TRVST
Traceability & Verification System for Health Products

Version: 1.0
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Frequently Asked Questions

Q. What is TRVST?

The Traceability and Verification System (TRVST) is a collaboratively designed solution that allows countries to verify the authenticity of health products and enables traceability. TRVST was developed under the Verification and Traceability Initiative (VTI), a multi-stakeholder partnership composed of UNICEF, Gavi, The Bill & Melinda Gates Foundation, the Global Fund, USAID, national regulatory authorities in Nigeria and Rwanda, Vital Wave, and the World Bank.

TRVST is not intended to act as or replace national traceability systems. Its purpose is to act as a hub, enabling countries to verify products where they do not have national verification systems in place, extending the verification capabilities of existing national systems and providing better of products in the pre-country (upstream) supply chain. TRVST primary functions include the following:

- To verify products using a GS1 barcode on the secondary packaging of health products. The barcode contains the product code (GTIN), batch/lot identifier, expiry date and serial number. Un-serialized products can be verified using just the GTIN, batch/lot identifier and expiry date.
- To receive, send, and store traceability event data, allowing products to be tracked and traced using the GS1 Electronic Product Code Information Service (EPCIS) standards.

TRVST is already live and can be used to verify products against the data in its repository. The VTI is currently working to expand the number of products in TRVST and working with countries interested in deploying TRVST choosing from available verification modalities to suit country needs.

Q. Who governs and operates TRVST?

The VTI drives the strategy for the TRVST and advocates for countries and partners to join. The VTI is governed by a multi-partner Steering Committee formed by the Nigerian NAFDAC, the Rwanda FDA, UNICEF, GAVI, the Global Fund, USAID, the Bill & Melinda Gates Foundation and the World Bank. The Steering Committee sets the direction and defines the program scope. Three Task Teams bring VTI partners together to drive concrete actions on key initiative workstreams, and a Program Management Unit (PMU) manages the day-to-day tasks and facilitates the Steering Committee and Task Teams.

The TRVST is provided and managed by UNICEF at VTI's request, with support from the PMU. UNICEF is the legal entity behind TRVST, and thus the contracting party for all participants in the TRVST.

Q. What are the objectives of using the TRVST system?

TRVST has several objectives. Its primary objective is to increase supply chain visibility and to reduce the risk posed by falsified products. There are also secondary objectives. TRVST promotes the use of global standards for the identification and tracking of healthcare products. It also helps harmonize and promote the interoperability of national traceability systems through its data model and industry standard interfaces. Finally, it acts as an enabler and catalyst to the adoption of traceability by countries through the provision of simple verification tools and a hub for pre-country traceability event data.

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Q. Is the use of TRVST mandated or legislated?

The use of TRVST is currently voluntary. However, we tender requirements from donor organizations and governments are increasingly requesting the serialization of products and provision of data. Over time we expect TRVST will be used as the repository for serialization and traceability data where pre-country traceability is required.

Q. How secure is the TRVST technology platform?

The TRVST platform is implemented and managed by Solidsoft Reply, TRVST is based on the same technology they provide for the European Medicines Verification System (EMVS). The TRVST platform therefore has the necessary level of security for the sensitive data stored in the system.

Q. How does TRVST manage how data gets shared and with whom?

TRVST has a Data Sharing Protocol agreed by all parties signing the Participation Agreement or enterprise agreement, which establishes role-based access to TRVST data (e.g., verification event data, alerts, etc.).

Q. Will any personally identifiable information be stored in TRVST?

No. The system only stores information related to the packs being verified and the verification events. TRVST does not keep personal or patient information.

Q. How do I get involved if my organization wishes to participate?

If you or your country/organization wishes to participate in TRVST, please contact the PMU at traceability@vitalwave.com or any member of VTI in your country.

Q. How do companies submit serial numbers into the global repository?

TRVST is currently developing interfaces with key L4 providers to allow for automated product data submission. The system supports APIs that allow direct integration with L3/L4 systems using standards-based approaches.

Q. How can I view verification events?

TRVST provides a dashboard where participants can see the verification events based on their role as specified in the data sharing matrix.

Q. What actions do manufacturers need to take if verification of their products fails, or suspect activity is identified?

Suspect activity generates alerts that are sent to all concerned parties in accordance with the data sharing matrix agreed by all parties. Manufacturers are expected to investigate suspect activity in collaboration with country authorities.

Q. Are GTINs necessary for integration with TRVST?

Yes. TRVST requires each health product to be identified using a GS1-compliant barcode containing at least the GTIN, the batch and the expiry date. However, the most effective verification is performed at serial number level. Manufacturers are encouraged to have their products serialized.

Q. Do health product packs need to be serialized in order to be verified by TRVST?

No, TRVST can verify products against GTIN, batch and expiry date for those packs that are not serialized the verification at serial number level is the most effective and is recommended.

Q. What are the benefits of using TRVST for my country?

Through the VTI and TRVST, we are supporting countries with establishing foundations to aid in their journey to traceability to improve supply chain efficiencies and improve patient safety. Benefits include:

- Promotes standardization of products.
- Supports scanning to verify product authenticity.
- Supports identification of substandard and falsified products.
- Prevents supply chain diversion and intrusion.
- Helps to ensure high levels of quality and safety.
- Supports product recall.
- Enables targeted recalls.
- Informs supply chain stakeholders of recalled products.
- Provides transparency and visibility into the movement of the health products.
- Increases supply chain efficiencies.
- Provides access to aggregate data for analysis, reporting and decision making.
- Enables more rapid global coordination and response.

Q. What actions do country authorities and Market Authorization Holders need to take if verifications fail?

TRVST is a tool that enables country authorities and MAHs to identify in real time products that might be falsified and/or diverted, allowing them to take action. Country authorities and MAHs are expected to continue to follow their standard quality processes and procedures for handling failed verifications and suspect activity.

Q. How does my country begin verifying products using TRVST?

To being using TRVST, countries sign a letter of commitment and then work with partners to develop the project scope, plans and timelines. Countries will also need to sign a participation agreement before deployment to agree to data sharing protocols and other terms and conditions.

Q. Will TRVST support the regulatory authority and/or Ministry of Health to implement verification and traceability in my country?

TRVST allows different deployment modalities that can be adapted to the different levels of maturity of verification and traceability systems in countries. Countries can elect to use a self-service approach to planning and implementing TRVST or can pursue funding and additional support from VTI partners.

All participating countries and partners have access to planning and deployment resources, including training materials, budget planning, scoping and requirements guidance.

In addition, the vendor, Solidsoft Reply, provides help desk services and other technical support to countries using TRVST.

Q. What are the different ways to verify products in my country through TRVST?

The TRVST system is designed to support each country at their current level of verification maturity and to leverage existing investments. TRVST offers several options enabling countries to select a

modality that best fits their needs and plans and countries can change modalities as needed. Information on the modalities is provided below:

- **Modality A:** Standalone generic mobile application (provided by TRVST): Supply chain and health system workers scan vaccines with a smart phone application to validate their authenticity at any time. This is the most simple and easy to deploy off-the-shelf mobile application.
- **Modality B:** Customized mobile application (provided by TRVST): Supply chain and health system workers can scan vaccines with a smart phone application to validate their authenticity at any time. This application option is like modality A but allows a country to have market specific elements within the application (e.g., language, logo).
- **Modality C:** An existing country national mobile application is updated and interfaced with the TRVST system using an Application Programming Interface (API): Supply chain and health system workers can use their existing scanning or mobile device which is enhanced with the TRVST verification functionality to verify products registered in the repository.
- **Modality D:** Country national system (e.g. National Product Catalogue or Traceability system), is integrated with the TRVST system: Supply chain and health system workers can use their existing scanning or mobile device. The national system has a system-to-system API interface to access TRVST verification functionality to verify products registered in the repository.
- **Modalities E/F** (planned): Country national traceability system populated with TRVST data: Based on EPCIS event data the relevant data is transferred to the national system to allow national level traceability to occur. Modality E/F build on modality D's system-to-system API interface and verification functionality and enable the country to ingest country-specifical serialized data from TRVST.

Q. How will TRVST support implementation of national traceability systems?

TRVST provides an option for integration with national traceability systems through an Application Programming Interface (API) to exchange data between TRVST and the country system.

Q. What does it cost to implement and use TRVST?

Costs vary by country depending on existing investments that can be leveraged and the selected use cases and modality. Funding from partners may be available to support your country.