

COVID-19 Antigen Rapid Diagnostic Test: Digital Systems and User Requirements

System User Requirements Specifications for the General
Context





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Abbreviations

CBV	community-based volunteer
CO	clinical officer
COVID-19	coronavirus disease 2019
DHIS2	District Health Information Software 2
dSTARR	Digital Solutions to Support COVID-19 Antigen RDT Rollout
DSUR	Digital Systems and User Requirements
DTDS	digital tracking and decision support
EHT	environmental health technologist
FHIR	Fast Healthcare Interoperability Resource
FXNREQ	functional requirements
GRDT	general rapid diagnostic test
ID	identifier/identification
IND	indicator
ISCO	International Standard Classification of Occupations
NFXNREQ	non-functional requirements
PCR	polymerase chain reaction
RDT	rapid diagnostic test
SMS	short message service
WHO	World Health Organization

Background and objectives

The COVID-19 pandemic led to a proliferation of both digital health and diagnostic technologies to support pandemic response. The pandemic has been especially difficult in Africa, with understaffed, under-supported, and underprepared facilities having their workloads increased. The development of a digital tool is critical to support these health care workers by streamlining COVID-19 workflow and data management. There was a significant need to create a tool to harmonize/standardize the data being collected.

PATH—under the Digital Solutions to Support COVID-19 Antigen RDT Rollout (dSTARR) project—set out to move the needle on this by inclusive innovation using a human-centered design approach, during which the team conducted facility visits and user testing workshops in India, Senegal, and Zambia to support the development of multiple digital applications. This has been packaged as a blueprint following the [WHO Digital Adaptation Kits](#) framework.

This Digital Systems and User Requirements (DSUR) aims to provide a common language across various audiences—program managers, software developers, and implementers of digital systems—to ensure a common understanding of the appropriate health information content within the COVID-19 antigen rapid diagnostic test (RDT) health program area, as a mechanism to catalyze the effective use of these digital systems. The key objectives of this DSUR are to:

- Ensure adherence to public health and data use guidelines.
- Facilitate consistency of the health content that is used to inform the development of a person-centered digital tracking and decision support (DTDS) system.
- Build a mutual understanding among health program leads and digital health teams (including software developers) of the health content within the digital system, through a transparent mechanism to review the validity and accuracy of the health content.
- Provide a starting point of the core data elements and decision support logic that should be included within DTDS systems for COVID-19 antigen rapid diagnostic testing.

The information detailed in this DSUR reflects generic workflow processes, data, and decision support algorithms derived from the dSTARR project conducted in 2021–2023 by PATH, and other related WHO documents described below. In addition, this DSUR describes linkages to related services for COVID-19 antigen rapid diagnostic testing, such as screening, facility management of an infected patient, and considerations for community management. **Note that the DSUR outputs are intentionally broad and will need to be contextualized to local policies and requirements to support implementation at country level.**

What is digital tracking and decision support?

Digital tracking is the use of digitized records to capture and store clients' health information to enable follow-up of their health status and services received. This may include digital forms of paper-based registers and case management logs within specific target populations, as well as electronic patient records linked to uniquely identified individuals. Digital tracking makes it possible to register and follow up patient services and may be done through an electronic medical record or other digital forms of health records.

Digital Systems and User Requirements overview

Scope

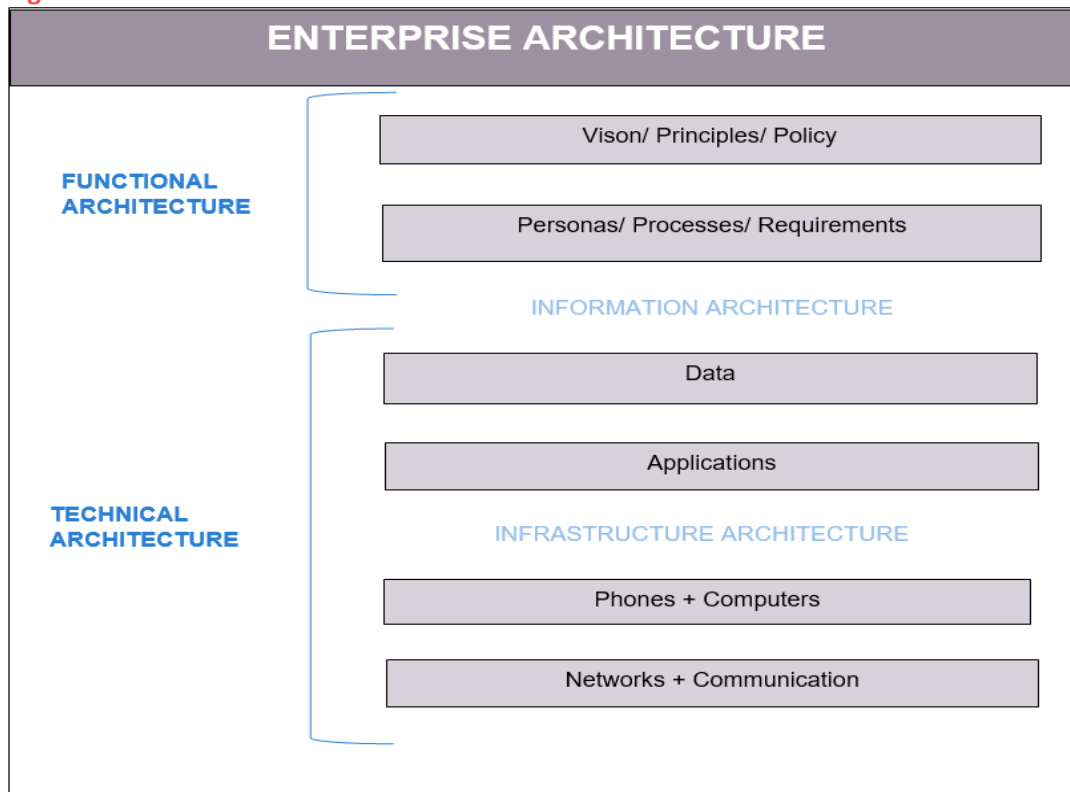
The scope of the DSUR components defined in this guideline is limited to the key processes below, which were identified as the health content requirements for a COVID-19 antigen rapid diagnostic testing DTDS system.

- Registration
- Screening
- Testing
- Examination
- Certificate generation
- Referral
- Scheduling follow-up
- Stock management
- Data aggregation

Enterprise architecture

Enterprise architecture (EA) refers to the discipline that helps organizations align their business processes, technology infrastructure, and information systems to achieve strategic goals. The below enterprise architecture provides a structured approach to design, implementation, and management of the necessary systems and processes inn the context of COVID-19 Ag RDT solutions.

Figure 1



Components

As shown in Figure 3, this DSUR comprises eight interlinked components, following the [WHO Digital Adaptation Kit's framework](#), which are: (1) health interventions and associated recommendations; (2) generic personas; (3) user scenarios; (4) generic business processes and workflows; (5) core data elements; (6) decision support logic; (7) indicators and performance metrics; and (8) high- level functional and non-functional requirements. All information within the DSUR represents a generic starting point, which can then be adapted according to the specific context.

Figure 3. Interlinked components of the COVID-19 antigen rapid diagnostic testing DSUR.



How to use the Digital Systems and User Requirements

Target audience

The primary target audience for this DSUR is health program managers within a country's ministry of health who will be working with their digital or health information systems counterparts in determining the health content requirements for a COVID-19 antigen rapid diagnostic testing DTDS system. The health program manager is responsible for overseeing and monitoring the implementation of the clinical practices and policies for the health program area, in this case, COVID-19 antigen rapid diagnostic testing.

The DSUR also equips individuals responsible for translating health system processes and guidance documents for use within digital systems with the necessary components to kick-start the process of developing a DTDS system in a standards-compliant manner. These individuals are also known as business analysts, who interface between health content experts and software development teams. Specifically, the DSUR contains key outputs, such as the data dictionary and decision support algorithms, to ensure the validity and consistency of the health content with the DTDS system.

Additionally, using this DSUR requires collaboration between health program managers and their counterparts in digital health and health information systems. Although each DSUR focuses on a particular health program area (in this case, COVID-19 antigen rapid diagnostic testing), the DSURs are envisioned to be used in a modular format and linked to other health program areas within primary health care settings to support integration across services.

Scenarios for using the DSUR

The DSUR may be used across various scenarios, some of which are listed in the table below.

Table 1. Scenarios for using the DSUR.

Scenario 1: Incorporating WHO guidelines content into existing DTDS systems	Countries that already have digital systems in place, such as electronic medical records and decision support tools, may use the information in the DSUR to cross-check whether the underlying content and data for specific health program areas—in this case, antigen rapid diagnostic testing—are aligned to WHO guidelines (see Component 1). Users of the DSUR can identify and extract specific decision algorithms that would need to be incorporated into their existing digital systems. By reviewing this systematic documentation, health program managers and implementers can more readily identify differences in workflows, data inputs, and decision support logics to examine the rationale for deviations and understand local adaptations of guideline content.
Scenario 2: Transitioning from paper to DTDS systems	Some countries may currently have paper-based systems they would like to digitize. The process of optimizing paper-based client-level systems into digital records and decision support may be overwhelming. Users in this scenario may review the DSUR as a starting point for streamlining the necessary data elements and decision support that should be in the optimized client-level digital system. Users may also then refer to the paper-based tools to determine whether there are missing fields or content that should also be included in the digital system.

<p>Scenario 3: Linking the aggregate health management information system (e.g., DHIS2) to DTDS systems used at point of care</p>	<p>In some instances, countries may already have a digital system for aggregate reporting and health management information but may not yet have implemented digital systems that function at the service-delivery level. The DSUR can guide the development of a digital client records system that operates at point of care and ensure there are linkages between the aggregate and service-delivery levels (e.g., community or facility level).</p> <p>As such, a component of the DSUR provides aggregate indicators derived from individual-level data to provide the linkage between these different levels. Complementary guidance dedicated specifically to aggregate-level data should also be consulted for supporting the use of routine data at the facility management and district levels.</p>
<p>Scenario 4: Leveraging data standards to promote interoperability and integrated systems</p>	<p>This DSUR includes data elements mapped to the RDT data model that are aligned to FHIR standards, to support the design of interoperable systems. The data dictionary in Web Annex A provides the necessary codes for different data elements, thus reducing the time for implementers to incorporate these global standards into the design of their digital systems.</p>

Notation guidance

Throughout this DSUR, there are identification (ID) numbers to simplify tracking and referencing of each component. Note that the DSUR represents an overview across the different components, and the comprehensive and complete outputs of each component (e.g., data dictionary) are included in appended spreadsheets. The notation guide is as follows:

Component 4: Business processes and workflows

- Each workflow should have a “Process name” and a corresponding letter.
- Each workflow should also have a “**Process ID**” that should be structured “**Abbreviated health domain**” (e.g., ZRDT). “Corresponding letter for the process” (e.g., A).
- Each activity in the workflow should be numbered with an “**Activity ID**” that should be structured “**Process ID**” from above “**Activity Number**” (e.g., ZRDT.B7).

Component 5: Core data elements (data dictionary)

Each data element should have a running number and a “**Data Element (DE) ID**” that should be structured “**Abbreviated health domain**” (e.g., ZRDT). “**DE**”. “*Sequential number of the data element*” (e.g., ZRDT.B7.DE.1, ZRDT.B7.DE.2).

Component 6: Decision support logic

Each decision support logic table should have a running number and a “**Decision support table (DT) ID**” that should be structured “**Abbreviated health domain**” (e.g., ZRDT). “**DT**”. “*Sequential number of the decision support table*” (e.g., ZRDT.DT.1, ZRDT.DT.2).

Component 7: Indicators and performance metrics

Each indicator should have an “**Indicator ID**” that should be structured “**Abbreviated health domain**” (e.g., ZRDT). “**IND**”. “*Sequential number of the indicator*” (e.g., ZRDT.IND.1, ZRDT.IND.2).

Component 8: High-level system requirements

- Each functional requirement should have a “**Functional requirement ID**” that should be structured “**Abbreviated health domain**” (e.g., ZRDT). “**REQ**”. “*Sequential number of the functional requirement*” (e.g., ZRDT.REQ.1, ZRDT.REQ.1).
- Each non-functional requirement should have a “**Non-functional requirement ID**” that should be structured “**Abbreviated health domain**” (e.g., ZRDT). “**NFXNREQ**”. “*Sequential number of non-functional requirements*” (e.g., ZRDT.NFXNREQ.1, ZRDT.NFXNREQ.2).

Component 1: Health interventions and recommendations

{Overview of the health interventions and WHO recommendations included in this DSUR. DSURs are meant to be a repackaging and integration of WHO guidelines and guidance documents in a particular health domain. The list of health interventions is drawn from the universal health coverage menu of interventions compiled by WHO.}

This DSUR focuses on the following health interventions and recommendations.

Key interventions

The key interventions for antigen rapid diagnostic testing programs are based on the [WHO universal health coverage compendium of interventions](#).

- Implementation of appropriate infection prevention and control measures.
- Community testing of symptomatic individuals meeting the case definition of suspected COVID-19.
- Detection and response to suspected outbreaks of COVID-19.
- Screening of asymptomatic individuals at high risk of COVID-19, including health care workers, contacts of cases, and other at-risk individuals.
- Clinical management of patients with suspected COVID-19 infection.
- Home care for patients with suspected or confirmed COVID-19 infection.
- Stock management of COVID-19 antigen RDT kits.

WHO guidelines, recommendations, and guidance

The DSUR is intended to reflect health recommendations and content that has already been published in WHO guidelines and guidance documents. The health content and interventions are drawn from the [antigen-detection in the diagnosis of SARS-CoV-2 infection recommendation from WHO](#).

Other guidelines represented in the DSUR include:

- [Use of antigen detection rapid diagnostics testing](#)
- [Diagnostic testing for SARS-CoV-2 infection](#)
- [Clinical management of severe acute respiratory infection when novel coronavirus \(nCoV\) infection is suspected](#)
- [SARS-CoV-2 antigen-detecting rapid diagnostic tests: an implementation guide](#)
- [Technical specifications for selection of essential in vitro diagnostics for SARS-CoV-2](#)

Component 2: Generic personas

Generic personas refer to fictional, generalized representations of users or stakeholders that are created to understand and address the needs, goals, behaviors, and characteristics of different user groups. These personas are not based on specific individuals but are constructed by combining common traits and attributes typically observed within a target user group. The purpose of creating generic personas is to help designers and developers gain a deeper understanding of the users they are designing for.

Table 2. Descriptions of key generic personas.

Occupational title	Description	Different names	ISCO code
Registered Nurse (Mary)	A graduate who has been legally authorized (registered) to practice after examination by a state board of nurse examiners or similar regulatory authority. Education includes three, four, or more years in nursing school, leading 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, nurse clinician	2221 (Nursing professionals)
Clinical Officer (Jacob)	Provides advisory, diagnostic, curative, and preventive medical services more limited in scope and complexity than those carried out by medical doctors. Works autonomously or with limited supervision of medical doctors and performs clinical, therapeutic, and surgical procedures for treating and preventing diseases, injuries, and other physical or mental impairments common to specific communities.	Primary care paramedic, advanced care paramedic, surgical technician, feldsher	2240 (Paramedical practitioners)
Laboratory Technician (John)	An individual who typically has completed formal training in biomedical science, medical technology, or a related field. This person performs clinical tests on specimens of bodily fluids and tissues in order to get information about the health of a patient, as well as tests and operates equipment for analysis of biological material, including blood and urine.	Medical laboratory technician, medical laboratory assistant	3212 (Medical and pathology laboratory technicians)
Environmental Health Technologist	Assesses, plans, and implements programs to recognize, monitor, and control environmental factors that can potentially affect human health, to ensure safe and healthy working conditions, and to prevent disease or injury caused by chemical, physical, radiological, and biological agents or ergonomic factors.	Environmental health officer, occupational health and safety adviser, occupational hygienist, radiation protection adviser	2263 (Environmental and occupational health and hygiene professionals)

Abbreviation: ISCO, International Standard Classification of Occupations.

Source: World Health Organization (WHO). Classifying health workers: Mapping occupations to the international standard classification [table]. Geneva: WHO; 2019. <https://www.who.int/publications/m/item/classifying-health-workers>.

Table 3. Descriptions of related persons.

In addition to the generic personas detailed above, there may be value in exploring other cadres and personas within the context of COVID-19 AgRDT services, such as facility in-charge. However, these were not identified as the central personas for the data and decision-support content detailed in this document. Additional personas related to the role of the targeted nurse and environmental health technologists are listed below.

Name	Description	Different names	ISCO code
Client	In the context of this document, an individual who seeks or has been identified for COVID-19 antigen rapid diagnostic testing.	Not applicable	Not applicable
District Health Information Officer	A manager who provides supervision of the monitoring system to ensure quality of care and data. Provides a link between the health center and central level to ensure patient monitoring needs are met (e.g., adequate staff, tools, and other resources) and conveys changes to national standards or norms.	District health manager, health management information systems focal point, monitoring and evaluation focal point, facility supervision manager	3252 (Medical records and health information technicians)
Data Entry Clerk	An individual who helps to record, organize, store, compute, and retrieve information, including patient records and registers. The knowledge and skills required are usually obtained as the result of on-the-job training or may include post-secondary education. Clerks may also transcribe data, tally data, fill in routine reports, and review the quality of data with others.	Data capturer	3252 (Medical records and health information technicians)
Facility In-Charge	Plans, directs, coordinates, and evaluates the provision of clinical and community health services at the health care facility. Provides overall direction, policy standards, and operational criteria for the units they manage, including supervising and evaluating the recruitment, training, and work activities of personnel. Monitors the use of health services and resources at the health care facility. Liaises with other health and welfare service providers, boards (including community boards), and funding bodies to coordinate the provision of services.	Health facility administrator	1342 (Health service managers)

Country context differences to note

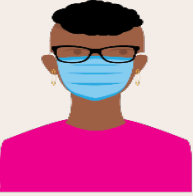
A persona is a depiction of a relevant stakeholder or “end user” of the system. Although the specific roles and demographic profiles of the personas will vary depending on the setting, the generic personas are based on the core competencies and credentials of different health care worker personas. Please note that these are developed based on synthesis across multiple contexts as a starting point, and further contextualization will be required according to the needs, motivations, and challenges of the targeted personas in each setting.


Abbreviation: ISCO, International Standard Classification of Occupations.


Source: World Health Organization (WHO). Classifying health workers: Mapping occupations to the international standard classification [table]. Geneva: WHO; 2019. <https://www.who.int/publications/m/item/classifying-health-workers>.

Detailed personas

Detailed personas were created based on research conducted by the PATH Living Labs team. They represent the different user types that interact with the system in a similar way. Personas provide understanding of users' needs, experiences, behaviors, and goals—to recognize that different people have different needs and expectations. Personas can also help in relating with the user for whom it is being designed. Personas make the design task less complex; they guide *ideation* processes; and help in achieving the goal of creating a good user experience for the target user group.

	Provider persona: Mary, Registered Nurse Age: 24–37 years old Experience: 10 months–12 years The nurse has access to a personal smartphone.
Responsibilities	<ul style="list-style-type: none"> • Screen clients for signs and symptoms of COVID-19. • Document patient and testing data in a laboratory request form and the COVID-19 register and/or available digital tools. • Perform nasopharyngeal swabbing of clients. • Conduct antigen rapid diagnostic testing. • Conduct clinical assessment of patient vitals, including blood oxygen level checks. • Refer positive patients for clinical or community management based on clinical assessment. • Treat patient symptoms. • Submit daily report of COVID-19 rapid diagnostic testing activities, including COVID-19 consumables usage information.
Context descriptions	<p>[Facility A] is a peri-urban facility in a densely populated area in [District A], [Country A]. The facility is understaffed, and trained health care workers generally share duties to manage the high workload. The facility is supported by community-based volunteers, but there is generally a low literacy level among the volunteers, which limits their level of support. The facility has access to solar power, but it is unreliable. There is also limited internet connectivity, and most services are still done manually. The facility offers COVID-19 antigen rapid diagnostic testing but does not conduct PCR testing on-site.</p>
Challenges	<ul style="list-style-type: none"> • Unavailability of standardized COVID-19 registers—all available registers are improvised, making it difficult for health care workers to know if they are collecting all the required information. • Redundancies in data capture—recording the same data in the line list and register. • Challenges accessing guidelines. • No tools for referral support, and thus are dependent on professional judgment to make referral decisions. • Limited space for testing in some facilities.
Opportunities	<ul style="list-style-type: none"> • Develop a digital data capture and management tool to remove redundancies and standardize data collection. • Digitize COVID-19 guidelines for health care workers for easier access. • Make the data management tool an online/offline hybrid to allow health care workers to input data offline and upload data for reporting when online. • Integrate a visual mapping component in a digital tool that can help to identify the risk of outbreaks in zones, with contact information of active community-based volunteers in the zones. • Option to print out hard copy records as backup in event of connectivity challenges/app failure.

	<p>Provider persona: Jacob, Clinical Officer</p> <p>Age: 28 years old Experience: 3 years The clinical officer has access to a personal smartphone.</p>
<p>Responsibilities</p>	<ul style="list-style-type: none"> • Screen clients for signs and symptoms of COVID-19. • Document patient and testing data in a laboratory request form and the COVID-19 register and/or available digital tools. • Perform nasopharyngeal swabbing of clients. • Conduct antigen rapid diagnostic testing. • Conduct clinical assessment of patient vitals, including blood oxygen level checks. • Treat patient symptoms. • Submit daily report of COVID-19 rapid diagnostic testing activities, including COVID-19 consumables usage information.
<p>Context descriptions</p>	<p>[<i>Facility A</i>] is a peri-urban facility in a densely populated area in [<i>District A</i>], [<i>Country A</i>]. The facility is understaffed, and trained health care workers generally share duties to manage the high workload. The facility is supported by community-based volunteers but there is generally a low literacy level among the volunteers, which limits their level of support. The facility has access to solar power, but it is unreliable. There is also limited internet connectivity, and most services are still done manually. The facility offers COVID-19 antigen rapid diagnostic testing but does not conduct PCR testing on-site.</p>
<p>Challenges</p>	<ul style="list-style-type: none"> • No tools for referral support, and thus are dependent on professional judgment to make referral decisions. • Booklets and/or guidelines are not easy to refer to in an emergency. • Lack of personal protective equipment.
<p>Opportunities</p>	<ul style="list-style-type: none"> • Digitize COVID-19 guidelines for health care workers for easier access. • Make the data management tool an online/offline hybrid to allow health care workers to input data offline and upload data for reporting when online. • Integrate a visual mapping component into a digital tool that can help to identify the risk of outbreaks in zones, with contact information of active community-based volunteers in the zones. • Optimize image-capture features of apps to reduce image sizes. • Option to print out hard-copy records as backup in event of connectivity challenges/app failure.

	<p>Provider persona: John, Laboratory Technician</p> <p>Age: 29–42 years old Experience: 4–5 years The laboratory technician has access to a personal smartphone and a facility computer.</p>
<p>Responsibilities</p>	<ul style="list-style-type: none"> • Perform nasopharyngeal swabbing of clients. • Conduct antigen rapid diagnostic testing. • Document patient and testing data in a laboratory request form, the COVID-19 register, and/or available digital tools. • Submit daily report of COVID-19 rapid diagnostic testing activities, including COVID-19 consumables usage information.
<p>Context descriptions</p>	<p>[Facility A] is a peri-urban facility in a densely populated area in [District A], [Country A]. The facility is understaffed, and trained health care workers generally share duties to manage the high workload. The facility is supported by community-based volunteers, but there is generally a low literacy level among the volunteers, which limits their level of support. The facility has access to solar power, but it is unreliable. There is also limited internet connectivity, and most services are still done manually. The facility offers COVID-19 antigen rapid diagnostic testing but does not conduct PCR testing on-site.</p>
<p>Challenges</p>	<ul style="list-style-type: none"> • The laboratory technician returns the RDT result in person, which is a challenge if their workload is heavy. • Inconsistent supply of logistics.
<p>Opportunities</p>	<ul style="list-style-type: none"> • Automate patient flow and records management (e.g., ordering an RDT is currently done through handwritten notes). • Develop an inventory management module with an ordering feature for consumables.

Additional considerations for contextualizing personas

Although this section provides an overview of the generic roles of the targeted personas, it is important to contextualize these personas to each unique setting. The generic personas described above can be supplemented by reflecting on these additional considerations:

- **Background and demographics** (whether they are from the community, familiar with digital devices, own a mobile phone/smartphone, etc.).
- **Local environment** and any relevant contextual information about their surroundings (e.g., work site characteristics; rural or urban; availability of electricity, water, internet; distance from nearest referral facility).
- **Expected roles and responsibilities:** What are the expected roles and responsibilities based on country context?
- **Actual roles and responsibilities:** What are the actual roles and responsibilities, if there is any difference from what is expected?
- **Context:** What is the level of internet connectivity? What is the distance to the nearest referral facility? Who are other personas/health care workers with whom they interact?
- **Challenges:** What are the day-to-day challenges the end user might face?
- **Motivations:** What does success look like to them? Are there targets they need to achieve?

Component 3: User stories

{User scenarios are narratives that describe how the different personas may interact with each other. The user scenarios are only illustrative and intended to give an idea of a typical workflow.}

How to interpret user scenarios for functional requirements

User scenarios are helpful tools not only to better understand the context in which a digital tool would operate, but also for insights into what key data elements would need to be recorded and accounted for in the database. Additionally, the context in which the tool would operate, illuminated by the user scenarios, provides insight into some functional and non-functional requirements that the system would also need. For example, highlighted in **yellow** are data elements that need to be recorded and/or calculated. Highlighted in **blue** is decision support logic that can be automated in the system. Highlighted in **green** are functional and non-functional requirements that should be included in the system.

Country-specific differences to note

This post-test scenario aligns with the scenario witnessed in the **Zambia** context. However, in the **Senegal** and **India** context, the patient is either hospitalized or sent home for self-quarantine (as opposed to community management).

Key personas

Health Facility In-Charge: *Lucy*
Patient: *Alex*
Clinical Officer: *Jacob*
Laboratory Technician: *John*
District Surveillance Officer: *Martha*
District Laboratory Technician: *Abel*
Community-based volunteer: *Beatrice*

Lucy, a facility in-charge at an urban health facility in Community Zone A, is at the outpatient department assisting health care workers who have been assigned to the department due to the number of clients/long queue. Lucy is particularly assisting with **screening of clients** by **checking their vitals**, including blood pressure and temperature. She also uses the COVID-19 screening form to **identify those who may have COVID-19 symptoms**. Lucy is recording **client details** in the outpatient register to capture their name, age, sex, address, and phone number. The vitals of the client are indicated on a piece of paper given to them as they go to see the clinic officer for clinical screening. During screening, Lucy notices that one of the clients, Alex, has some symptoms of COVID-19. Without alarming the other clients, Alex is quickly sent to the laboratory with a piece of paper requesting that a test be done.

John, a laboratory technician, conducts an antigen RDT upon receiving the request note from Alex. John also collects/indicates client details in an improvised register that captures the client's name, age, sex, address, and phone while waiting for the results. After 15 minutes, Alex's **results are ready and positive**, and John personally delivers them back to Lucy, who immediately ensures that Alex is isolated. Lucy then informs Jacob, the clinical officer, that they have a COVID-19 patient in the isolation room.

Jacob **conducts a clinical assessment of Alex's vitals**, including blood oxygen levels and temperature. With these, Jacob decides that Alex will be managed in the community. Jacob tells Alex that if at any time she feels unwell, she should not hesitate to come back to the health facility. Alex is **treated for the symptoms**, and Lucy walks her through the guidelines for community management to avoid infecting others. Lucy collects additional information from Alex, including the people she has been in contact with recently.

Beatrice, a community-based volunteer, comes to Lucy later in the day and requests the improvised COVID-19 register. Beatrice takes note of all those who tested positive on that particular day and takes down their details. Beatrice shares patient details with her fellow community-based volunteers for patients in their zones.

Beatrice calls Alex, who is from her zone, to check on how she is doing and make an appointment. Alex indicates the following day would be okay for her.

At the end of the day, Lucy **compiles the daily activities**, which she submits to Martha, the district surveillance officer.

Martha is also informed about the number of patients who have been referred for community management, except those going to the isolation center. Once Martha has received these reports from health facilities and other testing points, such as schools, she compiles a Consolidated Daily Testing Report. John also **submits a report of COVID-19 testing activities**, including COVID-19 consumables usage information, to Abel, the district laboratory supervisor, who compiles a consolidated daily testing data from all facilities in the district and provides a Daily District Testing and Inventory/Stock Status Report for COVID-19 to the provincial biomedical specialist.

**Processes
(See Component 4)**

- Documentation of client details in a register in the outpatient department.
- Screening clients for COVID-19 symptoms.
- Antigen rapid diagnostic testing.
- Clinical assessment of patient.
- Referral for community management.
- Identification of community management patients using a register.
- Reporting to the district/province.

Key personas

Community-based volunteer: Beatrice
Patient: Alex
Contact person: Christian
Clinical Officer: Jacob

It is a Tuesday afternoon in Community Zone A, where Beatrice, a community-based volunteer, works.

A day before, Alex was identified as one of the **COVID-19-positive patients referred for community management**. Beatrice had called Alex to ask her for the preferred time to visit her, so she makes a follow-up call to confirm the appointment, and Alex is agreeable to being visited. Beatrice meets Alex, and their discussion starts with information, education, and communication on COVID-19 and its management.

Beatrice then asks Alex some questions for contact tracing. Christian, one of Alex's contacts, is exhibiting **signs and symptoms of COVID-19** and is **referred to the health facility for testing**. While monitoring the patient's vitals, Beatrice documents the patient's condition in the monitoring form and uses a digital tool when it is available.

Alex is visited by Beatrice daily for 14 days. Beatrice checks her temperature and oxygen level every day to **monitor for improvements**. If the symptoms worsen, Beatrice is ready to **refer Alex back to the health facility**.

On the 14th day of the community management, Alex's condition is stable. Beatrice refers Alex back to the health facility, where Jacob **conducts a clinical assessment** to ascertain if Alex can be discharged from community management.

**Processes
(See Component 4)**

- Community management of patient.
- Documentation of patient's progress.
- Reporting to the facility in-charge.
- Referral to the health facility.
- Discharge from community management.

Key personas	Registered Nurse: <i>Alice</i> Patient: <i>Albert</i> Environmental Health Technologist: <i>Melody</i>
<p>Alice is a registered nurse at a rural health facility where she and Melody, the environmental health technologist, are the only trained staff. Alice receives Albert, who has come to seek medical services at the health facility, and collects his details, including village and zone, age, and sex, which she writes in an improvised register.</p> <p>Using a COVID-19 symptoms checklist, Alice screens for signs and symptoms of COVID-19 and asks for Albert's travel details so that she can determine if he is eligible for antigen rapid diagnostic testing or not. Alice notes that Albert has some symptoms of COVID-19, and she conducts the antigen RDT, which indicates that Albert is COVID-19 positive.</p> <p>Albert is moved to another room for isolation and observation. Alice continues to monitor Albert by checking his vitals from time to time, including his oxygen levels. After a few hours, Albert's oxygen levels are still normal, and he has no fever, which informs Alice's decision to refer Albert for community management. Albert receives treatment and counseling on how he should live to avoid infecting others in the community, and is sent back home.</p> <p>At the end of the day, Alice compiles a daily report, which includes the number of tests done, number of positive cases, and consumables used. She sends it to the district surveillance officer through WhatsApp.</p>	
Processes (See Component 4)	<ul style="list-style-type: none"> • Documentation of client details in a register in the outpatient department. • Screening clients for COVID-19 symptoms. • Antigen rapid diagnostic testing. • Clinical assessment of patient. • Referral for community management. • Identification of community management patients using a register. • Reporting to the district/province.

Component 4: Business process and workflows

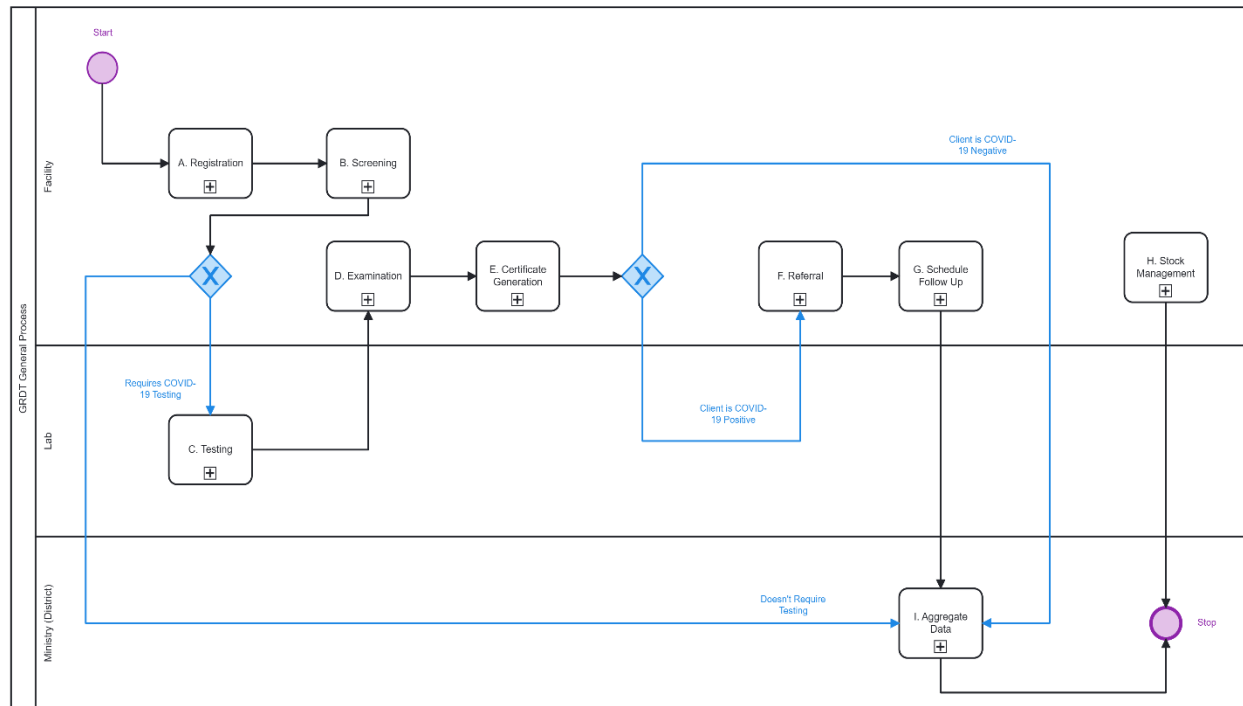
{A business process is a set of related activities or tasks performed together to achieve the objectives of the health program area, such as registration, screening, and referrals. Workflows are a visual representation of the progression of activities (tasks, decision points, interactions) that are performed within the business process.}

Overview of key generic COVID-19 antigen rapid diagnostic testing processes

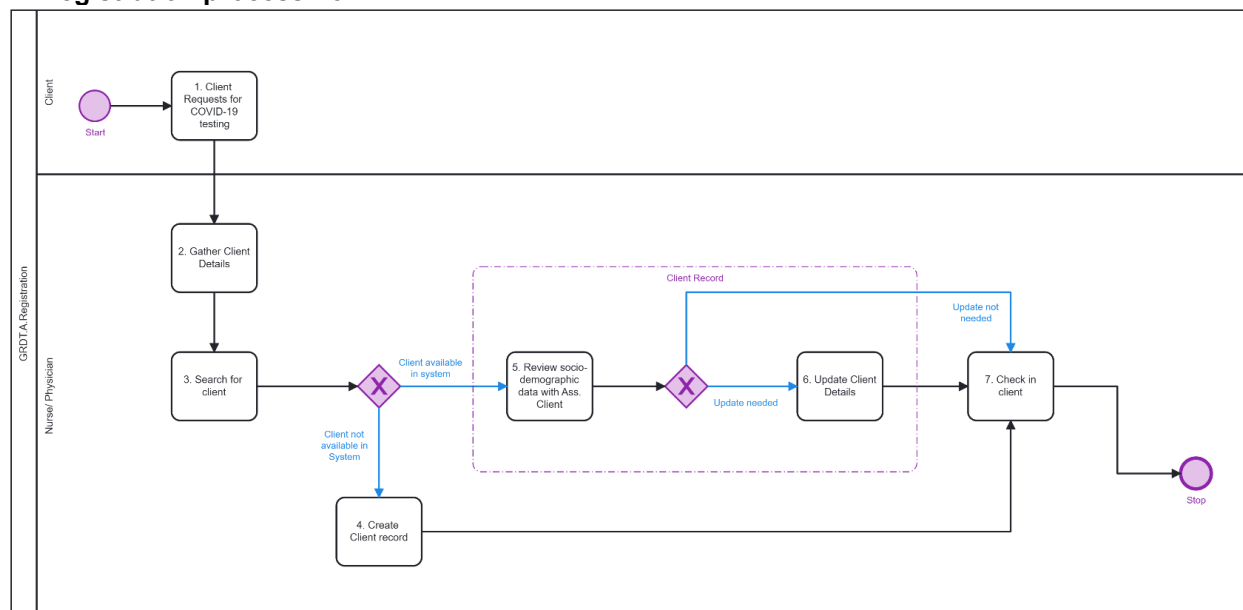
	Process name	Process identifier	Personas	Objectives	Task set
	Title	Identifier used to reference this process throughout the DSUR	Individuals interacting to complete the process	A concrete statement describing what the process seeks to achieve	The general set of activities performed within the process
A	Registration	GRDT.A	<ul style="list-style-type: none">• Client• Nurse• Clinical officer	Ensure client is located in the system with updated personal details or, if not located, entered into the system.	<i>Starting point: Client visits facility and asks for COVID-19 testing</i> <ul style="list-style-type: none">• Search for client record.• Review and update client record.• Create a new client record.• Check in client.
B	Screening	GRDT.B	<ul style="list-style-type: none">• Client• Clinical officer• Nurse	Capture details on initial screening of a client for signs and symptoms of COVID-19.	<i>Starting point: Check client for signs and symptoms of COVID-19</i> <ul style="list-style-type: none">• Update client's COVID-19 vaccine status.• Check client for signs and symptoms of COVID-19.• Refer client for testing.
C	Testing	GRDT.C	<ul style="list-style-type: none">• Client• Nurse• Clinical officer	Capture details on COVID-19 antigen RDT for a qualifying client.	<i>Starting point: Patient is referred for testing</i> <ul style="list-style-type: none">• Input test reference details.• Input RDT details.• Start test timer (<i>optional</i>).• Record test results.

	Process name	Process identifier	Personas	Objectives	Task set
D	Examination	GRDT.D	<ul style="list-style-type: none"> Client Nurse Clinical officer 	Capture details on examination of a positive/negative RDT result by a clinical officer to establish if a retest is required.	<p><i>Starting point: Health care worker receives COVID-19 test results</i></p> <ul style="list-style-type: none"> Receive COVID-19 test results. Determine if retest is required. Refer for treatment/ hospitalization/ community management or self-quarantine.
E	Certificate generation	GRDT.E	<ul style="list-style-type: none"> Client Nurse Clinical officer 	Generate a COVID-19 digital test result certificate for proof of either a negative or a positive COVID-19 test result.	<p><i>Starting point: Health care worker and client have received examined COVID-19 test results</i></p> <ul style="list-style-type: none"> Receive examined COVID-19 test results. Generate digital certificate, if required. Provide for digital signing of the certificate.
F	Referral	GRDT.F	<ul style="list-style-type: none"> Nurse Environmental health technologist Clinical officer 	Capture details on referral of positive clients for clinical care or community management.	<p><i>Starting point: Review determined medical condition of patient</i></p> <ul style="list-style-type: none"> Review medical condition of patient. Call ambulance for facility-based management. Contact community-based volunteer for community management.
G	Scheduling follow-up	GRDT.G	<ul style="list-style-type: none"> Nurse Environmental health technologist Clinical officer 	Provide routine health promotion and follow-up with patient under community management.	<p><i>Starting point: Patient referred to community management</i></p> <ul style="list-style-type: none"> Schedule patient's next visit Conduct basic assessment during visit. Determine if medical intervention is required.
H	Stock management	GRDT.H	<ul style="list-style-type: none"> Stock manager 	Track usage of the COVID-19 RDT kits at the facility.	<p><i>Starting point: Stock is distributed to the facility</i></p> <ul style="list-style-type: none"> Initialize stock. Distribute stock to different service centers. Generate stock usage report.
I	Data aggregation	GRDT.I	<ul style="list-style-type: none"> Facility staff District health officer/staff Facility in-charge 	Aggregate client-level data into validated reports; use these data and submit reports at the facility level.	<p><i>Starting point: Time for periodic (usually monthly) reporting</i></p> <ul style="list-style-type: none"> Check data quality. Correct fixable errors. Generate and review aggregate reports. Submit for approval. Provide feedback and any changes required.

Generic COVID-19 antigen rapid diagnostic testing process flow



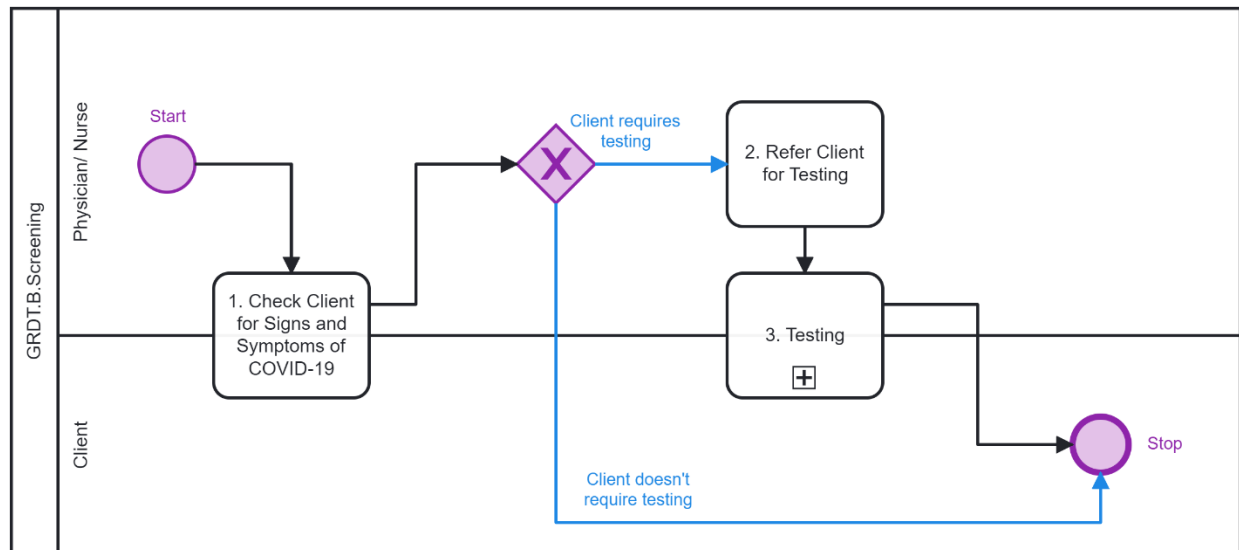
A. Registration process flow



Country-specific differences to note

In the **Zambia** context, the patient's national identification number is used as the unique identifier, as opposed to a unique, system-generated identifier. Tracking of vaccination information is practiced in **India** and **Senegal**. For the **India** context, data collected is in alignment with the Indian Council of Medical Research [COVID-19 Testing Laboratories - Register form](#).

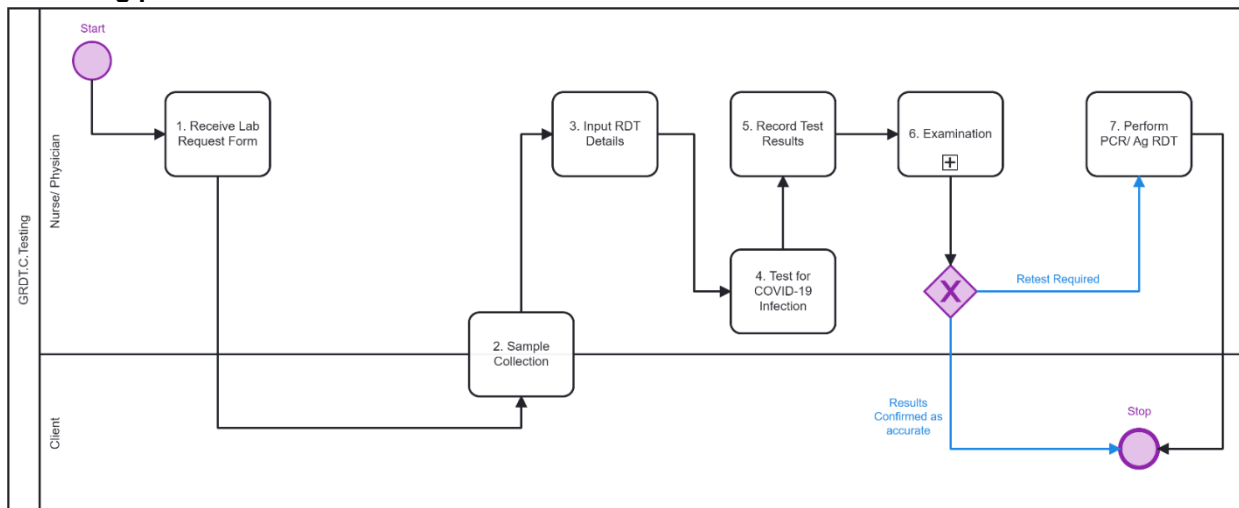
B. Screening process flow



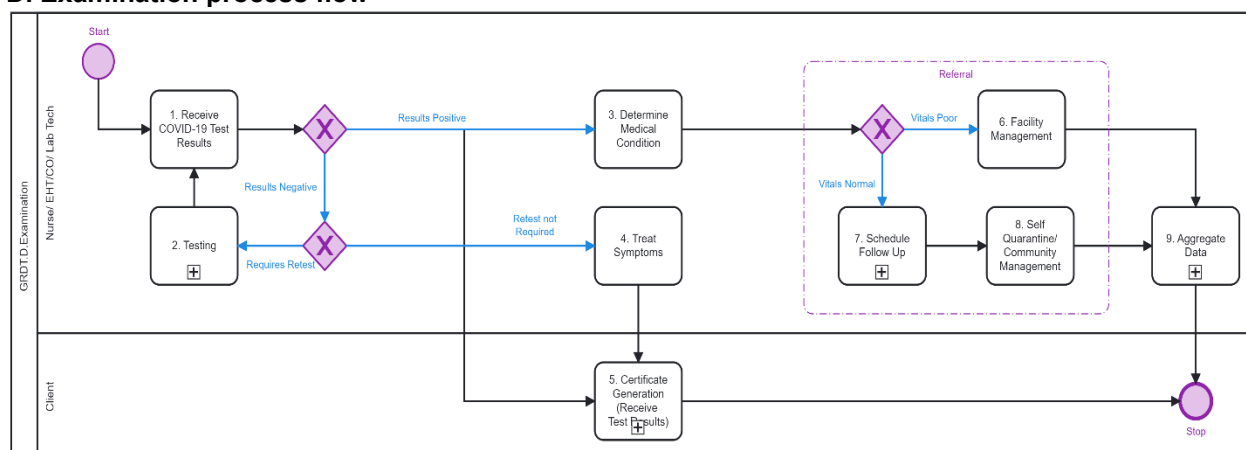
Country-specific differences to note

In the **Zambia** context, patients may be referred to different testing locations to get a COVID-19 antigen RDT (e.g., respiratory care center or laboratory). Information for contact tracing is recorded in the **India** and **Zambia** contexts but not in **Senegal**.

C. Testing process flow



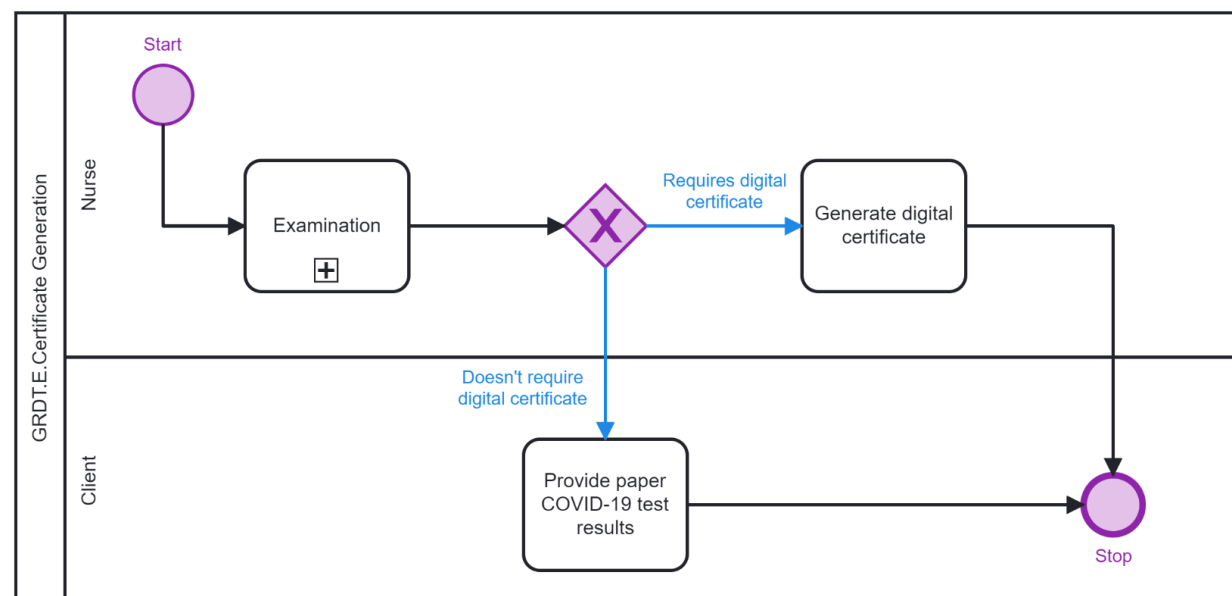
D. Examination process flow



E. Certificate generation process flow

Country-specific differences to note

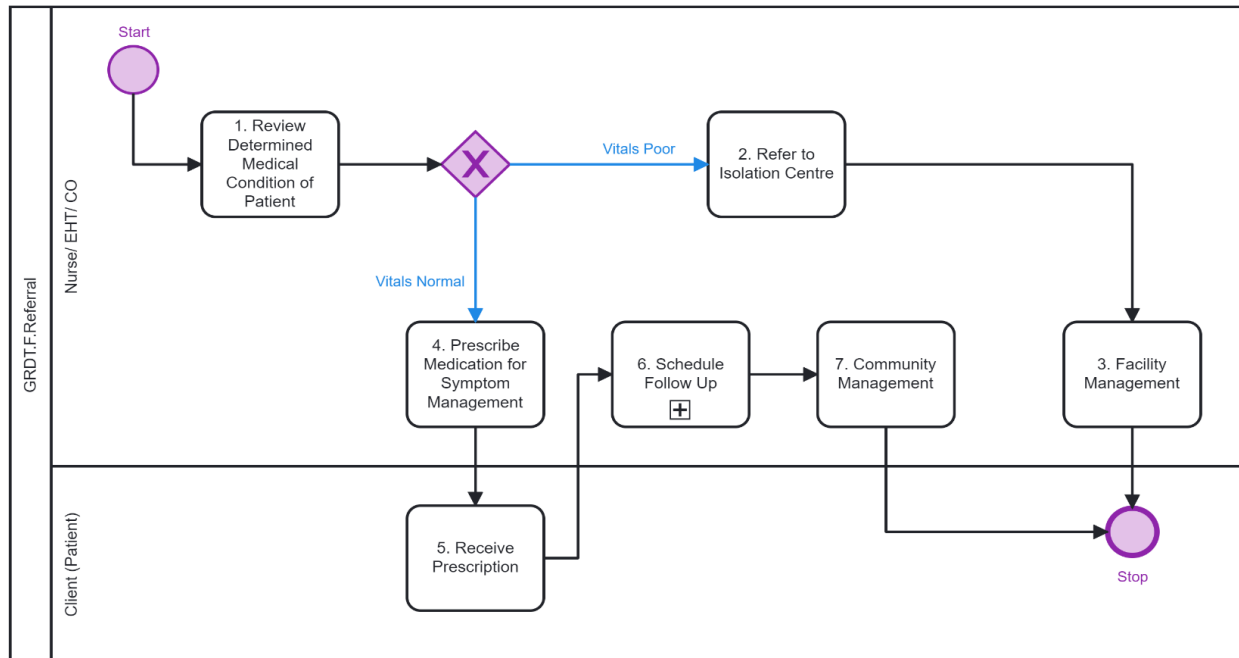
In the **India** and **Senegal** contexts, in case a retest is required for a COVID-19-positive patient, the health care worker refers the patient for PCR testing as opposed to another antigen RDT. In the **Zambia** context, the patient is referred for another RDT.



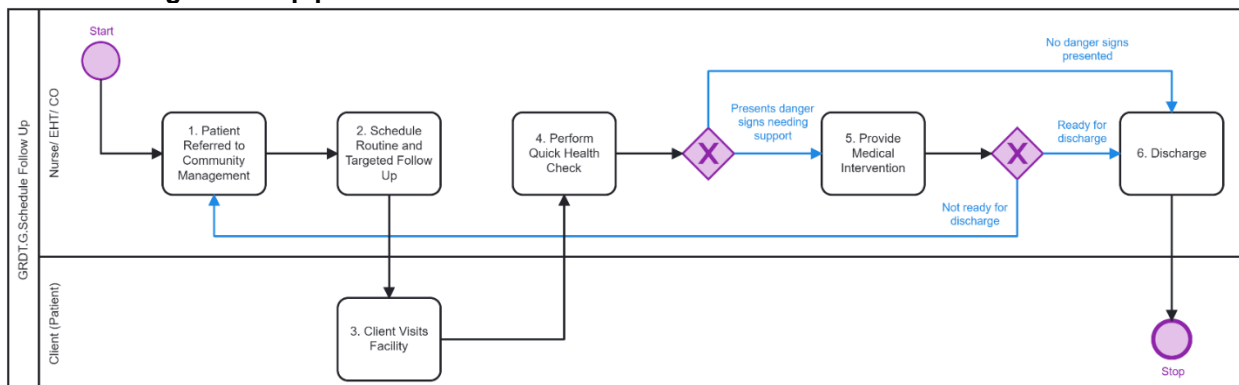
Country-specific differences to note

In the **India**, **Senegal**, and **Zambia** contexts, a digital certificate is not provided to the patient. The patient is given their RDT report in paper-based format. The patient may also receive a notification via SMS, when a phone number was provided at registration.

F. Referral process flow



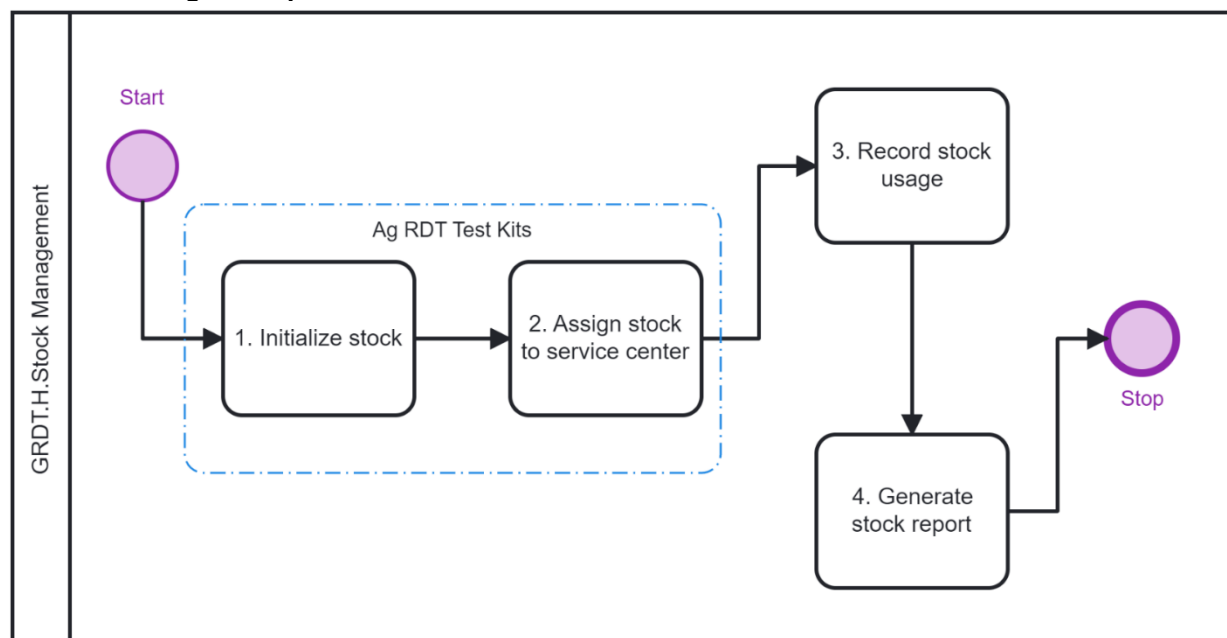
G. Scheduling follow-up process flow



Country-specific differences to note

In **Zambia**, the patient may be referred for either community management and monitored by a CBV for 14 days or referred to a hospital. In the **India** and **Senegal** contexts, the patient is either hospitalized or advised to self-quarantine.

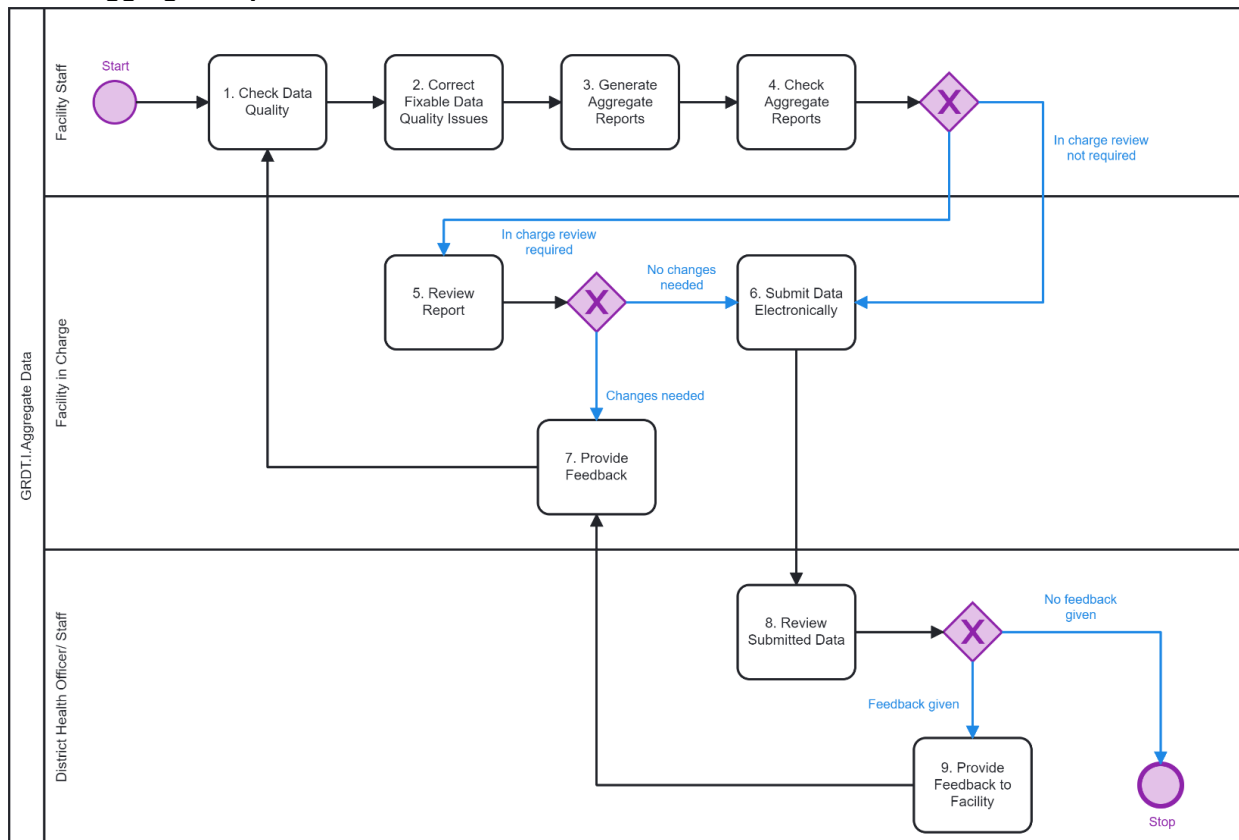
H. Stock management process flow



Country-specific differences to note

This process is created in alignment with the Senegal context. India and Zambia do not track stock usage at the facility level.

I. Data aggregation process flow



Country-specific differences to note

In the [Senegal](#) context, COVID-19-positive patients referred to a hospital or self-quarantine are not tracked. However, tracking of pregnant women found to be COVID-19 positive is a national indicator.

Component 5: Core data elements

This section outlines the minimum set of data corresponding to different points of the workflow within the identified business processes. This dataset can be used on any software system and lists the data elements relevant for service delivery and executing decision support logic, as well as for populating indicators and performance metrics. Although this section provides a high-level overview of the data elements, a more complete data dictionary in spreadsheet form detailing the input options, validation checks, and concept dictionary codes is available in [Web Annex A](#).

Inclusion of a data element in the table does not by itself indicate that collection of the data is required. Additionally, some data elements are dependent on other data elements.

Activity identifier/name	Data element identifier	Data element name	Description and definition
Business process GRDT.A: Registration			
GRDT.A2. Gather Client Details	GRDT.A2.DE.1	Client ID	Unique, system-generated patient identifier
	GRDT.A2.DE.2	Client First Name	Client's first or given name
	GRDT.A2.DE.3	Client Family Name	Client's last or family name
	GRDT.A2.DE.4	Client Birth Date	Client's date of birth, capturing day, month, and year of birth
	GRDT.A2.DE.5	Age	Estimated age in years of the client, captured if client birth date is unknown
	GRDT.A2.DE.6	Sex	Client's biological sex at birth, either male or female
	GRDT.A2.DE.7	Contact Number	Number where client may be reached
	GRDT.A2.DE.8	Client Address	Client's address, including street name, district/county, city, and region
	GRDT.A2.DE.9	Client Occupation	Client's current occupation/profession
	GRDT.A2.DE.10	Next of Kin	Client's next of kin details, including name, address, and contact number
GRDT.A7. Check in Client	GRDT.A7.DE.1	Purpose of Visit	Client's purpose for visiting the facility
Business process GRDT.B: Screening			
GRDT.B1. Check Client for Signs and Symptoms of COVID-19	GRDT.B1.DE.1	COVID-19 Vaccine Status	Client's COVID-19 vaccination status information
	GRDT.B1.DE.2	Vaccine Type	Type of vaccine used by the client for COVID-19 vaccination
	GRDT.B1.DE.3	Number of Doses	Number of vaccine doses the client has received
	GRDT.B1.DE.4	Fever or history of fever	Existence or patient-reported recent history of

Activity identifier/name	Data element identifier	Data element name	Description and definition
		(>37.5°C) (Y/N)	fever based on thermometer reading of ≥37.5°C
	GRDT.B1.DE.5	If yes, please provide temperature	Temperature from thermometer
	GRDT.B1.DE.6	Sore throat (Y/N)	Patient-reported existence of sore throat
	GRDT.B1.DE.7	Cough (Y/N)	Patient-reported existence of cough
	GRDT.B1.DE.8	Runny nose (Y/N)	Patient-reported existence of runny nose
	GRDT.B1.DE.9	Shortness of breath (Y/N)	Patient-reported existence of shortness of breath
	GRDT.B1.DE.10	Diarrhea (Y/N)	Patient-reported existence of diarrhea
	GRDT.B1.DE.11	Have you had these symptoms for more than 14 days? (Y/N)	Patient-reported existence of any symptoms more than 14 days
	GRDT.B1.DE.12	Contact with a person with confirmed or under investigation for COVID-19 in the last 14 days? (Y/N)	Patient-reported interaction of contact with suspect case of COVID-19
	GRDT.B1.DE.13	Have you traveled outside [city of facility] in the last 14 days? (Y/N)	Patient-reported travel outside of facility location
	GRDT.B1.DE.14	Vitals Status	Status of client's vitals
	GRDT.B1.DE.15	Request for testing (Y/N)	Client is requested to take a COVID-19 test
GRDT.B2. Refer Client for Testing	GRDT.B2.DE.1	Today's date	Date of screening
	GRDT.B2.DE.2	Code	Facility Code
	GRDT.B2.DE.3	Province	Name of facility province location
	GRDT.B2.DE.4	District	Name of facility district location
	GRDT.B2.DE.5-DE.11	Client Details	Client registration details
	GRDT.B2.DE.12	Hospital/Institution	Name of facility
	GRDT.B2.DE.13	Reasons for testing	Specification of why patient has presented for testing
	GRDT.B2.DE.14	Comorbid conditions (select all that apply)	Client's pre-existing comorbid conditions
Business process GRDT.C: Testing			
GRDT.C1. Receive Laboratory Request Form	GRDT.C1.DE.1	Received by	Name of provider receiving patient information at testing collected at registration and screening
	GRDT.C1.DE.2	Date of receipt	Date of receiving patient information at testing

Activity identifier/name	Data element identifier	Data element name	Description and definition
			collected at registration and screening
	GRDT.C1.DE.3	Time of receipt	Time of receiving patient information at testing collected at registration and screening
GRDT.C2. Input Test Reference Details	GRDT.C2.DE.1	Patient ID	Unique, system-generated patient identifier, linking patient to test reference details
	GRDT.C2.DE.2	Test Number	Unique, system-generated instance of a test
	GRDT.C2.DE.3	Test Location	Geocodes of where test is being conducted, collected from device
	GRDT.C2.DE.4	Sample Type	Indicates how biological sample was collected
	GRDT.C2.DE.5	Reason Test	Indicates reason for performing test
	GRDT.C2.DE.6	Repeat Test (Y/N)	Indicates whether the test being conducted immediately follows another, in the event of a failed or inconclusive test
	GRDT.C2.DE.7	Reason Repeat	Indicates reason for repeating test
GRDT.C3. Input RDT Details	GRDT.C3.DE.1	RDT Manufacturer	Name of the RDT device manufacturer
	GRDT.C3.DE.2	RDT Name	Device/RDT model name as assigned by the manufacturer
	GRDT.C3.DE.3	RDT Code	Unique identifying code assigned by the manufacturer to each device
	GRDT.C3.DE.4	RDT Lot Number	Lot or batch number to which the individual device belongs
	GRDT.C3.DE.5	RDT Expiry Date	Expiry date of the device with respect to the lot number
	GRDT.C3.DE.6	RDT Start Time	Time at which test was begun
GRDT.C5. Record Test Results	GRDT.C5.DE.1	RDT Result	Specification of antigen RDT result
	GRDT.C5.DE.2	RDT End Time	Time at which the antigen RDT result was read by health care worker
	GRDT.C5.DE.3	Image of RDT	Image taken from camera phone or tablet of antigen RDT result
Business process GRDT.D: Examination			
GRDT.D1. Receive COVID-19 Test Results	GRDT.D1.DE.1	RDT Result	Specification of antigen RDT result
	GRDT.D1.DE.2	Received by	Name of provider receiving antigen RDT result
	GRDT.D1.DE.3	Date of receipt	Date at which the antigen RDT result was received by provider
	GRDT.D1.DE.4	Time of receipt	Time at which the antigen RDT result was received by provider
	GRDT.D1.DE.5	Retest required? (Y/N)	Whether or not retest is required based on

Activity identifier/name	Data element identifier	Data element name	Description and definition
			antigen RDT result
	GRDT.D1.DE.6	Retest reason	Specification of why retest is required
	GRDT.D1.DE.7	Additional notes	Image taken from camera phone or tablet of antigen RDT result
GRDT.D.3 Determine Medical Condition	GRDT.D3.DE.1	COVID-19 Symptoms	Checklist of COVID-19 symptoms
	GRDT.D3.DE.2	Danger Signs	Diagnostic signs that patient may be in danger or severe distress
	GRDT.D3.DE.3	Vitals	Provider-determined vitals classification
	GRDT.D3.DE.4	Referral	Provider-determined referral suggestion based on signs and symptoms
GRDT.D4. Treat Symptoms	GRDT.D4.DE.1	Treatment Received? (Y/N)	Whether or not any kind of treatment was provided to patient
	GRDT.D4.DE.2	Prescription Given? (Y/N)	Whether or not any kind of medicine or prescription was provided to patient
	GRDT.D4.DE.3	Type of Prescription	Prescription given (list all)
	GRDT.D4.DE.4	Additional Notes	Any extra notes by provider regarding treatment or prescription
Business process GRDT. E: Certificate generation			
GRDT.E.3 Generate Digital Certificate	GRDT.E3.DE.1	Client First Name	Client's first or given name
	GRDT.E3.DE.2	Client Family Name	Client's last or family name
	GRDT.E3.DE.3	Client ID	Unique identifier for the tested person, according to the policies applicable to each country; there can be more than one unique identifier used to link records (e.g., national, health, medical record)
	GRDT.E3.DE.4	RDT Brand	The brand or trade name used to refer to the test conducted
	GRDT.E3.DE.5	RDT Manufacturer	Name of the manufacturer of the test conducted
	GRDT.E3.DE.6	Date and time of sample collection	Date and time when sample was collected
	GRDT.E3.DE.7	RDT Result	Specification of antigen RDT result
	GRDT.E3.DE.8	Test center or facility name	A codable name or identifier of the facility responsible for conducting the test
	GRDT.E3.DE.9	Test center country	The country in which the individual was tested
	GRDT.E3.DE.10	Certificate issuer	The authority or authorized organization that issued the test result certificate

Activity identifier/name	Data element identifier	Data element name	Description and definition
	GRDT.E3.DE.11	Health certificate identifier	Unique identifier for a physical and/or digital health folder that contains one or more test events and associated certificates of a tested person
	GRDT.E3.DE.12	Certificate valid from	Date and time at which the test result certificate became valid; no health or clinical inferences should be made from this date
	GRDT.E3.DE.13	Certificate schema version	Version of the core dataset and HL7 FHIR implementation guide that the certificate is using
Business process GRDT.F: Referral			
GRDT.F1. Review Determined Medical Condition of Patient	GRDT.F1.DE.1-DE.3	Patient Details	Patient registration details
	GRDT.F1.DE.4-DE.7	Test Details	Details around the antigen RDT that was conducted
	GRDT.F1.DE.8-DE.24	Medical Examination Details	Details of medical examination
	GRDT.F1.DE.25	Vitals	Provider-determined vitals classification
	GRDT.F1.DE.26	Referral	Provider-determined referral suggestion based on signs and symptoms
	GRDT.F1.DE.27	Completed by	Name of health care worker/provider who conducted the medical examination
GRDT.F6. Prescribe Medication for Symptom Management	GRDT.F6.DE.1	Prescription Given? (Y/N)	Whether or not any kind of medicine or prescription was provided to patient
	GRDT.F6.DE.2	Type of Prescription	Prescription given (list all)
	GRDT.F6.DE.3	Additional Notes	Any extra notes by provider regarding treatment or prescription
	GRDT.F6.DE.4	Administrator ID	Unique identifier of the health care worker or practitioner who is conducting the examination
	GRDT.F6.DE.5	Administrator Name	Name of the health care worker or practitioner who is conducting the examination

Activity identifier/name	Data element identifier	Data element name	Description and definition
Business process GRDT.G: Scheduling follow-up			
GRDT.G2. Schedule Routine and Targeted Follow-Up	GRDT.G2.DE.1	Patient First Name	Client's first or given name
	GRDT.G2.DE.2	Patient Family Name	Client's last or family name
	GRDT.G2.DE.3	Patient ID	Unique, system-generated patient identifier
	GRDT.G2.DE.4	Test Location	Facility name where antigen rapid diagnostic testing was conducted
	GRDT.G2.DE.5	RDT Result	Specification of antigen rapid diagnostic test result
	GRDT.G2.DE.6	Date of Medical Examination	Date of patient examination
	GRDT.G2.DE.7	Additional Notes	Any extra notes by provider regarding antigen rapid diagnostic test
	GRDT.G2.DE.8	Residence	Residence of patient where community management will be provided
	GRDT.G2.DE.9	Community Management Period	The number of days the patient should be under community management
	GRDT.G2.DE.10	Follow-up date	Date of patient community management and treatment follow-up with facility

Additional considerations for adapting the data dictionary

Some settings may require the inclusion of additional data elements into the full dataset or changes to response options based on contextual differences. Additionally, the transition from paper-based forms to digital systems may require some reflection on whether data elements currently on the paper forms should be incorporated into the digital system.

Component 6: Decision support logic

Components of the decision support tables

Decision identifier	The name of the decision, describing what algorithm or logic is represented (e.g., whether a client needs to be retested for COVID-19). The decision identifier should correspond to the number on the overview table, above.			
Business rule	The description of the decision that needs to be made based on IF/THEN statements with the appropriate data element name for your variables. The rule should demonstrate the relationship between the input variables and the expected outputs and actions within the decision support logic.			
Trigger	The event that would indicate when this decision support logic should appear within the workflow, such as the activity that would trigger this decision to be made.			
Inputs		Output	Action	Annotations
These inputs are the variables that need to be considered to determine the consequent actions or outputs.	If there are multiple input entries on the same row, these different inputs are considered as “AND”—conditions that need to be in place at the same time.	The resulting action or decision based on the combination of input entries. This statement immediately follows “THEN.” Examples of outputs may include a diagnosis, alerts/prompts for referrals, or counseling.	Concrete measures to be taken based on the output (e.g., refer, provide counseling, conduct test, etc.). In some cases, output and action may be the same.	Additional explanations or descriptions, including possible pop-up alert messages and relevant background information. This section can also include the written content that would appear in the pop-up messages notifying the health care worker of the appropriate next steps, which can include counseling, case management approach, or referral.
Inputs placed on different rows are considered as “OR” and can be considered independently of the inputs on other rows.				

Decision ID	GRDT.DT.1 Client referred for COVID-19 management and treatment				
Business rule	After client screening, health care worker establishes if a COVID-19 test is required				
Trigger	GRDT.D Examination				
RDT results (GRDT.D1.DE.1)	Retest (GRDT.D1.DE.5)	Vitals (GRDT.D6.DE.16)	Output	Action	Annotation
Negative	No	N/A	Client's result is negative, and they do not require a retest.	Treat symptoms (GRDT.D.5)	Recommendations around retesting of the client and vitals categorization are at the discretion of the health care worker.
Negative	Yes	N/A	Client's result is negative, but a retest is required.	Testing (GRDT.C)	
Positive	N/A	Normal	Client's result is positive, and their vitals are normal.	Schedule follow-up (GRDT.H), self-quarantine/ community management	
Positive	N/A	Poor	Client's result is positive, and their vitals are poor.	Facility management	

Decision ID	GRDT.DT.2 Treatment and management of COVID-19-positive patients				
Business rule	Health care worker reviews the examination results and facilitates patient referral and management				
Trigger	GRDT.F Referral				
Vitals (GRDT.F1.DE.25)	Ambulance called	CO/CBV informed (GRDT.F3.DE.3)	Output	Action	Annotation
Poor	No	N/A	Patient's vitals are poor and isolation center is within the facility.	Refer to facility management	N/A
Normal	N/A	Yes	Patient's vitals are normal and CO/CBV has been contacted.	Prescribe medication for symptom management, schedule follow-up (GRDT.H), and refer to community management/self-quarantine	
Normal	N/A	No	Patient's vitals are normal and patient has been advised to self-isolate.	Schedule follow-up (GRDT.H)	

Abbreviations: CBV, community-based volunteer; CO, clinical officer.

Component 7: Indicators and performance metrics

This section details indicators and performance metrics that would be aggregated from core data elements identified in [Component 5](#). The list in this table is a minimum set of indicators that can be aggregated for decision-making, performance metrics, and subnational and national reporting based on data collected from individual-level, routine health systems.

Indicators

Indicator code	Indicator name	Numerator		Denominator	
		Definition	Computation	Definition	Computation
GRDT.IND.1	Percentage of COVID-19 RDTs conducted per day	Number of COVID-19 RDTs conducted per day	COUNT of COVID-19 RDTs conducted per day	Total number of clients who were screened and recommended for COVID-19 rapid diagnostic testing	COUNT of all clients who were screened and recommended for COVID-19 rapid diagnostic testing
GRDT.IND.2	Percentage of COVID-19 RDT-positive cases reported per day	Number of COVID-19-positive cases reported per day	COUNT of COVID-19-positive cases reported per day from COVID-19 RDTs	Total number of clients who underwent COVID-19 rapid diagnostic testing	COUNT of all clients who underwent COVID-19 rapid diagnostic testing
GRDT.IND.3	Percentage of COVID-19 RDT-negative cases reported per day	Number of COVID-19-negative cases reported per day	COUNT of COVID-19-negative cases reported per day from COVID-19 rapid diagnostic tests	Total number of clients who underwent COVID-19 rapid diagnostic testing	COUNT of all clients who underwent COVID-19 rapid diagnostic testing
GRDT.IND.4	Percentage of COVID-19 RDT-positive patients referred to community management per day	Number of COVID-19-positive patients referred to community management per day	COUNT of COVID-19-positive patients referred to community management per day from COVID-19 RDT results examination	Total number of clients who underwent COVID-19 rapid diagnostic testing and were found to be positive	COUNT of all patients who underwent COVID-19 rapid diagnostic testing and were found to be positive
GRDT.IND.5	Percentage of COVID-19 RDT-positive patients referred to facility management per day	Number of COVID-19-positive patients referred to facility management per day	COUNT of COVID-19-positive patients referred to facility management per day from COVID-19 RDT results examination	Total number of clients who underwent COVID-19 rapid diagnostic testing and were found to be positive	COUNT of all patients who underwent COVID-19 rapid diagnostic testing and were found to be positive

Component 8: Functional and non-functional requirements

This section provides an overview of illustrative functional and non-functional requirements that may be considered to kick-start the process of designing or adapting the COVID-19 antigen rapid diagnostic testing DTDS system. Functional requirements describe the capabilities the system must have in order to meet the end users' needs and achieve tasks within the business process. Non-functional requirements provide the general attributes and features of the digital system to ensure usability and overcome technical and physical constraints. Examples of non-functional requirements include ability to work offline, multiple language settings, and password protection.

Functional requirements

Requirement ID	Process step	As a.....	I want to...
Business process GRDT.A: Registration			
GRDT.FXNREQ.001	Gather Client Details	Facility staff	generate a unique client identifier
GRDT.FXNREQ.002	Gather Client Details	Facility staff	have the ability to capture client's first or given name and family name
GRDT.FXNREQ.003	Gather Client Details	Facility staff	have the ability to capture client's date of birth and age
GRDT.FXNREQ.004	Gather Client Details	Facility staff	have the ability capture estimated age in years if client birth date is unknown
GRDT.FXNREQ.005	Gather Client Details	Facility staff	have the ability to capture client's biological sex at birth
GRDT.FXNREQ.006	Gather Client Details	Facility staff	have the ability to capture client's contact details
GRDT.FXNREQ.007	Gather Client Details	Facility staff	have the ability to capture client's address, including street name, district/county, city, and region
GRDT.FXNREQ.008	Gather Client Details	Facility staff	have the ability to capture client's next of kin details, including name, address, and contact number
GRDT.FXNREQ.009	Search for Client	Facility staff	have the ability to check whether client's information is already in the system
GRDT.FXNREQ.010	Check in Client	Facility staff	have the ability to capture client's purpose for visiting the facility
Business process GRDT.B: Screening			
GRDT.FXNREQ.011	Check Client for Signs and Symptoms of COVID-19	Nurse/EHT/CO	have the ability to capture client's thermometer reading and recent history of fever based on reading of $\geq 37.5^{\circ}\text{C}$

Requirement ID	Process step	As a.....	I want to...
GRDT.FXNREQ.012	Check Client for Signs and Symptoms of COVID-19	Nurse/EHT/CO	have the ability to capture client's symptoms associated with COVID-19 infection (e.g., reported existence of sore throat, shortness of breath)
GRDT.FXNREQ.013	Check Client for Signs and Symptoms of COVID-19	Nurse/EHT/CO	have the ability to capture all travel details of client if they have traveled outside of facility location
GRDT.FXNREQ.014	Check Client for Signs and Symptoms of COVID-19	Nurse/EHT/CO	have the ability to capture referral details of client in cases in which client has been referred to the facility for COVID-19 testing
GRDT.FXNREQ.015	Refer Client for Testing	Nurse/EHT/CO	have the ability to capture the date of client's COVID-19 screening
GRDT.FXNREQ.016	Refer Client for Testing	Nurse/EHT/CO	have the ability to capture the facility details of where screening was done
GRDT.FXNREQ.017	Refer Client for Testing	Nurse/EHT/CO	have the ability to capture specifically why client has presented for testing
GRDT.FXNREQ.018	Refer Client for Testing	Nurse/EHT/CO	have the ability to capture client's pre-existing comorbid conditions
GRDT.FXNREQ.019	Refer Client for Testing	Nurse/EHT/CO	have the ability to capture laboratory request details in case client is referred for COVID-19 testing
Business process GRDT.C: Testing			
GRDT.FXNREQ.020	Receive Laboratory Request Form	Nurse/EHT/CO/ laboratory technician	have the ability to review client's details on the laboratory request form for COVID-19 testing
GRDT.FXNREQ.021	Input Test Reference Details	Nurse/EHT/CO/ laboratory technician	have the ability to generate a unique, system-generated instance of a test
GRDT.FXNREQ.022	Input Test Reference Details	Nurse/EHT/CO/ laboratory technician	have the ability to capture geocodes of where test is being conducted, collected from device
GRDT.FXNREQ.023	Input Test Reference Details	Nurse/EHT/CO/ laboratory technician	have the ability to capture how biological sample was collected (e.g., type of sample collection, date of sample collection)
GRDT.FXNREQ.024	Input Test Reference Details	Nurse/EHT/CO/ laboratory technician	have the ability to track whether the test being conducted immediately follows another, in the event of a repeat test and reason for repeating test

Requirement ID	Process step	As a.....	I want to...
GRDT.FXNREQ.025	Input RDT Details	Nurse/EHT/CO/ laboratory technician	have the ability to capture RDT details (e.g., name of RDT device manufacturer, lot or batch number to which an individual device belongs)
GRDT.FXNREQ.026	Input RDT Details	Nurse/EHT/CO/ laboratory technician	have the ability to capture test details (e.g., time at which test began and the test results)
Business process GRDT.D: Examination			
GRDT.FXNREQ.027	Receive COVID-19 Test Results	Nurse/EHT/CO/ laboratory technician	have the ability to view antigen RDT results
GRDT.FXNREQ.028	Receive COVID-19 Test Results	Nurse/EHT/CO/ laboratory technician	have the ability to capture the details of provider receiving antigen RDT result
GRDT.FXNREQ.029	Forward Client Details to Surveillance for Contact Tracing	Nurse/EHT/CO/ laboratory technician	have the ability to capture contact-tracing details in cases of COVID-19-positive patients
GRDT.FXNREQ.030	Treat Symptoms	Nurse/EHT/CO/ laboratory technician	have the ability to capture treatment details for patient, (e.g., prescription given)
GRDT.FXNREQ.031	Referral	Nurse/EHT/CO/ laboratory technician	have the ability to determine referral suggestion based on patient's signs and symptoms
GRDT.FXNREQ.032	Determine Medical Condition	Nurse/EHT/CO/ laboratory technician	have the ability to capture date of patient examination
Business process GRDT.F: Referral			
GRDT.FXNREQ.037	Review Medical Condition of Patient	Nurse/EHT/CO	have the ability to view file of patient who has been referred for facility or community management
Business process GRDT.G: Scheduling follow-up			
GRDT.FXNREQ.044	Schedule Routine and Targeted Follow-Up	Nurse/EHT/CO	have the ability to view patient's file
GRDT.FXNREQ.045	Schedule Routine and Targeted Follow-Up	Nurse/EHT/CO	have the ability to capture the recommended number of days patient should be under community management
GRDT.FXNREQ.046	Schedule Routine and Targeted Follow-Up	Nurse/EHT/CO	have the ability to auto-calculate the date of patient community management and treatment follow-up with facility

Abbreviations: CO, clinical officer; EHT, environmental health technologist.

Non-functional requirements

Requirement ID	Category	Non-functional requirement
GRDT.NFXNREQ.001	Security – confidentiality	Provide password-protected access for authorized users
GRDT.NFXNREQ.002	Security – confidentiality	Provide a means to ensure confidentiality and privacy of personal health information
GRDT.NFXNREQ.003	Security – confidentiality	Provide ability for allowed users to view confidential data
GRDT.NFXNREQ.004	Security – confidentiality	Anonymize data that are exported from the system
GRDT.NFXNREQ.005	Security – confidentiality	Prevent remembering username and password
GRDT.NFXNREQ.006	Security – confidentiality	Automatically log out the user after specified time of inactivity
GRDT.NFXNREQ.007	Security – confidentiality	Provide encrypted communication between components
GRDT.NFXNREQ.008	Security – authentication	Notify the user to change their password the first time they log in
GRDT.NFXNREQ.009	Security – authentication	Adhere to complex password requirements
GRDT.NFXNREQ.010	Security – authentication	Provide a mechanism to securely change a user's password
GRDT.NFXNREQ.011	Security – authentication	Notify the user of password change to their account
GRDT.NFXNREQ.012	Security – authentication	Reset a user's password in a secure manner
GRDT.NFXNREQ.013	Security – authentication	Lock a user out after a specified number of wrong password attempts
GRDT.NFXNREQ.014	Security – authentication	Notify a user if their account is locked due to incorrect password attempts
GRDT.NFXNREQ.015	Security – authentication	Provide role-based access to the system
GRDT.NFXNREQ.016	Security – audit trail and logs	Log system logins and logouts
GRDT.NFXNREQ.017	Security – audit trail and logs	Record all authentication violations
GRDT.NFXNREQ.018	Security – audit trail and logs	Log all activities performed by the user, including date-and-time stamp
GRDT.NFXNREQ.019	Security – audit trail and logs	Log access to views of individual client records
GRDT.NFXNREQ.020	Security – audit trail and logs	Log access to data summaries, reports, analysis, and visualization features
GRDT.NFXNREQ.021	Security – audit trail and logs	Log exchange of data with other systems
GRDT.NFXNREQ.022	Security – audit trail and logs	Generate analysis of the usage of different system features and reports
GRDT.NFXNREQ.023	Security – audit trail and logs	Log all data and system errors
GRDT.NFXNREQ.024	Security – user management	Allow user with permission to create a new user and temporary password
GRDT.NFXNREQ.025	Security – user management	Provide role-based access

Requirement ID	Category	Non-functional requirement
GRDT.NFXNREQ.026	Security – user management	Allow roles to be associated with specific geographical areas and/or health care facilities
GRDT.NFXNREQ.027	Security – user management	Allow cascading of user management and assignment of roles
GRDT.NFXNREQ.028	Security – user management	Allow user to change their own password
GRDT.NFXNREQ.029	Security – user management	Allow admin user to request password reset
GRDT.NFXNREQ.030	Security – user management	Notify the user to regularly change their password
GRDT.NFXNREQ.031	Security – user management	Allow each user to be assigned to one or more roles
GRDT.NFXNREQ.032	Security – user management	Support definitions of unlimited roles and assigned levels of access, viewing, entry, editing, and auditing
GRDT.NFXNREQ.033	System requirements – general	Provide a unique version number for each revision
GRDT.NFXNREQ.034	System requirements – general	Enable earlier versions of a record to be recoverable
GRDT.NFXNREQ.035	System requirements – general	Enable deployment in an environment subject to power loss
GRDT.NFXNREQ.036	System requirements – general	Work in an environment that is subject to loss of connectivity
GRDT.NFXNREQ.037	System requirements – general	Generate identifiers that are unique across different installations or sites
GRDT.NFXNREQ.038	System requirements – general	Report version number when saving data to the database
GRDT.NFXNREQ.039	System requirements – general	Designed to be flexible enough to accommodate necessary changes in the future
GRDT.NFXNREQ.040	System requirements – general	Allow for offline and online functionality
GRDT.NFXNREQ.041	System requirements – general	Show the number of records not yet synchronized
GRDT.NFXNREQ.042	System requirements – general	Ability to easily back up information
GRDT.NFXNREQ.043	System requirements – general	Warn user if no valid backup for more than a predefined number of days
GRDT.NFXNREQ.044	System requirements – general	Must have the ability to store images and other unstructured data
GRDT.NFXNREQ.045	System requirements – scalability	Scalable to accommodate new demands
GRDT.NFXNREQ.046	System requirements – scalability	Able to accommodate at least [x number of] health care facilities
GRDT.NFXNREQ.047	System requirements – scalability	Able to accommodate at least [x number of] concurrent users
GRDT.NFXNREQ.048	System requirements – usability	User friendly for people with low computer literacy
GRDT.NFXNREQ.049	System requirements – usability	Provide informative error messages and tooltips

Requirement ID	Category	Non-functional requirement
GRDT.NFXNREQ.050	System requirements – usability	Alert the user when navigating away from a form without saving
GRDT.NFXNREQ.051	System requirements – usability	Support real-time data entry validation and feedback to prevent data entry errors from being recorded
GRDT.NFXNREQ.052	System requirements – usability	Simplify data recording through predefined drop-down menus or searchable lists, radio buttons, check boxes
GRDT.NFXNREQ.053	System requirements – usability	Support multiple languages
GRDT.NFXNREQ.054	System requirements – usability	Use industry-standard user interface practices and apply them consistently throughout the system
GRDT.NFXNREQ.055	System requirements – usability	Easy to learn and intuitive to enable user to navigate between pages
GRDT.NFXNREQ.056	System requirements – usability	Provide guidance to users to better support clinical guidelines and best clinical practices
GRDT.NFXNREQ.057	System requirements – usability	Be reliable and robust (minimize the number of system crashes)
GRDT.NFXNREQ.058	System requirements – usability	Adjust display to fit small screens (e.g., mobile phones)
GRDT.NFXNREQ.059	System requirements – configuration	Configure the system centrally
GRDT.NFXNREQ.060	System requirements – configuration	Configure business rules in line with guidelines and standard operating procedures
GRDT.NFXNREQ.061	System requirements – configuration	Configure error messages
GRDT.NFXNREQ.062	System requirements – configuration	Configure workflows and business rules to accommodate differences between facilities
GRDT.NFXNREQ.063	System requirements – interoperability	Communicate with external systems through mediators
GRDT.NFXNREQ.064	System requirements – interoperability	Provide access to data through application programming interfaces
GRDT.NFXNREQ.065	System requirements – interoperability	Link with insurance systems to verify eligibility and submit claims
GRDT.NFXNREQ.066	System requirements – interoperability	Exchange data with other approved systems
GRDT.NFXNREQ.067	System requirements – interoperability	Accept data from multiple input methods, including paper and geocoding (Global Positioning System)
GRDT.NFXNREQ.068	System requirements – interoperability	Communicate with external systems through mediators
GRDT.NFXNREQ.069	System requirements – hardware and connectivity	Allow for data exchange and efficient synchronization across multiple facilities and points of service when internet is available, even when it is intermittent and slow

Conclusion

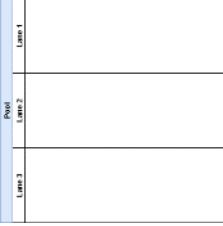
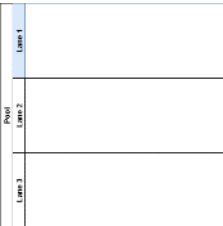




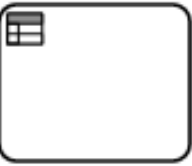
The COVID-19 pandemic has demonstrated the potential of the **Digital Systems and User Requirements for COVID-19 antigen rapid diagnostic testing** to transform health care delivery and response to public health emergencies. However, its successful implementation requires collaboration and investment from governments, health care providers, and technology companies. It also requires careful consideration of ethical, legal, and regulatory issues, such as data privacy and patient safety.







Going forward, DSURs can enable health care providers to deliver more efficient, effective, and patient-centered care, and help public health officials to respond rapidly to outbreaks and epidemics. By capitalizing on these opportunities, we can build more resilient and responsive health care systems that can better withstand future crises.

Questions and technical support

If you are interested in leveraging or adopting the DSUR and require technical assistance, please email the PATH Diagnostics team at diagnosticsteam@path.org.

Appendix A. Business process symbols used in workflows

Symbol	Symbol name	Description
	Pool	A pool consists of multiple “swim lanes” that depict all the individuals or types of users are involved in carrying out the business process or workflow. Diagrams should be clear, neat, and make it easy for all viewers to understand the relationship across the different swim lanes. For example, a pool would depict the business process of conducting an outreach activity, which involves multiple stakeholders represented by different lanes in that pool.
	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 family planning health worker may have one swim lane; the supervisor would be in another swim lane; the clients/patients would be classified in another swim lane. If the activities can be performed by either actor, then those activities can be depicted overlapping the two relevant swim lanes.
	Start event or trigger event	The workflow diagram should contain both a start and an end event , defining the beginning and completion of the task, respectively.
	End event	There can be multiple end events depicted across multiple swim lanes in a business process diagram. However, for diagram clarity, there should only be one end event per swim lane.
	Activity, process, step, or task	Each activity should start with a verb (e.g., “Register client,” “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 also be subprocesses of each activity.
	Activity with subprocess	This denotes an activity that has a much longer subprocess to be detailed in another diagram. If the diagram starts to become too complex and unhelpful, the subprocess symbol should be used to reference another process depicted on another page.
	Activity with business rule	This denotes a decision-making activity that requires the business rule, or decision support logic, to be detailed in a decision support table. This means 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.

Symbol	Symbol name	Description
	Sequence flow	This denotes the flow direction from one process to the next. The end event should not have any output arrows. All symbols (except start event) may have an unlimited number of input arrows. All symbols (except 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 intersect (cross) each other.
	Message flow	This denotes the flow of data or information from one process to another. This is usually used when data are shared across swim lanes or stakeholder groups.
	Gateway	<p>This symbol is used to depict a fork, or decision point, in the workflow, which may be a simple binary (e.g., yes/no) filter with two corresponding output arrows, or a different set of outputs.</p> <p>There should only be two different outputs that originate from the decision point. If you find yourself needing more than two “output” or sequence flow arrows, you most likely are trying to depict “decision support logic” or a “business rule.” This should be depicted as an “Activity with business rule” (above) instead.</p>
	Throw – Link	The “ Throw – Link ” serves as the start of an off-page connector. It is the end of the process when there is no more room on your page for that workflow. It is the end of a process on your current page or the end of a subprocess that is part of a larger process. There will need to be a “Catch – Link” that follows the “Throw – Link.”
	Catch – Link	The “ Catch – Link ” serves as the end of an off-page connector. It is the start of the new process on a different page from the “Throw – Link” or the start of a subprocess that is part of a larger process. There needs to be a “Throw – Link” that is aligned to the “Catch – Link.”
	Ad hoc subprocess	An ad hoc subprocess can contain multiple tasks. One or more tasks in this shape should be performed, and they can be performed in any order. However, not all of these activities need to be finished before moving on to the next activity.

Appendix B. Potential transferability of the Digital Systems and User Requirements for COVID-19 antigen rapid diagnostic testing to other health areas

The Digital Systems and User Requirements (DSUR) for COVID-19 antigen rapid diagnostic testing can be customized and applied in other testing health areas beyond COVID-19 testing, such as:

- Monitoring and diagnosis of other infectious diseases (e.g., malaria, HIV, and sexually transmitted infections).
- Antibiotic susceptibility testing.
- Blood glucose monitoring.
- Cholesterol screening.
- Immunological testing.
- Pregnancy testing.
- Point-of-care testing in resource limited settings.

The digital aspect of the DSUR for COVID-19 antigen rapid diagnostic testing can enable real-time data collection and analysis, remote monitoring, and increased access to other testing health care services in remote areas. This can improve the quality of care and patient outcomes, decrease costs associated with research and development of the DSUR, and increase efficiency of health care delivery.

In addition, customizing this DSUR and integrating it with systems currently in use in the health ecosystem for use in other health areas for multiple or potentially related diseases can also improve health care systems' overall preparedness and response to public emergencies, such as outbreaks of infectious diseases. The real-time data collection and analysis can help authorities make informed and timely decisions about deploying resources and implementing public health measures to control the spread of the disease. As point-of-care testing is becoming more common at a variety of health facility levels and the breadth of diseases is increasing, there is an important opportunity to provide health care workers with streamlined approaches to data collection for all relevant diagnostic testing.

The use of this DSUR in other rapid diagnostic testing health care areas can also facilitate research by providing high-quality data that can be used to better understand disease patterns, treatment outcomes, and drug efficacy. It can also facilitate the development of new diagnostic tools and strategies that can improve patient care and lead to better health outcomes.

Overall, the customization of this DSUR to other health care areas can improve health care delivery and response to public health emergencies, specifically through following a [human-centered design approach to business analysis](#). The use of digital technologies can help streamline patient care, improve accuracy of diagnosis, and reduce the burden on health care workers. It can also facilitate research and development of new treatment options.





Process flows and the related components included in this DSUR that may require only user validation and very little customization are [registration](#), [testing](#), [examination](#), [scheduling follow-up](#), [certificate generation](#), and [data aggregation](#). The processes that may require more detailed customization to align

with the RDT health area are [screening](#), [stock management](#), and [referral](#)—which may include facility management and community management.

However, it is important to note that widespread implementation of a DSUR requires significant investment in technology, infrastructure, and training for health care workers. Governments and health care organizations must work together to ensure these resources are available to all health care providers, especially in low-resource settings, to ensure equitable access to high-quality health care.

Appendix C. Living Labs site visit tools summary

A HUMAN-CENTERED DESIGN APPROACH TO BUSINESS ANALYSIS

Tool	Context of use	Additional notes
 1. Interview and Observation Guide.doc	<ul style="list-style-type: none"> • A summary tool that guides on how to conduct the observation and the areas to probe in the discussions. • This tool is a general guide and can be iterated on in the field (i.e., integrated into site walk-through observations and interviews and discussions). • This is the anchor user engagement tool; the rest of the tools build on this in specific areas, as outlined below. 	<ul style="list-style-type: none"> • The observer/interviewer can be creative in how this tool is applied in each context. • Not all elements may need to be discussed, as others may be observed with or without additional probes to get clarity.
 2. Living Labs Journey Map.pdf	<ul style="list-style-type: none"> • This is a high-level summary of key steps that a user takes in the work they do. • This is different from the task set included in the observation and discussion guide. • This tool looks at the journey the user embarks on as they start their day, go to the facility, do what they do while at the facility or in the community, and end their day. 	<ul style="list-style-type: none"> • The specific detailed steps of tasks the user performs are captured as part of the task sets in the observation and discussion guide.
 3. PATHOS.pdf	<ul style="list-style-type: none"> • This is a more detailed guide to the observation process to further understand the context in which the user works. • The PATHOS tool that helps to further understand, in specific terms, the working environment for the users, who they work with, what they use, and their overall perceived experience in that environment. 	<ul style="list-style-type: none"> • A more detailed and attentive look at the working environment and context is key to unlocking the potential of any intervention co-created with the user. • Intentional attention to this is a key part of the human-centered design process.
 4. Empathy Map.pdf	<ul style="list-style-type: none"> • This is a tool that brings empathizing to life, as at least one of the team members needs to pay attention to the experience and feedback from the users' perspectives. • The tool allows us to be intentional about perceiving the feedback from the users' points of view and, hopefully, get a better understanding of what they see, feel, and hear, and their perceived gains/pains. 	<ul style="list-style-type: none"> • This tool, like all others used, demands that we defer any prior experiences in similar contexts, assumptions, and biases. • We apply this tool using the best practices of interviewing and observation to immerse ourselves in the near-true experiences of the users.

Tool	Context of use	Additional notes
Process flow	<ul style="list-style-type: none"> • This is a high-level summary of process flows users take. • This is built from a combination of the task sets in the observation and discussion guide and the journey map. • This is key in mapping opportunities for optimizing the community data management processes and tools. 	<ul style="list-style-type: none"> • This is a tool that will be useful for any follow-up iterative user engagement in designing optimized tools and/or the digital community health tools.
User personas	<ul style="list-style-type: none"> • This tool uses synthesized data from site visits to define user personas by type and not based on individuals. • This is key in determining and documenting users who will interact with the optimized tools and/or digital community health tool(s). • Personas are developed as part of the initial synthesis and analysis of the qualitative data collected during the site visits. 	<ul style="list-style-type: none"> • This tool is not necessarily applied during site visits but is built based on the data collected. • The personas are developed based on collective attributes and not on those of an individual (i.e., based on roles, responsibilities, and decision-making).