Request for Information (RFI) No. 22015

On the subject of artificial intelligence applications for assisting in interpretation of x-ray images

1. Tel Aviv Sourasky Medical Center (hereinafter: "TAMC") hereby requests information on the subject of artificial intelligence applications for assistance in interpreting x-ray images (hereinafter: the "System").

Tel Aviv Sourasky Medical Center

2. Tel Aviv Sourasky Medical Center is the second-largest hospital in Israel, serving the entire population of the country's metropolis, including more than a million people entering the city each day for work, recreation, and business. Tel Aviv Medical Center is a municipal-governmental hospital, which incorporates four hospitals: Ichilov General Hospital, Lis Maternity and Women's Hospital, Dana-Dwek Children's Hospital, and Ida Sourasky Rehabilitation Hospital.

The project

3. TAMC is considering initiating a public tender process dealing with receiving services that include procurement of an artificial intelligence / machine learning / deep learning-based system for assistance in interpreting x-ray images currently existing in the market and available for integration with the Medical Center's systems.

The purpose of publishing the Request for Information – RFI

4. TAMC is seeking to publish a Request for Information in accordance with the provisions of Regulation 14A of the Mandatory Tenders Law, 5753-1993 (hereinafter: the "RFI"). The purpose of the RFI is to receive an answer to questions that TAMC has in relation to the system, these questions being aggregated and detailed in **Appendix A** of the Request for Information, with the aim of assisting TAMC with information deficits that it has, so that it will be able to draft the tender documents properly, should it decide to draft a tender on the matter.

5. **The information being requested**

5.1. TAMC is requesting information on the subjects set forth in **Appendix A** below, where **Appendix A** makes reference to the following information:

5.1.1 Appendix A (1): General questions.

5.1.2 Appendix A (2): Questions referring to the instrumentation specification.

5.1.3 Appendix A (#): Information security questionnaire for connection of medical instrumentation.

6. **General conditions**

6.1. This RFI is not a request for proposals and is not part of a tender process, meaning that it does not constitute any commitment towards any of its respondents. The RFI is intended only to acquire information, following which TAMC will consider continuing its actions according to professional and pertinent considerations.

6.2. This process does not commit TAMC in any way to issue a tender or to involve any party in a future tender, if and when published, and this process does not constitute any commitment or promise towards respondents and/or any person and/or entity.

6.3. TAMC reserves the right to publish another RFI and/or publish a tender and/or not to engage in any agreement with any of the respondents.

6.4. An answer to this RFI will not constitute a condition for participation in a tender that will be held after it, if held.

6.5. TAMC reserves the right to use information that will be received following respondents' answers without consideration for formulating and updating the services required and for examining the option of publishing a tender on the subject, at its sole discretion. The respondent will have no arguments in relation to copyrights or any other right.

6.6. If a tender proceeding is held in the future, TAMC will be allowed to change or add services, requirements, and conditions, at its professional discretion and in accordance with its needs.

6.7. If a tender is held, the respondents will be required to submit all of the documents that will be required within the tender documents and fulfill all conditions prescribed. The information that a respondent has submitted (if

submitted) within the answer to this RFI will not be considered as information submitted in the answer to the tender, and the information in the answer will not be used when judging or making reference to the future tender process.

6.8. All expenses involved in preparing and submitting the answer to this RFI are at the sole responsibility and expense of the respondents and the givers of information only. It should be emphasized that the respondents will not be entitled to any compensation or indemnification or refund and/or any payment from TAMC for submitting the answer to the RFI. TAMC will have no responsibility in relation to that answer.

6.9. The respondents will be barred from making, in relation to the information that will be received, any argument, demand or claim in relation to rights related to and/or arising from their answer to this RFP or the material or information that will be attached to the answer (including the use thereof).

6.10. A respondent submitting an answer to the attached questionnaire consents to all of its conditions and warrants that it will have no claims or demands from TAMC in relation to the use of the information that it will provide in the answer to this questionnaire.

6.11. If the information that will be provided within the answer contains components that are a commercial secret or professional secret of the respondent, this will be stated explicitly, indicating the confidential section.

6.12. A respondent submitting information in answer to this RFP warrants that within the information that it has submitted and/or any use made thereof as set forth above, rights, including copyrights and commercial secrets of a third party, will not be infringed. The respondent alone will assume the responsibility for any demand or claim arising from an argument that the use of the information submitted resulted in infringement of such a third party right, and it will identify TAMC immediately upon presenting a demand for any amount whose payment will be demanded and/or claimed owing to such a claim or demand, including expenses and attorney fees.

6.13. These RFI documents are the property of TAMC and are being lent to the respondents for preparing an answer to the RFI and submitting it only. The respondents are not allowed to copy, duplicate, or make any use of these RFP documents for any other purpose.

6.14. TAMC reserves the right to consult some or all of the respondents again, in writing or orally, including by direct meeting or conference, to get additional information on the subject of the RFP.

7. **Manner of submitting the answer**

7.1. The answer is to be submitted as a digital file and sent by email: tenders@tlvmc.gov.il by May 16, 2022, at 12:00 p.m.

7.2. TAMC is allowed to defer at any time the deadline for submitting the answer or for submitting clarification questions or publishing the answer thereto, and to change the instructions and conditions relating to this process, at its sole discretion.

7.3. The respondents are allowed to send clarification questions in relation to this answer by May 2, 2022, 12:00 p.m. to the email address tenders@tlvmc.gov.il. If the answer to a question requires it, the answer will be published on the Government Procurement Administration website at the address www.mr.gov.il

7.4. The answer is to be submitted as a scanned file.

7.5. The answer will be submitted in Hebrew, except for names of devices or professional names of studies.

7.6. The answer will be in the order of questions set forth in **Appendix A**. The respondent will be able to attach additional appendices to its answer.

7.7. TAMC reserves the right to contact, as required, any or all parties answering this RFI, with a request to complete information or for clarifications, showing presentations and demonstrations, for visiting customer sites that will be shown by the respondents and/or visiting the sites of respondents that answer this RFI.

7.8. TAMC is allowed to hold meetings with some or all of the respondents, at its sole discretion. The meetings will be held at TAMC's offices at 6 Weizmann Street in Tel Aviv. Representatives of TAMC will be invited to the meetings at TAMC's discretion. At the meetings, each respondent will be requested to show and demonstrate the capabilities of the System it uses to provide the requested services.

Appendix A (1): General questions

Part 1- Details of the respondent

1. General details

Contact persons	_____
Telephone	_____
Email	_____

2. General professional details

Is the respondent familiar with a system for providing services as requested? If so, what is the origin of this familiarity?	_____ _____ _____ _____ _____
What is the nature of the respondent's familiarity with the System? (As an advisor, authorized reseller, etc. – elaborate)	_____ _____ _____ _____
Is the respondent familiar with the company that is the manufacturer of the System?	_____ _____ _____ _____

If the respondent knows the company that is the manufacturer of the System, where is this company registered?	
If the company manufacturing the System is registered overseas, does the company have a representative office in Israel and/or an authorized reseller in Israel? And if so, which? And what is the nature of its specialty?	
What professional qualifications and licenses does the respondent believe are necessary for operating the System?	
What quality standard authorizations of the manufacturer / official representative / installer / maintainer does the respondent believe to be required	

for operating the System?	
What size and character of team does the respondent believe necessary to be maintained in Israel for supporting the System?	
What size and character of team does the respondent believe necessary to be maintained overseas for supporting the System?	
Where is the System's development team located?	
What does the respondent believe will be the flexibility / availability for modifications and improvements at the Medical Center's request?	
What does the respondent believe will be the release	

frequency of System versions?	_____ _____	
What is the manufacturer's seniority and experience in manufacturing the System?	_____ _____ _____ _____	
If relevant, what is the seniority and experience of the authorized reseller in marketing the System and providing services for the System?	_____ _____ _____ _____	
If the System's manufacturer has a licensed representative in Israel, is this the exclusive representative? (If not, list other representatives)	❒ Yes	❒ No Elaborate: _____ _____ _____ _____ _____ _____
What activity is the authorized reseller allowed to perform for the manufacturer?	_____ _____ _____ _____	

Since which year has the authorized reseller served as the manufacturer's representative in Israel?	_____ _____ _____ _____

Appendix A (2): Questions referring to the instrumentation specification

1. Information about the proposed System:

1.1. Explain the System's manner of operation and capabilities as follows:

1.1.1 The number and type of clinical findings that the product is capable of identifying / diagnosing. A partial list as an example follows:

1.1.1.1 Chest x-rays:

1.1.1.1.1 Infiltrate

1.1.1.1.2 Pleural effusion

1.1.1.1.3 Collapse

1.1.1.1.4 Nodule/ mass

1.1.1.1.5 Interstitial impression

1.1.1.1.6 Rib fractures

1.1.1.1.7 Pneumothorax

1.1.1.1.8 Pneumomediastinum

1.1.1.1.9 Pulmonary edema

1.1.1.1.10 Dilation of the mediastinum

1.1.1.1.11 Enlargement of the heart

1.1.1.2 Spinal x-rays

1.1.1.2.1 Fracture

1.1.1.2.2 Dislocation

1.1.1.3 Limb x-rays

1.1.1.3.1 Fracture (specify for which bones)

1.1.1.3.2 Dislocation (specific for which joints)

1.1.1.3.3 Soft tissue swelling

1.1.1.3.4 Fluid in a joint (specify for which joints)

1.1.1.3.5 Focal finding / mass

1.1.1.3.6 Accessory findings in adjoining tissues (for example, in a shoulder x-ray, reference to a lung)

1.1.2 Whether, in addition to the foregoing, the product is able to tag an image as "normal" compared to "abnormal".

2 For each of the clinical modules stated, what are the precision metrics of the module (recall, precision, accuracy, AUC)?

3 Has an article been published in peer-reviewed professional literature describing the product's performance? If so, please attach a reference for the publication.

4 Does the product have FDA approval? If so, for which clinical modules?

5 Does the product have CE approval? If so, for which clinical modules?

6 Does it have approval from the Ministry of Health's medical devices division?

7 Whom is the product intended for? (radiologists / clinicians / both)

8 How are the module's findings displayed to the physician? (Are the findings inserted into PACS? Is an application / widget used to display the findings? If possible, please attach a screenshot of the display to the physician).

9 Is the product integrated with the PACS/ RIS systems? Specifically, is there integration with the Philips – Algotec RIS and PACS systems installed at the Medical Center? If so, please specify the nature of the integration and how the information is displayed inside these systems.

10 Is there support for prioritization of cases for reading by a radiologist (marking as urgent / nonurgent)?

11 What is the running time of the algorithm for interpreting an x-ray image? How long does it take for the algorithm's answer to appear?

12 What is the technical architecture of the solution (servers / cloud environment / on-prem environment)?

13 What are the required computer resources (minimal and recommended) for running the solution?

14 Does the product interface with AI Marketplace (a product enabling users to choose an algorithm for performing an analysis without the need for specific integration with the product)? If so, which marketplace?

15 What is the business model of the proposed solution (purchase/ subscription / maintenance/ pay per use, etc.)?

16 What is the cost forecast (a nonbinding estimate) to analyze 100,000 images / 200,000 images?

17 Is the System an off-the-shelf product by the proposed manufacturer?

18 Optional activity volumes?

18.1 Does the System include modules or components that are purchased from another vendor?

18.2 Standards: the respondent is to specify the proposed equipment's conformance to the standards required in Israel and around the world.

19 Any other information about maintenance of the System, including comments on availability, activity hours and technical and applicative support.

20 The respondent must detail whether the technical and applicative support team has knowledge for optimal support of the System – breakdown of relevant professional authorizations? Availability? The support of the manufacturer – availability? Remote support while complying with information security requirements.

21 The respondent is to specify whether work during periodic repairs / services requires shutting down the entire System or allows for localized bypasses to maintain continuity of activity.

22 The respondent is to specify what it believes to be data communication components that are necessary for running the System, including details on:

22.1 The user stations;

22.2 Servers;

22.3 Database;

22.4 The proposed software components;

22.5 Additional software/hardware components;

22.6 Special communication and information security components required for use and protocols.

22.7 Information security questionnaire (attached as Appendix A – Part B).

22.8 The respondent will specify whether it is possible to integrate systems from various manufacturers.

22.9 The respondent will specify whether it identifies technical / infrastructure barriers to feasibility of the project, with details:

22.10 Free space for comments:

Appendix A (3): Information security questionnaire for connection of medical instrumentation

The respondent must fill in the following details:

	Subject	Respondent's answer
	Basic details	
1	Brief description of the System and its purpose	
2	Nature of the device	
	Respondent's details	
3	Name of the vendor	
4	Address	
5	Telephone No. of the respondent	
6	Name of contact person	
7	Telephone No. of contact person (landline + mobile)	
8	Email address of the contact person	
9	Does the respondent believe that vendors supplying machines of this kind should be compliant with the ISO27001 or ISO27799 information security and/or medical information security standards?	
	Access to systems	
10	Will the winning vendor need physical access to the customer's information systems for providing the services? If so, elaborate:	
11	Will the winning vendor need remote access to the customer's information systems for provision of the services? If so, elaborate:	
12	Within the provision of the services, does the winning vendor keep information about the customer on its premises? If so, elaborate:	
	Connection to the hospital network	

13	Is there any impediment to the subject of remote connections being performed via the customer's IT division only without third-party software?	
14	Is the connection of the device / System by landline?	
15	Does the device and/or System's connection include a Wi-Fi component? Yes/ No If not, please skip Sections 16-17 below.	
16	**<u>If there is a wireless (Wi-Fi) component</u>** Are the following protocols supported? IEEE 802.11A/G/N IEEE 802.11ac Does the wireless network card support strong login (PEAP/TLS 802.1X)?	
17	What is the network connection used for? With what intra-organizational system is the device intended to communicate? Using which protocol?	
Medical instrumentation		
18	What is the type and version of the System's operating system?	
19	Is there authorization for the System manufacturer to install enterprise antivirus software (such as ESET NOD 32)?	
20	Is it possible to put the instrumentation and operating system into the enterprise domain?	
Saving information, backups, and copies		

21	Does the equipment allow for backup of the local disk?	
22	Is there an option to connect a USB flash drive or any other external device?	
23	Is it possible to transfer information out of the System and/or into the System using a disk burner or other detachable media?	
Data handling		
24	Is it possible to store the system files, including the database, on the network servers?	
25	Is it possible to provide integration tools for the customer's information systems in a format written by the customer (inbound, outbound – patient information, case number, case details)	
26	Does the System support Hebrew?	
27	Is it possible to export data from the System to files in standard format? (HL7, txt, pdf, csv, XML, HTML, etc.). Please elaborate.	
Licensing		
28	Does the System require licensing?	
29	How is the licensing managed (parallel protection plug, USB, MAC, protection code, etc.)?	
30	Specify all licenses required for full operation of the System	
31	Does the licensing process require activation on the Internet?	
32	Is the license for a limited period?	
33	How many licenses are included in the System?	
Support		
34	What is the support level provided (by telephone or remote control of a station and/or remote control of a server and/or on-site visits)?	
Penetration tests		
35	Has the System passed penetration tests?	
36	If so • What were the findings? • Were the findings dealt with and how?	

Name of form filler	Company	Function

Signature	Date