

# Responding to Emerging Traceability Regulatory Trends in Africa



## Problem Statement

Global health trading partners need a standards-based mechanism to comply with emerging country regulatory mandates for serialized traceability data sharing with national systems.

## What is the Traceability Interoperability Platform (TIOP) Pilot Project?

TIOP is a pilot program to develop a data-sharing prototype for exchanging serialized traceability data between trading partners in response to emerging regulatory requirements in Africa. It tests a semi-centralized architecture using a designated point of access equipped with a trading partner directory with the goal of:

- ✓ Simplifying how suppliers share traceability information with trading partners without requiring integration to multiple point-to-point connections
- ✓ Simplifying how countries receive traceability information without multiple point-to-point connections or buy into a single central repository
- ✓ Supporting a competitive market for global and/or country-level solutions by sharing lessons and documentation with the global community
- ✓ Promoting a lean governance model to facilitate data exchange between authorized trading partners through minimizing data access and storage

## Enabling Global and National Traceability Objectives

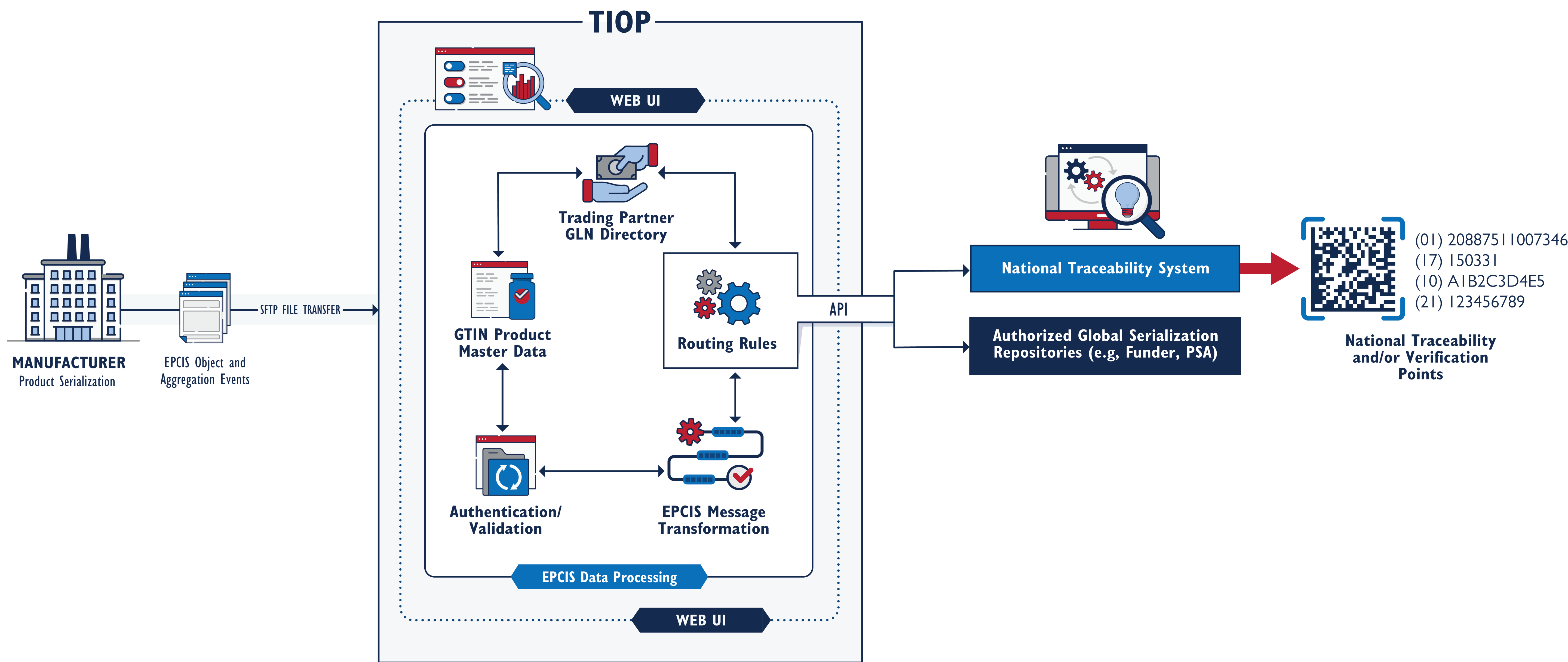
- ✓ Patient safety
- ✓ Supply chain efficiency
- ✓ Supply chain security
- ✓ Programmatic accountability
- ✓ Governance and regulatory compliance

## How Will Success of the Pilot be Measured?

- ✓ Serial numbers shared with countries in accordance with regulatory mandates
- ✓ Improved integration and interoperability across trading partner systems
- ✓ Participating trading partners support bringing solution to scale
- ✓ Open-source code published for broader use
- ✓ Document lessons to support community learning

## TIOP Architectural Design

Minimum viable product (MVP) for demonstrating data exchange for ARV products procured by GHSC-PSM for Nigeria and Zambia



## TIOP Functional Requirements

- ✓ Maintain a network of verified trading partners, enabling consistent communication with authorized trading partners across the supply chain using a directory look-up service
- ✓ Facilitate the capture of key visibility events exchanged including commissioning, aggregation, and shipping
- ✓ Enable compliance with GS1 standards including use of GTIN, GLN, and GS1 Electronic Product Code Information Services (EPCIS) standards for traceability information exchange