AI-ACVT RFP – Frequently Asked Questions (FAQs)

This FAQ document consolidates questions from potential partners regarding the AI-assisted cervix visualization tools (AI-ACVT) for cervical cancer screening in low- and middle-income countries (LMICs) RFP.

Technical Requirements

Q: What are the minimum technical specifications for the AI-ACVT solution (hardware and software)?
A: We invite respondents to propose the most appropriate technical configuration for their solution, including hardware (if applicable) and software components. Proposals should consider performance, usability in resource-limited settings, cost, and scalability across LMIC contexts.

Q: Are there requirements for image capture quality or standards?
A: Respondents are expected to ensure that their solution can reliably capture and process images of sufficient quality to support accurate clinical decision-making. Proposals should describe approaches to image quality assurance, including any automated quality checks or user guidance mechanisms.

Q: What are the expectations for output provided to end users?
A: We do not prescribe a specific output format. Respondents are encouraged to propose outputs that are clinically meaningful, easy to interpret for frontline healthcare workers, and aligned with intended use cases (e.g., screening, triage, or decision support).

Q: Is offline functionality required?
A: Yes.

Q: What turnaround time for results is expected?
A: Results are expected to be available during the same clinical encounter. Respondents should describe how their solution supports timely decision-making in point-of-care settings.

Q: Are there minimum performance thresholds (e.g., sensitivity, specificity)?
A: While no strict thresholds are specified, respondents are expected to demonstrate strong clinical performance and clear improvement over existing approaches such as VIA. Proposals should include plans for validating and substantiating performance claims.

Validation & Clinical Evidence

Q: What types of validation studies are required?
A: Proposals should include plans for prospective validation in real-world clinical settings, as well as external validation using independent datasets. Validation should reflect intended use cases and target populations, including LMIC settings.

Q: Are retrospective or single-site validation studies sufficient?
A: No, validation based solely on internal, retrospective, or non-representative datasets will not be considered sufficient to substantiate performance claims.

Q: What level of dataset size and site diversity is expected to demonstrate clinical validity and generalizability across LMIC settings?
A: No minimum dataset size is specified. Applicants should provide a clear rationale demonstrating that the dataset size and site diversity are adequate to support clinical validity and generalizability, and reflect the conditions of the intended real-world use in LMIC settings.

Q: What reference standards should be used?
A: Respondents should propose appropriate reference standards aligned with global best practices. For example, performance claims related to detection of CIN2+ should be anchored in histopathology where applicable.

Open Source, Data & Intellectual Property

Q: What components of the AI-ACVT solution will be made available to partners?
A: Partners may access AI-ACVT software developed and used in prior field-testing via Github: https://github.com/Global-Health-Labs/AVE-GHL. Respondents should describe how they intend to build upon, adapt, or integrate such components into their solution. More details on the model and performance to-date are available online:

- Internal validation of Automated Visual Evaluation (AVE) on smartphone images for cervical cancer screening in a prospective study in Zambia: https://pmc.ncbi.nlm.nih.gov/articles/PMC11176573/
- A Prospective 5-Country Observational Study of the Performance of a New Artificial Intelligence-Based Tool for Cervical Pre-Cancer Screening in the African Region: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4968226

Access to data collected in previous research will be determined on a case-by-case basis and subject to applicable data sharing agreements.

Q: Is it mandatory to build upon the GHL-developed models? What if applicants already have their own models validated and deployed?

A: Proposals are expected to clearly demonstrate how they will incorporate, adapt, or build upon relevant insights, data, or components from prior GHL work to ensure strong performance and contextual relevance in African LMIC settings.

For applicants bringing their own models, this means going beyond simply presenting an existing solution: they should outline how their models will be refined using GHL-derived learnings, benchmarked against GHL approaches where appropriate, and adapted to local epidemiological, operational, and data realities. The expectation is that even proprietary or pre-existing models will meaningfully engage with and extend prior GHL work, rather than operate in isolation.

Q: What rights will partners have to adapt and commercialize the solution?

A: Respondents are expected to adapt the solution as necessary to meet regulatory and local market requirements and propose plans to commercialise the solution in LMICs.

Q: Who owns data generated during deployment?

A: We expect respondents to propose data ownership and governance models, taking into account local regulations, partnerships with governments, and ethical considerations.

Q: How will any intellectual property rights developed using financial and/or technical support be managed?

A: All intellectual property arising from this work, including trained model weights, algorithms, software code, and training datasets, may be owned by the Respondent, provided that the Respondent undertakes through legally binding commitments to make the IP and/or the relevant products/ solutions available and accessible on an equitable basis to LMICs. Such commitments will be proportionate to the level of public and philanthropic funding provided.

Regulatory and Quality

Q: Which regulatory approvals are required?

A: Respondents should propose a regulatory strategy aligned with internationally recognized frameworks (e.g., IMDRF-aligned authorities such as EU MDR/IVDR or FDA pathways), as well as national regulatory requirements in the LMICs their proposal is targeting.

Q: What is the expected timeline for regulatory approval?

A: Respondents should present a credible plan to achieve regulatory authorization with a target for approval by the end of 2027, including key milestones and resource requirements.

Q: Are quality management certifications required?
A: Solutions should comply with relevant international standards (e.g., ISO 13485, ISO 14971, ISO 27001). Respondents should describe their current certifications and plans to meet applicable requirements.

Q: Will CHAI/Unitaid support regulatory processes?
A: Support may include financial assistance for regulatory consultants, sharing guidance, facilitating connections, and providing feedback on proposed strategies. Responsibility for regulatory submissions and approvals remains with the respondent.

Deployment & Operations

Q: What are the expectations for deployment in LMIC settings?
A: Respondents are expected to demonstrate how their solution will be deployed and operationalized in primary healthcare settings, including training, support, and integration into existing workflows.

Q: Which geographies are prioritized?
A: The initial focus is on the African region. Respondents may propose specific countries or regions within Africa based on feasibility, partnerships, and impact potential.

Q: Are deployments in other LMIC regions such as Southeast Asia considered within scope?
A: Deployments in other LMIC regions, including Southeast Asia, are within scope if applicants can demonstrate a robust strategy for expansion in such additional regions following introduction in Africa as part of their proposal.

Q: Are there minimum scale requirements?
A: There is no fixed minimum scale; however, respondents should demonstrate a credible pathway to multi-country scale-up within 24 months of initial market introduction.

Q: Who is responsible for training, maintenance, and support?
A: Respondents will be responsible for training healthcare workers, maintaining the solution, and providing ongoing technical and user support.

Integration & Interoperability

Q: Should the solution integrate with existing health systems?
A: Respondents are encouraged to design solutions that integrate with existing digital health systems and workflows, minimizing additional burden on end users.

Q: Are specific interoperability standards required?
A: We do not mandate specific standards. Respondents should propose approaches that enable interoperability and scalability across diverse LMIC health systems.

Commercialization & Pricing

Q: What are the expectations for pricing?
A: Respondents are expected to propose pricing models that prioritize affordability and broad accessibility for public-sector purchasers in LMICs. Solutions should be designed with cost constraints in mind from the outset, ensuring that pricing does not become a barrier to adoption at scale. Proposals should demonstrate how they will achieve the lowest feasible cost while still supporting long-term sustainability. The pricing structure should be fully transparent and include any one-off costs (deployment and installation) and recurring costs (licensing, hosting, maintenance etc).

Q: Does CHAI have a predefined price ceiling, target unit economics, or a specific pricing model in mind?
A: No, there is no predefined ceiling or required pricing model. However, affordability, accessibility and transparency will be central evaluation criteria, and we will compare proposed lifetime costs across applications. Solutions that demonstrate a clear commitment to minimizing total cost of ownership and maximizing access for LMIC purchasers will be strongly favored.

Q: What commercialization models are acceptable?
A: Respondents are invited to propose commercialization models (e.g., per-device, per-scan, subscription, per-use with caps, volume-based pricing) that best enable affordability, access, and scalability in LMIC settings. Regardless of structure, models should be explicitly designed to reduce financial barriers for purchasers and minimize budget/cost uncertainty for LMIC purchasers. Applicants are required to provide a transparent and comprehensive breakdown of all associated costs (including set-up, training, maintenance, and recurring fees) so that the full lifetime cost is clear and can be assessed in terms of accessibility.

Funding & Support

Q: What funding is available?
A: Selected partners may receive milestone-based catalytic funding (up to approximately $700,000 USD), subject to alignment and due diligence.

Q: Is co-investment required?
A: While not strictly required, co-investment is strongly encouraged, as available funding is expected to cover only a portion of total development and commercialization costs.

Q: What additional support will be provided?
A: Support may include technical assistance, regulatory guidance, access to partners and ministries, and market-shaping mechanisms (e.g., volume guarantees), as appropriate.

Governance, Ethics & Post-Deployment Monitoring

Q: What are expectations around AI governance and ethics?
A: Respondents should describe governance frameworks addressing data privacy, consent, bias mitigation, and equitable performance across populations.

Q: What are requirements for post-deployment monitoring?
A: Proposals should include plans for ongoing performance monitoring, management of model drift, incident reporting, and re-validation as needed.

Application & Selection Process

Q: What are the main evaluation criteria?
A: Proposals will be evaluated based on technical merit, regulatory strategy, domain expertise, operational feasibility, and affordability and access commitments.

Q: Who is eligible to apply?
A: Eligible applicants include organizations with demonstrated capability in AI-enabled medical device development, regulatory approval, and deployment. Partnerships and consortiums are encouraged.

Q: Is prior LMIC experience required?
A: While not strictly required, respondents should demonstrate the ability to operate effectively in LMIC contexts, either directly or through partnerships.

Q: Will multiple partners be selected?
A: While it depends on the strength and diversity of proposals received, we do not expect to appoint multiple partners.