100 Days Mission

IPPS International Pandemic Preparedness Secretariat

Implementation Report
Progress in 2025 & Priorities for 2026

Reducing the impact of future pandemics by enabling access to diagnostics, therapeutics, and vaccines within 100 days

An independent report from the **International Pandemic Preparedness Secretariat**

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ACKNOWLEDGEMENTS

This report represents independent views of the International Pandemic Preparedness Secretariat. However, we would like to acknowledge the numerous individuals that have contributed to the report and provided their time and insights, including Impact Global Health for their contributions to the 100DM Scorecard and review of the report, and implementation partners for their input provided through interviews and pro formas. A full list of contributors is listed in *Annex C*.

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Five Years On: Global Health Shifts Heighten the Imperative for the 100 Days Mission

We cannot allow progress toward the 100DM to stall. At this critical moment, coordinated and focused action across all stakeholders is essential to ensuring delivery of the 100DM.

Foreword from Dr Mona Nemer

CHAIR OF THE INTERNATIONAL PANDEMIC PREPAREDNESS SECRETARIAT AND CHIEF SCIENCE ADVISER OF CANADA

Five years ago, the world confronted a global pandemic that reshaped economies, societies, and health systems. The response to COVID-19 showed what is possible when science, policy, and global solidarity align: diagnostics, therapeutics, and vaccines (DTVs) were developed and deployed at unprecedented speed. These achievements demonstrated that rapid, coordinated action can save millions of lives. The 100 Days Mission (100DM) was created to ensure that this level of responsiveness becomes the norm, not the exception, in future pandemics.

Today, that mission is even more urgent.

The global health landscape of 2026 is markedly different from that of five years ago. While scientific capability continues to advance, the political and economic foundations that underpin preparedness have weakened. Many countries face contracting health and R&D budgets, geopolitical tensions are rising, and multilateral cooperation, essential for surveillance, pathogen sharing, and equitable access, is under strain. These systemic shifts risk slowing or reversing the progress made toward the 100DM.

At the same time, the world faces a growing and increasingly complex array of infectious disease threats. Pathogens continue to emerge and evolve. Climate change, urbanisation, plus increased movement of goods and people are amplifying the speed and scale of global health threats. However, the world's readiness to respond is not keeping pace with the threats. The greatest concern is not any single outbreak, but the widening gap between what science can do and what our political and financial systems are currently enabling.

Compounding this challenge is the significant contraction of global investment in pandemic preparedness and R&D for medical countermeasures, as governments navigate competing priorities amid global polycrisis. The steep decline in therapeutics funding, in particular, leaves a critical vulnerability in our ability to promote biosecurity and respond to viral threats. There is also a fragmented financing architecture for diagnostics development. Additionally, while vaccines are the best resourced countermeasures, their development is vulnerable to funding volatility, and there are late-stage pipeline gaps. The 100DM Scorecard 3.0 makes it clear – current progress remains heavily dependent on a small number of funders, creating an unstable and unsustainable foundation for global preparedness.

Yet there remain reasons for optimism. The historical adoption of the WHO Pandemic Agreement, nearly three years in the making, signals continued commitment to global pandemic preparedness. Its success, however, will depend on the negotiation of the Pathogen and Benefit Sharing (PABS) annex and the implementation of its recommendations.

Scientific and technological advances offer both new opportunities and new risks. Artificial intelligence is accelerating the discovery and design of countermeasures, enhancing surveillance, and improving predictive modelling. These tools could significantly shorten timelines for development across the DTV pipeline. However, they also introduce new biosecurity concerns, including potential misapplication or the creation of novel biological risks – whether intentional or accidental. Effective AI governance that balances innovation with safety will be essential.

All these dynamics place the 100 Days Mission at a pivotal moment. While the world has made meaningful progress, the path to achieving the mission's goals remains uneven and fragile. Sustained political leadership, targeted financing, and robust coordination across governments, industry, academia, philanthropy and multilateral institutions are needed to ensure the 100DM becomes an enduring global capability with equitable access to DTVs.

The International Pandemic Preparedness Secretariat (IPPS), established as a time-limited entity until March 2027, continues to track progress toward the 100DM goals. As that date fast approaches, this year's report offers a critical stocktake on how we are doing as a global community: outlining an honest assessment of where we stand, what we've achieved over the past year, and what remains to be done to deliver on the goals of the 100 Days Mission. **In short, as we move toward 2027, how close are we to ensuring rapid access and availability of DTVs when the next pandemic threat emerges?**

In 2025, IPPS identified the areas where collective action could most accelerate the 100 Days Mission, strengthening early-stage therapeutics R&D, improving coordination across the diagnostics ecosystem, and advancing clinical trial and regulatory capacity. And the past year has seen encouraging progress.

The Therapeutics Development Coalition has begun to move toward operational readiness, our diagnostics gap assessment with Foundation for Innovative New Diagnostics (FIND) and Brown University Pandemic Center clarified the structural barriers that must be addressed for diagnostics development, and the operationalisation of the Africa Medicines Agency marked an important step for regulatory harmonisation across Africa. In 2026, advances must now translate into tangible capability, which is sustainable in the long-term: delivering proof-of-concept projects for the Therapeutics Development Coalition, establishing clear leadership for the diagnostics recommendations, accelerating regulatory harmonisation, strengthening global pandemic preparedness and response (PPR) monitoring, and aligning political commitment through the G7, G20, and United Nations. As IPPS approaches the end of its original mandate, the imperative is to embed this work sustainably within the existing global health architecture. COVID-19 showed that millions of lives might have been saved with 100-day countermeasures; that lesson must continue to guide our efforts. To work towards this, in 2026 our priorities will be:

Essential Priorities for 2026

- Operationalise the **Therapeutics Development Coalition** through proof-of-concept projects for priority viral families
- Collaborate with partners in the **diagnostics ecosystem** to enhance coordination and implement recommendations from the **Diagnostics gap assessment**
- Highlight continued need for **vaccine investment,** and maintain engagement with vaccine partners to leverage synergies and ensure alignment across Dx, Tx and vaccines
- Agree on a **sustainable mechanism** for the potential consolidation of pandemic prevention, preparedness, response, and monitoring, and a long-term path for the **100DM scorecard** beyond the IPPS mandate

I would like to thank all the 100DM implementation partners who contributed to this report and who continue to drive progress towards the 100DM. More than ever, I am reminded that the success of the 100DM will depend on a global network of committed partners, strong public-private partnerships, and sustained engagement.

We cannot allow progress toward the 100DM to stall. At this critical moment, coordinated and focused action across all stakeholders is essential to ensuring delivery of the 100DM. It is imperative that we maintain momentum and embed these capabilities sustainably within the global health architecture, and harness technological advances towards this vital mission.

Executive Summary

THE 100 DAYS MISSION (100DM) provides a critical global ambition, but the 100-day target is not yet achievable in many areas. Significant gaps remain across diagnostics, therapeutics, vaccines and the systems required to deliver them at speed. This report therefore focuses on how far the global community still needs to go to realise the 100DM.

GLOBAL HEALTH SHIFTS

2025 marked a pivotal year for pandemic preparedness.

The World Health Organization (WHO) Pandemic Agreement, adopted at the 78th World Health Assembly in May 2025, set out the first global framework for equitable preparedness and response-effectively agreeing the "rules of the road" for future pandemic cooperation. As the access and benefit sharing annex is still being negotiated, future ratification and implementation of the final pandemic agreement by member states will become the decisive test of its success.

At the same time, **global health and research budgets contracted sharply.** Major donors, including the United States, United Kingdom, Germany, France and several European partners, reduced funding for international health and R&D. The closure of US programmes such as Biomedical Advanced Research and Development Authority's (BARDA) Project NextGen and the National Institutes of Health (NIH) Antiviral Drug Discovery (AViDD) centres, together with USAID's reduced vaccine commitments, has disrupted pipelines for DTVs and exposed how dependent the 100DM ecosystem remains on a small set of funders.

The 100DM Scorecard 3.0, which provides a data-driven assessment of global DTV readiness by tracking funding, pipelines and enabling conditions, reinforces these concerns. Its FY2024 findings highlighted growing vulnerability driven by funding concentration, and the dramatic cuts seen in 2025 now demonstrate how quickly this vulnerability can materialise. This year's results show continued pressures, including uneven regional capacity, stagnation across several R&D pipelines, and limited progress on core enablers. Overall DTV R&D funding declined again in FY2024, with investment remaining heavily concentrated in high-income countries. Expanding and diversifying investment, and strengthening regional R&D and manufacturing capacity, will be essential to sustain progress and reduce long-term risk.

These shifts underline the urgent need to diversify and expand global investment, strengthen regional capacities, and ensure the continued viability of the 100 Days Mission (100DM).

OUTBREAKS IN 2025

A series of significant outbreaks demonstrated the fragility of the global response system. Orthopoxvirus monkeypox (mpox) continues as a Public Health Emergency of Continental Security (PHECS), affecting 20 African countries and spreading to more than 40 globally. H5N1 has infected US poultry and dairy cattle with confirmed human spillover of sporadic cases, exposing weaknesses in zoonotic surveillance. Sudan ebolavirus in Uganda, Ebola Zaire in the DRC, Rift Valley Fever in Senegal, and Marburg in Tanzania and Ethiopia have all placed pressure on public health systems. Chikungunya has reached epidemic levels across 40 countries, including China's first mainland outbreak, and measles has resurged across the Americas, threatening elimination status.

These outbreaks underline the same persistent challenges: limited early detection, fragmented coordination, and unequal access to countermeasures. The 100DM framework remains central to closing these gaps.

R&D AND FUNDING LANDSCAPE

Investment in pandemic countermeasures continued to decline through FY2024, revealing deeper structural challenges that extend beyond funding contraction. Scorecard 3.0 shows that pipelines across diagnostics, therapeutics, and vaccines remain uneven, with several priority pathogen areas characterised by slow progression, limited mid-stage development, and ongoing attrition of candidates. For many viral families, early-stage scientific activity has not translated into sustained advancement toward clinical readiness, underscoring persistent barriers in translational research. Therapeutics experienced the steepest reductions, with several programmes paused or closed.

The Scorecard 3.0 identifies pipeline stagnation, with candidates clustered in early stages and several dropouts, including favipiravir, remdesivir and ASC10, due to waning outbreak activity or strategic shifts by pharmaceutical companies. Platform technologies such as mRNA, monoclonal antibodies, and AI enabled discovery continued to advance and show potential to accelerate future countermeasure development, but progress remains concentrated in a few regions and reliant on public funding from the United States and Europe. The Scorecard also indicates that R&D enablers, such as target product profiles, regulatory and clinical trial readiness, data-sharing frameworks, and other core capabilities that support accelerated product development, have seen limited recent progress, leaving critical gaps in the systems required to translate scientific advances into usable tools at speed.

Some regions have made encouraging gains: Africa now hosts nine WHO-recognised ML3 regulators; vaccine and mAb manufacturing capacity is expanding through Afrigen, Biovac and Institut Pasteur de Dakar and others and the African Medicines Regulatory Harmonisation initiative is streamlining approvals. These developments represent meaningful steps toward a more regionally distributed R&D and manufacturing ecosystem, an essential requirement for long-term 100DM success. However, they remain insufficient to offset global funding declines and pipeline stagnation.

Taken together, these trends show that while scientific innovation continues, structural weaknesses in pipeline continuity, mid-stage development, enabling systems, and regional capability distribution remain obstacles to achieving 100-day readiness.

Spotlights

Spotlights throughout the report highlight important cross-cutting areas with potential regional or global implications, including on Artificial Intelligence (AI), H5N1, and vaccine platform technologies. AI, in particular, has the potential to reshape MCM development. Large language models (LLMs) are improving antigen design, drug repurposing and disease surveillance through initiatives such as the Coalition for Epidemic Preparedness Innovations (CEPI) Pandemic Preparedness Engine and the `Massachusetts Institute of Technology's (MIT) VaxSeer. However, generative bio-design tools could lower barriers to biosecurity risks, including creating new or modified pathogens. In a financially constrained environment, it is vital that AI is treated as a core enabling platform for the 100DM community, supporting more efficient and equitable innovation while embedding responsible use and biosecurity safeguards.

PROGRESS TOWARD 100DM OBJECTIVES

Despite constrained funding, 2025 saw important advances across diagnostics, therapeutics, and vaccines, particularly where partners pursued more integrated and synergistic approaches.

Though progress has been achieved in advancing DTV capabilities, the real test now lies in translating these developments into effective operational practice during an emerging pandemic threat.

The launch of the WHO Global Diagnostics Coalition and the IPPS-FIND-Brown University Pandemic Center Gap Assessment provided a clearer blueprint for strengthening diagnostic readiness, identifying barriers, such as sample access, regulatory fragmentation, and sustainable financing. Advances were made in multiplex platforms, and technical work progressed on target product profiles for priority pathogens. Regional biobanking initiatives expanded, and laboratory capacity mapping supported more systematic identification of gaps. However, barriers remain significant. Sample access continues to be a major bottleneck, regulatory pathways remain fragmented, and market incentives for developers are weak. Although expanding, manufacturing capacity is not yet sufficient to ensure equitable access or rapid scale-up in a crisis.

In 2025, the Therapeutics Development Coalition (TxDC) advanced from concept to full operational readiness ahead of its 2026 launch, creating the foundation for a coordinated mechanism to accelerate early-stage antiviral R&D. This is particularly important as the therapeutics pipeline remains thin, with limited progression into mid-stage trials, continued attrition of candidates, and insufficient incentives to sustain early-stage development. The TxDC's coordinated, portfolio-based approach, combined with sustained investment, stronger risk-sharing models, and clearer access frameworks, will be critical to supporting efforts to translate scientific advances into deployable therapies at speed.

CEPI and partners advanced vaccine research on mpox, Marburg, Nipah, and pandemic influenza. **Regional innovation also accelerated, with Africa and Latin America expanding platform capacity, manufacturing networks, and regulatory maturity.** However, funding volatility, uneven regulatory capacity, supply chain constraints and vaccine hesitancy remain significant barriers.

Together, these achievements demonstrate steady progress across the vaccine pillar but also highlight the need to move from parallel efforts toward a more fully integrated system.

The 100 Days Mission cannot be achieved through siloed approaches. In 2025, the most meaningful gains came where diagnostics, therapeutics, and vaccines worked synergistically, sharing data, infrastructure, and innovation platforms. Advances in genomic sequencing, AI-assisted design, and modular manufacturing are now linking discovery pipelines across tools, with diagnostic data informing therapeutic and vaccine development. Coordinated regulatory efforts are aligning clinical trials and approval processes across medical countermeasures. Regional integration is building ecosystems capable of producing diagnostics, therapeutics, and vaccines simultaneously, exemplified by Africa's establishment of the African Medicines Agency and mutual reliance mechanisms that strengthen continental preparedness capacity.

AI is emerging as a unifying enabler across the entire medical countermeasure (MCM) spectrum, accelerating discovery while demanding responsible governance frameworks that enable innovation whilst mitigating potential biosecurity risks.

Financing mechanisms are also evolving to strengthen preparedness-response linkages. The G20 Joint Health and Finance Task Force has updated its operational playbook for response financing, focusing on "day zero" and surge financing. The reconvened G20 High Level Independent Panel has issued new recommendations to unlock MCM surge financing and establish clearer trigger frameworks for early response. Continued investments in regional manufacturing, pooled procurement

mechanisms, such as The Africa Medical Supplies Platform's (AMSP) pooled procurement instrument through Afreximbank, and national-level preparedness institutions like South Africa's newly established Institute for the Preparedness and Prevention of Pandemics (IP3) are building the foundation for sustained, coordinated pandemic response. These interconnected advances mark a shift from individual tool development toward a more cohesive, MCM ecosystem that should result in speedier and more resilient approaches to pandemic preparedness.

Additionally, as emphasised since the inception of the 100DM, true effectiveness will also rely on its adoption at both national and regional levels. **This year marked encouraging progress, with Rwanda integrating 100DM commitments into its National 2026-2040 Epidemic and Pandemic Preparedness Plan.** Notably, this includes the translation of the 100DM Scorecard to the national context, enabling systematic tracking of MCM R&D for pathogens posing the greatest risk to the population. Rwanda's example illustrates how countries can adopt and adapt the 100DM framework domestically, using the scorecard as a practical tool to monitor and strengthen national readiness, and a model that other countries could potentially adopt.

Though progress has been achieved in advancing DTV capabilities, the real test now lies in translating these developments into effective operational practice during an emerging pandemic threat. Coordination mechanisms and systems for rapid activation remain under-tested, and strengthening these operational foundations will be essential to improving future response performance.

PRIORITY ACTION AREAS FOR 2026

With the IPPS mandate concluding in 2027, 2026 is a decisive year. Feedback from partners and analysis from Scorecard 3.0 highlight four areas where focused action can drive meaningful progress.

Operationalise the Therapeutics Development Coalition

In 2026, the Therapeutics Development Coalition is expected to move from design to early implementation, with the aim of establishing its permanent governance structure and developing its investment case by end-2026. Given that the Coalition has received limited initial funding, early activities will be important for demonstrating its value and helping to mobilise further investment. The Coalition could initiate proof-of-concept projects for two initial priority viral families, aligned with WHO pathogen prioritisation frameworks, to begin advancing candidates through preclinical validation and early clinical stages.

These projects would serve to test the Coalition's partnership-based, risk-sharing model and help shape operational frameworks that could be expanded over time. Diversified financing models—drawing on public, philanthropic and private capital, may be needed to support sustainable translational R&D, supported by incentives that help tackle market failures. From the outset, the Coalition should consider how best to incorporate access principles, open data sharing, transparent licensing and support for regional manufacturing capacity, recognising that these will be important to improving timely and equitable access, though progress may be gradual.

Collaborate with partners in the diagnostics ecosystem to enhance coordination and implement recommendations from the 2025 Global Diagnostics Gap Assessment

In 2026, coordinated efforts from diagnostic partners, including industry, research institutions, governments, regulatory bodies, international organisations, and platforms such as the WHO Global Diagnostics Coalition, are essential for advancing the 100DM. Building on the 2025 gap assessment, stakeholders should collaborate to systematically address identified barriers across the diagnostics value chain. Partners should work towards establishing regional evaluation hubs organised by pathogen family to provide integrated validation support, and there should be efforts to enable rapid specimen mobilisation, particularly once the Pathogen Access and Benefit-Sharing (PABS) annex is finalised in May 2026. Governments and funders should allocate sustained funding for diagnostic R&D and market access, prioritising multiplex platforms and embedding diagnostics in routine healthcare systems through National Essential Diagnostics Lists and procurement policies with volume guarantees. Regulatory pathways and international regulations should be simplified and harmonised to reduce development timelines and improve equitable access. Neutral coordination mechanisms should reduce duplication across initiatives and ensure critical infrastructure receives sustained investment.

Highlight continued need for vaccine investment, and maintain engagement with vaccine partners to leverage synergies and ensure alignment across all three tools

Whilst vaccines have seen greater progress and advancements compared to diagnostics and therapeutics, significant challenges remain, including funding volatility, limited regulatory capacity, manufacturing and supply chain constraints, as well as vaccine hesitancy and misinformation. Sustained funding will therefore be essential to mitigate volatility and to ensure that synergies between vaccines, diagnostics, and therapeutics are fully leveraged. Continued alignment across all three tools will be critical so that advancements in vaccines reinforce progress in diagnostics and therapeutics, enabling a more integrated and resilient response.

Agree on a sustainable mechanism for the potential consolidation of pandemic prevention, preparedness, response, and monitoring, and a long-term path for the 100DM scorecard beyond the IPPS mandate

In response to outbreaks such as the COVID-19 pandemic, multiple monitoring mechanisms were established to strengthen global pandemic prevention preparedness and response. However, this proliferation of initiatives has also led to fragmentation, with different actors using varying approaches to assessing risk, readiness, and accountability.

Many of these mechanisms are scheduled to conclude between 2026 and 2028. As a result, there is increasing discussion among stakeholders about how best to ensure continuity and sustainability of monitoring efforts, including identifying appropriate long-term institutional arrangements for existing mechanisms. Among these initiatives is the 100 Days Mission Scorecard, alongside mechanisms such as the Global Preparedness Monitoring Board (GPMB) and others. While views differ on the extent and form of consolidation, stakeholders have highlighted the potential value of exploring options for greater coherence and coordination across monitoring efforts. Any such exploration would require close collaboration among those leading or contributing to existing initiatives, and careful consideration of design, governance, and scope.

The 2026 UN High-Level Meeting (HLM) on Pandemic Prevention Preparedness and Response presents a useful opportunity for Member States to consider future arrangements for pandemic preparedness monitoring, and serves as a key milestone to work toward. In the lead-up to the HLM, continued dialogue and alignment among partners will be important. At the same time, any future monitoring arrangements must be aligned with ongoing negotiations on the WHO Pandemic Agreement including the Intergovernmental Working Group's work on the PABS annex.

LOOKING AHEAD

2025 has shown both progress and fragility in global preparedness. Scientific innovation continues, but political and financial support remain uneven. The 100 Days Mission continues to provide a clear and measurable framework to support the delivery of accurate rapid diagnostics, an initial regimen of therapeutics and vaccines ready for large-scale deployment within 100 days of a pandemic threat being declared. **The year ahead will be decisive in translating any progress made into lasting systems for faster, fairer and more coordinated pandemic responses in future years.**

CHAPTER 1

Introduction

Reminder of the goals of the 100 Days Mission

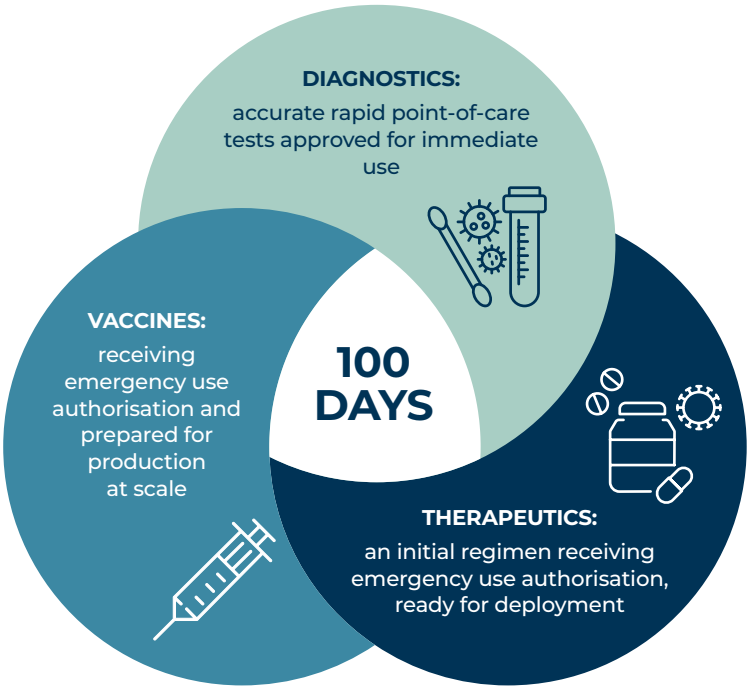
THE 100 DAYS MISSION (100DM) was conceived to ensure that the scientific breakthroughs, operational lessons, and collaborative momentum generated during the COVID-19 pandemic translate into durable preparedness.

Since then, the world has faced a steady drumbeat of new and recurring health emergencies that underscore the urgency of preparing and acting now. In just the past three years, the international community has responded to two mpox Public Health Emergency of International Concern (PHEIC) declarations, the spread of H5N1 across animal and human populations, escalating dengue transmission, localised Marburg and Ebola outbreaks, and a range of climate-amplified vector-borne and zoonotic threats.

These overlapping events reflect a new reality: **the interval between major health emergencies is shortening,** and the probability that the next outbreak could escalate into a global crisis remains high. The social and economic upheaval caused by recent epidemics has shown how unprepared systems amplify impact, particularly in settings with limited access to essential tools. Against this backdrop, the 100DM's core proposition remains clear – having safe, effective, and accessible diagnostics, therapeutics, and vaccines (DTVs) ready within 100 days can fundamentally alter the trajectory of future pandemics.

Preparedness demands sustained investment in research and innovation during interpandemic periods. Adopting a 100-Day Mission framework to strengthen the "marathon" of DTV development – from research through deployment – will naturally accelerate the "sprint" needed to rapidly deliver safe and effective MCMs when new threats emerge. This approach entails optimising emergency response workflows, advancing adaptable platform technologies for vaccines and therapeutics, and ensuring widespread availability of reliable diagnostic tools. Throughout this report, 'platform technologies' refers to disease-agnostic, scalable systems built on standardised manufacturing processes, analytical methods, and common backbones that can be rapidly customised for new pathogens while preserving predictable structure-function relationships.

Preparedness must therefore be built well before an emergency is declared. The Mission aims to ensure that diagnostics are rapidly deployable and adaptable, therapeutics are available for emergency use, and vaccines are ready for scale-up within 100 days of the identification of a Public Health threat. The most important element is that any trigger used be connected to clear pre-agreed actions for financing and accelerating product development and distribution, and off-ramps identified that will enable leverage of the response for future outbreaks.



How to Use This Report: Maintaining Momentum Towards the Goal

THIS YEAR'S REPORT CONTINUES TO PROVIDE A HIGH-LEVEL SYNTHESIS, of progress made by partners across DTV research and development, clinical trials, regulatory systems, surveillance, manufacturing, and financing. While the thematic areas remain consistent with previous years, the analysis reflects the evolving risk environment – one defined not by a single global pandemic, but by frequent regional emergencies that test the resilience of national, regional, and global systems.

Each section outlines the overarching goals and emerging trends, then assesses progress against the 2025 priority actions, identifies major barriers that have constrained achievement, and establishes priority actions for 2026 to advance the 100DM. Assessment of progress against the original recommendations, and more granular planned partner commitments and recommended priority actions are summarised in *Annex A* based on input from over 50 implementation partners from governments, industry, academia, Civil Society Organisations (CSOs) and international organisations (see *Annex C* for full list of contributors), in the form of survey responses, interviews and desk research.

As with previous editions, this report is not intended to catalogue every activity undertaken during the year. Instead, it highlights progress where it has systemic implications, identifies areas where momentum is stalling, and outlines a focused set of priorities for 2026. These priorities aim to sustain the Mission's long-term ambition: ensuring that the global community can consistently deliver critical medical countermeasures within 100 days, thereby reducing the likelihood that future outbreaks evolve into high-impact pandemics.

With the International Pandemic Preparedness Secretariat (IPPS) currently scheduled to sunset in 2027, the 2026 priorities focus on consolidating progress and establishing sustainable mechanisms to continue advancing the 100DM beyond the Secretariat's current mandate.

100 Days Mission Scorecard & Analysis

ACHIEVING THE 100 DAYS MISSION demands more than ambition, it requires clear, objective metrics to assess progress, identify gaps, and guide resource allocation. To meet this need, IPPS partnered with Impact Global Health (IGH) in 2023 to develop the 100 Days Mission Scorecard – an annual evidence-based tool that tracks global readiness to develop and deploy diagnostics, therapeutics, and vaccines within 100 days of a pandemic threat declaration.

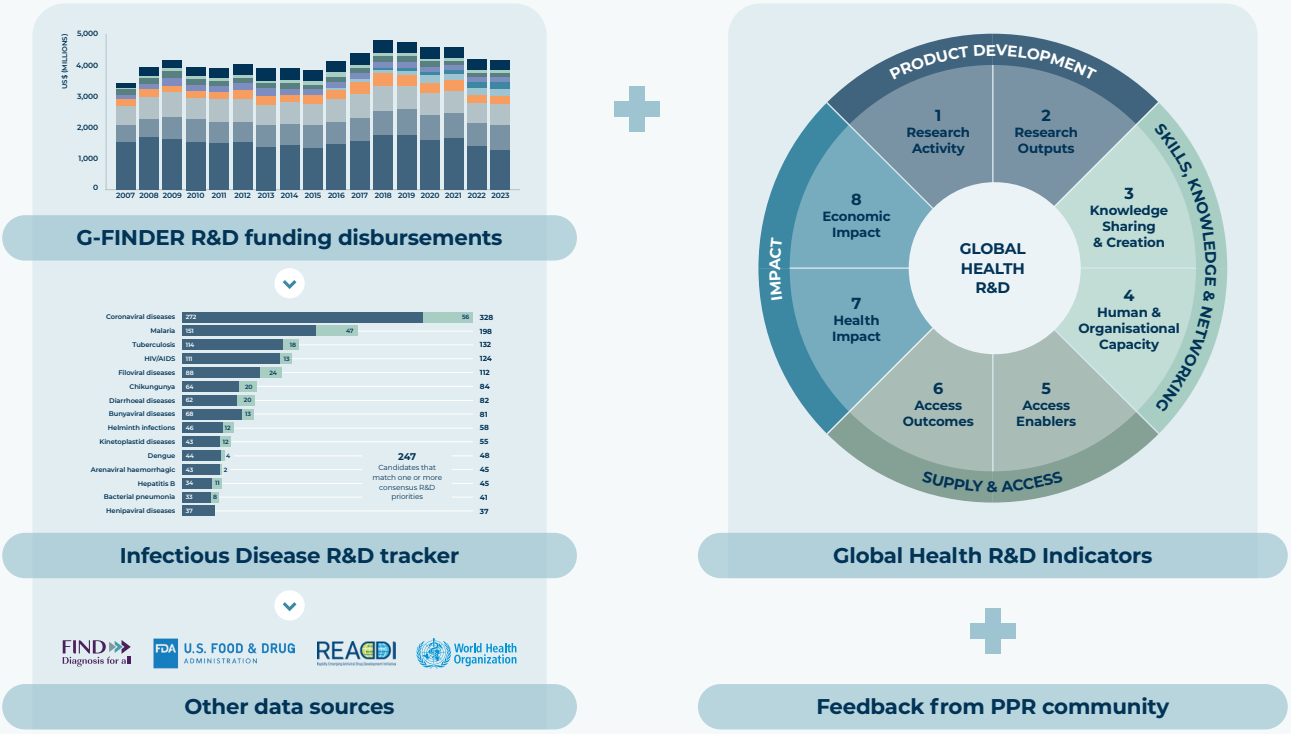
The Scorecard evaluates the R&D ecosystem across WHO priority pathogens, measuring three critical dimensions: current readiness (approved products and R&D funding), future preparedness (clinical pipelines and platform technologies), and enabling infrastructure (regulatory pathways and scientific tools).

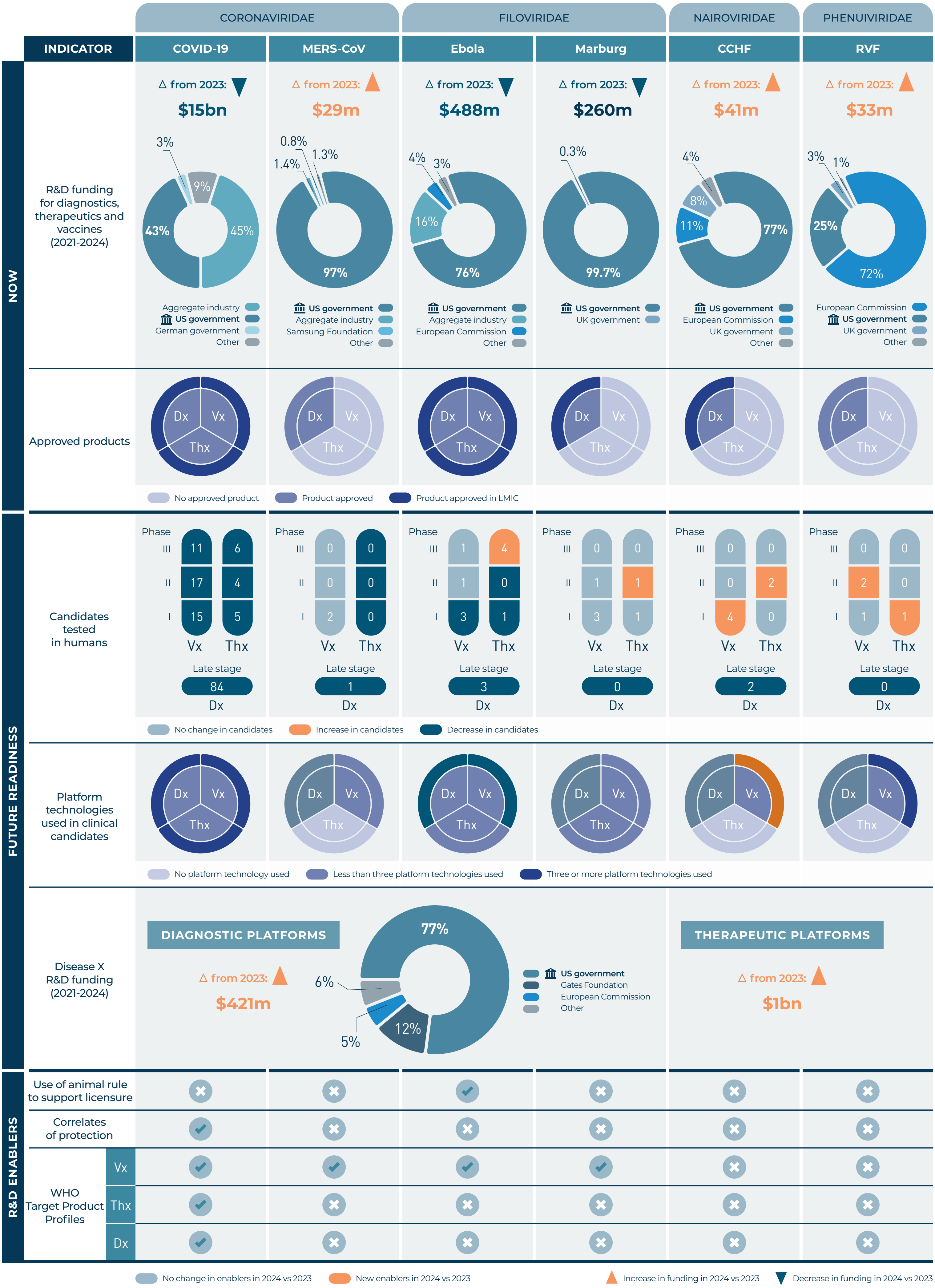
Pathogen selection is guided by the WHO's 2024 pathogen prioritisation framework, ensuring at least one representative virus from each priority viral family is included in the scorecard (see *Scorecard visual* and *Annex F Table 1*). For Scorecard 3.0, two pathogens – Influenza virus A (H5N1) and Hantaan virus (HTNV) – were added strengthening coverage across WHO priority viral families.

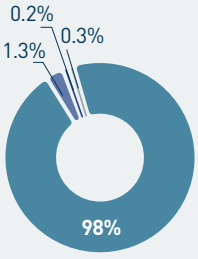
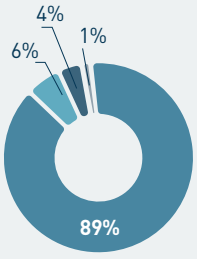
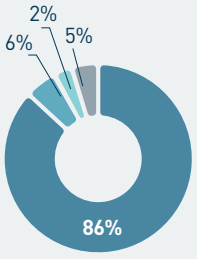
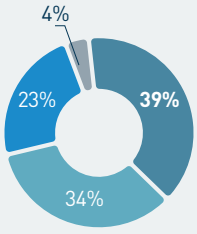
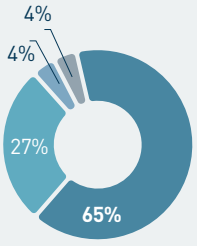
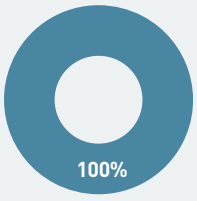
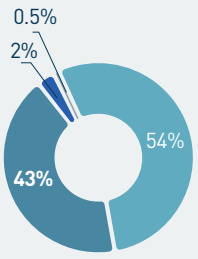
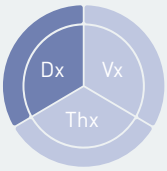
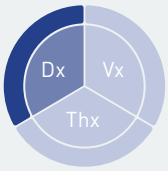
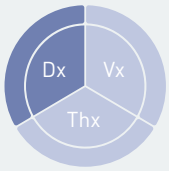
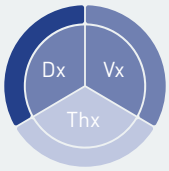
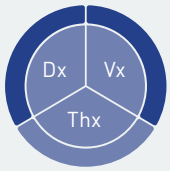
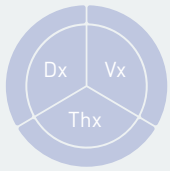
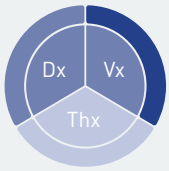
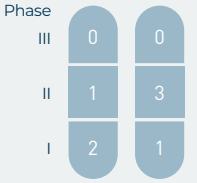
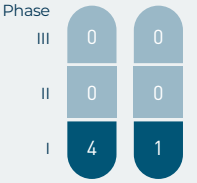
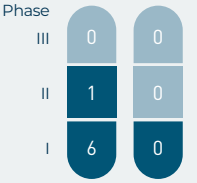
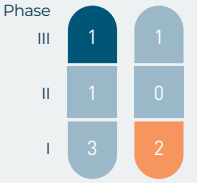
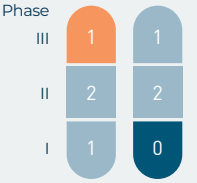
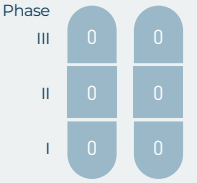
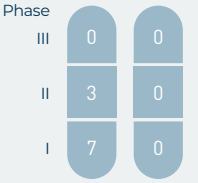
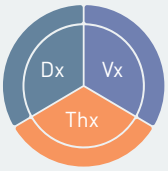
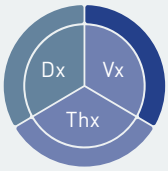
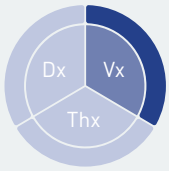
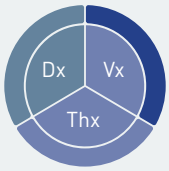
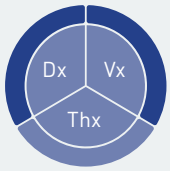
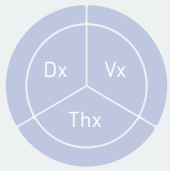
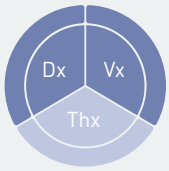
The 100 Days Mission Scorecard is curated by leveraging IGH's product development datasets on disbursed R&D funding (i.e. G-FINDER), approved products and candidates, and supplementing these with synthesised data from multiple sources (see *Annex E* for full methodology) through a collaborative stakeholder process (*Figure 1*). The Scorecard objectively identifies gaps, tracks progress for accountability, and provides actionable insights that supports R&D decision making through a series of evidence-based indicators that were drawn from the Global Health R&D Impact Framework[1].

This year's Scorecard 3.0 introduces methodological refinements to capture progress more accurately, including expanded pathogen coverage and updated pipeline assessments. It reveals both encouraging advances and persistent vulnerabilities that demand urgent attention.

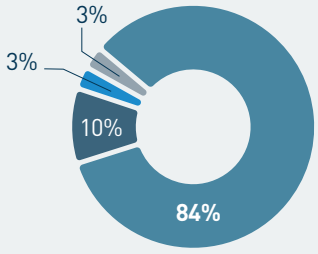
FIGURE 1 **Scorecard methodology**




CORONAVIRIDAE
FILOVIRIDAE
NAIROVIRIDAE
PHENUIVIRIDAE
INDICATOR
COVID-19
MERS-CoV
Ebola
Marburg
CCHF
RVF
NOW
FUTURE READINESS
R&D ENABLERS
R&D funding for diagnostics, therapeutics and vaccines (2021-2024)
∆ from 2023:
$15bn
$29m
$488m
$260m
$41m
$33m
COVID-19: 3% 9% 45% 43%
MERS-CoV: 0.8% 1.3% 1.4% 97%
Ebola: 4% 3% 16% 76%
Marburg: 0.3% 99.7%
CCHF: 4% 8% 11% 77%
RVF: 3% 1% 25% 72%
Aggregate industry
US government
German government
Other
US government
Aggregate industry
Samsung Foundation
Other
US government
Aggregate industry
European Commission
Other
US government
UK government
US government
European Commission
UK government
Other
European Commission
US government
UK government
Other
Approved products
Dx Vx Thx
No approved product
Product approved
Product approved in LMIC
Candidates tested in humans
Phase III II I
COVID-19: Vx 11 17 15; Thx 6 4 5
MERS-CoV: Vx 0 0 2; Thx 0 0 0
Ebola: Vx 1 1 3; Thx 4 0 1
Marburg: Vx 0 1 3; Thx 0 1 1
CCHF: Vx 0 0 4; Thx 0 2 0
RVF: Vx 0 2 1; Thx 0 0 1
Vx Thx
Late stage
84 1 3 0 2 0
Dx
No change in candidates
Increase in candidates
Decrease in candidates
Platform technologies used in clinical candidates
Dx Vx Thx
No platform technology used
Less than three platform technologies used
Three or more platform technologies used
Disease X R&D funding (2021-2024)
DIAGNOSTIC PLATFORMS
∆ from 2023:
$421m
77%
6%
12%
5%
US government
Gates Foundation
European Commission
Other
THERAPEUTIC PLATFORMS
∆ from 2023:
$1bn
Use of animal rule to support licensure
Correlates of protection
WHO Target Product Profiles
Vx
Thx
Dx
No change in enablers in 2024 vs 2023
New enablers in 2024 vs 2023
Increase in funding in 2024 vs 2023
Decrease in funding in 2024 vs 2023

ARENAVIRIDAE	PARAMYXOVIRIDAE	FLAVIVIRIDAE	TOGAVIRIDAE	POXVIRIDAE	HANTAVIRIDAE	ORTHOMYXOVIRIDAE
Lassa Fever	**Nipah**	**Zika**	**Chikungunya**	**Mpox**	**Hantaan** (new)	**H5N1** (new)
Δ from 2023: ▼ **$86m**	Δ from 2023: ▼ **$136m**	Δ from 2023: ▼ **$172m**	Δ from 2023: ▼ **$143m**	Δ from 2023: ▲ **$138m** * only 2023-2024 funding data available	* only 2024 funding data available **$7.5m**	* only 2024 funding data available **$40m**
						
US government Wellcome Korea mRNA Vaccine Initiative Other	US government Aggregate industry Gates Foundation Other	US government Aggregate industry Colombian government Other	US government Aggregate industry European Commission Other	US government Aggregate industry UK government Other	US government	Aggregate industry US government Canadian government Other
						
						
						

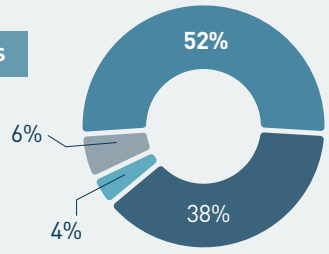
New platform technologies used, less than three | New platform technologies used, three or more | Decrease to no platform technology used | Decrease to less than three platform technologies used



US government
Gates Foundation
European Commission
Other

VACCINE PLATFORMS

Δ from 2023: ▲ **$862m**



US government
Gates Foundation
Aggregate industry
Other

✖	✖	✖	✖	✖	✖	✖
✖	✖	✖	✖	✖	✖	✖
✔	✖	✔	✖	✔	✖	✖
✖	✖	✖	✖	✔	✖	✖
✖	✖	✖	✖	✖	✖	✖

Highlights US government's leading role in this space | $ = US dollars | Vx - Vaccines; Thx - Therapeutics; Dx - Diagnostics | Due to rounding percentage totals may appear to exceed 100%

KEY PROGRESS UPDATES SINCE SCORECARD 2.0

Since the publication of Scorecard 2.0 in 2025, **there has been limited progress made to accelerate regulatory approvals and clinical development of diagnostics, therapeutics and vaccines (DTVs).** The funding landscape is at an inflection point as governments globally retreat from pandemic preparedness, and broader global health investment. Movement through the clinical pipeline remains slow, with only three vaccine candidates advancing: two into phase 2 (for Ebola and Rift Valley Fever (RVF)), and one into phase 3 for mpox. Few new R&D enablers were identified, with the publication of vaccine and therapeutic Target Product Profiles (TPPs) for mpox being the only additions.

The combination of declining funding, a stagnant pipeline and limited use of alternative R&D approaches paints a stark picture but also presents opportunities for impact. Policymakers, funders, and developers have considerable scope to revitalise the ecosystem and deliver on the ambition of the 100DM. Resource constraints often drive sectors towards more collaborative models; maximising efficiency and fostering innovation. Funders should embrace co-funding mechanisms, innovative financing and multilateral partnerships to ensure the highest return on investment and global health impact. Likewise, developers, manufacturers and researchers must leverage collaborations, prioritise transparency and data-sharing, and focus on low-cost innovations and alternative pathways to translate concepts into real world impact.

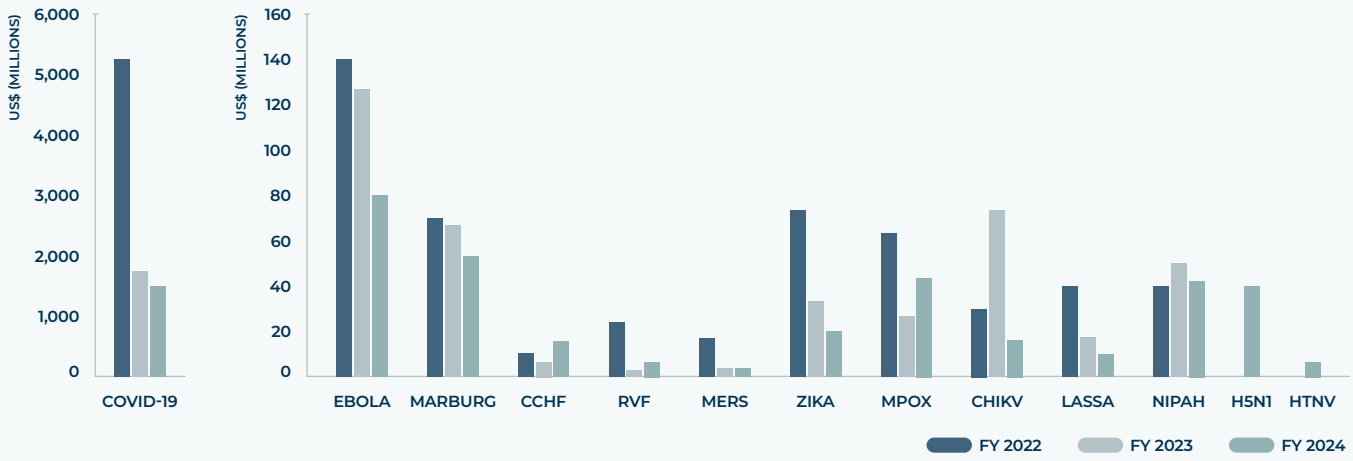
FUNDING LANDSCAPE[a]

Funding for disease-specific R&D for DTV's continued its downwards trend in FY2024[2]. COVID-19 investment fell by 18% and non-COVID priority pathogens down by 29% (excluding newly added pathogens – H5N1 and HTNV), highlighting growing pressure on the sector. Not all pathogens saw decreases. Mpox, Crimean-Congo Haemorrhagic Fever (CCHF) and RVF saw proportional increases in FY2024, though these gains came after significant reductions in FY2023. Other than COVID-19, which was down US$318 million (to US$1.5 billion which still dwarfs funding for other diseases), Chikungunya saw the biggest drop (down US$60m, 81%) following a funding spike in FY2023, although this is partly artificial due to a change in participation in the G-FINDER survey between FY2023 and FY2024. Zika and Ebola also saw significant drops of 39% and 37% respectively.

R&D funding remains reactive – as illustrated by mpox (*Figure 2*) – and overly reliant on the US government (*Table 1*). Despite the evolving situation with H5N1 since 2020, investment in FY2024 was low at just US$50 million – similar to levels seen for SARS-CoV-1 and Middle East respiratory syndrome (MERS) R&D prior to the COVID-19 pandemic. A key lesson from the COVID-19 pandemic was that early and strategic investment is critical to support an R&D ecosystem that can respond to outbreaks. Our data suggests this lesson has not yet been learned.

The US government was among the top three funders for every disease in FY2024 and the leading funder for all but three diseases. Two of these exceptions are

FIGURE 2 **R&D funding by priority pathogen FY 2022-2024**



[a] G-FINDER collects disbursement data on global R&D funding, 2024 refers to Financial Year 2024, as comprehensive forward-looking data is not currently available. For further details on how the data is collected, and what is included please see our methodology

diseases with ongoing outbreaks – mpox and H5N1 – for which industry has overtaken the US government as the largest funder. Industry engagement is positive since both public and private sectors are needed to push innovation to market. However, industry involvement in PPR has often been reactive, historically fluctuating with the waxing and waning of outbreaks, leaving disease R&D vulnerable to sudden reductions in funds. Engaging industry partners earlier and aligning with a longer-term, strategic vision would strengthen a proactive preparedness model and ensure sustained investment R&D.

The US government was also the top funder across all three platform technology product areas; that support product development for many different diseases and Disease X. Funding for platform technologies, increased by US$150 million (21%) in FY2024 following an even bigger increase the previous year. This increase spanned all product types, with a significant investment in antibody development and production and repurposing FDA approved therapeutics for use against different biological threat but the largest growth was in vaccine platforms (up 30%). While the FY2024 increase in platform technologies is encouraging in preparedness for Disease X, the shifting US government agenda in 2025 is sobering and signals that this could change. For example, in August 2025, BARDA terminated 22 mRNA R&D projects, including an inhalable powder-based mRNA vaccine under development by Emory University and Tiba Biotech's RNAi-based therapeutic for H1N1 influenza. The total value of the cuts to mRNA R&D was listed as $500 million, likely reflecting the maximum potential value of the contracts involved[3].

In the last two annual Scorecards, and reaffirmed in this year's, the US government holds a dominant role in supporting the global PPR R&D ecosystem. Looking at 2025, the fragility of the funding landscape has become even clearer in light of the decisive action from the US government to retreat from its commitments to the global health sector. Since January 2025, indiscriminate budget cuts have been made across most US agencies working in the global health and PPR space. It is not only the funding cuts themselves that have sent shockwaves through the community, but the disruptions to the architecture that support it. While some funding streams have resumed, the impact of the pauses on the US NIH's grant review panels will disrupt funding patterns[4] which are not yet captured by G-FINDER data. The dismantling of USAID also has downstream effects linked to its 2022 3-year commitment of $150 million to CEPI for vaccine development[5].

The US government is not alone in retreating from global health. In late February, the UK government announced plans to cut Official Development Assistance (ODA) from 0.5% of gross national income to 0.3% by April 2027, a 40% decrease, bringing funding to its lowest level since 1999[6]. Savings are earmarked to increase defence spending. Similarly, France and Germany have announced cuts to global health research funding including PPR, as they reprioritise national budgets towards defence[7]. Pandemic preparedness has a critical biosecurity dimension that connects it to broader defence priorities. As budgets are reallocated towards defence, renewed advocacy and strategic communications will be essential to ensure PPR funding is maintained rather than overlooked. In the absence of US leadership, no other governments are stepping up to fill the gap. This global trend jeopardises the progress made in the 100 Days Mission and risks a return to nationalistic research agendas that will not protect countries from pandemics. Critically, national security must be redefined; in the context of PPR it cannot be achieved through national means – it requires a collaborative and coordinated approach across borders. Rather than recreating a funding ecosystem dependent on a single government, there is an urgent opportunity to redefine a more resilient model grounded in multilateralism to safeguard populations and economies nationally, regionally and globally.

TABLE 1 **% and rank of US Government contribution to priority pathogen R&D 2024**

PATHOGEN	USG RANKING	USG % OF TOTAL
Marburg	1	100%
MERS	1	100%
Lassa	1	97%
HTNV	1	97%
Nipah	1	88%
Zika	1	87%
Ebola	1	86%
CCHF	1	72%
CHIKV	1	58%
COVID-19	1	55%
RVF	2	43%
H5N1	2	40%
Mpox	2	37%

APPROVED PRODUCTS

This year's Scorecard highlights both incremental progress and persistent gaps in approved products. The only new products approved in 2025 targeted pathogens with existing interventions: one vaccine for Chikungunya and two COVID-19 therapeutics, a drug and biologic. The two new pathogens added to Scorecard 3.0; H5N1 and HNTV; show contrasting levels of readiness. For H5N1, the landscape is relatively robust with six approved diagnostic tests; including five molecular tests and one lateral flow assay; and 18 vaccines currently approved by at least one regulator and licensed in 35 countries. Only one vaccine, AstraZeneca's Pandemic influenza vaccine, has been WHO pre-qualified underscoring differences in global access. In contrast, HNTV remains unaddressed with no approved products.

Bavarian Nordic's Vimkunya (PXVX0317), the first chikungunya vaccine for individuals aged 12 and older, received US FDA approval and was subsequently awarded a Tropical Disease Priority Review Voucher (PRV)[8]. The US FDA's PRV programme remains a significant industry incentive. However, eligibility is limited to a narrow set of pathogens: currently filoviruses (Ebola and Marburg), Zika, Chikungunya and Lassa fever[9]. This leaves other WHO priority pathogens that lack products vulnerable. Expanding eligibility and ensuring programme stability could strengthen its role in pandemic preparedness R&D. Discussions on creating a European counterpart to the PRV are ongoing, but alignment with global health PPR priorities will be critical to ensure product gaps are filled[10].

Shortly after Vimkunya's approval, Valneva's IXCHIQ chikungunya vaccine that had been approved for use in over 18's in 2023 received a label extension by the European Medicines Agency (EMA) for individuals aged 12 and older[11]. This vaccine also received market authorisation by the Brazilian Health Regulatory Agency (ANVISA) to support a phase 4 trial of the vaccine[12]. However, Valneva received a setback in August 2025 as FDA suspended IXCHIQ due to serious adverse events that were predominately seen in people over the age of 65[13]. Ensuring vaccines are available for deployment in all populations, including children, adolescents, pregnant and lactating women and the elderly, is key in responding to and controlling epidemics.

CLINICAL CANDIDATES

The Scorecards clinical pipeline shows limited progress with most candidates stalled in early phases despite the urgent need for new products. To provide a clearer picture of where gaps persist, this year's analysis applied a more rigorous methodology focused on identifying candidates in active development; meaning there was evidence of ongoing R&D activity in the last three years. Those with no updates since 2022 were classified as inactive and removed. We also updated the COVID-19 pipeline for the first time since Scorecard 1.0, resulting in the exclusion of several dormant candidates. In this report, "inactive" refers to candidates with no active R&D in the last three years while "dropped out" denotes candidates publicly confirmed as terminated, for example, due to failure to meet clinical endpoints or lack of disease transmission in waning outbreaks.

A like-for-like comparison (excluding COVID-19 and new diseases added to Scorecard 3.0) of the pipeline shows that it has shrunk, with the vast majority of active candidates in phase 1. Limited pipeline movement remains concentrated in translation from preclinical to phase 1, with just a one candidate across the vaccine and therapeutics pipeline, Bavarian Nordic's mpox paediatric MVA vaccine, transitioning from phase 2 to phase 3 efficacy trials There was no evidence that alternative pathways or R&D enablers were utilised to accelerate testing and approvals. A concerted, coordinated effort is needed to improve the health of the clinical pipeline; both funding and new approaches are required to de-risk future products.

The diagnostic pipeline declined significantly with a large number of candidates becoming inactive. The only late-stage Marburg diagnostic candidate also ceased development as the German developer, Midge Medical, closed in late 2024. A portion of the decrease was also attributed to the exclusion of diagnostics, which are primarily used for research purposes only and so do not represent pandemic countermeasure development.

The therapeutic pipeline showed variable progress. Two drugs, for Chikungunya and Lassa, and one biologic for RVF moved to phase 1, an important development given none of these pathogens have approved medicines. For RVF, this also represents the first therapeutic candidate to enter human trials. Three drugs for CCHF, COVID-19 and Marburg also progressed to phase 2, significant as CCHF and Marburg still have no approved products. All of the movement observed in Phase 3 focused on ebolavirus, including testing post-exposure prophylaxis regimens based on approved Ebola vaccines Ervebo and Inmazeb in combination with the antiviral drug, obeldesivir.

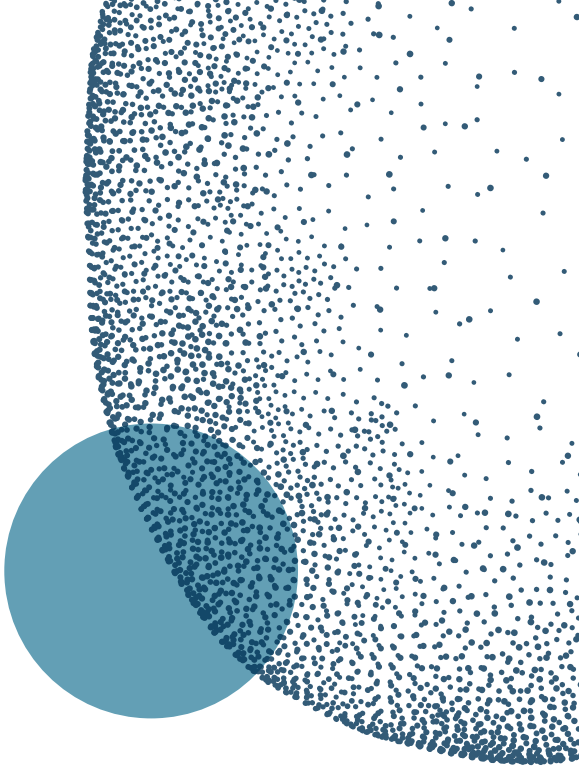
A number of therapeutic candidates were identified as inactive, including those for Ebola, Lassa and Nipah, and notably the entire MERS therapeutics pipeline

(three candidates). Separately, candidates dropped out of development. This included two late-stage Ebola trials. The phase 2 FORCE trial evaluating favipavir was terminated due to a waning outbreak and the pivotal phase 3 PALM Randomised Control Trial in DRC for remdesivir was stopped as it found that remdesivir had higher mortality than the two monoclonalantibody arms. Additionally, an mpox candidate was terminated due to the developer, Ascletis, ending its antiviral programs to pivot and focus on the metabolic disease market[14]. The therapeutics clinical pipeline remains sparse, with a non-existent phase 3 pipeline outside of chikungunya, Ebola and mpox. Without a robust preclinical pool of candidates, progress will stall. Addressing this needs a coordinated, multipronged approach to manage underlying drivers of stagnation – strengthening sector leadership, mitigating macroeconomic pressures on the market, and reinforcing the need to use R&D enablers to facilitate translation of candidates outside of outbreaks.

The vaccine pipeline saw most progress with several movements to phase 1 but limited advancement to phase 3. Ten candidates entered phase 1 trials including four for COVID-19 and others for CCHF, Chikungunya, Lassa fever, mpox, and Zika. Eight candidates moved to phase 2, including five COVID-19 candidates. Notably, ChAd3-SUDV – a candidate for Sudan ebolavirus for which no approved products exist – started phase 2 clinical trial in Uganda in June 2025 enrolling high-risk contacts during an outbreak. A ChAdOx1 RVF vaccine also began a phase 2 trial in Kenya in June 2025. Two Lassa vaccine candidates in phase 1 became inactive after they were removed from the developer's online pipeline as was a phase 2 Zika vaccine. Only one candidate progressed into phase 3, for mpox highlighting how late-stage clinical development still relies on active outbreaks and reinforcing the need use alternative approaches to enable testing outside of epidemics. The vaccine R&D ecosystem has proven more robust than the other product types, however this progress is under threat from changing national agendas particularly in the US and global vaccine hesitancy – successful vaccine development needs to be safeguarded.

For the two new pathogens, H5N1 and HTNV, the clinical pipelines show stark gaps. There are already approved diagnostics for H5N1 however these do not offer point of care testing and often focus on identifying influenza A rather than the H5 subtype. Therefore, it is concerning that there are no late-stage diagnostics in development. There are no approved therapeutics and no clinical candidates in development making this the largest gap for H5N1. There is a more buoyant vaccine pipeline with ten clinical candidates: six in phase 1 and four in phase 2. Given the current spread of H5N1 infections globally, it is concerning to see empty pipelines for two product types central to the 100 Days Mission.

For HTNV, in addition to having no approved products, there is no clinical pipeline. To contextualise the landscape of HTNV product development, preclinical candidates were reviewed with seven vaccines and three therapeutics identified. Further work is needed to progress these candidates. The use of R&D enablers should be explored to support this.



PLATFORM TECHNOLOGIES

Platform technologies – disease-agnostic, reproducible technologies that support product development by enabling streamlined regulatory processes and plug-and-play manufacturing – show uneven progress between product types. Across DTVs, the pathogens with the most diversity in platform technology use are those with commercial markets or large-scale outbreaks, like COVID-19 and mpox. Opportunities in platform technologies extend beyond development and testing. They include global harmonisation of regulatory frameworks to de-risk R&D across product types, especially diagnostics, and investing in scalable manufacturing capacity.

Therapeutics continue to lag in terms of platform diversity, with a persistent and clear binary between small molecule drugs and monoclonal antibodies (mAbs). Most mAbs are for Ebola (3) and COVID-19 (2), with one candidate developed for Chikungunya, Marburg, Nipah and RVF respectively. While the US FDA published draft guidance on therapeutic platform technology designation in May 2024, no further announcements have been made on the implementation of this framework, a growing concern given the political climate.

Viral vector and mRNA platforms remain the most used platforms in vaccine development, making up more than half of the platforms used. They are also being utilised across all scorecard pathogens with clinical vaccine pipelines (noting HTNV has no clinical vaccines). Viral vector platforms are being used for 11 pathogens. mRNA stands out as one of the most significant innovations to emerge from the COVID-19 Promising vaccine candidates for Nipah, Zika and Ebola are in development. However, major barriers remain to their deployment including endemic country manufacturing capacity and cold-chain infrastructure.

Late-stage diagnostics candidates remain dominated by conventional platforms like quantitative real-time reverse transcription polymerase chain reaction (qRT-PCR, nine candidates) and lateral flow assays (18 candidates). Most platform use is linked to mpox diagnostic development. Effective outbreak detection and case diagnosis requires multiple tools at different levels of the health care system – combining rapid point-of-care (POC) tests, laboratory diagnostic and surveillance tools. Limited diversity in POC testing reflects reliance on well-established, low-cost technologies. However a critical area for innovation is multiplexing, which enables differential diagnosis without requiring multiple separate tests.

R&D ENABLERS

R&D enablers are the ecosystem that facilitates the rapid development, testing, approval, manufacturing, and equitable delivery of medical countermeasures. **In the last year, no significant changes were observed across these enablers.**

Only two WHO Target Product Profiles (TPPs) were published, for mpox vaccines and therapeutics, in reaction to the outbreak. In the past year, there was no new use of the animal rule to support licensure or consensus correlates of protection (CoPs). Few CoPs are widely accepted, yet they offer an alternative pathway to licensure when traditional clinical endpoints are not feasible e.g. for pathogens with unpredictable epidemiology like Zika[15]. CoP's can streamline late-stage clinical trial by informing dose and regimen selection and enabling immune-bridging between populations[15]. Projects like CEPI and PATH's playbook on immune markers are helping to build shared scientific standards[16]. Similarly, the lack of standardised animal models for epidemic diseases is an obstacle to leveraging the Animal Rule pathway outside of outbreaks. Greater coordination is needed to support regulatory harmonisation and de-risk R&D to achieve 100DM goals.

This is also the case for the two new Scorecard pathogens; H5N1 and HTNV; neither has seen use of these R&D enablers. The WHO published Preferred Product Characteristics for Next-Generation Influenza Vaccines in May 2017 warrant updating and specific normative guidance on the development of an H5N1 vaccine is needed, especially in the context of the growing global cases of H5N1 in animals.

African PPR deep-dive

THE 100 DAYS MISSION SCORECARD GIVES A GLOBAL VIEW of how prepared the R&D ecosystem is to respond quickly to a pandemic. Since its inception, there have been calls for more Low- and Middle-Income Countries (LMIC)-focused indicators – especially around pandemic preparedness and response (PPR) capacity. In response, this year we have created an African capacity deep-dive to accompany the third Scorecard. This spotlight visually illustrates African laboratory, clinical trial, regulatory and manufacturing capacity to track regional skills needed to support the 100 Days Mission.

LABORATORY CAPACITY

In the event of an outbreak, high containment laboratory capacity is critical for pandemic response. Biosafety Level 4 (BSL-4) laboratory capacity – the highest level of biocontainment – is essential for studying the most dangerous pathogens such as filoviruses. For this pilot review of African capacity, publicly available data from Global Biolabs was used to identify countries with laboratories operating at BSL 4 containment level[17]. This targeted scope provides an initial benchmark for understanding where the most secure laboratories are located in Africa and to highlight gaps.

Currently, Africa has only two BSL-4 laboratories: the Emerging Viral Diseases Unit (UMVE) in Gabon and the Special Viral Pathogens Laboratory (SVPL) in South Africa. A third laboratory is under construction at the Institut Pasteur de Côte d'Ivoire's BSL-4 within the Center for High-Risk Infectious Pathogens (CEPRIS).

While BSL-4 labs are critical for handling the most lethal pathogens, many pathogens with pandemic risk could be managed in BSL-3 facilities, which play a role in supporting diagnosis, sequencing and product development. Therefore, we recognise that a coordinated network of BSL-3 and BSL-4 facilities, supported by robust biosafety and biosecurity practices, is needed for preparedness and R&D. However, this pilot highlighted the challenges of mapping BSL-4 capacity; there is no global mechanism tracking BSL-4 laboratories, there are no universal standards governing these labs and there is a dearth of centralised publicly available information. The data available from the Global Biolabs database dates from 2023, which represents an important time lag and further supports the need for a coordinated mechanism to collate this information on a regular basis. Regional initiatives like the African Society for Laboratory Medicine's (ASLM) LabMap, in partnership with the Africa Centres for Disease Control and Prevention (Africa CDC), aims to map continental laboratory capacity and will serve as a vital future resource.

CLINICAL TRIAL CAPACITY

Robust clinical trial capacity is a cornerstone of global health security and product development for diseases with pandemic or epidemic potential. Africa's unique epidemiological profile – marked by high pathogen diversity, frequent outbreaks, and a large, genetically diverse population – makes it critical that vaccines, therapeutics, and diagnostics are tested in the populations where they will ultimately be deployed. Without adequate trial infrastructure and leadership on the continent, products may lack locally relevant safety and efficacy data, hinder regulatory approval and delay the deployment of interventions during health emergencies putting everyone at higher risk. Since the COVID-19 pandemic, there have been a number of calls to strengthen and expand African clinical trial capacities. This pilot sought to capture the current African clinical trials capacity to support pandemic R&D.

Defining clinical trial capacity is complex and multifaceted encompassing physical infrastructure (sites, labs, storage, data systems), skilled personnel (principal investigators and research staff), organisational sponsorship, regulatory and ethics oversight, operational readiness for interventional trials, sustainable funding and partnerships, and transparent data management. For this pilot review, due to limitations of publicly available data, clinical trials capacity was defined as capacity to conduct interventional trials for 100DM Scorecard pathogens across DTVs from 2020-2025. A combination of data sources were used. Our primary source was the Clinical Trials Community Africa Network (CTCAN) platform – supported by the Science for Africa Foundation and NuvoteQ – which curates clinical trial information from the continent. This was supplemented by additional data extracted from the Pan African Clinical Trials Registry (PACTR) and ClinicalTrials.gov.

The data revealed clusters of clinical trial capacity in regions; Southern Africa makes up the largest portion, with 429 trials (42%), this is almost entirely concentrated in South Africa (407). While North Africa has almost no

clinical trials with the exception of Egypt and Tunisia, while East Africa accounts for 323 trials, (31%). There are also some hotspots where a number of trials are occurring within certain countries, but these are largely linked to single institutions with trial sponsorship often sitting with high income country organisations showing the need for improved African ownership of clinical trial leadership. For example, among the trials included in this analysis, only 5 of 107 in Kenya was led by a Kenyan institute while 14 trials were led by the University of Oxford. This can be linked back to institutional connections at the KEMRI- Wellcome Trust Research Programme and the University of Oxford– while clinical trial capacity is being developed in-country by these programmes, the organisational oversight is still removed. The picture was only slightly better in the case of Mali and Uganda, where 4 out of the 30 and 8 out of 88, respectively, were led by local institutes. There are pros and cons to having this type of trial capacity. There is benefit in having capacity routinely used for other disease areas to ensure sites are maintained and ready to be activated in the event of a pandemic. On the downside, a number of these institutions have high-income country or colonial ties, action is needed to support the transition away from this model.

Assessing clinical trial capacity is complex and available data is limited. Better information is needed to inform decision-making, but what current evidence does show is that capacity is concentrated within countries within each region and at specific institutions within countries. Further investment is needed to develop physical infrastructure, transfer knowledge and change funding mechanisms to empower African ownership and elevate African principal investigators. The European and Developing Countries Clinical Trials Partnership (EDCTP) has been pivotal in building African clinical trials capacity and the recent Memorandum of Understanding between Global Health EDCTP 3, and CEPI will focus on building capacity epidemic preparedness[18]. More broadly, the African Clinical Research Network (ACRN) is building an African-led, globally connected network of high-quality trial sites, laboratories, and trained personnel to strengthen clinical research capacity across the continent[19].

MANUFACTURING CAPACITY

The need for local manufacturing capacity in Africa – highlighted during COVID-19 and reaffirmed by mpox – remains critical. Diversified and harmonised regional DTV manufacturing capacity in Africa would strengthen preparedness, enable equitable access and create a more resilient supply chain, paving the way for faster progress towards the 100 Days Mission.

Similar to clinical trial capacity, defining manufacturing capacity is multifaceted and includes physical sites, line and dose capacity, drug substance vs drug product capacity, capacity to produce products utilising different platform technologies, technology transfers and more. However, comprehensive data on all these aspects is not publicly available limiting the ability to measure capacity holistically. For this analysis, we used the best publicly available data, collected by Africa CDC, PATH and CHAI for vaccines and IAVI for mAbs, aligning with their respective methodologies. Vaccine manufacturing capacity is captured in two ways; first, by identifying manufactures with sites that are either currently producing vaccines or have the potential to do so; and second, by assessing which sites have initiated or signed technology transfer agreements (TT's) and which are still awaiting TT's. For mAbs, capacity is based on information reported by sites themselves.

Ten manufacturers spread across six countries were identified as having vaccine manufacturing capacity. Five of these manufacturers have signed, or started, technology transfers to support production, including: Marbio (Morocco), Vacsera (Egypt), Institut Pasteur de Dakar (Senegal), Aspen Pharmacare (South Africa) and Biovac (Egypt). Five more vaccine manufacturers have the facilities and capacities to produce vaccines but are awaiting technology transfers: Eva Pharma (Egypt), Minapharm (Egypt), Biogeneric (Egypt), Saidal (Algeria) and Atlantic Biotech (Ghana).

For monoclonal antibodies (mAbs), 19 manufacturers were identified across Algeria, Egypt, Morocco, Tunisia, Ethiopia, Kenya, Rwanda, Uganda, Ghana, Nigeria and South Africa. This is higher than that of vaccines but reflects methodological differences in how mAbs data was captured. For mAbs, manufacturing information was captured through stakeholder consultations, landscape assessments, and digital mapping rather than detailed per-site capacity and technology transfer tracking used for vaccines.

Important data limitations: There is no globally accepted standard for capturing manufacturing capacity. Measuring it remains a complex task, constrained by the limited availability of public data. The data presented here represents the best publicly available information. Data gaps must be addressed to better understand the true and potential manufacturing capacity in Africa. In this review, diagnostics were excluded due to the lack of publicly available data, however this presents a future opportunity for tracking. There are several ongoing initiatives which will further delineate the landscape and provide better data, including from Regionalized Vaccine Manufacturing Collaborative (RVMC) who are developing a dashboard on regional vaccine manufacturing capacity.

REGULATORY CAPACITY

Mapping regulatory capacity is essential to evaluate Africa's ability to rapidly approve, monitor, and deploy vaccines, therapeutics, and diagnostics during outbreaks- critical for achieving the 100 Days Mission. In this pilot, regulatory capacity was defined as the presence of national regulatory authorities (NRAs) that have reached WHO-recognised maturity level 3 (ML3) indicating capability to approve medical products. Data was sourced directly from WHO's List of National Regulatory Authorities (NRAs) operating at ML3 and maturity level 4 (ML4). This analysis focused on capacity for vaccine and therapeutic approvals, as publicly available data on diagnostic approvals was not available.

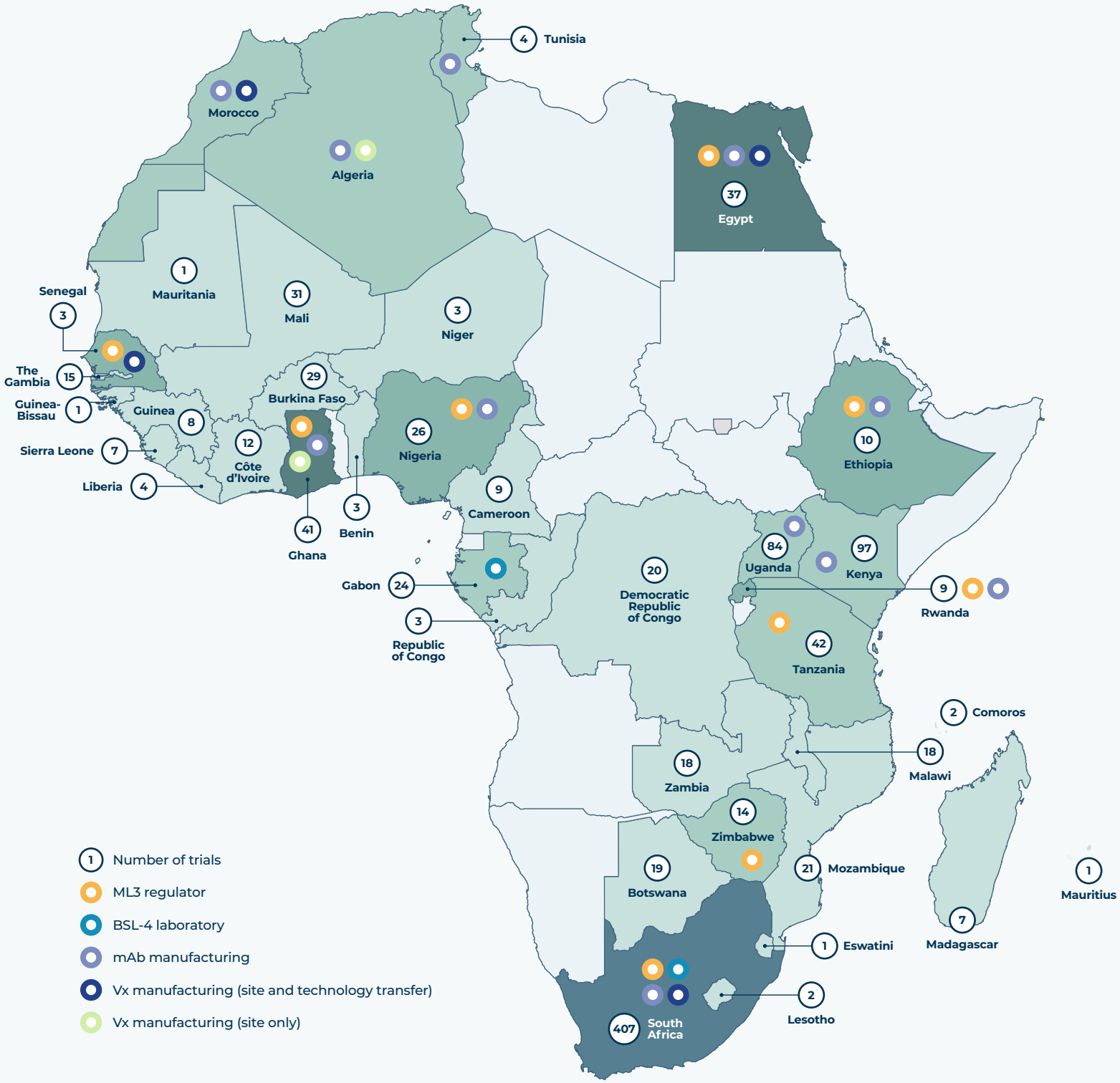
Regulatory capacity across Africa has grown since the COVID-19 pandemic, with several regulators achieving WHO ML3 status, including Ethiopia (Sept 2025), Senegal and Rwanda (Dec 2024), and Zimbabwe (June 2024). Notably, the Botswana Medicines Regulatory Authority (BoMRA) completed a self-benchmarking exercise with the WHO in August 2025 and is on track formal benchmarking in early 2027.

While these ML3 regulators approve medicines and vaccine, most countries do not have corresponding manufacturing capacity. This includes Ethiopia, Ghana, Senegal, Rwanda, Tanzania, and Zimbabwe. Currently, only two ML3 regulators oversee vaccine production: the Egyptian Drug Authority (EDA) and the South African Health Products Regulatory Authority (SAHPRA). In country vaccine production necessitates that regulators have oversight adding an additional layer of capacity. The lack of local vaccine manufacturing highlights the gap between regulatory maturity and vaccine production readiness which is needed to accelerate timelines under the 100 Days Mission.

The geographic distribution of ML3 regulators is relatively balanced across East, West and South Africa, but North Africa remains underrepresented apart from Egypt. Beyond national progress, the establishment of the African Medicines Agency (AMA) marks a pivotal shift toward regionalised regulation. In February 2025, a landmark Memorandum of Understanding (MoU) was signed by Africa's ML3 regulators under the African Medicines Regulatory Harmonization (AMRH) initiative. Once fully operational, AMA will coordinate joint assessments, enable mutual regulatory reliance, and support continent-wide approval pathways, positioning Africa to move from fragmented national oversight to a harmonised continental model.

Regulatory capacity has significantly improved on the continent in recent years, at both the national and regional level. The developments under AMA highlight how regionalisation of capacities can maximise available resources, streamline processes and avoid unnecessary duplication.

African PPR capacity deep-dive



COMPLEMENT OF CAPACITIES*

*The heat map colouring corresponds to a scale of 0-5 and represents how many capacities a country has: clinical trial capacity, ML3 regulator, Vaccine manufacturing capacity, mAbs manufacturing capacity, BSL-4 capacity

SYNTHESIS: COMPLEMENT OF CAPACITIES

To meet the 100 Days Mission coordination and harmonisation across the PPR ecosystem is needed. Rather than solely focusing on individual indicators, it is essential to consider the overarching complement of capacities at the national, regional and continental level and how these interact.

From both a research and implementation perspective, these capacities are intrinsically interlinked – having one without the other won't enable progress. For example, if a country can study a pathogen in a high-containment lab but lacks clinical trial networks or regulatory pathways, vaccine candidates cannot be tested or approved locally, and without manufacturing capacity, approved products cannot be produced at scale – showing how missing links stall the entire process.

Looking at individual countries, there are clear gaps. South Africa is the only country with all four capacities, followed by Egypt and Ghana with three each. However, the goal is not for every country to develop full end-to-end capabilities, as this would be duplicative and inefficient especially in resource constrained settings. Instead, broader coordination and harmonisation are needed to leverage existing infrastructure, fill strategic gaps and deliver benefit at scale.

Regionally there are significant opportunities to sustain the momentum behind harmonisation initiatives. Africa CDC and AUDA-NEPAD are driving several initiatives to strengthen Africa's health preparedness ecosystem. These include building regional clinical trial networks, upgrading laboratory systems and biosafety standards, harmonising regulatory frameworks through the African Medicines Regulatory Harmonization program, and scaling vaccine and biotherapeutics manufacturing via mechanisms like the African Vaccine Manufacturing Accelerator and Regional Capability Networks. These initiatives are often in partnership – such as those with CEPI, EDCTP and ASLM – showing the need for collaboration to achieve this goal[20,21].

Together, these efforts aim to create an integrated, continent-wide capacity for research, regulation, and production to respond rapidly to future health threats.

SPOTLIGHT

H5N1

BACKGROUND & CURRENT STATE

The influenza A (H5N1) virus has circulated in wild birds and poultry for two decades, crossing repeatedly into mammals and occasionally humans. Worldwide, more than 950 human cases and ~475 deaths have been reported to WHO as of Aug 2025[22]. Between January 1 and August 25, 2025, 27 human infections with H5N1 viruses have been detected globally, of which 23 were identified in 7 countries outside of the United States, including 10 infections that resulted in death[22]. Recent data show that H5N1 is not only affecting birds but dairy cattle herds in the United States[23] – highlighting the significant potential economic consequences for agricultural systems and food supply chains. Traces of H5 (including H5N1) have also been detected in wastewater systems in North America[24].

CONCERNING VIRAL CHARACTERISTICS

- **Historically high CFR in human infections** (WHO reports ~52 % CFR among confirmed cases)[25].
- **Demonstrated ability to cross species barriers:** livestock involvement, wastewater detection[23].
- **Known mutations under surveillance that could enhance human transmissibility or adaptation** – though no clear evidence yet of a transmissible human-adapted variant.

SURVEILLANCE GAPS REVEALED

- The large-scale dairy herd outbreaks in the U.S. indicate **delayed detection and containment.**
- **Under-detection of human cases:** the true number of mild or sub-clinical infections is unknown.
- Wastewater surveillance in several states has detected H5 viral genetic material, **indicating possible broader environmental dissemination.**
- **Limited genomic sequencing and timely sharing to track viral evolution globally** – especially in LMICs and livestock reservoirs[26].

CURRENT STATE OF MEDICAL COUNTERMEASURES (MCMs)

DIAGNOSTICS:

PCR-based assays available in reference laboratories for H5 bird-flu viruses.

- **Gaps:** Limited point-of-care diagnostics in agricultural/ remote settings; delayed milk testing in affected dairy herds; need for rapid syndromic panels that differentiate H5N1 from seasonal influenza or other respiratory infections[27].

THERAPEUTICS:

Neuraminidase inhibitors e.g. oseltamivir and zanamivir and cap-dependent endonuclease inhibitors e.g. baloxavir are in contingency stockpiles.

- **Gaps:** Uncertain effectiveness of these antivirals specifically against current H5N1 clades; no completed human clinical trials of H5-specific therapeutic regimens; limited data on optimal treatment protocols for severe H5N1 illness.

VACCINES:

At least 20 H5 influenza vaccines have been licensed in some jurisdictions as of September 2025[28].

- **Gaps:** Many vaccines are egg-based, thus vulnerable to poultry supply disruption; global stockpiles (under the PIP framework) reserve only ~10% of total global antigen for LMICs; cold chain requirements limit deployment in rural/LMIC settings; limited paediatric safety/ efficacy data[29,30].

KEY TAKE-HOME POINTS FOR THE 100DM

1. **Maintain heightened surveillance** in avian, mammalian (especially livestock) and environmental reservoirs (e.g., wastewater) to detect early signals of adaptation.
2. **Update MCM contingency planning:** review antiviral stockpile effectiveness, accelerate DTV readiness plans for H5N1 and ensure equitable access frameworks for LMICs.
3. **Foster cross-sectoral coordination** (animal health, human health, agriculture, environment) under One-Health approach to manage spill-over risks while strengthening diagnostics deployment.

CHAPTER 2

Investing to fill gaps in R&D

Synergies Across Development of Diagnostics, Therapeutics and Vaccines

IPPS WAS ESTABLISHED WITH A FUNDAMENTAL PREMISE: diagnostics, therapeutics, and vaccines function not as isolated countermeasures but as an integrated ecosystem whose collective impact exceeds the sum of its parts. Yet persistent silos between these domains – reinforced by fragmented funding streams and disconnected research communities – continue to limit the speed and efficiency of pandemic preparedness and response.

Integrated MCM strategies are essential as the global preparedness landscape evolves, facilitating faster detection-to-response timelines, more coherent R&D investment, and improved resilience across diagnostics, therapeutics, and vaccines (DTVs). Integration enables critical efficiencies across these fundamentally interdependent tools. Rapid diagnosis can immediately trigger intervention through test-to-treat pathways. Shared research and manufacturing platforms reduce duplication across countermeasures. Coordinated biospecimen collection and data sharing accelerate validation for all three domains.

In addition to these operational synergies, key interdependencies exist across the tools: diagnostics enable targeted therapeutic deployment and are essential for validating vaccines, whilst insights from therapeutic and vaccine development inform diagnostic target selection and assay design. While countermeasure-specific chapters detail domain-relevant synergies (see *Chapter 2*), this section highlights cross-cutting themes: collaborative models, shared infrastructure, biosecurity frameworks, artificial intelligence, innovative financing approaches, and governance structures spanning all three tools.

Progress in 2025 demonstrated both the potential and persistent limitations of cross-countermeasure coordination. The emergence of Collaborative Open Research Consortia (CORCs) – networks organised around viral families to advance diagnostics, therapeutics, and vaccines simultaneously – represents a structural innovation, yet coverage remains limited to priority pathogens. New biosecurity frameworks are embedding pandemic preparedness within broader health security architectures, though implementation varies significantly across regions.

Artificial intelligence is creating unprecedented opportunities for accelerating discovery while raising critical questions about responsible innovation and equitable access. Coordination mechanisms remain insufficient, and data sharing between domains falls short of what integrated preparedness requires. As IPPS approaches the conclusion of its mandate, these gaps underscore the urgent need for consolidated, long-term structures to maintain and advance the integration achieved to date.

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OPERATIONALISING MCM SYNERGIES THROUGH COLLABORATIVE MODELS

The most significant structural innovation has been the adoption of pathogen family-based approaches, which identify shared characteristics within viral families and enable more coherent preparedness strategies. Rather than developing countermeasures pathogen-by-pathogen, this approach leverages commonalities – shared viral mechanisms, similar diagnostic targets, overlapping therapeutic pathways – to accelerate development across diagnostics, therapeutics, and vaccines simultaneously.

WHO CORCs launched in 2025 for flavivirus, filovirus, arenavirus, and bunyavirus families[31–33], creating unified platforms for developing global R&D roadmaps spanning all three countermeasures. These consortia align research priorities, facilitate shared infrastructure access, and develop integrated Target Product Profiles (TPPs) that consider diagnostic, therapeutic, and vaccine needs from the outset. The CORCs have been rapidly activated during recent outbreaks: during the filovirus epidemic in 2025, the Filovirus CORC met on three occasions and promoted ten research priorities in the field of Marburg and Ebola Zaire, whilst the Phenuiviridae CORC recently met to prioritise research in the context of the Rift Valley fever epidemic in Senegal. National governments are increasingly mirroring this approach: UKHSA's Priority Pathogen Families reference tool guides R&D investment across 24 pathogen families, exemplifying how national frameworks can align with global coordination[34].

Supporting infrastructure initiatives are addressing critical bottlenecks. CEPI and PATH's Biospecimen Sourcing Initiative is accelerating the ethical collection of outbreak survivor samples to enable rapid assay and diagnostic standard development[35]. This addresses a critical bottleneck: the absence of well-characterised clinical specimens essential for validating diagnostic assays, identifying protective antibodies for therapeutics, and establishing correlates of protection for vaccines. However, intellectual property considerations and fragmented governance continue to create barriers to sharing materials across modalities.

In Europe, BE READY PLUS[36] is establishing groundwork for a future European pandemic preparedness partnership, while European Research Infrastructure on Highly Pathogenic Agents (ERINHA)[37] partners from across Europe, including the UK, continue to harmonise high containment procedures to enable safer collaboration across BSL-3 and BSL-4 facilities, addressing a critical constraint identified across medical countermeasure development.

Despite this progress, significant challenges remain. Among WHO priority pathogens, a full complement of TPPs has only been established for COVID-19. Chemistry, manufacturing, and controls (CMC) readiness remains fragmented: without aligned manufacturing standards, quality frameworks, and regulatory foundations, the synergies identified across diagnostics, therapeutics, and vaccines cannot translate into accelerated trials, coordinated licensure, or equitable deployment. Most critically, visibility across domains remains limited – researchers developing diagnostics often remain unaware of parallel therapeutic or vaccine development, constraining resource sharing and collaborative opportunities.

CROSS-FUNCTIONAL R&D INFRASTRUCTURE

Greater alignment in R&D design could accelerate development through more efficient use of shared resources. Cross-domain insights – such as biomarkers, epitope-mapping, and correlates of protection – can inform development across diagnostics, therapeutics, and vaccines.

At the system level, a critical opportunity has emerged with regulatory shifts towards non-animal models. The FDA's April 2025 announcement[38] to phase out animal testing requirements for mAbs and other drugs marks a significant regulatory shift, encouraging developers to use New Approach Methodologies such as organ-on-chip systems, organoids and AI-enabled computational modelling instead of traditional animal models[39].

Shared investment in these advanced models can span diagnostics, therapeutics and vaccines. Organ-on-chip systems that replicate human immune responses could inform vaccine reactogenicity assessments, therapeutic toxicity profiling, and biomarker discovery for diagnostics. This shared-platform approach reduces duplication and accelerates validation across all three countermeasures.

Building on this principle of shared resource efficiency, manufacturing platforms that produce recombinant proteins for vaccines or therapeutic antibodies can also be repurposed to generate diagnostic reagents. **By using a common production backbone, organisations can lower costs, streamline validation, and bring the entire DTV pipeline to market faster.**

Coordinated development of these platforms – supported by harmonised validation standards and cross-domain governance – will improve development success rates and accelerate the entire DTV pipeline.

In addition, the recently launched Pandemic PACT's Grant Tracker maps investments across pre-clinical and clinical research, capacity strengthening, and data systems that collectively underpin DTV development. These monitoring efforts highlight both progress and persistent gaps, and can be leveraged for coordinated investment across platforms, regulatory pathways, manufacturing and data sharing to meet the 100DM objectives[40].

BIOSECURITY AND PANDEMIC PREPAREDNESS

Sustained investment in countermeasures for outbreak-prone pathogens is essential to avoid security gaps that could threaten population health. **Stronger bridging mechanisms are needed between preparedness and biosecurity agencies[41,42].**

There is a clear opportunity to intentionally connect pandemic preparedness and the 100DM with biosecurity efforts. Biosecurity – measures protecting people, animals, plants, and ecosystems from biological risks ranging from naturally occurring infectious diseases to laboratory accidents, dual-use research, and deliberate biological attacks[43] – is a cornerstone of pandemic preparedness. Against a backdrop of emerging biotechnologies and global instability, biosecurity and biosafety risks are increasing. Biosafety – the safe working practices associated with handling biological materials, particularly infectious agents[44] – and biosecurity concerns are heightened as converging technologies that could transform public health also present dual-use challenges. By mitigating risks from natural, accidental, and deliberate sources, including engineered pathogens that could lead to global catastrophic biological events, biosecurity investments strengthen the same infrastructure and capabilities needed for effective pandemic response. This is critical to ensure that the facilities around the world handling high-consequence pathogens and emerging technologies can do so responsibly.

CEPI's biosecurity strategy, for example, highlights the role of a research funder in prioritising biosecurity and biosafety oversight, portfolio risk monitoring, and responsible innovation, while driving biosecurity and biosafety capability in support of equitable scientific collaboration – a requirement for achieving the 100 Days Mission. **Strengthening laboratory biosecurity and biosafety, particularly in the Global South, expands opportunities for responsible collaboration.** Indeed, CEPI is piloting ISO 35001 (the only performance-based international biorisk management standard for biosecurity and biosafety) across partner laboratories to support safe global collaboration[45]. Strong institutional biorisk management systems enable facilities to rapidly transition to emergency response work on pathogens they do not routinely handle, with protocols defined in advance rather than during crises.

As biosecurity frameworks expand, integrating pandemic preparedness from the outset ensures that investments in mitigating deliberate biological threats simultaneously strengthen capabilities for rapid countermeasure development against natural and accidental outbreaks. The relationship is reciprocal: having diagnostics, therapeutics, and vaccines available across all priority pathogens protects populations from biological threats regardless of origin, meaning that achieving the 100 Days Mission inherently advances biosecurity goals at global, regional, and national levels. This integration is essential to ensure the 100 Days Mission is achieved both rapidly and responsibly.

HARNESSING ARTIFICIAL INTELLIGENCE FOR PANDEMIC PREPAREDNESS

Artificial intelligence (AI) can act as the connective tissue across diagnostics, therapeutics, and vaccines by enabling shared data frameworks, predictive design, and cross-modality optimisation. At the discovery stage, AI-driven analyses of pathogen genomics and host responses can identify conserved viral targets simultaneously relevant for vaccine antigens, therapeutic inhibitors, and diagnostic biomarkers. Across development, platform technologies such as mRNA and monoclonal antibodies are increasingly optimised through machine learning to improve stability, manufacturability, and immune response profiles[46–48]. In clinical and regulatory science, AI has the potential to facilitate convergence through adaptive trial designs and shared data environments, allowing multiple countermeasure types to be evaluated under unified protocols. Emerging national strategies such as the UK AI for Science Strategy that combine data, compute and autonomous laboratory infrastructure, have the potential to compress development timelines and strengthen an integrated MCM ecosystem[49].

Beyond accelerating response timelines, AI fundamentally shifts preparedness toward anticipatory action – enabling the development of comprehensive pathogen libraries and validated candidate pools during interpandemic periods rather than starting discovery only after threats emerge. When implemented responsibly, with clear governance, equitable data access, and multi-sector coordination, AI could transform fragmented MCM R&D into a coherent, adaptive ecosystem that makes the 100 Days Mission attainable (see *Chapter 2, Spotlight: AI*).

Looking ahead, IPPS will engage key partners to explore how to embed AI capabilities across DTV R&D in support of the 100DM agenda. This will involve examining how AI can accelerate drug discovery, enable data-driven prioritisation, and strengthen integrated decision-making across DTVs.

When implemented responsibly, with clear governance, equitable data access, and multi-sector coordination, AI could transform fragmented MCM R&D into a coherent, adaptive ecosystem that makes the 100 Days Mission attainable.

INNOVATIVE CROSS-MCM FINANCING

Reverting to rigid, pre-COVID funding models with separate streams for diagnostics, therapeutics, and vaccines risks slowing discovery and forfeiting opportunities for synergy. **Integrated financing mechanisms can accelerate development by linking functions across the MCM spectrum.**

Portfolio and platform approaches offer another path to integration. Investors should balance product-specific support with funding for multi-product platforms. European Commission Health Emergency Preparedness and Response's (HERA) Medical Countermeasures Accelerator combines grants, procurement commitments, and venture finance to stimulate innovation across the DTV spectrum[50]. The Pandemic Antiviral Discovery (PAD) initiative exemplifies this approach by pooling philanthropic resources from the Novo Nordisk Foundation, the Gates Foundation, and Open Philanthropy to de-risk early-stage antiviral R&D[51]. Although focused on therapeutics, this model could be applied across the DTV spectrum, reducing risk for both early-stage developers and funders.

THE PATH FORWARD: SUSTAINING CROSS-MCM COORDINATION

The greatest missed opportunities in pandemic preparedness stem from siloed thinking that treats diagnostics, therapeutics, and vaccines as independent challenges. **Embedding cross-MCM coordination across priority-setting, R&D planning, regulatory design, and financing is vital to achieving the speed and integration required by the 100 Days Mission.**

This requires:

- **Structural integration** through governance mechanisms that convene stakeholders in joint decision-making rather than parallel tracks.
- **Shared metrics** that assess system-level outcomes rather than tool-specific outputs.
- **Sustained, cross-cutting financing** to support common infrastructure, coordination, and data platforms.
- **Knowledge-management systems** that ensure insights from one domain are rapidly translated to others.

The next phase of pandemic preparedness must therefore focus on establishing permanent, well-resourced coordination mechanisms anchored by clear mandates, stable governance, and predictable financing to sustain and expand the integration achieved to date. Such forward-looking structures will ensure that discoveries and investments across diagnostics, therapeutics, and vaccines reinforce one another, transforming fragmented innovation, readiness and response efforts into a coherent, agile, and equitable preparedness ecosystem.

SPOTLIGHT

AI

Artificial intelligence is transforming pandemic preparedness by reducing development timelines from years to months while expanding the scope of viable interventions. A significant strategic value lies in AI's capacity to front-load critical scientific work during interpandemic periods – systematically building knowledge infrastructure and candidate libraries in advance rather than waiting for pathogen emergence.

AI-enabled biomolecular design offers a significant opportunity to advance the 100 Days Mission. Protein language models, structure prediction tools, and other advanced AI systems enable unprecedented capabilities: predicting protein structures, identifying antigens for vaccines and diagnostics, designing therapeutic antibodies and small molecules, screening drugs for repurposing, and predicting viral evolution. For instance, structure prediction recently enabled systematic mapping of glycoproteins across the Flaviviridae virus family, revealing previously unknown fusion mechanisms that can inform countermeasure design[52].

CEPI's Pandemic Preparedness Engine exemplifies how these capabilities can be operationalised at scale[53]. As the world's first AI platform dedicated to pandemic preparedness, the Engine will integrate diverse data streams across the entire vaccine development pipeline – from genomic surveillance and viral phylogenetics to clinical trial results and regulatory submissions. By connecting these data sources, the platform aims to identify promising vaccine candidates faster and streamline decision-making throughout development. Similarly, MIT's VaxSeer demonstrates AI's predictive power for vaccine strain selection – its vaccine strain recommendations outperformed WHO selections in 9 of 10 influenza seasons over a decade[54].

AI-enabled genomic surveillance tools also provide significant opportunities to strengthen pandemic preparedness capabilities by improving pathogen threat identification and risk assessment. Machine learning approaches like UC Davis's VISTA system[55], developed in partnership with CEPI, identifies viral strains with elevated cross-species transmission potential, enabling focused monitoring. These technologies also support wider surveillance functions, including geographic pattern analysis for outbreak identification[56], detection of unusual signals within monitoring systems[57], cross-program data integration to strengthen surveillance ecosystem representativeness[58], and integration of multiple data types for early warning[59].

REALISING AI'S TRANSFORMATIVE POTENTIAL REQUIRES CAREFULLY NAVIGATING ASSOCIATED CHALLENGES AND RISKS, INCLUDING:

Data quality and model reliability

- **AI performance depends critically on training data quality and representativeness.** Incomplete datasets can produce models that fail against novel threats, while inherent model limitations affect prediction accuracy even with high-quality data.
- **Rigorous experimental validation and benchmarking frameworks are essential** to ensure computational predictions translate to functional countermeasures under real-world pandemic conditions.

Tool proliferation and selection difficulties

- Recent assessments documented over **1,100 biological AI systems across 76 countries,** with almost the same number of tools released in 2023 and 2024 as in the previous four years combined. Rigorous benchmarking is essential to prevent information overwhelm[60].

Biosecurity and dual-use concerns

- Recent assessments found that **almost one in four state-of-the-art biological AI tools raises immediate dual-use concerns[60].** Capabilities to generate synthetic viral sequences and simulate emerging pathogens raise particularly acute risks, as they could be misused for pathogen engineering.
- **Balancing open science with biosecurity requires robust governance frameworks and managed access** enabling legitimate research while preventing misuse. A Community Statement, supported by over 250 experts from more than 30 countries, outlines common international principles to guide the responsible development of AI for protein design[61].

Computational resource disparities and equity

- **Advanced AI capabilities remain concentrated in well-resourced settings,** risking widened preparedness gaps. Ensuring equitable access requires deliberate capacity building, technology transfer, and inclusive governance mechanisms.

Diagnostics R&D

Diagnostics are the intelligence engine of the 100 Days Mission, generating the actionable data that drives vaccine strain selection, therapeutic development priorities, manufacturing decisions, and public health response strategies. Yet the diagnostics ecosystem continues to suffer from chronic underinvestment and fragmented coordination – persistently deprioritised despite being the foundational capability that enables all other pandemic response efforts. Diagnostic authorisation and production readiness routinely miss the 100-day mark, with structural barriers across R&D, validation, regulatory review, manufacturing, procurement, and adoption creating delays that mean diagnostics arrive too late and are inequitably distributed.

Achieving the 100 Days Mission requires embedding pandemic-relevant diagnostics in routine healthcare rather than relying on crisis-only systems. Routine diagnostic testing – particularly syndromic and multiplex platforms – addresses everyday clinical needs while generating continuous pathogen monitoring data that enables early outbreak detection through geographically distributed infrastructure. Platforms developed for routine use sustain markets and manufacturing capacity between pandemics while providing the foundation for rapid outbreak response. The pathogen monitoring data generated drives vaccine strain selection by identifying emerging variants, informs therapeutic development priorities by revealing disease severity patterns and resistance trends, and enables biomanufacturing decisions through real-time surveillance. Co-developing and integrating diagnostics with other medical countermeasures – stratifying patients to appropriate countermeasures, enabling rapid treatment access, developing epidemiological and genomic surveillance technologies, community surveillance, and serving as clinical trial endpoints for both vaccines and therapeutics – ensures MCMs reach the right patients while generating real-world evidence that accelerates development and leveraging public policies towards more resilient health ecosystems. This integration improves clinical outcomes, reduces inappropriate prescribing, and creates commercial incentives that sustain diagnostic innovation while building deployment infrastructure that serves both routine care and outbreak response.

Progress was enabled by collaborative partnerships among governments, developers, and international organisations facilitating technology transfer and regional capacity building, alongside technical collaborations with academic institutions. Early regulatory harmonisation efforts through mechanisms like the African Medicines Agency and regional conversations in the Association of Southeast Asian Nations (ASEAN) show promise for streamlining approval pathways. Emerging trends – particularly modular diagnostic platforms capable of detecting multiple pathogens and AI-enabled tools for test interpretation and surveillance analytics – offer potential to accelerate response timelines. Realising this potential requires adapted regulatory frameworks for platform-based technologies, digital infrastructure connecting diagnostic data across MCM pipelines, and sustained investment in regional manufacturing capacity that maintains readiness between outbreaks.

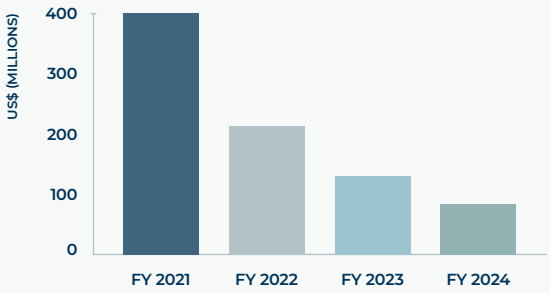
The 100 Days Mission for diagnostics

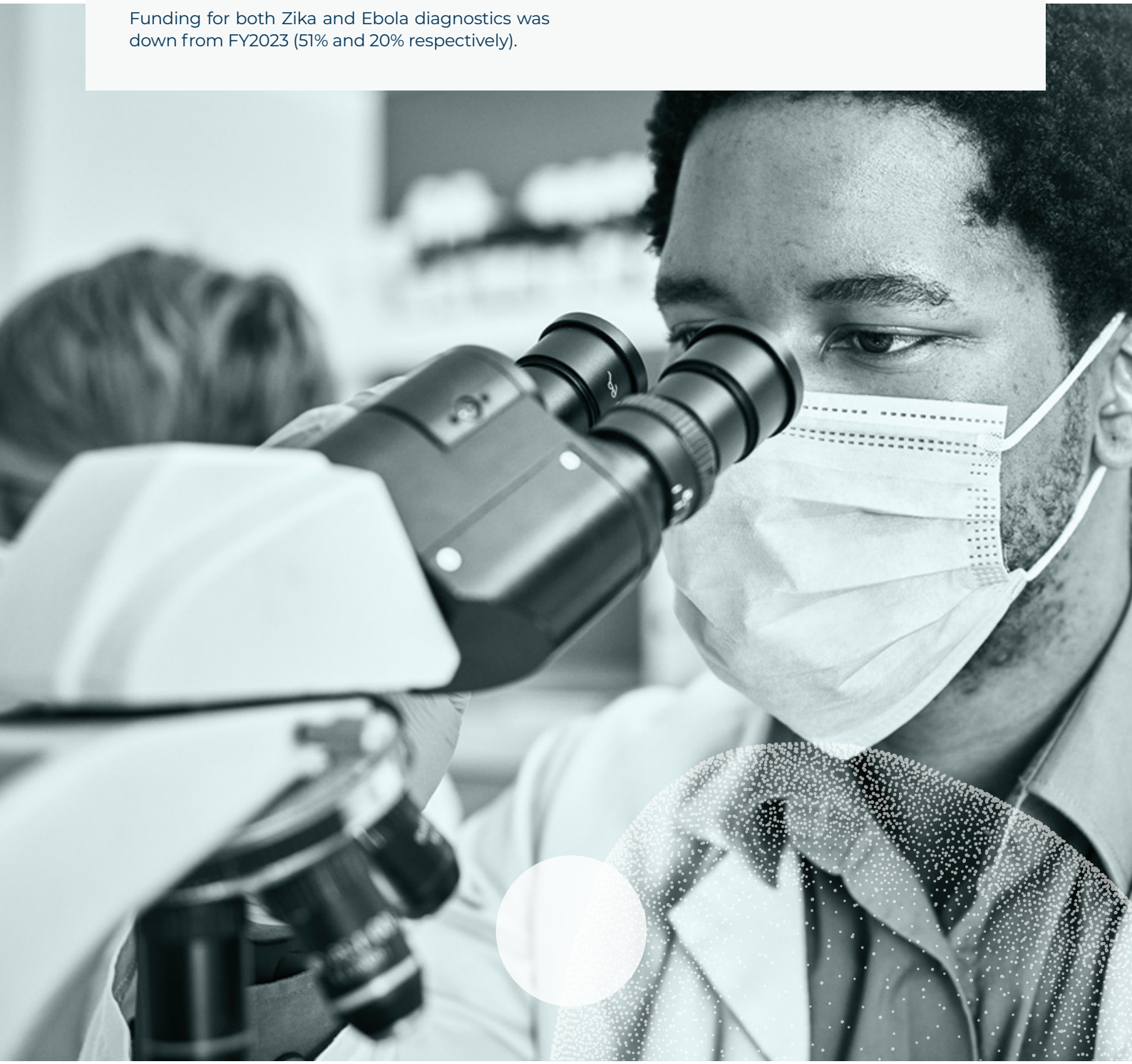
- Enhanced global collaboration among governments, industry, regulators and international organisations to create a sustainable diagnostics R&D ecosystem that can rapidly respond to emerging health threats.
- Development of comprehensive diagnostic libraries offering broad coverage for priority pathogen families, aimed at providing a foundation for rapid diagnostic development in response to new or emerging disease threats.

Funding for diagnostic R&D was down by 34% in FY2024, though this is skewed by the 41% drop in funding for COVID-19 diagnostics, while funding for non-COVID diagnostics increased moderately – by US$3m (21%) to US$17m – though from a low base.

Notably, funding for CCHF diagnostics increased tenfold, from just US$0.4m to US$4m, and MERS funding was almost four times its FY2023 level, though still at just US$1.1m.

Funding for both Zika and Ebola diagnostics was down from FY2023 (51% and 20% respectively).





PROGRESS AGAINST 2025 PRIORITY ACTIONS

Here we highlight a few key advances that could have broader impact on the diagnostics R&D ecosystem and wider adoption potential in the field; however, a more comprehensive overview of progress updates provided by implementation partners can be found in *Annex A*.

Implement de-risking strategies to accelerate diagnostic R&D and fund rapid point-of-care tests targeting priority pathogen families

Some progress is evident through multiplex diagnostic approaches that balance interpandemic utility with outbreak response capacity. Examples include RIGHT Foundation's funding of SD Biosensor's STANDARD M10 Flu/RSV/SARS-CoV-2 cartridge[62] and Cepheid's enhanced Xpert test with H5N1/FLU A&B/H3N2 variants[63]. Institutional support is reinforcing this direction through initiatives such as BARDA's I-CREATE, which prioritises pathogen-agnostic platforms[64].

Despite this progress, significant gaps persist. This year's advances have concentrated on respiratory pathogens and select viral families, with comprehensive panels covering all priority pathogens still absent. Target Product Profile development shows limited advancement – while the Foundation for Innovative New Diagnostics (FIND) published TPPs for Lassa fever[65] and Nipah virus[66], WHO published none for pandemic priority pathogens in 2025. Proactive co-development of diagnostics alongside vaccines and therapeutics from the earliest R&D stages remains largely absent, despite being essential for accelerated timelines and stronger business cases. WHO's newly established CORCs for priority viral families provide a structural mechanism to enable this integration, though implementation is still in early stages.

Accelerating progress requires coordinated action: funders must incentivise integrated MCM development from the outset, WHO and partner organisations should prioritise TPP development for all priority pathogens in appropriate test settings (centralised vs decentralised), and the field needs proof-of-concept demonstration projects proving the business case for co-development.

Strengthen sample access and build robust global biobanking networks

Significant progress was made with the WHO Pandemic Agreement adopted by consensus at the 78th World Health Assembly in May 2025, following three years of negotiations[67]. However, the Agreement cannot be opened for signature until the negotiations on the Pathogen Access and Benefit-Sharing (PABS) are concluded.

Some operational progress in biobanking is evident, building on work through existing networks including the FIND, Africa CDC, and Fiocruz networks[68–70]. During the mpox outbreak, WHO BioHub shared clade Ib material to over 40 laboratories and delivered its largest External Quality Assessment within 2-4 weeks post-PHEIC declaration. CEPI and PATH's Biospecimen Sourcing Initiative is developing harmonised guidance to reduce outbreak survivor sample collection from months to weeks[71] (see *Chapter 2, Synergies Across Development of Diagnostics, Therapeutics and Vaccines*).

Despite these developments, access to clinical samples and reference materials remains one of the most acute bottlenecks in diagnostic development. The Diagnostics 2025 Global Gap Assessment conducted by IPPS, Brown University Pandemic Centre, and FIND found that over 90% of stakeholders cited this as a critical constraint[72]. Stakeholders identified the establishment of regional validation hubs – organised by pathogen family and biosafety containment requirements – as an urgent priority. These hubs could provide standardised sample panels, reference materials, and regulatory-aligned evaluation services to accelerate comparative validation and reduce development timelines. The U.S. NIH RADx Tech Innovation Funnel and Independent Test Assessment Program (ITAP) demonstrated this model's effectiveness during COVID-19, enabling rapid, comparative assessment of multiple diagnostic platforms against common standards. Synthetic controls and in silico validation methods offer complementary approaches, particularly for high-containment pathogens where physical samples are scarce.

Accelerating progress requires moving beyond policy frameworks to operational infrastructure: establishing and funding regional validation hubs with harmonised standards, strengthening biobanking networks with improved data-sharing systems and sustainable financing models, expanding regulatory acceptance of synthetic validation materials, and developing mechanisms for rapid distribution of reference materials for product and process development.

Expand sustainable capacity for regional production

Diagnostics manufacturing remains concentrated among a small number of companies primarily based in Asia, Europe, and North America, creating severe vulnerabilities during health emergencies when LMICs face extended wait times and reduced access to essential tools[72].

Building on 2024 progress, foundational investments in regional diagnostic manufacturing capacity advanced in 2025, including demand aggregation mechanisms, technology transfer partnerships, and infrastructure development across African and Latin American regions, supported by partners including PATH through a Unitaid-supported grant. However, progress remains slower than comparable vaccine manufacturing initiatives, and critical constraints persist in access to validated technologies, skilled workforce, and quality systems. While technology transfer platforms like the WHO Health Technology Access Programme (HTAP) exist, they require substantial scaling to enable rapid activation within the 100-day timeline.

See the *Geo-Diversified Manufacturing* section in *Chapter 3* for comprehensive details on regional capacity-building initiatives and progress.

Simplify and harmonise diagnostic regulatory pathways

Fragmented regulatory pathways remain a critical bottleneck for diagnostic innovation and pandemic preparedness, with developers facing inconsistent requirements, duplicative evaluations, and extended approval timelines across jurisdictions incompatible with the 100-day mission timeline[72]. Many countries lack dedicated regulatory pathways for diagnostics or have multiple agencies with overlapping mandates for medical devices and diagnostics.

Progress at the global level shows mixed advancement. Standardised regulatory targets only exist for one pandemic priority pathogen, SARS-CoV-2, in the form of the WHO Technical Specifications Series, leaving manufacturers without comparable guidance for other priority pathogen families. However, WHO's December 2024 release of the Global Benchmarking Tool Plus Medical Devices (GBT+MD) expands the existing framework to include diagnostics, enabling systematic assessment of regulatory capacity[73]. The International Medical Device Regulators Forum's (IMDRF) Playbook for Medical Device Regulatory Reliance Programs – with final version expected in 2026 – will provide best practices for reliance models supporting global harmonisation[74].

Regional advances are accelerating harmonisation. The African Medicines Regulatory Harmonisation (AMRH) initiative's medical device assessment committee has developed comprehensive continental documents including emergency use listing SOPs for diagnostics, evaluation procedures for in vitro diagnostics (IVDs), and reliance guidance based on IMDRF frameworks[75]. The African Medical Supplies Platform exemplifies this progress in practice, having developed pre-qualification frameworks aligned with WHO-PQ standards through collaboration with the African Medicines Agency (AMA) and planning to integrate regulatory reliance pathways by 2026, targeting a 40% reduction in diagnostic approval timelines.

These advances signal growing momentum toward harmonisation, yet critical implementation gaps persist. Achieving 100-day mission timelines requires establishing diagnostic-specific regulatory frameworks, accelerating the operationalisation of reliance mechanisms, expanding WHO technical specifications to cover all priority pathogen families, and ensuring regional frameworks translate into measurable reductions in approval timelines and developer burden across all markets.

Strengthen international coordination

Fragmented initiatives and insufficient coordination have historically limited progress across the diagnostics ecosystem. In 2025, coordinated efforts advanced to address systemic barriers in diagnostic development and deployment.

The International Pandemic Preparedness Secretariat convened two cross-sectoral diagnostics roundtables in 2025, bringing together over 60 stakeholders from industry, regulators, governments, research institutions, funders, and international organisations to address regulatory harmonisation, sustainable financing, and market access challenges. IPPS conducted a comprehensive gap assessment in collaboration with Brown University Pandemic Center and FIND, mapping critical barriers across the diagnostics ecosystem and developing actionable recommendations[72]. Findings have been incorporated into G20 High Level Independent Panel (HLIP) discussions and present opportunities for engagement across other multilateral fora[76].

WHO launched the Global Diagnostics Coalition in May 2025 during the 78th World Health Assembly, providing the first dedicated global platform for coordinating diagnostics capacity strengthening across universal health coverage and emergency preparedness[77]. The Coalition supports implementation of World Health Assembly Resolution 76.5 on Strengthening Diagnostics Capacity. Regional approaches are also advancing, exemplified by HERA's planned pilot of a European Diagnostics Hub by 2026 to invest in next-generation diagnostic technologies that are rapidly deployable, scalable, and adaptable for point-of-care use[50].

Accelerating progress requires focused coordination to reduce duplication across initiatives, systematically address identified gaps, ensure critical infrastructure – including validation hubs and biobanking networks – receives sustained funding, and establish systems for collating and sharing data across regions. The field needs neutral facilitation capable of coalescing stakeholders around the biggest gaps, mobilising resources rapidly, linking stakeholders to concrete investments, and enabling data flows that support global surveillance without jurisdictional delays. Delivering operational solutions at the pace pandemic preparedness demands requires moving from consensus-building to action.

Embed best practices during interpandemic times

Progress in embedding diagnostics within routine healthcare systems remains limited, despite their role as the intelligence engine driving all pandemic countermeasure decisions. Integrating pandemic-relevant diagnostics into everyday clinical use sustains markets and manufacturing capacity between pandemics while generating continuous pathogen monitoring data that – alongside broader surveillance modalities – enables early outbreak detection.

Surveillance integration shows some progress in 2025, with enhanced coordination mechanisms, capacity building in LMICs, and integration of surveillance tools with risk assessment systems (see *Chapter 3, Surveillance*). Linking diagnostic testing to treatment pathways shows emerging progress through initiatives such as Unitaid's SAFEStart+ program, led by PATH, which links multiplex diagnostics detecting multiple infections to preventive treatment delivery through antenatal care78,79. Similarly, Unitaid grants for advanced HIV disease with Aurum link mpox point-of-care molecular diagnostics and other simplified testing to treatment through existing HIV and maternal health services for vulnerable populations[80].

However, critical gaps constrain systemic integration. Market demand signals through Essential Diagnostics Lists (EDLs) remain limited – despite the 2023 World Health Assembly resolution urging Member States to establish national essential diagnostics lists[81], only seven countries have publicly available National Essential Diagnostics Lists (NEDLs) as of late 2025[82–86]. Government procurement of multiplex diagnostics with data connectivity capabilities remains limited, and test-to-treat integration remains isolated rather than systematically embedded across health systems. Accelerating progress requires developing and demonstrating robust health economic rationale for multiplex platforms to support procurement decisions, government commitment to adopting NEDLs, procuring multiplex platforms with data connectivity for routine use, co-developing diagnostics alongside vaccines and therapeutics, and establishing digital infrastructure that enables diagnostic data to inform MCM development and deployment decisions.

MAJOR BARRIERS IN 2025

- **Fragmented financing architecture** creates unsustainable business models, with zero-market dynamics for emerging threats like Ebola, fragmented procurement for endemic diseases like dengue, and dual-market global access challenges for pandemic-potential pathogens. Traditional financing models inadequately support platform technologies requiring extended development timelines and higher upfront investments. Inadequate coordination of surge financing prevents manufacturers from scaling production rapidly during outbreaks.

- **R&D acceleration failures** persist, with chronic underinvestment in diagnostics R&D across public and private sectors. Lack of actionable Target Product Profiles for priority pathogens leaves manufacturers without clear development targets. Delayed access to pathogen sequence data slows assay and test development. Delayed access to pathogen sequence data slows assay and test development. Diagnostics remain weakly integrated with vaccine and therapeutic development pathways, hampering resource-efficient co-development and eroding commercial incentives for diagnostic innovation. Fragmented surveillance and digital infrastructure systems prevent diagnostics from delivering the timely, actionable information essential for outbreak detection and medical countermeasure deployment.

- **Sample access bottlenecks** constrain development, with scarcity of well-characterised specimens, insufficient reference standards, and fragmented validation systems especially problematic for high-containment pathogens and geographically restricted diseases.

- **Regulatory fragmentation** creates duplicative evaluations and extended approval timelines, with a lack of harmonised regulatory frameworks, standards, and evidence requirements across jurisdictions. Many countries lack dedicated diagnostic regulatory pathways. Insufficient regulatory agency capacity to evaluate emerging technologies, paper-based processes, and unpredictable emergency use authorisation requirements disproportionately burden LMIC-focused or small-scale developers, slowing patient access.

- **Manufacturing and supply chain vulnerabilities** leave LMICs behind during emergencies, with over-concentration of production amongst a small number of companies in Asia, Europe, and North America. Regional manufacturers face underinvestment in infrastructure and skilled workforce, raw material bottlenecks, and limited technology transfer mechanisms. Insufficient predictable demand during interpandemic periods prevents facilities from maintaining the capacity needed to pivot rapidly for pandemic response.

- **Limited clinical adoption and policy integration** constrain systematic embedding across health systems. Government procurement of multiplex diagnostics with data connectivity capabilities remains inadequate, driven in part by a lack of a clearly articulated health economic rationale. Without embedding diagnostics in routine healthcare, the field cannot sustain markets between pandemics, generate continuous pathogen monitoring data, or create deployment infrastructure serving both routine care and outbreak response.

- **Coordination failures** lead to duplicative initiatives, critical gaps in information sharing, and inefficient response activation during emergencies. Accelerating progress requires neutral facilitation capable of reducing duplication, systematically addressing gaps, ensuring critical infrastructure receives sustained funding, and establishing systems for collating and sharing data across regions.

PRIORITY ACTIONS FOR 2026

To overcome key barriers to achieving the 100 Days Mission goals, the following actions should be prioritised in 2026. IPPS will work with all partners to support their implementation (see *Annex A* for Planned Partner Commitments and Priority Actions):

Develop coordinated approaches to support diagnostics developers with access to clinical samples, reference panels, and regulatory-aligned evaluation services.

The PABS annex under the WHO Pandemic Agreement should be finalised with technical input by May 2026 to enable rapid specimen mobilisation. Regional evaluation hub models organised by pathogen family and biosafety requirements should be established, building on approaches such as the NIH RADx Tech Innovation Funnel, to provide integrated validation support linking developers to clinical samples, standardised evaluation, regulatory guidance, and manufacturing scale-up assistance. Coordination across regional initiatives should harmonise standards and ensure equitable access to validation infrastructure globally.

Accelerate diagnostic R&D for multiplex platforms embedded in routine care and establish mechanisms for integrated MCM development.

Development of clear TPPs for diagnostics, specifying requirements across diagnostic settings (centralised laboratory testing versus decentralised point-of-care) and use contexts (pre-pandemic surveillance versus pandemic response), is important for informed investment decisions. Investment should prioritise adaptable platforms and multiplex syndromic panels that expand priority pathogen family coverage, serving both routine care and emergency response. Co-development of diagnostics alongside vaccines and therapeutics should begin from the earliest R&D stages to accelerate timelines, strengthen business cases, and integrate diagnostics across the MCM continuum – informing strain selection and therapeutic priorities, serving as trial endpoints, enabling patient stratification, and linking testing to treatment. Pandemic-relevant diagnostics should be embedded in routine healthcare systems to generate continuous pathogen monitoring data for surveillance while sustaining markets and manufacturing capacity between pandemics. Governments should adopt National Essential Diagnostics Lists, procure multiplex platforms with data connectivity for surveillance integration, and implement procurement policies with volume guarantees to support regional manufacturing capacity.

Simplify and harmonise diagnostic regulatory pathways to reduce complexity, cost, and approval timeframes.

Regulators and WHO should expand technical specifications for rapid point-of-care tests beyond SARS-CoV-2 to additional priority pathogens. Regulators and WHO should collaborate through the Global Benchmarking Tool to support regulators to become WHO-Listed Authorities (WLAs) for medical devices, allowing recognition of their approvals. IMDRF and WHO should advance development of an Emergency Use Table of Contents to standardise emergency dossier requirements globally, giving developers clearer targets and enabling faster access across regions. Regulatory authorities should accelerate operationalisation of reliance mechanisms and emergency use listing procedures, adopting digital modernisation, including e-dossiers, electronic labelling and signatures, and common dossier templates. Regional evaluation hubs being established should provide regulatory-aligned validation support to streamline evaluations and generate evidence for WHO prequalification and Emergency Use Listing recognised across jurisdictions.

Strengthen Agile Coordination to Address Critical Ecosystem Gaps.

Enhance neutral coordination mechanisms that reduce duplication across initiatives and systematically address barriers identified in the 2025 gap assessment[72]. Strengthen agile facilitation to ensure critical infrastructure receives sustained funding, enable real-time global data and sample sharing networks, and link pathogen monitoring outputs to biomanufacturing and the diagnostics-therapeutics-vaccines continuum. Modernise how global monitoring systems interact with regional and national systems to generate actionable intelligence for MCM development and deployment decisions.

Diagnostics 2025 Global Gap Assessment

METHODOLOGY

30+ GLOBAL STAKEHOLDER INTERVIEWS

INDUSTRY	FINANCING & PROCUREMENT	REGULATION	RESEARCH & INTERNATIONAL
Altona, Bioaster, Bioclin, bioMérieux, Cepheid, Diatropix, Fiocruz, Global Access Dx, IDEXX, Molbio, Roche, SD Biosensor, Thermo Fisher, Wondfo	AMSP, CEPI, Gates, GHIC, HERA, IFC, MedAccess, Right Foundation, UNICEF	Ghana FDA, Health Canada, MHRA	Brown University Pandemic Center, PATH, UK National Measurement Laboratory, Unitaid

MIXED METHODS APPROACH

- **Structured interviews:** diverse global stakeholders across diagnostic value chain
- **Thematic analysis:** Computational analysis with predefined codes derived from 100DM framework, capturing both archetype-specific and cross-cutting themes
- **Desk research:** Academic literature, FIND PDxRI, DxConnect database, industry reports
- **Recommendations:** Prioritised by frequency, convergence, and feasibility

FINDINGS: CRITICAL BARRIERS

R&D
- Underinvestment
- R&D process & guidance gaps
- Single-pathogen business models
- Delayed access to sequence data
- Sample access bottlenecks

Regulatory Authorisation
- Harmonisation gaps
- Capacity constraints
- Weak emergency pathways
- Lack of modernisation

Manufacturing Distribution | Procurement Surge Capacity
- Concentrated global production
- Underinvestment in regional infrastructure/workforce
- Raw material bottlenecks
- Limited technology transfer

Financing
- Zero-market for emerging threats (e.g. Ebola)
- Fragmented procurement for endemic pathogens (e.g. Dengue)
- Dual-market global access challenges (e.g. H5N1)
- Insufficient tailored financing for Disease X

Cross-Cutting
- Coordination failures
- Limited clinical adoption
- Weak MCM development integration
- Fragmented surveillance and digital infrastructure

RECOMMENDATIONS

ACCELERATE R&D:

Developers, WHO, regulators: Co-develop practical Target Product Profiles for different use cases and outbreak phases

Funders, procurement agencies: Incentivize multiplex panels and modular platform technologies

Public health agencies: Strengthen pathogen sequence data sharing

SECURE SAMPLE ACCESS & VALIDATION:

WHO IGWG (with technical experts, industry): Finalise PABS annex with equitable access terms

Governments, multilateral funders, industry: Establish regional evaluation hubs organised by pathogen family/biosafety level

Standards community: Develop timely, characterised control materials and validation samples

ADVANCE REGULATORY HARMONISATION & MODERNISATION:

WHO, IMDRF, regional bodies, national regulators: Adopt international best practices (WHO Global Model Regulatory Framework, IMDRF standards) for risk-based oversight

WHO, IMDRF, regulators: Develop common dossier templates, standardised evidence requirements, and Emergency Use Table of Contents

Funders, regulators: Implement digital modernisation

BUILD GEO-DIVERSIFIED MANUFACTURING RESILIENCE:

IFIs: Prioritise investments in regional diagnostic manufacturing certified to international

WHO, DFIs, global and regional developers: Establish technology transfer partnership platforms

Regional manufacturers, governments: Invest in supply chain diversification and local reagent manufacturing in LMICs

DEPLOY FIT-FOR-PURPOSE FINANCING MECHANISMS:

DFIs, IFC working capital fund, governments, procurement agencies, private and philanthropic funders: Coordinate to deploy tailored market-specific incentives (advanced market commitments, volume guarantees, stockpiles)

Funders, investors: Shift toward investing in multi-pathogen syndromic panels and portfolio approaches supporting both pandemic response and inter-epidemic viability of platform technologies

DFIs, IFC, financial institutions: Establish surge financing mechanisms for rapid scale-up during outbreaks

STRENGTHEN DIAGNOSTIC ECOSYSTEM COORDINATION:

WHO: Operationalise the Global Diagnostics Coalition with a dedicated pandemic preparedness working group

Developers, funders: Integrate diagnostic development with vaccine and therapeutic pathways where appropriate

Developers, clinicians, economists, end users: Generate health economic evidence to drive adoption and policy prioritization

Governments, partners: Build integrated surveillance networks anchored in strong laboratory systems and real-time data sharing

HIGH-LEVEL NEXT STEPS

1. **Industry-Regulator Convenings.** IPPS and partners will facilitate regulator-industry convenings to advance convergence on dossier standards and emergency use pathways.
2. **Multilateral Engagement.** Strategic engagement with French G7 presidency and G20 Joint Finance and Health Task Force to advance diagnostic-specific financing mechanisms and regulatory harmonisation.
3. **Global Diagnostics Coalition Operationalisation.** Support the WHO Global Diagnostics Coalition's pandemic preparedness activities to coordinate stakeholder efforts across the diagnostic value chain.

Therapeutics R&D

Therapeutics are a core pillar of the 100 Days Mission, providing lifesaving treatment and reducing morbidity and mortality while vaccines are still in development, manufacturing, or deployment. Even when vaccines are available, therapeutics remain essential for immunocompromised populations, for settings where vaccine uptake or availability lags or where accessibility barriers limit coverage, and as pre- and post-exposure prophylaxis during outbreak response.

Yet the global therapeutics ecosystem remains structurally fragile, characterised by a narrow pipeline, chronic underinvestment, and uneven distribution of scientific and manufacturing capacity. Early-stage discovery, translational expertise, regulatory preparedness, clinical trial networks, and surge manufacturing capacity all remain insufficiently coordinated and resourced. These weaknesses constrain both the diversity of candidate therapeutics in development and the speed at which promising candidates can reach patients, undermining the ability to deliver timely, equitable access during outbreaks.

Meeting the 100 Days Mission requires embedding therapeutics development within a continuously functioning, globally distributed R&D and manufacturing system rather than relying on emergency-only mobilisation. Routine investment in novel and existing antiviral and monoclonal antibody platforms strengthens scientific capacity, maintains critical expertise between crises, and enables more rapid transitions from discovery to clinical testing during outbreaks. Integrated MCM development is especially important. Antiviral resistance studies guide companion diagnostic development and inform surveillance priorities. Monoclonal antibody programmes can rapidly deliver some of the first tools to combat a new pathogen in the event of a pandemic, while also generating epitope insights that support vaccine antigen selection. Therapeutics trials depend on diagnostic endpoints and generate real-world evidence that complements vaccine effectiveness data. Better coordination across these domains ensures that new fit-for-purpose treatments reach patients earlier, improves clinical outcomes, and creates incentives that sustain platform innovation and readiness.

The therapeutics ecosystem saw meaningful progress in 2025. Research institutions expanded antiviral and monoclonal antibody portfolios for priority viral families, advanced small-molecule inhibitor programmes, and generated datasets to train AI-driven discovery tools. Regional initiatives strengthened African and Latin American research networks, broadening participation in early-stage R&D. This includes initiatives such as Grand Challenges Africa Drug Discovery Accelerator (GC ADDA), which bring together a network of African research institutions focussed of drug development, spearheaded by H3D Foundation. Investments in rapid, low-cost monoclonal antibody manufacturing improved scalability, whilst regional manufacturing capacity grew through targeted investments in bioequivalence testing, biologics production, and RNA and cell therapy platforms.

The 100 Days Mission for Therapeutics

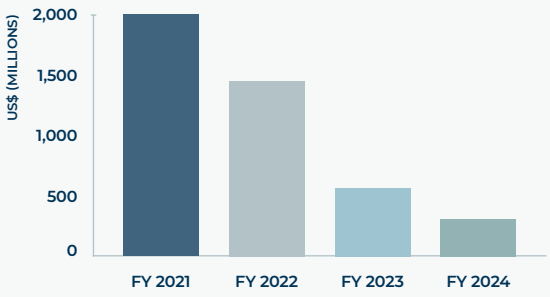
- Ensure sustained R&D funding throughout the development lifecycle.
- Develop at least two ‘phase 2 ready’ therapeutic candidates against the identified viral pathogen families of greatest pandemic potential.
- Develop scientifically rigorous and validated programmable platforms or technologies.

Partnerships between public, philanthropic, and industry actors enhanced access to enabling technologies. Governance structures matured as the Therapeutics Development Coalition moved toward operationalisation and international coordination advanced through alignment with WHO pathogen prioritisation frameworks and collaborative research consortia. These developments mark progress toward a more connected ecosystem capable of supporting rapid discovery, testing, and scaling for future outbreaks. Realising this potential requires sustained financing, modernised regulatory frameworks for platform-based therapeutics, digital infrastructure linking surveillance to drug design, and continued investment in regional capacity to maintain readiness between pandemics.

Funding for therapeutics R&D saw a 39% decline in FY2024, which followed an even bigger – 63% – decline in FY2023. This FY2024 decline was more heavily weighted on drug funding, which halved, however biologics funding was also down by a quarter.

This decline was seen across all pathogens, and while the dollar value of the drop in COVID-19 therapeutics was big (-US$155m), the decline in non-COVID therapeutics was still 31%.

Funding for COVID-19, Ebola and Zika therapeutics were all down around 45%, while CCHF halved, Lassa funding was down 56%, and most concerningly, Chikungunya therapeutic funding was down 95% – to just US$0.5m.



This decline is in large part due to declining US NIH funding (which near halved) and accounts for around half of the overall drop, and industry funding, which was down 71%.

PROGRESS AGAINST 2025 PRIORITY ACTIONS

This section highlights key advances with broad implications for the therapeutics R&D ecosystem and future 100DM readiness. Comprehensive organisation-specific progress updates are available in *Annex A*.

Operationalisation of the Therapeutics Development Coalition

The Therapeutics Development Coalition (TxDC) represents a significant structural innovation in therapeutic R&D for pandemic preparedness, addressing a critical market failure: traditional dynamics do not incentivise sufficient early-stage investment in pathogens with pandemic potential. Throughout 2025, the Coalition – a new way of working across pharmaceutical industry, academia, governments, and international organisations – transitioned from concept to operational design, with partners aligning on inclusive governance structures. An interim Portfolio Committee and Executive Board are being established to guide development of the Coalition's operating model, leveraging existing expertise and initiatives whilst avoiding duplication. Although the Coalition takes an end-to-end approach to therapeutic development, it prioritises early-stage R&D where gaps are most acute and investment needs are greatest.

The Coalition will focus on prioritising research areas of highest impact, potentially starting with two initial viral families as proof-of-concept work while building operational frameworks designed for future expansion. This approach balances the need for rapid demonstration of value with the practical constraints of resource mobilisation and partnership coordination. For more information on the TxDC, see the box below. Encouragingly, the Coalition was highlighted as a key initiative that the European Union (EU) would contribute to as part of the new EU Pandemic Preparedness Strategy[50].

Mapping of pipeline gaps to identify strategic funding opportunities

The International Readiness for Preventing Infectious Viral Disease's (INTREPID) fourth global landscape report published in April 2025[87] confirmed a plateau in new antiviral candidates, reinforcing the need for investment in under-addressed viral families. It highlighted a stagnant pipeline and concentration on SARS-CoV-2. Cumming Global Centre's programmes are helping diversify efforts across viral families[88]. The Pandemic Sciences Institute (PSI) has demonstrated the potential of AI-enabled discovery and low-cost platforms to derisk candidate development[42]. In addition, The INTREPID Alliance launched their Antiviral Toolbox in November 2025[89], an open-access resource including a registry of antiviral compound libraries, drug development tools such as target compound and product profiles, and landscape reports. These mapping outputs are now being used to inform a coordinated funding framework for therapeutics R&D, guiding funders towards the areas with the greatest need and highest potential impact.

Advancement of platform technologies and innovative approaches

Evidence of preclinical proof-of-concept expanded across multiple modalities: VHH antibodies for pandemic influenza, Nipah and dengue mAbs, broad-spectrum small molecules, and AI-enabled drug design. READDI's partnerships and PSI's OpenBind datasets advance computational approaches[42]. The INTREPID Alliance launched the Antiviral Toolbox in November 2025, an open-access resource including a Registry of Antiviral Compound Libraries, drug development tools, and pro bono advisory services to support researchers in accelerating antiviral discovery and development.

At the discovery and preclinical interface, the Cumming Global Centre for Pandemic Therapeutics (CGCPT) accelerated development across antibodies, nanobodies, RNA-based delivery systems, and broad-spectrum antivirals. Over the past year, the Centre advanced antiviral biologics pipelines, developed repositories for promising mAb and nanobody agents, and optimised Fc backbones for pathogen-agnostic use. It progressed broad-spectrum small molecules, including novel aptamer candidates for Hendra and Ebola, neuraminidase inhibitors for respiratory viruses, and antivirals targeting papain-like protease (PLpro). Model system advances included next-generation humanised mouse models and a comprehensive structural biology platform for rapid characterisation of pathogens of pandemic potential[88].

CGCPT's work on immune-modulation platforms aims to prevent secondary infections and target host proteins that regulate viral replication. Using mRNA and siRNA technologies, it is developing host-centric therapeutics and self-amplifying RNA antiviral platforms (SMART), as well as CRISPR Cas13-based therapeutics for respiratory pathogens. The Centre's integrated research model links discovery to translational readiness through a global partnership network spanning over 30 institutions across 10 countries, including co-funded collaborations with the Universities of Bonn and Calgary.

Key enablers of this progress include a AUD250 million philanthropic donation and AUD75 million cornerstone investment from the Victorian Government (in Australia), ensuring long-term research stability. Co-location at the Doherty Institute allows CGCPT to leverage existing infrastructure and global partnerships while directing funds primarily to research outputs rather than capital expenditure[88].

A platform trial programme is evaluating 16 respiratory antiviral regimens across COVID-19 (Platcov), influenza (Ad Astra) and RSV (Arsynal-FC) with over 3,200 participants enrolled across Thailand, Brazil, Laos, Nepal and Pakistan90. Additional readouts include a single-dose, long-lasting influenza candidate showing approximately 76% protection over a full season in 5,000 adults[91,92]; an interferon-alpha nasal spray reducing COVID-19 infections by 40% in adult cancer patients[93]; broad-spectrum small molecules that block viral surface carbohydrate binding in cells and mice; and an AI/open-science-origin coronavirus candidate (ASAP-0017445)[94,95].

The Council for Scientific and Industrial Research (CSIR) completed proof-of-concept process development for several biotherapeutics and is modernising a growing mAb platform with high-producer Chinese Hamster Ovary (CHO) and continuous manufacturing; mpox mAbs are progressing, with collaborations spanning ServareGMP, International Aids Vaccine Initiative (IAVI), Sunflower Therapeutics and the MIT AltHost Consortium (including Pichia and N. benthamiana hosts) to drive lower-cost production[96]. CSIR is pursuing SAHPRA licensure for a Good Manufacturing Practice (GMP) investigational facility and clinical-trial batch production[96]. At the manufacturing level, LifeArc's low-cost mAb Grand Challenge programme and CSIR's continuous bioprocessing drive affordable production, while Unitaid and AMSP translate these advances into regional supply chains. Brazil's Fiocruz and Butantan contribute enabling platforms for RNA and cell-based therapeutics[97,98].

MAJOR BARRIERS IN 2025

- **Technological and manufacturing constraints further inhibit equitable access.** The production of monoclonal antibodies and advanced biologics continues to be capital- and infrastructure-intensive, with limited GMP-compliant facilities in LMICs and high input costs across global supply chains. While innovative low-cost manufacturing pilots show promise, the absence of standardised technology transfer mechanisms and sustainable procurement commitments prevents these models from reaching operational scale.

- **Inadequate incentives for private investment remain a critical constraint.** Traditional market dynamics do not apply to pathogens with pandemic potential, particularly those that circulate episodically or remain quiescent between outbreaks. Without mechanisms such as advance purchase commitments, optimal stockpiling policies, transferable regulatory vouchers, and sustained government and multilateral funding across the value chain from academia to large companies, private sector engagement will remain limited.

- **Reduced funding for therapeutics development,** including cuts for funding for Antiviral Drug Discovery (AviDD) centres funded through the NIH which had approximately US (US$577 million), and were closed in 2025. Although Development Finance Institutions (DFIs) (European Investment Bank, International Finance Corporation, U.S. International Development Finance Corporation) are structuring surge finance facilities for MCM R&D, this is not enough to overcome the current reduction in funding.

- **Insufficient engagement and coordination with experienced industry partners hampers translation** of early research into clinical candidates. Therefore, the translational valley of death remains a problem in therapeutics development. While academic institutions excel at fundamental discovery, pharmaceutical companies possess critical expertise in medicinal chemistry, formulation, toxicology, clinical trial design, regulatory strategy, and manufacturing at scale.

PRIORITY ACTIONS FOR 2026

To overcome key barriers to achieving the 100 Days Mission goals, the following actions should be prioritised in 2026. IPPS will work with all partners to support their implementation (see *Annex A* for Planned Partner Commitments and Priority Actions):

- **Operationalise the Therapeutics Development Coalition with focused proof-of-concept projects, guided by the interim governance structure.**

  The Coalition aims to bring together a network of existing partners and stakeholders, to better align and coordinate Tx development, capacity and funding efforts. Throughout 2026, the Coalition should support proof-of-concept projects developed for two initial priority viral families aligned with WHO pathogen prioritisation framework, to support advancement of candidates through preclinical validation and early clinical stages. It should also seek to establish a longer term governance structure by the end of 2026. This work should demonstrate the value of partnership-based risk-sharing models while building operational frameworks that can be expanded to additional viral families.

- **Diversify and sustain financing through blended models that combine public, philanthropic, and private investment to fund translational R&D,**

  considering a range of derisking approaches and financing for different market archetypes. These initiatives should also be geo-diversified.

- **Promote responsible innovation through sustained investment in platform technologies and equitable access frameworks.**

  Provide sustained funding for adaptable technologies, such as cross-reactive monoclonal antibodies, nucleic acid delivery systems, and AI-enabled drug discovery to accelerate therapeutic development across viral families. Efforts should integrate open data sharing, transparent licensing, and regional manufacturing capacity to ensure that innovation translates into timely, affordable access. Embedding equity and accountability within these platforms will turn technological speed into sustainable, globally shared readiness.

Therapeutics Development Coalition

This year, the focus has been on bringing together multisectoral public-private partners to support the operationalisation of the Therapeutics Development Coalition (TxDC), over the course of the year **we have agreed on an operating model and key functions for the Therapeutics Development Coalition, which will focus on:**

1. **Advocacy and political engagement** to highlight the urgent need for Tx development
2. **Landscaping antiviral R&D** to identify gaps and opportunities for high impact investment
3. **Connecting funders and developers** to collectively address identified research gaps
4. **Developer support** through shared resources and collaborative infrastructure
5. **Embedding access** throughout the entire therapeutics' development process, and not just as an afterthought, in line with the WHO Pandemic Agreement.

This work builds on the foundation laid by 100 Days Mission partners including Unitaid, Drugs for Neglected Diseases initiative (DNDi), Rapidly Emerging Antiviral Drug Development Initiative (READDI), the INTREPID Alliance, Medicines Patent Pool (MPP), WHO, and International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) working with IPPS, following the publication of the 100DM Therapeutics Roadmap in 2024.

To support preparations for the operationalisation of the TxDC over the past year and ensure transparency and accountability in decision making for shaping the TxDC, **an interim governance structure has been established,** comprising of an interim Portfolio Committee and Interim executive board, comprising of representatives from across industry, academia, government, intergovernmental organisations, biotech, and different regions globally.

The gaps in therapeutic products pipeline, and the need for robust public-private partnership to address these gaps was also highlighted and agreed at the G20 level, most recently in the Chair's statement concluding South Africa's G20 presidency.

The Therapeutics Development Coalition has been highlighted by the EU as one of the initiatives the EU Medical Countermeasures Strategy aims to contribute to[50].

Vaccines R&D

Vaccines R&D remains the MCM area with the largest clinical pipelines and broadest platform diversity built through decades of multilateral collaboration and investment. Yet persistent vulnerabilities continue to constrain readiness: funding volatility, late-stage pipeline bottlenecks, regulatory pathway gaps, manufacturing capacity constraints, and insufficient portfolio diversity[99]. Political shifts and growing vaccine hesitancy are narrowing funding streams, with recent cuts to next-generation coronavirus and RNA platform programmes exposing near-term risks to pipeline breadth and sustainability[100]. Reliance on a small number of funders and catalysers is a vulnerability, particularly as U.S. investments contract, and major partners enter new strategic cycles (e.g., CEPI 3.0 in 2027). Collective responsibility across governments, industry, and philanthropy will be essential to sustain preparedness, diversify financing, and maintain end-to-end support – including late-stage R&D – across a range of platform technologies suited to different pathogens and populations.

Vaccine research also generates foundational immunological insights that accelerate development across diagnostics and therapeutics. Vaccine trials establish correlates of protection that inform therapeutic antibody target selection and guide diagnostic biomarker identification. Epitope mapping from vaccine immunogen design identifies conserved antigenic targets applicable to both diagnostic assay development and therapeutic antibody engineering. Vaccine trials also produce well-characterised immunological specimens from vaccinated individuals that serve as essential reference materials for diagnostic validation and provide proof-of-concept data on protective immune mechanisms. Progress on vaccines, meanwhile, remains closely interdependent with advances in diagnostics and surveillance (See *Chapter 2, Diagnostics R&D*), making early integration of companion diagnostic considerations essential for trial readiness and evaluation.

The 100 Days Mission for vaccines

- **Development of prototype vaccine libraries** for priority viral families, supported by geographically anchored capabilities that allow rapid vaccine development in response to new or emerging disease threats.
- **Availability of programmable vaccine platform technologies** that can be quickly repurposed to respond to a potential Disease X threat, with capability to rapidly scale equitable production.
- **Optimisation of vaccine platforms and of capacities to support both clinical development and outbreak response** – including equitable availability of investigational materials for clinical trials and scalable manufacturing capacity for licensed vaccines. Compliance with WHO TPPs remain a key measure. Access requires an end-to-end approach, including regionally owned and sustained capabilities that span the vaccine development value chain.

The scientific foundation to achieve the 100 Days Mission for vaccines exists, but translating this into real-world capabilities requires integrated operational readiness. Progress depends on tackling systemic barriers: diversifying financing to sustain interpandemic development, strengthening regulatory pathways that enable candidate progression outside outbreaks, and maintaining sustainable geo-diversified manufacturing models that balance routine production with surge capacity. While this section focuses on vaccines R&D, broader manufacturing progress is covered separately (see *Chapter 3, Geo-Diversified Manufacturing*). In 2025, candidate progression advanced across several high-priority viral families and adaptable platforms, supported by stronger international coordination at the viral-family level and regional regulatory harmonisation (see *Chapter 3, Regulatory Systems*). A global vaccine library – an accessible repository of prototype vaccine candidates, data, and platform constructs – remains a key enabling concept to shorten timelines for emerging pathogen response. Alignment among stakeholders on its design and governance will be essential to ensure continued progress and equitable access.

AI-driven tools (see *Chapter 2, Synergies Across Development of Diagnostics, Therapeutics and Vaccines; Spotlight: AI*) are beginning to reshape end-to-end vaccine development from immunogen and formulation design to clinical optimisation and real-time manufacturing oversight, but safe and responsible integration alongside robust data-governance frameworks will determine whether these innovations accelerate or hinder 100 Days Mission timelines[101].

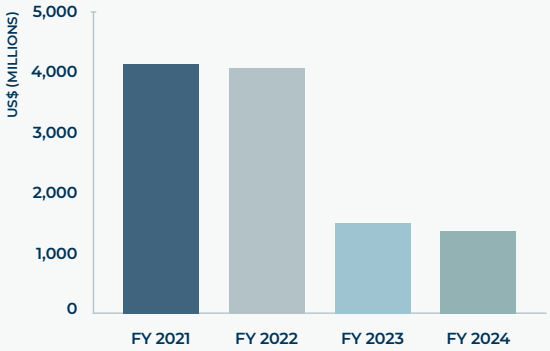
Political shifts and growing vaccine hesitancy are narrowing funding streams, with recent cuts to next-generation coronavirus and RNA platform programmes exposing near-term risks to pipeline breadth and sustainability.

Overall vaccine R&D funding remained relatively stable, declining by 8%. However, there was much more movement when looking at individual pathogens and funders.

COVID-19 vaccine funding remained relatively stable (down 9%), while Chikungunya (-79%), MERS (-44%), Zika (-38%), Marburg (-32%) and Ebola (-25%) all had much more significant declines.

This was balanced out by increases in other pathogen's vaccine funding, with Mpox funding more than doubling (up US$20m) and increases across all other remaining pathogens.

Similarly, looking at funders of vaccine R&D, a $342m drop in funding from industry was offset by a similarly sized increase in funding from the US BARDA (up US$382m).



PROGRESS AGAINST 2025 PRIORITY ACTIONS

This section highlights key advances with broad implications for the vaccines R&D ecosystem and future 100DM readiness. Comprehensive organisation-specific progress updates are available in *Annex A*.

Advancing clinical development of vaccine candidates for priority viral families

- **Pipeline progress:** vaccine development for priority viral families advanced in 2025, reinforcing progress toward a global vaccine library – an accessible repository of prototype candidates and data adaptable for novel pathogens. Coordination at the viral-family level through the WHO pathogen prioritisation framework and emerging CORCs is improving evidence sharing and derisking development. Notable milestones include Rift Valley fever and Nipah vaccines entering phase 1 trials, MERS and Lassa fever vaccines progressing to phase 2[45], the world's first phase 2 Nipah vaccine trial[102], and the first chikungunya vaccine to receive licensure in an endemic country[103]. During the mpox public health emergency, CEPI and partners launched a real-world study of the LC16m8 vaccine in the Democratic Republic of the Congo (DRC)[104], complementing Jynneos trials in young children[105], while WHO coordinated delivery of over 1.8 million doses to 15 African countries through the i-MCM Net Access and Allocation Mechanism (AAM)[106].

  CEPI's portfolio includes R&D and manufacturing projects that intersect with 13 viral families, with candidates advancing through phase 2 and prototype work under way on broadly protective coronavirus and Disease X vaccines[107]. Complementary efforts by the Pandemic Sciences Institute and Serum Institute of India, a member of the Developing Countries Vaccine Manufacturers Network (DCVMN) are expanding the ChAdOx1 platform across multiple high threat pathogens[42], while other members have been working on mpox and H5N1 candidates on MVA, mRNA, and protein platforms[108]. Moderna's phase 1/2 trials for mpox and pandemic influenza vaccines demonstrated potent, durable immune responses[109]. Collectively, these initiatives are strengthening regional innovation capacity and contributing knowledge to a global vaccine library.

- **Enabling science:** infrastructure for standardised evaluation and data sharing expanded through CEPI's Centralised Laboratory Network, with a database linking developers, national authorities, and surveillance partners for secure data exchange[45]. Research on immunological CoPs advanced with Wellcome and CEPI launching the Framework for the Evaluation of Early Vaccine Evidence (FEEVA) to support regulatory use of early efficacy data[110], PATH developing "playbooks" to guide CoP application in product development and regulatory decisions[16], and the Ellison Institute and University of Oxford applying AI to predict CoP using human challenge models[111].

  As prototype vaccine candidates progress, they generate data on antigen design, platform performance, and formulation that could underpin a global vaccine library. Systematic integration of these data through responsible AI tools, such as CEPI's AI-enabled Pandemic Preparedness engine concept[53] and Moderna's mRNA Access program[109] could optimise future vaccine design and accelerate safe development (see *Chapter 2, AI Spotlight*). Despite momentum, late-stage development remains under-resourced, especially for pathogens not actively circulating. Sustained, multi-phase financing and adaptive regulatory pathways will be essential to ensure promising candidates advance to licensure and contribute to a functional global vaccine library.

Sustaining investment in diverse vaccine platform technologies

Efforts to diversify vaccine platform technologies advanced across RNA, protein, viral vector, traditional and novel production modalities, though greater focus is needed on equitable, scalable technologies that can progress from proof-of-concept to sustainable deployment. In this context, vaccine-related platform technologies include both product and process innovation – spanning viral vector and nucleic acid platforms, as well as cross-cutting advances such as thermostabilisation and novel administration methods like microarray patches[112].

CEPI advanced next-generation technologies that could accelerate development of safe and effective vaccines for rapidly mutating pathogens, including nanoparticle[113], epitope-focusing[114], and bacterial-based mucosal platforms[115]. Complementary formulation and delivery innovations, such as thermostable and spray-dried mRNA vaccines[116,117], single-shot controlled-release formulations[118], and needle-free microarray patches[119], aim to overcome cold-chain and dosing constraints to improve equitable deployment. CEPI also launched a Platform Readiness Dashboard[120] to guide coordinated investment and identify capability gaps critical for 100DM readiness (see *Chapter 2, Spotlight: Platform Technology Innovation and Readiness*), and established the first adjuvant library, hosted by the UK UK Medicines and Healthcare products Regulatory Agency (MHRA), to accelerate development of more potent outbreak vaccines through targeted vaccine-adjuvant matchmaking[121]. Moderna added three Moderna-built and managed facilities in the UK, Canada and Australia[122]. In parallel, the European Commission launched a call to accelerate the development of next-generation influenza vaccines leveraging scalable platforms and novel administration routes[123].

Regional initiatives strengthened rapid response platforms tailored to local epidemiological and operational needs, with growing emphasis on South–South collaboration to expand vaccine development capacity. The WHO/MPP mRNA Technology Transfer Programme prepared to launch Phase 2.0, enabling LMIC manufacturers to scale GMP-grade mRNA production[124]. Within the hub, Afrigen and partners advanced mRNA vaccines for mpox, Rift Valley fever[125], and H5N1, transferring technology to 11 regional partners[126,127]. PATH advanced mRNA process optimisation using AI and led an RNA Network consortium in Africa[79]. Brazil's Fiocruz expanded RNA-based innovation through partnerships with Birmex, Pasteur and Sanofi, Quantoom, and PATH[98]. In Asia, Japan's SCARDA is establishing facilities capable of shifting from biopharmaceuticals to emergency vaccine production by 2028[128], while Indonesia's Bio Farma is developing mRNA and viral vector manufacturing capabilities[129], and Malaysia's Institute for Medical Research initiated early-stage mRNA and inactivated vaccine programmes[130]. Collectively, these initiatives are catalysing end-to-end regional ecosystems spanning R&D, regulatory capacity, and skilled workforce development.

Platform diversification continues to improve, but readiness remains uneven. The most advanced platforms are not always best suited for an equitable 100DM response due to supply-chain, dosing, and manufacturing limitations. Many innovations with strong access potential, such as thermostable or single-dose formulations, remain in preclinical stages and require sustained, risk-tolerant investment to reach phase 1 readiness. Balancing near-term platform readiness with long-term equity-oriented innovation remains a priority for 2026.

Identifying investment gaps in vaccine candidates and platform technologies

Progress in 2025 was limited toward systematically identifying and addressing investment gaps across vaccine candidates and platforms around which philanthropic, public, industrial, and other funders can coalesce to advance the most promising technologies into clinical development. To support this effort, CEPI is mapping vaccine candidates in development for priority and emerging pathogens[131], providing an initial foundation to guide their future funding toward the greatest gaps and opportunities. Strengthening coordination among major funders and partners remains a priority for 2026.

Establishing and implementing economic risk-sharing models to sustain vaccine manufacturing capacity

Incremental progress was made toward building risk-sharing frameworks to sustain geographically distributed manufacturing while maintaining commercial viability across market conditions. Building on regional technology transfer initiatives like WHO/MPP's mRNA Tech Transfer programme, new models are emerging to maintain manufacturing capacity. R3 Global, supported by Wellcome Leap, CEPI, and partners including Singapore and the UK Governments, is developing a globally distributed network of biofoundries and an equitable brokerage model for production allocation, establishing an economically sustainable RNA manufacturing platform capable of pivoting between routine biologics and pandemic response across diverse scales, with initial demonstrations in COVID-19 and rabies vaccines, and Cancer and Covid therapeutic antibodies that have progressed through pre-Investigational New Drug (IND) approvals[132,133]. In Europe, HERA launched the European Vaccine Hub to accelerate preclinical to phase 2 development and public-private partnerships to bridge early R&D and clinical translation of prototype vaccines, with similar pilot models planned for diagnostics in 2026 and therapeutics in 2027[50]. In Singapore, Wellcome and MSD invested in Hilleman Laboratories to de-risk low-cost, thermostable vaccines for LMICs, including technology transfer of a next-generation Ebola Zaire vaccine, establishing a dual-use facility that supports early-stage R&D between outbreaks while maintaining capacity to pivot for emergency manufacturing during crises[134].

New market-shaping initiatives focused on strengthening predictable demand and sustainable procurement pathways for outbreak vaccines. Gavi's decision to establish a global mpox vaccine stockpile to be launched in 2026 alongside a market-shaping roadmap, is an important step toward predictable demand and surge capacity for outbreak vaccines[135]. In Africa, AMSP aligned its procurement approach with Africa Centre for Disease Control and Prevention's (AfCDC) Platform for Harmonized African Health Product Manufacturing (PHAHM) framework to strengthen pooled procurement and create predictable demand for regionally manufactured vaccines[136]. Developing durable, economically viable models that maintain capacity between emergencies and ensure equitable access will be critical for 2026.

MAJOR BARRIERS IN 2025

- **Funding volatility and concentration** continue to undermine long-term vaccine R&D, with reductions in Official Development Assistance and shifting national priorities constraining budgets across major funders. The termination of multiple NIH-supported programmes for next-generation coronavirus vaccines[137] and RNA platform technologies[100], many of which could be adapted for other high-risk pathogens, highlights the near-term risk to pipeline diversity and sustainability. Broader diversification of financing, including greater participation from emerging economies, public–private partnerships, venture capital mechanisms, and pooled regional investments, is essential to sustain R&D and reduce dependence on a small number of dominant donors.

- **Regulatory capacity remains uneven.** Many LMIC authorities lack the resources and mechanisms for rapid review and emergency authorisation, delaying progression from preclinical to clinical stages and hindering regional trial implementation. Dedicated resourcing and greater regional harmonisation are needed to close these gaps (see *Chapter 3, Regulatory Systems*).

- **Manufacturing and supply-chain constraints persist,** with LMIC manufacturers facing long lead times for critical inputs such as enzymes, lipids, and single-use bioprocessing materials. Expanding local or regional production of raw materials and scalable GMP capacity, particularly in Africa, remains a priority (see *Chapter 3, Geo-Diversified Manufacturing*).

- **Vaccine hesitancy and misinformation continue to erode public trust,** undermining pull incentives for licensed vaccines and discouraging reinvestment in R&D[138].

PRIORITY ACTIONS FOR 2026

To overcome key barriers to achieving the 100 Days Mission goals, the following actions should be prioritised in 2026. IPPS will work with all partners to support their implementation (see *Annex A* for Planned Partner Commitments and Priority Actions):

- **Expand the global vaccine library through diversified investment and coordinated development.**

  Address critical gaps in the clinical pipeline by advancing the global vaccine library as a coordinated, multi-partner mechanism for vaccine development across priority viral families. The library approach should be supported by diversified financing to reduce reliance on a small number of funders and catalysers, with CEPI, WHO (through CORCs), national governments, and philanthropic and private-sector funders expanding milestone-based models that advance both broadly protective and viral-family-specific candidates toward preclinical and investigational milestones. Clear data-sharing mechanisms – defining access, curation, and ownership of antigen and sequence data – will be essential to ensure equitable global use. Improving visibility and coordination of R&D investments, including shared tracking of pipeline data and platform readiness, can help align funders around common priorities. Progress can be further accelerated through AI-enabled tools to prioritise viral families, optimise antigen and clinical trial design, and analyse immunogenicity, safety data, and immune correlates of protection.

- **Accelerate regulatory innovation beyond outbreak contexts.**

  WHO, regional (e.g., AMA, EMA) and national regulatory authorities, supported by CEPI and other implementing partners, should operationalise frameworks for correlates of protection, immunobridging, and animal rule pathways to enable accelerated licensure for priority vaccines. Strengthening regulatory convergence and secure data-sharing across regional networks will help validate innovative approaches, reduce duplication, and enable faster approvals while maintaining safety and quality standards.

- **Strengthen and diversify vaccine platform technology and manufacturing innovations for scalable, equitable pandemic response.**

  CEPI, PATH, DCVMN, the WHO/MPP Technology Transfer Programme, national R&D agencies, and developers should harness innovative technologies – such as microfluidics, continuous-flow manufacturing, and targeted delivery platforms – and responsible AI tools to design immunogens and identify platform–pathogen pairings that elicit optimal immune responses for diverse settings. Efforts should promote platform technology innovations, including mucosal and needle-free delivery systems and expanded access to adjuvants, to improve reach, acceptance, efficacy and durability across all settings. Funders and developers should align around a framework that balances near-term platform readiness with long-term equity-oriented innovation maturity and integrates these advances into distributed manufacturing initiatives (e.g. RVMC, G20 Coalition) to ensure sustainable and equitable access (see *Chapter 3, Geo-Diversified Manufacturing*).

- **Build vaccine confidence through transparency and engagement on safety and quality.**

  Public trust is essential to the success of the 100 Days Mission, which is grounded in the "marathon of preparedness" – the work done between outbreaks to ensure that within 100 days of a PHEIC being declared, safe, effective, and affordable medical countermeasures are ready for scaling. Clear communication that speed does not compromise safety or quality will be critical to building confidence in vaccines, platforms, and R&D processes. IPPS, working with WHO, national health authorities, developers, regulators, and funders, should strengthen transparency around 100 Days Mission messaging, clearly explaining how accelerated R&D maintains rigorous standards and places safety and efficacy at its core. Regional clinical trial networks can also serve as trusted platforms to engage stakeholders early in R&D and regulatory planning, reinforcing confidence and equitable uptake during emergencies.

SPOTLIGHT

Platform Technology Innovation and Readiness

Vaccine platform technologies are central to the 100 Days Mission because **they provide adaptable backbones that can be rapidly customised for new pathogens.** Regulatory bodies broadly define platforms as technologies built on standardised manufacturing processes, analytical methods and common backbones that preserve predictable structure-function relationships, particularly for nucleic acid, viral-vectored and subunit vaccines[120]. These shared characteristics allow regulators and developers to leverage prior knowledge, accelerating authorisation and manufacturing scale-up.

Meeting 100DM goals requires balancing platform maturity with suitability for outbreak use. CEPI's Platform Readiness Dashboard provides a structured assessment across six categories: adaptability, compatibility, suitability, regulatory familiarity, manufacturing and facility readiness[120]. The analysis shows that no platform is suited to all scenarios, reinforcing the need for a diverse portfolio of rapid response technologies matched to pathogen family, population needs and operational constraints such as administration route, boosting schedule, stability, cost of goods, and manufacturing readiness.

CASE STUDY: RNA

Although RNA platforms are not suitable for all pathogen types or outbreak scenarios, they remain a key rapid response technology, demonstrated by their strong safety, high efficacy and unprecedented development speed against SARS-CoV-2. Recent U.S. funding cuts to RNA programmes risk undermining preparedness at a time when the U.S. remains the dominant driver of global mRNA development, accounting for 72% of candidates in clinical development and raising concerns about future pipeline resilience[139,140].

At the same time, global investment and coordination signal the emergence of more geographically distributed capabilities. The WHO–MPP mRNA Programme has transferred technology to 11 LMIC partners and is moving into sustainability planning and development of regionally relevant pipelines[141]. R3 Global is establishing a distributed, scale-independent RNA manufacturing network supported by an equitable brokerage model, with the UK and Singapore as initial hubs within the emerging global biofoundry system[132,133]. The model integrates continuous flow manufacturing to reduce time and cost, alongside machine learning tools to optimise manufacturability, lowering the footprint and investment needed to build regional RNA capacity. It also focuses on economic and operational sustainability – a critical feature of platform technologies more broadly – enabling facilities to pivot between routine biologics and pandemic response through a therapeutic area-agnostic strategy that can scale up or down to meet local, regional, or global needs. Economic viability between outbreaks is essential, supported by balanced portfolios spanning oncology and infectious disease products that keep facilities operational.

FORWARD LOOK

Regulatory flexibility will be key to improving platform readiness, including the development of platform master files and wider use of platform-based guidance. Given that no platform is optimal for all outbreak scenarios, sustained investment in a diverse portfolio of platform technologies remains essential. As platform data accumulate, they can contribute to a global vaccine library to guide future platform selection and design (see *Chapter 2, Vaccines R&D*). Sustaining public confidence, including through targeted engagement to address misinformation will be essential to ensuring both uptake and trust in rapid response platforms.

CHAPTER 3

Embedding best practice between pandemics

Clinical Trials

CLINICAL TRIAL CAPACITY is an essential enabler of the 100 Days Mission, determining whether promising diagnostics, therapeutics, and vaccines can progress from research concepts to approved products deployed at scale.

Furthermore, **clinical trials are an indicator for innovation** and consequently a predictor of access to innovative therapies essential for 100DM preparedness. In 2025, efforts focused on strengthening clinical trial systems to support both routine and emergency needs, ensuring long-term sustainability while building readiness for rapid activation during outbreaks. Notable progress was achieved through the establishment of regional trial networks, establishment of reliance networks, enhanced cross-sector coordination, and the development of emergency trial frameworks.

Despite these gains, persistent challenges remain. Many networks are under-resourced, with inadequate human resources and digital infrastructure to support multi-country studies. Weak data governance, limited interoperability between platforms, and underinvestment in workforce development threaten to erode capacity between outbreaks. Achieving the 100 Days Mission will therefore require sustained political and financial commitment to maintain functional, trusted, and efficient clinical trial ecosystems worldwide.

PROGRESS AGAINST 2025 PRIORITY ACTIONS

This section highlights key advances with broad implications for the clinical trials ecosystem and future 100DM readiness. Comprehensive organisation-specific progress updates are available in *Annex A*.

Fostering Greater Network Convergence and Integration

The drive to integrate global and regional trial networks accelerated through initiatives under GloPID-R, Africa CDC, and WHO's R&D Blueprint. CEPI's research preparedness program (which supports countries in their ability to generate evidence in future outbreaks for any pathogen with epidemic/pandemic potential) expanded to East and Central Africa[142]. Regional consortia expanded multi-country site networks capable of hosting disease-agnostic, multi-functional trials adaptable to emerging pathogens. In Africa, clinical research platforms originally established for COVID-19 and Ebola were repurposed for mpox and other priority diseases.

Efforts to connect these networks with manufacturing and data-governance initiatives are improving readiness for future emergencies. Airfinity's epidemic forecasting models, which incorporate climatic variables to predict disease incidence and optimise trial recruitment, demonstrate how data-driven approaches can accelerate study activation[140]. However, sustained investment in human capital and digital infrastructure remains necessary to ensure that expanded networks can conduct large-scale, multi-phase studies efficiently.

Developing Clear Guidelines for Emergency Trials

WHO strengthened trial governance through the Global Action Plan for Clinical Trial Ecosystem Strengthening (GAP-CTS) released in April 2025[143] and the Global Clinical Trials Forum (GCTF) launched in October 2025[144]. The GAP-CTS serves as an implementation tool to make global clinical trial ecosystems more efficient, inclusive, and responsive to public health needs. It outlines nine priority actions to improve how clinical trials are funded, designed, approved, conducted, and reported. The GCTF is a multi-stakeholder platform supporting implementation of the GAP-CTS and WHO's Guidance for Best Practices for Clinical Trials. Together, these implementation tools support the adoption of new best practice guidance, enabling a common regulatory framework that facilitates better quality, streamlined trials – including in emergency settings.

Africa CDC and partners are adapting these guidelines for regional application through the Public Health Emergency Operations and Trials Framework, ensuring that national regulatory authorities and ethics committees can accelerate authorisation while safeguarding participant protection.

Adopting Preparatory and Innovative Approaches

Preparatory approaches advanced in 2025 through joint initiatives between WHO, CEPI, and trial networks to pilot master trial protocols, flexible designs for priority pathogens, and pre-authorised platforms. There were also several initiatives to increase investment to strengthen clinical trials globally. These mechanisms would enable immediate study initiation upon outbreak detection by pre-approving protocols that can be rapidly activated.

WHO advanced normative guidance on including pregnant, lactating, and immunocompromised populations in clinical trials[145] addressing historical exclusion of vulnerable populations from research. CEPI supported Jynneos mpox vaccine trials in young children and pregnant women[45], while the mpox GECIVO project includes pregnant and breastfeeding women in clinical characterisation studies[134], demonstrating progress toward more inclusive trial design.

Joint clinical-trial monitoring and continent-wide pharmacovigilance systems are being developed in collaboration with AMA, WHO, Africa CDC, and national regulatory authorities, supporting real-time data exchange and safety oversight. CEPI is supporting multiple vaccine safety and pharmacovigilance initiatives to ensure generation of robust safety evidence, to enable timely benefit-risk assessment of vaccines and accelerate their development and deployment[146].

GloPID-R in association with EDCTP recently launched the Global Research Improving Pandemic Preparedness (GRIPP) call worth up to 2 million euros to fund projects that strengthen clinical trial sites in LMICs, supporting the implementation of three of the actions outlined by the World Health Organization's Global Action Plan for Clinical Trial Ecosystem Strengthening (GAP-CTS)[147]. In addition, in September 2025, some of the largest funders of medical research committed through the signature of a joint statement, to implement WHO standards to strengthen clinical trial systems and ensure that research better serves patients and communities[148].

MAJOR BARRIERS IN 2025

- **Under-resourced clinical-trial networks:** Many networks lack sustained funding between pandemics, threatening rapid mobilisation when new outbreaks arise. Without stable financing, the hard-won capacity and expertise built through these initiatives could erode during interpandemic periods when political attention and resources shift elsewhere.

- **Limited preparedness for data sharing and trial transparency:** Clinical-trial data governance, safety-monitoring systems, laboratory capacity, and digital AI tools remain inconsistent across regions. These gaps delay data exchange, increase costs, and undermine trust in trial outcomes.

- **Human-resource and infrastructure gaps:** Shortages of trained data managers, trial statisticians, and technical specialists limit readiness to implement complex or adaptive study designs.

- **Limited expertise:** There is limited expertise to support regulatory and/or ethical oversight of clinical trials, especially for novel and complex trial designs such as adaptive platforms, novel therapies such as cell, tissue, genetic and advanced therapies.

- **Fragmented coordination:** Despite progress, interoperability between regional and global networks remains limited, constraining large-scale deployment and slowing activation during health emergencies.

- **Insufficient local and regional trial leadership:** Trial infrastructure remains heavily dependent on external institutions and stakeholders, limiting sustainable regional capacity for emergency response.

PRIORITY ACTIONS FOR 2026

Operationalise Regional Trial Networks and Shared Governance:

Strengthen regionally-led trial networks by establishing disease-agnostic consortia with shared governance across Africa CDC, Pan American Health Organization (PAHO), and ASEAN partners. This should be complemented by interoperable data-exchange platforms that connect regional and global research sites, enabling real-time evidence synthesis and coordinated trial activation during emergencies.

Scale Preparatory Trial Innovations:

Accelerate the uptake of pre-approved master protocols and adaptable trial designs for priority pathogens would allow studies to begin immediately after detection of a pathogen. This includes advancing inclusive trial designs that systematically incorporate pregnant, lactating, and immunocompromised populations, as well as children, from the outset. Creating interoperable data-sharing standards that link regulators, ethics committees, and developers in real time – while safeguarding participant information – further strengthens preparedness.

Ensure Sustainable Financing and Workforce Development:

Establish pooled financing mechanism led by development finance institution partners to maintain interpandemic clinical-trial capacity. This should also involve investing in regional training initiatives through Africa CDC, PAHO, and WHO Academy to develop skilled trial coordinators, data managers, regulatory, and ethics reviewers capable of supporting rapid activation during emergencies.

Regulatory Systems

REGULATORY SYSTEMS ARE CRITICAL TO THE 100DM, determining how swiftly promising health tools progress from research to approved, deployable products. In 2025, efforts focused on strengthening regulatory agility and harmonisation across regions while embedding sustainability into these systems.

Major advances were achieved through regional reliance models, continental frameworks, and inter-regional collaboration, notably through the operationalisation of the AMA, the establishment of similar frameworks in Latin America and Asia Pacific, and enhanced coordination among global regulatory authorities.

However, persistent fragmentation, uneven capacity, and funding instability continue to limit effectiveness. Many national regulatory authorities lack the regulatory science, technical and digital infrastructure to assess complex medical countermeasures, while shortages of trained personnel in biostatistics, clinical trial evaluation, and advanced therapies constrain throughput. Achieving the 100 Days Mission requires not only regulatory agility but also sustained financial commitment to system strengthening and workforce development.

PROGRESS AGAINST 2025 PRIORITY ACTIONS

This section highlights key advances with broad implications for the regulatory ecosystem and future 100DM readiness. Comprehensive organisation-specific progress updates are available in *Annex A*.

Strengthening Regional and Global Harmonisation

The operationalisation of AMA marked a milestone in continental oversight, integrating African Vaccine Regulatory Forum (AVAREF) as a Technical Committee and creating a network of 48 trained reviewers across 16 member countries. The AMRH initiative, initially established in 2009 to support regulatory harmonisation in Africa, was officially transitioned into the AMA, at the final AMRH conference. This unified framework supports joint scientific advice, clinical trial applications reviews, reliance models, and harmonised post-market surveillance, significantly shortening review timelines. Similar convergence initiatives are advancing globally through the Pan-American Network for Drug Regulatory Harmonization (PANDRH) and the ASEAN Joint Assessment Procedure, reflecting a global movement toward cross-regional alignment. WHO continues to provide technical assistance to help national authorities implement reliance and joint review models, fostering shared standards.

Advancing Innovation in Regulatory Practice and Governance

The UK Medicines and Healthcare products Regulatory Agency (MHRA) finalised – The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 – coming into force in April 2026, to accelerate approvals through notifiable pathways and reliance on trusted foreign authorisations[149]. Within the ACCESS Consortium (MHRA, TGA, Swissmedic, Singapore's HSA, and Health Canada), regulators are developing digital systems for shared assessments and international reliance, streamlining review processes while maintaining high safety standards[150].

In parallel, the UK published new post-market surveillance legislation for medical devices that enhances oversight and aligns Great Britain's classification system with the International Medical Device Regulators Forum (IMDRF), strengthening global harmonisation[34]. The WHO Pandemic Accord negotiations advanced through the Intergovernmental Negotiating Body, culminating in the creation of an Intergovernmental Working Group on Pathogen Access and Benefit-Sharing (PABS), which seeks to establish a legal foundation for transparent data and sample sharing.

Adopting Preparatory Regulatory Approaches

Preparatory mechanisms gained momentum through joint initiatives between WHO, CEPI, and regulatory networks to pilot platform technology master files and cloud-based data-sharing systems for medical countermeasures. CEPI's collaboration with the Accumulus Synergy platform, currently in a major pilot with 19 regulators, enables multi-country submissions and parallel review, and multilingual submissions through AI-facilitated translation to boost transparency and collaboration[151]. In Africa, continent-wide pharmacovigilance systems are being developed with AMA, Africa CDC, and national authorities to enhance real-time safety monitoring and data exchange.

Promoting Regulatory Equity and Inter-Regional Recognition

Advancing global regulatory equity remained a core objective in 2025. WHO's Global Benchmarking Tool continues to guide countries toward Maturity Level 3 regulatory capabilities, while twinning initiatives between mature and emerging agencies help accelerate progress. Africa CDC and Unitaid strengthened collaboration through a 2025 Memorandum of Understanding aligning regulatory, financing, and clinical research capacity, enabling health tools to be designed, tested, and produced within Africa[80,152]. Meanwhile, Unitaid, the Medicines Patent Pool, and major procurement agencies engaged in discussions to recognise approvals from qualified regulatory authorities meeting rigorous safety and quality standards, enhancing market incentives for regional manufacturers[80].

MAJOR BARRIERS IN 2025

- **Fragmented regulatory frameworks:** Regulatory systems remain misaligned, with uneven capacity to implement reliance and mutual-recognition mechanisms. Twenty-four African Union Member States have yet to ratify the AMA Treaty, creating uneven participation in harmonised processes.

- **Insufficient regulatory workforce capacity:** Shortages of trained regulatory scientists, clinical-trial assessors, GMP-facility assessors, and product reviewers – particularly in advanced technologies such as mRNA vaccines, monoclonal antibodies, and cell or gene therapies – limit review speed and depth.

- **Unstable financing for reliance mechanisms:** The sustainability of collaborative mechanisms such as AMA and regional harmonisation frameworks remains uncertain without predictable funding.

- **Weak digital and pharmacovigilance infrastructure:** Limited data-governance systems and real-time safety monitoring capacities undermine efficiency and public trust.

PRIORITY ACTIONS FOR 2026

Strengthen Regional Harmonisation and Reliance Pathways:

Reinforce AMA's technical capacity for joint reviews and coordinating training for national regulators under the African Regulatory Harmonisation Initiative. It also includes promoting greater convergence between regulatory networks in Africa, Latin America, and the Asia-Pacific region by advancing WHO-led mutual-recognition pilots.

Scale Preparatory Regulatory Innovations:

Expand the use of regulator-approved platform master files and cloud-based data systems supported by WHO and AMA guidance. It additionally requires establishing interoperable data-sharing standards that link regulators, ethics committees, and developers in real time while ensuring protection of participant data.

Promote Regulatory Equity and Mutual Recognition:

Advance WHO benchmarking and twinning programmes to help additional LMIC regulators reach Maturity Level 3. National and regional regulatory authorities must be supported to effectively implement new guidance (WHO Best Practice guidance and changes to ICH E6(R3)) to enable a more streamlined and responsive approach to clinical trials. Enable multilingual regulatory submissions to reduce barriers for regional developers. Procurement agencies, including United Nations Children's Fund (UNICEF), Gavi, and the Global Fund, should recognise regional approvals and stimulate demand for locally produced countermeasures.

Surveillance

SURVEILLANCE IS THE ENTRY POINT TO LAUNCHING THE 100 DAYS MISSION, without which an outbreak cannot be detected. Surveillance systems generate the pathogen monitoring data that drives decision-making across the entire MCM continuum.

Yet surveillance is too often treated as distinct from the broader diagnostics ecosystem despite their fundamental interconnection – surveillance relies on diagnostic tools, and routine diagnostic testing in healthcare settings alongside broader surveillance modalities like wastewater monitoring generates the continuous pathogen monitoring data essential for early outbreak detection. Indeed, Airfinity has demonstrated that SARS-CoV-2 wastewater concentrations closely correlate with hospitalisation trends, providing early warning signals to anticipate rising case levels and optimise vaccination campaigns[140]. Despite these benefits, surveillance systems continue to face fragmentation across jurisdictions, chronic underfunding, hesitancy in pathogen and data sharing, and insufficient integration with response mechanisms – delays that compromise the speed required for the 100 Days Mission.

While 2025 saw progress in capacity building and surveillance coordination, persistent barriers continue to threaten readiness. The incomplete PABS annex under the WHO Pandemic Agreement, US withdrawal from WHO, fragmented data systems, insufficient LMIC capacity for genomic surveillance, and weak linkages between surveillance detection and countermeasure development and deployment remain critical gaps. The WHO Hub for Pandemic and Epidemic Intelligence continues to lead global coordination efforts focused on implementing collaborative surveillance.

PROGRESS AGAINST 2025 PRIORITY ACTIONS

Here we highlight a few key advances; however, a more comprehensive overview of progress updates can be found in *Annex A*.

Implement Collaborative Surveillance

- CEPI integrated the Biothreats Emergence, Analysis and Communications Network (BEACON) disease surveillance program with VISTA risk assessment in September 2025, combining AI-powered monitoring with threat evaluation[153].
- HERA's Advanced Technology for Health INtelligence and Action IT system (ATHINA) first modules became operational in 2025, designed to integrate public health and supply chain data to generate intelligence on medical countermeasures[50].
- African Medical Supplies Platform utilised Africa CDC's epidemiological intelligence to enable automated procurement workflows triggered by surveillance signals[136].

Adopt a One Health Approach

- UK Cabinet Office developed prototype biothreats radar in the National Situation Centre that integrates human, animal, and plant health risks for near real-time assessment of emerging biological threats[154].

Support Capacity Building

- Data.org's Epiverse Phase 2, launched December 2024, placed fellows in 10 African countries' health ministries while training 120 practitioners in epidemiological data science[155].
- African Bioinformatics Institute launched in June 2025 with Wellcome support to build Africa's bioinformatics capacity[156].
- System (GIS)-mapping framework systematically maps laboratory diagnostic capacities across 27 African countries, providing governments with evidence to guide network optimisation[157].
- Fiocruz launched the Cria Saúde community-based surveillance project in six Rio de Janeiro territories, training 200 community health agents and establishing nuclei for participatory health surveillance[158].

MAJOR BARRIERS IN 2025

- **Data and pathogen sharing hesitancy:** WHO Pandemic Agreement adopted May 2025, but PABS annex incomplete (March 2026 target); US withdrawal from WHO risks fragmentation.
- **Fragmented data systems:** Siloed disease-specific programs prevent integrated multipurpose systems.
- **Insufficient global capacity:** Human resource constraints, staff turnover, gaps in genomic surveillance competencies.
- **Limited surveillance-response integration:** Detection rarely triggers automatic countermeasure procurement.

PRIORITY ACTIONS FOR 2026

Strengthen Surveillance-Response Integration:

Invest in digital infrastructure and laboratory networks that enable real-time data exchange between surveillance systems and response mechanisms, including automated linkages between outbreak detection and countermeasure procurement, deployment, and development.

Sustain Geo-Diversified Capacity Building:

Commit multi-year financing to enhance competencies in pathogen genomic surveillance, bioinformatics, and epidemiological data science in LMICs, with focus on addressing human resource constraints and staff retention. Support multipurpose surveillance approaches including routine diagnostic testing that serves both everyday clinical needs and outbreak detection.

One Health Surveillance:

Establish coordinated surveillance systems across human, animal, and environmental health sectors to address the interconnectedness of climate change, agriculture, and emerging infectious diseases, with shared data platforms and alert mechanisms to enable early detection of zoonotic threats, addressing the interconnectedness of climate change, agriculture, and emerging infectious diseases.

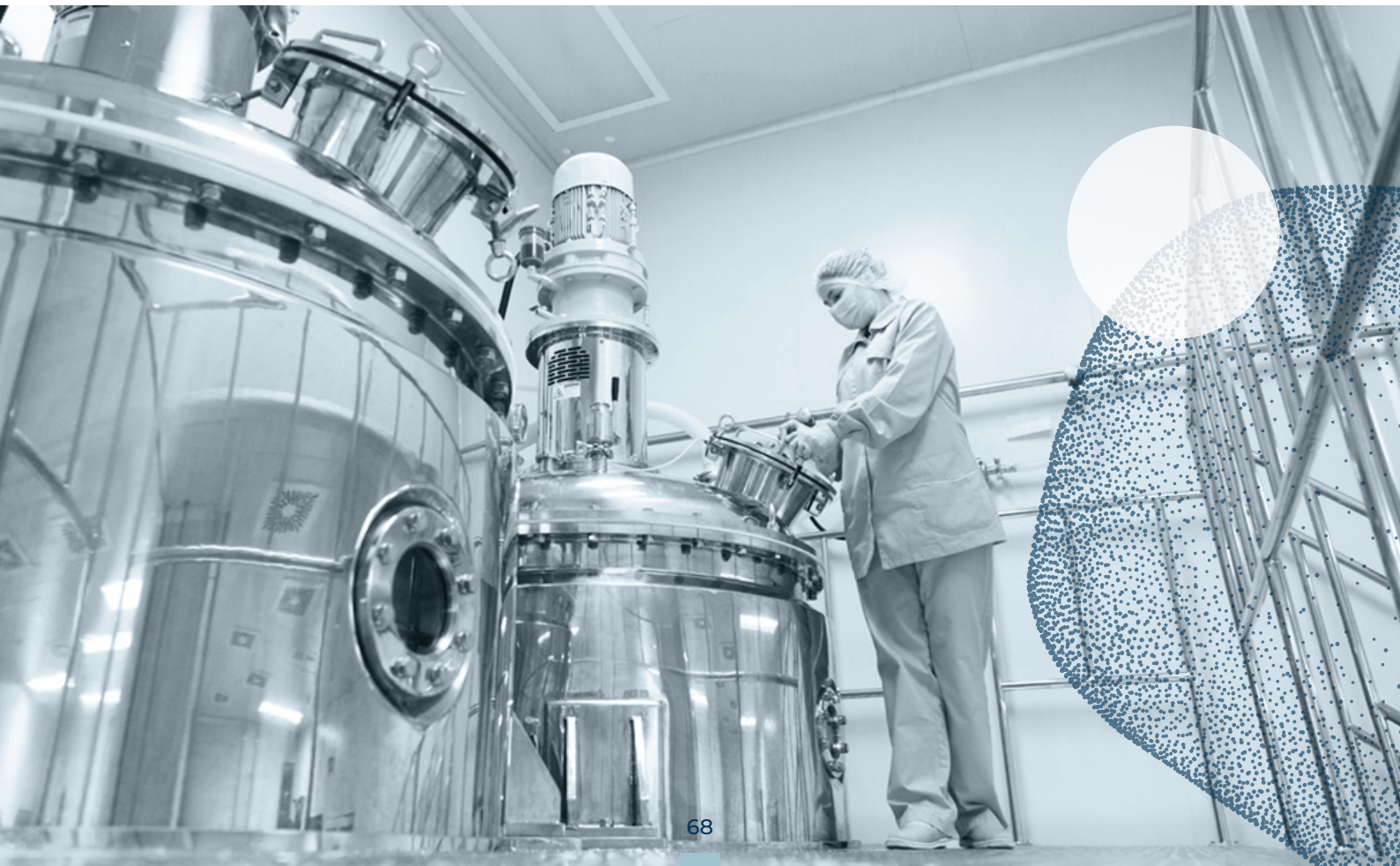
Geo-Diversified Manufacturing

CHEMISTRY, MANUFACTURING, AND CONTROLS (CMC) CAPABILITIES underpin the 100 Days Mission's ability to rapidly develop and scale diagnostics, therapeutics, and vaccines during crises while sustaining routine production between pandemics.

Regionalised, flexible, multi-product facilities – supported by resilient supply chains, open and adaptable platform technologies, and skilled workforces – can strengthen both equitable access and surge responsiveness.

Long-term viability, however, requires predictable demand and stable regulatory environments that allow facilities to balance public health and commercial portfolios. Equally critical is sustained routine manufacturing activity. Facilities without routine production cannot maintain the operational readiness, workforce capability, or regulatory currency needed for effective crisis response. Comprehensive training programmes and systematic monitoring are essential to build and maintain this operational capacity.

While regional manufacturing ecosystems continue to advance, progress remains uneven, and vaccine production is still the most mature area. The first global status report from the RVMC shows that regional manufacturers meet only 1%, 29%, and 25% of vaccine demand in Africa, ASEAN, and Latin America respectively, underscoring persistent gaps in scale, regulatory alignment, and innovation[159]. Partnerships and targeted financing are de-risking new production capabilities and enabling technology transfer but declining external assistance and uncertain domestic funding continue to threaten sustainability and readiness incentives for rapid response to outbreaks. Emerging efforts to strengthen pooled procurement, expand multi-purpose production capacity, and diversify supply chains are helping build more resilient, end-to-end manufacturing systems that can support both routine and emergency needs.



PROGRESS AGAINST 2025 PRIORITY ACTIONS

Here we highlight key advances against the 2025 priority actions, grouped to align with thematic areas from RVMC's first status report; a more comprehensive overview of progress can be found in *Annex A*.

FINANCE & DEMAND: pooled procurement, predictable demand, and sustainable financing mechanisms.

- **Cross regional:** The G20 HLIP recommended establishing a MCM Surge Financing Facility through the International Finance Corporation and partner Development Finance Institutions (DFIs) to provide rapid, blended financing and pooled procurement for regional manufacturers, expanding geographically diversified production of under-invested products such as diagnostics, personal protective equipment (PPE), and biomanufacturing[76,160].
- **Africa:** Africa CDC launched the African Manufacturing Market Intelligence and Network Analysis (AMMINA) platform to consolidate data on manufacturers, production capacities, and market trends[161], and is working with Afreximbank and other partners to design a continent-wide pooled procurement mechanism[162]. The AMSP aligned with the Platform for Harmonised African Health Manufacturing to operationalise pooled procurement and harmonise with AMA and global quality standards[136]. Gavi's African Vaccine Manufacturing Accelerator (AVMA) secured 18 expressions of interest, two technology-transfer deals, and progress toward the first African drug-substance manufacturer competing for a UNICEF tender by 2026[135].
- **ASEAN:** The ASEAN Vaccine Security and Self-Reliance (AVSSR) initiative advanced work to leverage the Asian market as an enabler of production, exploring options including pooled procurement mechanisms, convened high-level regional coordination meetings, human resource capacity building, and developed the ASEAN Vaccine Dashboard to enhance information sharing and regional preparedness[163].
- **LAC:** PAHO's Regional Revolving Funds demonstrated the impact of recent amendments to incentivise regional production, with regional manufacturers now representing almost one quarter of procured vaccine volume and around 30% of procurement value, up from less than 1% in 2020[159].

GOVERNANCE & REGULATION: coordination mechanisms and government support to incentivise regional manufacturing. See Regulation section for advances in regulatory alignment that support market access and harmonisation.

- **Cross regional:** RVMC published its 2040 Vision[164] and First Status Report[159], hosted a Sustainable Markets Convening[165], established a technical working group with Africa CDC, PAHO, and Thailand's NVI to strengthen regional alignment, and initiated cross-regional analyses on target pathways towards regionalised vaccine manufacturing in Latin America and the Caribbean (LAC) and ASEAN, complemented by financing and technology transfer landscapes[126]. The G20 Global Coalition on Regional and Local Production confirmed Fiocruz as its Secretariat and is developing the Terms of Reference. Fiocruz also expanded collaboration with Africa CDC and the Pasteur Network to advance vaccine R&D and strengthen South–South knowledge transfer to build resilient regional manufacturing ecosystems[166].
- **Africa:** Africa CDC, Gavi, and RVMC convened the 2nd Vaccines and Other Health Products Manufacturing Forum in Cairo in February 2025, yielding mRNA technology transfer agreements (EVA Pharma with DNA Script, Quantoom Biosciences, and Unizima, and a Biogeneric Pharma-Afrigen addendum), workforce development network launches, and reinforced commitments toward Africa's 60% manufacturing target by 2040[167,168].

TECHNOLOGY & SUPPLY: operational resilience, end-to-end technology transfer, and supply chain security.

- **Cross regional:** The WHO–MPP mRNA Technology Transfer Programme, led by Afrigen, validated its platform, transferred technology to 11 LMIC partners, advanced regionally relevant vaccine candidates toward GMP readiness, and began planning Phase 2.0 to support long-term sustainability[126,141]. Sanofi completed its Modulus modular manufacturing facilities in France and Singapore, capable of producing up to four vaccines or biologics simultaneously and transitioning between products in less than two weeks – a process that typically requires months in conventional facilities[169]. Wellcome Leap's R3 Global established RNA biofoundries in the UK and Singapore toward building a global network to advance continuous, low-cost RNA for rapid, scalable, and sustainable manufacturing of vaccines and therapeutics[133].
- **Africa:** Unitaid launched two complementary initiatives to strengthen Africa's manufacturing base for both routine health needs and pandemic surge capacity. The MADE programme, in partnership with PATH, builds sustainable diagnostic production through technical assistance, financing, and market shaping[79,170]. The MedSuRe Africa initiative, in partnership with USP, expands regional Active Pharmaceutical Ingredient (API) and finished product manufacturing while enhancing supply chain resilience[80,171]. Both initiatives include cross-cutting interventions in regulatory strengthening, intellectual property, and technology transfer. Institut Pasteur de Dakar celebrated its centenary with the inauguration of the expanded DIATROPIX diagnostic manufacturing site in Mbao, Senegal, supported by FIND and Unitaid. The ISO 13485-certified facility increased production capacity from 2 million to 75 million rapid diagnostic tests annually[172]. Separately, BioNTech, is in the final stages of construction of new mRNA manufacturing and quality control capabilities for primarily African markets in Kigali, Rwanda[173]. MPP, under its partnership with WHO's Health Technology Access Programme (HTAP) signed a sublicense agreement with Codix Bio, a Nigerian company to develop and manufacture rapid diagnostic tests (RDTs) using adaptable technology transferred from global in-vitro diagnostics company SD Biosensor[141].
- **LAC:** PATH and Fiocruz strengthened collaboration to expand regional technology development and local production capacity tailored to regional needs[174]. Instituto Butantan is increasing its capabilities with new BSL-3 QC labs, vaccine, mAb, and mRNA facilities, and a vial-filling plant, increasing annual capacity to over 650 million doses[97].
- **Europe:** The European Commission launched the RAMP-UP rapid-response manufacturing network and expanded the European Union Factory Assembly and Bioproduction (EU FAB) model to maintain multi-product surge capacity of up to 325 million doses for vaccines and other MCMs[175]. The UK government launched the Life Sciences Innovative Manufacturing Fund, implementing a cross-government Manufacturing Strategic Framework covering diagnostics, therapeutics, and vaccines that will benefit from the completion of the Moderna Innovation and Technology Centre, with capacity for up to 250 million doses per year[34].
- **North America:** Moderna's Canadian facility in Laval, Quebec, with capacity to produce up to 100 million doses annually, became Moderna's first international manufacturing facility outside the U.S. to produce mRNA vaccines. The facility operates in partnership with Novocol Pharma in Cambridge, Ontario for fill and finish operations[176]. Through Canada's Strategic Innovation Fund, investments supported expansion of biomanufacturing capacity including critical inputs for vaccines, therapeutics and diagnostics, sterile injectables, vaccine fill and finish, and genetic medicines[176].
- **Asia:** CEPI, Serum Institute of India and University of Oxford are collaborating to establish the world's largest investigational reserve of Nipah vaccines, ready to be deployed under emergency use during a future Nipah virus outbreak, helping generate critical data and potentially halt an epidemic in its tracks[177]. Vietnam's National Vaccine Company (VNVC) began construction of a manufacturing facility with US$77 million initial investment, aiming to produce 200 million vaccine doses annually upon completion in 2026[178]. Thermo Fisher Scientific opened a Bioprocess Design Center in Hyderabad providing bench-to-pilot scale capabilities for biologics and vaccine manufacturing in South Asia[179].

MAJOR BARRIERS IN 2025

- **Sustainable financing, market shaping, and demand:** High capital and operating costs, fragmented procurement, limited multi-year purchase commitments, insufficient funding to incentivise technology transfer or de-risk manufacturing for outbreak response, and uncertain forecasting weaken business viability for regional manufacturers, reducing surge readiness. This underscores the need for predictable demand, pooled procurement, and blended finance.

- **Capacity, technology transfer, and supply chains:** Limited GMP-certified capacity, workforce gaps, and restricted access to technology and know-how constrain production capability. Dependence on imported APIs and consumables, alongside inadequate pharmacovigilance and licensed logistics/storage infrastructure, further hinder resilience and discourage market authorisation holders from rolling out MCMs to certain geographies.

- **Regulation:** Fragmented regulatory frameworks, uneven NRA maturity, and limited reliance or emergency-use mechanisms delay facility licensure and product release.

- **Fragmented ecosystem coordination:** Poor coordination among researchers, manufacturers, regulators, and policymakers hinders technology transfer, facility development, and market access for regional manufacturers, despite growing partnerships and collaborative initiatives.

PRIORITY ACTIONS FOR 2026

See *Annex A* for Planned Partner Commitments and Priority Actions:

- **Strengthen market and financing mechanisms for regional production:**

  Implement the G20 HLIP recommendation to establish an MCM Surge Financing Facility and expand regional pooled procurement and multi-year market commitments to create predictable demand, supported by blended finance, demand visibility tools, and creation of emergency use stockpiles to maintain readiness and manufacturing ecosystem capacities between emergencies.

- **Advance regional manufacturing through adaptable and open platform technology development, clinical readiness, and end-to-end technology transfer:**

  Support LMIC manufacturers to achieve GMP certification and progress adaptable platform technologies and products into clinical development and production. Implement comprehensive training programmes with systematic monitoring to build and sustain skilled workforces. Build networked capacities that maintain routine manufacturing activities whilst enabling surge capacity. Strengthen public-private partnerships, expand technology transfer to include drug-substance and API capabilities, and increase local production of critical inputs to enable rapid, cost-effective manufacturing.

- **Accelerate regional regulatory harmonisation:**

  Implement reliance mechanisms and alignment with WHO, ICH and other standards to shorten approval timelines, increase mutual recognition across regions, and improve market access for locally manufactured products (see *Chapter 3, Regulatory Systems*).

CHAPTER 4

Finance & Governance

Sustainable pandemic financing

IN 2025, IPPS RECOMMENDED that action needed to be taken on strengthening the connection between preparedness and response financing with clearly defined operational triggers for organisational mobilisation, as well as sustained preparedness investments. Through a range of efforts, including South Africa's G20 leadership and new partnerships across philanthropy, public and private sectors, there has been evidence of progress under both of these recommendations.

1. STRENGTHENING PREPAREDNESS–RESPONSE FINANCING LINKAGES

- **The G20 Joint Finance Health Task Force (JFHTF)** updated its Operational Playbook for Pandemic Response Financing during South Africa's G20 presidency, with 3 core scenarios, scenario A: Respiratory Pathogen, Scenario B: Fluid-transmitted Pathogen, and Scenario C: Vector-borne Pathogen, and a focus on "day zero" and surge financing. A simulation exercise at finance deputies' level stress-tested the adequacy of financing responses and highlighted remaining gaps in day zero at risk financing[180].

- **Gavi activated its First Response Fund**, approving up to $50 million within 33 days of WHO's mpox PHEIC declaration to secure 500,000 vaccine doses and delivery costs. The Day Zero Financing Facility exemplifies integrated preparedness-response financing through its layered design: a $500 million First Response Fund providing immediately accessible at-risk capital, combined with $2 billion in development finance institution credit lines that can be rapidly activated against donor pledges – enabling immediate access to surge financing before pledged funds are disbursed[135].

- **G20 High Level Independent Panel** reconvened to focus on unlocking MCM surge financing and mobilising preparedness financing, with recommendations shared with G20 members. The recommendations for surge financing were officially published in the new HLIP report[76].

- **Center for Global Development (CGD)** published a framework[181] for designing trigger mechanisms for epidemic and pandemic financing and response, aiming to improve trigger effectiveness, reliability, and communication of their attributes and intended performance to stakeholders.

2. SUSTAINED PREPAREDNESS INVESTMENTS

- **CEPI** partnered with the European Investment Bank (EIB) and others to align global vaccine investment strategies and explore sustainable financing tools.

- **AMSP** continued leveraging Afreximbank's instruments for pooled procurement under the African Pooled Procurement Mechanism.

- **South African Medical Research Council (SAMRC)** maintained funding for the WHO/MPP mRNA tech transfer hub at Afrigen, set to enter Phase 2.0 in 2026.

- **Government of South Africa** initiated plans to fund the establishment of the Institute for the Preparedness and Prevention of Pandemics (IP3) institute to strengthen Southern Africa's capacity to anticipate, respond to, and recover from pandemics.

Nevertheless, there have been barriers to making progress in this area. Official Development Assistance (ODA) is projected to have declined by 9-17% globally in 2025[182]. While global health R&D is not exclusively funded by ODA, it forms a significant part. Across the public, philanthropic and private sectors, there have been competing priorities on resource allocation. Public and philanthropic funders face growing pressure to reallocate resources to other priorities, such as security or climate change. In the private sector, funders are diverting resources to areas of greater profit generation. This has resulted in key partners, such as WHO, having to eliminate programmes and downsize, limiting their technical capacity for outbreak response and ability to sustainably fund R&D, stockpiling, regulatory, and surveillance. A reduction in ODA and budgets more generally has meant that MDBs and the Pandemic Fund remain underpowered, with surge financing mechanisms also not yet fully enabled. PPR is also inconsistently integrated across national budgets, making it hard to measure, which is further limited by a lack of timely, comprehensive data overall to assess economic vulnerabilities.

PRIORITY ACTIONS FOR 2026

- **Integrate Day Zero Triggers into Decision Making:**

  Consider the frameworks proposed by JFHTF, CGD and others, integrate day zero triggers into pandemic financing and response systems.

- **Mobilise Domestic and Non-ODA Resources:**

  Unlock domestic resource mobilisation and stimulate private sector and humanitarian PPR financing. Where relevant, consider leveraging funding from biosecurity budgets.

- **Secure Sustainable Financing:**

  Renew commitments to global R&D production and MCM development, with targeted outreach to diversify funding sources, including non-traditional donors.

- **Advance Innovative Financing Models:**

  Scale blended finance, philanthropy-industry partnerships (such as the SAMRC–Government of South Africa–Gates-Wellcome matched funding to address USAID cuts, and the nascent Therapeutics Development Coalition), and grant-based mechanisms.

- **Strengthen Multilateral Development Banks Capabilities:**

  Enable at-risk financing and advance purchase lending for MCMs.

- **Enhance Data Systems:**

  Establish rigorous mechanisms to monitor financing outcomes and preparedness improvements.

Global Health Governance

GLOBAL HEALTH GOVERNANCE IN 2025 HAS BEEN STRENGTHENED. From the recommitment to multilateralism through the adoption of the WHO Pandemic Agreement in May and the amended International Health Regulations (IHRs) entering into force in September, to the recent initiatives reimagining the global health architecture to redistribute power and better respond to financial and geopolitical trends.

1. PANDEMIC AGREEMENT ADOPTION

- **The WHO Pandemic Agreement** was adopted in May 2025 at the 78th World Health Assembly (WHA), marking a major milestone in multilateral coordination. The Agreement represents an important step towards the founding principle of the 100 Days Mission – agreeing on the rules guiding a pandemic response well in advance so that no time is wasted during an outbreak.

- **IPPS commend WHO, the International Negotiating Body (INB) and Member States** for embedding several priorities which were highlighted in the original 100DM recommendations and which have the potential to contribute to the 100DM end goals, as set out in our public statement183. There was also significant effort by civil society in sustaining momentum around the negotiations, such as by the Pandemic Action Network (PAN) and Spark Street Advisors, who continued to advocate for equity in the Agreement.

- As part of its adoption, **the WHA established the Intergovernmental Working Group (IGWG)** to draft and negotiate the PABS Annex to the Agreement, as well as other tasks.

- While **ratification and the PABS Annex** are pending, the agreement sets a foundational framework for emergency coordination, equitable access, and R&D.

2. EQUITY, ACCESS, AND INNOVATION

- **The PABS system** aims to enable safe, transparent and accountable access and benefit-sharing for pathogen materials and sequence information, as well as equitable, rapid and timely sharing of DTVs. Negotiations for the PABS Annex are expected to conclude by the 79th WHA in 2026.

- To increase visibility over the current status of activities related to MCMs for pandemic response, **WHO's interim medical countermeasure network (i-MCM-net)** published a full landscape analysis report[184] mapping the MCM ecosystem across R&D, manufacturing, procurement, allocation, and delivery for three priority threats (pandemic influenza, novel coronaviruses, and Pathogen X), identifying critical gaps and proposing areas for action to strengthen equitable access globally.

In 2025, global health actors have published a series of recommendations of new initiatives to reform the global health architecture, in turn, making global health governance more equitable:

- **In June 2025, Gavi launched the Gavi Leap initiative**[185] which commits to a radical internal reform while also leveraging synergies with other global health agencies and catalysing reform of the global health architecture.
- **In June 2025, Spark Street Advisors**[186] examined progress of the Lusaka Agenda since 2023, identifying near-term, medium-term, and long-term priorities to identify concrete implementation proposals and emerging challenges. They also published a paper summarising the various initiatives focussed on changing the global health architecture.
- **In July 2025, Wellcome**[187] commissioned discussion papers that reflect five regional expert perspectives on reimagining an equitable and sustainable future for the global health architecture. These papers are being used to shape a global high-level meeting in early 2026 to build consensus on the future of global health and the changes that need to happen.
- **In August 2025, the Accra initiative**[188] was launched at the African Health Sovereignty Summit. Prioritising resilience, equity, sustainable financing and advancing Africa's leadership in health governance, the initiative sets a new framework for global health sovereignty, rooted in national ownership, country-led investment, and leadership.
- **In September 2025, eight global health experts**[189] co-authored a piece in Nature Medicine posing key questions on scope, operating model, transition, financing, and equity to reform the global health system.

These efforts have been made amidst challenging political headwinds. At the adoption of the WHO Pandemic Agreement, 11 Member States abstained, with some citing sovereignty concerns and the view that the agreement did not adequately address the needs of developing countries. The United States had also begun the year-long process of withdrawing from the WHO, citing concerns over undue political influence and the need for institutional reform; as a result, it did not participate in the vote. Engagement in global health governance processes has also been affected by a growing trend of distrust in science. Among both the public and political figures, the validity of scientific evidence and global health innovations is increasingly being questioned, threatening the long-term sustainability of global health initiatives.

PRIORITY ACTIONS FOR 2026

Conclude PABS Annex Negotiations:

Ensure timely, equitable access to pathogen samples and data to support rapid response and innovation remains at the centre of the PABS negotiations, whilst keeping the process outcome-oriented and time-bound.

Strengthen Advocacy and Civil Society Engagement:

Ensure civil society, technical experts and industry are consulted as part of negotiations, such as on the PABS Annex, to capture expertise and maintain political ambition.

Integrate Governance Frameworks:

Ensure alignment of global frameworks, such as the Pandemic Agreement and IHR amendments, with regional and national implementation strategies, whilst considering how to best embed equity and sustainability, in line with the recommendations to reform the global health architecture.

Counter Mis/Disinformation:

Governments must meaningfully engage with communities to understand concerns and address issues of inequity, vulnerability, and risk to restore confidence in science, health innovations, and governance bodies.

100DM Framework Outputs, Out

IPPS ACTIVITIES	100DM 2026 OUTPUTS
DIAGNOSTICS R&D	• Promote coordination mechanisms to facilitate implementation of 2025 Global Gap Assessment recommendations and identify key owners; • Enhance harmonisation of diagnostic regulatory pathways; Advocate for integration of multiplex pandemic diagnostics into routine healthcare systems
THERAPEUTICS R&D	• Catalyse the establishment of the Therapeutics Development Coalition's long-term governance, and agree two viral families for proof-of-concept pilot projects
VACCINES R&D	• Promote coordinated development of the global vaccine library; • Advocate for regulatory innovation frameworks beyond outbreak contexts; • Promote vaccine platform diversification and manufacturing innovation
CLINICAL TRIALS	• Advocate for operationalisation of regional trial networks with shared governance; • Promote the use of pre-approved master protocols and interoperable data-sharing standards
REGULATORY	• Work with WHO and regional regulatory bodies to strength harmonisation and reliance pathways and convergence between regional regulatory networks;
SURVEILLANCE	• Promote infrastructure investment for surveillance-response integration; • Advocate for sustained LMIC capacity building in genomic surveillance; • Advocate for coordination of One Health surveillance systems across sectors
SUSTAINABLE MANUFACTURING	• Advocate for surge financing facilities and regional procurement mechanisms; • Promote platform development and technology transfer for LMIC manufacturers; • Support regional regulatory harmonisation and reliance mechanisms
SUSTAINABLE FINANCING & PROCUREMENT	• Advocate for the integration of Day Zero triggers into decision making; • Promote the need to finance PPR sustainably and through innovative models; • Advocate for enhanced data systems to monitor financing outcomes.

comes, and Impact

> 100DM LONG-TERM OUTCOMES	IMPACT
• Diagnostics R&D coordinated; • Libraries provide broad coverage; • Diagnostics linked to testing & treatment	DTVs rapidly developed for equitable distribution by harnessing innovative technologies
• Advocacy for sustained and coordinated funding for antiviral R&D for pandemic and epidemic-prone diseases, and identification of high impact research R&D needs where funders could have most impact; • Development of antivirals for proof-of-concept viral families	
• Continued work on vaccine libraries covering WHO priority pathogen families; • Rapidly programmable platform technologies available and accessible globally; • Vaccine platforms optimised for rapid production at scale	
• Clinical trial sites are sustained between pandemics; • Best practices on clinical trial design and innovative and adaptive trial designs utilised, with systematic inclusion of vulnerable populations including pregnant women, lactating mothers, immunocompromised individuals, and children; • Master trial protocols pre-agreed for use in emergencies, emphasising real-world evidence for product licensure	High-quality clinical trials mobilised rapidly utilising sustainable geo-diversified infrastructures that generate population-relevant data
• Preparatory and harmonised regulatory frameworks adopted by regulators for pathogens where traditional randomised controlled trials are unfeasible; • Strengthened and aligned regulatory capacity in all regions with pharmacovigilance enabled from the outset	Products authorised for use in humans (e.g. EUA) in a 100-day timescale due to pre-emptive data generation
• International network(s) of global/regional/local surveillance systems powered by AI identifies outbreaks and enables trusted data sharing; • Reliable, fair, safe, and fit-for-purpose mechanisms for rapid exchange of pathogen samples enable equitable R&D efforts for DTVs	Pathogens are characterised using genomic sequencing and other integrated approaches, with surveillance data shared to prevent outbreaks from escalating into pandemics.
• There is capacity and capability to produce DTVs in each region; • The ecosystem supports voluntary licensing, technology transfer, supply-side incentives for investment and demand-side procurement mechanisms; • Developers and manufacturers align on platforms that can be adapted to produce both routine and pandemic products	Regions develop integrated manufacturing ecosystems capable of producing medical countermeasures, with facilities configured to respond rapidly to emerging threats and ensure equitable access to essential pandemic tools.
• Trigger-based financing mechanisms operationalised; • LMICs can purchase DTVs equitably	Countries have access to and can mobilise funding to reduce pandemic threat escalation.

CHAPTER 5

Forward Look: The Year Ahead

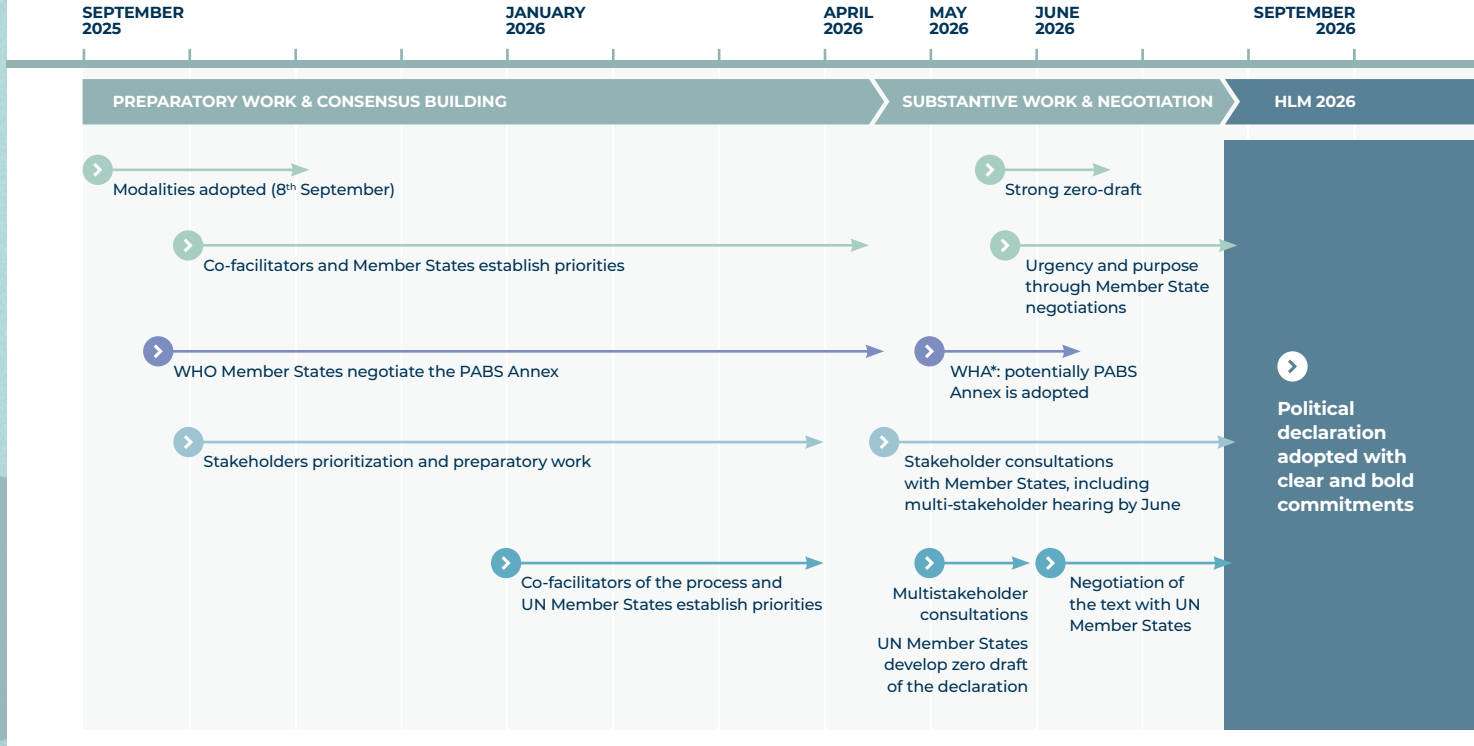
IN 2026, THE SECOND UN HIGH-LEVEL MEETING (HLM) ON PPR will take place. This offers an opportunity to renew interest and obtain high-level political support in PPR. The theme is "fostering a multilateral and intergenerational approach to prevent, prepare for and respond to pandemics and public health emergencies, through equity and the principle of solidarity", and the meeting's outcome political declaration will be co-facilitated by Chile and Viet Nam. It intends to address multilateral action for coordinated PPR and capacities and financing for strengthened PPR. Similar to the last HLM in 2023, there will be a multistakeholder hearing before the HLM, due in June 2026.

In order to successfully influence the HLM's outcome, it will be **essential to overcome the political fatigue surrounding PPR policy.** Member State negotiators are aiming to complete the PABS Annex of the WHO Pandemic Agreement by the next World Health Assembly, and there is uncertainty around the future of the Health Track in the US G20 and French G7 presidencies. Therefore, early, concerted and joined up action from across the PPR ecosystem will be crucial.

Since the last HLM in 2023, policy circles have continued to discuss monitoring and accountability for PPR. Advocates have underscored the need for a clear landscape of activities in order to support policy decision making and resource prioritisation. Recently, there have been several publications on this topic, and they have made the case that the increasing political support and investment in PPR following the West African Ebola epidemic and COVID-19 pandemic have also led to a rise in mechanisms that monitor different parts of the PPR ecosystem. However, there are gaps in these systems, including in synthesised pandemic risk assessment, monitoring of financing, equitable access, organisational readiness, and response and recovery, as well as questions about how these systems can best serve global, regional and country stakeholders.

Some of the proposals include **a Global Health Observatory[190], a Pandemic Risk Assessment Framework[191], and an Intergovernmental Panel on Pandemics[192]** – which have some clear, and nuanced differences, particularly in the area of risk assessment. These publications have coincided with conversations around the future of two global mechanisms for PPR – the IPPS, who partner with Impact Global Health to develop the 100DM Scorecard (see *Chapter 1, 100 Days Mission Scorecard & Analysis*) and are due to wind down in early 2027, and the GPMB, who will sunset in late 2026. A wider discussion has therefore started on the need for a consolidation of efforts, to plug gaps, maximise efficiencies and utility, and ensure tools like the 100DM Scorecard will not fall off a cliff-edge. IPPS will be working with partners to champion consolidated monitoring as a key outcome of the HLM in 2026.

TIMELINE OF KEY EVENTS LEADING UP TO UN HLM



Credit: Independent Panel, 2025

ANNEX A

Summary of Recommendations

Note: Progress summarised is not exhaustive but seeks to highlight updates of international relevance. Recommendations have been grouped by theme rather than original numerical order. Information in the table below has been collated from pro formas and interviews with the named implementation partners.

Diagnostics R&D

RECOMMENDATIONS:

2 **Build prototype** [vaccines and] **diagnostic libraries** applicable to representative pathogens of pandemic potential.

6 **Strengthen the role of the international system in R&D capability and coordination** for [therapeutics and] diagnostics. (Note that progress against this recommendation has been broadened to diagnostics R&D coordination more broadly, beyond a potential CEPI role.)

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
Cepheid has made available a combinatory test for SARS-CoV-2, influenza, and RSV that includes H5N1, influenza A & B, and H3N2 variants[63]. **RIGHT Foundation** has funded the advanced development of SD Biosensor's STANDARD M10 Flu/RSV/SARS-CoV-2 Fast multiplex RT-PCR cartridge and obtained a CE-IVDR, with plans to obtain SRA approval[62]. **GADx** has tests for Crimean Congo Haemorrhagic fever (CCHF) in technical transfer with Liverpool School of Tropical Medicine, Nipah virus in development with Oxford University, Avian flu in development with The Pirbright Institute, and is in the process of reinitiating work on alternative mpox antigens with the mpox consortium[193]. **Instituto Butantan** has developed, validated and implemented assays including anti-Chikungunya immunoglobulin detection[97]. **Fiocruz** worked on the development and adaptation of rapid tests for remote diagnostics and databases for the Brazilian Health System (SUS), including COVID-19 antigen and IgG antibody tests[98]. **LifeArc** is funding a prototype low-cost, wireless wearable device that continuously monitors vital signs that can predict progression to severe dengue[194]. **Oxford PSI** has published proof of concept work on the direct replacement of antibodies with non-animal derived binders in LFDs in collaboration with KTH and RMIT, and strengthened collaborations with antibody alternatives including nanobodies and peptide binders using Artifical Intelligence (AI) tools[42,195]. **Oxford PSI** has developed a prototype Nipah virus LFD in collaboration with GADx using nanobody/antibody pairing[42]. **Oxford PSI** has developed a prototype mpox LFD with acceptable analytical specificity and sensitivity, and has been awarded Medical Research Council (MRC) funding through the mpox consortia led by Glasgow for further LFD development innovations[42]. **Varro Life Sciences** has advanced its biosensor platform based on micro-immuno electrodes with pathogen-specific nanobodies, demonstrating rapid and accurate detection of respiratory pathogens in both breath and indoor air. Varro Life Sciences has formally pledged to open-source its patents[196]. **Aptitude** has secured a $9 million Partnership with the Biomedical Advanced Research and Development Authority (BARDA) to Develop Rapid Molecular Diagnostic for Ebolaviruses and Marburg Viruses[197]. **SAMRC** has invested in a project to evaluate and develop mpox diagnostics at the University of the Witwatersrand, led by the diagnostics working group of the South African Mpox Research and Surveillance Consortium (SAmpox)[127].	**Planned Partner commitments** • **Oxford Pandemic Sciences Institute (PSI)** will work on automating LFD development aided by machine learning tools through a pump priming grant from Oxford Global Health[42]. • **Oxford PSI** will develop high-throughput screening platforms for binders including those generated by AI to inform lateral flow devices (LFD)[42]. • **RIGHT Foundation** will works towards SRA approval (by 2027), and aim for country registrations in low-and middle income countries (LMICs) for the STANDARD M10 multiplex RT-PCR cartridge[62]. • **South Africa Medical Research Council (SAMRC)** will continue conceptualising a Diagnostic Innovation Accelerator to facilitate a coordinated pathway guiding projects from research through regulatory approval to market access using a hub-and-spoke cluster model. The accelerator will connect existing stakeholders and capabilities into a streamlined development pathway to progress diagnostics currently under development and rapidly develop diagnostics in response to future pandemics[127]. • **Varro Life Sciences** will launch the Pathogen Air Bio-Detector by end of 2026 and initiate US Food and Drug Administration (FDA)-monitored clinical trials for breath-based diagnostic during the 2026-27 influenza season[196]. • **Varro Life Sciences** will complete validation and regulatory readiness by 2025-26, begin clinical trials in Q4 2026, and commercialise its air-based pathogen detection system by 2026[196]. • **WHO** and partners will continue moving the Global Diagnostics Coalition forward as a necessary step in implementing the recommendations of the WHA Resolution 76.5[207].

2025 SUMMARY PROGRESS UPDATE

The Unitaid-funded SAFEStart+ program led by PATH in collaboration with the International Community of Women living with HIV Eastern Africa and the World Hepatitis Alliance has expanded access to new diagnostics that can detect multiple infections with a single test and reinforced antenatal care services to deliver preventive treatment[79].

Unitaid is supporting late-stage development and market entry for multi-disease and targeted next-generation sequencing technologies for primary and community health settings to reduce diagnostic delays and improve linkages to care[80].

Unitaid, in partnership with the **Clinton Health Access Initiative (CHAI),** is accelerating access to innovative, decentralised multi-disease molecular diagnostic tools. These multiplex platforms can detect multiple pathogens simultaneously, addressing both routine clinical needs and building capacity for rapid outbreak response[80].

Unitaid, through its grants in Africa operated with PATH and Aurum, is exploring implementation of point-of-care and near point-of-care molecular platforms for mpox to support decentralised testing and improve linkage to care, particularly among vulnerable populations including people with advanced HIV disease, pregnant women and newborns[80].

BARDA opens applications for its I-CREATE accelerator network hub, offering both proof-of-concept funding and places in the 2026 Accelerator Cohort. The programme prioritises next-generation diagnostics across five key areas: platforms for detection, continuous monitoring, and triage of infectious diseases and biological threats; high-sensitivity, low-cost, at-home molecular diagnostics for point-of-need use; alternative, user-friendly sampling and detection methods (e.g., breath-based); pathogen-agnostic approaches to infectious disease detection; and low-cost, deployable diagnostics for rural or resource-limited settings[198].

The ReadyDetect Next-Generation Diagnostics Competition launches, calling for diagnostics innovators to develop high-performance antigen tests with PCR-level sensitivity while maintaining rapid turnaround times and low costs[199].

BARDA awards True Diagnostics upward of $11 million to support the development, validation, and regulatory submissions of its VeriClear EbV MARV Rapid Antigen Test to detect and differentiate Ebola and Marburg viruses in fingerstick blood samples[200].

ASLM announced the launch of the Leadership Excellence for African Diagnostics (LEAD) initiative – a three-year partnership between Roche Diagnostics Africa and the ASLM to elevate laboratory leadership and strengthen diagnostic systems across Africa[201].

Fiocruz and **the Institute Mérieux** have expanded cooperation to improve research, training, and professional development for Brazil's Unified Health System, as well as to strengthen diagnostics and epidemiological and molecular surveillance of infectious diseases[202].

ASLM and **Biomed Connect** formed a strategic partnership to strengthen Africa's Lab workforce and diagnostics capacity[203].

Oxford PSI is developing Target Product Profiles for Avian flu in collaboration with UK Health Security Agency (UKHSA), Liverpool School of Tropical Medicine (LSTM), Institut Pasteur Madagascar (IP Madagascar), World Health Organization (WHO), Centers for Disease Control and Prevention (CDC) and others to demonstrate diagnostic value and design parameters[42].

FIND has updated critical landscape reports for Lassa fever, Nipah, Rift Valley fever, Middle East Respiratory Syndrome (MERS), Coronavirus, and Chikungunya, and finalised Target Product and Sample Profiles (TPPs/TSPs) for both Lassa and Nipah viruses to guide test developers[204].

FIND has developed a framework for country readiness assessment for priority pathogens, piloted across seven priority pathogens in seven countries to help Ministries of Health identify gaps and plan preparedness strategies[204].

The Foundation for Innovative New Diagnostics (FIND) partnered with Liberia's Ministry of Health to develop a national Viral Haemorrhagic Fevers Strategic Plan, which has called for regional collaboration through WAHO to develop testing algorithms for Lassa fever and other viral haemorrhagic fevers[204].

The Africa Centres for Disease Control and Prevention (Africa CDC) and the European Commission launched the Partnership to Accelerate mpox Testing and Sequencing in Africa (PAMTA), an initiative to boost diagnostics and outbreak response capabilities in mpox-affected African countries[205].

PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026

- **Oxford Pandemic Sciences Institute (PSI)** will work on automating LFD development aided by machine learning tools through a pump priming grant from Oxford Global Health[42].
- **Oxford PSI** will develop high-throughput screening platforms for binders including those generated by AI to inform lateral flow devices (LFD)[42].
- **RIGHT Foundation** will works towards SRA approval (by 2027), and aim for country registrations in low-and middle income countries (LMICs) for the STANDARD M10 multiplex RT-PCR cartridge[62].
- **South Africa Medical Research Council (SAMRC)** will continue conceptualising a Diagnostic Innovation Accelerator to facilitate a coordinated pathway guiding projects from research through regulatory approval to market access using a hub-and-spoke cluster model. The accelerator will connect existing stakeholders and capabilities into a streamlined development pathway to progress diagnostics currently under development and rapidly develop diagnostics in response to future pandemics[127].
- **Varro Life Sciences** will launch the Pathogen Air Bio-Detector by end of 2026 and initiate US Food and Drug Administration (FDA)-monitored clinical trials for breath-based diagnostic during the 2026-27 influenza season[196].
- **Varro Life Sciences** will complete validation and regulatory readiness by 2025-26, begin clinical trials in Q4 2026, and commercialise its air-based pathogen detection system by 2026[196].
- **WHO** and partners will continue moving the Global Diagnostics Coalition forward as a necessary step in implementing the recommendations of the WHA Resolution 76.5[207].
- **PATH** will establish a more current evidence-based landscape of multiplex platforms, both immuno-and molecular-based. PATH will also continue to work with country programs to understand mechanisms for registration and integration of multiplex platforms[79].
- **The European Commission Health Emergency Preparedness and Response (HERA)** will launch a pilot for a European Diagnostics Hub by 2026 to invest in and develop next-generation diagnostic tests and technologies that are quickly scalable, easily adaptable, and usable at point of care, addressing multiple pathogens and complementing rapid diagnostics development efforts[50].
- **MHRA** will continue to develop National Institute for Biological Standards and Control (NIBSC) biological reference materials for priority pathogens to support the development and quality control of diagnostics and the development of vaccines, including WHO International Standards. These, and existing materials, will be available through the nibsc.org site.

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
WHO launched the Global Diagnostics Coalition in May 2025, a broad grouping of diagnostics parties focused on improving access to timely and accurate diagnostics[77]. **The UKHSA Diagnostics Accelerator** has surveyed UKHSA and National Health Service (NHS) laboratories to understand the platform landscape and undertaken a gap analysis of the diagnostic portfolio[34]. **IPPS, the Brown University Pandemic Center, and FIND** published "Advancing the 100 Days Mission for Diagnostics: 2025 Global Gap Assessment," a report identifying key barriers in diagnostic preparedness and providing actionable recommendations to address them[72]. **The Lancet Commission on Diagnostics** published "Moving the dial on diagnostics: an update from the Lancet Commission on diagnostics" in June 2025, assessing progress on ten key recommendation areas[206].	**Priority Actions for 2026** • Develop coordinated approaches to support diagnostics developers with access to clinical samples, reference panels, and regulatory-aligned evaluation services. • Accelerate diagnostic R&D for multiplex platforms embedded in routine care and establish mechanisms for integrated MCM development. • Simplify and harmonise diagnostic regulatory pathways to reduce complexity, cost, and approval timeframes. • Strengthen Agile Coordination to Address Critical Ecosystem Gaps.

Therapeutics R&D

RECOMMENDATIONS:

3 **Develop prototype antiviral therapeutics,** including antibody therapies, for pathogens of pandemic potential. Note that progress against this recommendation has been broadened from respiratory to all pandemic pathogens (e.g., skin-to-skin, blood-borne)

5 **Invest in simplified cheaper routes** for producing monoclonal antibodies and other new therapeutic modalities.

6 **Strengthen the role of the international system in R&D capability and coordination for therapeutics** [and diagnostics]. Note that progress against this recommendation has been broadened to therapeutics R&D coordination more broadly, beyond a potential Coalition for Epidemic Preparedness Innovations (CEPI) role.

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
The Cumming Global Centre for Pandemic Therapeutics has made progress toward developing therapeutics for pathogens of pandemic potential, including work on establishing a rapid nanobody platform using mRNA immunisation, developing novel aptamer therapeutic candidates for Ebola, advancing a Self-amplifying mRNA Antiviral RNA Therapeutics (SMART) platform, and developing CRISPR Cas 13 antiviral therapeutics for respiratory pathogens[88]. **PSI Oxford** has made progress in preclinical therapeutics work including advancing research to elucidate the structure of the Nipah virus polymerase complex to identify therapeutic targets, working to identify small molecule inhibitors for SARS-CoV-2, MERS, mpox, Nipah, influenza and flaviviruses, and developing Nipah-specific monoclonal antibodies[42]. The broad-spectrum pan-coronavirus antiviral ASAP-0017445 has been formally nominated as a pre-clinical drug candidate by the non-profit medical research organisation **Drugs for Neglected Diseases initiative (DNDi).** ASAP-0017445 is the first coronavirus antiviral developed through crowdsourcing and open science, and the first with its origins in artificial intelligence (AI)[94]. **Emergent Biosolutions** has been building out facility capabilities for monoclonal antibody discovery and development for both internal programs and partnerships[208]. **Cidara** is awarded up to $339 million from BARDA to fund its flu candidate CD388, a prophylactic Fc conjugate[209]. **The EU launched COMBINE,** a €7.2 million Horizon Europe project coordinated by the Helmholtz Centre for Infection Research. The project uses Marburg virus as a model to develop a blueprint for identifying antiviral targets and therapeutic strategies against emerging viruses[210].	• **CSIR** will prioritise applications of both its monocloncal antibodies (mAbs) platform and flow chemistry platform for viral diseases of pandemic potential[96]. • **The Council for Scientific and Industrial Research (CSIR)** will work to secure SAHPRA licensure for its GMP pilot-scale investigational facility and produce clinical trial batches[96]. • **The Cumming Global Centre for Pandemic Therapeutics** will launch a global program for the Future Fellows Fund in 2026, focused on developing a global community of talent as part of network development, capacity building and knowledge exchange[88]. • **The Cumming Global Centre** will finalise recruitment of approx. 12 faculty lab groups on long-term research contracts, ensuring sustained research funding for ~100 researchers with a mission focus on developing platforms technologies for delivering novel therapeutics for pandemic pathogens[88].

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
Serum Institute of India signs a memorandum of understanding (MoU) with DNDi to advance the development of a new monoclonal antibody treatment for dengue in low- and middle-income countries[211]. **LifeArc** is collaborating with the Gates Foundation in a joint $5.25 million investment in lab-scale proof-of-concept for diverse manufacturing technologies to achieve low-cost mAbs with a target of $10/gram[194]. **CEPI** announced a $43.5 million partnership with AstraZeneca to advance development of novel VHH antibodies designed to target four pandemic influenza virus strains with both prophylactic and therapeutic potential[212]. **LifeArc** has partnered with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) to develop an affordable monoclonal antibody for prophylaxis and therapy against CCHFV[194]. **The LifeArc Dengue Innovation Awards** supported three academic researchers in Flavivirus endemic countries strengthening R&D in novel broadly reactive therapeutic modalities and biomarker indicators of severe haemorrhagic disease progression[194]. **The VITAL Hub** is offering proof-of-concept funding through a partnership with BARDA to develop innovative therapeutics. This funding supports projects focused on targeting specific cells and tissues for better results and activating the innate immune system for rapid, long-lasting protection against health security threats[213]. **The Therapeutics Development Coalition** transitioned from concept to operational design throughout 2025, establishing an interim governance structure comprising an interim Portfolio Committee and interim Executive Board bringing together multisectoral, public-private partners from pharmaceutical industry, academia, governments, and international organisations. The Coalition takes an end-to-end approach with a focus on early-stage R&D as the critical gap in the therapeutic development pipeline for pathogens with pandemic potential. **The Rapidly Emerging Antiviral Drug Development Initiative (READDI)** has embarked on a collaborative research partnership with the South Korea's National Institute of Infectious Diseases (KNIID), part of the National Institute of Health (NIH) within the Korea Disease Control and Prevention Agency (KDCA).The two groups will collaborate on the discovery and development of innovative antiviral therapies for virus pathogens of pandemic concern[214]. Through its foundation, **H3D Foundation,** now with co-sponsorship from The Gates Foundation and LifeArc, spearheaded the Grand Challenges Africa Drug Development Accelerator (GC-ADDA)- a network of African research institutions engaged in drug discovery research is taking full form[215]. **Council for Scientific and Industrial Research (CSIR),** South Africa has completed proof of concept process development for a pipeline of several biotherapeutics, focusing on monoclonal antibodies with a growing platform for mAb development and production that is being modernised to include high-producer Chinese hamster ovary CHO line and continuous manufacturing[96]. **CSIR** has advanced process development for mpox mAbs and developed several proposals for various pandemic mAbs with partners including ServareGMP, International Aids Vaccine Initiative (IAVI) and local South African industry[96]. **CSIR** is collaborating with Sunflower Therapeutics and Massachusetts institute of technology (MIT) AltHost Consortium for mAb platform process development using alternative, potentially more cost-effective hosts like Pichia and N. benthamiana to advance access through cost-effective production[96]. **SAMRC and the South African Department of Science Technology and Innovation (DSTI)** have invested in a project on plant-based expression of the 7D11 monoclonal antibody as a therapeutic candidate for mpox treatment at the CSIR[96]. **Fiocruz** has signed a three-year cooperation agreement with Mexico's Ministry of Health and Birmex in August 2025, focusing on research, development, and technology transfer programs involving messenger mRNA platforms for vaccines, therapies, and other health products[98]. **Fiocruz** partnered with PATH through a memorandum of understanding to accelerate innovation, production, and access to vaccines, diagnostics, and biopharmaceuticals in Brazil and Latin America[174]. **The INTREPID Alliance** published key articles advancing pandemic antiviral preparedness: "Antiviral Target Compound Profile for Pandemic Preparedness" in Nature Reviews Drug Discovery, "The Indispensable Value of Small-Molecule Antivirals in Epidemic and Pandemic Preparedness" in Clinical Infectious Diseases, and an assessment of significant gaps in the antiviral landscape for vector- and contact-transmitted viral infections of pandemic potential[216]. **The INTREPID Alliance** published key articles "Antiviral Target Compound Profile for Pandemic Preparedness" in Nature Reviews Drug Discover, and "The Indispensable Value of Small-Molecule Antivirals in Epidemic and Pandemic Preparedness" in Clinical Infectious Diseases[217].	• **The Cumming Global Centre** for Pandemic Therapeutics will establish a fund to enable researchers to move closer to commercialisation, and support capacity development in translation and commercialisation for research teams[88]. • **The Cumming Global Centre for Pandemic Therapeutics** will continue to establish global research co-funded partnerships with other research institutions to create a global network of partnerships which expand geographic reach, deepen research focus, and leverage investments. These research partnerships are complemented by the Centre's engagement with other partners to the IPPS roadmap[88]. • **Instituto Butantan** will initiate the development of a new production facility dedicated to advanced antibody-based therapeutics[97]. • **University of Oxford** will co-lead the OpenBind consortium to generate the world's largest collection of data on how drugs interact with proteins and support training of new AI models that can identify promising new drugs and accelerate molecule drug discovery. Target selection will include specified targets from viruses of pandemic concern, with machine learning technologies and datasets applicable to pre-designed compounds for outbreak-prone pathogens[42]. • **University of Oxford (PSI/ Centre for Medicines Discovery (CMD))** will seek follow-on funding for novel small molecule inhibitors to advance various preclinical and lead optimisation projects to the next development space, planned in partnership with DNDi for later-stage projects[42]. • In 2026, **the INREPID Alliance** will produce the 5th Edition of the Preclinical and Clinical Antiviral Landscape.

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
The INTREPID Alliance released on their website a deep dive analysis of the antiviral landscape for Orthopoxviruses with an emphasis on the situation for mpox treatment. This was followed up with a more detailed publication in Antiviral Research in September 2025[218]. **The INTREPID Alliance** launched the Antiviral Toolbox in November 2025, an open-access resource including a Registry of Antiviral Compound Libraries, drug development tools such as target compound and product profiles, landscape reports, and pro bono advisory service[89]. **The INTREPID Alliance** released the fourth edition of its Antiviral Clinical and Preclinical Development Landscape, a comprehensive analysis of the global pipeline of small-molecule antiviral compounds[87]. **The INTREPID Alliance** released a report/proceedings on "Catalyzing Funding for Antivirals and Preserving the Medical Countermeasures Enterprise in the United States" focusing on key policies needed to incentivise antiviral R&D[219]. **The INTREPID Alliance** consulted with regulatory leaders and formed a dedicated Regulatory Working Group to identify key regulatory policy initiatives to help create a favourable regulatory environment for the approvals of small molecule antivirals[219].	**Priority Actions for 2026** • Operationalise the Therapeutics Development Coalition with focused proof-of-concept projects. • Diversify and sustain financing through blended models that combine public, philanthropic, and private investment to fund translational R&D. • Promote responsible innovation through sustained investment in platform technologies and equitable access frameworks.

Vaccines R&D

RECOMMENDATIONS:

4 **Invest in modernising vaccine technology** by targeting vaccine preventable diseases.

12 **Stimulate a move towards innovative technologies** to reduce the complexity of vaccine manufacturing processes and make technology transfer and scalable manufacturing easier in a pandemic by investing in R&D.

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
Afrigen Biologics has progressed mRNA vaccine candidate development for mox, Rift Valley Fever (RVF), and H5N1 influenza. For mpox, Afrigen is collaborating with the University of Cape Town and EpiVax on mRNA construct design and immunogenicity studies. For RVF, Afrigen is working with CEPI, the International Vaccine Institute, and Quantoom using synthetic DNA and continuous manufacturing to reduce production timelines. For H5N1, Afrigen is supporting Sinergium Biotech's vaccine development through the WHO/Medicines Patent Pool (MPP) mRNA technology transfer programme[126]. **Developing Countries Vaccine Manufacturers Network (DCVMN)** members have made significant progress on mpox vaccine development across multiple platforms and partnerships. Bharat Biotech completed animal toxicity studies using similar MVA strain present in the Bavarian Nordic vaccine and is developing clinical plans. One of CNBG's subsidiaries-Shanghai Institute of Biological Products Company Limited has a candidate under phase one clinical trial in China. Bio-Manguinhos has a construct for Mpox that can be rapidly tested on its mRNA platform and is collaborating with another Brazilian institution on the development of a Modified Vaccinia Virus Ankara 4 vaccine, while IMBCAMS is developing an mpox vaccine using modified attenuated Guang 9 strain through gene editing. THSTI and Panacea Biotec are collaborating on a recombinant protein nanocage-based vaccine candidate with over 99% conserved antigens across clades, already evaluated in preclinical studies[108]. **CSIR** completed proof of concept process development for a pipeline of vaccine candidates, with Nipah and mpox VLP and subunit vaccines being developed. The Nipah program, co-funded by the USDA, progressed well towards an in vivo challenge study in pigs when funding was paused. The mpox vaccine project, developed in partnership with University of Cape Town (UCT) and Afrigen, entered animal antigenicity testing[96].	**Planned Partner commitments** • **CEPI** will progress vaccine library pre-clinical development for three viral families, advancing candidates in the Arenavirus family to investigational new drug status and achieving preclinical proof of concept for candidates in the Paramyxovirus and Phenuivirus families[45]. • **CEPI** will develop artificial intelligence-based software applied to a Disease X information database to accelerate viral family prioritisation and immunogen design[45]. • **CEPI** will advance pre-clinical development for broadly protective coronavirus and broadly protective filovirus candidates, with proof of concept demonstrated for BPCV candidate(s), and second-generation vaccine development initiated for filovirus[45].

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
PSI Oxford advanced clinical development across multiple priority pathogens using ChAdOx platform technology, completing first-in-human trials for the ChAdOx1 NipahB vaccine and completing Phase 1 studies for MERS vaccine in older adults. The ChAdOx1-LassaJ vaccine has been Good Manufacturing Practice (GMP) manufactured and is ready for first-in-human studies. Follow-up of participants and immunology readouts are ongoing from a Phase 1 trial of a ChAdOx vaccine for CCHF[42]. **The mRNA Technology Transfer Hub R&D program,** coordinated by SAMRC through the 10-partner South African mRNA Vaccine Consortium (SAMVAC), continued development and testing of novel ionizable lipids to optimise delivery and immunogenicity[127]. **PATH** completed a comparative assessment of four benchtop lipid nanoparticle mixing platforms for mRNA encapsulation, which included technical and operational evaluations and a six-month stability test of generated lipid nanoparticles, and submitted a manuscript of this analysis to Vaccine X[79]. **SAMRC and DSTI** invested in rapid development and preclinical evaluation of an mpox mRNA vaccine for clinical testing at Afrigen and UCT, and development of a virus-like particle (VLP) scaffold displaying MPXV antigens as a next generation mpox vaccine at CSIR and UCT[27]. **Osivax** receives $19.5 million BARDA support for universal flu vaccine candidate[220]. **Wellcome** and **Merck Sharp & Dohme (MSD)** are continuing their investment in Hilleman Labs by USD $75 million to de-risk low-cost, thermostable vaccines for LMICs, including technology transfer of a next-generation Ebola vaccine[156]. **CEPI** supported advancement of candidates into preclinical and clinical development including: University of Saskatchewan's broadly protective pan-sarbecovirus candidate[221]; Uvax Bio's nanoparticle-based MERS candidate[222]; Gennova Biopharmaceuticals Limited's saRNA Nipah virus candidate[223]; AdaptVac's broadly protective VLP-based filovirus candidate[224]; Stanford's AI-designed ferritin nanoparticle-based broadly protective filovirus candidate; and advancing Public Health Vaccines' Nipah candidate into phase 2 trials in Bangladesh[224]. **CEPI** initiated multiple innovative technology partnerships to advance next-generation vaccine platforms, including: POP BIO's SNAP nanoparticle protein vaccine platform, which enables rapid antigen purification in 30 minutes compared to conventional multi-day processes[113]; Centivax's epitope focussing technology for broad variant protection[114]; and Abera Bioscience's bacterial platform for enhanced intranasal vaccine delivery and mucosal immunity[115]. **CEPI** has been supporting breakthrough innovations in vaccine formulation and manufacturing processes, including: research into fungal antigen production as a cost-effective alternative to mammalian cell systems[225]; National Research Council of Canada's (NRC) optimised mammalian cell lines for accelerated vaccine production[226]; ACM Biolabs' thermostable mRNA technology for improved LMIC access[116]; Nagasaki University's nanoball mRNA delivery enhancement[227]; Ethris' room-temperature stable spray-dried RNA vaccines[117]; VitriVax's controlled-release technology for single-shot multi-dose administration[118]; Micron Biomedical's needle-free microarray delivery systems[119]; DNA Script's automated synthetic DNA template manufacturing[228]; University of Toronto's portable virus-like particle manufacturing platform[229]; and University of Sheffield's RNAbox for regional mRNA vaccine production[230]. **CEPI's Centralised Laboratory Network** has expanded to 20 members with the addition of Korea Disease Control and Prevention Agency and International Vaccine Institute, establishing the world's largest standardised vaccine testing network. CEPI is developing a shareable database to strengthen partnerships with key stakeholders including WHO, national health ministries, and regional surveillance networks for enhanced early response coordination[45]. **CEPI** published a Platform Readiness Dashboard and is facilitating alignment across the regulatory community on standardised definitions of platform technology[120]. **CEPI** launched a pioneering adjuvant library hosted by the UK Medicines Healthcare Products Regulatory Agency (MHRA), which serves as a vaccine-adjuvant matchmaking platform to enhance vaccine potency and accelerate outbreak response capabilities[121]. **CEPI** is supporting a real-world effectiveness study of the LC16m8 mpox vaccine in the Democratic Republic of the Congo to assess vaccine effectiveness and safety in African populations including children. The research leverages Japan's donation of 3 million LC16m8 vaccine doses[104]. **CEPI** partnered with Norway's University of Bergen, to conduct comprehensive mapping of global vaccine development for CEPI priority pathogens and emerging viral threats[131]. **CEPI** is developing the world's first AI platform dedicated to pandemic preparedness: the Pandemic Preparedness Engine. Working with research institutions and vaccine scientists globally, CEPI is creating an end-to-end digital research and development system designed to integrate multiple datasets into a single, secure platform[53].	• **CEPI** will progress Phase 1 and 2 clinical development for 12+ conventional candidates across 8 pathogens, including COVID-19, MERS, a broadly protective coronavirus candidate, filovirus, Lassa, mpox, Nipah, and Rift Valley Fever[45]. • **CEPI** will deliver investigational reserves for Nipah and Rift Valley Fever vaccines for emergency use[45]. • **CEPI** will achieve licensure and market authorisation for chikungunya vaccine product in an affected country, and complete studies to enable expanded use of licensed mpox vaccines by vulnerable populations[45]. • **CEPI** will advance Phase 1 clinical studies for 2 RNA platforms, integrating R&D and manufacturing supply chain innovations[45]. • **CEPI** will identify next generation viral vector platforms for development, targeting desired characteristics and access rights for rapid response[45]. • **CEPI** will publish its third five-year strategy (CEPI 3.0) in 2026, covering the period 2027-2031 and building on progress toward the 100 Days Mission while addressing persistent vulnerabilities in vaccine development for epidemic and pandemic threats[45]. • **Gavi** will publish a Market Shaping Roadmap for mpox vaccines by end-2025, and is working with WHO and other partners to launch the mpox vaccine stockpile, managed by ICG, by the second half of 2026[135]. • **PSI Oxford** will continue MERS, Nipah, and Lassa vaccine development through CEPI partnership and advance regulatory pathways, with plans to license MERS and Nipah vaccines through the European Medicines Agency's (EMA) immunobridging mechanism[42]. • **PSI Oxford** will progress the Junin virus programme to clinical trials through strategic partnership with Moderna utilising its mRNA platform and three international partners working on novel antigen design, including a planned comparison study of mRNA and viral vector approaches[42]. • **PSI Oxford** will advance platform technology development across priority pathogens, progressing a Chikungunya-Mayaro bivalent vaccine using both mRNA and viral-vector platforms toward Phase 1 trials, and advancing early stage work on West Nile virus vaccines, and Rift Valley Fever virus using ChAdOx and Moderna platforms[42]. • In addition to providing ongoing lipid nanoparticle encapsulation support to mRNA vaccine developers, **PATH** will expand capabilities to accommodate self-amplifying RNA (saRNA) constructs, as well as evaluating the potential of low-cost macrofluidic mixing platforms for use in encapsulation[79].

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
Oxford launches major new AI vaccine research programme with the Ellison Institute of Technology[111]. **Fiocruz** developed Brazil's first national mRNA platform for vaccines and therapies, filing the technology patent with Brazil's National Institute of Industrial Property[231]. **Fiocruz** signed a MoU with Institut Pasteur and Sanofi, establishing a three-way alliance to promote innovative vaccine technology solutions[232]. **Fiocruz** established partnerships with Quantoom Biosciences for RNA-based vaccine and therapy development, building on the successful implementation of Quantoom's Ntensify® mRNA production system at Bio-Manguinhos[233]. **Fiocruz** has signed a three-year cooperation agreement with Mexico's Ministry of Health and Birmex in August 2025, focusing on research, development, and technology transfer programs involving messenger mRNA platforms for vaccines, therapies, and other health products[98]. **Fiocruz** partnered with PATH through a memorandum of understanding to accelerate innovation, production, and access to vaccines, diagnostics, and biopharmaceuticals in Brazil and Latin America[174]. During Brazil's 2025 BRICS presidency, **Fiocruz** coordinated the BRICS Vaccine R&D Center. Key 2025 achievements include establishing a working group to structure the Electronic R&D Repository and advancing governance frameworks for the Center[234]. **The European Commission** launched a call for framework contracts in March 2025 to accelerate the development of next-generation influenza vaccines, focusing on scalable platforms and novel administration routes to strengthen preparedness for influenza pandemics[123]. **The European Commission** inaugurated the European Vaccine Hub (EHV) to strengthen Europe's vaccine readiness and responsiveness in times of pandemics. The Hub will be made up of a consortium of leading European organisations in vaccine development and national pandemic preparedness programmes[235].	**Priority Actions for 2026** • Expand the global vaccine library through diversified investment and coordinated development. • Accelerate regulatory innovation beyond outbreak contexts. • Strengthen and diversify vaccine platform technology and manufacturing innovations for scalable, equitable pandemic response • Build vaccine confidence through transparency and engagement on safety and quality.

Strengthening Global Surveillance

RECOMMENDATIONS:

7 **Governments should normalise the use of accurate diagnostics for coronavirus and influenza** in point-of-care and nonclinical settings.

8 **WHO should support an enhanced role for diagnostics** in the surveillance of pandemic threats.

21 **Explore the scope for a system** that enables biological samples to be collected and shared immediately and unhindered in a pandemic

22 **Support the recommendations of the Science Academies of the G7** and endorse the development of a roadmap towards a more systematic approach to data capture, standards, sharing and analysis for health emergencies.

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
Malaysia has aligned the WHO Pathogen Prioritisation Framework with its national health security framework and made molecular diagnosis available for most prioritised pathogens at reference laboratories[130]. **Malaysia** is exploring the development of rapid detection methods through multi-agency collaborations, including biosensor and rapid lateral flow technologies for infectious disease detection[130].	**Planned Partner commitments** • **AMSP** will expand data integration to include genomic surveillance outputs for predictive supply planning and deploy AI-driven forecasting tools linking case trends to commodity demand[136].

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
WHO, in collaboration with key partners and supporters, launched version 2.0 of the Epidemic Intelligence from Open Sources (EIOS) system, used globally for the early detection of public health threats[236]. **The Gates Foundation** has committed funding to the WHO Hub for Pandemic and Epidemic Intelligence for 4 years. Support will include bolstering the Hub's technical and advocacy capabilities to drive progress towards Collaborative Surveillance efforts nationally, regionally, and globally[237]. **ASLM,** in collaboration with Africa CDC and Member States, has developed a framework for Geographic Information System (GIS)-mapping of laboratory systems and network capacities in Africa[238]. **ASLM,** through Africa Pathogen Genomics Initiative, is facilitating the establishment of the AGARI platform for data sharing for priority pathogens[238]. **CEPI** and **PATH** have launched the US$2.5 million Biospecimen Sourcing Initiative to standardise and accelerate the ethical collection of outbreak survivor samples, making outbreak material ready to develop assays and standards in a matter of week[79]. **PATH** continues to support strengthening Wastewater environmental surveillance through product development as well as development of process controls to standardise interpretation across platforms. This work advance in collaboration with the UK MHRA[79]. **Data.org** launched Epiverse Phase 2, an initiative that aims to strengthen pandemic and epidemic intelligence in 10 African countries by 2026, focusing on data integration and accessibility to support decision-making processes. The initiative is implemented through strategic partnerships with WHO, LSHTM/MRCG, Universidad Javeriana, and AppliedEpi, with 10 Epiverse Fellows responsible for promoting national-level adoption[155]. **Data.org** has developed an adapted Epiverse curriculum, the Epiverse Data Science Training Program, for implementation across the 10 countries. This program includes 120 formal trainees in English and French cohorts, with over 700 additional data practitioners accessing materials in self-paced format[155]. **AMSP** has integrated with Africa CDC's epidemiological intelligence systems to identify supply-demand mismatches during outbreaks and supported Africa CDC's Public Health Emergency Operations Centres by sharing logistics intelligence for rapid response[136]. **AMSP** has facilitated regional pooled procurement and pre-positioning of emergency supplies (diagnostics, reagents, PPE), linking surveillance triggers to automated procurement workflows for faster mobilisation of critical commodities[136]. **BioPhorum** has established a Crisis Response and Management Team through its Supply Resilience Phorum collaboration, with a surveillance remit for pandemics and vaccine mitigation needs. The team conducts horizon scanning for emerging threats, with an established escalation process to recruit relevant subject matter experts. BioPhorum has an established relationship with BARDA on this activity and plans to extend engagement to HERA in the EU2[39]. **The National Health Service England's Clinical Respiratory Metagenomics Programme** has begun expanding its network of clinical metagenomics services to up to 30 NHS sites nationwide, enabling faster diagnosis and treatment for patients with severe respiratory illnesses. The expansion of the programme will contribute to a national respiratory pathogen surveillance system, integrated with mSCAPE (a UKHSA metagenomics initiative), to aid in the rapid detection of infectious diseases[34]. **CEPI** launched two major African-led research initiatives to develop comprehensive mapping of Rift Valley fever impact led by researchers in Kenya and Tanzania. Both employ One Health approaches to identify optimal sites for vaccine efficacy trials and develop outbreak prediction capabilities[45]. **CEPI** launched the Global South Leaders in Epidemic Analytics and Response Network (GS LEARN) in partnership with the Bill & Melinda Gates Foundation to strengthen technical expertise in infectious disease modelling in the Global South and enhance interdisciplinary collaborations within and across regions[45]. **CEPI** began the process of integrating the Biothreats Emergence, Analysis and Communications Network (BEACON), an open-source surveillance platform that leverages AI and global experts to rapidly collect and analyse information on emerging infectious diseases, with the Viral Intelligence & Strategic Threat Assessment (VISTA) tool. This integration will provide near real-time risk rankings of viruses with the greatest spillover and pandemic potential to help prioritise vaccine library and Disease X R&D investments[45]. **Fiocruz** launched the Cria Saúde community-based surveillance project in six Rio de Janeiro territories, training 200 community health agents and establishing nuclei for participatory health surveillance[158].	• **CEPI** will advance work on predicting viral escape mutations and monitoring variants of concern using novel AI modelling and wet lab methodologies[45]. • **CEPI** will establish the GS LEARN consortium to build epidemic analytics and response capacities in the Global South by strengthening and leveraging technical expertise and knowledge in infectious disease modelling and enhancing interdisciplinary collaborations[45]. • **Data.org** will conduct country needs assessments through Epiverse Fellows embedded in ministries of health and public health institutes to identify local challenges and support implementation of relevant Epiverse packages through 2026. Data.org will train 120 purpose-driven data practitioners by December 2025 with skills to support data-analysis to drive decision-making[155]. • **The Gates Foundation** will invest in advocacy to support routine integrated disease surveillance systems, address insufficient resources including trained workforce, funding, and laboratory strengthening, and maintain necessary political support needed to strengthen global disease surveillance and monitoring[237]. • **PATH** will strengthen internal capabilities for integrated disease surveillance that can be leveraged by country programs throughout the organisation. This will include both direct support to PATH-specific initiatives, as well as providing opportunities for thought leadership in global fora[79]. • **HERA** will operationalise an EU Wastewater Sentinel System by 2026 and launch a Global Wastewater Sentinel System through GLOWACON, collecting pathogen circulation data from strategic locations including airports across the EU and globally for early outbreak detection and timely medical countermeasures deployment[50].

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
Cidacs/Fiocruz Bahia developed Mixed Model of Artificial Intelligence and Next Generation (MMAING) for early detection of respiratory disease outbreaks using primary health care data[240]. **Fiocruz** lauched the 2nd edition of the Programa Educacional VigiFronteiras-Brasil to improve capacity building for surveilance in partnership with neighbouring countries in Latin America[241]. **Fiocruz** signed a Memorandum of Understanding with AIR Centre to establish international cooperation in Blue One Health, focusing on medication research, knowledge-sharing platforms, and sustainable scientific activities within the Atlantic Basin[242]. **UK Cabinet Office** developed prototype biothreats radar in the National Situation Centre that integrates human, animal, and plant health risks for near real-time assessment of emerging biological threats[154]. **The African Bioinformatics Institute** has officially launched with support from Wellcome, marking a major step toward building Africa's bioinformatics capacity and empowering local researchers to lead data-driven health innovation[243]. **Wellcome Trust** has funded a 5-year multi-country study led by ILRI to understand endemic Rift Valley Fever transmission across ecologically distinct African regions, focusing on epidemiology, vector-pathogen interactions, phylogenetics, biosocial dimensions, and environmental change[134]. **The Wellcome Trust/FCDO** co-funded mpox GECIVO project has launched as an African-led multi-country study across DRC, Cameroon, Nigeria, with partners in South Africa and the USA. The project aims to investigate the evolving mpox epidemiology, transmission dynamics, pathogenesis, immunology, and outcomes among children and adults, including pregnant and breastfeeding women[134]. **Wellcome Trust** is supporting the 7-1-7 initiative through funding operational research and strategic partnerships to understand bottlenecks that countries encounter when using the 7-1-7 principle, issuing 11 grants to date that have identified gaps including health care scepticism and appropriate diagnostics[134]. **Novo Nordisk Foundation** pledges up to $31 million to support AI-enabled system to monitor infectious disease outbreaks and bolster global pandemic preparedness[244].	**Priority Actions for 2026** • Strengthen Surveillance-Response Integration. • Sustain LMIC Capacity Building • One Health Surveillance

Improvements to Clinical Trials Capability

RECOMMENDATIONS:

9 **Scope out how an international network of clinical trial platforms could be implemented** to enable a coordinated and efficient approach to testing of DTVs.

18 **Explore the creation of regional mechanisms** to coordinate and prioritise clinical trials of DTVs.

11 **Transform the approach to clinical trial regulation,** shortening the time to authorise trials and streamlining the requirements and guidelines relating to trial conduct.

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
AMSP initiated a strategic partnership with Revital to localise production of clinical trial ancillaries and vaccine delivery kits for mpox and other outbreak-related studies, strengthening Africa's resilience for rapid-response trials[136]. **AMSP** provided supply-chain planning inputs for mpox-related adaptive platform trials to ensure timely availability of trial kits and ancillaries in participating countries[136].	**Planned Partner commitments** • **CEPI** will develop pre-approved, scenario-specific, adaptive clinical trial protocols for rapid deployment and evidence generation during outbreaks of CEPI priority pathogens & Disease X in consultation with WHO, regulators and regional & global experts[45].

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
PSI Oxford has advanced clinical therapeutics work including progressing dengue monoclonals toward clinical evaluation, evaluating tecovirimat for mpox in the PLATINUM trial, leading platform trials of potential antiviral and host-directed therapies for respiratory viruses, filoviruses, and dengue, and developing core outcome sets for clinical trials for Nipah and dengue[42]. **CEPI,** along with European and Developing Countries Clinical Trials Partnership 3 (EDCTP3), is funding clinical trials of Jynneos mpox vaccine in vulnerable populations in the Democratic Republic of the Congo, including infants and pregnant women, and is also supporting a trial in children to support potential label expansion for mpox vaccine use in the most vulnerable populations[245]. **The Sabin Vaccine Institute** has launched a multi-site phase 2 clinical trial, supported by the Biomedical Advanced Research and Development Authority, in the United States to test its Marburg vaccine candidate[246]. **Moderna's** phase 1/2 trials for mpox and pandemic influenza vaccines demonstrated potent, durable immune responses[109]. **Instituto Butantan** has trained pandemic H5N8 vaccine teams to prepare for situations requiring both preclinical and clinical trials to be conducted rapidly and efficiently[97]. **CEPI** has selected PATH to be the Technical Coordinating Partner to initially lead the Research Preparedness Program in East and Central Africa (RPECA Program), which aims to bolster local clinical trial capacity and disease outbreak readiness. **CEPI and PATH** are developing a study protocol that could be implemented to evaluate available vaccine candidates (or approved vaccines) during a Nipah Virus outbreak. **WHO** has launched the Global Clinical Trials Forum (GCTF), a global, multi-stakeholder network to strengthen clinical trial environments and infrastructure at national, regional and global levels[144]. **WHO** advanced normative guidance on including pregnant, lactating, and immunocompromised populations in clinical trials, addressing historical exclusion of vulnerable populations from research[145]. In January 2025, **International Council for Harmonisation (ICH)** published its updated Good Clinical Practice Principles and 'Annex 1' with some significant changes from R2, notably a new focus on prospective management of quality, proportionate risk management and data collection and the importance of generating reliable and informative results. The Good Clinical Trials Collaborative (GCTC) co-ordinated an expert response to 'Annex 2' which relates to trials with decentralised, pragmatic, or real-world data elements[247]. **The Good Clinical Trials Collaborative** launched two resources to support implementation of GCTC Guidance for Good Randomized Clinical Trials: an online learning course and an evaluation tool. The Good Clinical Trials Collaborative have also contributed to the development of the WHO course that will accompany their 'Guidance for best practices for clinical trials'[247]. The clinical trials working group of **GloPID-R** has developed a monitoring, evaluation & learning framework for its Living Roadmap on Clinical Trial Coordination and worked to map associated investments and policy changes across the consortium to track progress. In 2025, this work was made publicly available[248]. **GloPID-R** has updated its review on 'Addressing challenges for clinical research responses to emerging epidemics and pandemics: a scoping review', which was published by the eClinical Medicine in June, 2025[249]. **GloPID-R** developed a series of regional case studies that exemplify best practices in strengthening clinical trial ecosystems. These case studies illustrate how funders can effectively design and implement funding calls, supported by appropriate policy frameworks and funding mechanisms, to establish robust, responsive clinical trial infrastructures. The case studies are due to be published shortly[42]. **The International Severe Acute Respiratory and emerging Infection Consortium (ISARIC)** provided technical support to open the world's first clinical trial for Marburg treatments, activating the Platform Adaptive Randomized Trial for New and Repurposed Filovirus treatments (PARTNERS)[42]. **ISARIC** is collaborating with multiple partners to implement mpox4C (an mpox clinical characterisation protocol) in Africa and Europe for a global research context. Most notably, the protocol has been adopted by the mpox Research Consortium as part of the mpox-GECIVO Africa project, a multi-site observational study funded by Wellcome and FCDO. Within the UK, ISARIC activated the mpox4C during the first Clade Ib case presentation[42].	• **CEPI** will continue to increase operational readiness for research conduct in emergencies by building a consortium of regional stakeholders to identify and strengthen the capacity of clinical research[45]. • **Protas,** the former host of the now completed GCTC programme, will continue advocacy to advance the clinical trial environment and infrastructure as a founding member of the WHO Global Clinical Trials Forum (GCTF)[247]. • Members of the **Good Trials Prism** collaboration are planning to submit a Prism 2.0 grant application for further funding of their work going forwards, demonstrating how the Prism project has catalysed local ownership and that the GCTC guidance and resources will be adaptable to local contexts[247]. • In 2026, **GloPID-R** will offer the first round of funding through the first Global Research Improving Pandemic Preparedness (GRIPP) call. This call seeks to strengthen clinical trial capacity in LMICs during inter-epidemic periods by accelerating innovation, ethics and collaboration, ensuring low-resource settings are research-ready to lead and deliver effective, equitable trials in future outbreaks[42]. • The **GloPID-R** clinical trials working group will continue to map and report associated investments and policy changes across the consortium to track progress. The working group has developed a further set of indicators, tracking the impact of trial networks funded in an outbreak as well as the speed with which trial networks and platforms receive funds during an outbreak. Findings will be made publicly available in 2026, and support targeted action among the group[42]. • **WHO** will finalise the Clinical Trials Maturity Framework, which is currently under review by the technical advisory group at the WHO. Following review, the framework will undergo in-country piloting and subsequent revisions. The finalised document will serve as an essential component in establishing global standards for clinical trial units[42]. • **NIHR** has launched a competition for platform clinical trials to test infectious disease therapeutics. Funded studies are expected to begin in 2026[251]. • **The EU Commission** will propose an investment plan for clinical research to facilitate funding for multi-country clinical trials[252].

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
ISARIC has spearheaded the development of digital systems for research acceleration and data interoperability, such as the Clinical Epidemiology Platform. The platform is designed to reduce barriers to research data collection and analysis and improve interoperability within and across LMIC research systems. The open software applications for automated generation of case report forms and database files (BRIDGE) and data analysis visualisations (VERTEX) have been launched. Five ARChetype Case Report Forms (CRF) are now deployed for COVID, dengue, H1Nx, mpox, and yellow fever[42]. **ISARIC** undertook and published a scoping review of the infrastructure, capabilities, and capacities required to manage and assure the quality of clinical trials, enabled by funding through ISARIC 3.0 (co-funded by FCDO, Gates Foundation and Wellcome). This review was a key contribution to the development of the WHO Clinical Trials Unit Maturity Framework, currently under revision following stakeholder review. Development of the framework is being led by the PSI, through funding from WHO and ISARIC 3.0[42]. **The PSI Policy and Practice Research Group** has received a grant from WHO with UK Department of Health and Social Care To embed best practices during interpandemic times, WHO, with UK Department of Health and Social Care (DHSC) funds, has implemented the World Health Assembly Resolution (75.8) on strengthening the clinical trial ecosystem, including for pandemic preparedness research. This led to the development of the Global Action Plan for Clinical Trial Ecosystem Strengthening (GAP-CTS) to define, align and support funding policy and practice standards. Through this award, WHO worked with the University of Oxford Pandemic Sciences Institute Policy and Practice Research Group to systematically map the policies and practices of the world's major funders of clinical trials and ensure learning from the GloPID-R Funders group Roadmap for Clinical Trial Coordination related to pandemic preparedness research was captured. This work culminated in a joint statement on 25 September 2025, where the world's largest funders of medical research committed to implement WHO standards to strengthen clinical trial systems[42,250].	**Priority Actions for 2026** • Operationalise Regional Trial Networks and Shared Governance • Scale Preparatory Trial Innovations • Ensure Sustainable Financing and Workforce Development

Improvements to Regulation Processes

RECOMMENDATIONS:

16 **Governments and industry should share risk** to maintain vaccine manufacturing capacity.

Note: Recommendation 16 extended to cover manufacturing capacity across DTVs

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
AMSP aligned its procurement and supply-chain frameworks with Africa CDC's regulatory harmonisation agenda (AMA) to ensure that products and ancillaries for clinical trials meet harmonised standards and can move quickly across borders[136]. In February 2025, seven **WHO Maturity Level 3 National Regulatory** signed a Memorandum of Understanding facilitated by African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD) and Africa CDC to establish a framework for reliance on regulatory decisions, enabling information sharing and work-sharing to expedite approval processes for medicines, vaccines, and medical devices. This agreement represented a milestone for the African Medicines Regulatory Harmonization (AMRH) initiative, building trust in regulatory systems as AMRH moved toward operationalisation of the AMA[253]. The **AMRH** officially concluded as a programme, and the African Medicines Agency Institution, its legal successor, continues[254]. **CEPI** has continued progress towards an end-to-end safety and pharmacovigilance strategy, including establishing and expanding enabling partnerships and infrastructure. These include the Safety Platform for Emergency vACcines (SPEAC), the Background Rates of Adverse Events for Vaccine Evaluation (BRAVE), the International Network of Special Immunisation Services (INSIS), the CEPI-Pan American Health Organisation (PAHO) pharmacovigilance plan for technical cooperation in the Americas, and the International Network for Vaccine Safety Surveillance (INNOVATE)[255,256].	**Planned Partner commitments** • **CEPI** will continue working with the industry innovations consortium to engage with regulatory authorities to drive acceptance of platform technology data[45]. • **AMA** will advance progress towards a digital regulatory platform that will host joint scientific opinions, streamline protocol submissions for clinical trials, and provide data transparency across State Parties/Member States[261]. • **AMA** will continue to establish partnerships, relationships and alliances with a wide range of establishments along the innovation life cycle to enhance the ecosystem for clinical trials – from R&D through manufacturing to product safety[261].

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
CEPI is enabling multi-country regulatory submissions and expediting regulatory review through provision of a cloud-based data-sharing platform (Accumulus Synergy) - currently in a major pilot programme with 19 global regulators, to demonstrate how parallel vaccine reviews can boost transparency and collaboration[151]. **CEPI** and Wellcome launched the Framework for Evidence Evaluation in Vaccine Assessment (FEEVA) project in July 2025, a US$3 million collaboration with UNSW Sydney and Monash University. The four-year initiative will develop standardised frameworks for evaluating early vaccine evidence to support accelerated regulatory approvals during outbreaks, directly supporting the 100 Days Mission timeline[45,110]. **CEPI** is supporting a correlates of protection study led by Rwanda Biomedical Centre involving individuals who have recovered from Marburg virus infection and their close contacts, which will support advancing Marburg countermeasures toward licensure[257]. **PATH** is coordinating efforts to identify and evaluate potential correlates of protection to develop scenarios for their use in product development decisions and regulatory strategy. This project will map existing evidence and consult experts and other stakeholders to develop three disease-specific playbooks (filoviruses, mpox, and Lassa fever) and one disease-agnostic playbook[79]. As part of the COMBINE programme, the **EU Commission and EU Member States** have launched a pilot project to simplify and accelerate the evaluation of combined studies under the Clinical Trials Regulation (CTR) and In-vitro Diagnostic Medical Devices Regulation (IVDR)[258]. **The UK Medicines and Healthcare products Regulatory Agency (MHRA)** finalised The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, coming into force in April 2026, to accelerate approvals through notifiable pathways and reliance on trusted foreign authorisations[34,149]. **The UK** published new post-market surveillance legislation for medical devices that enhances oversight and aligns Great Britain's classification system with the International Medical Device Regulators Forum (IMDRF), strengthening global harmonisation[34]. Within the **ACCESS Consortium,** regulators are developing digital systems for shared assessments and international reliance, streamlining review processes while maintaining high safety standards[34]. **The Wellcome trust** committed funding of $12.3M over 5 years to AUDA NEPAD to support operationalisation of the African Medicines Agency and support initiatives to strengthen regulatory systems and clinical trial capabilities on a continental basis[134]. **The Wellcome Trust and Gates Foundation** are supporting Wits University to strengthen executive leadership regulatory capabilities of CEOs and senior officials at African regulatory agencies in efforts to progress and achieve WHO maturity level 3 status. The continental initiative, AMA, will rely on expertise at the national level in Africa to conduct its work[134]. **The NISH (National Immunisation Technical Advisory Groups (NITAGs) Support Hub),** continued to actively support the work of NITAGs in Africa; and EVIDA, (the WHO-PAHO initiative on Strengthening Evidence-informed Vaccine & Immunisation Decision-making and Appraisal in LMICs initiative), is strengthening and networking NITAGs in the Americas while encouraging them to collaborate with African NITAGs. Both projects are Wellcome funded[134]. **FDA** announces plan to phase out animal testing requirement for monoclonal antibodies and other drugs[38]. **WHO's** releases of the Global Benchmarking Tool Plus Medical Devices (GBT+MD) expanding the existing framework to include medical devices[73]. **The International Medical Device Regulators Forum (IMDRF)** published the "Playbook for Medical Device Regulatory Reliance Programs" to provide practical guidance on how regulatory bodies can use each other's work to streamline medical device approvals and enhance global patient access[74]. **The FDA** issued finalised guidance outlining the criteria for authorising emergency use of unapproved in vitro diagnostic tests (IVDs) during future public health emergencies[259]. Through its investments in regional manufacturing of therapeutics and diagnostics for equitable access, with PATH and USP as implementing partners, **Unitaid** is supporting interventions in regulatory strengthening, including collaboration with Africa CDC, the African Medicines Agency and AUDA-NEPAD to shape policy and regulation[80]. **Senegal and Rwanda** achieve WHO Maturity Level 3 in medicines regulation[260].	• **AMA** will continue working with WHO-AFRO and AVAREF in alignment of priorities, transfer of processes, and development of mechanisms for effective and sustainable clinical trial oversight[261]. • **The EU Commission** will propose an EU Biotech Act to make the EU regulatory system more conducive to biotech innovation in various biotech sectors[262]. • **AMSP** will integrate regulatory reliance pathways by 2026, targeting 40% reduction in diagnostic approval timelines[136]. **Priority Actions for 2026** • Strengthen Regional Harmonisation and Reliance Pathways • Scale Preparatory Regulatory Innovations • Promote Regulatory Equity and Mutual Recognition

Geo-Diversified Manufacturing

RECOMMENDATIONS:

16 **Governments and industry should share risk** to maintain vaccine manufacturing capacity.

Note: Recommendation 16 extended to cover manufacturing capacity across DTVs

2025 SUMMARY PROGRESS UPDATE

CEPI has developed and disseminated a Fast-Tracking Vaccine Manufacturing: CEPI's Rapid Response Framework for the 100 Days Mission. A tool that outlines peacetime preparatory and outbreak response activities in support of the 100 Days Mission[263].

CEPI launched a rolling seed-funding call CfP Innovative analytical technologies to improve vaccine manufacturing speed and equitable access to advance analytical technologies and innovations in analytical technologies that contribute to the goals of reducing the time of vaccine development, manufacturing and release[45].

The Pasteur Network launched the Vaccine Manufacturing Initiative, supported by Wellcome Trust, to strengthen collaborative vaccine manufacturing across member institutes including Institut Pasteur de Dakar, Fiocruz/Bio-Manguinhos, and Institut Pasteur. In May 2025, representatives convened in Casablanca to develop a roadmap for technology transfer, training programs, and joint manufacturing operations, leveraging the Network's combined capacity of over 525 million doses annually across 9 countries[264].

Valneva and Serum Institute of India announced an exclusive license agreement to enable supply of Valneva's licensed Chikungunya vaccine in Asia[265].

CSIR have completed construction of the first phase of a pilot-scale manufacturing facility for investigational protein-based products, including candidate vaccines, therapeutics and reagents[96].

Afrigen is establishing a plasmid DNA (pDNA) production platform, and plans to transition the pDNA R&D process to production in October 2025[126].

Afrigen is expanding its adjuvant production platform to be included in its GMP facility and is on target to achieve a SAHPRA GMP licence in Q3 2025 for its mRNA end-to-end platform[126].

The Institut Pasteur de Dakar (IPD) celebrated its centenary with the inauguration of the expanded DIATROPIX diagnostic manufacturing site in Mbao, Senegal[172].

Vietnam's National Vaccine Company (VNVC) began construction of a manufacturing facility with US$77 million initial investment, aiming to produce 200 million vaccine doses annually upon completion in 2026[178].

Thermo Fisher Scientific opened a Bioprocess Design Center in Hyderabad providing bench-to-pilot scale capabilities for biologics and vaccine manufacturing in South Asia[179].

Wellcome Leap's R3 Global is establishing a distributed network of biofoundries for rapid, cost-effective RNA medicine production. The program has secured sovereign partnerships with Singapore and the UK funding biofoundries, with additional partnerships ongoing. The program has advanced two therapeutics and two vaccines through pre-Investigational New Drug (IND) approvals with minimal recommendations, while making technical progress on continuous-flow manufacturing and software tools that optimise both the manufacturability and efficacy of protein translation[133].

The **SAMRC** is implementing a program on behalf of the DSTI and funded by the German Government through KfW involving substantial investments in infrastructure for vaccine development and pilot manufacturing, training and the digitisation of the South African Health Products Regulatory Authority. Three beneficiaries, Afrigen Biologics, the University of the Witwatersrand and the Council for Scientific and Industrial Research, have been selected to receive equipment support for pilot scale manufacturing of biologicals under GMP[127].

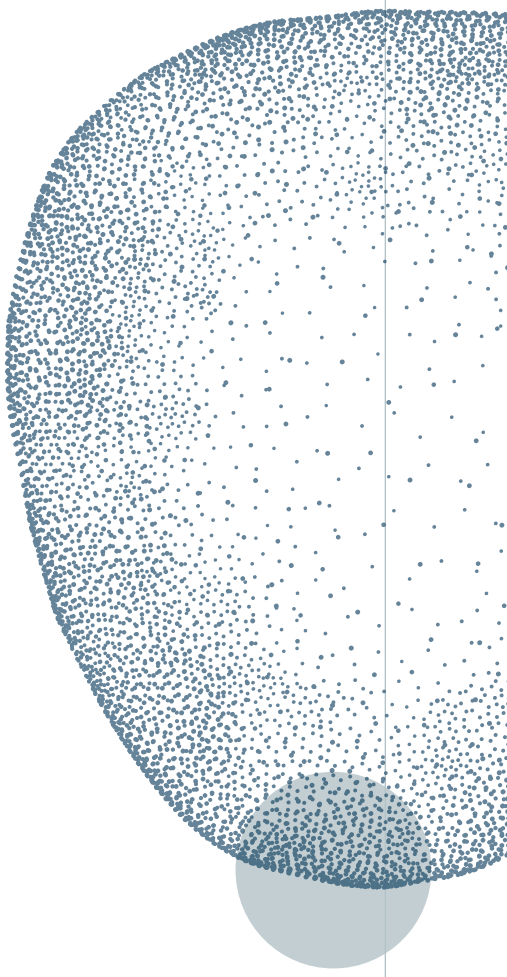
In August 2025, **Unitaid** launched the Medicines Supply Resilience (MedSuRe) Africa initiative. The program will work with African manufacturers to produce active pharmaceutical ingredients as finished pharmaceutical products. A key focus of the initiative is on diversifying and expanding production capacity for formulations that are likely to face scarcity during health emergencies. As part of this package, Unitaid is also providing a complementary grant to the MPP to support licensing work that will expand access[80].

PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026

Planned Partner commitments

- **CEPI** will enhance manufacturing capacity and capabilities for Vaccine Manufacturing Facility Network (VMFN) partners - focusing on technical capabilities, such as fill and finish expansion, building up supply chain infrastructure and improving collaboration between VMFN partners and supply chains[45].
- **CSIR** will aim to achieve SAHPRA licensure of the GMP pilot-scale manufacturing facility, and produce first-in-human clinical trial batches. CSIR will also prioritise monoclonal antibody and flow chemistry capabilities towards pandemic-relevant viral diseases[96].
- **Afrigen** plans to move the mRNA program into clinical trials as a pivotal step toward building an end-to-end vaccine manufacturing system on the African continent[126].
- **Butantan** are implementing additional manufacturing facilities at Instituto Butantan, including the CPMV – a multi-purpose vaccine facility with a BSL-3 area and an internal BSL-3 laboratory for analyses when necessary. Plans include constructing a new filling facility to expand infrastructure for the final processing of immunobiological products. Additionally, a new monoclonal antibody manufacturing facility is under development[97].
- **Wellcome Leap's R3 Global** will work toward establishing an LMIC-based biofoundry by 2027, conducting first GMP engineering runs in Q1 2026, and submitting first INDs by end of 2026[133].
- **HERA** will establish the Rapid Agile Manufacturing Partnership for Union Protection (RAMP-UP) by 2026, a voluntary network of EU-based manufacturers, innovators, and suppliers enabling rapid scale-up of medical countermeasures production during health emergencies[50].

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
Unitaid launched the Manufacturing to Accelerate Diagnostic Excellence (MADE) project, led by PATH and a consortium of partners. This initiative aims to reduce Africa's dependence on imported diagnostics by building a sustainable regional manufacturing base that can meet both routine health needs and surge demands during pandemics[80]. **PATH's Center for Vaccine Innovation and Access (CVIA)** continued to improve access to vaccines by working in partnership with vaccine manufacturers globally to develop and deliver new and better vaccines and to provide technical assistance to manufacturers in low- and middle-income economies that are working toward national licensure and World Health Organization prequalification (PQ)[79]. **The G20 Global Coalition on Regional and Local Production** confirmed Fiocruz as its Secretariat and is developing the Terms of Reference[166]. **Gavi's African Vaccine Manufacturing Accelerator (AVMA)** has achieved 18 formal EOIs from manufacturers, two technology transfer deals (EVA Pharma's mRNA platform and Biogeneric-Afrigen partnership), and progress toward the first drug-substance manufacturer competing for a UNICEF tender by 2026[135]. **H3D Foundation,** funded by the South African government as a national platform of the Technology Innovation Agency, has partnered with South African local API manufacturer, CPT Pharma, on a strategic project to demonstrate the potential of Synthetron Reactor technology and process innovation to support cost-competitive, greener, manufacturing processes for local production. Over the past year the process chemistry laboratory including the Synthetron Reactor has been installed and the pilot project team of 3 chemists has been assembled[266]. Through **European Research Infrastructure on Highly Pathogenic Agents (ERINHA),** UKHSA has supported the successful application for funding via EU Horizon, to establish a sustainable international high containment network[34]. The **UK** completed the **Moderna Innovation and Technology Centre** with capacity for up to 250 million doses per year[34]. Through Canada's Strategic Innovation Fund, **STEMCELL Technologies Canada** received up to CAD $49 million to support two new biomanufacturing facilities producing critical inputs for vaccines, therapeutics and diagnostics, Delpharm Inc. received up to CAD $60 million to expand biomanufacturing capacity for sterile injectables and vaccine fill and finish, and Entos Pharmaceuticals received up to CAD $62 million to construct a biomanufacturing facility for genetic medicines including DNA vaccine and therapeutic platforms[176]. **Moderna's Canadian facility in Laval, Quebec** produced its first mRNA vaccine doses, becoming Moderna's first international manufacturing facility outside the U.S. to produce. The facility can produce up to 100 million doses of mRNA respiratory vaccines annually, with fill and finish completed by partner Novocol Pharma in Cambridge, Ontario. Novocol Pharma completed expansion of its fill and finish facility and received an amendment to its good manufacturing practices license to fabricate vaccines[176]. **MPP,** under its partnership with **WHO's Health Technology Access Programme (HTAP)** signed a sublicense agreement with **Codix Bio,** a Nigerian company to develop and manufacture rapid diagnostic tests (RDTs) using adaptable technology transferred from global in-vitro diagnostics company SD Biosensor[141]. **MPP** is supporting **WHO** in conducting a global survey of manufacturers to assess current and potential future capacity for influenza antiviral production. The findings will inform seasonal influenza control and pandemic preparedness efforts. Aggregate data will be analysed for a peer-reviewed publication[141]. **WHO and MPP** Launch Phase 2.0 of the mRNA Technology Transfer Programme[267]. **MedAccess and Gavi** announce a new partnership to explore the development of a mechanism to improve the ability of manufacturers to expand regional production[268]. **Africa CDC** launched the African Manufacturing Market Intelligence and Network Analysis (AMMINA) platform to consolidate data on manufacturers, production capacities, and market trends[161]. **The Africa Medical Supplies Platform (AMSP)** aligned with the Platform for Harmonised African Health Manufacturing to operationalise pooled procurement and harmonise with AMA and global quality standards[136]. **The ASEAN Vaccine Security and Self-Reliance (AVSSR)** initiative advanced work toward a regional pooled procurement mechanism, convened high-level regional coordination meetings, and developed the ASEAN Vaccine Dashboard to enhance information sharing and regional preparedness[163]. **Africa CDC** unveils $3.2 billion Plan to Transform Vaccine and Drug Production. $2 billion will come from Afreximbank; Gavi is making $1.2billion available through the African Vaccine Manufacturing Accelerator. The combined investment is designed to expand existing manufacturing capacities and build new, state-of-the-art facilities capable of producing vaccines and essential drugs at scale[269].	**Priority Actions for 2026** • Strengthen market and financing mechanisms for regional production • Advance regional manufacturing through platform development, clinical readiness, and end-to-end technology transfer • Accelerate regional regulatory harmonisation



2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
The European Investment Bank (EIB) and **the European Commission** have teamed up with BioNTech to help advance a messenger RNA (mRNA) vaccine manufacturing facility in Kigali, Rwanda[173]. **PAHO's Regional Revolving Funds** demonstrated the impact of recent amendments to incentivise regional production, with regional manufacturers now representing almost one quarter of procured vaccine volume and around 30% of procurement value, up from less than 1% in 2020[270]. **RVMC** published its Vision in April 2025, outlining an agenda to achieve RVM by 2040, focusing on political action, demand predictability, and regulatory systems strengthening and harmonisation[164]. **RVMC** published its first vaccine manufacturing Ecosystem Status Report & Scorecard[165]. **Africa CDC, Gavi, and RVMC** convened the 2nd Vaccines and Other Health Products Manufacturing Forum in Cairo in February 2025, yielding mRNA technology transfer agreements (EVA Pharma with DNA Script, Quantoom Biosciences, and Unizima, and a Biogeneric Pharma-Afrigen addendum), workforce development network launches, and reinforced commitments toward Africa's 60% local vaccine manufacturing target by 2040[168].	

Sustainable Pandemic Financing & Procurement for Equitable Access

RECOMMENDATIONS:

13 **The International Monetary Fund (IMF) to explore expanding their Article IV consultation** with member countries to include a pandemic preparedness assessment, and draw on the analysis and expertise of others. Concurrently, multilateral development banks continue to support investment to strengthen and prepare health systems as part of their core day-to-day business.

15 **Governments should build in conditions into DTV funding contracts** for LMIC access to access DTVs at not for profit and scale, which is to be enacted if a PHEIC is declared.

23 **A PHEIC should trigger the activation of an automatic mechanism to procure and distribute DTVs.** Further work is needed to determine how such a facility could operate, and we recommend considering basing this on advance commitments that are pre-negotiated well before a pandemic.

24 As part of countries' bilateral DTV procurement, any advance purchase agreements with manufacturers should include a **requirement for products provided to LMICs to be provided at not for profit.** This must also be done within a similar timeframe to when HICs are supplied.

25 **Multilateral development bank loans** should be made available so LMICs can purchase DTVs above the 30% provided through the DTV financing facility in line with recommendation

23 **Normal access limits or policies applied by multilateral development banks** should not prevent countries receiving urgent finance during a pandemic.

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026

AMSP continued leveraging Afreximbank's financing instruments to support pooled procurement under the African Pooled Procurement Mechanism. Afreximbank provided trade finance and guarantees that enabled AMSP to secure advance purchase agreements for pandemic-related commodities, reducing supplier risk and accelerating delivery[136].

CEPI has launched a partnership with the US International Development Finance Corporation (DFC), with the intention to align discussions and investments in global vaccine initiatives, including exploring sustainable pandemic financing tools[271].

In June 2025 **Gavi** announced the extension of the **European Investment Bank's (EIB)** EUR 1 billion financing facility to support both routine immunisation and outbreak response programmes. The EIB facility, alongside the DFC frontloading facility and the FRF form the Day Zero Financing Facility, providing surge financing capacity of up to USD 2.5 billion to enable a vaccine response in fast moving outbreaks and pandemics[135].

Gavi implemented its first draw down from the First Response Fund, up to $50 million to finance vaccines and vaccine roll out for mpox[135].

The Gavi Board approved a new "Fragile and Humanitarian Approach" for 6.0, which will include a "Gavi Resilience Mechanism" to support efforts in fragile, emergency, outbreak and humanitarian settings. Importantly, the Gavi Resilience Mechanism can be used to help address smaller-scale outbreaks[135].

In February 2025 **the African Union** approved a framework for the Africa Epidemics Fund. The fund is expected to have both preparedness and response functions[272].

The Life Sciences Innovative Manufacturing Fund (LSIMF) was launched to provide up to £520 million in capital grants to UK-based life sciences manufacturers273. The Life Sciences Innovative Manufacturing Fund (LSIMF) was launched to provide up to £520 million in capital grants to life sciences manufacturers making investments in the UK[273].

The Fund for Science and Technology was launched to support research in AI, the environment and bioscience with $500 million in grants over the next four years[274].

Africa CDC published its strategy to enhance sustainability and reduce reliance on external donors in concept paper ' Africa's Health Financing in New Era[275].

Under South Africa's G20 Presidency in 2025, **the Joint Finance Health Task Force (JFHTF)** advanced cross-cutting priorities focusing on three strategic areas: improving finance-health coordination, better understanding and mitigating economic risks and vulnerabilities from pandemics, and enhancing readiness for large-scale pandemic response interventions. The JFHTF delivered key outputs including a report on Financing for Pandemic Preparedness: Ensuring Sustainable and Efficient Funding developed by WHO, Organisation for Economic Co-operation and Development (OECD), and World Bank; an updated Global Report on the Framework for Health, Social and Economic Vulnerabilities and Risks (FEVR) related to Pandemics; and an updated Operational Playbook for Pandemic Response Financing developed by the World Bank and WHO[180].

The G20 High Level Independent Panel (HLIP) published a G20 panel report on pandemic PPR financing, providing actionable recommendations to close urgent health security financing gaps[160].

Pandemic Fund establishes the External Advisory Council to bring in non-sovereign actors (including private sector, philanthropies, academia and think tanks) to shape and scale effective pandemic prevention[276].

Planned Partner commitments

- **CEPI** will develop and implement a co-development and co-financing strategy for Nipah vaccine licensure with a with National partner in the Global South. The strategy will include co-development objectives and shared financing to include in kind contributions, and elements required to progress a Nipah vaccine to licensure[45].
- **CEPI** will develop tailored financing options for late-stage R&D of selected priority pathogens – identifying potential co-funders and extending to purchasing options and access requirements[45].

Priority Actions for 2026

- Integrate Day Zero Triggers into Decision Making
- Mobilise Domestic and Non-ODA Resources
- Secure Sustainable Financing
- Advance Innovative Financing Models
- Strengthen MDB Capabilities
- Enhance Data Systems

Cross-Cutting

2025 SUMMARY PROGRESS UPDATE

WHO launched the Collaborative Open Research Consortium (CORC) for flavivirus, filovirus, arenavirus, and bunyavirus families, in partnership with Fiocruz31, Agence Nationale de Recherche sur le Sida et les Hépatites Virales (ANRS-MIE)[32] and UKHSA[33].

CEPI has initiated Board discussions to develop an AI strategy. A unified governance framework will be developed to govern AI initiatives, and equitable access will be a key principle of the strategy[45].

CEPI graduated its first cohort from the Global South Fellowship Programme and enrolled its second cohort. This programme fosters knowledge transfer, leadership development, and regional ownership by embedding pandemic preparedness capacity within local systems, reducing reliance on external expertise and strengthening globally distributed capabilities[45].

In August 2025, **the interim Medical Countermeasure network (i-MCM-Net)** published the full landscape analysis report mapping the current status of MCM activities for pandemic response[184].

PATH and **Bio-Manguinhos/Fiocruz** launched a collaboration to accelerate innovation, production, and access to vaccines, diagnostics, and biopharmaceuticals in Brazil, Latin America, and the Caribbean[174].

Africa CDC has allocated $1.6 million to nine National Public Health Institutes across Africa, designating them as Centers of Excellence. The selected institutes are in Ethiopia, Burkina Faso, Burundi, DRC, Liberia, Mozambique, Nigeria, South Africa, and Rwanda. These centers will serve as regional hubs for technical assistance, training, and mentorship to other African countries[277].

UKHSA published its Priority Pathogen Families reference tool, highlighting 24 pathogen families where it believes further research is most needed in the interests of biosecurity[278].

In April 2025 **13 new National Institute for Health and Care Research (NIHR) Health Protection Research Units (HPRUs)** and **2 Health Protection Research Focus Awards (HPFRAs)** were launched. Each HPRU is a collaborative research partnership between UKHSA and a university or groups of universities. All HPRUs covering infectious diseases, emergency preparedness or cross-cutting themes must have a research theme addressing pandemic preparedness. This is in addition to up to £5.5M for a dedicated HPRU on emerging zoonotic infections, further strengthening the UK's capacity to respond to future health threats. From 2026, the HPRU Network, which links HPRUs and HPRFAs to align with DHSC, UKHSA and wider government priorities, will introduce a Pandemic Preparedness and Biosecurity theme. This will aim to coordinate HPRU pandemic preparedness research and provide strategic leadership to strengthen UK pandemic R&D capacity[279].

Foreign Commonwealth and Development Office (FCDO) has launched a new four-year strategic partnership with Institut Pasteur de Dakar in Senegal, to build preparedness and respond to infectious disease outbreaks. This will strengthen regional disease surveillance, develop new vaccines, diagnostics, and biomanufacturing innovations, and build clinical trial capability, with partners such as Oxford and UKHSA[280].

In July 2025, the **UK** published the cross-government 'health and care R&D framework and governance structure for pandemic prevention, preparedness, and response' to enable the UK government research ecosystem to collaborate more effectively[281].

Five multidisciplinary university research hubs established under **Canada's Biomanufacturing and Life Sciences Strategy (BLSS)** continued overseeing the implementation of projects to advance diagnostics, therapeutics, and vaccines, including diagnostic platform development, AI-enabled antibody production, and next-generation lipid nanoparticle (LNP) RNA vaccine technology[176].

HERC signed an administrative arrangement with **EU HERA** in June 2025 to strengthen cooperation on medical countermeasures for preparedness and response to serious cross-border public health threats, developing cooperation in research and innovation, commercialisation challenges, and supply chain resiliency[176].

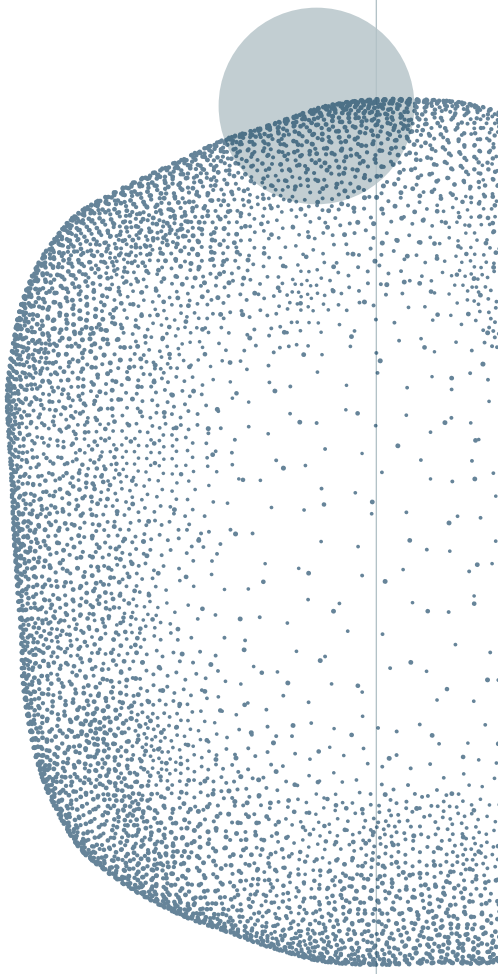
WHO Member States formally adopted by consensus the world's first Pandemic Agreement at the 78th World Health Assembly, representing a historic milestone in global health governance[67]. The Agreement culminated three years of negotiations through the WHO Intergovernmental Negotiating Body (INB), with contributions from civil society organisations, multilateral health initiatives, industry stakeholders, and technical experts. Friends of the 100DM, including the Pandemic Action Network, advocated for financing, equity and access provisions[282], while CEPI contributed advocacy on preparedness R&D, end-to-end collaboration, and access commitments[45].

PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026

Planned Partner commitments

- **The Intergovernmental Working Group (IGWG)** and its diverse partners will continue to advance progress on the PABS annex for submission to the Seventy-ninth World Health Assembly in May 2026[292].
- **The EU Commission** will promote One Health approaches in research and innovation by collaborating with Member States and other stakeholders to identify further priority areas that would benefit from One Health approaches, and develop guidance to support inter- and transdisciplinary research and innovation in One Health[293].
- **The EU Commission** will invest in integration of multi-modal generative AI technologies into multidisciplinary biomedical research via the Horizon Europe Work Programme[294].
- **BE READY NOW** will launch as Europe's coordinated pandemic preparedness research partnership, bringing together research organisations across Europe with significant funding committed for joint research programs[36].
- **HERC and HERA** will develop and strengthen cooperation in priority areas, namely research and innovation, challenges in commercialisation and scale-up, and supply chain resiliency.[176]

2025 SUMMARY PROGRESS UPDATE	PLANNED PARTNER COMMITMENTS AND RECOMMENDED PRIORITY ACTIONS FOR 2026
The Africa Pandemic Sciences Collaborative was launched, a new partnership between the Science for Africa Foundation and Pandemic Sciences Institute at the University of Oxford. The Collaborative aims to equip young African scientists with the support of senior scientists to address current and future challenges of epidemics and pandemics[283]. **Africa CDC** and strategic health partners operating in Central Africa have drawn up an outline of a joint 2026–2027 roadmap to strengthen health security in the Central African region[284]. **The ANRS-MIE** launched a call for projects targeting emerging and re-emerging infectious diseases research in low- and middle-income countries. The program funds collaborative research between French teams and LMIC partners, focusing on viral haemorrhagic fevers, respiratory viruses, and arboviruses[285]. **The European Commission** launched the new Medical Countermeasures Strategy through HERA as part of the Preparedness Union Strategy deliverables[286]. **HERA** operationalised the first modules of ATHINA (Advanced Technology for Health Intelligence and Action) in 2025, integrating data from EMA, ECDC, JRC and WHO to enhance medical countermeasures intelligence through foresight, horizon scanning, and future AI functionalities[50]. **HERA** established the DURABLE project, a network of 19 partners from academia and public health institutes providing biological intelligence and research across medical countermeasure categories including vaccines, therapeutics, diagnostics, PPE, and biocides[287]. **EU commission** announces Global Health Resilience Initiative, a flagship effort to cement the EU's role in shaping global health[288]. **The EU Global Gateway and Team Europe** continued to invest in regional vaccine, medicine, and health technology manufacturing in Africa and Latin America[175]. The **UK** is investing in £250 million in establishing a new biosecurity center designed to improve research into potentially pandemic-causing pathogens and protect against emerging public health threats[289]. **The Independent Panel** publish report 'The power to lead for a safer world', outlining six suggestions leaders should commit to in the political declaration of the 2026 UN High-level Meeting[290]. The amended **International Health Regulations** entered into force, introducing a new "pandemic emergency" alert level to strengthen international collaboration when health risks escalate beyond a PHEIC and pose pandemic risk with widespread health system impact and societal disruption. The amendments establish National IHR Authorities for coordinated implementation and include provisions to strengthen equitable access to medical products and financing based on equity and solidarity principle[291]. **CEPI** has been developing a Networks strategy to better integrate CEPI's-funded networks into CEPI's programmes/investments and encourage utilisation by external partners. This will include the implementation of demonstration projects to validate and enhance the value of cross-network delivery. It will also include funding capacity building to enhance CEPI-funded network capacity, including delivering trainings, and building new capabilities for increasing 100DM responsiveness (e.g., Clinical research preparedness, vaccine data base, biosecurity, etc.)[45]. **Wellcome Trust** funded the Center for Infectious Disease Research and Policy (CIDRAP) in partnership with WHO to develop a comprehensive Zika virus research agenda, resulting in a four-part series published in The Lancet Infectious Diseases and The Lancet Microbe in 2025. The series, featuring input from 130 global experts, outlines priority research agendas for diagnostics, vaccines and monoclonal antibodies development, non-human primate research models, and specimen and data sharing frameworks[134]. **Fiocruz** expanded collaboration through a Memorandum of Understanding with Africa CDC signed in May 2025, establishing a partnership to advance health innovation, manufacturing, research, and preparedness across Africa[98]. **HERC** signed an administrative arrangement with EU HERA in June 2025 to strengthen cooperation on medical countermeasures for preparedness and response to serious cross-border public health threats, developing cooperation in research and innovation, commercialisation challenges, and supply chain resiliency[176]. **Africa CDC and Unitaid** strengthened collaboration through a 2025 Memorandum of Understanding[152] aligning regulatory, financing, and clinical research capacity, enabling health tools to be designed, tested, and produced within Africa[80]. **BE READY PLUS** completed preparations for the European Partnership for Pandemic Preparedness, expanding its network of research organisations across Europe to coordinate infectious disease research response. The BE READY NOW proposal received positive evaluation from the European Commission. finalising frameworks for joint research funding and clinical trial networks ahead of the January 2026 launch[36].	



ANNEX B

Secretariat Governance detail

STEERING GROUP

The Secretariat is led by a small Steering Group which provides oversight, accountability, and strategic direction. The Steering Group meets on a quarterly basis and comprises representatives from the following organisations:

Select governments, including representatives from current, past, and incoming G7 and G20 presidencies
World Health Organisation (WHO)
Wellcome
Gates Foundation
International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
Science and Technology Expert Group (STEG) Co-Chairs
Dr Mona Nemer, Chief Science Adviser for the Canadian Government

IPPS SECRETARIAT

Armand Mbanya, Senior Technical Adviser
Ashley Giles, Senior Strategic Engagement Adviser
Bea Coates, Policy Officer
Caia Dominicus, Senior Technical Adviser
Colleen Loynachan, Senior Technical Adviser
Heulwen Philpot, Head of Secretariat
Ines Hassan, Acting Head of Secretariat
Pippa McCarthy, Team Coordinator
Sheila Mburu, Deputy Head of Secretariat

SCIENCE AND TECHNOLOGY EXPERT GROUP

The STEG provides technical input to the Secretariat. Reporting to the Steering Group, it delivers an assurance function for the annual report against the 100DM recommendations and galvanises support from the scientific community on pandemic preparedness through meetings, working groups, and assessments. It has subgroups focusing on specific issues, including diagnostics, therapeutics, manufacturing, clinical trials and regulatory matters, and R&D coordination.

Membership was drawn from an open global nominations process and includes members from a wide range of regions and sectors. Its members include:

Dr Victor Dzau, President of the National Academy of Medicine, U.S. (Co-chair)
Shingai Machingaidze, Head of Africa Strategy and Engagement at CEPI, South Africa (Co-chair)
Hala Audi, Business Strategy, Investment and R&D Partnerships, at Quantoom Biosciences, Belgium
Dr Rick Bright, CEO, Bright Global Health; Former Director of BARDA, U.S.
Dr Kelly Chibale, Professor of Organic Chemistry at the University of Cape Town, South Africa
Professor Tan Chorh Chuan, Permanent Secretary (National Research and Development & Public Sector Science and Technology Policy and Plans Office), Chairman (Agency for Science, Technology and Research), Chairman (MOH Office for Healthcare Transformation)
Dr Delese Mimi Darko, Director-General of the African Medicines Agency, Rwanda
Dr Ruxandra Draghia-Akli, Executive Vice-President, Head of Research and Development at Novavax, U.S.
Dr Ranna Eardley-Patel, Senior External Stakeholder and Project Lead, Manufacturing & Supply Chain, Division CEPI, UK
Dr Rosane Cuber Guimarães, Deputy Director of Quality at Bio-Manguinhos-Fiocruz, Brazil
Professor Ken Ishii, Director of the International Research and Development Centre for Mucosal Vaccines, University of Tokyo, Japan
Dr Yenew Kebede, Head, Division of Laboratory Systems & Networks at Africa CDC, Ethiopia
François Lacoste, Executive Vice-President Public Health, Medical & Scientific Affairs at Institut Merieux, France
Professor Teresa Lambe OBE, Professor of Vaccinology and Immunology at the University of Oxford, UK
Dr Dennis Liotta, Professor of Chemistry, Emory University, USA
Dr Umesh Shaligram, Executive Director, Serum Institute of India Private Limited, India
Dr Lynda Stuart, President and Chief Executive Officer, Fund for Science and Technology
Dr Renu Swarup, Former Secretary of the Department of Biotechnology, Ministry of Science & Technology, Government of India, India
Dr Jean-Francois Toussaint, Head of Research and Development at Sanofi Vaccines, France
Dr Niteen S Wairagkar, Founder and CEO, Vaccines for All, Consultant for Africa CDC Partnership for Africa Vaccine Manufacturing, Consultant in Vaccine Development at CEPI, India
Professor Yoshiaki Yamagishi, Associate Professor of Medical Center for Translational Research, Department of Medical Innovation, Osaka University Hospital, Japan

ANNEX C

Additional Contributors

The Secretariat would like to extend their thanks to representatives of all organisations listed below who have contributed to the 2025 100DM implementation report and ongoing efforts to prepare MCMs for pandemic response.

The Secretariat would like to thank colleagues at Impact Global Health, including Dr Lindsay Keir and Juliette Borri, for their contributions to the 100DM Scorecard, regional deep dive, and review of the report.

- Africa Medical Supplies Platform (AMSP)
- African Medicines Agency (AMA)
- African Society for Laboratory Medicine (ASLM)
- Afrigen Biologics
- Agence Nationale de Recherche sur le Sida et les Hépatites Virales (ANRS)
- Airfinity Ltd
- Bio-Manguinhos/Fiocruz
- Biophorum
- Cepheid
- Coalition for Epidemic Preparedness Innovations (CEPI)
- Council for Scientific and Industrial Research (CSIR)
- Cumming Global Centre for Pandemic Therapeutics (CGCPT)
- Data.org
- Developing Countries Vaccine Manufacturers Network (DCVMN)
- Emergent BioSolutions
- European Commission, Health Emergency Preparedness and Response (HERA)
- Foundation for Innovative New Diagnostics (FIND)
- G20 Joint Task Force on Finance and Health (JFHTF)
- Gates Foundation
- Gavi, The Vaccine Alliance
- Global Access Diagnostics (GADx)
- Global Research Collaboration for Infectious Disease Preparedness (GloPID-R)
- Good Clinical Trials Collaborative (GCTC)
- Government of Japan
- GSK
- H3D Foundation
- Health Emergency Readiness Canada (HERC)
- Impact Global Health
- Instituto Butantan
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
- INTREPID Alliance
- Italy, Ministry of Economy and Finance
- Johnson & Johnson
- Lancet Commission on Diagnostics
- LifeArc
- Malaysia, Ministry of Health
- Matahari Global Solutions
- Medicines Patent Pool (MPP)
- Moderna
- National Vaccine Institute, Thailand
- Pandemic Action Network (PAN)
- Pandemic Science Institute (PSI), University of Oxford
- Pasteur Network
- Program for Appropriate Technology in Health (PATH)
- Regionalised Vaccine Manufacturing Collaborative (RVMC)
- RIGHT Foundation
- South Africa Medical Research Council (SAMRC)
- UK Government: UKHSA, DHSC
- Unitaid
- Varro Life Sciences
- Walvax
- Wellcome
- Wellcome Leap R3 Global
- World Health Organization (WHO), i-MCM net

ANNEX D

Methodology

This report provides **detailed coverage of progress against the 100DM and each of the 25 recommendations** (from September 2024 to December 2025), based on **three data sources,** collected in Q4 of 2025:

- **Desk research** for relevant documents and datasets
- **Structured interviews** with key global health and PPR stakeholders
- **50+ pro forma surveys** from key stakeholders (listed in contributors)

DESK RESEARCH FOR RELEVANT DOCUMENTS AND DATASETS

Sources for desk research includes (but is not limited to):

- Implementation and strategy reports of key initiatives related to PPR
- Updated guidelines, protocols, and frameworks from regulatory authorities
- Press releases and publications from international organisations
- Resolutions and agreements from international governance fora
- Annual reports and press releases from relevant private sector organisations
- Peer reviewed research literature from academic institutions
- External evaluations of international progress towards PPR

COLLECTION OF PRO FORMA SURVEYS FROM KEY STAKEHOLDERS

Written input was requested from implementation partners through standardised pro formas across the following topics:

- Progress in 2025
- Plans to take forward 100DM and proposed milestones
- Alignment of 100DM with ongoing priorities and approach to implementation
- Organisations identified as collaborators and engagement framework
- Barriers, risks, and enablers to achieving 100DM
- Future path, progress indicators and what constitutes a successful outcome

The draft report was reviewed by key implementation partners who provided input and was finalised with input from the Secretariat Steering Group and STEG.

ANNEX E

Scorecard and African PPR Capacity Deep-Dive Indicators

TABLE 1 **Definition of 100DM scorecard indicators**

INDICATOR	CATEGORY	DEFINITION	SOURCE
R&D funding for diagnostics, vaccines and therapeutics (DTV)	Now	This indicator shows the total R&D funding invested by disease broken down by donor over a rolling 4-year period. For Scorecard 3.0, published in January 2026, this was financial years 2021-2024. This indicator is based on the scope of the G-FINDER project. G-FINDER tracks and analyses global investment in the research and development of new health technologies for global health issues such as neglected diseases, emerging infectious diseases, and sexual & reproductive health issues. G-FINDER does not, and is not intended to, capture investment in the entire spectrum of global health research. Many research activities that are extremely important for global health are excluded from this project because they are not related to the development of new tools for the diseases included in the scope.	Impact Global Health's (IGH)[295]
Approved products	Now	This indicator shows where vaccines, diagnostics and therapeutics have been approved for use for each disease. Approved products were defined as finished pharmaceutical products, drugs, vaccines, biologics, or diagnostics that had been granted a marketing authorisation by a medicines regulatory authority or had obtained WHO prequalification. The update was performed through desk-based research, which included reviewing regulatory databases (stringent and national regulatory authority), the WHO prequalification database and FIND's DxConnect platform[296]. Additional checks were conducted through AdisInsight and the landscape report prepared for the WHO Pathogen Prioritsation meeting[297]. The outer section of the visualisation also shows where products have been approved for use in LMICs. LMIC approval was defined as a product being approved by a National Regulatory Authorities (NRAs) of vaccine producing countries of maturity level 3 or above (as defined by WHO Listed Authorities framework) or has WHO prequalification. For Scorecard 3.0, published in January 2026, the data was updated for the period 30 August 2024 to 30 September 2025.	◦ IGH's infectious disease R&D tracker data[298] ◦ FDA's Vaccines Licensed for Use in the United States[299], Orange Book[300] and Emergency Use Authorizations[301] ◦ European Medicines Agency's medicines database[302] ◦ WHO prequalification database[303] ◦ Japanese PMDA's list of approved products[304] ◦ National Regulatory Authorities[305] (vaccine-producing) operating at maturity level 3 and above, with a publicly available approved products database. ◦ FIND's DxConnect platform[296]
Clinical candidates tested in humans	Future Readiness	This indicator shows the number of candidates for each disease that are being tested in humans. These are broken down by R&D stage and include phase 1,2,3 for vaccines and therapeutics and late-stage development for diagnostics. Candidates were defined as potential drugs, vaccines, vector control products, diagnostics, or platform technologies, currently under investigation that had yet to be approved by a medicines regulatory authority. Taking the product development pipeline built for the scorecard 2.0 as the starting point, the current review at an overarching level involved two distinct steps: ◦ Review of existing pipeline records to validate active development status and ensure that the clinical development of candidates included in the previous report has not terminated, been withdrawn, or been stopped. ◦ Review of clinical trial registries to capture candidates who have entered new clinical trials, including existing candidates starting new trials at the same or different phase, and new candidates entering the clinical development phase, not captured previously. Additional considerations outlined below For Scorecard 3.0, published in January 2026, the data was updated for the period 30 August 2024 to 30 September 2025.	IGH's infectious disease R&D tracker data[298] ◦ National Library of Medicine's online database of clinical research studies ◦ WHO's International Clinical Trials Registry Platform (ICTRP). ICTRP includes data from 20 trial registries from different countries or regions, such as the Chinese Clinical Trial Registry and the Pan African Clinical Trial Registry

INDICATOR	CATEGORY	DEFINITION	SOURCE
Platform technologies	Future Readiness	This indicator shows if platform technologies are being used to develop clinical candidates. The outer section shows where multiple technologies (i.e., >3) are being applied to the pipeline. The platform technology category includes vaccine, drug, and biologics platforms; adjuvants and immunomodulators; and general diagnostic platforms.	IGH's infectious disease R&D tracker data[298]
Use of animal rule to support licensure	R&D enablers	This indicator shows where the animal rule has been used to support product licensure. The animal rule is a principle for an alternative licensure pathway to allow for the approval of drugs and biological products when human efficacy studies are not feasible and is instead based on well-controlled animal studies, when the results of those studies establish that the drug or biologic product is reasonably likely to produce clinical benefit in humans. For Scorecard 3.0, published in January 2026, the data was updated for the period 30 August 2024 to 30 September 2025	U.S. FDA and EMA.
Generally accepted correlates of protection	R&D enablers	This indicator shows where there are generally accepted correlates of protection as defined by CEPI	Wellcome- and CEPI and Wellcome Vaccine Ecosystems.
WHO TPPs	R&D enablers	This indicator shows which diseases have active WHO Target Product Profiles for vaccines, diagnostics and therapeutics. The R&D priorities were updated based on the current status of the WHO R&D Blueprint's target product profile (TPP) for the individual pathogens. The TPP status was validated by reviewing: • WHO Target Product Profile Directory[306] (TPPD). Profiles set to active status were included. • As the TPPD is under redevelopment, the review included additional sources – the WHO R&D Blueprint's individual pathogen page, for example, Mpox[307].	• IGH's infectious disease R&D tracker data[298] • WHO TPP directory[306] • WHO R&D Blueprint individual disease pages
R&D funding for platform technologies	Disease X	This indicator shows total R&D funding invested into platform technologies broken down by donor over a rolling 4-year period. For Scorecard 2.0, published in January 2025, this was financial years 2020-2023. WHO recognises Disease X as an unknown pathogen that could cause a serious international epidemic. In G-FINDER this is captured as non-disease-specific R&D, for this indicator it includes the following categories: Therapeutic platforms include drug and biologic delivery platforms; Vaccines include vaccine platforms and adjuvants and immunomodulators.	IGH's G-FINDER R&D funding data[295]

ADDITIONAL SCORECARD 3.0 METHODOLOGICAL CONSIDERATIONS

Therapeutics and vaccines clinical candidates

For therapeutics and vaccines, the following additional principles guided the review process.

- Cutoff date for new trials: June 2024

Existing candidates' active development status criteria:

- A candidate is considered active if the associated clinical trial study status is not yet recruiting, enrolling by invitation or active, not recruiting.
- A candidate is considered inactive if the associated clinical trial study status is suspended, terminated or withdrawn. Additionally, a candidate is considered inactive if the associated clinical trial study status is completed on or before 2022, and there is no evidence to suggest the developers have published results or are planning to start another clinical trial with the same candidate.

There were three exceptions to the product development pipeline update.

- The COVID-19 pipeline inclusion criteria allowed only clinical trials that either started in 2024 or had a study status of not yet recruiting, enrolling by invitation, or active, not recruiting. This rule was also applied to the candidates captured in the previous review.
- The Hantaan virus had no candidates in clinical development. Therefore, a preclinical pipeline was built using Elsevier Limited's EMBASE drug research database.
- H5N1 was included for the first time; the cutoff date for the trial start date was 2022.

Diagnostics clinical candidates

The diagnostics pipeline was built solely on reviewing the FIND's DxConnect platform[296], with the Hantaan virus as the only exception, as the FIND platform did not cover it. For the Hantaan virus diagnostics review, the EMBASE database was used.

The inclusion criteria allowed only candidates categorised as early or late in development. Candidates categorised as research use only were excluded.

For H5N1 diagnostic tools to be included, the tests have to either subtype different influenza strains, including H5N1, or specifically detect the H5N1 strain.

TABLE 2 **Definition of African PPR capacity deep-dive indicators**

INDICATOR	DEFINITION	SOURCE
Laboratory capacity	Biosafety Level 4 (BSL-4) laboratory capacity is the highest level of biocontainment. This indicator was defined as countries with laboratories operating at BSL 4 containment level.	Global Biolabs[17]
Clinical trial capacity	Due to limitations of publicly available data, clinical trials capacity was defined as capacity to conduct interventional trials for 100DM Scorecard pathogens across DTVs from 2020-2025. A combination of data sources were used. Our primary source was the Clinical Trials Community Africa Network (CTCAN) platform – supported by the Science for Africa Foundation and NuvoteQ – which curates clinical trial information from the continent. This was supplemented by additional data extracted from the Pan African Clinical Trials Registry (PACTR) and ClinicalTrials.gov. Trial data was limited to intervention trials, started in 2021, and categorised as infection and infestations. Subsequently, all infection- and infestation-related trials were assigned a disease condition corresponding to the Scorecard pathogens.	◦ Clinical Trial Community (CTC) Platform[308], including: ◦ ClinicalTrials.gov ◦ Pan African Clinical Trial Registry (PACTR)[309] ◦ The South African National Clinical Trials Register (SANCTR)[310] ◦ International Standard Randomised Controlled Trial Number (ISCTRN)[311]
Manufacturing capacity	Using the best publicly available data and aligning with their respective methodologies the manufacturing capacity indictor was sub-divided by product. Vaccine manufacturing capacity is captured in two ways; first, by identifying manufactures with sites that are either currently producing vaccines or have the potential to do so; and second, by assessing which sites have initiated or signed technology transfer agreements (TT's) and which are still awaiting TT's. For mAbs, capacity is based on information reported by sites themselves.	◦ African Vaccine Manufacturing Mapping 2024 – Supply and Demand Landscape[312] ◦ Advancing a sustainable supply and demand ecosystem for monoclonal antibodies in Africa 2025[313]
Regulatory capacity	The indicator is defined as which countries have WHO recognised maturity level 3 (ML3) capacity and also highlights the scope of products (medicines; vaccines non-producing; vaccines producing). Data on diagnostic approvals is not available in this source.	WHO's List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3)1 and maturity level 4 (ML4)[305]

ANNEX F

Prioritisation of viral families of high pandemic potential

TABLE 1 **Prioritisation of viral families of high pandemic potential**

WHO 2018 PRIORITISATION (Scorecard 1.0)	WHO 2024 PRIORITISATION – viral families of high pandemic potential	SCORECARD 3.0
Arenaviridae		
Priority pathogen: · Lassa Fever virus	**Priority pathogen:** · Mammarenavirus lassaense (Lassa Fever virus)	**Scorecard pathogen:** · Lassa Fever virus
Coronaviridae		
Priority pathogens: · MERS-CoV · SARS-CoV-1	**Priority pathogens:** · *Subgenus* Merbecovirus (MERS-CoV) · *Subgenus* Sarbecovirus (SARS-CoV-1, COVID-19)	**Scorecard pathogens:** · MERS-CoV · COVID-19
Filoviridae		
Priority pathogens: · Ebola virus · Marburg virus	**Priority pathogens:** · Orthoebolavirus zairense (Zaire Ebola virus) · Orthoebolavirus sudanense (Sudan Ebola virus) · Orthomarburgvirus marburgense (Marburg virus)	**Scorecard pathogens:** · Ebola virus · Marburg virus
Flaviviridae		
Priority pathogen: · Zika virus	**Priority pathogens:** · Orthoflavivirus zikaense (Zika virus) · Orthoflavivirus denguei · Orthoflavivirus flavi	**Scorecard pathogen:** · Zika virus
Hantaviridae		**Orthohantavirus hantanense**
	Priority pathogens: · Orthohantavirus sinnombreense · Orthohantavirus hantanense	**Scorecard pathogen:** · Hantaan
Nairoviridae		
Priority pathogen: · Crimean-Congo Haemorrhagic Fever (CCHF)	**Priority pathogen:** · Orthonairovirus haemorrhagiae (CCHF)	**Scorecard pathogen:** · Crimean-Congo Haemorrhagic Fever (CCHF)
Orthomyxoviridae		**Alphainfluenzavirus Influenzae**
	Priority pathogens: · Alphainfluenzavirus Influenzae H1, H2, H3, H5, H6, H7, H10	**Scorecard pathogen:** · H5N1
Paramyxoviridae		
Priority pathogen: · Nipah and henipaviral diseases	**Priority pathogen:** · Henipavirus nipahense (Nipah virus)	**Scorecard pathogen:** · Nipah virus
Phenuiviridae		
Priority pathogen: · Rift Valley Fever (RVF)	**Priority pathogen:** · Bandavirus dabieense	**Scorecard pathogen:** · Rift Valley Fever (RVF)
Poxviridae		
	Priority pathogens: · Orthopoxvirus variola · Orthopoxvirus monkeypox (mpox)	**Scorecard pathogen:** · mpox
Togaviridae		
	Priority pathogens: · Alphavirus chikungunya (Chikungunya) · Alphavirus venezuelan	**Scorecard pathogen:** · Chikungunya

ANNEX G

Table of Abbreviations

ABBREVIATION	DEFINITION
AAM	Access and Allocation Mechanism
ACRN	African Clinical Research Network
AI	Artificial Intelligence
AMA	African Medicines Agency
AMMINA	African Manufacturing Market Intelligence and Network Analysis
AMRH	African Medicines Regulatory Harmonization
AMSP	Africa Medical Supplies Platform
ANRS-MIE	Agence Nationale de Recherche sur le Sida et les Hépatites Virales Maladies Infectieuses Emergentes
API	Active Pharmaceutical Ingredient
ASEAN	Association of Southeast Asian Nations
ASLM	African Society for Laboratory Medicine
ATHINA	Advanced Technology for Health INtelligence and Action IT system
AUDA-NEPAD	African Union Development Agency - New Partnership for Africa's Development
AVAREF	African Vaccine Regulatory Forum
AviDD	Antiviral Drug Discovery
AVMA	African Vaccine Manufacturing Accelerator
AVMs	African Vaccine Manufacturers
AVSSR	ASEAN Vaccine Security and Self-Reliance
BARDA	Biomedical Advanced Research and Development Authority
BEACON	Biothreats Emergence, Analysis and Communications Network
BoMRA	Botswana Medicines Regulatory Authority
BRAVE	Background Rates of Adverse Events for Vaccine Evaluation
BSL	Biosafety Level
CCHF	Crimean-Congo Haemorrhagic Fever
CDC	Centers for Disease Control and Prevention
CEPI	Coalition for Epidemic Preparedness Innovations
CEPRIS	Center for High-Risk Infectious Pathogens Infectious Pathogens
CFR	Case Fatality Rate
CGCPT	Cumming Global Centre for Pandemic Therapeutics
CGD	Center for Global Development
CHAI	Clinton Health Access Initiative
CHO	Chinese hamster ovary
CIDRAP	Center for Infectious Disease Research and Policy

ABBREVIATION	DEFINITION
CMC	Chemistry, Manufacturing, and Controls
CMD	Centre for Medicines Discovery
CoP	Correlates of protection
CORC	Collaborative Open Research Consortium
CRF	Case Report Form
CSIR	Council for Scientific and Industrial Research
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CSO	Civil Society Organisation
CTC	Clinical Trials Community
CTCAN	Clinical trials Community Africa Network
CTR	Clinical Trials Regulation
CVIA	Center for Vaccine Innovation and Access
DCVMN	Developing Countries Vaccine Manufacturers Network
DFC	Development Finance Corporation
DFI	Development Finance Institution
DHSC	Department of Health and Social Care
DNA	Deoxyribonucleic acid
DNDi	Drugs for Neglected Diseases initiative
DOD	Department of Defense
DRC	Democratic Republic of the Congo
DTV	diagnostics, vaccines and therapeutics
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EDA	Egyptian Drug Authority
EDCTP3	European and Developing Countries Clinical Trials Partnership 3
EDL	Essential Diagnostics List
EIB	European Investment Bank
EIOS	Epidemic Intelligence from Open Sources
EMA	European Medicines Agency
ERINHA	European Research Infrastructure on Highly Pathogenic Agents
EU	European Union
EUA	Emergency Use Authorisation
EU FAB	European Union Factory Assembly and Bioproduction
FCDO	Foreign Commonwealth and Development Office
FDA	Food and Drug Administration

ABBREVIATION	DEFINITION
FEEVA	Framework for the Evaluation of Early Vaccine Evidence
FEVR	Framework for Health, Social and Economic Vulnerabilities and Risks
FIND	Foundation for Innovative New Diagnostics
GADx	Global Access Diagnostics
GAP-CTS	Global Action Plan for Clinical Trial Ecosystem Strengthening
GBT+MD	Global Benchmarking Tool Plus Medical Devices
GC-ADDA	Grand Challenges Africa Drug Development Accelerator
GCTC	Good Clinical Trials Collaborative
GCTF	Global Clinical Trials Forum
GHTC	Global Health Technologies Coalition
GIS	Geographic Information System
GloPID-R	Global Research Collaboration for Infectious Disease Preparedness
GMP	Good Manufacturing Practice
GPMB	Global Preparedness Monitoring Board
GRIPP	Global Research Improving Pandemic Preparedness
GS LEARN	Global South Leaders in Epidemic Analytics and Response Network
HERA	European Commission Health Emergency Preparedness and Response
HERC	Health Emergency Readiness Canada
HIC	high-income country
HLIP	High Level Independent Panel
HLM	High-Level Meeting
HPFRA	Health Protection Research Focus Awards
HPRU	Health Protection Research Unit
HSA	Health Sciences Authority of Singapore
HTAP	Health Technology Access Programme
HNTV	Hantaan virus
IAVI	International Aids Vaccine Initiative
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICTRP	International Clinical Trials Registry Platform
IFC	International Finance Corporation
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IGH	Impact Global Health
IGWG	Intergovernmental Working Group
IHRs	International Health Regulations
IMDRF	International Medical Device Regulators Forum
IMF	International Monetary Fund
INB	International Negotiating Body
IND	Investigational New Drug
INNOVATE	International Network for Vaccine Safety Surveillance
INSIS	International Network of Special Immunisation Services

ABBREVIATION	DEFINITION
INTREPID	International Readiness for Preventing Infectious Viral Disease
IP3	Institute for the Preparedness and Prevention of Pandemics
IPD	Institut Pasteur de Dakar
IPPS	International Pandemic Preparedness Secretariat
ISARIC	International Severe Acute Respiratory and emerging Infection Consortium
ITAP	Independent Test Assessment Program
IVD	In Vitro Diagnostic
IVDR	In Vitro Diagnostic Regulation
JFHTF	Joint Task Force on Finance and Health
KDCA	Korea Disease Control and Prevention Agency
KNIID	Korea's National Institute of Infectious Disease
LAC	Latin America and the Caribbean
LEAD	Leadership Excellence for African Diagnostics
LMIC	Low- and middle-income countries
LSIMF	Life Sciences Innovative Manufacturing Fund
LFD	Lateral flow device
MADE	Manufacturing to Accelerate Diagnostic Excellence
MCM	Medical countermeasure
MDB	Multilateral development bank
MedSuRe	Medicines Supply Resilience
MERS-CoV	Middle East Respiratory Syndrome Coronavirus
MHRA	Medicines and Healthcare products Regulatory Agency
MIT	Massachusetts institute of technology
ML3/4	Maturity level 3/4
MMAING	Mixed Model of Artificial Intelligence and Next Generation
MOH	Ministry of Health
MoU	Memorandum of Understanding
MPP	Medicines Patent Pool
MRC	Medical Research Council
mRNA	Messenger ribonucleic acid
MSD	Merck Sharp & Dohme
MVA	Modified Vaccinia Ankara
NHS	National Health Service
NIH	National Institutes of Health
NIHR	National Institute for Health and Care Research
NITAGS	National Immunisation Technical Advisory Groups
NRA	National Regulatory Authority
NRC	National Research Council of Canada
ODA	Official Development Assistance
OECD	Organisation for Economic Co-operation and Development
PABS	Pathogen Access and Benefit-Sharing

ABBREVIATION	DEFINITION
PACTR	Pan African Clinical Trials Registry
PAD	Pandemic Antiviral Discovery
PAHO	Pan American Health Organization
PAMTA	Partnership to Accelerate mpox Testing and Sequencing in Africa
PAN	Pandemic Action Network
PANDRH	Pan-American Network for Drug Regulatory Harmonisation
PATH	Program for Appropriate Technology in Health
PCR	Polymerase Chain Reaction
pDNA	Plasmid DNA
PHAHM	Platform for Harmonised African Health Manufacturing
PHECS	Public Health Emergency of Continental Security
PHEIC	Public Health Emergency of International Concern
PIP	Platform for Influenza Preparedness
PLpro	Papain-like protease
POC	Point-of-Care
PPE	Personal Protective Equipment
PPR	pandemic preparedness and response
PSI	Pandemic Sciences Institute
PQ	Prequalification
RADx	Rapid Acceleration of Diagnostics
RAMP-UP	Rapid Agile Manufacturing Partnership for Union Protection
RCT	Randomised controlled trial
RDT	Rapid diagnostic tests
READDI	Rapidly Emerging Antiviral Drug Development Initiative
RVF	Rift Valley Fever
RVMC	Regionalised Vaccine Manufacturing Collaborative
SAHPRA	South African Health Products Regulatory Authority

ABBREVIATION	DEFINITION
SAMRC	South Africa Medical Research Council
SANCTR	South African National Clinical Trials Register
saRNA	Self-amplifying RNA
SFA	Science for Africa
SMART	Self-amplifying mRNA Antiviral RNA Therapeutics
SPEAC	Safety Platform for Emergency vACcines
STEG	Science and Technology Expert Group
SVPL	Special Viral Pathogens Laboratory
TPP	Target Product Profile
TSP	Target Sample Profile
TT	Technology Transfer
TxDC	Therapeutics Development Coalition
UCT	University of Cape Town
UKHSA	UK Health Security Agency
UN	United Nations
UNICEF	United Nations Children's Fund
USAID	US Agency for International Development
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USG	U.S. Government
VHH	Variable domain of Heavy-chain of Heavy-chain antibodies
VISTA	Viral Strain Identification and Assessment
VLP	virus-like particle
VMFN	Vaccine Manufacturing Facility Network
VNVC	Vietnam's National Vaccine Company
WHA	World Health Assembly
WHO	World Health Organization
WHO HTAP	WHO Health Technology Access Programme
WLAs	WHO-Listed Authorities

ANNEX H

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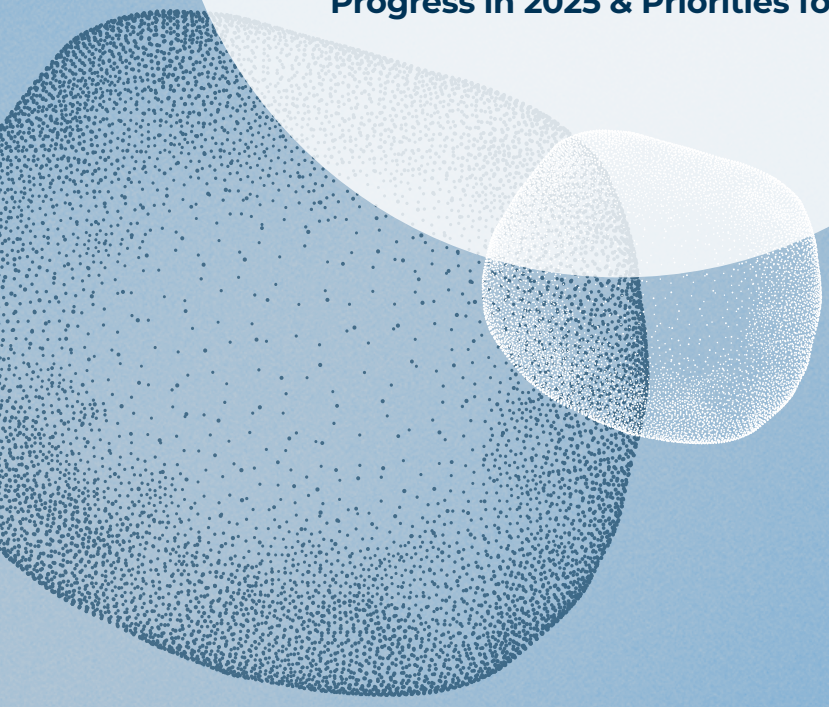
100 Days Mission

Implementation Report
Progress in 2025 & Priorities for 2026



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