

# 3<sup>E</sup> SOMMET GSI SUR LES SOINS DE SANTÉ EN AFRIQUE FRANCOPHONE (2024)



Thème: Réfléchir à la voie à suivre et à la manière d'évoluer vers la traçabilité. Le contenu abordera les principaux cas d'utilisation de la traçabilité, notamment la divergence, la contrefaçon et l'efficacité de la chaîne d'approvisionnement obtenue grâce aux codes-barres.

22 Août 2024 | 12:05 – 13:30 GMT / 8:05 – 9:30 HAE



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## Geraldine Lissalde Bonnet

*Vice-President Healthcare, GS1 Global Office*

Mrs. Bonnet leads the GS1 Healthcare team at the GS1 Global Office.

She works with colleagues around the world to enhance patient safety and supply chain efficiencies globally through the use of GS1 standards for AIDC (Automatic Identification and Data Capture), data synchronisation and traceability.

Prior to her current tenure, she led the GS1 Healthcare Global Public Policy Work Team for ten years. A lawyer by training, she started her career in the private sector, complemented by several years in the European Commission, in the Directorate-General for Health and Consumers.

She is an executive Board Member of the Fight the Fake Alliance.



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## Parambir S Gill

*Specialist, Supply Chain Digitalization, planning and Innovation, The Global Fund*

Parambir Gill is a strategic and tactical MIS leader who has managed the lifecycle delivery of enterprise solutions in private, federal and international development sectors.

Parambir has extensive experience in the successful digital transformation of public health solutions, public health supply chain information systems, and other related initiatives such as master data management, pharmaceutical registration and medicine safety surveillance systems in low to middle-income countries.



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# 3<sup>E</sup> SOMMET GSI SUR LES SOINS DE SANTÉ EN AFRIQUE FRANCOPHONE (2024)



## Ramy Guirguis

*Senior Information Technology Advisor USAID/GHTASC*

Dr. Guirguis holds a Ph.D, M.Sc., and B.Sc. in Computer and System Engineering. In his current role, he advises countries with respect to the automation of their national-level public health supply chain systems. He provides oversight to USAID's global MIS systems for supply chain.

He has over 30 years of professional experience in ICT and contributed to the transformation and modernization of several large enterprises and government agencies spanning many diverse sectors including telecommunications, financial, health, defense and development sectors for both public and private sectors in the USA and internationally. Dr. Guirguis is an Adjunct Professor at Georgetown, authored & co-authored several patents, presented/published at several international conferences.



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# 3<sup>E</sup> SOMMET GSI SUR LES SOINS DE SANTÉ EN AFRIQUE FRANCOPHONE (2024)



**Carl Leitner**

*Technical Officer, WHO Digital Health and Innovation*

Carl Leitner is the Technical Officer for Architecture and Informatics for WHO's Digital Health and Innovation team working on the SMART Guidelines approach. He has worked for over fifteen years in global digital health including the development and support to open-source digital health tools and standard development across a range of business domains in support of clinical health, public health and health system information needs.



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## Grant Courtney

*Traceability Lead (Independent Consultant) - UNICEF Supply Division*

Grant has spent 29 years working in the Healthcare and Consumer Goods Industry in both manufacturing, supply chain and commercial positions. He is a deep subject matter expert on traceability and serialisation with 14 years' experience, including leading GSKs serialisation deployment into European Commercial operations. Grant has worked closely with industry associations, manufacturers, the EMVO and EU Commission to design and implement the EU FMD legislation and systems.

He has also been a member of the GS1 Healthcare Leadership Team for 10 years and Co-chaired the Public Policy Forum, working with industry and governments to help shape legislation and the use of GS1 standards.



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## Max Kabalisa

*Manager, Digitalization and Traceability - UNICEF Supply Division*

Max is an accomplished supply chain program manager and health systems strengthening (HSS) expert, with 17 years of experience in Pharmaceutical Supply Chain Management. He has a wide-range experience in designing and implementing information systems such as eLMIS, ERPs, and information systems strategies in Africa and Asia.

He has extensive experience capacity-building, supervision, program evaluation, Project Management, Analytics, and Business Intelligence, Program Management, and IT Implementations.



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## Lindabeth Doby

*Sr. Digital Supply Chain Advisor, USAID*

Ms. Doby has over 25 years of experience in information systems implementation specializing in supply chain and financial systems as well as data standardization, data warehouses and visualizations. Ms. Doby advises numerous country digital supply chain topics and solutions ranging from global standards and traceability solutions, large Enterprise Resource Planning (ERP) systems, Warehouse Management Systems (WMS) and electronic Logistics Management Information Systems (eLMIS).

Ms. Doby regularly collaborates with colleagues from global donor organizations to promote global data standards, system interoperability and data exchange for better end to end supply chain visibility.

Prior to working with USAID, Ms. Doby managed several large projects for two financial institutions with extensive world-wide presence.

In addition to holding master degrees in Engineering (ME) and business (MBA), Ms. Doby is a certified Project Management Professional (PMP), Certified Supply Chain Professional (CSCP) and has volunteered extensive time in numerous civic organizations over the past twenty years.



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## Joseph Shobe

*Senior Managing Consultant, IBM*

Joseph Shobe has led or advised ERP implementations directly on over 30 different Supply Chain Management projects between 1998 and 2024. He has directed and deployed distribution, logistics and forecasting and supply chain planning solutions across several industries.

Over the past 15 years Joe has brought his supply chain optimization skills into healthcare, leading the deployment of supply chain management and advanced planning capabilities at several large healthcare provider organizations in the U.S.

He has brought together point-of-use technology and end-to-end supply chain monitoring to track and plan the execution of pharmacy and med/surge supplies.

In the GHSC-PSM program, Joe has led the planning and deployment of AIDC solutions in several countries in Africa, including Product Master Data Management and barcode data collection solutions to improve data quality and operational efficiencies.



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# Global Fund – Vision

- Improve end-to-end health product visibility and traceability
- Identify and implement efficiencies in the supply chain
- Prevent leakages and diversion by improving supply chain security
- Enhance availability of genuine health products at the service delivery level

## Global Fund – GS1 Support

- Global Fund officially supports the adoption and implementation of GS1 standards for health product identification
- Guide to Global Fund Policies on Procurement and Supply Management of health Products specifies the following:
  - Global Fund will continue to mandate GS1 in its framework purchase agreements upon renewal
  - Recipients will need formal requirement for supplier to comply with GS1 standards
  - Global Fund will support Country uptake of GS1 standards
- Global Fund Supply Chain Technical Brief recommends the following:
  - Country adoption of GS1 standards for health product identification
  - In-country supply chain information systems should support the use of GS1 standards in master data and for tracking purposes

# Global Fund – Community Guidance Support

- Global Fund has contributed to and supports the guidance for adoption of GS1 identifiers prepared by the TraceNet working group to manufacturers of insecticide treated nets
- Global Fund has contributed to and supports the Target Software Standards (TSS) that provide detailed specification for in-country supply chain information systems

## Global Fund – Initiative Support

- Global Fund is supporting the development of a comprehensive ITN campaign management tool being developed by eGov that will use GS1 identifiers for capturing data during storage, transport and distribution. The solution has already been used in Mozambique and Liberia
- Global Fund supports the use of the TRVST solution for traceability and verification and has supported pilots in Nigeria and Rwanda.
  - Global Fund is working with TRVST towards enabling suppliers to share GS1 data with TRVST so that it can be used in country

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**Ramy Guirguis** *Senior Information Technology Advisor USAID/GHTASC*

Dr. Guirguis holds a Ph.D, M.Sc., and B.Sc. in Computer and System Engineering. In his current role, he advises countries with respect to the automation of their national-level public health supply chain systems. He provides oversight to USAID's global MIS systems for supply chain. He has over 30 years of professional experience in ICT and contributed to the transformation and modernization of several large enterprises and government agencies spanning many diverse sectors including telecommunications, financial, health, defense and development sectors for both public and private sectors in the USA and internationally. Dr. Guirguis is an Adjunct Professor at Georgetown, authored & co-authored several patents, presented/published at several international conferences.

# Global Initiative 1 - Hosting of Product Catalogue Management Tool (PCMT) within WHO infrastructure



- WHO will be hosting the open source PCMT
- PCMT will support multiple catalogues so countries and organizations can host their catalogues
- Countries and organizations will also be able to share their product catalogue data as a global good

## GUIDING PRINCIPLES

Leveraging available standardized product data sets including the Open data set

Incorporating open international standards for product data

Aligning with OpenHIE architecture & adopting open-source tools

# Global Initiative 2 - Development of Digital Transformation Handbooks

- **WHO, with support from USAID is developing guidance handbooks on digital health supply chain, health product catalogue and traceability of reproductive health products through a community-driven collaborative approach**
- **The handbooks will provide step-wise guidance to countries along with risk management strategies and country case studies as references**

## GUIDING PRINCIPLES

Building on previous implementation experiences & best practices

Leveraging existing resources like Target Software Standards (TSS), Supply Chain Information Systems Maturity Model (SCISMM) & Product Catalog Management Tool (PCMT)

Utilizing open standards like HL7 FHIR

Incorporating DHSC within the overall Digital Health Ecosystem

Aligning with OpenHIE architecture & being software agnostic

Engaging WHO Regional Offices & public health community for inputs



# Handbook Development Process

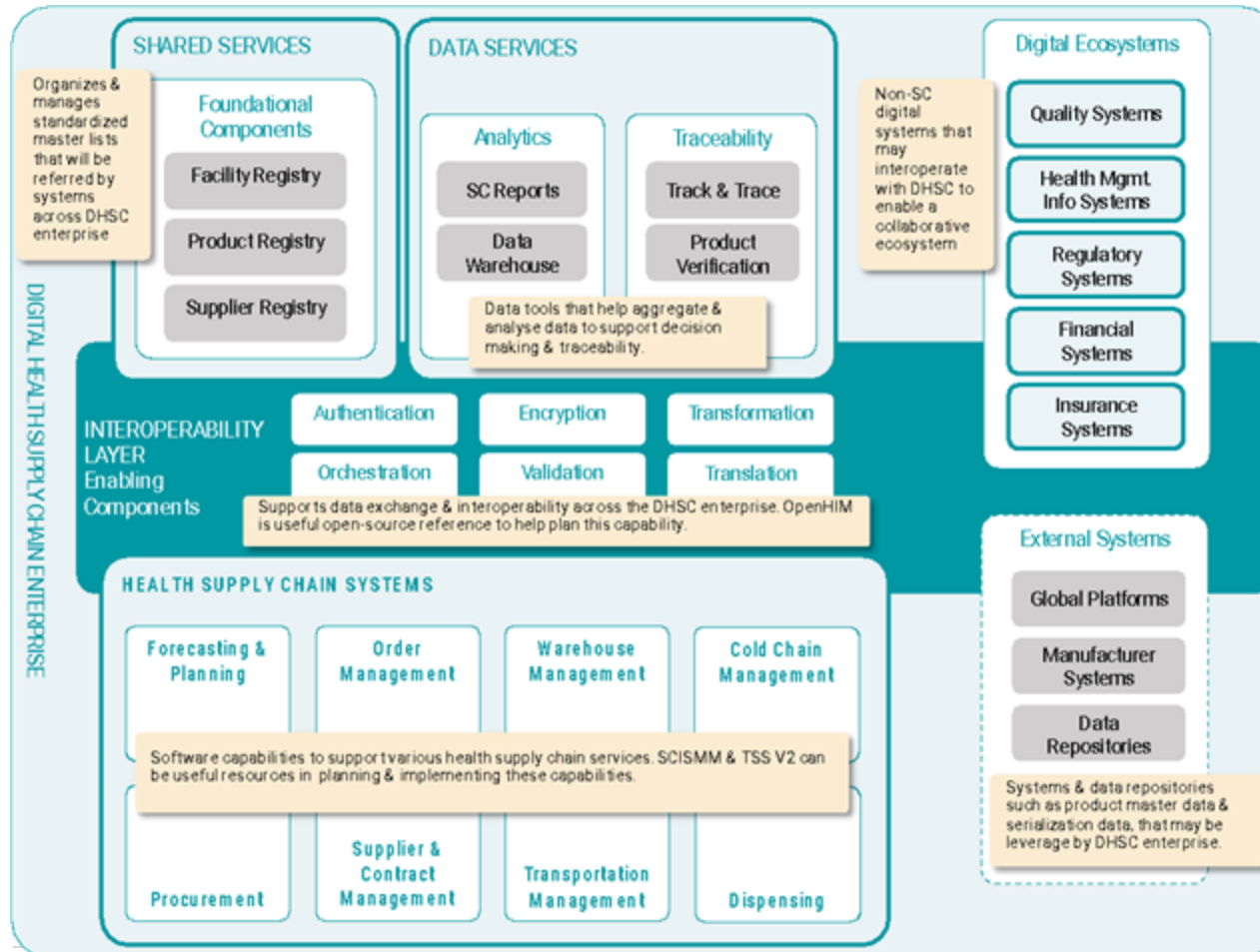
- The handbooks are being developed through the digital health supply chain (DHSC) small working group under the Digital Health and Interoperability (DH&I) working group
- The SWG has 50+ participants from 10+ countries and 20+ organizations including MOH, donors & implementation partners
- Feedback for handbooks is sought through dissemination workshops in various countries to ensure handbook is actionable (Rwanda, Malawi and Nepal)
- Feedback is also sought through public consultation

The SWG meets every 2<sup>nd</sup> Wednesday of the month from 9 to 10 AM US EST.  
If interested in contributing, please send an email to [leitnerc@who.int](mailto:leitnerc@who.int) or [jayaprakashj@who.int](mailto:jayaprakashj@who.int)

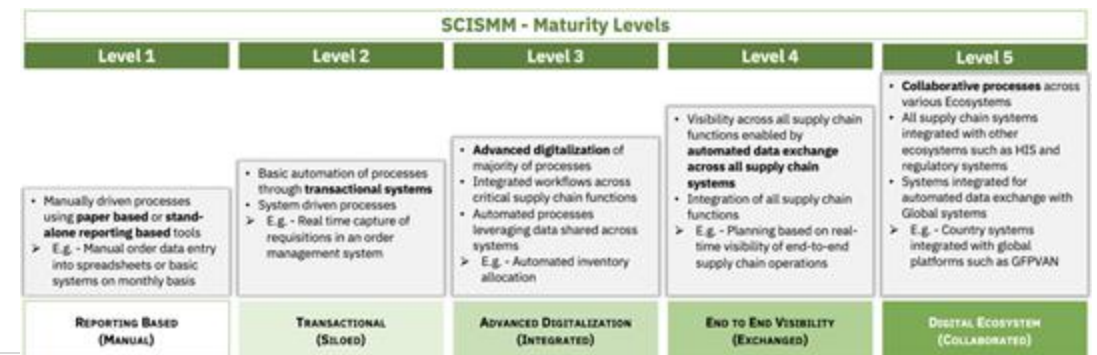
## The need for holistic guidance handbooks

- LMICs, in pursuit of health supply chain (SC) digitalization, are investing in SC system implementations
- There is a need for consolidated series of resources that can inform countries take a holistic approach to such investments
- While distinct resources such as maturity models, software standards & implementation experiences exist, use of resources to guide SC digitalization has been low due to challenges with access, knowledge or interpretation
- In addition, accelerated adoption of global standards like HL7 FHIR & GS1 is essential to enable interoperability & traceability.
- A community led and collaborative development of aggregated guidance handbooks will benefit countries in their digital supply chain journey

# Handbook 1 - Digital transformation handbook for health supply chain architecture (under publication)



- Highlights the importance of digital health supply chain architecture and its relevance to achieving end-to-end visibility and traceability
- Existing resources such as supply chain information systems maturity model (SCISMM) and target software standards (TSS) have been referenced in appropriate steps
- An architectural framework is provided that is based on digital implementation investment guide's (DIIG) digital health enterprise architecture



# Handbook 2 - Digital transformation handbook for health product catalogue

## Outline

1. Establish regulatory policies to promote product master data standardization
2. Define and institutionalize data management and governance policies
3. Deploy appropriate technology to manage National Product Catalogue
4. Develop change management procedures
5. Build capacity to sustainably manage National Product Catalogue
6. Leveraging WHO hosted product catalog management tool
7. Sharing product master data as a global good
8. Sharing country experiences

The handbook is currently under public consultation. Public comments can be provided by accessing the handbook and the feedback form through the link below

<https://www.who.int/news-room/articles-detail/call-for-public-comments--digital-transformation-handbook-for-health-product-catalogue>

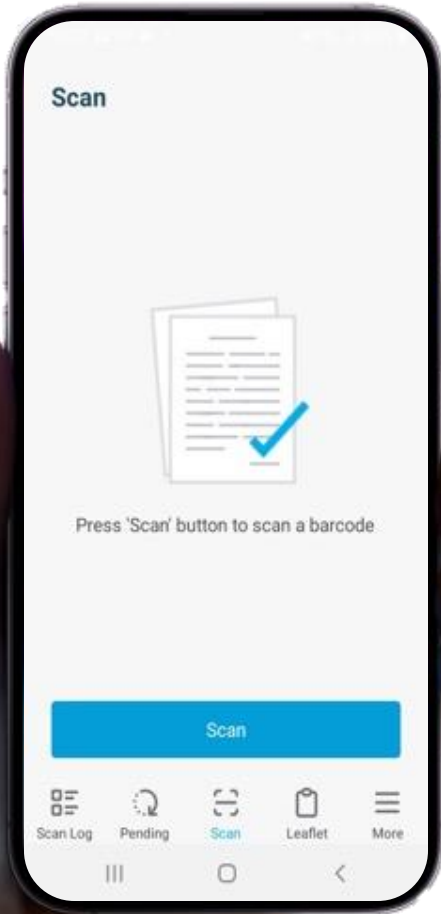
# Session 1: A deep dive into updates on global initiatives and resources available to develop effective traceability strategies

3rd Francophone Africa GS1 Healthcare Summit  
20-22 August 2024 (Virtual)





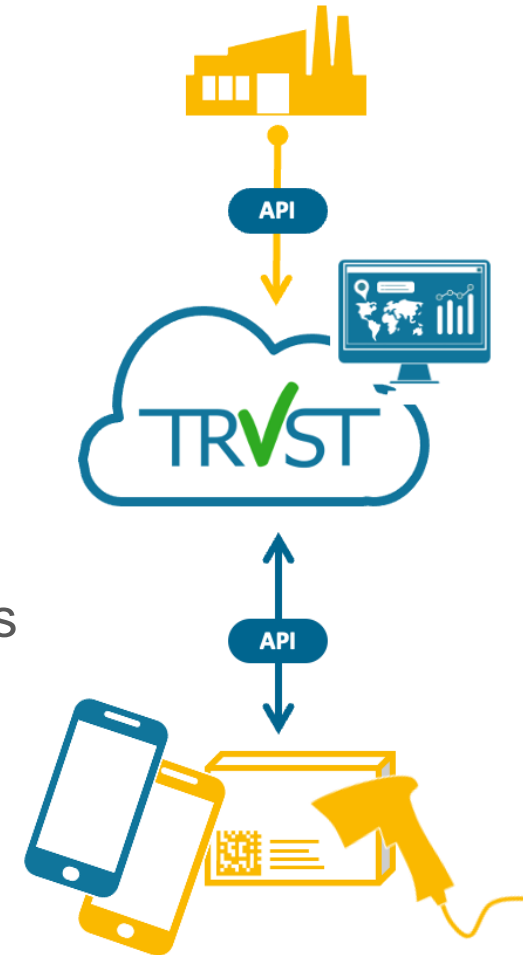
# What is TRVST *(pronounced trust)*



## Traceability and Verification System

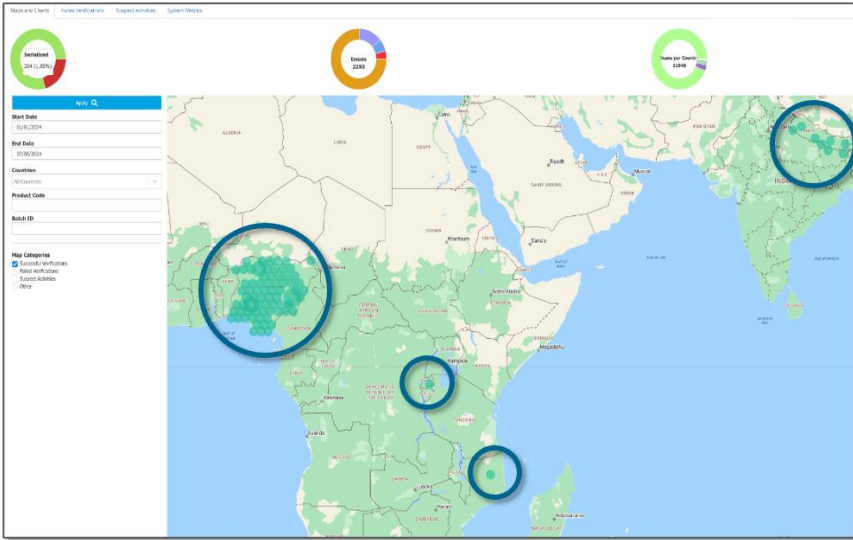
- Detect and reduce falsified medicines in LMICs
- Increase supply chain visibility and traceability
- Provide electronic leaflets
- Promote the use of GS1 standards
- Designed and deployed in partnership with countries, manufacturers and donor organisations

**A platform to increase knowledge and experience of traceability, bringing digital equity to LMICs**



# Current Status and 2025 focus

## Achievements to date



- Live in three countries and operational in four.
- Preparing for a live trial in Botswana in Q4/24.
- Over 65% of UNICEF procured vaccines are being uploaded to TRVST.
- Commitment to join TRVST from over 75% of UNICEF vaccine suppliers.
- Legal contract in place which governs system use and data sharing for TRVST.
- Over 11M serialised items in the system.
- Verified packs containing 2.6M doses.
- Zero false alert rate in Nigeria and Rwanda.

## Focus 24-25

- Establishing a strong **pipeline of countries** to implement in 2025.
- **Expand beyond vaccine** products – in partnership with The Global Fund, UNICEF and others.
- Work with system users to **enhance the system** to meet additional capabilities and usability.
- Provide SME support from TRVST on the **definition of TIOP** to provide community guidelines and standards.

Please contact us if you have interest in using TRVST or want to learn more

# Contact Information



**Grant Courtney**  
[gcourtney@unicef.org](mailto:gcourtney@unicef.org)

Traceability Lead (Independent Consultant) - UNICEF Supply Division



**Max Kabalisa**  
[mkabalisa@unicef.org](mailto:mkabalisa@unicef.org)

Manager, Digitalization and Traceability - UNICEF Supply Division





# Imagine a Future Where...

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



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

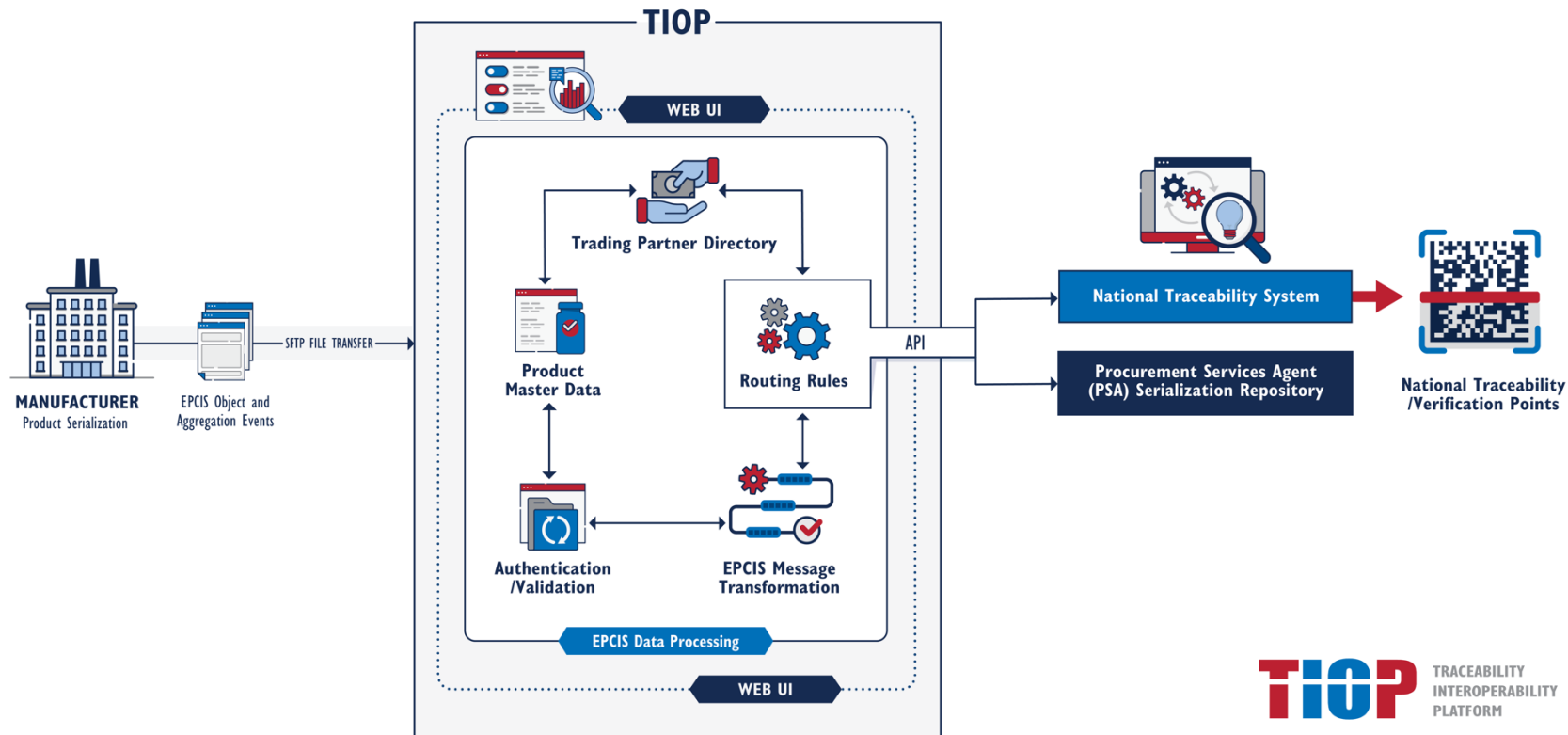
The TIOP pilot will help us understand what we need to get to this vision

# Why open traceability information exchange?

To impact national traceability outcomes, global health trading partners need a way to respond to impending national regulations requiring standardized packaging, master data sharing, and serialized event data sharing.

They need to approach this in a nimble and cost-effective way, utilizing scalable tools that are both readily available and reusable.

# What is TIOP?



The TIOP platform and companion business rules are being piloted to understand how authorized and approved trading partners can share traceability information with national regulatory authorities using the Electronic Product Code Information Services (EPCIS) standard. Key components include Authorization, Authentication, Trading Partner Directory, Routing Rules and an Interactive Dashboard .

## Results to-date

- Data roles and user rights defined; trading partner directory established
- Two ARV suppliers successfully onboarded on TIOP
- EPCIS events and message schema and supporting master data defined to respond to national regulatory mandates and aligned with global health community practices
- TIOP platform and temporary PSA EPCIS Repository developed (*in testing*)
- Continued community advocacy and engagement (national authorities, solution providers, implementing partners, donors, standards organizations) on the design, specifications and SOPs for event data exchange.
- Source code published on GitHub
- Documentation will be posted on the USAID Global Health Supply Chain Program – Global Standards and Traceability website: <https://www.ghsupplychain.org/globalstandards>



# Imagine this future at scale

## 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

Rapid response to regulatory requests; proactively addressing data quality issues that would hinder compliance

# How to learn more



Lindabeth Doby  
Sr. Digital Supply Chain Advisor  
USAID (USA)  
Email: [ldoby@usaid.gov](mailto:ldoby@usaid.gov)

Questions?

Thank you.



# Annex



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



# 2023 Global Visioning Workshop



2023 Global Visioning Workshop TWG – Geneva, Switzerland

- Bill & Melinda Gates Foundation
- European Commission
- The Global Fund for AIDS, Tuberculosis and Malaria
- Gavi Global Steering Committee on Quality Assurance of Medicines (GSC)
- GSI Global
- Nigeria National Agency for Food & Drug Control (NAFDAC)
- Rwanda Food & Drugs Authority (FDA)
- United Nations Children's Fund (UNICEF)
- United Nations Population Fund (UNFPA)
- U.S. Agency for International Development (USAID)
- USAID Global Health Supply Chain – Procurement and Supply Management (GHSC-PSM)
- Verification and Traceability Initiative (VTI) PMU
- World Health Organization (WHO)
- Zambia Ministry of Health (MOH)

# Session Objectives

Provide an overview of the Traceability Interoperability Platform (TIOP) pilot.

As envisioned, TIOP pilots the data exchange of serial numbers using Electronic Product Code Information Services (EPCIS) in way that demonstrates trading partners' compliance with emerging regulatory requirements while simplifying the connectivity requirements.

# TIOP MVP Pilot Objectives *(January 1 – September 30, 2024)*

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 and code from the MVP deployment and subsequent pilot adequately documented and shared as a global good.

**PHASE 1 - REQUIREMENTS**

**PHASE 2 – DESIGN**

**PHASE 3 – DEVELOP**

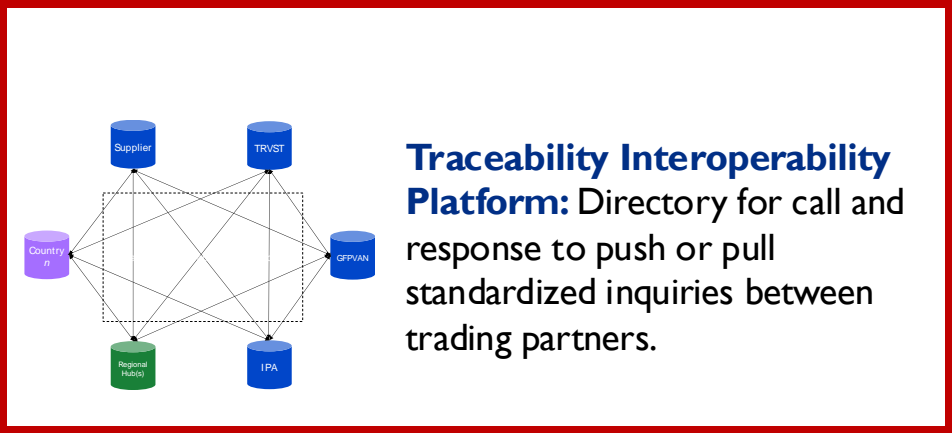
**PHASE 4 – IMPLEMENT**

**PHASE 5 – REPORT**

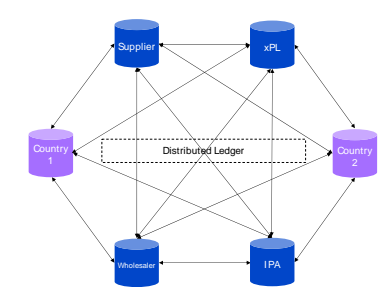
# 2023 Global Visioning Workshop Summary:

## Architectural Approaches

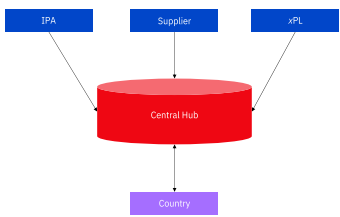
- Participants worked in groups to identify potential global architectural approaches that could meet the needs of prioritized use cases.
- Five global architectural approaches were identified and prioritized by the group for further exploration during the workshop.
- Details on each architectural approach can be found in the 2023 Global Visioning Workshop Playback Deck.
- \*Additional approaches were proposed but not prioritized for analysis during the workshop. Analysis was completed as part of deliverable development under the “Additional Architectural Approaches” section



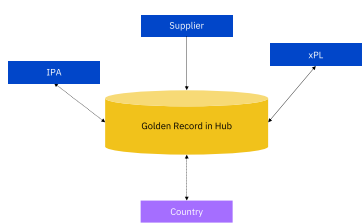
**Traceability Interoperability Platform:** Directory for call and response to push or pull standardized inquiries between trading partners.



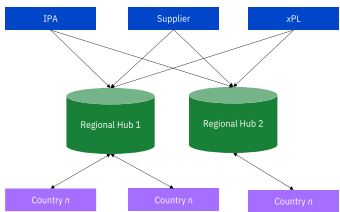
**Distributed Ledger Technology:** Leverage distributed ledger technology to create a permissioned and immutable record of supply chain events



**Central Hub:** Central hub stores serialized data; hub is integrated directly with trading partners and regional/national systems.



**The Golden Record:** Product custody holder checks out serial number from central hub when product is in their possession, creating a central repository with a clear audit trail



**Regional Hub(s):** Centralized regional hub(s) stores serialized data; hubs are integrated directly with trading partners and national systems.



# Definition of Success for the Pilot

## Documented Lessons

Lessons learned from the MVP deployment and subsequent pilot adequately documented and shared as a global good

## Open-Source Code

Code developed under this project made available as a global good

## MVP Delivered

Serial numbers shared with Nigeria and Zambia in a standardized format

# Lessons Learned

- The structure of the EPCIS Events must be able to respond to national regulations
- A trading partner directory is critical in the authorization and authentication process of data exchange
- Community alignment on data definitions and functional terms (etc. trading partner, GLN) is key for scale
- Data exchange mechanism must be flexible to account for the volume of data
- Product master data is foundational to exchanging traceability information
- Alignment with other Traceability Initiatives such as TRVST are critical for global harmonization processes



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Theme: Session 2: A panel discussion on traceability strategies to work collectively across global, regional, and national levels.

22 Août 2024 | 13:40 – 15:45 GMT / 9:40 – 11:45 HAE



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Tom Woods

*Global Steering Committee Chair*



Senior diplomatic and development experience focused on global cooperation, private sector development, government and international institutional relations, and expansion of international cooperation and good governance. Tom currently serves as the chairman of the Global Steering Committee for Quality Assurance.



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## *Prof. Christianah Mojisola Adeyeye*

*Director-General, National Agency for Food and Drug Administration and Control (NAFDAC)*

She has led NAFDAC in regulatory and administrative reforms by quality management approach and attainment of ISO 9001-2015. She has added strong governance structure and regulatory strengthening to NAFDAC through the WHO Global Benchmarking (ISO 9004 Audit) that resulted in attainment of Maturity Level 3. She led the Agency to take up the challenge of making the regulated product distribution in the supply chain more visible through Traceability, using COVID-19 vaccines as pilot. The Agency has successfully used GS1 to track and trace all Covid-19 vaccines in Nigeria, to support in-country serialisation for shipments that came with no serial barcoding and to recall a batch from the supply chain amongst other positive outcomes



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## Dr Yossounon CHABI

*Directeur Général de l'Agence Béninoise du Médicament et des autres Produits de santé ABMed  
Board Chair African Medicines Agency (AMA)*



### Pharmacien hospitalier

Ancien interne des hôpitaux de Paris à titre étranger, il a développé en 15 ans d'exercice, une expertise dans la gestion du médicament en milieu hospitalier et dans le domaine de la régulation du secteur pharmaceutique.



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*Trisha Long*

*VAN Data and Technology Project Manager, Reproductive Health Supplies Coalition (RHSC)*

She has been with the VAN for five years but has almost 20 years of experience in the reproductive health supplies community, providing guidance on the designing and operationalizing systems for supplies data collection and visibility (including some that evolved into the VAN).



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## Al Shiferaw

*Senior Program Officer, Digital Africa, Bill and Melinda Gates Foundation*



Al is currently a Senior Program Officer at the Bill and Melinda Gates Foundation. Previously, he led the development of digital tools that improved supply chain management and served as Technical Director for a number of digital health initiatives, helping the Ethiopian government build scalable systems used on the ground.



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