

REQUEST FOR INFORMATION (RFI)
TB CAD VALIDATION PROJECT

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1. LIST OF ACRONYMS AND DEFINITIONS:

Acronym	Definition
AI	Artificial Intelligence
CAD	Computer Aided Detection
CXR	Chest Radiograph
DICOM	Digital Imaging and Communication in Medicine standard
EU	European Union
HIV	Human Immunodeficiency Virus
LMIC	Low and Middle Income Countries
NAAT	Nucleic Acid Amplification Test
RFI	Request for Information
TB	Tuberculosis
WHO	World Health Organization

2. BACKGROUND INFORMATION:

Tuberculosis remains a main cause of morbidity and mortality globally, and the COVID-19 pandemic has had a large adverse impact on TB case finding over the past 2 years. Chest Radiograph (CXR) is an important tool that is available in many health care settings in low and middle income countries (LMICs), and may help in the screening of individuals for pulmonary tuberculosis and increasing case finding. However, in many settings, access to CXRs of acceptable quality and, more importantly, skilled human resources to read the CXRs, remain limited.

There is growing evidence regarding the diagnostic utility of artificial intelligence (AI) based diagnostics for use in LMICs, and a particular area of promise is computer aided detection (CAD) software for identification of CXR abnormalities. Recently FIND validated the use of several commercially available TB CAD products to aid in the screening of individuals with presumptive TB and to inform new policy recommendation for TB screening as provided by the World Health Organization (WHO). FIND now would like to expand our library of CXR images to be used in future validation of TB CAD tools for screening.

More about FIND and our programs can be found on www.finddx.org.

3. STATEMENT OF PURPOSE:

The purpose of this RFI is to allow FIND to assess and compare the performance of different CAD software tools for screening of pulmonary TB with the aim to inform future decision making and increasing evidence generation for policy making.

FIND makes no obligation or undertakings in any way to:

- Go to Tender; or
- Accept any RFI information received from a specific institution; or
- Include institutions responding to this RFI in any future tender invitation; or
- Any other commitment to supplier whatsoever, including any intention to form a contract with any institution for provision of this opportunity.

4. SCOPE OF WORK AND OBJECTIVES

FIND is seeking collaborators who are willing to provide digital CXRs and clinical data from finalized projects or studies to be used in our TB CAD validation project. This data will contribute to the independent performance evaluation and validation of CAD software tools for screening.

We are looking for finalized projects and studies that have systematically collected digital CXR images and demographic and clinical information from individuals that underwent CXR and reference testing to screen for TB. In this setting, CXR is performed to evaluate an individual regardless of symptoms, and who is not seeking care for her/himself due to TB symptoms. Screening use-cases are also sometimes referred to as health provider-initiated screening or active case finding in certain high risk groups.

For this RFI, FIND is seeking to expand its library of images and clinical information for a general population of adults (age > 15 years old) who are being screened for TB.

Additionally, FIND is interested in the following populations to evaluate the performance of CAD tools for screening in specific settings:

- 1.) Pediatric patients (age ≤ 15 years old) who are evaluated as a component of provider initiated TB screening or active case finding
- 2.) Individuals who are HIV seropositive and are evaluated as a component of provider initiated TB screening or active case findings.

We will prioritize data from LMIC countries for this RFI and our aim is to draw data from a variety of countries / regions.

Projects/studies are eligible if the following data was collected from all individuals:

- Individuals in your screening project are screened irrespective of whether they had symptoms (e.g. screening was provider-initiated and not patient-initiated)
- Posteroanterior (PA) view-CXR images in the form of DICOM, PNG, or JPEG files are available for a cohort of individuals who were tested within a defined period
- Digital CXR files have not been shared with CAD software developers for the use of training CAD software
- As a minimum, the following variables are known for all individuals in your cohort from which the sample will be drawn: age, gender, and, if done, test result of smear. Mycobacterial culture, and/or Xpert are required.
- You are willing to create de-identified digital CXR files which include a unique identification number that can link the digital file with the record containing the corresponding de-identified demographic and clinical information of an individual
- You are willing to prepare a dataset with personal level data of the sampled individuals, containing the same unique identification number as on the de-identified digital image.
- You have obtained the required ethical approval which allows you to share de-identified digital CXR files and clinical data for the purpose of the TB-CAD validation project.
- You agree that sharing of data will be done in full compliance with any applicable laws and regulations governing protected health information and other personal data (including the EU General Data Protection Regulation; www.eugdpr.org)

5. INFORMATION TO BE PROVIDED FOR THE RFI AND DELIVERABLES FOR THE TB CAD VALIDATION PROJECT

5.1 The following information should be provided in application for the RFI:

- A description of the project and explanation why it is considered eligible.
- A description of the patient population, variables collected, study period and study location, with a focus on the scope of work outlined above and in appendix A.
- A sample table with the total number of participants (TB cases and non-cases) identified in the study or project.
- An expected timeline for preparation and submission of data, including a clean dataset according to a predefined format, a data dictionary and a set of (de-identified) digital images.
- If appropriate, a reference to associated publications related to the specific study or project.

5.2 We expect the following deliverables from collaborators on the TB CAD validation project after award of the RFI:

- Agree with FIND on the collaboration, data sharing and usage agreement (the "Agreement").
- Sign the Agreement with FIND.
- Review and agree on the study protocol, as prepared by FIND.
- Agree with FIND on study or projects that are eligible and for which data will be contributed.
- Upon receipt of sampling number, fetch the agreed upon sample of digital CXR files.
- De-identify digital CXR files (remove them from any personal identifying information) and keep or assign a unique person identification number that can link the file to the demographic and clinical data for each subject included.
- Prepare a dataset (in .csv or other agreed upon format) with individual level data of the sampled individuals. This dataset should be removed from any personal identifying information, but contain the unique person identification number that can link the digital CXR file to the information in the dataset.
- Prepare a document outlining the study level information, including a description of the operationalization (definitions and coding) of the variables in the individual level dataset.
- Upload the data to the secure FIND server and notify us.
- Review draft versions of the study results that are prepared by FIND and be available to answer interim questions related to the data provided.
- Review, comment and approve final draft of the study report.
- Review, comment and approve final manuscript for publication.

5.3 What FIND offers to RFI collaborators:

- One author on any publication that arises from the TB CAD study using the data from your institute. For authorship rules we will follow the international standards on authorship, which can be found here: <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>.
- A negotiable compensation per image/subject is offered.

6. HOW TO APPLY

Submit applications via the FIND Technology Scouting Submission Webform. Please, select 'Tuberculosis' as the 'Disease Area' and 'TB CAD validation project' as the 'Disease Area Subtype' and proceed with the online submission. Prepare a proposal with details outlined in 5.1. Proposals must be prepared in English and should identify a primary investigator for the proposal with detailed contact information, by **30th June 2022**. Any correspondences are to be sent in English by e-mail to DHvalidation@finddx.org.

7. TIMELINES

	Activity	Expected date
1	Publication of RFI	29APR2022
2	Closing for submission of written queries	23JUN2022
3	Closing of RFI	30JUN2022
	*Decision on proposals selected for interview round	7JUL2022
4	*Start of interviews	14JUL2022
5	*Close of interviews / Final decision on accepted proposals	04AUG2022

*Subject to change depending on the number of applications

8. QUESTIONS AND COMMUNICATIONS PROTOCOL:

Please email questions to: dhvalidation@finddx.org. Questions will be accepted and responded to expediently until 23JUN2022.

9. CONFIDENTIALITY

If required, FIND can sign a Confidentiality Disclosure Agreement (CDA) with interested Applicants/Bidders prior to proposal submission. FIND will not disclose the proposal to third parties without the prior written agreement of the proposal submitter. Review of proposals will be carried out by an internal FIND team, all of whom are under confidentiality and are recused if found to have a potential conflict of interest (which they are obliged to disclose). Any specific questions concerning confidentiality should be addressed to the FIND team.

10. APPENDIX/ICES:
Appendix A: checklist for eligibility of data inclusion

Please check if your project of study meets our criteria and contact us if you are interested in collaborating on this project.

Eligibility criteria for study to contribute data to the TB CAD validation project	Your answer
1. Individuals in your screening project are screened irrespective of whether they had symptoms (e.g. screening was provider – initiated and not patient -initiated)	YES/NO
2. CXR images in the form of DICOM, PNG, or JPEG files are available for a cohort of individuals who were tested within a defined period	YES/NO
3. Digital CXR files have NOT been shared with CAD software developers for the use of training CAD software	YES/NO
4. The following variables are known for all individuals in your cohort from which a sample will be drawn:	
Age & gender	YES/NO
Test result of culture and/or WHO approved rapid TB NAAT test*	YES/NO
5. You are willing to create de-identified digital CXR files which only include a unique identification number that can link the digital CXR file with the record containing the corresponding de-identified demographic and clinical information on an individual	YES/NO
6. You are willing to prepare a dataset with subject level data of the sampled individuals, containing the same unique identification number as on the de-identified digital CXR image.	YES/NO
7. You have obtained or are willing to request the required ethical approval which allows you to share de-identified digital CXR files and clinical data for the purpose of the TB CAD validation project.	YES/NO
8. You agree that sharing of data will be done in full compliance with any applicable laws and regulations governing protected health information and other personal data (including the upcoming EU General Data Protection Regulation; www.eugdpr.org).	YES/NO

* WHO approved rapid TB NAAT tests can be found at:
<https://www.who.int/publications/i/item/9789240029415>

Institutions with study data who can answer YES to questions 1-8 are encouraged to apply for the RFI.