



The Global Language of Business

Traceability – Global Status – Developments worldwide

2nd African Healthcare conference

Lagos, Wednesday 18 September 2019





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USAID MTaPS: Strengthening Regulatory Systems in Low- and Middle- Income Countries

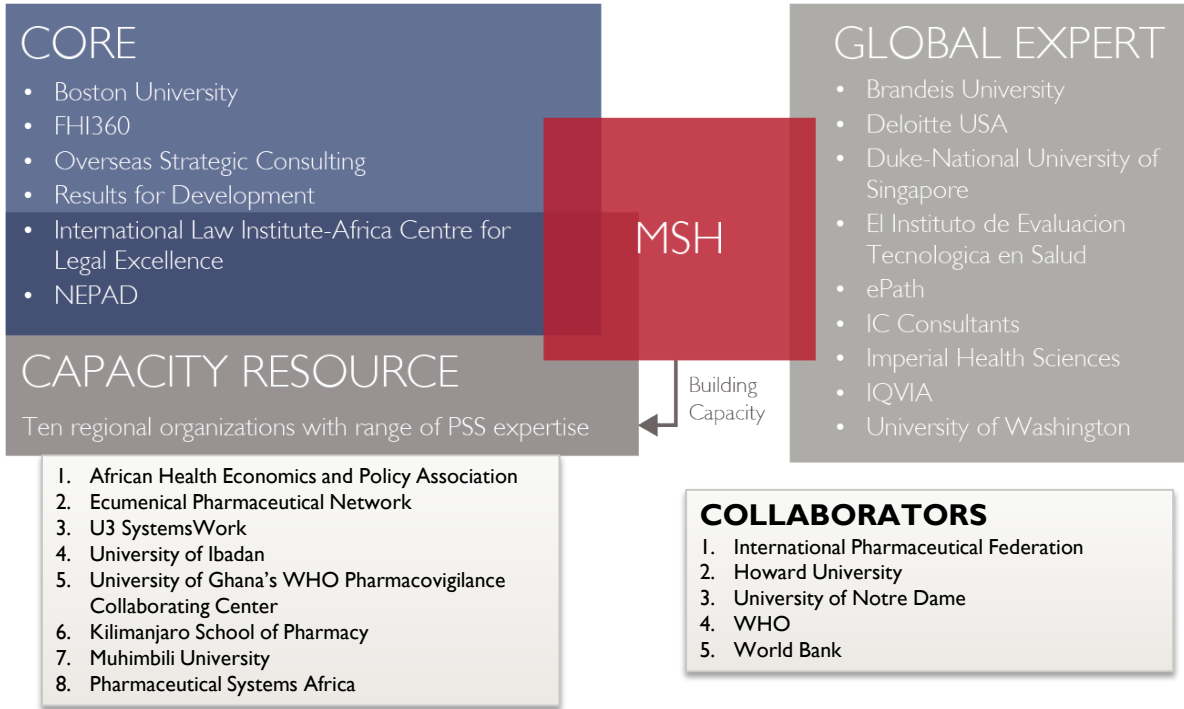
Comfort Ogar, Principal Technical Advisor, MTaPS
2nd African GS1 Healthcare Conference
18 September 2019, Lagos, Nigeria

Program Data

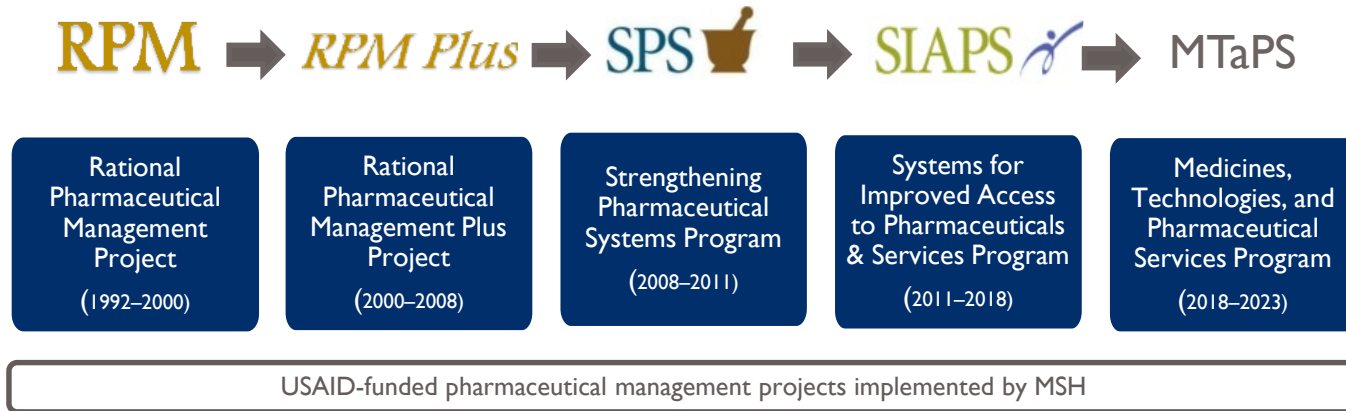
| | |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------|
| Name: | Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program |
| Funding Level: | Ceiling: \$169,706,489 |
| Duration: | 5 years September 20, 2018–September 19, 2023 |
| Place of Performance : | Worldwide The contract will work at the global level but will largely direct its efforts to USAID focus countries |



MTaPS Team



Evolution to MTaPS



Where We Currently Work

- Field Buy-ins

- Afghanistan
- Bangladesh
- Jordan
- Mozambique
- Nepal
- Philippines
- Rwanda
- Asia Regional Bureau

- GHSA Countries

- Burkina Faso
- Cameroon
- Cote d'Ivoire
- DRC
- Ethiopia
- Kenya
- Mali
- Senegal
- Tanzania
- Uganda

MTaPS Goal and Purpose

- **Goal:** enable low- and middle-income countries to strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality assured, and affordable essential medicines and pharmaceutical services.
- **Purpose** provide pharmaceutical system strengthening assistance for sustained improvements in health system performance and to advance USAID's goals of preventing child and maternal deaths, controlling the HIV/AIDS epidemic, and combatting infectious disease threats, as well as expanding essential health coverage.



MTaPS Program Objectives

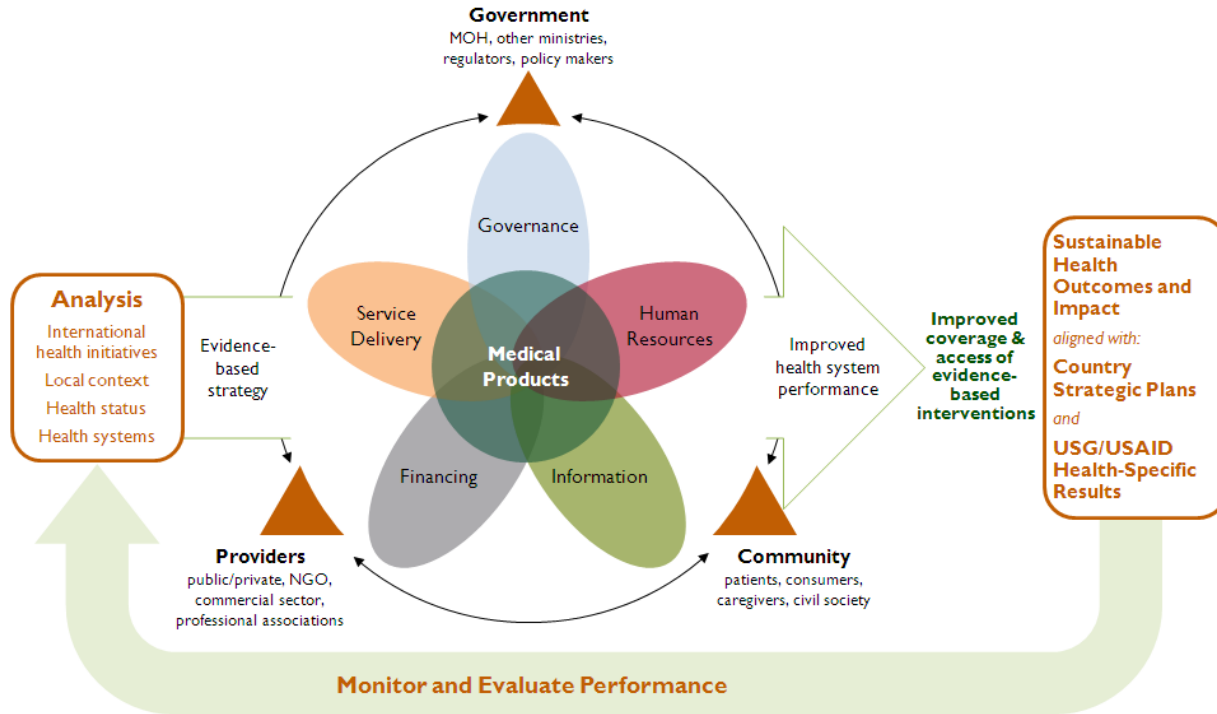
- Pharmaceutical sector **governance** strengthened
- **Institutional and human resource capacity** for pharmaceutical management and services increased, including **regulation** of medical products
- Availability and use of pharmaceutical **information for decision making** increased and global learning agenda advanced
- Pharmaceutical sector **financing**, including resource allocation and use, optimized
- **Pharmaceutical services**, including product availability and patient-centered care to achieve desired health outcomes, improved

MTaPS Guiding Principles

- Utilize a systems strengthening approach
- Optimize allocation and use of resources for medicines and related functions in health systems
- Build on and strengthen existing systems
- Support integration
- Build/strengthen the capacity of local nongovernmental organizations
- Support country-led coordination
- Provide global technical leadership



USAID's Pharmaceutical Systems Strengthening Approach



MTaPS Regulatory System Strengthening (RSS) Approach

MTaPS Regulatory System Strengthening (RSS)

Objectives

- Strengthening regulatory capacity and pharmaceutical-sector governance to protect the public from substandard and falsified products
- Promoting transparency and accountability through appropriate laws, regulations, policies, and standard operating procedures
- Improving human and institutional capacity to manage pharmaceutical regulatory systems and services, including protecting patient safety and slowing the emergence and spread of antimicrobial resistance



MTaPS Key Approaches for RSS (Governance)

- Assist countries to adopt model pharmaceutical legislation, policies, guidelines, and norms or update existing tools
- Help establish mechanisms to ensure oversight and enforcement of policies, laws, and regulations
- Support NMRAs' strategic planning for regulatory system strengthening with a focus on product registration



MTaPS Key Approaches for RSS (Institutional capacity)

- Develop NMRAs' institutional capacity through on-the-job training and knowledge sharing, and assist in establishing certification programs
- Strengthen/develop pharmaceutical regulatory professional and preservice programs in collaboration with MTAps partners Regional Centres of Regulatory Excellence in Africa and the Centre of Regulatory Excellence in Asia
- Support coordination and advocacy efforts for regional harmonization through regional economic communities and platforms like the African Medicines Regulatory Harmonization initiative

MTaPS Key Approaches for RSS (Data for decision)

- Support interoperability of regulatory data among countries through creation of data exchange systems, and use of information solutions such as Pharmadex and PViMS
- Improve pharmacovigilance (PV) systems through increasing reporting of adverse reactions and enhancing use of safety data
- Design active surveillance systems for monitoring new medicines to support the use of high-risk and novel technologies



Building on MTaPS Predecessor Programs

Previous RSS Support to Countries

- Conducted regulatory systems assessments in Angola, Bangladesh, Mozambique, Namibia and Mali
- Provided technical assistance to improve product registration processes in 11 countries
- Assisted NMRAs in 6 countries (Bangladesh, Benin, DRC, Ethiopia, Mozambique, and Namibia) to implement electronic information systems for registration



Previous RSS Support to Regional Initiatives NEPAD/AMRH

- Supported 3 regional regulatory harmonization initiatives to standardize regulatory practices across countries
 - African Medicines Regulatory Harmonization Initiative (AMRH)
 - East African Community (EAC)
 - Economic Community of West Africa States (ECOWAS)
 - PV systems strengthening in the East Africa region
- Development of the African Union Model Law on Medical Products Regulation
 - Selection and development of KPIs for Regional Centers of Regulatory Excellence (RCOREs) to increase Africa's regulatory workforce capacity
 - Development of M&E framework for RCORE activities
 - Participated in critical NEPAD-led meeting in Midrand, South Africa, at which the major players contributed to the reforms and reached consensus on key elements of the new governance framework

How MTaPS can help implement GSI standards

MTaPS RSS country support to implement GSI standards

- Support the drafting of policies, regulations, and/or guidelines that stipulate requirements and timelines for implementation of global standards
- Perform assessments of the market to determine status and adherence to GSI standards
- Analyze regulatory system readiness for GSI adoption and selection of the relevant traceability model
- Support regulatory bodies in strategic planning for adoption, implementation, and use of GSI standards

MTaPS RSS country support to implement GSI standards

- Analyze current stakeholder capabilities to apply standards, for example, suppliers using GSI standards, such as: Global Trade Item Number (GTIN), Serial Shipping Container Code (SSCC), and other standards
- Support implementation of strategies to improve stakeholder capacity, including use of GSI standards software and hardware, ,guidelines, websites, and eLearning courses
- Support steering committees and working groups implementing GSI standards, specifically as it pertains to the structure or terms of reference of the group(s)
- Support public health supply chains through deployment of technology for automated data capture and reporting to improve patient safety and traceability of medicines

MTaPS Regional support - NEPAD/AMRH (MTaPS Core Partner)

- Support efforts on regional regulatory collaboration for harmonized policies, guidelines, and procedures on the use of GSI standards
- Strengthen networks of countries for the exchange of knowledge, expertise, and lessons learned on implementing GSI standards
- Support regional knowledge dissemination and institutional capacity building/strengthening activities

Conclusion

- MTaPS' history and demonstrated capacity in regulatory systems strengthening and its experience in pharmaceutical systems strengthening can be leveraged to advance implementation of global standards in LMICs
- It will support countries and regional efforts to implement GSI standards for pharmaceutical product traceability
- We look forward to working with NMRAs in Africa to strengthen their regulatory systems to implement GSI standards and ensure safety for patients

Thank you



USAID
FROM THE AMERICAN PEOPLE

**MEDICINES, TECHNOLOGIES, AND
PHARMACEUTICAL SERVICES (MTaPS) PROGRAM**

Improved Access. Improved Services. Better Health Outcomes.

FOR MORE INFORMATION

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PHARMACIE



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Regulatory developments around the world

Ulrike Kreysa, Senior Vice President Healthcare, GS1 Global Office
2nd African GS1 Healthcare Conference
18 September 2019, Lagos, Nigeria

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The globally harmonised approach: a serialised secondary pack



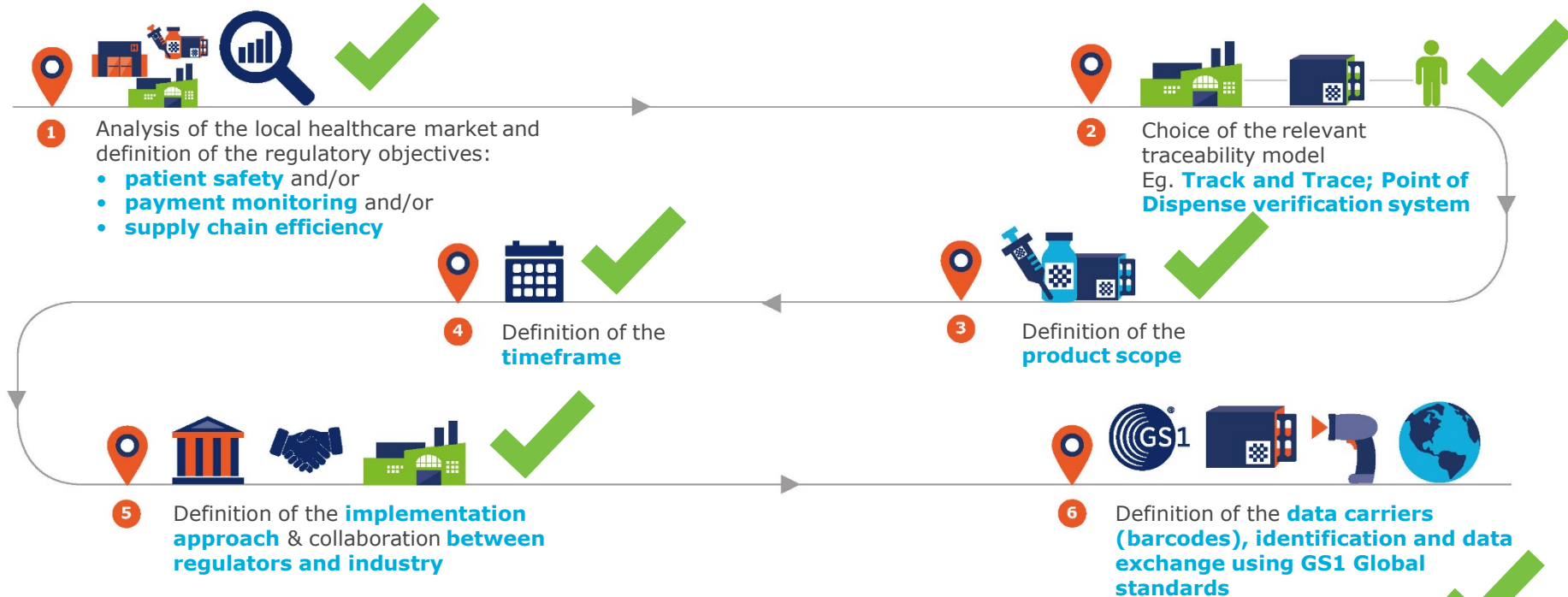
Product Identifier
(GTIN)

Serial Number

Expiry date

Lot/Batch number

The road to medicinal products traceability



www.gs1.org/docs/healthcare/Public-Policy/GS1_Healthcare-ROAD-MAP_FINAL.pdf

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Traceability Standards for Long Lasting Insecticide-treated Nets (LLINs)

Clerisse Lemke, PMI
2nd African GS1 Healthcare Conference
18 September 2019, Lagos, Nigeria

TraceNet

Problem Statement:

LLINs are not directly addressed by existing GS1 standards for healthcare, as they are not a pharmaceutical or medical device. A GS1 global health procurement requirement will enable identification, data capture, and data exchange for LLINs. Lack of this procurement requirement has limited end-to-end LLIN traceability from manufacturer to household resulting in inefficient and less effective distribution and allocation.

Objective:

Establish a feasible and achievable recommendation for a GS1 compliant LLIN identification, labeling, and data exchange requirement(s) with the donor, country, and manufacturer communities to support identification and traceability of LLINs.



Deliverable – Similar guideline but for LLINs

Use Cases



REDUCE INVENTORY
LOSS & DIVERSION



ENABLE REVERSE
LOGISTICS



SUPPORT LLIN
RESEARCH

TraceNet Process

- Biweekly Meetings: Collaborative forum focused on identify, capture and share components of GS1 to create the enabling environment in country for greater traceability of LLINs

| | |
|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Chairs</p> |  <p>The Global Fund</p> <p>USAID FROM THE AMERICAN PEOPLE</p> <p>CDC</p> <p>U.S. President's Malaria Initiative</p> |
| <p>Coordinator</p> | <p>USAID Global Health Supply Chain Program Procurement and Supply Management</p> |
| <p>Members</p> | <p>LLIN Manufacturers, USAID GHSC-PSM Country Directors, USAID GHSC Technical Staff, GS1, Innovative Vector Control Consortium</p> |



Outstanding Questions

- What is the demand for serialization?
- Are bales a trade item?
- What are the identifiers required on the individual net vs the bag?
- Additional use cases?

- And more we haven't thought of...



We appreciate feedback!

Contacts:

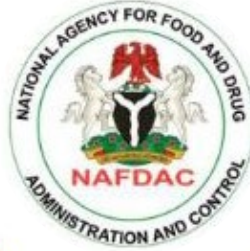
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Thank you!



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Be sure to complete each feedback form!



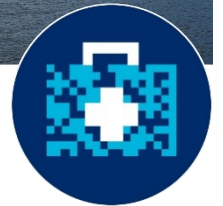
For every feedback form completed, we will donate 5USD to the chosen conference charity **"The North East Children Trust"**

<https://healthcare-nigeria.gs1.org/>



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COFFEE BREAK



Afternoon at a glance



| Wednesday 18 September 2019 | | |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| 13:10-14:15 | General Networking lunch & visit of marketplace | |
| 14:15-15:45 | Two parallel streams | |
| | Stream I – Government and regulatory body Think Tank – Discussing the possibility of regulatory alignment across Africa | Stream II – Traceability – global status – developments worldwide |
| 15:45-16:15 | Coffee break | |
| 16:15-17:45 | Two parallel streams | |
| | Stream I – Government and regulatory body Think Tank – Discussing the possibility of regulatory alignment across Africa | Stream II – Data as the base for supply chain |

Networking event at The Civic Centre tonight at 19:00



The Civic Centre

Ozumba Mbadiwe Avenue
Opposite 1004, Victoria Island
Lagos, Nigeria

PLEASE WEAR YOUR EVENT BADGE 😊

Bus departure: meet in the main hotel lobby at 19:00 sharp!

Bus return: beginning at 21:30 shuttle buses will take you back to the EKO Hotel

Dress code: Business casual

