

GUIDELINES FOR THE INTRODUCTION OF DIGITAL HEALTH SOLUTIONS AND INNOVATIONS IN UGANDA

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Foreword

Ministry of Health is committed to improving the application of digital health technologies to facilitate the attainment of its overall objective of delivering high-quality health services to all citizens in Uganda. This is in line with the call of Uganda Vision 2040 and the National Development Plan (NDP) III which require sectors to adopt Information Communication Technologies (ICTs) to Optimise service delivery.

To further the application of ICTs within the health sector, the Ministry of Health (MoH) developed the Uganda Health Information and Digital Health Strategic Plan 2020/21-2024/25 which promotes digital health innovations and the application of digital health solutions within the health sector.

However, the health sector in Uganda is characterised by a fragmented landscape of digital health solutions, innovations and pilot projects resulting in duplication of efforts and resources, and digital health systems that are never scaled.

These guidelines standardise introducing digital health solutions and innovations in the Ugandan health sector. The overall purpose is to realise interoperable, secure digital health solutions that adhere to existing legal and guiding frameworks. This will also result in digital health solutions and innovations that can be integrated into national health systems to promote scalability and sustainability. This will deliver a safer, better connected, and more sustainable healthcare system.

Dr. Henry G. Mwebesa

Director General, Health Services

Preface

Digital Health is a vital component of a health system and is a critical precursor for optimising health service delivery to achieve Universal Health Coverage (UHC). The Ministry of Health is mandated to provide high-quality and accessible health services to all people in Uganda.

The purpose of these guidelines is to standardise the implementation of digital health solutions and innovations to realise interoperable, secure digital solutions that adhere to the existing legal and guiding frameworks in Uganda.

In the past ten years, between 2015 and to date, various actors have supported numerous digital health innovations and solutions, mostly independent of the national health information system, resulting in the duplication of, and limited integration of the various health information platforms, which these guidelines aim to rectify going forward. I call upon all actors to follow these guidelines as new digital health solutions and innovations are being introduced into the country to avoid further fragmentation of systems.

Dr. Sarah Byakika

Commissioner Health Services

Department of Planning, Financing and Policy

Acknowledgement

The Ministry of Health expresses its profound gratitude to all departments and programs, the

Health Information Innovation and Research Technical Working Group (HIIRE TWG) and the

Digital Health Subcommittee who contributed technical inputs leading to the successful

completion of this document. Special appreciation goes to the Division of Health Information

Management (DHIM) and the Information Communication Technology (ICT) Section for the

overall guidance to ensure that the guidelines are aligned with the Uganda Health Information

and Digital Health Strategic Plan 2020/21-2024/25.

I acknowledge and thank all development and implementing partners that provided technical

support for this process, specifically UNICEF, CDC, MUSPH/METS, USAID and HISP.

DHIM is grateful for all the support, sacrifice and contributions that have been invested in its

successful development.

Finally, the Ministry of Health is grateful to the Ministry of Information Communication

Technology and National Guidance (MoICT&NG), National Information Technology

Authority Uganda (NITA-U), and all those institutions and individuals who have not been

specifically mentioned above, but who directly or indirectly contributed to the successful

development and finalisation of these Guidelines for the Introduction of Digital Health

Solutions and Innovations in Uganda.

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Mr. Paul Mbaka

Assistant Commissioner Health Services

Health Information Management

Abbreviations

DHTR Digital Health Tools Registry

DHIS2 District Health Information System

DHS Digital Health Subcommittee

HC Health Centre

HIIRE Health Information Innovation and Research

HMIS Health Management Information System

HSDP Health Sector Development Plan

HSS Health Systems Strengthening

ICT Information Communication Technology

NDP National Development Plan

PFP Private for Profit

PNFP Private Not for Profit

TWG Technical Working Group

WHO World Health Organization

Definition of Key Terms

Digital Health — Digital health is the systematic application of information and communications technologies, computer science, and data to support informed decision-making by individuals, the health workforce, healthcare organisations, and health systems, to strengthen resilience to disease and improve health and wellness.

Digital Health EcoSystem – The combined set of digital health components representing the enabling environment, foundational architecture and Information Communication Technology capabilities available in a given context or country.

Digital Health Intervention – A discrete technology functionality – or capability – designed to achieve a specific objective addressing a health system's challenges.

Digital Health Application – The software, information and communications technology (ICT) systems or communication channels that deliver or execute the digital health intervention and health content.

Electronic Medical Record (EMR) – An electronic record of health-related information on an individual that can be created, gathered, managed and consulted by authorised clinicians and staff within one healthcare organisation

Electronic Health Record (EHR) – An electronic record of health-related information on an individual that conforms to nationally recognised interoperability standards and that can be created, gathered, managed and consulted by authorised clinicians and staff across more than one healthcare organization.

Health Information — Health information is any personal information, whether oral or recorded in any form or medium, that; is created or received by a health care provider, health planner, public health authority, employer or the employer's agent, life insurer, school or university, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

Health Information Management - A process which involves the collection, analysis, storing, protecting and ensuring of the quality of client/patient health information. This

information can be either paper-based, a combination of paper and digital (hybrid) or increasingly, a fully electronic health record.

Health Information System (HIS) – Any organised effort to systematically collect, maintain and disseminate data relevant to the performance of a health system or any of its parts.

Health System – The complete universe of all activities that serve to maintain or improve the health and longevity of a population in a specific geography.

Interoperability – The ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged. The integration allows two applications to exchange information, interoperability allows many.

Personal Health Record (PHR) – An electronic record of health-related information on an individual that conforms to nationally recognised interoperability standards and that can be drawn from multiple sources while being managed, shared and controlled by the individual record owner.

User Department or Programme - The official Ministry of Health departments and programmes as per the documented Ministry of Health macrostructure.

1.0 Introduction

Health Information System is one of the core building blocks of any health system according to the World Health Organization (WHO). The daily business of health relies on information and communication and, increasingly, on the technologies that enable it, at every health service delivery level world over. In an increasingly digital world, spurred by technological advances, economic investment, and social and cultural changes, there is growing recognition that inevitably the health sector ought to integrate Information Communication Technology (ICT) into its operations. The Ugandan healthcare system, through its ongoing health sector reforms, aims to improve health outcomes. As part of these reforms, the Ministry of Health (MoH) developed and is implementing the Ministry of Health Strategic Plan 2020/2021-2024/2025. This was to address the key challenges facing Uganda's health system, set out priorities and key areas on which to focus health investment in the medium term, for both public and private partners, to optimally contribute to the attainment of both the health sector goals and the national goals as outlined in the National Development Plan III. The Ministry of Health recognises the potential of ICTs in transforming healthcare delivery by enabling information access and supporting healthcare operations, management, and decision-making. In light of the above, the Uganda Health Information and Digital Health Strategic Plan 2020/21-2024/25 with a vision of A health sector in Uganda driven by evidence and leveraging digital health to improve efficiency in service delivery.

1.1 Context

1.1.1 The Uganda Health Systems Structure

Uganda has an organised national health system and health delivery in place within the strategic framework and focus. The national health system comprises both the private and public sectors. The private health sector comprises Private Not for Profit (PNFP), and Private for Profit (PFPs). The public sector includes government health facilities and health services departments of different ministries. Some of the Ministry of Health functions have been delegated to national autonomous institutions like the National Drug Authority.

Health services delivery is decentralised within national, districts and health sub-districts. The lowest level of healthcare delivery is at the community level with volunteers in villages facilitating health promotion, service delivery, community participation, and empowerment. These are preceded by Health Centre IIs providing a first level of interaction between the

formal health sector and communities. These provide preventive, promotive, and curative services. The next level is the Health Centre IIIs which provide in-patient, simple diagnostic, and maternal health services. The next levels are Health Centre IVs and general hospitals, which provide broad services such as surgeries and blood transfusions, research, and training. The regional referral hospitals that are next in the hierarchy provide a higher level with more specialised clinical services and involve teaching and research. These are followed by national referral hospitals which are most comprehensive as they provide the highest level of specialist services in addition to all the other clinical services.

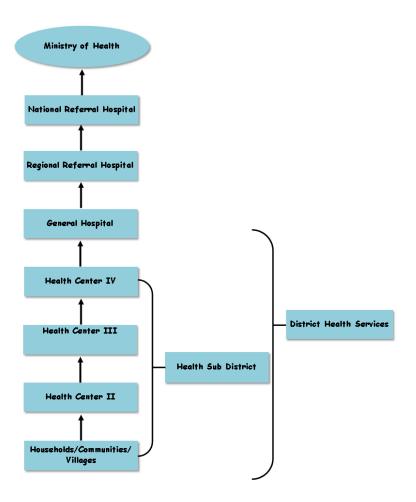


Figure 1: The Uganda Health Care System Structure

1.1.2 Ministry of Health Governance and Management Structures

The Ministry of Health governance structures derive their mandates from the corresponding policies and laws of Uganda. The health governance structures at the national and MoH include:

At the national level

- Cabinet: The cabinet is responsible for the overall leadership in the health sector.
- Parliament: The Parliamentary Health Committee provides overall oversight in the health sector.

At the Ministry of Health level, the structures include the Senior Top Management Committee (STMC), Top Management Committee (TMC), Health Policy Advisory Committee (HPAC), Senior Management Committee (SMC), Technical Working Groups (TWGs) and Departments.

Figure 2 outlines the strategic roles, structures and composition of the MoH governance and management structures. Further details can be obtained from the Implementation Guidelines for the Ministry of Health Governance and Management Structures, 2022.

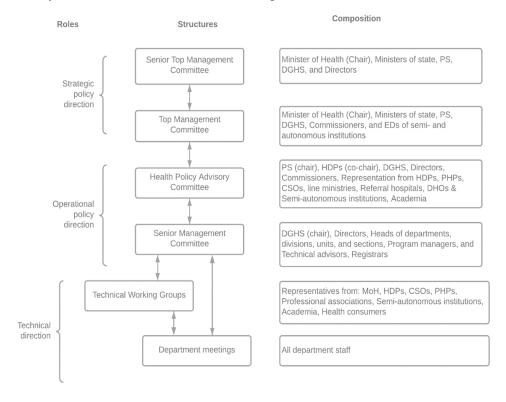


Figure 1: The MoH Governance and Management Structures¹

The individual departments are responsible for the implementation of interventions within their respective technical areas. The departments are further broken down into divisions and divisions into units. A breakdown of the various departments within MoH is detailed in **Figure 2**.

¹ Implementation Guidelines for the Ministry of Health Governance and Management Structures, 2022.

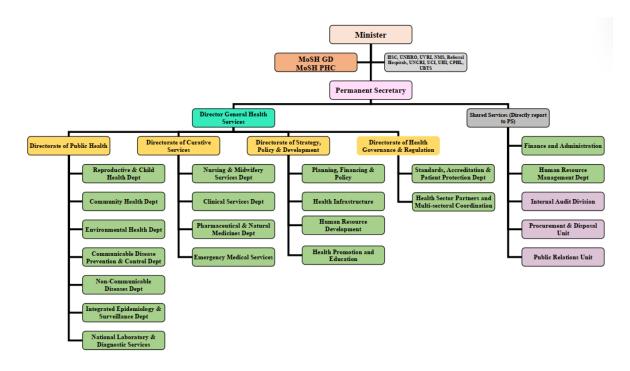


Figure 2: The Ministry of Health Macro Structure²

1.1.3 Data Flow Within the Uganda Healthcare System

All decisions at every level of healthcare service delivery are premised on data generated within the health sector in addition to other related sectors. As such, there is a need for data sharing across healthcare delivery at different levels for purposes of planning and decision-making. In Uganda, all health facilities must report a set of standard data defined within the national Health Management Information System (HMIS) to the Ministry of Health at various predetermined intervals (weekly, monthly, quarterly, and annually) to facilitate planning and policy formulation at the national level. Data to be collected is defined based on the health information needs of the country and it flows from the very first healthcare delivery level (community level) (see Figure 1) through the different subsequent levels and finally to the national level (Ministry of Health). Information technology as an enabler for health data management has been adopted to support the various data handling processes as shown in Figure 3.

² Ministry of Health Strategic Plan 2020/21-2024/25

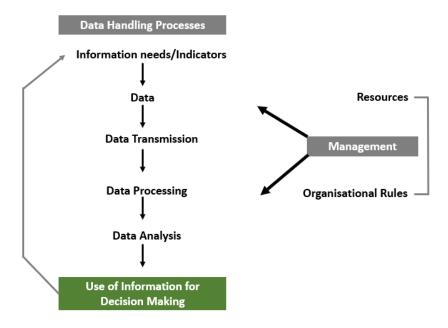


Figure 3: Data Handling Processes within the Uganda Healthcare System

For transmission, processing and analysis, Uganda adopted the District Health Information Software (DHIS2) to power its electronic Health Management Information System (eHMIS). Digital solutions implemented at the data collection stage are required to transmit the defined HMIS data set to eHMIS/DHIS2.

1.2 Situation Analysis

Digital health solutions and innovations are increasingly being adopted in Uganda to improve the quality of patient care, health data management and health program management. While international donors and health agencies have increased investment in ICT to support Health Systems Strengthening (HSS) in recent years, these investments have often resulted in a proliferation of pilot efforts rather than efforts to scale projects. Digital health systems and applications are often developed and implemented ad hoc, to meet the immediate requirements of specific activities or projects, with a limited focus on scalability. As a result, solutions that are successful in one locale are often unable to be integrated with other data systems or adopted by other, similar programs. The majority of the innovations have focused on the adoption of new products or services by individuals and their market-driven diffusion to the population at large. These innovations have typically emerged from negotiations between diverse stakeholders who compete to impose or at least prioritise their preferred version of that innovation. Thus, while many digital health interventions have succeeded in terms of adoption by a substantial number of end users, they have generally failed to gain the level of *acceptance* required for their integration into national health systems that would promote

sustainability and population-wide application. For example, by 2010, there were over 50 eHealth innovations in Uganda by almost as many donors, a situation that has been referred to as" *Pilotitis*" which is the act of continuously pursuing small healthcare projects but never scaling them, leading to duplication and short-lived benefits. This tremendous duplication of effort has not only led to a waste of resources but has also resulted in more complicated health systems. Rather than improve information flows among stakeholders, this series of non-integrated health systems has created disjointed "information islands" that have become barriers to effective communication. Furthermore, the useful lifespan of many projects is often determined by the availability of limited donor funding, and thus many cease to operate once initial development funding ends.

1.3 Purpose of Document

The guidelines seek to establish an effective, transparent and accountable framework for introducing digital health solutions and innovations.

1.4 Goal

To enhance healthcare delivery, patient outcomes, and system efficiency through the effective, equitable, and ethical integration of digital health technologies

1.5 General Objective

To standardise the processes of introducing digital health solutions and innovations into the Ugandan health sector that are capable of being integrated into the national health systems to promote scalability and sustainability.

1.5.1 Specific Objectives

- 1. Functionalise an appropriate governance framework for the introduction of digital health solutions and innovations in Uganda.
- 2. Define and standardise the processes for introducing, scaling, and sustaining digital health solutions and innovations.
- 3. Ensure interoperability of the digital health solutions and innovations with other Ministry of Health data systems.
- 4. Ensure adherence of digital health solutions and innovations to the existing legal and guiding frameworks in Uganda.

1.6 Scope

All digital health solutions and innovations being introduced into Uganda's health sector (private and public health sectors). This shall include donations of digital health solutions by donors and other stakeholders. The scope shall also include procurement of digital health solutions for both the private and public sectors. For the public sector, the Public Procurement and Disposal of Public Assets Act 2003 shall apply while for the private sector, the procurement guidelines as per the organisational policy shall apply.

1.7 Target Audience

This document is intended for;

- 1) The Ministry of Health Departments and Programs
- 2) Local Governments
- 3) Health workers
- 4) Technology and Implementing Partners
- 5) Development Partners and Donors/Funders
- 6) Health Policymakers
- 7) Researchers
- 8) Digital Health Solution Providers
- 9) Innovators
- 10) Academia
- 11) Procurement entities
- 12) Other relevant stakeholders.

1.8 Methodology

A highly consultative approach was used in the development of these guidelines. Stakeholders from various entities such as the Ministry of Health (MoH) Department and Programmes, Local Governments (LGs), Development Partners, Implementing Partners, Technology and Implementing Partners, Academia, Innovators, Technology Providers and other members of the Health Information Innovation and Research Technical Working Group (HIIRE TWG) supported the generation of a draft which was reviewed and later validated.

The validated guidelines were endorsed by the Ministry of Health's HIIRE TWG and the Senior Management Committee (SMC), and approved by Top Management for implementation within the health sector.

1.9 Underpinning Guiding Principles

- 1. Client Centered
- 2. Equity
- 3. Efficiency
- 4. Transparency and Accountability

1.10 Policy, Reference Guidelines and International Standards

These guidelines are premised on the following existing frameworks;

- 1. Public Procurement and Disposal of Public Assets Act 2003
- 2. The National Health Policy (NHP) III
- 3. Ministry of Health Strategic Plan 2021/2025
- 4. Uganda Health Information and Digital Health Strategic Plan 2020/21 2024/2025
- Guidelines and Standards for Acquisition of IT Hardware and Software for Ministries,
 Departments and Agencies
- 6. Uganda Digital Health Enterprise Architecture, Standards and Knowledge Guidelines
- 7. Uganda Health Data Protection, Privacy and Confidentiality Guidelines

1.11 Revision and Updates

These guidelines shall be reviewed and any proposed changes documented annually to maintain relevance and/or responsiveness to an evolving healthcare ecosystem and context. Relevant sections that will need to be added to the document shall follow the standard MoH approval processes. A new version number and date of approved updates shall be documented.

2.0 The Digital Health Solutions and Innovation Approval Process

All digital health solutions and innovations implemented in Uganda must adhere to the Uganda Digital Health Enterprise Architecture, Standards and Knowledge Guidelines. The set standards within the guidelines are based on the categories under which they fall. These broad categories include Electronic Medical Records Systems (EMR), Community Health Information Systems (CHIS), Laboratory Management Information Systems (LMIS), Radiology Information Management Systems, general electronic Health Management Information Systems, and Logistics Management Information Systems amongst others. To ensure adherence to the standards and accurate curation of all the solutions in the country, they are all required to undergo an approval process as elaborated below; -

2.1 Registration of the Digital Health Solution and Innovations

The initial stage in the approval process entails registration of the digital health solution and innovation with the Digital Health Subcommittee (DHSC) of the HIIRE TWG and will follow the following criteria.

- The registration of the solution or innovation shall be initiated by the Ministry of Health
 Departments and Programmes and all other relevant stakeholders including innovators
 through the DHSC email dhs@health.go.ug.
- Alternatively, registration shall also be initiated through the electronic portal known as
 the Digital Health Tools Registry (DHTR) which shall be accessed using the URL
 dhtr.go.health.ug. The link will be also accessed through the Ministry of Health
 website where it will be published.
- 3. The registration process shall be guided by the **Digital Health Systems Assessment**Criteria (DHSAC) as detailed in Appendix 1. At this stage, preliminary information about the solution or innovation being registered shall be captured. It is necessary to add here the mandatory details of the information that shall be provided at registration to further aid the assessment of the solution or innovation. Failure to provide the mandatory information shall result in non-qualification for the next stage. i.e. the form submission via the electronic portal shall be automatically validated against mandatory fields, uncompleted forms will not allowed to be submitted. Forms submitted via email shall be checked for completeness by the DHSC Secretariate team.
- 4. A confirmation or acknowledgement of successful form submission shall be received within 24 hours in case the DHTR electronic portal is used. In case of email submission, an acknowledgement email or confirmation of submission will be received within 5 working days.

2.2 Presentation to the Digital Health Subcommittee

Successfully registered solutions shall be scheduled for presentation to the DHSC and the following criteria will be followed;

- 1. Sections A, B and C of the **DHSAC** shall be fully completed by the digital health solutions providers or innovators before being scheduled.
- 2. A presentation template shall be shared with the solutions provider or innovator by the DHSC secretariate team or through download from the DHTR electronic portal.

- 3. A presentation scheduled shall be generated indicating the date, time and means of presentations and shall be shared with the solutions provider or innovator through the registered email.
- 4. A minimum of a week's notice shall be provided to allow for adequate preparations by the solutions provider or innovator.
- 5. All solutions or innovations shall be assessed based on **Digital Health Systems**Assessment Criteria (Appendix 1).
- 6. The DHSC shall seek clarifications concerning the solution or innovation up to **1-week** post-presentation to enable the team to produce a comprehensive assessment report.
- 7. The DHSC technical report shall be produced within **2 weeks** by the secretariate team and shared with members for further input and review.
- 8. Review and input by members of the DHSC shall be done within **1 week** after sharing the initial draft of the report by the DHSC secretariate team.
- 9. The final technical assessment report by the DHSC shall be shared with the solutions providers or innovators within **3 weeks** post presentation of the digital health by the solutions provider or innovator.
- 10. The report shall document clear recommendations and next steps for the solutions provider or innovators including;
 - a. Recommendation for endorsement of the solution or innovation by the relevant User Department or Programme in writing if there is a need.
 - b. Whether the solution or innovation has been endorsed for presentation to the HIIRE TWG or not. In case further clarifications or presentations are needed to be made to the DHSC, steps 3 to 9 under section 2.2 shall be followed.
- 11. In a situation where the DHSC determines that the solution passes the Digital Health Systems Assessment Criteria, a decision shall be made if a site visit is required if necessary, or endorsement to present to HIIRE TWG shall be granted. Solutions that do not fulfil the requirements shall be required to redo a presentation after effecting the recommendations of the DHSC.

2.2.1 Field Visit/Proof of Concept

In case a field visit is recommended, the Digital Health Subcommittee members shall then make a field visit to at least a site where the solution or innovation being assessed is being implemented. At this stage, the aim is to correlate the functionality as purported in the presentation to the DHSC to the actual operation in the real working environment. The field

visit report shall be compiled and shared with the DHSC secretariat team within five days of the field visit. The field visit report will incorporated within the earlier DHSC report to have a complete report.

Solutions that shall be found to be performing below expectation and not in line with the stated functionalities shall be requested to effect the recommendations from the DHSC before being endorsed to move to the next stage of evaluation.

All digital health solutions or innovations not endorsed by the HIIRE TWG shall not be presented to SMC.

2.3 Presentation to the Health Information Innovation and Research Technical Working Group (HIIRE TWG)

- 1. Recommendations from the Digital Health Subcommittee concerning the evaluated digital health solution or innovation shall be shared with the HIIRE TWG before scheduling the solution for presentation to the HIIRE TWG.
- 2. A User Department or Programme shall lead the presentation to the HIIRE TWG and introduce the solution, solution providers and innovators to the HIIRE TWG members before proceeding to present the proposed solution or innovation.
- 3. No presentation of the digital health solution or innovation shall be made to the HIIRE TWG in the absence of the User Department or Programme.
- 4. The HIIRE TWG shall only approve digital health solutions or innovations for the pilot.
- 5. The approved digital health solution or innovation for the pilot shall be communicated officially to all stakeholders concerned.
- In case of scale or formal adoption of digital health solutions or innovations, the HIIRE
 TWG shall only endorse the solution or innovations for presentation to the Senior
 Management Committee (SMC).
- 7. The HIIRE TWG recommendations and endorsement shall be documented in the meeting minutes and shared with the secretariat team of the SMC before the solution can be presented to the SMC.
- 8. All digital health solutions or innovations not endorsed by the HIIRE TWG shall not be presented to SMC.

2.4 Presentation to the Senior Management Committee (SMC)

Digital health solutions or innovations that need to be scaled or formally adopted shall be presented to the SMC. Also, solutions that need to be piloted but have a policy implication shall be presented to the SMC following HIIRE TWG recommendations.

- 1. Recommendations by the HIIRE TWG shall be implemented first by the digital health solutions provider, innovator, user department or programme before the endorsed solution or innovation is presented to the SMC.
- 2. A User Department or Programme shall lead the presentation to the SMC and introduce the solution, solution providers and innovators to the SMC members before proceeding to present the proposed solution or innovation.
- 3. No presentation of the digital health solution or innovation shall be made to the SMC in the absence of the User Department or Programme.
- 4. The SMC shall endorse the digital health solution or innovation for presentation to the Health Policy Advisory Committee (HPAC) in case of policy and financial implications.
- 5. Otherwise, the proposed digital health solution or innovation shall be endorsed for presentation to the Top Management Committee for approval.
- All recommendations by the SMC shall be implemented by the solution provider, innovator, user department or programme before proceeding to the next stage of approval.
- 7. The SMC recommendations and endorsement shall be documented in the meeting minutes and shared with the secretariat team of the HPAC or SMC before the solution can be presented to the next approval level.
- 8. All digital health solutions or innovations not endorsed by the SMC shall not be presented to HPAC or Top Management.

2.5 Presentation to the Health Policy Advisory Committee (HPAC)

In case the proposed digital health solution or innovation has a policy or financial implication, this will require endorsement by HPAC

Recommendations by the SMC shall be implemented first by the digital health solutions
provider, innovator, user department or programme before the endorsed solution or
innovation is presented to the HPAC.

- 2. A User Department or Programme shall lead the presentation to the HPAC and introduce the solution, solution providers and innovators to the HPAC members before proceeding to present the proposed solution or innovation.
- 3. No presentation of the digital health solution or innovation shall be made to the HPAC in the absence of the User Department or Programme.
- 4. HPAC shall endorse the digital health solution or innovation for presentation to the Top Management for approval.
- 5. All recommendations by the HPAC shall be implemented by the solution provider or innovator before proceeding to the next stage of approval.
- 6. The HPAC recommendations and endorsement shall be documented in the meeting minutes and shared with the secretariat team of the Top Management Committee before the solution can be presented to the next approval level.
- 7. All digital health solutions or innovations not endorsed by the HPAC shall not be presented to Top Management.

2.6 Presentation to Top Management Committee

- 1. Recommendations by the SMC or HPAC shall be implemented first by the digital health solutions provider, innovator, department or programme before the endorsed solution or innovation is presented to the Top Management Committee.
- A User Department or Programme shall lead the presentation to the Top Management Committee and introduce the solution, solution providers and innovators to the Top Management Committee members before proceeding to present the proposed solution or innovation.
- 3. No presentation of the digital health solution or innovation shall be made to the Top Management Committee in the absence of the User Department or Programme.
- 4. The Top Management Committee shall approve the digital health solution or innovation for procurement, scale or formal adoption.
- 5. All recommendations by the Top Management Committee shall be implemented by the solution provider or innovator, department and programme before procurement, scaling or implementation of the solution or innovation.
- 6. The Top Management Committee recommendations and approval shall be documented in the meeting minutes.

- 7. All digital health solutions or innovations not approved by the Top Management Committee shall not be procured, scaled or implemented.
- 8. The approved digital health solution or innovation shall be communicated officially to all stakeholders and recognised as a Ministry of Health official system.

3.0 General Considerations

- 1. All systems being implemented at various healthcare levels without official approval will be required to undergo steps 2.0 to 2.6 as part of the approval process.
- 2. For purposes of formal adoption or transition, and scale-up of the proposed digital health solution or innovation, the following supporting documentation will be needed in addition to the Digital Health Systems Assessment Criteria (DHSAC) documentation earlier defined in section Appendix 1.
 - a. System Transition Plan
 - b. System Sustainability Plan
 - c. System Capacity Building Plan.
 - d. System Specification Documentation
 - e. System User Requirements Documentation
 - f. System Scale-Up Plan
- 3. Further supporting documentation besides what is mentioned above may be needed by the various approving structures to make an informed decision. It will be upon the digital health solutions provider, innovator, relevant User Department or Programme to provide the needed information promptly.
- 4. All procurement of digital health solutions for the public sector shall follow the Public Procurement and Disposal of Public Assets Act 2003 while those of the Private Sector shall follow the procurement guidelines as per institutional policy.

4.0 Digital Health System Implementation Framework

Various entities will have different roles and responsibilities during the approval process and this is detailed below;

SN	Entity	Responsibility	
1	Top Management Committee	3. Strategic leadership, guidance, and oversight.	
		4. Approval of digital health systems or innovations for procurement and use in Uganda as official tools.	
		5. Monitoring and Supervision of digital health systems and innovations.	
2	Health Policy Advisory	1. Strategic leadership, guidance, and oversight.	
	Committee (HPAC)		

	T	1	
		2.	Ensure that digital systems are aligned with existing
			policies and laws.
		3.	Monitoring and Supervision of digital health systems
			and innovations.
		4.	Endorsement of digital health solutions or innovations
	G · M		for presentation to the Top Management Committee
3	Senior Management	1.	Strategic leadership, guidance, and oversight.
	Committee (SMC)	2.	Ensure digital systems are aligned with the needs of the departments and programmes.
		3.	Monitoring and Supervision of digital health systems
		٥.	and innovations.
		4.	Endorsement of digital health solutions or innovations
			for presentation to the Health Policy Advisory
			Committee or Top Management Committee.
4	Health Information,	1.	Approval of digital health solutions or innovations for
	Innovation and Research		piloting.
	Technical Working Group	2.	Monitoring and Supervision of digital health systems
	(HIIRE TWG)	3.	Give technical guidance and quality assurance for the
			proposed digital health solutions and innovations.
		4.	Ensure adherence of digital health systems and
			innovations to standards and guidelines.
		5.	Review and endorse proposed standards, guidelines,
			System Transition Plans, System Sustainability Plans,
			System Capacity Building Plans, System Specification
			Documentation, System User Requirements
			Documentation and System Scale-Up Plans.
		6.	Endorsement of digital health solutions or innovations
			for presentation to the Senior Management Committee
5	MoH/Department of Planning	1	Strategic leadership guidance and oversight
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		6.	Coordinating and Managing access to digital health
			systems
		7.	
5	MoH/Department of Planning, Finance and Policy	5.6.1.2.3.4.5.	Ensure adherence of digital health systems and innovations to standards and guidelines. Review and endorse proposed standards, guidelines, System Transition Plans, System Sustainability Plans, System Capacity Building Plans, System Specification Documentation, System User Requirements Documentation and System Scale-Up Plans. Endorsement of digital health solutions or innovations for presentation to the Senior Management Committee Strategic leadership, guidance, and oversight. Ensure digital systems are aligned with the needs of the departments and programmes. Monitoring and Supervision of digital health systems and innovations. Coordinate implementation of digital health solutions and innovations Prioritise areas of implementation in line with the Digital Health and Health Information Strategic Plan 2020/21 – 2024/25

6	Division of Health	1.	Coordinate implementation of digital health solutions	
	Information Management	1.	and innovations	
		2.	Recommend digital health systems for pilot and use	
			following a technical evaluation	
		3.	Prioritise areas of implementation in line with the	
			Digital Health and Health Information Strategic Plan	
			2020/21 – 2024/25	
		4.	Managing access to digital health systems	
		5.	Coordinate and ensure data and system management	
			with the support of stakeholders.	
		6.	Quality assurance of digital health solutions and	
			innovations	
		7.	Coordinating integration of digital health system with	
			other system	
		8.	Advise on changes and modifications to the digital	
			health systems	
		9.	Supervision of implementation teams.	
		10.	Coordinate the development of standards and	
			guidelines.	
		11.	Coordinate capacity-building programmes with	
			stakeholders	
		12.	Coordinate the development and implementation of	
			sustainability and transition plans for digital health	
		1.2	solutions with stakeholders.	
		13.	Ensure appropriate governance of digital health solutions and innovations	
		14	Resource mobilisation and funding for implementation	
		14.	of digital health systems.	
		15	Monitoring and Supervision of digital health systems	
		13.	and innovations.	
7	MoH/IT Section	1.	Provide hosting infrastructure for approved digital	
			health systems	
		2.	Security of digital health systems and hosting	
			environment	
		3.	Ensure data and system backup	
		4.		
			hosting	
		5.	Coordinating and Managing access to system hosting environments/backend.	
		6.	Define and Specify infrastructure requirements for	
		.	hosting health solutions	
		7.	Guide on	
		8.	Recommend digital system hosting strategies	
8	MoH/User Departments	1.	Participate in the digital health system user	
		_	requirements specification Programmatic quidance on the functionality of the	
		2.	Programmatic guidance on the functionality of the	
		2	digital health tools Participate and sign off on user acceptance tests for the	
		3.	Participate and sign off on user acceptance tests for the digital health systems or workflows.	
			uigitai neaitti systems oi wolkhows.	

9	Partners	4.	Technical assistance for the implementation of digital
	Tarthers	٦.	health systems and innovations
		5.	Resource mobilisation and funding for implementation
		٥.	of digital health systems.
		6.	Capacity building of MoH and Local governments on
		0.	1 •
		7	management and use of the digital health systems.
		7.	Participate in the development of standards and guidelines.
		8.	Monitoring and evaluation of the digital health system
		9.	Participate in the roadmap of the development of
			digital health systems within the health sector
		10.	Optimise implementation and adaptation of the
			approved digital health systems
10	Local Governments	1.	Support implementation of the approved digital health
			systems at the local government level
		2.	Coordination of implementation at the local
			government level (districts and cities) with partners
		3.	Supervision of implementation teams
		4.	Participate and sign off on user acceptance tests.
		5.	Implement the digital health system sustainability plan
			with the support of MoH and stakeholders.
11	Health Facilities	1.	Ensure data quality assurance and assessment.
		2.	Support health workers on the use of approved digital
			health systems
		3.	Conduct capacity building of the health workers on the
			approved digital health system.
		4.	Generate a list of users of the digital health system for
			approval by the Division of Health Information
			Management
		5.	Support the implementation of the approved digital
			health system at national and subnational levels.
		6.	Supervision of health workers within their catchment
			area
12	Digital Health Subcommittee	1.	Review and assess digital health systems with a view
			of alignment with national Digital Health and Health
			Information Strategic objectives.
		2.	Review existing digital health solutions versus new
			and/or parallel developments with a view to
			minimising duplications.
		3.	Technically review proposed investments to determine
			and advise on potential benefits.
		4.	Technically review and refine business case
			requirements to determine and advise on costs,
			benefits, timelines, and resources.
		5.	Technically review to determine availability and
			commitment of project sponsor.
		6.	Technically review to determine project management
			and project governance needs.
		7.	Provide recommendations for approval of business
			case/digital health solutions.

5.0 Monitoring, Evaluation and Dissemination

This Section outlines how the monitoring and evaluation of the Guidelines for the Introduction of Digital Health Solutions and Innovations in Uganda will be conducted. This shall be based on the Monitoring and Evaluation framework stipulated in the Uganda Health Information and Digital Health Strategic Plan 2020/21-2023/24 which is essential for compliance and effectiveness of the guideline. Therefore; the guideline shall be monitored in terms of the: -

- Dissemination of the guideline
- Compliance with the guideline

All records related to the endorsement and approval of digital health solutions and innovations shall be documented by the secretariat teams of the relevant endorsing and approving structures.

The status of the digital health solutions or innovations will be updated by the Digital Health Subcommittee secretariat team on the electronic Digital Health Tools Registry to enable easy reference and retrieval of information.

A checklist shall be developed to monitor the compliance of implementers with the guidelines.

5.1 Dissemination and Adoption of the Guidelines

The Guidelines for the Introduction of Digital Health Solutions and Innovations in Uganda shall be disseminated for adoption through:

- 1. Presentation of the guidelines to stakeholders.
- 2. Posting of the guidelines on the MoH websites and the electronic Library for access by the stakeholders.
- 3. Organising quarterly workshops to train digital health solutions providers, innovators and other relevant stakeholders.

Appendix 1: Digital Health Systems Assessment Criteria



Digital Health Systems Assessment Criteria (DHSAC)

Version 1.1

Table of Contents

The assessment criteria is made up of four core components. Sections A and B will provide the assessors the context required to understand your product and support your evidence. The core assessment criteria is defined in section C1-D1. Section D details the key Usability and Accessibility principles required.

The core criteria in Section C and D will determine the overall success of the assessment of your product or service.

A. Company Information (Non-assessed Section)

Information about your organisation and contact details.

Code	Question	Options
A1	Provide the name of your company	Free text
A2	Provide the name of your product	Free text
A3	Provide the type of product	App Wearable Software as a Service (SaaS) Other
A4	Provide the name and job title of the individual who will be the key contact at your organisation	Free text

A5	Provide the key contact's email address	Free text
A6	Provide the key contact's phone number	Free text
A7	Provide the registered address of your company	Free text
A8	In which country is your organisation registered?	Free text

7.

B. Value Proposition – (Non-assessed Section)

Please set out the context of the clinical, economic or behavioural benefits of your product to support the review of your technology. This criterion will provide the context of the product undergoing assessment.

Where possible, please provide details relating to the specific technology and not generally to your organisation.

Code	Question	Options	Supporting information
B1	Who is this product intended to be used for?	Patients Diagnostics Clinical Support Infrastructure Workforce Other	
B2	Clearly define the problem that is intended to		

	be solved by the proposed product.		
В3	Provide a clear description of what the product is designed to do and of how it is expected to be used	Free text	This question is a context question and therefore a high-level summary is required.
B4	Describe clearly the intended or proven benefits for users and confirm if / how the benefits have been validated	Free text	This question is a context question and therefore a high-level summary is required. If your product has had an evaluation or undergone clinical trials include this information.
B5	Have you scanned the health sector or carried out a landscape assessment to find out if there are similar existing solutions and what could be unique about the solution being proposed	Yes No Free text	
B6	Please attach one or more user journeys which were used in the development of this product Where possible please also provide your data flows	Provided Not available	This question is a context question, and it is expected that existing documentation will be provided. Data flows enable the assessor to understand how data moves through a product.

C. Technical Questions - Assessed Sections

C1 - Data Protection

Establishing that your product collects, stores and uses data (including personally identifiable data) compliantly.

This section applies to the majority of digital health technology products however there may be some products that do not process any held patient data or any identifiable data. If this is the case, the Data Protection Officer or another suitably authorized individual should authorise this data protection section to be omitted from the assessment.

Code	Question	Options	Supporting information	Scoring criteria
C1.1	Does your product have access to any personally identifiable data or MoH-held patient data?	Yes No	The <u>Data Protection and Privacy Act</u> 2019 applies to the processing of personal data.	To pass, the developer must confirm that they are compliant with the Data Protection and Privacy Act 2019.
C1.2	Please confirm where you store and process data (including any third-party products your product uses)	Uganda only Outside of Uganda	Individual organisations within the health sector are accountable for the risk-based decisions that they must take.	Individual organisations within the health sector are accountable for the risk-based decisions that they must take. Due consideration should be taken where data is processed and stored outside of Uganda.

C1.3	If you process or store data outside of the Uganda, please name the country and set out how the arrangements are compliant with current legislation.	Free text	Should comply with the <u>Data</u> <u>Protection and Privacy Act 2019</u>	To pass, the developer must demonstrate that the country in which data is processed or stored is compliant with current legislation or the organisation's policy (should this differ)

C2 - Technical Security

Establishing that your product meets industry best practice security standards and that the product is stable.

Dependent on the digital health technology being procured, it is recommended that appropriate contractual arrangements are put in place for problem identification and resolution, incident management and response planning and disaster recovery.

Please provide details relating to the specific technology and not generally to your organisation.

Code	Question	Options	Supporting information	Scoring criteria
C2.1	Please provide the summary report of an external penetration test of the product that included Open Web Application Security Project (OWASP) Top 10 vulnerabilities from within the previous 12-month period.	Provided No evidence available	The OWASP Foundation provides guidance on the OWASP top 10 vulnerabilities.	To pass, the developer must evidence that the product has undergone an external penetration test that included the OWASP top 10 vulnerabilities. The penetration testing/summary report must demonstrate there are no vulnerabilities that score 7.0 or above using the Common Vulnerability Scoring System (CVSS).

C2.2	Please confirm whether all custom code had a security review.	Yes - Internal code review Yes - External code review No No because there is no custom code		To pass, the developer must confirm that an internal or an external custom code security review has been undertaken. An external review is preferable; however, an internal code review would meet the baseline requirement.
C2.3	Please confirm whether logging and reporting requirements have been clearly defined.	Yes No	To confirm yes to this question, logging (e.g., audit trails of all access) must be in place. It is acknowledged that not all developers will have advanced audit capabilities.	To pass, the developer must confirm yes that logging and reporting requirements have been clearly defined.
C2.4	Please confirm whether the product has been load tested	Yes No	Load testing should be performed.	To pass, the developer must confirm yes that load testing has been performed.

C3 - Interoperability Criteria

Establishing how well your product exchanges data with other systems.

To provide a seamless care journey, it is important that relevant technologies in the health system are interoperable, in terms of hardware, software and the data contained within. Good interoperability reduces expenditure, complexity and delivery times on local system integration projects by standardising technology and interface specifications and simplifying integration. It allows it to be replicated and scaled up and opens the market for innovation by defining the standards to develop upfront.

Please provide details relating to the specific technology and not generally to your organisation.

Code	Question	Options	Supporting information	Scoring criteria
C3.1	Does your product expose any Application Programme Interfaces (API) or integration channels for other consumers?	Yes No		To pass, developers must demonstrate that they have API's that are relevant to the use case for the product, are documented and freely available and that third parties have reasonable access to connect. If the product does not have API's and there is a
C3.2	If yes, please provide detail and evidence: • The API's (e.g., what they connect to) set out the healthcare standards of data interoperability e.g., Health Level Seven	Free text		legitimate rationale for this considering the use case of the product then the MoH can accept this rationale.

	International (HL7) / Fast Healthcare Interoperability Resources (FHIR) Confirm they are documented and freely available Third parties have reasonable access to connect If no, please set out why your product does not have APIs.		
C3.3	Do you use any unique identifier to identify patient record data?	Yes No No because product does not identify patient record data	To pass, developers should detail how patients are uniquely identified within the system.
C3.4	Does your product have the capability for read/write operations with electronic health records (EHRs) using industry standards for secure interoperability (e.g. OAuth 2.0, TLS 1.2)	Yes No No because the product does not read/ write into EHRs	To pass, developers should confirm that the product has the capability to read/write into EHRs using industry standards for secure interoperability. If a product does not use industry standards, then a legitimate rationale should be set out and the security, usability and appropriateness of the methodology should be considered.

D. Key Principles for Success

The core elements defined in this section will form part of the overall review of the product or service and is a key part to ensuring that the product or service is suitable for use. The assessment will set a compliance rating and where a product or developer is not compliant highlight areas that the organisation could improve on with regards to following the core principles.

D1 - Usability and Accessibility - Scored Section

Establishing that your product has followed best practice.

Code	Question	Options	Supporting information	Weighted score	Scoring criteria
D1.1	Understand users and their needs in context of health care Do you engage user (including MoH user departments) in the development of the product?	Yes No Working towards it	User Department Report	10%	Developers should be awarded 10% if they demonstrate that user need has been taken in account through user research, search data, analytics or other data to understand the problem. The submission should confirm that the developer has considered, and tested user needs with appropriate stakeholders (stakeholders will differ depending on the product) and that as the product continues to iterate user engagement has continued.
D1.1.1	If yes or working towards it, how frequently do you consider user needs in your product development and what methods do you	Free text			If the developer selects working towards it and/or can only partially evidence the requirement, for example user need has only partially been considered or it is not considered on an ongoing basis they should be awarded 5%.

	use to engage users and understand their needs?				If the developer selects no to this question or cannot provide evidence that user need has been considered, they should be awarded 0%.
D1.2.1	Work towards solving a whole problem for users Are all key user journeys mapped to ensure that the whole user problem is solved, or it is clear to users how it fits into their pathway or journey? If yes or working towards it, please attach the user journeys and/or how the product fits into a user pathway or journey	Yes No Working towards it Provided No evidence available	User Department Report	10%	Developers should be awarded 10% if they attach supporting information showing that the product solves a whole user problem or that it is clear to users how it fits into their pathway or journey. If the developer selects working towards it and can provide evidence that goes some way to explaining how the whole user problem is solved or only partially explains how the product fits a user journey, they should be awarded 5%. If the developer selects no to this question or cannot provide evidence that shows the user journey or how the product fits into the pathway or journeys, they should be awarded 0%.
D1.3	Make the service simple to use Do you undertake user acceptance testing to validate usability of the system?	Yes No Working towards it	User Acceptance Testing	10%	Developers should be awarded 10% if they attach supporting information showing user acceptance testing to validate usability of the product. If the developer selects working towards it and can provide evidence that goes some way to demonstrate that user acceptance testing is being

D1.3.1	If yes or working towards it, please attach information that demonstrates that user acceptance testing is in place to validate usability.	Provided No evidence available		used to validate usability of the system, they should be awarded 5%. If the developer selects no to this question or cannot provide evidence that shows user acceptance testing to validate usability of the system, they should be awarded 0%.
D1.5	Create a team that includes multidisciplinary skills and perspectives Does your team contain multidisciplinary skills?	Yes No Working towards it	2.5%	Developers should be awarded 2.5% for confirming they have a multi-disciplinary team. If the developer selects working towards it or no to this question, they should be awarded 0%.
D1.6	Use agile ways of working Do you use agile ways of working to deliver your product?	Yes No Working towards it	2.5%	Developers should be awarded 2.5 % if they confirm they use agile ways of working. If the developer selects working towards it or no to this question, they should be awarded 0%.
D1.7	Iterate and improve frequently Do you continuously develop your product?	Yes No Working towards it	2.5%	Developers should be awarded 2.5% if they confirm they continually develop their product. If the developer selects working towards it or no to this question, they should be awarded 0%.

D1.8	Define what success looks like and be open about how your service is performing Do you have a benefits case that includes your objectives and the benefits you will be measuring and have metrics that you are tracking?	Yes No Working towards it		2.5%	Developers should be awarded 2.5% for confirming that the benefit case includes objectives and metrics that can be tracked. If the developer selects working towards it or no to this question, they should be awarded 0%.
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D2 - Cost - Scored Section

Establishing the total cost of ownership

Code	Question	Options	Supporting information	Weighted score	Scoring criteria
D2.1 D2.1.1	Understand the total cost of ownership Do you have financial support or a funding agency supporting the solutions development If yes, please provide detail and evidence:	Yes No Working towards it		5%	Developers should be awarded 5% if they attach supporting information showing that the product is already being funded. If the developer selects working towards it and can provide evidence that goes some way to explaining the organisations being engaged in financing the solution, they should be awarded 2.5%. If the developer selects no to this question or cannot provide evidence of funding they should be awarded 0%.
D2.1.2	If no, what cost is the Government of Uganda expected to meet? (Capital and Operation expenditure)	Free text			

D3 – Sustainability- Scored Section

Establishing the sustainability of the product.

Code	Question	Options	Supporting information	Weighted score	Scoring criteria
D3.1	Understand the sustainability of the product. Do you have a sustainability plan in place?	Yes No Working towards it		5%	Developers should be awarded 5% if they attach supporting information detailing the sustainability plan. If the developer selects working towards it and can provide evidence that goes some way to explaining the sustainability plans or work towards sustainability, they should be awarded 2.5%.
D3.1.1	If yes, please provide detail and evidence:				If the developer selects no to this question or cannot provide evidence of sustainability, they should be awarded 0%.

Supporting Documentation

Please ensure that when providing evidence, documents are clearly labelled with the name of your company, the question number and the date of submission.

Possible documents to be provided are:

- B6 User journeys and data flows
- C2.1- External Penetration Test Summary Report
- D1.2.1 User Journeys and/or how the product fits into a user pathway or journey
- D1.3 Supporting information showing user acceptance testing to validate usability
- D2.1.1 Supporting information showing available funding support for the product.
- D3.1.1 Supporting information detailing the sustainability plan.