



17th TechNet Conference

Panama City, Panama | October 16-19, 2023

Immunization Programmes That Leave No One Behind

www.technet-21.org

Advances in vaccine barcoding

Session 1

Sharvani Saraf, Gavi Market Shaping

Edward Wilson, JSI

Session 2

Malick Sogur, Logistics Officer, EPI, Ministry of Health The Gambia

Modou Njie, Senior ICT Officer, Ministry of Health The Gambia

Session 3

Pierre Dane, Vital Wave – Vaccine Traceability Initiative Project Management Unit

October 17, 2023

Accelerating implementation of barcodes on vaccine products in LMICs



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VIPS

VACCINE
INNOVATION
PRIORITISATION
STRATEGY



World Health
Organization



BILL & MELINDA
GATES foundation

PATH
P A T H

A global collaboration to prioritise and drive innovation to increase equitable vaccine coverage in low- and middle-income countries (LMICs)



Outcomes of the VIPS prioritisation process in May 2020

3 Innovations have been prioritised...

VIPS has prioritised **3 innovations with the broadest public health benefits and broad applicability** that can help **better meet country needs & contribute to coverage and equity goals as well as global health security.**

Microarray patches



Heat stable and CTC qualified vaccines



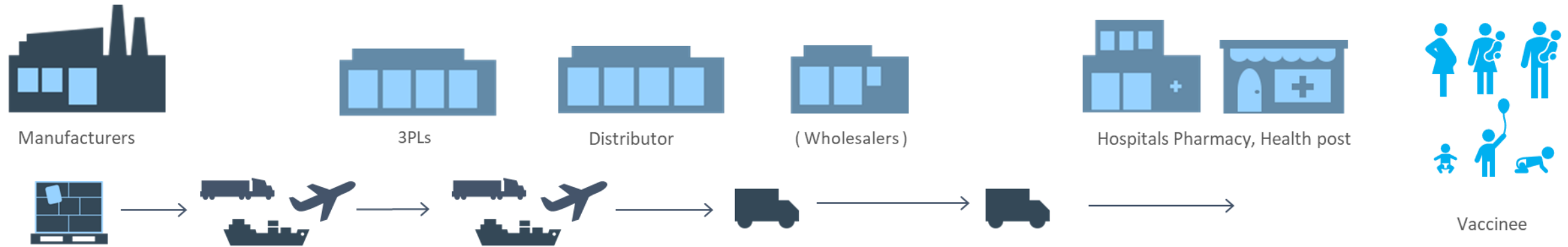
Barcodes on vaccine products



... and signaled to the market

Providing greater clarity to manufacturers and immunisation partners to make investment decisions

Using barcodes on vaccine products can have many benefits to immunization programmes



Barcodes can improve supply chain efficiency & inventory management – in real time

Patient safety benefits to ensure the right vaccine at the right time, reaches the right vaccinee, using the right dose, via the right administration route

Barcodes could become potential 'game changers' in immunisation programmes



Opportunities for impact



Vaccine introductions and scale-up

Catalytic - can **amplify the impact** of all supply chain and digitalisation initiatives – e.g., **visibility** into vaccine stocks and **automated inventory management** will benefit HPV and Malaria rollouts as well as C-19 integration, along with other vaccine introductions.



Reaching the unreached

Improved stock visibility and traceability can support **catch-up campaigns** and if linked with patient data, barcodes can help with **tailored and agile immunisation strategies** needed to reach the unreached.



Programmatic and financial sustainability

Automated inventory management enables **better vaccine forecasting, reducing stockout and wastage, CCE maintenance, optimization of distribution costs**, etc.



Pandemic prevention preparedness and response

Greater visibility, traceability and **verification** are important to ensure **timely response and build trust**, as seen with COVID-19 or Ebola. During new vaccine rollouts, **diversion** of vaccines is also a high risk which can be prevented through the use of barcodes.



Climate change

Adaptation: Same as above

Mitigation: Potentially optimize the supply chain – i.e., reduce the number of shipments/ trips based on stock availability, and therefore emissions, optimize the cold chain, reduce wastage.

But there remains a long road ahead to successfully implement and utilise barcodes in LMICs



VIPS has focused on identifying challenges and activities to accelerate the use of barcodes

2022

1

VALUE-ADDED ASSESSMENT



- **Identification of key use cases**
- **Specification needs** for each use case to inform labelling guidelines

2022-23

2

IMPLEMENTATION FEASIBILITY



- Assessment of **implementation feasibility, country readiness and high-level costs**

2023

3


BARCODES ROADMAP




- **Partner-aligned roadmap** including action plan to advance barcodes building on synergies with existing traceability initiatives

Extensive consultations with countries, manufacturers, global experts and Alliance partners

Extensive consultations

COUNTRY CONSULTATIONS
 **>80** interviews with **15** countries (incl. 2 HICs)

VACCINE MANUFACTURERS
 **~5** across HIC & LMIC markets

GS1, SUPPLY-CHAIN & REGULATORY EXPERTS
 **~8** interviews

DONOR AGENCIES
 **5** interviews

Alliance partners closely involved



Market Shaping & HSIS teams



Vaccine Centre and Supply Chain Strengthening Centre



MHP & IVB



Living Labs

Additional donor/partner buy-in



- BMGF
- USAID
- The Global Fund
- PAHO

Ongoing

Key takeaways from the assessment: Countries and manufacturers consulted see clear benefits of barcodes on secondary packaging and feasibility to implement

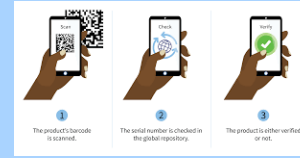
5 USE CASES PRIORITISED based on country and expert consultations



1. Automate **stock and inventory** management



2. Facilitate targeted **product recalls**



3. Verify **authenticity**



4. Link vaccine information with **patient records**



5. Facilitate reporting of **adverse events**

Countries and manufacturers consulted prioritise barcodes on secondary packaging

Secondary packaging



Barcode on secondary packaging

Both countries and manufacturers see **clear value** in using barcodes and implementation is seen as **feasible**, but needs systems, processes & policies to ensure sustainable adoption.

Primary packaging



Barcode on primary packaging

Both countries and manufacturers cite **perceived complexity & costs** of adding & using barcodes on vials. Priority is to increase utilization of secondary packaging first and generate evidence on primary packaging.

The barcodes roadmap identifies a long-term vision and short-term objectives to accelerate barcodes adoption in LMICs

LONG-TERM VISION

Ensure **equitable coverage** and **improve program efficiency** in LMICs via use of barcodes to enhance **health system digitalization**.

SHORT-TERM OBJECTIVES (2024-2030)



A

DEMONSTRATE IMPACT of barcodes to incentivize investment for scale-up

- *Data from pilots using barcodes on secondary packs*
- *Opportunistic data from pilots using barcodes on vials/ primary packaging*



B

Create an enabling environment for further scale up of barcodes

- *Global Policy and Country Guidance*
- *Global Data repository/ data sharing*
- *Barcoded vaccine supply*
- *Blueprints for implementation*



C

Provide targeted support to mature countries to implement & scale-up barcodes

- *Traceability system scale-up & interoperability*
- *Hardware & software*
- *Processes & Human Resources*

There is increasing momentum to accelerate adoption of barcodes

Evidence

Targeted implementation projects planned for secondary barcodes in ~3-4 advanced LMICs at a national/ regional scale in 2024-25

Supply

Mandatory requirements by UNICEF-Gavi to add GS1 barcodes on secondary packaging and preferential requirements upcoming to add serialization & aggregation

Traceability Systems

Gavi's eLMIS scale-up strategy focusing on at least 25 priority countries by 2025; **Global data repository** – e.g., **TRVST** - to enable data-sharing)

Policy

Activities to **harmonize global guidance** on labelling standards, product identification and data exchange



To mature along the traceability pathway and enable adoption of barcodes, countries will need to consider efforts along these dimensions

REGULATORY POLICY

- Participate in global and regional **consultations** on barcode harmonization, data standards, and regulatory approaches
- Implement **mandatory requirement of barcodes** based on harmonised global standards
- Invest in **traceability strategy development** for vaccines & non-vaccines
- Adopt policies to support **paperless** systems
- Adopt effective **governance** structures

SYSTEMS & TECHNOLOGY

- **Assess** the impact of barcode adoption on current systems and processes
- **Ensure traceability systems are interoperable** with barcodes (*e.g., data repository and eLMIS*)
- **Consider hardware** and equipment requirements holistically for programs
- **Integrate** scanning into existing workflows (*e.g., eLMIS*)


ORGANIZATIONAL CAPACITY

- Plan for required **change management**
- Adopt a user-centered **design** approach
- Dedicate monitoring and supervision **resources** to support implementation
- **Assess care provider needs** to implement different use cases

SYNERGIES WITH EXISTING INITIATIVES

- Incorporate vaccine traceability as part of **overall pharmaceutical traceability**
- Align traceability and barcode implementation plans

Summary of the roadmap



BARCODES ON VACCINE PRODUCTS
VIPS Alliance Roadmap

		TARGET OUTCOMES					
		TO1: Targeted Implementation	TO2-5: Enabling Environment			TO6: At-Scale Implementation	
			TO2: Barcoded Supply	TO3: Global Guidance	TO4: Country Regulation	TO5: Scaling Enabling Systems *	
Short Term	2023-2025	1.1a Identify minimum requirements for targeted implementation	2.1 Understand gaps on barcoded vaccine supply	3.1 Harmonize labeling standards for vaccines	4.1 Build engagement and buy-in amongst LMICs and country regulators	5.1 Expand TRVST data repository (onboarding vaccine manufacturers) for vaccines	6.1 Identify countries and use cases that could scale barcode use for vaccines
	2023-2025	1.1b Design and scope the targeted implementation	2.2 Understand barriers/ challenges for manufacturers to add barcodes	3.2 Update and expand WHO guidance on traceability	4.2 Analyse gaps on LMIC medical product traceability policies	5.2. Align barcode implementation with eLMIS scale up strategy and monitor	6.2 Build commitment from donors and governments and support scaled implementation in identified countries
Medium term	2026-2030	1.2 Conduct targeted implementation in 2-4 advanced LMICs	2.3 Define & implement market shaping mechanisms to incentivize industry	3.3 Update WHO labeling requirements for medicines and vaccines	4.3 Establish collaboration and sharing of learnings and best practices within countries	5.3 Support countries to build the required interface(s) between their systems	6.3 Develop guidance documents, blueprints and best practices for other countries
	2026-2030	1.3 Analyse and disseminate study results, including business case development	2.4 Provide technical support to manufacturers	3.4 Harmonize data exchange standards	4.4 Provide support for developing regulation to LMICs	5.4 Support countries for software & hardware upgrades	
Long term	2030+	1.4 Enhance the evidence base with other implementation opportunities	2.5 Vaccine secondary pack size optimization	3.5 Develop guidance on minimum specifications for barcode scanners	4.5. Invest in traceability strategy development & execution for at least 2 LMICs	5.5 Support countries to update their SOPs	6.4 Evaluate cost effectiveness, cost savings, and benefits of scaled implementation that could be used as learnings for other countries
	2030+		2.6 Monitor activities of vaccine industry to implement barcodes on primary packs	3.6 Develop guideline/ blueprint/ SOP for verification/authentication of vaccines and other medical products	4.8 Enable mandatory requirements for vaccines & medicines	5.6 Support countries to update their training curriculum and assess human resource capacity needs	

* Timelines for scale up of enabling systems are dependent on country readiness & maturity; for advanced countries, the aim is to scale up remaining systems in the short-med term while for less advanced countries this will occur in the med-long term.

We want to hear from you!

Please scan the QR code to provide quick responses



1. Do you have any questions for us?
2. If barcodes on vaccines are adopted in the countries you work with, **what do you see as the biggest benefit?**
3. **Do you think the activities shown in this presentation at a high-level could help increase adoption of barcodes in the countries you work with?**
If not, what else is needed in your opinion?

Use of Barcode to Mitigate Vaccine Wastage



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Use of Barcode to Mitigate Vaccine Wastage

Malick Sogur, Logistic Officer, EPI, MoH, Gambia

Modou Njie, Senior ICT Officer, DPI, MoH, Gambia

October 17, 2023

What is VVS?



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What is VVS?

- The Vaccine Visibility System (VVS) is an immunization eLMIS platform
- Deployed in The Gambia since 2018
- VVS is the first nationally scaled eLMIS that is barcode enabled and includes an offline mode so that persistent internet is not a requirement.
- The VVS uses a combination of mobile technology, cloud computing, and data analytics to provide real-time information on
 - Vaccine stocks
 - Distribution
 - Utilization at health facilities across the country

The Gambia Expanded Programme on Immunization Cold Chain System

March and September

Every Quarter

Every Month

Central Store

Regional Store

Health Facility

2°C- 8°C



M
oH

Barcode in use in The Gambia

Benefits

- Data accuracy
 - Captures Batch number & Expiry
- Saves time
 - No typing
- Easier lookup
 - Timely actions/ Application of the principle(FEFO)
 - Enabling better stock management via shipment tracking, expiry notifications, etc

Challenges

- Not all vaccines comes with barcode
- Limited Scanners available
- Secondary packaging only used to regional stores

Barcodes enable reduced vial wastage

- Scanning barcodes enters expiry and batch #s for all stock in country. Scanning reduces input errors.
- VVS system provides near real-time data visibility of where vaccines are stored to quickly find which CCE.
- VVS system identifies stock nearing expiry with warnings so staff can find and use these stock first.
- VVS also shows all facilities stock, so managers can reallocate stock to where needed before expiry.
- VVS also helps show consumption vs forecasts to reduce over stocking of vaccines at health facilities

Future use of barcodes in the Gambia

Vaccine packaging barcodes

- Use GTINs and SSCC barcode data on tertiary and secondary packaging to expedite data entry and recall
- Scan secondary packages when distributing and receiving vaccines in regions to ensure data accuracy

Other uses of barcodes

- VVS barcodes
 - Order requisition and distribution tracking – scan printed barcode to recall an order
- CCE barcodes
 - Scanning CCE to assign vaccines to a storage location (in/out)
 - ID CCE for managing cold chain

Next steps

Continue use of VVS and extend use via VVS Lite (tablet version)

Continue to add barcodes in VVS system as more suppliers have secondary packaging

Parallel stock reporting with WebSMT and VVS to compare and look for efficiencies



The Verification and Traceability Initiative

Traceability and Verification System (TRVST)



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Verification and Traceability Initiative

The VTI has the goal of fighting product falsification and diversion

- During the pandemic, several global stakeholders came together to overcome the risk of COVID-19 vaccines being falsified. There was an opportunity to address the need to verify COVID-19 vaccines, while at the same time building the path towards traceability for all health products.
- According to the WHO, an estimated **1 in 10 medical products in low- and middle-income countries is substandard or falsified.**
- The **Verification & Traceability Initiative (VTI)** was established in 2021 to support the development of systems which increase supply chain visibility and decrease the risk for falsified products through the use of traceability and GS1 standards.



The Verification and Traceability Initiative

The VTI has the goal of fighting product falsification and diversion

- VTI is formed by **Nigeria** and **Rwanda**, who are leading the use of serialization data to fight health products' falsification and diversion, and key players in global health: **Gavi**, **UNICEF**, **USAID**, the **World Bank**, the **Global Fund**, the **Bill & Melinda Gates Foundation**, the **European Commission**
- A component of the VTI is the **Traceability and Verification System (TRVST)**, a technology solution that **enables verification and pre-country traceability at a global scale**
- The **VTI Steering Committee** is supported by a **Project Management Unit**, which manages the **three task teams** around technology management, data sharing and country deployment. The VTI Steering Committee **endorsed UNICEF as the organization to host the TRVST** and manage the technology vendor providing the TRVST services.
- TRVST is based on the same technology as the European Medicines Verification System, which verifies every secondary pack of medication dispensed in the EU



Verification



Enables the identification of counterfeit/falsified/diverted product by validating that a scanned GS1 complaint product pack barcode is authentic.



Track and Trace

Ability to track the movement of health product and custody of ownership. The system tracks forward and back movements of the product, ability to indicate where the product is at given point in time within the supply chain levels.



End-to-end supply chain visibility

Scanning GS1 barcoded health product pack provide information on location , consumption and stock levels, hence allowing for an informed SC decisions .

The TRVST system components

TRVST is provided as “Platform as a Service” by SolidSoft Reply, the provider of the European Medicines Verification System

1 A standard interface to manufacturers

The TRVST will provide a standard **EPCIS** interface which will allow manufacturers to upload both product master data, batch and / or serialised pack data. During the early phase of deployment this data can be provided in a file and the TRVST solution provider will upload it manually.

2 The TRVST repository

The TRVST holds all the product data and event data (verification and traceability) in a secure repository, which can be scaled to any size as the scope and use of the TRVST grows over time.

3 Verification smart phone application

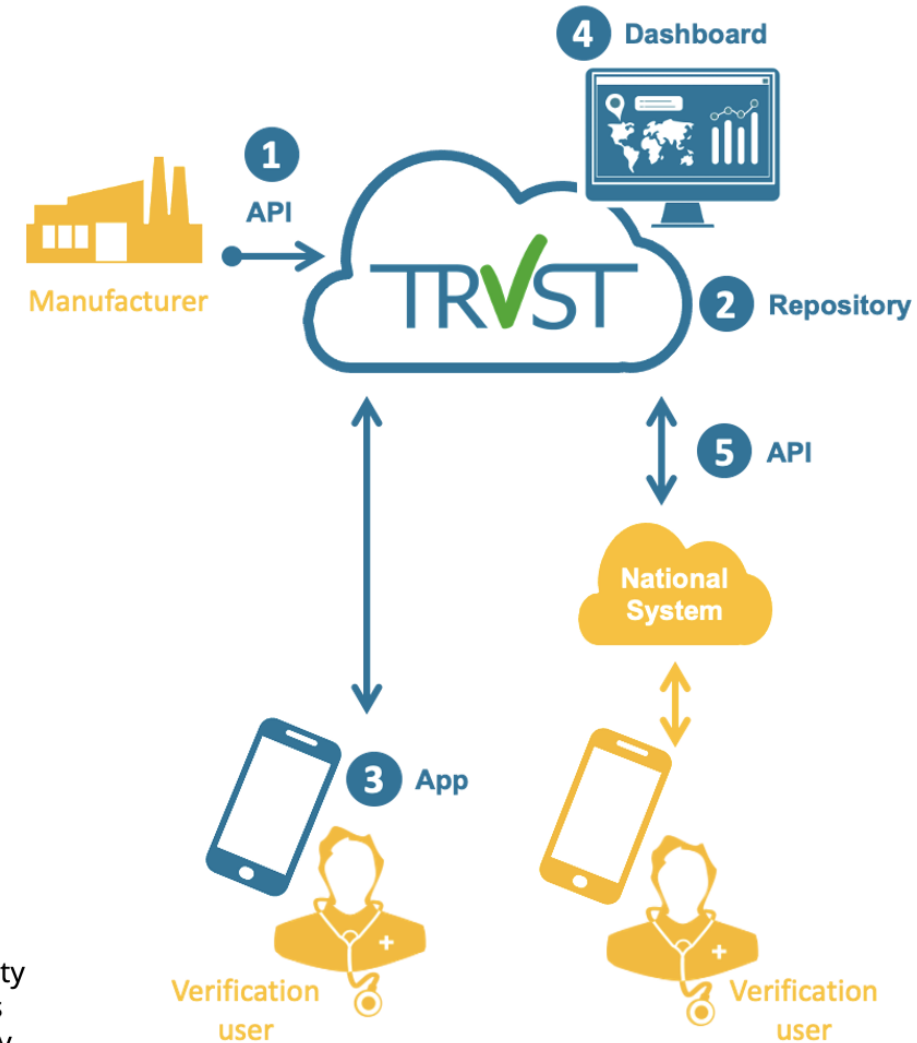
Users are able to verify products by scanning a barcode on the packaging using an existing phone application (Android and iOS). The data will then be sent to the TRVST repository for verification, and the response is sent back. National versions of the App may be made available on request of national authorities.

4 The TRVST dashboard

Users with role-based dashboard access can view event data (verification and, soon, traceability activity). Any verification failure or suspect activity is alerted to the manufacturer.

5 TRVST API interface to national systems

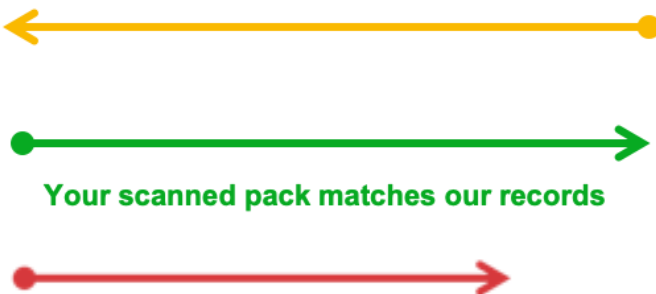
For countries with a national system for traceability, connection to TRVST is done via an API. Traceability and product data will be transferred to the national system through EPCIS events so that the products can be track and traced in national systems. Event data will be shared back to the TRVST so that supply chain visibility can be provided to donor organisations.



TRVST Verification Application

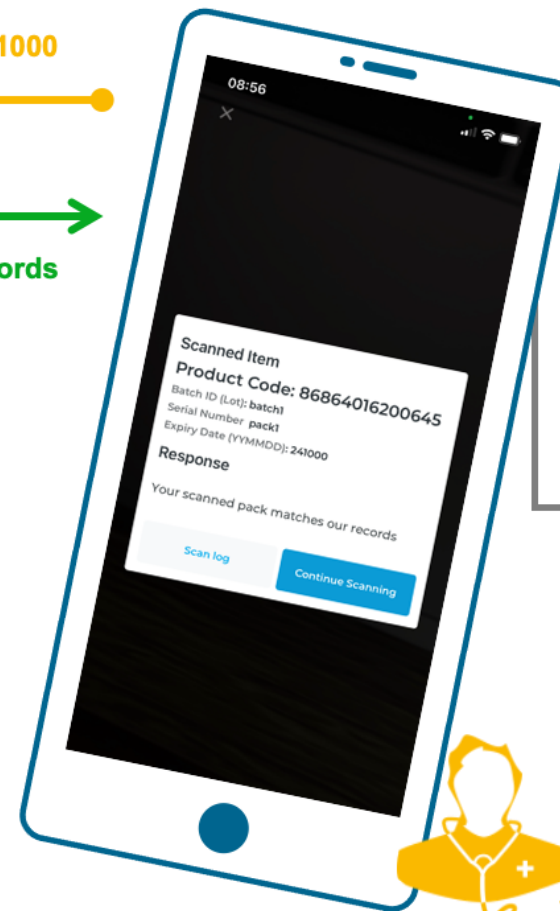


86864016200645 pack1 batch1 241000



	Scanned data	Manufacturer data	result
GTIN	86864016200645	86864016200645	✓
Serial Number	pack1	pack1	✓
Batch/ Lot	batch1	batch1	✓
Expiry Date	Oct 2024	Oct 2024	✓


	Scanned data	Manufacturer data	result
GTIN	86864016200645	86864016200645	✓
Serial Number	pack1	pack1	✗
Batch/ Lot	batch1	batch1	✓
Expiry Date	Oct 2024	Oct 2024	✓



Verification user

TRVST Surveillance Analytics

Test Admin
Traceability & Verification System
for Health Products
Welcome admin@example.com
Not admin@example.com? Please logout

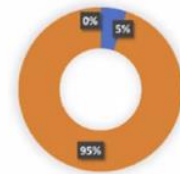


Traceability & Verification System
for Health Products

- Home
- Dashboards
- Reports
- Users
- User Roles
- Documents
- Settings
- Change Password
- Logout

Visualisation Demonstrator

Verifications



Countries

Nigeria

Rwanda

Outcomes

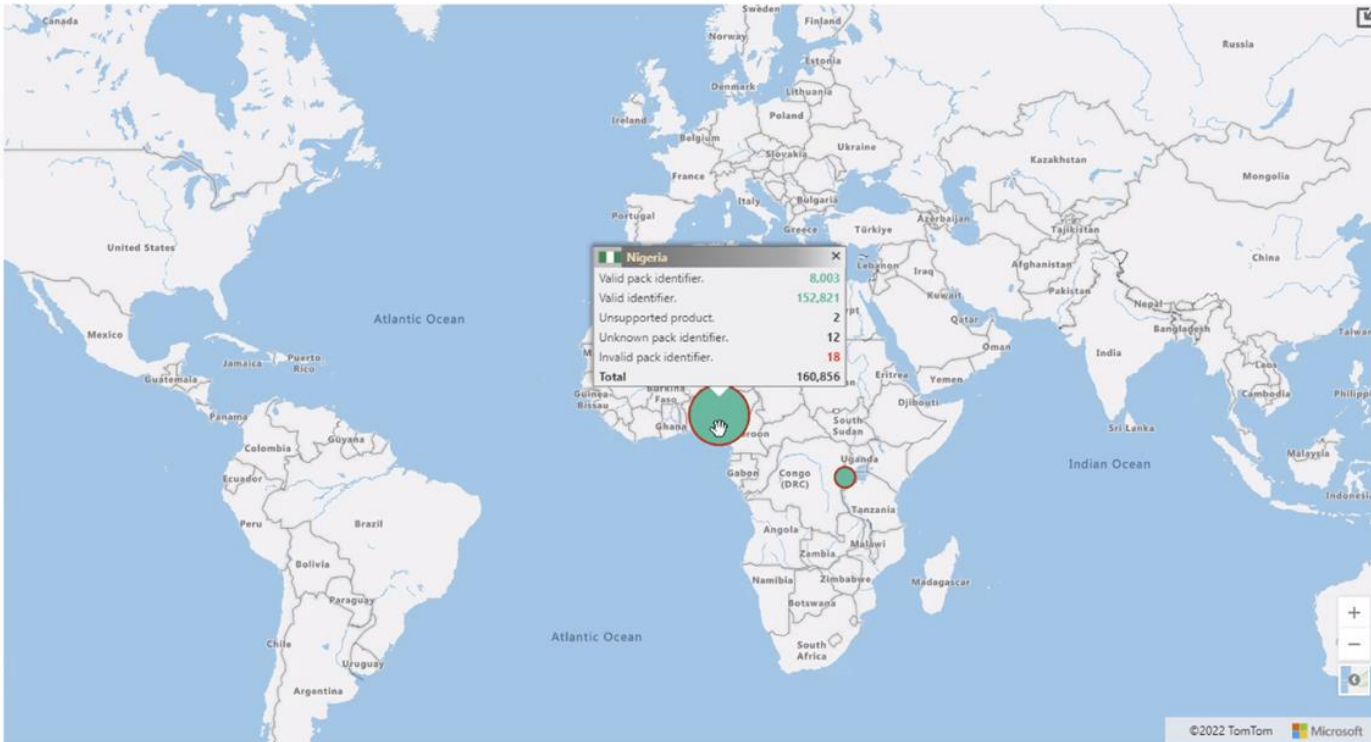
Verified

Potentially falsified

Other

Date range

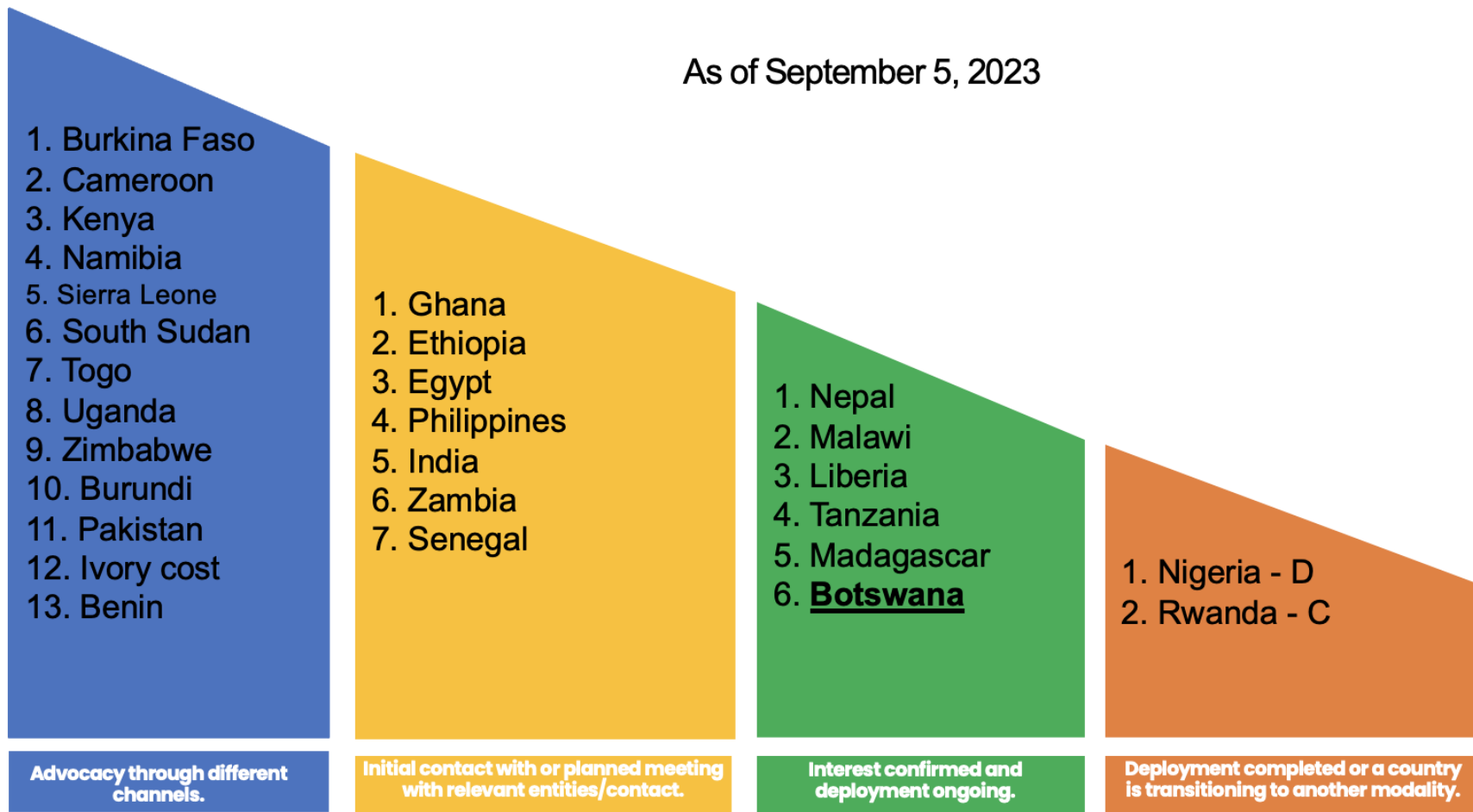
05/07/2022 - 02/10/2022



Timestamp (UTC)	Notification Identifier	Status	Country	User Location	Product Code	Batch ID	Onboarding Partner	Description
		Filtered ▾						
14/06/2022 11:10:25	GB-LLX-P2Y-393-1LE-JDK	Open	United Kingdo...	5060917510004	00122273084355		Johnson & Johnson	R1: The pack identifier has been verified 113 times R2: The pack identifier has been previously verified in the following countries SI R3: The pack identifier has been previously verified in Slovenia at 2022-06-13T19:37:15.000Z, ↗

Country Engagement

As of September 5, 2023



Early phase of exploration

Initial contact and knowledge about TRVST. No meeting has been set up yet for the discussions.

Advanced conversation

Key contact made with relevant authorities. Meeting underway for further discussions.

Deployment underway.

Interest confirmed, POC identified and initial deployment discussions on going.

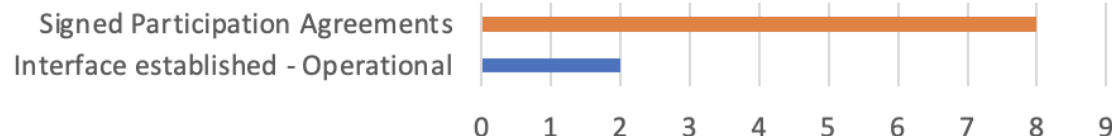
Deployment completed/upgrade

Selected modality has been implemented and possibly moving to improvement or transition.

Supplier Engagement - Vaccines

- Several vaccine suppliers have signed TRVST **Participation Agreements (PA)**
- Some have already established **interface for** automatic data upload onto TRVST when supplies are shipped to countries; these are promoted to the **Operational** phase.

Onboarding status as # Vaccine suppliers



Onboarding status in procured volume* (%)



42 % Vx Operational

- **Target: 75% of annual supply volume from our vaccine suppliers onboarded to TRVST** (Sign participation agreement/Enterprise agreement) **by end of 2023.**
- **Currently - 62%**

Conclusion

- TRVST is one of the flagship projects of the VTI, which has a broader goal of identifying other types of investments to support countries in their traceability and verification journey
- Through the TRVST project, the VTI has gathered learnings and best practices on:
 - Country and Manufacturer Engagement- blueprints
 - Data sharing and Governance
 - Priorities of Countries, Donors and Suppliers
 - Global Traceability Architecture
- The next phase will be onboarding of ARV manufacturers, and other ATM products



Thank You!

Speaker One, contact details

Speaker Two, contact details

Speaker Three, contact details

Speaker Four, contact details

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