



REPUBLIC OF RWANDA
MINISTRY OF HEALTH

RWANDA EPIDEMIC AND PANDEMIC PREPAREDNESS PLAN (REPP)

Strategy for Medical Countermeasures
Development 2026-2040

OCTOBER 2025

Table of Contents

FOREWORD

EXECUTIVE SUMMARY

CHAPTER 1 - STRATEGIC FOUNDATION

- 1 Introduction & Context
- 2 Strategic Rationale: Rwanda's Health Security Vision
- 3 Pathogen Prioritization and Market Landscape

CHAPTER 2 - MCMS STOCKPILING AND CLINICAL TRIALS PLAN

- 4 Introduction: From Response to Readiness
- 5 The Imperative for Comprehensive MCM Stockpiling
- 6 Integration with Rwanda's Hub for Pandemic Pathogen Sciences
- 7 Learning from Recent Outbreak Experiences
- 8 One Health Integration and Cross-Border Considerations
- 9 Clinical Trials Investment and Future MCM Development
- 10 Economic Rationale and Sustainability Framework
- 11 Implementation Strategy and Risk Mitigation
- 12 Regional Leadership and Global Health Security

CHAPTER 3- DEPLOYMENT OF EXISTING MEDICAL COUNTERMEASURES FOR PRIORITY PATHOGENS

- 13 Existing Medical Countermeasures for Priority Pathogens
- 14 Priority actions across all families
- 15 Development Plan for Stockpiling and Clinical Trials: A Three-Phase Approach (2026-2030)
- 16 Conclusion: Building Resilient Pandemic Preparedness

CHAPTER 4 - STRATEGIC DIRECTION

- 17 Strategic goals and objectives
- 18 Scientific Strategy and Hub Development

CHAPTER 5 - ENABLERS OF SUCCESS

- 19 Governance and Partnerships
- 20 Regulatory and Quality Excellence
- 21 Financing and Sustainability
- 22 Market Access and Commercial Strategy

CHAPTER 6- IMPLEMENTATION FRAMEWORK

- 23 Implementation Roadmap
- 24 Technical Action Plan for MCM Expansion
- 25 Monitoring, Evaluation, and Adaptive Management
- 26 Risk Management and Mitigation

CHAPTER 7 - FORWARD-LOOKING IMPACT

- 27 Strategic Significance and Call to Action
- 28 Conclusion



FOREWORD

Building Africa’s Shield Against Future Pandemics: The Time for Action is Now

The Rwanda Epidemic and Pandemic Preparedness Plan (REPP) marks a pivotal moment in our nation’s health security journey. Rwanda stands poised to become Africa’s premier hub for medical countermeasures research, development, and manufacturing by 2040. This comprehensive strategy aligns with the pandemic agreements and frameworks, ensuring our national preparedness contributes to global health security coordination.

Africa’s \$200 billion COVID-19 economic impact demonstrated that health threats pose existential risks to our continent’s development. No longer can we depend on external supply chains for life-saving medical countermeasures during emergencies. Our recent health emergency responses demonstrate both our ability to collaborate and rapidly respond to an outbreak. During the 2024 Marburg outbreak, Rwanda achieved a historic 22.7% case fatality rate—dramatically lower than the typical 50-88%. This success reflects decades of systematic health system investment, from our 58,000 community health workers to advanced digital surveillance systems.

COVID-19 taught us that no nation can rely solely on external supply chains for critical medical countermeasures. Africa must develop African solutions for African health challenges. REPP charts our path with a clear vision: by 2040, Rwanda will have a scientific capacity able to detect emerging threats, design and develop medical countermeasures, and manufacture vaccines and therapeutics. Through our Pandemic Innovation Hub featuring biosafety laboratories, we will serve people across the region while training the next generation of African scientists.

This strategy transforms pandemic preparedness into an economic driver, generating over \$650 million annually by 2040 while creating 1,500+ high-skilled jobs. With \$160 million secured internally mobilized through the Rwanda Health Emergency Preparedness, Response and Resilience Project and the Pandemic Fund Project, we have built a solid foundation for success.

REPP unites our institutions: the Rwanda Biomedical Centre (RBC), Rwanda Agriculture and Animal Resources Development Board (RAB), Rwanda Development Board (RDB), Rwanda Food and Drugs Authority (RFDA), University of Rwanda, and private sector partners—in service of a shared mission. Our enhanced National Health Intelligence Center (NHIC), National Public Health Emergency Operation Center (NPHEOC), and collaborative surveillance systems will anchor regional leadership across the region community. To international partners, we offer Rwanda as proof of what vision and commitment can achieve. To regional neighbors, we extend partnership invitations in building Africa’s pandemic preparedness capacity. To our citizens, we promise strengthened readiness through affordable, locally produced medical countermeasures.

The path is ambitious but achievable. Rwanda has consistently exceeded expectations in health system performance and innovation leadership. Now we focus this proven capability on pandemic preparedness, confident that our systematic approach will benefit the entire continent.

This plan represents more than pandemic preparedness; it embodies Africa’s determination to control its health destiny. We invite partners to join us in building a more resilient, self-reliant continent. The time for action is now.

Dr. Sabin NSANZIMANA
Minister of Health
Republic of Rwanda





EXECUTIVE SUMMARY

The Challenge & Opportunity

Africa's 99% dependency on imported medical countermeasures during COVID-19 exposed critical vulnerabilities that cost the continent \$200 billion and countless lives. Yet this challenge presents an unprecedented opportunity: a \$1+ billion regional market demanding locally-invented-developed-produced vaccines, diagnostics, and therapeutics designed for African conditions and timely delivered within hours, not weeks.

Rwanda's Strategic Response

The Rwanda Epidemic and Pandemic Preparedness Plan (REPP) represents a paradigm shift from reactive outbreak response to proactive health security leadership. Building on Rwanda's proven pandemic response excellence—including zero healthcare worker infections during the Marburg outbreak and a historic 22.7% case fatality rate (versus typical 50-88%)—this strategy transforms demonstrated capabilities into sustainable regional leadership.

The Vision: Regional Pandemic Innovation Hub

By 2040, Rwanda will serve as Africa's premier Pandemic Innovation Hub, providing comprehensive medical countermeasure coverage for 300+ million people while eliminating dependency on imported health security products. This framework positions Rwanda as the continent's first fully self-reliant pandemic preparedness center, anchored by world-class Scientific Infrastructure that rivals global research institutions.

Strategic Approach: Three Integrated Pillars

ANTICIPATE & ALIGN

Rwanda will establish 48-hour threat detection through AI-powered surveillance systems that integrate human, animal, and environmental health data streams. This pillar delivers 95% outbreak prediction accuracy via integrated One Health data while ensuring sub-48-hour regional response activation across EAC member states through coordinated emergency protocols.

INNOVATE & ACCELERATE

The Innovation pillar centers on a rapid medical countermeasure development capability supported by biosafety laboratory facilities and cutting-edge Scientific Infrastructure. This approach is complemented by Africa's most responsive regulatory framework, enabling emergency authorization pathways that maintain international safety standards while accelerating life-saving interventions.

MANUFACTURE & MOBILIZE

Manufacturing excellence targets 50+ million vaccine doses annually across multiple platforms, complemented by 25+ million diagnostic tests with field-deployable capabilities. This pillar achieves 70% self-reliance in finished medical products by 2040 through climate-resilient infrastructure and diversified supply chains that serve regional markets effectively.

Investment Framework & Returns

- **Investment:** \$500 million over 2026-2040, with \$160 million already secured through internal mobilization and the Pandemic Fund project.
- **Strategic Allocation:** The investment framework allocates \$300 million for core hub infrastructure and manufacturing capabilities, ensuring comprehensive production capacity across vaccines, diagnostics, and therapeutics. An additional \$200 million dedicated to Scientific Infrastructure and advanced research facilities under the Pandemic Innovation Hub will establish world-class research capabilities that rival global institutions and drive continuous innovation in pandemic sciences.
- **Economic Returns by 2040:** The economic transformation delivers \$650+ million annual revenue from manufacturing, technology transfer, and research services while creating 2,000+ high-skilled direct positions in biotechnology and research sectors. Foreign exchange benefits exceed \$400+ million annually through exports and import substitution, generating regional economic multiplier effects exceeding \$1.5 billion annually that benefit the entire East African Community.

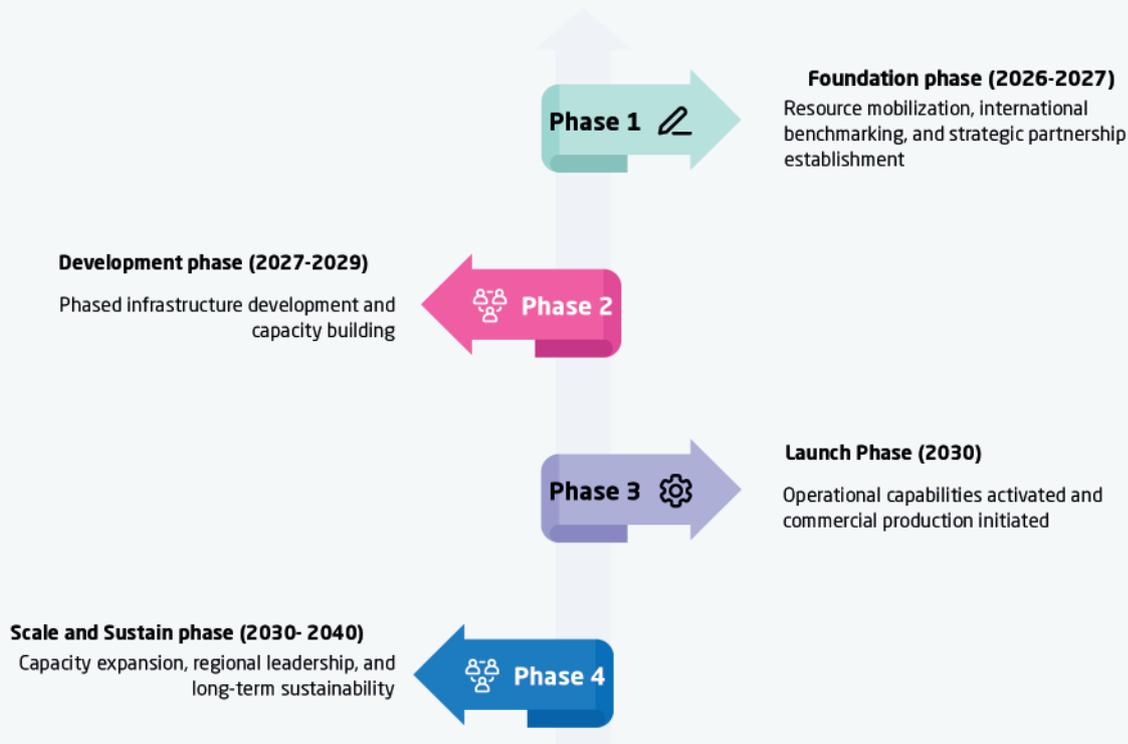




Investment Framework & Returns

- **Investment:** \$500 million over 2026-2030, with \$160 million already secured by internal mobilization and through the Pandemic Fund project.
- **Strategic Allocation:** The investment framework allocates \$300 million for core hub infrastructure and manufacturing capabilities, ensuring comprehensive production capacity across vaccines, diagnostics, and therapeutics. An additional \$200 million dedicated to Scientific workforce and advanced research facilities under the Pandemic Innovation Hub will establish world-class research capabilities that rival global institutions and drive continuous innovation in pandemic sciences.
- **Economic Returns by 2040:** The economic transformation delivers \$650+ million annual revenue from manufacturing, technology transfer, and research services while creating 2,000+ high-skilled direct positions in biotechnology and research sectors. Foreign exchange benefits exceed \$400+ million annually through exports and import substitution, generating regional economic multiplier effects exceeding \$1.5 billion annually that benefit the entire East African Community.

Implementation Timeline



Transformational Impact

REPP delivers four fundamental transitions that redefine Africa’s pandemic preparedness landscape. The transformation moves from 99% import dependency to complete self-reliance in medical countermeasures, while shifting from reactive response protocols to proactive countermeasure development capabilities. The geographic scope expands from a national focus to serving 300+ million people regionally, complemented by economic transformation from cost center operations to substantial annual revenue generation that creates a sustainable, profitable ecosystem supporting long-term growth and innovation.

Call to Action

Rwanda extends an open invitation to regional governments, international partners, and private sector innovators to join this historic undertaking. Together, we will build Africa’s shield against future pandemics while creating a sustainable, profitable ecosystem that serves both health security and economic development objectives. The foundation is set. The partnerships are forming. The time for Africa’s health independence is now.



1

STRATEGIC FOUNDATION





1. INTRODUCTION & CONTEXT

The Global Pandemic Preparedness Imperative

The COVID-19 pandemic fundamentally reshaped global understanding of health security, exposing critical vulnerabilities in medical countermeasure supply chains and highlighting the urgent need for regional self-reliance. Africa, despite representing 17% of the world's population, received less than 3% of global vaccine doses during the first year of the COVID-19 pandemic, while experiencing disproportionate economic losses exceeding \$200 billion. This stark disparity underscored a fundamental truth: pandemic preparedness is not merely a health issue but a matter of science sovereignty, economic security, and sustainable development.

The global response to COVID-19 revealed that existing international frameworks, while well-intentioned, could not adequately address the speed and scale required for effective pandemic response. Supply chain disruptions, export restrictions, and vaccine nationalism demonstrated that countries must develop indigenous capabilities to protect their populations during health emergencies. The World Health Organization's call for regional manufacturing hubs and the global commitment to pandemic preparedness through initiatives like the Pandemic Fund reflect growing recognition that distributed, regionalized capabilities represent the future of health security.

Africa's Health Security Challenge

Africa's pandemic vulnerability stems from structural dependencies that extend beyond medical countermeasures to encompass the entire health innovation ecosystem. The continent produces less than 1% of vaccines consumed globally while importing 99% of its pharmaceutical needs, creating supply chain vulnerabilities that become critical during emergencies. This dependency is not merely financial—it represents a fundamental gap in scientific capability, manufacturing infrastructure, and regulatory systems that undermines the continent's ability to respond rapidly to emerging threats.

The economic impact of this dependency extends far beyond direct health costs. During COVID-19, African economies contracted by 3.4% in 2020, with tourism-dependent countries experiencing losses exceeding 20% of GDP.

The delay in vaccine access prolonged economic disruption, while the absence of local diagnostic capabilities hampered effective surveillance and contact tracing efforts. These cascading effects demonstrate that health security dependencies create broader vulnerabilities that undermine economic stability and development progress.

Rwanda's Proven Foundation

Rwanda enters this strategic transformation from a position of demonstrated strength in health system performance and emergency response capabilities. The country's health system, built through systematic investment over two decades, provides universal health coverage to 95% of the population through a tiered delivery model that extends from 58,000 community health workers to specialized referral facilities. This foundation proved its resilience during multiple health emergencies, most recently during the 2024 Marburg virus outbreak, where Rwanda achieved the lowest recorded case fatality rate of 22.7% compared to typical rates of 50-88%.

The Marburg response demonstrated Rwanda's integrated approach to health emergencies, combining rapid diagnostic capabilities, coordinated surveillance systems, and effective therapeutic deployment. Prophylactic treatments successfully avoided massive transmission in the healthcare community, while the average recovery time for treated patients was reduced from 9.7 days to 4.3 days. This success reflected not only technical capabilities but also the coordinated response frameworks that enable rapid mobilization of resources and expertise across multiple sectors.

Rwanda's digital health infrastructure provides additional advantages for pandemic preparedness, with platforms including the Electronic Integrated Disease Surveillance and Response System (eIDSR), Health Management Information System (HMIS), and Laboratory Information Management System (LIS) delivering real-time data that supports evidence-based decision-making. These systems enhance surveillance capabilities while enabling rapid resource allocation during public health emergencies, providing the foundation for the advanced AI-powered systems envisioned under REPP.





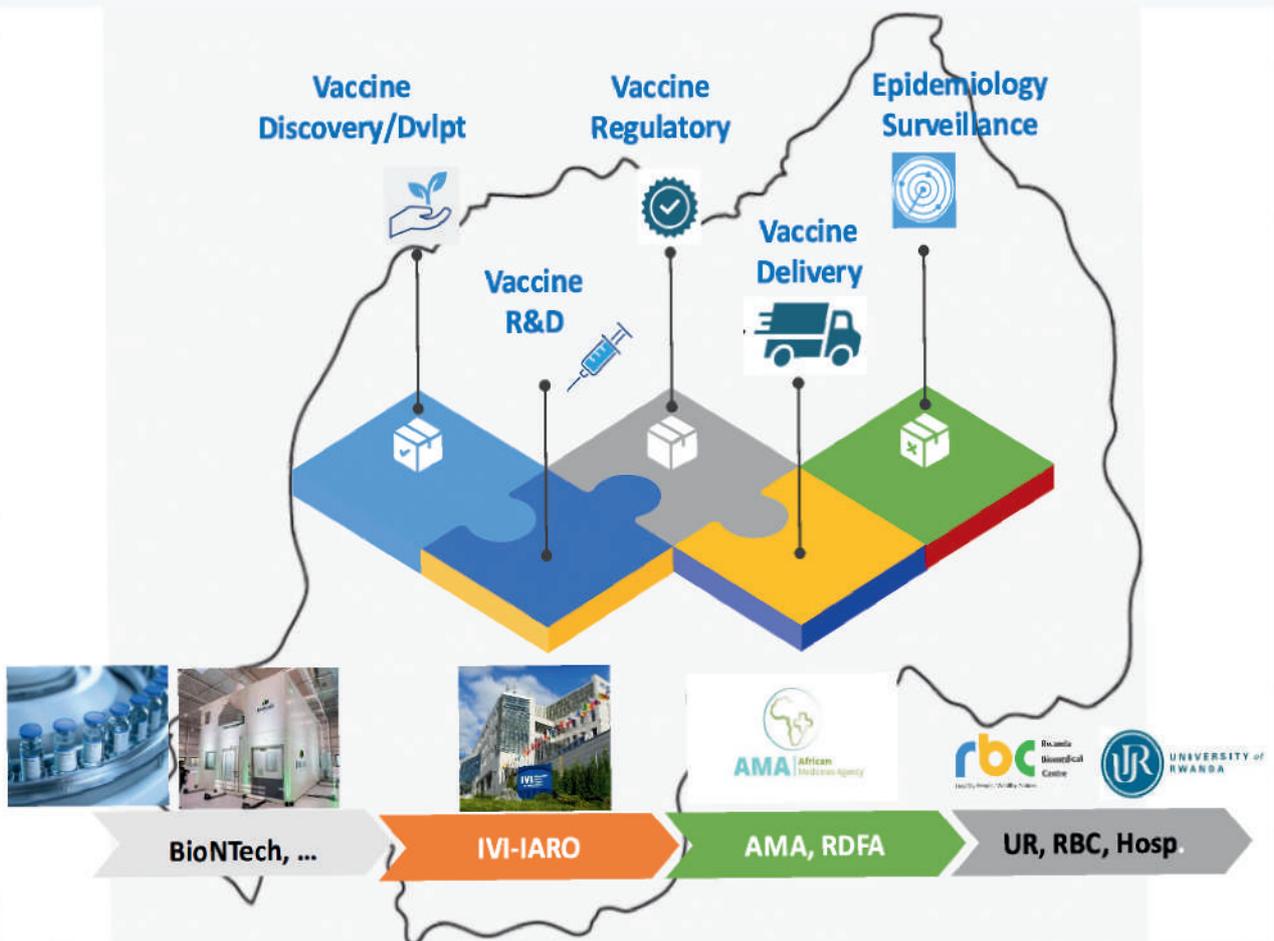
Existing Research and Development Infrastructure

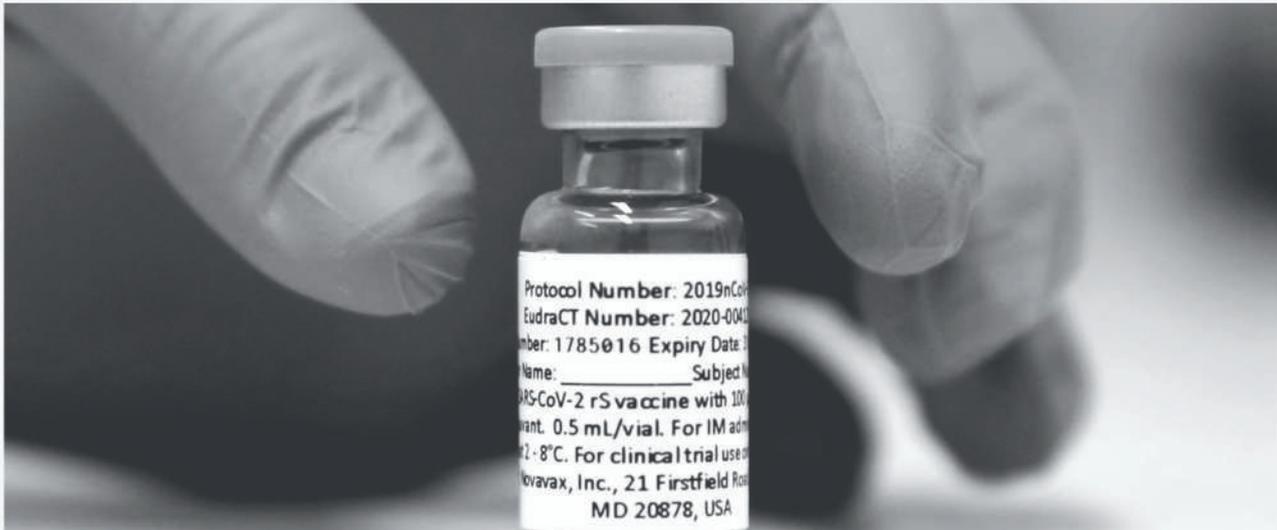
Rwanda’s existing R&D ecosystem provides a solid foundation for REPP implementation, encompassing the full value chain from vaccine discovery and development through regulatory approval and delivery. This comprehensive infrastructure demonstrates Rwanda’s systematic approach to building integrated biotechnology capabilities that span research, manufacturing, regulation, and clinical application across multiple institutional partners.

The current ecosystem integrates multiple institutions, including BioNTech partnerships, IVI-IARO collaborations, and regulatory frameworks through AMA and RFDA, while leveraging academic capabilities at the University of Rwanda and clinical expertise at RBC and partner hospitals. These partnerships create a networked approach to medical countermeasure development that combines international technology transfer with indigenous capacity building, ensuring both access to cutting-edge platforms and development of sustainable local expertise.

The BioNTech collaboration has established Rwanda’s foundation in mRNA vaccine technology and GMP manufacturing standards, while partnerships with the International Vaccine Institute and Institut Africain de Recherche en Organisation provide broader research networks and technical capabilities. The regulatory framework anchored by RFDA’s WHO ML3 status and integration with the African Medicines Agency creates pathways for both emergency response and continental market access.

Academic and clinical integration through the University of Rwanda’s biotechnology programs and RBC’s specialized laboratories, including BSL-3 facilities and advanced diagnostic capabilities, provide the research infrastructure and human capital development necessary for sustained innovation. This existing ecosystem creates multiple entry points for REPP implementation while providing proven operational experience in vaccine development, regulatory approval, and clinical deployment that will accelerate the transition to comprehensive pandemic preparedness capabilities.





The East African Regional Context

The East African Community represents a natural geographic and economic unit for regional pandemic preparedness, encompassing 300+ million people across six countries with combined healthcare spending exceeding \$8 billion annually. Kenya leads regional healthcare investment with a \$2.1 billion budget serving 54 million people, while Uganda and Tanzania represent significant markets with 47 million and 61 million populations, respectively. The Democratic Republic of Congo, despite infrastructure challenges, adds 95 million people to the potential market for locally-produced medical countermeasures.

Regional integration through the EAC provides frameworks for coordinated health security approaches, including harmonized regulatory standards, shared surveillance systems, and coordinated procurement mechanisms. The EAC Health Strategy emphasizes regional self-reliance and collaborative approaches to health challenges, creating policy alignment that supports integrated pandemic preparedness initiatives. Cross-border disease surveillance systems and joint outbreak response protocols provide operational foundations for expanded regional cooperation under REPP.

Economic integration within the EAC creates opportunities for distributed manufacturing and specialization that optimize resource utilization while building redundancy for supply chain resilience. Rwanda's geographic position at the center of the region, combined with excellent transport links and established trade relationships, positions the country as an ideal hub for regional medical countermeasure production and distribution that can reach any EAC capital within 72 hours.

Global Innovation Landscape and Opportunities

The global medical countermeasure landscape is experiencing unprecedented innovation driven by technological advances in mRNA platforms, viral vectors, and rapid diagnostic systems. The success of mRNA vaccines during COVID-19 demonstrated the potential for platform technologies that can be rapidly adapted to new threats, while advances in artificial intelligence and machine learning offer opportunities for predictive surveillance and accelerated drug discovery. These technological capabilities are increasingly accessible to developing countries through technology transfer partnerships and South-South collaboration.

International funding mechanisms, including the European Union, Pandemic Fund, CEPI, and public-private partnerships, provide unprecedented opportunities for developing countries to build indigenous pandemic preparedness capabilities. The global commitment to "missions" for pandemic countermeasure development aligns with Rwanda's strategic timeline while providing technical and financial support for achieving ambitious targets. These international frameworks explicitly recognize the need for distributed manufacturing capabilities that can serve regional populations effectively.





2. STRATEGIC RATIONALE: RWANDA'S HEALTH SECURITY VISION

Vision for Continental Health Sovereignty

Vision

To Transform Rwanda into regional's leading Pandemic Innovation Hub for medical countermeasures development and manufacturing, ensuring rapid, coordinated responses to pandemic threats while eliminating regional dependency on imported health security products by 2040.

Mission

To Build a sustainable, market-driven ecosystem that anticipates emerging health threats, accelerates innovation in medical countermeasures, and delivers life-saving interventions through coordinated national and regional partnerships.

Rwanda's health security vision extends beyond national borders to encompass continental transformation toward self-reliance and scientific excellence. This vision recognizes that true health security cannot be achieved in isolation but requires regional ecosystem development that builds collective capabilities while maintaining national sovereignty over critical health infrastructure. The approach positions Rwanda as a catalyst for broader African health security independence while ensuring that benefits flow throughout the region and continent.

The vision of continental health sovereignty addresses historical imbalances that have left Africa dependent on external sources for life-saving medical interventions. By developing indigenous capabilities for vaccine production, diagnostic manufacturing, and therapeutic development, Rwanda contributes to reducing the continent's \$14.5 billion annual pharmaceutical import bill while building scientific capacity that generates local innovation and economic value. This approach transforms health spending from a drain on foreign exchange reserves into investment in local economic development and scientific advancement.

Continental health sovereignty also encompasses regulatory independence, ensuring that African countries can authorize and deploy medical countermeasures based on local epidemiological needs and risk assessments rather than waiting for decisions from external regulatory authorities. Rwanda's advancement toward WHO ML4 regulatory status positions the country to lead regional regulatory harmonization while maintaining the agility required for emergency response during health crises.





Economic Transformation Through Health Innovation

Rwanda's strategic rationale positions health innovation as a driver of economic transformation that creates high-value employment while generating export revenues and reducing import dependencies. The biotechnology sector represents one of the fastest-growing segments of the global economy, with pandemic preparedness creating sustained demand for innovative medical countermeasures that address emerging threats and changing epidemiological patterns.

The economic transformation extends beyond direct manufacturing to encompass the broader innovation ecosystem, including research and development, intellectual property generation, technology transfer, and specialized services. By investing in cutting-edge scientific infrastructure and attracting top talent, Rwanda creates a foundation for sustained innovation that generates value across multiple sectors while positioning the country as a regional hub for biotechnology investment and development.

The approach recognizes that successful biotechnology development requires sustained investment in human capital, with returns that compound over time as local expertise grows and innovation capabilities expand. The 2,000+ high-skilled positions that will be created directly by REPP represent the foundation for broader sectoral development that could support 10,000+ positions across the biotechnology ecosystem by 2045, creating a sustainable economic base that contributes to Rwanda's transformation into a knowledge-based economy.

Climate Resilience and Environmental Sustainability

Rwanda's health security vision integrates climate resilience as a fundamental component, recognizing that changing environmental conditions are reshaping disease patterns and creating new pandemic risks. Temperature increases, altered precipitation patterns, and extreme weather events affect pathogen transmission dynamics, vector breeding cycles, and vaccine stability requirements, necessitating adaptive approaches that maintain effectiveness under changing conditions.

The strategic approach emphasizes sustainable technologies and circular economy principles that minimize environmental impact while building resilience against climate-related disruptions. Climate-controlled facilities utilize renewable energy sources and energy-efficient systems, while manufacturing processes incorporate green chemistry principles and waste reduction strategies. Supply chain resilience includes distributed storage networks and alternative transportation routes that maintain operational continuity during climate-related disruptions.

Environmental sustainability extends to the broader One Health approach that recognizes interconnections between human, animal, and environmental health systems. Climate-disease modeling capabilities inform countermeasure development priorities while environmental monitoring systems provide early warning of changing disease risks. This integrated approach ensures that pandemic preparedness efforts contribute to rather than detract from environmental sustainability and climate adaptation objectives.

Regional Leadership and South-South Cooperation

Rwanda's vision positions the country as a leader in South-South cooperation for health security, sharing knowledge, technologies, and capabilities with other developing countries facing similar challenges. This approach recognizes that African solutions to African problems often prove more sustainable and cost-effective than imported technologies that may not address local conditions and constraints effectively.

Regional leadership encompasses technology transfer, capacity building, and institutional development that extend Rwanda's capabilities throughout the East African Community and broader African continent. Training programs, technical assistance, and collaborative research initiatives build regional expertise while creating networks of cooperation that enhance collective security against pandemic threats. This approach multiplies the impact of Rwanda's investments while building sustainable partnerships that support long-term development objectives.





The South-South cooperation model also facilitates knowledge exchange with other middle-income countries that have successfully developed biotechnology capabilities, including Brazil, India, South Africa, and Southeast Asian nations. These partnerships provide access to proven technologies and implementation strategies while creating opportunities for collaborative innovation that addresses shared challenges in tropical disease management and health system strengthening.

Innovation Excellence and Scientific Advancement

Rwanda’s health security vision emphasizes scientific excellence and innovation leadership that positions the country among global leaders in pandemic preparedness research and development. This commitment extends beyond manufacturing capabilities to encompass fundamental research, technology development, and intellectual property generation that contributes to global scientific knowledge while addressing African health priorities.

The approach recognizes that sustainable competitive advantage in biotechnology requires continuous innovation and adaptation to emerging threats and technological opportunities. Investment in cutting-edge research infrastructure, international partnerships, and top scientific talent creates a foundation for sustained innovation that generates intellectual property and technological capabilities with global applications.

Scientific advancement also encompasses workforce development that creates a pipeline of African scientists and technicians capable of leading pandemic preparedness efforts across the continent. Graduate and postgraduate training programs, international exchange opportunities, and mentorship networks build human capital that extends far beyond Rwanda’s borders while contributing to the global scientific community’s understanding of tropical diseases and pandemic preparedness challenges.

3. PATHOGEN PRIORITIZATION AND MARKET LANDSCAPE

Predicting the pathogens that will be responsible for the next epidemic/pandemic

In June 2024, the World Health Organization (WHO) updated its list of priority pathogen agents capable of causing outbreaks, epidemics, or pandemics worldwide. Alongside this update, WHO experts proposed several mitigation strategies, including the implementation of medical countermeasures (MCMs) during health emergencies. Pathogen selection was based on three primary categories, as detailed in the following table.

Category	Criteria
Transmission Factors	<ul style="list-style-type: none"> • Reservoir of infection • Mode and efficiency of transmission • Spreading capabilities • Pre-existing immunity • Geographical distribution • Mutation rates • Impact of climate changes • Vaccines: availability, accessibility, effectiveness
Medical Countermeasures	<ul style="list-style-type: none"> • Treatments • Diagnostic tools • Clinical development progress • Case fatality rate without treatment
Virulence Factors	<ul style="list-style-type: none"> • Severity of induced diseases • High-risk populations • Mutations affecting virulence





Evidence-Based Pathogen Prioritization Framework

Rwanda’s pathogen prioritization integrates WHO threat assessments with market analysis and regional epidemiological data, targeting areas with the highest threat probability and commercial viability.

Pathogen Family	Population at Risk	Annual Market Opportunity	Surveillance-Market Integration	Commercial Rationale
Tier 1: Immediate Opportunity				
Filoviridae (Hemorrhagic Fever Viruses)	50+ million across the region	\$200+ million annually	Early detection of outbreaks detection 3-7 days through enhanced surveillance (IBS, EBS, WES and wildlife surveillance)	Historic 18-24 month outbreak cycles create predictable stockpile demand.
Phenuiviridae (Rift Valley Fever)	100+ million livestock-dependent communities	\$150+ million annually	Climate-integrated surveillance predicts outbreaks 2-4 weeks before peak transmission	Seasonal outbreak patterns correlated with rainfall create dual human-animal vaccine markets.
Tier 2: High regional potential				
Flavivirus (Arboviral Diseases)	300+ million urban population	\$500+ million annually	Urban wastewater surveillance detects early community transmission before clinical surge, enabling rapid diagnostic deployment	Rising urbanization and climate change expand transmission zones.
Influenza and Respiratory Pathogens	Universal coverage (300+ million)	\$1+ billion annually	Wastewater surveillance tracks variant emergence and seasonal patterns, informing universal vaccine formulation and stockpile rotation	Annual vaccination cycles create recurring revenue. Platform technologies enable rapid response to pandemic strains with surge pricing during emergencies
Tier 3: Emerging Opportunity & Disease X				
Coronaviridae (Emerging Coronaviruses)	Regional population (300+ million)	\$300+ million annually	AI-powered genomic surveillance in wildlife reservoirs provides 6-12 month early warning for spillover events	Post-COVID preparedness mandates create institutional demand for stockpiles.
Paramyxoviridae (Nipah and Related Viruses)	80+ million in fruit bat habitat zones	\$180+ million annually	One Health surveillance integrating bat ecology with human case detection enables predictive modeling of spillover risk	High case fatality rates drive premium pricing for therapeutics.

Market Analysis and Commercial Opportunity

The East African medical countermeasures market presents a growing commercial opportunity, driven by rapid population growth, rising healthcare needs, and increasing public and donor investment. The regional medical technology market is projected to reach US \$1.57 billion in 2026, with medical devices accounting for about US \$1.35 billion of this value. While much of the current demand is met through imports, there is significant scope for import substitution and regional manufacturing capacity development.

Countries such as Kenya, Tanzania, Uganda, and the Democratic Republic of the Congo represent distinct opportunity profiles—ranging from Kenya’s role as a procurement and financial hub, to Tanzania’s high-volume donor-supported market, Uganda’s strong research partnerships, and the DRC’s outbreak-driven demand for field-deployable solutions. Together, these dynamics create a compelling case for investment in localized production, technology transfer, and innovative delivery models that strengthen both commercial growth and regional health security.





Competitive Landscape and Strategic Positioning

East Africa's medical countermeasure market remains highly dependent on imports, exposing the region to long delivery times, high costs, and products not tailored to African realities. Global pharmaceutical companies dominate supply but focus mainly on developed markets, while African and Asian competitors face geographic, quality, or strategic limitations.

Rwanda stands out as a regional disruptor.

- Its central location allows delivery to any East African capital in less than 72 hours—far faster than traditional suppliers.
- Local manufacturing reduces import costs and currency risks, enabling affordable products with regional relevance.
- African-adapted innovation—such as thermostable vaccines, field-ready packaging, and simplified protocols—addresses gaps often overlooked by global manufacturers.
- Strong regulation, with Rwanda advancing toward WHO ML4 status, enhances trust and credibility for both local and international markets.

These combined advantages position Rwanda not only as a competitive alternative to imports but also as a regional hub for innovation, production, and distribution of countermeasures.

Technology Platform Strategy

Rwanda's technology strategy emphasizes platform-based approaches—flexible systems that can be rapidly adapted to emerging threats while building long-term capacity and intellectual property. This ensures both preparedness and commercial sustainability.

- **Vaccines:** mRNA, viral vector, and protein-based platforms allow fast, cost-effective responses to high-priority pathogens like hemorrhagic fevers and respiratory diseases, while supporting scale-up for regional needs.
- **Diagnostics:** Portable molecular systems and rapid point-of-care tests strengthen outbreak detection and surveillance, even in remote or resource-limited settings.
- **Therapeutics:** Monoclonal antibody platforms and small-molecule antivirals provide flexible treatment options, with a focus on affordability, stability, and ease of use.

By integrating these platforms, Rwanda is positioned to deliver faster response times, lower costs, and context-specific solutions. This strategic approach not only safeguards national health security but also creates a regional manufacturing and innovation hub, strengthening Africa's contribution to global pandemic preparedness.

Current Capabilities assessment

Rwanda's current pandemic preparedness capacity will be built on a comprehensive, tiered healthcare system that extends from the community health workers to specialized referral hospitals. The system comprises five national referral hospitals, three provincial hospitals, 34 district hospitals, and 510 health centers, all supported by a network of over 58,000 community health workers. This structure ensures broad access to essential healthcare services while maintaining the capability for specialized care and emergency response.

The laboratory network plays a vital role in Rwanda's healthcare infrastructure. Anchored by the National Reference Laboratory (NRL), which houses a BSL-3 facility for handling highly pathogenic viruses, the system includes regional and district laboratories that have proven invaluable during recent outbreaks. Despite these strengths, there remains a pressing need to expand capacity for specialized testing and research on pandemic viruses of concern. Notably, the recent establishment of the vaccine fill-finish capabilities at the Kigali manufacturing facility marks significant progress toward enhancing MCM capacity, although operational delays have prevented the facility from reaching full functionality.





Digital health systems form a cornerstone of Rwanda’s healthcare advancements, leveraging platforms such as the Electronic Integrated Disease Surveillance and Response System (eIDSR), Health Management Information System (HMIS), and Laboratory Information Management System (LIS) to deliver real-time data that supports evidence-based decision-making. These systems enhance surveillance, data collection, and resource allocation during public health emergencies. Despite these advancements, several critical gaps remain. Key areas requiring urgent development include expanding local vaccine manufacturing beyond current fill-finish operations, establishing a robust clinical trial infrastructure for rapid response to emerging threats, scaling up diagnostic production capacity, and enhancing therapeutic manufacturing capabilities. Addressing these challenges presents Rwanda with strategic opportunities to strengthen its healthcare ecosystem and assert itself as a leading regional hub for MCM development, pandemic preparedness, and health security in East Africa.

SWOT Analysis of the current Rwandan Pandemic Preparedness

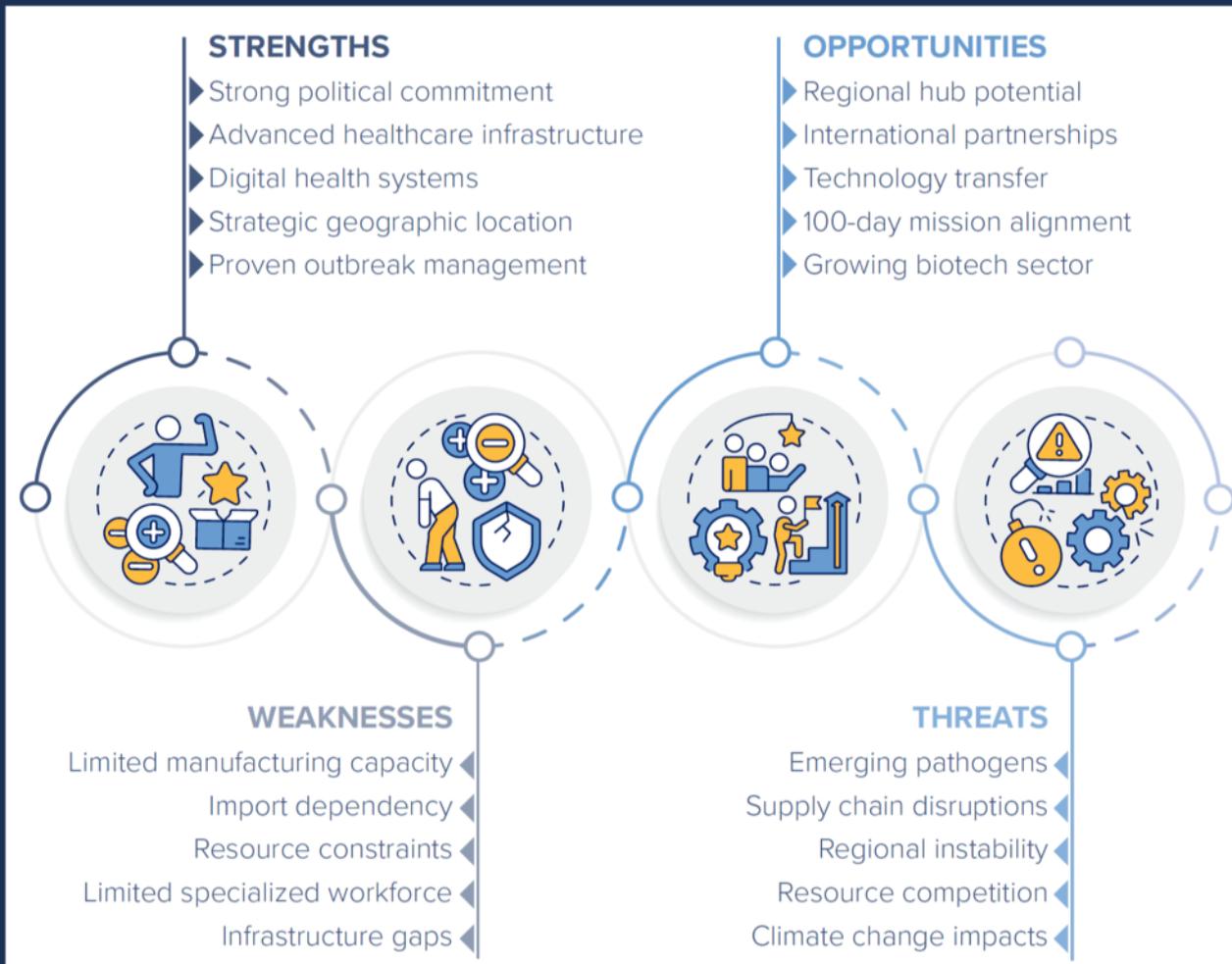


Figure summarizing SWOT analysis of strategic plans for pandemic preparedness in Rwanda

Rwanda demonstrates strong foundations for pandemic preparedness through robust political commitment, advanced healthcare infrastructure, and digital health systems.

However, the country faces significant limitations in manufacturing capacity, particularly for vaccines and therapeutics, along with dependence on imported materials and workforce constraints. Opportunities lie in establishing Rwanda as a regional Medical Countermeasures (MCM) hub through international partnerships and the growing biotech sector, leveraging the global mission initiative.

1. https://rbc.gov.rw/wp-content/uploads/2024/08/Rwanda_Mpox_SPRRP_V000_5_NB%5B1%5D%20abc.pdf
2. <https://africacdc.org/news-item/rwanda-launches-event-basedsurveillance-guidelines/>

2

MCMS STOCKPILING AND CLINICAL TRIALS PLAN





4. INTRODUCTION: FROM RESPONSE TO READINESS

Rwanda's pandemic preparedness strategy should represent a fundamental shift from a reactive outbreak management to a proactive readiness for emerging infectious disease threats. The Medical Countermeasures (MCMs) Stockpiling Plan emerges from lessons learned during recent outbreaks, particularly the 2020-2022 COVID19 pandemic, 2022-2024 Rift Valley Fever epidemic, the 2024 Marburg virus outbreak, the current Mpox crisis, as well as sporadic Ebola outbreaks in the Region.

The stockpiling plan is not merely an inventory management exercise; it should be seen as Rwanda's strategic commitment to ensuring equitable access to life-saving medical interventions during health emergencies. This approach recognizes that pandemic preparedness requires sustained investment during inter-epidemic periods, moving beyond the traditional cycle of crisis response and neglect that has characterized global health security for decades.

5. THE IMPERATIVE FOR COMPREHENSIVE MCM STOCKPILING

The COVID-19 pandemic starkly demonstrated how supply chain disruptions and vaccine nationalism can leave entire regions without access to essential medical countermeasures. Rwanda's experience managing the 2024 Marburg outbreak, where rapid deployment of advanced therapeutics, including the SAbIN Investigational candidate vaccine, monoclonal antibodies, and remdesivir, contributed to the dramatically reduced mortality rate, illustrates the transformative potential of having MCMs readily available for immediate deployment.

Current global MCM availability reveals critical gaps, particularly for diseases endemic to Africa. While Ebola now has WHO-prequalified vaccines and FDA-approved therapeutics, Marburg virus disease lacks approved vaccines despite ongoing Phase 2 clinical trials by the Sabin Vaccine Institute in Uganda and Kenya, and promising Phase 1 results from the University of Oxford's ChAdOx1 platform. Rift Valley Fever presents an even starker reality, with no approved human vaccines despite the disease's recurring impact on East African communities and livestock economies.

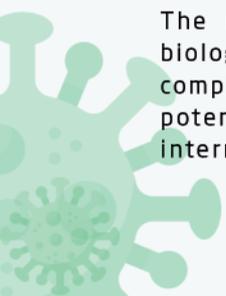
For Mpox, while the JYNNEOS vaccine provides effective protection, global supply constraints during the 2022 outbreak highlighted the vulnerability of depending on a single-source manufacturing. Rwanda's comprehensive stockpiling should adopt a comprehensive approach to address these vulnerabilities by diversifying suppliers, maintaining strategic reserves, and establishing frameworks for rapid procurement of emerging countermeasures.

6. INTEGRATION WITH RWANDA'S HUB FOR PANDEMIC PATHOGEN SCIENCES (HPPS)

The stockpiling plan should operate synergistically with Rwanda's ambitious vision to establish a future Hub for Pandemic Pathogen Sciences as a regional center of excellence for MCM development and manufacturing. The HPPS rapid response unit will be developed to provide expertise in biotechnology and bioengineering and should eventually reduce Rwanda's dependence on imported MCMs through local production capabilities.

The stockpiling strategy presented here provides essential bridge capacity while Rwanda builds indigenous MCM manufacturing capabilities across four key platforms: live-attenuated and inactivated vaccines, protein-based vaccines, nucleic acid-based vaccines (DNA and mRNA), and viral vector-based technologies. This dual approach, combining immediate stockpiling coupled with long-term manufacturing capacity development, will position Rwanda to serve both national needs and regional demand for essential MCMs.

The rapid response unit's planned expertise in plasmid production, vector engineering, and biologics manufacturing (including monoclonal antibodies and recombinant proteins) directly complements the stockpiling plan by providing quality control capabilities, technology transfer potential, and eventual domestic production alternatives for critical products currently procured internationally.





7. LEARNING FROM RECENT OUTBREAK EXPERIENCES

Rwanda's recent outbreak responses provide crucial insights that inform the stockpiling strategy. The Rift Valley Fever outbreak revealed how limited diagnostic capacity at district levels created bottlenecks in case identification and delayed targeted interventions. The stockpiling plan addresses this through substantial investment in RT-PCR testing capacity and strategic distribution of diagnostic resources to regional hubs.

The Marburg outbreak demonstrated the value of pre-positioned therapeutics and established emergency use authorization frameworks. Healthcare workers who received prophylactic monoclonal antibodies experienced zero infections, while patients treated with remdesivir showed clinical improvement. This experience directly informed the stockpiling plan's emphasis on therapeutic reserves and the development of clinical protocols for rapid deployment.

Both outbreaks highlighted the critical importance of cold chain infrastructure, with ultra-cold storage requirements for some vaccines and therapeutics presenting logistical challenges. The centralized National Stockpiling Facility design incorporates redundant temperature control systems, backup power generation, and 24/7 monitoring specifically to address these operational realities.

8. ONE HEALTH INTEGRATION AND CROSS-BORDER CONSIDERATIONS

The stockpiling plan explicitly incorporates One Health principles, recognizing that pandemic threats often emerge at the human-animal-environment interface. Rwanda's experience with both Rift Valley Fever (transmitted through livestock and mosquito vectors) and Marburg virus (with fruit bat reservoirs) demonstrates how effective pandemic preparedness requires coordinated approaches across health sectors.

The proposed wildlife surveillance strategy for filoviruses, including seasonal sampling of fruit bats in four key locations (Kigali-Bashyamba, Musanze caves, Lakes Kivu and Muhazi boundaries), exemplifies this integrated approach. The methodology development for detecting Marburg and Ebola viruses in bat populations provides early warning capabilities that inform stockpile activation decisions and targeted deployment strategies.

Regional coordination mechanisms built into the stockpiling plan acknowledge that pandemic threats transcend national boundaries. The East African Community's experience with cross-border livestock movement during the RVF outbreak demonstrates how uncoordinated responses can undermine individual country efforts. The stockpiling plan, therefore, includes provisions for regional cooperation, joint procurement mechanisms, and harmonized emergency use authorization protocols.

9. CLINICAL TRIALS INVESTMENT AND FUTURE MCM DEVELOPMENT

The stockpiling plan's substantial investment in clinical trials reflects Rwanda's commitment to addressing critical gaps in the MCM landscape. This investment strategy prioritizes diseases with the greatest regional impact and limited global commercial incentives for development.

Phase I and trials for next-generation Marburg vaccines could build upon promising early results from both the Sabin Institute's ChAd3 platform (currently in Phase 2 trials in Uganda and Kenya) and Oxford's ChAdOx1 approach (first-in-human trials initiated in July 2024). The inclusion of reserve procurement commitments for both platforms in the stockpiling budget demonstrates Rwanda's strategy of supporting multiple development pathways to minimize the risk of single-point failure.

Rift Valley Fever vaccine development represents perhaps the most critical gap, given the absence of approved human vaccines despite recurring outbreaks affecting East African populations and economies. The stockpiling plan's allocation of \$4 million for future RVF vaccine procurement provides Rwanda with immediate access to approved vaccines once they become available, while clinical trials investment supports accelerating their development.





The emphasis on novel approaches, including universal vaccines effective against multiple RVFV lineages and combination vaccines providing multi-pathogen protection, is in accordance with lessons learned from recent outbreaks about viral genetic plasticity and the co-circulation of multiple strains.

10. ECONOMIC RATIONALE AND SUSTAINABILITY FRAMEWORK

The stockpiling plan's total five-year investment of more than \$300 million represents approximately 0.5% of Rwanda's projected GDP over the period, a relatively modest investment given the potential economic impact of uncontrolled outbreaks. As an example, the 2014-2016 West Africa Ebola epidemic caused direct economic losses of \$2.8 billion according to World Bank estimates, not including broader impacts on trade, tourism, and social systems.

Rwanda's 2024 Marburg outbreak, despite its successful containment, required the mobilization of substantial resources, including international assistance, healthcare worker deployment, and contact tracing operations involving hundreds of personnel. The economic argument for stockpiling rests on the principle that proactive investment in MCM readiness costs significantly less than reactive outbreak response and is substantially more cost-effective than the economic disruption caused by uncontrolled epidemics.

The sustainability framework should incorporate multiple financing mechanisms, including international partnerships such as CEPI, the Gates Foundation, the European Union, and other multilateral institutions. A diversified funding approach should reduce dependence on domestic resources while building international collaboration networks that will enhance Rwanda's access to emerging MCMs and technical expertise.

Annual maintenance costs of \$6-9 million (representing 10-15% of the total stockpile value) reflect the reality that pandemic preparedness requires sustained investment. This includes not only product replacement due to expiration but also ongoing training, system maintenance, and capacity building to ensure operational readiness.

11. IMPLEMENTATION STRATEGY AND RISK MITIGATION

The phased implementation approach balances immediate needs with capacity building requirements. Phase 1 focuses on establishing infrastructure and procuring available MCMs, Phase 2 expands capacity and initiates major clinical trials, while Phase 3 emphasizes sustainability and technology transfer to local manufacturing.

Risk mitigation strategies address multiple potential failure points: supply chain disruptions (through diversified suppliers and regional cooperation), product failures (through multiple platform approaches), regulatory delays (through established emergency use frameworks), and funding constraints (through diversified financing and phased implementation). The centralized National Stockpiling Facility with regional distribution hubs will provide redundancy and accessibility while maintaining quality through standardized storage conditions and monitoring systems. The integration of advanced security systems, environmental controls, and transportation networks ensures both product integrity and rapid deployment capabilities.

12. REGIONAL LEADERSHIP AND GLOBAL HEALTH SECURITY

Rwanda's comprehensive stockpiling plan positions the country as a regional leader in pandemic preparedness, with implications extending far beyond national borders. The facility design and procurement quantities anticipate serving neighboring countries during regional outbreaks, while the clinical trials investment supports the development of MCMs with continental relevance. This approach aligns with global health security frameworks that recognize pandemic preparedness as a shared responsibility requiring sustained investment by countries most likely to face emerging threats. Rwanda's model should demonstrate how middle-income countries can take proactive leadership roles rather than remaining dependent on international assistance during health emergencies. The emphasis on technology transfer and eventual local manufacturing capacity represents a sustainable long-term vision that moves beyond stockpiling to indigenous MCM production. This evolution from consumer to producer of essential health technologies reflects Rwanda's broader development strategy and contributes to regional health security resilience.





Recent Outbreak Response Achievements

COVID-19

Managed multiple pandemic waves with case fatality rate below 1.5%, achieved >70% vaccination coverage, and maintained essential health services throughout

Mpox

Contained the Mpox outbreak with targeted vaccination, zero deaths, strong surveillance, contact tracing, and effective community engagement.



Marburg Virus Disease

Achieved lowest recorded case fatality rate (22.7%) through rapid deployment of investigational vaccines and therapeutics, effective contact tracing, and integrated laboratory support



SPOTLIGHT 1:

Rwanda's Marburg Success - Validation for REPP Strategy

The Challenge: In September 2024, Rwanda detected its first Marburg virus outbreak with initial concerns about potential widespread transmission and high mortality rates typical of filovirus infections.

The Innovation: Rwanda deployed an integrated medical countermeasure strategy incorporating vaccines and therapeutic countermeasures, domestic laboratory capacity, supply chain readiness, regulatory agility, and coordinated One Health response mechanisms.

The Results:

- 22.7% case fatality rate compared to the typical 50-88% in historical outbreaks
- Zero healthcare worker infections among those receiving prophylactic monoclonal antibodies
- 4.3-day average recovery time with remdesivir treatment versus 9.7 days without treatment
- Accelerated viral clearance in treated patients, reducing transmission risks by 60%

REPP Integration: This experience validates the strategic emphasis on advanced medical countermeasures while highlighting the importance of climate-resilient supply chains and flexible deployment protocols.



3

DEPLOYMENT OF EXISTING MEDICAL COUNTERMEASURES FOR PRIORITY PATHOGENS





SPOTLIGHT 2: Rwanda and the Global 100 Days Mission

The Challenge:

Emerging infectious diseases continue to spread faster than traditional medical countermeasure (MCM) development cycles can respond. Historically, it has taken years—not months—for vaccines, therapeutics, and diagnostics to reach affected populations. This delay has cost millions of lives globally. For Rwanda, situated at the heart of regional outbreak hotspots, such delays present an acute vulnerability given its high population density and porous borders.

The Innovation:

Rwanda has committed to embedding the 100 Days Mission into its national Epidemic Preparedness Plan (REPP 2026-2040). The 100 Days Mission is led by the International Pandemic Preparedness Secretariat (IPPS), alongside implementing partners such as the Coalition for Epidemic Preparedness Innovations (CEPI), focused on vaccines, as well as the World Health Organisation (WHO). The 100 Days Mission aims to develop and deploy effective MCMs within 100 days, identifying an epidemic threat.

Rwanda’s adaptation of the mission includes:

- Pre-negotiated supply and licensing agreements to guarantee access to novel vaccines and therapeutics in development.
- Clinical trial readiness platforms with streamlined ethical and regulatory pathways to allow “day-zero” trial initiation.
- Stockpiling of diagnostics and rapid genomic sequencing capacity, enabling near-real-time detection and variant monitoring.
- Integration with regional One Health surveillance systems, ensuring zoonotic threats like Rift Valley fever are identified early.
- Public-private partnerships to accelerate local fill-finish capacity, reducing reliance on external suppliers.

The Results (Projected Milestones):

- Within 100 days of a new high-threat pathogen emerging, Rwanda will have:
 - Diagnostics validated and deployed nationwide.
 - At least one candidate vaccine is entering Phase 1/2 clinical trials in-country.
 - Therapeutics secured under emergency use authorization.
 - A strategic reserve activated for ring vaccination and targeted treatment deployment.
- Through REPP implementation, Rwanda aims to achieve:
 - 70% local production capacity for priority MCMs, including vaccines and diagnostics.
 - Sub-12-hour deployment timelines for emergency stockpiles.
 - Integration of Rwanda’s trial and manufacturing hubs into CEPI’s global 100 Days Mission network.

REPP Integration:

The 100 Days Mission is not a parallel effort but the backbone of Rwanda’s MCM strategy. It transforms REPP from a reactive preparedness plan into a proactive innovation ecosystem. Rwanda’s integration ensures that when the next epidemic threat arises, the country will not only protect its own population but also contribute to the global public good, delivering vaccines, treatments, and diagnostics in record time for the region and beyond.





13. EXISTING MEDICAL COUNTERMEASURES FOR PRIORITY PATHOGENS

A core aim of REPP is to ensure Rwanda can rapidly deploy effective medical countermeasures (MCMs) against high-priority pathogens. This chapter summarizes the current global landscape of vaccines, therapeutics and diagnostics for five virus families prioritized for Rwanda – Filoviridae (Ebola, Marburg), Bunyavirales (Rift Valley fever virus, RVFV), Poxviridae (Mpox), Flaviviridae (dengue, Zika, yellow fever and West Nile viruses), and Coronaviridae (SARS-CoV-2 and related coronaviruses). The purpose is to create an inventory of available and products in clinical trials, identify critical gaps, and recommend concrete actions for REPP implementation (stockpiling, local assay and manufacturing capacity, and clinical trial readiness, and negotiated access or licensing). Status classifications below reflect approvals, ongoing clinical trials, and earlier-stage development as of September 2025.

Filoviridae (Ebola, Marburg)

Vaccines for filoviruses represent one of the most advanced examples of outbreak-driven MCM development. For Ebola (Zaire ebolavirus), an effective vaccine, rVSV-ZEBOV (Ervebo, Merck), is can be used in outbreak response and ring vaccination campaigns. Heterologous adenoviral/MVA prime-boost regimens (Ad26.ZEBOV followed by MVA-BN-Filo) have also been deployed and assessed in large studies. Marburg virus has no licensed human vaccine yet, but several candidates (including ChAdOx1-Marburg and Sabin-derived constructs) progressed through Phase 1 or early Phase 2 trials by 2024-2025 and remain high priorities for accelerated development and stockpiling.

Therapeutics: For Ebola, monoclonal antibody therapies, Inmazed (REGN-EB3) and Ebanga (ansuvimab/mAb114), are approved and recommended by WHO where available; they can substantially reduce mortality when given early. For Marburg, clinical therapeutic options remain investigational; antivirals such as remdesivir and investigational monoclonals (e.g., MBP091) have been used under expanded access or trial protocols during recent outbreaks.

Diagnostics: nucleic acid testing (RT-PCR) is the diagnostic backbone for filoviruses. Rapid antigen tests are limited; therefore, strengthening in-country PCR capacity and rapid sample transport is essential.

Operational recommendations: Rwanda should pre-negotiate supply access agreements for Ebola and Marburg monoclonals; participate in multinational Marburg vaccine efficacy networks to secure early supplies and trial inclusion; maintain validated PCR capacity and sample referral pathways.

Bunyavirales : Rift Valley fever virus (RVFV)

RVFV poses both veterinary and human threats, and a One Health approach is essential. Several **livestock vaccines** (e.g., Smithburn, Clone 13, and inactivated formulations) are licensed for veterinary use, but each has use-case limitations (e.g., safety in pregnant animals). No human vaccine is yet licensed; however, multiple candidates, such as viral vectors, live-attenuated and novel platforms including CEPI-supported constructs, entered Phase 1-2 stages.

Therapeutics: there are no approved targeted antivirals for human RVF; clinical management is supportive. **Diagnostics:** RT-PCR for virus detection and serology (IgM/IgG ELISA) for exposure are widely available, including in the Rwanda National Reference Laboratory (NRL), but robust point-of-care (POC) tests for rural deployment are limited.





Operational recommendations: Rwanda should support and participate in human RVF vaccine clinical trials in region (e.g. Clinical trial in Kenya with ChAdOx1 RVF), integrate livestock vaccination campaigns into outbreak preparedness, and invest in decentralized molecular and serology testing with a focus on POC solutions and One Health surveillance triggers.

Poxviridae: Mpox (MPXV)

Vaccines: The modified vaccinia Ankara platform MVA-BN (marketed as JYNNEOS/IMVANEX) is approved for Mpox and obtained WHO prequalification in 2024, facilitating procurement globally. Freeze-dried formulations improve field usability. **Therapeutics:** tecovirimat (TPOXX) is authorized for smallpox and could be used for Mpox disease treatment in Rwanda; other antivirals (cidofovir, brincidofovir) have conditional or limited use. **Diagnostics:** PCR from lesion swabs is the diagnostic standard, with genomic sequencing used for surveillance and variant characterization at Rwanda NRL.

Operational recommendations: Rwanda should secure procurement channels for MVA-BN, establish protocols for rapid deployment of tecovirimat through national stockpiles or access agreements, and integrate mpox PCR and genomic surveillance into the REPP diagnostics network.

Flaviviridae – Dengue, Zika, Yellow fever, West Nile

Vaccines: Yellow fever vaccine (YF-17D) remains a cornerstone of prevention in Africa. Dengue vaccines exist but with usage caveats: Dengvaxia requires careful serostatus-based policies, whereas TAK-003 (Qdenga) has broader performance data and approvals in several settings. Zika vaccine candidates and pan-flavivirus approaches are under development. **Therapeutics:** no broadly effective antivirals are approved for dengue/Zika/West Nile. Care is mainly supportive; several antiviral and immunotherapy candidates are in early development. **Diagnostics:** molecular assays (RT-PCR), antigen tests (NS1 for dengue), and serology are available, but cross-reactivity among flaviviruses complicates interpretation. Neutralization assays and sequencing are often required to confirm etiology.

Operational recommendations: Rwanda should prioritize diagnostic specificity (molecular testing and neutralization assays) and vector control integration.

Coronaviridae – SARS-CoV-2 and related coronaviruses

A breadth of **vaccine platforms** (mRNA, viral-vector, protein subunit, inactivated) are authorized for SARS-CoV-2, with updated formulations continuously developed to match variants. A mRNA platform is being constructed in Kigali with BioNTech collaboration. Approved **therapeutics** include oral antivirals (nirmatrelvir/ritonavir), remdesivir, and monoclonal antibodies, although monoclonal effectiveness is variant-sensitive and requires active monitoring. **Diagnostics:** PCR and antigen RDTs are widely available including at Rwanda NRL; genomics (NGS) is essential for variant surveillance.

Operational recommendations: Rwanda will keep supporting local manufacturing with BioNTech partnership, encourage assembly of high-demand diagnostics kits (Ag-RDTs), initiate and support clinical trial pathways and regulatory capacity for rapid evaluation of antivirals and monoclonals, and genomic surveillance for early detection of variant emergence.





14. PRIORITY ACTIONS ACROSS ALL FAMILIES

1. Create a living, RBC-hosted MCM inventory including WHO-prequalified vaccines, licensed therapeutics, and validated diagnostics; update it quarterly.
2. Pre-negotiate access and trial agreements with CEPI, WHO, manufacturers, and regional partners to secure rapid supplies and trial enrolment.
3. Invest in decentralized molecular diagnostics, POC testing, and genomic sequencing as core REPP capabilities.
4. Develop regulatory pathways (EUA and pre-approved trial protocols for rapid activation.
5. Integrate One Health strategies (veterinary vaccines and surveillance) for zoonotic threats like RVF.

These measures will ensure that REPP is anchored in current MCM realities while accelerating Rwanda’s capacity to produce, test, and deploy countermeasures regionally.

15. DEVELOPMENT PLAN FOR STOCKPILING AND CLINICAL TRIALS: A THREE-PHASE APPROACH (2026-2030)

This strategic plan positions Rwanda as the regional leader in medical countermeasures for high-threat pathogens through a carefully phased \$200 million investment over five years. The implementation approach addresses immediate vulnerabilities while building toward long-term sustainability and regional leadership in health security.

Phase 1: Emergency Stockpiling and Infrastructure (Years 1-2)

Budget Allocation: \$60 Million

The foundation phase focuses on establishing immediate protection capabilities for Rwanda’s 13.5 million population while building the infrastructure necessary for sustainable medical countermeasure management and deployment. Core objectives include establishing comprehensive emergency stockpiles, developing foundational storage and distribution infrastructure, creating regional coordination mechanisms, and building rapid deployment capabilities.

Strategic Stockpile Establishment (\$35 Million)

1. Filovirus Countermeasures (\$17 Million)

Category	Product / Candidate	Doses / Units	Est. Unit Cost (\$)	Total (\$M)
Vaccines	Ervebo (Ebola)	200,000	15	3.0M
	Sabin Marburg Vaccine (Phase II)	100,000	25	2.5M
Therapeutics	Anuvimab (Ebola)	2,000	2,000	4.0M
	Atoltivimab / Maftivimab / Odesivimab	1,000	2,500	2.5M
	Investigational Marburg therapeutics	1,000	3,000	3.0M
Diagnostics	RT-PCR systems and reagents	50,000	20	1.0M
	Rapid detection platforms	50,000	20	1.0M
TOTAL				17.0M





2. Mpox Countermeasures (\$10 Million)

Category	Product / Candidate	Doses / Units	Est. Unit Cost (\$)	Total (\$M)
Vaccines	JYNNEOS	400,000	15	6.0M
	ACAM2000	100,000	10	1.0M
Therapeutics	Tecovirimat	5,000	200	1.0M
Diagnostics	RT-PCR systems and reagents	50,000	20	1.0M
	Rapid detection platforms	50,000	20	1.0M
TOTAL				10.0M

3. Rift Valley Fever - One Health Approach (\$6.5 Million)

Category	Product / Candidate	Doses / Units	Est. Unit Cost (\$)	Total (\$M)
Vaccines	Human vaccines	100,000	20	2.0M
	Veterinary vaccines	500,000	5	2.5M
Therapeutics	None			
Diagnostics	RT-PCR systems and reagents	50,000	20	1.0M
	Rapid detection platforms	50,000	20	1.0M
TOTAL				6.5M

Infrastructure Development (\$20 Million)

1. Central Strategic Reserve Facility (\$12 Million)

The central facility will provide state-of-the-art storage and management capabilities essential for maintaining medical countermeasure integrity and enabling rapid deployment. Ultra-cold storage capacity (-80°C) totaling 2,000 cubic meters will accommodate vaccines requiring deep freeze storage, while multi-temperature warehousing spanning 10,000 cubic meters will house the majority of stockpiled products under appropriate conditions.

Advanced inventory management systems utilizing blockchain technology will provide transparent tracking and automated reorder capabilities, while comprehensive security and access control systems ensure product security. Backup power systems and environmental monitoring will maintain appropriate storage conditions even during infrastructure disruptions, while an integrated laboratory quality control suite will enable ongoing product quality verification.





2. Regional Distribution Network (\$8 Million)

Four provincial distribution hubs will be established at strategic locations throughout Rwanda, each with comprehensive cold chain capacity and rapid deployment capabilities. These facilities will enable distribution to any location within Rwanda within hours of decision-making, while border screening facilities will support early detection and response to imported cases. Mobile deployment units will provide additional flexibility for reaching remote areas or supporting cross-border emergency response efforts.

Quality Systems and Regulatory Framework (\$3 Million)

Rwanda FDA capacity enhancement will focus on developing streamlined pathways for emergency use authorization that balance speed with safety requirements. WHO prequalification pathway development will position Rwanda to contribute to global quality assurance efforts while ensuring access to international procurement mechanisms. Quality assurance laboratories will provide ongoing monitoring of stockpiled products to ensure maintained potency and safety throughout storage periods.

Emergency Deployment Capabilities (\$2 Million)

Rapid response teams will be trained and equipped for deployment within hours of outbreak notification, with comprehensive transportation and logistics capabilities enabling nationwide reach. Communication systems will ensure seamless coordination between national and local response levels, while community engagement protocols will facilitate effective cooperation during emergency deployments.

Phase 1 Critical Success Factors:

- Six-month deployment capability for all priority MCMs
- Less than 12-hour response time to outbreak alerts anywhere in Rwanda
- Regional coordination agreements established with DRC, Uganda, Burundi, and Tanzania
- Rwanda FDA emergency use authorization pathways are fully operational

Phase 2: Clinical Trial Leadership and Validation (Years 2-4)

Budget Allocation: \$80 Million

The clinical excellence phase transforms Rwanda into a regional hub for medical countermeasure research while generating African-specific safety and efficacy data essential for optimal deployment strategies. Core objectives include establishing Rwanda as the premier African clinical trial center, building comprehensive regulatory science capacity, and creating sustainable funding mechanisms for continued research leadership.

Clinical Trial Infrastructure (\$25 Million)

Good Clinical Practice (GCP) Facilities

A comprehensive clinical research ecosystem will be established through strategic investments in specialized facilities and capabilities. A 20-bed Phase I clinical research unit will be developed at a Rwanda reference hospital such as King Faisal Hospital, providing controlled environments for first-in-human studies and early safety assessments. Four regional Phase II/III outpatient research clinics will enable large-scale efficacy studies across diverse geographic and demographic populations.

Laboratory infrastructure expansion will include BSL-2 and BSL-3 capacity for safe handling of infectious agents and clinical samples, while electronic case report forms and data management systems ensure efficient data collection and regulatory compliance. A comprehensive biobank with automated storage systems will preserve samples for future research, while integrated pharmacovigilance systems monitor safety throughout clinical development programs.

Additional critical capabilities include a clinical research training center for ongoing education and certification, statistical analysis capacity for complex data interpretation, and comprehensive quality assurance systems ensuring compliance with international standards. Site preparation and specialized equipment investments will ensure world-class research capabilities across all facilities.





Animal Research Facilities (\$8 Million)

Non-human primate facilities with BSL-3 capacity will enable critical preclinical safety and efficacy studies that are essential for regulatory approval of medical countermeasures. Specialized rodent facilities with BSL-2 and BSL-3 capabilities will support broader research programs, while comprehensive veterinary care and specialized equipment ensure humane and scientifically rigorous research conduct.

Target Clinical Programs (\$35 Million)

Filovirus Therapeutics (\$15 Million)

The 2024 Marburg outbreak demonstrated the urgent need for effective therapeutics, with limited treatment options representing a critical vulnerability. Phase I/II trials for three investigational Marburg therapeutics will generate essential safety and efficacy data, while combination therapy studies will optimize treatment regimens for maximum clinical benefit. Pediatric safety studies will address dosing considerations for children, and post-exposure prophylaxis trials will develop protocols for healthcare workers and case contacts.

Mpox Vaccine Optimization (\$5 Million)

Resource-limited settings present unique challenges for vaccine deployment that require specialized research approaches. Dose-sparing studies will evaluate reduced-dose regimens that could extend vaccine supplies during outbreaks, while studies in immunocompromised populations, including those with HIV or malaria co-infection, will generate essential safety and efficacy data for high-risk groups.

RVF One Health Trials (\$4 Million)

Phase II human vaccine trials will advance the most promising candidates toward regulatory approval, while animal efficacy studies will optimize veterinary vaccination strategies. Vector control integration studies will evaluate combined approaches that address multiple transmission pathways simultaneously.

Partnership Development (\$12 Million)

International Collaborations (\$8 Million)

Participation in established clinical trial networks, including ALERRT (Accelerating Last Mile Ebola Research, Relief and Therapy) and ISARIC (International Severe Acute Respiratory and Emerging Infection Consortium), will provide access to protocols, expertise, and resources while ensuring Rwandan perspectives contribute to global research efforts. Regulatory harmonization efforts with the African Medicines Agency (AMA), the European Medicines Agency (EMA), and the FDA will reduce barriers to international product approval. Academic partnerships with institutions such as Oxford University will enable joint research protocols and technology transfer, while industry partnerships will provide access to investigational products and development expertise through collaborative agreements.

Regional Network Building (\$4 Million)

An East African Community clinical trial consortium will harmonize regulatory pathways and enable resource sharing across member states, while data sharing platforms will facilitate collaborative analysis and surveillance. Harmonized regulatory pathways will reduce barriers to multi-country trials and enable rapid deployment of successful interventions across the region.

Human Capacity Development (\$8 Million)

Sustainable clinical research leadership requires substantial investment in human capacity across multiple specialized areas. Clinical investigator training will certify 50 investigators in good clinical practice and specialized infectious disease research methodologies. Research nurse certification programs will train 200 nurses in clinical research protocols and procedures, ensuring adequate staffing for multiple simultaneous trials.

Biostatistics and data management training will develop 20 specialists capable of leading complex analytical efforts, while regulatory affairs training will prepare 15 professionals to navigate approval processes and ensure compliance with international standards. International fellowship programs will provide advanced training opportunities and maintain connections with global research networks.





Phase 2 Success Metrics:

- 15 clinical trials initiated across all priority pathogens
- 2,000 participants enrolled across all studies
- 3 investigational products advanced to Phase III development
- 5 regulatory approval applications submitted to the Rwanda FDA

Phase 3: GMP Manufacturing and Regional Supply (Years 4-5)

Budget Allocation: \$60 Million

The manufacturing excellence phase establishes Rwanda’s capability to produce priority medical countermeasures locally while building regional export capacity and creating sustainable revenue streams. Core objectives include achieving 70% local production of priority MCMs, establishing comprehensive regional export capacity, and building a complete value chain from research and development through manufacturing and distribution.

Manufacturing Infrastructure (\$35 Million)

Biopharmaceutical Manufacturing Complex (\$25 Million)

A comprehensive 15,000 square meter GMP manufacturing facility will be constructed adjacent to the Hub for Pandemic and Pathogen Science campus, enabling seamless integration between research and production activities. The biologics manufacturing suite will feature 2,000-liter single-use bioreactor systems for monoclonal antibody production, viral vector manufacturing platforms supporting both VSV and adenoviral systems, and integration with the existing BioNTech mRNA platform for expanded vaccine production capabilities.

Automated fill-finish systems with integrated inspection and packaging capabilities will ensure product quality and enable efficient scale-up, while comprehensive quality control laboratories will provide release testing and ongoing quality verification. Small molecule manufacturing capabilities will focus on API synthesis for critical antiviral compounds, with tablet formulation and packaging systems providing finished dosage forms.

Diagnostics manufacturing will establish assembly capabilities for rapid diagnostic tests using lateral flow technology and RT-PCR reagent kit packaging for molecular diagnostic distribution throughout the region. Quality assurance systems will ensure batch release testing meets international standards for all product categories.

Supporting Infrastructure (\$10 Million)

Pharmaceutical-grade utilities, including water for injection, clean steam, and compressed gases, will meet stringent manufacturing requirements across all production systems. Advanced HVAC systems with comprehensive environmental monitoring will maintain appropriate conditions for different manufacturing processes, while integrated waste treatment facilities will address environmental considerations. Laboratory information management systems will provide comprehensive data management and traceability throughout all manufacturing operations.

Technology Transfer Programs (\$15 Million)

Vaccine Technologies (\$8 Million)

Strategic partnerships will establish Rwanda’s capability to produce priority vaccines through comprehensive technology transfer agreements. Ervebo manufacturing technology from Merck will enable local production of this critical Ebola vaccine, while JYNNEOS production licensing from Bavarian Nordic will establish mpox vaccine manufacturing capacity. Platform technology development will focus on viral vector systems that can be rapidly adapted for new pathogens, directly supporting 100 Days Mission objectives.

Therapeutics Manufacturing (\$4 Million)

Monoclonal antibody production platforms will enable local manufacturing of therapeutic antibodies for multiple indications, while small molecule API production will focus on generic manufacturing of key antiviral compounds, reducing dependence on international supply chains for critical therapeutics.

Diagnostics Localization (\$3 Million)

RT-PCR kit production technology will support molecular diagnostic capabilities throughout the region, while rapid test manufacturing platforms will enable point-of-care diagnostic production for rural and resource-limited settings.





Regulatory Compliance (\$5 Million)

WHO prequalification preparation will ensure products meet international quality standards and enable export to global markets, while Good Manufacturing Practice certification processes will demonstrate compliance with stringent regulatory requirements. International harmonization efforts will ensure product acceptance by multiple regulatory authorities, and comprehensive pharmacovigilance systems will monitor safety signals throughout product lifecycles.

Market Development (\$5 Million)

Regional distribution networks through East African Community partnerships will create preferential market access, while supply chain optimization will ensure efficient distribution throughout target markets. Market access studies will identify opportunities and requirements for expansion beyond East Africa, while export promotion efforts will establish Rwanda as a reliable supplier of high-quality medical countermeasures.

Phase 3 Target Production Capacity (Annual):

- *Ervebo vaccine: 500,000 doses*
- *JYNNEOS vaccine: 1,000,000 doses*
- *Monoclonal antibodies: 5,000 treatment courses*
- *RT-PCR diagnostic kits: 1,000,000 tests*
- *Rapid diagnostic tests: 5,000,000 tests*

Implementation Timeline and Milestones

Investment Schedule (\$200 Million Total)

- *Year 1: \$35 million (Emergency stockpiling and infrastructure initiation)*
- *Year 2: \$25 million (Infrastructure completion and clinical capacity building)*
- *Year 3: \$45 million (Clinical trial peak activity and manufacturing development)*
- *Year 4: \$50 million (Manufacturing development and technology transfer)*
- *Year 5: \$45 million (Production scale-up and market development)*

Potential Funding Sources

Government of Rwanda - Annual budget allocations through the Ministry of Health will provide consistent baseline funding, while strategic reserve commitments through national security budgets recognize the defense implications of pandemic preparedness.

Development Partners - World Bank health security loans will provide large-scale financing with favorable terms, while African Development Bank regional health initiatives align with continental development goals. European Investment Bank global health security partnerships and existing bilateral partnerships will provide additional funding and technical expertise.

Private Sector - Pharmaceutical partnerships with revenue-sharing agreements will align commercial incentives with public health objectives, while foreign direct investment in manufacturing joint ventures will provide capital and technology transfer. Export credit facilities will enable equipment financing with competitive terms.

Multilateral Health Organizations - GAVI vaccine procurement guarantees and advance market commitments will provide revenue certainty, while CEPI research and development partnerships will support clinical development programs. WHO technical assistance will ensure compliance with international standards, and Africa CDC regional coordination support will strengthen continental health security.





Year-by-Year Implementation Milestones

Year 1: Foundation

- *Quarter 1-2* priorities include stockpile procurement initiation through vendor identification and contract negotiation, infrastructure design and permitting for central storage facilities, partnership agreement signing with international collaborators, and comprehensive staff recruitment and training programs.
- *Quarter 3-4* activities focus on strategic reserve facility construction completion, initial MCM procurement achievement of target quantities, regional distribution network establishment across four provincial hubs, and emergency deployment capability testing through comprehensive exercises.
- *Key milestones* include 50% of the target stockpile procured and quality-verified, a central storage facility fully operational with appropriate environmental controls, and successful completion of the first emergency deployment exercise demonstrating sub-12-hour response capability.

Year 2: Capacity Building

- *Quarter 1-2* emphasis shifts to clinical trial infrastructure development through GCP facility construction, comprehensive training program launch for clinical research staff, first investigational protocol approvals by ethics committees, and manufacturing facility design completion with site preparation.
- *Quarter 3-4* activities include Phase I clinical trial initiation for priority candidates, technology transfer negotiation advancement with international partners, regulatory pathway establishment for emergency use authorizations, and regional coordination agreement finalization with neighboring countries.
- *Key milestones* include achievement of 100% stockpile targets with appropriate quality assurance, initiation of three clinical trials with first participant enrollment, and manufacturing facility construction commencement with foundation completion.

Year 3: Clinical Leadership

- *Quarter 1-2* focuses on expanding the clinical trial portfolio with multiple Phase I/II trials actively recruiting participants, advancing manufacturing facility construction toward completion, expanding international partnership networks, and preparing regulatory submission documentation.
- *Quarter 3-4* priorities include Phase III trial preparation for advanced candidates, technology transfer implementation for priority products, quality system validation for manufacturing operations, and export market development through regional partnership negotiations.
- *Key milestones* include eight active clinical trials across all priority pathogen families, a manufacturing facility with 70% construction completion with major equipment installation, and submission of first regulatory approval applications to relevant authorities.

Year 4: Manufacturing Transition

- *Quarter 1-2* activities center on GMP facility commissioning and validation, technology transfer completion for priority products, comprehensive process validation studies, and market access preparation through regulatory submissions and partnership agreements.
- *Quarter 3-4* focuses on initial production campaign execution, WHO prequalification application submission, regional supply agreement negotiation and finalization, and revenue generation initiation through product sales.
- *Key milestones* include full manufacturing facility operational status with GMP certification, first locally-produced medical countermeasures released to market with appropriate quality verification, and export agreement signing with regional partners.





Year 5: Full Operation

- *Quarter 1-2* priorities include achieving full production capacity across all manufacturing platforms, regional market penetration through established distribution networks, sustainability achievement through diversified revenue streams, and strategic planning for next-phase expansion.
- *Quarter 3-4* activities focus on performance optimization through efficiency improvements, expansion planning for additional product lines or geographic markets, technology upgrade implementation for enhanced capabilities, and long-term sustainability planning through diversified partnerships.
- *Key milestones* include achievement of 70% local production target for priority MCMs, establishment of clear regional leadership position in medical countermeasure supply, and demonstration of financial sustainability through positive cash flow generation.

References

1. IPPS. 100 Days Mission: Implementation Report 2024. IPPS, 2025.
2. WHO. R&D Blueprint Priority Pathogens List 2024.
3. CEPI. New Vaccines for a Safer World: Backgrounder. Aug 2025.
4. FDA. Ervebo (rVSV-ZEBOV) product approval. <https://www.fda.gov/vaccines-blood-biologics/ervebo>
5. WHO Prequalification of Ervebo. <https://extranet.who.int/pqweb>
6. EMA. Ad26.ZEBOV/MVA-BN-Filo vaccine approval documents.
7. Oxford University. ChAdOx1 Marburg vaccine trial announcement, 2023.
8. ClinicalTrials.gov. ChAdOx1-Marburg Phase II trial (NCT05627327).
9. Sabin Vaccine Institute. Marburg vaccine pipeline update, 2024.
10. FDA. Inmazed approval.
11. FDA. Ebanga (ansuvimab) approval.
12. WHO Therapeutics for Ebola virus disease: Interim guidance, 2023.
13. NIH/NIAID. Marburg investigational therapeutics program update, 2024.
14. WHO. Ebola virus disease laboratory guidance, 2022.
15. FIND. Ebola diagnostic pipeline and evaluations, 2024.
16. FAO. Rift Valley fever vaccines for animals, 2023.
17. CEPI. RVF vaccine development portfolio.
18. CEPI/ICRAF. RVF human vaccine Phase II trial press release, 2025.
19. CDC. Rift Valley fever clinical guidance.
20. FIND. RVF diagnostics landscape, 2024.
21. WHO. Prequalification of Bavarian Nordic MVA-BN vaccine, 2024.
22. Bavarian Nordic. IMVANEX/JYNNEOS press releases.
23. CEPI. MVA-BN freeze-dried stability project report, 2024.
24. EMA. Tecovirimat authorization documents.
25. CDC. Tecovirimat, cidofovir, and brincidofovir use guidance.
26. ECDC. Monkeypox laboratory testing guidance, 2023.
27. WHO. Yellow fever vaccine fact sheet.
28. WHO. Dengvaxia guidance, 2022.
29. Takeda. Qdenga (TAK-003) approval announcements.
30. NIH. Zika vaccine candidate pipeline, 2024.
31. WHO. Dengue and Zika clinical management guidelines.
32. CDC. Diagnostic testing for dengue and Zika.
33. WHO. Emergency Use Listing (EUL) for COVID-19 vaccines.
34. EMA/FDA. Variant-updated boosters approvals, 2023-2024.
35. FDA. Paxlovid approval notice, 2023.
36. FDA. Remdesivir product label.
37. WHO. Monoclonal antibodies for COVID-19: guidance notes, 2024.
38. Africa CDC. Genomic surveillance strategy, 2024.



SCORECARD

About the Scorecard

The Medical Countermeasures (MCM) Scorecard presented here provides a structured overview of the current global landscape for vaccines, therapeutics, and diagnostics targeting priority pathogens of concern for Rwanda.

It benchmarks product availability, clinical trial readiness, and enabling R&D conditions across Ebola, Marburg, Rift Valley Fever, and Mpox. The scorecard highlights both existing opportunities and critical gaps that Rwanda must address through stockpiling, local research investment, and participation in global clinical trial networks.

The framework draws on methodologies and indicators developed by the IPPS and Impact Global Health (IGH) as part of the 100 Days Mission which aims to accelerate the development of diagnostics, vaccines and therapeutics.

The 100 Days Mission Scorecard served as a key reference in adapting global standards to Rwanda's context, ensuring alignment with international best practices while tailoring priorities to national and regional needs.



INDICATOR	FILOVIRIDAE		PHENUVIRIDAE	POXVIRIDAE	
	Ebola	Marburg	RVF	Mpox	
NOW	Investment: \$17 Million 		Investment: \$6.5 Million 	Investment: \$6.5 Million 	
	R&D Investments for Vaccines, Therapeutics and Diagnostics 2026-2040				
Approved products					
FUTURE READINESS					
	Candidates tested in humans				
Platform technologies used in clinical candidates					
R&D ENABLERS	Use of animal rule to support licensure	✓	✗	✗	
	Correlates of protection	✗	✗	✗	
	WHO Target Product Profiles	Vx	✓	✓	✗
		Thx	✗	✗	✗
Dx		✗	✗	✗	

\$ - US dollars | Vx - Vaccines | Thx - Therapeutics | Dx - Diagnostics



16. CONCLUSION: BUILDING RESILIENT PANDEMIC PREPAREDNESS

The Medical Countermeasures Stockpiling Plan represents more than procurement planning: it embodies Rwanda's commitment to protecting its population from pandemic threats while contributing to regional and global health security. By integrating immediate stockpiling needs with long-term capacity building, Rwanda will create a comprehensive framework that should address both current gaps and future requirements.

The substantial investment required reflects the true cost of preparedness, moving beyond the economy of emergency-only funding to establish sustainable systems capable of rapid activation when needed. Rwanda's experience managing recent outbreaks demonstrates both the potential impact of well-prepared MCM deployment and the continuing gaps that this comprehensive plan addresses.

Success will be measured not only in products stockpiled and facilities constructed, but in lives saved, economic impacts mitigated, and regional leadership established in building resilient health systems capable of protecting populations from future pandemic threats.

To consolidate this momentum, Rwanda should take the lead in establishing a regional stockpiling and deployment mechanism for medical countermeasures within the East African Community (EAC). Such leadership would ensure coordinated access, reduce duplication, and strengthen resilience across member states. This should include exploring complementary arrangements with regional partners for shared stockpiling facilities, coordinated deployment mechanisms, and harmonized regulatory frameworks. Moreover, Rwanda's growing clinical research infrastructure provides a unique opportunity to organize multi-country clinical trials at scale, maximizing scientific impact and accelerating access to effective countermeasures.

This comprehensive approach will provide a model for other countries facing similar challenges and demonstrate how proactive investment in MCM stockpiling, clinical trials, and regional collaboration can build the foundation for long-term resilience.



3

STRATEGIC DIRECTION



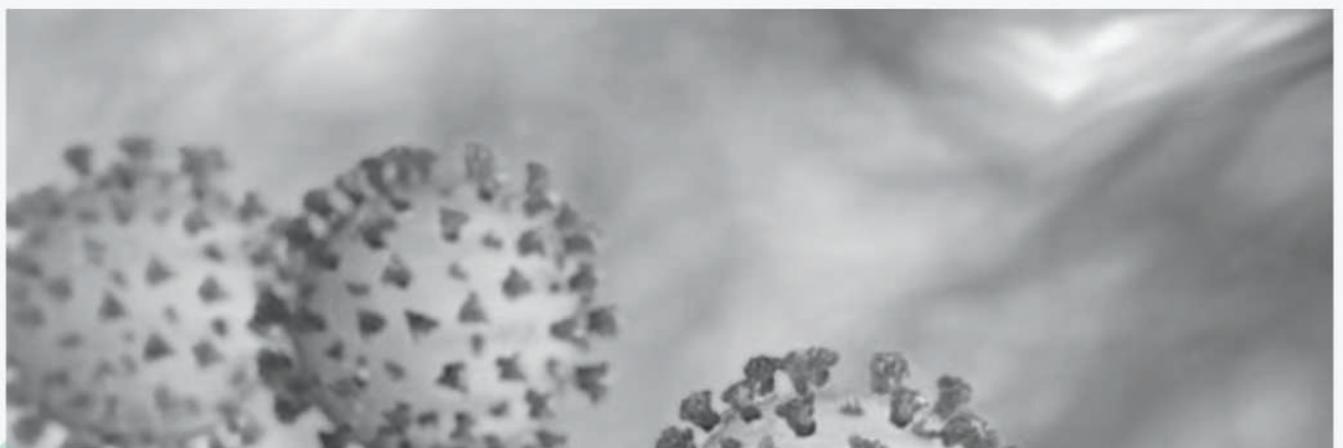
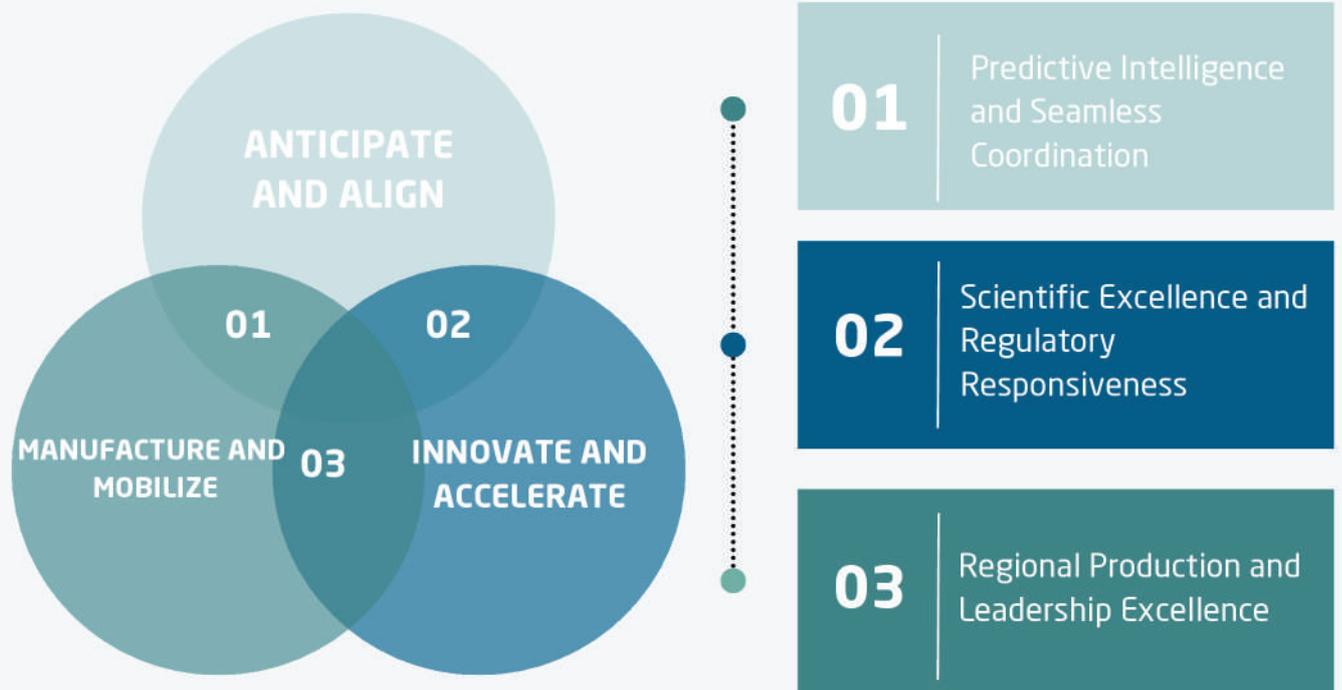


17. STRATEGIC GOALS AND OBJECTIVES

Overall Strategic Goal

Transform Rwanda into a self-reliant, scientifically advanced nation capable of rapidly detecting, understanding, and responding to pandemic threats, while serving as regional’s premier Pandemic Innovation Hub for medical countermeasures development, manufacturing, and regional distribution.

Strategic objectives





OBJECTIVE 1

ANTICIPATE AND ALIGN - SURVEILLANCE AND COORDINATION

GOAL:

Strengthen collaborative surveillance under a comprehensive One Health approach to achieve 95% accuracy in outbreak prediction with sub-48-hour response activation across regional member states through integrated human, animal, and environmental health data streams with coordinated regional response capabilities.

National Health Intelligence Centre Capabilities

The NHIC will establish cutting-edge AI-powered threat detection systems, achieving 95% predictive accuracy through sophisticated analysis of integrated One Health data streams. Advanced machine learning algorithms will process multi-sectoral data, including human health surveillance, livestock health monitoring, wildlife disease tracking, climate variables, environmental indicators, and socioeconomic factors to predict disease emergence patterns with unprecedented accuracy.

Deep learning networks train on historical outbreak patterns while predictive analytics platforms process 10,000+ data points daily from human, animal, and environmental sources. Natural language processing automates analysis of health reports and social media, while computer vision systems analyze satellite imagery for environmental risk factors and ensemble modeling combines multiple AI predictions to improve accuracy.

Collaborative Surveillance Coordination

The integrated surveillance system creates unified coordination structures linking human health, animal health, environmental health, and climate monitoring sectors through standardized data sharing protocols and coordinated response mechanisms. Sub-48-hour response activation protocols eliminate delays in emergency response deployment while incorporating real-time climate and environmental risk assessments. Inter-sectoral coordination establishes formal mechanisms linking human, animal, and environmental institutions through harmonized data collection procedures. Joint investigation teams conduct multi-disciplinary outbreak response under unified command structures with pre-established resource sharing agreements for equipment and expertise.

Wastewater and Environmental Surveillance (WES): Environmental surveillance through wastewater monitoring systems provides 3-5 day early warning before clinical detection. WES platforms monitor 15+ urban centers with real-time pathogen detection and antimicrobial resistance tracking integrated with clinical surveillance data.





Objective 2

INNOVATE AND ACCELERATE - RESEARCH ECOSYSTEM

GOAL:

Build a rapid response research ecosystem accelerating medical countermeasure development within 100 days, supported by Africa’s most responsive regulatory framework and diversified technology partnerships ensuring resilience against supply chain disruptions.

RWANDA PANDEMIC INNOVATION HUB

The centerpiece of Rwanda’s innovation strategy establishes the Rwanda Pandemic Innovation Hub as a world-class integrated facility spanning the entire product development lifecycle from basic research through commercial manufacturing with built-in climate resilience, technological flexibility, and supply chain diversification.

RWANDA PANDEMIC INNOVATION HUB STRUCTURE

INTEGRATED HUB ARCHITECTURE

The Rwanda Pandemic Innovation Hub operates as an integrated Science BioPark centered on a “One Stop Center Facilities” core that coordinates six specialized Components through seamless resource sharing and operational synergies. This hub-and-spoke design maximizes efficiency while maintaining specialized expertise across all medical countermeasure development activities.

Component Configuration and Integration encompasses Component 1 (Vaccine Development & Biomanufacturing), Component 2 (Diagnostic Innovation & Multi-omics), Component 3 (Therapeutic Development & Biotechnology), Component 4 (Animal Models, Preclinical & Clinical Excellence), Component 5 (Biomedical Engineering & Bioprocessing), and Component 6 (Quality Control & Regulatory Affairs). Each Component connects directly to the central hub enabling immediate collaboration and resource optimization.

Central Hub Coordination provides unified project management, shared equipment scheduling, quality assurance oversight, regulatory liaison, and international partnership coordination through the One Stop Center Facilities. This centralized approach ensures all Components operate as a coordinated ecosystem rather than independent units while maintaining specialized technical capabilities.

Operational Synergies enable research discoveries in vaccine development to immediately inform therapeutic approaches while diagnostic capabilities support all Components’ development activities. Materials, expertise, and data flow seamlessly between Components through standardized protocols and integrated data systems ensuring maximum innovation potential.

ONE STOP CENTER FACILITIES CORE FUNCTIONS

Shared Research Infrastructure includes advanced microscopy, mass spectrometry, next-generation sequencing, and AI computing clusters accessible to all Components through centralized scheduling. Specialized technician support ensures optimal equipment performance while maximizing utilization across Component activities, reducing per-Component investment requirements.

Integrated Data Management connects all Component activities through unified systems enabling real-time collaboration, shared databases, and coordinated analytics. Central Bioinformatics Core supports computational needs while maintaining data security and intellectual property protection across all research activities.

Administrative Integration streamlines operations through centralized procurement, human resources, financial management, and regulatory coordination. Shared services reduce overhead costs while ensuring consistent standards and procedures across all Component activities supporting overall hub efficiency and effectiveness.

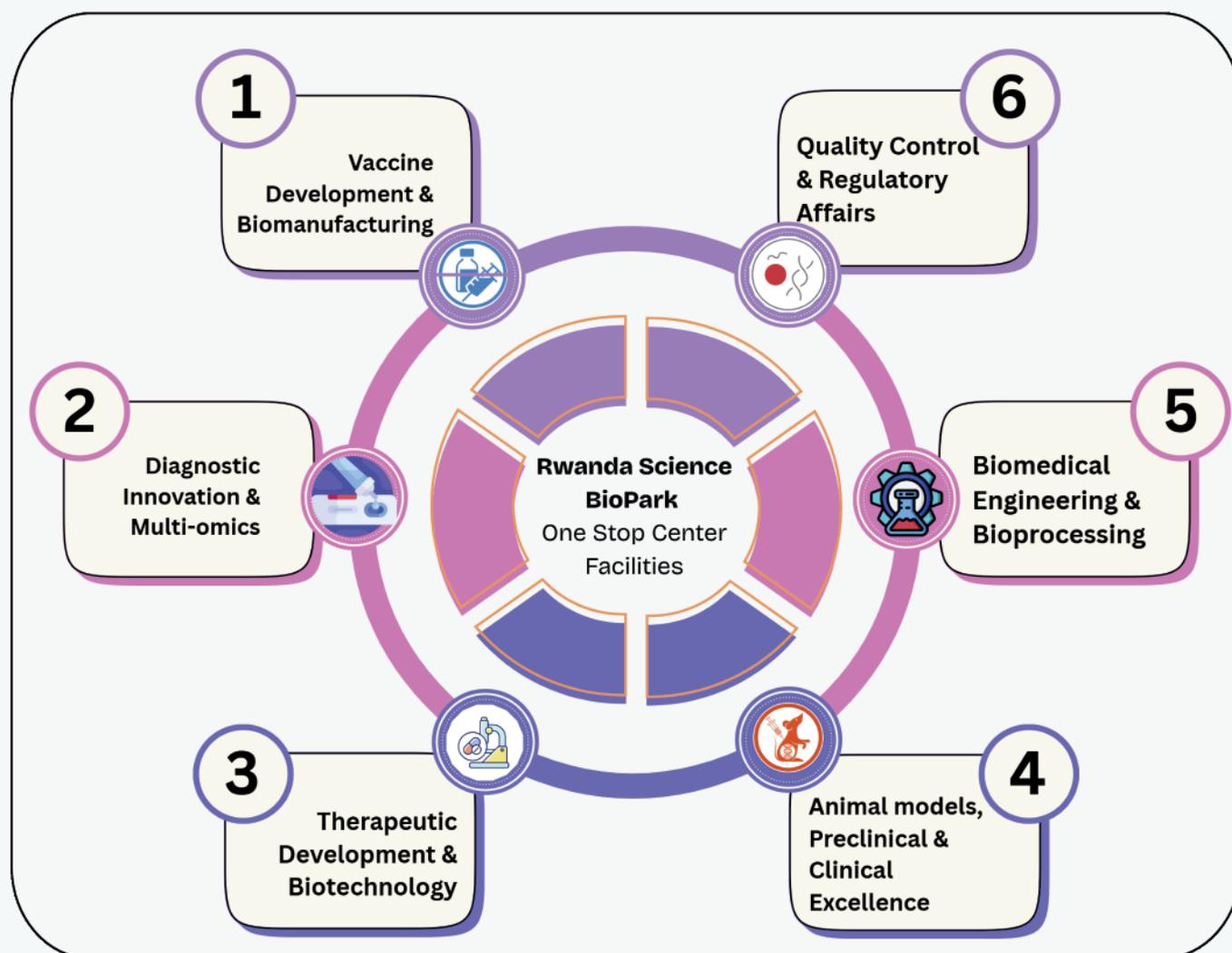


BIOPARK CAMPUS STRUCTURE

The Rwanda Pandemic Innovation Hub operates as a comprehensive Science BioPark built around six integrated components that share central infrastructure while maintaining specialized expertise.

Component 1 handles vaccine development and biomanufacturing; Component 2 focuses on diagnostics and multi-omics; Component 3 develops therapeutics and biotechnology; Component 4 manages animal models and clinical excellence; Component 5 provides biomedical engineering and bioprocessing; and Component 6 ensures quality control and regulatory affairs.

This hub-and-spoke design maximizes efficiency through shared resources, including advanced laboratories, AI computing clusters, and specialized equipment, while enabling seamless collaboration across all medical countermeasure development activities from research through commercial production.



**COMPONENT 1: VACCINE DEVELOPMENT & BIOMANUFACTURING FACILITY****Core Infrastructure**

Component 1 establishes comprehensive vaccine development and manufacturing capabilities through state-of-the-art production facilities designed for multiple platform technologies. The facility encompasses plasmid production cores that support downstream manufacturing processes, along with specialized mRNA production capabilities targeting at least two pandemic viruses of concern, including RVFV, Marburg, and EBOV.

Lipid nanoparticle production operates through dedicated mRNA-LNP facilities that integrate formulation and encapsulation processes. Viral vector manufacturing capabilities include BSL-3 and BSL-4 containment levels with cell culture bioreactors ranging from 10L to 1000L scale, enabling production of diverse viral vector platforms. Protein production units utilize both mammalian and insect cell expression systems to support subunit vaccine development and manufacturing.

Fill-finish operations provide automated capabilities for mRNA-LNP, protein, and vial filling with packaging systems that include emergency deployment protocols. Advanced quality control laboratories ensure real-time release testing and comprehensive stability studies that meet international regulatory standards while enabling rapid product deployment during health emergencies.

Strategic Capabilities

The facility maintains stable vaccine repositories containing 25+ validated candidates with enhanced temperature stability improvements that address African deployment conditions. Diversified platform technologies spanning mRNA, viral vector, and protein subunit systems provide comprehensive coverage of pandemic threats while enabling rapid adaptation to emerging pathogens.

Emergency stockpiles maintain pre-positioned doses through distributed storage networks that ensure rapid deployment capabilities across the region. Flexible manufacturing systems enable rapid platform switching within 72 hours, allowing immediate transition between different vaccine types based on emerging threat requirements. Sustainable bioprocessing innovations achieve a 40% reduction in production timelines while maintaining quality standards and reducing environmental impact.

Technology Partnership Diversification

Strategic partnerships ensure technology access and capability redundancy across multiple platforms. The primary mRNA partnership with BioNTech provides comprehensive technology transfer, including platform development, manufacturing processes, and quality systems. Backup mRNA capabilities through Moderna partnerships and University of Rwanda development programs create technology independence and innovation capacity.

Viral vector portfolios will leverage Oxford/AstraZeneca and Johnson & Johnson to ensure access to proven platforms while building indigenous development capacity. These partnerships combine technology transfer with knowledge development, creating sustainable capabilities that reduce long-term dependence on external technology sources while maintaining access to cutting-edge innovations and manufacturing expertise.





COMPONENT 2: DIAGNOSTIC INNOVATION & MULTI-OMICS FACILITY

Research Infrastructure

Component 2 establishes cutting-edge research capabilities through integrated multi-omics platforms designed for comprehensive pathogen analysis and biomarker discovery. The genomics platform incorporates next-generation sequencing technologies with environmental stability controls that ensure reliable performance under variable climate conditions. This capability enables real-time pathogen identification, variant tracking, and epidemiological surveillance essential for pandemic preparedness.

The robust proteomics suite features advanced mass spectrometry systems with temperature and humidity compensation mechanisms that maintain analytical precision across diverse deployment environments. Adaptive metabolomics laboratories utilize GC-MS and LC-MS platforms with climate-variable standards that accommodate the extreme temperature ranges and environmental conditions typical of African field settings.

The high-performance bioinformatics center provides specialized computing infrastructure for multi-omics data integration, enabling comprehensive analysis of complex biological datasets. This computational capability supports AI-driven pattern recognition, predictive modeling, and real-time data processing that transforms raw analytical data into actionable intelligence for outbreak response and countermeasure development.

Diagnostic Manufacturing Capabilities

Manufacturing capabilities focus on rapid, field-deployable diagnostic solutions that address African deployment requirements. Point-of-care production systems deliver 15-minute diagnostic results with stable performance across 4-45°C temperature ranges, ensuring reliability in diverse environmental conditions without requiring cold chain infrastructure.

Molecular diagnostic platforms encompass PCR, LAMP, and CRISPR-based detection systems that provide laboratory-quality results in field settings. Manufacturing capacity targets 20+ million tests annually through distributed production networks that ensure regional coverage and supply chain resilience. AI-powered diagnostic systems incorporate machine learning algorithms trained with climate-variable datasets, enhancing accuracy and reliability under challenging deployment conditions.

Adaptation Features

Temperature-stable reagent formulations maintain activity across extreme temperature ranges, eliminating cold chain requirements that often limit diagnostic deployment in resource-constrained settings. Solar-powered equipment integration enables renewable energy utilization for off-grid deployment, ensuring diagnostic capability in areas without reliable electrical infrastructure.

Rapid response kits provide pre-positioned diagnostic capabilities that enable immediate deployment during outbreak situations. These kits incorporate climate-adapted packaging, extended shelf life formulations, and simplified protocols that enable effective use by personnel with varying levels of technical training. The adaptation features ensure that diagnostic capabilities remain effective and accessible regardless of environmental conditions or infrastructure limitations, supporting comprehensive surveillance and response capabilities across diverse deployment scenarios.



**COMPONENT 3: THERAPEUTIC DEVELOPMENT & BIOTECHNOLOGY FACILITY****Production Platforms**

Component 3 establishes comprehensive therapeutic manufacturing capabilities through diverse production platforms optimized for African deployment conditions. Temperature-stable monoclonal antibody manufacturing utilizes CHO cell culture systems with stability optimization protocols that maintain therapeutic efficacy across extreme temperature ranges without requiring continuous cold chain infrastructure.

Accelerated small molecule synthesis employs automated chemistry platforms with climate-adapted processes that ensure consistent pharmaceutical quality despite environmental variability. Advanced cell and gene therapy capabilities include viral vector production systems with environmental controls that maintain product integrity while enabling scalable manufacturing of cutting-edge therapeutic modalities.

Sustainable natural products extraction leverages climate-resilient sourcing and processing methodologies that tap into Africa's rich biodiversity for therapeutic development. These platforms integrate traditional knowledge with modern pharmaceutical development approaches, creating opportunities for novel therapeutic discovery while supporting sustainable economic development in source communities.

Research Capabilities

Research programs focus on rapid-response therapeutic development that addresses pandemic threats through multiple complementary approaches. Emergency monoclonal antibody production capabilities enable rapid scale-up with distributed manufacturing networks that can respond to outbreak situations within days rather than months. These systems maintain validated production protocols while providing flexibility for novel target development.

Climate-stable small molecule platforms emphasize drug discovery with environmental stability as a primary design criterion, ensuring therapeutic effectiveness under challenging deployment conditions. Broad-spectrum antiviral programs target emerging pathogens through platform approaches that can be rapidly adapted to new threats, reducing development timelines while maintaining efficacy against diverse viral families.

Strategic therapeutic reserves maintain climate-controlled emergency stockpiles that provide immediate response capability during health emergencies. These reserves include validated therapeutics for priority pathogens alongside platform technologies that enable rapid development of treatments for emerging threats. The combination of immediate-use stockpiles and rapid development capabilities ensures comprehensive therapeutic coverage for both known and unknown pandemic threats.



**COMPONENT 4: PRECLINICAL & CLINICAL EXCELLENCE FACILITY****Preclinical Research Facilities**

Component 4 establishes comprehensive preclinical research capabilities through specialized biosafety laboratories that provide appropriate containment with advanced environmental controls. These facilities maintain precise research conditions while ensuring animal welfare standards and regulatory compliance for infectious disease research.

Adaptive disease model development creates infection models that accurately represent human disease pathogenesis, enabling reliable prediction of therapeutic performance. Advanced pharmacokinetics laboratories conduct comprehensive ADMET studies, providing a detailed understanding of drug absorption, distribution, metabolism, excretion, and toxicity profiles.

The digital pathology suite employs AI-enhanced analysis capabilities that accelerate pathological assessment and improve diagnostic accuracy. This integration of artificial intelligence with traditional pathology enhances research efficiency while providing detailed analysis of disease progression and therapeutic response.

Clinical Trial Capabilities

Clinical research infrastructure encompasses resilient Phase I safety centers with 50-bed capacity and intensive monitoring capabilities for comprehensive safety evaluation. Flexible Phase II efficacy hubs provide 200-participant capacity with adaptable protocols that enable efficient efficacy assessment across diverse patient populations.

Regional Phase III networks coordinate 10,000+ participant capacity across regional countries, creating comprehensive clinical research capabilities that serve regional populations while building local research expertise. Accelerated emergency use protocols enable 60-day evaluation pathways that maintain safety standards while enabling rapid therapeutic deployment during health emergencies.

COMPONENT 5: BIOMEDICAL ENGINEERING & BIOPROCESSING FACILITY**Engineering Capabilities**

Component 5 provides specialized bioprocessing optimization through advanced process development that ensures manufacturing consistency and scalability. Flexible scale-up engineering utilizes pilot-scale bioreactors with rapid reconfiguration capabilities that enable efficient transition from research to commercial production scales.

Sustainable continuous manufacturing integrates advanced bioprocessing technologies with efficient resource utilization, optimizing production while maintaining quality standards. Smart automation engineering employs robotics with predictive maintenance capabilities that minimize downtime while maximizing production efficiency.

Innovation Focus

Bioprocessing innovations target cost reduction through optimization strategies that achieve 40% reductions in manufacturing expenses while maintaining quality standards. Accelerated manufacturing protocols deliver 60% faster production cycles through process intensification and automation technologies.

Sustainable technologies emphasize efficient bioprocessing with reduced resource consumption through advanced process control and waste minimization strategies. Digital twin modeling provides process prediction capabilities, enabling optimization of manufacturing parameters before physical implementation while reducing development timelines.



**COMPONENT 6: QUALITY CONTROL & REGULATORY AFFAIRS CENTER****Quality Control Capabilities**

Component 6 establishes comprehensive quality assurance through advanced analytical laboratories that support method development and validation for diverse pharmaceutical products. Comprehensive microbiological testing provides sterility and bioburden assessment with rigorous monitoring protocols that ensure product safety and regulatory compliance.

Advanced potency assays enable comprehensive testing of therapeutic products, ensuring efficacy and consistency across production batches. Rapid release testing utilizes real-time batch certification with automated systems that accelerate product availability while maintaining rigorous quality standards.

Regulatory Affairs Excellence

Ultra-rapid emergency authorization capabilities provide 10-day approval pathways through pre-approved protocols that maintain safety standards while enabling immediate pandemic response. Accelerated WHO prequalification follows streamlined pathways with dedicated support that facilitates international market access and global health program integration.

Global regulatory harmonization ensures simultaneous compliance with ICH, EMA, and FDA standards, enabling international market access while maintaining efficiency in regulatory processes. Regional regulatory leadership provides training programs across regional countries with harmonized standards that build collective regulatory capacity while facilitating regional market integration.

**SPOTLIGHT 3:****AI-Driven Pathogen Research - Advancing Pandemic Science**

The Challenge: Traditional pathogen research requires years of laboratory experimentation to understand viral mechanisms and identify therapeutic targets, creating delays in countermeasure development that leave populations vulnerable during emerging outbreaks.

The Innovation: Rwanda's Pandemic Innovation Hub integrates AI-powered pathogen analysis with transformer-based models that predict viral evolution patterns, therapeutic resistance mechanisms, and host-pathogen interactions. The hub's multimodal AI systems analyze genomic, proteomic, and metabolomic data simultaneously to identify novel therapeutic targets within weeks rather than years.

The Expected Results:

- Computational prediction of viral enzymes vulnerabilities across multiple pathogen families
- AI-based cellular state reversal protocols that identify therapeutic interventions for infected cells
- Machine learning algorithms that accelerate drug discovery timelines by 60%
- Predictive modeling of viral evolution that enables proactive countermeasure development

REPP Integration: This computational approach validates REPP's emphasis on platform technologies and rapid adaptation capabilities, demonstrating how AI integration across all six components accelerates the entire medical countermeasure development pipeline from pathogen analysis through manufacturing optimization.





Objective 3

MANUFACTURE AND MOBILIZE - PRODUCTION EXCELLENCE

GOAL:

Create robust local production ensuring timely, equitable access to medical countermeasures across the EAC region while achieving 70% self-reliance by 2040 through climate-resilient infrastructure and diversified supply chain.

MANUFACTURING TARGETS BY 2040

Product Category	Annual Capacity	Technology Platforms	Climate Resilience Features
Vaccines	50+ million doses	mRNA, Viral vector , Protein (10M)	Temperature-stable formulations
Diagnostics	20+ million tests	Rapid antigen, PCR, biosensors	Field-deployable, solar-powered
Therapeutics	Regional stockpiles	Monoclonal antibodies, small molecules	Stability-enhanced formulations
Raw Materials	40% local content	Chemical precursors, biological reagents	Regional sourcing, climate-adapted

Regional Distribution Network

The regional distribution infrastructure establishes comprehensive supply chain capabilities that ensure reliable medical countermeasure delivery across East Africa within 72 hours of deployment activation. This network operates through robust logistics systems that maintain operational continuity, utilizing multiple transportation modes including road, rail, air, and lake transport to reach all regional destinations efficiently.

Distributed storage networks anchor the system through strategically positioned regional hubs equipped with specialized facilities that maintain product integrity throughout the supply chain. These hubs provide redundant storage capacity while ensuring geographic coverage that minimizes delivery distances and reduces transportation risks. The network design incorporates backup facilities and alternative routing protocols that maintain service continuity during facility maintenance or unexpected disruptions.

Emergency deployment protocols enable rapid response capabilities through pre-positioned assets strategically located across the region to minimize response times during health emergencies. These protocols include automated activation systems, pre-approved transportation arrangements, and coordinated deployment teams that can mobilize critical medical countermeasures within hours of outbreak detection. The emergency response framework integrates with existing health system protocols while providing enhanced capabilities for pandemic-scale deployment.

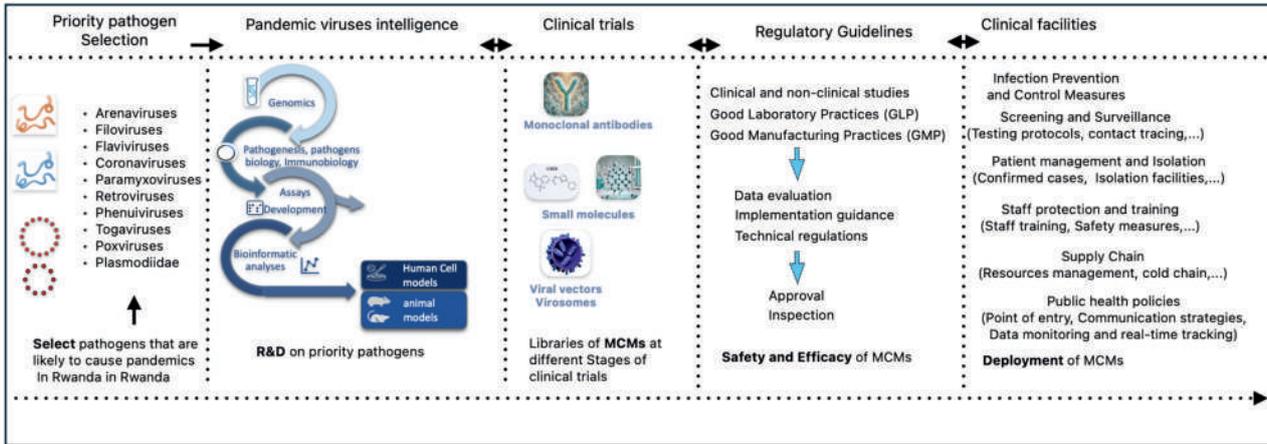
Real-time inventory management systems utilize AI-powered demand forecasting algorithms that optimize stock levels across all network locations while predicting regional needs based on epidemiological data, seasonal patterns, and historical consumption trends. These systems enable proactive inventory positioning, automated reorder protocols, and dynamic resource allocation that ensures availability while minimizing waste and storage costs. The integration of predictive analytics with operational management creates responsive supply chain capabilities that adapt to changing regional needs and emerging threats.





18. SCIENTIFIC STRATEGY AND HUB DEVELOPMENT

Pathogen Science: Biology to Medical Countermeasure Deployment



Rwanda’s pathogen science approach establishes a comprehensive pipeline from priority pathogen selection through medical countermeasure deployment, integrating research, development, and clinical implementation within a unified framework. The process begins with evidence-based selection of pathogens likely to cause pandemics in Rwanda, focusing on viral families including arenaviruses, filoviruses, flaviviruses, coronaviruses, paramyxoviruses, retroviruses, phenuiviruses, togaviruses, poxviruses, and plasmodiidae. This selection drives targeted research and development activities that combine genomic analysis, pathogen biology studies, and immunobiology research with bioinformatic analyses and both human cell and animal model systems.

The research foundation enables the development of diverse medical countermeasure libraries, including monoclonal antibodies, small molecules, and viral vectors or virosomes, which progress through different stages of clinical trials under comprehensive regulatory oversight. The regulatory framework encompasses clinical and non-clinical studies conducted under Good Laboratory Practices and Good Manufacturing Practices, with systematic data evaluation, implementation guidance, and technical regulations leading to approval and inspection processes that ensure the safety and efficacy of medical countermeasures.

The deployment phase integrates clinical facilities’ capabilities with comprehensive infection prevention and control measures, screening and surveillance protocols, patient management and isolation systems, staff protection and training programs, and robust supply chain management. Public health policies coordinate point of entry procedures, communication strategies, and data monitoring with real-time tracking systems that enable effective medical countermeasure deployment during pandemic responses. This integrated approach ensures that pathogen research translates directly into deployable medical countermeasures that protect regional populations while building scientific capacity for future pandemic preparedness.

PARTNERS FOR PANDEMIC VIRUSES’ INTELLIGENCE

To establish a sustainable R&D ecosystem focused on priority viruses—including the invention, development, and clinical trials of medical countermeasures (MCMs)—collaborations are essential at all levels, beginning with the creation of a well-trained local workforce. The strategic goal is to build a strong research network that facilitates timely information exchange, training opportunities, technology transfer, and innovation.

One example of a successful research network is Canada’s Pandemic Preparedness Hub (CP2H), a national initiative co-led by the University of Ottawa (Prof. John Bell) and McMaster University (Prof. Matthew Miller). CP2H aims to enhance Canada’s preparedness for future epidemics and pandemics by accelerating the translation of novel biotherapeutics from academic and industry settings into clinical testing and commercialization. To achieve this, CP2H unites eight academic institutions, 13 non-profit organizations, 22 private companies, and five government agencies in a coordinated effort.

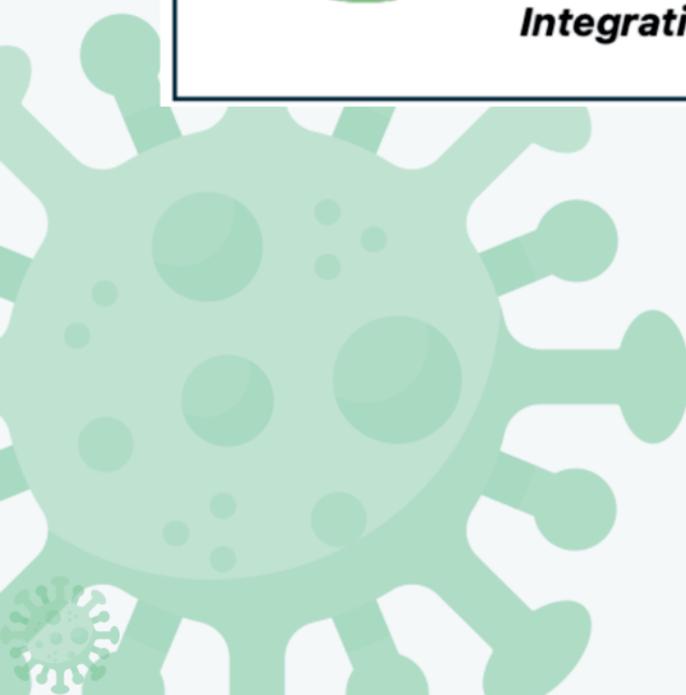
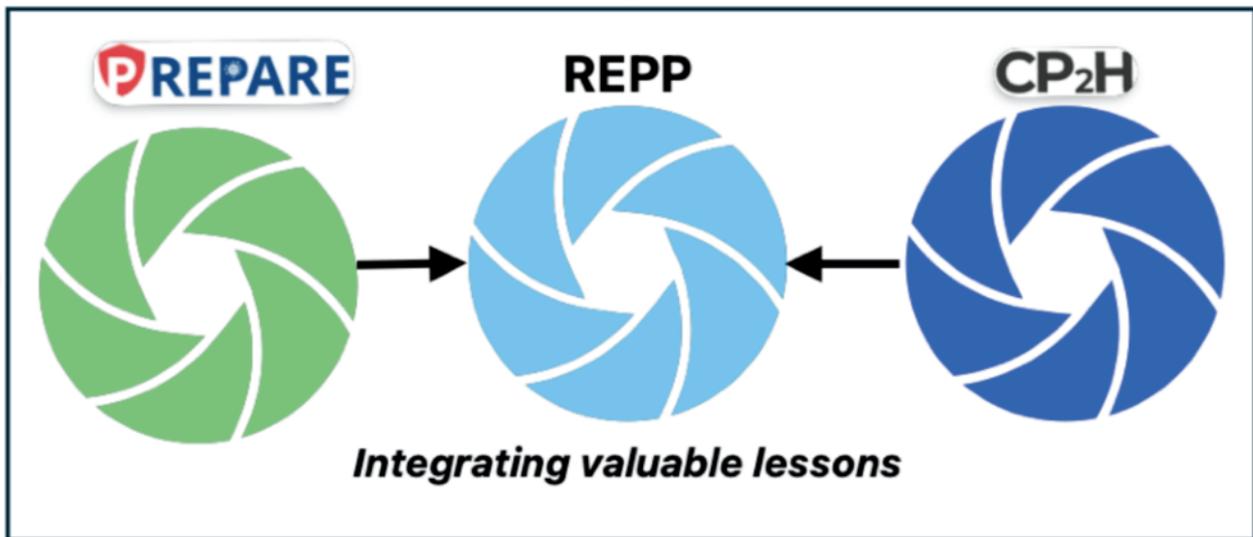




Another inspiring model is Singapore’s PREPARE initiative. Like Kigali in Rwanda, Singapore is an international travel hub with high population density, making it vulnerable to emerging infectious diseases. The country has extensive experience in managing epidemics and pandemics, including Nipah (1999), SARS (2003), the influenza pandemic (2009), Zika (2016), and COVID-19 (2019). PREPARE is built on a regional network and focuses on developing cutting-edge research capabilities and talent programs to strengthen epidemic preparedness and response. PREPARE also acknowledges the growing risk of future epidemics, driven by increased human mobility, climate change effects on disease vectors, and rising zoonotic infections worldwide. The initiative underscores the urgent need to anticipate Disease X, a yet-unknown, highly infectious, deadly, and rapidly mutating pathogen, before it emerges.

In summary, Singapore’s PREPARE initiative and Canada’s CP2H take distinct yet complementary approaches to epidemic and pandemic preparedness. PREPARE is designed with a strong regional focus, integrating epidemic response, surveillance, and capacity-building across its partners in the Asia-Pacific. In contrast, CP2H is centered on Canada, with a primary emphasis on biotherapeutic innovation and the commercialization of medical countermeasures for future pandemics.

Despite their differences, both initiatives share a common foundation in **leveraging networks of academic institutions, government agencies, and private-sector partners to strengthen global preparedness**. PREPARE builds upon Singapore’s extensive experience in managing past outbreaks, ensuring that its strategies are informed by real-world epidemic responses. Meanwhile, CP2H aims to bridge gaps in Canada’s biotherapeutic ecosystem by accelerating the development and deployment of novel therapeutics. Each model thus offers valuable lessons, and a combined approach could be particularly beneficial for Rwanda. By integrating PREPARE’s strengths in regional networking and capacity-building with CP2H’s expertise in translational research and commercialization, Rwanda REPP could establish a comprehensive and sustainable framework for epidemic preparedness and response.



GROUP LEADERS FOR SCIENTIFIC AND TRANSLATIONAL ACTIVITIES

Core research group leaders serve as principal investigators driving fundamental and translational research programs focused on priority pandemic pathogens. These leaders develop and execute comprehensive research projects that advance scientific understanding while directly informing medical countermeasure development and deployment strategies. Research programs encompass five primary areas that address critical knowledge gaps in pandemic preparedness. Host-pathogen interaction studies investigate molecular mechanisms of viral infection, cellular response pathways, and immune evasion strategies that inform therapeutic target identification. Medical countermeasure design and development programs focus on creating diagnostic tools, antiviral therapeutics, and vaccine platforms optimized for priority pathogens and regional deployment requirements.

Pathogen life cycle research examines viral replication mechanisms, transmission dynamics, and environmental stability factors that influence outbreak patterns and countermeasure effectiveness. Host immunity investigations explore innate and adaptive immune responses, vaccine-induced protection, and immunological correlates of protection that guide vaccine development and deployment strategies. Systems and computational biology approaches integrate genomic, proteomic, and epidemiological data to model pathogen evolution, predict outbreak patterns, and optimize countermeasure development timelines. These computational frameworks enable rapid response to emerging threats while building predictive capabilities that inform proactive pandemic preparedness strategies.

Each research group leader coordinates multidisciplinary teams that combine basic science research with translational applications, ensuring that scientific discoveries translate directly into deployable medical countermeasures. This integrated approach creates synergies between fundamental research and practical application while building sustainable scientific capacity that serves both immediate response needs and long-term pandemic preparedness objectives.

Sub-networks of core research Groups of the RWANDA PANDEMIC INNOVATION HUB and their collaborators





The Pandemic Innovation Hub incorporates specialized biosafety laboratories with escalating containment levels essential for comprehensive pathogen research and medical countermeasure development. Biosafety Level 2 facilities handle moderate-risk agents using standard microbiological practices, biological safety cabinets, and protective equipment, including lab coats, gloves, and face protection. These laboratories require controlled access, handwashing facilities, and proper decontamination of infectious materials through autoclaving.

Biosafety Level 3 laboratories manage serious respiratory pathogens, including tuberculosis, SARS-CoV-2, West Nile virus, and Rift Valley fever through enhanced containment measures. Features include controlled laboratory access, negative pressure ventilation systems, specialized protective equipment with solid-front gowns and respirators, and comprehensive decontamination protocols. All experiments occur within biological safety cabinets or containment devices.

Biosafety Level 4 facilities represent the highest containment level for life-threatening pathogens, including Ebola, Marburg, and Lassa fever viruses that lack treatments or vaccines. These completely isolated facilities require full-body positive-pressure suits, multiple decontamination procedures including showers and UV treatment, HEPA filtration systems, and strict protocols limited to highly trained personnel.

Animal facilities complement these capabilities with appropriate Level 2 and 3 containment for live animal research, incorporating additional safeguards against animal bites, scratches, and zoonotic transmission while preventing both pathogen and animal escape from containment systems.

Comparison of the different Biosafety laboratory levels

Feature	BSL-2	BSL-3	BSL-4
Agent Risk Level	Moderate risk to humans	Serious or potentially lethal via inhalation	High risk, life-threatening, no known treatment or vaccine
Examples of Agents	Salmonella spp., Hepatitis B, Influenza virus	Mycobacterium tuberculosis, SARS-CoV-2, West Nile virus	Ebola virus, Marburg virus, Lassa fever virus
Access Restrictions	Restricted during work	Controlled, restricted access	Strictly limited; highly secured
PPE Required	Lab coat, gloves, face protection as needed	Lab coat, gloves, respirator/face protection	Full-body, air-supplied, positive pressure suit
Work Conducted In	Open bench or biosafety cabinet for risky procedures	Biosafety cabinet (Class II or III)	Class III biosafety cabinet or positive pressure suit lab
Ventilation Requirements	Standard ventilation	Directional airflow; negative pressure; no air recirculation	Dedicated air supply and exhaust; HEPA-filtered; negative pressure
Facility Design	Standard lab with handwashing sinks and waste decontamination	Physical separation from access corridors; sealed surfaces	Isolated facility; decontamination chambers; sealed lab space
Decontamination Methods	Autoclave or chemical disinfection of waste	Autoclave, chemical disinfection, HEPA-filtered exhaust	Multiple decontamination steps; chemical showers, HEPA filters
Training Requirements	Basic lab training + specific BSL-2 procedures	Advanced training in handling airborne pathogens	Extensive training; emergency response protocols





Core Scientific Infrastructure: Genomics and Advanced Imaging Capabilities

The Pandemic Innovation Hub establishes two essential core facilities that serve as shared national resources supporting pathogen research across Rwanda and the regional Community. These facilities operate through collaborative partnerships with regional universities, hospitals, and research centers, ensuring equitable access to advanced technologies while driving innovation and capacity building throughout the region.

Genomics and Sequencing Core Facility

The genomics facility provides comprehensive high-throughput pathogen genomics and host response analysis capabilities. Core functions encompass sample preparation and quality control for viral DNA and RNA isolation, library preparation for RNA sequencing, whole-genome sequencing, and chromatin immunoprecipitation sequencing applications. The facility utilizes next-generation and third-generation sequencing platforms, including Illumina NovaSeq, Oxford Nanopore Technologies, and Pacific Biosciences systems, to generate high-quality genomic data.

Integrated bioinformatics capabilities support read alignment, genome assembly, variant calling, differential expression analysis, and multi-omics data integration. The facility provides comprehensive training programs and expert consultation services covering experimental design, data interpretation, and workflow optimization for researchers across the region.

Advanced Cell Imaging Facility

The imaging facility enables visualization of dynamic cellular processes and molecular interactions between pathogens and host cells. Instrumentation includes confocal, spinning disk, super-resolution, and live cell imaging systems that provide high-resolution, real-time visualization capabilities. Advanced software tools support image quantification, tracking, and morphometric analysis.

The facility offers comprehensive training programs, technical support, and method development services that equip researchers with advanced imaging capabilities. These core facilities integrate seamlessly with biomanufacturing platforms and clinical study units, creating a comprehensive research ecosystem that accelerates medical countermeasure development and regional scientific capacity.

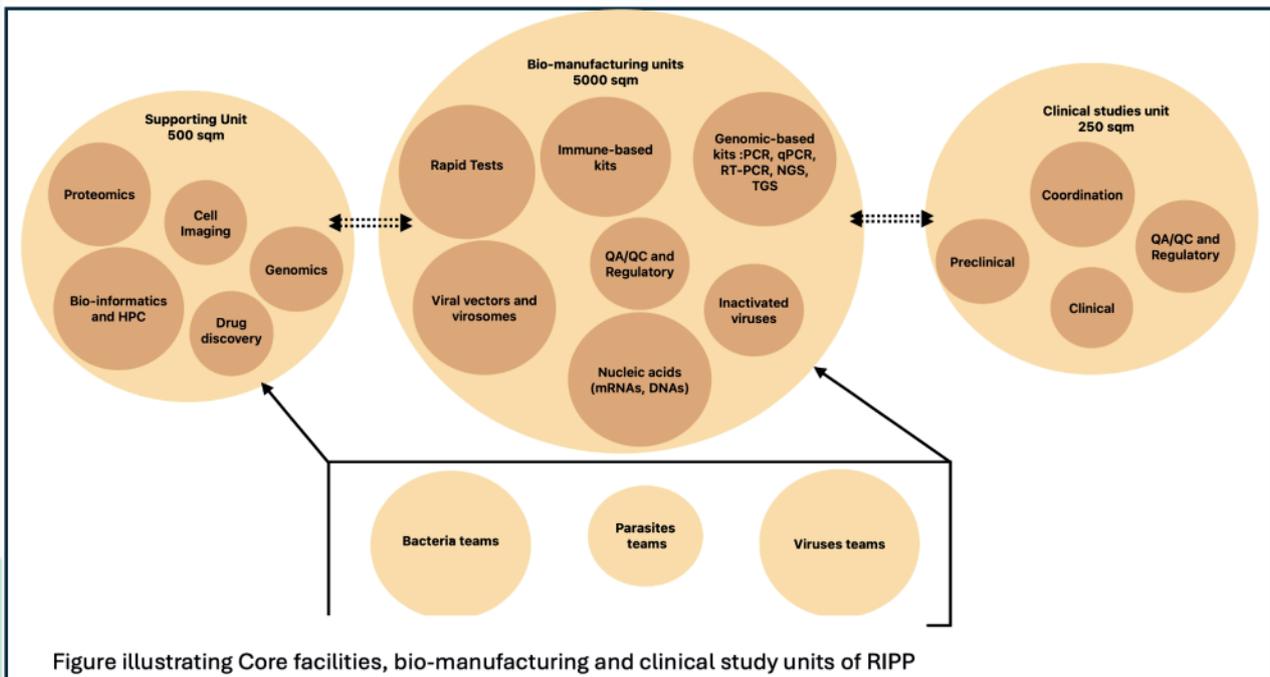
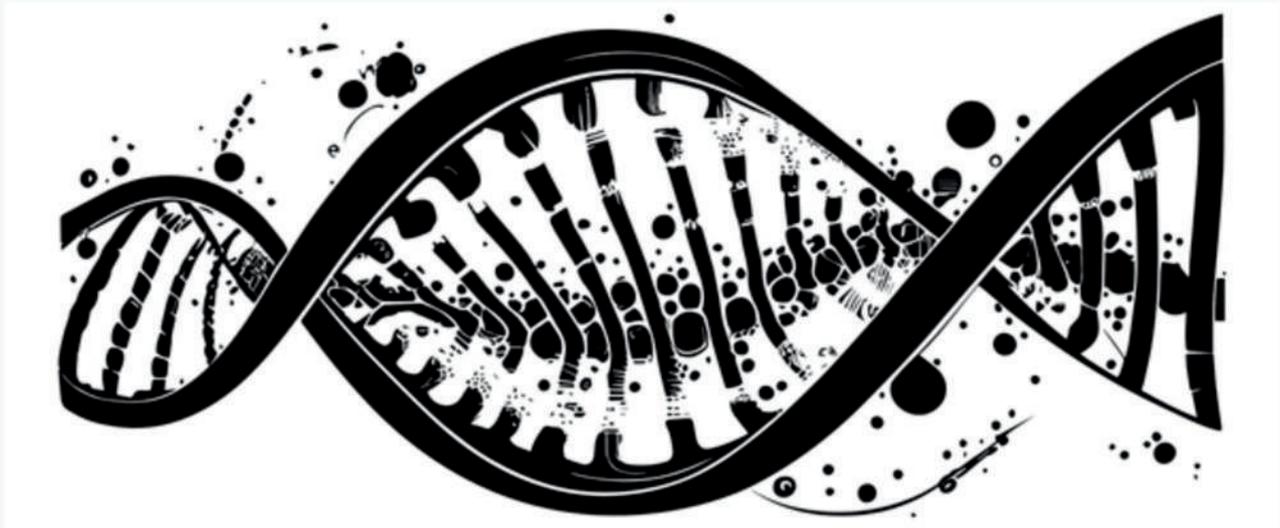


Figure illustrating Core facilities, bio-manufacturing and clinical study units of RIPP

Figure illustrating Core facilities, bio-manufacturing and clinical study units of Pandemic Innovation Hub



Scientific Excellence and Research Priorities

Pathogen-Focused Research Programs Research priorities align with evidence-based pathogen prioritization while building platform capabilities that address multiple threats effectively. Filovirus research programs focus on understanding viral mechanisms, developing broad-spectrum therapeutics, and creating vaccines effective against multiple strains. Rift Valley Fever research emphasizes One Health approaches addressing both human and animal health while developing vector control strategies and universal vaccines.

Flavivirus research programs address arboviral diseases, including Dengue, Zika, and Yellow Fever with emphasis on urban transmission dynamics and climate adaptation factors. Respiratory pathogen research develops platform technologies applicable to influenza, coronaviruses, and emerging respiratory threats while building rapid response capabilities for unknown pathogens.

Platform Technology Development Scientific strategy emphasizes platform approaches that enable rapid adaptation to emerging threats while building sustainable competitive advantages. mRNA platform development focuses on African pathogen priorities while building indigenous capabilities through University of Rwanda collaboration and international partnerships. Viral vector platforms optimize for single-dose convenience and thermostable formulations addressing African deployment constraints.

Diagnostic platform development emphasizes multiplex capabilities enabling simultaneous detection of multiple pathogens while incorporating AI-enhanced analysis for improved accuracy and clinical decision support. Therapeutic platforms focus on broad-spectrum approaches effective against pathogen families while maintaining cost-effectiveness for widespread deployment.

Advanced Research Infrastructure Scientific Infrastructure Investment of \$200 million establishes world-class research capabilities that rival global institutions while addressing African research priorities. BSL-4 laboratory facilities enable safe research on high-consequence pathogens while specialized containment systems support vaccine and therapeutic development. Advanced analytical capabilities include state-of-the-art mass spectrometry, nuclear magnetic resonance, and X-ray crystallography for molecular characterization and drug development.

Computational infrastructure supports AI and machine learning applications including pathogen modeling, drug discovery, and manufacturing optimization. High-performance computing clusters enable genomic analysis, protein modeling, and systems biology approaches while cloud integration facilitates collaboration with international research partners.





Human Capital Development and Talent Pipeline

Integrated One Health Training Programs - The workforce development strategy integrates specialized One Health laboratory training that spans human, animal, and environmental health sectors. Training programs encompass six core facility specializations: genomics and bioinformatics, proteomics and metabolomics, structural biology and biological imaging, animal models, insectaries and membrane feeding assays, and GMP bioproduction facilities.

PhD specialization tracks include computational genomics, functional genomics, clinical genomics, microbial genomics, quantitative proteomics, structural proteomics, clinical proteomics, metabolomics, X-ray crystallography, cryo-electron microscopy, NMR spectroscopy, bioprocess engineering, microbial biotechnology, plant biotechnology, animal biotechnology, insect biotechnology, parasitology, clinical chemistry, and structural chemistry.

Graduate and Postgraduate Training Programs Academic - program alignment integrates the University of Rwanda's biotechnology programs with hub activities through shared faculty, research projects, and training facilities. **Nine** new master's programs and a PhD in Translational Sciences align with Component specializations, while hub facilities provide advanced research opportunities that complement academic instruction.

International partnerships facilitate PhD exchange programs with leading institutions, while post-doctoral fellowship programs attract top talent for hub research activities. Training programs emphasize both fundamental scientific knowledge and practical skills required for biotechnology innovation and manufacturing excellence.

Joint registration programs between the University of Rwanda, INES, and international partner universities ensure sustainable capacity building while leveraging existing MSc programs. A dedicated capacity-building office within RBC coordinates postgraduate students and postdoctoral programs across all specialized tracks.

Professional Development and Career Pathways - Career development programs provide advancement opportunities across hub activities from technical positions through research leadership and management roles. International training opportunities through partner institutions build expertise while creating networks that support long-term collaboration and knowledge exchange.

Mentorship programs pair junior scientists with experienced researchers while leadership development initiatives prepare hub personnel for expanded responsibilities as capabilities grow. Professional certification programs ensure technical competency while creating pathways for career advancement across multiple specializations.

Regional Capacity Building Training programs extend beyond Rwanda to build regional expertise through hub facilities and technical assistance. Regional partnerships with Makerere University, University of Nairobi, and other institutions create networks for knowledge sharing and collaborative research while building human capital across East Africa.

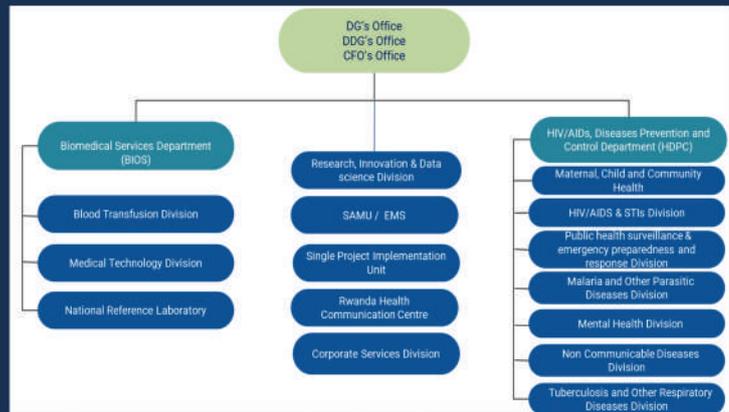
Technical assistance programs support capacity building in partner countries while creating opportunities for regional personnel to gain experience in advanced research and manufacturing through hub assignments. These programs multiply Rwanda's impact while building sustainable networks that support long-term regional development.



Resources Mapping and Current Capabilities

RWANDA BIOMEDICAL CENTRE (RBC) FOUNDATION INTEGRATION

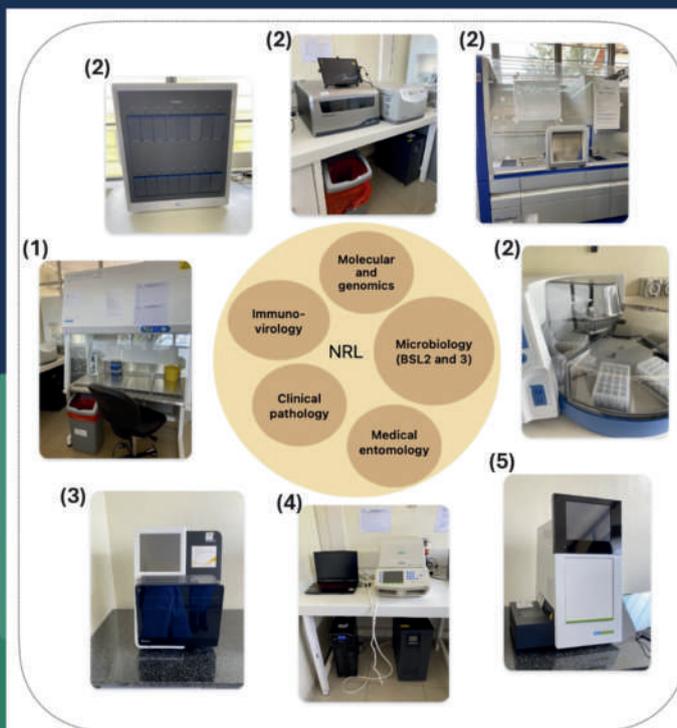
RBC provides an institutional foundation for Hub development through established research capabilities, producing 838 publications since 2012 with recent high-impact outputs including 80+ COVID-19 publications and 5 Marburg virus studies in leading journals. The Hub integrates existing RBC expertise while expanding capabilities through central coordination and specialized Component development.



National Reference Laboratory Integration

leverages current capabilities, including 80 trained professionals across molecular virology, immunology, microbiology, and clinical pathology, while addressing capacity limitations through hub-wide expansion. Current equipment, including biosafety cabinets, sequencing platforms, and PCR systems, integrates into shared infrastructure while new capabilities expand through specialized Component development.

Below is the illustration of major equipment in the National Reference Laboratory (NRL): (1) Biosafety cabinets (2) Robotic instruments, (3) NGS, (4) RT-PCR, and (5) Nucleic acids Q/A instruments



Capacity Enhancement Through Hub Model

addresses existing limitations, including limited senior leadership (2 PhDs among 80 staff), through recruitment across all Components. BSL-3 space expansion and BSL-4 development serve multiple Components, while specialized workforce development addresses gaps in pathogen biology, bioinformatics, and biotechnology through integrated training programs.

CENTRALIZED RESOURCE OPTIMIZATION

Equipment Sharing Strategy

maximizes high-cost equipment utilization through central scheduling serving multiple Components. Advanced analytical instruments, specialized manufacturing equipment, and research platforms serve hub-wide needs, reducing individual Component investment requirements while expanding capability access.

Integrated Expertise Development

enables researchers to work across Components, addressing complex challenges requiring multidisciplinary approaches. Central seminar series, shared training programs, and cross-component projects build a collaborative culture while developing comprehensive expertise in medical countermeasure development.



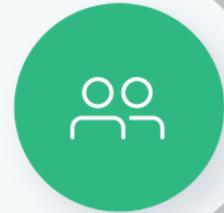
Rwanda One Health Project Integration

Rwanda’s One Health approach integrates across all hub Components addressing zoonotic disease priorities including viral hemorrhagic fevers, avian influenza, Rift Valley fever, trypanosomiasis, rabies, and brucellosis. Component 4 (Animal Models) provides specialized capabilities while all Components contribute to understanding animal-human-environment disease interfaces.



Wildlife Health Surveillance Integration expands through hub capabilities including Component 2 diagnostic development for wildlife pathogens, Component 1 vaccine development for animal populations, and Component 3 therapeutic development for zoonotic diseases. Central coordination ensures integrated approaches across human, animal, and environmental health sectors.

Cross-Component Research Coordination addresses One Health challenges through collaborative projects spanning multiple Components. Genomic surveillance involves Components 2 and 5, vaccine development engages Components 1 and 4, while therapeutic development utilizes Components 3 and 6 ensuring comprehensive zoonotic disease preparedness.



Climate-Disease Research examines environmental factors influencing pathogen emergence through hub-wide capabilities. Components 2 and 5 provide analytical capabilities while Components 1 and 3 develop climate-adapted countermeasures ensuring effectiveness under changing environmental conditions through observation and stakeholder feedback

Vector Ecology Integration utilizes hub capabilities for comprehensive vector-borne disease research. Diagnostic development in Component 2 enables vector pathogen detection while Components 1 and 3 develop targeted interventions addressing vector-borne transmission supported by Component 4 preclinical validation.





Academic Institutions Capacity Building

University of Rwanda Hub Integration

The Pandemic Innovation Hub establishes comprehensive integration with the University of Rwanda's biotechnology programs through shared faculty appointments, collaborative research projects, and unified training facilities that serve both academic and hub objectives. Academic program alignment connects existing biotechnology curricula with hub specializations, while nine new master's programs and a PhD in Translational Sciences provide specialized training across genomics and bioinformatics, proteomics and metabolomics, structural biology, bioprocess engineering, and clinical applications.

Infrastructure sharing creates seamless connections between university laboratories and hub facilities, enabling students to access cutting-edge equipment, including next-generation sequencing platforms, mass spectrometry systems, biosafety laboratories, and GMP bioproduction facilities. Hub personnel provide specialized training in advanced techniques while university faculty contribute research expertise, ensuring mutual benefit and continuous capability enhancement across both institutions.

Student pipeline development channels university graduates into hub positions through integrated training programs that span undergraduate internships, graduate research projects, and postdoctoral fellowships. The hub's core facilities serve as training grounds for computational genomics, functional genomics, clinical genomics, quantitative proteomics, structural proteomics, X-ray crystallography, cryo-electron microscopy, and bioprocess engineering specializations, while academic programs supply qualified candidates through established MSc programs at the University of Rwanda and INES.

International Collaboration Integration

International partnership coordination leverages global research networks through the International Center for Genetic Engineering and Biotechnology (ICGEB) and other strategic collaborations that span all hub components. These partnerships facilitate coordinated research projects, shared training programs, and technology transfer activities that enhance local capabilities while providing access to international expertise and resources.

Global network integration connects hub activities with leading international institutions through specialized partnerships across Components 1-6, creating pathways for technology transfer agreements, collaborative research initiatives, and joint training programs. The capacity building office within RBC coordinates postgraduate students and postdoctoral programs, facilitating joint registration between local and international universities to ensure program sustainability and global competitiveness.

These integrated academic partnerships ensure that the Pandemic Innovation Hub operates as both a regional center of excellence and a globally connected research institution, building local capacity while maintaining access to international scientific networks and cutting-edge technologies that advance Rwanda's pandemic preparedness capabilities.





Research Group Leadership and Qualifications

Hub-Wide Leadership Development

Cross-Component Leadership Structure positions research group leaders to collaborate across Components while maintaining specialized expertise. Leaders coordinate between Components, addressing complex challenges requiring multidisciplinary approaches while developing a comprehensive understanding of medical countermeasure development.

Integrated Recruitment Strategy develops African talent through international partnerships while attracting global expertise through competitive positioning. PhD development programs span multiple Components, while diaspora engagement and international recruitment ensure comprehensive leadership capabilities across hub operations.

Leadership Coordination Systems

Hub-Wide Performance Standards ensure consistent excellence across all Components through unified evaluation criteria, shared performance metrics, and coordinated professional development. Research leaders meet international standards while contributing to integrated hub objectives and regional capacity building.

Cross-Component Collaboration Requirements mandate research leaders to engage across Components through joint projects, shared resources, and collaborative problem-solving. Leadership development includes hub-wide perspective ensuring comprehensive understanding of medical countermeasure development while maintaining specialized expertise.

Graduate School and Training Programs

Integrated Training Architecture

Cross-Component Student Programs enable rotation through multiple Components, providing comprehensive medical countermeasure development experience. Students gain specialized expertise within Components while understanding integrated approaches through central training programs and cross-Component projects.

Hub-Wide Educational Resources provide shared training facilities, equipment access, and expert instruction across all Components. Central training programs complement Component-specific instruction while integrated research projects span multiple Components, ensuring a comprehensive educational experience.

Regional Training Integration

EAC Student Pipeline channels regional talent through integrated training programs serving all Components. Partnerships with Makerere University, University of Nairobi, and other regional institutions provide diverse student populations, while hub training creates a regional expertise network.

Training Program Coordination ensures students receive comprehensive preparation through Component rotations, central seminars, and integrated research projects. Hub-wide mentorship provides access to expertise across all Components while specialized training develops Component-specific competencies.

Laboratory Technician Development

Hub-Wide Technical Support

Integrated Technician Training provides comprehensive skills development across all Components through centralized programs and Component-specific specialization. Core competencies include biosafety, quality control, and equipment operation while Component specialization addresses specific technical requirements.

Cross-Component Technical Services enable technicians to support multiple Components through shared expertise and equipment operation. Central technical support provides specialized services while Component technicians develop comprehensive capabilities supporting hub-wide operations.

Regional Technical Capacity Building

External Training Programs extend technician development across Rwanda and EAC region through hub facilities and expertise. Regional technicians receive training in hub facilities while hub technicians provide technical assistance to regional institutions building comprehensive technical capacity network.

Career Development Integration provides advancement opportunities across Components through hub-wide technical career pathways. Technicians advance through specialized training, international opportunities, and leadership development while supporting hub operations and regional capacity building objectives.





Translational Unit Operations

Hub-Wide Innovation Coordination

Integrated IP Management coordinates intellectual property development across all Components, ensuring comprehensive portfolio development and strategic licensing. Central innovation management prevents duplication while maximizing commercial opportunities through coordinated development activities spanning multiple Components.

Cross-Component Technology Transfer facilitates innovation movement between Components, enabling vaccine discoveries to inform therapeutic development while diagnostic advances support clinical trial activities. Hub-wide innovation pipeline coordinates development, preventing silos while maximizing synergies.

Commercial Integration Strategy

Hub-Wide Business Development coordinates commercialization activities across Components through integrated market analysis, partnership development, and revenue optimization. Central business development supports Component-specific activities while ensuring hub-wide commercial success and sustainability.

Regional Market Integration leverages hub capabilities for comprehensive market penetration through coordinated product portfolios, integrated service offerings, and shared distribution networks. Cross-Component collaboration provides complete solutions while specialized expertise addresses specific market requirements, ensuring commercial success and regional impact.

This comprehensive scientific strategy and hub development framework establishes Rwanda as Africa’s premier integrated pandemic preparedness center through coordinated Component operations, shared resources, and collaborative innovation, ensuring sustainable capabilities supporting both national security and continental health sovereignty.



3

ENABLERS OF SUCCESS



19. GOVERNANCE AND PARTNERSHIPS

To develop a strong and sustainable talent pipeline, Rwanda's Epidemic, Pandemic Preparedness and Response (REPRP) efforts must be underpinned by robust, multisectoral partnerships involving the Rwanda Biomedical Centre (RBC), the Ministry of Health (MoH), the Ministry of Education (MoE), and key national institutions. According to Africa CDC's Partnerships for African Vaccine Manufacturing (PAVM) initiative, achieving the PAVM's 2040 goals, including advancing R&D and expanding local manufacturing of vaccines, diagnostics, and therapeutics, will require an estimated 12,500 skilled professionals across the continent.

Currently, Rwanda lacks a dedicated research team focused specifically on pandemic viruses. To address this strategic gap, we propose the establishment of a Hub for Pandemic Pathogen Sciences (HPPS), which would serve as a central hub for research, innovation, and workforce development in this critical area. The hub will implement a structured talent development roadmap to train and retain a highly skilled workforce, including:

1. Laboratory technicians
2. Laboratory managers
3. Research group leaders specializing in pandemic sciences

Several ongoing initiatives provide a strong foundation to build this talent pipeline. These include the Master's and PhD programs at the University of Rwanda, led by Prof. Léon Mutesa and funded by the European Union (EU). These programs include key fields such as clinical trials, human genetics and genomics, diagnostic immunology, infectious diseases, clinical pharmacology, experimental models, bioprocessing engineering, chemical engineering, and industrial pharmacy. The programs are being supported by the EU, the Swedish International Development Cooperation Agency (SIDA), and Expertise France.

Moreover, the newly established African Biomanufacturing Institute (ABI) at the University of Rwanda, led by Prof. Stephen Karengera and funded by Africa CDC through the East Africa Regional Capability and Capacity Network (RCCN), will also play a central role in training specialized talent in biomanufacturing, a key component of pandemic response and vaccine self-reliance.

Despite this progress, coordination across initiatives remains fragmented. We therefore propose the establishment of a national Steering Committee, under the joint oversight of the Ministries of Health, Education, Agriculture, and Environment. This high-level committee will serve as the central coordination mechanism to align education, research, and public health efforts in support of Rwanda's pandemic preparedness strategy. The Steering Committee will foster inter-institutional coordination among key stakeholders, including RBC, the Rwanda Agriculture Board (RAB), the Rwanda Environment Management Authority (REMA), the Rwanda Development Board (RDB), the Rwanda Food and Drug Authority (RFDA), and the University of Rwanda. While each institution will maintain its unique mandate, they will work together under a unified One Health-oriented framework that integrates human, animal, and environmental health.

This integrated approach, illustrated in the framework below, should align national efforts in surveillance, diagnostics, research, training, and manufacturing. It should minimize duplication, streamline communication channels, and promote the development of shared data systems, in line with regional and global best practices. With clearly defined roles, joint planning, and shared accountability, this governance structure will significantly strengthen Rwanda's capacity to detect and respond to emerging health threats, while maximizing the impact of investments, partnerships, and innovation across sectors.





SPECIFIC TECHNICAL THEMATIC AREA FOR GRADUATE SCIENTISTS, AND EXPECTED IMPACT

Thematic Area	Fundamental Discovery	Translated Product	Use Case / Impact
Molecular Virology	Viral entry, replication, and mutation mechanisms	Candidate antivirals; viral vector systems	Outbreak response and therapeutic interventions
Genomics & Surveillance	Whole-genome sequencing of pathogens	Real-time RT-PCR; CRISPR-based diagnostics	Rapid diagnostics and variant tracking
Zoonotic Spillover	Mapping of viral reservoirs in wildlife	Zoonotic risk maps and predictive surveillance models	Spillover prevention and early warning systems
Immunology	Host immune profiling (B-cell, T-cell responses)	Vaccine Antigen design; immune biomarker Panels	Vaccine development and immune monitoring
Protein Biology	Novel viral protein structures and functions	Protein subunit vaccines; monoclonal antibodies	Targeted prevention and treatment strategies
Microbiome & Host Factors	Impact of microbiota on pathogen susceptibility	Microbiome-informed therapeutics	Enhanced resilience to infection
Diagnostics Innovation	Optimization of isothermal amplification and biosensors	Point-of-care kits (LAMP, RPA, lateral flow assays)	Field-ready, rapid diagnostic tools
Bioinformatics & AI	AI-based pathogen evolution and spillover risk prediction	Digital surveillance dashboards; decision support tools	Enhanced epidemic forecasting and response
Biosafety & Biosecurity	High-containment laboratory SOPs and incident tracking	Training modules; quality assurance frameworks	Safe lab operations and regional biosafety capacity building



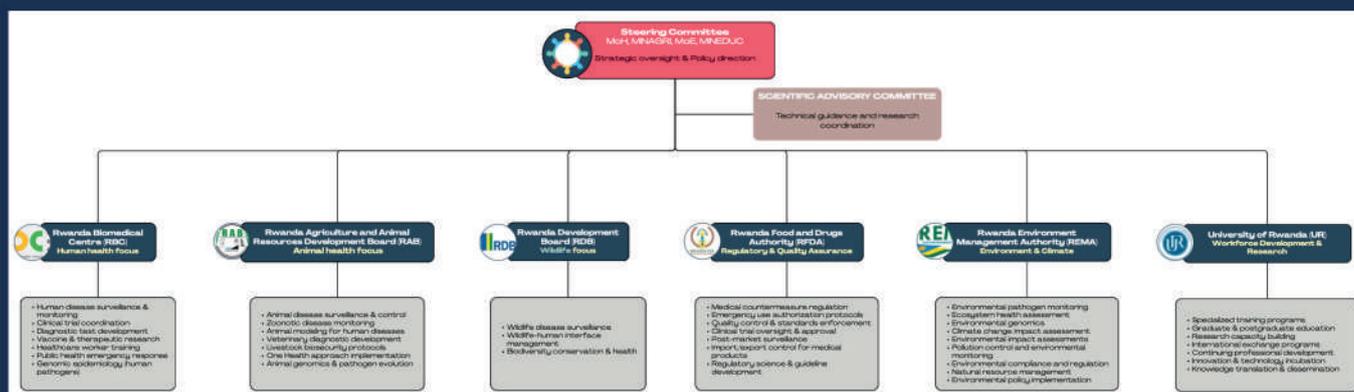


Figure 3. Coordination framework

RWANDA'S REGIONAL COLLABORATORS

A non-exhaustive list of regional partners is presented in Table 3. These partnerships are crucial for amplifying the regional impact of Rwanda's research on pandemic viruses, facilitating workforce exchange programs, fostering synergies in biomanufacturing and clinical trials, and strengthening funding acquisition. One key partner is Makerere University, which has extensive expertise in virology, particularly in the study of retroviruses (HIV), filoviruses (Ebola and Marburg), flaviviruses (Zika, Dengue, and West Nile viruses), and bunyaviruses (Rift Valley Fever virus). This wealth of experience positions Makerere University as a valuable collaborator for advancing research on emerging and re-emerging viral threats in the region. Another important partner is the Kenya Institute of Primate Research (KIPRE), which specializes in preclinical research using non-human primates, zoonotic diseases, and the One Health approach. KIPRE played a critical role in Kenya's COVID-19 response by establishing a molecular biology lab and a COVID-19 testing and research center. KIPRE has enhanced BSL-2 and BSL-3 facilities and trained personnel in molecular biology, bioinformatics, disease ecology, and infectious diseases to support early disease warning systems.

OTHER POTENTIAL AFRICAN COLLABORATORS

ACTIVE IN PANDEMIC SCIENCES

- Institute of Genomics and Global Health (IGH), Nigeria
- Centre for Epidemic Response and Innovation (CERI), Stellenbosch University
- Afrigen Biologics, South Africa - afrigen.co.za
- The Pasteur Network in Africa
- Africa CDC
- Science for Africa Foundation
- South Africa Medical Research Council

POTENTIAL INTERNATIONAL COLLABORATORS

International partners are grouped into three main categories to support Rwanda's epidemic and pandemic preparedness efforts:

1. ACADEMIC INSTITUTIONS WITH RESEARCH EXPERTISE IN PANDEMIC VIRUSES:

These institutions bring critical research capacity to high-priority viral families and will contribute to Rwanda's efforts to advance innovation in pandemic sciences.

Envisioned partners are:

- REGA Institute at KU Leuven (Belgium): expertise in filoviruses, flaviviruses, arboviruses, and coronaviruses.
- University of Marburg (Germany): expertise in filoviruses and hantaviruses.
- INSERM Lyon (France): expertise in henipaviruses and operation of BSL-4 containment facilities.
- New York University Abu Dhabi (UAE): expertise in bioinformatics, genomics, and artificial intelligence.
- University of Liège (Belgium): expertise in influenza viruses and One Health approaches.
- University of Ottawa (Canada): expertise in biomanufacturing and pandemic preparedness.
- Harvard Medical School (USA): expertise in systems biology and synthetic biology.
- Max Planck Institute for Infection Biology, Germany
- VIB Life Sciences Institute, Belgium
- Institute of Life Sciences Switzerland
- Pandemic Sciences Institute, University of Oxford
- Cambridge Biotechnology Business Institute
- Chungbuk National University mRNA Facility, South Korea

A special focus will be placed on how to translate cutting-edge research into actionable innovations for pandemic preparedness and response.

1. Henao-Restrepo, A. M. et al. Efficacy and effectiveness of an rVSV-vectored vaccine in preventing Ebola virus disease: final results from the Guinea ring vaccination, open-label, cluster-randomized trial (Ebola Ça Suffit!). *The Lancet* 389, 505-518 (2017).

2. European Medicines Agency (EMA). New vaccine for prevention of Ebola virus disease recommended for approval in the European Union | <https://www.ema.europa.eu/en/news/new-vaccine-prevention-ebola-virus-disease-recommended-approval-european-union> (2020).

3. CDC. History of Marburg Outbreaks. Marburg Virus Disease <https://www.cdc.gov/marburg/outbreaks/index.html> (2024).

4. Sibomana, O., Hakayuwa, C. M. & Munyantore, J. Marburg Virus Reaches Rwanda: How Close Are We to a Vaccine Solution? *Int. J. Infect. Dis.* 0, (2024).

2. GOVERNMENT AGENCIES AND NON-PROFIT ORGANIZATIONS

These organizations offer strategic support in containment, diagnostics, vaccine access, and financing:

- UK Health Security Agency (UKHSA): expertise in BSL-4 containment and animal models for high-risk pathogens.
- FIND: global access to diagnostic tools and expertise in diagnostic development.
- SABIN Vaccine Institute: access to vaccine development platforms and partnerships.
- Coalition for Epidemic Preparedness Innovations (CEPI): innovation and funding for vaccine and therapeutic development.
- European Union’s Health Emergency Preparedness and Response Authority (HERA): coordination and funding for pandemic response in Europe, with potential international collaboration.
- WHO Hub for Pandemic and Epidemic Intelligence: global surveillance, data sharing, and intelligence gathering.
- The Gates Foundation: innovations, resources, and global collaboration
- Chan Zuckerberg Biohub: biomanufacturing, cutting-edge pathogen sciences
- Centre for Outbreak Preparedness, Singapore
- International Pandemic Preparedness Secretariat (IPPS).
- UNEP: Environmental health surveillance and climate-epidemic modeling
- HERA (EU Health Emergency Preparedness and Response Authority): Regulatory coordination and technology validation

3. INDUSTRY PARTNERS FOR TECHNOLOGY TRANSFER, GMP, INTELLECTUAL PROPERTY (IP), AND COMMERCIALIZATION:

These partnerships are key to establishing local biomanufacturing capacity in Rwanda and supporting technology transfer under good manufacturing practices (GMP), IP management, and future commercialization of medical countermeasures (MCMs). Identified small and medium-sized enterprises (SMEs) include:

- Sagitta Biotech (Switzerland): development of virosome-based vaccines.
- RIBOPRO (Netherlands): specialization in mRNA therapeutics.
- TOKABIO (South Africa): development of advanced diagnostics.
- International Centre for Genetic Engineering and Biotechnology (ICGEB): advanced training in biomanufacturing processes and clinical trial management.
- Flagship Pioneering, Boston
- WIPO: Intellectual property strategy, GMP compliance pathways, and commercialization frameworks for locally developed technologies

Together, these regional and international partners will play a critical role in supporting Rwanda’s ambition to develop a sustainable, innovative, and responsive ecosystem for pandemic R&D and biomanufacturing.

We propose a benchmarking initiative to support the strategic implementation of Rwanda’s Epidemic and Pandemic Preparedness and Response Plan (REPP). The initiative would involve a series of targeted visits to some of the above institutions.



EXPECTED OUTPUTS OF THE BENCHMARKING EXERCISE

SHORT-TERM

1. A finalized and phased workforce development plan under REPP, tailored to both immediate and long-term capacity needs.
2. A refined strategic plan for the Rwanda HPPS, phased according to realistic implementation and budget scenarios.
3. An integrated plan to align Rwanda’s MCM strategy with the National Health Sector Strategic Plan V and the Rwanda One Health Strategic Plan.

LONG-TERM

1. A roadmap for institutional partnerships and collaboration phasing.
2. A sustainability framework addressing IP generation, funding models, and governance.
3. A shared national vision for scientific excellence in pathogen research and medical countermeasures development.

1. Breman, J. G. et al. Discovery and Description of Ebola Zaire Virus in 1976 and Relevance to the West African Epidemic During 2013-2016. *J. Infect. Dis.* 214, S93-S101 (2016).
2. Broadhurst, M. J., Brooks, T. J. G. & Pollock, N. R. Diagnosis of Ebola Virus Disease: Past, Present, and Future. *Clin. Microbiol. Rev.* 29, 773-793 (2016).
3. Barbiero, V. K. Ebola: A Hyperinflated Emergency. *Glob. Health Sci. Pract.* 8, 178-182 (2020).
4. Cross, R. W. et al. Oral administration of obeldesivir protects nonhuman primates against Sudan ebolavirus. *Science* 383, eadk6176 (2024).
5. Mohd, O. B. et al. The Development of Ebola Virus Outbreaks: A Review of Epidemiological Trends, Clinical Features, and Treatment Advances. *Cureus* 16, e74078 (2024).



COLLABORATION ROADMAP

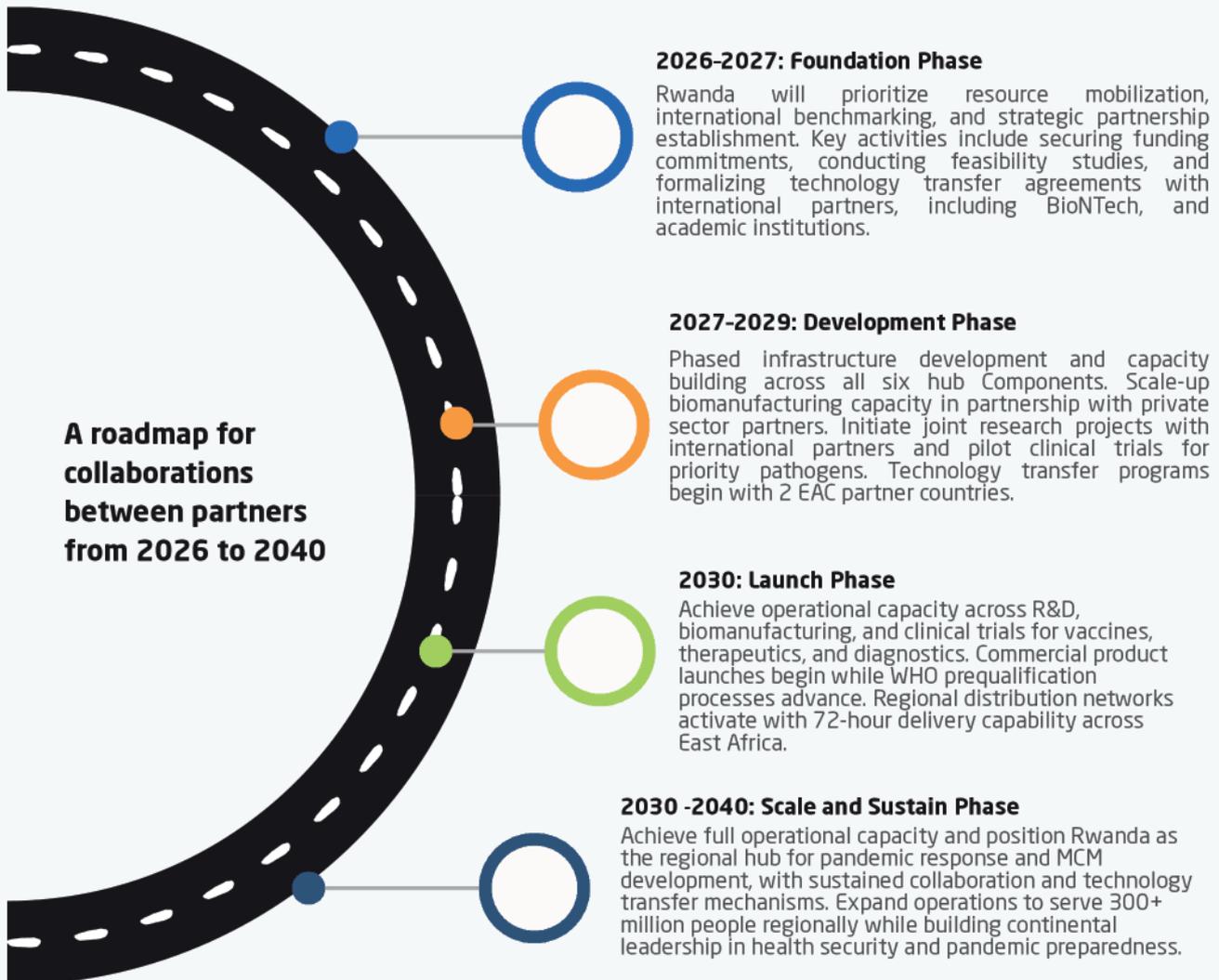
Rwanda is advancing a comprehensive national and regional strategy for epidemic and pandemic preparedness and response, building on lessons learned from recent outbreaks, including COVID-19 and the 2024 Marburg virus outbreak. While Rwanda has demonstrated success in containing these threats, critical gaps remain in research capacity, biomanufacturing, and workforce development. To address these challenges, Rwanda proposes the establishment of a Rwanda Pandemic Innovation Hub, organized into thematic research groups focusing on priority pathogen families and supported by dedicated computational and artificial intelligence (AI) and supporting units. Through a strong emphasis on translational research, the Institute aims to drive innovations that will enable the local development and manufacturing of vaccines, therapeutics, and diagnostics, and the capacity to conduct clinical trials, ultimately strengthening Rwanda’s ability to respond rapidly and effectively to future outbreaks.

National collaborations, led by the Rwanda Biomedical Centre (RBC), will engage the University of Rwanda and other national institutions to develop skilled scientific talent, supported by initiatives such as the Master’s in Biotechnology (MScB-UR), and upcoming programs in clinical trials, infectious diseases, genomics, and biomanufacturing. The African Biomanufacturing Institute (ABI) will further support workforce training in vaccine and therapeutic production.

Regionally, partnerships with Makerere University (virology and emerging viruses) and the Kenya Institute of Primate Research (preclinical and One Health research) will strengthen Rwanda’s capacity in surveillance and early-phase clinical trials.

International collaborations are structured into three categories:

1. Academic partners
2. Government agencies and non-profits
3. Industry partners



Through REPRP, Rwanda aims to build an integrated ecosystem for epidemic and pandemic preparedness that combines research excellence, workforce development, and manufacturing capacity. By aligning with global models such as Singapore’s PREPARE and Canada’s CP2H, Rwanda can lead regional efforts in pandemic response, ensuring equitable access to life-saving medical countermeasures. Collaborative engagement with regional and international partners will be essential to achieve these goals, making Rwanda a proactive and resilient player in the global health security landscape





20. REGULATORY AND QUALITY EXCELLENCE



RFDA Capacity Building Program

Regulatory Transformation Program (2026-2027)

Building on Rwanda's December 2024 achievement of WHO ML3 status, RFDA advances to ML4 capabilities through a comprehensive transformation addressing medical countermeasure regulation. The program recruits 25 regulatory specialists from the FDA, EMA, and WHO, providing technical leadership for biologics and emergency use authorization. Advanced laboratories and automated review systems enhance assessment capabilities while 100 RFDA personnel complete specialized training in pandemic countermeasures.

Personnel expansion leverages ML3 foundation: regulatory scientists grow from 15 to 45 positions with biologics expertise; quality assessors increase from 20 to 60 staff completing advanced GMP training; clinical reviewers expand from 5 to 25 specialists in vaccine and therapeutic evaluation; inspection teams grow from 10 to 30 professionals with biosafety facility expertise.

Advanced Capabilities Development

Building on ML3 achievements, advanced analytical capabilities establish a comprehensive biologics testing infrastructure. Laboratory facilities incorporate specialized equipment for vaccine potency, therapeutic characterization, and diagnostic validation. Digital platforms leverage existing ML3 systems with enhanced automation and AI-integrated quality control, reducing review timelines by 60%.

Emergency Authorization Framework and Rapid Response Protocols

Seven-Day Emergency Authorization Protocol Leveraging ML3 emergency capabilities, Rwanda develops world-class seven-day authorization protocols that maintain safety standards while enabling rapid pandemic response. The streamlined process optimizes application receipt from the current 1-day achievement to same-day processing, while technical review accelerates from existing capabilities to 3-day maximum using pre-positioned expert panels and parallel review processes.

Executive decision-making maintains authority and accountability while ensuring rapid deployment capability during health emergencies. Enhanced safety frameworks leverage existing ML3 standards while enabling rapid pandemic response through intensified post-market surveillance protocols and specialized risk communication strategies for pandemic countermeasures.

Enhanced Safety and Monitoring Systems ML4 emergency authorization maintains rigorous safety standards through enhanced post-market surveillance, leveraging existing systems with intensified monitoring protocols. Risk communication builds on ML3 transparency requirements with specialized pandemic countermeasure information and public engagement strategies that maintain confidence while enabling informed decision-making.

Pharmacovigilance systems integrate with international networks while providing real-time safety monitoring that informs regulatory decisions and public health recommendations. Adverse event reporting utilizes automated systems and AI-enhanced analysis that enable rapid signal detection and appropriate regulatory response.





International Harmonization and Mutual Recognition

ML3 Recognition, Leverage, and Global Integration - Rwanda's ML3 achievement enables advanced international partnerships and mutual recognition agreements that facilitate simultaneous submissions and regulatory harmonization. WHO listing capabilities enable coordinated global regulatory strategies while regional leadership through EAC builds on demonstrated regulatory excellence and proven emergency response capabilities.

Global engagement expands through ICH participation and international regulatory coordination that positions Rwanda among respected regulatory authorities. Technical expertise sharing and capacity building initiatives extend Rwanda's influence while building networks that support long-term collaboration and knowledge exchange.

Regional Regulatory Leadership and Harmonization - ML3 status positions Rwanda as the EAC regulatory leader, supporting harmonization initiatives and capacity building programs that create regional regulatory convergence. Technical assistance extends to neighboring countries while regional training programs share Rwanda's expertise and build collective capabilities across East Africa.

Continental coordination leverages ML3 recognition for AVAREF leadership and WHO-AFRO collaboration that positions Rwanda as a continental regulatory leader. Regional standards harmonization creates economies of scale while reducing regulatory burden for manufacturers serving multiple African markets.

Quality Systems and International Standards Compliance

Comprehensive Quality Management Framework - Quality systems implementation follows international standards, including ISO 13485 for medical devices, ICH guidelines for pharmaceuticals, and WHO prequalification requirements for global market access. Quality management encompasses all hub activities from research and development through manufacturing and distribution, ensuring consistent excellence across the entire value chain.

Statistical process control systems enable predictive quality management while comprehensive validation protocols ensure consistent performance and regulatory compliance. Quality culture development ensures organization-wide commitment to excellence while continuous improvement systems incorporate lessons learned and international best practices.

Manufacturing Quality and GMP Excellence - Good Manufacturing Practice implementation across all hub Components ensures international standards compliance while maintaining flexibility for emergency response requirements. Quality control laboratories provide real-time release testing while automated systems enable rapid batch certification and release for emergency deployment.

Environmental monitoring systems ensure consistent manufacturing conditions while change control procedures maintain quality during process optimization and scale-up activities. Supply chain quality management ensures consistent raw material quality while vendor qualification programs build reliable supplier networks that meet international standards.

Regulatory Science and Innovation Integration - Regulatory science programs advance understanding of product quality, safety, and efficacy while developing innovative approaches to regulatory evaluation that maintain safety while enabling innovation. Collaboration with international regulatory agencies builds technical expertise while contributing to global regulatory science advancement.

Innovation pathways accommodate novel technologies and emergency use applications while maintaining appropriate safety oversight. Adaptive regulatory approaches enable rapid evaluation of innovative products while building experience that informs future regulatory development and international best practice contribution.



21. FINANCING AND SUSTAINABILITY

Revenue Model with Market Realism

Diversified Revenue Architecture

REPP transforms pandemic preparedness from a cost center into a revenue-generating ecosystem, positioning Rwanda as the East African medical countermeasure leader. The model operates through five complementary streams targeting 300+ million people across the region.

Vaccine manufacturing forms the revenue cornerstone, generating \$200-350 million annually by 2040 through 40-65 million doses across mRNA, viral vector, and protein platforms. Rwanda's geographic advantage offers 72-hour delivery versus 2-4 weeks from traditional suppliers, commanding 15-20% regional premiums.

Diagnostic sales project \$50-90 million annually through rapid tests, PCR assays, and multi-omics platforms. This stream provides steady cash flow with recurring demand and lower manufacturing complexity than vaccines or therapeutics.

Therapeutic development targets \$65-120 million annually through monoclonal antibodies and antivirals designed for African conditions. Temperature-stable formulations create unique market advantages and premium pricing opportunities.

Technology licensing generates \$30-60 million annually from proprietary technologies, patent royalties, and pharmaceutical partnerships. Focus on African-adapted solutions creates valuable IP assets with global potential.

Services and training complete the portfolio with \$15-40 million annually through clinical trials, regulatory consultation, and workforce development programs.

Market Penetration Strategy

Domestic market achieves 100% penetration using cost-plus 15% pricing integrated with national healthcare systems. **EAC regional expansion** targets 60-80% penetration across 200+ million people using cost-plus 25% pricing supported by formal trade agreements. **African LDCs** employ cost-plus 10% pricing for 40-60% penetration with donor support mechanisms. **Commercial exports** use market-rate pricing with 50-60% margins targeting developed countries.

Economic Impact Analysis

Direct Economic Transformation

REPP creates 1,500+ high-skilled positions by 2040 averaging \$45,000 annually, generating \$67 million in direct payroll with 2.3x multiplier effects supporting 4,000+ families. Annual tax revenue exceeds \$120 million through corporate, VAT, and income taxes. Foreign exchange benefits exceed \$300 million annually through exports and import substitution.

Innovation Economy Development

Annual R&D investment reaches \$50+ million, creating regional innovation leadership. Supply chain development generates \$200+ million in EAC economic activity. Technology spillovers produce \$150 million in related industry advancement. Educational programs support 500+ graduate positions annually, building cross-sector expertise.

Return on Investment Analysis

Conservative projections show 420% ten-year ROI with 2029 break-even. Base case achieves 580% ROI with 2028 break-even. Optimistic scenarios reach 850% ROI with 2027 break-even. Net present values range from \$1.2-2.6 billion over 2026-2035.

Financial Risk Management

Revenue Diversification Strategy

Geographic distribution targets 60% EAC, 25% broader Africa, 15% international markets. Product portfolio allocates 45% vaccines, 20% diagnostics, 25% therapeutics, 10% services. Customer base spans 55% government, 30% private sector, 15% international organizations. Revenue timing structures 40% recurring contracts, 35% annual agreements, 25% spot sales.

Operational Risk Mitigation

Currency management employs 70% local sourcing with financial hedging. Competition response emphasizes quality differentiation, African-adapted formulations, and rapid delivery. Supply chain protection uses multiple suppliers, regional sourcing, and strategic inventory. Regulatory adaptation maintains international standards and diversified approvals.

Technology Risk Management

Innovation sustainability invests 15% revenues in R&D with platform flexibility and global partnerships. IP protection combines patents, trade secrets, and strategic partnerships. Clinical development employs diversified pipelines and risk-sharing collaborations. Technology obsolescence prevention maintains cutting-edge capabilities through continuous investment.

Financial Monitoring Systems

Real-time performance monitoring tracks revenue, costs, and market position with automated alerts. Scenario planning and stress testing ensure resilience under adverse conditions. Cash flow management employs forecasting, working capital optimization, and multiple credit facilities for operational security and growth capability.



REPP BUSINESS MODEL

<p>KEY PARTNERS</p> <p>Technology Partners</p> <ul style="list-style-type: none"> BioNTech (mRNA platforms) CEPI, WHO, EU-HERA (innovation & regulatory support) International research institutions (KU Leuven, University of Marburg) <p>Financial Partners</p> <ul style="list-style-type: none"> Internal mobilization, Pandemic Fund (\$160M secured) European Union Development finance institutions, bilateral donors Private equity and impact investors <p>Regional Partners</p> <ul style="list-style-type: none"> Regional governments (Kenya, Uganda, Tanzania, DRC, etc) Makerere University, University of Nairobi Regional healthcare organizations and distributors <p>Supply Chain Partners</p> <ul style="list-style-type: none"> Raw material suppliers (60% EAC sourcing target) Logistics providers (road, rail, air, lake transport) Cold chain and storage facility operators 	<p>KEY ACTIVITIES</p> <p>Research & Development</p> <ul style="list-style-type: none"> Pathogen research and vaccine design Diagnostic platform development Therapeutic discovery and optimization AI-powered threat detection systems <p>Manufacturing Operations</p> <ul style="list-style-type: none"> GMP vaccine production (50M+ doses annually) Diagnostic manufacturing (25M+ tests annually) Therapeutic production and formulation Quality control and batch release <p>Regulatory & Quality Assurance</p> <ul style="list-style-type: none"> WHO ML4 regulatory compliance Emergency use authorization (7-day capability) International prequalification processes Regional regulatory harmonization <p>Market Development</p> <ul style="list-style-type: none"> Customer acquisition and relationship management Distribution network establishment Technology transfer to regional partners Training and capacity building programs <p>KEY RESOURCES</p> <p>Physical Assets</p> <ul style="list-style-type: none"> Six-Component Pandemic Innovation Hub facility Biosafety laboratories and manufacturing equipment Climate-controlled storage and distribution centers Scientific Infrastructure (\$200M investment) <p>Intellectual Property</p> <ul style="list-style-type: none"> Proprietary vaccine and diagnostic platforms African-adapted formulations and processes Patents and trade secrets portfolio Technology licensing agreements <p>Human Capital</p> <ul style="list-style-type: none"> 2,000+ specialized scientists and technicians Regulatory affairs and quality professionals International advisory board and scientific forum Regional training and capacity building network <p>Strategic Assets</p> <ul style="list-style-type: none"> WHO ML4 regulatory status Regional distribution agreements Technology transfer partnerships Emergency response protocols 	<p>VALUE PROPOSITIONS</p> <p>Speed & Accessibility</p> <ul style="list-style-type: none"> Rapid delivery vs 2-4 weeks from traditional suppliers Early threat detection capability Rapid medical countermeasure development <p>African-Adapted Solutions</p> <ul style="list-style-type: none"> Climate-stable formulations for tropical conditions Products designed for African pathogen priorities Field-deployable diagnostics for resource-limited settings <p>Cost Leadership</p> <ul style="list-style-type: none"> 30-40% cost advantage over imported alternatives Local production eliminates import duties and logistics costs Tiered pricing ensuring affordability across market segments <p>Quality & Reliability</p> <ul style="list-style-type: none"> WHO ML4 regulatory standards International prequalification status Emergency response and surge capacity capabilities 	<p>CUSTOMER RELATIONSHIP</p> <p>Government Relations</p> <ul style="list-style-type: none"> Long-term procurement contracts and framework agreements Technical advisory services and policy consultation Emergency response partnerships and protocols <p>Institutional Partnerships</p> <ul style="list-style-type: none"> Training and capacity building programs Joint research and development initiatives Technology transfer and licensing agreements <p>Professional Networks</p> <ul style="list-style-type: none"> Healthcare provider education and support Clinical trial partnerships and collaboration Scientific conferences and knowledge sharing <p>Digital Engagement</p> <ul style="list-style-type: none"> Real-time inventory and order management systems Technical support and consultation platforms Training and certification programs <p>CHANNEL</p> <p>Direct Sales</p> <ul style="list-style-type: none"> Government-to-government procurement Direct institutional sales and contracts Emergency response and humanitarian deployments <p>Distribution Partners</p> <ul style="list-style-type: none"> Regional pharmaceutical distributors Healthcare logistics and supply chain providers Cold chain and specialized storage networks <p>Digital Platforms</p> <ul style="list-style-type: none"> Online ordering and inventory management Telemedicine and remote consultation support Training and certification platforms <p>Regional Networks</p> <ul style="list-style-type: none"> Regional country offices and representatives Technology transfer and manufacturing partners Academic and research institution collaborations 	<p>CUSTOMER SEGMENTS</p> <p>Government Procurement</p> <ul style="list-style-type: none"> Rwanda Ministry of Health (domestic market) Regional government health ministries National strategic reserves and emergency preparedness <p>Healthcare Institutions</p> <ul style="list-style-type: none"> Public hospitals and health centers Private healthcare providers Regional referral and specialty hospitals <p>International Organizations</p> <ul style="list-style-type: none"> WHO, UNICEF, Gavi global procurement Humanitarian organizations (MSF, IRC) Development partners and donor agencies <p>Private Sector</p> <ul style="list-style-type: none"> Pharmaceutical distributors and wholesalers Corporate health programs Insurance providers and health schemes
<p>COST STRUCTURE</p> <p>Fixed Costs (40% of total)</p> <ul style="list-style-type: none"> Infrastructure maintenance and utilities: \$50M annually Personnel costs (2,000+ employees): \$90M annually Regulatory compliance and quality assurance: \$25M annually <p>Variable Costs (45% of total)</p> <ul style="list-style-type: none"> Raw materials and manufacturing inputs: 60-70% of product cost Logistics and distribution: 5-10% of product cost Packaging and cold chain: 3-5% of product cost <p>Strategic Investments (15% of total)</p> <ul style="list-style-type: none"> R&D and innovation: 15% of revenue annually Technology licensing and partnerships: \$20M annually Regional expansion and capacity building: \$15M annually <p>Cost Optimization Strategies</p> <ul style="list-style-type: none"> 70% local sourcing to reduce currency risk Economies of scale through regional production Automation and digitization to reduce labor costs Renewable energy integration to reduce utility costs 	<p>REVENUE STREAM</p> <p>Product Sales (85% of revenue)</p> <ul style="list-style-type: none"> Vaccine sales: \$200-350M annually (45% of total) Diagnostic sales: \$50-90M annually (20% of total) Therapeutic sales: \$65-120M annually (25% of total) <p>Intellectual Property (10% of revenue)</p> <ul style="list-style-type: none"> Technology licensing: \$30-60M annually Patent royalties and IP agreements Platform licensing to regional partners <p>Services (5% of revenue)</p> <ul style="list-style-type: none"> Clinical trial services: \$15-40M annually Regulatory consultation and technical assistance Training and capacity building programs <p>Pricing Models</p> <ul style="list-style-type: none"> Cost-plus pricing: 10-25% markup depending on market segment Premium pricing: 15-20% above imports for superior value Emergency pricing: Below-cost during health crises with donor support 			





22. MARKET ACCESS AND COMMERCIAL STRATEGY

REGIONAL MARKET ASSESSMENT

East African Community Market Opportunity

The EAC market encompasses 269 million people across six countries with combined healthcare spending of \$8.05 billion annually. Kenya leads with a 54 million, \$2.1 billion healthcare budget, and \$180 million market opportunity. Uganda offers 47 million people with \$150 million potential, while Tanzania presents a 61 million population creating \$210 million opportunity.

Democratic Republic of Congo provides 95 million people despite infrastructure challenges, generating \$120 million in potential. Combined regional imports of \$1.73 billion create \$690 million addressable market through government procurement, private sector sales, and donor-funded programs.

Market Entry Strategy

Kenya employs direct sales leveraging established infrastructure and private demand. Tanzania uses phased entry through donor programs expanding to government contracts. Uganda focuses on government partnerships with development support. DRC emphasizes NGO collaborations addressing infrastructure limitations. Each strategy adapts to local procurement systems and payment mechanisms.

COMPETITIVE ANALYSIS

Global Competition Assessment

International pharmaceutical companies offer established supply chains but face high costs and 2-4 week delivery times. South African manufacturers provide continental presence but encounter distance disadvantages. Indian generics deliver low costs but face quality concerns and distance limitations. Chinese manufacturers have government support but encounter quality perception issues.

Rwanda's Competitive Advantages

Geographic proximity enables 72-hour delivery versus weeks from traditional suppliers. Cost leadership provides 30-40% lower production costs, while pandemic specialization focuses on African pathogen priorities. Integrated solutions combine products with services, while climate adaptation ensures extreme condition stability. Quality certifications meet international standards, commanding premium positioning.

PRICING AND ACCESS STRATEGY

Tiered Pricing Framework

Domestic market uses cost-plus 15% pricing integrated with universal health coverage. EAC partners receive cost-plus 25% reflecting proximity value through bulk purchase agreements. Least Developed Countries access products at cost-plus 10% with donor support. Commercial exports command cost-plus 60% generating premium revenues for cross-subsidization.

Access Guarantee Mechanisms

Emergency access maintains 25% production capacity for 48-hour regional deployment. Crisis pricing provides below-cost access during emergencies while strategic reserves enable immediate response. Advanced purchase agreements guarantee market access while technology transfer enables emergency licensing during critical situations.

Revenue Optimization

Geographic distribution targets 60% EAC, 25% broader Africa, 15% international markets. Product diversification spans vaccines, diagnostics, therapeutics, and services ensuring stability. Customer mix includes government procurement, private sales, and international partnerships reducing payment risk. Contract structure balances recurring agreements with flexible spot sales while value-added services create additional revenue streams.

This strategy positions Rwanda for sustainable regional growth while ensuring affordable access to essential medical countermeasures, creating viable business models supporting both commercial success and public health objectives.



4

IMPLEMENTATION FRAMEWORK





23. IMPLEMENTATION ROADMAP

Investment Framework

Strategic Investment Allocation

The Rwanda Epidemic and Pandemic Preparedness Plan (REPP) requires a total investment of **\$500 million** over the 2026-2040 period, strategically distributed across six core Components to establish Rwanda as East Africa's premier Pandemic Innovation Hub. This investment framework is designed to achieve maximum impact through coordinated development of complementary capabilities.

Component/Facility-Based Investment Distribution

Component/Facility	Investment	Primary Focus	Strategic Rationale
Component 1: Vaccine Development & Biomanufacturing	\$114M	mRNA, viral vector, protein platforms	Largest market opportunity, regional demand
Component 2: Diagnostics & Multi-omics	\$88M	Rapid testing, genomic surveillance	Critical for early detection, fastest ROI
Component 3: Therapeutics & Biotechnology	\$83M	Monoclonal antibodies, antivirals	High-value products, emergency stockpiles
Component 4: Clinical Research & Animal Models	\$73M	Phase I-III trials, preclinical studies	Regulatory pathway enabler
Component 5: Bioengineering & Bioprocessing	\$34M	Process optimization, scale-up	Cost reduction, efficiency gains
Component 6: Quality Control & Regulatory	\$11M	WHO prequalification, emergency protocols	Quality assurance, market access
Scientific Laboratory Infrastructure	\$82M	Advanced research facilities & workforce development	Research excellence, innovation leadership
Workforce Development Program	\$15M	PhD exchanges, MSc training, capacity building	Human capital development, expertise building





Current Funding Status and Security



Risk-Adjusted Investment Strategy

The investment framework employs a comprehensive risk-adjusted strategy built on three core pillars that collectively reduce project risk while maximizing return potential. The modular construction approach delivers significant operational advantages, enabling 50% faster implementation than traditional construction methods while achieving 20-25% cost reductions through standardization, incorporating climate-resilient design features, and providing expandable infrastructure for future growth capacity. Technology diversification further mitigates risk through multiple platform approaches within each operational Component, establishing backup technology partnerships, developing indigenous R&D capabilities, and implementing robust intellectual property protection strategies to safeguard competitive advantages. These risk mitigation measures support market-driven revenue projections that range from a conservative estimate of \$360M annual revenue by 2040, a base case scenario of \$475M, to an optimistic projection of \$660M, providing investors with multiple pathways to substantial returns while maintaining downside protection through the integrated risk management approach.





Strategic Implementation Overview and Phased Approach

The Rwanda Epidemic and Pandemic Preparedness Plan (REPP) implementation employs a three-phase approach over 2026-2040 that balances rapid capability development with sustainable institution building. This systematic progression ensures early operational capability while building comprehensive infrastructure and regional partnerships that support long-term sustainability and continental leadership.

Phase 1: Foundation (2026-2026) - Building Core Capabilities The foundation phase establishes essential infrastructure, core partnerships, and initial operational capabilities that provide immediate pandemic preparedness enhancement while creating the platform for subsequent expansion. Infrastructure development emphasizes climate-resilient construction using modular approaches that reduce implementation time by 50% while ensuring operational resilience under changing environmental conditions.

Core facility construction encompasses 60% of total infrastructure including primary manufacturing capabilities, essential laboratory facilities, and central coordination systems. Equipment installation proceeds across all six hub Components with emphasis on multi-purpose platforms that enable immediate operational capability while supporting future expansion and specialization.

Human capital development initiates with the recruitment of 300+ specialized personnel across technical, regulatory, and management functions, while comprehensive training programs build indigenous expertise through international partnerships and exchange programs. Technology transfer agreements with BioNTech and other key partners establish immediate access to proven platforms while building local adaptation capabilities.

Regulatory advancement targets the WHO ML4 designation through systematic enhancement of existing ML3 capabilities, including personnel expansion, infrastructure improvement, and digital system implementation. Early product development programs focus on high-priority pathogens, including filoviruses and Rift Valley fever, providing proof-of-concept demonstrations while building operational experience.

Phase 2: Scale-up (2027-2028) - Operational Excellence and Market Entry The scale-up phase transforms foundation capabilities into commercial operations while expanding regional partnerships and international market access. Manufacturing capacity reaches 25 million vaccine doses annually, with 40 million surge capability, complemented by diagnostic production capabilities serving regional markets with field-deployable products.

Platform integration enables coordinated operations across all hub Components while first commercial product launches demonstrate operational capability and market viability. WHO prequalification achievements provide international market access while emergency authorization protocols enable rapid deployment during health emergencies.

Regional partnership activation establishes technology transfer programs with 2 EAC countries, while distribution networks provide 72-hour delivery capability across all regional markets. Training programs extend to 150+ regional personnel while collaborative research initiatives build shared expertise and intellectual property.

Revenue generation targets \$100+ million annually from initial commercial operations while establishing market relationships that support subsequent expansion. Technology licensing begins generating intellectual property revenue while service offerings create additional income streams that support overall financial sustainability.

Phase 3: Regional Leadership (2029-2040) - Excellence and Continental Impact The excellence phase achieves full operational capacity across all capabilities while establishing Rwanda as the recognized continental leader in pandemic preparedness. Manufacturing capacity reaches 50+ million vaccine doses annually with comprehensive product portfolios addressing regional pathogen priorities and emerging threats.





Regional technology transfer expands to 4 EAC facilities while continental capacity building initiatives extend Rwanda's impact across Africa. Training programs serve 500+ continental personnel annually while research collaborations build shared capabilities that strengthen collective pandemic preparedness.

Revenue targets reach \$650+ million annually while creating 2,000+ direct high-skilled positions and 5,000+ indirect employment opportunities. International market expansion establishes Rwanda as a recognized global supplier while maintaining focus on African priorities and regional service.

Component-Specific Implementation Timelines and Milestones

Component 1: Vaccine Development & Biomanufacturing

Foundation Phase establishes climate-resilient GMP facility with 50% completion by end-2026, equipment installation from multiple suppliers by mid-2026, and recruitment of specialized biomanufacturing engineers and technicians. Technology agreements with BioNTech and Moderna provide immediate platform access while initial prototype development demonstrates capability.

2027 Platform Integration achieves GMP facility operational status with climate resilience features while mRNA vaccine platforms begin producing first prototypes. Initial production capacity reaches 8 million doses with 12 million surge capability, while emergency protocols enable 48-hour activation during health emergencies.

2028 Commercial Launch delivers the first commercial vaccine with WHO prequalification while production capacity increases to 18 million doses annually, with 25 million surge capability. Emergency protocols validation enables a reliable, rapid response, while international market entry begins through prequalification achievement.

2029 Advanced Manufacturing expands capacity to 35 million doses annually while multi-platform flexibility enables production across 4 vaccine types. Continuous manufacturing with sustainability features reduces environmental impact, while regional technology transfer initiatives begin with 2 EAC countries.

2040 Excellence Targets achieve 50+ million vaccine doses annually while maintaining 35+ validated candidates in the development library. Platform licensing generates \$15+ million annual revenue while technology transfer serves 4 EAC facilities, establishing Rwanda as the regional center for vaccine innovation and production.





Component 2: Diagnostic Innovation & Multi-omics

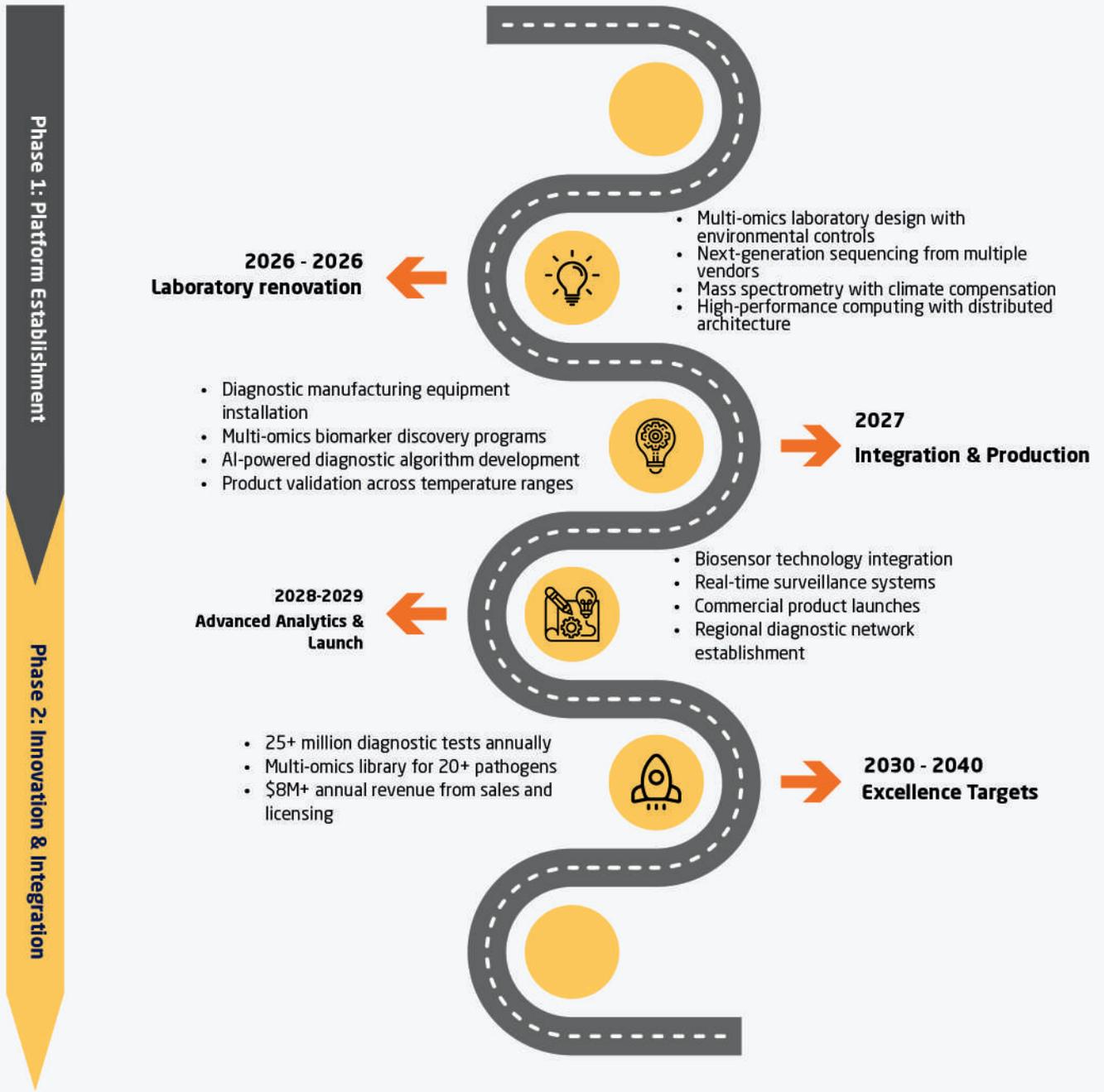
Platform Establishment completes multi-omics laboratory design with environmental controls while installing next-generation sequencing equipment, mass spectrometry systems, and high-performance computing infrastructure. Diagnostic manufacturing equipment installation proceeds alongside AI-powered algorithm development for enhanced analysis capability.

2027 Integration & Production achieves multi-omics biomarker discovery program operation while diagnostic manufacturing produces field-deployable tests for priority pathogens. Product validation across temperature ranges ensures African deployment capability, while biosensor technology integration enhances performance under challenging conditions.

2028-2029 Advanced Analytics & Launch implements commercial product launches while establishing real-time surveillance systems that provide early warning capability. Regional diagnostic network establishment creates a distributed capability, while advanced analytics provide superior performance compared to imported alternatives.

2040 Excellence Targets deliver 25+ million diagnostic tests annually while maintaining a multi-omics library for 20+ pathogens. Annual revenue reaches \$8+ million from sales and licensing, while regional network expansion provides comprehensive coverage across East Africa.







Component 3: Therapeutic Development & Biotechnology

Phase 1: Foundation (2026-2028) - Facility Renovation

Biotechnology Facility Renovation and Climate Resilience - Existing facility renovation incorporates climate resilience features with upgraded HVAC systems, backup power, and environmental monitoring. Modular renovation enables phased development while maintaining ongoing operations and accommodating future technology upgrades.

Production Systems Installation - Bioreactor systems installation spanning 5L-5000L scales for CHO cell culture and bacterial/yeast platforms. Temperature-stable monoclonal antibody manufacturing optimization for African deployment conditions. Protein purification equipment includes chromatography and automated downstream processing. Small molecule synthesis laboratory renovation incorporates automated chemistry with climate-adapted processes. Viral vector production areas enable cell and gene therapy development. Natural products extraction capabilities utilize sustainable sourcing from African medicinal plants.

Personnel and Capability Development - Recruitment targets 25+ specialized scientists, including protein engineers, medicinal chemists, and process development specialists. Training programs build expertise while international partnerships provide technology transfer and knowledge exchange.

Phase 2: Research Programs (2026-2028)

Monoclonal Antibody Development - Emergency production capabilities enable rapid scale-up for outbreak response. Development focuses on filovirus neutralizing antibodies, Rift Valley fever therapeutics, and broad-spectrum respiratory pathogen antibodies. Production optimization reduces costs while maintaining international quality standards.

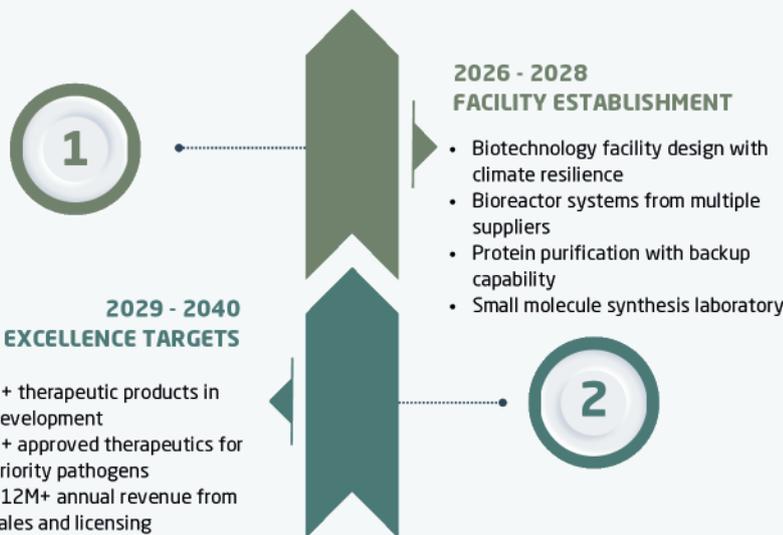
Small Molecule Drug Discovery - Broad-spectrum antiviral programs target pathogen families. Climate-stable formulations address deployment challenges including temperature extremes and extended storage. Medicinal chemistry optimization improves oral bioavailability and safety profiles.

Strategic Therapeutic Development Research programs emphasize viral entry inhibitors, replication inhibitors, and host-targeted approaches. Strategic reserves maintain climate-controlled emergency stockpiles with rotation protocols.

Phase 3: Excellence Targets (2029-2040)

Commercial Portfolio Achievement

- 8+ therapeutic products in the development pipeline
- 3+ approved therapeutics for priority pathogens
- 100,000+ monoclonal antibody treatment courses annually
- \$12+ million annual revenue from sales and licensing
- 150+ direct high-skilled positions created





Component 4: Animal models & Clinical Excellence

Phase 1: Foundation (2026-2026) - Infrastructure Renovation

BSL-2/BSL-3 Facility Renovation - Existing facility upgrade to climate-controlled animal housing with redundant environmental systems. BSL-3 area renovation enables high-consequence pathogen research while BSL-2 spaces accommodate routine activities. Enhanced containment includes negative pressure isolation and HEPA filtration upgrades.

Equipment Installation and Capacity Upgrade - Mobile deployment equipment installation for field research support. Facility capacity expansion to 500+ animals across multiple species. Laboratory equipment renovation encompasses diagnostic capabilities and monitoring systems. Personnel Development 15+ specialized veterinarians recruitment with infectious disease expertise. 50+ animal technicians through training programs. Research scientists in immunology, pharmacology, and disease modeling.

Phase 2: Scale-up (2027) - Clinical Launch

Disease Model Development - Infection models for priority pathogens incorporating climate adaptation factors. Pharmacokinetics laboratory renovation enables ADMET studies. Digital pathology suite installation provides AI-enhanced analysis capabilities.

Clinical Trial Infrastructure - 50-bed Phase I clinical trial center renovation with intensive monitoring capabilities. Regional healthcare network development for expanded trials. Electronic data systems implementation ensuring regulatory compliance.

Phase 3: Excellence (2028-2040)

Comprehensive Clinical Capabilities

- 20,000+ participant capacity across the regional network
- WHO recognition for clinical research excellence
- 30-day emergency evaluation protocols
- \$8+ million annual clinical services revenue





Component 5: Biomedical engineering & Bioprocessing

Phase 1: Foundation (2026-2028) - Laboratory Renovation

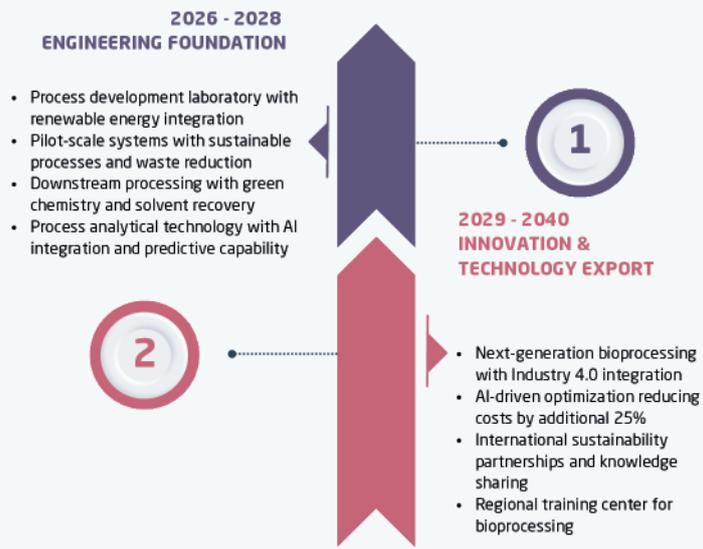
Process Development Laboratory Upgrade - Existing laboratory renovation with renewable energy integration, providing 40% operational energy. Pilot-scale systems installation with sustainable processes and waste reduction. Process analytical technology upgrade with AI integration and predictive optimization.

Sustainable Manufacturing Implementation Equipment renovation incorporating green chemistry principles with solvent recovery systems. Continuous manufacturing system installation reduces batch requirements. Environmental monitoring systems track resource consumption and sustainability metrics.

Phase 2: Innovation & Export (2029-2040)

Advanced Bioprocessing Achievement

- AI-driven optimization reduces costs by 40% and accelerates timelines by 60%
- Regional training center serving African bioprocessing professionals
- \$12+ million annual revenue from technology licensing and consulting
- Carbon-neutral manufacturing through renewable energy integration



Component 6: Quality control & Regulatory affairs

Phase 1: Foundation (2026-2028) - Laboratory Renovation

Analytical Laboratory Upgrade - Existing laboratory renovation with multi-platform analytical equipment and automated systems. Method development capabilities addressing African deployment conditions. Statistical process control implementation with real-time monitoring and predictive analytics.

Microbiological Testing Enhancement - Existing facility upgrade for comprehensive sterility testing with automated processing. Environmental monitoring system installation with predictive analytics. Rapid microbiological methods implementation reduces testing time.

Climate-Adaptive Testing Capabilities Potency assay development addressing temperature, humidity, and altitude variations. Stability testing chamber installation for African deployment conditions. Real-time batch certification system enabling rapid product release.

Phase 2: Excellence & Leadership (2029-2040)

WHO Collaborating Center Achievement

- International recognition enabling technical assistance provision
- 200+ international professionals trained annually
- \$15+ million revenue from technical assistance and advisory services
- 7-day emergency authorization capabilities
- Regional regulatory harmonization leadership across East Africa





Resource Allocation and Financial Management

Investment Phasing and Cash Flow Optimization - Financial management employs phased investment that optimizes cash flow while building capabilities systematically. Phase 1 requires \$200 million for infrastructure and initial operations while generating \$25 million revenue from early diagnostic sales and services.

Phase 2 investment of \$180 million supports manufacturing scale-up and regional expansion while revenue increases to \$100+ million annually from commercial operations. Phase 3 investment of \$120 million completes capability development while revenue reaches \$650+ million annually, creating positive cash flow that supports continued innovation and expansion. Working capital management ensures adequate liquidity while optimizing inventory levels and accounts receivable. Credit facilities provide additional financial flexibility while maintaining debt levels that support sustainable growth and operational resilience.

Human Resource Development and Capacity Building - Human capital investment prioritizes specialized technical expertise while building management and leadership capabilities that support long-term sustainability. International recruitment targets 50+ senior positions while domestic development programs create 1,500+ specialized positions by 2040.

Training and development investments reach \$15 million annually while international exchange programs build expertise and networks that support continued innovation. Career development pathways ensure retention while creating advancement opportunities that support organizational growth and leadership development. Regional capacity building extends expertise across East Africa while creating networks that support technology transfer and collaborative research. Training programs serve 500+ regional personnel annually while building institutional relationships that strengthen collective capabilities.

Regional Integration and Partnership Development

East African Community Coordination - Regional integration proceeds through systematic partnership development that builds complementary capabilities while avoiding unnecessary duplication. Kenya partnerships focus on market access and financial services while Tanzania collaboration emphasizes government procurement and donor coordination.

Uganda partnerships leverage scientific collaboration while building manufacturing capabilities that serve regional markets. DRC engagement emphasizes humanitarian applications while building long-term commercial relationships through NGO partnerships and government engagement. Technology transfer programs begin with 2 countries in 2027-2028, expanding to 4 countries by 2040 while creating regional manufacturing networks that provide redundancy and market access. Quality harmonization ensures consistent standards while regulatory coordination streamlines approval processes across regional markets.

Continental and International Partnerships - Continental partnerships extend Rwanda's influence through Africa CDC collaboration, AVAREF leadership, and South-South cooperation initiatives that share expertise while building collective capabilities. International partnerships provide technology access while creating opportunities for global market expansion and intellectual property development.

Development partner coordination ensures aligned support while maximizing impact through coordinated investment and technical assistance. Private sector partnerships create commercial opportunities while providing access to expertise and market networks that support long-term sustainability and growth. This comprehensive implementation roadmap provides detailed guidance for systematic capability development while maintaining flexibility to adapt to changing circumstances and emerging opportunities, ensuring successful achievement of REPP objectives while building sustainable institutions that serve regional and continental pandemic preparedness needs.





Resource Allocation and Financial Management

Investment Phasing and Cash Flow Optimization - Financial management employs phased investment that optimizes cash flow while building capabilities systematically. Phase 1 requires \$200 million for infrastructure and initial operations while generating \$25 million revenue from early diagnostic sales and services.

Phase 2 investment of \$180 million supports manufacturing scale-up and regional expansion while revenue increases to \$100+ million annually from commercial operations. Phase 3 investment of \$120 million completes capability development while revenue reaches \$650+ million annually, creating positive cash flow that supports continued innovation and expansion. Working capital management ensures adequate liquidity while optimizing inventory levels and accounts receivable. Credit facilities provide additional financial flexibility while maintaining debt levels that support sustainable growth and operational resilience.

Human Resource Development and Capacity Building - Human capital investment prioritizes specialized technical expertise while building management and leadership capabilities that support long-term sustainability. International recruitment targets 50+ senior positions while domestic development programs create 1,500+ specialized positions by 2040.

Training and development investments reach \$15 million annually while international exchange programs build expertise and networks that support continued innovation. Career development pathways ensure retention while creating advancement opportunities that support organizational growth and leadership development. Regional capacity building extends expertise across East Africa while creating networks that support technology transfer and collaborative research. Training programs serve 500+ regional personnel annually while building institutional relationships that strengthen collective capabilities.

Regional Integration and Partnership Development

East African Community Coordination - Regional integration proceeds through systematic partnership development that builds complementary capabilities while avoiding unnecessary duplication. Kenya partnerships focus on market access and financial services while Tanzania collaboration emphasizes government procurement and donor coordination.

Uganda partnerships leverage scientific collaboration while building manufacturing capabilities that serve regional markets. DRC engagement emphasizes humanitarian applications while building long-term commercial relationships through NGO partnerships and government engagement. Technology transfer programs begin with 2 countries in 2027-2028, expanding to 4 countries by 2040 while creating regional manufacturing networks that provide redundancy and market access. Quality harmonization ensures consistent standards while regulatory coordination streamlines approval processes across regional markets.

Continental and International Partnerships - Continental partnerships extend Rwanda's influence through Africa CDC collaboration, AVAREF leadership, and South-South cooperation initiatives that share expertise while building collective capabilities. International partnerships provide technology access while creating opportunities for global market expansion and intellectual property development.

Development partner coordination ensures aligned support while maximizing impact through coordinated investment and technical assistance. Private sector partnerships create commercial opportunities while providing access to expertise and market networks that support long-term sustainability and growth. This comprehensive implementation roadmap provides detailed guidance for systematic capability development while maintaining flexibility to adapt to changing circumstances and emerging opportunities, ensuring successful achievement of REPP objectives while building sustainable institutions that serve regional and continental pandemic preparedness needs.



24. TECHNICAL ACTION PLAN FOR MCM EXPANSION

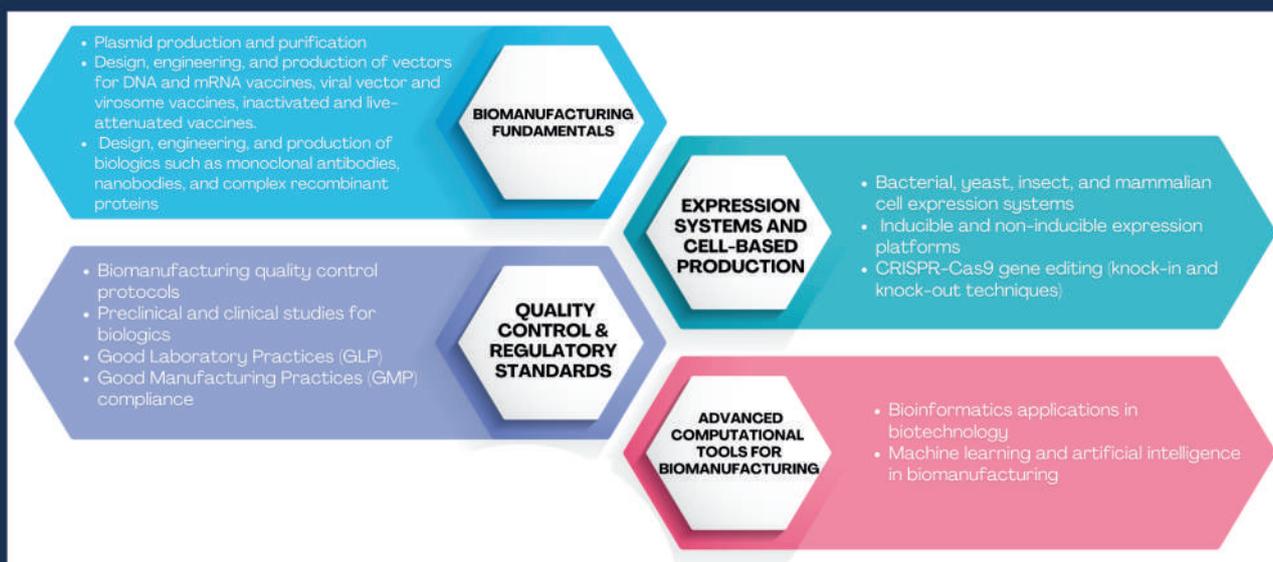
Rapid Response Unit Development and Emergency Capabilities

Emergency Response Capabilities

The Rapid Response Unit serves as the Rwanda Pandemic Innovation Hub's immediate deployment mechanism for emerging, re-emerging, or unknown pathogen X. This specialized unit maintains continuous readiness through pre-positioned expertise, validated protocols, and established supply chains, enabling 48-hour activation for any pandemic threat requiring urgent medical countermeasure development and deployment.

Core Response Functions include pathogen characterization within 24 hours using advanced diagnostic platforms, countermeasure selection from validated libraries or rapid development protocols, emergency manufacturing activation through pre-qualified systems, and immediate deployment through established distribution networks. The unit operates with dedicated personnel trained in emergency protocols while maintaining access to all Hub Component capabilities.

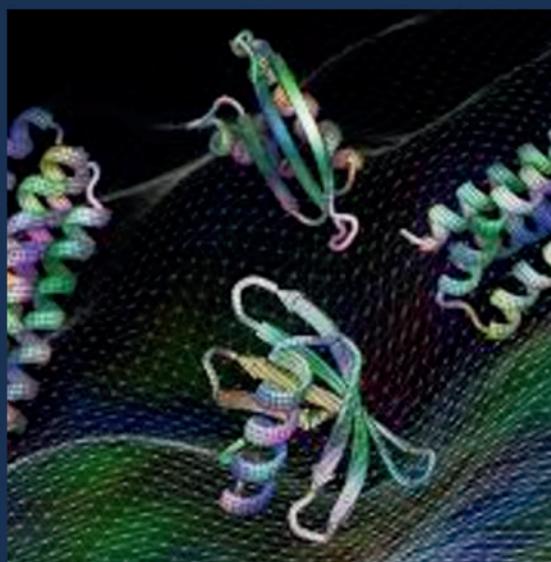
Technical Expertise Integration combines biomanufacturing fundamentals, including plasmid production, vector engineering, and biologics development, with advanced expression systems spanning bacterial, yeast, insect, and mammalian platforms. Thus, the following is the proposed ready-to-respond team of scientists that will be reskilled by international partners in biotechnology and bioengineering assays. Key topics will include:



Advanced Computational Integration

AI-Driven Response Systems employ machine learning algorithms for rapid pathogen analysis, countermeasure prediction, and deployment optimization. Bioinformatics applications support real-time genome analysis while artificial intelligence guides manufacturing decisions and resource allocation, ensuring optimal response speed and effectiveness.

Digital Twin Manufacturing enables rapid process optimization through virtual modeling of production systems. Computer simulations validate manufacturing parameters before physical production, while predictive algorithms optimize resource utilization and timeline compression, ensuring maximum efficiency during emergency response.





Initial Vaccine Manufacturing Strategy

Platform Technology Integration

Rwanda's vaccine manufacturing strategy establishes comprehensive capabilities across all major platform types through strategic partnerships and technology transfer agreements. mRNA platforms utilize BioNTech partnerships for immediate capability while developing indigenous expertise through the University of Rwanda collaboration.

Live-attenuated and inactivated vaccine capabilities address traditional platform requirements while **protein-based platforms** provide additional development options. Manufacturing capacity targets 50+ million doses annually across all platforms with surge capability reaching 75+ million during emergency conditions through optimized production scheduling and resource allocation.

CEPI Portfolio Implementation

Priority Pathogen Vaccines focus on CEPI-identified threats, including Chikungunya, Ebola, Lassa fever, MERS, Mpox, and Rift Valley fever, with particular emphasis on African-relevant pathogens. Initial manufacturing emphasizes proven platforms while developing next-generation approaches for enhanced efficacy and stability.

Technology Diversification Strategy ensures manufacturing capability across live-attenuated vaccines for Chikungunya and Rift Valley fever, inactivated virus platforms for emergency use, protein-based vaccines for COVID-19 variants, mRNA platforms for rapid response capability, and viral vector systems for established efficacy. Each platform serves multiple pathogens, reducing development costs while maximizing manufacturing flexibility.

Regional Production Coordination

EAC Technology Transfer establishes manufacturing capabilities in partner countries through coordinated development programs. Rwanda serves as a technology hub while Kenya, Uganda, and Tanzania develop complementary capabilities, ensuring regional manufacturing resilience and market coverage.

Quality Standardization ensures consistent product quality across regional manufacturing through shared protocols, joint training programs, and coordinated quality assurance. WHO prequalification pathways coordinate across regional facilities while regulatory harmonization streamlines approval processes.

Initial Diagnostic Manufacturing Strategy

Comprehensive Diagnostic Portfolio

Diagnostic manufacturing strategy addresses early detection requirements through rapid diagnostic tests, immunoassays, and genomic-based platforms targeting priority pathogens with particular emphasis on point-of-care deployment capabilities. Manufacturing targets 25+ million tests annually across multiple platforms with emergency surge capability reaching 40+ million tests.

Rapid Diagnostic Test Development focuses on antigen and antibody-based tests providing 15-30 minute results for field deployment. Manufacturing emphasizes temperature stability, long shelf life, and simplified use protocols enabling deployment in resource-limited settings without specialized equipment or training requirements.

Genomic Platform Integration develops PCR-based assays, isothermal amplification systems, and CRISPR-based detection for high-sensitivity pathogen identification. Point-of-care molecular platforms provide laboratory-quality results in field settings, while multiplex assays enable simultaneous detection of multiple pathogens.

Innovation and Quality Systems

Novel Diagnostic Development integrates biosensor technology, AI-enhanced analysis, and mobile platform connectivity for advanced diagnostic capabilities. Digital health integration enables real-time data transmission while AI algorithms enhance interpretation accuracy and clinical decision support.

Quality Management Implementation follows ISO 13485 standards with automated quality control, statistical process control, and comprehensive validation protocols. Quality systems ensure consistent performance, while regulatory compliance enables international market access through WHO prequalification and other approval pathways.

Regional Network Development

EAC Diagnostic Coordination establishes complementary manufacturing capabilities across regional partners, with Rwanda serving as the technology hub and quality coordinator. Standardized protocols ensure consistent performance while distributed manufacturing provides resilience and local market access.

Technology Transfer Programs share diagnostic manufacturing expertise with regional partners through training programs, technical assistance, and joint development projects. Regional diagnostic network provides 300+ million people while building indigenous technological capabilities.





25. MONITORING, EVALUATION, AND ADAPTIVE MANAGEMENT

Comprehensive Performance Monitoring Framework

Rwanda’s monitoring and evaluation system employs a results-based framework that tracks progress across strategic objectives while enabling adaptive management based on real-time performance data and changing circumstances. The system balances quantitative metrics with qualitative assessments that capture both operational performance and strategic impact across health security, economic development, and regional leadership dimensions.

Key Performance Indicators and Target Framework - Performance measurement organizes around three strategic objective areas with specific, measurable, achievable, relevant, and time-bound (SMART) indicators that enable objective assessment while providing actionable insights for management decision-making and strategic adjustments.

Anticipate and Align Performance Metrics: Surveillance effectiveness measures 95% outbreak prediction accuracy through AI-powered threat detection systems that process 10,000+ daily data points from integrated One Health sources. Response activation timing targets sub-48-hour activation across EAC member states while coordination effectiveness assessment evaluates inter-sectoral collaboration and resource sharing across human, animal, and environmental health systems.

Regional integration indicators track cross-border surveillance coordination, shared protocol implementation, and joint response capability development across East African Community partners. Early warning system performance measures detection sensitivity, false positive rates, and prediction timeline accuracy, while response coordination metrics assess mobilization speed and resource deployment effectiveness.

Innovate and Accelerate Performance Metrics: Research and development productivity measures medical countermeasure development capability through validated development timelines from pathogen identification to clinical deployment readiness. Innovation output tracking includes patent applications, intellectual property generation, technology transfer agreements, and collaborative research publications that demonstrate scientific advancement and knowledge creation.

Regulatory excellence metrics track WHO ML4 achievement and maintenance while measuring emergency authorization timeline performance against 7-day targets during health emergencies. Quality metrics encompass manufacturing compliance, product quality indicators, and international certification achievements that demonstrate operational excellence and market competitiveness.

Manufacture and Mobilize Performance Metrics: Production capacity measures annual vaccine production reaching 50+ million doses while diagnostic manufacturing achieves 25+ million tests annually across multiple platforms. Self-reliance indicators track 70% independence in finished medical products while regional distribution metrics measure 72-hour delivery capability across all EAC countries.

Economic impact assessment includes revenue generation targeting \$650+ million annually, employment creation reaching 2,000+ direct high-skilled positions, and foreign exchange benefits exceeding \$400+ million through exports and import substitution. Market penetration tracking measures customer satisfaction, market share growth, and competitive positioning across regional and international markets.

Data Collection and Management Systems - Data collection employs automated systems wherever possible while maintaining data quality and security standards that protect intellectual property and commercial information. Real-time dashboards provide management visibility while automated alerts enable rapid response to performance deviations and emerging challenges.

Integration with existing systems, including eIDSR, HMIS, and LIS, ensures comprehensive data coverage while minimizing additional data collection burden on operational personnel. Mobile data collection tools enable field-based monitoring while cloud-based systems provide secure access for stakeholders across multiple locations and institutions.





Evaluation Methodology and Assessment Framework

Systematic Evaluation Approach and Timeline Evaluation methodology combines internal monitoring with external assessment that provides objective performance evaluation and strategic guidance from independent experts. Annual evaluations assess progress against targets, while mid-term and final evaluations provide a comprehensive strategic assessment and recommendations for optimization and future development.

Internal evaluation processes include quarterly progress reviews, annual performance assessments, and continuous monitoring that enables real-time management adjustment and strategic optimization. External evaluations employ independent experts who provide objective assessments while offering strategic recommendations based on international best practices and comparative analysis. Stakeholder evaluation incorporates feedback from government partners, international collaborators, regional organizations, and beneficiary communities, which provides a comprehensive perspective on program impact and effectiveness. Customer satisfaction surveys, partner feedback sessions, and community consultations ensure responsive management that addresses stakeholder needs and expectations.

Impact Assessment and Outcome Evaluation - Impact assessment measures broader effects on health security, economic development, and regional capacity building that extend beyond direct program outputs to encompass systemic change and long-term sustainability. Health security impact includes reduced outbreak duration, improved response effectiveness, and enhanced regional preparedness capability.

Economic impact evaluation measures job creation, revenue generation, foreign exchange effects, and broader economic multiplier impacts that contribute to national development objectives. Social impact assessment includes community health improvements, educational advancement, and capacity building effects that create lasting benefits beyond direct program implementation. Regional impact evaluation assesses technology transfer effectiveness, capacity building outcomes, and collaborative relationship development that strengthens collective capabilities across East African Community partners. Continental impact measures include knowledge sharing, technical assistance provision, and leadership role development in African health security initiatives.

Adaptive Management and Continuous Improvement

Real-Time Adaptation and Strategic Flexibility - Adaptive management enables systematic learning and improvement through structured feedback loops that incorporate performance data, stakeholder input, and changing circumstances into ongoing strategy refinement and operational optimization. Management systems balance stability with flexibility while maintaining strategic focus and operational effectiveness. Performance review cycles include monthly operational reviews, quarterly strategic assessments, and annual comprehensive evaluations that enable systematic adaptation based on cumulative experience and changing conditions. Rapid response protocols address urgent issues while structured change management ensures stability during strategic adjustments.

Scenario planning and risk assessment inform adaptive strategies while contingency planning enables rapid response to unexpected challenges or opportunities. Strategic planning reviews incorporate lessons learned while maintaining long-term vision and strategic coherence across changing operational circumstances.

Learning Systems and Knowledge Management - Knowledge management systems capture lessons learned, best practices, and innovative approaches that inform continued improvement and enable knowledge sharing with regional and international partners. Documentation standards ensure systematic capture while knowledge-sharing platforms facilitate dissemination and collaborative learning.

Learning networks connect Rwanda's experiences with international best practices, creating opportunities for peer-to-peer learning and collaborative problem-solving. Communities of practice within Rwanda and across regional partners facilitate knowledge exchange while building collective expertise and collaborative relationships.

Innovation promotion encourages creative problem-solving while providing mechanisms for testing and scaling innovative approaches that improve performance and effectiveness. Innovation challenges and collaborative research initiatives stimulate creative solutions while building networks that support continued learning and development.





Accountability and Transparency Framework

Stakeholder Engagement and Communication - Transparency mechanisms include regular public reporting, stakeholder consultations, and open communication that builds public confidence while maintaining accountability to government, partners, and beneficiary communities. Reporting standards balance transparency with the protection of commercial and security-sensitive information.

Stakeholder engagement processes include government reporting, partner briefings, community consultations, and international updates that provide comprehensive communication while enabling feedback and input into ongoing strategy development. Communication strategies utilize multiple channels while ensuring accessibility and cultural appropriateness.

Public accountability mechanisms include parliamentary briefings, public forums, and media engagement that demonstrate responsible stewardship while building public support for continued investment and development. Academic partnerships enable independent research and analysis while contributing to global knowledge and best practice development.

Performance Accountability and Governance - Governance oversight includes ministerial supervision, parliamentary reporting, and international partner accountability that ensures responsible management while maintaining strategic autonomy and operational flexibility. Performance contracts establish clear expectations while providing flexibility for adaptive management and strategic optimization.

Financial accountability encompasses regular auditing, transparent reporting, and sound financial management that demonstrates responsible stewardship while enabling continued investment and support from government and international partners. Procurement transparency ensures competitive processes while maintaining commercial confidentiality where appropriate.

Regulatory compliance includes adherence to national and international standards while maintaining innovation capability and operational effectiveness. Quality assurance systems ensure consistent performance while enabling continuous improvement and adaptation based on operational experience and stakeholder feedback.

Continuous Quality Improvement and Excellence - Quality management systems encompass all aspects of operations from research and development through manufacturing and distribution, ensuring consistent excellence while enabling innovation and adaptation. International certification and recognition demonstrate achievement while providing external validation and market credibility. Professional development and capacity building ensure continued excellence while building indigenous expertise that reduces dependence on external technical assistance. Career development programs retain talent while building leadership capability that supports long-term sustainability and continued growth. Excellence recognition and awards acknowledge achievement while building morale and institutional pride that support continued performance and innovation. Benchmarking against international standards ensures competitive performance while identifying opportunities for continued improvement and excellence achievement.





26. RISK MANAGEMENT AND MITIGATION

Comprehensive Risk Assessment Framework

Rwanda’s risk management employs systematic identification, assessment, and mitigation of potential threats to REPP implementation and long-term sustainability. The framework addresses operational, financial, technical, market, and strategic risks while maintaining focus on pandemic preparedness objectives and regional health security priorities.

Strategic Risk Categories and Impact Assessment -

Risk assessment encompasses five primary categories that could impact implementation success and long-term sustainability: operational risks affecting day-to-day implementation, financial risks impacting funding and revenue generation, technical risks affecting research and manufacturing capabilities, market risks influencing commercial viability, and strategic risks affecting long-term positioning and regional relationships.

Operational risks include infrastructure failures, supply chain disruptions, personnel shortages, regulatory delays, and coordination challenges that could impair implementation timelines and capability development. Climate-related operational risks encompass extreme weather events, infrastructure damage, and supply chain disruptions that require specific mitigation strategies and contingency planning.

Financial risks include funding shortfalls, revenue shortfalls, currency fluctuations, cost overruns, and market competition that could impact financial sustainability and investment capability. Technical risks encompass technology failures, development delays, quality issues, intellectual property challenges, and competitive technology advancement that could affect technical capability and market positioning.

Market risks include demand fluctuations, competitive pressure, regulatory changes, customer concentration, and international market access restrictions that could impact revenue generation and commercial sustainability. Strategic risks encompass regional relationship changes, international partnership disruptions, policy changes, and geopolitical developments that could affect long-term positioning and strategic objectives.

Risk Probability and Impact Assessment Methodology -

Risk assessment employs quantitative and qualitative methods that evaluate probability and potential impact across short-term implementation and long-term sustainability timeframes.

High-impact, high-probability risks receive priority attention while comprehensive mitigation strategies address all identified risks through systematic planning and resource allocation.

Probability assessment utilizes historical data, expert judgment, and scenario analysis that consider both internal factors under Rwanda’s control and external factors influenced by regional and global developments. Impact assessment quantifies potential effects on implementation timelines, financial performance, technical capability, and strategic objectives while considering cascading effects and interdependencies.

Risk monitoring employs key risk indicators that provide early warning of emerging threats while enabling proactive mitigation before risks materialize into actual problems. Regular risk assessment updates incorporate changing circumstances and emerging threats while maintaining current and actionable risk management strategies.

Climate and Environmental Risk Management

Climate Vulnerability and Adaptation Strategies Climate risk management addresses projected environmental changes that could impact operations, supply chains, and pathogen emergence patterns while building resilience that maintains operational capability under changing conditions. Temperature increases of 2-4°C above current averages require enhanced cooling systems and climate-controlled facilities that maintain product quality and operational effectiveness.

Precipitation variability of ±20% necessitates flood protection, drainage systems, and water security measures that ensure continued operation during extreme weather events. Infrastructure design incorporates climate projections, while adaptation strategies address both gradual climate change and extreme weather events that could disrupt operations.





Financial Risk Management and Sustainability Assurance

Revenue Diversification and Market Risk Mitigation - Financial risk mitigation employs comprehensive strategies that address revenue volatility, market competition, and macroeconomic factors that could impact financial sustainability. Revenue diversification across geographic markets, customer segments, and product categories reduces concentration risk while providing resilience during market downturns or competitive challenges.

Geographic distribution targets 60% EAC, 25% broader Africa, and 15% international markets that provide market diversification while maintaining focus on African priorities and regional service. Product portfolio allocation of 45% vaccines, 20% diagnostics, 25% therapeutics, and 10% services creates balanced revenue streams with different risk profiles and market dynamics. Customer base diversification includes 55% government contracts, 30% private sector sales, and 15% international organization partnerships that reduce dependence on single customer segments while providing revenue stability through diverse purchasing patterns and budget cycles.

Currency and Operational Cost Management - Currency management employs 70% local sourcing strategies that reduce foreign exchange exposure while supporting regional economic development through local procurement and supplier development. Financial hedging instruments address remaining currency exposure while maintaining flexibility for operational optimization and cost management.

Cost management includes inflation protection through supplier agreements, efficiency improvement through operational optimization, and competitive positioning through cost leadership and value differentiation. Working capital management optimizes cash flow while maintaining adequate liquidity for operational requirements and strategic investment. Investment risk management includes portfolio diversification, due diligence processes, and performance monitoring that protect invested capital while generating appropriate returns for continued investment and capacity development. Financial reserves provide contingency funding while credit facilities ensure adequate liquidity during revenue fluctuations or unexpected expenses.

Operational and Technical Risk Mitigation

Supply Chain Resilience and Redundancy - Supply chain risk management develops redundant sourcing, strategic stockpiles, and alternative supply networks that maintain operational capability during disruptions. Supplier diversification includes multiple sources for critical materials, while supplier development programs build regional capabilities that reduce import dependence and transportation risks.

Strategic stockpiles maintain a six-month inventory for critical materials while rotation protocols ensure product quality and freshness. Climate-controlled storage maintains product integrity, while distributed storage locations provide redundancy against localized disruptions and transportation challenges.

Transportation diversification employs multiple routes and transportation modes, including road, rail, air, and lake transport, that provide alternatives during infrastructure disruptions. Real-time tracking systems monitor shipments, while automated contingency activation ensures rapid response to transportation delays or disruptions.

Technology, Innovation, and Risk Management - Technology risk mitigation includes platform diversification, technology backup systems, and continuous innovation investment that maintains competitive positioning while addressing technology obsolescence and competitive advancement. Platform flexibility enables adaptation to changing technology, while backup technologies provide alternatives during primary technology failures or limitations.

Intellectual property protection includes patent filing, trade secret management, and technology licensing that protect innovations while enabling commercial utilization and revenue generation. Technology transfer agreements provide access to advanced technologies while building indigenous capabilities that reduce dependence on external technology sources. Quality assurance systems ensure consistent product quality while maintaining compliance with international standards and regulatory requirements. Quality control includes real-time monitoring, statistical process control, and comprehensive testing that identifies issues before they affect product quality or customer satisfaction.





Human Capital and Institutional Risk Management - Human resource risk management addresses talent retention, succession planning, and capacity building that maintains institutional capability while reducing dependence on individual expertise. Competitive compensation and career development programs retain key personnel while succession planning ensures leadership continuity and institutional knowledge preservation.

Training and development programs build institutional capability while reducing dependence on external expertise and technical assistance. Knowledge management systems capture institutional knowledge while creating redundancy and institutional memory that supports continued capability and performance.

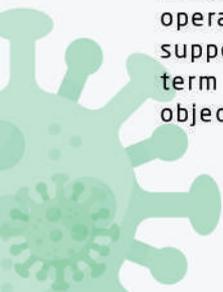
Institutional risk management includes governance systems, risk management policies, and compliance frameworks that ensure effective management while maintaining accountability and transparency. Regular policy review and institutional assessment identify areas for improvement while maintaining effectiveness and stakeholder confidence.

Crisis Management and Business Continuity - Crisis management protocols address emergency situations including natural disasters, security threats, health emergencies, and operational disruptions that could impact capability and performance. Emergency response protocols include evacuation procedures, communication systems, and coordination mechanisms that protect personnel while maintaining essential functions.

Business continuity planning includes alternative operation sites, backup systems, and rapid recovery protocols that minimize disruption while maintaining service to customers and partners. Essential function identification prioritizes critical capabilities while resource allocation ensures continued operation during reduced capacity situations.

Recovery planning includes damage assessment, reconstruction procedures, and capability restoration that enable rapid return to full operational capability following disruptions. Insurance coverage protects against major losses while financial reserves enable continued operation and recovery investment during crisis situations.

This comprehensive risk management framework ensures systematic identification, assessment, and mitigation of potential threats while maintaining operational effectiveness and strategic focus that supports successful REPP implementation and long-term sustainability serving regional health security objectives and continental leadership aspirations.



5

FORWARD-LOOKING IMPACT





27. STRATEGIC SIGNIFICANCE AND CALL TO ACTION

Transformational Impact on Continental Health Security

The Rwanda Epidemic and Pandemic Preparedness Plan (REPP) represents a paradigm shift that transforms Africa from a continent dependent on external medical countermeasures to a self-reliant region capable of protecting 300+ million people through indigenous capabilities. This transformation extends far beyond Rwanda's borders, establishing a new model for health security independence that demonstrates African innovation, scientific excellence, and economic viability.

Redefining Africa's Health Security Paradigm - REPP fundamentally alters the narrative of African health security from reactive dependence to proactive leadership. By 2040, Rwanda will demonstrate that African countries can achieve world-class standards in medical countermeasure development while serving regional populations more effectively than traditional suppliers. The 72-hour delivery capability versus 2-4 weeks from external sources exemplifies the operational advantages of regional self-reliance.

This paradigm shift creates ripple effects across the continent as other countries recognize the economic and security benefits of indigenous capabilities. Rwanda's success provides a replicable model while technology transfer programs accelerate regional adoption. The demonstration effect motivates continental investment in health security infrastructure while building political support for African-led solutions.

Economic Sovereignty and Value Creation - The transformation of pandemic preparedness from a cost center into a \$650+ million annual revenue generator demonstrates the economic potential of health security investment. This approach converts healthcare spending from a foreign exchange drain into domestic value creation while generating high-skilled employment and export revenue that strengthens national economic resilience.

Regional economic integration through medical countermeasure production creates new value chains while reducing collective import dependencies. The \$1.73 billion regional import substitution opportunity represents significant foreign exchange savings while building industrial capabilities that support broader economic development objectives across East Africa.

Scientific Excellence and Innovation Leadership

Establishing Rwanda as a Regional Innovation Hub - Rwanda's scientific infrastructure investment positions the continent as a contributor to rather than a consumer of global health innovation. The \$200 million Scientific Infrastructure creates research capabilities that rival global institutions while addressing African priorities often neglected by international research agendas.

Indigenous research capabilities enable African scientists to lead investigations into African health challenges while building intellectual property that generates long-term value. Patent development and technology licensing create sustainable revenue streams while establishing Rwanda as an innovator rather than a technology recipient.

Building Continental Scientific Capacity - Training programs serving 500+ continental personnel annually create networks of expertise that multiply Rwanda's impact across Africa. Graduate and postgraduate education programs produce the next generation of African scientists while international partnerships provide access to cutting-edge knowledge and methodologies.

Regional research collaborations address shared challenges while building collective capabilities that strengthen continental health security. South-South cooperation extends beyond Africa to build relationships with other developing regions facing similar challenges and opportunities.





Climate Resilience and Environmental Leadership

Demonstrating Climate-Adaptive Development - REPP's climate resilience integration demonstrates how developing countries can build infrastructure that adapts to rather than merely copes with environmental changes. Climate-controlled facilities, renewable energy integration, and environmental monitoring create operational models applicable across sectors and countries facing similar challenges. The One Health approach addresses interconnections between human, animal, and environmental health while building surveillance systems that anticipate rather than react to climate-related health risks. This integrated approach provides early warning capabilities while informing adaptation strategies that protect populations and economic investments.

Environmental Sustainability as Competitive Advantage - Sustainable manufacturing processes and circular economy principles reduce operational costs while minimizing environmental impact. These approaches demonstrate that environmental responsibility enhances rather than constrains economic competitiveness while building reputation advantages in increasingly sustainability-conscious global markets. Carbon-neutral manufacturing and renewable energy integration position Rwanda as an environmental leader while reducing operational vulnerabilities to energy price fluctuations and supply disruptions. Environmental certification creates market advantages while demonstrating commitment to global sustainability objectives.

Regional Integration and South-South Cooperation

Catalyzing Regional Health Security Integration - Rwanda's leadership will catalyze broader East African Community integration around health security while demonstrating the benefits of regional cooperation over national isolation. Technology transfer programs build complementary capabilities while avoiding unnecessary duplication and resource waste. Regional distribution networks and emergency response protocols create collective security while individual country investments multiply through collaboration. Regulatory harmonization reduces barriers while maintaining safety standards, creating economies of scale that benefit all regional partners.

Pioneering South-South Development Models - REPP will establish Rwanda as a leader in South-South cooperation while creating partnerships with other middle-income countries that have successfully developed biotechnology capabilities. These relationships provide technology access while creating opportunities for collaborative innovation and mutual capacity building. The model demonstrates that developing countries can achieve technological sovereignty through strategic investment, international partnerships, and systematic capability building. Success creates demonstration effects while building confidence in indigenous development approaches across the Global South.

Call to Action: Partnership for African Health Independence

Invitation to Regional Governments - Regional governments are invited to join Rwanda in building collective health security capabilities through coordinated investment, technology sharing, and collaborative development. Partnership opportunities include complementary manufacturing specialization, joint procurement initiatives, and shared research and development programs that optimize resource utilization while building redundancy. The East African Community framework provides existing mechanisms for coordination, while bilateral partnerships enable customized collaboration based on individual country capabilities and priorities. Regional integration creates markets sufficient to support viable biotechnology industries while building collective negotiating power in international partnerships.

Appeal to International Development Partners - International development partners are invited to support African health security independence through funding, technology transfer, and capacity building partnerships that create sustainable capabilities rather than perpetual dependence. Partnership models should emphasize knowledge transfer, institutional development, and long-term sustainability rather than short-term assistance. Technical partnerships provide access to cutting-edge technologies while building indigenous capabilities that enable continued innovation and development. Financial partnerships should support infrastructure development and capacity building while creating pathways to commercial sustainability and reduced dependence on external funding.





Engagement with Private Sector and Innovation Partners - Private sector partners are invited to participate in building African biotechnology capabilities through technology transfer, joint ventures, and market development partnerships that create mutual value while addressing African health priorities. Commercial partnerships should balance profit motives with developmental impact while creating sustainable business models.

Innovation partnerships with research institutions, biotechnology companies, and development organizations create opportunities for collaborative research while building African scientific capabilities. Intellectual property arrangements should support technology transfer while protecting innovations and creating incentives for continued collaboration.

The Imperative for Immediate Action

The Window of Opportunity - The current global focus on pandemic preparedness creates unprecedented opportunities for African countries to build indigenous capabilities with international support and cooperation. Funding mechanisms, including the Pandemic Fund, CEPI initiatives, and bilateral partnerships, provide resources while global recognition of distributed manufacturing needs creates political support.

This window of opportunity requires immediate action to secure funding, establish partnerships, and begin capability development before international attention shifts and resources become less available. Delayed action risks missed opportunities, while early action positions African countries as leaders rather than followers in global health security development.

Building on Current Momentum - Rwanda's proven capabilities in health system development, emergency response, and international cooperation provide unique foundations for pandemic preparedness leadership. Recent successes, including the Marburg outbreak response, demonstrate technical capabilities, while international recognition creates credibility and partnership opportunities.

Current investments in education, research, and infrastructure create synergies while existing partnerships provide pathways for expansion and deepening. Building on current momentum requires systematic capability development while maintaining strategic focus and operational excellence that demonstrates continued trustworthiness and competence.

The Urgency of Health Security Independence - Future pandemics are inevitable while current vulnerabilities remain unaddressed through traditional approaches based on external dependence and reactive responses. African health security independence represents both a moral imperative and a practical necessity for protecting populations while building economic resilience.

The choice between continued dependence and strategic independence determines Africa's future resilience, prosperity, and dignity in global health security arrangements. Action today creates capabilities that protect future generations while building economic opportunities that support continued development and prosperity.

Mobilization of African Diaspora and Leadership - African diaspora professionals are invited to contribute expertise, networks, and resources to continental health security development through professional engagement, technology transfer, and capacity building initiatives. Diaspora engagement creates knowledge bridges while building networks that support long-term collaboration and development.

Continental leadership, including African Union, Africa CDC, and regional organizations, are called upon to provide policy support, coordination mechanisms, and resource mobilization that accelerate African health security independence while building on existing frameworks and initiatives.





28. CONCLUSION

REPP as the Foundation for Africa's Health Security Future

The Rwanda Epidemic and Pandemic Preparedness Plan represents more than a national strategy: It embodies Africa's determination to achieve health security independence while demonstrating that developing countries can build world-class capabilities that serve both national and global interests. Through systematic investment in infrastructure, human capital, and institutional development, Rwanda positions itself as the catalyst for continental transformation in pandemic preparedness and health security. REPP's integrated approach addresses the full spectrum of pandemic preparedness requirements from early detection through manufacturing and deployment, while building sustainable science-driven economic value that supports long-term capability maintenance and expansion. The three-pillar strategy of (i) Anticipate and Align, (ii) Innovate and Accelerate, and (iii) Manufacture and Mobilize, create comprehensive capabilities while generating revenue streams that ensure financial sustainability and continued innovation.

Proven Foundations for Sustainable Success

Rwanda's proven track record in health system development, emergency response, and international cooperation provides a credible foundation for ambitious pandemic preparedness objectives. The successful management of multiple health emergencies, including COVID-19 and the 2024 Marburg outbreak, demonstrates technical capabilities while building confidence among international partners and regional collaborators. The systematic approach to infrastructure development, human capital formation, and institutional building reflects Rwanda's proven methodology for achieving ambitious development objectives while maintaining fiscal responsibility and operational excellence. International recognition, including WHO ML3 regulatory status, provides validation while creating pathways for continued advancement and global integration.

Comprehensive Impact Across Multiple Dimensions

Health Security Transformation - By 2040, Rwanda will serve 300+ million people across East Africa through comprehensive medical countermeasure coverage while achieving 70% self-reliance in finished medical products. The 48-hour threat detection capability, combined with countermeasure development, creates unprecedented regional preparedness while establishing Rwanda as Africa's health security anchor. Regional technology transfer and capacity building multiply Rwanda's impact while building collective capabilities that strengthen continental health security. Training programs, technical assistance, and collaborative research create sustainable networks while reducing regional dependencies on external support and expertise.

Economic Development and Job Creation - The transformation of pandemic preparedness into a revenue-generating ecosystem creates \$650+ million annual economic value while generating 2,000+ high-skilled positions that support knowledge economy development. Foreign exchange benefits exceeding \$400+ million annually through exports and import substitution strengthen national economic resilience while contributing to regional economic integration. Innovation economy development through research and development investment, intellectual property generation, and technology transfer creates long-term competitive advantages while positioning Rwanda among global biotechnology leaders. Economic multiplier effects exceeding \$1.5 billion annually demonstrate broader developmental impact beyond direct program benefits.

Scientific Excellence and Innovation Leadership - Scientific infrastructure investment of \$200 million establishes world-class research capabilities that contribute to global knowledge while addressing African priorities often neglected by international research agendas. Patent development and technology licensing create intellectual property assets while building Rwanda's reputation as an innovator rather than a technology recipient. Regional and continental capacity building through training programs, collaborative research, and technical assistance extends Rwanda's scientific impact while building networks that support continued innovation and knowledge sharing. International partnerships provide access to cutting-edge technologies while creating opportunities for collaborative research and mutual capacity building.





Climate Resilience and Environmental Leadership

REPP's climate adaptation integration demonstrates how developing countries can build infrastructure that thrives under changing environmental conditions while contributing to global environmental sustainability. Climate-controlled facilities, renewable energy integration, and environmental monitoring create operational models applicable across sectors and countries facing similar challenges. The One Health approach addresses interconnections between human, animal, and environmental health while building surveillance systems that anticipate climate-related health risks. Carbon-neutral manufacturing and circular economy principles demonstrate that environmental responsibility enhances economic competitiveness while contributing to global sustainability objectives.

A Model for Global Health Security Cooperation

Rwanda's approach demonstrates that developing countries can achieve technological sovereignty through strategic investment, international partnerships, and systematic capability building while contributing to global health security rather than remaining dependent on external provision. This model creates demonstration effects while building confidence in indigenous development approaches across the Global South. South-South cooperation extends beyond Africa to build relationships with other developing regions facing similar challenges while creating opportunities for technology sharing, collaborative innovation, and mutual capacity building. These partnerships multiply development impact while reducing dependence on traditional North-South assistance relationships.

The Path Forward: From Vision to Reality

The implementation roadmap provides detailed guidance for transforming an ambitious vision into an operational reality through systematic capability development, strategic partnership building, and adaptive management that responds to changing circumstances while maintaining strategic focus and operational excellence. Success requires sustained commitment from government, international partners, and regional collaborators while maintaining flexibility to adapt strategies based on implementation experience and changing global circumstances. The modular implementation approach enables phased development while creating early operational capability that demonstrates progress and builds momentum for continued investment and support.

A Legacy of Health Security Independence

REPP creates lasting change that extends far beyond its implementation timeline by establishing institutional capabilities, human capital, and partnership networks that continue generating value for decades. The investment in scientific infrastructure, regulatory excellence, and manufacturing capabilities creates enduring competitive advantages while building a foundation for continued innovation and development. Future generations of Africans will inherit health security capabilities that protect their populations while providing economic opportunities and scientific leadership that contribute to global health security. This legacy represents Rwanda's contribution to continental development while demonstrating the potential for African leadership in addressing global challenges.

The Time for Action is Now

The convergence of global pandemic preparedness focus, international funding availability, and Rwanda's proven capabilities creates an unprecedented opportunity for achieving health security independence while contributing to continental transformation. This window of opportunity requires immediate action to secure resources, establish partnerships, and begin capability development that positions Rwanda as Africa's health security leader. The choice between continued dependence and strategic independence determines not only Rwanda's future health security but also its role in continental development and global health leadership. REPP represents Rwanda's commitment to health security independence while extending an open invitation to partners who share the vision of African health sovereignty and global health security cooperation. The foundation is established. The partnerships are forming. The resources are mobilizing. The time for Africa's health independence is now, with Rwanda leading the transformation that will define the continent's health security future for generations to come.

The future of African health security begins today with Rwanda's leadership and the collective commitment of partners who recognize that health security independence serves both African development and global health security objectives. Together, we build not just pandemic preparedness capabilities, but the foundation for a healthier, more prosperous, and more resilient Africa.





REFERENCES

1. Nyatanyi, T. et al. Influenza sentinel surveillance in Rwanda, 2008-2010. *J. Infect. Dis.* 206 Suppl 1, S74-79 (2012).
2. Binagwaho, A. et al. The human resources for health program in Rwanda--new partnership. *N. Engl. J. Med.* 369, 2054-2059 (2013).
3. Binagwaho, A. et al. Rwanda 20 years on: investing in life. *Lancet Lond. Engl.* 384, 371-375 (2014).
4. Carlson, J. M. et al. HIV transmission. Selection bias at the heterosexual HIV-1 transmission bottleneck. *Science* 345, 1254031 (2014).
5. Butera, Y. et al. Genomic sequencing of SARS-CoV-2 in Rwanda reveals the importance of incoming travelers on lineage diversity. *Nat. Commun.* 12, 5705 (2021).
6. Mutesa, L. et al. A pooled testing strategy for identifying SARS-CoV-2 at low prevalence. *Nature* 589, 276-280 (2021).
7. Tegally, H. et al. The evolving SARS-CoV-2 epidemic in Africa: Insights from rapidly expanding genomic surveillance. *Science* 378, eabq5358 (2022).
8. Butera, Y. et al. Genomic and transmission dynamics of the 2024 Marburg Virus Outbreak in Rwanda. *Nat. Med.* (2024) doi:10.1038/s41591-024-03459-9.
9. Kim, D.-K. et al. A proteome-scale map of the SARS-CoV-2-human contactome. *Nat. Biotechnol.* 41, 140-149 (2023).
10. Ortiz-de-Lejarazu, R. et al. Viral respiratory tract infections diagnosis: a Spanish survey and consensus approach. *Diagn. Microbiol. Infect. Dis.* 113, 116831 (2025).
11. Trepte, P. et al. AI-guided pipeline for protein-protein interaction drug discovery identifies a SARS-CoV-2 inhibitor. *Mol. Syst. Biol.* (2024) doi:10.1038/s44320-024-00019-8.
12. Marzi, A. & Feldmann, H. Ebola virus vaccines: an overview of current approaches. *Expert Rev. Vaccines* 13, 521-531 (2014).
13. O'Donnell, K. L. et al. Single-dose replicon RNA Sudan virus vaccine uniformly protects female guinea pigs from disease. *Nat. Commun.* 16, 4199 (2025).
14. Balakrishnan, A. et al. A CRISPR homing screen finds a chloroquine resistance transporter-like protein of the Plasmodium oocyst essential for mosquito transmission of malaria. *Nat. Commun.* 16, 3895 (2025).
15. Yizhak, K., Gabay, O., Cohen, H. & Ruppin, E. Model-based identification of drug targets that revert disrupted metabolism and its application to ageing. *Nat. Commun.* 4, 2632 (2013).
16. Cheng, K. et al. Genome-scale metabolic modeling reveals SARS-CoV2-induced metabolic changes and antiviral targets. *Mol. Syst. Biol.* 17, e10260 (2021).
17. Xia, W., Mao, Y., Xia, Z., Cheng, J. & Jiang, P. Metabolic remodelling produces fumarate via the aspartate-argininosuccinate shunt in macrophages as an antiviral defence. *Nat. Microbiol.* 10, 1115-1129 (2025).
18. Ferruz, N., Schmidt, S. & Höcker, B. ProtGPT2 is a deep unsupervised language model for protein design. *Nat. Commun.* 13, 4348 (2022).
19. Knight, B. et al. Using machine learning models to predict the impact of template mismatches on polymerase chain reaction assay performance. *Sci. Rep.* 15, 16184 (2025).
20. Cui, H. et al. scGPT: toward building a foundation model for single-cell multi-omics using generative AI. *Nat. Methods* 1-11 (2024) doi:10.1038/s41592-024-02201-0.

