REQUEST FOR PROPOSAL (RFP)

Issued by Clinton Health Access Initiative
Funded by Unitaid

Title: Request for proposal to provide interventions to increase capacity for sustainable access to CD4 testing

Issue Date: 2nd December 2024

Deadline for Questions: 16th December 2024

Closing Date: 31st January 2025

Disclaimer:

The distribution of this document does not mean there is any commitment on the part of the Clinton Health Access Initiative (CHAI) and Unitaid to fund an applicant. CHAI and Unitaid will not reimburse or otherwise bear any costs associated with the development of this Request for Proposals (RFP) regardless of whether an organization is selected to implement the project. Please note that no fee is required to submit this application. CHAI and Unitaid make no representation or warranty and shall incur no liability whatsoever under any law as to the accuracy, reliability or completeness of the information contained in the RFP. This RFP is issued by CHAI and the Aurum Institute for planning and design purposes, with funding and technical support from Unitaid. Any information submitted in response to this RFP is provided to CHAI, Aurum and Unitaid voluntarily and may be discussed with the Bill & Melinda Gates Foundation (BMGF) to ensure similar investments are complementary and non-duplicative. CHAI, Aurum, and Unitaid shall not be under any obligation to procure any of the services or products described herein, and the issuance of this RFP shall not be construed as a commitment to enter commercial or other business relations. CHAI, Aurum, and Unitaid may use the information provided by respondents to the RFP to support strategic decisions and planning within its project portfolio or for internal purposes, including but not limited to the design of future Requests for Quotations (RFQs) or other solicitations which CHAI, Aurum, or Unitaid may issue. Any information submitted in response to this RFP that needs to be treated as "confidential" should be marked as such on the completed form by the respondent. When information is marked confidential, CHAI, Aurum, and Unitaid will take all reasonable measures to keep it confidential and will not share it with other entities or individuals outside of these organizations without the respondent's written authorization. However, this confidentiality commitment shall not apply if the information concerned, or any part of it (a) was known to any of the organizations before any disclosure by the respondent or (b) was in the public domain at the time of disclosure by the respondent, or (c) becomes part of the public domain 3 through no fault of the organizations, or (d) becomes available to any of the organizations from a third party who is not in breach of any legal obligation of confidentiality to the respondent. Information not marked as confidential will nevertheless not be shared with other entities or individuals outside the organizations without the respondent's written authorization unless that information has been anonymized or aggregated to deter identification of individual manufacturers (e.g., used without specifying individual Company or Organization names, product names, geographical location).

TABLE OF CONTENTS

List of Abbreviations

AHD	Advanced HIV Disease
BMGF	Bill and Melinda Gates Foundation
CHAI	Clinton Health Access Initiative
ERP	Expert Review Panel
GMP	Good Manufacturing Practice
HPV	Human Papillomavirus
LMIC	Low- and Middle-Income Countries
PLHIV	People Living with HIV
POC	Point-of-Care
PQ	Prequalification
RFP	Request for Proposal
SRA	Stringent Regulatory Authority
THRIVE	Transforming Advanced HIV Disease Care in LMICs through Comprehensive and Equitable Access
TPP	Target Product Profile
US FDA	United States Food and Drug Administration
WHO	World Health Organization

1. Overview

The Clinton Health Access Initiative (CHAI) invites interested and capable suppliers to submit proposals for interventions to increase capacity and sustainable access to CD4 testing.

This request for proposal (RFP) follows the earlier expression of interest (EOI) and is designed to evaluate opportunities to increase access to CD4 testing for people living with HIV (PLHIV) in low- and middle-income countries (LMICs), especially in high-burden countries where major gaps in screening for Advanced HIV Disease (AHD) persist, and there is a particular interest or need for point-of-care (POC) testing. All proposals will be evaluated by a steering committee comprised of representatives from CHAI, Aurum, and Unitaid. The steering committee will discuss promising proposals with the Bill & Melinda Gates Foundation (BMGF) to ensure complementarity of investments.

The goal is to issue awards for solutions that support sustainable access to POC testing, either with a product that is already approved by a Stringent Regulatory Authority (SRA) or the World Health Organization (WHO) Prequalification Programme (PQ) and commercially available or for a product dossier to be filed by selected manufacturers with an SRA or the WHO PQ and for the product to be registered in selected high-burden LMICs at an affordable price.

In this context, CHAI, Aurum, and Unitaid also seek to understand the extent to which manufacturers may be interested in receiving support towards achieving set target access requirements. The available support could be one or a combination of the following: regulatory assistance for registration and/or WHO PQ; support associated with technology transfer for regional manufacturing of a new POC CD4 test; support with transitioning some manufacturing capacities to Africa; support for WHO expert review panel quality assurance review; acquiring a POC CD4 test from another company and bringing it to market; advance market commitment for partner-funded procurement volumes. Manufacturers are encouraged to collaborate with civil society and/or implementing partners for engagement at the country level, to seek their input on the feasibility and sustainability of approaches, to identify critical gaps, and to develop implementation plans.

2. About THRIVE

The Unitaid-funded THRIVE (**T**ransforming Advanced **H**IV Disease Ca**R**e in LM**I**Cs through Comprehensi**V**e and **E**quitable Access) Project is implemented by a consortium led by CHAI. It includes Afrocab as the community and civil society engagement lead and Penta as the paediatric AHD research lead. The project will dramatically reduce mortality among adults and children living with HIV by enabling access to critical prevention, screening, and treatment commodities, and centering local leadership and community-owned solutions to find and serve people living with AHD where they are. For more information on the THRIVE project, go to: https://www.thriveinfo.org/.

About CHAI | 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.

About Aurum | The Aurum Institute is a proudly African organisation working to advance health, science and innovation to create a healthier world for future generations. We partner with governments, the private sector, and civil society to design and deliver high-quality care and treatment to people in developing communities. https://www.auruminstitute.org/

About Unitaid | 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.

Please note that all RFP enquiries should be directed to CHAI *(refer to contact information in Section 4);* ***Unitaid will not respond to RFP-related enquiries.***

3. Evaluation Aims and Process

The focus of this evaluation is to help inform future investments in CD4 market shaping.

The process for the evaluation is as follows:

CHAI will form an evaluation committee to review all the bids. To be considered for an award, the Manufacturer must meet the eligibility criteria specified in Section 7, demonstrate the availability of the required production and distribution structures to meet the demands of the CD4 market in low- and middle-income countries LMICs, and be willing to commit to an affordable selling price for LMICs (as defined by the WHO's Target Product Profile (TPP) for *Point-of-Care CD4 Tests to Support the Identification of Individuals with Advanced HIV Disease*), together with other commitments to access to be negotiated as part of the development/ commercialisation contract (see section 5(k) below). CHAI will then assess each eligible bid meeting the above criteria. The supplier(s) scoring the highest against the scoring criteria will move forward. The final decision will be reviewed and agreed upon through a steering committee comprised of Unitaid, Aurum, and CHAI.

4. Summary of Target Product

This RFP is open to manufacturers providing a viable, affordable, quality-assured solution for the LMIC market to accelerate widespread access to CD4 testing. Interested manufacturers should provide evidence and plans to scale up access to currently available POC CD4 testing options before the end of 2025 while manufacturers with tests in the pipeline should provide evidence and plans to bring these tests to market within 2.5 years (by the end of 2026). This means, at minimum, manufacturers should be ready to (i) file for approval by FDA or WHO PQ and (ii) ready to manufacture tests for commercial use.

5. Scope of Work

This RFP is designed to identify appropriate POC CD4 solutions for high-burden countries where major gaps in AHD screening persist and where there is a particular interest or need for POC testing. The goal is to support sustainable access to POC testing either with a product that is already approved by an SRA or WHO PQ and commercially available or for a product dossier to be filed by selected manufacturers with an SRA or WHO PQ and for the product to be registered in selected high-burden LMICs at an affordable price. There is a preference for proposals that include regional manufacturing in Africa or with some element of the final distribution already in place or planned for development.

CHAI (through its funder, Unitaid) will provide support for one or a combination of the following:

- Regulatory assistance for registration in target LMICs and/or SRA;
- Support associated with technology transfer for regional manufacturing of a new POC CD4;
- Support with transitioning some manufacturing capacities to Africa; support for WHO expert review panel quality assurance review;
- Supporting technology transfer of a POC CD4 test from another company and bringing it to market;
- Advance market commitment for partner-funded procurement volumes.

Manufacturers are required to commit to collaborating on a wide range of activities, which may include some or all of the following:

- Provision of a report that includes information on the status of test development, analytical method development and validation, and stability studies.
- Preparation and submission of a regulatory dossier for an SRA or the WHO PQ and the Expert Review Panel (ERP) and other acceptable regulatory mechanisms.
- Preparation and submission of a plan for regulatory filings and product commercialization in LMICs.
- Production and supply planning/commitment to cover at least five years (through 2030) that ensures the capacity to supply the target market within a mutually agreed manufacturing lead time.
- Supplying product at an affordable price (which may be at or below a ceiling price) to be finalized in the award contract on a continuous basis for qualified orders within a validity period. Other access commitments, such as supply security, minimum production volumes, etc., may also be necessary, depending on the conditions.

Manufacturers are encouraged to consult with civil society and/or implementing partners for engagement at the country level, to seek their input on the feasibility and sustainability of approaches, to identify critical gaps, and to develop implementation plans.

6. Instructions to Interested Parties

All proposals should be submitted in English and must be set out in two main parts:

a. The Declaration of Commitment;
b. The RFP Application in a separate Microsoft Excel file.

a. Declaration of Commitment

i. Proposals must be accompanied by a cover letter on company-headed paper showing the full registered and trading name(s), trading and registered office address, and business number of the agency. The letter must be signed by a person of suitable authority to commit the agency to a binding contract. It must quote the RFP title and include the declarations listed in Annex 1.

b. RFP Application

i. A complete RFP response should include the Excel sheet provided. Applicants must complete the application in its entirety, filling out all sections highlighted in pale yellow.

c. Submission: The proposal must be submitted electronically to the following email address AHDDx@clintonhealthaccess.org at least by **31 January 2025 by 11:59 pm GMT** with the subject '*Submission for Bid Ref:* RFP/CHAI/AHD/1024'. The proposal consists of the completed Microsoft Excel application and any additional attachments outlined in the application. Late/incomplete proposals will not be accepted in any circumstances. Proposals received after the due date or sent to any other email address will not be considered.

d. Queries: Any queries or clarifications on the RFP should be submitted via the email AHDDx@clintonhealthaccess.org by **16 December 2024 by 11:59 pm GMT** with the subject line '*Queries for Bid Ref:* RFP/CHAI/AHD/1024'. Responses will be shared in a Q&A file here. Any queries or clarifications received after the deadline will not receive a response.

e. Proposals will not be considered if received after the deadline or are missing any components of the proposal package (cover letter with declarations, RFP Application). CHAI reserves the right to request additional information, arrange interviews with the Manufacturer, visit the Manufacturer's premises and facilities, and conduct an audit to verify the information provided.

f. Timelines: The timeline for the RFP process is described below. Proposals received after the deadline will not be considered.

Bid Reference	**RFP/CHAI/AHD/1024**
Release of Request for Proposals	**2 Dec 2024**
Deadline for submitting questions by email	**16 Dec 2024 (11:59pm GMT)**
Proposals due/last date of submission of proposal	**31 Jan 2025 (11:59pm GMT)**

g. Questions and answers

i. A formal period during which questions regarding this RFP are answered will be held following the posting of the RFP on CHAI's website (please reference above for timeline). Questions should be sent via email to AHDDx@clintonhealthaccess.org

ii. All enquiries must be received via email by the stipulated deadline for questions. All questions and answers will be published on the CHAI website.

iii. It will not be possible to engage in telephone enquiries.

h. Eligibility: The RFP is open to Manufacturers who previously responded to the EOI for CD4 and who meet the following criteria:

- The company has previously submitted dossiers to WHO PQ, United States Food and Drug Administration (US FDA), or other SRA for any product and received Prequalification and/or SRA approval **OR** the Company will commit to submitting a dossier to US FDA (or other SRA to be mutually agreed) and/or WHO PQ with this product.
- The company's production facility operates under current Good Manufacturing Practice (GMP), has obtained or is in the process to obtain ISO 13485 certification, and/or the manufacturing site/unit has been successfully audited for GMP by WHO PQ or US FDA/SRA; Company must be able to provide evidence of certifications and/or completion of prior audits if they are engaged for further consideration for an award;
- The company has the proven ability to manufacture rapid diagnostic tests at a commercial scale **OR** is working on a downstream solution that will support cost-effective and sustainable access to an existing POC test for CD4;
- The company must agree to host and must pass a quality assurance/ GMP audit if they are engaged for further consideration for an award;
- The company may be required to establish a project team structure that includes representatives from one or more collaborating institutions (CHAI, Aurum, and Unitaid) and host regular meetings (in person and/or via teleconference) as/when required.

i. Costs of preparing documents

The Company will bear all costs associated with preparing and submitting an RFP.

j. Disclosure

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

k. Terms and Conditions

Terms and conditions for the development/commercialization contract (including binding commitments to access, such as affordable pricing) will be finalized during the negotiation process and shared with final selected Manufacturer(s). A formal agreement including these terms will be executed by CHAI and the selected Manufacturer(s) prior to initiation of the work.

7. Evaluation criteria

To be considered for an award, the Manufacturer must demonstrate the necessary experience in registering and supplying diagnostic tests in LMICS and manufacturing at scale. CHAI will assess each eligible proposal based on selection criteria under four categories:

Product

- Product's alignment with the WHO TPP for POC CD4 Tests

Development

- Product development plan
- Time to filing and regulatory plan
- Risk assessment and mitigation strategies
- Regulatory approval experience
- Product acceptability in LMICs
- Plans for regional manufacturing

Commercialisation

- Country registration and distribution experience
- Manufacturing capacity
- Affordable and volume-based pricing in accordance with LMIC context

Institutional Capabilities

- ISO certification readiness
- Project team

8. Conflict of Interest Disclosure

Suppliers bidding on CHAI business must disclose to the procurement contact listed in the RFP any actual or potential conflicts of interest. Conflicts of interest could be present if there is a personal relationship with a CHAI staff member that constitutes a significant financial interest, board memberships, other employment, and ownership or rights in intellectual property that may conflict with the supplier's obligations to CHAI. Suppliers and CHAI are protected when actual or perceived conflicts of interest are disclosed. When necessary, CHAI will create a management plan that mitigates potential risks presented by the disclosed conflict of interest in line with existing CHAI policies.

Annex 1: Forms to be completed by Responders

FORM A: RESPONSE TO REQUEST FOR PROPOSAL

This form must be completed, signed, and returned to CHAI.

[insert company letterhead]

1. We, the undersigned, have examined the information provided in your Request for Proposals (RFP) and offer to undertake the work described by the requirements as set out in the RFP. This proposal is valid for acceptance for 120 days, and we confirm that this proposal will remain binding upon us and may be accepted by you at any time before this expiry date.

2. We accept that any contract that may result will comprise the contract documents issued with the RFP and be based upon the documents submitted as part of our proposal.

3. Our proposal (technical and financial) has been arrived at independently and without consultation, communication, agreement, or understanding (for the purpose of restricting competition) with any other Respondent to or recipient of this RFP from CHAI.

4. All statements and responses to this RFP are true and accurate.

5. We understand the obligations regarding disclosure as described in the RFP guidelines and have included any necessary declarations.

6. We confirm that all personnel named in the proposal will be available to undertake the services.

7. We agree to bear all costs incurred by us in connection with the preparation and submission of this proposal and to bear any further pre-contract costs.

8. We fully accept responsibility for Security and Duty of Care for Personnel, and we understand the potential risks and have the knowledge and experience to develop an effective risk plan. We have the capability to manage their Duty of Care responsibilities throughout the life of the contract.

9. I *[name of signatory]* confirm that I have the authority of [insert name of company] to submit this proposal and to clarify any details on its behalf

10. I *[name of signatory]* confirm that the company will commit to an affordable selling price and to making the product accessible to LMICs as part of the development and commercialisation contract that follows, should an award be granted.

Name of authorized representative: _____

Title: _____

Signature: _____

Date: _____

Company name: _____
(please provide full registered and trading name(s))

Postal Address: _____
(please provide full trading and registered office address)

Telephone No.: _____

Email Address: _____

FORM B: Quality Audit Agreement

This form must be completed, signed, and returned to CHAI.

DECLARATION

Responder agrees that if selected for the RFP award, permission will be given to CHAI to conduct a quality audit in order to assess that the manufacturer is operating under cGMP. This will be a general GMP and Quality Systems audit, most likely performed by an independent third-party consultant. This audit will be scheduled directly with the manufacturer after the award has been granted.

Name of authorized representative: _____

Title: _____

Signature: _____

Date: _____

Company name: _____
(please provide full registered and trading name(s))