



Traceability and Verification System

PARTICIPANT ELIGIBILITY PROCEDURE

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Document control

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1 Introduction

The Traceability and Verification System (TRVST) is a digital platform developed through collaboration by a multi-stakeholder group called the Verification and Traceability Initiative (VTI). This platform enables countries to verify the authenticity of health products and improve end-to-end traceability across supply chains. TRVST is a powerful tool that significantly reduces the risks of falsified and diverted health products and supports the move toward national traceability of vaccines, medicines, and other health items.

TRVST is not intended to replace national traceability systems; instead, it functions as a global interoperability hub, connecting manufacturers, regulatory agencies, and national systems. The platform allows product verification where national systems are not yet established and supports traceability throughout the upstream supply chain before reaching the country level.

By design, TRVST ensures compliance with the regulations of National Drug Regulatory Authorities (NDRAs) pertaining to product verification and by providing transparency into product logistics. Additionally, it grants access to patient information leaflets (PILs) via barcode scanning. This feature supplies healthcare providers with accurate, up-to-date product information, facilitating informed decisions regarding patient care. Patients can also use this feature to authenticate their medications and access essential information about their treatments.

Manufacturers upload product master data, batch and lot numbers, expiry dates, and serial information into TRVST. These data are used to authenticate products when authorized users scan barcodes. Verification can be done directly through mobile or web interfaces or via data exchange between national systems and the TRVST Repository. The TRVST Repository acts as a central database that stores all product information and enables verification. This data exchange is managed through the TRVST Application Programming Interface (API), which facilitates secure communication and data sharing among systems.

Data sharing and security are core to TRVST's design. The platform complies with strict data governance and information security standards to protect the confidentiality, integrity, and availability of all exchanged data. These measures promote trusted collaboration among stakeholders while ensuring adherence to relevant data protection and privacy laws.

TRVST plays a crucial role in safeguarding the integrity of health supply chains, strengthening regulatory oversight, and enhancing patient safety.

The TRVST System Provider is responsible for the system's technical development and maintenance. UNICEF functions as the TRVST Organization and legal entity overseeing the management, governance, and stewardship of the data. This includes supervising system use, ensuring compliance with regulations, and managing the data shared on the platform.

More general information on TRVST is available in the [TRVST document repository](#).

The VTI welcomes the involvement of other relevant stakeholder organizations which play an active role in the health care supply chain in the further elaboration of the product verification at various levels of the supply chain.

This document

- describes the categories of eligible participants (TRVST User Organizations) who may engage with TRVST

- defines how third parties can engage with TRVST and become a participant and which system role they are assigned
- establishes a process to follow for exceptions

Terms and abbreviations used in this document are explained in the Enterprise Agreement.-

2 TRVST User Organization types

In this section, the various categories of eligible participants, i.e types of TRVST User Organizations, are outlined.

| Type | Description |
|---|---|
| TRVST Org | The TRVST Org is the system administrator and overall manager of TRVST operations. They are the primary interface with the TRVST System Provider and are responsible for ensuring that system Service-Level Agreements are adhered to, and that technical, operational, and business issues are identified and resolved. |
| TRVST System Provider / Service Desk | <p>The TRVST System Provider is responsible for day-to-day management of all operations of the platform on behalf of the TRVST participants. This role is technical in nature, and members will be part of the technology solution vendor technical team.</p> <p>The Service Desk Operator is responsible for onboarding users and integration of external systems (such as manufacturer data feeds), as well as responding to user queries, password reset requests and any other first line support. In addition, the operator will be responsible for monitoring the resolution of suspect activity alerts which have been reported to the Service Desk.</p> |
| PMU | The PMU acts at the direction of the VTI SteerCo, escalating and forecasting issues, supporting consensus building, and facilitating decision making across the initiative's multi-stakeholder governance structure. The PMU develops and manages workplans, including for the three Technical Task Teams; provides day-to-day management for the overall project and Task Teams; facilitates VTI SteerCo calls; and brings on Subject Matter Expert participation, as needed or requested by VTI SteerCo. |
| Country Authority¹ | A Country Authority is a governmental authority (Ministry of Health, national regulatory authority, or the like) in a country that is implementing the TRVST System for its country. A Country Authority user will access the dashboard to track, monitor and respond to verification events and the corresponding suspect activities. |
| Onboarding Partner | An OBP is the organization that is represented as the brand owner of the product and is expected to be the organization that will supply Barcode Batch and Serial Identification Data to the TRVST system. Non-manufacturers which |

¹ The terms "National Competent Authority" and "Country Authority" are used interchangeably in the context of the TRVST governance documents

carry out the serialization for the OBP, such as packers, will submit these data to the TRVST via the OBP.

Stakeholder

Other stakeholders include any other participants formally engaging with TRVST. They may be donors to TRVST or funders of products which are traced through the TRVST system, procurement agents, research institutions, or others. Depending on the type of stakeholder, different roles in the TRVST system might be assigned.

3 Engaging with TRVST

The VTI welcomes the involvement of other relevant stakeholder organizations which play an active role in the pharmaceutical supply chain in the further elaboration of the product verification at various levels of the supply chain. Any stakeholder that would like to become a participant in TRVST should follow the steps outlined below.

| # | Step | Description |
|---|--|--|
| 1 | Make request | Any legal entity interested in engaging with TRVST and falling into one of the categories of eligible TRVST User Organizations outlined in Section 2, may request to become a TRVST participant by sending an email with this request to the TRVST Project Management Unit. The email should include a short background on the legal entity itself, its interest in TRVST and which role they would like to be assigned. Typical roles for each category of participant are included in Annex A. The request as well as any questions related to becoming a participant of TRVST can be sent to the TRVST System Provider / Service Desk. Requests can be made either by external entities directly or by the SPOC of an existing TRVST participant on behalf of the external entity. |
| 2 | TRVST System Provider / Service Desk logs request | The TRVST System Provider / Service Desk logs, on behalf of the requestor, a helpdesk ticket and hands over the request to the Project Management Unit (PMU). |
| 3 | PMU reviews request | The TRVST Project Management Unit (PMU) reviews the request for completeness, carries out a preliminary check (e.g. if the type of participant corresponds to the desired TRVST System role), and clarifies any open points with the requestor. The TRVST PMU then forwards the request to the Data Sharing Task Team. |
| 4 | Data Sharing Task team clears request | The Data Sharing Task Team reviews all requests and may reach out to the requestor directly for a discussion. The Data Sharing Task Team will then confirm the suitable TRVST system role for the requestor. After clearance by the Data Sharing Task team, proceed to the next step. |
| 5 | VTI SteerCo approves request | The Data Sharing Task team submits the request in writing to the VTI Steering Committee. The VTI Steering Committee either approves the request through circulation or in a meeting, as required. The VTI Steering Committee must clear the request prior to proceeding to the next step. |
| 6 | Close help desk ticket | The PMU notifies the TRVST System Provider / Service Desk regarding the outcome of the process and asks them to close the help desk ticket. |

7 Handover to onboarding process

The PMU hands over the request and all relevant information to the TRVST System Provider / Service Desk to initiate the legal and technical onboarding. The onboarding will include the setup of the organization in the TRVST System, identification, and setup of a “Single Point of Contact” (SPOC), review and signature of the Enterprise Agreement and other steps. These steps are further described in the business processes maintained by the TRVST System Provider / Service Desk.

Annex A: System Roles for TRVST User Organizations

The figure below provides an overview of the TRVST System Roles available for eligible TRVST User Organizations. A detailed description of the TRVST system roles and rules around each role's access to data in the TRVST system is included in the Data Access Rules document, which is available in the [TRVST document repository](#).

| R2.1 - TRVST Participants & System Roles | System Role | | | | |
|--|--------------|-----|-------------------|--------------------|-------------|
| | System Admin | PMU | Country Authority | Onboarding Partner | Stakeholder |
| TRVST Org | ✓ | | | | |
| TRVST Solution Provider / Service Desk | ✓ | | | | |
| TRVST PMU | | ✓ | | | |
| Country Authority | | | ✓ | | |
| Onboarding Partner | | | | ✓ | |
| Other Stakeholders | | | | | ✓ |

Figure 1: TRVST System Roles assigned to TRVST User Organizations