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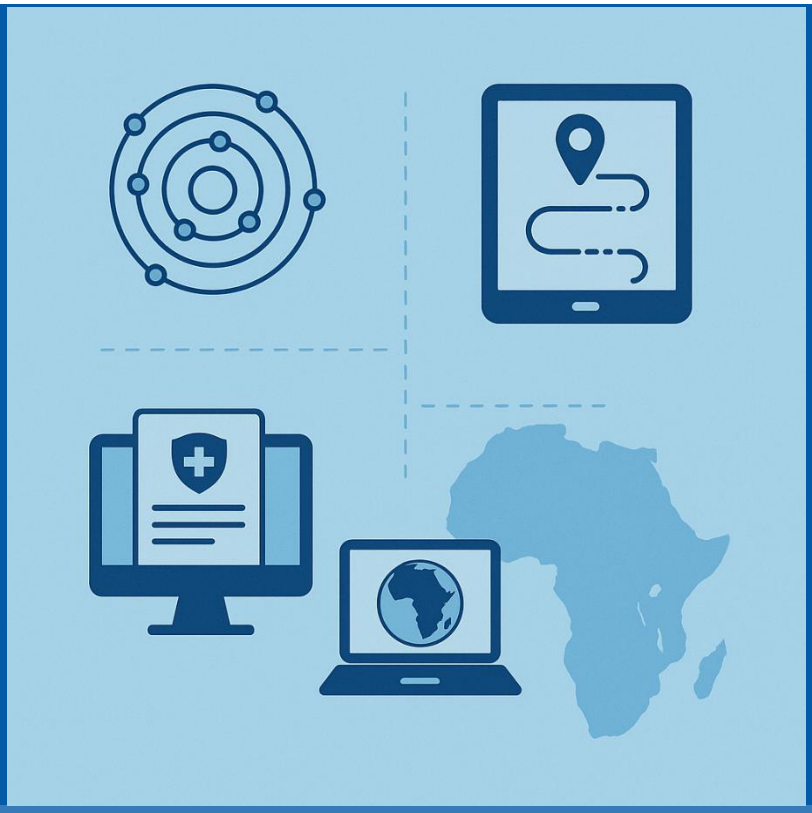

Process Evaluation of the Digital Innovation in Pandemic Control (DIPC) Initiative

Report #2: Piloting WHO's SMART Guidelines Approach

Evidence-Based Public Health| Centre for International Health Protection

Robert Koch Institute, October 2025

Process Evaluation of the Digital Innovation in Pandemic Control (DIPC) Initiative – *Report #2: Piloting WHO's SMART Guidelines Approach*

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Robert Koch-Institut
Nordufer 20
13353 Berlin

Internet: www.rki.de
E-Mail: zentrale@rki.de

Authors

Rita Dörner, Researcher, Evidence-Based Public Health, Centre for International Health Protection, RKI

John Arko-Mensah, Senior Lecturer, School of Public Health, University of Ghana

Patrick Fatoma, Assistant Lecturer & Researcher, Njala University, Sierra Leone

Eric Umar, Assistant Professor, Kamuzu University of Health Sciences, Malawi

Afrina Karim, Student Assistant, Evidence-Based Public Health, Centre for International Health Protection, RKI

Charbel El-Bcheraoui, Head, Evidence-Based Public Health, Centre for International Health Protection, RKI

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List of Acronyms

ANC	Antenatal Care
BMZ	Bundesministerin für Wirtschaftliche Zusammenarbeit und Entwicklung
CHIM	Centre for Health Information Management
DAK	Digital Adaptation Kit
DH	Digital Health
DIPC	Digital Innovation in Pandemic Control
DEA	Digital Ecosystem Assessment
DPPI	Department for Policy, Planning and Information
GHS	Ghana Health Service
DPPA	Digital Pandemic Preparedness Assessment Tool
EPI	Expanded Program on Immunisation
FHIR	Fast Healthcare Interoperability Resource
GIZ	Gesellschaft für Internationale Zusammenarbeit
HIC	High Income Country
HIS	Health Information System
HL7	Health Level Seven International
HCW	Healthcare Worker
ICT	Information and Communication Technology
IT	Information Technology
KI	Key Informant
KII	Key Informant Interview
LMICs	Low-and Middle-Income Countries
M&E	Monitor & Evaluation
MoH	Ministry of Health
NDHRM	National Digital Health Roadmap
PAHO	Panamerican Health Organization
PATH	Program for Appropriate Technology in Health
PPME	Policy, Planning, Monitoring & Evaluation
SDGs	Sustainable Development Goals
SMART	Standards-based, machine-readable, adaptive, requirements-based, and testable
SURD	Systems and Users Requirements Document
UHC	Universal Health Coverage
WHO	World Health Organization

Executive Summary

Background and Purpose

WHO SMART Guidelines (Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable), launched in 2021, provide a comprehensive framework for translating narrative WHO guideline recommendations into localised, interoperable digital health systems. The framework envisions progression through five layers: from narrative guidelines (L1) through human-readable Digital Adaptation Kits (L2), to machine-readable specifications (L3), deployable reference software (L4), and precision health models (L5).

The Digital Innovation in Pandemic Control (DIPC) initiative represented one of the first programmes globally to pilot SMART Guidelines implementation outside WHO technical assistance programmes. At the time of implementation, the Immunisation DAK had not yet been released; consequently, implementation partners developed a generic System and User Requirements Document (SURD) based on the SMART Guidelines DAK framework. This report presents findings from RKI's independent evaluation of DIPC's SMART Guidelines piloting in Ghana, Malawi, and Sierra Leone, examining relevance, implementation processes, and sustainability potential.

Methodology

The evaluation employed a qualitative process evaluation design grounded in the Consolidated Framework for Implementation Research (CFIR) and OECD DAC criteria. Data collection comprised comprehensive document reviews and 12 semi-structured key informant interviews with funders, implementation partners, and national-level stakeholders from Ghana (n=4), Malawi (n=2), and Sierra Leone (n=4), complemented by global-level stakeholders (n=2). Qualitative data analysis followed a thematic approach using predominantly deductive coding aligned with the evaluation framework. The evaluation received ethical clearance from review boards in all participating countries.

Key Findings

Relevance

The SMART Guidelines approach demonstrated strong methodological relevance for requirements specification (L2) across all countries. DAK and SURD localisation processes successfully translated global standards into country-specific requirements through structured, stakeholder-engaged workshops that clarified workflows, exposed data gaps, and promoted standardisation. All three countries completed L2 localisation: Ghana developed a comprehensive immunisation SURD enhancing DHIS2 eTracker; Malawi integrated DAK-derived requirements into an Electronic Immunisation Registry within MAHIS; Sierra Leone completed ANC DAK localisation for future PresTrack integration. These artefacts provided valuable institutional knowledge repositories capturing consensus on workflows and data elements that survive personnel turnover.

However, a critical "missing middle" emerged between L2 requirements and operational systems. Developers characterised SURDs as "too theoretical" for software development. In Malawi, this necessitated iterative facility visits where vendors worked with healthcare staff to understand workflow alignment. Requirements were often hard-coded into systems rather than translated through formal L3 processes—Ghana's eTracker enhancements and Malawi's EIR development bypassed the intended L3 layer. Readiness for implementation beyond L2 varied substantially: each country faced distinct constraints including technical versus governance barriers, infrastructure

deficits, or specialist capacity gaps. As pioneering work, DIPC navigated largely uncharted territory, with programme re-programming instigated by GIZ compressing timelines for government sensitisation and readiness assessment.

Implementation Processes

L2 specification processes succeeded through three enabling conditions: WHO DAK format providing common language; experienced facilitation anchoring discussions in real workflows; and visible ministry ownership. Countries achieved high fidelity to L2 targets, producing nationally endorsed specifications through disciplined, workshop-based localisation. The L2 work provided substantial added value by establishing authoritative requirements sources, addressing system gaps, and developing standards-aligned data dictionaries.

However, progression beyond L2 faced substantial barriers. Technical software development teams were engaged too late, limiting their ability to provide input during requirements development and familiarity with specifications. Stakeholders suggested technical teams should participate from Digital Ecosystem Assessment stages. Infrastructure deficits constrained operational deployment—Sierra Leone encountered unfunded prerequisites including insufficient devices, unreliable connectivity, and power challenges. All countries faced financing gaps where SMART Guidelines support covered L2 facilitation but not L3 development, infrastructure investments, or operational costs.

Governance fragmentation emerged as a critical constraint, documented most clearly in Ghana where institutional mandate fragmentation prevented integrated implementation despite strong specifications and technical capacity. Multiple parallel systems operated under different authorities: DHIS2 under GHS PPME, DHIMS under surveillance, SORMAS under disease control, GhLIMS under supply chain. Whilst technical capacity existed to implement specified integrations, governance friction between Ministry of Health and Ghana Health Service combined with competing mandates prevented coordinated action.

Interoperability remained a systemic bottleneck. No country achieved operational, standards-based data exchange between systems during the project period despite clear L2 specifications. Ghana's platforms continued operating independently; Malawi achieved strong internal MAHIS integration but external exchanges remained planned; Sierra Leone stakeholders rated interoperability at "one out of ten." This gap reflects the "missing middle" challenge—without intermediate artefacts bridging specifications to implementation-ready guidance, systems developed from the same requirements using incompatible approaches.

Sustainability

L2 artefacts constitute important institutional assets providing foundations for future development. Requirements documents serve as organisational memory, surviving personnel turnover and providing contractual clarity. Ghana established PPME-CHIM stewardship with governance processes for updating requirements and defined concrete interoperability requirements. Malawi embedded EIR within MAHIS, reinforced government-led governance through its "MAHIS-first" policy, and strengthened national capacity. Sierra Leone completed ANC DAK localisation, articulated DHIS2-centred architecture, and established pathways toward L3/L4 through planned hackathons. Integration within existing platforms created more realistic sustainability pathways than standalone applications.

However, no country achieved operational sustainability—domestically financed, interoperable implementations maintained through national capacity—within project timescales. This aligns with

literature documenting that successful implementations require five to seven years. All countries faced combinations of unfunded interoperability development, thin in-house capacity, external dependencies, and unclear long-term financing. Financial sustainability represents the critical gap: recurrent operational costs including device replacement, connectivity, technical support, and maintenance remained largely unfunded through domestic budgets. Formal mechanisms for ongoing DAK/SURD maintenance and evolution remained largely absent, with requirements documents risking obsolescence as guidelines evolve without designated stewards and update protocols.

Recommendations

On Relevance:

R1: Develop intermediate technical artefacts to bridge the "missing middle"

- Create standardised "layer 2.5" templates translating L2 requirements into developer-ready specifications, including detailed workflow diagrams, FHIR profile examples with cardinality constraints, comprehensive value sets with code mappings, and test cases
- Produce open-source reference implementations demonstrating correct L2 interpretation in code across common platforms (DHIS2, OpenMRS, FHIR-native systems)
- Establish conformance testing frameworks enabling automated validation of L2 specification compliance

R2: Establish differentiated implementation pathways based on country readiness

- Define three implementation tracks with clear entry criteria: Full Implementation (established infrastructure, strong governance), Capacity Building (emerging ecosystems requiring extended L3 preparation), Foundation (fragmented systems requiring selective L2 focus with concurrent infrastructure investments)
- Develop standardised readiness assessment instruments evaluating technical capacity, governance maturity, and infrastructure prerequisites to recommend appropriate pathway
- Contextualise success metrics to pathway, emphasising L2 completion quality for Capacity Building versus operational systems for Full Implementation

On Implementation Processes:

R3: Strengthen early technical team engagement and sustained capacity building

- Integrate technical development teams from Digital Ecosystem Assessment through L2 validation, ensuring developers understand specifications and contribute practical implementation perspectives during localisation
- Establish regional rosters of L3 technical specialists with FHIR implementation experience, available for extended engagements (3-6 months) providing hands-on assistance translating L2 requirements alongside national teams
- Structure L3 support explicitly for capability transfer through mentored practice, ensuring national teams progressively assume L3 production responsibility

R4: Strengthen governance mechanisms for cross-system coordination

- Support establishment of cross-institutional coordination mechanisms (digital health technical working groups) with explicit mandates for cross-system integration, clear decision-making authority, and membership spanning Ministry of Health, implementing agencies, and technical service providers
- Develop formal policy directives requiring standards-based implementation (FHIR, HL7, IHE profiles) with explicit timelines and enforcement mechanisms such as procurement restrictions
- Establish procurement criteria requiring demonstrated standards compliance, with technical conformance testing preceding vendor selection

R5: Address infrastructure and financing prerequisites for implementation phases

- Develop standardised costing frameworks for complete implementation cycles, explicitly quantifying L3 development requirements, infrastructure prerequisites (devices with replacement cycles, connectivity, hosting, power backup), and three-year operational transition support
- Require infrastructure readiness assessments before L2 initiation, identifying gaps in device availability, connectivity reliability, power stability, and hosting capacity with explicit plans addressing deficits
- Structure financing with progressive domestic co-financing expectations increasing from 20% during L2/L3 to 80%+ during sustainability transition

On Sustainability:

R6: Establish realistic multi-year transition support for cougizntry ownership

- Establish standardised multi-year support packages with clear phases: Years 1-2 (70-80% partner financing for L2/L3/L4), Years 3-4 (50% partner financing for operations), Years 5-7 (20% partner financing for capacity building as government achieves majority ownership)
- Require government co-financing commitments from inception with annual increases toward full ownership embedded in national health sector plans
- Establish clear operational milestones enabling progressive transition: system uptime thresholds, utilisation targets, data quality metrics, and demonstrated national capacity for autonomous system management

R7: Establish formal stewardship and governance processes for DAK/SURD maintenance

- Support countries to designate formal institutional stewards for DAK/SURD ownership with explicit mandates for requirements maintenance and change management authority
- Establish regular review and update cycles (annually or bi-annually) aligned with national guideline revision processes, bringing together clinical programme managers and digital health units
- Develop standardised change management protocols defining how requirements updates are proposed, evaluated, approved, and communicated to vendor partners, ensuring controlled evolution

Conclusion

DIPC's pioneering implementation demonstrates that SMART Guidelines L2 methodology is replicable across diverse contexts and produces valuable institutional artefacts. All three countries achieved meaningful accomplishments: validated specifications guiding ongoing investments, established stewardship arrangements, and strengthened capabilities in standards-based system design.

However, progression to operational, interoperable systems requires addressing systemic gaps: intermediate technical guidance, governance coordination mechanisms, sustained L3 capacity building, complete implementation cycle financing, and multi-year transition support. These findings reflect implementation realities in diverse LMIC contexts, illuminating enabling conditions required for success as the methodology continues to evolve.

The evaluation identifies opportunities to strengthen SMART Guidelines support based on these pioneering experiences, reflecting the natural learning process inherent in scaling innovative approaches. Country prospects vary based on existing infrastructure and capacity, but all three demonstrate forward momentum. DIPC's contribution lies in demonstrating that SMART Guidelines can work in practice whilst highlighting the resources, governance support, and multi-year commitment necessary for realising the full vision. The foundation has been established; sustained commitment extending beyond specification phases toward comprehensive implementation support operating over realistic timescales will determine the methodology's ultimate contribution to digital health transformation in low- and middle-income countries.

1 Introduction

1.1 Background

Global Immunisation Landscape

Vaccine-preventable diseases remain a significant cause of mortality among children under five years of age, claiming approximately 1.5 million lives annually, predominantly in Low- and Middle-Income Countries (LMICs) (Dimitrova et al., 2023). The World Health Organisation's (WHO) Expanded Programme on Immunisation (EPI), established in 1974, marked the commencement of a coordinated international effort to utilise immunisation as a critical public health intervention (Keja et al., 1988). Over the past five decades, the EPI has been instrumental in reducing child mortality and morbidity from diseases such as measles, polio, and diphtheria, preventing an estimated 2.5 million deaths annually (Oyo-Ita et al., 2011) and modelling studies project that vaccinations against ten critical pathogens could prevent approximately 69 million deaths between 2000 and 2030 (Li et al., 2021).

Despite these achievements and ongoing global efforts to expand immunisation coverage, significant challenges persist. In 2022, approximately 20.5 million children globally remained either unvaccinated or under-vaccinated (WHO, 2020). Alarmingly, the number of children receiving no immunisation doses increased from 12.9 million to 18.2 million between 2019 and 2021, with 97% of this increase occurring in LMICs (Rachlin et al., 2022; WHO/UNICEF, 2020). These statistics underscore persistent and widening inequities in healthcare access within and between countries. For instance, vaccination coverage in Ethiopia has been documented to vary dramatically from 20.6% to 91.7% across different regions, reflecting substantial disparities in socio-economic status and healthcare accessibility (Asmare et al., 2022).

The COVID-19 pandemic further exacerbated these disparities, disrupting vaccine supply chains and intensifying the divide between high-income countries and LMICs (Basu et al., 2023; Shet et al., 2022). The pandemic's impact on routine immunisation services resulted in widespread disruptions across 170 countries and territories, setting back decades of progress in global vaccination coverage (Shet et al., 2022). This crisis highlighted the fragility of immunisation systems in resource-constrained settings and underscored the urgent need for innovative approaches to strengthen vaccine delivery mechanisms.

Digital Health Solutions for Immunisation

In response to persistent coverage gaps and emerging challenges, WHO and global partners have increasingly advocated for the integration of information and communication technologies (ICT) into immunisation programmes (WHO, 2020). During the COVID-19 pandemic, high-income countries successfully implemented various digital health solutions to monitor immunisations, create vaccination records, issue digital certificates, and report adverse effects (Mc Kenna et al., 2023). These experiences demonstrated the potential of digital technologies to enhance the efficiency, accuracy, and reach of vaccination programmes.

In LMICs, digital health technologies are expected to play a key role in reaching underserved populations, particularly through 'last mile' efforts, thereby supporting progress towards the Sustainable Development Goals and Universal Health Coverage (WHO/UNICEF, 2020). The Global Alliance for Vaccines and Immunisation (GAVI) has similarly championed the use of ICT in its Digital Health Information Strategy 2022-2025, capitalising on the widespread adoption of mobile phones in

LMICs (GAVI, 2021). Currently, 70% of the world's seven billion mobile phone users reside in LMICs (WHO, 2022), and mobile broadband connections in Sub-Saharan Africa were projected to increase from 38% to 87% by 2025 (Radcliffe, 2018), creating unprecedented opportunities for mobile health (mHealth) interventions.

The digitalisation of healthcare processes, particularly in vaccination delivery, encompasses various tools including electronic health records (EHRs), mobile health applications, and data management systems. These technologies offer numerous potential benefits: increasing immunisation coverage, addressing logistical challenges, enabling effective tracking of patients' immunisation status, improving data accuracy for public health planning, and reducing administrative burden for healthcare and public health personnel (WHO, 2019). Whilst the benefits of digital technologies in clinical medicine are well established (Nafees et al., 2023; Tanhapour et al., 2023), their application in public health programmes within LMICs, particularly for disease prevention, remains less comprehensively understood. WHO has thus called for additional research and guidance to reduce vaccine-preventable diseases and improve access to new vaccines by 2030 (WHO, 2020).

The DIPC Initiative's Approach to Piloting WHO's SMART Guidelines in partner countries

DIPC's efforts to pilot the relatively recently introduced WHO SMART Guidelines approach (Mehl et al., 2021), was one of the selected programme areas under evaluation and forms the focus of this report.

WHO's SMART Guidelines provide a structured method for translating evidence-based standards into digital health interventions that are grounded in global data standards while being adapted to national policies and local clinical guidelines. These **S**tandards-based, **M**achine-readable, **A**daptive, **R**equirements-based, and **T**estable guidelines represent an operationalisation of WHO's vision to facilitate rapid, effective, global implementation of guideline recommendations in the digital age.

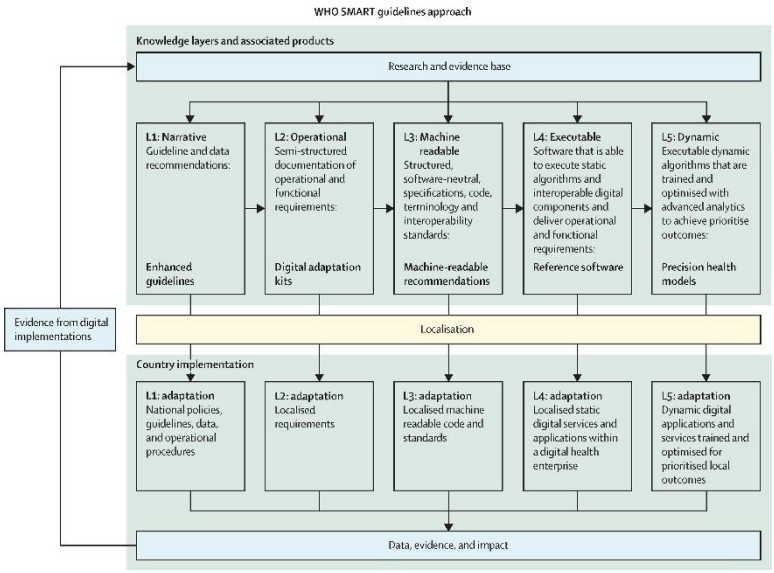

Figure 1. WHO SMART Guidelines Approach. (Adopted from Mehl et al., 2021)

Previously, the process of translating, operationalising, and incorporating health and data recommendations into digital systems has been largely unsystematic, slow, prone to error, and indifferent to technical standards, resulting in poor transparency and traceability. Moreover, many digital solutions are hard-coded, which hinders ongoing alignment with evolving evidence, update requirements and system interoperability needs.

The SMART guidelines comprise documentation, procedures, and blueprints to steer guideline localisation and implementation through digital systems. The approach instructs guideline developers on translating recommendations into specifications and standards; technologists on integrating recommendations into updatable digital systems; and countries on how to localise, make interoperable, institutionalise, and update digital systems consistent with evidence-based

recommendations. SMART guidelines content is, by design, software-neutral, formulated for adaptation into whichever software platforms a country has elected to use.

The framework comprises five knowledge layers, from narrative guidelines through to precision health models, offering a systematic, transparent, and testable pathway from global guidelines to localised digital systems at the country level.

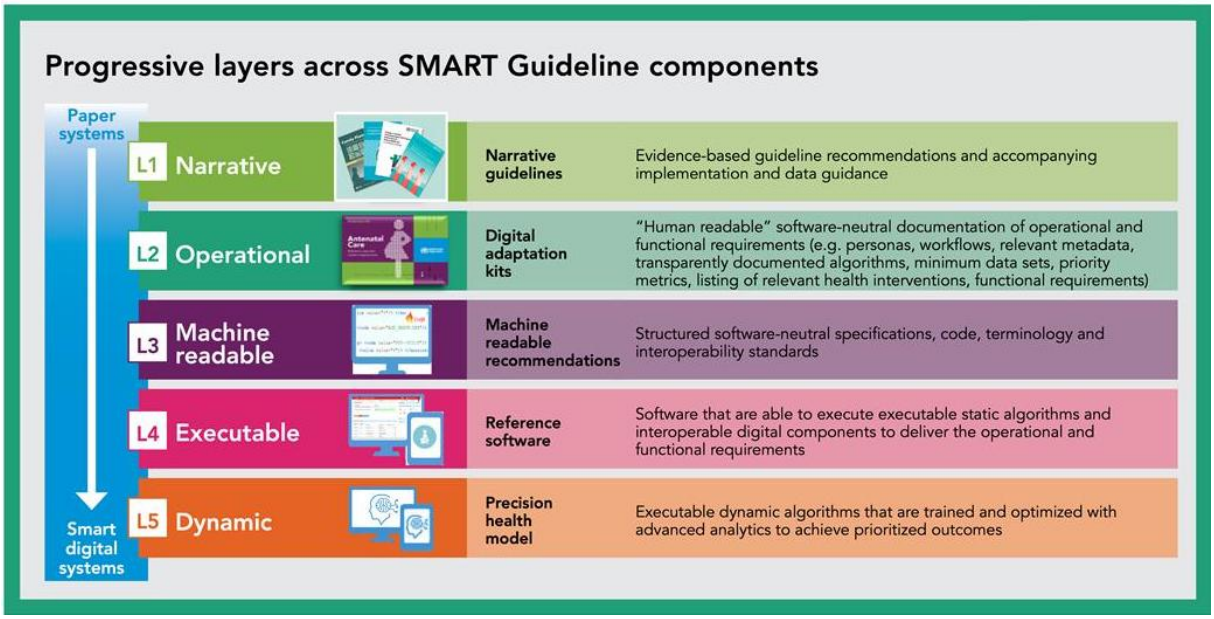

Figure 2. Progressive layers across SMART Guideline components (adopted from WHO, https://www.who.int/teams/digital-health-and-innovation/smart-guidelines/)

By moving from narrative guidance (L1), via human-readable software neutral documentation in form of Digital Adaptation Kits (L2) to software-neutral, machine-readable specifications (L3), to then the development of reference software able to execute static algorithms and interoperable digital components (L4) and finally towards precision health models, which are trained and optimised with advanced analytics (L5), the approach aims to accelerate the development, localisation and implementation of digital tools, while promoting interoperability and long-term sustainability of digital health systems (Mehl et al., 2021).

The Digital Innovation in Pandemic Control Initiative

Against this backdrop, the German Federal Ministry for Economic Cooperation and Development (BMZ), through the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ), launched the Digital Innovation in Pandemic Control (DIPC) initiative. Originally positioned under a COVID-19 emergency funding stream, and nested within GIZ's Digital Cluster, this five-country programme aimed to strengthen digital vaccine delivery systems in Ghana, Sierra Leone, Malawi, Tanzania, and Peru. The initiative focused on four key implementation components: (1) Digital Ecosystem Assessments to understand existing digital health infrastructure and capacity; (2) piloting of WHO's Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable (SMART) Guidelines Approach for immunisation; (3) Capacity Strengthening activities at multiple levels of the health system; and (4) integration of Gender, Equity, and Inclusion considerations into programme design and implementation.

The DIPC initiative was one of the first digital programmes globally to adopt and pilot this approach and pioneered in applying it within immunisation programmes in the partner countries. In doing so, the aim was to test and demonstrate how global standards and local requirements can be combined to generate clear, country-owned system and user requirements and to thereby contribute to the broader agenda of digital health systems strengthening in participating countries.

Noteworthy with respect to DIPC's focus on immunisation delivery is that at the time of the DIPC implementation, a critical component of the SMART guidelines approach, namely the DAK for Immunisation, had not yet been released for public adoption, whilst other DAKs had already been made available by WHO (e.g., DAK for Antenatal Care (ANC), HIV, Family Planning etc.). Consequently, piloting of the SMART guidelines approach in Sierra Leone pivoted from immunisation to ANC (where a WHO DAK was available), whilst the partner countries under the guidance of the DIPC implementation partner Digital Square developed a generic System and User Requirements Document (SURD) for Immunisation, which was based on the SMART Guidelines DAK framework. This served as an equivalent to the yet to be released Immunisation DAK at the time.

Implementation Challenges and the Know-Do Gap

Despite the promise of digital health technologies, their implementation at national scale in LMICs entails substantial challenges. Multiple factors can impede the adoption and effective integration of digital solutions, including limited infrastructure, low levels of digital literacy, inadequate training of healthcare workers, and insufficient engagement with key stakeholders at all levels of the health system (World Bank, 2023), to only name a few.

In implementation science, the 'know-do' gap highlights the disparity between research-based knowledge and its real-world application (Skolarus & Williams, 2024). This gap is particularly significant in digital health, which emphasises the need for identifying barriers and facilitators for effective translation of evidence into practice. Whilst numerous normative resources for digital health programming exist (Dörner et al., 2025), sharing evidence between stakeholders remains essential to inform and optimise current and future programmes. Process evaluations conducted alongside ongoing programmes can generate real-time evidence to inform programme adjustments and improvements, ensuring that digital health interventions remain relevant to country contexts, effective, and sustainable.

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1.2 Rationale

Overall Process Evaluation

Given the significant challenges and disparities highlighted in the current state of vaccination programmes in LMICs, there was a pressing need for rigorous implementation research and comprehensive process evaluations of digital health initiatives. The Robert Koch Institute (RKI) was contracted by GIZ to conduct an independent external process evaluation of the DIPC initiative in three countries: Ghana, Malawi, and Sierra Leone. Process evaluations examine the internal processes and implementation aspects of an initiative whilst placing the project into the wider context of ongoing national efforts. They focus e.g. on whether activities are being carried out as planned, the quality of work performed, and how internal management and resources impact programme execution.

The conduct of this process evaluation in accompaniment to the ongoing DIPC programme was important to generate evidence not only to inform the DIPC initiative itself, but also to contribute evidence on digital health programme implementation in Ghana, Malawi, Sierra Leone, and other LMICs more broadly. The implementation research approach adopted here, can provide important insights into the factors that facilitate or hinder the adoption and integration of digital solutions and supporting activities, allowing for refinement and optimisation of strategies to ultimately enhance vaccination coverage. Furthermore, disseminating evaluation findings is important for identifying effective practices and informing future rounds of digital health funding. Ultimately, this research aimed to bridge the 'know-do' gap, translating knowledge into actionable strategies that can be implemented in real-world settings, thereby advancing the global agenda for Universal Health Coverage and the Sustainable Development Goals.

Evaluation of DIPC's efforts to pilot WHO's SMART Guidelines approach

Within the broader DIPC evaluation, assessing the piloting of WHO's SMART Guidelines approach holds particular significance. Launched in 2021, SMART Guidelines represent WHO's strategic response to longstanding challenges in translating evidence-based recommendations into functional digital health systems. However, at the time of DIPC implementation, the approach remained largely theoretical, with limited empirical evidence on real-world implementation feasibility, country-level barriers and facilitators, or realistic timescales for progression through implementation layers. DIPC was among the first programmes globally to move SMART Guidelines from concept to country application, making rigorous evaluation critical for generating evidence that could inform both the DIPC initiative itself and the broader global community implementing or considering SMART Guidelines adoption. This evaluation addresses a crucial evidence gap: understanding how the SMART Guidelines framework performs under diverse country conditions, what enables or constrains progression beyond requirements specification, and what resources and timescales realistic implementation requires. These insights are essential for WHO, implementing partners, and national governments as SMART Guidelines expand to additional health domains and countries globally

1.3 Evaluation Objectives

The evaluation was designed around three primary objectives, each addressing critical dimensions of the DIPC initiative's implementation and potential for sustained impact:

1. **Relevance:** To examine the extent to which DIPC programme activities align with partner countries policies and priorities, meet target groups needs and were planned and implemented with relevant stakeholder engagement.

1. **Project Implementation:** To establish how the DIPC initiative evolved over time in each country relative to initial project plans, identifying aspects of implementation that worked well and those that did not, and identifying barriers and facilitators to implementation.

2. **Project Sustainability:** To examine the extent to which the DIPC initiative had the potential to yield sustainable results in participating countries, including an analysis of the DIPC component's integration into the national systems and the partner countries' capacity for independent continuation after the project ends.

1.4 Purpose of the Report

This report presents findings from the independent process evaluation of the DIPC initiative's pilot implementation of WHO's SMART Guidelines approach in Ghana, Malawi, and Sierra Leone. The evaluation examines how SMART Guidelines localisation aligned with country priorities and technical capacity (relevance), the factors that facilitated or constrained progression from requirements specification to operational systems (implementation processes), and the potential for sustained contribution to standards-based digital health development (sustainability). Drawing on qualitative data from key informant interviews, technical document review, and stakeholder perspectives from national governments, implementing partners, and technical experts, the report synthesises empirical evidence on real-world SMART Guidelines implementation in diverse LMIC contexts. The findings and recommendations aim to inform ongoing SMART Guidelines methodology refinement and future implementation support, contributing to the evidence base on effective approaches for translating evidence-based clinical guidelines into interoperable digital health systems.

2 Methodology

2.1 Study Design

The evaluation employed a qualitative process evaluation design grounded in the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009) to assess barriers and facilitators to the successful implementation of the Digital Innovation in Pandemic Control (DIPC) initiative across three countries: Ghana, Malawi, and Sierra Leone.

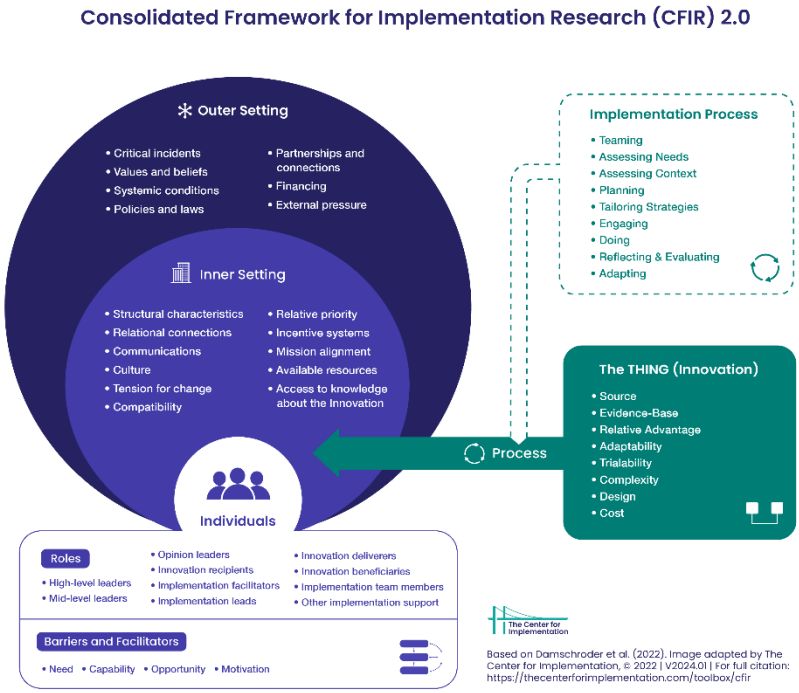

Figure 3. Consolidated Framework for Implementation Research (CFIR) 2.0 (based on Damschroder et al. (2022, adopted from The Centre for Implementation, 2022).

The evaluation framework integrated OECD Development Assistance Committee (DAC) criteria, including relevance and sustainability (OECD, 2021), to guide the formulation of evaluation questions. The focus of enquiry was structured according to the DIPC logic model, and four key implementation components were identify for detailed assessment:

1. Digital Ecosystem Assessments and the Development of a National Digital Health Road Map
2. Piloting of WHO's SMART Guidelines,
3. The implementation of DIPC-supported digital tools for immunisation,
4. Capacity Strengthening activities for digital literacy, and
5. The DIPC Initiative's Gender, Equity, and Inclusion efforts.

The evaluation utilised two primary data collection methods: comprehensive document reviews and semi-structured key informant interviews (KIIs). This mixed-method approach enabled triangulation of data sources to enhance the validity and depth of findings (Patton, 2015). Data collection was contextualised through direct observations during site visits to implementation locations.

2.2 Study Setting

We focused on three of the five DIPC partner countries, namely Ghana, Malawi and Sierra Leone. KIIs took place in the countries' capitals Accra, Freetown and Lilongwe.

2.3 Study Population and Sampling

Participants were purposively sampled to capture diverse perspectives on DIPC implementation from stakeholders at international, national, regional/provincial, district, and health facility levels. Overall, there were 4 stakeholder groups: 1) funders and implementing partners, 2) government officials, health service administrators, 3) Regional and district level public health officials and 4) healthcare providers, IT personnel at the health facility level.

Inclusion criteria required participants to: (1) occupy professional roles relevant to digital health systems, DIPC implementation, or national immunisation programmes; (2) serve as trainers, technical support staff, users, or beneficiaries of DIPC digital solutions; and (3) have been employed continuously for at least six months in their current role or facility. Persons under 18 years of age were excluded.

Sample size determination was based on the principle of data saturation, whereby interviews are to be continued until no new insights emerged and information becomes repetitive (Guest et al., 2006; Hennink & Kaiser, 2022). Based on systematic reviews demonstrating that saturation in semi-structured interviews typically occurs within 9-17 interviews in homogenous samples, and accounting for the heterogeneity of stakeholder groups in this evaluation, we anticipated conducting approximately 25 KIIs per country. The final sample sizes were 24 KIIs for Ghana, 23 KIIs for Sierra Leone and 22 KIIs for Malawi.

Participants were identified through document reviews, stakeholder lists provided by GIZ and implementing partners, health system network knowledge of the national researchers contracted to conduct the data collection and snowball sampling whereby interviewed participants referred additional relevant informants.

Health facilities included in this evaluation were selected à priori in consultation with the implementation partners and district/regional health offices and based on their involvement in DIPC activities and presence of trained staff. However, given that the process of SMART guidelines adoption in the partner countries involved mostly national level stakeholders and funders and implementers, the perspectives of regional, district and health facility staff were not obtained for this evaluation component.

2.4 Data Collection Methods

Document Review

The document review examined scientific literature, grey literature (including programme documents, and government policy papers), and project-specific materials (work plans, progress reports and stakeholder maps). This review provided contextual background on digital health landscapes, national immunisation programmes, and DIPC implementation processes in each country. Documents were obtained from publicly available sources or directly from implementing organisations and GIZ teams.

Interview Topic Guide

The overarching key informant topic guide consisted of five modules aligned with the main evaluation foci: 1. "Digital Ecosystem Assessments (DEAs) and National Digital Health Roadmap (NDHRM)

Development", 2. "Piloting of WHO's SMART Guidelines", 3. "Digital Tool Development, Roll-out and Training", 4. "Digital Literacy Training and eLearning Resources", and 5. "The Women in Digital Health Event in Ghana". Each module followed a common structure and question sequence, beginning with questions on the key informant's professional background and role in relation to the DIPC initiative, followed by topic-specific questions, and sub-questions and prompts addressing the evaluation criteria of "Relevance", "Implementation Processes" and "Potential for Sustainability", adapted to the respective module. Questions were partly taken and adapted from the CFIR topic guide repositories (CFIR, 2024) to capture key CFIR domains and constructs relevant to the evaluation criteria and overarching evaluation questions.

The topic guides were further refined into four tailored versions with adapted wording for different stakeholder groups: 1. programme implementers and funders, 2. national government officials, 3. regional and district public health officials, and 4. facility-level staff. During each interview, only the modules and questions relevant to the respondent's role were used. For example, and as previously stated, the module on "Piloting WHO SMART Guidelines" was administered exclusively to implementers, funders and national-level stakeholders.

Key Informant Interviews

The semi-structured key informant interviews (KIIs) were conducted face-to-face at locations convenient to participants (offices, health facilities, or university campuses) or remotely via the RKI-approved secure videoconferencing platform (Cisco Webex) when in-person meetings were not feasible. The majority of interviews lasted approximately 45-90 minutes and were conducted by trained members of the evaluation team. All in-country interviews were conducted by the national researchers from Ghana, Malawi and Sierra Leone. Global level interviews were conducted by the RKI team in Germany.

Prior to each interview, participants provided written informed consent (for in-person interviews). Participants were informed of their right to withdraw at any time and to choose how they wished to be cited in reports. Demographic information collected in form of a demographic questionnaire included e.g., gender, organisational affiliation, professional role, years of experience, and geographic location.

All interviews were audio-recorded with participants' consent and supplemented with field notes. Recordings were transcribed verbatim and anonymised as possible. Transcripts and consent forms were stored separately to maintain confidentiality.

2.5 Data Analysis

Qualitative data analysis followed a thematic approach guided by the CFIR framework and OECD DAC evaluation criteria (Braun & Clarke, 2006). Transcripts were coded using predominantly deductive codes derived from the evaluation framework and a minimal level of inductive codes which emerged from the data. The analysis process involved: (1) familiarization with data through repeated reading of transcripts, (2) generation of codebook closely aligned to the evaluation questions (3) coding of transcripts (4) data extractions and review of coded segments by evaluation topic (5) synthesis of text segments and development of themes according to evaluation questions (6) interpretation of themes in relation to evaluation objectives.

Data from document reviews were synthesised to provide context for interview findings and to triangulate information across sources. Country-specific analyses were conducted first, followed by

cross-country synthesis to identify common implementation barriers and facilitators, as well as context-specific factors influencing DIPC implementation.

Quality assurance measures included regular debriefing sessions among team members, joint codebook development with national researchers and the RKI team, peer review of coding and themes, and member checking where feasible. Reflexivity was maintained throughout the analysis process, with researchers explicitly considering how their positions and perspectives might influence interpretations.

2.6 Ethical Considerations

The evaluation received ethical clearance from the external ethics review boards in each participating country: the Ghana Health Service Ethics Review Committee (approval number GHS-ERC-025/08/24), and the Sierra Leone Ethics and Scientific Review Committee (approval number 020/10/2024). the Kamuzu University of Health Sciences - COMREC, Malawi (protocol number P.05/25-1585). Additional permissions were obtained from relevant health authorities including the Ghana Health Service Directorate, Malawi's District Health and Social Service offices, and Sierra Leone's Ministry of Health Directorate of Policy, Planning, and Information.

Informed consent was obtained from all participants prior to data collection, with comprehensive information sheets provided in advance. Participation was voluntary, and participants were informed of their right to withdraw at any time without consequences. Confidentiality was maintained through secure data storage practices, anonymisation of transcripts (as much as possible), and separation of identifying information from study data. Audio recordings and transcripts were stored on password-protected, encrypted servers compliant with European data protection regulations. Only members of the evaluation team had access to identifiable data, and findings are reported in aggregate form or with participant-chosen descriptors to prevent identification.

The evaluation adhered to principles of beneficence and non-maleficence, ensuring that data collection did not interfere with routine health service delivery and that findings would be used to improve DIPC implementation for the benefit of participating health systems.

2.7 Thematic Evaluation Focus of this Report

- DIPC Approach to Piloting the WHO SMART Guidelines: The Localisation of the WHO Digital Adaptation Kits (DAK), the development of the System User Requirements Documents (SURD)

3 Sample Description

Overall Evaluation Sample

In total, we conducted 72 key informant interviews across Ghana (n=24), Malawi (n=22), Sierra Leone (n=21) and a small global cohort of funders/implementers (n=3). The overall sample was intentionally weighted towards health workers at the health facility level, complemented by national decision-makers and global actors to capture planning and governance perspectives. A full demographic overview has been included in Annex 1 and more detail on the sample has been provided in the Methods Report (ref).

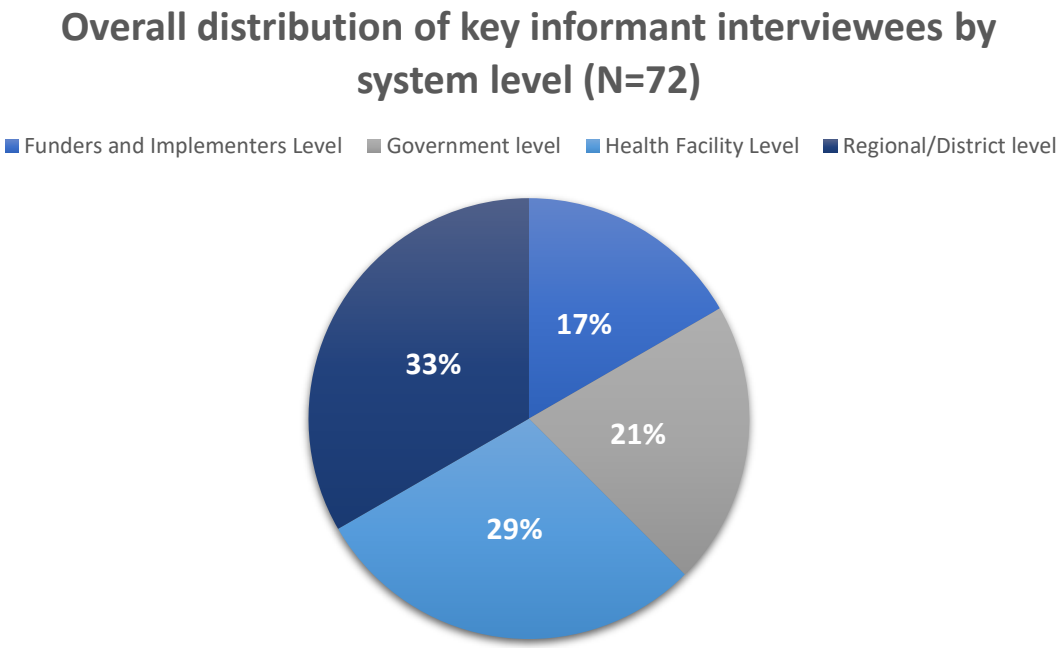

Figure 4. Proportion of Key Informants by "Role in relation to DIPC"

Evaluation Sample for the Component on WHO SMART Guidelines Piloting

Findings of the present evaluation component are based on responses from 12 stakeholders in total. This includes four KIs from Ghana (two implementation partners/funders; two national level stakeholders), four KIs from Sierra Leone (two implementation partners/funders; two national level stakeholders), two stakeholders from Malawi (one national level and one implementation partner/funder) complemented by the perspectives of two global level stakeholders (both belonging to the group of implementation partners/funders).

4 Findings

EVALUATION QUESTION

1. RELEVANCE:
TO WHAT EXTENT DID DIPC'S EFFORTS TO PILOT WHO'S SMART GUIDELINES RESPOND TO TARGET GROUP NEEDS, AND ALIGN WITH POLICIES, AND PRIORITIES?

2. IMPLEMENTATION PROCESSES:
HOW DID DIPC'S EFFORTS TO PILOT WHO'S SMART GUIDELINES IN PARTNER COUNTRIES EVOLVE RELATIVE TO THE INITIAL PROJECT PLANS?

WHICH ASPECTS OF THE IMPLEMENTATION WORKED WELL/DID NOT WORK WELL IN PARTNER COUNTRIES, INCLUDING ENABLING AND HINDERING FACTORS TO THE IMPLEMENTATION?

3. POTENTIAL FOR SUSTAINABILITY:
TO WHAT EXTENT DO THE DIPC INITIATIVE'S EFFORTS TO PILOT WHO'S SMART GUIDELINES HAVE POTENTIAL FOR SUSTAINABILITY?
TO WHAT EXTENT HAS THE PILOTING OF WHO'S SMART GUIDELINES BEEN DESIGNED FOR CONTINUATION OF EFFORTS ONCE ASSISTANCE THROUGH THE PROJECT CEASES IN THE PARTNER COUNTRIES?
CEASES IN THE PARTNER COUNTRIES?

4.1 Relevance

KEY TAKE-AWAYS FOR "RELEVANCE" OF DIPC'S PILOTING OF THE SMART GUIDELINES APPROACH

- ✓ DIPC WAS AMONG THE FIRST PROGRAMMES GLOBALLY TO MOVE WHO'S SMART GUIDELINES FROM CONCEPT TO COUNTRY PRACTICE, GENERATING CONCRETE LESSONS ON FEASIBILITY AND SEQUENCING.
- ✓ THE DAK/SURD SEQUENCE OFFERED A STRUCTURED, WHO-ALIGNED METHOD TO TRANSLATE GLOBAL STANDARDS AND NATIONAL IMMUNISATION AND ANC GUIDELINES INTO COUNTRY-SPECIFIC REQUIREMENTS, CLARIFYING WORKFLOWS, DATA ELEMENTS AND SYSTEM BOUNDARIES.

- ✓ RELEVANCE WAS APPARENT AT L2: COUNTRIES USED DAKS/SURDS TO REFINE INCUMBENT PLATFORMS RATHER THAN PURSUE IMMEDIATE L3/L4 BUILDS, ALIGNING AMBITION TO CURRENT CAPACITY AND INFRASTRUCTURE.
- ✓ COUNTRY-APPROPRIATE PATHWAYS EMERGED:
  - GHANA USED THE SURD TO UPGRADE DHIS2 ETRACKER (E.G., FOLLOW-UP LOGIC, STOCK STEPS);
  - MALAWI USED THEIR REFINED SURD TO BUILD AN EIR WITHIN MAHIS;
  - SIERRA LEONE LOCALISED THE ANC DAK FOR LATER INTEGRATION VIA PRESTRACK.

- ✓ STAKEHOLDER INCLUSION WAS BROAD BUT UNEVEN: WORKSHOPS AND VALIDATION ANCHORED PROGRAMME AND ICT NEEDS, YET EXTERNAL FACILITATION (E.G., PATH, UNICEF) REMAINED PIVOTAL AND NATIONAL TECHNICAL STEWARDSHIP VARIED.
- ✓ RESPONSIVENESS WAS STRONGEST FOR MANAGERS AND PROVIDERS (STANDARDISATION, CLEARER SPECIFICATIONS, IMPROVED DATA USE); CLIENT-LEVEL GAINS ARE LARGELY PROSPECTIVE AND DEPEND ON SUBSEQUENT IMPLEMENTATION AND GOVERNANCE.
- ✓ ADVANCING BEYOND L2 WAS CONSTRAINED BY SPECIALIST CAPACITY AND FINANCING FOR INTEROPERABILITY;

Figure 5. Key Take-Aways on "Sustainability Potential" of the WHO SMART Guidelines Piloting

Alignment with national policies and priorities

Across levels, respondents described the initial step, namely the SMART Guidelines L2 → DAK/SURD localisation process as a structured mechanism to translate global standards into contextually appropriate tools. Respondents consistently acknowledged that the DAK/SURD localisation process helped clarify workflows, identify data gaps, and promote standardisation of immunisation and maternal health processes. The frameworks' stepwise design was broadly viewed as relevant and aligned with WHO's digital health strategy, offering countries a reference for rationalising fragmented systems. Implementers and national stakeholders alike saw the exercise as a capacity-building opportunity, reinforcing local understanding of technical specifications and documentation processes. There was consensus that the DAK/SURD improved the conceptual and procedural quality of system design, even when ambitions to proceed through L2 to L4 was not realisable.

At the global level, implementers emphasised the importance of maintaining fidelity to the SMART Guidelines' logic, while recognising that most countries lacked the technical infrastructure and workforce to operationalise higher-level (L3–L4) components. "Downstream", this notion was reflected by national level government stakeholders and implementing partners in Ghana and Malawi who highlighted the need for pragmatic adaptation: aligning the SURD with existing platforms (DHIS2 & MAHIS) and workflows, and filling concrete data or functionality gaps, rather than replacing whole systems. In Sierra Leone, localisation was described as more procedural and funder/partner-driven, initially focused on contextualising WHO's ANC DAK as a pilot exercise, rather than responding to a domestically articulated immediate need. Thus, while global actors emphasised standardisation and reusability, national implementers focused on functionality, usability, and immediate system relevance.

Each country case offered distinct insights into this programme component's alignment with national priorities. In Ghana, the SURD development process facilitated by Digital Square was grounded in the country's existing digital systems and enabled enhancements that were seen as highly relevant. Unicef who supported the government in Sierra Leone during the SMART Guidelines piloting process, demonstrated strong procedural localisation of the ANC DAK through stakeholder workshops and a planned hackathon, but the process remained partly aspirational, with limited transition to L3 at the time of data collection, and continuing dependency on technical partners. Malawi provided a tangible example of adaptation and learning: while initial SURDs were first viewed as overly theoretical, they were iteratively refined through field engagement by the local software developers, resulting in stronger alignment with facility-level realities. At the global level, respondents openly acknowledged this tension between normative SMART guidance and country-specific pragmatism, which underscores that true responsiveness to country priorities and needs depends at least as much on SMART Guidelines logic and the DAK procedural framework, as it does on countries' ability to internalise, adapt, and sustain it. Several themes emerged with regards to the alignment with national policies and priorities:

Alignment in principle, adaptation in practice - Across countries, there was broad rhetorical alignment between the DAK/SURD approach and national digital health agendas. However, actual implementation reflected pragmatic adaptation rather than strict adherence to WHO's Smart Guidelines (L1 → L5). Countries integrated DAK principles selectively, using them to enhance existing systems or fill data gaps, rather than pursuing "innovation for the sake of innovation". This indicates that alignment was more operational than strategic: the DAKs served as reference tools to refine what already existed, not as readily adoptable blueprints for immediate systemic change.

The gap between global ambition and local capacity - Global stakeholders framed the DAK process as a pathway towards interoperability and digital maturity, yet national realities revealed limited technical capacity and competing priorities. Governments valued incremental improvement and ownership over radical change that was associated with for example L3/L4-product introductions, which may require "disruptive" resource-intensive system changes. The L2 level of the DAK proved most useful because it balanced global structure with local feasibility, whereas higher levels (L3–L4) remained mostly aspirational due to resource and skills constraints.

Local ownership through iterative learning - Whilst the DAK/SURD process relied on external technical facilitation, all three partner countries demonstrated growing ownership through adaptive learning and contextual refinement. Malawi's experience exemplifies this dynamic. After completing the initial DAK-aligned SURD localisation, local software vendors found the specifications "too abstract" to allow them to create the corresponding software solution. In response, the Malawi implementation partners encouraged the vendors to conduct health facility visits. This iterative process served multiple purposes: 1) for the vendors to understand first-hand how DAK/SURD work-flows aligned with front-line health care and immunisation routines and how SURD-specified requirements functioned in actual service delivery contexts, 2) the SURD itself was further refined and ultimately better reflected facility-level realities, even though the initial localisation process had already been deemed completed, and 3) importantly, the local software development team strengthened their technical capacity through intensive engagement with standards-based requirements specification. This pattern of learning-by-doing, where initial "abstractness" prompted further engagement between front-line health care staff and local software developers, demonstrates how countries can progressively build ownership and capability through the SMART Guidelines process itself.

Ghana and Sierra Leone demonstrated similar patterns of progressive ownership, though manifesting differently based on country contexts. Ghana's implementing team and the team from GHS's Centre for Health Information Management (CHIM), reportedly recognised that the initial SURD required deeper technical grounding to guide eTracker enhancements and interoperability specifications, actively sought stronger engagement with FHIR standards and DHIS2 architecture. This led to establishing clearer PPME-CHIM stewardship arrangements and defining pathways for ongoing SURD governance. However, implementation partners in Ghana also noted that earlier engagement of technical development teams, beginning as early as the Digital Ecosystem Assessment stage, would have facilitated the subsequent translation of the SURD into actual software specifications. This somewhat mirrors the Malawi experience, indicating that an earlier engagement of technical teams may facilitate the transition from L2 to software solutions.

Sierra Leone, operating under more constrained capacity conditions, focussed on extensive stakeholder engagement during ANC DAK localisation to build foundational awareness of standards-based requirements specification across fragmented institutional structures. Whilst Sierra Leone's transition to L3 implementation was still incomplete at evaluation, with a Hackathon to establish L3 was in planning, the localisation process had reportedly strengthened national understanding of SMART Guidelines methodology, including sensitisation activities in the districts, and established governance frameworks for future progression to integrate the localised ANC DAK into the national PresTrack application.

Across all three countries, the evaluation observed that requirements documents were refined through iterative engagement with implementation challenges as intended and this iterative engagement simultaneously addressed specification gaps and built technical capacity within national

teams and local vendor partners. Ghana and Malawi examples also highlight that an earlier engagement of technical teams would likely smooth the process.

Response to target group needs

Across Ghana, Malawi and Sierra Leone, the DAK–SURD localisation process largely met the immediate needs of health-system actors (programme managers, ICT units, district/national public health teams and front-line health workers) by exposing data and functionality gaps, providing a common specification language and by making ANC and immunisation workflows explicit in Sierra Leone and Ghana and Malawi respectively.

Responsiveness to end-users and clients (facility staff, caregivers, pregnant women) was not directly asked about during interviews with health facility staff, however it was evident in intent, given the user-centric approach inherent to the DAK-framework (e.g., persona development, work-flow specifications aligned to front-line needs) and also evident given the broad engagement of stakeholder including health facility staff during the DAK localisation workshops, as reported by implementation partners and national level stakeholders.

Several country-specific observations indicative of responsiveness to target groups needs were reported:

Ghana: The DAK framework-derived SURD, created by Digital Square/PATH was mapped onto the eTracker, missing functions (for example, client geo-location, clearer follow-up logic, stock steps and AEFI reporting) were specified and coded, and programme teams reported tangible improvements in defaulter tracing and outreach planning.

Malawi: The DAK-framework-derived SURD for Malawi was used design a new EIR within the MAHIS, meeting explicit national needs for a digitised immunisation registry, based on global data standards. Moreover, the process itself strengthened national design capacity.

In **Sierra Leone**, localisation of the ANC DAK built "standards literacy" and prepared a requirements pipeline for integration into the national PresTrack application; the benefits for frontline users remain prospective pending L3 development and DHIS2 interoperability.

The extent to which WHO SMART Guidelines introduction will directly respond to health worker and patient-level needs is beyond the scope of the collected data, as such "potential for relevance" can only be cautiously inferred. Findings suggest that the extent of responsiveness to target groups needs was strongly mediated by engagement of frontline staff. Iterative, structured involvement (as in Ghana) during the localisation process reportedly tightened the fit between documented workflows and actual practice. The earlier described software vendor-facility staff engagement in Malawi prompted useful SURD revisions and further improved ownership. In Sierra Leone, participation in the localisation processes was reportedly skewed more towards the strategic stakeholders and efforts for indicator alignment. The anticipated gains (for example, automated reminders, improved data access) are not yet evident, and the level of relevance to target groups needs will only become visible once DAK localisation efforts have been integrated into the Prestrack application.

While system-level improvements such as standardisation and data accessibility were advanced, governance, financing and custodianship arrangements needed to keep DAK/SURD artefacts "living" remain only emergent. Ghana has initiated DAK governance and some FHIR-related capacity building; Malawi and Sierra Leone now have clearer system designs but require named stewards, interoperability skills strengthening and funded update cycles.

Overall, key informant interviews indicate that the piloting of the SMART Guidelines approach was substantially responsive to the needs of system-level target groups by clarifying requirements and guiding coherent design. The findings show that responsiveness was strongest where localisation was coupled with concrete software changes and iterative frontline engagement.

Stakeholder engagement in planning and decision making

Across the three DIPC partner countries, piloting the SMART Guidelines through DAK/SURD localisation generally involved a broad and relevant mix of stakeholders, but with differing depth of engagement and reliance on external facilitation.

In **Ghana**, participation was highly comprehensive: GHS (PPME/CHIM, EPI, ICT), PATH/Digital Square, HISP, UNICEF, GIZ and facility cadres engaged through iterative workshops and reviews. The resulting SURD was adopted as a national reference, indicating strong contextual fit and emerging ownership.

In **Sierra Leone**, inclusion and participation was wide but coordination relied heavily on UNICEF; ministerial directorates participated, yet engagement was uneven across units and stewardship remained partly external.

In **Malawi**, Digital Square's technical stewardship was critical and anchored especially the early phases, with EPI and the Digital Health Division progressively assuming stronger roles.

Three cross-cutting features characterised the process.

1. Inclusivity by design: structured workshops and validation cycles consistently brought together government programmes, implementers and donors, which strengthened relevance and alignment with national priorities.
2. Second, global–local alignment: WHO's presence and use of the SMART/DAK methodology lent legitimacy and provided a shared language for requirements, while allowing contextual adaptation.
3. Third, facilitation as a catalyst: PATH/Digital Square, UNICEF and WHO provided the methodological scaffolding, resources and convening power that sustained engagement where ministerial capacity was thin.

At the same time, limitations were evident. Engagement at sub-national level and with some technical implementers was uneven, reducing translation of specifications into everyday workflows. Decision-making remained asymmetrical: global actors largely set process logic and quality guardrails, while national teams contributed contextual inputs and validation, appropriate for standardisation, but constraining full national methodological autonomy. Where reliance on external facilitation was high (notably Sierra Leone), ownership signals were weaker; where ministries led and iterated with frontline users (Ghana), ownership signals were stronger. This finding highlights on the one hand, that in piloting the SMART Guidelines approach, implementation partners and country stakeholders veered into highly innovative and to some extent "unknown" territory. On the other hand, it highlights the pressing needs for strengthening national stakeholders' capacities to conduct localisation processes more independently going forward.

As such, stakeholder engagement was sufficient to ensure contextualised specifications and policy alignment in all three countries. It was found to be strongest where ministerial leadership was visible and end-users were iteratively involved.

4.2 Implementation Processes

KEY TAKE-AWAYS FOR "IMPLEMENTATION PROCESSES" OF DIPC'S PILOTING OF WHO'S SMART GUIDELINES

- ✓ IMPLEMENTATION WAS STRONGEST AT L2: ALL THREE DIPC COUNTRIES USED DAKS/SURDS TO PRODUCE COUNTRY-OWNED FUNCTIONAL REQUIREMENTS; PROGRESSION TOWARDS L3/L4 WAS LESS EVIDENT AND CONTINGENT ON GOVERNANCE, FINANCING AND SPECIALIST CAPACITY.
- ✓ FIDELITY TO PLAN CORRELATED WITH WORKSHOP-BASED DAK/SURD LOCALISATION AND A CLEAR HANDOVER OUTPUT (DAK/SURD). DEVIATIONS (E.G., SIERRA LEONE'S PIVOT TO ANC DAK; MALAWI'S PERCEIVED "TOO THEORETICAL" SURD) REFLECTED CONTEXT-APPROPRIATE ADAPTATION RATHER THAN POOR EXECUTION.
- ✓ COUNTRY PATHWAYS DIVERGED BY STARTING POINT:
  - GHANA USED THE SURD TO DRIVE DHIS2 ETRACKER CHANGE REQUESTS;
  - MALAWI TENDERED A MAHIS-EMBEDDED EIR USING THE SURD;
  - SIERRA LEONE COMPLETED ANC DAK LOCALISATION AND SCHEDULED L3 CONVERSION VIA A UNICEF-SUPPORTED HACKATHON.
- ✓ THREE ENABLING CONDITIONS RECURRED:
  - THE WHO DAK-FRAMEWORK AS A COMMON LANGUAGE;
  - EXPERIENCED FACILITATION ANCHORED IN REAL WORKFLOWS (PATH/UNICEF); AND
  - VISIBLE MINISTRY OWNERSHIP THAT VALIDATED OUTPUTS AND GUIDED NEXT STEPS.
- ✓ OBSERVED ADDED VALUE ACCRUED IMMEDIATELY AT L2—SINGLE SOURCE OF TRUTH FOR REQUIREMENTS, PRACTICAL GAP-FILLING IN INCUMBENT SYSTEMS, AND A FORWARD-LOOKING DATA DICTIONARY FOR LATER INTEROPERABILITY—ESPECIALLY WHERE COUNTRIES USED EXISTING PLATFORMS.
- ✓ IMPLEMENTATION CONSTRAINTS WERE THE "MISSING MIDDLE" BETWEEN HIGH-LEVEL REQUIREMENTS AND DEVELOPER-READY SPECIFICATIONS (FHIR PROFILES, VALUE SETS, TEST CASES), THIN IN-COUNTRY ARCHITECTURE/FHIR SKILLS, AND BUDGETS INSUFFICIENT TO RETAIN THEM.
- ✓ INTEROPERABILITY REMAINED A SYSTEMIC BOTTLENECK: WITHOUT FUNDED STEWARDSHIP, NAMED PRODUCT OWNERSHIP, AND VENDOR CONTRACTS TIED TO L3 DELIVERABLES, SURDS/DAKS RISK REMAINING DESCRIPTIVE

Figure 7. Key Take-Aways for "Implementation Processes" of DIPC's Piloting of WHO's SMART Guidelines

Across Ghana, Malawi and Sierra Leone, DIPC delivered the SMART Guidelines approach at Layer 2 (L2). The countries used the WHO DAK or the equivalent DAK-framework based version of PATH/Digital Square's SURD to turn paper-based clinical guidelines for ANC (Sierra Leone) and immunisation (Ghana & Malawi) into clear, country-owned requirements. Moving beyond L2 to L3/L4 (machine-readable specifications and deployable software) was more challenging and hampered by governance, financing and specialist capacity.

Implementation relative to project plans

A late, funder-driven re-programming decision introduced the SMART Guidelines pilot as an innovative but time-compressed pivot. This curtailed early country sensitisation and planning windows, but implementation partners demonstrated high adaptability, standing up L2 localisation processes rapidly and aligning workshops, artefacts and handovers to the new direction.

Across settings, fidelity to plan was high given DIPC implementation partners' concentrated efforts on realising Layer 2 (L2) of the WHO SMART Guidelines approach, with disciplined, workshop-based localisation and a clear handover artefact (DAK/SURD). Perceived deviations reflected context-appropriate adaptation rather than slippage, which in several instances strengthened national ownership. Funder's ambitions to progress through the SMART Guidelines layers to L3/L4 over the course of the DIPC initiative were moderated by country priorities, ecosystem maturity and specialist capacity and the original multi-country L4 product concept was therefore re-scoped.

According to stakeholder interviews, the following trajectories of SMART Guidelines adoption evolved across the partner countries:

In **Ghana,** the implementation plan and schedule were followed closely. Digital Square/PATH convened GHS/EPI, UNICEF and facility actors and used their generic DAK-framework based SURD to then map front-line immunisation workflows, to produce a localised SURD translating agreed changes into DHIS2 requests. Any delay arose downstream in software development, not during localisation.

Sierra Leone pivoted from Immunisation to ANC because an immunisation DAK was not yet available at this stage of the DIPC project. L2 narrative localisation of the ANC DAK facilitated by UNICEF, was completed with broad stakeholder engagement and approval; L3 conversion (machine-readable artefacts) was planned at the time of the evaluation via a UNICEF-supported hackathon, with an integration of the requirements into the national Prestrack App foreseen in the future.

In **Malawi,** similar to the implementation processes adopted in Ghana, the generic SURD for immunisation was used to then localise the system and user requirements in line with Malawi's context. Beyond L2, Malawi's government prioritised the development of a functioning EIR (making use of the "L2 specification") over attempts to realise funders' SMART Guideline L3/L4 ambitions, even though the L2 did serve a valuable purpose during the EIR development process, as data standards and formats could be aligned and developers could draw on the workflow formats. Progress did slow at that point, as the SURD was deemed too abstract by the software vendors. However, as outlined earlier, despite a deviation from envisaged timelines, the additional time invested did provide added value in terms of local ownership and SURD-fit-to-context.

Overall, despite compressed lead times due to the late re-programming pivot, DIPC largely met L2 targets and delivered nationally endorsed specifications in the three partner countries that were evaluated. Observed departures from initial plans are deemed adaptive and justifiable given the country needs and levels of readiness.

Added value, and aspects of implementation that went well, including facilitators and enablers

Ghana: Facilitated, inclusive workshops reconciled national and facility practice with global data standards and national guidelines and yielded a localised SURD. The SURD became the EPI's first comprehensive design document, supported concrete module enhancements (e.g., growth monitoring) and offered a reference for future updates. Enablers: strong EPI leadership, PATH/Digital Square facilitation, multi-level participation, and the discipline of the WHO format. Interoperability thinking advanced (DHIS2–GhLMIS), however it remained aspirational at the time of data collection and contingent on financing.

Sierra Leone: Interview data were limited on this topic; however, the available stakeholder reflections suggests that the value of the SMART Guidelines piloting efforts in Sierra Leone were understood as prospective, yet highly coherent: having localised the ANC DAK, with a clear vision to code (Hackathon L3) and build a FHIR-enabled app interoperable with DHIS2 (L4) by adapting an existing platform (Prestrack – under development at the time of evaluation), and deliver end-to-end flows, reminders and data quality gains. The key enablers identified from the data were the existence of the national digital health roadmap (NDHRM), the SMART Guidelines methodology and the integration of the DIPC-supported outputs into a government endorsed tool, which holds a great deal of promise in terms of antenatal care for the country.

Malawi: At the time of data collection, the most pronounced perceived added value of the SMART Guidelines piloting was the institutional learning at the health system level. Moreover, using the L2 for the subsequent EIR development ensured that data formats and workflows are standardised and thus building strong infrastructural foundations (e.g., data dictionaries) for the future.

Across the three countries, three key enablers for the implementation of the SMART Guidelines approach emerged:

1. The WHO DAK format as a common language;
2. Experienced facilitation that keeps workshops anchored in real workflows; and
3. Visible ministry ownership.

Added value appears as institutional memory, practical improvements to existing systems, and a forward-looking data dictionary for later interoperability.

Remaining gaps, and aspects of implementation that did not go well, including challenges and barriers

Across contexts, findings suggest that the bottleneck for the implementation was not the concept of WHOs SMART Guidelines but the owned, financed pathway from L2 to L3/L4 and the countries' readiness, as such the "missing middle". While the WHO methodology ideally envisions progression from business requirements (L2) through technical specifications (L3) to reference software development (L4), this exact and direct pathway towards interoperable digital solutions was reportedly too ambitious within the project's timeframes and financial scope.

Instead, countries' immediate priority was to gain functioning digital tools for immunisation, and the implementation was adapted accordingly, whilst making use of some L2 components (e.g., data dictionaries, workflows). However, the technical complexity, skill requirements, financing needs, and timelines required for L3 and L4 work exceeded what countries could realistically undertake.

This manifested differently across settings. In Malawi, stakeholders explicitly stated they did not want to pursue the SMART Guidelines L3/L4 pathway, preferring to focus on more immediate operational needs, i.e., the development of an EIR to be nested within the national MAHIS system. In Ghana, the project successfully enhanced the DHIS2 eTracker according to SMART Guidelines L2 specifications. Moreover, system requirements for establishing interoperability between GHLIMS and DHIS2 were written, but lack of financing meant this could not be realised during the project period. Financing beyond DIPC to realise interoperability were unclear at the time of the evaluation. Regarding ongoing maintenance and updates to the DAKs, some institutional capacity was beginning to emerge in Ghana, but in Sierra Leone and Malawi, pathways towards building this capacity were less apparent.

Beyond these capacity and priority misalignments, several structural constraints limited progress. Countries face shortages of personnel with FHIR and systems architecture expertise, compounded by limited recurrent budgets to retain such specialists. A "missing middle" exists between high-level business requirements captured in DAKs and Software and SURDs and the executable technical specifications needed by developers. Vendor capacity and in-country quality assurance capabilities vary considerably across settings. Also, government priorities may shift over time, which can severely affect the sustained commitment needed to fully realise the SMART Guidelines approach. Finally, fragmented and project-based funding structures make it difficult to finance and sustain the multi-year technical work required for full L3/L4 implementation across diverse contexts.

Several barriers hampering the DIPC-supported SMART Guidelines piloting efforts emerged:

Ghana: Interoperability was the central weakness: SORMAS, DHIS2 and DHIMS do not interoperate, driving duplicate entry and user burden. L3/L4 translation stalled and L2 requirements were hard coded into the DHIS2 enhanced eTracker. Political will, financing and governance frictions (surveillance ownership; ministry–GHS disconnect) limited progress and despite existing technical capacities within GHS, much work relied on global rather than domestic funds.

Sierra Leone: Evidence from Sierra Leone on the topic was limited and there was no direct evidence on barriers in the dataset. However, the likely challenges for adopting the SMART Guidelines approach fully, can be inferred to some extent: e.g., limited capacity to update ANC DAK requirements without external support, a lack of interoperability across most applications currently in operation in-country, insufficient national developer capacity to integrate FHIR compliant L3 into the Prestrack app and subsequent quality assurance and assessments for app functionality.

Malawi: Multiple institutional and practical constraints emerged. The localised SURD produced through the L2 process lacked the technical detail developers needed, requiring rework before it could guide software development. Interoperability profiles and other L3 artefacts were not developed. While the technical pathway forward would require clear stewardship (a designated MoH/EPI owner with change control authority), translation of written requirements into developer-ready technical specifications, and vendor contracts tied to these deliverables, stakeholders indicated that these L3/L4 activities were not aligned with immediate country priorities or capacities.

Overall, the DIPC initiative successfully implemented the L2 phase of the SMART Guidelines approach across three countries, producing country-adapted business requirements, data dictionaries, and workflow specifications. The transition from L2 to L3/L4 was not pursued to completion in any setting, reflecting country priorities for immediate operational tools, available technical capacities, financing constraints, and project timelines. Countries adapted the approach to their contexts, using selected L2 components to enhance existing systems rather than progressing through the full technical pathway envisioned in the optimal SMART Guidelines framework. This pattern of selective adoption aligns with WHO's recognition that countries should adopt SMART Guidelines according to their readiness and needs. The L2 products generated represent tangible country-owned assets, though the persistent constraints identified, limited specialist workforce, fragmented funding, the "missing middle" between requirements and specifications, and variable vendor capacity, indicate that bridging from requirements to interoperable systems remains a substantial undertaking requiring capacities and resources beyond what was available within the DIPC project scope.

4.3 Sustainability Potential

KEY TAKE-AWAYS FOR "POTENTIAL FOR SUSTAINABILITY" OF DIPC'S PILOTING OF WHO'S SMART GUIDELINES

- ✓ **SUSTAINABILITY IS CONTINGENT ON BASIC OPERATIONAL ENABLERS:**
  - SMART GUIDELINES SHOULD BE TREATED AS A FLEXIBLE FRAMEWORK THAT COUNTRIES CAN ADAPT TO CURRENT ARCHITECTURES; SUSTAINABILITY DOES NOT REQUIRE IMMEDIATE PROGRESSION TO FROM L2 TO L3/L4/L5.
  - DAKS/SURDS REQUIRE ACTIVE STEWARDSHIP: ESTABLISH AND RESOURCE A ROUTINE GOVERNANCE CYCLE TO UPDATE SPECIFICATIONS AND TRANSLATE THEM INTO EXECUTABLE CHANGE REQUESTS.
- ✓ **COUNTRY SPECIFICS:**
  - **GHANA:** ASSETS ARE IN PLACE (SURD; DEFINED ETRACKER–GHLIMS INTERFACE; GHS STEWARDSHIP). PROGRESS NOW DEPENDS ON RING-FENCED BUDGETS FOR ROLLOUT AND ENFORCEMENT OF STANDARDS ACROSS PARALLEL PLATFORMS.
  - **SIERRA LEONE:** A COHERENT PATHWAY EXISTS (ANC DAK LOCALISED; PRESTRACK ROUTE TO L3), BUT LIMITED SPECIALIST CAPACITY, UNFUNDED RECURRENT COSTS AND ABSENT DHIS2 INTEROPERABILITY RISK CONFINING SOLUTIONS TO PILOTS.
  - **MALAWI:** THE EIR IS WELL INTEGRATED WITHIN MAHIS ON THE BASIS OF THE SURD; DURABILITY REQUIRES GOVERNMENT-RUN HOSTING/SUPPORT AND OPERATIONAL, STANDARDS-BASED EXCHANGES TO DHIS2 AND SUPPLY SYSTEMS.

Figure 8. Key Take-Aways for the "Potential for Sustainability" of DIPC's Piloting of WHOs SMART Guidelines

Across DIPC, piloting the SMART Guidelines through DAK localisation, followed by country-specific further adoption elements proved a practical way to connect WHO norms to real systems. Countries left the process with tangible assets, SURDs/DAK, clarified stewardship, and first-order interoperability priorities, yet sustainability remains contingent on execution conditions that vary by context.

Ghana now has a SURD that already guides eTracker enhancements and a defined eTracker–GhLIMS interface under GHS/PPM-CHIM stewardship, but progress depends on financed devices/connectivity and enforced DAK governance across a fragmented DHIS2/ DHIMS/SORMAS/GhLIMS landscape.

Sierra Leone has articulated a DHIS2-centred architecture, localised the ANC DAK, and planned a DSTI route to L3/L4 within PresTrack; however, thin specialist capacity, unfunded basics and pending FHIR/DHIS2 interoperability keep tools pilot-bound.

Malawi translated the data standards and workflows of the immunisation SURD into a MAHIS-embedded EIR, giving strong integration inside MAHIS, but outward interoperability to DHIS2 and supply systems was not delivered under DIPC and remains the critical gap. At the same time, the built capacity regarding SMART Guidelines processes are promising for durability.

As such, engaging countries into the SMART Guidelines methodology has been shown to work under the DIPC initiative. However, durability will be contingent on financed basics, government-owned operations, and turning specified exchanges into live services.

Sustainability potential of DIPC component

The SMART Guidelines approach proved most valuable as a structured process for localising guidance and producing standardised requirements documentation, rather than as a direct pathway to fully interoperable technical systems. Across countries, different sustainability factors emerged.

In **Ghana**, the process yielded concrete deliverables and established institutional ownership. GHS retained a SURD, interoperability requirements documentation, and an enhanced eTracker application. Stakeholders reported that the system architecture incorporated standards-based design principles, though sustainability depended on securing budgets for devices and data costs, establishing a governance cycle for updating requirements, and financing the development of the documented eTracker-GhLIMS data exchange.

Sierra Leone established a structured pipeline for digital health development: an ANC DAK at the requirements level, a technical training pathway for staff to develop implementation specifications, and strengthened platform oversight through a Community of Practice. Sustainability in this context depended on two critical factors: securing recurrent operational funding and achieving technical interoperability between health information systems. Without these, the PresTrack and immunisation applications would remain standalone tools unable to exchange data with other national systems.

Malawi demonstrated how the requirements documentation could guide national system development. DIPC produced an immunisation SURD, and the country implemented an Electronic Immunization Registry within the national MAHIS platform based on those requirements. This approach reduced system fragmentation and aligned digital tools with service delivery workflows. However, long-term sustainability required government-financed hosting and support infrastructure, as well as the eventual development of standards-based data exchanges between MAHIS, DHIS2, and logistics management systems.

Across all three settings, the approach successfully produced country-owned requirements and governance structures. However, sustained impact depended on transitioning from well-documented specifications to financed, operational systems with planned maintenance and evolution pathways.

Integration into the National System

Across the three settings, the SMART Guidelines approach informed the design of system integration strategies, though actual operational integration remained incomplete.

In **Ghana**, the process guided the selection of the DHIS2 eTracker platform, specification of system enhancements, and definition of a priority data exchange with GhLIMS, demonstrating alignment between WHO guidance and national platform choices. However, multiple national platforms continued to operate in parallel without data exchange capabilities, and the planned interoperability development remained unfunded at the time of evaluation, limiting broader institutional adoption.

Sierra Leone had established DHIS2 as the national backbone system and completed localisation of the ANC DAK, with plans to develop technical specifications for the PresTrack application. However, functional data exchange between PresTrack and DHIS2 had not been implemented. Most applications

operated independently, requiring duplicate data entry and limiting visibility into service delivery across platforms.

Malawi integrated the newly developed EIR directly within the MAHIS platform using the SURD produced through the DIPC process. This approach functioned well for internal data use across MAHIS modules, but data exchange with external systems, particularly DHIS2 for reporting and supply chain management tools, had not been established.

Across all three countries, the requirements documentation informed technically sound design decisions. However, actual system integration depended on the development, financing, and ongoing support of functional data exchanges, work that extended beyond the scope and timeline of the DIPC initiative.

National Capacity for Independent Continuation

All three countries demonstrated commitment to continuing the digital health initiatives beyond DIPC, with different operational conditions in each setting.

In **Ghana**, institutional stewardship was assigned to PPM-CHIM, GHS technical teams (with HISP support) possessed the capacity to work with the SURD, and a governance process for updating requirements was planned. Independent continuation depended on securing dedicated recurrent budgets for operational costs and completing the initial interoperability development to demonstrate the viability of the governance model in practice.

In **Sierra Leone**, several enabling conditions were established: policy alignment, completed requirements documentation, plans for developing technical specifications within the PresTrack application, and a partner coordination forum. However, technical capacity remained limited, and financing for essential infrastructure—devices, electricity, hosting, connectivity, and ongoing training—was not secured. Stakeholders assessed in-country operational capability at approximately 50% of what would be required for independent continuation.

In **Malawi**, institutional commitment and political support were evident. DIPC strengthened planning processes and produced a SURD that guided development of the EIR embedded within the MAHIS. However, government-employed developer positions remained scarce, system hosting continued to rely on partner support, and no functional data exchange between MAHIS and DHIS2 had been established. Independent continuation capability was limited until government-financed operations and external system interoperability could be achieved.

Across all three settings, sustained independent operation required several common elements: domestic budgets for recurrent operational costs, government-managed hosting and technical support, enforced governance processes for updating requirements, and at least one functional, standards-based data exchange to translate documented specifications into routine national practice.

5 Discussion

This evaluation examined DIPC's pioneering implementation of WHO's SMART Guidelines approach across Ghana, Sierra Leone, and Malawi, assessing relevance, implementation processes, and sustainability prospects. The evaluation identifies a consistent pattern across settings: the SMART Guidelines framework demonstrates strong methodological relevance and successfully facilitates L2 specification processes, whilst progression to operational, sustainable systems depends on contextual enablers including governance coordination, infrastructure investments, and sustained financing.

5.1 Relevance

Strong Methodological Relevance for Requirements Specification

The translation of narrative clinical guidelines into operational digital systems represents a longstanding challenge in digital health implementation. Haddad et al. (2020) documented that "building a digital tool for the adoption of WHO's antenatal care recommendations" requires methodological intersection of "evidence, clinical logic, and digital technology," highlighting the complexity of moving from narrative text to functional digital artefacts.

The evaluation demonstrates that DIPC's adoption of the SMART Guidelines approach provides a structured methodology addressing this translation challenge at the specification level. All three countries successfully completed L2 localisation processes, producing validated, country-owned requirements documents through collaborative processes engaging policy leadership, technical implementers, and frontline users. These findings align with recent documentation from WHO pathfinder countries, where Muliokela et al. (2025) reported successful structured DAK localisation across Ethiopia, Ghana, Malawi, Zambia, and Zimbabwe. The consistency suggests robust L2 methodology replicability across diverse contexts.

The value of L2 specification extends beyond immediate implementation to institutional knowledge preservation. Requirements documents serve as organisational memory artefacts, capturing consensus on clinical workflows, data elements, and validation rules that would otherwise remain tacit or dispersed across individuals. This finding resonates with implementation science literature on the importance of formalised documentation for organisational learning and reduced dependency on individual expertise (Gagliardi et al., 2011).

The "Missing Middle" Between Specification and Implementation

Whilst L2 processes demonstrated success, the evaluation identified a critical implementation challenge: the transition from validated requirements to operational code. Feedback across countries indicated need for earlier technical software team engagement. Developers characterised localised SURDs as "too theoretical" for software development, requiring extensive facility-level consultation before implementation could proceed. This extends recent literature noting that DAKs can be perceived as "abstract" and "overwhelming" (Muliokela et al., 2025), providing granular evidence of how this abstraction persists into implementation phases.

The implementation gap manifested in how countries actualised requirements. Requirements were often hard-coded into systems rather than translated through formal L3 processes—bypassing the SMART Guidelines-intended L3 layer. The findings highlight specific components that would support implementation: stronger technical team engagement throughout the process; developer-ready implementation guides translating L2 requirements into actionable software solutions; and practical resources including FHIR guidance, interface specifications, and quality assurance criteria. Without these bridging elements, the gap between high-level requirements and executable specifications remains difficult to navigate independently.

These technical translation challenges had direct implications for interoperability, which is central to the SMART Guidelines vision. WHO (2021) positions SMART Guidelines as enabling "standards-based, interoperable systems that can share accurate data and become part of stronger, more sustainable health information systems." The evaluation found that whilst all three countries articulated clear interoperability objectives during L2 specification, none achieved operational, standards-based data

exchange between systems during the project period. By accommodating country-specific priorities and readiness levels, DIPC-supported activities implemented solutions fitting local contexts and existing infrastructure. This gap between interoperability as design intent and operational reality reflects the "missing middle" challenge—without intermediate artefacts bridging specifications to implementation-ready guidance, systems developed from the same logical requirements using incompatible technical approaches.

Context-Dependent Appropriateness and Readiness Assessment

The digital health implementation literature increasingly emphasises context-appropriate intervention design and rigorous readiness assessment. Labrique et al. (2018) argued that "best practices in scaling digital health in LMICs" require "understanding the local context" and "assessing readiness" before implementation.

The evaluation demonstrated substantial variation in country readiness for SMART Guidelines implementation beyond L2 specification. Implementation of all layers was clearly not feasible within project timeframes, though country strategies aligned with context-specific programmatic adaptation. Key readiness bottlenecks included governance structures and specialist technical capacities. Readiness profiles varied: technical capacity existed in some settings but governance coordination limited progress; institutional commitment was strong in others yet specialist skills required development; infrastructure deficits and fragmented structures presented barriers in certain contexts.

As one of the first programmes to pilot SMART Guidelines at scale across multiple countries, DIPC navigated largely uncharted implementation territory. Late programme re-programming compressed timelines for government sensitisation and stakeholder engagement, limiting opportunities for structured upfront readiness assessment. The evaluation findings suggest that future SMART Guidelines initiatives would benefit from incorporating systematic readiness assessment earlier in planning, allowing implementation partners to tailor technical assistance, capacity-building approaches, and timelines to specific country contexts. Whilst WHO's framework appropriately recognises that countries should adopt the methodology according to their readiness and needs, translating this principle into practice requires explicit assessment tools and differentiated support models.

5.2 Implementation Processes

Successful L2 Specification Processes

The implementation science literature emphasises that structured, stakeholder-engaged processes improve intervention adoption and sustainability. Gagliardi et al. (2011) proposed that guideline "implementability" depends on systematic approaches to content adaptation, stakeholder validation, and documentation.

The evaluation findings demonstrate that L2 processes across all countries embodied these principles. Multi-level stakeholder engagement ensured specifications reflected both policy intent and operational realities, enabling consensus on contentious issues that had previously generated inconsistency. The consistency between DIPC and WHO pathfinder experiences (Muliokela et al., 2025) suggests robust L2 methodology replicability. The value of structured processes extended beyond specification outputs to institutional capacity building, with multi-stakeholder engagement creating shared understanding of digital health requirements across traditionally siloed programmes.

Infrastructure, Capacity, and Governance as Binding Implementation Constraints

Whilst L2 processes succeeded, progression to operational deployment faced substantial constraints. The digital health literature consistently identifies infrastructure deficits as primary barriers in low-resource settings. Agarwal et al. (2021) found that decision-support tool effectiveness depends critically on "infrastructure and implementation support."

The evaluation provides granular evidence of how infrastructure deficits constrain implementation despite successful L2 specification. Deployment faced unfunded prerequisites including insufficient devices, unreliable connectivity, power challenges, and unstable hosting. These gaps prevented point-of-service use, forcing dual workflows that negated efficiency benefits. The evaluation distinguished between infrastructure deficits and capacity constraints. Countries faced capacity limitations varying by context, some required specialised knowledge transfer rather than foundational capacity building; others faced fundamental capacity gaps requiring multi-year investment timelines misaligned with typical project cycles.

Governance gaps preventing coordinated action operated as critical implementation barriers even where L2 specifications clearly articulated integration requirements. The evaluation documented that institutional mandate fragmentation created coordination gaps preventing integrated implementation despite strong specifications and technical capacity. Multiple parallel systems operated under different institutional authorities, creating duplicate reporting burdens that specifications were designed to eliminate. This finding aligns with broader literature documenting that "most investments are vertical, partner-driven and programme-specific with limited system-wide impacts" (Karuri et al., 2022), creating parallel systems resistant to integration despite policy intent and technical feasibility.

The evaluation documented persistent financing gaps, with SMART Guidelines support covering L2 facilitation but not L3 development, L4 implementation, or post-deployment operations. This financing structure creates predictable patterns where specification succeeds but operationalisation stalls. The literature emphasises that "scaling digital health in LMICs" requires "sustainable financing" covering complete implementation cycles (Labrique et al., 2018). Converting L2 specifications into L3 artefacts requires skilled labour not covered by typical support packages. Beyond L3 development, operational systems require infrastructure investments and support systems representing recurrent costs extending beyond typical project budgets.

5.3 Sustainability

Institutional Artefacts as Sustainability Foundation

The implementation science literature distinguishes between intervention sustainability and institutionalisation, embedding within routine organisational structures beyond individual project timeframes (Scheirer & Dearing, 2011).

The evaluation demonstrates that L2 artefacts produced through SMART Guidelines processes provide valuable institutional foundations that persist independent of operational system status. Requirements documents serve as organisational memory, surviving personnel turnover, supporting vendor accountability through formalised specifications, and creating foundations for future development cycles. This extends recent literature documenting that pathfinder countries produced "country-owned requirements documents" through structured localisation (Muliokela et al., 2025).

However, whilst these institutional artefacts provide valuable foundations, they do not constitute operational sustainability. Requirements documents enable system implementations without ensuring them; specifications clarify interoperability without mandating it; documentation supports operations

without substituting for them. Moreover, the value of these artefacts depends on their continued relevance as clinical guidelines evolve, technologies advance, and implementation lessons emerge.

The evaluation found that formal mechanisms for ongoing DAK/SURD maintenance and evolution remained largely absent across settings. Without designated institutional stewards, regular review cycles, and clear change management processes, requirements documents risk obsolescence. Ghana initiated DAK governance processes, but explicit stewardship arrangements with maintenance mandates were not yet formalised across settings. This highlights that sustainability depends not only on initial specification quality but on institutionalised mechanisms ensuring requirements evolve with changing contexts, the sustainability value of L2 artefacts should be recognised as foundational rather than complete.

Nascent and Conditional Operational Sustainability

At evaluation, no country had achieved operational sustainability, domestically financed, standards-based, interoperable implementations maintained through national capacity. This aligns with literature documenting that successful digital health implementations require multi-year transitions. Mvundura et al. (2023) documented that Vietnam's successful national electronic immunisation registry required seven years of implementation and sustained government financing to move from pilot to full national scale.

The evaluation findings align with this literature on realistic sustainability timescales. Across settings, continued dependencies limited assured sustainability: reliance on external technical support for complex enhancements, unfunded integration work for planned interoperability, and unclear long-term financing mechanisms. Countries faced different combinations of thin in-house development capacity, external dependencies for technical innovations, and unfunded recurrent operations. These differentiated trajectories validate literature emphasising context-dependent sustainability prospects and the importance of realistic assessment of sustainability preconditions (Labrique et al., 2018).

Financial Sustainability as Primary Challenge

The literature consistently identifies financial sustainability—transition from donor to domestic budget integration—as the primary determinant of digital health system durability. Mvundura et al. (2020) documented that whilst electronic immunisation registries generate efficiency gains, "governments must budget for recurrent costs" including devices, connectivity, and support systems.

The evaluation demonstrates that none of the three countries achieved financial sustainability through domestic budget integration during evaluation timescales. This reflects both realistic transition horizons and structural challenges in digital health financing across LMICs. The evaluation documented three specific gaps. First, recurrent operational costs remained largely unfunded through domestic budgets even where governments expressed commitment to system ownership. Second, capital-versus-recurrent financing disparities created sustainability vulnerabilities, initial device procurement often succeeded through donor funding, whilst replacement cycles and ongoing connectivity required recurrent financing that countries struggled to secure. Third, integration within broader platforms provided more realistic sustainability pathways than standalone system financing, though this approach assumes that broader platforms themselves achieve financial sustainability, which is an assumption not universally valid where health information systems compete for limited domestic resources.

6 Recommendations

6.1 Relevance

R1: Develop Intermediate Technical Artefacts to Bridge the "Missing Middle"

Rationale: The evaluation identified a consistent implementation gap across all three countries between L2 specification and operational software development. Developers characterised localised SURDs as "too theoretical," requiring extensive facility consultation before implementation could proceed. This extends recent literature on DAK abstraction (Muliokela et al., 2025), demonstrating how the gap persists into implementation phases. Without intermediate artefacts bridging requirements to executable specifications, requirements were hard-coded into systems, vendor accountability was limited, and countries could not progress independently from specification to implementation.

Priority Actions:

- Develop standardised "layer 2.5" guidance and templates that translate L2 requirements into developer-ready specifications, including detailed workflow diagrams, FHIR profile examples with complete cardinality constraints, comprehensive value sets with code mappings, and test cases covering normal flows and edge cases
- Produce open-source reference implementations demonstrating correct interpretation of L2 requirements in code across common platform architectures (DHIS2, OpenMRS, FHIR-native systems), providing developers with working examples rather than abstract specifications alone
- Establish conformance testing frameworks enabling automated validation that implementations correctly interpret L2 specifications, supporting vendor accountability and national quality assurance capacity

R2: Establish Differentiated Implementation Pathways Based on Country Readiness

Rationale: The evaluation demonstrated substantial variation in country readiness for SMART Guidelines implementation beyond L2 specification. Each country faced distinct constraints: technical capacity existed in some settings but governance coordination limited progress; institutional commitment was strong in others yet specialist skills required development; infrastructure deficits and fragmented structures presented barriers in certain contexts. Current SMART Guidelines methodology applies relatively uniform processes across heterogeneous contexts, potentially risking creating unrealistic expectations when implementation challenges differ fundamentally. As one of the first programmes to pilot SMART Guidelines at scale, DIPC's experience identified the need for more systematic readiness assessment and context-appropriate implementation planning for future initiatives.

Priority Actions:

- Define three implementation pathways with clear entry criteria and realistic outcome expectations: Full Implementation (for countries with established infrastructure and strong governance), Capacity Building (for countries with emerging ecosystems requiring extended L3 preparation and governance strengthening), and Foundation (for countries with fragmented systems requiring selective L2 focus with concurrent infrastructure and governance investments)

- Develop standardised readiness assessment instruments evaluating technical capacity (existing digital health systems, in-house development capability, standards familiarity), governance maturity (coordination mechanisms, decision-making clarity, funding availability), and infrastructure prerequisites (connectivity, hosting, device availability) to recommend appropriate pathway
- Contextualise success metrics to pathway, emphasising L2 completion quality and capability development for Capacity Building pathways versus operational systems and demonstrated interoperability for Full Implementation pathways

6.2 Implementation Processes

R3: Strengthen Early Technical Team Engagement and Sustained Capacity Building

Rationale: The evaluation found that technical software development teams were reportedly not engaged early enough in the implementation process, limiting their ability to provide input during requirements development, and also their ability to become familiar with L2 specifications. In Ghana, stakeholders suggested technical teams should participate from the Digital Ecosystem Assessment stage; in Malawi, vendor engagement after requirements and L2 was specified, necessitated iterative facility visits and SURD refinement after L2 completion. Whilst these iterative processes ultimately strengthened outcomes and built local capacity, earlier engagement would have smoothed the transition from specification to implementation. The evaluation documented that L2 facilitation support is well-established, but no equivalent sustained support exists for L3 development and capacity transfer. Countries require not just L2 facilitation but ongoing technical mentoring enabling progressive assumption of L3 competence.

Priority Actions:

- Integrate technical development teams into SMART Guidelines processes from Digital Ecosystem Assessment through L2 validation, ensuring developers understand requirements specifications and contribute practical implementation perspectives during localisation
- Establish regional rosters of L3 technical specialists with demonstrated FHIR implementation experience and LMIC context familiarity, available for extended engagements (3-6 months) providing hands-on assistance translating L2 requirements into FHIR profiles, interface specifications, and test cases alongside national teams
- Structure L3 support explicitly for capability transfer through mentored practice, ensuring national team members progressively assume L3 production responsibility rather than external production of deliverables, building sustainable national capacity

R4: Strengthen Governance Mechanisms for Cross-System Coordination

Rationale: The evaluation documented that in Ghana, institutional mandate fragmentation created coordination gaps preventing integrated implementation despite strong L2 specifications and clear interoperability requirements. Multiple parallel systems operated under different institutional authorities, and whilst technical capacity existed to implement specified integrations, governance friction between Ministry of Health and Ghana Health Service combined with competing surveillance mandates prevented coordinated action during the project period. This finding demonstrates that technical specifications was not sufficient for achieving interoperability without governance frameworks mandating standards adoption and coordinating cross-system integration. Whether

similar governance fragmentation constrained progress in Malawi and Sierra Leone remains less clear from the evaluation data, but the Ghana case indicates governance structures warrant explicit attention in SMART Guidelines implementation planning.

Priority Actions:

- Support countries to establish cross-institutional coordination mechanisms (digital health technical working groups, interoperability governance committees) with explicit mandates for cross-system integration, clear decision-making authority, and membership spanning Ministry of Health, implementing agencies, major vertical programmes, and technical service providers
- Develop formal policy directives requiring standards-based implementation (FHIR, HL7, IHE profiles) for all digital health systems, with explicit timelines for new system compliance and enforcement mechanisms such as procurement restrictions and funding conditions
- Establish procurement criteria requiring demonstrated standards compliance, with technical conformance testing preceding vendor selection using standardised frameworks enabling objective assessment against L2/L3 specifications

R5: Address Infrastructure and Financing Prerequisites for Implementation Phases

Rationale: The evaluation documented that whilst L2 specification processes succeeded across all three countries, progression to operational deployment faced substantial infrastructure and financing constraints. All three countries faced financing gaps where DIPC's SMART Guidelines piloting support covered L2 facilitation but not L3 development, infrastructure investments, or operational costs, creating predictable patterns where specification succeeded but operationalisation stalled. The literature emphasises that digital health implementations require complete cycle financing and infrastructure investments to achieve sustainability (Mvundura et al., 2020), yet current support models inadequately address these prerequisites. Without explicit attention to infrastructure and financing requirements, specifications risk remaining aspirational.

Priority Actions:

- Develop standardised costing frameworks for complete SMART Guidelines implementation cycles, explicitly quantifying L3 development requirements, infrastructure prerequisites (devices with replacement cycles, connectivity solutions, hosting platforms, power backup), and three-year operational transition support to enable realistic budgeting
- Require infrastructure readiness assessments before L2 initiation, identifying gaps in device availability, connectivity reliability, power stability, and hosting capacity, with explicit plans addressing deficits through coordinated investments before expecting operational deployment
- Structure SMART Guidelines financing with progressive domestic co-financing expectations, e.g., increasing from 20% during L2/L3 phases to 50% during deployment to 80%+ during sustainability transition, building toward domestic ownership whilst providing bridge financing during capability development

6.3 Sustainability

R6: Establish Realistic Multi-Year Transition Support for Country Ownership

Rationale: Not unexpectedly, none of the three countries achieved financial sustainability for this project component, which we define as domestically financed operations maintained through national capacity, within the DIPC project timescales. This aligns with literature documenting that successful digital health implementations require five to seven years (Mvundura et al., 2023). Current project-cycle financing (two to three years) creates unrealistic expectations, generating predictable patterns where implementations begin but cannot achieve independence before projects end. All three countries faced different combinations of unfunded interoperability development, thin in-house capacity, external dependencies, and unclear long-term financing. Achieving sustainability requires extended support horizons with declining partner financing as countries progressively assume ownership.

Priority Actions:

- Establish standardised multi-year support packages with clear phases and declining partner financing: For example, years 1-2 focus on L2/L3/L4 implementation with 70-80% partner financing; Years 3-4 emphasise operational support with 50% partner financing as government assumes greater responsibility; Years 5-7 provide sustainability transition support with 20% partner financing focused on capacity building as government achieves majority ownership
- Require government co-financing commitments from inception with annual increases toward full ownership embedded in national health sector plans and medium-term expenditure frameworks, creating institutional accountability mechanisms beyond individual project commitments
- Establish clear operational milestones enabling progressive transition: system uptime thresholds, utilisation rate targets, data quality metrics, budget execution performance, and demonstrated national capacity for autonomous system management, independent troubleshooting, and standards compliance

R7: Establish Formal Stewardship and Governance Processes for DAK/SURD Maintenance and Evolution

Rationale: The evaluation found that whilst all three countries produced valuable L2 artefacts, formal mechanisms for ongoing maintenance and evolution of these requirements documents remained largely absent. Ghana initiated DAK governance processes, but Malawi and Sierra Leone lacked designated stewards and update protocols. Requirements documents risk becoming outdated as clinical guidelines evolve, technologies change, and implementation lessons emerge. Without named institutional owners, regular review cycles, and clear change management processes, L2 investments will not remain relevant over multi-year implementation horizons. Sustainability depends not only on initial specification quality but on institutionalised mechanisms ensuring requirements evolve with changing contexts.

Priority Actions:

- Support countries to designate formal institutional stewards for DAK/SURD ownership with explicit mandates for requirements maintenance, change management authority, and accountability for specification currency
- Establish regular review and update cycles (annually or bi-annually) aligned with national guideline revision processes, bringing together clinical programme managers, digital health

units, and implementation partners to assess specification adequacy and incorporate lessons from deployment experience

- Develop standardised change management protocols defining how requirements updates are proposed, evaluated, approved, and communicated to vendor partners and implementation teams, ensuring controlled evolution rather than ad hoc modifications

7 Conclusion

This evaluation examined DIPC's pioneering implementation of WHO's SMART Guidelines approach across Ghana, Sierra Leone, and Malawi, assessing relevance, implementation processes, and sustainability prospects. The evaluation identifies a consistent pattern across settings: the SMART Guidelines framework demonstrates strong methodological relevance and successfully facilitates L2 specification processes, establishing valuable institutional foundations. However, translating these foundations into operational, sustainable systems depends on contextual enablers including governance coordination, infrastructure investments, and sustained financing.

Achievements and Relevance

DIPC's piloting of the SMART Guidelines approach demonstrates strong foundational relevance to country digital health priorities. All three countries successfully completed L2 localisation, translating WHO's DAK framework-based guidance into country-owned requirements documents through structured, stakeholder-engaged processes. This achievement validates the layered methodology as a genuine advance over traditional guideline dissemination approaches. The L2 artefacts produced, comprehensive SURDs in Ghana and Malawi, validated ANC DAK in Sierra Leone, provide valuable institutional knowledge repositories that countries explicitly valued for documentation, stakeholder alignment, and implementation planning. These artefacts represent tangible outputs that survive personnel turnover and provide foundations for future development, constituting important institutionalisation achievements.

Implementation Challenges and the "Missing Middle"

However, methodological relevance for specification does not automatically translate to relevance for implementation. The evaluation identified what we characterised as the "missing middle", the gap between L2 requirements and operational systems, as a critical constraint across all settings. Developers found SURDs "too theoretical", requiring extensive facility consultation before implementation could proceed. Requirements were hard-coded into systems rather than translated through formal L3 processes. None of the three partner countries achieved operational, standards-based data exchange between systems during the project period, despite clear interoperability objectives articulated in L2 specifications.

Implementation processes validated L2 methodology effectiveness whilst exposing barriers to operationalisation. Infrastructure deficits, governance fragmentation, thin specialist capacity, and incomplete financing constrained progression beyond specification phases. As pioneering work piloting SMART Guidelines at scale, DIPC navigated largely uncharted implementation territory and generated valuable implementation insights. Programme re-programming instigated by GIZ, compressed timelines for government sensitisation and readiness assessment, yet the initiative successfully demonstrated L2 feasibility across diverse contexts whilst illuminating the systemic enablers required for progression: governance coordination mechanisms, sustained capacity building, and complete implementation cycle support extending beyond specification phases.

Context-Dependent Outcomes

The evaluation demonstrates that SMART Guidelines appropriateness varies substantially by national context. Countries exhibited different readiness profiles: some possessed technical capacity but faced governance coordination challenges; others demonstrated strong institutional commitment whilst requiring specialist skills development; infrastructure deficits and fragmented structures presented barriers in certain contexts. These differentiated contexts suggest that countries with established digital health infrastructure can plausibly progress beyond L2 with targeted support over multi-year timeframes, whilst countries with emerging capacity or fragmented systems require extended preparation and interventions addressing structural constraints alongside methodology support.

Sustainability Prospects

Sustainability prospects remain nascent and conditional. Whilst L2 artefacts provide valuable institutional documentation, no country achieved operational sustainability, i.e., domestically financed, standards-based, interoperable implementations maintained through national capacity, within DIPC's programme timescales. This finding aligns with literature documenting that successful implementations require multi-year horizons, substantially exceeding typical project cycles. The most durable outputs are institutional artefacts (e.g., DAK/SURD, interoperability requirements) and strengthened national understanding of standards-based requirements specification. However, the value of these artefacts depends on their continued relevance as contexts evolve. The evaluation found that formal mechanisms for ongoing DAK/SURD maintenance and evolution remained largely absent, highlighting that sustained impact requires not only initial specification quality but also institutionalised stewardship ensuring requirements remain current. Operational sustainability depends on concurrent achievements across multiple dimensions: sustained technical capacity, functional governance coordination, adequate infrastructure, progressive transition from donor to domestic financing, and mechanisms for ongoing requirements evolution.

Path Forward

The evaluation identifies opportunities to strengthen SMART Guidelines support based on lessons from this pioneering implementation. As the methodology continues to evolve, several areas merit attention: intermediate technical artefacts bridging specifications to developer-ready guidance; governance mechanisms for cross-system coordination; capacity building encompassing L3 competence; explicit attention to infrastructure and financing prerequisites; multi-year transition support enabling progressive country ownership; and stewardship processes ensuring requirements evolution. These insights reflect the natural learning process inherent in scaling innovative approaches across diverse contexts and provide foundations for iterative refinement of implementation support models.

The DIPC experience provides valuable evidence of implementation realities in diverse LMIC contexts. As pioneering work, it demonstrates both the feasibility of L2 implementation and the substantial systemic investments required for progression to operational, sustainable systems. Whether the global health community acts on these insights with resources and resolve commensurate with SMART Guidelines' transformative ambition will determine the methodology's ultimate contribution to digital health transformation in LMICs. The foundation has been established; realising the full vision requires sustained commitment extending well beyond specification phases toward comprehensive implementation support operating over realistic multi-year timescales.

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