**SECTION II – SCHEDULE OF REQUIREMENTS**

**Invitation to Bid (ITB) for the Establishment of Long-Term Agreement (LTA) with suppliers of Lightweight Portable Digital X-Ray Equipment and/or Computer-Aided Detection using Artificial Intelligence (CAD/AI) software for Tuberculosis (TB) detection**

**e-Sourcing Ref. ITB/2020/16706**

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# **SECTION 1: INTRODUCTION AND BACKGROUND**

## 1.1 StopTB Partnership secretariat / Global Drug Facility (GDF) hosted by UNOPS

The **Stop TB Partnership** (hereinafter referred to as StopTB) is a global multi-stakeholder partnership that seeks to achieve a world without tuberculosis (TB) through facilitating, catalyzing and coordinating the work of its partners through the secretariat of the Stop TB Partnership.

**United Nations Office for Project Services** (hereinafter referred to as UNOPS), based in Geneva, Switzerland, provides management and financial/programmatic oversight of Global and Country specific Portfolios, Clusters and Operations Centers including hosting services, fund management, management advisory services, implementing projects, procuring goods and services and managing human resources. UNOPS has been hosting the Stop TB Partnership secretariat since 2015 and provides administrative services to the StopTB Partnership secretariat.

**Global Drug Facility** (hereinafter referred to as “UNOPS/StopTB-GDF), is a key initiative of the Stop TB Partnership formed in 2001 to ensure access to quality-assured and affordable anti-TB medicines and diagnostics, laboratory equipment and supplies (hereinafter referred to as TB products) by employing innovative business approaches, efficient knowledge management for evidence-driven leadership in market management, strategic procurement, and high-quality procurement and supply services to its clients in countries.

## 1.2 UNOPS/StopTB-GDF’s mission and vision

Today, UNOPS/StopTB-GDF is the **largest supplier of quality-assured TB products** in the public sector worldwide. Since its inception, UNOPS/StopTB-GDF has supported and increased access to critical quality-assured TB products to 142 countries.

The key added value of UNOPS/StopTB-GDF is to offer a **full package of services** for ensuring market availability, affordability and provision of quality-assured TB products to countries in need, as well as to offer country support for facilitating access to and uptake of new medicines and diagnostic tools. UNOPS/StopTB-GDF’s services include active market-shaping, strategic procurement solutions, innovative logistics approaches, a Strategic Rotating Stockpile, pre-shipment inspection and quality control services, capacity-building and technical assistance.

## 1.3 Indication for the use of Lightweight portable digital X-ray equipment and Computer-Aided Detection using Artificial intelligence (CAD/AI) software

During 2018 UN High Level Meeting (UNHLM), all countries committed to ambitious targets for TB screening, diagnostic and treatment, that will only be achieved by introducing **new tools to improve countries’ ability to rapidly and effectively diagnose TB**.

As a fast and relatively inexpensive TB screening method, the World Health Organization (WHO) Global TB Programme recommends the **use of digital chest X-ray as a triage tool** to be followed with a laboratory test. Last advancements in digital X-ray technology resulted in increasingly lightweight portable devices, easy to be transported in relatively small cases, bags or backpacks, allowing easier logistics for screening of hard-to-reach populations while capturing high-quality images with low-dose radiation when combined to a high-sensitivity digital radiography unit.

In the past decade, machine learning / **Artificial Intelligence (AI)** also has undergone an evolutionary expansion and now allows to automatically read chest X-rays through dedicated **Computer-Aided Detection (CAD) software**, with an overall performance in detecting TB similar to human reading / interpretation. This seems to be a very encouraging option for low-resource settings hampered by a limited access to radiologists.

# **SECTION 2: OBJECTIVE OF THE ITB**

Following a market analysis revealing the existence of various commercially available **Lightweight portable digital X-ray equipment** and **Computer-Aided Detection using Artificial Intelligence (CAD/AI)** **software** for TB detection, UNOPS/StopTB-GDF launches this ITB to select supplier/s offering the best value for money products.

Suppliers are invited to provide for each item of a Lot an offer with **technical, financial, and logistic information**, that will be evaluated and awarded by UNOPS/StopTB-GDF against defined criteria.

UNOPS/StopTB-GDF will then sign with awarded supplier/s **One-year (1-year) Long-Term Agreement/s** (LTA/s) for the provision of Lightweight portable digital X-ray equipment and/or CAD/AI software together with related service (installation, training and maintenance) for TB detection (hereinafter referred to as “products”). With good performance of supplier(s) under LTA/s, the option to renew them for **two (2) additional periods** of **one (1) year** each may be offered under the same terms and conditions for a maximum of **three (3) years.**

# **SECTION 3: SPECIFIC INSTRUCTIONS FOR APPLICANTS**

For the general instructions to Applicants, please refer to the document ***Section I\_Instructions to Bidders***.

This section 3 provides specific instructions to Applicants for this tender.

## 3.1 Description of Lots

Products and services included in this tender are divided into following 3 Lots:

|  |  |  |
| --- | --- | --- |
| **Lot Description** | | **Number of items** |
| Lot 1 | Lightweight portable digital X-ray system - Full kit | 3 |
| Lot 2 | Lightweight portable digital X-ray system - Basic kit | 3 |
| Lot 3 | Computer-Aided Detection using Artificial Intelligence (CAD/AI) system | 5 |
| **Total items** | | **11** |

Applicants can bid for one or more lots. However, Applicants must offer 100% of the items specified for each lot.

## 3.2 Detailed technical specifications requirements for each item

Detailed technical specifications requirements for each item of the 3 Lots are provided in ***Annex 1\_Form D\_Technical Bid Form\_ITB16706*** with:

- Products technical specifications required for each product requested

- Service specifications required for each service requested

- Logistic technical information requested for each item

## 3.3 Submission of Bids by Applicants

Applicants shall complete and submit the following forms for the submission of their technical and financial Bids:

* + - 1. ***Annex 1\_Form D\_Technical Bid Form\_ITB16706***
      2. ***Annex 2\_Form C\_Price Shedule Form\_ITB16706***

For these 2 forms (Annexes 1 and 2), only Excel sheets corresponding to the Lots for which Applicants want to bid shall be completed.

In addition to the submission of above completed forms (Annexes 1 and 2) Applicants shall provide all documents listed in “*Checklist*” section and also in the Checklist ITB16706 document uploaded in “*Documents*” section of the eSourcing platform for this ITB as well as reply to “*Questionnaires*” section of the eSourcing platform.

Failure to provide requested documents and/or to respond to questionnaire/s may lead to Bids or products rejection.

## 3.4 Further information on documents to be submitted with the Bids

Below is more information about UNOPS/StopTB-GDF requirements for some documents requested in “*Checklist*” section and also in the Checklist\_ITB16706 document uploaded in “*Documents*” section of the eSourcing platform for this ITB.

**a) Regulatory Certificates and Declarations of conformity**

All products should be attested compliant to applicable international standards or regional / national equivalent, as applicable per **product’s risk classification**. This can be through relevant regulatory authority/Conformity Assessment Body (e.g., CE, US FDA, UL, etc.) **certification** and/or through **Declaration/s of conformity** from the manufacturer and this should include technical tests for safety and performance.

**b) User, technical and maintenance manual/s**

**User, technical and maintenance manual/s** should include provisions for safety (including radiation protection), utilization, transportation and maintenance operations of related product. They should be provided minimum in English and French, in PDF format and named as follows: « *Lot number\_Item number\_Product name\_manual* » (e.g. “*Lot1\_Sub-item1.1\_X-ray Generator\_manual*”).

**c) Recommended techniques and typical doses**

For Lot 1 and Lot 2: In case they are not a part of any manual**, recommended techniques and typical doses** for frontal and lateral chest X-ray of adult patients from 60 to 150 kg with chest thickness from 14 to 40 cm should be provided. They should be provided minimum in English and French, in PDF format. If not available in English and French, please provide a translated summary in both languages.

**d) List of accessories, consumables and spare parts**

For Lot 1 and Lot 2: An exhaustive list of accessories, consumables and spare parts should be provided including shelf lives, prices and availability for immediate offtake.

**e) Photos of offered products**

For Lot 1 and Lot 2: Applicants must submit photos of offered product/s and packaging with readable label information, minimum in English and in JPEG format.

These files shall be transmitted to UNOPS/StopTB-GDF through Cloud Content Delivery File Sharing Services. The downloadable internet link shall be provided in the submission. Please follow the below naming for photos:

|  |  |  |
| --- | --- | --- |
| **File naming** | **Naming example** | |
| Lot number\_Item number\_Product name | e.g.: | *Lot1\_Sub-item1.3\_X-Ray Detector* |
| Lot number\_item number\_Product name\_packaging | e.g.: | *Lot1\_Sub-item1.3\_X-Ray Detector\_packaging* |

# **SECTION 4: ITB EVALUATION PROCESS**

The ITB evaluation process is composed of 5 steps:

## 4.1 Evaluation of Applicants Eligibility (Pass/Fail)

Applicants eligibility will be evaluated applying a Pass/Fail methodology as a part of Preliminary Examination. Criteria used for evaluation are provided in document ***Section IV Evaluation criteria, point 1***. Non-eligible Applicants will be rejected from this ITB evaluation process.

## 4.2 Evaluation of Applicants Qualification (Pass/Fail)

Applicants qualification will be evaluated applying a Pass/Fail methodology, also as a part of Preliminary Examination. Criteria used for evaluation are provided in document ***Section IV Evaluation criteria, point 2.*** Non-qualified Applicants will be rejected from this ITB evaluation process.

## 4.3 Technical evaluation of offered products (Pass/Fail)

Only products offered by eligible and qualified Applicants will advance to technical evaluation, that UNOPS/StopTB-GDF will perform in 2 steps. Criteria used for technical evaluation are provided in document ***Section IV Evaluation criteria, point 3.***

### Step 1: Compliance with UNOPS/StopTB-GDF quality assurance requirements

Compliance of offered products to quality assurance requirements will be evaluated applying a Pass/Fail methodology. Non-compliant products will be rejected from this ITB evaluation process.

For Products offered by Applicants which are classified as Medical Devices and/or Software as a Medical Device (SaMD), the product must be compliant with following UNOPS/StopTB-GDF quality assurance requirements:

**-** Manufacturer/s should be **certified according to ISO 13485** or equivalent quality management systems;

**-** Products should demonstrate compliance with *Essential Principles of Safety and Performance of Medical Devices* through applicable documents as per **product’s risk classification[[1]](#footnote-1)** (i.e., Regulatory Authority device registration and/or Conformity Assessment Body certificate/s and/or Declaration/s of conformity);

**-** Only product/s compliant with EC and/or FDA requirements are accepted;

**-** If one sub-item of an item, or one item of a Lot is not QA compliant, the offer of the Applicant will be rejected for this Lot.

### Step 2: Compliance with UNOPS/StopTB-GDF technical specifications requirements

Only products that passed Step 1 of technical evaluation will advance to Step 2. Substantial compliance of technical specifications of products offered by Applicants with UNOPS/StopTB-GDF detailed technical specifications requirements described in ***Annex 1\_Form D\_Technical Bid Form\_ITB16706*** will be evaluated applying a Pass/Fail methodology.

Products substantially compliant will be accepted and products not compliant will be rejected.

If one sub-item of an item, or one item of the Lot is not substantially compliant, the offer of the Applicant will be rejected for this Lot.

## 4.4 Financial evaluation and Award process

Only products that passed the 2 steps of technical evaluation will advance to financial evaluation. The evaluation method is based on the products substantially compliant with the lowest prices.

Financial offers will be evaluated at the level of a Lot.

UNOPS/StopTB-GDF may award more than one supplier for each Lot.

UNOPS/StopTB-GDF has the right to cancel any Lot during ITB evaluation process.

For Lot 3: UNOPS/StopTB-GDF will only evaluate financial offer/s for which the CAD/AI software offered is compatible with the Lightweight portable digital X-ray system/s awarded for Lot 1 and/or Lot 2.

## 4.5 Notification of award to Applicants

After completion of ITB evaluation process, UNOPS/StopTB-GDF will notify Applicants if they are awarded or not for the Lots / products for which they submitted Bids.

UNOPS/StopTB-GDF will sign with awarded Applicant/s **one-year (1-year) Long-Term Agreement/s (LTA/s)**. With good performance of supplier/s under LTA/s, the option to renew them for **two (2) additional periods of one (1) year each** may be offered under the same terms and conditions for a maximum of **three (3) years.**

LTA/s in place will not be subjected to secondary bidding.

1. *GHTF/SG1/N78:2012: Principles of Conformity Assessment for Medical Devices* [↑](#footnote-ref-1)