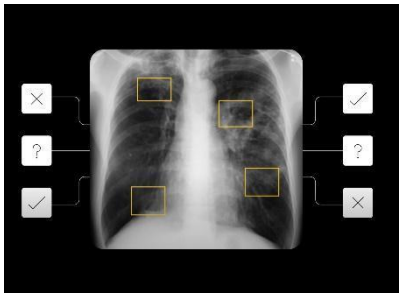
Outcome report on

Health Technology Assessment of AI-Assisted CXR for Interpretation for Tuberculosis:

A Rapid Health Technology Assessment

2023-24



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List of abbreviations

TB	Tuberculosis
CXR	Chest X-rays
PTB	Pulmonary Tuberculosis
WHO	World Health Organization
GoI	Government of India
AI	Artificial Intelligence
CAD	Computer-Aided Detection
CR	Computed Radiography
DR	Digital Radiography
RIS	Radiology Information System
PACS	Picture Archive and Communication System
CDSCO	Central Drugs Standard Control Organization
FDA	Food and Drug Administration
MDD	Medical Device Directive
MDR	Medical Device Regulation
TPP	Target Product Profiles
BMI	Body Mass Index
DL	Deep Learning
MTB	Mycobacterium tuberculosis
RIF	Rifampicin
ICMR	Indian Council of Medical Research
ROC	Receiver Operating Characteristic
PR	Precision-Recall
AUC	Area Under Curve
PPV	Positive Predictive Value
NPV	Negative Predictive Value
IEC	Information Education and Communication
TP	True Positive
TN	True Negative
FP	False Positive
FN	False Negative
PICO	Participants, Intervention, Comparator and Outcome
ICER	Incremental Cost-Effectiveness Ratio
GDP	Gross Domestic Product
WTP	Willingness to Pay
CET	Cost Effectiveness Threshold
LR	Literature Review
INR	The Indian Rupee
AMC	Annual Maintenance Contract
CMC	Comprehensive Maintenance Contract
OSWA	One-Way Sensitivity Analysis

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CHAPTER 1: INTRODUCTION

Tuberculosis (TB) remains a pervasive global health challenge, claiming millions of lives annually and posing a substantial burden, particularly in countries like India, where it is a leading cause of mortality. In 2020, India reported 2.5 million cases, contributing significantly to the global tuberculosis caseload and mortality statistics (1). Despite concerted efforts like National TB Elimination Programs (NTEP), Universal Access Initiatives, usage of real time information management systems and the implementation of rapid diagnostics and standardized treatment guidelines, effective screening and timely diagnosis continue to be formidable obstacles in the fight against this treatable yet persistent disease.

In response to this public health crisis, India has set ambitious targets through its National Tuberculosis Elimination Program to achieve "End TB Strategies" by 2025 (2). Over the past decade, the country has implemented various initiatives to enhance universal access to tuberculosis care, including mandatory case notifications, real-time information management systems, rapid molecular diagnostics, and standardized treatment guidelines. These initiatives have undoubtedly accelerated early diagnosis and treatment compliance, playing a crucial role in reducing morbidity and mortality associated with TB. (3)

Several studies have delved into the costs associated with tuberculosis treatment, revealing a range of expenses for patients, including direct and indirect costs (3–8). The goal of reducing catastrophic costs to zero aligns with the End TB strategy of the World Health Organization and the Government of India (GoI). As per the National TB Prevalence Survey Report of 2019-2021, the total median cost for TB diagnosis and treatment in various healthcare settings reflects the financial challenges faced by affected families.

Recognizing the evolving landscape of healthcare technology, recent advancements have seen the integration of Artificial Intelligence (AI) into the management and treatment of diseases. In the context of tuberculosis screening, AI-assisted CXR interpretation has emerged as innovative solutions. Studies have demonstrated the potential of AI in enhancing the sensitivity of CXR for tuberculosis screening, a crucial development for resource-constrained regions like India where the ratio of radiologists to the population is low (9). AI algorithms can identify subtle patterns and abnormalities in chest X-rays, enabling early detection and timely intervention. This early detection is crucial for initiating prompt treatment and curbing the spread of TB. Moreover, AI provides quantitative measurements of TB-related lesions, aiding in monitoring disease progression and evaluating treatment efficacy. The integration of AI into

radiology workflows optimizes the interpretation process, allowing healthcare professionals to focus on complex cases. Ultimately, AI-assisted solutions have the potential to revolutionize TB detection in radiography, contributing to improved patient outcomes and global public health efforts(10–12)

Computer-aided detection (CAD) refers to the use of specialized software to interpret abnormalities on chest radiographs that are suggestive of TB, a subset of AI, has shown promise in analyzing radiographic images for abnormalities, providing a potential solution to staffing issues.

This assessment explores the transformative impact of AI-assisted CXR interpretation tool for tuberculosis. Beyond clinical effectiveness, considerations include safety, cost-effectiveness, ethical implications, societal consequences, user acceptance, interoperability and systemic influence. These innovations represent significant progress in diagnostic methodologies, offering heightened accuracy and efficiency in the challenging landscape of TB detection.

Three interventions were set to be assessed, two related to AI assisted chest X-ray interpretation – qXR and Genki. A third intervention related to portable hand-held X-ray devise – Mine2In could not be carried out due to non-availability of data.

Description of the AI technologies used in the study

1. qXR, Qure.ai

It is a product developed by a start-up Qure.ai which uses Artificial Intelligence (AI) for interpreting Chest X ray using Deep Learning. qXR employs AI to perform binary classification of Chest X-Rays as Normal/Abnormal and identifies radiological signs of TB. The TB model scans for indicators such as pulmonary opacity, lymph node abnormalities, pleural effusion, and more. A TB score accompanies findings, representing algorithm confidence (0-1) in detecting TB signs. A threshold is set corresponding to score and calibrated based on the care setting. The technology has been implemented over 1500 sites across 80 countries. Its offline functionality, coupled with Cloud sync, ensures uninterrupted operation in low-bandwidth settings. Healthcare professionals has access to a dashboard to monitor program metrics, while the software supports major Computed Radiography (CR) and Digital radiography (DR) systems, including analog X-ray uploads. qXR integrates with hospital systems, enhancing radiology workflows.

Deployment and Usage: In India, qXR is deployed across 25 states, constituting a significant portion of total chest X-rays performed. Digital X-rays account for 90% of usage. The platform's monthly average exceeds 60,000 chest X-ray scans, with nearly 16,000 scans dedicated to TB screening.

Figure 1. qXR tool for CXR interpretation

It holds CDSCO approval - License Number: MFG/MD/2023/000181. Qure AI is also registered with UDYAM platform.

qXR was one of the three AI Assisted CAD software mentioned in the WHO guidelines for TB screening and triage using chest radiographs as an alternative to Radiologist, especially in areas where access to radiologists is difficult.(13)

Other international approval available for the product (Annexures -01)

- FDA approved 510(k) cleared for Breathing tubes
- MDD Class II A certified
- MDR Class II B certified

Qure. AI is deployed in the state of Maharashtra and Gujarat. In Maharashtra, there are two prominent government healthcare facilities actively managing patient cohorts. Indira Gandhi Municipal Hospital in Mira-Bhayendar and the District TB Centre in Gondia, Maharashtra. We

received data of 9,012 patients from both facilities. In Gujarat, Kutch District, a similar active site is underway. Though we have not received the data from Gujarat site.

2. Genki, DeepTek

Genki: Edge and Hub- AI for CXR Genki is an AI Assisted Chest X-Ray solution introduced by DeepTek. It is a public health screening solution designed for screening of Tuberculosis and other chest conditions like Pneumonia (Covid-19 and other community acquired disease), Cardiomegaly, Pleural pathologies, Lung Mass and Lung Nodules etc. used for screening and triaging. It is compatible within any X-Ray machine like hand held, portable or general X-Ray machine. It can work on any off the shelf standard configuration laptop assigned to the X-ray machine. It provides AI assisted reading for Computed radiography (CR) and Digital Radiography (DR) images of any make and manufacture.

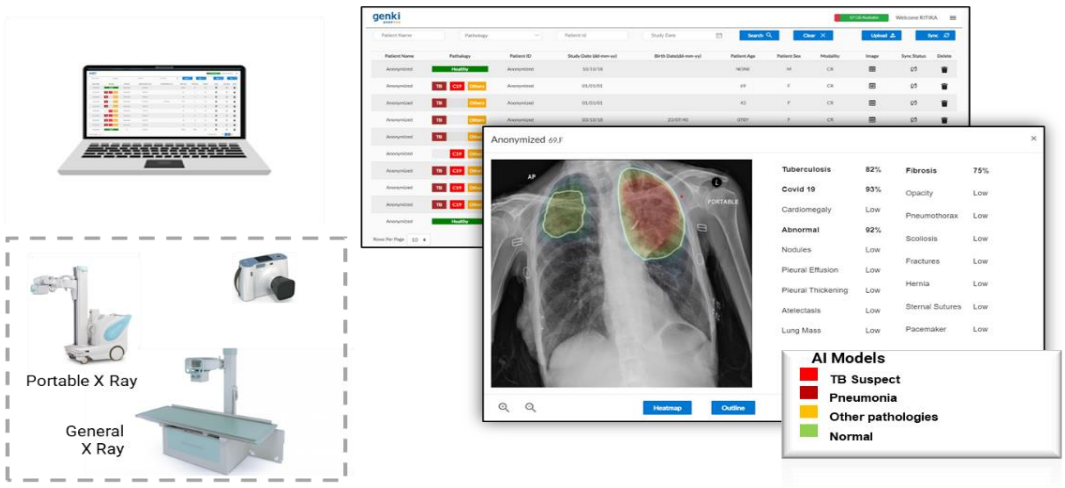

Figure 2. Genki tool for CXR interpretation

Genki has been widely used across India, Philippines, Thailand, Mongolia and several other regions globally.

Key highlights of the solution

- Enabling offline (without internet) triaging of Chest X-Ray
- RIS to capture patient details along with symptoms, co-morbidities, vulnerabilities, AI results and sputum test results
- End to End solution completing the patient communication loop
- Responsible AI features enabling post deployment surveillance (accuracy and bias analysis) and threshold tuning
- Customization of solution to fit into client workflow

National and International approvals

The Genki solution has obtained international approvals from the Thai FDA and the Kenya Pharmacy and Poison Board. Additionally, they have got approval from US FDA - which is the First Organ-Based Solution (CXR Analyzer). In India, they have obtained the approval from CDSCO. (Annexures -02)

For the past three years, DeepTek have actively worked in Tamil Nadu, partnering with the Greater Chennai Corporation. Presently, they are implementing this solution in six districts: Kancheepuram, Salem, Pudukkottai, Trichy, Tirunelveli, and Vellore. This initiative utilizes AI models in the field to screen a large at-risk population. We received data of 93,486 patients from all six facilities.

In Gujarat, a collaborative effort between the Surat Municipal Corporation, Ahmedabad Municipal Corporation, and Alert India has established a healthcare initiative. Though, we have not received the data from Gujarat site.

Role of Radiologist in TB diagnosis

Radiologists played a crucial role in Indian healthcare by interpreting chest X-rays to detect tuberculosis (TB) with a reported specificity of 65.9% and sensitivity of 82% (14) Due to a shortage of skilled radiologists in the public healthcare system, accurately and promptly diagnosing TB, a disease with a substantial burden in India, posed a significant public health challenge. The use of AI in study findings could be one of the solutions to address this issue in India.

CHAPTER 2: OBJECTIVES

Rationale behind the study

In Tuberculosis, early and timely detection plays a crucial role in preventing the further transmission of the infection, leading to a reduction in the overall incidence and prevalence of TB cases. The prognosis and treatment outcomes for TB patients heavily rely on early diagnosis and the prompt initiation of treatment. Delays in the diagnosis or treatment, whether originating from patients or healthcare systems, can have detrimental effects on treatment outcomes. Previous studies have investigated the various reasons behind diagnostic delays, encompassing factors related to both patients and healthcare systems (11–14). With the substantial patient load in public healthcare facilities, the integration of advanced technologies like AI in CXR has the potential to bridge the gap and expedite the timely diagnosis and treatment of TB patients.

Nevertheless, the introduction of AI interventions in CXR requires careful consideration of costs, as resources in public health settings are limited. To ascertain its practicality within the context of the Indian Public healthcare system, it is essential to conduct a cost-effectiveness study comparing conventional digital CXR with AI Assisted CXR tools. The study will help determine whether the benefits of AI in terms of improved diagnostic efficiency and early detection outweigh the associated costs, ensuring that AI technology can be effectively utilized to enhance TB diagnosis and management.

HTA Research Question

Are the AI-assisted CXR tools cost-effective for interpretation of TB?

Objectives

1. To compare the Interpretation and screening accuracy of AI Assisted CXR Interpretation with Manual Interpretation of CXR using Conventional Digital X-Ray Methods.
2. To conduct a comprehensive cost-effectiveness analysis of AI Assisted CXR in comparison with Manual Interpretation of CXR using Conventional Digital X-Ray Methods.

CHAPTER 3: REVIEW OF LITERATURE

Evidence on diagnostic accuracy and feasibility

Multiple independent studies have explored the role of AI /CAD software in TB diagnosis and screening. The studies collectively suggest that AI assisted solutions such as Qure.ai-qXR and Deeptak-Genki software's are offering promising potential in improving the accuracy and efficiency of TB screening using AI. They can assist in identifying abnormalities and may help in overcoming the challenges in resource-limited settings like India.

Qure.ai qXR v2.0 software showed a strong agreement with physician interpretations (92.4% concordance rate) (15). Additionally, two CAD software, qXRv2, and CAD4TBv6, were compared to culture-confirmed pulmonary TB as the reference standard, showing non-inferior accuracy to WHO-recommended values. Sensitivity varied in cases of smear-negative TB and among gender groups, with specificity lower in men; those with previous TB, older individuals, and those with lower BMI(16). In a separate study evaluating 12 CAD software solutions using a test library of CXR images, some performed similarly to expert readers, while Qure.ai and Deeptak significantly outperformed an intermediate reader at an accuracy of 54.7% and 52.6% (14). Another retrospective case-control study found that qXR CAD software, in detecting pulmonary TB using microbiologically-confirmed TB as the reference standard, exhibited good sensitivity 71% (95% CI: 0.66-0.76) and specificity 80% (95% CI: 0.77- 0.83) surpassing radiologists (17). Furthermore, an analysis comparing image quality between an ultra-portable X-ray system and two reference systems revealed differences in radiologist ratings, but AI software assessments showed no significant disparities. (18). In prison TB screening in Brazil, three AI algorithms performed similarly overall, and qXR meeting WHO requirements for a triage test at 90% sensitivity (19). Lastly, in a study in Bangladesh, five AI algorithms significantly outperformed radiologists in TB detection on CXRs. qXR and CAD4TB met WHO's Target Product Profiles (TPP) for triage tests with 90% sensitivity(10).

These studies collectively underscore the growing role of AI in revolutionizing TB diagnosis and screening. Qure.ai's AI tool displayed proficiency in interpreting CXRs, demonstrating its potential to assist in large-scale CXR annotation, even for complex cases like drug-resistant TB(20). Additionally, three Deep Learning (DL) systems, exhibited significantly enhanced specificities compared to radiologists (qXR:0.94, 95% CI: 0.92–0.97) reducing the need for Expert MTB/RIF tests by 66% while maintaining high sensitivity at 95% or better (21). However, challenges persist, including the cost of hardware and the scarcity of skilled

radiologists(22). Nevertheless, commercially available CAD solutions hold promise for TB programs with proper implementation guidance (23). Further studies highlighted the advantages of AI in TB, the comparability of AI solutions, and the critical considerations for CAD adoption within TB programs, offering a comprehensive view of AI's transformative potential in the fight against TB (24–27).

These findings collectively suggest that AI-assisted solutions hold promise in improving TB diagnosis and screening, especially in resource-limited settings, and can complement the expertise of radiologists. A summary of findings from the literature on evidence of AI interpretation is given below in table 1.

Table 1. Diagnostic accuracies obtained from various screening tests as reported

Author (Year)	Supported by**	Comparison between	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	ROC AUC (95% CI)	PR AUC (95% CI)	Threshold /Cut-off Score	PPV	NPV
Codlin et al (2021)	European Commission Horizon 2020 IMPACT TB Grant and Stop TB Partnership's TB REACH initiative, with funding from Global Affairs Canada	Software Performance _ qXR	-	-	-	0.82 (0.79–0.86)	0.41 (0.33–0.50)	-	-	-
		Software Performance _ Genki	-	-	-	0.78 (0.75–0.82)	0.28 (0.22–0.34)	-	-	-
		AI Vs Expert reader- 30+ Yrs. (qXR)	95.5% (90.4–98.3)	48.7% (45.4–52)	54.7% (51.7–57.8)	-	-	44.1	-	-
		AI Vs Intermediate reader- 05+ Yrs. (qXR)	82.0% (74.4–88.1)	65.9% (62.7–69)	67.9% (65.0–70.8)	-	-	76.5	-	-
		AI Vs Expert reader- 30+ Yrs. (Genki)	95.5% (90.4–98.3)	46.3% (43.0–49.6)	52.6% (49.5–55.7	-	-	31.1	-	-
		AI Vs Intermediate reader- 05+ Yrs. (Genki)	82.0% (74.4–88.1)	63.2% (59.9–66.3)	65.6% (62.6–68.5)	-	-	55.7	-	-

Author (Year)	Supported by**	Comparison between	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	ROC AUC (95% CI)	PR AUC (95% CI)	Threshold /Cut-off Score	PPV	NPV
Faiz Ahmad Khan et al. (2020)	Canadian Institutes of Health Research	microbiologically-confirmed PTB Vs software achieved (AI) (qXR)	93% (0·89–0·95)	75% (0·73–0·77)	-	0.92	-	-	-	-
Madlen Nash et al (2020) (18)	TMA Pai Endowment Chair at Manipal University Qure.ai (qXR)	qXR AI Vs microbiologically-confirmed PTB	71% (66- 76)	80% (77- 83)	-	0.81 (0.78- 0.84)	-	-	-	-
		Radiologists microbiologically-confirmed PTB	56% (50- 62)	80% (77- 83)	-	0.94 (0.92- 0.96)	-	-	-	-
		PTB-related abnormalities -pleural effusion with AI	-	-	-	0.94 (0.92- 0.96)	-	-	-	-
		PTB-related abnormalities -cavity with AI	-	-	-	0.84 (0.82-0.87)	-	-	-	-
		PTB-related- other abnormalities	-	-	-	0.75 (0.70 -0.80)	0.94 (0.91- 0.96)	-	-	-
Zhi Zhen Qin et al. (2019) (23)	The Government of Canada, the Bill &	Nepal Human Readers_ Senior Radiologist	96% (0.89 - 0.99)	48% (0.43-0.53)	0.57	0.94 (0.92-0.97)	-	-	-	-

Author (Year)	Supported by**	Comparison between	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	ROC AUC (95% CI)	PR AUC (95% CI)	Threshold /Cut-off Score	PPV	NPV
	Melinda Gates Foundation, the United States Agency for International Development, and the National Philanthropic Trust. Qure.ai (qXR)	Nepal _QXR AI	97% (0.91-0.99)	65% (0.6-0.69)	0.7		-	-	-	-
		Nepal Human Readers Junior Radiologist & Residents	87% (0.79 - 0.93)	69% (0.64-0.73)	0.72		-	-	-	-
		Nepal _QXR AI	87% (0.79 - 0.93)	81% (0.76-0.84)	0.69		-	-	-	-
		Cameroon Human Readers_ Radiologist	80% (0.52-0.96)	74% (0.71-0.78)	0.74		-	-	-	-
		Cameroon _QXR AI	80% (0.52-0.96)	95% (0.93- 0.96)	0.94		-	-	-	-
		Cameroon _Teleradiology Company	80% (0.52-0.96)	74% (0.71-0.77)	0.74		-	-	-	-
		Cameroon _QXR AI	80% (0.52-0.96)	95% (0.93- 0.96)	0.94		-	-	-	-

Author (Year)	Supported by**	Comparison between	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	ROC AUC (95% CI)	PR AUC (95% CI)	Threshold /Cut-off Score	PPV	NPV
		Roc01 qXR performance at Selected Thresholds	88% (0.8-0.93)	89% (0.87–0.91)	0.86		-	0.67	-	-
Thiego Ramon Soares et al (2022) (20)	US National Institutes of Health (grant numbers R01 AI130058 and R01 AI149620) and the State Secretary of Health of Mato Grosso do Su Qure.ai (qXR)	At 90% sensitivity, 4% prevalence for WHO Target Product Profile minimum target	NA	74.2 (60.2–81.3)	-	-	-	-	12.7	99.4
		pre-defined thresholds for WHO Target Product Profile minimum target	74.5 (68.8–79.7)	89.4 (87.9–90.8)	-	0.90 (0.88–0.92)	-	-	-	-
Zhi Zhen Qin et al. (2021) (21)	Government of Canada Qure.ai (qXR)	Radiologists' reading	38·9% (37·3 - 40·5)	88·9% (88·5 - 89·4)	-	-	-	0.91	39.1	89
		Binary classifications-A – AI	-	97·9% (97·7 - 98·1)	-	-	-		75.9	89.5
		Absolute difference between AI and Radiologists reading	-	8·9% (8·5 to 9·4)	-	-	-		36.8	0.5

Author (Year)	Supported by**	Comparison between	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	ROC AUC (95% CI)	PR AUC (95% CI)	Threshold /Cut-off Score	PPV	NPV
		Radiologists' reading	88·5% (87·4- 89·5)	62·5% (61·8 -63·1)	-	-	-	0.64	30	96.8
		Binary classifications-B- AI	-	76·7% (76·1- 77·2)	-	-	-		40.9	97.4
		Absolute difference between AI and Radiologists reading	-	14·2% (13·3-15·1)	-	-	-		10.8	0.6
		Radiologists' reading	95·0% (94·3 - 95·7)	45·7% (45·0 -46·4)	-	-	-	0.35	24.2	98.1
		Binary classifications-C- AI	-	63·5% (62·9 - 64·2)	-	-	-		32.2	98.6
		Absolute difference between AI and Radiologists reading	-	17·9% (16·9- 18·8)	-	-	-		8	0.5
		Sensitivity fixed at 90%- Comparison of AI algorithms against WHO's Target Product	90·2% (89·2–91·1)	74·3% (73·3–74·9)	-	-	-	0.6	-	-

Author (Year)	Supported by**	Comparison between	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	ROC AUC (95% CI)	PR AUC (95% CI)	Threshold /Cut-off Score	PPV	NPV
		Specificity fixed at 70%- Comparison of AI algorithms against WHO's Target Product	92·6% (91·7–93·4)	70·3% (69·6–70·9)	-	-	-	0.51	-	-
Stephen John et al (2023) (26)	The Stop TB Partnership's TB REACH Initiative, through funding from Global Affairs Canada Qure.ai (qXR)	Different screening combinations of symptoms and CXR with AI- Cough ≥ 2 weeks	40%	61.5%	-	-	-	-	13.5%	87.3%
		Different screening combinations of symptoms and CXR with AI- Cough OR Fever	67.1%	29.7%	-	-	-	-	12.5%	85.5%
Independent evaluation by Thailand Center of Excellence for Life Sciences (2023) (28)	Royal College of Radiology Thailand (RCRT) DeepTek (Genki)	Diagnostic efficiency of AI VS radiologists	0.9455	0.9561	0.9835	0.9835	-	0.22	0.95	0.9521
Independent Assessment Report (2020) (29)	Stop TB Partnership DeepTek (Genki)	Human Reader	81.8% (76.6-86.3%)	53.5% (51.7-54.8%)	-	-	-	-	-	-
		AI Reader	81.8%	53.4%	-	0.836	-	-	-	-

Author (Year)	Supported by**	Comparison between	Sensitivity (95% CI)	Specificity (95% CI)	Accuracy (95% CI)	ROC AUC (95% CI)	PR AUC (95% CI)	Threshold /Cut-off Score	PPV	NPV
			(76.6-86.3%)	(52.1 -54.7%)						
Independent Assessment Report (2020) (27)	Nanavati Hospital, Symbiosis Center for Medical Image Analysis, Symbiosis International University, and D Y Patil Hospital, D Y Patil University, Pune DeepTek (Genki)	AI Vs Radiologist	89% (0.87- 0.91)	86% (0.85- 0.86)	86% (0.85-0.86)	-	-	-	-	-

*WHO(28) AI or CAD Accuracy estimated Range Sensitivity at 95% CI: > 0.90 and Specificity at 95% CI: >0.70

**Major studies included in the review are supported by various national and international origination such as: ICMR, Bill & Melinda Gates Foundation, Welcome Trust- UK, US National Institutes of Health, Canadian Institutes of Health Research, Royal College of Radiology Thailand (RCRT), European Commission Horizon 2020, IMPACT TB Grant- Canada, The Stop TB, Research institutes like – Symbiosis, DY Patil & Nanavati Hospital

+ROC: Receiver operating characteristic curve, PR: Precision recall curve, AUC: Area under the curve, PPV: Positive predictive value, NPV: Negative Predictive Value

CHAPTER 4: METHODOLOGY

The study was a rapid HTA and it was conducted to answer the research question: whether the AI-assisted CXR tools cost-effective for interpretation of TB?

The sample for the study consisted of review of records of the patients who had undergone Chest X ray for the screening of tuberculosis in the selected facilities via the intervention mode i.e. AI based CXR (Genki and quer.ai) in the past one year and the patients who had been screened for TB via conventional mode i.e. digital X-ray in the same facilities before the onset of digital intervention.

Data collection tools and procedure

AI intervention: The data was collected from the manufacturers regarding the costs associated with their respective AI interventions in a structured proforma.

Comparator: The data concerning various costs associated with the use of the conventional digital CXR method were obtained from an existing study by HTA RRC at IIPHG on Operational Models and costing of CXR for TB Patients.

Costs related information: The costs related data were collected from manufacturers and intervention sites. Both capital and implementation costs associated with the AI-assisted X-Ray and conventional digital CXR method were collected. Capital cost included direct cost, developmental cost, setup cost which were annualized using useful life. The costs were categorized into infrastructure, furniture, machine & equipment and IT system costs. Implementation costs included indirect cost -fixed and recurrent cost, maintenance costs - software maintenance/troubleshooting cost, project activities cost, cost of confirmatory diagnosis, Human Resource (HR) (project/shared HR cost of the public health system), project activities cost, Information Education and Communication (IEC), capacity building-orientation training, training material/tools, cost of confirmatory diagnosis, cost associated with any consumables and reimbursement.

All capital costs, including setup costs, were annualized, considering a useful life span greater than one year. The recurrent and fixed costs were collected and summed up to determine the total cost. Costs were converted to constant values and reported as annualized costs in 2022-2023 prices. Additionally, all costs and clinical benefits were discounted at a fixed annual rate of 3% during that assessment period.

For Objective 1: To compare the Interpretation and screening accuracy of AI Assisted CXR Interpretation with Manual Interpretation of CXR using Conventional Digital X-Ray Methods.

Data for the outcome parameters/ diagnostic accuracies were obtained screened from the previous records of the selected healthcare facilities via a semi-structured tool prepared as per the requirement of the study for both comparator and intervention arm. (Annexure -03)

Calculations of the diagnostic accuracies: For calculation of the outcome measures (True Positive, True Negative, False Positive, False Negative) required in the study, we initially identified and targeted review of 6 research papers which reported clinical effectiveness of technologies in question. We had found four studies for qXR (Qure.AI) and one study for Genki (Deeptek) and one study for both (qXR and Genki) carefully selected to align indeed with our study objectives and predefined parameters. The previous researches were evaluated to calculate the pooled sensitivity and specificity of the AI assisted intervention which was used to calculate the diagnostic accuracies of the primary retrospective data received from the manufacturers. This, was then, used to derive the true negatives, true positives, false negatives, and false positives. This analysis was conducted based on a subset of

Pooled diagnostic accuracy: Sensitivity and specificity are performance matrix commonly used in the evaluation of diagnostic tests. Pooled sensitivity and specificity were used when combining the results of multiple studies or data sets (29). In this study we had adopted a subset of 6 studies. The formulas for pooled sensitivity and specificity are based on the concept of weighted averages.

1. Pooled Sensitivity (Se):

$$Se_{pooled} = \sum_{i=1}^{n} (TP_i) / \sum_{i=1}^{n} (TP_i + FN_i)$$

where:

n is the number of studies or data sets.

TP_i is the true positive count in the i-th study sample or data set.

FN_i is the false negative count in the i-th study sample or data set.

2. Pooled Specificity (Sp):

$$Sp_{pooled} = \sum_{i=1}^{n} (TN_i) / \sum_{i=1}^{n} (TN_i + FP_i)$$

where:

TN_i is the true negative count in the i-th study sample or data set.

FP_i is the false positive count in the i-th study sample or data set.

Note: *When pooling sensitivity and specificity, it's important to consider the weights of each study or data set, especially if the studies have different sample sizes. Weighted averages can be used to give more importance to larger studies in the pooling process.*(30,31)

- The diagnostic accuracies (True Positive, True Negative, False Positive, False Negative) of the cases were calculated from the total number of patients as provided by the sample facilities.
- For calculating the values for (TP, FP, TN and FN), pooled sensitivity and specificity values from the literature were used on total number of patients provided using the formulae* (Annexure 04).

The diagnostic accuracy of the selected AI assisted models with conventional digital CXR method were used to evaluate the outcome parameters of the study. The different data variables used are given below.

a) **True positive:** A patient diagnosed positive through screening and confirmed positive via the microbiological diagnostic tests.
b) **False Positive:** A patient diagnosed positive through screening but confirmed negative via the microbiological diagnostic tests.
c) **True Negative:** A patient diagnosed negative through screening and confirmed negative via the microbiological diagnostic tests.
d) **False Negative:** A patient diagnosed negative through screening but confirmed positive via the microbiological diagnostic tests.

For Objective 2: To conduct a comprehensive cost-effectiveness analysis of AI-Assisted CXR in comparison with manual interpretation of CXR using conventional digital X-Ray methods.

The study utilized the decision tree analysis to assess the cost-effectiveness of the AI-assisted CXR interpretation tools (Quer.ai and Genki) compared to manual interpretation of CXRs using conventional digital X-Ray methods for detecting TB.

Decision Tree

A decision tree was constructed to illustrate the method-based approaches to calculate the outcome (Figure 3), with branches representing the potential outcomes of the test, including true positive, false positive, true negative, and false negative results. The outcomes of the decision tree were the number of cases detected and the total costs associated with each approach.

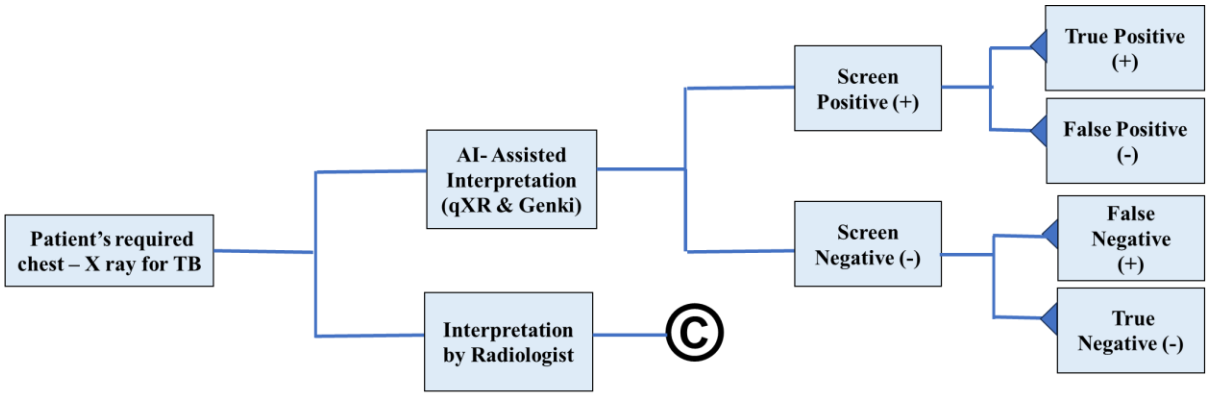

Figure 3. Decision tree for the study

Cost-Effective Analysis (CEA)

The study employed cost-effective analysis based on an economic model, conducted from a health system perspective. The primary objective was to ensure the efficient allocation of limited resources to maximize societal benefits.

Table 2. Participants, Intervention, Comparator and Outcome of the study

PICO	Description of the components of PICO
Population	Patients screened for potential TB-related chest pathology in the last Six months
Intervention	AI-Assisted interpretation of chest X-Ray 1. **Qure.ai – qXR** 2. **DeepTek – Genki**
Comparator	Manual Interpretation by Radiologist of CXR using Conventional Digital X-Ray methods

Outcome	1. Diagnostic Accuracy in interpretation using AI Assisted CXR method as compared to conventional digital CXR. (Accurate and early detection) 2. ICER: Cost per Case Interpreted/Screened

ICER: The interventions were assessed based on cost-effectiveness thresholds. An intervention was considered cost-effective if its Incremental Cost-Effectiveness Ratio (ICER), was less than 1 time the GDP of India. If the ICER falls between 1 and 3 times the GDP, it is deemed cost-effective, while values exceeding 3 times the GDP are considered not cost-effective.

Cost per case interpreted: For ICER calculation we used natural units percentage of correct diagnosis or case interpreted/screened. In this study, we calculated the specific health outcome achieved which was defined as AI tools being used to screen positive or negative for the health condition. The Incremental Cost Effectiveness Ratio was the summary measure used to report the cost-effectiveness of competing interventions.

Sensitivity analysis: A sensitivity analysis was performed to assess the impact of uncertainty in the input parameters on the results. One-way sensitivity analyses were conducted to evaluate the impact of changes in key parameters on the ICER. In one-way sensitivity analysis, upper and lower limits with 95% Confidence Interval values of the model inputs depending on the availability have been used and reported as tornado diagrams and the results were reported in a cost-effective plane.

Willingness to Pay Threshold: The willingness to pay threshold (WTP) was considered for determining cost-effectiveness. Currently, a cost-effectiveness threshold (CET) for India is not available. So, for the purpose of this assessment, we used the one-time GDP per capita for the year 2022, as suggested in the Indian reference case for conducting economic evaluations in health technology assessments(32).

CHAPTER 5: RESULTS

The result comprises of two parts: 1) Estimation of diagnostic accuracy, 2) Determining the cost effectiveness

1) Estimation of diagnostic accuracy

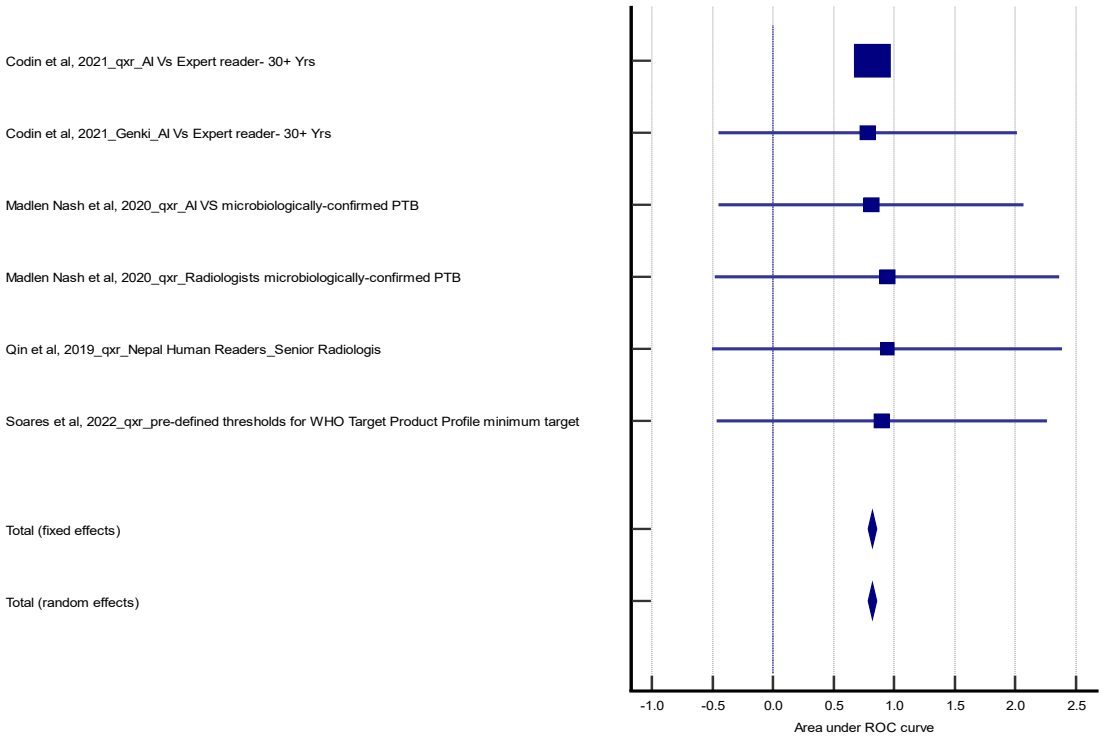

Figure 4. Forest plot based on ROC

We calculated the overall accuracy of the reported AUC values from the primary studies (16-18, 20, 23) and it suggests that cumulative value of AUC is 0.820, which is statistically significant and indicates the overall adequate accuracy of AI assisted tools as compared to standard reference. The findings of the meta-analysis are robust due to lack of heterogeneity (I^2 value is 0.000%) and there is no publication bias in it. This result suggests that, on an average, the AI-assisted methods in the included studies perform well in diagnosing the condition. (Figure 4)

Table 3. Calculation of Diagnostic Accuracies for the included studies

Authors	use of AI	Sample Size	Sensitivity	Specificity	TP*	FP*	FN*	TN*
For qXR (Intervention)								
Codlin et al, 2021	qXR AI Vs Expert reader- 30 Years plus Experience	1032	95.5	48.7	127	461	6	438
Faiz khan et al 2020	microbiologically-confirmed PTB Vs software achieved (AI)	2198	93	75	1901	38	143	115
Madlen Nash et al, 2020	_qXR AI Vs microbiologically-confirmed PTB	929	71	80	468	54	191	216
Qin et al, 2019	qXR_Nepal Human Readers Senior Radiologist	1196	96	48	1102	25	46	23
Qin et al, 2021	AI Vs Radiologist	23954	90.2	74.3	19489	603	2117	1744
Pooled Values		**29309**	**90.22**	**68.21**	**23088**	**1182**	**2504**	**2536**
For Genki (Intervention)								
Codlin et al, 2021	Genki_AI Vs Expert reader- 30 Years plus Experience	1032	82	65.9	109	307	24	592
Independent evaluation by Thailand Center of Excellence for Life Sciences (2023)	Royal College of Radiology Thailand (RCRT), 2023_Genki_ Diagnostic efficiency of AI VS radiologists	300	94.5	95.61	268	1	16	16
Pooled Values		**1332**	**90.41**	**66.38**	**377**	**308**	**40**	**608**
For Radiologist (Comparator)								
Codlin et al, 2021	30 years plus Experience	1032	95.5	42.2	127	520	6	379
Codlin et al, 2021	05 years plus Experience	1032	82	57.1	109	386	24	513
Pooled Values		**2064**	**88.72**	**49.61**	**236**	**906**	**30**	**892**

* Theses values were derived using sensitivity and specificity estimate, except the Codin et al, 2021 study

Based on our estimations, we determined the pooled sensitivity and specificity for qXR to be 90.22% and 68.21%, respectively. Similarly, for Genki, the pooled sensitivity and specificity were estimated at 90.41% and 66.38%. In comparison, the comparator yielded a pooled sensitivity of 88.72% and a pooled specificity of 40.61% (Table 3).

Table 4. Diagnostic accuracies as screened by the different modalities.

Screening Results	**qXR**	**Genki**	**Radiologist**
Positive by AI	5308	79429	2305
True Positive (TP)	5113	76415	2150
False Positive (FP)	195	3014	155
Negative by AI	973	14057	426
False Negative (FN)	554	8106	273
True Negative (TN)	419	5951	153
Total Sample size	6281	93486	2731

The total number of true positive cases were calculated and found to be 5113, 76415 and 2150 respectively for qXR, Genki and Radiologist respectively. Similarly, the total number of false positives were found be 195, 3014 and 155 respectively.

The total number of false negative cases were calculated and found to be 554, 8106 and 273 respectively for qXR, Genki and Radiologist respectively. Similarly, the total number of true negatives were found be 419, 5951 and 153 respectively (Table 4).

2) Determining the cost effectiveness

A decision tree was parameterized on MS Excel spreadsheet to estimate change in outcome and cost as a result of implementation of AI solutions compared to Radiologist from health system perspective. Transition probabilities were derived from secondary literature. Details of transition probabilities and other data used for populating the decision tree is presented below. The Table 5 & 6 shows data considered for purpose of decision analytic modelling in intervention and control arm.

Table 5. Calculation of transition probabilities for intervention and control arm – qXR Qure. ai

Transition Probabilities		**Intervention and Comparator**			**Remarks**		
Transition from	**Transition To**	**Transition Probabilities**	**%**	**Source**	**Lower Bounds**	**Upper Bounds**	**Remarks**
Intervention Arm: qXR							
Transition probability of Positive (TP+FP)	Positive	0.85	84.51	Secondary	0.8282	0.8620	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Negative (FN+TN)	Negative	0.15	15.49	Secondary	0.1518	0.1580	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened_ TP	True Positive	0.96	96.33	Secondary	0.9440	0.9825	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened _ FP	False Positive	0.04	3.67	Secondary	0.0360	0.0375	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened _ FN	False negative	0.57	56.94	Secondary	0.5580	0.5808	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened_ TN	True Negative	0.43	43.06	Secondary	0.4220	0.4392	Pooled Sensitivity & Specificity from evidence synthesis
No. of Beneficiaries	No. of Beneficiaries		6281	Secondary	0.0000	0.0000	Data from Maharashtra sites

Cost of Positive (TP+FP)	Positive	1597.91	159791.08	Calculated	1565.9526	1629.8690	calculated based on secondary data
Cost of Negative (FN+TN)	Negative	292.91	29291.02	calculated	287.0520	298.7684	calculated based on secondary data
Cost _Screened _TP	True Positive	1539.208	153920.837	Calculated	1508.4242	1569.9925	calculated based on secondary data
Cost _Screened _FP	False Positive	58.702	5870.245104	Calculated	57.5284	59.8765	calculated based on secondary data
Cost _Screened _FN	False negative	166.775	16677.51686	Calculated	163.4397	170.1107	calculated based on secondary data
Cost _Screened _TN	True Negative	126.135	12613.50102	Calculated	123.6123	128.6577	calculated based on secondary data
Cost of Interpretation	Cost of Interpretation	0.3010	**30**	Primary	0.2950	0.3071	From the providers end
Avg. Age of Cohort	Age of cohort	0.150	15	Secondary	0.1470	0.1530	India TB Report 2023
Comparator Arm: Radiologist							
Transition probability of Positive (TP+FP)	Positive	0.84	84.40	Secondary	0.8271	0.8609	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Negative (FN+TN)	Negative	0.16	15.60	Secondary	0.1529	0.1591	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened TP	True Positive	0.93	93.28	Secondary	0.9141	0.9514	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened _ FP	False Positive	0.07	6.72	Secondary	0.0659	0.0686	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened _ FN	False negative	0.64	64.08	Secondary	0.6280	0.6537	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened_ TN	True Negative	0.36	35.92	Secondary	0.3520	0.3663	Pooled Sensitivity & Specificity from evidence synthesis
No. of Beneficiaries	No. of Beneficiaries		2731	Secondary	0.0000	0.0000	Data from Maharashtra sites
Cost of Positive (TP+FP)	Positive	2299.00	229900.40	Calculated	2253.0239	2344.9840	calculated based on secondary data
Cost of Negative (FN+TN)	Negative	424.89	42489.18	calculated	416.3940	433.3897	calculated based on secondary data
Cost _Screened _TP	True Positive	2144.41	214441	Calculated	2101.5190	2187.2953	calculated based on secondary data
Cost _Screened _FP	False Positive	154.60	15459.7	Calculated	151.5049	157.6887	calculated based on secondary data

Cost _Screened _FN	False negative	272.29	27229.0	Calculated	266.8440	277.7356	calculated based on secondary data
Cost _Screened _TN	True Negative	152.602	15260	Calculated	149.5500	155.6540	calculated based on secondary data
Cost of Interpretation	Cost of Interpretation	0.997	**100**	Secondary	0.9775	1.0173	calculated based on secondary data (HTAIn RRC-IIPHG CXR costing study)
Avg. Age of Cohort	Age of cohort	0.150	15	Secondary	0.1470	0.1530	India TB Report 2023

Table 6. Calculation of transition probabilities for intervention and control arm – Genki- DeepTek

Transition Probabilities		**Intervention and Comparator**			**Remarks**		
Transition from	**Transition To**	**Transition Probabilities**	**%**	**Source**	**Lower Bounds**	**Upper Bounds**	**Remarks**
Intervention Arm: Genki							
Transition probability of Positive (TP+FP)	Positive	0.85	84.96	Secondary	0.8326	0.8666	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Negative (FN+TN)	Negative	0.15	15.04	Secondary	0.1474	0.1534	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened_ TP	True Positive	0.96	96.21	Secondary	0.9428	0.9813	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened _ FP	False Positive	0.04	3.79	Secondary	0.0372	0.0387	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened _ FN	False negative	0.58	57.67	Secondary	0.5651	0.5882	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened_ TN	True Negative	0.42	42.33	Secondary	0.4149	0.4318	Pooled Sensitivity & Specificity from evidence synthesis

No. of Beneficiaries	No. of Beneficiaries		**93486**	Secondary	0.0000	0.0000	Data from Tamil Nadu sites
Cost of Positive (TP+FP)	Positive	17851.65	1785164.91	Calculated	17494.6162	18208.6821	calculated based on secondary data
Cost of Negative (FN+TN)	Negative	3159.31	315930.75	calculated	3096.1213	3222.4936	calculated based on secondary data
Cost _Screened _TP	True Positive	17174.253	1717425.335	Calculated	16830.7683	17517.7384	calculated based on secondary data
Cost _Screened _FP	False Positive	677.396	67739.57939	Calculated	663.8479	690.9437	calculated based on secondary data
Cost _Screened _FN	False negative	1821.822	182182	Calculated	1785.3852	1858.2580	calculated based on secondary data
Cost _Screened _TN	True Negative	1337.486	133748.5856	Calculated	1310.7361	1364.2356	calculated based on secondary data
Cost of Interpretation	Cost of Interpretation	0.225	**22**	Primary	0.2203	0.2292	From the providers end
Avg. Age of Cohort	Age of cohort	0.150	15	Secondary	0.1470	0.1530	India TB Report 2023
Comparator Arm: Radiologist							
Transition probability of Positive (TP+FP)	Positive	0.84	84.40	Secondary	0.8271	0.8609	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Negative (FN+TN)	Negative	0.16	16	Secondary	0.1529	0.1591	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened TP	True Positive	0.93	93.28	Secondary	0.9141	0.9514	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened _ FP	False Positive	0.07	6.72	Secondary	0.0659	0.0686	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened _ FN	False negative	0.64	64.08	Secondary	0.6280	0.6537	Pooled Sensitivity & Specificity from evidence synthesis
Transition probability of Screened_ TN	True Negative	0.36	35.92	Secondary	0.3520	0.3663	Pooled Sensitivity & Specificity from evidence synthesis
No. of Beneficiaries	No. of Beneficiaries		**2731**	Secondary	0.0000	0.0000	Same comparator use

Cost of Positive (TP+FP)	Positive	2299.00	229900.40	Calculated	2253.0239	2344.9840	calculated based on secondary data
Cost of Negative (FN+TN)	Negative	424.89	42489.18	calculated	416.3940	433.3897	calculated based on secondary data
Cost _Screened _TP	True Positive	2144.41	214441	Calculated	2101.5190	2187.2953	calculated based on secondary data
Cost _Screened _FP	False Positive	154.60	15459.7	Calculated	151.5049	157.6887	calculated based on secondary data
Cost _Screened _FN	False negative	272.29	27229.0	Calculated	266.8440	277.7356	calculated based on secondary data
Cost _Screened _TN	True Negative	152.602	15260	Calculated	149.5500	155.6540	calculated based on secondary data
Cost of Interpretation	Cost of Interpretation	0.997	**100**	Secondary	0.9775	1.0173	calculated based on secondary data (HTAIn RRC-IIPHG CXR costing study)
Avg. Age of Cohort	Age of cohort	0.150	15	Secondary	0.1470	0.1530	India TB Report 2023

The incremental cost of delivering AI solutions in healthcare system

Table 7. Cost description of Radiologist

Description	**Cost (INR)**	**Remarks**
Radiologist	2,36,400	Comparator costing adopted from the previous study – DHR HTAIn IIPHG costing study: 197000- 10 % of total salary - per day 11*5- read: 55 Minutes, per day 6- 8 hour per day duty time
Data entry operator	37,554	12518: 25% time to CXR
X-ray printed	6,860	Data from 2 SDH from Maharashtra
Grand Total	2,80,814	
No of Patients	2731	In Yr. 2021-2022
Per Patient cost	103	
Cost per case interpreted/screened (after 3% discount)	100	3% discount as per HTAIn user guidelines/Manual

The cost sheet (Table 7) offers a comprehensive view of the financial aspects associated with delivering radiology services, the costing methodology involves adopting comparator costing from a previous study, with the Radiologist's cost set at INR 19,700 at 10% of the total salary and annualized. Other contributors to the overall cost were the data entry operator with a shared unit cost of INR 12,518 and X-ray printing material with a unit cost of INR 05. The Grand Total, representing the sum of all costs amounts to a per interpretation cost of 103. Hence, the per interpretation costs was found to be INR 100 at 3% discounted price.

Table 8. Cost sheet for qXR – AI interpretation

Sr. No.	Description	Product	Cost (INR)	Remarks
1	Usage-based scan cost (Per scan)	qXR	25	This cost for the software license is inclusive of AI processing of Chest X-Ray including all the operational and capital cost of technology. Which includes human resources, user training, deployment and Integration, dedicated client support, life cycle management, and cost for maintenance of the software.
2	Internet connection cost (Shared)		1	Cost provided by local service provider in facility
3	X-ray Printing cost		5	Standard printing cost from facility
	Total cost		31	
	Cost per case interpreted/screened (after 3% discount)		**30**	3% discount as per HTAIn user guidelines/Manual

The cost breakdown of qXR was provided through manufacturer and it is outlined as follows. The usage-based scan cost per scan was set at INR 25, covering the software license inclusive of AI processing for Chest X-Ray. This includes operational and capital expenses related to technology, including human resources, user training, deployment and integration, dedicated client support, life cycle management, and software maintenance.

Total cost collections include the usage-based scan cost, internet connection cost, and X-ray printing cost, totaling INR 31. However, the discounted cost at 3% and the cost per case interpretation was INR 30. Details are given in the table 8.

Note: The above-mentioned costs depict the online mode of the device. For an on-premise deployment in offline mode, a cost of INR 3 lakh (exclusive of tax) is applicable. The manufacturers were unable to provide a detailed breakup due to its proprietary nature because none of the x-ray units in India deployed with offline AI solution.

Table 9. Cost sheet for Genki – AI interpretation

Cost description of Genki – DeepTek Solution				
Sr. No.	**Description**	**Product**	**Cost (INR)**	**Remarks**
1.	Cost of a solution per unit	Genki Software License	1,57,608	Offline/Edge AI-based Chest X-ray triaging solution. It connects with any CR or DR machine, and can also process photos of analogue scans. The system covers two pathologies (Normal/Abnormal and TB)
2.	The expected life of solution	5 Years	-	Unlimited Scans for Unlimited Period- This is Perpetual License and our Assumption was applied: expected life of tech is maximum 5 Years
3.	Transportation cost of the device	For Genki Workstation by couriers	5,000.00	Genki Workstation delivered
4.	Installation & Training Cost	In Person	50,000.00	Installation and training can be done online. In person visit is not essential
5.	Mode of availability in the Field	Offline mode		The Genki solution works offline without the need for the internet.
6.	Hardware: Laptop or PC	Genki Workstation	16,000	The laptops or PCs needed are standard off-the-shelf products. They can be independently procured and need not be provided by us. Also, the solution can be installed on the X-ray machine workstation (laptop/PC) if the specs of the machine are adequate. our Assumption was applied: expected life of device is maximum 5 Years.
7.	Server costing	RIS-VIM Server- - per year per Genki License (i.e. per year per X Ray)	60,000	This includes features like Centralized server-based scan / data aggregation and storage, Patient Registration, Vulnerability Assessment, recording of sputum results and comprehensive analytics and dashboard ensuring efficient execution of the screening programs
		Augmento + RIS-VIM Server- per year per Genki License (i.e. per year per X Ray)	1,10,000	In addition to the above-mentioned features, this includes a zero-footprint PACS viewer, Radiologist Review Mechanism, Smart Reporting, Notifications, and Responsible AI, enabling tracking of the real-world

				performance of AI and its biases, if any, post-deployment.
8.	Other hardware such as Wi-Fi Router Wi-Fi Receiver Extension Cord	Networking Equipment	4,500	The equipment might be essential to enable connectivity between the X-ray machine and the Genki Workstation.
9.	Annual Maintenance cost	Genki AMC	50,000	AMC services are available as an optional service.
10.	Comprehensive Maintenance cost	Genki Workstation	20,000	CMC services are available as an optional service.
11.	Insurance of equipment		-	
12.	Total cost of one Solution		2,83,108	All the applicable cost annualized at expected life
13.	In Tamil Nadu 6 centres are using		16,98,648	
14.	Total Number of Patients from facilities		93486	(Year – Dec 2022- Nov 2023)
15.	usage-based scan cost (Per scan)		18	
16.	X-ray Printing cost		5	Standard printing cost from facility
	Total cost		23	
	Cost per case interpreted (after 3% discount)		**22**	3% discount as per HTAIn user guidelines/Manual

The Genki Edge system integrates with various Digital X-ray machines (DX/DR/CR) without any additional integration costs. The total cost of the overall solution is INR 9,14,500. The perpetual license cost for the Genki Edge software solution is INR 7,25,000 per X-ray machine (Table 9).

The license encompasses two pathologies, distinguishing between Normal/Abnormal and TB conditions. With an assumed lifespan of five years, the perpetual license ensures unlimited scans during this period. Maintenance and support provide after the first year, the maintenance and support cost will be INR 50,000 per year. Genki Edge hardware is a standard off the shelf laptop or PC that can be purchased at INR 80,000. Server costs, including RIS-VIM Server and Augmento + RIS-VIM Server, contribute INR 60,000 and INR 1,10,000 per year. Other networking equipment's are priced at INR 4,500, while optional maintenance services (AMC and CMC) are available at INR 50,000 and INR 20,000.

The total cost of one Genki Solution, annualized over its expected lifespan, amounts to INR 2,83,108. Notably, in Tamil Nadu, six centres are already utilizing this solution at a cumulative cost of INR 16,98,648, serving a substantial patient population of 93,486. The usage-based scan cost is INR 23. The per case interpretation cost, after a 3% discount is INR 22.

Cost-effectiveness Plane

Table 10. Incremental Cost-Effectiveness Ratio (ICER) for AI Solution for study Population

ICER Values	**qXR**	**Genki**
Difference in Cost	-740.29	841.02
Difference in outcome Cases detected	0.075	0.075
ICER	**-9,864.77**	**11,286.93**

Cost-effective analysis for qXR and Genki are shown in Table 10. The Incremental Cost-Effectiveness Ratio (ICER) was used as a key metric in decision modelling to assess the cost and outcomes. The ICER value was calculated on the basis of cost per case interpreted/screened. The ICER value per cases interpreted/detected for qXR INR - 9,864.77, with a negative difference in cost of INR 740.29 indicating the cost of qXR less than the conventional mode. The ICER value per cases interpreted/screened for Genki, was INR 11,286.93 with a positive difference in cost of INR 841.02 indicating that the cost of Genki to be less than the conventional mode. The ICER values for both the AI assisted technologies were below the per capita GDP of India (2022), which was INR 1,97,440.48. Both the AI assisted technologies were found to have similar outcomes in terms of per cases detected 0.075. Both interventions were in the acceptable quadrants (q1 and q2) of cost-effective plane. The ICER for qXR falls under the dominant quadrant (q2). For Genki, the ICER is found to be INR 11,286.93 per case detected to achieve similar outcome (0.075) indicating that the intervention was effective but more cost-intensive. The Cost-effectiveness plane for both interventions is presented in Figure 5 and 6.

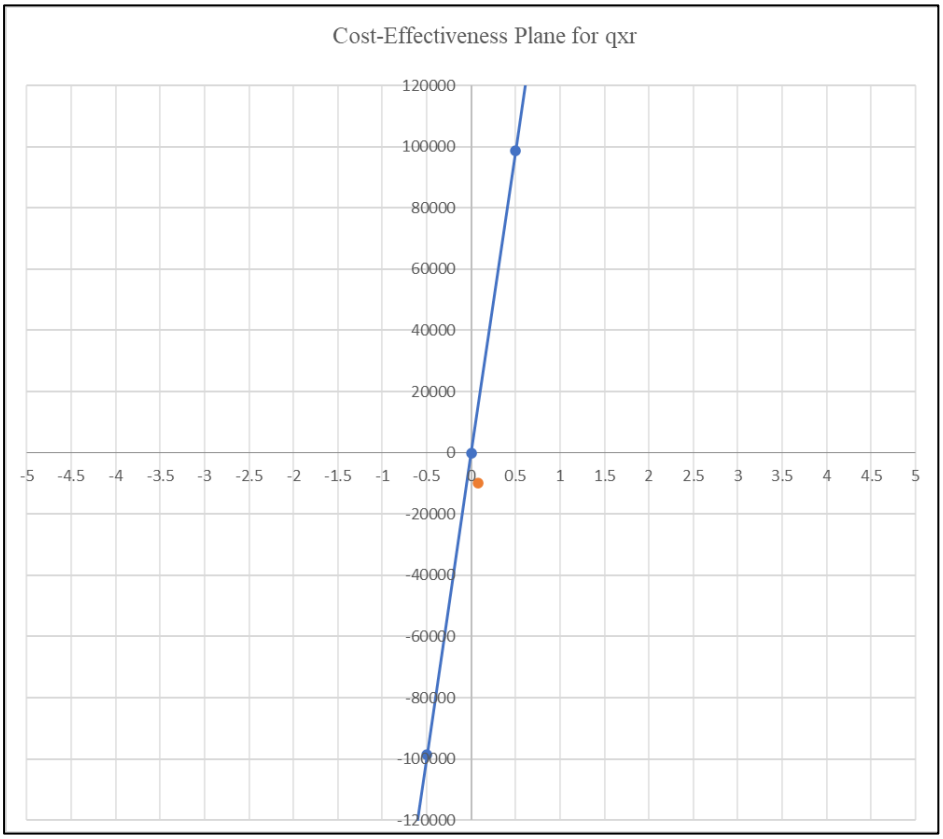

Figure 5. Cost-effectiveness Plane for qXR

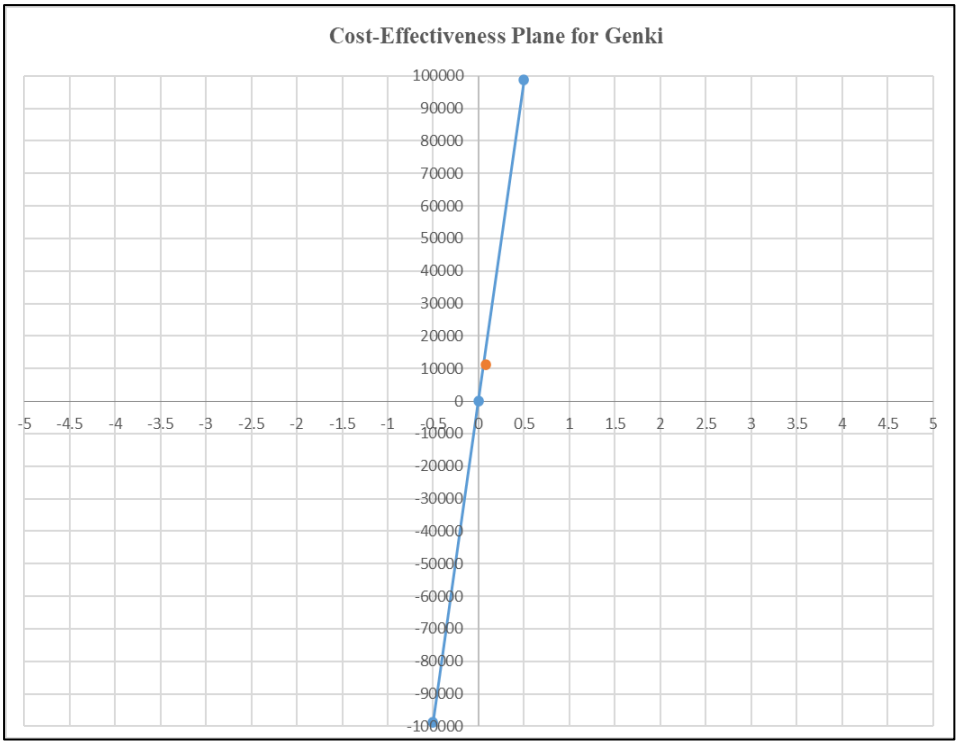

Figure 6. Cost-effectiveness Plane for Genki

Note: The AI solution falls under the dominant quadrant, making intervention acceptable and preferred option.

One-Way Sensitivity Analysis

In one-way sensitivity analysis, 95% CI values for utility values for the model input parameters were used and reported as tornado diagrams. The tornado diagram of one-way sensitivity analysis shows that ICER value is slightly changed when the input parameters is changed in multiple indicators. The ICER values are provided with corresponding lower and upper bounds for various parameters such as true/false positive and negative rates.

The tornado diagram visually highlights the parameters with the most significant impact on the ICER, aiding in the identification of key contributors to uncertainty. As mentioned above, there are few factors which influence the model however, sensitivity analysis provides valuable insights at acceptable level for decision-makers, guiding efforts to improve parameter estimation and reduce uncertainty in the cost-effectiveness analysis (Figure 7 & 8).

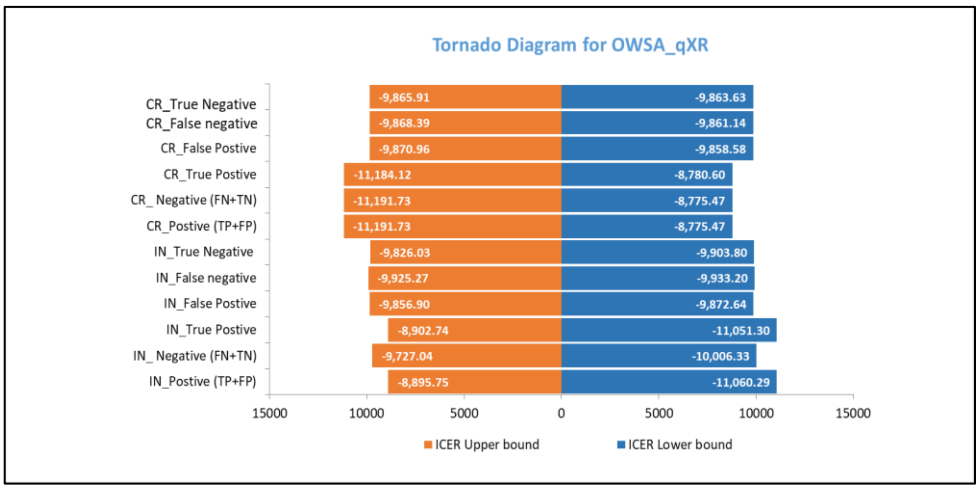

Figure 7. One-way sensitivity analysis for qXR

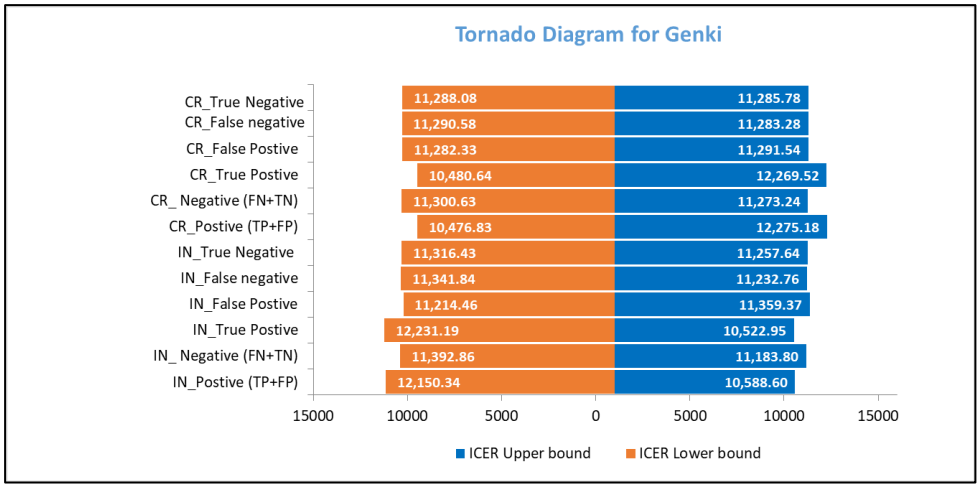

Figure 8. One-way sensitivity analysis for Genki

Threshold Analysis

The cost of the AI solution significantly influences the overall expenditure associated with implementing AI screening tool in the program. Consequently, a threshold analysis was conducted to determine the cost range below which purchase of the AI solution proves to be cost-effective. The ICER values were computed by systematically increasing the cost, and the point at which these ICER values cease to be cost-ineffective was found out. The resulting ICER values are graphically represented below (Figure 9 & 10).

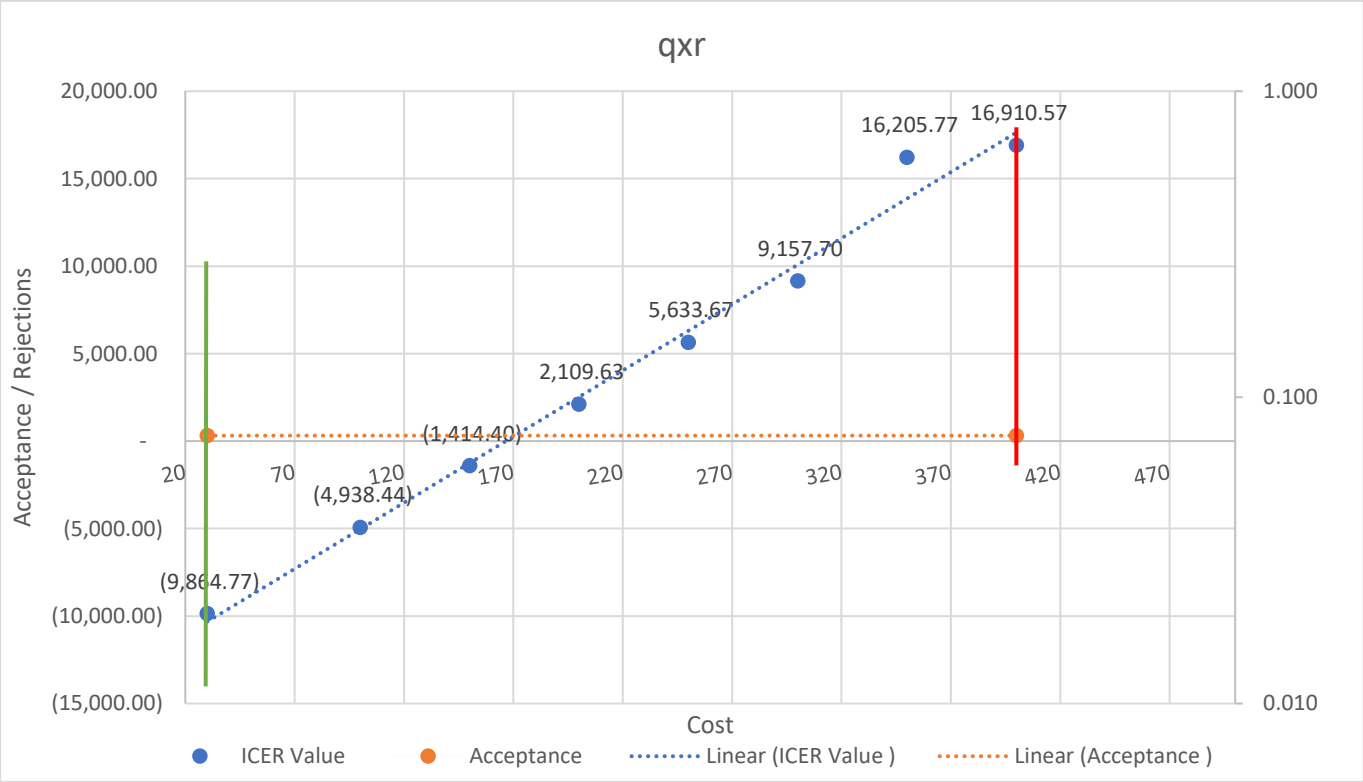

Figure 9. Threshold analysis for qXR

The ICER value at the cost of INR 30 to 400 suggests that, the AI solution qXR is cost-saving compared to a routine care scenario. However, as the cost per screening increases, the ICER values turn positive, indicating a higher cost for gaining additional effectiveness. The acceptance threshold is met at the highest level of INR 16,910.57 suggesting that, from an evaluation point, the AI solution is not acceptable when the cost per screening reaches to INR 410.

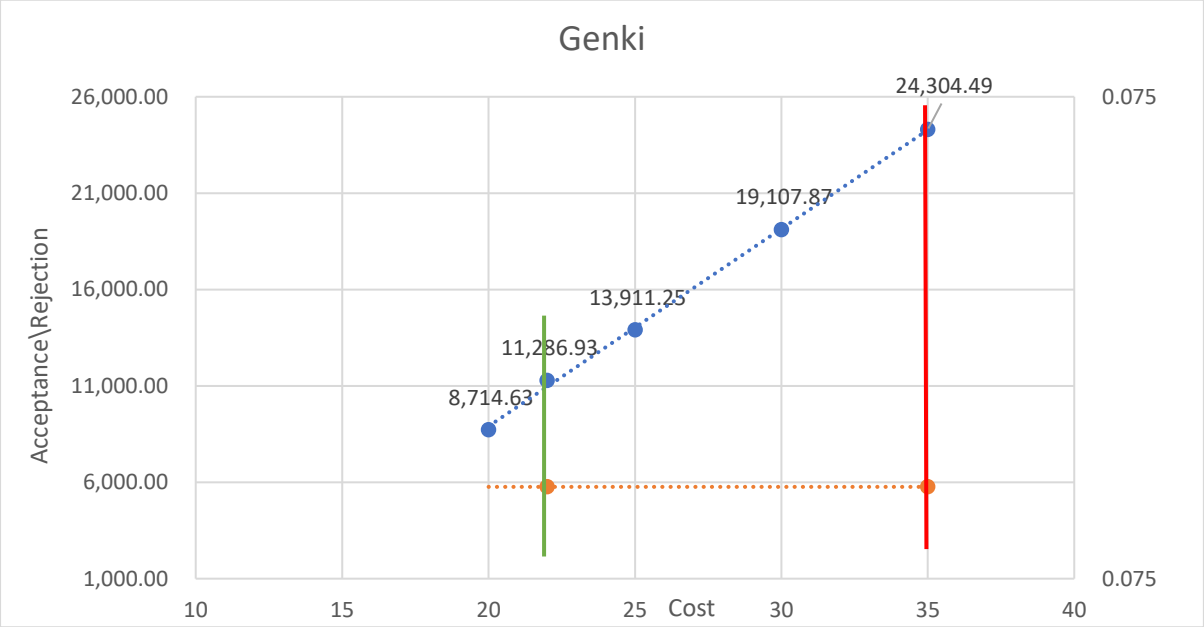

Figure 10. Threshold analysis for Genki

Notably the AI solution- Genki remains cost-effective and acceptable at a cost of INR 22 (ICER 11,286.93), with the threshold limit of per GDP capita income of India-2022 being INR 1,97,440.48. For gaining one unit of health benefit, healthcare system can maximum spend an amount of INR 35.

Major Finding

- The Incremental Cost-Effectiveness Ratio (ICER) for qXR was found to be -9,864.77 INR per case detected, while for Genki, it was 11,286.93 INR per case detected. Both ICER values are below the per capita GDP of India for the year 2022 (1,97,440.48 INR), indicating cost-effectiveness.
- The ICER for qXR falls under the dominant quadrant (q2), indicating its dominance over routine care. For Genki, although more cost-intensive, it remains cost-effective, meeting the per capita GDP threshold.
- Threshold Analysis: Indicates the cost range below which purchase of the AI solution is cost-effective. qXR is cost-saving compared to routine care up to INR 400 per screening cost. Genki will remain cost effective up to INR 35 per screening.

CHAPTER 6: DISCUSSION

Our study's findings shed important light on the relative cost-effectiveness and diagnostic accuracy of two AI systems, qXR and Genki, when compared to radiologists.

There are now a number of AI-based tools available for TB-CXR image interpretation (10). According to studies published in the literature, the use of AI in the interpretation of CXRs has shown promising outcomes in terms of increasing accuracy and efficiency, especially in resource-constrained countries like India. High percentages of concordance between expert interpretations and AI-assisted solutions are demonstrated(33). The strength, accuracy, and resource availability of new technology must be weighed against their increased price. Our study's goal is to ascertain how affordable AI-based technologies are for interpretation in relation to radiologists.

In context to accuracy of AI based interpretation tools, we had adopted the pooled sensitivity and specificity from the available literature as it is well established and recorded under various studies. Based on our study findings, we observed that both the intervention qXR and Genki demonstrated high pooled sensitivity and specificity as compared to the Radiologists.

Both the intervention falls within the acceptable quadrants q1 and q2 of cost-effective plane. The qXR ICER value falls under the dominant quadrant which suggests that intervention is not only cost effective but cost saving in comparison to routine care scenario.

Limitations of the Study

- The study’s limitations included the partial data availability, relying on manufacturer for the data provision, assumptions underlying in the economic model.
- The study was undertaken from the provider’s perspective because of time limitation.
- For assessment of cost & effect, we did not match the cases. We used secondary data from the user department for model inputs.

CHAPTER 7: CONCLUSION

The pooled sensitivity and specificity of the intervention are 90% and 68%, respectively, which means that the intervention falsely misses 10% of the cases and falsely detects 30% of the cases. However, this meets the non-inferior accuracy as per WHO consolidated guidelines on systematic screening for tuberculosis.

Both interventions fell within the acceptable cost-effectiveness range. This indicates that AI assisted interventions can enhance screening procedures by addressing the issue of human resource constraints and reducing the delays in the diagnosis and treatment initiation in Tuberculosis. The decision on which intervention (in NTEP diagnostic algorithm) to choose deceits with the policymakers.

As it was a rapid HTA, long-term effects were not thoroughly explored. There is a scope for primary study to evaluate diagnostic accuracy in Indian public health settings. Future research should consider a broader scope to provide a more comprehensive understanding of the technology.

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Acknowledgment

We sincerely thank everyone involved in the successful completion of the “Health Technology Assessment of AI-Assisted CXR for Interpretation for Tuberculosis” at the Regional Resource Centre for Health Technology Assessment, Indian Institute of Public Health Gandhinagar.

Special acknowledgments to Genki and qXR stakeholders, including Dr. Asha Fredrick (STO, Tamil Nadu), K Ravi Shankar (SNLI, WJCF), Dr. Balnath Chakor (CTO, Mira Bhayendar), and Dr. Nitin Suresh Kapase (DTO, GMC, Gondia).

Gratitude to HTAIn, the Department of Health Research (GOI), especially Dr. Kavitha Rajshekhar and Dr. K V Jagadeesh for their support.

Thanks to all healthcare professionals, researchers, and institutions for their valuable contributions in advancing our understanding of AI-assisted CXR and handheld portable screening devices for tuberculosis diagnosis.

HTA RRC
Indian Institute of Public Health Gandhinagar

Annexures 01 qure.ai Approvals

An:1.1 CDSCO approval - Licence Number: MFG/MD/2023/000181

सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2023/000181

1. M/s Qure.ai Technologies Private Limited, Level 7, Oberoi Commerz II, Goregaon East, Mumbai 400063, IndiaMumbai, Mumbai City, Maharashtra (India) - 400063 Telephone No.: 9176744321 FAX: 02268505800 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s QURE.AI TECHNOLOGIES PRIVATE LIMITED, Level 7, Commerz II, International Business Park, Oberoi Garden City, Off. W. E. Highway, Goregaon East, Mumbai, Maharashtra, 400063, Mumbai City, Maharashtra (India) - 400063 Telephone No.: 9176744321 FAX: 02268505800

2. Details of medical device(s) [Annexed]

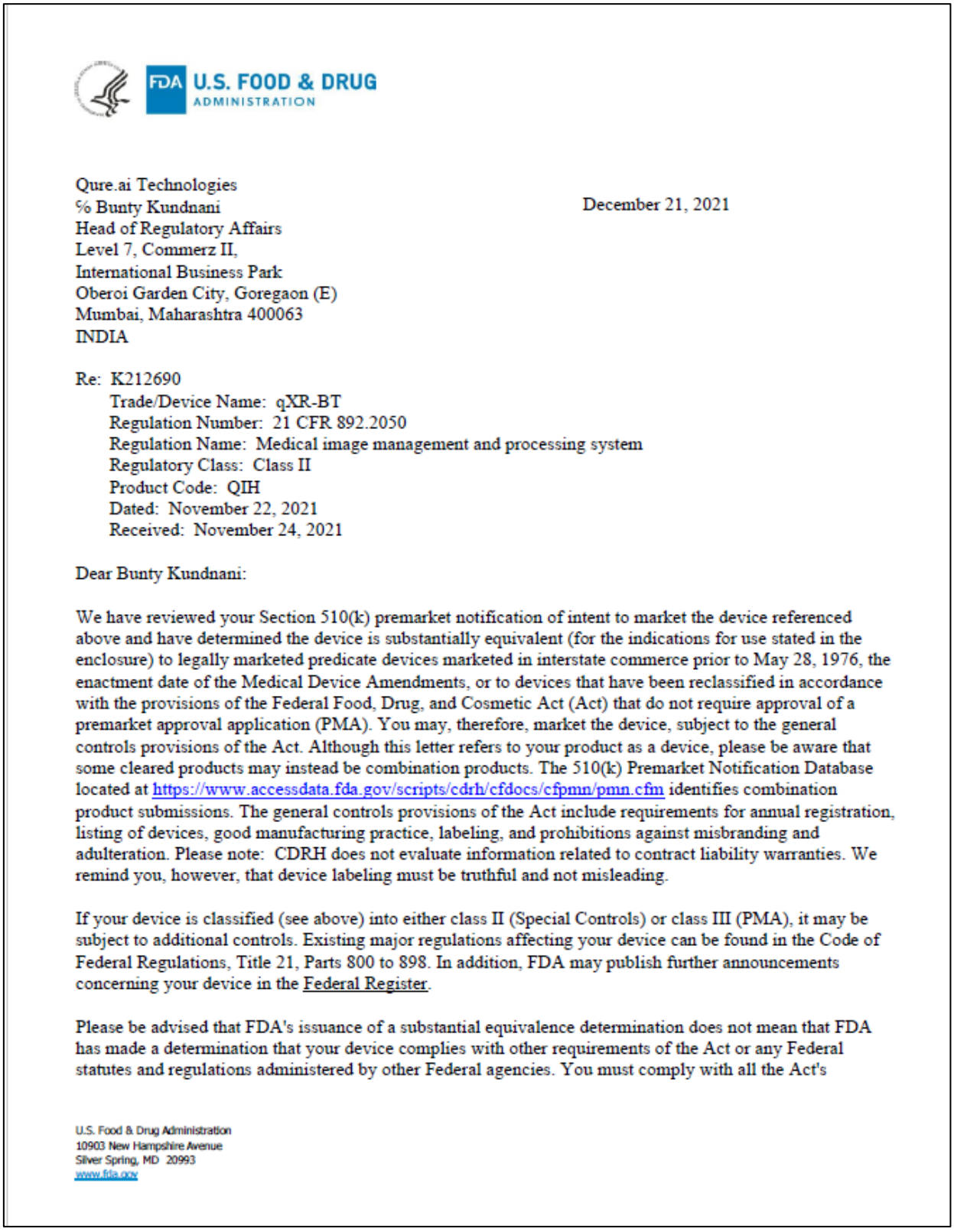
3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:qER Model No.:NIL Intended Use:qER is a radiology computer aided triage and notification software indicated for use in the analysis of non-contrast head CT scans. The device is intended to assist trained medical specialists by indicating the presence of the following findings on head CT scan images: Intracranial hemorrhage, mass effect, midline shift, cranial fracture, infarct, ASPECT score, and cerebral atrophy. qER uses an artificial intelligence algorithm to analyze images in parallel to the ongoing standard of care image interpretation and highlight head CT scans containing critical findings. As an added feature, the device can outline the above pathologies on the head CT scan. The user is presented with preview images highlighting the abnormal findings, that are meant for informational purposes only and not intended for diagnostic use The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of the device are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage and prioritization of medical images for review. Notified clinicians are responsible for viewing the original head CT scans as per the standard of care. Class of medical device:Class B Material of construction:software Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL

Page 1 of 2

An:1.2 FDA approved (510(k) cleared for Breathing tubes



U.S. FOOD & DRUG ADMINISTRATION

Qure.ai Technologies
% Bunty Kundnani
Head of Regulatory Affairs
Level 7, Commerz II,
International Business Park
Oberoi Garden City, Goregaon (E)
Mumbai, Maharashtra 400063
INDIA

December 21, 2021

Re: K212690
Trade/Device Name: qXR-BT
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: November 22, 2021
Received: November 24, 2021

Dear Bunty Kundnani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

An: 1.3 MDD Class II A certified

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 106322 0001 Rev. 00

Manufacturer: QURE.AI TECHNOLOGIES PRIVATE LIMITED
Level 7, Commerz II
International Business Park
Oberoi Garden City, Goregaon (E)
Mumbai 400063
INDIA

Product Category(ies): Computer aided radiology software application for analysis of head CT scans and chest X-rays.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: IND20190119

Valid from: 2020-07-13
Valid until: 2024-05-26

Date, 2020-07-13

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 1
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An:1.4 MDR Class II B certified

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DS-MDR-033

TÜV SÜD PRODUCT SERVICE

EU Quality Management System Certificate (MDR)
Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)
No. G10 106322 0004 Rev. 00

Manufacturer: QURE.AI TECHNOLOGIES PRIVATE LIMITED
Level 7, Commerz II
International Business Park
Oberoi Garden City, Goregaon (E)
Mumbai 400063
INDIA

SRN Manufacturer: IN-MF-000018096

Authorized Representative: Advena Ltd
Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, MALTA

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 106322 0004 Rev. 00

Report No.: TPS0735

Valid from: 2023-01-18
Valid until: 2028-01-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-01-18

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TÜV

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DS-MDR-033

TÜV SÜD PRODUCT SERVICE

EU Quality Management System Certificate (MDR)
Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)
No. G10 106322 0004 Rev. 00

Classification: IIb
Device Group: Z11069092 - VARIOUS DIGITAL BIOIMAGING MANAGEMENT INSTRUMENTS - MEDICAL DEVICE SOFTWARE
Intended Purpose: Computer-aided detection (CAD) and notification software intended to be used in the analysis of radiological scans

The validity of this certificate depends on conditions and/or is limited to the following: -

An:1.5 FDA Approval: Pnuemothorax and pleural effusion

U.S. FOOD & DRUG ADMINISTRATION

Qure.ai Technologies
% Ayushi Mahendra
Senior Regulatory Affairs Specialist
Level 7, Commerz II
International Business Park
Oberoi Garden City, Goregaon (E)
Mumbai, Maharashtra 400063
INDIA

August 22, 2023

Re: K230899
Trade/Device Name: qXR-PTX-PE
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QFM
Dated: July 24, 2023
Received: July 24, 2023

Dear Ayushi Mahendra:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

An:1.6 Information Security Management System ISO 27001:2013

Alcumus ISOQAR

Certificate of Registration

This is to certify that the Management System of:

Qure.AI Technologies Private Limited

Registered Office:
Floor 6 & 7, Oberoi Commerz II, International Business Park, Oberoi Garden City, Goregaon East, Mumbai - 400 063, Maharashtra, India

New Office:
We Work, Raheja Platinum, Marol CHS road, Off Andheri –Kurla Road. Marol, Andheri East, Mumbai, Maharashtra

has been approved by Alcumus ISOQAR and is compliant with the requirements of:

ISO 27001:2013

Certificate Number:	18431-ISN-001
Initial Registration Date:	09 September 2020
Re-issue Date:	10 November 2022
Current Expiry Date:	09 September 2023

Scope of Registration:

The Information security management system of Qure.AI covers all assets, used in Qure Product Engineering including IT, Operation and Implementations, Research and Development supported by HR, admin, sales and marketing operating out of Qure.ai Technologies Pvt. Ltd. Raheja Platinum, Sag Baug Road, Off Andheri – Kurla Rd, Marol, Andheri East, Mumbai 400059. This is in accordance with the Qure.AI_ISMS StatementOfApplicability_V1.0 dated 4-1-2020

Signed:
Alyn Franklin, Chief Executive Officer
(on behalf of Alcumus ISOQAR)

This certificate will remain current subject to the company maintaining its system to the required standard. This will be monitored regularly by Alcumus ISOQAR. Further clarification regarding the scope of this certificate and the applicability of the relevant standards' requirement may be obtained by consulting Alcumus ISOQAR.

Alcumus ISOQAR Limited, Alcumus Certification, Cobra Court, 1 Blackmore Road, Stretford, Manchester M32 0QY.
T: 0161 865 3699 F: 0161 865 3685 E: isoqarenquiries@alcumusgroup.com W: www.alcumusgroup.com/isoqar

An:1.7 Medical Device Quality Management System ISO 13485:2016

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 106322 0002 Rev. 01

Holder of Certificate: QURE.AI TECHNOLOGIES PRIVATE LIMITED
Level 7, Commerz II
International Business Park
Oberoi Garden City, Goregaon (E)
Mumbai 400063
INDIA

Facility(ies): QURE.AI TECHNOLOGIES PRIVATE LIMITED
Level 7, Commerz II, International Business Park, Oberoi Garden City, Goregaon (E), Mumbai 400063, INDIA

See Scope of Certificate

Certification Mark:

Scope of Certificate: **Design and Development, Sales, Service and Installation of Standalone Software Application for Analysis of Medical Images.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 106322 0002 Rev. 01

Report No.: TPS0735

Valid from: 2023-05-27
Valid until: 2025-12-08

Date, 2023-05-26

Christoph Dicks
Head of Certification/Notified Body

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Annexures 02 DeepTek approvals

An: 2.1 Thailand FAD approval - Importation license no: 66-2-2-2-0005907

แบบ บ.จ.น. ๑

ใบรับแจ้งรายการละเอียดนำเข้าเครื่องมือแพทย์ Importation License

ใบรับแจ้งรายการละเอียดที่ 66-2-2-2-0005907 Importation license no : 66-2-2-2-0005907

ใบรับแจ้งรายการละเอียดฉบับนี้ให้ไว้แก่ This importation license is for

บริษัท บีเจซี เฮลท์แคร์ จำกัด BJC Healthcare Co., Ltd

ผู้จดทะเบียนสถานประกอบการนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนที่ สน. 389/2554 Registation importer no. 389/2554
เพื่อแสดงว่าเป็นผู้แจ้งรายการละเอียดนำเข้าเครื่องมือแพทย์ตามมาตรา ๑๙ แห่งพระราชบัญญัติเครื่องมือแพทย์
พ.ศ. ๒๕๕๑ และที่แก้ไขเพิ่มเติม สำหรับเครื่องมือแพทย์ For hereby declare that (company above) is a importer according toArticle 19 of the Medical Device Act B.E. 2551 (2008) and the amendedMedical Device Act B.E. 2562 (2019), 2nd edition.

GENKI Edge

รายละเอียดเครื่องมือแพทย์ ตามเอกสารแนบท้าย See attached
Product Description

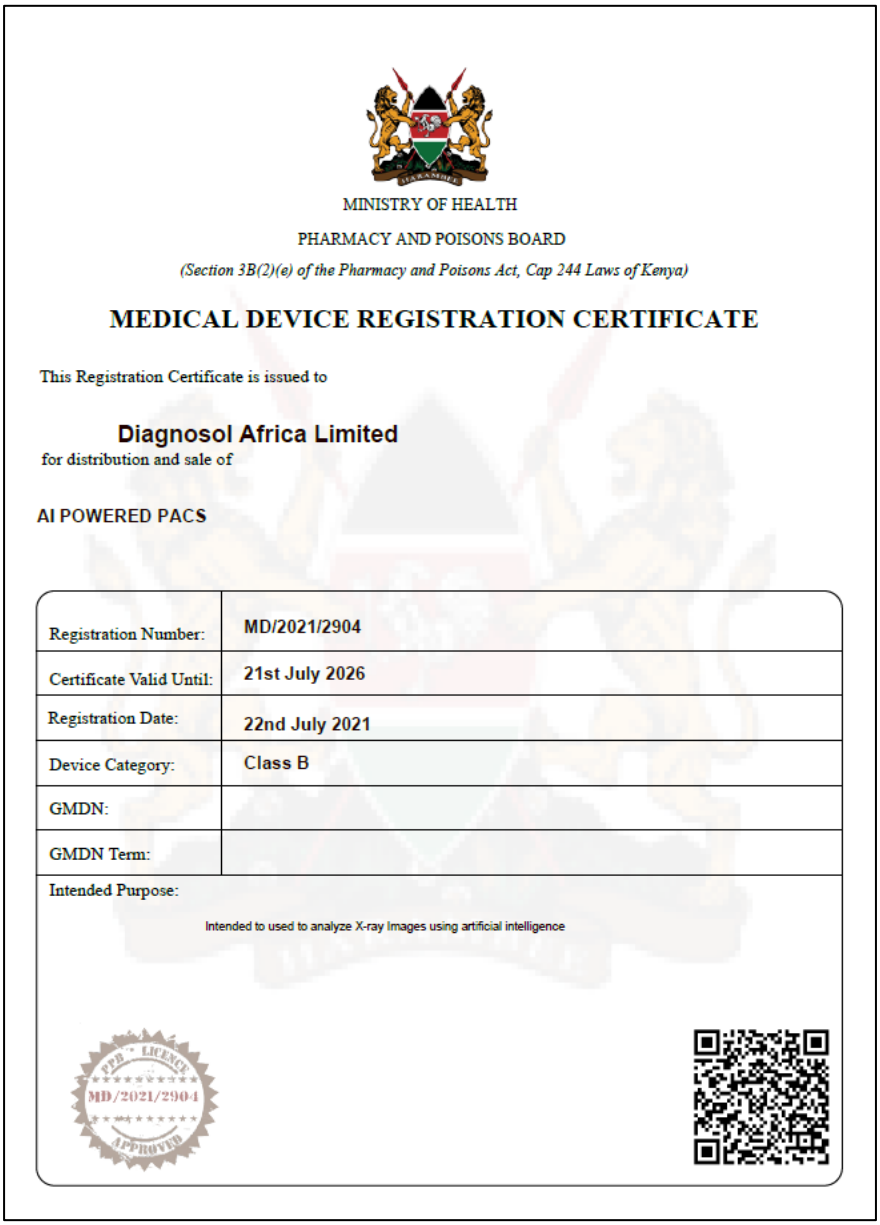
ชื่อและที่ตั้งของสถานที่ผลิตเครื่องมือแพทย์ ตามเอกสารแนบท้าย See attached
Name and address of Manufacturing site

ณ สถานที่นำเข้าเครื่องมือแพทย์ชื่อ Place of Importer บริษัท บีเจซี เฮลท์แคร์ จำกัด BJC Healthcare Co., Ltd.
ตั้งอยู่เลขที่ Address Street 99
ตรอก/ซอย รูเบีย Rubia ถนน สุขุมวิท 42 Sukhumvit 42 หมู่ที่ -
ตำบล/แขวง พระโขนง Prakanong อำเภอ/เขต คลองเตย Klongtoey
จังหวัด กรุงเทพมหานคร Bangkok รหัสไปรษณีย์ 10110 Post code โทรศัพท์ 0 2146 5411 Tel โทรสาร 0 2712 2242 Fax
ชื่อและที่ตั้งของเจ้าของผลิตภัณฑ์ Product Owner
DeepTek Medical Imaging Private Limited, 12-13, Acropolis Apartment, ITI Road, Near Anand Park, Aundh, Pune -411 007, Maharashtra, India

ใบรับแจ้งรายการละเอียดฉบับนี้ใช้ได้จนถึงวันที่ 31 ธันวาคม พ.ศ. 2570 และให้ใช้เฉพาะ
สถานที่ซึ่งระบุไว้ในใบรับแจ้งรายการละเอียดเท่านั้น This license is allowed to use until 31 December 2027
ออกให้ ณ วันที่ 21 เดือน เมษายน พ.ศ 2566
Issued date was 21 April 2023

(ลายมือชื่อ) Food and Drug Administration สำนักงานคณะกรรมการอาหารและยา
(ตำแหน่ง) กระทรวงสาธารณสุข Ministry of Public Health
ผู้อนุญาต
Licenser

An: 2.2 Kenya Registration Certification



MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

(Section 3B(2)(e) of the Pharmacy and Poisons Act, Cap 244 Laws of Kenya)

MEDICAL DEVICE REGISTRATION CERTIFICATE

This Registration Certificate is issued to

Diagnosol Africa Limited

for distribution and sale of

AI POWERED PACS

Registration Number:	MD/2021/2904
Certificate Valid Until:	21st July 2026
Registration Date:	22nd July 2021
Device Category:	Class B
GMDN:	
GMDN Term:	

Intended Purpose:

Intended to used to analyze X-ray Images using artificial intelligence

PPB LICENCE MD/2021/2904 APPROVED

MAH Details:

DEEPTEK MEDICAL IMAGING PRIVATE LIMITED 411007 0000 MAHARASHTRA

Manufacturing Sites :

DEEPTEK MEDICAL IMAGING PRIVATE LIMITED,

Device Accessories:

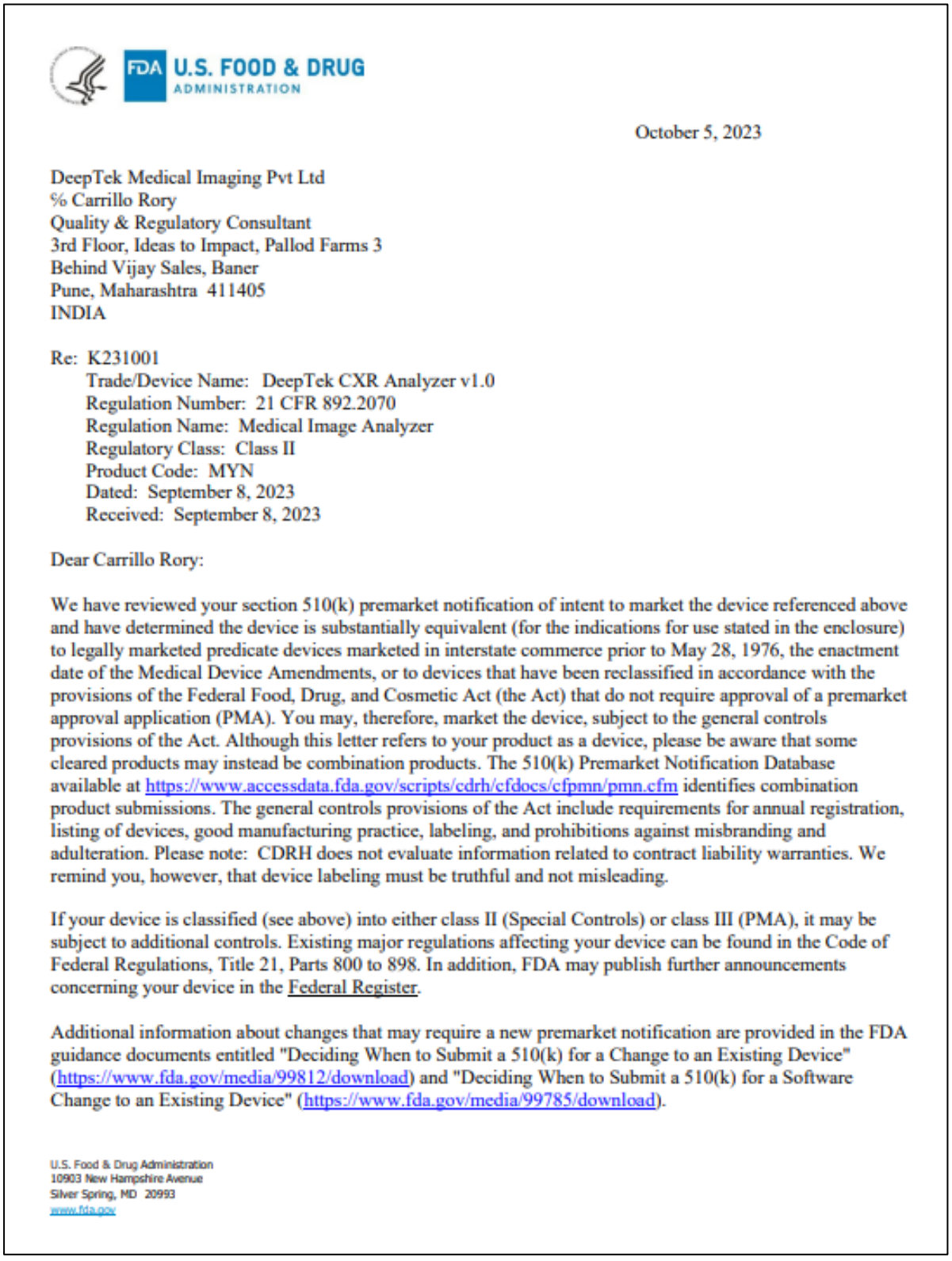
' ' ' ' ' ' ' '

Device Group:

Device Sub-group/Sub-sets:

AUGMENTO and GENKI

An.: 2.3 US FDA Approval letter



U.S. FOOD & DRUG ADMINISTRATION

October 5, 2023

DeepTek Medical Imaging Pvt Ltd
% Carrillo Rory
Quality & Regulatory Consultant
3rd Floor, Ideas to Impact, Pallod Farms 3
Behind Vijay Sales, Baner
Pune, Maharashtra 411405
INDIA

Re: K231001
Trade/Device Name: DeepTek CXR Analyzer v1.0
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: September 8, 2023
Received: September 8, 2023

Dear Carrillo Rory:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

An.: 2.3 CDSCO approval

सह आयुक्त (पुणे विभाग)
यांचे कार्यालय
अन्न व औषध प्रशासन (म.राज्य)
सेक्टर क्र. ४, प्लॉट नं. १ व २,
एफ. डी. ए. भवन,
पिंपरी चिंचवड नवनगर विकास प्राधिकरण,
लिंक रोड, अॅकार्ड हॉस्पिटल शेजारी, मोशी,
पुणे -४१२१०५

"Your Service is Our Duty"
"आपली सेवा आमचे कर्तव्य"

Office of Joint Commissioner (Pune Division)
Food & Drug Administration M. S.
Sector No. 4, Plot No. 1 & 2,
F. D. A. Bhavan,
Pimpri Chinchwad Navnagar Vikas Pradhikaran,
Link Road, Near Accord Hospital, Moshi,
Pune- 412105
Email –fdapunedrug@gmail.com

No. Drug/Mfg/MD/285/2023-24/Zone- 2 Date - 18 / 09 /2023

To,
M/s Deeptek Medical Imaging Private Limited,
3rd Floor, Ideas to Impact, Pallod Farms 3, Behind Vijay Sales,
Baner, Pune, Maharashtra (India) – 411045

Subject - Drugs & Cosmetics Act 1940 & Rules Threreunder.
Licence to Manufacture for sale or for distribution of Class A or Class B Medical Devices in form MD-5, under Medical Device Rule, 2017 regarding.

Ref - Your online application file No. MFG/MD/2023/84943, dt - 14/02/2023

Sir,

With reference to your application under Ref above, you are hereby granted fresh licence in form MD-5 No. MFG/MD/2023/000849 dt- 18/09/2023 to Manufacturing of Medical Devices of Class B as per the list of Products duly approved and endorsed by SLA.

Yours

Encl - As above

(S. V. Pratapwar)
Joint Commissioner (Drugs)(Pune Div.)
& Licensing Authority
Food & Drugs Administration, M.S. Pune

Annexure 03 Data Collection Tools

An.: 3.1 Tool for data collection for Intervention

Device / AI Information – QXR / Genki								
Location	Total (n)	Device/AI - Interpretation		Device/AI - positive		Device/AI - negative		Treatment initiation
		Positive	Negative	Microbiology-Positive	Microbiology-Negative	Microbiology-Positive	Microbiology-Negative	
Total								

Screening to Interpretation time to perform one CXR / interpretation (Process flow)	
How often do you use Technologies (AI tools or Portable device): Frequency of use in a week	

User Feedback	
Strength (user friendly software/Performance/ Technical Supports etc)	
Challenges/Weakness (technical support/limitations/issues related to technology)	
Scope for improvement (if any)	

Additional information on Cost	
Cost of Technology you paid	
Any Additional cost is required to manage (Please Specify) This includes all the associated Healthcare cost & technology	

*Sections which are not applicable please mention 'NA'.

An.: 3.2 Tool for data collection for Comparator

The details of the diagnostic accuracy of the conventional digital CXR method shall be records of the selected healthcare facilities.						
Device Information – Digital X-ray machine						
Model No –						
Type –						
Duration - last 6 months						
Location	**Total (n)**	**Digital X-ray machine**		**Digital X-ray positive**		**Digital X-r**
		Positive	Negative	Microbiology-Positive	Microbiology-Negative	Microbiology-Positive
Total						

Screening to Interpretation time to perform one CXR / interpretation (Process flow)	
How often do you use Technologies: Frequency of use in a week	

User Feedback	
Strength (user friendly software/Performance/ Technical Supports etc)	
Challenges/Weakness (technical support/limitations/issues related to technology)	
Scope for improvement (if any)	

Additional information on Cost	
Cost of Technology you paid	
Any Additional cost is required to manage (Please Specify) **This includes all the associated Healthcare cost & technology**	

*Sections which are not applicable please mention 'NA'.

Annexure 04 Calculation of TP, FP, TN and FN

1 **True Negative (TN) = Specificity*Actual Negative**

Actual Negative = N-Actual Positive

Actual Positive = Specificity *N/100

2 **True Positive (TP) = Sensitivity*Actual Positive**

Actual Positive = Sensitivity *N/100

3 **False Negative = Actual Positives - True Positive**

Actual Positive = Sensitivity *N/100

4 **False Positive = False Positive rate * Actual Negative**

Actual Negative = N-Actual Positive

False Positive rate = (1 - Specificity)