USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
PROCUREMENT AND SUPPLY MANAGEMENT

ANSWERING SUPPLIER QUESTIONS REGARDING THE GLOBAL RFP

Thank you to all of you for your thoughtful questions. We have answered all questions that were sent to us, and this document provides our answers to those questions.

We would also like to ask suppliers if you feel like it would be beneficial to have another round of questions in a couple of weeks and/or have a possible conference call. If you would be interested in either option, please email *Global_VL_RFP@ghsc-psm.org* to let us know.

We have grouped the questions and answers into the following sections:

AMMENDMENTS TO ORGINALLY SHARED DOCUMENTS

Annex 6

- In T3 “Key performance indicators,” KPI 10 has been updated to clarify that though measured monthly, it refers to orders in the last quarter

Annex 7

- In A1 “Data for Priority Countries,” Mozambique has 7 labs in difficult to serve locations, however there was no Tier 2 lab component for the pricing table for Mozambique on Tab P2 “Country Services Pricing”. The updated Annex 7 now includes 2 additional rows for the possible surcharge for difficult to reach laboratories in Mozambique.
- In A1, for Uganda, the VL and EID volumes were reversed, this has now been corrected
- In A1, for Tanzania, laboratory data was missing 1 quarter of data, that has now been corrected
- In P1, rows 10-12 were updated

Annex 8

- A word version has been provided

CLARIFICATIONS

Please clarify the terms “supplier” and “manufacturer” in the context of Diagnostics. Can the supplier also be considered the 3rd party organization (e.g.: local distributor in country)?
Supplier and manufacturer are the same in this case. We intend to contract directly with the manufacturer. Any terms will be applicable to all distributors who may wish to become part of the contract. .

For the 6 countries, the data in A1 of Annex 7 shows National Target and Actuals. Please specify what are "Actuals". Is it the number of tests performed in the country or number of tests procured?
The data shown in A1 of Annex 7 that refers to "Actuals" represents number of tests performed and not number of tests procured.

Regarding Annex 7, P1: volumes shown in the Instructions P1 list volumes that do not correspond to the volumes listed in the tiers for the country specific pricing tables. Should we use the volumes within the country specific tables?
The volume tiers from Table P1a and the country specific tiers in P2 are not intended to match. The market shares and expected volume tiers in Table P1a are to be used for the global reagents & consumables pricing and represent aggregate volumes across all countries. Country specific service pricing should be filled in P2, using the volume tiers specified for each individual country. We have used this structure because it allows flexibility to capture the effects of different scale economics: e.g., there may be a situation where share we provide a supplier with a large global commitment, but in which one of the countries served has a limited volume. The supplier would enjoy high economies of scale in reagent and consumable production and in any large countries served, but would have low economies of scale for service provision in that smaller country.

Please note that we are making a minor correction to Table P1. The examples given in rows 10-12 were not updated and do not match the Table P1a - Conventional diagnostics volume guarantees. In the updated Annex 7, the numbers now match Table P1a.

What is meant by a weighted average price?
For legacy equipment (equipment that is already installed in country and is owned by the Ministry of Health or another party), instrument lease, installation and removal prices will not be applied when computing total price.
Every country will have only one country pricing under which all products and services will be purchased. This single all-inclusive price will be based on a weighted average considering the percentage of owned equipment vs. equipment operated under reagent rental model. The weighted average will be adjusted when owned equipment is phased out or new equipment is introduced revisited a maximum of once every 6 months) and the new price will be mutually confirmed by PSM and the supplier.

Weighted average will take into account capacity of the machines.

What is the cold chain shipping qualifications?
Qualification: Manufacturer/Distributor must have SOPs for packaging and labeling.

Procedures must have enough information to reproduce acceptable results that were achieved during shipping qualification (qualified packaging configuration + specified qty of dry ice/preconditioned gel packs, etc. + primary qualified shipping container)

BASIC ORDERING AGREEMENT (ANNEX 1)

With regards to all questions related to Annex 1, please note that we will not be providing written responses to individual supplier questions as part of this response to RFP questions. Instead, as noted in section 1.11.e of the RFP, we will on-board successful offerors without an existing BOA by negotiating the basic terms and conditions that constitute a Basic Ordering Agreement on an individual basis with each supplier. We encourage all bidders without an existing BOA to provide our RFP team with your point of contact for these negotiations. For successful offerors holding a BOA, as noted in section 1.11.e of the RFP, the award will be in the form of a fixed unit price and service level agreement annex to the BOA and we will negotiate any amendments to existing terms and conditions on an individual basis as needed within that annex.

For all successful offerors, Chemonics will negotiate the applicable Annex and reserves the right to update the “Quality Assurance Testing, Inspection and Acceptance” section of the BOA from time to time as instructed by USAID or the USAID Identified and funded GHSC QA contractor (“GHSC-QA”). Chemonics will provide written notice to the Supplier of these updates. The timing of the effectiveness of these updates will be determined by the terms and conditions set forth in the BOA with that supplier.

To note, suppliers may include conditional language as part of their bid (e.g., to enable confidence around pricing levels submitted), although the final contract language including this provision will be subject to negotiation with PSM.

QA VL TECHNICAL QUESTIONNAIRE (ANNEX 8)

Is there a requirement for primary/secondary label language?
There is no additional GHSC-QA requirement on use of multiple label languages beyond any existing country regulator requirements.

Time to result question states that it is from "sample collection to the final result being read". Please confirm if this should state "from sample arrival to the laboratory"?
This question relates to the run time of the sample on the machine. The time starts when the sample is placed in the instrument and finishes when the result is read.

Please define % bias and how it is evaluated/measured?
We request that manufacturers provide their definition and methodology for determining % bias when providing their answers

For a manufacturer of modular instruments, how should we fill in this document for all configurations?
If the same manufacturer wishes to submit various products and/or platforms, then Part II (i.e. Sections 3 – 7) should be repeated for each product-platform combination. We expect that many questions will be a simple copy paste, require a few modifications per product or platform. We will also send out the Word document version of Annex 8 to facilitate this process.

Is the questionnaire required only for HIV Viral Load and not for EID or any of the other analyses mentioned in the RFP?
Annex 8 is required for both HIV Viral Load and EID testing under RFP 1.3 "RFP structure and scope", bullet #1 on page 9. It is not required for other analytes mentioned. The manufacturers may provide annexes to the questionnaire with the reference to the questionnaire numbering.

Is it necessary to provide all of the SOPs?
The documents under Annex 8 are requested for RFP and are necessary as part of the technical evaluation of the products and manufacturers. In part, this is due to internal requirements of the PEPFAR program to conduct independent QA assessments. We understand that this may be a significant amount of documentation and appreciate your efforts in assembling it.

SUBMISSIONS AND EVALUATION

Should the cover letter and certifications be submitted with the Technical Proposal or the Pricing Proposal or separately?
Please submit them together with the technical proposal. Only the pricing proposal should be submitted separately.

Within Annex 1, should section 49 be submitted as a separate email or with the Technical or Pricing Proposal?
Section 49 can be submitted either separately or with the technical proposal.

Other than section 49 of Annex 1, Is there anything else within the BOA that should be submitted with the proposal?
Submission of master data through the GDSN is requested on a voluntary basis within six months of this BOA start date and will be mandatory as of December 30th, 2019

Within seven (7) days of an award with a value of $30,000 or greater unless exempted, the Supplier shall report its identifying data required by FAR 52.204-10 (including executive compensation, if applicable) in the required questionnaire and certification found in herein. If the Supplier maintains a record in the System for Award Management (www.SAM.gov), the Supplier shall keep current such

registration, including reporting of executive compensation data, as applicable, and the data is not required to be submitted in the above referenced certification.

Please describe the circumstances in which a late submission would be considered. Will the other Offerors be notified that a late submission has been accepted?
Late offers may be considered at the discretion of PSM. PSM cannot guarantee that late offers will be considered. Suppliers that foresee the need to make a late submission should request an extension by email no later than 3 weeks before proposals are due, including a clear reason for the request. PSM may approve the extension (or a partial extension) at its discretion, and would provide all suppliers with the same extension. PSM does not anticipate notifying all offerors of acceptance of a late submission.

Regarding Vendor Managed Inventory, is this is a requirement rather than an option?
A bid for VMI services is requested for most, but not all countries. Where not requested, it is intentionally omitted from the pricing table. Providing a bid for VMI services is required for these countries, though it does not imply that all countries will necessarily move to VMI after awards.

Section 1.11.b lists a series of criteria that will be each scored 1-5, please describe how each of these criteria will be weighted against each other. Also, please describe how these criteria will be weighed against the offered pricing. Please confirm that no criteria, other than the criteria listed in 1.11b and pricing, will be considered in making the determination. If any other criteria will be considered please specify.
The technical scoring rubric (A1 of Annex 6) defines the technical evaluation criteria that will be used. The most important of these are the two mandatory global requirements - which will lead to disqualification if not met.

The remaining technical criteria will be weighed against each other according to a set of priorities to be set by PSM headquarters and field staff. Though these priorities may differ by country depending on the most pressing needs of the lab programs, the 6 criteria for country specific services are more important than the global and value-added considerations and will be weighed as such.

Awards will be made via detailed discussion with country stakeholders considering both technical and cost scores, and the award decision will be based on a determination of best value. PSM does not anticipate using any criteria for award determination in addition to those in A1 of Annex 6 (the same as those listed in 1.11b) and pricing, other than the need to establish an appropriate diversity of supply for each country to mitigate supply risk.

PRICING & VOLUME COMMITMENTS

Regarding section 1.3b: “This single price will be a weighted average price across installed and new machines based on capacity/expected usage. This single weighted average price would be recalculated as necessary whenever new instruments are placed in country.” How often is the price adjusted, for example, after each new placement? Please elaborate on the mechanism of how this will be managed.
The country's weighted average price will be adjusted after each new batch of instrument placement and verification, (revisited a maximum of once every 6 months) and the new price will be mutually confirmed by PSM and the supplier.

Regarding section 1.3b: "We will not make adjustments to the installed base of recently placed machines under those specific agreements for the minimum of the remainder of the initial term of those sub-contracts or one year since award." When the remaining time for the initial term is greater than 1 year, will this be honored or does this statement imply that the maximum term to be honored is 1 year?

PSM will honor any time bound firm volume commitments in existing contracts, if such commitments exist. However, to PSM's knowledge there are no such commitments in place. Suppliers are requested to provide any such binding contracts with volume commitments beyond one year.

Regarding section 1.3b: "We will not make adjustments to the installed base of recently placed machines under those specific agreements for the minimum of the remainder of the initial term of those sub-contracts or one year since award." Does honoring the initial terms of the contract also apply to the prices offered in these recent awards?

The new and improved prices (global reagents and consumables price and country service prices) resulting from this RFP will apply to all of the supplier's volume. They will apply both to currently existing and new additional volume that results from this RFP award. Any recent volume commitments for recently placed instruments will be maintained as agreed upon. We expect pricing received through the RFP to be more competitive than existing pricing. However, where it is not, the current pricing would last until current agreement expiration.

How will the volumes be monitored and how frequently in order to implement the pricing in the tiers? If new volume tiers are reached, how will the new pricing be implemented and over what time frame? If volume of testing for a manufacturer declines to a lower pricing tier what would happen related to pricing?

A firm volume commitment will be made for remainder of FY2019, and a preliminary volume commitment based on proposed COP funding for FY 2020 will be made (to be confirmed in Oct. once COP budget is approved). Volumes for FY2020 and subsequent years are dependent on funding approvals, but market share commitments are firm assuming suppliers are meeting agreed performance levels.

This means that contract awards will guarantee suppliers that they will have at least that share of PEPFAR's total volume. Global and country procurement volumes will be reviewed quarterly to ensure that they are tracking towards commitments, and PSM and suppliers can possibly renegotiate pricing tiers on an annual basis if they mutual wish to do so.

It is likely that PEPFAR will procure more than what is guaranteed, however suppliers are not expected to offer a lower price for volume that was not committed to in advance (supplier and PSM can jointly consider changing commitments and price for subsequent years, but supplier will not be expected to provide a lower price in that year).

If suppliers are meeting the agreed upon performance levels, PSM will not reduce their agreed upon share of procured volume. PSM may procure a higher share from a supplier than what is committed since PSM will likely reserve some flexibility in yearly procurement and not commit 100% of expected volume.

If PSM procures less than minimum share commitment, PSM will work with the supplier to establish a remediation plan (which could include an increase in volume or price for subsequent years).

Page 8, discusses guaranteeing volumes for single year or multi-year volume share commitments. However, in Annex 7 it reads "Volumes for FY 2020 and subsequent years are dependent on funding approvals, but market share commitments are firm assuming suppliers

are meeting agreed performance levels". Considering that volume is not guaranteed after 2020 as it will be pending based on funding approval. We run into the risk of pricing assuming certain volumes that might not come. How can we mitigate the risk of pricing for 900,000 tests and actual approved comes at 450,000 (theoretical numbers)?

All procurement is subject to PEPFAR funding availability and supplier performance. Concrete volume guarantees beyond the current fiscal year are not possible given that PEPFAR does not provide multi-year funding. There is a distinction between expected volume and what PEPFAR can commit to contractually, but recent experience is that PEPFAR has received appropriations in line with its program goals for the last few years. However, we are not permitted to go beyond a statement of the expected volume until the U.S. Government appropriations are made into law. Quantities procured have been increasing recent years, and are projected to continue to increase in the future.

Regarding Annex 7, tab P3 - If complete service bid pricing is provided on P2 for the top 6 countries, how is this captured on P3 table for these countries, when only space for current services is included? How can any adjustments be shown beyond the reagents/consumable pricing?

Table P3 is only asking for existing pricing (split by reagents & consumables, and services) in all countries the manufacturer is present in. The existing price will be automatically updated based on the new reagents & consumables price.

For the 6 countries included in P2, the adjustments in service pricing will be seen by comparing P2 and P3, nothing needs to be done in P3 other than specify current prices and services offered.

Regarding Annex 7, tab P3 – Please define what is included in services column G? For example, where would we capture instrument surcharge, maintenance, distribution, taxes, duties, customs, etc. for current pricing?

Current service pricing should encompass all current services being provided by the manufacturer in that country (e.g. instrument surcharge, maintenance, distribution, taxes, duties, customs).

Does the RFP Forecast override the already existing forecast? If existing Country/Lab pricing is more favorable – will these prices last until current agreement expiration (then default to global RFP pricing) or will they be extended to be co-terminus this new global RFP term?

The RFP forecast is based on country data received by PSM; however, where significant differences are noted from prior forecasts, these should be discussed with PSM.

We expect pricing received through the RFP to be more competitive than existing pricing. However, where it is not, the current pricing would last until current agreement expiration.

Regarding Annex 7: How should we submit Country Services Pricing for different size analyzers?

Please use the optional box for additional detail that can be found below every country's table. This box can be used to submit any additional details on country services pricing, including any differences between instrument platforms and any comments on opportunities to reduce pricing by changing service levels. If this approach is insufficient for your needs, you may duplicate the country pricing tab and indicate accordingly which platform is represented in each tab.

The term cited in this RFP is given as 3 years. Do we understand that individual instrument contracts or multiples thereof can be started at any point during the 3 years? If so, will volume guarantees for those contracts which begin in year 2 or 3 be for 3 years or for the remaining term of this program – that is to say terminating in 2022?

Awards that result directly from this RFP will be given in 2019, and so the 3 year guarantees would end in 2022. However, PSM and suppliers can renegotiate at different points after award date (e.g. after a year if there is a mutual desire to commit more volume), and theoretically these renegotiated commitments may extend beyond 2022

KPIS

Do corrective maintenance visits count towards the minimum of 2 yearly preventive maintenance visit?
Suppliers are in fact encouraged to take advantage of any corrective maintenance visit to perform preventative maintenance on the instrument requiring corrective maintenance, and any other instrument in the lab. However, the expectation remains of having a preventive maintenance visit every six months. As an illustrative hypothetical examples, if a suppliers performs preventive maintenance in January, and then an instrument requires corrective maintenance in March and supplier performs preventive maintenance in March, the next preventative maintenance visit could be rescheduled to September instead of July.

What does Chemonics consider on time? Please explain in more detail what is the forecasted timing and how is it calculated?
On-time-delivery requires the shipment to arrive within 7 day grace period after or 14 day period before the committed Goods Availability Date (GAD) per the incoterms.

Does forecasted timing refer to agreed delivery date? Please clarify when the "clock" begins for an order? Is this when sent to vendor and receipt confirmed by vendor? Signed PO or SPA?
Forecasted date is the confirmed Goods Availability Date (GAD) in all cases. Such expectation is officially set at the moment a purchase order or its equivalent is fully-executed. In the case of DAP/DDP Incoterm, the confirmed GAD is often equivalent to the Agreed Delivery Date (ADD).

Through a PO modification mechanism, the confirmed GAD can be officially modified with official USAID Mission approval.

Please clarify how KPI #11 is different from KPI #10? Please specify how this KPI is calculated.
KPI 10 has to do with the timing of delivery (i.e. % of orders delivered on time). KPI 11 has to do with the quantity delivered (i.e. % of ordered quantity agreed actually delivered)

Please clarify exactly how instrument utilization would be calculated? (ex: would 100% utilization be equal to the full 8-hours worked per day, or does 100% utilization imply the machine is operated 24/7)?
Utilization assumes an 8-hour working day (and not calendar day). Utilization also includes other molecular tests operated on the instrument as applicable.

How will poor performance of an instrument be defined in order to require replacement (e.g. MTBF < x months, < x % of specifications…)?
Poor performance here refers to persistent, unresolvable issues that prevent the machine from achieving its anticipated utilization or testing load. Manufacturers may propose a specific definition or could use an uptime of below 80% and MTBF < 2 months

Who are the responsible parties for collecting, maintaining, and reporting the data for the KPIs (i.e. self-reported by the lab, standardized logbooks for completion, etc.)? What is the format and process for reporting to PSM and the Ministry of Health on a monthly basis? Can reporting be extended to cover longer periods of performance beyond 1 month?

The manufacturer will be the party responsible for the KPI report. PSM and laboratory stakeholders will provide necessary support to allow data accessibility. Manufacturers should expect to submit the report electronically each month, together with any commentary (e.g., remediation actions if service levels achieved do not meet targets). Every quarter, there will be a performance review meeting with PEPFAR /MOH/other stakeholders. We encourage the manufacturer to leverage automation and standardized operating procedures for effective and efficient data management. The format and process of reporting will be clearly outlined in a Service Level Agreement as part of the all-inclusive reagent rental contract. Manufacturers will be expected to work with their in-country partners and other lab stakeholders to establish the data collection process. Underlying performance data should be collected, categorized, uploaded, and made audible on a monthly basis based on the clear presentation of job cards, certifications and testing reports. PSM is open to suggestions of how to approach the monthly performance reporting data collection, report generation, and decision making based on the report, in the most efficient manner.

DISTRIBUTORS' AND OTHER PARTNERS' ROLE

Is the expectation that Chemonics will now want all invoicing to come from the manufacturer directly? Can distributor be an extension of manufacturer for both distribution activities and invoicing?

We intend to contract directly with the manufacturer. Any terms will be applicable to all distributors who may wish to become part of the contract. It may be possible for manufacturers to invoice through their distributors. However, such invoices must be based on the agreed-upon all-inclusive country price provided by the manufacturer and detailed in the contract with the manufacturer. No additional markups or extra fees will be acceptable.

Would it be possible to grant to the Supplier the right to assign the contract to one or several of its affiliates?

We are asking manufacturers to provide oversight of distributor performance and take corrective action if distributors do not perform. We do not believe this is possible under a structure where the contract is simply assigned to the distributor. Instead, we suggest a structure in which distributors are subcontracted by the manufacturer. However, we are open to suggestions of how to accomplish our goals via alternative contracting structures.

Please define criteria for acceptable partner performance in country.

In-country partners must meet the service levels specified in the Technical Submission Template. The manufacturer is directly responsible to manage their partner's performance so that they are meeting or exceeding the key performance indicator targets agreed for each country.

INCOTERMS

What detail can be shared on what exactly is exempt for the USAID program in the 6 priority countries and if this is covered for all product categories relating to HIV-1 VL and EID testing, including instruments brought into country under reagent rental which may incur duty?

Duties are waived for reagents /consumables procured and donated by PEPFAR. The waiver procedures are specific to each country. For the instruments to be placed by the manufacturers, PEPFAR intends to secure country duty waivers as well. The process for that is currently under investigation, PSM will provide clarity on this at a later stage.

Value Added Tax is also waived on reagents /consumables imported by PSM. Payment of the VAT for the in-country service, including 3rd Party Logistics, is under the responsibility of the supplier, and will not be waived unless otherwise advised.

PSM will work with suppliers in obtaining the necessary waivers and co-developing processes.

Regarding "the Supplier shall not pay any host country taxes, VAT, tariffs, duties, levies, etc. from which this USAID program is exempt". Please confirm that we do not need to include these aspects in the "all-inclusive pricing".
Do not include these aspects given the DAP incoterm. For further detail please reference previous question.

Regarding KPI 10 in Annex 6, T3 - "Percentage of Orders delivered on time (within 7 day grace period after or 14 day period before forecasted timing)". Does this measurement apply to all incoterms?
Yes. The measurement applies to all incoterms as it is measured from the confirmed Goods Availability Date (GAD) on the fully-executed PO. In the case of FCA, EXW, and CIP, the actual GAD is the date when the goods are packed all of the required shipping documents (Commercial Invoice, Packing List, COA, COO) are provided to PSM. In the case of DAP and DDP, the actual GAD is the date of the delivery, which must be captured on the Proof of Delivery at the specified delivery destination.

Is DAP the only Incoterm accepted as there are other incoterms mentioned in the BOA?
The Basic Ordering Agreement provided in Annex 1 is provided as an illustrative example only. When providing bids, please use the incoterms specified in the Bid Submission Templates (Annexes 6 and 7) which are FCA for the global reagents and consumables bid and DAP for country distribution bids. We are open to discussing other incoterms if there are mutually beneficial reasons to do so.

If DAP is the accepted Incoterm, can you confirm that waivers will be obtained by GHSC-PSM for the 6 priority countries? If the waivers are not available or not received on time, is there a process for reimbursement to suppliers?
We expect to obtain duty waivers for goods imported with DAP incoterm following country waiver procedures. In the case that a waiver is not obtained or is delayed, and if, after written approval from PSM, Supplier makes a payment to ensure the goods clear customs in a timely fashion, Supplier will be reimbursed for that cost.

Page 9, requests pricing based on FCA incoterm, but page 28 states that Chemonics may use CIP, DAP and DDP at their discretion. Please describe under what circumstances FCA would not be used. Who would cover the cost for potential incoterms changes?
When providing bids, please use the incoterms specified in the Bid Submission Templates (Annexes 6 and 7) which are FCA for the global reagents and consumables bid and DAP for country distribution bids. We are open to discussing other incoterms if there are mutually beneficial reasons to do so. The Basic Ordering Agreement provided in Annex 1 is provided as an illustrative example only and is superseded by Page 28 (which refers to in-country distribution) and the Bid Submission Templates.

The document states the preferred Incoterm to be FCA. In other places, shipment to end users by local distribution partners is requested. Please can you clarify those Incoterms you intend to use.

We are breaking freight into two separate portions. The global reagents & consumables bid is FCA incoterm to supplier port. For bids on the final delivery of goods, covered in the country service pricing, the incoterm requested is DAP.

Please clarify the Incoterms for proof of delivery documentation. On page 28, FCA is mentioned as the preferred Incoterm under Section 11; however, DAP is specified on page 20 under Section 2.2.

When providing bids, please use the incoterms specified in the Bid Submission Templates (Annexes 6 and 7) which are FCA for the global reagents and consumables bid and DAP for country distribution bids. We are open to discussing other incoterms if there are mutually beneficial reasons to do so. The Basic Ordering Agreement provided in Annex 1 is provided as an illustrative example only and is superseded by Page 28 (which refers to in-country distribution) and the Bid Submission Templates.

Are the costs incurred by any Incoterm other than FCA payable in addition or included in the price? Are customs duties reimbursed by the client in case of DDP Incoterm?

When providing bids, please use the incoterms specified in the Bid Submission Templates (Annexes 6 and 7) which are FCA for the global reagents and consumables bid and DAP for country distribution bids. We are open to discussing other incoterms if there are mutually beneficial reasons to do so. The Basic Ordering Agreement provided in Annex 1 is provided as an illustrative example only and is superseded by Page 28 (which refers to in-country distribution) and the Bid Submission Templates.

If supplier provides quote for Incoterm other than FCA, then this quote should include any additional costs. Chemonics does not reimburse customs duties paid by supplier unless approved in advance.

SHELF LIFE

Please define how shelf life is calculated?

Remaining Shelf Life = Date of Clearance - Date of Manufacturing

Actual Maximum Shelf Life = Date of Expiration - Date of Manufacturing

PSM will calculate Percentage as RSL divided by AMSL

To expedite order approval process, PSM welcomes the manufacturer to provide a written statement of Average MSL and will bring to in-country stakeholders' attention for formal acceptance.

Whilst the term shelf life applies to pharmaceutical products, it does not fit well with diagnostics products. Can this be re-phrased to refer to remaining months of stability?

PEPFAR requires the vendor to provide all certificates of analysis (COA), which must include both the manufacturing date and expiry date for each batch/lot. The shelf life should then be determined in the form of months of stability, in addition to providing a remaining percentage.

PEPFAR has been collaborating with relevant stakeholders to rationalize the requirement originally set by in-country authorities.

Regarding KPI 9 from T3 in Annex 6: Shelf life remaining when reagents clear customs. Please clarify how this KPI is calculated. Is this for every shipment or the average for all monthly shipments? Quarterly shipments?

The reagent order approval process requires SKU-specific shelf life information based on the lots provided.
For the KPI, we measure the average shelf life of the reagent and consumable SKUs. This average is to be calculated monthly for every country.

DATA SYSTEMS

What is meant by "bidirectional communications with LIS to allow testing order automation"? Does is simply refer to order query and result upload, or is more required?
Bidirectional communications means that the suppliers' platform should be capable of receiving LIS data (including but not limited to testing orders) and transmitting data back to LIS (including but not limited to results and instrument performance record).

What are the responsibilities of the supplier relating to LIS integration?
We welcome a comprehensive proposal including technical approach, major milestones, your available technical team (internal and/or subcontractors), their technical qualification, and example projects. The actual scope of work will depend on the labs' current system and in-country resources available.

In the proposal, please articulate your approach and technical resources to manage both development and maintenance activities.

Is the expectation for supplier collaboration with the LIS manufacturer (ex: supplier would provide all supporting documentation and address questions relating to its equipment to support the LIS manufacturer)?

Yes, but actual scope of work will depend on the type of support in need to accomplish LIS integration. The proposal should focus on the 6 priority countries.

We welcome a comprehensive proposal including technical approach, major milestones, your available technical team (internal and/or subcontractors), their technical qualification, and example projects. The actual scope of work will depend on the labs' current system and in-country resources available.

In the proposal, please articulate your approach and technical resources to manage both development and maintenance activities.

What is the data system that PSM is using?
PSM's information system includes a messaging module to automatically push and pull transactional data in real-time. PSM will review the selected manufacturer's proposal and provide the appropriate level of system access.

Through the proposal, manufacturers are given the opportunity to provide a system design that allows secures data transmission, storage, management, and analytics of non-patient data to enable effective lab performance management.

What access would the supplier have to the PSM data system to allow for automatic transmission?
PSM system access will be granted on an as-needed basis, given the system architecture proposed by the manufacturer. PSM will provide detailed requirements for data exchange to allow for supplier development of an appropriate API interface.

Is this data system a global solution, country solution or lab level solution?
PSM /PEPFAR works on managing non-patient performance data at the global-level. Manufacturers are encouraged to provide a solution that allows data sharing with the MoH LIS at the country level and with PSM's database at the global level. This may require development of the appropriate API interfaces to allow for the data exchange. Manufacturers are encouraged to lead instrument software updates in-country to minimize disruptions to remote accessibility.

Who will be responsible for providing connectivity and maintaining it to support KPI monitoring? (ex MOH?)
The MOH will be responsible, with the support of other country stakeholders and implementing partners. For locations that have connectivity challenges, suppliers are requested to propose solutions.

GENERAL TECHNICAL QUESTIONS

Regarding Deliverable No. 2 from Section 2: Proofs of Delivery (PODs) for Reagents and Consumables with Temperature Data for Cold Chain, Temperature monitoring device for cold chain. What is the % of packages that need to be monitored on one transport?
PSM recommends no less than one temperature monitoring device per tertiary shipping configuration (up to pallet unit). Example: 30 bottles per carton -> 100 cartons per case -> 15 cases per pallet shipper -> 980 pallets per cargo container = 980 TMDs

The temperature monitoring device is to be placed in same location as defined during shipping qualification, OR

i) Placed within close proximity to commodity in order to monitor commodity temperature (such as within a qualified cold chain carton or within a qualified cold chain case of cartons in the above example)

ii) Container with TMD should be on the top corner of the palletized configuration (in the above example).

iii) Pallet with TMD enclosed should be the last pallet loaded into the cargo container.

Regarding Annex 6 T1 Global Service Levels "If equipment is performing well and no updated technology is available, replacement cycle can be extended for several years at GHSC-PSM's discretion." How is "updated technology" defined?
Updated technology refers to new instruments or significant improvements/updates to existing instruments that cannot be done on-site after instrument is installed (for example, the next generation of the supplier's diagnostic instrument platform).

Regarding Annex 6 T1 Global Service Levels "Supplier provides comprehensive instrument insurance, including force majeure. Suppliers are requested to provide exhaustive list of what is covered and what is excluded." As instruments will be financed through reagent rental, the legal ownership remains with manufacturer and therefore all risk are assumed by the manufacturer. As such, why is there a need for an "exhaustive list"?
We ask that you confirm that the Ministry of Health and GHSC-PSM will not be liable for loss or damage to new or existing leased equipment placed in country facilities, and will not be required to insure such equipment against loss or damage with the exception for loss or damage due to gross negligence. Any other exclusions should be listed.

Among the criteria to be considered in the RFP is the ability to remotely monitor performance and troubleshoot issues. (E.g., Sections 1.2.1, 1.11.B, 1.7.B.2 (Tables T3, T4), 2.1C) What are the intended consequences if Supplier cannot meet its contractual obligations related to remote monitoring or troubleshooting due to insufficient telecommunication capabilities at the local site (e.g., local internet has been switched off, insufficient bandwidth)?

Suppliers will not be responsible for their inability to perform remote monitoring or troubleshooting in the event of connectivity problems tied to an identified force majeure event or mutually identified extended issues. PEPFAR will work with countries and suppliers to resolve any such issues as swiftly as possible.

Suppliers will be expected to develop alternative plans and methods for monitoring and troubleshooting in the event of connectivity problems. Suppliers are requested to submit a brief explanation of their alternative plans and methods for monitoring and troubleshooting in the event of connectivity problems.

What is the expected timeline for implementation in countries where our offer is not yet established.

We would like suppliers to provide an estimated timeline for implementation in new countries. This should be no more than 18 months from expected award date (June 2019) and a shorter duration is preferable.

Does Chemonics intend to invite suppliers to participate in the installed-base mapping exercises? This is of particular significance to those whose systems are adaptable to different levels of the healthcare continuum

We request that suppliers fill in their current instrument footprint in Table T5 - Installed Base from Annex6.Suppliers that have POC instruments do not need to fill out Table T5 with every individual POC instrument placed, but we request that you fill in the number of POC instruments by province or state.

We will engage suppliers as needed on an individual basis to complete any mapping exercise.