

DAY 2

Vaccine Track and Trace:

Traceability and Verification System (TRVST), barcode specifications and tender requirements

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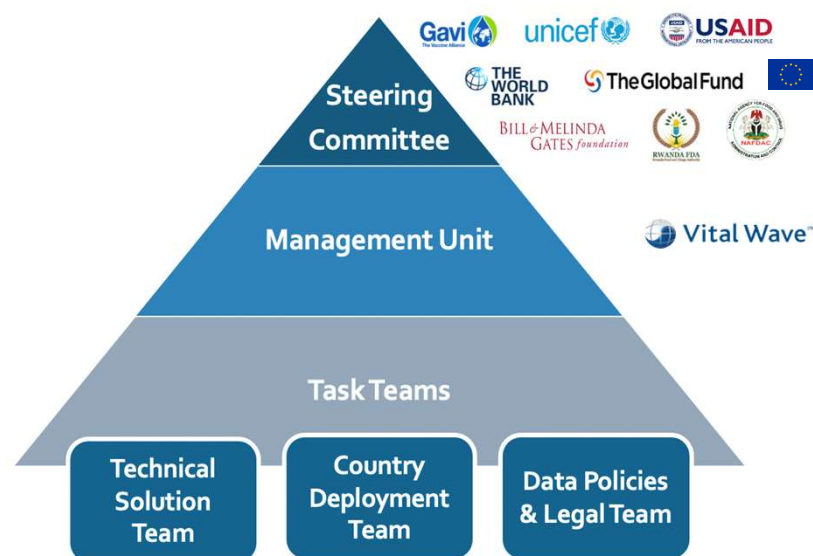
VACCINE
INDUSTRY
CONSULTATION
2023

- Overview TRVST
- Supplier onboarding to TRVST
- Barcode needs
- Tender requirements
- Advocacy for earliest implementation of novel preferred requirement by vaccine suppliers

Overview of the Verification and Traceability System (TRVST – Pronounced as “TRUST”).

Verification and Traceability Initiative (VTI)

A multistakeholder initiative which was created to address the impact of falsified and diverted products, within National supply chains with a vision towards national traceability of all vaccines, medicines and health products.



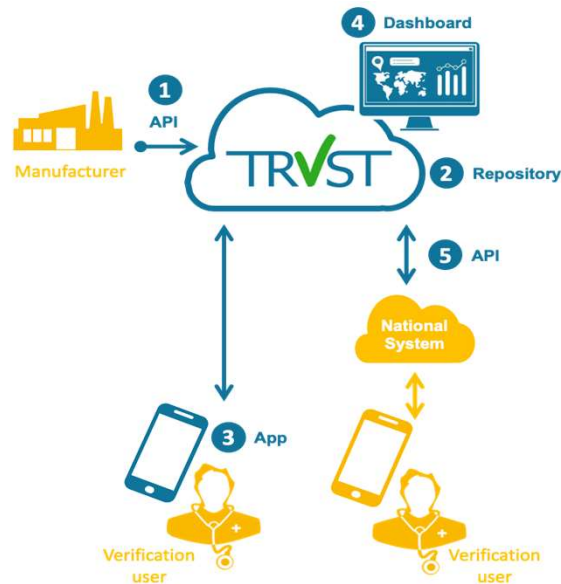
Verification and Traceability Initiative (VTI) Rationale:

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

TRVST – Traceability and Verification System

The system is made up of 5 basic elements:

- 1) A standard interface to manufacturers
- 2) The TRVST repository
- 3) Verification smart phone application and API
- 4) The TRVST dashboard
- 5) TRVST API interface to national systems



TRVST has three major capabilities for vaccine and pharmaceutical products:

Verification



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

Track and Trace



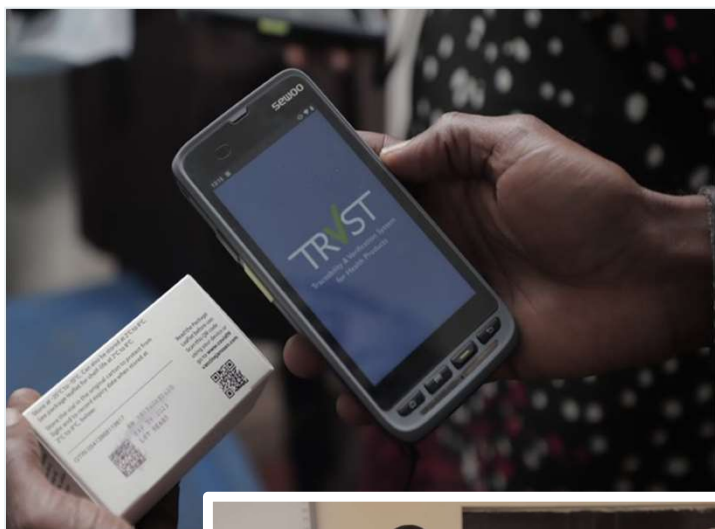
Ability to track the movement of health product and custody of ownership. The system tracks forward and back movements of the product, ability to indicate where the product is at given point in time within the supply chain levels.

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 .

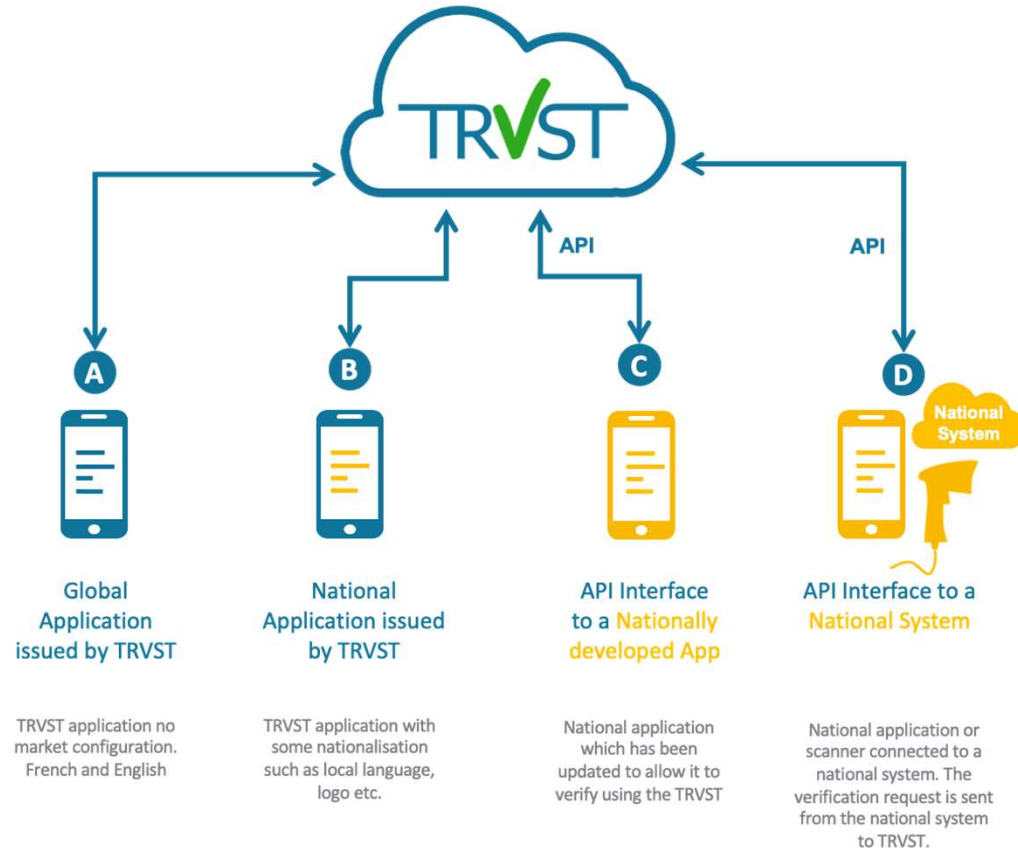
Benefits of TRVST



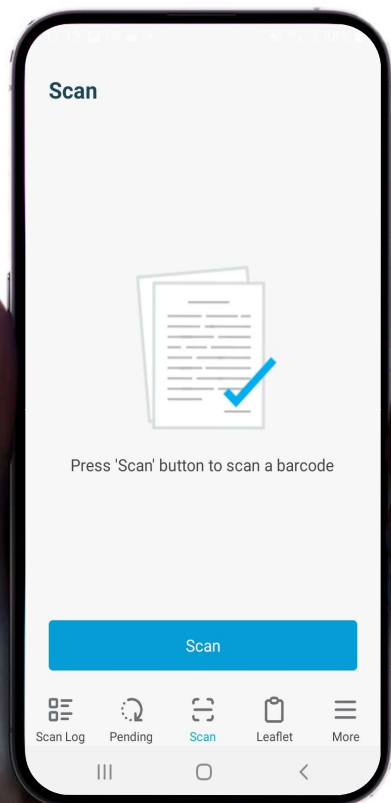
- **Improving patient safety** by minimizing patients' exposure to risk associated with falsified health products.
- **Support regulatory authorities** taking fast actions in their jurisdiction and concerted risk mitigation actions to prevent flow of falsified health product into the national supply chain.
- Foundation for a **fully-fledged national traceability system**.
- Facilitate **product recalls**, mitigate shortages of medicines and improve pharmacovigilance.
- Improve supply chain end-to-end visibility, hence **increasing supply chain efficiency**.
- Setting the stage to **enable the use of widely** accepted international data sharing standards such as **GS1 standards**.

TRVST verification modalities

- There are several different modes of verification tools being made available. Each of these modes has been given a letter A – D.
- This is to ensure TRVST is able to work with countries using the most appropriate tools to meet national requirements.
- **Modality A:** The most simple and easy to deploy is an off the shelf global application issued by TRVST.
- **Modality B:** The next is similar to A but allows a country to have market specific elements such as language etc. within the app
- **Modality C:** The third is an API which allows an already existing national application to be updated and interfaced to the TRVST system.
- **Modality D:** Finally the TRVST will provide a system to system API interface for countries with a national system.

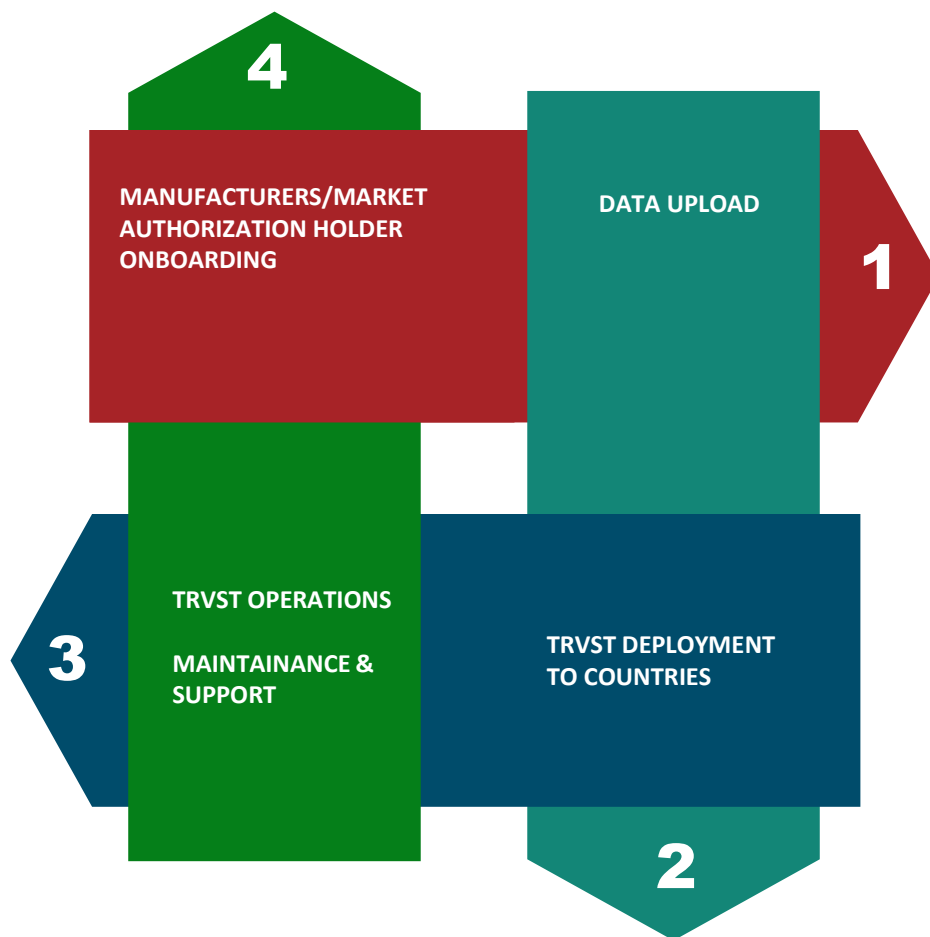


The TRVST Application



- Scans and verifies the data in the 2D DataMatrix
- Can work off line and then upload verification requests once back online
- The scan also captures the geo-location of the scan with a time and date.
- User persona data is also captured but does not identify the individual.
- Currently available in English and French
- The single application will work for multiple countries using a different “skin”.
- Verification responses can be country specific
- We can make the app public or put behind passcode access
- The app also allows access to digital leaflets

TRVST deployment processes



- Legal engagement
- Participation/Enterprise Agreement signed.
- API built OBPs vs TRVST
- APIs – EPCIS based to support T&T

- Serialized data upload to TRVST (Manual/automatic)
- Product Master Data
 - GTIN, Batch/Lot, Expiry data and S/N

- Solicit interest and agree for deployment.
- Selected Modality (Verification modality)
- Interface with NPC/National System if any.
- Identification of key users and training.

- Scanning for verification, T&T and E2E visibility
- System maintenance and monitoring.
- Change requests and upgrades

TRVST - Key Achievements to date ...

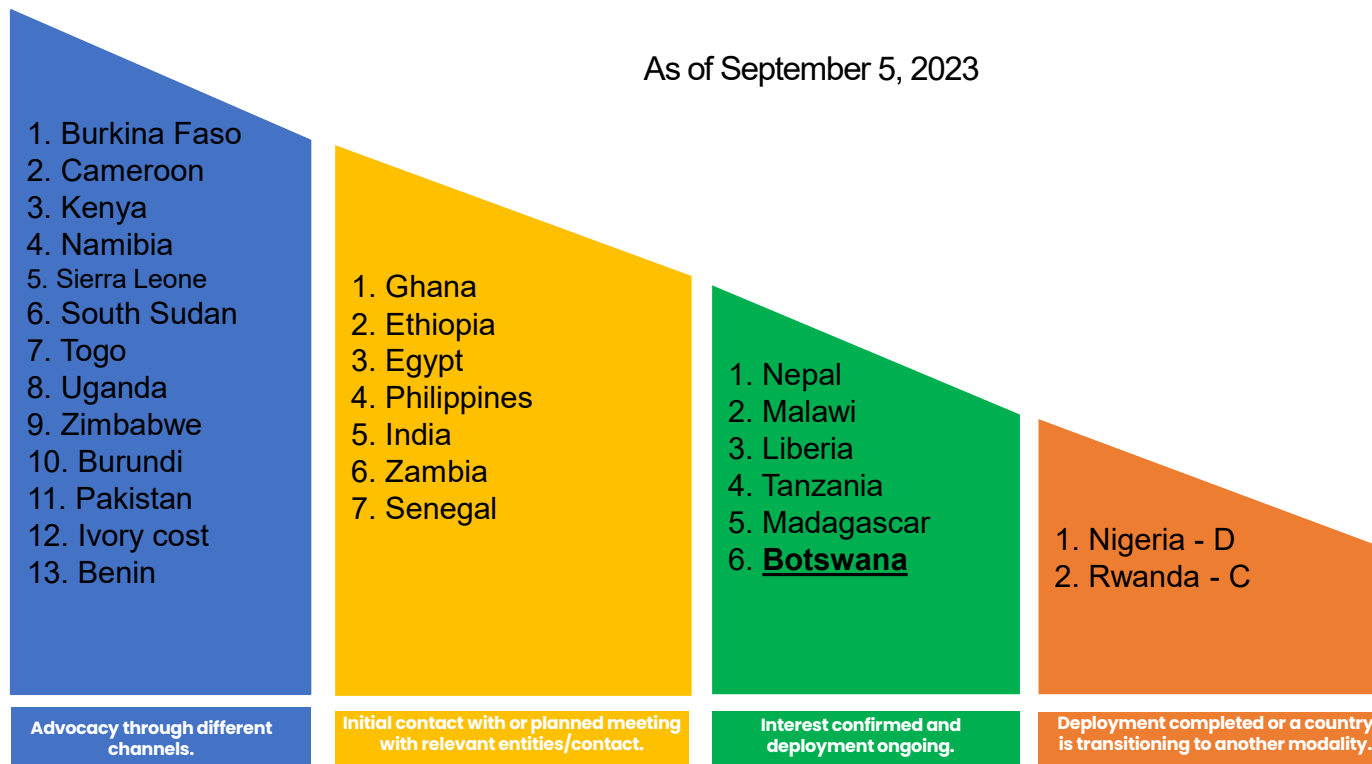
- **Technology:** System live (Release 2.1) and trialed in live country environments
- Fully scalable and secure system utilizing GS1 standards.
- **Data sharing and manufacturer engagement:** Participation Agreements signed by several stakeholders including 8 manufacturers and 18+ vaccine manufacturers ongoing discussions for onboarding.
- **TRVST deployment:** Successful training and trial of the mobile app in both Nigeria and Rwanda, and several other countries confirming their interest in a TRVST deployment.
- **Blueprints developed:** Country deployment and Manufacturer engagement blueprints developed and tested, now in use.
- **Partner alignment:** Major donors aligned in support of TRVST: UNICEF, WHO, GAVI, USAID, The Global Fund, Gates foundation, The World Bank, European Commission, Africa CDC, Manufacturers, LMICs.

EU commission – has provided financial support ~ \$2 Million and Africa CDC has added TRVST as one of the flagship projects with UNICEF



TRVST - Key Achievements to date ... - onboarding of countries - pipeline

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.

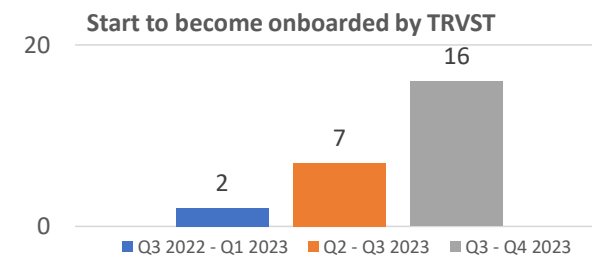
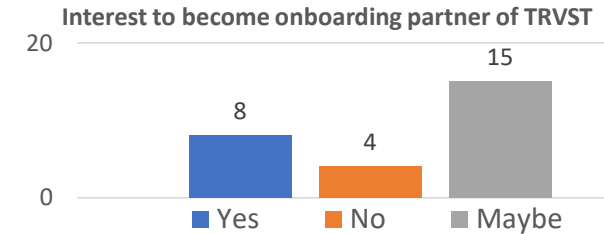
Deployment completed/upgrade

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

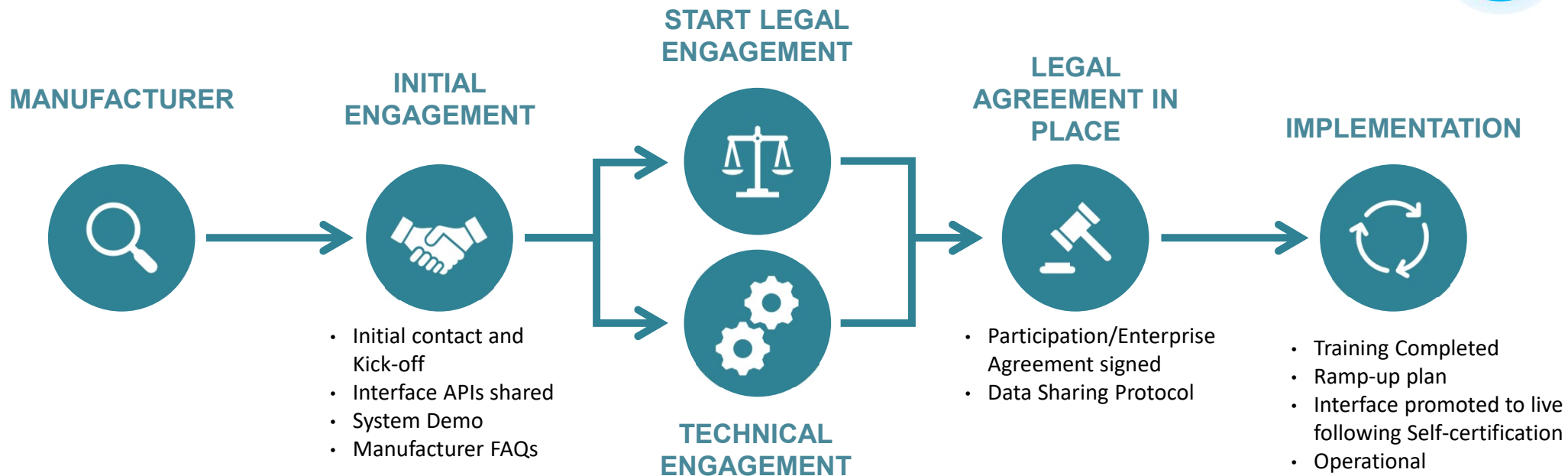
Supplier onboarding to TRVST

TRVST – onboarding vaccine suppliers

- UNICEF flagged TRVST onboarding opportunity to suppliers in **VIC 2022**
- We included 2 questions in VIC to gather initial understanding of manufacturers appetite to become onboarded to TRVST on short notice: **Volunteering for becoming an on-boarding partner for TRVST** (uploading data, incl. SNs)
 1. Is your company **interested** to become an on-boarding partner for TRVST? (Yes/No)
 2. **By when** would your company be able to start/become onboarded? (i. Between Q3 2022-Q1 2023; ii. Between Q2-Q3 2023; iii. Between Q3-Q4 2023)
- Based on responses provided we conclude that **majority of suppliers would like to become onboarded**, but many require additional information on requirements from TRVST and need to understand what it takes (supplier resources) to become onboarded.
- As a result, we **have hold 2 webinars** to allow information exchange between TRVST and digitalization/serialization leads of all suppliers as well as to provide further opportunity to confirm **supplier's voluntary onboarding**



Onboarding Process Flow

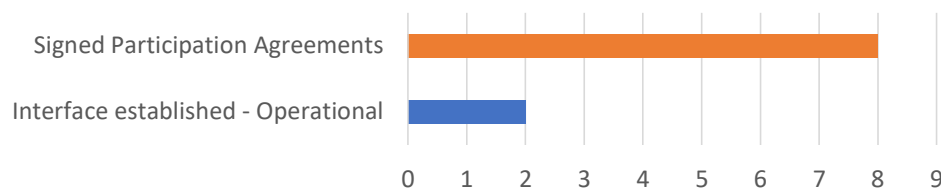


Documentation including interface API, system demo and FAQs can be accessed on:
<https://login-ite.trvst4hp.org/Documents>

TRVST - Key Achievements to date ... - onboarding of vaccine suppliers

- 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* (%)



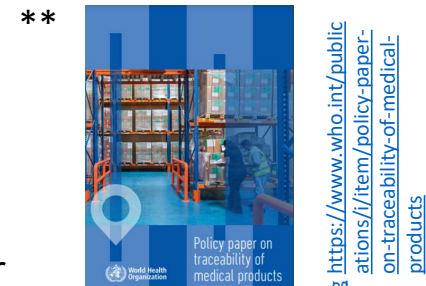
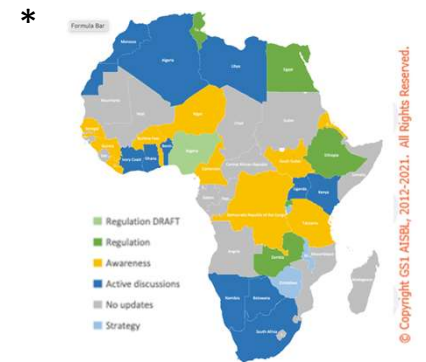
42 % Vx Operational

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

Barcode serialization needs and new tender requirements

Serialization requirement need (Towards implementing for multiple use cases)

- Required in order to **enable**:
 - Identification of the unique secondary pack for verification
 - Mitigate falsification
 - Traceability of the specific secondary pack through the supply chain
 - Mitigate diversion
 - Enable supply efficiencies, increase supply security
- Serialization **need is underlined** by:
 - National regulations that evolve and follow GS1 standards (see*):
 - **Entry requirement** for national markets – more and more countries will require serialization in order to allow import of supply to their country
 - WHO Member state driven policy on traceability of medical products (see **)
 - International Procurement Agencies (June 2023) – Global Standards Technical Implementation Guideline for Global Health Commodities (endorsed by UNICEF for Vaccines; see ***)
- **Serialization**
 - Include serial number on secondary packaging and higher level,
 - On top of: GTIN, Expiry date and Batch/Lot no.
 - Ensure aggregation of data

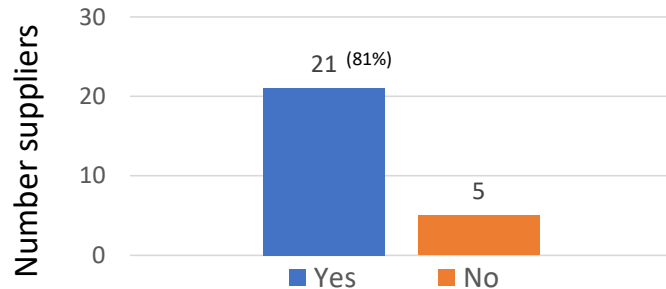


<https://www.who.int/publications/item/policy-paper-on-traceability-of-medical-products>

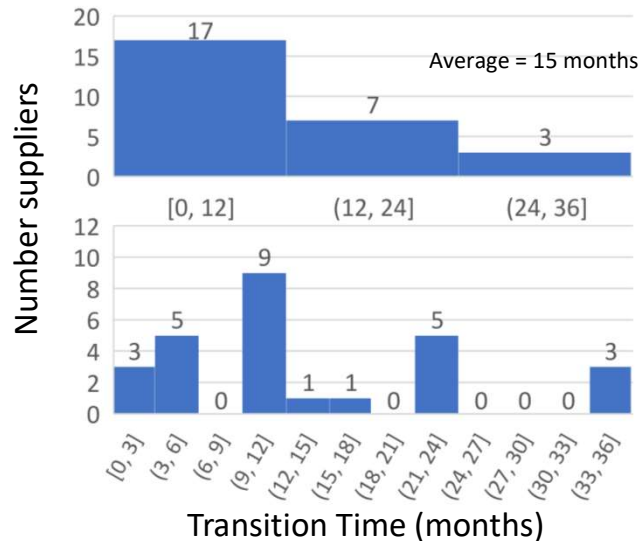
<https://www.ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities>

Towards a serialized barcode tender requirement

Will you supply serialized vaccine with a preferred requirement?



Expressed Transition Time
(# suppliers vs months-bin)



- In the **VIC 2022**, UNICEF highlighted to vaccine industry a potential **future state** of procured vaccines being **serialized**
- We included 2 questions in VIC to gather initial understanding of manufacturers preferences related to tender requirement (shift) for serialized barcodes: **Barcoding tender requirement shift** in UNICEF tenders (including SNs on secondary pack + aggregation)
 1. Would a preferred “serialization (SNs)” requirement make a difference (will vaccine industry supply SN-ed vaccines if a preferred requirement is in place)?
 2. What would be a reasonable transition time (timeline for shift) for vaccine industry for “serialization (SNs)” implementation on vaccine supply?
- **Conclusions**
 - Majority of suppliers (81%) indicated that a **preferred requirement** would suffice to provide serialized vaccines
 - Majority of suppliers (17 out of 27) indicated that a transition time in the range of 12 months is reasonable; with a few suppliers indicating a reasonable transition period being for them 24 (5) or 36 (3) months



Over the course of 2022 & 2023 more vaccine suppliers have been starting with implementation of serialization

Tender requirements

Current

- Mandatory requirement
 - GS1-barcodes on secondary pack and higher levels, including GTIN, Lot number and expiry date

20. BAR CODES

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. Please refer to "Annex C - UNICEF Guidelines for Vaccine Barcode Specifications" for further information.

New

- Addition of **preferred** requirement:
 - GS1-barcodes on secondary pack and higher levels, including GTIN, Lot number, expiry date and **serial number**
 - GS1-barcodes of different packing levels are **aggregated**
 - **Data** encoded by barcodes is **made available to/in TRVST** via an automated interface

Implementation

- Ask to suppliers to implement preferred requirement **as fast as possible** (preferred requirement from today onwards)
- Preferred requirement will be reflected in **tender docs**, including updated annex on vaccine barcode specifications

Ask to vaccine suppliers - Advocacy for earliest implementation

- Implement preferred requirement as soon as possible to enable the use of barcodes by countries.
- Where challenges arise with (earliest) implementation of the preferred requirement highlight this to your UNICEF account manager/focal point.
- For initiating the onboarding to TRVST connect with: Jean-Pierre Amorij, [jamorij\[AD\]unicef.org](mailto:jamorij[AD]unicef.org)

QUESTIONS



DISCUSSION

THANK YOU

unicef



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