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Traditional, Complementary & Integrative Medicine (TCIM) Research: international standards & guidelines in an era of digital intelligence

传统、补充与整合医药学研究: 数智时代的国际标准与规范

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King's CICM:

✓ Built on our world-leading health sciences & care;

King's College London in World University Rankings (QS 2026*):

- **No. 1** in Nursing
- **No. 4** in Dentistry
- **No. 11** in Life Sciences and Medicine

✓ 22 King's staff and 55 Honorary Advisors (TCM etc);

✓ Using science to unite TCM and Western medicine.

King's College London

St Thomas' Hospital

Maudsley Hospital

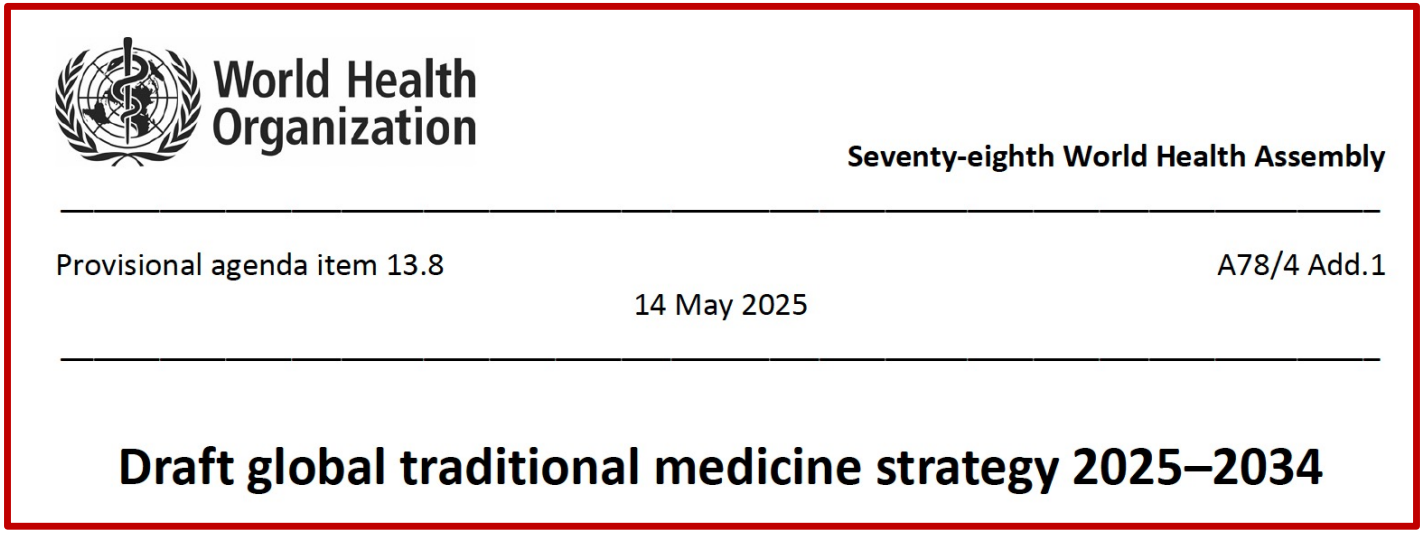
King's College Hospital

Guy's Hospital

* **QS**: Quacquarelli Symonds, the name of the British company that publishes the rankings.

New WHO Traditional Medicine Strategy—Four Objectives

1. Building evidence base;
2. Creating appropriate regulatory mechanisms;
3. Integrating safe & effective TCIM into health systems;
4. Optimising the cross-sector value of TCIM and empowering communities.



World Health Organization

Seventy-eighth World Health Assembly

Provisional agenda item 13.8 — A78/4 Add.1

14 May 2025

Draft global traditional medicine strategy 2025–2034

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Talha Burki. *Lancet.* May 31, 2025; 405:1897-8

- The WHO strategy **repeatedly highlights the importance of research**.
- "We now have this **amazing opportunity** to contribute to the development of TM using **frontier scientific methods**".
  - AI, maturing omics technologies, systems biology & pharmacology, innovative RCTs, real-world research and implementation science;
  - Significant progress has been made in developing international standards and GP guidelines, yet unprecedented challenges are also being faced.

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Great progress has been made in the past decade in developing TCIM-related guidelines & standards, as showcased at "Sharing" & "Publications" of our website

- **GP-TCM, WHO, ConPhyMP guidelines** on herbal naming, QC, extraction and chemical analysis.
- **WHO guidelines** on TM terminologies, herbal GMP, acupuncture nomenclature, and benchmarks for acupuncture, tuina & massage training and practice.
- **ISO standards** of TCM and Indian medicine materials and products;
- **WFCMS standards** on TCM venues, training & assessment; and
- Reporting guidelines and novel extensions published by **The Equator Network**…

Aim of This Talk

An update on the development of AI & digital technologies in health & TCIM and related international standards and guidelines.

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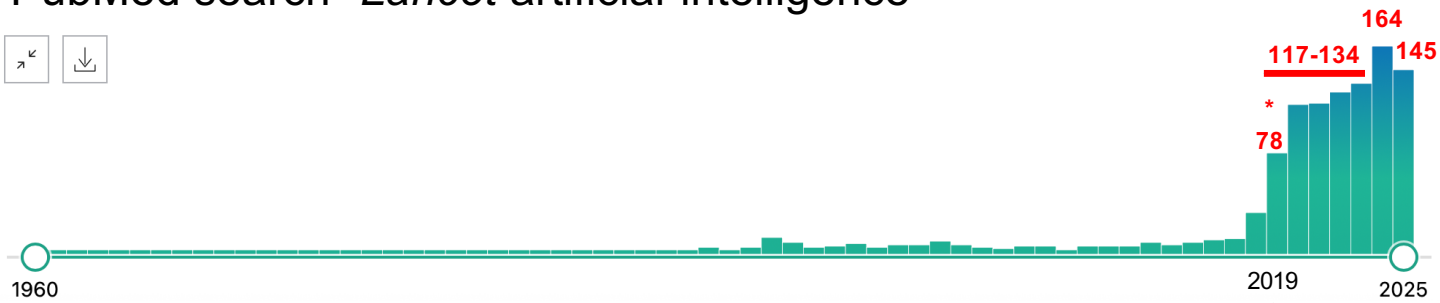
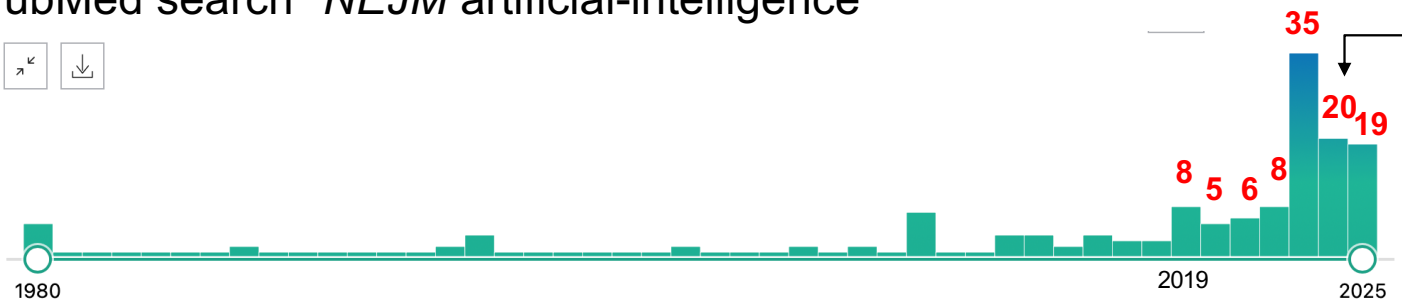
Surge in research on AI and medicine (by 24 Oct. 2025)

PubMed search "*Lancet* artificial-intelligence"



May 2019: *Lancet Digit Health was launched*

PubMed search "*NEJM* artificial-intelligence"



Jan. 2024: *NEJM AI was launched*

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A joint report by the Medical Schools Council and Health Data Research UK urged medical schools to boost AI and Data Science Training, Feb. 2025

https://www.medscape.co.uk/viewarticle/medical-schools-urged-boost-ai-and-data-science-training-2025a10002zv?ecd

https://www.medschools.ac.uk/media/3238/data-science-in-the-medical-curriculum.pdf

The Digital Health Competencies in Medical Education Framework: An International Consensus Statement Based on a Delphi Study.
Car J, et al. JAMA Netw Open. 2025 31st Jan;8(1):e2453131.

Professor Josip Car
Professor of Population and Digital Health Sciences
Head of School of Life Course & Population Sciences
King's College London

The FDA issued the first Draft Guidance on AI for drug development in Jan. 2025; submit Comments by 7th Apr 2025 (still allowing late comments)

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological

Warraich HJ, et al. **FDA Perspective** on the Regulation of AI in Health Care and Biomedicine. **JAMA**. 2025 Jan 21;333(3):241-247.

- "The FDA has authorised almost 1000 AI-enabled medical devices";
- "…received hundreds of regulatory submissions for drugs that used AI in their discovery and development."

A onling fundamental change: From AI tools to AI agents

The of Agentic AI Teammates in Medicine.
Zou J, Topol EJ. *Lancet* Feb. 2025;405:457

Editorial. **Rapid generative AI rollout in health care.**
Lancet Digit Health. 2025 Aug;7:100909.

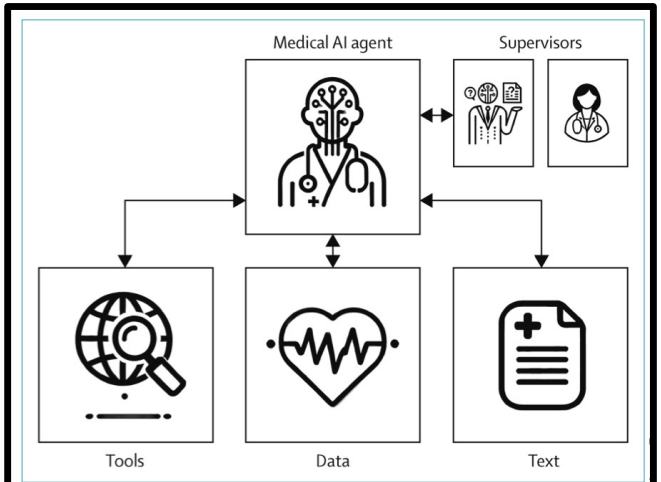

Figure: Medical AI agent orchestrating tools and data while monitored by human clinician and AI reviewer

- **The USA:** On June 30, Microsoft generative AI (genAI) system outperforms physicians in diagnosing complex cases: 80% by genAI vs 20% by experts.
- **The UK:** https://www.gov.uk/government/news/world-first-ai-system-to-warn-of-nhs-patient-safety-concerns（Press release: On June 30 ）
- **Europe***: Delphi-2M*, a modified LLM, analyses medical records and lifestyle to provide risk estimates for >1,000 diseases (Shmatko A et al. *Nature 2025;:647:*248–56 (published Sep 17/ 6 Nov.).
- **China:** DeepSeek has been deployed in hundreds of Chinese hospitals for diagnostics, decision support, and hospital management (*JAMA* 2025;333:1866-9)

These rapid rollout are despite apparent potential risks:

- **Deskilling (cognitive debt?), poor evaluation, regulation risk, patient safety and quality of care** —echoing **an open letter from leading AI researchers and ethicists** in March 2023 called for a pause on developing new genAI systems,...

18 August 2025

AI Is the New Dr Google — Across the Globe

https://www.medscape.com/viewarticle/chatgpt-your-clinic-whos-expert-now-2025a1000lqt

20 August 2025

UK Clinicians Want Clearer AI Guidance and Oversight

https://www.medscape.co.uk/s/viewarticle/uk-clinicians-want-clearer-ai-guidance-and-oversight-2025a1000lz4

29 August 2025

Why AI in Healthcare Still Struggles in **Europe**

https://www.medscape.co.uk/s/viewarticle/why-artificial-intelligence-healthcare-still-struggles-2025a1000muu

9 Sep 2025

AI chatbots are already biasing research; we must establish guidelines for their use now

(**Lin Z.** *Nature* 2025;**645**: 285)

4 Sep 2025

Major NHS AI-scribe trial shows 'transformative' patient benefits

https://www.digitalhealth.net/2025/09/major-nhs-ai-scribe-trial-shows-transformative-patient-benefits/

12 Sep 2025

It takes a network: Clinicians are building AI healthcare from the ground up.

https://healthinnovationnetwork.com/insight/it-takes-a-network-clinicians-are-building-ai-healthcare-from-the-ground-up/

- **Responsible AI UK:** An international ecosystem for responsible AI research and innovation: https://rai.ac.uk/about-us/
- **The Responsible AI Institute**: A global and member-driven non-profit dedicated to enabling successful responsible AI efforts in organizations: https://www.responsible.ai/

Key Developments in AI application in TCM:

1. **ShennongAlpha, an AI-powered knowledge portal for standardised naming, translation and AI-based chat**, developed by Westlake University. (Yang Z et al. *Cell Discov.* 2025 Apr 1;11:32): https://shennongalpha.westlake.edu.cn/
2. **General LLM for TCM** diagnosis & prescription (Liu Y, et al. *NPJ Digit Med*. 2025 Jul;8:466)
   - **LLMs performed comparably to acupuncturists in Western diagnosis** and showed variable performance in TCM-specific tasks.
   - **GPT-4o, Qwen 2.5 Max, and Doubao 1.5 Pro outperform other LLMs in TCM diagnosis and acupoint selection.**
3. **Tianyi** and **TCMEval**, a TCM all-rounder LLM and a comprehensive evaluation benchmark, were jointly developed by BUCM, NUCM, CACMS, Capital Medical University. (Liu Z et al. *Information Fusion.* Feb. 2026;126(Part B): 103663

Other TCM AI platforms and TCM big models:

- CloudPhar 星斗云: https://www.taslypharma.com/kygx.jhtml
- Ancient & Modern Medical Case Cloud Platform 古今医案云平台: http://yiankb.com
- Dajing TCM 大经中医: https://www.dajingtcm.com/dajinggpt
- ShenNong-TCM-LLM 神农中医药大模型: https://github.com/michael-wzhu/ShenNong-TCM-LLM?utm_source=medsci
- Zhongjing TCM LLM 仲景中医大语言模型： https://github.com/SupritYoung/Zhongjing
- Huangdi Model 黄帝模型: https://github.com/Zlasejd/HuangDI
- Materia Medica Model 本草模型: https://github.com/SCIR-HI/Huatuo-Llama-Med-Chinese

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In July 2025, a WHO technical brief mapped global use of AI in 6 areas of TM

1. In health care:
- Diagnosis and prediction-based diagnosis.

2. In clinical care
- AI-based clinical decision support systems
- AI-powered trial design.

3. In health research and drug development
- Application of AI for drug development and health research.
  - Pattern recognition for drug development.
  - Genetic information analysis
  - Identification and direct utilization of TM plants.

4. In health system management and planning
- Utilizing hospital management information systems

5. In preserving and advancing Traditional Medicine knowledge
- Online repositories for TM knowledge
- Defensive protection against biopiracy.
- Conservation and identification of biodiversity.
- Natural language processing & automated literature reviews
- Translating Indigenous Knowledges.

6. In policy-making for Traditional Medicine
- Data governance models.
- Agreements between national entities and Indigenous Peoples, and local communities for data advancement.

WHO. Mapping the application of AI in TM. Technical brief. World Health Organization, published on 11 July 2025
https://www.who.int/publications/i/item/9789240107663

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Areas of interest were identified

Other areas of interest with little supporting evidence

- Docking/simulation studies
- Pathway identification
- Artificial chemical sensors
- Comparative studies
- Data augmentation
- Cross-disciplinary learning
- Crowdsourcing
- AI collaboration platforms

Global regulatory landscape was mapped

Table 1 Regulatory landscape governing TM, AI and AI in health in WHO regions and Member States

WHO region	Number of Member States	National policy on TM (2018)[4] (*15*)	AI regulations or initiatives (any) (*55*)	Related AI policy initiatives in health (*56*)
African Region	47	41 (87%)	8 (17%)	3 (6%)
Region of the Americas	35	11 (31%)	10 (29%)	9 (26%)
South-East Asia Region	11	9 (82%)	4 (36%)	3 (27%)
European Region	53	11 (21%)	42 (79%)	19 (36%)
Eastern Mediterranean Region	21	9 (43%)	6 (29%)	1 (5%)
Western Pacific Region	27	15 (56%)	7 (26%)	4 (15%)
Global	194	96 (53%)	77 (36%)	39 (19%)

WHO. Mapping the application of AI in TM. Technical brief. World Health Organization, published on 11 July 2025
https://www.who.int/publications/i/item/9789240107663

WHO's General Guidance on Ethics and Governance of AI in Health

The guidance identifies five major areas commonly associated with risks and challenges in the application of AI in health:

1) scientific and research domains;
2) the development of digital infrastructures;
3) targeting underrepresented and vulnerable population groups;
4) strategizing investment, procurement and public finance initiatives; and
5) addressing diversity, languages and cultural contexts.

WHO's Guidance on Regulatory Considerations on AI for Health

The guidance addresses some of the AI risks, and approaches to risk management from a total product lifecycle perspective. It underscores intended use and analytical and clinical validation, data quality, privacy and data protection, as well as engagement and collaboration.

WHO. Mapping the application of AI in TM. Technical brief. World Health Organization, published on 11 July 2025
https://www.who.int/publications/i/item/9789240107663

Five Risks and Five Risk Management Aspects

Main Risks

- Biopiracy threat.
- Gaps in digital infrastructure and literacy
- Inadequate data infrastructure.
- Insufficient engagement with and recognition of TM
- Localisation vs integration of AI solutions in TM

Risk Management

Problem identification

- Critically assess the appropriateness and necessity of AI technologies.
- Evaluate institutional readiness and workforce competences
- Review legal frameworks

Design

- Prioritising usability and human factors in AI applications for TM.
- Apply a participatory design approach.
- Include ethical considerations and values.
- Be mindful of good-quality data.
- Develop targeted communications to interpret AI models

Development

- Create benchmarking frameworks.
- Ensure ethical and regulatory compliance.
- Conduct comparative analysis to validate the performance of AI models.
- Reduce disparities in AI training and testing data.

Deployment

- Set up post-market surveillance mechanisms.
- Engage end users for adverse event reporting.

Post-market and beyond

- Monitor and anticipate adverse events.

WHO. Mapping the application of AI in TM. Technical brief. World Health Organization, published on 11 July 2025
https://www.who.int/publications/i/item/9789240107663

The EQUATOR Network: 26 AI and Machine Learning Related Guidelines

https://www.equator-network.org (accessed 19/09/2025)

5 key guidelines

1. **CONSORT-AI:** Reporting guidelines for **clinical trial reports** for interventions involving AI
2. **SPIRIT-AI:** Extension Guidelines for **clinical trial protocols** for interventions involving AI
3. **TRIPOD+ AI:** updated guidance for reporting clinical **prediction models** that use regression or machine learning methods
4. **TRIPOD-SRMA:** Transparent reporting of multivariable **prediction models** for individual prognosis or diagnosis: checklist for systematic reviews and meta-analyses
5. **TRIPOD-Cluster:** Transparent reporting of multivariable **prediction models** developed or validated using clustered data

21 Additional Guidelines

6 The **STARD-AI r**eporting guideline for diagnostic accuracy studies using AI

7 Reporting guideline for Chatbot Health Advice studies: the **CHART** statement

8 **ELEVATE-GenAI**

9 Report ing guideline for the use of Generative AI tools in MEdical Research: the **GAMER** Statement

10 Development, Evaluation, and Assessment of Large Language Models (**DEAL**) Checklist

11 Guidelines for reporting AI studies in medicines, pharmacotherapy, and pharmaceutical services: **Medin AI** development, validation and statement

12 Clinician-informed explainable AI evaluation checklist with metrics (**CLIX-M**) for AI-powered clinical decision support systems

13 The **TRIPOD-LLM** reporting guideline for studies using large language models

14 **REFORMS** : Consensus-based Recommendations for Machine-learning-based Science

15 Consolidated Health Economic Evaluation Reporting Standards for Interventions that use AI (**CHEERS-AI**)

16 Consolidated Reporting Guidelines for Prognostic and Diagnostic Machine Learning Modeling Studies: Development and Validation

17 **MINIMAR** (MINimum Information for Medical AI Reporting): Developing reporting standards for artificial intelligence in health care

18 Presenting AI, deep learning, and machine learning studies to clinicians and healthcare stakeholders: an introductory reference with a guideline and a Clinical AI Research (**CAIR**) checklist proposal

19 Recommendations for Reporting Machine Learning Analyses in Clinical Research

20 Checklist for AI in Medical Imaging (**CLAIM**) : 2024 Update

21 Reporting guideline for the early-stage clinical evaluation of decision support systems driven by AI: **DECIDE-AI**

22 Standardized Reporting of Machine Learning Applications in Urology: The **STREAM-URO** Framework

23 **AI in dental research**: Checklist for authors, reviewers, readers

24 Proposed Requirements for Cardiovascular Imaging -Related Machine Learning Evaluation (**PRIME**) : A Checklist: Reviewed by the American College of Cardiology Healthcare Innovation Council

25 Minimum information about clinical AI modeling: the **MI-CLAIM** checklist

26 Guidelines for Developing and Reporting Machine Learning Predictive Models in Biomedical Research: A Multidisciplinary View

Problems Identified (Bedi S, et al. *JAMA* 2025;333:319-28)

- In this systematic review of **519 studies** published between January 1, 2022, and February 19, 2024, **only 5% used real patient care data for LLM evaluation**.
- **Accuracy was evaluated, while fairness, bias, and toxicity assessments were less studied.**
- **Hence, current evaluations of LLMs in healthcare are fragmented and insufficient**.

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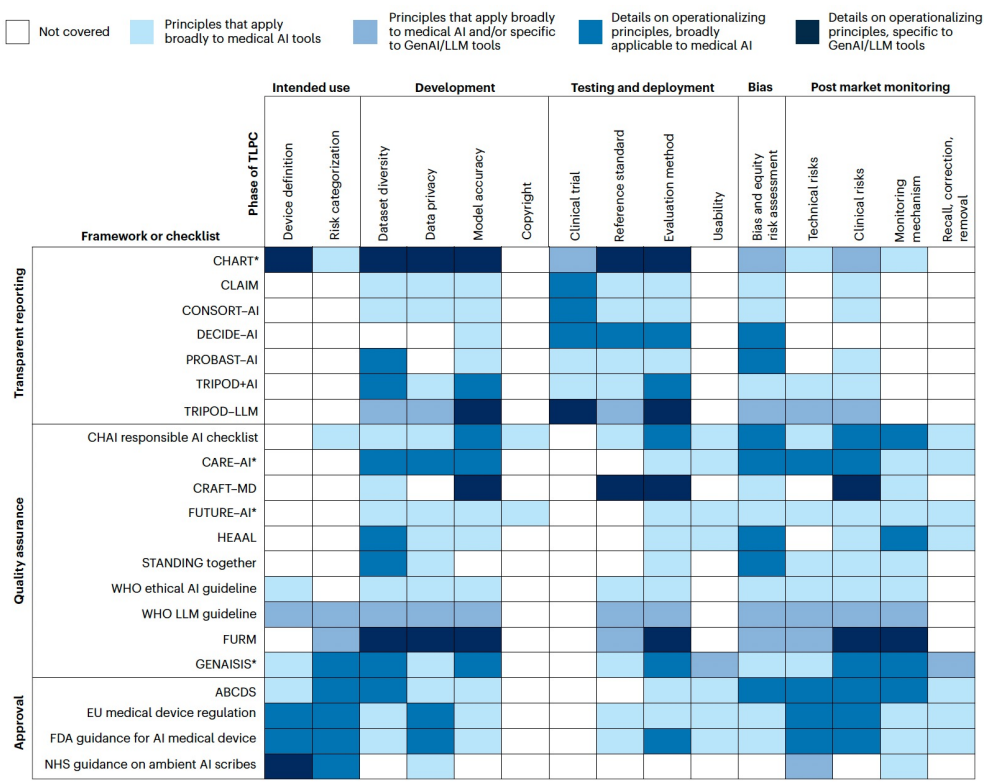
Problems: Critical gaps and grey areas identified by the POLARIS-GM consortium (Partnership for Oversight, Leadership, and Accountability in Regulating Intelligent Systems–Generative Models in Medicine) (Ong et al. *Nat Med* 30 June 2025)

- **41 experts from Singapore, China, Australia, UK, USA, Germany, Netherlands** advocate for POLARIS-GM, an **evidence-based, scenario-based, risk-stratified framework** designed to adapt to regional, clinical, and resource variations.
- It proposes comprehensive benchmarks, clinically relevant performance metrics, and post-market surveillance tailored to the unique features of genAI in health care.
- POLARIS-GM is an ongoing multi-phase project…



CONCLUSIONS

- AI and digital technologies are rapidly evolving within TCIM and broader healthcare, presenting significant opportunities and challenges.
- Established guidelines, such as those from EQUATOR and the WHO, provide a solid foundation for further improvement.
- To ensure responsible AI use and robust TCIM research outcomes, *evolving AI-specific guidance* must be applied in conjunction with both general good practice principles and TCIM-specific guidelines.

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