Request for Proposal:

Service Agreement for Research Partner to Support Development of Computer Vision Solution

(For Auto-reading of Drug Resistant TB Diagnostic Test Strips)

Contents Outline

Section 1: General instructions to the bidder

RFP Specification: Technology partner for design, development, and deployment support of 'AI Tool for auto reading and interpretation of Test Strips used for diagnosis of drug resistant Tuberculosis (TB)'.

RFP Notification Date: 10th December **,** 2020

Submission Deadline: On or before 1700 hours, **03rd** January 2021

Submission Correspondence: Nodal Person- General Correspondence - Aditya Nayan, Partnerships and Fundraising Manager

Correspondence Email: RFP@wadhwaniai.org

Source where detailed RFP documents can be found: www.wadhwaniai.org;

Submission Procedures:

The Applications should be as per the following before closing date:

 a. Proposal must be submitted through e-mail as mentioned above with Annexure **1** duly filled by the authorised representative of the bidding agency with electronic signature via company mail id.

 b. The above email should have the **subject line- 'Bid submission- RfP Technical Service Request - LPA'**. Such email should have separate file attachments titled 'Technical Proposal' and 'Financial Proposal' in alignment with the WIAI template (furnished as annexures at the end).

 c. WIAI reserves the right to waive irregularities and to reject any or all bids.

 d. WIAI may, at any time before the closing date, for any reason, whether on its own initiative or in response to a clarification requested by a (prospective) bidder, modify the RFP by written amendment.

 e. Amendments could include modification of the project scope or requirements, the project timeline expectations and/or extension of the closing date for submission.

 f. WIAI also reserves the right to negotiate with the selected bidder in the event that the price exceeds available funds.

 g. Responses to this Request for Proposals are required to be submitted **On or before 17:00 hrs on 3rd January, 2021**

h. Delay submitted proposals shall be rejected. Only the Procurement committee will have the right to consider in specific situations.

i. Incomplete proposals that do not respond to the TOR fully and properly shall be summarily rejected.

j. Once the RFP is advertised, applications received from competitive firms shall be evaluated in a fair and transparent, unbiased manner using objective criteria based on technical and financial competencies of the individual agency.

k. WIAI will examine the proposals to determine whether they are complete, whether any computational errors have been made, whether the documents have been properly signed, and whether the proposals are generally in order.

Opening, Evaluation and Agreement:

The Bid may be opened by WIAI at any time after the submission deadline. All Bids Satisfying the requirements of this RFP will be evaluated to establish which of the applicant(s) best fulfils the needs of WIAI.

·   WIAI anticipates entering into an agreement with this/these applicant(s) to execute the proposed work.

·   This RFP does not commit WIAI to award a grant or to pay any costs incurred in the preparation of a Proposal for the goods and/or services offered.

·   WIAI reserves the right to accept or reject any or all Proposals received as a result of this request, to negotiate with all qualified applicant(s) or to cancel this RFP, if it is in the best interests of WIAI to do so. The decision of WIAI shall be final.

·   Only shortlisted vendor(s) shall be contacted and may be invited for a detailed technical presentation.

·   Selection will be based on internal evaluation criteria.

Proposal Contents:

Proposals should include vendor's description of the work that would be performed along with following information:

- Contact information: i) name of the vendor; ii) postal address; iii) telephone/Fax; iv) email address

- Copy of registration certificate, GST, PAN Card, etc.

- The contact information of a representative of your firm with whom WIAI can communicate as an official point of contact

- ITR or Audited financial report for the last three financial years.

- Management/Investor presentation (should include Company Profile, summary financials, key ratios, latest achievements)

- Detailed note on relevant past experience of your firm along with clientele and official publications of work.

- Past Clientele profile details for last 3 years along with budget of work undertaken and geography coverage area

Section 2: Background and overview

About Wadhwani Institute for Artificial Intelligence (WIAI)

The Wadhwani Institute for Artificial Intelligence (Wadhwani AI) is an independent non-profit research institute developing AI solutions for social good. Our mission is to develop AI solutions to overcome challenges of societal importance in domains such as health, agriculture, financial inclusion, and infrastructure. We are supported by reputed global organisations like the Bill and Melinda Gates Foundation, Google, and USAID, among others. We currently work closely with

the Government of India and multiple State governments to collaborate on solutions in the domain of healthcare and agriculture.

Project overview

WIAI is looking to develop an AI-powered automated tool for interpreting "Line Probe Assay (LPA)" test results with real time data integration into designated Management Information Systems (MIS).

Background information

- Tuberculosis (especially drug resistant TB) is one of the biggest global health challenges.
- Identification of drug resistance in TB patients in an early and timely manner is critical for modifying standard treatment regimes based on individual drug susceptibility.
- This enhances the treatment success rates and significantly reduces mortality, morbidity and also breaks the chain of transmission.
- LPA is a WHO endorsed rapid molecular DNA based test for the diagnosis of Drug Resistance Tuberculosis (DRTB).
- FL-LPA picks up drug resistance to First Line Anti TB Drugs (Isoniazid and Rifampicin) while SL-LPA picks up drug resistance to Second line Anti TB drugs (Fluoroquinolones and second line injectables).
- The LPA testing process is an output of a complex interaction between a series of probes (reagents) and specific segments of TB bacterial DNA called genotypes (wild types and mutations) which are visible as dark bands of varying intensities against a white background.
- First line and second line LPA use different probes that indicate sensitivity to first line and second line drugs respectively.
- Each individual patient LPA test result is captured over a special slender paper strip with 27 bands, which is interpreted by lab technicians & microbiologists to infer sensitivity to various drugs.
- Multiple LPA test strips are serially pasted on to a LPA results sheet and are interpreted manually in the lab using a reference paper card. An image of the LPA sheet with strips is depicted in Annexure 2

- Different patterns of the presence or absence of bands specific to different locations/genes determine the sensitivity/resistance of the TB strain in the patient's sample to different treatment regimens.
- Currently, LPA strips are pasted on 'LPA results sheets' (see Annexure 4) which are manually read by trained laboratory technicians and microbiologists in CDST labs to interpret the patterns (based on predefined rules) to determine sensitivity/resistance to various treatment regimens.
- Wadhwani AI is looking to develop and deploy an artificial-intelligence based product to improve laboratory workflows in reading and reporting results of LPA tests. The desired computer vision solution (deployed as a software application) would
  - Reduce the time taken to interpret patient wise LPA test result strips,
  - Improve the accuracy of the interpretation process and
 - Directly transmit information to the designated information systems for public health action.

  To sum up, such a solution enables faster initiation of TB patients on most appropriate and accurate treatment regimen.
- **Wadhwani AI will drive data collection, product design and development (i.e. engineering of the product) and is looking for a research partner to drive development of the core computer vision algorithm, work closely with the WIAI team in integrating these algorithms with the product, and iteratively improve the algorithm to meet performance criteria in pre-pilot validation, pilot validation, deployment and scaling phases. Wadhwani AI has already developed a Proof-of-Concept model based on heuristics.**

Section 3: Scope of work

WIAI is developing a solution to automate the interpretation of LPA test results. The solution is expected to reduce the human effort involved in interpreting LPA strips, capture information available in the LPA results sheet and transmit the information to designated servers. Outcomes of the solution will include improved accuracy of strip interpretation, improved efficiency and lab throughput, and faster initiation of treatment on appropriate treatment regimens for people with TB.

WIAI is looking for organisations with technical expertise in the design and development of computer vision applications, preferably with experience in working with health programs or sensitive data. The organisation will provide expertise to design, develop and iteratively improve a computer vision algorithm with features specified in the scope of work.

Overall project scope
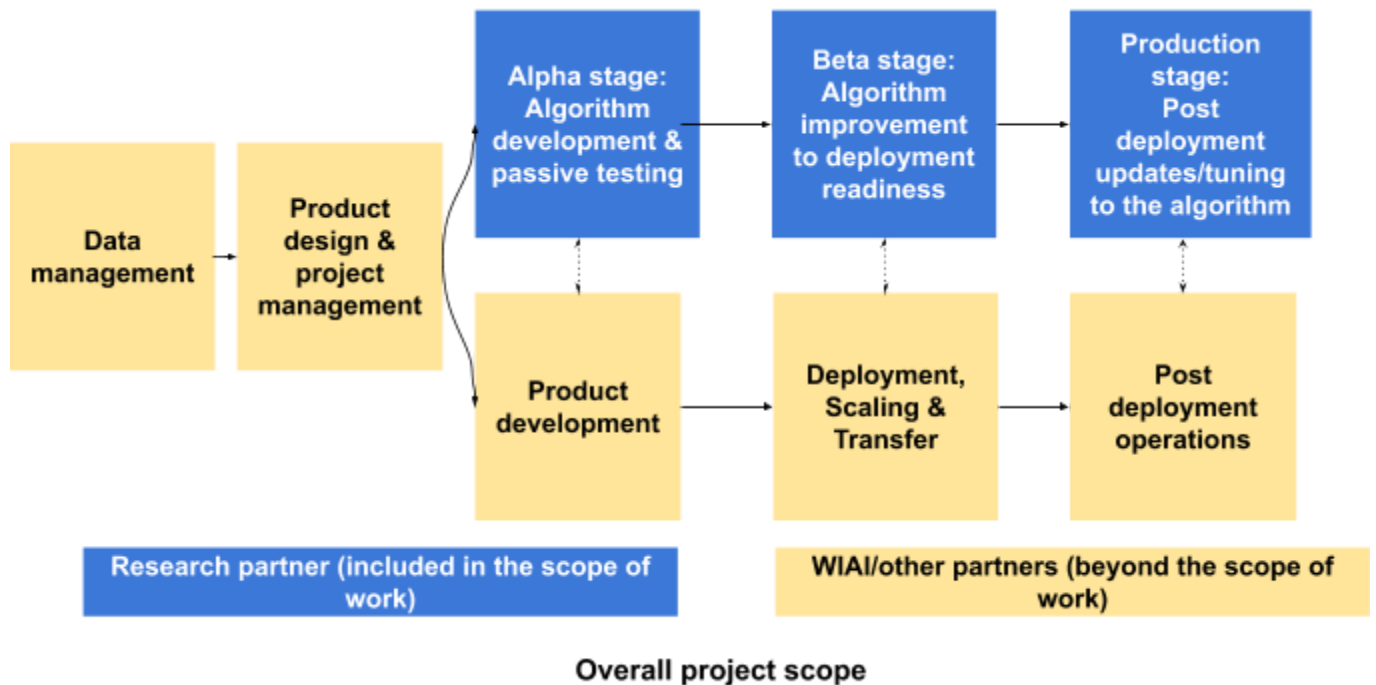
Core scope of work

1. **Algorithm development [via Technical Service Agreement- Research Partner]:**

   a. The algorithm should be capable of accepting as inputs scanned images of LPA results sheets (image in annexure 4) for both First Line LPA (FL LPA) & Second Line LPA (SL-LPA).

   b. The key functions expected of the algorithm

      i. **Strip identification:** Determine the bounding boxes **of all** the strips in the image(see image in annexure) to a high degree of accuracy. Strips can reasonably be expected to be found in the center of the sheet. Produce the bounding boxes of the strips, as an intermediate data, and measure the offsets and overlap with ground truth.

      ii. **Band identification:** Within each strip, identify presence/absence of individual bands. The algorithm should also incorporate a technique for uncertainty estimation that flags doubtful cases. It is acceptable if the algorithm flags a number of test strips (upto **5%**) as 'not determinable'. However, of the strips that are identified and for which bands are read, the identification of presence/absence of bands should have high sensitivity (95%) and specificity (95%). For each band prediction, provide a confidence score for the prediction (presence, absence, no-call) that asserts the trust placed by the algorithms on the prediction. Please see Annexure-3 for detailed performance metrics.

   c. It is desirable that over the course of the algorithm development, the research partner furnishes WIAI with-

      i. Technical approach & design

      ii. Explanations of the interpretations using saliency maps, visual markers, etc.

      iii. provide ablation studies

   d. It is expected that algorithm development will be an iterative process and is likely to include:

i. **Alpha development:** A phase of initial development with testing performance on a predefined data set, and subsequent improvements during passive deployment to develop a pilot-ready version.

ii. **Beta development:** Improvements to the algorithm during the pilot phase towards a deployment ready solution. This may include a certification/validation process around which the pilot may be designed. The deployment architecture will need to be co-developed with the engineering team to support the deployment of multiple versions of the algorithm for different users.

iii. **Post deployment updates to the algorithm:** The research partner will also need to provide long-term support for updating and maintaining the algorithm for an extended period post deployment.

e. We expect the implementation, during all stages of the development, to follow software engineering best practices, such as such as a code readability, modularity, extensibility, among others

f. The algorithm should be packaged for deployment within a software application (either locally for Windows desktops or as a secure cloud service). This will involve liaising with the engineering team of the project.

What constitutes success?

- Performance of the algorithm will be evaluated at various stages of the project and the algorithm will need to meet the **performance criteria** at each of these stages (see Annexure 3 for details of performance criteria)
  - ○ *Alpha stage (Initial algorithm development):*
    - Meet defined performance thresholds against a representative test set. (The test set will comprise of scanned and annotated images of the LPA results sheet of FL-LPA and SL-LPA collected from a majority of CDST laboratories). For details on the size and annotations expected for the test set, see Annexure 4.

■ *Passive evaluation (pre-pilot testing):* Meet defined performance thresholds during 2 weeks of prospective data collection (fresh unannotated scanned images that are collected daily from a representative set of labs). The passive evaluation phase is to allow for iterative development of the algorithm to address different points of failure.

○ **Beta stage** *(Pilot testing):* Meet defined criteria in real-world settings during field/pilot testing (in Culture & Drug Sensitivity Testing CDST Labs). The pilot will involve real users taking action based on the recommendations of the product (i.e. algorithm integrated as a software application with a user interface). Deploying the algorithm will involve significant collaboration with the project's engineering team. The pilot phase is expected to provide an additional opportunity for iterative development to address new failure points that may emerge with outcome being a deployment-ready solution.

○ **Production stage** *(Post deployment):* Meet and improve upon performance on defined performance criteria in deployment settings for an extended period (3 to 5 years) through periodic updates.The specifics of long term support and costing will be defined in the contracting stage after technical presentations are made.

Information regarding other related components of the project

The designated 'Research partner' identified through this RfP will provide support for the design and development of the algorithm. The 'Research partner' is expected to work closely with WIAI and partners across pre-pilot phase (including user research), pilot testing, deployment, scale up and maintenance stages. For context, other aspects of the project are outlined here.

1. **Data Management [by WIAI]:**
   a. Data acquisition - Build a representative dataset of FL-LPA and SL-LPA result sheets from CDST labs across the country. Facilitate data gathering during the passive evaluation stage.
   b. Annotation of LPA results sheets in the test data set (see Annexure 4 for details)
   c. Establish baselines:

      i.   *Field baseline:* Digitized annotations of collected data will form the *field baseline* to measure performance of the current manual system

      ii.   *Ground truth:* An expert panel of microbiologists will annotate a subset of data collected to be used as the ground truth for comparison

2. **Product design and project management [by WIAI]**

    a. Product and solution design including user research, specifying functional and non-functional requirements of all components, user flow & wireframes.

    b. Product management support by organizing sprints, clarifying requirements and making design choices over the project lifecycle.

    c. Project management across the development lifecycle from initial development, pre-pilot testing (passive validation of the algorithm, unit testing and user testing), pilot testing and deployment

3. **Product development [by WIAI]**

    a. Develop a deployable software application integrated with the computer vision algorithm. Develop additional components of the solution such as data exchange layers, an admin portal, user management modules, and analytics

4. **Deployment, scaling & transfer [by WIAI/other partners]**

    a. Scale solution deployment from pilot sites to full scale deployment

    b. Documentation, training, program management and analytics to track adoption, retention, usage & impact

    c. Transfer ownership of the built systems to relevant stakeholders of CTD/relevant partners with hand holding

5. **Post-deployment Operations, Maintenance and Support [by WIAI/partners]**

- Periodic updates such as UI/UX changes, functional updates, and maintain backend infrastructure with periodic security assessments
- Provide phone, email and in person support against agreed SLAs upto 3-years post deployment (with option to extend)

Key project stages and timelines

WIAI is committed to a full scale deployment by December 2021. Expected timelines for various stages of the project and support expected from the 'Research partner' across these stages are outlined below.

Project Timelines Overview:
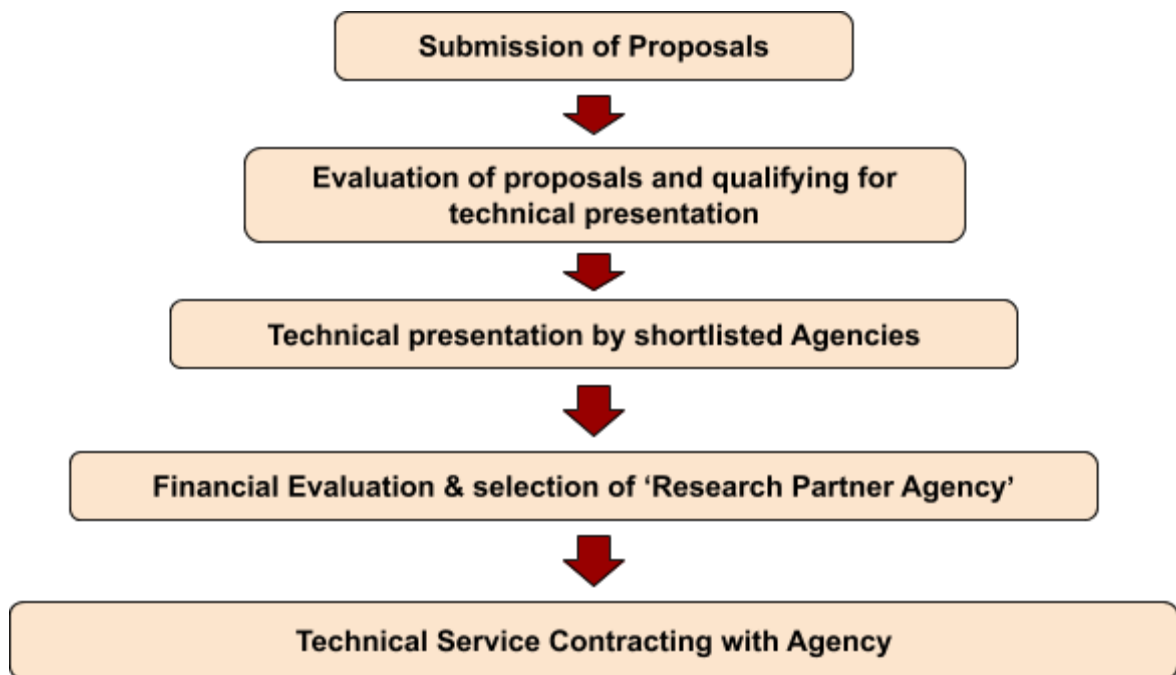
Project Phase	Sub Component	Accountability	Oct-Dec 20	Jan-Mar 21	Apr-Jun 21	Jul-Sep 21	Oct-Dec 21
	Data collection; Data processing and annotation	WIAI	▓				
	RFP Notification for Technical Service Agreement	WIAI	▓				
Data Acquisition	Onboarding Research Partner; Expert evaluation of error (algo vs human)	WIAI		▓			
Pre Passive Validation	Tech PoC iteration to algorithm on predefined dataset ready for passive validation.	Sub contracted Agency		▓			
Passive Validation & Pilot Ready certification	Passive validation in CDST labs;	Sub contracted Agency		▓	▓		
	Development of tool (engineering effort) for active field testing	WIAI		▓	▓		
	Preparation for active validation (SOPs, training, limited integration)	WIAI			▓		
	Active field testing in various settings & Monitoring	Sub Contracted Agency + WIAI				▓	▓
	Preparation for workflow integration and training of staff	WIAI					▓
Pilot (Beta)	Technical integration with Nikshay/LIMS	WIAI					▓
Scaling & Deployment	Scale up to multiple labs with hand-holding	WIAI					▓
Post Deployment Upgrades & Maintenance	Post Deployment Algorithm Updates	Sub contracted agency					▓
	Long Term Maintenance & Updates	Research Agency					▓

Section 4: Bidding, Contracting & Financials

- Subsequent to the successful submission of proposals, WIAI may, at its discretion, ask any bidder for clarification of any part of its proposal.
- No change in price or substance of the proposal shall be sought, offered or permitted during this exchange.
- All the proposals found to be in compliance with the general instructions to the bidders, shall be fairly evaluated in a transparent manner by the WIAI Procurement & Evaluation Committee.

Overview of the bidding and Technical Service Request process

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┌─────────────────────────────────────────┐
│         Submission of Proposals          │
└─────────────────────────────────────────┘
                    ⬇
┌─────────────────────────────────────────┐
│  Evaluation of proposals and qualifying  │
│        for technical presentation        │
└─────────────────────────────────────────┘
                    ⬇
┌─────────────────────────────────────────┐
│ Technical presentation by shortlisted    │
│                Agencies                   │
└─────────────────────────────────────────┘
                    ⬇
┌─────────────────────────────────────────┐
│ Financial Evaluation & selection of      │
│       'Research Partner Agency'          │
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                    ⬇
┌─────────────────────────────────────────┐
│ Technical Service Contracting with Agency │
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Evaluation of Quality- Elements

The evaluation of Quality of bids will be based on a 3 phased evaluation by the WIAI Procurement & Evaluation Committee -

    A. Technical Proposal Score (100 points)

    B. Technical Presentation Score (100 points)

    C. Financial Evaluation of bid.

A) *Stage of Technical Proposal Evaluation:*

Elements of Technical Proposal Score Break Up (100 Points)

Section	Details to be furnished with proposal	Weight
Previous experience in Computer vision applications projects	● Domain experience of computer vision applications (preferably in Health Care) ● Demonstrated experience in handling sensitive data	20 Points
Qualification of staff/leadership	● Bio/profile of Team Lead ● Publications	10 Points
Technical depth of proposal	● Detailed description of approach to the problem and desired solution along with committed timelines for deliverables ● Strategy for edge cases handling. ● Understanding of the performance metrics.	30 Points
Professional References based on previous work assignments	Weighted scoring- depending on duration & quantum of experience/ size and impact of previous projects. Weightage of reference. Recognitions	10 Points
Financial competence	Scoring will be dependent on points like Company Profile, Financial stability, Debts, Revenues & other key ratios.	30 Points

● Organizations whose technical proposals are found eligible will be contacted for next stage i.e. Technical Presentation from respective organizations in a standard template communicated separately by WIAI to shortlisted firms.

● An Organization who is technically proficient but isn't Financially competent will not be selected irrespective of scores in technical points

B) Stage of Technical Presentation Evaluation

- Shortlisted firms qualifying for this stage shall be separately intimated by WIAI by email and requested to make a technical PPT presentation using a standardized template designed by the technical leadership of WIAI on a designated date and time.
- The individual bidders will be scored, interviewed & compared over a 100 point scale
- Technical presentation will be evaluated by a technical committee consisting of WIAI leadership based on the criteria outlined in the following section 'Elements of evaluation'

Weighted scoring for elements of evaluation- Technical Presentations*

Section	Details to be furnished with proposal	Weight
Problem Definition and Approach Outline	What will be solved and how will it be solved	20 points
Assumptions		5 points
Stated risks		10 points
Rationale of selected approach	Compare & contrast the different alternative approaches towards the solution (evidence based/ literature backing)	20 points
System integration	How this proposed solution fits into an overall solution within existing systems	15 points
Best Practices	AI/ML Algorithms	5 points
Non-functional requirements (ML Engineering)		5 points
Support and Scaling	How will the solution be scaled up & maintained	15 points
Extensibility & model for innovation		5 points

- *The top 3 scoring firms in this round will be shortlisted for financial proposal evaluation.*

**C) Stage of Financial Evaluation of the Bid**

- All the financial bids aligning with the template furnished by WIAI (annexure 5b) representative of individual firms shall be secured and kept in hold by the Procurement committee and shall not be opened upfront.

- After shortlisting the top 3 scoring bids in the technical presentation, the corresponding financial bids of agencies will be opened and evaluated by the WIAI Procurement & Evaluation Committee.

Ultimately, from the 3 available choices, WIAI awards the contract to the proposal which is in best alignment with the WIAI technical requirements, under allocated budget for the grant and adherent to project timelines

Note: It is important to know that, while costing is an important element, the agency quoting L1 (lowest financial bid) may or may not be awarded the contract, as WIAI follows a Combined Quality Cum Cost Based System (CQCCBS) methodology for decision making.

Summary of bidding process & research partner selection for service agreement
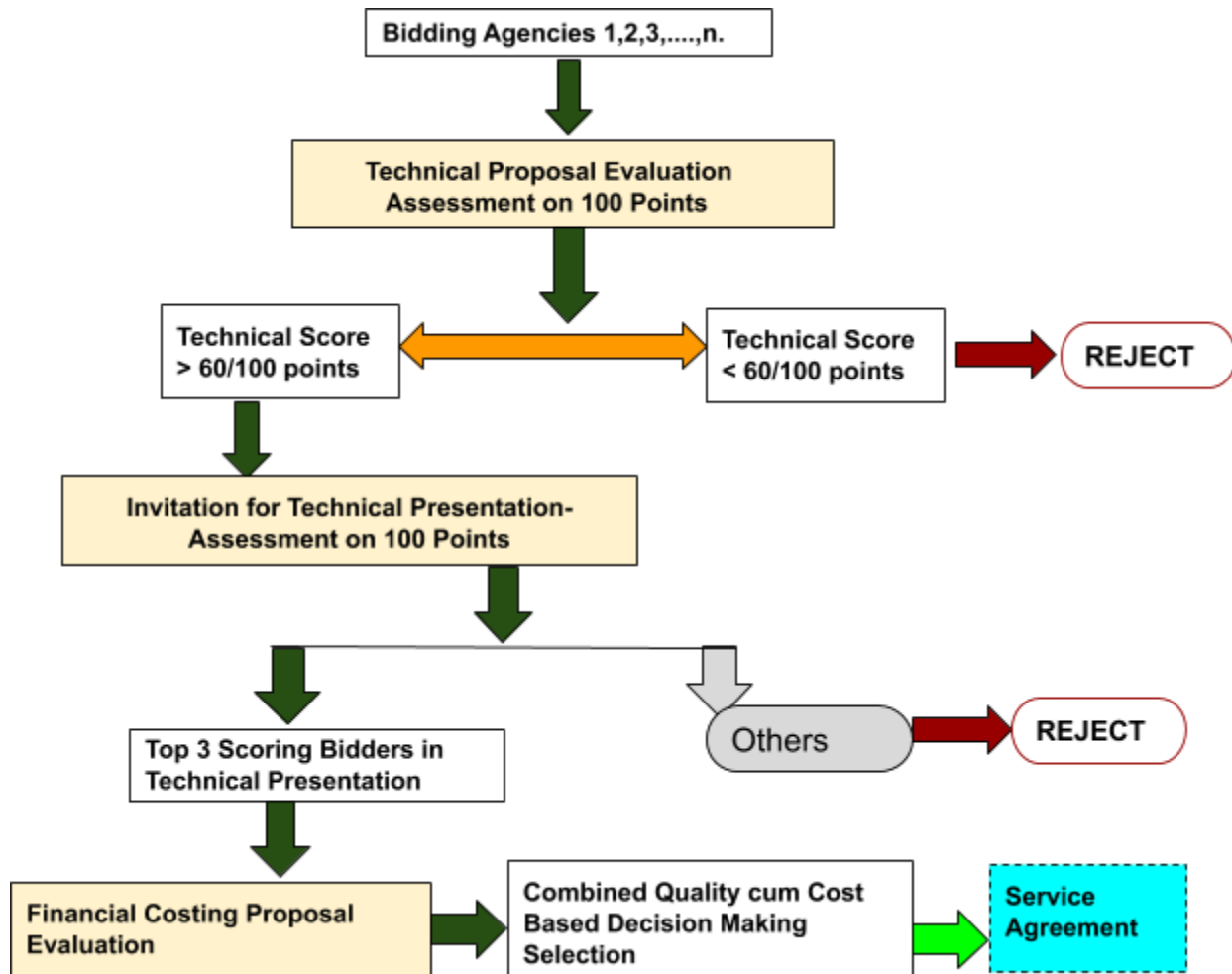
Contracting and financials

A financial bid submitted as part of the proposal will include a bid for the expected overall cost of executing the work defined in the 'Scope of work' section (this cost should primarily include HR and direct costs for delivery. Cloud infrastructure, logistics and other costs will be covered by WIAI.

Guidelines for including costs in the financial proposal

Costs to be included

1. **Human resources -** Include the costs of technical experts, developers & engineers required to address the problem across all stages of the project (for alpha development, beta development, and post-deployment updates to the algorithm)

2. **Overheads and other operational costs**

Costs to be excluded (as these will be supported/reimbursed by WIAI)

1. **Cloud Infrastructure -** Cost towards data hosting and server management, maintenance, database related costs, security and other related costs.

2. **Travel & logistics related costs -** Any cost towards field travel for various reasons (training/ monitoring/ supervision/ quality assurance, etc.)

Payment disbursement

Payment will be made based on 'stages' of the project and can be expected in the following tranches:

1. Post signing of contract
2. End of Alpha development
3. End of Beta development
4. Periodic payments post-deployment

The end-point of each stage will be to meet the project deliverables (outlined under 'Contract Terms') and defined performance criteria (see 'What constitutes Success?' defined under the 'Scope of Work' and Annexure 2)

Contract terms

Minimum deliverables

- Reporting & progress
    - The type of progress information to be provided (status report etc) on a fortnightly or weekly basis.
    - Definition of steps to solve the problem, plan and associated timeline.
    - Their internal checks to ensure that the solution is robust, well designed and well written.
    - Documentation of technical work, and usage of the software
- Artefacts
    - Well defined interface that can be directly consumed in engineering (either a local deployment or as an API)
    - Code & documentation

Non Negotiable Timelines to meet

- Meeting pre-pilot, pilot & deployment timelines as per the roadmap presented earlier

Legal Terms & conditions

The selected Bidder shall be required to abide the following (including but not limited to) terms and Conditions of the Contract

1. **WIAI SPECIFIC POLICIES AND PROCEDURES**

    The Bidder shall perform the Scope of Work in accordance with the requirements of the Policies on the website and keep itself abreast of any changes in the Policies.

2. **EXAMINATION OF RECORDS**

2 .1 Upon request, the Bidder shall provide WIAI or its designated entities/persons with access to any materials relevant to the Contract, including the following:

        2.1.1. electronic documents;

2.1.2 financial books;

2.1.3 documents;

2.1.4 papers; and

2.1.5 other records which document transactions related to the Contract.

2.2 The Bidder's obligation to provide access commences from the date on which the Contract is made and continues for a period of three (3) years following the completion of the Scope of Work.

3. **ASSIGNMENT**

The Contract is intended to cover a relationship between the parties only. The Bidder shall not assign, delegate, sub-contract, mortgage, charge or otherwise transfer the Contract or any interest or benefit arising out of, or in connection with, the Contract to a third party without the prior written approval of WIAI.

4. **CHANGES TO CONTRACT**

WIAI and the Bidder may change the terms of the Contract by written agreement only.

5. **BIDDER'S LIABILITY FOR PERSONAL INJURY AND/OR PROPERTY DAMAGE**

5.1 If the Bidder , its employees, agents or contractors directly or indirectly causes any loss in connection with claims arising out of services/scope of work performed as mentioned herein or otherwise relating to any damage to person or property during the performance of the Contract, the Bidder will bear all liability on behalf of WIAI.

If someone (including any third party) makes a claim against WIAI (whether during or after the completion and/or termination of the Contract) for any loss or damage to person or property directly or indirectly caused by the Bidder, its employees, agents or contractors during the performance of the Contract, the Bidder must indemnify and hold WIAI harmless from and against any and all loss, damage or liability, whether criminal or civil, suffered by WIAI in connection therewith and reimburse WIAI for any costs it has incurred in connection therewith (including actual legal costs on a full indemnity basis) whether during or after the completion and/or termination of the Contract.

5.2 For the purpose of clause above mentioned, "claim" shall mean all demands, claims and liabilities (whether criminal or civil, in contract, tort or otherwise) for losses, damages, legal costs and other expenses of any nature whatsoever and all costs and expenses (including without limitation legal costs) incurred in connection therewith.

6 DEFAULT

6.1 A Default is anything the WIAI considers to be a significant breach of the contract including:

6.1.1 failure to perform an obligation under the Contract within the agreed time; or

6.1.2 failure to deliver outputs of satisfactory capability, quality or reliability.

6.2 In the event of a Default by the Bidder, the WIAI shall write to the Bidder setting out the Default and the time by when the Bidder must fix it. If the Bidder fails to fix the Default within the time specified, WIAI may immediately terminate the Contract by issuing a written Notice of Termination to the Bidder.

6.3 Termination under this clause does not affect the rights and/or remedies either part may have accumulated up to the date of termination including the rights and/or remedies the WIAI may have in relation to the Default.

7 RIGHTS IN DATA AND INTELLECTUAL PROPERTY

7.1 If intellectual property or confidential information is required to enable the Bidder to provide the services/perform the scope of work, the Bidder shall be solely responsible for obtaining approvals for the use of any intellectual property and/or confidential information that belongs to anyone else (i.e. third parties).

7.2 WIAI shall own all intellectual property and confidential information that it creates in relation to the Services. WIAI shall own all intellectual property and confidential information that the Bidder creates as a result of performing the services/scope of work. In particular, WIAI shall own the following:

7.2.1 all data resulting from performance of the Contract, regardless of its form, format, or media;

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7.2.2   all data (other than that owned by third parties) used in performing the Contract regardless of its form, format, or media;

7.2.3   all data delivered under the Contract making up manuals or instructional, institutional, research and training materials;

7.2.4   all processes provided for use under the Contract; and

7.2.5   all any other data delivered under the Contract.

7.3   If the Bidder wishes to use the intellectual property and/or confidential information (mentioned in clause above) for purposes that are not in relation to the performance of the Services, it must obtain prior written consent from WIAI.

7.4   The Bidder consents to WIAI's use of the Bidder's own intellectual property and/or confidential information if the WIAI requires the Bidder's own intellectual property and/or confidential information to use the services.

7.5   The Bidder shall protect all intellectual property and/or confidential information belonging to the WIAI vigorously to the extent permissible by law. If the Bidder has a reasonable suspicion that there has been any event that infringes the rights of the WIAI in relation to its intellectual property and/or confidential information, it will inform WIAI immediately in writing and shall not oppose and cooperate with WIAI to the full extent with respect to any such request for a protective order or other relief.

8   CONFLICT OF INTEREST

8.1 The Bidder warrants, agrees and undertakes that neither it nor its employees, servants and/or agents has any arrangement, interest, activity, or relationship that could impair the Bidder's ability to act impartially and effectively in the delivery of the services and performance of the scope of work as required under the Contract.

8.2 The Bidder shall exercise its responsibility in the best interests of WIAI and shall not engage in any activities that would conflict with the Contract.

8.3 If the Bidder becomes aware of any actual or potential conflict of interest as defined in

Clause 8.1 and 8.2 above, the Bidder shall immediately notify WIAI in writing of (i) any such actual or potential conflict of interest and (ii) the procedures it intends to implement to resolve any such actual or potential conflict of interest.

8.4 WIAI may suspend the services, terminate the Contract or take any other actions that WIAI considers as appropriate in its sole discretion, if any actual or potential conflict of interest as defined in 8.1 and 8.2 above arises. If the WIAI directs the Bidder to take action(s) to resolve that conflict, the Bidder shall comply with any such direction(s).

9   **CONFIDENTIALITY**

9.1   The Bidder shall not, either during the term of the Contract or after the termination of the Contract, disclose to a third party any information that it may acquire in consequence of this Contract relating to the services, the Contract or WIAI's operations without the prior written consent of the WIAI

9.2 The Bidder's obligations in Clause 9.1 shall not apply to any information which:

●   is publicly available or becomes publicly available other than by reason of the Bidder's default;

●   the Bidder is required to disclose by order of a court of competent jurisdiction

9.3 The Bidder shall ensure that its employees, servants and/or agents comply with the provisions of this Clause 9.

10.   **INSURANCE**

The Bidder shall maintain and pay all premiums in respect of an insurance policy or policies relevant to the delivery of the services with policy limits and provisions conforming to such requirements as WIAI may from time to time prescribe and shall ensure that WIAI shall be entitled to the benefit of such insurance

11. **SUSPENSION OF SERVICES**

 WIAI may, at any time, give a written order to the Bidder, suspending all, or part, of the services. WIAI has full and sole discretion to decide the length of the suspension. Upon receiving the order, the Bidder must immediately comply with its terms and take all steps necessary to minimize any and all costs resulting from the suspension. WIAI and the

Bidder shall negotiate any adjustment to the price and/or schedule for completing the services, which may result from the suspension.

12 TERMINATION BY WIAI

12.1 WIAI may terminate this Contract, in whole or in part, by issuing a written Notice of Termination. WIAI may terminate this Contract without giving any reasons. If this Contract is terminated, the WIAI and the Bidder shall negotiate the rights, duties, and obligations of the parties, including but not limited to compensation to the Bidder and/or the WIAI. Any compensation to the Bidder must not exceed the total value of the Contract

12.2 Upon receiving a Notice of Termination, the Bidder shall immediately stop work as specified in the notice, except if directed otherwise by WIAI.

12.3 Upon receiving a Notice of Termination, the Bidder shall submit a final termination settlement proposal to WIAI. The settlement proposal must include a certification from the Project Head of the actual costs the Bidder has incurred.

12.4 If the Bidder fails to submit the termination settlement proposal within seven (7) days from the date of the Notice of Termination, the WIAI may in its sole discretion determine the amount, if any, due to the Bidder following the termination.

12.5 Upon termination of the Contract, subject as provided in this clause and except in respect of any accrued rights, neither Party shall be under any further obligation to the other.

12.6 Termination under this clause does not affect the rights and/or remedies which either Party may have accrued or accumulated up to the date of termination of the Contract.

13 INTERPRETATION

 Should a dispute about the meaning of any term in the Contract arise, WIAI may make a written determination as to the term's meaning. A written determination made under this clause shall be final and conclusive between the Parties.

14 LAW & JURISDICTION

The laws of California, USA shall govern this Contract. The parties to the Contract agree to submit to the non-exclusive jurisdiction of the Courts of the California.

15 **COMMUNICATIONS**

15.1   All communications relating to this Contract shall be in writing & may be delivered by email ([RFP@wadhwaniai.org)](RFP@wadhwaniai.org)

16   **ENTIRE AGREEMENT**

This Contract is the entire agreement between WIAI and the Bidder in relation to the matters set out in this Contract. No other terms and conditions may be included or implied. Any warranty, representation, guarantee or other term or condition not contained in this Contract has no effect.

17   **ILLEGALITY AND SEVERABILITY**

If any provisions of this Contract are held unenforceable or invalid for any reason, the remaining provisions of this Contract will continue to be in full force and effect.

18   **WAIVER**

18.1   A party's failure, delay or relaxation in exercising any power or right it has under this Contract does not mean that the Party has given up (i.e. waived) that power or right.

18.2   A Party exercising a power or right does not stop it from:

- further exercising that power or right; or
- exercising any other power or right under this Contract

19. **REASONABLENESS**

19.1   The Bidder confirms it has had the opportunity to receive independent legal advice relating to all the matters relating to this Contract.

19.2   The Bidder agrees that, having considered the terms of this Contract as a whole, the terms of this Contract are fair and reasonable.

20 **PARTNERSHIP**

This Contract does not create a partnership between the Bidder and WIAI.

21 **FORCE MAJEURE**

21.1. A Force Majeure Event is any event which is beyond the reasonable control of the Contractor or the WIAI and which makes it impossible to perform an obligation under this Contract, including the following:

- acts of God, lightning strikes, earthquakes, volcano eruptions, floods, storms, explosions, fires, pandemics and any natural disaster;
- acts of war (whether declared or not), invasion, acts of foreign enemies, mobilisation, requisition, or embargo;
- acts of public enemies, terrorism, riots, civil commotion, malicious damage, sabotage, rebellion, insurrection, revolution, military usurped power, or civil war; or
- contamination by radio-activity from any nuclear fuel, or from any nuclear waste from the combustion of nuclear fuel, radio-active toxic explosion, or other hazardous properties of any explosive nuclear assembly or nuclear component of such assembly.

21.2 A party that does not perform an obligation under this Contract shall not be in breach to the extent that a Force Majeure Event caused the non-performance.

21.3 Where the Bidder thinks there is likely to be a delay in performing an obligation under this Contract because of a Force Majeure Event the Bidder shall:

- immediately notify the WIAI in writing of:

21.3.1 the likely delay and how long the Bidder thinks it will last; and

21.3.2. details of the likely effect on the services and the Bidder's ability to perform the Contract;

- take all reasonable steps to lessen (i.e. mitigate) the effects of any delay; and
- use its best efforts to continue to perform its obligations under the Contract.

21.4 The WIAI and the Bidder shall, as soon as practicable after receiving the notification, discuss whether the Contract can continue. If, following that discussion, the WIAI and the Bidder

agree that the Contract can continue they may:

- continue the Contract unchanged; or
- change the Contract as per discussions.

22 COSTS AND EXPENSES FOR PREPARATION AND EXECUTION OF CONTRACT

Except as otherwise provided for in the Contract, the parties shall bear their own costs of and incidental to the preparation and execution (i.e. signing) of the Contract.

23 REPORTING AND COORDINATION ARRANGEMENTS

The Contractor shall liaise closely and work in collaboration with a Project Overseer in performing the Services in the Contract. The Contractor shall keep the Project Overseer informed of progress of the Services, timelines and budget. The Project Overseer shall be assigned by the APEC Member Economy which has requested this project.

24 FAILURE TO AGREE WITH THE TERMS AND CONDITIONS OF THE RFP

Failure of the successful Bidder to agree with the proposed Contract Terms & Conditions(included but not limited to the ones stated in the RFP) as shall constitute sufficient grounds for the annulment of the award, in which event WIAI may award the contract to the next best value Bidder or call for new proposals from the interested Bidders.

Annexures

1. **Process of interpreting LPA strips (i.e. user flow)**

2. **Performance criteria**

3. **Data description**

4. **Proposal template(s)**

Annex 1: Process of interpreting LPA strips

Background: As mentioned before, it is reinforced that-

- First Line Anti TB Drugs include Rifampicin(R) and Isoniazid (H). FL-LPA is used to detect sensitivity/Resistance to Rifampicin and Isoniazid.
- The gene which determines sensitivity/resistance to Rifampicin drug is called **RpoB.** This gene is present in the DNA of the bacteria which causes Tuberculosis.
- On the other hand, Isoniazid resistance is determined by 2 genes- **'INH A' and 'Kat G'.**
- Every gene can have two expressions- 1) Wild Type- 'WT' (natural form) 2) Mutant- 'MUT' (this is the modified variant)
- Resistance Detected= Presence of *at least one* Mutant form of the drug related gene
- Resistance Inferred= Absence of *all* wild type forms of corresponding drug gene.

First Line LPA (Rifampicin Interpretation Rules)			
Target region	**Probe**	**Result interpretation**	**Clinical Interpretation**
rpoB WT1	rpoB WT1 not developed	Resistance to rifampicin inferred	Rifampicin is not effective
rpoB WT2	rpoB WT2 not developed	Resistance to rifampicin inferred	
rpoB WT2/3	rpoB WT2 and WT3 not developed	Resistance to rifampicin inferred	
rpoB WT3/4	rpoB MUT1 developed	Resistance to rifampicin detected	
	rpoB WT3, WT4 and MUT1 not developed	Resistance to rifampicin inferred	
rpoB WT4/5	rpoB WT4 and WT5 not developed	Resistance to rifampicin inferred	
rpoB WT5/6	rpoB WT5 and WT6 not developed	Resistance to rifampicin inferred	
rpoB WT7	rpoB MUT2A developed	Resistance to rifampicin detected	
	rpoB MUT2B developed		
	rpoB WT7, MUT2A and MUT2B not developed	Resistance to rifampicin inferred	
rpoB WT8	rpoB MUT3 developed	Resistance to rifampicin detected	
	rpoB WT8 & MUT3 not developed	Resistance to rifampicin inferred	

H- LPA Interpretation			
Target region	Probe	Result interpretation	Clinical Interpretation
katG WT	katG MUT1 or MUT2 developed	Mutation associated with high-level increase in MIC detected.	Isoniazid is unlikely to be effective even at high dose
	katG WT, MUT1 and MUT2 not developed		
inhA WT1	inhA MUT1 developed	Mutation associated with at least low-level increase in MIC detected. Resistance to Eto/Pto detected.	Isoniazid at high dose is likely effective. Ethionamide/prothionamide are not effective.
	inhA MUT2 developed	Mutation associated with at least low-level increase in MIC detected. Resistance to Eto/Pto likely detected.	Isoniazid at high dose is likely effective. Ethionamide/prothionamide are likely not effective.
	InhA WT1, MUT1 and MUT2 not developed	Mutation associated with at least low-level increase in MIC detected. Resistance to Eto/Pto likely inferred.	
inhA WT2	InhA MUT3A developed	Mutation associated with at least low-level increase in MIC detected. Resistance to Eto/Pto likely detected.	Isoniazid at high dose is likely effective. Ethionamide/prothionamide are not effective.
	InhA MUT3B developed		
	InhA WT2, MUT3A and MUT3B not developed	Mutation associated with at least low-level increase in MIC inferred. Resistance to Eto/Pto likely inferred.	

Similar logics are applied for Second- line LPA results interpretation. Only difference is for SL-LPA, the drugs are different and hence the genes are different which determine resistance.

- gyrA/gyrB (stands for Gyrase A/B) - Gene mutation if present may correlate with resistance to Fluoroquinolones (Oflaxacin, Levofloxacin, Moxifloxacin)
- rrs/eis- if gene mutation present it may correlate with resistance to injectable drugs called Aminoglycosides (Amikacin, Kanamycin,Capreomycin)
- embB- if this gene mutation is present, it may correlate with resistance to Ethambutol.

SL- LPA Interpretation of Fluoroquinolone drugs			
Target region	**Probe**	**Result interpretation**	**Clinical Interpretation**
gyrA WT 1	gyrA WT1 not developed	Resistance to Lfx inferred. Mutation associated with at least low-level increase inMIC for Mfx inferred.	Levofloxacin is not effective. Moxifloxacin could be used at higher dose. The regimen should be reevaluated based on phenotypic DST results at CB.
gyrA WT2	gyrA MUT1 developed	Resistance to Lfx detected. Mutation associated with atleast low-level increase inMIC for Mfx detected.	
gyrA WT2	gyrA MUT2 developed		
gyrA WT2	gyrA WT2, MUT1 and MUT2 not developed	Resistance to Lfx inferred.Mutation associated with atleast low-level increase inMIC for Mfx inferred.	
gyrA WT3	gyrA MUT3A developed	Resistance to Lfx detected. Mutation associated with at least low-level increase in MIC for Mfx detected.	
gyrA WT3	gyrA MUT3B developed	Resistance to Lfx detected. Mutation associated with high-level increase in MIC for Mfx detected.	Levofloxacin is not effective. Moxifloxacin is not effective.
gyrA WT3	gyrA MUT3C developed		
gyrA WT3	gyrA MUT3D developed		
gyrA WT3	gyrA WT3, MUT3A, MUT3B, MUT3C, MUT3D not developed	Resistance to Lfx inferred. Mutation associated with at least low-level increase in MIC for Mfx inferred.	Levofloxacin is not effective. Moxifloxacin could be used at higher dose. The regimen should be reevaluated based on phenotypic DST results at CB.
gyrB WT	gyrB MUT1 developed	Resistance to Lfx detected. Mutation associated with at least low-level increase in MIC for Mfx detected.	
gyrB WT	gyrB MUT2 developed		

gyrB WT	gyrB WT, MUT1 and MUT2 not developed	Resistance to Lfx inferred. Mutation associated with at least low-level increase in MIC for Mfx inferred.	
SLI - LPA Interpretation (Second Line Injectable Drugs)			
Target region	**Probe**	**Result interpretation**	**Clinical Interpretation**
rrs WT1	rrs MUT1 developed	Resistance to Km, Am, Cm detected	Amikacin, kanamycin and capreomycin are not effective.
	rrs WT1 and MUT1 not developed	Resistance to Km, Am*, Cm inferred	Kanamycin and capreomycin are likely not effective. Phenotypic DST result should guide the choice to use Amikacin in the treatment regimen.
rrs WT2	rrs MUT2 developed	Resistance to Km, Am, Cm detected	Amikacin, kanamycin and capreomycin are not effective.
	rrs WT2 and MUT2 not developed	Resistance to Km, Am, Cm inferred	Amikacin, kanamycin and capreomycin are likely not effective.
eis WT1	eis WT1 not developed	Resistance to Km inferred. Resistance to Am and Cm not detected.	Amikacin and Capreomycin are likely effective. Kanamycin is not effective.
eis WT2	eis MUT1 developed	Resistance to Km detected. Resistance to Am and Cm not detected.	Amikacin and Capreomycin are likely effective. Kanamycin is not effective.
	rrs WT2 and MUT2 not developed	Resistance to Km inferred. Resistance to Am and Cm not detected.	Amikacin and capreomycin are likely effective. Kanamycin likely not effective.
eis WT3	eis WT3 not developed	Resistance to Km, Am, Cm not detected	Amikacin, kanamycin and capreomycin are likely effective.

Annex 2: Key steps in the user flow, expected outputs of the algorithm and performance Metrics

Note: Auxiliary metrics are dependent on the performance on key metrics outlined below. Auxiliary metrics are to be reported in the interest of transparency, to understand performance on reported outputs. However, performance metrics to be prioritised are both key metrics i.e. Identification of strips, Identifying presence of each band).

Key performance metrics

Steps/user flow of algorithm	Outputs for FL-LPA	Outputs for SL-LPA	Performance metric	Acceptable threshold
Key metric 1: Identification of strips and bounding boxes	- Present. (Provide the bounding boxes of the identified strips) - Absent	- Present - Absent Same as FL-LPA	**Sensitivity** - Number of indices where the algorithm correctly identified presence of strip /number of indices where strips are truly present. **Negative predictive value** - Number of indices which the algorithm correctly marked as "absent"/Number of indices where there is no strip Report the overlap and offsets of the bounding boxes with ground truth.	Sensitivity > 95%
Key metric 2: Identifying presence of each band/genotype (i.e. WT1, WT2, MUT1, etc.) **with a confidence score for each call**	For each of 27 bands (CC, AC, TUB + 3 LCs + 21 WT/MUT bands) for FL-LPA: - Present - Absent - N/A Along with the predictions, report a confidence score, which asserts the trust placed by the algorithm in the prediction.	For each of 27 bands (CC, AC, TUB + 3 LCs + 21 WT/MUT bands) for SL-LPA: - Present - Absent - N/A Same as FL-LPA	**Sensitivity** - Number of bands are correctly identified as present/Number of bands present in the test set **Specificity** - Number of bands that are correctly identified as absent/Number of bands that are actually absent in the test set Report sensitivity for each of these categories: 1. **Region level** - Base (CC, AC, TUB) - RpoB - InHa - KatG - etc. 2. **Band level** (Eg. RpoB LC, WT1, MUT1, etc ...)	**Region level** Sensitivity> 98% for FL-LPA; Sensitivity> 98% for SL-LPA. Specificity> 98% (FL-LPA) & > 98% (SL-LPA) **Band level:** Sensitivity> 90% Specificity> 90%

Auxiliary performance metrics:

Steps/user flow of algorithm	Outputs for FL-LPA	Outputs for SL-LPA	Performance metric	Acceptable threshold
Auxiliary metric 1: Identifying validity of the test (identify CC, AC, TUB, multiple LC bands)	- TB not detected - Successful test - Indeterminate test (one locus is missing) - Unsuccessful test (CC error, AC error, missing 2 or more loci, algorithm error) - (Algorithmic error/not readable)	- TB not detected - Successful test - Indeterminate test (one locus is missing) - Unsuccessful test (CC error, AC error, missing 2 or more loci, algorithm error) - Algorithmic error (not readable)	This metric is defined while prioritising successful tests. **Sensitivity -** Number of strips correctly identified as successful/Number of strips available that are 'successful tests' **Specificity -** Number of strips that are correctly identified as unsuccessful, indeterminate or 'TUB not detected'/Number of strips where the test is unsuccessful, indeterminate or 'TUB not detected'	**Sensitivity> 95%** **Specificity> 95%**
Auxiliary 2: Final interpretation of LPA strips (i.e. resistance/sensitive to different classes)	For all tests, report: - MTB (detected, not detected, indeterminate) - R resistance RpoB (detected, not detected) - H resistance (Katg detected, InhA detected, not detected)	For all tests: - FQ resistance (gyrA/gyrB detected, not detected) - SLID resistance (EIS detected, RRS detected, not detected)	**Sensitivity -** Number of strips which are identified correctly as resistant to a particular drug class/Number of strips that are resistant to that particular drug class **Specificity -** Number of strips which are correctly identified as sensitive to a particular drug class/Number of strips in the test set that are actually sensitive to that particular drug class	**Both Sensitivity & Specificity> 95% for FL-LPA.** **For SL-LPA, both sensitivity and specificity > 90%**

Annex 4: Data Features- LPA Strip, LPA results sheet sample images

What constitutes data?

Images of LPA result sheets (Primary dataset)

1. **Raw data** constitutes images (scanner based images/taken with a mobile phone camera) of lab sheets with multiple LPA strips affixed in a standard template with appropriate human annotations.

2. **Processed data** constitutes the same images catalogued, formatted and annotated

2(b)- LPA results sheet

GenoType MTBDRplus 96

VER 2.0
0304A-0713-03-2

IRL

Date: 05 / 10 / 2019 (dd / mm / yyyy)

SN	Lab ID	RMP sensitive	RMP resistant	INH sensitive	INH resistant
49.	9943	S		S	
50.	9944	S		S	
51.	9945	S		S	
52.	9946	S		S	
53.	9947	S		S	
54.	9948	S		S	
55.	9951	S		S	
56.	9952	S		S	
57.	9954	S		S	
58.	9955	MTBC NOT DETECTED			
59.	9957	S		S	
60.	9961	S		S	
61.	9962	S		S	
62.	9965	S			R
63.	9966	S		S	
64.	9968	S		S	
65.	9969	S		S	
66.	9972	S		S	
67.	9975	S		S	
68.	9976	S			R
69.	9977	S		S	
70.	9979	S		S	
71.	9980	S		S	
72.	9981	S		S	

LOT 01001920   HYB ____ min   STR ____ min   SUB ____ min

2(b) Sample of key parts of the LPA results sheet using First Line- Line Probe Assay
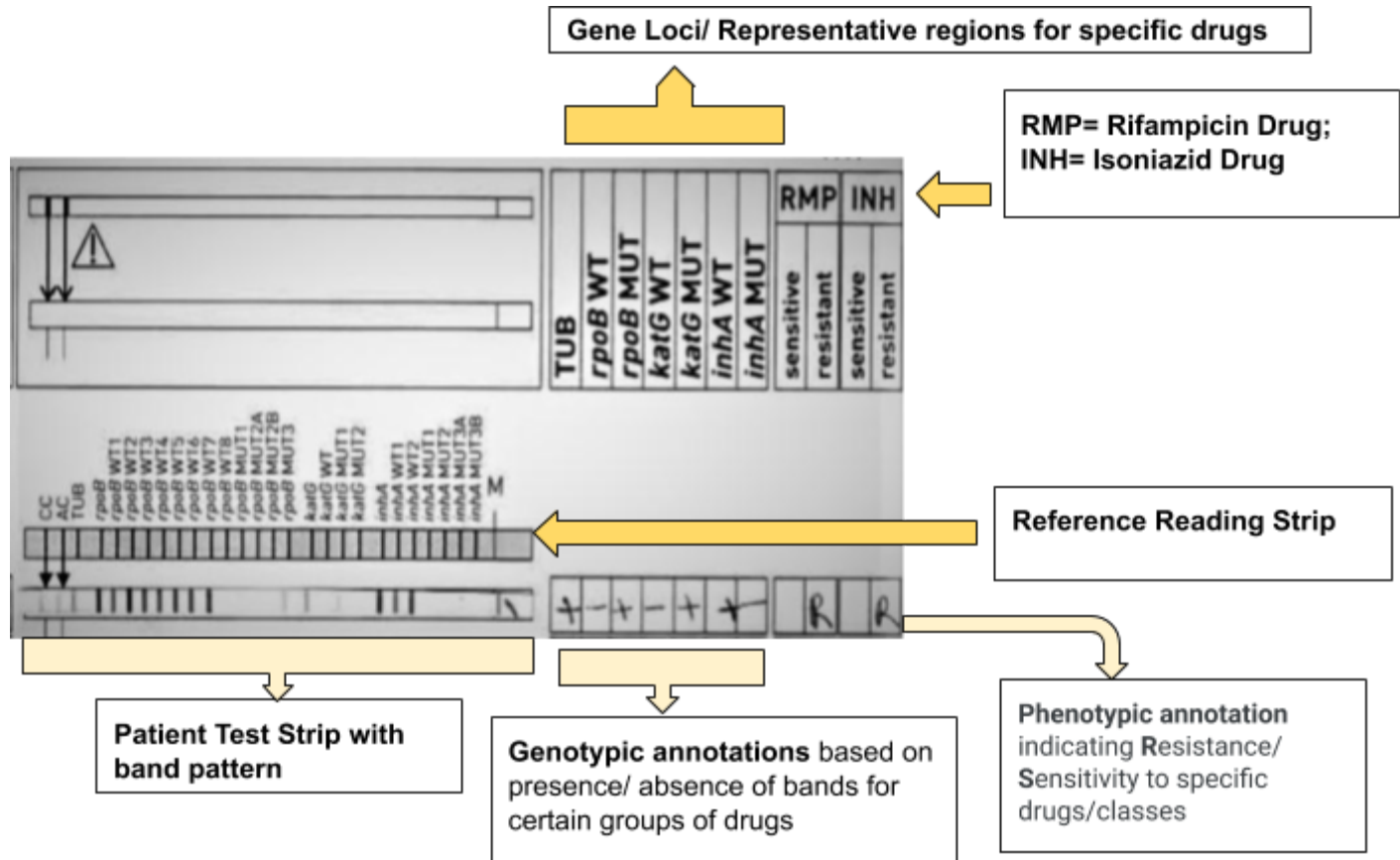
2(c) Annotations that can be expected in the initial data set

Basic annotations available after the annotation exercise include:

- For each sheet, annotated polygons enclosing the strips present.
- For each strip, band level presence/ absence.
- For each strip, digitized version of interpretations ((+/-) and (R/S)), as seen on the sheet.

Annex 4(a)- Technical Proposal Template

Bidding agency details & undertaking

General Information –To be filled by Agency

Sl. No.	Item	Agency Details
1	Name and address of the agency/company, telephone number, fax, mobile number, email address.	
2	Type of organization (Whether Proprietorship, partnership, private proprietor/partners).	
3	Name, address, contact no and email id of the Directors/Proprietor/Partners.	
4	GST Registration No.(Please attach copy).	
5	Year of formation of the agency/company (Please attach copy)	
6	Since when have you been working in this field.	
7	Please provide your Clientele List (Contact No/address/email).	
8	Audited financial reports for the last 3 years (Please attach copy).	

Undertaking

I have read the terms and conditions of ToR and understand that in case any of the statements furnished by the undersigned is found to be false OR if any / all the terms and conditions are not complied with, the ToR is liable to be cancelled by WIAI. I agree that the decision of the WIAI in this regard would be final and binding on the ToR.

I also certify that I have understood all the terms and conditions indicated in the ToR document and hereby accept the same completely.

Date :   Signature of the authorized signatory of the agency

Place :   with official seal/ stamp

It is requested that Offerors organize their Technical Proposals as noted below- This request is prerequisite for the Project to review the submitted material thus enabling a rapid decision and contracting process.

Technical Proposal Requirements: The technical proposal must be written in English. There should be a maximum of 10 type-written pages, excluding appendices/supporting documents, with no more than 3 pages covering Company Information and Relevant Past Performance. (Format - Type: Times New Roman, Font Size 11, Margins: 1" all around)

The technical proposal shall address the subjects outlined below:

A. Firm Information

- Provide the name, address and license of your firm.
- Provide the contact information for your primary contact for this project.
- Please describe your firm's management structure.
- Identify the Key Personnel that would be working on this project assuming an award.
- Please include a brief statement about the capabilities, notable past achievements summary under 2 pages.
- Please furnish technical credentials and competencies of the lead team personnel (CVs must be provided, not exceeding 2 pages).

B. Past Performance

- Please outline the experience your firm has had in performing work
- For each former and/or current project, please include the name of the client and his or her contact information (current and most recent information required, within the last year).
- The quality of the work performed by the Offeror,
- The capability performed by the Offeror,
- The timeliness of the effort of the Offeror, and
- Whether the Client would use Offeror's services should they have similar needs in the future?

C. Technical Approach

Please submit a detailed technical write-up of the proposed implementation strategy and management for this specific project. Offerors must include a Gantt Chart Schedule.

Annex 5(b)- Financial Proposal Template

Financial Proposal Requirements:
- The financial proposal must include a financial bid. The financial bid will include an overall dollar value for executing the scope of work. This bid will be treated as a single number for the purpose of financial evaluation of the proposals.
- The amount specified in the financial proposal shall exclude GST.
- In addition to the financial bid, the financial proposal can include details demonstrating the break up of expected costs, in the budget template below.
- It is expected that there are logical linkages between budget items and activities proposed. More details can be included in the rationale column.
- WIAI may ask for reasoning/detailed working for costs mentioned in the proposal at later stage

.

Financial proposal (include human resource and other direct costs)					
Particulars	**Unit Basis (Daily/monthly/yearly)**	**No. of units**	**Unit Rate**	**Total Cost**	**Rationale**
Personnel					
Other (Specify)					
Total (A)					