



REPORT OF THE

TRACEABILITY IMPLEMENTATION FOR

COVID-19 VACCINES

DISTRIBUTED IN NIGERIA

PUBLIC SECTOR PILOT

MAY, 2021

IMPLEMENTATION OF TRACEABILITY FOR COVID-19 VACCINES

1. INTRODUCTION

NAFDAC was established by Decree No. 15 of 1993 as amended by the ACT Cap N.1 LFN 2004 to regulate and control the importation, exportation, manufacture, advertisement, **distribution**, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals. The ACT places the burden of drug distribution, sale and use and security on the Agency. The goals of her regulatory control are as follows:

- Safeguard the health of the population.
- Establish a prevention, detection and response mechanism and minimize substandard falsified medicines, narcotics, foods and other regulated products.
- Improve Regulated Products supply chain security
- Establish a traceability system to accomplish the above goals.

A core component of the Nigeria second National Strategic Health Development Plan (NSHDP II) is to “improve availability and functionality of health infrastructure required to optimize service delivery at all levels” as well as “ensure that quality medicines, vaccines, and other health commodities and technologies are available, affordable and accessible to all Nigerians.”

In line with the NSHDP II Plan the Federal Government of Nigeria and its development partners advocated for increased application of standards to strengthen stewardship and technical leadership in supply chain management and commodity security including the application of standards in strengthening pharmaceutical commodity management systems and data management. This goal was formalized with the development of the Nigeria National Pharmaceutical Traceability formally launched by Honorable Minister for Health (HMH) on the 8th of October 2020.

In order to better understand current capabilities and implications of the implementation of traceability for all actors in the supply chain including manufacturers, wholesalers, distributors and healthcare providers, NAFDAC is implementing a scalable project as part of the regulatory strengthening and underscoring of its mandate in conjunction with National Primary Health Care Development Agency (NPHCDA) and GS1 Nigeria in which the Covid-19 Vaccine will be tracked through the Healthcare Supply Chain. NAFDAC’s priority objectives for this implementation aligns with the Nigeria National Pharmaceutical Traceability Strategy that guided the development of a comprehensive operational plan.

NAFDAC seeks to implement traceability for COVID-19 vaccines using GS1 standards to:

- Uniquely identify each unique secondary pack of the vaccine
- Uniquely identify locations in the supply chain through which the vaccine will be distributed
- Identify personnel who have custody of the vaccine
- Track the movement (events) of the vaccine as it moves through the supply chain at every point through the scanning of the 2D Matrix barcodes on the vaccine
- Use the traceability data to support the pharmacovigilance activities for the vaccine

The product of interest was Covishield® – the Astra Zeneca brand of Covid-19 Vaccine manufactured by The Serum Institute of India.

2. OBJECTIVES

2.1 General Objectives

To implement with healthcare supply chain actors a traceability pilot for Covid-19 Vaccine using GS1 standards, that provides knowledge of the requirements to deploy a national traceability system and provides data to support pharmacovigilance for the vaccines.

2.2 Specific Objectives

The success of the project will among other things:

- Serve as a proof of concept and assure stakeholders that traceability is fully implementable in Nigeria for vaccines, medicines and medical devices.
- Enable NAFDAC and stakeholders better understand the implications of implementing traceability and help to set realistic requirements and timelines for all.
- Provide reliable data on movement of the vaccines through the supply chain to the end user useful for detection of potential infiltration of the supply chain, reduction of incidences of wastage and expiration, shortages, pilferage.
- Support the design and validation of a traceability model according to local country requirements and the development of a prototype system that can be tested real time.
- Contribute to development of NAFDAC guidelines on technical and functional requirements to build the necessary infrastructure for implementation of traceability in Nigeria.
- Provide learnings and make recommendations of improvement to the existing road map for traceability implementation.

3. SCOPE

The Scope of the Pilot is as follows:

- To scan 2D matrix codes on the secondary packaging of the Covid-19 vaccines expected to be used within Nigeria using specified data capturing devices, a mobile application TRACKGENIC[®] developed for the pilot and the NAFDAC Ports Clearance Application PIDCARMS.
- To maintain a data repository for reference and traceability of each secondary pack which contains 50 multi-dose vials of 10 doses per vial, manufactured by Serum Institute of India for AstraZeneca.
- Locations through which the Vaccine will be tracked will be from the NPHCDA National Strategic Cold Store at Abuja to 37 State Cold stores including that of the FCT and at least One (1) selected Local Government Cold Store in each State and One (1) Healthcare Facility in each selected Local Government.
- The Covid-19 vaccines will also be tracked from the FCT and Lagos Cold Stores to Two (2) Pharmacovigilance Sentinel Healthcare Facilities which include the University of Abuja Teaching Hospital Gwagwalada and the Lagos University Teaching Hospital.

4. OUT OF SCOPE

- Primary Packaging Traceability at point of administration to 10 patients per single use vial
- Traceability to locations not specified in the scope.

5. METHODOLOGY

5.1 Packaging and Location Features

Packaging with the Identification of the vaccine at the level of the Secondary Package with the following traceability features:

- Global Trade Item Number (GTIN) + batch number + expiry date + serial number where the combination of the Serial Number +GTIN uniquely identifies every product pack (see Figure 1 below)
- Global Location Number (GLN) to uniquely identify each supply Chain partner
- 2D-Datamatrix barcode embedding traceability data + Human Readable Interpretation

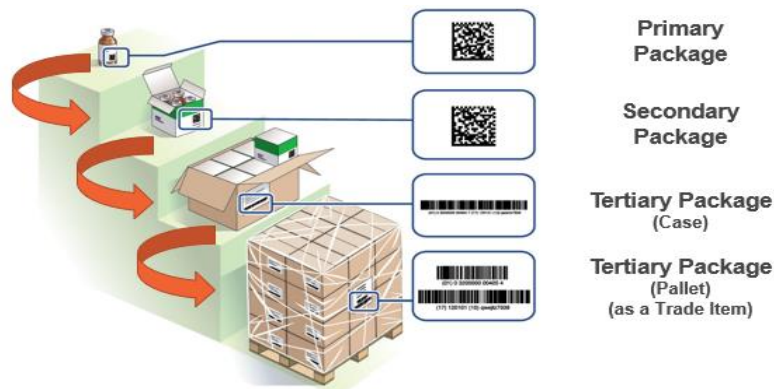


Figure 1: Packaging Levels

5.2 Supply Chain Map

The Phase 1 of the traceability pilot involved tracking the movement of the COVID-19 vaccines forward through the supply chain to the recipients and tracing the origin of the vaccine back to the manufacturer. The vaccines will be scanned at different points from the port of entry to the recipient as shown in Figure 2 below.

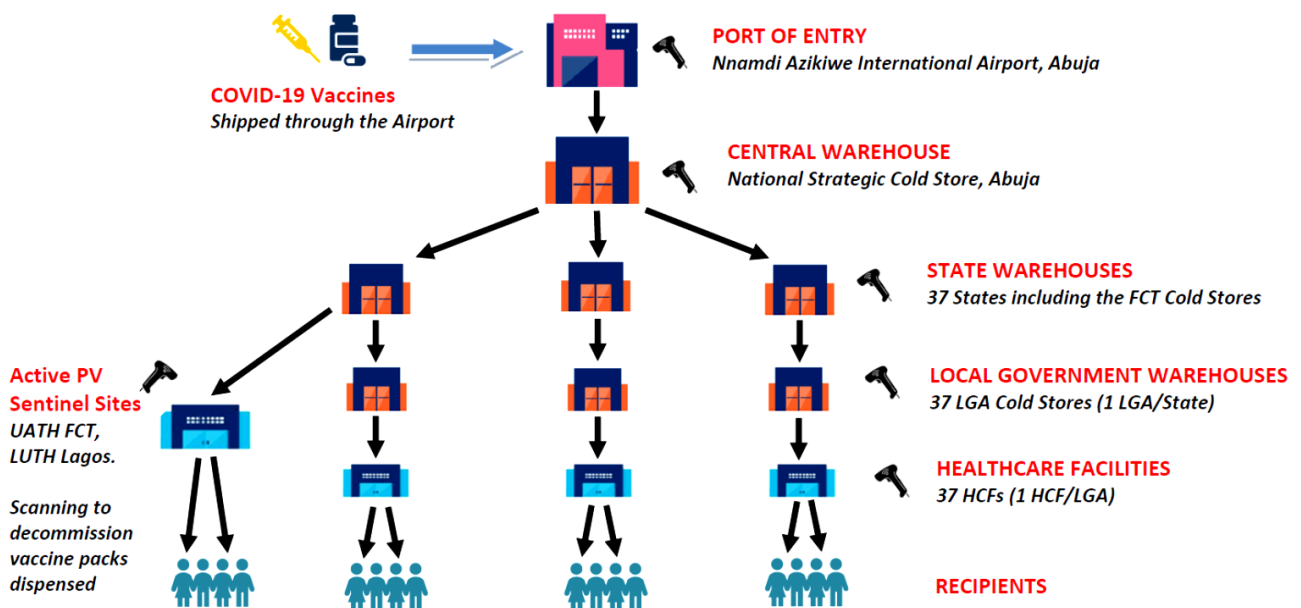


Figure 2: Phase 1 COVID-19 Traceability Pilot Supply Chain Map

5.3 Schedule and Timelines

The Figure 3 below shows the schedule of the traceability pilot implementation for COVID-19 vaccines.

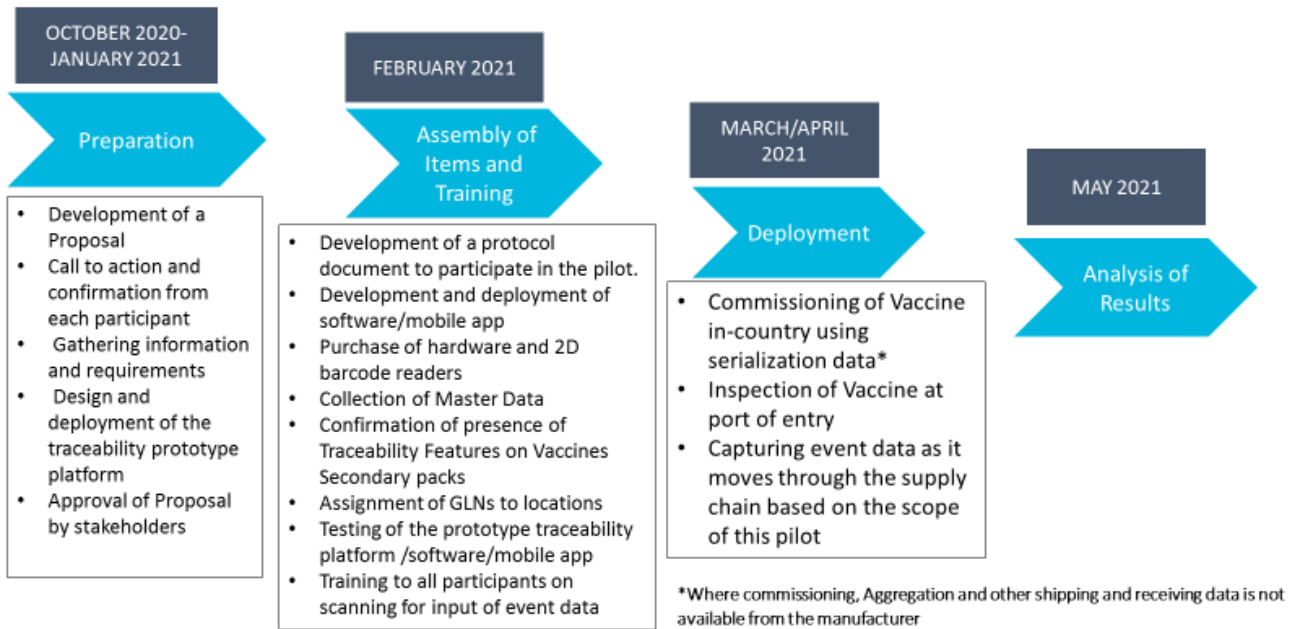


Figure 3: Schedule for Traceability of COVID-19 Vaccines for the Phase 1 Pilot

5.4 Data Analysis

Data was analyzed using the R language and environment for statistical computing. Preliminary data management involved data cleaning to identify and handle scan data capture errors. Exploratory analysis was performed to show the distribution of the scan data. Data of expected distribution was obtained from the manually captured records of the National Strategic Cold Store. Results of the analyzed data are presented in tables and figures.

5.4.1 Inclusion Criteria

Only scan data that captures the correct Electronic Product Code format of the GS1 standard 2D data matrix as well as the correct GLN format for Locations/Read Points was VALID and included in the analysis

5.4.2 Exclusion Criteria

All scan data that captured an incorrect format of the EPC code or the GLN Read Point was INVALID and excluded from the analysis.

6. RESULTS

6.1 Statistics

Table 1: General Shipment and Item Commissioning Information

Parameter	Details	Remarks
Date of Shipment	02 March 2021	
Product Information	ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)	GTIN: 18901213006973
Port of Entry	Nnamdi Azikiwe International Airport, Abuja, Nigeria	GLN: 6157000000395
Location of Port Inspection and Item Commissioning	National Strategic Cold Store, off Bill Clinton Drive, Airport Road, Abuja, Nigeria	GLN: 6157000000425
Total Number of Vaccines in Shipment Expected based on Documentation	7,848 Secondary Packs of 50 multidose vials	3,924,000 doses
Total Number of Vaccines Commissioned during Port Inspection	7,672 Secondary Packs of 50 multidose vials	3,836,000 doses
Total Number of Vaccines Not Commissioned based on Documentation	176 Secondary Packs of 50 multidose vials	88,000 doses
Percentage of Vaccines Commissioned to Vaccines on Shipment Expected. Benchmark 100%	97.76%	

Data captured during the scanning of the COVID-19 vaccine traceability pilot were categorized into valid and failed scans as shown below.

Table 2: Scan Data Statistics

Scan Data Category	Description	Total Scans Detected	% Scan
Failed Scans	Poor Barcode Scanning	1,354	8.46 %
	Scan Location Not Captured	1,343	8.40 %
Valid Scans		13,300	83.14 %
Total Scans		15,997	100.00 %

Valid Barcode Scanning Distribution across States in Nigeria

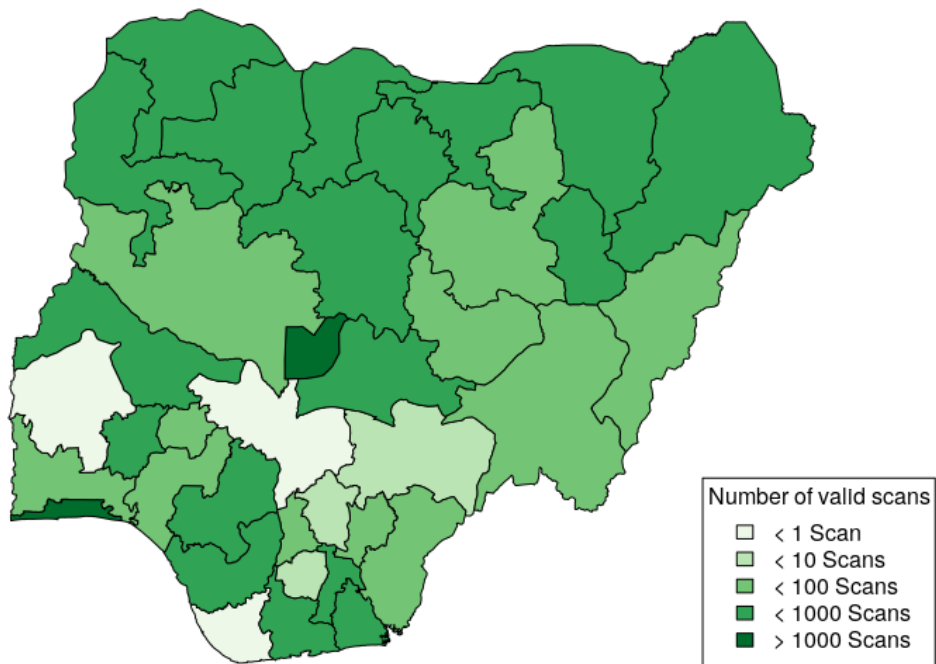


Figure 4: Distribution of Valid Scans for COVID-19 vaccines across States of Nigeria

Poor Barcode Scanning Distribution across States in Nigeria

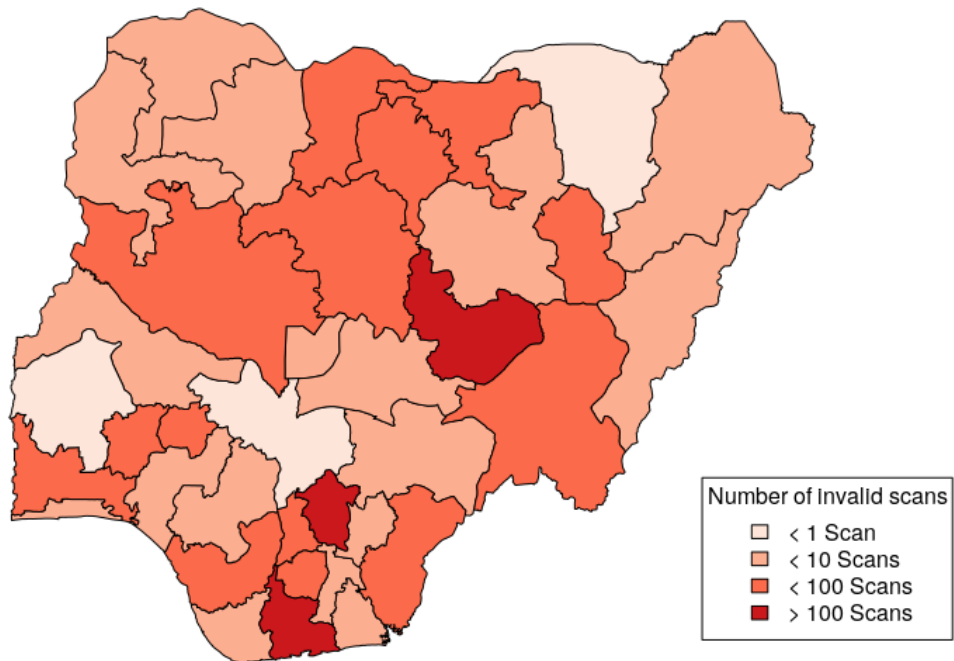


Figure 5: Distribution of Failed Scans for COVID-19 vaccines across the States of Nigeria

Table 3: Batch Information of Expected and Commissioned Vaccines

Lot Number	Total Expected	Total Commissioned	% Commissioned
4120Z030	764,460 doses	758,500 doses (1517 packs of 500 doses)	19.77 %
4121Z005	2,284,860 doses	2,214,000 doses (4428 packs of 500 doses)	57.72 %
4121Z006	874,680 doses	863,500 doses (1727 packs of 500 doses)	22.51 %

The expected number of COVID-19 secondary packs distributed across the country were in most of the cases higher than the data of the scanned packs reported due to the exclusion of scan data for reasons of poor barcode scanning and the failure to capture the scanning Global Location Number during the scanning process.

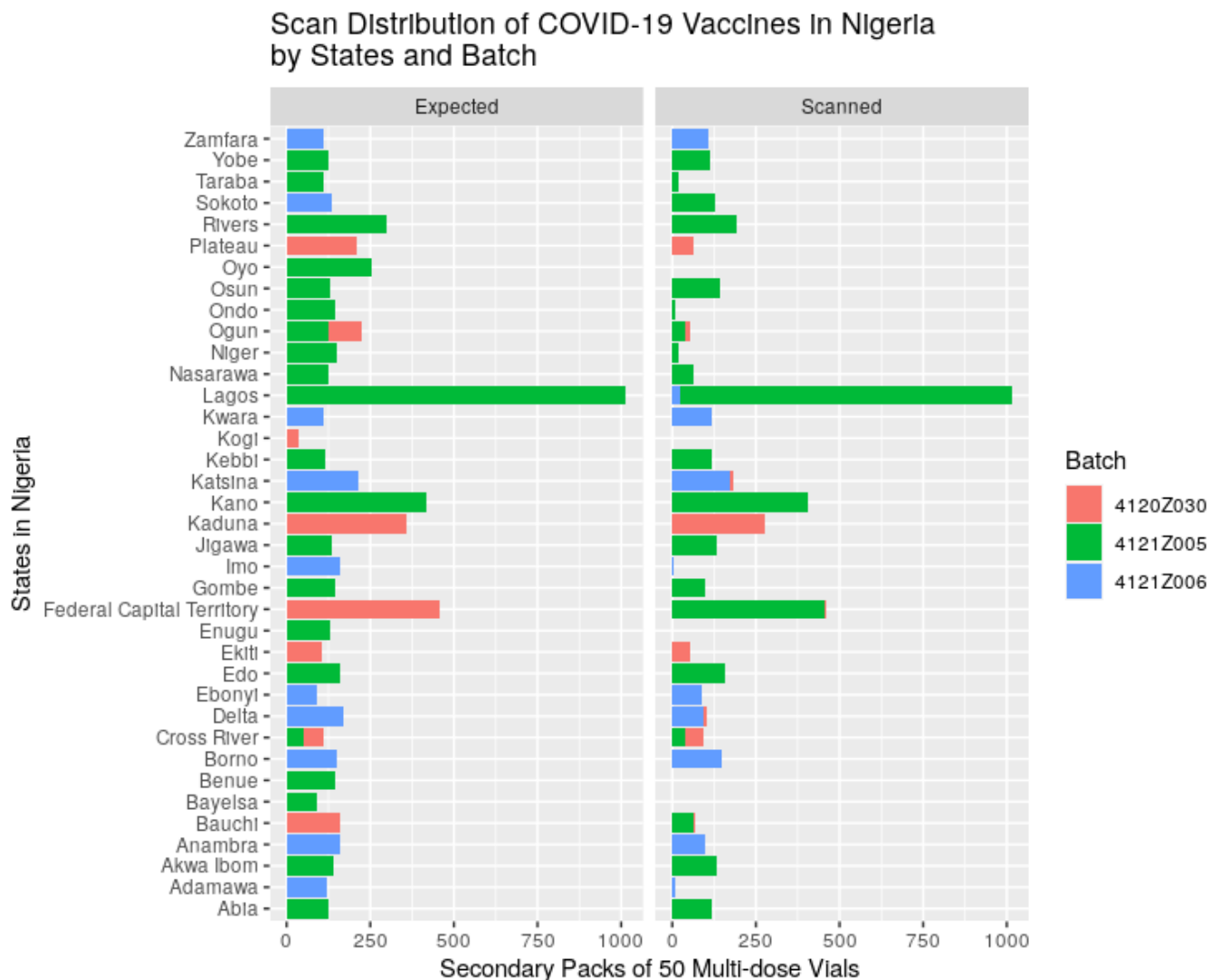


Figure 6: Batch Distribution detected by scanning across the States of Nigeria

Table 4: Distribution of batches detected from Valid Scans across States in Nigeria

S/N	States	Batches detected from valid scans (Number of 50-multidose secondary packs)		
		4120Z030	4121Z005	4121Z006
1	Abia	0	118	0
2	Adamawa	0	0	11
3	Akwa Ibom	0	131	0
4	Anambra	0	0	98
5	Bauchi	4	64	0
6	Benue	0	1	0
7	Borno	0	0	149
8	Cross River	3	0	0
9	Delta	7	0	94
10	Ebonyi	0	0	90
11	Edo	0	160	0
12	Ekiti	55	0	0
13	Enugu	0	1	0
14	Federal Capital Territory	3	457	0
15	Gombe	0	97	0
16	Imo	0	0	3
17	Jigawa	0	131	0
18	Kaduna	275	0	0
19	Kano	0	404	0
20	Katsina	7	0	173
21	Kebbi	0	118	0
22	Kwara	0	2	118
23	Lagos	0	990	24
24	Nasarawa	0	61	0
25	Niger	0	19	0
26	Ogun	12	41	0
27	Ondo	0	11	0
28	Osun	0	143	0
29	Plateau	62	0	0
30	Rivers	53	231	0
31	Sokoto	0	125	1
32	Taraba	0	19	0
33	Yobe	0	114	0
34	Zamfara	0	0	106



Figure 7: Commissioning Event at the National Strategic Cold Store, FCT, Nigeria using handheld barcode scanners to the NAFDAC Ports Clearance System.

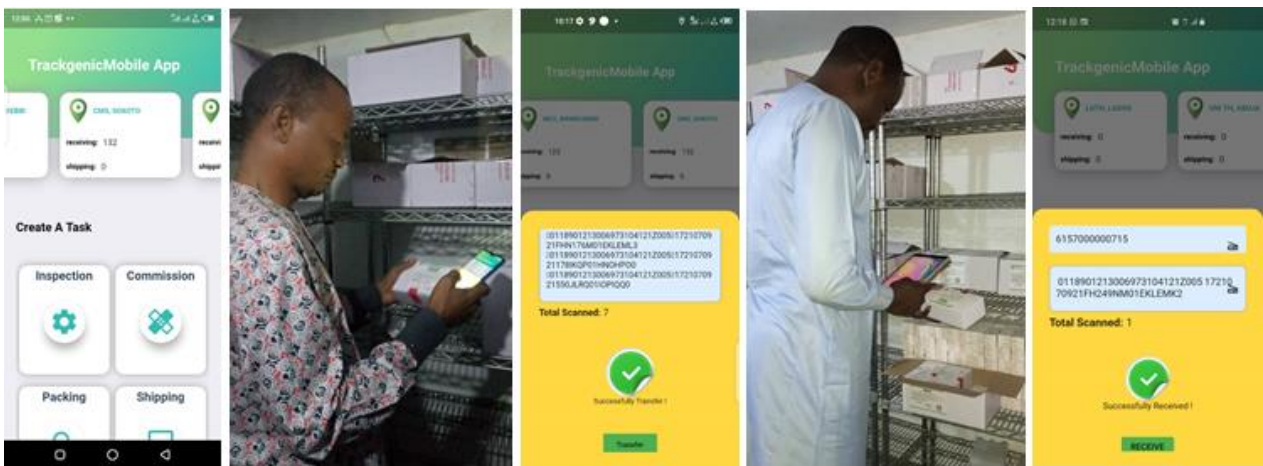


Figure 8: Receiving/Inspection Event using the Trackgenic® mobile app at some State Cold Stores



Figure 9: Vaccine Scanning at some State Cold Stores in Nigeria

Table 5: Global Location Numbers (GLN) registered by Facility types across States in Nigeria

S/N	States	Type of Location/Facility						State Totals
		Port of Entry	National Cold Store	Zonal Cold Store	State Cold Store	LGA Cold Store	Health Facility	
1	Abia	-	-	-	1	5	5	11
2	Adamawa	-	-	-	1	-	-	1
3	Akwa Ibom	-	-	-	1	-	17	18
4	Anambra	-	-	-	1	-	-	1
5	Bauchi	-	-	1	1	1	1	4
6	Bayelsa	-	-	-	1	8	-	9
7	Benue	-	-	-	1	-	-	1
8	Borno	-	-	-	1	-	-	1
9	Cross River	-	-	-	1	-	4	5
10	Delta	-	-	1	1	-	-	2
11	Ebonyi	-	-	-	1	3	-	4
12	Edo	-	-	-	1	1	4	6
13	Ekiti	-	-	-	1	3	13	17
14	Enugu	-	-	1	1	1	3	6
15	Federal Capital Territory	1	1	-	1	-	3	6
16	Gombe	-	-	-	1	1	24	26
17	Imo	-	-	-	1	1	-	2
18	Jigawa	-	-	-	1	-	-	1
19	Kaduna	-	-	-	1	-	7	8
20	Kano	-	-	1	1	1	1	4
21	Katsina	-	-	-	1	2	3	6
22	Kebbi	-	-	-	1	21	-	22
23	Kogi	-	-	-	1	-	-	1
24	Kwara	-	-	-	1	-	-	1
25	Lagos	1	-	1	1	14	36	53
26	Nasarawa	-	-	-	1	1	-	2
27	Niger	-	-	1	1	1	5	8
28	Ogun	-	-	-	1	-	-	1
29	Ondo	-	-	-	1	2	2	5
30	Osun	-	-	-	1	5	26	32
31	Oyo	-	-	-	1	-	-	1
32	Plateau	-	-	-	1	15	70	86
33	Rivers	-	-	-	1	-	-	1
34	Sokoto	-	-	-	1	-	7	8
35	Taraba	-	-	-	1	-	42	43
36	Yobe	-	-	-	1	-	6	7
37	Zamfara	-	-	-	1	14	-	15
TOTAL		2	1	6	37	100	279	425

6.2 Discussion

The traceability pilot implemented for the COVID-19 vaccines sought to demonstrate the feasibility of scanning the vaccines in order to provide visibility of the product through the supply chain. Crucial to this activity is the availability of event data from the manufacturer that includes the commissioning and aggregation data prior to the shipping of the product for ease of verification of the products. In the case of this pilot study, the event data was not provided by the manufacturers or Marketing Authorization Holders. This occasioned the scanning and commissioning of every secondary pack shipped to Nigeria during the pilot. A total of 7,672 packs of 50 multi-dose vials which accounted for 97.76% of the expected vaccines were successfully commissioned. The omitted packs could be due to scan errors or omission of some packs during the scanning.

Although activities were carried out as scheduled, the implementation was limited by the non-availability of mobile android-enabled scanners at the level of the States, LGAs and Healthcare Facilities. The alternative solution adopted was the use of personal mobile phones for installation of the scanning mobile application for scanning across the States. Scanning at the level of the States was carried out with the use of the Trackgenic® mobile app installed on android phones. The scanning activities at the National Strategic Cold Store and the Lagos State Cold Store were however carried out using hand-held scanners to the NAFDAC Ports Inspection Clearance System (PIDCARMS).

Analysis of the scan data collected during the COVID-19 traceability pilot did show valid scans from 34 States including the FCT. The invalid scans were due to poor and inefficient data capture quality as well as the non-capture of location GLN when the scan was done. Kogi and Oyo States were the only locations where no scanning was done due to late response of actors to participate in the pilot while all the scans from Bayelsa State were poorly captured. The issues that resulted in the invalidation of 2,697 (16.86%) of total scans across the States can be attributed in part to the unavailability of mobile scanners for efficient scanning across the various locations and insufficient time to properly test the Trackgenic® mobile app and train users hands-on to properly capture scan data across the States.

The batch distribution detected by scanning across the States were largely as expected when compared to the manual capture of the doses distributed to the States. Nonetheless, there were some discrepancies observed in the batches detected by scanning in Lagos, Katsina, Delta and Bauchi States as well as the Federal Capital Territory. These could be due to discrepancies in the recorded data and the actual products sent. It could also be due to incorrect GLN capture at the point of scanning at another location. Automated data capture by scanning has great potential in limiting data capture errors and should be adopted to strengthen the supply chain in Nigeria. The Trackgenic® mobile app will be further upgraded to ensure validation of GLN and scan data before transmission.

In order to implement traceability for the vaccines, there was registration of Global Location Number (GLN) for locations and facilities where the vaccines would pass through. A total of 425 locations were assigned GLNs across the different States and the FCT. Some States provided the details of locations and facilities promptly and had more GLN registration than others. States like Plateau, Lagos, Taraba, Osun and Gombe were the top 5 States with the highest GLN registrations due to relatively higher registration of Healthcare Facilities (HCF) within the States. Other traceability pilots that target distribution to HCFs at State levels could be conducted in these States.