



Artificial Intelligence in TB: What Clinicians Should Know in 2026

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Accreditation Statement



Accreditation Statement

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UAN Number: JA0000238-0000-26-036-L99-P

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IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1.0 Interprofessional Continuing Education (IPCE) credit for learning and change.

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A record of attendance will be provided to all registrants for requesting credits in accordance with state nursing boards, specialty societies or other professional associations.

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Available Credit

- 1.00 ACPE,
- 1.00 *AMA PRA Category 1 Credit™*
- 1.00 ANCC
- 1.00 Attendance
- 1.00 IPCE

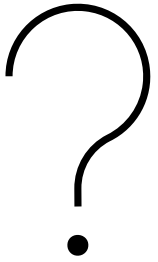
Disclosure:

No relevant financial disclosures to report and no mention of off-label use of any medications or products

Learning Objectives

- Define AI applications in TB care
- Recognize AI tools used in screening
- Explain AI benefits in clinical settings

Polling Question



In my facility/ jurisdiction, AI (Artificial Intelligence) is used in healthcare delivery

- A. On a regular basis
- B. Occasionally
- C. Not yet
- D. I don't know

In 2026, focus should be on:

- Teaching Safe, Responsible Use of AI
- Understanding Ethics Implications
- Getting Healthcare Professionals involved in AI Development/implementation/ ethical use
- ...as the AI Field is developing at a speed already surpassing human “controls”

AI Started as SURP

“ The Constitutional Convention of AI”

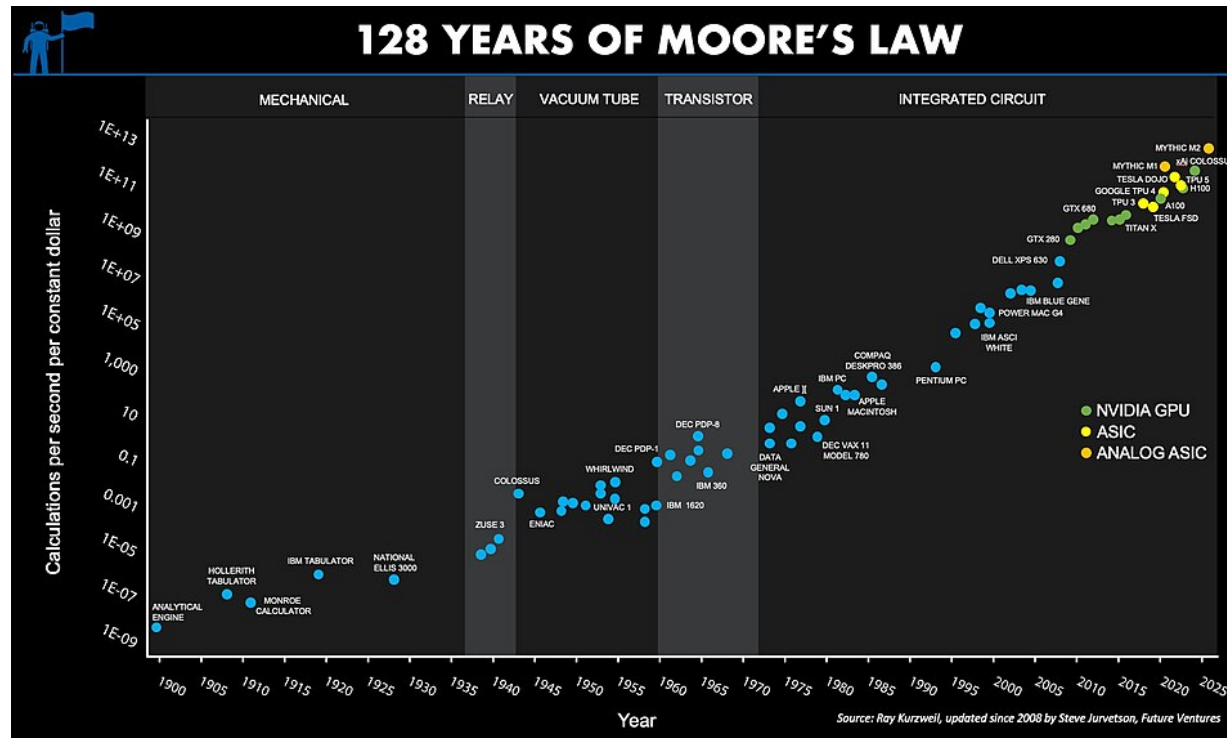
- “We propose that a 2-month, 10-man study of artificial intelligence be carried out during the summer of 1956 at Dartmouth College in Hanover, New Hampshire. The study is to proceed on the basis of the conjecture that every aspect of learning or any other feature of intelligence can in principle be so precisely described that a machine can be made to simulate it.”

A PROPOSAL FOR THE
DARTMOUTH SUMMER RESEARCH PROJECT
ON ARTIFICIAL INTELLIGENCE

J. McCarthy, Dartmouth College
M. L. Minsky, Harvard University
N. Rochester, I. B. M. Corporation
C. E. Shannon, Bell Telephone Laboratories

AI Boom – post- 2020's

- Intersection of Computing Power, Critical Mass of available Info, Development of Transformer Architecture, and investment in AI.

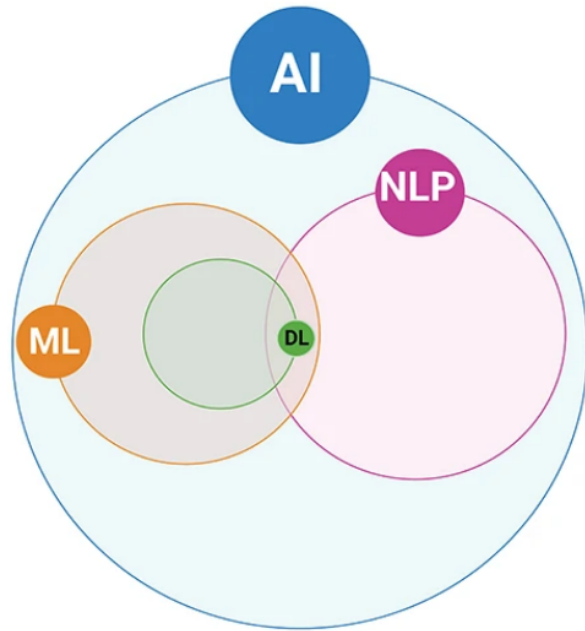


Definitions

- ***Artificial Intelligence (AI)***: Machine programs trained to do cognitive tasks typically requiring a human.
- ***Machine Learning (ML)*** : A process of training machines to recognize patterns. Deep learning is a type of ML that uses complex layers of hidden data
- ***Supervised Learning***: ML using sorted data to train a model
- ***Unsupervised Learning***: ML aims to find patterns in data content

- ***Deep Learning***: A type of ML that uses “deep” layers of artificial “neural” networks to teach computers to interpret data in a way inspired by the human brain.
- ***Language Learning Models (LLM’s)*** : a type of AI that can process and generate human-like text. LLM’s are trained on large amounts of data, such as internet databases, and use deep learning to analyze unstructured data and recognize patterns.

Understanding the Relationship Between AI, ML, DL, and NLP

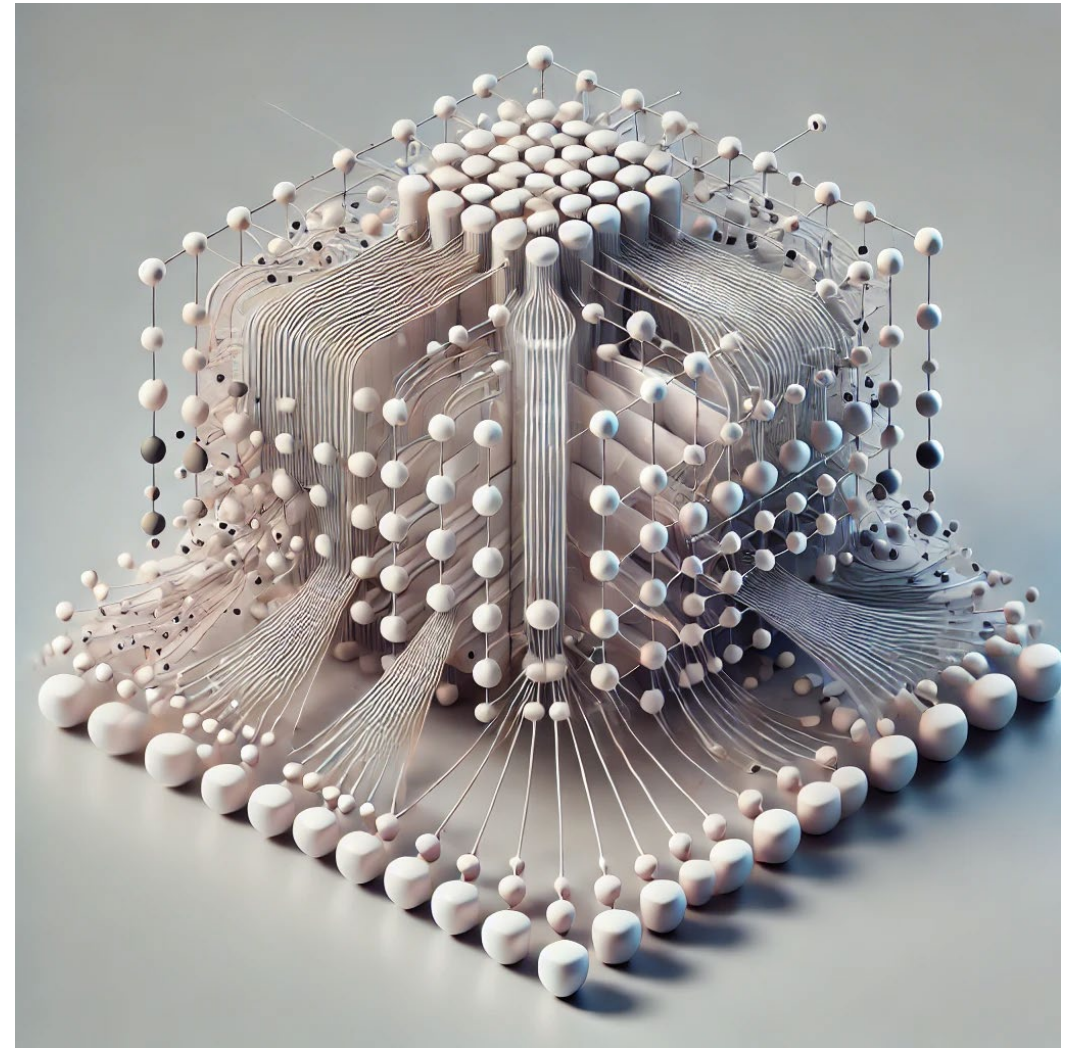
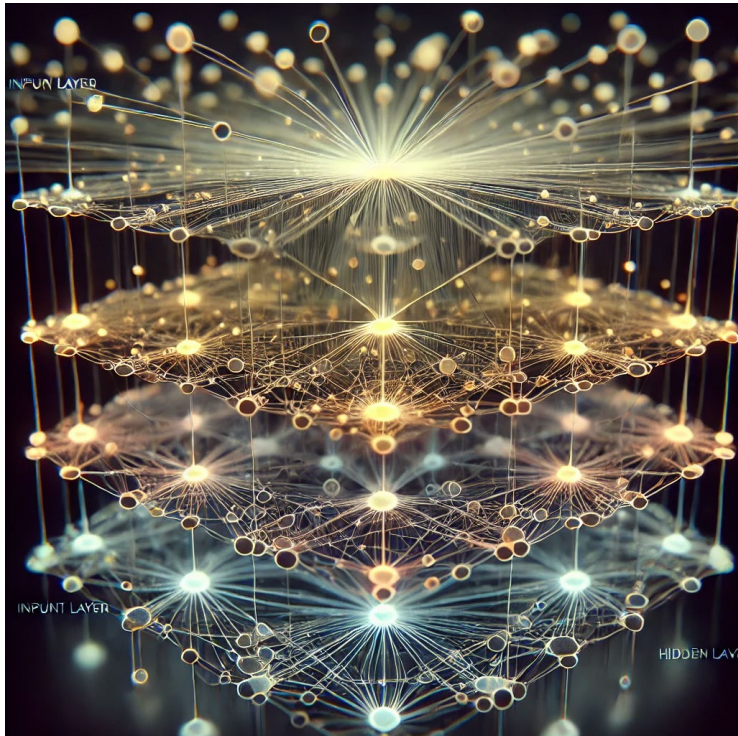


- AI is a broad field that includes anything related to making machines smart.
- NLP is the branch of AI focused on teaching machines to understand, interpret, and generate human language.
- ML is a subset of AI that involves systems that can learn by themselves.
- DL is a subset of ML that uses models built on deep neural networks to detect patterns with minimal human involvement.

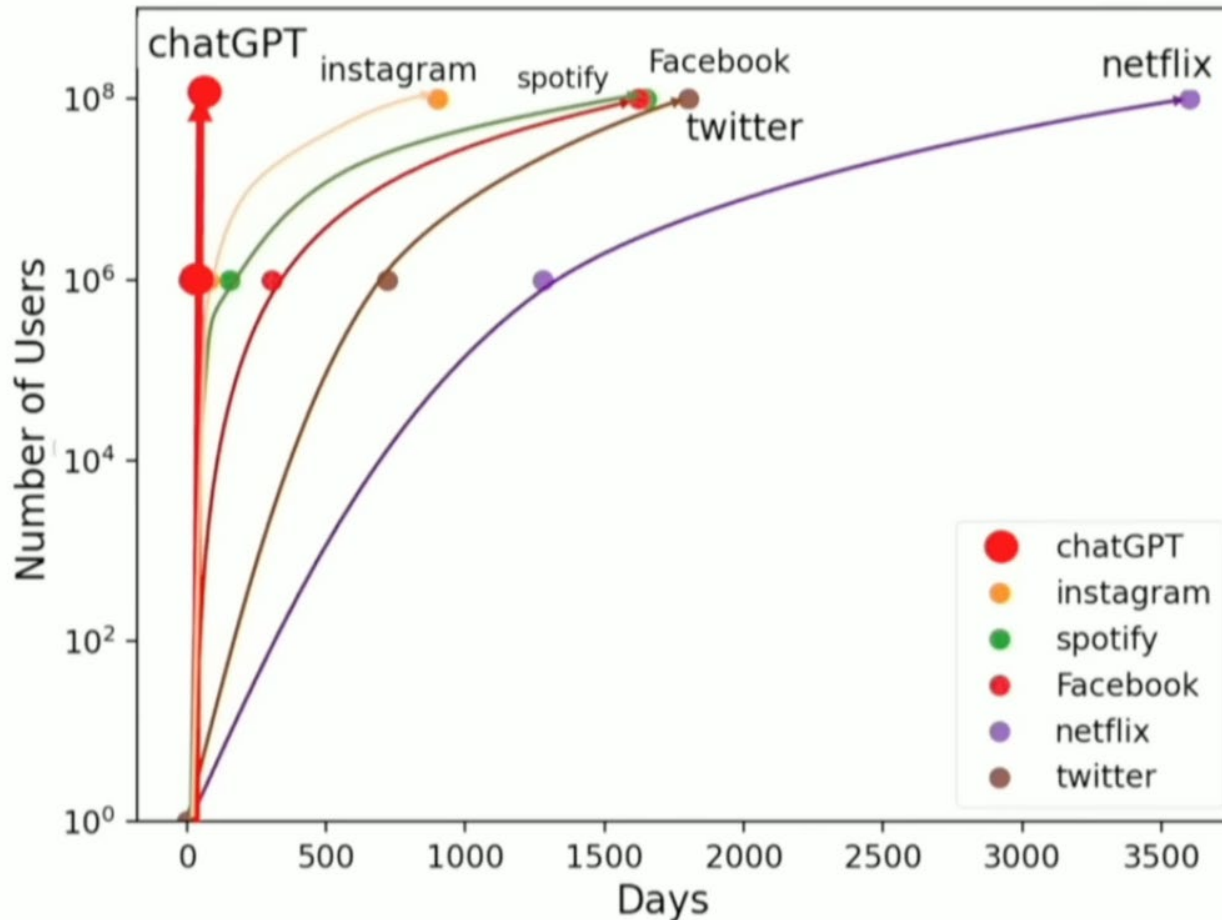
Tracing the Evolution of AI with a Better Understanding of the Relationship Between AI, ML, DL, and NLP

Alowais, S.A., Alghamdi, S.S., Alsuhebany, N. *et al.* Revolutionizing healthcare: the role of artificial intelligence in clinical practice. *BMC Med Educ* **23**, 689 (2023). <https://doi.org/10.1186/s12909-023-04698-z>. Creative Commons Attribution 4.0 International License

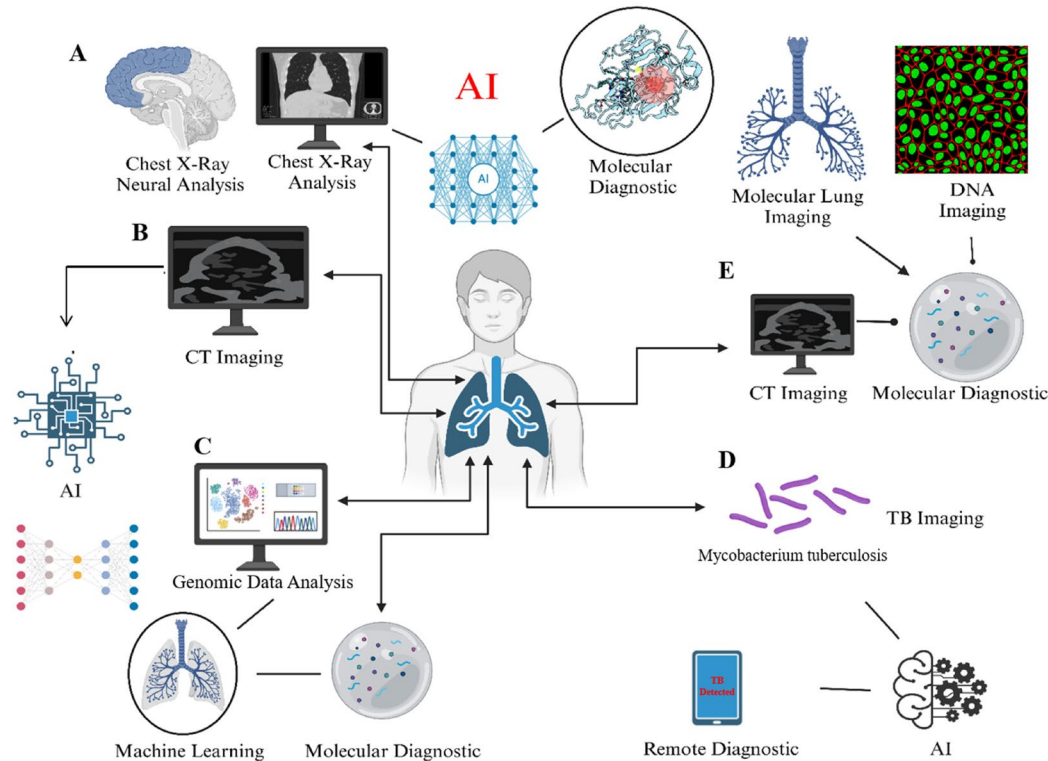
Neural Network and LLM Representation



“Public AI” launch-5 days to reach 1 million users. 2 months to 100 million users



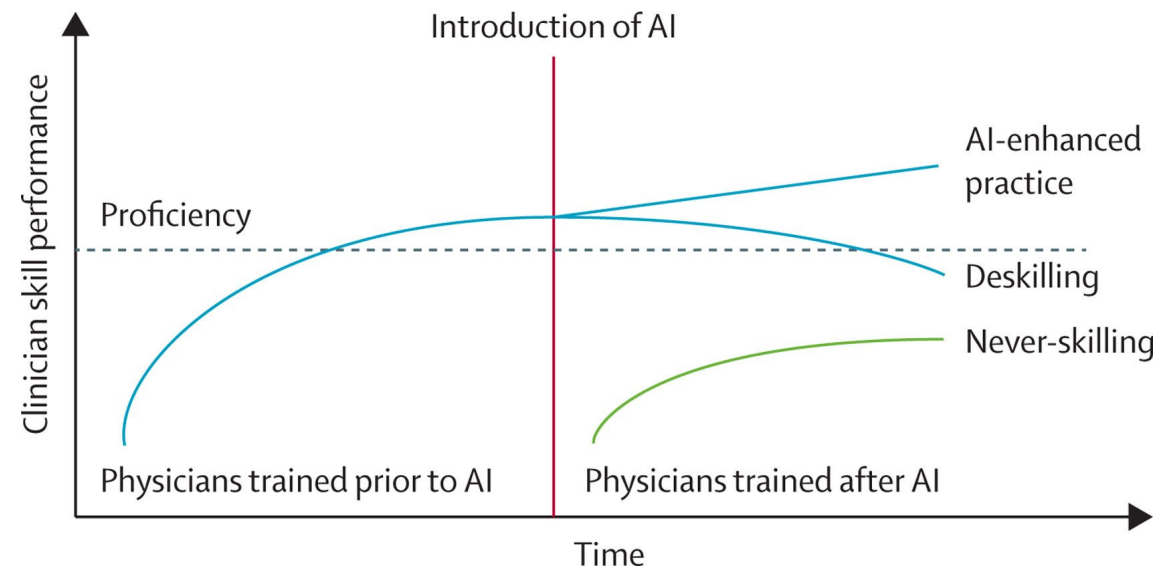
AI in TB: Possibilities-Endless



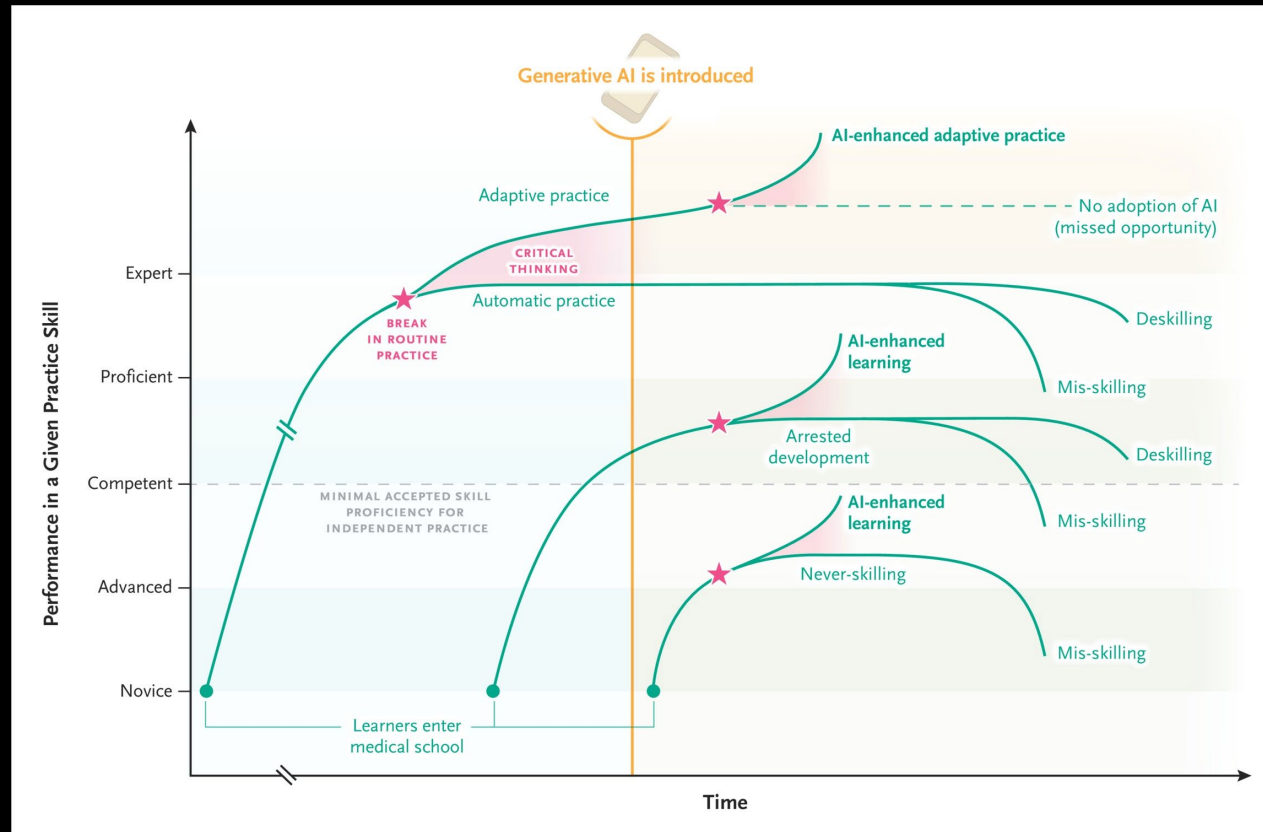
S.Memon et al., Integration of AI and ML in Tuberculosis (TB) Management: From Diagnosis to Drug Discovery- Creative Commons Attribution (CC BY) license (<https://creativecommons.org/licenses/by/4.0/>).

AI For Learners- Enhancing or Dumbing Down?

- **Preserving clinical skills in the age of AI assistance**
- Berzin, Tyler M et al. - The Lancet, Volume 406, Issue 10513, 1719



Development of Adaptive Practice and the Effects of AI.

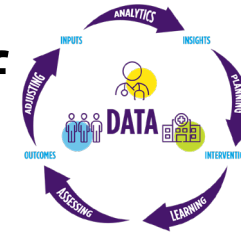


Abdulnour R-EE et al. N Engl J Med 2025;393:786-797



The NEW ENGLAND
JOURNAL of MEDICINE

AI tensions across the spectrum of medical training












	Pre-clinical	M3-M4 (UME)	PGY (GME)
Potential Threats	Passive use = Never skilling	PHI, FERPA Unsupervised learning	Assessment vs Coaching (Autonomy tension) Deskilling
Opportunities	Active use = Augmented learning	Low stakes, low cost automated practice Precise, actionable, & timely insights	Level setting Deliberate practice Precision gap analysis Tailored excellence Automated credentialing

Undifferentiated learner



Independent physician

GPT versus Resident Physicians — A Benchmark Based on Official Board Scores

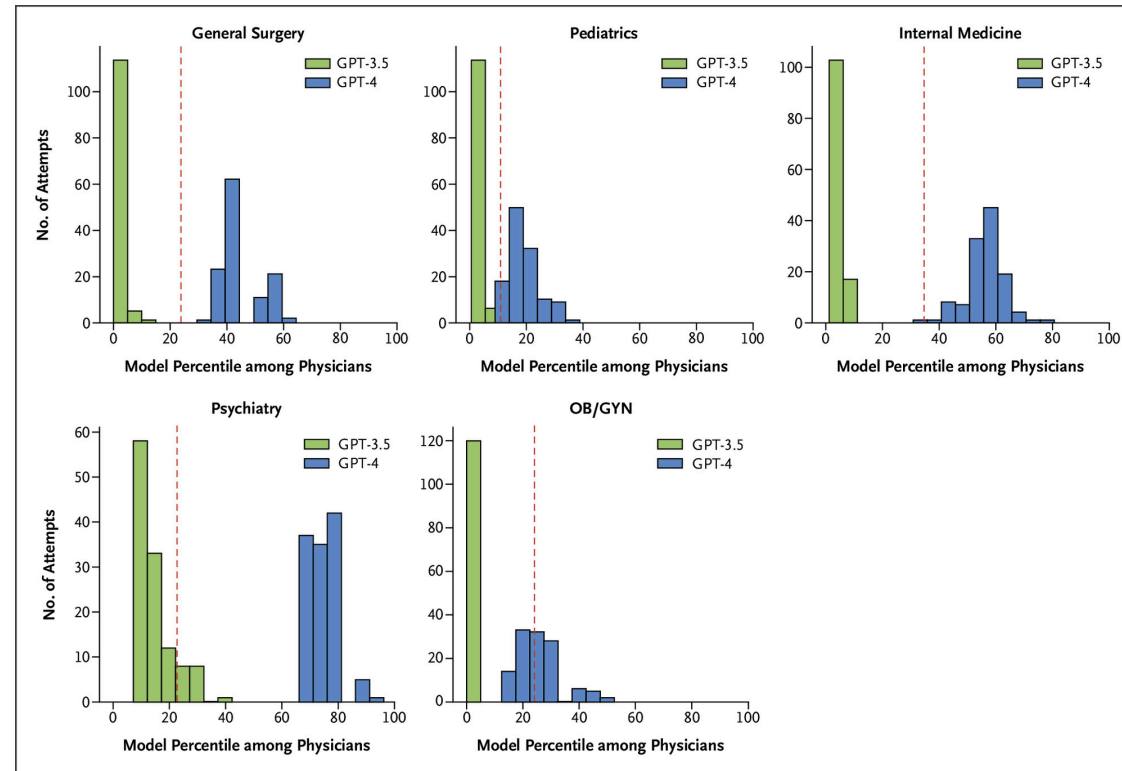
Authors: Uriel Katz, M.D.  , Eran Cohen, M.D. , Eliya Shachar, M.D. , Jonathan Somer, B.Sc. , Adam Fink, M.D. , Eli Morse, M.D. , Beki Shreiber, B.Sc. , and Ido Wolf, M.D.  [Author Info & Affiliations](#)

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GPT-3.5 DOES NOT PASS MEDICAL BOARDS

GPT-4 PASS WITH FLYING COLORS

We are now way past that- are LLM's expert?

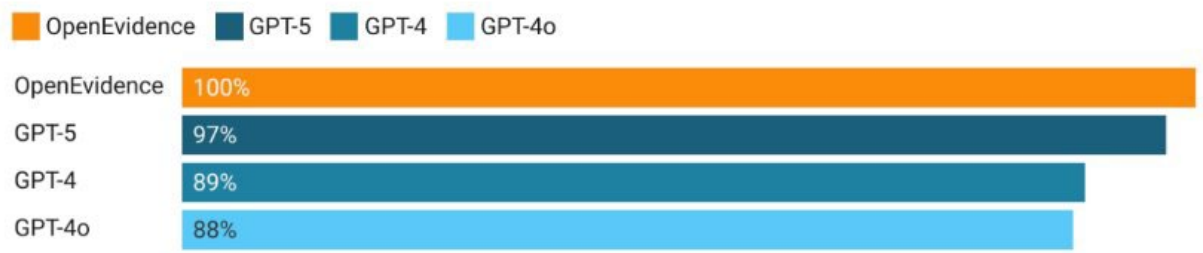


OpenEvidence Creates the First AI in History to Score a Perfect 100% on the United States Medical Licensing Examination (USMLE)

August 15, 2025



Score on the United States Medical Licensing Examination

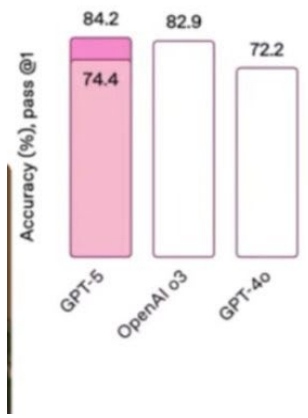


USMLE dataset: Kung TH, Cheatham M, Medenilla A, Sillos C, De Leon L, et al. Performance of ChatGPT on USMLE: Potential for AI-assisted medical education using large language models. PLOS Digital Health. 2023;2(2):e0000198. doi:10.1371/journal.pdig.0000198. 8/15/25

Academic

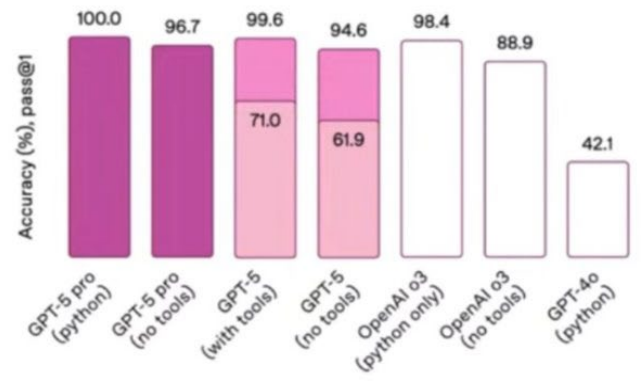
MMMU

College-level visual problem solving
● Without thinking ● With thinking



AIME 2025

Competition math
● Without thinking ● With thinking



When Systems Fail

Why AI Can Give Wrong Advice

- **Hallucinated facts:** AI may invent citations or data.
- **Outdated data:** Training data may predate the latest clinical guidelines/ Give too much weight to recent data
- **No clinical context:** AI doesn't examine patients or factor in unique presentations.
- **Generalized responses:** AI often gives one-size-fits-all advice, or generalities when one precise response is needed.

If a person was seen walking at 6 PM and entered his house at 8 PM, was he alive at 7 PM

Yes — assuming the timeline is accurate, he was alive at 7 PM.

If he was:

- Seen walking at 6 PM, and
- Entered his house at 8 PM,

then he must have been alive at some point between those times in order to enter the house at 8 PM. Therefore, at 7 PM (which falls between 6 and 8), he would necessarily have been alive.

Unless this is intended as a trick question with missing information (e.g., mistaken identity, inaccurate timestamps, etc.), the logical answer is yes.



Do you know how your predecessor chatgpt 3.0 answered this

I don't have access to specific past responses generated by earlier versions like "ChatGPT 3.0," nor do I have a database of how it answered individual questions.

However, this is a classic logic question, and earlier versions would very likely have answered the same way: yes, assuming the timeline is accurate and there's no trick involved.

If you're asking because you saw a different answer somewhere, I'd be curious what it said — sometimes the twist depends on hidden assumptions.



+ Ask anything

ChatGPT can make mistakes. Check important info.

He said that there is no way to know. He could have been alive at 6 PM, and at 8 PM, but then resurrected in between or there could have been other circumstances

That's a fair point — it comes down to what assumptions you're allowed to make.

- **In ordinary real-world reasoning**, "seen walking at 6" and "entered his house at 8" implies continuous normal life in between, so **yes**, he was alive at 7.
- **In strict logic / riddle mode**, the statements only guarantee he was alive at *some moment* at 6 and *some moment* at 8. They **don't explicitly state** he was alive continuously, so weird edge cases (mistaken identity, staged footage, time stamps wrong, "entered" meaning carried in, resurrection, etc.) mean **there's no airtight proof** about 7.

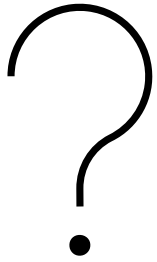
So:

- **Common-sense answer**: yes.
- **Pedantic/logic-lawyer answer**: you can't know for sure.

If you want to make the question unambiguous, you can add: "continuously observed" or "with no gaps" or "under normal biological assumptions."



Polling Question



What type of AI tools do you use?

- A. Free, public version (example : ChatGPT, OpenEvidence)
- B. Step-up, paid public version (ChatGPT Plus, Copilot Premium, etc)
- C. Institutional License (Chatgpt.edu, Copilot Enterprise, etc)
- D. Do not use

You, as Learner- and AI Power User



What AI Will Help You Do

Clarify Research Problems

Brainstorm synonyms, Medical Subject Headings MeSH terms, and alternate comparators to refine your PICO question.

Search Smarter

Draft reproducible search strings with AND/OR logic to be used with databases.

Screen Efficiently

Triage abstracts, cluster cluster themes, and generate evidence maps to organize findings.

Structure Methods

Outline study designs, variables, and potential potential biases as starting points for validation.

Write Responsibly

Follow institution guidelines, cite original articles, and disclose AI assistance transparently.



Critical Guardrails

AI Is Not a Source

Never copy-paste AI output as final text. Treat it as scaffolding, verify every claim against peer-reviewed literature, and cite original works.

Be Transparent

When AI meaningfully shapes your work, include an appropriate disclosure statement in methods or acknowledgments consistent with APA guidance.

Protect Privacy & Reduce Bias

Never input identifiable patient data. Prompt AI to list possible biases and plan mitigation strategies before mentor sign-off.

Using AI-Generated Summaries



Key Principles

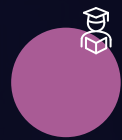
- Use AI summaries to decide which articles are most relevant
- Read the most important papers in full yourself
- Never copy-paste AI text directly into your paper
- Write summaries using your own understanding and voice
- Cite original articles, not AI tools

This workflow ensures you maintain academic integrity while leveraging AI efficiency.

Why Use "Approved" AI Tools ?



Tool X- Secure, authenticated
authenticated access with
institutional credentials



Educational support and
tutoring




Zoom AI/ Teams Companion

Meeting summaries and
transcription- stay secure

What "Approved" Means

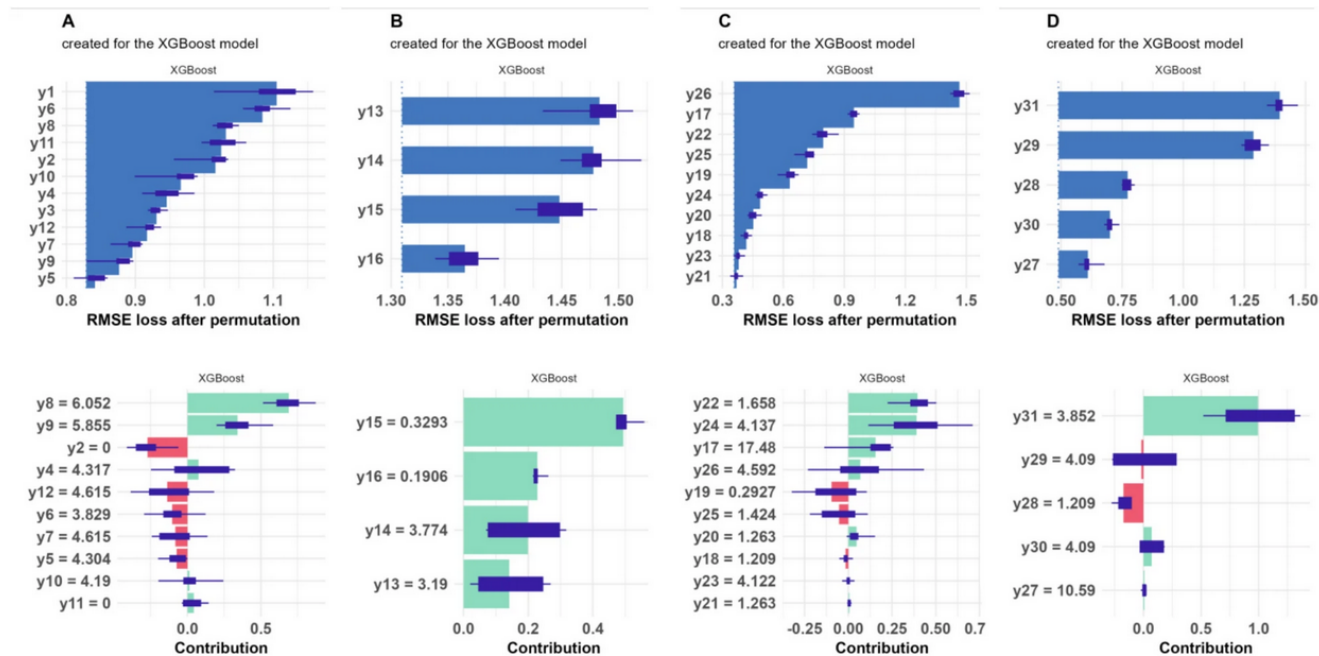
IT Governance has reviewed these tools for secure network use. When
When you authenticate with @institution credentials:

- Data is encrypted and secure
- Your data cannot train LLMs for others
- AI accesses only data you have permission to use

 **Important:** Never create free accounts for other AI tools using
tools using Institution credentials. Always use personal email if
email if you need personal AI tools- and NEVER put institution
institution data in free LLM's/AI tools.

Explainable artificial intelligence (XAI)

- XAI encompasses a collection of procedures and techniques that enable human users to understand and have confidence in the outcomes and output generated by ML algorithms.
- Mitigates the “black box” effect frequently encountered while using AI models (Ex: SHAP models)
- “restores credibility” vis-à-vis of human cognition
- For now, AI Analysis/ Decision Making is better seen as always needing a “human in the loop”
- **AI can identify patterns in huge datasets**

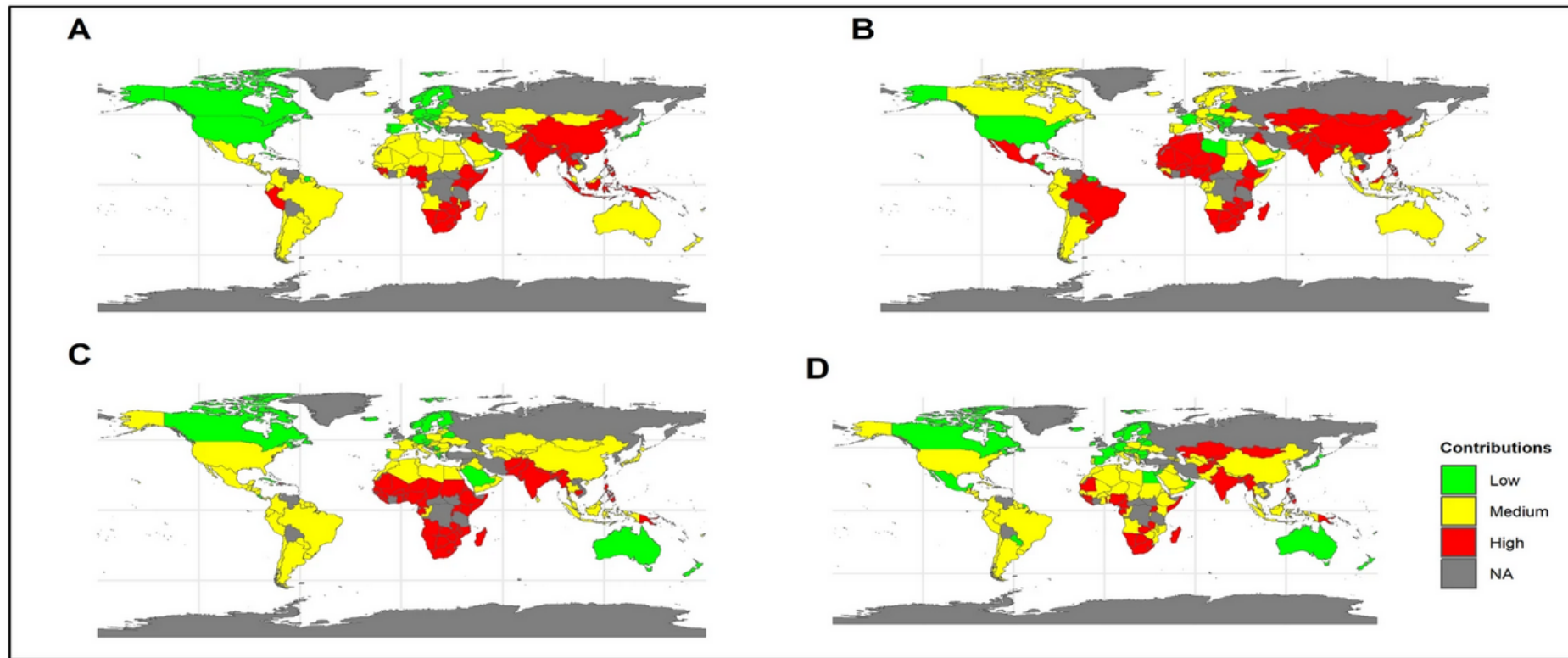


Feature important of **A**) TB treatment and HIV-related TB factors, **B**) Health risk factors, **C**) Socio-demographic and economic factors, **D**) Environmental and land use factors, **E**) overall factors. × 1: Incidence of tuberculosis (per 100,000 population per year); × 2: Number of incident tuberculosis cases (HIV-positive cases); × 3: Incidence of tuberculosis (per 100,000 population) (HIV-positive cases); × 4: Deaths due to tuberculosis among HIV-negative people (per 100,000 population); y1: Treatment success rate for new TB cases; y2: Treatment success rate for previously treated TB cases; y3: Treatment success rate for HIV-positive TB cases; y4: Treatment success rate for patients treated for MDR-TB; y5: Treatment success rate for XDR-TB cases; y6: New cases tested for RR-/MDR-TB (%); y7: Previously treated cases tested for RR-/MDR-TB (%); y8: Confirmed cases of RR-/MDR-TB; y9: Cases started on MDR-TB treatment; y10: TB patients with known HIV status (%); y11: Tested TB patients HIV-positive (%); y12: HIV-positive TB patients on ART (antiretroviral therapy) (%); y13: Prevalence of tobacco use (%); y14: Age-standardized prevalence of hypertension among adults aged 30 to 79 years (%); y15: Most sold brand of cigarettes—retail price in US\$ at official exchange rates; y16: Most sold brand of cigarettes—Taxes as a % of price (total tax); y17: Population, total; y18: GDP growth (annual %); y19: Hospital bed density (per 10,000 population); y20: Density of physicians (per 10,000 population); y21: Density of pharmaceutical personnel (per 10,000 population); y22: Domestic general government health expenditure (%); y23: Life expectancy at birth (years); y24: Mortality rate under 5 per 1000 live births; y25: Population growth (annual %); y26: Access to electricity; y27: Land area (sq. km); y28: Arable land (% of land area); y29: Agricultural land (% of land area); y30: Forest area (% of land area); y31: Air pollution.

Utilizing artificial intelligence to predict and analyze socioeconomic, environmental, and healthcare factors driving tuberculosis globally
Md. Siddikur Rahman & Abu Bokkor Shiddik *Scientific Reports* volume 15,
 Article number: 13619 (2025) CC license 4.0

Socioeconomic, environmental, and healthcare factors driving tuberculosis globally

From: [Utilizing artificial intelligence to predict and analyze socioeconomic, environmental, and healthcare factors driving tuberculosis globally](#)



Global mean SHAP contribution of **A)** TB treatment and HIV-related TB factors, **B)** Health risk factors, **C)** Socio-demographic and economic factors, **D)** Environmental and land use factors. The map was created in R (version 4.4.2, <https://cran.rstudio.com>) using the `naturalearth` package, which provides natural earth map data for visualization. The `sf` package was used for spatial data handling to ensure accurate representation of geographic boundaries.



Simple AI Applications in Patient care

AI Chatbots may offer timely support and personal advice 24/24 to patients in need

- TB Treatment Support Tools launched through Univ. Washington Responsible Health AI lab. Includes Spanish language Chatbots
- Univ. of Georgia's School of Computing developed deep learning models that could recognize patterns of adherence using DOT Selfie project. This project aims to improve TB medication adherence in resource limited settings.
- YOU Could create your own AI agent/ train an LLM to focus on the care gaps that you are seeing in your practice. When appropriately supervised, this could act as a clinician enhancer.
- Ambient Listening tools may revolutionize the way you interact, document, and communicate with your patients (especially the new generation)




Various Frequent AI Tools for the clinician (Harvard AI Conference, 2025)

AI Resources

Tool	Potential Use	Examples	Notes
Open Evidence	<p>Clinical Care ▾</p> <ul style="list-style-type: none"> Aggregate, synthesize, and visualize peer-reviewed medical literature 	<ul style="list-style-type: none"> Clinical decision support Patient instructions / translation Build differential diagnoses Clinical letters (ex. PA denial) 	<ul style="list-style-type: none"> Founded in 2021 Need NPI to register but is free Not HIPAA compliant PICO framework useful
<p><i>Other clinical decision support tools:</i></p> <p>Clinical Key AI Dyna AI UpToDate</p>	<p>Clinical Care ▾</p>	<ul style="list-style-type: none"> Clinical decision support 	<ul style="list-style-type: none"> Associated costs (vs openevidence above is free)
Glass Health	<p>Clinical Care ▾</p>	<ul style="list-style-type: none"> Draft differential diagnoses and assessment/plan options to consider 	
ChatGPT	<p>Education - Direct Teaching ▾</p> <p>Clinical Care ▾</p>	<ul style="list-style-type: none"> Multilevel learning multiple choice question generation Grading unstructured questions Qualitative analysis of feedback Draft patient instructions 	<ul style="list-style-type: none"> OpenAI o1 Hub OpenAI
Custom GPTs	<p>Clinical Care ▾</p>	<ul style="list-style-type: none"> Some organizations have set up PHI-compliant AI interfaces, i.e. a homemade version of ChatGPT that has much of the functionality but interacts with a HIPAA compliant interface. If you aren't already aware of this existing, it can be worth reaching out!! (example from Vanderbilt: https://www.vumc.org/dbmi/GenerativeAI) Shown example in conference of U-M GPT, which is for UM students/faculty/staff 	
<p><i>Ambient AI (if your institution has/allows):</i></p> <p>Dragon Ambient eXperience (DAX)</p>	<p>Clinical Care ▾</p>	<ul style="list-style-type: none"> Microsoft and Nuance Ambient listening, conversational AI, generative AI Documentation / Note generation EHR integration 	

Article

A New Artificial Intelligence-Based Method for Identifying Mycobacterium Tuberculosis in Ziehl–Neelsen Stain on Tissue

Sabina Zurac ^{1,2,3,†} , Cristian Mogodici ^{2,†}, Teodor Poncu ^{2,4,†}, Mihai Trăscău ^{2,4,*}, Cristiana Popp ^{1,2,*}, Luciana Nichita ^{1,2,3}, Mirela Cioplea ^{1,2}, Bogdan Ceachi ^{2,4} , Liana Sticlaru ^{1,2}, Alexandra Cioroiu ^{1,2}, Mihai Busca ^{1,2}, Oana Stefan ¹, Irina Tudor ¹, Andrei Voicu ², Daliana Stanescu ², Petronel Mustatea ^{2,5}, Carmen Dumitru ¹  and Alexandra Bastian ^{1,3}

¹ Department of Pathology, Colentina University Hospital, 21 Stefan Cel Mare Str, Sector 2, 020125 Bucharest, Romania; sabina_zurac@yahoo.com (S.Z.); luciana.nichita@umfcd.ro (L.N.); mirelacioplea@yahoo.com (M.C.); liana_ro2004@yahoo.com (L.S.); dragusin_alexandra88@yahoo.com (A.C.); thanatogenesis@gmail.com (M.B.); oana.stefan93@yahoo.com (O.S.); irinafrincu@yahoo.com (I.T.); carmendumitru2004@yahoo.com (C.D.); alexandra.bastian@umfcd.ro (A.B.)

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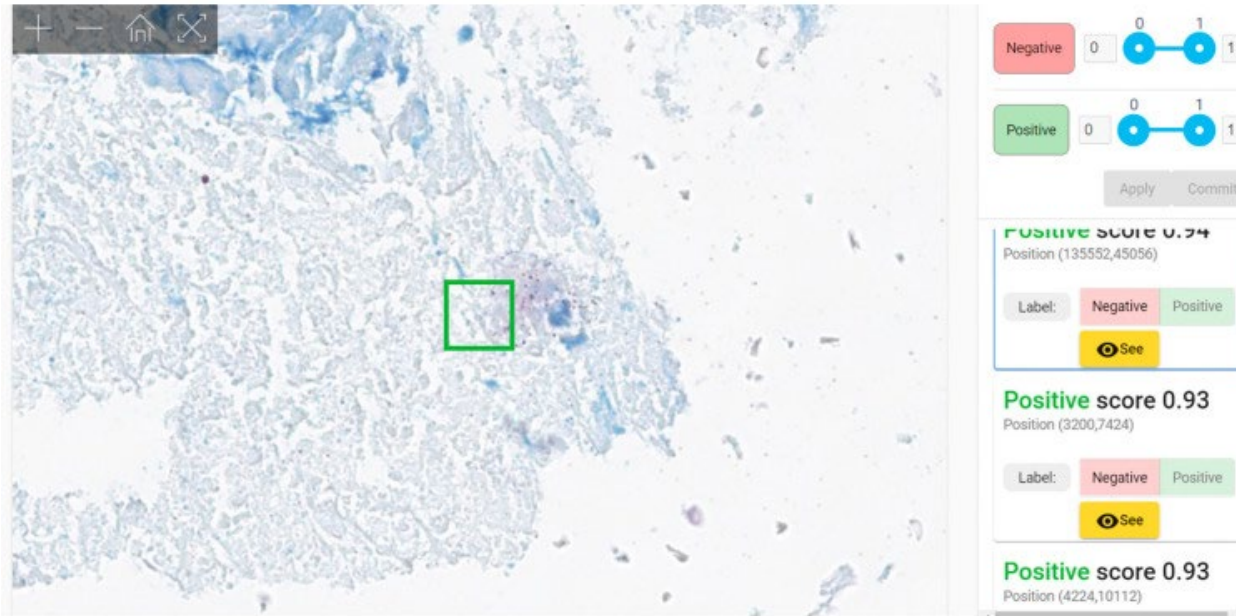
³ Department of Pathology, Faculty of Dental Medicine, University of Medicine and Pharmacy Carol Davila, 37 Dionisie Lupu Str, Sector 1, 020021 Bucharest, Romania

⁴ Department of Computer Science, Faculty of Automatic Control and Computers, University Politehnica of Bucharest, 313 Splaiul Independenței, Sector 6, 060042 Bucharest, Romania

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- DX of MTB in tissue can be difficult especially in atypical cases with granulomas and other mimicking etiologies
- Since the bacillus is small, pathologist spends significant time analyzing slides
- Authors observed that unacceptable rates of errors occur even when resident errors are excluded from diagnosis
- Authors developed an AI-assisted model based on a large training dataset. AI automatically detects potential positives, in less time. Final decision regarding diagnosis belongs to pathologist
- The clinical test presented 98.33% accuracy, 95.65% sensitivity, and 100% specificity for the AI-assisted method



AI-Assisted Improved Diagnosis and Time Savings

Paucibacillary lesion identified as TB by 6 of 8 pathologists, average of 12.5 minutes. AI time to detection was 9 seconds

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HOT TOPIC: AI-Aided TB Detection- Imaging



- Born out of necessity- in the battle against TB, resources are still scarce
- AI software variants from Qure.ai received FDA breakthrough device designation in February of 2024 and was WHO endorsed for field detection of TB
- Computer aided detection and diagnosis device that analyses Chest X-rays to localize all noted radiological signs suggestive of TB and provide an accompanying conclusion regarding the presence or absence of TB.
- STOP TB / REACH Award/ Grant

WHO consolidated guidelines on tuberculosis

Module 2: Screening

Systematic screening for
tuberculosis disease

3.2 Use of computer-aided detection software for automated reading of digital chest radiographs

10. Among individuals aged 15 years and older in populations in which TB screening is recommended, computer-aided detection software programmes may be used in place of human readers for interpreting digital chest X-rays for screening and triage for TB disease (*new recommendation: conditional recommendation, low certainty of evidence*).

Table 4. Sensitivity and specificity ranges of computer-aided detection software and human readers interpreting digital chest radiographs for detection of bacteriologically confirmed TB across three software programmes, from three independent evaluations of the software in a range of populations and settings

Type of case and type of reader	Accuracy estimate range	
	Sensitivity	Specificity
WHO target product profile	> 0.90	> 0.70
Screening use case		
CAD software	0.90–0.92	0.23–0.66
CXR with human reader	0.82–0.93	0.14–0.63
Triage use case		
CAD software	0.90–0.91	0.25–0.79
CXR with human reader	0.89–0.96	0.36–0.63

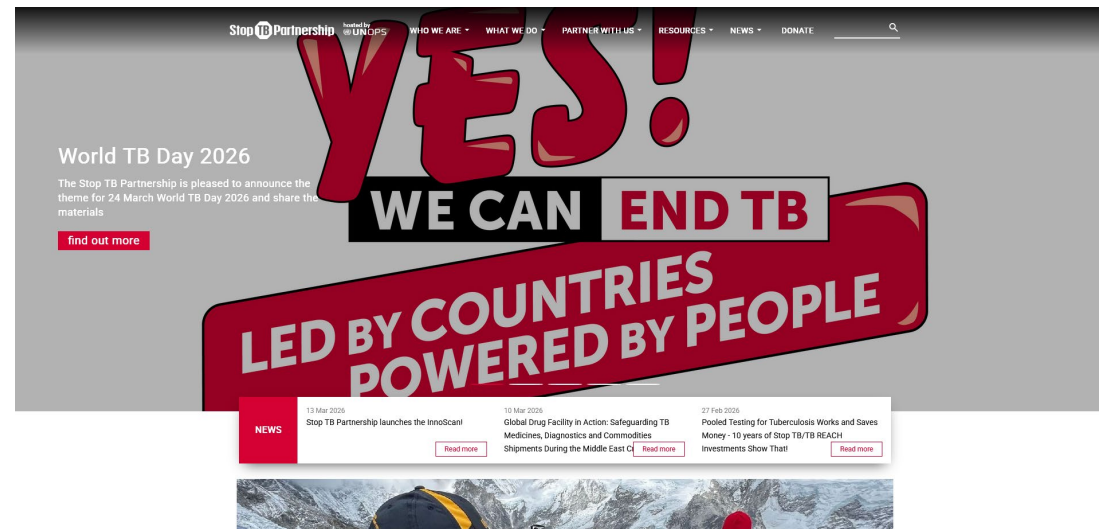
CAD: computer-aided detection; CXR: chest X-ray.

Implementation of CAD CXR detection

(WHO Module 2- detection)

- There is substantial variation in the diagnostic accuracy (sensitivity and specificity) of CAD programs across settings, even when using the same technology set to the same threshold. Thus, it will be essential to calibrate the threshold to be used for any given software for each setting and population in which it will be used in order to ensure that the accuracy, predictive values, overall yield and requirements for further diagnostic testing are as expected. Further guidance on calibrating CAD in a new setting is provided in the operational handbook accompanying the guidelines, which links to a protocol for collecting the requisite data and a web-based tool to assist with the analysis of data and calculation of receiver operating characteristic curves and sensitivity and specificity values across a range of thresholds.
- The feasibility of implementing CAD depends heavily on the setting, including ensuring access to the required equipment for conducting digital radiography, a stable internet connection and required maintenance for the hardware and software. The required resources and the cost-effectiveness will depend on the setting, including the availability and salaries of human readers.
- Based on : CAD4TB V6 (Delft Imaging), Lunit INSIGHT CXR V1 (Lunit) and qXR V2 (Qure.ai)

Welcome to the [Stop TB Partnership](#) and [FIND](#) resource centre on computer-aided detection products for the diagnosis of tuberculosis





AI SOFTWARE WITH CURRENT CERTIFICATIONS:

the depth of testing, post-market surveillance, as well as the ability to support end users.

 <p>Genki</p> <p>Certification: US FDA 510(k) clearance, CE Class IIb, Indian CDSCO + 5 others</p> <p>Development : On the Market</p> <p>Intended Age Group 4+ Years</p>	 <p>CAD4TB</p> <p>Certification: v7: CE Class IIb certified from 4 ages and above / v8: pending CE receipt</p> <p>Development : On the Market</p> <p>Intended Age Group 4+ Years</p>	 <p>RADIFY</p> <p>Certification: SAHPPA, US FDA 510(k) clearance, ISO 13485:2010</p> <p>Development : On the Market</p> <p>Intended Age Group 0+ Years</p>	 <p>InferRead DrChest</p> <p>Certification: CE Class IIb</p> <p>Development : On the Market</p> <p>Intended Age Group 10+ Years</p>
 <p>JF CXR-1</p> <p>Certification: China NMPA Class III</p> <p>Development : On the Market</p> <p>Intended Age Group 15+ Years</p>	 <p>JVIEWERX(JLD-02K)</p> <p>Certification: CE Marked Class I, Japan PMDA</p> <p>Development : On the Market</p> <p>Intended Age Group 10+ Years</p>	 <p>Lunit INSIGHT CXR</p> <p>Certification: CE MDR Class IIa, Korea MFDS</p> <p>Development : On the Market</p> <p>Intended Age Group 4+ Years (CE), 14+ Years (Korea)</p>	 <p>DeepCatch X TB</p> <p>Certification: Korean MFDS Approved (overseas market only)</p> <p>Development : On the Market</p> <p>Intended Age Group 15+ Years</p>
 <p>NEXUS AI CXR 1.0</p> <p>Certification: CE IIb, ISO 13485</p> <p>Development : On the Market</p> <p>Intended Age Group 15+ Years</p>	 <p>ChestEye, ChestLink</p> <p>Certification: ChestEye: CE Class IIb, ChestLink: CE Class IIb</p> <p>Development : On the Market</p> <p>Intended Age Group 18+ Years</p>	 <p>Inspectra CXR</p> <p>Certification: Thai FDA Notification Certificate, HSA Singapore Authorization</p> <p>Development : On the Market</p> <p>Intended Age Group 15+ Years</p>	 <p>qXR</p> <p>Certification: CE Class IIb MDR (qXR v4.1), US FDA Breakthrough Device + 9 others</p> <p>Development : On the Market</p> <p>Intended Age Group 3+ Years</p>
 <p>AXIR</p> <p>Certification: CE Marked Class IIa</p> <p>Development : On the Market</p> <p>Intended Age Group 10+ Years</p>	 <p>Rayscape CXR</p> <p>Certification: CE Marked Class I, CE MDR class IIa (pending), ISO 13485</p> <p>Development : On the Market</p> <p>Intended Age Group 10+ Years</p>	 <p>ZYing M-D IntelReport, Mag</p> <p>Certification: China NMPA Class II, China NMPA Class III (Pending)</p> <p>Development : On the Market</p> <p>Intended Age Group 15+ Years</p>	 <p>Yuno Med-Chest X-ray, Pro</p> <p>Certification: CE MDD v1.1, CE MDR v1.2(2025.02), Korea MFDS v1.2, + 3 others</p> <p>Development : On the Market</p> <p>Intended Age Group 19+ Years</p>

AI SOFTWARE IN DEVELOPMENT:

AI Solutions: Certification Pending

 <p>Chest AI</p> <p>Certification: Pending</p> <p>Development : On the Market</p> <p>Intended Age Group 0+ Years</p>	 <p>TBXNet++</p> <p>Certification: Pending</p> <p>Development : On the Market</p> <p>Intended Age Group 10+ Years</p>
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AI Solutions: Under Development

 <p>TXnet</p> <p>Certification: Pending</p> <p>Development : Under Development</p> <p>Intended Age Group 18+ Years</p>	 <p>OpenTB (Provisional)</p> <p>Certification: Pending</p> <p>Development : Under Development</p> <p>Intended Age Group 18+ Years</p>	 <p>EIRL Chest TB</p> <p>Certification: Thai FDA (pending)</p> <p>Development : Under Development</p> <p>Intended Age Group 18+ Years</p>	 <p>DeepCheX</p> <p>Certification: Pending</p> <p>Development : Under Development</p> <p>Intended Age Group 18+ Years</p>
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<https://www.ai4hlth.org/products>

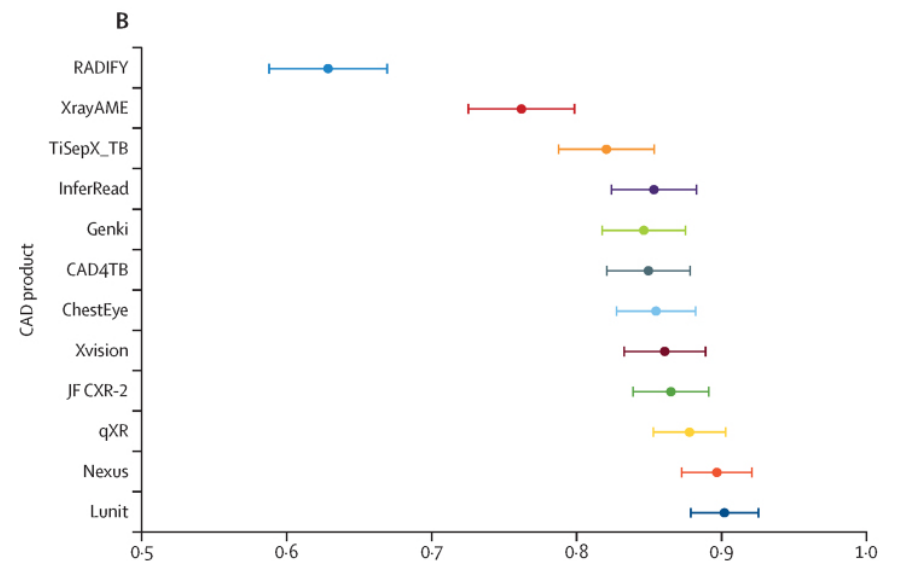
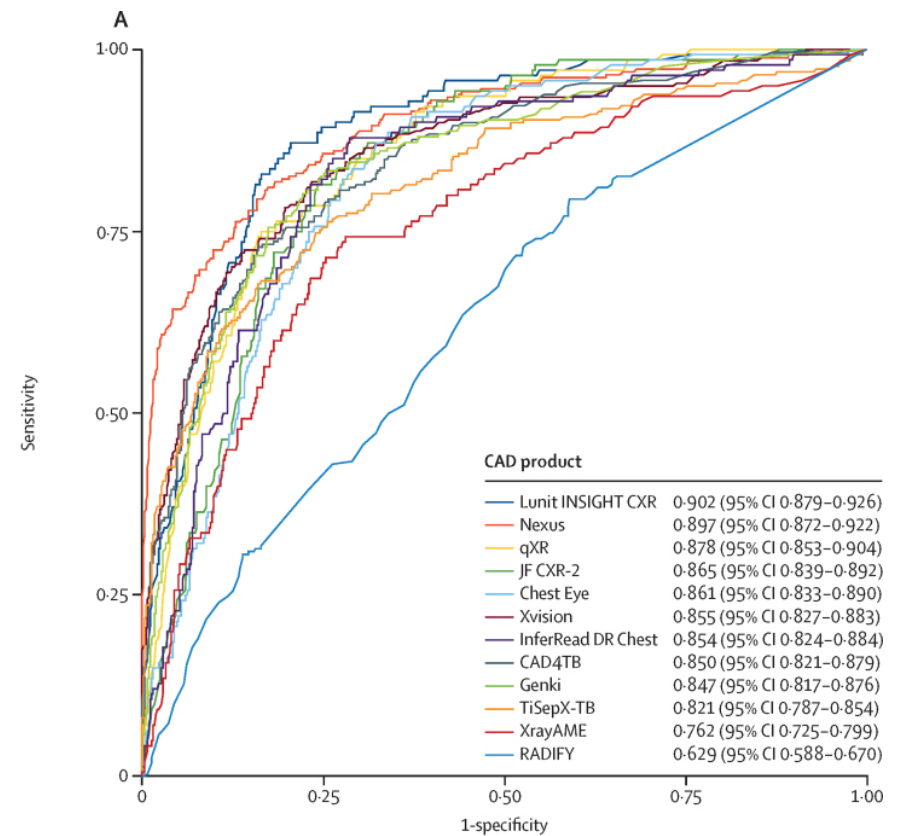
Variability of CAD Software TB Detection

- Several previously unevaluated products performed similarly to those evaluated by WHO. Thresholds differed across products and demographic subgroups.
- All products generally performed worst in older individuals, people with previous tuberculosis, and people with HIV
- Need for standardization

Qin ZZ. Et al., Computer-aided detection of tuberculosis from chest radiographs in a tuberculosis prevalence survey in South Africa: external validation and modelled impacts of commercially available artificial intelligence software. *Lancet Digit Health*. 2024 Sep;6(9):e605-e613.

At 90% sensitivity, five products achieved greater than 60% specificity: Lunit, Nexus, JF CXR-2, qXR, and ChestEye, with Lunit and Nexus achieving the 70% target

Qin ZZ. Et al., Computer-aided detection of tuberculosis from chest radiographs in a tuberculosis prevalence survey in South Africa: external validation and modelled impacts of commercially available artificial intelligence software. Lancet Digit Health. 2024 Sep;6(9):e605-e613.

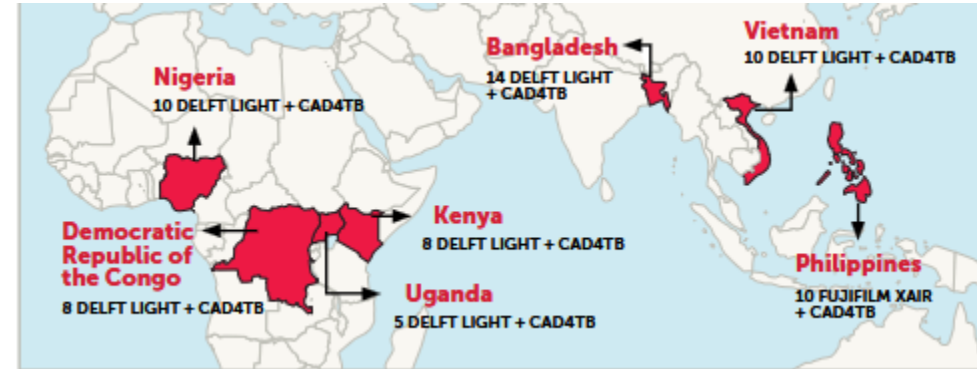


How useful is a portable X-Ray CAD System?

The introducing New Tools Project (iNTP) represented the largest multi-country roll-out of ultra-portable digital X-ray systems and computer-aided detection (CAD) software for tuberculosis (TB) screening programs (STOP TB partnership)

STOP TB PARTNERSHIP | USAID INTRODUCING NEW TOOLS PROJECT (iNTP)

Results: Ultra-portable X-ray and computer-aided detection (CAD)

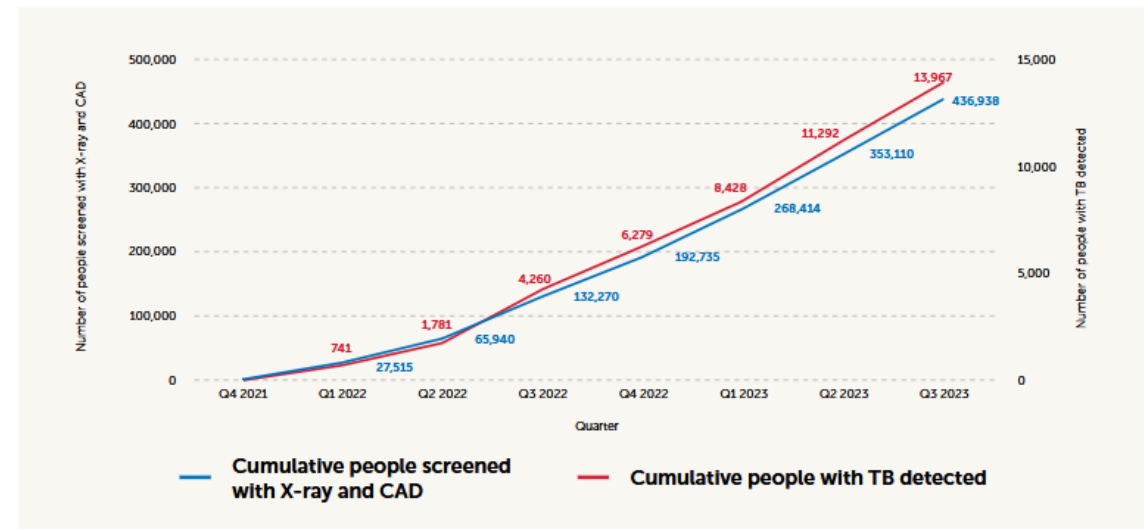


- Ultra-portable digital X-ray systems are battery-operated, emit low radiation, and can be packed into backpacks or cases for transportation to field settings. CAD software leverages artificial intelligence (AI) to identify signs of TB in chest X-rays (CXR) and can be used alongside or as an alternative to human readers
- Project Deployed to 7 Countries
- Total number of people reached for screening: 436,938
- People diagnosed with TB: 13,967
- People with lung abnormalities suggestive of TB detected by CAD and who received a confirmatory test: 42,097

Results- USAID STOP TB partnership

<https://www.stoptb.org/>

Figure 1: Cumulative number of people screened with X-ray and CAD, and people with TB detected by the project



Other Fields of Use

- AI-powered monitoring of cough counts as a prediction of TB disease and/or treatment progression
- AI-powered classification of cough sounds for TB screening
- <https://www.stoptb.org/what-we-do/accelerate-tb-innovations/digital-health-technology-hub/ai-powered-cough-analysis-and-monitoring>

Title (Year)	AI algorithm	Validation type	Performance
HeAR- Health Acoustic Representations (2024)	HeAR	Internal	AUC: 0.652 (0.520, 0.784).
Detection of tuberculosis by automatic cough sound analysis (2018)	Un-named AI	Internal	AUC: 0.95 Sensitivity: 95%
Accelerating cough-based algorithms for pulmonary tuberculosis screening: Results from the CODA TB DREAM Challenge (2024)	Various, un-named AI	Internal	AUC ranged between 0.689 (0.647,0.732)- 0.743 (0.703,0.780) across algorithms
Predicting tuberculosis from real-world cough audio recordings and meta data (2024)	Various, un-named AI	Internal	Average AUC across algorithms: 0.70± 0.05
Automatic cough classification for tuberculosis screening in a real-world environment (2021)	Un-named AI	Internal	AUC: 0.94 Sensitivity: 93%
Acoustic epidemiology of pulmonary tuberculosis and COVID-19 leveraging explainable AI/ML (2022)	Timbre	External	Sensitivity: 80-83% against microbiological reference standard Sensitivity: 59% against radiological reference standard
TBscreen: A passive cough classifier for tuberculosis screening with a controlled dataset (2024)	TBscreen	Internal	AUC ranged from: 0.61 (± 0.14) to 0.86 (±0.03), depending on the dataset. Sensitivity ranged from: 0.16 (± 0.11) to 0.80 (± 0.03), depending on the dataset
Early detection of tuberculosis with machine learning cough audio analysis: Towards more accessible global triaging usage (2023)	Un-named AI	Internal	AUC: 88%
Development and clinical validation of Swaasa AI platform for screening and prioritization of pulmonary TB (2023)	Swaasa	External	AUC: 0.90 Sensitivity: 75%

- Over 10 studies showing value of cough monitoring, especially in resource-poor settings
- AI analyses cough sounds to predict whether TB was present or absent. To evaluate AI, studies then compared AI's prediction to microbiological and clinical reference standards that indicated if individuals truly had TB or not
- Mapping identified high performance of AI for TB cough classification, with the area under the receiver operating characteristic curve, an indication of overall accuracy, ranging from 0.61 [\pm 0.14] (TB screen in Kenya) to 0.95 (algorithm in South Africa). In studies where it was reported, sensitivity was generally high but ranged from 0.16 \pm 0.11 to 0.95.

- AI use in Precision Medicine / Connection with TDM
- AI use to speed up drug discovery in TB
- Scrub data from EHR's and extract "TB indicators" flags as well as research level data

FDA now has regulatory framework re : AI enabled Medical Devices

The screenshot shows the FDA website page for Artificial Intelligence-Enabled Medical Devices. The page is titled "Artificial Intelligence-Enabled Medical Devices" and is part of the "Software as a Medical Device (SaMD)" section. The page content includes an introduction, a description of the AI-Enabled Medical Device List, and a list of contents. The page is displayed in a browser window with the URL <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices>.

Artificial Intelligence-Enabled Medical Devices

The FDA encourages the development of innovative, safe, and effective medical devices, including devices that incorporate artificial intelligence (AI).

The AI-Enabled Medical Device List is a resource intended to identify AI-enabled medical devices that are authorized for marketing in the United States. Digital health innovators can refer to this list to gain insights into the current device landscape and regulatory expectations, which can help foster innovation and ensure public safety. This list can also provide transparency for healthcare providers and patients to clearly identify when medical devices use AI technologies.

Contents of the AI-Enabled Medical Devices List:

- The devices in this list have met the FDA's applicable premarket requirements, including a focused review of the device's overall safety and effectiveness, which includes an evaluation of study appropriateness for the device's intended use and technological characteristics.
- A direct link to the FDA's database entry of an AI-enabled medical device is provided. The database entry contains releasable information, such as summaries of safety and effectiveness. Note, the summaries are not all inclusive and do not include most of the information that may be submitted in an application.
- The list is not a comprehensive resource of AI-enabled medical devices. Instead, the list includes AI-enabled medical devices that were identified primarily based on the use of AI-related terms in the summary descriptions of their marketing authorization document and/or the device's classification. The set of AI terms is based on the [FDA Digital Health and Artificial Intelligence Glossary](#).

Software as a Medical Device (SaMD)

- [Clinical Decision Support Software Frequently Asked Questions \(FAQs\)](#)
- Artificial Intelligence-Enabled Medical Devices**
- [Artificial Intelligence in Software as a Medical Device](#)
- [Good Machine Learning Practice for Medical Device Development: Guiding Principles](#)
- [Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles](#)
- [Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles](#)

Content current as of: 03/04/2026

Regulated Product(s)
Medical Devices

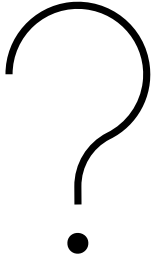
[Feedback](#)

Regulatory Efforts (Arguably not Enough)

- Health AI regulation has primarily come from states, however, HHS has issued a strategy document and enacted White House Policy for a National AI Strategy. FDA enacted a digital health advisory committee.
- In 2025, 47 states introduced more than 250 bills including health AI regulation. Of those, 33 became law in 21 states
- In 2026, 200 bills regarding AI are being considered.



Polling Question



What keeps you up at night regarding AI?

- A. Nothing
- B. Fear it will replace me
- C. Fear it will replace my kids
- D. Fear it is not regulated enough

Questions and Answers





Thank you