The Verification & Traceability Initiative

Supporting countries to reduce the urgent risk of falsified and diverted COVID-19 products in national supply chains with a vision toward national traceability of all vaccines, medicines, and health products.

WHY

As COVID-19 vaccine distribution ramps up worldwide, there has been an upsurge in the production and distribution of falsified and sub-standard vaccines and related COVID-19 supplies. The development of one of the most valuable and highest-demand vaccines in history has already been sited as a risk by the COVAX Facility, the GAVI Audit and Finance Committee, and UNICEF, and evidence from Interpol and the Oxford Data Observatory has corroborated this.

The need for product quality verification and traceability extends beyond COVID-19 vaccines to all health products. The highest risk is in low- and middle-income country (LMIC) national supply chains, where governance structures, tools, and technical capacity for active monitoring for falsification are limited and traceability systems are either non-existent or in the early stages of development. Falsified vaccines and medicines cost LMICs $30billion/year and over $200billion globally[1].

COVID-19 pandemic investments can accelerate implementation of traceability investments to protect beneficiaries safety from falsified health products while strengthening the digital foundations to optimize supply chains for all public health and routine healthcare use cases.

WHAT

The **Verification & Traceability Initiative**, led by BMGF, GAVI, UNICEF, USAID, the Global Fund, and the World Bank, will establish a Global Trust Repository (GTR) that can verify the authenticity of health product information sent to its application programming interface (API) or scanned using a complementary, off-the-shelf verification application (already in use). The GTR will initially be loaded with COVID-19 vaccine data from manufacturers to address the urgent risk of falsified or diverted COVID-19 vaccines. However, the GTR will be designed to support end-to-end (E2E) traceability of all vaccines, HIV, TB, and malaria medicines, and other health products. The Verification & Traceability Initiative will also support country deployment in alignment with existing verification and traceability efforts. Utilization of the GTR or verification application are options in the suite of WHO recommended and current country approaches to protect patient safety.

Verification can be integrated into existing supply chain management and vaccination campaign workflows by supply chain and health worker cadres without requiring a significant change in existing processes. Additionally, a secure and password-protected global dashboard will allow authorized users to monitor trends in verification events and suspect activity, and utilize as a proxy for product movement in the supply chain. Investigation of suspicious scans by decision makers will require in-country procedures to be adapted and/or drafted in consultation with existing government, supply chain, and development partners.

Importantly, the GTR and mobile verification application are **built on the GS1 supply chain standard**, ensuring their interoperability with other GS1-enabled supply chain information systems. While the GTR will initially support verification of COVID-19 vaccines, its use of the GS1 standard will allow its functionality and scope to be expanded over time to cover other health products and use cases, including traceability, product recall, and supply chain automation and analysis.

Depending on the existing digital health ecosystem within any country, the GTR can be used through two different modalities:

(1) **Standalone mobile application:** For countries where no existing national traceability or verification system exists. Supply chain and health system workers can scan vaccines with a smart phone application to validate their authenticity at any time. This application will be easy to use and require minimal additional training.

(2) **Integrated with traceability system:** For countries with an existing national traceability or health product management system. Supply chain and health system workers can use their existing product scanning system, which can interface with the GTR's API to verify products registered in the GTR.

WHEN

Immediate Term

Early Adopters (2-5 countries) will be by end of 2021. By **early 2022** the GTR, GTR API, an off-the-shelf mobile verification application, and a software development kit (SDK) to support easy integration of verification functionality into other traceability applications will be made available in the public domain for immediate use.

The Verification & Traceability Initiative will provide **direct technical and financial support to early adopter country partners** to implement and use the GTR in their countries, and share lessons learned to improve the solution for other geographies. Each early adopter will be asked to identify and recruit a subject matter expert to work within the country structures to scale the use of the solution for verification.

Medium to Long Term

The Verification & Traceability Initiative will serve as a platform for discussions on traceability and as a catalyst for the digitization of health product supply chain systems over the next three-to-five years. The GTR, GTR API, mobile verification application, and verification SDK are key digital components designed specifically to integrate within a broader, standards-based digital health ecosystem that supports other supply chain and health system functions. Successful implementation of the verification use case opens the door to additional use cases and traceability of routine vaccines, medicines, and other health products in the future, including:

- **Monitoring the supply chain** for identification of falsified vaccines and other medicines as a mechanism for product recalls in post-marketing surveillance.
- **Expanded track-and-trace functionality**, including integration with logistics management information systems (LMIS) to enable real-time identification of inventory positions across the supply chain network.
- **Innovation and development of new GS1-enabled applications** for consumers, supply chain partners, and healthcare providers.
- **Integration with electronic health record systems (EHRs)** to facilitate pharmacovigilance, adverse event reporting, health outcomes analysis, ordering, and billing.

WHAT ACTIONS MUST AN "EARLY ADOPTER COUNTRY" TAKE – AND WHAT WILL THEY GAIN

The effective prevention of falsified, sub-standard products, and diversion requires collaborative partnership across all organizations involved in public health programming and routine supply chain management. The Verification & Traceability Initiative invites active discussion with all country partners. Early Adopter and Steady State country participants will need to:

1. **Hire a full time traceability subject matter expert** who may sit in the MoH, UNICEF, USAID PSM, The Global Fund PMU or other entity which is currently driving country owned traceability efforts. Funds for early adopters provided
2. **Assess/Revie Digital Readiness –** Development partners, including CDC, GAVI, GIZ, UNICEF, USAID, WHO and the World Bank, are increasingly supporting a variety of similar "digital readiness tools". Where possible, tap into the resources of DICE, UNICEF T4D colleagues and partners. This will also enable success.
3. **Develop a budgeted workplan with the key partners within existing country structures,** i.e. supply chain working group, including, but not exclusive to: MoH, regulatory authorities in health and technologies; public-sector healthcare providers; private-sector healthcare providers; supply chain operators; in-country global donors; Immunization, HIV, TB and Malaria programs; technology experts
4. **Train, build skills and establish help desk function** for the main stakeholders who will i) scan; 2) conduct dashboard analytics; 3) investigate suspect scans; and 4) other needs
5. **Early Adopters provide iterative feedback for Verification and Traceability Deployment Package** to inform about barriers, challenges and solutions to optimize

Countries which choose to by EARLY ADOPTERS will benefit from

1. **Funding** for the SME and either partial or full amount for the budgeted workplan

2. **Technical support** from UNICEF Supply division and Program (immunization supply chain); Technology for Development (T4D), USAID, The Global Fund and specific GS1-enabled traceability expertise.
3. **Distinct advantage in leveraging additional funding for traceability** from GAVI HSS grants, Global Fund grants, USAID, World Bank and UNICEF for investments in vaccine, medicines, and health products traceability. Each agency has prioritized verification and traceability as a COVID-19 health system strengthening intervention with long term impacts - a wise investment.
4. **Leadership demonstrated on preventing falsification of COVID-19 vaccines –** a COVAX Facility and UNICEF identified risk. Other countries will learn from your efforts.

[1] WHO, A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products, 2017.

To learn more about the Verification & Traceability Initiative or to get involved as an early adopter, please contact the Project Management Unit for the Verification & Traceability Initiative (Vital Wave) or UNICEF

traceability@vitalwave.com ; klegins@unicef.og