The Verification and Traceability System (TRVST)

The Power of Verification and Traceability

Max Kabalisa UNICEF



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Traceability & Verification System for Health Products





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Supply chain Transformation and Traceability



Supply chain transformation

The process of automating key supply chain core functional areas such as Procurement, warehousing and inventory management, transport, and distribution of medical supplies and pharmaceuticals. Digitalization allows for real-time monitoring, data analysis, and automation, resulting in more efficient and transparent supply chain operations.



Traceability and verification - TRVST

It's a holistic interoperable system that enables product **identification**, **traceability**, and **in-depth visibility** of the supply chain.

Verification is the process of confirming the authenticity and legitimacy of healthcare products, including medicines, vaccines, and other pharmaceuticals.

Its purpose is to ensure that these products are genuine and come from authorized and reputable sources. By verifying health products, we can prevent the distribution and use of counterfeit, substandard, or falsified products, which could potentially harm or be ineffective for patients.

Track and trace allows the monitoring of product movement forward and back and SC custody of ownership and provides real-time E2E SC visibility.





The challenge

Falsified vaccines and medicines put lives at risk by causing harm to individuals and failing to treat diseases for which they are intended.

Every year counterfeit and falsified vaccines and medicines cost low and middle-income countries \$30 billion per year; and over \$200 billion globally.

<u>Nigeria</u> issued warning of "fake vaccines" in market. <u>China</u> detected fake vaccines ready to be shipped to Africa. And charging for C19 counterfeit vaccines in <u>Mexico</u>.

These are attempts to defraud national regulatory authorities or Ministries of Health.



Sources: WHO, A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products, 2017; <u>ABPI Website</u> <u>accessed on 2 August</u>; Times of India, <u>Surge in fake certificates as new players flood market with COVID-19 med products</u>, accessed on 1 August 2020. BBC News April 2020, Coronavirus Fuels a Surge in Fake Medicine; Courtney, G., <u>European Pharmaceutical Review</u>.





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









Some key elements are at the core of the TRVST system and services to all stakeholders



Country engagement: Countries sign up for the participation to TRVST by signing a participation/enterprise agreement and lead pilots and national rollouts of verification & traceability



Supplier onboarding: Suppliers sign up for the participation/enterprise agreement and agree to share their serialized product data by connecting to TRVST through an API



Partnership & organisation: Donors and key technical partners join the TRVST project and support it through funds, strategic inputs, technical assistance, governance and operational support



Technology development: The TRVST solution is provided by a credible and experienced vendor, and continuously evolves undergoing cycles of development/upgrade, testing, rollout and user support

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The value proposition for TRVST



- Verification smart phone application and API
- The TRVST dashboard
- TRVST API interface to national systems for verification and traceability

• **Improving patient safety** by minimizing patients' exposure to risks associated with falsified health products.

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



The TRVST system components



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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.

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.



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.



The TRVST dashboard

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



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.



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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







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

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How verification works – verification unicef@ match



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Verification Management Dashboard - Maps and Charts

TRVST provides map-based Visualisation based on geo-location verification data.

OBPs can only visualise their own products and pack data.

The user specifies a date range.

Together with specific countries they are interested in. All countries is the default.

The data can be further restricted by map category including potentially falsified, Suspicious activities or even successful verifications.

Alternatively the user can specify a specific Product Code or Batch.











Maps and Charts

The user can zoom-in to see aggregate totals for Failed verifications (denoted in purple) and Suspect Activity (denoted in green)

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Maps and Charts

The user can zoom-in to an individual scan and observe the activity details (popup).







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 Nigeria Rwanda and Nepal, 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 country deployment.





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TRVST: Manufacturer onboarding.



- 62% by volume of doses of Vaccine Manufacturers supplying UNICEF have signed a Participation Agreement to join TRVST.
- Of this 42% have an automatic interface already established with TRVST.
- 20% are currently building automatic interfaces.
- 38% discussions are ongoing.

Target for 2023 = 75%.









To learn more about the Verification & Traceability Initiative or to get involved, please contact the Program Management Unit

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