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# Commercialization of medical artificial intelligence technologies: challenges and opportunities

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Artificial intelligence (AI) is already having a significant impact on healthcare. For example, AI-guided imaging can improve the diagnosis/treatment of vascular diseases, which affect over 200 million people globally. Recently, Chiu and colleagues (2024) developed an AI algorithm that supports nurses with no ultrasound training in diagnosing abdominal aortic aneurysms (AAA) with similar accuracy as ultrasound-trained physicians. This technology can therefore improve AAA screening; however, achieving clinical impact with new AI technologies requires careful consideration of commercialization strategies, including funding, compliance with safety and regulatory frameworks, health technology assessment, regulatory approval, reimbursement, and clinical guideline integration.

Artificial intelligence (AI) technologies are already having significant impacts in healthcare[1]. For example, AI-guided imaging has shown promise in the management of vascular diseases, including carotid, aortic, and peripheral artery disease, which collectively affect over 200 million individuals globally and lead to significant mortality/morbidity related to catastrophic complications such as aneurysm rupture, stroke, and limb loss[2–4]. These diseases are typically managed by vascular specialists who rely on imaging modalities including ultrasound, computed tomography (CT), and fluoroscopy for diagnosis/treatment[5]. Recent advancements, such as three-dimensional reconstruction software and fluoroscopic roadmaps, have transformed pre-operative planning and intra-operative guidance[5]. However, despite the growing availability of AI tools, their integration into routine diagnostic vascular imaging remains limited. This is largely due to persistent financial, regulatory, and implementation challenges that impede clinical translation. Many AI solutions are developed without adequate alignment to regulatory pathways or quality assurance frameworks, which hinders their adoption in practice[6]. This is particularly concerning given that vascular diseases are frequently underdiagnosed[7]. For example, abdominal aortic aneurysms (AAA) are often captured incidentally on medical images obtained during the investigation of other abdominal concerns, including assessment of liver, gallbladder, and kidney conditions, rather than actively screened for despite guideline recommendations[8]. Consequently, many AAA's remain undetected until rupture, which carry mortality rates up to 80%[9]. AI-enhanced imaging holds potential to increase screening uptake and facilitate timely, elective intervention prior to rupture[10]. In this article, we examine a recently developed deep learning algorithm for AAA screening and explore the broader challenges and opportunities associated with commercializing AI technologies to deliver tangible clinical impact.

## From algorithm to impact: a validated AI tool for aneurysm screening

Ultrasound screening for AAA is systemically underperformed primarily due to the global shortages of trained ultrasound technicians and imaging specialists, particularly in low-resource settings[11,12]. Chiu and colleagues (2024) recently developed and prospectively validated an AI tool that supports nurses with no ultrasound training in diagnosing AAA with 100% sensitivity and 97.8% specificity[13]. The study enrolled 184 patients visiting outpatient cardiology clinics at a hospital in Taiwan[13]. The median age was 72 years, 57% were males, and there was a relatively high prevalence of comorbidities, including hypertension (71%), diabetes (35%), and heart disease (45%), reflecting a typical vascular patient population[13]. The deep learning algorithm provides real-time guidance to users, showing them where to place the ultrasound probe on the patient and automatically detects the aorta to measure its maximal diameter[13]. Guided by this software, nurses completed AAA ultrasounds in 37 seconds on average, with 87.5% being of sufficient diagnostic quality, comparable to ultrasound-trained physicians[13]. This technology can improve AAA screening, particularly in underserved areas with limited imaging specialists[13]. While promising, expert human-in-the-loop should be maintained, whereby an ultrasound-trained physician regularly monitors the results to ensure that the AI system is functioning appropriately[13]. Additionally, larger studies in different clinical settings and geographic locations are needed to validate and assess the generalizability of the model's performance[13]. Furthermore, achieving broad clinical impact with new AI technologies requires careful consideration of commercialization strategies, including funding, compliance with safety and regulatory frameworks, health technology assessment, regulatory approval, reimbursement, and clinical guideline integration (Fig. 1).

## Opportunities and learnings from the successful commercialization of medical AI technologies

Several companies have successfully commercialized their medical AI technologies, including a US company founded in 2016 focused on neurological care and now expanding to other areas, including cardiovascular, trauma, and oncologic care[14]. To date, they have developed several FDA-cleared AI algorithms that analyze medical imaging data across various domains, including CT scans, electrocardiograms, and echocardiograms[14]. These tools support clinicians with respect to diagnosis and treatment decision-making for various pathologies, including cerebral aneurysm,

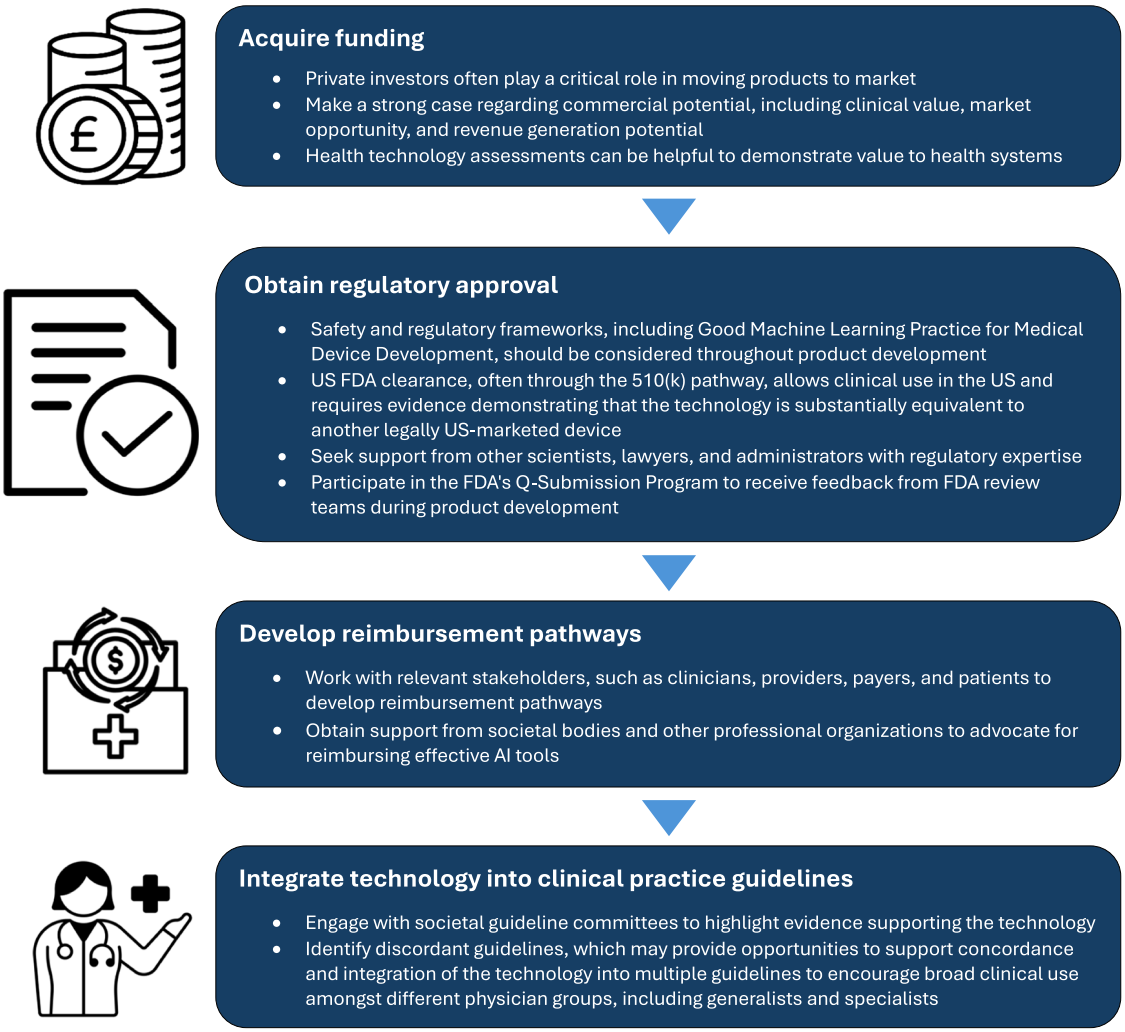


**Fig. 1 | Key steps for moving an artificial intelligence product from the research setting to routine clinical practice.** US United States, FDA Food and Drug Administration, AI artificial intelligence.

intracranial hemorrhage, ischemic stroke, pulmonary embolism, aortic dissection, and AAA, among others[14]. The company successfully built a suite of commercial products, generating revenue over $40 million in 2024[15].

There were several key factors for their success. First, they assembled a multidisciplinary team of clinicians/engineers who developed robust AI algorithms demonstrated through multiple peer-reviewed publications[16–20]. In this company, academics worked closely with industry partners and followed standardized approaches for medical device development in a quality management system from the outset, with market and regulatory considerations built in early on through International Organization for Standardization (ISO) certifications[21]. A preliminary health technology assessment demonstrated that such AI tools for ischemic stroke detection could save $11 million/year in the UK by identifying strokes that otherwise could have been missed[22]. Resultingly, the company obtained over $290 million in funding from investors to build and scale their products[23]. Using these funds, they developed and refined high-quality AI tools considering regulatory and quality requirements at each step of the process, leading to US Food and Drug Administration (FDA) clearance for their products[14,24]. Finally, they worked with the US Centers for Medicare and Medicaid Services to establish new billing codes with a view towards clinical guideline integration, including the use of an AI-based system for ischemic stroke detection at a reimbursement rate of $1040 per patient[25,26]. This pathway to reimbursement and coverage is a complex and variable process that typically takes many years and may fail[27,28]. Therefore, persistence, mentorship, and collaboration are critical to achieve success in translating novel technologies to routine clinical settings[27,28].

This company's path can guide investigators like Chiu and colleagues in bringing their AI innovations to market[13,14]. More broadly, to date, the FDA has approved over 1000 AI medical devices[29,30]. Therefore, there is a clear opportunity and precedent to obtain regulatory approval for and commercialize medical AI technologies[29,30].

## Financial, regulatory, and implementation barriers to commercializing medical AI technologies

**Investment and funding.** Despite the proliferation of medical AI research, few tools achieve the investment needed to reach clinical scale[31]. Academic

grants often end with algorithm development/validation, leaving a funding gap for product scaling/deployment[31]. Private investors play a critical role in bridging this gap[31]. However, they often require more than a high-performing model and seek compelling narratives about health system value and revenue generation potential[31]. Quantitative information regarding clinical impact (e.g., potential number of lives saved vs. comparators) and the nature/scale of the costs saved is often important to investors[32]. For diseases with relatively small markets, such as AAA's affecting less than 5% of the global population, obtaining private funding can be challenging[33,34]. Making a strong case regarding commercial potential is therefore critical. For instance, scalable AI-based AAA screening can prevent aneurysm rupture, reducing the costs associated with emergency surgery and saving lives[35]. Additionally, investors can capture a greater proportion of a smaller and niche clinical market with fewer competitors compared to other relatively saturated markets involving heart disease and cancer, where it may be more challenging for new companies/products to succeed[36]. Furthermore, the technology can be adapted to other vascular conditions, like carotid, peripheral artery, and venous disease, which also rely heavily on ultrasound imaging for diagnosis and management[37]. Health technology assessment is essential as it systematically evaluates the cost-effectiveness, safety, and sociocultural implications of new technologies, thereby demonstrating their value to individual health systems[38]. By highlighting clinical value and market opportunity, investigators improve their chances of obtaining sufficient funding to commercialize their products.

Algorithm development/validation are activities that should take place under guiding principles for Good Machine Learning Practice for Medical Device Development, such as the ones jointly identified by the US FDA, Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency[39]. When quality frameworks are not followed during product development, retrofitting them to align with regulatory guidelines can be very challenging[39]. Furthermore, routine and thorough documentation of best practices is critical to facilitate regulatory approval and commercialization[39].

**Obtaining regulatory approval**. Once a product has been developed, regulatory approval is required for broad clinical use[40]. This may be challenging as different jurisdictions often have varying AI regulations[40]. In the US, medical products/devices require FDA clearance/approval for clinical use[41]. However, obtaining FDA clearance for AI technologies, often through the 510(k) pathway, can be a significant hurdle requiring extensive data reviews[41]. Within the 510(k) pathway, investigators need to demonstrate that their technology is substantially equivalent to another legally US-marketed device[41]. Therefore, seeking support from scientists, consultants, and administrators with expertise in regulatory approval, often available at major academic institutions, is critical[42]. Early consultation with the FDA's Q-Submission Program is highly encouraged, allowing investigators to receive feedback from FDA review teams during product development[41]. Importantly, regulatory frameworks should be considered at product conception and revisited throughout development, with approval at the end if the process has been adequately followed[41,42].

**Reimbursement pathways**. Most AI tools lack dedicated billing codes and therefore, investigators must work with relevant stakeholders to develop reimbursement pathways to achieve financial sustainability[27]. Given that billing codes are often well-established, modifying them to include AI technologies may present significant challenges requiring buy-in from multiple stakeholders, including public and private insurers, clinicians, and patients[28]. Therefore, early engagement with these groups, often with the support of professional organizations, is essential for successful AI deployment[27,28]. Importantly, given the complexity of this process, often entangled with the requirement of extensive engagement with stakeholders in different sectors (payers, providers, patients, etc.), it is critical to seek guidance from experienced mentors and actively collaborate with key decision-makers to achieve success[27,28].

**Integration into clinical practice guidelines**. Clinical guideline integration legitimizes AI tools and guides medical practice, which often determines whether new technologies are implemented[43]. Investigators are encouraged to actively engage with guideline committees to highlight the evidence supporting their technology[43]. Additionally, investigators should identify discordant guidelines[43]. For example, the Society for Vascular Surgery recommends AAA ultrasound screening in men/women aged 65-75 with a smoking history or family history of AAA[8], while the US Preventive Services Task Force (USPSTF) limits their screening recommendation to men aged 65–75 with a smoking history[44]. A key reason for more restrictive USPSTF recommendations is the cost associated with widespread screening of a disease with relatively low prevalence[44]. AI-enhanced AAA screening can reduce costs and increase efficiency, potentially supporting more concordant guidelines[8,44]. Therefore, engaging with both the SVS and USPSTF may facilitate the integration of AI tools into multiple guidelines to encourage broad clinical use amongst different physician groups, including generalists and specialists[8,44]. Importantly, given the complex link between clinical guidelines, billing codes, and reimbursement pathways, and the need for all of these to be in place to support broad clinical use of new technologies, it is critical to continuously consider and work towards these various aspects during product conception, development, and implementation[27,28,43].

## Conclusions and recommendations

Medical AI technologies can improve healthcare and patient outcomes. However, achieving clinical impact requires more than algorithmic accuracy, it demands commercialization strategies that address investment, regulation, reimbursement, and practice integration. With hundreds of AI algorithms published but few adopted, now is the time to focus on the infrastructure and strategy needed for deployment[45]. We urge AI scientists to carefully consider the product to market process to develop AI tools with the greatest potential for clinical impact.

## Data availability

No datasets were generated or analyzed during the current study.

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## References

1. Bajwa, J., Munir, U., Nori, A. & Williams, B. Artificial intelligence in healthcare: transforming the practice of medicine. *Future Health. J.* **8**, e188–e194 (2021).

2. Lareyre, F. & Raffort, J. Artificial intelligence in vascular diseases: from clinical practice to medical research and education. *Angiology* https://doi.org/10.1177/00033197251324630 (2025).
3. Song, P. et al. The global and regional prevalence of abdominal aortic aneurysms: a systematic review and modeling analysis. *Ann. Surg.* **277**, 912–919 (2023).
4. Eid, M. A. et al. The global burden of peripheral artery disease. *J. Vasc. Surg.* **77**, 1119–1126.e1 (2023).
5. Sinha, K., Berczeli, M., Lumsden, A. B. & Roy, T. L. Imaging: new frontiers in vascular training. *Methodist Debakey Cardiovasc. J.* **18**, 39–48 (2022).
6. Zaidan, E. & Ibrahim, I. A. AI governance in a complex and rapidly changing regulatory landscape: a global perspective. *Humanit. Soc. Sci. Commun.* **11**, 1121 (2024).
7. Mastracci, T. M., Anand, S. S. & Aday, A. W. Peripheral artery disease: a high-risk yet understudied, underdiagnosed, and undertreated condition-a call to action. *Can. J. Cardiol.* **38**, 553–554 (2022).
8. Chaikof, E. L. et al. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. *J. Vasc. Surg.* **67**, 2–77.e2 (2018).
9. Howard, D. P. J. et al. Population-based study of incidence of acute abdominal aortic aneurysms with projected impact of screening strategy. *J. Am. Heart Assoc.* **4**, e001926 (2015).
10. Dahl, M., Liisberg, M., Stenehjem, M., Al Obeidi, I. & Sanddal Lindholt, J. Screening for abdominal aortic aneurysms still prevents ruptures: a secondary analysis of the VIVA trial. *J. Am. Coll. Cardiol.* **84**, 2494–2496 (2024).
11. Anjorin, A. C. et al. Underutilization of guideline-based abdominal aortic aneurysm screening in an Academic Health System. *Ann. Vasc. Surg.* **83**, 184–194 (2022).
12. Won, D. et al. Sound the alarm: the sonographer shortage is echoing across healthcare. *J. Ultrasound Med.* **43**, 1289–1301 (2024).
13. Chiu, I.-M. et al. Prospective clinical evaluation of deep learning for ultrasonographic screening of abdominal aortic aneurysms. *npj Digit. Med.* **7**, 1–6 (2024).
14. Viz.ai | AI-Powered Care Coordination. *Viz.ai, the Proven AI-Powered Care Coordination Platform* https://www.viz.ai/.
15. How Viz.ai hit $48.8M revenue with a 325 person team in 2024. *Latka* https://getlatka.com/companies/viz.ai.
16. Publications Archive. *Viz.ai, the Proven AI-Powered Care Coordination Platform* https://www.viz.ai/publications.
17. Pirahanchi, Y. et al. PFO-ACCESS: Augmenting Communications for Medical Care or Closure in the Evaluation of Patients With Stroke With Cardiac Shunts. *Stroke.: Vasc. Interv. Neurol.* **5**, e001707 (2025).
18. Colasurdo, M. et al. Estimation of ventricular and intracranial hemorrhage volumes and midline shift on an external validation data set using a convolutional neural network algorithm. *Neurosurgery* https://doi.org/10.1227/neu.0000000000003455 (2022).
19. Figurelle, M. E. et al. Viz.ai implementation of stroke augmented intelligence and communications platform to improve indicators and outcomes for a comprehensive stroke center and network. *AJNR Am. J. Neuroradiol.* **44**, 47–53 (2023).
20. Karamchandani, R. R. et al. Automated detection of intracranial large vessel occlusions using Viz.ai software: Experience in a large, integrated stroke network. *Brain Behav.* **13**, e2808 (2023).
21. Viz.ai Strengthens Information Security with ISO-27001:2022 Certification. *Viz.ai, the Proven AI-Powered Care Coordination Platform* https://www.viz.ai/news/viz-ai-strengthens-information-security-with-iso-certification.
22. van Leeuwen, K. G. et al. Cost-effectiveness of artificial intelligence aided vessel occlusion detection in acute stroke: an early health technology assessment. *Insights Imaging* **12**, 133 (2021).
23. Viz.ai revenue, valuation & growth rate. https://sacra.com/c/viz-ai/.
24. FDA approves stroke-detecting AI software. *Nat. Biotechnol.* **36**, 290–290 (2018).
25. Hassan, A. E. New technology add-on payment (NTAP) for Viz LVO: a win for stroke care. *J. Neurointerv. Surg.* **13**, 406–408 (2021).
26. Chen, M. M., Golding, L. P. & Nicola, G. N. Who will pay for AI? *Radiol. Artif. Intell.* **3**, e210030 (2021).
27. Parikh, R. B. & Helmchen, L. A. Paying for artificial intelligence in medicine. *NPJ Digit. Med.* **5**, 63 (2022).
28. Abràmoff, M. D. et al. A reimbursement framework for artificial intelligence in healthcare. *NPJ Digit. Med.* **5**, 72 (2022).
29. US Food & Drug Administration. Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices. https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices (2025).
30. Muralidharan, V. et al. A scoping review of reporting gaps in FDA-approved AI medical devices. *npj Digit. Med.* **7**, 1–9 (2024).
31. Wu, K. et al. Characterizing the clinical adoption of medical AI devices through U.S. Insurance Claims. *NEJM AI* **1**, AIoa2300030 (2024).
32. Thomas, R. & Chalkidou, K. Cost–effectiveness analysis. In *Health system efficiency: How to make measurement matter for policy and management [Internet]* (European Observatory on Health Systems and Policies, 2016).
33. Li, X., Zhao, G., Zhang, J., Duan, Z. & Xin, S. Prevalence and trends of the abdominal aortic aneurysms epidemic in general population–a meta-analysis. *PLoS ONE* **8**, e81260 (2013).
34. Monaco, L. et al. The complexity of funding rare disease research: an IRDiRC assessment of the landscape. *rdodj* **3**, 27 (2024).
35. Vervoort, D. et al. One-time screening for abdominal aortic aneurysm in Ontario, Canada: a model-based cost-utility analysis. *Can. Med. Assoc. J.* **196**, E112–E120 (2024).
36. National Academies of Sciences, E., Division, H. and M., Health, B. on G. & States, C. on G. H. and the F. of the U. Promoting Cardiovascular Health and Preventing Cancer. in *Global Health and the Future Role of the United States* (National Academies Press (US), 2017).
37. Nishimiya, K., Matsumoto, Y. & Shimokawa, H. Recent advances in vascular imaging. *Arterioscler. Thromb. Vasc. Biol.* **40**, e313–e321 (2020).
38. Trowman, R., Migliore, A. & Ollendorf, D. A. The value and impact of health technology assessment: discussions and recommendations from the 2023 Health Technology Assessment International Global Policy Forum. *Int. J. Technol. Assess. Health Care* **39**, e75 (2023).
39. US Food & Drug Administration. Good Machine Learning Practice for Medical Device Development: Guiding Principles (2025).
40. Lottes, A. E. et al. Navigating the regulatory pathway for medical devices—a conversation with the FDA, clinicians, researchers, and industry experts. *J. Cardiovasc. Transl. Res.* **15**, 927–943 (2022).
41. Office of the Commissioner (2025) U.S. Food and Drug Administration. *FDA* https://www.fda.gov/.
42. Dhruva, S. S., Darrow, J. J., Kesselheim, A. S. & Redberg, R. F. Experts' views on FDA regulatory standards for drug and high-risk medical devices: implications for patient care. *J. Gen. Intern. Med.* **37**, 4176–4182 (2022).
43. Jhawar, N. et al. Impact of professional society guideline publications in medicine subspecialties from 2012 to 2022: implications for clinical care and health policy. *Mayo Clin. Proc. Innov. Qual. Outcomes* **7**, 262–266 (2023).
44. US Preventive Services Task Force. et al. Screening for abdominal aortic aneurysm: US Preventive Services Task Force Recommendation Statement. *J. Am. Med. Assoc.* **322**, 2211–2218 (2019).
45. Ahmed, M. I. et al. A systematic review of the barriers to the implementation of artificial intelligence in healthcare. *Cureus* **15**, e46454 (2023).



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B.L., D.P., and R.L. developed the concept, wrote the paper, and amended the final version.

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