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.

THE RISK OF COUNTERFEIT AND DIVERTED VACCINES

As COVID-19 vaccine distribution ramps up worldwide, counterfeit vaccines have been found, presenting significant risks to the public health response and financial loss. The need for product quality verification and traceability extends beyond COVID-19 vaccines to all health products. Falsified vaccines and medicines cost low- and middle-income countries (LMICs) $30billion/year and over $200billion globally[1]. Investments in verification and traceability can protect beneficiaries from counterfeit health products while strengthening digitally enabled supply chains for all public health use cases.

For COVID 19 vaccines we need to be able to tell where the vaccines are coming from and which paths through the supply chain they have taken, including the time between each node of the chain.

COVID 19 vaccines, governments, funders and partners need to have information about COVID 19 vaccine stock levels and supply chains in order to ensure that the right products are available and can be transported to destinations where they are needed. The aim is to provide data to strengthen the manufacture and distribution of COVID 19 commodities and to ensure that the risk of shortages or expiration of products is minimized.

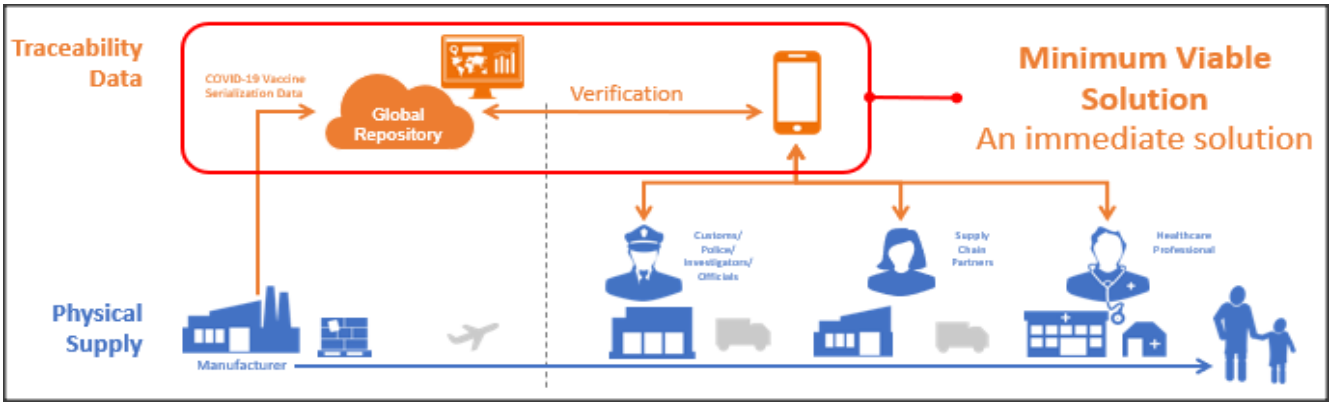
WHAT: A GLOBAL REPOSITORY AND VERIFICATION SOLUTION

The **Verification & Traceability Initiative**[2] will establish a global database of manufacturer health product information that can be used to verify if a scanned health product is authentic or counterfeit. Initially, the repository will be populated with COVID-19 vaccine serial numbers from vaccine manufacturers, to address the immediate risk of counterfeit COVID-19 vaccines from causing harm and financial loss. The global repository can also be populated with any batch and serial numbers for any type of health products that use the GS1 data standard for supply chain.

Supply chain workers and health workers will be able to scan health products as they are distributed to health facilities to verify that products are authentic before they are dispensed to patients. To do this, countries can:

(1) **Deploy the global repository verification mobile app.** Workers can download and use the verification mobile app on any smart phone to scan 2D data matrix codes on health product packaging. The app will check with the repository if the product is authentic or counterfeit. This is the minimum viable solution for immediate deployment, which will be easy to use and require minimal additional training (see Figure 1).

Figure 1: Minimum viable solution for using the global repository and verification mobile app.



[1] WHO, A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products, 2017.
[2] The Verification & Traceability Initiative is a global initiative led by the BMGF, GAVI, the Global Fund, UNICEF, USAID, and the World Bank.

(2) **Integrate the global repository with their existing national traceability system.** Workers can use any existing national system that they currently use to scan health products. This will require technical integration through the global repository's application programming interface (API) and/or mobile software development kit (SDK) by national system owners.

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. While the global repository of trusted health product information will initially support verification of COVID-19 vaccines, its use of the GS1 standard ensures it is interoperable with other GS1-enabled supply chain information systems and 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. Utilization of the global repository and repository verification application are options in the suite of WHO recommended and current country approaches to protect patient safety.

COUNTRY DEPLOYMENT OPTIONS

Countries interested in addressing the risk of counterfeit products can use the global repository through four different deployment models (see Figure 2). Countries may choose to deploy the global repository verification mobile app or to integrate an existing national system with the global repository technology. Countries may request financial, in-kind, or technical support from development partners for immediate deployment in early 2022. Self-service implementation guides will then be published by the Initiative, including lessons learned from initial deployments, to allow countries to deploy a verification solution (app or integration) independently in 2022.

Figure 2: Expected start time for different deployment models.

	Global Repository Verification App	Repository-to-National-System Integration
Partner Supported	**Early 2022** • Country partners facilitate deployment and user testing of mobile app along entire country supply chain, including last mile end users	**Early / Mid 2022** • Country partners secure data sharing agreements with appropriate system owners • Country system owners integrate with global repository API or mobile SDK
Self Service	**Early / Mid 2022** • Countries use the published implementation guides on VERIFICATION as self-service	**Mid / Late 2022** • Countries use the published implementation guides on INTEGRATION as self-service

Countries seeking partner support for immediate deployment must:

- ❑ (for COVID-19 vaccine verification use case only) Be a COVAX Facility participating country and currently receives serialized COVID-19 vaccines
- ❑ Have secured buy-in from appropriate government and partner organization leadership (see box on right)
- ❑ Be willing to commit national-level staff as well as supply chain and health worker time and effort to deploy, use, and provide training and support for the global repository verification solution
- ❑ Provide a letter of commitment documenting the named official who will be responsible for the deployment and the national-level budget and staff allocation that will be committed for deployment by the government and/or national regulatory authority
- ❑ (For integration only) Have the ability to secure data sharing agreements and technical resources (e.g., software developers) to integrate an existing national system with the global repository.

Potential Deployment Partners

- Ministries of health and ICT, including legal and communications departments
- Regulatory authorities in health and ICT
- Public-sector healthcare providers
- Private-sector healthcare providers
- Supply chain / cold chain partners
- Implementing partners
- Global donors providing financial or in-kind support for health product procurement or distribution
- Vaccine and other health product manufacturers
- Technology providers and software developers

To plan an immediate deployment, country partners must first define the scope of deployment, including the following decisions. The Initiative's country deployment task team is available to help in this process.

- ❑ **Deployment modality:** whether the global repository verification app or repository-to-national-system integration will be used
- ❑ **Country specific requirements:** are there any specific requirements for the solution to work in a local context (e.g., localization for specific languages) and will any hardware procurement (e.g., smart phones) be required

- ❑ **Geographic scope and users for initial deployment:** in which districts and with which supply chain and health workers will the verification solution first be deployed
- ❑ **Funding and partner support:** which partners will provide financial support, in-kind support, or technical assistance for the deployment, if needed
- ❑ **Partner agreements:** which partner(s) will manage the deployment and operations, which will use or support the verification solution, and what agreements are needed
- ❑ **Workflows and policies:** will new verification workflows or policies be required (e.g., when to scan and verify, when and how to investigate suspicious results) and who is responsible for their development and dissemination
- ❑ **Timeline for initial deployment:** what is a feasible timeline to establish agreements with all relevant partners, finalize verification workflows and policies, establish a system integration (if applicable), deploy the solution to selected locations, provide training to users, and start use
- ❑ **Monitoring and evaluation:** what metrics will be monitored to measure use and impact
- ❑ **Scale:** at what point in time and/or based on what metrics will the verification solution be scaled out to additional locations, if applicable

COUNTRY DEPLOYMENT SUPPORT AND FUNDING

Short-term funding

Funding to support immediate deployments of a verification solution (global repository app or integration) in two-to-five countries is available through the Verification & Traceability Initiative. Country partners interested in immediate deployment of a verification solution should indicate their interest and support requested to their local UNICEF or WHO country or regional office, or by emailing the Verification & Traceability Initiative's Program Management Unit (traceability@vitalwave.com).

Additional bridge funding for immediate deployments may also be available through the following COVID-19 response funding mechanisms. Interested country partners should contact their local partner offices for more information on how to use existing funding to support the global repository deployment.

- GAVI: COVID-19 Vaccine Delivery Support (CDS)
- USAID: American Rescue Plan Act (APRA)
- Global Fund: Procurement and Supply Chain Strategic Initiatives

As noted above, countries must provide a letter of commitment documenting the national-level budget and staff allocation that will be committed for deployment by the government and/or national regulatory authority to be eligible to receive additional bridge funding.

Long-term funding

For long-term operations and scaling of the solution to cover additional health products and use cases, countries can work with Initiative partners to leverage existing long-term funding vehicles, for example through Health Systems Strengthening funding provided by USAID, the Global Fund, and the World Bank to provide ongoing support to the appropriate government ministry and/or regulatory agencies.

The Initiative recognizes the need for putting together the total cost of ownership and the necessary resources to support continued operation and scale of the chosen verification solution, as well as its expansion to cover other health products. Long-term costs for ongoing country operation of a national verification and traceability solution will be variable and subject to change as lessons are learned through increasing use of the global repository of trusted health product information. Such lessons and costs will be captured in through immediate deployments by the Initiative's country deployment task team. Initiative partners are committed to working with early adopter countries to determine long-term annual operating costs and to find appropriate funding vehicles to support long-term country operations sustainably.

FUTURE EXPANSION

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 global repository, repository 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.

WHO resources for verification

- WHO policy paper on traceability of medical products
- WHO position on Bar-codes, QR codes and Vaccine Vial Monitors in the context of COVID-19 vaccines
- Information about the WHO's support for countries to prevent-detect-respond to SF medical products
- Meeting of the Member State mechanism on substandard and falsified medical products
- WHO efforts to develop a shortages database

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):

traceability@vitalwave.com