GHIT Fund
Global Health Innovative Technology Fund

THE AURUM INSTITUTE

CALL FOR EXPRESSION OF INTEREST

Invitation to Submit an Expression of Interest to Facilitate Technology Transfer and Establish African Manufacturing of the Lung Flute ECO for Sputum Induction to Support Tuberculosis (TB) Diagnosis in High-Burden Settings

Issue Date: 26 March 2026

Closing Date: 30 April 2026

Extended deadline : 20 May 2026

INSTITUTE OF TROPICAL MEDICINE ANTWERP

RIT/JATA The Research Institute of tuberculosis, Japan Anti-Tuberculosis Association

ACOUSTIC INNOVATIONS

List of abbreviations

AI	Acoustic Innovations
EOI	Expression of Interest
TB	Tuberculosis
NAFDAC	Nigeria's National Agency for Food and Drug Administration and Control
WHO	World Health Organization
SAHPRA	South African Health Products Regulatory Authority
LMICS	Low- and Middle- Income Countries
RIT	Research Institute of Tuberculosis
GHIT	Global Health Innovative Technology
LFE	Lung Flute ECO

Overview

Disclaimer Notice and Confidentiality

This Call for Expression of Interest (EOI) is issued by the Research Institute of Tuberculosis (RIT), in collaboration with the Aurum Institute and Acoustic Innovations, Co., Ltd., with funding and technical support from the Global Health Innovative Technology (GHIT) Fund. This EOI is intended for planning and design purposes only and should not be regarded as a Call for Proposals or a Request for Tender. Any information submitted in response to this EOI is provided voluntarily and may be reviewed by RIT, Aurum, Acoustic Innovations, and GHIT. None of these organizations shall be under any obligation to procure any of the services, technologies, or products described herein, and the issuance of this EOI shall not be construed as a commitment to enter into any commercial or other business relations. The information submitted may be used by RIT, Aurum, Acoustic Innovations, and GHIT to inform strategic decisions and planning within their respective project portfolios, including but not limited to the design of future Calls for Proposals or other solicitations which RIT, Aurum or Acoustic Innovations may issue.

Any information submitted in response to this EOI that needs to be treated as "confidential" should be marked as such on the completed form by the respondent. When information is marked confidential, RIT, Aurum, Acoustic Innovations, and GHIT will take reasonable measures to maintain confidentiality and will not disclose such information outside of the aforementioned organizations without written consent from the respondent. However, this confidentiality obligation shall not apply if the information concerned, or any part of it (a) was known to any of the organizations prior to disclosure by the respondent, (b) was in the public domain at the time of disclosure by the respondent, (c) becomes part of the public domain through no fault of the organizations, or (d) becomes available to 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).

This Call for Expression of Interest solicits interest from Africa-based manufacturers interested in supporting local production and technology transfer of the Lung Flute ECO (LFE), a non-invasive device for sputum induction to support tuberculosis (TB) diagnosis. The goal of this EOI is to identify potential manufacturing partners capable of facilitating local production in TB high-burden settings, thereby improving affordability and access in low- and middle-income countries (LMICs).

The Lung Flute ECO is a disposable, paper-based device designed to enable sputum production among individuals unable to expectorate spontaneously, addressing a key barrier in TB diagnosis. The LFE functions as a handheld positive expiratory pressure device that uses sound waves to loosen and mobilize lung secretions, promoting sputum expectoration. It features a simple tubular design with a paper mouthpiece connected to a reed that vibrates when the user exhales through it. The technology is already developed and available for manufacturing transfer and potential commercialization. Respondents may be interested in engaging at various stages, ranging from contract manufacturing to full-scale local production and distribution.

Manufacturers seeking technical, regulatory, and/or operational support to localize and scale production are encouraged to apply. Respondents do not need to currently manufacture or own the Lung Flute ECO device. This EOI will inform strategic planning by partners and contribute to broader global health efforts aimed at accelerating equitable access to innovative sputum induction solutions for TB diagnosis in LMICs.

This call for EOI is issued by RIT in collaboration with the Aurum Institute and Acoustic Innovations, Co., Ltd., with funding from GHIT. This collaboration seeks to leverage institutional expertise in TB innovation, diagnostics, and manufacturing partnerships to expand the availability of critical enabling technologies for TB care in high-burden regions.

TB Screening and Diagnosis

Tuberculosis remains a major public health challenge globally, with a disproportionate burden in low- and middle-income countries, particularly in Africa. Africa alone accounts for about 23% of global TB cases and 32% of TB deaths, with nearly 2.5 million new cases and over 400,000 deaths reported in 2023[1]. Seventeen of the 30 countries with the highest TB burden worldwide are in Africa, including South Africa, Kenya and Nigeria.[2] TB is a leading cause of death from a single infectious agent in Africa, ranking above HIV in adult mortality in some regions. Despite progress in detection and treatment, challenges such as limited health infrastructure, funding gaps, and high rates of HIV co-infection continue to impede TB control efforts.

Sputum analysis remains the cornerstone for diagnosing pulmonary TB, the most common and contagious form of the disease. The presence of *Mycobacterium tuberculosis* in sputum samples allows for bacteriological confirmation through microscopy, culture, or molecular tests, which is critical for accurate diagnosis and appropriate treatment initiation. However,

[1] https://worldhealthorg.shinyapps.io/tb_profiles/?_inputs_&tab=%22tables%22&lan=%22EN%22&entity_type=%22group%22&group_code=%22AFR%22

[2] WHO global lists of high burden countries for tuberculosis (TB), TB/HIV and multidrug/rifampicin-resistant TB (MDR/RR-TB), 2021–2025, available from: https://cdn.who.int/media/docs/default-source/hq-tuberculosis/who_globalhbcliststb_2021-2025_backgrounddocument.pdf

many patients, especially children and about 20-50% people living with HIV, struggle to produce sputum naturally, leading to missed or delayed diagnosis.[3] This gap not only represents a financial burden to the healthcare system but contributes significantly to the estimated millions of undetected TB cases globally and in Africa.

Early and accurate TB diagnosis helps in timely initiation of treatment, thereby reducing disease transmission and improving patient outcomes. In many LMICs, early TB diagnosis is hindered by issues like sample volume, quality, and high rejection rates at testing labs — with "insufficient sample" being the leading cause of sputum rejection. . The insufficient sputum samples are usually due to the inability of the clients to produce sputum. Training clinicians on sputum collection has helped with patient guidance, but challenges remain, especially clients' difficulty in producing sputum. Tools like the Lung Flute can help improve sample collection, volume, and quality. Specific data on sputum sample rejection rates due to insufficient sputum volume are limited. However, a study at the Rahima Moosa Mother and Child Hospital in Johannesburg found that 4.1% of paediatric sputum specimens were rejected for being below the minimum volume required for Xpert MTB/RIF testing and the 4% is above the 3% of allowable margin of error.[4] Additionally, a pilot study in Khayelitsha reported that 19% of specimens contained less than 1 mL of sputum, which is below the acceptable volume for TB testing.[5]

Sputum induction tools like the Lung Flute provide a non-invasive, effective method to aid sputum production in patients who cannot expectorate spontaneously. This simple, low-cost device uses sound waves to mobilize secretions from the lower respiratory tract, making it easier to collect samples for diagnostic testing. Studies have shown that sputum induction improves TB detection rates by increasing the yield of diagnostic samples, particularly in children and HIV-positive individuals who often have paucibacillary disease and difficulty producing sputum. In comparative studies, the Lung Flute outperformed nasopharyngeal aspiration and gastric lavage in sample yield and performed on par with more invasive methods like bronchoalveolar lavage and physiotherapy. [6]

By facilitating earlier and more accurate diagnosis, the Lung Flute and similar devices have proven particularly valuable in high-burden, resource-limited settings. Their use supports timely treatment initiation and helps curb TB transmission. In the context of Africa's high TB burden and persistent diagnostic challenges, scaling up access to such tools is essential for improving case detection and reducing TB-related morbidity and mortality.

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[3]Kasule, G., Hermans, S., Acacio, S., et al, Performance of stool Xpert MTB/RIF Ultra for detection of Mycobacterium tuberculosis among adult people living with HIV: a prospective multicentre diagnostic study. Lancet Microbe (2025). https://doi.org/10.1016/j.lanmic.2025.101085

[4]Gous N, Scott LE, Khan S, Reubenson G, Coovadia A, Stevens W. Diagnosing childhood pulmonary tuberculosis using a single sputum specimen on Xpert MTB/RIF at point of care. South African Medical Journal. 2015 Dec 1;105(12):1044-8.

[5]Fisher M, Dolby T, Surtie S, Omar G, Hapeela N, Basu D, DeWalt A, Kelso D, Nicol M, McFall S. Improved method for collection of sputum for tuberculosis testing to ensure adequate sample volumes for molecular diagnostic testing. J Microbiol Methods. 2017 Apr;135:35-40. doi: 10.1016/j.mimet.2017.01.011. Epub 2017 Jan 31. PMID: 28159630.

[6] Hepple, P & Ford, N & Mcnerney, Ruth. (2012). Microscopy compared to culture for the diagnosis of tuberculosis in induced sputum samples: A systematic review. The international journal of tuberculosis and lung disease : the official journal of the International Union against Tuberculosis and Lung Disease. 16. 579-88. 10.5588/ijtld.11.0617.

1. Summary of Target Product

The Lung Flute ECO is a disposable, paper-based, point-of-care tool used to induce sputum in individuals unable to produce specimens spontaneously. The LFE is intended to support TB diagnosis in LMICs, particularly those classified as TB high-burden countries, where access to quality diagnostic tools remains limited. It is designed specifically for low-resource settings where conventional sputum induction methods may not be feasible. The device's components include:

- A mouthpiece paper cone made from medical-grade or sterile paper.
- A paper body that houses the plastic reed.
- A plastic reed that produces acoustic vibrations.
- A sterile, easy-to-use packaging configuration for deployment at community and facility levels.

This EOI is open to manufacturers who can provide a viable, affordable, quality-assured solution for the LMIC market to accelerate widespread access to the Lung Flute ECO for sputum induction to support TB diagnosis. Interested manufacturers should provide evidence and plans to scale up local production and access to the Lung Flute ECO device before the end of 2026. Manufacturers with plans to establish manufacturing capacity or technology transfer in the pipeline should provide evidence and timelines to bring local production to market by the end of 2027).

The selected manufacturer should operate a Quality Management System (QMS) that conforms to ISO 13485:2016. The QMS should be fully implemented or anticipated to be fully implemented and maintained across all relevant manufacturing, quality control and regulatory processes associated with the Device. Where ISO 13485 is held, respondents must provide:

- A valid ISO 13485 certification
- Scope of certification
- Name of accredited certification body

Where certification is not yet obtained, respondents must provide:

- Evidence of alignment/progress towards ISO 13485 requirements
- A detailed implementation plan
- A defined timeline to certification

In addition, the selected manufacturing partner must demonstrate the capability to manufacture (or be working towards manufacturing) the device in compliance with applicable international standards, with a primary objective of achieving and maintaining conformity under:

- Regulation (EU) 2017/745 (EU MDR)
  - Class I
- South African Health Products Regulatory Authority
  - Anticipated class A
- Other applicable African National Regulatory Authorities (NRAs), as required
- The device is anticipated to be classified as a low-risk, non-invasive medical device. However, full documentation and regulatory compliance in line with MDR Annex II and III requirements will be expected.

The Lung Flute ECO is provided below to support manufacturer understanding of the device structure and primary components. This figure is intended for conceptual purposes only; full technical drawings and detailed manufacturing specifications will be supplied during the technology-transfer phase.

Figure 1. The complete Lung Flute ECO Components

Note: Detailed engineering drawings, component tolerances, and manufacturing blueprints will be provided by Acoustic Innovations during formal technology transfer.

2. Market Sizing: LFE Demand Estimates (Africa, 2027–2030)

The estimates below are provided to help prospective manufacturers understand the realistic scale of LFE demand across the African TB diagnostics market. Two scenarios are modelled using the same epidemiological base data but different testing multipliers (3× conservative vs 4× optimistic), reflecting variability in presumptive-to-confirmed TB case ratios across programme settings. All figures are derived from WHO Global TB Report 2025 data and peer-reviewed sputum scarcity literature. Non-TB indications are excluded from these estimates.

Shared assumptions across both scenarios

Parameter	Conservative (3×)	Optimistic (4×)
Africa TB incidence (2027 baseline)	2,620,000	2,620,000
Presumptive-to-positive testing multiplier	3×	4×
Baseline treatment coverage (2027)	74%	74%
Adult sputum scarcity rate	23%	23%
Child sputum scarcity rate	65%	65%

Projected Annual LFE Unit Demand — Conservative to Optimistic Range

Year	Conservative (3× multiplier)	Optimistic (4× multiplier)	Indicative Range (units/year)
2027	120,615	160,820	**120,600 – 160,800**
2028	128,068	170,758	**128,100 – 170,800**
2029	121,025	161,366	**121,000 – 161,400**

Year	Conservative (3× multiplier)	Optimistic (4× multiplier)	Indicative Range (units/year)
2030	114,368	152,491	**114,400 – 152,500**

Methodology note: *Projections assume African pulmonary TB incidence declining from 2,620,000 (2027) to 1,909,980 (2030) in line with historical trends. Treatment coverage rises from 74% to 86% over the period. The two scenarios differ only in the testing multiplier applied to derive the tested population from confirmed incidence (3× conservative vs 4× optimistic), reflecting realistic variability in how intensively programmes screen presumptive TB patients. LFE eligibility applies age-specific sputum scarcity rates (23% adults, 65% children), with a further residual fraction representing patients who cannot produce sputum even when assisted. These figures represent conservative estimates of addressable device volumes and are intended to orient manufacturers on production planning horizons. Actual uptake will depend on programme rollout, procurement partnerships, and pricing agreements.*

Key sources: WHO Global TB Report 2025 (diagnostic testing and case notifications); WHO Africa TB profiles (adult/child incidence splits); Gaeddert et al. (2025) — sputum scarcity systematic review, adults (medRxiv 2025.11.02.25339326); Gaeddert et al. (2025) — sputum scarcity among children (medRxiv 2025.11.02.25339327).

3. Intent of the EOI

This EOI is issued to identify and engage African-based manufacturers capable of supporting the local production of the Lung Flute ECO. Currently manufactured by AI, the LFE is not being replaced or redesigned under this initiative. Instead, this EOI seeks to enable technology transfer and establish local manufacturing capacity of the LFE to ensure affordable, sustainable, and quality-assured access across LMICs.

There is no World Health Organization (WHO) Target Product Profile for sputum induction devices, including the Lung Flute ECO. As such, this EOI is not soliciting alternative devices, but focuses solely on the expansion of access to the existing LFE through regional manufacturing and equitable distribution. This EOI aims to:

- Identify and shortlist qualified African manufacturers and suppliers with capacity to produce the Lung Flute ECO device and/or its components (paper body, plastic reed, mouthpiece, final assembly).
- Assess the technical, operational, and regulatory readiness of interested manufacturers.
- Facilitate technology transfer and capacity-building in collaboration with Acoustic Innovations, Aurum, and RIT.
- Support the establishment of sustainable, regional supply chains for high-quality and affordable Lung Flute ECO devices.
- Enable future procurement and large-scale distribution via global health stakeholders, national health systems, and implementing partners.

RIT, Aurum, Acoustic Innovations and GHIT seek to understand the extent to which manufacturers may be interested in potentially receiving support towards achieving set target access requirements. The available support could be one or a combination of the following:

- Regulatory assistance for national approvals.
- Support for expediting progress towards ISO 13485 and/or EU MDR
- Technical support for technology transfer, including Standard Operating Procedures, Quality Control protocols, and production line setup.
- Assistance in transitioning or expanding manufacturing capacity in Africa.
- Advance market commitments and strategic procurement planning.
- Engagement with implementing partners and civil society organizations to ensure contextual relevance and country-level uptake.

Manufacturers are encouraged to collaborate with civil society and implementing partners to ensure feasibility, sustainability, and alignment with country-level needs. Interested manufacturers should indicate willingness to collaborate on activities including:

- 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 2031) that ensures the capacity to supply the target market within a mutually agreed manufacturing lead time.
- Agreement to supply 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. Depending on the conditions, other access commitments, such as supply security, minimum production volumes, etc., may also be necessary.

Selected manufacturers will be expected to:

- Manufacture components (paper body and/or mouthpiece) per Acoustic Innovations' provided specifications and blueprints.
- Assemble and package the final Lung Flute ECO product in a sterile, point-of-care format for facility and community use in accordance with public health standards.
- Source or adapt production of medical-grade or sterile paper.
- Comply with relevant medical quality standards such as the ability to manufacture to ISO 13485 and meet EU MDR Class I requirements and local regulatory requirements (e.g. NAFDAC, SAHPRA, etc).
- Collaborate in the development of a regulatory strategy supporting multi-market access, including selected African jurisdictions. Regulatory compliance and participation will be treated as a core strategic requirement of the partnership.
- Participate in technology transfer sessions, including hands-on training and knowledge-sharing facilitated by Acoustic Innovations.
- Commit to long-term production and supply (at least through 2030).
- Ensure readiness for national regulatory submissions.
- Support scale-up to meet regional/global demand.

All pricing and licensing agreements related to products developed under this technology transfer and regulatory review project will align with the Global Health Innovative Technology (GHIT) Fund's Data Access Policy and Product Access Policy.

4. Instructions to interested parties

a) Expression of Interest (EOI)

i. All EOIs should be submitted in English and be signed by an authorized representative of the Responder on both the cover letter and the "General Information" tab of the Excel form.

ii. The following documents shall be completed and submitted with the EOI response. EOI responses will not be considered if either of these components is missing. Only applicants who respond to the EOI will be invited to respond to any potential future Request for Proposal:

- The cover letter should include a summary of the manufacturer's proposed approach to local production of the Lung Flute ECO, an overview of the support required to enable successful technology transfer, regulatory registration, and market access in target LMICs, and a statement of commitment to engage further in the process to achieve the objectives of this call.
- The Excel form detailing company information, prior experience, and details about the proposed product.
- Excel form detailing evidence of QMS Requirements

EOIs should be submitted via e-mail with the subject line Expression of Interest – LFE to: aurumaccessprocurement@auruminstitute.org

b) Timelines

The timeline for the EOI process is described below. EOIs received after the deadline will not be considered.

EOI Released	26 March 2026
EOI Related Questions Due	10 April 2026
EOIs Due	30 April 2026
Extended EOI Deadline	20 May 2026

*Late submissions will not be accepted

c) Questions and answers

iii. A formal period during which questions regarding this EOI are answered will follow the posting of the EOI on the GHIT and partner websites. (Please reference above for timeline).

iv. Please submit questions **by 10 April 2026**
Questions should be sent via email to:
aurumaccessprocurement@auruminstitute.org

v. All enquiries must be received via email by the stipulated deadline for questions.

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

5. Eligibility

The EOI is open to all manufacturers who meet the following criteria and technical requirements:

- Be a legally registered African based company authorized to operate as a device manufacturer, with the ability to produce medical-grade components from paper and/or plastic.
- Demonstrate the ability to produce the Lung Flute ECO device in accordance with precise design and performance specifications suitable for medical use.
- Company's production facility operates under current Good Manufacturing Practice (GMP), has obtained or is in the process to obtain ISO 13485 certification and ideally has experience with African device registration pathways.
- Company has the proven ability to manufacture the LFE at a commercial scale OR is working on a downstream solution that will support cost-effective and sustainable manufacturing of the LFE.
- The company may be required to establish a project team structure that includes representatives from one or more of the collaborating institutions (RIT, Aurum, Acoustic Innovations, and GHIT) as/when required.
- Willing to participate in training, design transfer, regulatory engagement, and site evaluations.
- Support public sector pricing strategies and affordability goals and commit to equitable distribution across LMICs.
- Commit to use of high-quality, medical-grade paper and acoustic components to ensure consistent product quality, safety and reliability.
- Demonstrated financial capacity to sustain production until commercialization.
- Ability to meet agreed ceiling pricing
- Experience with sterile medical device packaging (preferred)

Manufacturers with established regional manufacturing capacity and/or presence in Africa are strongly encouraged to apply.

b. Costs of preparing documents

All costs associated with preparing and submitting an EOI will be borne by the Company.

c. 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.

6. The Aurum Health Institute Company Information

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/

7. The Research Institute of Tuberculosis Company Information

The Research Institute of Tuberculosis, part of the Japan Anti-Tuberculosis Association, is a leading global center dedicated to tuberculosis research, training, and technical cooperation. Based in Tokyo, Japan, RIT works to advance TB prevention, diagnosis, and treatment through

scientific research, innovation, and collaboration with international partners, particularly in high-burden, low- and middle-income countries. https://jata.or.jp/english/

8. Acoustic Innovations, Co., Ltd. Company Information

Acoustic Innovations Co., Ltd. is a Japanese company specializing in acoustic technology solutions. The company develops innovative products that leverage sound wave technology, including medical devices like the Lung Flute series for respiratory therapy and diagnostics. https://acoustic-innov.com/index.htm

9. GHIT Fund Information

The Global Health Innovative Technology Fund is a Japan-based international public-private partnership that mobilizes Japanese innovation and investment to advance global health. GHIT Fund brings together governments, multiple pharmaceutical companies, and private funders to support the research and development of new drugs, vaccines, and diagnostics for infectious diseases such as malaria, tuberculosis, and neglected tropical diseases. By facilitating international collaborations and funding R&D partnerships, the GHIT Fund aims to accelerate the creation of innovative health technologies to address the needs of low- and middle-income countries. https://www.ghitfund.org/en