

CALL FOR EXPRESSIONS OF INTEREST

Invitation to submit an Expression of Interest (Eol) to commercialize and deploy AI-based Automated Visual Evaluation (AVE) for cervical cancer screening in LMICs

Issue date: 15 August 2025

Closing date: 15 September 2025

Disclaimer Notice

This call for Expressions of Interest (Eol) is issued by the Clinton Health Access Initiative (CHAI) and Unitaid for planning purposes in respect to their market shaping activities only. CHAI and Unitaid shall not be under any obligation to purchase or procure any of the services or products or provide financial or technical support to a respondent, and the issuing of this Eol shall not be deemed to be a commitment by CHAI and Unitaid to enter into commercial or other business relations.

Any information submitted in response to this Eol is provided on a voluntary basis. CHAI and Unitaid may use the information provided by respondents to inform strategic decisions, understand demand for the product, plan within their portfolio, and for their own internal purposes, including but not limited to, the design of future Eols, Requests for Proposals, or other solicitations.

All respondents are solely responsible for costs and expenses incurred in connection with this Eol including the preparation and submission of responses and participation in all future stages of this process. Under no circumstances will CHAI and Unitaid be liable for any costs or expenses borne by a respondent or any of its supply chain, partners or advisors in this process.

1. Overview

The Clinton Health Access Initiative (CHAI) and Unitaid invite technology developers, digital health innovators, and medical device manufacturers to submit an Expression of Interest (EoI) to support the commercialization¹ and deployment² of AI-assisted Automated Visual Evaluation (AVE) for cervical cancer screening in low- and middle-income countries (LMICs).

Background

Cervical cancer is a preventable cause of death, but more than 350,000 women die from it every year. More than 90% of those deaths are in low- and middle-income countries (LMICs), where access to preventive services is limited. In 2020, the World Health Organization and its 190+ member countries agreed to a 10-year plan towards elimination of cervical cancer - the first time an elimination goal has been set for a cancer. A critical component of that plan is the screening of women aged 30-49 for precancerous lesions.

Problem

In LMICs, screening is done by visual inspection of the cervix with acetic acid (VIA), in which a health worker examines the cervix with the naked eye for precancerous lesions. Though low-cost and scalable, VIA has poor accuracy and high variability. In high-income markets predominantly HPV testing is used instead, but financing constraints currently prevent widespread use and scale-up of HPV testing in LMICs.

Solution

An AI-assisted Automated Visual Evaluation (AVE) tool - in which a healthcare worker uses a low-cost smartphone to take a photo of the cervix during a pelvic exam and receives a real-time positive or negative result - can augment the VIA process and increase the efficacy of screening.

Current status

Following internal validation by Global Health Labs, the AVE tool was placed onto a custom-built Android app and evaluated for diagnostic accuracy in a five-country study which enrolled more than 25,000 women. This study found that AVE outperforms VIA on detection of precancerous lesions (71.8% sensitivity versus 36.6% sensitivity), enabling more accurate, affordable, and accessible screening.

Market Size

Meeting the WHO elimination targets requires around 500M screenings over a 10-year period in LMIC settings, or 50M screenings per year.³ Given performance advantages and interest expressed by national stakeholders, we anticipate that AVE has the potential to comprise a significant share of total screening volumes by the end of the decade.

Social Impact

AVE has generated enormous interest among national programs in LMICs due to its potential to cost-effectively scale up quality screening, save women's lives, and avert spending on treatment for invasive cancer. At scale, AVE could transform service delivery, contribute to achieving the WHO elimination

¹ Commercialization: the process of bringing a technology or product from development to the market. It includes completion of product development; regulatory approval; business planning; manufacturing; partnership development; and market and sales.

² Deployment: refers to the actual implementation and use of the product in the field. It includes distribution and logistics; integration; training and capacity building; technical support; and monitoring and evaluation.

³ Cervical cancer screening programmes and age-specific coverage estimates for 202 countries and territories worldwide: a review and synthetic analysis. Bruni, Laia et al. *The Lancet Global Health*, Volume 10, Issue 8, e1115 - e1127

targets, and forge a repeatable path to sustainable scale for other impactful digital health tools across LMICs.

Through this EoI and a subsequent Request for Proposals (RfP) process, CHAI and Unitaid aim to identify partners with the interest and capability to advance AVE market entry and availability through regulatory approval, commercialization, and deployment by the end of 2027.

In parallel to this EoI/RfP process, the core AVE asset package including model code will be open-sourced to promote innovation and improvements to the model. Any derivatives of the model will not be required to be open-sourced; partners will be free to create proprietary models and products using the AVE asset package. CHAI and Unitaid are open to facilitating partnership and collaboration among eventual winners of RfP process and developers, students, innovators, and other users of the open-source package, though such partnership will not be required of RfP winners. Respondents should include in their Submission (see Section 4 below) any concerns or objections to the open-sourcing plan, if applicable.

2. Objectives of Call for EoI

This Call for EoI aims to:

- Identify potential partners to advance, commercialize, and deploy AI-assisted Automated Visual Evaluation (AVE) sustainably across LMICs;
- Gather information on feasible deployment models (including set-up service and maintenance, warranty expectations, license lengths), pricing strategies, and approaches for integration with existing digital health platforms;
- Understand the technical, commercial, and regulatory support required to bring AVE to market and ensure successful implementation;
- Assess interest in collaborative partnerships aimed at improving access, ensuring affordability, and aligning with the priorities and capacities of LMIC health systems.

A subsequent Request for Proposals is expected to be issued in Q4 2025 to select commercial partners. Entities that respond to this EoI will be prioritized for invitation to submit proposals under the RfP process.

3. Target Product Profile (Summary)

A full Target Product Profile is included in Annex 1. Key features include:

- **Product:** Non-invasive imaging software that captures a quality cervical image, applies a machine learning algorithm to support image interpretation, and provides a positive or negative result, indicating likely presence or likely absence of precancerous lesions.
- **Intended Use:** Triage test for HPV-positive women or standalone screening aid where HPV testing is not available.
- **Target Setting:** Wide deployment including decentralized primary care settings in Africa.
- **Target Users:** Frontline health workers currently performing cervical cancer screening (e.g., nurses, midwives).
- **Performance:** Sensitivity and specificity $\geq 70\%$.
- **Regulatory Compliance:** Meet appropriate international GMP (good manufacturing practices) with a pathway toward SRA and LMIC approvals. Depending on final product this could include IEC 62304, ISO 13485, and/or ISO 14971.

4. Submission Requirements

Interested parties should submit a document summarizing:

- **Company details**, including current regulatory-approved AI-based product offerings and geographic footprint, especially any prior or current projects in CHAI/Unitaid focal countries: Kenya, Malawi, Nigeria, Rwanda, Zambia, Zimbabwe
- Potential approach to **productize, secure regulatory approvals, and commercialize AVE**
- Potential **deployment (technical and implementation) and pricing** approach
- **Support needs** for regulatory approval, commercialization, and scale-up and why such support would be necessary (See Section 5 below)
- Confirmation of willingness to do the following if selected through subsequent RfP process:
 - Share relevant technical documentation and development plans;
 - Pursue timely regulatory approval;
 - Price the solution affordably for LMICs;
 - Explore integration with digital health platforms;
 - Engage local stakeholders and implementation partners;
 - Collaborate under the terms of a future data sharing agreement;
 - Agree to access commitments regarding affordability of AVE, including short and long-term maximum price targets, to be determined through collaborative consultation with the selected partner(s) and prospective public sector buyers; and
 - Ensure that the AVE-related intellectual property (IP) including the future IP is managed in a manner which furthers and is consistent with the access commitments.

Respondents may be invited to respond to follow-up questions regarding their submission.

5. Support Available from CHAI and Unitaid

Subject to alignment and due diligence, selected partners may be eligible to receive:

- Milestone-based seed funding;
- Technical assistance on AI/ML refinement and validation;
- Facilitation of regulatory submissions and/or in-country validation studies;
- Market shaping interventions (e.g., advance purchase commitments, volume guarantees);
- Facilitation of strategic partnerships with hardware providers and LMIC governments.

Respondents are encouraged to clearly indicate in their submission document the type and nature of support they would require (from within or beyond the list above) to enable successful commercialization and deployment of the AVE solution. Submissions should also explain why the proposed support is critical to achieving impact in LMIC settings.

6. Data Access and Sharing

CHAI intends to make anonymized, de-identified training data available to selected partners for the purpose of model training and validation, under a data-sharing agreement aligned with principles of ethical use, responsible innovation, and public sector access. While CHAI does not claim IP over models or tools developed using the data, recipients will be expected to commit to access-friendly licensing and avoid restrictive IP claims that could hinder affordability or future research.

7. Eligibility Criteria

This EoI is open to entities able to:

- Develop, commercialize, and/or deploy AVE as a standalone application, bundled device, or as a module integrated into existing digital health tools or platforms used in LMICs.
- Manufacture or supply compatible hardware (e.g., smartphones, camera add-ons) or establish partnership with such entities, if required.

- Demonstrate experience in AI-based health tools, digital health platform integration, and sustaining supply, support, and training for such systems.
- Make submissions to stringent regulatory authorities and national regulatory authorities, ensure ongoing compliance, and demonstrate ability to operate under relevant quality standards / ISO certifications.
- Engage with CHAI, Unitaid, and LMIC partners to align with public health objectives. Operate at scale in LMICs and provide a continuous supply of AVE at scale in LMICs by 2027.

8. Timelines

Activity	Date
Eol released	15 August 2025
Deadline for questions	26 August 2025
Eol submissions due	15 September 2025

9. Submission Instructions

Submit the required documents via email to cxca.procurement@clintonhealthaccess.org with the subject line: “Expression of Interest - AVE”

- Responses must be in English and submitted by an authorized representative.
- Late submissions will not be considered.

For questions, please email cxca.procurement@clintonhealthaccess.org by 26 August 2025. Anonymized questions and CHAI responses may be made publicly available at a future date; if you would prefer your question remain confidential, please clearly indicate CONFIDENTIAL on your question submission.

About the Partners

- **CHAI:** A global health organization committed to saving lives and reducing disease burden in LMICs.
- **Unitaid:** An international organization hosted by WHO that invests in innovations to prevent, diagnose, and treat major diseases in LMICs.

We look forward to your submissions and to partnering in the global effort to eliminate cervical cancer.