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MANILA SUPPLY CHAIN UNIT (MSCU)	
TO: Bidders	FROM: Procurement Support Manila Supply Chain Unit
1 NO. OF PAGES INCLUDING COVER SHEET: 12	DATE: 16 February 2024
SUBJECT: REQUEST FOR PROPOSAL (RFP) MSCURFP# 24-065 for the provision of LIMS Integration with Laboratory Instruments Solution Pilot for IOM Manila Clinic – Amendment No. 2.	

In reference to the Request for Proposal issued last 07 February 2024 via UNGM and IOM website for the provision of LIMS Integration with Laboratory Instruments Solution Pilot for IOM Manila Clinic Services. This Addendum No.002 is issued to address inquiry and clarification and amend instruction to the bidders.

   A. **To update RFP Instructions to bidders:**
   i.   **Form A: Proposal Confirmation is hereby amended:**
   - Proposal confirmation is hereby accepted not later than 21 February 2024 10:00AM Manila time, by email via mscuprocurement@iom.int

   ii. **Section 3: Data Sheet**
   - **Item no. 27 Deadline for proposal submission is hereby extended:**
        26 February 2024, 10:00AM Manila time, proposal submission email address mscubids@iom.int

iii. **Section 5: Terms of Reference**
- Item no. 10 Timeline / Timescale is hereby updated:
    IOM expects the partner to start the project by 3rd Week of March 2024 and deliver the project within two (2) months.

B. **Summary of Technical Clarifications and Minutes of the Presentation held on 15 and 16 February 2024 – 3:00PM -4:00PM Manila time via Zoom Conference**
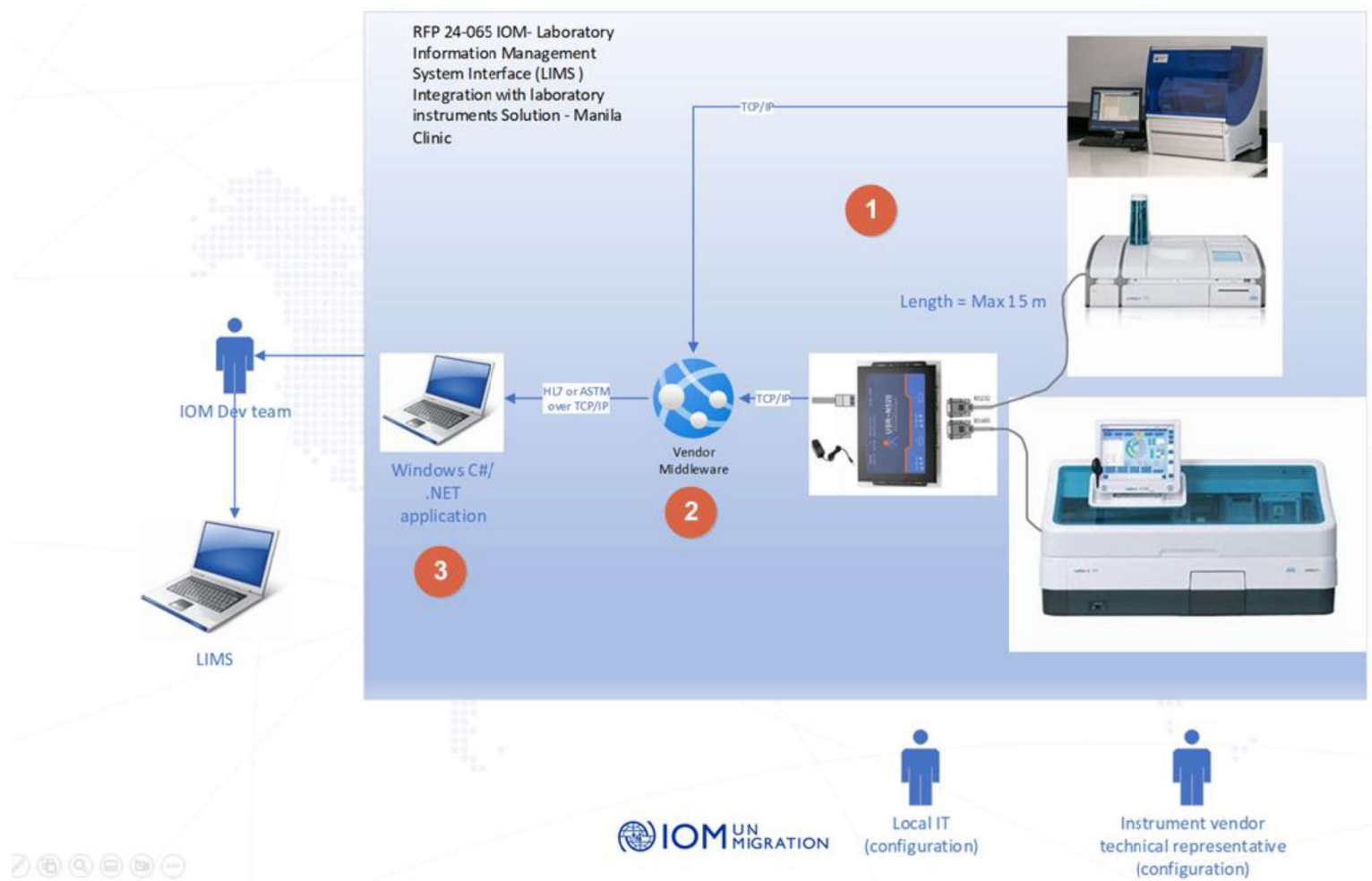
Facilitator – Ann Loren YU
Presenter - Sorin Pavel ROSOI

i. **The scope of the project as originally stated in the RFP was clarified during the presentation, to include the items within the blue box (refer to diagram).**

(1) Configure the instruments from the laboratories to communicate via different modes such as TCP/IP, RS232 or RS485 depending on the instrument. The vendor can use any device for this purpose.
(2) Convert the information to output the messages containing test results sent by these instruments in HL7 or ASTM format over TCP/IP. It is up to the vendor how this would be done. The vendor could propose a middleware to integrate and consolidate the information.
(3) Develop a Windows C#/.Net application that can extract the contents of the messages, enable viewing of the test results, including units of measure and any errors reported by the instruments. The source code of this application should be provided.

Any software license or hardware equipment that the vendor would use should be included in the financial proposal. The vendor shall be responsible for the procurement of that software or hardware as part of the project.

The selected vendor will be supported by (a) local IT for configuration in the clinic, and (b) instrument technical representative for configuration of the machines as needed to modify the parameters. The instrument representative will not install any software on the machines as part of this project.

RFP 24-065 IOM- Laboratory Information Management System Interface (LIMS) Integration with laboratory instruments Solution - Manila Clinic

TCP/IP

1

Length = Max 15 m

IOM Dev team

HL7 or ASTM over TCP/IP

TCP/IP

Vendor Middleware

2

Windows C#/ .NET application

3

LIMS

Local IT (configuration)

Instrument vendor technical representative (configuration)

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ii. **What is out of scope of the project was also clarified:**
Integration with IOM LIMS is not part of this contract. This will be done by IOM development team as indicated on the diagram.

iii. **In response to concerns raised about project delivery, IOM decided to the adjust the scope and timeline:**
(1) In terms of instrument coverage, scope is reduced from eight to five instruments of IOM Manila Clinic, keeping only the ones listed below. The integration order should follow the sequence as specified in the list.
a. Cobas e411
b. Cobas c111
c. Dynex DS2
d. BD BACTEC™ MGIT™ 960
e. Gene Expert GXIV 4D
(2) In terms of project duration, delivery timeline is extended from 1 to 2 months.

C. **Questions and Answers from 15 February 2024 Zoom Conference**

Item No.	Vendor's Clarification	IOM Technical Team Response
1.	Tech Eval says: "we will buy or license the software", the RFP terms of reference mention about delivering the source code to IOM : should we understand there is some flexibility on the hand-over of the proposed solution?	This comment pertains to the licenses needed for any middleware. The vendor shall include the cost in the financial proposal and be responsible for procuring them.
2.	Pavel talks about a "black box solution" which needs to be compatible with .NET/C# technology : does that mean that the middleware may include other libraries/modules, not necessarily written with	No specific requirements for the Middleware technologies.

	.NET/C# as long as the compatibility is ensured?	
3.	RFP mentions about 1 month effort, we believe it is very short to produce quality work. If we propose an answer with slightly longer project schedule, is it acceptable?	The project timeline has been updated to two months duration.
4.	Can you confirm the name and the exact model of the device called "GeneExpert"? We could not find a device with that exact name. We could find information on devices called "GeneXpert" (https://www.cepheid.com/en-US/systems/genexpert-family-of-systems/genexpert-system.html), with 3 different models: GeneXpert® II, GeneXpert® IV, GeneXpert® XVI. - The Cobas c411 does not exist, is it the Cobas e411?	<table><thead><tr><th>Name of Equipment</th><th>Model</th></tr></thead><tbody><tr><td>Serology Analyzer</td><td>e411</td></tr><tr><td>Chemistry Analyzer</td><td>c111</td></tr><tr><td>ELISA</td><td>DS2</td></tr><tr><td>MGIT</td><td>MGIT 960</td></tr><tr><td>GeneXpert</td><td>GXIV 4D</td></tr></tbody></table>

5.	So the priority is made for the cobex. Do you have any documentation regarding the message types (ASTM?) from the box?	Provided in bid bulletin 2: Yes, see example for one machine: 1H|\^&|||c111^Roche^c111^4.3.0.1835^1^15236|||||host|RSUPL^BATCH|P|1|20230914123835 00 2P|1|| 4B 3O|1||NBO2336941||R|||||N||||||||||20230914123835|||F EF 4R|1|^^^690|70|umol/L||N||F||SYS||20230914102512 9E 5C|1|I||I 4F 6M|1|RR^BM^c111^1|22|22|20\\0\\0\\0\\0\\53\\54\\52\\54\\54\\54\\50\\52\\51\\52\\185\\204\\220\\235\\247\\260\\273\\283\\292\\305|0.003768 45 7L|1|N 0A
6.	Should we discuss on this meeting the questions already submitted in written form? e.g. TOR 5.9.: "Working outside of regular working hours may be required (to accommodate the laboratory operations)". Could you please elaborate?	Technical team will be able to organize few hours during the normal working hours. Most likely after 4:00PM and after 5:00PM. The idea here is to not affect the existing operations. Further details of schedule will be provided to the awarded vendor.

D. Questions and Answers from 16 February 2024 Zoom Conference

Item No.	Vendor's Clarification	IOM Technical Team Response
1.	Will the lab provide detailed specification for each instrument (connectivity	Yes, we have all the technical information associated with the instruments including technical specifications.

		setup, technical specifications etc.)?	
2.		Are you requesting a custom developed application or wanting to purchase a Commercial off-the-shelf software that is capable of interfacing the instruments?	Vendors can propose any solution you may have, subject to technical evaluation. Please refer to the scope as clarified in section B of this document.
3.		Is it really one month project ? if so what is the use of having 2-4 week sprint based approach (Pg no 4, point no 8 - in TOR document)	As stated above the project timeline has been updated to two (2) months duration. The sprint duration was mentioned to align with IOM's other projects, but the vendor will be given the flexibility to plan its own project.
4.		Is this a fixed bid or T&M project. If it is fixed bid what is the relevance of subpoint 3 under point 5 in TOR. i.e "The vendor is responsible with the elasticity of the team (as example, he can start with one developer and add another one later)." Especially given timeline of just one month	Yes, it is a fixed bid. Composition of the team can be planned by the vendor.
5.		Can you please give an extension of one week for the submission of Bid?	Extension has been posted via bid bulletin no.2 – extension until 26 February 2024 – 10:00AM Manila Time.
6.		Just to reiterate, the scope is to provide a laboratory network that is able to interface with all of these "isolated" instruments,	Yes, the scope is to gather information for all these instruments. The instrument conveys the message, and the format specified must match that of the instrument's output.

	communicate with each one of them using the specific protocol of each of these instruments, and ultimately gather all of this data and provide it in the application? And as follow up, if that is the case, HL7 and or ASTM is intended to be the format between the midleware and app or that's the format that is actually output by the instruments?	
7.	Can you provide test-result data samples for each instrument type ?	Yes, see below and also section C, question #5 above.

```
Roche Diagnostics        Immunoanalyzer  cobas e 411     S/N 66V311

Result Report                    Operator-ID: inoh       2024/02/15, 16:50    2/15
                                                                              MAM

Sample/Control ID     Seq.  |  Pos.  |  Test        | Dil | RPos | Result  | Flag

                      207   | 0-10   | A-HCVII 0    |     | 15   | .079    | IMA
                            |        | HBSAGII 0    |     | 14   | .361    |

                      208   | 0-11   | HIVCOMPT 0   |     | 12   | 236     | IMA
                            |        | Syphilis 0   |     | 1    | 118     |
```

c111   V4.3.0.1835   15483
mich   12.02.2024 10:59

Order Details:

Sample ID
Order ID
Order state   All accepted

S Test   Flag   Result
a ALP2S   71.4U/L
a ALTL   27.1U/L
a UA2   262.2umol/L

c111   V4.3.0.1835
mich   12.02.202

Order Details:

Sample ID
Order ID
Order state   All accepted

S Test   Flag   Result
a GLU2   4.72mmol/L
a CRE2   52.2umol/L
a ASTL   17.6U/L

Plate: 16FEB2024MAM

Assay: DS2 QFT-Plus_v2.6   Q. C. Passed

SPREADSHEET RESULTS

MULTITUBE BOOLEAN FUNCTION RESULTS

Sample Id	Nil	TB1	TB2	Mitogen	TB1-Nil	TB2-Nil	Mitogen-Nil	Result
	0.10	0.19	0.22	> 10	0.09	0.12	> 10	NEGATIVE
	0.08	0.08	0.07	0.57	0.00	-0.01	0.49	INDETERMINATE - Low Mitogen
	0.06	0.16	0.17	> 10	0.10	0.11	> 10	NEGATIVE
	0.14	1.08	0.98	> 10	0.94	0.84	> 10	POSITIVE

BACTEC MGIT 960

Unloaded AST Set Report

Instrument Number	Current Date/Time	Temperature A	B	C	Software Version	Page Number
2	02/16/24 12:12	36.6°C	36.8°C	36.6°C	V6.01B	1

Sequence No: 439220140986   **TIP:** 7;12   **SOP:** 02/08/24 11:31   **Removed Date:** 02/16/24

Access No: **Isolate No:** 2

Tube Position	Growth Unit	Status	Concentration	Drug Name
B/A1 3	400	C		Growth Control
B/A1 4	0	S	100.0 ug/mL	Pyrazinamide

Sequence No: 439550160566   **TIP:** 6;13   **SOP:** 02/09/24 12:44   **Removed Date:** 02/16/24

Access No: **Isolate No:** 1

Tube Position	Growth Unit	Status	Concentration	Drug Name
B/D1 3	400	C		Growth Control
B/D1 4	0	S	1.00 ug/mL	Streptomycin
B/D1 5	400	R	0.10 ug/mL	Isoniazid
B/D1 6	400	R	1.00 ug/mL	Rifampin
B/D1 7	0	S	5.00 ug/mL	Ethambutol

Sequence No: 439220070857   **TIP:** 6;23   **SOP:** 02/09/24 12:44   **Removed Date:** 02/16/24

BACTEC MGIT 960
Unloaded Negatives Report

Instrument Number	Current Date/Time	Temperature A	B	C	Software Version	Page Number
2	02/15/24 08:38	36.5°C	36.9°C	36.6°C	V6.01B	1

Tube Position	Accession Number	Sequence Number	Growth Unit	TIP	Removal Date	Protocol Length	Start of Protocol
A/A11		430149798045	0	43;17	02/15/24	42	01/02/24 14:53
A/A20		430149798021	0	43;17	02/15/24	42	01/02/24 14:53
A/C07		430149797883	0	43;17	02/15/24	42	01/02/24 14:53
A/C11		430149797907	0	42;19	02/15/24	42	01/03/24 12:46
A/D02		430149797940	0	42;19	02/15/24	42	01/03/24 12:46
A/D03		430149797956	0	42;19	02/15/24	42	01/03/24 12:46
A/D08		430149797882	0	42;19	02/15/24	42	01/03/24 12:46
A/D15		430149797898	0	42;19	02/15/24	42	01/03/24 12:46
A/G10		430149797963		42;19	02/15/24		

11

BACTEC MGIT 960
Unloaded Positives Report

Instrument Number	Current Date/Time	Temperature A	B	C	Software Version	Page Number
2	02/15/24 08:39	36.4°C	36.6°C	36.4°C	V6.01B	1

Tube Position	Accession Number	Sequence Number	Growth Unit	Tube Status	TTD	Date Positive	Protocol Length	Start of Protocol
A/A08		430149794311	383	+	5;20	02/13/24	42	02/07/24 16:40
A/B10		430149798974	11870	+	4;9	02/13/24	42	02/08/24 15:30
A/B13		430149799038	13339	+	3;19	02/12/24	42	02/08/24 15:30
A/G07		430149795249	97	+	15;14	02/15/24	42	01/30/24 16:04
A/L07		430149791741	42265	+	9;23	02/12/24	42	02/02/24 12:26
A/M05		430149795321	479	+	13;11	02/13/24	42	01/30/24 16:06
C/K19		430149795226	179	+	15;22	02/14/24	42	01/29/24 15:48
C/N12		430149795258	20808	+	13;23	02/12/24	42	01/29/24 15:49

GeneXpert PC   02/16/24 2:12:54 PM

Test Report

Sample ID*:
Test Type: Specimen
Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-XDR	1	In Vitro Diagnostic

Test Result: MTB DETECTED;
                   INH Resistance NOT DETECTED;
                   FLQ Resistance NOT DETECTED;
                   AMK Resistance NOT DETECTED;
                   KAN Resistance NOT DETECTED;
                   CAP Resistance NOT DETECTED;
                   ETH Resistance NOT DETECTED

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SPC-ahpC	25.7	256	NA	PASS
inhA	0.0	-919	NEG	PASS
katG	31.6	412	POS	PASS
fabG1	11.5	107037	NEG	PASS
gyrA1	23.6	366	POS	PASS
gyrA2	29.0	238	POS	PASS
gyrA3	0.0	-385	NEG	PASS
gyrB2	16.4	5260	POS	PASS
rrs	16.1	837	POS	PASS
eis	19.7	140	POS	PASS

User:	Arvie Roxanne Pamiloza		
Status:	Done	Start Time:	02/16/24 12:44:19 PM
Expiration Date*:	10/20/24	End Time:	02/16/24 2:11:34 PM
S/W Version:	6.4	Instrument S/N:	110004816
Cartridge S/N*:	705988946	Module S/N:	210021760

GeneXpert PC   02/16/24 2:12:54 PM

Test Report

Sample ID*:
Test Type: Specimen
Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Ultra	4	In Vitro Diagnostic

Test Result: MTB NOT DETECTED

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SPC	25.6	146	PASS	PASS
IS1081-IS6110	0.0	1	FAIL	PASS
rpoB1	0.0	-2	INVALID	PASS
rpoB2	0.0	3	INVALID	PASS
rpoB3	0.0	10	INVALID	PASS
rpoB4	0.0	4	INVALID	PASS

User:	Arvie Roxanne Pamiloza		
Status:	Done	Start Time:	02/16/24 12:45:46 PM
Expiration Date*:	07/21/24	End Time:	02/16/24 1:50:10 PM
S/W Version:	6.4	Instrument S/N:	805288
Cartridge S/N*:	505949652	Module S/N:	694140
Reagent Lot ID*:	44331	Module Name:	D1
Notes:			
Error Status:	OK		

Errors
<None>

8.	What are the types of test results we need to process during Pilot phase? For example, as HL7 has custom formats depending on test type, depending on amount of test types, coverage of many test types might translate to increased implementation time.	Name of Equipment	Model	Tests Run
		Serology Analyzer	e411	HIV,Syphilis, Hep B and Anti-HCV
		Chemistry Analyzer	c111	Serum Creatinine, Glucose, Uric Acid, AST, ALT, ALP
		ELISA	DS2	IGRA
		MGIT	MGIT 960	TB culture and DST
		GeneXpert	GXIV 4D	MTB/Rif Ultra, Xpert Xpress SARS CoV-2

9.	In form H you are asking for CVs of key personnel and they should also sign a statement of exclusivity and availability for this project. This is somehow contradicting with the possibility of vendor to freely decide team composition during the project	CV of key personnel should be provided. Statement of exclusivity and availability for the project can be signed by the Director or the Lead Manager of the project on behalf of the team composition.
10	In relations to Bid bulletin no.2 item no. 24: Regarding the Operating system, which version of Windows will it run (10, 11), which edition (professional, enterprise, LTSB)? Is it 32 bits, 64	Operating system: Windows 10 Pro and higher .NET: compatible 4.6.1

	Bits? for the implementation, we will need to know which OS the .NET/C# is expected to run on: Windows version number, edition, 32 or 64 bits.	

Approved by: ___Ilyas MASIH (Feb 20, 2024 10:26 GMT+8)___
                Ilyas MASIH
                OIC - MSCU Head

Date: Feb 20, 2024