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# Deliverable 6.4

# Policy-oriented output report

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| **Deliverable No.** | D6.4 | **Due Date** | M18 |
| **Description** | This deliverable reviews key EU and African regulations on medical devices and environmental impact, assessing their applicability in resource-limited settings. It examines EU frameworks such as the IVDR, the Environmental Impact Assessment Directive, and the Waste Framework Directive, alongside WHO guidelines. Where African regulations are lacking, EU standards are proposed as reference. The deliverable concludes with a policy brief highlighting regulatory gaps and recommendations for harmonized and sustainable diagnostic implementation. | | |
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| 24/12/2025 | 0.4 | UGH | UGH reviewed the draft |
| 31/12/2025 | 1.0 | UCBM | First version ready |

# List of abbreviations

| Abbreviation | Definition |
|---|---|

| | |
|---|---|
| AFM | Atomic Force Microscopy |
| AI | Artificial Intelligence |
| AP | Associated Partner |
| ASSURED | Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free, Deliverable |
| BioGFET | Graphene Field-Effect Transistor Biosensor |
| BRD | BRIDG OÜ |
| CA | Consortium Agreement |
| CAD | Computer-Aided Design |
| CEN | European Committee for Standardization |
| CFS | Certificate on the Financial Statements |
| CLSI | Clinical and Laboratory Standards Institute |
| CoMUC | Certificate on the Compliance of Usual Cost Accounting Practices |
| COVID-19 | Coronavirus Disease 2019 |
| CRISP-DM | Cross-Industry Standard Process for Data Mining |
| Ct | Cycle Threshold |
| DMP | Data Management Plan |
| DNA | Deoxyribonucleic Acid |

| | |
|---|---|
| DPO | Data Protection Officer |
| DRC | Democratic Republic of the Congo |
| EBOV | Ebola Virus |
| ECA | European Court of Auditors |
| ECDC | European Centre for Disease Prevention and Control |
| EDCTP | European & Developing Countries Clinical Trials Partnership |
| EDV | Ebola Disease Virus |
| ELISA | Enzyme-Linked Immunosorbent Assay |
| EPF | European Patients' Forum |
| EPHA | European Public Health Alliance |
| EPPO | European Public Prosecutor's Office |
| EU | European Union |
| FAIR | Findable, Accessible, Interoperable and Reusable |
| FET | Field-Effect Transistor |
| FIWARE | Open-source platform for smart applications |
| GFAP | Glial Fibrillary Acidic Protein |
| GFET | Graphene Field-Effect Transistor |

| | |
|---|---|
| GDPR | General Data Protection Regulation |
| GH | Global Health |
| GP | Glycoprotein |
| ICT | Information and Communication Technologies |
| IEC | International Electrotechnical Commission |
| IFN-γ | Interferon-gamma |
| IgA | Immunoglobulin A |
| IgG | Immunoglobulin G |
| IgM | Immunoglobulin M |
| INRB | Institut National de Recherche Biomédicale |
| IoT | Internet of Things |
| IPC | Infection Prevention and Control |
| IPR | Intellectual Property Rights |
| ISO | International Organization for Standardization |
| IVD | In Vitro Diagnostic |
| KPI | Key Performance Indicator |
| LIB | Libelium LAB S.L. |

| | |
|---|---|
| LMICs | Low- and Middle-Income Countries |
| LoB | Limit of Blank |
| LoD | Limit of Detection |
| LoQ | Limit of Quantification |
| LSTM | Long Short-Term Memory |
| MDR | Medical Device Regulation |
| miRNA | Micro-RNA |
| MQTT | Message Queuing Telemetry Transport |
| MSCA | Marie Skłodowska-Curie Actions |
| NGO | Non-Governmental Organization |
| NGSI-LD | Next Generation Service Interfaces – Linked Data |
| NP | Nucleoprotein |
| OLAF | European Anti-Fraud Office |
| OSS | Open-Source Software |
| PAB | Project Advisory Board |
| PCB | Printed Circuit Board |
| PCR | Polymerase Chain Reaction |

| | |
|---|---|
| PHEIC | Public Health Emergency of International Concern |
| PM | Project Manager |
| PMB | Project Management Board |
| PoC | Point of Care |
| PoCT | Point-of-Care Testing |
| PPE | Personal Protective Equipment |
| QC | Quality Control |
| R&D | Research and Development |
| RNA | Ribonucleic Acid |
| RNN | Recurrent Neural Network |
| RT-PCR | Reverse Transcription Polymerase Chain Reaction |
| SEN | Sensitive |
| SME | Small and Medium-Sized Enterprise |
| SO | Specific Objective |
| SOP | Standard Operating Procedure |
| SVM | Support Vector Machine |
| TNF-α | Tumour Necrosis Factor-alpha |

| | |
|---|---|
| TRL | Technology Readiness Level |
| UCBM | Università Campus Bio-Medico di Roma |
| UCM | Universidad Complutense de Madrid |
| UGH | University of Ghana |
| UGR | Universidad de Granada |
| VP40 | Viral Protein 40 |
| WHO | World Health Organization |
| WP | Work Package |
| XPS | X-ray Photoelectron Spectroscopy |

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# Abstract

This deliverable presents the outcomes of Task 6.4 of the EPoCA project and documents the work carried out to support the ethical, legal and governance dimensions of the platform's development and future deployment. Building on the regulatory and ethical frameworks established in earlier project phases, the deliverable focuses on their progressive operationalisation within the project context and their alignment with evolving technical developments. The report covers activities conducted up to the current reporting period and reflects the transition from conceptual framework definition to structured application and internal validation.

During this phase, ethical, legal and data governance considerations were systematically assessed in relation to the technical architecture of the EPoCA platform, including data collection, processing and analysis workflows, AI-supported decision-making components and cross-border data use scenarios. Particular attention was paid to data protection requirements, accountability mechanisms and context-specific challenges associated with deployment in African settings. The work was supported through internal reviews, partner interactions and document analysis, allowing assumptions and safeguards to be examined against real project developments.

Rather than presenting final regulatory approvals or binding ethical decisions, this deliverable provides process-level evidence of implementation, highlighting how proposed mechanisms have been applied, tested and refined within the project. The outputs described here establish a coherent governance baseline that will support continuous monitoring, regulatory engagement and ethical oversight in subsequent project phases, ensuring ongoing alignment with European regulatory requirements while remaining responsive to contextual and societal considerations in target deployment environments.

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# Executive summary

Deliverable 6.4 reports on the work carried out under Task 6.4 of the EPoCA project to address the ethical, legal and governance aspects associated with the development and prospective deployment of the EPoCA diagnostic platform. Building on the regulatory and ethical foundations established in earlier deliverables, this report marks a further step toward the practical application and refinement of governance mechanisms within the project. The focus of this deliverable is on documenting activities undertaken during the reporting period and demonstrating how previously defined principles have been translated into operational processes.

Throughout this phase, the proposed governance mechanisms were applied internally to project activities, with particular emphasis on their interaction with technical and data-related developments. Ethical risks, legal obligations and data governance requirements were examined in relation to data flows, AI-enabled components and decision-support functionalities, as well as to cross-border data use and future deployment scenarios in African contexts. This work was informed by internal document reviews, structured partner consultations and cross-work package exchanges, enabling the identification of practical challenges and the refinement of safeguards to ensure proportionality, transparency and accountability.

The deliverable does not aim to provide final regulatory outcomes or ethical approvals, which are dependent on subsequent technical validation and external engagement. Instead, it offers structured evidence of processes, tools and decision-making pathways that are now operational within the project and capable of supporting continuous ethical oversight. These outputs contribute to a coherent and adaptive governance approach, providing a robust basis for ongoing monitoring, stakeholder engagement and regulatory interaction as the project progresses toward validation and implementation.

# Statement of originality

This deliverable contains original, unpublished work produced by the EPoCA consortium, except where clearly indicated otherwise. All sources of previously published material and contributions from third parties have been properly acknowledged through appropriate citation, quotation, or both, in accordance with academic and ethical standards.

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# 1. Regulatory Processes

Effective epidemic preparedness depends not only on the availability of innovative diagnostic technologies but also on the regulatory systems that enable their safe, rapid and equitable deployment. For point-of-care (PoC) diagnostics intended for high-threat pathogens such as Ebola, regulatory pathways determine how quickly tests can reach affected populations, the level of evidence required for their approval, and the mechanisms that govern their use during public-health emergencies.

Across regions, regulatory maturity varies widely. The European Union (EU) provides one of the most comprehensive frameworks for in vitro diagnostics, integrating strict performance, safety and post-market surveillance requirements. In contrast, many African countries are in the process of strengthening or harmonising their diagnostic regulatory systems, with growing support from continental initiatives such as Africa CDC (Centres for Disease Control and Prevention) and WHO (World Health Organization). Understanding these differences is essential for designing technologies like the EPoCA platform that must operate effectively across diverse regulatory environments.

This section analyses the regulatory needs for epidemic-prone diagnostics, reviews the relevant EU legislation, maps the regulatory landscape across African partner countries, and integrates international standards for emergency preparedness. It concludes with a comparative analysis to identify regulatory gaps, transferable elements and feasible pathways for rapid authorisation and safe deployment of PoC platforms in low-resource and high-risk settings.

## 1.1 Introduction to Regulatory Needs

**Diagnostic needs for epidemic-prone diseases**

Outbreaks caused by high-risk pathogens like Ebola bring very concrete diagnostic challenges. In real settings, early detection is often difficult, and tests must combine high sensitivity and specificity while still giving results fast enough to guide the response. On top of that, many laboratories working in emergencies operate with limited staff, equipment, or cold-chain capacity, so platforms need to function reliably under these constraints. Biosafety and waste handling also become everyday concerns during an outbreak, not abstract requirements. Finally, because pathogens evolve and new variants can appear unexpectedly, diagnostic tools must be easy to update or adapt so they remain useful throughout the entire response.

In practical terms, these needs translate into several operational requirements during an outbreak. Diagnostic tests must deliver results quickly (ideally within one to two hours) to support timely decisions on containment. They also need solid analytical performance and clinical validation in the local population, as false positives or negatives can have serious consequences in emergency settings. At the same time, the platforms must remain reliable under challenging environmental conditions, including heat, humidity or an unstable electricity supply, which are common in many field laboratories. Finally, clear biosafety procedures and safe waste management are essential to ensure that diagnostics can be deployed safely and effectively outside well-equipped facilities.

**Importance of regulatory strengthening for emergency preparedness**

Regulatory systems play a critical role in ensuring the quality, safety and effectiveness of diagnostic technologies, and in enabling rapid deployment during public-health emergencies. Weak or fragmented regulatory systems may delay product approval, allow the circulation of unvalidated tests, or hinder post-market quality oversight. Strengthening regulatory capacity includes both the technical ability to evaluate diagnostics and clear governance mechanisms for accelerated decision-making (e.g., emergency use authorisation, derogations, fast-track procedures).

When regulatory systems are robust and well-structured, they reduce the time between innovation and clinical availability, while increasing the confidence of healthcare workers and the general public in the diagnostics being deployed. Stronger regulatory frameworks also support more effective epidemiological surveillance and data interoperability, ensuring that diagnostic information can be reliably integrated into outbreak-response systems. In addition, they help prevent environmental and safety risks associated with the large-scale use and disposal of diagnostic devices during epidemics, ultimately enhancing both preparedness and health-system resilience.

### Overview of the EPoCA platform and regulatory relevance

The EPoCA platform is conceived as a modular point-of-care (PoC) diagnostic solution designed to enable rapid pathogen detection in epidemic contexts. It integrates hardware, reagents and data-processing software, placing it within the scope of both in vitro diagnostic (IVD) and medical device (MD) regulatory frameworks. From a regulatory perspective, the platform raises important considerations related to device classification, the nature and extent of analytical and clinical evidence required for approval, the management of software and algorithm updates, and the fulfilment of post-market obligations such as performance surveillance and the safe handling of diagnostic waste.

In this context, key regulatory aspects include determining the appropriate product classification and corresponding approval route, defining a robust analytical and clinical validation strategy applicable across diverse geographic and epidemiological settings, and ensuring compliance with interoperability, cybersecurity and personal data-protection requirements. It is also essential to establish comprehensive environmental and waste-management plans to support safe and sustainable large-scale deployment during outbreaks.

### Methodology for regulatory and comparative analysis

To map the regulatory landscape and conduct an EU–Africa comparative assessment, a mixed-methods approach will be applied:

1. **Document review:** analysis of international guidance (WHO), EU regulatory frameworks (IVDR/MDR), environmental directives and regional guidelines.
2. **Regulatory mapping:** identification of national requirements (evaluation procedures, emergency pathways, labelling and packaging rules, waste-management obligations).
3. **Surveys and interviews:** engagement with national regulatory authorities, regional bodies (Africa CDC), reference laboratories and private-sector stakeholders to capture practical experiences and barriers.

4. **Comparative analysis:** development of coherence matrices, identification of regulatory gaps and transferable elements, and assessment of feasibility for adoption in Low and Middle-Income Countries (LMICs).
5. **Validation:** workshops with key stakeholders to refine findings and recommendations.

The methodology is expected to generate several key outputs. First, it will produce a regulatory map for each country or region, outlining the applicable approval routes and providing indicative timelines for authorisation processes. It will also deliver a gap-analysis matrix that compares European and African regulatory systems, highlighting areas of divergence, structural weaknesses and opportunities for alignment. In addition, the work will lead to a set of actionable recommendations aimed at harmonising and strengthening emergency-use procedures across regions. Finally, the methodology will yield reproducible tools (such as a survey questionnaire and a methodological flowchart) that can support future regulatory mapping exercises and facilitate continuous updates.

## 1.2 European Regulatory Framework

The European regulatory landscape for diagnostics and medical technologies is defined by a comprehensive set of instruments that ensure product quality, safety, performance and environmental responsibility (Table 1). Two central regulations govern the assessment and market authorisation of medical devices and in vitro diagnostics, complemented by environmental directives that apply to manufacturing, deployment and end-of-life management. For a platform such as EPoCA, understanding the interplay among these instruments is essential to guarantee compliance, facilitate market entry and inform its potential applicability in non-EU settings.

Table 1 – Summary of EU Regulatory Instruments Relevant to EPoCA

| Instrument | Main focus | Relevance for EPoCA |
|---|---|---|
| **IVDR (EU) 2017/746** | Safety, performance and post-market surveillance of IVDs | Core regulatory framework for EPoCA diagnostic components, especially high-risk and digital diagnostics |
| **MDR (EU) 2017/745** | Safety and clinical evidence for medical devices | Applies to hardware and accessory components integrated into the EPoCA platform |
| **Environmental Impact Assessment Directive** | Environmental effects of manufacturing activities | Shapes sustainability requirements for production and industrial facilities |
| **Waste Framework Directive** | Waste prevention and hazardous waste management | Relevant for biological waste and single-use materials generated during use |
| **Emergency Authorisation Mechanisms** | Accelerated access during public-health emergencies | Enables rapid deployment of EPoCA in outbreak contexts |
| **EU Regulatory Coherence** | Integrated application of regulatory instruments | Requires a unified regulatory strategy across the EPoCA lifecycle |
| **Applicability Beyond the EU** | EU standards as international reference | Facilitates regulatory acceptance and deployment in African partner countries |

## In Vitro Diagnostic Medical Devices Regulation (IVDR)

The In Vitro Diagnostic Medical Devices Regulation (IVDR) (EU) 2017/746 [1] establishes the requirements for analytical and clinical evidence, performance evaluation, quality management, and post-market surveillance for all IVDs placed on the EU market. Under the IVDR, many diagnostics (especially those intended for high-risk pathogens) are classified into higher-risk classes, requiring notified body involvement, comprehensive technical documentation and continuous post-market performance follow-up. The regulation also emphasises traceability, laboratory validation and the integration of robust cybersecurity and software lifecycle controls, which are particularly relevant for digital or algorithm-based components of the EPoCA platform.

### Medical Devices Regulation (MDR)

The Medical Devices Regulation (MDR) (EU) 2017/745 [2] applies when PoC platforms incorporate hardware elements that fall under medical device classification rather than pure IVD scope. The MDR introduces strengthened requirements for clinical evidence, safety and risk management, as well as enhanced obligations for manufacturers regarding labelling, vigilance and post-market clinical follow-up. For modular or multi-component diagnostic solutions that integrate sensors, cartridges or accessory devices, the MDR may apply in parallel with the IVDR, requiring a clear determination of the device's principal intended purpose.

### Environmental Impact Assessment Directive and Waste Framework Directive

Beyond product performance and safety, EU environmental legislation also plays a significant role. The **Environmental Impact Assessment Directive** (2011/92/EU and amendments) [3] requires systematic evaluation of potential environmental effects associated with industrial facilities, including sites involved in diagnostic manufacturing or reagent production. While the directive does not regulate individual devices, it shapes the environmental obligations of producers, particularly regarding energy use, emissions and sustainable production processes. Complementing this, the **Waste Framework Directive** (2008/98/EC) [4] sets the foundations for waste management, promoting the waste hierarchy (prevention, reuse, recycling and safe disposal) and defining responsibilities for hazardous waste generated during diagnostic use. For outbreak-response diagnostics like EPoCA, considerations include the management of biological waste, single-use plastics and reagent cartridges under safe and environmentally responsible conditions.

### Coherence among EU regulatory instruments

Ensuring coherence among EU regulatory instruments is essential for complex diagnostic platforms that combine hardware, software and biological components. The IVDR, MDR and environmental directives operate under different scopes but must be applied in an integrated manner during product development, technical documentation and conformity assessment. Manufacturers must therefore establish a unified regulatory strategy that covers device classification, safety and performance demonstration, data protection obligations and environmental compliance from design to end-of-life.

### Emergency authorisation and crisis governance

The EU also maintains mechanisms for emergency authorisation and crisis governance, particularly relevant for outbreak-prone pathogens. During public-health emergencies, temporary derogations under the IVDR and MDR allow accelerated or conditional access to diagnostic devices when justified by urgent needs. The EU Health Emergency Preparedness and Response Authority coordinates crisis governance, supporting rapid assessment, supply-chain stabilisation and pooled procurement. These mechanisms ensure that high-priority diagnostics can be deployed more quickly while maintaining essential safety and performance safeguards.

### Applicability in non-EU contexts

Although EU legislation is binding only within EU and EEA countries, its applicability in non-EU contexts is significant. Many African countries reference EU regulatory standards, adopt elements of EU classification systems or rely on CE-marked diagnostics for national approval. Regional initiatives, including harmonisation programmes led by Africa CDC and several Regional Economic Communities, increasingly use the IVDR and MDR as benchmarks for strengthening their own regulatory frameworks. This makes EU regulations highly relevant for global health technologies intended for multi-country deployment.

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### Alignment of EPoCA with EU regulations

In this context, ensuring the alignment of the EPoCA platform with EU regulations is essential not only for potential EU market access but also for building credibility, facilitating regulatory acceptance in partner African countries and supporting future emergency-use pathways. Compliance with the IVDR and MDR, together with responsible environmental and waste-management practices aligned with EU directives, will help position EPoCA as a robust, high-quality diagnostic solution adaptable to diverse regulatory and operational environments.

## 1.3 African Regulatory Mapping

Mapping the regulatory landscape across African partner countries is essential to understand the diversity of approval pathways, identify opportunities for harmonisation and determine how PoC diagnostics such as EPoCA can be deployed efficiently during epidemics. Given that regulatory maturity varies widely across the continent, a structured and reproducible approach is required to capture country-specific processes, emergency-use mechanisms and institutional responsibilities (Figure 1).

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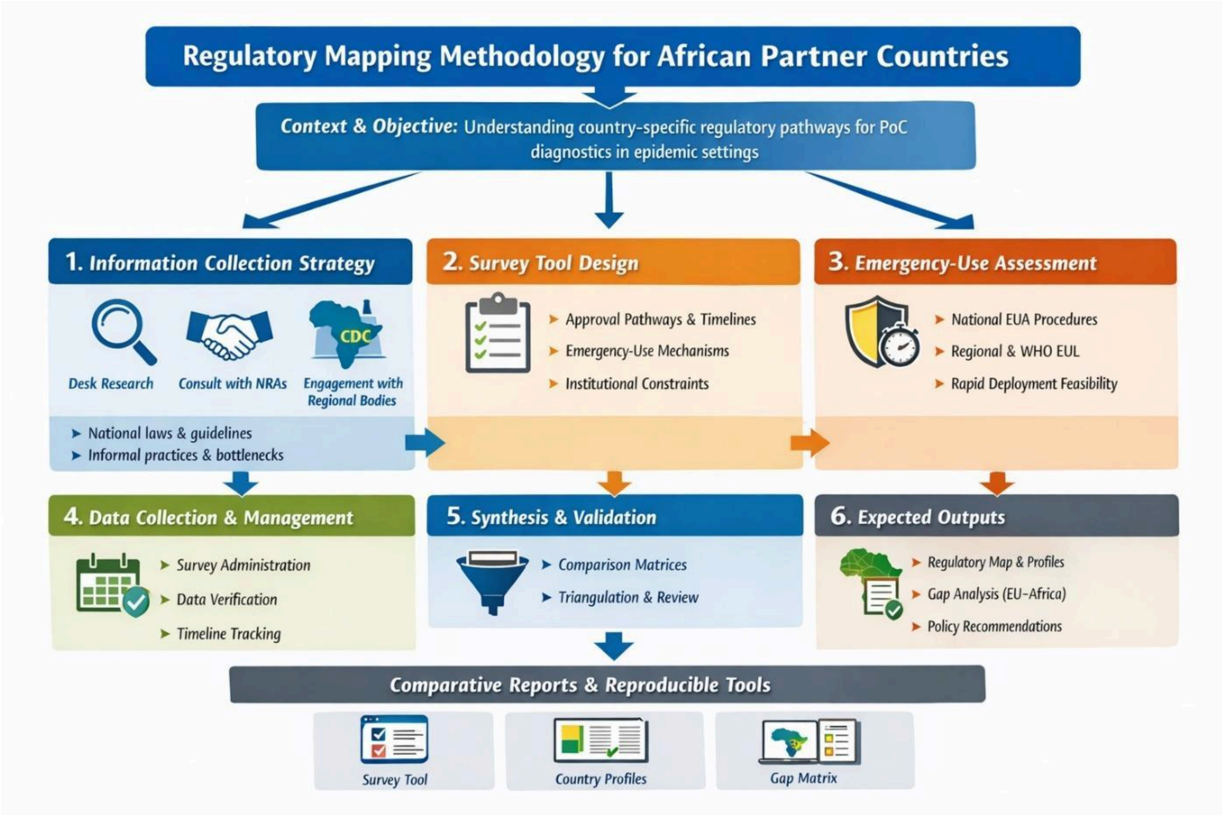


Figure 1 – African Regulatory Mapping Approach

### Strategy for collecting regulatory information

The strategy for collecting regulatory information combines desk research, targeted consultation with national regulatory authorities (NRAs) and engagement with regional bodies such as Africa CDC and regional economic communities. Desk research allows the consolidation of publicly available laws, guidelines and procedural documents, while direct communication with NRAs provides clarification on practical implementation, unofficial practices, bottlenecks and ongoing reforms. This mixed strategy ensures that both formal regulatory provisions and real-world procedures are captured.

### Survey tool design

A survey tool will be developed to collect harmonised information from participating countries. The questionnaire will cover diagnostic approval pathways, classification systems, documentation requirements, timelines, post-market obligations, emergency-use mechanisms, and administrative or institutional constraints. Its design will follow principles of clarity, comparability and flexibility, allowing responses from countries with varying degrees of regulatory complexity. The tool will also gather contextual information, such as availability of reference laboratories, surveillance infrastructure and reliance on international approvals (e.g., WHO prequalification, CE marking).

#### Assessment of emergency use procedures

A key component of the mapping exercise is the assessment of emergency-use procedures, including mechanisms for expedited review, derogations, conditional authorisation and reliance pathways during outbreaks. Many African NRAs operate accelerated procedures informally or through temporary national decrees; others rely on regional mechanisms such as the African Medicines Agency progression or WHO emergency use listing (EUL). Assessing these practices will help determine the feasibility of deploying platforms like EPoCA in emergency settings.

#### Data collection responsibilities and timeline

Clear responsibilities for data collection and timeline management will be established to ensure consistency across countries. National focal points or regulatory experts will be responsible for administering the survey, validating responses, and liaising with NRAs when clarification is needed. The overall timeline will include phases for survey dissemination, data retrieval, verification, follow-up interviews and final consolidation. Regular progress checkpoints will support the timely completion and accuracy of the mapping.

#### Method for synthesis and validation

The method for synthesis and validation will combine qualitative content analysis with cross-country comparison matrices. Data will be triangulated across sources, checked against national legislation and validated through direct communication with NRAs or regional authorities when necessary. The final synthesis will categorise regulatory systems according to maturity, clarity of processes, efficiency of emergency-use pathways and alignment with international standards.

#### Expected regulatory-mapping outputs

The exercise will generate several expected outputs, including a comparative regulatory map across African partner countries, detailed country profiles describing approval routes and timelines, and a matrix identifying gaps and convergence points relative to EU regulations. Additional outputs include practical recommendations to strengthen emergency-use mechanisms, and reproducible tools such as the survey questionnaire and methodological flowchart to support future regulatory assessments and updates.

## 1.4 International Regulatory Standards

This section is aligned with the principles outlined in Annex 3 of the WHO Global Model Regulatory Framework for Medical Devices, including In Vitro Diagnostic Devices (WHO, 2021) [5], which provides guidance on regulatory requirements, essential principles of safety and performance, and emergency-use considerations.

**WHO ASSURED criteria**

The WHO ASSURED criteria define the essential quality benchmarks for diagnostics intended for use in resource-limited settings:

> **ASSURED: A**ffordable, **S**ensitive, **S**pecific, **U**ser-friendly, **R**apid and Robust, **E**quipment-free (or minimal equipment), **D**eliverable to end users.

These criteria serve as a foundational reference for evaluating technologies suitable for decentralized and outbreak settings across African health systems. For this project, the ASSURED framework will be used to inform the selection and assessment of diagnostic tools and to ensure alignment with WHO priorities for equitable access.

**WHO outbreak preparedness regulatory guidance**

WHO provides emergency-focused regulatory guidance to support countries in rapidly deploying new diagnostics and medical technologies during public health emergencies. Relevant components include:

- Pathways for emergency use listing pavof diagnostics and IVDs.
- Guidance on risk-based regulatory evaluation during outbreaks.
- Recommendations for post-market surveillance and field performance monitoring in emergency contexts.

- Templates and norms supporting accelerated review while maintaining minimum safety and performance requirements.

This guidance will be integrated into the regulatory review strategy to ensure that the project aligns with international best practices for outbreak preparedness and response.

**Africa CDC strengthening initiatives**

Africa CDC is leading several initiatives aimed at harmonizing and strengthening regulatory capacity across the continent, including:

- The African Medicines Agency EUL operationalization framework.
- The Partnerships for African Vaccine Manufacturing gand associated quality systems strengthening.
- Efforts to standardize regulatory data sharing, mutual recognition, and joint dossier review among regional economic communities.
- Capacity-building programs targeting national regulatory authorities and laboratory networks.

These initiatives will inform the project's regulatory-mapping approach and help identify opportunities for alignment with ongoing continental regulatory reforms.

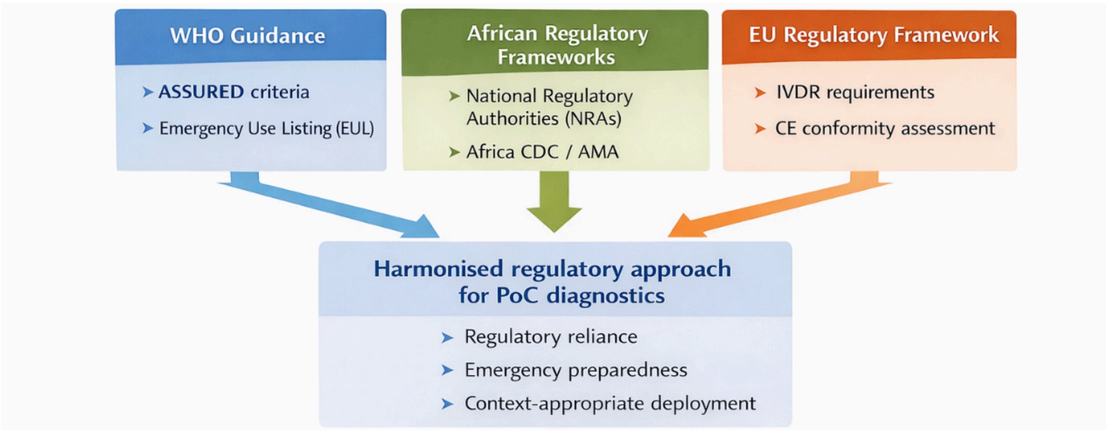


Figure 2 – Integration of WHO, EU and African regulatory frameworks for PoC diagnostics

**Integration of WHO, EU and African regulatory frameworks**

The regulatory evaluation will include a comparative analysis of WHO norms, EU IVDR requirements, and African regulatory frameworks at both national and continental levels. The objective of this analysis is to identify convergences and divergences in performance, safety, and quality requirements, and to map opportunities for regulatory reliance that enable African authorities to leverage WHO Prequalification, EU conformity assessments, and other trusted evaluations (Figure 2). In addition, the assessment aims to develop a harmonized interpretation of requirements that is relevant for diagnostics intended for use in African contexts, and to inform recommendations for streamlined regulatory pathways that support both local adoption and international market readiness. This integrated approach ensures that the regulatory strategy is globally informed while remaining context-appropriate and aligned with African public-health priorities.

## 1.5 Comparative Regulatory Analysis

A comparative assessment of EU and African regulatory frameworks through the lens of international WHO standards reveals both convergence and significant gaps, structural barriers, and opportunities for transferring robust regulatory elements. This analysis is particularly relevant for PoC/IVD platforms such as EPoCA, which are intended for deployment in diverse and resource-limited settings.

**EU vs. African regulatory gaps**

The EU regulatory framework, governed by Regulation (EU) 2017/746 (IVDR) for in vitro diagnostics [1] and Regulation (EU) 2017/745 (MDR) for medical devices [2], represents one of the most comprehensive and stringent systems globally, covering safety, performance, traceability, post-market surveillance, risk management, and technical documentation requirements. In contrast, many African countries still lack fully developed regulatory systems that comprehensively address these aspects. The WHO Global Model Regulatory Framework (GMRF) recognizes this heterogeneity and proposes a stepwise approach to implementing controls, beginning with basic regulations and advancing toward more complex systems.

Key gaps in African contexts often include the absence of binding legislation for IVDs, limited or under-resourced (NRAs), lack of systematic quality control, insufficient post-market surveillance, unclear authorization pathways, inadequate biomedical waste management, and the absence of standardized classification or traceability systems. These gaps create a mismatch with EU standards and pose risks to the safety, efficacy, and sustainability of IVD deployment without targeted regulatory strengthening.

### Transferable elements of EU regulation

Despite these differences, many elements of EU regulations recognized by WHO as good practices can be adapted for African contexts. These include risk-based classification and conformity assessment, quality management system (QMS) requirements, post-market surveillance mechanisms, traceability and unique device identification, and flexible reliance or recognition pathways allowing LMIC authorities to leverage WHO prequalification, CE marking, or other trusted evaluations. When adapted appropriately, these elements can strengthen regulatory capacity, support access to high-quality diagnostics, and ensure safety and efficacy in diverse deployment settings.

### Barriers to adoption in LMICs

Several structural barriers may hinder the transfer of EU regulatory elements into LMICs. Limited human and technical resources, insufficient laboratory infrastructure, lack of legislation, weak institutional capacity, high implementation costs, and limited regulatory expertise all impede full adoption. The GMRF proposes a phased, capacity-building approach to overcome these challenges, but implementation requires sustained investment, training, and international cooperation.

### EUA pathways relevant for PoC platforms

Emergency Use Authorization (EUA) pathways are critical for enabling rapid deployment of PoC platforms like EPoCA during public health crises. The WHO GMRF provides guidance on risk-based, staged approaches that allow reliance on prior assessments from trusted authorities. Such pathways enable urgent access to diagnostics with sufficient evidence of quality, performance, and safety, without requiring a full conventional regulatory review. For EPoCA, designing the platform in compliance with international standards (including technical documentation, validation, QMS, and traceability) would facilitate accelerated adoption in African countries through reliance-based or EUA pathways during outbreaks.

This analysis highlights a pronounced asymmetry between the advanced EU regulatory framework and the emerging regulatory systems in many African countries. Nonetheless, transferable elements exist, particularly those promoted by the WHO GMRF, that can serve as a bridge. Full adoption requires institutional commitment, resources, and a phased approach beginning with basic but robust regulations and evolving toward more sophisticated frameworks. For global health initiatives like EPoCA, this comparative strategy enables the design of a "universal" regulatory approach from the outset, compatible with both EU standards and the operational realities of LMICs, ensuring safe, effective, and sustainable deployment.

# 2. Health Technology Assessment

## 2.1 HTA Considerations for IVDs & PoC Devices

Health Technology Assessment (HTA) for IVDs and PoC devices must consider both **analytical and clinical performance**, as these are central to evaluating the reliability, accuracy, and overall utility of diagnostic technologies. Analytical performance includes measures such as sensitivity, specificity, precision, reproducibility, and robustness under real-world conditions, while clinical performance assesses the impact on patient outcomes, including the ability to detect disease early, guide treatment decisions, and support public-health interventions.

Equally important is the **policy relevance of rapid PoC diagnostics**, especially in contexts where timely decision-making can prevent outbreaks, reduce transmission, and optimize resource allocation. Rapid PoC tests enable decentralized testing in settings with limited laboratory infrastructure, improve access to diagnosis in remote or underserved areas, and facilitate faster clinical and public-health responses. From an HTA perspective, the assessment of PoC diagnostics therefore combines technical performance data with considerations of health-system integration, feasibility of implementation, and potential to address unmet clinical or epidemiological needs. By integrating these dimensions, HTA provides a comprehensive basis for policy-makers to make informed decisions regarding adoption, reimbursement, and deployment of PoC diagnostic technologies.

## 2.2 Environmental Impact Assessment

Environmental considerations are increasingly important in the assessment of IVDs and PoC devices, particularly given their widespread use during outbreaks. **Lifecycle analysis** provides a framework to evaluate the environmental footprint of these technologies, from raw material sourcing and manufacturing to distribution, use, and end-of-life disposal (Figure 3). This perspective is crucial for understanding the cumulative impact of diagnostic programs on ecosystems and public health, especially when devices are deployed at scale.

Outbreak scenarios generate substantial volumes of diagnostic waste, including single-use plastics, reagents, test cartridges, and potentially biohazardous material. Managing this waste presents significant challenges, particularly in LMICs, where waste collection, segregation, treatment, and disposal infrastructure may be limited. Inadequate waste management can lead to environmental contamination, occupational health risks for healthcare workers, and broader public-health concerns.

Developing **environmentally sustainable strategies** for PoC diagnostics in LMICs requires careful planning and innovation. Approaches may include designing devices with biodegradable or recyclable materials, optimizing supply chains to minimize packaging and transport emissions, implementing centralized or mobile waste-treatment solutions, and providing training to healthcare personnel on safe handling and disposal. Integrating these strategies from the outset helps ensure that rapid diagnostic deployment during outbreaks does not inadvertently create additional environmental or health risks, supporting both sustainable development and effective epidemic response.

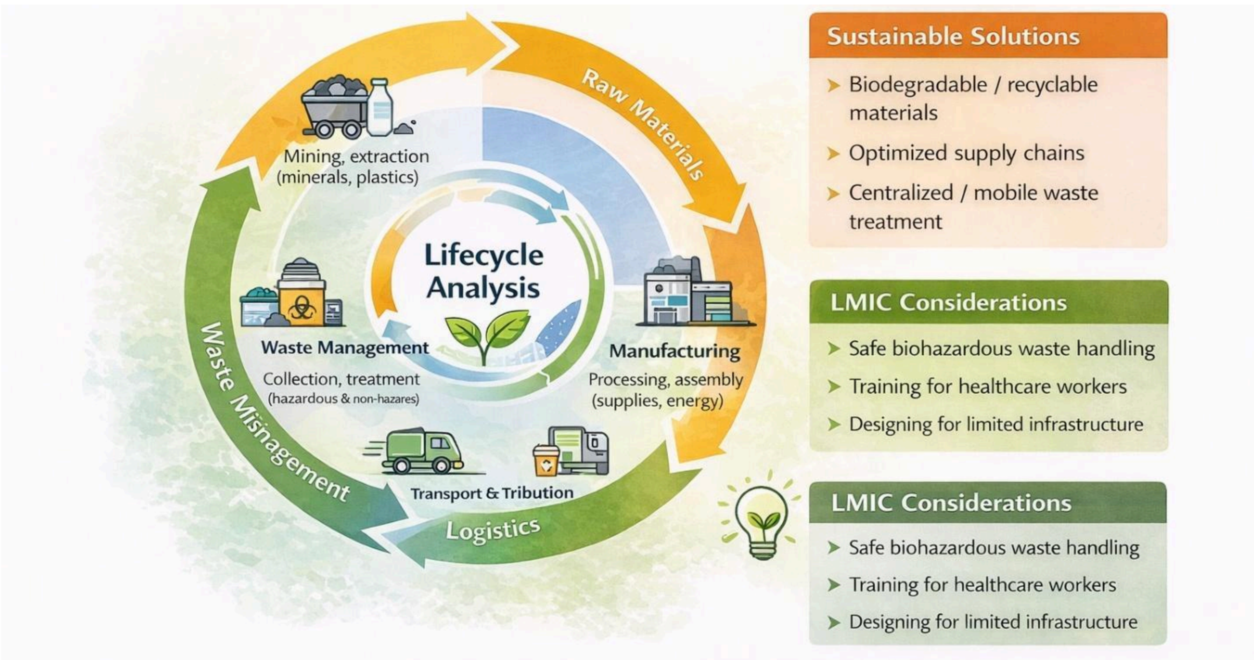


Figure 3 – Environmental Considerations for IVDs and PoC Diagnostics

## 2.3 Ethical, Data Governance and Societal Considerations

The adoption of IVDs and PoC technologies (particularly those incorporating digital components) raises a series of ethical, governance and societal considerations that must be addressed to ensure responsible and equitable implementation. **Data governance** is a central dimension, as PoC devices often collect personal or sensitive health information that must be handled in accordance with principles of privacy, informed consent, secure data storage, and responsible data-sharing. Ensuring robust cybersecurity and clear governance frameworks is essential to protect individuals' rights and maintain trust, especially in settings where legal protections or institutional capacities may be limited.

As algorithmic tools become increasingly integrated into diagnostic platforms, issues of **AI ethics and transparency** also become relevant. Algorithmic decision-making should be explainable, validated, and free from biases that could disproportionately affect certain populations. Clear documentation of algorithm updates, training datasets, and performance across diverse demographic and epidemiological contexts is essential to ensure accountability and fairness.

PoC diagnostics deployed during outbreaks also intersect with broader questions about **surveillance and civil liberties**. While rapid diagnostics can strengthen public-health response and epidemiological monitoring, they must be implemented in ways that avoid stigmatization, coercive testing practices, or disproportionate surveillance of vulnerable groups. Balancing public-health objectives with individual rights is essential to maintaining legitimacy and public confidence.

**Societal acceptability** is another key factor shaping the success of diagnostic interventions. Local perceptions of credibility, cultural norms around testing, and previous experiences with health authorities all influence uptake. Engagement with communities, transparent communication, and alignment with local values can support positive reception and sustained use.

**Operational feasibility in low-resource settings** must also be considered, as ethical principles are closely linked to practical realities. Limited infrastructure may constrain secure data handling, safe device operation, or proper waste disposal, creating ethical implications that extend beyond technical performance. Ensuring that deployment strategies account for these constraints (from training and maintenance to end-of-life disposal) is essential to safeguarding both users and the environment.

Taken together, these considerations highlight that ethical and governance dimensions are not separate from technical performance but integral to evaluating and deploying IVD and PoC technologies responsibly. A holistic approach ensures that innovations support public-health goals while respecting individual rights, community expectations, and environmental sustainability.

## 2.4 Economic Evaluation and Public Value Assessment

The economic evaluation of diagnostic technologies is essential to ensure that solutions are not only clinically effective but also financially viable and scalable across diverse health systems.

**Cost-effectiveness analyses** help determine whether a diagnostic intervention provides sufficient health benefits relative to its costs, particularly in the context of preparedness and response to public health threats. These evaluations consider direct costs (equipment, reagents, workforce) and indirect costs (training, infrastructure, supply chain resilience), offering insights into long-term sustainability.

In LMICs, **economic barriers** such as limited funding, fragmented procurement systems, and high dependency on imported diagnostic components can significantly hinder adoption. Assessing these constraints is crucial for identifying feasible, context-appropriate diagnostic solutions that can be implemented without compromising equity or access.

Beyond monetary considerations, evaluating the **public value of diagnostics** highlights their role in prevention and early detection, which can drastically reduce disease burden and healthcare expenditure. High-value diagnostics enable timely interventions, limit transmission, and improve outcomes by supporting data-driven decision-making at both clinical and population levels. Recognizing this broader societal value is key for prioritizing investments and integrating diagnostics into national preparedness strategies.

# 3. Health Technology Management

Effective health technology management is critical to translating diagnostic innovation into real-world impact, ensuring that devices not only meet regulatory standards and clinical needs but are also produced, supplied, and managed in ways that sustain health system resilience. In the context of epidemic preparedness, the capacity to innovate, manufacture, and distribute diagnostics such as PoC platforms determines the timeliness and equity of responses. This requires attention to global innovation ecosystems, cross-sector partnerships, industrial capabilities, and resilient supply chains that can withstand shocks and adapt to evolving health threats.

## 3.1 Innovation, Manufacturing and Supply Chain Ecosystem

The innovation and manufacturing landscape for IVDs and medical devices in the EU is characterised by high technical standards, robust research and development ecosystems, and targeted public investment that together support competitiveness at the global level. European initiatives continue to mobilise funding, stimulate public-private collaboration and advance technologies with digital and artificial intelligence features, contributing not only to economic growth but also to public-health preparedness. Such efforts strengthen the capacity of companies (particularly small and medium-sized enterprises) to innovate and bring advanced diagnostic solutions to market, while also generating skilled employment and reinforcing the overall resilience of the healthcare technology sector.

In contrast, many countries in Africa face persistent challenges in establishing local production and manufacturing capacity for diagnostics. Heavy reliance on imports for tests, reagents and device components can expose health systems to supply disruptions, as witnessed during recent global health emergencies. There is growing recognition of the need to stimulate **technology transfer and local production**, supported by targeted investments in regional manufacturing hubs, skills development and regulatory harmonisation. Initiatives by global health partners aim to lay foundational capacity that can be leveraged for future health priorities, equipping local industries to engage meaningfully in the production of quality-assured diagnostics and therapeutics.

A **mission-oriented innovation** approach can provide a powerful framework for aligning public policy, industrial strategy and global health goals. Drawing on lessons from large-scale public-private collaboration during the COVID-19 pandemic (such as the rapid development and global mobilisation of the Oxford-AstraZeneca vaccine) the mission-oriented model emphasises clear societal objectives, strategic public investment, conditionalities that promote public value, and the co-creation of markets that prioritise equitable access. In this model, state investment plays an active role in shaping innovation pathways rather than simply correcting market failures, with coordinated action across government, industry and research communities to drive breakthroughs in areas of major public-health need. These insights highlight the potential for similarly structured partnerships to accelerate development and deployment of diagnostic technologies in epidemic-prone settings. [6]

Regulatory support is also a pivotal driver of innovation. Clear guidelines, streamlined approval mechanisms and harmonised standards can reduce barriers to entry for novel PoC and rapid tests, enabling faster uptake while maintaining safety and performance. Regulatory frameworks that facilitate iterative improvements, data interoperability, and digital integration encourage manufacturers to invest in next-generation diagnostics that respond to emergent health challenges.

Finally, **strengthening resilient supply chains** is essential to ensure that manufacturing and distribution networks can function effectively under stress. This includes diversifying sources of critical inputs, adopting flexible production models, improving logistics and warehousing capacities, and enhancing coordination among public authorities, private sector partners and international organisations. A resilient supply chain reduces vulnerability to international disruptions, supports equitable access across regions, and reinforces the overall integrity of epidemic preparedness systems.

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## 3.2 Procurement and Market Shaping

Procurement plays a strategic role in translating diagnostic innovation into equitable access, particularly in the context of epidemic preparedness. Beyond a transactional function, procurement mechanisms can actively shape markets by incentivising quality, sustainability and timely availability of diagnostics, including PoC platforms and rapid tests. Well-designed procurement policies enable health systems to secure reliable supplies during emergencies while supporting innovation and long-term system resilience.

In many LMICs, procurement of diagnostics during outbreaks is constrained by fragmented purchasing, limited forecasting capacity and dependence on external donors or emergency funding. These constraints can delay access, reduce bargaining power and limit the ability to enforce quality and sustainability standards. During health emergencies, ad hoc procurement approaches further exacerbate inequities and expose systems to price volatility and supply shortages.

Strategic procurement approaches (such as pooled procurement, advance purchase agreements and framework contracts) can mitigate these risks by consolidating demand, improving predictability for manufacturers and strengthening negotiating power. When aligned with preparedness planning, such mechanisms support rapid mobilisation of diagnostics while reducing uncertainty across the supply chain. Experience from EU joint procurement initiatives demonstrates the value of coordinated purchasing in enhancing access and stabilising markets during crises.

Procurement can also serve as a lever to promote environmentally sustainable practices and responsible lifecycle management. By integrating environmental and waste-management criteria into tender specifications, policy-makers can incentivise the development and uptake of diagnostics that minimise environmental impact, an often-overlooked challenge during large-scale outbreak responses.

Finally, procurement strategies that prioritise equitable access and regional capacity-building can contribute to more balanced global markets. Linking procurement policies to technology transfer, local or regional manufacturing and workforce development can strengthen long-term preparedness while reducing reliance on emergency imports. In this way, procurement becomes not only a mechanism for purchasing diagnostics, but a central policy tool for shaping markets in support of resilient, equitable and sustainable epidemic preparedness systems.

## 3.3 Strategic Capacity Building

Building strategic capacity is essential to ensure that diagnostic technologies contribute effectively to epidemic preparedness and response. Strengthening preparedness and response capabilities requires coordinated investment in workforce skills, infrastructure, and operational systems that allow rapid deployment and sustained use of PoC diagnostics in outbreak scenarios.

**Regulatory harmonisation between regions**, particularly EU–Africa, is a critical enabler of capacity building. Aligning standards, approval pathways and quality assurance mechanisms reduces barriers to deployment, accelerates adoption of new diagnostics, and supports interoperability across health systems. Establishing clear coordination mechanisms between EU and African stakeholders ensures that technical guidance, procurement strategies, and emergency response measures are implemented efficiently and consistently.

**Local workforce development and infrastructure strengthening** are central to resilience. Training health professionals, laboratory personnel, and supply chain operators, combined with investment in facilities and maintenance capabilities, ensures that PoC devices can be reliably used, maintained, and integrated into routine and emergency care. **Lifecycle management** (including preventive maintenance, spare parts availability, and end-of-life planning) is key to sustaining device functionality over time, avoiding interruptions during critical periods.

**Post-market surveillance** is another cornerstone of strategic capacity. Monitoring device performance, safety, and usage in real-world conditions provides data to inform regulatory updates, procurement decisions, and deployment strategies. This continuous feedback loop enhances the reliability of diagnostics, supports adaptive responses to emerging threats, and reinforces trust among users and communities.

By investing strategically in these areas, policy-makers can ensure that diagnostic innovations do not remain isolated technical achievements but are fully operationalised to strengthen health systems, reduce vulnerabilities, and improve outbreak preparedness and response across regions.

## 3.4 Strategic Recommendations

The development of strategic recommendations will be further refined based on the feedback and insights received from our African partners. Building on this collaborative input, this section will focus on actionable measures across key areas that are critical to strengthening epidemic preparedness and response (Figure 4).


Figure 4 – Strategic recommendation framework for strengthening preparedness and equitable access to PoC diagnostics, informed by African partner input.

- **Optimised regulatory pathways:** Streamlining approval processes and harmonising standards to enable faster deployment of PoC diagnostics during emergencies.
- **Preparedness strengthening through diagnostic standards:** Establishing clear, evidence-based standards to guide the development, evaluation, and use of diagnostics in outbreak-prone contexts.

- **Improving sustainability:** Integrating environmental considerations, lifecycle management, and responsible procurement practices to reduce the ecological footprint of diagnostics.
- **Enhanced innovation ecosystems:** Supporting mission-oriented innovation, technology transfer, and capacity-building to foster locally adapted, high-quality diagnostic solutions.
- **Better procurement & affordability:** Leveraging strategic procurement mechanisms, pooled purchasing, and forecasting to improve access, reduce costs, and promote equitable distribution of diagnostics.
- **Priority actions for policy-makers:** Identifying immediate and long-term steps that decision-makers can take to reinforce health system resilience, strengthen regional collaboration, and ensure equitable and timely access to diagnostics.

Further elaboration of these recommendations will follow in the final version of the policy brief, reflecting the practical insights, constraints, and opportunities identified by our partners on the ground.

## 3.5 Conclusions

Effective epidemic preparedness depends not only on the availability of innovative diagnostic technologies but also on robust regulatory frameworks, resilient supply chains, and strategic capacity across health systems. Our analysis highlights several key gaps that limit the timely deployment and equitable use of PoC diagnostics, particularly in LMICs. These include fragmented regulatory pathways, limited local manufacturing and maintenance capacity, and challenges in procurement, affordability, and sustainability.

There is a clear opportunity for enhanced EU–Africa cooperation to address these gaps. Harmonising regulatory standards, supporting technology transfer, and implementing coordinated procurement and capacity-building initiatives can strengthen preparedness, accelerate access to diagnostics, and promote equitable health outcomes during outbreaks.

Looking ahead, fostering long-term resilience for PoC diagnostics requires integrated strategies that combine regulatory optimisation, innovation support, sustainable practices, and strategic workforce and infrastructure development. By prioritising these areas, policy-makers can ensure that diagnostic technologies not only meet immediate emergency needs but also contribute to stronger, more adaptive health systems capable of responding to future epidemic threat.

Looking ahead, the mechanisms and processes described in this deliverable will support continuous ethical monitoring, regulatory engagement and context-sensitive adaptation as the project advances. Further refinements will be carried out in alignment with technical validation activities and stakeholder interactions in subsequent project phases.

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