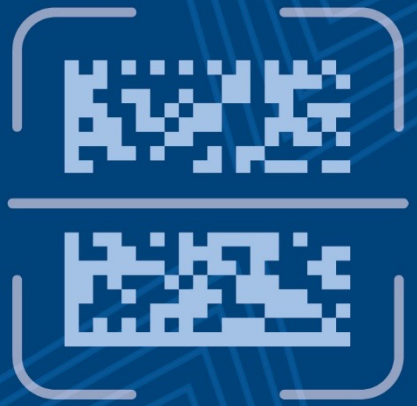
2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)



Welcome Note & Participant Introductions

July 19, 2023| 8:00 – 8:30 EDT / 12:00 – 12:30 GMT

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2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Dr. Ramy Guirguis

Senior Information Technology Advisor USAID/GHSTA

Dr. Guirguis holds a Ph.D, M.Sc., and B.Sc. in Computer and System Engineering. In his current role, Dr. Guirguis advises countries with respect to the automation of their national-level public health supply chain systems. Dr. Guirguis also provides an oversight to USAID's global MIS systems for supply chain. He has over 30 years of professional experience in information and communications Technology and contributed to the transformation and modernization of several large enterprises and government agencies spanning many diverse sectors including the: telecommunications, financial, health, defense and development sectors for both public and private sectors in the USA and internationally. Dr. Guirguis represented the DoD at several standards bodies, in the U.S. and overseas. He was a member of the U.S. expert delegation at several ISO/IEC JTC1/SC37 standards meetings. Dr. Guirguis is an Adjunct Professor at Georgetown, authored & co-authored several patents, presented/published at several international conferences. He is an IEEE Senior Member, PMI member and Certified Project Management Professional (PMP) and was a Senior Fellow at GMU International Cyber Center.

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2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Glenn Milano

Sr. Advisor, Office of Population and Reproductive Health, USAID Global Health Bureau

Glenn Milano is a Sr. Advisor in the Office of Population and Reproductive Health in USAID's Global Health Bureau where he oversees supply chain planning and forecasting activities and investments. Mr. Milano has 20 years of experience innovating in the health supply chains and has worked with leading organizations such as The Centers for Disease Control, US Department of Veterans Affairs and the National Institutes of Health where he designed and implemented strategic programs in sourcing, analytics, logistics and decision support. His entrepreneurial and collaborative approach brings new solutions to protracted problems. He is a former champion amateur cyclist, national record holder and member of the US National Cycling team. Currently, he lives in Chevy Chase Maryland with his wife and two children and, in his spare time, Glenn hones his skills as a pizza maker, gardener and painter.

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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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Renaud de Barbuat

CEO, GS1 Global Office

Renaud is a seasoned executive with more than 30 years' experience in driving digital transformation in global large-scale companies from different sectors. As the leader of GS1, Renaud has the ambition to build on the success of the past 50 years that led to broad adoption of the GS1 Standards to better serve industries in their digital transformation journey to ultimately benefit consumers and patients.

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2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

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 was 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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2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Josh-Kunin Goldsmith

Senior Director, GHSC-TA Francophone Task Order

Josh is the GHSC-TA Francophone Task Order Director. He is a dynamic, versatile, and proven leader with more than two decades of experience. He brings expertise in project management, technical assistance, communications, and business development. He has successfully developed and led complex international development projects with combined budgets over $400 million, delivering results to beneficiaries in agriculture, education, governance, health focused on Afghanistan, Burkina Faso, the DRC, Ghana, Guatemala, Haiti, Ivory Coast, Lebanon, Mali, Nigeria, Philippines, Somalia, and Senegal. As a management consultant, he provided both private and public sector clients with expertise related to change management, training design and delivery, strategic communication, and organizational development. Josh is fluent in French and Haitian Creole, and proficient in Spanish.

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Meeting Etiquette

- This is an interactive session! Do ask questions and share!
- Do use the chat functionality to ask questions / share thoughts on the topic BEING DISCUSSED
- If you put a comment and / or question in the chat box, please indicate to whom the question and / or comment is directed
- If you want to use voice, use the "Raise Hand" functionality on Zoom and a moderator will invite you to speak
- Please turn Off your cameras and stay on Mute if you have not been invited by the moderator to speak
- To access the simultaneous translation, click on the globe in the menu bar and select the French or English channel
- Use Zoom's non-verbal feedback icons to share your reactions

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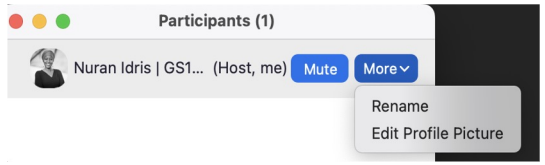
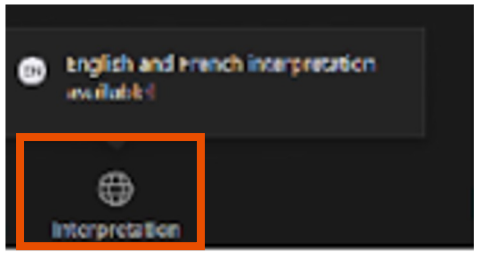
Ways to improve your Zoom experience

- Change your screen name

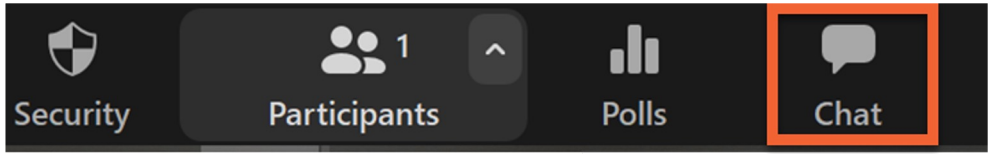


In the "Participants" list on the right side of the Zoom window, hover over your name, click "More" and click "Rename"

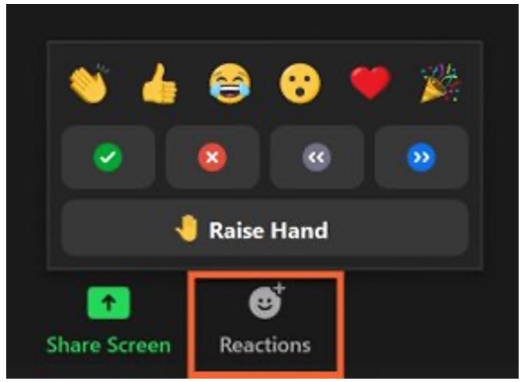
- To access the simultaneous translation, click on the **globe** in the menu bar and select the French or English channel



- Click the **Chat** button in the bar at the bottom of your screen to open the chat window



- In the bottom menu bar,
- Click the **Reactions** button to access emojis and to raise your hand during Q&A



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2nd Francophone Africa GS1 Summit (2023): Objectives

1. Review progress updates from African countries in approaching digital health supply chain transformation and pharmaceutical traceability using global standards

2. Understand the concept of digital health supply chain transformation and how it is enabled by product traceability

3. Review updated suite of resources available to support digital health supply chain transformation with a focus on product traceability

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2nd Francophone Africa GS1 Summit (2023): Agenda

DAY 1: Building from the foundation for traceability systems and the NPC

8:00 – 8:15 EDT **12:00 – 12:15** GMT	**Welcome Note** • Representative for USAID – *Ramy Guirguis, Glenn Milano* • Representative for GS1 Global Office – *Renaud de Barbuat* • Representative for WHO – *Carl Leitner* • Representative for GHSC-TA Francophone TO – *Josh Kunin-Goldsmith*	Virtual
8:15 – 8:30 EDT **12:15 – 12:30** GMT	**Participant introductions**	Virtual
8:30 – 10:00 EDT **12:30 – 14:00** GMT	**A Summary of Highlights since 2022 Francophone Africa GS1 Summit** This session summarizes highlights from the 2022 Francophone Africa GS1 Summit, where participants built foundational knowledge on global standards for traceability and use of the NPC. The session will invite last year's presenters to share their country updates since May 2022, and will share progress from the broader region of Africa. ***Facilitator:*** *Angela Elong (GHSC-TA Francophone TO)* ***Presenters:*** *Prof Mojisola Adeyeye (NAFDAC, AMRH), Maximilien Kpodjedo (Presidency of the Republic of Benin), Youssonon Chabi (Benin Regulatory Authority - ABRP), Edouard Jose Munyangaju (Rwanda FDA), Atany Nyansa (Togo Directorate of Pharmacy, Medicines and Laboratories) - invited, Dalkoi Lamboni (Togo Directorate of Pharmacy, Medicines and Laboratories) - invited*	Virtual
10:00 – 10:30 EDT **14:00 – 14:30** GMT	**Various Stakeholder Roles in Enabling Product Traceability** In view of the earlier presentations, highlight the key stakeholders involved and recommendations / best practices for stakeholder engagement as a prerequisite for success. Including the don'ts. ***Presenter:*** *Sophie Molle (GS1 Global Office)*	Virtual
10:30 – 11:00 EDT **14:30 – 15:00** GMT	**An Introduction to Digital Health Supply Chain Transformation** Wrapping up Day 01 and setting up Day 02: this session will introduce the concept of digital health supply chain and how it fits into the broader context of what's been discussed/presented during the meeting so far. ***Presenters:*** *Ramy Guirguis (USAID/PRH), Swaroop Jayaprakash (WHO), Carl Leitner (WHO)*	Virtual

8:00 – 8:15 HAE **12:00 – 12:15** GMT	**Note de bienvenue** • Représentant de l'USAID – *Ramy Guirguis, Glenn Milano* • Représentant de GS1 Global Office – *Renaud de Barbuat* • Représentant de l'OMS – *Carl Leitner* • Représentant du GHSC-TA Francophone TO – *Josh Kunin-Goldsmith*	Virtuel
8:15 – 8:30 HAE **12:15 – 12:30** GMT	**Présentation des participants**	Virtuel
8:30 – 10:00 HAE **12:30 – 14:00** GMT	**Un résumé des résultats du Sommet GS1 sur les Soins de Santé en Afrique Francophone 2022** Cette séance résume les faits saillants du Sommet GS1 Afrique francophone 2022, au cours duquel les participants ont acquis des connaissances fondamentales sur les normes mondiales de traçabilité et l'utilisation du CNP. La séance invitera les présentateurs de l'année dernière à partager leurs mises à jour de pays depuis mai 2022, et partagera les progrès de la région Africaine. ***Animateur du panel:*** *Angela Elong (GHSC-TA Francophone TO)* ***Présentateurs:*** *Prof Mojisola Adeyeye (NAFDAC, AMRH), Maximilien Kpodjedo (Présidence de la République du Bénin), Youssonon Chabi (Autorité de Régulation du Bénin ABRP), Edouard Jose Munyangaju (FDA Rwandais), Atany Nyansa (DPML Togo) - invité, Dalkoi Lamboni (DPML Togo) - invité*	Virtuel
10:00 – 10:30 HAE **14:00 – 14:30** GMT	**Le rôle des différentes parties prenantes dans la mise en œuvre de la traçabilité** Au regard des présentations précédentes, cette séance permet de souligner les principales parties prenantes impliquées ainsi que les recommandations / meilleures pratiques en matière d'engagement des parties prenantes, une condition préalable à la réussite de la démarche. La séance portera également sur les pratiques à éviter. ***Présentateur:*** *Sophie Molle (Bureau mondial GS1)*	Virtuel
10:30 – 11:00 EDT **14:30 – 15:00** GMT	**Une introduction à la transformation numérique de la chaîne d'approvisionnement en santé** Clôture de la première journée et préparation de la deuxième journée : cette session présentera le concept de la transformation numérique de la chaîne d'approvisionnement en santé et la manière dont il s'inscrit dans le contexte global de ce qui a été discuté/ présenté au cours de la réunion jusqu'à présent. ***Présentateur:*** *Ramy Guirguis (USAID/PRH), Swaroop Jayaprakash (WHO), Carl Leitner (WHO)*	Virtuel

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2nd Francophone Africa GS1 Summit (2023): Agenda

DAY 2: Enabling digital health supply chain transformation

8:00 – 8:15 EDT 12:00 – 12:15 GMT	**Introduction to the Day/Summary of day before**	Virtual
8:15 – 8:30 EDT 12:15 – 12:30 GMT	**The Role of GS1 Standards in Digital Health Supply Chain Transformation** A brief introduction of how global GS1 standards can enable the digital supply chain transformation in country healthcare settings. ***Presenter:*** *Pete Alvarez (GS1 Global Office)*	Virtual
8:30 – 9:15 EDT 12:30 – 13:15 GMT	**Panel Discussion on Traceability Architecture Approaches - Part 1: Foundation - Zambia, Rwanda, Ethiopia** This session provides a high-level overview of the efforts done by countries that are starting their health product traceability journey focusing especially on the foundational efforts in defining their architecture. ***Facilitator:*** *Dah El Hadj Sidi (GHSC-TA Francophone TO)* ***Panelists:*** *Heran Gerba (Ethiopian FDA), Al Shiferaw (JSI), Jean Baptiste Byiringiro (Rwanda MOH), Matthews Mwale (Zambia MOH), Petros Lukonde (Zambia MOH)*	Virtual
9:15 – 9:30 EDT 13:15 – 13:30 GMT	**Q&A**	Virtual
9:30 – 10:15 EDT 13:30 – 14:15 GMT	**Panel Discussion on Traceability Architecture Approaches - Part 2: Traceability Systems - Türkiye, Argentina, India, South Africa** High level overview from countries that have set up pharmaceutical traceability and/or integrated global GS1 standards into supply chain digital transformation. ***Facilitator:*** *Nuran Idris (GS1 Global Office)* ***Panelists:*** *Cihan Korucu (GS1 Türkiye), Mario Abitbol (GS1 Argentina), Subrato Dey (GS1 India), Michele Francis Padayachee (GS1 South Africa)*	Virtual
10:15 – 10:30 EDT 14:15 – 14:30 GMT	**Q&A**	Virtual
10:30 – 10:45 EDT 14:30 – 14:45 GMT	**A Review of the WHO Digital Supply Chain Architecture Handbook** ***Presenters:*** *Swaroop Jayaprakash (WHO) & Carl Leitner (WHO)*	Virtual
10:30 – 10:45 EDT 14:30 – 14:45 GMT	**Closing Remarks: Next steps & recommendations** This session will provide a recap of resources available to support countries embarking on their traceability journey including providing key contact information for support. Furthermore, the countries will discuss what needs to happen to have more dialogue and what next steps each country wishes to take.	Virtual

8:00 – 8:15 HAE 12:00 – 12:15 GMT	**Introduction à la journée/Résumé de la veille**	Virtuel
8:15 – 8:30 HAE 12:15 – 12:30 GMT	**Le rôle des normes GS1 dans la transformation numérique de la chaîne d'approvisionnement en matière de santé** Une brève introduction sur la façon dont les normes mondiales GS1 peuvent permettre la transformation numérique de la chaîne d'approvisionnement dans les environnements de soins de santé des pays. ***Présentateur:*** *Pete Alvarez (Bureau mondial GS1)*	Virtuel
8:30 – 9:15 HAE 12:30 – 13:15 GMT	**Table ronde sur les approches de l'architecture de la traçabilité – Partie 1: La fondation - Zambie, du Rwanda, et de l'Éthiopie** Cette session offre une vue d'ensemble des efforts réalisés par les pays qui commencent leur parcours de traçabilité des produits de santé, en se concentrant particulièrement sur les efforts fondamentaux dans la définition de leur architecture. ***Animateur du panel:*** *Dah El Hadj Sidi (GHSC-TA Francophone TO)* ***Panélistes:*** *Heran Gerba (FDA éthiopienne), Al Shiferaw (JSI), Jean Baptiste Byiringiro (MS Rwanda MOH), Matthews Mwale (Zambia MOH), Petros Lukonde (Zambia MOH)*	Virtuel
9:15 – 9:30 HAE 13:15 – 13:30 GMT	**Q&R**	Virtuel
9:30 – 10:15 HAE 13:30 – 14:15 GMT	**Table ronde sur les approches de l'architecture de traçabilité - Partie 2 : Les systèmes de traçabilité - Turkiye, l'Argentine, l'Inde, et l'Afrique du Sud** Un aperçu des pays qui ont mis en place la traçabilité pharmaceutique et/ou intégré les normes mondiales GS1 dans la transformation numérique de la chaîne d'approvisionnement. ***Animateur du panel:*** *Nuran Idris (Bureau mondial GS1)* ***Panélistes:*** *Cihan Korucu (GS1 Türkiye), Mario Abitbol (GS1 Argentine), Subrato Dey (GS1 Inde), Michele Francis Padayachee (GS1 l'Afrique du Sud)*	Virtuel
10:15 – 10:30 HAE 14:15 – 14:30 GMT	**Q&R**	Virtuel
10:30 – 10:45 HAE 14:30 – 14:45 GMT	**Une revue du "WHO Digital Supply Chain Architecture Handbook"** ***Présentateurs:*** *Swaroop Jayaprakash (WHO) & Carl Leitner (WHO)*	Virtuel
10:30 – 10:45 HAE 14:30 – 14:45 GMT	**Conclusion: Prochaines étapes et recommandations** Cette session permettra de récapituler les ressources disponibles pour aider les pays qui s'engagent dans la traçabilité et de fournir des informations sur les personnes à contacter pour obtenir de l'aide, y compris les informations relatives aux contacts clés pour l'assistance. En outre, les pays discuteront de ce qu'il faut faire pour renforcer le dialogue et les prochaines étapes que chaque pays souhaite entreprendre.	Virtual

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Presentation of Participants / Présentations des participants

- In the chat box:
  - Name
  - Organization
  - Title
  - Country

Group Photo / Photo Virtuelle!

Turn on your cameras / Allumez vos caméras!

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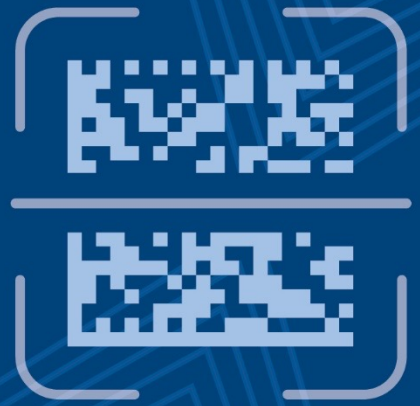

Un résumé des résultats du Sommet GS1 sur les Soins de Santé en Afrique Francophone 2022

19 juillet 2023 | 12:30 – 14:00 GMT / 8:30 – 10:00 EDT

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Angela Elong

Technical Director, GHSC-TA Francophone Task Order

- Ms. Elong is a Global Health Specialist with 9 years of experience working on health supply chain programs including technical areas of laboratory systems strengthening, monitoring and evaluation, data management, HIV/AIDS, malaria, family planning. She currently serves as Technical Director for GHSC-TA Francophone TO. Ms. Elong joined Chemonics in 2017 to lead the design and implementation of health supply chain monitoring and evaluation systems in West Africa and Haiti and facilitate the roll-out of project initiatives. She currently works on activities related to data visibility and digital supply chain to build awareness of global standards (GS1), pharmaceutical traceability, to engage countries to the Global Family Planning Visibility and Analytics Network, and to improve logistics data availability and quality across countries in the region. Ms. Elong holds a M.Sc. in Epidemiology from Imperial College of London, and a M.Ed. in Educational Psychology from the University of Bristol.

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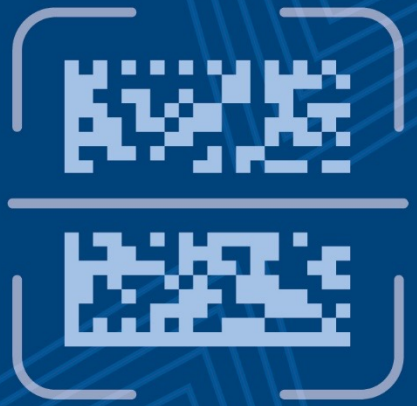

A Summary of Highlights since 2022 Francophone Africa GS1 Summit - Nigeria
July 19, 2023 | 12:30 – 14:00 GMT / 8:30 – 10:00 EDT

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2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

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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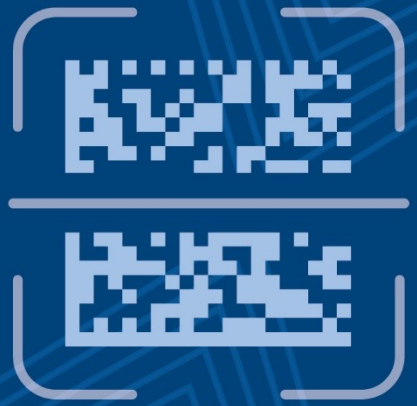
2E SOMMET GS1 SUR LES SOINS DE SANTE EN AFRIQUE FRANCOPHONE (2023)



Benin, 19 – 20 juillet 2023

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Dr Yossounon CHABI

Directeur Général de l'Agence Béninoise de Régulation Pharmaceutique, ABRP

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.

2E SOMMET GS1 SUR LES SOINS DE SANTE EN AFRIQUE FRANCOPHONE

Maximilien KPODJEDO

Président du comité de coordination du projet traçabilité des médicaments au Bénin

Expert en gouvernance, résilience des systèmes d'information et transformation digitale, en 29 ans de carrière.

Chargé de Mission au Numérique du Président de la République du Bénin,

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TRACABILITE DES MEDICAMENTS AU BENIN (ePHARMACIE)

OBJECTIF PRINCIPAL:

Mettre en œuvre un système de traçabilité des produits pharmaceutiques de qualité tout au long de leur chaîne d'approvisionnement, base sur les normes GS1.

OBJECTIFS SPECIFIQUES:

1. Créer un catalogue national des produits pharmaceutiques (CNPP) basé sur un système de codification/nomenclature structuré.
2. Analyser les données relatives aux transactions des produits pharmaceutiques dans les secteurs public et privé.
3. Assurer la traçabilité des médicaments basée sur les numéros de série locaux a la boite

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PRÉSENTATION DE LA SOLUTION ePHARMACIE

- Absence de système de codification des produits pharmaceutiques
- Pas d'interopérabilité entre les systèmes d'enregistrement (SIGIP-ARP) et de gestion logistique des transactions (SAGE, eSIGL) des produits
- Risque d'introduction des produits de contrefaçon dans la chaîne d'approvisionnement
- Manque de visibilité sur les flux des produits
- Difficultés d'analyse des données d'importation des produits
- Nombre limité de produits avec les standards GS1 (GTIN, SSCC)

PRÉSENTATION DE LA SOLUTION ePHARMACIE

DEFINITION DE LA SOLUTION ePHARMACIE

- Solution de bout en bout permettant d'assurer le suivi et la disponibilité des produits pharmaceutiques de qualité et leur traçabilité selon des normes et standards internationaux GS1, de la production à la délivrance aux patients.
- Elle offre l'opportunité de:
  - Mise en œuvre d'un système de codification national pour tous les produits pharmaceutiques du secteur public et privé au BENIN
  - Renforcement du suivi du statut des Autorisations de Mise sur le Marché
  - Renforcement du suivi des importations des produits pharmaceutiques
  - Intégration des normes internationales telles que les standards GS1 (GTIN, GLN, SSCC)
  - Identification des médicaments issus de la contrefaçon et leurs flux
  - Suivi de la disponibilité des produits pharmaceutiques et les tendances de consommations
  - Appui à la mise en œuvre d'une couverture universelle de santé (ARCH)

PRÉSENTATION DE LA SOLUTION ePHARMACIE

STATUT DU PROJET ePHARMACIE

- Projet d'une durée prévisionnelle de 36 mois
- Démarrage en septembre 2021 et piloté par un Comité de suivi mis en place par le Gouvernement
- Elaboration d'une 1ère version du Catalogue National des Produits Pharmaceutiques (CNPP) mis en place en mars 2022
  - Génération et utilisation du code unique de produit commercial (CUPC)
  - 7129 produits pharmaceutiques commerciaux codifiés et inclus dans le catalogue généré par la nouvelle version du SIGIP-ARP (DCI n=1529, Generic Presentation n=4331)
  - 9827 produits enregistrés à ce jour dans le SIGIP

PRÉSENTATION DE LA SOLUTION ePHARMACIE

STATUT DU PROJET ePHARMACIE

- Développement de la plateforme ePharmacie et des sous projets avec l'appui de Chemonics Int
  - Mise à jour et intégration avec eSIGL (gestion des stocks des médicaments)
  - Mise à jour des systèmes de gestion des médicaments des acteurs de la chaine en cours (exple SAGE de SoBaps)
- Revue règlementaire de la traçabilité des médicaments en cours
- Communication avec tous les acteurs de la chaîne de traçabilite en cours
- Gestion des transactions logistiques par scanners pour les codes produits en cours
- TE projet avant extension 48%

PRÉSENTATION DE LA SOLUTION ePHARMACIE

STATUT DU PROJET ePHARMACIE

- Echange des flux d'informations entre ePharmacie et les sous-systèmes en cours
- Extension des objectifs (Fevrier-Juillet 2023) avec prorogation de la durée du projet (TBD)
- Recrutement d'un AMOA en cours sur tout le projet

Défis (1/2)

- Assurer l'adhésion des parties prenantes à chaque étape
- Finaliser la mise à jour du CNPP et son déploiement:
  - ✓ Nécessité de mise à jour du CNPP en raison de l'absence d'informations nécessaire à la création du code unique de produit commercial (CUPC) pour certaines désignations (Plusieurs médicaments distribués par la SOBAPs S.A et n'ayant pas encore d'AMM, produits cependant répertoriés dans le CNPP).
  - ✓ Sensibilisation des acteurs (grossistes, officines) a l'utilisation du CUPC.
  - ✓ Mise en œuvre technique (ePharmacie) et règlementaire de l'usage des CUPC par les acteurs
  - ✓ Nécessité de la digitalisation du SIGIP pour en faciliter l'accès, et les opérations critiques de l'ABRP, et des acteurs, la correction des différents insuffisances enregistrées dans le système et les mises à jour des fonctionnalités en synchronisation avec ePharmacie.

Défis (2/2)

- Mettre à jour la règlementation pharmaceutique pour supporter la traçabilité
  1. Inventaire et niveau des textes règlementaires (adéquation entre directives opérationnelles et textes généraux)
  2. Conduite du changement et communication
- Mettre à jour les systèmes existants des secteurs public et privé pour ePharmacie (challenge à relever avec l'extension des objectifs)
- Mettre à jour les POS
- Engager les fabricants/fournisseurs pour l'utilisation et l'obtention des identifiants GS1 et la gestion des commandes/réceptions des produits au format EDI

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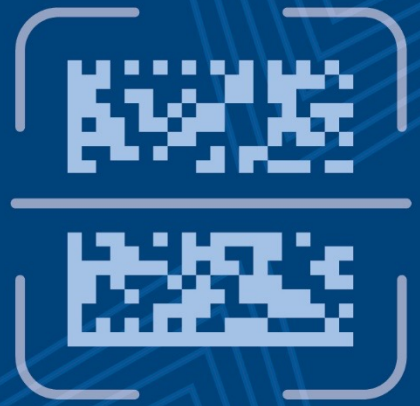
2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)



Un résumé des résultats du Sommet GS1 sur les Soins de Santé en Afrique Francophone 2022 – Burundi

19 Juillet 2023 | 12:30 – 14:00 GMT / 8:30 – 10:00 EDT

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Salvator Sindayigaya

Directeur des Médicaments à usage Humain – ABREMA, Burundi

Salvator Sindayigaya est un pharmacien par profession, gradué à l'Université Nationale du Rwanda, il y a presque 10 ans. Il a travaillé dans différents volets de la vie du secteur pharmaceutique au Burundi, dont la chaine d'approvisionnement et la réglementation.

Pendant une année, il a travaillé dans une pharmacie d'officine à Kigali, Rwanda, avant de rejoindre le Ministère de la Santé au Burundi, au Département de la Pharmacie, du Médicament et des Laboratoires (DPML) en charge de la réglementation d'alors, où il a servi dans différents postes pendant 5 ans. Pendant ces 5 années, il a été en charge de la pharmacovigilance, mais également de l'enregistrement des Médicaments.

En 2018, il a rejoint le Programme VIH où il a servi en tant que PSM Manager, en assurant la gestion de la chaine d'approvisionnement des produits de lutte contre le VIH. Par après, en 2020, il a travaillé pour le Projet USAID/GHSC-PSM, géré par Chemonics International, en tant que Senior Supply Chain Manager, où il était chargé de la gestion de la chaine d'approvisionnement des produits de lutte contre le VIH, le Paludisme et les produits de santé de la reproduction.

En 2021, il a été nommé Directeur des Médicaments à usage Humain à l'Autorité Burundaise de Régulation des Médicaments à usage humain et des Aliments « ABREMA », qui venait d'être créée, et occupe ce poste jusqu'à nos jours.

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Travail effectué sur le développement de la stratégie de traçabilité

Etape 1: Evaluation de l'état des lieux de l'utilisation des normes mondiales GS1 au Burundi:

Déjà réalisée

- ❑ Visite et entretien de l'expert consultant aux différentes parties prenantes de la chaine d'approvisionnement sur l'état des lieux de l'utilization des norms GS1
- ❑ La visite a eu lieu dans les institutions suivantes:
  - La Centrale d'achat des Médicaments Essentiels
  - Les industries pharmaceutiques
  - Quelques pharmacies grossistes de choix
  - L'Autorité réglementaire
  - Quelques programmes de santé publiques
- ❑ Elaboration du rapport de l'état des lieux des norms GS1 par le même consultant
- ❑ Partage du rapport à l'équipe d'elaboration de la stratégie GS1

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Travail effectué sur le développement de la stratégie de traçabilité

Etape 2: Elaboration d'une stratégie nationale et d'une feuille de route sur les normes de traçabilité pharmaceutique GS1: Déjà réalisée

- ❑ Mise en place de l'équipe multidisciplinaire chargée de l'élaboration de la stratégie nationale sur les normes GS1
- ❑ Atelier d'élaboration de la stratégie nationale des normes GS1 par toutes les parties prenantes à savoir:
  - L'Autorité de régulation des médicaments,
  - La Centrale d'Achat
  - Les représentants des programmes de santé publiques
  - Les représentants des industries pharmaceutiqeus
  - Les représentants des pharmacies grossistes
  - Les représentants des partenaires au développement
  - L'expert consultant sur les norms GS1
- ❑ Elaboration du premier draft de la stratégie et d'une feuille de route des norms GS1

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Travail effectué sur le développement de la stratégie de traçabilité

Etape 3: Finalisation de la stratégie des normes GS1: Déjà réalisée

- ❑ Mise en place de l'équipe restreinte de finalisation du document élaboré
- ❑ Travail de finalisation du document par l'expert consultant
- ❑ Partage du document par l'expert consultant à l'équipe restreinte
- ❑ Travail de retouche et nettoyage du document par l'équipe restreinte

Travail effectué sur le développement de la stratégie de traçabilité

Etape 4: Validation et signature du document: Prévue en août 2023

- ❑ Organiser un atelier de validation de la stratégie des normes GS1: Prévu en Début Août
- ❑ Travail de finalisation du document par l'équipe restreinte: prévu juste après l'atelier de validation
- ❑ Transmission du document de stratégie des normes GS1 au Cabinet du Ministre de la Santé pour signature: Fin Août 2023

MERCI POUR VOTRE AIMABLE ATTENTION!!!

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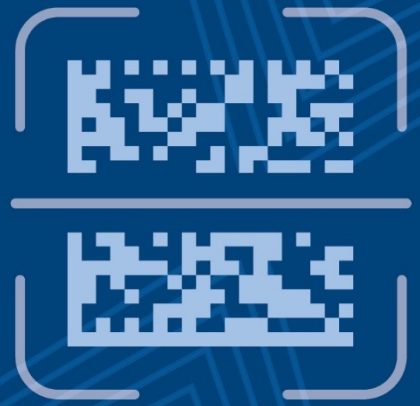

A Summary of Highlights since 2022 Francophone Africa GS1 Summit - Rwanda

July 19, 2023 | 12:30 – 14:00 GMT / 8:30 – 10:00 EDT

2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Munyangaju Jose Edouard

Medicines Registration and variations assessment Analyst at Rwanda Food and Drugs Authority

- Munyangaju Jose Edouard is Rwandan with experience in pharmaceutical regulatory affairs including inspections of pharmaceutical establishments and the registration and market authorization activities for the safety and quality of medicines. He is currently working with the Rwanda Food and Drugs Authority in the department of the Food and Drugs Registration and Assessment and he is the focal point of Rwanda FDA in the development and implementation of the Track and Trace systems for pharmaceutical products.

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Since May 2022, Rwanda FDA has worked on the development of regulations and guidelines

- Traceability Directive, Product & Labelling guideline, Master Data Guideline
- To protect the public from falsified, substandard, unregistered, expired, recalled or otherwise harmful pharmaceuticals;
- To set out a system in which the identification, authentication and traceability of a pharmaceutical product is enabled from manufacturers to points of dispense (e.g. hospitals, retail outlets, healthcare providers)
- To improve data visibility and efficiency in the pharmaceutical supply chain;
- To inform supply chain actors about the mandatory requirements for the identification, authentication and traceability of pharmaceutical products.

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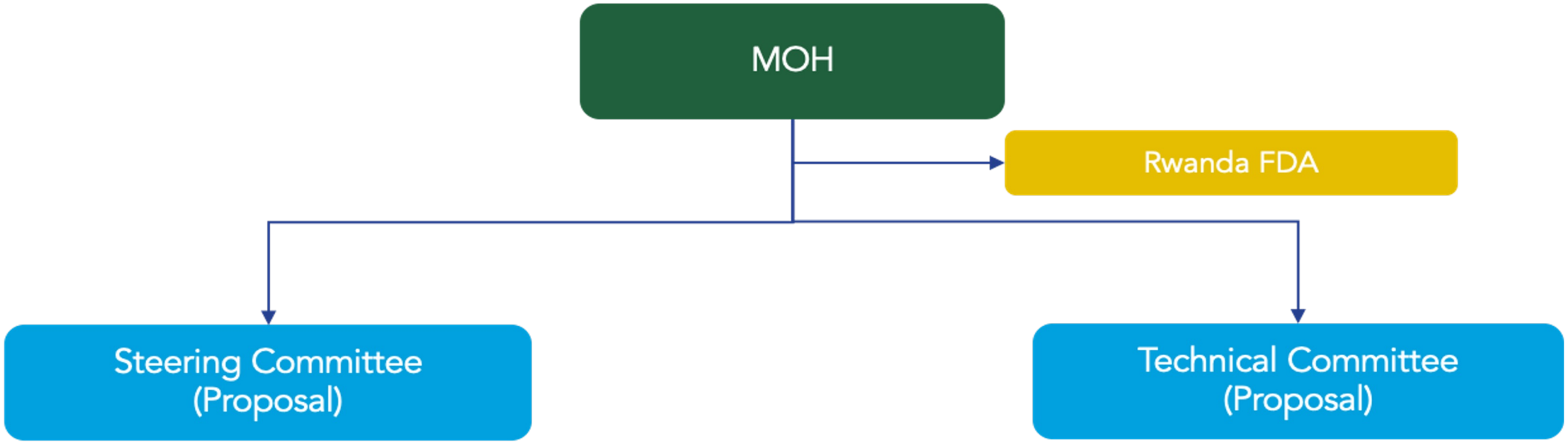
This included defining a governing body to guide the process



- Rwanda FDA
- MOH Representatives
- Distributor Ass.
- Pharmacy Ass.
- Private sector Ass
- Donor Agencies Rep

- Rwanda Public Procurement Authority
- Rwanda Information Systems Authority
- Rwanda Bureau of Standards
- Rwanda Biomedical Centre

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Digital Supply Chain Supported by Global Standards

- Regulations and guidelines that will support the implementation of the global standards for traceability of the pharmaceutical products in Rwanda were approved and published online by Rwanda FDA, including:

    1) Regulations governing the implementation of identification, data capture, and data sharing for traceability of pharmaceutical products

    2) Guidelines for identification and labelling of pharmaceutical products

    3) Guidelines for product and location master data sharing

- Rwanda National Product Catalogue (NPC) is now the single source of product master data for the entire public health supply chain (CMSs, SDPs)
- **HIE and NPC :** An API integration to consume the essential drugs and consumables within EMR was established through HIE)
- **NPC Mobile Application:** Published to Play Store/under review.

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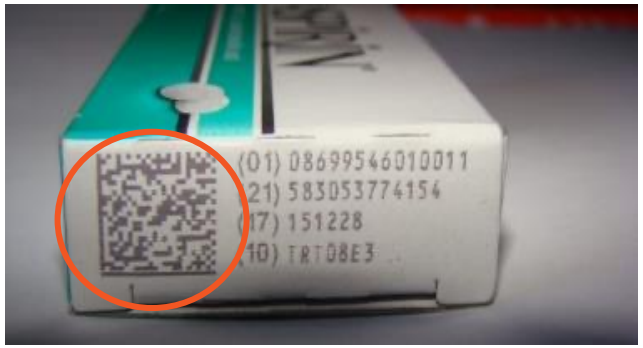
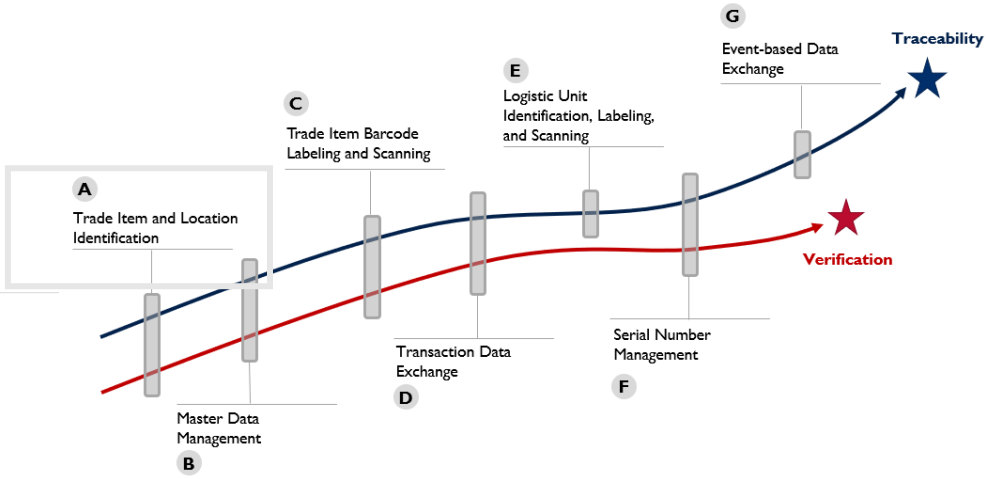
Why is Policy and Regulation Important for Standards Adoption and Enabling Traceability?

- Policy and regulation is key for putting in place enforceable foundational requirements to implement traceability across the supply chain.
- All organizations need to describe trade items and locations in the same way in order to understand where a product is coming from and where it is going.
- Regulations may also be used to address several different objectives. Through policy and regulation, a regulator can establish what is required from trading partners for identification of trade items and locations/legal entities and what data must be encoded in a data carrier in accordance with established standards.



GTIN: (01) 0869954601001
Batch: (10) TRT08E3
Expiry: (17) 151228
S/N: (21) 583053774154

Source: GS1 Global Office



Key Milestones for Regulation & Policy Development

CURRENT STATE ANALYSIS

Review current legal frameworks and document current state for product identification and packaging regulations; Document amendments required to achieve traceability objectives.

1

2

REGULATION & POLICY

Draft or amend directive that will mandate in-scope pharmaceuticals are identified and labelled with minimum standards-based requirements and appropriate data can be exchange to enable traceability objectives

IDENTIFICATION & LABELLING GUIDELINES

Draft and publish guidelines that will provide entities subject to requirements with the information required to effectively comply with product identification and labelling requirements.

3

4

DATA EXCHANGE GUIDELINES

Draft and publish guidelines that define what product identification data entities subject to requirements must provide where, at what frequency, and in what format.

COMPLIANCE MONITORING

Establish, resource, and operationalize mechanism to monitor compliance with requirements of products entering the market, manage exceptions, and penalty framework

5

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Key Considerations

Timelines

When will entities be expected to comply with requirements?

Packaging Levels

What packaging levels will be subject to the requirement and how will compliance deadlines differ between these?

Product Scope

Which products will initially be subject to the requirements?

Identification and Data Carrier Requirements

What data carriers and application identifiers will be required at each packaging level?
Will serialization be in-scope?
How will these align with global standards?

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Key Objectives: Traceability Directive

- Establish policy for manufacturers and distributors to follow for identifying products and locations using GS1 standards:
  - Ability to identify trade items with unique identifiers at every point in the distribution chain, from manufacturer to patient
  - Ability to identify trading partners with unique location identifiers
  - Ability to share product master, transactional, and event data across all systems that use it.
- Establish a realistic timetable for manufacturers and distributors to meet the regulations that supports Rwanda's traceability strategic plan:
  - Assess local supplier's ability to conform to regulations
  - Establish goals for master data sharing, batch/lot verification of product, and traceability of product

Article 5. General requirements for unique identification

- The unique identifier for a trade item shall consist of a GTIN, expiration date, batch/lot number, and/or serial number that shall be assigned and labelled, at the latest, when the trade item is physically created and packaged by the manufacturer of the product.
- When a new trade item is created by co-packing of two or more physical items (e.g., creating a kit, overpacking), the re-packager shall assign a new unique identifier?
- The unique identification data carrier for all secondary and higher packaging levels in scope shall remain on or attached to the pharmaceutical throughout the life cycle.

Article 6. Composition of the unique identifier

- The unique identifier shall be a numeric or alphanumeric string captured in a machine-readable data carrier and human-readable form on the label of the pharmaceutical package that is unique to a given secondary packaged trade item, tertiary packaged trade item or logistic unit..
- The unique identifier of the secondary and tertiary package indicated by product lists published by the Authority shall consist of the following data elements:
  - GTIN
  - Batch/lot number
  - Expiration date
  - Serial number
- Logistic units shall be identified with a Serial Shipping Container Code (SSCC.)
- When the logistic unit is an orderable trade item, the logistic unit shall be identified with an SSCC and a GTIN.
- The relationship between the unique identifiers of different packaging levels shall be captured in the manufacturer's electronic internal systems.

Article 18 – Transition Provisions

Any pharmaceutical product manufactured, imported, distributed and dispensed without the unique identifier before the effective date of these regulations and are not repackaged or re-labelled thereafter, may be placed in the market until their expiration date.

Within 1 year of the effective date of these regulations:	• Master data for all listed pharmaceutical trade items, their packaging levels, and their locations and legal entities and pharmaceutical products shall be shared with the authority
Within 1 year of the entry into force of these regulations:	• Listed pharmaceutical trade items in secondary packages and higher packaging levels shall be identified with a GTIN, batch/lot number and expiration date encoded in the specified data carrier
Within 2 years of the entry into force of these regulations;	• Listed pharmaceutical trade items in secondary packages and higher packaging levels shall be identified with a GTIN, batch/lot number, expiration date, and **serial number** encoded in the specified data carrier • Logistic units containing listed pharmaceutical trade items shall be identified with a SSCC encoded in the specified data carrier

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Key Objectives: Labelling Guideline Activity

- Establish a guideline for the identification and labelling of pharmaceutical products to create an enabling environment for pharmaceutical traceability, which aims to:
  - Specify how to implement that regulation in accordance with good global practices that leverage GS1 standards.
  - Promote trust in the pharmaceutical sector and the healthcare system
  - Create supply chain efficiencies from manufacturers to patient receipt
- The guideline is intended to provide trading partners with further information on how to implement this mandate as required to distribute pharmaceutical products in the Rwanda market

Section 2 – Product Identification and Labeling Requirements

Secondary Pack Trade Item

AI	Description	Required by
01	GTIN	No later than 1.0 years after the entry into force of the guideline
17	Expiration Date	No later than 1.0 years after the entry into force of the guideline
10	Batch/Lot	No later than 1.0 years after the entry into force of the guideline
21	Serial Number	No later than 2.0 years after the entry into force of the guideline

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

Tertiary Pack Logistic Unit

AI	Description	Required by
00	Serial Shipping Container Code (SSCC)	No later than 2.0 years after the entry into force of the guideline

Tertiary Pack Trade Item

AI	Description	Required by
01	GTIN	No later than 1.0 year after the entry into force of the guideline
10	Batch/Lot	No later than 1.0 year after the entry into force of the guideline
17	Expiration Date	No later than 1.0 year after the entry into force of the guideline
21	Serial Number	No later than 2.0 years after the entry into force of the guideline

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

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Secondary Pack Trade Item Identification and Labeling Requirements

- Secondary and tertiary pack trade item requirements

AI	Description	Required by
01	GTIN	No later than 1.0 years after the entry into force of the guideline
17	Expiration Date	No later than 1.0 years after the entry into force of the guideline
10	Batch/Lot	No later than 1.0 years after the entry into force of the guideline
21	Serial Number	No later than 2.0 years after the entry into force of the guideline

- Encoded in the data carrier

FNC Opening Character	AI	GTIN	AI	Expiration Date	AI	Batch/Lot Number	FNC Separator	AI	Serial Number
FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

Secondary packaging data carrier example

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

Tertiary Pack Trade Item Identification and Labeling Requirements*

- Tertiary pack trade item requirements

AI	Description	Required by
01	GTIN	No later than 1.0 years after the entry into force of the guideline
17	Expiration Date	No later than 1.0 years after the entry into force of the guideline
10	Batch/Lot	No later than 1.0 years after the entry into force of the guideline
21	Serial Number	No later than 2.0 years after the entry into force of the guideline

- Encoded in the data carrier

FNC Opening Character	AI	GTIN	AI	Expiration Date	AI	Batch/Lot Number	FNC Separator	AI	Serial Number
FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

* In instances where a tertiary pack trade item is also considered a logistic unit, the SSCC can be applied in lieu of the serial number.

Tertiary Pack Logistic Unit Identification and Labeling Requirements

- Tertiary pack logistic unit requirements

SSCC example

AI	Description	Required by
00	Serial Shipping Container Code (SSCC)	No later than 2.0 years after the enactment of the guideline

- Encoded in the data carrier

FNC Opening Character	AI	SSCC
FNC1	00	006141411234567890

If a logistic label is used with only a GS1 DataMatrix, care must be taken to ensure trading partners are able to scan this barcode. See the GS1 General Specifications for further information.

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

Key Objectives: Location and Product Master Data Sharing Guideline

- Support implementation of existing regulation and statutory instruments governing sharing of product and associated locations master data for pharmaceutical products authorized to be distributed in the market to:
  - Identify trade items with unique identifiers at every point in the distribution chain, from manufacturer to patient
  - Identify trading partners with unique location identifiers
  - Share product master, transactional, and event data across all systems that use it.
- Establish guidance for synchronizing data between manufacturers/distributors and the Rwanda National Product Catalog:
  - Using the established Rwanda FDA Attribute List, including mandatory and optional data elements
  - Using Rwanda FDA data exchange format
  - Evolving the data exchange capabilities with trading partners over time

Steps for Synchronizing Master Data with Rwanda FDA

- Manufacturers and distributors are guided in the steps they must take to begin sharing master data, including:
    1. Assigning a Global Location Number (GLN) for each of the relevant locations or legal entities, including Brand Owner, manufacturing location, and MAH
    2. Assign a GTIN to each level of the trade item packaging hierarchy
    3. Gather the product and location attribute data on each trade item packaging hierarchy level
    4. Populate the Rwanda FDA Product and Location Master Data Submission Form
    5. MAHs are expected to ensure that the master data provided for registered products is maintained and updated as necessary
- Future enablement of direct submission of product and location master data to the Rwanda National Product Catalog (NPC)

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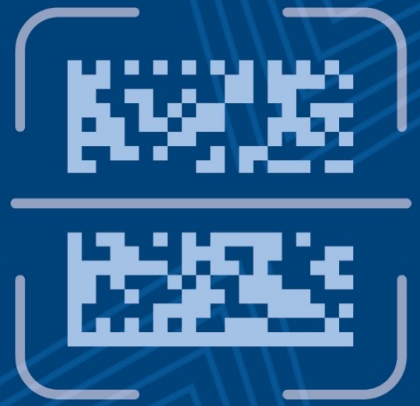

Un résumé des résultats du Sommet GS1 sur les Soins de Santé en Afrique Francophone 2022 - Togo

~~19 juillet 2023 | 12:30 – 14~~:00 GMT / 8:30 – 10:00 EDT

2ND FRANCOPHONE AFRICA GS1 HEALTHCARE SUMMIT (2023)

Dr Christ Kossivi

Pharmacien, DPML Togo

Dr Christ KOSSIVI est pharmacien spécialisé dans le management et le leadership de la chaine d'approvisionnement des produits de santé avec plus de 8 ans d'expérience aux niveaux central, régional et périphérique. Lauréat du Programme Présidentiel d'Excellence (PPE4), il a développé des compétences en tant qu'analyste de projet sur la feuille de route gouvernementale 2020-2025. Il travaille actuellement à la Direction de la pharmacie du médicament et des laboratoires plus précisément à la cellule d'inspection pharmaceutique. Assistant au Chef division pharmacie depuis 2021, il est membre actif au sein :

- du comité de lutte contre les produits de santé de qualité inférieure et falsifiée ;
- du comité technique d'élaboration de la stratégie de la chaine d'approvisionnement des produits de santé 2023-2026,
- du centre national de Pharmacovigilance,
- du comité UEMOA d'élaboration des Bonnes pratiques de distribution pharmaceutique

Entre autres, il est aussi une personne ressource du groupe technique de travail vaccination covid-19.

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QUELLES STRATEGIES POUR LA TRACABILITE DES PRODUITS DE SANTE AU TOGO ?

Plan de présentation

1. Introduction
2. Analyse de la maturité du secteur pharmaceutique
3. Identification des besoins de traçabilité du secteur pharmaceutique
4. Objectifs stratégiques et activités à mettre en œuvre

1. INTRODUCTION

Préalables pour une bonne mise en œuvre (MEO) de la traçabilité des produits de santé (PS) :

- Engagement politique +++ : activité technique nécessitant la collaboration de nombreux intervenants dans CAPS (professionnels de la santé, douanes et police des frontières, ministère du commerce, patients, etc…) ;

- Choix des standards de traçabilité des PS ;

- Textes administratifs (décrets, arrêtés, notes de service) à prendre ;

- Formations et sensibilisations.

2. ANALYSE DE LA MATURITÉ DU SECTEUR PHARMACEUTIQUE

2.1. Cadre réglementaire

Forces :
- CSP sanctionne les infractions les infractions dans le secteur pharmaceutique ;
- La loi définit le rôle et les responsabilité des acteurs du secteur.

Faiblesses :
- IL n'y a pas de cadre réglementaire sur la traçabilité des produits de santé.

2.2. Cadre institutionnel

Forces :
- Il existe une autorité de régulation pharmaceutique ;
- Il existe des procédures d'octroi des AMM ;
- Il existe des procédures d'octroi des agréments pour structures pharm.

Faiblesses : (à suivre)

2. ANALYSE DE LA MATURITÉ DU SECTEUR PHARMACEUTIQUE (Suite)

2.2. Cadre institutionnel

(suite)

Faiblesses :

- Contrôles et inspection de la CAPS insuffisantes ;
- Autorisation spéciales d'importation (ASI) pour certains PS sans AMM ;
- Non marquage des Numéros d'AMM sur les médicaments (comme le recommande l'OMS) ;
- Non monitorage des PS commandés/importés au Togo.

2.3. Grossistes - répartiteurs

Forces :

- Assure la livraison de PS aux formations sanitaires (pharmacies, hôpitaux, …
- L'étiquette à coller sur l'emballage des PS permet un suivi entre la formation sanitaire et le grossiste concerné.

3. IDENTIFICATION DES BESOINS DE TRAÇABILITÉ DES PS

(i) **Besoin d'un contrôle accru du secteur** : pour garantir l'entière conformité des activité de la CAPS ;

(ii) **Besoin de règlementer et standardiser la traçabilité des PS** : en s'appuyant sur des standard internationaux ;

(iii) **Besoins d'informations centralisées et fiables** : dans le système d'approvisionnement légal, en traçant les PS tout au long de la CAPS.

4. OBJECTIFS STRATÉGIQUES *(ET ACTIVITÉS À METTRE EN ŒUVRE)*

(i) Renforcer le cadre règlementaire de MEO *(créer un comité de pilotage ; adopter un plan stratégique ; évaluer le cadre règlementaire ; …)*

(ii) Construire une solution informatique pour soutenir la MEO de la traçabilité *(définir l'architecture et les nouveaux processus de traçabilité ; concevoir, développer et déployer la solution retenue pour la traçabilité des PS ; …)*

(iii) Renforcer les capacités de l'autorité togolaise de régulation pharmaceutique (analyser les défis et les besoins pour assurer la missions de la DPML ; renforcer les capacité ; …)

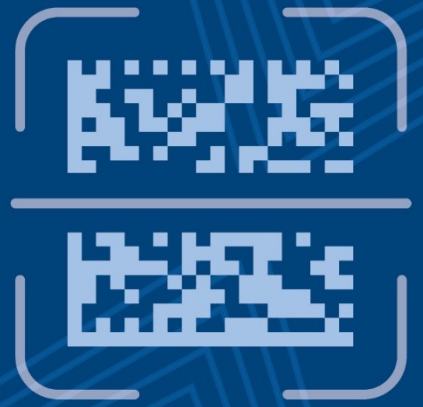
4. OBJECTIFS STRATÉGIQUES *(ET ACTIVITÉS À METTRE EN ŒUVRE)* **(suite)**

(iv) Renforcer les connaissances, la communication et la collaboration avec toutes les parties prenantes *(élaborer un plan de communication et de collaboration ; créer des supports de communication et de collaboration ; …)*

(v) Faire adopter les standards GS1 aux acteurs de la CAPS *(Code à faire scanner par les acteurs ; …)*

(vi) Accroitre le contrôle des PS afin d'améliorer l'efficacité de la CAPS grâce aux données de traçabilité *(identifier le type d'informations à collecter ; définir le processus de collecte et d'utilisation des données ; …)*

QUESTIONS & ANSWER
QUESTIONS & RÉPONSES



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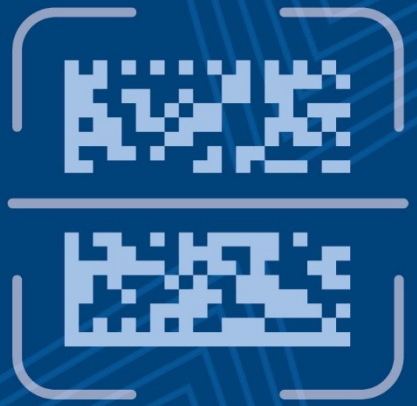

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Sophie MOLLE

Senior Manager Healthcare, GS1

Sophie.molle@gs1.org

- *Après avoir passé 8 années dans le domaine de la lutte anti-fraude et anti-contrefaçon à l'Organisation Mondiale des Douanes à Bruxelles et chez Cotecna Inspection à Genève, Sophie a rejoint GS1 Healthcare en 2017 et dirige depuis le programme global d'adhésion à la communauté GS1 Healthcare et plus particulièrement le partenariat avec les offreurs de solution.*

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Principes fondamentaux à retenir

Les offreurs de solution n'opèrent pas exclusivement dans le domaine de la santé, la plupart touche à d'autres secteurs également (biens de consommation courante, automobile, vente au détail, etc…).

Les offreurs de solution sont des organisations commerciales et rejoignent GS1 afin de mieux répondre aux besoins et attentes de leurs clients.

En matière de santé, les offreurs de solution houent un rôle clé dans le déploiement des standards GS1 et doivent impérativement avoir une relation forte avec les fabricants, distributeurs, professionnels de la santé et les autorités gouvernementales.

GS1 doit s'assurer que les offreurs de solution soient des ambassadeurs des standards GS1 et fournissement des conseils précis à leurs clients sur la meilleure façon de mettre en œuvre et d'utiliser les standards GS1.

GS1 n'est PAS un offreur de solutions

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Etat des lieux de la communauté des offreurs de solution

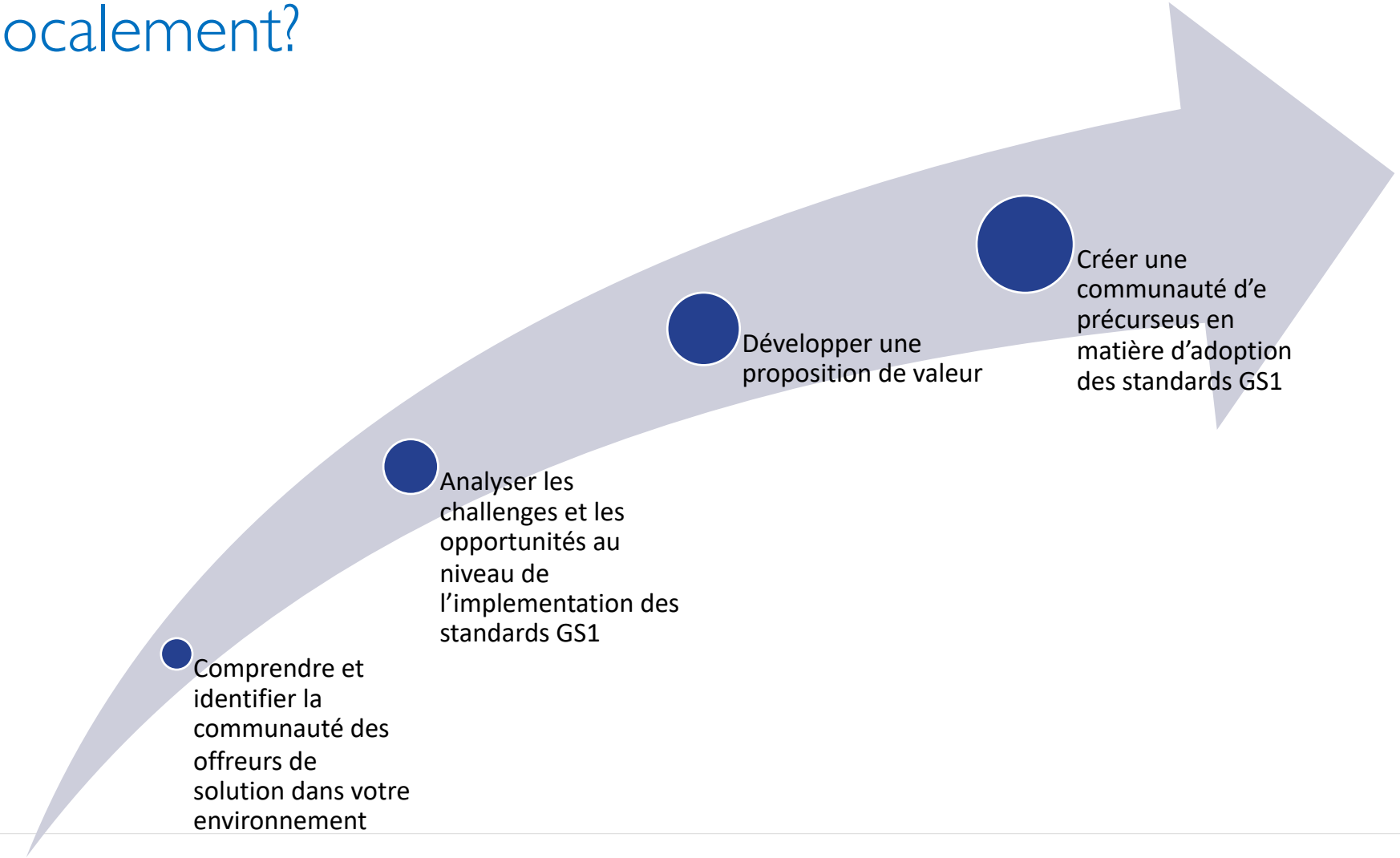
- Le cadre réglementaire de la traçabilité pharmaceutique se met en place dans différents pays (Benin, Rwanda, Togo, Zambia) donc les offreurs de solutions locaux y voient des opportunités de développement commercial.

- Ces organisations ont tendance à développer des solutions propriétaires, non interopérables qui ne répondent qu'à certains besoins avec une mise en oeuvre limitée sans prendre en compte le contexte global.

- Ces mêmes organisations utilisent la carte GS1 afin de remporter des marchés bien que leurs solutions ne soient pas conformes avec les standards GS1.

Il est nécessaire de mitiger ce risque.

Comment engager au mieux la **communauté** des offreurs de solution localement?



Comment la communauté GS1 Healthcare peut-elle vous aider?

Outils techniques

- GS1 Barcode Syntax Resource
- Programmes GS1 partenaires
- Programmes de certification

Outils de formation

- Formations complémentaires sur les standards utilisés dans la santé
- Formations sur les concepts de traçabilité et d'identification unique des dispositifs médicaux
- Accès aux outils de public policy

Outils de communication

- Conférences GS1 Healthcare
- Groupes de travail composés d'offreurs de solution et d'organisations GS1 locales
- Visibilité sur les sites internet dédiés

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Questions & Réponses

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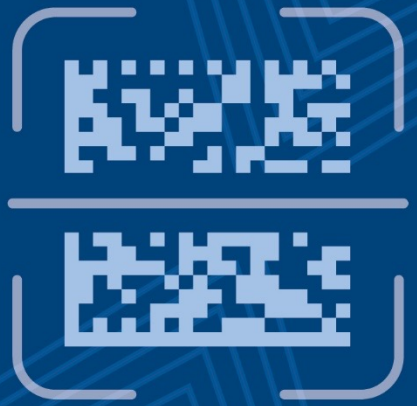

An Introduction to Digital Health Supply Chain Transformation

July 19, 2023 | 10:30 – 11:00 EDT / 14:30 – 15:00 GMT

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Dr. 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, Dr. Guirguis advises countries with respect to the automation of their national-level public health supply chain systems. Dr. Guirguis also provides an oversight to USAID's global MIS systems for supply chain. He has over 30 years of professional experience in information and communications Technology and contributed to the transformation and modernization of several large enterprises and government agencies spanning many diverse sectors including the: telecommunications, financial, health, defense and development sectors for both public and private sectors in the USA and internationally. Dr. Guirguis represented the DoD at several standards bodies, in the U.S. and overseas. He was a member of the U.S. expert delegation at several ISO/IEC JTC1/SC37 standards meetings. Dr. Guirguis is an Adjunct Professor at Georgetown, authored & co-authored several patents, presented/published at several international conferences. He is an IEEE Senior Member, PMI member and Certified Project Management Professional (PMP) and was a Senior Fellow at GMU International Cyber Center.

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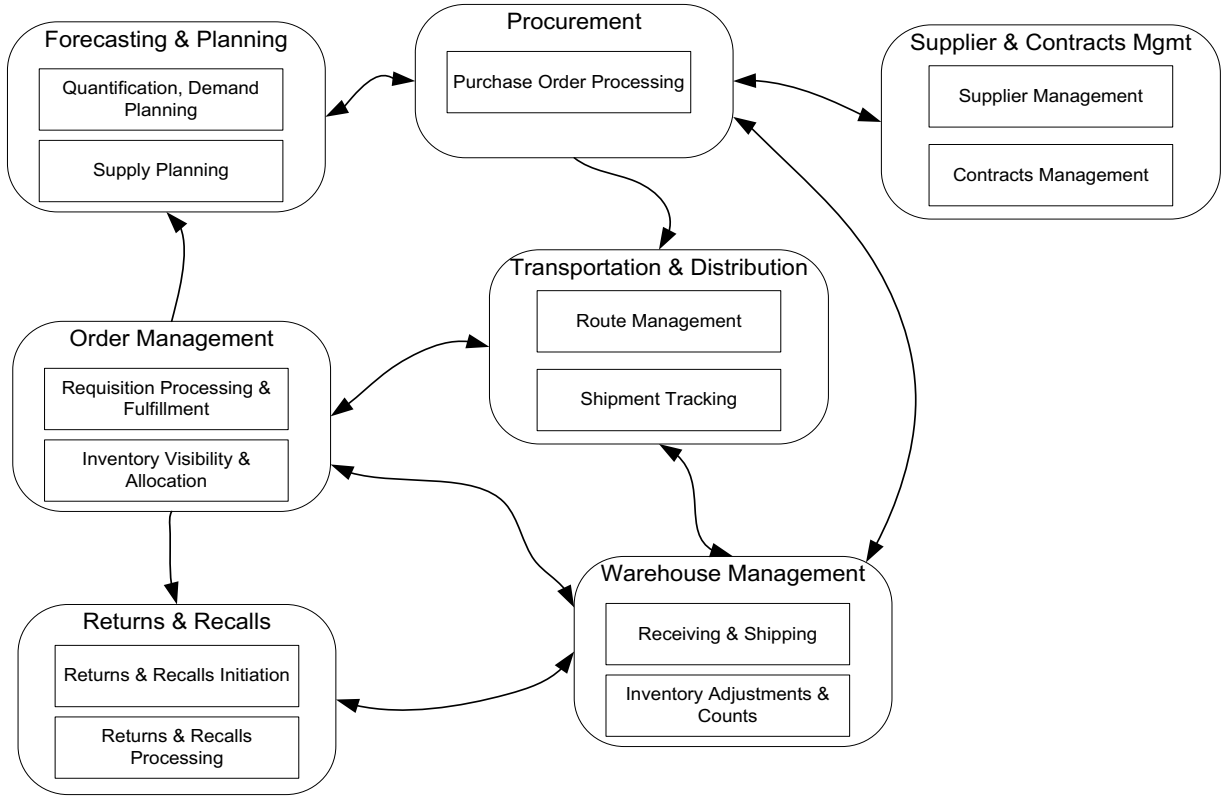
Supply chain information systems coordinate execution of SC processes for efficient flow of commodities



- SCIS form the back-bone in managing & coordinating the physical, informational & process flows from planning to consumption of commodities

- Without effective SCIS, commodities as well as data/information will move at a slower pace, limiting visibility, impeding decision-making and ultimately impacting the ability to serve patients

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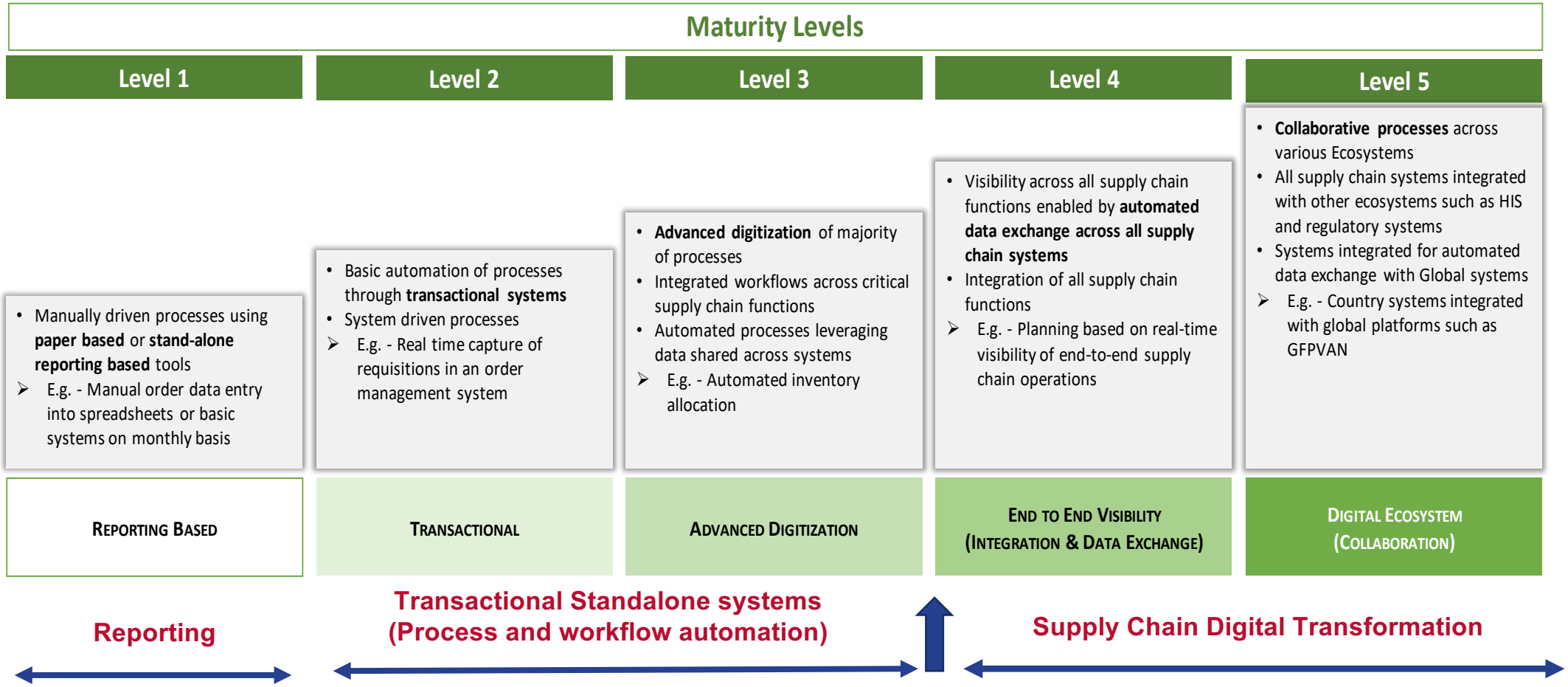
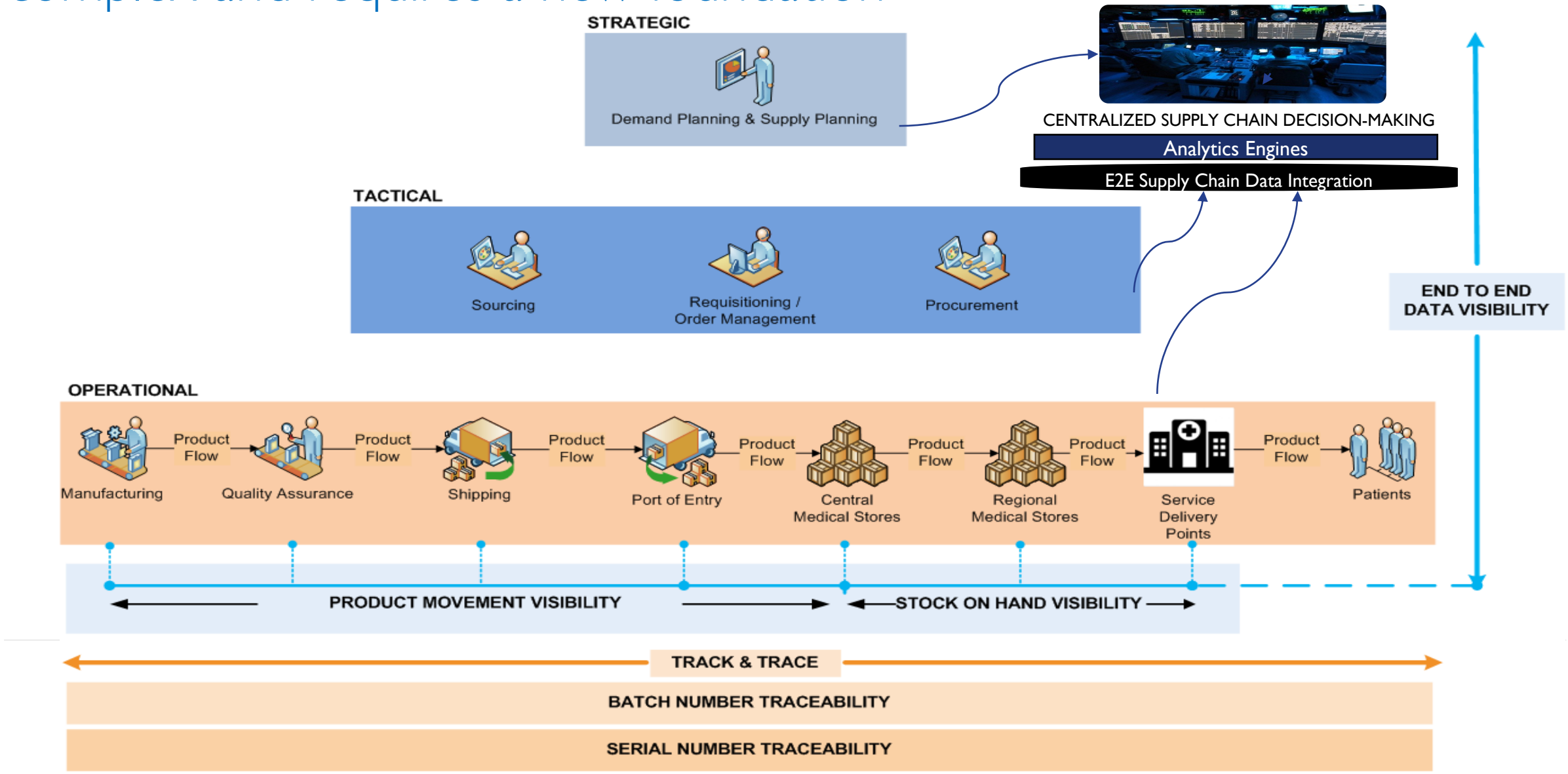
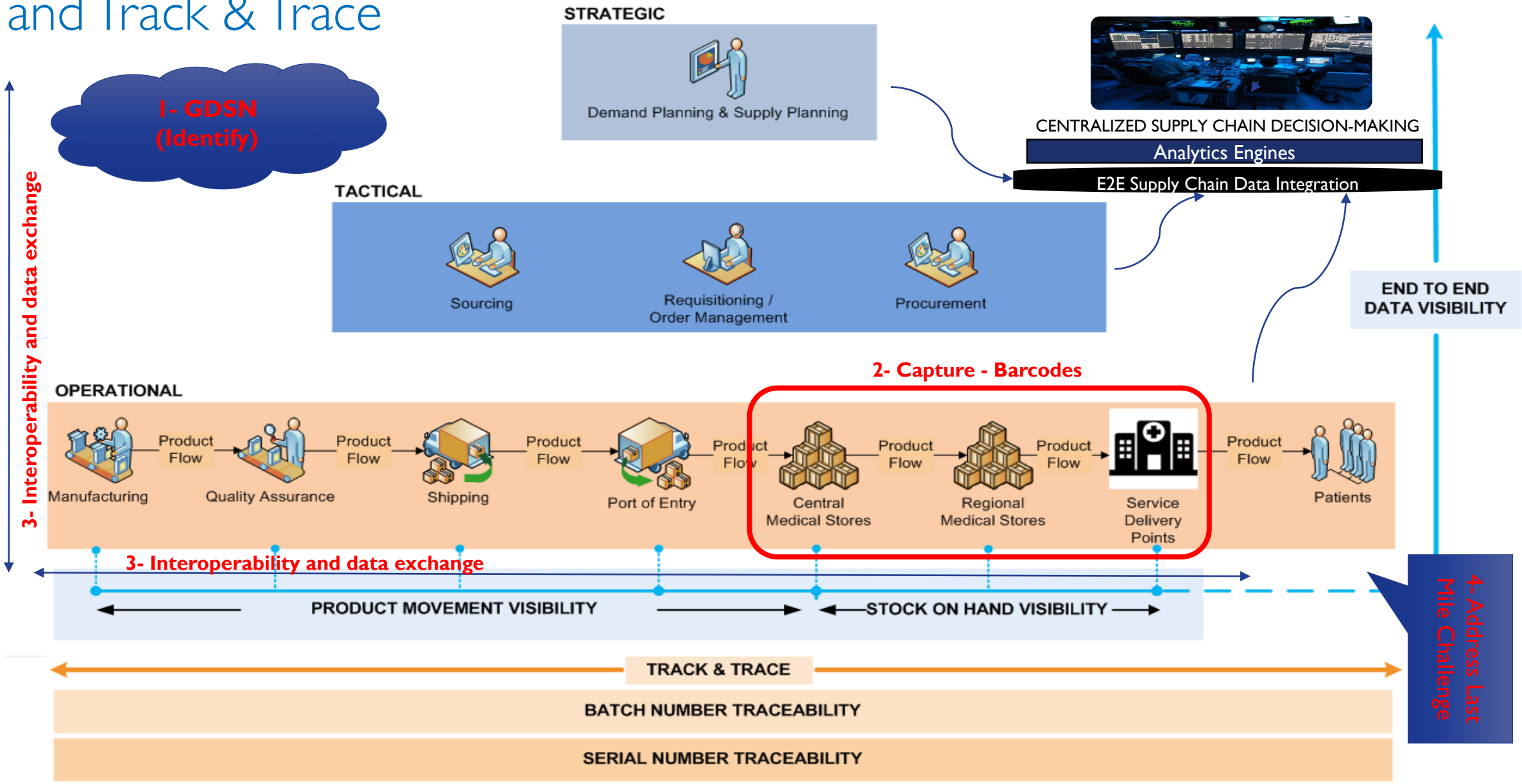
The Supply Chain Information System Maturity Model defines five maturity levels



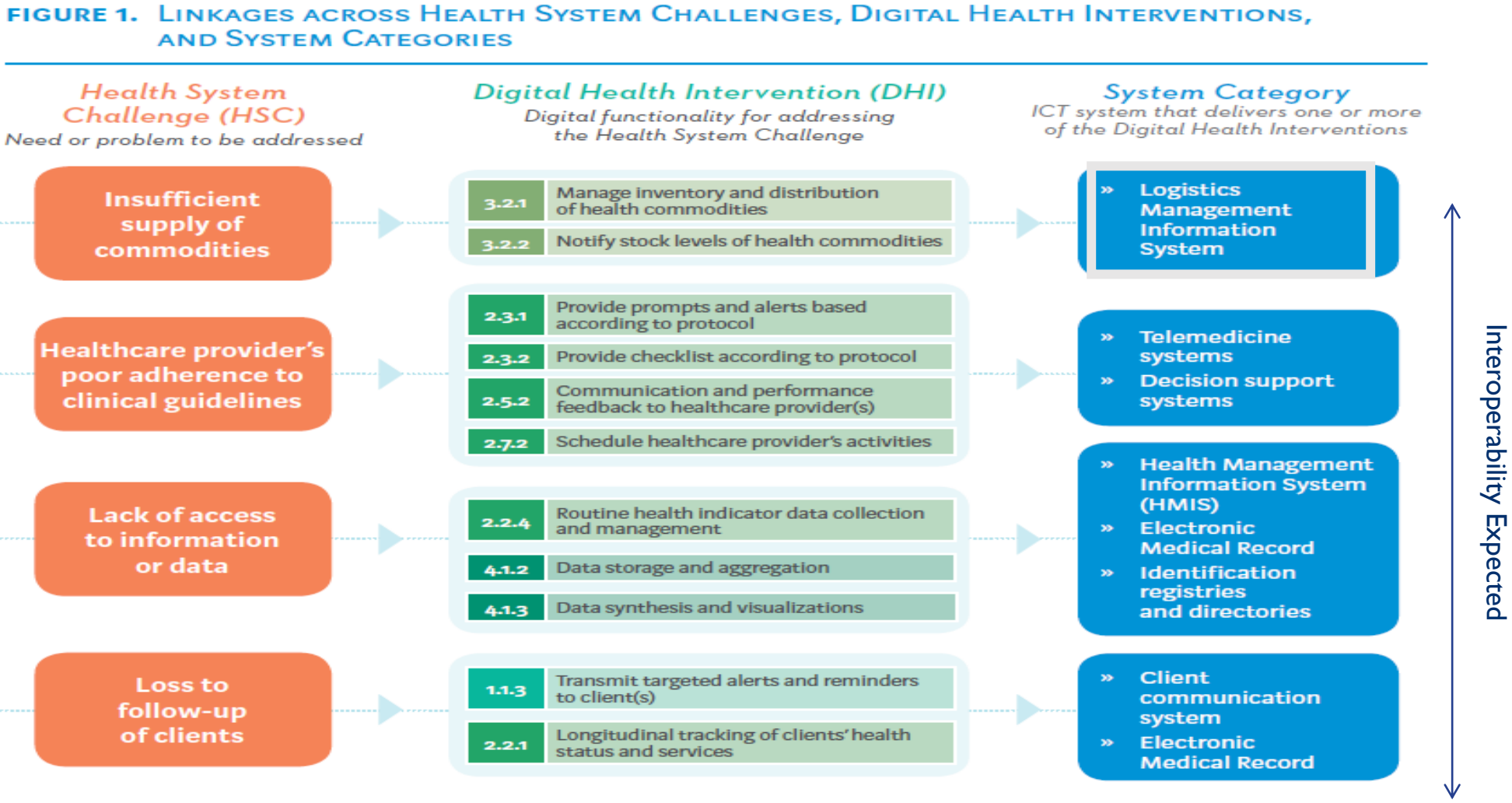
End-to-End Data Visibility and Track and Trace is increasingly complex and requires a new foundation



Global Standards Need to be the foundation for E2E Visibility and Track & Trace



Supply Chain Information Systems Are A Component of Digital Health Interventions



WHO Classification of digital health interventions v1.0 – 2018

Supporting Digital Health Transformation Through GS1 Based NPC

GS1 Standards

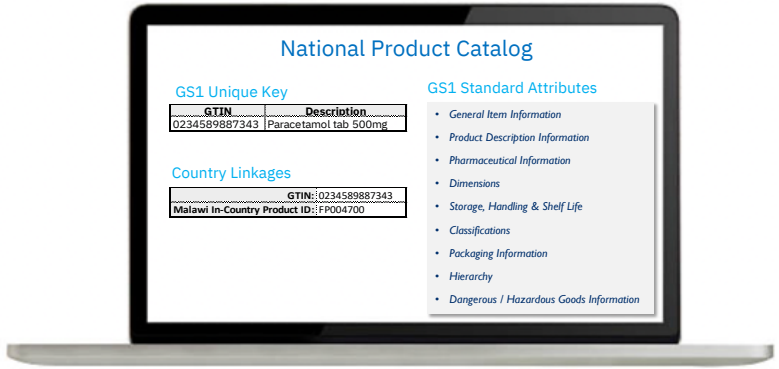
Identify

Capture

Share

Use

NPC

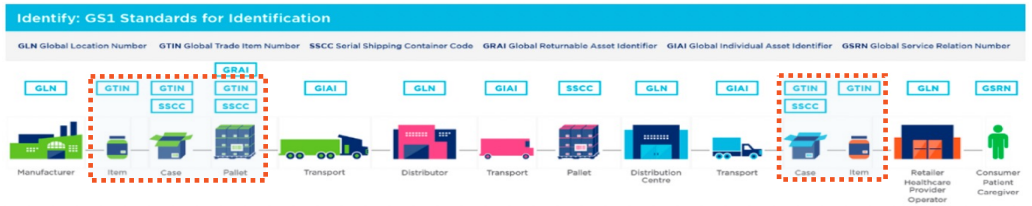


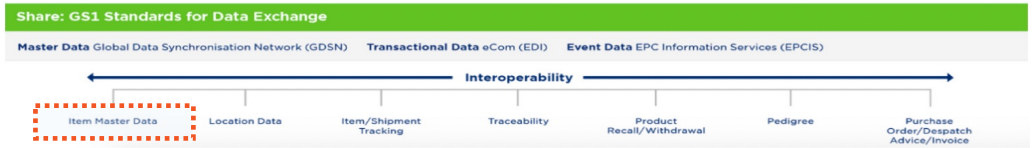
Identify

Capture

Share

Use





Traceability

Product Verification

✓**Identify:** Serve as the **authoritative source** of GS1 product identifier and standard attributes for all systems in the country

✓**Capture:** Foundation for **AIDC** (Facilitates use of GS1 Barcodes that contain GTINs)

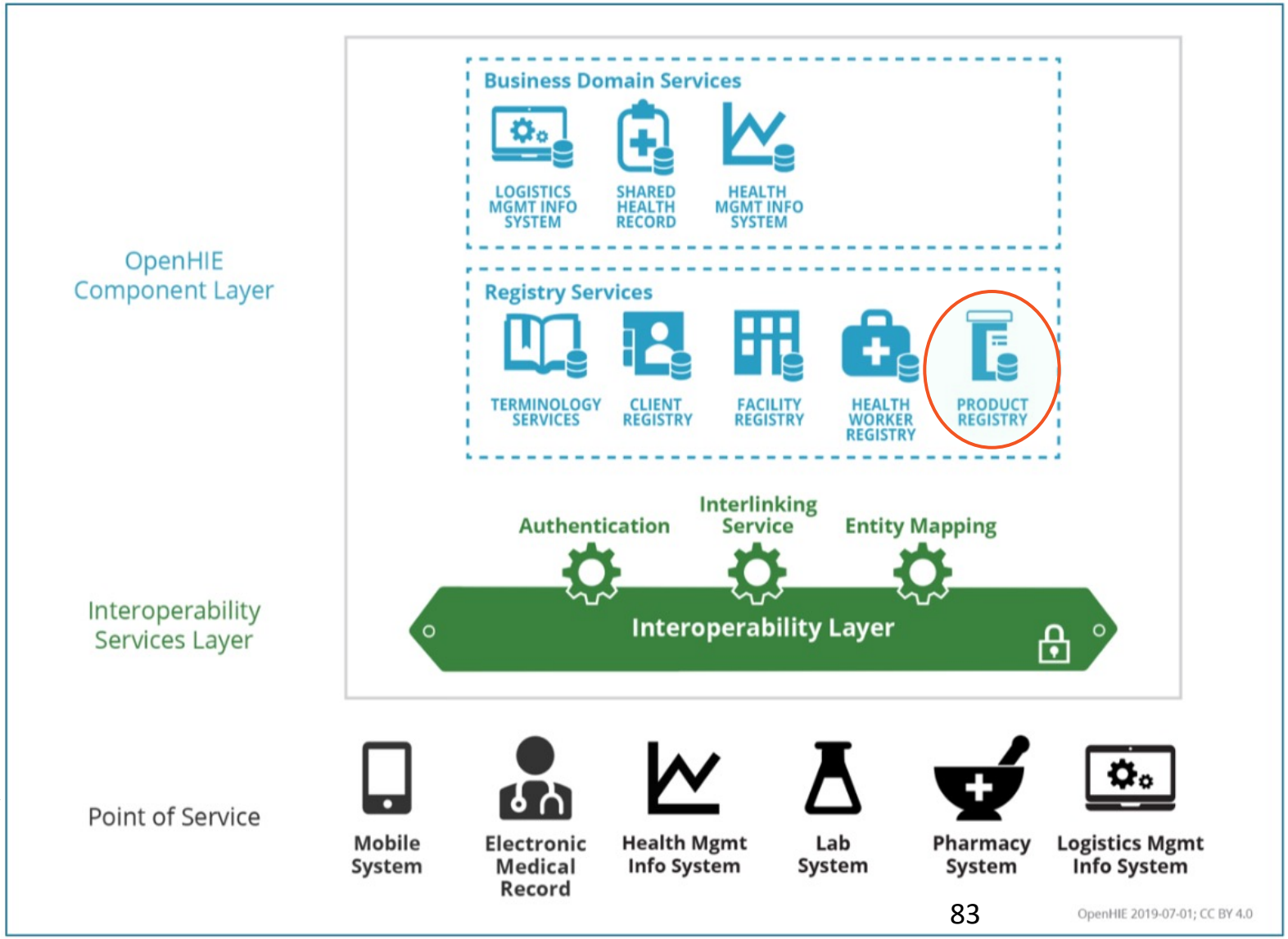
✓Supports **Interoperability** by sharing GTINs & GS1 Item Master Data and Enables **integration with legacy systems** through mapping GTINs to legacy system product IDs

✓Foundation for **Traceability, E2E Data visibility,** through use of **GTIN**s across all Supply Chain Levels & Systems

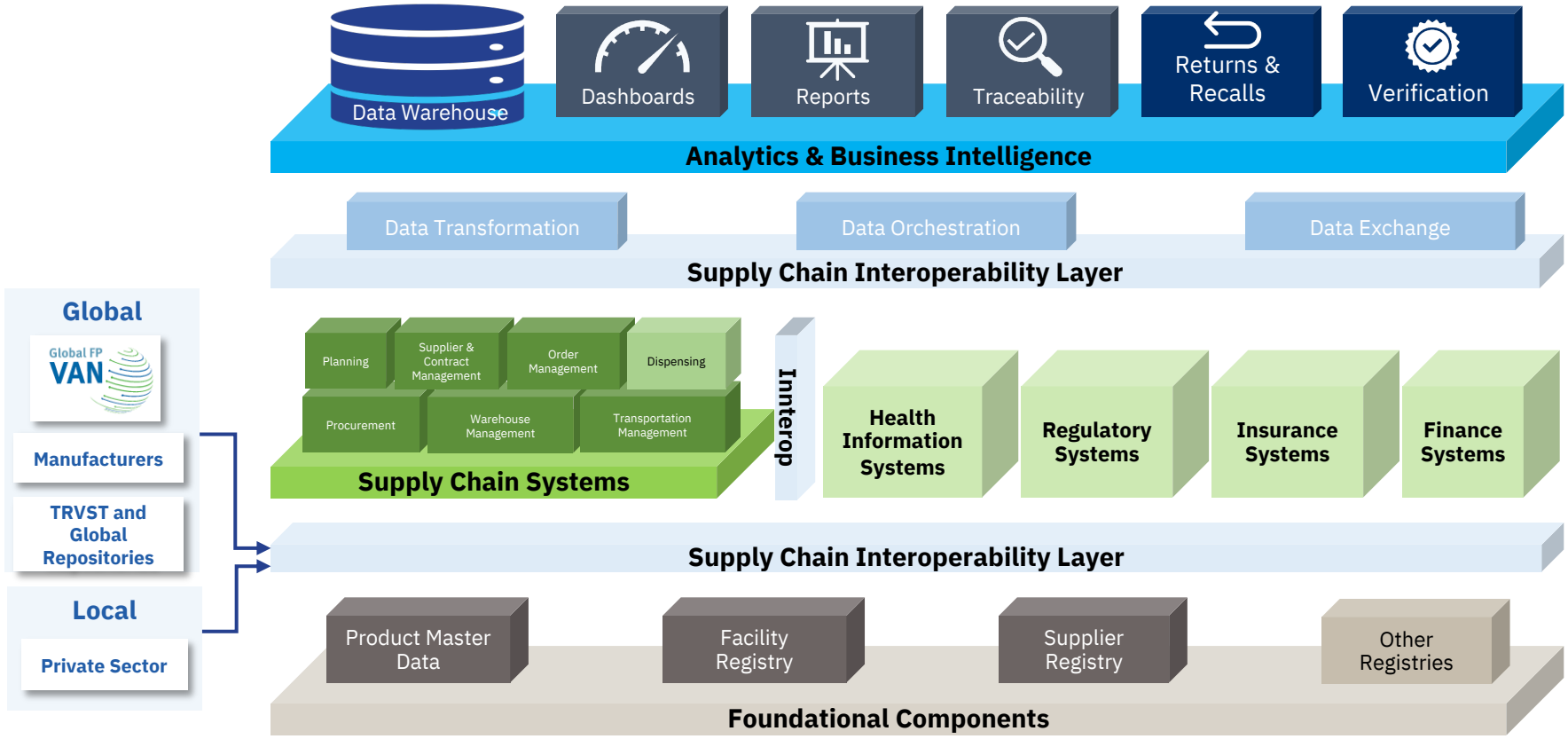
NPC Serves as Product Registry in OpenHIE's Architecture

- OpenHIE is an international community working in low resource settings that is dedicated to improve the health system through open and collaborative, development and support of country driven, large scale health information sharing architectures.

- OpenHIE **Architecture is** a service-oriented health information exchange architectural framework to enable sharing health data across information systems.



Digital Supply Chain as part of the larger Digital Health Ecosystem Architecture



This is a logical architecture of the digital health ecosystem where supply chain systems interoperate with others such as HIS, Regulatory, Finance and Insurance.

Foundational Components of the Supply Chain Digital Transformation

- The Foundational Components should be used across all the digital health eco-system:
  - Master facility list and GLNs
  - Standards based (GS1) master product registry (National Product Catalog)
  - Interoperability layer
  - Data and analytic layer independent from applications and capable of integrating data from multiple sources

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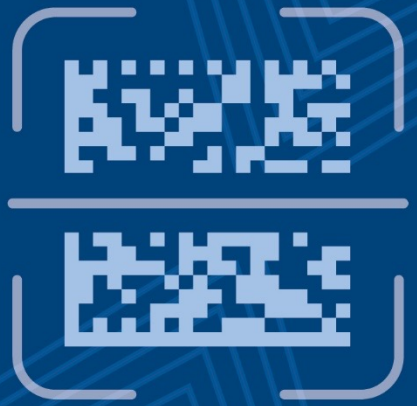

WHO SMART Guidelines and Digitized Product Catalogue

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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 was 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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Swaroop Jayaprakash

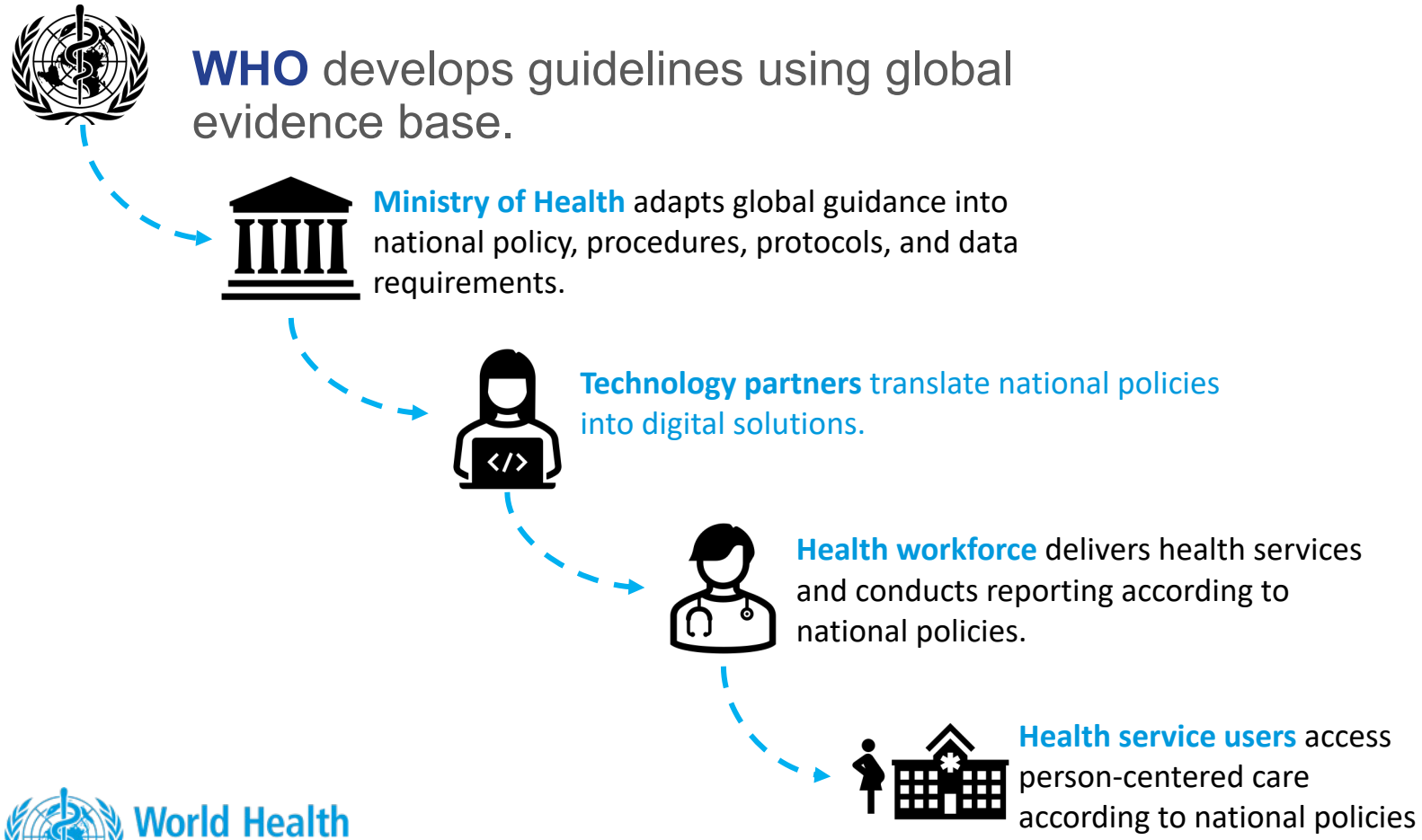
Digital Supply Chain Consultant, WHO

In his 22+ years of experience in IT he has designed & implemented large scale supply chain management systems for customers in retail, distribution, telecom & manufacturing. He helped design & implement ARTMIS application that facilitates procurement & distribution for USAID GHSC-PSM program. He developed the Supply Chain Information Systems Maturity Model (SCISMM) in collaboration with USAID, to help countries assess supply chain information system capabilities. He recently facilitated the development of digital supply chain strategy & architecture in Malawi & Rwanda.

Global Strategy Policy Actions

- Recommends defining “a national digital health architecture blueprint or road map, adopt **open-source health data standards** and aim for **reusable systems or assets** including interoperability of health information systems both at national and international levels in order to establish an innovative integration of **different digital technologies using shared services, ensuring data are of good and comparable quality**”
- “The global strategy promotes **syntactic and semantic interoperability** with WHO norms and standards as a cornerstone of health information to enable sharing of information in a connected world.”

Digital tools can help facilitate the adoption and integration process, but if done inappropriately, can lead to questionable results

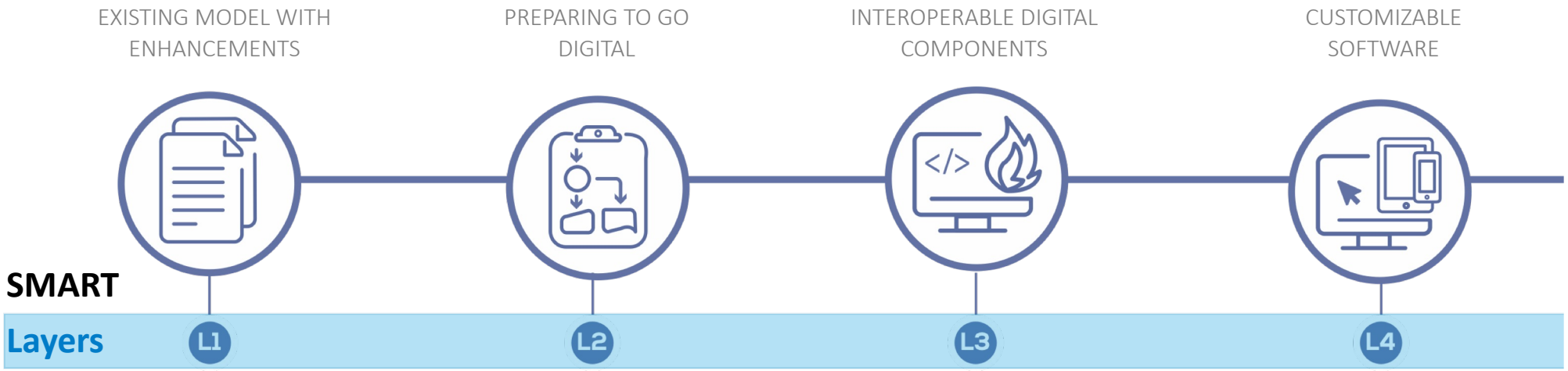


- **Difficult to operationalize** intentionally vague guideline content into digital systems with fidelity
- Infrequently digitized with **interoperability standards**, and **architectural good practice**, leading to siloed systems
- "**Black box**" digital systems become **difficult to maintain** sustainably in the long-term

World Health Organization

SMART Guidelines are health and data Content Digital Public Goods

Standards-based, **M**achine Readable, **A**daptive, **R**equirements-based, **T**estable



- Reinforce operational specificity in existing guidelines
- Digital curation of recommendations
- Panels include informatics and standards experts

- Digital Adaptation Kit (DAK) – requirements document
- Human-readable components
- Describes how a digital tool should function
- Data dictionaries mapped to ICD, LOINC

- FHIR Implementation Guide (IG) documentation
- Based on Clinical Practice Guidelines IG
- Consistent execution across systems - software as a function
- Decision support services and indicator calculations (CQL)

- Fully executable software tools
- Mechanism for real-time updates
- Interoperate with national systems

WHO SMART guidelines: optimising country-level use of guideline recommendations in the digital age - The Lancet Digital Health

Current status of SMART Guidelines development in WHO

Health Domain (L1)	Digital Adaptation Kits (L2)	Machine Readable (L3)			Executable Software (L4)	
		Data	Logic	Forms	Not on FHIR	FHIR-based
Antenatal Care (**ANC**) *+ Adolescent Sexual Reproductive Health (ASRH) overlay*	✓	✓	✓	✓	✓	In progress*
Family Planning (**FP**) *+ ASRH overlay*	✓	✓			MVP	
Sexually Transmitted Infections (**STI**) *+ ASRH overlay*	Will be published soon	✓				
HIV	Will be published soon	In progress				
Immunizations **(EIR)**	Will be published soon	Will be published soon				Being discussed
Child Health in Emergency Settings **(Em Care)**	Will be published soon	In progress				In progress
Digital Documentation of COVID-19 Certificates: **Vaccination Status**	✓	✓	✓	✓		✓
Digital Documentation of COVID-19 Certificates: **Test Results**	✓	✓	✓	✓		✓
Self Care – Sexual and Reproductive Health	In progress					
Tuberculosis **(TB)**	In progress					
Neglected Tropical Diseases **(NTD)**	Being discussed					
Nutrition	Being discussed					
Postnatal Care **(PNC)**	Being discussed					
Health financing	Being discussed					
Primary Health Care	Being discussed					
Emergency Care	Being discussed					
Cervical cancer	Being discussed					
Intrapartum care	Being discussed					

L1: Narrative | Existing model with enhancements

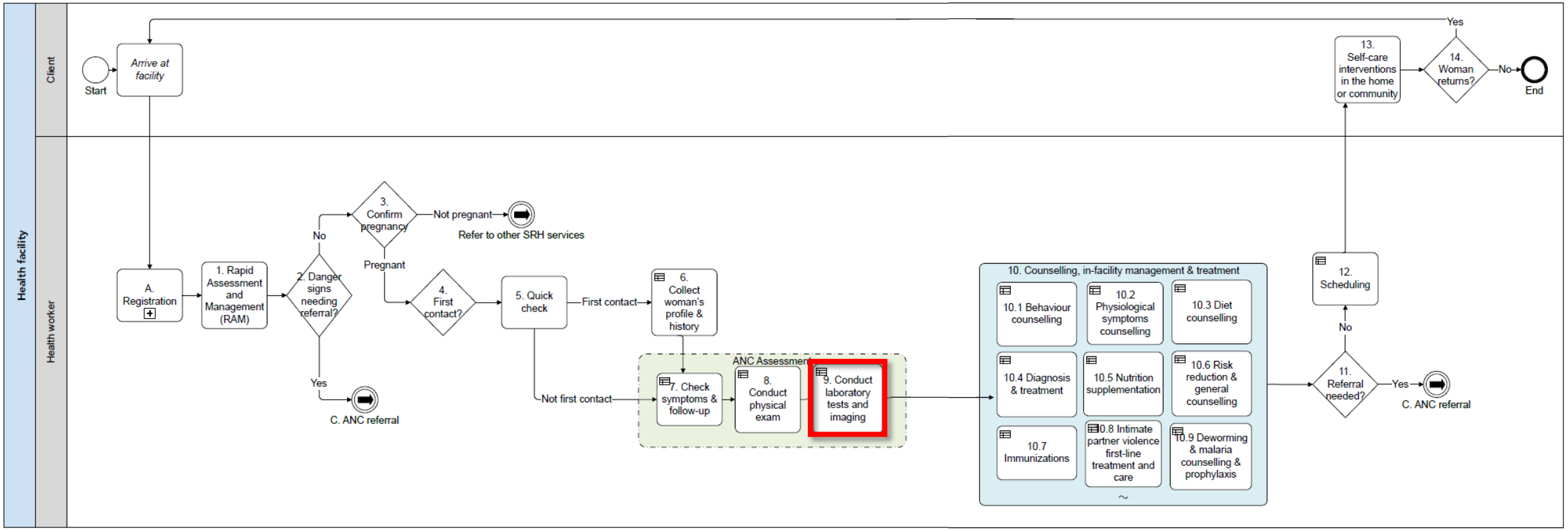
Current guideline format from the guideline document

Iron and folic acid supplements	**A.2.1:** Daily oral iron and folic acid supplementation with 30 mg to 60 mg of elemental iron[b] and 400 µg (0.4 mg) of folic acid[c] is recommended for pregnant women to prevent maternal anaemia, puerperal sepsis, low birth weight, and preterm birth.[d]	Recommended
	A.2.2: Intermittent oral iron and folic acid supplementation with 120 mg of elemental iron[e] and 2800 µg (2.8 mg) of folic acid once weekly is recommended for pregnant women to improve maternal and neonatal outcomes if daily iron is not acceptable due to side-effects, and in populations with an anaemia prevalence among pregnant women of less than 20%.[f]	Context-specific recommendation
Anaemia	**B.1.1:** Full blood count testing is the recommended method for diagnosing anaemia in pregnancy. In settings where full blood count testing is not available, on-site haemoglobin testing with a haemoglobinometer is recommended over the use of the haemoglobin colour scale as the method for diagnosing anaemia in pregnancy.	Context-specific recommendation

Source: https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/anc-positive-pregnancy-experience/en/

L2: Operational | Preparing to go digital

ANC Consultation workflow



Source: [Digital Adaptation Kit for Antenatal Care: Operational requirements for implementing WHO recommendations in digital systems]

L2: Operational | Preparing to go digital

Indicator calculation for % of women who have received iron and folic acid supplements

Indicator code	Indicator name	Numerator		Denominator		Disaggregation	Reference
		Definition	Computation	Definition	Computation		
ANC.IND.2	**Percentage of pregnant women who received iron and folic acid (IFA) supplements for 90+ days**	Number of pregnant women who received the recommended number of IFA tablets during all previous contacts	COUNT of number of women who were prescribed IFA tablets at each ANC contact they have had	Total number of antenatal clients with a first contact	COUNT of all women whose records were closed (ANC close form) in the last reporting period due to any of the reasons below: » live birth » stillbirth » miscarriage » abortion » woman died » lost to follow-up » moved away	Age (10–14, 15–19, 20+) Education level (none, don't know, primary, secondary, higher)	WHO ANC monitoring framework *(43)*

- Indicators can be aggregated from individual level data rather than a separate reporting system
- Each 'variable' must be encoded to a standard terminology (ICD, ICHI, ICF, LOINC)
- Data dictionary, decision support logic, indicator tables, functional and non-functional requirements are in spreadsheet formats

Source: Digital Adaptation Kit for Antenatal Care: Operational requirements for implementing WHO recommendations in digital systems

L3: Machine-readable | Interoperable digital components

Same recommendations in standards-based software code format

ANC.DT.25 Anaemia, iron and folic acid supplementation:
When: *named-event:* ANC.B9. Conduct laboratory tests and imaging
Then:

Anaemia can be diagnosed if Hb level is less than 11 in first or third trimester or Hb level less than 10.5 in second trimester; OR there is no Hb test result recorded, but woman has pallor. If a woman is diagnosed with anaemia during pregnancy, conduct counselling for managing and treating anaemia. Her daily elemental iron should be increased to 120 mg until her haemoglobin (Hb) concentration rises to normal (Hb 110 g/L or higher). Thereafter, she can resume the standard daily antenatal iron dose to prevent recurrence of anaemia. The equivalent of 120 mg of elemental iron equals 600 mg of ferrous sulfate heptahydrate, 360 mg of ferrous fumarate or 1000 mg of ferrous gluconate. Please refer to iron sources listed below for additional guidance that can be provided.

If: *applicability:* ((((“Blood haemoglobin test result” < 110 g/L) AND (“Gestational age” ≤ 12 weeks)) OR ((“Blood haemoglobin test result” < 110 g/L) AND (“Gestational age” ≥ 28 weeks))) OR ((“Blood haemoglobin test result” < 105 g/L) AND (13 weeks ≤ “Gestational age” ≤ 27 weeks))) OR ((“Blood haemoglobin test conducted” = FALSE) AND (“Pallor present” = TRUE)) *(Should Conduct REQUIRED anaemia counselling)*
Then:

Conduct REQUIRED anaemia counselling:
“Amount of iron prescribed” = 120 mg:
“Type of iron supplement dosage provided” = “Daily”:
“Amount of daily dose of folic acid prescribed” = 0.4 mg:

If a woman is not diagnosed for anaemia, iron and folic acid supplementation is still recommended. Due to the population's high anaemia prevalence, a daily dose of 60 mg of elemental iron is preferred over a lower dose. A daily dose of 400 micrograms (0.4 mg) folic acid is also recommended. The equivalent of 60 mg of elemental iron is 300 mg of ferrous sulfate heptahydrate, 180 mg of ferrous fumarate or 500 mg of ferrous gluconate. Please refer to iron sources listed below for additional guidance that can be provided.

If: *applicability:* ((((“Blood haemoglobin test result” ≥ 110 g/L) AND (“Gestational age” ≤ 12 weeks) AND (“Population prevalence of anaemia” ≥ 40%)) OR ((“Blood haemoglobin test result” ≥ 110 g/L) AND (“Gestational age” ≥ 28 weeks) AND (“Population prevalence of anaemia” ≥ 40%))) OR ((“Blood haemoglobin test result” ≥ 105 g/L) AND (13 weeks ≤ “Gestational age” ≤ 27 weeks) AND (“Population prevalence of anaemia” ≥ 40%))) OR ((“Blood haemoglobin test conducted” = FALSE) AND (“Pallor present” = FALSE) AND (“Population prevalence of anaemia” ≥ 40%)) *(Should \”Anaemia counselling conducted\” IS OPTIONAL)*
Then:

“Anaemia counselling conducted” IS OPTIONAL:
“Amount of iron prescribed” = 60 mg:
“Type of iron supplement dosage provided” = “Daily”:
“Amount of daily dose of folic acid prescribed” = 0.4 mg:


```
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        "description" : "Conduct REQUIRED anaemia counselling",
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ester or Hb level less than 10.5 in second trimester; OR there is no Hb test result recorded, but woman h
as pallor.\n\nIf a woman is diagnosed with anaemia during pregnancy, conduct counselling for managing and
treating anaemia. \n\nHer daily elemental iron should be increased to 120 mg until her haemoglobin (Hb) c
oncentration rises to normal (Hb 110 g/L or higher). Thereafter, she can resume the standard daily antena
tal iron dose to prevent recurrence of anaemia.\n\nThe equivalent of 120 mg of elemental iron equals 600
mg of ferrous sulfate heptahydrate, 360 mg of ferrous fumarate or 1000 mg of ferrous gluconate.\n\nPlease
refer to iron sources listed below for additional guidance that can be provided. ",
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            "label" : "WHO ANC recommendations (2016): B1.1, A.2.1, A.2.2 (3)\nPregnancy, childbirth, p
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eeks)))\n  OR ((\"Blood haemoglobin test result\" < 105 g/L)\n  AND (13 weeks ≤ \"Gestational age\" ≤ 27
weeks)))\n  OR ((\"Blood haemoglobin test conducted\" = FALSE)\n  AND (\"Pallor present\" = TRUE))",
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          },
          {
            "title" : "\"Amount of daily dose of folic acid prescribed\" = 0.4 mg"
```

Country Example: Malawi

Ministry of Health and Population – Malawi

Malawi Supply Chain Systems Architecture for Commodity Tracking and Tracing

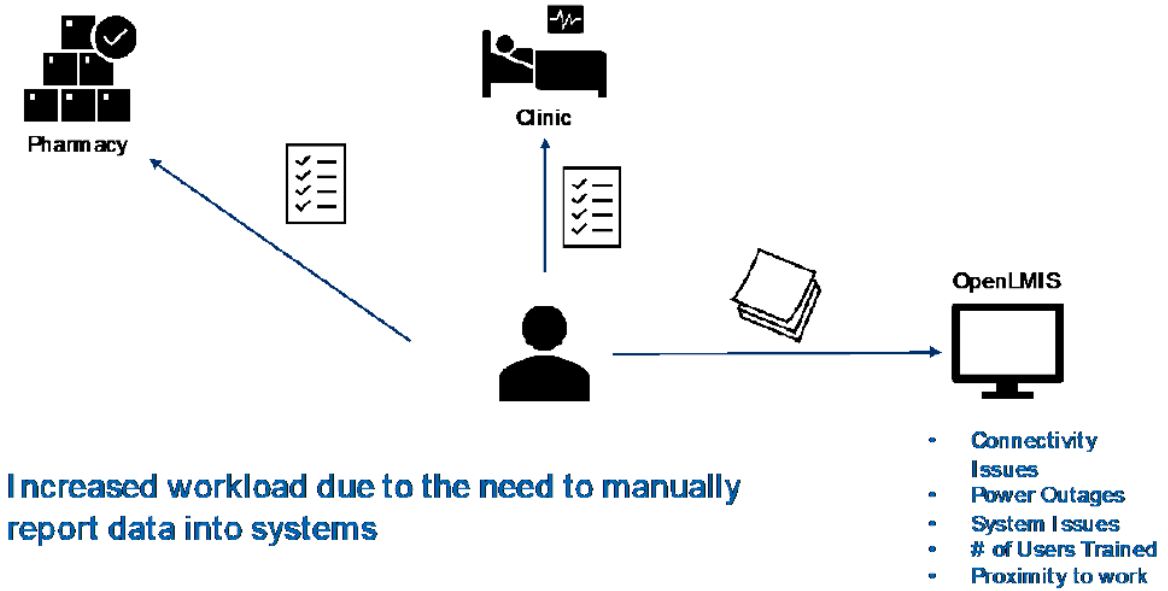


Figure 5. Operational Challenges at Downstream Facilities

- Stock-outs
- Need for emergency orders and stock transfers by facilities
- Overload of manual processes
- Manual data entry leading to errors
- Clarity on consumption versus issue, impacting forecasting and distribution
- Use of multiple overlapping systems

Country Example: Malawi

Ministry of Health and Population – Malawi

Malawi Supply Chain Systems Architecture for Commodity Tracking and Tracing

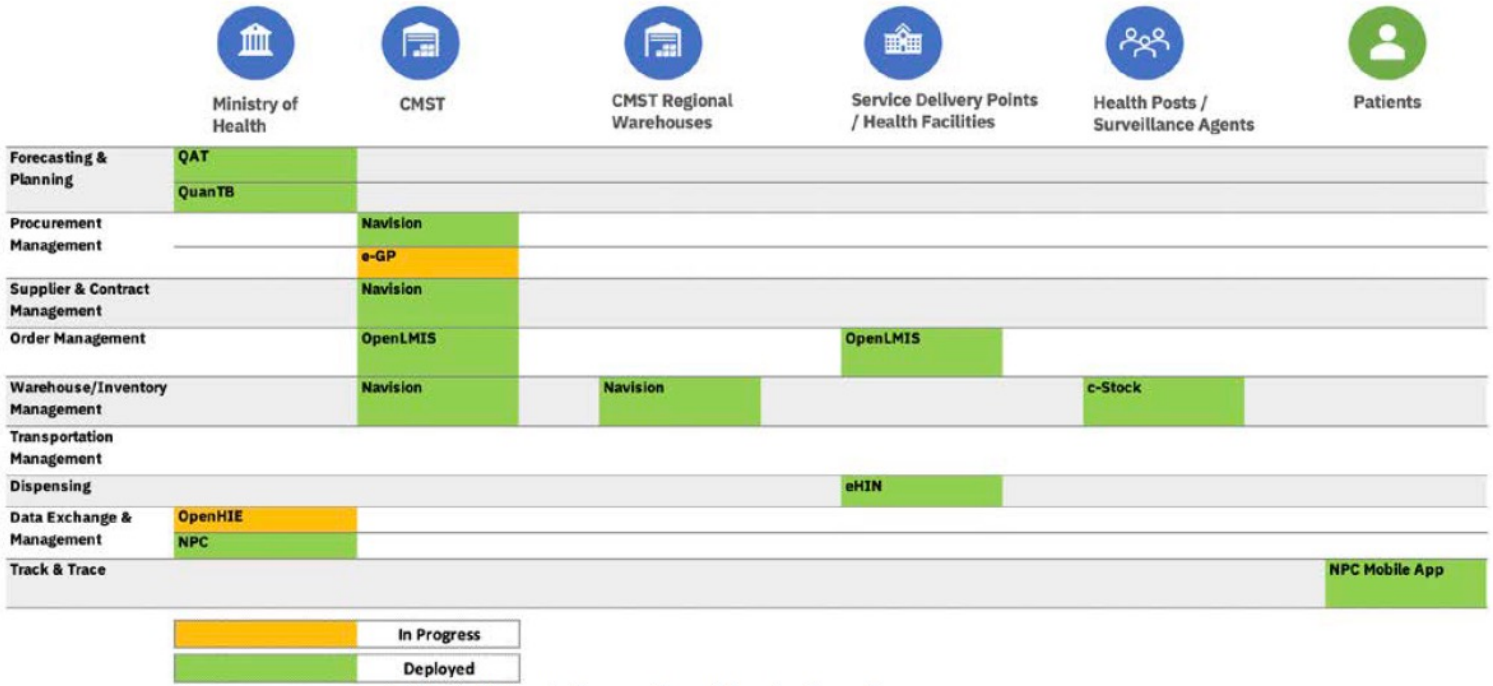


Table 1. Malawi's Existing Digital Supply Chain Footprint

Country Example: Malawi

Ministry of Health and Population – Malawi

Malawi Supply Chain Systems Architecture for Commodity Tracking and Tracing

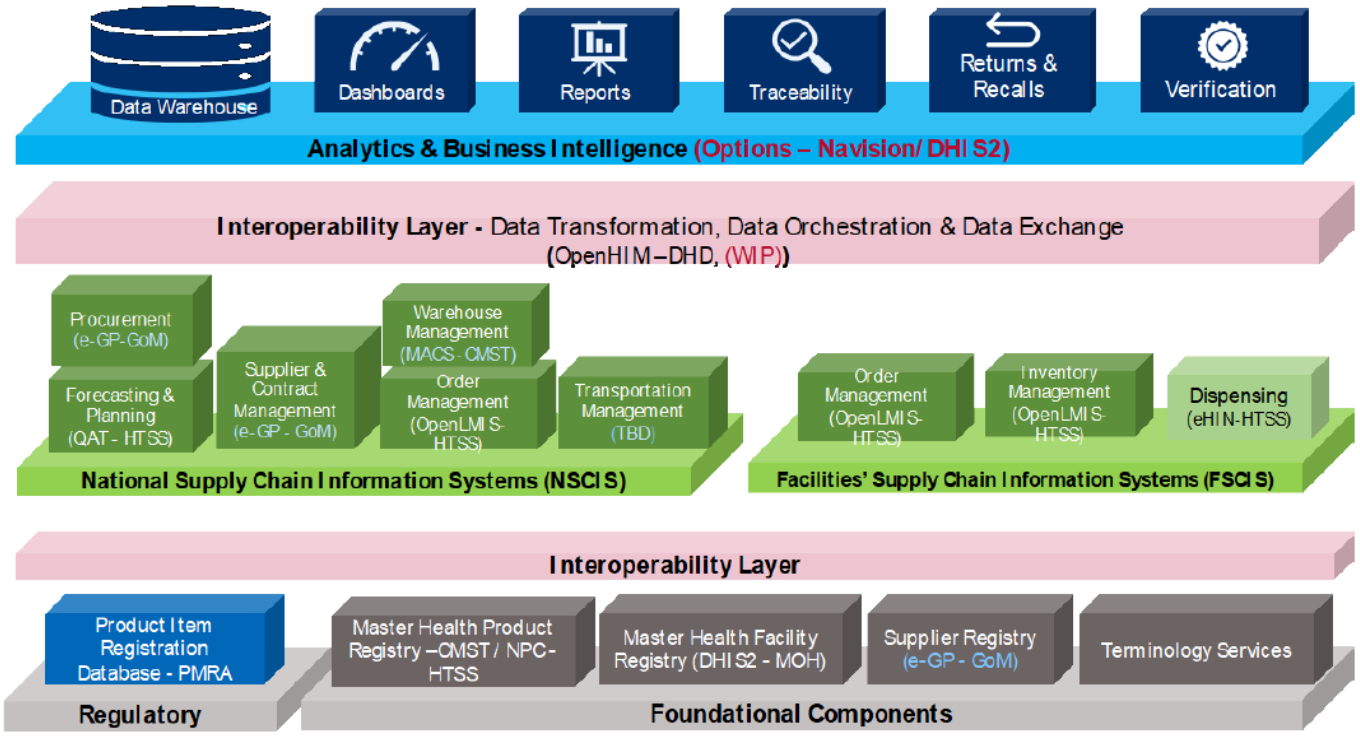
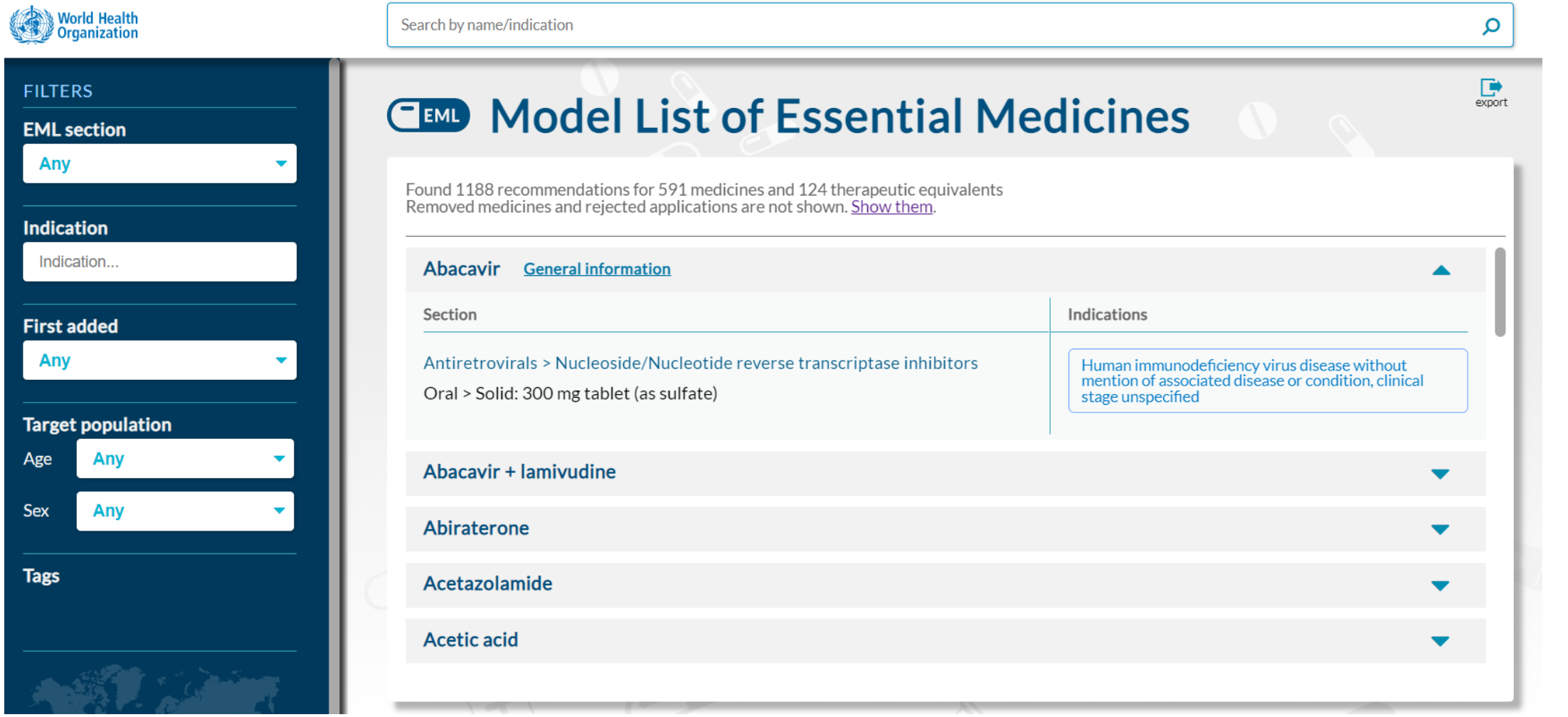


Figure 17. Malawi To-Be Supply Chain Logical Architecture

Product master data management: As noted in the as-is architecture section, NPC serves as the product master data management tool and has been operational in Malawi since mid 2021. To leverage the benefits of standardized data managed within NPC, NPC will be integrated with SC systems and HIS. The integration will be accomplished through the interoperability layer.



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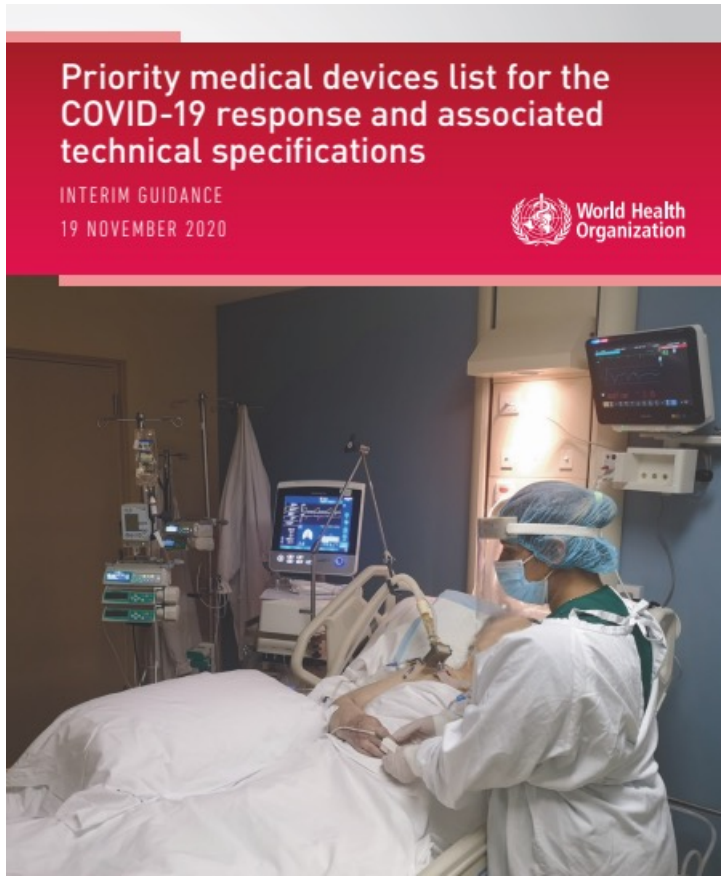

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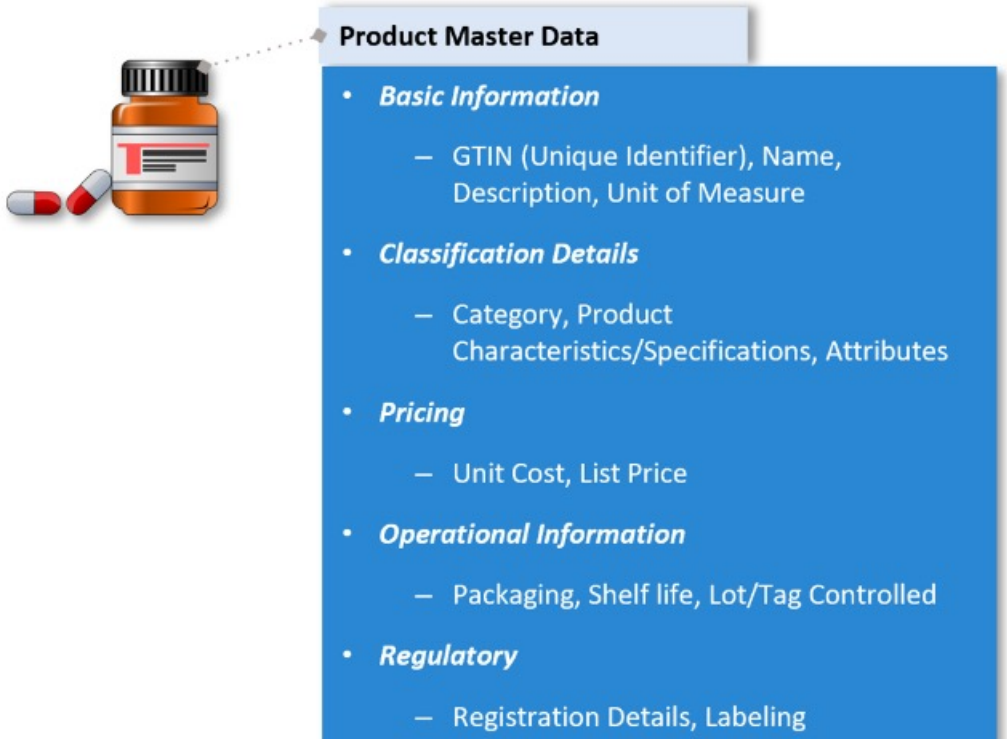
GS1

National Product Catalog

A key component on this is the use of online National Product Catalog (NPC). This tool facilitates the adoption of standardized product information, thus eliminating the need for manual interventions to keep all supply chain actors in synch, which represents a very common challenge for national healthcare supply chains in low- and middle-income countries.

Product Master Data



Category	Attributes (GS1 Nomenclature)	Definition
GENERAL ITEM INFORMATION	Item Id (gtin)	The Global Trade Item Number is the standard 14-digit representation of the number used to identify all trade items in GDSN
	Hierarchy level (tradeItemUnitDescriptorCode)	Describes the hierarchical level of the trade item. (each, case, pallet)
	Brand Name (brandName)	The recognizable name used by a brand owner to uniquely identify a line of trade item. This is recognizable by the consumer.
	Functional Name (functionalName)	Describes use of the product by the consumer. Should help clarify the product classification associated with the GTIN.
	Country Of Origin (placeOfProductActivity/countryOfOrigin/countryCode)	The country code (codes) in which the goods have been produced or manufactured, according to criteria established for the purposes of application of the value may or may not be presented on the trade item label.
PRODUCT DESCRIPTION INFORMATION	Product Description (tradeItemDescription)	An understandable and useable description of a trade item using brand and other descriptors.
	Manufacturer GLN (manufacturerOfTradeItem/gln)	The Global Location Number used to identify the organization that manufactures this trade item.
	Manufacturer Name (manufacturerOfTradeItem/partyName)	The name of the manufacturer of this trade item.
PHARMACEUTICAL INFORMATION	Dosage Form (dosageFormTypeCodeReference)	A dosage form is the physical form of a medication that identifies the form of the pharmaceutical item.
	Route of Administration Description (enumerationValueDescription)	The description for the method(s) of administering the product. In pharmacology and toxicology, a route of administration is the path by which a drug, fluid, or other substance is brought into contact with the
HIERARCHY	Child Item (gTIN (child) (nextLowerLevelTradeItemInformation)	Unique product identification number (GTIN) for a child item with a higher-level trade item (parent) in a product hierarchy. This item may repeat in the case of a combination pack (multiple GTINs in lower level).
	Total Quantity of Next Lower Level Trade Item (totalQuantityOfNextLowerLevelTradeItem)	This represents the Total quantity of next lower level trade items that this trade item contains.
SHELF LIFE	Shelf Life from Production (minimumTradeItemLifespanFromTimeOfProduction)	The period of days, guaranteed by the Manufacturer, before the expiration date of the product, based on the production.

VAN INTRODUCES GROUNDBREAKING PRODUCT CATALOG MANAGEMENT TOOL

15th January 2020

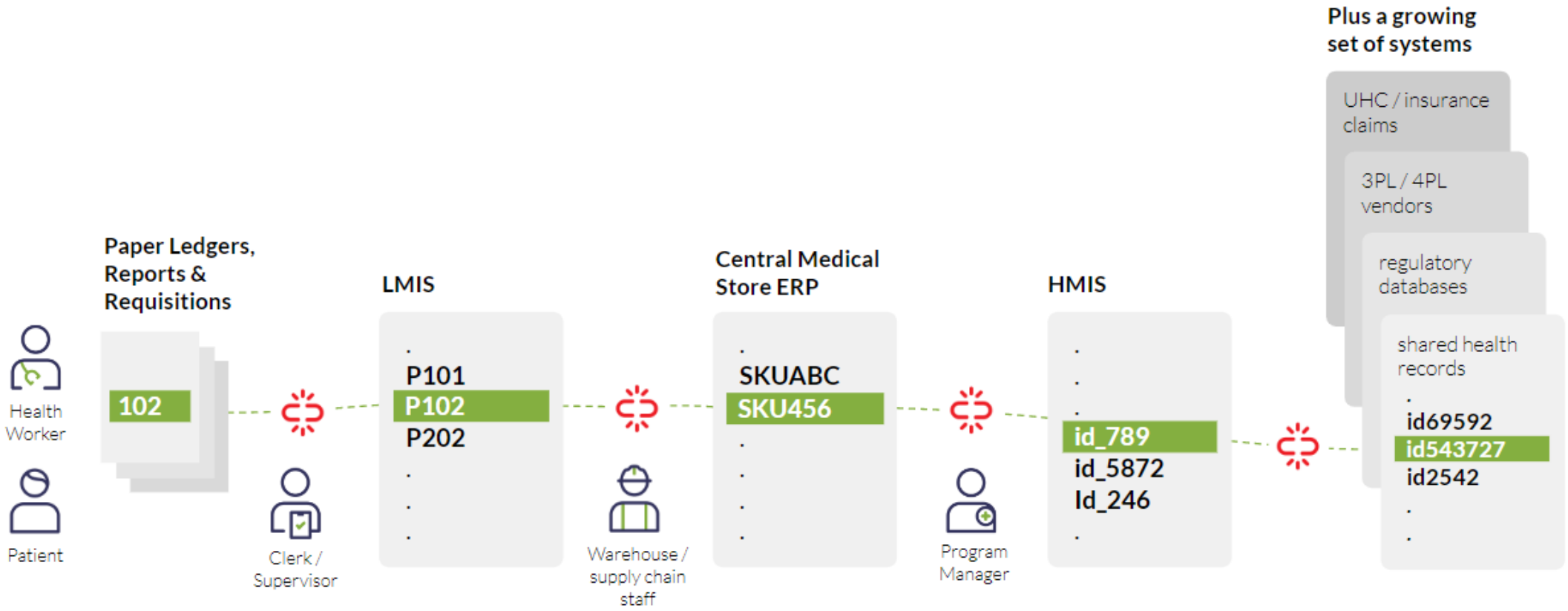
Global FP VAN members and other key health supply chain stakeholders came together in Washington, DC recently to learn more about the groundbreaking Product Catalog Management Tool (PCMT). Health systems around the globe face challenges with inconsistent product identifiers (the ID numbers and barcodes used to manage inventory and delivery of medicines). These inconsistencies undermine supply chain efficiency and visibility. ID numbers differ across hundreds of paper and digital systems, contributing to a heavy manual effort and low data quality. PCMT is a user-friendly tool for publishing and managing product catalogs; GFPVAN is the first PCMT user, managing its family planning product catalogue in the tool and using it as the definitive global source for product information for family planning products.

PCMT interoperates with many systems in LMIC countries using global standards such as GS1. GS1 – a business language designed to improve the efficiency, safety and visibility of supply chains. If GS1 were used by all organizations and countries, everyone would be referencing the same product identifiers, which helps increase efficiencies in supply chain management. If shared data standards are defined, these harmonized standards can make transactions efficient, speedy, and effective.

In National Health Systems

Each stakeholder has different needs for product information, across many systems and organizations.

There are no consistent product identifiers to connect the dots.



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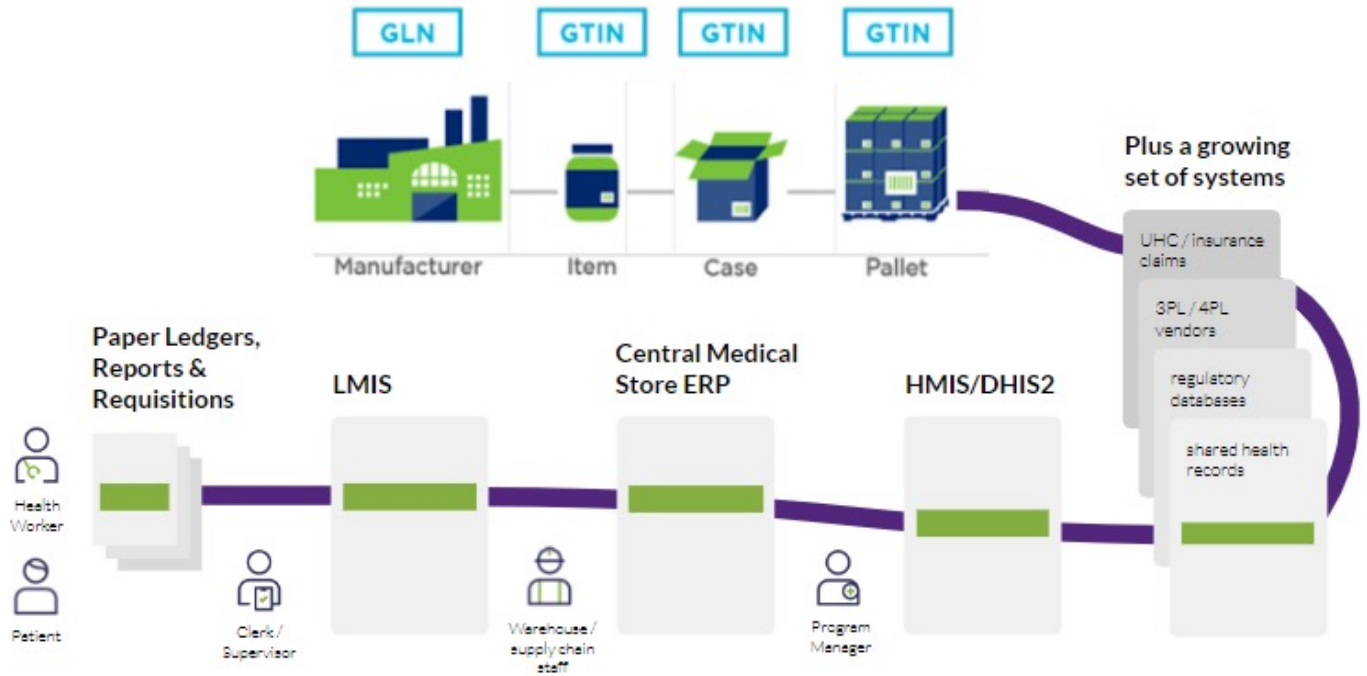
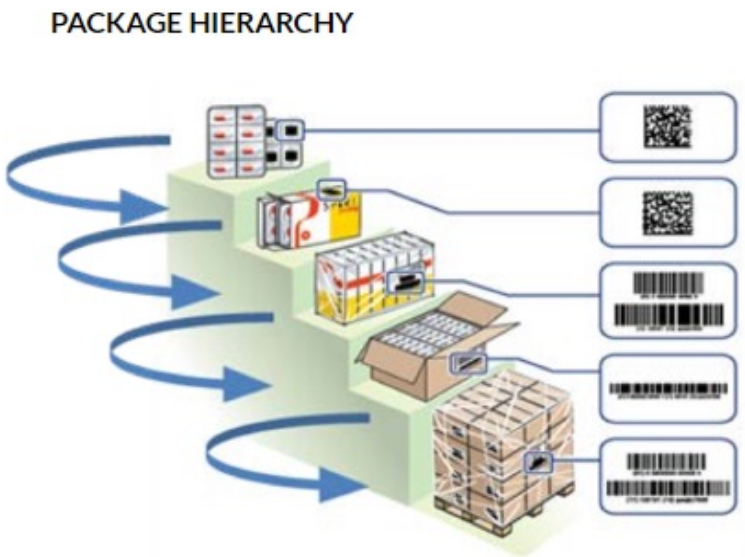
GS1

PCMT and GS1

PCMT supports using GS1 identifiers, sourcing manufacturer data through the GDSN, and mapping GTINs to local identifiers





Product Registry for WHO SMART Guidelines

- Feature development and hosting of PCMT to support country adaptation workflows for SMART Guidelines as core component of the planned SMART Guidelines Exchange Platform including multi-tenant support and synchronization with HL7 FHIR compliant terminology services
- Publication of product master data such as the Global Product Catalog (GPC) and the RHSC Family Planning Catalogue with the capacity to expand to other health areas
- Incorporation of key WHO product catalogues into the hosted PCMT environments
- Incorporating approaches to implementing standardized national product catalogues (NPC) in the digital supply chain architectural approaches handbook, being developed as part of WHO SMART guidelines

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