REPUBLIC OF KENYA

DIGITAL HEALTH AGENCY

Kenya Digital Health Certification Framework



2025

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KENYA DIGITAL HEALTH CERTIFICATION FRAMEWORK

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Digital Health Agency P.O. Box 29409-00100
Nairobi, Kenya.
Website: https://www.health.go.ke/

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Foreword



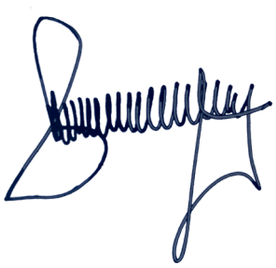
The advancement of digital technologies presents an extraordinary opportunity to reimagine health service delivery in Kenya, and as the Digital Health Agency, we are committed to leading the change in leveraging digital innovation to strengthen our health system, ensuring all Kenyans have access to high-quality healthcare.

The Kenya Digital Health Certification Framework is a cornerstone of this transformation by offering a structured and transparent process for certifying digital health solutions deployed in the country, ensuring their functionality, security, interoperability, and alignment with the national health priorities. More than a regulatory tool, this framework is a catalyst for innovation – designed to promote trust in digital health solutions by upholding the highest standards of patient care and data protection.

In an age where health data is a strategic asset, we must ensure its integrity, protection, and accessibility for decision-making. This framework enshrines these principles by establishing clear criteria and governance structures to guide solution developers, implementers, and users. It also fosters standardization and harmonization across platforms, which are essential to enabling seamless information exchange and delivering person-centered care.

The Digital Health Agency is committed to, in collaboration with the Ministry of Health, County governments, and our partners, ensuring the effective and seamless operationalization of the certification process, which includes conducting periodic reviews of the framework to ensure a secure and resilient digital health ecosystem.

This framework presents our shared vision for a functional and secure digital health ecosystem, and I urge all our stakeholders to embrace it and collaboratively work to realize its promise.



Silas Simatwo
Chairman, Board of Directors
Digital Health Agency

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Preface and Acknowledgement



The adoption of digital health solutions is integral to the equitable delivery of the highest standard of healthcare to all Kenyans. Whilst the country has made sustainable strides in harnessing the power of technology in our health system, the rapidly evolving technological landscape necessitates a governance process of ensuring the functionality, security, and robustness of digital health solutions deployed in the country.

The Certification Framework builds upon the Digital Health (Health Information Management) Regulations, 2025, to provide a structured and coordinated process for assuring the functionality, security, and interoperability of digital health solutions deployed across the country. It works hand in hand with the Kenya Digital Health Standards and Guidelines, which outline the technical and operational benchmarks against which these solutions are assessed. Together, these documents serve as references for solution developers, implementers, policymakers, and health professionals committed to advancing Kenya's digital health transformation.

Developed through an extensive stakeholder consultation and guided by international best practices, this Framework ensures a practical and future-oriented approach to the governance of digital health technologies in Kenya, charting a pathway towards a secure, standardized, innovative, and responsive Kenyan health system. I extend my deepest gratitude to all the stakeholders: patient groups, healthcare workers, experts, development partners, and the MOICDE, for participating in the development of this document. Your insight and expertise shaped this Framework into a comprehensive and practical document.

Special appreciation goes to the DHA team and the Ministry of Health through the Directorate of Health Financing, Digital Health, Policy, and Research Standards, for the unwavering support in leading the development of this Framework. In particular, I recognize Dr. Ayub Manya, Dr. Wesley Ooga, and Dr. Jeremiah Mumo for the key role they played in this process.

I also acknowledge and appreciate the funding and technical support provided by the US. Centers for Disease Control and Prevention through the UW's International Training and Education Center for Health (I-TECH). Their support was invaluable in enabling the development of this certification framework. I further recognize the contributions of the following partners, whose contributions greatly enriched the framework's quality, breadth, and relevance: the World Health Organization (WHO), USAID, Intellisoft Consulting, HELINA, Palladium Group Kenya, PATH, UoN – Health IT & TAP projects, Savannah Informatics, Medtronic Labs, and EDARP.

Finally, we extend our heartfelt thanks to all individuals, institutions, and partners dedicated to advancing Kenya's digital health ecosystem. Your commitment ensures that Kenya's health sector continues to evolve, capitalizing on technology to deliver better, more equitable care to every Kenyan



Eng. Antony Lenaiyara
Chief Executive Officer,
Digital Health Agency

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Executive Summary

Kenya's health sector is undergoing a digital transformation aimed at enhancing service delivery, improving efficiency, and ensuring the privacy and security of patient information. **The Kenya Digital Health Standards and Guidelines** are designed to regulate, guide, and set expectations for the deployment of digital health solutions that contribute to the country's healthcare goals. These guidelines are critical to ensuring that digital health systems meet the necessary standards for functionality, security, and interoperability, ultimately ensuring that they can deliver safe, effective, and reliable healthcare services.

The Regulatory Landscape

In recent years, Kenya has enacted several pieces of legislation to support the digital health ecosystem. **The Data Protection Act, Cap. 411C (2019)** was a pioneering step in safeguarding personal data, and it designates health data as sensitive personal data, subject to strict confidentiality and security requirements. In addition, the **Digital Health Act, No. 15 of 2023** creates a comprehensive legal framework for the use of digital technologies in healthcare. This Act establishes the **Digital Health Agency,** the primary body responsible for overseeing digital health practices and ensuring the security and privacy of health data.

The Certification Framework

- At the heart of this framework is a Certification Process that aims to ensure digital health solutions meet the required standards of functionality, security, interoperability, and compliance with legal frameworks. The Certification Framework defines the criteria that digital health solutions must meet, which include:
- Functionality: Ensuring that digital health solutions meet the needs of healthcare providers and patients and enhance service delivery.
- Reporting and Public Health Alerts: Enabling systems to effectively report on public health matters and share critical information in real-time.
- Security, Privacy, and Confidentiality: Implementing measures that safeguard sensitive health data and ensure systems comply with national and international standards for data protection.
- Information Exchange and Interoperability: Ensuring seamless integration and data exchange across different health systems to improve the coordination of care.

Governance and Implementation

The Digital Health Agency is tasked with managing the certification process and ensuring that digital health solutions align with the standards set by the government. The Agency also plays a crucial role in updating these guidelines and ensuring compliance across the healthcare ecosystem. The Ministry of Health oversees this process, aligning the certification efforts with broader health policies and regulations. Furthermore, County Governments are instrumental in ensuring the implementation of these standards at the local level.

The Certification Process

The certification process consists of several stages:

1. Self-Attestation and Application: Digital health solution providers are required to confirm their system's compliance before submitting for certification.
2. Document Review: Detailed documentation, including system specifications and privacy policies, is reviewed by the Digital Health Agency.
3. Certification Testing/Audits: Systems undergo a thorough audit to assess compliance with all criteria outlined in the framework.
4. Re-certification and Ad-hoc Audits: Periodic re-certification ensures that systems continue to meet the standards over time.

The ultimate goal of this framework is to create a standardized and secure digital health environment that benefits all stakeholders, including healthcare providers, patients, and policymakers. By ensuring that digital health solutions are not only functional but also secure, interoperable, and compliant with national and international standards, Kenya aims to build a trusted digital health ecosystem that supports universal health coverage and improved patient outcomes.

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Abbreviations and Acronyms

DHA	Digital Health Agency
DHS	Digital Health Solution
DPA	Data Protection Act
DPIA	Data Protection Impact Assessment
EHR	Electronic Health Record
EMR	Electronic Medical Record
HRMIS	Human Resource Management Information System
ICT	Information and Communications Technology
IDSR	Integrated Disease Surveillance and Response
IT	Information Technology
MoH	Ministry of Health
PAS	Patient Administration System
SHA	Social Health Authority

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Definition of Terms

"Digital health solution" means a digital health application, intervention or initiative and includes digital health technology infrastructure including telehealth systems and electronic health information systems and the provision of education and training support for e-Health initiatives;

"Health data controller means a natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purpose and means of processing of health data;

"Health Information System" means a health ecosystem designed to manage health and health related system data that provides the foundations for decision-making and includes a system that collects, collates, stores, manages, analyses, synthesises, transmit patient's or client's electronic health record, and uses health and health related data for operational management or a system supporting healthcare policy decisions and includes any electronic system that captures, stores, manages, and/or transmits data related to public health, or to activities within the health sector including:

1. Electronic Medical Records (EMRs);
2. Electronic Health Records (EHRs);
3. primary care systems;
4. district-level routine information systems;
5. disease surveillance systems;
6. pharmacy information systems;
7. Laboratory Management Information;
8. Hospital Patient Administration Systems (PAS);
9. Human Resource Management Information Systems (HRMIS); and
10. Claims Management Systems.

"System implementer or owner" means an individual or institution responsible for the procurement, development, integration, modification, operation and maintenance of an information system and who shall be responsible for onboarding of their system into the Health Information Exchange framework;

"System vendor or developer" means an individual or institution whose principal product is a digital health solution targeted for use in the Kenyan health sector and includes a system owner where the vendor owns the product;

"Testing laboratory" means a designated facility for testing individual IT systems which includes black-box functional testing, regression testing, load testing, installation, usability and security testing;

"Testing tool or script" means a set of instructions, written using a scripting or natural language, performed on an information system under test conditions to verify that the system performs as expected and meets the minimum requirements; and

"System users" includes health facilities including public, private and faith-based facilities, counties, the Social Health Authority (SHA), health care providers, system developers and other persons seeking to have their system certified by the Digital Health Agency.

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Introduction

Kenya's digital health landscape encompasses robust health information systems, data protection laws and a commitment to improving health outcomes while safeguarding sensitive information. Ensuring security mechanisms within the digital ecosystem is therefore crucial for the maintenance of trust and advancing healthcare delivery.

Kenya enacted the Data Protection Act, Cap. 411C in 2019, reinforcing the right to privacy and strengthening the protection of personal data. The Data Protection Act, Cap. 411C also categorizes health data as sensitive personal data, laying emphasis on the importance of ensuring privacy, confidentiality and security of health data throughout the data management cycle. The Digital Health Act, No. 15 of 2023 was further enacted to regulate the use of digital technologies in healthcare with the aim of enhancing the efficiency, accessibility and quality of healthcare services while ensuring the protection of the data and privacy of patients.

The Digital Health Act, 2023 is a landmark legislation in Kenya that sets out a comprehensive framework for the provision of digital health. It establishes the Digital Health Agency to manage digital health services and systems and establishes the Comprehensive Integrated Health Information System. The Act also defines health data governance, classifies health data, sets principles for data use and designates the Digital Health Agency as the custodian of health data. The Act further addresses confidentiality, privacy and security of data as it emphasizes informed consent and the protection of sensitive personal information. Additionally, the Act promotes e-health service delivery structures and provides a framework for e-waste management and health tourism.

An analysis of the information systems within the health sector depicts that these systems have varying capabilities with some systems being advanced and innovative while others remain less developed. To bridge the digital health solution gap and to adopt a standards-based approach, the Digital Health Act, 2023 proposes a certification process to deal with disparities including:

1. Balancing advancement and innovation-the certification process aims to support the advancement of less developed digital health solutions to improve their capabilities while encouraging innovation among more capable and advanced systems;
2. Minimum criteria for all systems-the certification framework advocates for minimum or baseline criteria that all systems must meet to allow them to adequately and effectively be used in the health sector and to enable efficient information exchange. These criteria ensure uniformity and essential functionality across the spectrum of digital health solutions;
3. Security and confidentiality-building reliable and secure digital health solutions is paramount as robust information security mechanisms guarantee the protection and availability of sensitive health data;

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4. Standardization for effective exchange-utilization of uniform standards is essential for accurate and timely health information exchange. Standardized abbreviations, codes and terms facilitate interoperability and information exchange. Although existing standards serve as a foundation, there are barriers arising from different interpretations and versions; and
5. System assessment-independent evaluation schemes are crucial for assessing the compliance of digital health solutions. It is critical that collaborative initiatives are employed in establishing evaluation criteria that offer benchmarks for both existing and market-ready systems.

Certification frameworks generally establish the standards and criteria that digital health solutions shall meet to be certified. The frameworks ensure that digital health solutions adhere to best practices, promote interoperability, protect patient data and support the overall goals of the health ecosystem. They also provide clarity and consistency in the certification process which builds trust among users and stakeholders.

The Certification Framework aims to create a robust ecosystem of digital health solutions that benefit patients, providers and policymakers by fostering innovation, ensuring security and promoting standardized practices. The Certification Framework is also primary meant to be used by digital health solutions providers who seek to have their digital health solution certified and may also be utilized by certification bodies as a benchmark tool during certification of digital health solutions. The framework further helps system implementers to ascertain that the systems they acquire are from a certified digital health solution provider.

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1 Certification Framework

1.1 Criteria

This certification framework is a guide to systems that seek to be onboarded into the national health information exchange and ensures compliance with regulations by setting standards for functionality, security, privacy, reporting, interoperability and the exchange of health information. It also provides assurance to stakeholders that systems meet requirements and may be trusted with sensitive personal data, promoting consistency and interoperability. The framework further provides a guide for the Digital Health Agency, digital health solution providers, System owners or implementers, health data controllers and health data processors on the requirements and specifications for progression through the certification process.

The Certification Framework thus sets out the framework that governs the certification process including defining what is to be certified, what it means to be certified and the process for achieving and maintaining certification. It also defines the obligations of the digital health solution being certified to meet applicable conformance requirements. Certification therefore ensures that a digital health solution meets the established health-sector standards and is aligned, and complies with the Health Act, Cap. 241, the Digital Health Act, No. 15 of 2023, and Data Protection Act, cap. 411C, and all other relevant laws and regulations.

The Certification Framework mainly focuses on criteria including —

1. Functionality;
2. Reporting and public health alerts;
3. Security, privacy and confidentiality; and
4. Information exchange and interoperability.

1.1.1 Functionality

This criterion defines the range of operations and/or services that a digital health solution shall be able to run without significantly compromising the objectives of existing regulations. This criterion focuses on patient care and service delivery as components in meeting the objective of improving the quality of care. It also applies to all digital health solutions, including hospital information systems, community health solutions, pharmacy information systems, laboratory information systems, mHealth, telehealth solutions, telemedicine solutions, digital health apps, radiology information systems, logistics management systems, claims management systems, human resources for health systems, clinical decisions support systems and referral tracking systems.

1.1.2 Reporting and Public Health Alerts

This criterion includes the guidelines that support routine reporting and notification for public health emergencies of reportable conditions or diseases. It aims to strengthen the routine reporting requirements entrenched in the Integrated Disease Surveillance and Response (IDSR) reports and required by international health regulations. Notifications submitted to the MoH and the National Public Health Institute including emergency operation centres are a key component of any digital health solution. Additionally, immunization

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registries, civil registries and other registries should be capable of receiving reports from the digital health solution. The digital health solutions should also provide ad-hoc reports for strategic planning within the county and national health systems.

The reporting requirements will be guided by the needs of the various users and shall include—

1. Immediate reportable diseases, as it occurs;
2. IDSR reporting on a weekly and monthly basis,
3. Public health events, as it occurs;
4. Diseases or events of international concern, as it occurs;
5. Registries; and
6. Routine reporting

1.1.3 Security, Privacy and Confidentiality

This criterion includes policies governing the security of sensitive personal data, system access controls, role-based user authentication, data integrity issues, encryption, data minimization, data retention audit trails and adherence to the Data Protection Act, Cap. 411C. This criterion is aimed at ensuring compliance with international and national regulations for securing sensitive personal data and digital health interventions against unauthorized access. This criterion also includes the criteria for regulating—

1. Integrity of patient records;
2. Authentication and authorisation;
3. Legal documents; and
4. Data back-up and recovery policies

1.1.4 Information Exchange and Interoperability

This criterion addresses the ability of systems to share or transfer information across systems, independent of the platform, using standard data formats and common infrastructure practices. A digital health solution should comply with the defined interoperability standards and should be able to exchange data seamlessly with Kenya National Health Information exchange as defined in the Kenya Health Enterprise Architecture in compliance with the Digital Health Act, 2023. By implementing common data standards, health information systems shall enhance the efficiency of information exchange enabling them to meet a wide range of data collection and reporting needs more effectively.

The criteria cover aspects, whose measures are clearly defined including on the period when the requirements should have been met by already existing or running system, including—

1. Definition of core data elements where the data to be collected and exchanged shall be determined;
2. Core data interchange formats where the interchange standards and document architectures for structuring data elements as the data elements are exchanged including through HL7, SDMX-HD shall be provided;
3. Terminologies where the medical terms and concepts used to describe, classify and code the data elements and the data expression languages and syntax that describe the relationships among terms or concepts shall be provided; and
4. Knowledge representation where standard methods for electronically representing medical literature, clinical guidelines and any other

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similar information to support decision-making.

The Certification Framework also defines specifications and criteria including—

1. **Required** (MUST) sets of the requirements that *all* systems *must* meet to be certified;
2. **Recommended** (SHOULD) sets of the requirements that certified systems *should* have but are given a specific amount of time to adopt or implement and which after the grace period, *must* be implemented; or
3. **Optional** (MAY) set of specifications that are not mandatory but are desirable.

1.2 Certification Governance Structure

The Digital Health Agency shall have a central role in the certification process as mandated by the Digital Health Act, 2023. In so doing, the Agency shall ensure that the defined processes are aligned with the health sector' strategic objectives particularly on the digital transformation agenda of the sector.

1.2.1 Publication of the Certification Framework

The Digital Health Agency is tasked with the publication and enforcement of the certification framework, ensuring its accessibility to stakeholders and its adherence to established standards and regulatory requirements. The Agency therefore plays a pivotal role in promoting transparency, consistency and accountability in the certification process which will ultimately foster trust in digital health solutions and facilitate seamless information exchange in the healthcare ecosystem. For purposes of ensuring this, the Digital Health Agency shall perform functions including—

1. Managing the certification process;
2. Supporting the review and publication of the digital health standards and guidelines;
3. Disseminating standards and guidelines and the Certification Framework;
4. Developing test methodologies, test data and scripts;
5. Reviewing and revising test methodologies and plans;
6. Facilitating arbitration services on contentious issues;
7. Reviewing and improving the Certification Framework every two (2) years; and
8. In collaboration with the Ministry of Health, reviewing, updating and developing new standards, and modifications or revisions to existing standards.

In addition to managing the certification process, the Digital Health Agency shall—

1. Maintain an up-to-date inventory of all certified digital health solutions being used in the country and ensure the availability of a publicly accessible portal;
2. Refer non-certified digital health solutions to national or regional labs for pre-certification testing;
3. Identify existing systems and advise system owners and vendors of certification requirements;
4. Require new digital health solution vendors to provide proof of certification prior to implementation of their systems;

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5. Enforce the regulatory provisions on certification; and
6. Provide feedback to the Ministry of Health based on challenges encountered during implementation.

1.2.2 The Role of the Ministry of Health in the Certification Process

The Ministry of Health plays a pivotal role in the certification process by defining standards that are used. In addition, oversight by the Ministry of Health on the Digital Health Agency ensures the enforcement of the defined standards which guarantees that certified solutions meet the highest quality benchmarks. The MoH further aligns certification and standards with sector regulations and the broader health agenda therefore facilitating the integration of certified digital health solutions into the healthcare ecosystem.

1.2.3 The Role of Counties in the Certification Process

The County Governments, through their Departments of Health, are essential in the certification process as they are not only the users of digital health systems but also, they oversee health service delivery in the devolved units.

A county government shall—

1. In collaboration with the Digital Health Agency, maintain an inventory of all digital health solutions in use within the county;
2. Refer non-certified systems to the Digital Health Agency;
3. Identify existing systems and advise system owners and vendors of certification requirements;
4. Require new digital health solution provider entrants to provide proof of certification prior to implementation of their systems;
5. Enforce the recommendations of the Digital Health Agency; and
6. Provide feedback to the Digital Health Agency based on challenges encountered during implementation of the certification requirements.

1.2.4 Testing Labs/Sandbox Environment

The Digital Health Agency shall collaborate with relevant institutions to set up and certify laboratory-based testing environments for the purposes of assessing the conformity of a digital health solution with the established criteria. The testing labs shall be set up in various locations throughout the country to ensure that these labs may be accessed by all potential applicants.

The functions of the testing labs shall be to—

1. Perform tests based on the guidelines issued by the Digital Health Agency;
2. Provide technical reports on testing to aid in decision-making on certification;
3. Provide a testing environment for the development of standards and criteria;
4. Assist with technical input on standardisation; and
5. Assist with field testing or demonstration of existing digital health solutions or interventions.

1.2.5 Role of the System Owners/Implementers in the Certification Process

Digital health system owners and implementers play a critical role in the

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certification process as they ensure that their systems meet the standards set by the Ministry of Health and are compliant with the Certification Framework.

Digital health system owners and implementers shall—

1. Obtain a comprehensive understanding as system owners or implementers must thoroughly understand the certification requirements prescribed by the Digital Health Agency;
2. Ensure compliance as it is the responsibility of system owners or implementers to ensure that their systems comply with the criteria specified in the Certification Framework;
3. Facilitate certification as system owners or implementers are required to present their systems for certification and fulfil any additional requirements as requested by the Digital Health Agency;
4. Provide prompt updates to the Digital Health Agency on any system changes that may require recertification which ensures the continued compliance and effectiveness of their digital health solutions; and
5. Ensure versioning transparency as system owners or implementers should keep the Digital Health Agency informed on system versioning particularly where different instances of the same system are implemented in various sites across the country.

1.3 Certification Process

This section defines the processes which a digital health solution must undergo to achieve certification. In this certification process, —

1. The test procedures are developed directly from the type of DHS criteria;
2. Every type of DHS/Criterion/functionality must have a test procedure associated with it so that the implementation of each requirement can be verified.;
3. The Digital Health Agency shall develop the functionality tests for each type of digital health solutions; and
4. The Ministry of Health shall develop standards and guidelines for each type of DHS.

The certification process shall be completed within thirty days from the date of the application for certification provided that the certification audit may be scheduled on a date that suits both the digital health solution developer and the Digital Health Agency.

Each digital health solution being considered for certification must pass through six stages—

1. Self-attestation and application;
2. Document review;
3. Scheduling and testing;
4. Certification;
5. Re-certification and *ad hoc* audits; and
6. Appeals.

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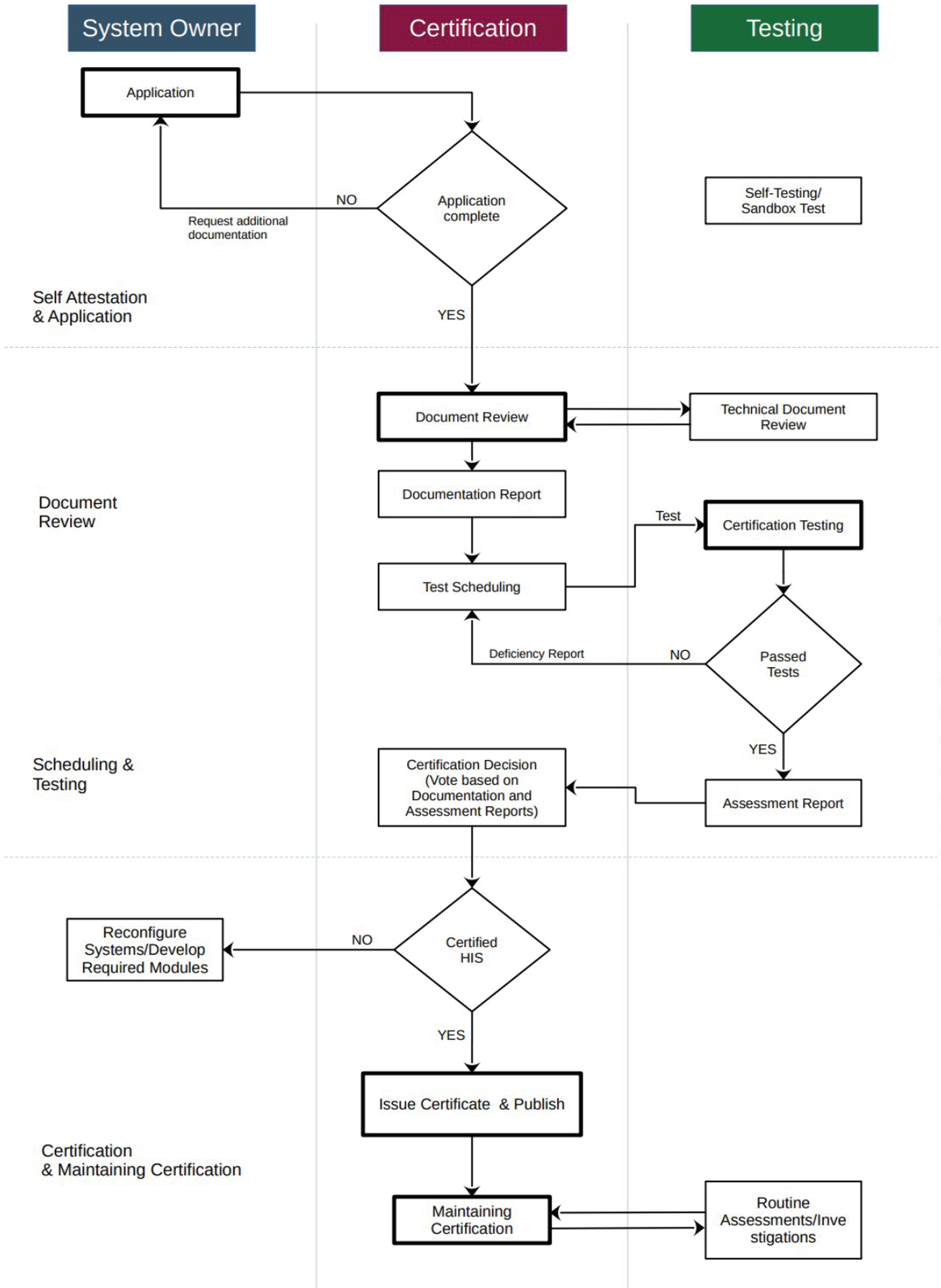


Figure 1. A logical flow diagram of the certification process

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1.3.1 Self-Attestation and Application

The objective of this step is to encourage and facilitate the development and availability of digital health solutions that meet the minimum standards set by the MoH which all systems in the health sector are expected to comply with. Prior to applying for certification, each digital health solution provider shall undertake self-attestation to ensure that its system conforms to the applicable requirements and is ready for certification. This self-attestation step is intended to help digital health solution providers to identify the minimum compliance tests expected for certification.

An interactive web-based self-attestation tool shall be provided by the Digital Health Agency through a web portal. This self-attestation tool will be employed to determine which systems may proceed to the next stage of the process. The main aim of this step is therefore to ensure that only those systems that qualify for certification testing make it to the application stage.

The DHA will also prescribe all the requirements to be fulfilled for purposes of commencing the process of certification. In addition to self-attestation therefore, a digital health solution developer should review and acquaint themselves with the applicable standards and guidelines and certification requirements before submitting the application for certification.

Submission of an application for certification with the relevant product documentation will enable the Digital Health Agency to fully understand the scope of the operations and functionalities of a digital health solution.

1.3.2 Documentation Review

A DHS developer shall, in submitting a digital health solution for certification, provide documents for review which shall include—

1. A corporation certificates or identifying documents;
2. System manual and requirement specification;
3. evidence of registration with the office of the Data Protection Commissioner as a data processor and data controller;
4. A Data Protection Impact Assessment Report;
5. A Security, Privacy and Confidentiality Policy; and
6. A System Back-up and Recovery Policy.

The DHA will thereafter review the documentation submitted and where the documentation is satisfactory, the DHS will proceed to the next stage of the certification process.

1.3.3 Certification Testing/Audits

All digital health solutions must undergo a certification audit. The purpose of the digital health solution audit is to determine how well a digital health solution adheres to the criteria set out in section 2.1. The DHA will therefore ascertain that the submitted documentation, demonstrations, self-attestation results and any other requisite supporting information demonstrate that the digital health solution meets the minimum requirements.

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During this audit, an auditor shall review the system against the certification requirements scoring tool and document in the audit any non-conformances observed.

The certification audits shall be non-consultative, and the auditors are not permitted to instruct or advise a DHS owner on how to meet requirements while the audit is in progress.

1.3.4 Testing/Audit Report

At the conclusion of the certification audit in section 2.3.4, the DHA shall submit a certification testing/audit report to a DHS developer informing the developer of all observed non-conformances, the decision on the certification of the DHS and the issuance of a certificate. Each certification scheme in the audit report shall have unique time-line requirements for conformance. A DHS shall secure certification where it meets the requirements for conformance set out in the audit report.

The DHA shall review the evidence submitted and accept corrective actions where these actions are sufficient to resolve the noted non-conformance. Where the submitted corrective actions do not sufficiently resolve the non-conformance, the DHA shall reject the corrective actions and the DHS vendor shall be required to re-submit the application for certification of a DHS within a specific period.

The auditors shall not make the final decision on the certification of a DHS. An independent team within the DHA, that does not include any of the auditors, shall make the final determination on the certification based on their review of the audit report and evidence of close-out of non-conformances. The certificate of conformity shall only be issued within thirty (30) days from the date of the completion of the audit where a final decision has been made on the application for certification.

The DHA shall notify the DHS provider in writing of the audit result and shall list the DHS in the certification register and issue a certificate to the DHS provider.

The certification register shall be published on the certification program's website, clearly indicating the areas of functionality for which the DHS product has been certified.

1.3.5 Re-certification and *Ad Hoc* Audits

To secure recertification, developers of digital health solutions are required to maintain all certified functionalities and minimum requirements for a period of at least two (2) years. Throughout the implementation of the DHS, developers must perform necessary updates and bug fixes to ensure continued conformity with the certification requirements.

The Digital Health Agency shall conduct *ad hoc* audits to check compliance and adherence to the certificate of conformity. The Digital Health Agency shall conduct a fresh audit where there are reported breaches of the certificate of conformity.

In the event that a non-conformance arises out of—

1. audits or investigations, the DHS provider must

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correct the non-conformance issues and prevent their recurrence before certification is issued; or

2. changes in standards and guidelines, the DHS provider shall be granted a grace period to meet the criteria.

Where a re-certification audit occurs close to the initial certification anniversary, any non-conformances must be addressed before certification is issued.

The DHA may, where necessary, conduct a further site visit to verify the corrective actions taken by the DHS provider.

All digital health solutions are required to document change logs and any system change affecting security and interoperability shall require a fresh audit.

In the event of system breaches, the DHS provider/user must notify the DHA of the breach and the implemented solution.

1.3.6 Review

A DHS owner or a DHS developer who is dissatisfied with the outcomes of the certification audit may file an appeal to the Complaints Committee in the manner set out in the Digital Health (Health Information Management) Regulations, 2024.

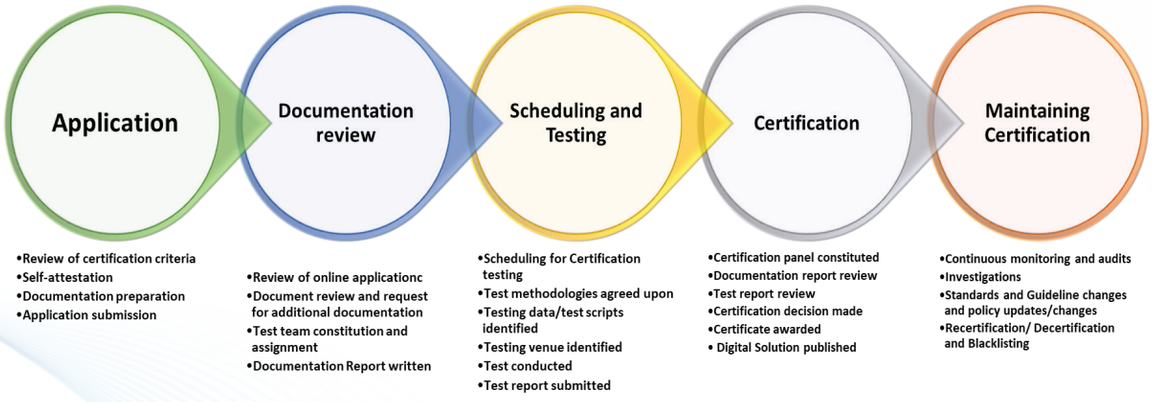


Figure 2. The certification process.

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1.3.7 Certification Criteria

The criterion in this section sets out the minimum functionality that must be implemented prior to certification. These functionalities shall be applicable to all point of care (POC) systems intending to use the enterprise services maintained by the Digital Health Agency.

	Certification Goal	Certification Aspects	Standards and Guidelines	Criteria Type (Required, Recommended , Optional)	System Type or Category
Functionality	**Demographics**	Ability to electronically record, change, and access patient demographic data in a standardised way including: 1. Sex/Gender 2. Date of birth 3. Residence details 4. Contact information; a. Phone number b. Next of kin contact 5. Next of kin relation 6. ID Number/Passport/ Birth Certificate/Alien Number	Digital Health Solutions Standards and Guidelines	Required	All DHS solution s
	Computerised Provider	Ability to electronically record, change, and access	Digital Health Solutions	Required	EMR - mandatory

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	Order Entry (CPOE)	The following order types, at a minimum: • Medications • Dispensing • Laboratory • Radiology/Imaging • Physiotherapy • Occupation Therapy • Nutrition • Social Work • Counselling • Family Health History • Vital Signs • BMI and Growth Charts • Billing • MCH Clinical Encounter	Standards and Guidelines	(Based on the solution)	
	Problem List	Electronically record, change, and access a patient's active problem list in KENHDD	Digital Health Solutions Standards and Guidelines Health Information Exchange standards and Guidelines	Required	All DHS solution s
	HPT	Electronically record, change, and access a patient's active prescribed	Digital Health Solutions Standards and Guidelines	Required	EMR-Mandatory

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		HPT list, as well as HPT history: - HPT Registry in instances where EHR technology would be used to perform external transmissions Electronically record, change, and access a patient's active HPT allergy list, as well as HPT allergy history - Encourage EHR technology developers to include capabilities that may go beyond certification requirements, particularly where that may improve patient safety - EHR technology natively records HPT allergies directly into HPT Registry			

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	Allergy List	Electronically record, change, and access a patient's active allergy list, as well as medication allergy history - Encourage EHR technology developers to include capabilities that may go beyond certification - Requirements, particularly where that may improve patient safety	Digital Health Solutions Standards and Guidelines		EMR - Mandatory
	Clinical Decision Support (CDS)	Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions based on each one plus at least one of the following data: - Problem list (KENHDD) - Medical list (HPT Registry) - HPT allergy list	Digital Health Solutions Standards and Guidelines Health Information Exchange standards and Guidelines	Optional	EMR- Optional

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		- Non-HPT allergy list - Demographics - Laboratory tests and values/results - Vital signs			
	Clinical Summary	Enable a user to create a clinical summary for a patient, in human-readable format and exchangeable via the Kenya HIE Minimum data elements: - Biodata information clinically Relevant information defined in the FHR profile. - Medication details - Prescription Request - Practitioner Identifier - Organization Identifier - Encounter Details - Care Plan is scheduled care for a specific clinical outcome.	Digital Health Solutions Standards and Guidelines Health Information Exchange standards and Guidelines	Required	All DHS Solutions

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		- Devices or other Health Technologies and products			
	Electronic Prescribing	Electronically create prescriptions and prescription-related information for electronic transmission (including diagnostic test results, problem list, medication lists, medication allergies, discharge summary, procedures) upon request.	Digital Health Solutions Standards and Guidelines		
	Clinical Quality Measures	- Capture electronically record all the data identified in the designated standard. - Calculate electronically calculate every clinical quality measure for which it is presented for certification. Import electronically import a data file formatted in accordance with the designated standard.	Kenya Digital Health Standards and Guidelines	Required	All DHS Solution s

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		- Export electronically exports a data file formatted in accordance with the designated standard. - Electronic submission. Electronically create a data file for transmission of clinical quality measurement data			
	Patient List Creation	The system should be able to: - schedule, - create a patient list, - make appointments and send alerts	Digital Health Solutions Standards and Guidelines	Optional	All DHS Solution s
Reporting and Alerts	**Immediate Reportable Diseases**	As per MOH Guidelines/ SOPs -	Digital Health Solutions Standards and Guidelines	Required	All DHS/1 solution s
	IDSR Reporting (Weekly)		Digital Health Solutions Standards and Guidelines		
	Public Health Events		Digital Health Solutions		

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	Diseases or Events of International Concern		Digital Health Solutions Standards and Guidelines		
	Routine Health Reporting		Digital Health Solutions Standards and Guidelines		
Data Exchange and Interoperability	**Data Transmission and Exchange**	View, download, and transmit information as per Kenya National HIE to the Kenya National Core Digital Health Services	Health Information Exchange standards and Guidelines	Required	All DHS Solution s
	Interoperability	- Unstructured Data Exchange—the exchange of human-interpretable unstructured data, such as free text. - Structured Data Exchange—the exchange of human-interpretable structured data intended for manual and/or automated handling, but			

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		requiring manual compilation, receipt, and/or message dispatch. Seamless Sharing of Data—involves the automated sharing of data amongst systems based on a common exchange model. - Seamless Sharing of Information—the universal interpretation of information through data processing based on co-operating applications.			
	Security, Privacy, and confidentiality	Protect electronic health information created or maintained by the certified Digital Health through the implementation of appropriate technical capabilities. - Ensure the confidentiality, integrity, and availability of all electronic health information the system	Digital Health Solutions Standards and Guidelines Security, Privacy and Confidentiality Standards and Guidelines	Required	All Digital Health solution s

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		creates, receives, maintains, or transmits. - Protect against any reasonably anticipated threats or hazards to the security or integrity of such information. Protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required under law. - Authentication, access control, and authorization • Digital Health unique identification & authentication, • Authentic ate Unique User • Establish Permitted User Access - Auditable events and tamper resistance (audit			

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		trail and reports) - Version/Amendment tracking - Automatic log-off - Emergency access - Encryption of data at rest and data in transit - Integrity - Conduct the Data Protection Impact Assessment			

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1.4 Testing Methods

The scope of certification identifies the specific tests or types of tests or capability for which the DHS is certified. The objective of testing is to establish whether the DHS complies with the requirements for certification and may competently perform the tasks for which certification is sought.

1.4.1 Self-Attestation

In the context of digital health solutions, self-attestation refers to an approach that would allow a DHS developer, guided by a checklist of the minimum set of requirements, to make the claim that their DHS is compliant with a reasonable level of confidence. The DHS methodology is intended to guide the application process such that the DHS vendor knows exactly what requirements their system would be tested against for compliance. The underlying premise supporting the DHS methodology is that DHS developers provide an honest attestation of their system and can demonstrate it during testing. The DHS methodology also helps to identify the category to which a digital health solution belongs, and the appropriate tests required under the identified category.

Self-attestation is the initial step in certification testing and results in recommendations as to which documentation should be submitted with the application for certification of a DHS.

1.4.2 Document Review

Upon the completion of the self-attestation process in section 2.4.1 and where the DHS vendor is confident that he or she can apply for certification, the DHS vendor shall submit the requisite documentation including any requisite certificates guided by the recommendations made during the self-attestation process.

The DHS vendor shall scan the documents and submit the same electronically to the Digital Health Agency for review provided that the DHS vendor shall present the original and/or physical documents during testing for validation.

The DHS vendor must also be able to demonstrate that he or she has met the certification requirements of other relevant government agencies by submitting documentary evidence of the relevant approvals issued by such government agencies. This requirement ensures that the certification process considers any existing regulations and guidelines in relation to implementation of ICT systems.

Where any relevant document is missing, the Digital Health Agency shall cooperate with the DHS vendor for purposes of ensuring that all relevant documentation is made available before initiation of the certification process. The Digital Health Agency shall thereafter file a documentation report which shall form part of the final evaluation for certification.

1.4.3 Demonstrations/Test Labs

Demonstration tests are conducted for purposes of evaluating the conformance of a digital health solution to the specified standards and criteria and determining whether a DHS should be certified or not. These tests are not intended to

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demonstrate the capabilities of a digital health system.

The demonstrations under this section shall be guided by test scenarios or scripts with specific output goals defined and published by the testing body. The test scenarios or scripts may change where the testing body deems it necessary.

Demonstration testing may also be conducted as projected presentations or as field tests and in such instances, this testing shall only be effective where the testing—

1. Uses test scripts or scenarios that have been reviewed and accepted as representative of the minimum requirements and which makes the tests scripts or scenarios to be of fixed-build standard throughout testing; or
2. Represents, as closely as practicable, the typical operational use of the digital health solution;
3. Provides sufficient test observations to produce results that are satisfactory or that may be replicated using another method, and where any of these conditions cannot be fulfilled in the demonstration testing, the digital health solution shall be deemed as not meeting the minimum requirements for the DHS testing methodology making it non-compliant.

1.1.4 Field Testing

Field testing refers to a methodology that applies only to existing or currently operating systems seeking certification. It involves performing the assessment and/or tests on site, on the premises where the DHS is operational, or in a setting that ensures a full review of system requirements.

The field testing shall be performed under one of the two categories. Category one where the testing body goes to the field site and performs the assessment in the operating environment or category two where the vendor runs a duplicate platform in a test environment that simulates the actual operating environment to avoid service disruptions in the operational setting).

The conditions for the choice and method of performing field testing for a DHS shall be agreed on in advance by the testing body and the DHS vendor.

1.4.5 Full Testing

Every aspect of a digital health solution is tested to determine whether it meets the specified standards and requirements. Full testing is only applicable to systems that the DHS vendor feels have fully met the certification requirements for each category and is encouraged for testing fully customized products. Although the phased/modular approach is recommended, it is the prerogative of the DHS vendor to decide whether he or she wants to do a complete or full test. In the case of a full test, the DHS vendor must apply for full testing of the DHS and to suggest that the system meets the entire criteria stipulated in the Certification Framework. Assuming the testing procedures are adequate, full testing provides the highest possible level of assurance that the DHS product fully conforms to the certification standards.

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1.4.6 Investigations

Investigations apply to systems already in use and to certified systems that experience alleged failures during actual use and are under investigation to determine the cause(s) of failure or non-compliance for the purposes of suggesting appropriate corrective action.

This Certification Framework will rely on two or more of the methods set out in section 2.4 during the certification process. The choice of method shall depend on the DHS vendor and the designated standards for the criteria under which the testing shall be done.

The choice of the testing method may affect both the cost of the certification program and the level of confidence ascribed to it. During the assessment of a DHS, deficiencies or non-conformity to certification requirements may be identified including that —

1. A system may be unable to perform a test, or type of test, for which certification is sought; and
2. The digital health solution does not conform to a standard/criterion, is not adequately documented, or is not completely implemented in accordance with the documentation provided by the DHS vendor.

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APPENDICES

Appendix 1 (a): Patient-Facing Digital Health Solution Core Functional Requirements Review tool

This digital health solution review tool shall be used to populate a summary score sheet provided in appendix 1(b). Specific processes within the review tool shall comprise the total score for the different functional requirements. A system must meet all the processes in a specific functional area to be awarded the aggregate score.

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1. Basic Demographic and Clinical Health Information

No.	Procedure	Expected Result	Actual result	Pass / Fail	Comments
a.	Capture Patient/client details	The system should provide fields to capture patient's/client details based on MOH 204A or 204B System to auto generate Unique Patient Identifier (UPI)			
b.	Capture next of kin details	The system should capture next of kin names, telephone number and relationship			
c.	Search for a patient's record by name or unique identifier.	The system should have broad search parameters e.g. identification numbers, name, telephone number, clinic name, clinic number, to allow selection of the intended patient's record			
d.	Capture duplicate patient record	The system should be able to detect and flag entry of duplicate patient records through matching using unique codes such as: unique identifier, telephone number, national id number, next of kin			
e.	Display a patient's medical Digital Health Solution.	The system should be able to capture, display, and report all existing/active diagnoses and differential diagnoses associated with a patient per retention policy, medications and treatment given, and clinical notes			
f.	Enter a new diagnosis	The system should be able to follow standardized nomenclature such as ICD 10 or SNOMED when capturing a patient's problem list			

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		Should be able to update the problem list on each visit. System to allow capturing of additional problem on one visit			
g.	Capture a new diagnosis on the system	The system should allow update of the master list either to add or deactivate			
h.	Capture the date of onset of illness for a test patient	The system should capture the first date of diagnosis of a condition and automatically calculate the time duration to-date and treatment provided			
i.	Retrieve a medication Digital Health Solution for any of the patients/ clients.	The system should retrieve a list of the patient's active medications, and previous medications The system should capture, display, and report all medication changes			
j.	Look up standard formulation medications.	The system should maintain medication lists using generic names, standard formulations, and dosing frequency			
k.	Capture a patient's weight, height, and temperature.	The system should facilitate capture, display, and report vital signs measures such as temperature, height, weight, blood pressure, respiratory rate, and heart rate System should calculate BMI/BSA			
l.	System to allow linking of mother and child records using the PUI	System should facilitate linking of mother and child records and provide alerts as necessary			

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m.	Capture a child's demographic information on the system.	The system should provide fields to capture specific patient demographic information e.g. the growth chart details And other medical conditions noted e.g. jaundice etc.			
n.	Capture risk factors to any one of the test patients	The system should capture, modify and display risk factors, which are defined as any attribute, characteristic or exposure of an individual that increases the likelihood of developing a disease or injury			
o.	Enter family medical Digital Health Solution	The system should capture and display family medical Digital Health Solution, e.g. diagnosed cases of diabetes			
p.	List allergies	The system should record, modify and retrieve a patient's active and Historical allergies, non-allergy intolerances, and adverse reactions, including those caused by medication, food, and environmental products			
q.	Capture adverse drug reactions on a patient record.	The system should support capture of reported adverse drug reactions			
r.	Capture adverse drug reactions on immunization	The system should support capture of adverse events following immunization (AEFI)			
s.	Generate a patient summary based on data filled at different service points within the facility.	The system should capture and display all procedures and their corresponding results			

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t.	Place a laboratory or radiology order for a patient	The system should capture and display all diagnostic tests and their corresponding results			
u.	System to have a referral mechanism	The system should communicate electronically with the Kenya Master Facility List (MFL) and the Community Facility List to facilitate referrals/ linkages between facilities			
v.	Capture and Display patient lifestyle interventions	The system should capture and display patient lifestyle interventions and recommendations			

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2. Security and Confidentiality

No.	Procedure	Expected Result	Actual result	Pass / Fail	Comments
a.	Attempt access to the system without surname or password	The systems should enforce the need for a username and password before granting user access			
b.	Create a new username and password with a receptionist role or with the lowest available role	The system should facilitate creation of usernames and passwords and allow for specific roles to be granted			
c.	Log in with the created username and password.	The system should be able to assign unique identity to users			
d.	Open a patient's record and capture a new diagnosis of Poliomyelitis.	The system should restrict access to patient diagnosis information on a receptionist's role			
e.	Leave the system idle for 10 minutes.	The system screen should lock after a facility-determined time of inactivity			
f.	Unlock the system with the created username and password.	The system should show the opened patient record with the captured information still in its place			
g.	Request access to the system database to view the stored patient records.	The Health Data and Passwords should be in encrypted format using a known standard such as AES 512			

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h.	Access the audit log.	The system should contain a list of all the performed activities alongside the logged in users with respective times when the activities took place. The system should indicate the original data that changed			
i.	Access the system atabase as database (DB) User and edit a record	The database should capture the Terminal a User logged in from, Timestamp, DB Object Changed, and Data Changed			
j.	Access DB as default User Systems	The Database should not be accessible to default users, all database users should be defined individually, and role based			
k.	Access DB as operating system super user	The database should not be accessible.			
l.	Attempt to restore backup	Restoration should be successful, with all security measures functional			
m.	Attempt to log in with the wrong password or Username	System should lock the user out for a stipulated period. System should log the failed login attempts			
n.	Disable or expire a user account	System should lock user account			
o.	Attempt to login with disabled or expired account	System access denied			
p.	Delete a user account.	System should flag account as deleted and not purge the record from the database			

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3. Order Entry and Prescribing

3.1 Prescription Orders

No.	Procedure	Expected Result	Actual result	Pass / Fail	Comments
a.	Facilitate prescription order entry	The system should be able to capture, record, and display electronic medication orders including the name of the drug, dosage, route of administration, frequency, duration, form of drug and instruction for use			
b.	Review preferred drug list for a particular disease treatment. e.g. TB, fever in paediatrics	The system should display a preferred drug list			

3.2 Laboratory Orders

No.	**Procedure**	**Expected Result**	**Actual result**	**Pass / Fail**	**Comments**
a.	Issue a laboratory diagnostic test	The system should capture, modify and display laboratory test orders, including Test Name, specimen type, Request Time. Clinician Name, Clinician Signature			
b.	Print the requested laboratory/ diagnostic test orders.	The system should display and export orders in human-readable format.			
c.	Review of results	The system should display and export the test results in readable format fully signed and reviewed by two lab techs			

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3.3 Diagnostics and Imaging Orders

No.	Procedure	Expected Result	Actual result	Pass/ Fail	Comments
a.	Order radiological tests	The system should capture, modify, and display the following information Imaging Site, Image View, Imaging Type, Clinician Name, Clinician Signature, Order Time			
b.	Print the requested radiology/ diagnostic test orders.	The system should display and export orders in human-readable format			
c.	Access the verified lab results	The system should display and export the test results in readable format fully signed and reviewed by two Lab Technologists			

4. Clinical Decision Support

No.	Procedure	Expected Result	Actual result	Pass / Fail	Comments
a.	Modify the Threshold for initiation of any supported treatment	The system should be able to capture, modify and display clinical data fields to facilitate clinical decision support			
b.	Generate a report on the number and type of alerts responded to by each user.	The system should be able to automatically track, record, and generate reports on the number and type of alerts presented, and the number and type of alerts responded to by each user			

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c.	Login as an administrator and update the business rules for an alert.	The system should be able to allow administrators to customize alerts and alert criteria, to best suit local needs and circumstances			
d.	Add adverse drug reactions for amoxicillin and aspirin	The system should automatically generate, alerts for medication allergies, non-allergy intolerance, and adverse reactions			
e.	Prescribe penicillin to a patient.	The system should display alerts related to side effects of nausea, or vomiting may occur. These are meant to assist medication administration			
f.	Prescribe a drug that has been recalled as at the time of the system review	The system should display alerts when recalled drugs are prescribed			
g.	Generate a report on all captured dverse drug reactions.	The system should support pharmacovigilance reporting, including adverse drug reactions, adverse events, and medication errors			
h.	Capture on the system a reminder to vaccinate children at the time of enrolment for any service.	The system should issue reminders to users for preventive care and health management services, e.g. vaccinations, screenings, and clinical treatment guidelines for specific diagnoses			
i.	Capture symptoms of cholera into the system to facilitate monitoring for timely alerts of looming outbreaks.	The system should facilitate automated surveillance of notifiable diseases. The system should maintain facility-specific surveillance thresholds and send alerts when thresholds are met. The system should support capture of the rumour log			

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5. Health information and reporting

No.	Procedure	Expected Result	Actual result	Pass / Fail	Comments
a.	Create an electronic copy of the discharge instructions and procedures for a patient.	The system should be able to create an electronic copy of the discharge instructions and procedures for a patient, in human readable format, at the time of discharge to provide to a patient on electronic media, or on paper			
b.	Generate and display graphical trends	The system should provide clinical dashboards to display graphical trends of patient data related to health, care, and treatment			
c.	Generate a list of patients' conditions	The system should generate patient lists by specific conditions, to be used for quality improvement, reduction of disparities, research, and outreach			
d.	Submit an aggregated health facility report.	The system should generate and submit aggregated health facility reports to the national level District Digital Health Solution (digital health solution)			
e.	Generate standard administrative reports e.g. staff allocation reports etc.	The system should generate standard administrative reports such as service utilization, length-of-stay, and staff allocation			

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f.	Modify a report to include trends related to a particular morbidity at the facility.	The system should create and modify user-defined reports per facility			

6. Exchange of electronic information

No.	Procedure	Expected Result	Actual result	Pass / Fail	Comments
a.	Export/import patient's record in HL7 format.	The system should generate patient summary information as a clinical document using a recognized standard			

7.Billing

No.	Procedure	Expected Result	Actual result	Pass / Fail	Comments
a.	Capture waivers and exemptions	The system should waivers and exemptions capture			
b.	Capture bills patients	The system should patient bill details capture			
c.	Generate and print the invoices	The system should allow for printing receipts and invoices for medication dispensed to the patients.			

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Appendix 1 (b): Patient-Facing Digital Health Solution Core Functional Requirements Score Sheet

Feature/Description	References	Implemented Not Implemented	Reviewers Comments	Score 1 point for each fully met requirement, otherwise any non-compliance results in zero score
1. Basic demographic and clinical health information				
Uniquely identify a patient	1a - 1b, 1d, 1l			
Capture Individual demographic data	1c, 1m, 1o			
Generated patient's problem list	1e – 1i			
Provide Kenyan Essential Medication list	1j			
Capture Vital signs and physiologic measures	1k			
Capture risk factors	1n			
Capture Allergies, intolerances, and adverse drug reactions	1p-1r			
Capture medical Digital Health Solution	1s			
Support procedures and test results	1t			

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Support referrals, hospitalizations, and discharges	1u			
Support lifestyle interventions and recommendations	1v			
Security and Confidentiality				
Allow authorized users to access electronic health information	2a, 2c, 2i – 2k, 2m-2p			
Support role-based system access	2b, 2d			
Lock an electronic session after a facility-determined time of inactivity	2e, 2f			
Encrypt and decrypt electronic health data	2g			
Maintain an audit log	2h			
Support data backup	2l			
Order Entry & Prescribing				
Support medication orders	3.1a - 3.1b			
Support laboratory test orders	3.2a – 3.2c			
Support diagnostic and imaging orders	3.3a - 3.3c			
Clinical Decision Support				
Access to clinical fields and algorithms	4a – 4c, 4h-4i			

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Support alert & Reminders	4e – 4g			
Health information and reporting				
Generate discharge summaries	5a			
Provide clinical dashboards to isplay graphical trends of patient data.	5b			
Generate patient lists by specific conditions	5c			
Submit aggregated health facility reports to the national level District Digital Health Solution (DDIGITAL HEALTH SOLUTION2)	5d			
Generate standard administrative reports	5e			
Create and modify user-defined reports	5f			
Exchange of electronic information				
Import patient record in HL7 format	6a-6b			
Billing				
Bill for provided commodities or services	7a-7c			

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Appendix 2 (a): Patient-Facing Digital Health Solution Non- Core Functional Requirements Review tool.

This review tool provides a guide to evaluate the systems non-core functions which are considered good to have. It provides a guide on tasks that the target systems are expected to meet to pass for a digital health solution selection of functions.

1.Patient Education

No.	Procedure	Expected Result	Actual result	Pass/ Fail	Comments
a.	Access patient education materials available on the system.	The system should support patient education by allowing customized patient education materials per patient need			
b.	Generate a list of education materials already provided to existing patients and informal caregivers.	The system should support patient education by tracking education materials provided to patients, The system should support patient education by providing education materials for informal caregivers			

2.Administrative Processes Support

No.	Procedure	Expected Result	Actual result	Pass/ Fail	Comments
a.	Give a patient/client an appointment as appropriate.	Scheduling data should be accessible through the PHC EMR system, to support scheduling management for patient appointments			

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b.	Generate a report on bed occupancy in the facility	Scheduling data should be accessible via the PHC EMR system, to support scheduling management for patient admissions			
c.	Allocate a patient to the operation theatre	Scheduling data should be accessible via the PHC EMR system, to support scheduling management for patient surgery/procedure schedule			
d.	Indicate that a patient has HEALTH INSURANCE Cover during registration/admissions	The system should provide notification of eligibility for insurance			
e.	Enter the eligibility criteria for clinical trials.	The system should provide the ability to capture the criteria for eligibility for clinical trial recruitment			
f.	Flag a drug as having been recalled.	The system should provide a listing of all patients who have received a recalled drug			

3. Inventory Management

No.	Procedure	Expected Result	Actual result	Pass/ Fail	Comments
a.	Capture product information	The system should show product information. e.g. Batch numbers, manufacturer, and expiry dates			

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b.	Capture stock movement	The system should capture product movement between service delivery points			
c.	Capture suppliers' information	The system should accept, modify and display products and suppliers' information			
d.	Capture invoicing details	The system should capture details as per the invoice			
e.	Capture details of unusable products	The system should capture products for return to the supplier or for disposal. The system should adjust stock levels			
f.	Capture stock status	The system should indicate stock taking Digital Health Solution			
g.	Capture stock reorder levels	The system should show maximum and minimum stock and reorder levels, and reorder quantities and send notice of items out of stock			

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Appendix 2 (b): Patient-Facing Digital Health Solution Non-Core Functions Review Score Sheet

The tool in this appendix is a summary score sheet that would facilitate review of the digital health solution non-core functions.

Feature/Description	References	Implemented Not Implemented	Reviewers Comments	Score 1 point for each fully met requirement, otherwise any non-compliance results in zero score
1.Patient Education				
Allow system users to access education materials	1a			
Track education materials provided to patients	1b			
Administrative Process Support				
Support patient scheduling management	2a			
Support patient eligibility for insurance, clinical trial recruitment, drug recall and chronic disease management	2b-2f			
Billing Management				
Access information on products with waivers and exemptions	3a			
Track value of products issued to patients by the pharmacy	3b			
Facilitate printing of receipts and invoices for medication dispensed to the patients	3c			

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Appendix 3(a): Non-patient Facing digital health solution Core Functions Review Tool

This appendix provides a tool to guide the review of the non-patient facing digital health solution that is found in health facilities. The tool provides a guide of the target systems identifying the level of conformance with specific functional requirements.

1. Exchange of Electronic Data

No.	Procedure	Expected Result	Actual result	Pass / Fail	Reference	Comments
a.	Extract data contained in the system in a standard file format	System should facilitate data extraction in standardized file formats that can be understood by other systems				
b.	Import standard format of data into the system	System should accept standardized data format extracted by another electronic system				

2. Profile Management

No.	Procedure	Expected Result	Actual result	Pass/ Fail	Reference	Comments
a.	Display an items profile including date acquired, supplier, expiry date whereit exists, item value, movement between departments.	The system should facilitate provision of summary information on items whose data it collects				

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b.	Update a captured item's information	The system should facilitate editing and updating of captured items information including issuance and addition				

3. Reporting

No.	Procedure	Expected Result	Actual result	Pass/ Fail	Reference	Comments
a.	Query the system to display collected information based on any of the defined reports	The system should facilitate data output through predefined reports				
b.	Query the system to display collected information based on a customized report	The system should facilitate data output through customized reports				

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Appendix 3 (b): Patient-Facing Digital Health Solution Non-Core Functions Review Score Sheet

The tool in this appendix is a summary score sheet that would facilitate review of the digital health solution non-core functions.

Feature/Description	References	Implemented / Not Implemented	Reviewers Comments	Score 1 point for each fully met requirement, otherwise any non-compliance results in zero score
Exchange of electronics data				
System can exchange data with other systems.	1a – 1b			
Profile management				
System provides summary information on subject items.	2a – 2b			
Reporting				
System provides a mechanism for extracting captured data.	3a – 3b			

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