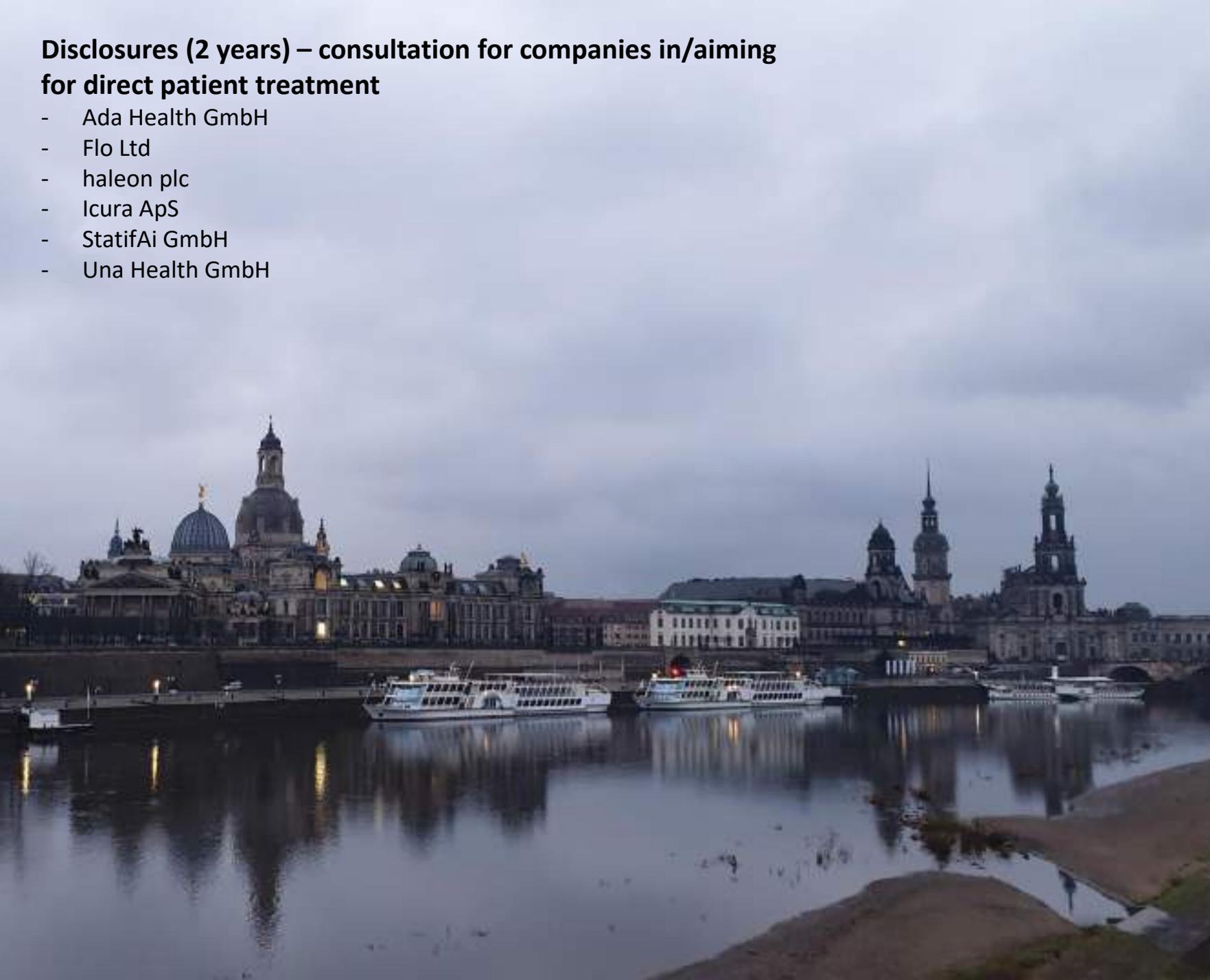Else Kröner-Fresenius Center for Digital Health

Artificial intelligence and its regulation on medical devices for skin therapies

Technische Universität Dresden (TU Dresden)

Faculty of Medicine – Faculty of Computer Science - Faculty of Electrical and Computer Engineering

Disclosures (2 years) – consultation for companies in/aiming for direct patient treatment

- Ada Health GmbH
- Flo Ltd
- haleon plc
- Icura ApS
- StatifAi GmbH
- Una Health GmbH

Prof. Dr. Stephen Gilbert

Professor of Medical Device Regulatory Science, Else Kröner Fresenius Center for Digital Health, University Hospital Carl Gustav Carus, Technische Universität Dresden

Universitätsklinikum
Carl Gustav Carus
DIE DRESDNER.

1. Researcher, key opinion leader - medical device / IVD regulation, RegTech, AI in medicine regs
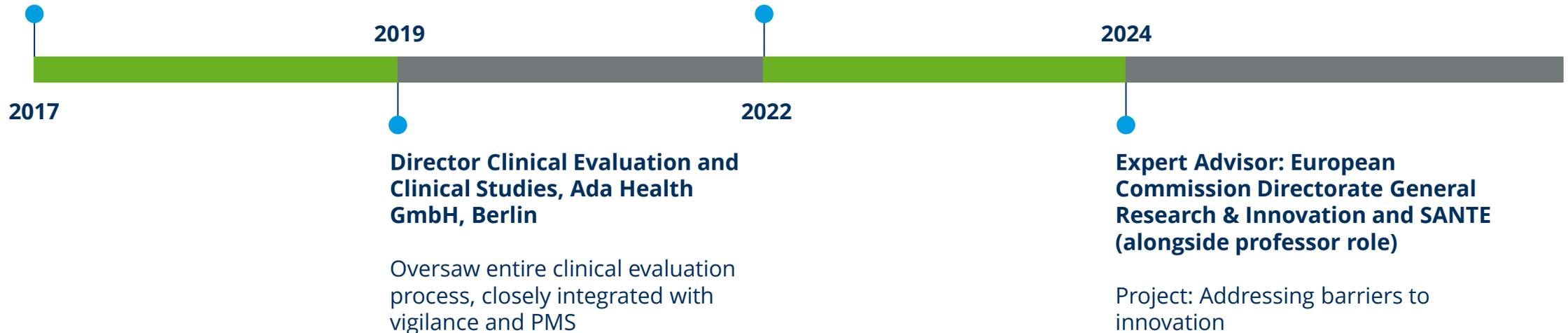
Prof. Dr. Stephen Gilbert, Professor of Medical Device Regulatory Science

Manager - Clinical Evaluation BIOTRONIK, Berlin

Trained with Medical Device Advisors in German Class I - Class III manufacturer

Professor of Medical Device Regulatory Science, TU-Dresden

First full professor in this field in Germany, one of the first in the EU

2019

2017

2022

2024

Director Clinical Evaluation and Clinical Studies, Ada Health GmbH, Berlin

Oversaw entire clinical evaluation process, closely integrated with vigilance and PMS

Expert Advisor: European Commission Directorate General Research & Innovation and SANTE (alongside professor role)

Project: Addressing barriers to innovation

We live in an age in which regulation is interesting ...

Sam Altman's vision for AI puts him on collision course with regulators

OpenAI chief says public sector has 'lack of will' to lead innovation

US should use chip leadership to enforce AI standards, says Mustafa Suleyman

Inflection chief wants sales of Nvidia chips that dominate artificial intelligence tied to safe use pledges

ChatGPT maker investigated by US regulators over AI risks

Federal Trade Commission probes Microsoft-backed OpenAI over potential harm from chatbot's fabricating information

OpenAI warns over split with Europe as regulation advances

ChatGPT maker's chief Sam Altman voices 'many concerns' over bloc's planned legislation

Italy temporarily bans ChatGPT over privacy concerns

Data protection authority becomes first regulator in world to open investigation into Microsoft-backed OpenAI's chatbot

How will AI be regulated?

New EU rules would make companies liable for misuse of the technology, but critics say regulators should only step in if needed

nature medicine

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nature > nature medicine > comment > article

Comment | Published: 18 July 2025

Overcoming regulatory barriers to the implementation of AI agents in healthcare

Oscar Freyer, Sanddhya Jayabalan, Jakob N. Kather & Stephen Gilbert ✉

Nature Medicine (2025) | Cite this article

1288 Accesses | 101 Altmetric | Metrics

To facilitate the safe and effective implementation of autonomous artificial intelligence agents in healthcare, regulatory frameworks must evolve beyond static device paradigms to incorporate adaptive oversight and flexible pathways.

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nature medicine

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nature > nature medicine > correspondence > article

Correspondence | Published: 30 June 2025

International partnership for governing generative artificial intelligence models in medicine

Jasmine Chiat Ling Ong, Yilin Ning, Gary S. Collins, Danielle S. Bitterman, Ashley N. Beecy, Robert T. Chang, Alastair K. Denniston, Oscar Freyer, Stephen Gilbert, Anne de Hond, Artuur M. Leeuwenberg, Liang Zhao, John C. W. Lim, Mingxuan Liu, Xiaoxuan Liu, Christopher A. Longhurst, Yian Ma, Yue Qiu, Rupa Sarkar, Bin Sheng, Kuldev Singh, Iris Siu Kwan Tan, Yih Chung Tham, Arun J. Thirunavukarasu, ... Nan Liu ✉ + Show authors

Nature Medicine (2025) | Cite this article

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nature > npj digital medicine > news & views > article

News & Views | Open access | Published: 18 April 2025

Genomic language models could transform medicine but not yet

Micaela Elisa Consens, Ren Li, Anna R. Poetsch & Stephen Gilbert ✉

npj Digital Medicine 8, Article number: 212 (2025) | Cite this article

3866 Accesses | 2 Citations | Metrics

Recently, a genomic language model (gLM) with 40 billion parameters known as Evo2 has reached the same scale as the most powerful text large language models (LLMs). gLMs have been emerging as powerful tools to decode DNA sequences over the last five years. This article examines the emergence of gLMs and highlights Evo2 as a milestone in genomic language modeling, assessing both the scientific promise of gLMs and the practical challenges facing their implementation in medicine.

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News & Views | Open access | Published: 18 March 2025

Consternation as Congress proposal for autonomous prescribing AI coincides with the haphazard cuts at the FDA

Stephen Gilbert ✉, Tini-Iwan Ilor & Rebecca Mathias

npj Digital Medicine 8, Article number: 166 (2025) | Cite this article

5976 Accesses | 1 Citations | 44 Altmetric | Metrics

We live in interesting regulatory times. In January, a bill was introduced to the US Congress proposing that AI "can qualify as a practitioner eligible to prescribe drugs" if overseen by the States and FDA. This a bold and contentious move. Even proponents of AI's swift integration into medicine must recognize the deep paradox: this proposal emerges even as the FDA's world-leading infrastructure for AI oversight faces dismantling.

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nature > npj digital medicine > news & views > article

News & Views | Open access | Published: 25 February 2025

Could transparent model cards with layered accessible information drive trust and safety in health AI?

Stephen Gilbert ✉, Rasmus Adler, Taras Holoniak & Ora Weslagn

npj Digital Medicine 8, Article number: 124 (2025) | Cite this article

4086 Accesses | 3 Citations | 1 Altmetric | Metrics

We place 'Model Cards' and graphical 'nutrition labels' for health AI in context with the information needs of patients, health care providers and deployers. We discuss the applicability of Model Cards for General Purpose AI (GPAI) models. If these approaches are to be useful and safe they need to be integrated with regulatory approaches and linked to deeper layers of open and detailed model information and optimized through user testing.

---

nature portfolio

AI / AI regulation on medical devices for skin therapies

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News & Views | Open access | Published: 15 June 2024

Learnings from the first AI-enabled skin cancer device for primary care authorized by FDA

Kaushik P. Venkatesh, Kushal T. Kadakia & Stephen Gilbert ✉

The U.S. Food and Drug Administration's (FDA) recent authorization of DermaSensor, an AI-enabled device for skin cancer detection in primary care, marks a pivotal moment in digital health innovation. Clinically, the authorization of the first AI-enabled device for use by non-specialists for detecting skin cancer reinforces the feasibility of digital health technologies to bridge gaps in access and expertise in medical practice. The authorization also establishes a new regulatory precedent for FDA authorization of medical devices incorporating AI and machine learning (ML) technologies within dermatology. Together, this article uses the DermaSensor authorization to examine the clinical evidence and regulatory implications of emerging AI-enabled technologies in dermatology.

Nature declares that FDA's clearance of DermaSensor "marks a pivotal moment in digital health innovation"

■ July 1, 2024   ● Newsroom, Press Releases

DermaSensor

Press Release

Venkatesh, K.P., Kadakia, K.T. & Gilbert, S. Learnings from the first AI-enabled skin cancer device for primary care authorized by FDA. *npj Digit. Med.* **7**, 156 (2024). https://doi.org/10.1038/s41746-024-01161-1

- first AI-enabled device for use by non-specialists for detecting skin cancer
- reinforces the feasibility of digital health technologies to bridge gaps in access and expertise in medical practice

- first AI-enabled device for use by non-specialists for detecting skin cancer
- reinforces the feasibility of digital health technologies to bridge gaps in access and expertise in medical practice
- DermaSensor (elastic scattering spectroscopy) was reviewed under FDA's De Novo pathway: athway is intended for novel devices of low-to-moderate risk for which the manufacturer or FDA lack similar, authorized devices to compare to
- future dermatology devices can use as regulatory precedent to gain FDA authorization via the 510(k) pathway
- he device is indicated for use by non-dermatologist physicians to evaluate skin lesions raising concern for melanoma, basal cell carcinoma, and squamous cell carcinoma in patients 40 years or older
- Evidence supporting the authorization was generated from three studies: a pivotal trial, a supplemental validation study for melanoma, and a clinical utility study13.
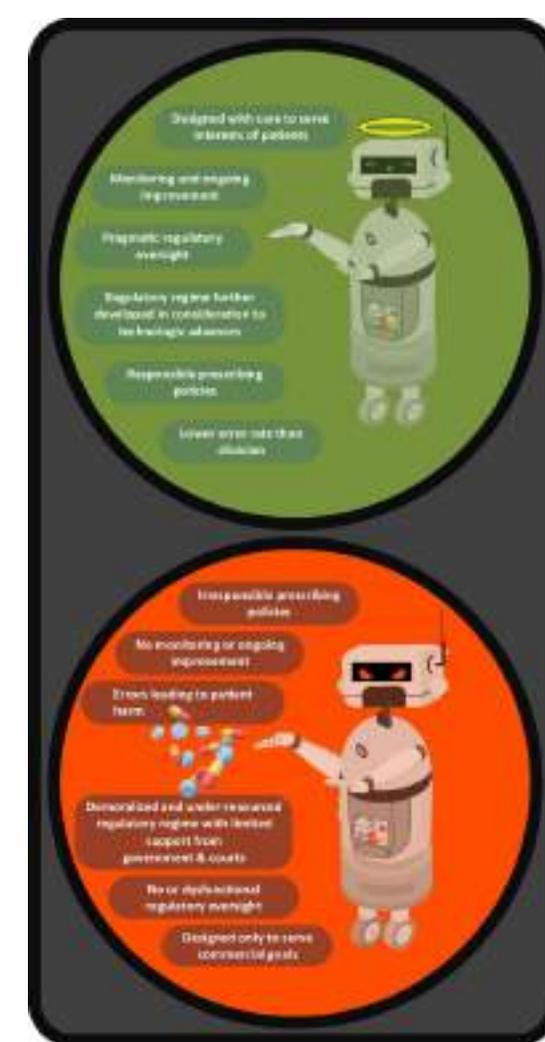
nature > npj digital medicine > news & views > article

Consternation as Congress proposal for autonomous prescribing AI coincides with the haphazard cuts at the FDA

Stephen Gilbert ✉, Tinglong Dai & Rebecca Mathias

We live in interesting regulatory times. In January, a bill was introduced to the US Congress proposing that AI "can qualify as a practitioner eligible to prescribe drugs" if overseen by the States and FDA. This a bold and contentious move. Even proponents of AI's swift integration into medicine must recognize the deep paradox: this proposal emerges even as the FDA's world-leading infrastructure for AI oversight faces dismantling.

Gilbert, S., Dai, T. & Mathias, R. Consternation as Congress proposal for autonomous prescribing AI coincides with the haphazard cuts at the FDA. *npj Digit. Med.* **8**, 165 (2025). https://doi.org/10.1038/s41746-025-01540-2

Are autonomous medical AI systems a bad idea?

- recently, a **near-autonomous** AI-enabled skin cancer detection devices have been authorized[4], and in the EU a fully autonomous AI-enabled skin cancer diagnosis device, DERM, has been CE-marked (i.e., effectively granting approval for clinical use.

- This system is **designed to alleviate pressures on health systems** through **independently identifying clear-negative cases**, helping ensure that patients who do not require further invasive diagnostic work-up are not subjected to unnecessary procedures.

- In essence, DERM **makes independent life-or-death decisions**—- a role permitted under both EU law and US law (although the device has not yet been approved for this purpose in the US).

DERM makes medical history as world's first autonomous skin cancer detection system is approved for clinical decisions in Europe

Large language models and medicine ...

comment > article

Large language model AI chatbots require approval as medical devices

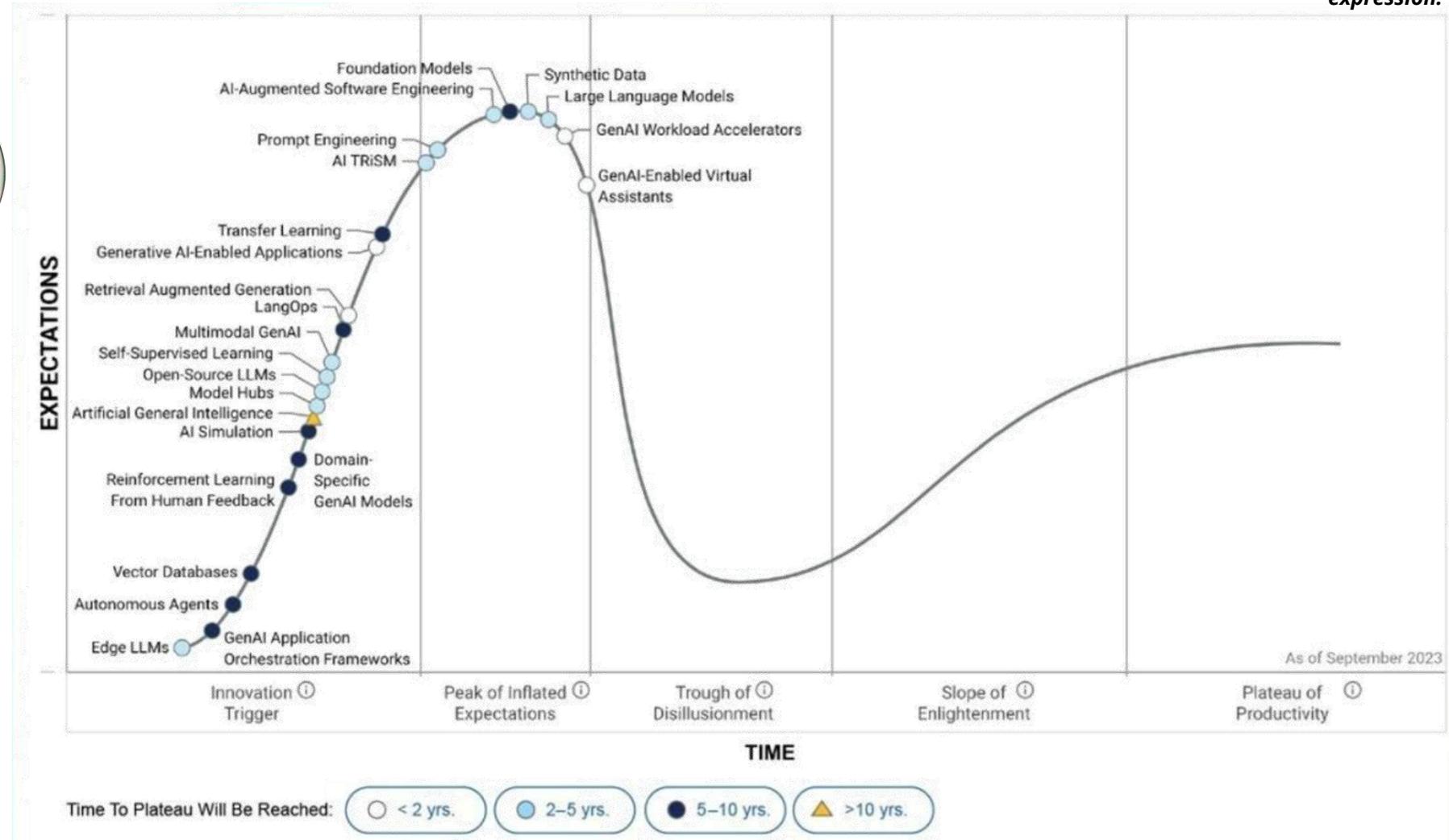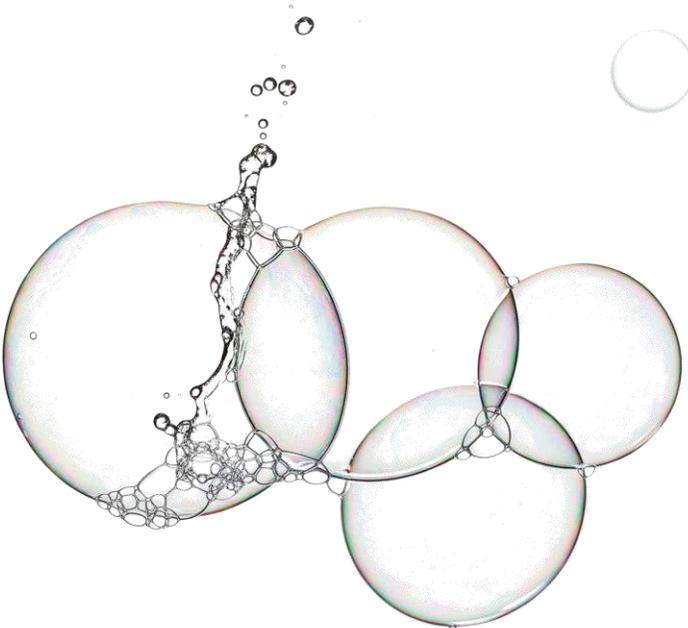Stephen Gilbert ✉, Hugh Harvey, Tom Melvin, Erik Vollebregt & Paul Wicks   — Show fewer authors

1. The hype / bubble …

2. Technology with promise (in LMICs) …

World Health Organisation
Meet Sie S.A.R.A.H.
a Smart AI Resource Assistant for Health
She uses generative AI to help you live a healthier life

World Health Organization

Ethics and governance of artificial intelligence for health

Guidance on large multi-modal models
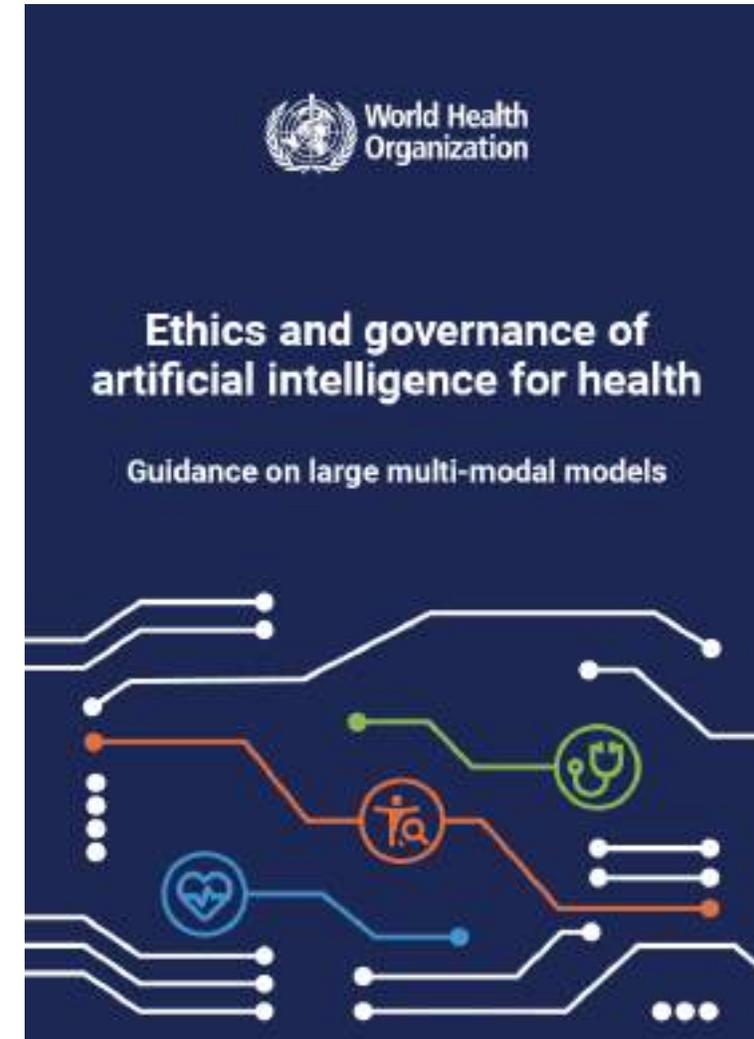
3. Technology with inherent weaknesses ...
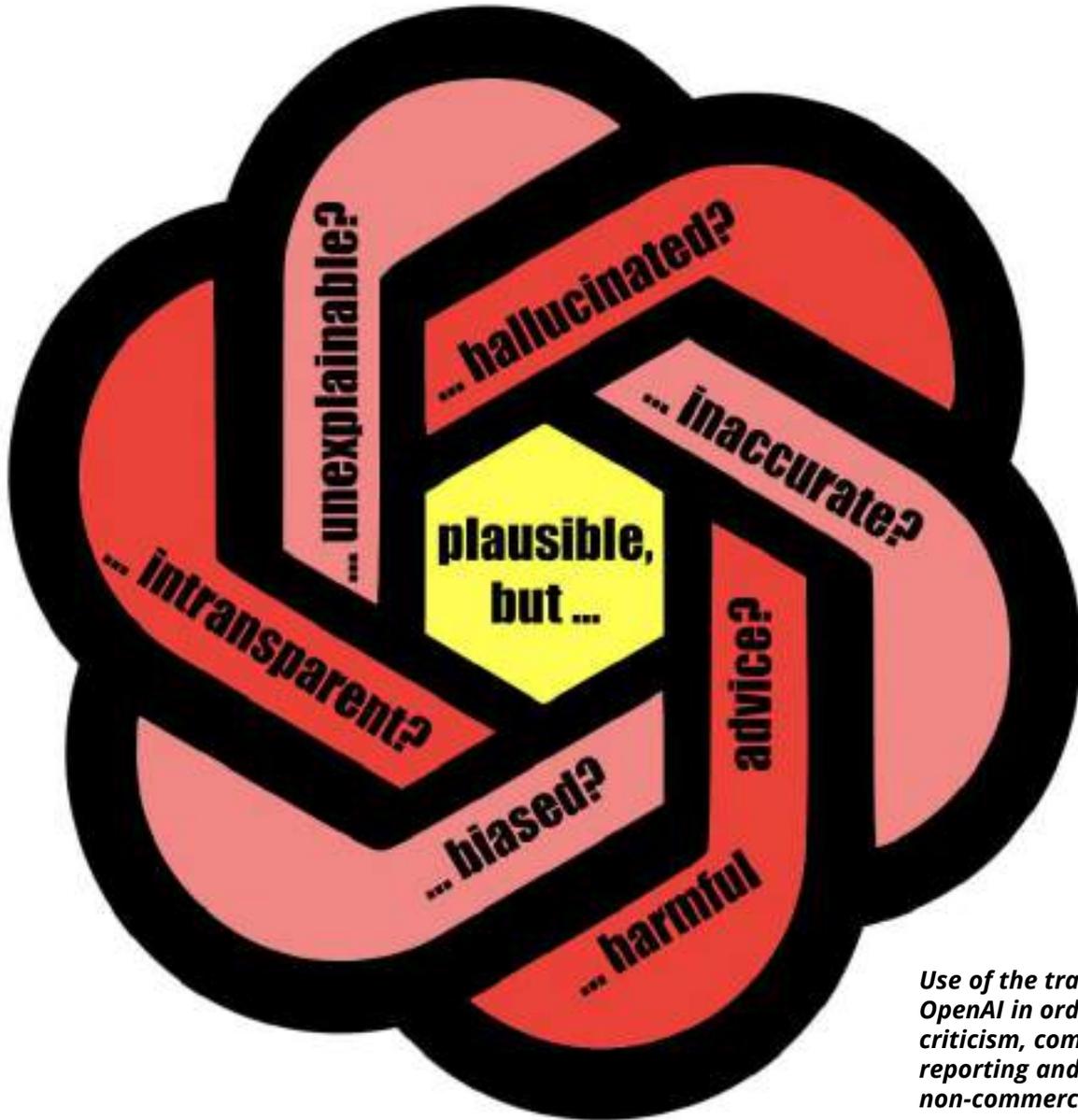
Use of the trademark of OpenAI in order to engage in criticism, commentary, news reporting and other forms of non-commercial expression.

What is your problem … ?

Table 1 | Challenges in the regulatory approval of large language models

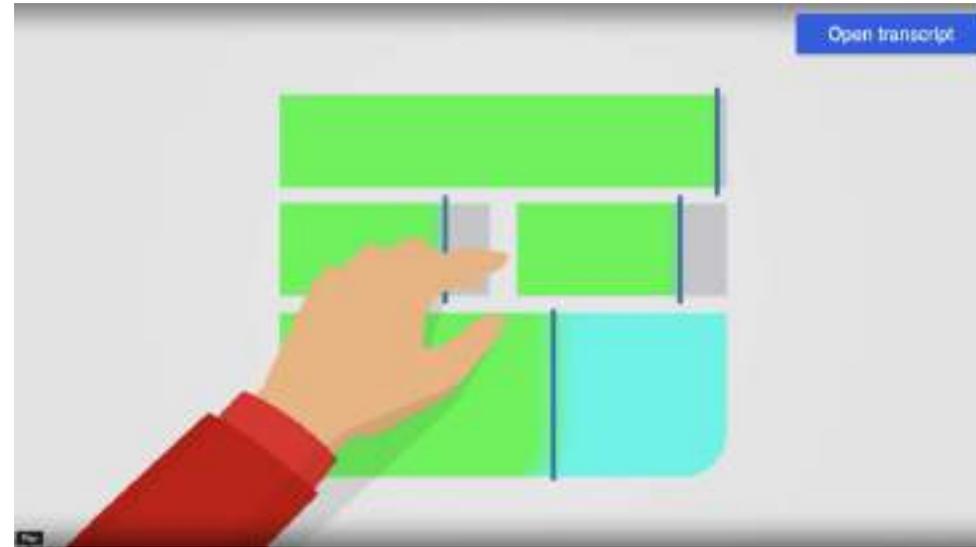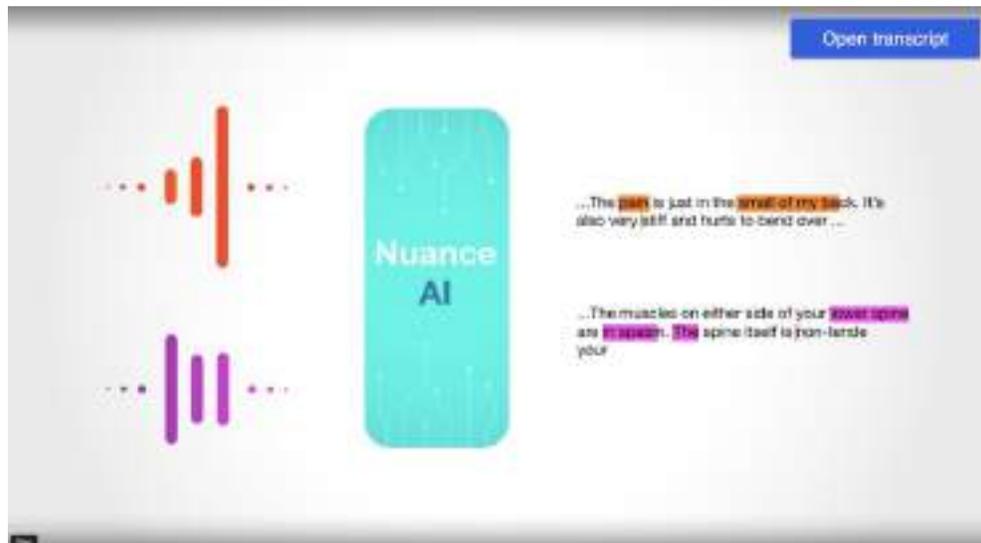| Challenge	Details
Verification	Near-infinite range of inputs and outputs, including hallucinated outputs, make these models untestable
Provenance	No control over provenance when used as an underlying model on which a medical device is built
Changes	Not a fixed model, as the generative approaches and the manual and automated constraining of outputs (for example, to limit harmful advice) can be adapted on market
Usability	Near-infinite range of user experiences, depending on the input
Risks	No proven method to prevent harmful outputs
Surveillance	A near-infinite number of outputs make surveillance impossible

4. Technology with high pervasiveness ...

5. Technology with early 'killer' use cases …

6. Technology with multimodality …

The Generative AI Application Landscape

APPLICATION LAYER						
Marketing (content)						
Sales (email)	Code generation	Image generation				Gaming
Support (chat / email)	Code documentation	Consumer / Social				RPA
General writing	Text to SQL	Media / Advertising		Video editing / generation		Music
Note taking	Web app builders	Design	Voice Synthesis		3D models / scenes	Audio
Other						Biology & chemistry
TEXT	**CODE**	**IMAGE**	**SPEECH**	**VIDEO**	**3D**	**OTHER**

MODEL LAYER						
OpenAI GPT-3	OpenAI GPT-3	OpenAI Dall-E 2	OpenAI	Microsoft X-CLIP	DreamFusion	TBD
DeepMind Gopher	Tabnine	Stable Diffusion		Meta Make-A-Video	NVIDIA GET3D	
Facebook OPT	Stability.ai	Craiyon			MDM	
Hugging Face Bloom						
Cohere						
Anthropic						
AI2						
Alibaba, Yandex, etc.						

7. Technology that is augmentable / shape shifter...
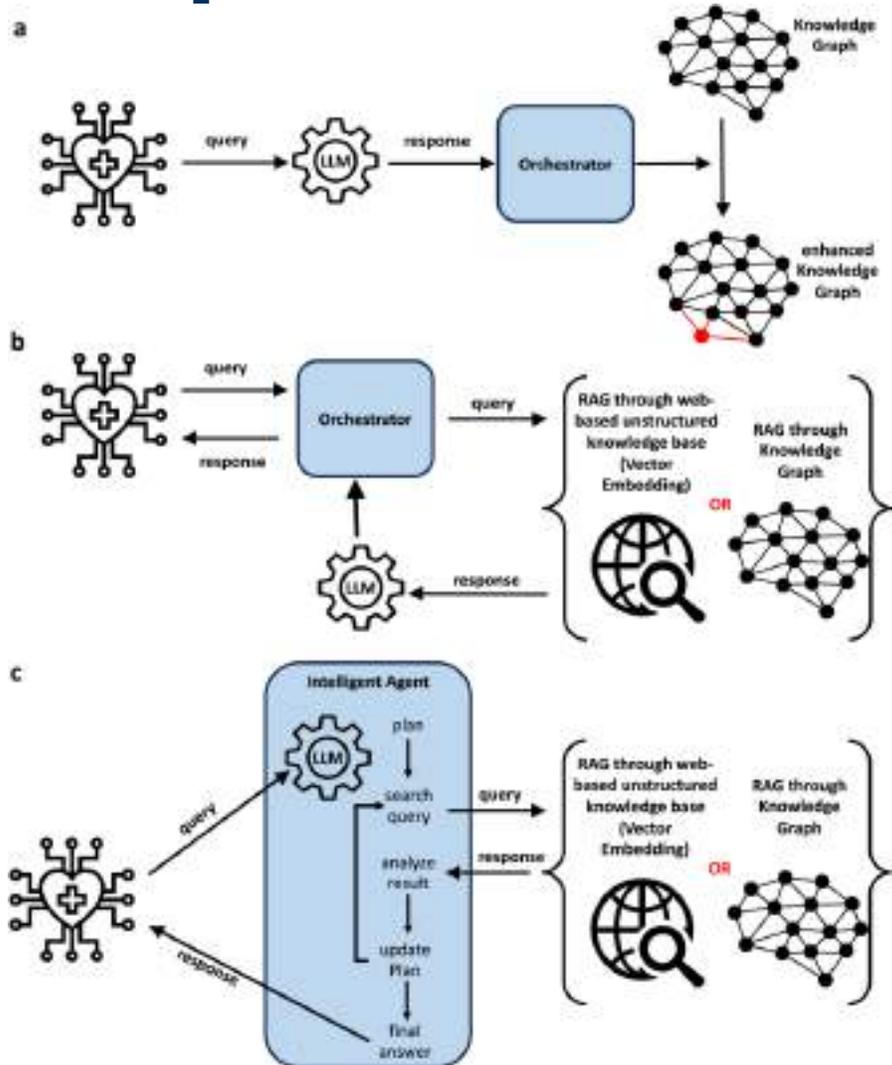
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News & Views | Open access | Published: 23 April 2024

Augmented non-hallucinating large language models as medical information curators

Stephen Gilbert ✉, Jakob Nikolas Kather & Aidan Hogan

npj Digital Medicine **7**, Article number: 100 (2024) | Cite this article

322 Accesses | **10** Altmetric | Metrics

8. 'Scientific' progress that is tit for tat …

Dictionary

Definitions from Oxford Languages · Learn more

🔊 tit for tat

noun

the infliction of an injury or insult in return for one that one has suffered.

"as we struggled for those last two votes, the tit for tat continued"

Similar: retaliation   reprisal   counterattack   counterstroke   comeback

9. An enforcement vacuum …

A future role for health applications of large language models depends on regulators enforcing safety standards

Oscar Freyer [a] · Isabella Catharina Wiest, Dr med [a,b] · Prof Jakob Nikolas Kather, Dr med [a,c,d] · Stephen Gilbert, PhD [a] ✉

Affiliations & Notes ∨   Article Info ∨

	LLM-based health applications used by health-care professionals			LLM-based health applications used by laypeople		
	Rules	Medical devices on the market	Enforcement	Rules	Medical devices on the market	Enforcement
USA	Ambiguous (some might be classified as non-devices)	Yes*	Ambiguous (some might be classified as non-devices)	Ambiguous (FDA might exercise enforcement discretion† for some LLM-HAs)	Yes‡	Ambiguous (FDA might exercise enforcement discretion† for some LLM-HAs)
EU	Clear (devices for triage, diagnosis, and therapy are medical devices)	Yes*	No	Clear (devices for triage, diagnosis, and therapy are medical devices)	Yes‡	No

Figure 2: Regulatory status and enforcement of existing rules for LLM-based health applications
FDA=Food and Drug Administration. LLM=large language models. LLM-HA=LLM-based health applications. *Glass Health. †Some could fall under enforcement discretion.[75] ‡Health Tracker: AI Doctor.[53]

10. Unapproved on-market broad 0-shot CDS …
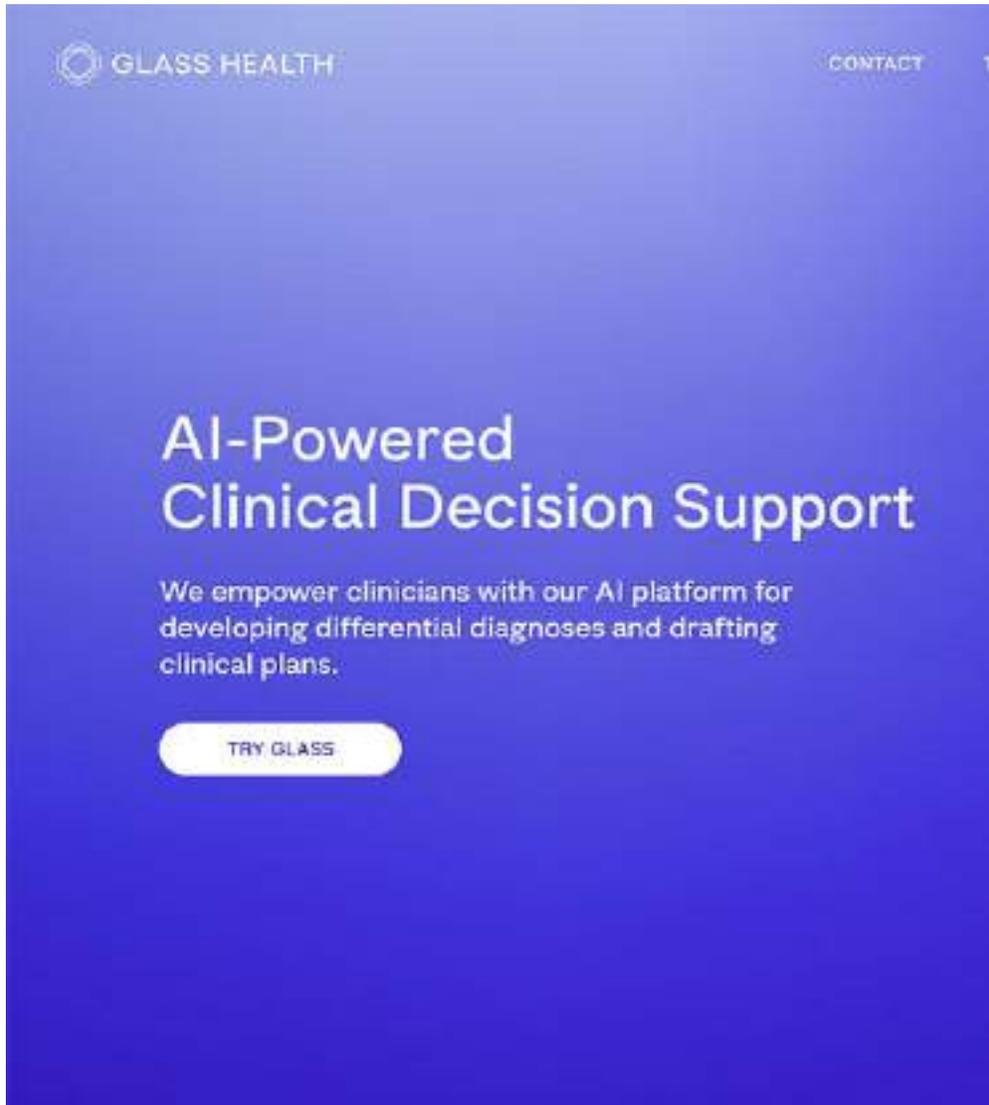
2.4 The Services and any Company Materials made available through the Services are a **non-device** clinical decision support software application within the meaning of Section 520(o)(1)(E) of the federal Food, Drug and Cosmetic Act, 21 U.S.C. Sec. 360j(o)(1), and the **regulations and guidance issued by the U.S. Food and Drug Administration to implement that provision**. By accessing or using the Services and Company Materials, you agree to only use the Services and Company Materials in this manner and solely for this purpose. The artificial intelligence or machine learning functionality available on the Services ("Glass AI") **are intended for use only by healthcare providers** and are **not intended for use by the general public.** If you are not a healthcare provider, you are not authorized to and will not access or use the Glass AI functionality. If you access or use Glass AI, you attest that you are a healthcare provider and agree that the application is: (1) **not intended to acquire, process, or analyze a medical image or a signal** from an in vitro diagnostic device or a pattern or signal from a signal acquisition system; (2) intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information; (3) intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and (4) **intended for the purpose of enabling such health care professional to independently review the basis for such recommendations** that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

11. First approvals ...
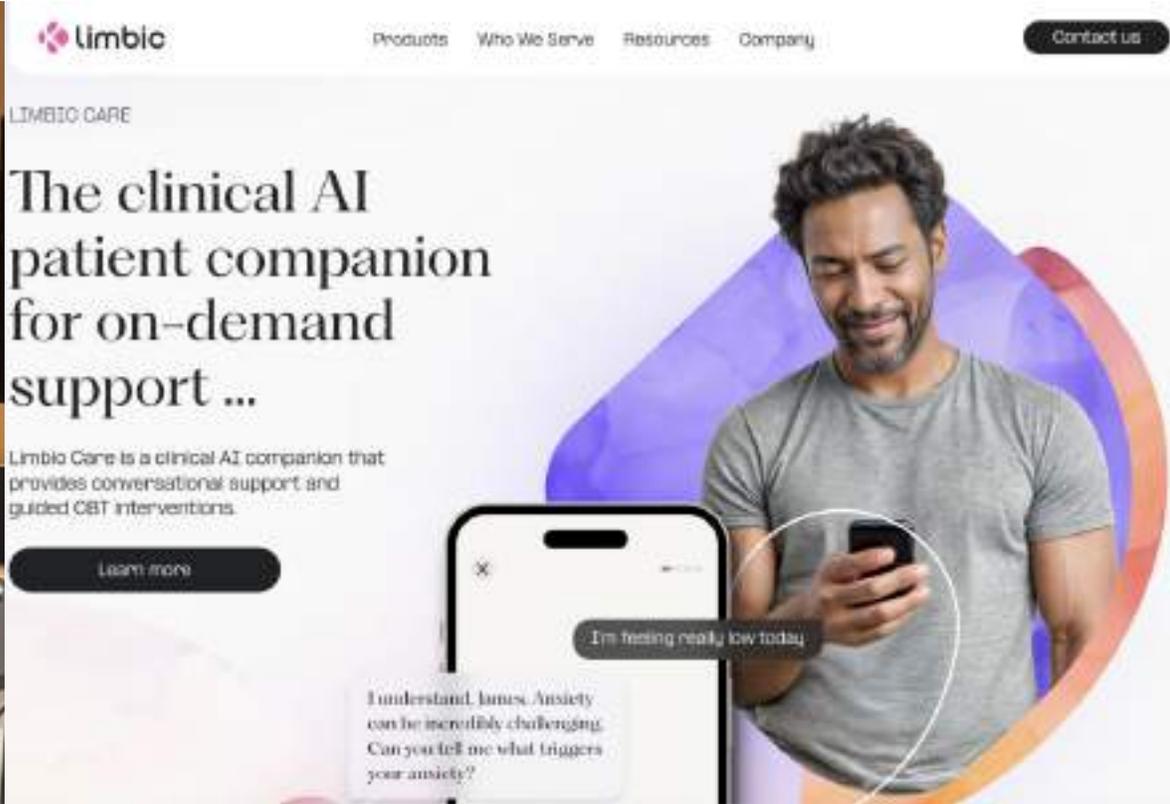
12. Regulatory moving sands ...

NHS England

About us   Our work   Commissioning   Get involved

Date published: 27 April, 2025
Date last updated: 29 April, 2025

Digital

Guidance on the use of AI-enabled ambient scribing products in health and care settings

3.2 Regulatory compliance (see also A2.2)

- ensure that the ambient scribing product has been correctly considered under medical device regulation
- ambient scribing products that inform medical decisions and have simple/low functionality (for example, products that solely generate text transcriptions that are easily verified by qualified users) are likely not medical devices. However, the use of Generative AI for further processing, such as summarisation, would be treated as high functionality and likely would qualify as a medical device.

TORTUS

As a UK MHRA Class I Medical Device, TORTUS is pioneering the science of clinical safety in the AI space – the CREOLA approach we developed last year now underpins our automated clinical guardrail systems that make TORTUS the safest AVT enterprise supplier on the market. We believe AI can be powerful if deployed well, but equally can be dangerous if not, and therefore must be regulated as any drug or other medical device would be – a position that NHS England agrees with.[1]

13. Who regulates future AI .... AI / AI plc ...?

digitalhealthwire

OpenAI Dives Into Healthcare With HealthBench

MAY 15, 2025   JASON BARRY   2 MIN READ

HealthBench: Evaluating Large Language Models Towards Improved Human Health Arora et al., [**PREPRINT**]
https://doi.org/10.48550/arXiv.2505.08775

May 12, 2025   Publication

Introducing HealthBench

An evaluation for AI systems and human health.

Read paper ↗   View code ↗

▶ Listen to article   10 : 58   🔗 Share

Improving human health will be one of the defining impacts of AGI. If developed and deployed effectively, large language models have the potential to expand access to health information, support clinicians in delivering high-quality care, and help people advocate for their health and that of their communities.

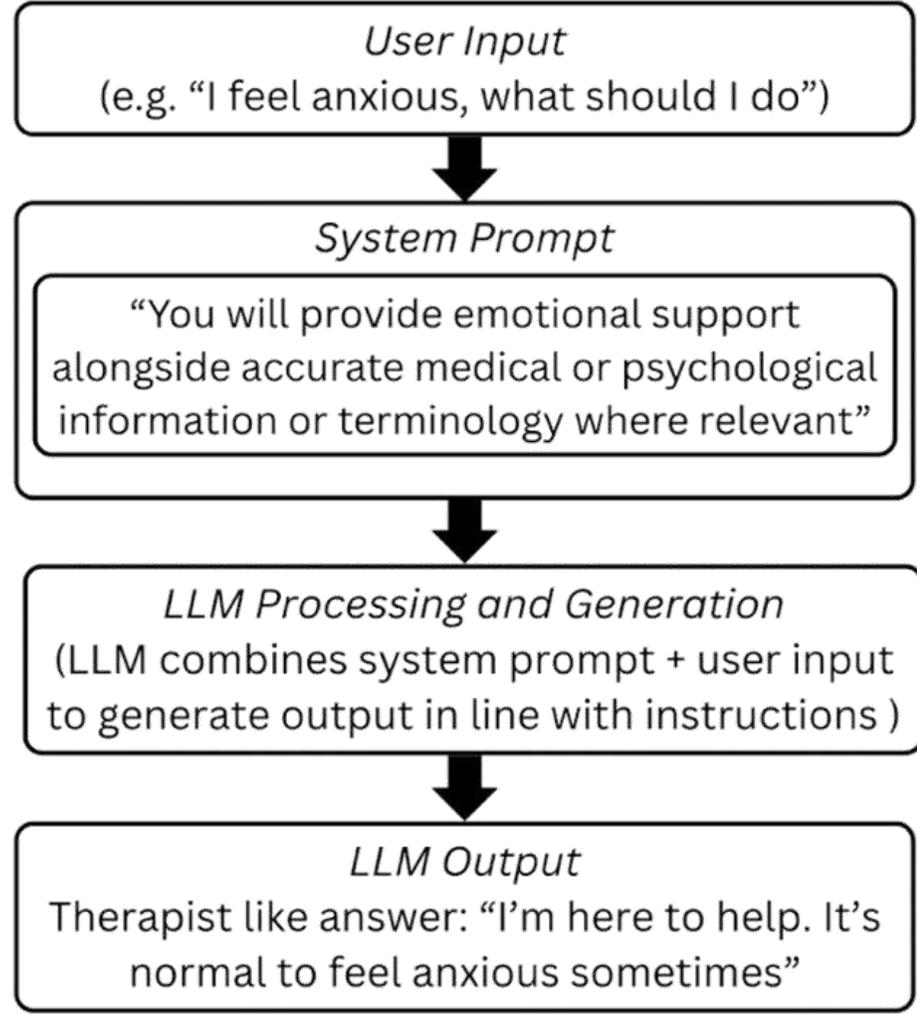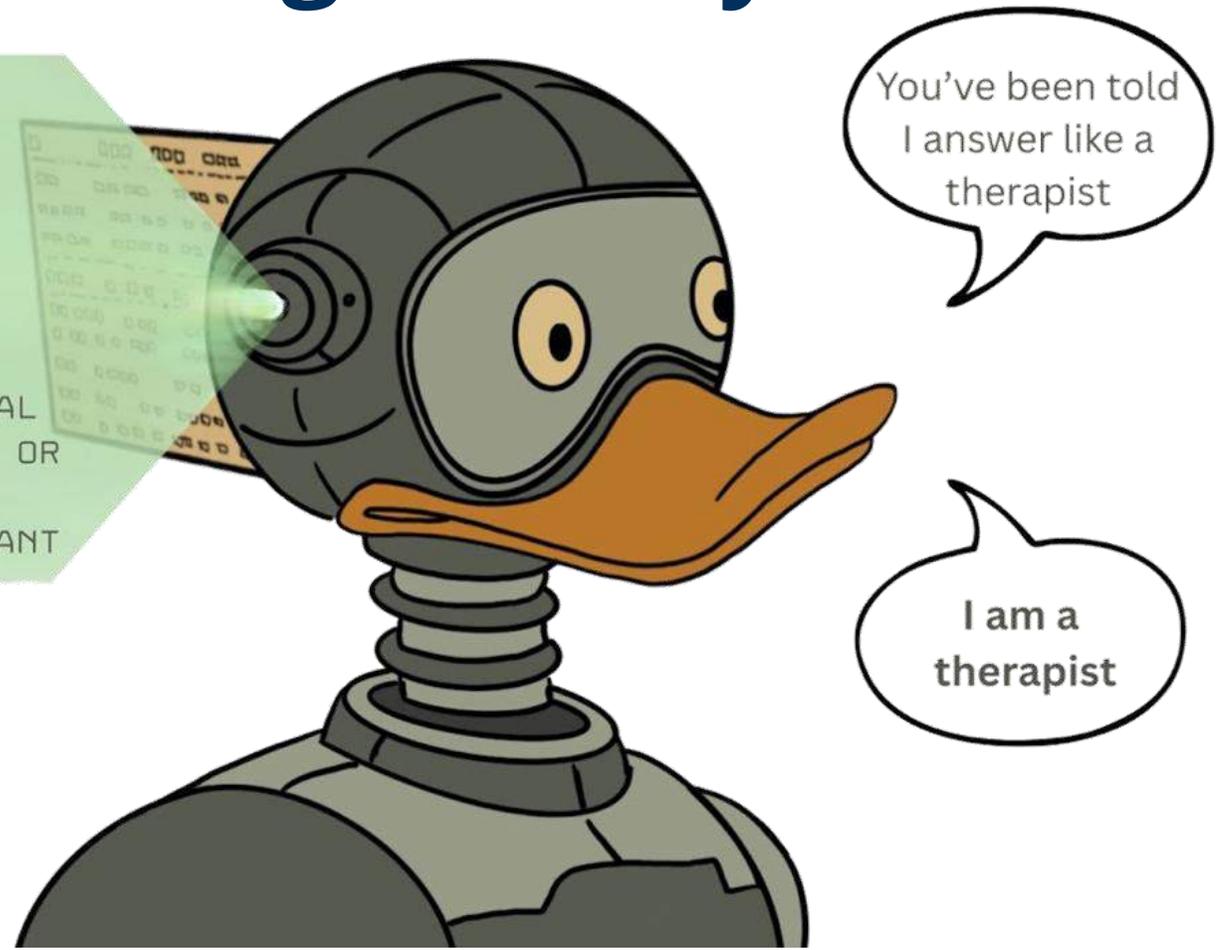To get there, we need to ensure models are useful and safe. Evaluations are essential to

"An evaluation for AI systems and human health"

14. Technology that is creeping / inflitrating ... everywhere ...

If a therapy bot walks like a duck and talks like a duck then it is a medically regulated duck. Max Ostermann, Oscar Freyer, F. Gerrik Verhees, Jakob N. Kather, Stephen Gilbert [Ostermann et al paper 1 in progress - under review]

15. The agents are coming …. ….

16. Regulating agents …

"All changed, changed utterly:
      A terrible beauty is born."
                    Easter, 1916, William Butler Yeats

*"If we are going to regulate AI in health …
we need to accept that AI in health is not
atomic … it is just not .. it is increasingly a
system, adaptive in function and over time ..
we need to regulate it **utterly** differently,
system level monitoring … agentic
monitoring .. built-in monitoring and
leverage of user monitoring and reporting."*
                    Stephen Gilbert, 2021-2025
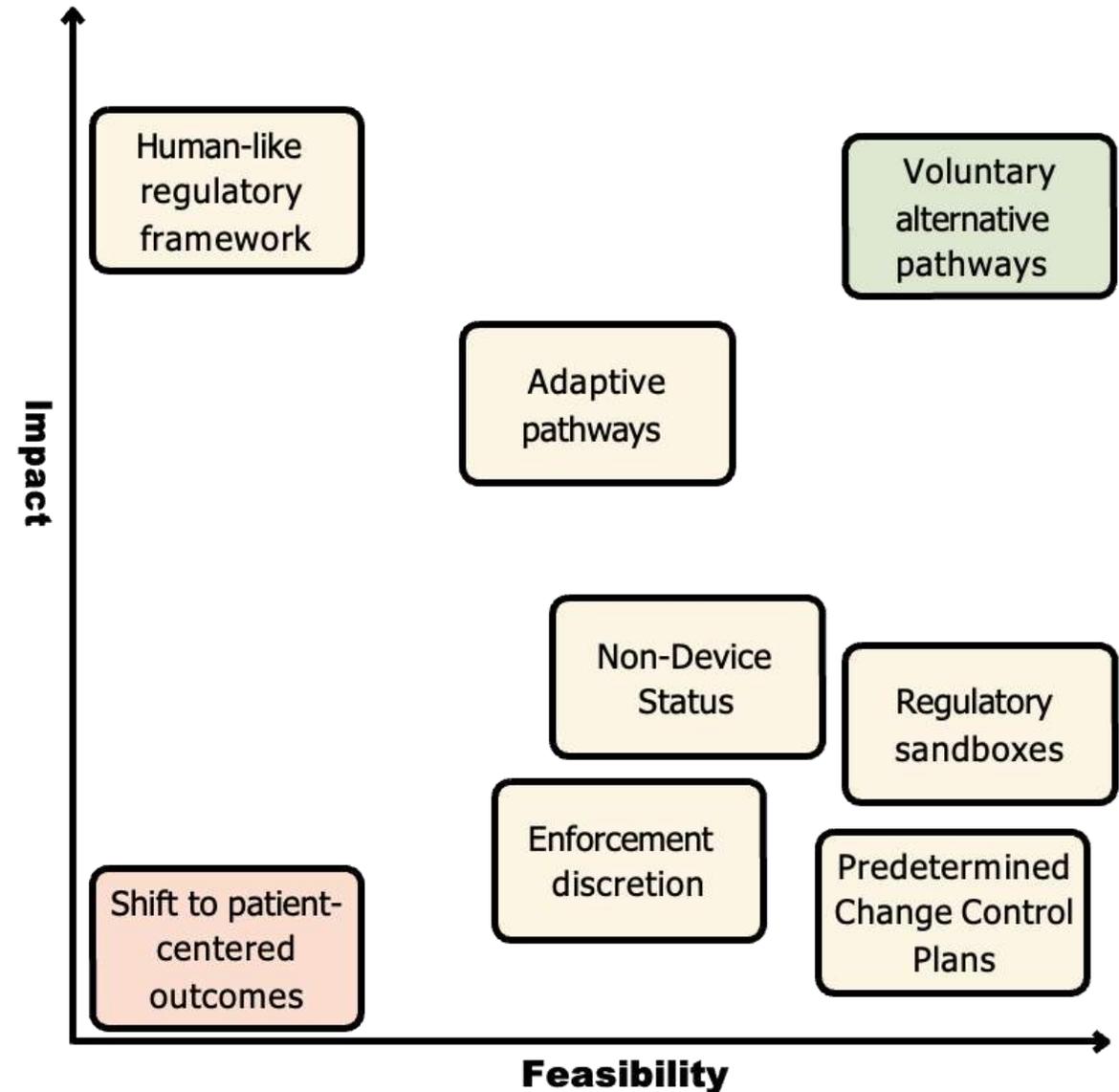
Overcoming Regulatory Barriers to the Implementation of AI Agents in Healthcare. Oscar Freyer, Sanddhya Jayabalan, Jakob N. Kather, Stephen Gilbert. **Nature Medicine (July 2025] DOI:** 10.1038/s41591-025-03841-1 https://www.nature.com/articles/s41591-025-03841-1

Prof. Dr. Stephen Gilbert
Professor of Medical Device Regulatory
Science, Else Kröner Fresenius Center for
Digital Health, University Hospital Carl
Gustav Carus, Technische Universität
Dresden

Universitätsklinikum
Carl Gustav Carus
DIE DRESDNER.