TIOP

TRACEABILITY INTEROPERABILITY PLATFORM

Leveraging serialization to position patient safety at the center of a connected, secure, and open global supply network

USAID FROM THE AMERICAN PEOPLE

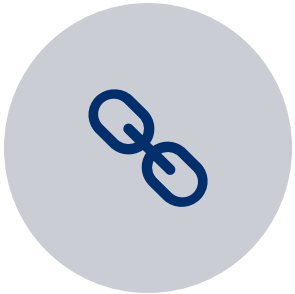
PEPFAR U.S. President's Emergency Plan for AIDS Relief

Global Health Supply Chain Summit

Today's Agenda

USAID's approach to enabling traceability leveraging GS1 standards

The role of serialization in enabling pharmaceutical traceability



Overview of the Traceability Interoperability Platform (TIOP)

Results & Lessons Learned from TIOP pilot

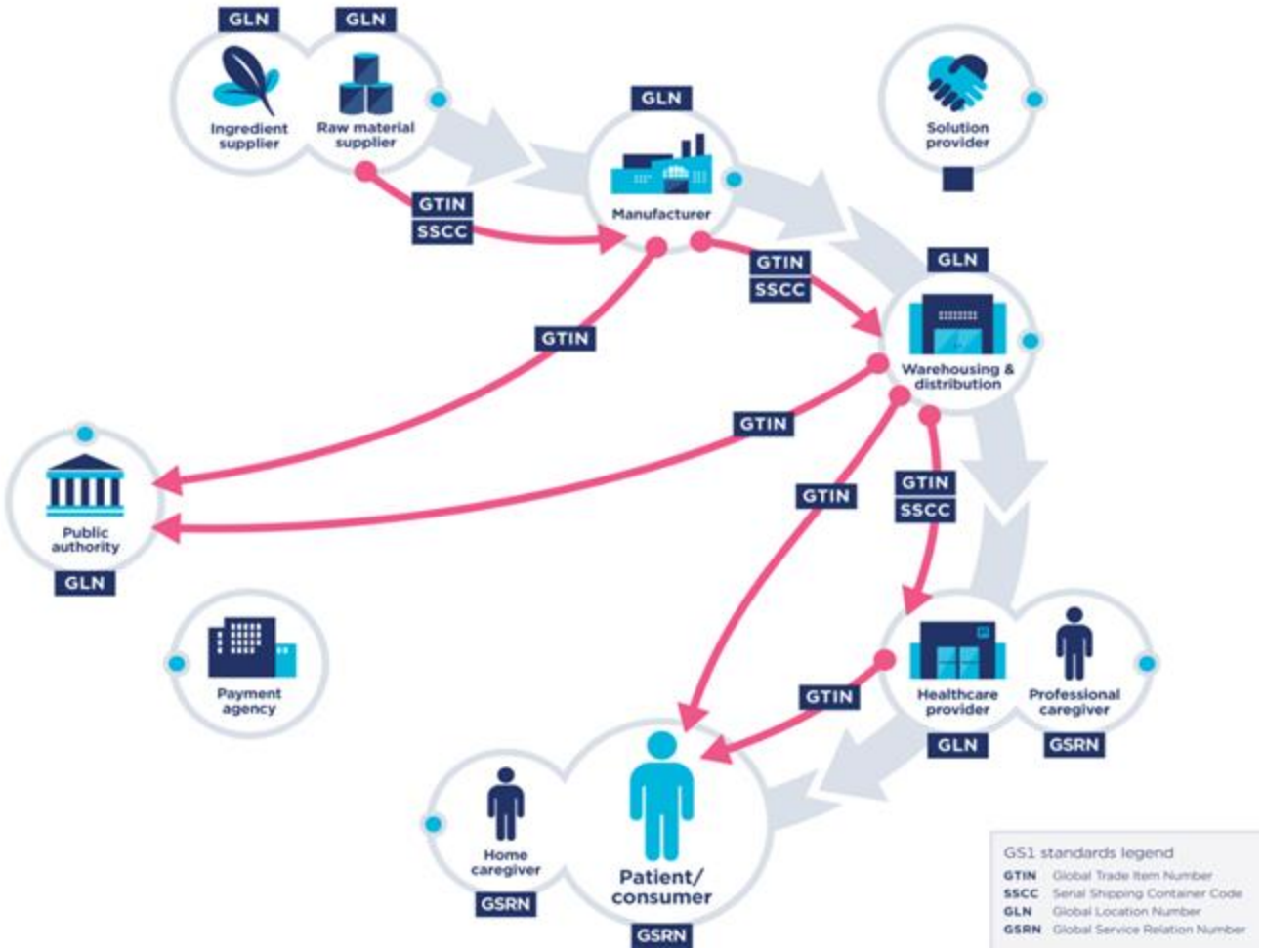
USAID's approach to enabling traceability

Traceability supports a number of supply chain objectives

		Patient Safety	Supply Chain Security	Supply Chain Efficiency	Data Visibility
ADDRESS	SF or stolen product detected in the legitimate supply chain	■			
	Theft or diversion of products from the legitimate supply chain		■		
	SF or stolen product that is obtained by the patient/end user	■			
IMPROVE	Accuracy and efficiency of procurement operations			■	
	Efficiency of "reverse" logistics processes (e.g., those used for returns, recalls)	■		■	
	Visibility of product "status" (e.g., expiry, recalls)	■		■	
	Efficiency of inventory management and distribution			■	
	Efficiency of payment and payment monitoring processes		■		■
	Pharmacovigilance and control of treatment outcomes	■			■
ENABLE	Visibility into where the product is within the supply chain		■		
	Visibility to decrease or eliminate reimbursement fraud		■		■
	Harmonized trade/customs clearance procedures for pharmaceutical products			■	

Content Source: GS1 Global Office

GS1 Identification Keys Enable a Digital Thread

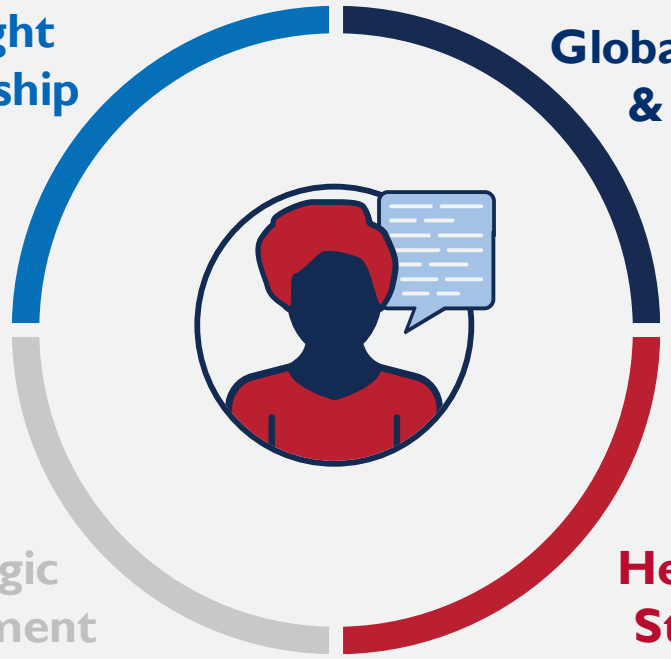


See it in action!

Content Source: GS1 Global Office

Our Global Standards Approach

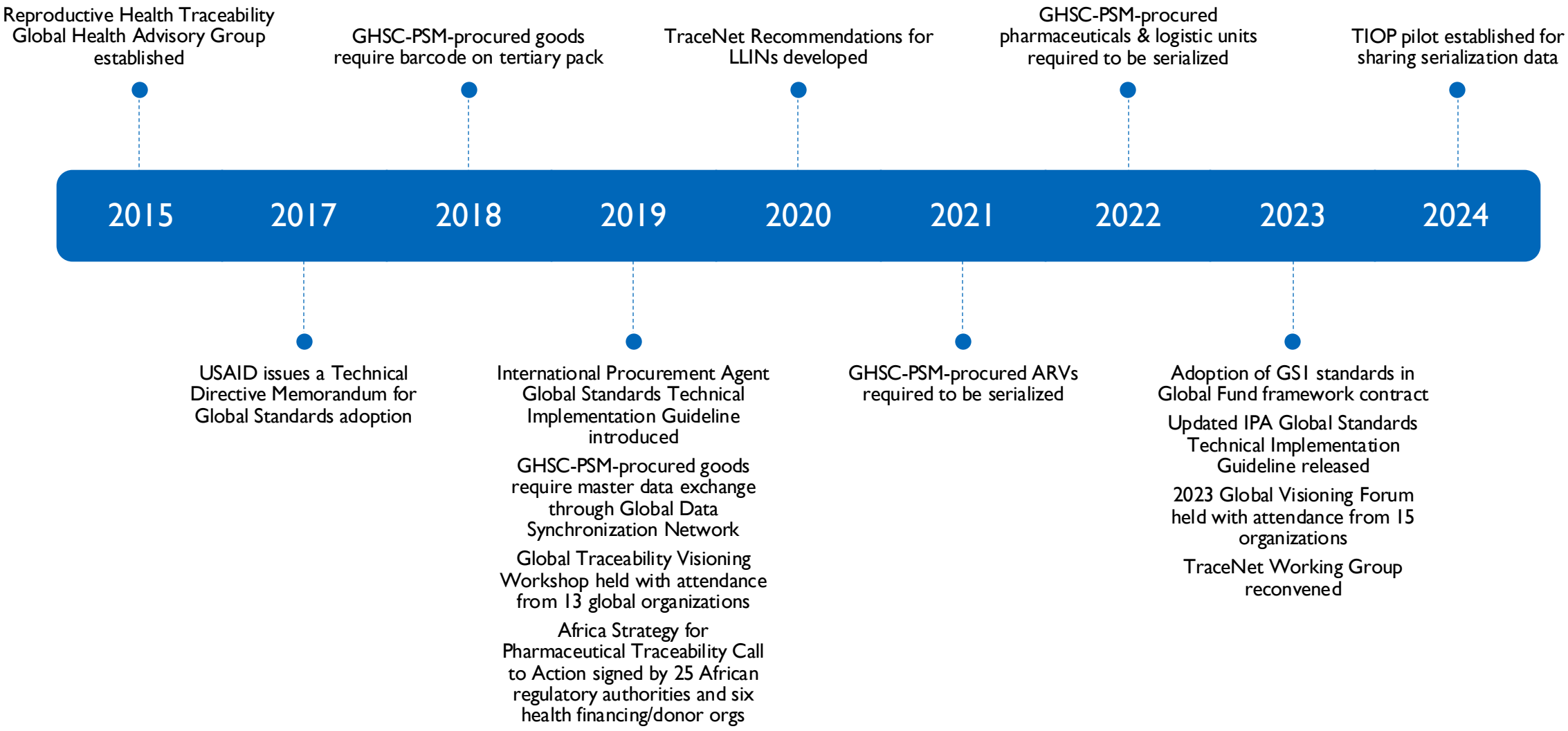
What We Do



Our Objectives

- Implement supply chain efficiencies
- Enable end-to-end data visibility
- Improve supply chain security
- Advance patient safety

Key milestones for Global Standards implementation

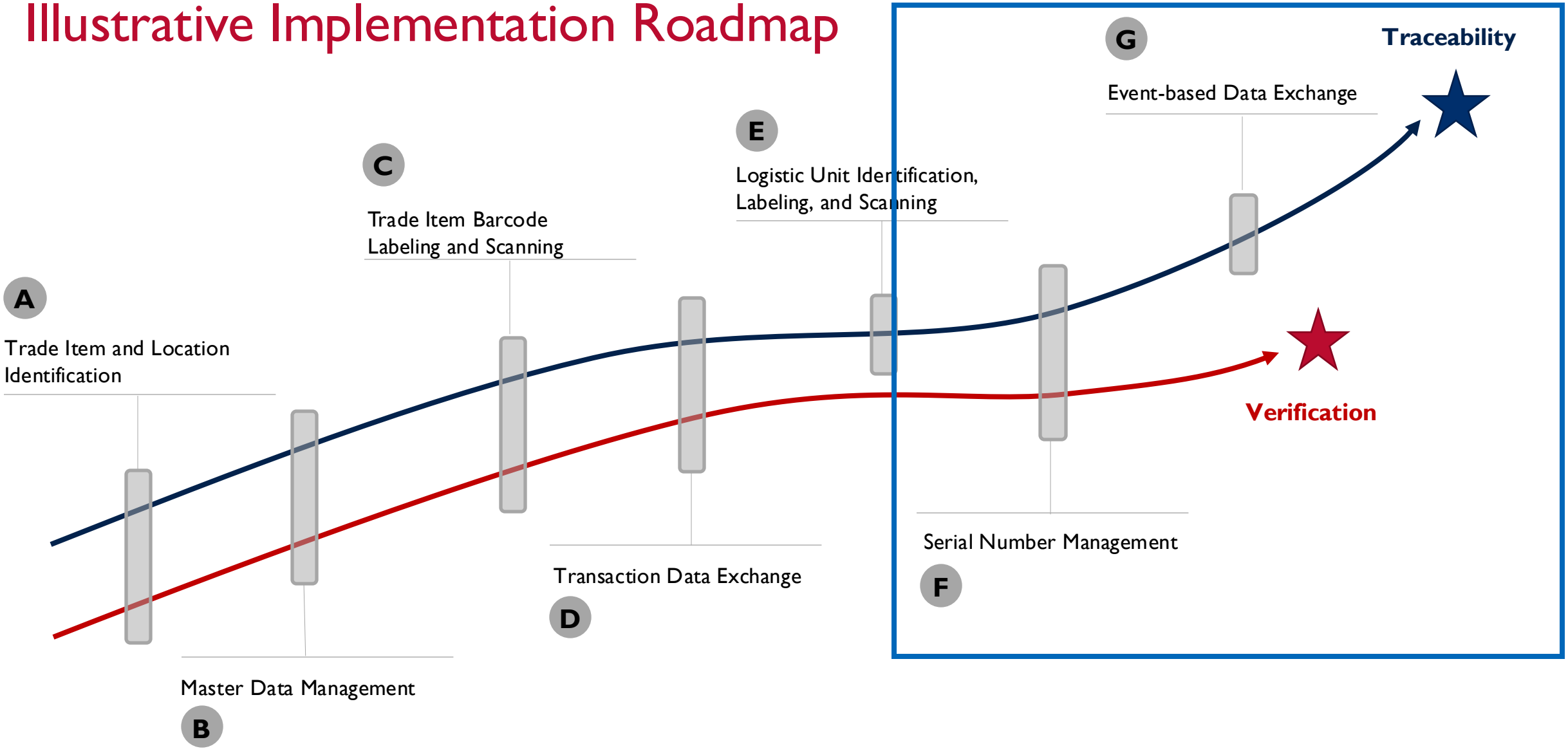


The role of serialization

Illustrative example only

Each country will develop an implementation plan based on their vision and strategy

Illustrative Implementation Roadmap



Emerging Traceability Regulatory Trends in Africa

There is a growing need to meet emerging country regulatory mandates for serialized traceability data sharing with national systems.


Rwanda


Ethiopia


Zambia


South Africa


Nigeria


Ghana

National use cases differ depending on localized pain points

Verification

- Prevent Substandard & Falsified medicines from reaching end users
- Improve consumption data and visibility
- Ensure products are authorized for distribution on the market
- Prevent reimburse fraud
- Patient interaction
- Pharmacovigilance
- Adverse event reporting

Track and Trace

- Diversion of product from the public sector supply chain
- Visibility of where product is in the supply chain
- Programmatic accountability
- Recall management

Why Open Traceability Information Exchange?

Trading partners can share traceability information in response to national regulatory requirements with fewer connections allowing regulatory authorities to pursue their traceability mandates to advance:

- Patient Safety
- Supply Chain Efficiency
- Supply Chain Security
- Product Recalls
- Integration & Interoperability
- Risk, Governance & Compliance

The TIOP pilot will help us understand what is required to execute this vision

Overview of the Traceability Interoperability Platform (TIOP)

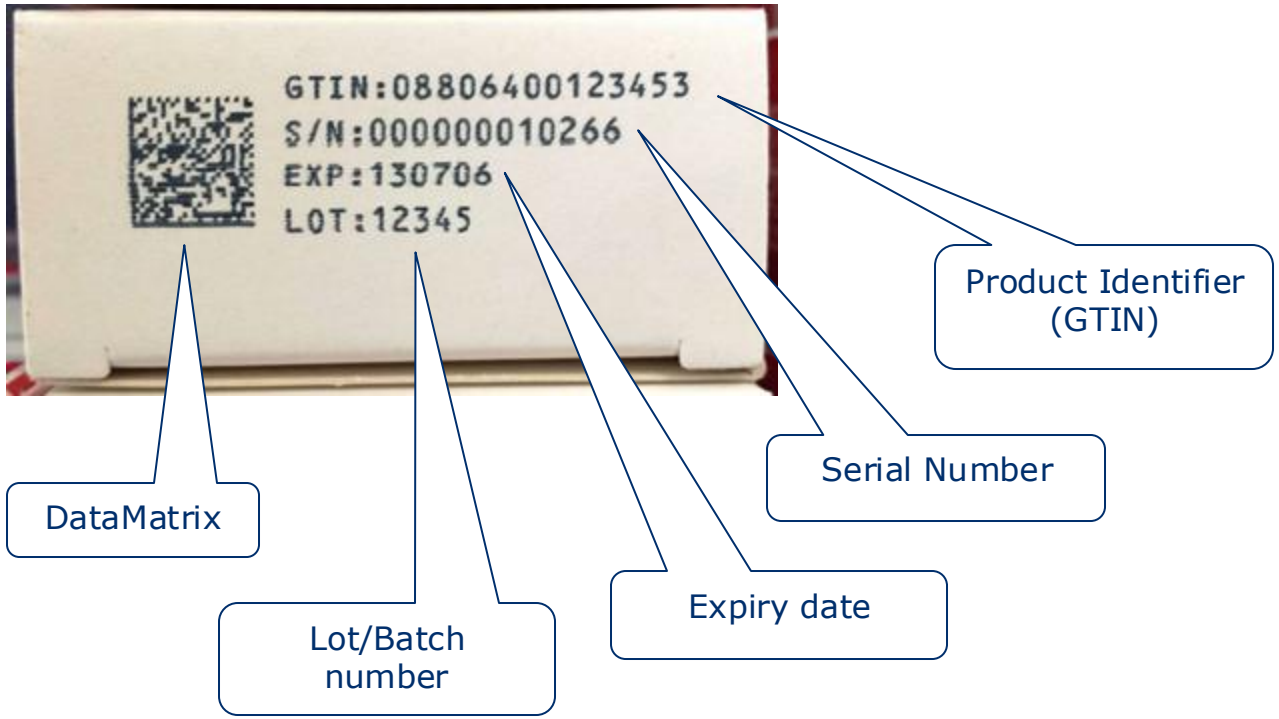
TRACEABILITY
INTEROPERABILITY
PLATFORM

The TIOP MVP 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 LLMICs.

It tests a semi-centralized architecture using a designated point of access equipped with a trading partner directory.

The Future Scale of Data

With the implementation of serialization, data exchange needs **multiply**



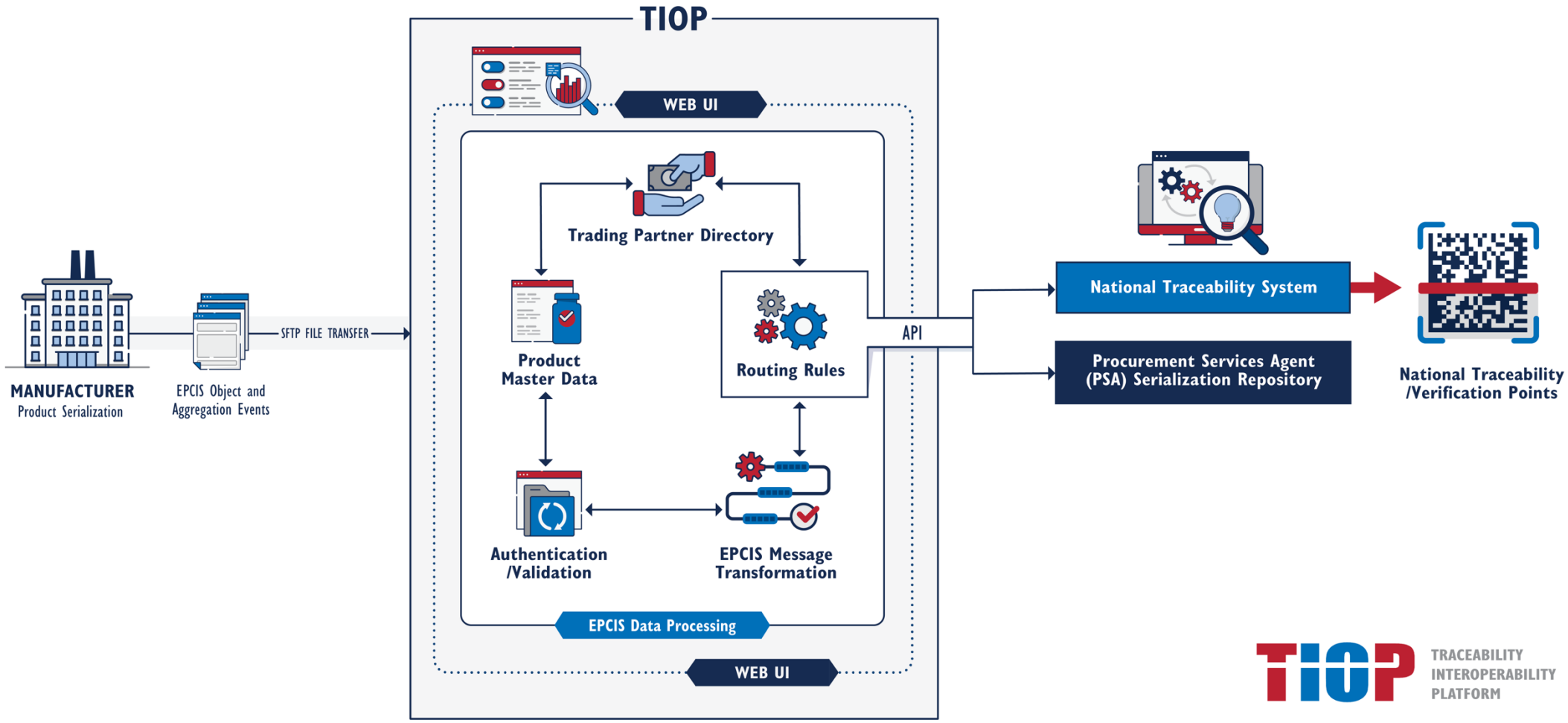
The three types of supply chain data

SUPPLY CHAIN INFORMATION DATA TYPES	DEFINITION	EXAMPLES OR DESCRIPTION
MASTER DATA	ITEM: product identifiers and associated descriptive attributes LOCATION: facility (legal entity) identifiers and associated descriptive attributes	ITEM: Manufacturer, brand name, item description, unit of measure, net content, shelf life LOCATION: Address, contact information, role
TRANSACTION DATA	Information about production, planning ordering, delivering, paying, and other transaction-related processes that occur through the supply chain	Order quantity, units sold, stock on hand, forecasted units, price
EVENT DATA	Information about the physical movement and status of products as they move through the supply chain	Commissioning, shipping, receiving, decommissioning

What is the traceability information exchanged?

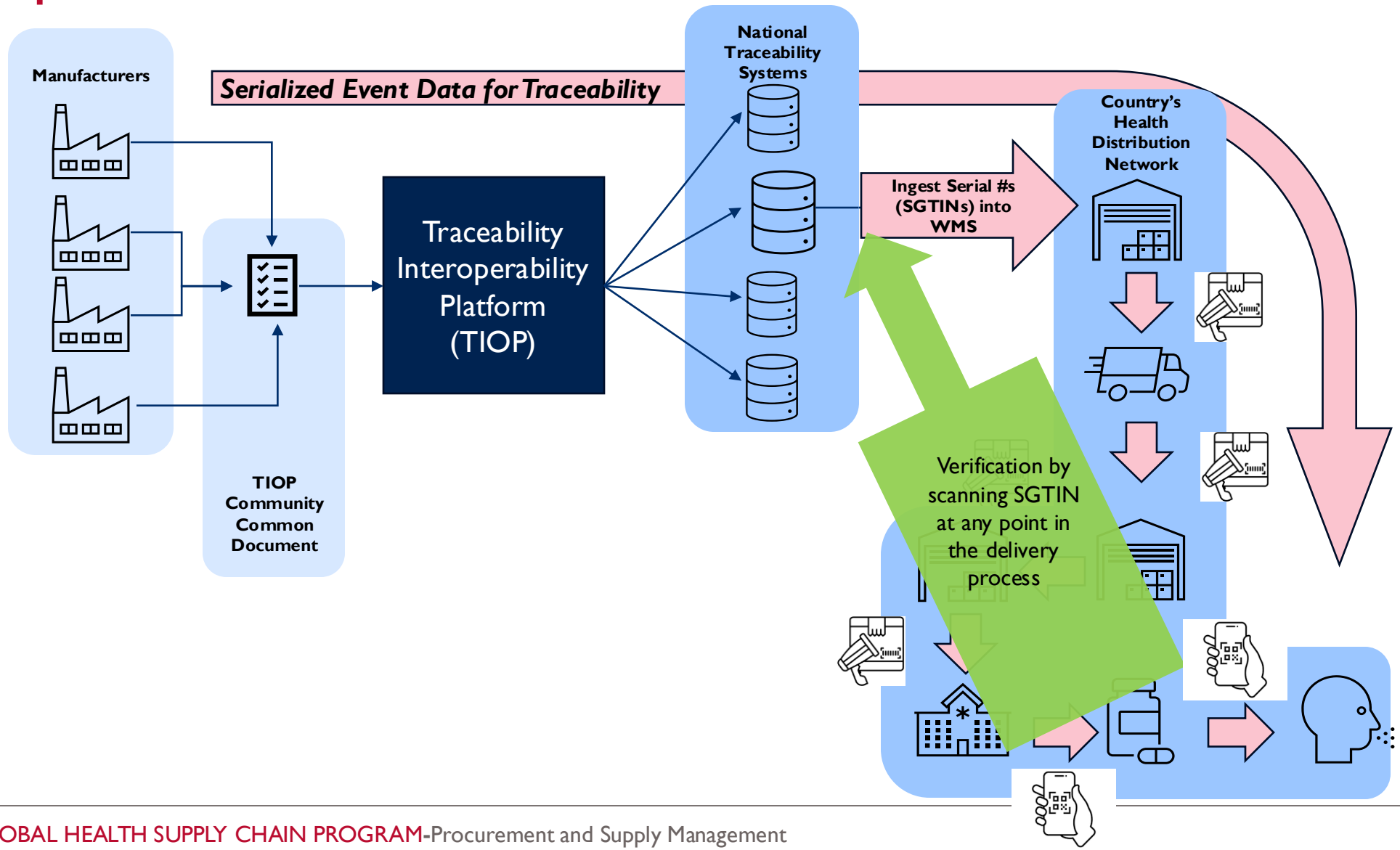
TIOP EPCIS Visibility Dimensions	
What	Suppliers provide introduction (commissioning) of specified trade items via visibility object events, including the SGTIN of the item, SGTIN of the case, SGTIN of the pallet (if applicable), and SSCC of the pallet. They also provide the linkage between different packaging hierarchies (eaches into cases and cases onto pallets) via aggregation events.
When	The moment in time at which an EPCIS event occurred, all references in the local time zone offset. Event time is fully specified in the EPCIS standard.
Where	• GLN of manufacturers / suppliers involved in the product traceability process. (business location). • The Read Point GLN where the event took place
Why	*Business Step:* Suppliers to indicate in EPCIS event documents that objects have been commissioned, packed and shipped. *Business Transaction List:* Requires Business Transaction List for only the Shipping Business Step, including the purchase order number of the PSA and supplier Invoice #. *Destination List:* TIOP will require the Recipient GLN and NTS GLN for the Business Step "shipping"
Other	Recipient information: bill-to and National Traceability System (NTS) GLN Instance/Lot master data: batch/lot and expiry

TIOP Architecture



TIOP TRACEABILITY INTEROPERABILITY PLATFORM

Example Use Case at National Level - Verification and Traceability



Results & Lessons Learned from TIOP Pilot

Lessons Learned

FLEXIBILITY TO MEET INTEGRATED SYSTEMS' NEEDS

Traceability System Validation must adapt to meet NTS requirements.

Attributes may vary to meet NTS requirements.

TIOP should be flexible to support both **push and pull Integration** mechanisms.

MASTER DATA SHARING CHALLENGES

Automated **Trading Partner and Location Data** Sharing mechanism needed.

Market Authorization requires validation and attention to collection mechanisms.

UNIQUE PARTNERS IN GLOBAL HEALTH

Segregation in repository currently implemented by PSA, may require additional roles in future.

Trading Partner Vocabulary must be tailored to fit unique needs of global health

Summary: Measures of Success

Integrated Supply Network

Share to one vs shared to many places

Standards-based

Mechanism built on standards; mitigate responding to multiple formats and unique requirements from different national authorities

Regulatory Compliance

Prepared to meet regulatory requests allowing countries to proactively track products, conduct recalls, assure patient safety, detect falsified medicines etc.

Global Good

Open-source code, data schemas, and design published as a global good

Documented lessons to support community learning

Global Health Supply Chain Summit

Thank you.

USAID FROM THE AMERICAN PEOPLE

PEPFAR U.S. President's Emergency Plan for AIDS Relief

The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project is funded under USAID Contract No. AID-OAA-I-15-0004. GHSC-PSM connects technical solutions and proven commercial processes to promote efficient and cost-effective health supply chains worldwide. Our goal is to ensure uninterrupted supplies of health commodities to save lives and create a healthier future for all. The project purchases and delivers health commodities, offers comprehensive technical assistance to strengthen national supply chain systems, and provides global supply chain leadership. For more information, visit ghsupplychain.org.

Annex

TIOP MVP Objectives

1. Demonstrate the sourcing, exchange, and management of serialized event data from USAID suppliers to inform future strategy for traceability data sharing
2. Initiate serialized data collection to be leveraged in future programming when products are in circulation in USAID-supported countries
3. Enable countries access to serialized event data, upon request, in support of their own traceability initiatives
4. Lessons learned, code from the MVP deployment, and pilot results adequately documented and shared as a global good

Lessons Learned

Traceability System Validation—TIOP validations must be flexible to adapt to different expectations and validations from National Traceability Systems.

Supplier Data Exchange—L4 solution providers may not be able to support a push system to proactively push EPCIS messages; in this case, it is recommended that TIOP flex to accommodate different connectivity models

Trading Partner Vocabulary—The typical vocabulary used to describe events does not always fit the specific needs of the global health supply chain, where recipients are often not the procurers. As a result, bill-to information was used as a proxy for PSA in TIOP.

Market Authorization—Countries must collect, populate, and maintain master data through standard mechanisms (e.g. GDSN) prior to event data exchange. Market authorization data collected through the GDSN is often insufficient and requires manual validation prior to population as business rules.

Trading Partner and Location Data Sharing—To support the TIOP MVP, trading partner data was exchanged via template and email between the PSA, suppliers, and NTS. This does not meet the needs of event data exchange at scale, which is for a dynamic, permissioned single source of truth.

Attributes—Some NTS systems may require additional data, such as the batch/lot and expiry information needed by Nigeria. This can be accommodated through additional requirements and message extensions.

Segregation—Data segregation is required to protect information security within the EPCIS repository. At the current implementation, bill-to is used to segregate this information by PSA.

Future Design Considerations

Technical Design Enhancements

- Data segregation by supply chain role
- Separation of repository and TIOP platform
- API Gateway

User Interface & Communication

- Master data interface
- Two-way message communication
- Additional traceability information
- Capture quantity of serial numbers in reporting

Enhanced Validation

- EPCIS Schema validation
- Validation for unique national traceability systems

Expanded Data Scope

- Add temperature monitoring of shipments
- Error Declaration

Digital Global Good

- Achieving status as a digital global good once appropriate benchmarks of maturity and scale are realized

Additional Use Cases

Repacking & 3rd Party Logistics

Currently, TIOP shares data from manufacturers directly to a country's NTS

Many shipments are more complicated, passing through warehouses, repacking facilities, and/or 3PL

Future enhancements may define each movement of goods as a separate event; i.e. warehouses would be considered both a destination and a supplier in each event

Additional BizSteps/EPCIS Events

Currently, TIOP captures events at 3 key business steps: commissioning, packing and shipping

Additional steps may include:

- Decommissioning
- Disaggregation
- Recall
- Void_Shipping

Greater Global Integration

There is potential to integrate TIOP with another communication or verification system, such as TRVST

This would enhance serial number storage, verification tools and overall data share to broaden the reach of traceability

Key Outputs from the TIOP MVP Pilot

Traceability Interoperability Platform (TIOP) & ARV Traceability Data Exchange Pilot Final Technical Report

SOP Document

Onboarding Guidelines

Future Design Considerations

Trading Partner Registry Business Use Case

Source Code Package (GitHub Page)

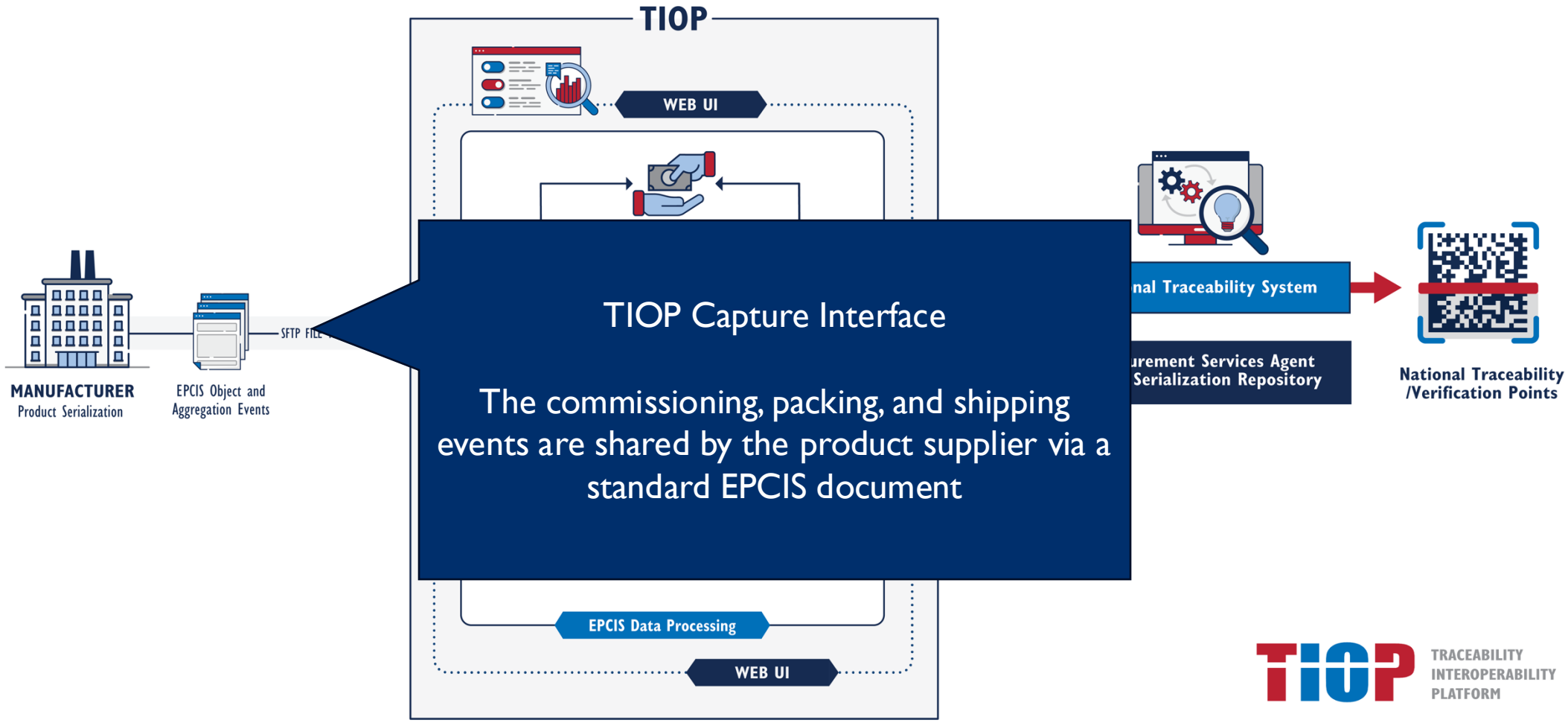
User Guides

Recorded Demo

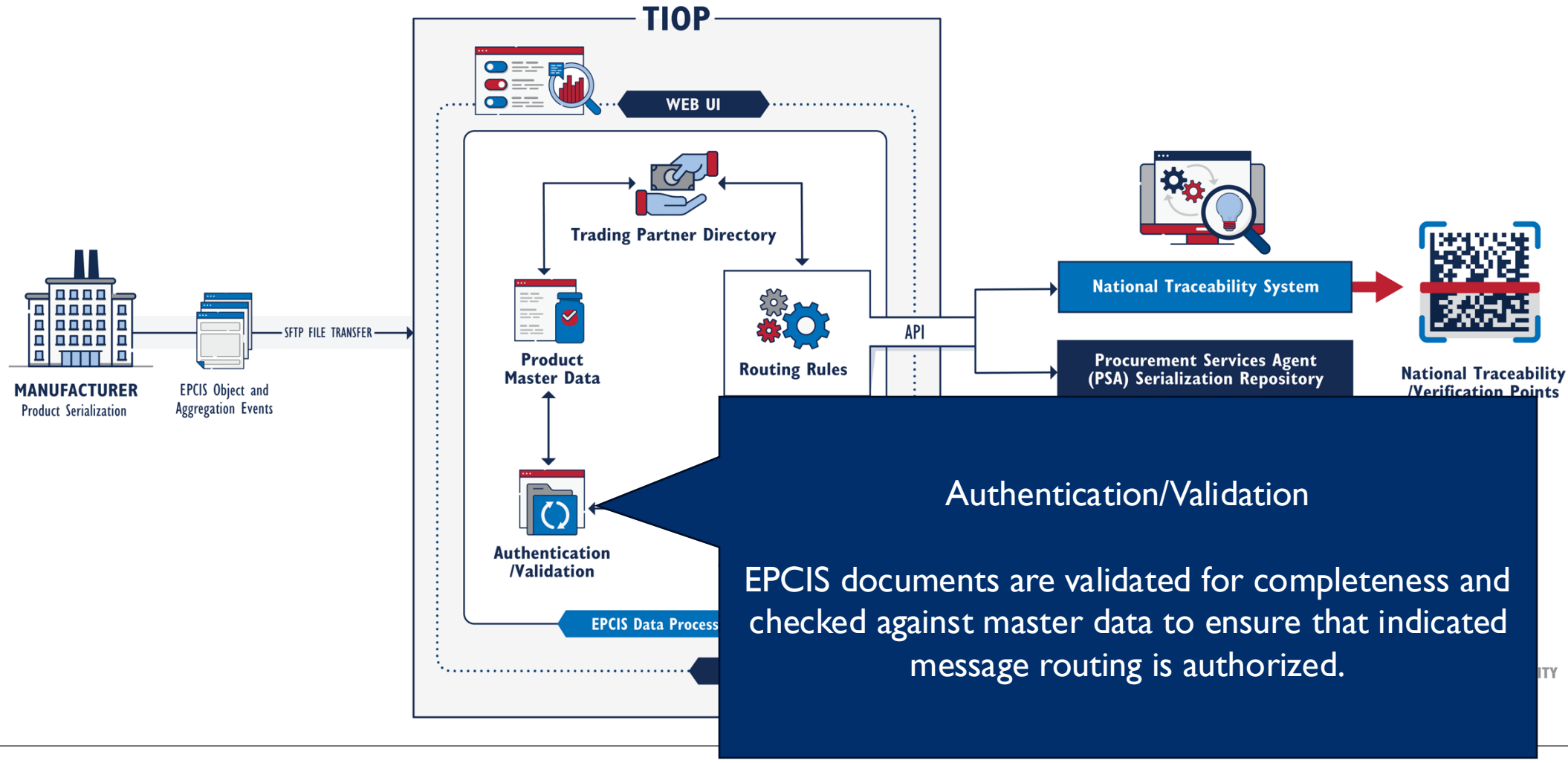
Onboarding Requirements

1. Ability to send/receive an EPCIS V document not older than versions of EPCIS V1.0/1.1.
2. Ability to formulate an EPCIS document in standard format
3. TIOP will need the list of IP addresses that will access the TIOP SFTP server (Suppliers/Manufacturers only).
4. Information to share with GHSC-PSM includes:
   - Global Location Number (GLN) values that identify trading partners
   - Location and contact information of trading partners
   - Country API details for TIOP connectivity
   - Validation of the Product master data that TIOP will acquire, including validating the MAH# provided by the manufacturer
5. Product master data for in-scope items shared via GDSN

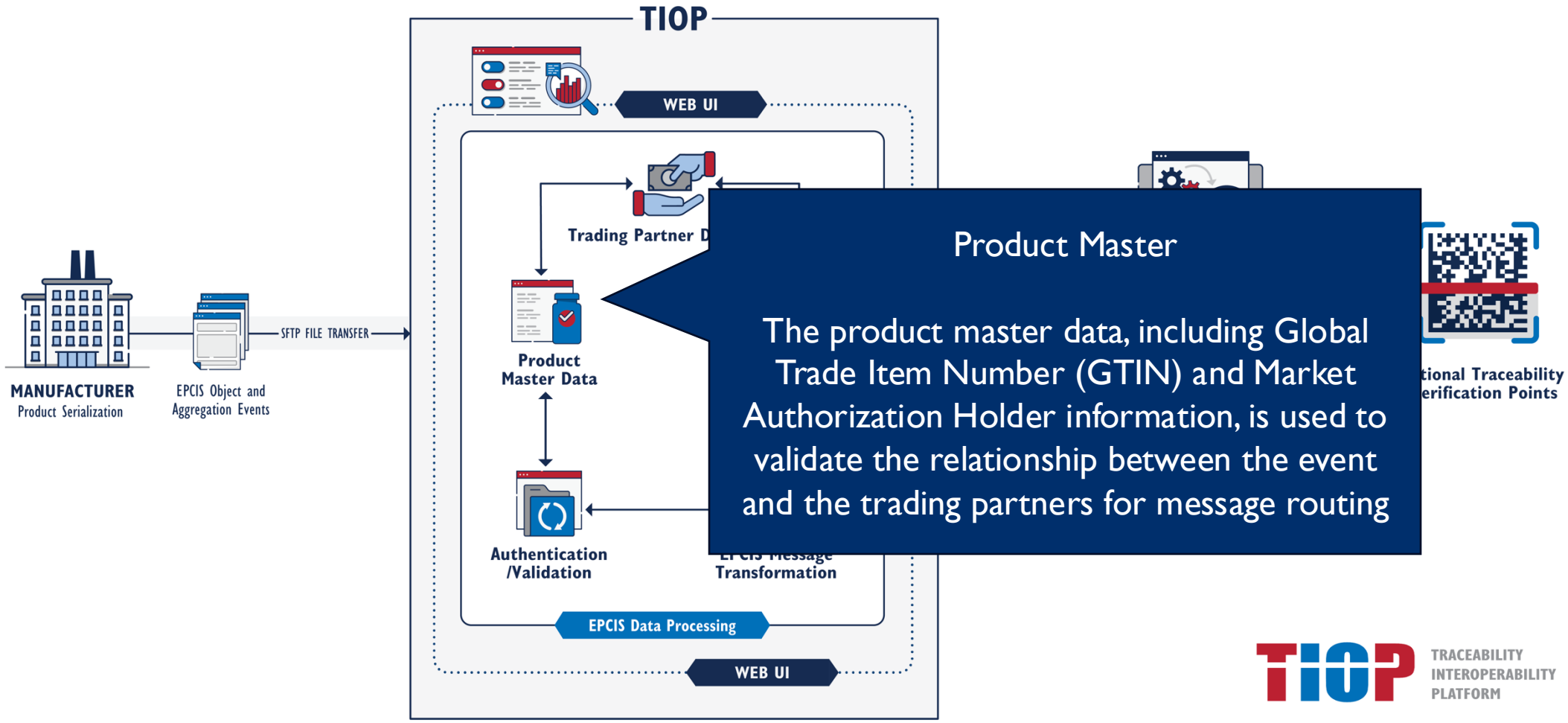
TIOP Architecture



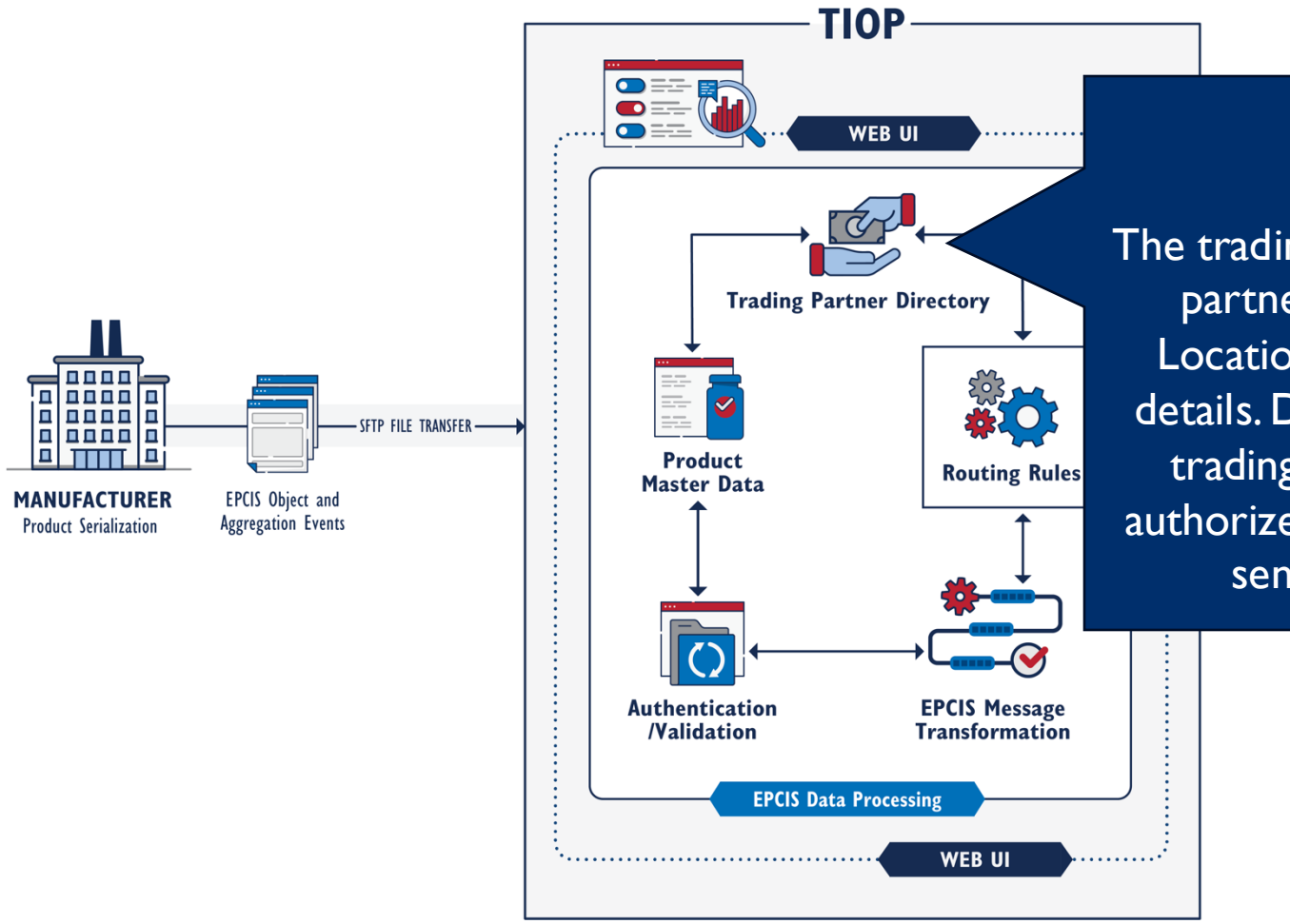
TIOP Architecture



TIOP Architecture



TIOP Architecture

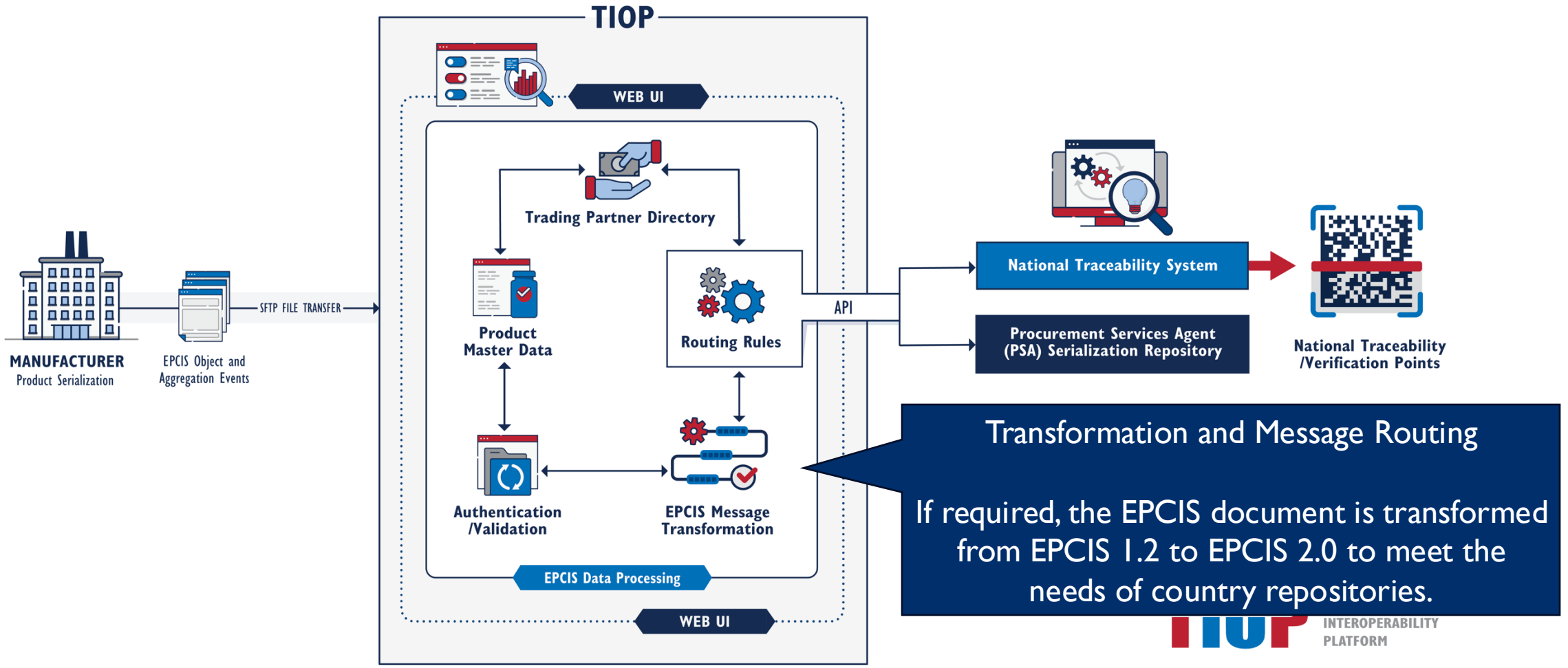


Trading Partner Directory

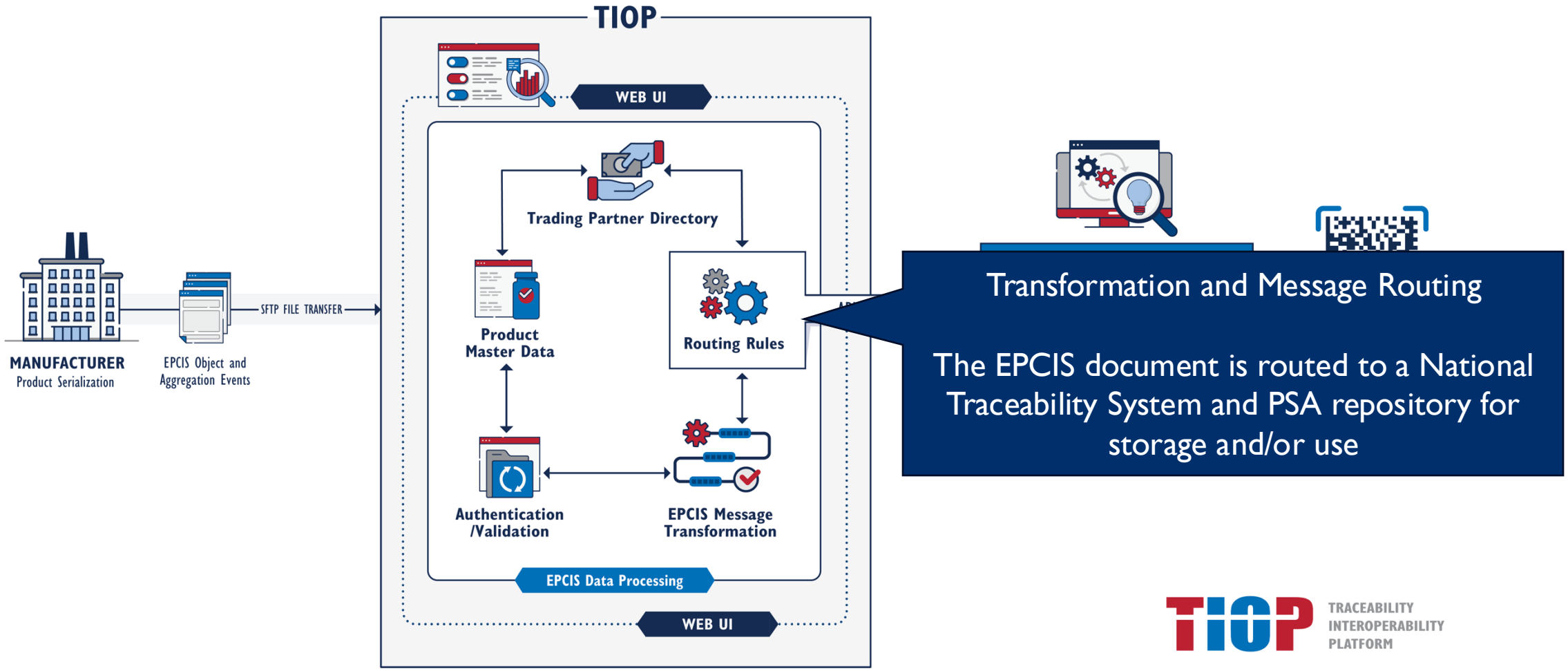
The trading partner directory contains trading partner information such as the Global Location Number (GLN) and key contact details. Documents are validated against this trading partner directory to ensure that authorized and intended trading partners are sending and receiving documents.

TIOP TRACEABILITY INTEROPERABILITY PLATFORM

TIOP Architecture

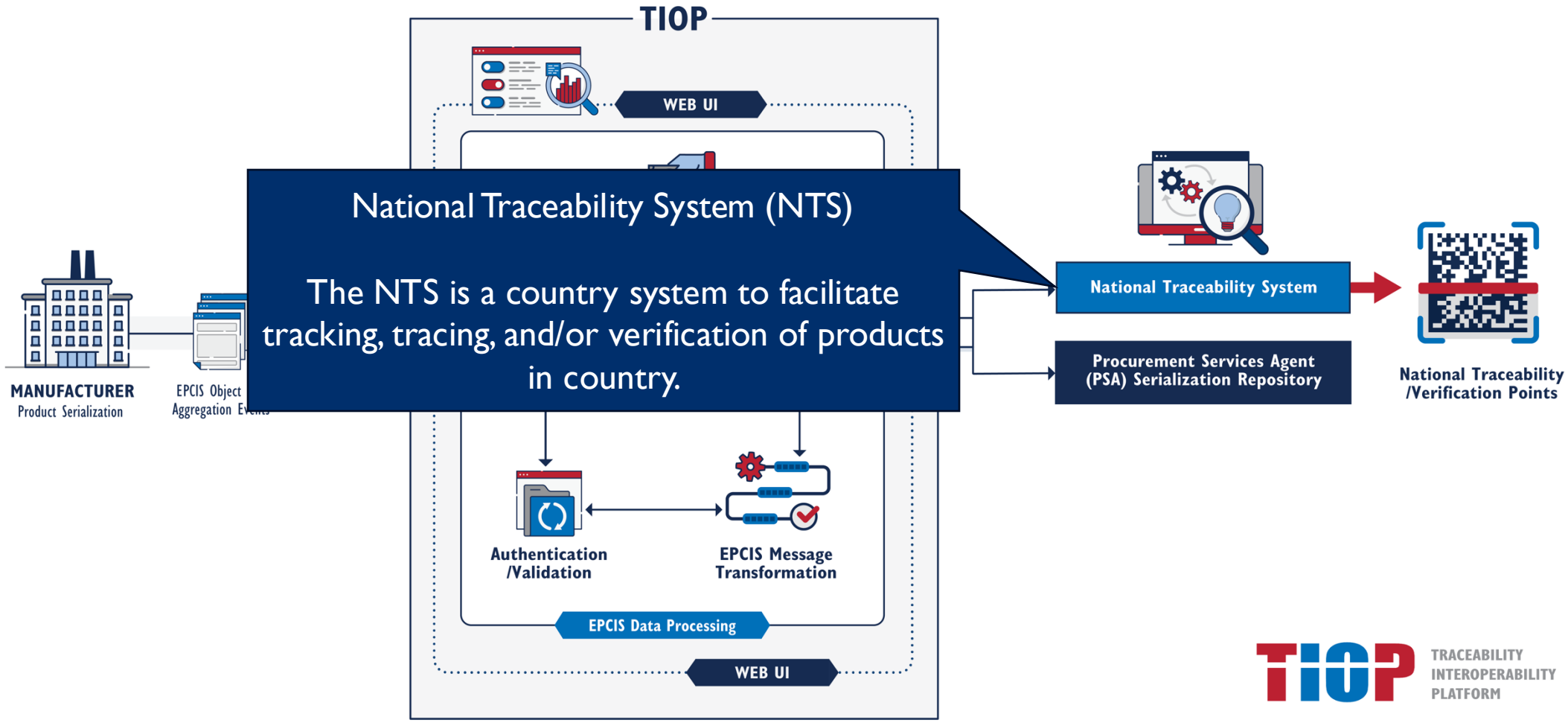


TIOP Architecture

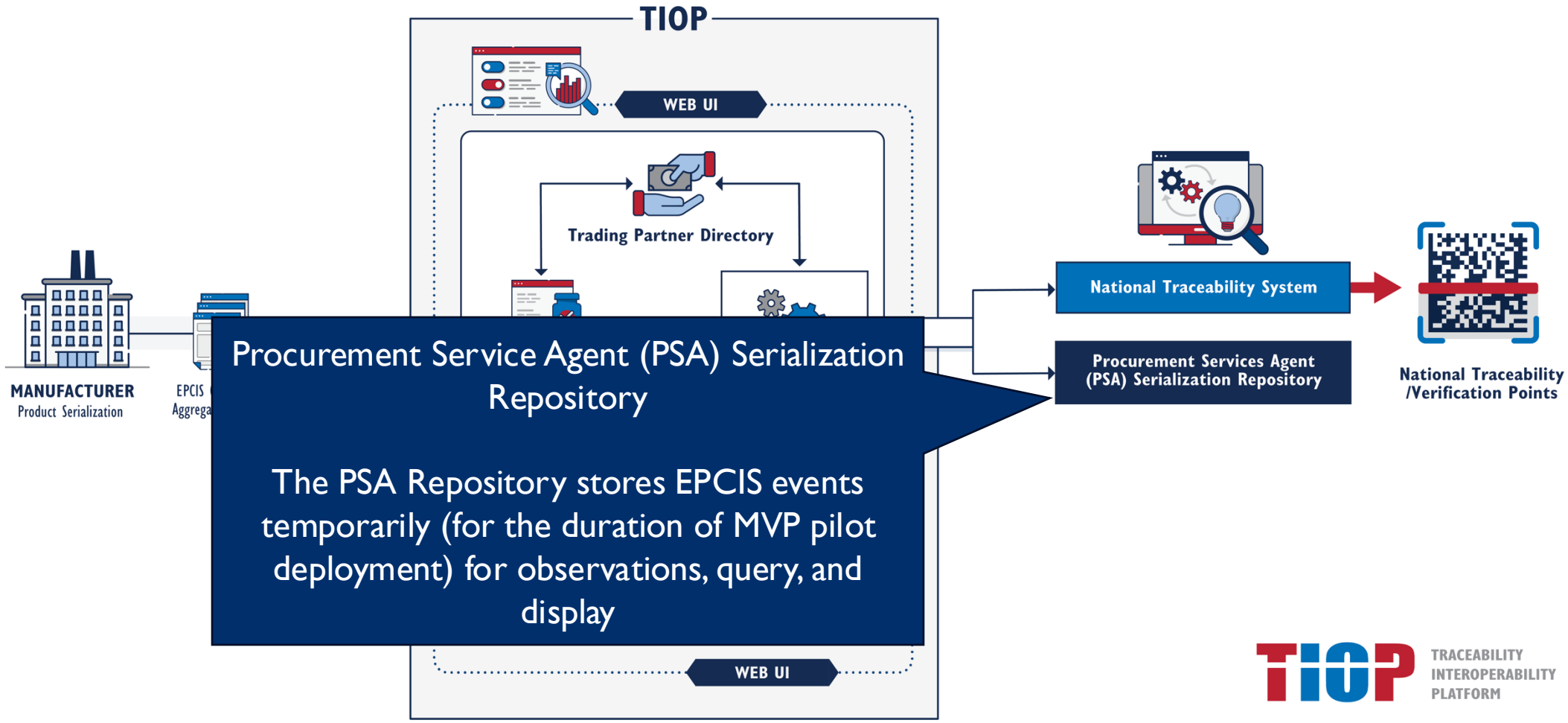


TIOP TRACEABILITY INTEROPERABILITY PLATFORM

TIOP Architecture



TIOP Architecture



TIOP TRACEABILITY INTEROPERABILITY PLATFORM

TIOP Architecture