emergencies Programme, Regulation & Prequalification, Diagnostics Task Force) Wondfo, and additional diagnostics, biosecurity and infectious disease experts, including Mona Nemer, François Lacoste, Rick Bright, Renu Swarup, Rosane Cuber Guimarães, Delese Mimi Darko, Seth Berkley, and Jennifer Nuzzo.

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Case study pathogen information

Ebola virus (Filoviridae)

Ebola virus is a filovirus that causes severe hemorrhagic fever, with case fatality rates ranging from 25-90%. Endemic to Central and West Africa, the virus spreads through direct contact with bodily fluids and causes sporadic but devastating outbreaks. Current diagnostic capabilities include WHO EUL-listed molecular and antigen platforms and U.S. FDA Emergency Use Authorization RT-PCR assays deployed via the U.S. Laboratory Response Network, with major developers including Altona Diagnostics, bioMérieux (BioFire), Cepheid, OraSure Technologies, and SD Biosensor. Point-of-care options remain limited, with available rapid antigen tests for Zaire ebolavirus showing variable sensitivity across platforms. Key challenges include infrastructure requirements that limit deployment in resource-constrained outbreak settings and complex biosafety requirements for validation. While Ebola is one of the relatively few WHO priority pathogens with a published diagnostic target product profile (TPP), the existing TPP is limited to Zaire ebolavirus and does not address other species such as Sudan ebolavirus, which has caused recent outbreaks and faces significant diagnostic gaps. There remains a significant need for further development of highly sensitive validated point-of-care tests that allow for detection of multiple ebolavirus species.

Dengue virus (Flaviviridae)

Dengue virus is a climate-sensitive, mosquito-borne flavivirus endemic to tropical and subtropical regions across Southeast Asia, the Americas, and parts of Africa. The virus causes over 100 million symptomatic cases annually and has experienced unprecedented geographic expansion in recent years. The virus exists in four distinct serotypes (DENV1-4), with sequential infections increasing the risk of severe dengue due to antibody-dependent enhancement. Diagnostic approaches vary by stage of infection: RT-PCR and NS1 antigen testing are most effective in the acute phase (first week of illness), while IgM/IgG serology becomes more useful typically after a week. Commercial platforms provide a mix of molecular PCR (e.g., Altona, Roche, Thermo Fisher, SD Biosensor) and antigen/antibody assays (e.g., Abbott, Bioclin, Boditech Med, Fiocruz, InBios, SD Biosensor), with multiplex PCR assays available for simultaneous detection of all four dengue serotypes. However, point-of-care rapid tests show variable sensitivity and specificity and cross-reactivity with other flaviviruses (Zika, yellow fever). Secondary infection detection remains complex, requiring combined antigen and antibody testing approaches. Affordable, validated multiplex tests that differentiate dengue serotypes from other febrile illnesses are needed. While dengue diagnostics have not undergone WHO Prequalification, in May 2025 WHO's Expert Review Panel for Diagnostics (ERPD) recommended seven products for time-limited procurement in emergencies.

H5N1 influenza (Orthomyxoviridae)

H5N1 avian influenza is a highly pathogenic virus with pandemic potential, primarily spreading through contact with infected birds or contaminated environments. While human cases remain rare and sustained human-to-human transmission is limited, H5N1 has shown concerning evolution globally, with a new genotype (B3.13) identified in over 130 dairy herds across 12 U.S. states in 2024. This agricultural outbreak has had significant economic repercussions and demonstrates the virus's potential to trigger pandemics through cross-species transmission. Molecular testing includes RT-PCR assays targeting influenza A matrix genes and H5-specific hemagglutinin genes, available through regional or country-specific laboratory networks (e.g. the U.S. CDC Laboratory Response Network). Commercial platforms (e.g., bioMérieux, IDEXX, Molbio, Roche, SD Biosensor, Thermo Fisher) provide influenza A and B diagnostics, including molecular and rapid assays, but most seasonal influenza A tests detect H5N1 only at the type level and cannot provide critical subtype differentiation. Due to the virus' high mutation rate, rapid antigen tests show variable ability to detect H5N1 and reduced sensitivity for emerging strains. Stakeholders noted that comprehensive influenza A and B detection, including emerging subtypes, offers a more scalable and sustainable approach for clinical and public health use than focusing solely on H5N1specific kits. Key challenges include subtype differentiation limitations that prevent distinguishing pandemic H5N1 from seasonal influenza strains outside specialized reference laboratories, dual-use human/veterinary considerations that complicate regulatory pathways and deployment strategies, and the need for platforms capable of rapid adaptation to emerging variants while maintaining compatibility with existing influenza surveillance systems.

Diagnostics funding landscape for outbreak-prone pathogens

Diagnostics funding for outbreak-prone pathogens remains limited, reactive, and concentrated among a small set of public funders.

Table 3 provides a non-exhaustive landscape of funding streams for outbreak-prone pathogen diagnostics, split by **upstream (R&D)** and **downstream (manufacturing and procurement)**, with some funders spanning both. While Table 3 illustrates a diversity of potential funding streams, actual funding patterns reveal concerning concentration among dominant funders and COVID-19-specific allocations.

Table 3. Non-exhaustive landscape of diagnostics funders for outbreak-prone pathogens.

<table>
<tr><th>Funder type</th><th>Upstream (R&D)</th><th>Downstream (manufacturing, procurement)</th></tr>
<tr><td rowspan="2">Public</td><td>U.S. Centers for Disease Control (CDC); South Africa for Scientific and Industrial Research (CSIR); Indian Council of Medical Research (ICMR); Japan International Cooperation Agency (JICA); UK National Institute for Health and Care Research</td><td>National governments; Nigeria Presidential Initiative for Unlocking the Healthcare Value Chain (PVAC)</td></tr>
<tr><td colspan="2">U.S. Biomedical Advanced Research and Development Authority (BARDA); European Commission/Health Emergency Preparedness and Response Authority (HERA); UK Foreign, Commonwealth & Development Office (FCDO); National Institutes of Health Rapid Acceleration of Diagnostics initiative (NIH RADx)</td></tr>
<tr><td rowspan="2">Multilateral (Procurement agencies; MDBs, DFIs)</td><td></td><td>Asian Development Bank (ADB); Africa CDC; African Development Bank (AfDB); Africa Medical Supplies Platform (AMSP); Global Fund; PAHO Strategic Fund; UNICEF</td></tr>
<tr><td colspan="2">Gavi; International Finance Corporation (IFC); Unitaid; World Bank</td></tr>
<tr><td rowspan="2">Philanthropic</td><td>ELMA Philanthropies; Mérieux Foundation; LifeArc; Open Philanthropy; RIGHT Foundation</td><td>Rockefeller Foundation; Skoll Foundation</td></tr>
<tr><td colspan="2">Gates Foundation; Wellcome</td></tr>
</table>

PDP	DNDi; FIND; PATH	
Private Sector / PPP	GHIT Fund	Global Health Investment Corporation (GHIC); MedAccess
	Private manufacturers	
NGO / Implementer		Clinton Health Access Initiative (CHAI); Médecins Sans Frontières (MSF)

R&D funding takeaways

- **Scorecard highlights pipeline gaps:** The 100 Days Mission Scorecard, developed by IPPS and Impact Global Health using G-FINDER data, tracks R&D funding disbursements across priority pathogens and shows significant gaps in the diagnostics pipeline, particularly for rapid POC tests.
- **Funding is dominated by public sources, particularly U.S. agencies:** From 2019–2023, diagnostics R&D funding across Scorecard 2.0 pathogens was 86% public, 8% industry, and 7% philanthropy. The top five funders were U.S. NIH, U.S. BARDA, Aggregate Industry, the European Commission, and U.S. DOD (**Figure 1a**). In 2023, >87% of diagnostics R&D funding came from U.S. government agencies, rising to 98% when excluding COVID-19-specific expenditures (**Figure 1b**). This overreliance on a single nation's funding priorities leaves the field vulnerable, with global research continuity exposed to national political cycles and economic fluctuations. Building a more diverse funding ecosystem, drawing on governments, philanthropies, and industry partners (Table 3), is essential to strengthen global resilience.
- **Diagnostics R&D outside COVID-19 remains extremely low:** In 2023, only $13m was reported for non-COVID diagnostics R&D across Scorecard 2.0 pathogens, compared with $158m for vaccines and $189m for therapeutics. The vast majority (about 90%) of diagnostics R&D funding for epidemic diseases focused on COVID-19 (**Figure 1c–d**), underscoring the need to diversify funding sources and better align investments with regional priorities.

Funding landscape for case-study pathogens (G-FINDER data)

- **Ebola:** Funding in 2023 was $8.3m, driven primarily by BARDA (85%) and U.S. NIH (15%).
- **Dengue:** Funding in 2023 was $3.3m, fragmented across several small awards: U.S. NIH (62%), Flemish Agency for Innovation and Entrepreneurship (17%), Colombian Minciencias (13%), Grand Challenges Canada (3%), and Indian Department of Science and Technology (1%). While dengue is not included in the 100 Days Mission Scorecard 2.0, corresponding R&D funding and pipeline data are available in the G-FINDER portal and Impact Global Health neglected disease pipeline report.
- **Influenza H5N1:** Data is now being collected under the G-FINDER survey and will be included in Scorecard 3.0 (January 2026).

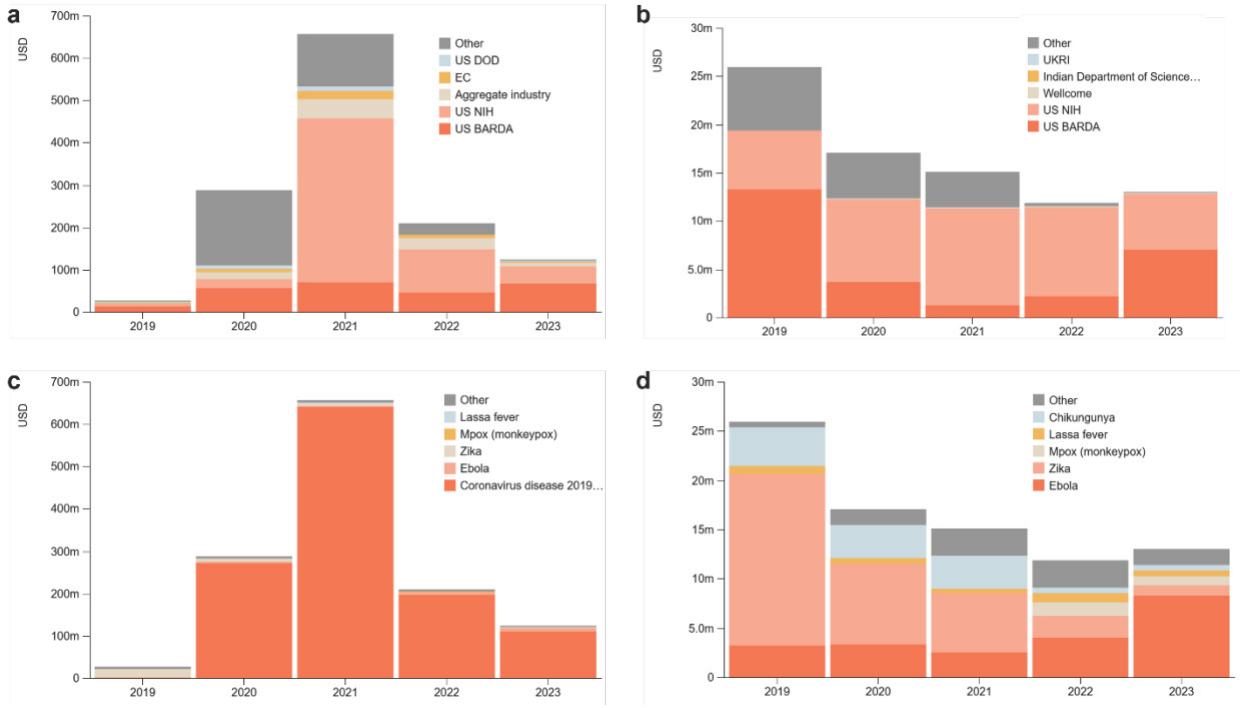

Figure 1. Diagnostics R&D funding for Scorecard 2.0 pathogens (2019–2023) from G-FINDER data: funders including (a) and excluding (b) COVID-19 investments; pathogen-specific funding including (c) and excluding (d) COVID-19 investments.

Abbreviations

100DM - 100 Days Mission
ADB - Asian Development Bank
ACT-A - Access to COVID-19 Tools Accelerator
AER - Adverse Event Reporting
AfDB - African Development Bank
AI - Artificial Intelligence
AMA - African Medicines Agency
AMC - Advanced Market Commitment
AMRH - African Medicines Regulatory Harmonization
AMSP - Africa Medical Supplies Platform
APEC - Asia-Pacific Economic Cooperation
BARDA - Biomedical Advanced Research and Development Authority
BSL-4 - Biosafety Level 4
CDC - Centers for Disease Control
CEPI - Coalition for Epidemic Preparedness Innovations
CHAI - Clinton Health Access Initiative
CORCs - Collaborative Open Research Consortiums
COVID-19 - Coronavirus Disease 2019
CSIR - Council for Scientific and Industrial Research
DENV - Dengue Virus
DFI - Development Finance Institution
DNDi - Drugs for Neglected Diseases initiative
DOD - Department of Defense
EMA - European Medicines Agency
EQA - External Quality Assessment
ERPD - Expert Review Panel for Diagnostics
EU - European Union
EUA - Emergency Use Authorization
EUL - Emergency Use Listing
FCDO - Foreign, Commonwealth & Development Office
FDA - Food and Drug Administration
FIND - Foundation for Innovative New Diagnostics
G20 - Group of Twenty
G7 - Group of Seven
GADx - Global Access Diagnostics
GHIC - Global Health Investment Corporation
GHIT - Global Health Innovative Technology
GHTF - Global Harmonization Task Force
HIC - High-Income Country
HIV - Human Immunodeficiency Virus
HTAP - Health Technology Access Programme
i-MCM-Net - Interim Medical Countermeasures Network
ICMR - Indian Council of Medical Research
ICMRA - International Coalition of Medicines Regulatory Authorities
IDAP - Innovative Devices Access Pathway

IEC - International Electrotechnical Commission
IFC - International Finance Corporation
IFI - International Finance Institution
IgG - Immunoglobulin G
IgM - Immunoglobulin M
IGWG - Intergovernmental Working Group
IMDRF - International Medical Device Regulators Forum
IPPS - International Pandemic Preparedness Secretariat
ISO - International Organization for Standardization
ITAP - Independent Test Assessment Program
IVD - In Vitro Diagnostic
JICA - Japan International Cooperation Agency
LMIC - Low- and Middle-Income Country
MCM - Medical Countermeasures
MDB - Multilateral Development Bank
MDSAP - Medical Device Single Audit Program
MHRA - Medicines and Healthcare products Regulatory Agency
MPP - Medicines Patent Pool
MSF - Médecins Sans Frontières
MVP - Minimum Viable Product
NCBI - National Center for Biotechnology Information
NGO - Non-Governmental Organization
NIH - National Institutes of Health
NIHR - National Institute for Health and Care Research
NS1 - Non-structural protein 1
PABS - Pathogen Access and Benefit-Sharing
PAHO - Pan American Health Organization
PCR - Polymerase Chain Reaction
PDP - Product Development Partnership
PEQAP - Pandemic EQA Providers
PGDSP - Pathogen Genomic Data-Sharing Platform
PHEIC - Public Health Emergency of International Concern
PMS - Post-Market Surveillance
POC - Point-of-Care
PPE - Personal Protective Equipment
PPP - Public-Private Partnership
PQ - Prequalification
PVAC - Presidential Initiative for Unlocking the Healthcare Value Chain
R&D - Research and Development
RADx - Rapid Acceleration of Diagnostics
RCT - Randomized Controlled Trial
REPL - Read-Eval-Print Loop
RSV - Respiratory Syncytial Virus
RT-PCR - Reverse Transcription Polymerase Chain Reaction
SARS-CoV-2 - Severe Acute Respiratory Syndrome Coronavirus 2
TB - Tuberculosis
ToC - Table of Contents

TPP - Target Product Profile
UK - United Kingdom
UKHSA - UK Health Security Agency
UN - United Nations
UNICEF - United Nations Children's Fund
US/U.S. - United States
WHA - World Health Assembly
WHO - World Health Organization
WLA - WHO Listed Authority

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