INVITATION OF EXPRESSION OF INTEREST (EOI) FOR THE SUPPLY OF PORTABLE DIGITAL CHEST X-RAY EQUIPMENT AND COMPUTER-ASSISTED DETECTION SOFTWARE FOR TB SCREENING IN INDIA

Reference: EOI-001/2022

Introduction
The Clinton Health Access Initiative, Inc. (CHAI) invites Expressions of Interest (EOI) from Original Equipment Manufacturers (OEM)/Medical Equipment Suppliers/Distributors/Medical Software Firms interested and having capacity to supply digital chest X-ray (dCXR) equipment and computer-assisted detection (CAD) software for tuberculosis (TB) to support active-case finding activities across multiple states in India.

Background
a. CHAI is a global health organization committed to saving lives, reducing the burden of disease, and strengthening and sustaining high-quality health systems in low- and middle-income countries. CHAI has been working in India since 2004 in close partnership with under the guidance of the Ministry of Health and Family Welfare (MoHFW) at the both the Central and State’s levels on an array of high-priority initiatives aimed at improving health outcomes for people living with HIV/AIDS, TB, hepatitis C, and providing effective care and treatment for children suffering from malnutrition, diarrhoea, pneumonia, and malaria. CHAI focuses on improving market dynamics for medicines and diagnostics, lowering prices for treatment, accelerating access to lifesaving technologies, and helping build capacity required for high-quality care and treatment programs.

b. Under the C-19 Project funded by Global Fund to Fight AIDS, Tuberculosis, and Malaria (the Global Fund), CHAI is undertaking an active case finding initiative to increase TB diagnosis in India.

c. Studies indicate it takes ~55 days after the onset of symptoms for a patient to be correctly diagnosed with TB and initiated on appropriate treatment. During this period, patients are most likely to be infectious and spread TB within their communities. Screening through chest X-ray has been shown effective in identifying individuals with suspected TB; however, only 11 percent of public health facilities in India have X-ray devices. These machines are typically available only at community health centres or district hospitals. Lack of infrastructure at the community level coupled with unavailability of qualified radiologists to interpret chest X-rays leads to significant delays in screening and diagnosis of TB.

d. To address these delays amongst high-risk communities, the project aims to undertake active case finding with hand-held X-ray machine integrated with computer aided design (CAD) software. Deployment of a high-sensitive screening tool (dCXR) alone with high throughput interpretation (CAD) and subsequent linkage to CBNAAT for diagnostics would reduce delays in diagnostics and pre-treatment loss to follow-up (LTFU). The hand-held X-ray machines will be deployed in a mix of urban and rural districts across Uttar Pradesh, Bihar, Rajasthan, Gujarat, Tamil Nadu, Kerala, Uttarakhand, and Haryana to understand operational feasibility in different types of geographies with diverse profiles of high-risk communities.

Objective
The project would aim to generate local evidence and demonstrate various use cases for ultra-portable dCXR + CAD to improve TB case finding and reduce diagnostic delays. Local evidence would lead to
greater buy-in at the state level and facilitate effective transition of project activities and support future scale-up using domestic budgets.

The purpose of this Invitation for EOI is to:

- Provide information to potential respondents on this opportunity;
- Invite potential respondents to submit EOIs for this opportunity;
- Elicit information from the market to assist in the preparation of a Request for Proposals (RFP); and
- Evaluate submissions to select shortlisted respondents for upcoming RFP.

Scope of Work

This invitation involves the provision of up to 50 ultra-portable, digital X-ray devices with associated accessories and CAD software for up to four million scans.

The EOI should have the following components:

1. **Device Specification**
   i. Ultra-portable handheld digital chest X-ray unit (generator and detector)
   ii. CAD installation and license (Interface compatible with the X-ray unit with workstation software for image viewing/printing)
   iii. Picture Archiving and Communication System (PACS)
   iv. Standard accessories including laptop, printer, X-ray generator stand and frame, X-ray detector stand and frame
   v. Device specs to be furnished as per Annex A.

2. **Capabilities to fulfil quantity and timeline requirements**
   50 devices delivered in batches between April 2022 and September 2023.

3. **Licensing and approvals**
   i. Stringent Regulatory Authority (SRA) approval as per the Global Fund Quality Assurance Policy for Diagnostic Products [Includes United States, EU, Japan, Canada, Australia].
   ii. AERB approval – suppliers committed to file for AERB approval before April 2022 will be considered.
   iii. Fulfillment of any other license requirements

4. **Service level agreements**
   i. Terms and coverage of warranty
   ii. Lead time of replacement / repair

5. **Demonstrated relevant experience**
   i. Detailed description of any relevant experience of importing / supplying of device
   ii. In-depth knowledge from experience of the device performance over a sustained period.

6. **Details of all cost components**
   i. Device and installation
   ii. Taxes and duties
   iii. License costs of workstation software for 4 million scans over 2 years
   iv. Maintenance/warranty
   v. Any other costs

Further details will be provided in the upcoming RFP for shortlisted respondents.
Minimum Qualification and Evaluation Criteria

Interested firm should provide information demonstrating that they have the required qualifications and relevant experience to perform the services. The shortlisting shall be based on the following criteria and information furnished by the firm in regard to the following as per Format enclosed as Annexure-B.

i. Firm must be a legal entity registered under Companies Act, 1956 or a partnership firm registered under Limited Liability Partnership Act, 2008. It should be registered with Goods and Service Tax Authorities (GST) and should be operating for last three years. Joint Ventures are not allowed.

ii. Annual turnover for each of the last three years (2018-19, 2019-20 & 2020-21) should not be less than Rs. 5 Crore for Importer and Distributor and Rs. 20 Crore for Manufacturer and Distributor.

iii. Prior relevant demonstrated experience: (a) of handling/distribution of the device/comparable device; (b) knowledge (and evidence, ideally) of device performance and sustainability in the last 3 years.

iv. Regulatory approvals/quality assurance for the devices and CAD software

v. Device specifications, including ability to provide integrated dCXR + CAD package

vi. All 6 components detailed in Scope of work

vii. Key contacts person and contact details.

Submissions

Interested organisations must submit their EOI (electronically to the email ID indiaprocurement@clintonhealthaccess.org) no later than 23:59 hrs (IST) March 8, 2022. For any clarification/queries please write to us at indiaadmin@clintonhealthaccess.org with EOI reference number by February 26, 2022.

CHAI may contact respondents for further discussions regarding submissions and to elicit feedback on the upcoming RFP.

Annexures

Annex A: Target Product Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>dCXR unit</td>
<td></td>
</tr>
<tr>
<td>Radiation dose</td>
<td>Less than 150 kV</td>
</tr>
<tr>
<td>Output</td>
<td>Antero-posterior or posterior-anterior</td>
</tr>
<tr>
<td>Output dimension</td>
<td>570 x 620 x 1720mm ±5%</td>
</tr>
<tr>
<td>Weight</td>
<td>Less than 10 kg</td>
</tr>
<tr>
<td>Throughput</td>
<td>&gt;50 X-rays per hour</td>
</tr>
<tr>
<td>CAD</td>
<td></td>
</tr>
<tr>
<td>Integration</td>
<td>Seamlessly integrated with dCXR unit and performance validated with device (evidence provided)</td>
</tr>
<tr>
<td>Input type</td>
<td>DICOM 3.0 image</td>
</tr>
<tr>
<td>Classification sensitivity</td>
<td>&gt;0.90</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Classification specificity</td>
<td>&gt;0.70</td>
</tr>
<tr>
<td>Output processing time</td>
<td>&lt;30 seconds</td>
</tr>
</tbody>
</table>
| Features                    | • Ability to record patient details, including symptoms  
                              • Dashboard to review program summary  
                              • Cybersecurity provisions such as firewalls to protect sensitive patient information |

**PACs**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compatibility</td>
<td>Hardware agnostic</td>
</tr>
<tr>
<td>Storage</td>
<td>5000-10000 images per device</td>
</tr>
<tr>
<td>Storage speed</td>
<td>10-20 seconds</td>
</tr>
</tbody>
</table>

**Annexure B: Format for Expression of Interest**

The expression of interest must be submitted as per the following format:

(***Note:** In case, documents submitted are in any language other than English, the consultant shall submit a self-certified copy of translated document in English (along with originals).)

**Section 1: Organisation Details**

**PART 1**

1. **Name of Organisation**

2. **Details of Organisation**

3. **Information about Organisation**

4. **Details of the person who will be primary point of contact for any communication related to the RFP process.**

5. **Annual turnover for the last three financial years**

<table>
<thead>
<tr>
<th>Financial year</th>
<th>Annual Turnover (Rs. Crores)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018-19</td>
<td></td>
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<tr>
<td>2019-20</td>
<td></td>
</tr>
<tr>
<td>2020-21</td>
<td></td>
</tr>
<tr>
<td><strong>Average for 3 yrs</strong></td>
<td></td>
</tr>
</tbody>
</table>
# Section 2: Documents to be Submitted

<table>
<thead>
<tr>
<th>Eligibility Criteria</th>
<th>Documentary Evidence</th>
<th>Page no. in Doc</th>
</tr>
</thead>
</table>
| 1. Firm must be registered legal entity registered under Companies Act, 1956 or a partnership firm registered under Limited Liability Partnership Act, 2008. It should be registered with Goods & Service Tax Authorities (GST) and should be operating for last three years. Joint Ventures are not allowed. | - Copy of certificate of incorporation issued by relevant authority.  
- Copy of GST registration number  
- Copy of PAN and TAN number.                                                                                                                      |                 |
| 2. Annual turnover from software development and related IT services, for the last three years (2016-19, 2019-20 and 2020-21) should not be less than Rs. 10 crores per year for Importer and distributor and Rs. 20 Crores per year for Manufacturer and Distributor. | - Statutory Auditor’s Certificate and financial statements for the Last three financial years (i.e. 2018-19, 2019-20, and 2020-21) that provides the information as per the specific requirements of eligibility criteria.  
OR  
Financial Statements duly certified by the chartered accountant.  
OR  
Self-certification by the authorized signatory of the Eol mentioning the Annual Turnover for the last three years supported by financial statements or Annual Auditor Reports (for FY 2018-19, FY 2019-20, FY 2020-21) clearly indicating the annual turnover.  
*Unaudited financial statements certified by the Company auditor for the latest year i.e. 2020-21 (in case the auditor certified statement for 2020-21 is not available).*  
*Please note: The annual turnover quoted must be the annual turnover of the Eol Respondent and not its Parent/child company.*   | -               |
| 3. Prior relevant demonstrated experience:  
(a) handling / distribution of device / comparable device;  
(b) knowledge (and evidence, ideally) of device performance and sustainability in the last 3 years | Relevant experience details for a maximum of 3 contracts in the last 3-year period should be submitted.  
a. Copy of Contract/Work Order.  
b. Copy of completion certificate or letter from authorised client representative stating completion of scope of services in case of completed projects or stating timely delivery of services from scope in case of ongoing project. | -               |
**Annexure C: Calendar Dates for milestones**

The following table enlists important milestones and timelines for the interested companies:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Milestone</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Release of Expression of Interest (EOI)</td>
<td>February 15, 2022</td>
</tr>
<tr>
<td>2</td>
<td>Last date for submission of written questions</td>
<td>February 26, 2022</td>
</tr>
<tr>
<td>3</td>
<td>Response to queries</td>
<td>Ongoing with last date February 28, 2022</td>
</tr>
<tr>
<td>4</td>
<td>Last date for submission of EoI response</td>
<td>March 8, 2022</td>
</tr>
<tr>
<td>5</td>
<td>RFP issue date</td>
<td>March 22, 2022</td>
</tr>
</tbody>
</table>