Core Principles of the Verification and Traceability Initiative

Change Control:

2021-09-22 - Working Version v1.0.0: Data Sharing Task Team

Purpose

- The GTRs main purpose is to detect falsified and diverted products and to protect the safety of supply chains.

Defined Scope

- The scope of the GTR is the verification of products in order to detect those that are falsified.
- The scope of the GTR will initially be limited to COVID-19 vaccines across low- and middle-income countries and across sources of funding (donor or otherwise), with a view to expanding to other products.
- The scope of the GTR may evolve based on the initial proof of concept, experience, and demand. Any modification of the scope or functionality of the GTR will be subject to approval by the GTR Steering Committee, and formal change control process.

Defined Data Ownership, Access and Confidentiality

- The protection and confidentiality of data held and generated by the system is key to the success and credibility of the system.
- Data sharing, including related permissions, is defined in the Data Sharing Protocol endorsed by the Steering Committee in accordance with the Data Governance Framework, and accepted by all participants in the system.
- Data submitted by a participant belong to that participant.

System Agnostic, Accessible & Non-proprietary

- The proposed product verification solution should meet the criteria of being practical, affordable, interoperable, scalable, and accessible.
- Unnecessarily complex and costly solutions should be avoided.
- Vendor-specific solutions should not be enforced.
- The system is open to continuous iteration and improvement based on countries' needs and feedback as well as the thought leadership of the Steering Committee.

Low Technology Burden

- The usage of the system will not be limited to serialized products.
- Products with GTINs and Batch/Lot numbers should be scannable by the system.
- Advanced technology platforms should not be required to use the system. E.g., countries should be able to use low-tech mobile tools to verify products.

Patient Safety

- As key stakeholders in the verification process, the GTR members and users are committed to working together to establish an efficient, viable, and effective system to protect patients against the threat of falsified medicines.
- The establishment and management of spoke product verification systems should be undertaken by relevant stakeholders according the GTR governance framework, building on the current coding environment in the various countries, and meeting the needs of patients and all players in the supply chain.
- There may be an inclusion of health protection agencies in this framework.
- The system should respect all applicable data privacy standards and will not collect or store patient information.

Standards Based and Interoperable

- The platform should be based on global standards and best practices, in particular GS1 GTIN and EPCIS.
- Integration of country systems with the GTR should aim to enhance interoperability and strengthen existing systems.

Maximization of Benefit

- The GTR should provide benefit to all stakeholders in order to encourage use (in the absence of legislation).

Inclusive

- The initiative 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.