

Digital transformation handbook for reporting substandard and falsified medical products

World Health Organization

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Abbreviations and acronyms

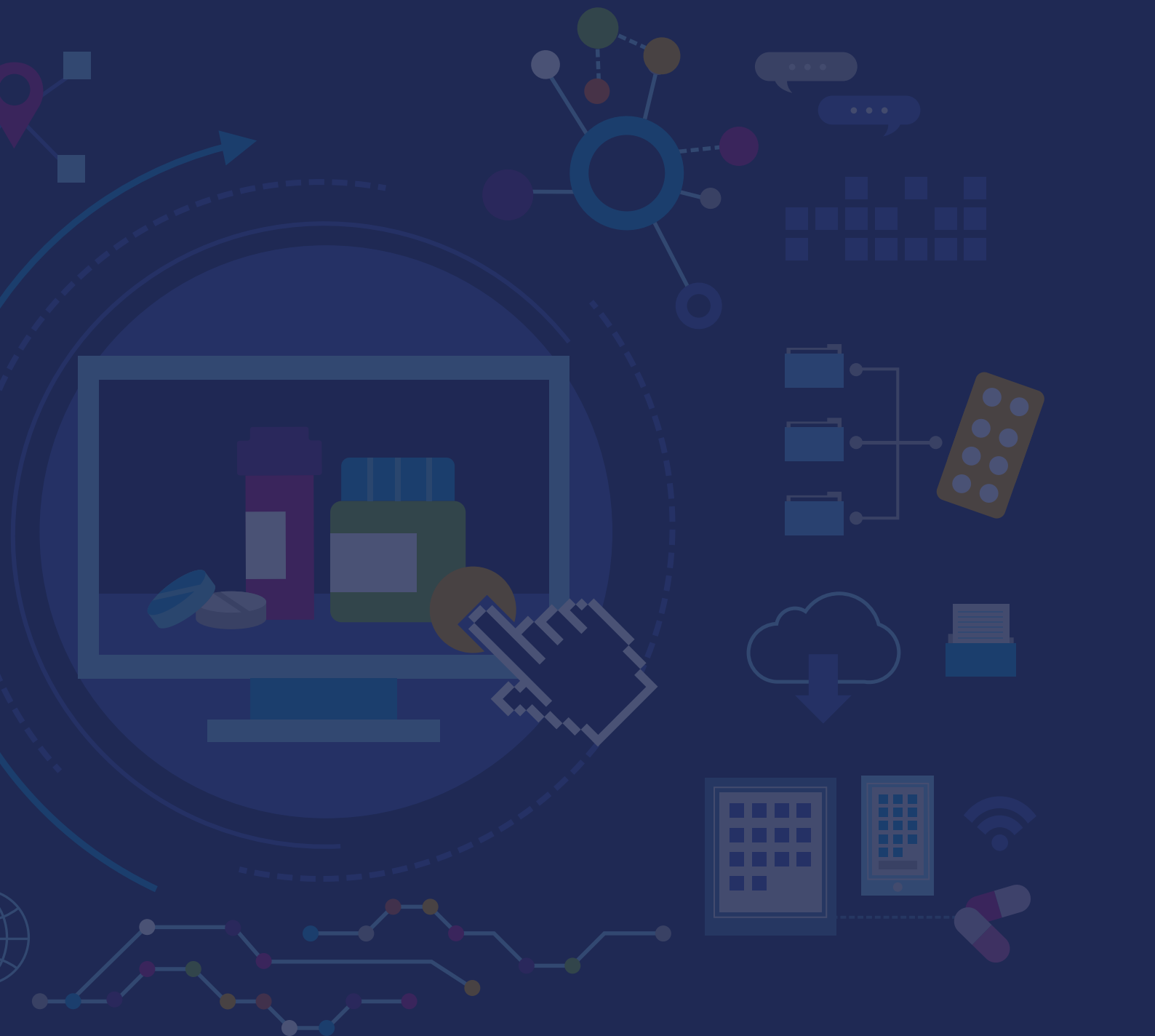
BPMN	Business Process Model and Notation
DIIG	*Digital implementation investment guide* (WHO)
FHIR	Fast Healthcare Interoperability Resources®
GSMS	Global Surveillance and Monitoring System (WHO)
HL7	Health Level Seven®
ICT	information and communication technology
ID	identity/identification/identifier
ITU	International Telecommunication Union
LMICs	low- and middle-income countries
M&E	monitoring and evaluation
NMRA	national medicines regulatory authority
PMS	post-market surveillance
RACI	responsible, accountable, consulted, informed
Rb-PMS	risk-based post-market surveillance
SaaS	software as a service
SMART	standards-based, machine-readable, adaptive, requirements-based and testable
UAT	user acceptance testing
UHF	United Health Futures
WHO	World Health Organization

Glossary

Active pharmacovigilance	Proactive measures that are taken to detect adverse events *(1)*.
Adverse drug reactions	Harmful, unintended reactions to medicines that occur at doses normally used for treatment *(2)*.
Business process	A set of related activities or tasks performed together to achieve the objectives of the health programme area, such as registration, counselling and referrals *(3)*.
Data element	A unit of data that has a specific and precise meaning *(4)*.
Digitization	The process of converting and organizing data from paper records into a digital format for easier entry, storage and retrieval. Digitization is the initial step towards digital transformation *(5, 6)*.
Digitalization	The process of digitally automating and simplifying processes to streamline individual health programmes and reducing manual efforts for greater efficiency. Digitalization is the second step towards digital transformation *(5, 6)*.
Digital transformation	The process of digitally optimizing and driving systems-level changes by leveraging innovation, analytics and feedback mechanisms to improve person-centred health systems. Digital technologies are used to fundamentally change and improve how health services are delivered and accessed across all health programme areas *(5, 6, 7)*.
Enabling environment	Attitudes, actions, policies and practices that stimulate and support effective and efficient functioning of organizations, individuals and programmes. The enabling environment includes legal, regulatory and policy frameworks and political, sociocultural, institutional and economic factors *(3)*.
End user	People who will be using the digital system(s).
Enterprise architecture	A blueprint of business processes, data, systems and technologies used to help implementers design increasingly complex systems to support the workflow and roles of people in a large enterprise, such as a health system *(3)*.
Evaluation	The systematic and objective assessment of an ongoing or completed intervention with the aim of determining the fulfilment of objectives, efficiency, effectiveness, impact and sustainability *(8)*.
Falsified medical products	Medical products that deliberately or fraudulently misrepresent their identity, composition or source. Any consideration related to intellectual property rights does not fall within this definition. Such deliberate or fraudulent misrepresentation refers to any substitution, adulteration or reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product *(9)*.
Features	The characteristics of your system that include look and feel as well as what the system can do (e.g. “approval workflow” can be a feature of a product master data management solution).
Functional requirements	Capabilities the system must have to meet the end users’ needs and achieve tasks within the business process.

Generic product or product information	In this handbook, the terms "generic product", "product" or "product information" pertain to the general identifying details of a health product, excluding any manufacturer-specific information.
Health care professional	An individual who provides health care treatment and advice based on formal training and experience. This includes a wide range of occupations such as doctors, nurses, pharmacists and other allied health professionals *(10).*
Interoperability	Ability of different applications to access, exchange, integrate and use data in a coordinated and consistent manner through the use of shared application interfaces, value sets, concepts and standards, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize health outcomes.
Member State Mechanism (MSM)	A mechanism established by WHO to address the issue of tackling substandard and falsified medical products in a transparent and inclusive way, from a public health perspective and expressly excluding considerations of intellectual property rights *(11).*
Monitoring	The continuous process of collecting and analysing data to compare how well an intervention is being implemented against expected results *(8).*
Non-functional requirements	General attributes and features of the digital system to ensure usability and overcome technical and physical constraints. Examples of non-functional requirements include the ability to work offline, multiple language settings and password protection.
Open source	Open-source software is software with source code that is published and made freely available to the public, enabling anyone to inspect, modify and enhance the code. While the source code is open to everyone, this does not mean that implementation of software is necessarily without costs. An open-source software must have a licence approved by the Open-Source Initiative *(12).*
Open standards	Standards that are documented and made freely available to the public, which are developed, approved and maintained via a collaborative and consensus-driven process. Open standards facilitate interoperability and data exchange and are intended for widespread adoption *(13).*
Organogram	A visual representation of the organization structure showing the hierarchy of various roles and their reporting relationships.
Passive pharmacovigilance	Passive surveillance that mainly involves spontaneous adverse effects reports from case series and other safety reports.
Persona	A generic aggregate description of a person involved in or benefiting from a health programme.
Pharmacovigilance	The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine-related problem *(14).*
Polypharmacy	The concurrent use of multiple medications *(15).*
Post-market surveillance (PMS)	The practice of monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market, through collection and evaluation of experiences relating to the product *(16).*
Registry	A governed, authoritative and centralized information system that captures, stores and maintains the unique attributes and identifiers of health facilities, health service users, products and/or health workforce using predefined canonical minimum data etc.

SMART Guidelines	Standards-based, Machine-readable, Adaptive, Requirements-based and Testable Guidelines are recommended digital capabilities, health and data content aligned with normative recommendations. They represent packages of comprehensive documentation and reusable digital health components (e.g. health content, interoperability standards, code libraries, algorithms, technical and operational specifications) that facilitate country adaptation and adoption of clinical and public health protocols, health systems strengthening recommendations, and data and interoperability standards into digital health information systems with fidelity. SMART Guidelines serve as a starting point and as foundational specifications to advance the development of robust person-centred digital systems. These specifications are software-agnostic, context-agnostic and are applicable to all levels of digital maturity *(17, 18).*
Substandard products	Medical products authorized by national regulatory authorities but that fail to meet either national or international quality standards or specifications or, in some cases, both *(9).*
Trade item	Products or services that are priced, ordered or invoiced at any point in the supply chain *(19).*
Unregistered	A medical product that has not undergone evaluation and/or approval by the national regulatory authority for the market in which it is marketed/ distributed or used, subject to permitted conditions under national or regional regulation and legislation. This medical product may or may not have obtained the relevant authorization from the national/regional regulatory authority of its geographical origin *(9).*
User acceptance testing (UAT)	User acceptance testing is done to see whether the end users are satisfied with the end product *(20).*
Workflow	A visual representation of the progression of activities (tasks, events, decision points) in a logical flow illustrating the interactions within the business process *(21).*



Introduction

Substandard and falsified medical products pose a multilayered threat to the stability of health systems. They endanger health, through either therapeutic failure or adverse effects, and they undermine public trust in health care. They also risk jeopardizing global efforts working to suppress antimicrobial resistance, threatening the long-term efficacy of key life-saving medicines. Further to their impacts on health, substandard and falsified medical products have adverse socioeconomic consequences and increase poverty by damaging individual productivity, income and social mobility. These factors lead to wasted resources and increased out-of-pocket spending. Economic losses compound the health impacts of substandard and falsified medical products, completing a downward spiral of negative effects *(22).*

WHO and Member States have agreed on the following definitions *(23):*

> "Substandard medical products", also called "out-of-specification", are authorized medical products that fail to meet either their quality standards or their specifications, or both.
>
> "Falsified medical products" deliberately and or fraudulently misrepresent their identity, composition or source.

With globalization, opportunities for substandard and falsified medical products to enter the market and formal supply chain are increasing. A 2017 estimate, based on multiple studies over the previous decade, suggested that one in ten medical products in low- and middle-income countries (LMICs) could be substandard and falsified *(24).* The growing complexity and online presence in supply chains further obscure the entry points of falsified products. As LMICs transition to universal health coverage, the demand for medicines from public sector and insured patients increases *(25).* In some cases, government procurement measures aim to contain costs and reduce medicine prices by procuring medicines at higher volumes *(26).* Reduced prices due to higher volume spending (i.e. restricted pricing) negatively affect the incentives of pharmaceutical companies, which may lead to cost-cutting and underinvestment in quality assurance, increasing the risk of substandard products; or encouraging companies to withdraw from the market, providing opportunities for falsifiers to enter *(26).*

Detection of these products in circulation is one of the key steps required to reduce their prevalence. However, most substandard and falsified medical products can only be identified by professionals with the use of laboratory technologies *(27).* In cases where resources are limited, and technology is not widespread, risk-based post-market surveillance (Rb-PMS) of medical products becomes essential for identifying suspect products. Unlike conventional post-market surveillance (PMS), Rb-PMS focuses on prioritizing and allocating resources based on the level of risk associated with products. Once identified, these products can be further investigated by national medicines regulatory authorities (NMRAs), in collaboration with the police or other law enforcement agencies if there is an indication of possible criminal activity.

Reporting of substandard and falsified medical products

Reporting suspected substandard and falsified medical products allows NMRAs to investigate them more thoroughly than the reporter. When a case of a substandard and falsified medical product is confirmed, relevant authorities can quickly remove the product from the supply chain and market, impose sanctions and address system weaknesses. In the long term, this should improve product quality and reduce the chances of substandard and falsified medical products entering the market *(27).*

In addition to reducing prevalence at a national level, NMRAs can report data on substandard and falsified medical products to WHO's case reporting system for substandard and falsified medical products – the WHO Global Surveillance and Monitoring System (GSMS) – to facilitate global action on the issue. Effective global coordination against these products requires high-quality and frequent reporting and data exchange.

Health care professionals can play an important role in reporting products they suspect of being ineffective or defective, in turn increasing the capacity of NMRAs to successfully identify substandard and falsified products. Health care professionals are ideally placed to notice suspicious products as they are at the frontline of health care and able to spot therapeutic failure

or adverse effects. They are also familiar with the appearance and effects of genuine medical products. Data from the GSMS indicate that many of the most serious cases were first reported by health care professionals. However, the data also showed that medical doctors, nurses and midwives are less likely to report their suspicions compared with other stakeholders *(28).*

Currently, many countries rely on paper-based reporting systems for identifying substandard and falsified medical products. While these systems can be effective, the manual nature of reporting often discourages busy health care professionals from participating. Additionally, the inconsistencies between data provided by various paper reporting procedures can lead to significant issues at the regulatory level, as the submitted data are often not standardized. In some countries, there are no formal reporting systems in place, leading to reliance on verbal recounts of suspect products *(27).*

This underscores the critical need for adopting standards-based digital solutions to support and improve the reporting of substandard and falsified medical products. Digital reporting systems, such as smartphone applications, streamline the process, making it more accessible and efficient for health care professionals. For instance, in a pilot project coordinated by WHO, smartphone applications for reporting substandard and falsified medical products were developed and successfully implemented in Indonesia and the United Republic of Tanzania *(27, 28).* These digital tools not only facilitate more consistent and standardized data collection but also enhance the overall capacity of regulatory authorities to monitor and address the prevalence of substandard and falsified medical products effectively.

Who this handbook is for

This handbook has been developed for countries, organizations and teams seeking to plan and implement digital solutions for reporting substandard and falsified medical products by health care professionals and aims to provide guidance to the various target audiences across the different implementation phases and areas, as outlined in Table 1.

Table 1. Intended audience for the handbook

Handbook section – phases	Illustrative target organizations	Illustrative target user teams and roles	Purpose of the section
1. Assess the current state and enabling environment	Ministry of health NMRA Digital health departments	Senior management/ leaders Technical/systems team Regulatory/monitoring/ pharmacovigilance teams	To help assess the current situation. This includes identifying existing barriers to reporting, assessing the current digital landscape and readiness and reviewing the current procedures and policies that will inform the digital solution.
2. Establish a shared understanding and governance framework	Ministry of health NMRA Digital health departments Other stakeholders such as funders and implementation partners, medical product industry representatives, health care professional associations	Senior management/ leaders Regulatory/monitoring/ pharmacovigilance teams Health care professional association representatives	To help define goals and establish leadership and governance framework. This outlines the importance of fostering cooperation among stakeholders, setting clear objectives and developing a strategic plan that aligns with national digital health strategies.
3. Define the future state	Ministry of health NMRA Digital health departments Other stakeholders such as funders and implementation partners, medical product industry representatives, health care professional associations	Senior management/ leaders Regulatory staff Technical/enterprise architects and team Regulatory/monitoring/ pharmacovigilance teams Health care professional association representatives	To provide guidance on developing an investment roadmap and aligning the reporting application with a holistic enterprise architecture.
4. Determine the requirements	Ministry of health NMRA Digital health departments Other stakeholders such as funders and implementation partners	Technical/enterprise architects and team Regulatory/monitoring/ pharmacovigilance teams	To help define the reporting application's functional and non-functional requirements, based on user scenarios.

Handbook section – phases	Illustrative target organizations	Illustrative target user teams and roles	Purpose of the section
5. Plan the implementation	Ministry of health NMRA Digital health departments	Project managers Technical/system/ enterprise architects and team	To provide guidance on developing a comprehensive plan and budget to implement the substandard and falsified reporting application.
6. Monitor, evaluate and scale	Ministry of health National regulatory authority Implementation partners	Technical team Regulatory/monitoring/ pharmacovigilance teams	To help develop a framework for monitoring and evaluation (M&E) of the performance and effectiveness of the substandard and falsified reporting application.
7. Share implementation experiences	Ministry of health National regulatory authority Implementation partners	All: Senior management/ leaders Technical/systems team Regulatory/monitoring/ pharmacovigilance teams Health care professional association representatives Regulatory staff Technical/enterprise architects and team Project managers	To share real-world implementation experiences and lessons learned.

How to use this handbook

This handbook provides guidance to countries on how to adopt digital solutions for reporting of substandard and falsified medical products. It outlines various steps to ensure a comprehensive approach that aligns with existing digital health guidance and other intersecting strategies and architectures.

This handbook can be a useful resource in the following scenarios:

- When moving from a paper-only based reporting system to a digital reporting system.
- When moving to a unified digital solution and approach, e.g. when there are some groups of health care professionals using paper-based systems while others using digital systems.
- When combining isolated digital reporting systems to create a complete, connected and interoperable digital reporting system.
- When evaluating existing digital solutions for enhancement to support reporting of substandard and falsified medical products.

Before using this resource

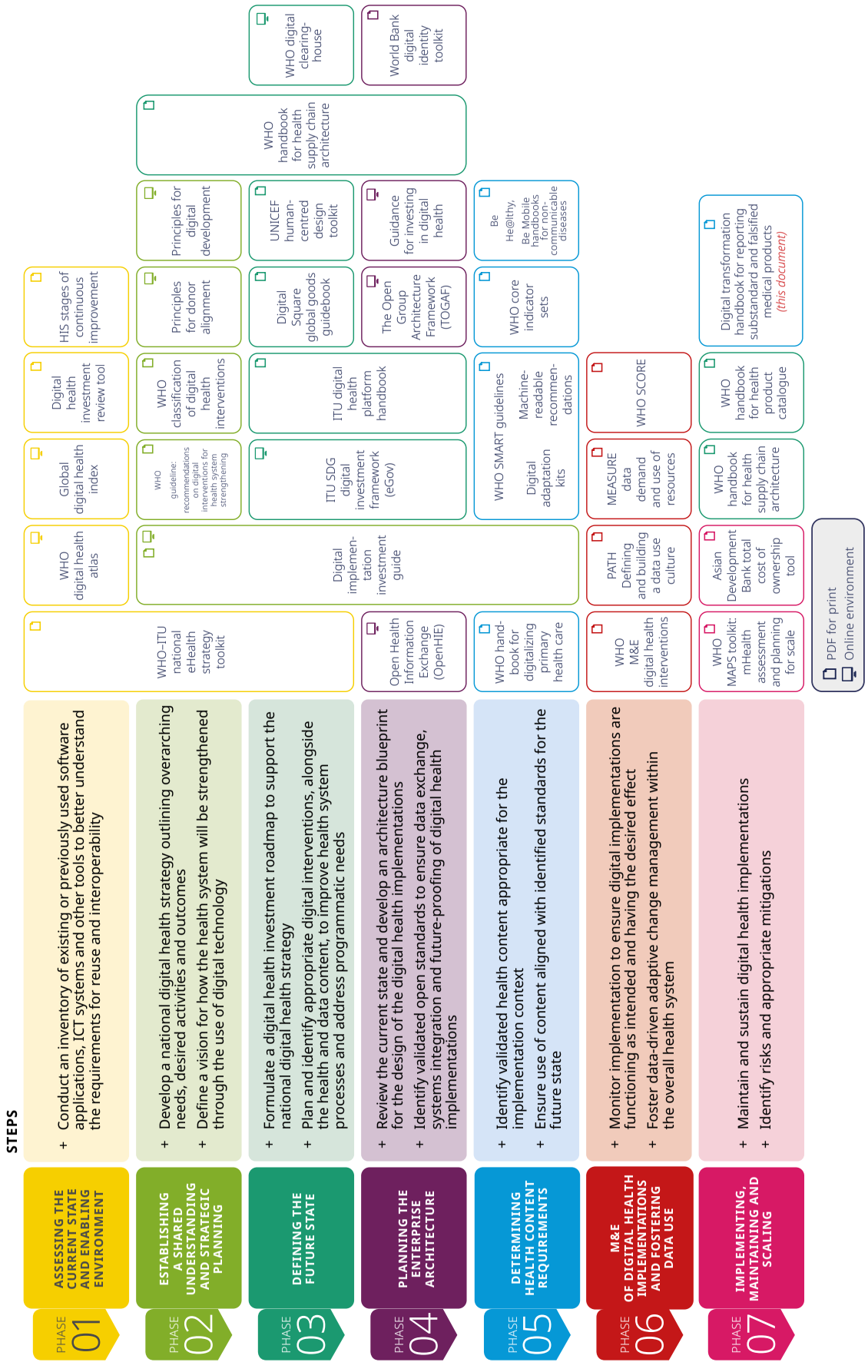
The key assumption for users of this resource is that a comprehensive digital health strategy exists. In addition, it would be beneficial to have a comprehensive digital health supply chain strategy that aligns with the digital health strategy.

If there are no national digital health and supply chain strategies, refer to the *National eHealth strategy toolkit* produced jointly by WHO and the International Telecommunications Union (ITU) *(29),* the *Global strategy on digital health 2020–2025 (30)* (which has been extended to 2027 during the Seventy-eighth World Health Assembly) and the *Digital transformation handbook for health supply chain architecture (31).* Additionally, the *SDG digital investment framework* developed by ITU and the Digital Impact Alliance provides more guidance on developing a digital health architecture that leverages a whole-of-government approach and digital public goods *(32).*

These are many other resources for implementing digital health interventions and systems available from WHO, other United Nations agencies and numerous nongovernmental organizations (see Fig. 1).

This handbook uses the framework and approaches set forth in the *Digital implementation investment guide (DIIG),* which helps governments and technical partners plan a digital health intervention *(3).*

Fig. 1. Planning and implementing a digital health enterprise: phases, steps and resources



Source: Digital implementation investment guide (DIIG) (WHO; 2020) *(3)*.

This handbook also aligns with WHO's SMART Guidelines Initiative. SMART Guidelines are Standards-based, Machine-readable, Adaptive, Requirements-based and Testable recommended digital capabilities, health and data content aligned with normative recommendations *(17).* SMART Guidelines are WHO's approach to systematize and accelerate the consistent application of recommended, life-saving interventions in the digital age.

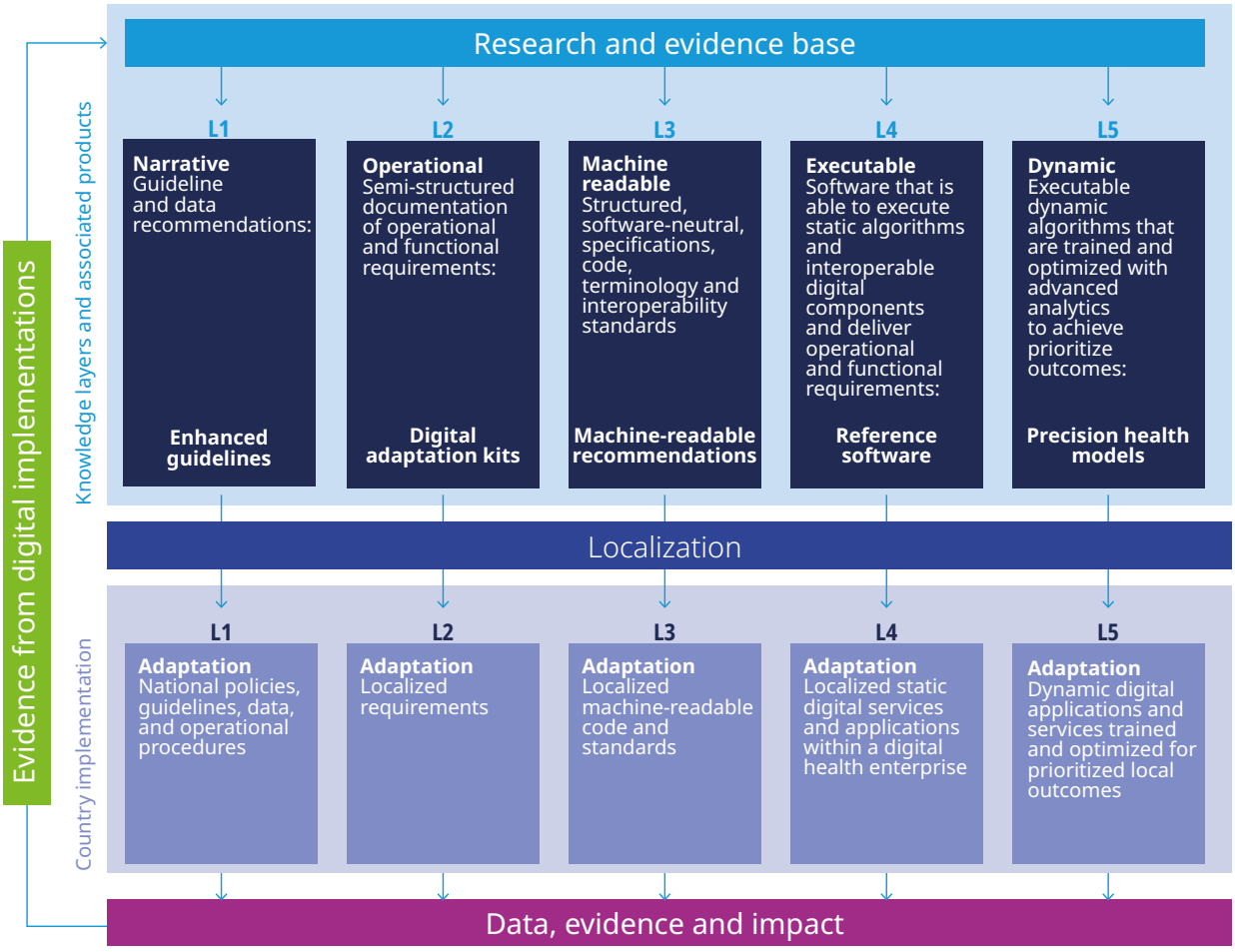
SMART Guidelines are a comprehensive set of reusable digital health components which provide a five-step pathway, with each layer increasing in complexity, to advance the adoption of best clinical and data practices. The five knowledge layers comprise:

- L1 Narrative: enhanced clinical, public health guidelines and data recommendations
- L2 Operational: digital adaptation kits (DAKs)
- L3 Machine readable: machine-readable recommendations
- L4 Executable: reference applications and services
- L5 Dynamic: precision health model.

These layers inform developers how to translate recommendations into specifications and standards; technologists how to integrate recommendations into updatable digital systems; and countries how to localize, make interoperable, institutionalize and update digital systems consistent with evidence-based recommendations *(17).* Each layer can be adapted and localized within the country context (Fig. 2).

This handbook, following SMART Guidelines, offers guidance on L1 and L2 for adapting guidelines to implement a digital solution for reporting substandard and falsified medical products.

Fig. 2. WHO's SMART Guidelines approach



Source: WHO SMART guidelines: optimising country-level use of guideline recommendations in the digital age (Mehl et al., 2021) *(18).*

How this handbook was developed

This handbook draws on the knowledge of health care professionals and NMRAs globally and has collated the lessons learned from their experiences. It builds on insights from a pilot phase, benchmarking exercises with national authorities, consultations with Member States on substandard and falsified medical product reporting barriers, public feedback on a drafted version of the handbook and the latest round of consultations for this final product. Practical examples and templates were also informed by real-world implementation of substandard and falsified medical product reporting tools in Indonesia and the United Republic of Tanzania.

The steps outlined in this handbook are also informed by the Principles for Digital Development (Annex 1). Some methodologies and templates have been adopted from prominent sources such as the *Digital implementation investment guide (DIIG) (3)* and WHO/ITU *National eHealth strategy toolkit (29)*.

1. Assess the current state and enabling environment



A comprehensive assessment of the current state and the enabling environment is necessary before implementing a digital reporting system for substandard and falsified medical products. This chapter outlines the areas that should be analysed and the factors to consider. The inputs needed to inform this step and the anticipated outputs of this phase are listed below.

Inputs

- National health strategy, digital health strategy and architecture blueprint
- National health, data and other applicable policies applicable to substandard and falsified medical products
- Standard operating procedures for reporting substandard and falsified medical products
- List of existing and planned digital and paper reporting systems for substandard and falsified medical products
- Metrics on reporting such as reporting rates
- List of stakeholders
- List of existing digital health and supply chain systems

Outputs

- Situational analysis report, including digital systems landscape analysis
- Stakeholder matrix

Resources (see page 50)

- *Global digital health monitor*
- *HIS stages of continuous improvement toolkit*
- *Supply chain information system maturity model*
- *Digital transformation handbook for health supply chain architecture*

1.1 Analyse key stakeholders

To implement an effective digital substandard and falsified reporting solution, it is essential to identify and analyse stakeholders. Stakeholders include government officials, health care providers, funding organizations, the medical product industry, technology vendors and implementers, civil society and other partners. The analysis should outline their roles in substandard and falsified medical products, pharmacovigilance and digital health. It should help mobilize support and engage key players by examining responsibilities, information flows and power dynamics. Consultations with NMRAs, ministries of health, civil society, industry associations, health care professional associations, funders and other relevant partners are valuable to ensure a comprehensive analysis.

Creating a stakeholder matrix to outline responsibilities, interests and influence will help in better coordination and expectation management. The sample questions provided in Table 2 facilitate comprehensive stakeholder analysis across various dimensions. See the RACI (responsible, accountable, consulted, informed) matrix example (Annex 4).

1.2 Assess the digital readiness

Different levels of preparedness for deploying digital technologies will influence the design, implementation and adoption of reporting apps. As one of the first steps, a digital readiness assessment should be conducted to ensure solutions are tailored to the existing infrastructure, capacity and context. The outputs from the assessment should inform the necessary resources, enabling environment, budget and funding support for planning, implementation and operationalization of the substandard and falsified reporting system.

The following areas should be reviewed to assess the country's digital readiness.

- **National digital health strategy.** Review the country's national digital health strategy as well as the corresponding digital health

Table 2. Stakeholder analysis: sample questions

Roles and responsibilities 	What is this stakeholder's current role in managing or reporting substandard and falsified medical products? How does this stakeholder contribute to pharmacovigilance or digital health efforts? What decisions can this stakeholder make regarding digital substandard and falsified reporting systems? Are they implementers, advisors, funders, regulators or end users?
Information flows and interactions 	What data does this stakeholder generate, use or depend on related to substandard and falsified products? Who do they share this information with, and how frequently? Are there any existing digital platforms or tools they use that must integrate with the substandard and falsified reporting system?
Influence and power 	How much influence does this stakeholder have over policy, funding or system design decisions? Can this stakeholder help or hinder the adoption of the digital reporting system? Who do they influence or rely on for decision-making?
Interests and expectations 	What are this stakeholder's main concerns or interests in relation to substandard and falsified reporting? What outcomes would they expect or value from this system? Are there any incentives or risks for them in engaging with this initiative?
Engagement and collaboration 	Have they been engaged in similar initiatives before? If so, what worked well or poorly? What is the best way to engage them – technical working groups, one-on-one meetings, formal memoranda of understanding? Are there any other partners or intermediaries they trust and collaborate with?
Capacity and resources 	Does this stakeholder have the technical, financial or human resource capacity to contribute to or implement the system? Will they need support, training or tools to fulfil their responsibilities?

architecture blueprint, implementation plan and supporting budget, if available. A country's digital health strategy is a key pillar in identifying, prioritizing and addressing barriers and enablers for digital health. If there is no specific digital health strategy, there may be a health or medical information policy that addresses digital health information, or regional WHO strategies which can be adopted. The *Global digital health monitor (33)*, for example, is a tool which can be used to assess the progress on preparedness and adoption of digital health.

- **Understand the enabling policy and regulatory environment.** Identify existing digital health and regulatory policies that support the deployment of digital applications, in particular, digital reporting applications. These policies provide the foundation for implementation and ensure compliance with national digital health standards. Furthermore, determining the leadership and political priorities that align with or support the implementation is essential, as strong leadership and political will can significantly drive the success of digital health initiatives.
- **Digital health governance framework.** The presence of an existing digital health governance framework should also be assessed. If it exists, it can provide structured guidance and support for implementation, fostering an environment of accountability and efficiency.
- **Human resources.** Evaluating the human resource capacity, including the skills and expertise of health care professionals and other stakeholders, is vital. Adequate training and capacity-building efforts will need to be put in place to ensure that the workforce can effectively utilize and maintain the digital reporting systems.
- **Technology infrastructure.** Perform a comprehensive evaluation of network coverage, data connectivity, electricity availability, and the required devices such as desktops, smartphones and other hardware. This assessment should determine network coverage across the entire country, including regional, rural and remote areas, while identifying any potential challenges.
- **Security and privacy protection.** Conduct an evaluation of the operational and governance requirements for security, privacy, data ownership and stewardship within the country.

See Table 3 for sample questions to support this evaluation. Evaluate legal and regulatory frameworks to ensure secure handling and sharing of sensitive data, including patient information and proprietary commercial data.

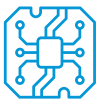
The results of the assessment should inform planning necessary investments during implementation and operation stages.

1.3 Assess current substandard and falsified reporting practices

Current practices. Conduct an analysis of current practices, challenges and barriers faced in reporting substandard and falsified medical products. The outputs of the analysis should be used to develop optimal business processes and workflows within the application. It is important to examine substandard and falsified reporting procedures and their challenges, alongside pharmacovigilance procedures to identify potential opportunities for synergy. The integration of these processes can enhance their mutual effectiveness in reporting. As part of this analysis key pharmacovigilance structures, systems, procedures and mechanisms within the country should be identified. This could include the existence of basic infrastructure to enable pharmacovigilance operations and reporting, policy and regulatory frameworks, and the collection, analysis and evaluation of adverse drug reactions.

- **Data collection tools.** Evaluate the current data collection tools and processes for pharmacovigilance and substandard and falsified medical products reporting. This typically involves a reporting form that gathers all essential information on a suspected adverse drug reaction or substandard and falsified medical product. Various tools are used to deploy these reporting forms across countries, including electronic or digital forms (such as applications or web-based forms), paper-based forms or a combination of both.
- **Digital tools.** Conduct a landscape analysis to identify existing or previously used software applications and other tools related to medical products or similar use (e.g. pharmacovigilance reporting tools) as well as related digital technologies. Identify current registry systems such as product registry and facility registry and if an interoperability layer exists. This inventory aids in identifying opportunities for reuse of existing applications and the required interoperability across systems. In some countries digital tools may already be in use for pharmacovigilance activities. **If digital tools are already in use for pharmacovigilance reporting, it is advantageous to incorporate substandard and falsified reporting into existing pharmacovigilance applications.** Assess how the tools are currently utilized, including the information flow from the receipt of the report to the integration of the data into global databases and the sequence of this process. This aspect is as crucial as

Table 3. Assessing the technology infrastructure

Assessing network coverage, connectivity and electricity 	Obtain or calculate the World Economic Forum Network Readiness Score. Obtain the availability of electricity at the facility level, including the availability for 8 hours a day. Obtain the percentage of health care facilities with internet access. Obtain the number of mobile phone users per health care facility.
Guiding questions 	What is the affordability and quality of internet across the country, especially in urban versus rural areas? Do they vary across provinces or regions? Do the existing 3G and 4G stations sufficiently cover the population? What is the number of mobile broadband users and internet subscriptions? Does the prevalence of smartphones exceed access to computers with wired internet connections?
Hardware and software availability 	Obtain the proportion of health care facilities with functioning and accessible mobile devices. Assess in-country data storage centres, servers or cloud-based storage availability. Explore the national hardware inventory. Explore the inventory of systems and platforms. Explore penetration of computers and high-speed internet, mobile phones and other smart devices in health care facilities and the general public.
Infrastructure 	What national, state and regional computing infrastructure exists across the country, including components such as server farms, data centres, support systems and personnel, etc.? Can existing infrastructure components scale up to support broader national use? Have there been large-scale e-health or other information and communication technology (ICT) infrastructure projects that have failed or stalled? If so, what were the primary reasons?
Security 	Are there robust cybersecurity measures in place to protect digital infrastructure, systems and data? Is there a comprehensive incident response plan in case of security breaches? Are regular security audits conducted to identify vulnerabilities and mitigate risks? Are there laws and regulations in place to address cybercrime and protect against unauthorized access?
Privacy 	Are there legal frameworks and regulations in place to safeguard individuals' privacy rights? Is there awareness among citizens about their privacy rights and how their data are being used? Are organizations required to obtain consent before collecting and processing personal data? Is there a designated authority responsible for overseeing privacy-related issues?
Data ownership 	Are there clear laws and regulations defining data ownership rights? Do individuals have control over their personal data and the ability to access, modify or delete it? Are there mechanisms in place to ensure organizations do not unlawfully claim ownership of user-generated data? Are there guidelines for data sharing and collaboration between different entities while respecting data ownership?

confirming the existence of a data collection tool, as it ensures that any collected data are fully utilized and provided to the relevant organizations. Sample questions to support this evaluation are provided in Table 4.

Consider using the *Classification of digital health interventions v1.0 (34)* to systematically categorize the digital solutions as part of the landscape analysis. See Annex 5 for a template for listing existing software applications.

Barriers. Understanding the barriers to reporting substandard and falsified medical products is crucial for the effective implementation of reporting systems. Identify these barriers and understand the reasons behind them. This ensures that the design and deployment of reporting tools are tailored to meet the needs of NMRAs, health care professionals and other stakeholders. This understanding is vital for creating a robust and efficient reporting system that can mitigate the challenges faced by users, thereby enhancing the overall effectiveness of the reporting process. Various potential barriers are outlined in Table 5 along with potential solutions that can be considered and evaluated within the country context when developing the reporting solution. Further analysis of barriers is provided in Annex 6.

Table 4. Assessing current substandard and falsified reporting practices

Assessing data collection for pharmacovigilance 	Confirm whether there is a standard adverse drug reaction reporting form in your country. Confirm whether there is a standard adverse drug reaction reporting form available to the general public. If there is a form, identify whether it contains relevant fields to report suspected medication errors. Identify whether there are relevant fields to report suspected substandard and falsified medical products. Identify whether there are relevant fields to report therapeutic failure or inefficacy.
Assessing data collection for substandard and falsified medicines 	Confirm whether there is a standard reporting form for substandard and falsified medical products used in your country, and whether it is independent of the standard adverse drug reaction reporting form. If there is a reporting form present, document the data fields. These could include: • product name • product type • registration or marketing authorization number • manufacturer • expiry date • adverse reaction reported or harm caused • outcome of adverse reaction • estimated number of patients affected • option to upload a photo if form is digital.
Guiding questions to explore data usage 	Is there a process in place for collection, recording and analysis of adverse drug reaction reports? • Does an information flow chain exist including causality assessments, feedback to reporters and an electronic database? • Are adverse drug reaction reports flowing into global databases (e.g. Vigilance hub, Vigiflow and Vigibase)? • What percentage of reports deemed satisfactory and submitted to the national pharmacovigilance centre were passed into global databases? Is there a process in place for collection, recording and analysis of substandard and falsified medical product reports? • Does an information flow chain exist including feedback for reporters and an electronic database? • Are reports of substandard and falsified medical products flowing into global databases (for example, the GSMS)?

Table 5. Common challenges and barriers to substandard and falsified reporting and potential solutions

Category	Challenges and barriers	Potential solutions
Health care professional capacity	Health care professionals overburdened with work Time constraints Fear of repercussions	Integrating app into existing workflow Automating data capture Minimizing manual data entry Reducing data requirements to the minimum needed for further analysis Protect the identity of reporter
Regulatory support	Under-resourced NMRAs Lack of legal authority Lack of trained personnel	Designing features for report processing, follow-up and feedback Providing training and resources Integrating NMRA feedback Legislating need for reporting by health care professionals
Health care system practices	Polypharmacy, the use of multiple medicines by one patient, preventing health care professionals from pinpointing the effects of individual medicines Lack of continuity of care	While polypharmacy and lack of continuity of care are beyond the scope of reporting technology, the digital solution can be designed to account for these challenges by: • providing detailed guidance on how to report suspect products in the context of polypharmacy • designing the solution to be flexible and adaptable to different health care settings
Economic factors	Economic and reputational damage for suppliers of having to recall medical products Cost of internet access and data	Providing offline reporting options that can sync online when on Wi-Fi network Providing financial incentives for reporting
Social factors	Fear of reporting due to reputational, professional or personal reasons Fear of legal consequences	Providing options for anonymous reporting[a] Incorporating regulatory and legal protection as part of reporting and investigative processes
Education	Lack of awareness substandard and falsified medical products and how to recognize them	Integrating guidance on substandard and falsified medical products detection within the reporting application
Technology	Lack of digitalization of the reporting process, requiring health care professionals to use lengthy or paper-based reporting systems Lack of, or limited, connectivity	A user-friendly reporting solution that is intuitive and appropriately automated Providing offline reporting options that can sync online when on Wi-Fi network

Notes: [a] Anonymizing the reporting of suspected substandard and falsified medical products is highly valuable because it encourages more reports by reducing fear of legal, professional or personal repercussions. It protects vulnerable individuals, such as health care professionals, patients or whistleblowers, particularly in environments where retaliation is a risk. Anonymity also helps focus investigations on the evidence rather than the identity of the reporter, building public trust in the reporting system. However, challenges include difficulties in following up for more details, assessing credibility and managing potential false reports.

End of chapter checklist

After finishing the steps outlined in this chapter, there should be a comprehensive current state analysis of the key stakeholders including:

- ☐ Digital readiness
- ☐ Enabling environment
- ☐ Technology infrastructure
- ☐ Current reporting procedures
- ☐ Barriers to reporting



2. Establish a shared understanding and governance framework



Implementing digital reporting systems requires more than just technology. It calls for a clear, strategic and participatory approach that aligns regulatory policy, governance and leadership. This section explores how countries can establish a shared understanding of the challenges and opportunities surrounding substandard and falsified medical products and create a strategic plan to ensure sustainable, effective adoption of digital health tools.

Inputs

- Current state analysis report
- Stakeholder matrix
- Existing regulatory policies on substandard and falsified medical products

Outputs

- New and/or amended regulatory policies on substandard and falsified medical products
- Governance structures and mechanisms updated and/or established
- Strategic goals for reporting of substandard and falsified medical products

Resources (see page 50)

- *Digital implementation investment guide (DIIG)*
- *Digital transformation handbook for health supply chain architecture*
- *Digital transformation handbook for health product catalogue*
- *WHO global benchmarking tools*
- *WHO Global Surveillance and Monitoring System*

2.1 Review regulatory policies for substandard and falsified medical products reporting

The regulatory framework is the backbone for any substandard and falsified medical products reporting system, shaping data flow, privacy, liability and enforcement mechanisms. Before implementing a digital reporting system, countries should evaluate existing regulatory policies, identify gaps and determine whether new regulations or legislative amendments are necessary to support the implementation, operationalization and adoption.

- **Pharmacovigilance and quality surveillance integration.** Substandard and falsified medicines reporting often intersects with pharmacovigilance systems. Harmonize regulations and encourage cross-functional use of data to foster a more holistic approach to medicine safety and quality.
- **Reporting obligations.** Clarify which entities – retailers, health care workers, customs, law enforcement, manufacturers, distributors, health facilities – are *required* to report. Establish timelines and processes for mandatory or voluntary submissions.
- **Enforcement mechanisms.** Ensure that regulatory authorities have the legal mandate and capacity to act on digital reports by conducting timely investigations, imposing sanctions or initiating withdrawals or recalls where necessary.

2.2 Align policy with stakeholders

Tackling substandard and falsified medical products requires more than a single institution. Effective policy depends on multisectoral collaboration across:

- **Law enforcement and customs.** Align policies to enable swift data sharing with customs officers and law enforcement, who often spearhead investigations and border control.
- **Health financing and procurement agencies.** Support policy coordination with procurement bodies and insurance systems to detect falsified products within supply chains or reimbursement claims.
- **Innovation and ICT ministries.** Collaborate with digital innovation and ICT agencies to integrate the reporting system with existing national eHealth strategies or digital infrastructure.
- **Regional and global regulatory authorities.** Work to harmonize regulations and support national authorities, e.g. European Medicines Agency, African Medicines Agency or WHO.

2.3 Establish governance and leadership

Establish a robust governance structure for coordinating the multiple stakeholders involved in substandard and falsified medical product reporting. Define clear roles and responsibilities to avoid duplication of effort, enhance transparency and create a stable platform for decision-making.

A governance structure often includes:

- **National steering committee.** Led by the ministry of health or NMRA, this committee provides strategic oversight, ensures alignment with national health goals and mobilizes resources. The national steering committee drives and makes key strategic decisions on substandard and falsified medical products reporting.
- **Technical working group.** Comprised of subject matter experts (e.g. medical product regulators, IT specialists, pharmacovigilance experts), working under the leadership of a steering committee, the technical working group would be responsible for the design, planning and implementation details.
- **Advisory council.** External experts, professional associations, patient advocacy groups and private sector partners can offer insights on best practices, user expectations and emerging technologies to the national steering committee and/or technical working group. However, they do not have any decision-making ability.

As part of the overall governance structure, strong leadership is critical for sustaining momentum and ensuring accountability across the following stakeholders:

- **Ministry of health/NMRA.** Responsible for providing political support and securing funding to shape regulatory policies that guide digital reporting and data governance.
- **Project champion.** Typically, a high-level official or recognized expert who can advocate for the project across government and partners. They engage health care professional associations, civil society and private sector players such as manufacturers and distributors and are responsible for mobilizing stakeholders to obtain buy-in and address policy barriers.
- **Digital health coordinator/project manager.** Responsible for overseeing daily implementation tasks and engaging key stakeholders. They ensure alignment with the national architectural blueprint and roadmap, maintaining quality and timeliness of deliverables. They facilitate partnerships, communication campaigns and user feedback loops.

2.4 Set the strategic goals

Define strategic goals for the substandard and falsified reporting application so that it is built to appropriately address prioritized needs. These goals should be:

- **Specific.** For instance, reduce the average detection-to-notification time for suspected substandard and falsified medical products from 14 days to 2 days.
- **Measurable.** Use indicators like the number of detected substandard and falsified incidents, time to regulatory action, or user engagement metrics in the digital reporting platform.
- **Achievable.** Align goals with available resources and capacity. Overly ambitious targets can undermine stakeholder confidence if they are continually missed.
- **Relevant.** Ensure every goal ties directly to better patient safety, stronger regulatory action or improved supply chain transparency.
- **Time-bound.** Assign deadlines or milestones to each goal (e.g. 12 months post-launch, 24 months post-launch).

2.5 Analyse and mitigate risk

Digital transformations often face multiple risks – technical, financial or political. Conduct a risk analysis early in the strategic planning process to allow for appropriate mitigation measures to be put in place. Examples of risk include:

- **Technical risks.** System failures, cybersecurity threats, interoperability challenges.
- **Financial risks.** Funding shortfalls, changes in donor priorities or excessive long-term maintenance costs.
- **Political and stakeholder risks.** Shifting government priorities, lack of stakeholder cooperation or data ownership disputes.

Annex 7 provides a template for risk management to identify, assess and prioritize these risks, creating mitigation strategies and contingency plans.

Successful digital transformation of substandard and falsified medical product reporting processes depends on collaboration, careful policy consideration and proactive governance. By taking these strategic steps, countries can lay the groundwork for an effective, sustainable digital reporting system that ultimately safeguards the quality of medicines and protects public health.

End of chapter checklist

After finishing the steps outlined in this chapter, there should be a comprehensive current state analysis of the key stakeholders including:

- ☐ New and/or amended regulatory policies on substandard and falsified medical products
- ☐ Governance structures and mechanisms established
- ☐ Strategic goals for reporting of substandard and falsified medical products



3. Define the future state



Building upon the previous sections, this section delves into the critical aspects of defining the future state for the reporting solution. In transitioning from identifying and establishing governance structures and regulatory policies, it becomes essential to strategically map out the envisioned state of digital transformation in substandard and falsified medical product reporting. This section provides guidance on defining the future state by creating an investment roadmap and aligning the solution with an enterprise architecture considering various technological factors.

Inputs

- Strategic goals for reporting of substandard and falsified medical products
- Current state analysis report

Outputs

- Digital investment roadmap for the substandard and falsified reporting solution
- Digital health enterprise architecture (new or revised)

Resources (see page 50)

- *Digital implementation investment guide (DIIG)*
- *Digital transformation handbook for health supply chain architecture*
- *Digital transformation handbook for health product catalogue*

3.1 Develop a digital investment roadmap

To ensure the successful implementation and sustainability of the substandard and falsified reporting solution, develop a structured investment roadmap detailing priorities across short-, medium- and long-term horizons, focusing on foundational infrastructure, functional enhancements and the integration of advanced technologies. The investment roadmap will help guarantee that the reporting solution remains effective, sustainable, scalable and adaptable to future health needs.

The investment roadmap for the substandard and falsified reporting solution should consider and outline clear priorities across short- (e.g. 1–2 years), medium- (e.g. 3–5 years) and long-term (e.g. 5 years and beyond) horizons.

- **Short-term.** These are the foundational elements necessary for the initial launch and basic operation of the reporting system such as data collection features and secure data storage, Without these, the system will not be functional or trustworthy.
- **Medium-term.** These features enhance the usability, analytical capabilities and interoperability of the system, making it more effective and valuable over time such as the ability to report through multiple channels – desktop, mobile, tablet – seamlessly. These are crucial for the system's growth and impact.
- **Long-term.** These priorities focus on the sustainability, adaptability and continuous improvement of the system such as advanced analytics and digitized feedback mechanisms. They ensure the system remains relevant and effective in the face of evolving challenges and technological advancements.

Priorities may, however, be set depending on factors such as available resources, the immediate needs of the stakeholders, and the specific context of the substandard and falsified medical product problem being addressed, e.g. some "medium-term" priorities may be addressed in the "short-term" depending on urgency, scope, scale and potential immediate public health impact (see Table 6).

Table 6. Short-, medium- and long-term priorities

Attribute	Short-term priority (initial implementation)	Medium-term priority (enhancement and integration)	Long-term priority (sustainability and evolution)
Core functionality and user experience			
Intuitive and user-friendly interface	X		
Multi-channel reporting	X (start with key channels like web/ mobile)	X (expand to other relevant channels)	
Offline reporting capabilities		X (crucial for accessibility in some areas)	
Structured data collection	X		
Multimedia evidence upload	X (essential for visual verification)		
Real-time notifications and alerts	X (critical for immediate action)		
Multilingual support		X (if targeting diverse populations)	
Data management and analysis			
Secure data storage and management	X (fundamental for trust and compliance)		
Centralized database	X (essential for data aggregation)		
Advanced search and filtering	X (necessary for efficient analysis)		
Data visualization and analytics		X (for identifying trends and insights)	X (refining and expanding analytical capabilities)
Integration with other systems		X (for enhanced information sharing)	X (deepening and broadening integrations)
Audit trail	X (for accountability and transparency)		
Collaboration and communication			
Role-based access control	X (essential for security and workflow)		
Communication tools		X (facilitating interaction between stakeholders)	
Feedback mechanisms		X (encouraging continued reporting)	X (improving feedback based on user needs)
Regulatory compliance and governance			
Compliance with standards	X (non-negotiable from the outset)		X (adapting to evolving regulations)
Clear reporting pathways	X (guiding users effectively)		
Data validation and verification	X (ensuring data quality)	X (improving validation rules over time)	
Scalability and maintainability			
Scalable architecture		X (planning for future growth)	X (ensuring continued scalability)
Easy maintenance and updates		X (ensuring long-term viability)	X (optimizing maintenance and update processes)
Adoption of emerging technologies			X

3.2 Link to the enterprise architecture

The DIIG provides an enterprise architecture framework for digital health interventions (Fig. 3).

> "A digital health enterprise architecture, if available in the country, outlines current and planned business processes, data, systems and technologies and provides an overview of the standards, information exchange and interoperability profiles that can be optimized across the enterprise. A clearly established enterprise architecture describing how different processes, data, systems and technologies function together is crucial for guiding interoperability to support data exchange between digital health applications, as well as collective functioning goals. An enterprise architecture blueprint lays the foundation for scaling up and sustaining digital health applications that are standardized and interoperable and that will facilitate access to higher quality, more complete information, in turn resulting in better decisions and more improved health outcomes across multiple areas." *(3)*

A digital health enterprise architecture should be developed in alignment with the DIIG framework if one has not already been developed. If a digital health enterprise architecture is already in place, it should be aligned with the DIIG framework. As shown in Fig. 3, the substandard and falsified reporting application will fall under the point of service applications category.

Linking to the digital health enterprise architecture will guide how other digital health applications interoperate with the substandard and falsified reporting application. The architecture will demonstrate how the substandard and falsified reporting application interacts with other components, such as registry services, to uniformly identify facilities, clients and products during reporting. This architecture will provide critical insights for the following key technology considerations.

Open standards and interoperability. Identify and implement validated open standards to ensure effective data exchange and interoperability of systems. Open standards will future proof the digital health implementations and promote interoperability. The enterprise architecture will help establish a standardized data exchange framework that allows for the seamless flow of information between the reporting application and the different systems and stakeholders. This will facilitate more efficient reporting and monitoring of substandard and falsified medical products.

Resources (see page 50)

- *The TOGAF® standard, tenth edition*
- *FHIR® – Fast Healthcare Interoperability Resources*

Cybersecurity and data protection. Prioritize cybersecurity and data protection in the design and implementation of the digital solution. Develop and enforce comprehensive cybersecurity policies and procedures to safeguard sensitive data. Implement robust encryption methods, access controls and regular security audits to mitigate potential risks. Ensure compliance with relevant data protection regulations and standards to maintain the privacy and security of patient information.

Resources (see page 50)

- *Cybersecurity and privacy maturity assessment and strengthening for digital health information systems*
- *Addressing future cybersecurity threats in digital health: report of the technical consultation, Geneva, Switzerland, 12-14 December 2023*

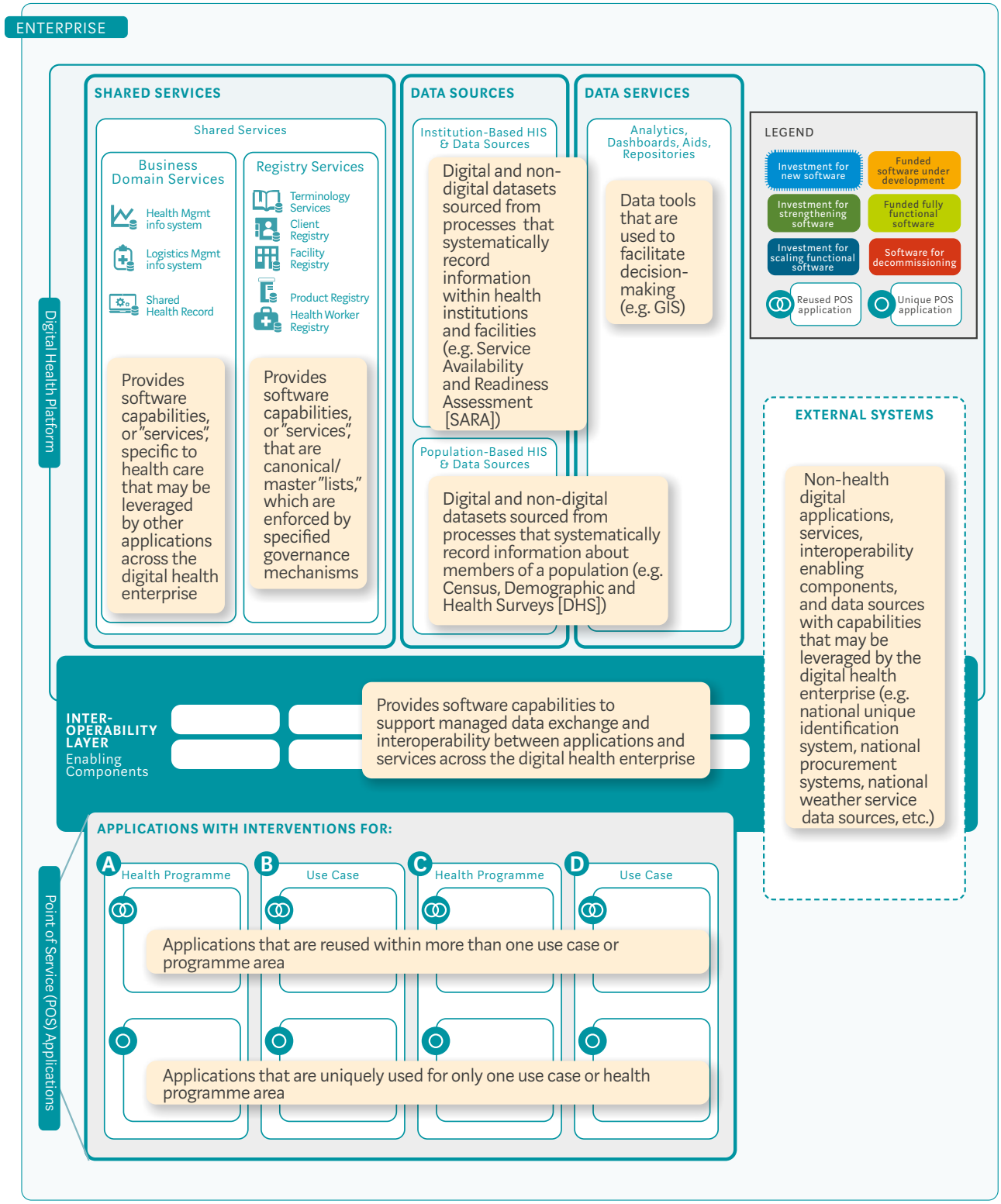
End of chapter checklist

After finishing the steps outlined in this chapter, there should be a comprehensive current state analysis of the key stakeholders including:

- ☐ Digital investment roadmap for the substandard and falsified reporting solution
- ☐ Digital health enterprise architecture that includes the substandard and falsified reporting application



Fig. 3. DIIG digital health enterprise architecture framework



Source: Digital implementation investment guide (DIIG) (WHO; 2020) *(3)*.

4. Determine the requirements



It is essential to thoroughly understand how users will engage with the system, the processes they will execute, and the data they will handle within the application before proceeding with the development and implementation of the digital reporting system. This section provides an overview of the key considerations for developing comprehensive requirements that will facilitate successful user adoption of the application.

Inputs

- National health strategy, digital health strategy and health policies and scope for the reporting application
- Health information system, privacy, security and data use policies OR new and/or amended regulatory policies on substandard and falsified medical products
- Digital health enterprise architecture blueprint and high-level requirements for meeting interoperability standards (new or revised)
- Current state analysis report including infrastructure readiness OR situational analysis report, including digital systems landscape analysis
- Standard operating procedures for reporting substandard and falsified medical products
- Existing paper forms
- End user and key stakeholder interviews and insights
- Digital investment roadmap for the substandard and falsified reporting solution
- Governance structures and mechanisms updated and/or established
- Strategic goals for reporting of substandard and falsified medical products
- Stakeholder matrix

Outputs

Documentation requirements including:

- User personas
- User scenarios
- As-is and to-be business processes
- Data dictionary
- Decision logic algorithms
- Functional and non-functional requirements
- List of indicators and calculation method

Resources (see page 50)

- *Digital implementation investment guide (DIIG)*
- *Digital adaptation kits*
- *Human-centred approach for health*
- User persona template (Annex 2)
- Key user personas (Table 7)
- Business process modelling and notation (Annex 3)
- Reference data elements (Section 4.4)
- Reference requirements (Section 4.5)

4.1 Identify user personas

Identify key user personas and related user personas. A user persona is a generic depiction of a relevant stakeholder or end user who would be interacting with the reporting system. Personas help identify the wants, needs and constraints of the end users. User personas can be based on real individuals or a fictional character that represents a combination of real individuals and stories. The closer the personas are to reality, the more likely the system will meet real needs. See Annex 2 for a user persona template.

The reporting system is primarily utilized by skilled health care professionals working within all levels of health care settings. Skilled health care professionals include:

- Doctor/medical practitioner
- Nurse
- Pharmacy technician
- Pharmacist
- Dentist
- Public health worker

See Tables 7 and 8 for examples of user personas.

4.2 Define user scenarios

Define clear user scenarios for each identified persona (see Table 9). These scenarios help translate roles into specific, practical use cases, ensuring that solutions are tailored to local workflows, digital readiness and user capacities. A good user scenario should describe the context, the user's objective, the challenges they face and how the tool addresses them. This approach supports more intuitive design, targeted training and successful adoption – leading to better data quality and programme outcomes.

Table 7. Examples of key user personas

Occupational title	Description	Different names	ISCO code
Doctor	A legally qualified and licensed practitioner of medicine, concerned with maintaining or restoring human health through the study, diagnosis and treatment of disease and injury, through the science of medicine and the applied practice of that science. A medical doctor requires training in a medical school. Depending on the jurisdiction and on the university providing the training, these may be either undergraduate or graduate-entry courses. Gaining a basic medical degree may take 5–9 years, depending on the jurisdiction and the university providing the training.	Family doctor, general practitioner, medical doctor, specialist doctor (e.g. paediatrician, pulmonologist, psychiatrist), non-specialist doctor	2211 (generalist medical practitioner) 2212 (specialist medical practitioner)
Nurse	A graduate who has been legally authorized (registered) to practise after examination by a state board of nurse examiners or similar regulatory authority. Education includes 3, 4 or more years in nursing school, and it leads to a university or postgraduate university degree, or the equivalent. A registered nurse has the full range of nursing skills.	Registered nurse, nurse practitioner, clinical nurse specialist, advance practice nurse, practice nurse, licensed nurse, diploma nurse, graduate nurse, nurse clinician	2221 (nursing professionals)

Occupational title	Description	Different names	ISCO code
Community health worker	Community health workers provide health education, referral and follow-up; case management and basic preventive health care; and home visiting services to specific communities. They provide support and assistance to clients and their families in navigating the health and social services system.	Health extension worker, community health volunteer, village health worker, treatment supporter, outreach worker, lay health worker, peer counsellor	3253 (community health workers) 3259 (health associate professionals not classified elsewhere)
Laboratory technician	A person who performs clinical tests on specimens of bodily fluids and tissues to obtain information about the health of a patient or cause of death. They use approved assays (e.g. phenotypic culture-based, line-probe assays) and operate equipment such as microscopes, polymerase chain reaction machines and flame photometers for analysis of biological material including sputum, stool, blood, urine, pleural fluid, cerebrospinal fluid and respiratory samples. This category includes occupations for which competent performance usually requires formal training in biomedical science, medical technology or a related field.	Medical laboratory technician, pathology laboratory technician, medical laboratory assistant, pathology technician, laboratory personnel, laboratory worker	3212 (medical and pathology laboratory technician)
Pharmacist	Pharmacists store, preserve, compound and dispense medicinal products. They counsel on the proper use and adverse effects of drugs and medicines following prescriptions issued by medical doctors and other health professionals. They contribute to researching, testing, preparing, prescribing and monitoring medicinal therapies for optimizing human health.	Chemist, clinical pharmacist, community pharmacist, hospital pharmacist, retail pharmacist, dispensing chemist	2262 (pharmacists)

Note: ISCO – International Standard for Classification of Occupations.

Table 8. Related user persona

Occupational title	Description	Different names	ISCO code
Individual	In the context of this document, an individual is a person who is given medical care, which may include screening, diagnosis, care or treatment services.	Patient, health service user, client, infant, child	N/A

Note: ISCO – International Standard for Classification of Occupations.

Table 9. Typical user scenario for health care professionals reporting substandard and falsified medical products

Professional	Discovery	Initial action	Accessing reporting app	Completing the report	Submitting the report	Follow-up / feedback
Pharmacist	Dispensing medication; notices discrepancies in packaging (e.g. wrong label, broken seal), unusual appearance of the drug (e.g. different colour, texture), or receives a complaint from a patient about ineffectiveness or adverse effects.	Isolates the suspect product, verifies details with the supplier/ manufacturer, if possible, advises the patient (if applicable) to consult their doctor, and checks internal pharmacy records for similar issues.	Opens the reporting app on the pharmacy computer or their secure mobile device. May need to log in with their professional credentials.	Enters product details (name, batch number, manufacturer, expiry date), describes the observed anomaly, patient details (if applicable, with consent), and any initial actions taken. May upload photos of the suspect product, uploads photos.	Reviews and submits report, receives automatic confirmation message.	Receives a notification with tracking number, from the regulatory authority acknowledging receipt of the report. May be contacted for further information or receive updates on the investigation's outcome and any public health alerts.
Doctor (general practitio-ner)	Patient presents with unexpected adverse drug reaction or a lack of therapeutic response to a prescribed medication, or reports obtaining medication from an unverified source.	Documents the patient's symptoms and medication history, considers alternative diagnoses, and discontinues the suspect medication if deemed necessary.	Accesses the reporting app via the electronic health record system on their clinic computer or uses a dedicated mobile app on their smartphone.	Provides patient details (anonymized as per regulations), medication details, describes the adverse event or lack of effect, includes any relevant lab results or clinical observations, and notes the suspected source of the substandard and falsified product.	Reviews and submits report, receives confirmation message.	Receives tracking number, status updates, and further action notifications. May receive inquiries from the regulatory authority for additional clinical information or be informed of any resulting changes in treatment guidelines or public health advisories.
Nurse	Identifies unusual patient reactions or discrepancies in medication appearance, packaging defect.	Isolates the medication, informs the prescribing doctor immediately, monitors the patient closely, and documents the observation in the patient's chart.	Opens the reporting app on the hospital's computer system or uses a handheld device with the app.	Records patient details, medication name and batch number, describes the observed issue, documents the patient's condition, and includes details of the notification made to the doctor.	Reviews and submits report, receives confirmation message.	Receives tracking number, status updates, and further action notifications. May be asked for further details by the pharmacy or regulatory authority and is informed of any corrective actions taken within the hospital.
Dentist	Notices unusual packaging or inefficacy in dental products (e.g. administers a local anaesthetic and observes an unexpected patient reaction) (e.g. inadequate anaesthesia, allergic reaction) or notices a problem with the packaging or appearance of the anaesthetic.	Manages the patient's immediate reaction, discontinues use of the suspect product, and documents the incident in the patient's dental record.	Accesses app via the practice computer or tablet, logs in.	Enters details of the anaesthetic (name, batch number), describes the patient's reaction, details any observed defects in the product, and includes the patient's relevant medical history, uploads photos.	Reviews and submits report, receives confirmation message.	Receives tracking number, status updates and further action notifications. May be contacted by the dental board or regulatory authority for more information.

Professional	Discovery	Initial action	Accessing reporting app	Completing the report	Submitting the report	Follow-up / feedback
Midwife	Administers medication during labour or postpartum and observes an unusual patient response or a defect in the medication packaging.	Stops using the suspicious product. Prioritizes patient safety, manages the patient's condition, notifies the attending doctor, and documents the incident.	Uses the reporting app on the hospital's system or a dedicated mobile app.	Records patient details, medication information, describes the observed issue and the patient's condition, and details the notification to the doctor, uploads photos.	Reviews and submits report, receives confirmation message.	Receives tracking number, status updates, and further action notifications. May be involved in follow-up investigations within the maternity unit and receives information on any changes to medication protocols.
Laboratory technician	Analysing a drug sample as part of quality control or a forensic investigation and detects inconsistencies in composition, concentration, or purity.	Documents the findings meticulously, flags the sample as suspect, and notifies the laboratory supervisor.	Accesses the reporting app on the laboratory computer system.	Provides sample details, describes the analytical findings, notes the deviations from the expected specifications, and includes any relevant chain-of-custody information, attaches test results.	Reviews and submits report, receives confirmation message.	Receives tracking number. May be involved in further testing and receives updates on any regulatory actions.
Public health worker	Investigating a disease outbreak and identifies a pattern of treatment failures or unusual adverse events associated with a particular medication in the community.	Isolates suspicious batch, collects detailed information on affected individuals, medications used, and potential sources, and reports the findings to the relevant health authorities.	Accesses the reporting app on a laptop or mobile device, potentially in the field.	Enters aggregated data on affected individuals, details the suspect medication, describes the observed pattern of events, and includes any relevant epidemiological information, uploads photos.	Reviews and submits report, receives confirmation message.	Receives tracking number, participates in follow-up investigations and receives updates on any public health interventions.
Pharmacy technician	Assists a pharmacist in dispensing medication and notices discrepancies in the physical appearance of the drug product, its packaging, or labelling.	Isolates suspicious batch, informs supervising pharmacist.	Accesses the reporting app on the pharmacy computer system under the supervision of the pharmacist.	Documents the product details, describes the observed anomaly, and notes the actions taken under the pharmacist's guidance, uploads photos.	Reviews and submits report, typically under the pharmacist's credentials or with their co-signature receives confirmation message.	Receives tracking number, status updates, and further action notifications.
Paramedic	Administers medication in an emergency setting and observes an unexpected patient reaction or a problem with the medication's packaging or appearance under difficult field conditions.	Focuses on stabilizing the patient, documents the observed issue as accurately as possible under the circumstances, and relays the information to the receiving hospital.	Uses a resilient mobile device with the reporting app, designed for use in emergency situations.	Enters essential details (medication, observed problem, patient's condition), noting the challenging circumstances of the observation.	Submits the report electronically as soon as stable connection is available.	Receives confirmation. May be contacted for further details after the emergency and receives updates on any relevant safety alerts.

4.3 Develop business processes and workflows

A business process is a set of related activities or tasks performed together to achieve specific objectives, such as reporting substandard and falsified medical products in this case *(35)*. Workflows are a visual representation of the progression of activities (tasks, interactions, decision points) that are performed within the business process *(35)*. The activities in a workflow include those that are manual and machine automated.

A business process matrix (see Table 10 for example) is useful for:

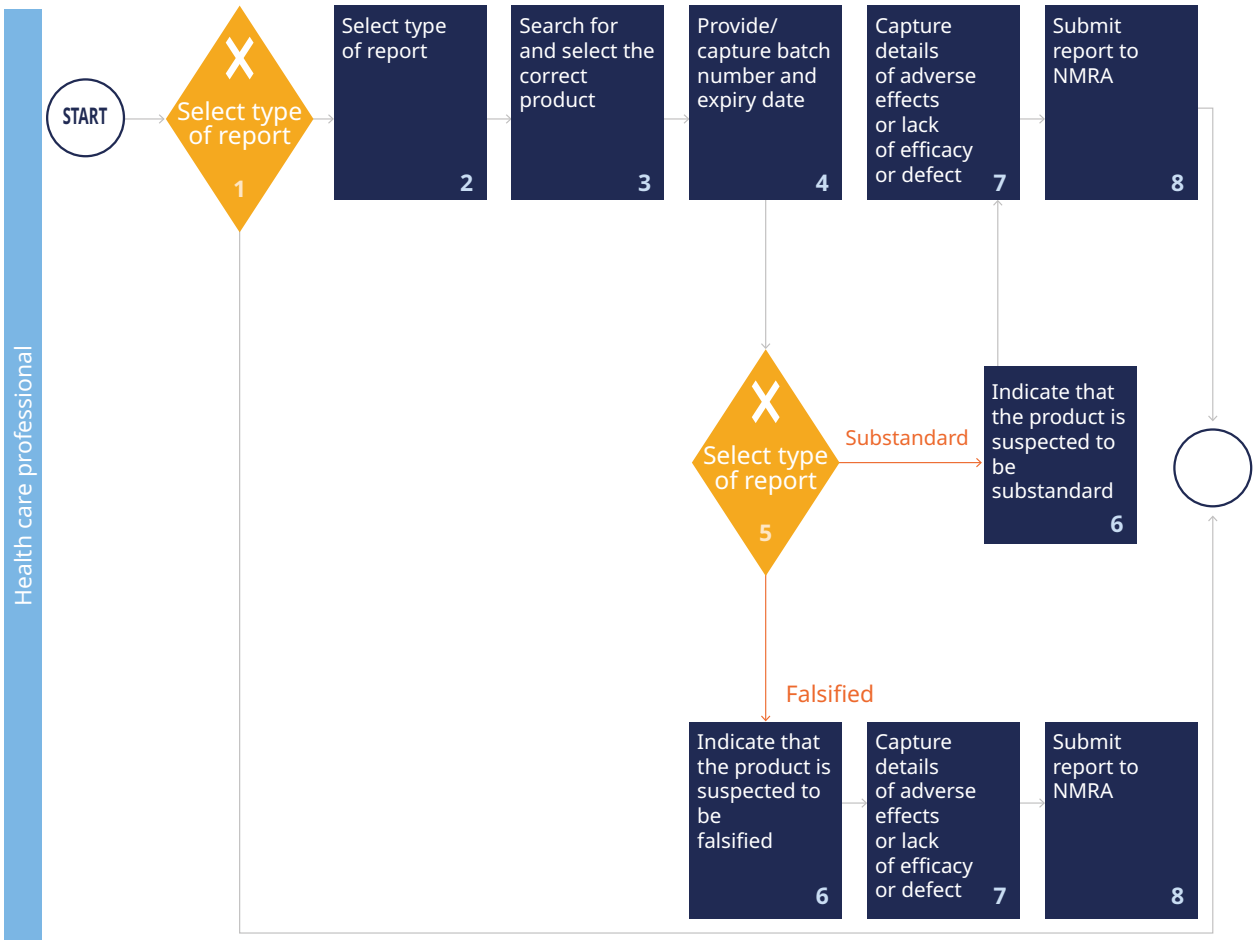
- taking stock of the business processes that need to be mapped;
- gaining clarity about who the key stakeholders are and how they will interact with the substandard and falsified reporting tool;
- gaining clarity on the linkages across different levels of the health system that enable integrated service delivery of care pathways; and
- determining a clear start and endpoint for each business process based on previous desk reviews, interviews and service-delivery observations *(4)*.

Develop workflows to illustrate the various activities required to achieve each business process. Create as-is workflows to identify gaps and develop to-be workflows to address these deficiencies. Conventional diagramming techniques should be employed to ensure that the workflow is universally comprehensible. It may be necessary to generate multiple maps, with connectors indicating their linking points. Business Process Model and Notation (BPMN) version 2.0 *(36)* is a widely adopted set of diagramming conventions. Adhering to this standard documentation convention is crucial to facilitate collaboration and comparisons across systems. See Annex 3 for BPMN symbols.

Table 10. Business process matrix example

Process name	Process ID	Personas	Objectives	Task set
Title	**ID used to reference this process**	**Individuals interacting to complete the process**	**A concrete statement describing what the process seeks to achieve**	**The general set of activities performed within the process**
Suspect product detection and reporting by pharmacist	SF-REP-001	Pharmacist, patient (optional), supplier/ manufacturer, regulatory authority	To enable pharmacists to promptly identify, isolate, document and report suspected substandard or falsified medical products to regulatory authorities using a digital system.	1. Identify anomalies in medication appearance, packaging, or reported effectiveness. 2. Isolate the product and verify with supplier/manufacturer if needed. 3. Advise the patient, if applicable. 4. Log into the digital reporting tool. 5. Enter product and incident details, including optional patient info and photos. 6. Submit the report and receive confirmation. 7. Receive tracking number and follow-up communication from the authority.

Fig. 4. Example workflow depicting the process of reporting substandard and falsified medical products



4.4 Outline data requirements

A data dictionary is a repository of information about the data elements such as description, data type and other characteristics. A data dictionary will be a useful input to designing the solution and facilitating understanding across multiple stakeholders. Data dictionaries should utilize terminology standards (e.g. International Classification of Diseases [ICD-11], SNOMED-GPS) and syntactic interoperability standards (e.g. HL7 FHIR). These standards ensure consistent and high-quality data exchange across various digital systems, regardless of the time, health topics, or different health care providers and facilities involved.

The data elements that health care professionals will collect will be defined in the data dictionary and included in the reporting application in appropriate activities of the workflow. A sample list of data elements is provided in Table 11 and can be tailored to the country's context.

4.5 Gather requirements

Functional and non-functional requirements outline what the reporting application needs to do and how it should perform. These requirements guide developers and stakeholders in designing, developing and deploying the application. They define the application's purpose, features, functionality and behaviour.

Illustrative functional and non-functional requirements are provided in Tables 12 and 13 as a starting point. This can be adapted and expanded to meet the needs of the country and the specific context.

Table 11. Data elements example

Activity ID and name	Data element ID	Data element name	Description and definition
SFR.A1 Report substandard or falsified product	SFR.A1.DE1	Region	The region within the country from where the substandard and falsified medical product is being reported.
	SFR.A1.DE2	Type of report	
	SFR.A1.DE3	Product ID	The product identification number.
	SFR.A1.DE4	Product description	The description of the product.
	SFR.A1.DE5	Type of product	
	SFR.A1.DE6	Batch number	The identification number of the batch that the substandard and falsified medical product belongs to, as printed on the product package.
	SFR.A1.DE7	Expiry date	The predetermined date, as printed on the product package, beyond which the product is not safe or effective to be used.
	SFR.A1.DE8	Substandard or falsified?	Whether the product being reported is substandard or falsified.
	SFR.A1.DE9	Product suspected to have caused adverse reaction or unexpected lack of efficacy?	Whether the substandard and falsified medical product caused any adverse reactions.
	SFR.A1.DE10	Reporting reason/description of the issue	The reason for reporting the product as substandard and falsified.

Table 12. Sample list of functional requirements

Requirement ID	Activity description	As a ...	I want ...	So that ...
SFR.FXNREQ.001	Reporting substandard and falsified medical product	Health care professional	The system to identify the region from where the report is being submitted, based on my profile.	The region is systematically recognized without requiring manual data entry or selection.
SFR.FXNREQ.002	Reporting substandard and falsified medical product	Health care professional	To be able to select the type of report from a predefined list.	I can select the appropriate option without having to type every time.
	Reporting substandard and falsified medical product	Health care professional	To be able to search a product.	I can select the correct brand of product (from the right manufacturer).
	Reporting substandard and falsified medical product	Health care professional	The system to assign applicable type to the selected product.	I will not have to manually enter or select the type of product.
	Reporting substandard and falsified medical product	Health care professional	To be able to capture the product's batch number and expiry date.	The details of the product are associated with the report being submitted.
	Reporting substandard and falsified medical product	Health care professional	To be able to indicate whether the product is identified as substandard or if it is falsified.	The NMRA can take appropriate steps.
	Reporting substandard and falsified medical product	Health care professional	To be able to indicate whether the product caused adverse effects or unexpected lack of efficacy.	The NMRA can take appropriate steps.

Table 13. Sample list of non-functional requirements

Requirement ID	Category	Non-functional requirement
SFR.NFXNREQ.001	Security – confidentiality	Provide password-protected access for authorized users.
SFR.NFXNREQ.002	Security – confidentiality	Provide a means to ensure confidentiality and privacy of personal health information.
	Security – confidentiality	Provide the ability for allowed users to view confidential data.
	Security – confidentiality	Provide end-to-end encryption of data.
	Security – confidentiality	Data at rest must be encrypted by the IT solution. Industry best practice cryptographic algorithms must be enforced by the IT solution.
	Security – confidentiality	Provide encrypted communication between components.
	Security – confidentiality	For sensitive data, secure data destruction processes must be in place. There must be evidence of secure data destruction.
	Security – confidentiality	Provide secure data transmission methods to prevent others from seeing data sent from one computer to another by using data encryption and private networks across public networks.
	Security – confidentiality	Data must be encrypted on all removable media used by the IT solution. (i.e. USB memory stick, external hard drives).
	Security – confidentiality	A solution should have all levels of technical support for security controls.
	Security – authentication	Notify the user to change their password the first time they log in.
	Security – authentication	Adhere to complex password requirements.
	Security – authentication	Lock a user out after a specified number of wrong password attempts.
	Security – authentication	Notify a user if their account is locked due to wrong password attempts.
	Security – authentication	Provide role-based access to the system: users of the system get access on a need-to-know and need-to-use basis.
	Security – authentication	Multi-factor authentication must be enforced.
	Security – authentication	When authentication is required, all systems or applications should integrate with the single sign on authentication scheme (SAML; OpenID Connect) of the NMRA.
	Security – audit trail and logs	Log system logins and logouts (successful/unsuccessful).
	Security – audit trail and logs	Record all authentication violations, recorded by IP address, date, time and user credentials.
	Security – audit trail and logs	Log all activities performed by the user, including action category, IP address, date, time and user credentials.
	Security – audit trail and logs	Log access to data summaries, reports, analysis and visualization features.
	Security – audit trail and logs	Log exchange of data with other systems.
	Security – audit trail and logs	Log all data and system errors.
	Security – audit trail and logs	Audit history/trail/logs for all records should not be editable.
	Security – user management	Allow user with permission to create a new user and temporary password.
	Security – user management	Provide role-based access.
	Security – user management	Allow roles to be associated with specific geographical areas or health care facilities.
	Security – user management	Allow cascading user management and assignment of roles.
	Security – user management	Allow user to change their own password.
	Security – user management	Allow admin user to request password reset.
	Security – user management	Notify the user to regularly change their password.

Requirement ID	Category	Non-functional requirement
	Security – user management	Allow each user to be assigned to one or more roles.
	Security – user management	Support definitions of unlimited roles and assigned levels of access, viewing, entry, editing and auditing.
	Security – general	Perform periodic vulnerability scans and penetration testing when required.
	Security – general	The hosting provider should produce evidence that security controls are in place (i.e. network and web application firewalls; proxy; etc.) including evidence of recent security audits and security penetration tests.
	Security – general	All vendors have to mitigate security risk assessment outputs provided by NMRA as part of the price of the delivery.
	Security – general	There must be a governance mechanism to ensure confidential and sensitive data (to be determined through a separate confidentiality undertaking) is sufficiently protected in accordance with the highest standards, and in compliance with all applicable laws, ordinances, rules and regulations (including the United Nations Principles on Personal Data Protection and Privacy).
	Security – general	Provide a facility to set and maintain authorization access for data entry, validation, update, inquiry and report outputs.
	System requirements – general	Provide a unique version number for each revision.
	System requirements – general	Enable earlier versions of a record to be recoverable.
	System requirements – general	Enable deployment in an environment subject to power loss.
	System requirements – general	Work in an environment that is subject to loss of connectivity.
	System requirements – general	Generate IDs that are unique across different installations or sites.
	System requirements – general	Report version number when saving data to the database.
	System requirements – general	Be designed to be flexible enough to accommodate necessary changes in the future.
	System requirements – general	Allow for offline and online functionality.
	System requirements – general	Show the number of records that are not yet synchronized.
	System requirements – general	Have the ability to easily back up information.
	System requirements – general	Warn user if no valid backup for more than a predefined number of days.
	System requirements – general	Must have the ability to store images and other unstructured data.
	System requirements – general	Use standardized master data to identify health products and facilities.
	System requirements – general	The solution should be designed and certified according to ISO 27000 family.
	System requirements – general	All application software code must be created with exclusive intellectual property rights to NMRA.
	System requirements – general	The developer of software solution must ensure the legality of third-party software components usage. Open source and other similar type of software licences are preferred with no or minimum costs for usage.
	System requirements – general	System must support the transformation of report data into charts or graphs or any other standard visual representations.
	System requirements – general	System must support the creation and export of reports to MS Word, MS Excel, Email or PDF or any other universal standard.
	System requirements – general	System must support the import of data and reports in pdf, xls, rtf, txt, doc, csv formats.

Requirement ID	Category	Non-functional requirement
	System requirements – general	Documentation – detail design documentation, administrators' documentation; support to create user guide documentation must be provided as a part of the price for the project.
	System requirements – general	Vendor to provide evidence of all internal testing including security testing results with corrective actions defined.
	System requirements – general	Training – administrators' and users' training must be provided as a part of the price for the project.
	System requirements – general	Support service contract must be ensured together with project realization contract.
	System requirements – scalability	Scalable to accommodate new demands.
	System requirements – scalability	Be able to accommodate at least [x number of] health care facilities.
	System requirements – scalability	Be able to accommodate at least [x number of] concurrent users.
	System requirements – scalability	Be able to accommodate more than [x number of] concurrent users.
	System requirements – usability	Be user-friendly for people with low computer literacy.
	System requirements – usability	Provide informative error messages and tool tips.
	System requirements – usability	Alert the user when navigating away from the form without saving.
	System requirements – usability	Support real-time data entry validation and feedback to prevent data entry errors from being recorded.
	System requirements – usability	Simplify data recording through predefined dropdown or searchable lists, radio buttons and check boxes.
	System requirements – usability	Support multiple languages – English, French, Spanish, Chinese, Russian, Arabic.
	System requirements – usability	Use industry-standard user interface practices and apply them in a consistent manner throughout the system.
	System requirements – usability	Easy to learn and intuitive to enable users to navigate between pages.
	System requirements – usability	Provide guidance to users to better support clinical guidelines and best clinical practices.
	System requirements – usability	Be reliable and robust (minimize the number of system crashes).
	System requirements – usability	Adjust display to fit small screens (such as mobile phones).
	System requirements – usability	Enable use via a web interface and mobile applications for use on various technology devices such as computers, laptops, tablets and mobiles – responsive design must be applied.
	System requirements – usability	Allow for localization such as branding with national regulatory authority and/or national/regional organization logos.
	System requirements – usability	Provide ability to store information such as name and batch number from images.
	System requirements – usability	Provide ability to scan data carriers such as barcodes to identify and store the encoded information.
	System requirements – usability	Automatically save data periodically to prevent loss from power outages or distractions.
	System requirements – usability	Portal should take no more than X seconds to load the First Contentful Paint and return search results no more than X seconds for users on desktop computers and mobile devices. The portal should be able to adapt to low bandwidth settings by deprioritizing delivery of non-crucial elements.
	System requirements – configuration	Configure the system centrally.

Requirement ID	Category	Non-functional requirement
	System requirements – configuration	Configure business rules in line with guidelines and standard operating procedures (using the decision logic and contextual query language + Fast Healthcare Interoperability Resources [FHIR]).
	System requirements – configuration	Configure error messages.
	System requirements – configuration	Configure workflows and business rules to accommodate differences between facilities.
	System requirements – configuration	Architecture for development, UAT and production environments must be distinct from each other.
	System requirements – interoperability	Communicate with external systems through mediators.
	System requirements – interoperability	Provide secure access to data through application programming interfaces to interface with other SMART guideline reference app solutions, incumbent solutions (e.g. registration systems) and reporting tools.
	System requirements – interoperability	The reference application must have an FHIR back end/FHIR native and leverage the workstream 3 content (CQL + FHIR resources).
	System requirements – interoperability	Be interoperable with external systems through mediators.
	System requirements – interoperability	Exchange data with other approved systems.
	System requirements – interoperability	Accept data from multiple input methods including paper and geocoding (global positioning system).
	System requirements – hardware and connectivity	Allow for data exchange and efficient synchronization across multiple facilities and points of service when the internet is available, even when it is intermittent and slow.
	Requirements for delivery	Vendors to have a technical change and configuration management process in place that is compliant with the Information Technology Infrastructure Library framework.
	Requirements for delivery	Vendors to have secure software development processes in place (e.g. Open Web Application Security Project Secure Coding Practices).
	Requirements for delivery	Vendor to ensure disaster recovery/business continuity processes in place. This should include backups applications and/or services, replicas and automated failover processes. A disaster recovery plan and periodic testing is obligatory.
	Requirements for delivery	Project final acceptance and last payment milestone to be provided after the go-live following by stabilisation period accepted on agreed UAT results.

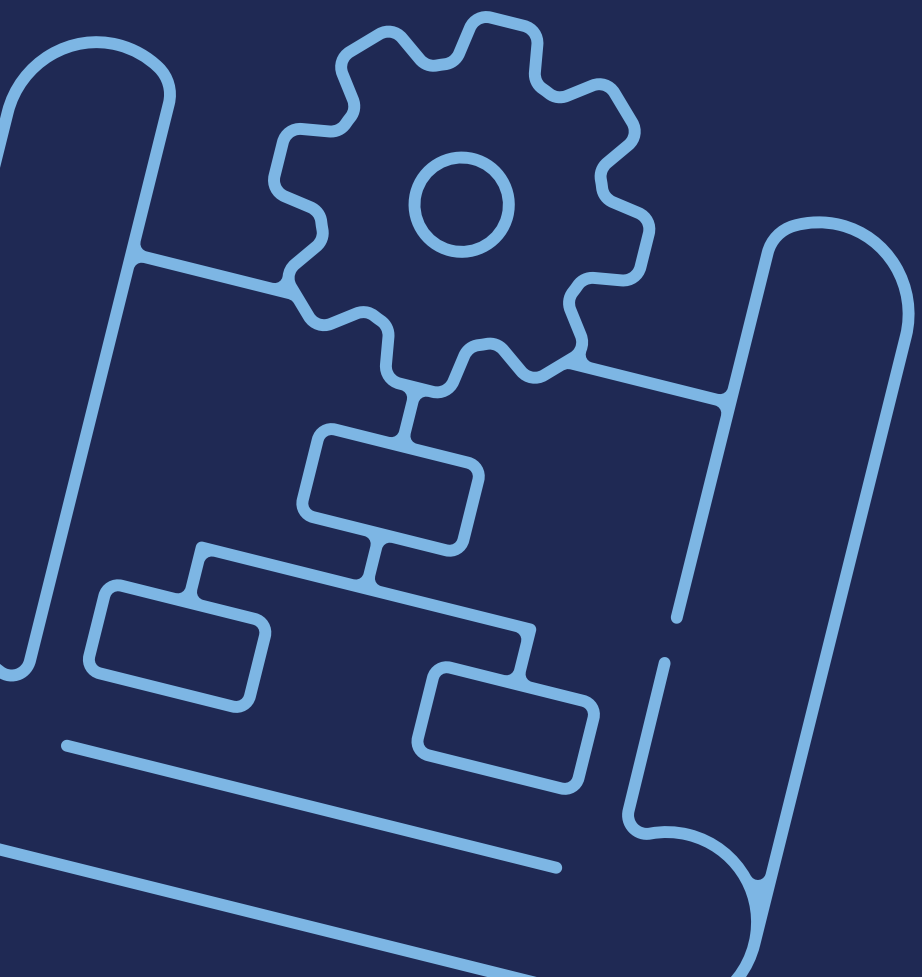
End of chapter checklist

After finishing the steps outlined in this chapter, there should be a comprehensive current state analysis of the key stakeholders including:

- ☐ User personas
- ☐ Business process and workflow details
- ☐ Data dictionaries with required data elements
- ☐ Functional and non-functional requirements for the reporting application
- ☐ Barriers to reporting



5. Plan the implementation



Once you have defined the future state and the requirements for the substandard and falsified reporting application, the next step is to implement the system. This chapter provides guidance on planning the implementation, including the creation of a detailed budget.

Inputs

- Requirements documentation
- Digital investment roadmap for the substandard and falsified reporting solution
- Digital health enterprise architecture
- Current state analysis report
- Stakeholder matrix

Outputs

- Project management plan
- Budget, including total cost of ownership

Resources (see page 50)

- *Digital implementation investment guide (DIIG)*
- Principles for Digital Development (Annex 1)
- *National eHealth strategy toolkit*
- *Digital transformation handbook for primary health care: optimizing person-centred point of service systems*
- *Digital transformation handbook for health supply chain architecture*

Effective planning is critical for the successful implementation of the substandard and falsified reporting application. This process involves a structured approach to developing the implementation plan, budgeting for all phases of the project and executing key steps to ensure sustainability and scale. The steps outlined in Table 14 serve as a practical roadmap to guide implementers through this process.

When implementing the substandard and falsified reporting application, consider various technology options such as:

- open source
- packaged applications
- cloud-based software as a service (SaaS).

Table 14. Steps involved in planning the implementation of the substandard and falsified reporting application

Develop implementation plan	Develop budget	Implement
Develop project charter	Identify cost drivers	Select appropriate software option
Develop project management plan	Estimate total cost of ownership	Choose implementation partner and configure app
Define monitoring and analysis framework	Create budget matrix	Integrate with existing systems
	Identify funding sources	Validate and test
		Train users
		Rollout across facilities

Evaluate the deployment options, including public, private or hybrid cloud, as well as on-premises solutions. Choose technology solutions that are cost-effective, reliable and easily scalable. Ensure that the chosen technology aligns with the overall enterprise architecture and integrates seamlessly with existing systems.

Tip: It is important to recognize that although open-source applications may be free, implementing them can still incur costs. Factors such as required features, time, effort, cost and national IT and data sovereignty policies should be considered when choosing the appropriate option as long-term maintenance costs could potentially be higher depending on the context and capacity available.

This is a critical decision that significantly impacts the application's functionality and efficiency, and it should fit within the enterprise architecture outlined in Section 3.2. See Table 15 for various options to consider, each with its unique advantages and constraints.

Table 15. Software options

Option	Advantages	Considerations	Challenges
Packaged off-the-shelf application	Saves time and effort, readily deployable	Might require customization	May not meet all specific requirements
Software as a service (SaaS)	Cloud-based, ongoing support and updates	Reliability of vendor, scalability, data sovereignty, IT policies	Feasibility depends on policies and vendor evaluation
Enhancing an existing application	Cost-effective, partially meets requirements	Extending functionalities, integrating new features	May require significant enhancements
Building one from scratch	Meets all specific needs, maximum flexibility	Custom development	Higher costs, longer development time
Selecting and enhancing an open-source solution	Customizable, cost-effective	Requires skilled personnel	Customization and ongoing maintenance needed

End of chapter checklist

After finishing the steps outlined in this chapter, the following outputs should be available:

- ☐ Project management plan
- ☐ Budget
- ☐ Substandard and falsified reporting application



6. Monitor, evaluate and scale



As noted in WHO's *Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment (8)*:

> "During the maturity life cycle of a digital health intervention, concurrent monitoring and evaluation (M&E) activities should be planned, often in parallel, supporting each other. As the intervention matures, the M&E needs will evolve – from monitoring the system's technical functionality and stability, towards continuous, real-time monitoring of its consistency in producing the expected outputs, at a pre-defined level of quality. The evaluation of the digital health system and intervention over time is an attempt to attribute a range of outcomes to the technology-based intervention – from assessing how easily end-users can interact with the system (usability), to the health impacts attributed to the intervention (efficacy/effectiveness), to the affordability of the system (economic/financial evaluation)."

Inputs

- Historical and/or baseline data and analysis on substandard and falsified reporting
- Project management plan
- Stakeholder matrix

Outputs

- M&E plan
- Operations and sustainability planp

Resources (see page 50)

- *Digital implementation investment guide (DIIG)*
- *Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment*
- *Digital transformation handbook for primary health care: optimizing person-centred point of service systems*

6.1 Develop a monitoring and evaluation plan

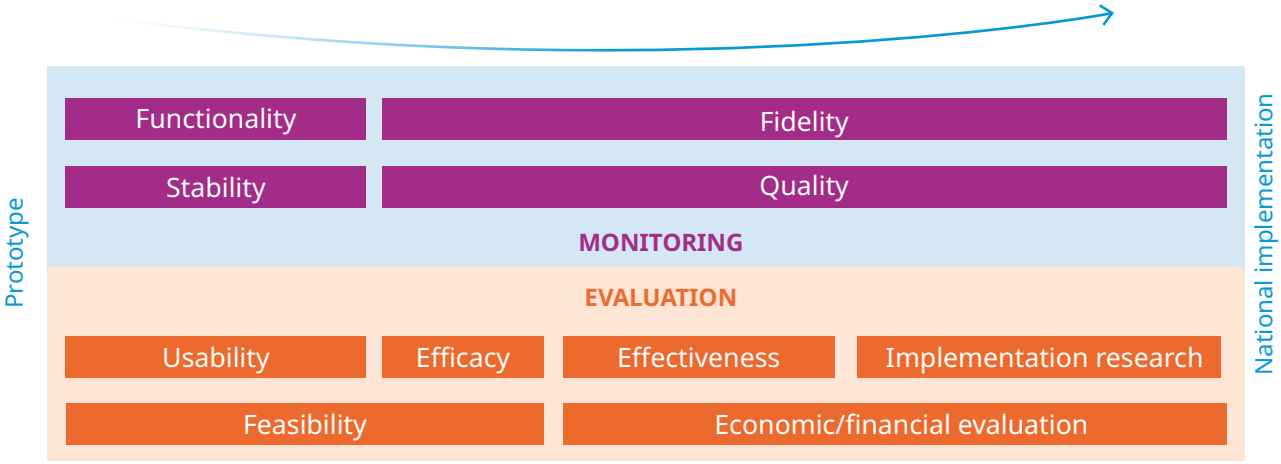
To define the goals of M&E activities and create a detailed plan, it is important to understand the distinctions and connections between monitoring and evaluation. As explained in WHO's *Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment (8)*, monitoring focuses on measuring properties that are intrinsic (inward) to the digital intervention; evaluation concentrates instead on metrics that are extrinsic (outward) to the intervention. Ideally, the intention is to demonstrate attribution, i.e. to show that the changes in these extrinsic metrics have occurred as a result of the digital intervention.

> "Evaluation asks whether the project is doing the right things, while monitoring asks whether the project is doing things right." Pritchett et al., 2013 *(37)*.

Fig. 5 illustrates the M&E needs over the life of a digital intervention such as the substandard and falsified reporting application.

Fig. 6 further illustrates the specific monitoring needs and examples across various stages of the digital solution's maturity.

Fig. 5. Intervention maturity over time



Source: Adapted from WHO's *Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment* (WHO; 2016) *(8)*.

Fig. 6. Illustrative stages of the substandard and falsified reporting application maturity life cycle

Stage of maturity	1 & 2: Pre-prototype/ prototype	3: Pilot	4: Demonstration	5: Scale-up	6: Integration/ sustainability
					
Monitoring goals	Functionality, stability	Fidelity, quality			
Stages of evaluation	Feasibility/ usability	Efficacy	Effectiveness	Implementation science	
Illustrative number of system users	10–100	100–1000	10 000+	100 000+	
Illustrative measurement targets	• Stability (system uptime/failure rates) • Performance consistency • Standards adherence (terminology, interoperability, security)	• User satisfaction • Workflow "fit" • Learning curve (design) • Cognitive performance/ errors • Reliability	• Changes in process (time to X) • Changes in outcome (system performance/ health)	• Changes in process/ outcome in less controlled environment • Reduction of cost • Total cost of implementation • Error rates • Learning curve of users	• Improvements in coverage • Changes in policy, practices attributable to system • Extendability to new use-cases • Adaptability to other cadres of users • Health impact

Source: Adapted from WHO's *Monitoring and evaluating digital health interventions: a practical guide to conducting research and assessment* (WHO; 2016) *(8)*.

Similarly, the following illustrative questions can help with the evaluation needs across the substandard and falsified reporting application's life cycle (Table 16).

Table 16. Evaluation needs across the substandard and falsified reporting application life cycle: sample questions

Usability 	Is the substandard and falsified reporting application usable by the targeted end user(s), and does it fit within their workflow? How steep is the learning curve before a user can demonstrate proficient use of the reporting application? What are the rates of error – in using the system or in workflows – as a result of system use/misuse?
Efficacy 	Has the substandard and falsified reporting application changed processes (e.g. time between event X and response Y) in a research or controlled setting such as a pilot? Has the substandard and falsified reporting application changed outcomes (e.g. increased reporting by health care professionals) in a research or controlled setting such as a pilot?
Effectiveness 	Has the substandard and falsified reporting application changed processes (e.g. time between event X and response Y) in a non-research setting? Has the substandard and falsified reporting application changed outcomes (e.g. increased reporting by health care professionals) in a non-research setting?
Cost 	Has the substandard and falsified reporting application reduced costs associated with substandard and falsified reporting or substandard and falsified medical product incidences in general? Has the substandard and falsified reporting application introduced costs that are commensurate with benefits provided?

Taking these considerations into account, develop a comprehensive M&E plan by following the detailed steps outlined in Table 17.

Table 17. Steps in developing a comprehensive M&E plan

Step 1	Establish an underlying framework that guides the M&E process. The framework should outline how the reporting application is expected to work and what outcomes it aims to achieve. It serves as a blueprint for the entire M&E process, ensuring that all activities are aligned with the stated goals.
Step 2	Clearly identifying evidence needs and evaluation objectives is essential. Determine what data are required to evaluate the reporting application accurately and what the objectives of the evaluation are. This step involves setting clear, measurable goals that the M&E activities will seek to achieve, such as improving substandard and falsified reporting rates or reducing substandard and falsified medical product incidence rates. Link the objectives with the timing and stage of the substandard and falsified reporting application's maturity.
Step 3	Design the process that will guide the M&E activities. This involves selecting the appropriate methodologies, tools and techniques to collect and analyse data. The design should be robust, ensuring that it can provide reliable and valid results that can inform decision-making.
Step 4	Determine who will be responsible for carrying out the M&E activities. This involves identifying and training personnel who have the necessary skills and expertise to conduct M&E activities effectively. It may also involve partnering with external organizations or experts to ensure the evaluations are carried out to the highest standards.
Step 5	Timing and resource allocation are critical components of an effective M&E plan. Create a timeline that outlines the different stages of the implementation and operations when M&E activities will be carried out, ensuring they align with the substandard and falsified reporting application's implementation schedule. Additionally, resources must be allocated to support these activities, including funding, personnel and data collection tools.
Step 6	All the above details must be summarized into an M&E implementation plan. This plan will outline the steps and processes for carrying out M&E activities, detailing how data will be collected, analysed and reported. It should also include mechanisms for reviewing and updating the M&E plan to ensure it remains relevant and effective over time.

Select metrics for monitoring and evaluation

Identify the right metrics for assessing the performance and effectiveness of the reporting application. Table 18 lists a few illustrative measures for reference.

Table 18. Reference measures for assessing the substandard and falsified reporting application

Category	When	Potential measures
Quality 	Pre-launch and during implementation	Feedback from end users on usability Timestamps on report submissions Number of substandard and falsified report submissions/worker Average number of errors or data quality/integrity issues per report (e.g. data completeness rate) Time it takes to submit a report
Fidelity 	During implementation	Substandard and falsified report data completeness Incidences of poor connectivity or power outages impacting report submission Report accuracy rate
Stability 	Pre-launch	Application uptime Response time (measure average response time and response time during peak usage) Offline-online performance Volume of transactions
Functionality 	Pre-launch	Fit-gap analysis against requirements Availability of required report fields Ease of data entry for users Data validation error rate
Investment 	Pre-implementation and post-launch	Cost-benefit analysis Return on investment analysis

6.2 Develop an operations and continuous improvement plan

Develop an operations plan to sustain the ongoing operations and continuous improvement of the reporting application, ensuring its reliability and efficiency. The operations plan addresses strategies to scale the application, including expanding the user base and adding new features; as well as the maintenance and update strategy to support continued usage by existing users. By implementing a comprehensive operations and sustainability plan, stakeholders can manage resources effectively, maintain robust performance, accommodate growth and evolving needs, and stay abreast of emerging cybersecurity threats.

Establishing an operations and sustainability plan is a critical step to ensure the long-term success and reliability of the substandard and falsified reporting application. This plan should include details of stakeholders that will own and maintain the reporting application. These stakeholders could be internal teams responsible for daily operations or external partners providing specialized support. Clearly defining the roles and responsibilities of each stakeholder will ensure accountability and streamline the maintenance and update process. Additionally, it is crucial to identify the required resources, such as maintenance personnel, cybersecurity oversight, hardware, network infrastructure, and backup power. These resources are fundamental to the smooth operation and resilience of the application, preventing disruptions due to technical failures or power outages.

Recurring knowledge management needs, including training, updating job aids, recruitments and job rotations, must also be addressed in the plan. Continuous training programmes will keep the maintenance personnel and other stakeholders equipped with the latest skills and knowledge to manage the application effectively. Updating job aids and recruiting new staff when necessary, will help maintain a high level of operational efficiency. Job rotations can prevent burnout and ensure that team members have a well-rounded understanding of the system.

Furthermore, the plan should outline the recurring costs for the required resources, system subscriptions, knowledge management, cybersecurity, M&E and efforts to maintain and operate the application. A comprehensive financial strategy is essential to cover these recurring operational costs, ensuring the sustainability of the application. This strategy should include budgeting for unexpected expenses and exploring potential funding sources.

A robust plan for data backups and system redundancy must be devised to mitigate the impact of system failures. Regular data backups will safeguard against data loss, while system redundancy will ensure that the application remains functional even if one component fails. Implementing a change management and governance process for new requirements arising from evolving needs will keep the application relevant and responsive to changing demands. This process should include mechanisms for evaluating and prioritizing new requirements, as well as a structured approach to implementing changes.

End of chapter checklist

After finishing the steps outlined in this chapter, the following outputs should be available:

- ☐ M&E plan
- ☐ Operations and sustainability plan

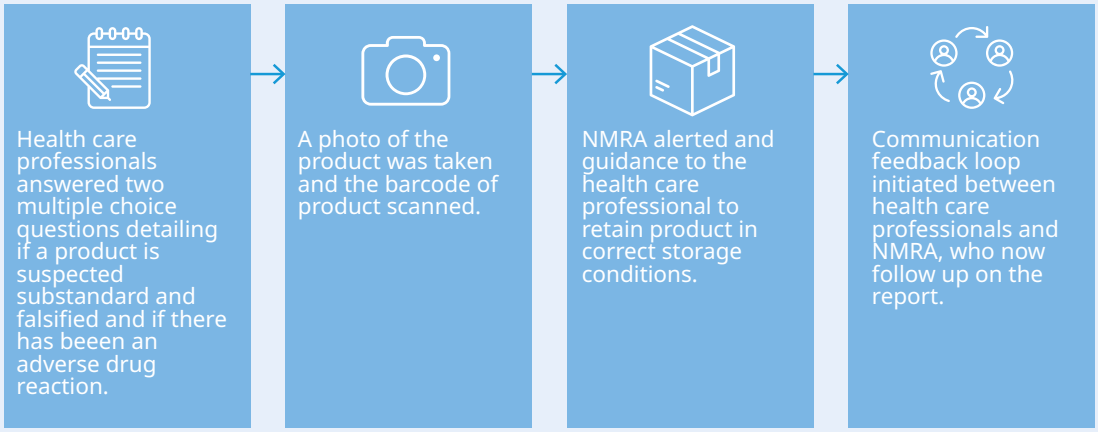


7. Share implementation experiences



Case study: Indonesia and and the United Republic of Tanzania

A smartphone app was developed and piloted in Indonesia and the United Republic of Tanzania to help health care professionals report a suspected substandard and falsified medical product to the NMRA. The pilot study focused on providing a reporting app that was easy, simple to use, reliable and fast.



Additional app functions

- App users had access to an outbox to store a report offline. Once network coverage was obtained, the alert automatically sent to the server.
- Users could save draft reports to complete at another time.
- Alerts provide a direct link to the WHO Medical Product Alert webpage.
- Users were able to translate the app into local languages.

Pilot study evaluation

In both Indonesia and the United Republic of Tanzania, the pilot study yielded a total of 36 reports of 27 medical products submitted using the smartphone app. In addition, the pilot study increased awareness and education surrounding substandard and falsified medical products, with health care professionals learning techniques on how to identify substandard and falsified medical products.

	Successes	Areas requiring improvements
Application/ reporting	• Health care professionals liked the simplicity, user-. friendliness and convenience of the smartphone app compared with paper-based reporting. • Health care professionals appreciated how the app created a feedback loop with NMRAs. • Health care professionals preferred taking and uploading photographs of the suspect product versus manually filling in information.	• Older models of various smartphones experienced issues of incompatibility with the app. • In the United Republic of Tanzania, weak/unreliable internet connectivity led to some installation and login issues. • NMRAs felt the back end was not fit for purpose, leading to app and website delays. • Health care professionals suggested adding features such as displaying a history of all submitted reports and NMRA and WHO alerts on confirmed substandard and falsified medical products.
Feasibility	• Health care professionals appreciated the limited manual data entry. • NMRA staff praised the flexibility of not having to be office-bound to receive reports. • The workload associated with the pilot app was deemed manageable. • Strong support from management/ supervisors was pivotal to increase trust and ensure the success of the app rollout.	• NMRAs expressed concern about the impact of a broader rollout in light of competing priorities. • The app included a feature to schedule and assign follow-up to an NMRA staff member. This had to be removed mid-pilot due to useability issues. The NMRA resorted back to maintaining two systems – the pilot website and Excel.

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Annexes



Annex 1. Principles for Digital Development

Understand the existing ecosystem 	Trust starts with a thorough understanding of the dynamic cultural, social and economic context in which you are operating.
Share, reuse and improve 	Build on what works, improve what works and share so that others can do the same.
Design with people 	Good design starts and ends with people that will manage, use and ideally benefit from a given digital initiative.
Design for inclusion 	Consider the full range of human diversity to maximize impact and mitigate harm.
Build for sustainability 	Build for the long-term by intentionally addressing financial, operational and ecological sustainability
Establish people-first data practices 	People-first data practices prioritize transparency, consent and redress while allowing people and communities to retain control of and derive value from their own data.
Create open and transparent practices 	Effective digital initiatives establish confidence and good governance through measures that promote open innovation and collaboration.
Anticipate and mitigate harms 	Harm is always possible when it comes to technology. To avoid negative outcomes, plan for the worst while working to create the best outcomes.
Use evidence to improve outcomes 	Evidence drives impact: continually gather, analyse and use feedback.

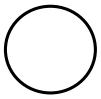
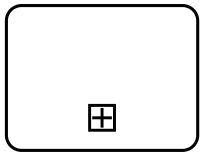
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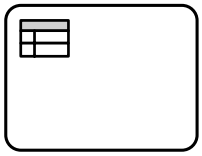
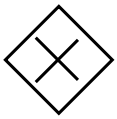
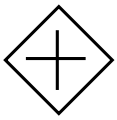
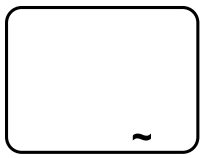
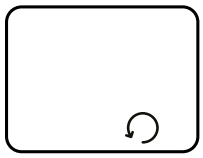
Annex 2. User persona template

A user persona template/worksheet that summarizes each and every type of end user (e.g. pharmacists, doctors, nurses, dentists, midwives, paramedics, laboratory technicians, public health workers, veterinarians and pharmacy technicians) should be completed.

Persona occupation (e.g. nurse)	
Demographics Gender Age Community of origin Language(s) used Education level	
Expected roles and responsibilities Daily Weekly Monthly	**Behaviour patterns** Regularly prescribes medications Uses electronic health records daily Attends medical conferences and workshops Dispenses or administers medications and monitors patient reactions Uses mobile apps for quick reference and reporting Participates in community health programmes Uses existing pharmacy dispensing/stock software
Context description Do they own their own mobile device? If yes, what kind? Level of familiarity with digital tools? What kind of environment is this persona working in? Rural or urban? Internet connectivity? Availability of electricity and water? Homogenous or heterogenous population?	
Challenges/pain points *Note: It is beneficial to include quotes given directly from interviews for the persona you are creating.* What are the routine challenges faced by this user? Sufficient training and performance monitoring? Workload/time constraints due to busy schedule? Complexity of existing reporting system? Lack of feedback on reported issues? Limited access to easy-to-use reporting tools? Too many reporting forms to complete?	
What does success look like *Note: This does not have to be strictly professional success. An overall perception of success can greatly impact performance in a professional setting. Sometimes the target health worker occupational group is a group of volunteers, so providing health services may not be their priority.* What are their motivations? Commitment to patient care, professional responsibility? Complete coverage of health care service providers? What indicators are they measured on? What are their performance management metrics? User-friendly (intuitive and easy navigation) platform? Availability in multiple devices (phone, tablet, desktop)? Feedback mechanism? Seamlessly integrated with other existing systems?	

Annex 3. Business Process Model and Notation (BPMN) symbols

Symbol	Symbol name	Description
	**Pool**	The pool assumes process control and assigns tasks. A **pool** consists of one or more "swim lanes" that depict all the individuals or types of users involved in carrying out the business process or workflow. Diagrams should be clear, neat and easy for all viewers to understand the relationships across the different swim lanes. For example, a pool could depict the business process of conducting an outreach activity, which involves multiple stakeholders represented by different swim lanes. A business process diagram can contain two or more pools that connect through message flows (messages received from outside the pool) – this indicates different process owners collaborating and exchanging information. For example, in the case of a referral, health facility "A" (the referring facility) represents the process owner that internally assigns the tasks for the actors represented as swim lanes. Health facility "B" (the receiving facility) has allocated its own pool and is considered a different process owner with the same role. These two facilities exchange information relevant for a referral (e.g. client history, referral details), represented as message flows, but each facility has control only over the internal activities, without directly impacting the activities of the other facility.
	**Swim lane**	Each individual or type of user is assigned to a **swim lane**, a designated area for noting the activities performed or expected by that specific actor. For example, a [health domain abbreviation] health worker may have one swim lane, the supervisor another swim lane and the clients another swim lane.
	**Start event or trigger event**	The workflow diagram should contain a **start event** and an end event, defining the beginning and completion of the task.
	**Start event message**	This is a type of a **start event**. In some instances the workflow can start with a **message**. A "message" in business process model and notation does not mean only letters, emails or calls, but also includes information exchanged between two different systems (e.g. data exchange, notifications). Any action that refers to a specific addressee and represents or contains information for the addressee is a message.
	**End event**	Multiple **end events** can be depicted across multiple swim lanes in a business process diagram. For clarity, there should be only one end event per swim lane.
	**Activity, process step or task**	Each **activity** should start with a verb, such as "register client" or "calculate risk". Between the start and end of a task, there should be a series of activities noting the successive actions performed by the actor for that swim lane. There can be subprocesses for each activity.
	**Activity with subprocess**	This denotes an activity that **has a much longer subprocess**, which is detailed in another diagram. If the diagram is too complex, the subprocess symbol should be used to reference another process depicted on another page.

Symbol	Symbol name	Description
	**Activity with a business rule**	This denotes a decision-making activity that requires the business rule, decision-support logic or scheduling logic to be detailed in a decision-support table. This means that the logic described in the decision-support table will come into play during this activity as outlined in the business process. This is usually reserved for complex decisions.
	Sequence flow	This denotes the flow direction from a process to the next process. The end event should not have any output arrows. All symbols (except for the start event) may have an unlimited number of input arrows. All symbols (except for the end event and gateway) should have one and only one output arrow, leading to a new symbol, looping back to a previously used symbol or to the end event symbol. Connecting arrows should not cross over each other.
	Message flow	This denotes the flow of data or information from a process to another process. This is usually used for when data are shared across pools.
	**Exclusive gateway**	This depicts a fork or decision point in the workflow. This may be a simple binary (e.g. yes/no) filter with two corresponding output arrows, or a different set of outputs. Only two different outputs should originate from a decision point. If more than two output or sequence flow arrows are needed, you are likely trying to depict decision-support logic or a business rule, which should be depicted as an **activity with a business rule** instead (see above).
	**Parallel gateway**	This is used to model concurrency in a process. This type of gateway allows forking into multiple paths of execution or joining multiple incoming paths of execution. An important difference between this and other gateway types is that the **parallel gateway** does not evaluate conditions.
	**Throw – link event**	This serves as the start of an off-page connector. It is the end of the process when there is no more room on the page for that workflow. It is the end of a process on the current page or the end of a subprocess that is part of a larger process. A **catch – link** event must follow the **throw – link** event.
	**Catch – link event**	This serves as the end of an off-page connector. It is the start of a new process on a different page from the **throw – link** event or the start of a subprocess that is part of a larger process. A **throw – link** event must be aligned to a catch – link event.
	**Ad hoc subprocess**	An **ad hoc subprocess** can contain multiple activities (tasks or subprocesses), which can be executed in any order, executed several times or skipped. However, not all these activities need to be finished before moving on to the next activity.
	**Loop activity**	This indicates that the activity repeats until a defined condition applies or ceases to apply. The condition on which a loop executes is included as an annotation.

Source: Business Process Model and Notation [website]. Milford, MA: Object Management Group; 2026 (https://www.omg.org/spec/BPMN/2.0).

Note: The BPMN standard outlines additional conventions and nuanced symbols that can be used. The above selection of symbols should be sufficient, though, for the purposes of illustrating the business process workflows in a clear, standard way.

Annex 4. Stakeholder RACI matrix

A sample template for a stakeholder RACI matrix. This can be adjusted to include stakeholders and activities relevant to the country's context.

	Stakeholders						
Activities	NMRA	Ministry of health	Imple-mentation partner	Medical product industry	Health care pro-fessionals	Others…	Others…
Define project scope	A	R	C	I	I	I	I
Gather requirements	I	R	C	C	C	I	A
Design UI/UX	I	C	C	I	C	C	A

Notes: R (responsible) – person/organization that does the work; A (accountable) – decision-maker, approves the work; C (consulted) – provides input, must be consulted before the task is completed; I (informed) – needs updates on progress but not directly involved; UI – user interface; UX – user experience.

Annex 5. Template for assessing the current software applications

This table is a template for assessing the current information systems landscape and identifying systems and gaps.

	Ministry of health	Regulatory authority	Central warehouse	Branch warehouse	Service delivery point	Community health worker	Individuals
Forecasting and planning	Planning system						
Procurement management							
Supplier and contract management							
Order management			OpenLMIS	OpenLMIS	OpenLMIS		
Warehouse management			ERP			RapidSMS	
Transportation management							
Dispensing					OpenClinic		
Analytics	Health analytics platform						
Pharmacovigi-lance							Pharmacovig-ilance mobile app
Cold chain management							
Foundational components	NPC						
Regulatory		Registration system					
		NPC mobile app					

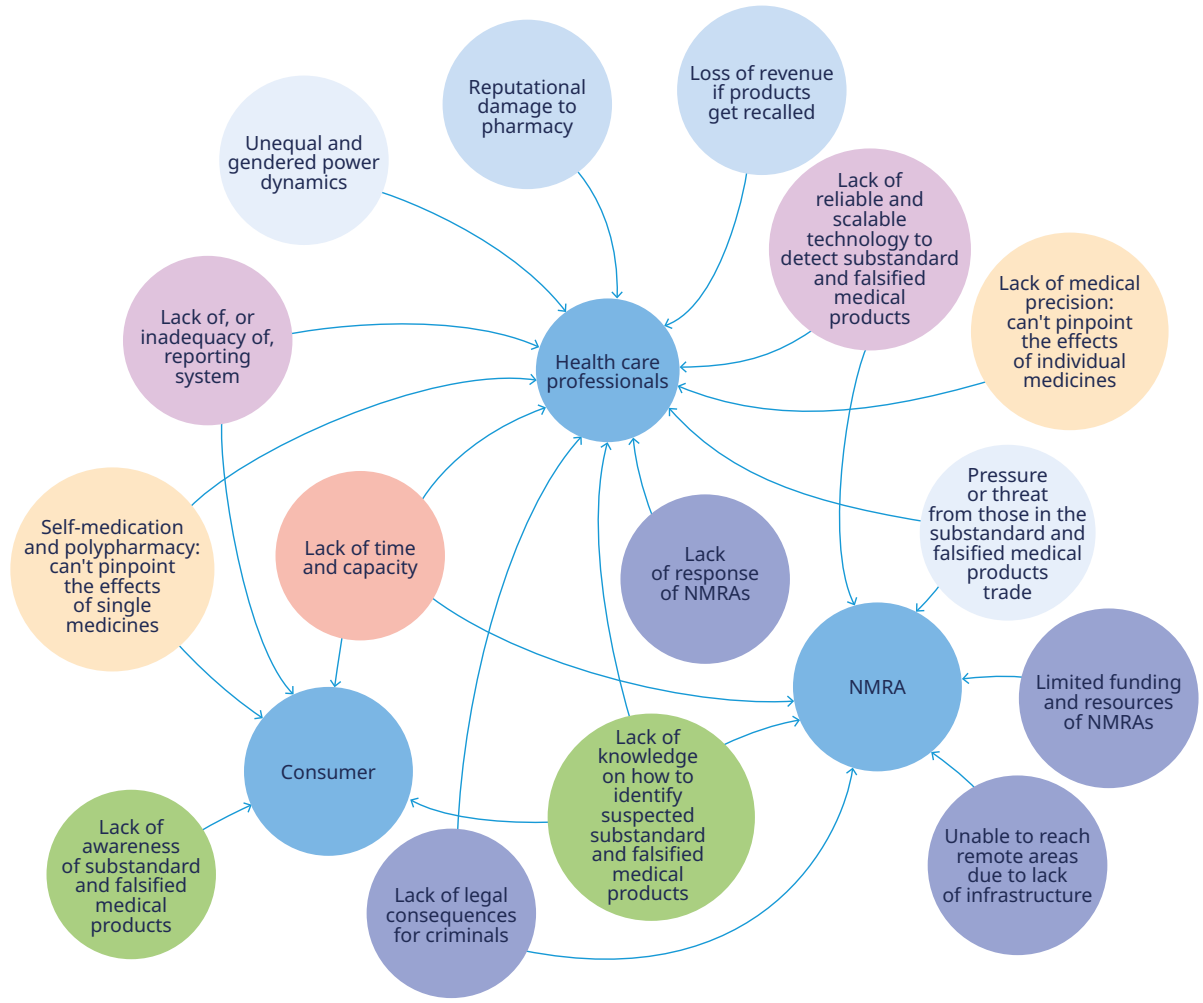
Deployed

In progress

Notes: ERP - enterprise resource planning; LMIS - logistics management information system; NPC - national product code.

Annex 6. Barriers to reporting

An example analysis showing the barriers to reporting substandard and falsified medical products.



Annex 7. Risk management template

The following table is a template for ranking risks and identifying mitigation steps.

001

Risk title	Description	Priority	Impact	Probability	Status
Inadequate training	IF system training is not delivered with appropriate content for the audience, THEN the adoption and use of the system may fail.	Low	Major	Medium	Mitigate

Mitigation steps	Owner	Raised	Reviewed	Closed
Perform a skills assessment for each user before completing the training plan. Complete a training needs assessment before conducting training. Target and adapt training to meet the needs of the training audience.		28-01-2024	16-08-2025	

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