



Traceability and Verification System

NOTIFICATION AND ALERT PROCEDURE

Version: 02.00 (20 January 2026)

Document control

| Version | Date | Author | Changes |
|---------|-----------------|----------------|---|
| 00.01 | 16 Feb 2024 | G Courtney | First draft release |
| 00.02 | 19 Feb 2024 | G Courtney | Second draft |
| 00.03 | 5 Mar 2024 | A Blecken | Revised draft |
| 01.00 | 13 Mar 2024 | A Blecken | Final version |
| 02.00 | 20 January 2026 | Richard Wilder | Revision based on input from EA signatories and further internal review |
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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.

This document is based on the functionality of TRVST and defines the process to review and document an alert resulting from a verification failure.

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

2 Principles

The key principles of how TRVST notifications and alerts are implemented are:

1. This document provides a framework for how to manage alerts within TRVST. It is intended to **complement existing quality management processes** already in place at the MAH and National Competent Authorities (NCA)¹, and not replace them.
2. Only scenarios which could be **caused by a potential falsified product** will generate an alert.
3. TRVST cannot **definitively indicate if a pack is fake** and should not be used as the only indication of the authenticity of a product.
4. TRVST Org (UNICEF) provides TRVST as a tool to be used by users. TRVST Org (UNICEF) has no accountability for the management of falsified alerts or suspect activity. The response to a verification alert is the **primary accountability of the market authorisation holder (MAH)** of the product. The MAH is accountable to carry out pharmacovigilance activities for the healthcare products it is responsible for, which includes the monitoring of the quality of the product and potential falsification.
5. The MAH should **work in partnership with the National Competent Authorities (NCA)**, where the alert was triggered, to establish if the alert has been triggered by a falsified product.
6. National legislation or National Competent Authority (NCA) requirements **take precedence** over the process provided in this document.

3 Alerts and OpCodes

TRVST does the verification by making a comparison between stored and scanned data. It carries out the comparison against three (GTIN, Lot, Exp) or all four fields (GTIN, SN, Lot, Exp) depending on whether the product is serialized or not. Figure 1 is a visual representation of this comparison.



Figure 1: Verification visualization model

TRVST describes the outcome of this comparison in 64 scenarios. An example of five of these are shown in Figure 2.

| Examples | | | | | |
|------------|--|-------------------------|---|--|--|
| Scenario | GTIN is invalid (not the correct format) | Verification successful | Verification successful but product expired | Verification successful but batch/lot under recall | Verification not successful batch/lot does not match |
| OpCode | 61020008 | 11110100 | 11111000 | 11111100 | 41020003 |
| Alert Sent | No | No | No | No | Yes |

KEY

- Data invalid (format issue)
- Data does not match
- Data provided / matches
- No data provided or available
- Data available
- Expired
- Recalled
- Recall expected

Figure 2: Verification examples

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

The 64 scenarios are then further grouped into 38 different responses that TRVST provides when an item is scanned. Each response is allocated a specific Operation Code (OpCode).

An example for a successful verification, for instance, is Operation Code 11110100, where all four scanned fields match the data stored in TRVST. This is expected to be the most common response to a scan (second column in Figure 2 above). As the verification has been successful, there is no alert generated by TRVST and the user receives a message back to say the scanned pack matches the TRVST records (see Figure 3).

Operation code 11111000 is similar, as all the fields match the verification is successful, however, the item is beyond its shelf-life (third column in Figure 2 above). Once again, no alert is generated.

Another example Operation Code is 41020003 for when there is a failed verification where the batch/lot does not match. Therefore, an alert is generated (fifth column in Figure 2 above).

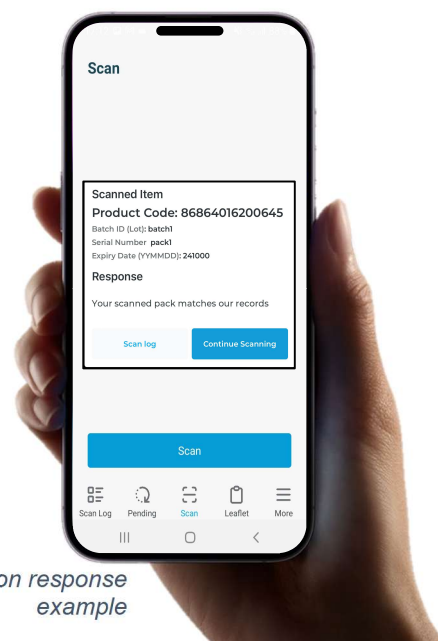


Figure 3: Successful verification response example

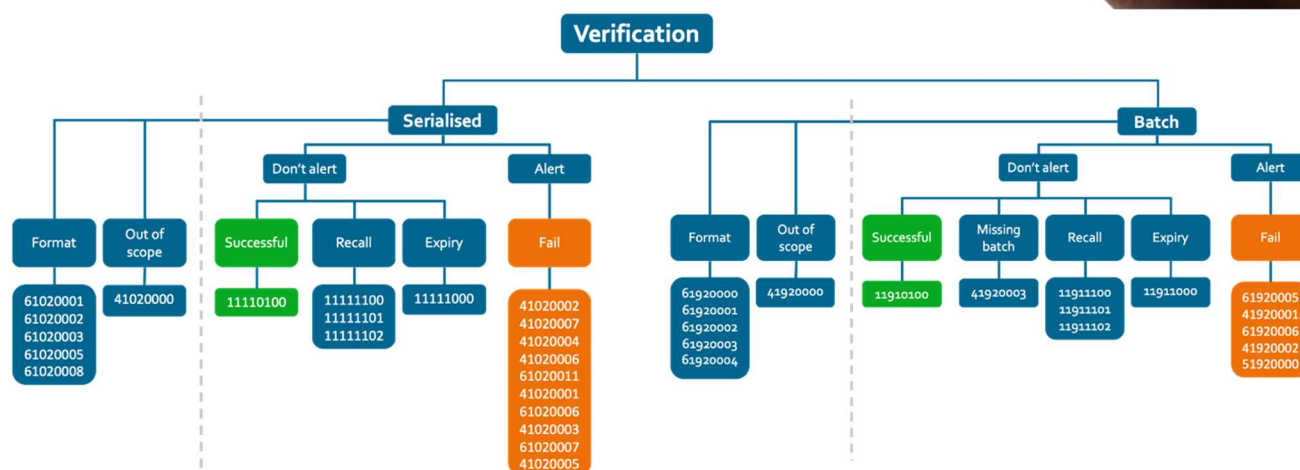
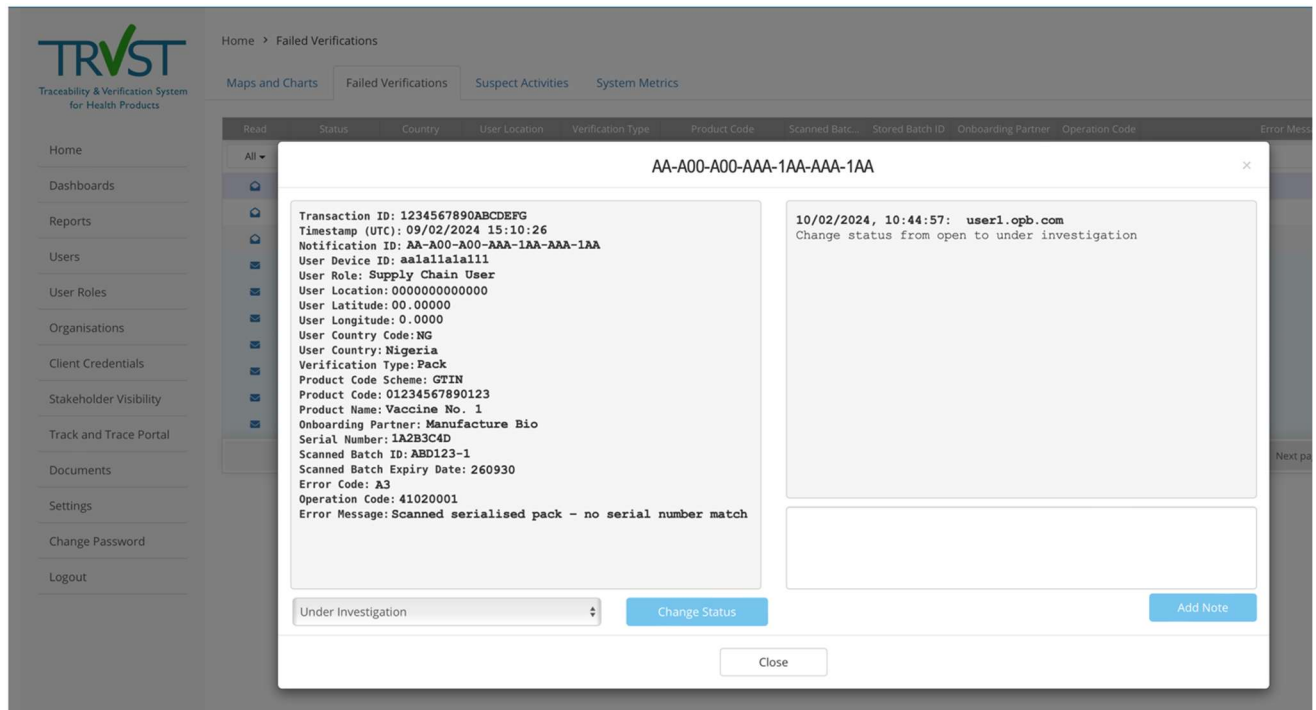


Figure 4: Scenarios and Operation Codes for Verification

Figure 4 provides an overview of all scenarios and corresponding Operation Codes. Only scenarios which could be caused by a potential falsified product will generate an alert and need to be addressed through the process described in this document, this includes ten operation codes for serialized products and five for non-serialized products as shown in figure 4. More details on all scenarios and Operation Codes and alerts are included in the [TRVST training materials](#).

Figure 5 shows an alert within TRVST. The Operation Code is provided along with the error message. The detail of the alert will vary depending on the scenario and if the pack was serialized or not. The status of the alert is shown at the bottom of the window (in the example below: 'Under Investigation'), and any notes about the alert will be shown in the notes section on the right-hand side. TRVST keeps a log of all the notes added against an alert, including a timestamp and identification of the user who added the note.



The screenshot displays the TRVST web application interface. On the left is a sidebar menu with options: Home, Dashboards, Reports, Users, User Roles, Organisations, Client Credentials, Stakeholder Visibility, Track and Trace Portal, Documents, Settings, Change Password, and Logout. The main header shows the breadcrumb 'Home > Failed Verifications' and navigation tabs: 'Maps and Charts', 'Failed Verifications' (active), 'Suspect Activities', and 'System Metrics'. Below the header is a table with columns: Read, Status, Country, User Location, Verification Type, Product Code, Scanned Batch, Stored Batch ID, Onboarding Partner, Operation Code, and Error Message. A modal window titled 'AA-A00-A00-AAA-1AA-AAA-1AA' is open, displaying transaction details and a status change log.

Transaction Details:

- Transaction ID: 1234567890ABCDEF
- Timestamp (UTC): 09/02/2024 15:10:26
- Notification ID: AA-A00-A00-AAA-1AA-AAA-1AA
- User Device ID: aalalalalall
- User Role: Supply Chain User
- User Location: 00000000000000
- User Latitude: 00.00000
- User Longitude: 0.00000
- User Country Code: NG
- User Country: Nigeria
- Verification Type: Pack
- Product Code Scheme: GTIN
- Product Code: 01234567890123
- Product Name: Vaccine No. 1
- Onboarding Partner: Manufacture Bio
- Serial Number: 1A2B3C4D
- Scanned Batch ID: ABD123-1
- Scanned Batch Expiry Date: 260930
- Error Code: A3
- Operation Code: 41020001
- Error Message: Scanned serialised pack - no serial number match

Status Change Log:

- 10/02/2024, 10:44:57: user1.opb.com
- Change status from open to under investigation

At the bottom of the modal, there is a dropdown menu set to 'Under Investigation', a 'Change Status' button, an 'Add Note' button, and a 'Close' button.

Figure 5: Alert within TRVST

Procedure

Table 1 and Figure 6 below describe the process to be followed when TRVST generates an alert. It is important to note that TRVST cannot definitively indicate if a pack is fake and should not be used as the only indication of the authenticity of a product. The system alerts stakeholders to potential issues within the supply chain which can then be further monitored and investigated if required.

The scope of the process described below starts from the point the alert is triggered through to the point at which the alert has been identified as a potential falsified product. Once a potential falsified product has been identified through the TRVST the Market Authorization Holder (MAH) and National Competent Authority (NCA) should work together to fully investigate the issue.

The investigation and documentation of an alert investigation should be carried out in the knowledge that it may be used in evidence in a court of law and should therefore be done in such a way as to fulfil any legal rigour required.

Table 1: TRVST alert assessment process

| Step | Description | Detail / Comment | R | A | C | I |
|--|---|---|---|-------|-----|------------|
| Start | System generates alert and sends a notification. | Alerts according to the scenario and associated Operation Code as described in Section 3 above | | TRVST | | NCA MAH |
| Market Authorization Holder (MAH) | | | | | | |
| M1.1 | Check the status of the alert in TRVST. | Either click on the link with the email alert message or log directly into TRVST. | | MAH | | |
| Is the alert resolved and the root cause identified? | | Check the notes and status of the alert. If alert resolved and root cause identified go to M1.2, otherwise go to M1.3 | | MAH | | |
| M1.2 | Document accordingly and close internal investigation. | If the alert has been resolved document in accordance with the MAH's Quality Management System procedures. | | MAH | | |
| M1.3 | Mark alert as under investigation in TRVST and assess if this was a MAH related issue. | If the alert has not been resolved, move the alert into the status 'under investigation' within TRVST and add a note describing steps being taken to investigate. | | MAH | | TRVST |
| Has the alert been caused by a MAH related issue? | | <p>The MAH can be the root cause of an alert in some instances, for example when failing to upload the serialized batch data for an item.</p> <p>The MAH should review the alert and understand if they have caused the issue.</p> <p>There is also an opportunity at this point to identify any other potential issue which may explain the reason for the alert.</p> <p>If the alert has been caused by a MAH related issue, go to M1.5, otherwise go to M1.4</p> | | MAH | | |
| M1.4 | Add a note to the alert in TRVST and inform the National Competent Authority and Procurer of the product. | If the MAH is not the root cause of the alert, then this should be documented in the TRVST by adding a note to the alert in TRVST with outcome of the MAH's analysis. Any other relevant observations can be added which may help the NCA follow up on the alert. | | MAH | NCA | Procurer |

| | | | | | | |
|--|--|---|-----|-----|------------------|----------|
| | | <p>The MAH contacts the NCA and notifies them that the alert is not caused by the MAH and agrees on how to proceed with the investigation of the alert.</p> <p>The MAH also informs the organization which procured the product.</p> | | | | |
| M1.5 | Add a note to the alert in TRVST and inform the National Competent Authority. | <p>If the MAH is the cause of the alert, then the MAH documents this in the note of the TRVST alert and changes the status to closed.</p> <p>The MAH contacts the NCA and notifies them that the alert has been resolved.</p> <p>Follow the MAH's Quality Management System processes to document the issue, establish the cause and put in place any fix and preventative actions.</p> | | MAH | | NCA |
| M1.6 | On conclusion of the investigation add a note to the alert in TRVST with the outcome and mark as closed. | <p>If a suspect product investigation was carried out, then a note should be added to TRVST with the outcome of this investigation and the alert closed.</p> <p>If the investigation was inconclusive, but no further action is going to be taken, then the alert can also be closed.</p> | MAH | NCA | TRVST | Procurer |
| National Competent Authority | | | | | | |
| A1.1 | Check the status of the alert in TRVST. | The NCA either clicks on the link with the email alert message or logs directly into TRVST. | | NCA | | |
| Is the alert resolved? | | The NCA checks the notes and status of the alert. If the alert has already been resolved go to A1.2, otherwise go to A1.3 | | NCA | MAH | |
| A1.2 | Document accordingly and close internal investigation. | If the alert has already been resolved, the NCA documents in accordance with national procedures and closes the internal investigation. | | NCA | | |
| Did the verification use the TRVST app? | | <p>There may be potential for the root cause to be the result of a local scanner or software issues. The TRVST application has been tested to ensure it does not cause any data corruption or scanning issues.</p> <p>If the verification used the TRVST app, go directly to step A1.6, otherwise continue with step A1.3.</p> | | NCA | TRVST | |
| A1.3 | Mark alert as under investigation and assess if national system related issue. | The NCA changes the status of the alert to 'under investigation' within TRVST and add a corresponding note with details on the steps taken. | | NCA | | |
| Is the root cause a national system related issue? | | The NCA establishes if the alert has been caused by any local scanner or software related issues. This may include contacting the location where the scan occurred if provided as part of the alert data. | | NCA | Location of scan | |
| A1.4 | Add a note to the alert in TRVST with outcome of the NCA analysis. | If there are no known or identified issues with the national scanners or software, the NCA adds a note to the alert. Proceed with step A1.6, otherwise continue with step A1.5 | | NCA | | |
| A1.5 | Add a note to the alert in TRVST with root cause, mark as closed, take corrective or preventative actions. | <p>If there are known or identified issues with the national scanners or software, then add a note to the alert with the details of this.</p> <p>The NCA puts in place any corrective or preventative actions to resolve the issue and communicates to</p> | | NCA | | TRVST |

| | | | | | | |
|---|------------------------------|--|-----|-----|---------------------------|----------|
| | | TRVST. TRVST will then provide this feedback to relevant users of the system. Process ends. | | | | |
| A1.6 | Contact MAH | The alert may be the result of an issue with the MAH systems. The NCA contacts the MAH to check if this is a MAH related issue. | | NCA | MAH | |
| Has the alert been caused by a MAH related issue? | | The MAH reviews the alert to ensure they were not the root cause. Go to “Has the alert been caused by a MAH related issue?” above. If the MAH were the root cause, then the alert should be closed in TRVST by the MAH. | MAH | NCA | | |
| A1.7 | Initiate local investigation | <p>If the alert was not caused by the MAH, then at this point the scanned product is possibly a falsified product, and an investigation should be carried out in partnership with the MAH and procurer of the product.</p> <p>This should be done in accordance with each organization's procedures which they have in place.</p> <p>Reference can also be made to any other alerts or suspect activity in the TRVST system, which may provide further information on the scale or location of falsified products.</p> | MAH | NCA | TRVST Location of scan | Procurer |
| End | | | | | | |

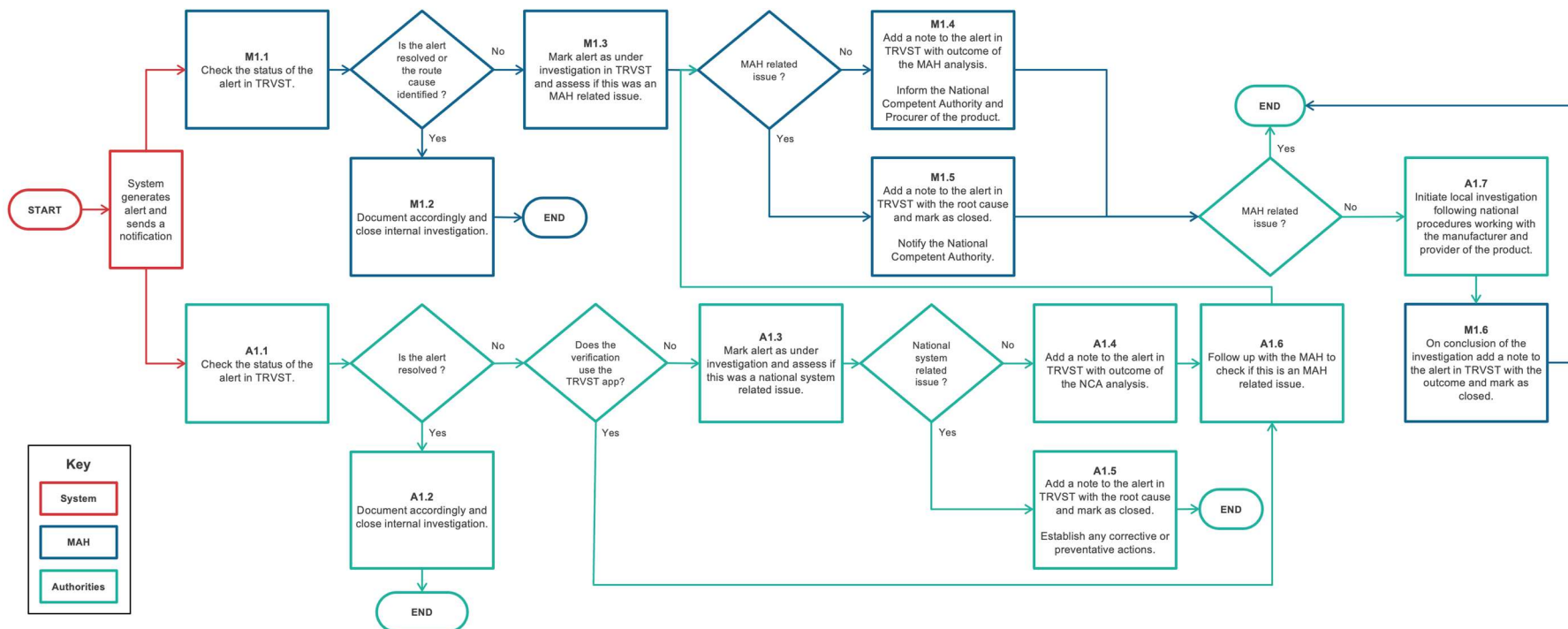


Figure 6 6: TRVST alert assessment process (flowchart).