

The Global Language of Business

#### **Essential Vaccines Traceability**

37th Global GS1 Healthcare Conference

Paris, France 15-17 November 2022

#### How to ask questions



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2. Tap on Open Q&A

Do you have a question for the presenter? Be the first one to ask!
)

#### 3. Enter your question









# No questions from Audience



#### Panellists





Mr. Gregory Reh & Health Care **Industry Leader** Deloitte

Mr Rajinder Suri Global Life Sciences Chief Executive Officer **Developing Countries** Vaccine Manufacturers Network(DCVMN)

Mr John Kayode **Assistant Chief Regulatory Officer** National Agency for Food and Drug Administration (NAFDAC) Nigeria

Mr Max Kabalisa Manager Digitalization and Traceability UNICEF

**Mr Grant Courtney Principal Consultant** Smarter and Safer Prodcuts – Consultant to UNICEF

**Ms. Cliona Kiersey Chief Pharmacist HSE National** Immunisation Office



USE of GS1 standards to improve vaccines supply chain efficiency and product safety

Rajinder Suri

**CEO-DCVMN** 

November 15, 2022





#### **GS1 Standards**

GS1 standards create a common foundation for business by <u>uniquely identifying</u>, <u>accurately capturing</u> and <u>automatically sharing</u> vital information about products, locations, assets and more!





#### Key Benefits <u>of GS1 Standards</u> <u>Barcoding</u>

- Identification of counterfeit products
- Accurate recording of product movement and allow effective recall management
- GS1 barcoding helps to reduce errors, prevent vaccine distribution failures and enable better traceability
- GS1 standards bring transparency and help improve supply chain coordination, decreasing the risk of vaccine diversion, date expiration and fake vaccines proliferation

Protecting people from global diseases since 2000.



#### **Strategic Focus**

1. To make vaccine supply chain in countries more responsive and resilient for improved supply security!

2. Collaborate to promote and enhance innovations in strengthening the vaccine supply chain!!



#### **Key Supply Chain Issues & Priorities**



Survey Results & Decisions in 6/2019

- Traceability (Track and Trace)
- Sharing supplier audits
- Vaccine exposure monitoring (VVM, Heat stability testing (CTC)
- Stockpiling
- Environmental impact
- New packaging and delivery technologies

Publication: Roadmap for strengthening the vaccine supply chain in emerging countries; manufacturers perspectives, Vaccine X, 2020 Jun 9;5: 100068 - https://pu.bmed.ncbi.nlm.nih.gov/32775997/

#### **Traceability Consortium**

In 2021-22 Traceability consortium moved forward with barcoding pilots on primary and secondary packaging:

#### ➤ 6 members

- 2 Self Funded
- 4 supported by DCVMN
- 3 on primary, 3 on secondary packaging
- > All projects completed successfully by end Q2'22
- Bio Farma's nationwide track and trace system implemented for COVID-19 vaccine with plan to move to other vaccines
- Full reporting of the lessons learnt from the 6 traceability pilots, including a peer-reviewed article
- Specific advocacy with DCVMN members for the barcoding of primary packaging will be mapped out

#### Established Need:







#### GAVI announcement: Vaccine manufacturer GS1compliance

GS1barcoding on the secondary packaging will be a requirement by latest 3 lst December 2021 for vaccine tenders backed by Gavi financing and issued by UNICEF

#### UNICEF

https://www.unicef.org/supply/stories/gavi-announcement-vaccine-manufacturer-gsl-compliance

## Labelling (Primary) and Cartoning (Secondary Packaging)





#### Vaccine Distribution Management System

BUMNINTUK biorarma kimia farma

**indofarma** 

Government Program Vaccines



#### Objectives

BUMNINUKA biorormo kimia farma

indofarma







Digitalization Vaccine distribution process





Displaying Realtime monitoring vaccine distribution





To Improve accuracy for monitoring and evaluating vaccine distribution

#### **CONFIDENTIAL PT. BIO FARMA (PERSERO)**

#### Benefits





## Barcode identification & authentication

The system provide identification and authentication of vaccine authenticity identity by providing GS1 QR code on vaccine packaging.



#### Temperature Monitoring

The system monitor the temperature condition of the vaccine with a temperature sensor, so that the quality of the vaccine can be monitored.



BUMN UNTUK biocormo kimia farma

The system perform distribution and tracking of shipments from the starting point to the last point.

💋 indofarma

## Security Delivery Monitoring

The system equipped with GPS sensor, door lock, SOS button so delivery can be monitored to ensure security

#### Lessons Learnt

#### Healthcare -**Product Identification (Establish System)**





#### **Scope of Government** Support

#### NRA – BPOM Indonesia

- **Regulation of Track & Trace System** 1.
- Reporting data of Track & Trace System 2.

#### **Ministry of Health**

- Coordination of all health services 1.
- Coordination of all stakeholders 2.

#### Implementation of TnT

- Manufacture process : machine, and other equipment
- Reporting data to NRA System

#### **CONFIDENTIAL PT. BIO FARMA (PERSERO)**

2D codes on primary & secondary vaccine packages implemented by the Traceability consortium members between June 2021 and October 2022

	BHARAT BIOTECH Sharel Grober	(indiar	printers packaging	
	bioparmo	internete	buaset becycling	
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		Chea	incomery packaging	LOT 202200001-2 SN- 2075163796606317
Frair Previousnamer	Og annasina tanne Kitangjutan	Argenities	инстатовку раскафия;	ecor binant Human Papillomavirus Bivalent (Types 16,18) Vaccine (Escherichia coli)
Reside com	INNOVAX Server Instant	Chuna	-sectorsy backaging	С. 18957802780009 С. 18957802780009 С. 18957802780009 С. 18957802780009 5. 19 00000000155 ЕКК 09.2028 С. 18957802780009 С. 1895780278009 С. 18957802780009 С. 18957802780009 С. 18957802780009 С. 18957802780009 С. 18957802780000000155 С. 1895780278 С. 18957802 С. 1895780278 С. 18957802 С. 189578000000000000000000000000000



## CONT Thank you

#### COVID-19 VACCINES TRACEABILITY PILOT IN NIGERIA

John Olusola KAYODE Assistant Chief Regulatory Officer NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

NAFDAC MANDATE: Regulate and control the manufacture, importation, exportation, **distribution**, advertisement, sale and use drugs, cosmetics, chemicals, detergents, medical devices and packaged water



#### 2<sup>nd</sup> African GS1 Healthcare Conference



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#### GS1 Healthca Conferen

### The Call to Action



## Nigeria – Traceability strategic plan

Federal Government of Nigeria hosted a collaborative workshop driven by FMOH and NAFDAC in June 2019 and Launched the Pharmaceutical Traceability Strategy using *GS1 Standards* 

#### Establish Governance Structure

- Lead strategy
- Advocacy
- Collaboration
- Resource Mobilization
- Oversight of implementation

Strengthen Regulatory Environment

- Develop and disseminate Regulation
- Publish guidelines for implementation
- Enforce compliance

Create Supply Chain Efficiency

- Standardized Identification
- Automated Data Capture
- Automated Reporting

Build and Sustain Technology

- Support interoperability of health systems
- Implement traceability
- Improve data visibility

#### Enable use of Standards

- Identification of commodities
- Authentication of commodities at service delivery points in public and private sectors.



#### **COVID-19 Traceability Pilot – Implementation**

#### <mark>Methodology</mark>

- Unique Product Identification
  - Secondary pack level
  - In-country serialization (non-serialized)



#### In-Country serialization cases

- Assignment of Global Location Number (GLN)
  - > 2400 facilities across Nigeria
- Product scanning along the supply chain -March 2021 - June 2022:
  - 1,085,109 packs commissioned
  - **167,265 packs** comprising **15 GTINs** and 74 batches across **358** locations nationwide.



Valid Barcode Scanning Distribution across States in Nigeria



#### Distribution of valid and invalid scans

Poor Barcode Scanning Distribution across States in Nigeria





#### **COVID-19 Traceability Pilot – Achievements**

April - June 2022 (Before training and scanner deployment) 2nd Quarter, 2022 Distribution of Product Items across States Items Last Scan Location

Data: Geo-location where Items were last scanned

Increased Scanners July - September 2022 mobilization of (After training and scanner deployment) Training support for 3rd Quarter, 2022 In-country serialization traceability Distribution of Product Items across States Items Last Scan Location Increased buy-in and Targeted Stakeholder ownership sensitizations Improved coverage Improved • Regulatory recall regulatory Visibility monitoring and • Supply chain security control Published • Draft Traceability Regulation Regulatory Master Data Guidelines guidance Routine immunization vaccines Scalable pilots for • Antimalarial, TB, HIV, priority medicines Data: Geo-location where Items were last scanned **Controlled** medicines

Source: NAFDAC Traceability information System https://traceability.nafdac.gov.ng

## Thank you



## COVID-19 Vaccine Global Procurement and Delivery

unicef 🕑

for every child

A GS1-enabled verification and traceability journey: A vision toward traceability for all health products

GS1 Healthcare Conference Paris – Nov 2022

Max Kabalisa - Manager, Digitalization and Traceability UNICEF Global Supply Division, Copenhagen, DK

**Grant Courtney** - Consultant, Traceability Lead Smarter and Safer Product Ltd.

## Supply chain dashboard: \$8.3 Billion worth of commodities delivered to LMICs

#### **Deliveries**



**1.84 Billion Vaccine Doses delivered to 146 Countries** and Territories via COVAX as of November 2022



#### Cold chain equipment

more than **9900** CCE + ultra-cold chain freezers.



Syringes Over 3.03 billion syringes



Oxygen supplies Over 59000 oxygen concentrators



**PPE 1.2 billion** items of PPE



#### Diagnostic tests Over 12.4 million tests.



#### **Therapeutics**

Over 33.5 million units of dexamethasone



Data for other commodities as of August 2022

## The VTIs goal is to support countries in their verification and traceability journey





#### **Verification and Traceability Initiative (VTI) Rationale:**

- COVAX Risk Register: Falsification
- Built TRVST a foundation for traceability
- VTI is the multi-stakeholder governance
- Digital equity paramount principle
- Learned from EMVO
- UNICEF is the legal entity behind TRVST.

#### What is the TRVST?

First global GS1-enabled system for LMICs Regulators to monitor patient safety and enable progress on the "Supply Chain Visibility Journey"

## Introduction to TRVST



- TRVST is both a system to allow verification or traceability using GS1 standards.
- It is not intended to be a national traceability system.
- It acts as a hub for donated products, with the ability to track and trace them in the precountry supply chain.
- Through an interface, the traceability event data can then be passed to the national systems.
- The national system can return a summary of the national traceability event data to provide supply chain visibility for donated products.
- Product verification will continue to be offered to countries with no national systems.

## **Upcoming Priorities**

Following the successful live trial in Nigeria and Rwanda (June 22) the VTI has the following next steps.

- Enhance TRVST functionality based on lessons learned and move towards creation of a self-starter package for countries to deploy on their own.
- Onboard additional manufactures and expand into other health products.
- Deploy TRVST in additional countries, starting with Malawi and Nepal.
- Integrate TRVST capabilities into national systems through an API in Rwanda and Nigeria.
- On-going discussions with major medicines and health commodities such USAID and The Global Fund to include data into TRVST beyond vaccines.



#### **Presentation Contributors**

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unicef (2) for every child

#### THANK YOU

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#### Barcoding: a mandatory technical requirement in all COVAX and UNICEF tenders

"

For tenders issued after October 2019, the following language is included in all vaccine tenders as part of mandatory technical requirements:

#### Bar Codes

With implementation latest 31st December 2021, bar codes are required on all packaging levels used by manufacturers for supply to UNICEF, with the exception of primary packaging. Bar codes shall conform to GS1 standards, allowing through a unique company prefix to identify vaccines available in the global supply chain from each manufacturer. The bar codes shall include Global Trade Item Number (GTIN), lot number and expiry date.

"



Exceptionally for the Covid-19 tender, the following is included as a preferred characteristic:

In addition to the standard requirements, serialisation is required.

#### **Barcoding Requirements for Vaccines**

GS1-barcodes on secondary packaging and higher level, covering: GTIN, Expiry date and Batch/Lot no. ٠



supply of vaccines from **1 January 2022** and onwards

readable information)

A guideline on the barcoding specifications has been shared with UNICEF suppliers in 2021 and will be • included in UNICEF tenders (part of new tender template)

#### **Falsification Remains a Risk**

150 reports of incidents on quality issues with COVID-19 vaccines linked to 41 different countries. *Source:* Medical Product Quality Report: COVID-19 vaccines, Issue 5 IDDO



#### Figure 2. Countries with public reports on COVID-19 vaccine quality issues on the Medicine Quality Monitoring Globe.

Countries linked to incidents are indicated in orange. If a public report mentions a product name or a company, these details are indicated on the map, with in red the information that was added since the last issue. Ox-Az: Oxford-AstraZeneca, and J&J: Johnson & Johnson.

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Please join us for a live demonstration of the TRVST system in the market place



These will take place during the networking and lunch breaks





Traceability & Verification System for Health Products

presented by:





## HE

## TrackVax

Keeping Track of the COVID-19 Vaccine in Ireland Cliona Kiersey, Chief Pharmacist, HSE National Immunisation Office





## HE The Challenge... and complexity

Irish population to be vaccinated fast

#### Traditional Vaccines Eg: Flu and Childhood vaccines 1 box, 10 pre-filled syringes



- ✓ Pre-filled syringes
- ✓ Fridge product+2°C +8°C
- ✓ Shelf-life = Expiry Date
- ✓ User friendly products for vaccinators



#### COVID-19 Vaccines E.g: Comirnaty 195 vials, 1,170 doses



- ✓ Multi-dose vials requiring dilution
- ✓ 5-7 doses per vial
- ✓ Unstable compound
- ✓ Variety of expiry dates, "Use Before Date" (120 hours => 1 month) when thawed "Discard time" =6 hours
- ✓ Re-labelling requirements
- ✓ New and Complex issues for vaccinatorseach vaccine type had unique specifications

#### E.g: Spikevax/Moderna 10 vials, 50 doses





- Included NEW safety measures (highlight product identity and shelf life)
- ✓ Scanning removed potential human error

#### **H** Batch Traceability in one Beep !!! FMD Barcode

(where applicable)





## **H** Batch of Saline also captured every time Vial of Comirnaty concentrated supplied/dispensed

#### 1. Scan Comirnaty concentrate (HSE ScanMe Label)



#### 3. Batch details for Vaccine + Saline recorded every time



Capturing of the diluent details is equally important
Discard Time included in Vial & Syringe labels

## **L** Vial label - Handwritten vs Printed with Barcode

Vials required discard time after initial puncture to be recorded





## HE Sample Labels: Tray, Syringe, Staff







Syringes clearly labelled with Batch and Discard time

> Increased Speed, Efficiency and Safety of the process

#### F Paper based tracking of the COVID-19 vaccine Prior to TrackVax





Hand written vial label



ASTRAZENECA VACCINE Dose: 0.5ml Drawn up:\_\_\_:\_\_hrs Checked: \_\_\_\_ Hand written syringe label (2 checks)



10/03/2021	vaccination	Clinic	AstraZeneca	Batch No.		
Wial 1	10 Doses	11 Doses	12 Doses	ABVSUUL		
Vial 1			/	I I OFFI		
Vial 2			/			
Vial 3			/	5		
Vial 4			/	ABV6514		
Vial 5			/			
Vial 6						
/ial 7						
/ial 8						

#### **H** Real-time tracking of the Vaccine – TrackVax Dashboard Clonskeagh CVC Nov 2022



#### Real-time Reporting of the Vaccine – TrackVax Example: National Dashboard for July 2021 H=

	From: <	01-Jul-2021 >	To: <	31-Jul-	2021 >									
	Vaccine: A11	Vaccines			•	·								
	Location: A11	Locations												
S	Summary	Current Stock	Jsage	Discar	ds Di	iscard C	odes	Yield T	rend	Stock H	lolding	Stock I	Expiry	Reports
				Manada I			004 1- 0		2004)					
				vaccine u	Jsage (In	u, 01-Jul-2	2021 to S	at, 31-Jul-2	2021)					
		Vaccination Type	Maximum Doses	Obtained Doses	Unobtained Doses	Discarded Doses	Expected Doses	Actual Doses	Average Vial Yield	Doses Yield (vs Maximum)	Doses Yield (vs Paid For)	Vials %	Syringes %	
		Comirnaty PF	763,185	733,225	29,960	3,523	655,053	729,702	6.69	95.61%	111.40%	82.70%	17.30%	
		Moderna MO	138,747	129,436	9,311	291	115,402	129,145	11.17	93.08%	111.91%	86.89%	13.11%	
		Vaxzevria AZ	237,462	225,197	12,265	724	197,689	224,473	11.34	94.53%	113.55%	82.80%	17.20%	
		Janssen JJ	168	154	14	2	126	152	5.43	90.48%	120.63%	32.14%	67.86%	
		TOTAL	1 130 562	1 099 012	51 550	4 5 4 0	068 271	1 083 472		05.08%	111 00%	83.00%	16 79%	

#### **Really rich dataset:**

Information available at National Level – by site, by batch, by vaccine type, full accountability for every dose



#### **End of Session and Reconciliation of** vaccine usage



Session Summa	Report Id: 00010762				
Citywest Convention	Centre Vaccination Centre	Facility ID: 890951	Facility GLN: 5393055890951		
UDD Name: City West Vaccination Cer	tre	UDD Code: 3004568	Printed: Page: 07-Nov-2022 1		
Responsible Person:	GSRN: 539400004040120040	RP's Tel No.	Site Tel No.:		

#### Vaccine Reconciliation Summary

Code	Opening Stock Vials	UDD Received Vials	Supplied Vials	Closing Stock Vials	Target Doses	Actual Yield	Discarded Doses	Maximum vs Actual +/-	Average Vial Yield	Unret'd Vials	CoVax CoVax Doses Doses +/-
PF	2,971		-621	2,350	4,347	4,252	24	-71	6.85		TrackVa
MO	120			120							MMUNIS
AZ	80		-	80						_	LG
JJ	6			6							- IJ~
MB				_							Disca
Tota Vials	ls: 3,711		-1,155	2,556	4 2 4 7	4 959	24	74			Discard T (Exp/Use I
Doses	23,233		4,347	18,886	4,347	4,252	24	-/1			Cold chai

#### ✓ End of Session report for 1 Central Vaccination Centre ✓ Includes summary and breakdown of Discard codes

Session Details: I	Report Id: 00010762		
Citywest Convention (	Centre Vaccination Centre	Facility ID: 890951	Facility GLN: 5393055890951
UDD Name: City West Vaccination Cent	re	UDD Code: 3004568	Printed: Page: 07-Nov-2022 2
Responsible Person:	GSRN: 539400004040120040	RP's Tel No.:	Site Tel No.:

#### iscarded Doses Summary 1

Reason For Discard	Total	PF	MO	AZ	JJ	MB	NX	FT	CC	QIVS	ITFL
Discard Time Exceeded											
Exp/Use By Date Exceeded											
Cold chain failure											
Storage problem (e.g. stored sideways)											
Dropped/Damaged	6	6									
Quality Defect (eg. Coring)	12	12									
Reconstitution Issue (Operator Issue)	6	6									
Patient Moved											
Unobtained Dose											
Insufficient Clients to administer											
Totals:	24	24									



#### **J** SAFE, EFFECTIVE, EFFICIENT, EQUITABLE PROGRAMME & MORE



#### Reporting (Local & National)

Useful data on vial yields and stock expiry dates to assist in keeping wastage to a minimum. Estimated 75,000 doses were saved based on early detection of discrepancy on vial yield due to appropriateness of syringes used. In Spring/Summer 2021 250k additional valid doses administered above the listed vial content.



#### **Data Quality Improvements**

Automated, Accurate and timely end-of-session reports for the national vaccine administration system (prevented data inaccuracies from developing)



#### Time Savings a) Pharmacy: 0.5 – 1 est. FTE\* b) Administration vaccine record: 20% time saving in recording vaccine details in national system (manual input vs scan)



#### Medication Safety Clear Labelling of vaccine type, discard time, batch number



Standardised and repeatable processes used at all sites



#### Efficiency

CVCs were able to ramp up as numbers for vaccinations increased—a very challenging situation to support without TrackVax in place



#### Staff Engagement

Very easy to use system that adapted to working practices and assisted in standardisation across CVCs



## **H** TrackVax Project Acknowledgements

#### **1. WHO Europe Article**

published 9th Sep 2022



Ireland tracks its way to COVID-19 vaccine delivery success



9 September 2022 1 News release | Reading lime: 3 min (937 words)

## 2. Award Winning

- IT Project of the Year at the 2022 CIO Awards
- Best Use of Information Technology at the Irish Healthcare Awards 2022
- Finalist in the HSE Excellence Awards 2022





Video & Case study:

WHO Article https://www.who.int/ireland/news/item/09-09-2022-ireland-tracksits-way-to-covid-19-vaccine-delivery-success



## THANKYOU





#### **H The Key Successes for Traceability** Learnings

- > Full Accountability in an environment of limited supply and public demand
- Real-time & Accurate National Reports (rich data set)
- Visibility: End of day reconciliation compared to paper based reporting, Trackvax provided timely, accurate, informative (usage trends) standardised reports
- Vaccine usage including reporting discard codes (eg: early detection of Quality issues and medication safety)
- TrackVax increased certainty of valid doses
- Collaboration & co-design with multiple stakeholders, and allowed system users take ownership and continuously propose improvements





## HE What's Next?

- Flu vaccine added
- >TrackVax mobile
- Upgrade of Schools Immunisation System to include barcode scanning and traceability
- Traceability at dose level for all vaccines (from manufacturers)?





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	🖬 Mentimeter
-	Please enter the code
L	
	Submit
	The code is found on the screen in front of you

#### 2. Tap on Open Q&A

Ask me anything		Questions from audience	×
Click the button to participate!	Then	Do you have a question for the presenter? Be the first one to ask!	
C Open Q&A			

#### 3. Enter your question



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## Enjoy

the networking dinner at the Musée des Arts forains !

a baroque palace decorated as a 18th century carnival style

Starting at 7.15 pm

53 Avenue des Terroirs de France, 75012 Paris

5 minutes walking distance, straigt on from the hotel.

#### How to get there

Rercy Village Les Pavillons de Bercy - Musée des Arts prains

Zara

9

#### See you at 19.15 pm !

Pullman Paris Centre Bercy

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#### Thanks to our exhibitors!













