CALL FOR EXPRESSION OF INTEREST

Early Market Access Vehicle for Omega VISITECT® CD4 Advanced Disease

Issue Date: 28 April 2020

Open Call till 30 September 2021

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1. Purpose

In sub-Saharan Africa, more than a third of all people with HIV who initiate antiretroviral therapy (ART) ultimately present with Advanced HIV Disease (AHD). AHD is defined in adults, adolescents and children older than 5years with a CD4 cell count <200cells/mm3 or WHO stage 3 or 4 event. Additionally, all children younger than five years old with HIV are considered as having AHD. Approximately 10 percent of these patients die within the first three months of starting ART. In 2017, the World Health Organization recommended a package of care proven to reduce mortality from AHD. However, timely CD4 cell count testing, a critical first step for the identification of people with AHD who are eligible for elements of the package of care, remains a gap, as only a subset of health facilities can provide same day CD4 testing across low- and middle-income countries(LMICs).

The Omega VISITECT® CD4 Advanced Disease Rapid Test ("VISITECT®") is a disposable, instrument-free, point-of-care test for identifying people with AHD. As a semi-quantitative lateral flow assay, the test indicates if the patient's CD4 count is above or below 200 cells/µL[1]. Because it can be used by non-laboratory technicians, the VISITECT® has the potential to decentralize same-day CD4 results to lower levels of health facilities, transforming how an AHD package of care can be provided in LMICs. Following an ERPD category 2 "no objection" report in December 2019, the VISITECT® is now listed on the Global Fund's "List of HIV Diagnostic test kits and equipment classified according to the Global Fund Quality Assurance Policy.

Unitaid has established the Early Market Access Vehicle (EMAV), to be led by the Clinton Health Access Initiative, Inc. (CHAI). The goal of the EMAV is to accelerate access to the groundbreaking VISITECT® from Omega Diagnostics in a wide set of countries. Unitaid and CHAI invite interested governments and partners to submit an expression of interest (EOI) to participate in the EMAV.

2. Early Market Access Vehicle (EMAV) Overview

Unitaid and CHAI have engaged with Omega Diagnostics to launch a Unitaid-funded, CHAI-coordinated funding mechanism that will enable eligible buyers to procure VISITECT® and facilitate evidence generation and user experience in a wide group of countries. Additionally, the EMAV will inform national implementation and planning, and design effective systems and processes, such as training curricula and quality assurance, to support routine use of Omega's VISITECT® test.

Summary features of the EMAV:

Global access ceiling price[2]	US$ 3.98 Ex works
Unitaid's maximum commitment[3]	500,000 tests
Minimum number of tests per implementer	10,000

[1] The sensitivity and specificity of the Omega VISITECT® CD4 Advanced Disease Rapid Test compared to flow cytometry are 89.3% and 92.3% with capillary blood, respectively, and 86.3% and 92.8% with venous blood.

[2] Eligible countries for access price presented in Appendix A.

[3] Unitaid will finance up to a maximum of 500,000 tests that have been approved during the eligibility period Unitaid will only cover EXW cost of the product. Eligible countries or buyers will be responsible for PSA fees, freight, and other procurement costs as well as taking ownership of securing waivers and covering in-country distribution costs.

Maximum number of tests per country	50,000
Maximum number of implementers per country[4]	4
Validity of the EMAV	April 2020 – December 2021[5]
Coordinating team secretariat[6]	CHAI, as part of the Unitaid / CHAI Advanced HIV Disease Initiative, will serve as the secretariat for the EMAV. The EMAV secretariat will be responsible for the review and approval of all submissions, as well as coordination of order fulfillment with the manufacturer.
Ceiling price validity period	The Ceiling Price would remain in effect from 28 April 2020 until 31 December 2021. Dependent upon the success of the EMAV, Unitaid, CHAI, and Omega will make best efforts to ensure that the ceiling price is maintained or reduced beyond 2021.

3. EMAV Participation

a. The EMAV is open to all high-burden HIV countries receiving PEPFAR or Global Fund funding.

b. The Applicant must meet the following eligibility criteria:

i. Evidence of understanding of the AHD burden in the country/program.

ii. Ability to provide an AHD implementation plan that clearly outlines an algorithm for managing results of diagnostic tests.

iii. Ability to ensure access to a package of care that includes screening, treatment and/or prophylaxis of opportunistic infection such as TB and cryptococcal meningitis; rapid ART initiation, particularly for those PLHIV with low CD4 count; and adherence support.

iv. An indication to establish a product use case which defines plan for product integration into the existing CD4 network and country operational plans. This may be accompanied by a baseline assessment of the current CD4 footprint where available.

v. Pathway/commitment to importation waiver and/or in-country registration. Product registration or relevant import waiver will be required before products can be delivered.

vi. Commitment to sustain AHD management with or without the VISITECT® CD4 Advanced Disease test.

[4] This requirement may not apply if there is a government/partner entity coordinating EMAV activities at country level. Preference will be given to models with a coordination government or partner entity in countries.

[5] Offer is limited to the maximum commitment of 500,000 tests and subject to availability of a quality assured product through WHO prequalification or Expert Review Panel for Diagnostics (ERPD) renewal.

[6] Unitaid to seek support from PEPFAR and GF for approval of requests, through a clearance process or establishment of an ad-hoc screening committee.

vii. A proven track record in successful implementation of public health projects in resource limited settings.

c. EMAV Procurement approach

i. EMAV procurement will be channeled through the PEPFAR (GHSC-PSM) and the Global Fund (Pooled Procurement Mechanism (PPM)/wambo.org) platforms and the respective procurement services agents. Required approvals should be sought the by the applicant in this regard.

ii. Other eligible buyers including Ministries of Health or implementing partners who are not supported through PEPFAR or GF funding (or do not have access to wambo.org) should consult directly with the EMAV secretariat to establish an appropriate procurement approach.

iii. The Applicant will be requested to specify the preferred procurement channel on the Expression of Interest (EOI) form.

d. Freight and other PSM Costs

i. Unitaid through CHAI will only fund the ex-works costs of the product.

ii. Unitaid requires the eligible buyer to be responsible for all PSM related costs, including, but not limited to: procurement services agent fees, freight, insurance, pre-shipment inspection, customs clearance, and in-country distribution.

iii. Unitaid, in exceptional circumstances through CHAI, may approve the use of EMAV funding to pay for these PSM related costs; such orders should be placed by CHAI, using the Global Fund PPM/wambo.org platform.

e. EMAV Reporting

i. EMAV Implementers will be required to provide monthly reports on AHD implementation to the EMAV secretariat using a standardized reporting form (see example questions in Annex C).

4. EOI Process

a. Submission of EOI

Beginning on 28 April 2020, CHAI will accept Expressions of Interest (EOI) to the EMAV on a rolling basis through 30 September 2021 (or when maximum volume commitment is delivered, whichever comes first). Parties interested in participation in the EMAV may submit an EOI using the response form (see below) during this time. Following submission of an EOI, the EMAV

secretariat will assess the application and notify the applicant of the decision reached within 3 weeks. Please note that incomplete applications will not be processed.

i. All Applicants should submit the completed EOI form to emav@clintonhealthaccess.org.

ii. PEPFAR and the Global Fund partners should copy their respective focal point when submitting the EOI.

b. Selection Criteria

In the event that eligible application requests exceed the total funding available for the EMAV or the maximum implementer positions per country is surpassed, CHAI and Unitaid will agree to a set of evaluation criteria and a selection methodology to assess which of the eligible proposals should be selected.

c. Confidentiality

Information which the Applicant considers to be proprietary or confidential should be clearly marked as such. All such information will be treated as confidential and used for EMAV internal purposes only.

d. Disclosure

Information relating to the examination, clarification, and evaluation of responses shall not be disclosed to Applicant or any other persons not officially concerned with such process.

e. Questions

For immediate questions or comments regarding the EOI process or the EMAV, please email emav@clintonhealthaccess.org.

5. The Clinton Health Access Initiative, Inc. Company Information

The Clinton Health Access Initiative, Inc. (CHAI) is a global health organization committed to saving lives and reducing the burden of disease in low- and middle-income countries, while strengthening the capabilities of governments and the private sector in those countries to create and sustain high-quality health systems that can succeed without our assistance. For more information, please visit: http://www.clintonhealthaccess.org.

6. Unitaid Company Information

Unitaid is an international organization that invests in innovations to prevent, diagnose and treat HIV/AIDS, tuberculosis and malaria more quickly, affordably and effectively. Unitaid works to improve access to diagnostics and treatment for HIV co-infections such as hepatitis C and human papillomavirus (HPV). For more information, please visit: http://www.unitaid.org.

VISITECT® Advanced Disease Early Market Access Vehicle

EARLY MARKET ACCESS VEHICLE APPLICATION FORM

Please complete this form and return to emav@clintonhealthaccess.org. The information in this form is necessary to process your request for participation in the VISITECT® Advanced Disease Early Market Access Vehicle (EMAV).

Name of requesting entity:

PLEASE PRINT

PART A – Application details

1. Preliminary Details

EMAV FOCAL POINT FOR RESPONDING ENTITY ("Applicant"):

Name:	Title:
Organization:	Country:
Phone #:	Email:
Country / Countries of Interest:	

2. Applicant Information

A. Source of implementing partner funding for AHD-related activities: PEPFAR/GF/ Government/ Others, specify:

B. Number of sites covered by partner for HIV services:

C. Number of sites being proposed for the EMAV from the above:

D. Prior or current experience implementing AHD interventions (please include specifics regarding sizes and types of interventions):

3. Country AHD Program

A. HIV Burden:

B. Prevalence of AHD in Country:

C. Number of PLHIV on ART:

D. Number of Facilities Providing ART:

E. Percentage of ART facilities Providing CD4 Testing:

F. Number of ART facilities with a conventional CD4 Instrument:

G. Number of ART facilities with a POC CD4 Instrument:

H. What type of CD4 instruments exist in country? *(List all with name of Equipment and Manufacturing)*

I. How is CD4 testing currently being used in-country

- ☐ **Baseline Evaluation**
- ☐ **Treatment Monitoring**
- ☐ **Treatment Failure Evaluation**
- ☐ **Workup for PLHIV returning to care**
- ☐ **Not currently in use**
- ☐ **Other, please specify**

J. Does the host country have existing guidance on AHD? ☐ **Yes** ☐ **No**

If no, is this in development? ☐ **Yes** ☐ **No**

(Attach existing AHD guidelines where available)

K. Which elements of the AHD package of care are currently available in country?

- ☐ **TB LAM**, provided through ☐ **national program** ☐ **partner site**
- ☐ **CrAg screening**, provided through ☐ **national program** ☐ **partner site**
- ☐ **Fluconazole Preemptive Treatment**, provided through ☐ **national program** ☐ **partner site**
- ☐ **CM Treatment**, provided through ☐ **national program** ☐ **partner site**
- ☐ **TB Preventative Treatment, provided through** ☐ **national program** ☐ **partner site**
- ☐ **Other, please specify:**

4. Plans for introduction of VISITECT®

A. In a sentence or two, please provide a narrative on the objective and intended approach for deploying the VISITECT® CD4 Advanced Disease.

B. Quantity of VISITECT® tests is required by the applicant asking for through the EMAV:

C. Number of sites where VISITECT® test will be deployed:

D. What other elements of the AHD package of care will be available at the facilities that will receive VISITECT®?

- ☐ **TB LAM**
- ☐ **CrAg screening**
- ☐ **Fluconazole Preemptive Treatment**
- ☐ **CM Treatment**
- ☐ **TB Preventative Treatment**
- ☐ **Other, please specify:**

E. Please explain how the catalytic procurement of VISITECT® through the EMAV will inform implementation planning, including timeline and future plans for national scale up of AHD diagnosis and management (500 words):

F. Please select the facility types at which the applicant intends to introduce VISITECT®: *(Select All that apply)*

- ☐ **Facilities with a conventional CD4 instrument**
- ☐ **Facilities with a POC CD4 instrument**
- ☐ **Facilities without any CD4 instrument**
- ☐ **Other, please specify:**

G. Is there a clear use case for AHD continuous funding after this initial catalytic procurement?

- ☐ **Yes**
- ☐ **No**

H. What are the potential funding sources for continuity of the AHD package of care diagnosis and management beyond EMAV?

I. Is the country/implementing partner committed to share monthly summary data/information on implementation progress and lessons learned with Unitaid, CHAI and the relevant Ministry of Health?

- ☐ **Yes**
- ☐ **No**

5. Supply Chain

A. Is VISITECT® CD4 Advance Disease registered in the country or is an importation waiver available? (If yes skip next question)

- ☐ **Yes**
- ☐ **No**

B. If no, will the applicant/supporting donor process the importation waiver to enable receipt of commodities and their use in clinical management?

- ☐ **Yes**
- ☐ **No**

C. Estimated time duration to receive waiver approval_____

D. Will the applicant/supporting donor cover costs for procurement services agent fees, freight, insurance, waivers, warehousing and distribution to implementation sites?

- ☐ **Yes**
- ☐ **No**

E. If a Ministry of Health or Global Fund Principal Recipient (PR), will the respondent prefer to order the commodity directly via wambo.org?

- ☐ **Direct GF Wambo platform**

☐ **CHAI order placement**

Please state consignee details below:

Name:	Title:
Organization:	Country:
Phone #:	Email:

PART B– DECLARATION

This form is being submitted on behalf of [REQUESTING ENTITY] , to provide a non-binding expression of interest for participation in the EMAV for VISITECT® CD4 Advanced Disease Rapid Test, an initiative of the Unitaid-CHAI Advanced HIV Disease (AHD) project.

As part of the EMAV, we understand that the donation of the VISITECT® CD4 Advanced Disease Test aims to generate country experience with and use case for on the VISITECT® CD4 Advanced Disease Rapid Test. This experience should also help expand the knowledge of Advanced HIV Disease and inform potential national roll-out of the diagnosis and treatment of Advanced HIV Disease. Participation in the EMAV is not a commitment to continue to procure the VISITECT® test; however, should relevant government stakeholders, including the Ministry of Health find a valid use case, we would support continuous use of the VISITECT® test.

We also acknowledge that we understand the basic terms of the EMAV to be that:

i. CHAI will coordinate the various mechanisms to procure the VISITECT® CD4 Advanced Disease rapid test for country use, as part of the Unitaid-CHAI AHD Initiative;

ii. CHAI will serve as a secretariat of, the EMAV, including, but not limited to, activities relating to the (1) general advisory, introduction, and oversight of the EMAV activities in-country, and (2) the coordination of other partners who will be leveraging the EMAV in-country.

iii. Approved applicants commit to share EMAV summary data on implementation progress and lessons learned with Unitaid, CHAI and the relevant Ministry of Health and shall provide reports, in such timely and accurate manner as is practicable, on distribution, consumption, utilization, and/or loss of the VISTECT product, upon the reasonable request of CHAI.

This submission constitutes only an expression of interest for a possible participation in the EMAV. By submitting this expression of interest, we acknowledge that we meet the basic eligibility criteria for EMAV participation, as outlined above.

We understand that after submission of this expression of interest, if the Unitaid-CHAI AHD Initiative deems that the criteria for participation has been met, and accepts the application, it will make arrangements to finalize our participation

in the EMAV and notify us of the next steps required. In the event that the Unitaid-CHAI AHD Initiative does not approve our application to participate in EMAV, the secretariat will notify us of the decision.

By submitting this expression of interest, we confirm that we have verified that there are no legal or regulatory barriers that would prevent us from meeting the basic terms outlined above. Where necessary, we confirm that we will obtain any waivers and/or exemptions required under applicable laws or regulations to enable the initiation of the EMAV activities in country.

We understand that issue of the expression of interest by CHAI and submission of our response is not a commitment by either party to enter into such discussions or such collaboration. We further understand that Unitaid and CHAI reserve the right to enter into collaboration discussions and a resulting collaboration with one or multiple parties, with no parties, or to cancel this expression of interest at their sole discretion.

Finally, we acknowledge that our relationship with Unitaid and CHAI is that of independent parties, and that the EMAV will act as means of procurement, rollout, monitoring and evaluation, and potential scale-up planning for Advanced HIV Disease management program. We confirm that all the information provided here is true.

SIGNATURE

Authorized Representative Name: Title:

Authorized Representative Signature: Date:

Company Name:

Company Address:

Telephone No.: Email:

Annex A: List of Countries Eligible for the Ceiling Price

Low-Income Countries		
Afghanistan	Guinea-Bissau	Sierra Leone
Benin	Haiti	Somalia
Burkina Faso	Korea, Dem. People's Rep.	South Sudan
Burundi	Liberia	Syrian Arab Republic
Central African Republic	Madagascar	Tajikistan
Chad	Malawi	Tanzania
Congo, Dem. Rep	Mali	Togo
Eritrea	Mozambique	Uganda
Ethiopia	Nepal	Yemen, Rep.
Gambia, The	Niger	
Guinea	Rwanda	

Lower-Middle Income Countries		
Angola	India	Papua New Guinea
Bangladesh	Indonesia	Philippines
Bhutan	Kenya	Sao Tome and Principe
Bolivia	Kiribati	Senegal
Cabo Verde	Kyrgyz Republic	Solomon Islands
Cambodia	Lao PDR	Sudan
Cameroon	Lesotho	Timor-Leste
Comoros	Mauritania	Tunisia
Congo, Rep.	Micronesia, Fed. Sts.	Ukraine
Cote d'Ivoire	Moldova	Uzbekistan
Djibouti	Mongolia	Vanuatu
Egypt, Arab Rep.	Morocco	Vietnam
El Salvador	Myanmar	West Bank and Gaza
Eswatini	Nicaragua	Zambia
Ghana	Nigeria	Zimbabwe
Honduras	Pakistan	

Upper-Middle Income Countries[1]		
Albania	Fiji	Namibia
Algeria	Gabon	Nauru
American Samoa	Georgia	North Macedonia
Argentina	Grenada	Paraguay
Armenia	Guatemala	Peru
Azerbaijan	Guyana	Romania
Belarus	Iran, Islamic Rep.	Russian Federation
Belize	Iraq	Samoa

Bosnia and Herzegovina	Jamaica	Serbia
Botswana	Jordan	South Africa
Brazil	Kazakhstan	Sri Lanka
Bulgaria	Kosovo	St. Lucia
China	Lebanon	St. Vincent and the Grenadines
Colombia	Libya	Surinam e
Costa Rica	Malaysia	Thailand
Cuba	Maldives	Tonga
Dominica	Marshall Islands	Turkey
Dominican Republic	Mauritius	Turkmenistan
Ecuador	Mexico	Tuvalu
Equatorial Guinea	Montenegro	Venezuela, RB

Notes:
Upper middle-income countries will be eligible to access the Ceiling Price for procurements through United Nations-related organization, non-governmental organizations and not-for-profit organizations, development and/or public health financing mechanisms, or a procurement agent appointed by any of these entities. South Africa is the exception to this stipulation and will be eligible to access the Ceiling Price through all Eligible Buyers defined above.

Eligibility for accessing the ceiling price extends to public sector buyers and funders such as:

i. Governments of Eligible Countries.

ii. United Nations-related organizations, non-governmental organizations and not-for-profit organizations.

iii. Development and/or public health financing mechanisms, or a procurement agent appointed by any of the entities above.

The ceiling price does not apply to product sales to “for-profit” private sector entities.

Annex B: Product List

Packaging (primary and secondary pack, pack size)			
Pack	**Number of units**	**Dimensions L x H x W (cm)**	**Weight in kg**
VISITECT®CD4 Advanced Disease kit	25 tests	20.0 x 7.5 x 14.0	0.400kg
VISITECT®CD4 Advanced disease RapidTest - Shipment	50 kits (50 x 25 tests)	60 x 50 x 47	23.5kg

Contents of 1 VISITECT®CD4 Advanced Disease kit	
• 25 pouches with the test and desiccant	• 25 retractable lancets
• buffer, 1 bottle, 7 ml	• 25 alcohol swabs
• 30µl sampling device for capillary blood only	

Consumables and accessories not included	
• disposable gloves	• vacuum tube (venous sample only)
• dry gauze or tissue	• vacuum tube needle (venous sample only)
• Band aids	• precision pipette capable of delivering 30µL and tips (venous sample only)
• pen	
• sharps bin	
• timer	

Annex C: Reporting Metrics

Monthly reporting to the EMAV secretariat is required. EMAV implementing partners will be asked to submit reports that include metrics such as, but not limited to:

i. Lead time from order placement to delivery
ii. Number of VISITECT® tests used in the reporting month
iii. Number of PLHIV in need of AHD screening who were screened with VISITECT® during the reporting period
iv. Number of PLHIV diagnosed with AHD using VISITECT®, who received TB testing using TB LAM or GeneXpert
v. Number of PLHIV diagnosed with AHD using VISITECT® who received CrAg screening