

Demystifying service-level agreements for molecular-based testing: a VL/EID PEPFAR experience

ASLM August 15, 2024





Agenda

1. Background and common challenges in the HIV viral load testing space
2. Evolution of PEPFAR's all-inclusive reagent rental model
3. What is a Service-Level Agreement? Key elements of PEPFAR's global SLAs
4. Achievements, lessons learned, and recommendations for implementation of SLAs
5. Next steps and upcoming sessions for the ASLM Lab CoP



Objectives today

- We will share our experience on how we conducted two global tenders (RFPs) among primary diagnostics suppliers on behalf of PEPFAR and negotiated global SLAs.
- We will also share our lessons learned and our expertise acquired during the implementation of these contracts globally and at country levels.
- We hope it will help you accelerate SLA adoption and supplier performance management with your manufacturers and distribution partners.

Background

Background

- Improving price transparency and service performance and building a healthy supplier market was key for PEPFAR to transform molecular laboratory testing and provide cost effective and efficient services for better health outcomes.
- In 2019, acting on behalf of PEPFAR, GHSC-PSM project conducted a first global viral load (VL) and early infant diagnosis (EID) RFP (so-called Wave-1 Global RFP) that established a global price for reagents and consumables, and all-inclusive pricing for high-throughput, lab-based HIV viral load and early infant diagnosis testing in the six highest volume PEPFAR-supported countries.
- In 2023, GHSC-PSM concluded the Wave-2 of the Global VL & EID RFP, which extended the all-inclusive reagent rental approach to an additional 42 PEPFAR-supported countries through global service-level agreements (SLAs) with three major global manufacturers (Abbott, Hologic and Roche).
- The all-inclusive pricing and service terms for VL/EID testing are now available to all buyers with PEPFAR funds.
- The arrangement includes reagents and consumables required to conduct a VL/EID test; diagnostic instrument lease, installation, and removal; end-user initial and on-going training; maintenance of instruments; supply chain services; and instrument remote connectivity and data reporting.
- Benefits of SLAs include standardization of services and contract terms across procurement agencies and donors; harmonized mechanisms to manage suppliers' performance; and potential financial savings.

The focus of PEPFAR efforts on establishing the all-inclusive reagent rental model has been on HIV VL/EID testing in high-throughput laboratories (Process 1)

Process 1. At a national or regional lab, on a high-throughput instrument



Patient blood sample taken at a clinic or hospital



Sample transported to a national or regional lab



Lab conducts the test in parallel with tens or hundreds of other samples



Result is reported back to patient, and doctor may adjust treatment if needed

Process 2. At a clinic, on a point-of-care instrument



Patient blood sample taken at a clinic or hospital



Test is conducted individually on-site (90+ mins)

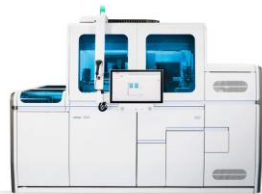


Result is reported back to patient (potentially in same visit), and doctor may adjust treatment if needed

Roughly 90-95% of testing in PEPFAR-supported countries is done in labs. The all-inclusive reagent rental model has therefore been **focusing on the market for lab-based testing**

In this market, suppliers provide instruments, reagents and consumables for running tests, and support services (e.g., maintenance, training, data connectivity)

Instruments



Typically encountered problems with the management of VL/EID testing programs

- No national strategy for VL procurement. Laboratories procure reagents through fragmented system
- Reagents and consumables stocked out
- Capital procurement with equipment without lasting service contracts
- No standard national plan for equipment maintenance or contract for it resulting in backlogs due to equipment downtimes
- While a maintenance contract is in place, there is no mechanism for enforcing it or monitoring actual performance by service providers
- Too many instruments (excess capacity) or inefficient utilization

We understand that many of ASLM's Lab CoP countries face the same problems with supply chain and equipment maintenance as PEPFAR used to have

Summary of Self-Assessment on VL testing among ASLM Lab CoP member states (2019-2022)* shows that SCM and equipment maintenance areas have the lowest level of maturity (75% of respondents described them as foundational or low)

Table 1: HIV Viral Load Testing Cascade Self-Assessment Scorecard

	Country 1	Country 2	Country 3	Country 4	Country 5	Country 6	Country 7	Country 8	Country 9	Country 10	Country 11	Country 12	Country 13	Country 14	Country 15	Country 16	Country 17
Domain																	
Demand Creation for HIV VL testing	3	4	3	2	3	3	3	3	3	4	1	4	3	4	4	4	4
Specimen Collection and Processing	2	3	3	2	3	1	1	1	3	1	1	3	3	4	4	3	3
Sample Transportation	2	3	2	2	3	1	2	2	1	1	1	3	3	3	4	2	3
HIV VL Testing	4	3	1	2	4	2	1	2	2	1	1	2	3	2	4	2	4
Waste Management and Biosafety	3	3	2	3	4	3	2	3	2	1	1	2	2	1	4	1	2
Supply Chain Management and Equipment Maintenance	2	2	1	2	2	2	2	3	2	1	1	3	3	2	3	2	2
Results Utilization	3	2	1	2	3	1	2	2	3	1	1	3	3	3	3	3	4
Leadership and Management	3	4	3	3	4	4	4	3	4	2	2	4	4	4	4	4	4

Key: Four progressive levels of scores of maturity of the system (domain)

■ 1 (foundation level) ■ 2 ■ 3 ■ 4 (fully matured)

Some countries require more dedicated TA

*Adopted from the 6th Annual Lab CoP meeting report, October 11-13, 2022

Evolution of PEPFAR's all-inclusive reagent rental model

Faced with the critical challenges in the VL testing space, PEPFAR adopted an innovative approach to strategic procurement of commodities and services – the All-Inclusive Reagent Rental Model, which led to establishing SLAs with global suppliers



Challenges

Lack of all-inclusive service packages

No formal supplier contracts and service levels

Lack of data transparency

High variations in pricing



Strategies used in the Global RFPs for VL and EID testing

Developed standardized, **all-inclusive service package** for suppliers to bid on for all countries

Established **standardized service agreements** and KPI tracking, with regular supplier performance dialogues

Made **suppliers contractually accountable** for their distributors' performance

Required suppliers to **enable automated reporting** of operational data from all instruments

Aggregated PEPFAR spend to maximize buying power

Leveraged new entrant (Hologic) to promote competition

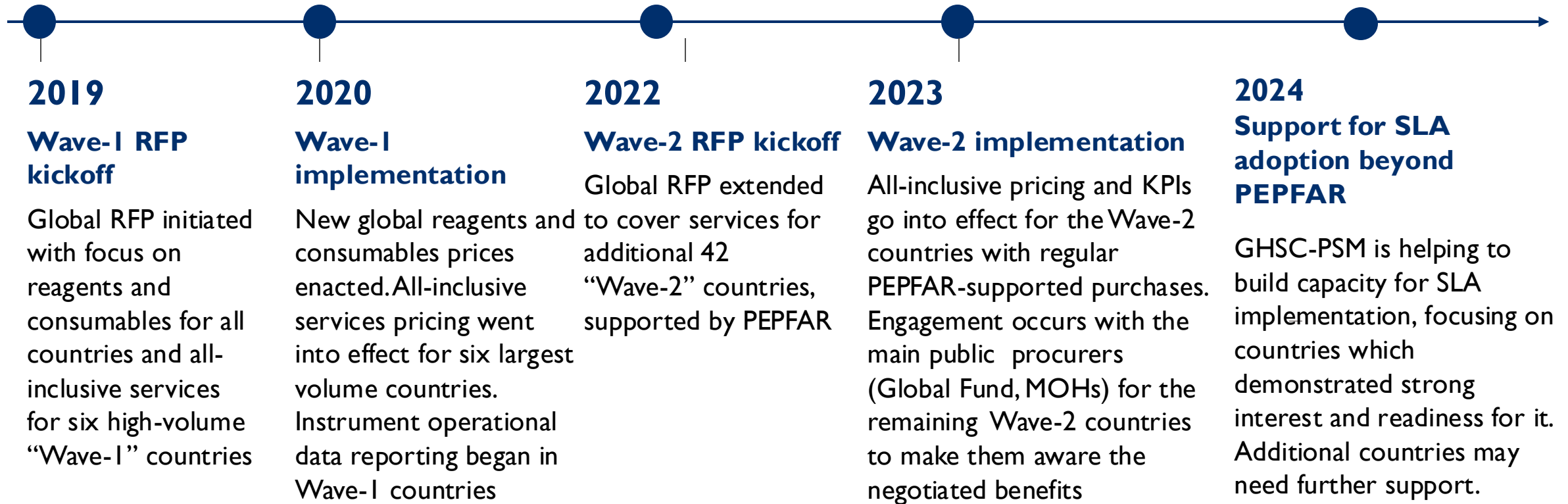
Restructured global pricing approach:

- Global price for reagents & consumables by supplier
- All-inclusive pricing per test
- Price transparency for individual country services
- Volume-based discounts

Problems with supply chain management and equipment maintenance can be tackled through these interventions:

Problem	Solution
Capital procurements and equipment graveyards	> Instrument leasing instead of outright purchase, and upgrading of older equipment
Too many instruments (excess capacity) or inefficient utilization	> Minimum utilization requirements on instruments > Integration of testing – expansion to other disease areas
Provision of commodities only	> Provision of commodities and services to include cost per patient test for reagents, consumables, controls and some wastage
Instruments with prolonged downtime and overdue maintenance	> Maintenance terms and KPIs for performance monitoring and accountability
Reagents and consumables stocked out	> Shifting more responsibility to vendor via different incoterms and/or vendor managed inventory
Data systems not available or with limited integration. Long TAT of results return	> Holistic approaches to data ecosystems: interfaces between health information systems, laboratory information systems, instruments, use of KPIs and other data for decision making

Evolution of PEPFAR’s global SLAs: The timeline



Now, nearly 50 countries are included in the PEPFAR Global Viral Load Initiative

 **28 countries in Africa**

 Cameroon	 Angola	 Botswana	 Kenya
 Cote d'Ivoire	 Benin	 Burundi	 Moz.
 DRC	 Burkina Faso	 Namibia	 Nigeria
 Eswatini	 Ghana	 Senegal	 Uganda
 Ethiopia	 Liberia	 South Sudan	 Zambia
 Lesotho	 Malawi	 Togo	 Tanzania
 Rwanda	 Mali	 Sierra Leone	 Zimbabwe

 **10 countries in Latin America & Caribbean**

 Haiti	 Guatemala
 Bahamas	 Guyana
 Brazil	 Nicaragua
 El Salvador	 Panama
 Honduras	 Jamaica

 **10 countries in Asia & Europe**

 Cambodia	 Philippines
 India	 Thailand
 Indonesia	 Ukraine
 Kazakhstan	 Vietnam
 Nepal	 Papua New Guinea

What is included in the PEPFAR's SLAs?

What is an SLA? It's not a new concept

- A Service Level Agreement (or SLA) is a **contract** between a service provider/vendor (*in this case, **the Supplier***) and an organization (*in this case, **GHSC-PSM***) that ensures both parties abide by defined conditions they are both obligated to meet.
- The establishment of an SLA between a buyer and a vendor provides a **platform** that sets-up the **service terms** of the contract and establishes **standardized evaluation criteria** by which the buyer can assess the performance of the vendor.
- PEPFAR's SLA is designed as an Annex to a standalone supply framework agreement, such as a Basic Ordering Agreement

BOA vs. SLA: main differences in purpose and content

Basic Order Agreement (BOA)

- Period of agreement
- List of products falling under the agreement
- Packing & Shipment packaging requirements
- Delivery process & Required documents
- Inspection & Acceptance of goods
- Payment terms & Invoice requirements
- Supplier warranties
- Dispute resolution
- Contract termination

Service Level Agreement (SLA)

- Ordering process
- Pricing details
- Equipment leasing, installation, and removal
- Equipment training
- Equipment maintenance
- Reporting requirements
- Key performance indicators (KPIs)

The all-inclusive standard service package in SLAs include:

Category	What is included?
Instrument lease, installation and removal	Equipment lease and installation costs, including placement, delivery of machines to site, inspection of machines, initial end user training and instrument removal at end of life or end of contract
Service and maintenance, insurance, and ongoing end user training	All aspects of servicing and maintaining instruments and providing ongoing end user training, including insurance, preventative maintenance, repairs and replacements, and necessary updates
Connectivity and data reporting	Automated reporting of operational data from instruments
Commodity supply chain management	Freight and logistics of reagents and consumables delivered to an agreed place, per incoterms (e.g. the central medical store)
Equipment upgrades	Planned enhancements and upgrades to instruments

SLAs are as effective as they are monitored and managed against established service levels, hence the need for Key Performance Indicators (KPIs)



Category	Areas tracked in key performance indicators
Service and maintenance, insurance, and ongoing end user training	<ul style="list-style-type: none">▪ Preventative maintenance visits per instrument per year▪ Average response for equipment breakdown▪ Average time to repair▪ Instrument outages after regular maintenance▪ Average uptime working days per quarter▪ Average number rejected runs or failed tests
Connectivity and data reporting	<ul style="list-style-type: none">▪ Average "uptime" of automated reporting systems at least once per day▪ Quarterly Reports submitted on-time
Commodity supply chain management	<ul style="list-style-type: none">▪ Share of reagents and consumables in a delivery with required shelf life remaining▪ Share of reagents and consumables delivered in full and on time

Under the SLAs, suppliers are responsible for monitoring and reporting regularly on 10 key performance indicators.

This enables countries to hold them accountable for their performance and quality of services

Note: Additional detail can be found on the appendix

What is NOT in PEPFAR's SLAs for molecular VL testing:

- POC instruments
- Other assays besides HIV (but they may be added in the future)
- Other services beyond the standard package (e.g. sample transportation or waste management not included)
- VMI is an additional services, at extra charge and with its own SOW and multi-stakeholders' Roles & Responsibilities
- While there are KPIs on shelf-life compliance and On-Time and In-Full delivery, SLAs won't automatically address all issues behind stockouts problems.
- Quantification remains a responsibility of a buyer/country as well as timely order placements with considerations of suppliers' lead times. Buyers need to regularly share accurate forecasts with suppliers.

Demystifying concepts around all-inclusive agreements

Some countries and buyers shy away from exploring all inclusive SLAs due to common misconceptions. Below are a couple of examples

Myth	Fact
All-inclusive SLA makes a country to omit important procurement protocol that may lead to audit findings later	An SLA is the final outcome of a refined RFP process that makes sure all procurement and negotiation protocols are observed to get the best prices and service terms. Then countries will choose the respective suppliers based on final negotiation.
It is extremely difficult to put an SLA in place	After the PEPFAR RFP and finalized negotiations on SLAs, there is now a whole process outlined on how to achieve this and an example of a template SLA for other buyers to adapt to their needs
SLA management concerns only for buyer (procurement agent), donor and supplier	The SLA management via KPI monitoring is a collaborative approach for a country with a main focus on MOH taking responsibility to ensure all suppliers are monitored regardless of donor source of funds. For example, where platforms share reagents from GF and PEPFAR, information on machine is available on same platform and performance can be monitored

Impact and Lessons of global SLA implementation

The global SLA implementation by GHSC-PSM has had a measurable impact on pricing for all VL/EID reagents and consumables and on the laboratory supply chain towards services which are more cost effective, efficient, and responsive to patient needs

>50 million

VL and EID **tests procured** by PEPFAR 2020 - 2023 under the global all-inclusive SLAs with Abbott, Roche and Hologic

>137 million

Cumulative savings on these orders since 2020, compared with pre- global RFP prices

\$2 - \$3

Average savings per test across the PEPFAR portfolio



Supplier **performance KPIs tracked** under global SLAs and **issues being identified and rectified** in a timely manner. Instances of backlogs due to poor instrument performance reduced

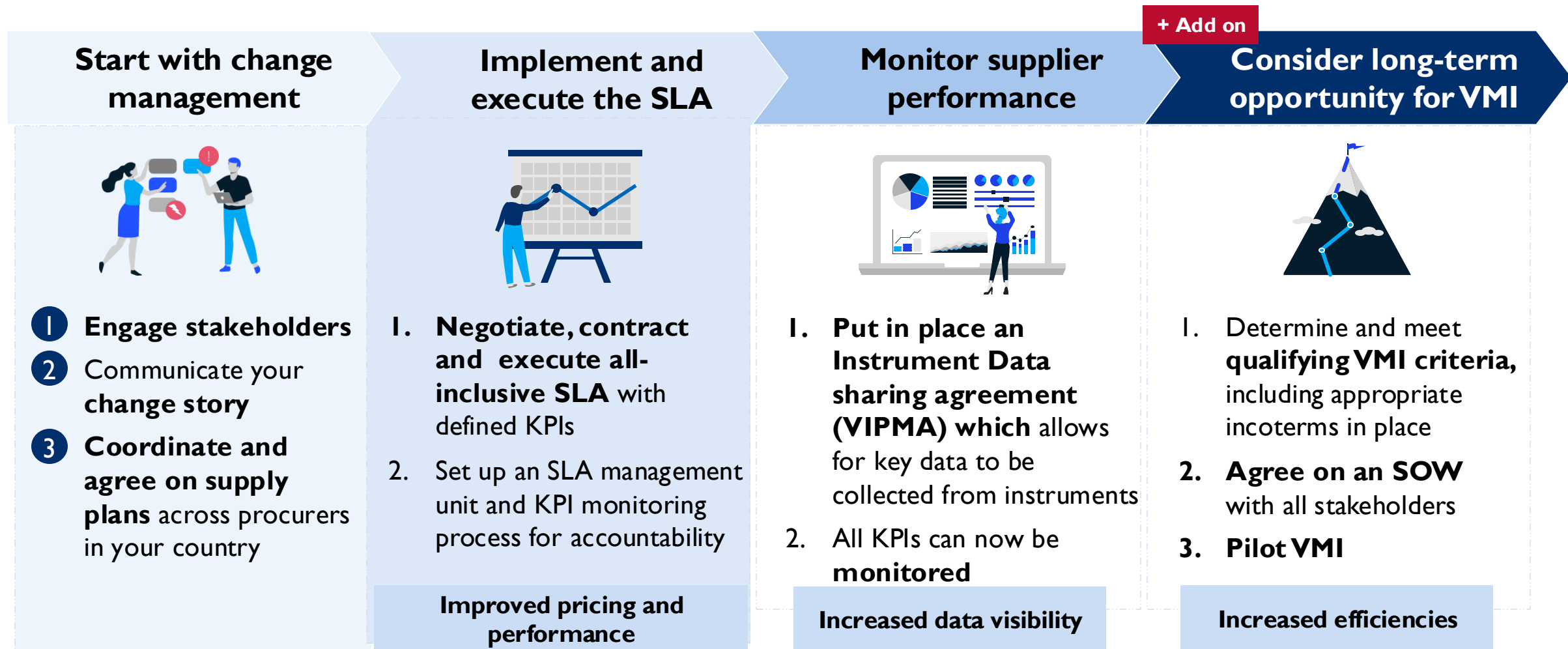


Instruments **automatically reporting operational data** to the suppliers' instrument data platforms and PSM's global dashboard



The relationship between GHSC-PSM and diagnostics manufacturers has changed from transactional, ad hoc-procurement activities to a **long-term, mutually beneficial strategic partnerships**

Based on our experience, we recommend this process for setting up and implementing SLAs for the HIV VL testing:



More advice for you to consider:

- Bring every stockholder to the table in planning and execution of SLAs and ensure your all-inclusive SLA has your country's best interest written explicitly
- If your country/organization can firmly commit to certain volume of annual procurement, this may bring substantial cost savings per test for the country compared to existing contracts
- Regular performance monitoring will strengthen relationships between vendors and customers, fostering better collaboration and efficiency in the supply chain
- The importance in having KPIs as part of the contract and also ensuring monitoring of performance of the contract
- Need for countries to have data sharing agreements with suppliers for them to access data and use to improve service

PEPFAR endeavors to share its experience and expertise in strategic procurement of VL reagents and services with other donors and national governments.

May 2024, GHSC-PSM conducted a comprehensive capacity building workshop in **Ethiopia** for countries who expressed interest and readiness to implement SLAs.

10

Countries represented

75

Workshop participants

24

Organizations represented

12

Workshop and training sessions

15

Hours of tutorials conducted in 3 days



Did any of you participate in the SLA workshop in Addis-Ababa in May 2024?





Next steps



Summary

- A Service Level Agreement (or SLA) is a contract between a service provider/vendor and an organization, which ensures both parties abide by defined terms and conditions they are both obligated to meet.
- PEPFAR's all-inclusive SLAs for VL testing improve a generic SLA by including globally standardized requirements for services, incoterms and the pricing
- For PEPFAR it has been a cost-effective way to scale up VL and EID testing while improving services and suppliers' accountability
- This approach has been used by PEPFAR for instrument-based testing, molecular currently, but it can be applied to any instrument-based testing strategy
- KPIs help monitor supplier and instrument performance on a quarterly basis and provide data to identify opportunities for improvement.
- A data sharing agreement (VIMPA) ensures that instrument performance data can be shared with necessary stakeholders
- Components of the SLA's implementation build a foundation towards a future adoption of VMI and potentially other services

What's Next?

- This presentation on PEPFAR's global SLAs is the first that we are doing for ASLM however it will not be the last
- USAID and GHSC-PSM are planning up to five more sessions for ASLM's Lab CoP
- Subsequent sessions will discuss specific technical components of SLA implementation, such as contracting, pricing, KPI management, VMI, new instrument placements and more. They will include country examples and case studies.
- The next presentation (currently scheduled for October 3rd) will go more into detail on KPI management and include a country's experience with the process.
- We would love to hear your feedback and with your help decide on topics of particular interest for future sessions.



Thank you! Merci! Obrigado!

If you have any questions, please reach out to GHSC-PSM Strategy team at **GSCStrategy-Lab-HQ@ghsc-psm.org**

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