



SUPPLIER SUMMIT

**USAID Global Health
Supply Chain Program
Supplier Summit**
February 21-23, 2017

MALARIA RAPID DIAGNOSTIC TESTS (RDTs)



USAID
FROM THE AMERICAN PEOPLE



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



USAID
FROM THE AMERICAN PEOPLE



U.S. President's Malaria Initiative

PROGRAM OVERVIEW: PRESIDENT'S MALARIA INITIATIVE GHSC-PSM TASK ORDER 2



U.S. PRESIDENT'S MALARIA INITIATIVE (PMI)

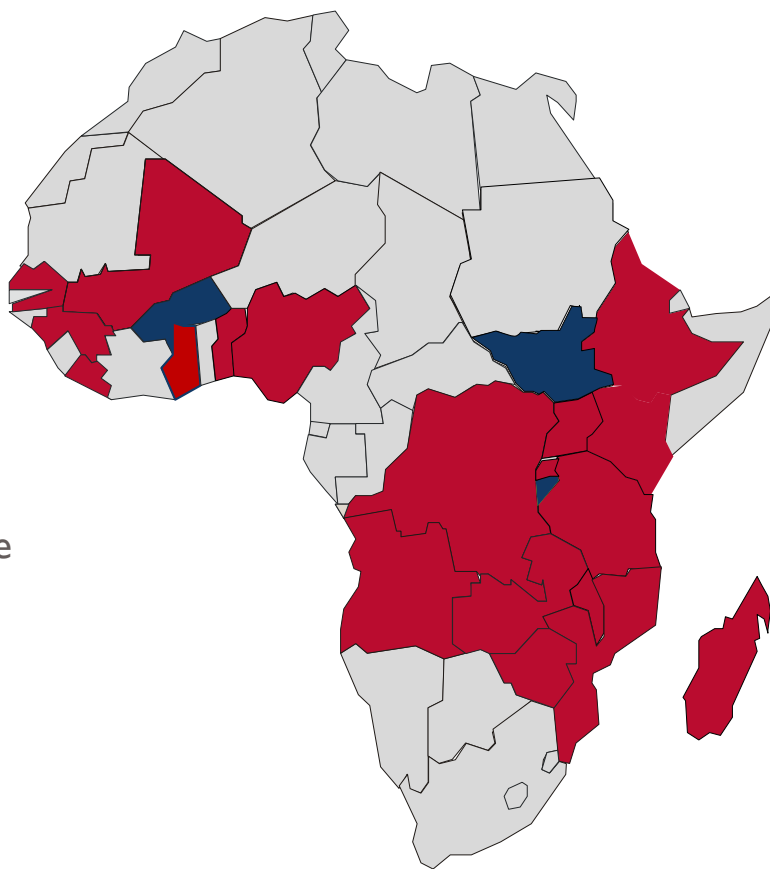
Work with PMI-supported countries and partners to further reduce malaria deaths and substantially decrease malaria morbidity towards the long-term goal of elimination

PMI'S OBJECTIVES

- Objective 1
 - Reduce malaria mortality by one-third from 2015 levels in PMI supported countries, achieving a greater than 80% reduction from PMI's original baseline levels
- Objective 2
 - Reduce malaria morbidity in PMI supported countries by 40% from 2015 levels
- Objective 3
 - Assist at least five PMI supported countries to meet the WHO criteria for national or sub-national pre-elimination

CURRENT PMI FOCUS COUNTRIES

- Angola
- Benin
- DRC
- Ethiopia
- Ghana
- Guinea
- Kenya
- Liberia
- Madagascar
- Malawi
- Mali
- Mozambique
- Nigeria
- Rwanda
- Senegal
- Tanzania
- Uganda
- Zambia
- Zimbabwe



- Burkina Faso*
- Burundi*
- South Sudan*

- Burma
- Cambodia
- Thailand/Regional



*non-presence countries

MALARIA OPERATIONAL PLANS (MOPs)

- One-year costed implementation plans for PMI Focus Countries
- Country led!
- MOPs review current status of malaria control and prevention policies and interventions; also identifies challenges and unmet needs to achieve NMCP national goals, and provides a description of planned PMI-funded activities
- Each MOP has been endorsed by the U.S. Global Malaria Coordinator and reflects collaborative discussions with the national malaria control programs and partners in country
- Standardized formats – primary focus for external partners are tables 1 & 2
- Available publically on the PMI website
 - <https://www.pmi.gov>
- Jennifer / Alexis to add bullet on gap analysis?



MOP TIMELINE

Month	Activity
Feb. – Jun. 2016	FY17 MOP development visits (writing the MOP)
Apr. – Aug. 2016	FY17 MOP HQ review & revision
Oct. 2016	MOP approval after IAG convene (posted online by November)
Mar. – Jun. 2017	FY18 MOP development visit (time to write the MOP again) FY17 MOP reprogramming (revised table 2 posted on-line) -Add/remove activities -Change activities: implementing partner, budget or scope -Program additional funding
May – Jul. 2017	Start placing commodity orders outlined in FY17 MOP
Sep. 2017 +	FY17 funding available
Oct. 2017 – Sep. 2018	Implement activities in FY17 MOP (for orders to arrive in CY 2018)

For more information on how the MOPs are incorporated into supply plans, please attend the breakout session on “Global Forecasting and Supply Planning”

MALARIA RDTs

Malaria RDTs contribute to the reduction of malaria morbidity and mortality by :

- Assisting with the diagnosis of malaria by detecting evidence of malaria parasites in human blood.
- Allowing the rapid and accurate detection of malaria infections in remote areas
- Facilitating the rational use of anti-malaria drugs



MOST COMMON RDTs ORDERED BY USAID PROGRAMS

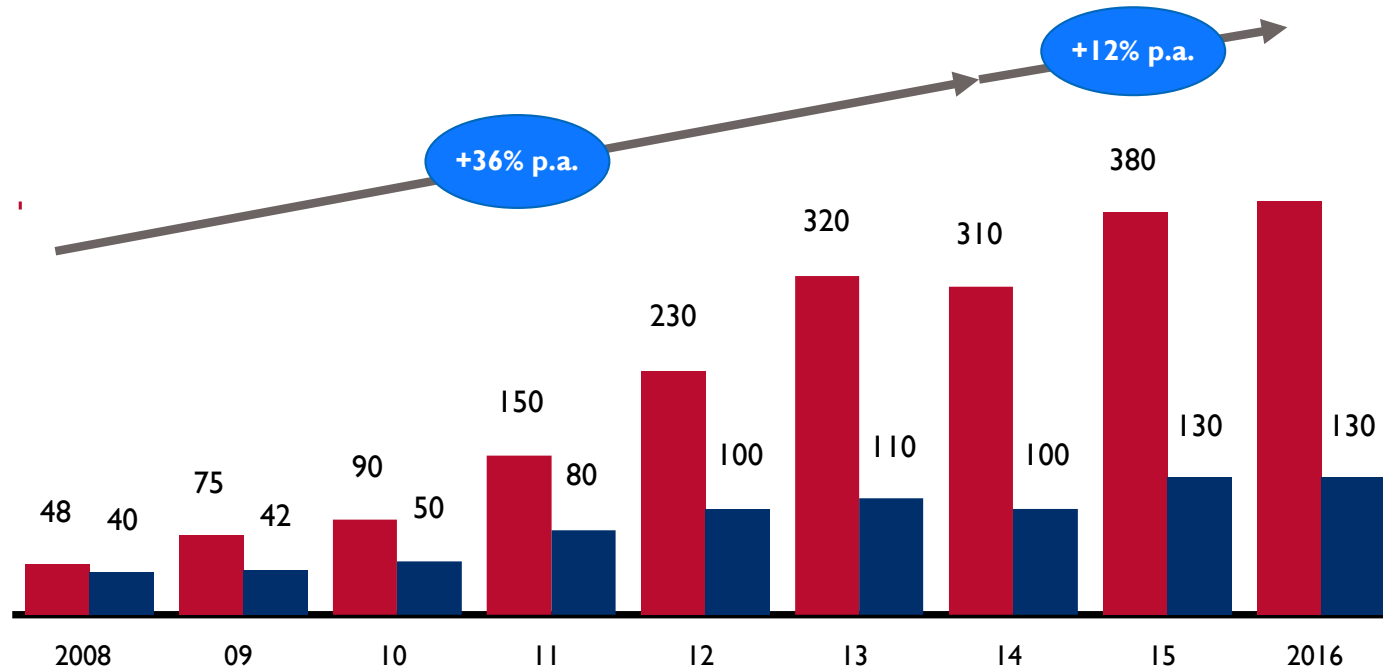
- HRP2 (P. falciparum)
- HRP2 and aldolase (distinguishing P. falciparum / mixed infection from non-falciparum alone)
- Falciparum-specific LDH and pan-specific LDU (distinguishing P. falciparum mixed infection from non-falciparum alone)
- HRP2 and pan-specific LDH
- HRP2, pan-specific pLDH and vivax-specific pLDH OR pan-specific aldolase only

RDT DEMAND FORECASTING

2016 GLOBAL MALARIA RDT MARKET SIZE ~390M UNITS

Global Malaria RDT market size and value over time
Million units, \$Million

■ RDTs sold
■ RDT market value



Key considerations

- After 2010, market **grew rapidly** due to **WHO recommendation to test all patients** with suspected malaria
- 2008 – 14 saw aggressive volume growth at **36% CAGR**
- Growth is **concentrated in Africa** with 46% CAGR (2012-2014)
- Growth has slowed in recent years** (2013-16, 12% CAGR); 2016 market ~390M units

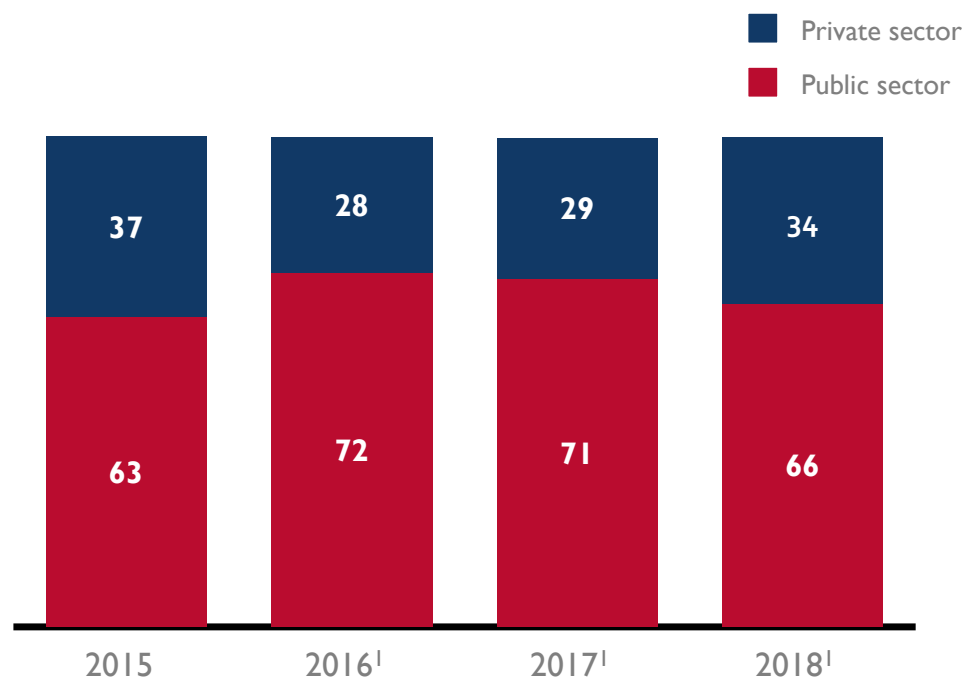
SOURCE: 2015 WHO Product Testing Programme review, 2016 UNITAIDS Malaria RDT technology landscape, team analysis

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PUBLIC SECTOR ACCOUNTS FOR APPROXIMATELY 60-70% OF GLOBAL MALARIA RDT PROCUREMENT

% Public and private channel RDT procurement
2015-18, % Volume



Key considerations

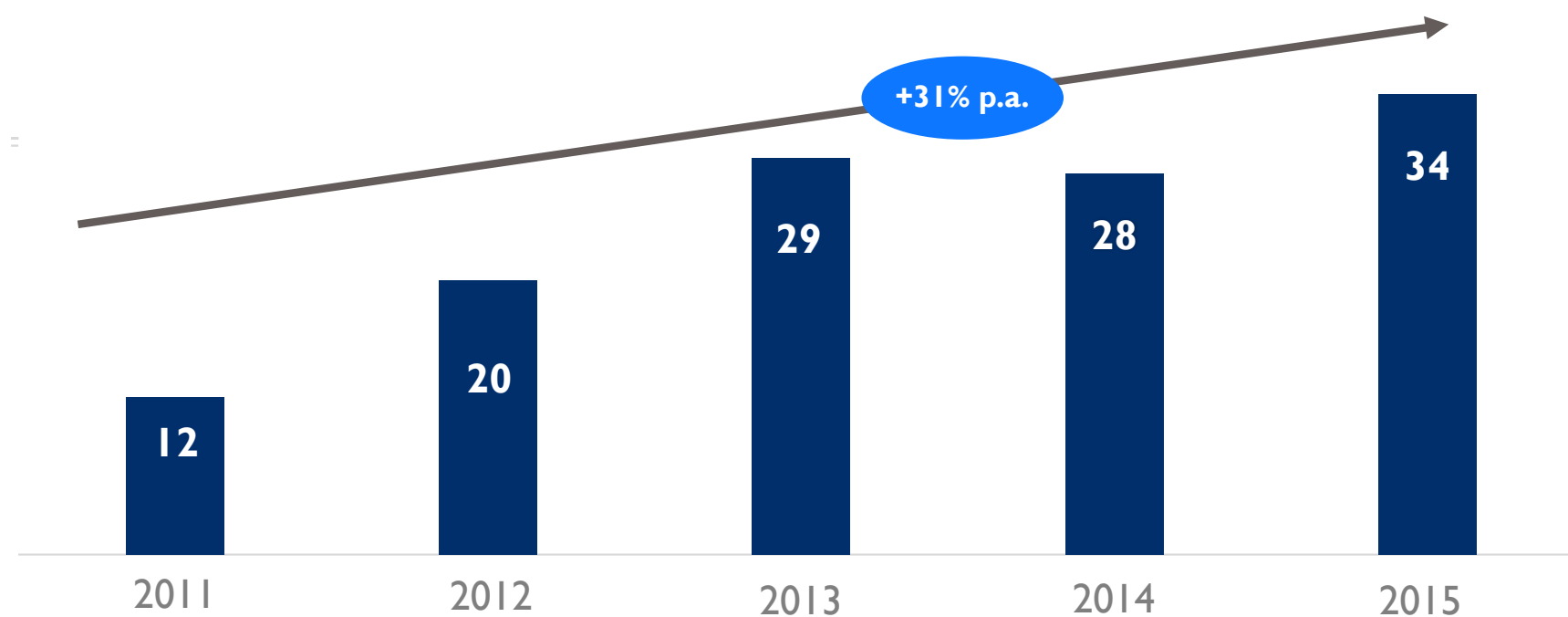
- Public and private channel breakdown expected to remain **relatively constant in the next few years** (70% public sector)
- Moderate growth in public RDT procurement from 2015 -16 largely **driven by increased planned procurement in the public sector**, primarily in Africa
- USAID makes up ~35% of public sector procurement** and ~50% of donor market

^I 2016 December volume projected; 2017 and 2018 breakdown based on demand forecasts

SOURCE: 2015 Global Malaria Diagnostic and Artemisinin Treatment Commodities Demand Forecast

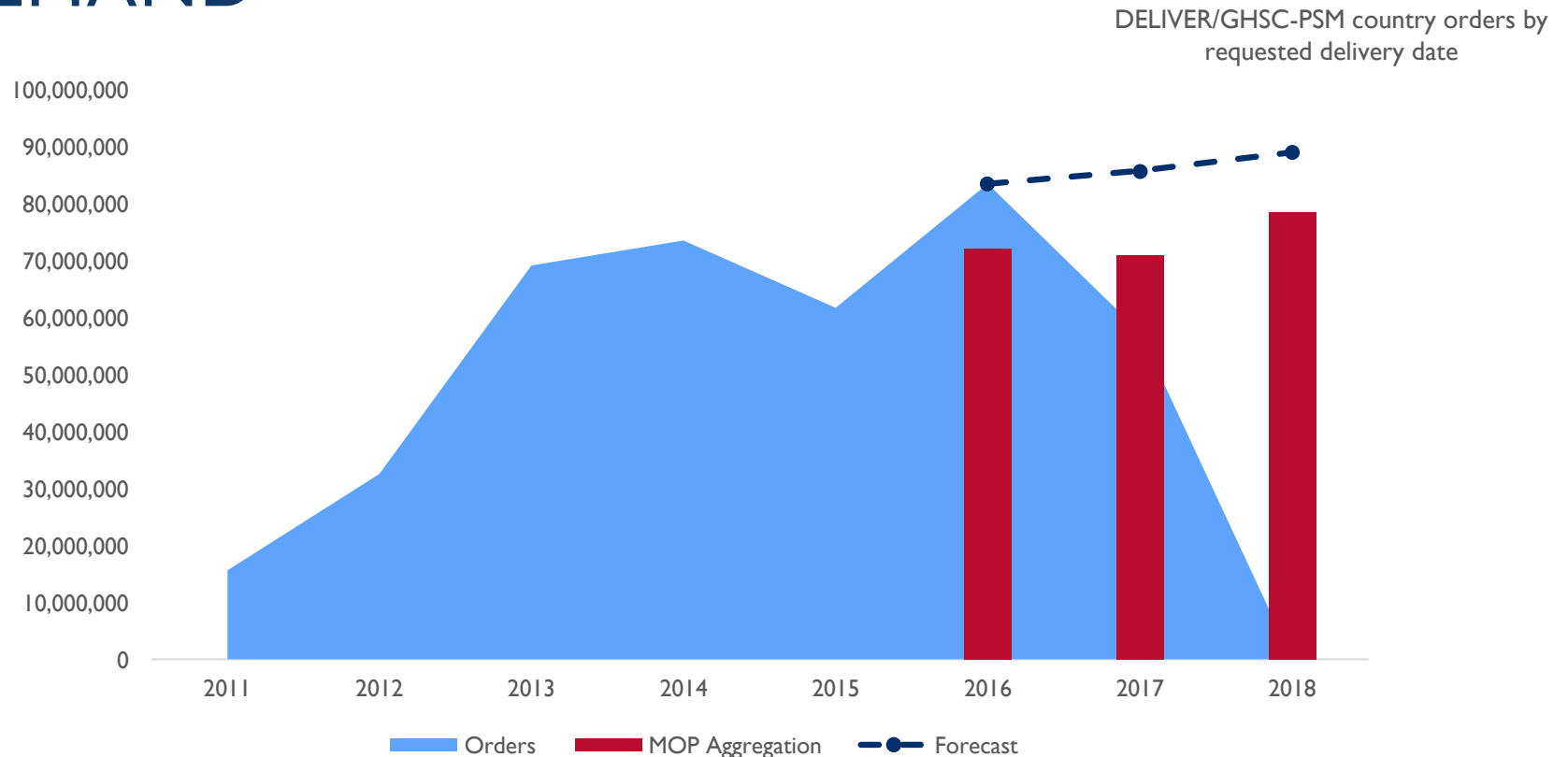
USAID SPENDING ON RDTs HAS TRIPLED OVER THE LAST 5 YEARS IN RESPONSE TO INCREASED DEMAND

USAID Spending On Malaria Rdt's Over Time
2011-15, Spend In \$M



| SOURCE: Internally reported PMI transactions, 2016 UNITAIDS Malaria RDT technology landscape

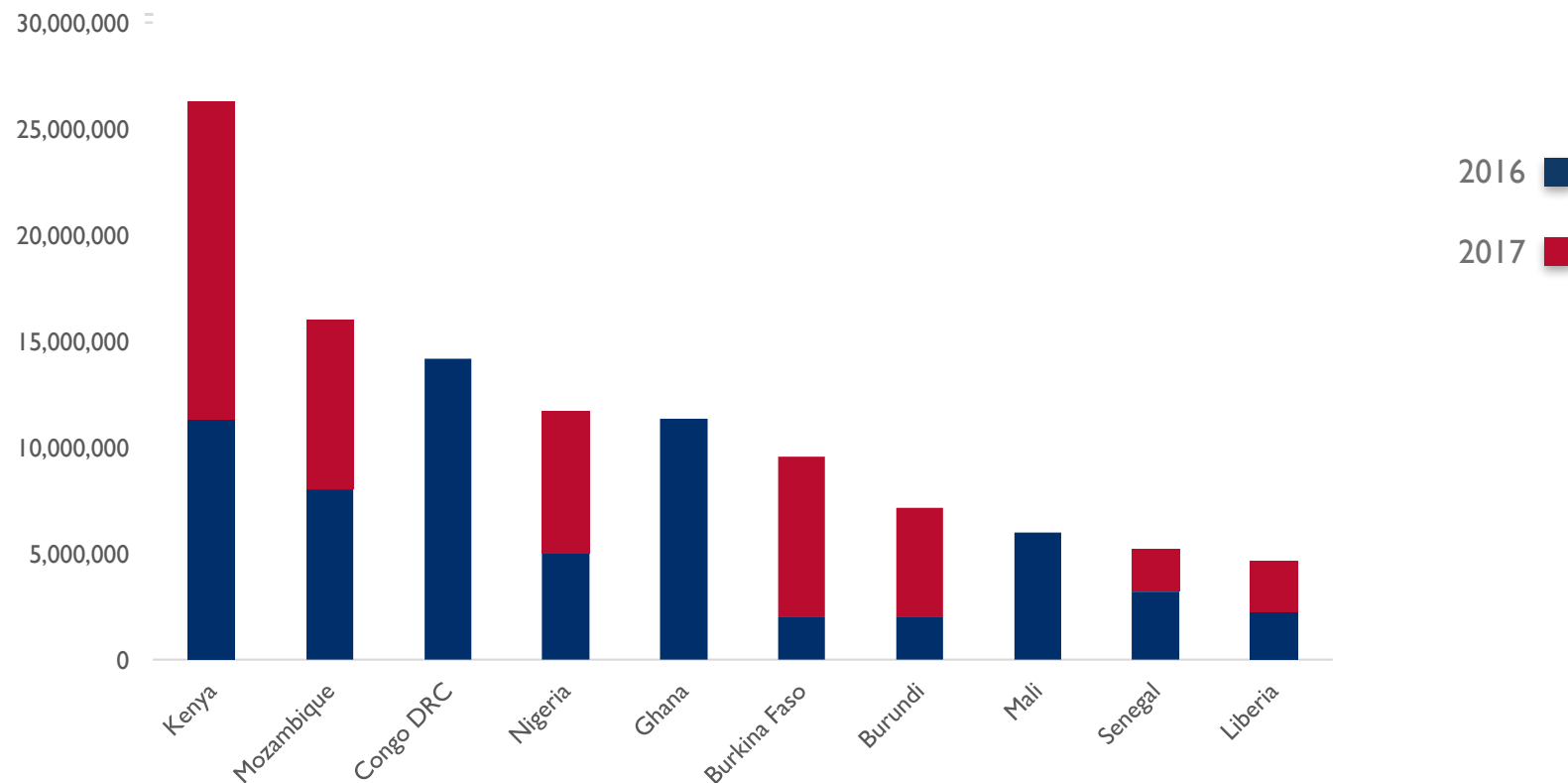
USAID HISTORICAL ORDERS & FORECASTED DEMAND



- For 2016 and 2017 orders to date, the top 10 procuring countries account for approximately 80% of the total RDT orders
- Procurements requested for 2017 have exceeded 63% of total MOP aggregation, excluding Burundi and Burkina Faso, where MOPs are not currently available

TOP 10 USAID COUNTRIES BY VOLUME 2016-2017

DELIVER/GHSC-PSM country orders by
requested delivery date



GHSC-PSM SOURCING STRATEGY FOR MALARIA (RDTs)

CONSIDERATIONS FOR EFFECTIVE RDT PROCUREMENT

- Quality-assured
- Adequate Shelf Life
- On-time Delivery
- Affordability/Funding
- Stock Availability
- Supply Reliability



SOURCING STRATEGY

Current State

- IDIQs (March/April 2017) with pre-selected RDT manufacturers.
 - Evaluate bids with AQSCIR-P methodology
 - Award subcontract
 - Conduct simplified Request for Quotations to receive best prices, registration status, lead time, etc.

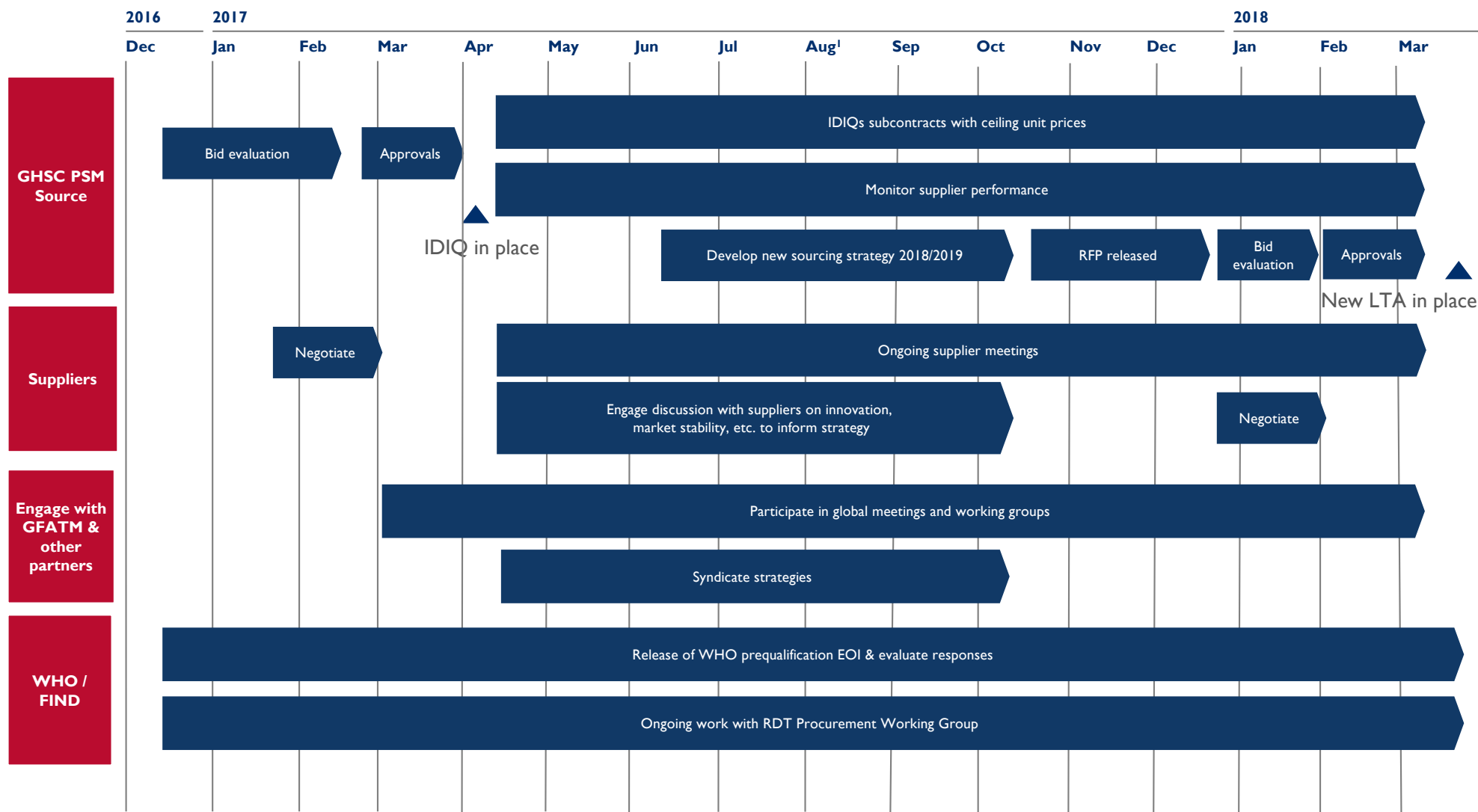


MID-TERM TENDERING APPROACH FOR RDTs PROCUREMENT

	2015-2016	2017	Considerations for 2018
Tendering Mechanism	100% spot	100% Long-term agreements (IDIQs)	100% Long-term agreements (IDIQs); exploring alternatives (e.g. – volume allocations)
Price Structure	Ceiling	Ceiling	Exploring fixed price vs ceiling price
Number of Suppliers	6 suppliers	6 suppliers	TBD suppliers

RDT SOURCING CALENDAR

For informational purposes only; subject to change



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GHSC-PSM EVALUATION CRITERIA

EVALUATION CRITERIA (AQSCIR-P)

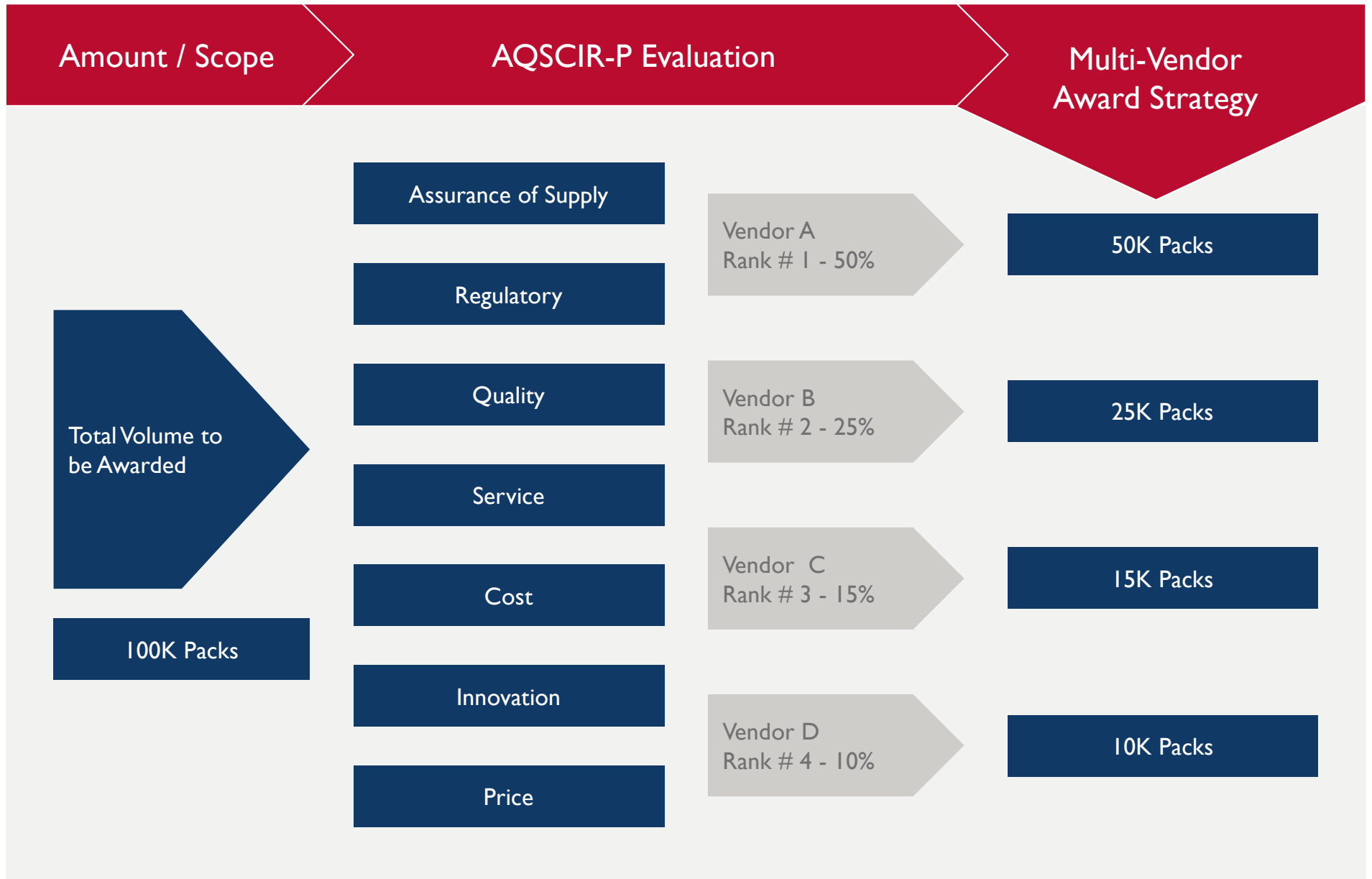
EXAMPLES

Assurance of Supply	<ul style="list-style-type: none">• Production capacity• Quantity in stock (when required)• Past performance
Regulatory	<ul style="list-style-type: none">• Administrative requirements• Registration in country
Quality	<ul style="list-style-type: none">• QA requirements (USFDA, WHO, GHSC-QA)• Shelf life• Stability studies / climatic zone standards
Service	<ul style="list-style-type: none">• Lead time (stock, fresh production)• Customer service• Product Identification
Cost	<ul style="list-style-type: none">• Specific / Unique label language• Unique Distribution requirements
Innovation	<ul style="list-style-type: none">• Serialization• Packaging optimization• New /improved products
Price	<ul style="list-style-type: none">• FCA Unit price

Criteria and %
Weights are
tailored to the
Commodity
and/or Product
and Specific
Sourcing
Strategy

BEST VALUE AWARD STRATEGY TO ACHIEVE DESIRED MARKET OUTCOME

GHSC-PSM APPROACH FOR MULTI-VENDORS AWARD



MALARIA RDTs QUALITY ASSURANCE (QA) OVERVIEW

MALARIA QA/QC REQUIREMENTS FOR RDTs

Commodity	QA Eligibility Requirements
RDTs	<ul style="list-style-type: none">• The <i>P.falciparum</i> panel detection score at least 75% at 200 parasites μl.• The <i>P.vivax</i>, panel detection score at least 75% at 200 parasites μl.• The false-positive rate should be less than 10%.• The invalid rate should be less than 5%.

Commodity	QC Requirement
RDTs	<ul style="list-style-type: none">• Each batch:<ul style="list-style-type: none">- Pre-shipment

MALARIA QA INTERACTION IN PROCUREMENT PROCESS

Establish List of Pre-selected Suppliers

- Clear eligibility criteria in solicitation
- Receive supplier bids, including dossier
- Recommendation based on evaluation of quality proposal

Tender to List of Pre-selected Suppliers or One-off Procurements

- Use of standard QA requirements and terms and conditions

Execute QC Requirements

- Pre-shipment testing on each batch

WHO PREQUALIFICATION

Revision to WHO Recommendations for Malaria RDT Procurement¹

Following on changes to WHO procedures for malaria RDT procurement eligibility announced in May 2016, participation in the product testing scheme also requires an application to the WHO Prequalification of in vitro diagnostics programme. In addition to responding to this Expression of Interest and submitting a product for evaluation in Round 8, participants will be required:

- to fill a WHO prequalification pre-submission form,
- to complete a product dossier,
- to submit to a manufacture site inspection, and
- to pay the associated fees.*

¹ <http://www.who.int/malaria/news/2016/rdt-call-for-testing-round8/en/>

QA CASE STUDY: BUFFER SOLUTION EVAPORATION

- QA controls for buffer solution remain a priority
 - RDTs vulnerable to high temperatures and humidity
 - The stability of individual single-use buffer vials had evaporated after 18 month stability testing at 37°C

WHO advice on action to be taken by manufacturers:

- To source and validate new buffer vial material, including accelerated stability testing at varying temperatures and humidity.
- To consider production of smaller kit configurations e.g. 5 or 10 RDTs per box, and containing a multi-use buffer bottle.

GHSC-PSM STRATEGIC PRIORITIES



STRATEGIC PRIORITIES OVERVIEW

- Support healthy market development
- Ensure product registration (where required)
- Vendor managed inventory
- Implement global standards for product identification

RDTs IDEAL FUTURE MARKET

Dimensions

Ideal 12-18 month outlook

Global capacity	<ul style="list-style-type: none">▪ Continued high quality production capacity to meet private and public demand
Affordability & funding	<ul style="list-style-type: none">▪ Consolidation of pricing ranges across countries requiring similar products▪ Payment of fair price that takes into account sustainable supplier margins and ensures quality and rewards innovation
Supply risk	<ul style="list-style-type: none">▪ Sustainable prices and margins in public sector market across major procurers to secure longer term supply security and innovation▪ Increase in supplier diversity (4-5 high quality, responsive suppliers)
Product quality & appropriateness	<ul style="list-style-type: none">▪ 2+ major suppliers investing in RDT innovation, including G6PD testing, HRP2 deletion, increased sensitivity, cheaper manufacturing methods or medical technologies▪ Effective WHO process transition; continued investment in RDT quality standards at field level

ENSURE PRODUCT REGISTRATION

- Not all countries require RDTs to be registered
- Where registration is required, we seek 2+ suppliers with valid registrations
- PMI focus countries that require registration:

- | | |
|--------------|------------|
| ✓ Ethiopia | ✓ Nigeria |
| ✓ Ghana | ✓ Tanzania |
| ✓ Madagascar | ✓ Uganda |
| ✓ Malawi | ✓ Zambia |



VENDOR MANAGED INVENTORY

- Benefits of VMI
 - Reduction in one-off purchase orders
 - Can replenish based on inventory levels = fewer stockouts and less inventory
 - Reduced product production lead time
 - No transit to 3rd party warehouse
 - No repacking/relabeling
 - Increased product shelf life upon delivery



ADOPTION OF GLOBAL STANDARDS FOR IDENTIFICATION, DATA CAPTURE, AND EXCHANGE

- Implement global standards for:
 - Product and location identification
 - Packaging, presentation, and data capture
 - Data exchange of orders, shipment status and delivery notification
- Goal is to achieve:
 - End to end data visibility
 - Supply chain efficiency
 - Supply chain security

For more information, we suggest you attend the following sessions:

- Implementation of GSI Global Standards for Product Identification
- Data Exchange with GHSC

RESOURCES AND RECOMMENDATIONS

RESOURCES

- WHO Prequalification Expression of Interest
- USAID ADS Chapter 312 on Restricted Commodities
- U.S. President's Malaria Initiative
- Malaria Operational Plans (MOPs)

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The USAID Global Health Supply Chain-Procurement and Supply Management project provides commodity procurement and logistics services, strengthens supply chain systems, and promotes commodity security. We support USAID programs and Presidential Initiatives in Africa, Asia, Latin America, and the Caribbean, focusing on HIV/AIDS, malaria, and population and reproductive health commodities.

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