EXPLAINER: Building a Healthier Kenya: Understanding the Kenya - US Health Cooperation Framework and Safeguarding Our Data[1]

Introduction: Why this agreement matters

The Governments of Kenya and the United States of America signed an important "Cooperation Framework on Health" on 4 December 2025 to work together to strengthen Kenya's health system and improve the well-being of all Kenyans. This framework which is extendable outlines how both countries will collaborate over the next five years (starting December 2025) to achieve a healthier future, aligned with Kenya's vision for Universal Health Coverage and Kenyans' constitutional right to the highest attainable standard of health (Constitution of Kenya, 2010, Article 43(1)(a)). This framework is a wide-ranging instrument that affects how Kenya prepares for disease outbreaks, manages health data, supports health workers, funds health services, and responds to emergencies.

Crucially, a separate Data Sharing Agreement was also signed on 4 December 2025, which governs how health data from programs supported under the Framework will be shared with the U.S. Government. While both documents speak the language of cooperation and preparedness, they also reshape who decides, who pays, who controls information, and who is accountable in Kenya's health system.

Both the Cooperation Framework on Health and the Data Sharing Agreement are the subject of Constitutional Petition E816 of 2025 currently pending in the High Court, which raise, among other issues, public participation, the role of Parliament in approving such instruments, public finance violation and right to privacy and the protection of health data.

This brief breaks down what this partnership means for Kenyans, how its objects will be achieved, and why it is essential for Kenyans to understand and advocate for its successful implementation, with a particular focus on data sovereignty and protection.

PARAGRAPH 1: OBJECTIVES OF THE COOPERATION FRAMEWORK

This opening paragraph highlights that Kenya and the United States want to work together to strengthen health systems, prepare for outbreaks, improve laboratories, and use health data more effectively.

Paragraph 1 outlines the objectives of the framework to include collaboration in the elimination of HIV, TB, malaria and other emerging infectious diseases and to "strengthen the Kenyan health system so that it can become more self-reliant". Promotion of U.S. interests abroad is also stated as an objective and it is reinforced through other provisions on "Promote American and Kenyan interests" (2.6.2.3), market access for U.S. investment (2.6.2.4.3) and support for American companies (2.7.6).

[1] This work was coordinated by Allan Maleche, Timothy Wafula, and Catherine Namulanda from KELIN. KELIN acknowledges support from Belice Odamna (consultant) and is grateful to the Preclusion Project for its technical review of this explainer.

PARAGRAPH 2: AREAS OF COOPERATION

What this paragraph says

Paragraph 2 outlines the areas of collaboration including:

1. **Surveillance and outbreak response (2.1):** Kenya aims to detect infectious disease outbreaks within **7 days**, notify US authorities within **1 day** and respond effectively within **7 days**. This means quicker action to protect communities from diseases like cholera, flu and other emerging threats. The US will support assessing Kenya's systems, training health professionals and providing funds for personnel, equipment and setting up national and regional emergency centres. Kenya will provide salaries for these crucial staff, taking increasing ownership over time.
   Of note is the provision that Kenya intends to allow medicines, vaccines and other medical tools that have been approved or authorised for emergency use by the U.S. Food and Drug Administration (FDA) to be used, on the strength of that approval, when responding to outbreaks, in accordance with applicable legislation in Kenya.

   What it really means

   Kenya aims to develop a robust national surveillance and outbreak response system, led by the Kenya National Public Health Institute (KNPHI) whose goal is to detect infectious disease outbreaks within 7 days, notify the U.S. Government within 1 day, and initiate an effective response within 7 days. The U.S. government will support this by assessing Kenya's systems, training health professionals across One Health sectors (an approach that links human, animal and environmental health), and providing funding for essential personnel, equipment and the establishment of 10 KNPHI regional hubs and 20 county Emergency Operation Centres (2.1.2.9). Kenya commits to providing salaries for key staff, gradually taking over these costs (2.1.2.5). A significant aspect is Kenya's intention to accept U.S. Food and Drug Administration (FDA) approvals or Emergency Use Authorizations for medical countermeasures during outbreaks, provided they meet Kenyan legal requirements (2.1.2.7).

   Why this matters

   This is crucial for national and global health security. Rapid detection and response to outbreaks can save lives, prevent widespread disease, and protect economic stability. The commitment to timely notification enables international partners like the U.S. to be prepared and offer support. The one-day notification, however, runs specifically to the U.S. Government (3.3.2), and Kenya's response is to include consultation with the U.S. on that response (3.3.3). Kenya's increasing ownership of salaries and infrastructure ensures the long-term sustainability of the system. The FDA provision expedites access to critical medical tools during emergencies, which is vital when speed is of the essence.

   What people should watch or ask

   During implementation, stakeholders and citizens must look out for:

   - **Adherence to the 7-1-7 metric:** How effectively and consistently Kenya achieves the stated 7-1-7 (detect-notify-respond) metric for various infectious diseases. Monitoring any responses developed by the Government of Kenya, either independently or jointly with the United States Government in relation to outbreak response efforts, adhere to Kenya's constitutional values and principles, are grounded in a human rights-based approach, and ensure that the public is kept adequately informed of any interventions undertaken during outbreak responses.

- **Funding transition**: Transparency and success in Kenya's gradual assumption of salary costs for field epidemiologists and other positions (as per table in 2.1.2.5), ensuring no gaps in personnel or services during this transition.
- **Operationalization of KNPHI and Emergency Operation Centres (EOCS**): Timely and effective establishment and full operationalization of the KNPHI, 10 regional hubs and 20 County Emergency Operation Centres (2.1.2.9)
- **Applicable Kenyan legal requirements for FDA approvals:** Clarity on what specific "Kenyan legal requirements" must be met for automatically accepting FDA approvals (2.1.2.7) and how this process will be streamlined without compromising local safety and efficacy standards.
- **Integrated training impact**: The effectiveness of the comprehensive training across One Health sectors and academic institutions (2.1.2.4) in building a skilled and resilient workforce.
- **Notification to the U.S.**: What information will be sent to the U.S. Government within one day of detecting an outbreak, and through which channel (3.3.2)? How does this sit with Kenya's separate duty to notify the World Health Organization under the International Health Regulations (2005)? Will it be limited to aggregate case information, or could it include patient details or samples?

2. **Laboratory systems (Modernizing our labs for accurate diagnosis) (2.2)**: Kenya will have a strong network of laboratories, from national to county level, equipped to quickly and accurately identify diseases ensuring reliable test results for treatment and disease control. The US is currently funding laboratory supplies and health workers, with Kenya gradually taking over 100% of this funding by 2030. Kenya plans to add these laboratory workers to its payroll in 2028 and to ensure that most of its biosafety laboratories meet high safety and quality standards by 2030.

   What it really means
   Kenya plans to establish a strategically coordinated, tiered laboratory network (national, regional, county) capable of rapidly and accurately detecting, identifying, and characterizing pathogens, while also ensuring blood safety (2.2.1, 2.2.2). The USG currently provides substantial funding for laboratory commodities and supports 515 frontline laboratory workers. The plan is for USG funding for these commodities to decline gradually, with Kenya fully funding them from 2029 (2.2.3.2, 2.2.4.1) and ensuring that 90% of Level 2 and eight Level 3 biosafety laboratories, and one Level 4 laboratory, meet international accreditation standards (e.g. ISO 35001, ISO 15189) by 2030 (2.2.3.5, 2.2.3.6).

   Why this matters
   Modern, well equipped, and accredited laboratories are fundamental for accurate diagnosis, disease surveillance, and guiding public health interventions. This transition builds Kenya's self-reliance in a critical area of health security. Local ownership of funding and personnel makes the system sustainable and less vulnerable to external funding fluctuations. Meeting international standards ensures the quality and reliability of test results, which is essential for patient care and outbreak management.

   What people should watch or ask
   During implementation, stakeholders and citizens must look out for:
   - **Smooth funding transfer:** How the gradual reduction of USG funding for lab commodities and the corresponding increase in Kenyan funding will be managed to prevent any disruptions in supply (2.2.3.2).

- **Absorption of lab workers:** The successful and fair integration of 515 lab workers into the Kenyan government payroll by 2028, ensuring job security and equitable compensation (2.2.3.4).
- **Accreditation timelines:** Concrete progress and verification that laboratories, especially Level 2, 3 and 4 biosafety labs, achieve and maintain international accreditation standards by 2030 (2.2.3.5, 2.2.3.6).
- **Specimen transport transition**: The full transition of sample transport support to Kenya by 2029 (2.2.3.7) and whether all systems meet global biosafety standards.
- **Diagnostic network optimization**: The effectiveness of transitioning diagnostic network optimization support to Kenya by 2027 (2.2.3.8).
- **County laboratories**: The U.S. supports about 3,500 county laboratories in 2026 for an estimated amount US$3,313,024. Kenya is expected to fund these laboratories and related services in full by 2030 (2.2.3.10). Consistent with the principles of devolution, which level of government will meet these costs and how are county governments being involved in the implementation in order to ensure that they can meet these new budgetary needs?

3. **Commodities and Supply chain (Ensuring medicine reach Kenyans, safely) (2.3):** Essential medicines, vaccines and health products will be reliably available across Kenya. The partnership aims to prevent medicine shortages, theft, or counterfeit products. The Kenya Medical Supplies Authority (KEMSA) will be the central body purchasing, storing and distributing U.S.-funded commodities by the end of 2026, with Kenya taking full financial responsibility by 2031 (2.3.3.1). Kenya will implement tracking systems to ensure accountability and reduce loss, safeguarding Kenyans' access to vital supplies.

   What it really means

   Kenya intends to have an integrated health care commodity supply chain system, with Kenya Medical Supplies Authority (KEMSA) serving as the central entity for national pooled procurement, warehousing, and distribution to public, faith-based and private health facilities (2.3.1). The USG plans to transition procurement, warehousing and distribution of its lab and other commodities to KEMSA by December 31 2026 (2.2.4.3,2.3.3.5). While the USG initially provides significant funding for commodities, Kenya will gradually increase its financial responsibility, aiming for 100% funding of these commodities by 2031 (2.3.2.2, 2.3.3.1). Kenya will implement tracking systems (e.g. Global Standards 1-GS1, e-POD) to prevent loss, diversion or falsification of health products (2.3.2.3,2.3.2.4) and both governments will adopt a vendor-managed inventory system (2.3.2.6).

   Why this matters

   A robust and transparent supply chain is critical for ensuring that essential medicines, vaccines, and health products are consistently available where and when needed. This prevents stockouts that can undermine treatment, public health campaigns, and emergency responses. Kenya taking operational responsibility for its supply chain by the end of 2026 and full financial responsibility by 2031 signifies a major step towards self-sufficiency and improved health outcomes. The tracking systems enhance accountability and build public trust in the system.

   What people should watch or ask

   - **KEMSA transition timeline:** The successful and complete transfer of USG procurement, warehousing, and distribution functions to KEMSA by December 31, 2026 (2.3.3.5).

This includes developing a robust transition framework and KEMSA institutional readiness assessment (2.3.3.6).

- **Establishment of the Monitoring and Evaluation Unit:** How the Monitoring and Evaluation Monitoring Unit will be established, criteria for establishment of the unit as well as the timelines in which the evaluation will be carried out. Upon evaluation of KEMSA will the evaluation findings be made public. (2.3.2.4)
- **Funding shift impact**: How the gradual reduction of USG commodity funding and the corresponding increase in Kenyan domestic resources (2.3.3.1, 2.3.3.8) are managed to prevent any gaps in commodity availability or price spikes.
- **Inventory management and insurance**: Confirmation that Kenya insures USG-funded commodities in its supply chains (2.2.4.4) and the effectiveness of the vendor-managed inventory system for key commodities (2.3.2.6).
- **Tracking and accountability:** The implementation and effectiveness of GS1 for tracing commodities (2.3.2.3) and strengthened national systems for detecting and investigating loss, diversion, or falsification of health commodities, including timely notification to the USG. Upon notification of loss or diversion of commodities, what measures will be undertaken to prevent any future incidents. (2.3.2.4, 2.3.2.5)

4. **Investing in Healthcare workers (2.4):** The Kenyan government aims to integrate some of the healthcare professionals currently supported by the U.S. Government into its national health workforce. Together, both governments aim to enhance primary healthcare services by developing the skills of existing staff, optimizing their roles, and actively engaging community health promoters.

What it really means

The Government of Kenya intends to integrate healthcare professionals currently supported by the USG (e.g. nurses, clinical officers, laboratory workers, pharmacy workers, HIV testing and counselling service providers) into its national health workforce (2.4.1, 2.4.2.1). This absorption is planned to occur by June 30, 2028 (2.4.2.2). Both governments aim to enhance primary healthcare by developing the skills of existing staff, implementing task-shifting strategies, and actively involving community health promoters. The USG intends to fund 28,668 full-time equivalent (FTE) positions in 2026 and 21,407 in 2027 and none from 2028. Kenya intends to fund 13,293 new FTE positions from 2028 (2.4.3.1).

Why this matters

Integrating these essential workers into the national system provides long-term employment stability and ensures continuity of vital health services. It supports Kenya's goal of achieving Universal Health Coverage by strengthening the health workforce, particularly at the primary healthcare level. Capacity building and task-shifting maximize the efficiency and reach of the health system.

What people should watch or ask

- **Absorption process details**: The specific plan and progress for absorbing 13,293 of the 28,668 USG-funded frontline healthcare worker positions into the Kenyan government payroll by June 30, 2028 (2.4.2.2, 2.4.3.1), ensuring fair terms, salaries and benefits commensurate with direct government employment. As health is a devolved function between the national government and county governments, coordination with county governments is paramount

in ensuring there is equitable distribution of health workers across national and county government.

- **Continuity of services:** Measures in place to ensure that the transition of workers does not lead to any disruption in the provision of healthcare services, especially for vulnerable populations (2.4.2.3, 2.7.7). Note that lay cadres such as mentor mothers, seasonal malaria workers and community health workers are to be integrated "and/or task-shifted" to government cadres (2.4.2.3), so some peer-led services may not continue in their current form.
- **Training and task-shifting impact**: Evidence of effective capacity-building programs, successful implementation of task-shifting to optimize roles, and the active engagement of community health promoters (2.4.1).
- **Support for FBOs:** How the commitment to ensuring continuity of services in faith-based health facilities (2.7.7) is operationalized during and after the transition of USG-funded workers.

5. **Data systems (Digital health for better care and data security) (2.5):** This section is read together with the Data Sharing Agreement: Kenya is rolling out the TaifaCare Hospital Management Information System (HMIS) and other digital tools like the Electronic Community Health Information System (eCHIS), as mandated by the Digital Health Act. These systems will be integrated and secured. The U.S. Government will fund significant improvements and infrastructure for these digital systems.

   What it really means

   Kenya is undertaking a digital health transformation, operationalizing comprehensive integrated health information management systems (HMIS) like TaifaCare, Electronic Community Health Information System (eCHIS), National Public Health Intelligence Information System (NPHIIS), All Disease Outbreak Module (ADAM), and National Logistics Management Integrated System (NLMIS), as mandated by the Digital Health Act, 2023 (2.5.1-2.5.4). These systems will be interconnected through a health information exchange and warehoused in national and county data banks (2.5.6, 2.5.7). The USG will provide significant funding ($175,000,000 over the framework) for infrastructure, development, maintenance, cloud computing, and hardware for these digital systems, focusing on integration, module enhancement, data quality, and security (2.5.9.1 – 2.5.9.4).

   Why this matters

   Digital health systems are foundational for modern healthcare, enabling efficient service delivery, evidence-based decision-making, and robust disease surveillance. Integration of systems avoids fragmentation and improves coordination. USG investment accelerates this critical transformation, while Kenya's Digital Health Act provides the legal framework. Data sharing is essential for effective collaboration, but it requires strong governance.

   What people should watch or ask

   - **Data Sharing Agreement Specifics:**
     - *The Data Sharing Agreement states that Kenya shall not provide individual-level data or Personally Identifiable Information (PII) "to the maximum extent practical."* This wording is a major red flag – citizens must demand that "to the maximum extent practical" means **NEVER**, under any circumstances, should PII or individual-level data

be shared with the U.S. Government. Any sharing of such data would have to meet the strict conditions for sending sensitive personal data out of Kenya in strict compliance with the principles established under the Data Protection Act, 2019 as well as section 49 of the Act which requires that processing of sensitive personal data out of Kenya shall only be effected upon obtaining consent of a data subject and on obtaining confirmation of appropriate safeguards.

- *Aggregate data only:* the agreement specifies that data shared will be "aggregate level data" (Article 2(c)), meaning summarized statistics, not individual patient records, and citizens must ensure this is strictly enforced and in compliance with the Data Protection Act.
- *Login credentials:* The agreement mentions the "provision of login credentials or other secure access mechanisms" to the U.S. Government – while intended for aggregate data, citizens must demand absolute transparency and strict controls to prevent these credentials from being used to access anything other than anonymised, aggregate data. The potential for misuse or breach, even if unintended, is real.
- *Data ownership:* Kenya retains sole ownership of the data and intellectual property in "covered data systems" – while positive, citizens must ensure this ownership is not compromised by the U.S. Government's access.
- *Data as a bargaining chip:* The Data Sharing agreement at Article 2 (c) (iv) states that "any reduction or cancellation of funding by U.S. Government will result in restriction by Government of Kenya in provision of data and information …" Read carefully, this clause restricts what Kenya gives the U.S. if U.S. funding is cut. It does not affect Kenya's own access to its data. Kenyans' health data is a national strategic asset, not a commodity to be withheld or provided based on foreign funding. The Kenya Government must ensure that all data sharing with the U.S. stops if U.S. funding ends, and that data access is never traded for continued funding.

- **Interoperability and integration:** The actual effectiveness of integrating various systems (TaifaCare, eCHIS, NLMIS, surveillance systems) and achieving seamless data flow across different levels and functionalities (2.5.8.2, 2.5.8.18).
- **Data security and governance:** Robust implementation of cybersecurity protocols, data security frameworks, and adherence to the Digital Health Act and general data protection principles, given the sensitive nature of health data (2.5.8.18, 2.6.2.2.4.6).
- **Transition of existing systems:** The smooth migration of existing USG-supported data systems to the Digital Health Agency (2.5.8.4), which was due before 1 April 2026, to ensure no data loss or service disruption.
- Impact on decision making: Whether the improved data systems genuinely lead to data-driven decision making, automated performance management, and enhanced surveillance capabilities (2.5.8.2, 2.6.2.2.4.5).

6. **Strategic interventions for a resilient system (2.6):** This framework will address major health challenges like HIV, TB, malaria, maternal and child health, and polio. It focusses on integrating services, strengthening national health insurance (Social Health Authority), exploring local manufacturing of health products in partnership with U.S. companies, and enhancing disaster preparedness.

What it really means

This framework outlines strategic interventions to address major health challenges like HIV, TB, malaria, maternal health, and polio (2.6.2.1). Key focus areas include integrating quality services into national health insurance (Social Health Authority – SHA), strengthening domestic financing to reduce donor dependency, building local manufacturing capacity for health products (diagnostics, vaccines, drugs), and enhancing preparedness for public health emergencies (2.6.2.2, 2.6.2.3). Kenya aims for self-reliance in strategic assistance, with USG support primarily for surveillance, outbreak response, and the introduction of innovative health technologies (2.6.1).

Why this matters

These interventions represent a comprehensive approach to building a sustainable and self-reliant health system. Shifting towards domestic financing and local manufacturing strengthens national ownership and reduces vulnerability to external shocks. A robust SHA can improve equitable access to healthcare. Focusing on core health burdens through integrated services aims for more efficient and effective outcomes.

What people should watch or ask

- **SHA operationalization and benefits package**: How the SHA's benefits package will be updated to include HIV, TB, and other donor-funded services, and how the SHA's institutional capacity will be built (2.6.2.1.1.1, 2.6.2.1.1.3).
- **Domestic financing framework**: The development and implementation of a national health-sector financing transition framework to guide increased fiscal ownership by Kenya (2.6.2.1.1.2, 2.6.2.2.1.1).
- **Tangible manufacturing progress:** Tangible steps and outcomes in exploring local manufacturing efforts for diagnostics, vaccines, biologics, and pharmaceuticals (2.6.2.3.1.2, 2.6.2.3.1.11).
- **Innovation rollout:** The processes and timelines for developing and rolling out innovative diagnostics, drugs, and vaccines (2.6.2.1.1.5, 2.6.1).
- **Integration of services:** The effectiveness of integrating services (e.g. PMTCT into MNCH) to improve maternal and child health outcomes (2.6.2.1.1.4).
- **Unified national digital health architecture:** The framework seeks to operationalize a unified national digital health architecture integrating service provision, surveillance and outbreak detection, HRH, HPT, laboratory and financing data. There needs to be further clarification on how this unified national digital health architecture and how information including health data will be shared in compliance with the Digital Health Act and the Data Protection Act. (2.6.2.3.1.1
- **Biobanking, genomics and data standards:** The Framework contemplates a national biobanking system (2.6.2.1.2.4), a BSL-4 laboratory (2.6.2.1.2.7), a genomic surveillance network (2.6.2.1.3.2) and "embedding American standards for data governance and interoperability" (2.6.2.5.2). There needs to be clarity on what consent, governance and benefit-sharing rules will apply to human samples and genetic data, and how any American standards will sit with the Digital Health Act, 2023 and the Data Protection Act, 2019.
- **Strategic assistance funding:** Strategic interventions are the largest U.S. funding line, about US$748 million over five years (2.6.3.1), yet most of the activities in 2.6.2 are things the Participants "may" or "plan to" do. Ask how this money will be allocated and reported.
- **Laboratory waste:** The Framework provides for laboratory waste management systems, including a high-capacity incinerator and a glass crushing system (2.6.2.1.2.11). Ask where

these will be sited and how they will comply with Kenya's environmental and health care waste rules.

7. **Additional responsibilities of parties (2.7):** To strengthen this health partnership, Kenya and the U.S. will arrange tax exemptions for the assistance provided. Kenya also intends, by 31 December 2026, to rely on U.S. FDA approvals or emergency authorizations as a basis for authorizing corresponding health products, subject to verification of "product sameness" and review by the Pharmacy and Poisons Board. This covers routine medicines, vaccines, biologics and diagnostics, not only emergency products. The U.S. will help train Kenya's regulatory staff, and both countries' drug regulators (U.S. FDA and Kenya's Pharmacy and Poisons Board) will share information to improve health product oversight and coordination. Furthermore, the parties plan to expand partnerships with private companies to enhance supply chain logistics, diagnostic services, and health technology, and support American companies looking to establish operations in Kenya under local laws. Both governments also acknowledge the vital work of faith-based health facilities and will continue to collaborate with them to deliver frontline services.

What it really means

Kenya and the U.S. commit to negotiating tax-exemption mechanisms for assistance provided under the framework (2.7.1). Kenya intends to apply "reliance principles" to U.S. FDA approvals and Emergency Use Authorizations as a basis for authorizing corresponding health products by 31 December 2026, subject to verification of product sameness and the review processes of the PPB (2.7.2). The USG will support capacity building for Kenyan regulatory staff, and both countries' drug regulators (FDA and Kenya's Pharmacy and Poisons Board – PPB) will share information to enhance oversight (2.7.3,2.7.4).

The parties will expand private sector partnerships for supply chain, diagnostics and health technology, and support American companies establishing operations in Kenya (2.7.5,2.7.6). The framework also acknowledges the vital work of faith-based health facilities and states an intention to continue working with them (2.7.7).

Why this matters

- **Efficient aid:** Tax exemptions ensure that US assistance is maximized, directly benefitting health programs without being reduced by local taxes.
- **Accelerated access**: Accepting FDA approvals can significantly speed up access to life-saving medicines and technologies in Kenya, particularly for new and emergency products. However, it also shifts part of the regulatory judgment to a foreign regulator, hence the need to ensure that the Pharmacy and Poisons Board's own review remains meaningful and not a mere formality.
- **Regulatory strengthening:** US support for Kenyan regulatory staff and inter-agency information sharing enhances Kenya's ability to ensure product safety and quality independently.
- **Economic growth and innovation**: Encouraging private sector engagement and supporting American companies can bring investment, technology transfer, and job creation, fostering innovation in Kenya's health sector.
- **Continuity of care:** Acknowledging FBOs ensures that a significant portion of healthcare delivery, often reaching underserved populations, continues to be supported.

What people should watch or ask

- **Tax exemption details**: The timely negotiation and specific mechanisms for implementing tax exemptions (2.7.1), ensuring clarity on what is covered and how it's applied.

- **"Verification of product sameness":** The exact process and criteria for "verification of product sameness" (2.7.2) for FDA-approved products. This needs to be transparent and efficient, without creating new bureaucratic hurdles that negate the benefit of accepting FDA approvals. Will this involve physical inspection, documentation review or other methods?
- **Information sharing protocol**: The specific protocols and frequency of information sharing between the US FDA and Kenya's PPB (2.7.4), ensuring it is robust enough to prevent substandard or falsified products from entering the market.
- **Balance with local industry:** How support for American companies and reliance on FDA approvals will be balanced with efforts to develop and protect Kenya's own emerging pharmaceutical and medical device manufacturing industry (2.6.2.3.1.2, 2.6.2.3.1.11).
- **FBO engagement:** Specific plans for how the USG and Government of Kenya will continue to support faith-based health facilities, especially during the transition of USG-funded activities (2.7.7).

PARAGRAPH 3: PERFORMANCE INDICATORS

What this paragraph says

This paragraph outlines both outcome and process metrics through identified outcome indicators and process indicators. Some outcome indicators identified in the cooperation agreement include % of people with HIV who know their status, % of people who know their status on treatment, % of people on antiretroviral treatment (ART) who are virally suppressed, number of malaria deaths in children under 5, number of TB deaths (of notified TB cases), number of polio and measles cases, and facility maternal and neonatal mortality rates. On process, the parties will work together to achieve identified metrics yearly, some metrics include number and percentages of people on ART, number of new HIV diagnoses and pregnant and breastfeeding mothers living with HIV on ART and malaria, TB, polio and measles cases and treatment.

Notably, the Kenyan government aims to detect suspected infectious disease outbreaks with epidemic potential within 7 (seven) days of emergence, notify the U.S. government within one day of detection and complete initial response actions to respond effectively within 7 days of notification, including "engaging in consultation with the U.S. Government on Kenya's response" (3.3.3). In summary, these commitments demonstrate Kenya's proactive approach to swiftly manage public health threats and enhance collaboration with the U.S. government.

What this really means

The paragraph describes a framework for measuring health outcomes and processes related to infectious diseases and treatments. It lists specific indicators to track processes, such as the percentage of people living with HIV who know their status and are receiving treatment, as well as the number of cases of malaria, tuberculosis (TB), polio, and measles, facility maternal mortality and neonatal. The cooperation framework sets a collaborative goal for both parties to achieve these metrics annually. Additionally, it highlights Kenya's commitment to quickly detect and respond to potential disease outbreaks within specified timeframes.

Why this Matters

This framework is important because it establishes clear goals for improving public health, particularly in managing diseases like HIV, malaria, TB, polio, and measles as well as maternal morality and neonatal mortality. By setting measurable indicators, it allows both the Kenyan government and the U.S. government to assess progress and effectiveness in health interventions. The commitment to

quick outbreak detection and response is crucial for preventing widespread health crises and protecting vulnerable populations.

What people should watch or ask

During the implementation of this agreement, people should monitor whether the defined outcome and process metrics are being effectively measured and reported. Questions to consider include:

- Are the data collection methods accurate and consistent, how will the data be collected including consent sought from participants during the data collection?
- How often are the metrics reviewed, and are both parties following through on their commitments?
- These indicators also decide whether Kenya qualifies for performance incentives (6.2) and are the basis of the U.S. outcome and process audits (5.1, 5.2). Have the 2025 baselines been verified, and will annual results be published?

Moreover, it's vital to inquire about the effectiveness of responses to detected outbreaks and whether they are completed within the promised timelines. Additionally, stakeholders should check for transparency in reporting the gathered data related to the health indicators outlined.

PARAGRAPH 4: IMPLEMENTATION

What this paragraph says

Within ninety (90) days of signing the Framework, parties will develop a detailed implementation plan which includes implementation timelines for all the areas outlined in paragraph 2. A Joint Health Framework Steering Committee (JHFSC) composed of senior representatives from both governments and other key stakeholders as mutually decided by parties will be established. The JHFSC is expected to meet at least quarterly to monitor implementation of the framework, review progress and propose areas of possible modification.

What this really means

This part of the agreement sets up the immediate next steps after the framework is signed. First, within three months (90 days), both Kenya and the U.S. will create a detailed plan, complete with specific timelines, for putting all the agreed-upon cooperation activities into action. Second, a special committee, called the Joint Health Framework Steering Committee (JHFSC), will be formed. This committee will include important representatives from both governments and other relevant groups they both choose. The JHFSC is expected to meet at least every three months to check on how the agreement is progressing, review what has been achieved and suggest any necessary changes.

Why this Matters

This clause is crucial for several reasons:

- **Translates intent into action**: It ensures that the broad goals of the cooperation framework don't just remain on paper but are translated into concrete, actionable steps with clear deadlines.
- **Provides oversight and accountability:** The establishment of the JHFSC creates a formal body responsible for monitoring progress, identifying challenges, and ensuring that both parties are upholding their commitments. Regular quarterly meetings reinforce this accountability.

- **Allows for adaptability:** By enabling the JHFSC to "propose areas of possible modification," the framework can remain flexible and responsive to changing circumstances, new data, or unforeseen challenges over its five-year duration.
- **Fosters collaboration:** It mandates ongoing dialogue and joint decision-making through the JHFSC, which is essential for successful international cooperation.

What people should watch or ask

To ensure this clause is effectively implemented, citizens and stakeholders should:

- **Scrutinize the JHFSC composition:** Who are the "senior representatives" and "other key stakeholders" on the JHFSC? What criteria will be used in selection of members of the JHFC?Willl there be representation of other government institutions such as office of the data protection, council of governors who are key in the implementation of this framework? Do they have the necessary expertise, authority and commitment to effectively guide and monitor the framework? Is the JHFSC inclusive - are communities, civil society organizations and key populations represented? Is there a balance of perspectives? Because "other key stakeholders" are chosen jointly by the two governments (4.3), civil society and the Council of Governors should demand to be included in the JHFSC.
- **Confirm timely development of the plan:** was the detailed implementation plan created within the 90-day deadline, which fell in early March 2026? If it has not been published, anyone can request it from the Ministry of Health in terms of Article 35 of the Constitution and the Access to Information Act, 2016. Is it comprehensive and does it include specific, measurable timelines for all areas of cooperation outlined in Paragraph 2 of the framework? Does the implementation plan consider the needs of all, including vulnerable and marginalised populations and the health services they need?
- **Assess meeting effectiveness:** Are the JHFSC meetings taking place quarterly? Do they have clear agendas, documented discussions, and actionable follow-up? Are progress reports transparent and accessible? Will the progress reports be made publicly available?
- **Understand modification processes:** How will suggested modifications from the JHFSC be formalized and integrated into the framework or its plans? Is there a clear process for adopting changes?
- **Evaluate resource allocation:** Is the JHFSC adequately resourced (e.g. staff, budget, data analysis tools) to effectively perform its monitoring, review and modification functions?

PARAGRAPH 5: AUDIT

What this paragraph says

The U.S. Government intends to fund a survey for up to $10 million in each of 2027 and 2029 to objectively measure the outcome metrics in Paragraph 3.1 of the cooperation framework. The design and execution of the survey will be decided by both parties. The government of Kenya acknowledges its commitment to provide data access or information requested for reporting purposes "in order to continue with implementation" of the Framework (5.6). Information shared for audit purposes is expected to be subject to existing Kenyan laws and regulations and to the concurrence of the Office of the Data Protection Commissioner (5.7).

Several audits will be commissioned, including:

1. Outcomes metrics audit (5.1)
2. Process metric audit (5.2)

3. Supply chain audit (5.3)
4. Co-investment audit (5.4)
5. Regulatory compliance audit, including the Helms Amendment (5.5)

What this really means

This section outlines how the effectiveness and compliance of the health cooperation framework will be monitored and audited. It states that the U.S. Government will fund surveys (up to $10 million in each of 2027 and 2029) to objectively measure if the overall goals of the framework are being met. The design and execution will be jointly decided by both parties. Additionally, the Kenyan government acknowledges its commitment to providing necessary data and information for reporting purposes, ensuring compliance with existing Kenyan laws and regulations. The paragraph also specifies five key types of audits that will be conducted to ensure proper implementation: an Outcomes Metric Audit (Page 24, Paragraph 5.1), a Process Metric Audit (Page 25, Paragraph 5.2), a Supply Chain Audit (Page 25, Paragraph 5.3), a Co-Investment Audit (Page 25, Paragraph 5.4), and a Regulatory Compliance Audit(Page 25, Paragraph 5.5).

Why this Matters

This set of provisions is critical for ensuring accountability, transparency and the effective use of resources within the cooperation framework.

- **Accountability:** The surveys and audits provide concrete mechanisms to verify that both governments are upholding their commitments and that the stated objectives are being achieved.
- **Transparency:** By requiring data provision and various audits, the framework promotes openness in how funds are used and how progress is measured.
- **Risk Management**: The specific audits (especially supply chain, co-investment, and regulatory compliance) are designed to detect and prevent issues like fraud, misuse of funds, or non-adherence to legal and policy requirements, thereby protecting the integrity of the partnership.
- **Informed Decision-Making**: Objective measurement and audit findings offer valuable data for evaluating the frameworks impact, identifying areas for improvement, and guiding future health interventions.
- **Data Protection**: The requirement that audit information be subject to Kenyan law and the concurrence of the Office of the Data Protection Commissioner (5.7) is a strong safeguard in the Framework.

What people should watch or ask

During the implementation of this clause, stakeholders should pay close attention to:

- **Survey integrity:** How will the “objective measurement” for the surveys be defined and ensured? Are the survey methodologies robust and unbiased? Are both parties genuinely collaborating on their design and execution?
- **Data Accessibility and Compliance:** Is the Kenyan Government consistently providing requested data in a timely and complete manner for reporting and audit purposes? How is compliance with Kenyan Data Protection laws and the Data Protection Commissioner being verified in practice? Are data privacy concerns adequately addressed? Has the Data Protection Commissioner given its concurrence under 5.7, and if so, on what conditions?
- **Audit Independence and Follow-Through:** Who conducts these audits (e.g. independent third-party auditors, government internal audit functions)? Are their findings publicly

accessible and what mechanisms are in place to ensure that recommendations from these audits (Outcomes, Process, Supply Chain, Co-Investment, and Regulatory Compliance) are promptly and effectively addressed by both governments?

- **Addressing Specific Audit Concerns:** For example, in the Regulatory Compliance Audit (Page 25, Paragraph 5.5), Kenya is to provide information "needed to monitor compliance with applicable law and legal requirements of Kenya, including to confirm no U.S. Government funding is being used for the performance of abortion as a method of family planning or to motivate or coerce any person to practice abortions". Noting that abortion is permitted under certain circumstances in Article 26(4) of the Constitution of Kenya, and further that Article 43(1) guarantees every person the right to the highest attainable standard of health including reproductive health, people should ask what is the place of access to safe and legal abortion services in light of this regulatory compliance audit?
- **Impact of Audit Findings:** What are the consequences if an audit reveals significant discrepancies, inefficiencies or non-compliance? How does this impact future funding or the continuation of specific activities in this framework?

PARAGRAPH 6: CO-INVESTMENT AND PERFORMANCE BENCHMARKS

What this paragraph says

This paragraph outlines the financial commitments and incentives designed to foster Kenya's ownership and sustainability in the health partnership. It consists of two main components:

- **Co-investment (6.1):** Kenya commits to increasing its domestic health expenditures annually by specific amounts (ranging from 10 billion KES in FY 2026/2027 to 50 billion KES by FY 2029/2030) relative to a 2025 baseline. This co-investment must come from funds raised directly by the Government of Kenya (including loans), explicitly excluding grants or funds by other donors. Failure by Kenya to meet these financial commitments may lead to the U.S. Government reducing or ceasing its funding, potentially on a 1:1 basis.
- **Performance Incentives (6.2**): If Kenya achieves all the process and outbreak response metrics outlined in 3.2 (process indicators) and 3.3 (infectious disease outbreak response metrics) in the framework for 2027 and 2028, it is expected to be eligible for a performance incentive, the amount of which is not stated. The USG reserves discretion to build a composite score for calculating eligibility, in consultation with Kenya and in a way that avoids reducing Kenya's eligibility (6.2.2), and these incentives can be used by Kenya for any health-related costs allowed under the framework.

What this really means

This paragraph represents a strategic shift towards greater financial accountability and self-sufficiency for Kenya's health system. It means:

- **Kenya's budget priority:** The Kenyan government must make explicit and growing annual financial commitments from its own national budget to health initiatives supported by this framework. This is framed as a plan rather than a legal obligation but missing it can trigger U.S. funding cuts, so in practice it will directly shape national fiscal planning.
- **Consequences of non-compliance**: If Kenya does not meet these self-funding targets, it directly risks losing a corresponding amount of USG assistance across various health programs, potentially hindering progress in areas like disease surveillance, laboratory modernization, and commodity supply.

- **Reward for results:** By achieving defined health performance targets (e.g. rapid outbreak response, improved maternal health metrics, etc), Kenya can unlock additional funding, providing a tangible benefit for effective program execution.
- **Direct national control:** The push for USG funds to flow through Kenyan government mechanisms aims to build and strengthen Kenya's own financial management and programmatic oversight capabilities, reducing reliance on external implementing partners.

Why this Matters

This paragraph is important for several reasons outlined below:

- **Sustainability of health system**: It fosters long-term sustainability by transitioning financial responsibility from donor aid to domestic resources. A healthy system primarily funded by its own government is inherently more stable and resilient.
- **National ownership and sovereignty:** It strengthens Kenya's ownership and control over its health agenda and resource allocation. By increasing its financial stake, Kenya solidifies its role as the primary driver of its health development.
- **Accountability and efficiency:** The explicit co-investment targets and performance incentives introduce a robust layer of accountability for both financial input and programmatic output, encouraging more efficient use of resources and better health outcomes.
- **Fiscal space for health:** The commitment to increased domestic health expenditure can create the necessary fiscal space to address broader health challenges, achieve universal health coverage, and fund essential services that might otherwise be under-resourced.
- **Shift in aid modality:** Moving towards government-to-government funding reinforces national systems and reduces the fragmentation often associated with project-based donor funding.

What people should watch or ask

Given the significance of the provisions of this paragraph, several critical points require close attention during implementation:

- **Clarity on "domestic government health expenditures" (6.1.3):**
    - **Watch for:** How the precise definition is jointly agreed upon. Ambiguity could lead to disputes or allow for misclassification of funds.
    - **Ask:** What specific budget lines, at both national and county levels, will constitute "domestic government health expenditures"? How will the 2025 baseline be established, and will it be transparently communicated?
- **Impact of funding reductions on programs (6.1.1, 6.1.4):**
    - **Watch for:** Any immediate or cascading negative effects on health programs and service delivery if Kenya fails to meet co-investment targets and USG funding is reduced.
    - **Ask:** What mitigation strategies are in place to safeguard critical health services in the event of USG funding reductions? Will there be a grace period or a phased reduction process?
- **Transparency and verification of co-investment:**
    - **Watch for**: The rigor and transparency of the auditing mechanisms (as mentioned in Paragraph 5.4) to ensure that Kenya's co-investment is genuinely new domestic funding and not merely re-labelled external aid.
    - **Ask:** How will USG and GOK jointly verify Kenya's financial contributions? What data sources and reporting frequency will be used? Since loans count towards Kenya's co-investment (6.1.1), how much of it will be borrowed, and on what terms?

- **Equity and distribution of resources:**
    - **Watch for:** Whether increased domestic spending and USG funds channelled through GOK mechanisms are equitably distributed across all regions and prioritize essential services, particularly at the primary healthcare level.
    - **Ask:** How will the allocation of these increased domestic funds be transparently tracked to ensure they reach the intended health priorities and geographical areas, including rural and underserved communities?
- **Performance incentive targets and measurement (6.2.1):**
    - **Watch for**: The specific details of the process and outbreak response metrics, and the method for calculating Kenya's eligibility for performance incentives.
    - **Ask:** Are the performance metrics realistic and measurable? How will data for these metrics be collected, verified, and audited to ensure accuracy and prevent perverse incentives?
- **Transition to government-to-government funding (6.1.5):**
    - **Watch for:** The effectiveness of transitioning funds through GOK development funding. Potential challenges could include delays, bureaucratic inefficiencies, or capacity gaps within GOK financial management systems.
    - **Ask:** What capacity building support will be provided to GOK financial institutions to manage these funds efficiently and accountably? What safeguards are in place to ensure timely disbursement and prevent corruption?

PARAGRAPH 7: IMPLEMENTING PARTNERS

What this paragraph says

Both parties acknowledge the importance of moving to on-budget, government-to-government funding and sunsetting all implementing partners outside of this government-to-government mechanism in order to maximise the Kenyan government's ability to deliver on the outcomes in Paragraph 3 of this framework. The U.S. Government intends to share with the Government of Kenya all contractual documents utilised in the engagement with implementing partners in Kenya, "to the maximum extent practicable and consistent with U.S. laws and regulations" (7.2).

Within 90 days of signing of the cooperation framework, parties will conduct an in-depth review of U.S. government funded programs, identify implementing partners for termination or discontinuation, modification or continuation of their contracts by the U.S. government. For any implementing partners whose contracts have been modified or continued, their engagement is expected to be through Government of Kenya mechanisms by 31 March 2026, to the maximum extent practicable under U.S. law (7.4).

The Government of Kenya notes its intention to ensure continuity of services in faith-based health facilities currently supported by the U.S. government.

If the two governments cannot agree on an implementation plan, including the details of government-to-government funding, either may revisit the performance indicators, the co-investment terms and U.S. funding levels (7.6).

What this really means

This section of the framework (primarily covered under Page 27, Paragraph 7) outlines a significant shift in how the cooperation will be managed. Both U.S. and Kenyan governments agree to move away

from using external "implementing partners" (like NGOs or other organizations that directly receive U.S. funds to carry out health programs) and instead transition towards a direct government-to-government funding model. The goal is to maximize Kenya's own ability to deliver health services and build a sustainable health system that is less dependent on external funding and partners. To facilitate this, the U.S. Government will share all relevant contractual documents of its current implementing partners with the Government of Kenya. Within 90 days of signing the framework, both parties will conduct a thorough review of U.S. – funded programs to decide which existing implementing partners will have their contracts terminated, modified, or continued. For any partners whose contracts are modified or continued, their engagement with the health programs is expected to be integrated through Kenya government mechanisms by March 31, 2026. The Kenyan government intends to ensure continuity of services in faith-based facilities currently supported by the U.S. government (7.5).

Why this Matters

This shift in implementation strategy is crucial for several reasons:

- **Kenya Self-Reliance:** It directly supports Kenya's long-term goal of building a self-reliant and durable health system, reducing dependence on foreign entities for service delivery. This aligns with the objective of strengthening the Kenyan health system as mentioned in Page 5, Paragraph 1.1.
- **Increased Accountability:** By channelling funds directly through government mechanisms, it aims to increase accountability and transparency in the use of resources within Kenya's public sector.
- **System Integration:** It promotes the integration of externally funded programs into Kenya's national health structure, potentially streamlining operations and reducing duplication.
- **Sustainability:** The transition seeks to embed health programs within Kenya's own systems, making them more likely to continue and be financed domestically in the long run.
- **Efficiency:** Consolidating efforts under government oversight can lead to more efficient resource allocation and coordination.

What people should watch or ask

Given the significance of this transition, stakeholders should closely monitor:

- **Service Continuity:** Will the phasing out or modification of implementing partner contracts lead to any disruptions in essential health services, especially for vulnerable populations or in specific regions? How is the continuity of services, particularly in faith-based health facilities, being explicitly ensured? Will faith-based health facilities provide crucial health services including reproductive health services to key populations and other vulnerable populations?
- **Timeliness of Transition:** Are the deadlines for the in-depth review (90 days) and the integration of partners into Kenyan mechanisms (March 31, 2026) being met? Delays could create gaps in service delivery.
- **Capacity of Kenyan Mechanisms**: Does the Government of Kenya have the necessary administrative, financial management, procurement and technical capacity to effectively absorb and manage the programs previously run by implementing partners? Are there sufficient training and resources being provided to ensure a smooth handover and continued quality of service?
- **Transparency of Review Process:** How are decisions made regarding which partners are terminated, modified or continued? Is the review process fair, transparent, and based on objective performance criteria?

- **Legal and Contractual Implications:** How are the contractual and legal aspects of terminating or transitioning partners being managed to avoid disputes or negative impacts on project staff and beneficiaries?
- **Financial Flow and Oversight:** Once the funds are channelled directly to the Government of Kenya, what robust financial management and oversight systems are in place to prevent misuse, waste, or fraud, including for activities managed by external partners? This relates directly to the audit clauses in Paragraph 5 of the Framework

PARAGRAPH 8: SPECIMEN TESTING

What this paragraph says
Parties will continue specimen testing, including genetic sequencing and sharing data on detected pathogens subject to the existing laws and regulations of the Government of Kenya. Unlike most of the Framework, this paragraph refers only to Kenyan law.

What this really means
This paragraph signifies a continued collaborative effort between the U.S. and Kenyan Governments in public health surveillance. Specifically, they will persist in analysing biological samples (specimen testing), which includes advanced genetic analysis (genetic sequencing), to identify and track disease-causing organisms (pathogens). The crucial condition for all these activities is that they must strictly follow the existing laws and regulations of Kenya.

The accompanying Data Sharing Agreement (DSA) is about health program data rather than samples, but it is relevant to any data that flows from specimen testing:

- **Data Governance:** All data provision by Kenya will be in accordance with Kenya's Data Protection Act, 2019, Digital Health Act, 2023 and other relevant Kenyan laws (DSA, Page 2, Article 2(a)).
- **Data Type:** To the maximum extent practical, Kenya will not provide individual-level data or personally identifiable information (PII) to the U.S. Government. Instead, data will be shared primarily as "aggregate level data from aggregate systems, dashboard, and reporting tools" (DSA, Page 2, Article 2(a) and (c)). This matters for any patient information attached to sequencing results, such as age, location or date of sampling.
- **Data Ownership:** The Government of Kenya explicitly retains sole ownership of the data and all associated intellectual property rights (DSA, Page 3, Article 3(d)).
- **Confidentiality and Security:** Both parties commit to maintaining confidentiality and protecting data, with the U.S. Government agreeing to notify Kenya of any unauthorized access to PII or any other data breach, within the timeframe set by Kenyan law (DSA, Pages 2 to 3, Article 3(b)).
- **Governing Law**: In case of any conflict between U.S federal laws and Kenyan laws regarding data sharing under Article 2, the laws and regulations of the Republic of Kenya shall prevail (DSA Pages 4 to 5, Article 5 (f)). This priority rule is limited to data sharing "under Article 2". It is therefore not clear that it covers how the U.S. stores, uses or disposes of data under Article

Why this Matters

The commitment in Paragraph 8 is vital for several reasons:

- **Enhanced Disease Control**: Genetic sequencing of pathogens is a powerful tool for rapidly identifying disease outbreaks, tracking their spread, detecting new variants, and understanding antimicrobial resistance. This directly supports the Cooperation Framework's objective of detecting, preventing and responding to infectious disease threats (Cooperation Framework, Preamble Page 2).
- **Public Health Security**: Sharing this highly specific data allows both nations to better protect their populations from cross-border health threats and informs global health security efforts.
- **Responsible Data Handling**: The emphasis on compliance with Kenyan law, particularly Kenya's data protection laws, is critical. It builds trust by ensuring that sensitive biological and health information is used ethically and legally, balancing public health needs with individual privacy rights.
- **Sovereignty and Control**: Explicitly stating Kenya's data ownership and the precedence of its laws ensures that Kenya maintains control over its national health data, which is recognized as a strategic asset (DSA Page 1, Preamble).

What people should watch or ask

Given the sensitive nature of genetic data and the complexities of international data sharing, stakeholders should pay close attention to:

- **Anonymization Protocols**: How are the specific technical and administrative protocols for anonymizing and aggregating sequencing results, and the patient information attached to them, implemented to reliably remove PII before sharing with the U.S. Government? Are these protocols transparent and auditable?
- **Scope of Data Shared**: Is there a jointly developed and publicly accessible list of the "Covered Data Systems," the specific types of data to be provided, and the authorised users and types of access, as mentioned in the DSA Page 2, Article 2(a)? This ensures clarity on what data is being shared.
- **Data Security Measures:** What robust cybersecurity and physical security measures are in place for the "Covered Data Systems" in Kenya to ensure the integrity and confidentiality of the genetic data, especially as Kenya is responsible for system functionality, security, and integrity (DSA Page 3 Article 4 (a)?
- **Incident Response**: How will the U.S. Government's commitment to notify Kenya of any unauthorised access or data breaches involving PII (DSA Page 3 Article 3(b) be practically implemented, including timelines and reporting structures?
- **Use Limitations:** How is it confirmed that the genetic and other health data shared is only used for the agreed upon public health purposes outlined in the Cooperation Framework and not for other purposes (DSA Page 3, Article 3(c))? Article 3(a) allows use for purposes consistent with the "metrics or activities" referenced in Paragraphs 1, 2, 4 and 5 of the Framework, and Paragraph 1 sets out the objectives of the cooperation, which include to "promote U.S. interests abroad" (1.1). What mechanisms exist for monitoring adherence to these limitations?
- **Benefits and IP from Genetic Data**: Genetic sequencing can lead to new discoveries. How will the provisions for "benefits arising thereof" (requiring separate subsidiary agreements) and "publications and authorships" (including Kenyan co-authorship and approvals) (DSA Page 3, Articles 3(e) and 3(f)) be applied to discoveries or intellectual property stemming from jointly analysed genetic data? This ensures equitable sharing of the outcomes.

- **Clarity on Precedence of Laws**: While Kenyan laws prevail in case of divergence (DSA, Article 5(f)), are there clear guidelines or precedents for how such divergences would be identified and addressed in practice, particularly for complex and evolving areas like genetic data sharing?

PARAGRAPH 9: APPLICABLE LAWS

What this paragraph says

The Framework is expected to be implemented in accordance with applicable law and the rules and regulations of both the Government of Kenya and the U.S. Government.

What this really means

This statement is a fundamental legal principle governing the entire cooperation. It means that every activity, project, and decision carried out under the Kenya-United States Cooperation Framework on Health must be in full compliance with:

- All existing laws, rules, and regulations of the Government of Kenya. This includes the Constitution and all Statutes, policies, ministerial regulations and other government directives
- All existing laws, rules and regulations of the U.S. Government. This would encompass all federal laws, agency regulations and policies relevant to foreign assistance and health cooperation (e.g. the Helms Amendment referenced in the Cooperation Framework, Page 25, Paragraph 5.5 on Regulatory Compliance Audit)

In essence, neither party is expected to implement any part of the Framework in a way that violates its own domestic laws or those of the other party. The DSA restates this principle for data, stating that it "is intended to be implemented by the Parties in compliance with applicable Kenyan and U.S. laws, respectively" (DSA, Page 4, Article 5(f)). Importantly, for the data under Article 2, "the laws and regulations of the Republic of Kenya shall prevail" in case of divergence (DSA, Page 5, Article 5(f)).

Why this Matters

This paragraph is paramount for several reasons:

- **Legality and Legitimacy**: It ensures that all cooperative actions are lawful, preventing illegal activities and providing a legitimate basis for the Framework's operations.
- **Sovereignty and Respect**: It respects the sovereignty of both nations by affirming that their respective legal systems must be adhered to.
- **Risk Mitigation**: It helps prevent legal disputes, liabilities, and potential political issues that could arise from non-compliance with national laws.
- **Trust and Predictability**: Adhering to established legal frameworks fosters trust between the cooperating parties and provides a predictable environment for implementation.
- **Protection of Rights**: It ensures that the rights of individuals (e.g. data privacy) and the obligations of governments are upheld during the cooperation. The DSA reinforces this by stating that PII will not be provided to the U.S. Government "to the maximum extent practical", which is a qualified commitment rather than an absolute one.
- **Data Governance (DSA specific):** The DSA highlights Kenya's robust legal framework for data and gives precedence to Kenyan laws in the event of any conflict, which is vital for maintaining national control over sensitive health data.

What people should watch or ask

Given the Paragraph and the accompanying DSA, citizens and stakeholders should watch for or ask:

- **Legal Harmonization Efforts**: Are there clear mechanisms in place to identify potential conflicts or inconsistencies between Kenya and U.S. laws, rules and regulations before activities are implemented? How will these be resolved, especially considering that Kenyan law prevails for data sharing conflicts?
- **Due Diligence and Legal Review**: What processes are being followed to ensure that every planned activity undergoes a thorough legal review by both Kenyan and U.S. legal experts to confirm compliance?
- **Transparency and Reporting on Compliance**: How will adherence to this Paragraph be monitored and reported? Will compliance reports be made public, especially concerning sensitive areas like data sharing or regulatory requirements?
- **Capacity Building for Legal Frameworks**: Are resources and training being provided to relevant personnel in both governments to understand and apply legal frameworks of both nations effectively, particularly in areas like digital health and intellectual property?
- **Data Anonymization and De-identification**: How are the specific technical and legal standards for data anonymization and de-identification rigorously applied to ensure that no individual-level data or PII is shared with the U.S. Government, consistent with the DSA Page 2, Article 2 (a)?
- **Policy Evolution**: As laws and regulations, especially digital health laws, and others evolve in both countries, how will the Framework adapt to remain compliant? Is there a process for regularly updating legal interpretations and implementation guidelines?
- **Dispute Resolution Process**: In the event of irreconcilable legal difference, what specific steps will be taken beyond "consultations and negotiations through diplomatic channels" to prevent the stalling or termination of critical health programs?

PARAGRAPH 10: FUNDING

What this paragraph says

The Framework is intended to cover only activities funded by the U.S. Department of State and the Government of Kenya subject to the availability of funds, personnel and other resources.

What this really means

This clause establishes a clear and specific understanding of who will fund the activities outlined in the Cooperation Framework. It means that:

- **Exclusive funding**: All programs and initiatives under this framework will only be financially supported by two entities: the U.S. Department of State and the Government of Kenya. This does not stop other donors from funding health in Kenya. Its main practical effect is to limit the Framework, and therefore the DSA, to activities funded by the U.S. Department of State. U.S.-funded health activities in Kenya that are funded by other U.S. agencies fall outside both instruments.
- **Resource dependency**: The actual execution and success of these cooperative activities are contingent upon the availability of essential resources. Indeed, under paragraph 10.1 of the Framework "all activities... are subject to the availability of funds, personnel, and other resources".

Why this Matters

This clause is fundamental to the operational integrity and sustainability of the entire cooperation:

- **Clear Accountability**: It explicitly defines the financial responsibility of the two participating governments, leaving no ambiguity about who is obligated to provide resources for the Framework's activities.
- **Predictability and Planning**: By specifying the funding sources, it enables more accurate financial planning and resource allocation for the agreed-upon health programs.
- **Empowering Domestic Ownership**: By focusing on funding from these two governments, it encourages the Government of Kenya to take greater financial ownership and integrate these health initiatives into its national budget, aligning with broader goals of self-reliance mentioned in the Preamble of the Cooperation Framework.
- **Risk Management**: It implicitly highlights that if funds, personnel or other resources are not available from these two parties, the planned activities may be affected or unable to proceed.

What people should watch or ask

To ensure effective implementation and address potential challenges, stakeholders should focus on:

- **Transparency of Resource Allocation:** Are both governments consistently allocating the promised funds and other resources as detailed in the supporting documents (e.g. the funding tables in Appendix 1 of the Cooperation Framework, Page 32)? Are there clear, accessible reports on these allocations and expenditures?
- **Sufficiency of Resources:** Is the "availability of funds, personnel and other resources" genuinely sufficient to meet the ambitious goals and metrics outlined in Paragraph 3 of the Framework? Are there any identified gaps or shortfalls?

PARAGRAPH 11: CONFIDENTIALITY

What this paragraph says

Unless authorized, parties will not disseminate or make available any information exchanged under this Cooperation Framework to any third party (with the exception of the parties' contractor support personnel) or to use the information for purposes other than which such information was provided, without prior written consent of the party that provided the information. The paragraph also says that either party may make the Framework itself public, so confidentiality cannot be a reason to withhold the Framework.

What this really means

This paragraph outlines strict rules for how information exchanged between the U.S. and Kenyan governments under the Cooperation Framework must be handled. It establishes a general principle of confidentiality, meaning that:

- **No unauthorized sharing:** Neither party can share or make available any information obtained under this Framework with any outside group or individual ("third party") unless they have explicit permission to do so. The framework further allows either party to make this framework public, unless justified and in line with the Access to Information Act, the contexts of this framework should be made available to the public.
- **Limited Exception for Contractors:** The only explicit exception is for "contractor support personnel" who might need access to perform their duties related to the Framework.

- **Purpose-Limited Use:** The information can only be used for the specific reasons it was initially provided within the context of the Cooperation Framework. It cannot be repurposed for other uses.
- **Consent Required for Changes**: If a party wishes to share information with unauthorized third parties or use it for purposes other than originally intended, they must obtain prior written consent from the party that originally provided that information.

This is reinforced by Article 3 (b) – Confidentiality and Article 3(c) – Prohibited use, of the DSA. The DSA further specifies that the "U.S. Government shall take all reasonable measures to protect the confidentiality of information contained within the Covered Data Systems" and notify Kenya of any unauthorised access, use, or disclosure of PII or other data breaches. The U.S. is to protect confidentiality "in accordance with U.S. data protection standards", while all confidentiality measures "shall abide by applicable laws and regulations of the Republic of Kenya".

Why this Matters

Confidentiality is a cornerstone of any effective international cooperation and health system, especially when dealing with sensitive health and government data:

- **Builds Trust**: Knowing that shared information will be protected fosters trust and encourages open communication and collaboration between the U.S. and Kenyan Governments
- **Protects Sensitive Information**: It safeguards patient privacy, national health security information, proprietary research data, and other sensitive governmental communications from unauthorized access or misuse. This is critical given the DSA's focus on health data.
- **Ensures Ethical Data Use**: By limiting the use of information to its intended purpose, it prevents exploitation or misapplication of data, upholding ethical standards in public health programs.
- **Legal Compliance**: It ensures adherence to relevant data protection laws in both countries (e.g. Kenya's Data Protection Act, 2019 and Digital Health Act, 2023 as highlighted in the DSA)
- Maintains Program Integrity: Unauthorized disclosure or misuse of information could undermine the effectiveness and public perception of the health cooperation programs.

What people should watch or ask

To ensure this critical paragraph is effectively upheld, stakeholders should monitor and inquire about:

- **Clear Procedures for Consent**: How are requests for "written consent" handled? Is there a transparent, documented process for seeking and granting permission for broader dissemination or alternative use of information?
- **Definition and Oversight of "Contractor Support Personnel":** Who constitutes "contractor support personnel" in practice? The DSA also allows data audits by the U.S. Government "or its contractors" (Article 4(b)). What vetting, training and contractual obligations are in place to ensure these individuals and entities also adhere to strict confidentiality and purpose-limited use rules? Are there specific data access agreements with these contractors?
- **Data Anonymization and Aggregation:** Given the DSA's emphasis on not sharing PII with the U.S. Government - DSA Page 2 Article 2 (a), how are data anonymization and aggregation processes rigorously implemented and verified before information is exchanged to prevent re-identification?
- **Monitoring and Audit Mechanisms:** What systems are in place to actively monitor compliance with confidentiality and purpose-limited use? Are the regular audits mentioned in the

Cooperation Framework (and the joint data audits under Article 4(b) of the DSA) specifically checking for adherence to these data handling rules?

- **Data Breach Response Plan:** Beyond notification (as required by the DSA, Article 3(b)), what are the clear, agreed upon protocols for responding to a data breach, including investigation, containment, mitigation and communication to affected persons and the public, in accordance with both Kenya and U.S. laws?
- **Training and Awareness**: Are all personnel involved in handling information exchanged under the Framework receiving mandatory, regular training on data confidentiality, security protocols, and the consequences of non-compliance?

PARAGRAPH 12: PRIVILEGES, IMMUNITIES, AND FACILITIES

What this paragraph says

No provision of the Cooperation Framework should be interpreted as a waiver of the privileges, immunities and facilities parties enjoy by virtue of international agreements and laws applicable to each party.

What this really means

This is a standard disclaimer which means that by simply participating in this specific health cooperation framework, neither the U.S or Kenyan government is giving up or diminishing any of the special legal protections they already hold. These protections, such as diplomatic immunity, sovereign immunity, and other operational facilities, stem from pre-existing international agreements (like treaties) and their respective national laws. Essentially, this framework is not intended to remove or reduce any of those established legal rights and benefits. It does not create any new immunity for U.S. officials, contractors or implementing partners; it only preserves what already exists. The DSA has a similar clause (Article 5(e)), which expressly mentions “immunity from suit”.

Why this Matters

This paragraph is crucial for maintaining the legal and operational capacity of both sovereign entities:

- **Protects Sovereignty**: It affirms that participating in a collaborative health initiative does not equate to surrendering inherent sovereign rights and protections.
- **Ensures Operational Freedom**: It safeguards the ability of each government and its authorized personnel to function without being unduly subjected to the legal jurisdiction or constraints of the other party beyond what is already established by international law.
- **Mitigates Legal Risk**: Without such a clause, there could be an unintended interpretation that the Framework implies a waiver of these significant legal protections, potentially exposing officials or government assets to claims or legal challenges in foreign courts.
- **Facilitates Confidence**: It provides both parties with confidence that their broader legal status remains intact, encouraging greater cooperation within the specific scope of the health framework.

What people should watch or ask

While it is a standard clause, its practical implications can be complex:

- **Clarity on specific protections**: What specific “international agreements and laws” (e.g. the Vienna Convention on Diplomatic Relations, Kenya’s Privileges and Immunities Act (Cap. 179 Laws of Kenya), the U.S. Foreign Sovereign Immunities Act) are most relevant to these privileges and immunities of personnel and assets involved in this framework?

- **Interactions with domestic law**: How would this clause be applied if an action taken under this framework, or a specific provision within it, were perceived to challenge or test the limits of these privileges and immunities under either party's domestic law?
- **Dispute resolution for privilege claims**: If a disagreement arises where one party believes its privileges or immunities are being impinged upon, how would such a specific issue be resolved within the Framework's broader dispute resolution mechanism (Cooperation Framework, Page 29 Paragraph 14.1 and Data Sharing Agreement Page 5 Article 5 (h) which both specify "consultations and negotiations through diplomatic channels")?
- **Application to third parties**: While the clause directly applies to the two governments, how does it indirectly affect the legal status of or protections of entities like contractors or implementing partners operating under the framework?
- **"Governing Law" context**: The DSA, Page 5 Article 5 (f) states that for data sharing under Article 2, Kenyan laws and regulations shall prevail in case of divergence. While this specific rule for data sharing clarifies precedence, it also highlights the need to understand how the "non waiver" clause interacts with specific rules of legal precedence in other areas of the framework.
- **Remedies for individuals**: Because existing immunities, including the U.S. Government's immunity from suit, are preserved, a Kenyan whose data is mishandled may find it hard to sue the U.S. Government directly.

PARAGRAPH 13: NOTICES

What this paragraph says

This paragraph provides those designated to receive any notices under the Cooperation Framework. Each party may by notice to the other party designate additional representatives or substitute other representatives for those designated under this paragraph.

What this really means

This paragraph establishes the official communication channels and designated individuals for any formal correspondence between the U.S. and Kenyan governments regarding the framework.

- **Designated Contacts:** It explicitly names the initial primary contacts: for the U.S. Government, it's the Chief of Mission at the U.S. Embassy in Nairobi; for the Kenyan Government, it's the Cabinet Secretary of the Ministry of Health. Specific physical and email addresses are provided for these officials.
- **Flexibility in Designation:** It allows each party to change or add to these designated representatives. If either government wishes to appoint new or additional persons to receive notices, they must do so by providing a written notification to the other party.
- **Written Communication:** All formal communications (notices, requests, etc) under this Framework are required to be in writing and sent to the specified addresses.

This ensures that crucial official information is directed to the appropriate channels and individuals. The DSA has its own notices clause (Article 5(d)). It is worth noting that this clause designates the Principal Secretary, Medical Services, as the Kenyan contact for purposes of notices, whereas Paragraph 13 of the Framework names the Cabinet Secretary for Health.

Why this Matters

This clause is essential for several reasons:

- **Legal clarity and compliance**: It formalizes communication, preventing disputes over whether a notice was properly delivered or received. This is critical for legal obligations, timelines, and procedural fairness under the framework.
- **Operational efficiency:** By designating specific points of contact, it streamlines communication, reduces confusion, and ensures that important updates, requests or formal notifications reach the relevant decision-makers promptly.
- **Accountability:** The designated officials are responsible for receiving and acting upon official communications, thereby creating clear lines of accountability for administrative aspects of the cooperation.
- **Adaptability:** The provision allowing parties to change their designated representatives offers flexibility. This is important for a multi-year agreement where personnel or organizational structures may evolve over time without requiring a full amendment of the framework itself.
- **Risk mitigation**: It helps mitigate the risk of miscommunication or missed deadlines, which could otherwise jeopardize the implementation or status of the cooperative activities.

What people should watch or ask

To ensure this clause functions effectively, stakeholders should:

- **Maintain up-to-date contact information:** Regularly verify that the listed contact information (physical addresses and email) for both designated officials remains current. If there are changes, ensure the formal written notification process is followed immediately.
- **Internal distribution protocol**: Within each government, confirm that robust internal procedures are in place to ensure that any notice received by the designated official is promptly and accurately disseminated to all relevant departments, technical teams, and individuals involved in the Framework's activities.
- **Confirmation of receipt:** For particularly critical notices, (e.g. regarding potential discontinuation, major modifications or significant audit findings), establish a practice of requesting a formal acknowledgement of receipt from the other party to prevent future disputes.
- **Clarity on "written notice":** While an email address is provided, seek clarity on whether electronic mail to the designated address is considered a legally sufficient "written notice" or if a physical letter to the postal address is always required for formal communications. Ambiguity could lead to legal challenges.
- **Designation of alternates/ backups**: Encourage both parties to formally designate alternate representatives for receiving notices, especially to cover periods of leave, travel, or unforeseen absence of the primary designated official, to ensure continuous communication.

PARAGRAPH 14: RESOLUTION OF DIFFERENCES

What this paragraph says

Parties will resolve any differences arising from or in connection with the interpretation or performance of this Cooperation Framework through consultations and negotiations using diplomatic channels.

What this really means

This paragraph specifies the agreed-upon method for handling any disagreements or issues that arise between the U.S. and Kenyan governments concerning this Cooperation Framework. It states that:

- **Amicable resolution**: Both parties commit to resolving disputes peacefully and cooperatively
- **Methods**: The primary methods for resolution are "consultations and negotiations." This implies direct discussion and dialogue between representatives of both governments.
- **Channel:** These discussions will be conducted through "diplomatic channels," meaning official communications and interactions typically handled by foreign ministries and embassies, rather than through litigation and other adversarial processes.
- **Scope:** This applies to any differences related to how the Framework is "interpreted" (what its provisions mean) or how it is "performed" (how its activities are carried out).

The DSA has its own, firmer resolution of differences clause (Page 5, Article 5(h)), stating "the parties shall resolve any differences between them arising from or in connection with the interpretation or performance of this agreement solely through consultations and negotiations through diplomatic channels."

Why this Matters

This dispute resolution clause is extremely important for a stable and effective international cooperation:

- **Preserve relationship**: It prioritizes maintaining a constructive and friendly bilateral relationship.
- **Avoids escalation:** It provides a clear, non-adversarial path for addressing disagreements, preventing them from escalating into larger diplomatic incidents or legal battles.
- **Flexibility and customization:** Consultations and negotiations allow for flexible, mutually acceptable solutions that consider the unique context of the cooperation, rather than imposing rigid legal outcomes.
- **Cost effective**: Diplomatic resolution is typically far less costly and time-consuming than formal legal proceedings.
- **Ensures continued cooperation:** By having a mechanism to iron out differences, the overall framework can continue to function effectively even when specific issues arise.

What people should watch or ask

While the paragraph promotes amicable resolution, its practical implementation requires careful attention:

- **Defined process for "consultations and negotiations":** Are there specific internal guidelines or established norms for how these consultations and negotiations will be initiated, structured and documented?
- **Timelines for resolution**: Are there any implied or agreed upon timelines for responding to or resolving a dispute once it has been formally raised through diplomatic channels?
- **Involvement of the Joint Health Framework Steering Committee (JHFSC):** Given the JHFSC's role in monitoring implementation and proposing modifications (Cooperation Framework Page 24, Paragraph 4.3), will the JHFSC be the primary forum for initial consultations and negotiations on Framework-related disputes, or will it be elevated immediately to higher diplomatic levels?
- **Mechanisms for impasse**: What happens if consultations and negotiations through diplomatic channels fail to resolve a significant difference? While the clause doesn't specify further steps (like mediation or arbitration), it is important to understand if there are any unspoken understandings or fallback options, or if an unresolved dispute could lead to discontinuation (Cooperation Framework, Page 31 Paragraph 22.1)

- **Transparency of disputes**: To what extent will the public or other stakeholders be informed about the nature of disputes and their resolution process?
- **Record-keeping:** How will the discussions, proposals, and outcomes of these consultations and negotiations be documented to ensure institutional memory and consistent application of the framework?

PARAGRAPH 15: SEPARATE AGREEMENTS

What this paragraph says

For furtherance of implementation of the Areas of Cooperation, parties may enter into subsidiary agreements to give effect to any provisions of the Cooperation Framework, including financing agreement(s), data sharing agreements and specimen testing agreements.

What this really means

This paragraph outlines a practical approach for detailing specific aspects of the broader health cooperation. It means that:

- **Enabling detailed implementation**: To effectively carry out the "Areas of Cooperation" set out in Paragraph 2 of the Framework, the parties don't need to put every single detail into the main document.
- **Optional, specific agreements:** Instead, they have the flexibility to create additional, smaller agreements ("subsidiary agreements"). These agreements will focus on provisions of the main framework and "give effect" to them, meaning they will add the necessary operational and legal specifics.
- **Examples provided**: The clause explicitly list examples of such detailed agreements:
    - Financing agreement(s) – specifying how much money will be exchanged and managed
    - Data sharing agreement(s) – detailing the terms for exchanging health data
    - Specimen testing agreement (s) – outlining protocols for sharing and testing biological samples

The DSA is an example of such a subsidiary agreement, as it spells out the terms and conditions for data provision, use, confidentiality and responsibilities that are broadly alluded to in the main framework. Several key details, such as the list of Covered Data Systems, are left to be agreed later. The other subsidiary agreements contemplated by the Framework, including financing agreements, tax-exemption agreements (2.7.1) and any specimen testing agreement, have not been made public.

Why this Matters

This clause is vital for the flexibility, practicality and legal robustness of the overall cooperation.

- **Flexibility and Adaptability:** It allows the main Cooperation Framework to remain a high-level strategic document, while enabling detailed operational aspects (like data sharing or specific funding mechanisms) to be worked out in separate, more nimble agreements. This means the overall framework does not need to be constantly amended for every minor operational detail.
- **Specificity and Enforceability**: Subsidiary agreements can provide the granular detail and legal specificity needed for complex activities (like data sharing protocols or financial transfers) that wouldn't fit into a broad framework. This makes these specific provisions more actionable and enforceable.

- **Addresses diverse needs**: Different aspects of cooperation (e.g. funding vs. data vs. laboratory work) often require distinct legal considerations and operational procedures. Subsidiary agreements allow for these specialized needs to be met appropriately.
- **Focus on core areas**: It enables the parties to focus on agreeing to the core principles and objectives in the main framework, with the understanding that the "how-to" will be finalised in subsequent, targeted agreements.

What people should watch or ask

It is important to monitor implementation of this paragraph closely and look out for the following:

- **Timely development of subsidiary agreements:** Are the necessary subsidiary agreements being developed and signed in a timely manner? Delays in creating these detailed agreements could hinder the implementation of the main Framework's objectives. The Ministry of Health should publish each subsidiary agreement once it is signed.
- **Consistency with the main framework**: Are the terms of the subsidiary agreements fully consistent with the overarching principles and objectives laid out in the main Cooperation Framework? They should elaborate, not contradict.
- **Clarity and detail:** Do the subsidiary agreements provide sufficient clarity and detail to guide implementation effectively? For example, the DSA specifies the form of data (aggregate), access mechanisms and legal compliance (DSA Page 2), but leaves the list of Covered Data Systems, data types and authorized users to be agreed later (Article 2(a)).
- **Comprehensive coverage:** Are all provisions of the Framework that require further detailing being addressed by appropriate subsidiary agreements? What about areas not explicitly listed as examples, like those related to intellectual property (Cooperation Framework, Pg 30, Para 18).
- **Oversight and coordination:** How will the various subsidiary agreements be managed and coordinated? Will the JHFSC also oversee the development and implementation of these subsidiary agreements?
- **Legal precedence and conflict resolution**: In cases where a subsidiary agreement might seemingly conflict with the main framework, which document takes precedence? The DSA states that for data sharing under Article 2, Kenyan laws and regulations shall prevail (DSA Pg 5 Article 5 (f)), but the relationship between the main framework and a subsidiary agreement in other areas might need clarification.

PARAGRAPH 16: PARTICIPATION IN SIMILAR ACTIVITIES

What this paragraph says

This Cooperation Framework does not keep the parties from working on similar activities with other groups or agencies that are not included in this framework.

What this really means

This statement of non-exclusivity means:

- **No restrictions on other work**: Entering this Cooperation Framework does not prevent either the U.S. Government or the Government of Kenya from engaging in other, separate activities with different countries, organizations or agencies.
- **Focus on "similar activities":** This freedom specifically applies to activities that are "similar" in nature to those covered by this Framework.

- **"Not otherwise covered":** It explicitly states that this applies to activities "not otherwise covered by this framework." This means activities that are either outside the scope of this specific framework or handled through different arrangements.

In essence, this Framework is one avenue for health cooperation, but it's not the only avenue. Both parties retain the right to pursue other bilateral or multilateral health initiatives.

Why this Matters

This paragraph is important for several reasons:

- **Strategic flexibility:** It grants both governments the necessary flexibility to pursue their broader foreign policy and public health objectives without being constrained solely by the terms of this one agreement. They can adapt to new global health challenges or seize new opportunities for collaboration as they arise.
- **Maximizing global health impact:** For the U.S., it means it can continue its global health efforts with various partners worldwide. For Kenya, it means it can diversify its health partnerships and seek assistance or collaborate with other nations or organizations on similar health issues to maximize benefits for its population.
- **Avoids unintended limitations**: Without this clause, there might be an ambiguous interpretation that by signing this framework, the parties implicitly agree not to work on similar health issues with anyone else, which would be an undue restriction.
- Resource diversification: It allows both parties to tap into different funding sources, expertise and best practices from various partners, which can strengthen overall health outcomes.

What people should watch or ask

While this paragraph ensures flexibility, its implementation requires careful management to avoid pitfalls:

- **Coordination and duplication:** How will the U.S. and Kenyan governments ensure that similar activities pursued outside the framework do not lead to duplication of effort, conflicting strategies, or inefficient use of resources? Is there a broader coordination mechanism for all health sector engagements?
- **Information sharing (or lack thereof):** While this framework doesn't restrict other collaborations, what level of information sharing is expected or desired regarding "similar activities" conducted with other partners, especially if those activities could impact or be impacted by this framework's goals?
- **Resource prioritization:** How do both governments ensure that commitments made under this framework are not undermined by resource allocation decisions made for other "similar activities" with different partners?
- **Ensuring consistency:** Do the principles, standards, and values upheld in these other "similar activities" align with those of the framework, particularly concerning ethical standards, data privacy and human rights?
- **Impact of Framework's goals:** Is there a process to periodically assess whether external "similar activities" are inadvertently detracting from or, conversely, contributing positively to the goals and progress of the cooperation framework?
- **Transparency of other engagements:** To what extent will information about other "similar activities" be made transparent to relevant stakeholders e.g. the JHFSC?

PARAGRAPH 17: BASIC PRINCIPLE OF IMPLEMENTATION

What this paragraph says

The participants agree to follow internationally recognized principles and values that match their local laws.

What this really means

This paragraph sets a foundational ethical and legal standard for the entire cooperation. It means that:

- **Global standards as a guide:** Both U.S. and Kenyan governments commit to upholding accepted norms and ethical guidelines e.g. in areas like human rights, public health ethics, data protection, accountability, and good governance in all their collaborative activities.
- **Domestic law is paramount**: Crucially, the implementation of these international principles and values must always be "consistent with their applicable domestic laws." This implies that while they aim for global best practices, no action under the framework should violate national laws, rules and regulations of either country. If there is perceived conflict, the domestic legal framework will likely take precedence or guide the interpretation of the international principle.

The DSA reiterates and operationalises this principle, for instance:

- **Page 2, Article 2 (a):** States that Kenya "shall provide data according to the Data Protection Act, 2019, the Digital Health Act, 2023 and other applicable laws and regulations in Kenya."
- **Page 3, Article 3 (b):** Emphasizes that "all data confidentiality measures shall abide by applicable laws and regulations of the Republic of Kenya."
- **Page 3, Article 4 (d):** Requires the U.S. government to "comply with all applicable Kenyan and U.S. laws and regulations in its use of data derived from the Covered Data Systems."
- **Page 5, Article 5 (f):** Explicitly states "in the event of any divergence between the laws and regulations of the Republic of Kenya and U.S. Federal laws applicable to data sharing under Article 2, the laws and regulations of the Republic of Kenya shall prevail." This is a clear example of how domestic law (Kenyan in this specific data context) takes precedence.

Why this Matters

This clause is essential for grounding the cooperation in shared ethical foundations while respecting national sovereignty:

- **Ethical and Responsible Conduct**: It ensures that all activities are conducted with integrity, fairness, and respect for human dignity, aligning with global best practices in health and data governance.
- **Legitimacy and trust:** Adherence to both international principles and domestic laws enhances the legitimacy of the framework and builds public trust in the collaborative efforts.
- **Respect for sovereignty**: The "consistent with domestic laws" qualifier is vital. It acknowledges and upholds the sovereign right of each nation to define and enforce its own legal framework, preventing external principles from overriding national legislation. This is particularly sensitive in areas like health and data.
- **Harmonization, not subordination**: It encourages a process of harmonization where international best practices are adopted in a manner compatible with national legal systems, rather than simply imposing external standards.

- **Stronger data governance:** For the DSA, this principle is foundational, ensuring that data sharing occurs under strong legal protections, particularly Kenya's domestic data privacy laws, which are paramount in this context.

What people should watch or ask

To ensure this principle is effectively applied, stakeholders should consider:

- **Specific definition of principles:** Are there agreed upon definitions or examples of these "internationally recognized principles and values" that are most relevant to this framework? (e.g. principles of equitable access to health, non-discrimination, responsible data stewardship, ethical research conduct).
- **Conflict resolution protocol:** What is the established process for identifying and resolving potential inconsistencies or conflicts between a particular international principle and a domestic law? The DSA offers a clear rule for data sharing (Kenyan law prevails), but how will other types of conflicts be handled?
- **Legal expertise and review:** Are legal experts from both governments regularly reviewing planned activities to ensure compliance with both sets of requirements? This is especially crucial for areas not as explicitly defined as data sharing.
- **Transparency of compliance**: How will adherence to both international principles and domestic laws be monitored and reported? Will these compliance efforts be transparent, and will stakeholders have access to information on how potential conflicts are addressed?
- **Capacity building for compliance:** Are there efforts to strengthen the capacity of personnel in both countries to understand and apply the complex international principles and domestic laws, especially as the legal frameworks evolve?
- **Dynamic nature of law**: How will the framework adapt to changes in either domestic laws or evolving international principles and values over its five-year duration?

PARAGRAPH 18: INTELLECTUAL PROPERTY

What this paragraph says

All intellectual property rights related to any research, products, or services created together by the parties will be decided individually based on applicable laws and relevant international agreements. Each party can use, share, or modify this intellectual property with the other party's written consent. If either party wants to use the intellectual property for purposes beyond what is outlined in the cooperation framework, parties will address that situation with a separate agreement.

What this really means

This paragraph lays out how ownership and usage rights will be managed for new creations resulting from the collaboration. For instance:

- **Case by case IP determination (18.1):** When U.S. and Kenyan governments jointly develop any new research findings, products, or services under this Framework, the ownership and rights to these creations (intellectual property or "IP") will not be automatically assigned. Instead, they will be decided on an individual basis for each specific creation. These decisions must follow existing national laws of both countries and any relevant international agreements they are party to.
- **Joint use requires consent (18.2):** For any IP developed together, either party is allowed to use, copy, adapt, modify, publish, share, licence, or transfer that IP, but only with the express written permission of the other party.

- **External use needs separate agreement (18.3):** If one party wants to use this jointly developed IP for purposes that fall outside the defined scope of the Cooperation Framework, they cannot do so unilaterally. They must negotiate and enter into a brand new, separate agreement with the other party to address the terms and conditions of such external use.
- **Regarding the DSA:**
    - The DSA specifically addresses intellectual property rights related to the data itself and the Covered Data Systems. On Page 3 article 3 (d) – Data Ownership, it clearly states "The U.S. government acknowledges that the Government of Kenya retains sole ownership of the data and all intellectual property rights in Covered Data Systems. No licence or conveyance of any such rights in the data is granted or implied under this agreement." This means that while the Cooperation Framework's IP clause covers jointly developed research/products/services, the DSA ensures Kenya retains full IP ownership of the underlying health data and systems that are the foundation for the framework.

Why this Matters

This IP clause is crucial for fostering innovation, protecting investments, and ensuring equitable benefits from collaboration:

- **Encourages innovation**: Clear rules about IP encourage both parties to invest resources and expertise into joint research and development, as they know their contributions and potential benefits will be recognized and protected.
- **Prevents disputes**: IP is often a contentious area in collaborations. By outlining a clear process for determining ownership and usage, this clause aims to prevent future disagreements and legal battles over valuable assets.
- **Fairness and equity**: The requirement for case-by-case determination and mutual consent for use ensures that benefits derived from joint IP are shared equitably and that neither party can exploit the creations without the other's agreement.
- **Protects commercial value:** Many innovations have significant commercial or strategic value. This clause safeguards that value for both governments.
- **Distinguishes data from IP**: The DSA's specific clause on Kenya's sole ownership of data and data systems IP (DSA page 3 Article 3 (d)) is a critical distinction. It ensures that the act of sharing data for cooperation does not transfer ownership of that data or its underlying systems, reinforcing data sovereignty.

What people should watch or ask

Effective implementation of this IP clause requires careful attention to detail, including:

- **Clear "case-by-case" process**: How and when will IP rights for each new research, product, or service be determined? What specific criteria will be used? Who will be involved in these decisions? Is there a template or standardized approach for these determinations?
- **Default ownership/ Licence terms:** If a "case-by-case" agreement isn't explicitly reached for a specific output, what are the default assumptions or fallback positions for ownership and usage?
- **Definition of "applicable laws" and "international agreements":** Which specific national laws and international agreements are most relevant to IP rights in the context of this health cooperation? Having clear understanding of these will be crucial.
- **"Written consent" mechanism**: Is there a clear, efficient process for requesting and granting "written consent" for using, sharing, or modifying jointly developed IP? What constitutes a valid consent?

- **Negotiation of "Separate agreements":** What is the expected framework or starting point for negotiating "separate agreements" when a party wants to use joint IP outside the framework's scope? This can be a complex negotiation point.
- **Tracking and documentation**: How will all jointly developed IP be tracked and documented? How will decisions regarding ownership, usage rights, and consent be formally recorded and made accessible for both parties?
- **Link to "Benefits arising thereof" (DSA):** The DSA mentions that "benefits obtained based on insights derived from data provided shall require entering into other subsidiary agreements" (DSA Page 3, Article 3(f)). This directly relates to IP, as insights can lead to new IP. How will the IP clause in the Cooperation Framework and this "benefits" clause in the DSA be harmonized to ensure fair and consistent handling of all new value created?

PARAGRAPH 19: LEGAL STATUS

What this paragraph says

The cooperation framework is not an international agreement and does not give rise to rights or obligations under international or domestic law.

What this really means

This is a critical declaration about the document's legal nature. It explicitly states that:

- **Non-binding document:** The Cooperation Framework is not a legally binding treaty or international agreement in the traditional sense. It does not carry the same legal force as a treaty that requires ratification and creates legally enforceable commitments under international law.

No legal rights or obligations: As a direct consequence of its non-binding status, the framework's provisions do not create any legally enforceable rights for either party, whether under international law or their respective domestic laws. This does not however mean the Kenyan government can act outside Kenyan law when it implements the Framework. Every decision taken under it must comply with the Constitution and other Kenyan laws, and can be challenged in Kenyan courts, including as administrative action.

Essentially, the framework is a statement of political intent and shared objectives, a roadmap for collaboration based on good faith and mutual understanding, rather than a legally enforceable contract.

The DSA is worded differently. Article 5(g) of the DSA (Page 5) states: "This Agreement does not constitute an international agreement and the legal obligations under this Agreement do not arise under international law." Unlike paragraph 19.1 of the Framework, this does not say that the DSA creates no rights or obligations under domestic law. On the contrary, it refers to "legal obligations under this Agreement" (DSA, Article 5 (g)). Its status under Kenyan law is therefore less settled than the Framework's. Either way, the Kenyan government's duties under the Data Protection Act, 2019 apply in full to any data it shares.

Why this Matters

This legal status significantly impacts the nature of the cooperation:

- **Flexibility and speed**: Declaring a document non-binding often allows for quicker negotiation and implementation, as it avoids lengthy domestic and international legal and ratification processes typically required for treaties. It also avoids parliamentary approval and public participation.

- **Political commitment vs. legal enforcement**: It relies heavily on the political will and good faith of both governments. Compliance is driven by shared interests, diplomatic pressure and reputational concerns, rather than the threat of legal action.
- **Reduced legal risk**: For both parties, it minimizes the direct legal liabilities and risks that would be inherent in a fully binding international agreement.
- **Framework for further action:** Although the main framework is expressed to be non-binding and the DSA's status is less clear, they set the stage for other activities or agreements which could be legally binding. For instance, specific grants or contracts made under the framework might be legally enforceable.

What people should watch or ask

Given the non-binding nature of the framework and the uncertain status of the DSA, stakeholders and citizens must critically assess:

- **Reliance on good will:** How robust is the underlying political commitment and mutual trust between the U.S. and Kenyan Governments? If disagreements arise (as per Cooperation Framework, Page 29, Paragraph 14.1 and DSA Page 5, Article 5 (h), both referring to "consultations and negotiations through diplomatic channels"), without legal obligations, the resolution entirely depends on political will.
- **Consequences of non-compliance**: What are the actual implications if one party fails to uphold a commitment (e.g. Kenya not meeting co-investment targets, or the U.S. not providing funding)? The U.S. may reduce or stop funding if Kenya misses its co-investment (6.1.1, 6.1.4), all activities are subject to the availability of funds (10.1), and either side may withdraw on six months' notice (22.1). There is no equivalent remedy for Kenya if U.S. funding falls short.
- People should watch out for the court's decision on the binding nature the DSA. It has been raised before court that while the agreement indicates that it's not binding, the agreement has detailed obligation, timelines, financial obligations that affect public finance as well as implications on the right to health and privacy. The court's decision on this will be critical in follow up and accountability.

PARAGRAPH 20: COMMENCEMENT AND DURATION

What this paragraph says

The activities under the cooperation framework will start once both parties sign it. This cooperation framework will last for five (5) years, after which the parties will review how the activities have been carried out and may agree to extend if they both decide to do so.

What this really means

This paragraph sets the timeline for the collaborative activities:

- **Immediate start:** The activities outlines in the Cooperation Framework are intended to begin as soon as both the U.S. and Kenyan governments officially sign the document.
- **Fixed term**: The framework is designed to operate for a period of five (5) years from its commencement.
- **Mandatory review:** At the end of the five-year period, both parties commit to reviewing everything that has been done under the framework.
- **Optional extension:** Based on the outcomes of this review, and only if both governments mutually agree, the cooperation framework can be extended for an additional period.

It is important to note a distinction from the DSA, Page 4 Article 5(a) "Duration" – states that "it shall remain in force for seven (7) years as per Article 2(b) of this agreement." This means the provision of data under the DSA is intended for a longer duration (7 years) than the initial overall Cooperation Framework activities (5 years).

Why this Matters

This clause is essential for structuring the collaboration and ensuring its effectiveness:

- **Provides clarity and certainty:** It sets clear expectations for when work begins and how long the initial phase will last, which is crucial for planning, resource allocation and project management.
- **Ensures accountability and evaluation:** The mandatory five-year review forces both parties to assess their progress, identify successes and failures, and understand the impact of their joint efforts. This promotes accountability.
- **Facilitates adaptation:** The option to extend based on a review allows for flexibility. If the framework is successful and relevant, it can continue. If it needs adjustments or has met its objectives, it can be allowed to expire or be significantly modified.
- **Signals long-term commitment (with reviews):** While not indefinite, a five-year term signals a significant commitment to a sustained cooperation, balanced by the prudence of periodic evaluation.
- **Distinct data durability**: The longer 7-year duration for data provision in the DSA (Page 4, Article 5 (a)) suggests that the data infrastructure and exchange mechanisms are viewed as having a more enduring utility, potentially serving future cooperation beyond the initial five-year cycle of the broader framework. It also means data could keep flowing to the U.S. for two years after the U.S. funding commitments under the Framework end, unless the DSA is ended or Article 2(c)(iv) (restriction of data if U.S. funding is cut) is applied.

What people should watch or ask

To ensure effective implementation and manage the lifecycle of the framework, stakeholders should pay attention to:

- **Clarity on "commencement"**: Was the framework signed by both parties, thus initiating activities?
- **Metrics for the five-year review:** What specific criteria and metrics will be used to evaluate "how the activities have been carried out"? Will these align with the Performance Indicators outlined in paragraph 3 of the framework (pages 22 to 24)? Is the review process clearly defined and transparent?
- **Process for extension**: What is the procedure for proposing and agreeing to an extension? Who initiates it? What factors will heavily influence the decision to extend? Will the review findings be the sole basis for extension, or will other political/strategic considerations play a role?
- **Transition planning (if not extended)**: If the framework is not extended, what are the plans for transitioning or sunsetting the activities to ensure that achievements are sustained and essential services continue, especially for activities that have become integrated into Kenya's domestic health system?
- **Alignment of timelines (framework vs. DSA):** Given the 5-year duration of the Cooperation Framework and the 7-year duration for data provision under the DSA, what happens to data collection and sharing in years 6 and 7 if the main cooperation framework is not extended? Will the data still be collected and shared, and for what purpose, if the broader activities have ceased? This potential misalignment needs a clear understanding.

- **Involvement in review**: Who will be involved in the five-year review process? Will it include the JHFSC and will broader stakeholders be consulted?

PARAGRAPH 21: MODIFICATION

What this paragraph says

The cooperation framework may be modified by the mutual decision of the parties in writing, with the modifications being operative on a date mutually determined by the parties.

What this really means

This paragraph defines how the framework itself can be changed over time. It states that:

- **Joint agreement is required**: Any alterations or updates to the framework must be agreed upon by both U.S. and Kenya governments. Neither party can unilaterally change the terms.
- **Formal documentation:** All agreed-upon changes must be put down "in writing" to ensure clarity, accuracy and a formal record.
- **Agreed-upon effective date**: The date on which these modifications take effect will also be decided and agreed upon by both parties.

The DSA contains a very similar provision on Page 4 Article 5 (c), stating, "this agreement may be amended by mutual written consent of the parties." This confirms that both the overarching framework and its subsidiary data agreement follow the same principle of modification.

Why this Matters

This modification clause is crucial for the long-term viability and effectiveness of the framework:

- **Flexibility and adaptability:** Over a five-year (or potentially longer) period, circumstances, scientific understanding, policy priorities, or operational realities may change. This clause provides the necessary flexibility to adapt the framework to new conditions without having to terminate and restart the entire cooperation.
- **Ensures shared ownership**: By requiring "mutual decision" and "written" agreement, it reinforces the principle of equal partnership and shared ownership of the framework. Neither party can impose changes on the other.
- **Maintains relevance**: The ability to modify the framework allows it to remain relevant and responsive to evolving public health needs and strategic objectives throughout its duration.
- **Stability and predictability:** While allowing for change, the requirement for mutual written agreement ensures that modifications are deliberate, documented, and transparent, providing a stable and predictable environment for cooperation.
- **Reduces rigidity:** Without such a mechanism, the framework could become outdated or unworkable, potentially leading to its premature discontinuation.

What people should watch or ask

To ensure that modifications are handled effectively and transparently, stakeholders should consider:

- **Initiation of modifications**: What is the established process for proposing a modification? Which body or official is responsible for identifying the need for a change and formally initiating discussions?
- **Decision-making processes**: How will the "mutual decision" be reached? Will the JHFSC play a key role in discussing, recommending, or approving modifications? What level of approval is required within each government (e.g. ministerial, parliamentary)?

- **Transparency of proposed changes:** Will proposed modifications, along with their rationale, be made public or accessible to the relevant stakeholders before they are finalised? This is particularly important for changes that might impact specific programs or beneficiary groups.
- **Documentation and dissemination**: How will modifications be formally documented? Will they be appended to the original framework or will a new consolidated version be issued? How will these changes be communicated to all personnel and partners involved in implementation?
- **Impact assessment**: Before a modification is agreed upon, is there a process to assess its potential impact on existing activities, resource allocations, performance indicators, and any subsidiary agreements (like the DSA)?
- **Alignment of modifications:** If a modification to the main framework impacts provisions covered by the DSA, how will the corresponding modification to the DSA be ensured and synchronized? (as both documents have similar modification clauses, this should be straightforward but requires coordination.)
- **Effective date implementation**: How is the "mutually determined" operative date communicated and implemented to ensure all relevant parties are aware and ready to comply with the new terms from that date?

PARAGRAPH 22: DISCONTINUATION

What this paragraph says

Either party can stop participating in the cooperation framework by providing six (6) months' notice to the other party through official diplomatic channels.

What this really means

This paragraph establishes the terms for either the U.S. government or the Kenyan government to end their participation in the framework. It means that:

- **Unilateral right to withdraw:** Either government has the right to decide to stop being part of the cooperation framework.
- **Formal notice required:** This decision cannot be abrupt. The party wishing to withdraw must inform the other party in writing.
- **Advance warning:** There must be a six (6) month advance notice period. This allows time for an orderly wind-down or transition.
- **Official channels:** The notice must be delivered through "diplomatic channels," meaning official government-to-government communication pathways (e.g., embassies, foreign ministries).

The DSA on Page 4, Article 5(b) – Termination refers to the Framework, stating that the DSA "may be terminated …consistent with Paragraph 4.6 of the Cooperation Framework." However, the Framework has no paragraph 4.6 as Paragraph 4 ends at 4.3. While this cross reference is likely to have been an error, it leaves unclear whether the DSA ends if either government withdraws from the Framework under paragraph 22. Read literally, the only clear way to end the DSA is by mutual written consent. Article 5 (b) further provides that "In the event of termination, access to pertinent data for audit purposes shall be provided to the U.S. Government with prior approval from the Government of Kenya." This means Kenya's consent remains a precondition for U.S. audit access even after the DSA is terminated.

Why this Matters

This discontinuation clause is essential for several reasons:

- **Sovereign right to exit**: It respects the sovereign right of both nations to decide on their foreign policy and cooperative engagements, including the ability to withdraw from non-binding frameworks.
- **Orderly transition:** The six-month notice period is critical – it provides a necessary window for both parties to:
    - Wind down ongoing activities
    - Reassign personnel
    - Manage existing projects and commitments
    - Minimize disruption to services or beneficiaries
    - Plan for data preservation and transfer, especially relevant given the DSA.
- **Risk management:** It offers a clear, predefined exit strategy, which reduces uncertainty and potential for conflict if one party's circumstances or priorities change significantly.
- **Flexibility in non-binding agreements**: In a non-binding framework, having a clear process for discontinuation provides a structured way to end cooperation that doesn't rely solely on mutual consent to stop, which might be difficult to obtain in some circumstances.

What people should watch or ask

If either party considers or gives notice for discontinuation, stakeholders should critically examine:

- **Clarity of the notice:** Is the written notice unambiguous regarding the intent to discontinue and the effective date? Was it delivered through the correct diplomatic channels (likely those specified in Paragraph 13 of the Cooperation Framework)?
- **Transition plan:** What specific plans are being developed during the six-month notice period to ensure an orderly transition? This includes:
    - *Program Continuity*: How will essential health services and ongoing projects be sustained or transferred to other entities?
    - *Resource reallocation*: How will funds, personnel, and other resources previously dedicated to the framework be managed or reallocated?
    - *Data management*: As per the DSA (Page 4, Article 5(b)), how will access to pertinent data for audit purposes be managed, and what is the process for obtaining approval from the Government of Kenya for this access? Will there be specific protocols for archiving or destroying data collected under the framework?
    - *Asset management*: What happens to equipment, infrastructure, or other assets jointly acquired or funded under the framework?
- **Rationale for discontinuation:** What are the stated reasons for discontinuing? Understanding these reasons is vital for future engagement and for learning lessons from the cooperation.
- **Impact assessment:** What is the anticipated impact of discontinuation on health outcomes, local capacity, and the overall bilateral relationship? Has a thorough assessment been conducted?
- **Stakeholder engagement:** How will beneficiaries, implementing partners (especially those whose contracts are now funneled through the Kenyan government per Paragraph 7, Page 27 of the framework), and other stakeholders be informed and engaged during the discontinuation process?
- **Financial reconciliation:** How will all financial commitments and outstanding balances be reconciled during the six-month period?

CONCLUSION: OUR COLLECTIVE FUTURE DEMANDS VIGILANCE

This Cooperation Framework offers significant potential benefits for Kenya's health system. However, the associated Data Sharing Agreement contains clauses that require **immediate and sustained citizen vigilance**. Data protection is not just an abstract concept; it is fundamental to our privacy, security, and national sovereignty. By understanding the details and actively engaging in advocacy, we can ensure this partnership truly delivers on its promise for a healthier, more prosperous Kenya, without compromising the fundamental rights of its citizens.

Citizens must therefore be actively involved and hold the government accountable, especially in the following critical areas:

1. **Demand full implementation of the Health Cooperation Framework:**
    - **Healthcare workers:** Hold the Kenyan Government accountable for absorbing the 13,293 U.S.-funded health worker positions it plans to take on by June 2028, and for a clear plan for the remaining positions and for lay cadres such as mentor mothers, to ensure continuity of crucial services and secure employment.
    - **Domestic funding:** Insist on Kenya Government's commitment to increasing domestic funding for health as outlined, to reduce reliance on external partners and strengthen Kenya's health sovereignty.
    - **KEMSA capacity:** Ensure KEMSA is fully capable of managing the entire health commodity supply chain transparently and efficiently, free from corruption and inefficiencies.
2. **Vigorously safeguard health data (focus on the Data Sharing Agreement):**
    - **Absolute prohibition of PII sharing:** citizens must demand that no individual-level data or PII is ever shared with the US Government. If any exception is ever made under the "maximum extent practical" wording, it must meet the conditions for sending sensitive personal data out of Kenya in section 49 of the Data Protection Act, 2019, respect the right to privacy in Article 31 of the Constitution of Kenya, 2010, and be disclosed publicly.
    - **Strict control over access mechanisms:** demand complete transparency and rigorous safeguards regarding "login credentials" provided to the U.S Government. These must be strictly limited to accessing only aggregated, anonymized data, with clear audit trails and mechanisms to prevent any access to underlying PII.
    - **Unconditional Data Sovereignty:** the DSA links data provision to U.S. funding (Article 2(c)(iv)), but it restricts what Kenya gives the U.S., not Kenya's own access to its data. Kenya's health data is a national asset and it should NEVER be used as a bargaining tool for foreign aid. Citizens must advocate for the Kenyan Government to maintain unconditional control and access to its data, irrespective of funding changes.
    - **Define "covered data systems":** demand a clear, publicly accessible list of which health data systems are covered by this agreement, precisely what aggregate data types will be shared, and who the authorized users are (Article 2(a)).
    - **Adherence to Kenyan Law**: reiterate that Kenya's Data Protection Act, 2019 and the Digital Health Act, 2023 must always prevail in all data sharing arrangements, including data storage and disposal. This matters because the DSA's rule that Kenyan law prevails (Article 5(f)) is limited to data sharing under Article 2, while Article 3(a) also applies U.S. federal records requirements to storage and disposal.

3. **Insist on transparency and accountability for both the Cooperation Framework and the Data Sharing Agreement:**
    - Call for regular, public reports on the progress of both the Cooperation Framework and the Data Sharing Agreement, including financial expenditures, achievement of health targets and audits specifically on data access and use.
    - Demand that such reports include details on any instances where the "maximum extent practical" clause for PII was invoked, and the justification for it, if any.
4. **Strengthen local ownership:** support initiatives that build Kenya's capacity to lead its own health agenda, including local manufacturing of health products and robust training for health workers.
5. **Monitor health outcomes:** pay attention to the specified outcome metrics (e.g. reductions of HIV, TB, malaria deaths, improvements in maternal health) and advocate for interventions if targets are not met.
6. **Coordination with the Council of Governors (COG) and County governments:** The successful implementation of this Cooperation Framework critically hinges on robust coordination between Kenya's national government and its 47 county governments, as county health services are a devolved function under Part 2 of the Fourth Schedule to the Constitution of Kenya, 2010. While the framework establishes national strategies for surveillance, laboratory systems, supply chain, workforce integration, and digital health, the delivery of these services, management of local health facilities, deployment of personnel, and collection of granular data primarily occurs at the county level. Without active and meaningful engagement, buy-in, and harmonized planning with county governments, national initiatives like the operationalization of county emergency centers, the integration of thousands of healthcare workers into payrolls, the distribution of commodities, and the rollout of digital health systems like TaifaCare, HMIS and eCHIS will face significant operational hurdles. Effective collaboration is therefore essential to ensure resources reach the frontline, strategies translate into tangible improvements in health service delivery across all communities, and Kenya's health system truly becomes more resilient and self-reliant.