



Traceability and Verification System

DATA GOVERNANCE FRAMEWORK

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Document control

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00.01	1 Dec 2021		Data Sharing Task Team
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00.10	27 July 2023	Alexander Blecken	Document shared with Data Sharing Task Team, VTI Steering Committee and other stakeholders
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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 facilitates 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 the proper administration of their health products.

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](#).

This document:

- describes the overall data governance framework of TRVST
- identifies all TRVST policies, procedures, and protocols (collectively referred to as 'Data Governance documents') that relate to data access and sharing, confidentiality, information security or otherwise concern the management of data in TRVST; and
- establishes and clarifies the framework for decision-making around data sharing and governance in TRVST

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

2 Framework

All participants are required to comply with the Data Governance documents as a condition of their participation in the TRVST. They acknowledge their compliance through an Enterprise Agreement, and acceptance of the Terms of Use.

Data Governance documents are established, maintained, and updated by approval of the VTI Steering Committee based on the recommendation of the TRVST Data Task Team.

All Data Governance documents are available either on the [TRVST Document Repository](#) or through the Project Management Unit.

3 Data Governance Documents

Each of the Data Governance Documents referred to below may be found here: <https://login-ite.trvst4hp.org/Documents>.

3.1 Participant Eligibility Procedure

As new participants join the Verification and Traceability Initiative, each must be assigned a role to interact with the TRVST and will be granted the appropriate data access. The Participant Eligibility Procedure details the process for adding and assigning roles to new participants.

3.2 Data Access Rules

The Data Access Rules define the different user roles that interact with the TRVST System and have access to data stored in the TRVST system. The document also describes the types of data held by the TRVST System and incorporates the Data Sharing Matrix which shows details on user roles and their access to data stored in the TRVST system.

3.3 Information Security Procedure

The purpose of this document is to define at a high level the Information Security policies and controls that are being applied during operation of the TRVST System. These policies and controls take into account the risks relating to the confidentiality, integrity and availability of TRVST information and continuity of the operational TRVST system. These include industry-standard security measures such as multi-factor authentication, password expiration, and the suspension of inactive user accounts. Other measures specific to the operation of the TRVST are also detailed in this document.

3.4 Information Security Incident Response Procedure

A Data Breach is an information security incident leading to the accidental, unlawful, illegitimate or unauthorized destruction, loss, alteration, access, use or disclosure of Data transferred, stored or otherwise

processed through the TRVST System. The Information Security Incident Response Procedure describes the actions which need to be taken without delay in case of a suspected or actual data breach. The Information Security Incident Response Procedure is complementary to existing information security and data breach policies and procedures of the TRVST Org and the TRVST System Provider.

3.5 Privacy Notice

The protection of data containing personal information is essential to upholding rights to privacy and personal information protection for all users of the TRVST system. Data containing personal information belonging to or identifying individual users of the TRVST are covered under this policy. The TRVST Privacy Policy states what personal data TRVST collects and stores and how it processes and safeguards personal data.

3.6 Notification and Alert Procedure

In the event of verification failures and possible subsequent identification of suspect activity and alerting, a defined process will be followed to investigate the issue. This process is defined in the 'Notification and Alert' procedure and will reference the Verification Business Processes developed for TRVST users.

4 Changes to Data Governance Documents

All modifications to this Data Governance Framework and to any of the Data Governance Documents (for the avoidance of doubt, expressly excluding modifications to the Enterprise Agreement itself) referenced above must be as recommended by the Data Sharing Task Team and approved by the VTI Steering Committee or the governing body for TRVST as provided for in Section 1.7 of the Enterprise Agreement..

Step	Description
1	Any TRVST stakeholder, including all TRVST User Organizations, TRVST Users as well as collaborators may provide suggestions for changes to the Data Governance documents.
2	A request, including justification for the change, must be submitted in writing to the Data Sharing Task Team, through the TRVST Project Management Unit (pmu@trvst4hp.org).
3	<p>The Data Sharing Task Team will review all requests. The requestor should be prepared to make a presentation on its request if so requested by the Data Sharing Task Team on its request. The Data Sharing Task Team will make recommendations on the request through discussion and striving for a consensus. In their deliberations, they consider the merits of the request following principles of mutual benefit and transparency and ensuring that no stakeholders are disadvantaged by the change. The deliberations should also consider the resource implications of the suggested change.</p> <p>Discussions on requests should only be undertaken when a representative quorum of the Data Sharing Task Team is reached, including at least one member of each role, as defined in the Data Governance Framework.</p> <p>Should a decision by consensus not be possible, the Data Sharing Task Team will vote on the request and a simple majority will be sufficient to proceed.</p>
4	The PMU will now invite TRVST User Organizations to provide feedback on the proposed change within three weeks. The PMU will provide the consolidated feedback to the Data Sharing Task Team.

- 5 The Data Sharing Task Team reviews and considers the feedback from the TRVST User Organizations and may then make amendments to the relevant documents, and may redistribute the documents for further feedback, should the Data Sharing Task Team members deem this is necessary. Decision making follows the process described in Step 3.
- 6 When proposed changes are ready for consideration and decision, the Data Sharing Task Team submits them to the VTI Steering Committee. The VTI Steering Committee will review and consider the recommendation of the Data Sharing Task Team and make a decision by simple majority vote.
- 7 Once approved, changes will be planned for release at a cadence of no more than once every 6 months. The Single Point of Contact of each participant organization will receive written notice of the pending release, including a table detailing all non-editorial changes to the Data Governance Documents, at least 60 days prior to the intended release date.
- 8 All signatories to the Enterprise Agreement will be bound to the approved changes from the date the changes to the relevant Data Governance Documents have been released.
- 9 The PMU will make updated Data Governance Documents available on the [TRVST Document Repository](#).